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EFICÁCIA DO LASER CIRÚRGICO DE DIODO NO TRATAMENTO DA HIPERPLASIA FIBROSA INFLAMATÓRIA

Universidade Federal de Minas Gerais
Faculdade de Odontologia
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Tese apresentada ao Colegiado do Programa de Pós-Graduação da Faculdade de Odontologia da Universidade Federal de Minas Gerais, como requisito parcial para obtenção do grau de doutor em Odontologia - área de concentração em Estomatologia.

Orientador: Prof. Dr. Ricardo Alves Mesquita

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Paulo Reglus Neves Freire
(1921 – 1997)
Educador brasileiro

LISTA DE SÍMBOLOS E SIGLAS

®	Marca registrada
100x	Cem vezes
AsGaAl	Arseneto de Gálio e Alumínio
CNPq	Conselho Nacional para o Desenvolvimento Científico e Tecnológico
CO2	Dióxido de Carbono
COEP	Comitê de Ética em Pesquisa
CONSORT	Consolidated Standards of Reporting Trials
Er–YAG	Érbio–Ítrio–Alumínio–Garnet
FFH	Focal Fibrous Hyperplasia
FH	Fibrous Hyperplasia
FHID	Fibrous Hyperplasia Induced by Denture
HE	Hematoxilina e Eosina
HFI	Hiperplasia Fibrosa Inflamatória
KTP	Potassium-titanium-phosphorous
Mg	Miligrama
mW	Miliwatts
Nd:YAG	Neodimio-Ítrio-Aluminio-Garnet
nm	Nanômetro
PTR	Prótese Total Removível
SPSS	Statistical Package for Social Sciences
UFMG	Universidade Federal de Minas Gerais
VAS	Visual Analog Scale
W	Watt
µm	Micrômetro

RESUMO

O objetivo deste trabalho foi avaliar a eficácia do laser cirúrgico de diodo no tratamento da hiperplasia fibrosa inflamatória comparada com a técnica convencional utilizando o bisturi em um ensaio clínico randomizado. Trinta e oito pacientes com hiperplasia fibrosa inflamatória foram avaliados. No grupo controle os pacientes foram submetidos ao tratamento com bisturi, e no grupo de estudo ao tratamento com laser cirúrgico de diodo. Os pacientes do grupo de estudo foram tratados utilizando um laser de diodo em um comprimento de onda de 808nm em modo contínuo, com uma média de potência de 2.96W. Uma escala visual numérica foi aplicada para avaliar a dor pós-operatória, as alterações funcionais durante a fala, a mastigação e a satisfação do paciente em relação ao tratamento. Adicionalmente, o tipo de anestesia, a necessidade de medicação analgésica pós-operatória, a presença de sangramento, edema e o tempo de cirurgia também foram avaliadas. A relação entre os grupos tratados com relação à dor pós-operatória e alterações funcionais, foi avaliada através do teste U de Mann-Whitney. A relação entre os grupos e o tempo de cirurgia foi avaliada pelo teste t student devido à distribuição normal dos dados. As variáveis categóricas foram avaliadas pelo teste qui-quadrado ou pelo teste exato de Fisher. Trinta e quatro pacientes foram analisados em conformidade com os critérios de inclusão e exclusão. O tempo de cirurgia foi significativamente menor no grupo de estudo ($p= 0.04$). A necessidade de medicação analgésica no período pós-operatório foi significativamente maior no grupo controle ($p= 0.01$). A cura clínica das feridas pós-operatórias foi significativamente maior no grupo de estudo ($p= 0.01$). O laser cirúrgico de diodo provou ter efetivo desempenho no manejo da hiperplasia fibrosa inflamatória com mínimo sangramento, menos invasivo evitando o uso suturas, e diminuindo o tempo da cirurgia. Assim, o laser de diodo demonstrou ser menos invasivo quando comparado com a cirurgia com bisturi. Ao contrário, a cicatrização da ferida operatória provou ser mais rápida com o uso do bisturi quando comparado com o laser cirúrgico de diodo.

Palavras chaves: laser cirúrgico de diodo, hiperplasia, cirurgia bucal

ABSTRACT

The objective of this study was investigated the efficacy of diode laser surgery in the treatment of inflammatory fibrous hyperplasia compared with conventional technique using a scalpel in randomized clinical trial. Thirty eight patients with inflammatory fibrous hyperplasia were evaluated. In the control group, patients were submitted to scalpel surgery; in the study group, patients were submitted to treatment with diode laser surgery. The patients of the study group were treated using an 808nm diode laser in a continuous mode, with a mean of potency of 2.96W. A numeric visual analogue scale was applied to assess the post-operative pain, functional alterations during speech and chewing and patient satisfaction with the treatment modalities. Additionally, type of anesthesia, needed of postoperative analgesic medicine, bleeding, post-operative edema and time of the surgery were assessed. The relationship between groups with post-operative pain and functional alterations was assessed by the U Mann-Whitney test. The relationship among groups with time of the surgery was assessed by student t test due to normal distribution of the data. Categorical variables were assessed by Chi-Square test or Fisher exact test. Thirty-four patients were analyzed in accordance with inclusion and exclusion criteria. The time of surgery was significantly minor in the study group ($p= 0.04$). The need of analgesic medicine in the post-operative period was significantly higher in the control group ($p= 0.01$). However, clinical healing of the post-operative wounds was significantly higher in the study group ($p= 0.01$). The diode laser surgery proved to be well-tolerated by patients reducing the needed of analgesic medicine in the postoperative period when compared with scalpel surgery. Furthermore, the diode laser surgery proved to be effective in the management of fibrous hyperplasia with minimal bleeding, less invasive avoiding sutures, and decreasing the time of surgery. Thus, diode laser demonstrated less invasiveness when compared with scalpel surgery. By contrast, wound healing proved to be faster with scalpel surgery when compared with diode laser surgery.

Keywords: Diode laser surgery, hyperplasia, oral surgery

SUMÁRIO

1. INTRODUÇÃO

A população idosa tem aumentado comparada com outras faixas etárias em muitos países, incluindo no Brasil. A população acima dos 60 anos de idade deve passar de 14,9 milhões (7,4% do total), em 2013, para 58,4 milhões (26,7% do total), em 2060 no Brasil. No período, a expectativa média de vida do brasileiro deve aumentar dos atuais 75 anos para 81 anos (IBGE, 2013), representando um aumento significativo na população idosa. Desta forma, o bem estar e a qualidade de vida desta população torna-se um desafio para profissionais da área da saúde. Assim, é essencial o conhecimento não só fisiológico, mas também das alterações patológicas e principalmente formas de tratamento que possibilite um melhor conforto para este grupo etário (Freitas et al., 2008).

Países em desenvolvimento como o Brasil, onde desigualdades sociais são encontradas, um grande número de idosos são desdentados, requerendo o uso de próteses totais removíveis (PTR). As PTR podem melhorar a qualidade de vida restabelecendo a função do sistema estomatognático; entretanto, podem causar lesões na mucosa bucal. Entre as alterações patológicas comumente encontradas em associação ao uso de PTR mal adaptadas está a hiperplasia fibrosa inflamatória (HFI) (Coelho, 2004, Firoozmand et al., 2005).

A HFI representa um aumento do número de tecido da mucosa bucal em resposta a uma irritação crônica de baixa intensidade, cujo o importante fator causal é uma prótese total removível mal adaptada (Firoozmand et al., 2005).

Clinicamente a HFI varia em relação à coloração, consistência, localização e tempo de evolução. É uma doença comum que afeta principalmente pacientes do gênero feminino na sexta e sétima décadas de

vida, representando 16,7% das doenças relacionadas ao uso de próteses removíveis (Cutright, 1971; Budtz-Jorgensen, 1981; Pinto-Coelho and Zucoloto, 2000; Coelho et al., 2004).

O tratamento mais comumente realizado para a HFI é a remoção cirúrgica com auxílio do bisturi associado à retirada do fator irritante (Monteiro et al., 2012). Em casos de lesões extensas, a não coaptação dos bordos da ferida cirúrgica é necessária para não causar a perda de profundidade do vestíbulo bucal e dificuldades de adaptação de uma nova prótese dentária. Desta forma, a cicatrização da ferida acontece por segunda intenção (Niccoli-Filho et al., 1999; Monteiro et al., 2012).

Lasers de alta intensidade tem se tornado mais uma ferramenta no tratamento de lesões bucais. Vários tipos de lasers tem sido descritos para o uso nos tecidos moles da cavidade oral incluindo potássio-titânio-fósforo (KTP), neodimio-ítrio-aluminio-garnet (Nd:YAG), dióxido de carbono (CO2) e lasers de diodo com semi-condutores. Os benefícios do laser de alta intensidade para o tratamento das lesões da cavidade oral têm sido reportados na literatura, entre eles podemos citar: incisão precisa, hemostasia eficiente evitando o uso de suturas, possibilidade de diminuição do tempo operatório e redução bacteriana na ferida operatória (Romanos e Nentwig, 1999).

Considerando os benefícios do laser, este trabalho teve como relevância avaliar outra forma de tratamento, utilizando o laser cirúrgico de diodo, no tratamento da HFI comparada com a forma clássica de tratamento com a utilização do bisturi.

2. SÍNTESE BIBLIOGRÁFICA

2.1 Hiperplasia Fibrosa Inflamatória (HFI)

A HFI é uma lesão reacional de tecido conjuntivo fibroso em resposta a irritação local ou por traumatismo crônico de baixa intensidade, normalmente por próteses mal adaptadas ou eventualmente por hábitos parafuncionais. A HFI é considerada um processo proliferativo não-neoplásico. Lesões proliferativas não neoplásicas correspondem a crescimentos teciduais, geralmente, em resposta a um estímulo crônico de longa duração (Tamarit-Borràs et al., 2005; Firoozmand et al., 2005).

HFI induzida por prótese tem sido designada por outros sinônimos: epúlide fissurada, hiperplasia fibrosa induzida por prótese, hiperplasia de irritação por prótese, hiperplasia papilar inflamatória, hiperplasia gengival inflamatória e hiperplasia por dentadura (Budtz-Jorgensen, 1981; Bezzon et al., 1994; Jin et al., 2010).

Esta lesão caracteriza-se por um crescimento, limitado, de consistência firme que pode ser ulcerado ou não, e desenvolve-se lentamente cessando-se após a remoção do agente causal. Adicionalmente, sua coloração varia de eritematosa a pálida e assintomática na maioria dos casos. Entretanto o paciente pode queixar-se de dor se a área estiver ulcerada ou sobreposta por infecção fúngica por *Cândida sp*. Os aspectos clínicos variam de uma lesão inflamada e ulcerada a uma lesão fibrosa. A borda da prótese total ou parcial frequentemente adapta-se convenientemente aos lóbulos da lesão (Firoozmand et al., 2005).

Ao exame histopatológico observa-se hiperplasia de tecido conjuntivo fibroso com vasos sanguíneos abundantes e infiltrado inflamatório mononuclear

de intensidade variável. Menos frequentemente, leucócitos polimorfonucleares também podem ser observados. A camada epitelial é geralmente hiperparaceratinizada e demonstra hiperplasia (Tamarit-Borràs et al., 2005; Firoozmand et al., 2005).

O tecido conjuntivo fibroso varia de acordo com o estágio de desenvolvimento da lesão, onde, em muitos casos, a mesma lesão pode apresentar diferentes achados histopatológicos. Tecido conjuntivo maduro com grupos de feixes de colágeno e muita proliferação vascular podem ser observados em lesões recentemente formadas e expostas a trauma contínuo. Em áreas distantes da irritação direta ou aquelas que têm sido expostas a trauma por um longo período, tecido conjuntivo maduro pode ser encontrado onde fibras colágenas são predominantes e o número de células e vasos sanguíneos é reduzido. Em áreas de ulceração focal onde há irritação ativa, a camada de epitélio pode estar menos desenvolvida ou ausente (Firoozmand et al., 2005).

O diagnóstico clínico da HFI é realizado através das características clínicas. Entretanto, há a necessidade de ocasionalmente realizar exames radiográficos para determinar se o tecido ósseo está envolvido. O diagnóstico é baseado na observação clínica da hiperplasia e confirmação histopatológica da hiperplasia fibrosa inflamatória (Firoozmand et al., 2005).

O tratamento da HIF é realizado através da remoção cirúrgica. Entretanto, a remoção cirúrgica é ocasionalmente desnecessária e deve ser considerada somente quando não há contra-indicações sistêmicas. A remoção pode ser feita utilizando um bisturi, eletrocautério, crioterapia, e recentemente a utilização dos lasers cirúrgicos (Firoozmand et al., 2005; Suter et al., 2014).

2.2 Tratamento da Hiperplasia Fibrosa Inflamatória

Frequentemente, o tratamento da HFI é a remoção cirúrgica com o uso do bisturi. Entretanto, esta técnica está significativamente associada à diminuição da profundidade do sulco vestibular e algumas vezes a perda do vestíbulo oral. Este problema pode ser reduzido através da realização da vestibuloplastia com aprofundamento do vestíbulo e não união das bordas cirúrgicas. Entretanto, a não sutura da ferida cirúrgica pode dificultar a hemostasia, principalmente em pacientes com discrasias sanguíneas ou em uso de anticoagulantes e anti-agregantes plaquetários (Monteiro et al., 2012).

Além disso, a utilização da técnica convencional para tratamento de lesões dos tecidos moles está mais associada à dor e desconforto durante a fala, mastigação e alimentação no período pós-operatório quando comparado com outras técnicas de tratamento, entre elas o uso do eletrocautério e os sistemas de lasers cirúrgicos (Haytac & Ozcelik, 2006).

A utilização do eletrocautério é uma opção no tratamento da HFI, entretanto produz uma úlcera por lesão termal importante. Além disso, prejudica a avaliação histológica completa da peça cirúrgica devido à necrose tecidual extensa das margens da lesão (Tamarit-Borrás, 2005).

Os lasers cirúrgicos ou de alta intensidade tem demonstrado ser uma ferramenta útil no tratamento das lesões de tecidos moles da região oral e maxilofacial entre elas pode-se citar: a HFI, a mucocele, o papiloma, o adenoma e o hemangioma (Romanos & Nentwig, 1999).

2.3 Lasers de alta intensidade

A palavra LASER é o acrônimo Light Amplification by Stimulated Emission of Radiation (Amplificação da Luz por Emissão Estimulada de Radiação). Ao contrário de outras fontes de luz, lasers emitem radiação eletromagnética colimada, monocromática e coerente. Estas características proporcionam aos lasers várias e únicas aplicações. Os mais comuns lasers cirúrgicos emitem comprimentos de onda na parte infravermelho do espectro de luz, sendo eles: laser de neodimio:ítrio–alumínio–garnet (Nd–YAG, λ=1,064 nm), laser de érbio–ítrio–alumínio–garnet (Er–YAG, λ=2.94 μm), e laser de CO2 (λ=10.6 e 9.6 μm). Dentro da parte visível do espectro eletromagnético, lasers de argônio emitem luz entre 458 e 515 nm, e lasers excimer estão localizados na parte ultravioleta do espectro (100 to 400 nm). Lasers de diodo emitem comprimentos de onda de λ= 810 e 980 nm (Deppe & Horch, 2007).

Para se determinar se o laser é adequado para incisão, vaporização ou coagulação devem-se levar em consideração os seguintes parâmetros: 1) comprimento de onda, 2) fluência da energia, 3) características ópticas do tecido e 4) como o laser é aplicado. Em modo contínuo o laser proporciona uma constante e estável deposição de energia. Sistemas de laser pulsado, ao contrário, proporcionam explosões de energia no tecido. Lasers dentro do comprimento de onda ultravioleta (100 a 380 nm) são capazes de ionizar os tecidos, processo este conhecido como dissorção fotoquímica. Lasers com maiores comprimentos de onda, especialmente dentro do comprimento de onda infravermelho (700 a 10.000 nm), causam significante aquecimento tecidual. A maioria dos lasers cirúrgicos está inserido neste comprimento de onda, também podendo ser denominados como lasers termais. A luz destes

lasers é rapidamente convertida em energia termal, causando desnaturação de proteínas, decomposição tecidual, micro-explosões de células ricas em água e carbonização (Deppe & Horch, 2007; Strauss & Fallon, 2004).

2.3.1 Laser de Diodo

O laser de diodo é um semicondutor que utiliza elementos no estado sólido (ex: gálio, arsênio, alumínio, índio) para transformar energia elétrica em energia luminosa. A energia luminosa dos lasers de diodo é rapidamente absorvida pelos tecidos moles e pobremente absorvida pelos tecidos duros em um comprimento de onda entre 805 a 980 nm (Kravitz and Kusnoto, 2008).

Lasers de diodo são portáteis, compactos, menos onerosos em relação a outros sistemas de lasers e tem se mostrado eficiente e confiável para uso em cirurgia oral e maxilofacial. Dependendo do tipo de lesão, o laser de diodo pode ser utilizado em modo contínuo ou modo pulsado. A energia é depositada no tecido por contato ou não através de uma fibra óptica. No comprimento de onda de 980 nm a penetração óptica é menor que no laser de Nd: YAG (1064 nm), sendo útil no tratamento de lesões superficiais (Romanos and Nentwig, 1999; Strauss and Fallon, 2004).

Quando utilizado em modo de contato, com um comprimento de onda contínuo e em baixa potência os lasers cirúrgicos de diodo são uma ferramenta útil para excisão, cauterização e redução bacteriana dos tecidos moles (Bader, 2000). Além disso, tem demonstrado efeito biomodulador residual quando aplicado no modo desfocado, proporcionando melhor reparo tecidual (Romanos & Nentwig, 1999). Pode ser utilizado para remoção de lesões orais sem a necessidade de anestesia infiltrativa, somente com anestesia tópica (Desiate et

al., 2009). A incisão marginal de lesões usando o laser de diodo é mais precisa comparado com outros sistemas de lasers, incluindo o laser de CO2 e Nd:YAG (Romanos & Nentwig, 1999).

3. JUSTIFICATIVA

O tratamento da HFI é frequentemente realizado através da remoção cirúrgica com bisturi. Entretanto, este tratamento pode levar a perda de profundidade de vestíbulo, nos casos associados ao rebordo alveolar, devido à aproximação das bordas da ferida, ou deixar uma ferida cirúrgica cruenta provocando dificuldade para a hemostasia, dor, dificuldade para mastigar e dificuldade de fala. Além disso, a necessidade de remoção de sutura no pós-operatório pode proporcionar dor e sangramento de intensidade leve a moderada. O laser de diodo possui propriedades específicas entre elas: incisão precisa, hemostasia imediata, cauterização das terminações nervosas periféricas podendo ser utilizado sob anestesia tópica, menor tempo para cicatrização devido ao efeito biomodulador e redução bacteriana. Desta forma, justificou-se avaliar a eficácia do laser cirúrgico de diodo no tratamento na HFI comparada com a técnica convencional de remoção utilizando o bisturi através um estudo de ensaio clínico randomizado.

4. OBJETIVOS

4.1 Objetivo geral

Avaliar a eficácia do laser cirúrgico de diodo no tratamento da HFI comparada com a técnica convencional de remoção cirúrgica utilizando o bisturi.

4.2 Objetivos específicos

- Avaliou-se a eficácia do laser cirúrgico de diodo no tratamento da HFI quanto ao tempo de cicatrização total da ferida operatória;

- Avaliar a eficácia do laser cirúrgico de diodo no tratamento da HFI comparando com técnica convencional de remoção com bisturi quanto:

- a dor pós-operatória;

- ao edema;

- alterações funcionais durante a alimentação e/ou mastigação;

- as alterações funcionais durante a fala;

- quanto ao tempo cirúrgico em minutos dos procedimentos;

- Avaliou-se a necessidade ou não de anestesia infiltrativa nos pacientes tratados pelo laser cirúrgico de diodo;

- Avaliou-se histologicamente o dano tecidual provocado pelo laser cirúrgico de diodo no tecido da HFI;

- Avaliou-se a satisfação do paciente ao término do tratamento.

5. HIPÓTESE

O laser cirúrgico de diodo, quando comparado com a técnica de remoção com bisturi, é eficaz no tratamento da HFI.

6. METODOLOGIA

6.1 Desenho do estudo

Foi realizado um ensaio clínico randomizado no qual todos os pacientes com diagnóstico clínico de HFI associado à prótese removível ou não, foram submetidos a tratamento cirúrgico. No grupo controle as lesões foram removidas pela técnica convencional utilizando uma lâmina de bisturi número 15 após anestesia infiltrativa (Cloridrato de lidocaína 2% com epinefrina 1:100.000; Alphacaine 100, DFL Indústria e Comércio S.A., Rio de Janeiro, Brasil). Suturas interrompidas ou contínuas foram utilizadas dependendo da localização e tamanho das lesões para controle da hemostasia. No grupo estudo, os pacientes foram submetidos à remoção das lesões utilizando o laser cirúrgico de diodo (AsGaAl – Arseneto de Gálio e Alumínio) com os seguintes parâmetros: 1) comprimento de onda de 808 nm, 2) potência média de 2.96 W (variação 2.0 a 3.5 W), 3) em modo contínuo por contato, e 4) fibra óptica de 600 µm. Inicialmente somente anestesia tópica (Emla® AstraZeneca do Brasil LTDA, São Paulo,Brasil ou Benzocaína 20%, DFL Indústria e Comércio S.A., Rio de Janeiro, Brasil) foi utilizada. Em caso de qualquer incômodo por parte do paciente, a anestesia infiltrativa foi realizada. Ambos os grupos foram acompanhados por 8 semanas até a completa cicatrização da ferida cirúrgica.

As duas modalidades de tratamento foram avaliadas através de: 1) tempo de cicatrização total da ferida cirúrgica, acompanhando o paciente por um período de oito semanas; 2) avaliação do edema no momento do 7° dia pós-operatório por questionamento; 3) avaliação da dor no momento do 1° e 7° dia pós-operatório; 4) avaliação das funções de mastigação durante a alimentação e fala no 1° e 7° dia pós-operatório; 5) tempo de procedimento

cirúrgico; 6) satisfação do paciente em relação às formas de tratamento. O tempo de cicatrização das lesões foi avaliado através da medida da ferida cirúrgica em milímetros e semanalmente até o momento de cicatrização completa da ferida cirúrgica. A dor pós-operatória e funções foram avaliadas através da escala análoga visual numérica de 0 a 10. Em relação à dor pós-operatória a marcação 0 significa “sem dor” e 10 significa “pior dor imaginável” (Mannion et al, 2007). Em relação às funções a marcação 0 significa “sem desconforto” e 10 significa “desconforto extremo” (Haytac and Ozcelik, 2006). O mesmo pesquisador registrou os escores no 1° e 7° dia pós-operatórios. O tempo operatório foi registrado em cronometro digital levando em consideração somente o ato cirúrgico em si, desconsiderando o processo de anestesia tópica ou infiltrativa. A satisfação do paciente foi avaliada em escala análoga visual numérica de 0 a 10, quando 0 significa “totalmente insatisfeito” e 10 significa “totalmente satisfeito” (Peñarrocha et al, 2007).

Todos os pacientes foram orientados a tomar a mesma medicação analgésica contendo paracetamol (750mg Tylenol®, de 6 em 6 horas, Johnson & Johnson do Brasil Indústria e Comércio de Produtos para Saúde Ltda, São Paulo, Brasil) caso fosse necessário. A necessidade de uso de analgésico foi avaliada entre os grupos controle e estudo.

Os dados foram coletados e anotados em ficha clínica específica para cada paciente (Anexo 2).

Cada paciente incluído na pesquisa foi locado no grupo estudo ou controle através da técnica de amostragem aleatória simples.

Todos os espécimes cirúrgicos foram encaminhados ao laboratório de Patologia Bucomaxilofacial da UFMG para confirmação histopatológica da HFI.

No grupo intervenção o dano tecidual causado pelo laser cirúrgico foi avaliado histologicamente. Os espécimes foram fixados em formol 10% tamponado e emblocados em parafina. Os cortes de 4 µm foram corados com hematoxilina e eosina (HE). A desnaturação termal histológica foi avaliada no espécime até o final da desnaturação termal visível em aumento óptico final de 100x (Angiero et al., 2012). Alterações morfológicas no epitélio de revestimento e na lâmina própria foram avaliadas.

6.2 Universo

Foram estudados indivíduos independente de sexo e idade, com diagnóstico clínico HFI, encaminhados à clínica de Patologia, Estomatologia e Radiologia da Faculdade de Odontologia da UFMG. Este projeto foi aprovado pelo comitê de ética em Pesquisa (COEP) da Universidade Federal de Minas Gerais (CAAE: 23083713.1.0000.5149) (Anexo 1).

Os pacientes foram esclarecidos da não maleficência e da beneficência do tratamento e puderam negar a participação na pesquisa, porém continuaram a receber algum tipo de tratamento. Aqueles que interessaram em participar da pesquisa leram e assinaram o Termo de Consentimento Livre e Esclarecido (ANEXO 3).

Ao final da pesquisa, os resultados foram divulgados à comunidade científica independente de serem inéditos ou que contrariem as hipóteses propostas no estudo. A confidencialidade da identidade dos participantes foi resguardada.

6.3 Critérios de inclusão e exclusão

Foram incluídos no estudo todos os indivíduos com diagnóstico clínico de HFI. Para inclusão dos indivíduos as lesões apresentaram as seguintes características clínicas: 1) lesão hiperplásica localizada em qualquer parte da mucosa bucal associada diretamente a um trauma específico de prótese parcial ou total removível mal adaptada, hábito de mordedura ou hábito de sucção, 2) lesão de coloração e sintomatologia variável e 3) consistência variável. Pacientes em uso de próteses removíveis suspenderam o uso por 15 dias antes do tratamento.

Pacientes em uso contínuo de medicação analgésica ou antiinflamatória, pacientes imunodeprimidos ou imunossuprimidos, diabéticos e hipertensos descontrolados foram excluídos do estudo.

Todos os casos encaminhados com diagnóstico diferente de HFI, ou que não se encaixaram nos critérios descritos, foram submetidos à biópsia incisional ou excisional para confirmação diagnóstica e tratados adequadamente.

Os pacientes que necessitaram de confecção de nova prótese removível foram encaminhados adequadamente.

6.4 Plano Amostral

Foi realizado um ensaio clínico com todos os pacientes encaminhados à Clínica de Patologia, Estomatologia e Radiologia em um período de 10 meses após aprovação do comitê de ética (Anexo 1), onde todos os indivíduos foram submetidos ao tratamento proposto, sendo 50% dos casos tratados com o laser cirúrgico de diodo comparado com 50% dos casos tratados pela técnica convencional de remoção com bisturi.

O tamanho da amostra e a definição do erro do tipo I e do erro do tipo II foram baseados na literatura de acordo com os estudos de *Haytac and Ozcelik* (2006) e *El-Kholey (2013), e* devido à escassez de trabalhos com o desenho de estudo proposto associando o tratamento de HFI com o laser cirúrgico de diodo.

6.5 Análise estatística dos dados

Os dados foram submetidos à análise estatística utilizando o software SPSS (versão 17.0, Chicago, IL, USA). As amostras foram submetidas a testes de normalidade (Shapiro-Wilk). Em amostras com distribuição normal foram aplicados o teste-t de Student. Em amostras com distribuição não-normal foi aplicado o teste Mann-Whitney. Para as variáveis categóricas o teste qui-quadrado ou teste exato de Fisher foram aplicados. Análise de sobrevida em relação ao tempo de cicatrização e os grupos foi avaliado pelo método de Kaplan-Meier. Significância estatística foi alcançada quando os valores de $p \leq 0.05$.

7. RESULTADOS

Os resultados foram escritos em língua inglesa na forma de dois artigos.

7.1 Artigo 1

Submetido ao periódico Journal of Cranio-Maxillofacial Surgery (qualis – A2/ Fator de impacto 1.5) e aguardando resposta dos revisores.

Ms. Ref. No.: JCMS-D-14-00443
Title: Diode laser surgery in the treatment of fibrous hyperplasia: a prospective study
Journal of Cranio-Maxillofacial Surgery

Dear Márcio,
Your submission "Diode laser surgery in the treatment of fibrous hyperplasia: a pilot study" has been assigned manuscript number JCMS-D-14-00443. To track the status of your paper, please do the following:

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Kind regards,
Jörg Wiltfang, MD, DMD, PhD
Editor-in-Chief
Journal of Cranio-Maxillofacial Surgery

Title: Diode laser surgery in the treatment of fibrous hyperplasia: a prospective study

Running title: Diode laser in the treatment of fibrous hyperplasia

Key words: diode laser, hyperplasia, oral surgery

Abstract

Fibrous hyperplasia is frequently treated by surgical incision with a scalpel associated with retirement of chronic trauma. However, hemostasis of the surgical wound is especially difficult for patients with hemorrhagic disorders or those undergoing antithrombotic therapy without the suturing of the wound borders. High-power lasers have been applied as a useful tool in the management of soft tissue lesions. Therefore, the present study aimed to present a prospective study of fibrous hyperplasia treated using a high-power diode laser. Fifteen patients with fibrous hyperplasia were enrolled in this study. Laser irradiation was performed using an 808 nm diode laser with an optical fiber of 600 μm, at a potency of 2.0W to 3.5 W (average 2.96 W), in a continuous-wave mode. The treatment performance of fibrous hyperplasia using a high-power diode laser was determined by evaluating the pain, postoperative functional alterations, edema, secondary infection, bleeding, and satisfaction of the patients after treatment. Diode laser surgery proved to be effective and presented a good performance in the treatment of fibrous hyperplasia. Randomized clinical trials may be performed to compare diode laser and other laser systems with conventional surgery and electrosurgery in the management of fibrous hyperplasia and other oral lesions.

Key words: diode laser, hyperplasia, oral surgery

Introduction

Hyperplasia is an increase in the number of cells in any portion of human tissues,including the oral cavity tissues. Fibrous hyperplasia (FH) is caused by a low-intensity chronic trauma, often provoked by ill-fitting dentures or by parafunctional habits,and is represented by an increase in fibroblast cells and collagen fibers (Canger et al., 2009). FH is a frequent oral mucosal disease that affects 5% to 16.7% of the population (Cobert et al., 1994; Coelho et al., 2004).

FH first appears as a limited-size growth, with a fibrous to flaccid consistency, and an erythematous to pale color lesion that may be ulcerated. FH presents a slow growth that ceases with the removal of the traumatic agent. In the majority of cases, as FH is painless, the patient may not realize its existence. However, the patient may complain of pain if the area is ulcerated or has an associated infection caused by a fungus, such as Candida *ssp*. Moreover, the flange of the complete or partial denture often fits conveniently into the folds of the lesion (Firoozmand et al., 2005; Freitas et al., 2008).

FH is frequently treated by surgical incision with a scalpel associated with retirement of chronic trauma. Scalpel techniques are associated with a loss of sulcus depth and/or with the full elimination of the vestibule in cases induced by ill-fitting dentures (Keng and Loh, 1992). Also, hemostasis of the surgical wound is especially difficult for patients with hemorrhagic disorders or those undergoing antithrombotic therapy without the suturing of the wound borders (Keng and Loh, 1992; Niccoli-Filho et al., 1999; Monteiro et al., 2012).

Electrocautery has been applied in the management of oral tissues and provides enhanced hemostasis by sealing blood vessels before cutting. However, cutting performance is harmed by muscle fasciculation, and wound

healing is delayed by extensive thermal damage when compared to scalpel surgery (Liboon et al., 1997).

High-power lasers have been applied as a useful tool in the management of soft tissue lesions. Surgical lasers have been usedto treat oral lesions, including: 1) potassium-titanium-phosphorous (KTP), 2) neodymium-yttrium-aluminium-gamet (Nd:YAG), 3) carbon dioxide (CO2), and 4) diode lasers with semiconductors (Romanos and Nentwig, 1999; Angiero et al., 2012). High-power diode lasers, as compared toother high-power lasers,are more portable, compact, and cost effective. Diode lasers have wavelengths of between 805 and 980nm that can be used in continuous or pulsed mode, according to the clinical recommendation,using an optical fiber with or without contact (Jackson and Lauto, 2002).

High-power diode lasers can be applied in the management of oral tissues due to high absorption by water and hemoglobin, thus providing positive results in periodontal surgery, tissue alteration related to orthodontic treatments, and oral lesions (Romanos and Nentwig, 1999; Elanchezhiyan et al., 2013; El-Kholey, 2014). Considering that diode laser surgery may well produce a solid performance in thetreatment of oral diseases, including FH, and that prior literature is based on case reports (Niccoli-Filho et al., 1999; Monteiro et al., 2012), the current study aimed to present a pilot study of FH managed using a high-power diode laser.

Patients and methods

This study was approved by the ethics committee and informed written consent forms were obtained from all participants. Fifteen patients with FH were

recruited from the Oral Medicine Clinic of the Universidade Federal de Minas Gerais (UFMG), Belo Horizonte, in a period of 10 months. The selection of cases included patients who presented FH induced either by dentures or by parafunctional habits. Patients with limited-size growths, with flaccid to a fibrous consistency, that were sessil or pedicle,with an erythematous to pale color,and that were associated with dentures or parafuctional habits were enrolled in this study. Dentures were removed 2 weeks before the surgical procedures to eliminate inflammation and/or chronic pain. Patients currently using anti-inflammatory or analgesic medications as well as patients with non-controlled deseases were excluded.

Surgical procedures

Topical anesthesia (Emla ® AstraZeneca do Brasil LTDA, São Paulo, Brazil or Benzocaine 20%, DFL Indústria e Comércio S. A., Rio de Janeiro, Brazil)was applied to all patients. Infiltrative anesthesia with 2% lidocaine and adrenaline at 1:100.000 (DFL Indústria e Comércio S. A., Rio de Janeiro, Brazil) was applied if the patient complained of any kind of pain. Slight traction of the lesion using mosquito forceps was performed to facilitate the application of the diode laser incision. Sutures were not performed. The surgical specimens were fixed in 10% buffer formalin and sent for histopathological analysis.

Laser parameters

Laser irradiation was performed using an 808 nm diode laser (Thera Lase Surgery, DMC LTDA, São Carlos, Brazil), with an optical fiber of 600 µm, at a potency of 2.0 W to 3.5 W (average 2.96 W), in a continuous-wave mode.

Post-surgical evaluations

The treatment performance of FH with high-power diode laser was determined by evaluating pain, postoperative functional alterations, edema, secondary infection, bleeding, and patient satisfaction with the treatment. The patients were asked to separately rate the degree of pain and postoperative functional alterations, which included discomfort during eating and speech,on a 10cm horizontal visual analog scale (VAS) by placing a vertical mark to assess the position between the two endpoints (Mannion et al., 2007). The left endpoint of the pain scale was designated as “no pain, and the right endpoint was marked as unbearable pain.” The end-points of the scales for the degree of discomfort during eating and speech were marked as no discomfort on the left side and unbearable discomfort on the right side. The patients were asked to mark the position between the two endpoints that best described their personal perception of the degree of pain and discomfort during eating and speech that they had experienced on postoperative days 1 and 7. The hatch mark placed by the patient was measured to the nearest centimeter; the scores for the degree of pain and functional complications were between 0 and 10. A single operator recorded these scores on postoperative days 1 and 7. After completion, all recordings were analyzed. All patients were instructed to use the same analgesic medicine containing paracetamol, if needed to alleviate the pain, and were subsequently analyzed. In addition, the patients were asked whether or not an edema was present. Secondary infection was investigated by the presence or absence of local exudation and fever. Bleeding was investigated by its presence or absence. Clinical healing was assessed by the weekly follow-up

of the post-operative wounds until they had been completely healed. Patient treatment satisfaction was evaluated after post-surgical wounds had been completely epithelized. A visual analogue scale (VAS) was applied to verify the satisfaction degree: 0 = totally unsatisfied and 10 = totally satisfied with the treatment (Peñarrocha et al., 2007).

Post-surgical care

All patients underwent special oral hygiene care, especially as regards hot, hard, and acidic foods, during the post-surgical laser period. Patients were instructed not to ingest any form of analgesic during the post surgical period, except in case of unbearable pain.

Results

The clinical profiles of patients and data concerning FH lesions treated with diode laser surgery are presented in Table 1.

Patient ages ranged from 12 to 76 years (mean 56.13 ± 17.55 years). The study sample consisted of 12 females (80%) and 3 males (20%). Ten (66.67%) patients presented a clinical diagnosis of FH induced by denture (FHID), while five (33.33%) presented a diagnosis of focal FH (FFH). The size of the lesions ranged from 5 to 90 mm (Mean: 33 mm). Six (40%) patients with FHID presented a lesion on the superior vestibule, three (20%) patients presented the lesion on the lower vestibule, and one (6.67%) presented the lesion on the floor of the mouth. Two (13.33%) patients with FFH presented lesions on the buccal mucosa, two (13.33%) on the lower lip, and one (6.67%) on the upper lip. Twelve (80%) patients needed infiltrative anesthesia, while

three (20%) needed only topic anesthesia to remove the lesions. All lesions were removed without the need for complementary sutures to control the bleeding during and after diode laser surgery. No edema was reported by eleven (74.34%) patients, while four (26.66%) reported edema in the post-operative period. The patients classified the intensity of pain on the first post-operative day as no pain in 53.33%, mild in 27.67%, moderate in 13.33% and severe in 6.67%. On day 7, the patients classified the edema as no pain in 66.67%, mild in 26.66%, moderate in 6.66%; no patients reported unbearable pain. Regarding analgesic medication in the post-operative period, twelve (73.33%) patients reported no need for use, while three (26.67%) took an analgesic due to moderate or severe pain. Considering functional alterations during the chewing reported by the patients on the first post operative day, no discomfort was reported in 66.66% of the cases, mild discomfort in 13.34%, moderate in 13.34%, and severe in 6.65%. On day 7, no discomfort was reportedin 60% of the patients, mild discomfortin 26.66%, severe in 13.33%, and moderate in 6.66%. Considering functional alterations during speech reported by the patients on the first post operative day, no discomfort was reported in 46.67%, mild discomfort in 33.33% and moderate in 20%. In the same category, on day 7, no discomfort was reported in 66.67% of the patients, as compared to mild discomfort in 20% and moderate discomfort in13.33%. No patient reported unbearable discomfort. All patients were totally satisfied with the treatment. No persistent bleeding or infections could be observed. All patients presented a clinical healing of the surgical wounds in a period that ranged from 3 to 5 weeks (mean 3.5 weeks). Regarding patients with a diagnosis of FHID (66.67%), no vestibule depth decreases could be identified

after the clinical healing of the surgical wounds, which left a minimal mucosa scar (Figure 1).

In all specimens, microscopic analysis showed oral mucosal fragments with hyperplastic stratified squamous epithelium, propria lamina of the densely collagenized connective tissue, and chronic inflammatory cells. A band of coagulation necrosis was present in the lower border of the specimens (opposite to the epithelium) (Figure 2).

Discussion

The current study aimed to verify the performance of diode laser surgery on the treatment of FH. The main observations included: 1) diode laser surgery proved to be effective on the treatment of FH, 2) diode laser surgery shows low postoperative pain and no complications, 3) diode laser surgery shows low discomfort during chewing and speech in the postoperative period, 4) all patients were satisfied with the applied treatment,and 5) there was minimal thermal damage in the treated specimens.

Laser surgery treatment has been used as an adjuvant or substitute to conventional therapies due to several advantages, including cutting, ablation or vaporization, hemostasis, bacterial reduction, and surgical procedures without infiltrative anesthesia (Romanos and Nentwig, 1999; Kara, 2008; Aras et al., 2010).

Diode laser is considered a good cutting device for oral tissues (Romanos and Nentwig, 1999). However, more tissue damage occurs than with the use of a scalpel (Jin et al., 2010), but this damage is not prejudicial to the specimen tissue, especially when the specimens contained a diameter of at

least 5 mm (Angiero et al., 2012). In the current study, the tissue damage was minimal, and only one lesion was measured at 5 mm in diameter. In addition, the laser characteristics and settings, such as power output, wavelength, emission modalities, type of optical fiber, and affinity with target tissues can control the width and severity of the thermal damage caused to the tissue (Angiero et al., 2012). By contrast, diode laser surgery provides a thermal damage zone of less than 1 mm, which allows for surgical precision and excellent hemostasis within a dry operative field (Coleton, 2004; Strauss and Fallon, 2004). Hemostasis caused by laser surgery is due to the increase in platelet activation at the end point of the wound, which leads to the sealing of the blood vessels (Mordon et al., 2002).

Rapid wound healing with diode laser surgery has been described in prior literature (Elanchezhiyan et al., 2013). This benefit is related to the photobiomodulation phenomenon, which works at cellular levels by promoting faster healing with a toxin reduction through the accceleration of lymphatic flow, thereby helping to reduce pain, enhance repair, and induce regeneration (Bornstein, 2004; Elanchezhiyan et al., 2013). The current results demonstrated that each of the 15 cases of FH treated with diode laser surgery with specific parameters presented a clinical healing without complications in an average time of 3.5 weeks.

Considering surgical procedures without infiltrative anesthesia, Fornaini et al. (2007) reported the surgical management of oral tissues with only topical anesthesia using diode and Nd:YAG laser systems. However, Aras et al. (2010) demonstrated that, when compared with diode lasers, a lower quantity of infiltrative anesthesia was required when using Er:YAG lasers. In the present

study, twelve (80%) patients needed infiltrative anesthesia, while three (20%) needed only topic anesthesia to remove the lesions.

Management of oral tissues causes post-operative pain and functional discomfort during chewing and speech (Aras et al., 2010). Benefits of laser surgery systems, as compared to the use of scalpels, in decreasing post-operative pain and functional complications have been demonstrated in randomized clinical trials reported in prior literature (Haytac and Ozcelik, 2006). These benefits may be explained due to the protein coagulum that is formed on the wound surface, thereby acting as a biological dressing, sealing the end of sensory nerves, as well producing photobiomodulation (Elanchezhiyan et al., 2013). Moreover, less edemas have been reported when using laser surgery systems, which is related to the sealing of the lymphatic vessels (Cernavin et al., 1994; Coleton, 2004). In this prospective case series study, the post-operative follow-up was uneventful with no edema in 74.34% of the patients. The majority of patients (73.33%) reported no need to take analgesic medication in the post-operative period. Additionally, the majority of patients reported no or mild pain on post-operative day 1 (80%) and day 7 (93.33%). Considering functional alterations during chewing, the majority of patients reported no or mild discomfort on post-operative day 1 (80%) and day 7 (86.66%). Regarding functional alterations during speech, the majority of patients reported no or mild discomfort on post-operative day 1 (80%) and day 7 (86.67%).

Therefore, diode laser surgery proved to be effective and presented a satisfactory performance in the treatment of FH. The use of diode laser surgery allowed for suitable and accurate incisions without requiring sutures, thus

decreasing surgery time and maintaining the vestibule fundus in patients with FHID. However, randomized clinical trials may be performed to compare diode laser and other laser systems with conventional surgery and electrosurgery in the management of FH and other oral lesions.

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Conflict of interest

None declared

Ethical Approval

Approved by the Ethics Committee of Universidade Federal de Minas Gerais, under protocol number 23083713.1.0000.5149.

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Table 1 – Clinical profile of the patients and data of fibrous hyperplasia treated with diode laser surgery

Patients	Age	Gender	Lesion	Size (mm)	Site	Anesthesia	Edema	Pain Day 1/Day 7	Analgesic use	Chewing Day 1/ Day 7	Speech Day 1/Day 7	Complication	Healing time (weeks)
1	66	F	FHID	40	Superior vestibule	Infiltrative	Yes	0/6	No	0/6	3/0	No	4
2	12	M	FFH	20	Buccal mucosa	Infiltrative	No	0/0	No	0/2	0/0	No	3
3	63	F	FFH	10	Buccal mucosa	Topical	Yes	2/0	No	0/0	3/0	No	4
4	64	M	FHID	30	Superior vestibule	Infiltrative	No	0/0	No	0/0	0/0	No	4
5	63	F	FHID	35	Lower vestibule	Infiltrative	No	0/0	No	9/7	5/5	No	3
6	54	F	FFH	5	lower lip	Topical	No	1/0	No	0/0	0/0	No	3
7	51	F	FHID	20	Floor of the mouth	Infiltrative	No	0/0	No	0/0	2/0	No	3
8	24	M	FFH	10	Upper lip	Infiltrative	No	0/1	No	0/1	1/4	No	3
9	76	F	FHID	20	Superior vestibule	Infiltrative	Yes	0/0	No	0/0	0/0	No	3
10	66	F	FHID	90	Superior vestibule	Infiltrative	No	9/2	Yes	0/2	0/3	No	5
11	52	F	FHID	20	Superior vestibule	Infiltrative	No	4/0	Yes	4/0	4/0	No	3
12	62	F	FFH	70	Lower lip	Infiltrative	Yes	0/0	No	1/0	0/0	No	4
13	64	F	FHID	60	Lower vestibule	Infiltrative	No	3/2	No	0/0	3/3	No	4
14	49	F	FHID	50	Lower vestibule	Infiltrative	No	6/3	Yes	5/3	5/2	No	4
15	76	F	FHID	15	Superior vestibule	Topical	No	3/0	Yes	3/0	0/0	No	3
Total	Mean: 56,1 Range: 12-76 years	80% F 20% M Ratio F/M: 5/1	66.67% FHID 33.33% FFH	Mean: 33mm Range: 5-90mm	40% Superior vestibule 20% Lower vestibule 13.33% Lower lip 13.33% Buccal mucosa 6.67% Upper lip 6.67% Floor of the mouth	80% Infiltrative 20% Topical	74.34% No 26.66% Yes	Day 1: 53.33% No 26.67% Mild 13.33% Moderate 6.67% severe Day 7: 66.67% No 26.66% Mild 6.67% Moderate	73.33% No 26.67% Yes	Day 1: 66.66% No 13.34% Mild 13.34% Moderate 6.65% Severe Day 7: 60% No 26.66% Mild 13.33% Severe 6.66% Moderate	Day 1: 46,67% No 33.33% Mild 20% Moderate Day 7: 66.67% No 20% Mild 13.33% Moderate	None	Mean: 3.5 Range: 3-5

F- Female; M- Male; FHID- Fibrous Hyperplasia Induced by Denture; FFH- Focal Fibrous Hyperplasia; 0: No; 1-3: Mild; 4-6: Moderate; 7-9: Severe; 10: Unbearable

Figures and Legends

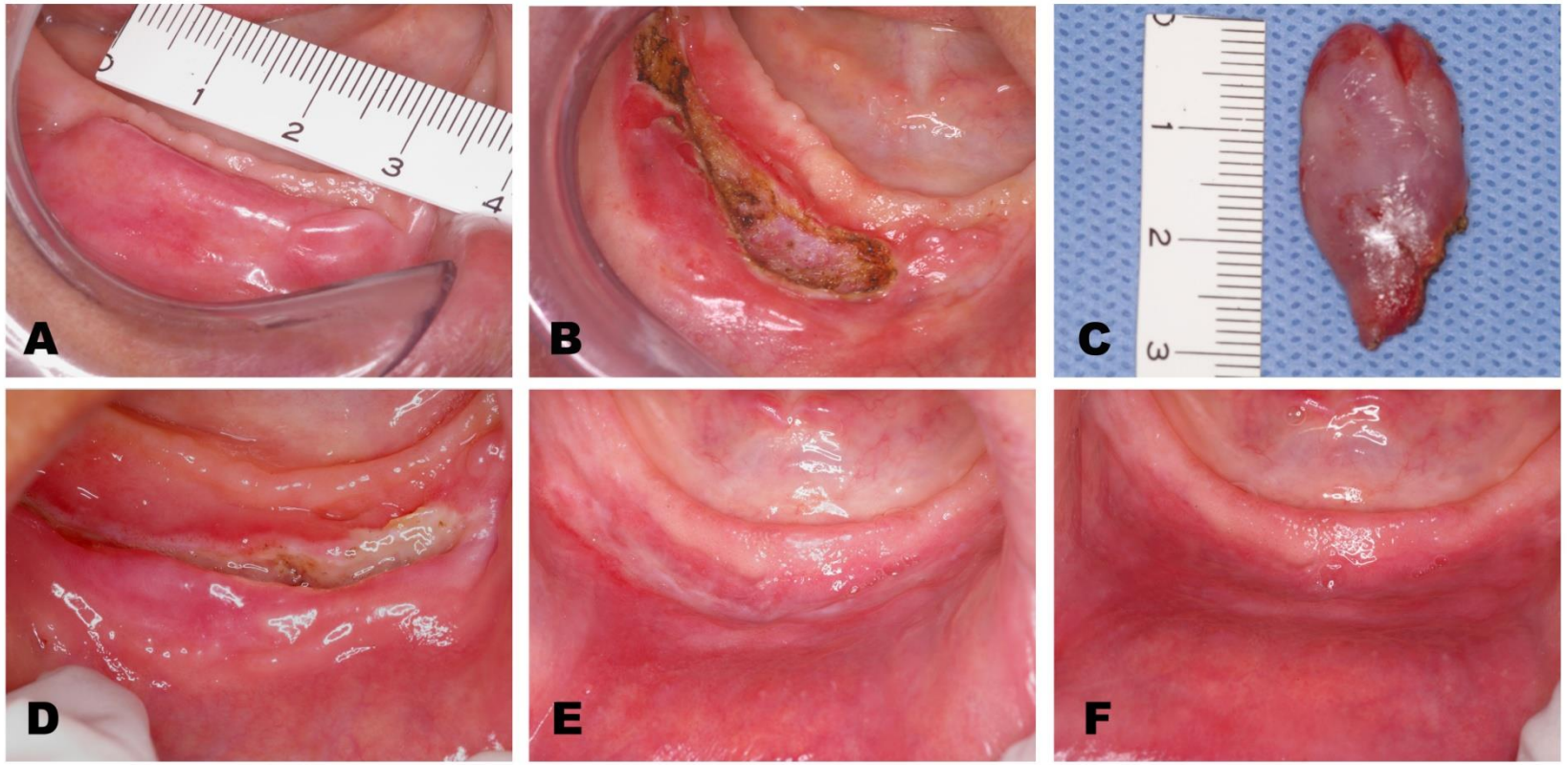

Figure 1- Clinical aspects of fibrous hyperplasia after having undergone diode laser surgery. A- Fibrous hyperplasia induced by dentures with a mucosa-like color and a size of 30 mm in largerst diameter. B- Immediate post-surgical aspect of the wound treated with diode laser surgery. Excellent hemostasis can be observed. C- 30 mm surgical specimen was sent for histopathological analysis. D- Postoperative aspect of the wound after 7 days; an ulcer of 30 mm in size recovered by a pseudomembrane can be observed. E- Postoperative aspect of the wound after 15 days; an accelerated wound healing process can be observed. F- Complete healing of the wound after 21 days; there has been no decrease in vestibule after clinical healing and a minimal mucosa scar is present.

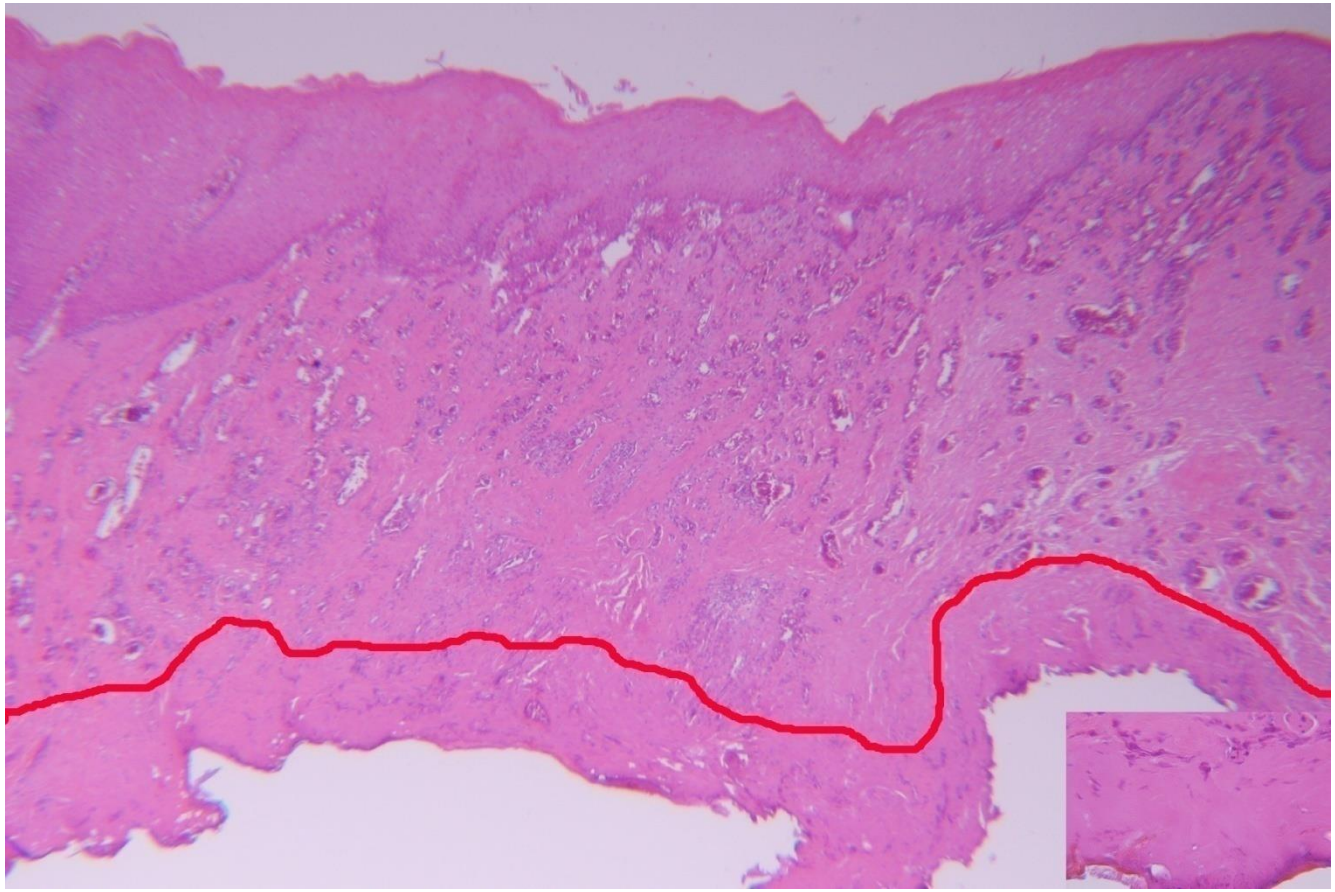

Figure 2- Fragment of fibrous hyperplasia submitted to diode laser surgery. An oral mucosal fragment with hyperplastic stratified squamous epithelium and lamina propria can be observed, represented by densely collagenized connective tissue and chronic inflammatory cells. A band of coagulation necrosis is present on the lower border of the specimens, opposite to the epithelium and outlined by a red line (Haematoxylin and eosin, 25X magnification original). Lower right box illustrates detailed coagulation necrosis (Haematoxylin and eosin, 400X original magnification).

7.2 Artigo 2

Artigo submetido ao periódico International Journal of Oral and Maxillofacial Surgery (qualis – A1/ Fator de impacto 1.5) em 19 de maio de 2014 e encontra-se aceito para publicação..

Journal title: International Journal of Oral & Maxillofacial Surgery

Corresponding author: Prof. Márcio Bruno Amaral

Article title: Diode laser surgery versus scalpel surgery in the treatment of fibrous hyperplasia: a randomized clinical trial

Manuscript number: IJOMS-D-14-00408R2

Dear Prof. Amaral,

I am pleased to confirm that your manuscript has been accepted and sent to the Technical Editor for editing.

Once we have the final edited version of your paper a second confirmation acceptance letter will be sent to you directly.

Yours sincerely

Jacqui Merrison

Administrative Editor

Title: Diode laser surgery versus scalpel surgery in the treatment of fibrous hyperplasia: a randomized clinical trial

Running title: Diode laser versus scalpel surgery in treatment of fibrous hyperplasia

Key words: diode laser surgery, hyperplasia, clinical trial

Abstract

Fibrous hyperplasia (FH) is treated by surgical incision using a scalpel, together with the removal of chronic trauma. However, scalpel techniques do not provide the haemostasis that is necessary when dealing with high vascular tissues. Diode laser surgery can be used in the management of oral tissues due to its high absorption by water and hemoglobin, and has provided good results in periodontal surgery and oral lesions. The aim of this present study was to compare the effects of diode laser surgery to those of the conventional technique in patients with fibrous hyperplasia. A randomized clinical trial was performed in which surgical and postoperative evaluations were analyzed. On comparison of the laser- treated (study group) patients to those treated with a scalpel (control group), significant differences were observed in the duration of surgery and the use of analgesic medications. Over a 3-week period, clinical healing of the postoperative wound was significantly faster in the control group as compared to the study group. In conclusion, diode laser surgery proved to be more effective and less invasive when compared to scalpel surgery in the management of fibrous hyperplasia. However, wound healing proved to be faster when using scalpel surgery.

Introduction

Fibrous hyperplasia is a chronic low-grade irritation occurring as a consequence of ill-fitting dentures. Fibrous hyperplasia is frequently the result of the resorption of the alveolar ridge in such a way that the denture moves further into the vestibular mucosa, leading to fibrous hyperplasia that proliferates over the flange. Additionally, parafunctional habits can also induce a focal fibrous hyperplasia.[1]

Fibrous hyperplasia is a frequent oral lesion that affects 5% to 16.7% of the population. [2, 3] Its commonly appears as a small-sized, painless lesion with fibrous to flaccid consistency that is pale to erythematous in color and that can be found in any part of the oral cavity.[4,5] Fibrous hyperplasia occurs as a result of chronic irritation to grow, and when the source of trauma is removed, the lesion commonly decreases in size or regresses.[4]

Conventionally, fibrous hyperplasia is treated by surgical incision using a scalpel, together with the removal of chronic traumatic factors. Scalpels have been used for many years due to their case of use, accuracy, and minimal damage to the surrounding tissues. However, haemostasis of the surgical wound can be difficult, especially for patients with haemorrhagic disorders or those on anti-thrombotic therapy, without a suturing of the wound borders. [6,7-9] In the management of fibrous hyperplasia, haemostatic problems can be controlled by the use of electrocautery, which provides enhanced hemostasis by sealing blood vessels before cutting. However, cutting performance can be reduced by muscle fasciculation, while wound healing is delayed by extensive thermal damage when compared with scalpel surgery.[6,10] It is important to consider that the significant loss of sulcus depth and/or full elimination of the

vestibule can appear in cases induced by ill-fitting dentures when suturing is performed on the wound borders.[7]

Surgical laser systems have been applied in the treatment of oral lesions. The main types are: 1) potassium-titanium-phosphorous (KTP), 2) neodymium-yttrium-aluminum-gamet (Nd:YAG), 3) carbon dioxide (CO_2), and 4) diode lasers with semiconductors.[11,12] Diode laser systems are portable, compact, and cost effective when compared with other high-power lasers. Diode lasers have a wavelength of between 805 and 980nm, which can be used in continuous or pulsed mode, depending on the clinical requirement, using an optical fiber with or without contact.[13] Diode laser surgery is often used in the management of oral tissues due to high absorption by water and haemoglobin, and has provided sound results in periodontal surgery, tissue alteration related to orthodontic treatment, and oral lesions.[11,14-16]

Considering that (1) diode laser surgery appears to be a good option for the treatment of oral diseases, including fibrous hyperplasia; (2) only a few clinical studies have been published;[8,9] and (3) the conventional treatment using scalpels can lead to clinical complications, the aim of the present study was to compare the effects of diode laser surgery with conventional techniques using scalpels.

Patients and methods

Patients and study design

Patients were recruited consecutively from the oral medicine clinic of the study university in Belo Horizonte, Brazil, from February to October 2013. The cases included 38 patients with fibrous hyperplasia caused either by dentures or by

parafunctional habits. Sample size was calculated based on dependent variables (postoperative pain and postoperative functional alterations) and analyzed considering a 95% confidence interval. The parameters used to perform the sample size calculation were identified from studies with a similar design published in the literature. [16,17] Limited-sized lesions with flaccid to fibrous consistency, sessil or had a pedicle, that were pale to erythematous in color, and that were associated with dentures or parafunctional habits, were included in this study. Dentures were removed 2 weeks prior to treatment to eliminate inflammation and/or chronic pain. Patients currently using anti-inflammatory or analgesic medications were excluded. The lesions were measured in their largest diameter with a millimeter rule. A randomized clinical trial was carried out and patients were divided into two groups. A computer-generated list of random numbers was used to allocate subjects to the groups, considering a randomization ratio of 1:1 (Microsoft Office Excel Software, 2007). This study was approved by the Human Research Ethics Committee (protocol number 23083713.1.0000.5149) and was conducted in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement.[18] Patients signed a statement of informed consent prior to inclusion in this study.

Surgical procedures

The control group (conventional technique using a scalpel) consisted of 19 patients. For these patients, after infiltrative anesthesia with 2% lidocaine and adrenaline at 1:100.000 (DFL Indústria e Comércio S. A., Rio de Janeiro, Brazil) was applied. Following this, the fibrous hyperplaisa was removed through incisions, using a number 15C surgical blade with the aid of mosquito forceps to

provide slight traction of the lesions. The surgical procedures were performed under conditions of continuous bleeding, which was controlled by applying a pressure dressing. Continuous suturing of the wound borders was performed to control the bleeding and did not lead to a decrease in the buccal vestibule (Figure 2). The study group (diode laser technique) consisted of 17 patients. For these patients, topical anesthesia alone (Emla ® AstraZeneca do Brasil LTDA, São Paulo, Brazil) was first applied to the lesions. Infiltrative anesthesia with 2% lidocaine and adrenaline at 1:100.000 (DFL Indústria e Comércio S. A., Rio de Janeiro, Brazil) was applied if the patient complained of any kind of pain. Slight traction of the lesion using mosquito forceps was performed to facilitate the application of the diode laser incision. Suturing was not performed (Figure 2). While the laser was in use, an assistant was asked to hold the suction tip near the region of the surgery. Protective glasses were worn by both professionals and patients. For both groups, the surgical specimens were fixed in 10% buffer formalin and sent for histopathological analysis.

Laser parameters

Laser irradiation was performed using an 808nm diode laser (Thera Lase Surgery, DMC LTDA, São Carlos, Brazil), with an optical fiber of 600 µm, at a potency of 2.0W to 3.5W (average 2.96W) in a continuous-wave mode.

Surgical and postoperative evaluations

The following parameters were assessed for both surgical techniques: (1) type of anesthesia; (2) time of surgery; (3) bleeding; (4) oedema; (5)secondary infection; (6) postoperative pain; (7) analsegic usage; (8) postoperative

functional alterations, i.e: eating and speech; (9) clinical healing; and (10) patient satisfaction.

The patients were asked to rate the degree of pain and postoperative functional alterations (discomfort during eating and speech) on a 10 cm horizontal visual analogue scales (VAS).[19] The left endpoint of the pain scale was designated as “no pain”, while the right endpoint was marked as “worst pain imaginable.” The end-points of the scales for the degree of discomfort during eating and speech were marked as no discomfort on the left side and worst imaginable discomfort on the right side. The patients were asked to mark the position between the two endpoints that best described their personal perception of the degree of pain and discomfort during eating and speech that they had experienced on postoperative days 1 and 7. The mark placed by the patient was measured to the nearest centimeter; the scores for the degree of pain and functional complications were between 0 and 10. A single operator recorded these scores on postoperative days 1 and 7. All patients were instructed to use the same analgesic medicine containing paracetamol (750mg, four times/day), if needed to alleviate the pain, and analgesic usage were subsequently analyzed. In addition, the patients were asked whether or not an edema was present. Secondary infection was investigated by assessing the presence or absence of local exudation and fever. Bleeding during the postoperative period was recorded as present or absent. Clinical healing of the postoperative wounds was assessed at the weekly follow-ups; of these were measured with a millimeter ruler in their largest diameter until they had been completely healed. The time of the surgery was mesuared by a digital cronometer.

Patient satisfaction with treatment was evaluated after complete clinical healing of the postsurgical wounds, with complete epithelialization. A visual analogue scale (VAS) was applied to establish the degree of satisfaction: 0 = totally unsatisfied and 10 = totally satisfied.[20]

Postsurgical care

During the post-surgical period, all patients underwent special oral hygiene care, especially as regards hot, hard, and/or acidy foods. Patients were instructed not to ingest any form of analgesic during the postsurgical period, except in case of unbearable pain.

Statistical analysis

The data analysis was performed using the Statistical Package for Social Sciences (SPSS for Windows, version 17.0; SPSS Inc., Chicago, IL, USA); this analysis included descriptive statistics and association tests for comparisons between the two groups. The Shapiro–Wilk test was used to evaluate the distribution of the numerical variables (normal or non-normal), following which of parametric or non-parametric tests, as appropriate, were applied. The Mann-Whitney U-test was used to compare numerical variables, while the X^2 test or Fisher's exact test was applied for categorical variables. The Student's t-test was used to compare the duration of surgery due to the normal distribution of the data. The time of healing (in days) of the post-operative wounds was displayed by means of the Kaplan-Meier method. The results of the Kaplan-Meier plots were compared by applying the Log Rank test. The level of significance of the statistical differences was set at $P \leq 0.05$.

Results

A total of 38 patients agreed to participate in this trial. However, the lesions of two patients regressed after removing their dentures, and 2 patients did not participate in all postoperative stages. Therefore, 34 patients were analyzed in this study (Figure 3); 27 (79.4%) females and 7 (20.6%) males, and they ranged in age from 12 to 80 years (mean= 58.1 years). The fibrous hyperplasia was caused by dentures in 26 (76.5%) of the patients; while focal fibrous hyperplasia was found in 8 (23.5%) patients. The size of the fibrous hyperplasia ranged from 5 to 90 mm (mean= 31.47 mm) in the study group (Figure 1), and from 8 to 60 mm (mean = 24.18 mm) in the control group (figure 2). No statistically significant difference in the size of the lesions was found when comparing the two groups (p= 0.06).

The duration of surgery was shorter in the study group, but the patients reported more oedema. More analgesic medication was consumed by patients in the control group, but the time of clinical healing of the postoperative wounds was shorter in this group. These differences were statistically significant (Table 1). Clinical healing of the postoperative wounds was statistically faster in the control group in the third week. No significant differences between the two groups were found regarding subjective pain, postoperative functional alterations (eating and speech), bleeding, and type of anesthesia (Table 1). No Secondary infection was observed in etheir group, and all patients in both groups reported total satisfaction with the treatment. Additionally, time of healing was compared between both groups, demonstrating that less time was

required to healing of the postoperative wounds in the control group (Table 1, Figure 4).

All specimens presented oral mucosal fragments with hyperplastic stratified squamous epithelium, lamina propria of the densely collagenized connective tissue, and chronic inflammatory cells. In the study group, a band of coagulation necrosis was present in the lower border of the specimens (opposite to the epithelium) (Figure 5). No tissue damage caused by the diode laser was observed, thus allowing proper histopathological diagnosis of the specimens.[12]

Discussion

The present study aimed to verify the efficacy of diode laser surgery when compared to scalpel surgery in the treatment of FH. The main observations showed that diode laser surgery. The following observations were made for the diode laser surgery: (1) this technique was clinically effective in treating fibrous hyperplasia without sutures and with minimal surgical bleeding, (2) the duration of surgery was reduced, and (3) there was a decreased need for analgesic medications.

The results of the present study demonstrated diode laser surgery to be effective in the treatment of fibrous hyperplasia without the need for sutures. Diode laser surgery is now a viable alternative to the scalpel surgery in the treatment of fibrous hyperplasia. As oral tissues consist mostly of water, and considering the affinity of diode lasers for water and hemoglobin, this type of surgery is readily applicable in oral tissue surgery, including for the treatment of fibrous hyperplasia.[8,11,15,16]

Although the present study did not show there to be of significantly less postoperative pain or in eating and speech for diode laser surgery patients when compared to those undergoing scalpel surgery, this study did show a lesser need for analgesic medication in the postoperative period for the diode laser sugery group. These results are in accordance with those from other studies reported in the literature that have assessed these types of parameters considering diode laser surgery in themanagement of oral tissues.[15,16]

Classically, surgery for fibrous hyperplasia involves grasping or traction of the lesion with a haemostat and incising below the lesion, creating a irregular-shaped wound, often with copious bleeding, as well as the placement of sutures in the wound borders to avoid a decrease in vestibular fundus and to control the bleeding.[4] In most cases, the patients experiences postsurgical bleeding and pain, and sutures can futher increase bleeding and pain during eating.[17] In addition, the removal of sutures from the mucosa can lead to pain, because sutures may be buried in the mucosa.[17,21] On the other hand, diode laser surgery demonstrated excellent hemostasis of the oral mucosa with minimal bleeding; sutures were not necessary in any of the cases in this study. These results are supported by Haytac and Ozcelik (2006),[17] who compared CO_2 laser surgery with scalpel surgery on frenectomies. Moreover, in the present study, the duration of surgery with diode lasers was significantly reduced when compared to scalpel surgery. By contrast, El-Kholey[16] (2014) found no significant difference patients undergoing diode laser surgery and patients undergoing scalpel surgery with regard the duration of the second stage of dental implant surgery; however, the sutures were not performed in either groups.

Regarding clinical healing of the surgical wound, this has been reported to be faster after diode laser surgery compared to scalpel surgery,[15,22] due to photobiomodulation at the cellular level; rapid healing is promoted by a reduction in toxins as a result of accelerated lymphatic flow, thereby enhancing repair and inducing regeneration.[22] By comparison, other studies have demonstrated that diode lasers tend to produce more pronounced changes in oral tissues than do conventional scalpel surgical procedures, due to thermal damage tissues, with a corresponding greater inflammatory reaction and delay in tissue organization only in the initial stage.[23,24] In the present study, clinical healing was significantly faster in the control group (3 weeks) when compared to study group. However, all lesions were completely healed within 5 weeks. Moreover, the presence of oedema was significantly higher in the study group. By contrast, studies reported previously in the literature have demonstrated less oedema with laser systems, which are most commonly related to the sealing of the lymphatic vessels.[25,26] In this study, the high number reporting oedema may be explained by the fact that the sizes of the lesions were larger in the study group, thus causing more thermal damage on tissues, leading to an increase in oedema; however, the size of the lesions treated with the two different modalities were not significantly different.

Kara[27] (2008) has suggested that neodymium:yttrium-aluminum-garnet laser frenectomies provide a patient betternperception of success than that seen with conventional surgery, in the present study, no differences between diode laser surgery and scalpel surgery could be observed when considering patient satisfaction with the treatment.

Although there was no group blinding in the current study, which may have led to outcome bias related to the subjective variables, it would have been impossible to blind the patients to the different surgical procedures. Further, multicentre studies should be performed to provide additional data concerning laser surgery and the management of oral lesions.

In conclusion, diode laser surgery proved effective in the management of fibrous hyperplasia, decreasing the duration of surgery and the need for analgesic medication, minimizing bleeding, and eliminating the need for sutures. Furthermore, patients tended to tolerate this procedure quite well. Thus, diode laser surgery demonstrated less invasiveness when compared to scalpel surgery. By contrast, wound healing proved to be faster with scalpel surgery when compared with diode laser surgery.

Funding

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Conflict of interest

None declared

Ethical Approval

Approved by the UFMG Ethics Committee, under protocol number 23083713.1.0000.5149.

Acknowledgments

The authors would like to thank the National Council for Scientific and Tecnological Development (CNPq: #309209/2010-2, #472045/2011-3).

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Table 1- Summary and statistical analysis of the parameters evaluated on study and control groups.

Parameters	Study group	Control group	P-value
Anesthesia			
Topical n (%)	4 (12%)	0	0.10 ‡
Infiltrative n (%)	13 (38%)	17 (50%)	
Duration of surgery, min (mean ± SD)	5.4 ± 3.6	7.8 ± 3.2	**0.04**†
Oedema			
Oedema n (%)	12 (71%)	6 (35%)	**0.03****
No oedema n (%)	5 (29%)	11 (65%)	
Pain			
Pain day 1 (range; median)	0-9; 0	0-8; 2	0.38*
Pain day 7 (range; median)	0-6; 0	0-7. 0	0.42*
Analgesic usage			
Yes (%)	6 (35%)	13 (76.5%)	**0.01****
No (%)	11 (65%)	4 (23.5%)	
Eating			
Eating day 1 (range; median)	0-9; 0	0-8; 0	0.79*
Eating day 7 (range; median)	0-7; 0	0-6; 0	0.60*
Speech			
Speech day 1 (range; median)	0-1; 1	0-9; 0	0.47*
Speech day 7 (range; median)	0-5; 0	0-6; 0	0.22*
Clinical healing of the postoperative wounds in days			
Days (mean ± SD)	24.29 ± 4.37	21.41 ± *1.69*	**0.01*** **
Size of the postoperative wounds in millimeter			
Week 1 (range; median)	5-90; 20	5-50; 20	0.54*
Week 2 (range; median)	0-70; 10	0-30; 10	0.06*
Week 3 (range; median)	0-50; 0	0-10; 0	**0.01***
Week 4 (range; median)	0-20; 0	0	0.31*

SD = Standard Deviation; *Mann-Whitney U-Test; ‡Fisher's Exact Test; †Student t Test; **X^2 Test; ***Log Rank test – Test of equality of survival distributions for the different levels of treatment.

Figures and Legends

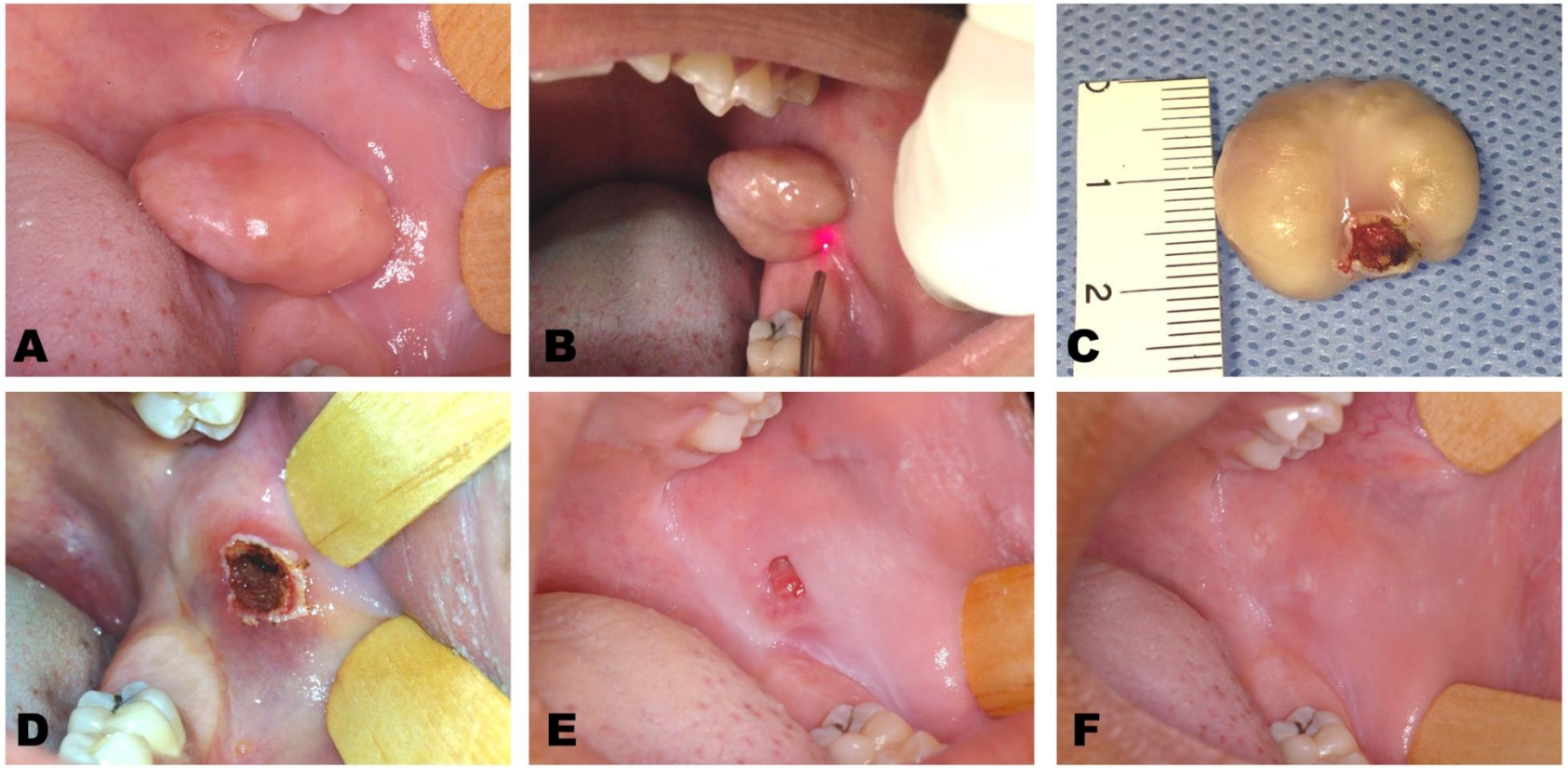

Figure 1 - Clinical aspects of fibrous hyperplasia (HF) after having undergone diode laser surgery. A- Focal fibrous hyperplasia induced by parafuncnional habit with a mucosa-like color, firm consistency and pedicled. B- Laser irradiation with a optical fiber of 600µm could be observed. C- 20 mm surgical specimen was sent for histopathological analysis. D- Immediate post-surgical aspect of the wound treated with diode laser surgery. Excellent hemostasis could be observed. E- Post-operative aspect of the wound after 7 days. An ulcer of 8 mm in size recovered by a pseudomembrane could be observed. F- Complete healing of the wound could be observed after 21 days. Minimal mucosa scar was present.

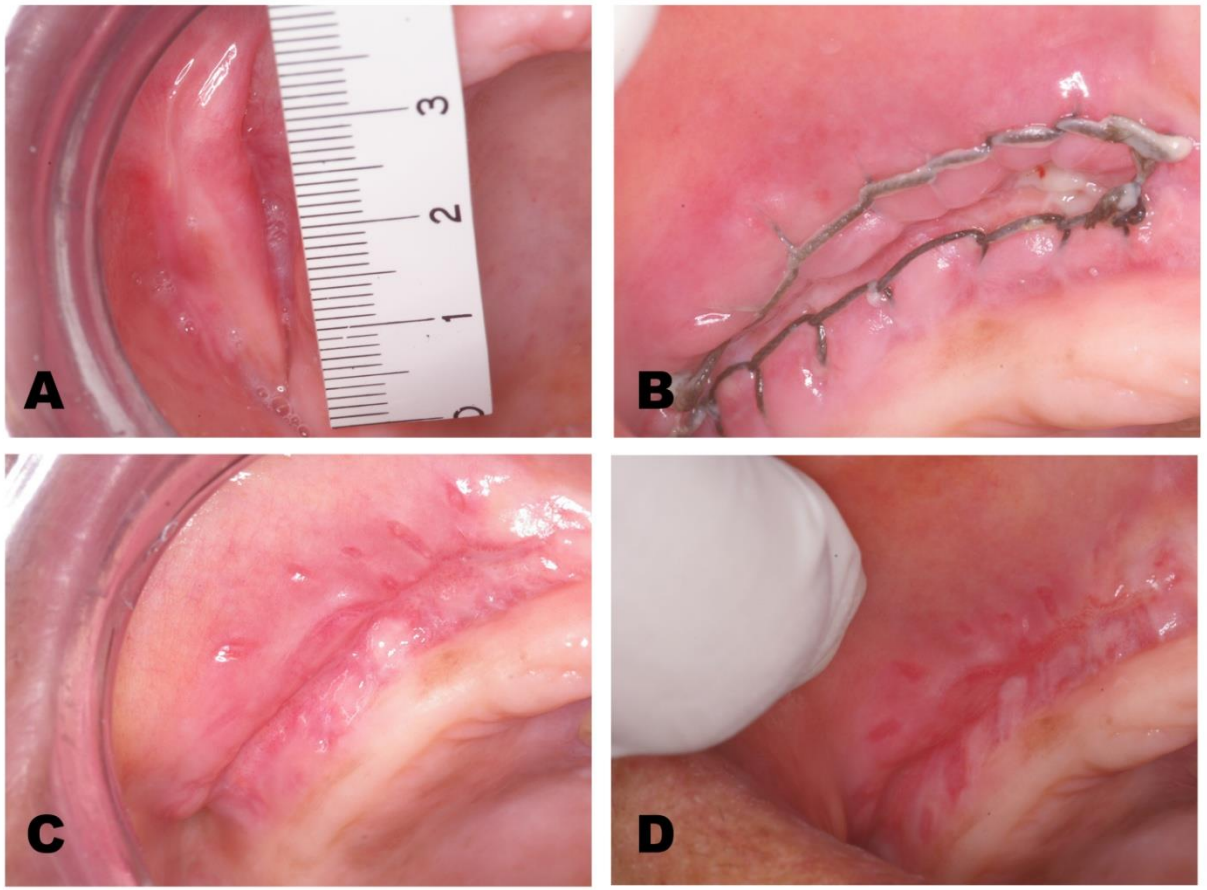

Figure 2 - Clinical aspects of fibrous hyperplasia after having undergone scalpel surgery. A- Fibrous hyperplasia induced by dentures with a mucosa-like color and a size of 40 mm in high diameter. B- Post-operative aspect of the wound after 7 days with continous sutures. An ulcer of 30 mm in largest size recovered by a pseudomembrane could be observed. C- Postoperative aspect of the wound after 21 days. D- Complete healing of the wound could be observed after 28 days. Significant mucosa scar was present.

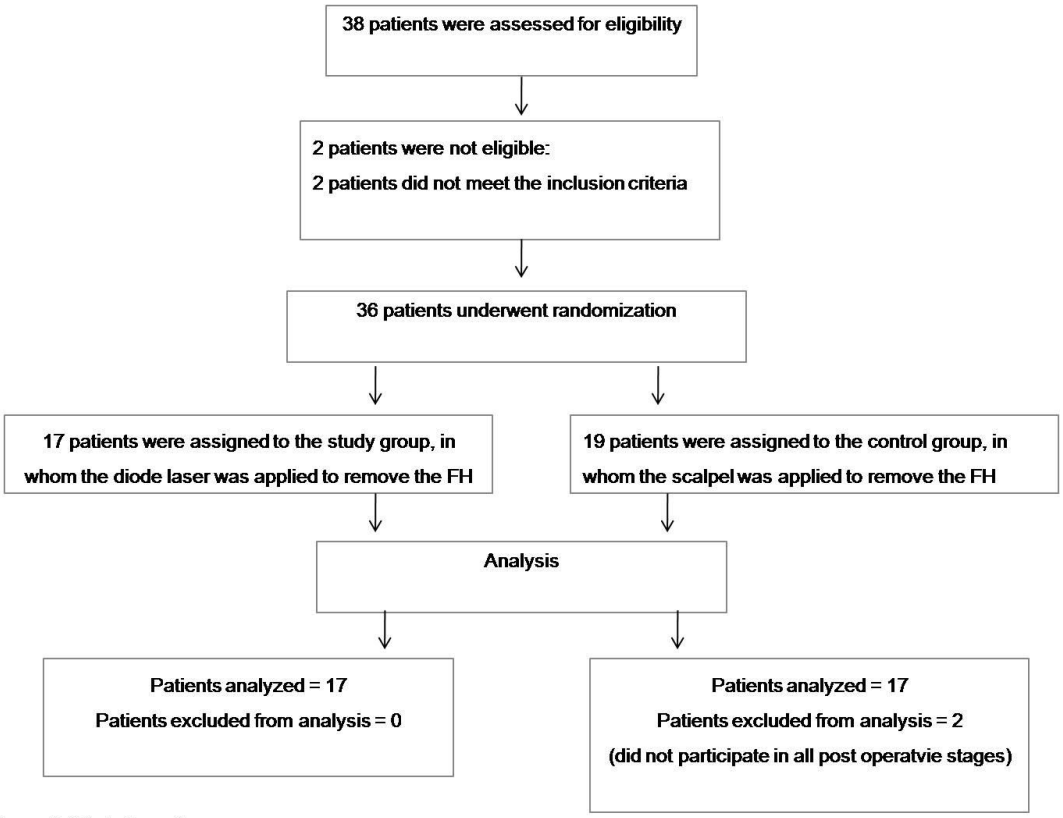

Figure 3. Study flow diagram.

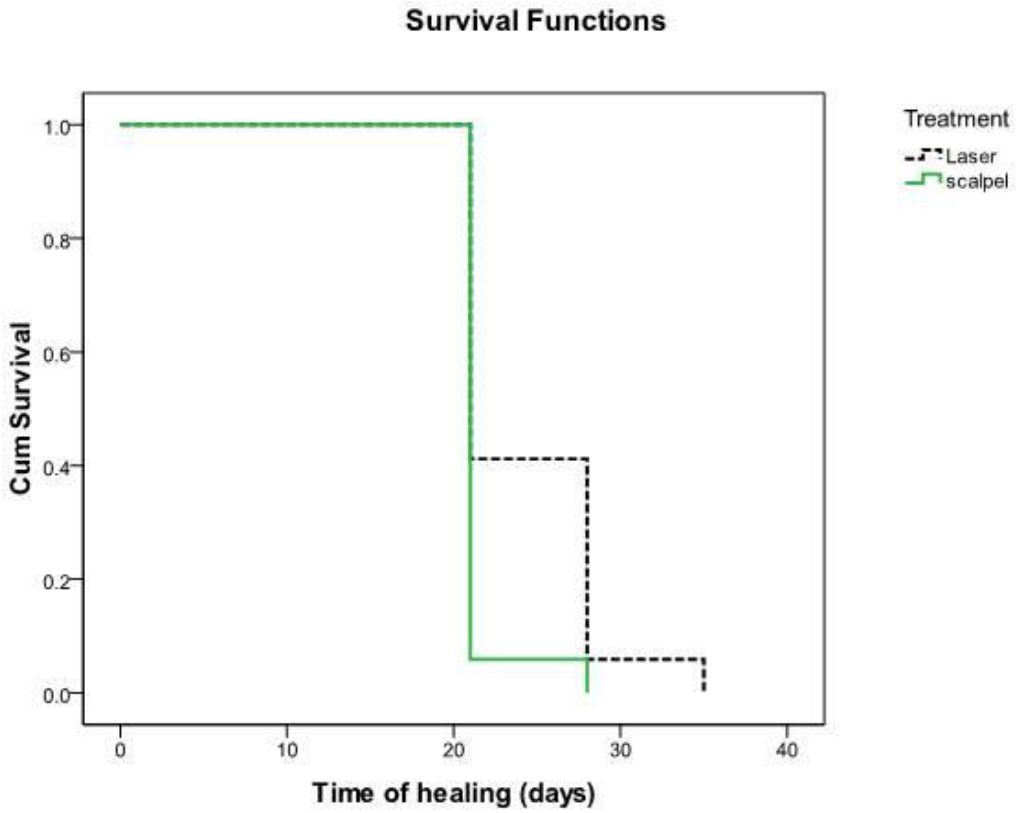

Figure 4- Graphic of survival time of healing of the post-operative wounds comparing the control group and study group in days.

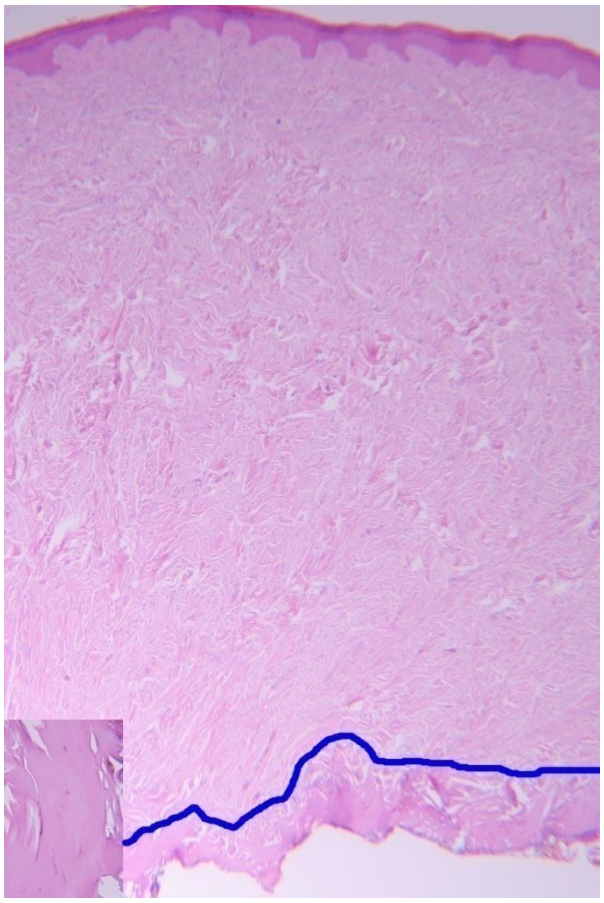

Figure 5- Fragment of focal fibrous hyperplasia submitted to the diode laser surgery. It is observed an oral mucosal fragment with hyperkeratinized stratified squamous epithelium and propria lamina is represented by a densely collagenized connective tissue. A band of coagulation necrosis is present in the low border of specimens, opposite to the epithelium and delimited by blue line (Haematoxylin and eosin, 25X magnification original). Low left box demonstrate the necrosis of coagulation in detail (Haematoxylin and eosin, 400X magnification original).

8- CONSIDERAÇÕES FINAIS

O laser cirúrgico de diodo provou ser efetivo e apresentou resultados satisfatórios no tratamento da HFI com os parâmetros utilizados neste estudo. O uso do laser de diodo permitiu incisões precisas sem a necessidade de suturas, assim, diminuindo o tempo de cirurgia e mantendo o fundo de vestíbulo oral inalterado em pacientes com HFI associada ao uso de próteses removíveis.

O ensaio clínico permitiu comparar de forma efetiva o laser cirúrgico de diodo em relação à técnica convencional utilizando o bisturi. Entretanto, o desenho do estudo não permitiu o cegamento dos grupos o que pode resultar em viés com relação às variáveis subjetivas, mas se torna impossível cegar procedimentos cirúrgicos totalmente diferentes. Assim, estudos multicêntricos devem ser realizados levando em consideração o laser cirúrgico de diodo e o tratamento das lesões da cavidade oral.

9 – CONCLUSÕES

O laser cirúrgico de diodo provou ter efetivo desempenho no manejo da hiperplasia fibrosa inflamatória com mínimo sangramento evitando o uso de suturas, e diminuindo o tempo da cirurgia. Assim, o laser de diodo demonstrou ser menos invasivo quando comparado com a cirurgia utilizando o bisturi. Ao contrário, a cicatrização da ferida operatória provou ser mais rápida com o uso do bisturi quando comparado com o laser cirúrgico de diodo.

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ANEXOS

Anexo 1 – COEP

UNIVERSIDADE FEDERAL DE MINAS GERAIS
COMITÊ DE ÉTICA EM PESQUISA - COEP

Projeto: CAAE – 23083713.1.0000.5149

Interessado(a): Prof. Ricardo Alves de Mesquita
Departamento de Odontologia Social e Preventiva
Faculdade de Odontologia- UFMG

DECISÃO

O Comitê de Ética em Pesquisa da UFMG – COEP aprovou, no dia 22 de janeiro de 2014, o projeto de pesquisa intitulado **"Eficácia do laser cirúrgico de diodo no tratamento da hiperplasia fibrosa inflamatória: ensaio clínico randomizado"** bem como o Termo de Consentimento Livre e Esclarecido.

O projeto será encaminhado, com o devido parecer, à CONEP, para avaliação final. O pesquisador deverá aguardar esta aprovação final para iniciar a pesquisa.

O relatório final ou parcial deverá ser encaminhado ao COEP um ano após o início do projeto.

Profa. Maria Teresa Marques Amaral
Coordenadora do COEP-UFMG

FICHA CLÍNICA (ANEXO 2)

IDENTIFICAÇÃO DO PACIENTE

NOME

DATA DE NASCIMENTO **COR** **GÊNERO**

ENDEREÇO **TELEFONE**

CIDADE **CEP**

REVISÃO DE SISTEMAS

DISTURBIOS ENDÓCRINOS

DISTÚRBIOS CARDIOVASCULARES

DISTÚRBIOS GASTROINTESTINAIS

DISTÚRBIOS GENITO-URINÁRIO

DISTÚRBIOS RESPIRATÓRIOS

DOENÇA INFECTO-CONTAGIOSA (HEPATITE, HERPES, AIDS)

FAZ USO CONSTANTE DE ALGUM MEDICAMENTO?

ALERGIAS

EXAME INTRA-ORAL

TIPO DE LESÃO:

ASPECTO CLÍNICO

TAMANHO

LOCALIZAÇÃO:

LASER ( ) **CONVENCIONAL ( )**

TIPO DE ANESTESIA

tópica ( ) **infiltrativa ( )**

AVALIAÇÃO DO EDEMA

Presente ( ) **ausente ( )**

AVALIAÇÃO DA DOR PÓS-OPERATÓRIA

1° dia **7° dia**

NECESSIDADE DE USO MEDICAÇÃO ANALGÉSICA

não ( ) **sim ( )**

AVALIAÇÃO DAS ALTERAÇÕES FUNCIONAIS (ALIMENTAÇÃO/MASTIGAÇÃO)

1° dia **7° dia**

AVALIAÇÃO DAS ALTERAÇÕES FUNCIONAIS (Fala)

1° dia **7° dia**

AVALIAÇÃO CLÍNICA POS TRATAMENTO

Tamanho da ferida pós-operatória

1° semana: ____mm

2° semana:____mm

3° semana:____mm

4° semana:____mm

COMPLICAÇÕES (DESCREVER)

SATISFAÇÃO APÓS O TRATAMENTO

Anexo 3 – TCLE

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Prezado paciente e/ou responsável:

Gostaríamos de convidá-lo a participar da pesquisa intitulada “Efeito do laser de diodo de alta intensidade no tratamento da hiperplasia fibrosa: ensaio clínico randomizado”, com o objetivo de tratar a hiperplasia fibrosa, que é uma lesão presente na boca e relativamente comum. Este documento tem como finalidade propor sua participação nesta pesquisa. Gostaríamos de contar com sua colaboração, esclarecendo que a pesquisa consiste em preenchimento de ficha clínica própria e tratamento da hiperplasia fibrosa por duas técnicas sendo elas: 1) remoção cirúrgica pela técnica convencional utilizando o bisturi; e 2) remoção cirúrgica com laser de diodo. Todos os pacientes terão de ter diagnóstico clínico Hiperplasia Fibrosa. A técnica com o laser cirúrgico de diodo consiste em remoção da lesão através de uma luz vermelha capaz de cortar e coagular somente com anestesia tópica (pomada). Alguns casos serão aplicados o laser cirúrgico de diodo e outros não. Sua colaboração é muito importante e você não pagará nada por este tratamento. Você participa se quiser. Se você assinar concordando em participar e se arrepender, você pode desistir a qualquer momento. Se você tiver alguma dúvida, pode perguntar que esclarecemos sempre que for necessário. Este tratamento é feito em 1 ou mais sessões, com retornos periódicos para avaliação clínica da lesão. O atendimento será feito na Faculdade de Odontologia da UFMG, na Clínica 04. Os possíveis riscos deste estudo são a possibilidade do não desaparecimento total da lesão. Poderá haver algum desconforto, como dor, dificuldade para mastigar e para falar por certo período de tempo. O objetivo desta pesquisa também é avaliar a dor, dificuldade para alimentar/mastigar e dificuldade para falar, por isso, pedimos para prestar bastante atenção a estes sintomas, se vier a desenvolver. Já o possível benefício do uso do laser cirúrgico é o desaparecimento total da lesão com apenas um procedimento cirúrgico com menos dor e sangramento pós-operatório. Lembramos que laser é de uso corrente na prática clínica odontológica. O método convencional de remoção desta lesão é o cirúrgico. Todos os examinadores são dentistas e pesquisadores e estão aptos a fazer este exame e tratamento. Todos os seus dados serão confidenciais, sua identidade não será revelada publicamente, em hipótese alguma, e somente os pesquisadores envolvidos neste projeto terão acesso a estas informações, que serão utilizadas para fins de pesquisa. Duas cópias de igual teor do termo de consentimento livre e esclarecido (TCLE) serão assinadas onde uma deverá ficar com o pesquisador e outra com o participante da pesquisa. Desde já agradecemos sua

colaboração e o convidamos a participar desta pesquisa. Os telefones dos pesquisadores para quaisquer esclarecimentos são: Prof. Márcio Bruno F. Amaral – 91789845, Prof. Dr. Ricardo Alves Mesquita – 3409 2499. **COEP/UFMG**: Campus Pampulha: Unidade Administrativa II – Prédio da FUNDEP, 2º andar. Telefone: 3409-4592.

Eu, , estou ciente de ser portador(a) de hiperplasia fibrosa. Apresentando este diagnóstico clínico, concordo em participar de um estudo que objetiva tratar a Hiperplasia Fibrosa.

Após entender os objetivos e métodos da pesquisa descritos anteriormente, voluntariamente autorizo e aceito participar desta pesquisa. Comprometo-me também a fazer os retornos para avaliação e/ou necessidade de novo procedimento cirúrgico convencional ou com laser cirúrgico.

Tenho pleno conhecimento de que o principal objetivo é o tratamento da Hiperplasia Fibrosa, com a possível remissão da lesão.

Dou pleno direito de uso dos dados para fins de pesquisa e de divulgação em jornais e/ou revistas científicas especializadas no País e no Exterior.

Declaro que li e entendi as informações fornecidas acima. Tive a oportunidade de fazer perguntas e todas as minhas dúvidas foram esclarecidas.

Belo Horizonte, de de 20 .

Assinatura do paciente ou responsável

Documento de Identidade