UNIVERSIDADE ESTADUAL DE CAMPINAS
FACULDADE DE ODONTOLOGIA DE PIRACICABA

MARIO ROBERTO PERUSSI

DETERMINAÇÃO DAS CARACTERÍSTICAS MECÂNICAS DE PLACAS ESPECIAIS PARA FIXAÇÃO ÓSSEA NA REGIÃO ORBITAL

DETERMINATION OF THE MECHANICAL CHARACTERISTICS OF SPECIAL PLATES FOR BONE FIXATION IN THE ORBITAL REGION

PIRACICABA
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RESUMO

As fraturas do soalho orbital foram descritas pela primeira vez por Mackenzie em Paris em 1884. Posteriormente, Smith descreveu pela primeira vez o aprisionamento de fragmentos ósseos no músculo reto inferior e foi o primeiro a usar o termo “fratura por explosão”. Uma fratura por explosão é causada pela recessão da borda orbital quando a pressão intraorbital aumenta rapidamente devido a um impacto forte e direto no olho ou um impacto na borda orbital. Com a finalidade de verificar se cada modelo de placa testada atende aos requisitos biomecânicos pertinentes à sua aplicação no corpo humano de forma a garantir a segurança e a eficácia deste produto de uso em saúde, o presente trabalho teve por objetivos formular critério de aceitação para os componentes, estabelecendo, com base em requisitos biomecânicos, os índices de desempenho mecânico que devem ser alcançados pelo componente; e avaliar os resultados obtidos nas caracterizações físicas realizadas para o produto. E, assim, verificar aspectos de segurança e eficácia do produto. Foram analisadas as seguintes placas: Micro Placa Orbital 8 Furos e a Micro Placa T 7 Furos. A seleção das dimensões dos itens ensaiados foi baseada no critério de pior cenário. No caso das placas este critério indica submeter aos testes a região da placa que apresenta menor seção transversal, que geralmente encontra-se posicionada no foco da fratura, além disso, as placas de menor espessura foram selecionadas para grupos com mesmas características geométricas. Comparando as tensões para o momento fletor no “limite de resistência a fadiga” registrados nos ensaios de cada modelo de placa e o correspondente índice de desempenho formulado, os seguintes coeficientes de segurança foram calculados. Como resultado, obteve-se que o modelo de placa mais crítica da família apresenta segurança quando comparados os resultados dos ensaios de fadiga, o que representa uma condição de carregamento cíclico mais próxima da ocorrida in vivo. Nos dois casos as placas foram testadas com as regiões de menor seção transversal ou geralmente localizadas no foco da fratura, submetidas aos maiores valores de momento fletor alcançados nos ensaios. Conclui-se que nas duas placas avaliadas foram testadas com as regiões de menor seção transversal ou geralmente localizadas no foco da fratura, submetidas aos maiores valores de momento fletor alcançados nos ensaios.

Palavras-chave: fraturas orbitárias, órbita, anatomia.

ABSTRACT

Fractures of the orbital floor were first described by Mackenzie in Paris in 1884. Later, Smith described for the first time the imprisonment of bone fragments in the lower rectus muscle and was the first to use the term “explosion fracture”. An explosion fracture is caused by the recession of the orbital border when the intraorbital pressure increases rapidly due to a strong and direct impact on the eye or an impact on the orbital border. In order to verify that each model of tested plate meets the biomechanical requirements relevant to its application in the human body in order to ensure the safety and efficacy of this product for use in health, the present study aimed to formulate an acceptance criterion for the components, establishing, based on biomechanical requirements, the mechanical performance indices that must be achieved by the component; and evaluate the results obtained in the physical characterizations performed for the product. And, thus, verify aspects of safety and effectiveness of the product. The following plates were analyzed: Orbital Micro Plate 8 Holes and Micro Plate T 7 Holes. The selection of the dimensions of the tested items was based on the worst-case criterion. In the case of the plates, this criterion indicates that the region of the plate with the smallest cross-section, which is usually positioned in the focus of the fracture, should be tested. In addition, the thinner plates were selected for groups with the same geometric characteristics. By comparing the stresses for the bending moment at the “fatigue resistance limit” recorded in the tests of each model of plate and the corresponding performance index formulated, the following safety coefficients were calculated. As a result, it was obtained that the most critical plate model in the family is safe when comparing the results of the fatigue tests, which represents a cyclic loading condition closer to that which occurred in vivo. In both cases, the plates were tested with the regions with the smallest cross-section or generally located at the fracture site, subjected to the highest values of bending moment achieved in the tests. It is concluded that in the two plates evaluated were tested with the regions of smaller cross section or generally located in the focus of the fracture, submitted to the highest values of bending moment achieved in the tests.

Keywords: orbital fractures, orbit, anatomy.

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1. INTRODUÇÃO

Um dos aspectos importantes do subsídio ao paciente politraumatizado, é que o mesmo necessita seguir alguns princípios protocolares como o ABC do trauma, admitindo para um secundário período, o tratamento das fraturas faciais, salvo quando este coloque em risco a compressão de espaços aéreos ou intensos sangramentos. Em fraturas da face, os ossos nasais são os mais frequentemente acometidos, ficando o arco zigomático numa posição secundaria; e o osso frontal mais conservado (Bailey, 2001).

O esqueleto do terço médio da face consiste de um sistema de suportes horizontais e verticais arranjados de forma estruturalmente complexa que conserva as extensões horizontais e verticais, protegendo as estruturas órbitas, seios paranasais, cavidades oro nasal. Os “pilares” de suportes verticais compreendem os processos nasais da maxila, zigomáticos da maxila e pterigoide da maxila, que se originam nos alvéolos maxilares e se dirigem para a base do crânio (Prado et al., 2016).

A margem orbital superior e a estrutura espessa óssea da região da glabela formam uma “viga frontal “de onde os esteios verticais se ancoram. Inferiormente, o esqueleto facial forma um sistema complexo com margens inferiores da orbita, o processo alveolar maxilar, o palato, os processos zigomáticos dos ossos temporais e as asas maiores do osso esfenoide. O conhecimento deste complexo do esqueleto da face é fundamental para a prática de uma apropriada estabilização das fraturas sem defeitos estéticas funcionais (Prado et al., 2016).

Do ponto de vista anatômico, o osso zigomático configura o ângulo do sistema de apoio e adapta a estética da região malar, se relacionando às estruturas confinantes craniofaciais por meio de quatro projeções superficiais e duas profundas. As projeções superficiais colaboram para desenvolver dois arcos, vertical e horizontal, cuja encontro forma a proeminência malar. O arco vertical determina a região de suporte zigomaticomaxilar e o arco horizontal se desdobra da maxila ao osso temporal. As projeções profundas, esfenoidal e do assoalho da órbita, desenvolvem as paredes lateral e inferior da órbita (Endo, 1928).

A principal função das correções das fraturas está na anatômica com estabilização dos ossos afetados até a sua consolidação e o restabelecimento das funções a eles associadas, bem como da simetria e dos contornos faciais.

De forma muito concisa as correções do complexo zigomático desarticulado podem ser simplificadas pela reconstrução dos dois básicos arcos de contorno. O reparo do arco horizontal restaura as projeções lateral e anterior da bochecha, e a restauração do arco vertical restitui a altura da proeminência zigomática em relação ao terço médio da face. O reposicionamento do osso zigomático pode ser empregado como parâmetro para a restauração de fraturas orbitais associadas (Litschel e Suárez, 2015).

Dados morfológicos disponíveis e dados *in vivo* e de análise de elementos finitos (AEF) de estresse, tensão e regimes de deformação nos ossos do esqueleto facial de humanos e primatas não humanos sugerem que o conceito de pilares e contrafortes não descreve precisamente o comportamento biomecânico do esqueleto facial humano durante a mastigação (Prado et al., 2016).

Durante a mordida molar, por exemplo, os regimes de tensão, deformação e não deformação corroboram com a ideia de que o pilar canino e o pilar zigomático são carregados durante a compressão, e em vez disso, e com base nos resultados de quatro grupos de pesquisa independentes, durante a mordida molar, o complexo zigomático humano é carregado principalmente em flexão e cisalhamento. Assim, o conceito de pilar zigomático não recebe suporte na literatura de primatas humanos ou não humanos (Prado et al., 2016). Assim dados de propriedades do material ósseo deveriam ser mais realizados de forma a suportar ou não a tese da existência dessas estruturas, bem como estudos mais detalhados dos padrões de deformação e deformação. Até estudos detalhados de microarquitetura óssea, como já apresentados para *Sapajus*, deveriam ser realizados em humanos, de forma a verificar se deve ou não se deve descartar a possibilidade de microarquitetura óssea corroborando a existência de um pilar zigomático (Prado et al., 2016).

Dito isso, chegamos a compreender que uma melhor concepção da biomecânica do complexo zigomático é importante para o aprimoramento dos métodos de reparo craniofacial pós-trauma. Uma razão pela qual as controvérsias persistem sobre a melhor localização e tipo de fixação para o reparo de fraturas do complexo zigomático é que a biomecânica básica desta região não é bem compreendida (Karlan e Cassisi, 1979; Ellis et al., 1985; Rinehart et al., 1989; Davidson et al., 1990; Ellis, 1991; Rudderman e Mullen, 1992; Swift, 1993; Kasrai et al., 1999; Rohner et al., 2002; Deveci et al., 2004; Hanemann et al., 2005). Por outro lado, ainda acreditamos que além de aprofundar nossa compreensão da biomecânica do zigoma, sobre a deformação óssea in vivo e AEF da região zigomática e sobre pilares e contrafortes faciais é fundamental discutir o espaço para melhorias nas técnicas e tecnologias dos projetos de implantes.

Na tentativa de criar o melhor ambiente para a consolidação da fratura sem comprometer a qualidade óssea em outros lugares, como no caso de reparo de fraturas craniofaciais, cirurgia ortognática e implantodontia dental. Dessa forma um estudo mais detalhado da natureza exata do estresse, tensão e deformação das placas de fixação poderá igualmente acarretar numa compreensão de como preservar os ambientes normais de deformação no osso distante aos locais de fratura e nas regiões onde as próprias placas foram ancoradas de forma a maximizar a remodelação e modelagem óssea.

2. ARTIGO

Title: DETERMINATION OF THE MECHANICAL CHARACTERISTICS OF SPECIAL PLATES FOR BONE FIXATION IN THE ORBITAL REGION*

***O presente estudo foi submetido para apreciação e possível publicação no periódico internacional "*Brazilian Dental Journal*" (ANEXO 1).**

ABSTRACT

The aim of this study was formulated an acceptance criterion for the components, establishing, based on biomechanical requirements, the mechanical performance indices that must be achieved by the component. The following plates were analyzed: Orbital Micro Plate 8 Holes and Micro Plate T 7 Holes. The selection of the dimensions of the tested items was based on the worst-case criterion. By comparing the stresses for the bending moment at the "fatigue resistance limit" recorded in the tests of each model of plate and the corresponding performance index formulated, the following safety coefficients were calculated. The finite element analysis was performed by means of a computer simulation that followed the guidelines given by the mechanical test. As a result, it was obtained that the most critical plate model in the family is safe when comparing the results of the fatigue tests, which represents a cyclic loading condition closer to that which occurred in vivo. In both cases, the plates were tested with the regions with the smallest cross-section or generally located at the fracture site, subjected to the highest values of bending moment achieved in the tests. In conclusion the two plates evaluated were tested with the regions of smaller cross section or generally located in the focus of the fracture, submitted to the highest values of bending moment achieved in the tests.

Keywords: plates, orbital fractures, mechanical testing.

INTRODUCTION

Fractures of the orbital floor were first described by Mackenzie in Paris in 1884 (Ng et al., 1996). Later, Smith described for the first time the trapping of bone fragments in the lower rectus muscle and was the first to use the term “burst fracture” (Hwang et al., 2017).

An explosion fracture is caused by the recession of the orbital border when the intraorbital pressure increases rapidly due to a strong and direct impact on the eye or an impact on the orbital border. The tissue of the orbit protrudes out of the orbital cavity; may result in abnormal eye movements and diplopia. In addition, enophthalmia can be caused by an increase in orbital volume (Fujino, 1974). Explosion fractures occur more frequently in vulnerable areas around the ocular fundus and in the ethmoidal lamina of the medial orbital wall and can cause isolated fracture of the orbital medial wall and fracture of the orbital floor. Occasionally, they are accompanied by other types of fractures, such as fractures of the zygomatic complex (Kwon et al., 2010).

The graft materials used for orbital fracture include autologous bone, titanium mesh plate and absorbable sheet (Gart and Gosain, 2014). The external cortical bone plates of the ilium and the skull are used as autologous bone grafts; however, its use is only possible at the expense of the donor site. They are also difficult to match with the fracture site. Titanium mesh plates do not require a donor site and have often been reported to provide favorable surgical results. They are, however, difficult to remove when an infection occurs. Therefore, absorbable sheets are used mainly, but it is difficult to process the plate to suit the shape of the bone defect site during the operation, especially when the fracture covers a wide area of the medial wall towards the lower wall.

A method for creating and processing a three-dimensional material model is known, but it still takes time to fold one-dimensional absorbable sheets into a suitable three-dimensional shape, due to its hardness (Gordon et al., 2012). If the absorbable sheets are pre-molded to the normal orbital shape, the operative time can be reduced. Thus, the aim of this study was evaluated the mechanical characteristics of two plates for orbital fracture were evaluated with the goal of being applied clinically.

MATERIAL AND METHODS

Sample

The following plates were analyzed: Orbital Micro Plate 8 Holes and Micro Plate T 7 Holes. The selection of the dimensions of the tested items was based on the worst-case criterion. In the case of the plates, this criterion indicates that the region of the plate with the smallest cross-section, which is usually positioned in the focus of the fracture, should be tested. In addition, the thinner plates were selected for groups with the same geometric characteristics.

The plates were selected because they have the smallest thickness among all the special plates object of registration and, in addition, they have length and number of holes that allows the tests to be carried out as established in ASTM F382. The smallest thickness directly impacts the moment of inertia of the critical section and, consequently, the bending moment supported by the plate. Regarding variations in length, it is worth noting that during the design stages of the plates, they are analyzed in terms of tension due to flexion, the main way of loading this type of product. In the case of stresses due to bending, a typical case of the ASTM F382 tests, the stress is proportional to the deformation and the latter varies linearly from the neutral line to the analyzed surface, that is, the stresses vary linearly to the surface. This variation occurs only in the plane of the cross section, considering the loads imposed during the flexion tests by 4 points recommended by the technical standard. Thus, it is possible to conclude that regardless of the tested length, for plates with variation only in length and with the same cross section, the flexural strength (bending moment that generates the stresses) will be the same for all models. This consideration allows to select only one plate length that represents the set.

Acceptance criteria

The design analysis methodology based on the fulfillment of an acceptance criterion meets the precepts of analysis and risk management employed in medical products and are based on the grounded establishment of values and / or characteristics against which the product's behavior is judged. satisfactory or not (pass or not pass). The criterion must be the synthesis of the biomechanical requirements relevant to the application of the product in the human body.

For the formulation of criteria for the acceptance of osteosynthesis plates, an analysis was made of the biomechanics of bone fixation with plates and of the biomechanical characteristics of the bone structure associated with the application of the plates, to identify the functional requirements necessary for each model considered.

Performance index

Based on the data presented above, the following performance index was formulated for the plates object of this record:

Flexion resistance (σ_{rup})
$\sigma_{rup} > 21,26$ kgf/mm^2 (greater flexural strength recorded by Dempster & Coleman in the mandible)

The performance index is compared with the fatigue strength limit minus the uncertainty found in the tests.

Analysis of the data

By comparing the stresses for the bending moment at the “fatigue strength limit” recorded in the tests for each plate model and the corresponding formulated performance index, the following safety factors are calculated in table 1.

Table 1. Safety factors in each Plate model.

Plate Model	**Stress at the fatigue resistance limit recorded in the test:** $\sigma_{max} = M\ y/I$	**Safety coefficient (SC) for flexural strength in the frontal plane:** $SC = \sigma_{max}/\sigma_{rup}$

Orbital Micro Plate 8 Holes	02.01.0013.0008 σ_{max} = 23.07 kgf/mm^2	1.08
Micro Plate T 7 Holes	02.01.0029.0007 σ_{max} = 37.28 kgf/mm^2	1.75

The maximum stresses were calculated based on linear elastic theory and for the critical section of the plate along the test length, with M = bending moment at which the plates support 1,000,000 cycles. The value of I is the moment of inertia of the critical section of the plate and y is the distance from the point of analysis to the midline.

RESULTS

Mechanical test

The most critical plate model in the family is safe when comparing the results of fatigue tests, which represents a cyclic loading condition closer to that which occurred in vivo. In both cases, the plates were tested with the regions with the smallest cross-section or generally located at the fracture site, subjected to the highest values of bending moment achieved in the tests. The plates are able to withstand 1 million cycles without failure.

The mechanical test revealed that the Fatigue resistance flexor moment was 11.7 Nmm for Orbital Micro Plate 8 Holes and 19.0 Nmm for Micro Plate T 7 Holes.

DISCUSSION

Islamoglu et al. (2002) evaluated the complications of miniplates, and screws used for maxillofacial fractures in relation to the fracture site. Traffic accidents were the cause of all fractures in the study. For 7 years (1994-2001), titanium miniplates and screws were used to stabilize maxillofacial fractures. In 66 patients, 87 fractures were stabilized with 296 miniplates and 1184 screws. The average age of the patients was 31 years (age range 6-64 years). The percentage of male patients was 77% and the percentage of female patients was 23%. Mini plates and screws were used in six patients (10%) who were under 15 years of age at the time of surgery. The follow-up period varied between three months and 7 years. The overall rate of removal of the plate and screw was 7%. Removal rates according to the fracture site are mandible 4.4%; 1.4% zygomaticofrontal suture; infraorbital border 0.7%; maxilla 0.3%, and the frontal sinus wall 0.3%. The causes of removal were 2% infection; extrusion 1.7%; visibility 1.4%; pain 1%; lack of consolidation 0.7% and fracture of the miniplates 0.3%. The minimum period between insertion and removal was 3 months and the maximum period was 14 months. Infection and extrusion were the main complications for the removal of miniplates and mandibular screws, while miniplates and screws were removed from the zygomatic bone due to visibility under the skin in most patients. The maxilla was the least operated region for the removal of implants. In all patients in this study, the physical symptoms of the preoperative were reduced after removal. The authors point out that miniplates and screws are very useful tools in the treatment of maxillofacial fractures, but sometimes they must be removed. In the series of authors, the removal rate was 7% and this rate may vary according to the severity of the trauma and the fracture site.

Murthy and Lehman (2005) analyzed titanium plates used for maxillofacial trauma in 76 patients to define risk factors for plate removal. Medical records of 76 consecutive patients in a single institution, over a 10-year period, were retrospectively reviewed. The variables studied were age, sex, type of trauma, diagnosis, type of fracture, diagnosis of fracture, the location of the plate, the surgical approach, and the reasons for removing the plate. Fractures were classified as panfacial (42%), rupture (3%), middle third of face (28%), zygomatic (26%), mandibular angle (6%), mandibular ramus (7%) and symphysis (9%). All removed plates were located at the mandibular angle (30%) and symphysis (20%). When the location of the plate was analyzed, 68% of the plattes were placed on the upper part of the middle third and 32% were placed on the mandible. Of 163 plates that were placed, 6 plates (3.7%) were removed. The reasons for removal include infection, osteomyelitis, synchronous mandibular fractures, and infections are the main reason for plate removal.

Shaw et al. (2004) compared the complication rates of miniplates in relation to reconstruction plates in the fixation of vascularized grafts in segmental mandibular defects. 143 consecutive cases carried out between 1993 and 2001 were retrospectively analyzed. Data were collected from a computerized database system. In the series, 49% of patients received miniplates and 51% received reconstruction plates. There were no significant differences in the rates of complications. The choice was mainly determined by the preference of the consultant.

In terms of safety and efficacy, the studies presented indicate that the system has associated with it, a history of success in clinical studies (in vivo), which provide it with sufficient subsidies for its use in humans to be continued. In terms of physical and chemical characterizations, the studies presented indicate that the plates are safe and effective, since the Safety Coefficient calculated for all analyzed variables was greater than 1.

In conclusion, the most critical plate model in the family is safe when comparing the results of the fatigue tests, which represents a cyclic loading condition closer to that which occurred in vivo. In the two plates evaluated, they were tested with the regions with the lowest cross-section or generally located at the fracture site, submitted to the highest values of bending moment achieved in the tests.

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3. CONCLUSÃO

No presente estudo, o modelo de placa mais crítica da família apresenta segurança quando comparados os resultados dos ensaios de fadiga, o que representa uma condição de carregamento cíclico mais próxima da ocorrida in vivo. Nas duas placas avaliadas foram testadas com as regiões de menor seção transversal ou geralmente localizadas no foco da fratura, submetidas aos maiores valores de momento fletor alcançados nos ensaios.

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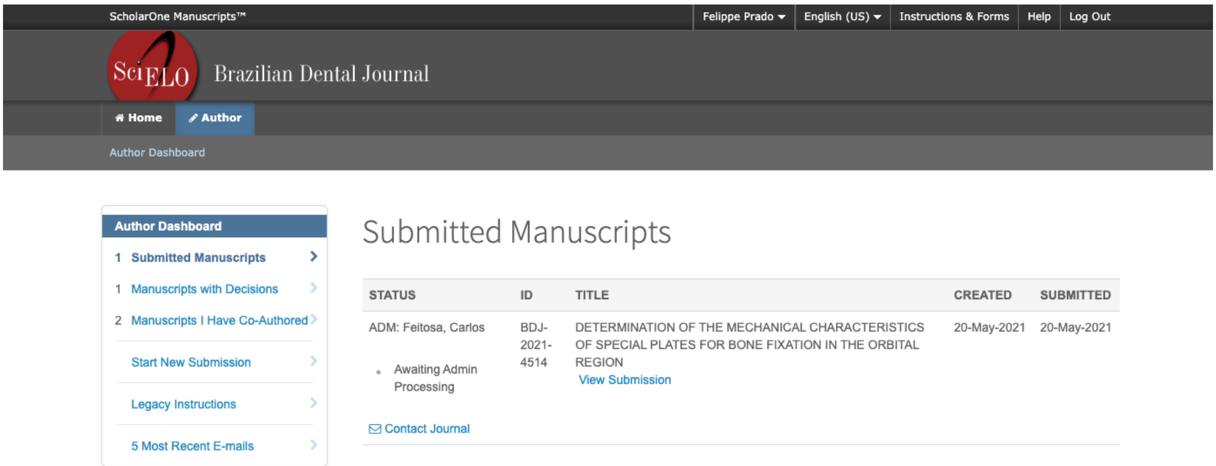
* De acordo com as normas da UNICAMP/FOP, baseadas na padronização do International Committee of Medical Journal Editors - Vancouver Group. Abreviatura dos periódicos em conformidade com o PubMed.

ANEXOS

ANEXO 1: Comprovante de Submissão



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ANEXO 2: Comprovante de originalidade e anti-plágio

DETERMINAÇÃO DAS CARACTERÍSTICAS MECÂNICAS DE PLACAS ESPECIAIS PARA FIXAÇÃO ÓSSEA NA REGIÃO ORBITAL

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