Laura Davison Mangilli

**Programa de avaliação e tratamento fonoaudiológico para a
reabilitação da função mastigatória de indivíduos submetidos à cirurgia
ortognática por deformidade dentofacial**

Tese a ser apresentada à Faculdade de Medicina
da Universidade de São Paulo para obtenção do
título de Doutor em Ciências

Programa de Ciências da Reabilitação

Área de Concentração Comunicação Humana

Orientadora: Profa. Dra. Claudia Regina Furquim
de Andrade

São Paulo

2012

Dados Internacionais de Catalogação na Publicação (CIP)

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Programa de avaliação e tratamento fonoaudiológico para a reabilitação da função mastigatória de indivíduos submetidos à cirurgia ortognática por deformidade dentofacial / Laura Davison Mangilli. -- São Paulo, 2012.

Tese(doutorado)--Faculdade de Medicina da Universidade de São Paulo. Programa de Ciências da Reabilitação. Área de concentração: Comunicação Humana.

Orientadora: Claudia Regina Furquim de Andrade.

Descritores: 1.Mastigação 2.Cirurgia ortognática 3.Sistema estomatognático
4.Avaliação 5.Resultado de tratamento

USP/FM/DBD-059/12

Dedico esse trabalho aos meus pais, ***Maria Amélia e Irineu***, expressando meu reconhecimento pela incondicional presença em minha vida.

Este trabalho é resultado da colaboração direta e indireta de várias pessoas. Externo minha gratidão a todas elas, em particular:

À **Profa. Dra. Claudia Regina Furquim de Andrade**, inicialmente pela confiança e oportunidade profissional na etapa em que me encontrava no início deste projeto. Pela orientação segura, empenho e dedicação em nossos trabalhos. Minha admiração e agradecimento pelo exemplo pessoal, profissional e de pesquisadora.

Aos **Professores do Curso de Fonoaudiologia** do Departamento de Fisioterapia, Fonoaudiologia e Terapia Ocupacional da Faculdade de Medicina da Universidade de São Paulo, pelos ensinamentos que me foram transmitidos ao longo desses anos.

Ao **Dr. Nivaldo Alonso** pela confiança em nosso trabalho e viabilização de estudos junto ao Grupo de Cirurgia Cranio-maxilo-facial do Departamento de Cirurgia Plástica e Queimaduras do Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo.

Ao **André** por confiar em mim e estar sempre me incentivando a buscar minhas realizações.

AGRADECIMENTOS

Ao meu irmão, **Paulo**, e minha cunhada, **Elaine**, pelo carinho, incentivo e admiração.

À fonoaudióloga e amiga **Dra. Fernanda Chiarion Sassi**, pelo auxílio, dedicação, companheirismo, compreensão, confiança, e ensinamentos.

Às fonoaudiólogas e amigas **Danielle P. Moraes, Gisele C. de Medeiros, Fabíola S. Juste, Talita Fortunato-Tavares e Beatriz Ercolin** por compartilharem seus conhecimentos e se mostrarem grandes amigas e incentivadoras.

Às **fonoaudiólogas** da Unidade de Apoio de Fonoaudiologia pela alegria e cumplicidade no nosso dia a dia, e pela ajuda e compreensão nos momentos mais difíceis.

Aos **Drs. Endrigo Bastos e Paulo Câmara**, e aos **médicos assistentes, fellowships e residentes** do grupo de Cirurgia Cranio-maxilo-facial do Departamento de Cirurgia Plástica e Queimaduras do HCFMUSP pelo auxílio durante minha permanência no grupo. Agradeço pelo auxílio à pesquisa, pela recepção junto ao grupo e por confiar em nosso trabalho.

À **Unidade de Apoio de Fonoaudiologia do ICHC** e ao **Departamento de Cirurgia Plástica e Queimaduras do HCFMUSP**, que viabilizaram este estudo. Obrigada a todos os profissionais e funcionários

AGRADECIMENTOS

que estiveram envolvidos neste trabalho e pela convivência durante esta etapa.

Aos **pacientes deste estudo e seus familiares**, pela confiança e pelos momentos de aprendizado e satisfação profissional.

Ao **Aristides Correia**, pelo cuidado na análise estatística deste trabalho.

A **Maria Cristina Correra de Godoy e Maria Beatriz Leite Costa**, pela disponibilidade e carinho com que sempre me auxiliaram.

Aos meus **familiares** por sempre me darem coragem para buscar a minha realização e por compreenderem o meu percurso.

Esta dissertação está de acordo com as seguintes normas, em vigor no momento desta publicação:

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Abreviaturas dos títulos dos periódicos de acordo com *List of Journals Indexed in Index Medicus*.

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LISTA DE ABREVIATURAS E SIGLAS

FMUSP: Faculdade de Medicina da Universidade de São Paulo

ICHC: Instituto Central do Hospital das Clínicas

UTI – MI: Unidade de Terapia Intensiva de Moléstias Infeciosas

CAPES: Coordenação de Aperfeiçoamento de Pessoal de nível Superior

UTIs: Unidades de Terapia Intensiva

LIM: Laboratório de Investigação Médica

HC-FMUSP: Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo

CPRTI: Comissão Permanente do Regime de Tempo Integral

EG: *experimental group*

IC: *intructed group*

CG: *controlled group*

sEMG: *surface electromyography*

TMJ: *temporomandibular joint*

NHANES III: *Third National Health and Nutrition Examination Survey*

CAPPesq HCFMUSP: Comissão de Ética para Análise de Projetos de Pesquisa do Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo

OMES Protocol: *The Orofacial myofunctional evaluation protocol with scores*

MVC: *maximum voluntary teeth clenching on cotton rolls*

CI: *confidence interval*

CPGs: *Central Pattern Generators*

ICU: *intensive care unit*

OD: *oropharyngeal dysphagia*

LISTA DE ABREVIATURAS E SIGLAS

SLP: *Speech-Language pathologists*

ASHA: *American Speech-Language-Hearing Association*

ASHA NOMS: *American Speech-Language-Hearing Association National Outcome Measurement System*

TROF: *time until reintroduction of oral feeding*

TUD: *time until decannulation*

TRFT: *time until removal of feeding tubes*

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Mangilli LD. *Programa de avaliação e tratamento fonoaudiológico para a reabilitação da função mastigatória de indivíduos submetidos à cirurgia ortognática por deformidade dentofacial*. [tese]. São Paulo: Faculdade de Medicina, Universidade de São Paulo; 2012.

INTRODUÇÃO: Indivíduos com deformidade dentofacial apresentam alterações faciais verticais e/ou ântero-posteriores, com conseqüente presença de oclusão instável e pobre intercuspidação dentária, que podem causar comprometimentos nas funções do Sistema Miofuncional Orofacial sendo verificadas geralmente adaptações funcionais para cada tipo de deformidade. O objetivo desta tese foi realizar um ensaio clínico randomizado cuja variável de relevância foi a resposta funcional da mastigação após intervenção fonoaudiológica experimental em pacientes submetidos à cirurgia ortognática. **MÉTODOS:** Todos os pacientes submetidos à cirurgia ortognática, num período de 12 meses, que concordaram em participar do estudo. Os pacientes foram randomicamente distribuídos em dois grupos: grupo experimental (EG=6) e grupo de instrução (IG=5). O grupo controle foi constituído por indivíduos com oclusão dentária normal (CG=6). Os pacientes do EG foram submetidos a um protocolo de tratamento fonoaudiológico estruturado em seis sessões com enfoque técnico na função da mastigação. Os pacientes do IG foram submetidos a duas sessões supervisionadas de instruções direcionadas aos cuidados com a mastigação (tratamento padrão). As variáveis adotadas para a comparação dos grupos foram obtidas por meio de avaliação clínica e de avaliação eletromiográfica de superfície (EMGs), sendo elas: mobilidade orofacial, desempenho durante as funções de deglutição/mastigação, movimentos mandibulares e atividade elétrica dos músculos mastigatórios. Esses parâmetros foram avaliados pré e pós-cirúrgico longo prazo (12 meses). Os indivíduos do CG foram testados em dois momentos distintos com um intervalo de 12 meses entre os mesmos. **RESULTADOS:** após um ano da realização da cirurgia ortognática o EG apresentou melhora significativa na mobilidade orofacial ($p = 0,001$); no desempenho durante as funções de deglutição/mastigação ($p = 0,001$); na lateralização da mandíbula ($p = 0,001$) e na protrusão da mandíbula ($p = 0,011$). Os dois grupos de pacientes (EG e IG) não apresentaram diferenças significativas para os resultados da EMGs – atividade elétrica dos músculos mastigatórios - nos diferentes momentos. O CG não apresentou variações significativas de desempenho para qualquer das variáveis investigadas na comparação entre os diferentes momentos. **CONCLUSÃO:** os resultados sugerem que o tratamento fonoaudiológico experimental demonstrou resultado positivo. Não foram identificados efeitos adversos. Houve aderência ao tratamento. O tamanho da amostra, embora relevante para a área, exige cuidado quanto ao poder de generalização dos resultados.

Descritores: 1. Mastigação; 2. Cirurgia Ortognática; 3. Sistema Estomatognático; 4. Avaliação; 5. Resultado de Tratamento.

Mangilli LD. *Evaluation and treatment program for the rehabilitation of mastication of patients who underwent orthognathic surgery for dentofacial deformity*. [tese]. São Paulo: Faculdade de Medicina, Universidade de São Paulo; 2012.

INTRODUCTION: Individuals with dentofacial abnormalities present facial alteration - in the vertical and/or anterior posterior plane -, with consequent unstable occlusion and poor dental intercuspation. These alterations can cause impairments in the functions of the orofacial myofunctional system, and functional adaptations are usually observed for each type of deformity. The aim of this thesis was to conduct a randomized clinical trial that the relevance variable was the functional response of the mastication after the rehabilitative experimental program in patients submitted to orthognathic surgery. **METHODS:** All patients underwent to the orthognathic surgery, in a period of 12 months, which agreed to participate of this study. Patients were randomized assigned into two groups: experimental group (EG = 6) and group instruction (GI = 5). A control group consisted of individuals with normal dental occlusion (CG = 6). The EG patients underwent a structured treatment protocol, in six sessions, with technical focus was on the function of mastication. Patients in the IG were submitted to two supervised sessions for instruction related to the look out of mastication (standard treatment). The variables adopted for the comparison groups were obtained by clinical evaluation and by assessment of surface electromyography (sEMG) that was: orofacial mobility, masticatory/deglutition clinical performance, jaw movements and muscle activation (electrical activity) of the masticatory muscles. These parameters were evaluated pre-and postoperative long-term (12 months). The subjects in the CG were also tested in two distinct moments, with a one year interval. **RESULTS:** One year after orthognathic surgery, EG showed a significant improvement in orofacial mobility ($p=0.001$), masticatory/deglutition clinical performance ($p=0.001$), jaw lateralization ($p=0.001$) and jaw protrusion ($p=0.011$). Both groups of patients presented no significant differences for the sEMG results. The CG presented no significant variations in performance for any of the investigated variables when comparing the different time points. **CONCLUSION:** The results suggest that the rehabilitative experimental program demonstrated a positive result. No adverse effects were identified. There was adherence to the treatment. The sample size, although relevant to the area, requires careful about the power of generalization of the results.

Descriptors: 1. Mastication; 2. Orthognathic surgery; 3. Stomatognathic System; 4. Evaluation; 5. Treatment Outcome.

A escolha da temática desta tese baseou-se em alguns questionamentos atuais sobre o sistema miofuncional orofacial e sobre a atuação fonoaudiológica. Nos doze anos de vivência nesta área verifico algumas situações deficitárias em relação à comprovação com base científica dos resultados da prática fonoaudiológica, onde são observados os benefícios e aplicações positivas de terapêuticas específicas.

Há pouca evidência científica que demonstre o processo de reabilitação do sistema miofuncional orofacial nos casos de alterações, principalmente nas relacionadas às deformidades craniofaciais. Poucos estudos discorrem sobre como ocorre o retorno das funções orofaciais após a alteração e/ou lesão, não sendo comprovadas ainda possíveis intervenções.

A exposição de todos esses anos à prática fonoaudiológica demandou muito estudo e, principalmente, propiciou grande crescimento profissional. Um dos conceitos que considero de grande relevância na área são os preceitos da prática baseada em evidências, que permitem e permitirão a validação da prática fonoaudiológica, assim como a busca pela determinação de melhores técnicas e abordagens. A utilização de princípios metodológicos na fonoaudiologia é de extrema necessidade.

No ano de 2002 concluí o bacharelado em Fonoaudiologia pela Faculdade de Medicina da Universidade de São Paulo. Nos quatro anos em

que desenvolvi minhas atividades discentes pude experienciar os primeiros contatos com a pesquisa científica, participando da elaboração e efetivação de projetos de pesquisas, apresentando-os em congressos da área, conjuntamente com os professores do curso, inclusive com minha atual orientadora Profa. Dra. Cláudia R. F. de Andrade. Também conclui o projeto de iniciação científica - **Compreensão e nomeação de fotografias e figuras em crianças de cinco e seis anos e com quadros psiquiátricos** – sob orientação da Profa. Dra. Cláudia I. Scheuer, o qual gerou minha primeira publicação em periódico nacional de impacto da área, no ano de 2004. Percebi que esta atividade me agradava muito, mas que essa linha de pesquisa ainda não era a mais adequada ao meu perfil.

Entre 2003 e início de 2005 exerci a atividade profissional em um consultório particular, cujo aprendizado foi de grande importância para o delineamento da linha de pesquisa que desenvolveria dali em diante. Foi com a Dra. Esther M. G. Bianchini e em seu consultório que adquiri o conhecimento e a prática na área de motricidade orofacial, principalmente na subárea da atuação fonoaudiológica junto às alterações Crânio-Maxilo-Faciais.

Meu retorno à Universidade ocorreu no ano de 2005, quando a Profa. Dra. Cláudia R. F. de Andrade me recebeu em seu Laboratório de Investigação Fonoaudiológica da FMUSP. Essa reinserção possibilitou o meu ingresso nas atividades de pesquisa das Funções da Face do ICHC. Na

época, a Profa. Dra. Claudia R. F. de Andrade estava estruturando um Serviço de Fonoaudiologia no ICHC, nos moldes do que se espera de um serviço de fonoaudiologia: responsabilidade, ética, compromisso e ciência. Minha atividade, nesta etapa, foi associada a uma das ações desse processo de implantação do serviço, e foi direcionada à parceria da Fonoaudiologia com a Divisão de Moléstias Infecciosas e Parasitárias do ICHC.

A Unidade de Terapia Intensiva de Moléstias Infecciosas do ICHC (UTI – MI) apresentava uma grande demanda de pacientes internados com diagnóstico de tétano com dificuldades de alimentação, que não recebiam o atendimento fonoaudiológico necessário. Foi então sistematizado um projeto de pesquisa voltado a essa realidade clínica, que consistiu em: observação e planejamento estratégico para diagnóstico; avaliação e tratamento dos pacientes com doenças pertinentes a esta UTI (tétano, botulismo, leptospirose, tuberculose, hepatite, febre hemorrágica, AIDS etc.). Após um período de seis meses foi elaborado o projeto de minha dissertação de mestrado - **Disfagia e Tétano - caracterização fonoaudiológica de pacientes em UTI** – que foi finalizado em 2008, originando dois estudos científicos, já publicados em periódicos internacionais de impacto nas áreas de Medicina Tropical e Reabilitação Orofacial. O primeiro deles foi publicado no ano de 2009, no periódico *Acta Tropica*, e é referenciado como: Mangilli LD, Sassi FC, Santos SS, Andrade CRF. Oral sensorimotor function for feeding in patients with tetanus. *Acta Tropica*. 111:316-320, 2009. Em 2011,

no periódico *Oral Rehabilitation* foi publicado o segundo artigo, referenciado como: Mangilli LD, Sassi FC, Jacomo A, Andrade CRF. Evaluation of oral-motor movements and speech in patients with tetanus of a public service in Brazil. *Journal of Oral Rehabilitation*. 38:564-570, 2011.

Essa parceria está consolidada – Divisão de Fonoaudiologia do ICHC e à Disciplina de Moléstias Infecciosas e Parasitárias do ICHC e hoje tanto a UTI quanto a enfermaria de Moléstias Infecciosas e Parasitárias passaram a ter cobertura diária da Fonoaudiologia. O modelo de avaliação e tratamento propostos inicialmente continuou a ser aplicado, e modificações/atualizações com base na prática baseada em evidências foram e tem sido consideradas.

Após a concretização dessa etapa, foi iniciado um novo desafio. O intuito então foi a aproximação da Fonoaudiologia e da Disciplina de Cirurgia Plástica e Queimaduras do ICHC, com o objetivo de estudar e aperfeiçoar o acompanhamento fonoaudiológico dos pacientes desta clínica; uma vez que a ocorrência de alterações do sistema miofuncional orofacial é prevalente nas patologias acompanhadas pela mesma.

A equipe da Disciplina de Cirurgia Plástica e Queimaduras do ICHC não contava com a participação da Fonoaudiologia direta e estruturada nos moldes dos princípios metodológicos para avaliação e tratamento dos pacientes. Os pacientes que necessitavam de tratamento fonoaudiológico eram encaminhados para reabilitação após a constatação de um problema

e/ou dificuldade, muitas vezes num momento tardio, no qual o padrão de alteração já se encontrava instalado. Muitas vezes esse trabalho era desenvolvido fora do hospital. Ainda em 2008 foi estruturada e oficializada a nova parceria, e o Serviço de Fonoaudiologia do ICHC assumiu o acompanhamento fonoaudiológico dos indivíduos atendidos pela Disciplina de Cirurgia Plástica e Queimaduras. Novamente fez-se um período de estudo, observação e planejamento estratégico para diagnóstico, avaliação e tratamento dos pacientes e após este período foi elaborado o projeto de pesquisa de minha Tese de Doutorado - **Programa de avaliação e tratamento fonoaudiológico para a reabilitação da função mastigatória de indivíduos submetidos à cirurgia ortognática por deformidade dentofacial**. Este estudo se desenvolveu nos três anos subseqüentes - tendo sido o primeiro ano subsidiado por Bolsa de Fomento da CAPES - e é aqui apresentado como o primeiro estudo da tese, intitulado *Rehabilitative management of mastication after orthognathic surgery: a randomized controlled trial*.

Novamente a parceria atingiu seus objetivos e hoje contamos com atividades concretas e consolidadas junto à Disciplina de Cirurgia Plástica e Queimaduras. Atualmente o Serviço de Fonoaudiologia do ICHC dispõe de seis profissionais para o desempenho das atividades direcionadas aos pacientes “da plástica”, e pelo menos mais cinco alunos de graduação e pós-graduação acompanham essas atividades anualmente, buscando-se a formação de profissionais com experiência na área. Muitos estudos

científicos têm sido desenvolvidos, e projetos de pesquisas delineados para o futuro.

No ano de 2010, fui contratada pela Divisão de Fonoaudiologia do ICHC. Desde essa data venho desempenhando formalmente a função de gerenciar as atividades desempenhadas pelos fonoaudiólogos do serviço junto às unidades de internação do ICHC (UTIs e enfermarias) e junto aos Ambulatórios de Função da Face, que hoje englobam as patologias relacionadas às Deformidades Craniofaciais, Traumas de Face, Alterações na Articulação temporomandibular, Fissuras labiopalatinas, Paralisia Facial, Queimaduras de face e pescoço e Síndrome da Apnéia Obstrutiva do Sono.

No ano de 2011 me inscrevi no concurso para Pesquisador Científico I dos LIMs – Laboratórios de Investigação Médica do HC-FMUSP (Edital CPRTI nº 001/2011) para concorrer à vaga de Fonoaudiólogo. Após longo período de preparação e da realização do concurso público, pude comemorar mais essa conquista, fui indicada como pesquisadora científica. No ano de 2012 inicio uma nova etapa, tendo agora como atividade o desempenho da função de Pesquisador Científico na área de Fonoaudiologia, no Laboratório de Investigação Médica LIM - 34 do HC-FMUSP.

Essa tese é apresentada na forma de dois artigos científicos. No final do ano de 2011 houve mudanças nas regras da Pós-graduação da

Faculdade e foi permitido ao aluno de pós-graduação que defendesse seu estudo com a apresentação de artigo científico decorrente do mesmo, aprovado para a publicação em periódico arbitrado. Buscamos apresentar essa tese nestes moldes, mas frente ao curto prazo de tempo que decorreu desde a divulgação desta norma, não foi possível a conclusão do processo de confirmação do aceite do primeiro estudo aqui apresentado. O mesmo foi enviado a periódico arbitrado e encontra-se em análise.

Durante o meu doutorado foi desenvolvida uma pesquisa paralela, que foi um desdobramento do estudo do mestrado. A idéia dessa pesquisa – a proposição de um programa de reabilitação da função de deglutição e dos movimentos orofaciais de pacientes com tétano – surgiu a partir da sugestão de um dos revisores da *ACTA TROPICA* propondo que fosse desenvolvido um procedimento clínico de acompanhamento dos pacientes com tétano. Essa pesquisa foi concluída e originou o segundo artigo científico aqui apresentado, já aceito para a publicação na *ACTA TROPICA*, intitulado *Rehabilitative management of swallowing and oral-motor movements in patients with tetanus of a public service in Brazil*.

Assim, compõem essa tese os dois artigos oriundos das duas pesquisas realizadas no período. A partir do doutoramento, com a entrada na carreira de pesquisadora, poderá então ser delineada uma linha de pesquisa sólida, voltada para os estudos das funções da face.

REHABILITATIVE MANAGEMENT OF MASTICATION AFTER ORTHOGNATHIC SURGERY: A RANDOMIZED CONTROLLED TRIAL

ABSTRACT

Objective: To verify the effectiveness of a systematic rehabilitative program for mastication in patients submitted to orthognathic surgery.

Design: A randomized controlled trial was undertaken.

Subjects: Eleven patients were randomly assigned to an experimental group (EG) (n=6) or instruction group (IG) (n=5). A control group (CG) with 6 individuals with normal dental occlusion was included.

Interventions: The EG underwent a 6 session orofacial myofunctional treatment protocol and the IG received 2 supervised sessions for instruction related to perception of the stomatognathic system and adequate performance during mastication.

Main measures: Outcome variables were orofacial mobility, masticatory/deglutition clinical performance, jaw movements and muscle activation verified through surface electromyography (sEMG). Outcome measures assessed before and one year after orthognathic surgery. The CG was also tested in two distinct moments (one year interval).

Results: One year after orthognathic surgery, EG showed a significant improvement in orofacial mobility ($p=0.001$), masticatory/deglutition clinical performance ($p=0.001$), jaw lateralization ($p=0.001$) and jaw protrusion ($p=0.011$). The IG showed a significant improvement in the masticatory/deglutition clinical performance ($p=0.049$) and in jaw protrusion

($p=0.016$). Both groups of patients presented no significant differences for the sEMG results. The CG presented no significant variations in performance for any of the investigated variables when comparing the different time points.

Conclusion: The results suggest that patients who underwent orthognathic surgery can benefit from rehabilitative orofacial myofunctional techniques. Further research is warranted to compare outcomes obtained in long-term follow-ups.

Keywords: clinical evaluation; controlled clinical trial; electromyography; exercise program; motor control

INTRODUCTION

Orthognathic surgery combined with orthodontic treatment aims to reestablish the harmony of a maxillomandibular relationship, promoting variations in facial skeleton that may ultimately change the muscular and functional activities ^{1,2} – i.e. improves occlusal contacts ³⁻⁶, masticatory efficiency ^{4,6}, the eletromyographic activity of the masticatory muscles ⁶⁻⁸, the bite force ^{4-6,9,10} and thickness of the masseter muscle ⁸. Therefore, it is important for the clinician to be able to accurately predict the soft tissue changes resulting from alterations of hard tissue ^{11,12}.

ARTIGO 1: REHABILITATIVE MANAGEMENT OF MASTICATION AFTER
ORTHOGNATHIC SURGERY: A RANDOMIZED CONTROLLED TRIAL

Dentofacial abnormalities refer to an abnormal position of the mandible, the maxilla or both. Patients with dentofacial abnormalities may experience problems in mastication and in producing clear speech, may present adaptations of the oral motor system and important functional compromise of the stomatognathic apparatus, and may also have temporomandibular joint (TMJ) syndrome ^{4,13-17}. According to data from the Third National Health and Nutrition Examination Survey - NHANES III ^{18,19}, which was conducted between 1989 and 1994, malocclusions falling into categories outside the limit of orthodontic correction alone (severe Skeletal Class II and III) occur in about 4% of the population. Other studies, however, indicate that dentofacial deformities (isolated to the jaw or extended to multiple craniofacial structures), affect about 20% of the population ^{20,21}.

During orthognathic surgery, structural modifications are performed very rapidly. These modifications, more frequently than often, have an impact on the physiology of the stomathognathic apparatus ²². In order for soft tissue structures to execute their functions adequately, new neuromuscular schemes are necessary ^{8,23}. Literature indicates that this is a very difficult step in treatment and that inadequate adaptive patterns can be installed and perpetuate if intervention is inappropriate ²³.

Previous research has suggested that patients with severe skeletal deformities have impairments in movement outside the range of that seen in unaffected individuals ^{24,25}. If functional impairments exist presurgically in

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orthognathic surgery patients, and should these impairments persist postsurgically, there may be an increased susceptibility to postsurgical hard-tissue relapse because of a lack of soft tissue adaptability. Therefore, restoration of normal function and long-term stability are indispensable for successful surgical procedures for the correction of dentofacial deformities. Both function and stability, however, may be compromised by inadequate or incorrect postoperative muscular rehabilitation after orthognathic surgery. Muscle atrophy, denervation, alteration of fiber types, myofibrosis, decreased muscle mass, and morphologic alterations of the condyle are biologic consequences of orthognathic surgery and intermaxillary fixation which can have profound clinical consequences^{23,26,27}.

The orthognathic surgery can produce complications during the postoperative period - i.e. situations of acute pain and inflammation – as a consequence of fractures and incisions in the mucosa. The inadequate management of soft tissue and prolonged surgical time could be the causes of acute facial oedema, hematoma and ecchymosis in the face and neck, as well as functional disorders involving swallowing and breathing, which can affect patients' integrity²².

To evaluate the success of orthognathic surgery, surgeons have relied on patient's satisfaction and the long-term stability of results. However, for the evaluation of surgical outcomes on functional ability, the parameters of mastication provide a more appropriate assessment of function^{4,11,28}. A

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number of parameters to quantify the function of the masticatory system have already been reported. These include chewing efficiency, maximum bite force, electromyography activity of the masticatory muscles, and maximum range of mandibular motion^{6,8,11,15,16,29}.

Several studies have reported that individuals with dentofacial deformities, when compared to individuals with normal dental occlusion, have lower EMG activity in the masticatory muscles^{4,7,8,15,28,30,31}, lower occlusal force^{8,15,28,30-33}, few occlusal contacts^{4,8,34}, and lower masticatory efficiency^{8,15,35}. In some studies, chewing efficiency improved after surgical correction but did not reach control values^{15,35}; in others, improvement could not be shown^{15,36,37}. Long-term increases in maximum voluntary bite forces after surgery have been reported, but effects of orthognathic surgery on the occlusal forces generated during mastication remain unknown²⁸.

Despite the fact that decreased muscular extensibility and strength, increased muscular fatigability, hipomobility, and alteration of the biomechanical efficiency and length of the masticatory muscles are documented clinical consequences, no systematic method of obviating such problems through muscular rehabilitation has yet been published^{23,38}.

The purpose of this study was to verify the effectiveness of a systematic rehabilitative program for mastication in patients submitted to orthognathic surgery.

METHODS

This clinical trial was set in an experimental study. Intragroup and intergroup differences (experimental groups and control group) were evaluated. The experimental period was from March 2009 to October 2011. Before enrollment, all subjects signed informed consent to participate in the study, which was approved by the Ethics Committee of the University of São Paulo, Brazil (CAPPesq HCFMUSP 0373/09).

Participants

The target population consisted of Skeletal Class III orthognathic surgery patients. Patients were diagnosed by the team of surgeons and dentists of the Department of Reconstructive Plastic Surgery and Burns of a large Brazilian School Hospital (*Hospital das Clínicas*): 42 patients were classified as Skeletal Class III; 16 patients were classified as Skeletal Class III as a consequence of cleft palate (surgically repaired); 1 patient was classified as Skeletal Class III as a consequence of facial trauma (surgically repaired); 4 patients were classified as Skeletal Class III as a consequence of acromegaly (clinically treated); 5 patients were classified as Skeletal Class III as a consequence of syndrome – e.g. Crouzon, Apert, Rubeinstain-Tauby.

Inclusion criteria were: adults (age above 18 years), agreement to perform orthognathic surgery and to undergo all of the necessary procedures

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determined by the multidisciplinary team (i.e. orthodontic preparation, clinical orofacial myofunctional and electromyographic assessment, surgery, post surgery orthodontic treatment, post surgery clinical orofacial myofunctional and electromyographic assessment and orofacial myofunctional treatment when necessary). Exclusion criteria were: previous orthognathic surgery; previous head and neck surgery; neurologic and/or systemic diseases; facial trauma; syndromes; cognitive impairment; and communication and hearing deficits.

Out of the 68 patients in the accessible population, 57 were excluded, and the remaining 11 patients were randomly assigned to an experimental group (n=6) or instruction group (n=5). The groups were balanced by age by using a stratification system that generates a sequence of numbers (from a table of correctively ordered permutations). The sequence assigned to patients was placed in envelopes containing the allocation to each study group.

All patients were submitted to orthodontic treatment before and after surgery and to orofacial myofunctional follow-up. Presurgical orthodontic treatment was performed in order to align level and decompensate the teeth. After orthognathic surgery, occlusal adjustments were made to obtain the largest possible number of dental contacts during bite. Surgical treatments were performed with bilateral sagittal split ramus osteotomy and/or combined

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LeFort I, and surgical stabilization was performed with internal rigid fixation with titanium mini bone plates and screws.

Data from the literature indicate that individuals submitted to orthognathic surgery present improvement in mastication after surgery. However, these patients, when compared to subjects with normal dental occlusion, still present lower performances when considering the masticatory muscles. For this reason a control group, composed by 6 individuals with normal dental occlusion were included in the study. Inclusion criteria for this group were: adults (age above 18 years); absence of stomatognathic system alterations; absence of alterations in the scapular region; complete permanent dentition (absence/extraction of the third molar was accepted); Skeletal and Angle's Class I facial pattern; and absence of malocclusion. Exclusion criteria were: previous orthodontic treatment; and history of previous oral motor intervention.

The flow of participants is illustrated in Figure 1.

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Figure 1. Flow of participants through the randomized trial.

Procedures

The methodology and procedures adopted for orofacial myofunctional assessment are described below:

Clinical Assessment

Participants of all groups underwent clinical assessment. Individuals were examined while sitting on a chair in a room with appropriate lighting.

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The Orofacial myofunctional evaluation with scores (OMES Protocol) ³⁹ was used for this assessment. This protocol was constructed based on previous models of evaluation, with the addition of numerical scales that reflect the physical characteristics and orofacial behaviors of the subjects. The reliability and validity of these measures were demonstrated previously ³⁹⁻⁴¹.

The evaluation was performed, according to a protocol, and the components of the stomathognathic system, i.e., lips, tongue, jaw, and cheeks, were evaluated in terms of mobility and performance during deglutition and mastication functions. The individuals were evaluated individually by visual inspection during the session and the evaluation was later complemented by the analysis of images recorded on a digital camera (DMC-FS3LB-P, Panasonic).

For the evaluation of mobility, the individuals were asked to perform separate movements of the lips, tongue, jaws and cheeks. In the analysis, separate movements of each component, precise and without tremor, were considered to be normal. Dysfunction was considered to be present when lack of precision in the movement, tremor, associated movements of other components (e.g. lips accompanying the movements of the tongue) and inability to perform the movement were observed. The examiner attributed scores using a 3-point scale: 3 = normal; 2 = insufficient ability and 1 = absence of ability or being unable to perform the task.

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To complement the analysis, the extension measurements (in mm) of the jaw movements were also considered and carried out using a digital caliper sliding type - Digimess Pró-Fono; Pró-Fono Produtos Especializados para Fonoaudiologia Ltda, Brazil.

For deglutition, the pattern was considered to be normal when the individuals presented the tongue contained in the oral cavity, contraction of elevator muscles, and anterior sealing of the oral cavity without effort. For mastication, the subject was instructed to chew the food in habitual manner. In the analysis of images recorded on video, the following parameters were considered: chewing, whether alternated bilateral, simultaneous bilateral, chronic unilateral (95% of the time on the same side of the cavity), or anterior; unilateral chewing preference (66% of the time on the same side), or anterior, and total time needed to consume the food measured with a digital chronometer (Nike, WR0016-001P – 10 LAP).

As described in the specific protocol, chewing and deglutition function were scored as normal (3), mild dysfunction (2), or severe dysfunction (1). Other behaviors (e.g. movement and/or altered posture of the head and of other parts of the body, food escape and uncoordinated jaw movements) were defined as normal when they received a score of 2 and altered when they received a score of 1.

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All participants were evaluated by two experienced speech-language pathologists. The examiners were properly calibrated in orofacial myofunctional evaluation and presented a high level of agreement (>0.87).

Surface Electromyography (sEMG) Evaluation

Two muscle groups were examined in the study: the anterior temporal muscles and the masseter muscles.

All EMG recordings were made using standard surface sensors (SDS500). We used the Miotool 400 (Miotec® Biomedical Equipments, Brazil) 4-channel computer-based system and disposable double electrodes (SDS 500 Ag/AgCl, contact surfaces with 10mm diameter). This EMG system has wide bandpass filter, bandwidth (RMS) 20 to 500 Hz and a 60-Hz notch filter. The system uses the Active Electrode, a compact sensor assembly that includes a miniaturized instrument preamplifier. Locating the amplifier at the electrode site allows artifacts to be canceled and the signal boosted before being transferred down the electrode cable (noise level $< 5\mu\text{V}$ RMS). Each EMG record was full-wave and low-passed filtered. The computer program indicates mean, SD, minimum, maximum and range of muscle activity during each trial. Muscle activity (EMG) was quantified in microvolts (μV).

The interelectrode distance was 10mm; four sets of two bipolar pre-gelled stick-on surface electrodes were applied to the skin on each side of

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the face, over the anterior temporal muscles and masseter muscles to record myoelectrical activity during specific tasks involving the masticatory muscles. This electrode arrangement had a third electrode as ground positioned on the right wrist. Electrical impedance at the sites of electrode contact was reduced because skin was scrubbed with alcohol gauze pads.

The electric activity of the above mentioned muscles were assessed during ^{1,5}:

- Rest - Participants remained seated with their heads positioned horizontally according to the Frankfort plane. After the pairs of EMG electrodes were placed over the skin each participant was instructed to remain quiet and relaxed for the period of 1 minute. Three separate recordings of resting condition were made, with the duration of 30 seconds each;
- Maximum voluntary teeth clenching on cotton rolls (MVC) – two 10mm thick cotton rolls were positioned on the mandibular second premolars/first molars of each subject. The subject was invited to clench as hard as possible, and to maintain the same level of contraction for 5s; during tests performance, the subjects were verbally encouraged to perform at their best. All subjects repeated the test three times;

To avoid any fatigue effect, a rest period of at least 3 minutes was allowed between each test. Subjects were instructed that, during clenching, they should not feel additional muscular/articular pain.

sEMG Data analysis

Surface EMG traces were evaluated for onset, peak and offset of activity during clenching events (Figure 2). Onset was identified as the point of upward excursion of the sEMG trace from resting baseline that led into the clenching event. Peak was the highest amplitude point of the sEMG clenching trace. Offset was the point at which sEMG activity returned to baseline. Computer software calculated the mean value of the action potential during the movements (onset-peak-offset). In order to compare the results between participants, sEMG amplitude values were normalized relative to rest in order to give evidence to possible differences.

In order to perform intra and between group comparisons, the average sEMG amplitude obtained in all teeth clenching tasks was standardized against the activity of the rest task.

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Note: sEMG trace of the anterior temporal muscle, left side, during the clenching task; ON = onset; OFF = offset.

Figure.2. sEMG trace

sEMG Data reliability

Because subjective judgment was used for sEMG measures, interjudge reliability was estimated. To establish interjudge reliability of the measurements used in the study, a second experienced staff member, who was blinded to the original results, measured the same parameters of 15 randomly selected samples from the 51 total clenching events. Intraclass correlation coefficients were high for all comparisons (range of lower 95% confidence interval [CI] = .9433-.9859), suggesting strong consistency between examiners.

Intervention protocol

Figure 3 describes the times of assessment, follow-up and procedures adopted for each group:

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Note: EG=experimental group; IG=instructed grup; CG=control group

Figure 3. Times of assessment, follow-up and procedures for each group

Intervention procedures are described below:

Experimental Group (EG)

Patients in the experimental group underwent an orofacial myofunctional treatment protocol. Rehabilitation sessions were conducted based on current strategies of oral-motor therapy^{23,36,42-52}. This protocol was planned by the speech pathologists on the basis of the following main objectives: favoring drainage of edemas and pain relief; mobility of the masticatory and associated muscles; mandibular posture and mobility without restrictions or deviations; symmetry between masticatory muscle pairs; rehabilitation and coordination of the muscles of the stomatognathic system, as well as equilibration of the stomatognathic functions in a manner compatible with occlusion (i.e. exercises were used to strengthen and improve the posture of lips and tongue, and corrective work was performed on deglutition and mastication).

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The treatment protocol was administered in the following order: orientation and perception of the stomatognathic system; manual drainage of edemas; manipulation and stretching of the neck muscles region; exercises of lips mobility; exercises of tongue mobility; manipulation and stretching of the masticatory muscles (masseter, temporalis, medial and lateral pterygoids) and associated muscles (sternocleidomastoid and trapezius); exercises of the jaw mobility (opening, closing, laterality, protrusion and retraction); strengthening exercises of the buccinators muscles; exercises for the functionality of the orofacial myofunctional system (posture of lips, tongue and jaw; functions of breathing, swallowing and chewing) (Appendix 1).

Once a week for six weeks, the experimental group received a forty minutes session of orofacial myofunctional treatment. A home exercise program was prescribed during each session. The protocol implies in continuous and daily practices - participants were asked to perform exercises at least three times a day. After the first six weeks, the experimental group underwent four sessions for maintenance purposes (two sessions twice a month and two sessions once a month). The total treatment duration was of five months.

Instruction Group (IG)

The instruction group underwent two supervised forty minutes therapy sessions along the six weeks following surgery. These sessions involved the

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perception of the stomatognathic system, especially in terms of adequate performance during mastication. Specific exercises were not given and patients were instructed to try to reproduce the adequate pattern of mastication at all meals (i.e. alternated bilateral, with lip closure; with coordination activity of the tongue and mandible).

Control group (CG)

As the sEMG test–retest is a critical issue ^{4,5,53}, participants of CG were also tested in two distinct moments (testing occurred with 1 year interval) in order to verify possible changes in the sEMG measurements as a result of retesting.

Data Analysis

All quantitative data were entered in a SPSS 17.0 database. The Shapiro-Wilk and Levene tests indicated that data presented a normal and homogeneous distribution. For this reason, the ANOVA test was used for within and between group comparisons ($p < 0.05$).

RESULTS

Table 1 shows a description of the general data regarding age, mobility (OMES), performance during deglutition and mastication functions

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(OMES), jaw movements (OMES) and MVC at baseline (i.e. pre assessment moment). As observed, statistical analysis indicated no significant differences among the groups for age. Most of the other aspects presented significant differences.

Table 1. Significant between-group baseline differences

	Patients (n=11)		Control Group	p value
	EG (n=6)	IG (n=5)	CG (n=6)	
Age (years)				
Mean (SD)	28.67 (6.09)	26.50 (5.55)	29.33 (4.76)	0.704
Mobility (OMES)				
Mean (SD)	43.50 (3.94)	40.80 (3.90)	49.83 (4.36)	0.007*
Performance				
deglutition/mastication				
(OMES)				0.001*
Mean (SD)	17.00 (1.55)	16.40 (2.30)	20.50 (0.84)	
Jaw movements in mm				
(OMES)				
Opening - Mean (SD)	44.70 (6.11)	46.54 (2.87)	53.17 (5.64)	0.034*
Lateralization R – Mean (SD)	4.34 (2.33)	5.39 (0.091)	8.64 (1.30)	0.001*
Lateralization L – Mean (SD)	7.39 (3.10)	4.74 (1.85)	9.13 (1.60)	0.024*
Protrusion – Mean (SD)	4.85 (1.49)	6.53 (2.11)	8.34 (1.73)	0.014*
MVC				
Temporal R - Mean (SD)	18.22 (13.02)	15.79 (6.80)	34.74 (17.59)	0.066
Temporal L – Mean (SD)	18.43 (17.09)	21.13 (11.51)	44.87 (16.16)	0.020*
Masseter R – Mean (SD)	11.35 (12.69)	10.83 (7.88)	50.30 (44.08)	0.046*
Masseter L – Mean (SD)	12.06 (8.38)	12.88 (8.30)	46.05 (42.19)	0.070

Note: n – number of individuals; EG – experimental group; IG – instruction group; CG – control group; SD – standard deviation; OMES – orofacial myofunctional evaluation with scores; mm – millimeters; MVC – maximum voluntary teeth clenching on cotton roles; R – right; L – left; * significant results

Regarding OMES results, when looking at the multiple between group comparisons, EG and IG did not present significant differences in performance in all of the pre assessment variables (mobility - $p=0.879$; performance in deglutition/mastication – $p=1.00$; jaw opening – $p=1.00$; jaw

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lateralization to the right side – $p=0.947$; jaw lateralization to the left side – $p=0.239$; jaw protrusion – $p=0.418$). As expected, individuals in the CG presented better performances (mobility – IGxCG $p=0.008$; performance in deglutition/mastication – EGxCG $p=0.007$, IGxCG $p=0.003$; jaw opening – EGxCG $p=0.041$; jaw lateralization to the right side – EGxCG $p=0.002$, IGxCG $p=0.018$; jaw lateralization to the left side – IGxCG $p=0.022$; jaw protrusion – EGxCG $p=0.013$).

Regarding sEMG results, significant muscle activation differences were observed only for the left temporal muscle and the right masseter muscle. In both situations, CG presented higher sEMG activity when compared to the groups of patients (left temporal muscle – EGXCG $p=0.03$; right masseter muscle – EGXCG $p=0.047$).

Table 2 shows a description of the general data regarding mobility (OMES), performance during deglutition and mastication functions (OMES), jaw movements (OMES) and MVC after one year follow-up. Statistical analysis indicated several significant differences. Overall, the multiple between group comparisons indicated that EG improved in performance when compared to IG in all variables of the OMES. This improvement was confirmed by significant differences in mobility (EGxIG - $p=0.001$), performance in deglutition/mastication (EGxIG - $p<0.001$) and in lateralization to the right side (EGxIG - $p=0.048$). It is important to highlight that EG presented few follow-up outcomes that were significantly different from CG

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(mobility – EGxCG $p=1.00$, IGxCG $p=0.003$; performance in deglutition/mastication – EGxCG $p=0.874$, IGxCG $p=0.001$; jaw opening – EGxCG $p=0.130$, IGxCG $p=0.010$; jaw lateralization to the right side – EGxCG $p=0.411$, IGxCG $p=0.002$; jaw lateralization to the left side – EGxCG $p=0.036$, IGxCG $p=0.017$; jaw protrusion – EGxCG $p=0.366$, IGxCG $p=0.72$).

Table 2. Significant between-group follow-up differences

	Patients (n=11)		Control Group	p value
	EG (n=6)	IG (n=5)	CG (n=6)	
Mobility (OMES)				
Mean (SD)	52.33 (4.08)	41.60 (2.61)	50.50 (3.73)	0.001*
Performance				
deglutition/mastication (OMES)				
Mean (SD)	21.17 (0.98)	17.60 (1.34)	20.50 (0.84)	0.001*
Jaw movements in mm (OMES)				
Opening - Mean (SD)	46.95 (3.26)	43.00 (3.98)	52.84 (5.59)	0.010*
Lateralization R – Mean (SD)	7.61 (1.11)	5.33 (1.15)	8.87 (1.74)	0.003*
Lateralization L – Mean (SD)	6.43 (2.15)	5.92 (1.05)	9.18 (1.46)	0.010*
Protrusion – Mean (SD)	6.19 (2.16)	5.16 (1.44)	7.86 (1.55)	0.066
MVC				
Temporal R - Mean (SD)	17.79 (12.76)	12.36 (7.01)	45.20 (21.44)	0.006*
Temporal L – Mean (SD)	21.97 (11.70)	9.65 (4.86)	49.86 (30.44)	0.012*
Masseter R – Mean (SD)	9.97 (4.39)	9.56 (7.97)	51.61 (59.20)	0.105
Masseter L – Mean (SD)	13.48 (5.31)	14.49 (15.53)	33.73 (21.80)	0.079

Note: n – number of individuals; EG – experimental group; IG – instruction group; CG – control group; SD – standard deviation; OMES – orofacial myofunctional evaluation with scores; mm – millimeters; MVC – maximum voluntary teeth clenching on cotton rolls; R – right; L – left; * significant results

Regarding sEMG follow-up outcomes, no significant differences between the groups of patients (EGxIG) were observed. Patients continued to present lower significant sEMG activation for the right temporal muscle (EGxCG – $p=0.023$; IGxCG – $p=0.010$) and the left temporal muscle when compared to CG (IGxCG – $p=0.014$).

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Improvements between baseline results and follow-up assessments were verified by within group comparisons considering pre assessment results and those obtained one year after surgery (OMES and sEMG evaluations). As shown on Table 3, EG presented significant improvement in most of the OMES variables, while individuals in IG presented improvement in only two aspects of the assessment. Both groups of patients presented no significant differences for the sEMG results. Once again, CG presented no significant variations in performance for any of the investigated variables when comparing the different time points.

Table 3. Within group significant differences for OMES and sEMG results

Baseline x Follow-up	EG (p-value)	IG (p-value)	CG (p-value)
Mobility (OMES)	0.001*	0.420	0.461
Performance			
deglutition/mastication (OMES)	0.001*	0.049*	1.000
Jaw movements in mm (OMES)			
Opening	0.271	0.121	0.871
Lateralization R	0.001*	0.943	0.745
Lateralization L	0.383	0.331	0.967
Protrusion	0.011*	0.016*	0.310
MVC			
Temporal R	0.936	0.559	0.065
Temporal L	0.635	0.173	0.505
Masseter R	0.805	0.836	0.814
Masseter L	0.836	0.829	0.087

Note: OMES – orofacial myofunctional evaluation with scores; sEMG – surface electromyography; n – number of individuals; EG – experimental group; IG – instruction group; CG – control group; SD – standard deviation; ; MVC – maximum voluntary teeth clenching on cotton rolls; R – right; L – left; * significant results

DISCUSSION

Recently, increased regulation has required rehabilitation programs to report their results and outline the goals of the rehabilitation process

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effectively and efficiently. Evidence-based rehabilitation focuses on establishing relationships between interventions and results. Because this practice analyzes results based on evidence, it requires professionals in the field to identify, implement, and organize the goals of the rehabilitation process in order to improve its effectiveness⁵⁴⁻⁵⁷.

Although our study has limitations, such as a small sample size, it is the first randomized controlled trial to investigate the effects of a systematic rehabilitative program for patients submitted to orthognathic surgery. Overall, the results indicated that patients who underwent the rehabilitative program (EG) presented significant improvement in almost all orofacial myofunctional clinical variables. Patients in IG, however, presented improvement in aspects related to performance in deglutition and mastication. This can be explained by the fact that the two supervised therapy sessions involved the perception of adequate performance during mastication. Based on these results, patients in IG will be invited to undergo the rehabilitative program.

We found that the proposed set of exercises had no influence on the recovery of muscle activation as measured by the electrical muscle potential captured during MVC. This finding is in agreement with other studies that detected no changes in the EMG activity of masticatory muscles 12-18 months after surgery^{4,35}. Our results suggest that for patients submitted to orthognathic surgery, the recovery of the masticatory function precedes the physiological recovery of muscle function.

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Because skeletal Class III patients have both a jaw deformity and an occlusal problem, qualitative differences such as bilateral imbalance and masticatory movement are suspected⁵. Furthermore, because of interindividual differences of the masticatory function (i.e. high standard deviations, especially for MVC task, including CG), it is difficult to show significant differences for treatment outcomes. A small set of studies have indicated that a few months after surgery patients show some improvement in muscle performance, but sEMG values still remain well below the control group^{1,5,15}. This was not observed in our study, significant differences were not observed for sEMG values for all patients (EG and IG) one year after surgery. Other studies indicate that improvement in muscle performance is only observed 2 to 5 years after surgery, but sEMG values still remain below the control group^{3,16,28}.

The set of exercises used in the current study was developed over the last 30 years and has previously been shown to be effective in controlled studies with different pathologies (e.g. brain stroke, head and neck cancer, oral breathing, obstructive sleep apnea syndrome etc.)^{23,36,42-52,58-62}. There is proof of the concept that muscle training will improve the oral myofunctional system and, consequently, the orofacial functions.

Significant improvements in jaw movements were observed for both groups of patients. When looking attentively at the results, both groups of patients presented improvement in jaw protrusion. This was an expected

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result since orthognathic surgery for Skeletal Class III patients aims at reestablishing maxillomandibular balance. Changes in hard tissue resulting from surgery procedures (independently of the adopted surgery technique) has a direct positive impact on the tempormandibular joints, and consequently on jaw movements ⁶³⁻⁶⁶. The groups of patients differed in jaw lateralization improvement. Only patients in EG presented significant changes for this variable, even though this was observed exclusively for the right side. This result is supported by the fact that the treatment protocol involved jaw mobility exercises. The literature points that jaw mobility is directly related to the masticatory muscles and, consequently, to the masticatory efficiency ^{23,65-67}. Although not investigated in the present study, authors have shown that masticatory side preferences can be related to differences in the activation of the masticatory muscle and in jaw lateralization ^{62,68}. This finding should be considered in future revisions of the proposed therapy program.

The body of literature on motor behaviors indicates that motor patterns are mediated by central neuronal circuits known as Central Pattern Generators (CPGs) ⁶⁹⁻⁷². At the moment, several CPGs are under analysis. Literature has suggested that there is a great variability in cell and synaptic properties, and that different networks of neurons are interrelated to produce the final characteristics of movements. Peripheral orofacial sensory inputs can alter the excitability of the inferior facial motor neurons and can contribute to movement control ⁶⁹⁻⁷².

Objective data on orofacial myofunctional rehabilitation of patients submitted to orthognathic surgery is limited, and there are currently no standardized quality indicators for rehabilitation programs. We would like to stress that this study was designed to test the hypothesis that a set of orofacial myofunctional exercises are effective in optimizing functionality of orofacial muscles of patients who underwent orthognathic surgery, therefore reducing muscle relapse.

Our study demonstrated that patients who underwent orthognathic surgery can benefit from rehabilitative orofacial myofunctional techniques. The proposed therapy program significantly improved orofacial myofunctional mobility, performance during deglutition and mastication and jaw mobility. Further research is warranted to compare outcomes obtained in long-term follow-ups.

Clinical messages

- Orofacial myofunctional therapy can contribute to improving the masticatory and orofacial function of patients who underwent orthognathic surgery.
- However, a programme of 6 treatment sessions produces no significant improvement in the physiology of the masticatory muscle function.

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Conflict of Interest Statement

None declared

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

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Appendix 1 – Treatment Protocol

Sessions 1 and 2:

Activity, procedure, effect and duration of activities

Activity	Procedure	Effect of activity	Time of activity
Instruction	To instruct the patient about the orofacial myofunctional therapy goals; provide information on the stomatognathic functions and myofunctional disorders	Increase self-perception of the orofacial myofunctional system	~15 minutes
Edema drainage	bilateral light continuous and descendent manipulation of the face.	Remove interstitial fluid	~2 minutes
Stretching of the neck muscles	Patients are instructed to: <ul style="list-style-type: none"> . cock neck right and left; . tilt head forward and backwards; . tilt head right and left. 	To increase oxygenation and relax the neck muscles	3 blocks of 10 repetitions each Interval of 30s between each block
Lips mobility	Patients are instructed to protrude and retract lips with mouth closed	To increase muscle oxygenation, mobility and remove interstitial fluid	3 blocks of 10 repetitions each Interval of 30s between each block
Tongue mobility	Patients are instructed to: <ul style="list-style-type: none"> . place the tip of the tongue against the front of the palate and to slide the tongue slowly backwards; . repeat alternatively the oral and nasal vowel /a/ intermittently 	To increase muscle oxygenation, mobility and coordination	3 blocks of 10 repetitions each Interval of 30s between each block

Patients are instructed to perform the same activities at home, at least three times a day.

Sessions 3 and 4:

Activity, procedure, effect and duration of activities

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Activity	Procedure	Effect of activity	Time of activity
Instruction	To instruct the patient about the orofacial myofunctional therapy goals; provide information on the stomatognathic functions and myofunctional disorders	Increase self-perception of the orofacial myofunctional system	~5 minutes
Edema drainage	bilateral light continuous and descendent manipulation of the face.	Remove interstitial fluid	~2 minutes
Manipulation and stretching of the masticatory muscles (masseter and temporalis) and associated muscles (sternocleidomastoid and trapezius)	Patients are instructed to perform circular manipulation applied to the masticatory and associated muscles, one at a time	to increase blood flow and tissue oxygenation, and to remove metabolic residues, promoting the remission of muscle tension and spasms.	~1 minute for each muscle group
Jaw mobility	Patients are instructed to: . open and close the mouth, in a slow and controlled manner . lateralize and slide the jaw to the right as far as possible (should not feel any pain); . lateralize and slide the jaw to the left as far as possible (should not feel any pain); . protrude the jaw in a slow and controlled manner.	To increase mobility and movement control and symmetry	2 blocks of 10 repetitions each Interval of 30s between each block
Lips and cheeks strength	Patients are instructed to recruit the buccinators muscle against the finger that is introduced in the oral cavity, pressing the buccinators muscle outward	To increase muscle strength	3 blocks of 10 repetitions each Interval of 30s between each block
Tongue mobility	Patients are instructed to: . touch the base of the tongue with a spatula/tooth brush; . to move the tongue as fast as possible sideways	To reposition the tongue (dorsum in a lower position) and to improve symmetry between the activation of the intrinsic and extrinsic tongue	3 blocks of 10 repetitions each Interval of 30s between each block

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	(left and right)	muscles	
Breathing	Patients are instructed to: . maintain lips sealed during breathing; . to perceive the tongue against the palate; . to maintain nasal breathing	To improve perception and to adapt breathing	~5 minutes
*Mastication	Patients are trained for alternate bilateral chewing. The supervised exercise consists of alternate bread mastication.	To improve perception and to adapt mastication	~5 minutes
*Swallowing	Patients are trained to use the tongue in the palate, closed teeth, without perioral contractions, while swallowing. The supervised exercise consists of bread and water swallowing.	To improve perception and to adapt swallowing	~5 minutes

* These exercises aim to correct position of the tongue while eating and targets the appropriate functionality and movement of the tongue and jaw.

Patients are instructed to perform the same activities at home, at least three times a day, and to incorporate the breathing, mastication and swallowing patterns in daily activities.

Sessions 5 and 6:

Activity, procedure, effect and duration of activities

Activity	Procedure	Effect of activity	Time of activity
Manipulation and stretching of the masticatory muscles (masseter and temporalis) and associated muscles (sternocleidomastoid and trapezius)	Patients are instructed to perform circular manipulation applied to the masticatory and associated muscles, one at a time	to increase blood flow and tissue oxygenation, and to remove metabolic residues, promoting the remission of muscle tension and spasms.	~1 minute for each muscle group

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Jaw mobility	<p>Patients are instructed to:</p> <ul style="list-style-type: none"> . open and close the mouth, in a slow and controlled manner . lateralize and slide the jaw to the right as far as possible (should not feel any pain); . lateralize and slide the jaw to the left as far as possible (should not feel any pain); . protrude the jaw in a slow and controlled manner. 	To increase mobility and movement control and symmetry	<p>3 blocks of 10 repetitions each</p> <p>Interval of 30s between each block</p>
Lips and cheeks strength	<p>Patients are instructed to recruit the buccinators muscle against the finger that is introduced in the oral cavity, pressing the buccinators muscle outward</p>	To increase muscle strength	<p>1 block of 10 repetitions each and 1 block of 10 repetitions each in a holding position (isometric)</p> <p>Interval of 30s between each block</p>
Tongue mobility	<p>Patients are instructed to:</p> <ul style="list-style-type: none"> . to voluntarily maintain the dorsum of the tongue in a lower position; . to move the tongue as fast as possible sideways (left and right) 	To reposition the tongue and to improve symmetry between the activation of the intrinsic and extrinsic tongue muscles	<p>3 blocks of 10 repetitions each</p> <p>Interval of 30s between each block</p>
Breathing	<p>Patients are instructed to:</p> <ul style="list-style-type: none"> . maintain lips sealed during breathing; . to perceive the tongue against the palate; . to maintain nasal breathing 	To improve perception and to adapt breathing	~5 minutes
*Mastication	<p>Patients are trained for alternate bilateral chewing. The supervised exercise consists of alternate bread mastication.</p>	To improve perception and to adapt mastication	~10 minutes
*Swallowing	<p>Patients are trained to use the tongue in the palate, closed teeth, without perioral contractions, while swallowing. The</p>	To improve perception and to adapt swallowing	~10 minutes

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supervised exercise
consists of bread and
water swallowing.

* These exercises aim to correct position of the tongue while eating and targets the appropriate functionality and movement of the tongue and jaw.

Patients are instructed to perform the same activities at home, at least three times a day, and to incorporate the breathing, mastication and swallowing patterns in daily activities.

REFERENCES

- 1.Sforza C, Peretta R, Grandi G, Ferronato G, Ferrario VF. Soft tissue facial planes and masticatory muscle function in skeletal Class III patients before and after orthognathic surgery treatment. J Oral Maxillofac Surg 2008; 66:691-698.
- 2.Jorge TM, Brasolotto AG, Gonçalves ES, Nary Filho H, Berretin-Felix G. Influence of orthognathic surgery on voice fundamental frequency. J Craniofac Surg 2009; 20(1):161-4.
- 3.Ohkura K, Harada K, Morishima S, Enomoto S. Changes in bite force and occlusal contact area after orthognathic surgery for correction of mandibular prognathism. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2001; 91(2):141-5.
- 4.Iwase M, Ohashi M, Tachibana H, Toyoshima T, Nagumo M. Bite force, occlusal contact area and masticatory efficiency before and after

ARTIGO 1: REHABILITATIVE MANAGEMENT OF MASTICATION AFTER
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- orthognathic surgical correction of mandibular prognathism. *Int. J Oral Maxillofac. Surg* 2006; 35:1102-1107.
5. Nakata Y, Ueda HM, Kato M, Tabe H, Shikata-Wakisaka N, Matsumoto E, Kob M, Tanaka E, Tanne K. Change in stomatognathic function induced by orthognathic surgery in patients with mandibular prognathism. *J Oral Maxillofac Surg* 2007; 65:444-451.
 6. Trawitzki LVV, Dantas RO, Mello-Filho FV, Marques W. Masticatory muscle function three years after surgical correction of class III dentofacial deformity. *Int. J. Oral Maxillofac. Surg* 2009; 39(9):853-6.
 7. Throckmorton GS, Buschang PH, Ellis E. Improvement of maximum occlusal forces after orthognathic surgery. *J. Oral Maxillofac. Surg* 1996; 54:1080-1086.
 8. Trawitzki LVV, Dantas RO, Mello-Filho FV, Marques W. Effect of treatment of dentofacial deformities on the electromyographic activity of masticatory muscles. *Int. J. Oral Maxillofac. Surg* 2006; 35:170-173.
 9. Throckmorton GS, Ellis III E. The relationship between surgical changes in Dentofacial morphology and changes in maximum bite force. *J Oral Maxillofac Surg* 2001; 59(6):620-7.
 10. Ueki K, Marukawa K, Shimada M, Nakagawa K, Yamamoto E. Changes in occlusal force after mandibular ramus osteotomy with and without Le Fort I osteotomy. *Int J Oral Maxillofac Surg* 2007; 36:301-304.
 11. Altug-Atac AT, Bolatoglu H, Memikoglu UT. Facial soft tissue profile following bimaxillary orthognathic surgery. *Angle Orthod* 2008; 78(1):50-7.

ARTIGO 1: REHABILITATIVE MANAGEMENT OF MASTICATION AFTER
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12. Islam R, Kitahara T, Naher L, Hara A, Nakata S. Lip morphology changes following orthognathic surgery for class III malocclusion. *Angle Orthod* 2010; 80(2):344-53.
13. Yamaguchi H, Sebata M. Changes in oral functions and posture at rest following surgical orthodontics treatment and myofunctional therapy. Evaluation by means of video recording. *Int Orofacial Myology* 1995; 21:29-32.
14. Wong LLN, Samman N, Whitehill TL. Are hearing and middle ear statuses at risk in Chinese patients undergoing orthognathic surgery? *Clin Otolaryngol Allied Sci* 2002; 27(6):480-4.
15. van den Braber W, van den Glas H, van den Bilt A, Bosman F. Masticatory function in retrognathic patients, before and after mandibular advancement surgery. *J Oral Maxillofac Surg* 2004; 62:549-554.
16. van den Braber W, van den Bilt A, van den Glas H, Rosenberg T, Koole R. The influence of mandibular advancement surgery on oral function in retrognathic patients: a 5-year follow-up study. *J Oral Maxillofac Surg* 2006; 64:1237-1240.
17. Hassan T, Naini FB, Gill DS. The effects of orthognathic surgery on speech: a review. *J Oral Maxillofac Surg* 2007; 65:2536-2543.
18. Proffit WR, Fields HW, Moray LJ. Prevalence of malocclusion and orthodontic treatment need in the United States: estimates from the NHANES III survey. *Int Adult Orthodon Orthognath Surg* 1998; 13:97-106.
19. Ackerman M. Evidence-based orthodontics for the 21st century. *JADA* 2004; 135:162-167.

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20. Wolford LM, Fields RT. Surgical planning. In: Booth PW, Schendel SA, Hausamen JE, editors. Maxillofacial surgery. London: Churchill-Livingstone, 1999:1205-57.
21. Ong M. Spectrum of Dentofacial Deformities: a retrospective survey. Ann Acad Med Singapore 2004; 33:239-42.
22. Kimura-Fujikami T, Cabrera-Muñoz ML, Del Valle-Espinoza A. Laserterapia en cirugía ortognática. Gac Méd Méx 2005; 141(1):27-33.
23. Bell Y, Lehtinen R, Peltomaki T et al. Function of masticatory system after surgical-orthodontic correction of maxillomandibular discrepancies. Proc. Finn. Dent. Soc 1993; 89(3-4):101-1-7.
24. Weeden J, Trotman CA, Faraway J. Three-dimensional analysis of facial movement in normal adults: influence of sex and facial shape. Angle Orthod 2001; 71(2):132-140.
25. Nooreyazdan M, Trotman CA, Faraway JJ. Modeling facial movements: II. A dynamic analysis of differences caused by orthognathic surgery. J Oral Maxillofac Surg 2004; 62(11):1380-6.
26. Goldspink G, Tabary JC, Tardieu C, Tardieu G. The effect of denervation on the adaptation of sarcomere number and muscle extensibility to the functional length of the muscles. J Physiol 1974; 236:733-742.
27. Glineburg RW, Laskin DM, Blaustein DI. The effects of immobilization on the primate temporomandibular joint. J Oral Maxillofac Surg 1982; 40:3-8.
28. Youssef RE, Throckmorton GS, Ellis E 3rd. Comparision of habitual masticatory cycles and muscle activity before and after orthognathic surgery. J Oral Maxillofac Surg, 1997; 55(7):699-707.

ARTIGO 1: REHABILITATIVE MANAGEMENT OF MASTICATION AFTER
ORTHOGNATHIC SURGERY: A RANDOMIZED CONTROLLED TRIAL

- 29.Oland J, Jensen J, Melsen B. Factors of importance for the functional outcome in orthognathic surgery patients: a prospective study of 118 patients. J Oral Maxillofac Surg 2010; 68(9):2221-31.
- 30.Tate GS, Throckmorton GS, Ellis E, Sinn DP. Masticatory performance, muscular activity, and occlusal force in pre-orthognathic patients. J Oral Maxillofac surg 1994; 52:476-481.
- 31.Tate GS, Throckmorton GS, Ellis E, Sinn DP, Blackwood MS. Estimated masticatory forces in patients before orthognathic surgery. J Oral Maxillofac surg 1994; 52:130-136.
- 32.Ellis III E, Throckmorton GS, Sinn DP. Bite forces before and after surgical correction of mandibular prognathism. J Oral Maxillofac Surg 1996; 54:176-181.
- 33.Iwase M, Sugimori M, Kurachi Y, et al. Changes in bite force and occlusal contacts in patients treated for mandibular prognatism by orthodontic surgery. J Oral Maxillofac Surg 1998; 56:850-855.
- 34.Nagai I, Tanaka N, Noguchi M, Suda Y, Sonoda T, Kohama G. Changes in occlusal state of patients with mandibular prognathism after orthognathic surgery: a pilot study. Br J Oral Maxillofac Surg 2001; 39:429-433.
- 35.Kobayashi T, Honma K, Shingaki S, Nakajima T. Changes in masticatory function after orthognathic treatment in patients with mandibular prognathism. Br J Oral Maxillofac Surg 2001; 39(4):260-5.
- 36.Kobayashi TH, Nakajima T, Hanada K. Masticatory function in patients with mandibular prognatism before and after orthognathic surgery. J.Oral. Maxillofac. Surg 1993; 51(9):997-1003.

ARTIGO 1: REHABILITATIVE MANAGEMENT OF MASTICATION AFTER
ORTHOGNATHIC SURGERY: A RANDOMIZED CONTROLLED TRIAL

- 37.Zarrinkelk HM, Throckmorton GS, Ellis EIII. A longitudinal study of changes in mastigatory performance of patients undergoing orthognathic surgery. J Oral Maxillofac Surg 1995; 53:777-782.
- 38.Edlund J, Hansson T, Peterson A, Willmar K. Sagittal Splitting of the mandibular ramus. ,Sacr J. Plast. Reconstr Surg 1978; 13:437-443.
- 39.Felício CM de, Ferreira CLP. Protocolo of orofacial myofunctional evaluation with scores. International Journal of Pediatric Otorhinolaryngology 2008; 72:367-375.
- 40.Dworkin SF, Sherman J, Mancini L, Ohrbach R, Leresche L, Truelove E. Reliability, validity, and clinical utility of the research diagnostic criteria for temporomandibular disorders axis III scales: depression, non-specific physical symptoms, and graded chronic pain. J Orofac Pain 2002; 13:207-220.
- 41.Pehling J, Schiffman E, Look J, Shaefer J, Lenton J. Friction, interexaminer reliability and clinical validity of the temporomandibular index: a new outcome measure for temporomandibular disorders. J Orofac Pain 2002; 16:296-304.
- 42.Kabat H, Knott M. Proprioceptive facilitation technics for treatment of paralysis. Phys Ther Rev 1953; 33:53-64.
- 43.Knott M. Neuromuscular facilitation in the treatment of rheumatoid arthritis. Phys Ther 1964; 44:737-739.
- 44.Altmann EBC. Myofunctional therapy and orthognathic surgery. Int. J. Orofacial Myology 1987; 13(3):2-12.

ARTIGO 1: REHABILITATIVE MANAGEMENT OF MASTICATION AFTER
ORTHOGNATHIC SURGERY: A RANDOMIZED CONTROLLED TRIAL

45. Bailey LJ, Duong HL, Proffit WR. Surgical class III treatment: long-term stability and patients perceptions of treatment outcome. *Int. J. Adult. Orthodon. Orthognath. Surg* 1998; 13(1):35-44.
46. Nary-Filho H, Gonçalves ES, Berretin-Felix G, et al. Evaluation of the soft tissues following surgically assisted maxillary expansion associated with the simple V-Y suture. *Int. J. Adult. Orthodon. Orthognath. Surg* 2002; 17(2):89-97.
47. Robbins J, Gangnon RE, Theis SM, Kays SA, Hewitt AL, Hind JA. The effect of lingual exercise on swallowing in older adults. *J Am Geriatr Soc* 2005; 53:1483-1489.
48. Lazarus C. Tongue strength and exercise in healthy individuals and in head and neck cancer patients. *Semin Speech Lang* 2006; 27:260-267.
49. Ibayashi H, Fujino Y, Pham TM, Matsuda S. Intervention Study of exercise program for oral function in healthy elderly people. *Tohoku J. Exp. Med* 2008; 215:237-245.
50. Namura M, Motoyoshi M, Namura Y, Shimizu N. The effects of PNF training on the facial profile. *J. Oral Sci* 2008; 50:45-51.
51. Dalemans R, Wade DT, van den Heuvel WJ, Witte LP. Facilitating the participation of people with aphasia in research: a description of strategies. *Clin Rehabil* 2009; 23(10):948-959.
52. Castro-Sanchez AM, Mataran-Penarrocha GA, Arroyo-Morales M, Saavedra-Hernandez M, Fernandez-Sola C, Moreno-Lorenzo C. Effects of myofascial release techniques on pain, physical function, and postural

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- stability in patients with fibromyalgia: a randomized controlled trial. Clin Rehabil 2011; 25(9):800-813.
53. Felício CM, Couto GA, Ferreira CLP, Mestriner JrW. Reliability of masticatory efficiency with beads and correlation with the muscle activity. Pró-Fono Revista de Atualização Científica 2008; 20(4):225-30.
54. Weiner JB, Alexander JA, Shortell SM, Baker LC, Geppert JJ. Quality improvement implementation and hospital performance on quality indicators. Health Res and Educ Trust 2006; 41(2):307-33.
55. Hospital Report Research Collaborative. Hospital Report: Acute Care, A joint initiative of the Ontario Hospital Association and the Government of Ontario. 2007. Available from <http://www.health.gov.on.ca>
56. Weir E, d'Entremont N, Stalker S, Kurji K, Robinson V. Applying the balanced scorecard to local public health performance measurement: deliberations and decisions. BMC Public Health. 2009; 9:127.
57. Frain MP, Tschopp MK, Bishop M. Predictors of Outcomes in Rehabilitation. J Rehabil 2009; 75(1):27-35.
58. Valera FC, Travitzki LV, Mattar SE, Matsumoto MA, Elias AM, Anselmo-Lima WT. Muscular, functional and orthodontic changes in preschool children with enlarged adenoids and tonsils. Int. J. Pediatr. Otorhinolaryngol 2003; 67(7):761-770.
59. Guimarães KC, Drager LF, Genta PR, Marcondes BF, Lorenzi-Filho G. Effects of oropharyngeal exercises on patients with moderate obstructive sleep apnea syndrome. Am J Resp Crit Care Med 2009; 179:962-966.

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60. Schindler A, Vincon E, Grosso E, Miletto AM, Di Rosa R, Schindler O. Rehabilitative Management of Oropharyngeal Dysphagia in AcuteCare Settings: Data from a Large Italian Teaching Hospital. *Dysphagia* 2008; 23:230–236.
61. Steele CM. On the plausibility of upper airway remodeling as an outcome of orofacial exercise. 2009; 179(10):858-859.
62. Felício CM, Melchior MO, Silva MAMR. Effects of orofacial myofunctional therapy on temporomandibular disorders. *CRANIO* 2010; 28(4):249-60.
63. Fujimura K, Segami N, Sato J, Kanayama K, Nishimura M, Demura N. Advantages of intraoral verticosagittal ramus osteotomy in skeletofacial deformity patients with temporomandibular joint disorders. *J Oral Maxillofac Surg* 2004; 62:1246-1252.
64. Kim Y, Yun P, Ahn J, Kim J, Kim S. Changes in the temporomandibular joint disc position after orthognathic surgery. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2009; 108:15-21.
65. Sforza C, Ugolini A, Rocchetta D, Galante D, Mapelli A, Gianni AB. Mandibular kinematics after orthognathic surgical treatment – A pilot study. *British Journal of Oral and Maxillofac Surgery* 2010; 48:110-114.
66. Yazdani J, Ebrahimi H, Talesh KT, Khashabi E, Pourshahidi S, Tadbir AA. Comparing the effect of 3 orthognathic surgical methods on the mandibular range of movement. *J Craniofac Surg* 2010; 21:703-705.
67. Harper RP, Bruin H, Burcea I. Muscle activity during mandibular movements in normal and mandibular retrognathic subjects. *J Oral Maxillofac Surg* 1997; 55:225-233.

- 68.Felício CM, Ferreira CLP, Medeiros APM, Silva MAMR, Tartaglia GM, Sforza C. Electromyographic índices, orofacial myofunctional status and temporomandibular disorders severity: a correlation study. J Electromyogr Kinesiol 2011; epub ahead of print.
- 69.Barlow S, Estep M. Central pattern generation and the motor infra structure for suck, respiration and speech. Journal of Communication Disorders 2006; 39(5):366-380.
- 70.Lund J, Kolta A. Brainstem circuits that control mastication: do they have anything to say during speech? Journal of communication disorders 2006; 39(5):381-390.
- 71.Barlow ST. Central pattern generation involved in oral and respiratory control for feeding in the term infant. Otolaryngology & Head and Neck Surgery 2009; 17:187-193.
- 72.Guetin PA, Steuer I. Key central pattern generators of the spinal cord. Journal of neuroscience research 2009; 87(11):2399-2405.

**REHABILITATIVE MANAGEMENT OF SWALLOWING AND ORAL-
MOTOR MOVEMENTS IN PATIENTS WITH TETANUS OF A PUBLIC
SERVICE IN BRAZIL**

Abstract

When looking at developing countries, the prolonged intensive medical and nursing care required by many patients places extra demands on an already stretched healthcare budget. The purpose of this study was to verify the effectiveness of a systematic rehabilitative program for swallowing and oral-motor movements in intensive care unit patients with the diagnosis of tetanus. Forty-five patients who were clinically diagnosed with tetanus were included in the study. Participants were divided in two groups: GI – consisted of 18 tetanus patients who were consecutively admitted to the infectious disease ICU from January 2002 to December 2005, prior to the existence of a systematic swallowing and oral-motor intervention; GII – consisted of 27 tetanus patients who were consecutively admitted to the infectious disease ICU from January 2006 to December 2009 and were submitted to a specific rehabilitative management of swallowing and of the oral-motor movements. Results indicate that the proposed rehabilitative program reduced by approximately 50% the time patients remained in the ICU. The significant improvement observed in patients with tetanus who were submitted to the rehabilitative program for swallowing and oral-motor movements occurred in conjunction with a reduction in the amount of time necessary to reintroduce oral feeding, to decannulate and to remove the feeding tubes. In conclusion,

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swallowing/muscle exercise, in patients with severe/very severe tetanus, seem to promote the remission of muscle tension and seem to maximize functional swallowing.

Key-words: Deglutition disorders; tetanus; stomatognathic system; muscle rehabilitation.

1. Introduction

The incidence of tetanus is higher in underdeveloped countries (Veronese et al., 1991; Idema et al., 2002; Dundar et al., 2005; Stubbel et al., 2007) and still remains a significant health problem. Since the introduction of protective vaccination programs and public health advances, tetanus has become rare in developed countries (Shin et al., 2002). During the last decades its occurrence in Brazil has progressively decreased. Although epidemiological data in Brazil about the distribution of tetanus among different age groups are scarce and privilege neonatal tetanus, the incidence of the disease is of approximately 0.6/100,000 inhabitants. Lethality, however, is high – around 43.1% - even though management in intensive care units has improved considerably (Litvoc et al., 1991; Moraes and Pedroso, 2000).

Since the lethality of the disease is high, tetanus requires careful clinical observation and advanced life support in intensive care unit (ICU) and

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can be influenced by several factors, such as severity of clinical presentation, age of the patient, and selected treatment (Veronese et al., 1991; Thwaites and Farrar, 2003; Meadure et al., 2005). Most frequently invasive mechanical ventilation and tracheostomy are necessary since patients have difficulty in maintaining airway permeability. For this reason, physicians should be extremely cautious when weaning patients with tetanus from mechanical ventilation. The use of prolonged tracheostomy and gastric tube due to dysphagia, choking and patient inability to clear secretions is also very common (Thwaites and Farrar, 2003).

Normal deglutition, mastication and speech require the coordinated activity of muscles of the mouth, pharynx, larynx, and esophagus, which are innervated by the central and peripheral nervous system (Hammond and Goldstein, 2006). Literature (Bleck, 1991; Veronese et al., 1991; Bleck, 1995; Tapajós, 1996) describes that cases of generalized tetanus, descendent or ascendant, frequently present alterations in the muscles responsible for deglutition, resulting in swallowing and phonation deficits, dehydration, choking, sialorrhea and trismus.

Previous study (Mangilli et al., 2011) indicated that the oral motor movements and speech in patients with tetanus in an ICU environment are severely compromised, with the exception of palate elevation and saliva swallowing (Mangilli et al., 2009). The presence of trismus or lockjaw is the most common presenting sign in patients with tetanus, producing an inability

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to open the mouth (Logemann, 1983; Ott, 1998; Hammond and Goldstein, 2006; Mangilli et al., 2009; Mangilli et al., 2011). Also, studies have suggested that the strength and status of the oral-motor system muscles in these patients do not present the necessary integrity for satisfactory performance.

When considering the swallowing function, the most frequent observed characteristic in this population is that muscle hyperactivity hinders or prevents the organization of excitability and sequential inhibition of the striated muscles responsible for the passage of the bolus from the pharynx to the stomach, a condition considered necessary by specialists in the area (Logemann, 1983; Hammond and Goldstein, 2006; Ott, 1998). The literature also indicates that the presence of tongue movement deficits, frequent in patients with tetanus, are related to alterations in water swallowing tests, suggesting that oral feeding is unsafe (Mangilli et al., 2009).

Clinical characteristics of oropharyngeal dysphagia (OD) in patients with tetanus have been identified, deriving from sensorimotor functions of the oropharynx. They include abnormal gag, cough and voice change after swallow, abnormal tongue movement, lingual discoordination, delayed oral and pharyngeal transit and delay triggering of swallow (Mangilli et al., 2009).

Oropharyngeal dysphagia is potentially life-threatening with consequences such as: malnutrition, dehydration, aspiration pneumonia,

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increased risk of complications, discharge to nursing home and higher mortality (Logemann et al., 1999; Perry and Love, 2001; Finestone and Greene-Finestone, 2003). There are also financial costs, including longer length of intensive care unit (ICU), expenses for antibiotics, X-rays, increased nursing time and physician consultations (Hinchey et al., 2005; Hammond and Goldstein 2006). In developing countries, the prolonged intensive medical and nursing care required by many patients places extra demand on an already stretched healthcare budget (Hinchey et al., 2005; Hammond and Goldstein, 2006).

When considering speech, the literature suggests motor function-specific abnormal characteristics for patients with very severe tetanus, indicating the presence of rigidity as an interfering factor in articulatory precision and movement rate (Mangilli et al., 2011).

Speech-Language pathologists (SLP) are trained to evaluate and treat oral motor function disorders, make the recommendation for oral or non-oral feeding in patients with oropharyngeal dysphagia (Logemann et al., 2008), as well as advise physicians regarding tube changes (Hinchey et al., 2005; Hammond and Goldstein, 2006). The participation of these professionals in multidisciplinary teams aims to prevent and to reduce complications resulting from alterations of the oral motor function thereby reducing the length of hospital stays and the rate of readmissions due to complications (Finestone

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and Greene-Finestone, 2003; Hinchey et al., 2005; Hammond and Goldstein 2006; Logemann et al., 2008).

The purpose of this study was to verify the effectiveness of a systematic rehabilitative program for swallowing and oral-motor movements in patients with tetanus.

2. Materials and methods

An observational, descriptive, cross-sectional study was conducted with tetanus patients who were admitted to the Infectious and Parasitic Diseases Intensive Care Unit (ICU) of a large Brazilian School Hospital (Hospital das Clínicas) between January 2002 and December 2009. This ICU has seven beds designated for patients with tetanus, botulism, leptospirosis, hepatitis, hemorrhage fever, aids and other conditions. The study design was approved by the Ethics Committee for the Analysis of Research Projects (CAPPesq HCFMUSP no. 841/06). Prior to their enrolment, all participants (prospective patients) and their respective families were informed of the purpose and procedures, after which all gave informed consent.

Forty-five patients who were clinically diagnosed with tetanus were included in the study. The inclusion criteria also considered absence of surgical procedures involving head and neck, absence of neurological disease, cognitive impairment, or impairment of the consciousness level, and

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age above 18 years. All research and data gathering procedures were performed at the beginning of the convalescence phase. For patients with tetanus, convalescence is determined based on the ability of the individuals to breathe spontaneously, without need for mechanical ventilation or with intermittent use of mechanical ventilation only. After the withdrawal of sedation, patients had to present a level of consciousness that allowed the understanding of verbal instructions. The consciousness level of all patients was determined by the Mini-Mental State test (Folstein et al., 1975). All participants presented scores within normal limits (26.38 ± 0.51).

Participants were divided in two groups: GI (retrospective) – consisted of 18 tetanus patients, 17 male and 1 female, who were consecutively admitted to the infectious disease ICU from January 2002 to December 2005, prior to the existence of a systematic swallowing and oral-motor intervention; GII (prospective) – consisted of 27 tetanus patients, 24 male and 3 female, who were consecutively admitted to the infectious disease ICU from January 2006 to December 2009. Participants of GII underwent specific rehabilitative management of swallowing and of the oral-motor movements.

The quality indicators (ASHA, 2002; Frank et al., 2007; Schindler et al., 2003; Wesling et al., 2003; Schindler et al., 2008; White et al., 2008; Moraes and Andrade 2011) used to compare both groups were: tetanus severity, according to the scale of prognostic indicators proposed by Bleck (1991) and Veronese et al. (1991); clinical assessment of dysphagia at the

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beginning of the convalescence phase and at discharge from hospital, according to the American Speech-Language-Hearing Association National Outcome Measurement System (ASHA NOMS) (ASHA, 1998; Wesling et al., 2003); time until reintroduction of oral feeding (TROF) expressed in number of days; time until decannulation (TUD) expressed in number of days and time until removal of feeding tubes (TRFT) expressed in number of days. For GI, data was gathered from medical records registered in patients' files. For GII, data was gathered pre and post application of the specific swallowing and oral-motor intervention program.

2.1. Clinical Assessment of Dysphagia

The ASHA NOMS swallowing level scale is a multidimensional tool designed to measure both the supervision level required and diet level by assigning a single number between 1 to 7 (Table 1).

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Table 1. ASHA NOMS swallowing level scale

Level 1	Individual is not able to swallow safely by mouth. All nutrition and hydration is received through non-oral means (e.g. nasogastric tube).
Level 2	Individual is not able to swallow safely by mouth for nutrition and hydration but may take some consistency with consistent maximal cues in therapy only. Alternative method of feeding is required.
Level 3	Alternative method of feeding required as individual takes less than 50% of nutrition and hydration by mouth, and/or swallowing is safe with consistent use of moderate cues to use compensatory strategies and/or requires maximum diet restriction.
Level 4	Swallowing is safe but usually requires moderate cues to use compensatory strategies, and/or individual has moderate diet restriction and/or still requires tube feeding and/or oral supplements.
Level 5	Swallow is safe with minimal diet restriction and/or occasionally requires minimal cueing to use compensatory strategies. May occasionally self cue. All nutrition and hydration needs are met by mouth at mealtime.
Level 6	Swallowing is safe, and individual eats and drinks independently and may rarely require minimal cueing. Usually self cues when difficulty occurs. May need to avoid specific food items (e.g. popcorn and nuts), or requires additional time (due to dysphagia).
Level 7	Individual's ability to eat independently is not limited by swallow function. Swallowing would be safe and efficient for all consistencies. Compensatory strategies are effectively used when needed.

For both groups participants' specific diet level and level of supervision required were used to assign the ASHA NOMS swallowing scale. As described earlier, initial diet and supervision levels were documented at the beginning of the convalescence phase and at discharge from hospital. Therapists assigning the ASHA NOMS swallowing level had successfully passed specific training tests.

2.2 Swallowing management and oral-motor intervention

Participants of GI underwent no specific or systematic swallowing management and oral motor intervention. All patients had record of using tracheostomy and probe as an alternative feeding method. Also, records found in 12 (67%) out of 18 patients' files indicated sporadic swallowing assistance follow-up based exclusively on the reintroduction of oral feeding

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(i.e. attempts to reintroduce oral feeding based on the observation of clinical signs such as cough, choking and change in voice quality) and use of postural techniques (i.e. changes in head posture during swallowing).

Participants of GII underwent a specific controlled swallowing and oral-motor rehabilitation program. Prior to therapeutic intervention, all patients were using tracheostomy and probe as an alternative feeding method – oro-gastric probe and plastic cannula with insufflated cuff. In order to begin therapeutic intervention, these patients had to breathe spontaneously, with no effort, and without the insufflated cuff. This training was performed by the multidisciplinary team during the time patients remained in the ICU. Rehabilitation sessions were conducted based on current strategies of swallowing and oral-motor therapy (Kabat and Knott, 1953; Knott, 1964; Logemann, 1983; Jean, 1986; Altmann, 1987; ASHA 1990; Goldsmith, 2000; Perry and Love, 2001; Nary-Filho et al. 2002; Ertekin and Aydogdu, 2003; Finestone and Greene-Finestone, 2003; Leslie et al., 2003; Valera et al., 2003; Logemann and Sonies, 2004; Hammond and Goldstein, 2006; Ibayashi et al., 2008; Namura et al., 2008; Schindler et al. 2008). All participants were seen once a day by a trained speech-language pathologist for approximately 40 minutes. The intervention program involved two areas of stimulation that were performed simultaneously as described below:

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Swallowing rehabilitation

- Larynx: (1) lateral mobilization passive maneuver - firmly grip the larynx with one hand and move it sideways (for approximately 1 minute); (2) prolonged emission of vowel /i/ using a high pitched voice (three blocks with five repetitions each and 30 seconds interval between each block). The purpose of this maneuver/exercise was to improve larynx elevation and its anteroposterior movement during swallowing.
- Pharynx/Larynx sensitivity: (1) tactile stimulation – using a spatula/cotton swab, touch the oro and nasopharynx, base of the tongue and posterior wall of the pharynx using different pressures and touching different points (for approximately 1 minute); (2) thermic stimulation - using a spatula/cotton swab embedded in ice cold water, touch the oro and nasopharynx, base of the tongue and posterior wall of the pharynx using different pressures and touching different points (for approximately 1 minute); (3) gustatory stimulation - using a spatula/cotton swab embedded in citric liquid (e.g. lemon juice), touch the oro and nasopharynx, base of the tongue and posterior wall of the pharynx using different pressures and touching different points (for approximately 1 minute). The purpose of these stimulation maneuvers was to improve the sensitivity of the pharynx and larynx and consequently improve the excitability threshold of the gag and swallowing reflexes.

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- Palate exercise: repeated rhythmic slow emission of vowel /a/ (three blocks with ten repetitions each and 30 seconds interval between each block). The purpose of this exercise was palate mobilization through the recruitment of the musculus uvulae, levator veli palatini and tensor veli palatini. All of these muscles are responsible for closing the veli palatini (upper airway) during swallowing.
- Clearance and protection maneuvers (i.e. these maneuvers were performed only when the patient was on an oral diet): (1) effortful swallowing - the maneuver consists of swallowing, but the patient must try to squeeze all of the muscles of swallowing as hard as possible. This maneuver was performed while swallowing food. In essence, the purpose of this maneuver was to improve the contact among the different muscles used during the act of swallowing, intensifying oral propulsion and maximizing functional swallowing; (2) multiple swallowing – the maneuver consists of swallowing several times the same bolus (at least three swallows per bolus). The purpose of this maneuver was to eliminate possible food residues from the oral cavity and pharyngeal recesses, indirectly contributing for functional swallowing.

It is important to highlight that prior to performing the clearance and protection maneuvers, all patients of GII were submitted to the blue dye test (Logemann, 1983) to ensure absence of food penetration and/or aspiration. The blue dye test is used as a component of dysphagia assessment for

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patients with tracheostomy tubes. It ensures safety when consenting cuff deflation/food/fluid trials. The test involved giving the patient a food or liquid that is dyed blue. The nurse or respiratory therapist performed the suction of the trach after the patient swallowed the bolus to check for blue dye in the airway, indicating that the patient failed the test. Only one food or liquid was tested at the time. For those patients who failed the test, the speech-language pathologist continued performing the swallowing maneuvers/exercises without using food/liquid. Patients were retested as often as necessary until safe oral feeding was possible. Once the patient was eating, the speech-language pathologist was responsible for food consistency progression (i.e. homogeneous pasty, liquid, heterogeneous pasty, solid consistencies).

Oral-motor rehabilitation

- Manipulation of masticatory and associated muscles: bilateral light rotational and descendent manipulation of the masticatory (masseter and temporal) and associated (sternocleidomastoid and trapezius) muscles (for 1 minute at each muscle sight). The purpose of this maneuver was to increase blood flow and tissue oxygenation, and to remove metabolic residues, promoting the remission of muscle tension and spasms.
- Tongue exercise: (1) placing the tip of the tongue against the front of the palate and sliding the tongue backward; (2) protrusion of the tongue outside the mouth and placing the tip towards the upper and

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lower lip (moving the tongue up and down); (3) protrusion of the tongue outside the mouth and moving the tongue body to the right and left. All exercises were performed in three blocks, with 10 repetitions each, and with rest intervals of 30 seconds. The purpose of these exercises was mandible mobilization through the recruitment of the suprahyoid and submental muscle groups.

- Mandibular exercise: (1) opening and closing of the mouth, movements should be performed without effort and jaw deviation; (2) lateralization of the jaw, first to one side and then to the other, movements should be performed without effort and anterior jaw deviation; (3) protrusion of the jaw, movements should be performed without effort and jaw deviation. All exercises were performed in two blocks, with 10 repetitions each, and with rest intervals of 30 seconds. The purpose of these exercises was to improve muscle coordination through the mobilization of the mandible, to gain muscle mass and flexibility, to increase tissue oxygenation, muscle endurance and strength.
- Chewing. (1) Alternate bilateral chewing whenever feeding. The supervised exercise consisted of alternate bread mastication. This exercise aimed for the correct position of the tongue while eating and targeted the appropriate functionality and movement of the tongue and jaw. Participants were instructed to incorporate this mastication pattern whenever they were eating.

2.3 Data Analysis

In order to compare group characteristics of age and tetanus severity the Fisher's Exact test was used. The Kolmogorov-Smirnov test was used to verify data distribution. The Mann-Whitney test was used for between-group comparisons and the Wilcoxon Signed Ranks test for within group comparisons. The adopted significance level was of 5% for all analysis.

3. Results

Table 2 shows the characterization of age of GI and GII. Due to differences in gender distribution, this analysis was restricted to male individuals only (GI – n=17; GII – n=24). Statistical analysis indicated no between-group differences for this variable. Considering the severity of tetanus, the groups presented the following distribution: GI – 15 individuals with severe tetanus and 3 individuals with moderate/mild tetanus; GII – 26 individuals with very severe/severe tetanus and 1 individual with mild tetanus. Once again, due to differences in severity distribution, this analysis was restricted to male individuals with very severe/severe tetanus only (GI – n=14; GII – n=24). According to the Fisher's Exact test, no between-group difference was observed for this variable ($p=0.243$).

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Table 2. Age characterization of GI and GII

	Age Mean (SD)
GI	44.1 (15.7)
GII	51.6 (8.7)
p-value	0.176

Note: Age – in years.months; SD – standard deviation; p-values obtained with the Fisher's Exact Test.

Table 3 and 4 show the ASHA NOMS results at the convalescence phase (ASHA 1) and at discharge from the hospital (ASHA 2). For comparison purposes, values for the ASHA NOMS were re-categorized as follows: L1 – Levels 1 and 2; L2 – Levels 3 and 4; L3 – Levels 5 to 7. As observed on Table 3, most of the participants of GI (n=14) and GII (n=24) were classified as not being able to swallow safely by mouth and were receiving all nutrition and hydration through a nasogastric tube (L1 - ASHA NOMS Level 1 and 2) at the convalescence phase. At discharge from the hospital most of the participants of GI and GII had their swallowing ability classified between Levels 5 and 7 (L3) (i.e. performances varied between “could swallow safely but presented diet restriction and required cues to use compensatory strategies”, and “swallowing was safe and rarely required minimal cueing to use compensatory strategies”). Although both groups presented significant improvement in swallowing (Table 4), GII presented better swallowing abilities at the time of hospital discharge.

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Table 3. ASHA NOMS results for GI and GII

	L	GI (n/%)	GII (n/%)
ASHA 1	1	9/64.29	21/87.5
	2	3/21.434	1/4.17
	3	2/14.29	2/8.33
ASHA 2	1	0/0.00	1/4.17
	2	6/42.86	2/8.33
	3	8/57.14	21/87.5

Note: ASHA 1 - swallowing assessment at the convalescence phase; ASHA 2- swallowing assessment at discharge from hospital; L1 – ASHA NOMS Levels 1 and 2; L2 – ASHA NOMS Levels 3 and 4; L1 – ASHA NOMS Levels 5 to 7; n – number of individuals; % percentage of individuals.

Table 4. Within-group comparison of ASHA NOMS results

	ASHA 1 Mean (SD)	ASHA 2 Mean (SD)	p-value
GI	1.5 (0.76)	2.5 (0.51)	0.002
GII	1.2 (0.60)	2.9 (0.28)	< 0.001

Note: ASHA1– swallowing assessment at the convalescence phase; ASHA 2- swallowing assessment at discharge from hospital; SD – standard deviation; p-values obtained with the Wilcoxon Rank Test.

Table 5 shows the between-group comparison for the quality indicators of time until reintroduction of oral feeding, time until decannulation and time until the removal of feeding tubes (GI - n=14; GII - n=24). Significant differences were observed for all of the considered variables, indicating that, in general, participants of GII improved their swallowing condition in less than half of the time (i.e. number of days) than those in GI.

Table 5. Between-group comparison of quality indicator results

	TROF Mean (SD)	TUD Mean (SD)	TRFT Mean (SD)
GI	41.9 (11.2)	47.4 (14.0)	45.7 (14.0)
GII	12.9 (22.1)	14.6 (22.9)	14.7 (21.3)
p-value	< 0.001*	< 0.001*	< 0.001*

Note: TROF - time until reintroduction of oral feeding expressed in number of days; TUD - time until decannulation expressed in number of days; TRFT -time until removal of feeding tubes expressed in number of days; SD – standard deviation; p-values obtained with the Mann-Whitney Test.

4. Discussion

Recently, increased regulation has required rehabilitation programs to report their results and outline the goals of the rehabilitation process effectively and efficiently. Evidence-based rehabilitation focuses on establishing relationships between interventions and results. Because this practice analyzes results based on evidence, it requires professionals in the field to identify, implement, and organize the goals of the rehabilitation process in order to improve its effectiveness (Weiner et al., 2006; Hospital 2007; Weir et al., 2009; Frain et al., 2009).

Although our study has limitations such as a small sample size and does not have the safeguards of a randomized clinical trial, it is the first controlled study to investigate the effects of a systematic rehabilitative program for swallowing and oral-motor movements in patients with tetanus. The proposed rehabilitative program reduced by approximately 50% the time patients remained in the ICU. The significant improvement observed in patients with tetanus who were submitted to the rehabilitative program for swallowing and oral-motor movements occurred in conjunction with a reduction in the amount of time necessary to reintroduce oral feeding, to decannulate and to remove the feeding tubes. Despite a significant improvement occurred in both groups of patients (i.e. submitted and not submitted to the rehabilitative program), according to the ASHA NOMS swallowing level scale, patients submitted to the swallowing/muscle training

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exercise presented a safer, more efficient swallowing and a better ability to eat independently at discharge from the hospital.

The set of swallowing/muscles exercise used in the current study was developed over the last 30 years and has previously been shown to be effective in controlled studies with different pathologies (e.g. brain stroke, head and neck cancer, oral breathing, obstructive sleep apnea syndrome etc.) (Kabat and Knott, 1953; Knott, 1964; Jean, 1986; Altmann, 1987; ASHA 1990; Goldsmith, 2000; Perry and Love, 2001; Nary-Filho et al. 2002; Ertekin and Aydogdu, 2003; Finestone and Greene-Finestone, 2003; Leslie et al., 2003; Valera et al., 2003; Logemann and Sonies, 2004; Hammond and Goldstein, 2006; Burkhead et al., 2007; Ibayashi et al., 2008; Namura et al., 2008; Schindler et al. 2008, Guimarães et al., 2009; Steele, 2009). There is proof of the concept that muscle training will improve the oral myofunctional system and, consequently, the swallowing function.

Because of the high incidence of dysphagia in hospitals and its possible consequences, it is critical to effectively diagnose and manage feeding disorders. In addition to the pathological impact of feeding disorders, it is important to consider the financial aspects of health care as well as the patient's quality of life and the burden of dysphagia on caregivers (ASHA 2002; Schindler et al., 2003).

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The body of literature on swallowing disorder in patients with tetanus is limited, and there are currently no standardized quality indicators for swallowing rehabilitation programs. It is essential to introduce quality indicators in order to clearly understand and manage the quality of health care. Using quality indicators in hospital units improves the analysis of performance over time as new procedures and technology are introduced (Moraes and Andrade, 2011). We would like to stress that this study was designed to test the hypothesis that a set of swallowing/muscle exercise is effective in optimizing swallowing and muscle function in severe/very severe tetanus patients, reducing the amount of time in the ICU (i.e. reducing hospital costs and decreasing bed turnover).

5. Conclusions

In conclusion, swallowing/muscle exercise, in patients with severe/very severe tetanus, seem to promote the remission of muscle tension and seem to maximize functional swallowing. Our results suggest that this set of exercises is a promising procedure to be adopted with ICU tetanus patients.

References

Altmann, E.B.C., 1987. Myofunctional therapy and orthognatic surgery. *Int. J. Orofacial Myology*. 13(3), 2-12.

ARTIGO 2 - REHABILITATIVE MANAGEMENT OF SWALLOWING AND ORAL-MOTOR
MOVEMENTS IN PATIENTS WITH TETANUS OF A PUBLIC SERVICE IN BRAZIL

American Speech-Language-Hearing Association, 1990. The role of the speech-language pathologist in assessment and management of oral myofunctional disorders. *Int. J. Orofac. Myol.* 16(1):2.

American Speech-Language-Hearing Association National Outcome Measurement System (NOMS), 1998. Adult Speech-Language Pathology training manual. Rockville, MD: ASHA.

American Speech-Language-Hearing Association, 2002. Knowledge and Skills Needed by Speech-Language Pathologists Providing Services to Individuals With Swallowing and/or Feeding Disorders [Knowledge and Skill]: 1-9.

Bleck, T.P., 1991. Tetanus. In: Scheldw, M., Whitky, R.J., Durack, D.T.(Eds.), *Infections of the Central Nervous System*. New York: Raven Pres Ltd, pp.603-624.

Bleck, T., 1995. *Clostridium tetani*. In: Mandell, G.L., Douglas, R.G., Bennett, J.E. (Eds.), *Principles and Practise of infectious disease*. 4th ed. Edinburgh: Churchill Livingstone, pp.2173-2178.

Burkhead, L.M., Sapienza, C.M., Rosenbek, J.C., 2007. Strength-training exercise in dysphagia rehabilitation: principles, procedures, and directions for future research. *Dysphagia*. 22, 251-265.

ARTIGO 2 - REHABILITATIVE MANAGEMENT OF SWALLOWING AND ORAL-MOTOR
MOVEMENTS IN PATIENTS WITH TETANUS OF A PUBLIC SERVICE IN BRAZIL

Dundar, V., Yumuk, Z., Ozturk-Dundar, D., Erdogan, S., Gacar, G., 2005. Prevalence of tetanus Immunity in the Kocaeli Region, Turkey. *Jpn. J. Infect. Dis.* 58, 279-282.

Ertekin, C., Aydogdu, I., 2003. Neurophysiology of swallowing. *Clinical Neurophysiology.* 114, 2226-2244.

Finestone, H.M., Greene-Finestone, L.S., 2003. Rehabilitation medicine: 2. Diagnosis of dysphagia and its nutritional management for stroke patients. *CMAJ.* 169(10),1041-1044.

Folstein, M.F., Foltein, S.E., McHugh, P.R., 1975. "Mini-mental state". A practical method for grading the cognitive state of patients for the clinician. *J. Psychiatr Res.* 12, 189-198.

Frain, M.P., Tschopp, M.K., Bishop, M., 2009. Predictors of Outcomes in Rehabilitation. *J Rehabil.* 75(1), 27-35.

Frank, U., Mader, M., Sticher, H., 2007. Dysphagic patients with tracheotomies: a multidisciplinary approach to treatment and decannulation management. *Dysphagia.* 22(1), 20-29.

ARTIGO 2 - REHABILITATIVE MANAGEMENT OF SWALLOWING AND ORAL-MOTOR
MOVEMENTS IN PATIENTS WITH TETANUS OF A PUBLIC SERVICE IN BRAZIL

Goldsmith, T., 2000. Evaluation and treatment of swallowing disorders following endotracheal intubation and tracheostomy. *Int Anesthesiol Clin.* 38(3), 219-42.

Guimarães, K.C., Drager, L.F., Genta, P.R., Marcondes, B.F., Lorenzi-Filho, G., 2009. Effects of oropharyngeal exercises on patients with moderate obstructive sleep apnea syndrome. *Am J Respi Crit Care Med.* 179, 962-966.

Hammond, C.A.S., Goldstein, L.B., 2006. Cough and aspiration of food and liquids due to oral-pharyngeal dysphagia – ACCP Evidence-Based Clinical Practice Guidelines. *CHEST.* 129(1), 154-168.

Hinchey, J.A., Shepard, T., Furie, K., Smith, D., Wang, D., Tonn, S., 2005. Formal Dysphagia Screening Protocols Prevent Pneumonia. *Stroke.* 36, 1972 –1976.

Hospital Report Research Collaborative, 2007. Hospital Report: Acute Care, A joint initiative of the Ontario Hospital Association and the Government of Ontario. Available from <http://www.health.gov.on.ca>

Ibayashi, H., Fujino, Y., Pham, T.M., Matsuda, S., 2008. Intervention Study of exercise program for oral function in healthy elderly people. *Tohoku J. Exp. Med.* 215, 237-245.

ARTIGO 2 - REHABILITATIVE MANAGEMENT OF SWALLOWING AND ORAL-MOTOR
MOVEMENTS IN PATIENTS WITH TETANUS OF A PUBLIC SERVICE IN BRAZIL

Idema, C.D., Harris, B.N., Ogunbanjo, G.A., Dürrheim, D.N., 2002. Neonatal tetanus elimination in Mpumalanga Province, South Africa. *Tropical Medicine and International Health*. 7(7), 622-624.

Jean, A., 1986. Control of the central swallowing program by inputs from the principal receptors. A review. *J Auton Nerv Syst*. 10, 225-233.

Kabat, H., Knott, M., 1953. Proprioceptive facilitation technics for treatment of paralysis. *Phys Ther Rev*. 33, 53-64.

Knott, M., 1964. Neuromuscular facilitation in the treatment of rheumatoid arthritis. *Phys Ther*. 44, 737-739.

Leslie, P., Carding, P.N., Wilson, J.A., 2003. Investigation and management of chronic dysphagia. *BMJ*. 32(6), 433-436.

Litvoc, J., Leite, R.M., Katz, G., 1991. Aspectos epidemiológicos do tétano no estado de São Paulo (Brasil). *Rev. Inst. Med trop*. 33(6), 477-484.

Logemann, J.A., 1983. Evaluation and treatment of swallowing disorders. Austin – Texas: Proed, p.240.

Logemann, J.A., Veis, S., Colangelo, L., 1999. A screening procedure for oropharyngeal dysphagia. *Dysphagia*. 14, 44-51.

ARTIGO 2 - REHABILITATIVE MANAGEMENT OF SWALLOWING AND ORAL-MOTOR
MOVEMENTS IN PATIENTS WITH TETANUS OF A PUBLIC SERVICE IN BRAZIL

Logemann, J.A., 2008. Treatment of oral and pharyngeal dysphagia. *Phys Med Rehabil Clin N Am.* 19(4), 803-816.

Mangilli, L.D., Sassi, F.C., Santos, S.S., Andrade, C.R.F., 2009. Oral sensorimotor function for feeding in patients with tetanus. *Acta Tropica.* 111, 316-320.

Mangilli, L.D., Sassi, F.C., Jacomo, A., Andrade, C.R.F., 2011. Evaluation of oral-motor movements and speech in patients with tetanus of a public service in Brazil. *Journal of Oral Rehabilitation.* 38, 564-570.

Meaudre, E., Pernod, G., Gaillard, P.E., Kaiser, E., Cantais, E., Ripart, J., Palmier, B., 2005. Mandibular nerve blocks for the removal of dentures during trismus caused by tetanus. *Anesth Analg.* 101, 282-283.

Moraes, D.P., Andrade, C.R.F., 2011. Indicadores de qualidade para o gerenciamento da disfagia em Unidades de Internação Hospitalar. *J Soc Bras Fonoaudiol.* 23(1), 89-94.

Moraes, E.N., Pedrosa, E.R.P., 2000. Tétano no Brasil: doença do idoso? *Rev. Inst. Med trop.* 33(3), 271-275.

ARTIGO 2 - REHABILITATIVE MANAGEMENT OF SWALLOWING AND ORAL-MOTOR
MOVEMENTS IN PATIENTS WITH TETANUS OF A PUBLIC SERVICE IN BRAZIL

Namura, M., Motoyoshi, M., Namura, Y., Shimizu, N., 2008. The effects of PNF training on the facial profile. *J. Oral Sci.* 50, 45-51.

Nary-Filho, H., Gonçalves, E.S., Berretin-Felix, G., Souza, P.C.U.S., 2002. Evaluation of the soft tissues following surgically assisted maxillary expansion associated with the simple V-Y suture. *Int. J. Adult. Orthodon. Orthognath. Surg.* 17(2), 89-97.

Ott, D.J., 1998. Observer variation in evaluation of videofluoroscopic swallowing studies: a continuing problem. *Dysphagia.* 13, 148-150.

Perry, L., Love, C.P., 2001. Screening for dysphagia and aspiration in Acute Stroke: a systematic review. *Dysphagia.* 16, 7-18.

Schindler, A., Grosso, E., Tiddia, C., Cavalot, A.L., Ricca, G., Ottaviani, F., Schindler, O., 2003. Swallowing disorders: management data. *Acta Otorhinolaryngol Ital.* 23, 180–184.

Schindler, A., Vincon, E., Grosso, E., Miletto, A.M., Di Rosa, R., Schindler, O., 2008. Rehabilitative Management of Oropharyngeal Dysphagia in AcuteCare Settings: Data from a Large Italian Teaching Hospital. *Dysphagia.* 23, 230–236.

ARTIGO 2 - REHABILITATIVE MANAGEMENT OF SWALLOWING AND ORAL-MOTOR
MOVEMENTS IN PATIENTS WITH TETANUS OF A PUBLIC SERVICE IN BRAZIL

Shin, D.H., Park, J.H., Jung, P.J., Lee, S.R., Shin, J.H., Kim, S.J., 2002. A case of maternal tetanus in Korea. *J Korean Med Sci.* 17, 260-262.

Steele, C.M., 2009. On the plausibility of upper airway remodeling as an outcome of orofacial exercise. *Am J Respir Crit Care Med.* 179(10), 858-859.

Stubbel, M., Mortelmans, L.J.M., Desruelles, D., Swinnen, R., Vranckx, M., Brasseur, E., Lheureux, P.E., 2007. Improving tetanus prophylaxis in the emergency department: a prospective, Double-blind cost-effectiveness study. *Emerg Med J.* 24(9), 648-653.

Tapajós, R., 1996. Tétano. In: Neto-Reá, A., Tesser, A.L., Silva-Sobrinho, E.X. (Eds.), *Medicina de Emergência e Medicina Intensiva*. São Paulo: Know Med, pp 30-35.

Thwaites, C.L., Farrar, J.J., 2003. Preventing and treating tetanus. *BMJ.* 326, 117-118.

Valera, F.C., Travitzki, L.V., Mattar, S.E., Matsumoto, M.A., Elias, A.M., Anselmo-Lima, W.T., 2003. Muscular, functional and orthodontic changes in preschool children with enlarged adenoids and tonsils. *Int. J. Pediatr. Otorhinolaryngol.* 67(7), 761-770.

ARTIGO 2 - REHABILITATIVE MANAGEMENT OF SWALLOWING AND ORAL-MOTOR
MOVEMENTS IN PATIENTS WITH TETANUS OF A PUBLIC SERVICE IN BRAZIL

Veronese, R., Focaccia, R., Tavares, W., Mazza, C.C., 1991. Tétano. In: Veronese, R. (Ed.), Doenças Infecciosas e parasitárias. 8ª ed. São Paulo: Guanabara Koogan, pp.447-466.

Weiner, J.B., Alexander, J.A., Shortell, S.M., Baker, L.C., Geppert, J.J., 2006. Quality improvement implementation and hospital performance on quality indicators. Health Res and Educ Trust. 41(2), 307-33.

Weir, E., d'Entremont, N., Stalker, S., Kurji, K., Robinson, V., 2009. Applying the balanced scorecard to local public health performance measurement: deliberations and decisions. BMC Public Health. 9, 127.

Wesling, M., Brady, S., Jensen, M., Nickell, M., Statkus, D., Escobar, N., 2003. Dysphagia outcomes in patients with brain tumors undergoing inpatient rehabilitation. Dysphagia. 18, 203-210.

White, G.N., O'Rourke, F., Ong, B.S., Cordato, D.J., Chan, D.K.Y., 2008. Dysphagia: causes, assessment, treatment and management. Geriatrics. 63(5), 15-20.

APROVAÇÃO

A Comissão de Ética para Análise de Projetos de Pesquisa - CAPPesq da Diretoria Clínica do Hospital das Clínicas e da Faculdade de Medicina da Universidade de São Paulo, em sessão de 17/06/2009, **APROVOU** o Protocolo de Pesquisa nº **0373/09**, intitulado: "**PROGRAMA DE AVALIAÇÃO E TRATAMENTO FONOAUDIOLÓGICO PARA REABILITAÇÃO DA FUNÇÃO MASTIGATÓRIA DE INDIVÍDUOS SUBMETIDOS À CIRURGIA ORTOGNÁTICA POR DEFORMIDADE DENTOFACIAL**" apresentado pelo Departamento de **FISIOTERAPIA, FONOAUDIOLOGIA E TERAPIA OCUPACIONAL**, inclusive o Termo de Consentimento Livre e Esclarecido.

Cabe ao pesquisador elaborar e apresentar à CAPPesq, os relatórios parciais e final sobre a pesquisa (Resolução do Conselho Nacional de Saúde nº 196, de 10/10/1996, inciso IX.2, letra "c").

Pesquisador (a) Responsável: **Profa. Dra. Claudia Regina Furquim de Andrade**

Pesquisador (a) Executante: **Laura Davison Mangilli**

CAPPesq, 17 de Junho de 2009

Prof. Dr. Eduardo Massad
Presidente da Comissão de
Ética para Análise de Projetos
de Pesquisa

**HOSPITAL DAS CLÍNICAS DA FACULDADE DE MEDICINA DA UNIVERSIDADE DE SÃO PAULO-
HCFMUSP**

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

DADOS DE IDENTIFICAÇÃO DO SUJEITO DA PESQUISA OU RESPONSÁVEL LEGAL

- 1. NOME:**
DOCUMENTO DE IDENTIDADE Nº: **SEXO:** .M ☐ F ☐
DATA NASCIMENTO:/...../.....
ENDEREÇO **Nº** **APTO:**
BAIRRO: **CIDADE**
CEP:..... **TELEFONE: DDD** (.....)
- 2. RESPONSÁVEL LEGAL**
NATUREZA (grau de parentesco, tutor, curador etc.)
DOCUMENTO DE IDENTIDADE **SEXO:** M ☐ F ☐
DATA NASCIMENTO:/...../.....
ENDEREÇO: **Nº** **APTO:**
BAIRRO: **CIDADE:**
CEP: **TELEFONE: DDD** (.....).....
-

DADOS SOBRE A PESQUISA

- 1. TÍTULO DO PROTOCOLO DE PESQUISA:** Programa de avaliação e tratamento fonoaudiológico para a reabilitação da função mastigatória de indivíduos submetidos à cirurgia ortognática por deformidade dentofacial

PESQUISADOR : Laura Davison Mangilli

CARGO/FUNÇÃO: Fonoaudióloga INSCRIÇÃO CONSELHO REGIONAL Nº 13493/SP

UNIDADE DO HCFMUSP: Departamento de Fisioterapia, Fonoaudiologia, e Terapia Ocupacional da Faculdade de Medicina da Universidade de São Paulo

- 3. AVALIAÇÃO DO RISCO DA PESQUISA:**

RISCO MÍNIMO	X	RISCO MÉDIO	☐
RISCO BAIXO	☐	RISCO MAIOR	☐

- 4. DURAÇÃO DA PESQUISA :** 48 meses

HOSPITAL DAS CLÍNICAS DA FACULDADE DE MEDICINA DA UNIVERSIDADE DE SÃO PAULO-HCFMUSP

1 – Desenho do estudo e objetivo(s):

O(a) senhor(a) está sendo convidado(a) a participar de uma pesquisa desenvolvida na área de Fonoaudiologia. A seguir explicarei os objetivos e a importância deste estudo.

Esta pesquisa tem como objetivo apresentar formas de avaliar e tratar pessoas que realizarão a cirurgia ortognática, assim como o(a) senhor(a), visando/buscando principalmente a correção da mastigação. Sabe-se que a fonoaudiologia pode trabalhar para adequar/corrigir as funções como respiração, mastigação, engolir e falar, após a realização da cirurgia, mas existem poucos estudos que mostram como a avaliação e o tratamento podem ser realizados.

Com a realização deste estudo poderemos melhorar o atendimento oferecido aos pacientes que realizarão a cirurgia ortognática.

2 – Descrição dos procedimentos que serão realizados, com seus propósitos e identificação dos que forem experimentais e não rotineiros:

Esse estudo será realizado com dois grupos de participantes: aqueles que realizarão tratamento fonoaudiológico precoce e aqueles que realizarão tratamento fonoaudiológico não precoce. Os dois grupos serão avaliados e tratados da mesma forma, mas o momento do início do tratamento será diferente para os grupos. Para o grupo de participantes que realizarão o tratamento precoce, o início do tratamento será aproximadamente no 45º dia após a cirurgia. Para o grupo de participantes que realizarão o tratamento não precoce, o início do tratamento será aproximadamente no 90º dia após a cirurgia.

A forma de divisão dos participantes será realizada por meios já determinados, através de métodos legais e frequentemente utilizados em pesquisas semelhantes.

O grupo de tratamento não precoce representará a forma como o tratamento fonoaudiológico é realizado hoje em dia - encaminhamento médico realizado com 90 dias da cirurgia. O grupo de tratamento precoce representará uma nova possibilidade de tratamento fonoaudiológico – encaminhamento médico realizado aproximadamente com 45 dias da cirurgia. Essa nova possibilidade de tratamento fonoaudiológico foi discutida entre médicos, dentistas e fonoaudiólogos, e se acredita que o paciente possa se beneficiar do tratamento quando este for iniciado anteriormente ao padrão realizado hoje em dia (aproximadamente 90 dias após a cirurgia).

3 – Relações dos procedimentos rotineiros e como são realizados:

As avaliações serão realizadas em uma única sessão, de aproximadamente 90 minutos, na qual o(a) senhor(a) realizará:

- avaliação clínica: serão utilizados meios de avaliação (protocolos) de pesquisas anteriores, que verificarão a situação dos músculos de seu rosto e pescoço e como estes estão funcionando (para respirar, engolir e mastigar). O fonoaudiólogo solicitará alguns movimentos e funções de seu rosto, pescoço e cabeça e vai avaliar se esses movimentos e funções estão sendo realizados da forma correta.

- Teste de Eficiência Mastigatória (EM): para a avaliação da mastigação será solicitado que o(a) senhor(a) mastigue três cápsulas com grãos (que não cairão em sua boca), uma delas da forma como está acostumado, outra somente do lado direito e outra somente do lado esquerdo. Conforme a quebra/trituração dos grãos que estarão dentro da cápsula mastigada a eficiência de sua mastigação será avaliada.

- Exame de Eletromiografia de Superfície (EMGs): esse exame avaliará o funcionamento dos músculos responsáveis pela sua mastigação. Para isso, será colocado em sua pele – na região das têmporas (ao lado da testa) e das bochechas (logo a frente da orelha) um eletrodo. Será pedido que o(a) senhor(a) permaneça sem realizar nenhum movimento com o rosto e pescoço durante 30 segundos e será avaliado o funcionamento dos músculos no repouso. Depois será pedido que o(a) senhor(a) aperte um dente contra o outro (morda) durante 5 segundos e será avaliado o funcionamento dos músculos. Logo após, será colocado um pedaço de algodão entre os seus dentes e pedido que o(a) senhor(a) aperte um dente contra o outro (morda) durante 5 segundos e será avaliado o funcionamento dos músculos. Por último, será pedido que o senhor mastigue as cápsulas com grãos e será avaliado o funcionamento dos músculos na mastigação.

O tratamento será realizado no Hospital das Clínicas. O(A) senhor(a) deverá comparecer ao hospital uma vez por semana, por seis semanas seguidas (6 sessões), e cada sessão terá quarenta minutos de duração. Será realizado o **Programa Fonoaudiológico de Promoção da Função Mastigatória em pacientes submetidos à cirurgia ortognática**, que busca a correção dos músculos e das funções realizadas pelo seu rosto e pescoço. Para isso serão realizadas orientações; atividades

em que o(a) senhor(a) terá que ter atenção na forma como mastiga, engole, fala e respira; exercícios com os músculos do rosto e pescoço; e treinos de mastigar, engolir, falar e respirar da forma correta. Será solicitado que o(a) senhor(a) faça alguns exercícios e treinos em casa (diariamente, no mínimo três vezes por dia) de algumas atividades aprendidas e realizadas durante as sessões.

4 – Descrição dos desconfortos e riscos esperados nos procedimentos dos itens 2 e 3:

As atividades programadas tanto na avaliação como no tratamento não trazem nenhum desconforto ao indivíduo e nenhum risco.

5 – Benefícios para o participante:

Trata-se de estudo experimental testando a hipótese de que a intervenção fonoaudiológica precoce poderá auxiliar a retomada da mastigação de forma mais rápida e mais adequada possível. Somente no final do estudo poderemos concluir a presença de benefícios para essa intervenção. Caso esses benefícios não sejam comprovados, será garantido os participantes do grupo do tratamento precoce a realização do tratamento não precoce.

6 – Relação de procedimentos alternativos que possam ser vantajosos, pelos quais o paciente pode optar:

Não existem procedimentos alternativos que possam ser vantajosos aos pacientes.

7 – Garantia de acesso:

Em qualquer etapa do estudo o senhor(a) terá acesso aos profissionais responsáveis pela pesquisa para esclarecimento de eventuais dúvidas. Os investigadores são a Profa. Dra. Claudia Regina Furquim de Andrade e a fonoaudióloga Laura Davison Mangilli que podem ser encontrado na Rua Cipotania, 51 - Campus Cidade Universitária - CEP 05360-160 - São Paulo, SP, Brazil - Tel: 11 3091-8406. Se você tiver alguma consideração ou dúvida sobre a ética da pesquisa, entre em contato com o Comitê de Ética em Pesquisa (CEP) – Rua Ovídio Pires de Campos, 225 – 5º andar – tel: 3069-6442 ramais 16, 17, 18 ou 20, FAX: 3069-6442 ramal 26 – E-mail: cappesq@hcnet.usp.br

8 – É garantida a liberdade da retirada de consentimento a qualquer momento e deixar de participar do estudo, sem qualquer prejuízo à continuidade de seu tratamento na Instituição;

09 – Direito de confidencialidade: As informações obtidas serão analisadas em conjunto com outros pacientes, não sendo divulgado a identificação de nenhum paciente;

10 – Direito de ser mantido atualizado sobre os resultados parciais das pesquisas, quando em estudos abertos, ou de resultados que sejam do conhecimento dos pesquisadores;

11 – Despesas e compensações: não há despesas pessoais para o participante em qualquer fase do estudo, incluindo exames e consultas. Também não há compensação financeira relacionada à sua participação. Se existir qualquer despesa adicional, ela será absorvida pelo orçamento da pesquisa.

12 - Compromisso do pesquisador de utilizar os dados e o material coletado somente para esta pesquisa.

Acredito ter sido suficientemente informado a respeito das informações que li ou que foram lidas para mim, descrevendo o estudo “Modelo de controle de tratamento para função mastigatória”. Eu discuti com a Profa. Dra. Claudia Regina Furquim de Andrade e/ou Fga. Laura Davison Mangilli sobre a minha decisão em participar nesse estudo. Ficaram claros para mim quais são os propósitos do estudo, os procedimentos a serem realizados, seus desconfortos e riscos, as garantias de confidencialidade e de esclarecimentos permanentes. Ficou claro também que minha participação é isenta de despesas e que tenho garantia de acesso a tratamento hospitalar quando necessário. Concordo voluntariamente em participar deste estudo e poderei retirar o meu consentimento a qualquer momento, antes ou durante o mesmo, sem penalidades ou prejuízo ou perda de qualquer benefício que eu possa ter adquirido, ou no meu atendimento neste Serviço.

ANEXO II

Assinatura do paciente/representante legal Data / /

Assinatura da testemunha Data / /

para casos de pacientes menores de 18 anos, analfabetos, semi-analfabetos ou portadores de deficiência auditiva ou visual.

(Somente para o responsável do projeto)

Declaro que obtive de forma apropriada e voluntária o Consentimento Livre e Esclarecido deste paciente ou representante legal para a participação neste estudo.

Assinatura do responsável pelo estudo Data / /