Degradation of lingual orthodontics archwires
The effect of corrosion and nickel release on their properties

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1. Introduction

1.1 Lingual orthodontics: a brief history of the beginning

In 1970 Craven Kurz, a Northamerican orthodontist based in Beverly Hills, who was an associate professor of Occlusion and Gnatology at the UCLA School of Dentistry, started investigating about the way of performing fixed multibracketed treatments with a lingual approach, that is, by bonding the brackets in the lingual surfaces of teeth. The reason was purely aesthetics. Some of Dr. Kurz's patients were fashion and cinema celebrities that needed orthodontic therapy but could not allow themselves to be under visible fixed orthodontic treatment for a long time. The only way of fulfilling both conditions was to hidden the brackets where they could not be seen. The perceived embarrassment of wearing braces was the reason for avoiding the traditional "outside braces".

Dr. Kurz bonded plastic Lee Fisher brackets at the anterior teeth combined with metallic brackets at the posterior sectors, all of them at the lingual sides. These brackets were seen to be suitable because, given they were plastic brackets, they could be reshaped when the occlusion and crowding made them impossible to fit well.

A research team was formed once an orthodontic manufacturer saw the possibility of commercialising this appliance. Craig Andreiko, Frank Miller and Dr. Craven Kurz were the initial components of Ormco's Task Force. Ormco had before tried to make a lingual bracket system but it did not consolidated.

A petition for the patent of the new bracket with an inclined anterior bite plane was done the 15th of November of 1976. It was manufactured as the Kurz Lingual Appliance. The patent gave rise to the development of the product. The industrial manufacture started in 1979 and it could be said to be the first lingual appliance to be ever made. The first clinical assays consisted of a monitored treatment of 100 lingual cases by Dr. Kurz at his private practice and were followed for 3 years. The initial steps of the technique can be studied at the article written by Kurz et al which is one of the earliest documented work[1].

At the same time, Dr. Kinya Fujita, a Japanese orthodontist from the Kanagawa Dental University, started investigating about a lingual approach for the orthodontic treatment but motivated by different reasons that the ones that led Dr. Kurz bonding lingual. Some of Dr.

Fujita's patients practised fighting and the hits they received around the orofacial area resulted in wounds at the oral mucosa due to the impact of the vestibular brackets on it. The only way of completely solving the problem, being treated by a multibracketed fixed appliance and practising fighting, was to bond the brackets at the lingual sides. The first outcomes and experiences of the technique were published by Dr. Fujita in two articles[2,3].

Aesthetics and safety during contact sports were the reasons that gave rise to the new orthodontic approach that could be fully described as a new treatment philosophy which is nowadays known as lingual orthodontics.

1.2 Evolution of the technique

From the very beginning, different evolutions could be observed at the United States of America and Europe.

There was a boom at the US when the appliance was introduced at the orthodontic market. The initial boom was followed by an almost total abandonment of the technique by most of the orthodontists, even by some of the clinicians that took part at the development of the appliance. The problem was that clinicians did not have a consolidated practice and protocols.

The main reasons of the crisis were the poor results obtained by the vast majority of the orthodontists with the lingual approach and the inherent difficulty of the treatment. The basic problem was the lack of systematization of the technique: treatment protocols were inexistent. This was due to the fact that there were not many finished cases that could be used as such to establish a reliable protocol. A second reason was the lack of knowledge about the new biomechanics of the lingual appliance. Most orthodontists were thinking labial although using lingual appliances. Unwanted effects, like the bowing effect in all its dimensions, were not under control. Physical and biological conditioning factors did not react in the same way when forces were applied at the lingual surfaces when compared to the labial. Prescriptions and forces were still based on the labial approach although they were translated to the lingual sides.

It could even be said that some biomechanical points were not still fully understood in labial orthodontics around the late 1970s when using the preadjusted appliance with the straight archwire approach. Therefore, a thorough understanding of the unwanted effects that the archwires had on the dentition once engaged was not still achieved. It is easy to understand that the good control of the case and the anchorage control are of paramount importance during the orthodontic treatment. If they were still not fully understood in the late 1970s for vestibular orthodontics, lingual orthodontics translation of this point was still very immature.

A technique unrelated factor that led lingual orthodontics to a sudden crisis was the expectation that surrounded the birth of the new appliance and the new treatment. The media gave a huge and massive coverage of the appliance and the fact that some doctors were already treating patients with fixed orthodontics but in a non visible way. Many people started asking for such a treatment and many orthodontists, eager to keep up with the demand, did not have other way that starting the cases with no previous experience. Big expectations on a new technique that had not been clinically proven gave rise to deceptions of the same magnitude. People had been made aware of the technique too early: a complete understanding, protocolization and results of the technique had not still been achieved.

The evolution of the technique followed different paths in Europe and the rest of the world. The introduction of the technique was smoother and constant and the consolidation was better. It did not experience such an abrupt start and it was not introduced to the patients in a massive way and the media did not take part on it. These facts gave enough time for systemizing the diagnostics and treatment protocols. Special characteristics related to the lingual approach like the important laboratory phase for bracket placement were also developed.

Lingual bracket designs have been refined and diverse laboratory techniques have been implemented in order to undergo indirect bonding, which is one of the main points of the technique due to the fact that direct bonding on lingual surfaces is very difficult due to access and dryness control. Achieving the correct position for the brackets is of paramount importance for the final result of the treatment. It is obviously important because, otherwise, it is difficult to let the brackets express their built-in prescriptions in the ideal manner. Different authors have systemized the archwires sequences according to their own experiences in relation to space management (obtaining space or space closure techniques), anchorage control and different aesthetic considerations that should be taken into account before the treatment starts and during its progress. In this way the bases of the lingual technique had been set before being put massively into practice in Europe and the rest of the world.

The bracket initially designed by Dr. Kurz has evolved much during the past 30 years. It nowadays exists in its seventh generation as the Ormco Kurz 7th generation lingual bracket. There are different bracket systems for the lingual treatment available from different companies although there are not as many as for the vestibular technique. The STb bracket designed by Dr. Scuzzo and Dr. Takemoto, the Incognito bracket by Dr. Wiechmann, the Adenta's bracket and Dr. Fujita's bracket could be said to be the most known systems. It has to be said that the

Kurz 7th generation bracket system provides the widest accumulated experience so far in lingual orthodontics as most lingual orthodontics books and articles written so far show. The STb bracket seems to be performing very well in moderate cases: it seems to act in a very quick way as some authors and presentations show[4] although more evidence is still needed.

Among others, the main responsibles for the evolution of the lingual technique in Europe and Middle East are Dr. Didier Fillion (France), Dr. Giuseppe Scuzzo (Italy), Dirk Wiechmann (Germany), Dr. Pablo Echarri (Spain), and Dr. Silvia Geron (Israel) and Dr. Rafi Romano (Israel). Non-European specialists that have played an important role are Dr. Jack Gorman, Dr. Bob Smith, Dr. Richard Alexander, Dr. Moody Alexander, Dr. James Hilgers, Dr. Bob Scholz and Dr. Mario Paz (all of them from USA), Dr. Stuart McCrostie (Australia), Dr. Toshiaki Hiro (Japan), Dr. Kyoto Takemoto (Japan) and Dr. Hee-Moon Kyung (Korea)

The evolution and consolidation of the technique has been the frame for the creation of lingual orthodontic societies all around the world. Some textbooks have been published on the technique together with specific journals and articles on the lingual technique. In March 2006 the World Society of Lingual Orthodontics held the first meeting as a congress in New York (USA) that got together for the first time most of the specialists that practice the lingual technique. Different presentations were held to show the results and research that so far was being carried out in different countries. This event could be said to be the first maturity sign of the technique since the initial efforts of Dr. Kurz and Dr. Fujita.

There are now enough reasons and facts to state that the lingual technique is a valid alternative in the orthodontic treatment whose characterization relies on the invisible setting of the brackets which is a very important feature for many adult patients. There are studies that assess the impact that visible appliances have on the decision of not undertaking an adult orthodontic treatment although being necessary[5] and they clearly show this as a main concern.

Besides the improved aesthetics as a good reason to choose a lingual approach, there are some clinical scenarios in which a lingual treatment can be more effective than a vestibular approach. Anterior front intrusion, maxilar arch expansion and upper molar distalization are benefited from the lingual approach due to the biomechanical considerations of teeth movement defined by the bracket position in relation to the center of resistance of teeth. A small but not less important advantage of the lingual treatment is that vestibular teeth sides are not altered by bracket bonding with acid etching and adhesives. Some authors also remark the fact that lingual gingival margins are less affected by treatment induced periodontal problems than vestibular gingival margins when a conventional vestibular treatment is performed[6].

Lingual technique does also have disadvantages when compared to the vestibular treatment. Lingual brackets are usually quite disturbing for the tongue. Speech is slightly affected for some time given the location of the appliances. Lingual treatment also needs a very close and intense relation with the laboratory from the very start of the case. As it was previously said, indirect bonding requires special laboratory techniques for a correct and precise bracket placement. It is normally performed with transfer trays. Much attention has to be put on small details of the laboratory work and treatment planning. Treatment sessions tend to be longer than for the vestibular approach given that the access to the appliances is more difficult. Increased chair time makes the treatment more expensive: it easily doubles the cost of a vestibular treatment. Working ergonomics is more complex and demanding. Postural back pain resulting from poor ergonomics is also an important point for many orthodontists' discouragement when thinking on the lingual technique. Nonetheless, most of these disadvantages can be somewhat overcome although it may not be in a complete way.

The following photo shows an upper and lower arch treated with a lingual appliance.

1.3 Justification of the thesis

Lingual orthodontics has reached a maturity status that enables it to be a widely spread technique as it is starting to be. As the technique has been clearly defined and proven, with variations introduced by different authors, archwire sequences and bracket systems are nowadays quite established. Now that the main points have been made clear, other considerations regarding the treatment can be made. There are unknown points that need being unveiled so to understand the implications that the use of the appliances can have on the progress of the treatment and particularly on the patient.

As in other fields like medicine and biology, safety and biocompatibility of any device designed to be used for therapeutic purposes has to be checked. Interactions of any implantatory device with the surrounding environment should be studied to assess the risk that the device represents for the patient. Dental implants, hip prostheses, cardiovascular stents and the vast array of aesthetic surgery devices used in breast surgery and facial treatments are some of the most popular examples.

Orthodontic appliances could be forgotten when listing such devices. It normally occurs because there is a tendency to establish an association between safety and biocompatibility concerns with invasive surgical procedures.

The oral cavity represents a harsh environment for the orthodontic appliances. Physical, chemical and mechanical changes have been studied both in archwires and brackets while being used in an orthodontic treatment. This fact has been the object of study of many articles published at the main orthodontic journals [7-32].

One of the main concerns about orthodontic appliances set in the oral cavity is corrosion. Orthodontic appliances are continually under the corrosive action of saliva and the fluids present in the oral cavity. Besides saliva, extrinsic fluids coming from food intake, surrounding interactions of the environment (swimming pool water, sea water, etc) and the products used for the oral care and hygiene (toothpastes and mouthwashes) are responsible of interactions with the orthodontic appliances. Most of the studies published so far have focused on the effect of the corrosion on materials like stainless steel (ss), Nickel-Titanium (NiTi), Copper-nickel-titanium (CuNiTi), Titanium Molybdenum (TMA), Chromium-Cobalt (CrCo) of brackets and archwires[7-12].

The purpose of the present thesis is to be a basic and initial contribution to the knowledge about the corrosive behaviour of the archwires commonly used in lingual orthodontics. Once corrosive behaviour is understood, conclusions could be drawn regarding clinical implications both for the progress of the treatment and the patients' safety.

The present thesis is only focused on the archwires. Brackets corrosion was not studied. This is not due to the fact that they are not believed to undergo corrosion but to the design of the study. The fact of studying the archwires alone simplifies the design of the experimentation and helps obtain reproducible results. There is also an important quantitative difference between both components of the orthodontic appliance: while brackets normally remain for the whole length of treatment, archwires are only engaged for relatively short periods of time and then they are replaced by other archwires when indicated. This is another reason for deciding a study focused only in one of the components. The study of metal-to-metal interactions were avoided, so galvanic behaviour was not be included in the study although it better explains the real clinical scenario for the reasons stated above.

There is a further reason for studying the archwires as a single unit. At the initial stages of the technique, the archwires used in lingual orthodontics were not specifically designed for the technique, that is, they were vestibular orthodontic archwires adapted for lingual use. There is now the possibility of using archwires specifically manufactured for lingual orthodontics (Ormco lingual orthodontics series) and there exists the need of studying whether they behave in the same way as the archwires manufactured for vestibular orthodontics or not, and to what extent differences exist.

To our knowledge, there is no published data on the corrosive behaviour of lingual orthodontics' archwires. Several objectives were set in order to study the corrosive behaviour of the archwires.

The objectives of the thesis are:

1. To study the as-received microscopical aspect of the lingual orthodontics archwires and the surface structural changes of the archwires after being in contact with a saline preparation for 30 days through scanning electronic microscopy (SEM) and atomic force microscopy (AFM)

2. To study the basic corrosive properties of the archwires in order to determine the potential of corrosion and the pitting potential for each archwire and also the microscopical effects of corrosion on archwires with SEM and AFM after anodic potentiostatic polarization.

3. To study the ionic release of Ni of the Ni containing archwires to evaluate its potential

danger for the patient.

4. To evaluate the changes that corrosion may have on the martensitic and austenitic phase transformations of the nickel and titanium archwires.

These objectives seek a better understanding of the lingual orthodontics archwire behaviour under an in vitro simulated corrosive environment. The understanding of the corrosive behaviour of lingual orthodontics' archwires assessing the safety wants to be a contribution towards the evolution of the technique and a starting point for further research on the field.

1.4 General introduction to corrosion

Sciences that deal with structural matters study the behaviour of the matter under normal conditions of use. Their objective is to understand how they will behave and whether they will fulfill or not the expectations for a given use. It is clear that this kind of studies also help establishing the limitations of the material or structures which is most times of paramount importance.

Questions like the flexibility that the wings of a commercial aircraft have, the force that civil engineering construction beams can hold, the impact that a car structure can absorb on a frontal collision are to be known so to establish the limitations of the structures and give use recommendations. As it can be seen, consequences derived from a lack of knowledge could imply a severe danger for the lives of many people.

In these considerations, manufacturing optimization is an important key point. Manufacturing an excessively expensive but safe structure may not be commercially viable. Then optimization plays an important role when establishing safe enough limits for structural design and commercial viability. It is obvious that structural demands are very different if comparisons are established among different things like an aircraft engine or a conventional car engine. Safety degrees have to be reasonably applied for a particular application avoiding useless comparisons that would lead nowhere. In addition to that, safety working limits have to be reasonable when compared to the manufacturing costs.

The aging of structures is related to its conditions of use. Aging and degradation is normally related to chemical, physical and mechanical reasons. Most of these factors act together in a way that they add up their effects and it is sometimes difficult to isolate them as unique causes of aging and degradation. These factors can be studied individually but it should always be taken into account that the environment is very rich. Therefore, when a model is looked for in order to establish predictions about a particular behaviour, simplicity of the experimental set-up may be detrimental for the understanding of the real scenario, and it always has to be born in mind.

The study of the corrosion of structures can be very important if the above mentioned applications are imagined. During the past two decades a very important field is being present in the biomedical area. Many surgical and non-surgical treatments imply the use of devices that will be in contact with the human body for a period of time and in a differently located area, closer or further away from vital structures and placed in a more or less invasive way according to the therapeutic procedure. These considerations gave rise to the knowledge area of biomaterials which deals with important issues such as biocompatibility.

Mechanical, physical and chemical properties of materials and the related host responses to a given device are the main areas of biomaterials science. An official definition of biomaterials science has been set as "the study and knowledge of the interactions between living and non-living materials", being biomaterial "a material intended to interface with biological systems to evaluate, treat, augment or replace any tissue, organ or function of the body"[33].

The present thesis studies the Ni release of the archwires in simulated in vitro conditions and the effect that the loss of Ni has on the phase transformation temperatures of NiTi containing archwires.

The Real Academia de la Lengua Española dictionary contains a very accurate definition of corrosion that has been seen to be more complete for the purposes of this introduction that the definition contained at the Webster's Encyclopedic Unabridged Dictionary of the English Language and that it is as follows:

Corrosión. (Del lat. Corrōsum, sup de corrodre, corroer). f. Acción y efecto de corroer.|| 2. Quím. Destrucción paulatina de los cuerpos metálicos por acción de agentes externos, persista o no su forma.

(translated by the author)

Corrosion. (From latin. Corrōsum, corrodĕre, to corrode). fem. Action and effect of corroding. || 2. Chem. Progressive destruction of metallic bodies due to the action of extrinsic agents, may its shape be conserved or not.

Corrosion is therefore an effect studied from the point of view of chemistry. It deals with metallic structures that can be represented by a wide variety of metals and metal combinations (alloys). The cause of corrosion is linked to an external agent, that is, it is not an intrinsic problem of the metals. In addition to it, the destruction is performed in a progressive way in time. The external agents could be diverse, like the metallic structures affected by them. Depending on the level of study, structural changes can be observed or not. This should be taken into account very carefully because a particular technique could be unable to detect a change in the surface of the metal while other, with higher sensitivity, could detect it. So both techniques could lead to opposed conclusions of the same situation. Although the shape or the structure of the body may seem to be intact different techniques should be used before stating that corrosion is not present.

Corrosion is an electrochemical process in which a metal reacts in a harsh environment and it transforms itself into an oxide or a different compound that shows an increased thermodynamical stability for that environment and actual conditions. The reaction that takes place is a reduction-oxidation, known as redox type reaction.

There are three classically established elements in a corrosion reaction:

1. The element that is being oxidized by giving away its electrons, called reductor in which corrosion is observed: the ANODE.
2. The element that reduces itself by capturing the electrons, called oxidizing, and producing the corrosion: the CATHODE.
3. The media that acts as the electron transportation agent: the ELECTROLYTE.

1.5 Corrosion of orthodontic appliances in the oral cavity

The oral cavity is a very agressive environment for the orthodontic appliances, prosthetic structures and restorative elements.

One of the most surprising initial statements related to the study of orthodontics archwires' corrosion is the fact that they are affected by the corrosive action of saliva. Orthodontics archwires engaged in mouth undergo chemical degradation that can be confirmed by a loss of structure by SEM and ionic release testing. Although the bulk of the structure of the archwire may seem untouched, the fact is that there has been a chemical process by which a loss of substance and a structural damage has occurred.

According to some studies, saliva can contain up to 500 mg/L of Cl^- ions. It has been seen that this ionic concentration is able to induce corrosive transformations in stainless steel structures[34]. The resistance to corrosion that stainless steel archwires have is altered by the effect that Cl^- ions have on the passivating surface of stainless steels[35]. Stainless Steels of the American Iron and Steel Institute (AISI) reference like 304 and 306, which are commonly used in orthodontics, are not able to withstand the action of HCl under any concentration or temperature[35-37]. The effect of Cl^- ions has to be taken into account as an intrinsic factor because it is produced by the own body. But an external supply could also be present. For instance the contact that an orthodontic patient can have with chloride treated waters (swimming pools, sea water) or antiseptic agents commonly used in dental therapeutics like chlorhexidine. Even breathing, which could be thought to be an insignificant activity, can add up its effect on the oral cavity corrosive environment. It has been seen that an urban mouthbreathing person can inhalate in 2 hours an equivalent volume of one cubic metre which in certain urban environments could contain up to 2.3 mg of sulphur dioxide[38].

There is another ion which has focused much of the attention on the corrosion study of archwires: Fl^-. The preventive effect that this ion has on the resistance of the enamel of teeth against the acidic attack is a very well known fact. Different fluoride containing solutions have been studied by many authors as being related to the corrosive degradation of orthodontics' archwires, mainly stainless steel and nickel-titanium alloys[7-12]. All of them have remarked the corrosive action due to fluorides on the metallic surfaces of archwires with different degrees of affectation. Most of the cited studies have related a change in the mechanical properties of the archwires due to the corrosive effect.

Some in vitro studies have just been performed with artificial saliva preparations like the Fusayama preparation or Fusayama modified preparations[13-16]. This is most times used as a control group for the corrosion studies above mentioned related to chloride and fluoride ions. There are also artificial saliva preparations different from the Fusayama related preparations[17-24].

There are also in vivo studies that confirm the existence of archwires corrosion. These studies have been performed on archwires that had been worn by orthodontic patients for a period of time[25,26]. These in vivo studies have the advantage that they are performed on real environments but they do have big design limitations in order to achieve comparisons once results are obtained.

Taking into account the variability present among patients it is difficult to establish equal testing environments and therefore reach free biased conclusions. Saliva composition, saliva segregation, hygiene habits, food intake, acidic intrinsic conditions are among a wide variety factors that would interfere with the need of a scenario significantly similar for the test. In addition to this, the number of patients normally limits the specimens to be tested and compared and normally only one arch per patient will be studied in a particular environment.

In vivo studies do have another limitation. The oral microorganisms population changes from patient to patient. It could be said that there are three groups of microorganisms that can be involved in corrosion: sulfite reductors, sulfite oxidants, acid producers and bacteria related to iron.

Some examples of sulfite reductors are: Bacteroides corrodens, Desulfovibrio desulfuricans and Desulfotomaculum. Sulfite oxidants examples are Thiobaccilum ferroxidans, Beggiatoa y and Thiotrix. Acid producer microorganisms are known due to their relation with caries and because they are also able to atack dental amalgams. The main microorganism is Streptococcus mutans[39].

Microorganisms that are able to assimilate iron are Sphaerotilus, Hyphomycrobium and Gallionella[40,41].

1.6 Health concerns linked to corrosion: ionic release and host interactions

Corrosion would not be such an important issue if it was only related to structural damage of orthodontic appliances and other type of devices used in prosthetic and conservative dentistry.

Corrosion is followed by a loss of material in form of ions. There are some ions that are quite reactive for the oral mucosa because they can trigger allergic reactions. Nickel, which is one of the main components of archwires in different alloy systems, is popularly known to be allergenic. This is one of the main points of the present thesis. Archwires corrosion is linked to a loss of ions that could lead to an allergic reaction depending on the severity of the corrosion process. This is the point where biomaterials science with the special concern for safety and biocompatibility of materials can offer a very good contribution.

From the patients' point of view, Ni toxicity is the main concern. Archwires' performance reduction in delivering a particular force in aligning teeth, levelling an arch, derotating them or establishing torque could be anecdotical when compared to health implications that the corrosive effects could have on patients.

All devices designed for therapeutical use have to be tested previously to their use in order to determine the interactions that could have with the host. It is true that there are devices that require a more invasive surgical procedure or are placed in compromised locations where function is very important, like cardiovascular valves and stents and hip prostheses. It is true that the setting of an orthodontic appliance is not as invasive as the previously stated locations but it does not mean that toxic or allergic considerations should be of less importance. It is easy to understand that not always the invasivity of deep anatomic spaces implies that the implantated device should cause bigger biocompatibility and safety problems like wearing, allergies and rejection. A non-surgical therapeutic device setting like orthodontic appliances set-up, although routinely performed, has to be controlled for the reactions that Ni could elicit. As it is known, Ni can elicit allergic reactions that are produced in an immediate manner or it can cause a cellular affectation of non-allergic nature that, although being clinically silent could end up being an important health problem.

For instance, it is known that Ni containing alloys used for orthopaedic surgery in arthroplastic applications have a Ni leaching flow that range from 0,81 μg/h to 0,0081 μg/h, depending on the weight of the patient. These results imply that, considering a standard weight of 70 kg, a person would be exposed to a leaching that ranges from 5 to 500 mg/year of Ni[42]. Results of Ni leaching from orthopaedic devices can not be directly compared to orthodontics due to the fact that, most times, the connective tissue that forms around the implantated device helps covering the prosthesis reducing the direct contact with body fluids and related structures. The harshness of the oral environment enables Ni reactivity to be very high, so although being a less invasive procedure than orthopaedic surgery, orthodontic appliances bonding should be continually monitored.

Orthodontic appliances are placed in a very interesting scenario. The oral cavity is covered by different types of oral mucosa and a wide variety of histologic structures can be found in a very limited space. The oral mucosa is known for its good absorption and bidirectional flow of substances with the environment. In addition to it, the oral cavity is not a sterile area. It could roughly be said that it is not as external as the skin but not as internal as the stomach. It is not irrelevant to take into account that orthodontic appliances may be or not dangerous. Daily experience with jewels shows that there are many cases of allergic reactions due to rings, earrings and piercings. Even buttons used in some trousers like jeans and coins can elicit allergic reactions due to their Ni content.

Bearing all this in mind, it is not exaggerated to act with caution before an orthodontic appliance is bonded although being a routinely done procedure.

Orthodontic appliances are in constant contact with the oral cavity and the saliva. High Ni containing alloys are most times used in the archwires and brackets. A NiTi archwire typically contains about 50 to 54% of Ni in weight, so it is quite a large amount of Ni that allows a fair enough possibility of Ni leaching[43]. Other archwires like stainless steels do have a smaller amount of Ni to be leached.

The Food and Drug Administration (FDA) has a classifying system that helps assigning a level of risk to all devices that will be in contact with the human body. The elements used for the orthodontic therapy fall under a wide list of materials used in dentistry. Most of the orthodontic materials are under the 872.5410 code.

Metallic brackets have been assigned a class I which implies that they are items designed for medical use that represent a low risk. Plastic brackets belong to class II, so they are thought to represent a higher risk than the metallic ones. Ceramic brackets do not even fall under any classification for being absolutely inert. Although risk is being classified, comparisons can not be established with medical devices used in medicine that imply a bigger risk like those used in angioplasty, catheters and pacemakers.

The worldwide spread regulatory system for general dental materials, instruments and equipment of any kind is based on the International Standard Organization (ISO) system carried out by different commitees according to the field. The Comité Européen de Normalisation is encharged of transforming ISO regulations to the European standards. Then, every country in Europe ends up making its own adaptations. In the United States, the American Dental Association (ADA) and the American National Standard Institute (ANSI) establishes the national standards. Formulation spans over a different variety of requirements like composition, packaging, labelling and health and safety issues. But it seems that the orthodontic specifications are too general. For instance, ADA nº32 only contains a superficial and general description of orthodontic archwires with no particular requirements with regards to physical, mechanical, chemical or surface properties. ISO/CD 15841 is the first edition of the international standard for orthodontic wires that seems tries to give more specific guidelines. But in any case, the fulfilment of these requirements are not compulsory for manufacturers and vendors, who are left free for formulating their own standards and requirements for the products. As a practical implication, a lot of a specific alloy could differ from another without being a really important issue.

The passive protective film present at most of the alloys used in orthodontics archwires (stainless steel, nickel-titanium, copper-nickel-titanium, chromium-cobalt, etc) is not always able to avoid ionic leaching due to corrosion processes.

It has been widely documented in different articles that Ni has adverse effects[44-47]. Some studies confirm that Ni is responsible of the allergic reactions and toxic interactions, causing more severe allergic reactions than other metallic elements[44,45,48]. Regarding allergic reactions, it has been seen Ni sensibilization in orthodontic patients that had never before presented problems with Ni and that had even been treated with NiTi archwires previously[47]. It has been demostrated that some archwires release Ni in such a way that it causes linfocyte proliferation and that could be the reason why patients that have been previously sensibilized can present allergic reactions due to the Ni leaching in a corrosive environment[49]. Different contact allergic reactions in the oral mucosa have been described with Ni solutions.

Although some studies have not been able to determine cytotoxic effects derived from the use of Ni-Ti alloys[50,51], some authors have found cytotoxic reactions derived from the contact with the material showing that some arches release Ni in such a way that causes linfocytic proliferation[46,52].

The International Agency for Research on Cancer (IARC) established metallic Ni as possibily carcinogenic and also the components that include it[53-55] although there are no clinical evidences about it.

Experience so far aquired in implantology, and some studies especifically focused on metal biocompatibility of elements prepared to be in a close contact with the human body, like the bone, show the absence of cytotoxicity of Ti[56-58], the commonly alloyed element of Ni. This is the reason why the cytotoxic effects of NiTi archwires should focus on the Ni as the causing agent of the allergic and cytotoxic reactions above mentioned. Accumulated evidence on Ni links it to a wide variety of pathologic reactions that can be identified at a cellular and molecular level[59-67].

It is known that quantities as small as 2,5 ng/ml (ppm) of Ni are able to alter the quimiotactic actions of leucocytes and that they foster a neutrofile transformation modifying its shape and becoming more spherical making them slower when moving[62]. If we focus on the amounts of Ni that could be found in saliva due to the contact with alloys used in dentistry, it has been seen that monocytes and endotelial cells are able to activate themselves and the expression of molecule 1 in endotelial cells and intercellular adhesion is affected by this fact[63,69].

Even considering concentrations that fall in the no toxicity range, it is known that they could even cause a direct harm to the DNA bases and induce specific fractures at the DNA strands (specifically in one of them)[64]. There is also an indirect mechanism that by means of an enzymatic inhibition avoids repairing the fractured DNA[65]. In addition, at concentrations known to be non toxic, there is a mechanism that is affected at a molecular level: microsatellite-like grouped mutations triggered by Ni that are able to cause an inhibition on the nucleotide escision reparation system that lead to genetic mutations[66,67].

Studies carried out on animals have shown that different structures like liver and spleen[70], bone marrow and blood[71] and repiratory tract[72,73] are affected by metallic dissolution.

Although the study of corrosion has most times being focused on the NiTi alloy due to the fact that its use is very widely spread in orthodontics, it should never be forgotten that there are other alloys that contain Ni in their chemical formulation like stainless steels and chromium-cobalt. So, although the commercial name of the alloy does not explicit the Ni content, it has to be accounted for in the mentioned alloys.

All this information has been provided in order to understand the importance that Ni release has on patients. It could be said to be the most important safety parametre to be studied in relation to archwires used in orthodontics.

So summing up, the degradation of archwires can shed two consequences:

1. There can be a loss of the physical properties of the archwires which would somehow affect the clinical progress of the orthodontic treatment.
2. There is an ionic release that depending on the species and concentration of the released element could lead to allergic and toxic reactions for the patient.

According to the objectives of the present thesis, Ni leaching is assessed in lingual archwires in order to establish their safety limits. It is also studied in order to determine whether it is or not related to a change in the phase transformation temperatures of the NiTi containig archwires, which from the clinical point of view would be one of the main points.