UNIVERSITAT DE BARCELONA

Percutaneous Approaches to Distal Metatarsal Osteotomies (DMOs) for the most common Forefoot Diseases

Carlo Biz

PERCUTANEOUS APPROACHES

TO DISTAL METATARSAL OSTEOTOMIES (DMOs)

FOR THE MOST COMMON FOREFOOT DISEASES

Doctoral thesis dissertation

presented by Carlo Biz for the degree of Doctor of Philosophy at the University of Barcelona

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DOCTORAL PROGRAM IN MEDICINE AND TRANSLATIONAL RESEARCH

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4. ABBREVIATIONS AND ACRONYMS

AOFAS: American Orthopaedic Foot and Ankle Society

APC: Akin Percutaneous Osteotomy

CPDFUs: Chronic Plantar Diabetic Foot Ulcers

CTD: Claw Toe Deformity

DMAA: Distal Metatarsal Articular Angle

DMDO: Distal Metatarsal Diaphyseal Osteotomies

DMMO: Distal Metatarsal Metaphyseal Osteotomy

DMOs: Distal Metatarsal Osteotomies

FU: Follow-up

GRECMIP: Groupe de Recherche et d'Enseignement en Chirurgie Mini-Invasive du Pied

HV: Hallux Valgus

HVA: Hallux Valgus Angle

IMA: Intermetatarsal Angle

K-Ws: Kirschner Wires

LSTR: Lateral Soft-Tissue Release

MBs: Metatarsal bones

MIFAS: Minimally Invasive Foot & Ankle Society

MIIND: Minimally Invasive Intramedullary Nail Device

MIMOs: Minimally invasive metatarsal osteotomies

MIS: Minimally Invasive Surgery

MR: Magnetic Resonance

MTPJ: Metatarsophalangeal Joint (MTPJ)

MTT: metatarsal

P1: Proximal Phalanx

PDFUs: Plantar Diabetic Foot Ulcers

RIO: Reverdin-Isham Osteotomy

TSP: Tibial Sesamoid Position

VAS: Visual Analogue Scale

5. LIST OF THE ARTICLES IN THE THESIS

Thesis in compendium of publications format. The thesis consists of 2 objectives and 6 articles:

1. **Biz C**., Corradin M., Kuete Kanah W.T., Dalmau-Pastor M., Zornetta A., Volpin A., Ruggieri P. *Medium-Long-Term Clinical and Radiographic Outcomes of Minimally Invasive Distal Metatarsal Metaphyseal Osteotomy (DMMO) for Central Primary Metatarsalgia: Do Maestro Criteria Have a Predictive Value in the Preoperative Planning for This Percutaneous Technique?* Biomed Res Int. **2018** Nov 15; 2018:1947024. PMID: 30581846 DOI: 10.1155/2018/1947024. **IF 2018: 2.197, Q3 Biotechnology & Applied Microbiology**

2. **Biz C.**, Ruggieri P. *Minimally Invasive Surgery: Osteotomies for Diabetic Foot Disease.* Foot Ankle Clin*. 2020* Sep;25(3):441-460. PMID: 32736741 DOI: 10.1016/j.fcl.2020.05.006. **IF 2020: 1.653, Q3 Orthopaedics**

3. **Biz C.**, Belluzzi E., Crimì A., Mori F., Ruggieri, P. *Minimally invasive metatarsal osteotomies (Mimos) for the treatment of plantar diabetic forefoot ulcers (PDFUs): A systematic review and meta-analysis with meta-regressions.* Appl. Sci. **2021**, 11(20), 9628. doi.org/10.3390/app11209628. **IF 2021: 2.838, Q2 Materials Science, Multidisciplinary**

4. **Biz C**., Gastaldo S., Dalmau-Pastor M., Corradin M., Volpin A., Ruggieri P. Minimally Invasive Distal Metatarsal Diaphyseal Osteotomy (DMDO) for Chronic Plantar Diabetic Foot Ulcers. Foot and Ankle International, **2018**, 39(1), pp. 83–92. PMID: 29110516 DOI: 10.1177/1071100717735640. **IF 2018: 2.341, Q2 Orthopaedics**

5. **Biz C**, Fosser M., Dalmau-Pastor M., Corradin M., Rodà M.G., Aldegheri R., Ruggieri P. *Functional and radiographic outcomes of hallux valgus correction by mini-invasive surgery with Reverdin-Isham and Akin percutaneous osteotomies: A longitudinal prospective study with a 48-month follow-up*. Journal of Orthopaedic Surgery and Research, 2016, 11(1), 157. PMID: 27919259 DOI: 10.1186/s13018-016-0491-x. **IF 2016: 1.545, Q3 Orthopaedics**

6. **Biz C.**, Crimì A., Fantoni I., Tagliapietra J., Ruggieri P. *Functional and Radiographic Outcomes of Minimally Invasive Intramedullary Nail Device (MIIND) for Moderate to Severe Hallux Valgus.* Foot Ankle Int. **2021** Apr;42(4):409-424. PMID: 33319594 DOI: 10.1177/1071100720969676. **IF 2021: 3.569, Q2 Orthopaedics**

6. THESIS SUMMARY

6.1 Abstract

Title: Percutaneous Approaches to Distal Metatarsal Osteotomies (DMOs) for the Most Common Forefoot Diseases

Introduction: Minimally Invasive Surgery (MIS) became popular among surgeons from the end of the last century, and a fundamental step in the development of this surgical treatment was the foundation of GRECMIP (Groupe de Recherche et d' Enseignement en Chirurgie Mini-Invasive du Pied) in 2002. This group, incorporated soon in the international Minimally Invasive Foot & Ankle Society (MIFAS), improves and promotes MIS of the foot and ankle by organising annual courses worldwide. This surgical approach is characterised by minimal access, generally smaller than 3.5 cm, that allows 1-day surgery hospitalisation and several benefit for patients: less pain, decrease of post-operative complications and lower recovery and rehabilitation times.

Hypothesis: minimally invasive DMO, performed at different levels of the distal part of metatarsal bones MBs (1^{st}-5^{th}), as a single or an associate procedure, with or without fixation, (temporary by Kirschner Wises (KWs) or permanent by MIIND, may be an effective surgical treatment option for achieving metatarsalgia symptom resolution, healing of Plantar Diabetic Foot Ulcers (PDFUs) and Hallux Valgus (HV) correction.

Objectives: the aims of this thesis in compendium of publications format were to:

1. prospectively evaluate the clinical and radiographic outcomes of patients complaining of the most common forefoot diseases, treated by each of the following 4 DMOs by MI or percutaneous approaches:

- Distal Metatarsal Metaphyseal Osteotomy **(DMMO)** for persistent central primary metatarsalgia, associated or not to HV and lesser toe deformities;
- Minimally Invasive Metatarsal Osteotomies **(MIMOS)**, considering only the Distal

Metatarsal Osteotomies **(DMOs)**, such as the Distal Metatarsal Diaphyseal Osteotomies **(DMDO)** for CPDFUs;

- Reverdin-Isham **(RIO)** in combination with Akin Percutaneous Osteotomy **(APO)** and Lateral Soft-Tissue Release **(LSTR)** for correction of mild-to-severe HV;

2. Clarifying and describing their proper indications to guide orthopaedic surgeons in the choice of procedure according to the type and severity of the foot pathology to treat:

- metatarsalgia by **DMMO** [1];
- **CPDFUs** [2, 3] by **MIMOs**, including only the distal ones, such as: **DMDO** [4];
- mild to moderate HV by **RIO** in combination with **APO** and **LSTR** [5];
- severe HV by **MIIND** [6].

Materials, Methods and Results: a consecutive series of patients with diagnosis of mild-to-severe HV, associated or not to central primary metatarsalgia with or without neuropathic plantar ulcerations were enrolled in this thesis project - cohort studies. Clinical evaluation was assessed pre-and post-operatively using the American Orthopaedic Foot and Ankle Society (AOFAS) scores, Visual Analogue Scale (VAS) for patient satisfaction and complications were recorded. Computer-assisted measurements of antero-posterior radiographs were taken pre-and post-operatively to analyse intermetatarsal angle (IMA), distal metatarsal articular angle (DMAA), hallux valgus angle (HVA), and tibial sesamoid position (TSP) for HV correction, as well as the Maestro criteria index for metatarsalgia and CPDFU treatment. Further, the bridging bone/callus formation, the articular surface congruency and the metatarsal index were evaluated. Statistical analysis was carried out using the paired t-test. Statistical significance was set at $p < 0.05$. Finally, a review of the recent literature regarding several MIMOS proposed from 1980 until June 2021 was performed following PRISMA guidelines.

Hence, 203 consecutively enrolled patients met the inclusion criteria and were considered in the analyses. The median patient age at the time of the surgery was 58.4 ± 18.2 years. There were 164

women (80.8%) and 39 men (19.2%). The following six publications report the clinical-functional and radiographic outcomes of the original articles and review already published in indexed scientific journals (Q2-Q3) relating to the *4 operative minimally invasive techniques analysed:*

1. For the **DMMO** to treat metatarsalgia, the following was included:

- **Biz C**, Corradin M, Kuete Kanah WT, Dalmau-Pastor M, Zornetta A, Volpin A, Ruggieri P. *Medium-Long-Term Clinical and Radiographic Outcomes of Minimally Invasive Distal Metatarsal Metaphyseal Osteotomy (DMMO) for Central Primary Metatarsalgia: Do Maestro Criteria Have a Predictive Value in the Preoperative Planning for This Percutaneous Technique?* Biomed Res Int. **2018** Nov 15; 2018:1947024. doi: 10.1155/2018/1947024.

2. For **MIMOs** to treat CPDFUs [2, 3], considering only the **DMOs**, such as the **DMDO** [4], the following were included:

- **Biz C**, Ruggieri P. Minimally Invasive Surgery: *Osteotomies for Diabetic Foot Disease*. Foot Ankle Clin. **2020** Sep;25(3):441-460. doi: 10.1016/j.fcl.2020.05.006.
- **Biz C**.; Belluzzi E.; Crimì A.; Bragazzi N.L.; Nicoletti P.; Mori F.; Ruggieri P. *Minimally Invasive Metatarsal Osteotomies (MIMOs) for the Treatment of Plantar Diabetic Forefoot Ulcers (PDFUs): A Systematic Review and Meta-Analysis with Meta-Regressions.* Appl. Sci. 2021, 11, 9628. https:// doi.org/10.3390/app11209628.
- **Biz C,** Gastaldo S, Dalmau-Pastor M, Corradin M, Volpin A, Ruggieri P. *Minimally Invasive Distal Metatarsal Diaphyseal Osteotomy (DMDO) for Chronic Plantar Diabetic Foot Ulcers.* Foot Ankle Int. **2018** Jan;39(1):83-92. doi: 10.1177/1071100717735640.

3. For the percutaneous procedure **RIO** in combination with **APC** and **LSTR** used to treat mild to moderate HV [5], the following was included:

- **Biz C**, Fosser M, Dalmau-Pastor M, Corradin M, Rodà MG, Aldegheri R, Ruggieri P. *Functional and radiographic outcomes of Hallux Valgus correction by mini-invasive surgery with Reverdin-Isham and Akin percutaneous osteotomies: a longitudinal prospective study with a 48-month follow-up.* J Orthop Surg Res. **2016** Dec 5;11(1):157. doi: 10.1186/s13018-016-0491-x.

4. For **MIIND** used to treat moderate to severe HV [6], the following was included:

- **Biz C**, Crimì A, Fantoni I, Tagliapietra J, Ruggieri P. *Functional and Radiographic Outcomes of Minimally Invasive Intramedullary Nail Device (MIIND) for Moderate to Severe Hallux Valgus.* Foot Ankle Int. **2021** Apr;42(4):409-424.

Conclusions: *DMMO* is a safe and effective minimally invasive method for the treatment of biomechanical central metatarsalgia.

MIMOs including only the distal ones such as DMDO are effective procedures for the treatment of complicated CDPFUs under the heads of lateral MBs, resistant toe ulcers and recurrent pressure ulcers, mainly those with healing delay or because of previous forefoot amputations with unbalancing of the metatarsal formula.

RIO in combination with APO and LSTR is a safe, effective and reliable procedure for the correction of mild-to-moderate symptomatic HV, with a low number of complications and without osteosynthesis.

MIIND is a viable procedure for the correction of moderate to severe HV at long-term follow-up (FU), with a low rate of complications and recurrence.

6.2 Resumen de la Tesis

Título: Abordajes percutáneos de osteotomías metatarsianas distales (DMO) para las enfermedades más comunes del antepié

Introducción: La Cirugía Mínimamente Invasiva (Minimally Invasive Surgery, MIS) se popularizó entre los cirujanos a partir de finales del siglo pasado. Un paso fundamental en el desarrollo de este tratamiento quirúrgico fue la fundación del GRECMIP (Groupe de Recherche et d'Enseignement en Chirurgie Mini-Invasive du Pied) en 2002. Este grupo, incorporado recientemente en la Minivally Invasive Foot and Ankle Society (MIFAS), mejora y promueve la MIS de pie y tobillo organizando cursos anuales en todo el mundo. Este abordaje quirúrgico se caracteriza por un acceso mínimo, generalmente menor de 3,5 cm, que permite la hospitalización de 1 día y varios beneficios para los pacientes: menos dolor, disminución de las complicaciones postoperatorias y menores tiempos de recuperación y rehabilitación.

Hipótesis: las DMO mínimamente invasivas, realizadas a diferentes niveles de la parte distal de los metatarsianos MB (1º-5º), como procedimientos únicos o asociados, con o sin fijación, (temporales por Kirschner Wires (KWs) o permanentes por MIIND), puede ser una opción de tratamiento quirúrgico eficaz para lograr: la resolución de los síntomas de la metatarsalgia; curación de las úlceras plantares del pie diabético (PDFU); y corrección del HV.

Objetivos: los objetivos de esta tesis en formato compendio de publicaciones fueron:

1. evaluar prospectivamente los resultados clínicos y radiográficos de los pacientes que se quejan de las enfermedades más comunes del antepié, tratados por cada uno de los siguientes DMO mediante MI o enfoques percutáneos:

- Reverdin-Isham (RIO) en combinación con osteotomía percutánea de Akin (APO) y liberación lateral de tejido blando (LSTR) para la corrección de HV de leve a grave;
- Osteotomía Metatarsal Metafisaria Distal (DMMO) para la metatarsalgia primaria central persistente, asociada o no a HV y deformidades de los dedos menor del pie;
- Osteotomías Diafisarias Metatarsianas Distales (DMDO) para CPDFU;

2. aclarar y describir sus indicaciones adecuadas para guiar a los cirujanos ortopédicos en la elección del procedimiento en relación con el tipo y la gravedad de la patología del pie a tratar:

- metatarsalgia por DMMO [1];
- CPDFUs [2, 3] por MIMOs, incluyendo solo los distales, como: DMDO [4];
- HV de leve a moderado por RIO en combinación con APO y LSTR [5];
- HV severa por MIIND [6].

Materiales, Métodos y Resultados: una serie consecutiva de pacientes con diagnóstico de HV (de leve a grave), asociada o no a metatarsalgia primaria central con o sin ulceraciones plantares neuropáticas, fueron incluidos en este proyecto de tesis. La evaluación clínica se evaluó antes y después de la operación utilizando las puntuaciones de la American Orthopaedic Foot and Ankle Society (AOFAS), la escala analógica visual (VAS) para la satisfacción del paciente; se registraron también las complicaciones. Se tomaron mediciones asistidas por computadora de radiografías anteroposteriores antes y después de la operación, analizando: ángulo intermetatarsiano (IMA), ángulo articular metatarsiano distal (DMAA), ángulo hallux valgus (HVA) y posición tibial sesamoideo (TSP) para la corrección del HV; Índice de criterios de Maestro para el tratamiento de metatarsalgia y UCPPD. Además, se evaluaron la formación de callo óseo, la congruencia de la superficie articular y el índice metatarsiano. El análisis estadístico se llevó a cabo utilizando la prueba t pareada. La significación estadística se fijó en $p < 0,05$. Finalmente, se realizó una revisión de la literatura reciente sobre varios MIMOs propuestos desde 1980 hasta junio de 2021 siguiendo las pautas PRISMA.

Por lo tanto, 203 pacientes reclutados consecutivamente cumplieron con los criterios de inclusión y fueron considerados en los análisis. La mediana de edad de los pacientes en el momento de la cirugía fue de 58,4 ± 18,2 años. Había 164 mujeres (80,8%) y 39 hombres (19,2%). En la evaluación preoperatoria, la puntuación AOFAS total media fue de 51,4 ± 9,3 puntos. En la cohorte de pacientes diabéticos, la duración media de las 35 UCPPD presentadas en el momento de la cirugía fue de 10,3 ± 3,8 meses. El sitio de úlcera más frecuente fue debajo de la cabeza del tercer metatarsiano con 11/35

úlceras. En la revisión de la literatura se incluyeron 8 estudios.

Las siguientes seis publicaciones informan los resultados clínico-funcionales y radiográficos de los artículos originales y revisiones ya publicados en revistas científicas indexadas (Q2-Q3), en relación con las 4 técnicas mínimamente invasivas quirúrgicas analizadas:

1. Para la Osteotomía Metafisaria del Metatarso Distal **(DMMO)** para tratar la metatarsalgia [1] se incluyó:

- **Biz C**, Corradin M, Kuete Kanah WT, Dalmau-Pastor M, Zornetta A, Volpin A, Ruggieri P. *Medium-Long-Term Clinical and Radiographic Outcomes of Minimally Invasive Distal Metatarsal Metaphyseal Osteotomy (DMMO) for Central Primary Metatarsalgia: Do Maestro Criteria Have a Predictive Value in the Preoperative Planning for This Percutaneous Technique?* Biomed Res Int. **2018** Nov 15; 2018:1947024. doi: 10.1155/2018/1947024.

2. Para las Osteotomía Metatarsiana Mínimamente Invasiva **(MIMO)** para tratar las UPCPD [2, 3], considerando solo las Osteotomías Metatarsianas Distales **(DMO)**, como la Osteotomía Diafisaria Metatarsiana Distal **(DMDO)** [4], se incluyeron:

- **Biz C**, Ruggieri P. Minimally Invasive Surgery: *Osteotomies for Diabetic Foot Disease*. Foot Ankle Clin. **2020** Sep;25(3):441-460. doi: 10.1016/j.fcl.2020.05.006.
- **Biz C**.; Belluzzi E.; Crimì A.; Bragazzi N.L.; Nicoletti P.; Mori F.; Ruggieri P. *Minimally Invasive Metatarsal Osteotomies (MIMOs) for the Treatment of Plantar Diabetic Forefoot Ulcers (PDFUs): A Systematic Review and Meta-Analysis with Meta-Regressions.* Appl. Sci. **2021,** 11, 9628. https:// doi.org/10.3390/app11209628.
- **Biz C,** Gastaldo S, Dalmau-Pastor M, Corradin M, Volpin A, Ruggieri P. *Minimally Invasive Distal Metatarsal Diaphyseal Osteotomy (DMDO) for Chronic Plantar Diabetic Foot Ulcers.* Foot Ankle Int. **2018** Jan;39(1):83-92. doi: 10.1177/1071100717735640.

3. Para la técnica percutáneo Osteotomía de Reverdin-Isham **(RIO)** en combinación con Osteotomía Percutánea de Akin **(APO)** y Liberación Lateral de Tejido blando (LSTR) utilizada para tratar el HV leve y moderado [5], se incluía:

- **Biz C**, Fosser M, Dalmau-Pastor M, Corradin M, Rodà MG, Aldegheri R, Ruggieri P. *Functional and radiographic outcomes of Hallux Valgus correction by mini-invasive surgery with Reverdin-Isham and Akin percutaneous osteotomies: a longitudinal prospective study with a 48-month follow-up.* J Orthop Surg Res. **2016** Dec 5;11(1):157. doi: 10.1186/s13018-016-0491-x.

4. Para el dispositivo de clavo intramedular mínimamente invasivo **(MIIND)** utilizado para tratar la HV moderado y grave [6], se incluía:

- **Biz C**, Crimì A, Fantoni I, Tagliapietra J, Ruggieri P. *Functional and Radiographic Outcomes of Minimally Invasive Intramedullary Nail Device (MIIND) for Moderate to Severe Hallux Valgus.* Foot Ankle Int. **2021** Apr;42(4):409-424.

Conclusiones: El DMMO es un método mínimamente invasivo seguro y eficaz para el tratamiento de la metatarsalgia central biomecánica.

Los MIMO, incluidos solo los distales, como el DMDO, son procedimientos efectivos para el tratamiento de CDPFU complicadas bajo las cabezas de MB laterales, úlceras resistentes del dedo del pie y úlceras por presión recurrentes, principalmente aquellas con retraso en la curación o como consecuencia de amputaciones previas del antepié con Desequilibrio de la fórmula metatarsiana.

RIO en combinación con APO y LSTR es un procedimiento seguro, eficaz y fiable para la corrección de la HV sintomática de leve a moderada, con un bajo número de complicaciones y sin osteosíntesis.

MIIND es un procedimiento viable para la corrección de la HV de moderada a grave en el seguimiento a largo plazo (FU), con una baja tasa de complicaciones y recurrencia.

7. INTRODUCTION

7.1 General Aspects

This PhD Thesis is the result of several years of formation and learning in Health Sciences, specifically in the field of Orthopaedic Surgery. It is presented as a compendium of six publications that have resulted from research performed in collaboration with Professors of the University of Padova and both national and international orthopaedic surgeons. All of the publications presented in this project are in the area of Clinical and Surgical Orthopaedics, specifically focused on the most frequent foot and ankle pathologies (metatarsalgia, PDFUs and HV) and with a marked orientation towards the field of minimally invasive surgical treatments.

MIS became popular among surgeons from the end of the last century thanks to the work of Dr De Prado and Dr Ripoll who, corroborated by Dr. Golanó and his anatomical studies, spread this approach first in Spain and then in Europe [7]. A fundamental step in the development of this surgical treatment was the foundation of GRECMIP, started in France in 2002 by the encounter of French surgeons with leaders in arthroscopic and MIS of the foot and ankle: Dr De Prado (Spain), Dr S. Isham (USA) and Prof. Niek Van Dijk (Netherlands) [8]. This group, incorporated soon in the international (MIFAS), improves and promotes MIS of the foot and ankle by organising annual basic and advanced courses worldwide. These courses are dedicated to arthroscopic and percutaneous approaches of the foot and ankle with a theoretical part and workshops on sawbones and specimens [9]. These approaches are characterised by minimal access for portals, generally smaller than 3.5 cm, that allow 1-day surgery hospitalisation and several benefits for patients such as less pain, decrease of post-operative complications and less recovery and rehabilitation times. These advantages of using the MIS technique are the reason why development and research should be pursued in this field.

Currently, MIS represents an innovative approach and is becoming more popular because of lower complication rates registered during the treatment of the most common foot pathologies, such as metatarsalgia, PDFU and HV [4]. Different minimally invasive and percutaneous osteotomies, at

different levels of the distal MBs, generally by a dorsal approach and without head resection or metalworks, have been proposed including osteoclasis, a V-shaped cut, a Gauthier osteotomy or oblique cuts such as in a Weil osteotomy or its variants [10, 11].

In this thesis, the work conducted in the field of MIS applied to forefoot surgery is presented with specific mentions of the **Distal Metatarsal Osteotomies (DMOs)**, including the following:

1. *Distal Metatarsal Metaphyseal Osteotomy* ***(DMMO)*** for the treatment of metatarsalgia [1];
2. *Minimally Invasive Metatarsal Osteotomies* ***(MIMOs)*** for the treatment of (CPDFUs), including only the Distal Osteotomies (DMOs) [2, 3] such as
   - the *Distal Metatarsal Diaphyseal Osteotomy* ***(DMDO)*** [4];
3. *Reverdin-Isham Osteotomy* ***(RIO)*** in combination with ***Akin Percutaneous Osteotomy (APO)*** and ***Lateral Soft-Tissue Release (LSTR)*** for mild to moderate HV correction [5];
4. *Minimally Invasive Intramedullary Nail Device* ***(MIIND)*** for moderate to severe HV correction [6].

7.2 Padua Orthopaedic Department Protocols for DMOs

The DMOs adopted by our institution and described in this thesis are performed following the general MIS principles as originally described by De Prado [7] and then adapted for the different pathologies to treat (Metatarsalgia, CPDFUs and HV) in a standardized protocol developed in the Padua Orthopaedics and Orthopaedic Oncology Department.

7.2.1 Pre-operative Protocol

7.2.1.1 Clinical and Radiographic Assessment

Both clinical and radiological assessment is used for pre-operative planning. The general aspects of the different pathologies are evaluated: affected side, plantar hyperkeratosis lesions, seat of pain/skin lesion, including ulcers, symptomatic metatarsophalangeal joint (MTPJ) instability (using the

Lachman test), and relative clinical signs of dorsal dislocation, as well as grade of HV severity when present. A decision is made as to where the osteotomy should be performed to rebalance plantar pressures and create a harmonious curve, with a tolerance of ±1 mm for criteria Maestro 1 and 2, ±2 mm for criteria Maestro 3. A normal or harmonious forefoot shows a geometrical progression of 2 regarding the relative lengths of the lesser MBs compared to the SM4 line, the line passing through the mid-third of the M4 head (+2 mm proximally/center M4 head/-4 mm distally (**Figure 1**).

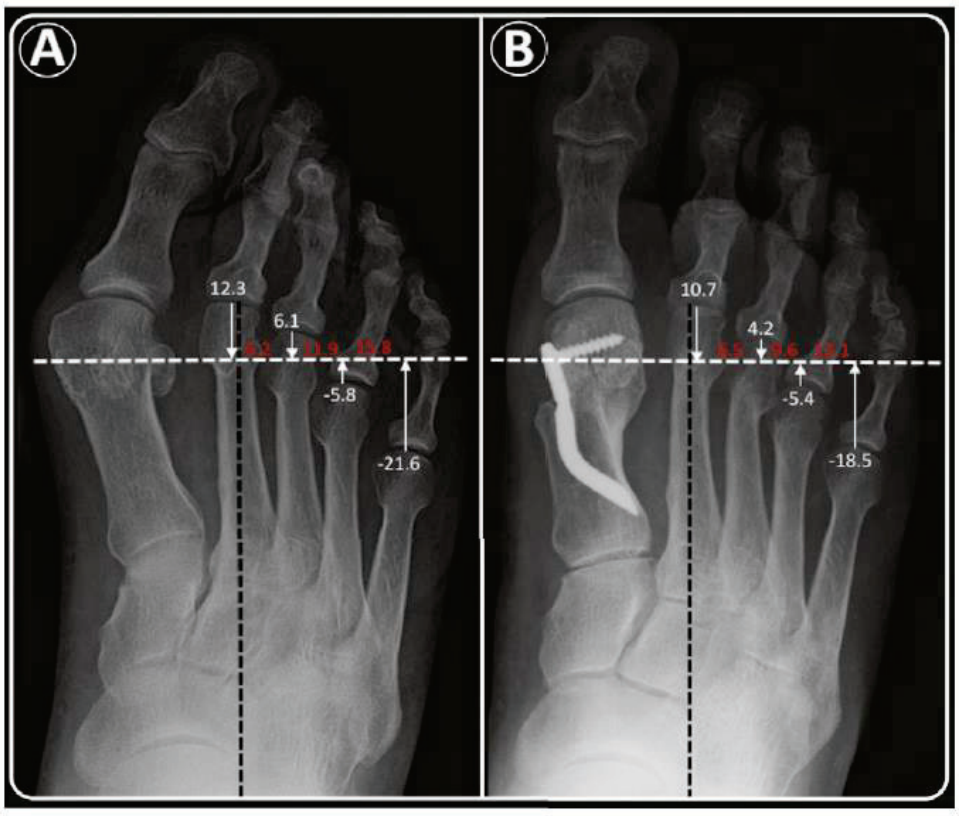

Figure 1. *Weight-bearing radiographic and respective bone images of DMDO showing the position of the second MTB with respect to the ground at preoperative period* ***(A)****, and the result of an ideal osteotomy performed proximal to the neck with potentially greater elevation from the ground at post-operative period* ***(B)****. In both radiographic images, the SM4 line is represented by the dashed line in white [4].*

DMOs are carried out only on the MB responsible for the pathology. However, if shortening the MB

would make the neighbouring MBs too long, resulting in a disharmonious morphotype with a high risk of a transfer lesion, the adjacent MB is also shortened by an additional DMO.

7.2.1.2 Equipment

Among the specific tools necessary, various burrs of different size and form, adapted for Mm960 (produced by Medic Micro, Switzerland), a modular power driver for MIS, are used. During the different operations, the patients are in a supine position, adequately anaesthetised by a regional ankle block [13], with the operated foot protruding from the table. No ankle joint tourniquet is applied as it is not required for these techniques and, more importantly, it is not indicated in diabetic lower limb surgery. All operations are performed under image intensifier guidance.

7.2.1.3 Anaesthesia

Prophylactic antibiotic (Cefazolin: 2g) is administered before surgery, and thromboembolic prophylaxis with Nadroparin Calcium injections is prescribed the same evening and for a 30-day period. Anaesthesia consists in a conscious sedation in association with a regional ankle block [12] performed under ultrasound control, which combines five nerves, three superficial: saphenous, sural and superficial peroneal nerves; and two deep: tibial and deep peroneal nerves (**Figure 2**).

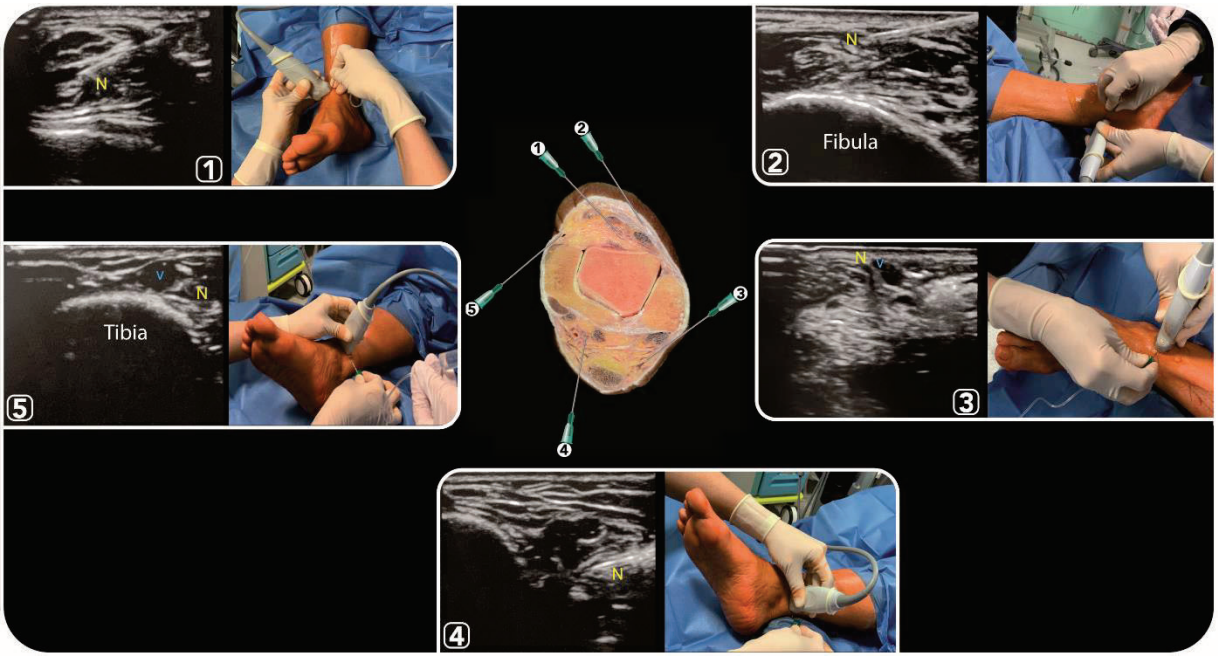

Figure 2. *Anatomical, ultrasound and clinical images of* ***ankle block*** *procedures, which involve anaesthetising five separate nerves: two deep (posterior tibial and deep peroneal) and three superficial nerves (superficial peroneal, sural and saphenous).* ***(1) Deep Peroneal Nerve:*** *it innervates the ankle extensor muscles, the ankle joint and the web space between the first and second toes. A transducer placed in the transverse orientation at the level of the extensor retinaculum will show this nerve (DPN) lying immediately lateral to the anterior tibial artery (ATA) on the surface of the tibia.* ***(2) Superficial Peroneal Nerve:*** *it innervates the dorsum of the foot and emerges to lie superficial to the fascia, 10–20 cm above the ankle joint on the anterolateral surface of the leg and divides into two or three small branches. A transducer placed transversely on the leg, approximately 5-10 cm proximal and anterior to the lateral malleolus, will identify the hyperechoic nerve branches (SPN) lying in the subcutaneous tissue immediately superficial to the fascia.* ***(3) Sural Nerve:*** *it innervates the lateral margin of the foot and ankle. This nerve (SUN) can be traced back along the posterior aspect of the leg, running in the midline superficial to the Achilles tendon and gastrocnemius muscles, in the immediate vicinity of the small saphenous vein (V).* ***(4) Posterior Tibial Nerve:*** *it provides innervation to the heel and sole of the foot. This nerve (N) can be seen posterior to the posterior tibial artery (PTA) and vein (PTV) using a linear transducer placed transversely at*

the level of the medial malleolus. The nerve typically appears hyperechoic with a honeycomb pattern. ***(5) Saphenous Nerve:*** *it innervates the medial malleolus and a variable portion of the medial aspect of the leg below the knee. This nerve (SAN) travels down the medial leg alongside the great saphenous vein (SV). Because it is a small nerve, it is best visualised 10–15 cm proximal to the medial malleolus using the great saphenous vein as a landmark [12].*

Alternatively, a sciatic-femoral regional ultrasound-guided nerve block can be used (**Figure 3**) [12].

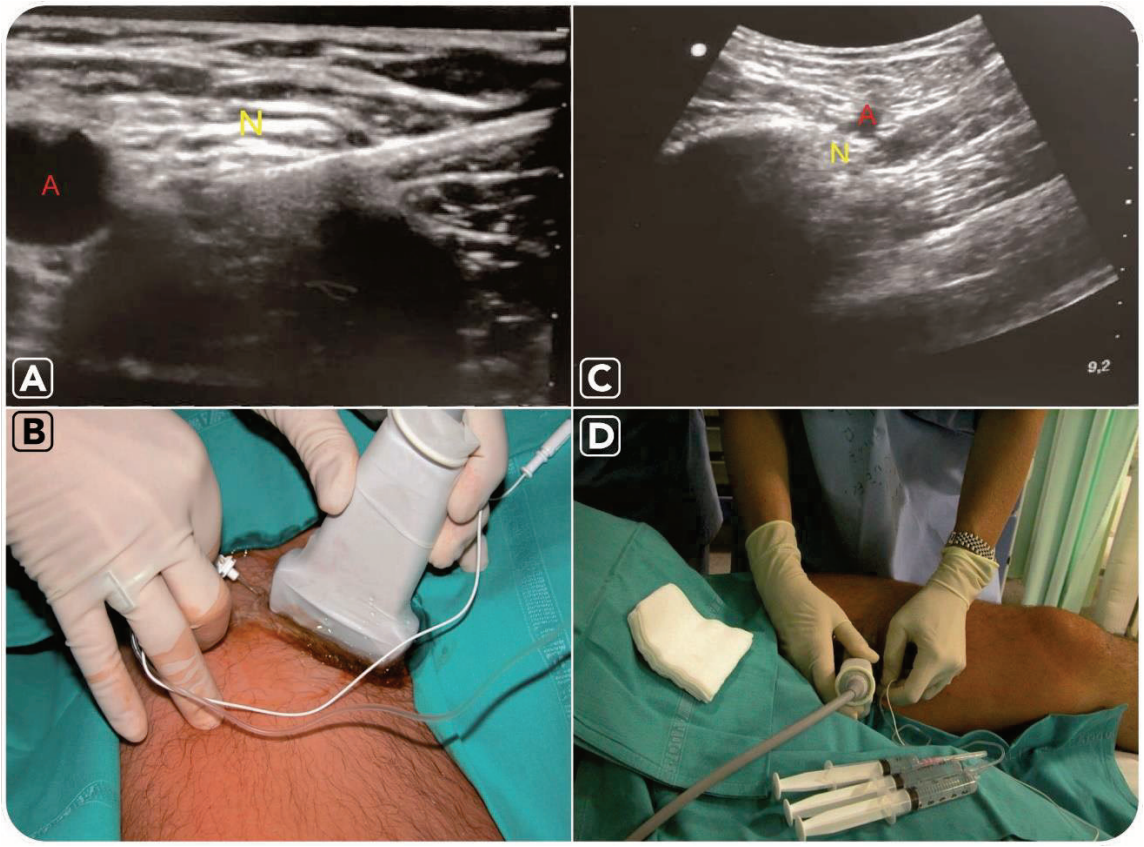

Figure 3. *Ultrasound* ***(A-C)*** *and clinical* ***(B-D)*** *images of femoral-sciatic nerve block procedures with the patient lying in a supine position. For* ***femoral block (A-B)****, using an ultrasound-guided technique* ***(A)****, the needle is advanced through the fascia lata and iliac until an adequate position with respect to the femoral nerve (FN) is reached. The site of needle insertion* ***(B)*** *is located at the femoral crease but below the inguinal crease and immediately lateral to the pulse of the femoral artery (FA). For* ***sciatic block (C-D)****, using an ultrasound-guided technique* ***(C)****, the sciatic nerve*

(SCN) is seen as a hyperechoic oval structure sandwiched between the adductor magnus muscle and the hamstring muscles. The nerve is typically visualised at a depth of 6–8 cm, under the femoral artery (FA), the femur and the adductor magnus muscle. The needle is inserted in plane from the medial aspect of the thigh and advanced toward the sciatic nerve ***(D)*** *[12].*

7.2.2 Post-operative Protocol

7.2.2.1Bandage

Because normally no osteosynthesis material is used to fix the bone position in these operative procedures, the bandage is a very important tool to maintain the metatarsal head position achieved with the operation. Consequently, its application is performed with the utmost care and attention. The crisscross bandage is traced between all inter-metatarsal spaces, crossing it over the medial (lateral) aspect of all of the osteotomies performed in order to reinforce the strength of the bandage. Gentle traction is used to maintain the toe in light hypercorrection and plantar inclination; the first toe is gently placed in overcorrection when HV correction has been performed. Finally, the forefoot is covered with tubular gauzes, except for the distal part of the toes and nails. (**Figure 4A**).

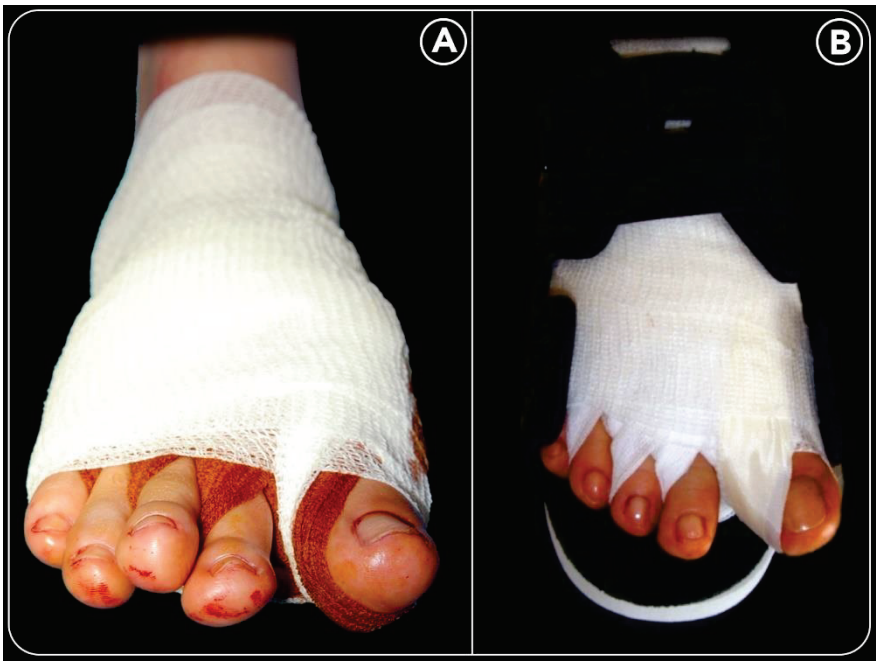

Figure 4: *Example of post-operative bandage* ***(A)*** *and rigid flat-soled orthopaedic shoe* ***(B)*** *[5].*

7.2.2.2 Suggestions after Surgery

The patients are allowed to walk as much as they can tolerate the same evening after surgery at discharge, using a rigid flat-soled orthopaedic shoe for the following 30-day period (**Figure 4B**). Antero-posterior and lateral X-rays of non-weight-bearing feet are taken before the patients are discharged. A thromboembolic prophylaxis (Natrium Enoxaparin: 4,000 IU/day) and an anti-edemigen therapy (Leucoselect, Lymphaselect and Bromelina: 1 cp/day) is recommended for 30 days, starting from the day of the surgery. Moreover, an analgesic therapy is prescribed for 2 weeks with Etoricoxib (90 mg, 1 cp/day) in the morning, also to prevent articular ossification; if pain persists, Paracetamol/phosphate Codeine (1 g, max x3/day) is prescribed. In cases of contraindications because of medication allergies or concomitant pharmacological therapy, only Paracetamol is suggested.

All patients are seen once a week for a month in our out-patient clinic. The first visit is 8 days after surgery. The original bandage is removed and substituted by a simpler bandage, but always with a slight overcorrection. During the 3 weekly visits, the bandage is changed in the same way. One month after surgical treatment, the bandage is removed completely, and after taking antero-posterior weight-bearing and lateral X-rays (and sesamoid view when possible), an interdigital silicone orthoses space maintainer is positioned between the first and second toes. Patients are instructed to wear it for three months to help the first toe to maintain its correct position until complete osteotomy consolidation. They are then able to walk with comfortable shoes allowing total load on the operated foot. The only recommendations for the patient are to be careful with rough surfaces, sports and any other activities with forefoot overload. No specific physiokinesis therapy is suggested to restart daily activities.

7.3 Distal Metatarsal Osteotomies (DMOs): operative procedures

7.3.1 Distal Metatarsal Metaphyseal Osteotomy (DMMO) for the Treatment of Metatarsalgia

7.3.1.1 DMMO: general aspects and indications

Within the last decade, innovative DMMO has proved to be an alternative surgical approach, being a percutaneous extra-articular metatarsal neck osteotomy without any internal fixation [13-15], which permits the MB lengths to be set automatically upon weight bearing. The percutaneous DMMO is probably the easiest percutaneous osteotomy to perform technically, the first that is usually taught during MIFAS courses and suggested when surgeons approach MIS for the first time. It is indicated to treat patients with persistent central primary metatarsalgia, associated or not with HV and lesser toe deformities. This osteotomy can restore a harmonious foot morphotype according to the Maestro criteria, distributing the pressure on the foot evenly and resolving the symptoms [1]. Further, the technique results in less postoperative stiffness than the standard Weil osteotomy [16]. More recently, this percutaneous procedure was modified to reduce the plantar pressure of the MBs over chronic plantar ulcers in diabetic patients, promoting ulcer healing [4, 17].

Central metatarsalgia, one of the most common problems in orthopaedic clinical practice, is a term used to indicate a painful condition localised in the plantar forefoot region between the 2nd and 4th metatarsal heads and/or the MTPJ [18-20], often associated with the most frequent forefoot disorders such as HV and lesser toe deformities. This condition is not a diagnosis but a symptom for which there can be several contributing factors [21]. Metatarsalgia syndrome can be classified as primary or biomechanical, secondary and iatrogenic [20, 22, 23]. Primary or biomechanical metatarsalgia is the most important, accounting for about 90% of cases [19]. It is caused by intrinsic abnormalities of metatarsal anatomy and the relationship between the MBs and the rest of the foot, resulting in an overload to the forefoot [24]. Its most common cause is a long second MB [25]. Individuals presenting congenital brevity of the 1st MB (M1) or severe HV may complain of pain in the forefoot caused by incompetence of the first ray in its weight-bearing function, creating transfer pressure to lesser MBs,

in particular the 2nd (M2). Other causes of primary metatarsalgia include disproportionate length of M2 or the 3rd MB (M3), congenital deformities of the metatarsal heads, tightness of the gastrocnemius muscles or triceps, fixed equinus of the foot, pes cavus and any hindfoot abnormality that results in overloading of the forefoot [26, 27]. Maestro and Besse have studied forefoot structure to define ideal forefoot morphology with precise criteria [25]. Forefoot alterations cause imbalance in weight-bearing distribution that may lead to mechanical overload on the affected metatarsal heads and may evolve to pain and plantar callosities [28, 29].

First-step metatarsalgia treatment is conservative, including physical therapy and stretching exercises for gastrocnemius and soleus tightness, functional foot orthoses and shoe modifications to lessen the pressure on the forefoot, debridement of calluses associated with painful keratosis when present and judicious use of corticosteroid injections [30]. However, when these conservative measures fail and the metatarsalgia becomes recalcitrant, it requires surgical treatment with or without procedures on the first ray [31, 32].

The primary goal of surgery is to relieve pain and restore an ideal forefoot morphology with a normal distribution of pressure in the forefoot [16, 33, 34]. Multiple surgical procedures have been described for this syndrome [13, 14, 18, 35-40]. However, the Weil osteotomy (and its modifications) has been the preferred technique employed by surgeons for many years in Europe [16, 40, 41]. This procedure consists of an open intra-articular osteotomy performed after preoperative planning based on the criteria of Maestro to calculate the appropriate metatarsal length from anteroposterior standing radiographs [5, 25, 27, 42], which provides longitudinal decompression. It was originally designed to restore the proper lengths of the lesser MBs and evenly redistribute the pressures on the forefoot. However, the main complication, estimated to be among at least 10 to 30% of cases, is postoperative stiffness, with other commonly described problems including floating toe, recurrence and transfer metatarsalgia [4, 15, 23, 43].

7.3.1.2 DMMO: surgical technique

The surgical technique is performed according to the same principles and the same general indications described by M. De Prado [16] (**Figure 5**).

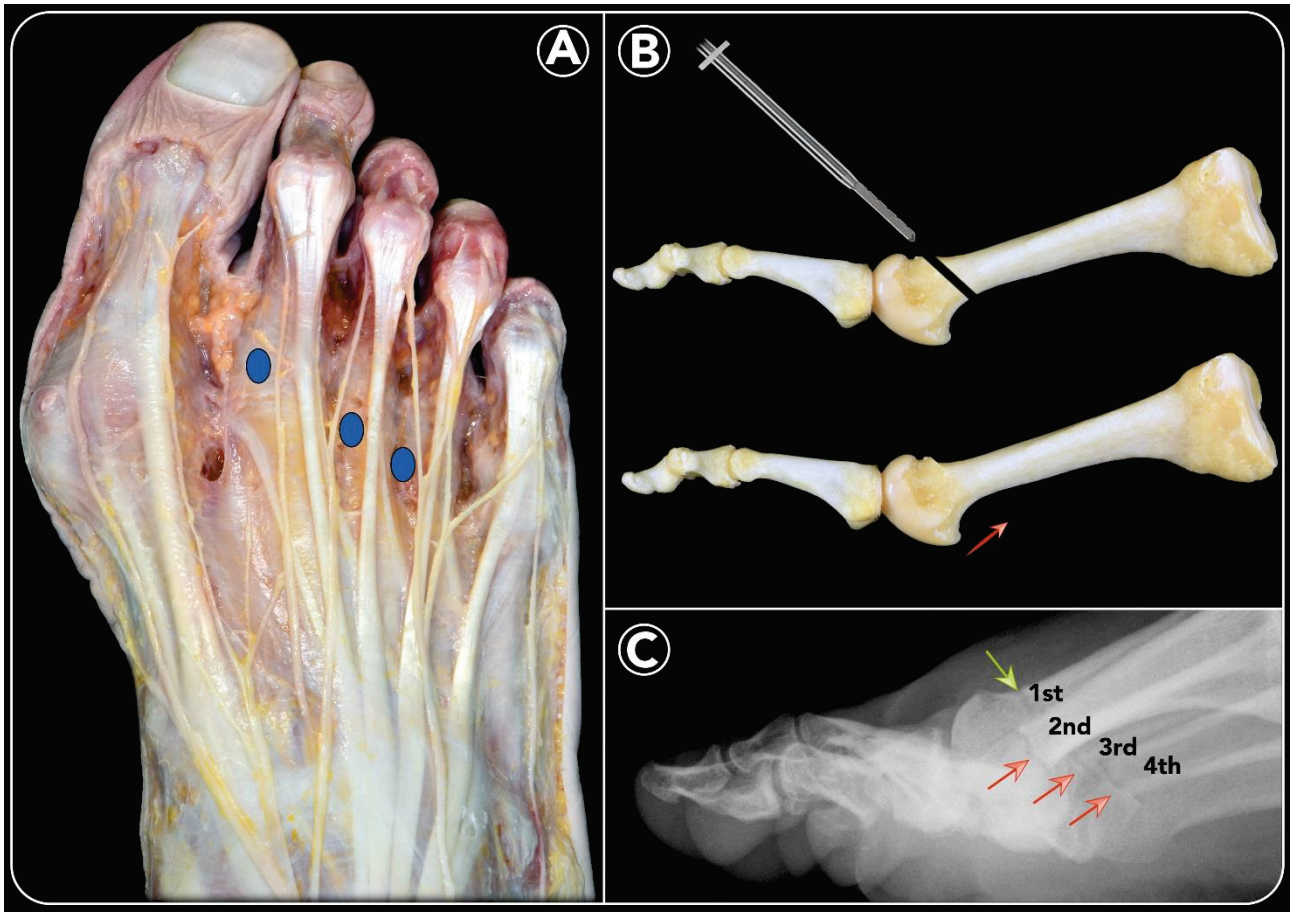

Figure 5. *Distal Metatarsal Metaphyseal Osteotomy (DMMO): Dissection of the dorsum of the foot showing the extensor apparatus and the innervation pattern of the foot and toes. Blue circles highlight the incision points for percutaneous DMMO* ***(A)****. Bone preparation of an ideal DMMO procedure performed at the level of the M-neck and the final result showing the shortening and elevation of the M-head* ***(B)****. Weight-bearing lateral radiographic view showing the site of the DMMO (red arrow) on each lesser MB; green arrow corresponds to Reverdin-Isham osteotomy for HV correction during the same operation* ***(C)*** *[1].*

During the operation, the patient is in a supine position, with the operated foot protruding from the table. During this percutaneous procedure, the surgeon holds the metatarsophalangeal joint between

the thumb and index finger of his non-dominant hand [13]. Using a small scalpel blade (SM64) in his dominant hand, an incision of 5 mm is made parallel to the extensor tendons at the dorsal side of the medial (or lateral) border of each metatarsal head that needs to be shortened (**Figure 6A**) [31]. The side of the incision depends on the surgeon's laterality and which foot is being operated on. The scalpel is advanced at an oblique angle of about 45° until it reaches the dorsal aspect of the distal MB, at the neck level, to undergo osteotomy. Through the same incision, first a bone rasp specific for percutaneous surgery is inserted, using it to separate the periosteum at the level of the osteotomy site (**Figure 6B**). Then, a Shannon Isham burr (2.0 x 12 mm), adapted for Mm960 (produced by Medic Micro, Switzerland), is introduced until it reaches the metatarsal neck where the periosteum was previously removed (**Figure 6C**). Fluoroscopy is used to confirm the correct position of the osteotomy site on the distal diaphysis of the MB (**Figure 6D**).

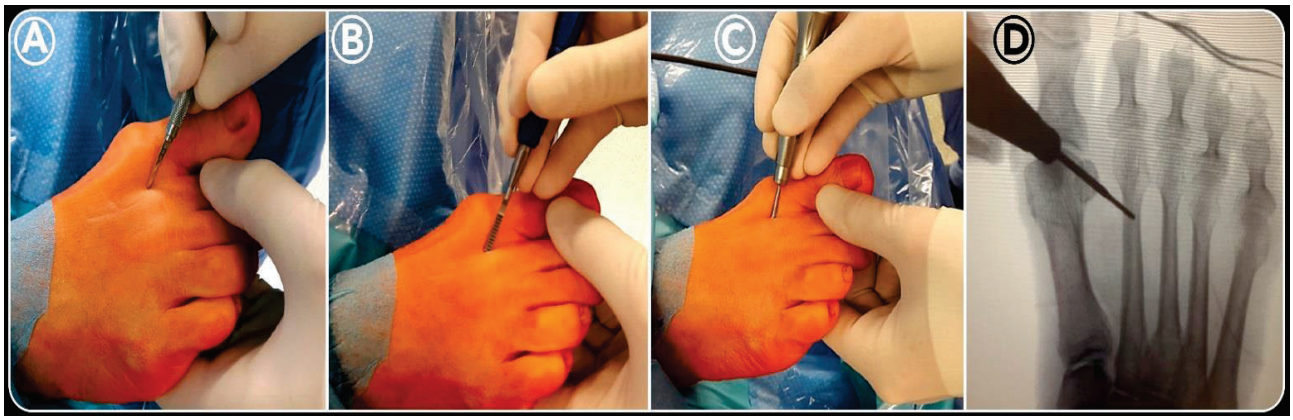

Figure 6. *DMMO intra-operative images (1st): using a small scalpel blade (SM64), an incision of 3-5 mm was made parallel to the extensor tendons at the dorsal side of the medial border of each M-head that needed to be shortened. The scalpel was advanced at an oblique angle of about 45° until it reached the dorsal aspect of the distal MB at the level of the neck* ***(A)****. Through the same incision, first a bone rasp was inserted, using it to separate the periosteum at the level of osteotomy* ***(B)****. Then, a Shannon Isham burr (2.0 x 12 mm) was introduced until it reached the metatarsal neck* ***(C)****. Fluoroscopy was used to confirm the correct position of the osteotomy site on the distal metaphysis of the MB* ***(D)*** *[1].*

In this position, the cutting is started with an angle of approximately 45° with respect to the long axis of the MB in a dorsal-distal to proximal-plantar direction, with rotary motion, extending to the contralateral cortex (**Figures 7B and 5B**). The lateral cortical surface is cut first in this way, then the plantar, medial and lastly, the dorsal cortical surface. During the osteotomy process, the incision site is irrigated by normal saline, as the burr can cause excessive heat, causing first skin burn and resulting subsequently in fibrosis and pseudoarthrosis at the bone level. Further, this lavage is useful to remove bone debris, preventing periarticular ossifications in the stab canal. To verify the completion of the osteotomy of each MB operated, manual traction on the corresponding toe is applied under fluoroscopic control (**Figure 7B**). Upon completion of the osteotomy, the bone is manually compacted, applying pressure in the distal-proximal direction of the interested metatarsal, pushing the metatarsal head dorsally and producing contact of the trabecular bone, since no internal fixation is used (**Figure 5C**).

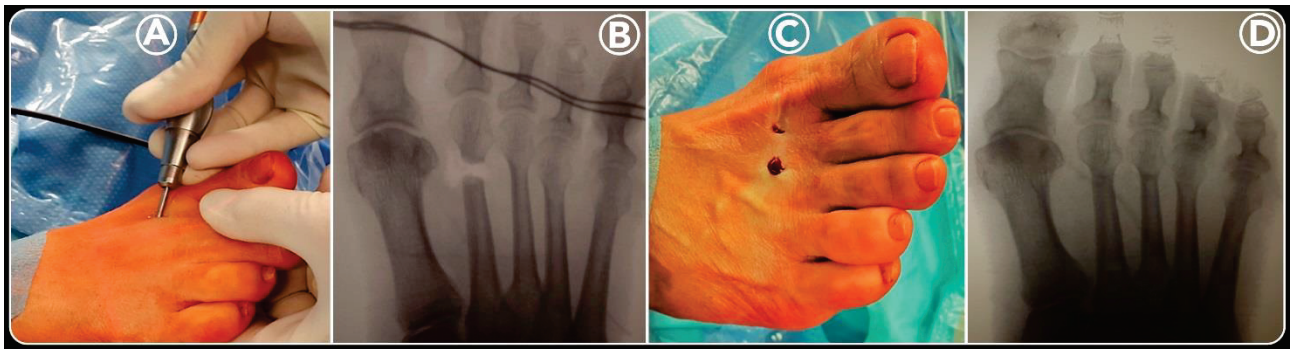

Figure 7. *DMMO intra-operative images (2nd): in this position, the DMDO was performed with an angle of approximately 45° with respect to the long axis of the MB in a dorsal-distal to proximal-plantar direction, with rotary motion, extending to the contralateral cortex* ***(A)****. To verify the completion of the osteotomy of each MB operated, manual traction on the corresponding toe was applied under fluoroscopic control* ***(B)****. Before closing the wounds by resorbable sutures* ***(C)****, the MBs were manually compacted, applying pressure in the distal-proximal direction, pushing their heads dorsally. Finally, after bandage application, a final radiographic check was made to evaluate the correction obtained* ***(D)*** *[1].*

The number of metatarsal osteotomies performed in each forefoot should be planned according to how much the metatarsal formula is altered according to the Maestro criteria (**Figure 1**). Before closing the wounds by absorbable sutures (**Figure 7C**), a final radiographic check is made to evaluate the correction obtained (**Figure 7D**).

*7.3.*2 Minimally Invasive Metatarsal Osteotomies (MIMOs) for Chronic Plantar Diabetic Foot Ulcers (PDFUs), including only the Distal Osteotomies (DMOs), such as the Distal Metatarsal Diaphyseal Osteotomy (DMDO)

7.3.2.1. MIMOs, DMOs and DMDO: general aspects and indications

MIMOs are minimally invasive surgical techniques, that find their applications in the treatment of CPDFUs and are performed without internal fixation. Their purpose is to favour the reduction of bone-induced pressure by promoting a lessening of metatarsalgia and/or the healing of CPDFU by trying to restore the metatarsal parabola of the forefoot. These procedures have emerged as an alternative to the traditional Weil osteotomy as it solves the problems of stiffness encountered in Weil osteotomy and offering several advantages typical of MIS [1-3, 17]. Due to its nature, the MIMO minimizes the tissue damage derived from surgical aggression, at the same time solving the mechanical causes that led to ulcer formation. The main purpose of this procedure is to decrease the pressure plantar to the affected metatarsal head. Further, since full weight bearing in a post-operative flat shoe is allowed immediately after surgery, the post-operative period is more comfortable for the patients.

Among these, DMMO [44], a technique used routinely in the last decade for the treatment of metatarsalgia, has been used to treat CPDFUs [1, 4]. A variant of this technique is the DMDO [4]. This procedure is based on a distal osteotomy more proximal to the metatarsal neck, not only to reduce the pressure on the ulcer and consequently favouring its healing, but also to restore the metatarsal parabola, preventing recurrent or transfer skin lesions [4].

The prevalence of diabetic foot complication is lower for woman than for men, and it is higher in patients affected by diabetes type 2 compared to those with diabetes type 1 [45]. It is estimated that 19–34% of patients with diabetes are likely to be affected with a PDFUs during their lifetime [46]. Because there is an increased number of newly diagnosed diabetics, the incidence of DFUs is estimated to grow in the next years [47]. The aetiology of DFUs is multifactorial: peripheral

neuropathy, poor glycaemic control, calluses, foot deformities, improper foot care, ill-fitting footwear, peripheral artery disease and dry skin are involved in the etiopathogenesis [47, 48].

The University of Texas Diabetic Wound Classification System (UTDWC) [49, 50], which takes into account the size and depth of the ulcer as well as the presence or absence of infection and ischemia, is used to grade and evaluate the CPDFUs preoperatively (**Table 1**). The size of the ulcers is determined as described by Coughlin, using a transparent sheet at each clinical evaluation to determinate the ulcer's diameter [51]. Their treatment continues to be challenging because of the high number of unhealed pressure ulcers found at one year after treatment (20%) and because of the high recurrence rate of about 40% within one year [52].

Ulcer	***Grade***			
Stage	**0**	**I**	**II**	**III**
A	Pre- or post-ulcerative lesion completely epithelialized	Superficial wound, not involving tendon, capsule, or bone	Wound penetrating to tendon or capsule	Wound penetrating to bone or joint
B	Pre- or post-ulcerative lesion completely epithelialized with infection	Superficial wound, not involving tendon, capsule, or bone with infection	Wound penetrating to tendon or capsule with infection	Wound penetrating to bone or joint with infection
C	Pre- or post-ulcerative lesion completely epithelialized with ischemia	Superficial wound, not involving tendon, capsule, or bone with ischemia	Wound penetrating to tendon or capsule with ischemia	Wound penetrating to bone or joint with ischemia
D	Pre- or post-ulcerative lesion completely epithelialized with infection and ischemia	Superficial wound, not involving tendon, capsule, or bone with infection and ischemia	Wound penetrating to tendon or capsule with infection and ischemia	Wound penetrating to bone or joint with infection and ischemia

Table 1. *The University of Texas Diabetic Wound Classification (UTDWC) used to grade CPDFUs [49, 50].*

The common goals of MIMO procedures are not only to favour the reduction of bone-induced pressure on the CPDFU and consequently promote its healing, but also to restore the metatarsal parabola of the forefoot, preventing recurrent, transfer skin lesions and possible future wound and bone infection [3]. Due to the preserved soft tissue covering and its characteristic stiffness in diabetic foot, the primary stability of these osteotomies is so high that successive osteosynthesis is not only unnecessary, but it would be harmful in preventing the dorsal elevation of the MB with respect to the ulcer level. The patient is asked to walk on the operated foot in the immediate postoperative period to elevate the head dorsally and to release plantar pressure.

It is important to highlight that DMOs should be performed only in patients not responsive to medical treatment. Ongoing severe and systemic infections and inability to complete postoperative protocol, including full weight bearing, are the contraindications reported in the literature [53], to which a study [3] presented in this thesis adds severe ischemia, gangrene and insufficient vascular perfusion of the feet. According to several authors [14], arthritis and stiffness of MTPJ are not absolute contraindications for DMO since the osteotomy performed involves the metatarsal diaphysis.

The preoperative evaluation of patients undergoing DMOs is both clinical and radiographic. In addition to the general characteristics of the patient, the clinical assessment involves the evaluation of aspects of the metatarsalgia, such as the site of pain and areas of hyperkeratosis, or of the plantar ulcer, for which the location, size and grade are considered using different grading scales. In case DMO is applied in diabetic patients, the general characteristics of diabetes are also considered. Regardless of the reasons leading to the intervention, the radiographic evaluation is based on the use of Maestro criteria [25] to decide on which metatarsals to perform the osteotomy to preserve or reconstitute a harmonious metatarsal formula. It is important to emphasise that the DMO should only be performed on the metatarsals directly responsible for the symptomatology unless the osteotomy alters the metatarsal formula favouring the risk of recurrence; in this case, the adjacent metatarsals must also be shortened.

7.3.2.2. MIMOs, DMOs and DMDO: surgical techniques

Different procedures for MIMOs were proposed during the years since 1986 [4, 11, 54-59], but all shared the same operative characteristics. MIMOs proposed by different authors were performed in a minimally invasive way using portals smaller than 5 mm open on the dorsal side of the foot at the different level of the lesser MBs, between the proximal diaphysis and the head. All authors performed osteotomies in oblique sliding shape, and osteosynthesis material was never used if not KWs to fix the osteotomies temporarily. Several authors [13, 14] agree on the importance of weight bearing as early as the first postoperative day using a rigid flat-soled orthopaedic shoe.

The first DMOs described by a metatarsal neck osteotomy of the metatarsal bones was Wray [59] in 1986 who osteotomised obliquely, starting proximally on the dorsum but proceeding distally and plantar-ward at an angle of 45°. Then in 1990, Tillo et al. [11] proposed four different types of DMOs: osteoclasis of the MB head, V-osteotomy, shortening colectomy and oblique sliding osteotomy. Almost three decades later, in 2016, Tamir et al. [56] performed a perpendicular or short oblique osteotomy at the neck or diaphysis of the metatarsal bone.

In 2018, in an article included in the current thesis [4], a DMDO was described for the first time with an angle of approximately 45° with respect to the long axis of the lesser MBs such as that described by Wray previously but performed in a dorsal-distal to proximal-plantar direction at the level of the distal diaphysis. Similarly, Tamir et al. [57] treated in 2020 another series of patients using a MIMO perpendicular to the first MB distal metaphysis and, in the same year, Chiu et al. [54] moved the site of ostectomy proximal to the metatarsal neck with the purpose of preserving MTPJ function. Finally, in 2021, Tamir et al. [58] proposed a new minimally invasive floating distal metatarsal oblique osteotomy.

The operative technique, as described by D. Redfern for DMMO, involves the patient lying in a supine position with the operated foot protruding from the table. General or regional anaesthesia and antibiotic prophylaxis are administrated before surgery [13]. A burr is inserted through a 5 mm incision made in the intermetatarsal space at the level of the head of the metatarsal to be operated,

and under fluoroscopic guidance, the osteotomy is made at 45° in the dorsal-distal to plantar-proximal direction (**Figure 8**) [1, 3, 4].

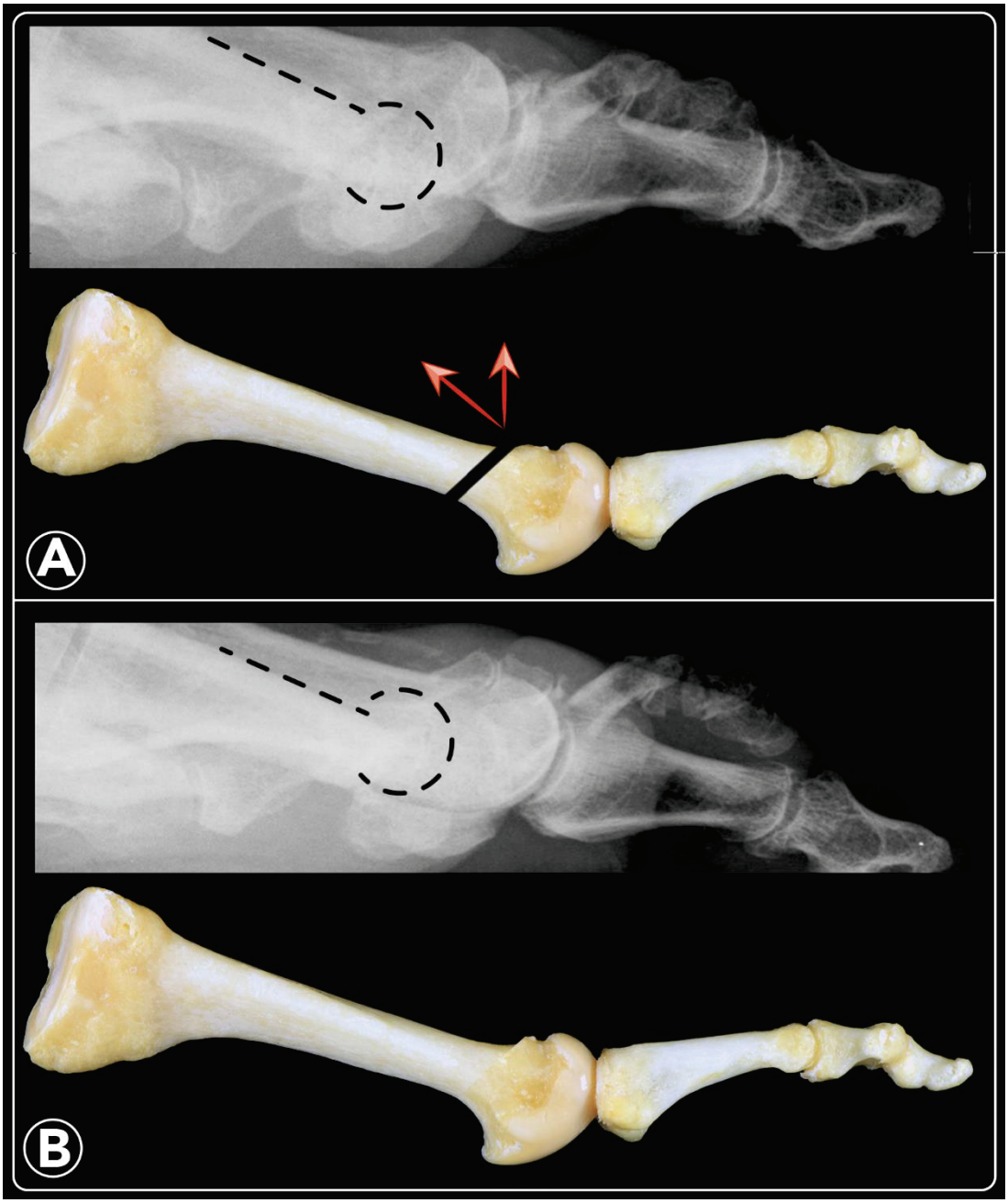

Figure 8. *Weight-bearing radiographic and respective bone images of DMDO showing the position of the second MTT bone with respect to the ground at preoperative period* ***(A)****, and the final result of an ideal osteotomy performed proximal to the neck with potentially greater elevation from the ground at post-operative period* ***(B)*** *[4].*

When concomitant HV is present in diabetic patients, MIIND or RIO techniques, associated or not to F1 AKIN osteotomy, can be performed.

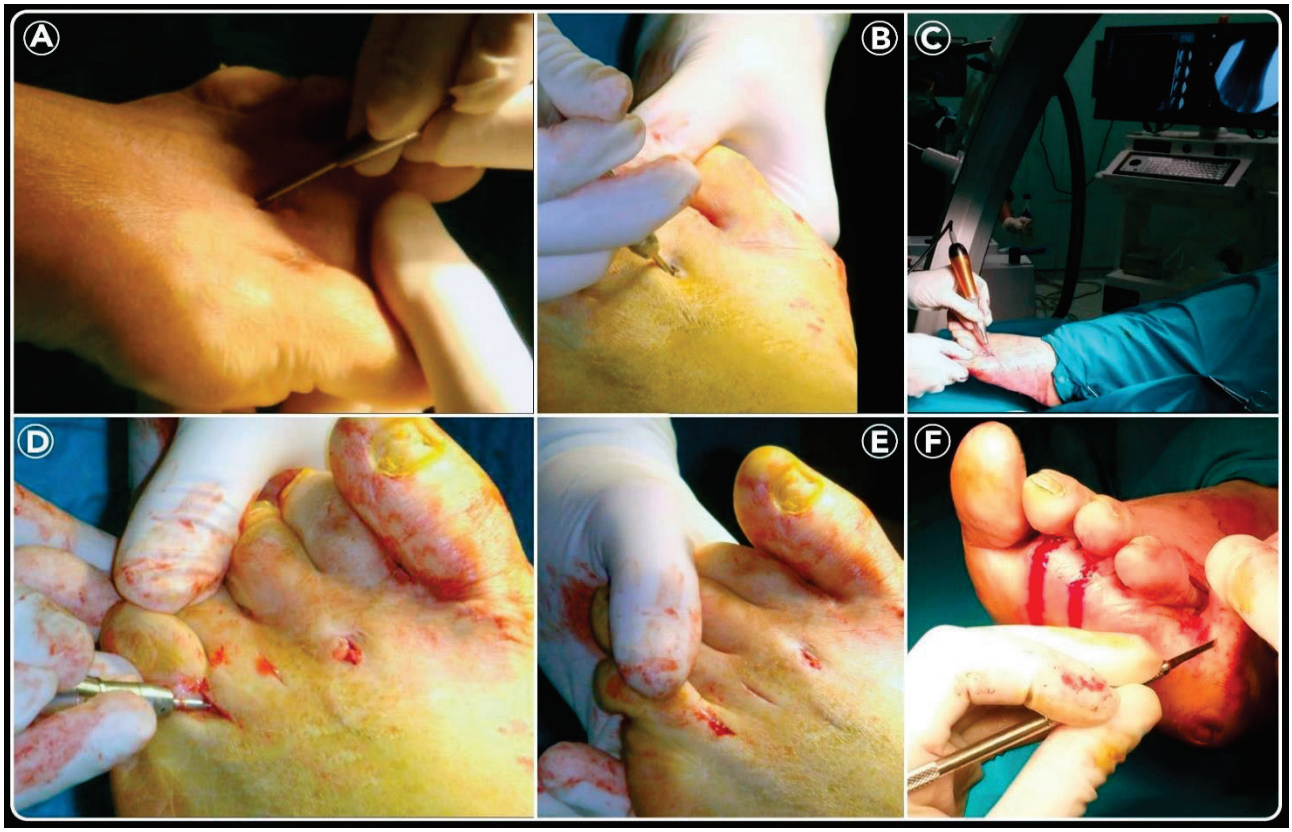

Figure 9. *DMDO intra-operative images: a 12-mm Shannon Isham burr is introduced through a 5-mm portal until it reaches the metatarsal (MTT) neck* ***(A)*** *and then is retracted a few millimetres proximally where the periosteum was previously removed by a bone rasp* ***(B)****. During the different surgical phases, several fluoroscopic controls are used to confirm the correct position of the osteotomy site on the distal diaphysis of the MTB to verify its completion and following compaction and to check if a more harmonious forefoot morphotype has been restored* ***(C)****. The DMDO is performed with an angle of approximately 45° with respect to the long axis of the MTB in a dorsal-distal to proximal-plantar direction, with rotary motion, extending to the contralateral cortex* ***(D)****. Upon DMDO completion, the bone is manually compacted, exercising pressure in the distal-proximal direction of the treated MTT, pushing its head dorsally* ***(E)****. Finally, an associated claw toe deformity, in this case flexible, is treated by extensor and flexor percutaneous tenotomy* ***(F)*** *[4].*

The DMDO is the technique personally described in 2018 [4]. An incision of 5 mm is made parallel to the extensor tendons by a small scalpel blade (SM64) at the dorsal side of the medial (or lateral) border of each metatarsal head that needs to be shortened (**Figure 9**). The side of the incision depends on the surgeon being right or left-handed and which foot is being operated on. The scalpel is advanced at an oblique angle of about 45° until it reaches the dorsal aspect of the distal metatarsal bone, proximal to the neck, to undergo osteotomy. Through the same incision, first a bone rasp specific for percutaneous surgery is inserted, using it to separate the periosteum at the level of osteotomy. Then, a Shannon Isham burr (2.0 x 12 mm), adapted for Mm960 (produced by Medic Micro, Switzerland), is introduced until it reaches the metatarsal neck (**Figure 9A**) and then retracted a few millimetres proximally where the periosteum was previously removed (**Figure 9B**). Fluoroscopy is used to confirm the correct position of the osteotomy site on the distal diaphysis of the metatarsal bone (**Figure 9C**). In this position, the cutting is started with an angle of approximately 45° with respect to the long axis of the metatarsal bone in a dorsal-distal to proximal-plantar direction, with rotary motion (**Figure 9D**), extending to the contralateral cortex. In this way, the lateral cortical surface is cut first, then the plantar, medial and lastly, the dorsal cortical surface.

During the osteotomy process, the incision site is irrigated by normal saline as the burr can cause excessive heat, causing first skin burn and resulting subsequently in fibrosis and pseudoarthrosis at the bone level [5, 60]. Further, this lavage is useful to remove bone debris, preventing periarticular ossifications in the stab canal. Upon completion of the osteotomy, the bone is manually compacted, exercising a pressure in the distal-proximal direction of the interested metatarsal, pushing the metatarsal head dorsally and producing contact of the trabecular bone since no internal fixation is performed (**Figures 9E and 8B**). The number of metatarsal osteotomies performed in each forefoot was planned according to how much the metatarsal formula was altered according to the Maestro criteria. In the cases of associated interphalangeal HV or claw toe deformity, in order to prevent toe ulcerations, they are treated as described by De Prado [35]: the first by percutaneous Akin osteotomy, the second through extensor and flexor tenotomies in cases of flexible deformity, or associated

osteotomies of phalanges in cases of fixed deformity (**Figure 9F**).

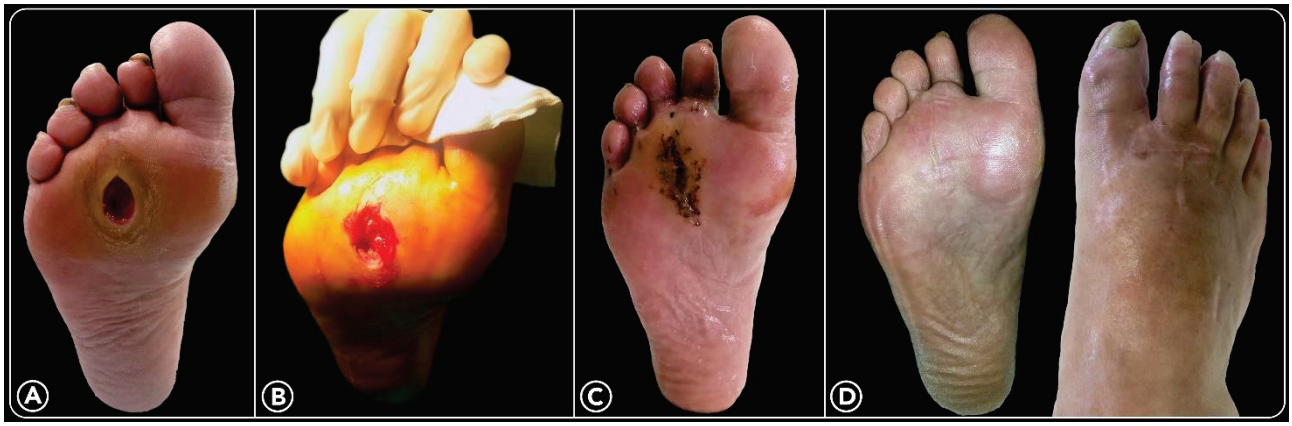

Figure 10. A *70-year-old type II diabetic male patient having undergone DMDO of the 2nd, 3rd and 4th MTT bone for a Grade IIIB ulcer extending into the MTPJ on his right foot and percutaneous osteotomy of P1 of the 2nd toe associated with percutaneous tenotomies for claw deformity. Clinical images at preoperative* ***(A)****, intraoperative period* ***(B)****, 1-month follow-up* ***(C)*** *and 3-month follow-up* ***(D)****, showing the complete healing of the ulcer [4].*

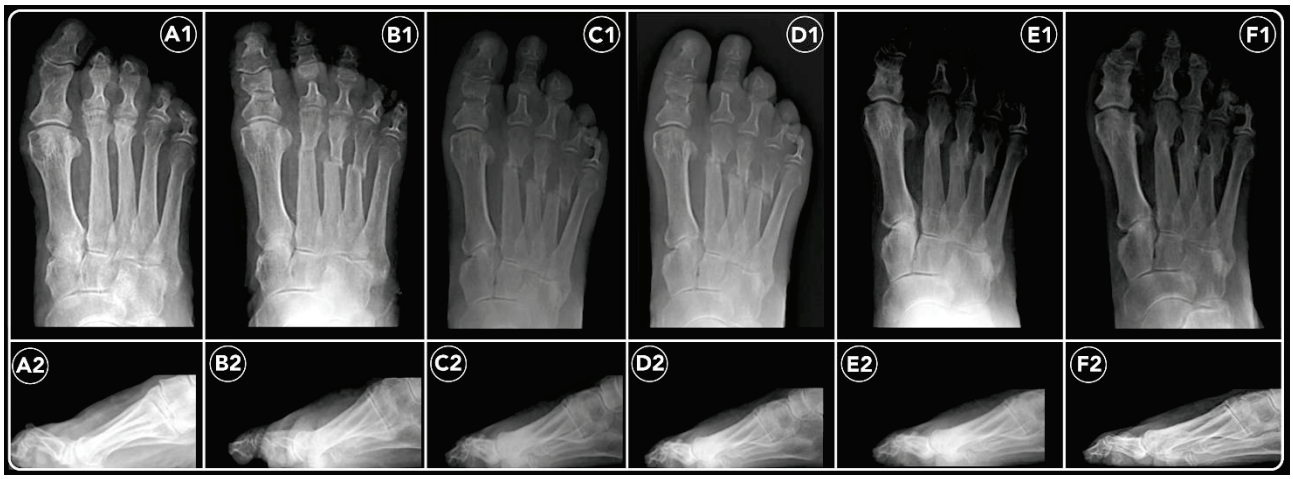

Figure 11. *The same diabetic patient of figure 11 having undergone the described procedures, radiographic images:* ***(1)*** *antero-posterior and* ***(2)*** *lateral view at preoperative period* ***(A)****, immediate postoperative period* ***(B)****, 1-month follow-up* ***(C)****, 3-month follow-up* ***(D)****, 12-month follow-up* ***(E)*** *and 48-month follow-up* ***(F)****, showing bone callus consolidation and its remodelling maintaining the elevation of the MTT head and having adapted to the load, has ossified in a new dorsal position [4]*

After accurate ulcer debridement, a chronic ulcer is converted into an acute wound (**Figure 10B)**, permitting the normal stages of healing to ensue [61, 62], while the rest of the wounds are closed with absorbable sutures.

7.3.3 Reverdin-Isham Osteotomy (RIO) in Combination with Akin Percutaneous Osteotomy (APO) and Lateral Soft-Tissue Release (LSTR) for Mild to Moderate HV Correction

7.3.3.1 RIO, APO and LSTR: general aspects and indications

The Reverdin-Isham technique is a percutaneous osteotomy performed with a minimally invasive approach in the treatment of mild to moderate HV, often in association with AKIN osteotomy of proximal phalanx (P1). Both are performed without osteosynthesis material to align the first ray and correct the HV. It should be clarified that the Reverdin-Isham osteotomy and the Akin are not completed, as the lateral cortex of the MTT-1 and the P1 are preserved [35, 63].

This technique was developed in 1980 by Dr Isham who modified the Reverdin osteotomy by performing the medial wedge osteotomy on the head of the first metatarsal at an angle from dorsal-distal just proximal to the articular surface on the dorsal side of the metatarsal head to the plantar-proximal direction just proximal to the articular surface on the plantar side of the metatarsal head to preserve and reposition the articular surface [63]. At the end of the last century, this percutaneous procedure became widespread first in Spain and then in Europe by M. De Prado and P.L. Ripoll through their surgical practices and international theoretical-cadaveric courses, supported by the anatomical studies of Pau Golanó [35].

RIO finds its applications in the correction of mild to moderate HV. According to Mann and Coughlin parameters [51, 64], HV can be defined mild when the Hallux Valgus Angle (HVA: the angle between the long axis of I metatarsal and proximal phalanx) is less than 20° and the Intermetatarsal Angle (IMA: the angle between long axis of I and II metatarsal) is less than 11°. If HVA is from 20° to 40° and IMA is from 11° to 16°, HV is classified as moderate.

Pre-operative planning includes both clinical and radiographic evaluation: the clinical evaluation includes the patient's general history, his clinical and biographical characteristics and the physical and clinical assessment of a painful HV. In pre-operative planning, it is essential to obtain standing antero-posterior, lateral and sesamoid X-rays in order to accurately assess the characteristics of HV,

such as IMA, HVA values and tibial sesamoid displacement, and to be able to classify it correctly. According to the literature [20], [21], RIO is defined by five major steps: exostosectomy, Reverdin-Isham osteotomy, tenotomy of the adductor hallucis tendon and lateral capsulotomy, Akin osteotomy, always associated with this technique, and bandaging. The surgical technique performed by our team is described in detail in a paper [5] presented in the current PhD thesis. Because it is a minimally invasive surgical technique, the patient is able and encouraged to walk as much as he/she can tolerate already in the evening after surgery using a rigid flat-soled orthopaedic shoe. In addition, no physiokinesis therapy is required.

7.3.3.2 RIO, APO and LSTR: surgical technique

An incision of 3-5 mm long is made at the plantar side of the medial border of the first metatarsal head (**Figure 12A**). Through this medial approach, a small scalpel is introduced within the joint

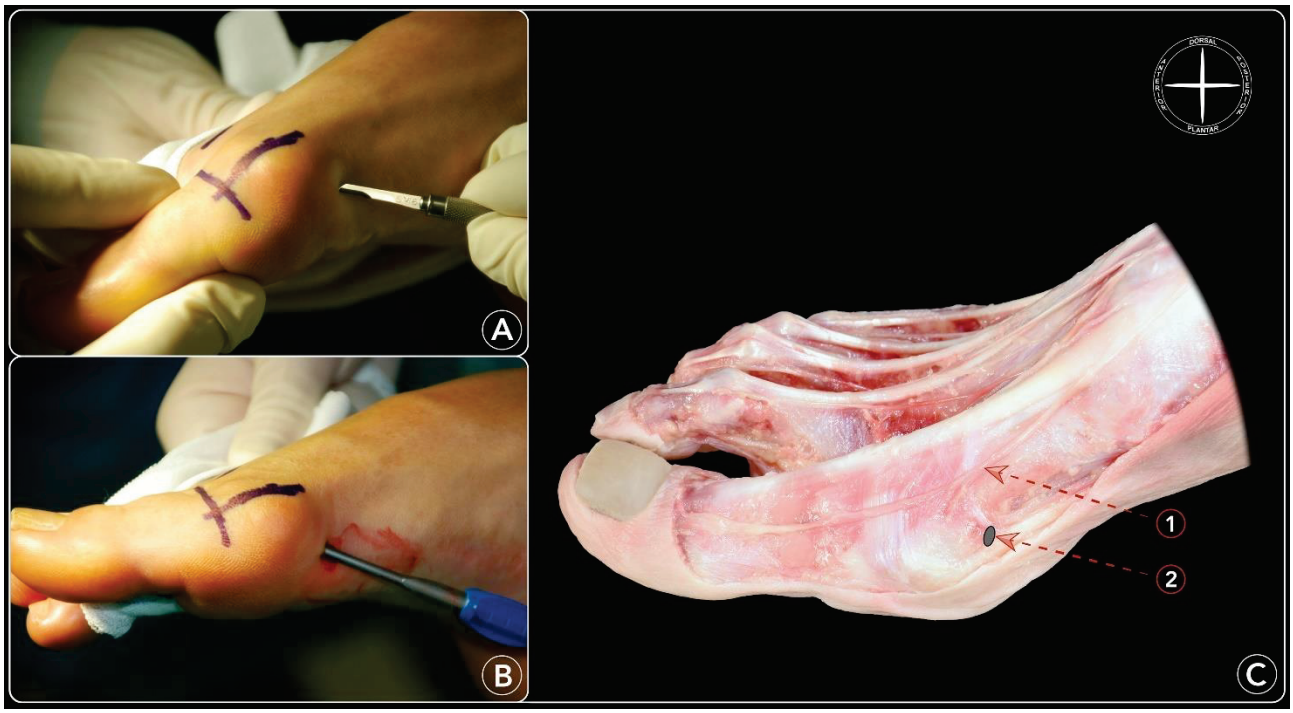

Figure 12: *Portal placement* ***(A)*** *and rasp introduction* ***(B)****. The protocolised incision protects the dorsomedial cutaneous nerve of the hallux* ***(C)****: 1. Dorsomedial cutaneous nerve of the hallux. 2. Point of incision for Reverdin-Isham osteotomy [5].*

capsule of the MTPJ of the big toe. By a sweeping movement, the medial capsule is separated from the exostosis, subsequently using also a rasp **(Figure 12B)**. The location of this incision prevents damage of the dorsomedial cutaneous nerve of the hallux [7] **(Figure 12C)**. Then a cylindrical burr (3.1 x 15 mm) is introduced to perform exostosectomy, and the dorsal medial prominence is removed from the first metatarsal head until a flat surface is obtained, assessed under manual palpation and fluoroscopic control. Finally, the bony detritus is extruded manually. Through the same incision used for the exostosectomy, a Shannon Isham burr (2 x 12 mm) is introduced at the junction of metaphysis and epiphysis to perform RIO. It is applied to the flat bone surface, achieved previously by exostosectomy, at an angle of approximately 45° to the long axis of the first metatarsal bone, keeping the articular cartilage surface of the first MB head as the reference point on the dorsal cortex, and the medial sesamoid bone as the reference point on the plantar cortex **(Figure 13A)**. In this position, under fluoroscopic control, the osteotomy is started following a distal-dorsal and proximal-plantar direction, extending until the lateral cortex, but without cutting it. At this point, the burr is slightly withdrawn to preserve a few millimetres of the lateral cortex, and the osteotomy of the plantar cortex is performed completely. Then, a Wedge burr (3.1x 13 mm or 4.1 x 13 mm, depending on the DMAA value) is used to create a wedge with a medially oriented base. At the point of closing the wedge, osteoclasis of the preserved lateral cortex is achieved, modifying the orientation of the articular surface, normalising the DMAA value and adding intrinsic stability to the osteotomy by producing contact of the trabecular bone (**Figure 13B**).

A longitudinal skin incision is performed on the first web space, 2-3 mm lateral to the extensor hallucis longus tendon. The blade is longitudinally introduced in contact with the lateral surface of the base of the proximal phalanx; then the blade is rotated 90º laterally, and the first toe is forced in varus, allowing the adductor hallucis tendon to be sectioned and the lateral part of the capsule joint to be cut. Movement of the blade is carefully controlled in order to avoid a complete capsulotomy, which could produce joint instability. In this way, tenotomy of the adductor hallucis tendon and lateral capsulotomy are performed. Once lateral soft-tissue release is complete, a new incision 3 to 5 mm

long on the lateral surface of the base of the proximal phalanx of the first toe is performed, just medial to the extensor tendons.

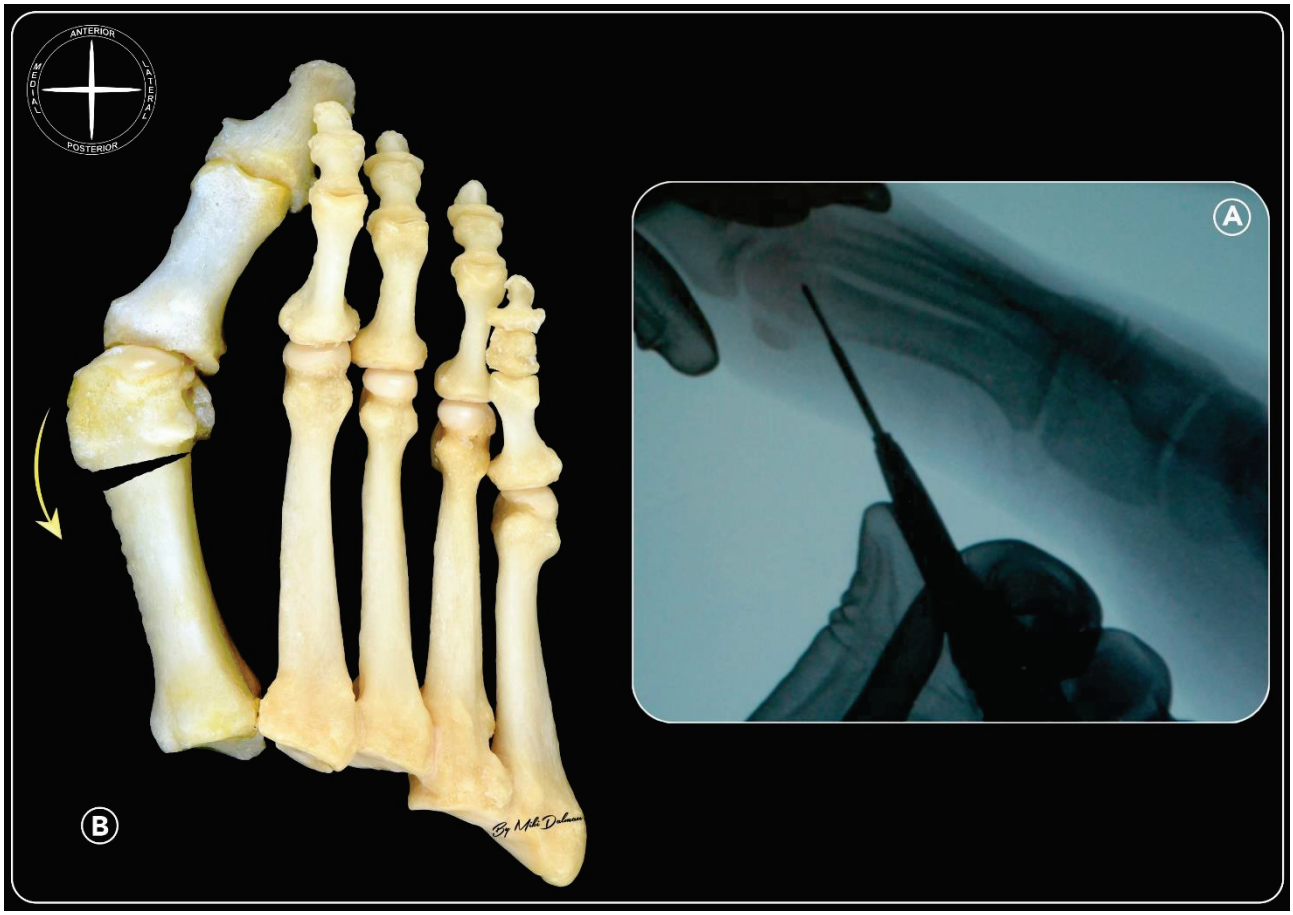

Figure 13: *Reverdin-Isham osteotomy: intraoperative fluoroscopic imagine showing the proper position and inclination of the burr with to respect the distal first metatarsal bone* ***(A)****; the final result of an ideal closing wedge osteotomy with a medial base that corrects also the DMAA* ***(B)*** *[5].*

Using a small scraper, the periosteum is removed from the lateral surface of the base of the proximal phalanx. Then, using a wedge burr (3.1x 13 mm), a wedge osteotomy named APO (with medial base) is performed; as in the osteotomy on the head of the first metatarsal, the lateral cortex is preserved. Closing of the osteotomy and osteoclasis of the lateral cortex is achieved by means of a forced varus movement of the toe.

7.3.4 Minimally Invasive Intramedullary Nail Device (MIIND) for Moderate to Severe HV Correction

7.3.4.1 MIIND: general aspects and indications

MIIND is an open minimally invasive technique that, like DMMOs and RIO, involves a decrease of recovery times, smaller scars and a greater range of early postoperative motion. For the MIIND procedure, an intramedullary nail, commercially known as Endolog, is used for osteotomy fixation. This has been produced since 2006 by Medical2, Castel nuovo del Garda, Verona, Italy. The device is a titanium endomedullary nail with a curved shape (TA6V ELI - ASTMF 136), treated with anodic oxidation and laser markings [65].

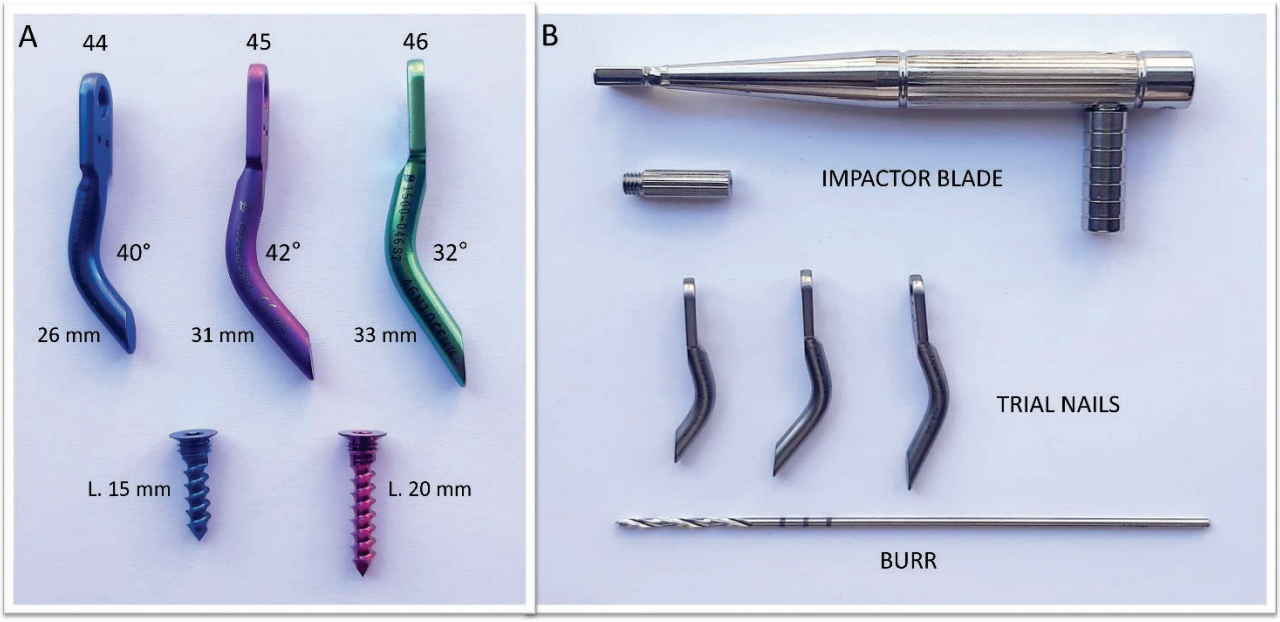

Figure 14. *Image of the three different sizes of MIIND (44, 45, and 46), each with different degrees of curvature (40, 42 and 32 degrees, respectively) and lengths (26 mm, 31 mm and 33 mm). Two 3.66 mm titanium angular stable screws (15 mm and 20 mm) are available for its fixation* ***(A)****. The complete kit of the device including impactor blade for its application, trial nails for test during surgery and burr to perform the screw hole* ***(B)*** *[6].*

The term Endolog was coined by its inventor Giuseppe Lodola: “Endo” is a reference to the endomedullary nature of the nail, while “LoG” is short for his own initials [65]. It is formed by a curvilinear cylindrical body with a diameter of 4.5 mm and a blade inclined by 4 degrees with respect to the axis of the nail, which serves to push for lateral translation of the metatarsal head. The Endolog is available in three sizes (44, 45 and 46) with three different degrees of curvature (32°, 40° and 42°) and three different lengths (26 mm, 31 mm and 33 mm). It is fixed to the metatarsal head using a 3.66 mm titanium angular stable screw, available in three different lengths (15 mm, 20 mm and 25 mm), which stabilises the osteotomy site and the translation of the metatarsal head (**Figure 14**).

It is provided with dedicated instruments that include an impactor with a special drill guide, three test sizes of the nail, a graduated drill tip and a screwdriver. These features give the device maximum biocompatibility, no interference in case of magnetic resonance (MR) scan, absolute sterility, traceability of the system and adherence to the European legal rules (93/42CE). No other available device has the unique technical characteristics of this nail apart from the predecessor of the Endolog, the “Hallux Splint” [66].

The MIIND technique is recommended and used in the Padua Orthopaedic Department in cases of moderate to severe HV. According to Mann and Coughlin parameters [51, 64], if HVA is of 20° to 40° and IMA is of 11° to 16°, HV is classified as moderate, HV is defined severe if HVA > 40° and IMA > 16°.

Pre-operative assessment involves both clinical and radiographic steps: the clinical evaluation includes the patient's general and clinical history, and the physical and clinical assessment of HV, while standing antero-posterior and lateral X-ray views are obtained to evaluate the grade of the HV. Preoperative planning is useful for choosing the most appropriate size of the implant to guarantee an adequate translation of the head according both to the severity of the HV and to the first MB medullary cavity. However, it is not possible to standardize the exact lateral translation of the first MB, that is the reason why trial nails in different sizes are provided and used intraoperatively.

The MIIND technique is described in the literature in several papers [67, 68]. Our experiences are

also reported [6, 65]. The various authors performed the operation in the same standardized manner and, also for this procedure as in percutaneous ones, the patients are allowed and encouraged to walk as much as he/she can tolerate using a rigid flat-soled orthopaedic shoe already in the evening of the surgery.

7.3.4.2 MIIND: surgical technique

Differently from the previous percutaneous procedure described, a tourniquet is applied and left in place at the level of the ankle when using MIIND. A 4 cm percutaneous dorsal-medial longitudinal incision is made at a point corresponding to the exostosis of the first MB, avoiding the dorsal digital branch of the medial cutaneous nerve, and the neurovascular bundle is protected appropriately. Then the capsular incision is performed in a dorsal longitudinal orientation along the line of the skin incision. Capsular and ligamentous tissues are freed around the first MB head dorsally and medially, and the bone is liberated from the periosteum. A cuneiform osteotomy is performed using a standard oscillating saw in a distal to proximal direction, from 2-4 mm to zero, to remove the dorsomedial eminence of the first metatarsal head and to produce a flat surface on the head to support the impactor's blade upon which the device is assembled **(Figure 15A)**. For a correct position of the device, perfect coplanarity and maximum adherence of the pallet support to the flat surface previously created on the metatarsal head is crucial (**Figure 15B**). Two 1.8 mm KWs acting as joysticks are inserted to allow lateral translation of the metatarsal head, making it possible to correct both the DMAA and the dislocated sesamoid apparatus due to pronation of the big toe. A linear osteotomy, at times perpendicular to the proximal level of the neck and at times oblique to lengthen or to shorten the MB, is performed. Once the trial device is assembled on the impactor, it is introduced into the medullary with lateral displacement of the head (**Figure 15C**). The correction attained is checked clinically and under fluoroscopy before the final device is applied. The correction and the implant are stabilised applying temporary 1.2 mm KWs through the holes of the device. The head is fixed to the implant with a screw long enough to provide angular stability (**Figure 15D**).

Once the wire is removed and before closing the capsule and suturing the skin with 2-0 absorbable stitches, it is necessary to regulate the medial angle of the metatarsal neck to prevent conflict of the bone with the soft tissues and skin. A compression dressing and tape are applied to maintain a slight hypercorrection of the hallux, and it is changed weekly.

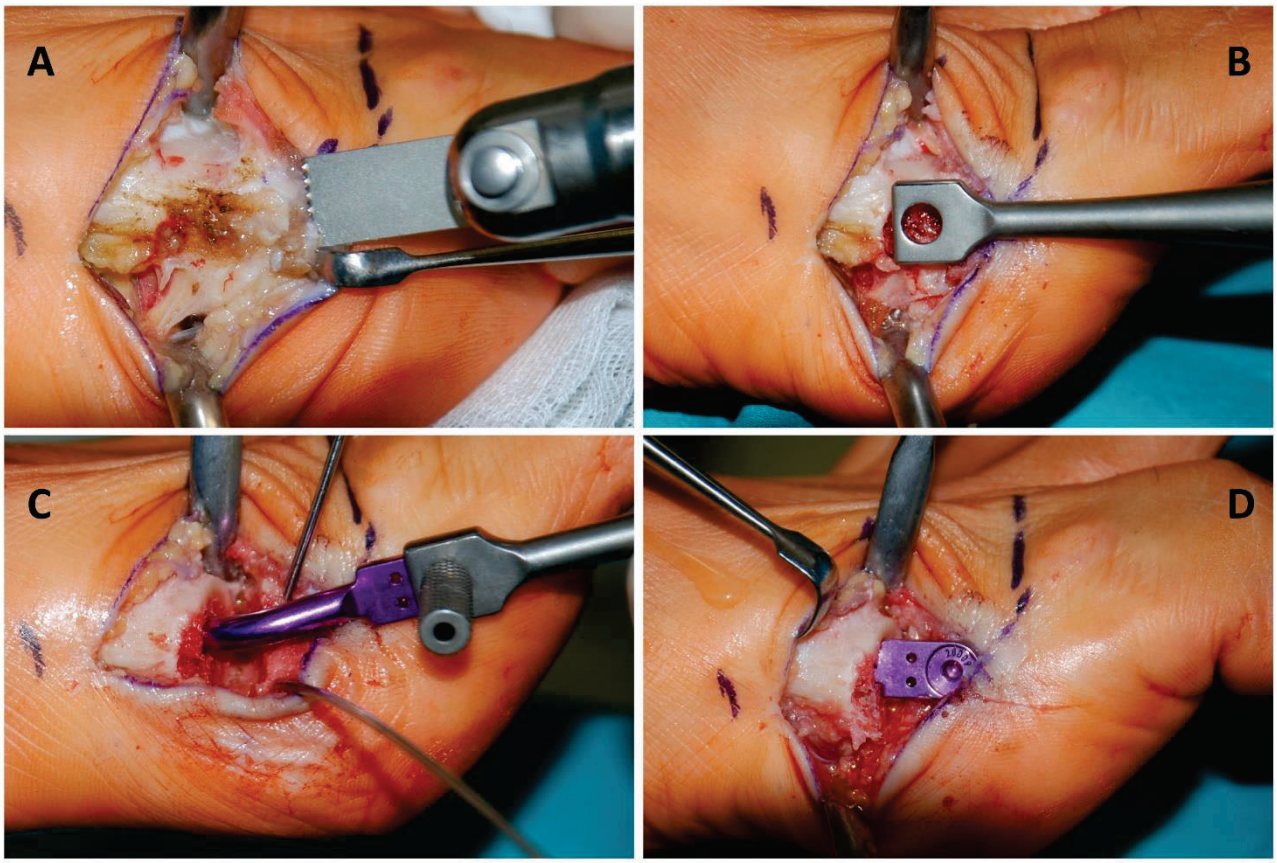

Figure 15. *Intraoperative images showing the main steps of the MIIND technique: bunionectomy is performed to remove the medial eminence by a standard oscillating micro-saw in a distal to proximal direction* ***(A)****. A flat surface on the I-MTTH is made to support the impactor blade and assure maximum adherence with the blade pallet support* ***(B)****. The MIIND-45 is applied definitively to maintain the correction by progressive lateral displacement and contemporary derotation of the I-MTTH. Previously, a linear osteotomy is performed at the proximal level of the neck and the trial nail is introduced into the medullary cavity to verify the adequate alignment of the first ray* ***(C)****. Finally, the I-MTTH is fixed to the MIIND implant with a 20 mm-screw, providing angular stability* ***(D)*** *[6].*

To study only the efficacy of the MIIND technique on correction of HV deformity, no soft-tissue procedures, such as the most common adductor hallucis tendon release, lateral capsulotomy, fibular sesamoidectomy, extensor halluces brevis or longus tendon lengthening is performed.

8. HYPOTHESIS

The hypothesis of the present project is that DMOs, performed at different levels of the distal part of MBs (from 1st to 5th), as single or associate procedures, with or without fixation, (temporary by KWs or permanent by MIIND), may be effective surgical treatment options for achieving:

- metatarsalgia symptom resolution;
- healing of PDFUs even when they are chronic (CPDFUs);
- mild to severe HV correction.

9. OBJECTIVES

First, the main objective of our project is to present an accurate, extended surgical and anatomical description of 4 percutaneous or minimally invasive techniques (DMOs) that have been selected because of their importance for the treatment of the most frequent forefoot pathologies:

1. Distal Metatarsal Metaphyseal Osteotomy **(DMMO)**;
2. Minimally Invasive Metatarsal Osteotomies **(MIMOs)** considering only Distal Metatarsal Osteotomies **(DMOs)** such as Distal Metatarsal Diaphyseal Osteotomies **(DMDOs)**;
3. Reverdin-Isham **(RIO)** in combination with Akin Percutaneous Osteotomy **(APO)** and Lateral Soft-Tissue Release **(LSTR)**.

Secondly, the following percutaneous and minimally invasive procedures have been studied with the objective of clarifying and describing their proper indications to guide orthopaedic surgeons in the choice of procedure in relation to the type and severity of the foot pathology to treat:

1. *Distal Metatarsal Metaphyseal Osteotomy **(DMMO)*** for the treatment of metatarsalgia [1];
   - *Distal Metatarsal Diaphyseal Osteotomy **(DMDO)*** [4] for the treatment of plantar diabetic foot ulcers (PDFUs) [2, 3];
2. Reverdin-Isham Osteotomy **(RIO)** in combination with ***Akin Percutaneous Osteotomy*** and

Lateral Soft-Tissue Release for mild to moderate HV correction [5];

3. Minimally Invasive Intramedullary Nail Device **(MIIND)** for moderate to severe HV correction [6].

10. MATERIAL, METHODS, AND RESULTS IN THIS ARTICLE-BASED THESIS

The following six publications report the clinical-functional and radiographic outcomes of the original articles and review already carried out and published in indexed scientific journals (Q2-Q3) relating to the ***4 operative percutaneous and MI techniques*** analysed in this thesis.

10.1 Distal Metatarsal Metaphyseal Osteotomy (DMMO) for the treatment of metatarsalgia

For this percutaneous procedure the following article [1] was included:

- ***Medium-Long-Term Clinical and Radiographic Outcomes of Minimally Invasive Distal Metatarsal Metaphyseal Osteotomy (DMMO) for Central Primary Metatarsalgia: Do Maestro Criteria Have a Predictive Value in the Preoperative Planning for This Percutaneous Technique?*** Biomed Res Int. **2018** Nov 15; 2018:1947024. doi: 10.1155/2018/1947024. PMID: 30581846; PMCID: PMC6276525.

  The purpose of this prospective study was first to evaluate the safety and effectiveness of DMMO in treating central metatarsalgia, identifying possible contraindications. The second objective was to verify the potential of DMMO to restore a harmonious forefoot morphotype according to Maestro criteria. A consecutive series of patients with metatarsalgia was consecutively enrolled and treated by DMMO. According to Maestro criteria, preoperative planning was carried out by both clinical and radiological assessment. Patient demographic data, AOFAS scores, 17-FFI, MOXFQ, SF-36, VAS, and complications were recorded. Maestro parameters, relative morphotypes, and bone callus formation were assessed. Statistical analysis was carried out ($p < 0.05$). Ninety-three patients (93 feet) with a mean age of 62.4 (31-87) years were evaluated. At mean follow-up of 58.7 (36-96) months, all the clinical scores improved significantly ($p < 0.0001$). Most of the osteotomies (76.3%) had healed by 3-month follow-up, while ideal harmonious morphotype was restored only in a few feet (3.2%). Clinical and radiological outcomes were not different based on principal

demographic parameters. Long-term complications were recorded in 12 cases (12.9%). DMMO is a safe and effective method for the treatment of metatarsalgia. Although Maestro criteria were useful to calculate the metatarsal bones to be shortened and a significant clinical improvement of all scores was achieved, the ideal harmonious morphotype was restored only in a few feet. Hence, our data show that Maestro criteria did not have a predictive value in clinical outcomes of DMMO.

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Research Article

Medium-Long-Term Clinical and Radiographic Outcomes of Minimally Invasive Distal Metatarsal Metaphyseal Osteotomy (DMMO) for Central Primary Metatarsalgia: Do Maestro Criteria Have a Predictive Value in the Preoperative Planning for This Percutaneous Technique?

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Academic Editor: Sheldon Lin

Background. The purpose of this prospective study was first to evaluate the safety and effectiveness of Minimally Invasive Distal Metatarsal Metaphyseal Osteotomy (DMMO) in treating central metatarsalgia, identifying possible contraindications. The second objective was to verify the potential of DMMO to restore a harmonious forefoot morphotype according to Maestro criteria. *Methods*. A consecutive series of patients with metatarsalgia was consecutively enrolled and treated by DMMO. According to Maestro criteria, preoperative planning was carried out by both clinical and radiological assessment. Patient demographic data, AOFAS scores, 17-FFI, MOXFQ, SF-36, VAS, and complications were recorded. Maestro parameters, relative morphotypes, and bone callus formation were assessed. Statistical analysis was carried out ($p < 0.05$). *Results*. Ninety-three patients (93 feet) with a mean age of 62.4 (31-87) years were evaluated. At mean follow-up of 58.7 (36-96) months, all of the clinical scores improved significantly ($p < 0.0001$). Most of the osteotomies (76.3%) had healed by 3-month follow-up, while ideal harmonious morphotype was restored only in a few feet (3.2%). Clinical and radiological outcomes were not different based on principal demographic parameters. Long-term complications were recorded in 12 cases (12.9%). *Conclusion*. DMMO is a safe and effective method for the treatment of metatarsalgia. Although Maestro criteria were useful to calculate the metatarsal bones to be shortened and a significant clinical improvement of all scores was achieved, the ideal harmonious morphotype was restored only in a few feet. Hence, our data show that Maestro criteria did not have a predictive value in clinical outcomes of DMMO.

1. Introduction

Central metatarsalgia, one of the most common problems in orthopaedic clinical practice, is a term used to indicate a painful condition localized in the plantar forefoot region between the 2nd and 4th metatarsal heads and/or the metatarsophalangeal joint [1–3], often associated with the most frequent forefoot disorders, such as hallux valgus (HV) and lesser toe deformities. Ten percent of the general population has had some form of pain in the metatarsal region during their lifetime, the majority being female [4, 5]. This condition is not a diagnosis but a symptom for which

there can be several contributing factors [6]. Metatarsalgia syndrome can be classified as primary or biomechanical, secondary, and iatrogenic [3, 7, 8]. Primary or biomechanical metatarsalgia is the most important, accounting for about 90% of cases [2]. It is caused by intrinsic abnormalities of metatarsal anatomy and the relationship between the metatarsal bones (MBs) and the rest of the foot, resulting in an overload to the forefoot [5]. Its most common cause is a long second MB [9]. Individuals presenting congenital brevity of the 1st metatarsal (M1) or severe HV may complain of pain in the forefoot caused by incompetence of the first ray in its weight-bearing function, creating transfer pressure to lesser metatarsal, in particular the 2nd metatarsal (M2). Other causes of primary metatarsalgia include disproportionate length of M2 or the 3rd metatarsal (M3), congenital deformities of the metatarsal heads, tightness of the gastrocnemius muscles or triceps, fixed equinus of the foot, pes cavus, and any hindfoot abnormality that results in overloading of the forefoot [10, 11]. Maestro and Besse have studied forefoot structure to define ideal forefoot morphology with precise criteria [9]. Forefoot alterations cause imbalance in weight-bearing distribution that may lead to mechanical overload on the affected metatarsal heads and may evolve to pain and plantar callosities [4, 12].

First-step metatarsalgia treatment is conservative, including physical therapy and stretching exercises for gastrocsoleous tightness, functional foot orthoses and shoe modifications to lessen the pressure on the forefoot, debridement of calluses associated with painful keratosis when present, and judicious use of corticosteroid injections [13]. These can be sufficient to achieve satisfactory results in 85% of cases [8] and should always be carried out before considering surgery in the management of this condition [3].

However, when these conservative measures fail and the metatarsalgia becomes recalcitrant, it requires surgical treatment with or without procedures on the first ray [14, 15]. The primary goal of surgery is to relieve pain and restore an ideal forefoot morphology with a normal distribution of pressure in the forefoot [16–18]. Multiple surgical procedures have been described for this syndrome [1, 19–26]. However, the Weil osteotomy (and its modifications) has been the preferred technique employed by surgeons for many years in Europe [17, 26, 27]. This procedure consists of an open intra-articular osteotomy performed after preoperative planning based on the Maestro's criteria to calculate the appropriate metatarsal length from anteroposterior standing radiographs [9, 11, 27, 28], which provides longitudinal decompression. Although it was originally designed to restore the physiologic cascade of the lesser MBs and evenly redistribute the pressures on the forefoot, the main complication, estimated to be among at least 10 to 30% of cases, is postoperative stiffness, while other commonly described problems include floating toe, recurrence, and transfer metatarsalgia [8, 29–32]. For these reasons, this procedure has generated considerable controversy.

Within the last decade, innovative Distal Metatarsal Metaphyseal Osteotomy (DMMO) has proved to be an alternative surgical approach, being a percutaneous extra-articular metatarsal neck osteotomy without any internal fixation [19, 20, 29], which permits the metatarsal lengths to be set automatically upon weight bearing. This technique results in less postoperative stiffness than the standard Weil osteotomy [17]. More recently, this percutaneous procedure was modified to reduce the plantar pressure of the MBs over chronic plantar ulcers in diabetic patients, promoting ulcer healing [33].

Hence, the primary purpose of this prospective study was to specifically evaluate the safety and effectiveness of Minimally Invasive Distal Metatarsal Metaphyseal Osteotomy (DMMO) in treating patients with persistent central primary metatarsalgia, associated or not with HV and lesser toe deformities, identifying possible contraindications in relation to some demographic parameters (age, gender, BMI, and smoking). The second objective was to verify the potential of DMMO in restoring a harmonious foot morphotype according to Maestro's criteria and if these radiographic parameters are correlated with clinical outcomes, maintaining the predictive value of these criteria during preoperative planning also for this percutaneous surgery.

2. Material and Methods

2.1. Patients. At our institution, between January 2009 and December 2013, a consecutive series of 131 Caucasian patients with diagnosis of central primary metatarsalgia resistant to conservative treatment was enrolled in this prospective study. All patients underwent DMMO, performed by a single surgeon, the senior author (C.B.), trained in minimally invasive surgery (MIS), who followed and checked the patients personally during the postoperative period. All subjects participating in this study received a thorough explanation of the risks and benefits of inclusion and gave their oral and written informed consent to publish the data. This study was approved by the Institutional Ethics Committee and performed in accordance with the ethical standards of the 1964 Declaration of Helsinki as revised in 2000 and those of Good Clinical Practice.

2.2. Inclusion and Exclusion Criteria. Patients with diagnosis of central primary metatarsalgia between M2 and M4 of a biomechanical etiology in the plantar foot area were enrolled consecutively and prospectively with precise inclusion criteria over a 5-year period. Ages ranged from 18 to 90 years. Only symptomatic patients with persistent pain, with or without forefoot plantar hyperkeratosis lesions, unresponsive to conservative and orthotic treatment performed for at least 6 months, were included in this study and underwent DMMO on a single foot. Associated forefoot pathologies included HV, metatarsophalangeal (MTP) joint instability or dislocation, and flexible or fixed lesser toe deformities. Exclusion criteria were as follows: arthritis and stiffness of MTP joint, congenital deformities of the foot, hallux rigidus, Freiberg's infraction, Morton's neuroma, and diagnosis of rheumatic, metabolic, neurologic, infective, or psychiatric pathologies. Furthermore, patients were excluded if they had previous trauma or foot and ankle surgery, or any form of secondary or iatrogenic metatarsalgia.

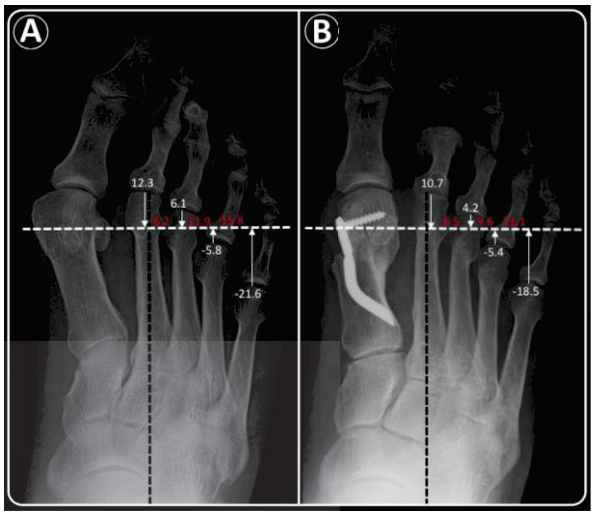

Figure 1: *Maestro criteria*: example of radiographic marks, relative measurements (millimeters in white) for each lesser MB, and their difference with the consecutive one (millimeters in red) on anteroposterior radiographs of a forefoot of our series, performed to calculate the number of MBs to be shortened during radiographic planning and to identify the corresponding morphotype pre- and postoperatively. According to these criteria, the forefoot was classified as *"unclassified non-harmonious"* in the preoperative period (A) and as *"non-harmonious 1"* at the last follow-up after DMMO (B). Endolog technique was also performed for HV correction.

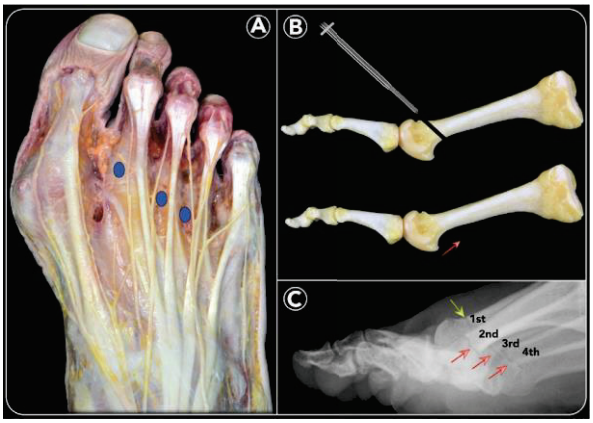

Figure 2: *Distal Metatarsal Metaphyseal Osteotomy (DMMO):* dissection of the dorsum of the foot showing the extensor apparatus and the innervation pattern of the foot and toes. Blue circles highlight the incision points for percutaneous DMMO (A). Bone preparation of an ideal DMMO procedure performed at the level of the M-neck and the final result showing the shortening and elevation of the M-head (B). Weight-bearing lateral radiographic view showing the site of the DMMO (red arrow) on each lesser MB; green arrow corresponds to Reverdin-Isham osteotomy for HV correction during the same operation (C).

2.3. Preoperative Planning. Both clinical and radiological assessment were used for preoperative planning. The general aspects of metatarsalgia were evaluated: affected side, plantar hyperkeratosis lesions, site of metatarsalgia, symptomatic MTP joint instability (using the Lachman test), and relative clinical signs of dorsal dislocation. With these data, it was decided where the osteotomy should lead to rebalance plantar pressures and create a harmonious curve, with a tolerance of ±1 mm for Maestro criteria 1 and 2, ±2 mm for Maestro criteria 3. A normal or harmonious forefoot shows a geometrical progression of 2 regarding the relative lengths of the lesser metatarsals compared to the SM4 line, the line passing through the mid-third of the M4 head (+2 mm proximally/center M4 head/-4 mm distally). The line of the osteotomy was drawn from the center of the lateral sesamoid through the central or distal third of the M4 head, perpendicular to the axis of the foot (Figure 1). The DMMO was carried out only on the metatarsal of symptomatic MTP joints unless this shortening would make the neighboring metatarsal too long, resulting in a disharmonious morphotype with a high risk of a transfer lesion. The adjacent metatarsal was also shortened in these cases.

In a second step, associated deformities, when present, were assessed and then corrected during the same operation. Surgical procedures on the first ray were performed according to our institutional protocol: HV correction by Reverdin-Isham percutaneous osteotomy for mild-moderate deformity, or Endolog technique for moderate-severe deformity, both generally followed by percutaneous Akin osteotomy [29, 34]. In addition, percutaneous lateral soft-tissue release and percutaneous tenotomy of extensor and/or flexor, in association with (or not) phalange percutaneous osteotomies, were tailored based on the lesser toe deformities, flexible or fixed.

2.4. Operative Technique. The surgical technique is performed according to the same principles and the same general indications described by M. De Prado [20, 21] (Figure 2). During the operation, the patient is in a supine position, with the operated foot protruding from the table. No ankle joint tourniquet is applied, as it is not required for this technique. Prophylactic antibiotic (Cefazolin: 2 g) is administered before surgery. The anesthesiologist performs a regional block of the foot, involving superficial nerves (saphenous, sural, and superficial peroneal) and deep nerves (deep peroneal and tibial).

2.5. Minimally Invasive Distal Metatarsal Metaphyseal Osteotomy (DMMO). The surgeon holds the metatarsophalangeal joint between the thumb and index finger of his non-dominant hand [19]. Using a small scalpel blade (SM64) in his dominant hand, an incision of 5 mm is made parallel to the extensor tendons at the dorsal side of the medial (or lateral) border of each metatarsal head that needs to be shortened (Figures 2(A) and 3(A)) [14]. The side of the incision depends on the surgeon's handedness and which foot is being operated on. The scalpel is advanced at an oblique angle of about 45° until it reaches the dorsal aspect of the distal MB, at the neck level, to undergo osteotomy (Figure 3(A)). Through the same incision, first a bone rasp specific for percutaneous surgery is inserted, using it to separate the periosteum at the level of the osteotomy site (Figure 3(B)). Then, a Shannon

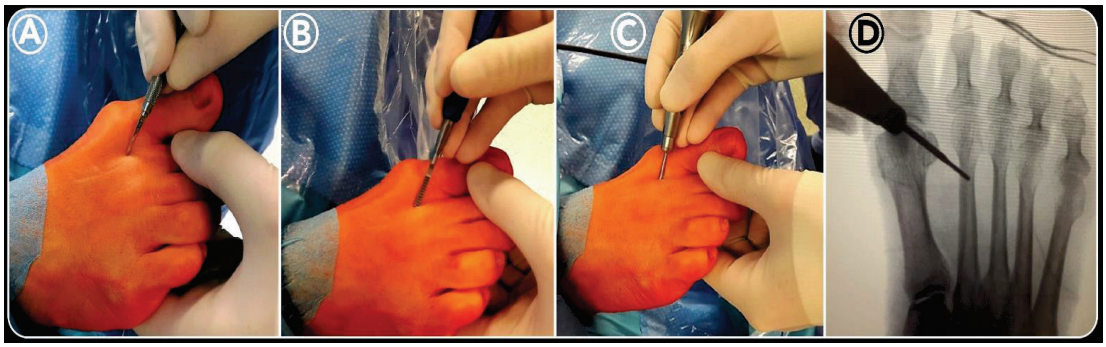

Figure 3: *DMMO intraoperative images (1st):* using a small scalpel blade (SM64), an incision of 3-5 mm was made parallel to the extensor tendons at the dorsal side of the medial border of each M-head that needed to be shortened. The scalpel was advanced at an oblique angle of about 45° until it reached the dorsal aspect of the distal MB at the level of the neck (A). Through the same incision, first a bone rasp was inserted, using it to separate the periosteum at the level of osteotomy (B). Then, a Shannon Isham burr (2.0 × 12 mm) was introduced until it reached the metatarsal neck (C). Fluoroscopy was used to confirm the correct position of the osteotomy site on the distal metaphysis of the MB (D).

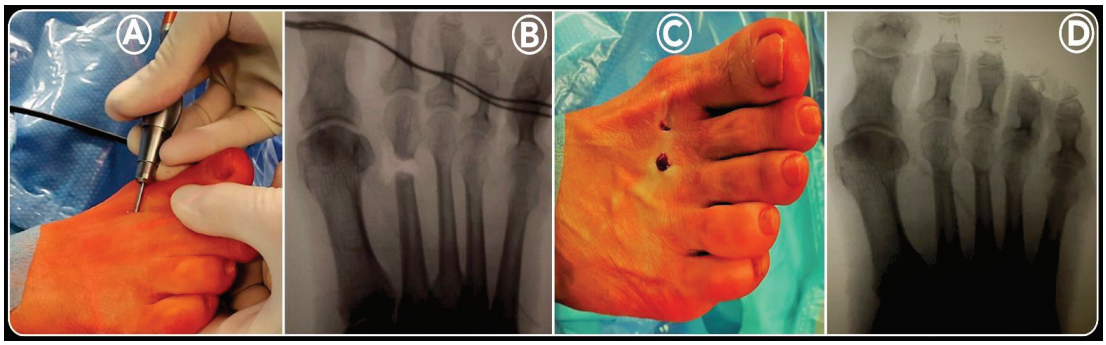

Figure 4: *DMMO intraoperative images (2nd):* in this position, the DMMO was performed with an angle of approximately 45° with respect to the long axis of the MB in a dorsal-distal to proximal-plantar direction, with rotary motion, extending to the contralateral cortex (A). To verify the completion of the osteotomy of each MB operated on, manual traction on the corresponding toe was applied under fluoroscopic control (B). Before closing the wounds by resorbable sutures (C), the MBs were manually compacted, applying pressure in the distal-proximal direction, pushing their heads dorsally. Finally, after bandage application, a final radiographic check was made to evaluate the correction obtained (D).

Isham burr (2.0 × 12 mm), adapted for Mm960 (produced by Medic Micro, Switzerland), is introduced until it reaches the metatarsal neck where the periosteum was previously removed (Figure 3(C)). Fluoroscopy is used to confirm the correct position of the osteotomy site on the distal diaphysis of the MB (Figure 3(D)). In this position, the cutting is started with an angle of approximately 45° with respect to the long axis of the MB in a dorsal-distal to proximal-plantar direction, with rotary motion, extending to the contralateral cortex (Figures 2(B) and 4(A)). In this way, the lateral cortical surface is cut first, then the plantar, medial, and, lastly, the dorsal cortical surface. During the osteotomy process, the incision site is irrigated by normal saline, as the burr can cause excessive heat, causing first skin burn and resulting subsequently in fibrosis and pseudoarthrosis at the bone level. Further, this lavage is useful to remove bone debris, preventing periarticular ossifications in the stab canal. To verify the completion of the osteotomy of each MB operated on, manual traction on the corresponding toe was applied under fluoroscopic control (Figure 4(B)). Upon completion of the osteotomy, the bone is manually compacted, applying pressure in the distal-proximal direction of the interested metatarsal, pushing the metatarsal head dorsally and producing contact of the trabecular bone, since no internal fixation is performed (Figure 2(C)). In our cohort, the number of metatarsal osteotomies performed in each forefoot was planned according to how much the metatarsal formula was altered according to the Maestro criteria (Figure 1). Before closing the wounds by resorbable sutures (Figure 4(C)), a final radiographic check was made to evaluate the correction obtained (Figure 2(D)).

2.6. Bandage. Because there is no osteosynthesis material in this surgery, the bandage is a very important tool in order to maintain the metatarsal head position achieved with the operation. Consequently, its application was performed with the utmost care and attention. The crisscross bandage was traced between all intermetatarsal spaces, crossing it over the

medial (lateral) aspect of all of the osteotomies performed in order to reinforce the strength of the bandage. Gentle traction was used to maintain the toe in light hypercorrection and plantar inclination. Finally, the forefoot was covered with tubular gauzes, except for the distal part of the toes and nails.

2.7. Postoperative Protocol. All patients followed the same postoperative protocol and were followed in the same standardized manner by the senior author (C.B.). The patients were allowed to walk as much as they could tolerate the day after surgery using a rigid flat-soled orthopedic shoe for the following 30-day period. The patient was discharged the same day, warned of the possible persistence of swelling for 1-3 months, of pain, and of the presence of clicks in the forefoot due to movements in the osteotomy sites. This factor is very important as metatarsal length sets automatically upon weight bearing of the foot [9, 14]. Anteroposterior and lateral X-rays of non-weight-bearing feet were taken before the patients were discharged. We recommended an antibiotic oral prophylaxis for a week, as well as thromboembolic prophylaxis (Natrium Enoxaparin: 4.000 IU/day) and an anti-edemigen therapy (Leucoselect, Lymphaselect, and Bromelina: 1 tablet/day) for 30 days starting from the day of the surgery. Moreover, an analgesic therapy was prescribed for 2 weeks of Etoricoxib (90 or 60 mg, 1 tablet/day) in the morning, also to prevent heterotopic ossification when the comorbidities of the patient permitted, or, alternatively, Paracetamol (1g, 1 tablet 2x/day). All of the patients were seen once a week for a month in our outpatient clinic. The first visit was 8 days after surgery. The original bandage was removed and substituted by a simpler bandage. During the 3 weekly visits, the bandage was changed in the same way. One month after surgical treatment, the bandage was totally removed after taking anteroposterior weight-bearing and lateral X-rays. The patients were then able to walk with comfortable shoes, allowing total load on the operated foot. No specific physiokinetic therapy was suggested to restart daily activities. However, controlled return to sports was not allowed for 3 months after surgery.

2.8. Patient Assessment. The clinical and radiological analyses were carried out, respectively, by two independent investigators, the junior authors (W.T.K.K. and A.Z.), not involved in the primary surgical treatment of the patients. For this study, all patients were subjected to clinical and radiographic evaluation with the same protocol prior to surgery as well as regular follow-ups, following our institutional standard aftercare algorithm, according to this study protocol, to AOFAS accepted guidelines [15, 35], and based on the Maestro criteria [9]. For methodological reasons, the immediate postoperative X-rays at discharge, as well as the one-month radiographic control, were not included for the radiographic evaluation: the first because it was a non-weight-bearing radiograph; the second because although it was prescribed as weight-bearing, in some cases it was not performed because the patients had pain or were afraid to place the operated foot on the ground without an orthopedic shoe. Finally, the clinical-functional and radiographic data were compared based on patients' demographic parameters (age, gender, BMI, and smoking) and the number of osteotomies.

2.9. Clinical Functional Outcome Measures. The clinical preoperative evaluation included a complete clinical history of the patients, their main characteristics (age, gender, BMI, dominant side, smoking, occupation, and anesthesia ASA class), and physical examination of the foot for preoperative planning, as well as the percutaneous procedures to perform (number of metatarsals to treat). To evaluate clinical outcomes at the preoperative period and last follow-up (FU), the following and most used questionnaires for forefoot assessment were used according to our study protocol:

(i) The 100-point AOFAS hallux metatarsophalangeal-interphalangeal scale [35, 36] was the only questionnaire used to assess clinical outcomes at the different FU points (preoperatively, 3-, 6-, and 12-month FU), and the difference of median values (Δ) between preoperative and the last evaluation was calculated;

(ii) The Foot Functional Index (17-FFI) [35, 37] to measure the persistence of pain, disability, and restriction of activity with 17 number rating scales from 0 to 10;

(iii) The Manchester-Oxford Foot Questionnaire (MOXFQ) [35] to establish how frequent the restrictions in specific situations were, including 16 questions divided into three basic domains: pain (five), walking/standing (seven), and social interaction (four);

(iv) The Short Form 36 (SF-36) to identify the overall health reported by the subjects;

(v) The Visual Analog Scale (VAS) to quantify patient satisfaction with a score from 0 to 10.

Finally, during the last clinical check-up, patients were asked about their ability to work and possible modification of their daily activities. Additionally, any complications were recorded.

2.10. Radiographic Outcome Measures. Routine standing anteroposterior and lateral X-ray views were obtained before surgery, at discharge, at one-month after surgery, and at different FUs (3-, 6-, 12-month, and last FU), according to our study protocol (Figures 5 and 6), respecting the Maestro method (weight-bearing, 15°-30° inclination of the X-ray beam, 1 m distance from the foot to the X-ray source). They were analyzed at our institution in a standardized manner using electronically computer-assisted Maestro measurements for weight-bearing radiographs provided by our MedStation program (the X-ray database of our hospital). This software allows the retrieval of electronically computer-assisted measurements from weight-bearing radiographs to minimize investigator bias.

Our sample was classified radiographically according to Maestro and Besse criteria [9], adding to this classification one more group to include those feet that did not reflect any morphotype as defined by Maestro parameters (Table 1). Hence, our cohort was divided into the following:

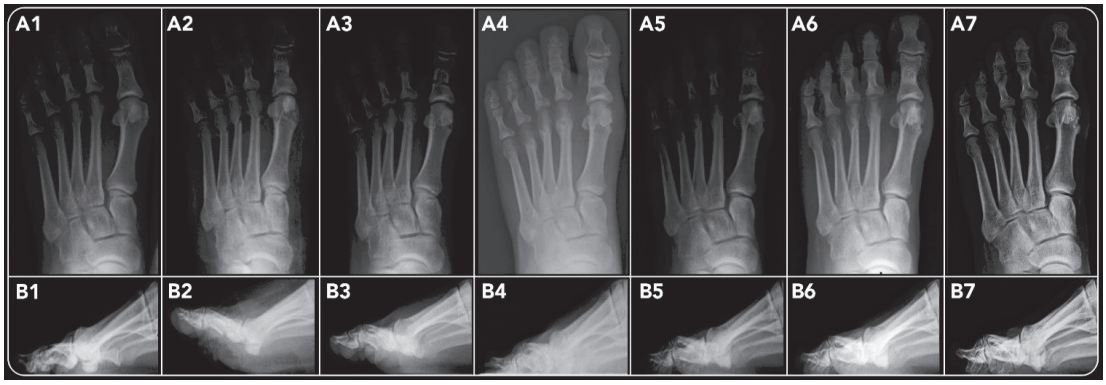

Figure 5: *(Case 1):* a 47-year-old female patient having undergone DMMO of the M2, M3, and M4 in addition to Reverdin-Isham and Akin percutaneous osteotomies for HV correction of her left foot. Radiographic images of anteroposterior (A) and lateral views (B): at preoperative period (1), immediate postoperative period (2), 1-month follow-up (3), 3-month follow-up (4), 6-month follow-up (5), 12-month follow-up (6), and 52 months after surgery (7), showing bone callus consolidation and its remodeling, maintaining the shortening and elevation of the head of the MBs treated.

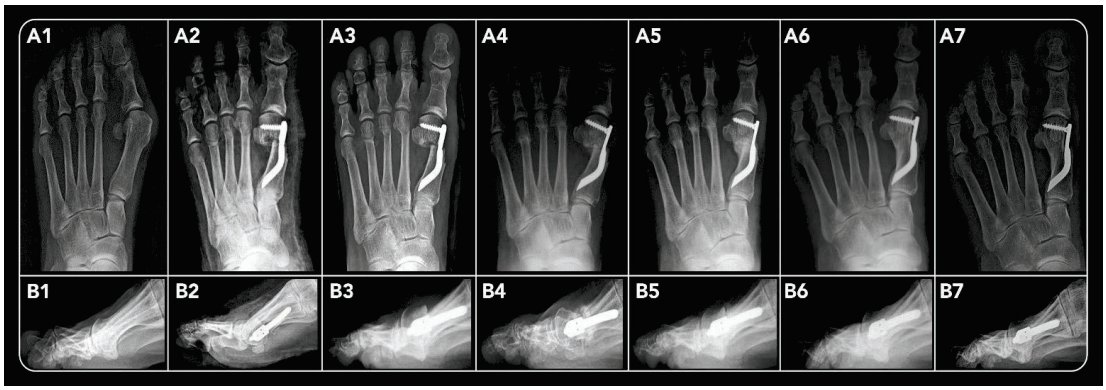

Figure 6: *(Case 2):* a 58-year-old female patient having undergone DMMO of the M2, M3, and M4 in association with Endolog technique for HV correction of her left foot, radiographic images of anteroposterior (A) and lateral views (B): at preoperative period (1), immediate postoperative period (2), 1-month follow-up (3), 3-month follow-up (4), 6-month follow-up (5), 12-month follow-up (6), and 48 months after surgery (7), showing bone callus consolidation and its remodeling, maintaining the shortening and elevation of the head of the MBs treated.

(1) *Harmonious Morphotype, "normal forefoot,"* characterized by the SM4 line starting from the center of the lateral sesamoid bone and passing through the middle third of the 4th metatarsal (M4) head, perpendicular to the sagittal foot axis, and a geometrical progression of 2 of the lesser metatarsals;

(2) *Nonharmonious Morphotype-1,* characterized by the SM4 line passing through the middle third of the M4 head, but the geometric progression of the lesser metatarsals is altered; M2 and M3 are too long;

(3) *Nonharmonious Morphotype-2 is* the "*M4M5 hypoplasia*" morphotype, in which the SM4 line is disjointed and the perpendicular line to the M2 axis from the center of the sesamoid bone is distal to the middle third of the M4 head; the perpendicular line from the fifth metatarsal tip to the sagittal M2 axis is proximal to the distal pole of the lateral sesamoid bone (0.5–2 cm in severe hypoplasia);

(4) *Nonharmonious Morphotype-3,* "M1 long," characterized by a geometrical progression of 2 of the lesser metatarsal, which is generally correct; however, the SM4 line is displaced distally because the lateral sesamoid migrates distally with the M1 head.

(5) *Unclassified Nonharmonious Morphotype:* this last group (our addition) includes all patients who do not belong to any of the forefoot morphotypes described by Maestro.

The radiographic evaluations included the Maestro criteria index [9] using the preoperative and the last FU anteroposterior standing X-rays. The relative length of each metatarsal was determined by drawing a line perpendicular to the axis of the foot and then measuring the distances (in millimeters) from each metatarsal head to this line (Figure 1), while also taking into account the relationship between the length of M1 and the length of the remaining MBs.

Table 1: Classification of forefoot morphotypes according to Maestro criteria, including the added unclassified ones.

Forefoot Morphotypes	Maestro Radiographic Parameters	Percentage usually in the normal population	Study Cohort	
			Preoperative	Last Follow-up
Harmonious	Harmonious Geometrical progression of 2 of the lesser M-bones with tolerance of 20% (±1 mm for M2M3 and M3M4, ± 2mm for M4M5)	31%	7.5% (7/93)	3.2% (3/93)
Non-harmonious 1	M2M3 increased with M3M4 and M4M5 normal; M2M3 decreased with M3M4 increased and M4M5 correct; M2M3 normal with M3M4 increased and M4M5 correct; M2M3 and M3M4 increased with M4M5 correct.	30%	32.3% (30/93)	20.4% (19/93)
Non-harmonious 2	M4M5 hypoplasia: M3M4 and M4M5 increased	37%	43% (40/93)	18.3% (17/93)
Non-harmonious 3	M1 > M2	2.4%	0% (0/93)	0% (0/93)
Unclassified Non-harmonious	Feet that did not reflect any Morphotype	-	17.2% (16/93)	58.1% (54/93)

In anteroposterior and lateral standing view radiographs, callus formation and the absence of radiolucent lines were checked to determine bone union at the different FUs. Complete osteotomy healing time was then analyzed in relation to the main patient parameters and procedure variables, according to the study protocol (age, sex, BMI, smoking status, and number of MBs treated), in order to verify possible statistically significant correlations.

2.11. Statistical Analysis. Statistical analyses were performed by an independent statistician from the Department of Statistics at our University. The data is presented as the mean (plus standard deviation) or median (range) for continuous variables and as numbers for categorical measures. For the statistical evaluation of the clinical and radiological scores obtained with the various scales and the parameters of the Maestro formula before surgery and at last FU, we used Student's t-test. The Wilcoxon test was used to analyze the relationship between the variations of the healing time and the following variables: age, BMI, smoking status, and the number of metatarsals on which we performed osteotomies. Statistical significance was considered for $p < 0.05$.

3. Results

3.1. Patient Data. During a five-year period, 131 Caucasian patients (131 feet) with diagnosis of persistent central metatarsalgia were treated by DMMO in a single foot at our institution. We could not evaluate 38 patients (38 feet) as 12 refused to participate in FU assessment (one was unsatisfied with the clinical results and refused to come back for evaluation, and the remaining 11 were pleased with their results but were unable to come for evaluation); 6 did not complete clinical and/or radiographic assessment of the different FU points according to our postoperative control, while at the time of the last FU evaluation, 7 were located in a home for the elderly, 2 were dead, and a FU address could not be retrieved for 11 people. Hence, 93 patients (93 feet) completed different FUs until the last one according to the study protocol (Table 2). There were 14 men (15.1%) and 79 women (84.9%). At the time of surgery, the mean age was 62.4 ± 13.4 (range 31 to 87) years. The average FU period was 58.7 ± 12.7 (range 36 to 96) months, and most of the patients (53; 56.9%) were operated on between 60 and 79 years of age. In 43 cases (46.2%), the dominant limb was affected, while the nondominant limb was affected in 50 cases (53.8%). Regarding risk factors, 16 patients were obese (17.2%), 21 (22.6%) were active smokers, and 22 (23.7%) had comorbidities (hypertension, BPCO, and vascular disease). Hence, according to the ASA (American Society of Anesthesiologists) classification for globally estimated surgical risk, there were 56 ASA 1 patients (60.2%), 26 ASA 2 patients (28%), and 11 ASA 3 patients (11.8%).

During the 93 single foot operations, 198 DMMOs were performed as follows: osteotomies were localized only on the M2 in 23 feet (24.7%), on M2 and M3 in 35 (37.6%), and finally on three metatarsals (M2-M3-M4) in 35 (37.6%) (Table 3). In 86 (92.5%) of the 93 feet, associated procedures were performed tailored to patient's clinical presentation. Reverdin-Isham percutaneous osteotomy was performed in 29 feet for the correction of mild-moderate HV deformities and Endolog technique in 52 feet for moderate-severe ones, followed by percutaneous Akin osteotomy and percutaneous lateral soft-tissue release in some cases, according to our protocol. Further, we carried out flexor and extensor tenotomies in 31 feet for the correction of claw toe flexible deformities and associated osteotomies of the proximal phalange in 16 feet for the correction of fixed ones.

Table 2: Patients' characteristics and their potential risk factors: mean (± standard deviation) and absolute (and relative) frequency (%).

Demographic Parameters	Value
Gender	
Males	14/93 (15.1)
Females	79/93 (84.9)
Age (years)	62.4 ± 13.4
30 - 39	7/93 (7.5)
40 - 49	11/93 (11.8)
50 - 59	17/93 (18.3)
60 - 69	27/93 (29)
70 - 79	26/93 (27.9)
≥ 80	5/93 (5.4)
BMI (kg/m^2)	25.7 ± 4.3
>30	16/93 (17.2)
Smoking	
Yes	21/93 (22.6)
No	72/93 (77.4)
Right feet	
Dominant	78/93 (83.9)
Left feet	
Dominant	15/93 (16.1)
Comorbidities	
Hypertension	2/93 (2.2)
COPD	19/93 (20.4)
Vascular disease	1/93 (1.1)
ASA	
1	56/93 (60.2)
2	26/93 (28)
3	11/93 (11.8)

Abbreviations: ASA: *American Society of Anesthesiologists*; BMI: *Body Mass Index*; COPD: *Chronic Obstructive Pulmonary Disease*.

3.2. Clinical Functional Outcomes. At the preoperative evaluation, the mean AOFAS score of the patients was 48.6 ± 7.3 (range 22 to 65) points. Limitation in daily and recreational activities was present in 49 cases (52.7%). At different FU points, the mean AOFAS score was 66.6 ± 8.4 (range 42 to 82) points, 72.3 ± 10.6 (range 42 to 87) points, and 75.6 ± 12.1 (range 35 to 95) points at 3-, 6-, and 12-month FU, respectively, while it was 84.1 ± 14.4 (range 35 to 100) points at last FU. Hence, in our cohort, the AOFAS score improved significantly after surgery with respect to the preoperative value ($p < 0.0001$), reporting good and excellent results in 79 (84.9%) feet (Figure 7). The mean preoperative 17-FFI was 43.2 ± 9.7 (range 24.7 to 64.7) points, while the average at last FU was 7.8 ± 12.2 (range 0 to 54.6) points. Hence, also the 17-FFI improved significantly after surgery with respect to the preoperative value ($p < 0.0001$). The mean MOXFQ-Pain, -Walking, and -Social preoperative scores were 11.4 ± 2.4 (range 7 to 16) points, 15.8 ± 3.7 (range 10 to 23) points, and 4.8 ± 1.4 (range 0 to 8) points, respectively, while their mean values at last FU were 2.1 ± 3.1 (range 0 to 16) points, 3.9 ± 4.5 (range 0 to 24) points, and 0.8 ± 1.6 (range 0 to 8)

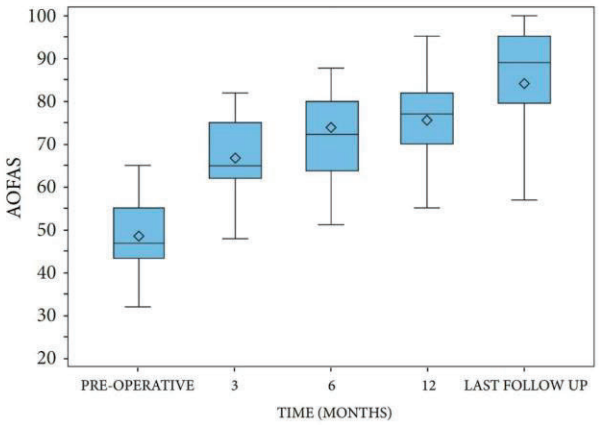

Figure 7: Graph of the statistical analysis of AOFAS scores at preoperative period, 3-6-12 months after surgery, and mean last follow-up of 58.7 months.

points, respectively (Figure 8). The two components of the SF-36 (ISF and ISM) had, respectively, an average of 49.5 ± 8.6 (range 23.2 to 63.9) points and 49.5 ± 8.6 (range 23.2 to 63.9) points preoperatively, while being 49.5 ± 8.6 (range 23.2 to 63.9) points and 50.7 ± 7.5 (range 11.4 to 63.6) points at last FU, respectively. The mean VAS score was 2.4 ± 1.7 (range, 0 to 6) points at last FU, with respect to 5.1 points at the preoperative period. Among the patients operated on, at last FU, 49 (52.7%) kept their job after surgery and 2 (2.1%) had to change. The other patients were retired (23.7%) or homemakers (22.6%). In addition, 73 (78.5%) patients did not change their shoes. There was a reduction of patients with hyperkeratosis (from 77.4% to 9.7%) and MTP instability (Lachman test positive from 41.9% to 19.4%), as well as clinical signs of dorsal subluxation (from 15.1% to 6.5%) of these patients.

3.3. Radiographic Outcomes. In our sample, all radiographic parameters of the Maestro criteria were significantly different at the last FU compared to the preoperative period ($p < 0.001$). The forefoot *Harmonious Morphotype*, presented in 7 cases (7.5%) in the preoperative period, was identified only in 3 cases (3.2%) at last FU. A *Nonharmonious Morphotype-1* was present in 30 cases (32.3%) preoperatively with respect to 19 cases (20.4%) at last FU. A *Nonharmonious Morphotype-2* was present in 40 cases (43%) preoperatively with respect to 17 cases (18.3%) at last FU, and an *Unclassified Morphotype* was present in 16 cases (17.2%) with respect to 54 cases at last FU (58.1%). No cases of forefoot *Nonharmonious Morphotype-3* were found (Table 1).

Signs of bone callus formation were observed in 71 out of 93 feet (76.3%) at 3 months FU, while the other patients (23.7%) presented signs of osteotomy consolidation at 6 months postoperatively. Hence, all osteotomies were healed at 6 months after surgery (Figures 5(A5)-(B5) and 6(A5)-(B5)). The analysis of the possible variation of healing time based on patient parameters considered (age, sex, BMI, smoking, and number of metatarsals operated on) did not show statistically

Table 3: Number of the metatarsal bones operated on according to the foot side and number of osteotomies performed by DMMO in our series.

Site of osteotomy	Feet treated by DMMO			Number of DMMO Performed
	Right feet	*Left feet*	*Total*	
M2	11 (24.4%)	12 (25%)	23 (24.7%)	23 (11.6%)
M2-M3	17 (37.8%)	18 (37.5%)	35 (37.6%)	70 (35.4%)
M2-M3-M4	17 (37.8%)	38 (37.5%)	35 (37.6%)	105 (53%)
Total	45 (48.9%)	48 (51.6%)	93 (100%)	198 (100%)

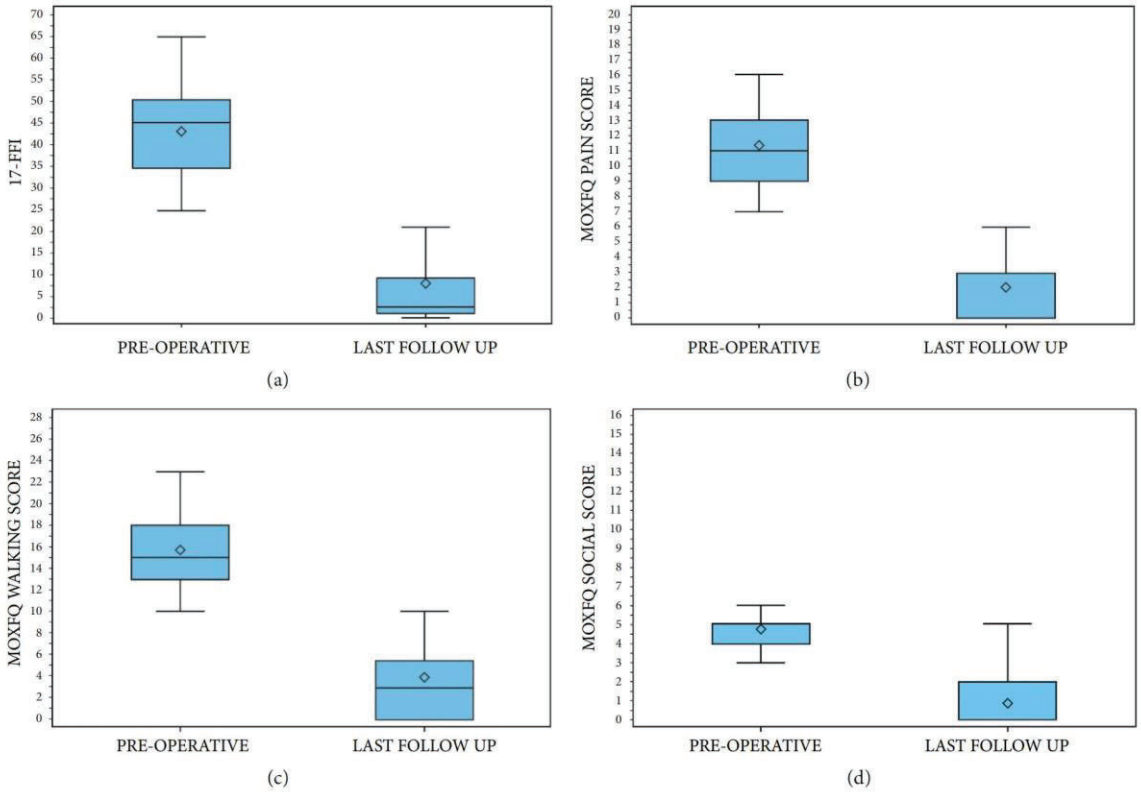

Figure 8: Graphs of the statistical analysis of 17-FFI (a), MOXFQ-PAIN (b), MOXFQ-WALKING (c), and MOXFQ-SOCIAL (d) scores ($p < 0.0001$), shown for each of the results at preoperative period and at mean last follow-up of 58.7 months.

significant correlation: age ($p > 0.1621$), gender ($p > 0.5923$), BMI ($p > 0.3234$), smoking habits ($p > 0.9638$), and number of metatarsals operated on ($p > 0.3571$).

3.4. Complications. Short-term complications were present in 31 cases (33.3%): swelling (27 patients, 29%) and paresthesia (6, 6.4%), all resolved within 3 months from surgery. In addition, there were 23 cases (24.7%) of delayed union, completely healed at 6-month FU. Because of portal burns during operation, 3 patients (3.2%) presented delayed wound healing, which healed completely in four weeks and did not require subsequent surgery. Long-term complications were recorded in 12 cases (12.9%): 9 cases (9.7%) of persistent stiffness (ROM: $< 30^{\circ}$) and 3 cases (3.2%) of transfer metatarsalgia on the M4. The latter patients were subjected to additional DMMO of the symptomatic MB. There were no infections, nonunion or malunion of the osteotomy, floating-toe deformity, soft tissue complications, residual instability or subluxation, or evidence of avascular necrosis of the metatarsal head.

4. Discussion

In the last fifteen years, DMMO became popular in Europe by the Spanish surgeon De Prado first and then by the GRECMIP (Groupe de Recherche et d'Enseignement en Chirurgie Mini-Invasive du Pied) as an alternative surgical technique to the traditional Weil osteotomy. Because of the perceived potential advantages of a dynamic correction offered by DMMO, and the stiffness and floating toe caused by Weil osteotomy [19], the percutaneous procedure now tends to be preferred over open osteotomies [10, 23].

However, the optimal treatment of metatarsalgia and the restoration of an ideal forefoot morphotype remain controversial [2, 3].

The purposes of this prospective study were first to specifically evaluate the safety and effectiveness of DMMO in treating persistent central primary metatarsalgia, identifying possible contraindications. The second was to verify the potential of DMMO in restoring a harmonious foot morphotype according to Maestro criteria and if these radiographic criteria are correlated with clinical outcomes, maintaining a predictive value for these criteria in the preoperative planning for this technique.

In our cohort, clinical outcomes improved significantly in each clinical score after surgery with respect to preoperative values, and the clinical results at the last FU were satisfactory (Figures 7 and 8). The AOFAS and MOXFQ scores over time showed a statistically significant improvement ($p < 0.0001$). The 17-FFI scores, which evaluate the clinical-functional appearance of the foot, showed excellent results with a statistically significant difference between pre- and postoperative periods ($p < 0.0001$). A significant reduction of pain (VAS scale: 2.4 vs 5.1 points) and formation of plantar callosities was obtained, associated with a considerable improvement in the quality of daily life in our patients as shown by SF36 ($p < 0.0001$). Further, osteotomy consolidation was present in 76.3% of feet after 3 months from surgical operation and in 100% at 6-month FU. The incidence of recurrence or transfer lesions was negligible. Henry [17] found similar healing times for DMMO, confirming that this technique requires longer healing time than the Weil osteotomy but with better results. Further, our results showed no variation of healing time based on age, sex, BMI, smoking, and number of metatarsals treated.

Jardé [18] affirmed that the patients in whom postoperative alignment of the metatarsal heads after Weil osteotomies had most closely met the Maestro criteria had better results than those in whom the match was less exact [9, 14]. However, in our patient group, reconstruction of an ideal curve of Maestro was obtained only in three of 93 of feet (3.2%), despite precise preoperative planning (Table 1). Hence, we found no correlation between having a harmonious and mathematically correct distal metatarsal parabola and clinical outcomes. In fact, our study showed that although the restoration of the ideal harmonious architectural Maestro curve of the forefoot was not achieved by DMMO, the procedure guaranteed balanced redistribution of the plantar pressure forces and relief of metatarsalgia not only in the immediate postoperative period, but also at medium-long term FU.

In our series, 81 feet (87%) were operated on concurrently for associated HV, in which instability of the first ray is implicated and can be a predisposing or exacerbating cofactor for metatarsalgia. This hypermobility is usually radiographically and clinically assessed in both sagittal and coronal planes, in the latter, in dorsal and also in dorsomedial directions, as recently proposed [38]. Similarly, a more complete approach to preoperative planning for metatarsalgia treatment, such as the research for new criteria and morphotypes in the coronal plane, should be promoted, as in a previous study of the preoperative planning of the Weil osteotomy [27]. In fact, Bevernage concluded that radiographic preoperative planning for metatarsalgia treatment only in the anteroposterior plane is clearly a simplification of a complex pathology because this pathology requires a three-dimensional correction [27]. The ideal preoperative planning for the more recent DMMO should take into account the potential proximal shift of the osteotomized metatarsal heads in both sagittal and coronal planes. However, this assessment is difficult to carry out as it should foresee the metatarsal head displacement not only at the operating table but also after load resumption by walking in the postoperative period, identifying new radiological and biomechanical criteria for the ideal foot morphotype. From our results, it is questionable if Maestro parameters can adequately represent this, maintaining their predictive value. After DMMO, the metatarsal heads consolidate into a more proximal position due to mechanical loading allowed after surgery by weight-bearing. This is in contrast to the Weil procedure, where the osteotomies, synthesized by screws, remain fixed after surgery, reflecting the ideal position calculated by the preoperative planning. For these reasons, it is the opinion of the authors that there is a need for revised radiological criteria that correlate radiological metatarsal alignment with clinical outcomes before and after this percutaneous technique.

Numerous complications related to DMMO have been reported [14, 19, 32, 39], but in our study, we had a low rate of short-term complications, such as transitory swelling, paresthesia, and skin burns, while delayed unions were resolved by 6-month FU. The main long-term complication was persistent stiffness (9.7%), and 3 cases (3.2%) of transfer metatarsalgia were resolved with a second percutaneous operation by M4 osteotomy. We had no cases of floating-toe deformity, residual instability or subluxation, infection, pseudarthrosis, avascular necrosis, or displacement of the metatarsal head, which are the most undesirable complications [14, 15, 22, 32]. We did not identify any risk factors that increased complications in our group. Redfern does not recommend DMMO in the presence of significant arthritis and stiffness of MTPJ because it is associated with increased risk of pseudarthrosis. However, this aspect was one of our exclusion criteria.

To the best of our knowledge, this is the first prospective, single-center study reporting clinical and radiographic outcomes of DMMO for the treatment of primary central metatarsalgia in a consecutive, single-surgeon patient series. The number of patients and the mean FU of almost 60 months were superior to previous published studies [25, 26, 30, 32]. For clinical evaluation of our sample, internationally validated scores were used, except for the AOFAS score, which, although it remains the most widespread health measurement in foot and ankle clinical practice, has been only partially validated [36]. For radiographic evaluation, the traditional method of Maestro [9] was used to perform X-ray foot images and to classify them both pre- and postoperatively, even to determine which MBs to shorten by DMMO during preoperative planning. The findings of

this study should be interpreted within the context of its limitations. They are partially linked to the limited scientific literature on this subject and the poverty of cases of pure metatarsalgia. Most of the feet in our cohort included HV deformity, causing a potential bias of this study, and plantar pressure measurements were not performed.

5. Conclusion

First, Distal Metatarsal Metaphyseal Osteotomy (DMMO), often associated with percutaneous or open techniques for HV correction and percutaneous soft tissue and/or bone procedures in cases of lesser toe deformities, is a safe and effective minimally invasive method for the treatment of biomechanical central metatarsalgia. Further, age, gender, BMI, and smoking are not potential contraindications. Thus, DMMO can be considered a suitable alternative technique to traditional ones. Second, during preoperative planning, Maestro criteria were proved to be useful to calculate which MBs needed to be shortened to prevent transfer metatarsalgia and a significant clinical improvement of all scores assessed was noted at last follow-up. However, the ideal harmonious curve of the forefoot was restored by DMMO only in a few feet and a limited number of harmonious forefoot morphotypes were consequently found in the postoperative period. Hence, our data show that Maestro criteria do not have a predictive value in clinical outcomes of DMMO. Additional studies are required to find radiographic measurements more specific for the preoperative planning of this percutaneous technique.

Data Availability

The data used to support the findings of this study are available from the corresponding author upon request.

Ethical Approval

This study was approved by the Institutional Ethics Committee (N° 4065/AO/17) and performed in accordance with the ethical standards of the 1964 Declaration of Helsinki as revised in 2000 and those of Good Clinical Practice.

Consent

The patients gave their oral and written informed consent to the publication of their anonymous and clustered data and anonymous pictures.

Disclosure

This is a longitudinal prospective study. Level of evidence is IV, case series.

Conflicts of Interest

The authors declare that they have no conflicts of interest related to the publication of this manuscript, and they have not received benefits or financial funds in support of this study.

Authors' Contributions

Carlo Biz, operating surgeon, contributed to study concept and design and drafting of the paper; Wilfried Trepin Kuete Kanah and Alessandro Zornetta contributed to data collection and statistical analysis; Miki Dalmau-Pastor contributed to anatomical background and figures; Marco Corradin and Andrea Volpin contributed to analysis and interpretation of data; Pietro Ruggieri contributed to study concept and final approval of the version to be published.

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10.2 Minimally Invasive Metatarsal Osteotomies (MIMOs) for the treatment of CPDFUs

Among these procedures, only Distal Osteotomies **(DMOs)**, such as the *Distal Metatarsal Diaphyseal Osteotomy **(DMDO)*** were considered, and the following two original articles (a; c) [3, 4] and a systematic review (b) were included [2]:

a. ***Minimally Invasive Surgery: Osteotomies for Diabetic Foot Disease.*** Foot Ankle Clin. **2020** Sep;25(3):441-460. doi: 10.1016/j.fcl.2020.05.006. PMID: 32736741 [3].
b. ***Minimally Invasive Metatarsal Osteotomies (MIMOs) for the Treatment of Plantar Diabetic Forefoot Ulcers (PDFUs): A Systematic Review and Meta-Analysis with Meta-Regression***s. Appl. Sci. **2021**, 11, 9628. https:// doi.org/10.3390/app11209628 [2].
c. ***Minimally Invasive Distal Metatarsal Diaphyseal Osteotomy (DMDO) for Chronic Plantar Diabetic Foot Ulcers***. Foot Ankle Int. **2018** Jan; 39(1):83-92. doi: 10.1177/1071100717735640. PMID: 29110516 [4].

a. ***Minimally Invasive Surgery: Osteotomies for Diabetic Foot Disease.*** Foot Ankle Clin. **2020** Sep;25(3):441-460. doi: 10.1016/j.fcl.2020.05.006. PMID: 32736741 [3].

   DMDO, sometimes associated with percutaneous extensor and flexor sternotomies in cases of claw toe deformity and percutaneous osteotomies of phalanges in cases of fixed deformities of lesser toes, is an effective procedure for the treatment of complicated CPDFUs under the heads of all lateral MB (including the fifth). Resistant toe ulcers and recurrent pressure ulcers, mainly those with delayed healing or those of previous forefoot amputations with an unbalanced metatarsal formula, can be treated effectively by DMDO. For diabetic patients, the main advantages of this method, performed by distal ankle block, without tourniquet, and with very low risk of complications are minimal surgical scars and tissue damage, immediately post-operative weight bearing, absence of osteosynthesis and consequent potential infection of metal fixation, reduction of the previous high plantar pressures by the restoration of a harmonic balanced forefoot arch and rapid ulcer healing.

Minimally Invasive Surgery: Osteotomies for Diabetic Foot Disease

Carlo Biz, MD[a,b,*], Pietro Ruggieri, MD, PhD[a]

KEYWORDS

• Minimally invasive surgery • Percutaneous surgery • Neuropathic ulcers
• Distal metatarsal osteotomies • Distal metatarsal diaphyseal osteotomies
• Metatarsalgia • Diabetic foot

KEY POINTS

- The treatment of diabetic foot ulcers is still challenging, but the application of minimally invasive surgery now represents a strategic management of these lesions to achieve health goals, highly uncertain until a few years ago.
- Minimally invasive distal metatarsal diaphyseal osteotomy (DMDO) is based on a distal osteotomy proximal to the metatarsal neck to reduce the pressure on the ulcer and favor its healing.
- The DMDO technique enables the restoration of the original harmonic distal parabola of the forefoot when possible, or the creation of a new balanced forefoot arch, promoting the healing of chronic pressure ulcers.
- This technique, in association with percutaneous osteotomies and tenotomies of phalanges, protects diabetic patients with minimal tissue damage, immediate postoperative weight bearing, and reduced risk of potential infections, because it does not require metal fixation.
- In a recent preliminary prospective study, DMDO was proved to be a safe and effective method for promoting the healing of chronic diabetic foot ulcers, regardless of their severity.

Video content accompanies this article at http://www.foot.theclinics.com.

INTRODUCTION

The diabetic foot could seem hopeless because the prognosis of diabetic patients over the years often becomes inexorably worse. It is known that more than half of

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all nontrauma amputations are done in diabetic patients because of a higher risk of developing peripheral vascular disease, deep infections, abscesses, osteomyelitis, or gangrene (**Fig. 1**) in an extremity.[1] In up to 84% cases,[2,3] the causative factor of these sequelae are diabetic foot ulcers (DFUs), the most common complication of diabetes type 1.[1] However, amputations may not be the most effective solution because they could be complicated by infections, which tend to be polymicrobial in diabetics (**Fig. 2**). Patients with pressure ulcers have a 2.5-fold increased risk of death compared with diabetic patients without DFUs. Further, DFU development is associated with 5% mortality during the first year and 42% mortality within 5 years.[4]

DFUs range from 2.2% in United Kingdom to 6.3% globally.[5] The prevalence of diabetic foot complication is lower for women than for men, and it is higher in patients affected by diabetes type 2 compared with those with diabetes type 1.[6] It is estimated that 19% to 34% of patients with diabetes are likely to be affected with a DFU during their lifetimes.[7] Because there is an increased number of newly diagnosed diabetics, the incidence of DFUs is expected to increase in the coming years.[8]

The cause of DFUs is multifactorial; peripheral neuropathy, poor glycemic control, calluses, foot deformities, improper foot care, ill-fitting footwear, peripheral artery disease, and dry skin are involved in the etiopathogenesis.[5,8] Their treatment continues to be challenging because of the high number of unhealed pressure ulcers found at 1 1year after treatment (20%) and because of the high recurrence rate of about 40% within 1 1year.[9]

At present, there is a new strategy: the successful application of minimally invasive surgery in the treatment of these dramatic lesions.[10] The distal metatarsal metaphyseal osteotomy (DMMO),[11] a technique used routinely in the last decade for the treatment of metatarsalgia, has been used to treat chronic plantar diabetic foot ulcers

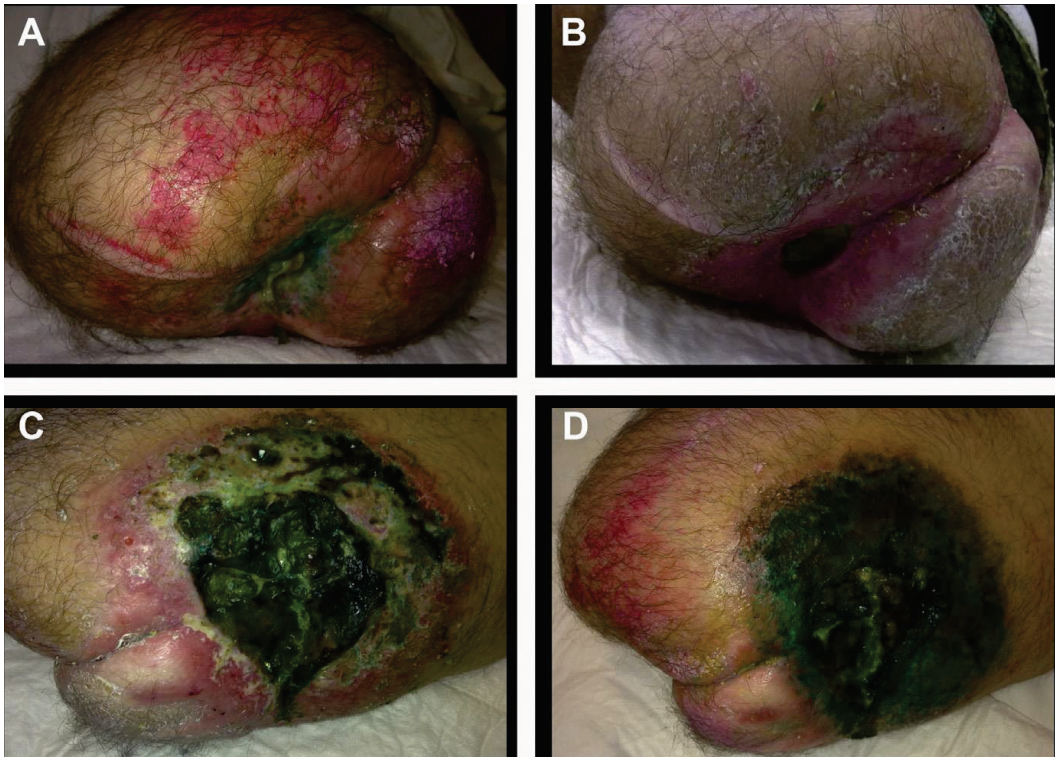

Fig. 1. Polymicrobial infection of the distal (*A*, *B*) and lateral (*C*, *D*) aspect of an above-knee amputation stump in a 48-year-old man.

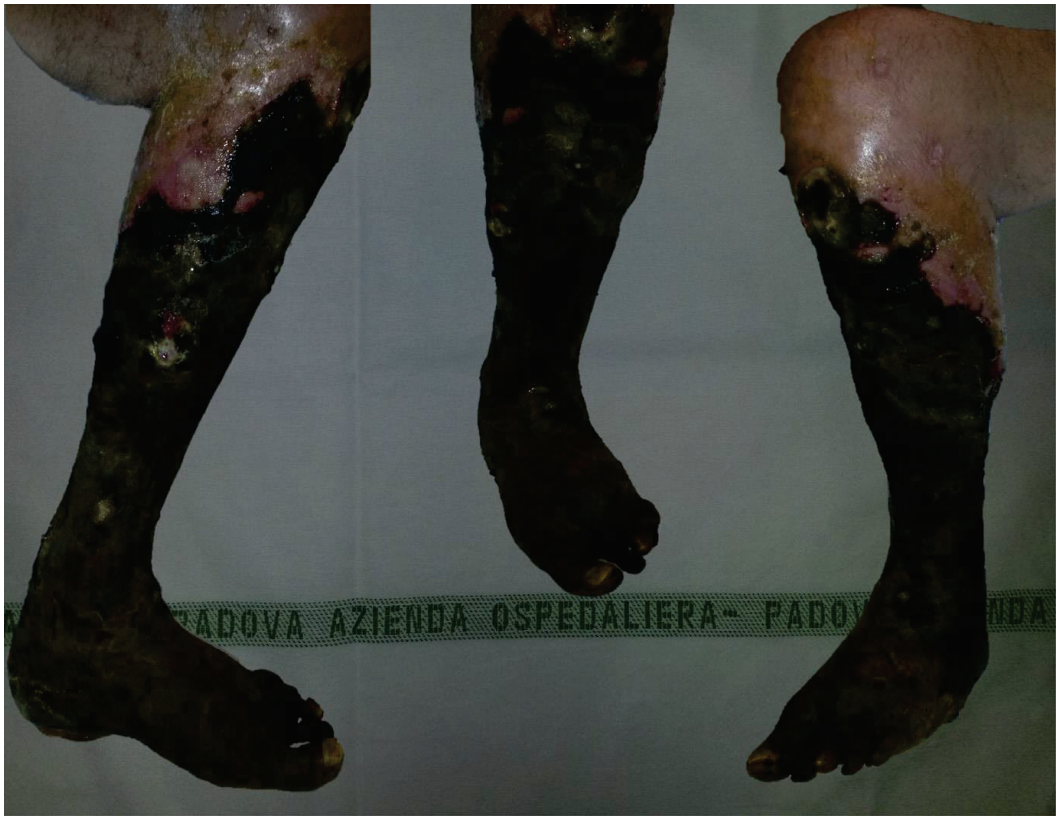

Fig. 2. Dry gangrene of the distal lower limb in a 52-year-old diabetic man with peripheral arterial disease and previous diabetic ulcers, who had refused amputation several times.

(CPDFUs).[12,13] A variant of this technique is the minimally invasive distal metatarsal diaphyseal osteotomy (DMDO).[13] This procedure is based on a distal osteotomy more proximal to the metatarsal neck, not only to reduce the pressure on the ulcer and consequently favoring its healing but also to restore the metatarsal parabola, preventing recurrent or transfer skin lesions.[13]

CLINICAL AND RADIOGRAPHIC APPROACH TO DIABETIC PATIENTS

There is substantial evidence from the literature that intensive foot care using a multidisciplinary approach is successful in reducing both hospitalization[14] and limb amputation rates in the diabetic population.[15–17] For this reason, in our center, it is routine practice for all patients with foot diabetic disease to be reviewed regularly by a multidisciplinary team. According to the institutional protocol, the clinical evaluation includes a complete clinical history of the patients, their characteristics (gender, age at the time of surgery, affected side, comorbidity, hemoglobin A1c, total CO_2, polymerase chain reaction, and peripheral vascular and neurologic status). The general aspects of the diabetic foot and related ulcers are evaluated. Routinely, the University of Texas Diabetic Wound Classification System[18,19] is used to grade CPDFUs (**Table 1**), whereas the ulcer's diameter and the major axes of the wounds are determined manually using a transparent sheet, as described by Coughlin and colleagues.[20]

In this way, patients with foot ulcers are evaluated for the most appropriate management: conservative or surgical. When the foot and ankle surgeon believes surgery is indicated, patients are referred for metatarsal percutaneous osteotomies and/or

Table 1
The University of Texas diabetic wound classification system

Ulcer	Grade			
Stage	0	I	II	III
A	Preulcerative or postulcerative lesion completely epithelialized	Superficial wound, not involving tendon, capsule, or bone	Wound penetrating to tendon or capsule	Wound penetrating to bone or joint
B	Preulcerative or postulcerative lesion completely epithelialized with infection	Superficial wound, not involving tendon, capsule, or bone with infection	Wound penetrating to tendon or capsule with infection	Wound penetrating to bone or joint with infection
C	Preulcerative or postulcerative lesion completely epithelialized with ischemia	Superficial wound, not involving tendon, capsule, or bone with ischemia	Wound penetrating to tendon or capsule with ischemia	Wound penetrating to bone or joint with ischemia
D	Preulcerative or postulcerative lesion completely epithelialized with infection and ischemia	Superficial wound, not involving tendon, capsule, or bone with infection and ischemia	Wound penetrating to tendon or capsule with infection and ischemia	Wound penetrating to bone or joint with infection and ischemia

Lavery LA, Armstrong DG, Harkless LB. Classification of diabetic foot wounds. J Foot Ankle Surg. 1996;35(6):528–31; with permission

lesser toe tenotomies. The number of metatarsal osteotomies that must be performed in each forefoot is planned according to how much the metatarsal formula is altered, following the Maestro criteria. In this way, it is decided where the osteotomies should lead to rebalance plantar pressures, to create a harmonious curve and to promote ulcer healing.[21] Further, in the cases of associated hallux valgus (HV) or claw toe deformities (CTDs), with or without ulcers, the local forefoot surgery protocol is followed. For HV, the surgery is Reverdin-Isham percutaneous osteotomy for mild to moderate HV deformity,[22] or the Endolog technique for moderate to severe HV deformity, both generally followed by percutaneous Akin osteotomy.[23] For toe deformities, the general treatment is as described by Redfern and Vernois,[24] recently simplified for diabetic patients with CTD.

SURGICAL TECHNIQUE

Surgical Procedures Described for Minimally Invasive Distal Metatarsal Diaphyseal Osteotomy Performed on the Left Foot by a Right-handed Surgeon (Videos)

- Patient position (Video 1): the patient must be in a supine position during the operation, with the operated foot protruding from the table. For 2 reasons, an

ankle joint tourniquet is not required for this technique: blood is necessary to facilitate the removal of bone debris to be eliminated in the form of bone paste; and, more importantly, it is not indicated in diabetic lower limb surgery because of the problematic vascular peripheral system.

- Anesthesia: a regional block of the foot, involving deep nerves (deep peroneal and posterior tibial) and superficial nerves (saphenous, sural, and superficial peroneal) is recommended. A prophylactic antibiotic (cefazolin: 2 g) is administered before surgery.
- Equipment: a small scalpel blade (SM64), bone rasp, and periosteal elevator; a Shannon Isham burr (2.0 × 12 mm); a 20-mL syringe with normal saline solution; a fluoroscopy system for radiographic check; a power-driven burr, which has to provide a speed of approximately 2000 to 6000 rpm to avoid bone necrosis; bandages and tubular gauze for the final dressing.
- Portals (see Video 1): for surgery on a left foot by a right-handed surgeon, the top of the metatarsal head must first be palpated with the left thumb. Then, moving a few millimeters proximally at this level in the interspace on the right side of the head (ie, the lateral side for the left foot), an incision of 5 mm is made parallel to the extensor tendons by a small scalpel blade (SM64) at the dorsal side of the medial (or lateral) border of each metatarsal head that needs to be shortened. Care must be taken to avoid the network of veins at this level, which is usually visible because of the vasodilatation after the previous ankle block. The side of the incision depends on whether the surgeon is right or left handed; which foot is being operated on; and, more importantly, how much the metatarsal bone (MB) must be shortened in order to lift its head and facilitate the healing of the CPDFU.
- Osteotomy site (Video 2): the scalpel is moved forward at an oblique angle of about 45° until it reaches the dorsal aspect of the distal MB, proximal to the neck, to undergo osteotomy. Through the same incision, first a bone rasp specific for percutaneous surgery is inserted, and the periosteum is separated at the level of the osteotomy. A path is then prepared for the burr by using a periosteal elevator and positioning it obliquely at a 45° angle to the metatarsal axis, against the neck, which can be done by feel, using the instrument to move along the flare on the proximal part of the neck, from neck to distal diaphysis, mirroring the movement needed then for the osteotomy and detaching the tissues, which tend to be very stiff in diabetic feet.
- Osteotomy (Videos 3 and 4): a Shannon Isham burr (2.0 × 12 mm) is introduced until it reaches the metatarsal neck. It is then retracted a few millimeters proximally where the periosteum was previously removed. Fluoroscopy allows confirmation of the correct position of the osteotomy site on the distal diaphysis of the MB. In this position, cutting is started with an angle of approximately 45° with respect to the long axis of the MB in a dorsal-distal to proximal-plantar direction, with rotary motion, extending to the contralateral cortex (**Fig. 3**A). The lateral cortical surface is cut first in this way, then the plantar, medial, and lastly the dorsal cortical surface. Beginning with the section of the lateral cortex, the osteotomy is started with the motorized burr moving in a plantar and medial direction and ends with the section of the dorsal cortex, which is performed by pivoting in a rotational movement from the point of skin entry, involving a supination of the wrist of 90°. Thus, the burr comes to lie nearly flat on the foot at 90° to the metatarsal axis in the anteroposterior plane.
- Portal irrigation (see Video 4): the incision site is irrigated by normal saline during osteotomy because the burr can cause excessive heat, first burning the skin and subsequently resulting in fibrosis and pseudoarthrosis at the bone level.[22,25] The

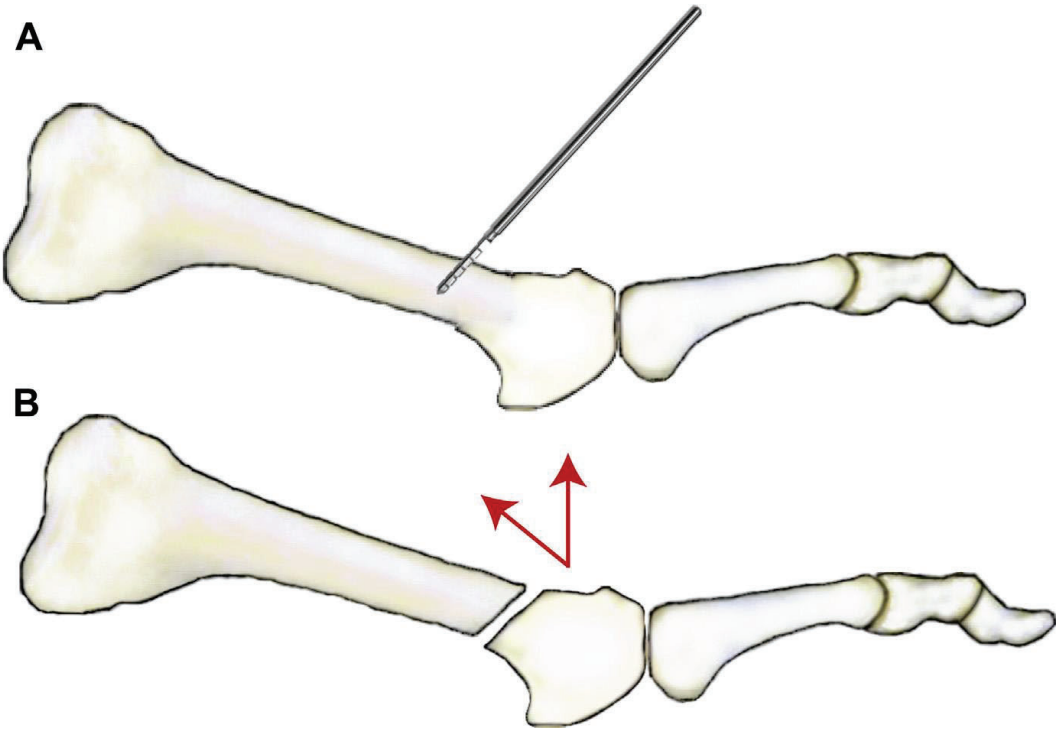

Fig. 3. The DMDO is performed with a 12-mm Shannon Isham burr with an angle of approximately 45° with respect to the long axis of the MB in a dorsal-distal to proximal-plantar direction (*A*). Hence, an ideal osteotomy has been performed proximal to the neck with potentially greater elevation of metatarsal head from the ground (*B*).

lavage is also useful to remove bone debris, preventing periarticular ossifications in the stab canal.

- Compacting of osteotomy sides (Video 5): the bone is manually compacted on completion of the osteotomy by exercising pressure in the distal-proximal direction of the MB of interest, pushing the metatarsal head dorsally and producing contact of the trabecular bone, because no internal fixation is performed. The toe must be mobilized along the metatarsal axis to ensure that the metatarsal heads can move together under full weight bearing. This movement allows mobilization of periosteal adhesions that could promote the shortening and elevation of the distal part of the MB during walking (**Fig. 3**B).
- Ulcer debridement: by accurate ulcer debridement, the CPDFU is converted into an acute wound in order to enable the normal stages of healing,[26,27] whereas resorbable sutures should be used to close the rest of the wounds.

Tenotomies and Osteotomies for Lesser Toe Deformities

As stated by Redfern and Vernois,[24] percutaneous surgical techniques are particularly effective for the correction of lesser toe deformities and may be advantageous in cases considered at higher risk of cutaneous or vascular complications, such as diabetes and neuropathic feet. Hence, ulcers at the dorsal aspect of the proximal interphalangeal (PIP) joint, usually caused by rubbing against the toe box of shoes, can be prevented in areas of hyperkeratosis or treated through multiple percutaneous tenotomies and phalangeal osteotomies of the lesser toes.

For these different procedures, anesthesia and antibiotic prophylaxis, patient position without tourniquet, minimally invasive equipment, and portal irrigation are the

same as in DMDO, except for the burr, which should be a Shannon Isham burr (2.0 × 8 mm).

In our experience, to simplify this surgery, we apply Piclet's technique as originally described in 2009[28] and published in 2018:[29]

- Tenotomies (Video 6): by a short plantar incision just proximal to the metatarsophalangeal joint (MTPJ), a flexor digitorum brevis tenotomy, followed by a second plantar incision at the level of PIP for its release, and flexor digitorum longus (FDL) tenotomy are performed in patients with flexible deformity.
- Phalanx osteotomies (Video 7): through the first plantar incision, associated P1, and sometimes P2, osteotomies are also performed in patients with fixed deformity.
- Toe extension (see Video 7): finally, to obtain proper correction in both cases, a forced extension is always applied as well as a final extensor digitorum longus/extensor digitorum brevis tenotomy only when further improvement of the correction is required.

Bandage

The bandage is very important to maintain the correction obtained after surgery because there is no osteosynthesis material in this operation. Surgeons wishing to attempt these techniques must be familiar with the proper wrapping of the bandage to control the metatarsal axis and toe position in the postoperative period while healing occurs.

- Tape is used for bandages, which are bent and crisscrossed, tracing between all intermetatarsal spaces, crossing them over the medial (lateral) aspect of each of the osteotomies performed (depending on the foot side) to reinforce the strength of the bandage.
- To maintain the toe in slight plantar inclination, gentle traction is used.
- Tubular gauze is used to cover the forefoot, except for the distal part of the toes and nails to check distal vascularization of the foot.

Postoperative Care

According to our postoperative protocol:

- Before the patient's discharge, anteroposterior and lateral radiographs of non–weight-bearing feet should be taken.
- The day after surgery, the patients are allowed to walk using a rigid flat-soled orthopedic shoe for the following 30-day period. (This is very important because metatarsal length is set automatically on weight bearing of the foot.[22])
- Oral antibiotic prophylaxis for a week is recommended starting from the day of the surgery, as well as thromboembolic prophylaxis (natrium enoxaparin: 4000 IU/d) and an antiedemigen therapy (Leucoselect, Lymphaselect, and Bromelina: 1 tablet/day) for 30 days. An analgesic therapy is prescribed for 2 weeks (etoricoxib, 60 mg, 1 tablet/day in the morning), also to prevent heterotopic ossification when comorbidities of the patient permit it, or alternatively, paracetamol (1 g, 1 tablet x2/day).
- Each of the patients is seen once a week for a month on an outpatient basis. The first control is 8 days after surgery. The original bandage is removed and substituted by a simpler bandage. At the next 3 weekly visits, the bandage is changed in the same way.
- The bandage is totally removed 1 month after surgery if the ulcer is completely closed, and anteroposterior weight-bearing and lateral radiographs are taken. The patient is then able to walk with comfortable shoes or orthopedic footwear

(according to previous foot deformity), allowing total load on the operated foot. If the ulcer is not completely healed, the patient is seen every week for medication until total healing of the lesion.

Indications and Contraindications

Percutaneous procedures correcting foot deformities, thereby decreasing plantar pressure by internal floating metatarsal and phalangeal osteotomies in case of rubbing against the toe box of shoes, are indicated when conservative methods fail, usually after at least 6 weeks of off-loading orthotic treatment and standard conservative treatment. The general indications are largely the same as for metatarsal head resection, arthroplasty resection, and bunionette correction.[30,31] Further, because of the tiny percutaneous portal incisions, the osteotomies and tenotomies of the forefoot can often be considered in situations where there is poor local soft tissue, or previous amputations of toes and/or MBs with scarring. During the operation, the number of metatarsal osteotomies performed in each forefoot is planned according to how much the metatarsal formula of preoperative radiographs was altered according to the Maestro criteria.[12,13,21] It should generally be considered almost obligatory to perform the osteotomies to the second, third, and fourth MBs in order to avoid a transfer lesion developing under the third or fourth metatarsal heads. The presence of significant arthritis and stiffness in the associated MTPJ and the consequent association of reported increased risk of nonunion in this situation[12,24] is not a contraindication for DMDO, as it is a diaphyseal osteotomy. In addition, the authors strongly believe that ulcers with chronic infection, or ulcers penetrating deep structures (IIIB), osteomyelitis of the MBs or the distal phalanx, ankle brachial index less than 0.5, or flat pulse volume recording at the ankle level are relative, but not absolute, contraindications for the procedure in the absence of associated cellulitis.

On the contrary, the few absolute contraindications of these percutaneous procedures are:

- Severe ischemia and gangrene
- Insufficient vascular perfusion
- Extensive soft tissue infection presenting as cellulitis of the foot or toe

Complications

The potential complications of these percutaneous techniques, mostly minor, have been well described[13,24,30,32,33]: ulcer recurrence, ulcer transfer, superficial infection, malunion, and nonunion. However, they are reported in lower percentages than those that occurred after standard care. In particular, persistent moderate swelling of the forefoot for more than 6 weeks without infection has been described, which has been resolved after complete callus formation at the osteotomy levels,[13] whereas, more recently, some cases of exuberant callus formation were noted.

To the best of our knowledge, no cases of major complications (deep wound infection, MB osteomyelitis or avascular necrosis of metatarsal head, and acute Charcot osteoarthropathy) have been reported in the literature. However, it is possible that, with longer follow-up (FU) and a larger patient group, an increase in the number of complications of this evolving disease could occur.

RESULTS

All these procedures were managed as described in the following case series.

Case 1

A 52-year-old female patient with a past medical history of type I diabetes, resolved after kidney and pancreas transplant. She presented with right foot distal neuropathy, HV, metatarsalgia, hyperkeratosis, fixed CTDs, having undergone DMDO of the second, third, and fourth metatarsal bone for a IIIB chronic ulcer extending into the MTPJ. Three years prior she had presented with a IIIB CPDFU over the lateral aspect of the MTPJ of the fifth ray of the same foot, caused by osteomyelitis. A transmetatarsal amputation of the right foot was suggested at another institution, which the patient refused. She attended our orthopedic clinic for a second opinion, where a fifth MB head resection and minimally invasive regularization through the same ulcer was proposed with success. Clinical (**Fig. 4**) images at preoperative, 3-month, 6-month, and 72-month FU showed complete healing of both CPDFUs, reduction of the hyperkeratotic areas, and maintenance of the results obtained. Radiographic (**Fig. 5**) images at preoperative, 3-month, 6-month, and 72-month FU showed bone union and remodeling.

Case 2

A 68-year-old type II diabetic female patient having undergone percutaneous osteotomy of P1 of the second, third, and fourth toes, associated with percutaneous FBB, FDL tenotomies, and PIP release for CTD of her right foot and percutaneous lengthening of hallux flexor tendon of her HV for recalcitrant IC ulcers of the toes. Clinical images (**Fig. 6**) at preoperative, 2-month, and 60-month FU showed complete healing of the ulcer and toe realignment without recurrence.

Case 3

A 67-year-old type II diabetic male patient having undergone DMDO of the fourth and fifth MBs for a IB CPDFU. Clinical (**Fig. 7**) and radiographic (**Fig. 8**) images at preoperative, 1-month, 3-month, and 52-month FU showed complete healing of the ulcer and bone union.

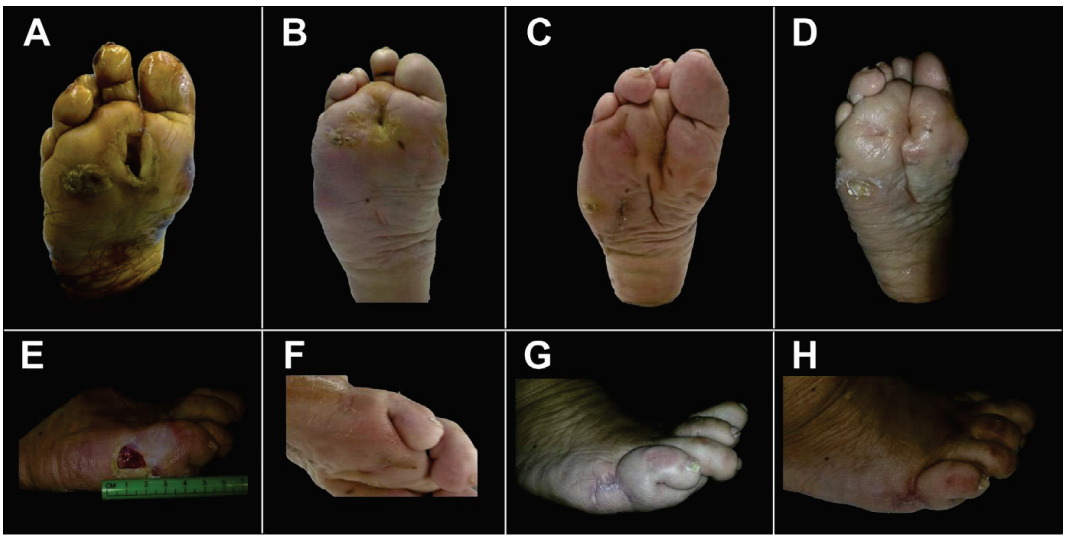

Fig. 4. Case 1: clinical images at (*A-E*) preoperative, (*B-F*) 3-month, (*C-G*) 6-month, and (*D-H*) 72-month follow-up.

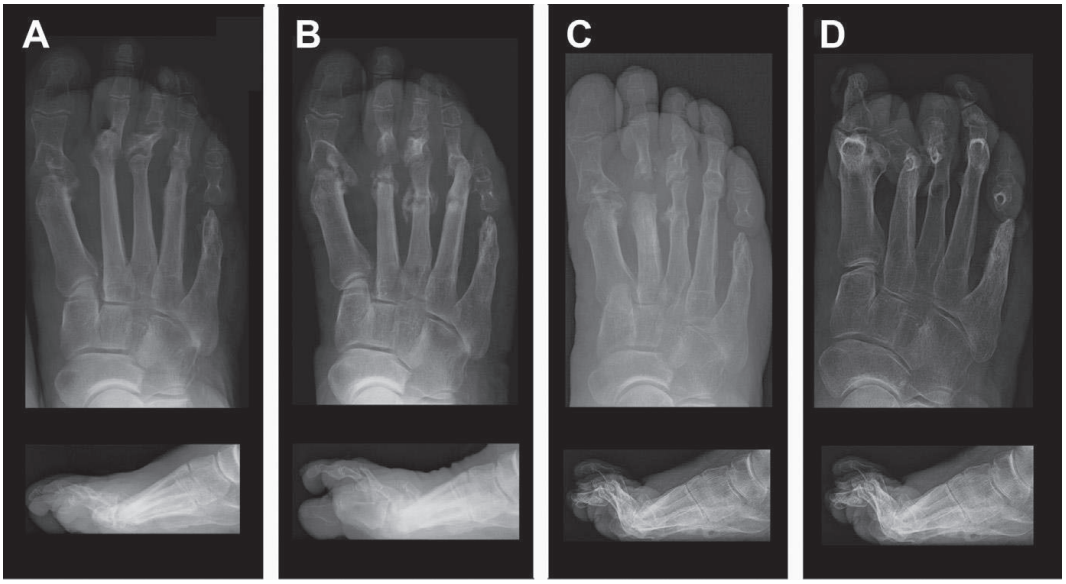

Fig. 5. Case 1: Radiographic images at (*A*) preoperative, (*B*) 3-month, (*C*) 6-month, and (*D*) 72-month follow-up.

Case 4

A 61-year-old type I diabetic male patient who underwent an Endolog technique for moderate-severe HV correction, percutaneous Akin osteotomy, DMDO of the second, third, fourth, and fifth MBs for a IIB CPDFU, percutaneous osteotomy of P1 of the second toe for associated fixed CTD and percutaneous FBB, FDL tenotomies, and PIP release of the second, third, fourth, and fifth toes for fixed (second) and flexible CTDs of his right foot. Clinical (Fig. 9) images at preoperative, 2-month, and 34-month

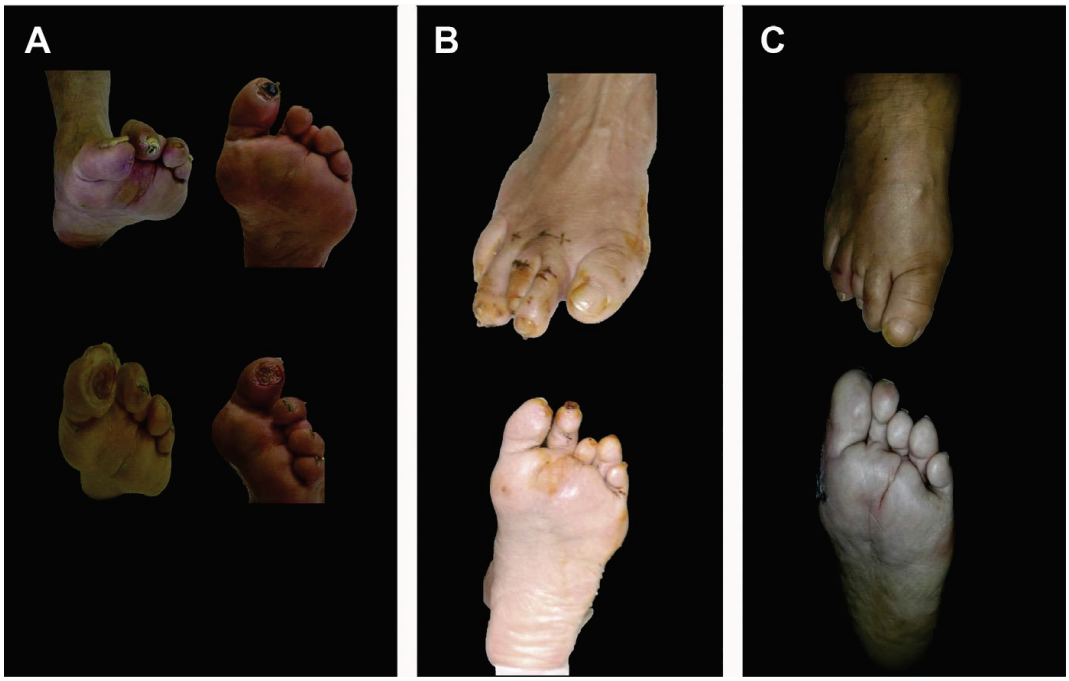

Fig. 6. Case 2: clinical images at (*A*) preoperative, (*B*) 2-month, and (*C*) 60-month follow-up.

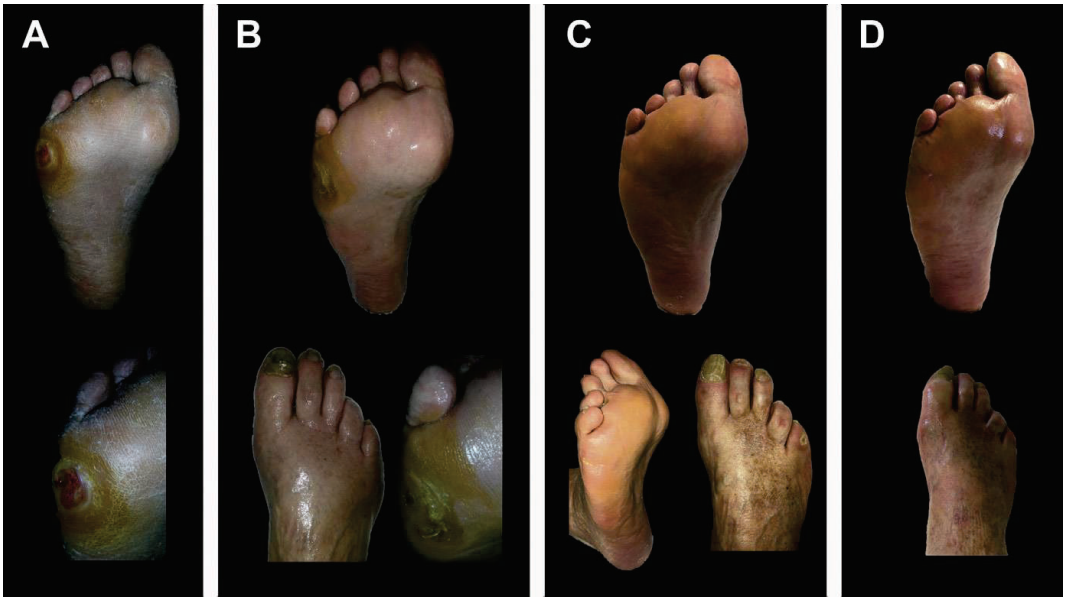

Fig. 7. Case 3: clinical images at (*A*) preoperative, (*B*) 1-month, (*C*) 3-month, and (*D*) 52-month follow-up.

FU and radiographic (**Fig. 10**) images at preoperative, 2-month, 6-month, and 34-month FU, showing complete healing of the ulcer and toe realignment, bone union with exuberant callus formation, and metatarsal rebalance.

Case 5

An 80-year-old type II diabetic male patient who had previously undergone bilateral forefoot amputations at another institution a few years prior came to our orthopedic clinic for recalcitrant IIIB CPDFUs on both feet. The proposed plan included a double DMDO of the third MB and a simple DMDO of the fourth and fifth MBs associated with percutaneous FBB, FDL tenotomies, and PIP release for flexible CTDs of

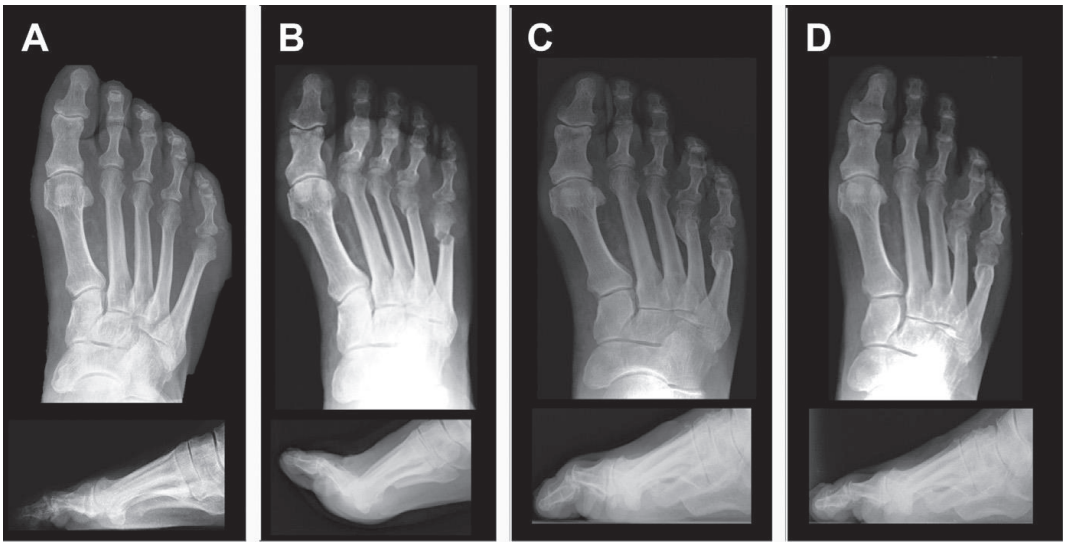

Fig. 8. Case 3: radiographic images at (*A*) preoperative, (*B*) 1-month, (*C*) 3-month, and (*D*) 52-month follow-up.

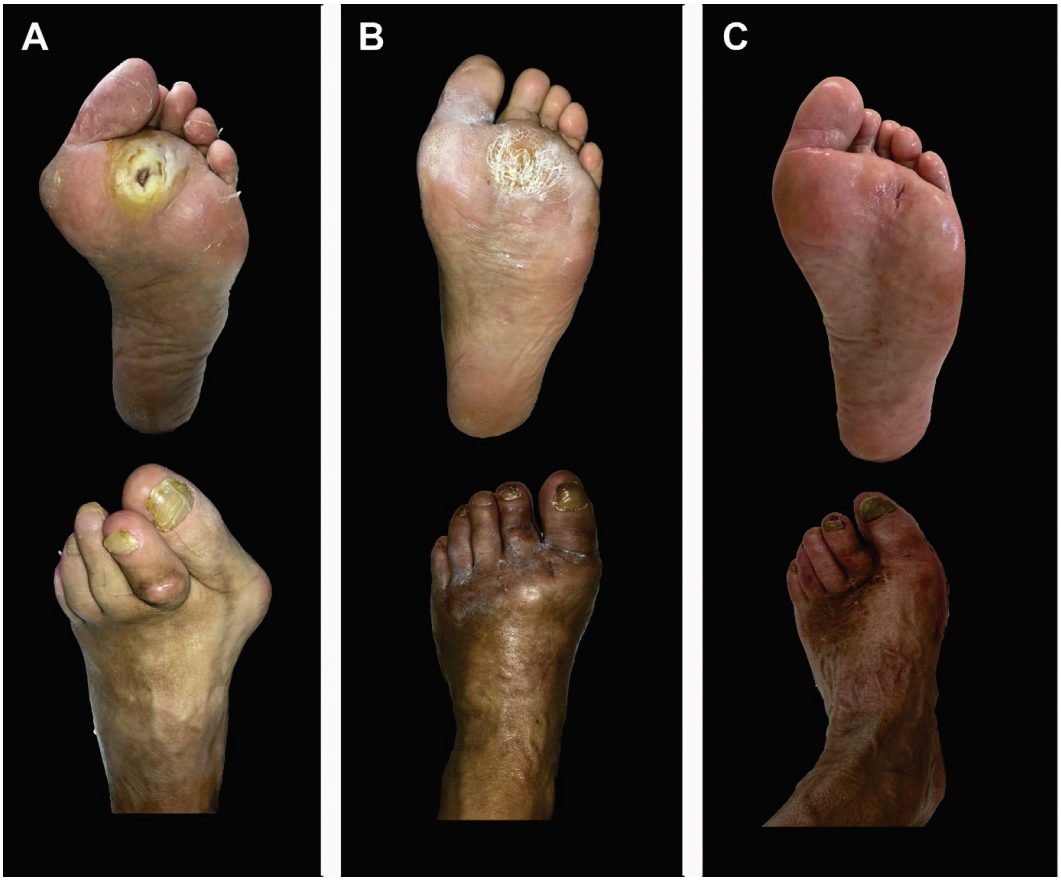

Fig. 9. Case 4: clinical images at (*A*) preoperative, (*B*) 2-month, and (*C*) 34-month follow-up.

the right foot. Clinical (Fig. 11) images at preoperative, 2-month, 3-month, and 6-month FU showed complete healing of the ulcer on the right foot; radiographic (Fig. 12) images at preoperative, 2-month, and 6-month FU showed bone union and remodeling.

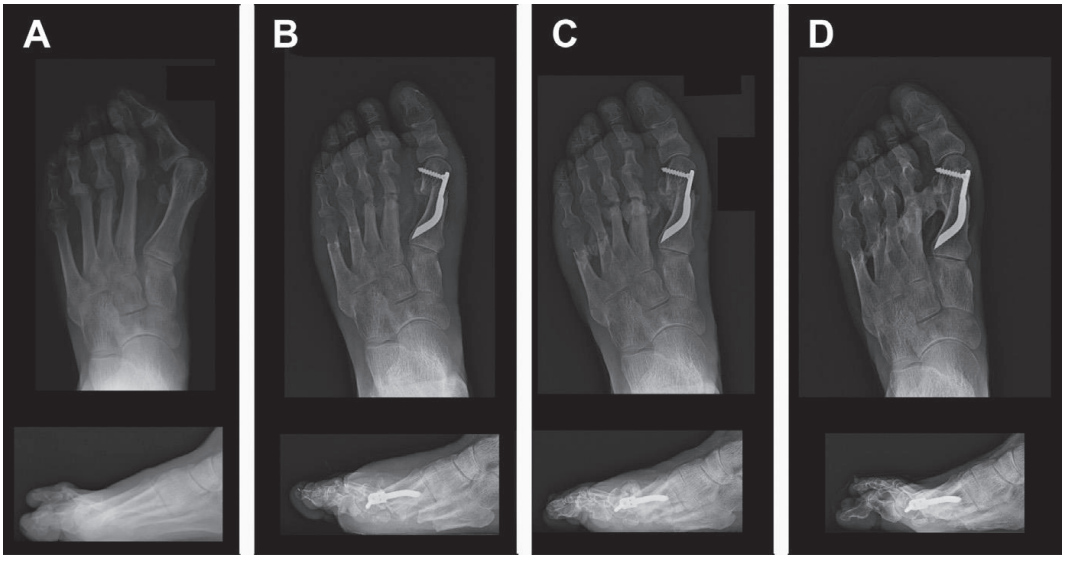

Fig. 10. Case 4: radiographic images at (*A*) preoperative, (*B*) 2-month, (*C*) 6-month, and (*D*) 34-month follow-up.

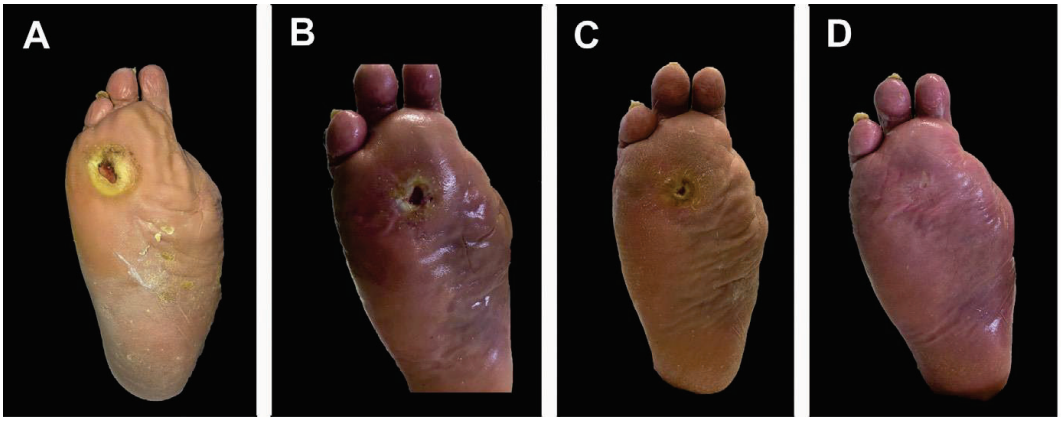

Fig. 11. Case 5: clinical images (right foot) at (*A*) preoperative, (*B*) 2-month, (*C*) 3-month, and (*D*) 6-month follow-up.

During the same operation, this patient underwent DMDO of the second and third MBs, associated with percutaneous FBB, FDL tenotomies, and PIP release for CTDs of the left foot. During the first month of weekly medications, the second metatarsal head had to be removed because of exposure through the ulcer. Clinical (**Fig. 13**) images at preoperative, 2-month, 3-month, and 6-month FU showed complete healing of the ulcer on the left foot. Radiographic (**Fig. 14**) images at preoperative, 2-month, and 6-month FU showed bone union and remodeling.

Case 6

As shown in the video clip, this 76-year-old type I diabetic man had undergone DMDO of the second, third, fourth, and fifth MBs for a IIB CPDFU, and percutaneous

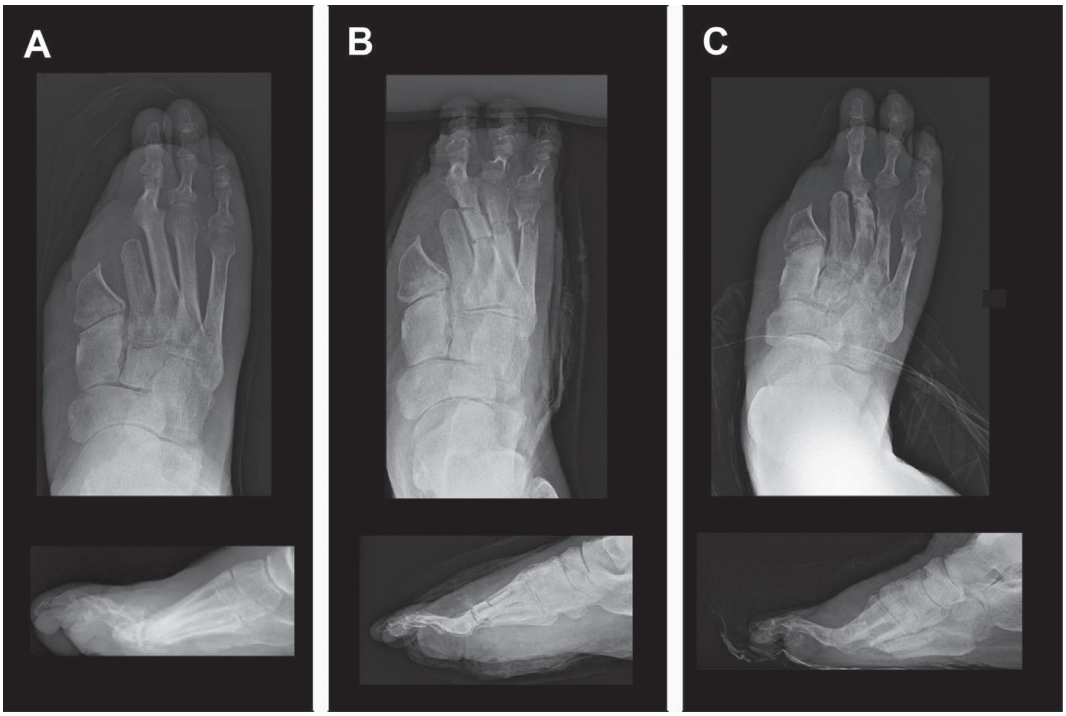

Fig. 12. Case 5: radiographic images (right foot) at (*A*) preoperative, (*B*) 2-month, and (*C*) 6-month follow-up.

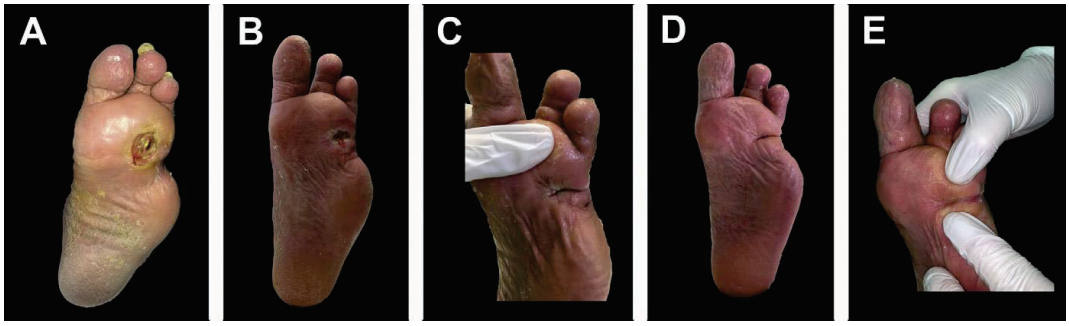

Fig. 13. Case 5: clinical images (left foot) at (*A*) preoperative, (*B*) 2-month, (*C*) 3-month, and (*E*) 6-month follow-up.

osteotomy of P1 of all lesser toes associated with percutaneous tenotomies and PIP release for CTDs of his right foot. Clinical images (Fig. 15) at preoperative, 1-month, 2-month, and 6-month FU showed the complete healing of both ulcers. Radiographic images are also provided (Fig. 16) at preoperative and 2-month FU. This case was complicated by a lengthy period of forced bed rest immediately after surgery for cardiology problems, therefore standing radiographs were not obtained during the following clinical FUs. Nonetheless, on the lateral radiograph projection, as marked by the red arrow, the metatarsal heads appear lifted (see Fig. 16B).

WHY SHOULD PERCUTANEOUS OSTEOTOMIES BE PERFORMED IN DIABETIC FOREFEET?

State of the Art

Within the last decade, the well-known DMMO and the innovative distal oblique metatarsal minimal invasive osteotomy (DOMMO) have proved to be alternative surgical

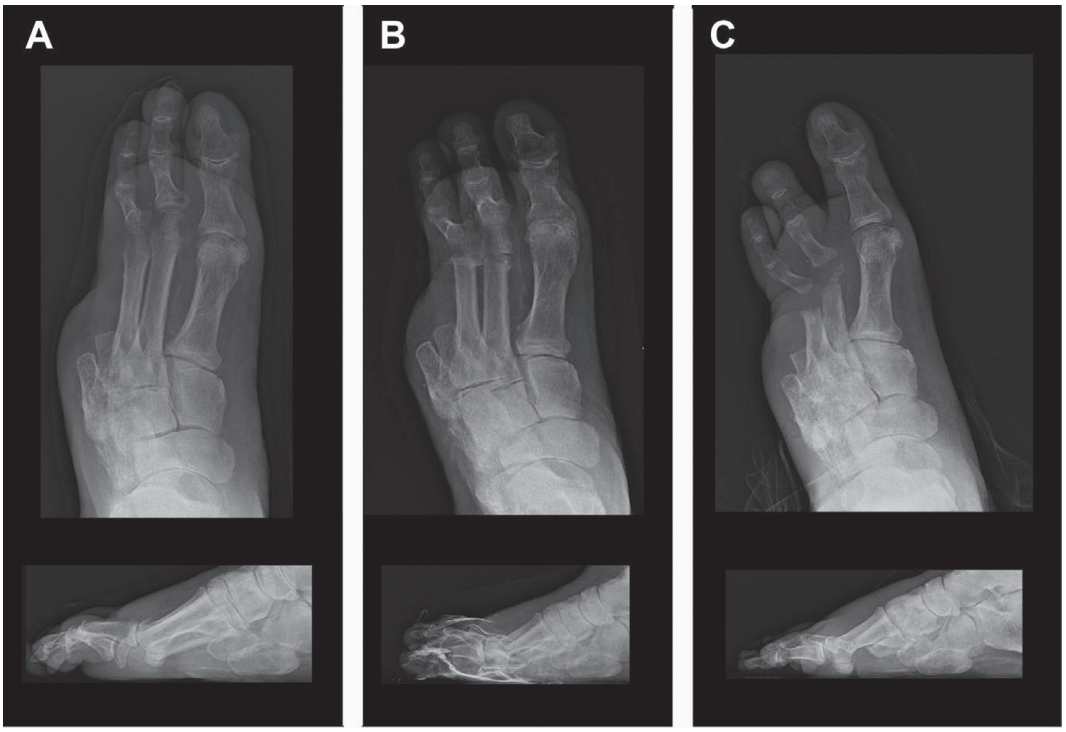

Fig. 14. Case 5: radiographic images (left foot) at (*A*) preoperative, (*B*) 2-month, and (*C*) 6-month follow-up.

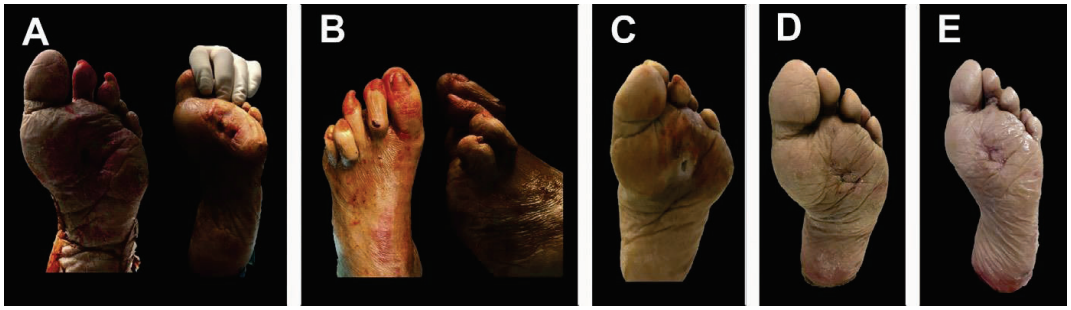

Fig. 15. Case 6: clinical images at (*A-B*) preoperative, (*C*) 1-month, (*D*) 2-month, and (*E*) 6-month follow-up.

approaches for central primary metatarsalgia.[11,24,34,35] More recently, this percutaneous procedure was modified to reduce the plantar pressure of the MBs over CPDFUs in diabetic patients, promoting ulcer healing.[13] In the 1990s, Vitti and colleagues[36] showed that the presence of diabetes is an independent predictor of poor healing after forefoot surgery, but many studies have found that the diabetic status fails to predict outcomes from limited amputation.[37,38] In this regard, the authors believe that any external insult to the diabetic foot could only worsen the diabetic status, leading to more proximal, and sometimes not even resolutive, amputation. For these reasons, percutaneous surgery is a valid alternative to traditional conservative treatments,[39] such as non–weight bearing for a long period and total contact

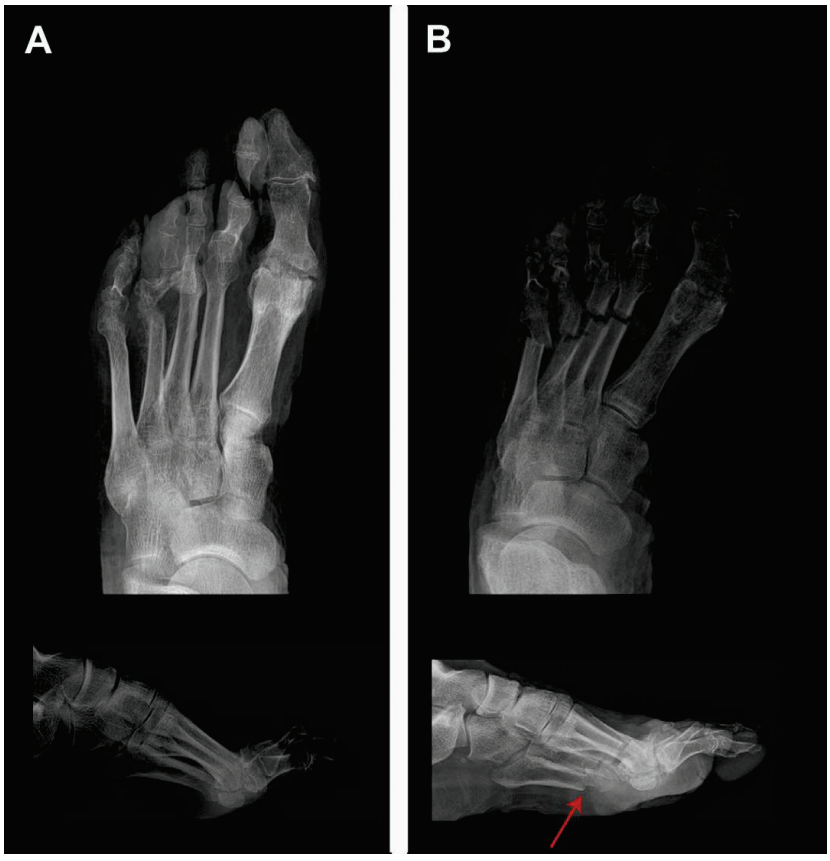

Fig. 16. Case 6: radiographic images at (*A*) preoperative and (*B*) 2-month follow-up, where the metatarsal heads appear lifted, as marked by the red arrow.

cast.[40–42] Afterward, continued care is required with special shoes and orthotics to prevent recurrence. Hence, these conservative methods often fail because of complications or lack of compliance.[43]

By its nature, minimally invasive surgery minimizes the tissue damage derived from surgical aggression, solving at the same time the mechanical causes that led to ulcer formation. The main purpose of this procedure is to decrease the pressure plantar to the affected metatarsal head. Further, because full weight bearing in a postoperative flat shoe is allowed immediately after surgery, the postoperative period is more comfortable for the patients. This result can also be achieved by more popular surgical techniques: plantar condylectomy, Weil osteotomy, closing wedge metatarsal osteotomy with metal fixation, and Helal osteotomy.[33,44–47] However, they tend to have high complication rates because of wound dehiscence and/or postoperative infections.

CPDFUs were initially hypothesized to be lesions caused by overactivity of both the long extensor and long flexor.[48] However, the authors believe that the major causative factor is not muscle imbalance but the progressive collapse of the transversal axis of the foot.[13] Because internal fixation is not used in the DMDO technique, avoiding potential infection of the metalwork, the osteotomized metatarsal heads are shifted, adapting to the load toward a new position, which is translated in a slightly dorsal direction, where the heads ossify. In this way, the use of percutaneous techniques enables:

- First, obtaining a better distribution of plantar pressure on the MBs, resulting in a lengthening of the load under the ulcer, promoting its rapid healing.[49,50]
- Second, restoring the original harmonic distal parabola of the forefoot when possible, or creating a new balanced forefoot arch. In order to respect the Maestro criteria,[21] it is often necessary to shorten the MB to a greater degree, performing a diaphyseal osteotomy much more proximal to the neck.

From the mechanical point of view, Redfern and Vernois[24] correctly stated that making the osteotomy more proximal to the neck is a technique error when performing DMMO, causing MB displacement in dorsal rotation and a consequent overelevation of the metatarsal head, making a DOMMO preferable in these cases. In contrast, this is exactly the main goal of performing DMDO for CPDFU treatment.

The applications of minimally invasive surgery for the treatment of diabetic disease is not new. In 1990, Tillo and colleagues[33] was the first to propose a dorsal osteoclasis at the level of the metatarsal neck for the treatment of DFUs, reporting a recurrence rate of 6% and a transfer lesion rate of 26.5% during a 17-month FU. In 1999, Fleischli and colleagues[32] described a dorsiflexion metatarsal base osteotomy fixed by pins for the treatment of CPDFU. Although good results were reported with a high healing rate (95%), complications occurred in 68% of cases, including acute Charcot disease, deep wound infections, and transfer ulcers.

A recent meta-analysis of the contemporary management of diabetic neuropathic foot ulcerations reveals disappointing functional outcomes,[31] and percutaneous surgery for CPDFUs by metatarsal osteotomies was found to be a poorly investigated topic. Contrary to the traditional surgical techniques, only 4 case series studies could be located in the literature.[31] In these analyses, despite the common association between decreased healing rates and severity and duration of CPDFUs,[31] the healing rates and time found by the different investigators proved far better than those reported with standard care in terms of ulcer duration and severity, knowing that included ulcers were all either recurrent or recalcitrant to initial standard care. Further, complications (ulcer recurrence, ulcer transfer, infection, and nonunion) were less frequent with respect to those reported following standard care.

Another recent evidence-based review challenges the classic guidelines on diabetic forefoot ulcer management.[31] It shows that off-loading surgery probably yields better outcomes than conservative treatment. Specifically, metatarsal head resection, arthroplasty resection, and metatarsal osteotomies at different levels generated excellent healing rates with short healing durations and low recurrence rates. Thus, these investigators concluded that floating osteotomies could be used more often and proposed earlier in the course of DFUs.

In the last few years, Tamir and colleagues[48] described the use of percutaneous tenotomies for the treatment of diabetic toe ulcers and mini-invasive floating osteotomies for the treatment of resistant or recurrent DFUs, reporting excellent results. Although they treated ulcers exclusively of University of Texas grade IA, their findings were confirmed by our results reported recently and updated in this article (42.9% of CPDFUs of grade IIIB).[13]

SUMMARY

The DMDO is an effective procedure for the treatment of complicated CPDFUs under the heads of lateral MBs (even the fifth), resistant toe ulcers, and recurrent pressure ulcers, mainly those with healing delay or as a consequence of previous forefoot amputations with unbalancing of the metatarsal formula. DMDO is effective even when associated with percutaneous extensor and flexor tenotomies in cases of CTD and percutaneous osteotomies of phalanges in case of fixed deformities. For diabetic patients, the main advantages of this method, performed by distal ankle block, without tourniquet, and with a very low risk of complications, are:

- Minimal surgical scars and tissue damage
- Immediately postoperative weight bearing
- Absence of osteosynthesis and consequent potential infection of metal fixation
- Reduction of the previous high plantar pressures by the restoration of a harmonic balanced forefoot arch
- Rapid ulcer healing

DISCLOSURE

The authors have nothing to disclose.

SUPPLEMENTARY DATA

Supplementary data related to this article can be found online at https://doi.org/10.1016/j.fcl.2020.05.006.

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b. ***Minimally Invasive Metatarsal Osteotomies (MIMOs) for the Treatment of Plantar Diabetic Forefoot Ulcers (PDFUs): A Systematic Review and Meta-Analysis with Meta-Regressions.*** *Appl. Sci.* ***2021****, 11, 9628. https:// doi.org/10.3390/app11209628 [2].*

PDFUs are frequent injuries affecting and heavily limiting the quality of life in diabetic patients. PDFUs can be treated both conservatively (with a high recurrence rate) or surgically (with a high rate of complication). Recently, minimally invasive surgery (MIS), performed by small incisions, has been increasingly applied on diabetic feet due to its encouraging outcomes and low complication rate. This systematic review with meta-analysis and meta-regression aims to evaluate for the first time the effectiveness of minimally invasive metatarsal osteotomies (MIMOs) in treating PDFUs and reducing their recurrence rate. A literature search of PubMed/MEDLINE, ISI/Web of Science and Scopus databases was carried out with the keywords "(metatarsal osteotom*) OR (metatarsal AND osteotom*) AND diabet* AND (feet OR foot OR forefoot) AND ulcer", covering the period from 1980 until June 2021 following PRISMA guidelines. The JBI critical appraisal tool was used for Quality Assessment. Healing rate/time, infection rate, recurrence rate, non-union rate and complication rate were evaluated. When possible, these values were pooled and expressed in effect size (ES), and their 95% confidence interval (CI) was computed. Meta-regression analysis (both uni- and multivariate) was conducted. Eight studies were included in the review, including 189 patients. The healing rate of these studies ranged between 55.1 and 100%, infection rate from 3.3–31.8%, recurrence rate from 0.0% and 13.6% and non-union rate from 4.5–30.0%. Overall complication rate was reported in three studies and ranged from 44.9 to 68.2%. Meta-analysis of the various rates revealed an overall healing rate of 91.9% (range from 74.9 to 97.8%), infection rate of 10.9% (4.2–25.2%), recurrence rate 7.2% (3.6–14.2), non-union rate 16.9% (10.2–26.7) and finally, the complication rate was computed at 53.2%. Satisfactory short- to medium-term clinical and radiographic results were reported by

the studies included in this review, supporting that MIMOs represent an effective surgical approach to treat PDFUs. However, poor quality in the methodology of some studies and the lack of long-term data were reported. Therefore, randomised controlled trials, prospective studies and long-term follow-up studies are needed.

applied sciences

MDPI

Review

Minimally Invasive Metatarsal Osteotomies (MIMOs) for the Treatment of Plantar Diabetic Forefoot Ulcers (PDFUs): A Systematic Review and Meta-Analysis with Meta-Regressions

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Abstract: Plantar Diabetic Foot Ulcers (PDFUs) are frequent injuries affecting and heavily limiting the quality of life in diabetic patients. PDFUs can be treated both conservatively (with a high recurrence rate) or surgically (with a high rate of complication). Recently, minimally invasive surgery (MIS), performed by small incisions, has been increasingly applied on diabetic feet due to their encouraging outcomes and low complication rate. This systematic review with meta-analysis and meta-regression aims to evaluate for the first time the effectiveness of minimally invasive metatarsal osteotomies (MIMOs) in treating PDFUs and reducing their recurrence rate. A literature search of PubMed/MEDLINE, ISI/Web of Science and Scopus databases was carried out with the keywords "(metatarsal osteotom*) OR (metatarsal AND osteotom*) AND diabet* AND (feet OR foot OR forefoot) AND ulcer", covering the period from 1980 until June 2021 following PRISMA guidelines. The JBI critical appraisal tool was used for Quality Assessment. Healing rate/time, infection rate, recurrence rate, non-union rate and complication rate were evaluated. When possible, these values were pooled and expressed in effect size (ES), and their 95% confidence interval (CI) was computed. Meta-regression analysis (both uni- and multivariate) was conducted. Eight studies were included in the review, including 189 patients. The healing rate of these studies ranged between 55.1 and 100%, infection rate from 3.3% to 31.8%, recurrence rate from 0.0% and 13.6% and non-union rate from 4.5–30.0%. Overall complication rate was reported in three studies and ranged from 44.9 to 68.2%. Meta-analysis of the various rates revealed an overall healing rate of 91.9% (range from 74.9 to 97.8%), infection rate of 10.9% (4.2–25.2%), recurrence rate 7.2% (3.6–14.2), non-union rate 16.9% (10.2–26.7) and finally, the complication rate was computed at 53.2%. Satisfactory short- to medium-term clinical and radiographic results were reported by the studies included in this review, supporting that MIMOs represent an effective surgical approach to treat PDFUs. However, poor quality in the methodology of some studies and the lack of long-term data were reported. Therefore, randomized controlled trials, prospective studies and long-term follow-up studies are needed

Keywords: diabetes; diabetic ulcers; foot; foot ulcer; meta-analysis; metatarsal bone; metatarsalgia; minimally invasive surgery; osteotomy; systematic review

1. Introduction

Plantar Diabetic Foot Ulcers (PDFUs) are severe and dreadful complications occurring in diabetic patients, representing even today, a medical and surgical challenge in terms of treatment and a protracted process with high recurrence rates. In diabetic patients, it has been estimated that approximately 25% of hospitalisations are directly related to foot problems [1], and the lifetime risk of developing foot ulcers is around 19–34% [2]. This devastating complication can lead to a substantial number of hospital admissions involving a great deal of medical resources, have a profound negative impact on the quality of life and often result in diabetic foot osteomyelitis and can end up in a lower limb amputation if not recognized and treated promptly on time [3,4]. However, a lower-extremity amputation may not be the most effective solution, as it could be complicated by polymicrobial infections, becoming another serious adverse event with even higher mortality rates [5]. Diabetic patients with pressure ulcers have a 2.5-fold increased risk of death compared with diabetic patients without PDFUs. Further, PDFU development is associated with 5% mortality during the first year and 42% mortality within 5 years [6]. In addition to performing multidisciplinary work, the implementation of a health education program would be important to favour the prevention of diabetic foot ulcers and reduce the risk of amputation [7].

Many factors are involved in PDFU development: for instance, poor glycemic control, peripheral neuropathy, peripheral vascular disease and foot deformity [8]. Trauma, such as ill-fitting shoes and high mechanical pressure resulting from structural deformities in the insensitive diabetic foot, play a significant part in the development of ulceration [9]. Further, duration of diabetes (>10 years), older age, retinopathy, nephropathy, poor foot care habits, barefoot walking and haemoglobin A1c (HbA1c) have been linked to PDFUs [2,9,10]. Other risk factors, especially dyslipidemia, smoking and hypertension, increase the risk of foot problems by altering both blood supply and immune responses to trauma and infection [3]. In these cases, the main therapeutic goal is to promote tissue healing while preserving adequate foot function [11]. It has been shown that infrared thermography could be a useful technique to detect temperature variability in the foot area, allowing diagnosis and prevention of injuries [12,13].

Once a PDFU is observed at the first clinical evaluation, the essential management principles are antibiotic therapy, tissue debridement of superficial skin lesions and off-loading foot pressure until healing is achieved [11]. To reduce the pressure on the affected part and promote wound healing, primary conservative methods remain the restriction of weight-bearing. Several methods of off-loading are available such as total contact casts, removable cast walkers, therapeutic footwear, foot orthoses, custom shoes, custom braces, padding and strapping therapy [14–16]. Nonetheless, there is no consensus in the literature for the optimal off-loading strategy [15,17,18].

It is estimated that about 77% of all PDFUs treated conservatively can initially be healed within 1 year [19]. However, after starting full weight bearing, their recurrence rate is 40% in the following first year after care, 60% within the first 3 years and 65% within 5 years [2]. Further, although PDFUs can heal with appropriate local treatment and shoe modification, a significant number of patients have chronic ulceration despite prolonged treatment, and even when primary healing has occurred, ulcer recurrence is frequent [20].

Hence, surgical treatment is indicated in case of failure of conservative management. The traditional operative methods, including both bone procedures and tendon balancing [20–22], are often correlated with high complication rates, such as infections and wound recurrences [23–25]. For these reasons, a conservative surgery sparing a toe, a metatarsal bone, or a ray would be less traumatic and more acceptable by patients when feasible [26].

Currently, minimally invasive surgery (MIS) represents an innovative approach and is becoming more popular because of lower complication rates [27]. Different minimally invasive and percutaenous osteotomies, at different levels of the distal metatarsal bones,

generally by a dorsal approach and without head resection, have been proposed including osteoclasis, a V-shaped cut, a Gauthier osteotomy or oblique cuts such as in a Weil osteotomy or its variants [28,29].

The common goals of these minimally invasive or percutaneous procedures is not only to favor the reduction of bone-induced pressure on the PDFU and consequently promote its healing, but also to restore the metatarsal parabola of the forefoot, preventing recurrent, transfer skin lesions and possible future wound and bone infection [6]. Due to the preserved soft tissue covering and its characteristic stiffness in diabetic foot, the primary stability of these osteotomies is so high that successive osteosynthesis not only is not necessary, but it would also be harmful in preventing the dorsal elevation of the metatarsal bone with respect to the ulcer level. In fact, the patient is asked to walk on the operated foot in the immediate postoperative period to elevate the head dorsally and to release plantar pressure. Technically, the bone cut is usually perpendicular to the metatarsal neck [26].

Recently, some authors reported the outcomes of perpendicular or oblique osteotomies using minimally invasive techniques located at different levels of the metatarsal neck or at the distal diaphysis [27,30]. These include a variant of the most widespread Distal Metatarsal Metaphyseal Osteotomy (DMMO) [31], a percutaneous technique used routinely in the last decade for the treatment of metatarsalgia [27,32].

A recent meta-analysis about the contemporary management of diabetic neuropathic foot ulcerations revealed disappointing functional outcomes [33]. Moreover, the meta-analysis showed that minimally invasive surgery for PDFUs by metatarsal osteotomies is a poorly investigated topic [33], contrary to the several traditional surgical techniques explored in the literature [20–22,33].

The goals of this systematic review with meta-analysis and meta-regressions were to critically evaluate the available literature to establish if there is sufficient evidence demonstrating that minimally invasive metatarsal osteotomies (MIMOs) proposed for PDFU treatment are (1) effective in achieving ulcer healing and (2) effective in preventing recurrence of ulcers, and (3) to summarize their rates of post-operative complications.

2. Materials and Methods

2.1. Study Reporting

The present Systematic Review and Meta-Analysis was conducted using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines (PRISMA), which were used to monitor all steps of the research [34]. The study protocol has been registered with the Open Science Framework depository (Identifier code: DOI 10.17605/OSF.IO/NX7CA).

2.2. Search Strategy

From 1 to 30 June 2021, an electronic search was conducted in the three following databases: PubMed/MEDLINE, ISI/Web of Science (WoS) and Scopus. In these databases, an advanced search was carried out using the following specific keywords and Boolean terms: "(metatarsal osteotom*) OR (metatarsal AND osteotom*) AND diabet* AND (feet OR foot OR forefoot) AND ulcer". A date filter was then inserted to cover the period from 1980 until June 2021. The earliest reference found for the use of the procedure in toe deformities in any patient population was dated 1986 [35].

2.3. Selection Criteria

Only studies written in English, which included a minimally invasive metatarsal osteotomy as surgical treatment, were selected. Randomized clinical trials, cohort studies, case-control studies, case series and case reports were considered eligible. Studies reporting outcomes for the hallux and/or lesser toes were included. As PDFUs may be multifactorial, diabetic patient groups with or without neuropathy or peripheral

arterial disease were included. Studies were included if they used a concurrent secondary procedure (e.g., flexor, extensor tenotomies of lesser toes).

2.4. Exclusion Criteria

All articles written in languages other than English, were without data or that were off-topic were discarded. Studies were excluded if they involved non-diabetic patients and did not report outcomes of diabetic and non-diabetic patients separately. Letters, commentaries, opinion pieces, book chapters and reviews were also excluded.

2.5. Outcome Measures

The following were selected as the main outcomes for evaluating the effectiveness of metatarsal osteotomies: healing rate, treatment time, revision surgeries and possible complications. The size, the grade with the Texas Classification of Diabetic Foot Wound (if present) and number of ulcers were also compared as outcome measures. If present, pre- and post-intervention AOFAS score values and VAS scale values were taken into account.

2.6. Selection Method

The selection was made by reading the abstracts of all of the articles found. If the abstracts met the inclusion criteria, the full-text manuscript was retrieved and analyzed. A cross-reference search of the selected articles was also performed to obtain other relevant articles for the study.

Finally, the selected articles and references were reviewed and assessed independently by two reviewers (FM and PN) and all queries were discussed and resolved by the supervisory team (CB and EB) in regular meetings. Data extraction was completed independently by assessors (EB and NLB). If there was disagreement among the investigators regarding the inclusion or exclusion criteria, the senior investigator (PR) made the final decision. The level of agreement was high, with a kappa statistic > 0.80.

2.7. Data Extraction

The studies that were selected as includible were ordered in an Excel file in which the data extraction was completed independently. Data were extracted for the various studies, (authors, publication date, study design, level of evidence) and for the patients included: number of patients, sex, age, type of intervention, type of diabetes, number of ulcers, ulcer grade, ulcer age, wound size, diabetes treatment, ankle brachial index (ABI), healing rate, outcomes (AOFAS, VAS) and complications.

2.8. Quality Assessment

Given the study design of the included studies, the Joanna Briggs Institute (JBI) critical appraisal tool [36], consisting of an 11-point checklist, was used to assess the methodological quality of studies retained in the analysis and to recognize any potential risk of bias.

2.9. Statistical Analysis

When possible (in the presence of at least two estimates), findings from the retained investigations were pooled together. More specifically, rates were synthesized and expressed as effect sizes (ES), applying the logit event rate technique, which is one of the available approaches to meta-analyze proportions [37], together with the Freeman–Tukey transformation (or arcsine square root transformation). ESs were computed with their 95% confidence intervals (CIs). Moreover, ESs were pictorially represented and inspected by means of forest plots. When there were enough studies, meta-regression analyses (both uni- and multivariate) were conducted on covariates and moderators of interest.

Heterogeneity among studies was assessed by means of Cochran's Q and I^2 statistics. If the amount of inconsistency across studies was >50.0% and statistically significant, a mixed-effect model was applied instead of a fixed-effect model. Evidence of publication bias was evaluated by conducting the trim-and-fill analysis and visually inspecting the funnel plot. It is worthy stressing that funnel plots were provided for each ES computed, even though findings from the publication bias assessment should be interpreted with caution when the number of available studies retained in the meta-analysis is low.

All statistical analyses were conducted by means of the commercial Comprehensive Meta-Analysis Software version 3.3.070 (Biostat Inc., Englewood, NJ, USA).

3. Results

3.1. Search Yield

The search results and selection process are shown in Figure 1 using the PRISMA flow-chart. In the end, eight research papers met the criteria of selection and thus were included in this review.

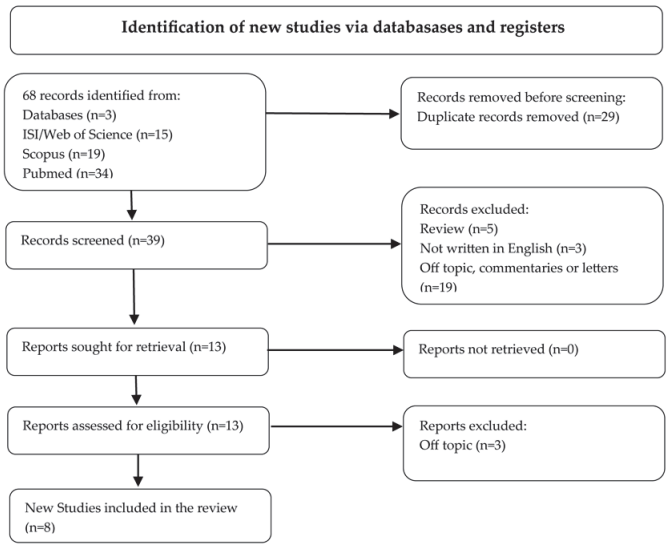

Figure 1. Systematic Reviews and Meta-Analyses (PRISMA) flow chart representing the process for inclusion of papers. For this study, nine articles were assessed for eligibility after screening: among these, 8 new studies were included in the analysis [34].

3.2. Quality assesment

The quality assessment, using the JBI critical appraisal tool [36], of the research included is reported in Table 1.

3.3. Study Characteristics

Study characteristics are reported in Table 2.

3.4. Outcomes of the Selected Studies

Study characteristics are described in Table 3.

Table 1. Quality Assessment with JBI Critical Appraisal Checklist for Case Series.

Checklist	Wray et al., 1986 [35]	Tillo et al., 1990 [29]	Fleischli et al. 1999 [38]	Tamir et al., 2016 [30]	Biz et al., 2018 [27]	Tamir et al., 2020 [39]	Chiu et al., 2020 [40]	Tamir et al., 2021 [41]
Were there clear criteria for inclusion in the case series?	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Was the condition measured in a standard, reliable way for all participants included in the case series?	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Were valid methods used for identification of the condition for all participants included in the case series?	NA	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Did the case series have consecutive inclusion of participants?	NA	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Did the case series have complete inclusion of participants?	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Was there clear reporting of the demographics of the participants in the study?	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Was there clear reporting of clinical information of the participants?	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Were the outcomes or follow up results of cases clearly reported?	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Was there clear reporting of the presenting site(s)/clinic(s) demographic information?	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Was statistical analysis appropriate?	NA	No	No	No	Yes	Yes	Yes	Yes
Total number of NO	7	1	1	1	0	0	0	0

Table 2. Study characteristics.

	Wray et al. 1986 [35]	Tillo et al. 1990 [29]	Fleischli et al. 1999 [38]	Tamir et al. 2016 [30]	Biz et al. 2018 [27]	Tamir et al. 2020 [39]	Chiu et al. 2020 [40]	Tamir et al. 2021 [41]
N° of patients	1	52	20	17	30	21	16	32
Gender (males/females)		(38/14)	(13/7)	(16/1)	(20/10)	(16/5)	(12/4)	(29/3)
Age (mean ± SD)	52	55.4	62 (range 31–82)	57 (range 42–75)	66.7 ± 6.8 (range, 53–75)	64 (range 45–83)	57.81	60.1 ± 7.5
Type of diabetes	NA	27: type I; 25: type II	NA	NA	2 type 1; 28: type II	NA	NA	2
HbA1C	NA	NA	NA	8.1 (median 7.1, range 4.9 to 12.2 g/dL)	7.1% ± 0.8% (range, 5.9–8.4%)	8.1% (range 6.4–13.8)	9.14 (range, 5.2–13.2 g/dL)	7.9% ± 1.7% (63 ± 18 mmol/mol)
Wound Size	NA	NA	NA	NA	16.3 ± 0.6 (range, 5–25) mm	length 21.8 ± 9.0 mm, width 15.8 ± 7.6 mm,	5.72 (cm^2)	mean area 97.9 ±86.6 mm^2 (range 19.6–392.7 mm^2, median 78.5
Ulcer grade	NA	NA	NA	All 1A [1]	IA [2]: 4; IIA: 2; IIB:6; IIC:2; IIIA:2; IIIB:15; IIIC:1; IIID:3	All 1A [1]	NA	A0 [1]: 3; A1:30; A2:1
Ulcer age (months)	NA	NA	NA	19 (median 11, range 1 to 60)	10.3 ± 3.8 (range, 6–19)	NA	NA	median of 1.5 months (range 0.5–18)
Mean follow-up (months)	24	19	17 (range 4–66)	NA	25.3 ± 10.0 (range, 18–71)	19.3 (median 17.6, range 12–34)	15.2 (±3.21)	18.6 months (median: 18.4, range 12.2–27.5)

[1] Texas classification. [2] UTDWC Classification.

Table 3. Outcomes extracted from the studies retained in the present systematic review and meta-analysis with meta-regressions.

	Wray et al., 1986 [35]	Tillo et al., 1990 [29]	Fleischli et al., 1999 [38]	Tamir et al., 2016 [30]	Biz et al., 2018 [27]	Tamir et al., 2020 [39]	Chiu et al., 2020 [40]	Tamir et al., 2021 [41]
Healing rate	27/49 (55.1%)	1/1 (100.0%)	21/22 (95.5%)	20/20 (100.0%, 17/20, 85.0%, completely healed; 3/20, 15.0%, improved)	30/30 (100.0%)	19/21 (90.5%)	14/16 (87.5%)	31/32 (96.9%)
Healing time	NA	NA	40 days (range of 8 to 113 days)	Six weeks	7.9 ± 4.0 (range 4–17) weeks; ulcers with a diameter 1.5 cm or less required 6.8 ± 4.1 (range 4–17) weeks to heal, while ulcers with a diameter more than 1.5 cm required 9.4 ± 3.6 (range 4–15) weeks	Mean of 3.7 (median 3, range 2–11) weeks; in 13 of the 21 patients, the wound was healed within 3 weeks or less	2.14 (±1.38) months	Mean of 3.7 weeks (SD 4.2, median 3, range 1–23, IQR 2–4)
Peak pressure under the head of the osteotomized metatarsal	NA	NA	NA	NA	NA	NA	NA	Decreased from 338.1 to 225.4 kPa (33%, $p < 0.0001$) following surgery; the pressure time integral under the head of the osteotomized metatarsal decreased as well from 82.4 kPa·s to 65.0 kPa·s (21%, $p < 0.0001$)
AOFAS score preop	NA	NA	NA	NA	55.3 ± 8.3 (range, 42–71)	NA	NA	NA
AOFAS last follow-up	NA	NA	NA	NA	81.4 ± 9.1 (range, 64–100)	NA	NA	NA
VAS (satisfaction) post op	NA	NA	NA	NA	9.8 ± 0.7 (range, 7–10)	NA	NA	NA
Infections	NA	NA	7/22 (31.8%; 3/22, 13.6%, deep wound infections were successfully treated with irrigation and debridement, pin removal, and antibiotics; 4/22, 18.2%, superficial wound infections successfully treated with pin removal	1/20 (5.0%)	1/30 (3.3%, wound infection by *Streptococcus agalactiae*)	3/21 (14.3%, related to the surgery within 1 year, one needing excision of the first metatarsal head, one requiring drainage, and one requiring hospitalization for administration of intravenous antibiotics)	NA	2/32 (6.3%, operative site infections that recovered with parenteral and oral antibiotics, respectively; one was a deep postoperative wound infection and one was a foot infection not related to the surgery)

			and oral antibiotics)					
Wound discharge	NA	NA	NA	NA	NA	5/21 (23.8%, without other signs of infection, which were successfully treated with oral antibiotics)	NA	NA
Necrosis	NA	NA	NA	NA	NA	1/21 (4.8%, necrosis of the fifth toe related to the casting, resulting in the amputation of the toe)	NA	NA
Swelling	NA	NA	NA	NA	18/32 feet (56.3%, persistent moderate swelling of the forefoot for more than 6 weeks without infection, which improved after some months with complete callus formation at the osteotomy levels and without further treatment)	NA	NA	NA
Recurrence/relapse	NA	3/49 (6.1%)	3/22 (13.6%; residual deformity from acute Charcot episode, resulting in plantar midfoot ulcers under bony prominences)	NA	NA	NA	0/16 (0.0%)	1/32 (3.1%, under the callus formed at the osteotomy site)
Acute Charcot	NA	NA	7/22 (31.8%, treated with serial total contact casting until the resolution of the acute inflammatory process and bony consolidation identified on radiographs)	NA	NA	NA	NA	NA
Non-unions	NA	NA	1/22 (4.5%, asymptomatic)	6/20 (30.0%, asymptomatic, 6 months after the procedure, three after osteotomy of the neck and three after osteotomy of the shaft)	NA	3/21 (14.3%, asymptomatic)	NA	4 (12.5%, asymptomatic)
Transfer lesions	NA	13 (26.5%, transfer	2/22 (9.1%, under adjacent metatarsal	2/20 (10.0%; one below the fourth metatarsal head 5	NA	3/21 (14.3%, five transfer lesions in three patients)	2/16 (12.5%, at an average of	4/32 (12.5%; under the heads of adjacent metatarsals)

		ulceration; six patients (12.2%) developed transfer calluses)	heads)	months after an osteotomy of the second metatarsal neck and the other below the second metatarsal head, 10 months after osteotomy of the third metatarsal neck)			7.5 months after the surgical procedure)	
Loss of screw fixation	NA	NA	1/22 (4.5%, with an acceptable metatarsal alignment being maintained)	NA	NA	NA	NA	NA
Redo-surgery	NA	NA	2/22 (9.1%, exostectomy)	NA	NA	NA	NA	3/32 (9.4%, two patients were treated conservatively, while three had further offloading surgery)
Overall complications	NA	22/49 (44.9%)	15/22 (68.2%; major complications occurred in 13/22 cases, 59.1%; minor complications were noted in 6/22 cases, 27.3%)	NA	NA	NA	NA	18/32 (56.3%; 23 adverse events/complications in 18 patients, 16 of which not related to surgery)

3.5. Systematic Review

3.5.1. Healing Rate and Healing Time

Healing rate was reported in eight studies and ranged from 55.1 to 100.0%. In the study by Tamir et al. (2016) [30], 17/20 lesions (85.0%) completely healed, while the remaining 3/20 (15.0%) improved. In six studies [27,30,38–41], the healing rate was greater than 90.0%. Healing time was reported in six studies and ranged from 1 to 2 months [27,30,38–41].

3.5.2. AOFAS and VAS

Preoperative AOFAS score was reported only in one study [27]. It was computed at 55.3 ± 8.3 (range 42–71), whereas AOFAS at last follow-up was 81.4 ± 9.1 (range 64–100). Postoperative VAS for satisfaction was reported in the study by Biz et al. (2018) and was computed at 9.8 ± 0.7 (range 7–10).

3.5.3. Peak Pressure under the Head of the Osteotomized Metatarsal

This outcome was reported only in 1 study [41]. The outcome was found to decrease from 338.1 to 225.4 kPa (33%, $p < 0.0001$) following surgery; the pressure time integral under the head of the osteotomized metatarsal decreased as well from 82.4 kPa to 65.0 kPa·s (21%, $p < 0.0001$).

3.5.4. Infection Rate

Infection rate was reported in five studies and ranged from 3.3–31.8% [27,30,38–41]. All infections were successfully resolved after administration of antibiotics. Wound discharge rate was reported only in one study [39] and was computed at 23.8%. Similarly, necrosis rate was reported only in one study [39] and was 4.8% (one case of necrosis of the fifth toe related to the casting, resulting in the amputation of the toe).

3.5.5. Non-union Rate

Non-union rate was reported in four studies, ranging from 4.5 to 30.0%, and all of them were asymptomatic [30,38,39,41].

3.5.6. Swelling Rate

Swelling rate was reported only in noe study [27], where 18 out of 32 feet were found to be swollen. Swelling rate was computed at 56.3%, and was persistently moderate, affecting the forefoot for more than 6 weeks without infection. It improved after some months with complete callus formation at the osteotomy levels and without further treatment.

3.5.7. Recurrence/Relapse Rate

Recurrence/relapse rate was reported in four studies and ranged from 0.0 to 13.6% [29,38,40,41]. Loss of screw fixation was reported only in 1 study [38], with one case being reported (4.5%, with an acceptable metatarsal alignment being maintained). Redo-surgery rate was reported in two studies, ranging from 9.1 to 9.4%.

3.5.8. Acute Charcot

This adverse outcome was reported only by Fleischli et al. (1999) [38]. Seven cases (31.8%) were reported and treated with serial total contact casting until resolution of the acute inflammatory process and bony consolidation was identified on radiographs.

3.5.9. Transfer Lesion Rate

Transfer lesions rate was reported in six studies and ranged from 9.1 to 26.5% [29,30,38–41].

3.5.10. Overall Complication Rate

Overall complication rate was reported in three studies and ranged from 44.9 to 68.2% [29,38,41].

3.6. Meta-Analysis

3.6.1. Healing Rate

The overall healing rate resulted 91.9%, ranging from 74.9 to 97.8%. Due to the significantly high amount of heterogeneity among studies (I^2 = 80.0%; Q = 30.04), a mixed-effect model was implemented. With the meta-regression analysis, it was found that the age of the recruited populations tended to become older through the years in a significant way (coefficient = 0.2724 (SE = 0.1180), p = 0.0209) (Table 4). The lowest ES was reported in the study by Tillo et al. (1990) [29], who recruited the highest number of diabetes type 1 patients (coefficient = 0.0522 (SE = 0.0102), p = 0.0000) and performed a variety of surgical procedures (Q = 27.24, p = 0.0000). However, these moderators resulted not significant with the multivariate meta-regression analysis. Evidence of publication bias could be detected with visual inspection of the funnel plot (Figure 2) and with the trim-and-fill analysis, resulting in an "adjusted" ES of 70.9%, ranging from 41.0 to 89.5% (four studies were trimmed/removed).

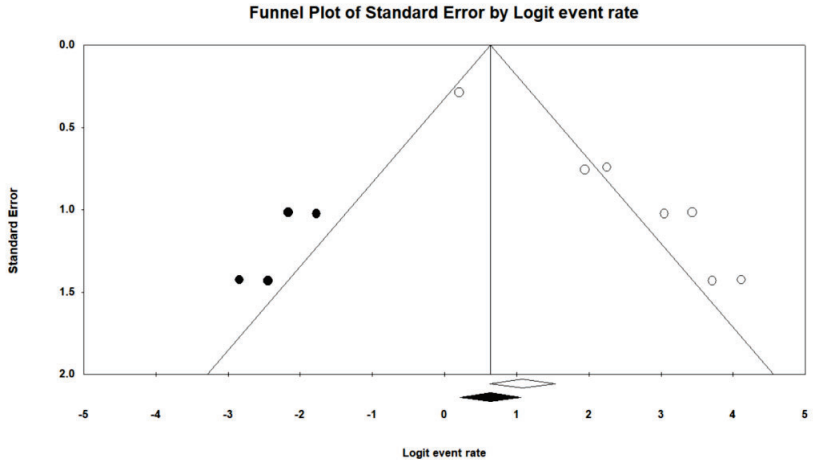

Figure 2. Funnel plot for the effect size of healing rate showing evidence of publication bias with four studies being trimmed/removed. White circles are the effect sizes of the studies included in the present systematic review and meta-analysis, while black circles represent effect sizes not reported by published studies, probably due to publication bias. If the corresponding observed effect sizes are trimmed/removed, the overall effect size (white diamond) becomes the "adjusted" overall effect size (black diamond).

3.6.2. Infection Rate

The overall infection rate was 10.9%, ranging from 4.2 to 25.2%. Due to the significantly high amount of heterogeneity among studies (I^2 = 61.0%; Q = 10.27), a mixed-effect model was applied. With the meta-regression analysis, a significant impact of the type of surgery (Q = 8.90, p = 0.0117) could be found, with the lowest ES reported in the study by Tillo et al. (1990) [29]. Study year (coefficient = −0.0799 (SE = 0.0295), p = 0.0067) was another significant moderator, with infection rates improving (decreasing) throughout years. Follow-up time had a borderline impact on ES estimation (coefficient =

−0.2980 (SE = 0.1529), p = 0.0513). There were not enough studies to perform a multivariate meta-regression analysis. Visual inspection of the funnel plot and the trim-and-fill analysis revealed no evidence of publication bias.

3.6.3. Recurrence/Relapse Rate

The overall recurrence/relapse rate was 7.2% [95%CI 3.6–14.2]. Due to the null amount of heterogeneity among studies (I^2 = 0.0%; Q = 2.57), a fixed-effect model was chosen. No significant moderators could be found with the meta-regression analysis. No evidence of publication bias could be detected, both with visual inspection of the funnel plot and with the trim-and-fill analysis.

3.6.4. Non-Union Rate

The overall non-union rate was 16.9% [95%CI 10.2–26.7]. Due to the low to moderate amount of heterogeneity among studies (I^2 = 38.6%; Q = 4.89), a fixed-effect model was applied. No significant moderators could be found with the meta-regression analysis. No evidence of publication bias could be found, both with visual inspection of the funnel plot and with the trim-and-fill analysis.

3.6.5. Transfer Lesion Rate

The overall transfer lesion rate was 17.4% [95%CI 12.1–24.4]. Due to the low amount of heterogeneity among studies (I^2 = 8.3%; Q = 5.45), a fixed-effect model was conducted. With the meta-regression analysis, diabetes type (coefficient = −0.0206 (SE = 0.0091), p = 0.0241) was significant, whereas age (coefficient = −0.1253 (SE = 0.0706), p = 0.0759), type of surgery: Q = 4.99, p = 0.0825) and study year (coefficient = −0.0286 (SE = 0.0153), p = 0.0610) resulted statistically borderline. They were not significant with the multivariate meta-regression. No evidence of publication bias could be detected both with visual inspection of the funnel plot and with the trim-and-fill analysis.

3.6.6. Redo-Surgery Rate

The overall redo-surgery rate was computed to be 9.3% [95%CI 3.9–20.4]. Due to the null amount of heterogeneity among studies (I^2 = 0.0%; Q = 0.00), a fixed-effect model was conducted. However, there were not enough studies to perform meta-regressions and publication bias analysis.

3.6.7. Overall Complication Rate

The overall complication rate was 53.2% [95%CI 43.4–62.7]. Due to the low to moderate amount of heterogeneity among studies (I^2 = 40.9%; Q = 3.38), a fixed-effect model was applied. There were not enough studies to perform a meta-regression analysis. Evidence of publication bias could be found, both upon visual inspection of the funnel plot (Figure 3) and with the trim-and-fill analysis, which resulted in an "adjusted" effect-size of 44.9% [95%CI 37.2–52.9], with two studies being trimmed/removed.

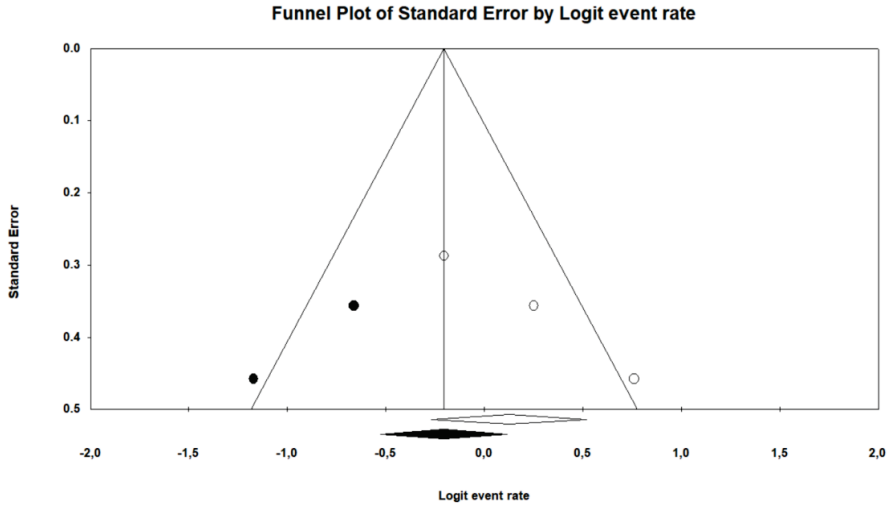

Figure 3. Funnel plot for the effect size of overall complication rate showing evidence of publication bias with two studies being trimmed/removed. White circles are the effect sizes of the studies included in the present systematic review and meta-analysis, while black circles represent effect sizes not reported by published studies, probably due to publication bias. If the corresponding observed effect sizes are trimmed/removed, the overall effect size (white diamond) becomes the "adjusted" overall effect size (black diamond).

Table 4. Outcomes obtained from meta-analysis with meta-regressions, pooling the studies included in the present systematic review.

Outcome	Effect Size	Moderators	Publication Bias
Healing rate	91.9% [95%CI 74.9–97.8] I^2 = 80.0%; Q = 30.04; mixed-effect model	**Univariate Metaregression** Age: coefficient = 0.2724 (SE = 0.1180), *p* = 0.0209 Gender: coefficient = 0.0353 (SE = 0.0708), *p* = 0.6182 Type of surgery: Q = 27.24, *p* = 0.0000 Diabetes type: coefficient = 0.0522 (SE = 0.0102), *p* = 0.0000 Length of diabetes: coefficient = –0.1606 (SE = 0.2705), *p* = 0.5526 Glycated hemoglobin: coefficient = –0.9868 (SE = 0.6758), *p* = 0.1442 Study year: coefficient = 0.0733 (SE = 0.0312), *p* = 0.0189 Follow-up time: coefficient = 0.1664 (SE = 0.2708), *p* = 0.5389 Ulcer's grade: coefficient = –0.0163 (SE = 0.0179), *p* = 0.3646 **Multivariate Metaregression** Age: coefficient = –0.0077 (SE = 0.1954), *p* = 0.9688 Diabetes type: coefficient 0.0576 (SE = 0.0424), *p* = 0.1742 Study year: coefficient = 0.0056 (SE = 0.0627), *p* = 0.9283	"Adjusted" effect-size = 70.9% [95%CI 41.0–89.5]; trimmed k = four studies

Infection rate	10.9% [95%CI 4.2–25.2] I^2 = 61.0%; Q = 10.27; mixed-effect model	**Univariate Metaregression** Age: coefficient = −0.0034 (SE = 0.2100), p = 0.9872 Gender: coefficient = −0.0515 (SE = 0.0369), p = 0.1630 Type of surgery: Q = 8.90, p = 0.0117 Diabetes type: coefficient = 0.2245 (SE = 0.2094), p = 0.2837 Length of diabetes: coefficient = −0.3405 (SE = 0.4261), p = 0.4242 Glycated haemoglobin: coefficient = 1.2551 (SE = 1.1480), p = 0.2743 Study year: coefficient = −0.0799 (SE = 0.0295), p = 0.0067 Follow-up time: coefficient = −0.2980 (SE = 0.1529), p = 0.0513 Ulcer grade: coefficient = 0.0132 (SE = 0.0130), p = 0.3121 **Multivariate Metaregression** Not enough studies	No publication bias; trimmed k = zero studies
Recurrence/relapse	7.2% [95%CI 3.6–14.2] I^2 = 0.0%; Q = 2.57; fixed-effect model	**Univariate Metaregression** Age: coefficient = 0.1129 (SE = 0.1279), p = 0.3774 Gender: coefficient = −0.0655 (SE = 0.0462), p = 0.1564 Type of surgery: not enough studies Diabetes type: coefficient = 0.0042 (SE = 0.0196), p = 0.8291 Length of diabetes: not enough studies Glycated haemoglobin: not enough studies Study year: coefficient = −0.0264 (0.0332), p = 0.4266 Follow-up time: coefficient = −0.1327 (SE = 0.3539), p = 0.7077 Ulcer grade: not enough studies	No publication bias; trimmed k = zero studies
Non-unions	16.9% [95%CI 10.2–26.7] I^2 = 38.6%; Q = 4.89; fixed-effect model	**Univariate Metaregression** Age: coefficient = −0.1842 (SE = 0.1591), p = 0.2470 Gender: coefficient = 0.0529 (SE = 0.0316), p = 0.0944 Type of surgery: Q = 1.5676 (SE = 1.1323), p = 0.1662 Diabetes type: cannot be performed because of collinearity issues Length of diabetes: not enough studies Glycated haemoglobin: not enough studies Study year: coefficient = 0.0521 (SE = 0.0613), p = 0.3947 Follow-up time: not enough studies Ulcer	No publication bias; trimmed k = zero studies

		grade: not enough studies	
Transfer lesions	17.4% [95%CI 12.1–24.4] I^2 = 8.3%; Q = 5.45; fixed-effect model	**Univariate Metaregression** Age: coefficient = −0.1253 (SE = 0.0706), p = 0.0759 Gender: coefficient = −0.0226 (SE = 0.0266), p = 0.3963 Type of surgery: Q = 4.99, p = 0.0825 Diabetes type: coefficient = −0.0206 (SE = 0.0091), p = 0.0241 Length of disease: coefficient = 0.0042 (SE = 0.2281), p = 0.9854 Glycated haemoglobin: coefficient = 0.0034 (SE = 0.7250), p = 0.9962 Study year: coefficient = −0.0286 (SE = 0.0153), p = 0.0610 Follow-up time: coefficient = 0.2248 (SE = 0.1964), p = 0.2523 Ulcer grade: not enough studies **Multivariate Metaregression** Age: coefficient = 0.0397 (SE = 0.1313), p = 0.7622 Diabetes type: coefficient = −0.0364 (SE = 0.0291), p = 0.2122 Study year: coefficient = 0.0210 (SE = 0.0390), p = 0.5898	No publication bias; trimmed k = zero studies
Redo-surgery	9.3% [95%CI 3.9–20.4] I^2 = 0.0%; Q = 0.00; fixed-effect model	Not enough studies	Not enough studies
Overall complications	53.2% [95%CI 43.4–62.7] I^2 = 40.9%; Q = 3.38; fixed-effect model	Not enough studies	"Adjusted" effect-size = 44.9% [95%CI 37.2–52.9]; trimmed k = two studies

4. Discussion

In the recent literature, PDFU healing is still described as a challenging and protracted process with high recurrence rates, negatively affecting the patients' quality of life and potentially leading to amputation [42–44]. A normal wound closure follows a dynamic process comprising four sequential phases: hemostasis, inflammation, proliferation and remodeling [45]. However, the process of wound healing is affected negatively in patients with diabetes. Specifically, the process starts with a decrease of fibrinolysis with an imbalance of cytokines affecting wound healing. Moreover, angiogenesis is decreased by hyperglycemia. Cell migration (keratinocytes and fibroblasts) is decreased with a negative impact on extracellular matrix production and thus causing a deficient re-epithelialization [46].

Several methods have been proposed to treat PDFUs [20–22,24]. However, the current crucial issue is to relieve the pressure because the wound never heals until the pressure is off-loaded. There are many methods to relieve it [47] including body weight reduction, total contact casts [48], corrective shoes with customized insoles [49] and even

surgical correction, such as metatarsal head resection and ray amputation [20–22,33]. In this context, MIS has been proposed as an effective intervention [24]. Its main objectives are primarily the healing of PDFUs by relieving the pressure on them; secondarily, the prevention of ulcer recurrence, transfer lesions and local infections [6].

Many reports showed the more traditional surgical procedures (metatarsal head resection, metatarsal osteotomy and exostectomy, metatarsal head resection, arthrodesis) and tendon balancing (Achilles' tendon lengthening, gastrocnemius recession, and/or plantar fascia release) can achieve good to excellent results on diabetic ulcer healing, regardless of their grade severity and dimensions [1–3]. However, open surgical bone procedures are often correlated with high complication rates, such as wound recurrence or postoperative infection, while tendon balancing presents risks of tendon overlengthening, rupture and plantar flexion weakness [21,38,50].

To the best of our knowledge, no previous systematic review has provided quantitative evidence synthesis regarding the mere efficacy of MIMOs for diabetic foot ulcerations.

The goal of the present systematic review and meta-analysis was to identify the available body of evidence of these MIMOs regarding their effectiveness in promoting PDFU healing and in preventing their recurrence and to summarize the rates of post-operative complications.

4.1. MIMOs for PDFU Healing and Prevention (1986–2021)

From 1986 to the present, in different decades, relatively few original studies regarding MIMOs for PDFUs have been published. In the eight original articles included in this review, different osteotomy shapes have been proposed [27,29,30,35,38–41]. Despite the heterogeneity of the surgical methods, a systematic, common approach to the diabetic foot was found: all osteotomies were performed in a minimally invasive way carried out by an incision less than 3 cm performed by a dorsal foot approach, predominantly at the level of the lesser distal metatarsal bones, drawn down in oblique slide shape and without fixation or only temporary. Among the different authors, none used fixation except for the surgical procedures described by Fleischli et al. (1999) [38]. More commonly, as originally proposed by Wray et al. (1986), a metatarsal neck osteotomy of the metatarsal bones, osteotomized obliquely, starting proximally on the dorsum but proceeding distally and plantar-ward at an angle of 45°, was described [35]. With some differences, Tillo et al. (1990) proposed four different types of distal metatarsal bone osteotomies: osteoclasis of the head, V-osteotomy, shortening colectomy and oblique slide osteotomy [29]. Later, Fleischli (1999) was the only one to suggest a dorsally based, closing wedge metaphyseal osteotomy at the base of the metatarsal bones, temporarily fixed in most cases with K-wires [38].

In the 21st century, Tamir et al. in 2016 used a perpendicular or short oblique osteotomy performed at the neck or diaphysis of the metatarsal bone, with healing of the plantar lesion being reported in most of the cases [30]. More recently, Biz et al. (2018) treated a series of 30 patients by distal metatarsal diaphyseal osteotomies, performed with an angle of approximately 45° with respect to the long axis of the metatarsal bone in a dorsal-distal to proximal-plantar direction [27]. Similarly, in 2020 Tamir et al. [39] treated another series of 21 patients using a mini-invasive osteotomy without fixation, perpendicular to the first metatarsal bone metaphysis, similar to that described by Giannini et al. for Hallux Valgus (HV) percutaneous correction [51]. In the same year, Chiu et al. (2020) proposed a diaphyseal ostectomy proximal to the level of the metatarsal neck to preserve metatarsophalangeal joint function [40]. However, in the case of the metatarsophalangeal joint, severe destruction or stiffness was reported; even the joint was removed with the osteotomized bone segment [40]. In 2021, Tamir et al. treated 32 patients with metatarsal distal oblique osteotomies without fixation, described as minimally invasive floating distal metatarsal osteotomy [41].

In this review, only single series, case series, study design, level IV of evidence, some with poor methodological quality and different outcome measures were examined. The studies included used heterogeneous outcome evaluation parameters, and only the study by Biz et al. [27] evaluated the patients' AOFAS and VAS scores, both pre-operatively and at the last follow-up. Only Tamir et al. (2021) used the reduction of pressure under the metatarsal head after osteotomy as a measure of clinical outcome (from 82.4 kPa preoperatively to 65 kPa in the follow-up measures) [41]. The inclusion criteria of these studies consisted of participants with diabetes of both types (1 and 2) or not specified and at different stages of disease progression, further increasing the difficulty in comparing the different studies. Finally, some studies included people with no sensory neuropathy, while other studies included participants with sensory neuropathy, in both cases associated to previous foot ulceration.

Reliable scientific evidence is essential to guide the use of MIS in clinical practice applied to the diabetic feet for the management of PDFUs. Overall, the studies analyzed in this review report encouraging and promising results following MIMOs with regard to ulcer healing (range 55.1–100.0%), mean healing time (range from 1 to 2 months) and recurrence rates (range 0.0–13.6%). In the study by Tamir et al. (2016), 17/20 lesions (85.0%) completely healed, while the remaining 3/20 (15.0%) improved [30]. Thus, if we consider the other six studies (case report excluded), the healing rate was greater than 90.0% [27,30,38–41]. Healing time was reported in six studies and ranged from 1 to 2 months [27,30,38–41].

Hence, the most important finding of this review is that MIMOs are an effective intervention in PDFU management, not only for promoting healing but also for reducing their recurrence by achieving a better distribution of plantar pressure on the metatarsal bone with a low incidence of complications.

Relating to the severity of the ulcers, based on their clinical experience [6,27], the authors strongly believe that MIMOs can be an alternative valid treatment also for PDFUs with chronic infection, ulcers penetrating deep structures (IIIB), and ulcers with osteomyelitis of the metatarsal bones or the proximal phalanx. These challenging feature presentations, or evolution of diabetic feet, becoming increasingly frequent, in association to other vascular complications, such as ankle brachial index below 0.5 or flat pulse volume recording at the ankle level, should be considered as relative, but not absolute, contraindications for MIMOs [6,52]. As the PDFU represents the main access door for the bacteria causing foot osteomyelitis, resolving the first promotes the healing of the second, avoiding long-term antibiotic therapy, which causes progressive bone damage in diabetic patients [53]. However, the few absolute contraindications of these percutaneous procedures must be well known by clinicians and surgeons: severe ischemia and gangrene, insufficient vascular perfusion and extensive soft tissue infection presenting as cellulitis of the foot or toe.

Finally, it is the opinion of the authors, that the best approach to diabetic foot ulcers remains multidisciplinary, with a team that should include endocrinologists, podiatrists, wound care nurses, vascular, general and orthopedic surgeons, and infectious disease specialists. For this reason, in particular for PDFU management, referral to a diabetic care clinic is advised for the most appropriate indication of treatment [6].

4.2. MIMO Complications

This review showed an overall complication ranged between 44.9 and 68.2%. The most frequent complications were swelling (56.3%) reported in one study [27], radiographical nonunion (4.5–30.0%), infections (3.3–31.8%), transfer lesions (9.1–26.5%) and ulcer recurrences (0–13.6%). Radiographical non-union, although very frequent, was reported in four studies (range 4.5–30.0%) and in all cases described as asymptomatic [29,38,40,41], probably because of sensory neuropathy. Only in Fleischli's study, a fixation was used to prevent nonunion, using temporary K-wires or cancellous bone

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screws [38]. However, as expected by the presence of metalwork, the technique was burdened by a higher infection rate (31.8%) compared to the other studies.

Infections often adversely affect the healing of PDFUs. Infection rate was reported in five out of 8 studies and ranged from 4.2 to 25.2% [27,30,38–41]. They were mainly treated successfully with oral or intravenous antibiotics. Only six cases, reported in three studies [27,38,41], required subsequent surgical treatment to eradicate a deep infection. Wound discharge rate was reported only in one study and was computed at 23.8% [39]. Similarly, necrosis rate was reported only in one study and was 4.8% (one case of necrosis of the fifth toe related to the casting, resulting in the amputation of the toe) [39].

Transfer lesions were reported in six studies (range 9.1–26.5%) and usually described under the heads of the adjacent metatarsals [29,30,38–41]. These lesions occur when a correct metatarsal parabola is not re-established in the forefoot [6]. In two studies, transfer lesions were reported to appear at a mean of 10 and 7.5 months, respectively, (after the osteotomy procedures) [30,40]. This is probably due to the resumption of patients' normal walking and incorrect overloading of the lateral metatarsal bones. The highest transfer lesion rate (26.5%) was found in the report by Tillo et al. (1990) [29] (excluding the case report of Wray (1986) [35]), but considering all of the other papers, the transfer lesion rate was 17%.

The recurrence/relapse pooled rate of the ulcers was 7.2%. It has to be considered that this rate is higher in the first studies related to the 90s [29,38], while thereafter only 1 case was described by Tamir et al. 2021 [41]. Only four patients needed an off-loading redo -surgery; the only other cases that required further surgery are the six patients who had deep infections.

Swelling rate was reported only in one study, where 18 out of 32 feet were found to be swollen [27]. Swelling rate was computed to be 56.3% and was persistently moderate, affecting the forefoot for more than 6 weeks without infection, which improved after some months with complete callus formation at the osteotomy levels and without further treatment.

Finally, acute Charcot foot, the most fearsome complication, was reported only by Fleischli et al. (1999) in seven cases (31.8%), who were traditionally treated by serial total contact casting until the resolution of the acute inflammatory process and bony consolidation identified by radiographs [38].

The eight studies considered had a total population of 189 patients; however, regarding the clinical outcomes and complications, statistical analysis presented a heterogenicity that was not statistically significant (except in the case of the healing rate and overall complication rate analysis). Although the outcome measures of the eight papers included in this review presented an outstanding healing rate of 91.9% (ranging from 74.9 to 97.8%), in the 1990s, Tillo et al. [26], who recruited the highest number of diabetes type 1 patients (coefficient = 0.0522 (SE = 0.0102), $p = 0.0000$) and performed a variety of surgical procedures (Q = 27.24, $p = 0.0000$) reported the lowest healing rate. However, these moderators were not significant with the multivariate meta-regression analysis. Further, the results of the meta-analysis showed that age of the recruited populations tended to become older through the years in a significant way (coefficient = 0.2724 (SE = 0.1180), $p = 0.0209$). This may reflect a better glycemic control of the disease due to pharmacological improvements, which resulted in the occurrence of complications, including ulcers, at a later age [54].

The meta-analysis revealed a significant impact of the type of surgery (Q = 8.90, $p = 0.0117$) on the infection rate, with the study of Tillo et al. [29] reporting the lowest ES. The infection rates decreased as the year of publication of the study increased (Q = −0.0799 (SE = 0.0295), $p = 0.0067$), likely due to the progress in clinical management of the patients and for the better glycemic control obtained. The other factor to be considered is that among the older studies, the one by Fleischli et al. [38] is the only study where fixation tools (K-wires and screws) were used. This technique led to a higher rate of deep and superficial wound infections compared to other more modern techniques. All of the other

authors did not perform internal fixation or pinning after osteotomy. Regarding recurrence/relapse rate, non-union rate and redo-surgery rate, no significant moderators were identified. Meta-regression analysis of overall complications was not possible due to the low number of studies. Importantly, the diabetes type was found to be a moderator of transfer lesion rate (Q = −0.0206 (SE = 0.0091), $p = 0.0241$), but the statistical significance was lost with the multivariate meta-regression. However, it must be underlined that only three studies specified diabetes type of the patients [27,29,41]. Thus, further studies are needed to verify this point.

4.3. Strengths and Limitations

This systematic review has several strengths. It included all studies published to date on the topic since 1975. Extensive search strategies were employed with detailed, careful and critical assessment to identify risk of bias in compliance with the PRISMA guidelines. Moreover, meta-regressions were conducted, both uni- and multivariate. However, the review is limited mainly by the methodological deficiencies of included studies. All eight publications described in this review are retrospective case series and are therefore vulnerable to bias. The absence of randomization and a control group means that any changes observed are the result of an uncontrolled pre-post analysis instead of a comparative analysis with control subjects who received an alternative treatment such as current standard conservative care. The small sample size of each study poses a further difficulty in generalizing the findings. Only one study performed an a priori power analysis of the minimum sample size required [41]. The other limitation of this review is the heterogeneity of study design and outcome measures of the studies included. Several surgical procedures in the included studies were carried out at different levels of metatarsal bones by surgeons with different levels of experience; hence, there may be potential bias. Further, the different patients' outcomes scores used by the authors may have contributed to the observed significant heterogeneity among studies, impairing comparability and assessment of the merits of each technique. Further, only studies published in English were included; however, our review did not lose much data from studies published in other languages, as only one was in German [55]. Finally, another limit of this review is the large time frame taken into consideration. As already mentioned, the difference over time regarding the clinical management of diabetic patients has played a fundamental role in the improvement of PDFU outcomes. Better results found in most recent articles can be explained by looking at the improvement of the management of diabetic patients in a multidisciplinary way. In the future, it would be interesting to investigate the specific role of the healing of PDFUs in terms of lengthening the prognosis quo ad vitam of diabetic patients and its economic impact on National Health Services.

5. Conclusions

Satisfactory short- to medium-term clinical and radiographic results were reported by the studies included in this systematic review and meta-analysis with meta-regressions, suggesting that MIMOs performed at the different level of the metatarsal bones and without fixation may be an effective surgical treatment option for achieving healing of PDFUs, even when they are chronic, and preventing their recurrence in the forefoot of both type-1 and type-2 diabetic patients. However, these results should be interpreted with caution due to the poor quality and methodological deficiencies identified in some included studies, their limited evidence in providing appropriate functional and radiographic outcome measures (all level IV) and the complete lack of data concerning long-term follow-ups.

For these reasons, randomized controlled trials and prospective, longitudinal research studies, recruiting an adequate number of participants, investigating the combination of foot-loading factors, good glycemic control, and their interaction on PDFU healing are needed. Certainly, higher quality evidence would better support and

promote the use of the MIMOs as a treatment option for achieving and maintaining healing of PDFUs in people with diabetic and neuropathic feet.

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c. ***Minimally Invasive Distal Metatarsal Diaphyseal Osteotomy (DMDO) for Chronic Plantar Diabetic Foot Ulcers.*** *Foot Ankle Int.* ***2018*** *Jan; 39(1):83-92. doi: 10.1177/1071100717735640. PMID: 29110516 [4].*

The aims of this prospective study were first to evaluate the safety and effectiveness of minimally invasive DMDO for treating a consecutive series of diabetic patients with CPDFUs, and second to assess their clinical-functional and radiographic outcomes. A consecutive series of patients affected by diabetes mellitus with CPDFUs, not responsive to previous non-operative management, underwent DMDO. The CPDFUs were evaluated using the University of Texas Diabetic Wound Classification System (UTDWC). Demographic parameters of patients, AOFAS scores, VAS scores, healing times and complications were recorded. Maestro's criteria and bone callus formation were analysed radiologically. Statistical analysis was carried out ($p < 0.05$). Thirty consecutive enrolled patients with a mean age of 66.7 (range 53-75) years presented 35 CPDFUs with a mean diameter of 16.3 mm and a mean duration of 10.3 months. The most frequent grade of the UTDWC was IIIB (42.9%). All ulcers recovered at a mean healing time of 7.9 ± 4.0 (range 4-17) weeks. AOFAS scores improved significantly from 55.3 to 81.4 points ($p < 0.001$). At a mean follow-up of 25.3 months (18-71), no cases of ulcer recurrence were recorded, while a major complication, a wound infection, required longer healing time. DMDO is a safe and effective method in promoting CPDFU healing, regardless of the grade of severity, by the reduction of the high plantar pressure under the metatarsal heads; secondly, this technique improves functional and radiographic outcomes with few complications.

Article

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Minimally Invasive Distal Metatarsal Diaphyseal Osteotomy (DMDO) for Chronic Plantar Diabetic Foot Ulcers

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Abstract

Background: The aims of this prospective study were first to evaluate the safety and effectiveness of minimally invasive distal metatarsal diaphyseal osteotomies (DMDOs) for treating a consecutive series of diabetic patients with chronic plantar diabetic foot ulcers (CPDFUs) and second to assess their clinical-functional and radiographic outcomes.

Methods: A consecutive series of patients affected by diabetes mellitus with CPDFUs, not responsive to previous nonoperative management, underwent DMDO. The CPDFUs were evaluated using the University of Texas Diabetic Wound Classification System (UTDWC). Demographic parameters, Foot & Ankle Society (AOFAS) scores, visual analog scale (VAS) scores, healing times, and complications were recorded. Maestro et al criteria and bone callus formation were analyzed radiologically. Statistical analysis was carried out ($P < .05$). Thirty consecutive enrolled patients with a mean age of 66.7 (range, 53-75) years presented 35 CPDFUs with a mean diameter of 16.3 mm and a mean duration of 10.3 months. The most frequent grade of the UTDWC was IIIB (42.9%).

Results: All ulcers recovered with a mean healing time of 7.9 ± 4.0 (range, 4-17) weeks. AOFAS scores improved significantly from 55.3 to 81.4 points ($P < .001$). At a mean follow-up of 25.3 months (range, 18-71), no cases of ulcer recurrence were recorded, while a major complication or a wound infection required longer healing time.

Conclusion: Minimally invasive DMDO was a safe and effective method in promoting CPDFU healing, regardless of the grade of severity, by the reduction of the high plantar pressure under the metatarsal heads. This technique improved functional and radiographic outcomes with few complications.

Level of Evidence: IV, case series.

Keywords: minimally invasive surgery, percutaneous surgery, neuropathic ulcers, distal metatarsal osteotomies, distal metatarsal diaphyseal osteotomies, diabetes mellitus, diabetic foot

Diabetic foot ulcers are a common occurrence in about 15% of diabetic patients with peripheral neuropathy,[3,9,39] often leading to complications such as deep infection, abscess, and osteomyelitis,[13,40,47] and are a major worldwide health care concern.[44] Because of these complications, diabetic patients with recurrent plantar pressure foot ulcers have been estimated to require amputation in 71% to 85% of cases.[13,28,41] It is known that more than 60% of nontraumatic lower limb amputations occur in diabetic patients, and pressure ulcers are the causative factor in up to 84% cases.[8,39]

Ulcerations of the plantar aspect of the foot are frequently correlated with peripheral neuropathy, vascular disease, and elevated local pressure under the metatarsal heads due to a plantar flexion deformity of 1 or more of the metatarsal bones.[12,21,30,31,45] When these lesions become resistant, they have often been shown to be associated with higher rates of depression and lower quality of life for diabetic patients.[23]

Nonoperative management with total contact casts, cast walkers, or custom-made orthotics or shoes can be efficacious with a structured prevention program,[42] but in more than half of cases, there tends to be ulcer recurrence and iatrogenic complications.[3,16,19,50] The traditional operative methods, including both bone procedures (osteotomy, exostectomy,

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metatarsal head resection, arthrodesis) and tendon balancing (Achilles tendon lengthening, gastrocnemius recession, and/or plantar fascia release), aim to reduce abnormal plantar pressure at the site of the ulcer, improving healing and reducing risk of recurrence.[13,14,49] However, operative bone procedures are often correlated with high complication rates, such as wound recurrence or postoperative infection,[17] while tendon balancing presents risks of tendon overlengthening, rupture, and plantar flexion weakness.[13,33]

Currently, minimally invasive surgery (MIS) performed with minimal skin incisions (1-3 mm), an intraoperative image intensifier, and without internal fixation represents one of the most innovative approaches in forefoot surgery, including diabetic patients.[3,4,43] Since 2000, this method has been rapidly becoming popular, particularly for hallux valgus correction[4] and metatarsalgia treatment,[15,22] but it has also found several applications for the management of other common foot and ankle problems,[35] including posttraumatic arthritis and Charcot foot.[5,7]

Distal metatarsal metaphyseal osteotomy (DMMO),[22] a percutaneous extra-articular lesser metatarsal neck osteotomy, originally adopted by our institution as an alternative to the traditional Weil osteotomy[24] for metatarsalgia treatment, was subsequently applied to reduce the plantar pressure of the metatarsal head responsible for skin ulcerations in diabetic feet. However, in these cases, the need to shorten the metatarsal bone to a greater degree has led us to perform a distal osteotomy more proximal to the neck, not only to reduce the pressure on the ulcer and consequently favoring its healing but also to restore the metatarsal parabola by trying to satisfy the criteria by Maestro et al[34] and preventing recurrent or transfer skin lesions.

Thus, the aims of this prospective study were to evaluate the safety and effectiveness of minimally invasive DMDO in treating a consecutive series of patients with chronic plantar diabetic foot ulcers (CPDFUs) and to assess their clinical-functional and radiographic outcomes after this percutaneous surgery.

Methods

Between January 2010 and September 2016, a consecutive series of diabetic patients, who had not responded to nonoperative treatment during at least a 6-month period for one or more neuropathic ulcerations under their metatarsal heads (second to fifth), except the first, were enrolled in this prospective cohort study at our institution. Each patient with CPDFU underwent a percutaneous operative procedure that was performed by the senior author, who followed and checked the patients personally during the postoperative period. Before surgery, all patients followed the same standardized nonoperative care protocol at our institution's multispecialty diabetic foot clinic. This involved previous preliminary educational section[6,44] and, according to the lesion grade, daily topical medications and dressing, low-level periodic debridement and oral or intravenous antibiotic therapy (if infected and/or necrotic wounds), and use of pressure-relieving diabetic shoes or custom-made footwear.[1,6]

All patients participating in this prospective study received a thorough explanation of the risks and benefits and gave their informed consent. This study was approved by the Institutional Ethics Committee and performed in accordance with the ethical standards of the 1964 Declaration of Helsinki as revised in 2000 and those of Good Clinical Practice.

Thirty consecutive enrolled patients met the inclusion criteria and were considered in the analyses (Table 1). There were 10 women and 20 men. The mean patient age at the time of the surgery was 66.7 ± 6.8 (range, 53-75) years. A total of 28 of 30 patients had type 2 diabetes mellitus (DM) (8/30 treated with insulin, 6/30 with insulin and oral therapy, and 14/30 treated with only oral therapy), while 2 of 30 had type 1 DM (2/30 treated with insulin). The mean duration of their diabetes history was 18.1 ± 8.8 (range, 6-33) years, and all patients presented with peripheral neuropathy. The mean value of hemoglobin A1c (HbA1c) was 7.1% ± 0.8% (range, 5.9%-8.4%), while the mean values of transcutaneous oxygen tension (TcO_2) and C-reactive protein were 44.8 mm Hg and 6.3 mg/dL, respectively. Mean follow-up was 25.3 ± 10.0 (range, 18-71) months, and none of the patients was lost during the follow-up period.

Inclusion and Exclusion Criteria

For the inclusion criteria of this study, patients had to present a unilateral, plantar CPDFU, under the heads between the second and fifth metatarsal bones that did not heal after at least 6 months of nonoperative treatment by a team of our institution specifically trained in diabetic foot care. Furthermore, they had to be diagnosed with DM for a duration of at least 5 years with HbA1c less than 8.5%.

Exclusion criteria were as follows: ulcer under the first metatarsal head, bilateral foot ulceration or associated diabetic toe ulcers, absent distal pulse on clinical examination, peripheral vascular disease associated with TcO_2 on the dorsum of the foot less than 25 mm Hg, active infection as determined by abnormal blood parameters (alteration of C-reactive protein [CRP] >150 mg/L), or local signs of infection (cellulitis or suppuration). Furthermore, patients with a history of contralateral partial foot or leg amputation, foot trauma or foot and ankle surgery, and pancreas transplantation were excluded.

Operative Technique

Minimally invasive DMDO. During the operation, the patient was in a supine position and adequately anesthetized by a regional ankle block, with the operated foot protruding from the table (Figure 1). No tourniquet was required for this technique, and more important, it was not indicated in

Table 1. Patients' Characteristics and Their Potential Risk Factors.[a]

Characteristic	Value
BMI, kg/m^2	29.43 ± 2.83
BMI >30	18/30 (60.00)
DM, y	18.1 ± 8.81
HbA1c, %	7.13 ± 0.82
≤7%	18/30 (60.00)
>7%	12/30 (40.00)
C-reactive protein, mg/dL	3.6 ± 3.2
TcO_2, mm Hg	44.8 ± 2.1
Heart failure	16/30 (53.33)
Carotid artery stenosis	14/30 (46.67)
Chronic kidney disease	6/30 (20.00)
Maculopathy	18/30 (60.00)
Vasculopathy	18/30 (60.00)
Neuropathy	30/30 (100.00)
Smoker	
Yes	14/30 (46.67)
No	16/30 (53.33)
ASA classification	
3	28/30 (87.50)
4	4/30 (12.50)

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; DM, diabetes mellitus; HbA1c, hemoglobin A1c; TcO_2, transcutaneous oxygen tension.
[a]Values are presented as mean ± standard deviation or number (%).

this diabetic lower limb surgery. The surgery was performed after administration of a prophylactic antibiotic (cefazolin: 2 g) and under image intensifier guidance. An incision of 5 mm was made parallel to the extensor tendons at the dorsal side of the medial (or lateral) border of each metatarsal head that needed to be shortened. The side of the incision depended on the surgeon being right- or left-handed and which foot was being operated on. The scalpel was advanced at an oblique angle of about 45 degrees until it reached the dorsal aspect of the distal metatarsal bone, proximal to the neck, to undergo osteotomy. Through the same incision, first a bone rasp specific for percutaneous surgery was inserted, using it to separate the periosteum at the level of osteotomy. Then, a Shannon Isham burr (2.0 × 12 mm), adapted for Mm960 (produced by MedicMicro, Sainte-Croix, Switzerland), was introduced until it reached the metatarsal neck (Figure 1A) and then retracted a few millimeters proximally where the periosteum was previously removed (Figure 1B). Fluoroscopy was used to confirm the correct position of the osteotomy site on the distal diaphysis of the metatarsal bone (Figure 1C). In this position, the cutting was started with an angle of approximately 45 degrees with respect to the long axis of the metatarsal bone in a dorsal-distal to proximal-plantar direction, with rotary motion (Figure 1D), extending to the contralateral cortex. In this way, the lateral cortical surface was cut first, then the plantar and medial surface, and, last, the dorsal cortical surface (Figure 2A). During the osteotomy process, the incision site was irrigated by normal saline as the burr can cause excessive heat, causing a skin burn resulting in a nonhealing wound or in fibrosis and/or pseudoarthrosis of the osteotomy.[4,36] Furthermore, this lavage was useful to remove bone debris, preventing periarticular ossifications. Upon completion of the osteotomy, the bone was manually compacted, exerting pressure in the distal-proximal direction of the metatarsal, pushing the metatarsal head dorsally and producing contact of the trabecular bone, since no internal fixation was performed (Figures 1E and 2B). The number of metatarsal osteotomies performed in each forefoot was planned according to how much the metatarsal parabola was altered, following the Maestro et al[34] criteria. Furthermore, to prevent toe ulcerations, cases of associated interphalangeal hallux valgus (HV) or claw toe deformity were treated as described by De Prado et al[15]: the first by percutaneous Akin osteotomy, the second through extensor and flexor tenotomies in cases of flexible deformity (Figure 1F), or associated osteotomies of phalanges in cases of fixed deformity. After accurate ulcer debridement, a chronic ulcer was converted into an acute wound (Figure 3B), permitting the normal stages of healing to ensue,[26,32] while the rest of the wounds were closed with absorbable sutures.

Bandage. A bandage soaked in saline solution was applied. Because there is no osteosynthesis material in this surgery, the bandage is a very important tool to maintain the correction obtained after the operation. With a tape for bandages, the bend of the crisscross bandage was then traced between all inter-metatarsal spaces, crossing them over the medial (lateral) aspect of the number of osteotomies performed (depending on the foot side) to reinforce the strength of the bandage. Gentle traction was used to maintain the toe in slight plantar inclination. Finally, the forefoot was covered with tubular gauzes, except for the distal part of the toes and nails.

Postoperative protocol. All patients followed the same postoperative protocol. The patients were allowed to walk as much as they could tolerate the day after surgery using a rigid flat-soled orthopedic shoe for the following 30-day period. This aspect is very important as metatarsal length was set automatically upon weightbearing.[21] Anteroposterior and lateral x-rays of nonweightbearing feet were taken before the patients were discharged. We recommended antibiotic oral prophylaxis for a week, as well as thromboembolic prophylaxis (natrium enoxaparin: 4.000 IU/d) and an antiedema therapy (Leucoselect, Lymphaselect, and Bromelina: 1 tablet/d) for 30 days, starting from the day of the surgery. Moreover, analgesic therapy was prescribed for 2

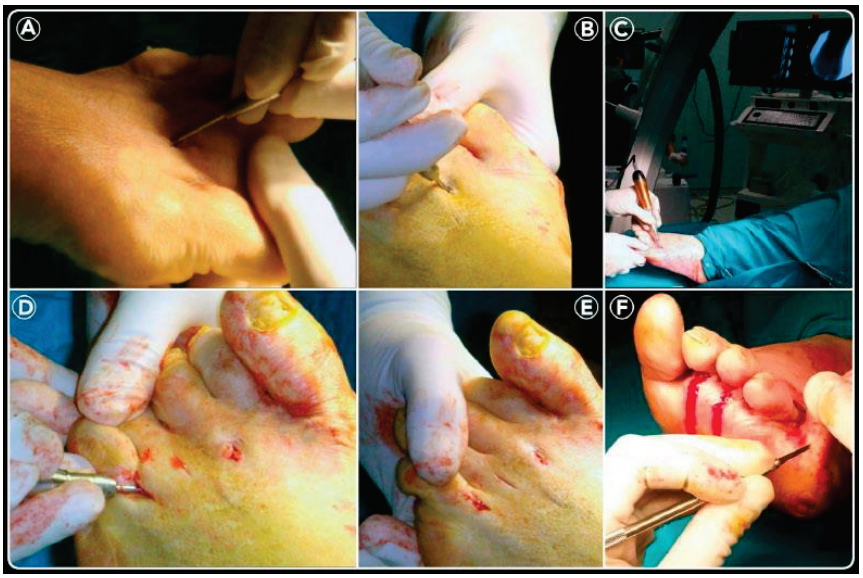

Figure 1. Distal metatarsal diaphyseal osteotomy (DMDO) intraoperative images: a 12-mm Shannon Isham burr is introduced through a 5-mm portal until it reaches the metatarsal (MTT) neck (A) and then is retracted a few millimeters proximally where the periosteum was previously removed by a bone rasp (B). During the different operative phases, several fluoroscopic control views are used to confirm the correct position of the osteotomy site on the distal diaphysis of the MTT bone to verify its completion and following impaction to check if a more harmonious forefoot morphotype has been restored (C). The DMDO is performed at an angle of approximately 45 degrees with respect to the long axis of the MTT bone in a dorsal-distal to proximal-plantar direction, with rotary motion, extending to the contralateral cortex (D). Upon DMDO completion, the bone is manually impacted, exercising pressure in the distal-proximal direction of the treated MTT, pushing its head dorsally (E). Finally, an associated claw toe deformity, in this case flexible, is treated by extensor and flexor percutaneous tenotomy (F).

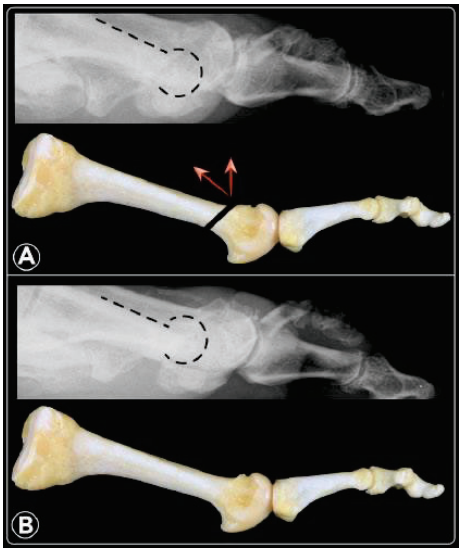

Figure 2. Weight-bearing radiographic images of distal metatarsal diaphyseal osteotomy showing the position of the second metatarsal bone with respect to the ground preoperatively (A) and the final result of an ideal osteotomy performed proximal to the neck with potentially greater elevation from the ground postoperatively (B).

weeks of etoricoxib (60 mg, 1 cp/d) in the morning, also to prevent heterotopic ossification when the comorbidities of the patient permitted, or alternatively paracetamol (1 g, 1 tablet ×2/d).

Each patient was seen once a week for a month in our outpatient clinic. The first visit was 8 days after surgery. The original bandage was removed and replaced with a simpler bandage. At the next 3 weekly visits, the bandage was changed in the same way. One month after operative treatment, if the ulcer was completely closed, the bandage was totally removed, and after taking anteroposterior weight-bearing and lateral x-rays, the patient was then able to walk with comfortable shoes, allowing full weight on the operated foot. If the ulcer was not completely healed, the patient was seen every week until total lesion closure. After healing, the only recommendations for the patient were to be careful with rough surfaces, sports, and any other activities with forefoot overload. No specific physical therapy was suggested.

Patient assessment. The clinical and radiological analyses were carried out by 2 independent investigators, the junior authors, not involved in the operative treatment of the patients. Each patient underwent radiographic assessment with the same protocol before surgery, as

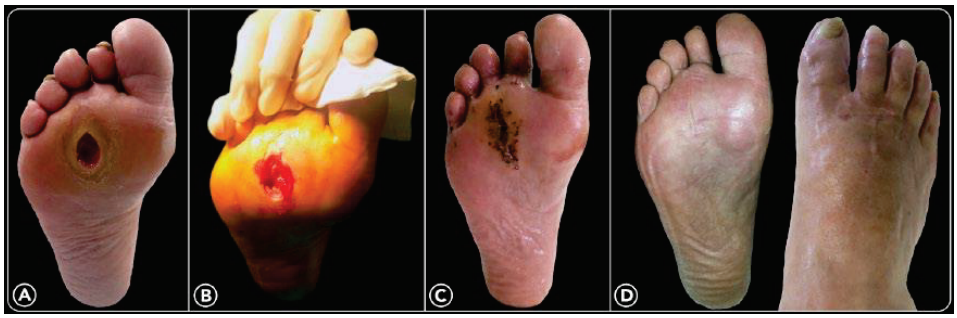

Figure 3. A 70-year-old man with type 2 diabetes having undergone distal metatarsal diaphyseal osteotomy of the second, third, and fourth metatarsal bone for a grade IIIB ulcer extending into the metatarsophalangeal joint (with contiguous) on his right foot and percutaneous osteotomy of P1 of the second toe with associated percutaneous tenotomies for claw deformity. Clinical images at preoperative (A), intraoperative (B), 1-month follow-up (C), and 3-month follow-up (D), showing the complete healing of the ulcer.

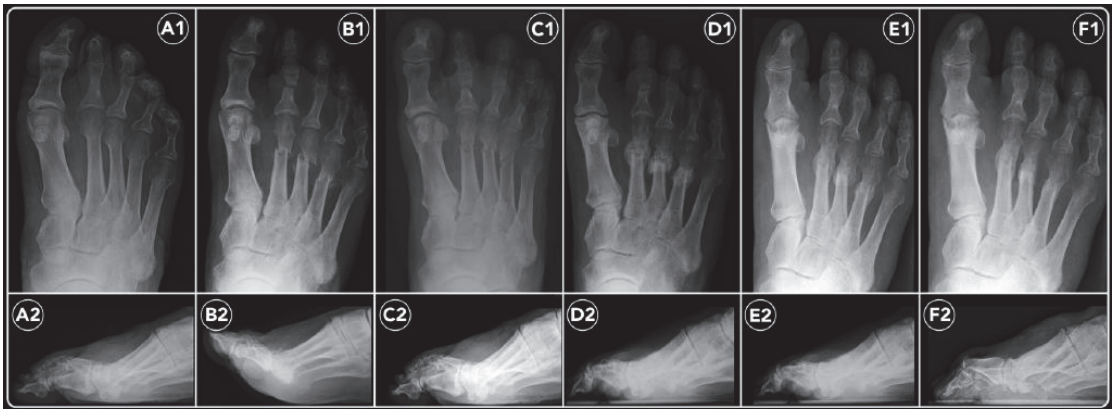

Figure 4. The same diabetic patient in Figure 3 having undergone distal metatarsal diaphyseal osteotomy of the second, third, and fourth metatarsal (MTT) bones and percutaneous osteotomy of P1 of the second toe associated with percutaneous tenotomy for claw deformity of his right foot. Radiographic images: (1) anteroposterior and (2) lateral view at the preoperative period (A), immediate postoperative period (B), 1-month follow-up (C), 3-month follow-up (D), 12-month follow-up (E), and 48-month follow-up (F), showing bone callus consolidation and its remodeling, maintaining the elevation of the heads of the treated metatarsals. Due to the effect of load by immediate deambulation, the MTTs ossified in a new position, more dorsal with respect to preoperatory. In this way, the plantar pressure on the ulcer was reduced because it was better redistributed on the forefoot..

well as at 1, 3, and 6 months and at final follow-up, according to the American Orthopaedic Foot & Ankle Society (AOFAS) accepted guidelines[27] and based on the criteria of Maestro et al.[34] Furthermore, the University of Texas Diabetic Wound Classification System (UTDWC),[29,37] which takes into account the size and depth of the ulcer, as well as the presence or absence of infection and ischemia,[2] was used to grade and preoperatively evaluate the CPDFUs, while the size of the ulcers was determined as described by Coughlin et al,[11] using a transparent sheet at each clinical evaluation to determinate the ulcer's diameter. The major axes of the wounds were measured manually from the areas of the ulcers (Figure 3A).

Clinical-functional and radiographic outcomes. The clinical preoperative evaluation included a complete clinical history of the patients and their characteristics (sex, age at the time of surgery, affected side, comorbidity, HbA1c, TcO_2, PCR, and peripheral neuropathy). The 100-point AOFAS hallux-metatarsophalangeal-interphalangeal scale was used to assess clinical outcomes,[25] and the difference (Δ) between preoperative and postoperative median values was calculated. Furthermore, all patients were evaluated with the visual analog scale (VAS), and any complications were recorded.

Radiographically, routine standing anteroposterior x-ray views were obtained before surgery and at different follow-ups, according to our protocol (Figure 4). For

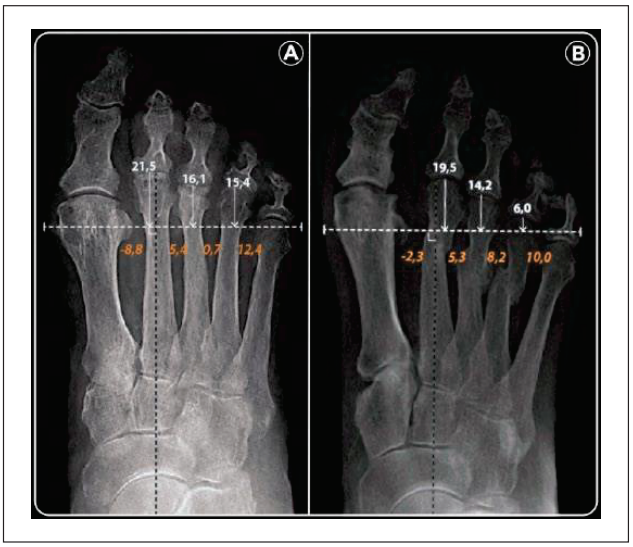

Figure 5. M1M2 index and Maestro et al[34] criteria: radiographic marks and measurements on the anteroposterior radiographs (A) at the preoperative period during radiographic planning to calculate the number of metatarsal bones to shorten and (B) at the last follow-up to verify the operative correction and whether the forefoot morphotype was more harmonious after distal metatarsal diaphyseal osteotomy.

methodological reasons, the immediate postoperative x-ray at discharge was not included for the radiographic evaluation because it was a nonweightbearing radiograph. The radiographic evaluations included the M1M2 index and Maestro 1 (M1), Maestro 2 (M2), and Maestro 3 (M3), according to criteria by Maestro et al,[34] using the preoperative and the last follow-up x-rays (Figure 5). This index quantifies the levels of disorders of harmony of the forefoot and the metatarsal length, which can cause metatarsalgia and skin lesions.[34] Finally, callus formation in anteroposterior and lateral view radiographs and the absence of radiolucent lines were checked to determine bone union.

Statistical analysis. Statistical analyses were performed by an independent statistician from the Department of Statistics at our university. The data are presented as the mean ± standard deviation or median (range) for continuous variables and as numbers for categorical measures. For the statistical evaluation of the clinical and radiological scores obtained with the AOFAS scale and the parameters of the formula by Maestro et al[34] before surgery and at last follow-up, we used the paired Student *t* test. We used the Wilcoxon 2-sample test to compare healing time for different grades of ulcers. The significance threshold was set at .05.

Results

Thirty-five CPDFUs were treated with 32 operations. Three patients had ulcerations on the same foot at the same time, and 2 patients were operated on bilaterally at different times. The mean duration of the CPDFUs at the time of surgery was 10.3 ± 3.8 (range, 6-19) months. The most frequent ulcer site was under the third metatarsal head with 11 of 35 ulcers, followed by the fifth metatarsal head with 9 of 35 ulcers, while 8 of 35 ulcers were under the second and 7 of 35 ulcers under the fourth metatarsal heads. Before DMDO, plantar ulcers had a mean diameter of 16.3 ± 0.6 (range, 5-25) mm. According to the UTDWC, there were 4 of 35 ulcers of grade IA, 2 of 35 of grade IIA, 6 of 35 of grade IIB, 2 of 35 of grade IIC, 2 of 35 of grade IIIA, 15 of 35 (42.9%) of grade IIIB, 1 of 35 of grade IIIC, and 3 of 35 of grade IIID (Table 2 and Figure 3).

Table 2. University of Texas Wound Classification System.

	Grade, No. (%)			
Stage	I	II	III	Total
A	4 (11.43)	2 (5.71)	2 (5.71)	8 (22.86)
B	0 (0)	6 (17.14)	15 (42.86)	21 (60.00)
C	0 (0)	2 (5.71)	1 (2.86)	3 (8.57)
D	0 (0)	0 (0)	3 (8.57)	3 (8.57)
Total	4 (11.43)	10 (28.57)	21 (60.00)	35 (100)

During the 32 operations, 102 DMDO procedures were performed to treat 35 CDPUs in 32 feet as follows: 27 involving the second, 28 the third, 26 the fourth, and 21 the fifth metatarsals. In 26 of 32 operations, associated procedures were performed only on the toe considered at risk of ulceration: flexor and extensor tenotomies in 17 of 32 operations for the correction of claw toe flexible deformities and associated osteotomies of the proximal phalange in 9 of 32 operations for the correction of fixed deformities, while percutaneous Akin osteotomy was performed in 6 of 32 operations for the correction of interphalangeal HV.

All patients were considered healed at the final follow-up for lesion resolution (Figures 3D). Their mean healing time was 7.9 ± 4.0 (range, 4-17) weeks. As for the UTDWC,[29,37] grade I and II ulcers required 5.0 ± 1.8 (range, 4-9) weeks to close completely, while grade III ulcers took 9.7 ± 4.0 (range, 4-17) weeks (Figure 3) ($P < .0017$). With respect to their dimensions, ulcers with a diameter 1.5 cm or less required 6.8 ± 4.1 (range, 4-17) weeks to heal, while ulcers with a diameter more than 1.5 cm required 9.4 ± 3.6 (range, 4-15) weeks ($P < .046$).

Clinical-Functional and Radiographic Outcomes

At the preoperative evaluation, the mean total AOFAS score of the patients treated was 55.3 ± 8.3 (range, 42-71) points, while at the last follow-up, it was 81.4 ± 9.1 (range, 64-100) points with a mean improvement of 26.1 ± 6.5 points ($P < .0001$) (Figure 6). At the final follow-up, the mean VAS score was 9.8 ± 0.7 (range, 7-10) points. Signs of bone callus formation were noted in 15 of 32 feet at the 1-month follow-up,

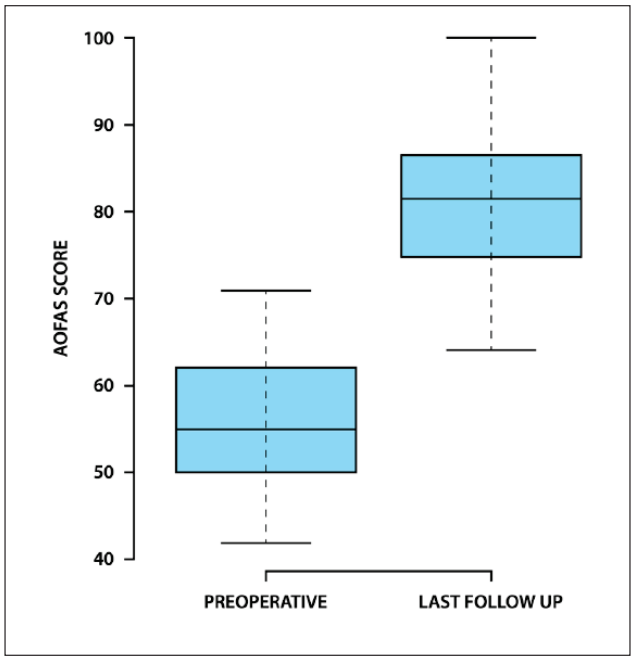

Figure 6. Graph of the statistical analysis of American Orthopaedic Foot & Ankle Society (AOFAS) scores ($P < .0001$) at preoperative period and last follow-up.

Table 3. Radiographic Mean Values of M1M2 Index and Maestro et al[34] Criteria, Including Ranges, at Preoperative Period and Last Follow-up.

	Preoperative	Last follow-up
M1M2 index, mm	−1.8 (−8.8 to 2.8)	1.1 (−5.0 to 5.3)
Maestro 1, mm	3.7 (0.1 to 8.45)	5.7 (0.5 to 7.7)
Maestro 2, mm	11.4 (0.7 to 15.3)	8.0 (4.3 to 11.75)
Maestro 3, mm	13.1 (4.7 to 17.6)	10.6 (5.3 to 16.5)

while at 3 months, 26 of 32 feet presented complete healing of the osteotomies. At the last follow-up, all feet presented signs of definitive bone consolidation, including Akin osteotomies when performed (Figure 4F). According to Maestro et al[34] criteria, the M1M2 index was −1.8 ± 4.4 (range, −8.8 to 2.8) points before surgery and 1.1 ± 4.5 (range, –5.0 to 5.3) mm at last follow-up. Furthermore, Maestro 1, Maestro 2, and Maestro 3 changed at the last follow-up with respect to the preoperative period (Table 3 and Figure 5). Hence, all parameters of Maestro et al[34] criteria were significantly different at the last follow-up compared to the preoperative period ($P < .001$).

Complications

Major complications occurred in only 1 patient because of wound infection by *Streptococcus agalactiae*. He was a 73-year-old man with a 20-year DM history and a history of insulin therapy, neuropathy, and vascular disease, presenting a grade IIIB ulcer. He recovered in 17 weeks after intravenous antibiotic therapy. Furthermore, persistent moderate swelling of the forefoot for more than 6 weeks without infection was noted in 18 of 32 feet, which improved after some months with complete callus formation at the osteotomy levels and without further treatment. Finally, no cases of healing failure, transfer ulcers, or recurrence were encountered at last follow-up. No cases of wound infection or wound breakdown, metatarsal bone osteomyelitis, or acute Charcot osteoarthropathy were found. No cases of malunion, delayed union, or nonunion were recorded. There were no cases of thromboembolism, avascular necrosis, or displacement of the metatarsal head.

Discussion

A recent meta-analysis of the contemporary management of diabetic neuropathic foot ulcerations reveals relatively disappointing functional outcomes.[45] In this context, the purpose of our study was to test the application of percutaneous distal metatarsal osteotomy for the treatment of CPDFUs, representing a valid opportunity for the improvement of diabetic patients' outcomes. In our cohort, the mean CPDFU healing time was 7.9 ± 4.0 weeks, which was directly influenced by the diameter and degree of the ulcers. Ulcers with a diameter of more than 1.5 cm took longer to heal compared to smaller ones ($P = .046$) while grade I and II ulcers took less time to heal than those of grade III ($P = .0017$). However, despite the dimensions and the UTDWC grade of the ulcers, at the medium follow-up of 25.3 ± 10.0 months, not only did all heal without recurrence, but the mean AOFAS score of our diabetic patient series also significantly improved ($P < .0001$).

In this percutaneous technique, osteotomy fixation by pinning or any other internal hardware is not indicated because of the high risk of infection in diabetic patients. Even though we did not use them, a single case of deep infection occurred in our series. Nevertheless, it was successfully resolved by hospitalization with intravenous antibiotic therapy. No cases of osteotomy nonunion were recorded, while Tamir et al[45] reported a 30% rate of nonunion, and no evidence of metatarsal head avascular necrosis was found. There was no case of acute Charcot disease, no transfer or recurrent lesions were observed at last follow-up, and in most cases, the normal arch of the foot was restored. These are good short-medium term outcomes, although it is possible that with a longer follow-up and a larger patient group, secondary transfer pressure lesions could appear, increasing the number of complications. However, the aim of DMDO was not only to reduce pressure caused by the single collapsed metatarsal bone on the related ulcer but also to restore a harmonic balanced forefoot arch as much possible by operating also on the adjacent bones to prevent the risk of transfer lesions.

Plantar metatarsal ulcers due to pressure under the metatarsal heads, similar to the painful hyperkeratotic areas of metatarsalgia in nondiabetic patients, were initially hypothesized to be lesions caused by overactivity of both the long extensor and long flexor.[46] However, we believe this muscle imbalance is not the major causative factor; rather, in agreement with other authors,[18] the progressive collapse of the transverse axis of the foot, with consequent depression of the metatarsal heads, distal migration of the metatarsal fat pad, and increase in the local pressure, seems to be implicated in recalcitrant ulcer pathogenesis. By percutaneous osteotomies, modifying the position of the metatarsal heads to a mild dorsally translated position, it is possible first to achieve a better distribution of plantar pressure on the metatarsal bone, resulting in a decrease of the load under the ulcer and in a promotion of its healing,[13,20] and, second, to restore the original harmonic distal parabola of the forefoot or create a new balanced forefoot arch (Figures 2 and 5).

Redfern and Vernois[38] correctly stated that making the osteotomy more proximal to the neck is a technique error when performing DMMO for metatarsalgia treatment, as the point of rotation of the osteotomy moves proximally, causing its displacement in dorsal rotation and a consequent overelevation of the metatarsal head. In contrast, this was exactly the main goal of performing minimally invasive DMDO for CPDFU treatment. According to the Maestro et al[34] criteria, our series showed significant changes in the average values. These results are probably due to the percutaneous floating osteotomies, which permit the retraction and dorsiflexion of the metatarsal heads. In this way, adapting to the load, the metatarsal heads ossify in a new dorsal position. Furthermore, to respect the Maestro et al[34] criteria, it was necessary to shorten the metatarsal bone to a greater degree, performing the osteotomy more proximal to the neck. In this aspect, our osteotomy is different from the more popular DMMO.[20]

In the literature, only a few studies evaluate the percutaneous operative treatment of CDPFUs. Tillo et al[48] were the first to propose a dorsal osteoclasis at the level of the metatarsal neck for the treatment of chronic neuropathic ulcers in a series of 52 diabetic patients, reporting a recurrence rate of 6% and a transfer lesion rate of 26.5% during a 17-month follow-up. In 1999, Fleischli et al[17] described a dorsiflexion metatarsal base osteotomy fixed by pins for the treatment of chronic neuropathic forefoot ulcers in a series of 20 diabetic patients. Although good results were reported with a high healing rate (95%), complications occurred in 68% of cases, including acute Charcot disease (32%), deep wound infections (14%), and transfer ulcers (9%). More recently, Tamir et al[45] described the use of 20 mini-invasive floating osteotomy procedures for the treatment of resistant or recurrent diabetic foot ulcers, reporting excellent results. Although they treated only UTDWC grade IA ulcers in a series of 17 diabetic patients, with only 11 patients treated by insulin, their findings were confirmed by our results. Our short- and medium-term outcomes showed the percutaneous technique was effective in all of our patients with nonhealing ulcers but good metabolic control (HbA1c <8.5%).

To our knowledge, this is the first prospective, single-center study reporting outcomes of minimally invasive DMDO for the treatment of CDPFUs under the lateral metatarsal heads (second to fifth) in a consecutive, single-surgeon patient series. The number and homogeneity of patients and the mean 25-month follow-up are comparable to previous published studies.[14] The main limitation of this preliminary report was the use of the AOFAS score for the chief outcome measure, which, although it remains the most widespread health measurement in foot and ankle clinical practice, was only partly validated.[10] Furthermore, as there is no specific method for the evaluation of metatarsal diabetic ulcers, some clinical aspects may have been overlooked. Consequently, the application of a specific clinical score to assess diabetic foot problems would increase the validity of this study. Nevertheless, several reports have shown that AOFAS scale scores are reliable and can be used to formulate valid conclusions related to foot and ankle quality-of-life issues.[16,25] Another weakness is the lack of a control group, which would be useful to compare the results of this percutaneous technique. However, all of our patients had previous nonoperative management of the ulcer for at least 6 months that was not effective. Finally, we lacked plantar pressure measurements.

Conclusion

In conclusion, our preliminary data showed that minimally invasive DMDO, sometimes combined with percutaneous extensor and flexor tenotomies in cases of claw toe deformity and percutaneous Akin osteotomy for interphalangeal HV, was a safe and effective method in successfully promoting ulcer healing in diabetic patients with CDPFUs under the heads of lateral metatarsal bones (second to fifth), regardless of their UTDWC grade severity and dimensions. We believe the most important aspects of this method was the reduction of the previous high plantar pressure by restoration of a harmonic balanced forefoot arch. Finally, this minimally invasive modified technique, performed under ankle block with minimal surgical scars and absence of osteosynthesis, improved functional and radiographic outcomes of our diabetic patients with few complications at short- to medium-term follow-up.

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Declaration of Conflicting Interests

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10.3 Reverdin-Isham Osteotomy (RIO) in combination with **Akin Percutaneous Osteotomy (APO)** and **Lateral Soft-Tissue Release (LSTR)**

For these percutaneous procedures, used to treat mild to moderate HV, the following original articles [5] were included:

- ***Functional and radiographic outcomes of Hallux Valgus correction by mini-invasive surgery with Reverdin-Isham and Akin percutaneous osteotomies: a longitudinal prospective study with a 48-month follow-up.*** J Orthop Surg Res. **2016** Dec 5;11(1):157. doi: 10.1186/s13018-016-0491-x. PMID: 27919259; PMCID: PMC5139107.

  MIS represents one of the most innovative surgical treatments of HV. However, long-term outcomes still remain a matter of discussion within the orthopaedic community. The purpose of this longitudinal prospective study was to evaluate radiographic and functional outcomes in patients with mild-to-severe HV who underwent RIO and APO, following exostosectomy and STLR. Eighty patients with mild-to-severe symptomatic HV were treated by MIS. Clinical evaluation was assessed pre-operatively, as well as at 3 and 12 months after surgery and at final follow-up of 48 months, using the AOFAS Hallux grading system. Patient satisfaction and complications were recorded. Computer-assisted measurement of antero-posterior radiographs was taken pre-operatively, as well as at 3 and 12 months after surgery and at 48-month follow-up, analysing the IMA, the HVA, the DMAA and the TSP. The bridging bone/callus formation was also evaluated at the different radiographic follow-ups, while the articular surface congruency and the metatarsal index were calculated only preoperatively and at last follow-up. Patient satisfaction was assessed using the VAS. Statistical analysis was carried out using the paired t-test. Statistical significance was set at $p < 0.05$. The mean AOFAS score was 87.15 points at the final FU of 48 months, and the VAS score was 8.35/10. The postoperative radiographic assessments showed a statistically significant improvement compared with preoperative values. The mean corrections of each angular value at the last follow-up were as follows: IMA 3.90°,

HVA 12.50°, DMAA 4.72° and a tibial sesamoid position of 1.10. The articular surface was congruent in 77 (96.25%) cases and incongruent only in 3 (3.75%). The complete healing of the osteotomies was achieved in all series at 3-month follow-up. However, the results obtained in the correction of the severe HV deformities were less encouraging. MIS with RIO and APO, in combination with previous exostosectomy and subsequent LSTR, is a safe, effective and reliable procedure for correction of mild-to-moderate HV. However, it requires a long learning curve because of the inherent difficulty of the mixed different surgical procedures.

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RESEARCH ARTICLE Open Access

Functional and radiographic outcomes of hallux valgus correction by mini-invasive surgery with Reverdin-Isham and Akin percutaneous osteotomies: a longitudinal prospective study with a 48-month follow-up

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Abstract

Background: Minimally invasive surgery (MIS) represents one of the most innovative surgical treatments of hallux valgus (HV). However, long-term outcomes still remain a matter of discussion within the orthopaedic community. The purpose of this longitudinal prospective study was to evaluate radiographic and functional outcomes in patients with mild-to-severe HV who underwent Reverdin-Isham and Akin percutaneous osteotomy, following exostosectomy and lateral release.

Methods: Eighty patients with mild-to-severe symptomatic HV were treated by MIS. Clinical evaluation was assessed preoperatively, as well as at 3 and 12 months after surgery and at final follow-up of 48 months, using the American Orthopaedic Foot and Ankle Society (AOFAS) hallux grading system. Patient satisfaction and complications were recorded. Computer-assisted measurement of antero-posterior radiographs was taken preoperatively, as well as at 3 and 12 months after surgery and at 48-month follow-up, analysing the intermetatarsal angle (IMA), the hallux valgus angle (HVA), the distal metatarsal articular angle (DMAA) and the tibial sesamoid position. Also, the bridging bone/callus formation was evaluated at the different radiographic follow-ups, while the articular surface congruency and the metatarsal index were calculated only preoperatively and at the last follow-up. Patient satisfaction was assessed using the visual analogue score (VAS). Statistical analysis was carried out using the paired *t* test. Statistical significance was set at $p < 0.05$.

Results: The mean AOFAS score was 87.15 points at the final follow-up of 48 months, and the VAS score was 8.35/10. The post-operative radiographic assessments showed a statistically significant improvement compared with preoperative values. The mean corrections of each angular value at the last follow-up were as follows: IMA 3.90°, HVA 12.50°, DMAA 4.72° and a tibial sesamoid position of 1.10. The articular surface was congruent in 77 (96.25%) cases and incongruent only in 3 (3.75%). The complete healing of the osteotomies was achieved in all series at 3-month follow-up. However, the results obtained in the correction of the severe HV deformities were less encouraging.
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Conclusions: Minimally invasive surgery with Reverdin-Isham and Akin percutaneous osteotomy, in combination with previous exostosectomy and subsequent lateral soft-tissue release, is a safe, effective and reliable procedure for correction of mild-to-moderate HV. However, it requires a long learning curve because of the inherent difficulty of the mixed different surgical procedures.

Trial registration: ClinicalTrials.gov PRS Protocol Registration and Results System: NCT02886221

Keywords: Hallux valgus, Reverdin-Isham osteotomy, Akin osteotomy, Minimally invasive surgery, Percutaneous distal osteotomy, First ray, Forefoot

Background

Hallux valgus (HV) is a common, complex and progressive deformity of the forefoot with multiple clinical symptoms and a multifactorial aetiology [1]. Painful HV is more frequent in women between 40 and 60 years old, although it can appear in younger people because of biomechanical influence, hind and midfoot pathologies or sports activities, which might cause an overload on the first ray [2, 3]. For its correction, a wide variety of bony procedures are described, associated or not with soft tissue release, including osteotomies at the level of the head, midshaft and base of the first metatarsal, as well as arthrodesis of the first metatarso-cuneiform joint [4–7]. This demonstrates the complexity of the disease and the lack of a unique and most appropriate treatment, the choice of which continues to generate controversy [8].

At present, minimally invasive surgery (MIS) performed with minimal skin incisions (1–3 mm), an intraoperative image intensificator and without internal fixation [9] represents one of the most innovative approaches in forefoot surgery. This percutaneous dynamic management combines different procedures, most arising from the traditional open distal metatarsal osteotomy, in a mixed surgical strategy, according to the complexity of the deformity to be corrected [10–14]. These methods are rapidly becoming popular, as they are quick to perform, allow 1-day hospitalization, decrease post-operative morbidity as well as recovery and rehabilitation times, and chiefly because they are better accepted by patients [9, 15].

Although the most commonly performed percutaneous procedures have already been well described, providing equal effectiveness, sometimes superior, to traditional open surgery [16], their use is not equally accepted and their outcomes still remain a matter of discussion in the orthopaedic community, particularly in cases where no internal fixation is used [17, 18]. The Reverdin-Isham percutaneous osteotomy was described as a novel intra-articular medial closing wedge osteotomy of the distal metatarsal, in combination with an Akin osteotomy, both performed without fixation, to align the first ray by medial rotation of the first metatarsal head and distal metatarsal articular angle (DMAA) correction [15, 19–26]. Reverdin-Isham is not a complete osteotomy, as the MTT-1 lateral cortex is preserved; the closing wedge ensures contact of the metatarsal head with the metaphysis, and a special bandage is applied after surgery. In this way, no internal fixation is necessary. This allows the osteotomy to heal with the toe in its proper position, due to early weight bearing.

Since the end of the last century, MIS became widespread first in Spain and then in Europe by M. De Prado and P.L. Ripoll through their surgical practices and international theoretical-cadaveric courses, supported by the anatomical studies of Pau Golanó [20]. In 2002, the group GRECMIP (Groupe de Recherche et d'Enseignement en Chirurgie Mini-Invasive du Pied) began a project to develop and promote this new surgical treatment [26]. However, to the best of our knowledge, no previous study has evaluated the long-term results of this technique. Thus, the aim of this prospective study was to evaluate the radiographic and clinical outcomes of patients with mild-to-severe HV treated by MIS with Reverdin-Isham and Akin percutaneous osteotomy, following exostosectomy and lateral soft-tissue release.

Methods

Between May 2010 and May 2012, a consecutive series of 80 Caucasian patients with diagnosis of mild-to-severe HV were enrolled in this prospective study at our institution and underwent the Reverdin-Isham percutaneous osteotomy, following percutaneous Akin osteotomy and percutaneous lateral soft-tissue release. All of these operative procedures were performed by a single surgeon, the senior author (C.B.), who followed and checked the patients personally during the post-operative period. All subjects participating in this prospective study received a thorough explanation of the risks and benefits of inclusion and gave their oral and written informed consent to publish the data. Approval from the General Clinical Directorate of our institution was obtained to introduce the novel technique before starting the operations. The study was performed in accordance with the ethical standards of the 1964 Declaration of Helsinki as revised in 2000 and those of Good Clinical Practice.

Inclusion and exclusion criteria

Patients with diagnosis of mild to severe HV were enrolled consecutively and prospectively with precise inclusion criteria over a 2-year period. Ages ranged from 25 to 80 years. Only symptomatic patients with severe pain were included in this study. Exclusion criteria were as follows: congenital deformities of the foot, hallux rigidus, previous first ray trauma or foot and ankle surgery, diagnosis of rheumatic, dismetabolic, neurologic, infective or psychiatric pathologies. Furthermore, patients were excluded if they had painful fixed lesser toe deformities, signs of metatarsalgia or Morton's neuroma.

Surgical procedures

The different procedures for MIS HV correction, as adopted by our institution, were performed as described by De Prado [20]. Among these specific tools, various burrs of different size and form, adapted for Mm960 (produced by Medic Micro, Switzerland), a modular power driver for MIS, were used. During the operation, the patient was in a supine position, with the operated foot protruding from the table. No ankle joint tourniquet was applied, as it is not required for this technique. Prophylactic antibiotic (Cefazolin 2 g) was administered before surgery, and thromboembolic prophylaxis with Nadroparin Calcium injections was prescribed the same evening and for a 30-day period. Anaesthesia consisted in a conscious sedation in association with a regional ankle block, which combines five nerves: three superficial: saphenous, sural and superficial peroneal nerves, and two deep: tibial and deep peroneal nerves.

Exostosectomy

An incision of 3–5 mm long was made at the plantar side of the medial border of the first metatarsal head (Fig. 1a). Through this medial approach, a small scalpel was introduced within the joint capsule of the metatarsophalangeal joint of the big toe. By a sweeping movement, the medial capsule was separated from the exostosis, subsequently using also a rasp (Fig. 1b). The location of this incision prevents damage of the dorsomedial cutaneous nerve of the hallux [20] (Fig. 1c). Then, a cylindrical burr (3.1 × 15 mm) was introduced, and the dorsal medial prominence was removed from the first metatarsal head until a flat surface was obtained, assessed under manual palpation and fluoroscopic control. Finally, the bony detritus was extruded manually.

Reverdin-Isham osteotomy

Through the same incision used for the exostosectomy, a Shannon Isham burr (2 × 12 mm) was introduced at the junction of metaphysis and epiphysis. It was applied to the flat bone surface, achieved previously by exostosectomy, at an angle of approximately 45° to the long axis of the first metatarsal bone, keeping the articular cartilage surface of the first metatarsal head as reference point on the dorsal cortex, and the medial sesamoid bone as the reference point on the plantar cortex (Fig. 2a). In this position, under fluoroscopic control, the osteotomy was started following a distal-dorsal and proximal-plantar direction, extending until the lateral cortex, but without cutting it. At this point, the burr was slightly withdrawn in order to preserve a few millimetres of the lateral cortex, and the osteotomy of the plantar cortex was performed completely. Then, a Wedge burr (3.1 × 13 mm or 4.1 × 13 mm, depending on the DMAA value) was used to create a wedge with a medially oriented base. At the point of closing the wedge, osteoclasis of the preserved lateral cortex was achieved, modifying the

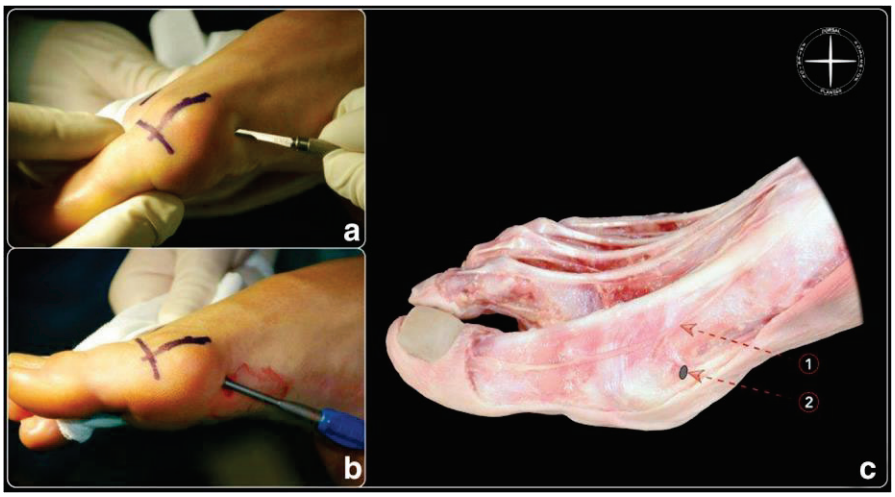

Fig. 1 Portal placement (**a**) and rasp introduction (**b**). The protocolised incision protects the dorsomedial cutaneous nerve of the hallux (**c**): *1* dorsomedial cutaneous nerve of the hallux, *2* point of incision for Reverdin-Isham osteotomy

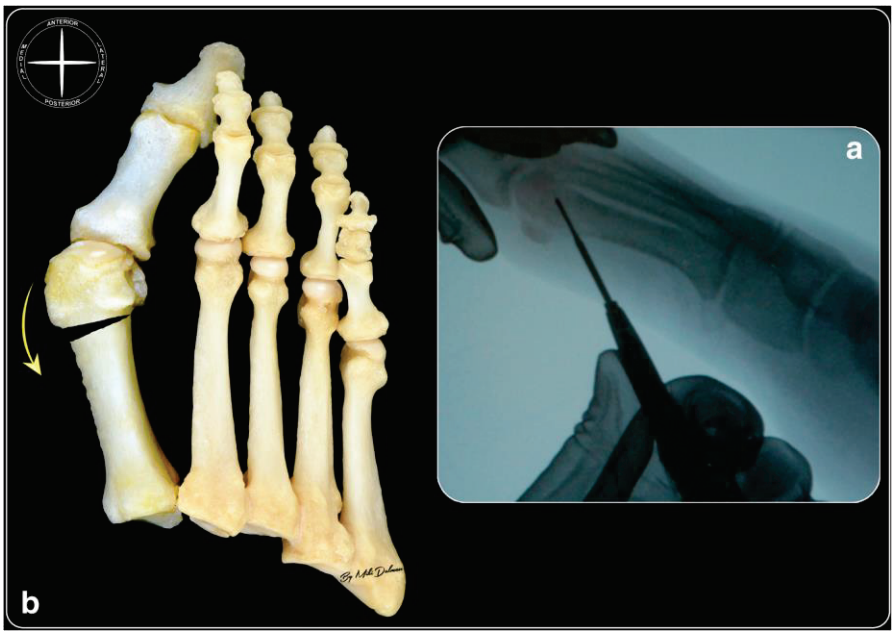

Fig. 2 Reverdin-Isham osteotomy: intraoperative fluoroscopic imagine shoving the proper position and inclination of the burr to respect the distal first metatarsal bone (**a**). The final result of an ideal closing wedge osteotomy with a medial base that corrects also the DMAA (**b**)

orientation of the articular surface, normalizing the DMAA value and adding intrinsic stability to the osteotomy by producing contact of the trabecular bone (Fig. 2b).

Tenotomy of the adductor hallucis tendon and lateral capsulotomy

A longitudinal skin incision was performed on the first web space, 2–3 mm lateral to the extensor hallucis longus tendon. The blade was longitudinally introduced in contact with the lateral surface of the base of the proximal phalanx; then, the blade was rotated 90° laterally and the first toe forced in varus, causing the adductor hallucis tendon to be sectioned and the lateral part of the capsule joint to be cut. Movement of the blade was carefully controlled in order to avoid a complete capsulotomy, which could produce joint instability.

Akin osteotomy

Once lateral soft-tissue release was performed, a new incision 3 to 5 mm long on the lateral surface of the base of the proximal phalanx of the first toe was performed, just medial to the extensor tendons. Using a small scraper, the periosteum was removed from the lateral surface of the base of the proximal phalanx. Then, using a Wedge burr (3.1 × 13 mm), a wedge osteotomy (with medial base) was performed; as in the osteotomy on the head of the first metatarsal, the lateral cortex was preserved. Closing of the osteotomy and osteoclasis of the lateral cortex was achieved by means of a forced varus movement of the toe.

Bandage

After completing the surgery with suture of the capsule and cutaneous sutures of related cuts, a bandage was applied. Because there is no osteosynthesis material in this surgery, the bandage is a very important tool in order to maintain the correction obtained with the operation. Consequently, its application was performed with the utmost care and attention. The first toe was gently placed in overcorrection. Then, with a tape for bandages, the bend of the crisscross bandage was traced between the first and second toes, crossing them over the medial aspect of the exostosectomy in order to reinforce the strength of the bandage. Gentle traction was used to maintain the toe in light hypercorrection and plantar inclination. Finally, the forefoot was covered with tubular gauzes, except for the distal part of the toes and nails (Fig. 3a).

Post-operative protocol

All patients followed the same post-operative protocol and were followed in the same standardized manner by the senior author (C.B.). The patients were allowed to walk as much as they could tolerate the same evening after surgery at discharge, using a rigid flat-soled orthopaedic shoe for the following 30-day period (Fig. 3b). Antero-posterior and lateral X-rays of non-weight-bearing feet were taken before the patients were discharged. We recommended a thromboembolic prophylaxis (Natrium Enoxaparin: 4000 IU/day) and an anti-edemigen therapy (Leucoselect, Lymphaselect and

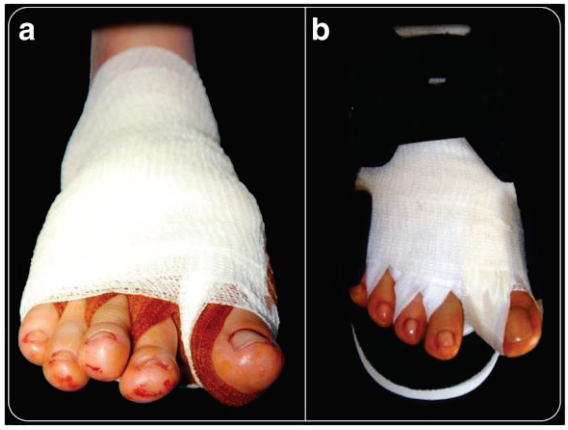

Fig. 3 Example of post-operative bandage (**a**) and rigid flat-soled orthopaedic shoe (**b**)

Bromelina: 1 cp/day) for 30 days, starting from the day of the surgery. Moreover, an analgesic therapy was prescribed for 2 weeks with Etoricoxib (90 mg, 1 cp/day) in the morning, also to prevent articular ossification; if pain persisted, Paracetamol/phosphate Codeine (1 g, max ×3/day) was prescribed. All of the patients were seen once a week for a month in our out-patient clinic. The first visit was 8 days after surgery. The original bandage was removed and substituted by a simpler bandage, but always with a slight overcorrection. During the three weekly visits, the bandage was changed in the same way. One month after surgical treatment, the bandage was totally removed, and after taking antero-posterior weight bearing and lateral X-rays (and sesamoid view when possible), an interdigital silicone orthoses space maintainer was positioned between the first and second toes. Patients were instructed to wear it for 3 months to help the first toe maintain its correct position until complete osteotomy consolidation. They were then able to walk with comfortable shoes, allowing total load on the operated foot. The only recommendations for the patient were to be careful with rough surfaces, sports and any other activities with forefoot overload. No specific physiokinesis therapy was suggested to restart daily activities.

Patient assessment

The clinical and radiological analyses were carried out, respectively, by two independent investigators, the junior authors (M.F. and M.G.R.), not involved in the primary surgical treatment of the patients. The first is a resident of our clinic; the second is an orthopaedic surgeon of a different unit. For this study, all of the patients underwent clinical and radiographic assessment with the same protocol before surgery, as well as at 3 and 12 months and finally at 48 months after surgery, according to the American Orthopaedic Foot and Ankle Society (AOFAS) accepted guidelines [27]. For methodological reasons, the immediate post-operative X-rays at discharge, as well as the 1-month radiographic control, were not included for the radiographic evaluation: first, because it was a non-weight-bearing radiograph and, second, because, although it was weight bearing, in some cases, the sesamoid projection was not performed as the patients had pain or were afraid to excessively dorsiflex the big toe.

Functional outcome measures

The clinical preoperative evaluation included a complete clinical history of the patients, their main characteristics (gender, age at the time of surgery, affected side) and physical examination of the foot. The 100-point AOFAS hallux-metatarso-phalangeal-interphalangeal scale [28] was used to assess clinical outcomes, and the difference (Δ) between preoperative and post-operative median values was calculated. Furthermore, all patients were investigated with the visual analogue scale (VAS). Additionally, any complications were recorded.

Radiographic outcome measures

Routine standing antero-posterior, lateral and sesamoid X-ray views were obtained before surgery and at different follow-ups, according to our protocol. They were analysed at our institution in a standardised manner using electronically computer-assisted measurements for weight-bearing radiographs. The following parameters were evaluated: intermetatarsal angle (IMA: normal value <10°), proximal articular surface angle (DMAA: normal value <6°), hallux valgus angle (HVA: normal value <15°), tibial sesamoid position (using the recommended classification system by the American Foot and Ankle Society [29]), articular surface congruency, metatarsal index [30–32], callus formation in antero-posterior and lateral view radiographs and absence of radiolucent lines to determine bone union.

The relationship among the IMA, HVA values and tibial sesamoid displacement was then used to classify the deformities into three groups according to the presence of one of these Mann and Coughlin parameters [1, 28, 29, 33, 34]:

a) Mild HV was defined as an IMA ≤11° and HVA <20° and less than 50% subluxation of the medial sesamoid (grade 1).
b) Moderate HV was an IMA >11 but <16° and HVA of 20° to 40°, with 50 to 75% subluxation of tibial sesamoid (grade 2).
c) Severe HV was an IMA ≥16° and HVA of >40° and more than 75% subluxation of tibial sesamoid (grade 3).

For each of these angles and tibial sesamoid positions, the difference (Δ) between preoperative and postoperative median values and the effectiveness of procedure correction (%) was calculated.

Statistical analysis

Statistical analyses were performed by an independent statistician from the Department of Statistics at the University of Padua. The data is presented as the mean (plus standard deviation) or median (range) for continuous variables and as numbers for categorical measures. For the statistical evaluation of the angular values and the clinical scores obtained with the AOFAS scale pre-intervention and different follow-ups, we used the Student t test. For angular values not normally distributed, we used the Wilcoxon test of signed ranks. The change in position of the medial sesamoid was analysed by testing the symmetry of Bowker, an extension of the McNemar test for tables larger than 2×2. All p values were two-sided, using a significance level of $p < 0.05$.

Results

Eighty feet, 43 right and 37 left, of 80 consecutively enrolled patients, met the inclusion criteria and were considered in the analyses. The median patient age at the time of the surgery was 51 ± 15.5 years (range 26–78). There were 75 women (93.4%) and 5 men (6.6%). None of the patients was lost during the different follow-ups.

Clinical outcomes

At the preoperative evaluation, the mean total AOFAS score of the patients treated was 54.1 ± 8.3 points (range 39–85). The median of the results was 52 points, and only 12 cases obtained over 60 points. Limitation in daily and recreational activities was implicated in 74 cases (92.50%).

At the different follow-ups until the final one, the mean total AOFAS score of the patients treated improved progressively and significantly (Tables 1 and 2; Figs. 4 and 5): 72.20 points (range 44–100) at 3-month follow-up, 78.60 points (range 44–100) at 12-month follow-up and 87.15 points ± 12.83 (range 52–100) at the final follow-up ($p< 0.0001$). At the final follow-up, the pain was mild, occasional or absent in 73 cases (91.25%). Only two patients (2.50%) still had difficulty or limitation in daily and recreational activities. At the final follow-up period, the mean VAS score was 8.35/10 (3–10).

Radiographic outcomes

According to the Mann and Coughlin grading system, 7 (8.75%) patients were classified in group A (mild HV), 56 (70.0%) in group B (moderate HV) and 17 (21.25%) in group C (severe HV). The radiographic outcomes of our cohort are summarized in Table 3, while the radiographic results for each subgroup are reported in Table 4. Regarding bone/callus formation, complete healing of the osteotomies was noted in all series at 3-month follow-up (Fig. 6).

Intermetatarsal angle (IMA)

The mean IMA value decreased from 12.90° ± 2.83° (range 7.50°–20.00°) preoperatively to 9.00° ± 2.04° (range 5°–14°) at the 48-month follow-up (Fig. 7a), with a mean correction of 3.90° and an effectiveness of 30.23% ($p < 0.05$).

Hallux valgus angle (HVA)

The mean preoperative HVA was 26.40° ± 6.75° (range 10°–47.5°). The mean value at the 48-month follow-up assessment was 13.90° ± 6.25° (range 0°–34.00°), with a mean correction of 12.50° (Fig. 7b) and an effectiveness of 47.35% ($p < 0.05$).

Distal metatarsal articular angle (DMAA)

The mean preoperative DMAA was 10.12° ± 4.26° (range 3.5°–26.00°). The mean value at the 48-month follow-up examination was 5.40° ± 3.19° (range −1.00° to 15.00°) with a mean correction of 4.72° (Fig. 7c) and an effectiveness of 46.64% ($p < 0.05$).

Medial sesamoid position

The mean preoperative dislocation of the medial sesamoid was 2.40 ± 0.64 (range 1–3). Its mean value at the 48-month follow-up assessment was 1.30 ± 0.63 (range 0–3), with a mean correction of 1.10 (range 0–3) and an effectiveness of 45.83% ($p < 0.0001$) (Fig. 7d).

Articular surface congruency

In the preoperative period, 61 patients (76.25%) had a congruent articular surface and 19 (23.75%) incongruent. At final follow-up, 77 patients (96.25%) had a congruent articular surface and only 3 (3.75%) incongruent.

Metatarsal index

In the preoperative period, the metatarsal index of patients was Minus (M1 < M2) in 34 cases (42.5%), Plus Minus (M1 = M2) in 28 cases (35.0%), and Major (M1 > M2) in 18 cases (22.5%). At the last follow-up, it resulted Minus (M1 < M2) in 58 cases (72.5%), Plus Minus

Table 1 AOFAS score at different follow-ups

	Preoperative	3 months	12 months	48 months	p value
Mean AOFAS score (pts)	54.1 (±8.3)	72.2	78.6	87.1 (±12.8)	$p < 0.0001$

Table 2 AOFAS score before surgery and at final follow-up (48 months)

	Preoperative (%)	Last follow-up (%)
Pain		
None	2.5	62.5
Mild, occasional	19	28.75
Moderate, daily	78.5	8.75
Severe, almost always present	0	0
Activity limitations		
No limitations	7.5	76.5
Limited daily and recreational activities	60	21
Severe limitation	32.5	2.5
Footwear requirements		
Fashionable, conventional shoes	13.5	44
Comfort footwear, shoe insert	82.5	56
Modified shoes or brace	4	0
MTP joint motion		
Normal or mild restriction >75°	82.5	61
Moderate restriction 30°–74°	17.5	37.5
Severe restriction <30°	0	1.5
Callus related to hallux MTP-IP		
No callus or asymptomatic callus	39	93.75
Callus symptomatic	61	6.25
Alignment		
Good, hallux well aligned	0	68.75
Fair, no symptoms	0	23.7
Poor obvious symptomatic malalignment	100	7.5

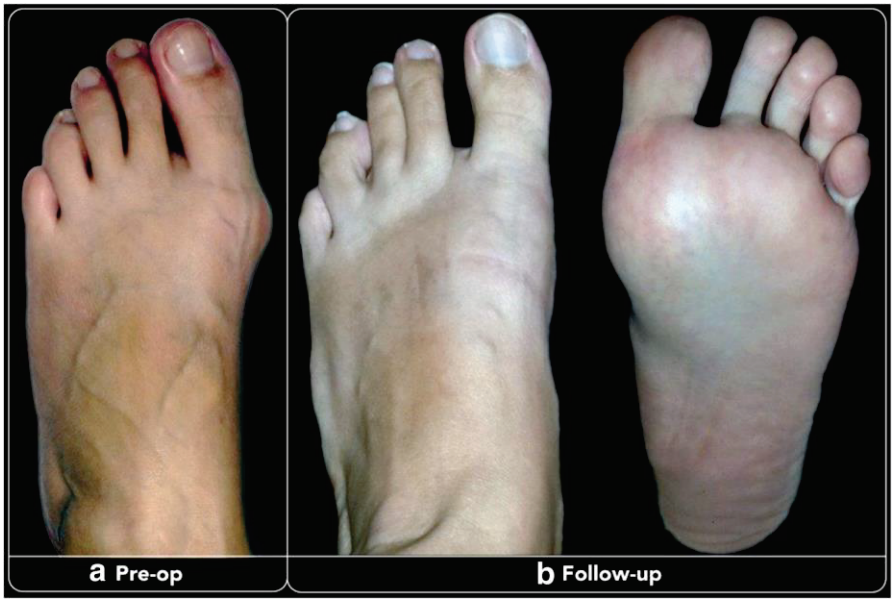

Fig. 4 Pre-op (**a**) and at 48-month last follow-up (**b**) clinical images of a 36-year-old woman after having undergone percutaneous Reverdin-Isham osteotomy, lateral release and Akin osteotomy for mild HV correction

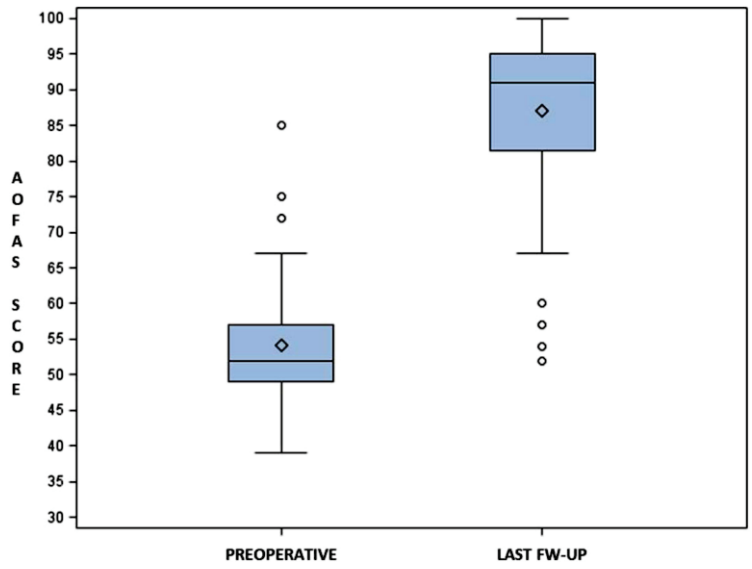

Fig. 5 Graph of statistical analysis of preoperative and post-operative AOFAS scores ($P \leq 0.05$)

(M1 = M2) in 19 cases (23.75%), and Major (M1 > M2) in 3 cases (3.75%).

Complications

Complications occurred in 25 patients (31.25%): six major and 19 minor. The major complications (7.5%) included five cases of recurrence and one case of severe stiffness (ROM <30°). The minor (23.75%) complications were slight loss of normal range of MTP joint motion (ROM 30°–74°) in 16 cases. In three other cases, minor complications were resolved over time. Because of portal burns during operation, two patients presented delayed wound healing, which healed completely in 4 weeks and did not required subsequent surgery. One patient complained of dysesthesia of the skin distal to the interphalangeal joint of the big toe because of neuritis of a cutaneous sensory dorsal branch, an infrequent complication caused by incorrect surgical access, which had resolved spontaneously by the final follow-up. We did not encounter any cases of hallux varus due to overcorrection, malunion, delayed union or non-union. There were no cases of thrombo-embolism, no cutaneous or deep infections nor avascular necrosis of the metatarsal head. No case of dorsal displacement of the metatarsal head was recorded in this study.

Discussion

Although in the last few years, the number of studies regarding the effectiveness of MIS in HV correction has increased [35–37], to the best of our knowledge, this is the first prospective, single-centre study reporting outcomes of Reverdin-Isham percutaneous osteotomy in a consecutive, single surgeon, large patient series with a median follow-up of 48 months. Furthermore, no other report in the literature has assessed the results of this procedure at three different follow-ups. The study was designed to evaluate, on the basis of clinical and computer-assisted radiographic data, the validity and reliability of this percutaneous techniques for correction of mild to severe HV deformity.

In our cohort, the mean AOFAS score improved significantly until the last follow-up (Tables 1 and 2). An increase of 18.1 points 3 months after surgery was seen, further 6.7 points at 12 months and 33 points at the last follow-up. Moreover, more than half of the patients scored more than 90 points, while the median, statistically the more "powerful indicator," was 91 points, in contrast to 52 points in the preoperative period. This clinical improvement was also evident in all patient subgroups, almost in the same way, maintaining unaltered the gradient correlated to the degree of the deformity. In the sub-groups, the mean AOFAS score at the last follow-up was 87.1 points ($\Delta = +32.1$) in the mild HV group, 86.6 ($\Delta = +32.7$) in the moderate HV group and 83.7 ($\Delta = +30.2$) in the severe one. Overall, the AOFAS score found in our study was comparable to those reported by different authors not only using minimally invasive techniques [10, 12, 13, 25, 26, 38], with or without osteosynthesis, but also with series of open surgical procedures using Chevron, Scarf or proximal metatarsal osteotomies [10, 13, 19, 39, 40]. In particular, our data was similar for patient demographic aspects and complications, including stiffness; however, our group of patients had a larger sample size and follow-up duration [10, 13, 19, 39]. At the last follow-up, only seven patients reported daily pain, compared to 63 cases (78.5%) of the

Table 3 Angular values (IMA, HVA and DMAA), sesamoid position, metatarsal index and congruency of the metatarso-phalangeal-I articular surface

	Pre-op	3-month FU	12-month FU	48-month FU	Efficacy (%)
IMA (degrees)					
Tot. (DS)	*12.9 (2.8)*	*9.0*	*9.0*	*9.0 (2.0)*	*30.23*
Mild	9.1			7.1	22.0
Moderate	12.1			9.0	27.3
Severe	16.6			10.0	39.2
HVA (degrees)					
Tot.	*26.4 (6.7)*	*12.3*	*13.1*	*13.9 (6.2)*	*47.35*
Mild	16.4			9.8	40.2
Moderate	26.0			14.2	45.0
Severe	32.0			14.7	54.0
DMAA (degrees)					
Tot.	*10.12 (4.3)*	*5.0*	*5.2*	*5.4 (3.2)*	*46.64*
Mild	6.3			3.9	38.1
Moderate	10.0			5.3	47.0
Severe	12.4			6.5	47.6
Sesamoid Position (pts)					
Tot.	*2.4 (0.6)*	*1.1*	*1.2*	*1.3 (0.6)*	*45.83*
Mild	2.0			0.9	55.0
Moderate	2.3			1.3	43.5
Severe	2.8			1.7	39.3
Metatarsal Index					
M1 < M2	34			58	
M1 = M2	28			19	
M1 > M2	18			3	
MTP-I Art. Sup.					
Congruent	61			77	
Incongruous	19			3	

Table 4 Preoperative and last follow-up (48 months) angular values

	Mild HV	Moderate HV	Severe HV	*p* value
IMA				
Preoperative	9.1 (±0.7)	12.1 (±1.9)	16.6 (±2.1)	$p < 0.0001$
Last follow-up	7.1 (±0.8)	9.0 (±1.9)	10.0 (±2.2)	$p < 0.0001$
HVA				
Preoperative	16.4 (±3.1)	26.0 (±4.93)	32.0 (±7.7)	$p < 0.0001$
Last follow-up	9.8 (±5.8)	14.2 (±5.9)	14.7 (±7.3)	$p < 0.0001$
DMAA				
Preoperative	6.3 (±1.22)	10.0 (±4.0)	12.4 (±4.7)	$p < 0.0001$
Last follow-up	3.9 (±2.5)	5.3 (±3.0)	6.5 (±3.9)	$p < 0.0001$
Sesamoid position				
Preoperative	2.0 (±0.6)	2.3 (±0.6)	2.8 (±0.4)	$p < 0.0001$
Last follow-up	0.9 (±0.7)	1.3 (±0.6)	1.7 (±0.7)	$p < 0.0001$

preoperative period, while most of the subjects (73 cases; 91.5%) reported no pain or only mild occasional pain (Table 2). These percentages are similar to those of other studies [10, 24, 25]. Despite the anti-edema prophylaxis adopted, 40% of our subjects complained of swelling of the foot and ankle, which remained for more than a month after the operation. Apparently, the causes of both prolonged pain and swelling in these cases were related to the delayed formation of bone callus until the complete healing of the osteotomies seen at 3-month follow-up.

According to the AOFAS scale, the alignment was considered good in 55 cases (69%), discrete in 19 cases (23.5%) and poor in 6 (7.5%). Overall, in 92.5% of our cases, there was improvement, which is comparable with that reported in the literature [10, 25, 35, 38–44] (Figs. 5 and 6).

One of the possible side effects of Reverdin-Isham percutaneous osteotomy, as it is an intra-articular medial

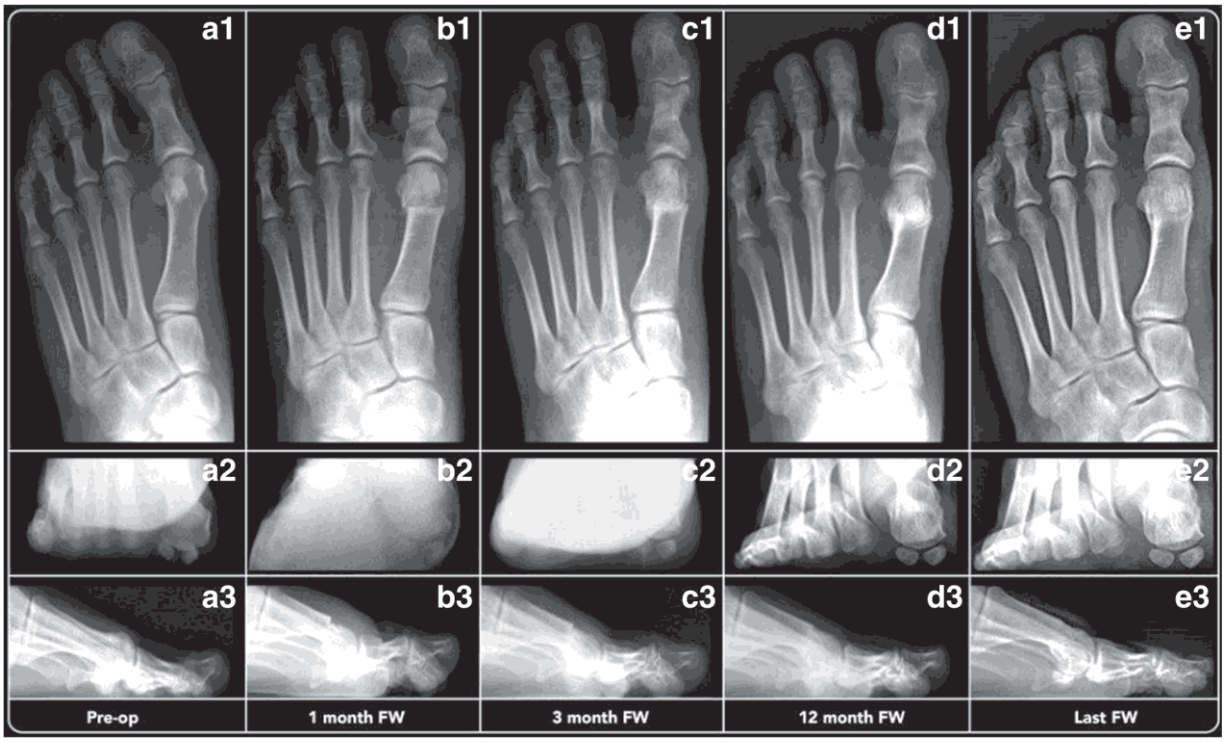

Fig. 6 A 36-year-old woman with mild HV: *1* antero-posterior radiographic images, *2* sesamoid and *3* lateral view at preoperative period (*a*), 1-month follow-up (*b*), 3-month follow-up (*c*), 12-month follow-up (*d*) and 48-month follow-up (*e*), showing the maintained correction of the deformity

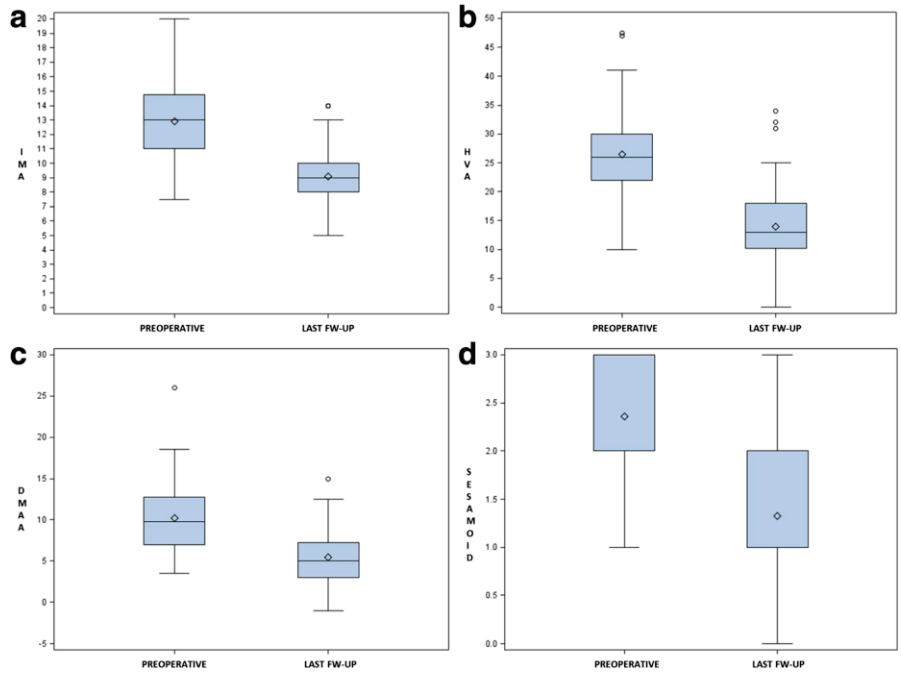

Fig. 7 Graph of statistical analysis of preoperative and post-operative different angular values ($p \leq 0.05$): IMA (**a**), HVA (**b**), DMAA (**c**) and tibial sesamoid position (**d**)

closing wedge osteotomy, is the stiffness of the first metatarso-phalangeal joint [45, 46], which was noticed also in our cohort. Before the operation, 66 cases (82.5%) presented with preserved range of motion and the other 14 cases (17.5%) with slight limitation. After surgery, the joint movement was completely normal in 49 cases (61%) and was slightly reduced in another 30 cases (37.5%), while severe limitation to the flexion-extension was present only in an elderly patient. In accordance with Bauer et al., the potential cause could be the remains of bony fragments in the joint and the capsular tissues, produced during the extensive exostosectomy and the lack of accurate cleaning of the work area with rasps and irrigation with normal saline solution [35].

There were three intraoperative complications, which had resolved spontaneously by the final follow-up: one neuritis of a cutaneous sensory dorsal branch and two skin burns around the portal. Several studies have been reported in the literature [47, 48] comparing the complication rate between diathermy and scalpel for skin incision, without showing any significant differences. However, to the best of our knowledge, no study has examined the complication rate of surgical burr in MIS. In our experience, it is a fundamental surgical aspect to avoid putting too much manual pressure on the burr during the performance of osteotomies, rather accompanying it gently with the fingers during the entire process; otherwise, the resistant bone can push the burr to the edges of the portal, causing skin burn.

With regard to radiographic analysis (Table 3), all correction angular values obtained in our cohort were statistically significant ($p < 0.0001$). Although the distal closing wedge osteotomy has been described without resulting in any lateral translation of the metatarsal head, the IMA decreased from a mean value of 12.9° at preoperative examination to a mean value of 9.0° at the final follow-up, with a difference of 3.9° and an efficacy of 30.5% in angular value correction. In agreement with Bauer et al. [10, 21, 35], the Reverdin-Isham osteotomy has a slight impact on this angle, reporting an IMA mean improvement of about just 3°, again a better mean correction of about 8° and 15° for the DMAA and HVA, respectively. According to our experience, the efficacy in IMA correction is probably explained by the combined action between the three different surgical steps of the procedure. First, during the application of manual force to perform the lateral cortex osteoclasis at the step of the wedge closing, a minimum translation of the metatarsal head occurs (Fig. 6 B1–E1). It is known that distal osteotomies allow achieving proximally 1° of IMA correction for each millimetre of metatarsal head lateral translation [49, 50]. Second, the tenotomy of the adductor hallucis tendon and lateral capsulotomy contributes to the lateral movement of the first metatarsal axis, further decreasing its varus. Third, Isham in his original paper of 1991, stated that the average reduction of the IMA is especially noted when the procedure is performed in association with Akin osteotomy [19].

For the HVA, the effectiveness in angular value correction was 47.4%, with a preoperative mean value of 26.4° and 13.9° at the last follow-up, respectively. One of the objectives of distal osteotomies is to reduce the DMAA by a medial rotation of the metatarsal head. In the analysed sample, average correction efficacy was 46.1%; the mean preoperative angular value was 10.2° and 5.4° at the final follow-up. According to Coughlin [29], it is very important to correct DMAA, since a stable recovery can be achieved only by setting up the bone structure, re-orienting articular surfaces and re-equilibrating muscle forces of the first ray, avoiding the retraction of soft tissue and peri-articular adhesions. As reported in the literature [10, 24, 35, 39, 42], confirmation of the re-orientation of the forces on the muscle-ligamentous compartment was seen as restoration of the articular congruency and sesamoid compartment alignment.

Reverdin-Isham percutaneous osteotomy was a reliable procedure in correcting the different radiological parameters considered in this analysis, and our data are comparable with the reported angular corrections obtained with other percutaneous or open distal metatarsal osteotomies [13, 39, 42, 51]. Derotation of the metatarsal head (DMAA), and the anatomical reduction of the tibial sesamoid, necessary to prevent the recurrence of valgus [52], were all maintained until the last follow-up (Table 3). However, the results obtained in the correction of the HV severe deformities were less encouraging. In fact, the correction efficacy of the different single angles analysed, although high, was in some cases not sufficient to report them as in the normal range (Table 4). The six major complications of our series occurred in the severe forms, with an IMA greater than 15°. Hence, in accordance with Bauer et al. [10], we believe this is the angular value limit, beyond which the use of only Reverdin-Isham osteotomy as described is not recommended.

The first strength of this study is its nature: a prospective evaluation of a consistent group of 80 patients with the same fixed follow-up points. A 48-month follow-up can be considered a long follow-up period compared with previous published studies. Further, all operations and the post-operative controls were always performed in the same way by the same surgeon (C.B.). All clinical and radiographic data were collected and analysed separately by the same two independent investigators, who were not involved in the patients' treatment and one not belonging to our unit. The main limitation of this study is the lack of a control group, which would be useful to compare the results of this percutaneous technique. However, as reported by several authors [15, 42, 44, 53], MIS includes different

techniques, and the heterogeneity of the groups examined in various reports does not permit at present an effective comparison and clear conclusions. For these reasons, we believe that long-term follow-up with multicentre studies and randomized controlled clinical trials comparing Reverdin-Isham osteotomy outcomes to those of other percutaneous methods would provide useful information for the validity and reliability of MIS in the treatment of forefoot deformities.

Conclusions

Based on our experience in MIS with the first cohort of patients described in this report, we conclude that Reverdin-Isham and Akin percutaneous osteotomy in combination with previous exostosectomy and following lateral soft-tissue release is a safe, effective and reliable procedure for correction of mild-to-moderate symptomatic HV. Good results remained consistent at the mid-term follow-up point. The most important aspects that should encourage the use of this percutaneous technique are its minimally invasive nature, the low number of complications, the absence of osteosynthesis, distal ankle block anaesthetic technique, early weight bearing and good cosmetic results with minimal surgical scars.

Abbreviation

AOFAS: American Orthopaedic Foot and Ankle Society; DMAA: Distal Metatarsal Articular Angle; GRECMIP: Groupe de Recherche et d'Enseignement en Chirurgie Mini-Invasive du Pied; HV: Hallux Valgus; HVA: Hallux Valgus Angle; IMA: Intermetatarsal Angle; MIS: Minimally Invasive Surgery; VAS: Visual Analogue Scale

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Availability of data and materials

The dataset supporting the conclusions of this article is available at our institution.

Authors' contributions

CB contributed to the study concept and design and wrote the paper. MF and MGR carried out the data collection and analysis. MDP participated in the figure design and review. MC interpreted the data. RA and PR participated in the final review. The manuscript has been read and approved by all of the listed authors, who declare that this article represents honest work.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

The patients gave their oral and written informed consent to the publication of their anonymous and clustered data and anonymous pictures.

Ethics approval and consent to participate

This clinical practice observational study was performed in accordance with the ethical standards of the 1964 Declaration of Helsinki as revised in 2000 and those of Good Clinical Practice. Further, the approval from the Padua Hospital General Clinical Directorate was obtained to introduce the novel technique before starting the operations and analyse their clinical and radiographic outcomes during the study. For these reasons, ethics approval of Padua Hospital Ethical Committee was not mandatory. All patients received a thorough explanation of this study and informed consent to participate was obtained from the participants.

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10.4. Minimally Invasive Intramedullary Nail Device (MIIND)

For this MI technique, used to treat moderate to severe HV, the following original article [6] was included:

- ***Functional and Radiographic Outcomes of Minimally Invasive Intramedullary Nail Device (MIIND) for Moderate to Severe Hallux Valgus.*** Foot Ankle Int. **2021** Apr;42(4):409-424. doi: 10.1177/1071100720969676. PMID: 33319594.

  This study was aimed at assessing clinical and radiographic outcomes of the MIIND, to correct moderate to severe HV and the long-term persistence of its effects. This case series study involved 100 patients, 84 women and 16 men **(**mean age 59 years), who underwent the MIIND procedure with a mean follow up of 97 months. Assessment was performed preoperatively, postoperatively, at 6 and 12 months and at last FU. Clinical outcomes were evaluated with AOFAS scores, VAS and patient satisfaction. The IMA, HVA, DMAA and TSP were assessed. Statistical analysis was performed. The mean AOFAS score improved from 57.9 to 90.5 points, VAS scale resulted 1.50 ± 2.04 and patient satisfaction was 8.65 ± 1.41. The mean correction of the HVA and IMA showed a significant correction; however, the effect of time was not statistically significant on DMAA. Sex (p = .047), severity (p = .050), associated procedures (p = .000) and preoperative angle (p = .000) showed significant association with HVA correction and its persistence over time. Age was not statistically significant. Complications: 9 cases of superficial wound infection and 6 recurrences. The MIIND technique proved a viable procedure to correct moderate to severe HV with a low rate of complications and recurrence, producing significant correction of most radiographic parameters assessed and their persistence even at long term.

Article

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Functional and Radiographic Outcomes of Minimally Invasive Intramedullary Nail Device (MIIND) for Moderate to Severe Hallux Valgus

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Abstract

Background: This study was aimed at assessing clinical and radiographic outcomes of the Minimally Invasive Intramedullary Nail Device (MIIND) to correct moderate to severe hallux valgus (HV) and the long-term persistence of its effects.

Methods: This case series study involved 100 patients, 84 women and 16 men (mean age, 59 years), who underwent the MIIND procedure with a mean follow-up of 97 months. Assessment was performed preoperatively, postoperatively, at 6 and 12 months, and at last follow-up. Clinical outcomes were evaluated with American Orthopaedic Foot & Ankle Society (AOFAS) scores, visual analog scale (VAS), and patient satisfaction. Intermetatarsal angle (IMA), metatarsophalangeal hallux valgus angle (HVA), distal metatarsal articular angle (DMAA), and tibial sesamoid position were assessed. Statistical analysis was performed.

Results: The mean AOFAS score improved from 57.9 to 90.5 points, VAS scale was 1.5 ± 2.0, and patients' satisfaction was 8.7 ± 1.4. The mean correction of the HVA and IMA showed a significant correction; however, the effect of time was not statistically significant on DMAA. Sex ($P = .047$), severity ($P = .050$), associated procedures ($P = .000$), and preoperative angle ($P = .000$) showed significant association with HVA correction and its persistence over time. Age was not statistically significant. Complications were 9 cases of superficial wound infection and 6 recurrences.

Conclusions: The MIIND technique proved a viable procedure to correct moderate to severe HV with a low rate of complications and recurrence, producing significant correction of most radiographic parameters assessed and their persistence, even at long term.

Level of Evidence: Level IV, case series study.

Keywords: bunion correction, distal osteotomy, Endolog, forefoot disorders, hallux valgus, Minimally Invasive Intramedullary Nail Device, minimally invasive surgery

Hallux valgus (HV) surgery is one of the most frequently performed orthopedic interventions of the forefoot.[53] Nevertheless, its ideal operative treatment, in relation to the severity of deformity, is still debated among foot and ankle surgeons.[51,66] Operative correction is the standard treatment of symptomatic HV, as it is more effective compared to nonoperative methods.[22] For this reason, many different open, minimally invasive (MI) and percutaneous operative procedures have been proposed,[6,40,49] but their choice seems to depend in most cases on the surgeon's experience and preferences or patients' demands rather than a proper radiographic preoperative assessment and consequent protocol of care.[23,50,62]

To standardize the treatment according to HV severity, distal first metatarsal (I-MTT) osteotomies are generally indicated for mild or moderate deformities.[23,40,64] However, because it is mostly the site of the osteotomy that determines the potential of angular correction, this remains limited in cases of distal procedures.[28] Hence, to correct moderate to severe HV, proximal I-MTT osteotomies are preferred for their higher corrective potential.[54,70,72]

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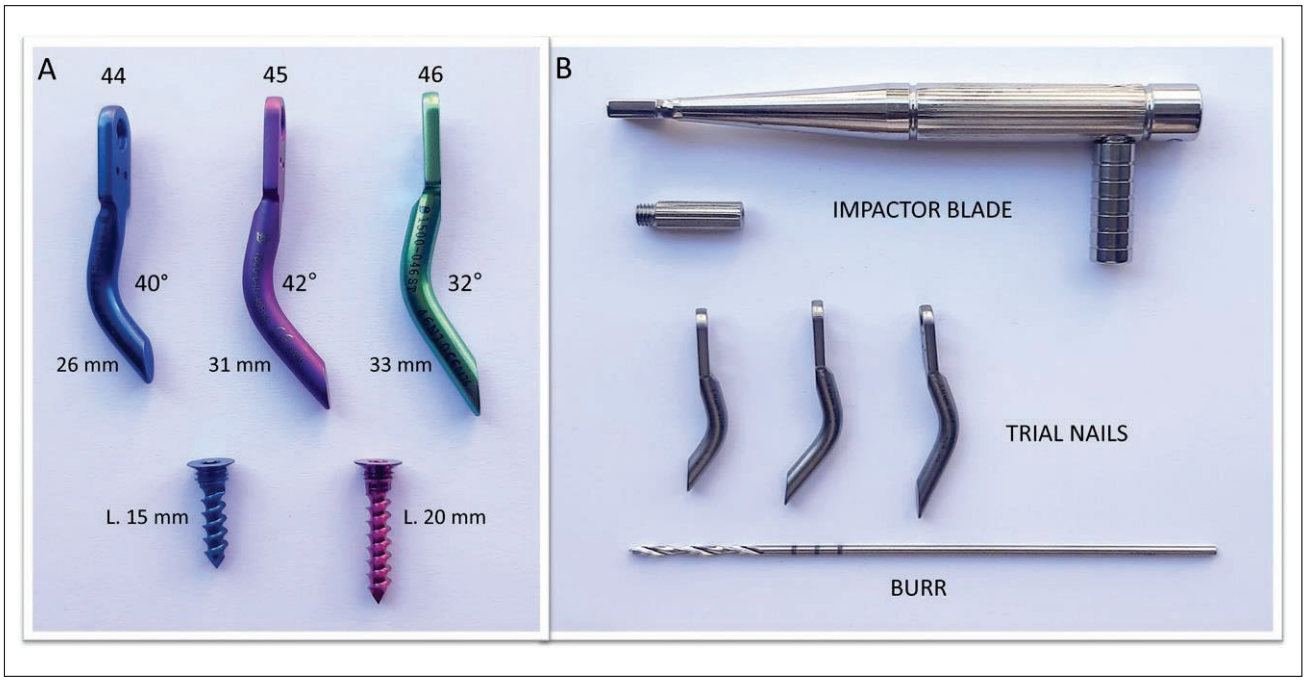

Figure 1. (A) Image of the 3 different sizes of the Minimally Invasive Intramedullary Nail Device (44, 45, and 46), each with different degrees of curvature (40, 42, and 32 degrees, respectively) and lengths (26 mm, 31 mm, and 33 mm); two 3.66-mm titanium angular stable screws (15 mm and 20 mm) are available for its fixation. (B) The complete kit of the device, including impactor blade for its application, trial nails for test during surgery, and burr to make the screw hole.

Nevertheless, an associated Akin osteotomy is often suggested for these procedures.[67]

Recently, MI procedures have become popular for their decreased recovery times, smaller scars, and a greater range of early postoperative motion.[6,32,44,47,49,61] Among these, a Minimally Invasive Intramedullary Nail Device (MIIND), produced under the name of Endolog (by Medical Due), has been proposed for mild to severe HV correction, and it has shown encouraging results at medium-term follow-up.[4,5,21] Our initial experience with this device showed the most evident functional improvements for moderate to severe HV,[5] while for mild HV, purely percutaneous procedures are preferred at our institution.[6]

The MIIND consists of a curvilinear cylindrical titanium body with a diameter of 4.5 mm and a blade inclined by 4 degrees with respect to the axis of the nail. It is available in 3 sizes (44, 45, and 46) with 3 different degrees of curvature (40, 42, and 32 degrees, respectively) and 3 different lengths (26 mm, 31 mm, and 33 mm). Using a 3.66-mm titanium angular stable screw, available in 2 different lengths (15 mm and 20 mm), it is fixed to the first metatarsal head (I-MTTH), stabilizing the osteotomy site (Figure 1). This device produces progressive lateral displacement of the I-MTTH, up to 100% with respect to the metatarsal neck (MTTN), and its contemporary derotation, allowing multiplanar correction of the HV and the anatomic reduction of the sesamoids without performing lateral release (LR). Furthermore, it does not require routine removal.

Despite the extensive literature on the operative treatment of this deformity, very few studies, mostly retrospective, have been conducted on a longer term follow-up on the different osteotomies proposed for bunion surgery and none regarding the MIIND.[23,62] A recent review on HV recommended that research should be directed toward assessing outcomes at long-term follow-up postoperatively.[39] Hence, the aim of this case series study was to assess clinical and radiographic results of the MIIND technique for the correction of moderate to severe HV in a subsequent, wide series of patients, at different follow-up points, with a final one at long term. Our study hypothesis was that this mini-incision procedure with direct view of the I-MTT can achieve and maintain satisfactory functional and radiographic outcomes over time with an acceptable complication rate after moderate to severe HV treatment.

Methods

Patients

In this single-center, case series study, clinical and radiological data were prospectively collected and retrospectively analyzed. Local ethics committee approval was obtained.

All patients with a diagnosis of moderate to severe HV, having failed conservative management and fulfilling the following inclusion criteria, were enrolled consecutively from September 2009 to September 2012 before evaluating their outcomes. Inclusion criteria were age between 20 and 80 years (according to the indications of our institutional forefoot operative protocol), moderate to severe HV with persistent pain in the area of the I-MTTH, and having particular discomfort while wearing shoes. According to the presence of one of these Mann and Coughlin parameters,[18] moderate HV was defined as an intermetatarsal angle (IMA) >11 degrees but <16 degrees and metatarsophalangeal hallux valgus angle (HVA) of 20 to 40 degrees, with 50% to 75% subluxation of the tibial sesamoid, tibial sesamoid position (TSP: grade 2); severe HV was an IMA ≥16 degrees and HVA of >40 degrees and more than 75% subluxation of the tibial sesamoid (TSP: grade 3). Symptomatic HV was the only indication for operative treatment. Pain was evaluated using a visual analog scale (VAS) for rating pain, ranging from 0 to 10 points (with 0 denoting no pain and 10 denoting the worst pain imaginable); only patients reporting VAS ≥5 were operated on. Specific patient exclusion criteria were as follows: previous foot surgery or trauma, diagnosis of diabetes mellitus, rheumatic diseases, foot neuropathy, vascular insufficiency, generalized joint laxity or hypermobility of the first ray more than 8 mm, and hallux rigidus.

We used these strict selection criteria to avoid possible confounding factors, having hypothesized for some of them a probable impact on the generalizability of our results. Specifically, we excluded some conditions, such as generalized joint laxity or hypermobility,[8] which, while having a specific correlation with HV, are usually treated in a different way.[29,38]

At our institution during the 3-year enrolled period, a consecutive series of 100 patients (45 right and 55 left feet), including 84 women and 16 men (male/female = 1:5.3) with a mean age of 59.0 ± 12.1 years (range, 20-80 years), underwent the MIIND technique for moderate (grade 2: 69) and severe (grade 3: 31) symptomatic HV.

Operative Technique

In this case series, the preoperative protocol, postoperative management, and the 1-day hospital stay detailed operative procedure for MIIND implantation were executed only by the senior author, as previously described.[5] Anesthesia consisted of conscious sedation in association with a regional ankle block. The patient was in a supine position and a tourniquet was applied at the level of the ankle. The operative procedure started with a 3-cm dorsal-medial longitudinal incision centered on the I-MTT. Then, the capsular incision was performed along the line of the skin incision. A very minimal, oblique bunionectomy removed the prominent medial eminence. This allowed the support of the impactor's blade upon which the device was assembled (Figure 2A). Perfect coplanarity and maximum adherence of the pallet support to the flat surface previously created on the I-MTTH were essential for a correct position of the MIIND (Figure 2B). The oblique bunionectomy was carried out with a thickness no more than 2 to 4 mm from the distal part of the medial eminence, close to the articular surface, to zero at the level of the MTTN, allowing lateral translation and at the same time derotation of the I-MTTH, which were pushed and maintained by the nail after its application. For this purpose, two 1.6-mm Kirschner wires, acting as joysticks, were inserted to allow the derotation of the metatarsal head during its lateral translation. A linear osteotomy was then performed at the proximal level of the MTTN. The trial nail device was assembled on the impactor and then gently introduced into the medullary cavity with progressive lateral displacement of the MTTH and its concomitant derotation, correcting the distal metatarsal articular angle (DMAA) and sesamoid subluxation. Before the right size of MIIND was applied, the correction obtained was checked clinically and under fluoroscopy (Figure 2C). The MTTH was fixed to the implant with a screw long enough to provide angular stability (Figure 2D). It was necessary to regulate the medial angle of the MTTN using the micro-saw to prevent conflict of the bone with the soft tissues and skin before closing the capsule and suturing the wound.

Although preoperative planning was useful for choosing which size of the implant could guarantee adequate translation of the head according to the severity of the HV (ie, MIIND-45, presenting the greatest curvature, allows the greatest translation) and width of the I-MTT bone medullary cavity (Figure 3A), it was not possible to standardize the exact lateral translation of the I-MTTH. Hence, trial nails in the different sizes were used intraoperatively.

According to the preoperative degree of valgus (grade 3) or in cases of concomitant hallux valgus interphalangeus (HVI) greater than 10 degrees or an HVA persisting more than 10 degrees after MIIND application, a percutaneous Akin osteotomy was performed. For the other common pathologies of the forefoot, the following adjunctive operative procedures were carried out: distal metatarsal metaphyseal osteotomy (DMMO) for metatarsalgia,[5,30] and/or percutaneous osteotomy of the proximal phalanx for fixed deformities of the lesser toe, and/or percutaneous tenotomy of the flexor and extensor tendons in cases of flexible or fixed lesser toe deformities.[7]

As the MIIND technique provides a linear extra-articular osteotomy to the proximal level of the neck, the release of the soft tissues on the lateral side of the first metatarsophalangeal joint (I-MTPJ) was not performed, nor was lateral capsulotomy of the joint carried out for repositioning of the sesamoids.

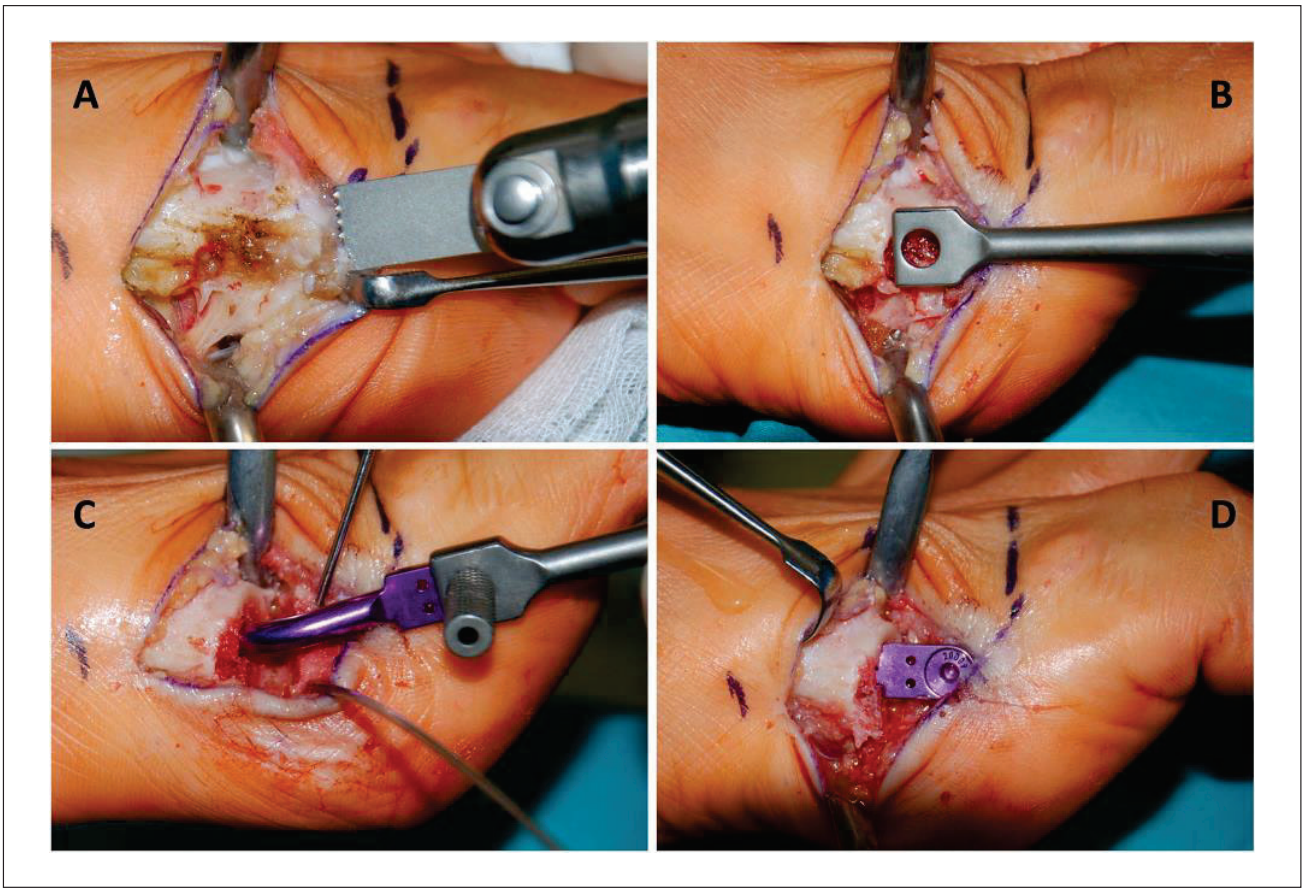

Figure 2. (A) Intraoperative images showing the main steps of the Minimally Invasive Intramedullary Nail Device (MIIND) technique: bunionectomy is performed to remove the medial eminence by a standard oscillating micro-saw in a distal to proximal direction. (B) A flat surface on the first metatarsal head (I-MTTH) is made to support the impactor's blade and ensure maximum adherence with the blade pallet support. (C) The MIIND-45 is applied definitively to maintain the correction by progressively lateral displacement and concomitant derotation of the I-MTTH. Previously, a linear osteotomy was performed at the proximal level of the neck and the trial nail was introduced into the medullary cavity to verify adequate alignment of the first ray. (D) Finally, the I-MTTH is fixed to the MIIND implant with a 20-mm screw, providing angular stability.

Postoperative Protocol

Anteroposterior and lateral x-rays of feet were taken before the patients were discharged and at 1-month follow-up (the first were not included for the radiographic evaluation because they were nonweightbearing). The patients were allowed to walk as much as they could tolerate the same evening after surgery at discharge using a rigid flat-soled orthopedic shoe for the following 30-day period, according to the indications of our institutional forefoot postoperative protocol also used for other MI techniques.[6]

A prophylactic antibiotic was administered only before surgery, and thromboembolic prophylaxis with nadroparin calcium was prescribed the same evening for a 10-day period. We recommended an antiedemigen therapy (Leucoselect, Lymphaselect, and Bromelain [Laborest]: 1 tablet/d) for 30 days, starting from the day of the surgery, and an analgesic therapy for 2 weeks with Etoricoxib (90 mg, 1 cp/d) in the morning, also to prevent heterotopic ossification. All patients were seen once every 2 weeks for a month in our outpatient clinic, where functional taping was replaced at the first appointment.

Clinical and Radiological Outcome Measures

The clinical and radiological analyses were carried out by 2 independent investigators, senior orthopedic residents and junior authors, who were not directly involved in the patients' operative treatment. The resident who performed clinical assessment was blinded to the type of procedure used. After a period of training in HV measurement techniques by the senior author, the resident who performed radiographic evaluation used a digital workstation and software (MedStation program) to minimize bias during the measurements.[16]

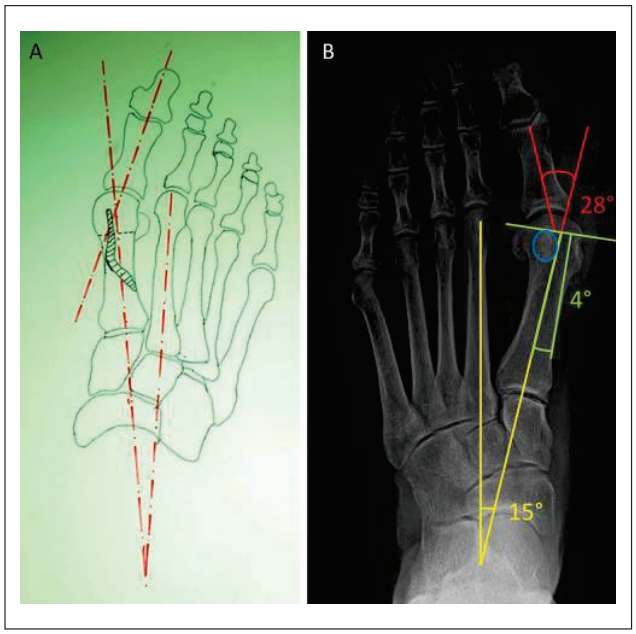

Figure 3. (A) Image of preoperative planning before surgery to choose the right size of the implant, to ensure adequate translation of the head according to the hallux valgus severity and width of the first metatarsal bone medullary cavity. (B) Example of electronically computer-assisted measurements (MedStation program) from weightbearing anteroposterior radiographs of the following angles and tibial sesamoid position (TSP) to define the deformity according to Mann and Coughlin parameters[15]: intermetatarsal angle (15 degrees), hallux valgus angle (28 degrees), distal metatarsal articular angle (4 degrees), and TSP (circle).

Clinical evaluations were performed pre- and postoperatively at 6 months, 12 months, and last follow-up. The hallux-metatarsophalangeal scale by the American Orthopaedic Foot & Ankle Society (AOFAS) was used. A VAS for rating pain was evaluated at last follow-up. The patients were asked whether they were satisfied with the overall result of the procedure or not, using the VAS for patient satisfaction, ranging from 0 to 10 points (with 0 indicating no satisfaction and 10 denoting complete satisfaction for the performed procedure).

All patients underwent radiographic assessment before surgery and postoperatively at 1 month, as well as at 6 months, 12 months, and the final follow-up. Radiological outcomes were evaluated using the MedStation program, which allows the retrieval of electronically computer-assisted measurements from weightbearing radiographs of the following angles (Figure 3B): IMA (normal value <10 degrees), DMAA (normal value <6 degrees), and HVA angle (normal value <15 degrees).[2,25,57] Sesamoid dislocation was detected and classified according to the system recommended by the AOFAS evaluating the TSP.[18]

The relationship between the IMA values, HVA values, and tibial sesamoid displacement was used to classify the deformities into 2 groups, moderate HV or severe HV, as explained above. Any complications were recorded, including HV recurrence (defined as HVA >20 degrees and IMA >11 degrees) and hallux varus (defined as HVA <0 degrees).

Statistical Analysis

Statistical analysis was performed by an independent statistician from another university, blinded to the type of treatment. Before any data processing, statistical figures were visually inspected for capturing potential outliers (ie, those values more than 1.5 times the interquartile range below the first or above the third quartile). Normality of data distribution was verified performing the D'Agostino-Pearson omnibus test. Continuous parameters were expressed as mean $\pm$ standard deviation, together with median and range, whereas categorical variables were computed as percentages where appropriate. A generalized linear model for repeated measures (before operative intervention, after operative intervention at 1 month, 6 months, 12 months, and last follow-up) was used. The homogeneity of covariance matrices and the independence assumptions were checked. The sphericity assumption was verified carrying out Mauchly's W test. In case of sphericity violation (when the F test was significant) and with epsilon values (ε, quantitatively measuring the extent of departure from sphericity) less than 0.75, the Greenhouse-Geisser correction was adopted to properly adjust for the degrees of freedom of the interaction effect between different time points and the sample group. Otherwise (in case of ε greater than 0.75), the Huynh-Feldt correction was carried out. Effect size was estimated by computing the partial eta squared (η_p^2) and interpreted using the following rule: small if <0.06, moderate in the range 0.06 to 0.14, and large if >0.14. This generalized linear model was applied for investigating changes in the IMA, DMAA, and HVA parameters at the different time points. Post hoc tests using the Bonferroni correction for pairwise comparisons were conducted, computing the estimated marginal means and mean differences with their 95% CI. Changes in the sesamoid position before and after the operative intervention at last follow-up (mean, 97 months) were assessed performing the Wilcoxon test, computing the Hodges-Lehmann median difference with its 95% CI. All statistical analyses were conducted using the Statistical Package for Social Sciences (SPSS for Windows version 24.0; SPSS, Inc). For all analyses, figures with P values equal to or less than .05 were considered statistically significant, unless otherwise specified, such as in those cases in which protection against multiple testing should be ensured. Using the open-source software G*Power (version 3.1.9.2; Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany), to detect a moderate effect size (0.10) based on a recent systematic review of the literature,[24] given an α error probability of 0.05 and power of 0.95, with different time points and with

correlations among the measurements ranging from 0.8 to 0.9, a minimum number of 45 to 88 patients was computed. Sampling adequacy and adequate power were confirmed by post hoc power analysis computed by SPSS.

Results

Patient Characteristics

Descriptive characteristics of the studied population, associated procedures performed, and preoperative and postoperative radiographic parameters of the enrolled patients are reported in Table 1. As described, other operative corrections were performed in 42% of the cases. The mean long-term follow-up was 97 (range, 84-120) months, and none of the patients were lost during the different follow-ups, including the final one (Figure 4).

Clinical Outcomes

The AOFAS score improved significantly after operative intervention, remaining higher over time ($F = 38.82$, $\eta_p^2 = .29$, large effect size, $P = .000$). The time × severity interaction was not significant, but it trended toward significance ($F = 3.14$, $\eta_p^2 = .03$, small effect size, $P = .051$). With the between subjects effects test (Table 2), estimated marginal means of AOFAS scores in patients with severe HV were significantly lower with respect to those with moderate HV (62.4 ± 1.8 vs 68.4 ± 1.2, respectively; mean difference 6.0 ± 1.8 [95% CI, 2.38-9.56], $F = 10.88$, $\eta_p^2 = .10$, moderate effect size, $P = .001$), reflecting a significant increase at each follow-up for moderate HV, whereas for severe HV, the increase tended to stabilize after 1 month from the surgery. Severity ($F = 9.40$, $\eta_p^2 = .09$, moderate effect size, $P = .003$) and preoperative score ($F = 28.85$, $\eta_p^2 = .24$, large effect size, $P = .000$) were associated with improvement in the HVA after operative intervention and its persistence over time (Table 3 and Figure 5A), with scores much lower in patients with moderate HV severity.

At the last follow-up, mean satisfaction of the operative intervention was 8.7 ± 1.4, and perceived pain for the VAS scale was 1.5 ± 2.0. The former parameter did not differ between patients undergoing or not undergoing additional procedures (8.6 ± 1.3 vs 8.7 ± 1.5, respectively, $P = .432$), whereas the 2 groups of patients differed in terms of HV severity, resulting in higher satisfaction in less severe cases (8.9 ± 1.2 vs 8.2 ± 1.7, $P = .041$). VAS for rating pain did not differ in terms of additional surgical procedures (1.7 ± 2.0 vs 1.3 ± 2.1, $P = .168$) and HV severity (1.3 ± 1.9 vs 2.1 ± 2.3, $P = .090$) between the 2 groups of patients.

Radiological Outcomes

IMA significantly decreased after operative intervention, remaining lower over time ($F = 20.54$, $\eta_p^2 = .18$, large effect size, $P < .001$), stabilizing after 6 months from the operation. The time × severity interaction ($F = 5.00$, $\eta_p^2 = .05$, small effect size, $P = .004$) also was statistically significant. With the between subjects effects test (Table 2), estimated marginal means were higher for severe HV compared to moderate HV (6.8 ± 0.3 vs 10.2 ± 0.4, respectively, mean difference 3.4 ± 0.4 [95% CI, 2.60-4.21], $F = 69.69$, $\eta_p^2 = .42$, large effect size, $P < .001$), with statistically significant differences at each follow-up, as shown in Figure 5B. Preoperative angle ($F = 14.35$, $\eta_p^2 = .13$, moderate effect size, $P < .001$) was associated with correction of IMA after operative intervention and its persistence over time (Table 3).

The effect of time was not statistically significant on the DMAA ($F = 0.61$, $\eta_p^2 = .01$, small effect size, $P = .653$). With the between subjects effects test (Table 2 and Figure 5D), estimated marginal means for severe HV were higher than for moderate HV (10.9 ± 0.9 vs 7.6 ± 0.6, respectively, mean difference 3.3 ± 0.9 [95% CI, 1.50-5.02], $F = 13.57$, $\eta_p^2 = .13$, moderate effect size, $P < .001$), with statistically significant differences after 6 months from surgery. Similarly, the estimated marginal mean was higher in patients not undergoing other procedures (10.6 ± 0.8 vs 7.9 ± 0.7, mean difference 2.7 ± 0.9 [95% CI, 0.94-4.42], $\eta_p^2 = .09$, moderate effect size, $P = .003$), particularly after 6 months from the operation (Figure 6B).

Severity ($F = 13.68$, $\eta_p^2 = .13$, moderate effect size, $P < .001$), other procedures ($F = 6.11$, $\eta_p^2 = .06$, small effect size, $P = .015$), and preoperative angle ($F = 362.88$, $\eta_p^2 = .79$, large effect size, $P < .001$) were associated with correction of the DMAA after operative intervention and its persistence over time (Table 3).

HVA significantly decreased after operative intervention over time ($F = 10.65$, $\eta_p^2 = .10$, moderate effect size, $P < .001$). The interactions of time × age ($F = 4.72$, $\eta_p^2 = .05$, small effect size, $P = .008$), time × severity ($F = 13.46$, $\eta_p^2 = .12$, moderate effect size, $P < .001$), and time × other procedures ($F = 12.99$, $\eta_p^2 = .12$, moderate effect size, $P < .001$) were statistically significant.

Operative intervention had a statistically significant impact on TSP (median position 2 before intervention and median position 1 at last follow-up [mean, 97 months] after intervention, Hodges-Lehmann median difference −1.5 [95% CI, −1.5 to −1], $P < .001$).

In the between subjects effects test (Table 2), the estimated marginal mean for male patients was higher compared to females (20.2 ± 1.5 vs 16.8 ± 0.7, mean difference 3.5 ± 1.7 [95% CI, 0.15-0.6.78], $F = 4.29$, $\eta_p^2 = .04$, small effect size, $P = .041$). Estimated marginal mean for severe HV was higher compared to moderate HV (23.2 ± 1.2 vs 13.8 ± 0.9, mean difference 9.4 ± 1.3 [95% CI, 6.84-11.88], $F = 54.37$, $\eta_p^2 = .36$, large effect size, $P < .001$), with statistically significant differences at each follow-up, as shown in Figure 5C. The estimated marginal mean was higher in patients who did not undergo other

Table 1. Descriptive Statistics of the Studied Population.

Parameter	Value[a]
Sex, No. (%)	
Female	84 (84)
Male	16 (16)
Age, y	59.0 ± 12.1; 59 [20-80]
Severity, No. (%)	
2 moderate HV	69 (69)
3 severe HV	31 (31)
Feet, No. (%)	
Right	45 (45)
Left	55 (55)
Other surgical procedures, No. (%)	42 (42)
IMA, deg	
Preoperative	14.4 ± 2.5; 13.9 [10.5-21.1]
1-month postoperative	4.5 ± 2.5; 4.5 [0.0-13.0]
At 6 months	6.3 ± 3.1; 6.2 [0.7-13.0]
At 12 months	6.3 ± 3.1; 6.1 [0.7-13.2]
At last follow-up	6.4 ± 3.3; 6.0 [0.6-13.9]
Postoperative correction	9.9 ± 2.6; 10.0 [4.1-18.1]
Correction at 6 months	8.1 ± 2.8; 8.2 [−1.2 to 15.2]
Correction at 12 months	8.1 ± 2.8; 8.2 [−1.3 to 15.2]
Correction at last follow-up	8.0 ± 3.2; 8.1 [−1.3 to 15.2]
Mean correction	8.5 ± 2.5; 8.3 [0.1-15.1]
Loss of correction	1.9 ± 3.2; 1.5 [−8.6 to 10.0]
DMAA, deg	
Preoperative	14.8 ± 8.7; 13.0 [0.6-43.2]
1-month postoperative	6.3 ± 5.3; 5.3 [0.0-25.4]
At 6 months	7.5 ± 4.9; 6.9 [0.2-22.8]
At 12 months	7.5 ± 5.2; 6.6 [0.4-22.0]
At last follow-up	7.5 ± 5.2; 6.3 [0.7-22.2]
Postoperative correction	8.5 ± 9.7; 6.7 [−10.5 to 41.0]
Correction at 6 months	7.3 ± 7.9; 5.7 [−6.7 to 35.6]
Correction at 12 months	7.3 ± 8.0; 5.7 [−6.7 to 35.2]
Correction at last follow-up	7.3 ± 7.7; 5.5 [−4.40 to 35.1]
Mean correction	7.6 ± 7.9; 5.8 [−5.10 to 36.7]
Loss of correction	−1.2 ± 6.4; −1.1 [−21.1 to 22.7]
HVA, deg	
Preoperative	35.3 ± 9.4; 35.0 [20.8-66.68]
1-month postoperative	8.3 ± 9.1; 8.9 [−24.9 to 31.9]
At 6 months	11.8 ± 9.2; 11.7 [−20.9 to 36.4]
At 12 months	12.0 ± 8.6; 12.1 [−9.0 to 36.5]
At 97 months	12.2 ± 8.2; 12.2 [−2.4 to 36.4]
Postoperative correction	27.1 ± 11.3; 25.0 [8.0-64.5]
Correction at 6 months	23.6 ± 10.7; 21.8 [3.2-54.4]
Correction at 12 months	23.4 ± 10.3; 21.6 [2.9-52.6]
Correction at last follow-up	23.1 ± 10.1; 21.7 [1.9-51.1]
Mean correction	24.3 ± 10.2; 22.7 [5.1-54.3]
Loss of correction	4.0 ± 6.8; 2.9 [−15.9 to 27.8]
AOFAS score, points	
Preoperative	26.2 ± 5.7; 27 [19-42]
At 6 months	69.6 ± 10.0; 72 [24-82]
At 12 months	81.4 ± 11.7; 84 [28-97]
At last follow-up	87.6 ± 14.9; 91 [10-100]

(continued)

Table 1. (continued)

Parameter	Value[a]
TPS, No. (%)	
Preoperative position	
2	70 (70)
3	30 (30)
Postoperative position at last follow-up	
0	33 (33)
1	38 (38)
2	23 (23)
3	6 (6)
Satisfaction (0-10)	8.7 ± 1.4; 9 [2-10]
VAS pain (0-10)	1.5 ± 2.0; 0 [1-9]
Complications, No. (%)	
Superficial wound infection	9 (9)
Recurrence	6 (6)

Abbreviations: AOFAS, American Orthopaedic Foot & Ankle Society; DMAA, distal metaphyseal articular angle; HV, hallux valgus; HVA, hallux valgus angle; IMA, intermetatarsal angle; TPS, tibial sesamoid position; VAS, visual analog scale.
[a]Values written as mean ± SD; median [range], unless otherwise noted.

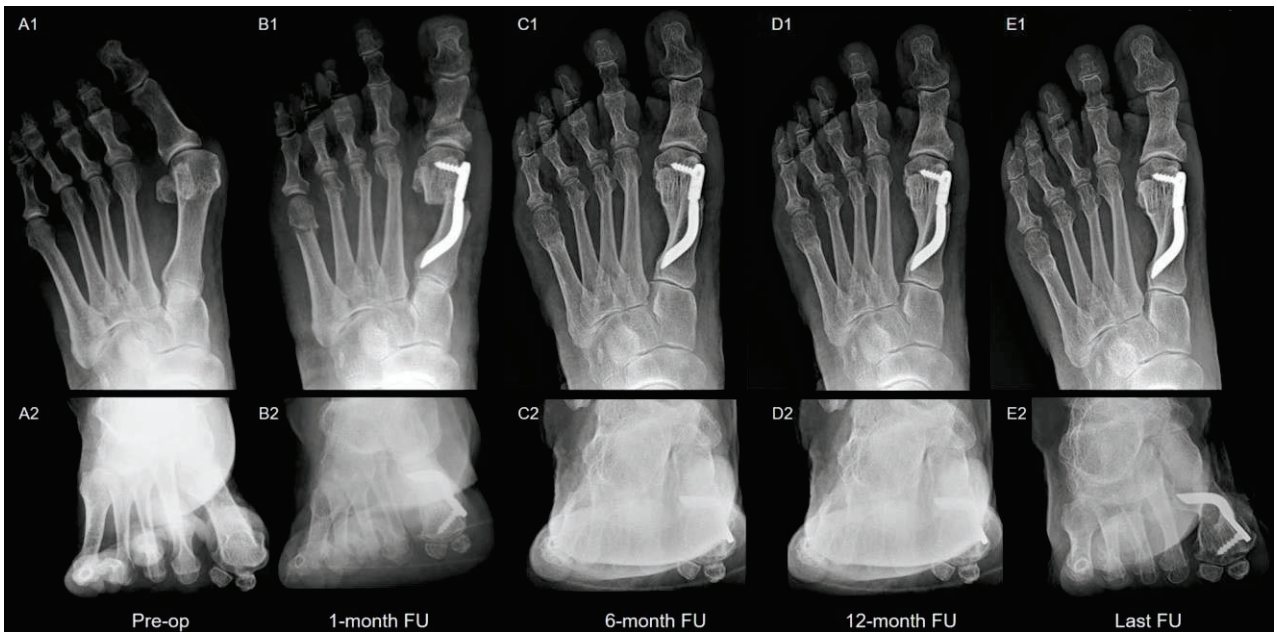

Figure 4. Case 1: A 68-year-old woman having undergone the Minimally Invasive Intramedullary Nail Device technique in addition to Akin percutaneous osteotomies for severe hallux valgus correction of her left foot. Weightbearing radiographic images of (1) anteroposterior and (2) sesamoids axial views at (A) preoperative period, (B) 1-month follow-up, (C) 6-month follow-up, (D) 12-month follow-up, and (E) last follow-up of 101 months after surgery, showing bone callus consolidation and its remodeling, maintaining the correction of the different radiographic parameters analyzed. FU, follow-up.

procedures (20.7 ± 1.1 vs 16.3 ± 1.0, mean difference 4.5 ± 1.3 [95% CI, 1.97-6.96], $F = 12.58$, $\eta_p^2 = .12$, moderate effect size, $P = .001$), particularly after 6 months from the operation, as shown in Figure 6A. Sex ($F = 4.06$, $\eta_p^2 = .04$, small effect size, $P = .047$), severity ($F = 3.94$, $\eta_p^2 = .04$, small effect size, $P = .050$), undergoing other procedures ($F = 17.93$, $\eta_p^2 = .16$, large effect size, $P < .001$), and preoperative angle ($F = 44.22$,

Table 2. Impact of the Variables Under Study on the IMA, DMAA, HVA, AOFAS Score, and Their Persistence Over Time.

Parameter	*F*	Statistical significance (*P* value)	Effect size
IMA			
Intercept	61.5	.000	—
Age	0.6	.434	0.0
Sex	2.9	.093	0.0
Severity	69.7	.000	0.4
Other procedures	0.1	.807	0.0
DMAA			
Intercept	10.6	.002	—
Age	1.2	.277	0.0
Sex	0.1	.750	0.0
Severity	13.6	.000	0.1
Other procedures	9.3	.003	0.1
HVA			
Intercept	45.1	.000	—
Age	0.6	.452	0.0
Sex	4.3	.041	0.0
Severity	54.4	.000	0.4
Other procedures	12.6	.001	0.1
AOFAS score			
Intercept	223.1	.000	—
Age	0.0	.939	0.0
Sex	0.3	.598	0.0
Severity	10.9	.001	0.1
Other procedures	0.8	.386	0.0

Abbreviations: AOFAS, American Orthopaedic Foot & Ankle Society; DMAA, distal metaphyseal articular angle; HVA, hallux valgus angle; IMA, intermetatarsal angle; —, not applicable.

$\eta_p^2 = .32$, large effect size, $P < .001$) were associated with correction of the HVA after operative intervention and its persistence over time (Table 3 and Figure 6A). Furthermore, no statistically significant correlations were found between severity, additional surgical procedures, age or sex, and complication rate between patients undergoing or not undergoing additional procedures (all $P > .05$).

Finally, to verify the real effectiveness of MIIND in HV correction regardless of Akin osteotomy, a sensitivity analysis was performed, excluding those patients having undergone additional Akin osteotomy (20%). This analysis confirmed the effectiveness of the minimally invasive nature of MIIND in HVA correction ($F = 360.49$, $P < .001$) in both groups of patients (undergoing or not undergoing Akin), in whom no statistically significant impact on DMAA could be found in either group ($P > .05$).

Complications

There were superficial wound infections in 9 patients that were treated successfully with antibiotic therapy. No cases of osteomyelitis or postoperative lesser transfer metatarsalgia were recorded. Six cases of recurrence were observed at the last follow-up, while no cases of hallux varus due to overcorrection, malunion, delayed union, or nonunion were found. Only 6 of the 100 implants were removed 4 years after surgery because of occasional pain or irritation from the device. None of the patients experienced postoperative avascular necrosis of the I-MTTH.

Discussion

In accordance with the recommendations given in the literature[23,62] for correction of mild to moderate HV, several distal MTT osteotomies have been reported to yield good clinical results.[67] However, only a relatively small amount of correction of this deformity is possible, and some shortening of the I-MTT results in consequent risk of avascular necrosis of the I-MTTH and transfer metatarsalgia. To our knowledge, only a few short- to medium-term retrospective studies have reported the outcomes involving the MIIND technique.[4,5,20,21] Hence, this study was designed to evaluate its potential on the basis of clinical and radiographic data, even at long-term follow-up, in the correction of moderate to severe HV by a single surgeon and a large series of patients prospectively enrolled.

Table 3. Determinants of the Improvement in the IMA, DMAA, HVA, AOFAS Score, and Their Persistence Over Time.

Parameter	*F*	Statistical significance (*P* value)	Effect size
IMA			
Intercept	0.0	.890	—
Age	0.7	.413	0.0
Sex	2.9	.093	0.0
Severity	2.4	.122	0.0
Other procedures	0.0	.982	0.0
Preoperative angle	14.4	.000	0.1
DMAA			
Intercept	5.1	.026	—
Age	0.3	.583	0.0
Sex	1.0	.320	0.0
Severity	13.7	.000	0.1
Other procedures	6.1	.015	0.1
Preoperative angle	362.9	.000	0.8
HVA			
Intercept	4.0	.050	—
Age	1.6	.212	0.0
Sex	4.1	.047	0.0
Severity	3.9	.050	0.0
Other procedures	17.9	.000	0.2
Preoperative angle	44.2	.000	0.3
AOFAS score			
Intercept	98.7	.000	—
Age	0.0	.988	0.0
Sex	0.4	.550	0.0
Severity	9.4	.003	0.1
Other procedures	0.4	.548	0.0
Preoperative angle	28.9	.000	0.2

Abbreviations: AOFAS, American Orthopaedic Foot & Ankle Society; DMAA, distal metaphyseal articular angle; HVA, hallux valgus angle; IMA, intermetatarsal angle; —, not applicable.

The main expectations of the patients before HV surgery are pain relief and improvement in wearing footwear and walking ability.[15,63,68,69] In this case series, the MIIND technique, sometimes performed in association with Akin osteotomy and/or other lateral procedures (42%), resulted in good to excellent clinical and radiographic outcomes. Most of our patients' expectations were satisfied, maintaining the results at last follow-up: mean VAS of 1.5 ± 2.0 and satisfaction rate of 8.7 ± 1.4. The mean AOFAS score improved from 26.2 to 69.6 points 6 months after surgery and remained high over time, with 81.4 points at the 12-month follow-up and 87.6 at the last follow-up of 97 months. The severity of the deformities ($P = .003$) and the preoperative AOFAS scores ($P < .001$) were associated with improvement in the HVA after surgery and its persistence over time. As expected regarding the different grades of deformity, postoperative mean AOFAS scores among patients with severe HV were significantly lower with respect to those with moderate HV ($P = .001$), even if the loss of correction over time trended toward significance ($P = .051$).

Our clinical results not only compare favorably to earlier reports,[4,20,21] in which the postoperative AOFAS score had ranged from 82.2 to 93, but also show that good outcomes can be maintained in the long term. In a systematic review,[44] 5 distinct groups of a total of 25 studies regarding current MI operative techniques were compared: Bosch and modifications (11 studies), chevron and Akin (5), Reverdin-Isham (4), MIIND (3), and distal soft tissue release [DSTR] and fixation (Akin or arthroscopically assisted DSTR and M1-M2 screw fixation; 2 studies). Although no MI techniques have shown superiority over others, the MIIND group showed excellent results in all of the studies assessed,[5,20,21] giving a mean improvement in AOFAS score of 62.7 points vs 36.9 points achieved by the remaining 4 groups of studies analyzed and vs 61.4 points reported by the present study at longer follow-up of 97 months, which demonstrates the long-lasting effectiveness of the MIIND system. This evident improvement of the AOFAS score in the MIIND group could be attributed to the lesser severity of preoperative clinical aspects

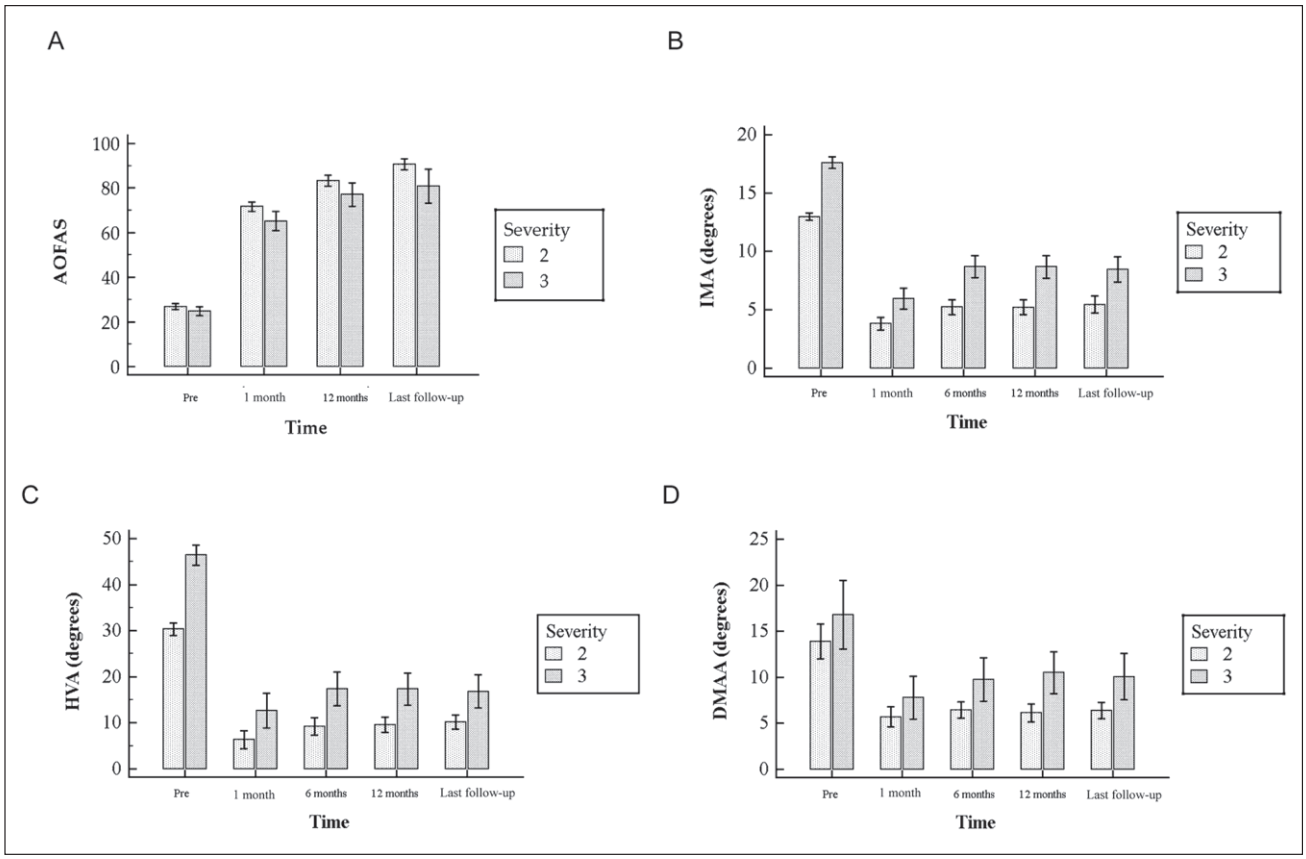

Figure 5. The impact of hallux valgus severity (2: moderate hallux valgus; 3: severe hallux valgus) on (A) AOFAS score, (B) IMA, (C) HVA, and (D) DMAA over time. AOFAS, American Orthopaedic Foot & Ankle Society; DMAA, distal metatarsal articular angle; HVA, hallux valgus angle; IMA, intermetatarsal angle.

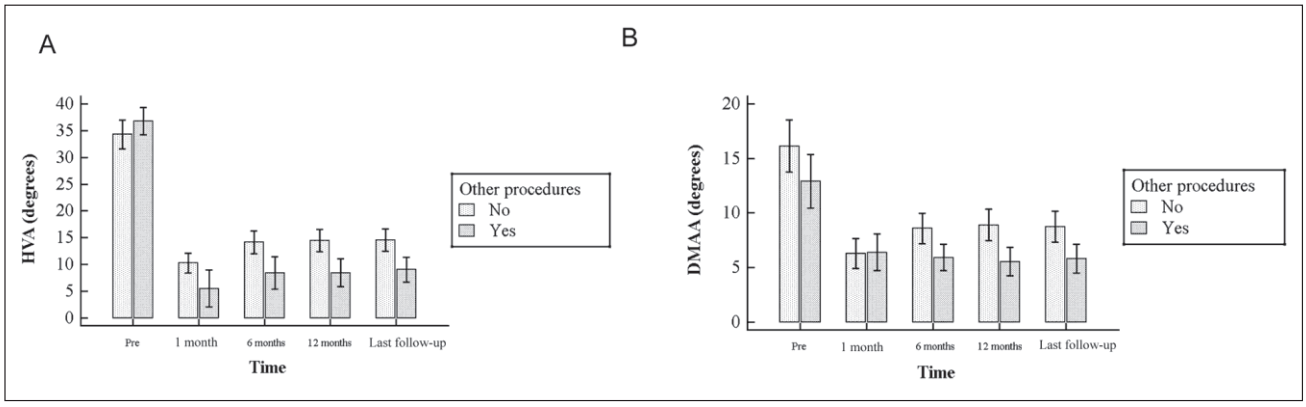

Figure 6. The impact of undergoing other procedures on (A) HVA and (B) DMAA. DMAA, distal metaphyseal articular angle; HVA, hallux valgus angle.

of the HVs included in the groups of the other MI techniques (AOFAS mean values: 55.8 points). In the MIIND group, more symptomatic HVs were treated (AOFAS mean values: 27.7 points). Furthermore, Malagelada et al[49] believe that these excellent results would be due to the hybrid nature of the MIIND procedure, completely different from traditional open distal osteotomy techniques, combining open surgery (direct view of

the metatarsal) with those of percutaneous procedures (minimal skin incision and relying on fluoroscopic control), allowing proper correction of both moderate and severe forms of HV.

A recent randomized controlled trial pointed out no statistically significant differences between MIIND and Reverdin-Isham percutaneous osteotomy in the treatment of mild to moderate HV, providing both good to excellent outcomes.[21] However, distal metatarsal osteotomies,[10,19,47-49] particularly the intra-articular ones, such as Reverdin-Isham,[3,6] can lead to a greater risk of I-MTPJ stiffness, probably due to the need to perform LR. On the contrary, the MIIND, applied after an extra-articular osteotomy and without LR, reduces this risk.[5,21]

Data from the present study suggest that the multiplanarity of the correction (IMA), the large lateral displacement of the I-MTTH and its derotation (DMAA),[59] the clinical correction of valgus (HVA),[56] and the anatomic reduction of the tibial sesamoid (TSP)[55] had an important role for preventing the recurrence of valgus in almost all of our cases over time. Hence, this successful angular correction in this large series fully supports prior studies in which the MIIND was shown to be an effective method to correct moderate and severe angular values at short to medium follow-ups.[4,5,20,21] In 4 previous studies[4,5,20,21] ranging in size from 20 to 194 patients, the average correction of the HVA varied from 13.9 to 20.1 degrees, while the IMA was corrected by 5.95 to 9.9 degrees. In the current analysis, the long-term mean correction of the IMA, HVA, and TSP was 7.8, 20 degrees, and position 1, respectively, which was significantly different compared to the preoperative values ($P < .001$). However, regarding the persistence of DMAA correction over time, statistical significance was not achieved ($P = .653$), probably because of the presence of a high incidence of abnormal DMAA in our case series, rather than a real lack of decrease of its values. The severity of the deformity correlates significantly with the correction of DMAA ($P < .001$). In the MIIND technique, the DMAA correction is due to triplane movement of the I-MTTH after osteotomy exerted by the device during its gradual application. It is maintained by the angular stable screw fixation in the desired position between the nail and the I-MTTH until bone consolidation. Failure to achieve proper fixation may result in a higher incidence of complications, including delayed union and malunion, which lead to first ray dorsiflexion and recurrence. Technically, an excessively oblique placement of a fixation screw may lead to penetration of the I-MTPJ, causing progressive degenerative arthritis of this joint.

It has been shown that there is a significant relationship between reduction of sesamoids and recurrent deformities.[11,55,65] In the present study, a significant improvement of TSP was achieved because the device permitted the derotation and relocation of the I-MTTH during lateral translation above the sesamoids without performing the LR of the sesamoid complex. During the MIIND technique, surgeons should be meticulous in the correction of IMA and HVA by proper bunionectomy, linear osteotomy, and adequate I-MTTH lateral translation to achieve the optimal balancing of the sesamoid complex. Our previous[5] and present findings, in line with those of other reports,[14,41,45] suggest that LR is not necessary when a distal extra-articular osteotomy is performed. Associating LR, whether open or MI, to an extra-articular distal osteotomy could involve an overcorrection and consequent hallux varus,[9,13,28] increase the risk of postoperative stiffness of the I-MTPJ,[42] and cause neurovascular injuries.[33] In particular, a correlation between avascular necrosis and open LR has been found during traditional distal osteotomy techniques,[33,71] while a high risk of neuritis has been found after LR in the MI procedure.[1,46]

A high rate of simultaneous additional procedures was recorded (42%), including 20 Akin osteotomies, which positively influenced HVA values and significantly correlated with the severity of deformity. Hence, further procedures were required because of the severity of forefoot deformities. However, the sensitivity analysis, performed after exclusion of patients who underwent additional Akin procedures (20%), confirmed the effectiveness of MIIND in HVA correction ($F = 360.49$, $P < .001$).

Female sex was observed to be associated with effective correction of the HVA after surgery[31,58] and its persistence over time ($P = .047$). However, in line with the recent literature,[12] the male patient group achieved greater correction of HVA than the female patient group ($P = .041$). Age did not have any impact on the radiological parameters assessed; hence, the MIIND technique can be used in adults within a wide age range (20-80 years).

Complications

A common complication after distal I-MTT osteotomy is HV recurrence, mainly due to undercorrection,[28,37] with rates reported to be as high as 16%.[43] Often, the recurrences have been described in connection with different operative methods, independent from the implementation of an Akin osteotomy.[35,36] This loss of correction has been shown to correlate with the preoperative HVA, IMA, DMAA, TSP, and I-MTPJ congruency.[59,60]

Among the current MI techniques, the complication rates varied widely even within the same groups.[49] The Bosch technique was reported to have 0% complication rates by some authors[26] and 22% by others.[14] The Reverdin-Isham

technique varied from a 5%[3] to 73%[27] rate of complications. This last high complication rate was due to the exclusive evaluation of children younger than 16 years, showing high rates of recurrence. In the chevron Akin group, complications were between 0% and 40%.[34,49] However, if the early stages subgroups from the analysis are excluded, the overall complication rate becomes 13%.[49] In the other studies published regarding the MIIND,[4,5,20,21] the incidence of complications ranged from 0% to 5%. In 1 study, the recurrence of deformity or undercorrection was reported to be 2%.[4] In our study, 6 of 100 patients (6%) complained of HV recurrence. None of these patients underwent operative revision because all patients had good functional outcomes at last follow-up with an AOFAS score >70 and a VAS for satisfaction rated as "good" in 5 cases and "fair" in 1 case.

In our series, there were no sequelae associated with metallic fixation, such as loosening or breakage of the implant; no cases of malposition of the device or the I-MTTH with consequent delayed or nonunion were recorded. As the MIIND provides completely internal fixation, the risk of infection is reduced with respect to other techniques that use percutaneous K-wires.[52] No deep infection of soft tissues or osteomyelitis was found among our patients. However, there have been a few cases of hardware intolerance with occasional pain or irritation. Thus, 6 implants were removed 4 years after surgery with resolution of symptoms. This was probably due to the technical characteristics of the MIIND, which is completely endomedullary except for the blade (8 mm long × 2.3 mm wide × 14 mm high) fixed on the lateral part of the head, which could have been the cause of soft tissue irritation in these cases.

Although implant removal is associated with increased costs and further surgery, we found this small nail to be easy to remove without risk of I-MTT bone fractures. Avascular necrosis of the I-MTTH, the most serious complication of HV operative correction by distal osteotomy, was not observed in this case series or in our previous one or other similar experiences with the MIIND.[4,5,20,21]

Strengths and Weaknesses

The strengths of our study include (1) the prospective data collection of this case series, whose size was calculated a priori, with the same fixed follow-ups until the long-term one; (2) the large consecutive patient inclusion (100 implants); (3) the standardization of patient operations and aftercare; (4) the analysis of the clinical and radiographic outcomes, carried out separately by independent investigators (the one who performed clinical assessment was blinded to the type of procedure used); and (5) the multivariable statistical analysis, performed by an independent statistician, also blinded to the type of operative treatment. We are also aware of its weaknesses: (1) single-center, case series study and single surgeon for all operations, aspects that could have affected the generalizability of the operative procedure; (2) the retrospective analysis of prospectively collected data and the lack of a control group, which prevented us from comparing results; and (3) the use of the AOFAS score for the outcome measure, which, although it was the most widespread health measurement in foot and ankle clinical practice when the data collection began, was only partly validated[17] and may have overlooked some clinical aspects, such as psychological ones. This physician-based score does not have items directly related to psychological health and does not adequately consider the patient's point of view.[17] For these reasons, VAS for patients' satisfaction was used in this study. For future studies, other scores are now available (eg, the Foot and Ankle Outcome Score, which has been shown to be a valid score for assessing patients with HV).[73]

Conclusion

Being aware that a single ideal procedure adequate to cover all deformities of HV has not been described, our data showed that the MIIND technique was a viable procedure for correction of moderate to severe HV at long-term follow-up, with a low rate of complications and recurrence. In our series of adult patients with a wide age range, the device allowed improvement of variable preoperative clinical and radiographic cases, resulting in a significant reduction of most radiographic parameters and a significant improvement of clinical scores, maintaining these results over time. Furthermore, in cases of concomitant forefoot disorders, additional percutaneous osteotomies, such as Akin and DMMO, can be associated successfully.

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Availability of Data and Materials

The data set supporting the conclusions of this article is available at our institution.

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11. DISCUSSION

Distal metatarsal osteotomies (DMOs) became popular in the last thirty years in Europe by the Spanish surgeon De Prado first and then by the GRECMIP and MIFAS as an alternative surgical technique to traditional procedures. Because of the perceived potential advantages of a dynamic and aesthetic correction offered by these percutaneous osteotomies, and the stiffness and floating toe caused by more complex traditional ones such as the Weil osteotomy [13], these percutaneous procedures now tend to be preferred over open traditional osteotomies [26, 37].

Concerning the clinical outcomes of DMOs, metatarsalgia treatment using DMOs in the first cohort of patients treated at our institution and analysed in the prospective study published in 2018 showed a significant improvement in each clinical score after surgery with respect to pre-operative values, and the clinical results at the last FU continued to be satisfactory [1]. Specifically, the AOFAS and MOXFQ scores over time showed a statistically significant improvement, and the 17-FFI scores, which evaluate the clinical-functional appearance of the foot, showed excellent results with a statistically significant difference between pre- and postoperative. A significant reduction of pain (VAS scale) and formation of plantar callosities was obtained, associated with a considerable improvement in the quality of daily life in our patients as shown by SF36. The incidence of recurrence or transfer lesions was negligible.

Jardé [34] reported that the patients in whom postoperative alignment of the metatarsal heads after Weil osteotomies had most closely met the Maestro criteria, had better results than those in whom the match was less exact [25, 31]. However, reconstruction of an ideal curve of Maestro was obtained only in 3 of 93 feet (3.2%) in our patient group, despite precise preoperative planning, but this did not have an impact on the patient's outcomes. Thus, we found no correlation between clinical outcomes and having a harmonious and mathematically correct distal metatarsal parabola. After DMMO, the MB heads consolidate into a more proximal position due to mechanical loading by weight bearing allowed after surgery. This is in contrast with the Weil procedure where the

osteotomies, synthesised by screws remain fixed after surgery, theoretically create the ideal position calculated by the preoperative planning. This study regarding DMOs for metatarsalgia treatment showed that the procedure guaranteed balanced redistribution of the plantar pressure forces and relief of metatarsalgia not only in the immediate postoperative period but also at medium- to long-term FU although the restoration of the ideal harmonious architectural Maestro curve of the forefoot was not achieved by DMMO.

The application of the principles DMOs to the diabetic foot led to satisfying and even surprising results sometimes. Overall, the studies analysed in the recent review [2] included in this thesis give encouraging and promising results for MIMOs for ulcer healing, mean healing time and recurrence rates. Therefore, the most important finding of the review was that DMOs are an effective intervention in CPDFU management for promoting healing and for reducing their recurrence as well by achieving a better distribution of plantar pressure on the metatarsal bone with a low incidence of complications. Based on our previous clinical experiences [3, 4], we strongly believe that MIMOs are a valid alternative treatment also for CPDFUs with chronic infection, ulcers penetrating deep structures (IIIB) [48, 49] and ulcers with osteomyelitis of the MBs or the proximal phalanx. Because CPDFUs are the main access for bacteria causing foot osteomyelitis, promoting ulcer healing leads to the healing of oteomyelitis, avoiding long-term antibiotic therapy, which causes progressive bone damage in diabetic patients [69]. Clinicians and surgeons need to know the few absolute contraindications of these percutaneous procedures: severe ischemia and gangrene, insufficient vascular perfusion and extensive soft tissue infection presenting as cellulitis of the foot or toe.

DMOs for the treatment of diabetic disease are not new. Tilo was the first to propose a dorsal osteoclasis at the level of the metatarsal neck for the treatment of DFUs in 1990, reporting a recurrence rate of 6% and a transfer lesion rate of 26.5% during a 17-month-FU [11]. In 1999, Fleischli et al. described a dorsiflexion metatarsal base osteotomy using fixation with pins for the treatment of CPDFUs [55]. Good results were reported with a high healing rate (95%), but complications occurred in 68% of cases, including deep wound infections, transfer ulcers and acute Charcot disease.

Internal fixation is not used in DMO techniques, avoiding potential infection of the metalwork. The osteotomised metatarsal heads are shifted, adapting to the load toward a new position, which is translated in a slightly dorsal direction where the heads ossify. In this way, the use of percutaneous techniques enables obtaining an improved distribution of plantar pressure on the MBs, resulting in a lengthening of the load under the ulcer, which promotes its rapid healing [33, 70], as well as restoring the original harmonic distal parabola of the forefoot when possible or creating a new balanced forefoot arch. To respect the Maestro criteria [25], it is often necessary to shorten the MB to a greater degree by performing a diaphyseal osteotomy much more proximal to the neck.

A recent meta-analysis of the contemporary management of diabetic neuropathic foot ulcerations reveals relatively disappointing functional outcomes [71]. DMOs for CPDFUs were unfortunately found to be a poorly investigated topic. Contrary to traditional surgical techniques, only four case series studies could be found in the literature [4, 11, 55, 56]. In these reports, despite the common association between decreased healing rates and severity and duration of CPDFUs [71], the healing rates and time found by the authors proved much better than those reported with standard care in terms of ulcer duration and severity, knowing that included ulcers were all either recalcitrant to initial standard care or recurrent. Complications (ulcer recurrence, ulcer transfer, infection and nonunion) were found to be less frequent with respect to those reported following standard care.

Following the recommendations given in the literature [72, 73] for the correction of mild to moderate HV, several DMOs have been reported to yield good clinical results [74]. However, only a relatively small degree of correction of this deformity is possible, and some shortening of the I-MB results in the consequent risk of avascular necrosis of the I-MB head and transfer metatarsalgia. The main expectations of the patients before HV surgery are pain relief and improvement in wearing footwear and walking ability [75-78], which was satisfied in both articles analysed for this report.

In the cohort of the study on RIO published in 2016 and included in the present thesis, the mean AOFAS score improved significantly until the last FU [5]. This clinical improvement was also evident in all patient sub-groups, almost in the same way, maintaining unaltered the gradient correlated to the

degree of the deformity [8, 79-83], with or without osteosynthesis, but also with a series of open surgical procedures using Chevron, Scarf or proximal metatarsal osteotomies [63, 79, 81, 84, 85].

One of the possible side effects of RIO, because it is an intra-articular medial closing wedge osteotomy, is the stiffness of the first MTPJ [86, 87], which was observed also in the cohort analysed in the study published in 2016. Joint movement was slightly reduced by another 37.5% after surgery, while severe limitation to flexion-extension was present only in one elderly patient. In accordance with Bauer et al., the potential cause could be bony fragments remaining within the joint and the capsular tissues produced during the extensive exostosectomy and lack of thorough cleaning of the work area with rasps and lavage with normal saline solution [88].

The AOFAS score found in our study was comparable overall to the scores reported by different authors not only using minimally invasive techniques [8, 79-83], with or without osteosynthesis, but also with series of open surgical procedures using Chevron, Scarf or proximal metatarsal osteotomies [63, 79, 81, 84, 85]. Our data were similar for patient demographic aspects and complications including stiffness; however, our group of patients had a larger sample size and follow-up duration [63, 79, 81, 84].

Only a few short- to medium-term retrospective studies have reported the outcomes involving the MIIND technique, including a study published in 2015 that reported our initial experience with the Endolog device [1, 67, 68, 89]. The study included in this thesis and published in 2021 was designed to evaluate its potential based on clinical and radiographic data, even at long-term FU, in the correction of moderate to severe HV by a single surgeon and a large series of patients prospectively enrolled. The MIIND technique, sometimes performed in association with Akin osteotomy and/or other lateral procedures, resulted in good to excellent clinical and radiographic outcomes. Most of our patients' expectations were satisfied, maintaining the results at the last FU. The severity of the HV and the preoperative AOFAS scores were found to be associated with improvement in the HVA after surgery and its persistence over time. The postoperative mean AOFAS scores among subjects with severe HV were significantly lower with respect to those with moderate ones as expected, even

if the loss of correction over time trended toward significance. These clinical results not only compare favourably to earlier reports [67, 68, 89], where the postoperative AOFAS score had ranged from 82.2 to 93, but also show that good outcomes achieved can be maintained in the long term. In a systematic review [90], 5 distinct groups of a total of 25 studies regarding current MI operative techniques were compared: Bosch and modifications (11 studies); chevron and Akin (5); Reverdin-Isham (4); MIIND (3); DSTR and fixation (Akin or arthroscopically assisted DSTR and M1–M2 screw fixation; 2 studies). Although none of these DMOs have shown superiority over others, the MIIND group showed excellent results in all of the studies assessed [1, 68, 89], which confirms the long-lasting effectiveness of the MIIND system. This noticeable improvement of the AOFAS score in the MIIND group could be attributed to the lesser severity of preoperative clinical aspects of the HVs included in the groups of the other MI techniques. In the MIIND group, more symptomatic HVs were treated. Malagelada and colleagues [90] believe that these remarkable results could be due to the hybrid nature of the MIIND procedure, completely different from traditional open distal osteotomy techniques, combining mini-open surgery (allowing direct view of the metatarsal) with those of percutaneous procedures (with minimal skin incision and relying on fluoroscopic control), allowing proper correction of both moderate and severe forms of HV. A recent randomised controlled trial found no statistically significant differences between MIIND and RIO in the treatment of mild-moderate HV, providing both good to excellent outcomes [68]. However, DMOs [84, 85, 90-92] and the intra-articular ones, such as RIO [5, 79], can lead to a greater risk of I-MTPJ stiffness, probably because of the need to perform STLR. MIIND in contrast, applied after an extra-articular osteotomy and without STLR, reduces this risk [65, 89].

Regarding the radiographic aspects of Distal Metatarsal Osteotomies (DMOs)**,** Henry reported similar healing times for DMMO [16], confirming that this technique requires a longer healing time than the Weil osteotomy but gives better results. In accordance, the results of the study about DMMO published in 2018 and included in this thesis, showed no variation in healing time based on age, sex,

BMI, smoking and number of metatarsals treated [1]. In our series, osteotomy consolidation was present in 76.3% of feet after 3 months from surgical operation and in all feet at 6-month FU.

Jardé [34] stated that the patients for whom postoperative alignment of the metatarsal heads after Weil osteotomies had most closely met the Maestro criteria had better results than those for whom the match was less exact [25, 31]. No correlation was found between having a harmonious and mathematically correct distal metatarsal parabola and clinical outcomes. This study showed that, although the restoration of the ideal harmonious architectural Maestro curve of the forefoot was not achieved by DMMO, the procedure guaranteed balanced redistribution of the plantar pressure forces and relief of metatarsalgia not only in the immediate postoperative period but also at medium to long term FU.

The ideal preoperative planning for the DMOs should consider the potential proximal shift of the osteotomised metatarsal heads in both sagittal and coronal planes. However, this assessment is difficult to perform because it must anticipate the metatarsal head displacement not only at the operating table but also after load resumption by walking in the post-operative period, identifying new radiological and biomechanical criteria for the ideal foot morphotype. From these results, it is questionable if Maestro parameters can adequately represent this and maintain their predictive value. After DMOs, the metatarsal heads consolidate into a more proximal position due to mechanical loading allowed after surgery by weight bearing. This contrasts with the Weil procedure, where the osteotomies, synthesised by screws, remain fixed after surgery, reflecting the ideal position calculated by the preoperative planning. For these reasons, there is a need to revise the radiological criteria needed to correlate radiological metatarsal alignment with clinical outcomes before and after this percutaneous technique.

A recent systematic review published in 2021 about DMOs for CPDFU showed good to excellent results regarding radiographic consolidation of the several osteotomies proposed in the literature [2]. The non-union rate was reported to range from 4.5% to 30.0%, but all of the patients were asymptomatic [55-58]. The most adverse complications were reported only by Fleischli et al. (1999)

[55], in cases of acute Charcot foot. In their article, 7 cases (31.8%) were reported and treated with total contact casting until resolution of the acute inflammatory process and bony consolidation as verified on radiographs.

Regarding personal experience with DMOs for CPDFUs, specifically DMDO described in 2018 and the radiographic results, all feet treated presented signs of definitive bone consolidation, including Akin osteotomies when performed [4]. Further, no cases of healing failure, MB osteomyelitis or acute Charcot osteoarthropathy were found at the final FU. There were no cases of malunion, delayed union or non-union, and there were no cases of displacement of the metatarsal head or avascular necrosis.

Although osteotomy fixation by any internal metalwork is not indicated in this percutaneous technique, especially considering the high risk of infection in diabetics, a single case of deep infection occurred in the series analysed. However, it was successfully resolved by hospitalisation using intravenous antibiotic therapy.

Similar to the painful hyperkeratotic areas of metatarsalgia in non-diabetic patients, plantar metatarsal ulcers that develop from pressure under the metatarsal heads were initially hypothesised to be lesions caused by over-activity of the long extensor and long flexor [93]. This muscle imbalance however is probably not the major causative factor. In agreement with other authors [94], a probable cause of recalcitrant ulcer pathogenesis is the progressive collapse of the transversal axis of the foot with consequent prolapse of the metatarsal heads, distal migration of the metatarsal fat pad and increase of local pressure.

Modifying the position of the metatarsal heads by DMOs to a mild dorsally translated position, it is possible first to achieve a better distribution of plantar pressure on the MB, resulting in a lengthening of the load under the ulcer and favouring its healing [33, 70],[13,20] and second, to restore the original harmonic distal parabola of the forefoot or create a new balanced forefoot arch. Redfern and Vernois [13] correctly stated that making the osteotomy more proximal to the neck is a technique error when performing DMMO for metatarsalgia treatment because the point of rotation of the osteotomy moves proximally, causing its displacement in dorsal rotation and a consequent over-elevation of the

metatarsal head. This was exactly the principal goal of performing DMOs for CPDFU treatment. The MB over-elevation is stabilised by surrounding soft tissues, which are stiffer in diabetic patients compared to the normal population.

As for the radiographic analysis carried out for the cohort of the study published in 2016 regarding RIO for HV treatment, all correction angular values obtained a statistically significant improvement after the operation, which was maintained at the final FU of 48 months [5]. Although the RIO has been described without resulting in any lateral translation of the metatarsal head, the IMA decreased and an efficacy in angular value correction was achieved. In agreement with Bauer et al. [79, 88, 95], the RIO has a slight impact on this angle, reporting an IMA mean improvement of about just 3°, again a better mean correction of about 8° and 15° for the DMAA and HVA, respectively. According to our experience reported in this thesis with RIO, the efficacy of IMA correction can probably explained by the concerted action of the three surgical steps of the procedure. First, during the application of manual force to perform the lateral cortex osteoclasis at the step of the wedge closing, a minimum translation of the metatarsal head occurs. It is known that DMOs can achieve 1° of IMA correction proximally for each millimetre of MB head lateral translation [96, 97]. Second, the tenotomy of the adductor hallucis tendon and lateral capsulotomy confers lateral movement of the first metatarsal axis, further decreasing its varus. Third, in his original article published in 1991, Isham reported that the average reduction of the IMA is especially evident when the procedure is performed in association with APO [63].

One of the objectives of the RIO technique is to reduce the DMAA by a medial rotation of the metatarsal head, and in the analysed sample, the average correction efficacy was 46.1% at final FU. According to Coughlin [51], it is imperative to correct DMAA because a stable recovery can be achieved only by setting up the bone structure, re-orienting articular surfaces and re-equilibrating muscle forces of the first ray, which avoids the retraction of soft tissue and peri-articular adhesions. As reported in the literature [79, 84, 88, 98, 99], confirmation of the re-orientation of the forces on the

muscle-ligament compartment was seen as restoration of the articular congruence and sesamoid compartment alignment.

It is now possible to state that RIO is a reliable procedure for correcting the different radiological parameters discussed in the analysis above, and the data reported by our personal experience in DMOs in 2016 are comparable with the reported angular corrections obtained with other percutaneous or open distal metatarsal osteotomies [81, 84, 97, 99]. However, the results obtained in the correction of the HV severe deformities were less encouraging. The correction efficacy of the different single angles analysed to test RIO, although high, was in some cases not sufficient to report them as in the normal range (Tab. 4).

Data from the MIIND study published in 2021 [6], suggest that the multiplanarity of the correction (IMA), the large lateral displacement of the I-MB head and its derotation (DMAA) [100], the clinical correction of valgism (HVA) [101] and the anatomic reduction of the tibial sesamoid (TSP) [102] had an important role for preventing the recurrence of valgism in almost all of our cases over time. The successful angular correction in this large series fully agrees with prior papers in which the MIIND is shown to be an effective method to correct moderate and severe angular values at short to medium FUs [65, 67, 68, 89]. Regarding the persistence of DMAA correction over time however, statistical significance was not achieved, probably because of the presence of a high incidence of abnormal DMAA in our case series rather than a real lack of decrease in its values. Clearly, the severity of the deformity correlates significantly with the correction of DMAA. In the MIIND technique, the DMAA correction is due to movement of the I-MB head in three planes after osteotomy, caused by exertion of the device during its gradual application. It is maintained by the angular stable screw fixation in the desired position between the nail and the I-MTTH until bone consolidation.

Failure to achieve proper fixation may result in a higher incidence of complications, including delayed union and malunion, which lead to first-ray dorsiflexion and recurrence. Technically, an excessively oblique placement of a fixation screw may lead to penetration of the I-MTPJ, causing progressive degenerative arthritis of this joint. It has been demonstrated that there is a significant relationship

between the reduction of sesamoids and recurrent deformities [102-104]. In the presented study, a significant improvement of TSP was achieved because the device permitted the derotation and relocation of the I-MB head during lateral translation above the sesamoids without performing the LR of the sesamoid complex. Our previous [65] and recent findings [6], in line with those of other articles [105-107], suggest that LR is not necessary when a distal extra-articular osteotomy is carried out. Associating STLR, whether open or MI, to an extra-articular distal osteotomy could involve an overcorrection and consequent hallux varus [108-110], increase the risk of postoperative stiffness of the I-MTPJ [111] and cause neurovascular injuries [112]. Specifically, a correlation between avascular necrosis and open STLR has been found during traditional distal osteotomy techniques [112, 113], while a high risk of dorsal nerves and digital neuritis have been shown after STLR in the MI procedure [114, 115].

A high number of simultaneous additional procedures was reported (42%), including 20 additional APOs, which positively influenced HVA values and significantly correlated with the severity of deformity. These extra procedures were required because of the severity of forefoot deformities. However, the sensitivity analysis, performed after the exclusion of patients who underwent additional Akin (20%), confirmed the effectiveness of MIIND in HVA correction. Female sex was observed to be associated with effective correction of the HVA after surgery [116, 117] and its persistence over time. However, in agreement with the recent literature [118], the male patient group achieved greater correction of HVA than the female patient group. Age did not have any impact on all radiological parameters assessed; hence, the MIIND technique can be used in male and female adults within a wide age range (20-80 years).

Numerous complications of DMOs have been reported in the literature [13, 18, 31, 43]. However, in the study regarding DMMO published in 2018 [1], a low rate of short-term complications was described: transitory swelling, paraesthesia and skin burns, while delayed unions were resolved by 6-month FU. The main long-term complication was persistent stiffness and cases of transfer metatarsalgia, the seconds was resolved with a second percutaneous operation by M4 osteotomy. No

cases of floating-toe deformity, residual instability or subluxation, infection, pseudarthrosis, avascular necrosis or displacement of the metatarsal head, which are the most undesirable complications, were recorded [31, 32, 36, 43].

In the recent review published in 2021 and included in this thesis, DMOs for CPDFUs showed an overall complication rate between 44.9% and 68%, most of them minor [2]. The most frequent complication reported in the literature remains foot swelling (56.3%) also for these DMOs. The swelling is generally persistent and moderate, affecting the forefoot for more than 6 weeks, improving after some months with complete callus formation at the osteotomy sites and without further treatment [4]. Probably because of the sensory neuropathy of these patients, radiographic non-unions (4.5%-30.0%) are often described as asymptomatic [11, 54, 55, 58]. Infections (4.2%-25.2%) often adversely affect the healing of plantar CPDFUs. They are usually superficial and treated successfully with oral or intravenous antibiotics. However, when exceptionally deep infections appear, subsequent surgical treatment is mandatory [4, 54-58]. When fixation is used to prevent non-union, using temporary K-wires or cancellous bone screws, a higher infection rate (31.8%) has been reported [55]. Finally, the following complications were reported in the literature for MIMOs: non-healing wound (23.8%) and bone necrosis (4.8%), transfer lesions (9.1%-26.5%) and ulcer recurrence (7.2%). Recurrence rate was higher in the first studies from the 90s [11, 55], but it has decreased exceptionally in later years [58].

In the nineties, Tillo was the first to propose a dorsal osteoclasis at the level of the metatarsal neck for the treatment of chronic neuropathic ulcers in a series of 52 diabetic patients. He reported a recurrence rate of 6% and a transfer lesion rate of 26.5% at 17-month FU [11]. In 1999, Fleischli et al. [55] described a dorsiflexion metatarsal base osteotomy fixed by pins for the treatment of CPDFUs in a series of 20 diabetic patients. Although good results were reported with a high healing rate (95%), complications occurred in 68% of cases, including acute Charcot disease (32%), deep wound infections (14%) and transfer ulcers (9%). More recently, Tamir et al. described the use of 20 minimally invasive floating osteotomy procedures for the treatment of resistant or recurrent DFUs,

reporting excellent results [93]. Although they treated ulcers exclusively of University of Texas Grade IA in a 17-diabetic-patient series, with only 11 patients treated by insulin, their findings were confirmed by our results.

Finally, our short and medium-term outcomes described in 2018 showed the DMDO was effective in all of our patients with non-healing ulcers but good metabolic control (HbA1c < 8.5%) [4]. Among results reported first in 2018 and then in this thesis, there were other three intraoperative complications, which had resolved spontaneously by the final FU: one neuritis of a cutaneous sensory dorsal branch and two skin burns around the portal.

Concerning DMO complications for HV correction, the rate varied from 5% [79] to 73% [119]. This latter high complication rate was due to the exclusive evaluation of children younger than 16 years of age showing high rates of recurrence. A common complication after DMOs of the first ray is HV recurrence, mainly due to under-correction [110, 120]; rates have been reported to be as high as 16% [121]. This loss of correction has been shown to correlate to the preoperative HVA, IMA, DMAA, TSP and I-MTPJ congruence [100, 122].

Regarding our experience with RIO, we found 6 major and 19 minor complications [5]. The major complications (7.5%) included recurrence and severe stiffness, and among the minor, slight loss of normal range of MTP joint motion. There were also three intraoperative complications, which had resolved spontaneously by the final follow-up: one neuritis of a cutaneous sensory dorsal branch and two skin burns around the portal. Several studies have been reported in the literature [87, 123] comparing the complication rate between diathermy and scalpel for skin incision, without showing any significant differences. However, it seems that no study has examined the complication rate of the surgical burr in MIS. In our experience, it is a fundamental surgical aspect to avoid putting too much manual pressure on the burr during the performance of osteotomies. The burr must be accompanied gently with the fingers during the entire process; otherwise, the resistant bone can push the burr to the edges of the portal causing skin burn.

Among the DMOs for HV correction, the complication rates varied widely even within the same groups [90]. The Bosch technique was reported to have 0% complication rates by some authors [80] and 22% by others [105]. In the chevron Akin group, complications were between 0 and 40% [90, 124]. However, if the early stages subgroups from the analysis are excluded, the overall complication rate becomes 13% [90]. In the other studies published regarding the MIIND [65, 67, 68, 89], the incidence of complications ranged from 0 to 5%. Only in one, the recurrence of deformity or under-correction was reported with a rate of 2% [67].

In our study, there were 6 out of 100 patients (6%) who complained of HV recurrence. None of these patients underwent operative revision because all patients had good functional outcomes at the final FU. There were no sequelae associated with metallic fixation, such as loosening or breakage of the implant and no cases of malposition of the device or the I-MB head with consequent delayed or non-union. Since the MIIND provides complete internal fixation, the risk of infection is greatly reduced compared to other techniques that use percutaneous K-wires [125]. No deep infection of soft tissues or osteomyelitis were found among our patients. However, there have been a few cases of hardware intolerance with occasional pain or irritation. For these reasons, 6 implants were removed 4 years after surgery with resolution of symptoms. Avascular necrosis of the I-MB head, the most serious complication of HV operative correction by distal osteotomy, was not observed in this case series, nor in our previous one nor in other similar experiences with the MIIND [65, 67, 68, 89].

The MIIND technique shows an overall rate of complications from 4% to 7.5%, mostly minor in the literature [126]. Among minor complications, there is recurrence in 2.8% of operated feet, and the infection of a superficial wound involves 2.5% of cases [126]. Removal of the implant because of pain was required in 2.2% of cases, but that is the only major complication reported [126].

Regarding the publications reporting the clinical-functional and radiographic outcomes of DMOs for the treatment of the most common forefoot diseases analysed in this thesis, different strengths and weaknesses were observed. To the best of our knowledge, the study published in 2018 was the first prospective, single-centre study reporting clinical and radiographic outcomes of DMOs for the

treatment of primary central metatarsalgia in a consecutive, single-surgeon patient series [1]. The number of patients and the mean FU of almost 60 months was superior to previous published studies [15, 39, 40, 43]. For the clinical evaluation of our sample, internationally validated scores were used, except for the AOFAS score, which, although it remains the most widespread health measurement in foot and ankle clinical practice, has only been partially validated [127]. For radiographic evaluation, the traditional method of Maestro [25] was used to perform X-ray foot images and to classify them both pre- and postoperatively, even to determine which MBs to shorten by DMMO during preoperative planning. Most of the feet in our cohort included HV deformity, causing a potential bias in this study, and plantar pressure measurements were not performed.

Regarding the DMOs for the treatment of CDPFUs under the lateral metatarsal heads (2^{nd}-5^{th}), the preliminary report published was the first prospective, single-centre study reporting outcomes of DMOs in a consecutive, single-surgeon patient series [4]. The number and homogeneity of patients and the mean 25-month FU were comparable to previously published studies [128]. For this investigation as well, the main limitation was the use of the AOFAS score for the chief outcome measure, which as stated above, remains the most widespread health measurement in foot and ankle clinical practice, but has only been partially validated [127]. Furthermore, as there is no specific method for the evaluation of metatarsal diabetic ulcers, some clinical aspects may have been overlooked. Another weakness is the lack of a control group, which would be useful to compare the results of this percutaneous technique. However, all our patients had previous non-operative management of the ulcer for at least 6 months that was not effective. Finally, we lacked plantar pressure measurements also in this report [4]. For the article published in 2020 regarding the osteotomies for diabetic foot disease, strengths and weaknesses were observed as the surgical technique of DMDO and its applications were described by using videos and reporting a case series [3].

The systematic review of DMOs for CPDFU treatment has several strengths. It included all studies published to date on the topic since 1975 [2]. Extensive search strategies were employed with detailed,

careful and critical assessment to identify the risk of bias in compliance with the PRISMA guidelines. Moreover, meta-regressions were conducted, both uni- and multivariate. The review is limited mainly by the methodological deficiencies of the included studies. All eight publications described in the review are retrospective case series and are therefore vulnerable to bias. The absence of randomisation and a control group means that any changes observed are the result of an uncontrolled pre-post analysis instead of a comparative analysis with control subjects who received an alternative treatment such as current standard conservative care. The other limitation of this review is the heterogeneity of study design and outcome measures of the studies included. Several surgical procedures in the included studies were carried out at different levels of metatarsal bones by surgeons with different levels of experience; thus, there may be potential bias [2].

The first strength of this study published in 2016 about DMOs for HV correction is its nature: a prospective evaluation of a consistent group of 80 patients with the same fixed FU points [5]. A 48-month FU can be considered a medium to long FU period compared with previously published studies. Further, all operations and the post-operative controls were always performed in the same way by the same surgeon, the author of this thesis. All clinical and radiographic data were collected and analysed separately by the same two independent investigators who were not involved in the patients' treatment and one not belonging to our unit [5].

The main limitation of this study is the lack of a control group, which would be useful to compare the results of this percutaneous technique. However, as reported by several authors [92, 99, 129, 130], DMOs include different techniques, and the heterogeneity of the groups examined in various reports does not currently permit an effective comparison and clear conclusions. For these reasons, long-term FU with multi-centre studies and randomised controlled clinical trials comparing RIO outcomes to those of other percutaneous methods would provide useful information for the validity and reliability of DMOs in the treatment of forefoot deformities.

Similarly, the strengths of the study published in 2021 about MIIND [6] include the following: the prospective data collection of the case series, whose size was calculated *a priori*, with the same fixed

FUs until the long-term one; the large consecutive patient inclusion (100 implants); the standardization of patient operations and aftercare; the analysis of the clinical and radiographic outcomes, carried out separately by independent investigators, with the one who performed clinical assessment blinded to the type of procedure used; the multivariable statistical analysis, performed by an independent statistician, also blinded to the type of operative treatment [6]. Also for this report, there were certainly some weaknesses: single-centre, case series study and single surgeon for all operations, aspects that could have affected the generalisability of the operative procedure; the retrospective analysis of prospectively collected data; the lack of a control group, which prevented us from comparing results; the use of the AOFAS score for outcome measure and VAS for patients' satisfaction [6].

Finally, future randomised controlled clinical trials comparing the d*ifferent Distal Metatarsal Osteotomies (DMOs)* analysed in this thesis (Distal Metatarsal Metaphyseal Osteotomy *DMMO* [1]; Minimally Invasive Metatarsal Osteotomies *MIMOs* such as Distal Metatarsal Diaphyseal Osteotomies *DMDOs* [2-4]; Reverdin-Isham *RIO* [5] and Minimally Invasive Intramedullary Nail Device *MIIND* [6]) to other conservative and traditional operative methods are necessary to provide further useful information for foot and ankle surgeons already performing MIS for the treatment of the most common forefoot pathologies: metatarsalgia, chronic plantar diabetic foot ulcers and mild to severe hallux valgus.

12. CONCLUSIONS

Considering the different results presented and discussed in this thesis, it is possible to conclude that:

1. **Distal Metatarsal Metaphyseal Osteotomy (DMMO),** often associated with percutaneous, minimally invasive or open techniques for hallux valgus correction and percutaneous soft tissue and/or bone procedures in cases of lesser toe deformities, is a safe and effective method for the treatment of biomechanical central metatarsalgia. Hence, this procedure can be considered a suitable alternative technique to traditional ones. However, the pre- and post-operative Maestro radiographic criteria do not have a predictive value in its clinical outcomes.
2. **Minimally Invasive Metatarsal Osteotomies (MIMOs) including only the distal ones such as the Distal Metatarsal Diaphyseal Osteotomy (DMDO)** are effective procedures for the treatment of complicated CDPFUs under the heads of lateral metatarsal bone and recurrent pressure ulcers, mainly those with healing delay or because of previous forefoot amputations with unbalancing of the metatarsal formula. Further, DMDO is effective even when associated with percutaneous extensor and flexor tenotomies in cases of claw toe deformity and percutaneous osteotomies of phalanges in cases of fixed deformities because both deformities are responsible for resistant toe ulcers.
3. **Reverdin-Isham Osteotomy (RIO) in combination with Akin Percutaneous Osteotomy and Lateral Soft-Tissue Release** is a safe, effective and reliable procedure for correction of mild to moderate symptomatic hallux valgus with a low number of complications and no osteosynthesis, allowing early weight-bearing and resulting in good cosmetic results with minimal surgical scars.
4. **Minimally Invasive Intramedullary Nail Device (MIIND)** is a viable procedure for correction of moderate to severe hallux valgus at long-term FU with a low rate of complications and recurrence. In cases of concomitant forefoot disorders, it can be associated with APO and DMMO.

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