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AVALIAÇÃO MECÂNICA DA UTILIZAÇÃO DE PLACAS E PARAFUSOS DE TITÂNIO E ABSORVÍVEIS PARA FIXAÇÃO DE OSTEOTOMIA SAGITAL DO RAMO MANDIBULAR.

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PÓS-GRADUAÇÃO - *STRICTO SENSU*

Pontifícia Universidade Católica
do Rio Grande do Sul

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Tese apresentada como parte dos requisitos obrigatórios para a obtenção do título de Doutor em Odontologia, área de concentração em Cirurgia e Traumatologia Bucomaxilofacial, pela Pontifícia Universidade Católica do Rio Grande do Sul.

Linha de Pesquisa: Crescimento, desenvolvimento e deformidades dentofaciais

Orientador: Prof. Dr João Batista Blessmann Weber

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DEDICATÓRIA

Dedico este trabalho:

Ao anjo que ainda me cuida, minha mãe Mirna. A maior incentivadora para que Eu trilhasse o caminho da pesquisa e da docência. Talvez com algum atraso mas estou chegando lá.....

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SUMÁRIO

O presente trabalho foi realizado com apoio da Coordenação de Aperfeiçoamento de Pessoal Nivel Superior – Brasil (CAPES) – Código de Financiamento 001.

INTRODUÇÃO GERAL

Considerado um avanço significativo no sistema de fixação estável das osteotomias mandibulares, a utilização de placas e parafusos é amplamente descrita na literatura[1]. No entanto, a forma de utilização desses materiais, bem como o tipo de material empregado ainda pode gerar controvérsia. Encontram-se trabalhos relatando a utilização de placas e parafusos ou ainda uma combinação de ambos (técnica híbrida) constituídos de uma liga de titânio ou absorvíveis. Ainda, nenhum tipo de fixação estável é descrito por autores como necessário na estabilidade de algumas osteotomias; quando os pacientes são submetidos ao bloqueio maxilo-mandibular (BMM) por tempo determinado.[3] Portanto, diferentes tipos de osteotomias ósseas mandibulares podem ser realizadas e fixadas com diferentes combinações de placas e/ou parafusos de diferentes materiais na resolução das deformidades dentofaciais.[5-12]

As formas de fixação disponíveis mais comumente utilizadas são combinações de placas e parafusos metálicos (liga de titânio) que conferem estabilidade ao procedimento cirúrgico de osteotomias mandibulares.[14] Menos comum, a utilização de placas e parafusos absorvíveis também encontra-se descrita na literatura, apresentando vantagens e desvantagens quando comparada à técnica tradicional que emprega placas e parafusos de ligas de titânio.[15]

Geralmente a fixação com parafusos e placas de titânio permite contato ósseo entre os fragmentos osteotomizados, estabilidade inicial e possibilita rápido retorno

do paciente às suas atividades de rotina. No entanto, algum torque condilar e alterações oclusais são descritos na literatura dependendo do sistema de placas adotado.[3.5.12]

Diversas vantagens podem ser enumeradas quando se utiliza o tipo de fixação estável absorvível, entre elas: a forma biodegradável deste material e sua biocompatibilidade.[16] Ainda, ausência de interferência em exames de imagem como radiografias, tomografias ou principalmente ressonância magnética; fácil manipulação favorecendo a adaptação anatômica no sítio cirúrgico; absorção seguida de neoformação óssea no local de osteossíntese sem presença de processo inflamatório ou fibrose e nenhuma necessidade de reintervenção para remoção do material de osteossíntese.[16.24.25]

A utilização do sistema absorvível e a avaliação de sua resistência mecânica, quando comparada, aos sistemas tidos como tradicionais, se resultados positivos forem obtidos, pode representar uma vantagem na fixação estável das osteotomias mandibulares, já que os materiais absorvíveis não necessitam ser removidos após a cirurgia.[27.31]

Portanto, a realização do presente estudo pretende verificar a capacidade de resistência mecânica da fixação estável, seja esta realizada pelo sistema de placas e parafusos absorvíveis ou pelo material de titânio e compará-las.

OBJETIVO GERAL

- Verificar a resistência mecânica de placas e parafusos na fixação da osteotomia Sagital do ramo mandibular - (OSRM).

OBJETIVOS ESPECÍFICOS

- Realizar estudo comparativo de 02 tipos diferentes de fixação estável – a fixação com sistemas de placas de titânio e placas absorvíveis.

- Realizar estudo comparativo entre 02 métodos de fixação estável absorvível.

- Realizar estudo comparativo entre 03 métodos de fixação estável de titânio.

ABSTRACT

BIOMECHANICAL EVALUATION OF THE USE OF ABSORBABLE PLATES FOR RIGID FIXATION OF SAGITAL SPLIT RAMUS OSTEOTOMY

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• KeyWords: Sagital split ramus osteotomy, Internal rigid fixation, Absorbable plates, Biomechanical evaluation.

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Abstract: The rigid fixation of bone segments after mobilization has been purposes of study for many years. The use of plates and screws is responsible for a number of benefits to those who are used. Initial stability, fast and comfortable patient return to normal activities, good masticatory function and no need for maxillo-mandibular block for a long time; are some of the main advantages of rigid internal fixation. In addition to the titanium plates and screws can be used polyglycolic acid copolymers DL associated with the polylactide. This combination of features define plate and absorbable screw. Biocompatibility, less of genotoxicity, bioabsorption and easy handling are some characteristics of this material. However, similar initial stability to these plates still requires further studies. Therefore, the aim of this study is mechanically evaluate the stability of plates and absorbable screws in the technique of sagittal split osteotomy; the most widely used technique for jaw function in mandibular orthognathic surgery. Using a in vitro study, 15 hemimandibles (NACIONAL-JAÚ.SP) was evaluated with the design of the sagittal split osteotomy and fixed with different materials. Divided into 03 groups of five hemimandibles, the samples were submitted compression tests at different displacements. The displacements ranged from 1 to 5mm and the applied force was measured in Newtons (N). The results showed that there is a statistically significant difference in initial resistance when comparing conventional plates (Titanium) to absorbable plates. The conventional plates (titanuin) presented greater stability when compared to absorbable plates.

Introduction

Essential prerequisites for bone healing of fractures and osteotomies include sufficient vascularization, immobilization of bone segments and anatomical reduction[1]

Internal fixation with titanium plates and screws has been accepted as the 'gold standard' in orthognathic surgery to achieve immobilization[2]. While titanium fixation has the advantages of good mechanical and handling properties allowing the patients to functionally load their masticatory system immediately following surgery; a disadvantage of this material is the long time it may remain in situ[2,3]. Between 5% to 40% of the cases, if left in situ, removal of the titanium plates and screws may be required[3.4] For several possible reasons, such as palpability of the plates, sensitivity to temperature stimulation, interference with electromagnetic and ionizing radiation, titanium particles in overlying soft tissues and regional lymph nodes, induced growth restriction, and mutagenic effects, which have been verified in many studies over the past few decades the titanium may be removed[2]. Actually, recently it was reported that titanium miniplates is a new risk factor for the development of the bisphosphonate-related osteonecrosis of the jaw[4]

These limitations of titanium fixation brought about the development of bioabsorbable fixation, which reduces or even eliminate the problems associated with titanium and may offer some clinical advantages for the fixation of facial bones during orthognathic surgery. However, biodegradable fixation systems may also have their limitations and it is not used widely in orthognathic surgery due to controversy regarding skeletal stability[2].

Several studies have compared skeletal stability between bioresorbable (uhydroxyapatite/ poly-(L-lactic) acid (u-HA/PLLA) and poly-Llactic acid (PLLA) plates) and titanium fixation in orthognathic surgery. The bioresorbable fixation is a comparable alternative in terms of skeletal stability[5]. The resorbable system is a good system for rigid internal fixation in specific conditions where muscular and stress

forces are not a determining factor in fragment displacement. The use of biodegradable plates should be recommended for minimally loaded situations[6].

However, concerns remain about the stability of fixation, the length of time required for their degradation and especially the possibility of complications, such as foreign body reactions. In addition, the process of degradation of these devices into carbon dioxide and water may take as long as 2 years[7]. Also adverse tissue reactions to degradation products have been reported[8]. Therefore according to the literature, biodegradable osteosynthesis must be removed in a second operation in 0% to 31% of the cases[9].

Resume, the use of resorbable plates and screws remains unpopular for internal fixation among oral and maxillofacial surgeons. Although a number of clinical studies regarding the safety of absorbable materials in maxillofacial fixation have been recently published[4].

The aim of this study is mechanically evaluate the stability of plates and absorbable screws in the technique of sagittal split osteotomy; the most widely used technique for jaw function in mandibular orthognathic surgery.

Material and methods

The experimental study, 15 replicates of human hemimandibules by polyurethane are used. (Nacional, Jaú, São Paulo, Brazil). The synthetic mandibles were chosen because they exhibit uniform mechanical properties and a hard foam cortex that reasonably reproduces the mandibular bone. For the standardization of the study, hemimandibules come from the same manufacturing. The osteotomy were performed by the manufacturer according to the technique of sagittal split osteotomy (SSO). The advancements of the distal segments were 5mm and the specimens were divided into 3 groups with 5 hemimandibulas each. The materials used were

titanium (Medartis - Switzerland) and absorbable system, and all plates were installed following a standardization based on a previously made acrylic models.

In group 1, a fixation with absorbable mini-plate of 4 holes of the system 2.0mm (Ínion - USA) was used of the mandible with 4 screws of 2.0x5.0mm perpendicular to the hole of the plate. In group 2 absorbable fixation mini-plate of 12 holes each, of the system 2.0mm (KLS Martin - Germany) of 08 2.0x5.0mm perpendicular screws to the holes of the plates. And for the group 3 a regular titanium plate was used (Medartis – Switzerland) from the 2.0mm system with 4 screws of 2.0x5.0mm, perpendicular to the holes of the plate.

The SSO technique pattern with a 5mm advancement of the mandibular segments was performed. This method was proposed by Asprino et al. They suggested using a guide made of acrylic resin for the advancement and attachment of miniplates and screws. The hemimandibules were fixed in a test platform made exclusively for the research, in which the proximal and distal segments were stabilized allowing the free movement of the segments while the loads were applied. Figure1 (Attached II)

LOADING TEST

The 3 groups of samples were loaded linearly from top to the bottom in the first molar area using the universal EMIC DL-2000 by São José dos Pinhais – Brasil. (Figure 2) Attacehd III. The material test unit produced linear displacement at a rate of 1 mm / minute, and the strength forces required to displace the distal segment of 1 mm, 2 mm, 3 mm, 4 mm and 5 mm were recorded. The data of movement (in millimeters) and load in Newntons (N) were obtained in all groups.

Compression loads were recorded in Newtons and subjected to Statistical analysis was performed with the program R v. 3.5 with a significance level of 0.05. The data were represented by Mean, Standard Deviation, Minimum mediana and Maximum. To compare the force required to move each type of plate were used mixed Linear Models.

Results

Figure 3 (Attached IV) shows the force required to move each sample in 1, 2, 3, 4 and 5 millimeters. The thick lines have the average force required to move the plates of each type into 1, 2, 3, 4 and 5 millimeters.

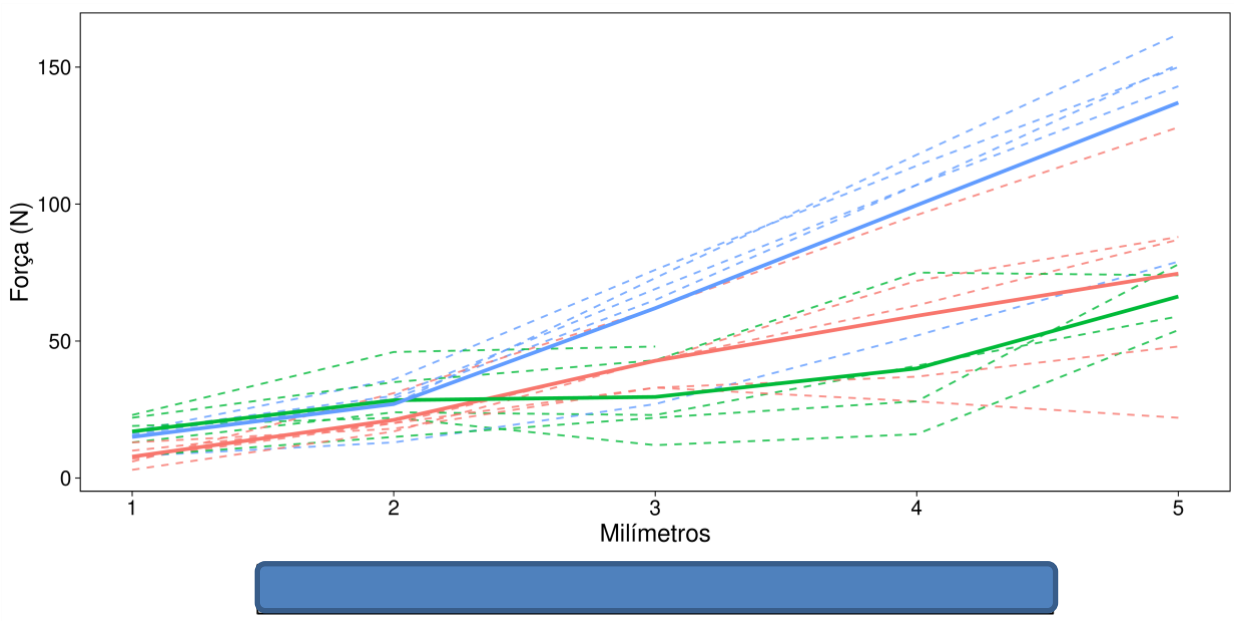

Figure 3: Profile graphic with the force behavior required to move each plate. The thick lines represent the mean forces. (Orange Line - Ínion Absorbable plate) – (Green Line - KLS Absorbable plate) and (Blue line - Medartis titanium plate).

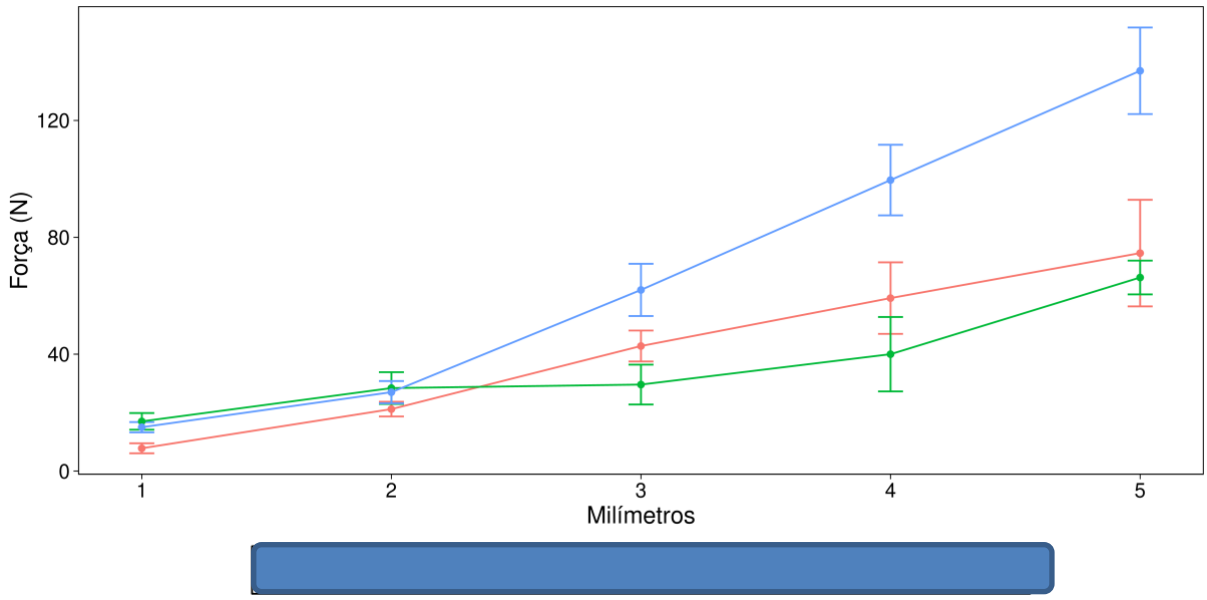

Figure 4 (Anexo V): Graphic of the mean force needed to move the plates. Vertical bars represent the standard error of the means. (Orange Line - Ínion Absorbable plate) – (Green Line - KLS Absorbable plate) and (Blue line - Medartis titanium plate).

To understand the behavior of the plates we have to ajust a Linear Mixed Model (repetead measures model) to analyse the results and statistically understand the force required to move each type of plate a certain amount of millimeters. The Test t results for this model and there was a statistically significant difference between the average force required to move a different plates in different moments.

The force required to move the absorbable and titanium plates are very similar in 1 and 2 milimeters of dislocation. After that we notice that the force to move titanium plates is bigger than to move absorbable plates. The results showed that was statistically significant difference of force to move titanium plates when was compared with absorbable plates; which means that titanium plates could offer more stability to the mandibular sagittal osteotomy.

Discussion

Fixation systems with absorbable plates and screws have been the subject of research in recent decades. The most widely used absorbable material has been described as a copolymer formed by the polyglycolic acid associated with D-L polylactide. Sarkarat et al. presented a study in which they compared, through the finite element method, the most stable configuration for the rigid internal fixation of the mandibular sagittal osteotomy with absorbable plates. The studied models were submitted to loads of 75, 135 and 600N. Among the fixation possibilities studied, the authors report that the use of 02 straight miniplates (2.0mm system) with 4 screws (size 6mm) obtained greater primary stability.[10]

However, fixation with absorbable material presents lower clinical performance than conventional fixation with titanium plates and screws.[11.12] This condition suggest the need for maxillo- mandibular fixation in the early postoperative period.[13.14.15] . Appropriate plates design increases the performance of biodegradable osteosynthesis.[12] Albougha et al. in 2015 suggest that the increase in stability when use of absorbable plates is directly related to the use of double plate Y[12]. A randomized clinical trial conducted by Bakelen et al. in 2015 showed that long-term stability with biodegradable fixation was not statistically different than stability with titanium plates[3]. The justification for this it is related to the immediate postoperative period, when muscle function is significantly reduced and appropriate instruction to patients should be rigorously applied[16]

Another review by Laine et al. (2004)[17] showed an excellent result in the use of absorbable material after revision of 320 bilateral mandibular osteotomies. No patient was submitted to maxillo-mandibular block and only use of elastic guides was required for the period of 05 to 07 weeks. Only 14 patients presented minor

complications (8.4% of the sample), such as dehiscence of sutures, plate exposure, infection and need for removal material. Stable occlusion immediately after surgery allows correct placement of the bone fragments and success regardless of the absorbable material used.[17] Interesting research suggests that the increase of initial stability in the fixations with absorbable material will be obtained when there is an association of 01 L-shaped plate at the uppermost edge of the OSRM.[18]The increase in resistance to the clockwise rotation movements of the osseous segments can be observed. Moreover, the square shape of the absorbable plates seems to offer a advantage when compared to the standard straight plates.[18]

Recent study compared the stability of the absorbable material with standard titanium material through a systematic review of the international literature and meta-analysis. The surgeon's understanding of the type of surgery, the magnitude of the movement, the aesthetic need, as well as the patient's clinical condition should direct the choice of FIR. large movements can lead to major relapses and major advances without bone contact are more unstable. Thus, it was concluded that the stability of the absorbable material is similar to the titanium plates when maxillary treatment and clockwise rotations of the maxillomandibular complex with mandibular advancement are performed. In movements like mandibular setback the titanium material presented better results[5]

From the point of view of genotoxicity and inflammatory response, the work of Oliveira et al. reports that the absorbable polymers are quite stable; not presenting significant risk of cellular alterations, genetic mutations or foreign body reaction; being therefore similar to the titanium material widely used in the rigid internal fixation of mandibular osteotomies.[19]

Several advantages can be enumerated when using this type of absorbable fixation; among them: the biodegradable form of this material, which can initiate its absorption in the organism between 9 and 15 weeks[20]. Biocompatibility, in which, by hydrolysis the material is absorbed by the organism in the form of carbonic gas and water[20]. Initial stability similar to conventional titanium plates and screws, providing safety in their use[21.22]. Absence of interference in imaging tests such as radiographs, CT scans or mainly magnetic resonance imaging.[4.12]. Absorption followed by bone neoformation at the osteosynthesis site without inflammatory process or fibrosis and no need for reintervention for removal of osteosynthesis material [4.12.13.20.]

However, as shown by Van Bekelen et al. who report the occurrence of need for removal of 2.2x absorbable plates higher than when using titanium material. This important multicenter randomized clinical study conducted by Van Bekelen in 2013 took into account surgeries performed in 4 referral centers by different professionals and a postoperative follow-up (PO) of 2 years. Most of the absorbable plates that needed to be removed caused abscess formation and inflammatory processes. Probably due to the poor vascularization of the dense mandibular cortex or the low pH generated by the degradation of lactic acid[3]. Occlusal stability and masticatory function were similar after 2 years of OP. Still, there was no significant difference in the palpability of plates by patients[3]

Other authors show that innumerable complications can occur when absorbable system is used. Yang and colleagues in 2013 performed a meta - analysis and suggest that the use of absorbable material does not yet have totally safe parameters for its use. Notably, reaction to the foreign body and mobility of bone segments was more frequent than when titanium was used for rigid internal fixation.[4] Difficulty in palpation has been reported as a major advantage of absorbable

material. He concluded by placing the need for further randomized and clinical studies to ensure the use of absorbable material.[4]

In addition, difficulty of manipulation, in which the material must be preheated; the need to reduction time for drilling; expensive sterilization process; high cost of the material and the bad resistence for torsional forces are also reported as difficulties when using absorbable material.[20]

Considering this experiment, the perform fixation of mandibular sagittal split osteotomy with titanium plate was more resistant than absorbale plate. Statistical differences were detected and absorbale plate system still unpopular among surgeons.

Competing interests

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Ethical approval

Not required

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ARTIGO 02

ABSTRACT

BIOMECHANICAL EVALUATION OF THE USE OF THREE DIFERENT TITANIUM PLATES FOR RIGID FIXATION OF SAGITAL SPLIT RAMUS OSTEOTOMY

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• KeyWords: Sagital split ramus osteotomy, Internal rigid fixation, titanium, Biomechanical evaluation.

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Abstract: The rigid internal fixation of bone segments after mobilization has been purposes of study for many years. The use of plates and screws is responsible for a number of benefits to those who are used. Initial stability, fast and comfortable patient return to normal activities, good masticatory function and no need for maxillo-mandibular blocking for a long time; are some of the main advantages of rigid internal fixation. Therefore, the aim of this study is mechanically evaluate the stability of three different method fixation with plates in the technique of sagittal split ramus osteotomy (SSO); the most widely used technique for jaw function in mandibular orthognathic surgery. SSO was performed in 15 polyurethane synthetic mandible replicas. The distal segments were advanced 5mm and the specimens were grouped according to the fixation method: four-hole standard miniplate, two four hole standard miniplate and adjustable plate (Slider). Mechanical evaluation was performed by apllying compression loads to first molar using a Instron universal testing machine until a 5mm displacement of the segments. Compression loads were recorded in Newtons (N) and subjected to Statistical analysis was performed with the program R v. 3.5 with a significance level of 0.05. The data were represented by Mean, Standard Deviation, Minimum mediana and Maximum. To compare the force required to move each type of plate were used mixed Linear Models. The results showed that the stability of SSO was better accomplished using a double titanium plate and the adjustable plate demonstrated the worst resistance.

Introduction

Mandibular bilateral sagittal split osteotomy (BSSO) gained popularity among surgeons from the description of the sagittal division of the vertical ramus by Traumer and Obwegeser in 1955. The major modifications of this technique, still in

use today, were suggested by Dal Pont in 1961, becoming the osteotomy predominantly used for correction of dentofacial deformity of the mandible. It has been indicated of correction to mandibular deformities.[1]

Bone stabilization has progressed from osteosynthesis with steel wire and maxillomandibular fixation (MMF) to the use of titanium plates and screws and biodegradable materials. [2] In the mid-1980s, rigid internal fixation (RIF) began to be more used to stabilize the BSSO segments, in conjunction with a MMF period of 2 to 6 weeks. Since then, numerous studies have been published on the stability of BSSO fixed rigidly with bicortical screws and without any postoperative MMF. It is currently believed that MMF is not only unnecessary when combined with rigid fixation of sagittal osteotomies, but may also lead to adverse effects on the temporomandibular joint (TMJ).[3]

Titanium is considered the gold standard material of fixation systems in maxillofacial surgery. Different internal fixation methods were then developed to allow mobilization and early function after the use of BSSO [2.] Among the internal fixation methods we have bicortical titanium screws, titanium mini-plates with monocortical screws and hybrid techniques.

In recent years there has been great interest in what type of fixation provides greater stability of osteotomized bone segments and generates less morbidity or complications [5]. Studies by William Proffit et al., 1996 have revealed the existence of the hierarchy of stability and predictability of orthognathic procedures. The isolated mandibular advancement was considered to be very stable. We can then assume that any fixation technique that adds stability to the isolated mandibular surgery would increase the stability and predictability of combined maxillary and mandibular

surgery. Some studies show that the use of bicortical screws in conjunction with mini-plates present better biomechanical properties. In addition, the plate and screw-locking mini-plate systems have advantages such as less possibility of screw loosening, greater stability, less need for plate adaptation and less occlusal alteration[7] However, there is still no consensus as to the best method of fixation for BSSO. Therefore, the choice of fixation type is usually based on the preference and personal experience of each surgeon[8]

As current trends in fixation systems have attempted to decrease plate size and thickness while maintaining tensile and compression forces, the *IN VITRO* biomechanical tests of the various internal fixation systems prove to be a useful tool in minimizing problems and establishing the ideal fastening system. The aim of this study was to compare the biomechanical stability of three different methods of standard plates for osteosynthesis after forward 5mm mandibular sagittal split osteotomy.

Material and methods

The experimental study, 15 replicates of human hemimandibules by polyurethane are used. (Nacional, Jaú, São Paulo, Brazil). The synthetic mandibles were chosen because they exhibit uniform mechanical properties and a hard foam cortex that reasonably reproduces the mandibular bone. For the standardization of the study, hemimandibules come from the same manufacturing. The osteotomy were performed by the manufacturer according to the technique of bilateral sagittal split osteotomy (BSSO). The advancements of the distal segments were 5mm and the specimens were divided into 3 groups with 5 hemimandibulas each. The materials

used were titanium (Medartis, Basel / Switzerland) and all plates were installed following a previous standardization based on a previously made acrylic models.

In group 1, a fixation with 1 mini-plate of 4 holes of the system 2.0mm was used in the zone of tension of the mandible with 4 screws of 2.0x5.0mm perpendicular to the hole of the plate. In group 2 fixation was used with 2 straight mini-plates of 4 holes each, of the system 2.0mm, being 1 in the tension area and another in the compression area with 8 screws of 2.0x5.0mm perpendicular to the holes of the plates. And for the group 3 a slider plate (47x12mm) with 8 holes was used, from the 2.0mm system in neutral mandibular zone with 8 screws of 2.0x5.0mm, perpendicular to the holes of the plate.

For the standardization of the BSSO technique with a 5mm advancement of the hemimandibular segments, we used the method proposed by Asprino et al. They suggested using a guide made of acrylic resin for the advancement and attachment of miniplates and screws. The hemimandibules were fixed in a test platform made exclusively for the research, in which the proximal and distal segments were stabilized allowing the free movement of the segments while the loads were applied. (Figura 1)

LOADING TEST

The 3 groups of samples were loaded linearly from top to the bottom in the first molar area using the universal EMIC DL-2000 São José dos Pinhais – Brasil. Figura 2 (Anexo II). The material test unit produced linear displacement at a rate of 1 mm / minute, and the strength forces required to displace the distal segment of 1 mm, 2 mm, 3 mm, 4 mm and 5 mm were recorded. The data of movement (in

millimeters) and load in Newntons (N) were obtained in all groups. The peak load is the load at which the system begins to deform permanently.

Compression loads were recorded in Newtons and subjected to Statistical analysis was performed with the program R v. 3.5 with a significance level of 0.05. The data were represented by Mean, Standard Deviation, Minimum mediana and Maximum. To compare the force required to move each type of plate were used mixed Linear Models.

Results

Figure 5 shows the force required to move each sample in 1, 2, 3, 4 and 5 millimeters. The thick lines have the average force required to move the plates of each type into 1, 2, 3, 4 and 5 millimeters.

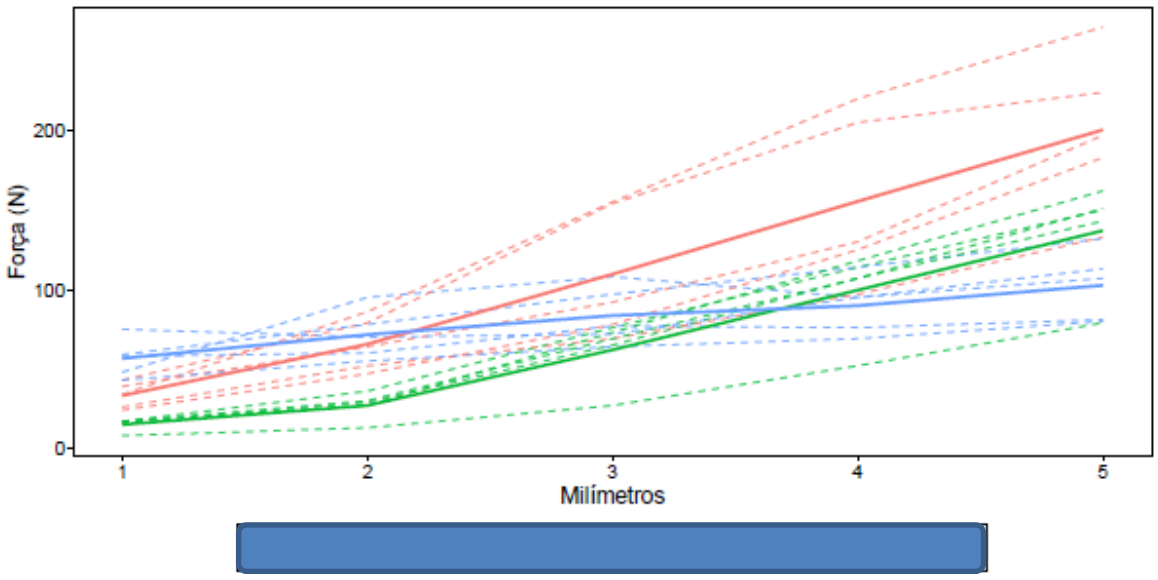

Figure 5 (Anexo VI): Profile graphic with the force behavior required to move each plate. The thick lines represent the mean forces. (Orange Line – Two titanium straight plate) – (Green Line – One titanium miniplate) and (Blue line – Slider titanium plate).

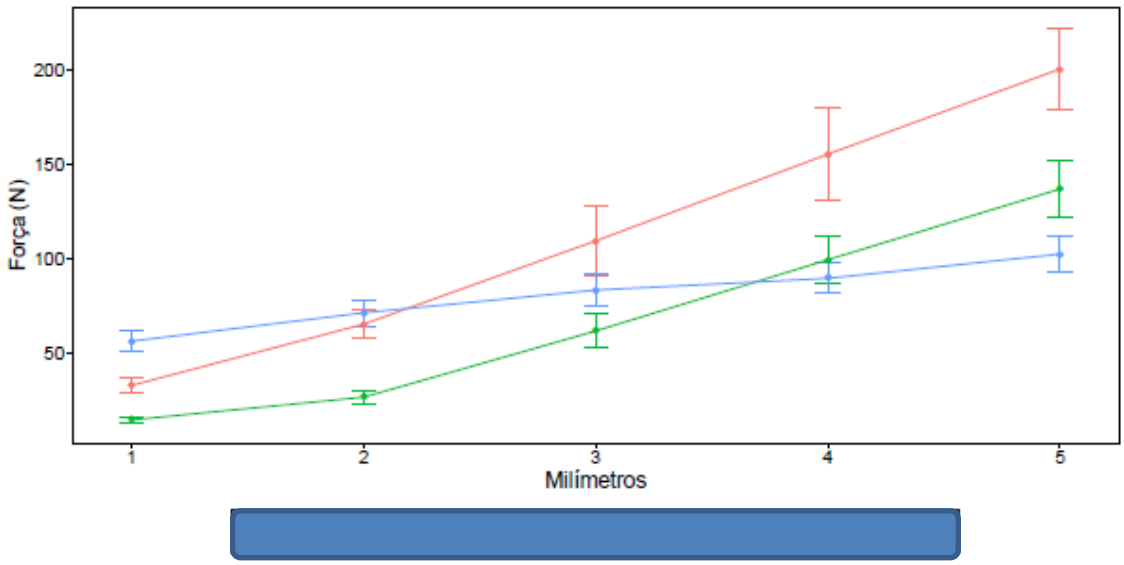

Figure 6 (Anexo VII): Graphic of the mean force needed to move the plates. Vertical bars represent the standard error of the means. (Orange Line – Two titanium straight plates) – (Green Line – One titanium plate) and (Blue line – Slider titanium plate).

To understand the behavior of the plates we have to ajust a Linear Mixed Model (repetead measures model) to analyse the results and statistically understand the force required to move each type of plate a certain amount of millimeters. Figure 8 presents the Test t results for this model and there was a statistically significant difference between the average force required to move a different plates in different moments.

The force required to move the slider titanium plate is bigger than others at the first two millimeters of dislocation. The slider titanium plate showed to be more resistence of the begin of the test. After that we noticed that the force to move two standard titanium miniplates was bigger than to move other plates. And the results showed that it was statistically significant. The difference of the force to move two straight titanium plates when is compared with one straight miniplate and slider

titanium plate was observed; wich means that two plates could offer more stability to the mandibular sagittal osteotomy.

Discussion

The resistance is invariably lower for miniplate fixation systems than bicortical screws **i**t is a consensus in the literature. This is due to the ability of the screws to stabilize the three-dimensional osteotomized segments by inserting fixation points simultaneously acting on both segments, limiting the bending action and torsional forces. The use of mini-plates with monocortical screws is based on the connection being installed at one point of the "bridge" miniplate between the segments providing greater freedom of twisting movement and, consequently, less resistance to fixation. However, this type of fixation has the advantage of lower compression between the segments, which could cause injury to the inferior alveolar nerve and lower condylar torque. In addition, in some situations, the miniplates are the better choice; as in cases of great movements and asymmetries. For some cases we can also customized the plates. Photoelastic tests proved that miniplates, all stress is concentrated around to the fixation system (plates and screws); which also explains the lower mechanical resistance of this technique compared to the positional screws.[8]

Different fixation methods after sagittal split osteotomy using three-dimensional finite element was analysed and confirmed that the use of 2.0 mm screws placed in a triangular configuration had a greater mechanical stability when compared to the linear configuration of the screws, two parallel miniplates and a single miniplate. However, the design of the rigid plate influences the mechanical

result obtained and the choice of the plate is very important in the fixation of the BSSRO[2]

AL-MORAISSI et al., in their systematic review and meta-analysis with the objective to identifying the postoperative skeletal stability with bicortical screws is similar or better than that found with the use of miniplate fixation when performing BSSRO for madibular advancement. In patients treated by mandibular class II malocclusion, there is no difference in stability when using bicortical screw fixation vs. miniplate fixation after BSSRO advancement surgery. The main of this systematic review and meta-analysis was that, despite the bicortical screw fixation founded a slightly better skeletal fixation than miniplate, the difference was not significant.[12]

Chuong et al. developed computer models of the mandible by 3D finite elements based on the geometry of the reconstructive CT scan. The mandibular deformity requiring surgical advancement was used. Finite element computer models were used to simulate a BSSRO with 8mm advancement. The stabilization of the distal segment with two internal fixation techniques was compared. It was interesting to note that the technique of better stability with less mechanical stress was the one used three bicortical screws in an inverted 'L' configuration in relation to the technique that used a titanium curve miniplate with 04 monocortical screws. However, at the present time, was not clear how to the mechanical stresses in the bone close to the osteotomy affect the healing process. This is an issue that should be verified in a validation studies in an animal model.[11]

Other study presented the biomechanical stability of six commonly used fixation techniques after a 5mm mandibular advancement. In conclusion, for mandibular advancements of 5 mm, the resistance forces measured at

displacements of 1, 3 and 5 mm were significantly higher for a 2.0 mm plate with an additional bicortical screw [7]

Sato et al. suggested that the hybrid technique increased the resistance and improved the distribution of the fixation with miniplate and monocortical screw. Although a large part of the in vitro biomechanical studies developed to date have described the advantages of the hybrid technique, there are disadvantages as: condylar twist, risk of alveolar nerve compression, difficulty to remove bicortical screws in case of infection and other complications that require fixation removal.[14]

Brasileiro et al. reported that there was no statistically significant difference for the vertical and lateral loads in the displacements of 1, 3 and 5 mm, when compared the techniques with a miniplate and monocortical screws and miniplate with the additional use of a bicortical screw. However, they concluded that the installation of a bicortical positional screw in the retromolar area can significantly optimize the resistance of the miniplate and the fixation system.[15]

Although the good results with bicortical screws to resist to masticatory forces compared to miniplates, clinical data showed no tendency to abandon the use of miniplates. That's because, clinically, this type of technique had very good results. Although it has lower stiffness, several studies have showed that during the first postoperative weeks, when there was a significant reduction of masticatory forces; the miniplates were capable to provide sufficient stabilization during the early stages of bone repair.[14.16.17.] Thus, it can be stated that in clinical conditions in which there was good bone contact and favorable movement, with consequent lower influence on muscles and related joints, any of the fixation techniques described can be used. However, in cases where immediate mandibular function is more critical, such as a patient with greater masticatory strength, the use of more rigid fixation techniques

may be advisable (linear screws at a 90 ° angle or an inverted L arrangement). In cases where large movement is necessary, with segments that have thin bone structures, as well as cases of bad split, the use of miniplates represents a better clinical option.[3.17]

The results of the present study were in agreement with the results founded in the study by Pereira Filho et al., In their *In Vitro* study, evaluated the resistance of the sagittal osteotomy fixation with a slider specifically designed adjustable plate (Slider) and compares it with two methods commonly used internal fixation. The conclusion was that bicortical positional screws provided the highest fastening strength, followed by conventional miniplates.[5] The adjustable plate (slider) provided unstable fixation, maintaining approximately 40% of the load values founded for bicortical screws. The use of this plate could even indicate a period of rigid intermaxillary fixation in the postoperative period. [5]

Although experimental models are unable to fully reproduce the complexity of mandibular function and anatomical structures of cortical bone, and it is not known if the healing process is affected by these differences, we believe that our study provided some information to influence the choice of fixation system to produce the maximum possible postoperative stability.

We can conclude that the more stable technique of internal fixation with miniplates in laboratory environment, to fixation the sagittal split osteotomy was the one that used two straight standard miniplates. However the fixation with a miniplate Slider was superior to the other two methods until to 2mm displacement, where it gradually lost its resistance.

Competing interests

None declared

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None

Ethical approval

Not required

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DISCUSSÃO GERAL

A busca pela previsibilidade após osteotomias mandibulares que permitam ao paciente rápido e confortável retorno às suas atividades normais, com um mínimo de complicações, tem sido objeto de inúmeros estudos. Alguns métodos de fixação interna rígida (FIR) otimizam o processo de cicatrização óssea e representam um significativo avanço na estabilidade dos procedimentos de cirurgia ortognática[5-12.24]. Sua utilização permite combinações de sistemas de placas e parafusos monocorticais ou somente parafusos bicorticais ou ainda utilização de técnicas híbridas[14] com material convencional de titânio. Também, utilização de placas e parafusos absorvíveis são descritos como seguros na literatura[34]. Segundo Ochs 2003[1] os critérios utilizados para a escolha da fixação interna rígida durante a osteotomia sagital do ramo mandibular (OSRM) devem considerar a anatomia óssea, a intensidade do movimento cirúrgico, presença ou não de terceiros molares, ocorrência de fraturas trans-operatórias indesejáveis, acesso cirúrgico realizado e visualização de campo operatório; bem como, relação do posicionamento dos segmentos proximal e distal, além da experiência do cirurgião. Peterson e colaboradores (2005)[2] estudaram diferentes métodos de fixação *in vitro* e relataram que o melhor resultado em diferentes tipos de cargas foi a utilização de parafusos bicorticais.

No entanto, Ayub e colaboradores (2000)[4] relataram que a fixação com parafusos bicorticais pode gerar torque excessivo em côndilo e consequente remodelação condilar, recidiva ou ainda perda de oclusão.

As principais complicações das fixações internas rígidas relacionadas à OSRM como perda de estabilidade, recidivas e deslocamento condilar; estão mais frequentemente relacionadas ao posicionamento condilar trans-operatório, ou quantidade de avanço mandibular, ângulo do plano mandibular, resposta de tecidos moles e músculos, incorreta aplicação da inserção de parafusos, ou ainda da habilidade do cirurgião; do que frequentemente relacionadas à eficácia da FIR utilizada.[3,5,12]

Haug e colaboradores (2002)[8] compararam o sistema *locking e não–locking (standard)* e observaram que o grau de adaptação das placas do sistema locking no sítio receptor não afeta a estabilidade da fixação; o que pode ocorrer quando da utilização de placas do sistema standard. Experiências similares realizadas *in vitro* observaram o mesmo efeito; quando placas do sistema *locking* obtiveram maior resistência mecânica do que placas tipo standard ou convencional. [6-7]

Mais estudos envolvendo placas tipo *locking* para estabilização da OSRM ainda precisam ser realizados, pois grande parte dos estudos levou em consideração a FIR em fraturas mandibulares.[8]

Com o objetivo de proporcionar maior passividade muscular e algum grau de remodelação do material; outros tipos de placas de titânio, com diferente design (placa ajustável), foram estudadas e relatos afirmam que sua resistência mecânica é cerca de 60% menor quando comparada à fixação estável com parafusos bicorticais,

ou 20% menor quando comparada às placas retas de titânio onvencionais na fixação da OSRM[14].

Outros autores apontam que a melhor configuração para a FIR dos segmentos ósseos é a diposição de parafusos bicorticais em formato L invertido. Em estudos tridimensionais e com elementos finitos e avaliação fotoelástica[19.20.22] resultado semelhante foi observado. No entanto, na prática clínica diversas combinações de FIR oferecem bom resultado levando em consideração a força média de 125N observada na mastigação[19].

Também sistemas de fixação com placas e parafusos absorvíveis tem sido motivo de pesquisas nas últimas décadas. O material absorvível mais utilizado foi descrito como um copolímero formado pelo ácido poliglicólico associado à D-L polilactide. Sarkarat e colaboradores (2012)[15] apresentaram um trabalho no qual compararam, através do método de elemento finito, qual a configuração mais estável para a fixação interna rígida da osteotomia sagital do ramo mandibular com placas absorvíveis. Os modelos estudados foram submetidos a cargas de 75, 135 e 600N. Dentre as possibilidades de fixação estudadas, os autores relatam que a utilização de 02 miniplacas retas (sistema 2.0mm) com 04 parafusos (tamanho 6mm) obtiveram maior estabilidade primária.[15]

No entanto, fixação com material absorvível apresenta performance clínica inferior do que fixação convencional com placas e parafusos de titânio.[21.27] Essa condição se evidencia na possibilidade de má-união óssea ou ainda tendência à recidiva[29.30] e autores sugerem a necessidade de bloqueio maxilo-mandibular no pós operatório precoce.[28] Apropriado design de placas aumenta a performance da osteossíntese biodegradável.[27] Albougha e colaboradores em 2015 sugerem que o

aumento da rigidez e portanto, da estabilidade, no uso das placas absorvíveis, está diretamente relacionado à utilização da placa duplo Y. No uso desta placa os parafusos fixados em formato triangular isolam a área entre os parafusos, enfraquecendo-a. No entanto, a área de osteotomia torna-se mais estável.[27]

Um estudo clínico randomizado realizado por Bakelen e colaboradores em 2015 mostrou que a estabilidade de longo prazo com fixação biodegradável não foi estatisticamente diferente do que a estabilidade com placas de titânio. A justificativa para isso encontra resposta no período pós-operatório imediato, quando a função muscular é significantemente reduzida e apropriada instrução aos pacientes deve ser rigorosamente aplicada[31]. Assim, a fixação biodegradável mostrou-se tão eficaz quanto placas de titânio e a escolha do design correto para a placa absorvível irá minimizar a chance de quebra ou fratura desta placa e aumentar a estabilidade de longo prazo da fixação[27].

Outra revisão realizada por Laine e colaboradores (2004)[32] mostrou excelente resposta na utilização de material absorvível após revisão de 320 osteotomias bilaterais do ramo mandibular. Nenhum paciente foi submetido à bloqueio maxilo-mandibular e somente uso de elásticos guias foi necessário pelo período de 05 à 07 semanas. Somente 14 pacientes apresentaram complicações menores (8.4% da amostra) como deiscência de suturas, exposição de placa, infecção e necessidade de remoção de material de síntese. Oclusão estável imediatamente após a cirurgia permite correto posicionamento dos fragmentos ósseos e sucesso independentemente do material de síntese utilizado. [32]

Outro estudo sugere que o aumento da estabilidade inicial nas fixações com material absorvível será obtida quando houver associação de 01 placa em formato L

na borda mais superior da OSRM[23] . O aumento da resistência aos movimentos de rotação horária dos segmentos óssoes poderá assim ser observado. Ainda, o formato quadrado das placas absorvíveis parece oferecer sútil vantagem quando comparado às placas retas standard.[23]

Recente estudo comparou a estabilidade do material absorvível com material standard de titânio através de uma revisão sistemática da literatura internacional e meta-análise.[35] O entendimento por parte do cirurgião do tipo de cirurgia, da magnitude do movimento, da necessidade estética, bem como da condição clínica do paciente devem direcionar a escolha da fixação estável. Sabidamente grandes movimentos podem levar a grandes recidivas e grandes avanços sem contato ósseo são mais instáveis. Assim, concluiu-se que a estabilidade do material absorvível é semelhante às placas de titânio quando recuos maxilares e rotações horárias do complexo maxilo-mandibular com avanço mandibular são realizados. Em movimentos como recuos mandibulares o material de titânio apresentou melhores resultados[35].

Do ponto de vista de genotoxicidade e resposta inflamatória, o trabalho de Oliveira e colaboradores[17], relata que os polímeros absorvíveis mostram-se bastante estáveis; não apresentando significativo risco de alterações celulares, mutações genéticas ou reação de corpo estranho; sendo portanto, semelhantes ao material de titânio largamente utilizado na fixação interna rígida das osteotomias mandibulares.

Portanto, diversas vantagens podem ser enumeradas quando se utiliza este tipo de fixação absorvível; entre elas: a forma biodegradável deste material, que pode iniciar sua absorção no organismo entre 9 e 15 semanas[16.] Biocompatibilidade, na qual, por hidrólise o material é absorvido pelo organismo na forma de gás carbônico e água[16 .] Estabilidade inicial similar às placas e parafusos convencionais

de titânio, propiciando segurança na sua utilização[24.25]. Ausência de interferência em exames de imagem como radiografias, tomografias ou principalmente ressonância magnética.[26.27] Fácil manipulação favorecendo a adaptação anatômica no sítio cirúrgico. Absorção seguida de neoformação óssea no local de osteossíntese sem presença de processo inflamatório ou fibrose e nenhuma necessidade de reintervenção para remoção do material de osteossíntese[16.26.27.28.] Importante estudo multicêntrico clínico randomizado realizado por Van Bekelen e colaboradores[33] em 2013 levou em consideração cirurgias realizadas em 04 centros de referência por diferentes profissionais e um acompanhamento pós-operatório (PO) de 02 anos. Oposto ao que se coloca na literatura, Van Bekelen e colaboradores relatam a ocorrência de necessidade de remoção de placas absorvíveis 2.2x maior do que quando utilizados material de titânio.[33]

Grande parte das placas absorvíveis que necessitaram ser removidas ocasionaram formação de abscessos e processos inflamatórios. Provavelmente pela pobre vascularização da densa cortical mandibular ou ainda pelo baixo PH gerado pela degradação do ácido láctico[33] Estabilidade oclusal e função mastigatória foram semelhantes após 02 anos de PO. Ainda, não houve diferença importante na palpabilidade das placas pelos pacientes[33].

Outros autores mostram que inúmeras complicações podem ocorrer quando sistema absorvível é utilizado. Yang e colaboradores em 2013[26] realizaram uma meta – análise e sugerem que a utilização de material absorvível não apresenta ainda parâmetros totalmente seguros para sua utilização. Notadamente observou-se reação à corpo estranho e mobilidade de segmentos ósseos mais frequente do que quando titânio era utilizado para fixação interna rígida. Dificuldade de palpação foi relatada como maior vantagem do material absorvível. Concluiu colocando a

necessidade de estudos randomizados e clínicos mais aprofundados para que possa assegurar o uso de material absorvível.

Ainda, dificuldade de manipulação, na qual o material deve ser pré-aquecido para possibilitar dobras; diminuição do tempo de fresagem e preparo de perfuração; processo de esterilização; alto custo do material e a resistência do mesmo em forças de torção[16] são também relatadas como dificuldades ou limitadores quando do uso de material absorvível.

Assim, considerando o experimento aqui realizado e a revisão de literatura, se pode concluir que apesar da literatura comprovar eficácia do método absorvível na estabilidade mecânica da OSRM, mediante a escolha de design apropriado de placas e osteotomias, associado à período inicial pós-cirúrgico de contenção maxilo-mandibular e experiência profissional; algumas desvantagens e insegurança ainda persistem e que a utilização do método continua impopular entre a maioria dos cirurgiões.

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ANEXO I

S I P E S Q

Sistema de Pesquisas da PUCRS

Código SIPESQ: 6930 Porto Alegre, 3 de dezembro de 2015.

Prezado(a) Pesquisador(a),

A Comissão Científica da FACULDADE DE ODONTOLOGIA da PUCRS apreciou e aprovou o Projeto de Pesquisa "AVALIAÇÃO MECÂNICA DE PLACAS E PARAFUSOS ABSORVÍVEIS PARA FIXAÇÃO INTERNA RÍGIDA DE OSTEOTOMIA SAGITAL DO RAMO MANDIBULAR" coordenado por JOAO BATISTA BLESSMANN WEBER. Caso este projeto necessite apreciação do Comitê de Ética em Pesquisa (CEP) e/ou da Comissão de Ética no Uso de Animais (CEUA), toda a documentação anexa deve ser idêntica à documentação enviada ao CEP/CEUA, juntamente com o Documento Unificado gerado pelo SIPESQ.

Atenciosamente,

Comissão Científica da FACULDADE DE ODONTOLOGIA

Figura 01: Base para suporte das hemimandíbulas

Figura 02: Máquina de ensaio mecânico EMIC DL-2000 - São José dos Pinhais – Brasil.

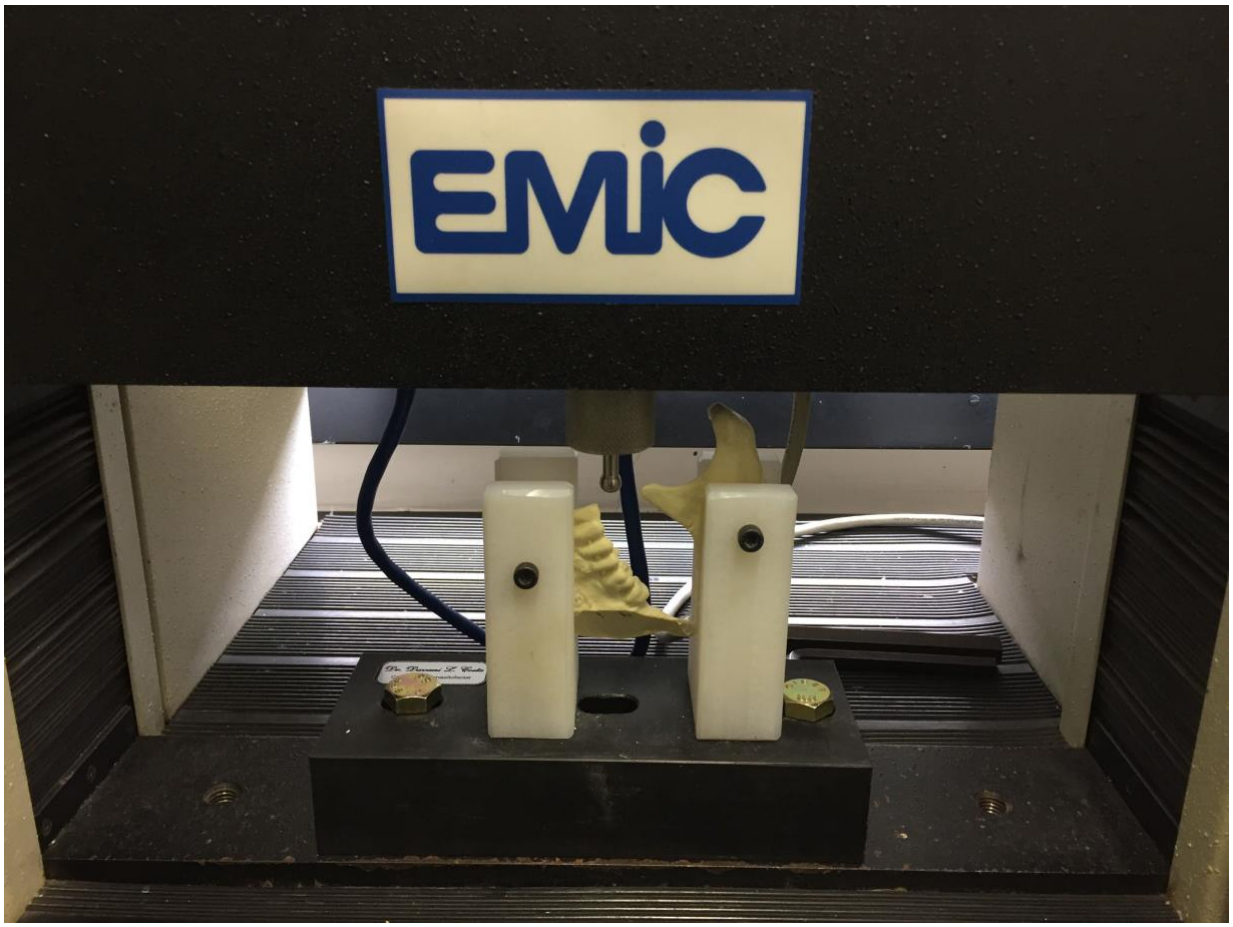


Figura 3: Gráfico de perfil com o comportamento da força necessária para mover cada uma das placas da amostra. As linhas grossas representam as forças médias. (Artigo 01)

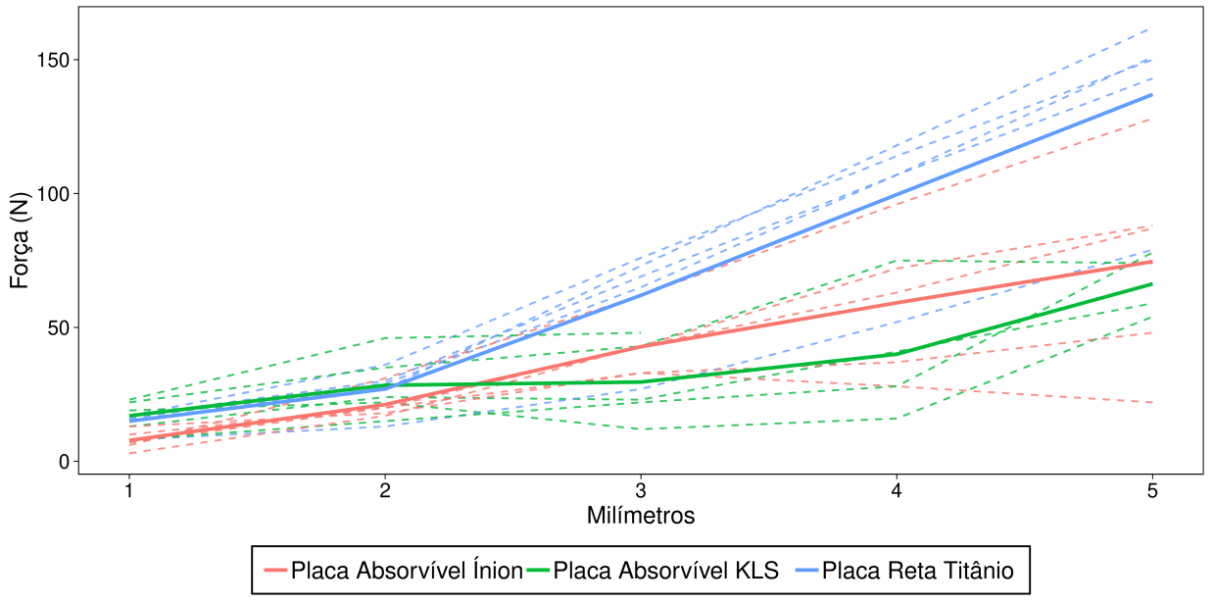


Figura 4: Gráfico das médias da força necessária para mover as placas de cada tipo. As barras verticais representam o erro-padrão das médias. (Artigo 01)

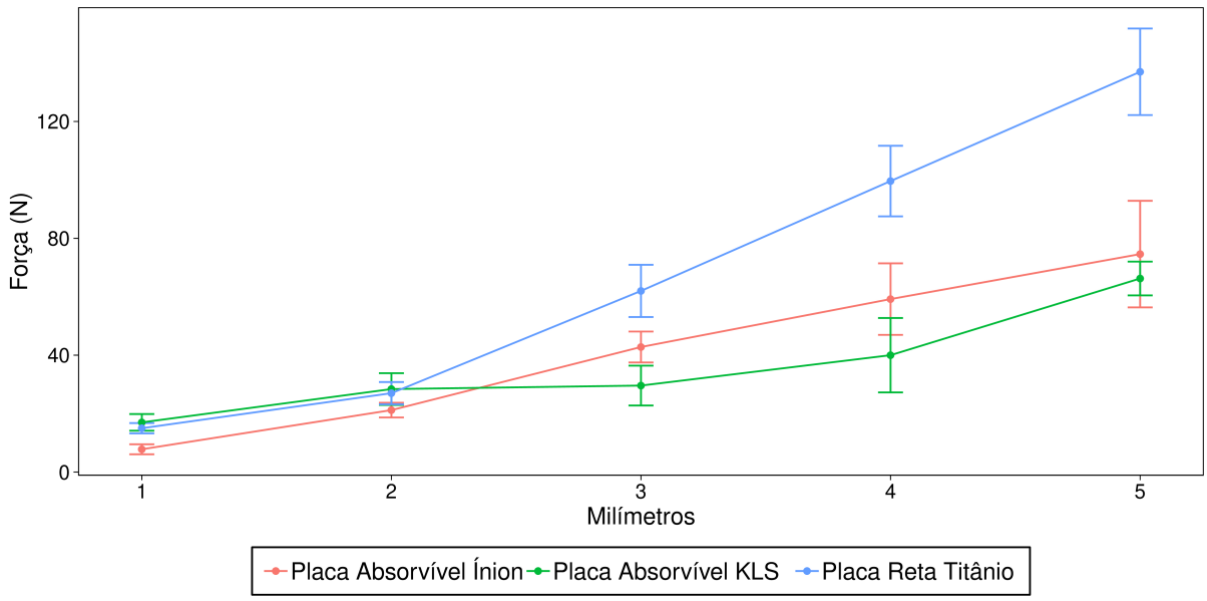
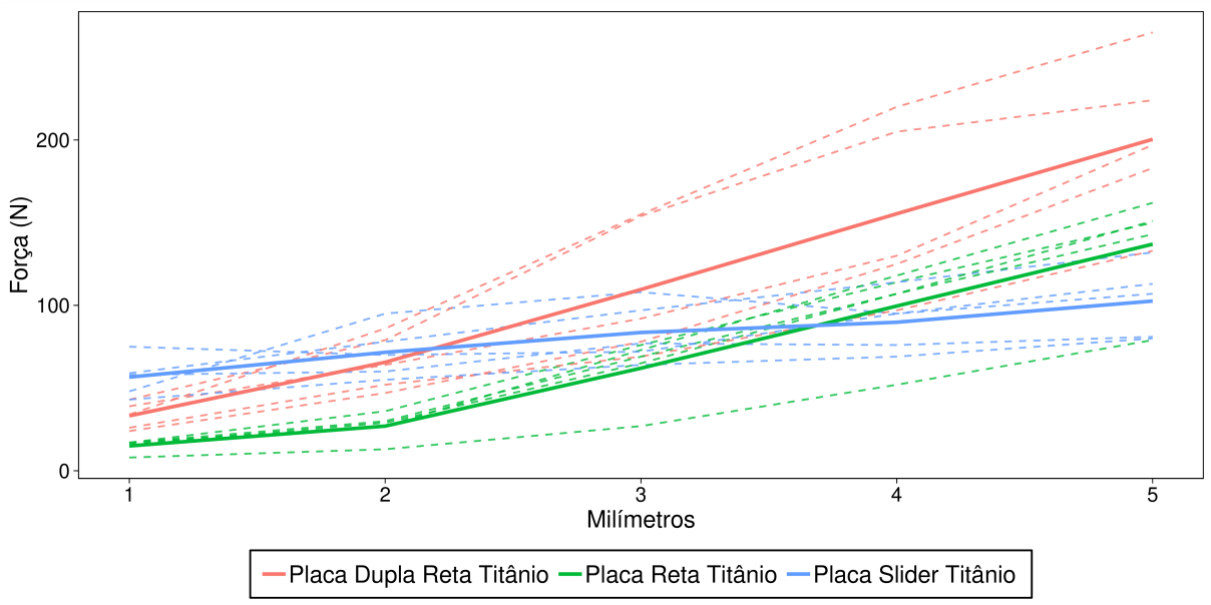
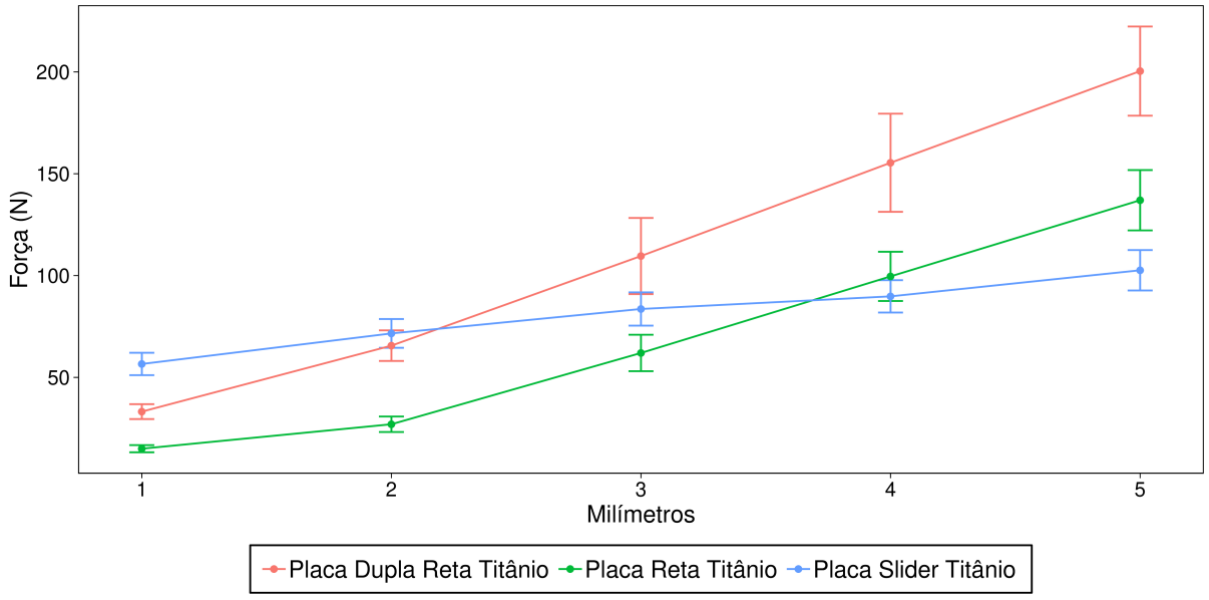


Figura 5 : Gráfico de perfil com o comportamento da força necessária para mover cada uma das placas da amostra. As linhas grossas representam as forças médias. (Artigo 02)



ANEXO VII

Figura 6: Gráfico das médias da força necessária para mover as placas de cada tipo. As barras verticais representam o erro-padrão das médias.
(Fig. 2 Artigo 02)



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