UNIVERSIDADE FEDERAL DE PERNAMBUCO
CENTRO DE CIÊNCIAS DA SAÚDE
PROGRAMA DE PÓS-GRADUAÇÃO EM ODONTOLOGIA

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AVALIAÇÃO DA BASE ALAR APÓS CIRURGIA ORTOGNÁTICA: comparação de dois tipos de plicatura nasal

Recife
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Dissertação apresentada ao Colegiado do Programa de Pós-Graduação em Odontologia do Centro de Ciências da Saúde da Universidade Federal de Pernambuco, como requisito parcial para a obtenção do grau de Mestre em Odontologia.

Área de concentração: Clínica Integrada

Orientador: Prof. Dr. Jair Carneiro Leão

Coorientador: Prof. Dr. Luiz Alcino Monteiro Gueiros

Recife
2019

Catalogação na Fonte
Bibliotecária: Mônica Uchôa, CRB4-1010

C376a Cavalcanti, Thames Bruno Barbosa.
Avaliação da base alar após cirurgia ortognática: comparação de dois tipos de plicatura nasal / Thames Bruno Barbosa Cavalcanti. – 2019.
55 f.: il.; 30 cm.

Orientador: Jair Carneiro Leão.
Dissertação (Mestrado) – Universidade Federal de Pernambuco, CCS. Pós-graduação em Odontologia. Recife, 2019.

Inclui referências, apêndices e anexos.

1. Cirurgia ortognática. 2. Cartilagens nasais alares. 3. Técnicas de sutura. I. Leão, Jair Carneiro (Orientador). II. Titulo.

617.6 CDD (22.ed.) UFPE (CCS2019-268)

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Aprovada em: 29 / 05 / 2019.

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Dedico este trabalho a minha esposa**, Ericka Paz de Melo Cavalcanti** que sempre me apoiou e incentivou nesta trajetória, estando presente em todos os momentos. Sem você, absolutamente, os obstáculos seriam bem maiores. Dedico também aos meus Filhos, **Heitor Paz de Melo Barbosa Cavalcanti e Bruno Paz de Melo Barbosa Cavalcanti** que são os bens mais preciosos da minha vida! Não podendo esquecer da **minha família,** que sempre foi a base para a construção de todos os sonhos realizados e os que ainda serão conquistados.

AGRADECIMENTOS

A Deus Por ter-me guiado em toda essa trajetória e por ter-me concedido sabedoria, saúde e oportunidade para que eu pudesse construir e concluir mais essa fase da minha vida.

Aos meus Orientadores, Prof. Dr. Jair Carneiro Leão e Prof. Dr. Luiz Alcino Monteiro Gueiros, pela confiança depositada em mim, pelos ensinamentos passados, pela compreensão, pelas exigências, pelos elogios, enfim, por todos os momentos que passamos juntos e que acrescentaram em meu crescimento profissional e amadurecimento pessoal. A conclusão desse trabalho significa a materialização de um esforço mútuo**,** dedicação e parceria. Muito agradecido por tudo!

Ao **Corpo docente da Pós-Graduação em Odontologia da UFPE**, por ter estado sempre ao nosso lado, nos orientandos e conduzindo durante esses dois anos com competência e respeito ao Programa do Mestrado em Odontologia 2017/2019.

Ao **Hospital da Restauração**, que foi como uma extensão do Mestrado, no momento da pesquisa.

Aos meus **colegas de Mestrado**, que durante dois anos compartilhamos nossas dificuldades para que, neste momento, possamos colher frutos para toda uma vida.

A todos os funcionários, **Tamires, Isaac, Dona Tânia** e em especial a nossa ex secretária **Oziclere**, meu abraço a todos.

Aos **pacientes**, pelos quais sempre tive muito carinho, ética, respeito e seriedade nos procedimentos, sem eles não teríamos nossa curva de aprendizado e não seríamos capacitados, meu eterno agradecimento.

RESUMO

A cirurgia ortognática é crucial para a correção das deformidades dentofaciais que geram alterações tanto esqueléticas, quanto nos tecidos moles. A base do nariz é uma das áreas mais susceptíveis a mudanças, podendo ser determinante para um planejamento cirúrgico harmônico. O presente estudo tem como objetivo comparar dois diferentes tipos de sutura utilizados na região da base do nariz, e observar qual tipo apresenta um resultado que melhor controle o alargamento nasal após os movimentos realizados pelo tecido esquelético, na osteotomia Le Fort I em cirurgia ortognática. O trabalho consiste em um ensaio clínico randomizado, onde os pacientes foram submetidos a uma avaliação pré-operatória para os critérios de inclusão ou exclusão do estudo, e após um período mínimo de 3 meses de convalescença, foram submetidos a uma nova análise para comparação estatística. 40 pacientes foram avaliados de acordo com o cálculo amostral e divididos em dois grupos randomizados, com 20 pacientes em cada grupo. 65% dos pacientes foram do sexo feminino, a discrepância maxilo mandibular mais prevalente foi o tipo classe III, a queixa inicial principal dos pacientes foi a estética e o alargamento no pós operatório apresentou diferenças com significância estatística ($p<0,001$) entre a técnica interna que teve uma média de (2,97 mm $\pm$ 0,76) e a técnica externa, com média (1,23 mm $\pm$ 0,72). Assim pode-se afirmar que a técnica externa controlou melhor o alargamento da base nasal após cirurgia ortognática, pois variou de 0,06 mm a 2,87 mm, enquanto que na técnica interna a variação foi de 1,50 mm a 4,23 mm. Ao correlacionar os movimentos realizados pela maxila na cirurgia, com o alargamento nasal não foi possível identificar a relação dos movimentos com o alargamento nasal, pois não apresentaram significância estatística ($p>0,05$). Podemos assim, afirmar que a cirurgia ortognática da maxila leva à um alargamento da base do nariz e da região alar, a técnica de sutura externa para controle do alargamento nasal se mostrou mais eficaz quando comparada com a técnica de sutura interna e os movimentos realizados pela maxila, não puderam ser relacionados com maior ou menor alargamento da base alar.

Palavras-chave: Cirurgia ortognática. Cartilagens nasais alares. Técnicas de sutura.

ABSTRACT

Orthognathic surgery is crucial for the correction of dentofacial deformities that generate both skeletal and soft tissue changes. The base of the nose is one of the areas most susceptible to changes, and may be determinant for a harmonic surgical planning. The present study aims to compare two different types of sutures used in the region of the base of the nose, and to observe which type presents a result that better controls the nasal enlargement after the movements made by the skeletal tissue, in the fort I osteotomy in orthognathic surgery. The work consists of a radomed clinical trial, where the patients were submitted to a preoperative evaluation for the inclusion or exclusion criteria of the study, and after a minimum period of 3 months of convalescence were submitted to a new analysis for statistical comparison. 40 patients were evaluated according to the sample calculation and divided into two radomed groups, with 20 patients in each group. 65% of the patients were females, the most prevalent mandibular maxillary discrepancy was type III, the initial complaint of the patients was aesthetic and the enlargement postoperatively presented differences with statistical significance ($p < 0.001$) between the internal technique which had an average of 2.97mm $\pm$ 0.76 and the external technique with a mean of 1.23mm $\pm$ 0.72. Thus, it can be stated that the external technique better controlled nasal base widening after orthognathic surgery, since it varied from 0.06mm to 2.87mm, while in the internal technique the variation was from 1.50mm to 4.23mm. When correlating the movements performed by the maxilla in the surgery, with the nasal enlargement it was not possible to identify the relation of the movements with the nasal enlargement, since they did not present statistical significance ($p > 0.05$). Thus, it is possible to affirm that orthognathic surgery of the maxilla leads to a widening of the base of the nose and the alar region, the external suture technique to control nasal enlargement was more effective when compared to the internal suture technique and the movements performed by the maxilla, could not be related to larger or smaller wing base enlargement.

Key words: Orthognathic Surgery. Nasal cartilages. Suturing techniques.

SUMÁRIO

1 INTRODUÇÃO

A correção de deformidades esqueléticas da face por meio de um tratamento ortodôntico-cirúrgico tornou-se uma opção segura e previsível, principalmente devido aos grandes avanços nas técnicas cirúrgicas, como uso da fixação interna rígida e da cirurgia de modelo, aliados ao preciso tratamento ortodôntico no preparo das oclusões. Assim este tipo de tratamento vem sendo bastante utilizado, onde os movimentos ósseos são milimetricamente calculados e executados cirurgicamente com excelentes resultados tridimensionais já bem descritos na literatura mundial [3-5].

A osteotomia Le Fort I é a técnica cirúrgica mais utilizada para corrigir as deformidades maxilares, foi descrita pela primeira vez em 1927 por Wassmund e já está bastante consolidada entre os cirurgiões bucomaxilofaciais, onde se pode obter um novo posicionamento do osso maxilar após movimentá-lo nos três planos espaciais[4, 6]. Esta técnica envolve a secção do osso maxilar nos pilares caninos, zigomáticos e pterigóides, separando-a do restante fixo da face, permitindo movimento exato que a maxila irá realizar[3, 7]. Este movimento preciso deve ser definido no plano de tratamento com o auxílio de análises clínicas, radiográficas e mais recentemente tomográficas[8, 9]. Para obter-se o movimento desejado na cirurgia, são confeccionados *splints* cirúrgicos durante a cirurgia de modelos, que serão utilizados no transoperatório[5]. Depois de se atingir a posição planejada, a maxila é fixada através dos princípios de fixação interna rígida[10].

A previsibilidade das alterações ósseas já são bem estabelecidas, a despeito dos bons resultados esqueléticos atingidos, no entanto, os efeitos que os tecidos moles sofrem com as cirurgias ortognáticas são menos previsíveis [11]. E apesar do principal objetivo da cirurgia ortognática ser uma melhora funcional, o componente estético é sem dúvida de extrema importância e sofre alteração, em especial a região da base alar que apresenta resultados muito variáveis[12].

A necessidade de quantificar as mudanças no tecido mole da face e prever os resultados cirúrgicos, objetivaram criar uma previsão da inter-relação entre as mudanças de tecido mole e ósseo da face[13]. E a região nasal é uma das áreas mais susceptíveis à mudanças, podendo ser determinante para um planejamento cirúrgico harmônico[14].

A quantidade e a direção do movimento maxilar nas cirurgias ortognáticas e suas relações com os tecidos moles, ainda não estão bem descritas na literatura. A

distensão muscular que ocorre durante o acesso para osteotomia Le Fort I, é uma consequência de prognóstico imprevisível, especialmente em situações críticas como grandes avanços e reposicionamento superior da maxila em indivíduos incapazes de tolerar o alargamento da base alar[15]; ou seja aqueles paciente que já tem a base do nariz no limite ou acima do padrão estético podem evoluir num pós operatório com um alargamento excessivo[16]. Embora existam muitas publicações sobre alterações dos tecidos moles após cirurgia ortognática, são necessários mais estudos prospectivos que estratifiquem por fatores confundidores, como magnitude do movimento, idade, sexo, raça, quantidade e qualidade dos tecidos moles [17].

Segundo Dantas et.al[18] o acesso vestibular maxilar para realização da osteotomia Le Fort I da maxila, causa o descolamento muscular da região nasal promovendo o alargamento da base alar. Este alargamento promove alterações antiestéticas que devem ser corrigidas com a plicatura da base alar, para devolução do seu comprimento normal, duas técnicas de suturas são bastante usadas para reconstituição da base nasal, sendo uma externa que rompe a pele e volta a cavidade bucal e outra interna apenas subcutânea[19, 20].

A técnica clássica, dita interna, foi descrita primeiramente em 1980 por Millard sendo utilizada para corrigir defeitos nasais em pacientes com fissura labial. Mas só em 1982 Collins e Epker descreveram sua utilização em pacientes submetidos a cirurgia maxilar do tipo Le Fort I[21, 22].

A técnica externa veio como alternativa para contenção do alargamento alar em 2002 descrita por Shams e Motamedi com o propósito de fazer este procedimento mais previsível e confiável, devido a apreenção da porção cutânea lateralmente a asa do nariz e não só da fibrocartilagem subcutânea como descrito na técnica interna[23, 24].

No entanto poucos estudos na literatura evidenciam qual técnica promove melhores resultados clínicos. O presente estudo, através de um Ensaio Clínico Randomizado, tem como objetivo geral avaliar o alargamento da base nasal dos pacientes submetidos a osteotomia Le Fort I. E como objetivo específico buscou-se identificar qual tipo de sutura apresentou melhor resultado clínico para controle do alargamento da base nasal após os movimentos realizados pelo tecido esquelético em cirurgia ortognática.

2 METODOLOGIA

2.1 Considerações éticas

O presente estudo foi aprovado pelo Comitê de Ética em Pesquisa do Centro de Ciências da Saúde da Universidade Federal de Pernambuco (CCS-UFPE) sob CAAE 81647317.9.0000.5208, Parecer 2.532.236 (Anexo 1). Todos os pacientes foram informados sobre o teor da pesquisa e após concordarem assinaram um termo de consentimento livre e esclarecido (Apêndice B).

Os riscos apresentados nesta pesquisa são aqueles inerentes a qualquer procedimento cirúrgico, como: sangramentos, infecção, parestesias locais (transitórias ou permanentes) na região maxilar e mandibular. E foram minimizados através de técnica cirúrgica acurada, uso de eletrocoagulação, antibioticoprofilaxia.

Os dados foram coletados através da ficha inicial (apêndice A), e serão armazenados pelo pesquisador pelo período mínimo de 5 anos.

2.2 Tipo de Estudo

Consiste em um Ensaio Clínico Randomizado.

2.3 Local da Realização da Pesquisa

O presente estudo foi realizado nas dependências do Hospital da Restauração – HR, mediante autorização pela diretoria através de carta de anuência (Anexo 2).

2.4 Cálculo Amostral

Para calcular o tamanho amostral foi utilizado o teste, a priori, do software Gpower 3.1.9.2 para o teste de hipóteses e para a diferença de médias entre dois grupos, assumindo tamanho de efeito de 1 em função da média de 2,5mm e 1,26mm dos estudo de Ritto (2010) com suas respectivas variâncias e desvio-padrão, alfa de

0,05 e poder de 0,80 que é considerado suficiente para encontrar a significância quando ela realmente existe. Entretanto, para corrigir o erro relacionado ao processo de coleta da amostra segundo recomendações para estudos com amostragem por estrato, foi acrescentado efeito de desenho de 20%. Diante disto, a amostra mínima necessária foi de 20 pacientes em cada grupo. No presente estudo a amostra final totalizou 40 pacientes, pois não houve nenhuma perda de seguimento amostral.

2.5 Seleção da Amostra

Todos os pacientes analisados nesta pesquisa foram oriundos do ambulatório de Cirurgia e Traumatologia Bucomaxilofacial do Hospital da Restauração, encaminhados para tratamento de deformidade dento- esqueléticas.

2.6 Critérios de Inclusão

Todos os pacientes que seriam submetidos a cirurgia ortognática de maxila com acesso em vestíbulo maxilar bilateral e osteotomia tipo Le Fort I e que no transoperatório seriam submetidos a plicatura nasal seja ela, intra oral ou extra oral.

2.7 Critérios de Exclusão

Pacientes com fendas labiais e/ou palatinas; apresentam história de trauma facial; ou que se submeteram a cirurgia de rinoplastia após a cirurgia ortognática e antes da avaliação clínica final; os que apresentarem deiscência no pós-operatório.

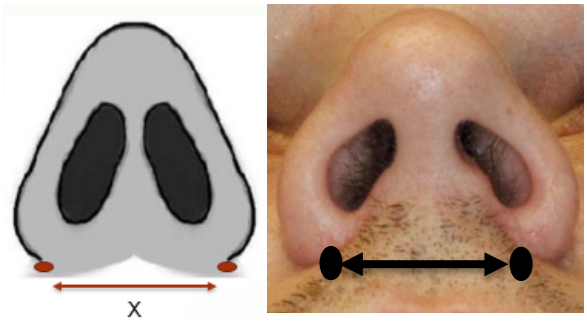
2.8 Instrumento de pesquisa

2.8.1 ANÁLISE INICIAL

Os pacientes foram submetidos a avaliação pré-operatória para cirurgia ortognática e critérios de inclusão do estudo, e os dados foram coletados através da ficha de atendimento inicial (Apêndice A).

Em caso de inclusão, realizou-se análise facial pré-operatória onde foi aferida as dimensões látero-laterais dos dois pontos craniométricos representados na base alar (alares Fig. 1) e anotados na ficha de atendimento inicial, sendo essa medida considerada a pré-operatória.

Figura 1 - Medida de referência da base alar nasal



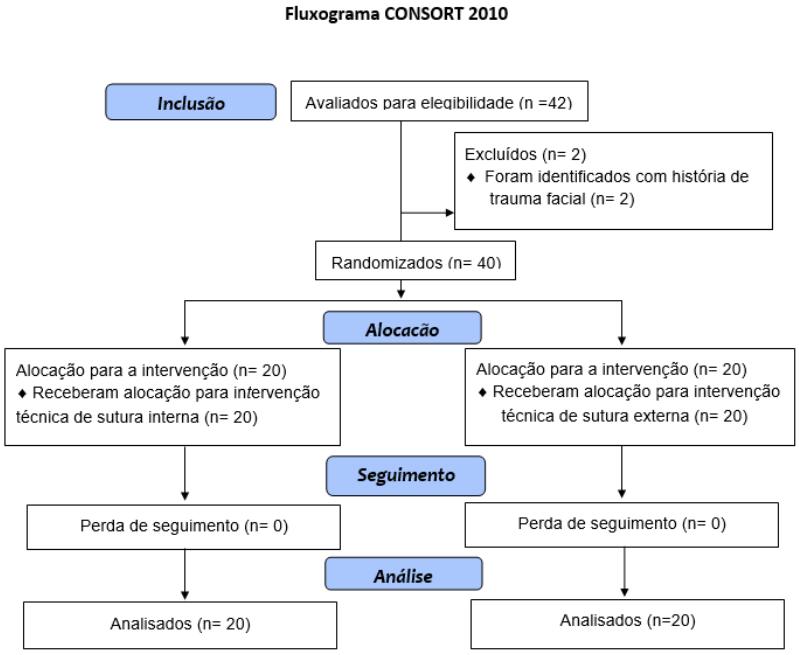
Fonte - Produção do próprio autor

2.8.2 RANDOMIZAÇÃO

A randomização foi realizada de modo a assegurar uma distribuição igual do número de participantes nos dois grupos de intervenção, sendo o grupo 1, pacientes submetidos a sutura interna e o grupo 2 pacientes submetidos a sutura externa. A escolha do tipo de sutura da base alar foi feita com a variação aleatória dos pacientes através de sorteio de envelopes pardos selados e numerados, onde o avaliador não sabia qual tipo de sutura foi realizado na cirurgia, pois o pesquisador responsável pelas medições pré e pós - operatórias não esteve presente nas cirurgias e não tinha ciência da técnica utilizada em cada paciente, o tipo de cirurgia realizada só foi revelado quando enviado os dados para análise estatística. Foram incluídos no estudo 42 pacientes para avaliação de elegibilidade, no entanto 2 pacienetes foram excluídos, devido a história de trauma facial com alteração dos tecidos moles. A amostra avaliada final foi um total de 40 pacientes divididos nos 2 grupos, conforme as diretrizes CONSORT (Consolidated Standards Of ReportingTrials[25]) (Fig. 2). Na alocação 40 envelopes idênticos pardos foram confeccionados, lacrados e misturados, 20 com a

descrição de técnica interna e 20 com a descrição de técnica externa, que era aberto pelo cirurgião na data da cirurgia.

Figura 2 - Fluxograma de recrutamento de pacientes nos grupos de estudo



Fonte - Consolidated Standards Of ReportingTrials

2.8.3 CALIBRAÇÃO

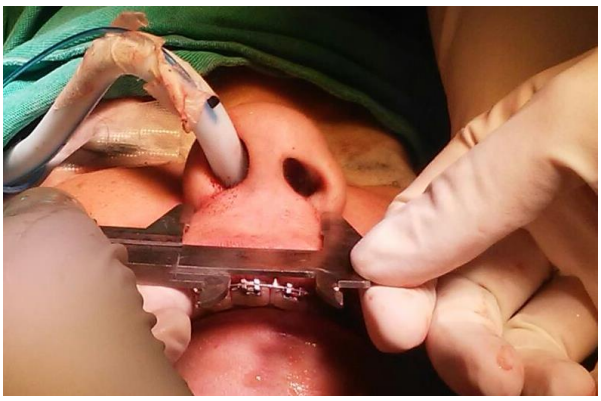
Todos os cirurgiões que operaram os pacientes da pesquisa, foram submetidos a uma calibração pelo pesquisador, para padronização das medidas alares transoperatórias e aplicação acurada da técnica cirúrgica já descrita na literatura.

2.8.4 PROTOCOLO DE INTERVEÇÃO CIRÚRGICA

Já com a intubação nasal realizada a largura da base alar foi aferida e gravada pelo cirurgião medida transoperatória (Fig. 3). Após os acessos e a conclusão das osteotomias maxilares e antes do fechamento da incisão vestibular intraoral, as bases alares são mobilizadas completamente. Isto envolve a liberação adequada do periósteo superiormente a partir do rebordo piriforme do nariz, próximo da base da asa. A sutura indicada através da abertura do envelope aleatoriamente, seja a interna ou externa foi realizada e a largura da base alar novamente medida com o mesmo

paquímetro, devendo esta medida coincidir com a que foi aferida ainda com o paciente sob intubação nasal. Estas medidas são importantíssimas durante o transoperatório, pois a presença do tubo causa alteração do diâmetro da narina podendo resultar em medidas errôneas caso fosse comparada com a medida pré-operatória (Fig.1). No entanto esta medida pré-operatória é fundamental na comparação final após 3 meses de cirurgia.

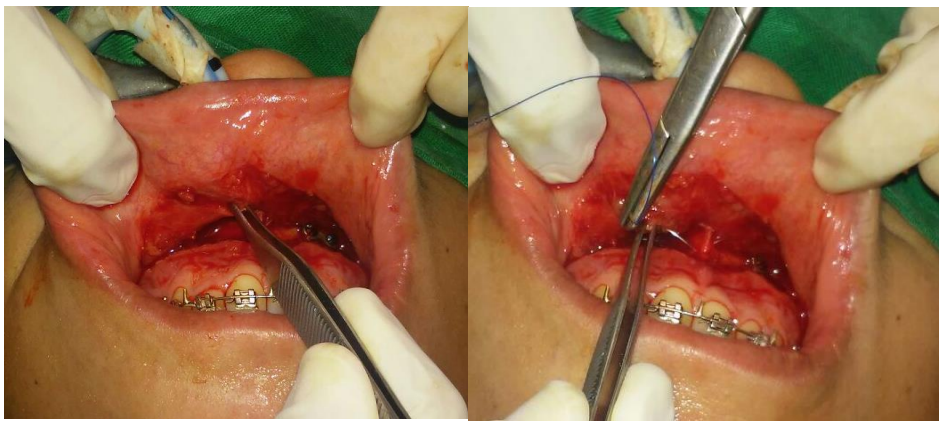
Figura 3 - Medida Transoperatória inicial



Fonte - Produção do próprio autor

Na técnica intra-oral o tecido de fibrocartilagem para apreensão é identificado através da aplicação de pressão sobre a região alar extra oral, faz-se então o pinçamento intraoral (Fig.4). Após isto ser realizado bilateralmente, com um fio não absorvível (prolene 3.0) e monofilamentado passado de uma "base alar" para a outra, ambas são puxadas em conjunto e observadas, através do movimento simétrico das asas do nariz. A sutura é então apertada para que a largura da base alar pré-determinada na medida inicial transoperatória seja conseguida (Fig.5).

Figura 4 - Técnica Interna - Pinçamento Intraoral



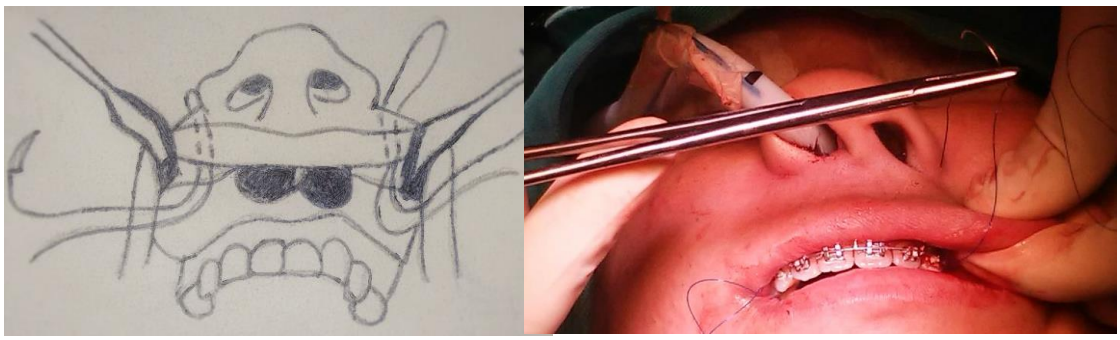
Fonte – Produção do próprio autor

Figura 5 - Técnica Interna – Sutura sendo realizada com simetria da Base Alar

Fonte – Produção do próprio autor

Na técnica externa um fio de sutura não absorvível (prolene 3.0) e monofilamentado com uma agulha espessa foi utilizado para transeccionar os tecidos da base alar, entrando pela incisão intraoral e saindo na pele da união da asa nasal com a face (Fig. 6). A agulha então, era reinserida na cavidade oral através do mesmo ponto de saída na pele, após atravessar a pele e antes de sair na incisão intraoral, a direção da agulha será alterada. Desta forma a sutura apreende o tecido da base alar e permanecerá sob a pele. O lábio estará então solto e a sutura é puxada para o lado oposto para checar o movimento da base alar. O mesmo procedimento foi aplicado ao lado oposto. Após passar em ambos os lados a sutura é apertada com atenção na região de base alar para que a largura pré-determinada na medida inicial transoperatória também seja conseguida.

Figura 6 – Técnica Externa



Fonte – Produção do próprio autor

A medida a obter no transoperatório deverá ser igual, tanto no início como no fim da cirurgia em ambas as técnicas, possibilitando assim, uma análise estatística comparativa fiel entre as duas suturas.

2.8.5 ANÁLISE FINAL

Depois de decorridos no mínimo 3 meses de cirurgia, os pacientes foram convocados para nova medida da base alar para comparação final da melhor técnica (Fig. 7). Sempre sendo utilizado para medida fiel tanto no pré, trans e pós-operatório um paquímetro digital marca King Tools (Fig. 8).

Figura 7 - Pré e Pós-operatório

Fonte - Produção do próprio autor

2.9 Análise estatística

2.9.1 MÉTODOS ESTATÍSTICOS

Os dados foram submetidos a estudo estatístico comparativo entre todos os grupos e períodos. A Normalidade foi verificada pelo teste de Shapiro Wilk. Foram aplicados os testes de t de Student para amostras independentes. E foi calculado o coeficiente de correlação de Pearson entre o alargamento e os movimentos, para verificar a significância entre a queixa e o tipo de procedimento realizou teste da razão de verossimilhança. Foi utilizado o programa estatístico IBM SPSS (Statistical

Package for Social Sciences), em sua versão 21.0, para a obtenção dos resultados. O valor da significância foi considerado quando $p \leq 0,05$.

Quadro 1.1 - Teste de Normalidade para as variáveis dos pré-operatório, pós-operatório e alargamento

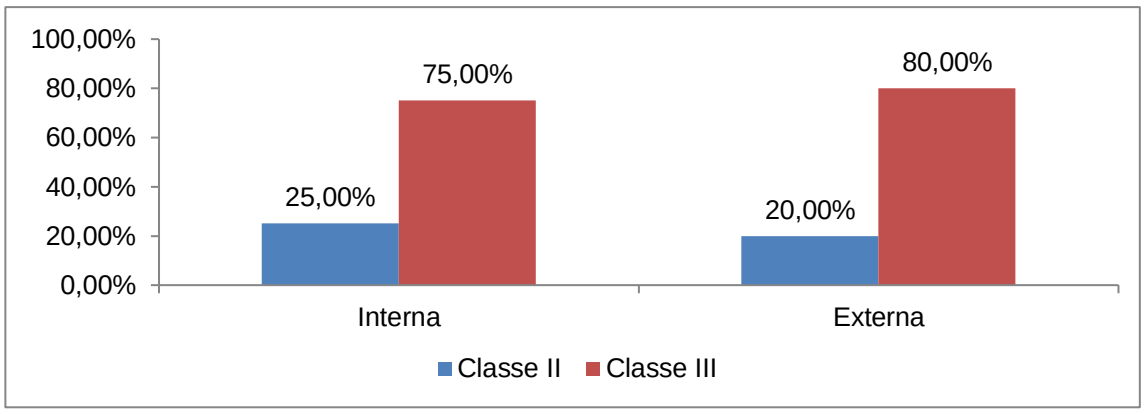
	Técnica	**Shapiro-Wilk**		
		Estatística	**Graus de liberdade**	**P-valor**
Pré-Operatório	Interna	0,987	20	0,990
	Externa	0,992	20	1,000
Pós-Operatório	Interna	0,982	20	0,956
	Externa	0,985	20	0,979
Alargamento	Interna	0,967	20	0,682
	Externa	0,974	20	0,834

Fonte - Produção do próprio autor

3 RESULTADOS

40 pacientes participaram deste estudo, foram randomizados e divididos em 2 grupos diferentes. No grupo 1, foi realizado o tipo de sutura da base alar pela Técnica interna com 20 pacientes e o grupo 2 pela Técnica externa também com 20 pacientes contemplando assim o cálculo amostral realizado. De acordo com o gênero 65,0% de todos os pacientes eram do sexo feminino, em relação ao diagnóstico da discrepância 75,0% dos submetidos a técnica interna eram classe III e os submetidos a técnica externa 80,0% eram da classe III, conforme apresentado no gráfico 01.

Gráfico 01 - Distribuição percentual do diagnóstico segundo o tipo de procedimento



Fonte - Produção do próprio autor

De acordo com a queixa inicial dos pacientes operados, a estética foi a de maior percentual com (55,0% na interna e 35,0% externa), seguida da queixa funcional (25,0% na interna e 30,0% na externa), e ambas estética + funcional em (15,0% na interna e 35% na externa), mas essas diferenças não são estatisticamente significantes (p=0,259), como apresentado na tabela 01.

Tabela 01 - Frequência absoluta e relativa da queixa segundo a técnica utilizada

Queixa	Técnica				Total		p-valor[1]
	Interna		Externa				
	n	%	N	%	n	%	
Estética	11	55,0	7	35,0	18	45,0	0,259
Funcional	5	25,0	6	30,0	11	27,5	
Estética+Funcional	3	15,0	7	35,0	10	25,0	
Apnéia do Sono	1	5,0	0	0,0	1	2,5	
Total	**20**	**100,0**	**20**	**100,0**	**40**	**100,0**	

Fonte - Produção do próprio autor – 1. teste da razão de verosssimilhança

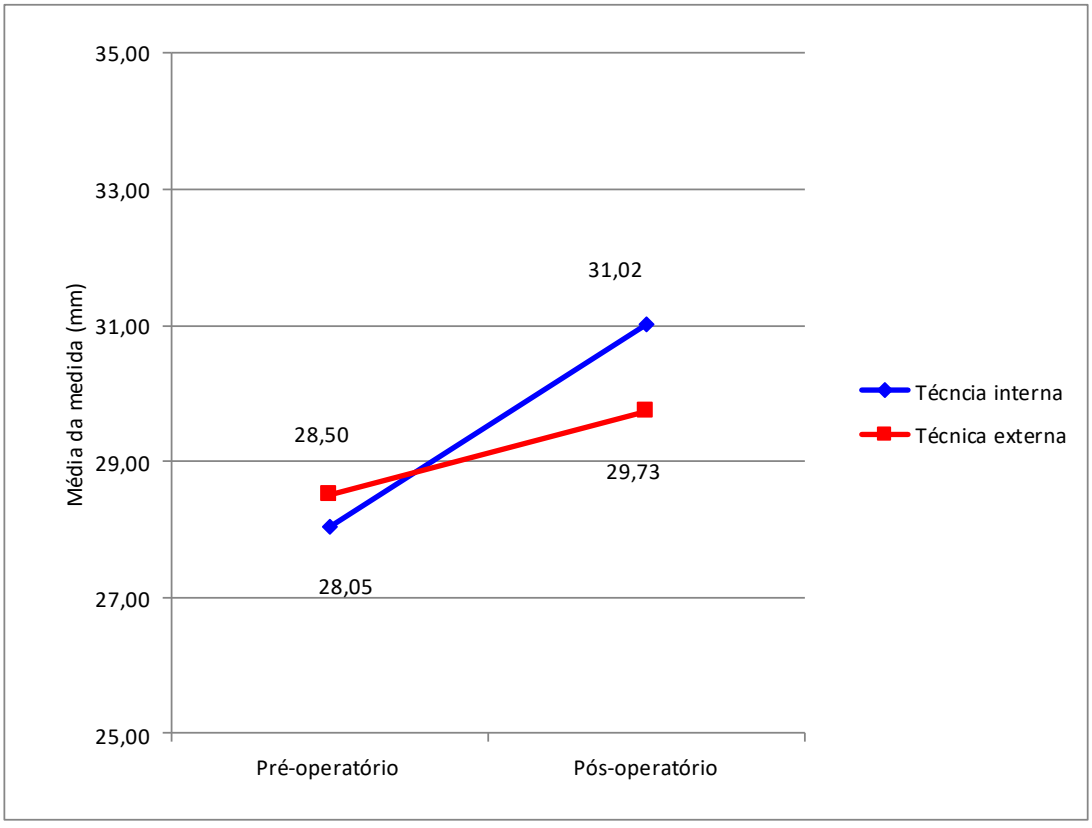
De acordo com a tabela 02, as medidas das bases alares no pré-operatório eram semelhantes nos dois grupos, pois não apresentou diferenças com significância estatística entre a interna (28,05 ± 3,65) e externa (28,50 ± 3,03), já no pós operatório essas médias variaram de 31,02 ± 3,86 na técnica interna e de 29,73 ± 3,11 na técnica externa como demonstrado no gráfico 2.

Tabela 02 - Medidas descritivas dos pacientes no momento pré-operatório nos dois tipos de sutura

		N	Média	Desvio-padrão	Mínimo	Máximo	p-valor[1]
Pré-operatório	Interna	20	28,05	3,65	21,74	35,80	0,673
	Externa	20	28,50	3,03	22,48	34,32	

Fonte - Produção do próprio autor - 1. Teste t de student para amostras independentes.

Gráfico 2 – Médias das medidas segundo a avaliação e técnica utilizada



Fonte - Produção do próprio autor

Já na tabela 03, o alargamento no pós-operatório apresentou diferenças com significância estatística (p<0,001) entre a técnica interna que teve uma média de (2,97 ± 0,76) e a técnica externa, com média (1,23 ± 0,72) – gráfico 3. Assim pode-se afirmar

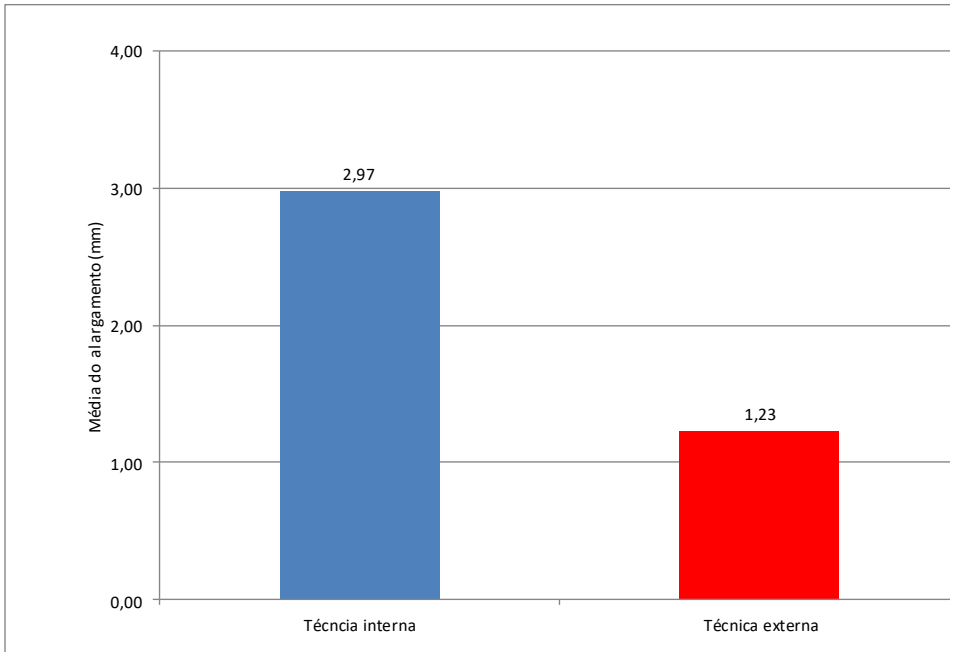
que a técnica externa controlou melhor o alargamento da base nasal após cirurgia ortognática, pois variou de 0,06 a 2,87 enquanto que na técnica interna a variação foi de 1,50 a 4,23. Nesta amostra não se verificou-se encurtamento da base do nariz apenas alargamento.

Tabela 03 - Medidas descritivas dos pacientes no alargamento pós-operatório nos dois tipos de sutura

		N	Média	Desvio-padrão	Mínimo	Máximo	p-valor[1]
Alargamento	Interna	20	2,97	0,76	1,50	4,23	<0,001*
	Externa	20	1,23	0,72	0,06	2,87	

Fonte - Produção do próprio autor - 1. Teste t de student para amostra independentes, * Estatisticamente significante.

Gráfico 3 – Médias do alargamento do pré para o pós-operatório segundo técnica utilizada



Fonte - Produção do próprio autor

Ao correlacionar os movimentos realizados pela maxila na cirurgia, seja ele de intrusão, extrusão ou avanço maxilar, com o alargamento nasal não foi possível identificar se com movimentos maiores existe mais alargamento, pois não apresentaram significância estatística (p>0,05)

Tabela 04 - Correlação entre o alargamento nasal e os movimentos maxilares

Técnica	Alargamento	Movimento		
		Avanço	**Intrusão**	**Extrusão**
Interna	Correlação de Pearson	**0,101**	**-0,233**	**-0,259**
	p-valor	0,671	0,324	0,271
	N	20	20	20
Externa	Correlação de Pearson	**0,121**	**-0,196**	**0,226**
	p-valor	0,612	0,408	0,338
	N	20	20	20

- Produção do próprio autor

4 CONCLUSÕES

Podemos concluir que, diante das variáveis investigadas, a cirurgia ortognática da maxila com osteotomia Le Fort I, independente do movimento realizado, leva a um alargamento da base do nariz e da região alar.

A técnica externa para controle do alargamento nasal se mostrou mais eficaz quando comparada com a técnica interna.

Os movimentos realizados pela maxila, não puderam ser relacionados com maior ou menor alargamento da base alar.

A partir destas observações, uma maior atenção deve ser dada aos pacientes que serão submetidos a cirurgia ortognática, pois o tipo de técnica de controle do alargamento nasal a ser utilizada, naqueles pacientes que não suportam esteticamente um maior alargamento nasal pós-operatório, irá interferir no resultado final estético.

4.1 Artigo – Comparison of two nasal base suture tecniques in orthognathic surgery: a randomized clinical trial

INTRODUCTION

Correction of skeletal deformities of the face through orthodontic-surgical treatment has become a safe and predictable option, mainly due to great advances in surgical techniques, such as the use of rigid internal fixation and model surgery, together with the precise orthodontic treatment in the preparation of occlusions [1]. Thus, this type of treatment has been widely used, where bone movements are millimetrically calculated and performed surgically with excellent three-dimensional results already well described in the literature [2-4].

The Le Fort I osteotomy is the most used surgical technique to correct maxillary deformities. It was first described in 1927 by Wassmund and is already well established among the maxillofacial surgeons, where a new positioning of the maxillary bone can be obtained after moving it in the three spatial planes [3, 5]. This technique involves the section of the maxillary bone in the canine, zygomatic and pterygoid pillars, separating it from the fixed rest of the face, allowing exact movement that the maxilla will perform [2, 6]. This precise movement must be defined in the treatment plan with the aid of clinical, radiographic and more recently tomographic analyzes [7, 8]. To obtain the desired movement in surgery, surgical splints are

made during model surgery, which will be used intraoperatively [4]. After the planned position is reached, the maxilla is fixed through the principles of rigid internal fixation [9].

The predictability of bone changes is already well established, despite the good skeletal results achieved, however, the effects that the soft tissues suffer from orthognathic surgeries are less predictable [10]. And although the main goal of orthognathic surgery is a functional improvement, the aesthetic component is undoubtedly of extreme importance and suffers alteration, especially the region of the alar base that presents variable results [11].

The need to quantify changes in soft tissue of the face and to predict surgical results, aimed to create a prediction of the interrelationship between facial and soft tissue changes [12]. And the nasal region is one of the areas most susceptible to changes, and may be determinant for a harmonic surgical planning [13].

The quantity and direction of maxillary movement in orthognathic surgeries and their relationships with soft tissues are still not well described in the literature. Muscle distension that occurs during access to Le Fort I osteotomy is a consequence of unpredictable prognosis, especially in critical situations such as major advances and superior repositioning of the maxilla in individuals unable to tolerate enlargement of the alar base [14]; or those patients who already have the base of the nose at or above the aesthetic standard can evolve postoperatively with excessive enlargement [15]. Although there are many publications on soft tissue alterations after orthognathic surgery, more prospective studies that stratify for confounding factors, such as magnitude of movement, age, gender, race, quantity and quality of soft tissues are necessary[16].

According to Dantas et.al[17], the maxillary vestibular access for Le Fort I osteotomy of the maxilla, causes the muscular detachment of the nasal region promoting the widening of the alar base. This enlargement promotes unsightly changes that must be corrected with the plication of the alar base, for return of their normal length, two suture techniques are widely used for reconstitution of the nasal base, one external and one internal[18, 19].

The classic technique, called internal suture, was first described in 1980 by Millard [20] and is used to correct nasal defects in patients with cleft lip. But only in 1982 Collins and Epker [21] described its use in patients undergoing maxillary Le Fort I type surgery.

The external suture technique came as an alternative to contain the wing enlargement in 2002 described by Shams and Motamedi[22] in order to make this procedure more predictable and reliable, due to the presence of the cutaneous portion laterally to the wing of the nose and not only of subcutaneous fibrocartilage as described in the internal technique [22, 23].

However, few studies in the literature show which technique promotes better clinical results. The present study, through a Randomized Clinical Trial, aims to evaluate the widening of the nasal base of patients submitted to orthognathic maxillary surgery. The main objective was to identify which type of suture presents the best clinical result for the control of the nasal base enlargement after the movements performed by the skeletal tissue in orthognathic surgery.

MATERIALS AND METHODS

Study Design

It consists of a randomized clinical trial and followed all the guidelines of the Consolidated Standards of Testing Reports CONSORT Statement [24] , the study was conducted in accordance with the Declaration of Helsinki in relation to medical research as revised in 2016. Ethical approval was obtained by the Research Ethics Committee of the Health Sciences Center of the Federal University of Pernambuco (CCS-UFPE) under CAAE 81647317.9.0000.5208, Opinion 2,532,236. All patients were informed about the content of the research and after agreeing signed a free informed consent form. The research was conducted between March 2017 and March 2019 at Hospital da Restauração, Recife, Brazil, by means of Letter of Prior Consent.

Participants

All the patients analyzed in this study came from the outpatient clinic of the Department of Surgery and Traumatology Bucomaxillofacial, referred for treatment of dento-skeletal deformity. The sample size was defined through a sample calculation, where Gpower 3.1.9.2 software was used to test hypotheses for the difference of means between two groups, assuming an effect size of 1 as a function of the mean of 2.5 mm and 1,26 mm of Ritto's study [3] with their respective variances and standard deviation, alpha of 0.05 and power of 0.80 that is considered sufficient to find significance when it actually exists. However, to correct the error related to the sample collection process according to recommendations for studies with stratum sampling, a design effect of 20% was added, totalizing a sample of 40 patients. The study included 42 patients to assess eligibility, however 2 patients were excluded due to a history of facial trauma with soft tissue alterations. Therefore, the minimum sample required was 20 patients in each group, totaling a final sample of 40 patients, as there was no loss of sample follow-up.

In the initial analysis all patients were submitted to the following inclusion criteria: undergo orthognathic surgery of the maxilla with access in the bilateral maxillary vestibule and Le Fort I type osteotomy and that in the intraoperative period they would be submitted to nasal

plication either intraoral or extra oral; and the following exclusion criteria present with a cleft lip and / or palate, have a history of facial trauma, or undergo rhinoplasty surgery after orthognathic surgery and before final clinical evaluation, those who have a postoperative dehiscence or who withdraw from participate in the survey.

Research Instrument

The patients were submitted to preoperative evaluation for orthognathic surgery and inclusion criteria of the study, and data were collected through the initial service record. In the case of inclusion, a preoperative facial analysis was performed where it was measured to the lateral-lateral dimensions of the two craniometric points represented in the alar base (alares) and annotated in the initial care record, being considered preoperative measurement (Fig. 1).

Randomization

The randomization was performed in order to ensure an equal distribution of the participants in the two intervention groups, group 1 being patients submitted to internal suture and group 2 patients being submitted to external suture. The choice of the type of suture of the wing base was made with the random variation of the patients through lottery of sealed and numbered brown envelopes, where the evaluator did not know which type of suture was performed in the surgery, since the researcher responsible for the pre and post measurements - operative was not present in the surgeries and had no knowledge of the technique used in each patient, the type of surgery performed was only revealed when the was data sent for statistical analysis. The final evaluated sample was a total of 40 patients divided into the 2 groups, according to the CONSORT (Consolidated Standards Of Reporting Trials)[24] guidelines (Fig. 2). In the allocation 40 identical brown envelopes were prepared, sealed and mixed, 20 with the description of internal technique and 20 with the description of external technique, which was opened by the surgeon at the time of surgery.

All the surgeons who operated on the patients of the research were submitted to a calibration by the researcher, for standardization of the intraoperative wing measurements and accurate application of the surgical technique already described in the literature.

Protocol of Interventions

Before the surgery started and with nasal intubation performed, the width of the alar base was measured and recorded by the surgeon - trans - operative. After the accesses and the conclusion of the maxillary osteotomies and before the closure of the intraoral vestibular incision, the wing bases are completely mobilized. This involves proper release of the periosteum superiorly from the pyriform ridge of the nose, near the base of the wing. The suture

indicated through the opening of the randomized envelope, either the internal or external was performed and the width of the base was reamed again with the same caliper, and this measure had to coincide with that which was still measured with the patient under nasal intubation. These measures are extremely important during the intraoperative period because the presence of the tube causes alteration of the diameter of the nostril and may result in erroneous measurements if compared with the preoperative measurement. However, this preoperative measurement is fundamental in the final comparison after 3 months of surgery.

In the intraoral technique the fibrocartilage tissue for seizure is identified by applying pressure to the extraoral oral region, then intraoral clamping is performed. After this is done bilaterally, with a non-absorbable and monofilamentated (prolene 3.0) yarn, passed from one "wing base" to the other, both are drawn together and observed through the symmetrical movement of the wings of the nose. The suture is then tightened so that the width of the pre-determined alar base in the initial transoperative measurement is achieved.

In the external technique a non-absorbable and monofilamentated suture (prolene 3.0) with a thick needle was used to transect the tissues of the alar base, entering through the intraoral incision and leaving the skin of the union of the nasal wing with the face. The needle was then reinserted into the oral cavity through the same exit point on the skin, after crossing the skin and before leaving the intraoral incision, the direction of the needle will be changed. In this way the suture grasps the tissue of the wing base and will remain under the skin. The lip will then be loose and the suture is drawn to the opposite side to check the movement of the wing base. The same procedure was applied to the opposite side. After passing on both sides the suture is carefully tightened in the base of the wing so that the pre-determined width in the initial transoperative measurement is also achieved.

The measurement to be performed intraoperatively should be the same, both at the beginning and at the end of surgery in both techniques, thus allowing a faithful statistical analysis between the two sutures. After a minimum convalescence period of 3 months after surgery, patients were called for a new measure of the alar base for final comparison of the best technique. Always being used for faithful measurement both in the pre, trans and postoperative a digital caliper brand King Tools.

Statistical methods

The data were submitted to a comparative statistical study between all groups and periods. Normality was verified by the Shapiro Wilk test. Student's t-tests were applied for independent samples. And the Pearson correlation coefficient was calculated between the

enlargement and the movements, to verify the significance between the complaint and the type of procedure performed likelihood ratio test. The statistical software IBM SPSS (Statistical Package for Social Sciences), version 21.0, was used to obtain the results. The significance level was considered when $p \leq 0.05$.

RESULTS

The initial characteristics were computed according to gender, where 65.0% of all patients were female, with respect to the diagnosis of mandibular maxillary discrepancy 75.0% of those submitted to the internal technique were class III and those submitted to external technique 80.0% were of class III and all other characteristics can be observed according to the base line (Fig. 3).

Among the initial complaints of operated patients, the aesthetic was the highest percentage (55.0% in the internal and 35.0% external), followed by the functional complaint (25.0% in the internal and 30.0% in the external), and both aesthetic + functional (15.0% in the internal and 35% in the external), but these differences are not statistically significant ($p = 0.259$), when the Likelihood Test was used.

Measurements of the basal alares in the preoperative period were similar in both groups, since they did not present differences with statistical significance between the means: internal (28.05mm ± 3.65) and external (28.50mm ± 3.03). Postoperatively, these averages ranged from 31.02 to 3.86 in the internal technique and from 29.73 to 3.11 in the external technique (Fig. 4). The minimum preoperative value in the internal was 21.74 mm and the maximum value was 35.80 mm, while in the external technique the minimum value was 22.48 mm and the maximum was 34.32 mm.

The postoperative enlargement presented differences with statistical significance ($p <0.001$) between the internal technique, which had an average of (2.97 ± 0.76) and the external technique, with a mean (1.23 ± 0.72). Thus, it can be stated that the external technique better controlled nasal base widening after orthognathic surgery, since it ranged from 0.06 to 2.87, while in the internal technique the variation was from 1.50 to 4.23 (Fig. 5). In this sample there was no shortening of the base of the nose only enlargement.

When correlating the movements performed by the maxilla in the surgery (Fig. 6), be it of intrusion, extrusion or maxillary advancement, with nasal enlargement it was not possible to identify if there were more or less enlargement with larger or smaller movements, since they did not present statistical significance ($p> 0.05$).

DISCUSSION

In the english literature, there is no consensus as to the best technique for the control of the enlargement of the alar base after orthognathic surgery involving the Le Fort I osteotomy procedure. Therefore, this work sought through the analysis of forty patients submitted to orthognathic surgery with involvement of the maxilla, to identify if the sutures of the nasal base, either by internal or external technique, are necessary and effective.

The postoperative prediction of the facial profile is desirable to achieve aesthetic success in treatment that is as important as functional success for both professionals and patients[25]. Facial changes in patients undergoing orthognathic maxillary surgery are multifactorial, so many studies try to establish norms to facilitate the surgical prediction of this type of face surgery. Studies have established different correlations between the soft and bony tissues with great variation, and this has indicated that many factors contribute to soft tissue response[26].

The surgical technique of Le Fort I type maxillary osteotomy includes procedures performed on bone and cartilaginous parts and soft tissues of the nose that can cause changes in nasal shape and function, and which may sometimes be unpredictable[27]. Nose deformity of the nose is often seen when the original structure of the base widens, becoming larger than the intercantal distance. In relation to the horizontal plane, the lateral-lateral distance of the wing base is approximately 2 mm wider than the intercantal distance (DIC), from one medial corner to the opposite. The ICD is generally between 31 to 33 mm. If DIC is abnormal, either due to traumatic telecan or to hypertelorism, the orbital distance (medial from the eye to the lateral corner) should be used as a reference for the nasal base[28].

Many studies have shown that Le Fort I osteotomy results in nasolabial changes, including enlargement of the alar bases and thinning of the

the upper lip, and these alterations may be anti-esthetic[29]. The suture of the alar base can be used to reduce nasal width increase, and several authors have reported its efficiency and suggest that this procedure limits the widening of the base width while others report not as effective. Rauso et al.[18] reports that many modifications to the technique have been described, so it is difficult to interpret these studies. However, the two techniques described by Milard[20] and Shams-Motamedi[22] are the most used nowwadays, so they were compared in our study.

For Moroi[30] a certain amount of enlargement of the wing base is expected after the Le Fort I osteotomy, and in most cases this effect is undesirable, so some surgical modifications have been added to the technique, such as the sutures of the wing processes. These techniques are also exemplified in the work of Howley et al[5] where different forms of incisions and sutures are used to try to better control this enlargement effect in the nasal and labial portions.

For Dantas et al.[17], the surgical technique of maxillary osteotomy also includes procedures performed on the bony and cartilaginous part and soft tissues of the nose which can cause changes in shape and surgeries for maxillary repositioning tend to cause elevation and advancement of the tip of the nose, as well as an enlargement of the nasal base. This study was performed in 21 patients who underwent surgery and were evaluated before and 6 months after the surgical procedure in relation to the movements of the nasal tip and modifications of the base of the nose. The results showed changes of nasal tip up in 85% of cases, to anterior in 80%, rotation in 80% and widening of the nasal base in 95%. This study corroborates with our study where 100% of our cases had nasal enlargement. Our transsurgical alveolar measurements had to be the same for a reliable evaluation of the suture technique, this enlargement in 100% of the cases is due to the deinsertion of the perinasal musculature, as Lee [31] points out. This result is extremely important because in subsequent surgeries in which no enlargement or reduction of the alar base is desired, a decrease of the transsurgical alveolar measurements should be performed in order to contain this enlargement, and the more precise technique for this result, as demonstrated in the our study, is the technique of external suture.

Azenha[10] evaluated alterations in the distance of the alar process in the pre and postoperative periods and observed if there was improvement in the subjective nasal respiratory quality and possible aesthetic alterations in the paranasal region of the patients submitted to the surgical expansion of the maxilla. The alar base distance measurements were performed in the immediate and postoperative preoperative periods of 180 days, and the verification of nasal respiratory quality and of possible aesthetic alterations were also observed in these periods. After statistical analysis using Test t, a significant increase in alares process distance ($p = 0.29$) was observed, however, patients' complaints were not observed. Already Schwarz et al.[32] do not indicate the suture of the alar base after surgical procedures of the maxilla. However, we understand that from the results obtained in this study, the suture of the alar base is performed in a preventive way of the nasal enlargement, in the procedures involving the Le Fort I osteotomies, resulting in a good facial harmony.

Ritto et al. [2] evaluated these two techniques of suture of the wing base, compared to preoperative and postoperative through standardized photographs, 35 patients were divided into 2 groups, but the mean enlargement of the internal suture group was of 2.50 mm (mm), while the mean enlargement of the external suture group was 1.26 mm. In addition, the standard deviation was lower for group 2, and the null hypothesis was rejected ($p < 0.05$), demonstrating that the difference between groups was statistically significant. It could be concluded that when

a more predictable and rigorous control of the base of the nose is objectified, the extra oral nasal plication fulfilled this function better.

Collins and Epker[21] however, suggest that the patient be extubated for the tightening of the nasal plication to be performed. We believe that this method is a risky one, since in extubation some complication may occur, necessitating reintubation, and the patient usually wakes up agitated, which makes it difficult to finalize the procedure. In our study we chose to measure these measurements even with the tube in position, and a preoperative measure was a reference for postoperative measurement after 3 months.

Because according to Raithatha[33] the alar base widens after maxillary surgery for several reasons such as detachment of the periosteum causing edema that expands the base of the nose. For Sojhi[34], the postoperative period necessary to evaluate the effects that an orthognathic surgery will have on the soft tissues of the face is not a consensus, and it has been suggested that this time is variable depending on the region to be evaluated, and the width of the alar base can be obtained with at least 3 months postoperatively.

However, after regression of this edema that revolves around three months, undesirable alterations may still persist, mainly in the nasal base, which should be compensated intraoperatively through the nasal sutures[28]. Mitchell et al.[35] differ from our opinion when they state that in patients who have an excess of basal alar width in the preoperative period, maxillary orthognathic surgery, associated or not with the nasal plication, will not reduce this width. Therefore, the authors recommend that these patients should undergo a Weir incision of secondary alar base, after maxillary surgery.

Wolford, Karras and Merha[36] also argue that it is easier to correct or control the width of the alar base at the time of surgery, rather than to submit the patient to another surgical procedure that may correct nasal imperfections.

We can conclude that, faced with the variables investigated, maxillary orthognathic surgery with Le Fort I osteotomy, independent of the movement performed, leads to an enlargement of the base of the nose and the alar region. The external technique to control nasal enlargement was more effective when compared to the internal technique and the movements performed by the maxilla, could not be related to a larger or smaller wing base enlargement. From these observations, greater attention should be paid to patients who will undergo orthognathic surgery, since the type of nasal enlargement control technique to be used, in those patients who do not aesthetically support greater postoperative nasal widening, will interfere in the final aesthetic result.

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FIGURES

Fig. 1 - Measurement of reference of nasal alar base

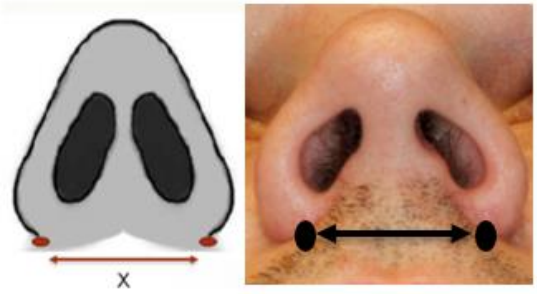

Fig. 2 - Flowchart of recruitment of patients in the study groups

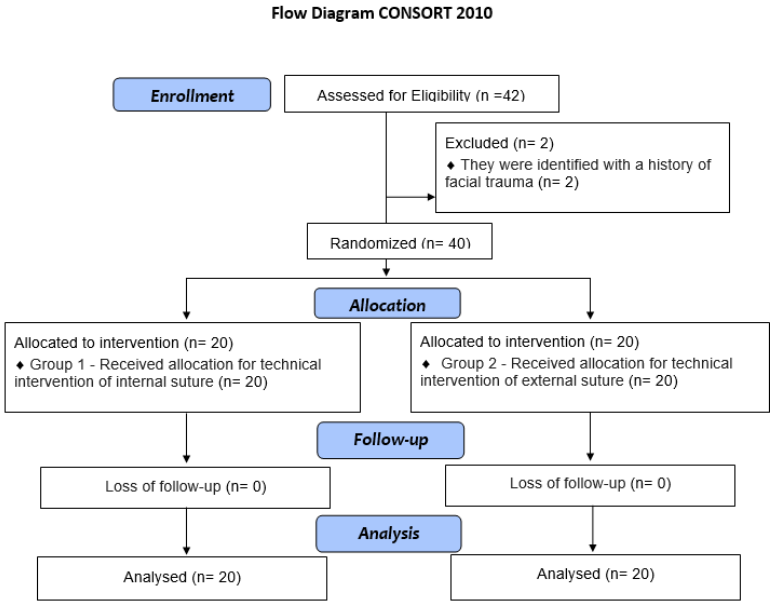

Fig. 3 Initial characteristics of the patients

Variable	Groups					
	Internal Technique		External Technique		Total Group	
	n	%	n	%	n	%
Total Group	**20**	**100,0**	**20**	**100,0**	**40**	**100,0**
• Sex						
Male	7	35,00	7	35,00	14	35,00
Female	13	65,00	13	65,00	26	65,00
• Age (Years)						
18 - 29	15	75,00	13	65,00	28	70,00
30 - 60	5	25,00	7	35,00	12	30,00
>60	0	0,00	0	0,00	0	0,00
• Main Complaint						
Aesthetic	11	55,0	7	35,0	18	45,0
Functional	5	25,0	6	30,0	11	27,5
Aesthetic and Functional	3	15,0	7	35,0	10	25,0
Sleep Apnea	1	5,0	0	0,0	1	2,5
• Diagnosis						
Class III	15	75,00	16	80,00	31	77,5
Class II	5	25,00	4	20,00	9	22,5

Fig. 4 Measurement means according to the evaluation and technique used

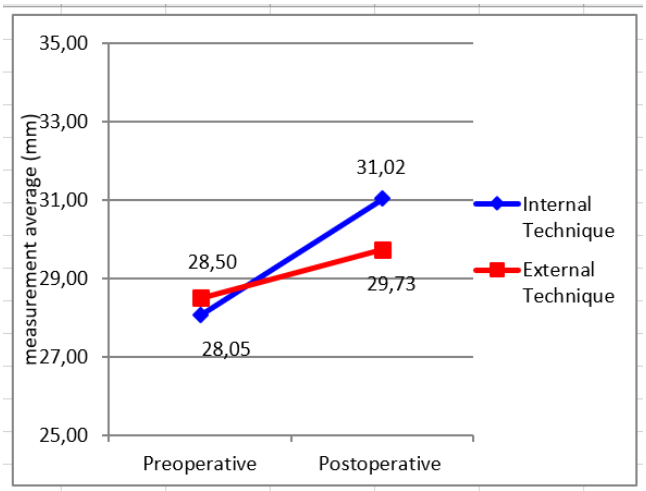

Fig. 5 - Descriptive measures of the patients in the postoperative enlargement in the two types of suture p <0.001

		N	Average	Standard deviation	Minimum	Maximum	p-value[1]
Enlargement	Internal	20	2,97	0,76	1,50	4,23	<0,001*
	External	20	1,23	0,72	0,06	2,87	

1 - Student t test for independent samples, * Statistically significant

Fig. 6 Correlation between nasal enlargement and maxillary movements

Technique	Enlargement	Movement		
		Advance	Intrusion	Extrusion
Internal	Pearson's correlation	**0,101**	**-0,233**	**-0,259**
	p-value	0,671	0,324	0,271
	N	20	20	20
External	Pearson's correlation	**0,121**	**-0,196**	**0,226**
	p-value	0,612	0,408	0,338
	N	20	20	20

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APÊNDICE A – FICHA DE ATENDIMENTO INICIAL

Hospital da Restauração – HR
Cirurgia e Traumatologia BucoMaxiloFacial

Nome: _____

Data de Nascimento: ___ /___ /___ Residente: _____

Fone: ( ) _____Cid Origem : _____

Queixa Principal: _____

Diagnóstico: _____

Cirurgia: _____

Movimentos Maxilares Realizados
Avanço Maxilar: _____
Intrusão maxilar: _____
Extrusão Maxilar:_____
Recuo Maxilar: _____

Análise Facial

Pré Operatório

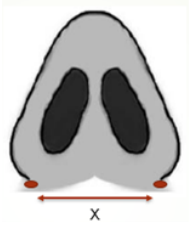
Data: ___/___/___

Base Alar: _____

Pós Operatório

Data: ___/___/___

Base Alar: _____



APÊNDICE B – TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

UNIVERSIDADE FEDERAL DE PERNAMBUCO -UFPE
PROGRAMA DE PÓS-GRADUAÇÃO EM ODONTOLOGIA
MESTRADO EM CLÍNICA ODONTOLÓGICA

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

(PARA MAIORES DE 18 ANOS OU EMANCIPADOS)

Convidamos o (a) Sr. (a) para participar como voluntário (a) da pesquisa **AVALIAÇÃO DA BASE ALAR APÓS CIRURGIA ORTOGNÁTICA: COMPARAÇÃO DE DOIS TIPOS DE PLICATURA NASAL**, que está sob a responsabilidade do (a) pesquisador (a) THAMES BRUNO BARBOSA CAVALCANTI - com endereço na Rua Taquaritinga 149 – Casa Amarela – Recife – PE – CEP 52070-649, Telefone (81) 996236585 e e-mail para contato thamesbruno@yahoo.com.br

Esta pesquisa está sob a orientação de: Jair Carneiro Leão - Telefone: (81) 2126.8000, e-mail jleão@ufpe.br.

Todas as suas dúvidas podem ser esclarecidas com o responsável por esta pesquisa. Apenas quando todos os esclarecimentos forem dados e você concorde com a realização do estudo, pedimos que rubrique as folhas e assine ao final deste documento, que está em duas vias. Uma via lhe será entregue e a outra ficará com o pesquisador responsável.

Você estará livre para decidir participar ou recusar-se. Caso não aceite participar, não haverá nenhum problema, desistir é um direito seu, bem como será possível retirar o consentimento em qualquer fase da pesquisa, também sem nenhuma penalidade.

INFORMAÇÕES SOBRE A PESQUISA:

- **Descrição da pesquisa**: Esta pesquisa será realizada para analisar a melhor forma de conter alargamento do nariz após a cirurgia ortognática e como objetivo pretende comparar 2 diferentes tipos de sutura utilizados na região de base do nariz, e observar qual tipo apresenta um resultado que melhor acompanhe os movimentos realizados pelos tecidos faciais. A coleta de dados será realizada em dois momentos, o primeiro um dia antes da cirurgia ortognática e o segundo após no mínimo três meses do procedimento cirúrgico. A consulta de avaliação será de forma rápida apenas para realização da medida da base do nariz com um paquímetro digital.
- **Esclarecimento do período de participação do voluntário na pesquisa, início, término e número de visitas para a pesquisa**. A coleta de dados será realizada em dois momentos, o primeiro um dia antes da cirurgia ortognática e o segundo após no mínimo três meses do procedimento cirúrgico. A consulta de avaliação será de forma rápida apenas para realização da medida da base do nariz com um paquímetro digital. Estas 2 consultas serão realizadas no próprio ambulatório de acompanhamento pré e pós cirúrgico.
- Os riscos envolvidos são os inerentes a qualquer procedimento cirúrgico, como por exemplos sangramentos, infecção, dormências locais (transitórias ou permanentes) na região maxilar e mandibular.

Todas as informações desta pesquisa serão confidenciais e serão divulgadas apenas em eventos ou publicações científicas, não havendo identificação dos voluntários, a não ser entre os responsáveis pelo estudo, sendo assegurado o sigilo sobre a sua participação. Os dados coletados nesta pesquisa, ficarão armazenados em pastas, sob a responsabilidade do Pesquisador Thames Bruno Barbosa Cavalcanti, no endereço Rua Taquaritinga 149 – Casa Amarela – Recife - PE, pelo período de mínimo 5 anos.

Nada lhe será pago e nem será cobrado para participar desta pesquisa, pois a aceitação é voluntária, mas fica também garantida a indenização em casos de danos, comprovadamente decorrentes da participação na

pesquisa, conforme decisão judicial ou extra-judicial. Se houver necessidade, as despesas para a sua participação serão assumidas pelos pesquisadores (ressarcimento de transporte e alimentação).

Em caso de dúvidas relacionadas aos aspectos éticos deste estudo, você poderá consultar o Comitê de Ética em Pesquisa Envolvendo Seres Humanos da UFPE no endereço: **(Avenida da Engenharia s/n – 1º Andar, sala 4 - Cidade Universitária, Recife-PE, CEP: 50740-600, Tel.: (81) 2126.8588 – e-mail:** cepccs@ufpe.br**).**

_____

(assinatura do pesquisador)

CONSENTIMENTO DA PARTICIPAÇÃO DA PESSOA COMO VOLUNTÁRIO (A)

Eu, _____, CPF _____, abaixo assinado, após a leitura (ou a escuta da leitura) deste documento e de ter tido a oportunidade de conversar e ter esclarecido as minhas dúvidas com o pesquisador responsável, concordo em participar do estudo **AVALIAÇÃO DA BASE ALAR APÓS CIRURGIA ORTOGNÁTICA: COMPARAÇÃO DE DOIS TIPOS DE PLICATURA NASAL**, como voluntário (a). Fui devidamente informado (a) e esclarecido (a) pelo(a) pesquisador (a) sobre a pesquisa, os procedimentos nela envolvidos, assim como os possíveis riscos e benefícios decorrentes de minha participação. Foi-me garantido que posso retirar o meu consentimento a qualquer momento, sem que isto leve a qualquer penalidade ou interrupção de meu acompanhamento/ assistência/tratamento.

Local e data _____

Assinatura do participante: _____

Impressão digital

Presenciamos a solicitação de consentimento, esclarecimentos sobre a pesquisa

e o aceite do voluntário em participar. (02 testemunhas não ligadas à equipe de pesquisadores):

Nome:	Nome:
Assinatura:	Assinatura:

ANEXO A – PARECER DO COMITÊ DE ÉTICA EM PESQUISA

UNIVERSIDADE FEDERAL DE PERNAMBUCO CENTRO DE CIÊNCIAS DA SAÚDE / UFPE-

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: AVALIAÇÃO DA BASE ALAR APÓS CIRURGIA ORTOGNÁTICA: COMPARAÇÃO DE DOIS TIPOS DE PLICATURA NASAL

Pesquisador: Thames Bruno Barbosa Cavalcanti

Área Temática:

Versão: 1

CAAE: 81647317.9.0000.5208

Instituição Proponente: Universidade Federal de Pernambuco - UFPE

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 2.532.236

Apresentação do Projeto:

Trata-se de uma pesquisa que tem a finalidade de ser a dissertação de mestrado do cirurgião-dentista Thames Bruno Barbosa Cavalcanti, aluno do programa de Pós-Graduação em Odontologia, com área de concentração em Clínica Integrada, do Centro de Ciências da Saúde da Universidade Federal de Pernambuco, que tem como orientador o Profª Drª Jair Carneiro Leão, e contará com a coorientação do Professor Luiz Alcino Monteiro Gueiros, e buscarão investigar qual o tipo de sutura realizada na base nasal após cirurgia ortognática controlam melhor o alargamento nasal.

Objetivo da Pesquisa:

Objetivo Geral: Avaliar o alargamento da base nasal dos pacientes submetidos a osteotomia Le Fort I e Identificar qual tipo de plicatura apresentará melhor resultado clínico para controle do alargamento da base nasal.

Objetivo Secundário:

1 Comparar dois diferentes tipos de sutura utilizados na região de base do nariz, 2- Observar qual tipo apresenta um resultado que melhor acompanhe os movimentos realizados pelo tecido esquelético.

Avaliação dos Riscos e Benefícios:

Os risos e benefícios estão claros no projeto e são pertinentes o seu estudo.

Endereço: Av. da Engenharia s/nº - 1º andar, sala 4, Prédio do Centro de Ciências da Saúde
Bairro: Cidade Universitária **CEP:** 50.740-600
UF: PE **Município:** RECIFE
Telefone: (81)2126-8588 **E-mail:** cepccs@ufpe.br

ANEXO B – CARTA DE ANUÊNCIA HOSPITAL DA RESTAURAÇÃO

GOVERNO DO ESTADO DE PERNAMBUCO
SECRETARIA DE SAÚDE DO ESTADO DE PERNAMBUCO
HOSPITAL DA RESTAURAÇÃO GOV. PAULO GUERRA

HOSPITAL DA RESTAURAÇÃO

CARTA DE ANUÊNCIA

*Eu, Dr. Miguel Arcanjo dos Santos Júnior, RG 1.861.808 / SDS, declaro estar ciente da pesquisa intitulada "**Avaliação da base alar após cirurgia ortognatia: Comparação de dois tipos de plicatura nasal** pesquisadora(a) Thames Bruno Barbosa Cavalcanti, sob a **Orientação do Profº. Jair Carneiro Leão. Coordenador Luiz Alcino Monteiro Queiroz** ,Em relação à pesquisa supracitada, informamos que o acesso do pesquisador ao local da pesquisa e a manipulação dos dados, **será autorizado somente após a emissão do parecer de aprovação do Comitê de Ética em Pesquisa.***

Declaro conhecer e cumprir com as resoluções Éticas Brasileiras em especial a resolução CNS 466 /12.

Esta instituição está ciente de suas corresponsabilidades como instituição coparticipante do presente projeto de pesquisa e de seu compromisso no resguardo da infraestrutura, segurança e bem-estar dos sujeitos de pesquisa nela recrutados, junto aos profissionais nesta Unidade Hospitalar.

Recife 14 dezembro de 2017

Dr. Miguel Arcanjo
CRM 8830
Diretor Geral - HR (6)

Dr. Miguel Arcanjo dos Santos Júnior
Diretor Geral
CRM 8830

Hospital da Restauração
Av. Agamenon Magalhães, s/nº - Derby - Recife/PE - CEP 52.010-040
Fone: (81) 3181-5407 / Fax: (81) 3181-5586
hrdiger@gmail.com

ANEXO C – NORMAS DA REVISTA CIENTÍFICA

International Journal of Oral and Maxillofacial Surgery

Guide for Authors

Would authors please note that the reference style for the journal has now changed. Please pay special attention to the guidelines under the heading "References" below

Authors wishing to submit their work to the journal are urged to read this detailed guide for authors and comply with all the requirements, particularly those relating to manuscript length and format. This will speed up the reviewing process and reduce the time taken to publish a paper following acceptance.

OnlineSubmission
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