UNIVERSIDADE DE SÃO PAULO
FACULDADE DE ODONTOLOGIA BAURU

NOUR JIHAD SALMAN

New design of titanium plate for minimally invasive treatment of mandibular fractures

Novo modelo de placa de titânio para tratamento minimamente invasivo de fraturas mandibulares

BAURU
2021

NOUR JIHAD SALMAN

New design of titanium plate for minimally invasive treatment of mandibular fractures

Novo modelo de placa de titânio para tratamento minimamente invasivo de fraturas mandibulares

Dissertação apresentada à Faculdade de Odontologia de Bauru da Universidade de São Paulo para obtenção do título de Mestre em Ciências no Programa de ciências Odontológicas Aplicadas, na área de concentração Cirurgia e Traumatologia Bucomaxilofacial.

Orientador: Prof. Dr. Eduardo Sant'Ana

Versão corrigida

BAURU

2021

Salman, Nour Jihad
New design of titanium plate for minimally invasive treatment of mandibular fractures / Nour Jihad Salman – Bauru, 2021
72 p.: 11 fig., 4 tab.; 31 cm.

Dissertação (mestrado) -- Faculdade de Odontologia de Bauru, Universidade de São Paulo, 2021.

Orientador Prof. Dr. Eduardo Sant'Ana.

FOLHA DE APROVAÇÃO

DEDICATÓRIA

I dedicate this project to God Almighty my creator, my strong pillar, my source of inspiration, wisdom, knowledge and understanding.

To my parents, Jihad and Ferial, for their everlasting support and love throughout my journey.

To my siblings, Hayfa, Manal and Hadi for believing in me, standing by me and never leaving my side. And for the lengthy conversations and valuable advices. To my precious niece Yara, and sister-in-law Hazar. Love you all.

To my advisor, Professor Eduardo Sant'Ana, for the friendship, support, trust, fruitful discussions and conversations and for the guidance and teachings along the way, I'm forever grateful.

AGRADECIMENTOS

To all the professors at the department of Surgery, Stomatology, Pathology and Radiology at FOB – USP, Prof. Dr. Osny Ferreira Junior, Prof. Dr. Eduardo Sanches Gonçales, Prof. Dr. Renato Yassatuka Faria Yaedú and Prof. Dr. Paulo Sergio Perri de Carvalho for their guidance and orientations during my program.

To Prof. Dr. Paulo Esteves Pinto Faria for the orientations and help to complete my project.

To my teacher and friend Prof. Dr. Andre Assaf for his valuable advices and teachings ever since my undergraduate university degree.

To my fellow colleagues at the department of Surgery, Stomatology, Pathology and Radiology for the friendship and acquaintanceship.

To Luciana Zanon for being supportive, gentle and for all the help and orientations during the program and beyond.

To all the employees at FOB – USP for their empathy, kindness and friendship.

To my professors at the department of Oral and Maxillofacial Surgery at FOAr – UNESP, Prof. Dr. Mario Francisco Real Gabrielli, Prof. Dr. Marisa Aparecida Cabrini Gabrielli, Prof. Dr. Marcelo Silva Monnazzi, Prof. Dr. Eduardo Hochuli Vieira, Prof. Dr. Valfrido Antonio Pereira Filho and Prof Dr. Jose Scarso Filho for all the teachings, guidance and experiences.

To all my colleague residents at the residency program at FOAr – UNESP for all the experiences and acquaintanceship during the three years of residency.

To my teacher and master GM. Sami Kiblawi and my friend Mr. Karim Khayat for all the support and help throughout my journey.

To my friends Houssam Baker, Mirvat Salhab, Laura Coube, Taha Saifi, Elie Abou Tayeh, and to many others for always being there, lifting me up and supporting me throughout my quest.

To Mr. Cesar Carita and the whole team at Traumec© Brazil for providing the plates and screws for the experiment, and for being always open for scientific innovation and advances.

To Nacional Ossos© Brazil for providing the polyurethane hemimandibles that were used as the test body for the experiments.

ABSTRACT

New design of titanium plate for minimally invasive treatment of mandibular fractures

Many treatment modalities and various fixation techniques for maxillofacial fractures were suggested in the literature. Some authors suggested new treatment patterns using different plating techniques, whereas others presented a new macrogeometry of fixation plates that aimed at improving biomechanical properties and material resistance. The purpose of this study is to evaluate, *in vitro*, the stability of a new model of titanium fixation miniplate for the fixation of maxillomandibular fractures. Therefore, an *in vitro* experimental study using polyurethane mandibles was conducted to evaluate the biomechanical properties of the new fixation plate (SS group) compared to a 2.0mm four-hole standard plate fixation following the Champy technique as a control (Ch group). In a universal testing machine, the experiments were performed upon fixation, analyzing and comparing the maximum force in Newtons (N), displacement at maximum force in millimeters (mm) and the time till the maximum force in seconds (s) between the two groups. As a result, group Ch showed superior results in fixation and stabilization of mandibular angle fracture, however, this experiment was performed at a mobile bone of the facial skeleton due to facility of performing the biomechanical tests and the presence of an established methodology, while the intended area of use would be facial fractures in non-mobile bones where direct muscle loading is minimal such as fractures of the frontozygomatic complex, zygomaticomaxillary complex, condylar neck and other maxillofacial fractures.

Key words: bone plates; fracture healing; fracture osteosynthesis; mandible; material resistance.

RESUMO

Novo modelo de placa de titânio para tratamento minimamente invasivo de fraturas mandibulares

Muitas modalidades de tratamento e várias técnicas de fixação para fraturas maxilofaciais foram sugeridas na literatura. Alguns autores sugeriram novos padrões de tratamento utilizando diferentes técnicas de fixação, enquanto outros apresentaram uma nova macrogeometria de placas de fixação que visam melhorar as propriedades biomecânicas e a resistência do material. O objetivo deste estudo é avaliar in vitro a estabilidade de um novo modelo de placa de titânio para fixação de fraturas do complexo maxilo-mandibular. Em uma mandíbula de poliuretano uma fratura padronizada na região de ângulo foi feita para avaliar a nova placa (grupo SS) comparada a utilização de uma placa do sistema 2.0 de quatro furos fixada na região pela técnica de Champy como controle (grupo Ch). Em uma máquina de ensaios universal foi realizado teste de compressão após a fixação das placas, sendo analisados e comparados entre os dois grupos, a força máxima em Newtons (N), o deslocamento na força máxima em milímetros (mm) e o tempo até a força máxima em segundos (s). Como resultados, o grupo controle (Ch) apresentou resultados superiores na fixação e estabilização da fratura do ângulo mandibular, porém, este experimento foi realizado em um osso móvel do esqueleto facial devido à facilidade de realização dos testes biomecânicos e à presença de uma metodologia estabelecida, enquanto a pretendida área de uso seria fraturas faciais em ossos imóveis onde a carga muscular direta é mínima, como fraturas do complexo frontozigomático, complexo zigomático-maxilar, côndilo e outras fraturas maxilofaciais.

Palavras-chave: placas osseas; consolidação de fratura; fixação interna de fraturas; mandíbula, resistência de materiais.

LIST OF ILLUSTRATIONS

- FIGURES

- GRAPHICS

LIST OF TABLES

TABLE OF CONTENTS

1 INTRODUCTION

1 INTRODUCTION

The mandible is the largest and strongest bone of the facial skeleton. It is a complex structure, being the only mobile bone of the head and neck region, constituted of the symphysis, parasymphysis, body, angle, ramus, condylar process and coronoid process. With the alveolar process being the part that bears the teeth (Prein, J. 1998).

Located at the base of the cranium, various ligaments and muscle fibers are inserted into the mandibular bone, influencing its function and movement. Of these muscles, the temporalis, masseter, lateral pterygoid and medial pterygoid muscles form the muscles of mastication (Sicher, H.; Dubrul, E.L.; Picosse, M. 1977).

The mandible is a highly susceptible bone in maxillofacial trauma, due to its prominent position in the face. It ranked only second (23.3%) to nasal fractures (58.6%) according to a retrospective study published by Allareddy et al. in 2011 (Allareddy V, Allareddy V, Nalliah RP, 2011). According to a study performed by Swearingen et al. in 1965, the energy required to cause a mandibular fracture ranges between 44.6 and 74.4kg/m, which is equal to that required to cause a zygomatic fracture, and about half of that required for a frontal bone fracture (Luce EA, Tubb TD, Moore AM, 1979 ; Halazonetis JA, 1968).

Areas of the mandible like the mental protuberance, mental foramen, mandibular angle and the condylar neck are considered areas of weakness (Halazonetis JA, 1968). The mandibular angle is one of the most common sites for fractures, with an average of 23% to 42% of all mandibular fractures (Suer BT, Kocyigit ID, Kaman S, et al., 2014). Its location at the junction of the mandibular ramus and mandibular body, in addition to other anatomic factors including the presence of mandibular third molars, thin cross-sectional area and the high impact of masticatory muscle function in the region, make it more vulnerable to fractures by traffic/sports accidents, physical violence, or pathologic conditions (Wallner J, Reinbacher K, Feichtinger M, et al., 2017 ; Ellis EI, 2010 ; Yamaji MAK, Oliveira Neto PJD, Ribeiro MDC, et al., 2015). Nevertheless, when discussing maxillofacial trauma, mandibular angle fractures alongside condylar fractures are the most debatable topics (Ellis EI, 2010).

Biomechanical analysis of the mandibular angle area demonstrates that, upon function, a tension zone is formed at the superior border (tooth side) of the body and angle of the mandible, and a compression zone forms at the inferior border. The neutral zone corresponds to the central area, which often comprises the neurovascular canal (Prein, J. 1998). Thus, mandibular angle fractures are referred to as favorable and unfavorable depending on the angulation of the fracture line, the force of muscle pull and the potential of consequent displacement of the fracture ends (Helkimo et al., 1977).

The main goal of mandibular fracture treatment is to obtain precise anatomic reduction, stable fixation and painless immobilization of the fractured region (Gear et al., 2005). Various treatment modalities have been suggested by the literature, ranging from conservative closed reduction to open reduction with non-rigid fixation to open reduction with rigid internal fixation using titanium plates or lag screws (Prein, J. 1998).

Internal fixation techniques became more popular with the introduction of Vitallium compression plating by Luhr in 1960s (Luhr HG, 1987), and further by the adoption of the double plate fixation protocol by the AO Foundation/Association for the Study of Internal Fixation AO/ASIF, that emphasized the need of absolute fracture stability to ensure primary healing (Schierle HP, et al., 1997). Nevertheless, further experiments showed that absolute internal fixation was not mandatory to achieve satisfactory healing of mandibular fractures (Michelet FX, Deymes J, Dessus B, 1973; Champy M, Lodde JP, Schmitt R, 1978), and a single miniplate fixation was first suggested by Champy et al. in 1978 (Champy M, Lodde JP, Schmitt R, 1978).

The main objective of rigid internal fixation is to immobilize the fractured bony segments in such a way that they remain stable during the period of osseus repair. This fixation technique was accepted in the 70’s in Europe and in the 80’s in the United States after the implementation of AO\ASIF principles. (Ellis III & Karas, 1992; Ellis, 1993).

Rigid internal fixation with miniplate has become the treatment of choice in mandibular fractures due to primary stability and immediate post-operative function without the need for prolonged intermaxillary fixation (Schierle HP, et al., 1997). Miniplates are used for the fixation of the condyle, body, angle and parasymphysis fractures, where minimal comminution with large intact bone segments provides the optimal conditions for treatment success. Although they can be used for the reduction and fixation of smaller bone fragments, extensive periosteal stripping causes damage to blood supply and can lead to necrosis and sequestration of mandibular bone (Chiodo, T.; Milles, M. 2009).

However, it is worth noting that regardless of the treatment method applied, mandibular angle fractures show the highest complication rates of all the mandibular fractures (TU, Tenhulzen 1985 ; Ellis III, Ghali 1991 ; Ellis III, Walker, 1996 ; Wittenberg et al., 1997 ; Ellis III, 1999 ; Sauerbier et al., 2010). Also, various complications have been linked to mandibular angle fractures despite the advances in surgical techniques and fixation material used in treatment (Iizuka T, Lindqvist C, Hallikainen D, 1991). Furthermore, Brucoli et al. reported the highest rate of complications such as infection, malunion, malocclusion, and neurologic damage, ranging from 0-23% linked to the treatment of mandibular angle fractures (Brucoli et al., 2019).

2 Literature Review

2 LITERATURE REVIEW

The objective of this literature review is to present evidence-based treatment modalities for mandibular angle fracture, including traditional techniques and innovated techniques utilizing custom-made fixation plates to achieve primary stability and longevity of the fixation apparatus.

To facilitate this review, studies were divided into two parts: studies discussing treatment of mandibular angle fractures and comparing different fixation techniques, and studies presenting new fixation plates and comparing them with traditional fixation techniques.

The search strategy of this integrative review was performed in MEDLINE (Medical Literature Analysis and Retrieval System Online, via PubMed), ELSEVIER (via Scopus), and Cochrane Library databases scanning the subjects using eight descriptors: “mandibular fracture” OR “mandibular trauma” OR “mandibular angle fracture”; “fixation” OR “osteosynthesis”; “miniplate” OR “titanium plate” OR “rigid internal fixation”; “new design” OR “novel structure” OR “customized plate”, in February 2021.

The initial selection and title and/or abstract analysis was performed according to the following inclusion criteria: studies evaluating mandibular fractures including mandibular angle region; studies presenting new fixation techniques or systems for treating mandibular angle fractures; in vivo, in vitro or finite element method studies; and studies reported in English language without time restriction regarding to publication date. Studies in non-English language were excluded.

Full-text reading was performed after initial selection according to inclusion criteria to define the final included studies. Reviewers performed additional discussion to solve any disagreements.

Part I – Studies discussing mandibular angle fracture:

Kelly and Harrigan, in 1975, defined any mandibular fracture distal to the second molar, and extending from any point in the curvature formed at the junction of the body and ramus of the mandible at the retromolar area to any point at the curvature formed at the inferior margin of the mandibular body and ascending ramus, as a mandibular angle fracture. (Kelly and Harrigan, 1975)

Michelet et al. (1973) described the technique of immobilization of mandibular angle fractures using 4 mm wide plates with 1.5 mm in diameter and screws from 5 to 7 mm in length, via intra-oral access, showing excellent results after analysis of 300 cases. Several authors have proposed modifications to this technique, particularly in the 1970s (Champy et al., 1976a; Champy et al., 1976b). Champy et al. (1978) proposed the installation of two screws per bone segment without the need for maxillomandibular block. They reported that this type of fixation is resistant enough to support the forces from the masticatory muscles, being an adequate method of osteosynthesis. Similar results have been observed in several studies (Kroon et al., 1991; Özden et al., 2006).

Although Champy's technique does not promote interfragmentary compression and primary bone repair, its success rate for treating angular fractures has been proven with many clinical studies, showing low complication rates. However, despite clinical trials, *in vitro* biomechanical studies evaluating fixation of the mandibular angle with Champy method demonstrate that the resistance of the monocortical plates to masticatory forces is insufficient (Champy et al., 1978; Kroon et al., 1991; Choi et al., 1995). This can be explained, however, by the fact that masticatory forces in postoperative patients remain lower than normal for many weeks, so that a less rigid fixation may be sufficient for the stability of the bony fragments during the bone repair phase (Shetty et al., 1995).

In 1987, Niederdellmann & Shetty performed a retrospective study to assess patients treated by compression fixation screws to gain interfragmentary compression in the mandibular angle region. The 2.7 mm screws were installed via intraoral access with transbuccal trocar approach. The authors reporta rate of 4% of infection, 6% persistent sensorineural disorders and 2% malocclusion. In conclusion, they considered the results highly satisfactory and the technique could be indicated for osteosynthesis of the mandibular angle (Niederdellmann, Shetty, 1987).

According to Ellis (2009), there is no consensus in the literature concerning the definition of mandibular angle fractures. Nevertheless, the literature agrees on two points. The first is the fact that the term “angle” refers to an anatomical area, although some disagree on the contents of that area. The second point refers to the fracture location at the superior border of the mandible, the junction of the ascending ramus and mandibular body, normally the location of third molars. However, disagreements on the fracture location at the inferior or posterior border of the mandible still exist. (Ellis III, 2009)

The mandible represents the second most frequent area of fracture in the maxillofacial skeleton due to its prominent position (Ogundare et al., 2003). Mandibular angle fractures are common, with an incidence rate ranging between 23% and 42% of all mandibular fractures (Safdar, Meechan, 1995; Schierle et al., 1997). This high incidence rate of fracture can be attributed to thin transversal bone thickness and the presence of third molars (Safdar, Meechan, 1995; Lee, Dodson, 2000). Other variables, like bone density, trauma severity and direction and point of impact also influence the fracture location.

Olson et al. (1982) encountered a high incidence of mandibular angle fracture, being the second most common fracture with a total of 24.5% of the 935 fractures included in his study. In 1992, Luyk et al. found that 23% of mandibular fractures occurred at the angle region, being the third most affected area in the mandible. A retrospective study published by Matos et al. in 2010 evaluated the epidemiology, treatment and complications of mandibular fractures with or without other facial fractures. They found out that the mandibular angle fractures ranked fourth among other mandibular fractures with 37 out of the 201 fractures included being at the angle region.

The introduction of rigid compression plates by Luhr in 1968 eliminated the need for post-operative maxillomandibular fixation (Kempers, Hendler, 2000).

Pieri et al. compared, in 2002, single-plate with biplanar fixation technique. They deduced that the miniplate placed along the inferior border enhanced the stability of internal fixation when compared to single-plating technique. They performed the experiment both *in vitro* and *in vivo*.

Boulourian et al. conducted a study in 2002 to assess the efficacy of treating mandibular angle fractures with a single 2.0mm titanium plate adapted along Champy’s lines of ideal osteosynthesis, followed-up by 2 weeks of maxillomandibular fixation.

The experiment included 31 patients with 44 mandibular fractures, distributed according to location to 31 angle fractures, 11 parasymphysis fractures and a single ramus and symphysis fracture. The results showed adequate bone healing in 100% of the cases, with very low post-operative complications rate, thus suggesting that this treatment modality is a viable treatment for mandibular angle fractures.

A retrospective study performed in 2015 by Bhatt et al. compared three different fixation systems of mandibular fractures. The study included 60 case records, 20 of which were treated with a single non-locking 2.0mm plates, 16 with a single locking 2.0mm plate and 24 with 2.5mm bioresorbable plate. Different variables were taken into consideration among the three groups. Pre-operative variables like age, sex, number of fracture lines and presence and absence of teeth in fracture line. The trans-operative variables including intraoral or transbuccal surgical access, number of screws applied and third molar preservation or extraction, also post-operative variables like secondary loss of reduction/ malocclusion, delayed union, infection and plate removal due to infection or patient's will. As a conclusion, the authors observed no difference in complication rates of mandibular angle fracture treated with the 3 different groups. However, this study had the limitations of a retrospective study like a small sample size and not including certain factors like smoking. (Bhatt K et al., 2015).

In 2013, Yazdani et al. conducted a prospective study to assess post-operative complications associated with mandibular angle fractures treatment using monoplanar and biplanar rigid internal fixation. Both single and double plate fixation systems showed a similar post-operative complications rate, favoring the single plate system for being simpler and more cost-efficient. (Yazdani et al., 2013)

Al-Tariri et al. conducted a study in 2015 to compare the stability of unfavorable mandibular angle fractures using two fixation systems: three-dimensional plate and double miniplate fixation. The study included 16 patients divided into two equal groups receiving the different fixation plates. They concluded that the three-dimensional plate was comparable to the double-plating system when it comes to sufficient post-operative stability for bone healing, optimal occlusion, and early return to function. (Al-Tariri et al., 2015)

Part II – studies presenting new fixation plates and comparing them with traditional fixation techniques:

In 2004, Feledy et al. performed an in vitro experiment in biomechanical models, in addition to a clinical study to test a new 2.0mm matrix miniplate for mandibular angle fracture treatment. The new plate showed to provide sufficient stability with a decreased rate of plate fracture, fracture ends mobility and subsequent infection. Moreover, another follow-up clinical study was published in 2013 by Wolfswinkel et al., proving the superior stability achieved by the new matrix strut plate, in addition to the low complication rate. (Feledy J et al., 2004 ; Wolfswinkel EM et al., 2013)

In 2007, Alkan et al. conducted a study to compare different plating techniques used in the treatment of mandibular angle fracture from a biomechanical point of view. The study was performed in vitro, on sheep mandibles, comparing 4 different plating techniques: Champy monoplate fixation, biplanar double plate fixation, monoplanar double plate fixation and a three-dimensional curved angle strut plate. The study demonstrated that 3D strut plates and double plating techniques had greater resistance to compression load than monoplating technique (Champy technique), and biplanar orientation had a more favorable biomechanical behavior than monoplanar orientation. (Alkan A et al. 2007)

Zix et al. performed a clinical experiment in 2007 to evaluate the clinical success of a new 3D miniplate used for treatment of mandibular angle fractures. The study included 20 patients with noncomminuted mandibular angle fracture, treated with the new 3D plating system. As a conclusion, the new 3D plate is a suitable method of fixation in case of simple mandibular angle fracture, it showed low post-operative complication rate and adequate fixation over a follow-up period of 6 months. (Zix J et al., 2007)

A new technique for mandibular angle fractures was suggested by Turgut et al. in 2008. The authors performed an *in vitro* experiment undergoing biomechanical comparison of 4 groups divided as follows: A- fracture fixation by one 4-hole miniplate with monocortical screws, B- fracture fixation by two 4-hole miniplates placing 3 bicortical and one monocortical screw in the superior plate with 4 bicortical screws in the inferior plate, C- fracture fixation by 2 4-hole miniplate using 4 monocortical screws in the superior and 4 bicortical screws in the inferior, and D- fracture fixation with 11 hole reconstruction plate with bicortical screws placed into proximal and distal 3 holes. The results showed a statistically significant difference between the groups A and B in terms of compression and bending strength, a statistically significant difference between groups B and C in compression testing, a similar result in terms of bending and side-bending strength between groups B and D. The authors concluded that fixation with biplanar dual-miniplate using 3 bicortical screws in the 3 proximal holes in the upper plate one monocortical screw in the distal fourth hole, and 4 bicortical screws on the lower border, showed superior results when compared with other fixation methods. (Turgut G et al., 2008)

In 2009, Kalfarentzos et al. presented a new 3D plate approach, and compared 4 different plating techniques: a square 3D miniplate with 2x2 holes, a curved 3D miniplate with 6x2 holes, 2 straight miniplates with 4 holes and 1 straight miniplate with 4 holes. The four groups were subjected to incisal and homolateral molar region loading. The first group presented a statistically significant higher torsional stiffness compared to the other groups. Whereas no statistically significant difference was noted among the groups concerning bending stiffness. (Kalfarentzos EF et al., 2009).

Hochuli-Vieira et al. presented, in 2011, a rectangular grid miniplate for fixation of mandibular angle fractures. 45 patients with mandibular angle fracture were included in this study, and received rigid internal fixation using a rectangular grid miniplate of a 2.0mm system and monocortical screws via intraoral approach. Follow-ups were made at 15 and 30 days and 3 and 6 months. The plate used in this study showed low complication rate, easy handling and easy adjustment with a low cost. However, this plating technique was indicated for fractures with sufficient interfragmentary contact. (Hochuli-Vieira et al., 2011).

In 2012, De Melo et al. introduced a new three-dimensional grid miniplate for treatment of mandibular angle fractures. The study presented a case report of a patient with mandibular angle fracture treated with the new three-dimensional grid miniplate with monocortical screws. The fracture showed good stability with no complications at the 8 months follow-up. (de Melo et al., 2012).

Suer et al. conducted an in vitro experiment in 2014 to test the stability and resistance to mechanical forces of a new miniplate design. The new miniplate design presented a six-hole titanium non-compression miniplate with one straight section and two lateral extensions. The experiment compared the new six-hole miniplate adapted to the superior border of the external ridge to a single straight six-hole titanium non-compression miniplate adapted at the superior border of the external oblique ridge according to Champy technique. The results showed that the new miniplate offers greater resistance to lateral displacement forces, and may also provide increased resistance to vertical compressive and tensile forces when compared to the conventional six-hole straight miniplate. (Suer BT et al., 2014)

In 2015, Rangel Goulart et al. published an experiment to develop a plate to be used for the treatment of mandibular angle fractures using finite element method. For this purpose, they compared three methods of internal fixation: two non-locking plates, two locking plates and a new design of locking plate. They concluded that the new plating system modified the mechanical behavior of the fractured region, resulting in less displacement between the fractured segments. However, the group with two-locking plating system showed greater mechanical resistance to force loading. (Goulart DR et al., 2015)

Pituru et al., in 2016, presented a new miniplate designed to offer maximum stability with minimal implanted volume and patient intrusion. The new six-hole plate showed the two middle slots to be horizontally oriented, parallel to the plate long axis, and the neighboring two slots to be vertically oriented with two standard holes on the two lateral holes of the plate. This design aimed at keeping the maximum strains developed in the cortical bone upon biting at lower values, thus preventing bone resorption. The experimental study was composed of *in vitro* biomechanical testing and finite element method analysis. The new plate design showed good fracture stability, with the advantage of reduced healing time and good quality of newly formed bone. (Pituru TS et al., 2016)

In 2017, In-Hee Woo et al. presented a new fixation method using the Yang's Keyhole (YK) plating system for the treatment of fractures of the mandibular angle and subcondyle regions. The YK system is a slightly modified sliding plate having a widened slot in the anterior region. The experiment was performed *in vitro* using mandibular replica models, comparing the conventional 4-hole miniplate to the YK plate. Also, a clinical study was carried on including 22 patients with mandibular angle and subcondylar fractures. The researchers concluded that the new fixation system

(YK plate) was reliable and convenient when applied to subcondyle and mandibular angle fractures. (Woo IH et al., 2017)

However, in 2017 Yun-feng Liu et al. developed a customized fixation plate with novel structure for mandibular angle fractures. The experiment was designed using finite element method, where 3D virtual mandible was reconstructed from CT images that simulate angle fracture with 1mm gap between the bone segments. The new plate was designed using topological optimization method, having a V pattern according to dimensions of standard miniplate. The study compared three fixation systems: one standard miniplate, two standard miniplates and the new V pattern miniplate design. As a conclusion, the customized fixation system demonstrated a good biomechanical behavior, significantly reducing the stress, strain and displacement within the plate when compared to the other two conventional fixation systems. (Liu YF et al., 2017)

Datarkar et al. presented a novel miniplate design for fixation of mandibular fractures in transition zone of parasymphysis-body region in 2018. The new plate represented a twin fork design, having the advantage of atraumatic plate positioning at the mental foramen region. A finite element method experiment was carried on for the purpose of comparing the biomechanical behavior of the new plate design with the conventional one miniplate and two miniplate fixation. The study concluded that the new miniplate design is superior in terms of stability, producing fewer equivalent stresses upon maximum force application. (Datarkar A et al., 2018)

In 2020, Sirin et al. performed an experimental study to examine the biomechanical stability of mandibular angle fractures treated by a single titanium miniplate in polyurethane models with different gonial angles. Three different types of polyurethane mandibles with low, normal and high gonial angle were compared when subjected to molar and incisal loading. The high gonial angle sample showed less resistance to the applied load. However, a clinical experiment should be performed to obtain more viable results. (Sirin Y et al., 2020)

In 2020, Pappachan et al. suggested a minimal access surgical technique for the fixation of mandibular angle fractures. The osteosynthesis is performed under local anesthesia with maxillomandibular fixation, starting with a small stab incision just below the attached gingiva, with minimal periosteal elevation and 4-hole miniplate introduction and fixation. The authors suggest the use of this technique in minimal or non-dislocated fractures, and they believe it can be an introduction for endoscopic approach for treatment of mandibular angle fractures. (Pappachan et al., 2020)

3 PROPOSITION

3 PROPOSITION

A new design of spiked-synthesis plate (SS plate) is suggested, which offers sufficient fracture ends stability, in addition to minimally invasive surgical technique promoting the use of less osteosynthesis material. Therefore, the proposition of this study is to evaluate, in a previously standardized fractured mandibular resin model, if this new fixation system is capable of maintaining the stability of mandibular fractures, compared to the technique proposed by Champy.

4 Material and Methods

4 MATERIAL AND METHODS

The customized fixation plate was designed to provide sufficient stability with a minimally invasive surgical technique requiring minimal access and periosteal elevation, and minimal osteosynthesis material. The new plate design consisted of a 2.0mm thickness two-hole plate, with micro-spikes positioned in a trigonal pattern at both sides of the plate in such a way to allow for 1.0mm in depth perforation of the cortical bone (Fig.1a).

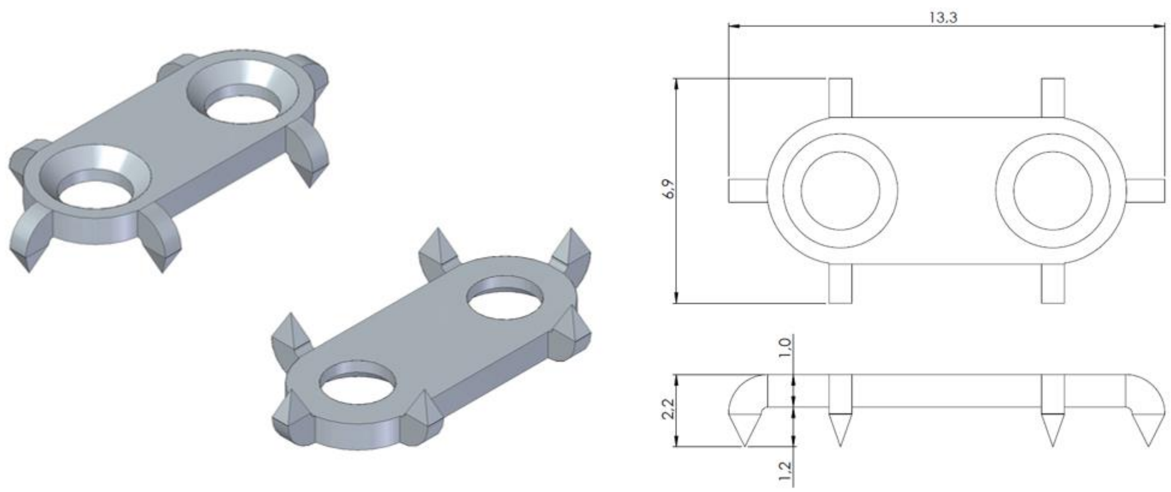


Fig 1 a. A new 2.0mm thickness two-hole plate design,
with micro-spikes positioned in a trigonal pattern.

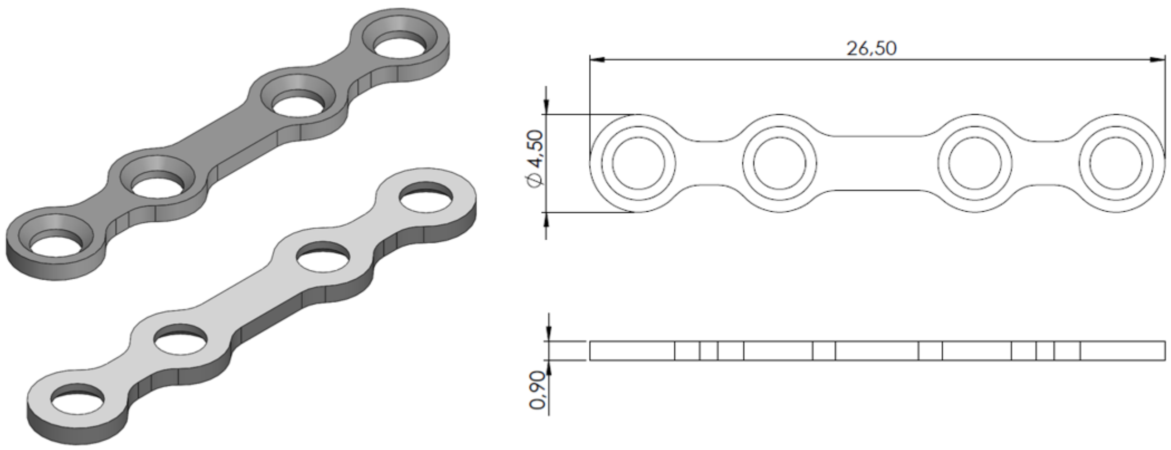


Fig 1 b. Conventional 2.0mm 4-hole fixation plate.

Hemimandibles:

For the purpose of this study, 38 edentulous polyurethane mandibular replicas (Nacional Ossos Ltda., Jau, Sao Paulo, Brazil) were used as a test model. Those replicas were sectioned at the median sagittal line, using a specially created mold, to produce 76 hemimandibles. The left-side hemimandibles were used for this study and were separated into 2 groups of 19 hemimandibles each.

The hemimandibles received a mandibular angle osteotomy to simulate a non-favorable angle fracture, also using a guide specifically created for this purpose, to ensure uniformity among samples (Fig. 2). The angle osteotomy simulated a non-favorable fracture extending from the junction of the superior border of the mandibular body and the anterior border of the ascending ramus of the mandible to the junction of the lower border of the mandible with the posterior border of the ascending ramus in an anteroposterior orientation. Moreover, the osteotomy presented a bevel extending from the buccal to the lingual border in a posteroanterior orientation. The idea behind this osteotomy design is to simulate the common non-favorable fractures occurring in the mandibular angle region.

Fixation plates and screws:

The study consisted of two groups, the control group (Ch group) and the test group (SS group). The following fixation material were utilized:

- 19 straight four-hole titanium plates of the 2.0mm system (0.9 mm x 26.5 mm x 4.5 mm) and 76 titanium screws of 2.0mm diameter and 6.0mm length (Traumec, Rio Claro, SP, Brazil). (Fig. 1b)
- 19 two-hole spiked-synthesis plate (SS-plate) of the 2.0mm system (2.2 mm x 13.3 mm x 6.9 mm) and 38 titanium screws of 2.0mm diameter and 6.0mm length (Traumec, Rio Claro, SP, Brazil). (Fig. 1a)

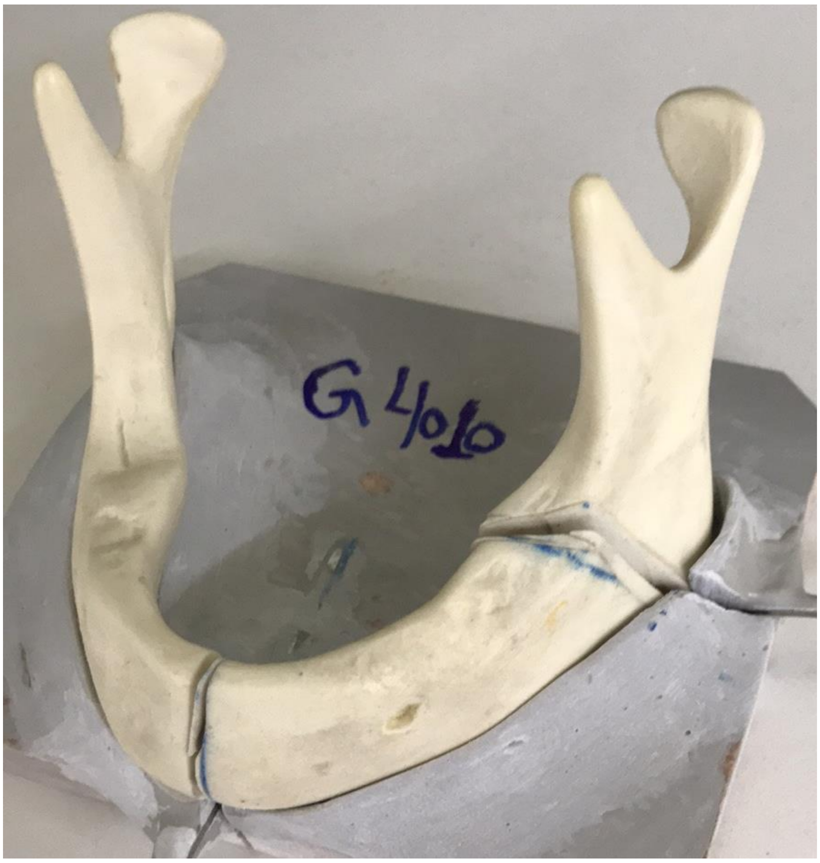


Fig. 2 – Polyurethane mandibular replica sectioned at the median sagittal line, with a left side mandibular angle osteotomy simulating a non-favorable fracture, with a bevel extending from the buccal to the lingual border in a posteroanterior orientation.

Sample preparation:

In the control group (Ch group), the osteotomies received fixation via a conventional straight 4-hole titanium plate with four titanium screws in a positional pattern. By using an acrylic guide, the plate was positioned in the tension zone according to the technique described by Champy et. al (Fig. 3), and using a drill of 1.5mm diameter, the monocortical screws were inserted and the plate was fixed in position.

Fig. 3 – Group 1, fixation with a conventional 4-hole titanium miniplate according to Champy principles.

In the test group (SS group), in order to fix the osteotomy, a two-hole spiked-synthesis plate (SS-plate) was applied, and two monocortical screws were inserted at 90º angle with the bone (Fig. 4). One screw was installed in the distal segment and the other in the proximal segment using a 1.5mm diameter drill. The plate was positioned at the buccal border in the neutral zone and above the mandibular canal region, using an acrylic guide specifically made for this purpose.

Fig. 4 - Group 2, fixation with a 2-hole new design titanium miniplate.

Mechanical tests:

The experiments were performed at the dental materials laboratory at the faculty of dentistry at the University of Riberão Preto (FO – UNAERP, Riberão Preto, SP). The Universal Testing Machine used for the purpose of performing the experiments was Instron Emic 23-5s (Instron, MA, USA) (Fig. 5).

Fig. 5 – The universal testing machine Instron Emic 23-5S

The fragments were reduced to the unfractured position using an acrylic guide (Fig. 6) and were fixed at the posterior end of the ramus segment to a metallic support that was in turn mounted on the machine for mechanical testing (Fig. 7). In the headstock of the testing machine, a force jig was fixed, and the force was applied at the speed of 10mm/min (Fig. 8). The force was applied to a standardized point at the superior border relative to the position of the mental foramen in the mandibular body, and a resin support was used to accommodate the head of the jig to the mandibular body, so that the force cell could not slip and generate an error during the test (Fig. 7). The mandibles were mounted to the testing machine, fixing the proximal part to a metallic block using two metallic screws. An acrylic guide was used to position the fixing screws to the ascending ramus so that the mandibles are fixed in the same direction and orientation, with the occlusal plane parallel to the horizontal plane of the machine.

Fig. 6 – The mandibular fragments reduced to the unfractured position using an acrylic guide.

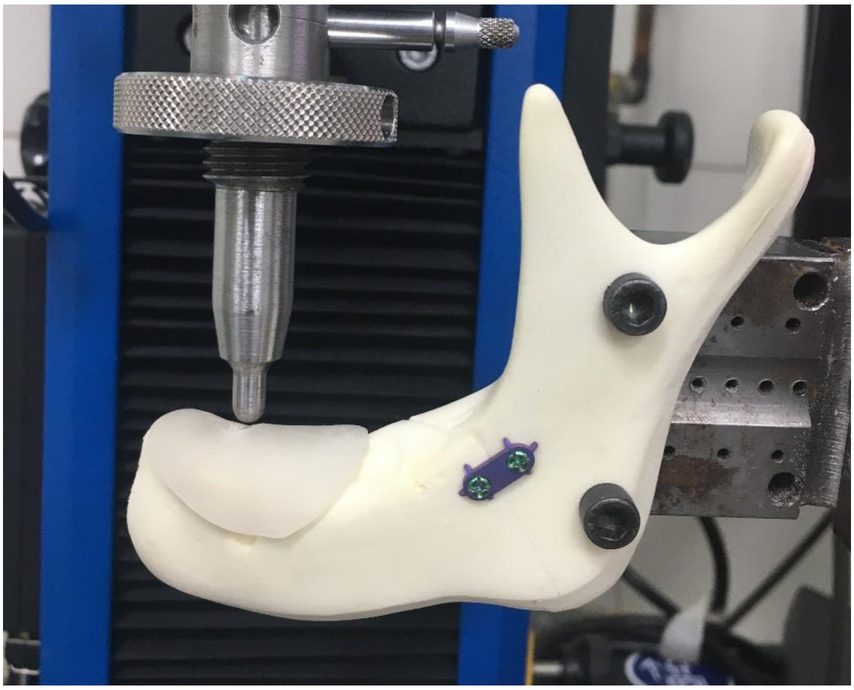


Fig. 7 – The posterior end of the ramus segment fixed to a metallic support that was in turn mounted on the machine of mechanical testing.

In the headstock of the testing machine, a force sensor was fixed. The machine was programmed to check the maximum resistance force, in N, exhibited by the system regarding a progressive load, at a displacement speed of 10 mm/min, the displacement in maximum force in mm, the tension to compression ratio at maximum force and the time till the maximum force in sec (Fig. 9). The variable tension to compression ratio at maximum force was not included in the analysis due to its irrelevance to the current experiment.

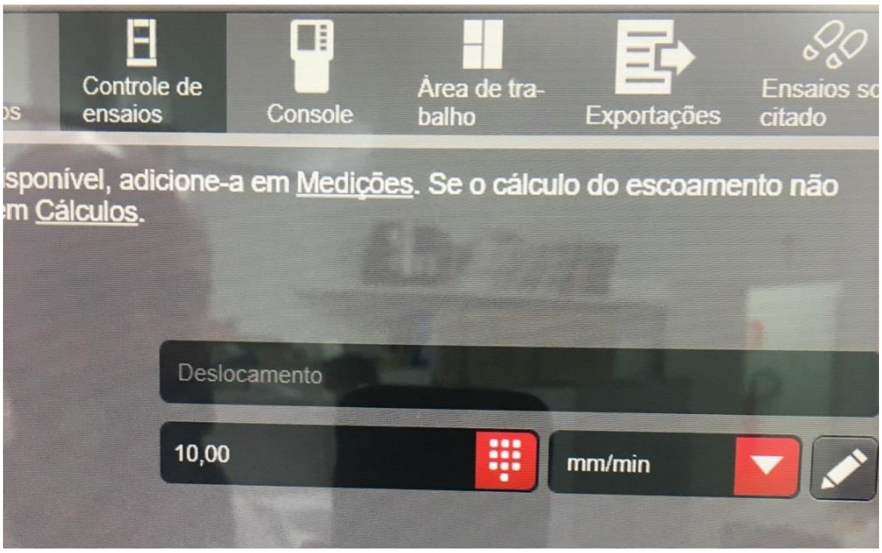
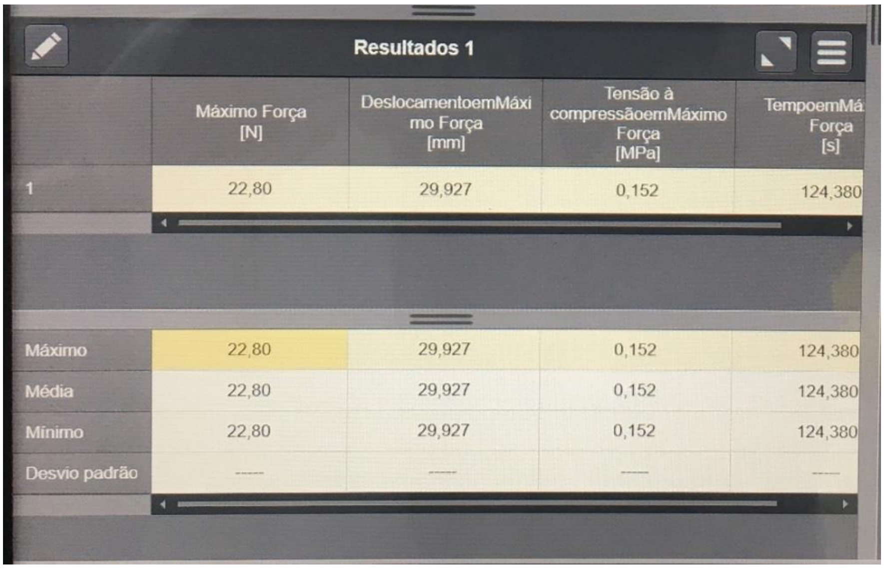


Fig. 8 – Force applied by the testing machine at the speed of 10mm/min.


Resultados 1

	Máximo Força [N]	DeslocamentoemMáximo Força [mm]	Tensão à compressãoemMáximo Força [MPa]	TempoemMá Força [s]
1	22,80	29,927	0,152	124,380
Máximo	22,80	29,927	0,152	124,380
Média	22,80	29,927	0,152	124,380
Mínimo	22,80	29,927	0,152	124,380
Desvio padrão	-----	-----	-----	-----

Fig. 9 - The machine programmed to check the maximum resistance force (N), the displacement in maximum force (mm), the tension to compression in maximum force (MPa) and the time till maximum force (sec).

In order to perform the tests, a vertical progressive force was applied to the area relative to the mental foramen at the mandibular body until a failure was observed in the fixation or a fracture in the hemimandible (Fig. 10).

Fig. 10 - A vertical progressive force applied until a fixation failure or a fracture in the hemimandible was observed.

Data analysis:

The data were transmitted to a computer that generated a graphic (Fig. 11) and a data spreadsheet of tested variables. The failure in the fixation was verified by the displacement of the headstock of the testing machine, and the sudden fall of the graph after passing the maximum force point.

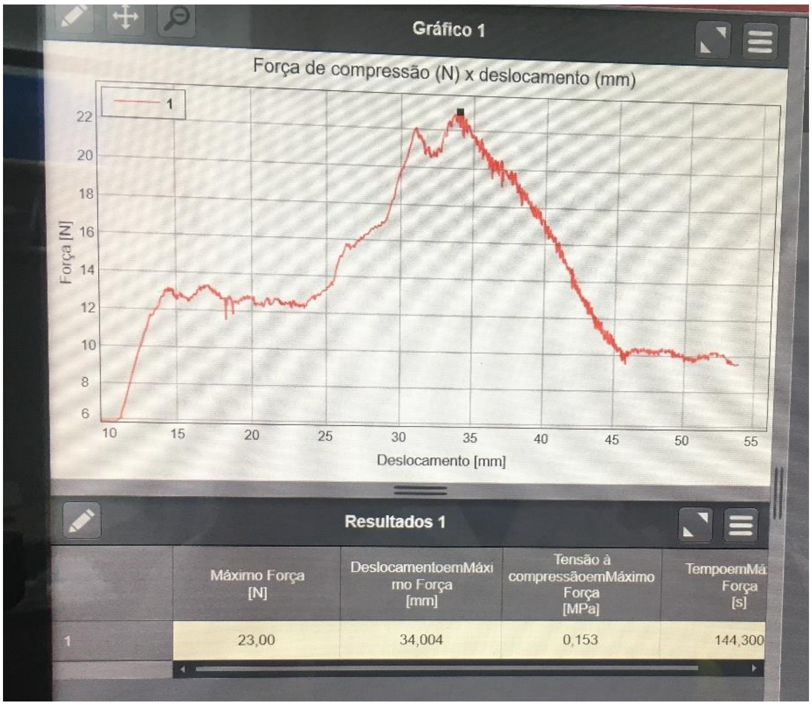


Fig. 11 – A graphic generated by the machine, showing the displacement versus the force applied. The maximum force is noted before the fixation failure.

5 RESULTS

5 RESULTS

The tests were performed *in vitro*, using edentulous polyurethane mandibles as the test body. Although polyurethane mandibles present inferior resistance when compared to human or animal bone sample, they offered a homogeneous sample, facilitating its adaptation to the testing machine, and the application of force to the mandible. However, a special guide had to be created to help position the force jig to the mandibular ramus, and avoid its slipping and subsequent erroneous results.

The data obtained were collected, organized into a spreadsheet and subjected to statistical analysis using t-test with fixation method as a variable, and using Shapiro-Wilk as normality test. (Table 1)

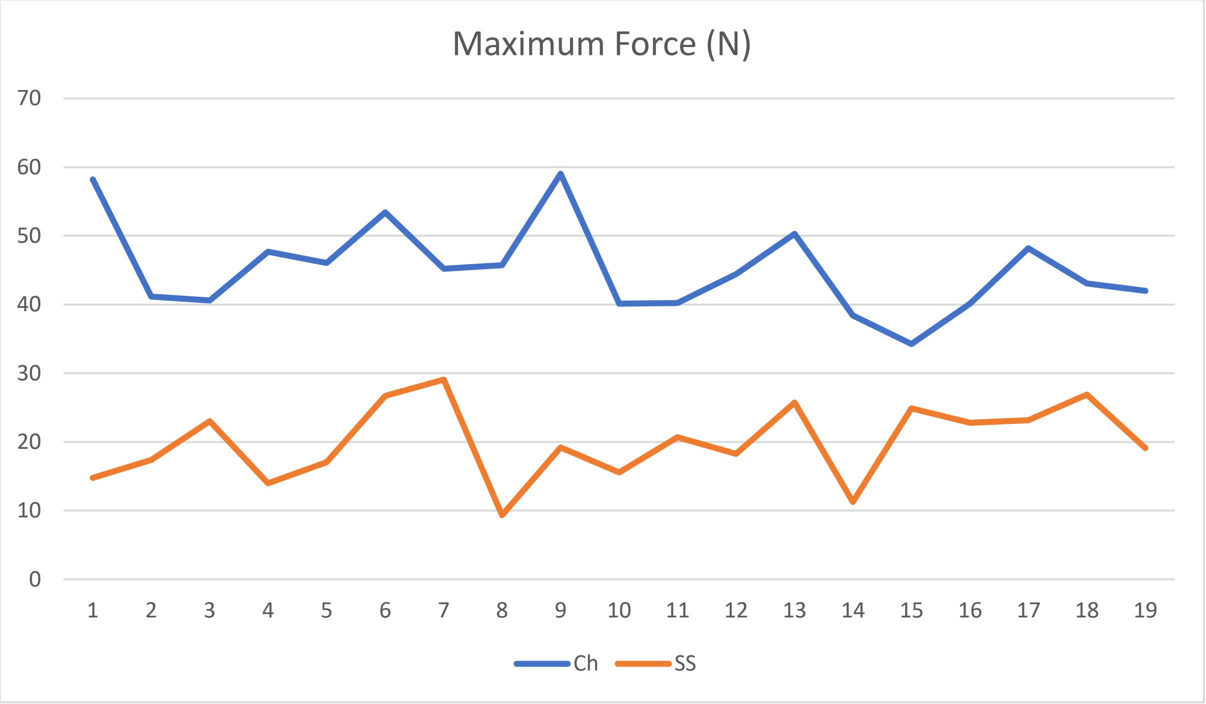
Table 1. the collected data of the different variables are organized into a spreadsheet for statistical analysis.

	Maximum Force (N)		*Displacement in Maximum Force (mm)*		*Time till Maximum Force (sec)*	
	Ch	**SS**	**Ch**	**SS**	**Ch**	**SS**
1	58.24	14.77	31.038	35.209	127.42	141.6
2	41.16	17.39	25.509	30.132	108.02	118.34
3	40.59	23	28.987	34.004	97.08	144.3
4	47.7	13.98	25.065	26.492	101.44	111.34
5	46.03	17.04	26.823	33.661	111.28	133.1
6	53.42	26.69	28.445	35.289	95.8	144.94
7	45.22	29.07	27.436	34.43	94.54	151.26
8	45.73	9.34	29.317	32.388	119.78	95.04
9	59.04	19.18	32.312	33.584	115.3	130.12
10	40.14	15.58	29.499	33.334	95.92	124.72
11	40.21	20.68	26.977	31.068	81.4	138.22
12	44.41	18.29	26.983	29.647	130.02	101.04
13	50.29	25.74	26.107	28.152	103.42	117.32
14	38.42	11.27	30.509	32.946	99.12	117.9
15	34.25	24.89	25.889	34.069	105.94	151.44
16	40.12	22.8	22.227	29.927	114	124.38
17	48.19	23.18	30.003	30.531	100.92	119.84
18	43.08	26.9	27.441	32.59	117.64	128.48
19	41.98	19.09	29.321	26.422	104.08	80.12
$\bar{X}$	45.17	19.94	27.89	31.78	106.48	124.92
SD	6.52	5.54	2.42	2.74	12.17	19.1

The results are presented as tables and graphics for a better understanding.

The mean and standard deviation for the three variables of both groups were calculated. And statistical analysis was performed using t-test for all the variables.

The values of the mean and standard deviation for the maximum resistance force (Table 2) showed that the control group Ch (mean 45 N, SD 6.5) had more resistance to tension force than the test group SS (mean 20N, SD 5.5). The results obtained for the maximum resistance force are shown in graph 1.



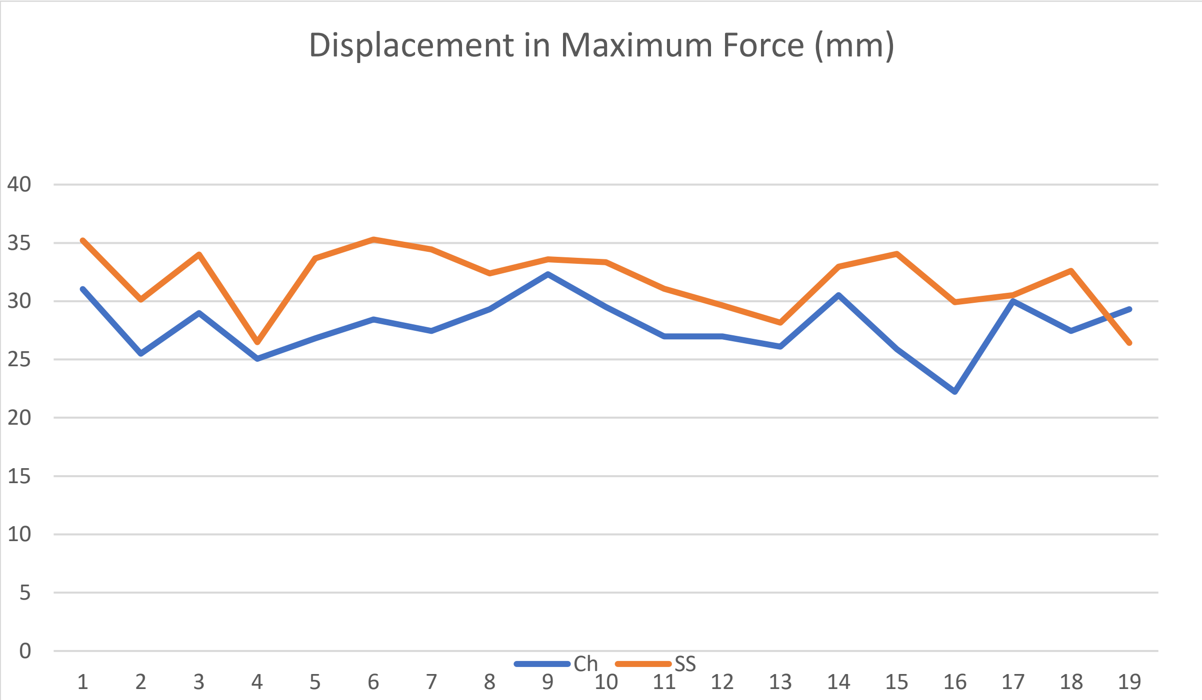
Graph 1. The maximum resistance force registered of both groups.

Dependent Variable: Maximum Force (N)

Table 2. The mean and standard deviation for the maximum force variable.

Group Name	N	Missing	Mean	Std Dev
Ch	19	0	45,169	6,525
SS	19	0	19,941	5,537

Also, the control group Ch showed less displacement at maximum force, averaging 28mm when compared to 32mm for the test group SS (Table 3). Graph 2 shows the difference.



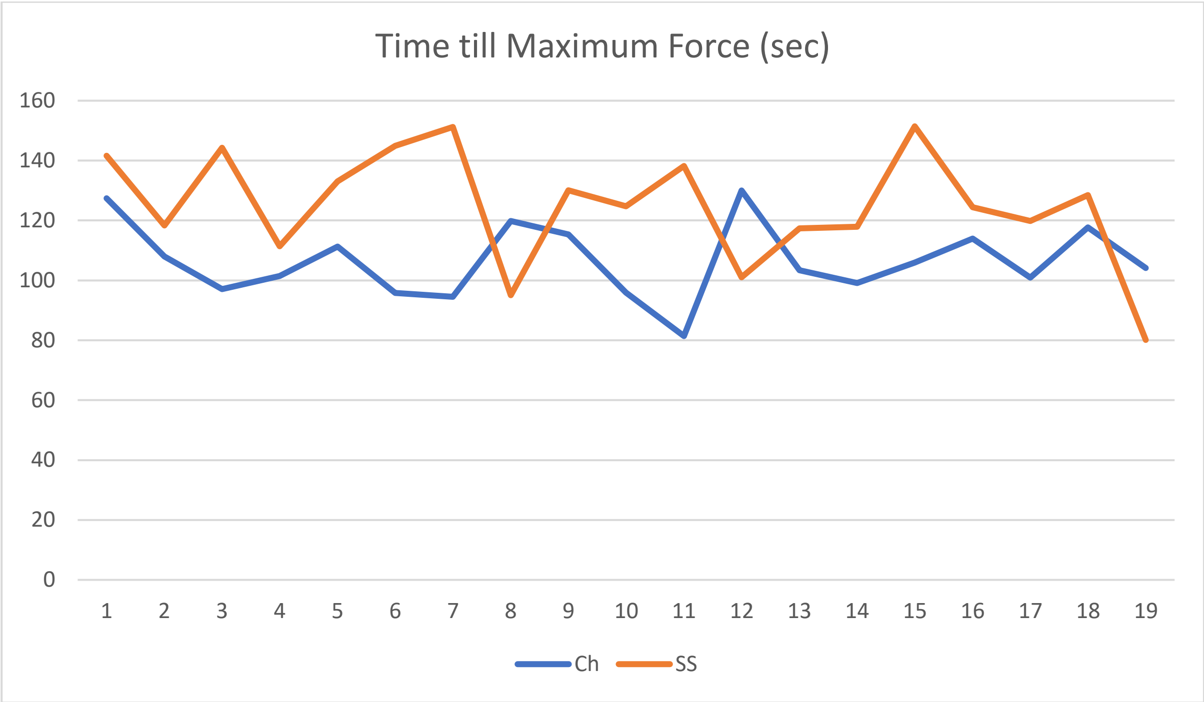
Graph 2. The displacement at maximum force registered for both groups.

Dependent Variable: Displacement in Maximum Force (mm)

Table 3. The mean and standard deviation for the displacement in maximum force variable.

Group Name	N	Missing	Mean	Std Dev
Ch	19	0	27,889	2,416
SS	19	0	31,783	2,743

However, the test group SS resisted for more time at maximum force, averaging for 125 seconds when compared to the control group Ch with an average of 106.5 seconds (Table 4). The results are presented in graph 3.



Graph 3. The time required to reach the maximum force in both groups.

Dependent Variable: Time till Maximum Force (sec)

Table 4. The mean and standard deviation for the time till maximum force variable.

Group Name	N	Missing	Mean	Std Dev
Ch	19	0	106,480	12,168
SS	19	0	124,921	19,099

The statistical analysis performed using t-test showed statistically significant difference between the two groups, showing more resistance and less displacement in favor of the control group Ch.

6 DISCUSSION

6 DISCUSSION

Mandibular angle fractures are, in addition to condylar fractures, the most common fractures of the mandible. However, they are biomechanically complex, because the highest load index in the mandible occurs in this area (Chacon et al., 2005). There is no consensus on the best method of internal fixation (Gear et al., 2005). The forces exerted by the mastication muscles show a higher influence at the mandibular angle region than other regions of the mandible (Shetty et al., 1992), the resultant forces are compression at the inferior border and tension at the superior border of the mandible (Levy et al., 1991)

Comparing different methods of treatment for angle fractures in 1999, Ellis III stated that open reduction via extra-oral access and internal fixation using a mandibular reconstruction plate AO/ASIF, similarly to single-plate fixation via intra-oral access presented treatment options with the least post-operative complications. Another prospective study performed by the same author in 2010, concluded that the use of single miniplate for the fixation of mandibular angle fractures was considered a simple procedure and associated with the lowest rate of complications. According to the author, shorter surgical time and surgeon's experience are paramount factors for lower complication rates. As a result, the comparison between different fixation plates for treatment of mandibular angle fractures, as performed in this experiment, is appropriate, since there may be a difference as to the resistance of each one of them when applying loads.

The study performed by Champy et al. (1976) and based on earlier experiments by Michelet et al. (1973), gave wider acceptance to the use of a single plate with monocortical screws placed at the superior border of the mandible ventral to the oblique ridge. This fixation technique is considered an efficient and reliable method of fixation of linear fractures of the mandibular angle. In the current study, the use of linear section at the mandibular angle region was indicated, as this pattern of fracture represents simple non-comminuted fractures. Single plate fixation is contraindicated in cases of fractures with minimal interfragmentary stability, as in cases of comminuted fractures or mandibular fractures with basal triangle (Hochuli-Vieira et al., 2011 ; Zix et al., 2007). The use of for this type of fixation plate would be contraindicated in multi-fragment or comminuted fracture.

In order to evaluate a given fixation system, mechanical tests are a fundamental component of the analysis. The use of fresh bovine ribs was common due to the ease of collection and use. However, they present anatomical limitations, as they do not resemble the mandibular angle region. Fresh frozen animal mandibles served as the material of choice for such experiments for a long time. Some studies evaluated and compared the mechanical properties of human bone, bovine bone and a synthetic polymer, concluding that there were significant differences between them. The human mandible has proven to be more resistant than other materials, and each type had a different elasticity coefficient (Foley & Beckman, 1992; Moraes, 1995; Kohn et al., 1995). However, the use of human or bovine bone poses another challenge, demonstrated in the great anatomical variability between specimens, making it difficult or even impossible to prepare a homogeneous sample. Nevertheless, for all the reasons mentioned above, the fresh bovine ribs and human or bovine mandibles were not used in this experiment.

Moreover, synthetic polyurethane mandibles were initially used for the purpose of training in orthopedic surgery. The main advantage was the proximity of the sensation during perforation and screw-insertion to that in natural bone, even though they don’t possess the same mechanical properties when compared to the latter. Ballistic tests performed by Schwieger in 2004 showed that polyurethane mandibles presented the same pattern of fracture as that of natural bone. For this purpose, polyurethane resin mandibles were used in this experiment, in an attempt to obtain standardization of the tests. Even though they don’t mimic the mechanical properties of the natural bone, studies demonstrate that this composition of polyurethane resin offers good results in mechanical strength tests, when compared to natural bone (Schwieger, 2004).

The displacement at maximum force is discussed among researchers. Foley er al. (1998) and Kohn et al. (1995) reported that a displacement of 3mm indicated the end of the experiment, stating that further displacement is considered non-physiological in biomechanical tests. However, Trivellato (2001) and Guimaraes-Filho (2003) stated that a displacement of 10mm, or when failure of material was noted if this occurs before the pre-determined displacement, is considered the endpoint of the experiment. Nevertheless, other authors advocated that the displacement limit is determined when the failure of the fixation system is observed (Bouwman et al., 1994; Asprino et al., 2006). In the current study, the failure of the fixation system was defined when the load cell reached the maximum force, and displacement at maximum force was measured and registered. In this form, the displacement of the fractured fragments and the time till the failure point was reached, were compared between the two fixation systems. The fact that the SS plate resisted for an average time slightly greater than the conventional Champy plate gives hope that the new fixation system, when used for the fixation of non-mobile bones can provide sufficient stability and resist displacement in a similar pattern to the conventional 4-hole plates currently used, with the advantage of using a minimally invasive surgical technique and using minimal synthesis material.

Schierle et al. (1997) conducted a randomized prospective clinical trial, where they found no statistically significant difference when comparing the use of a single plate for fixation of mandibular angle fracture at the tension zone, as per the technique proposed by Champy, to the use of a second plate at the compression zone at the lower mandibular border. Nevertheless, Choi et al. (1995) reported lower stability and resistance to the masticatory forces when using the single plate fixation suggested by Champy, compared to the double plate fixation technique.

Another factor to observe when analyzing the resistance of fixation material in mandibular angle fracture is that the majority of the experiments were performed *in vitro*, disregarding the fact that fixation and stability as that provided by construction plates and bicortical screws might not be of the same clinical value when considering patients in the post-operative phase. Moreover, various factors that affect the results *in vivo* are being neglected in an *in vitro* experiment. (Murphy et al., 1997; Peterson et al., 2005).

Van der Bilt et al. (2008) analyzed the bite force and jaw-muscle activity during both bilateral and unilateral activity in healthy dentate individuals. He included 81 individuals in his study, and ended up to an observation that the average bilateral bite force of 569N is significantly higher than the average unilateral bite force being 430N (right) and 429N (left).

Loukota and Shelton (1995) analyzed the maximum masticatory forces in young adults. They established that the estimated maximum masticatory force in a young adult with parafunctional habits was equivalent to 660N at the molar area, which showed to be higher than the masticatory forces generated in the early post-operative period in patients with mandibular fractures and rigid internal fixation.

Correspondingly, Tate et al. (1994) compared the masticatory forces of healthy patients to that of patients with surgical fixation of mandibular fractures. They observed that the patients in post-operative period showed much lower masticatory forces at the incisive region and molar region bilaterally, and this difference persisted for weeks post-operatively with gradual increase during the post-operative period. Similar results were observed by Gerlach and Schwarz in 2002, as they analyzed, over a period of 6 weeks, the bite force of 22 patients with mandibular angle fractures, treated by monoplate fixation as per Champy principles, and compared the results to a control group of 15 patients. The results showed that 1 week after surgical treatment of mandibular fracture, the fractured group showed 31% of maximum vertical loading force observed at the control group, and these values gradually increased during the post-operative period to 58% at the 6^{th} week post-operatively.

The principle of spiked synthesis is used in orthopedic surgery. The use of spiked plastic washers was introduced by Hurson and Sheehan in 1981, in a study illustrating their use with compression screws in the repair of the ligaments which have been avulsed from their bony origins. A biomechanical analysis of a novel spiked-washer repair in orthopedic fractures with ligament avulsion was presented by Vojdani et al. in 2018. They concluded that, when compared to the previously described suture and bone tunnel method, the spiked-washer repair method offered superior quasi-static biomechanical performance for fibular fractures.

To justify our proposition, we initially set out to test a new and minimized format of fixation system, which theoretically would be very applicable in non-mobile bones, such as those connected to the base of the skull and supposedly in fractures where a little space is available to install a fixation system. In order to test whether the system can resist for some time, it was decided to perform the test in an area where various experiments and studies were performed and where an adequate methodology is already established, such as the mandibular angle fracture. That would make for the first step towards testing a new miniplate system used to reduce fractures of the facial skeleton.

As previously established by several studies, the mandibular angle region presents difficulty in fixation and stability. Moreover, the study presented an unfavorable mandibular angle fracture with bevel extending from the buccal to the lingual border in an anteroposterior direction. Despite being a common fracture in the mandibular angle region, such a fracture design poses further difficulty for fixation due to the sliding of the fracture ends when submitted to force. Our proposal was to compare the new fixation system (SS plate) to the monoplate fixation technique proposed by Champy and previously established and endorsed by various authors and studies as the treatment of choice for treatment of mandibular angle fractures.

Based on the obtained results, it was observed that when compared to the Champy system, the new mini-plate design system with micro-spikes (SS plate), has shown to be inferior. However, in terms of resistance against the time of applied force, it was observed that despite the results being inferior to the Champy system, for fixation of mandibular fractures, the new system would show sufficient resistance for stabilization of fractures in non-mobile bones related to the facial skeleton.

The lack of clinical trials and studies with miniplates in non-mobile bones, as well as the technical difficulty in measuring the force and mobilization time of the bone fragments, made it difficult to perform our study in non-mobile bones. For that reason, we performed our experiment in the most debatable region in terms of stability and resistance, using the model of an unfavorable mandibular angle fracture as a basis for our experiment.

The obtained results showed that the SS plate has resisted the applied force for a longer time when compared to the Champy plate. However, it showed statistically inferior results in terms of resistance to maximum force and displacement at maximum force when compared to the Champy plate.

Certainly, new experiments and studies should be carried out to test the new system in other areas of the facial skeleton, both *in vitro* and *in vivo*.

Nevertheless, when it comes to intraoperative plate manipulation, and as a surgeon experienced with several fixation systems used around the world, it is believed that favorable clinical results will be encountered, since the system is easily manipulated and minimally invasive.

7 CONCLUSIONS

7 CONCLUSIONS

A new design of spiked-synthesis plate (SS plate) is suggested, which offers sufficient fracture ends stability, in addition to minimally invasive surgical technique promoting the use of less osteosynthesis material.

Based on the laboratory tests performed with statistical analysis, we can conclude that:

The new plate design is viable and easy to handle.

It can be easily applied mainly in areas where minimally invasive surgery is advantageous.

It has shown to be statistically inferior to the previously established Champy System in the mandibular angle region.

The spiked-synthesis system resisted for an adequate time in the force testing machine.

New studies and experiments must be carried out in order to better validate the use of this new fixation material.

REFERENCES

REFERENCES

1. Alkan A, Celebi N, Ozden B, Baş B, Inal S. Biomechanical comparison of different plating techniques in repair of mandibular angle fractures. Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 2007 Dec;104(6):752-6. doi: 10.1016/j.tripleo.2007.03.014. Epub 2007 Jul 24. PMID: 17651992.

2. Allareddy V, Allareddy V, Nalliah RP. Epidemiology of facial fracture injuries. J Oral Maxillofac Surg 2011;69:2613-8.

3. Al-Tairi NH, Shoushan MM, Saad Khedr MM, et al. Comparison of three-dimensional plate versus double miniplate osteosynthesis for treatment of unfavorable mandibular angle fractures. Tanta Dent J 2015;12:89–98.

4. Prein, J. (1998) *Manual of Internal Fixation in the Cranio-Facial Skeleton.* 1st ed. Berlin Heidelberg New York: Springer-Verlag.

5. Asprino L, Consani S, de Moraes M. A comparative biomechanical evaluation of mandibular condyle fracture plating techniques. J Oral Maxillofac Surg. 2006; 64(3): 452-6.

6. B. T. Suer, I. D. Kocyigit, S. Kaman, H. H. Tuz, U. Tekin, F. Atil. Biomechanical evaluation of a new design titanium miniplate for the treatment of mandibular angle fractures. Int. J. Oral Maxillofac. Surg. 2014.

7. Bhatt K, Arya S, Bhutia O, Pandey S, Roychoudhury A. Retrospective study of mandibular angle fractures treated with three different fixation systems. Natl J Maxillofac Surg. 2015 Jan-Jun;6(1):31-6. doi: 10.4103/0975-5950.168229. PMID: 26668450; PMCID: PMC4668730.

8. Bouwman JPB, Tuinzing DB, Kostense PJ. A comparative in vitro study on fixation of sagittal split osteotomies with Würzburg screws, Champy miniplates, and Biofix (biodegradable) rods. Int J Oral Maxillofac Surg. 1994; 23(1): 46-8.

9. Brian J. Hurson & James M. Sheehan (1981) The Use of Spiked Plastic Washers in the Repair of Avulsed Ligaments, Acta Orthopaedica Scandinavica, 52:1, 23-26, DOI: 10.3109/17453678108991752

10. Brucoli, M, Boffano P, et al., The “European Mandibular Angle” research project: the analysis of complications after unilateral angle fractures. Oral

Surgery, Oral Medicine, Oral Pathology and Oral Radiology,Volume 128, Issue 1, July 2019, Pages 14-17.

11. Chacon GE, Dillard FM, Clelland N, Rashid R. Comparison of strains produced by titanium and poly D, L-lactide Acid plating systems to in vitro forces. J Oral Maxillofac Surg. 2005 Jul;63(7):968-72. doi: 10.1016/j.joms.2005.03.013. PMID: 16003624.

12. Champy M, Loddé JP, Jaeger JH, Wilk A, Gerber JC. Osteosyntheses mandibulaires selon la technique de Michelet II – Presentation d’un nouveau material. Resultats Bases biomechaniques. Rev Stomat. 1976; 77: 577–83.

13. Champy M, Loddé JP, Jaeger JH, Wilk A. Osteosyntheses mandibulaires selon la technique de Michelet I - Bases biomechaniques. Rev Stomat. 1976; 77: 569–76.

14. Champy M, Lodde JP, Schmitt R, Jaeger JH, Muster D. Mandibular Osteosynthesis by Miniature Screwed Plates Via a Buccal Approach. J. max.-fac. Surg. 6 (1978) 14-21.

15. Chiodo T, Milles M. Use of monocortical miniplates for the intraoral treatment of mandibular fractures. *Atlas Oral Maxillofacial Surg Clin N Am 17 (2009) 19-25.*

16. Choi BH, Yoo JH, Kim KN, Kang HS. Stability testing of a two miniplate fixation technique for mandibular angle fractures. An in vitro study. J Craniomaxillofac Surg. 1995; 23(2): 123-5.

17. Datarkar A, Tayal S, Thote A, Galie M. An in-vitro evaluation of a novel design of miniplate for fixation of fracture segments in the transition zone of parasymphysis-body region of mandible using finite element analysis. J Craniomaxillofac Surg. 2019 Jan;47(1):99-105. doi: 10.1016/j.jcms.2018.11.004. Epub 2018 Nov 12. PMID: 30527379.

18. de Matos FP, Arnez MF, Sverzut CE, Trivellato AE. A retrospective study of mandibular fracture in a 40-month period. Int J Oral Maxillofac Surg. 2010 Jan;39(1):10-5. doi: 10.1016/j.ijom.2009.10.005. Epub 2009 Nov 14. PMID: 19914802.

19. de Melo WM, Antunes AA, Sonoda CK, Hochuli-Vieira E, Gabrielli MA, Gabrielli MF. Mandibular angle fracture treated with new three-dimensional grid miniplate. J Craniofac Surg. 2012 Sep;23(5):e416-7. doi: 10.1097/SCS.0b013e31825dad8f. PMID: 22976690.

20. Edward Ellis, G.E. Ghali, Lag screw fixation of mandibular angle fractures, Journal of Oral and Maxillofacial Surgery, Volume 49, Issue 3, 1991, Pages 234-243, ISSN 0278-2391, https://doi.org/10.1016/0278-2391(91)90212-5.

21. Edward Ellis, Treatment methods for fractures of the mandibular angle, International Journal of Oral and Maxillofacial Surgery, Volume 28, Issue 4, 1999, Pages 243-252, ISSN 0901-5027, https://doi.org/10.1016/S0901-5027(99)80152-0.

22. Ellis E 3rd, Walker LR. Treatment of mandibular angle fractures using one noncompression miniplate. J Oral Maxillofac Surg. 1996 Jul;54(7):864-71; discussion 871-2. doi: 10.1016/s0278-2391(96)90538-8. PMID: 8676232.

23. Ellis E 3rd. Management of fractures through the angle of the mandible. Oral Maxillofac Surg Clin North Am. 2009 May;21(2):163-74. doi: 10.1016/j.coms.2008.12.004. PMID: 19348981.

24. Ellis EI. A prospective study of 3 treatment methods for isolated fractures of the mandibular angle. J Oral Maxillofac Surg. 2010;68:2743–54.

25. Ellis III E, Karas N. Treatment of mandibular angle fractures using two mini dynamic compression plates. J Oral Maxillofac Surg. 1992; 50(9): 958-63.

26. Ellis III E. Rigid skeletal fixation of fractures. J Oral Maxillofac Surg. 1993; 51(2): 163-73. Review.

27. Feledy J, Caterson EJ, Steger S, Stal S, Hollier L. Treatment of mandibular angle fractures with a matrix miniplate: a pre-liminary report. Plast Reconstr Surg 2004;114(7):1711e6.

28. Foley WL, Beckman TB. In vitro comparison of screws versus plate fixation in the sagittal split osteotomy. Int J Adult Orthodon Orthognath Surg. 1992; 7: 147-51.

29. Gear AJ, Apasova E, Schmitz JP, Schubert W. Treatment modalities for mandibular angle fractures. *J Oral Maxillofac Surg.* 2005;63:655–663.

30. Gerlach KL, Schwarz A. Bite forces in patients after treatment of mandibular angle fractures with miniplate osteosynthesis according to Champy. Int J Oral Maxillofac Surg. 2002; 31(4): 345-8.

31. Goulart DR, Kemmoku DT, Noritomi PY, de Moraes M. Development of a Titanium Plate for Mandibular Angle Fractures with a Bone Defect in the Lower Border: Finite Element Analysis and Mechanical Test. J Oral Maxillofac Res. 2015 Jun 30;6(3):e5. doi: 10.5037/jomr.2015.6305. PMID: 26539287; PMCID: PMC4628493.

32. Halazonetis JA. The “weak” regions of the mandible. *British Journal of Oral Surgery.* 1968;6(1):37–48.

33. Helkimo E, Carlsson GE, Helkimo M. Bite force and state of dentition. Acta Odontol Scand. 1977;35(6):297-303. doi: 10.3109/00016357709064128. PMID: 271452.

34. Hochuli-Vieira E, Ha TK, Pereira-Filho VA, Landes CA. Use of rectangular grid miniplates for fracture fixation at the mandibular angle. J Oral Maxillofac Surg. 2011 May;69(5):1436-41. doi: 10.1016/j.joms.2010.06.182. Epub 2011 Jan 8. PMID: 21216065.

35. Hofer SH, Ha L, Ballon A, Sader R, Landes C. Treatment of mandibular angle fractures—linea obliqua plate versus grid plate. J Craniomaxillofac Surg 2012;40:807–11.

36. Iizuka T, Lindqvist C, Hallikainen D, Paukku P. Infection after rigid internal fixation of mandibular fractures: a clinical and radiologic study. J Oral Maxillofac Surg 1991;49:585–93.

37. Kalfarentzos EF, Deligianni D, Mitros G, Tyllianakis M. Biomechanical evaluation of plating techniques for fixing mandibular angle fractures: the introduction of a new 3D plate approach. Oral Maxillofac Surg. 2009 Sep;13(3):139-44. doi: 10.1007/s10006-009-0163-7. PMID: 19636597.

38. Kelly DE, Harrigan WF. A survey of facial fractures: Bellevue Hospital, 1948-1974. J Oral Surg. 1975 Feb;33(2):146-9. PMID: 1054389.

39. Kempers KG, Hendler BH. In: Fonseca RJ. Oral and maxillofacial surgery trauma. Philadephia: WB Saunders; 2000. Chap 2: p. 85-135.

40. Kohn DH, Richmond Em, Dootz ER, Feinberg SE, Pietrzak WS. In vitro comparision of parameters affecting the fixation strength of sagittal split osteotomies. J Oral Maxillofac Surg. 1995: 53(12): 1374-1383.

41. Kroon FH, Mathisson M, Cordey JR, Rahn BA. The use of miniplates in mandibular fractures. An in vitro study. J Craniomaxillofac Surg. 1991 Jul;19(5):199-204. doi: 10.1016/s1010-5182(05)80547-5. PMID: 1894737.

42. Lee JT, Dodson TB. The effect of mandibular third molar presence and position on the risk of an angle fracture. J Oral Maxillofac Surg. 2000 Apr;58(4):394-8; discussion 399. doi: 10.1016/s0278-2391(00)90921-2. PMID: 10759119.

43. Levy FE, Smith RW, Odland RM, Marentette LJ. Monocortical miniplate fixation of mandibular angle fractures. Arch Otolaryngol Head Neck Surg. 1991 Feb;117(2):149-54. doi: 10.1001/archotol.1991.01870140037002. PMID: 1991053.

44. Liu YF, Fan YY, Jiang XF, Baur DA. A customized fixation plate with novel structure designed by topological optimization for mandibular angle fracture based on finite element analysis. Biomed Eng Online. 2017 Nov 15;16(1):131. doi: 10.1186/s12938-017-0422-z. PMID: 29141673; PMCID: PMC5688740.

45. Loukota RA, Shelton JC, et.al. Mechanical analysis of maxillofacial miniplates: Br J Oral Surg 1995; 33: 174-179.

46. Luce EA, Tubb TD, Moore AM: Review of 1,000 major facial fractures and associated injuries. Plast Reconstr Surg. 1979 Jan; 63(1):26-30.

47. Luhr HG. Vitallium Luhr systems for reconstructive surgery of the facial skeleton. *Otolaryngol Clin North Am.* 1987;20:573–606.

48. Luyk NH, Ferguson JW. Fractures of the mandible: role of the general dentist. N Z Dent J. 1992 Apr;88(392):46-51. PMID: 1495632.

49. Michelet FX, Deymes J, Dessus B. Osteosynthesis with miniaturized screwed plates in maxillo-facial surgery. *J Maxillofac Surg.* 1973;1:79–84.

50. Moraes AC. Comparação entre duas técnicas de fixação rígida por meio de ensaio mecânico de compressão. [Tese]. Porto Alegre: UFRG, 1995.

51. Murphy MT, Haug RH, Barber JE. An in vitro comparison of the mechanical characteristcs of three sagital ramus osteotomy fixation techniques. J Oral Maxillofac Surg. 1997; 55(5): 489-94; discussion 494-5.

52. Niederdellmann H, Shetty V. Solitary lag screw osteosynthesis in the treatment of fractures of the angle of the mandible: a retrospective study. Plast Reconstr Surg. 1987; 80(1): 68-74.

53. Ogundare BO, Bonnick A, Bayley N. Pattern of mandibular fractures in an urban major trauma center. J Oral Maxillofac Surg. 2003 Jun;61(6):713-8. doi: 10.1053/joms.2003.50118. PMID: 12796884.

54. Olson RA, Fonseca RJ, Zeitler DL, Osbon DB. Fractures of the mandible: a review of 580 cases. J Oral Maxillofac Surg. 1982 Jan;40(1):23-8. doi: 10.1016/s0278-2391(82)80011-6. PMID: 6950035.

55. Ozden B, Alkan A, Arici S, Erdem E. In vitro comparison of biomechanical characteristics of sagittal split osteotomy fixation techniques. Int J Oral Maxillofac Surg. 2006 Sep;35(9):837-41. doi: 10.1016/j.ijom.2006.03.001. Epub 2006 May 9. PMID: 16687240.

56. Pappachan B, Agrawal R. Minimal access fixation of mandibular angle fracture. *Natl J Maxillofac Surg*. 2020;11(1):150-153. doi:10.4103/njms.NJMS_44_17

57. Peterson, GP, Haug, RH, Van Sickels, J. A biomechanical evaluation of bilateral sagittal ramus osteotomy fixation techniques. J Oral Maxillofac Surg. 2005; 63(9): 1317-24.

58. Pituru TS, Bucur A, Gudas C, Pituru SM, Marius Dinca O. New miniplate for osteosynthesis of mandibular angle fractures designed to improve formation of new bone. J Craniomaxillofac Surg. 2016 Apr;44(4):500-5. doi: 10.1016/j.jcms.2016.01.002. Epub 2016 Feb 2. PMID: 26888464.

59. Prein J, Rahn BA. Scientific and technical background. In: Prein J. Manual of internal fixation of the cranio-facial skeleton. Berling: Spreinger-Verlag; 1998. Chap. 1, p. 1-49.

60. Safdar N, Meechan JG. Relationship between fractures of the mandibular angle and the presence and state of eruption of the lower third molar. Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 1995 Jun;79(6):680-4. doi: 10.1016/s1079-2104(05)80299-9. PMID: 7621022.

61. Sauerbier S, Kuenz J, Hauptmann S, Hoogendijk CF, Liebehenschel N, Schön R, Schmelzeisen R, Gutwald R. Clinical aspects of a 2.0-mm locking plate system for mandibular fracture surgery. J Craniomaxillofac Surg. 2010 Oct;38(7):501-4. doi: 10.1016/j.jcms.2010.01.001. Epub 2010 Feb 13. PMID: 20156692.

62. Schierle HP, Schmelzeisen R, Rahn B, Pytlik C. One- or two-plate fixation of mandibular angle fractures. J Craniomaxillofac Surg 1997;25:162–8.

63. Schwieger K. Mechanical testing report MT_2004_ext01. Davos: Berend Link, Head Research Services, AO Research Institute; 2004

64. Shetty V, Caputo A. Biomechanical validation of the solitary lag screw technique for reducing mandibular angle fractures. J Oral Maxillofac Surg. 1992 Jun;50(6):603-7. doi: 10.1016/0278-2391(92)90442-3. PMID: 1593322.

65. Shetty V, McBrearty D, Fourney M, Caputo AA. Fracture line stability as a function of the internal fixation system: an in vitro comparison using a mandibular angle fracture model. J. oral maxillofac. Surg. 1995, 53(7): 791 – 801.

66. Sicher H., Dubrul E.L., Picosse M. In: Anatomia Bucal. Rio de Janeiro. Guanabara Koogan, 6ª ed. 1977, cap.3, p. 127-151.

67. Sirin Y, Yildirimturk S, Ay N, Gencel B. The Influence of the Gonial Angle on the Initial Biomechanical Stability of the Plate Osteosynthesis in Polyurethane Mandibles With Angle Fractures. J Craniofac Surg. 2020 May/Jun;31(3):871-875. doi: 10.1097/SCS.0000000000006099. PMID: 31895842.

68. Suer BT, Kocyigit ID, Kaman S, Tuz HH, Tekin U, Atil F. Biomechanical evaluation of a new design titanium miniplate for the treatment of mandibular angle fractures. Int J Oral Maxillofac Surg. 2014 Jul;43(7):841-5. doi: 10.1016/j.ijom.2014.01.011. Epub 2014 Feb 24. PMID: 24582290.

69. Swearingen JJ. *Tolerance of the Human Face to Crash Impact*. Stillwater, Okla, USA: Office of Aviation Medicine, Federal Aviation Agency; 1965.

70. Tate GS, Ellis III E, Throckmorton G. Bite forces in patients treated for mandibular angle fractures: implications for fixation recommendations. J Oral Maxillofac Surg. 1994; 52(7): 734-6.

71. Tu HK, Tenhulzen D. Compression osteosynthesis of mandibular fractures: a retrospective study. J Oral Maxillofac Surg. 1985 Aug;43(8):585-9. doi: 10.1016/0278-2391(85)90125-9. PMID: 3859607.

72. Turgut G, Kayali MU, Soydan AT, Gündüz O, Salman S, Oktar F, Baş L. Biomechanical comparison of a new technique of mandibular angle fractures: biplanar and bicortical superior proximal 3 holes and bicortical inferior plate fixation. J Craniofac Surg. 2008 Mar;19(2):428-32. doi:

10.1097/SCS.0b013e318165807b. Erratum in: J Craniofac Surg. 2008 May;19(3):871. Kayah, Mahmut Ulvi [corrected to Kayali, Mahmut Ulvi]. PMID: 18362721.

73. Vojdani S, Fernandez L, Jiao J, Enders T, Ortiz S, Lin L, Qin YX, Komatsu DE, Penna J, Ruotolo CJ. Novel Spiked-Washer Repair Is Biomechanically Superior to Suture and Bone Tunnels for Arcuate Fracture Repair. J Orthop Trauma. 2017 Mar;31(3):e81-e85. doi: 10.1097/BOT.0000000000000752. PMID: 27984448; PMCID: PMC5315587.

74. Wallner J, Reinbacher K, Feichtinger M, Pau M, Feigl G, Quehenberger F, Schwenzer-Zimmerer K, Zemann W. Osteosynthesis using cannulated headless Herbert screws in mandibular angle fracture treatment: a new approach? JCranio Maxillofac Surg. 2017;45:526–39.

75. Wittenberg JM, Mukherjee DP, Smith BR, Kruse RN. Biomechanical evaluation of new fixation devices for mandibular angle fractures. Int J Oral Maxillofac Surg. 1997 Feb;26(1):68-73. doi: 10.1016/s0901-5027(97)80852-1. PMID: 9081259.

76. Wolfswinkel EM, Kelley BP, Chike-Obi CJ, Weathers WM, Qashqai SM, Bullocks JM, et al. Treatment of mandibular anglefractures with a matrix strut miniplate. J Craniofac Surg2013;24(2):149e52.

77. Woo IH, Kim JW, Kim JY, Yang BE. A New Method of Fixation With the Yang's Keyhole Plate System for the Treatment of Mandible Fractures. J Craniofac Surg. 2017 Mar;28(2):508-512. doi: 10.1097/SCS.0000000000003312. PMID: 28027189.

78. Yamaji MAK, Oliveira Neto PJD, Ribeiro MDC, Pereira LC, Morais MD, Sverzut CE, Trivellato AE. Evaluation of in vitro resistance of different 2.0-mm titanium plates on the mandibular angle sectioning. Oral Maxillofac Surg. 2015;19:65–70.

79. Yazdani J, Taheri Talesh K, Kalantar Motamedi MH, Khorshidi R, Fekri S, Hajmohammadi S. Mandibular Angle Fractures: Comparison of One Miniplate vs. Two Miniplates. *Trauma Mon*. 2013;18(1):17-20. doi:10.5812/traumamon.9865

80. Zix J, Lieger O, Iizuka T. Use of straight and curved 3-dimensional titanium miniplates for fracture fixation at the mandibular angle. J Oral Maxillofac Surg. 2007 Sep;65(9):1758-63. doi: 10.1016/j.joms.2007.03.013. PMID: 17719394.