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EFICÁCIA DA TERAPIA A LASER DE BAIXA INTENSIDADE NA REDUÇÃO DO EDEMA, DOR E PARESTESIA NO PÓS OPERATÓRIO DE CIRURGIAS ORTOGNÁTICAS: ESTUDO RANDOMIZADO DUPLO CEGO CRUZADO

Goiânia
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EFICÁCIA DA TERAPIA A LASER DE BAIXA INTENSIDADE NA REDUÇÃO DO EDEMA, DOR E PARESTESIA NO PÓS OPERATÓRIO DE CIRURGIAS ORTOGNÁTICAS: ESTUDO RANDOMIZADO DUPLO CEGO CRUZADO

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Dedico este trabalho

Dedico este trabalho a Lorena, minha esposa, pelo companheirismo e paciência. Meu filho Giovanni que trouxe mais alegria a nossa casa. E aos meus pais que sempre me fizeram acreditar na realização dos meus sonhos e trabalharam muito para que eu pudesse realizá-los.

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SUMÁRIO

TABELAS, FIGURAS E ANEXOS

SÍMBOLOS, SIGLAS E ABREVIATURAS

ABREVIATURAS

BSSO: Bilateral sagittal Split osteotomy

Cm: centímetro

DE: densidade de energia

E: energia

EAV(VAS): escala analógica visual/visual analogue scale

H: Horas

IAN: Inferior alveolar nerve

J: joule

LBI: laser de baixa intensidade

LLLT: Low level laser teraphy

Mm: Milimetro

mW: miliwatt

Nai: nervo alveolar inferior

nm: nanometro

P: potência

S: segundo

T: tempo

α: alfa

λ: Gama

RESUMO

Este estudo teve como objetivo verificar a eficácia do uso de um protocolo de terapia laser de baixa intensidade para redução do edema, dor e disturbios neurossensoriais após cirurgias ortognáticas. Dez pacientes foram submetidos a osteotomia sagital bilateral com osteotomia Le Fort I recebendo aplicação da terapia laser de baixa intensidade em um dos lados e foram avaliados num periodo de 60 dias. O protocolo utilizado foi aplicação intra oral (λ = 660 nm (vermelho), ED = 5J/cm2, t = 10 s / ponto, P = 20 mW, E = 1,2 J por ponto) e extra oral (λ = 789 nm de infra-vermelho), DE = 30J/cm2, t = 20 s / ponto, P = 60 mW, E = 1,2 J por ponto) nos três primeiros dias pós operatorios . Depois do quarto dia, dez aplicações intra-orais e extra-orais foram realizadas (λ = 780nm (IR), DE = 70J/cm2, P = 70 mW, t = 40 / ponto, E = J 2,8, por ponto). Os dados pós operatorios entre os lados irradiados e não irradiados foram comparados e submetidos ao teste estatístico de Wilcoxon. Houve a recuperação da sensibilidade do labio inferior nos dois lados, mas no lado irradiado, essa recuperação foi mais rápida. O edema foi avaliado através do coeficiente de edema e a dor através de uma escala analogical visual. Não houve diferença estatisticamente significante entre o edema e a dor na avaliação imediatamente após a cirurgia entre os dois lados. O edema foi significantemente menor no lado irradiado nas outras avaliações pós operatórias (2.15 para 0.21) e lado não irradiado (2.72 para 1.29). A percepção de dor foi menos intensa do lado irradiado em 24 horas (1.20 vs 3.4) e 3 dias (0.60 vs 2.10), mas a partir do sétimo dia não observou-se dor

em nenhum dos lados. O protocolo de terapia laser de baixa intensidade aqui descrito melhora a resposta dos tecidos e reduzir a dor e inchaço resultante de cirurgias ortognáticas e acelerar a recuperação de distúrbios neurossensoriais resultantes da osteotomia sagital bilateral do ramo.

ABSTRACT

This study aimed to verify the effectiveness of using a low-level laser therapy protocol to reduce swelling, pain and neurosensory disturbance after orthognathic surgeries. Ten patients who underwent bilateral sagittal split (BSSO) with Le Fort I osteotomy and had low-level laser therapy on one side of the jaw were evaluated over a period of 60 days. The protocol used was intra oral application after surgery (λ = 660 nm (Red), ED = 5J/cm2, t = 10 s / point, P = 20 mW, E = 1.2 J per point). And extra oral application (λ = 789 nm infra-red), DE = 30J/cm2, t = 20 s / point, P = 60 mW, E = 1.2 J per point). After the fourth day, ten intraoral and extraoral applications were performed (λ = 780nm (infrared), DE = 70J/cm2, P = 70 mW, t = 40s / point, E = 2.8 J, per point). Irradiated and non-irradiated side data were compared post-operatively. In all assessments except the immediate post operative assessment, swelling and pain decreased. There is recovery of sensitivity on both sides, but on the irradiated side, recovery is faster and almost normal at the last evaluation. The data for the irradiated and non-irradiated sides were compared post-operatively. Fifteen, 30 and 60 days after surgery, sensitivity was recovered on both sides, but on the irradiated side, recovery was faster and was almost complete at the time of the last evaluation. Irradiated and non-irradiated sides were compared regarding swelling coefficient and Visual Analogue Scale for pain assessment. There were no significant differences between irradiated and non-irradiated sides regarding swelling and pain in the immediate post-operative assessment. Swelling significantly decreased in the irradiated side

in the following post-operative assessments, from 2.15 to 0.21 (non irradiated side: 2.72 to 1.29). Self-reported pain was less intense in the irradiated side in the 24-hr (1.20 vs 3.4) and 3-day (0.60 vs 2.10) assessments, but after 7 days of surgery either side did not show any pain. This lower-level laser therapy protocol can improve tissue response and reduce pain and swelling resulting from orthognathic surgeries and accelerate the recovery of neurosensory disorders resulting from BSSO.

1 INTRODUÇÃO

Em cirurgias odontológicas tem-se um processo inflamatório, resultante de incisões, descolamentos mucoperióteos e osteotomias. O edema assim é caracterizado e seu aparecimento é iminente, sempre que há um trauma por procedimento cirúrgico.

A cirurgia ortognática é o tratamento para pacientes que possuem deformidades dento faciais envolvendo o esqueleto facial e os dentes. Quando não é possível resolver o caso somente com o tratamento ortodôntico, uma vez que o problema está no excesso ou falta de crescimento do esqueleto facial e não somente na posição dos dentes, então se faz necessária a cirurgia ortognática.

As deformidades dento faciais podem ter origem nas síndromes e anomalias específicas (fatores teratogênicos, fatores embriológicos, microssomia hemifacial, Treacher Collins, fissuras faciais, crânio-sinostoses, Pierre Robin, etc.), distúrbios de crescimento após o nascimento, trauma facial, problemas musculares e hormonais, ou serem de origem genética quando existe algum familiar com as mesmas características.[1,2 3]

A técnica da osteotomia sagital bilateral de mandíbula, usada nas cirurgias ortognáticas, visa a correção das deformidades mandibulares de retrognatismo, prognatismo e assimetrias leves a moderadas. O emprego dessa técnica leva ao traumatismo mecânico do nervo alveolar inferior que se manifesta clinicamente como alteração de sensibilidade, ou parestesia, dos dentes inferiores e da região mentoniana.[2,3,4,5]

Além do trauma direto ao nervo alveolar inferior, nesse tipo de cirurgia tem-se um processo inflamatório resultante do trauma cirúrgico nos tecidos moles e duros, tais como as incisões, o descolamento mucoperiósteo e as osteotomias, que gera um desconforto doloroso e inchaço facial importante na fase pós operatória.

A inflamação inicia-se imediatamente após a lesão induzida pelo trauma cirúrgico, sendo uma resposta natural do organismo ao trauma lesivo, ela é um pré-requisito para que o processo de reparo aconteça. Visando o conforto do paciente, os cirurgiões devem lançar mão de todos os recursos para que o pós-operatório seja melhor, ou seja, reduzir ou modular beneficamente a resposta inflamatória pós-operatória.

O laser de baixa intensidade (LBI), também conhecido como laser terapêutico ou soft-laser, surgiu com Mester [6], na Hungria, em 1969. A utilização do raio laser é um fato relativamente recente e, a partir da década de oitenta, estudos sobre sua aplicação nas mais variadas áreas da estomatologia tem procurado investigar a viabilização do seu emprego como modalidade de tratamento de diferentes afecções do complexo maxilo-facial.

A laserterapia de baixa potência é feita por aparelhos que produzem energia menor que um Watt de potência, e os comprimentos de onda mais utilizados estão entre 600 e 800 nanômetros, conseqüentemente apresentam uma boa transmissão na pele e mucosas. Entre estes comprimentos de onda no espectro vermelho e infravermelho próximo, estão as radiações que produzem efeitos terapêuticos, como bioestimulação, proliferação, diferenciação e síntese de proteínas [7,8,9]. Os estudos

disponíveis na literatura [7,9, 8, 9, 10, 11, 12, 13,14,15,16] sugerem que a radiação laser tem ação anti-inflamatória.

A aplicação do laser de baixa intensidade no pós operatório de cirurgias bucomaxilofaciais é motivo de estudo na última década porém são poucos os trabalhos sobre seus efeitos em cirurgia ortognática. Este trabalho tem como objetivo avaliar a eficácia da terapêutica com lasers de baixa intensidade na redução do desconforto pós-operatório em cirurgias ortognáticas.

2 OBJETIVOS

2.1 Gerais

- Avaliar a ação do laser de baixa intensidade na redução do processo inflamatório e aumento da sensibilidade do lábio inferior em cirurgias ortognáticas.

2.2 Específicos

- Verificar a ocorrência de sinais e sintomas pós-operatórios em casos de cirurgia ortognática.

- Avaliar a ação do laser de baixa intensidade na modulação desses sinais e sintomas.

2.3 Hipótese

A laser terapia de baixa intensidade reduz o processo inflamatório e acelera a recuperação da sensibilidade do lábio inferior.

3 MÉTODO(S)

Este estudo clinico duplo-cego randomizado foi aprovado pelo Comite de Ética em Pesquisa com Seres Humanos do Hospital Universitário da Universidade Federal de Goiás (protocolo n º 101/2011) e registrado como um ensaio clínico (protocolo n º 01530100 NCT). Todos os participantes assinaram um termo de consentimento para se submeter ao tratamento.

O tratamento cirúrgico foi realizado no Departamento de Cirurgia Bucomaxilofacial do Hospital Universitário com 10 mulheres sem comprometimento sistêmico (idade 18-54 anos, média de idade de 30 anos) que se submeteram à cirurgia ortognática bimaxilar (osteotomia Le Fort I e osteotomia sagital bilateral) para correção de deformidades dentofaciais.

Os critérios de inclusão dessas pacientes foram: ausência de trauma facial ou lesões ao nervo alveolar inferior; nenhum distúrbio neurossensorial antes do tratamento; terceiros molares foram removidos pelo menos 6 meses antes da cirurgia ortognática; osteotomia sagital semelhante nos dois lados esquerdo e direito de acordo com tempo e manipulação mínima do nervo alveolar inferior e sem mentoplastia. Os critérios de exclusão foram ruptura feixe neurovascular; bad split da osteotomia sagital, infecção pós-operatória ou falta nas sessões de laserterapia. Todos os pacientes preencheram os critérios sem qualquer exclusão. O tamanho da amostra foi determinado pelo comportamento estatístico dos resultados. Todos os pacientes foram submetidos ao tratamento ortodontico pré-operatório para corrigir a posição dentária. Todos os pacientes foram operados pelo cirurgião mais experiente da equipe. Quatro dos

procedimentos envolviam impacção superior de maxila e avanço mandibular, com impactação maxilar média de 4 mm e a média de avanço mandibular de 6 mm. Os outros seis procedimentos envolviam avanço maxilar média de 5 mm, e recuo mandibular, com média de 3 mm. O tempo médio das cirurgias foi de 01 hora e 53 minuotos (intervalo de 1h32 minutos para 2h08 minutos).

As medicações foram padronizadas e dosadas de acordo com o peso do paciente, a fim de manter a mesma proporção de drogas. Pré e trnas operatórias: cefazolina, hidrocortisona, dexametasona, nausedron, tramadol e ranitidina. Pós-operatórias: dexametasona por 72 horas e tramadol proo 24 horas e cetorolaco após 24 horas em caso de dor.

Técnica cirúrgica

Antes de proceder à incisão cirúrgica, foi infiltrada da mucosa bucal ao longo de toda a superfície da maxila, solução de anestésico local com epinefrina (lidocaína a 2% com epinefrina 1:100.000), a fim de minimizar o sangramento e aumentar a analgesia durante o procedimento cirúrgico.

A técnica de osteotmia Le Fort I baseou-se no trabalho de Bell[1] (1975), a incisão de tecidos moles foi realizada bilateralmente a partir da linha média do fórnice acima dos incisivos centrais para a região do primeiro molar; após a incisão, a dissecção subperiosteal foi feito com um elevador periosteal expondo a parede lateral da maxila, a partir a junção pterigomaxilar à espinha nasal anterior e rebordo inferior da órbita.

A abertura piriforme foi exposta, e o mucoperiósteo foi elevado ao longo do rebordo piriforme, assoalho e a parede nasal lateral sob a concha inferior e, em seguida refletida com um elevador periostal para expor o assoalho do nariz.

Uma vez que a dissecção foi concluída, os pontos de referência foram estabelecidos antes de realizar osteotomia. Todos os pacientes foram submetidos a osteotomia Le Fort I alta com limite superior de 5 mm abaixo do forame infraorbital. A maxila foi posicionada por guias confeccioandos na cirurgia de modelos e fixada por quatro miniplacas sistema 2.0 lock e 16 parafusos colocados nos pilares canino e zigomático.

A técnica osteotomia sagital foi realizada utilizando os princípios da Trauner e Obwegeser[2] (1957) modificado por Epker[5] (1977). O ramo mandibular foi exposto bem como o feixe neurovascular alveolar inferior a partir do aspecto lingual do forame mandibular. Os cortes de osso horizontal e vertical foram feitos com uma broca 703. O corte sagital foi realizado com uma serra sagital. Divisão foi iniciada com uma seqüência cinzel conduzido diretamente para o corte sagital em contato com o osso cortical externo para minimizar lesões nervosas. Então, a pinça de separação foi posicionada no corte sagital, o elevador foi posicionado no corte ósseo vertical, a divisão mandibular foi cuidadosamente concluida e o defeito ósseo foi inspeccionado para identificar o feixe neurovascular alveolar inferior.

A mandíbula foi reposicionada usando um guia e o bloqueio maxilomandibular realizado. O segmento proximal foi posicionado manualmente, e a mandibula fixada com uma miniplca sistema 2.0 lock de cada lado com 04 parafusos, bloqueio maxilomandibular foi removido e a oclusão verificada.

Avaliação neurossensorial pré operatória

Seis pontos foram simetricamente marcados no lábio inferior e sensação labiomental foi avaliada no pré-operatório por discriminação de dois pontos (a agulha 25x7 foi utilizado para determinar a menor distância em milímetros que o paciente possa sentir os dois furos) e um teste sensorial (a mesma agulha foi usada para estimular os seis pontos ea sensação relatada foi atribuída uma pontuação, com 3 sendo percepção normal). Escores médios de cada região foram calculados e os dados foram coletados e armazenados para comparação com os dados pós-cirúrgicos.

Protocolo de aplicação do laser

A gálio-alumínio arsenieto de diodo dispositivo laser de baixa potência (Thera Laser, DMC Brasil, onda contínua, o tamanho do ponto 0.4 mm) foi usada. A superfície exposta ao laser foi limpa e seca antes da aplicação. As aplicações foram realizadas por outro cirurgião-dentista.

Um lado, chamado lado irradiado, foi escolhido aleatoriamente para a terapia a laser pela exposição intra e extra bucal. Quatro pontos distantes 1cm entre si sobre a ferida cirúrgica intra-oral foram expostos no pós operatório imediato, com 24, 48 e 72 horas após a cirurgia (λ = 660 nm (vermelho), ED = 5J/cm2, t = 10 s / ponto, P = 20 mW, E = 1,2 J por ponto). Oito pontos no ramo mandibular e corpo foram expostos no pós operatório, com , 24, 48 e 72 horas após a cirurgia (λ = 789 nm de infra-vermelho), DE = 30J/cm2, t = 20 s / ponto, P = 60 mW, E = J 1,2 por ponto). Dois pontos em cada lifonodo, pré-auricular, gânglios linfáticos jugular-digástrico e submandibular tiveram a mesma exposição. Energia total utilizada foi de 21,6 J por sessão.

Depois do quarto dia, com um intervalo de 48 horas, 10 aplicações foram realziadas em: 3 pontos intra bucais sobre a linha de incisão, distantes 1 cm entre si no caminho do nervo alveolar inferior; 4 pontos na mucosa labial inferior; 2 pontos no lábio inferior e 9 pontos no mento sempre 1 cm de distância entre cada ponto. (Λ = 780nm (IR), DE = 70J/cm2, P = 70 mW, t = 40 / ponto, E = J 2,8, por ponto). Energia total utilizada foi de 50,4 J por sessão.

O outro lado foi chamdo d então irradiado e a unidade de laser foi posicionada nos mesmos pontos, mas o laser não foi ativado.

Avaliação

1. Sensorial

Um observador avaliou os sintomas pós-operatórios repetindo o mesmo teste pré-operatório. Os dados coletados foram usados para calcular a pontuação média de cada região. O teste de discriminação de dois pontos e teste sensorial foram realizados imediatamente no pós-operatório, 15 dias, 30 dias e 60 dias após a cirurgia. O teste sensorial estimulou-se os pontos e à sensação relatada foi atribuída uma pontuação de 3 para sensibilidade normal, 2 para um estímulo que foi percebido, mas não normal, 1 para a percepção do estímulo, mas sem nenhuma idéia sobre a qualidade e 0 para nenhuma percepção . Com estes valores se obteve a média de cada lado em cada período específico e os lados irradiados e não irradiados foram comparados.

2. Dor e edema

A Escala Visual Analógica - VAS foi usado para medir a intensidade da dor no pós-operatório: pós-operatório imediato, 24 horas, 72 horas e uma semana. Os pacientes foram questionados sobre o grau de dor em cada período, onde 0 significa ausência de dor e 10 o nível máximo tolerável de dor. O tamanho do edema foi calculado usando a fórmula modificada de Carrillo[17] (1990) medindo a distância entre a ponta do queixo e lobo inferior da orelha no período pós-operatório: imediato pós-operatório 72 horas por semana de 15 dias e 30 dias. O comprimento de pós-operatório foi subtraído do comprimento base, o resultado foi dividido pelo comprimento da base e multiplicado por 100. O comprimento base utilizada foi a distância medida aos 2 meses pós-operatório. As medidas obtidas, em cada período, foram comparados entre os lados irradiado e não irradiado.

Análise estatística

Os dados foram inseridos em uma planilha do Microsoft Excel e importados para o IBM SPSS Statistics versão 19 (SPSS Inc., Chicago, EUA). O teste de Wilcoxon Signed Rank foi utilizada para analisar a associação entre as variáveis, comparando o laser e não-laser de grupos. Os valores de $P < 0,05$ foram considerados estatisticamente significativos.

4. PUBLICAÇÕES

Artigo 1

Título: **Low-level laser therapy improves neurosensory disorders resulting from bilateral mandibular sagittal split osteotomy: a randomized crossover clinical trial**

Autores: **Giovanni Gasperini, Isabel Cristina Rodrigues de Siqueira, Luciane Rezende Costa**

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Artigo 2

Título: Does low-level laser therapy decrease swelling and pain resulting from orthognathic surgery?

Autores: **Giovanni Gasperini, Isabel Cristina Rodrigues de Siqueira, Luciane Ribeiro Rezende Costa**

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Artigo1

Summary

Bilateral sagittal split osteotomy (BSSO) is a technique commonly used to correct mandibular disproportions but many patients experience hypoesthesia of the inferior alveolar nerve (IAN). The purpose of this study was to verify the effectiveness of using a low-level laser therapy protocol after BSSO. The 10 patients in our study, who underwent BSSO with Le Fort I osteotomy and had low-level laser therapy on one side of the jaw, were evaluated over a period of 60 days. The data for the irradiated and non-irradiated sides were compared post-operatively. Fifteen, 30 and 60 days after surgery, sensitivity was recovered on both sides, but on the irradiated side, recovery was faster and was almost complete at the time of the last evaluation. We suggest that this lower-level laser therapy protocol can improve tissue response and accelerate the recovery of neurosensory disorders resulting from BSSO. (NCT01530100)

Key Words

Low-level laser therapy, inferior alveolar nerve, sagittal split osteotomy, neurosensory disturbance

Introduction

Bilateral sagittal split osteotomy (BSSO) is a versatile technique first described by Trauner and Obwegeser in 1957 for correcting mandibular disproportions. Over the years, many modifications have been introduced by DalPont (1961), Hunsuck (1968), and Epker (1977). The purpose of these changes is to improve stability and reduce surgical complications.

The sensory nerve to the lower lip is the inferior alveolar nerve (IAN), it runs through the lower jaw in the region of the osteotomy bone cuts. After the surgery, many patients experience hypoesthesia of the lower lip and chin, which improves over a period of months. Studies report an 8.9% to 100% incidence of neurosensory disturbance immediately after BSSO (Becelli et al., 2002; Yoshioka et al., 2010; Yoshioka et al., 2011; Mensink et al. 2012; Yoshioka et al., 2012, Aizenbud et al., 2012).

Neurosensory disturbance of peripheral innervation remains a complex problem and is not always easily resolved. Treatment may consist of systemic administration of medication, physiotherapy, local electrical stimulation, nerve repair surgery, low intensity laser application and other therapies such as acupuncture (Leung et al., 2004).

Low-level laser therapy (LLLT) has been described in the literature as presenting a biomodulator effect and is indicated in cases of pain and tissue repair. Low level laser irradiation of the affected innervation path has resulted in sensory improvement (Khullar et al., 1996; Miloro and Repasky, 2001; Ladalardo et al., 2002; Enwemeka et al., 2004). The advantages of LLLT include no contraindications, no adverse effects, easy application and

easy handling of the apparatus. To penetrate the tissue, the energy delivered through a low intensity laser device undergoes multiple scattering, which affects its distribution. Absorption of this energy stimulates or inhibits enzymatic activities and photochemical reactions that induce cascades of reactions and physiological processes with therapeutic connotations. In this way, the laser mediates inflammation and activates the immune system with broad therapeutic effects (Reddy 2004).

There is very little literature about low-intensity laser therapy for recovery from BSSO-related neurosensory disorders and there are no studies comparing the irradiated and non-irradiated sides in the same patient. For this reason, the aim of this study is to evaluate an LLLT application protocol for accelerating the process of recovery from neurosensory disorders resulting from BSSO.

Material and methods

This randomized, crossover, double-blind clinical trial study was approved by the Research Ethics Board of the University Hospital, Federal University of Goias (protocol # 101/2011) and registered as a clinical trial (protocol # NCT 01530100). All subjects signed an informed consent form to undergo the treatment. The surgical treatment was conducted at the Oral and Maxillofacial Department of the University Hospital with 10 healthy women (age range, 18-54 years; mean age, 30 years) who underwent bimaxillary surgery (Le Fort I osteotomy and bilateral sagittal split osteotomy) to correct dentofacial deformities . Patient selection criteria were no facial trauma or IAN injury; no neurosensory disturbance before treatment; third molars were removed at least 6 months before the orthognathic surgery; similar sagittal split on left and right sides according to time and IAN minimal manipulation; no genioplasty. Exclusion criteria were neurovascular bundle rupture; a BSSO bad split; post-operative infection or missing laser application. All patients met the criteria without any exclusion. Sample size was determined by the statistical behavior of the results.

All patients underwent pre-operative orthodontic treatment to correct dental position. All patients were operated on by the same senior staff. Four of the procedures involved maxillary superior reposition and mandibular advancement, with mean maxillary impaction of 4 mm and mean mandibular advancement of 6 mm. The other six procedures involved maxillary advancement mean of 5 mm, and mandibular setback, mean of 3 mm.

Six points were symmetrically marked on the lower lip (figure 1) and labiomental sensation was evaluated pre-operatively by two-point discrimination (a 25x7 needle was used to determine the shortest distance in millimeters that the patient can feel the two punctures) and a sensory test (the same needle was used to stimulate the six points and the sensation reported was assigned a score, with 3 being normal perception). Mean scores for each region were calculated and the data were collected and stored for comparison with postoperative data

Surgical procedure

The pre, trans and post-operative medications were standardized and dosed according to patients' weight in order to maintain the same proportion of drugs. All patients received anti-microbial prophylaxis (cefazolin pre-operatively), steroids (hydrocortisone trans-operatively, dexamethasone post operatively until the third day after surgery) and analgesics (tramadol trans-operatively and every 8 hours for 24 hours after admission and ketorolac until 48 hours after the operation.

The BSSO technique was performed using the principles of Trauner and Obwegeser (1957) modified by Epker (1977). The mandibular ramus was exposed and the IAN nerve was exposed from the lingual aspect of the mandibular foramen. The horizontal and vertical bone cuts were performed with a 703 bur. The sagittal cut was performed with a sagittal saw. Splitting was initiated with a chisel sequence driven directly into the sagittal cut in contact with the external cortical bone to minimize IAN injuries. Then, the splitting forceps were positioned for a sagittal bone cut, the elevator was

positioned for a vertical bone cut, the mandibular split was carefully completed and the bone gap was inspected to identify the inferior alveolar neurovascular bundle.

The mandibula was repositioned using a surgical splint and a maxillomandibular fixation was performed. The proximal segment was manually positioned, a four-hole upper border miniplate and 6 mm monocortical screws stabilized the BSSO split and the IMM was removed.

Laser Protocol

A gallium-aluminium-arsenide diode low-level laser device (Thera Laser, DMC Brazil, continuous wave, spot size 0.4 mm) was used. The laser therapy-exposed surface was cleaned and air dried before application. The applications were performed by another dentist.

One side, called the irradiated side, was randomly chosen for laser therapy by intraoral and extraoral exposure. Four points 1 cm from the surgical wound were intraorally exposed immediately after and 24, 48 and 72 hours after the surgery (λ = 660nm (Red), ED = 5J/cm2, t = 10 s / point, P = 20 mW, E = 1,2 J per point). Eight points on the mandibular ramus and body were exposed immediately after, 24, 48 and 72 hours after the surgery (λ = 789 nm infra-red), DE = 30J/cm2, t = 20 s / point, P = 60 mW, E = 1.2 J per point). Two p points on the preauricular, jugular-digastric and submandibular lymph nodes were given the same exposure. Total energy used was 21.6 J per session.

After the fourth day, with an interval of 48 hours, 3 points 1 cm from the surgical wound on the path of the inferior alveolar nerve in the mandibular ridge were given ten intraroral applications. In addition, 4 points on the lower labial mucosa, 2 points on the lower lip and 9 points in the chin region 1 cm from the surgical wound were extraorally exposed. (λ = 780nm (infrared), DE = 70J/cm2, P = 70 mW, t = 40s / point, E = 2.8 J, per point). Total energy used was 50.4 J per session.

On the other, non-irradiated side, the laser unit was positioned at the same points but the laser was not activated.

Assessment

One trained person blinded to the laser application, assessed the post-operative symptoms by repeating the same pre-operative test. The data collected were used to calculate each region's average score. The two-point discrimination test and sensory test were performed immediately post-operatively, 15 days, 30 days and 60 days after surgery. The sensory test stimulated the exposed points and the sensation reported was given a score of 3 for normal sensitivity, 2 for a stimulus which was perceived but not normal, 1 for perception of the stimulus but with no idea about the quality and 0 for no perception. Means were determined for each side during each specific period and the irradiated and non-irradiated sides were compared.

Statistical analysis

Data were entered into a Microsoft Excel spreadsheet by the same person who was blinded to the procedure, and imported into IBM SPSS Statistics Version 19 (SPSS Inc., Chicago, USA). The Wilcoxon signed-rank test was used to analyze associations between the variables, comparing the laser and non-laser groups. Values of $P<0.05$ were considered statistically significant.

Results

All patients who were selected participated in the study and there were no exclusions. The laser therapy protocol was applied 6 times on the left side and 4 times on the right side. Neurosensory disturbance occurred on both the, irradiated and non-irradiated sides. In the immediate post-operative period there was no difference between the two sides, but over time the neurosensorial recovery of the irradiated side was faster than that of the non-irradiated side. The two-point discrimination test showed no significant differences sensations of irradiated and non-irradiated patients on chin skin in the immediate post-operative period (P = 0.273). Results on the sensory test were the same at the same evaluation point (P = 0.395) (table 1).

The sensitivity of the irradiated side had come back faster about 15 days after the surgery. There were significant differences between the two sides on the two-points discrimination test (P = 0.028) for chin skin. The sensory test also showed a significant difference between the sides (P = 0.005) (table 1).

30 days after the surgery, the differences between the irradiated and non- irradiated sides had increased and there were significant differences in chin skin sensitivity and on the two-point discrimination test (P = 0.007). The sensory test also showed a significant difference between the two sides (P = 0.005) (table 1).

60 days after the surgery, the difference between the irradiated and non-irradiated sides on the two-point discrimination test had increased and there were significant differences in chin skin sensitivity (P = 0.005). The difference between the sides on the sensory test decreased but it was still significant (P = 0.008) (Table 1).

No patients showed any adverse reactions to the treatment.

Table 1. Distribution of neurosensory disturbance and recovery at immediate post-operative, and after 15 days, 30 days and 60 days, comparing the groups (n=10, crossover design).

Post-operative measures	**Laser irradiation (mean ± SD)**		***P***
	Yes	**No**	
Two points discrimination test			
Immediately	4.88	5.60	0.273
15 days	5.59	5.93	0.028
30 days	5.33	5.90	0.007
60 days	4.72	5.70	0.005
Sensory test			
Immediately	0.86	0.61	0.395
15 days	1.83	1.11	0.005
30 days	2.46	1.63	0.005
60 days	2.75	1.95	0.008

Wilcoxon signed-rank test

Discussion

Our findings in this study are consistent with the literature (Aizenbud et al., 2002; Mensink et al., 2012; Yoshioka et al., 2010; Yoshioka et al., 2011; Yoshioka et al., 2012). There was a change in the sensitivity of the lower lip and chin in all patients on both the irradiated and non-irradiated side, but none of the patients had a total loss of sensitivity. We can conclude that the type of nerve damage that occurred was a combination of partial neuropraxia and axonotmesis. The low-level laser therapy protocol used in this study improved the recovery from neurosensory disorders resulting from orthognathic surgery in all patients studied.

In the immediate postoperative evaluation, it was expected that there would be no difference between the irradiated and non-irradiated sides because all factors related to surgery were similar. However, at this point, the only difference between the two sides would be the use of laser therapy, so any difference would be attributed to the use of the laser. The reason for applying laser therapy on only one side was to see if was really the laser that made the difference. This was unlike other studies, which compared laser-treated and non-laser-treated patients

In the 15, 30 and 60 day evalautions, there was recovery of sensitivity on both sides, but on the irradiated side, recovery was faster and had returned almost to normal on the last evaluation. The low-level laser therapy applied in our study accelerated recovery from neurosensitive disturbances resulting from surgery and the results are supported by several in vivo studies. Khullar et al (1996) conducted a study in which 13 patients were

divided into 2 groups, one that received LLLT and another who received placebo. They concluded that LLLT can improve mechanoreceptor perception in long-standing sensory aberrations in the IAN. Miloro and Repasky (2000) examined the potential benefit of perioperative and short-term postoperative low-level laser (LLL) therapy on objective and subjective neurosensory recovery after bilateral sagittal split osteotomy surgery and demonstrated that neurosensory recovery after bilateral sagittal split osteotomy procedures can be significantly improved, both in terms of time and the magnitude of return of function, with the adjunctive use of LLL therapy. Ladalardo et al (2001) reported clinical cases of peripheral nerve lesions and evaluated the efficiency of the diode laser in treating six patients who presented tongue paresthesia after surgical procedures which demanded regional mandible anaesthetic blockage. The patients' presenting symptomatology was the absence of gustative sensitivity, a decrease in sensitivity and an increase in the nociceptive threshold on the affected side of the tongue. The treatment carried out with LLLT proved to be efficient, resulting in restored sensitivity in all six treated patients.

In a systematic review, Jenkins and Carrol (2011) argue that most studies had insufficient data regarding light effects, often lacking necessary beam and dose information. If there is no standardization in beam measurement, dose calculation and the reporting of these parameters, advancing the field of LLLT will be more difficult as studies will not be reproducible, and outcomes in clinical research and practice will not be consistent.

We found ourselves in the same situation in preparing this study, thus the determination of reproducible parameters is the most important step in developing a protocol for applying low-level laser therapy. The data provided here make it possible to reproduce the protocol and use it in clinical practice and further research.

Care should be taken in reproducing any LLLT protocol because there is a tendency to prioritize the energy applied, but it is known that some application parameter changes also change the results. Lanzafame et al (2007) and Lopes et al (2009) carried out research with the same energy levels but with different density powers and obtained completely different results.

Thus no ideal low level laser therapy protocol for treating neurosensory disturbances arising from BSSO has been developed. In studies by Khullar et al (1996), the protocol used was 4 x 6 J per treatment along the distribution of the inferior alveolar nerve, at the following extraoral points: lateral third of lower lip, intraoral; buccally to the apex of the second premolar tooth and the apex of the second molar tooth; lingually in the region of the mandibular foramen, for a total of 20 treatments. Miloro and Repasky's protocols (2000) consisted of real LLLT (4 x 6 J per treatment) along the distribution of the inferior alveolar nerve at 4 sites, for a total of 7 treatments. Other studies (Suzuki et al., 2004; Enwemeka et al., 2004) used different protocols with different parameters and also had favorable results. Our protocol uses parameters presented in the literature with favorable results in different types of treatments. Despite a favorable statistical analysis, we note

a limitation to our work: a small sample. For future studies a larger sample should be used.

Neurosensory disorders are the most common complications arising from BSSO are an intrinsic complication of surgical technique and patients are aware of the possibility of their occurrence. Regarding surgical technique, Böckmann et al (2013) conducted a pilot study in pigs proposing an additional osteotomy in BSSO and conclued that it reduces the likelihood of bad splits and damage to the inferior alveolar nerve in pig mandibles. Hågensl et al (2013) suggested the technique extraoral vertical osteotomy subcondylar (EVSO) as a viable alternative if it is important to avoid alterations in sensation. Already Ueki et al (2012) tested the use of Biopex (α-tricalcium phosphate) in the gap between the proximal and distal segments and conclued that it did not Prevent recovery of the lower lip hypoaesthesia. then it can be seen that the prevention or treatment of neurosensory disorders resulting from BSSO are current issues and still not have a definitive solution.

The relationship between objective assessments and subjective evaluation of neurosensory disturbance is also unclear, so it is important to develop methods that are readily available and simple to use. Nonetheless, they rank as major postoperative complaints. The surgeon must resort to all possible means to prevent or reduce this complication.

Conclusion

Our findings suggest that the low intensity laser therapy protocol is a safe method that accelerates the recovery of IAN neurosensory disturbances in orthognathic surgery.

Sources of support

None.

Conflict of interest

None.

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Artigo 2

Abstract

Low-level laser therapy (LLLT) coud be an alternative to treat swelling and pain after orthognathic surgery, but there is a paucity of literature on the effects of its use. This study verified the efficacy of a LLLT protocol to reduce swelling and pain after orthognathic surgeries. Ten healthy patients who underwent bilateral sagittal split with Le Fort I osteotomy were randomly selected for this study. The LLLT protocol consisted of intraoral and extraoral application to one side of the face after the surgery (irradiated side) and, to the other side, the application was simulated (non-irradiated side). Irradiated and non-irradiated sides were compared regarding the swelling coefficient and Visual Analogue Scale for pain assessment. There were no significant differences between irradiated and non-irradiated sides regarding swelling and pain in the immediate post-operative assessment. Swelling significantly decreased in the irradiated side in the post-operative assessments: 3, 7, 15 and 30 days. Self-reported pain was less intense in the irradiated side in the 24-hr (1.2 vs. 3.4) and 3-day (0.6 vs. 2.1) assessments, but after 7 days of surgery neither side showed pain. This low-level laser therapy protocol can improve tissue response and reduce pain and swelling resulting from orthognathic surgery.

Keywords: Low-level laser therapy, orthognathic surgery, pain, swelling.

Short title: Laser after orthognathic surgery

Introduction

Orthognathic surgery is a procedure used to correct dentofacial deformities. The osteotomies most commonly used are the Le Fort I osteotomy, whose popularity dates from the study by Bell[1] in 1975, and bilateral sagittal split osteotomy (BSSO), first described by Trauner and Obwegeser[2] in 1957 and modified by DalPont[3] (1961), Hunsuck[4] (1968), and Epker[5] (1977). Pain and swelling are consequences of tissue injury and procedures such as cold therapy and use of drugs (analgesics and anti-inflammatories) help control these unwanted effects, but they present additional side-effects including gastric or intestinal irritation, cutaneous rash, neutropenia, and hepatic and renal disorders that can reduce their benefits[6].

An alternative to avoid the undesirable effects of the aforementioned therapies might be low-level laser therapy. LLLT is a relatively new topic in the biomedical sciences and in maxillofacial surgery in particular, and many more years will be needed to understand the mechanisms of action. LLLT has been described in the literature[7,8,9,10,11,12,13] as exerting a biomodulator effect and is indicated in cases of pain and tissue repair.

The advantages of using LLLT are no contraindications, no adverse effects, and easy apparatus handling and application[10,12]. To penetrate tissue, the energy delivered through a low-intensity laser-emitting device undergoes multiple scattering, which affects laser energy distribution. Absorption of this energy stimulates or inhibits enzymatic activities and photochemical reactions that induce reaction cascades and physiological processes with therapeutic connotations. The laser thus mediates

inflammation and activates the immune system, with broad therapeutic effects[7].

The investigators hypothesized that LLLT reduces inflammatory mediators resulting in better post-operative recovery. So the purpose of this study was to evaluate the efficacy of a LLLT protocol in post-operative swelling and pain associated with orthognathic surgery, comparing laser irradiated with non-irradiated facial sides, in the same person who was blinded to the treatment received. The investigators hypothesized that LLLT reduces inflammatory mediators resulting in better post-operative recovery.

Material and methods

Study design and participants

This randomized, crossover, double-blind clinical trial was carried out at the Oral and Maxillofacial Department of the Clinical University Hospital. The sample was determined by patients who needed bimaxillary orthognathic surgery by bilateral sagittal split and Le Fort I osteotomy to correct their dentofacial deformity. All patients underwent pre-operative orthodontic treatment to correct tooth position. All patients were operated by the same surgeon. The inclusion criteria were the following: no facial trauma or inferior alveolar nerve (IAN) injury; no neurosensory disturbance before treatment; third molars were removed at least 6 months before the orthognathic surgery; bilateral sagittal split osteotomy on both sides of the jaw took roughly the same time, with minimal IAN manipulation; and no genioplasty. Exclusion criteria were neurovascular bundle rupture; poor BSSO split; post-operative infection; and missing laser application.

This study was approved by the Research Ethics Board of the University Hospital, Federal University of Goias (protocol # 101/2011) and registered in the clinical trials database (protocol # NCT 01530100). All subjects signed an informed consent form to undergo the treatment and fulfilled the criteria set out without any exclusion.

Surgical procedure

A standard bilateral sagittal bilateral split osteotomy and Le Fort I osteotomy were performed. Pre-, trans-, and post-operative medications were standardized and dosed according to the patient's weight in order to keep the drugs in the same proportion. All patients received anti-microbial

prophylaxis (cefazolin pre-operatively), steroids (hydrocortisone trans-operatively, dexamethasone post-operatively until the third day after surgery), and analgesics (tramadol trans-operatively and every 8 hours during the first 24 hours after admission, and ketorolac until 48 hours after the operation).

Laser Protocol

A gallium-aluminium-arsenide diode low-level laser device (Thera Lase, DMC Brazil, continuous wave, spot size 0.4 mm) was used. The surface exposed to the laser therapy was cleaned and air-dried before the application. The applications were performed by a single trained professional who did not take part in the surgical procedure.

One side of the face, called the irradiated side, was randomly chosen by draw to receive laser therapy by intraoral and extraoral exposure. Over the incision line, the laser was applied to four points 1 cm apart in the immediate post-operative period and 24, 48, and 72 hours after the surgery (λ = 660 nm (Red), ED = 5 J/cm^2, t = 10 s/point, P = 20 mW, E = 1.2 J/point). In the mandibular ramus and body, the laser was applied to eight points in the immediate post-operative period and 24, 48, and 72 hours after the surgery (λ = 789 nm infrared), DE = 30 J/cm^2, t = 20 s/point, P = 60 mW, E = 1.2 J/point). The same exposure was used on two points on the pre-auricular, jugular-digastric, and submandibular lymph nodes (Figure 1). Total energy used was 21.6 J per session.

After the fourth day, 10 intraoral applications were performed at 48-hour intervals on three points 1 cm apart on the path of the inferior alveolar nerve on the mandibular ridge and three points on the lower labial mucosa.

Extraoral applications were performed on, two points on the lower lip, and nine points 1 cm apart in the chin region (λ = 780 nm (infrared), DE = 70 J/cm^2, P = 70 mW, t = 40s/point, E = 2.8 J/point) (figure 02). Total energy used was 50.4 J per session.

On the other side of the face, called the non-irradiated side, the laser unit was positioned on the same points but was not activated. During all applications patients were blinded by black glasses and by listening to music via headphones so that they did not know which side of the face had been irradiated.

Assessment

A single trained individual, blinded to the side of laser application, assessed post-operative swelling and pain.

Swelling size was calculated using the modified formula of Carrillo[13], measuring the distance between the tip of the chin and the lower lobe of the ear immediately post-operatively and then 72 hours, 1 week, 15 days, and 30 days post-operatively. The mandibular length in each time-assessment after the surgery was subtracted from the baseline length, and the result was divided by the baseline length and multiplied by 100. The baseline length used was the distance measured 2 months post-operatively.

A Visual Analogue Scale (VAS) was used to measure pain intensity in the post-operative period: immediately after the operation and 24 hours, 72 hours, and 1 week after the operation. Patients were asked about the degree

of pain in each period, with 0 defined as the absence of pain and 10 as the maximum tolerable level of pain.

In each session, patients were observed regarding any possible side effects from LLLT, such as burns or erythema.

Statistical analysis

Data were entered into a Microsoft Excel spreadsheet by one person who was masked to the procedure, and data was imported to IBM SPSS Statistics Version 19 (SPSS Inc., Chicago, USA). The Wilcoxon signed-rank test was used to analyze the associations between the variables, comparing the laser and non-laser groups. Mann-Whitney test compared different patients regarding the influence of surgical procedure on swelling and pain. Values of $P<0.05$ were considered statistically significant.

Results

Ten healthy women (age range 18–54 years; mean age 30 years) underwent Le Fort I osteotomy and bilateral sagittal split osteotomy to correct dentofacial deformities. Four of the procedures involved superior maxillary repositioning and mandibular advancement, with mean maxillary impaction of 4 mm and mean mandibular advancement of 6 mm. The other six procedures involved maxillary advancement with a mean of 5 mm and mandibular setback with a mean of 3 mm. The mean time for the surgeries was 1 hr 53 min, ranging from 1 hr 32 min to 2 hr 8 min (Table 1). The two types of surgery did not effect swelling (P=0.394) and pain (P=0.587) in the immediate post-operative assessment (Mann-Whitney test).

All patients selected participated in the study and there were no exclusions (Figure 3). The laser therapy protocol was applied six times on the left side and four times on the right side of the face. No patients showed any adverse reactions to the treatment.

There were no significant differences between irradiated and non-irradiated sides regarding swelling and pain in the immediate post-operative assessment (Table 2). Swelling was significantly less intense in the irradiated side in the post-operative assessments (Table 2). Pain was less intense in the irradiated side in the 24-hr and 3-day assessments, but at the seventh day post-operatively, neither side of the face showed any pain (Table 2).

Table 1. Distribution of swelling at immediate post-operative, 3 days, 7 days, 15 days, and 30 days. Occurrence of pain at immediate post-operative, 24 hours, 3 days, and 7 days. Comparing the groups (n=10, crossover design).

Post-operative measures	**Laser irradiation** (mean ± standard deviation**)**		***P***
	Yes	**No**	
Swelling test			
Immediately	2.15±1.13	2.72±1.37	0.173
3 days	4.48±.0.82	6.21±1.64	0.019
7 days	2.73± 0.95	4.32±1.36	0.005
15 days	1.51±1.00	2.52±1.10	0.047
30 days	0.21±0.35	1.29±0.81	0.012
Pain test			
Immediately	3.60±0.84	4.00±1.70	0.442
24 hours	1.20±0.91	3.40±1.89	0.007
3 days	0.60±0.51	2.10±1.10	0.007
7 days	0.00±0.00	0.00±0.00	1.0

Wilcoxon signed-rank test

Discussion

Every surgeon seeks to provide comfort to patients during recovery from surgical procedures. Pain and swelling are consequences of orthognathic surgery and need many procedures to be control. A new alternative to control these consequences is LLLT. This research showed that low-intensity laser therapy has important anti-inflammatory and analgesic actions, leading to reduced swelling and pain on the irradiated side.

Immediately after surgery, there was no difference between the irradiated and non-irradiated sides in either swelling or pain. This was expected because there was no time for laser biomodulation. If there had been any significant difference between the sides, this difference would have occurred for some other reason or would have been due to surgical complications and would therefore not have had validity in our assessment. A patient experiencing this would thus have been excluded from the research.

Over the first 24 hours, the difference between the two sides proves that the laser exerted a modulating effect on the inflammatory process; our hypothesis is that probably laser acted reducing stimulation of the nociceptors in the region with a consequent reduction in soreness. We chose not to measure swelling at this point because swelling peaks around 72 hours after surgery.

By the 72-hour post-operative evaluation, laser therapy had had time to act and a better result for the irradiated side was therefore expected. Pain and swelling were considerably lower on the irradiated side, justifying the indication of laser therapy in the initial periods of inflammation.

One week after surgery, no patients reported any pain on either side. The swelling still remained at this time, but with a major significant difference between the two sides. Over the first 15 post-operative days, differences between the two sides decreased. Bearing in mind the predictability of edema evolution and the behavior of the irradiated side, the laser's biomodulator effect occured primarily in the early stages of inflammation and decreased as inflammation mediators decreased.

The last evaluation, 30 days after surgery, was made 15 days after the previous analysis. It was expected that the inflammation would decrease and that longer low-level laser therapy application could bring about a better result. The difference between the irradiated and non-irradiated sides of the face still remained, and was greater than at the previous evaluation. This shows that a longer duration of therapy leads to better results.

Our results are contrary to those of Roynesdal et al.[15] who found that LLLT made no difference in reducing swelling and post-operative pain in third molar surgery. This contradiction is probably because studies of laser therapies in oral surgery are in their early days and parameters for laser application in oral surgery are still being developed. Our findings, however, are consistent with several studies in the literature that reported a reduction in edema and pain when low-level laser therapy was used[7,8,9,13,16, 17,18].

So far, an ideal LLLT protocol for reducing swelling and pain arising from orthognathic surgery has not been developed. Bjordal et al.[8] conducted a systematic review of randomized placebo-controlled trials to determine the mechanisms of action and clinical effects of laser therapy in acute pain.

Despite the different methodologies and protocols, these authors found that in laboratory tests, laser therapy can modulate pain by regulating the inflammatory factors with average doses of 7.5 J/cm^2. In animal studies, the worst results occurred in applications below 5 J and on only one point while the best results occurred when three or more points covering an area greater than 2.5 cm^2 were irradiated with a total power of 5.0 to 19.5 J. In our study, 21.6 J was used in each application performed up to 72 hours after surgery. After the fourth day, 50.4 J was used in 10 sessions. Another reason for increasing the energy was that the amount of inflammation in orthognathic surgery was expected to be greater than in other studies.

Another issue was that the baseline jaw length was obtained 2 months after surgery. It is known that surgery alters mandibular proportion. It is consequently not possible to use a pre-operative measurement. After 2 months, there was still some residual edema but this was very slight residual swelling behavior and the research data indicate that we can use this specific date.

The surgery procedures were not the same in all patients, and there were differences in bone movement and surgery time. Some procedures involved superior maxillary repositioning and mandibular advancement while other procedures involved maxillary advancement and mandibular setback. The mean time for the surgeries was 1 hr 53 min, ranging from 1 hr 32 min to 2 hr 8 min. Despite the different procedures and time of surgery, we consider that this is not a variable situation because pain and swelling were compared in the same patient in irradiated and non-irradiated sides and the surgery procedure inclusion criteria included being equivalent in both sides. If the

comparison were about irradiated and non-irradiated patients, this variable should be considered.

The determination of reproducible parameters is the most important step in developing a protocol for applying low-level laser therapy. The data provided here make it possible to reproduce the protocol and use it in clinical practice and further research. In a systematic review, Jenkins and Carrol[14] argue that most studies had insufficient laser-effect data, with beam and dose information frequently missing. If there is no standardization in beam measurement, dose calculation and the reporting of these parameters, advancing the field of LLLT will be more difficult as studies will not be reproducible, and clinical research and practice outcomes will not be consistent.

The LLLT protocol tested here was safe and able to reduce pain and swelling associated with orthognathic surgery. Further studies with new protocols could investigate different LLLT doses in order to improve recovery after orthognathic surgery.

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5 CONSIDERAÇÕES FINAIS

Este trabalho sugere que a terapia laser de baixa intensidade é um método eficaz para redução dos inconvenientes pós operatórios decorrentes da cirurgia ortognática. O edema, a dor e a parestesia foram menores no lado irradiado o que mostra que a aplicação do laser pode modular a inflamação e o processo de reparo dos tecidos.

Novos trabalhos deverão ser desenvolvidos com o objetivo de se estabelecer os limites de atuação da terapia laser de baixa intensidade bem como o protocolo ideal visto que até o momento ainda não se pode afirmar que um protocolo atinge o feito biológico máximo desejável.

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ANEXOS

Anexo I

Parecer do Comitê de Ética

ANEXO II

TLCE

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Você está sendo convidado (a) para participar, como voluntário, em uma pesquisa. Meu nome é Giovanni Gasperini, sou o pesquisador responsável e minha área de atuação é Cirurgia e Traumatologia Buco-Maxilo-Facial.

Após ler com atenção este documento ser esclarecido (a) sobre as informações a seguir, no caso de aceitar fazer parte do estudo, assine ao final deste documento, que está em duas vias. Uma delas é sua e a outra é do pesquisador responsável. Em caso de dúvida sobre a pesquisa, você poderá entrar em contato com o pesquisadores responsável, Dr. Giovanni Gasperini nos telefones: 3091 4020.

Em caso de dúvidas sobre os seus direitos como participante nesta pesquisa, você poderá entrar em contato com o Comitê de Ética em Pesquisa do Hospital das Clínicas da Universidade Federal de Goiás, nos telefones: 32 69 83 38 – 32 69 84 26

INFORMAÇÕES IMPORTANTES QUE VOCÊ PRECISA SABER SOBRE A PESQUISA:

1. Título do Projeto: **Estudo duplo cego, não randomizado, da eficácia da terapia a laser de baixa intensidade no pós-operatório de cirurgias bucomaxilofaciais**

Pesquisador Responsável: Giovanni Gasperini
Instituição a que pertence o Pesquisador Responsável: Universidade Federal de Goiás
Telefones para contato: (62) 3091 4020 - (62) 8122 8511

Esta pesquisa objetiva verificar se o uso do laser de baixa intensidade reduz o inchaço e a dor no período pós-operatório e também diminue a sensação de dormência no lábio.

O laser será aplicado por um profissional qualificado. As aplicações acontecerão no pós-operatório imediato e no pós operatório diariamente até 7 dias.

Para avaliar se houve ou não efeito pelo uso do laser, serão tiradas fotos pré e pós-operatórias que serão comparadas entre si, além de medidas de vários pontos na face buscando comparar um lado com o outro. Para verificar a sensibilidade será realizado um teste com agulhas que não perfurarão a pele, somente serão usadas para identificar a sensação ao toque.

As avaliações ocorrerão no período pós operatório sendo no pós imediato, 24horas, 48 horas, 72 horas, 7 dias e 15 dias pós-operatório.

Na forma utilizada nesta pesquisa não existe nenhum relato de complicações ou situações desconfortáveis pela aplicação do laser, mas no geral, o uso incorreto do laser pode levar a vermelhão na face, queimaduras e cicatrizes.

O uso do laser em saúde tem seus benefícios bem documentados, e essa pesquisa espera encontrar os mesmos benefícios do uso do laser, ou seja, diminuição do inchaço, da dor e da perda de sensibilidade após as cirurgias propostas.

O voluntário da pesquisa terá acesso direto ao pesquisador principal para solução de dúvidas de quaisquer natureza sobre o andamento da pesquisa e do tratamento.

Sua participação é voluntária e poderá a qualquer momento se desligar da pesquisa sem qualquer tipo de prejuízo ao seu tratamento.

As informações aqui colhidas são confidenciais não havendo exposição da identidade de nenhum voluntário.

O voluntário não terá nenhum tipo de gasto com o tratamento nem com o a pesquisa, pois as análises necessárias para a pesquisa, fazem parte da rotina de avaliação dos pacientes participantes.

Qualquer complicação decorrente da aplicação do laser será resolvida pelo Dr.Giovanni Gasperini sem ônus ao voluntário.

Nome e Assinatura do pesquisador _____

CONSENTIMENTO DA PARTICIPAÇÃO DA PESSOA COMO SUJEITO DA PESQUISA

Eu, _____ _____, RG_____/ CPF_____/ nº de prontuário_____/ nº de matrícula_____, abaixo assinado, concordo em participar do estudo ¨ Estudo duplo cego, não randomizado, da eficácia da terapia a laser de baixa intensidade no pós-operatório de cirurgias bucomaxilofaciais ¨ , sob a responsabilidade do Dr. Giovanni Gasperini,como sujeito voluntário. Fui devidamente informado e esclarecido pelo pesquisador Dr. Giovanni Gasperini sobre a pesquisa, os procedimentos nela envolvidos, assim como os possíveis riscos e benefícios decorrentes de minha participação. Foi me garantido que posso retirar meu consentimento a qualquer momento, sem que isto leve à qualquer penalidade ou interrupção de meu acompanhamento/ assistência/ tratamento.

Estou ciente também que havendo qualquer tipo de prejuízo à minha saúde comprovadamente decorrente da pesquisa terei direito à indenização.

Local e data _____

Nome e Assinatura do sujeito ou responsável: _____

Assinatura Dactiloscópica:

Nome e assinatura do Pesquisador Responsável_____

ANEXO III – Normas de publicação dos respectivos periódicos

Normas de publicação do Journal Of Craniomaxillofacial Surgery

Guide for Authors

- The following contributions will be accepted for publication:
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Venice, Italy, October 1983, and the 41st World Medical Assembly, Hong Kong, September 1989). The manuscript should contain a statement that the work has been approved by the appropriate ethical committees related to the institution(s) in which it was performed and that subjects gave informed consent to the work. Studies involving experiments with animals must state that their care was in accordance with institution guidelines. Patients and volunteers names, initials, and hospital numbers should not be used.

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Shaw WC, Semb G, Nelson P, Brattstrom V, Molsted K, Prahl-Andersen B, Gundlach KK: The Eurocleft project 1996-2000: overview. J Craniomaxillofac Surg 29:131 142, 2001.
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