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Original article

Preliminary study of elastic-tension digital neoprene orthoses for proximal interphalangeal joint flexion contracture

Utilisation des orthèses numériques en néoprène à tension élastique pour traiter les raideurs en flexion de l'articulation interphalangienne proximale: Étude préliminaire

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ABSTRACT

Flexion contracture of the proximal interphalangeal joint (PIPJ) is one of the most frequent complications in finger trauma. Orthoses are the most widely used method to optimize total end-range time (TERT). No previous studies showed that an elastic tension orthosis could be applied for longer than 12 h. We aimed to demonstrate that the elastic-tension digital neoprene orthosis (ETDNO) can achieve higher TERT and therefore better range of motion than other elastic-tension orthoses (ETO) described in the literature. A prospective study of treatment of PIPJ flexion contracture included 10 PIP joints in 8 patients who met the selection criteria. They were instructed to use the ETDNO for around 23 h per day as far as possible, during a period of 3 weeks. Patients reported a mean TERT of 20.6 h a day. PIPJ contracture improved by a mean Torque Range of Motion (TROM) of 23.5° at 500 g and 22.9° at 800 g of passive extension force during the 3-week treatment. Based on the results of this study, the ETDNO appears to offer a highly effective approach for improving PIPJ flexion contracture, increasing range of motion in extension. ETDNO's efficacy probably lies in the significantly improved comfort and low-profile design, enabling excellent compliance and thus optimizing TERT.
Level of evidence: Level III.

Mots-clés:
Raideur
Articulation interphalangienne proximale
Main
Traitement
Orthèse

RÉSUMÉ

La raideur en flexion de l'articulation interphalangienne proximale (IPP) est l'une des complications les plus fréquentes après traumatismes digital. L'utilisation d'orthèses pour obtenir le meilleur temps total en fin de traitement (TERT) est la méthode la plus utilisée pour traiter cette pathologie. Jusqu'à présent, aucune étude n'a documenté qu'une orthèse de tension élastique pourrait être appliquée plus de 12 heures. Nous avons cherché à démontrer que l'orthèse numérique en néoprène à tension élastique (ETDNO) peut atteindre des chiffres plus élevés de TERT et donc un meilleur résultat en amplitude de mouvement que les autres orthèses de tension élastique (ETO) décrites dans la littérature. Une étude prospective du traitement de la raideur en flexion IPP a inclus un échantillon de dix articulations IPP chez huit patients qui répondaient aux critères de sélection. Ces patients ont reçu l'instruction d'utiliser l'ETDNO environ 23 heures par jour pendant une période de 3 semaines. Les rapports des patients qui portaient l'ETDNO ont révélé qu'ils atteignaient un TERT moyen de 20,6 heures par jour. Les raideurs IPP s'étaient améliorées par une amplitude de mouvement rotatoire (TROM) moyenne de 23,5° à 500 g et de

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22,9º à 800 g de force d'extension passive pendant une période de traitement de trois semaines. Sur la base des résultats de cette étude, l'ETDNO semble offrir une approche très efficace pour améliorer les raideurs en flexion IPP, augmentant l'amplitude de mouvement (ROM) vers l'extension. Les chercheurs pensent que la raison de l'efficacité de l'ETDNO réside dans son confort considérablement amélioré et la conception à profil bas qui facilite une excellente compliance et optimise donc le TERT.
Niveau de preuve. – Niveau III.

Introduction

Proximal interphalangeal joint (PIPJ) flexion contracture frequently occurs after hand trauma. The literature describes pain, edema and immobilization procedures as the main causes of the tissue shortening that contributes to this condition [1]. Psychological issues also contribute [2]. Clinicians consistently choose orthoses to reduce flexion contracture and achieve range of motion (ROM) goals [3]. There is evidence that the key elements of orthosis treatment to increase PIPJ passive range of motion (PROM) are prolonged application of low-load stress, sufficient to position the shortened tissue at or near the end of its currently available length [3,4]. If the clinician fails to consider and control all 3 variables (time, load, and optimum tissue length), the desired result will not be achieved.

For effective modification of shortened tissue, Flowers et al. demonstrated the importance of time after the tissue has reached maximum tolerable length [3]. They demonstrated that doubling the time of end-range tissue tension doubled the improvement in ROM; there was a direct relationship between the amount of time the tissue was under tension at maximum tolerable length and the amount of change in ROM. They called this concept "total end-range time" (TERT). Consequently, clinicians widely accept that the amount of time the tissue remains in the end range is a critical factor in improving PROM, including PIPJ flexion contracture [1,3,4].

Flower et al. employed the serial casting method, using a tolerable but unknown force, and distributed pressure well enough to allow 24-h-a-day wearing, without interruption [3]. Thus, their results were achieved with 24-h-a-day TERT. They did not present 24 h a day as a recommendation but rather as an option. No studies have established the "optimal" duration of orthosis application, but subsequent studies sought to optimize TERT.

After a period of serial casting, additional degrees of passive extension become available [1,3]. Unfortunately, the serial cast cannot take advantage of this advanced "end-range position" until the therapist makes a new serial cast. This new cast captures the improved end range and progresses the joint to the next ROM level. Thus, this approach requires sequential cast changes, with frequent consultations. The nature of serial casting is a challenge for clinicians. Because of the need for both patient commitment to the approach and frequent return consultations, serial casting can create significant difficulties in continuity of compliance and therefore of follow-up. Experience shows that the optimal clinical setting for serial casting is residential, which is now rarely available. Because of this difficulty, subsequent studies treated PIPJ contracture using static progressive orthoses (SPO) [5] or elastic-tension orthoses (ETO) [6,7], to pursue progressive end-range positions. ETOs do not necessarily require the same number of repeated therapy sessions. However, they have not demonstrated the same length of continuous wearing time, and TERT may thus be significantly shorter.

In fact, none of the previous interventional studies using ETOs reported more than 12 h daily TERT [6–8]. This was using a 3-point pressure ETO and a force in the 200−250 g range. Glasgow et al. concluded that "it may not be clinically practical to expect patients to comply with a daily TERT beyond 12–14 h" [8]. While reporting improvement in ROM, no studies obtained full contracture resolution. Thus, PIPJ contracture treatment with ≤12 h TERT seems not to achieve successful contracture resolution.

Because of the difficulty with continuous ETO use, authors accepted intermittent orthosis treatment [6,7]. This suggests that the rehabilitation community should accept that ETO use must inherently be intermittent. Glasgow et al. coined the term "daily TERT" to describe orthosis wear time per day [7], on the assumption that it would necessarily be significantly less than 24 h.

In applying orthosis treatment to this problem, clinicians can choose from various types of force generators: serial static, static progressive, and elastic tension (often termed "dynamic" orthotic) [1,6–11]. Each type impacts orthosis design. However, there is no evidence defining clear indications for either a specific orthosis force generator, or a program to implement it.

When clinicians choose to apply an ETO, they may select from multiple design options [1,3,5–11]. These orthoses frequently incorporate moving components and, when custom-made, construction can involve great technical demands. The ETO generates a continuous force that creates tissue tension to at least the end-range of motion and often beyond. The spring-wire orthosis based on the Capener orthosis, offering a very low-profile option, is the model that clinicians most frequently use [1,6–8,12,13].

Research shows that contracture frequently recurs [14–16], especially with intermittent treatment. According to Bell-Krotoski and Figarola, "the greater the interruption, the slower the process" [9]. Flexion contracture angle characteristically lacks stability, and the attempts to intervene fail to generate predictable outcomes [1].

According to Fess, the forces that most commercially available PIP extension orthoses generate vary with the angle of joint contracture. They increase force by 20 g–100 g per 10° increase in flexion, quickly resulting in forces above those that previous studies recommended [17]. The clinician can customize the ETO force at 250 g for a specific joint position. However, if the flexion contracture increases, the orthosis tension set for the lesser angle will also increase. If the increase equals 10º, the orthosis will then generate up to 350 g force – an amount that exceeds the recommended limits [17,18]. As the forces increase, comfort decreases, and the orthosis may become too painful to tolerate. Even if the clinician customizes the elastic-tension orthosis force to a specific patient's finger in a specific joint position, without constant use the flexion contracture can increase again if orthosis use is intermittent.

Research into conservative treatment of PIPJ stiffness with currently available orthoses showed that treatment duration averages 4.3 months before a stable result is obtained [6]. As mentioned above, because serial cast application often requires frequent consultations over several months, researchers assessed 3-point pressure ETOs [6–8,10,12,13,17,18], which resulted in a maximum TERT of 12 h [6–8]. To increase daily TERT, we need to explore new therapeutic options.

The use of soft materials in conjunction with a circumferential ETO design may be a good option to increase daily TERT beyond 12 h. This design provides greater finger skin surface contact, minimizes inflammation risk, and manages edema [19].

Soft materials are not a new idea, and clinicians have explored the impact on comfort. Preliminary studies of silicone tubes [20] and neoprene [19] suggested that the circumferential neoprene Banana Splint™, when properly fitted, increased the contact surface between orthosis and finger, and could reach a range of forces between 100 g and 650 g from 10º to 80º. However, none of these studies described models with customized orthosis size for a specific patient.

Punsola-Izard et al. proposed the first soft custom-made orthosis, using neoprene with a design specific to the individual patient [21]. It consisted of a straight neoprene tube with an axial dorsal strip that generated extension tension. The therapist customizes the size of the tube to the size of the patient's finger. Since 2001, in our clinical practice, we have used this ETDNO method to improve passive extension in PIPJ flexion contracture. Most of the patients who received this ETDNO approach improved their PIPJ extension; many achieved extension to 0° or neutral PIP passive extension. In addition, some patients with flexion contracture <30º could wear the orthosis longer than 12 h, even keeping it for more than 20 h a day in some cases. This increase in daily wear time correlated with faster improvement. The ETDNO demonstrated promising clinical results [21]. Patients reported comfort, which facilitated compliance which in turn optimized TERT and extension improvement. However, no wear tolerance studies have been performed for ETDNO. In addition, because previous ETO studies did not employ an orthosis that patients could tolerate for more than 12 h a day, we do not know the effect of orthosis application for longer times.

The purposes of this study were to investigate whether: (1) ETDNO improves extension in patients with proximal interphalangeal joint flexion contracture; and (2) patients with PIPJ flexion contracture can wear the ETDNO for more than 12 h a day.

Patients and methods

A preliminary prospective clinical trial investigated the effectiveness of the orthosis in improving flexion contracture. The bioethics commission of the University of Barcelona approved the research protocol. The researchers carried out the study in accordance with the Declaration of Helsinki. Spanish Data Protection Law governed the handling of all data.

During a 6-month period, the researchers identified 17 patients presenting with PIPJ stiffness in our clinic. The cohort included only patients with PIPJ flexion contracture (Jupiter classification type 5: flexion within normal limits and extension equals active range of motion and passive range of motion [22]). To minimize the risk that patients receiving orthosis treatment would experience flexion loss, no included patients had concomitant extension contracture and flexion deficit. Patient selection included only trauma and Dupuytren release diagnoses[1] and excluded conditions such as rheumatoid arthritis and PIPJ replacement. Eight of the 17 patients (7 male and 1 female) met the specific selection criteria. Six had 1 finger with PIPJ pathology while 2 patients had 2. Table 1 shows diagnoses.

A single researcher (VP) collected data via interview and measurement. All subjects provided written informed consent before starting treatment. Duration of contracture ranged from 3 to 21 weeks. Flexion contracture ranged from 45º to 10º. The researcher collected additional baseline data on age, gender, time since injury or surgery, diagnosis, pre-treatment joint PROM, and medical and surgical history.

Table 1
Conditions affecting the PIP joint.

Patient number	Gender	Age	Diagnosis
1	M	46	Dislocation injury
2	M	33	PIP joint strain injury
3	M	71	Dupuytren postsurgical flexion contracture
4 F1	F	23	Flexor tendon injury
4 F2	F	23	Flexor tendon injury
5	M	36	Flexor tendon injury
6	M	59	Dupuytren postsurgical flexion contracture
7	M	35	Dislocation injury
8 F1	M	58	Intra-articular PIP joint fracture
8 F2	M	58	Intra-articular PIP joint fracture

M: male; *F*: female, *F1*: finger 1; *F2*: finger 2; *PIP:* proximal interphalangeal.

The researcher saw each patient 4 times: first consultation, plus once a week for 3 weeks on days 7, 14 and 21. At each consultation, patients were interviewed concerning daily TERT. They also underwent extension ROM evaluation. Firstly, PROM was evaluated manually (Fig. 1), followed by torque range of motion (TROM). For TROM evaluation, the investigator used a customized MAPS Therapy hand pegboard® (MAPS Therapy™, Barcelona, Spain) and an adapted plastic goniometer (Enraf-Nonius™, Barcelona, Spain). The therapist stabilized the proximal segment of the PIPJ with the pegboard, then applied the goniometer while exerting extension force at the neck of the middle phalanx (Fig. 2). TROM was evaluated at 500 g [7] and finally at 800 g [6]. Evaluations were performed 3 times, and the mean was recorded. We used these parameters for TROM because previous studies had reported them [6,7].

With this part of the finger secured, it was possible to apply traction to the distal aspect of the middle phalanx. A Haldex tension gauge (JID Tools, Jonard Industries™, Tuckahoe, NJ, USA) determined the specific levels of torque applied to the joint. We did not evaluate active range of motion (AROM) in extension because the status of the extensor apparatus, upon which extension AROM depends, was not the focus of this study. The treatment program comprised 4 sessions over a 3-week period. While Prosser [6] found that 80% of the improvement often occurred at the beginning of treatment and especially in the first 2 weeks, we wanted to allow for three weeks of treatment, to examine the progress we would obtain.

During the first session, the researcher interviewed the subject, collected data, and took the measurements of PROM and TROM at

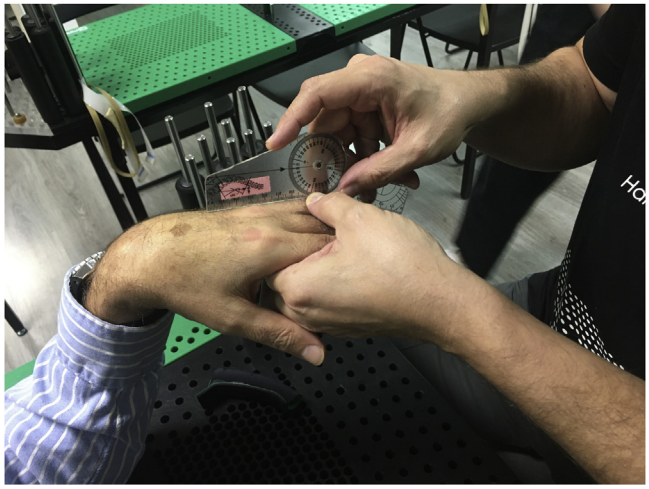

Fig. 1. Manual evaluation of finger PROM extension.

[1] Dupuytren patients achieved neutral PIP values after surgery, but subsequently, experienced PIP contracture recurrence.

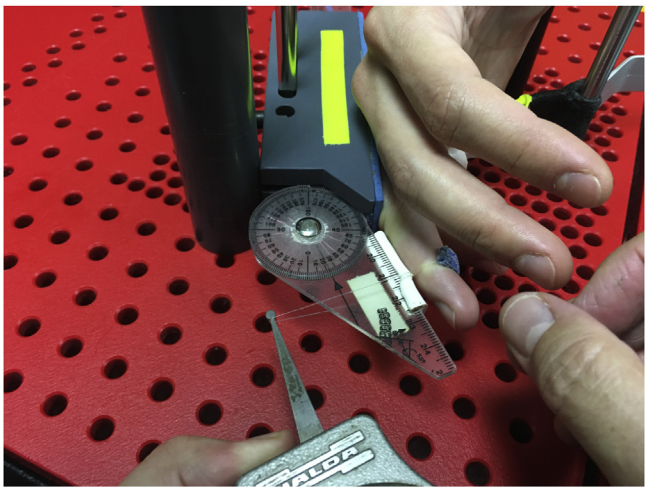

Fig. 2. Evaluation device: a MAPS therapy® pegboard to stabilize the MCPJ in 30º flexion and keep the wrist at 0º, a finger goniometer support on the dorsal aspect of the first phalanx, an adapted standard plastic goniometer (Enraf Nonius™) and a Haldex tension gauge (Halda Haldex™ 1000 g gauge tensiometer). The researcher placed a loop of inelastic nylon thread protected by thermoplastic around the volar distal part of the second phalanx and applied traction using the tensiometer.

500 g and 800 g force. Treatment started the same day. Initial treatment consisted of 15 min of hot-pack preconditioning with the hand in pronation and the fingers extended as far as possible.

During this initial session, the therapist produced the patient's first ETDNO (Fig. 3). All subjects received instruction to wear the orthosis for more than 23 h a day (i.e., 24 h a day, except for brief removal for hygiene purposes, or pain above 3 on a 10-point visual analog scale). In the following sessions, after removing the ETDNO and warming the area for 15 min, the researcher repeated the same measurements, at days 7, 14, and 21. When patients showed more than 5º improvement in extension, they received a new ETDNO. We noted that, over time, the resilience of the neoprene decreased, resulting in less tension in the device. ETDNO replacement re-established a higher level of tension.

Patient interview revealed that when the patients started wearing the ETDNO, they did not initially feel discomfort. However, some reported that, after 1 h of ETDNO use, they felt tension, leading to discomfort. This lasted for approximately 30 min and then resolved without the need to remove the ETDNO. Some patients also described nocturnal discomfort in the first 2 days. We knew that if this discomfort were not properly managed it could cause intermittency and, to increase compliance despite discomfort, patients were instructed: "During the first 48 h of orthosis use, in case of any discomfort, take the orthosis off for 1 h and then put it back on again. If discomfort during the first 48 h occurs during the night, then you should take the orthosis off and put it back on again in the morning. Following this initial 48-h period, you should wear the orthosis continuously."

When patients received a replacement ETDNO, some reported slight discomfort during the first 48 h. For this, they were instructed: "Remove the new ETDNO for 1 h and use the old ETDNO instead. If discomfort occurs during the night, use the old orthosis while sleeping."

Evaluation between the first and the third weeks documented change in PROM and in TROM at 500 g and at 800 g. The researchers tested the normal data distribution on Shapiro-Wilk test and compared the data using the parametric t-test.

Results

Patients wearing the ETDNO improved PIPJ extension passively (Figs. 4 and 5). They achieved a mean TERT of 20.6 h a day (Table 2). Most of the fingers (90%) were able to wear the ETDNO for more than 12 h; 40% of fingers achieved 23+ h daily TERT, removing the orthosis only for hygiene (maximum daily TERT). All patients except one reported being able to use the orthosis during their activities of daily living (ADL) and work activity.

The 60% of the sample that did not reach the maximum daily TERT (23+ h per day TERT) reported multiple reasons for the shortfall in the wear schedule. One patient —an osteopath— managed only 10 h a day because ETDNO use interfered with his work. Other patients reported night-time discomfort, especially during the first 2 days after an orthosis upgrade. Two patients stated that they wore the orthosis for 22 h per day and another one for 20.5 h per day. Claiming that he felt the orthosis was too strong, one patient with 2 injured PIP joints wore the 2 ETDNOs for 18 h. Two fingers (fingers 3 and 4) with flexion contracture of more than 30º (Fig. 4) presented erythema and pain on the dorsal aspect of the PIP joint (Fig. 5). These 2 patients also improved their PROM.

All patients treated in our study increased their passive PIPJ extension (Table 2). The mean passive extension gain was 23.2º ($t = -5.1$; $p < 0.0001$). The mean TROM extension gain was 23.5º at 500 g ($t = -5.1$; $p < 0.0001$) and 22.9º at 800 g ($t = -4.5$; $p < 0.0001$). There was no statistical difference between PROM and TROM at 500 g or PROM and TROM at 800 g.

Fig. 3. Elastic-tension digital neoprene orthosis (ETDNO).

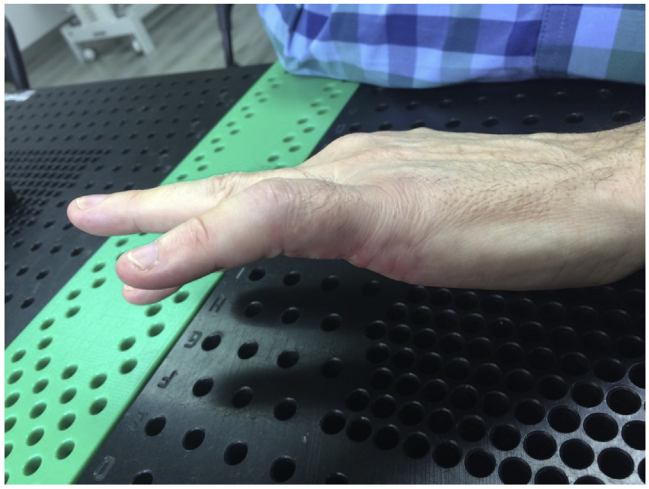

Fig. 4. Finger before being treated with the ETDNO.

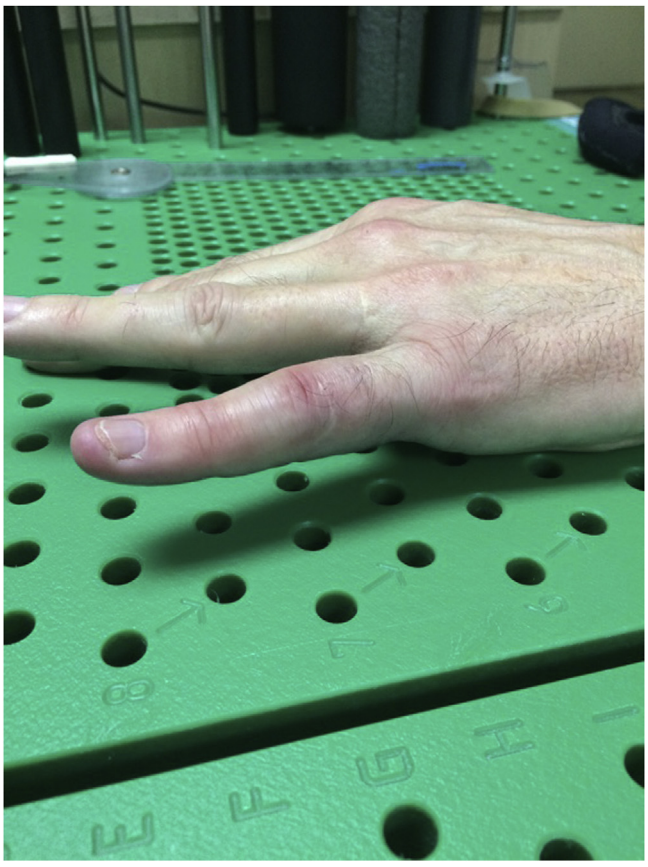

Fig. 5. Finger after treatment with the ETDNO, and PIPJ dorsal skin erythema.

Discussion

In this study, 40% of the PIPJs obtained a TERT of nearly 24 h a day, while 60% did not achieve this (Table 2). Mean TERT was 20.6 h. This result is higher than the daily TERT reported in literature. Prosser's patients, who received instructions to use an orthosis for between 8 and 12 h, achieved a mean daily TERT of 8 h using a hand-based customized ETO and 11 h using a Capener splint [6]. Glasgow et al. divided study subjects into 2 groups, both using a Capener splint. Patients receiving instructions to wear the orthosis between 8 to 12 h achieved 9.5 h wear. Those asked to wear the orthosis between 12 and 16 h achieved 11.5 h wear [8]. The present results refute the claim that "it may not be clinically practical to expect patients to comply with a daily TERT beyond 12–14 h" [8]. Although we did achieve greater daily TERT than reported elsewhere, our goal was to achieve even higher rates of 23 + hours. We may need to modify the forces according to each individual need. We do not know whether discomfort caused the primary interruption of use whether the interruption caused the discomfort because of recurrence of contracture. As mentioned above, increase in flexion contracture angle magnifies the force that an orthosis generates. We need to conduct further studies to understand cause and effect. Clinical experience with this method and technical procedures related to ETDNO construction will certainly benefit from improvement. Clinicians need to ensure that the orthoses are comfortable enough to wear for long periods without interruption. Maximizing TERT will optimize the desired outcomes.

The mean TROM extension improvement obtained in this sample of patients was 23.5º at 500 g and 22.9º at 800 g over a 3-week period. Prosser obtained a mean improvement of 18º using an ETO over a period of 8 weeks, with a mean TERT of 10 h. Glasgow et al., in a two-group study, used a Capener ETO. Group A wore the orthosis for 6–12 h and group B for 12–16 h. Over the 8 weeks, they obtained an increase in TROM at 500 g of 9.2º for group A and 12.8º for group B, and an increase in PROM of 18.4º for group A and 18.1º for group B. Group A obtained a mean 9.5 h TERT and Group B 11.5. All subjects used 250 g force. As Glasgow et al. [7] suggested, researchers need to do further studies that explore daily TERT beyond 12 h. In the past, because no patients tolerated ETOs beyond 12 h per day, such a study was not possible. The present study demonstrates that, with the ETDNO design, close to 24 h daily wear is indeed possible. Using this ETDNO design, we can pursue further research in this direction. Although the present results are an improvement on previous reports, we need to perform studies of higher quality that demonstrate the validity of 23+ hours compared to shorter daily TERT.

The circumferential ETDNO design increases the overall contact area for force generation, creating a well-distributed compression force. This compression makes the orthosis stable on the finger, minimizing shear forces between the finger and the orthosis. Clinical experience shows that the increased contact design of the ETDNO helps to minimize edema and to control scar volume [22]. Patients reported that the neoprene tends to increase digit warmth and may provide the added benefit of the combination of heat and stretch [23]. Ninety per cent of the subjects described the orthosis as easy to wear and indicated that it did not interfere with their ADL. Empirically, it seems that a patient experiences more comfort with a small soft circumferential orthosis and will wear it

Table 2
Extension improvement: PROM and TROM at 500 g and at 800 g and weekly TERT (total end-range time).

Patient	Extension at Day 1			Extension at Day 21			Extension improvement			TERT
	Passive	500 g	800 g	Passive	500 g	800 g	Passive	500 g	800 g	hours
1	−18	−16	−10	0	2	8	18	18	18	24
2	−34	−34	−32	4	6	10	38	40	42	20
3	−36	−35	−32	−22	−20	−16	14	15	16	24
4	−52	−52	−46	−28	−27	−24	26	25	22	24
5	−30	−28	−22	0	2	4	30	30	26	24
6	−26	−27	−25	0	3	12	26	30	37	22
7	−30	−30	−28	−6	−4	−2	24	26	26	22
8	−30	−28	−20	−8	−7	−5	22	21	15	10
9	−20	−19	−14	−0	0	3	20	19	17	18
10	−20	−18	−15	−6	−7	−5	14	11	10	18
Mean							23.2	23.5	22.9	20.6
p-value							$P < 0.0001$	$P < 0.0001$	$P < 0.0001$	
Standard deviation							4.9º	4.8º	4.9º	

TERT: total end-range time; *PROM:* passive range of motion; *TROM:* Torque range of motion.

for longer periods of time than a traditional 3-point pressure ETO. The increased TERT reported in this study strongly supports this conclusion.

The only drawback we detected for this approach to PIP orthosis treatment was skin compression, especially over the dorsal aspect of the PIP joint. As the finger modifies the tube's shape after ETDNO application, the amount of force each section of the ETDNO applies to the finger is relative to the degree of the PIP flexion contracture, severe contracture creating greater pressure in this area, causing pain. Erythema on the dorsal aspect of the PIP joint in flexion contractures exceeding 30º indicates skin distress (Fig. 5), suggesting that, in case of >30 ° contracture, the ETDNO design exceeds the upper limit of its therapeutic range of force. Evaluation of ETDNO forces at 30º will help to clarify the therapeutic force thresholds related to skin pressure, especially when patients attempt to wear the device for 23+ hours per day. Further studies will be needed to determine the forces that an ETDNO creates and to identify the safe therapeutic ranges that avoid skin irritation or injury.

This study focused on the efficacy of ETDNO in improving extension over a 3-week period, and not on full resolution of PIP flexion contracture. However, 3 of the patients did achieve neutral PIP with full contracture resolution. Prosser suggested that, ideally, follow-up for this condition would continue for at least 4.3 months because, in her study, no contracture resolved or stabilized within a 3-week period [6]. No subjects in previous studies achieved a neutral PIP even within this 4.3-month interval. We will need further research on treatment over longer periods to determine how much time is necessary to completely resolve flexion contracture using the ETDNO.

Conclusions

This study focused on one of the classic problems encountered in hand therapy: PIP flexion contracture. While until now, using ETOs, 12-h TERT seemed to be the maximum for the treatment of PIP stiffness, the present study showed that soft materials such as neoprene can improve TERT to 23+ h a day. This new method of elastic-tension digital orthoses to improve extension range of motion in PIP flexion contracture provides another effective technique in this indication.

This preliminary study provides evidence to support the use of ETDNOs, demonstrating efficacy in improving PIPJ flexion contracture to a greater degree and in a shorter time than previously studied ETOs. Efficacy seems to lie in the ability to apply acceptable levels of force for long periods of time in a manner that patients tolerate easily. Good tolerance results in better compliance, and compliance is the key to increasing TERT. ETDNO optimizes TERT because it combines the advantages of serial static orthoses, both comfort and "full-time wear", with the "end-range" advantages of ETO. This research strongly suggests that the ETDNO concept meets the optimal criteria of PIP flexion contracture orthosis design. ETDNOs are "low profile", inexpensive, and easy to customize to individual finger size.

Authors' contribution

Conceptualization Resources: VP, KS.
Data curation Software: VP, EO, JM, GR, NC, AC.
Formal analysis Supervision: VP, KS, ML, AC.
Funding acquisition Validation: VP.
Investigation Visualization: VP, EO, JM, GR, NC.
Methodology Writing - original draft: VP, KS.
Project administration Writing - review & editing: VP, KS, AC.

Conflict of interest

VP has commercial links with the MAPS Therapy company. The other authors certifies that they have no commercial associations that might pose a conflict of interest in connection with the submitted article.

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Ethical review committee statement

All experiments comply with the current Spanish laws, and ethical approval was granted by the committee of the University of Barcelona (Institutional Review Board IRB00003099).

Informed consent of patients

The informed consent of the patients was obtained by applying the current data protection law of Spain.

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