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LEANDRO STOCCO BACCARIN

ANÁLISE DE CORPOS DE PROVA MANDIBULARES UTILIZADOS PARA AVALIAÇÃO DE SISTEMA DE FIXAÇÃO ÓSSEA

ANALYSIS OF MANDIBULAR TEST SPECIMENS USED TO ASSESS A BONE FIXATION SYSTEM

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Orientador: Prof. Dr. Luis Augusto Passeri

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Dissertação de Mestrado apresentada ao Programa de Pós-Graduação em Ciências da Cirurgia da Faculdade de Ciências Médicas da Universidade Estadual de Campinas para obtenção do título de Mestre em Ciências.

Master's dissertation presented to the Surgery Sciences Postgraduation Programme of the School of Medical Sciences of the University of Campinas to obtain the MSc grade in Sciences.

ESTE EXEMPLAR CORRESPONDE À VERSÃO FINAL DA DISSERTAÇÃO DEFENDIDA PELO ALUNO LEANDRO STOCCO BACCARIN E ORIENTADA PELO PROF. DR. LUIS AUGUSTO PASSERI.

Assinatura do Orientador

CAMPINAS

2013

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Baccarin, Leandro Stocco, 1978-
Análise de corpos de prova mandibulares utilizados para avaliação de sistema de fixação óssea / Leandro Stocco Baccarin. -- Campinas, SP : [s.n.], 2013.

Orientador : Luis Augusto Passeri.
Dissertação (Mestrado) - Universidade Estadual de Campinas, Faculdade de Ciências Médicas.

1. Biomecânica. 2. Osteotomia sagital do ramo mandibular. 3. Avanço mandibular. I. Passeri, Luis Augusto, 1957-. II. Universidade Estadual de Campinas. Faculdade de Ciências Médicas. III. Título.

Informações para Biblioteca Digital

Título em inglês: Analysis of mandibular test specimens used to assess a bone fixation system.
Palavras-chave em inglês:
Biomechanics
Osteotomy, Sagittal split ramus
Mandibular advancement
Área de concentração: Fisiopatologia Cirúrgica
Titulação: Mestre em Ciências
Banca examinadora:
Luis Augusto Passeri [Orientador]
Jorge Vicente Lopes da Silva
Maurício Etchebehere
Data da defesa: 25-01-2013
Programa de Pós-Graduação: Ciências da Cirurgia

BANCA EXAMINADORA DA DEFESA DE MESTRADO

LEANDRO STOCCO BACCARIN

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Data: 25 de janeiro de 2013

Agradecimentos

À Universidade Estadual de Campinas, em nome do Exmo. Reitor, Prof. Dr. Fernando Ferreira Costa, pela excelência no ensino e pesquisa;

À Faculdade de Ciências Médicas em nome do Exmo. Diretor, Prof. Dr. Mario José Abdalla Saad, pela oportunidade de participar do programa de pós-graduação em Ciências da Cirurgia;

Ao Departamento de Cirurgia, em nome do chefe de Departamento, Prof. Dr. Joaquim Murray Bustorff Silva, e da Profa. Dra. Ilka de Fátima Santana Ferreira Boin, coordenadora do curso de pós-graduação em Ciências da Cirurgia, pela oportunidade ímpar e pela preocupação destes ilustres mestres em compartilhar suas melhores experiências e conhecimentos em sala de aula;

Ao Prof. Dr. Luis Augusto Passeri, pela acolhida, convivência e por todos os ensinamentos e orientações. Exemplo profissional a ser seguido;

Ao Departamento de Tecnologias Tridimensionais do Centro de Tecnologia da Informação Renato Archer – CTI, em nome do Prof. Dr. Jorge Vicente Lopes da Silva, Chefe de Departamento, pela oportunidade e apoio e pela confecção dos corpos de prova prototipados;

Aos funcionários do Departamento de Tecnologias Tridimensionais do Centro de Tecnologia da Informação Renato Archer – CTI, em especial a Airton Moreira da Silva, Anderson Aparecido Camilo, Pedro Yoshito Noritomi e Marcelo Fernandes de Oliveira pelas trocas de informações, assistência, desenvolvimento e confecção dos corpos de prova prototipados;

Ao Prof. Dr. Lourenço Correr Sobrinho e Sr. Marcos Blanco Cangiani, da Área de Materiais Dentários da Faculdade de Odontologia de Piracicaba - Unicamp, pela disposição e assistência laboratorial;

À Profa. Dra. Maria de Fátima de Gouveia, pelo seu entusiasmo e estímulo à pesquisa científica e à excepcional amizade;

À Profa. Thalita Regina Vieira e Oliveira e ao Prof. Dr. Renato Corrêa Viana Casarin, exemplos de grande coleguismo e paciência;

A toda minha família, em especial à minha amada esposa, Élida;

A Deus, pela alegria da vida.

Epígrafe

"O maior inimigo do conhecimento não é a ignorância,
é a ilusão do conhecimento."
(Stephen William Hawking)

Resumo

Objetivo: O objetivo deste trabalho é avaliar, por meio de testes biomecânicos, se materiais sintéticos diferentes, empregados para a confecção de corpos de prova apresentam comportamento biomecânico diferente, em comparação aos demais, ao simular *in vitro* a resistência ao carregamento de um método de fixação consagrado para OSRM.

Material: 30 réplicas de hemimandíbulas humana, sintéticas e padronizadas, com OSRM, divididas em três grupos de 10 amostras cada: Grupo A - plástico ABS, Grupo B - Poliamida, e Grupo C – Poliuretano. Estas foram fixadas por três parafusos bicorticais posicionais (16 mm de comprimento, sistema 2.0 mm), em disposição "L" invertido, utilizando-se guias de perfuração e avanço de 5 mm.

Métodos: Cada amostra foi submetida ao carregamento linear vertical e os valores de resistência ao carregamento registrado em 1, 3, 5, 7 e 10 mm de deslocamento. As médias e desvio padrão foram comparados, empregando-se análise de variância ($p<0.05$) e pelo teste Tukey.

Resultados: Notou-se uma tendência de menores valores no grupo B em relação aos grupos A e C. Nos deslocamentos 3 e 5 mm, houve uma diferença entre os grupos A e C para o grupo B ($p<0.05$). Nos deslocamentos 7 e 10 mm houve diferença entre os 3 grupos sendo os maiores valores encontrados no grupo C e os menores no grupo B ($p<0.05$).

Conclusões: Levando-se em consideração os resultados obtidos e o comportamento de cada material utilizado como substrato, podemos considerar que ocorreram diferenças significativas entre os materiais, quando comparados entre si.

Abstract

Purpose: The aim of this study was to assess through biomechanical testing if different synthetic materials used to fabricate test specimens have a different biomechanical behavior in comparison with other materials when simulating *in vitro* load resistance of a fixation method established for SSRO.
Material: Thirty synthetic and standardized human hemimandible replicas with SSRO were divided into three groups of 10 samples each. Group A - ABS plastic; Group B – Polyamide and Group C - Polyurethane. These were fixated with three bicortical position screws (16 mm in length, 2.0mm system) in an inverted L pattern using perforation guide and 5 mm advancement. *Methods:* Each sample was submitted to linear vertical load and load strength values were recorded at 1, 3, 5, 7 and 10 mm of displacement. The means and standard deviation were compared using the Analysis of Variance ($p<0.05$) and the Tukey's test.
Results: A tendency for lower values was observed in Group B in comparison with Groups A and C. At 3 and 5 mm of displacement, a difference between Groups A and C was found in comparison with Group B ($p<0.05$). At 7 and 10 mm of displacement a difference was found among the 3 groups, in which Group C showed the highest values and Group B the lowest ($p<0.05$).
Conclusions: Taking into consideration the results obtained and the behavior of each material used as a substrate, significant differences occurred among the materials when compared among them.

Lista de abreviaturas

OSRM	Osteotomia Sagital do Ramo Mandibular
DT3D	Divisão de Tecnologias Tridimensionais
CTI	Centro de Tecnologia da Informação Renato Archer
SSRO	Sagittal Split Ramus Osteotomy
ABS	Acrilonitrila Butadieno Estireno
mm	Milímetros
CT	Computed Tomography
TC	Tomografia Computadorizada
STL	Standard Triangulation Language
FDM	Fused Deposition Modeling (Modelagem por Fusão e Deposição)
SLS	Selective Laser Sintering (Sinterização Seletiva a Laser)
RP	Rapid Prototyping (Prototipagem Rápida)
Ti-6Al-4V	Liga Metálica, composta de Titânio, Alumínio e Vanádio
kgf	kilograma-força
N	newtons
ANOVA	Analysis of Variance (Análise de Variância)

Sumário

1. *Introdução Geral*

As técnicas de fixação de osteotomias sagitais dos ramos mandibulares (OSRM) apresentaram grande evolução, empregando-se conceitos como estabilidade, reparo ósseo primário, máximo contato ósseo entre os segmentos, ausência de bloqueio maxilomandibular, movimentação precoce e retorno precoce à função. Assim, a indicação do procedimento cirúrgico foi facilitado pelo emprego da fixação interna, de acordo com Van Sickels e Richardson (1).

A osteotomia sagital bilateral dos ramos mandibulares para tratamento das deformidades dentofaciais, via acesso intra-oral, foi descrita primeiramente por Obwegeser, em 1955, apesar de haver a descrição de um procedimento cirúrgico publicado por Schuchardt, em 1942, *apud* Blakey III e White Jr. (2) na literatura alemã, que remetia à osteotomia sagital.

Dois anos mais tarde, a técnica preconizada por Obwegeser, em conjunto com Trauner (3), foi publicada pela primeira vez na literatura americana e seu uso foi discutido, durante a apresentação de uma série de seminários nos Estados Unidos da América, em 1965, *apud* Kewitt et al.(4). Desde então, o desenho, o formato e a técnica cirúrgica da osteotomia têm sido frequentemente modificados, resultando em métodos mais modernos de redução, estabilização e fixação dos segmentos osteotomizados(5, 6).

Epker (7), em 1977, contribuiu com algumas modificações, baseadas em critérios biológicos. O músculo masseter não era descolado da porção lateral do ramo e o descolamento lingual era realizado apenas para visualizar a língula mandibular, conforme a técnica empregada atualmente.

Por outro lado, os princípios cirúrgicos e as vantagens do procedimento permaneceram inalterados, como a maior flexibilidade no reposicionamento dos dentes e segmentos distais, ampla sobreposição óssea dos segmentos depois do reposicionamento mandibular e mudanças mínimas na posição dos músculos mastigatórios e dos componentes da articulação temporomandibular (2).

Assim, após algumas modificações na técnica preconizada inicialmente por Obwegeser e Trauner (3), em 1957, o desenho básico atual da osteotomia sagital do ramo mandibular tinha se definido e muitos cirurgiões começaram a aplicá-la para o tratamento das deformidades mandibulares. Novamente, modificações foram propostas, agora no sentido de minimizar os problemas intra e pós-operatórios da técnica, conforme a evolução natural de qualquer técnica cirúrgica.

Tais evoluções permitiram a troca dos fios de aço por parafusos bicorticais e/ou miniplacas e parafusos para fixação interna e controle dos cotos osteotomizados com melhor contato ósseo.

Quando são empregados materiais de fixação interna estável, o descolamento é minimizado e otimizado, devido à facilidade de realização da técnica de fixação, independente da modalidade escolhida pelo cirurgião, como as placas e parafusos ou parafusos somente.

Com a fixação interna estável, o cirurgião é capaz de avaliar a oclusão após a conclusão do procedimento, permitindo flexibilidade no estágio intra-operatório, de modo que é vantajoso para completar a cirurgia mandibular antes da cirurgia maxilar conforme relataram Frost e Koutinick (8), em seu estudo utilizando miniplacas ortopédicas de metacarpo em cirurgias bimaxilares.

Blomqvist e Isaksson (9) compararam a estabilidade a curto-prazo avaliadas em dois grupos dos pacientes que se submeteram ao avanço mandibular, sendo que um grupo recebeu três parafusos posicionais bicorticais e o outro grupo miniplacas e parafusos monocorticais. Não foram notadas diferenças na estabilidade entre os dois grupos. Entretanto, ambos os grupos mostraram aumento na instabilidade quanto mais a mandíbula foi avançada.

A escolha da melhor técnica de osteossíntese das osteotomias faciais estaria baseada então na experiência de cada cirurgião, em cada caso específico de procedimento cirúrgico a ser realizado eletivamente, conforme relatou Guimarães Filho (10).

Quanto ao material empregado, Schardt-Sacco (11) afirmou que o titânio é o material mais comumente utilizado atualmente e é disponível tanto na forma pura ou como uma liga. É um material biocompatível e causa uma reação tecidual mínima. É um tipo de material mais maleável do que o aço inoxidável e o vitallium.

De acordo com Schardt-Sacco (11), a fixação interna promove muito mais vantagens óbvias do que a fixação esquelética a fios. No intra-operatório, a fixação interna promove controle dos segmentos ósseos, sendo que até mesmo áreas com pobre contato ósseo podem ser estabilizadas.

Quanto ao tipo de parafusos a serem utilizados, os autorosqueáveis são caracterizados por apresentarem no final de sua ponta ativa uma estria cortante aguda, que corta o osso através do furo-piloto previamente realizado e auxilia a inserção do parafuso, conforme relataram Ernberg e Asnis, em 1996 *apud* Gerlach et. al. (12).

Basicamente, as técnicas de fixação para OSRM podem ser executadas de 3 maneiras: utilizando-se 3 parafusos bicorticais, em disposição de "L" invertido ou "em linha", uma ou duas placas com parafusos monocorticais, e a técnica híbrida, que utiliza uma miniplaca e parafusos monocorticais associada a mais um parafuso bicortical em região retromolar, de acordo com Brasileiro et al. (13,14). Brasileiro et al. (14) definiram, através de testes biomecânicos, que o padrão "L" invertido proporciona melhor resistência em comparação às miniplacas e à técnica híbrida.

Independente do método de fixação a ser utilizado, a estabilidade é um fator essencial para o sucesso das OSRM e sua avaliação pode ser realizada através de testes biomecânicos. Estes testes da resistência dos métodos de osteossíntese contém variáveis como tamanho, número, configuração dos materiais e tipo de material empregado (13,14).

Testes biomecânicos, *in vitro*, de métodos de fixação óssea da OSRM dependem de modelos de simulação e apresentam uma importância considerável à aplicabilidade clínica, de acordo com Hammer et al.(15) e Scaf de Molon et al. (16). Experimentos em laboratório podem demonstrar e selecionar as melhores técnicas de fixação, quanto ao seu potencial de resistir a cargas que pudessem desestabilizar a união entre os segmentos osteotomizados, simulando a força de mordida e seus vetores de deslocamento (13-20), demonstrando, por comparação, a possibilidade de seu emprego com segurança em pacientes.

Para realizar os testes biomecânicos são empregados corpos de prova, sendo que estes podem ser produzidos em laboratório com material sintético, através de técnicas de prototipagem rápida ou replicação, com o objetivo da simulação da anatomia óssea ou simplesmente utilizando segmentos ósseos derivados de animais e cadáveres, ou ainda usando vegetais. Dentre os substratos ou corpos de prova de origem animal temos as mandíbulas cadavéricas humanas (21-26), mandíbulas frescas de carneiro (27,28), costelas bovinas (29-31) e de porco (17).

Quando são utilizados corpos de prova mandibulares de origem sintética é comum encontrarmos o poliuretano como o material de escolha (13,14,16,18,32-38). Não encontramos, até então, relatos na literatura da utilização de outro tipo de material sintético, diferente do poliuretano, como corpo de prova.

2. Objetivo

O objetivo deste trabalho é avaliar, por meio de testes biomecânicos, se materiais sintéticos diferentes, empregados para a confecção de corpos de prova, apresentam o mesmo comportamento biomecânico quando comparados entre si, ao simular *in vitro* a resistência ao carregamento de um método de fixação consagrado para OSRM.

3. Capítulo

(Artigo submetido para publicação em dezembro de 2012 no Journal of Cranio-Maxillofacial Surgery)

Analysis of mandibular test specimens used to assess a bone fixation system

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SUMMARY

Purpose: The aim of this study was to assess through biomechanical testing if different synthetic materials used to fabricate test specimens have a different biomechanical behavior in comparison with other materials when simulating *in vitro* load resistance of a fixation method established for SSRO.

Material: Thirty synthetic and standardized human hemimandible replicas with SSRO were divided into three groups of 10 samples each. Group A - ABS plastic; Group B – Polyamide and Group C - Polyurethane. These were fixated with three bicortical position screws (16 mm in length, 2.0 mm system) in an inverted L pattern using perforation guide and 5 mm advancement. *Methods:* Each sample was submitted to linear vertical load and load strength values were recorded at 1, 3, 5, 7 and 10 mm of displacement. The means and standard deviation were compared using the Analysis of Variance ($p<0.05$) and the Tukey's test.

Results: A tendency for lower values of displacements was observed in Group B in comparison with Groups A and C. At 3 and 5 mm of displacement, a difference between Groups A and C was found in comparison with Group B ($p<0.05$). At 7 and 10 mm of displacement a difference was found among the 3 groups, in which Group C showed the highest values and Group B the lowest ($p<0.05$).

Conclusions: Taking into consideration the results obtained and the behavior of each material used as a substrate, significant differences occurred among the materials when compared among them.

Keywords: Biomechanics, Osteotomy, Sagittal Split Ramus, Mandibular Advancement, Rapid prototyping

INTRODUCTION

The fixation techniques used in sagittal-split ramus osteotomy of the mandible (SSRO) have significantly improved with regard to stability, primary bone healing, maximum contact between the bone segments, absence of maxillomandibular blockage, and early return of function. Therefore, the indication for surgical procedure is facilitated by using internal fixation (*Van Sickels* and *Richardson*, 1996).

The fixation techniques used in SSRO may be performed in three ways: using three bicortical screws in an inverted L pattern or "in-line"; one or two plates with monocortical screws; and a hybrid technique that uses a plate and monocortical screws associated with another bicortical screw in the retromolar area (*Brasileiro et al.*, 2009; *Brasileiro et al.*,2012).

Mandibular osteotomies fixated with an inverted L pattern present greater rigidity and strength in comparison with other screw placement patterns for fixation of SSRO when submitted to strength tests (*Foley et al.*, 1989; *Kim et al.*, 1995).

Irrespective of the fixation method used, stability is an essential factor for the surgical success of the SSRO technique and it may be assessed by using biomechanical tests. However, strength tests of the osteosynthesis method present variables such as size, number, material configuration, and type of material used (*Brasileiro et al.*, 2009; *Brasileiro et al.*, 2012).

In silico biomechanical testing of methods of bone fixation of SSRO generally depends on the simulation models and it is considerably important with regard to the clinical applicability (*Hammer et al.*, 1995; *Scaf de Molon et al.*, 2011). Laboratory experiments and simulations can show and select the best fixation techniques regarding their potential to withstand loads that could destabilize the osseous union between the osteotomized segments, simulating the bite force and displacement vectors (*Ardary et al.*, 1989; *Foley et al.*, 1989; *Murphy* *et al.*, 1995; *Hammer et al.*, 1995; *Peterson et al.*, 2005; *Brasileiro et al.*, 2009; *Scaf de Molon et al.*, 2011; *Brasileiro et al.*, 2012) and showing by comparison those that could be potentially safely used into patients.

Test specimens are used to conduct biomechanical tests and these can be produced in the laboratory using synthetic material by means of rapid prototyping techniques or replication with the purpose of simulating bone anatomy, or simply by using bone segments from animals or cadavers or using vegetables.

Among the substrates or test specimens of animal origin, there are studies in the literature that use human cadaver mandibles (*Ardary et al.*, 1989; *Bouwman et al.*, 1994; *Schwimmer et al.*, 1994; *Kim et al.*, 1995; *Kohn et al.*, 1995; *Tharanon*, 1998), fresh sheep mandibles (*Foley* and *Beckmann*, 1992; *Uckan et al.*, 2001), bovine ribs (*Anucul et al.*, 1992; *Armstrong et al.*, 2001; *Trivelatto* and *Passeri*, 2006) and porcine ribs (*Foley et al.*, 1989).

Over the few last decades, the development of computing associated with a significant increase in precision mechanical engineering and availability of materials have allowed real synthetic models to be rapidly obtained from virtual models, creating the concept of rapid prototyping or solid free form manufacturing. This technology is used in many areas of knowledge, namely architecture, paleontology, biochemistry and medical applications (*Silva et al*., 2003), and it can produce test specimens to simulate human anatomy in details as opposed to other manufacturing techniques of synthetic test specimens. Polyurethane is the material of choice for fabricating mandibular test specimens of synthetic origin (*Hammer et al.*, 1995; *Van Sickels et al.*, 2005; *Peterson et al.*, 2005; *Brasileiro et al.*, 2009; *Sato et al.*, 2010; *Ribeiro-Junior et al.*, 2010; *Zizelmann et al.*, 2011; *Aymach et al.*, 2011; *Scaf de Molon et al.*, 2011; *Brasileiro et al.*, 2012). Up to the present, we have not found any studies in the literature that have used another type of synthetic material other than polyurethane or any other technique or technology to produce the test specimens to test the fixation of SSRO. There are no studies that compare the use of different test specimens in a biomechanical study of the fixation of SSRO.

The aim of this study was to assess by means of biomechanical testing if different synthetic materials used to fabricate test specimens have a different biomechanical behavior in comparison with other materials when simulating *in vitro* load resistance of a fixation method established for SSRO.

MATERIAL AND METHODS

To conduct the *in vitro* study, a model for testing resistance to bending load of cantilever was used on synthetic and standardized human hemimandible replicas produced with SSRO and fixated with three bicortical position screws in an inverted L pattern. The hemimandibles were divided into three groups of 10 samples each, according to the synthetic material used: Group A - ABS plastic; Group B – Polyamide and Group C - Polyurethane.

To fabricate the samples of Groups A and B a computed tomography (CT) of the mandible considered healthy was selected. The CT images were processed initially in the computer program InVesalius version 2.1 (DT3D, CTI, Campinas, Brazil) producing a three-dimensional image of the entire mandible from the reconstruction of axial CT images.

Then the computer program Magics RP version 16 (16.0.2.1) x 32 (Materialise NV, Leuven, Belgium) was used. The reconstructed three-dimensional image was virtually sectioned in the midline and only the three-dimensional image of the right hemimandible was kept. A virtual SSRO was simulated by separating the image of the hemimandible into two parts referring to the proximal and distal segments (Fig. 1).

Next, the images were transformed into the STL format (Standard Triangulation Language) for physical production of samples using two rapid prototyping technologies from the 3D Technologies Division of the Center

Information Technology Renato Archer (DT3D, CTI - Campinas, Brazil). Ten hemimandibles with simulated SSRO were made using ABS type thermoplastic material (Group A) obtained by the rapid prototyping technique by Fused

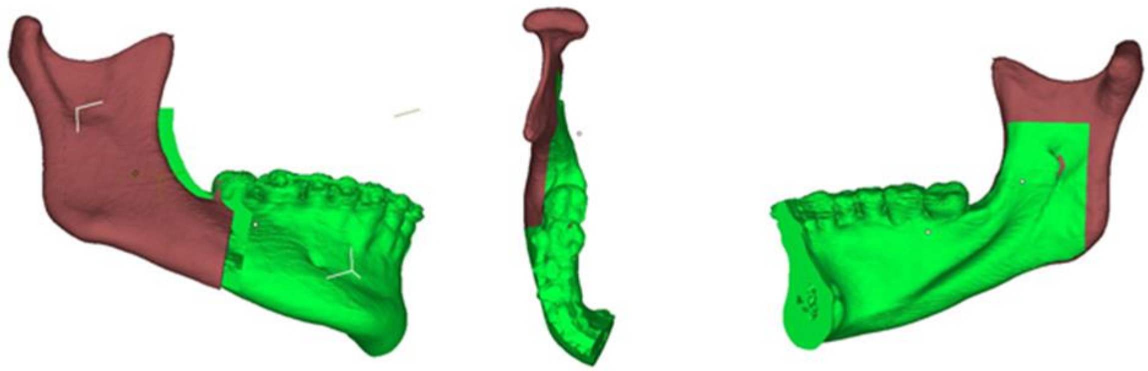

Figure 1 – Virtual models of SSRO design

Deposition Modeling (FDM) in the FDM Vantage i machine model (Stratasys Inc., Eden Prairie, MN, USA) - and ten other samples were made of polyamide (Group B) via the rapid prototyping using the Selective Laser Sintering technique (SLS) in the Sinterstation® HiQ™ SLS® machine system (3D Systems, Inc., Rock Hill, SC, USA).

The 10 hemimandibles in Group C were fabricated using the replica technique from physical models of a hemimandible with SSRO. The synthetic material used was expanded polyurethane foam and two segments - proximal and distal were also fabricated to simulate SSRO (Nacional Ossos, Jaú, Brazil).

To fixate the proximal and distal segments maintaining a standardized mandibular advancement of 5 mm and equal position of the screws for all samples, a virtual fixation guide was developed with the aid of the computer program Magics RP version 16 (16.0.2.1) x 32 (Materialise NV, Leuven, Belgium). The matrix images of the computed tomography of the hemimandible with SSRO were used. The guide was fabricated in ABS plastic by the FDM rapid prototyping technique and it was adapted perfectly to the samples produced through the rapid prototyping techniques in ABS Plastic (Group A) and Polyamide (Group B) (Fig. 2).

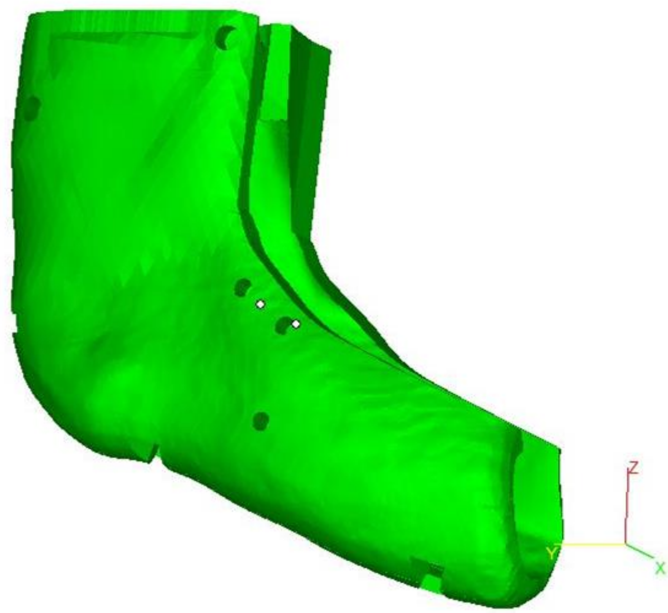

Figure 2 – Fixation guide and virtual perforation for hemimandibles.

Because the polyurethane hemimandibles (Group C) were different from an anatomical point of view in comparison with the prototyped samples (Groups A and B), the fabrication of a second standardized guide for fixation and mandibular advancement was required. For this purpose, the reverse engineering prototyping technique was used for digitizing the physical models. The polyurethane samples were manually scanned with a handheld 3D Scanner EXAscan (Creaform, Québec, Canada) generating digitized images that allowed the manufacture of a second guide for the hemimandibles also using rapid prototyping and ABS plastic. The location of the perforations and 5 mm advancement followed the same patterns of the guide used for Groups A and B.

The purpose of using two prototyped guides was to standardize the position of the proximal and distal segments with the 5 mm mandibular advancement and the perforations required in the exact locations for the placement of the fixation screws in all samples.

The samples were prepared and the inverted L technique was used for the fixation of the samples using 90 self-tapping position screws, made of commercially pure grade II titanium alloy (Ti-6Al-4V), measuring 16 mm in length, 2.0 mm diameter system - (MDT, Rio Claro, Brazil).

A 1.6-mm diameter bur was used for the perforation. Each sample in all groups received three position screws (Fig. 3).

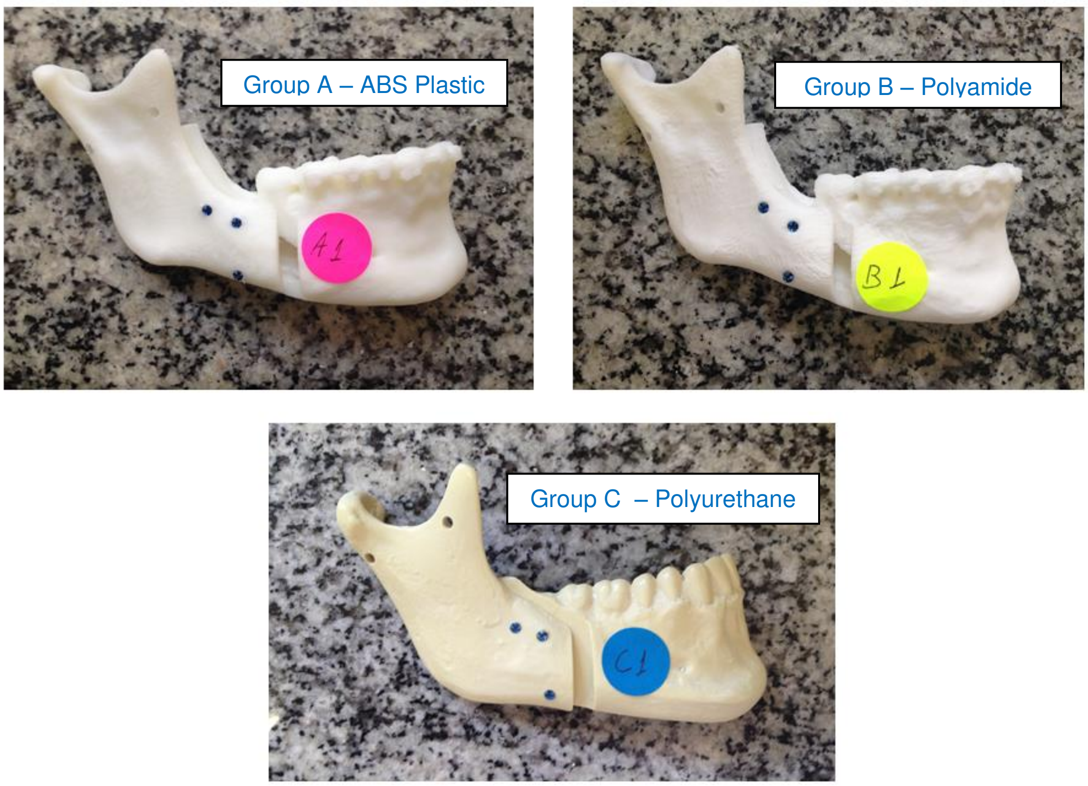

Figure 3 – Samples from Groups A, B, and C fixed with screws in inverted "L" pattern.

The biomechanical load test was performed in a universal loading testing machine (Instron Universal 4411, Instron, Inc. Canton, MA, USA) using rigid connections. The prepared samples were fixated on a metal support through two holes in the ascending ramus of hemimandibles, which allowed the correct positioning of samples on the test holder, positioning the mandibular occlusal plane perpendicular to the force application device. The samples in all groups were submitted to the application of linear vertical force from the top to the bottom in the occlusal region of the first molar (Fig. 4), requiring the fabrication of a groove to prevent sliding of the sample from the machine. The load was applied by a device coupled to the cell force of 50 kgf and the machine was programmed to apply progressive force at displacement speed of 10 mm/min.

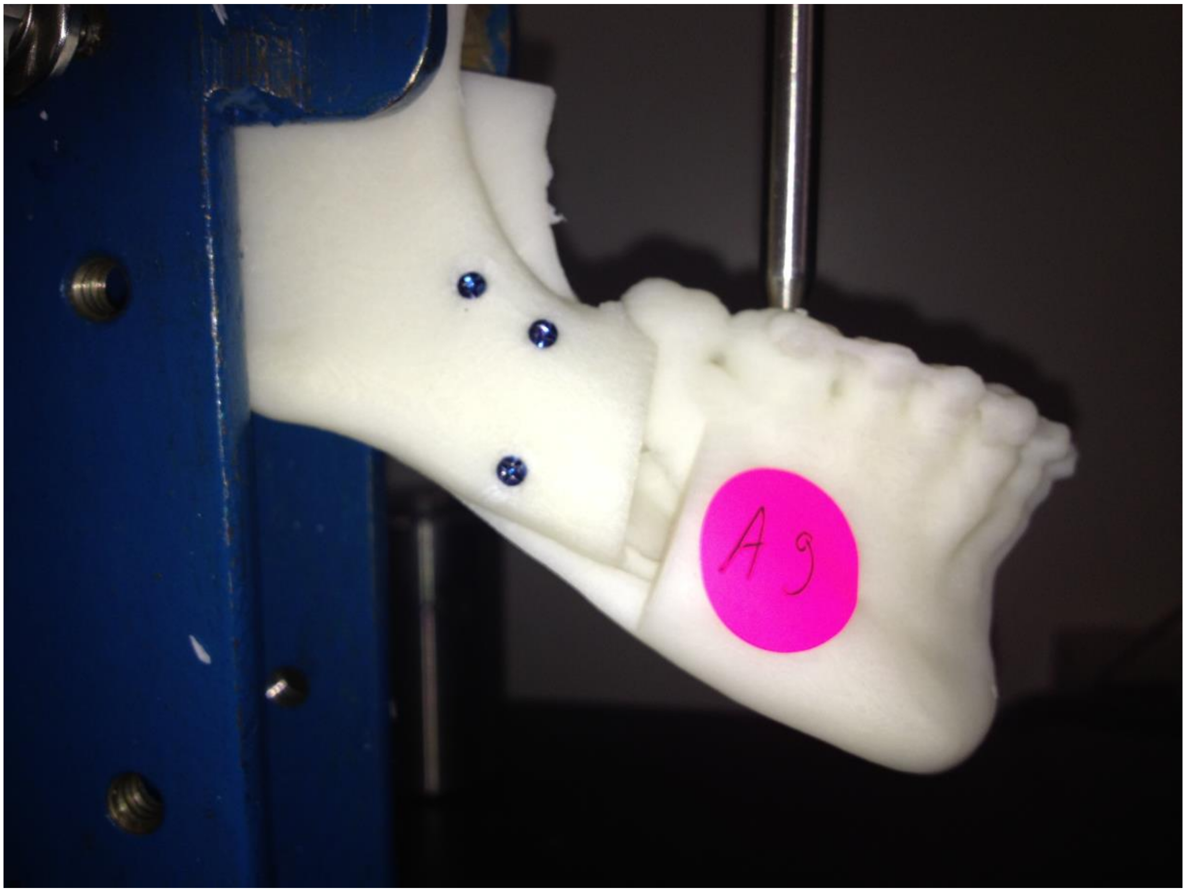

Figure 4 – Direction and location of force application during biomechanical tests.

The strength values were obtained in newtons (N) by the program Bluehill 2 (Instron Corporation, Norwood, MA, USA) coupled to the test machine during testing. The registration of the loading value was performed when displacement reached 1, 3, 5, 7, and 10 mm for each of the samples. These values were assessed by Tukey's test after analysis of variance to detect differences among the mean values. The SAS® 9.0.1 (SAS Institute, Cary, NC, USA) software was used at a level of significance of 5% for all the tests.

RESULTS

Table 1 shows the mean values obtained in each group for each displacement after performing the biomechanical testing in all the samples. Different letters in the vertical line indicate a statistically significant difference ($p<0.05$) among the groups according to ANOVA/Tukey's test ($p<0.05$) and Fig. 5 shows the vertical loading best-fit exponential tendency curves.

Table 1 – Mean values (N ± standard deviation) for each group (N) in every displacement.

Load (N)	Displacement (mm)				
	1 mm	**3 mm**	**5 mm**	**7 mm**	**10 mm**
Group A	15.4±8.4 a	51.5±9.8 a	87.9±12.3 a	119.2±14.0 b	150.2±12.9 b
Group B	7.0±3.7 a	27.4±5.0 b	49.8±5.0 b	68.4±5.0 c	89.2±6.2 c
Group C	14.1±10.2 a	63.2±33.3 a	135.4±34.7 a	197.0±37.4 a	166.8±54.0 a

Different letters in vertical columns indicate statistically significant difference between groups (ANOVA/Tukey's test, $p<0.05$)

By applying the tests, a statistical difference can be observed among the groups from displacement of 3 mm, with a tendency for lower strength values in Group B than in Group A and C. A difference was found for displacements of 3 and 5 mm between Groups A and C in comparison with Group B ($p <0.05$). At 7 and 10 mm of displacement a difference was found among the three groups, Group C showing the highest values and Group B the lowest ($p<0.05$).

With regard to the maximum compressive load values, shown in Table 2, Group B showed lower maximum load than Groups A and C, respectively.

As for maximum extension (Table 3), no statistically significant difference was found among the groups.

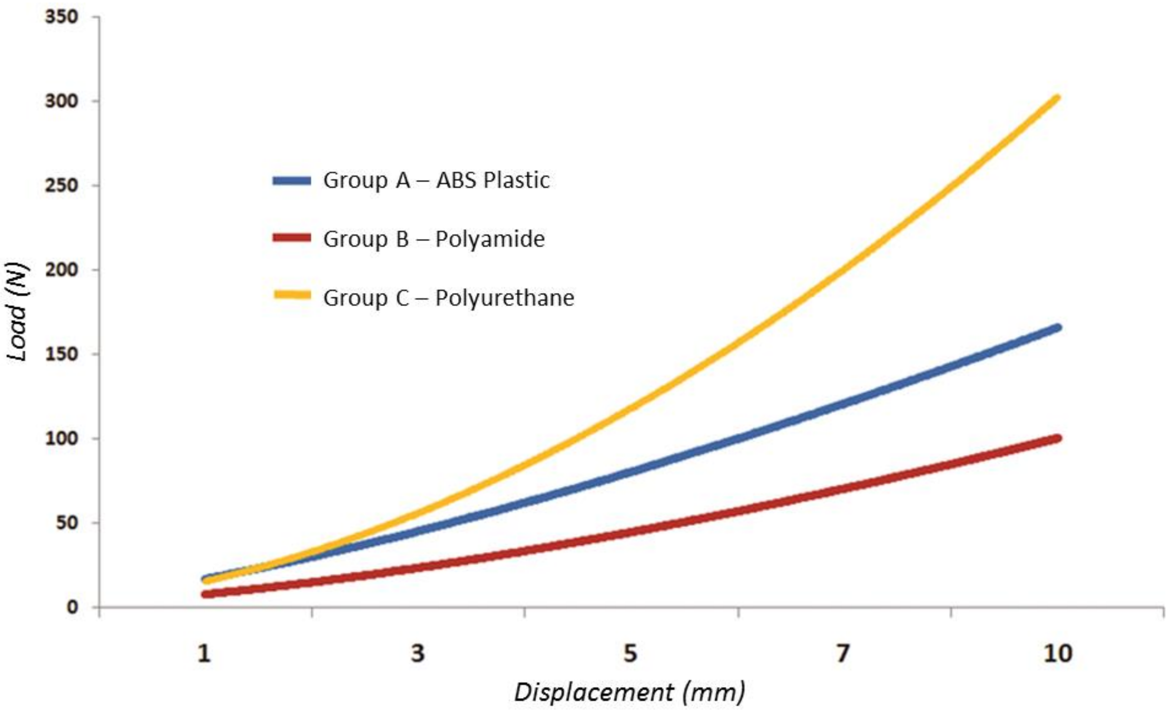

Figure 5 – Vertical loading best-fit exponential tendency curves

From the data obtained, the Shapiro-Wilk test was applied to determine the homogeneity of the data and it was confirmed ($p>0.05$). Therefore, for the intergroup comparison within each displacement assessed, analysis of variance (ANOVA) using Tukey's test was used to determine the differences found. For all tests, a level of significance of 5% was considered.

Table 2 – Maximum Compressive Load (newton)

	Maximum Compressive Load (N)
Group A	156.8±9.6 b
Group B	97.4±7.3 c
Group C	312.3±46.5 a

Different letters in vertical columns indicate statistically significant difference between groups (ANOVA/Tukey’s test, $p<0.05$)

Table 3 – Maximum Extension (millimeters)

	Maximum Extension (mm)
Group A	11.6±0.4 a
Group B	11.5±0.5 a
Group C	11.5±0.7 a

DISCUSSION

Although many studies have assessed the behaviors of different fixation methods for SSRO submitted to *in vitro* mechanical tests, no study has compared the differences among test specimens used for the tests in the same study. That is, the test specimens used were always made of the same synthetic, animal or vegetable material.

Screws are the most common types of implants used in orthopedic and maxillofacial surgeries whose properties have been deeply studied (*Brasileiro et al.*, 2009). The use of three 2.0 mm diameter screws, either using position or compression techniques, are considered the most cost effective, rigid and predictable way to fixate SSRO (*Ardary et al.*, 1989; *Murphy et al.*, 1995; *Hammer et al.*, 1995; *Ochs*, 2003; *Peterson et al.*, 2005; *Brasileiro et al.*, 2009; *Scaf de Molon et al.*, 2011). The most common way to fixate SSRO is using position screws, generally in an inverted L or triangular pattern, placed perpendicular to the bone surface using percutaneous guides. It is important to note that the geometric disposition of the screws seems to affect stability and resistance to functional forces, which is a more important characteristic than the diameter of the screws, and the use of higher screw diameters may not be necessary for adequate fixation. (*Obeid* and *Lindquist*, 1991;*Scaf de Molon et al.*, 2011). The fixation method used in the methodology of the present study is considered in the literature as being a resistant and stable method for SSRO (*Foley et al.*, 1989; *Kim et al.*, 1995).

The mandibular samples of ABS plastic and polyamide used as test specimens in this study were fabricated using the rapid prototyping technique. The technique enabled better detailed structural and anatomical reproduction of mandible, both of the cortical bone and cancellous bone, as well as of the tooth roots inserted into the bone in comparison with the polyurethane samples.

The synthetic mandibles produced with polyurethane were used as test specimens in many studies that simulated mandibular bone fixation of SSRO (*Brasileiro et al.*, 2009; *Scaf de Molon et al.*, 2011; *Aymach et al.*, 2011; *Brasileiro et al.*, 2012). However, in comparison with other materials used in this study, polyurethane only allowed the reproduction of the external anatomy of the mandibular bone. Internally, the polyurethane test specimen is totally solid and there is no differentiation between the cortical bone and cancellous bone. Consequently, we found that this is important characteristic of the polyurethane samples allowed greater engagement and larger contact surface of the entire body of the screw inserted in the test specimen to simulate fixation of the segments, influencing the increase of fixation rigidity in these samples. This did not occur with the ABS plastic and polyamide samples due to the better reproduction of the internal anatomy of the cortical bone and cancellous bone. In the samples from Groups A and B, the cancellous bone was reproduced as an empty space between the cortical bones and it was even possible to identify the roots of the mandibular teeth inserted into the alveolar bone with engagement and contact surface of the body of the screws only in the cortical walls, as it occurs clinically (Fig. 6).

When using synthetic test specimens for testing internal fixation, many variables and difficulties associated with the handling of human cadaver mandibles or animal bones are eliminated, such as the selection of standardized samples (*Kohn et al.*, 1995).

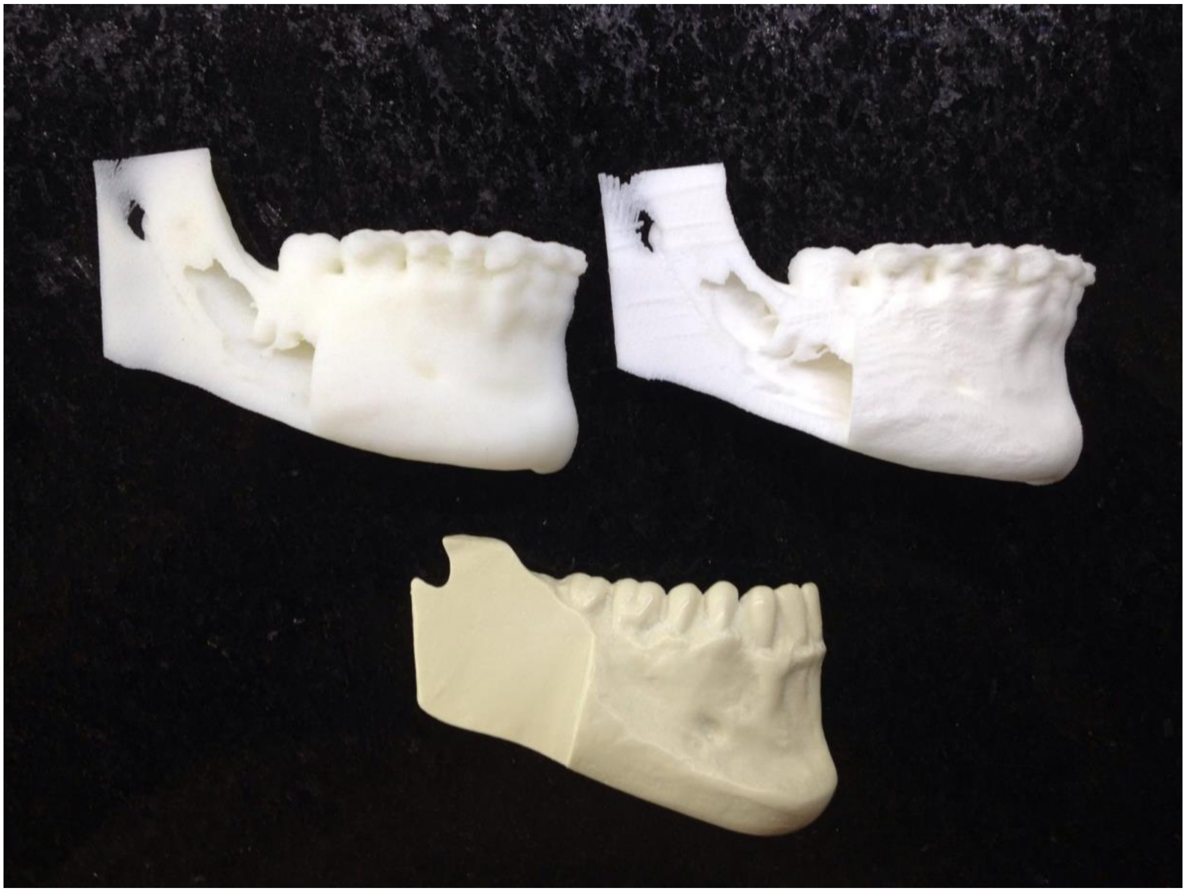

Figure 6 – ABS plastic, polyamide and polyurethane test specimens – internal anatomy in detail.

To facilitate the preparation of the samples, all the hemimandibles were fabricated in two segments, simulating SSRO. This procedure eliminated the need to manually perform osteotomy in the samples with a drill or saw, a procedure that could create variations in the design of the osteotomy and possible damage could cause changes in the results of the biomechanical testing, since it is impossible to reproduce SSRO manually in an equal manner in all samples (*Kohn et al.*, 1995; *Brasileiro et al.*, 2009).

With regard to the synthetic materials of choice for the fabrication of test specimens, we can affirm that polyurethane, until now, had been the only material cited and used as synthetic test specimen for biomechanical testing associated with internal fixation of SSRO. (*Hammer et al.*, 1995; *Van Sickels et al.*, 2005;

Peterson et al., 2005; *Brasileiro et al.*, 2009; *Sato et al.*, 2010; *Ribeiro-Junior et al.*, 2010; *Zizelmann et al.*, 2011; *Aymach et al.*, 2011; *Scaf de Molon et al.*, 2011; *Brasileiro et al.*, 2012). In this context, we opted to test, in addition to polyurethane, different materials such as ABS plastic and polyamide.

Brasileiro et al., 2009 and *Brasileiro et al.*, 2012 used guides fabricated in chemically active acrylic resin with the purpose of standardizing perforation and the position of screws and plates inserted into the test specimens, minimizing the variations of the technique used. With the same purpose, standardized fixation guides were developed to standardize the position of segments of test specimens with an advancement of 5 mm between segments. The guide facilitated the preparation of the samples.

Among the biomechanical properties of a given material, bending is the most important type of load in biomechanics and it is determined by the effect of force applied perpendicular to the long axis of a test specimen (*Brasileiro et al.*, 2009). Cantilever bending is the most common, that is, it is the effect of force applied to the extremity of the body fixated to another extremity (*Kohn et al.*, 1995; Cordey, 2000). This pattern was adopted in the present study. Several other studies simulating the properties of internal fixation methods in synthetic samples were also based on resistance to displacement by the cantilever bending forces (*Ardary et al.*, 1989; *Murphy et al.*, 1995; *Peterson et al.*, 2005; *Van Sickels et al.*, 2005; *Trivelatto* and *Passeri*, 2006; *Brasileiro et al.*, 2009; *Sato et al.*, 2010; *Ribeiro-Junior et al.*, 2010; *Zizelmann et al.*, 2011; *Scaf de Molon et al.*, 2011; *Brasileiro et al.*, 2012).

The methodology of load application for this experiment was also based on previous studies that used the Instron 4411 universal testing machine satisfactorily (*Trivelatto* and *Passeri*, 2006; *Brasileiro et al.*, 2009; *Vieira e Oliveira* and *Passeri*, 2011; *Brasileiro et al.*, 2012). Similarly, the Instron machine for mechanical testing was also used by other authors (*Foley et al.*, 1989; *Anucul et al.*, 1992; *Kohn et al.*, 1995; *Haug et al.*, 1999; *Armstrong et al.*, 2001; *Van Sickels* *et al.*, 2005; *Peterson et al.*, 2005) to assess loads with satisfactory scientific validation. Consequently, it was possible to measure the resistance loading values for each fixation method at different programmed displacements by evaluating the rigidity of the system in these studies. Rigidity is the parameter used to describe necessary force to obtain a given structural deformation and it may be summarized as follows: "rigidity" = "load" divided by "deformation", in which we can consider "load" as forces, moments, stresses, and "deformation" as displacement, deformation, curvature (*Baumgart*, 2000; *Vieira e Oliveira* and *Passeri*, 2011).

The expectation was that any failure that would have occurred in the system during mechanical testing would be associated with the synthetic material of which the test specimen was made of and not with the metal material used for fixation. The substrate should be considered the weakest resistance area of the system, especially if the clinical considerations to be mimicked suggest that, particularly in the initial phases of post-operative repair, the bone has minimal participation in stabilization (*Kohn et al.*, 1995).

An important feature of synthetic materials used in this study is related to the quality and finishing of the samples fabricated by the previously mentioned prototyping techniques. The quality of the ABS plastic and polyamide models with regard to their anatomical details and hardness, in comparison with the polyurethanes samples, suggest different mechanical behavior to linear loading than those obtained in earlier studies in which only test specimens fabricated exclusively from polyurethane were used. The prototyped test specimens (Groups A and B) simulated the internal and external mandibular anatomy more accurately to the cortical, cancellous and alveolar bones. When the polyurethane samples (Group C) were compared, although they simulated the external anatomy of the mandible very well, the internal anatomy was limited to a totally solid model, which obviously generated greater rigidity and compatible results, when compared to the previous ones.

However, as found in another study related to biomechanical testing (*Vieira e Oliveira* and *Passeri*, 2011), it is important to point out that laboratory measurements are auxiliary methods to determine the potential of simulated fixation methods and these can carefully be extrapolated to the clinical behavior of real methods since the test specimen may generate interferences. Thus, the more reliable the model, the more it is possible to extrapolate it to clinical situations.

Considering the results obtained, we found that the samples from Group B presented lower loading required to achieve the proposed displacements with a lower loading value and without deformation of the fixation material or breakage of the system. Group A, in turn, showed intermediate loading values compatible with flexibility and resistance showed by the ABS plastic; and Group C showed extremely high loading values in comparison with the other groups being compatible with the rigidity of polyurethane samples.

With regard to the clinical applicability and the results obtained, a deep study of the biomechanical characteristics of each material used is needed to compare the properties of the human mandibular bone, since the precise simulation of the human anatomy found in synthetic test specimens is not sufficient to affirm that the biomechanical behavior to loading is similar to the human mandible.

CONCLUSION

Taking into consideration the results obtained and the behavior of each material used as a substrate, the ABS plastic showed to be more flexible and polyurethane more rigid. Polyamide was the material that required less loading to obtain a given maximum displacement in this study in comparison with the other materials tested.

Therefore, significant differences in relation to loading were found when we used synthetic materials for fabricating different test specimens and the same fixation method for SSRO.

CONFLICT OF INTEREST STATEMENT

The authors disclose that they do not have any financial and personal relationships with other people or organizations that could inappropriately influence (bias) this work.

ACKNOWLEDGMENTS

The authors acknowledge the technical assistance provided by Dr. Lourenço Correr Sobrinho and Marcos Blanco Cangiani, from the Division of Dental Materials, Piracicaba Dental School, State University of Campinas. The authors are also grateful to Airton Moreira da Silva, Anderson Aparecido Camilo, Marcelo Fernandes de Oliveira and Pedro Yoshito Noritomi, from the Division of Tridimensional Technologies – Center for Information Technology Renato Archer – DT3D – CTI.

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4. Conclusões Gerais

Baseado na metodologia empregada para produção das amostras dos Grupos A e B (tecnologias de prototipagem rápida), em comparação com as amostras do Grupo C, foi possível definir algumas vantagens:

-Fácil reprodução da anatomia interna mandibular;

-Maior precisão e reprodutibilidade para as osteotomias (computacional);

-Melhor reprodução de detalhes anatômicos;

-Maior uniformidade das amostras;

-Maior flexibilidade para mudanças de estratégia durante o estudo, se necessário.

Portanto, o tipo de metodologia empregada para a produção das amostras pode influenciar no resultado dos testes de carregamento, uma vez que a técnica e o material de fixação foram sempre os mesmos para todos os Grupos, variando apenas o tipo de material e o método de confecção das amostras.

Em relação aos resultados obtidos e o comportamento de cada material utilizado como substrato, o plástico ABS demonstrou-se muito flexível e o poliuretano muito rígido. A poliamida, por sua vez, foi o material em que foi preciso menos carga para obter o máximo deslocamento determinado neste estudo, em relação aos demais materiais testados.

Há, portanto, diferenças significativas em relação ao carregamento, quando utilizamos materiais sintéticos diferentes para a confecção de corpos de prova e um mesmo método de fixação para OSRM.

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6. Anexos

6.1. Comprovante de submissão do artigo:

From: "Journal of Cranio-Maxillofacial Surgery" <wiltfang@mkg.uni-kiel.de>
Subject: Submission Confirmation
Date: 6 de dezembro de 2012 15:41:34 BRST
To: passeri@fcm.unicamp.br, luispasseri@gmail.com

Dear Luis,

We have received your article "Analysis of mandibular test specimens used to assess a bone fixation system." for consideration for publication in Journal of Cranio-Maxillofacial Surgery.

Your manuscript will be given a reference number once an editor has been assigned.

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Date: 7 de dezembro de 2012 04:15:30 BRST
To: passeri@fcm.unicamp.br, luispasseri@gmail.com

Ms. Ref. No.: JCMS-D-12-00610
Title: Analysis of mandibular test specimens used to assess a bone fixation system.
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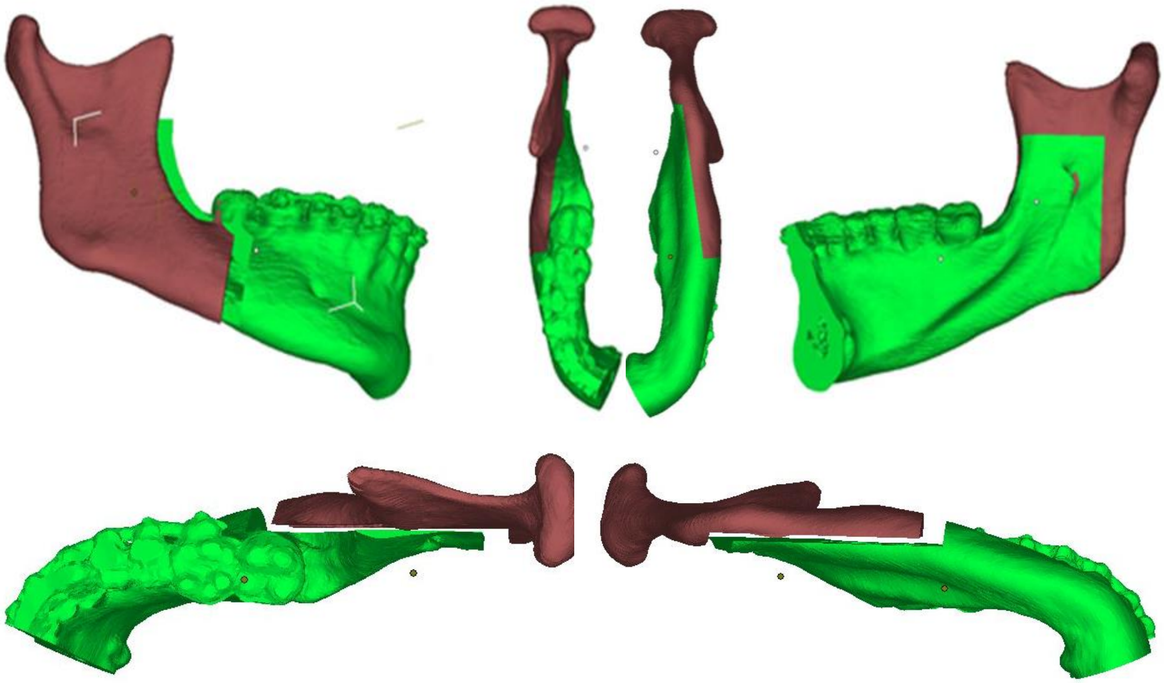
Thank you very much in advance,

Sincerely,

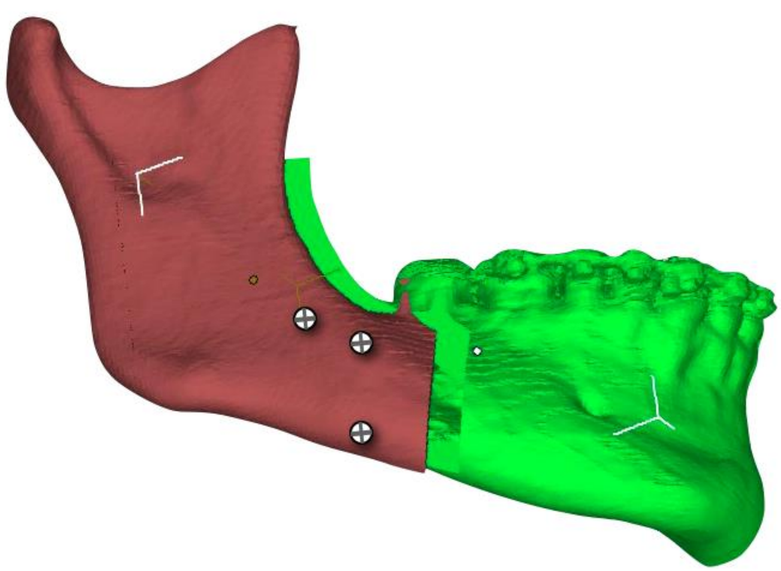
Leandro Stocco Baccarin.

Address correspondence to:
Dr Luis Augusto PASSERI, DDS, MSc, PhD
Division of Plastic Surgery, Department of Surgery (Head: Joaquim Bustorff, MD, MSc, PhD) Faculty of Medical Science, State University of Campinas, Brazil.
Address: R. Tessália Vieira de Camargo, 126, Cidade Universitária "Zeferino Vaz" - Campinas - SP - Brazil - Zip Code: 13083-887 - Phone: +55 19 3521-9450 –Fax: +55 19 3521-8043.
E-mail: passeri@fcm.unicamp.br;leandrobaccarin@gmail.com

6.4. Simulação do desenho da OSRM e avanço mandibular de 5 mm, em modelo virtual:

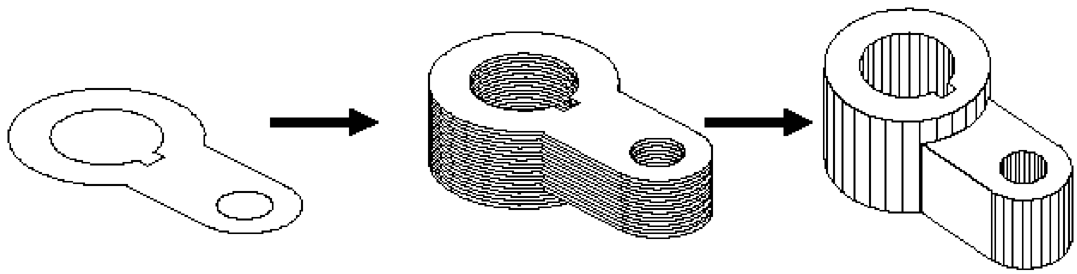


6.5. Simulação do método de fixação da OSRM com parafusos posicionais bicorticais em disposição “L” invertido, em modelo virtual:



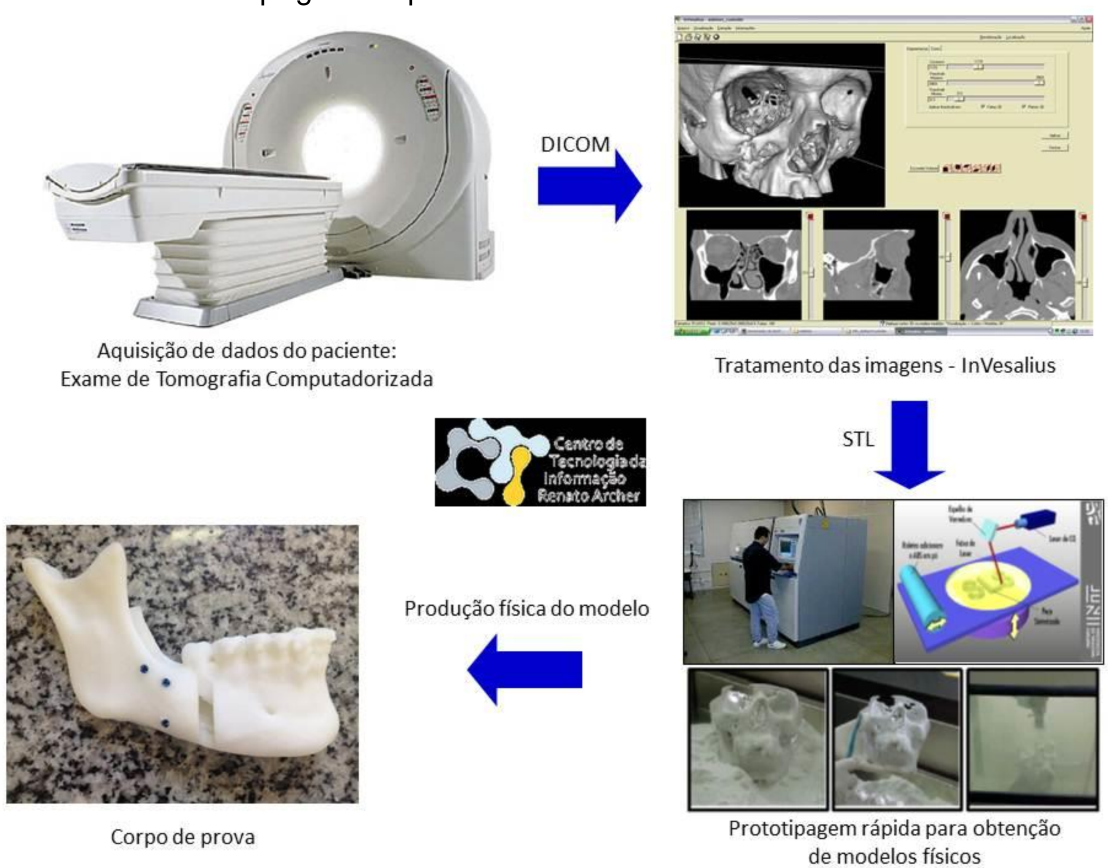
6.6. Prototipagem Rápida:

Construção por adição sucessiva de finas camadas de material



Fonte: Centro de Tecnologia da Informação Renato Archer – CTI/Divisão de Tecnologias Tridimensionais – DT3D. 2010.

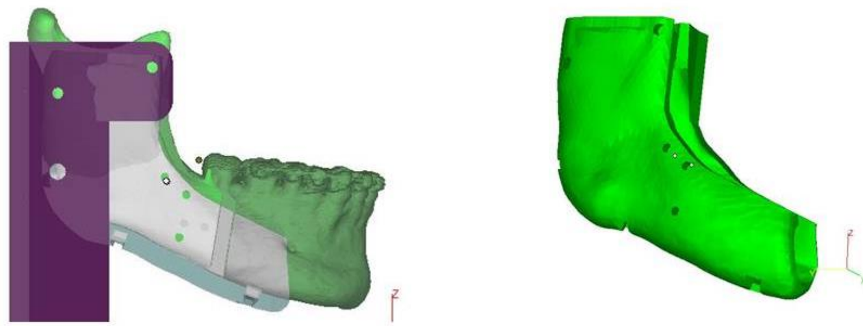
6.7. Prototipagem Rápida: Processamento



Fonte: Centro de Tecnologia da Informação Renato Archer – CTI/Divisão de Tecnologias Tridimensionais – DT3D. 2011.

6.8. Guia 1 para perfuração e avanço, amostras dos Grupos A e B:

-Guias de perfuração e avanço – Guia 1:
- -Padronização:
  - -Perfurações para instalação dos parafusos
  - -Avanço mandibular em 5 mm
- -Facilitar o preparo das amostras
- -Matriz: Imagens virtuais da Hemimandíbula
- -Produzido em Plástico ABS - prototipagem



Perfeita adaptação para as amostras prototipadas (Grupos A e B)

6.9. Guia 2 para perfuração e avanço, amostras Grupo C:

-Guias de perfuração e avanço – Guia 2:
- -Apenas para as amostras do Grupo C – Poliuretano:
- -Produzido a partir das imagens digitalizadas do Grupo C
- -Em Plástico ABS – prototipagem rápida

Fonte: Creaform Labs. [homepage on the internet]. Creaform; c2002-2013 [cited: 2013 Mar 6]. Available from: http://www.creaform3d.com/en/metrology-solutions/portable-3d-scanner-handyscan-3d/.

6.10. Preparo das amostras, Grupos A, B e C:

Grupo A – plástico ABS

Grupo B - poliamida

Grupo C - poliuretano

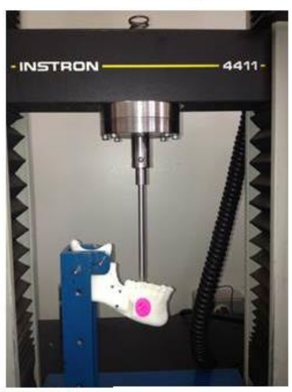
\`

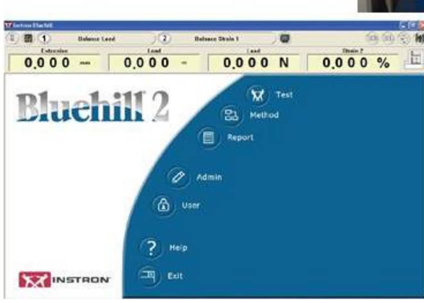
6.11. Testes biomecânicos:

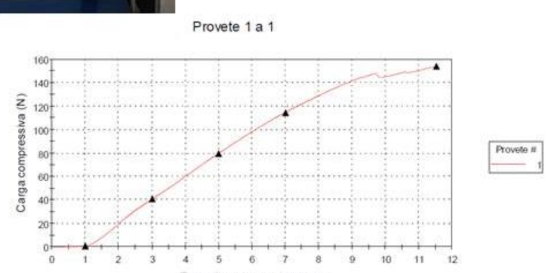
-Testes biomecânicos:

-Máquina de ensaio universal Instron® 4411

-Registro em newtons (N), software Bluehill® 2



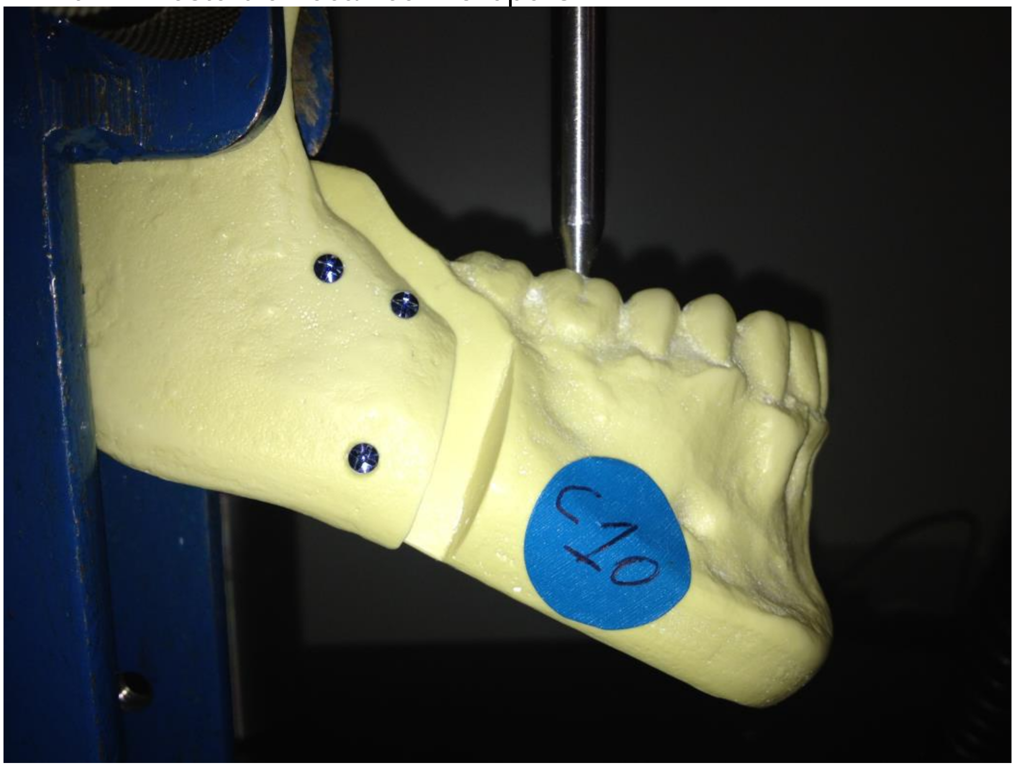




6.12. Teste biomecânico – Grupo A:

6.13. Teste biomecânico – Grupo B:

6.14. Teste biomecânico – Grupo C:



6.15. Detalhes e diferenças da anatomia interna, amostras dos Grupos A, B e C: