Renato Bigliazzi

ESTUDO LONGITUDINAL DAS ALTERAÇÕES DENTOESQUELÉTICAS À LONGO PRAZO DA MÁ OCLUSÃO DE CLASSE II, DIVISÃO 1ª TRATADA COM O BIONATOR DE BALTERS UTILIZANDO-SE A CEFALOMETRIA RADIOGRÁFICA E A MORFOMETRIA GEOMÉTRICA

Araçatuba-SP

2013

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Tese apresentada à Faculdade de Odontologia do Câmpus de Araçatuba – Unesp, para a obtenção do Grau de "Doutor em Odontologia" – Área de Concentração em Ortodontia.

Orientador: Prof. Dr. Francisco Antonio Bertoz

Araçatuba-SP

2013

Catalogação na Publicação (CIP)

Serviço Técnico de Biblioteca e Documentação – FOA / UNESP

Bigliazzi, Renato.

B593e Estudo longitudinal das alterações dentoesqueléticas à longo prazo da má oclusão de classe II, divisão 1ª tratada com o Bionator de Balters utilizando-se a cefalometria radiográfica e a morfometria geométrica / Renato Bigliazzi. – Araçatuba, 2013

72 f. : il ; tab. + 1 CD-ROM

Tese (Doutorado) – Universidade Estadual Paulista, Faculdade de Odontologia de Araçatuba

Orientador: Prof. Dr. Francisco Antonio Bertoz

1. Má oclusão de Angle Classe II 2. Aparelhos ortopédicos 3. Crescimento I. T.

Black D4

CDD 617.643

Dados Curriculares

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Dedicatória

Dedicatória

Aos meus pais, Neide e Mário

Responsáveis pela minha formação moral, intelectual e pelo espírito de união, amor e dedicação recebidos em todos os momentos de minha vida.

A minha irmã, Regiane

Por todo seu amor, generosidade e afeto com nossa família.

A minha amiga, Priscila

Pelo incentivo, apoio e amizade desde o início de minha carreira.

Aos amigos Eliana e Cristiano

Companheiros inseparáveis de todas as horas, com vocês a minha vida se torna muito mais feliz.

Agradecimentos Especiais

Agradecimentos Especiais

Ao meu orientador, mestre e amigo Prof. Francisco Antonio Bertoz

Que acreditou no meu potencial e me deu a oportunidade de realizar o sonho da Pós-Graduação. Obrigado por sua orientação e incentivo em todos esses anos. E ainda pelo seu exemplo de dedicação, dignidade e retidão quando se quer alcançar um objetivo.

Ao meu eterno mestre e amigo Prof. Kurt Faltin Jr.

Responsável pela minha formação ortodôntica, pelo meu ingresso na carreira universitária e de quem procurarei seguir, no decorrer da vida, o exemplo de trabalho e dedicação.

Aos meus amigos Derly T. N. de Oliveira e André P. de Magalhães Bertoz

Verdadeiros irmãos de coração. Obrigado pelo companheirismo, atenção e confiança no meu trabalho. Vocês fizeram desse período em Araçatuba e Fernandópolis, um momento de muita alegria em minha vida.

Ao amigo Paulo C. T. Duarte

Amigo, que tanto me ajudou e acolheu em sua casa, e sempre foi companheiro nas horas felizes e principalmente nas minhas dificuldades.

Agradecimentos

Agradecimentos

À **Faculdade de Odontologia de Araçatuba - UNESP** pela oportunidade de realização do curso de Doutorado.

A equipe de **Professores de Ortodontia** do Departamento de Odontologia Social e Infantil da Faculdade de Odontologia da Universidade Estadual "Júlio de Mesquita Filho": **Prof. Dr. Eduardo César Almada, Prof. Dr. Marcos Rogério de Mendonça e Prof. Dr. Osmar Aparecido Cuogui**, que me receberam com tanta atenção e carinho, contribuindo de maneira grandiosa na minha formação acadêmica.

A equipe de funcionários do Departamento de Odontologia Social e Infantil da Faculdade de Odontologia de Araçatuba, da Universidade Estadual Paulista "Júlio de Mesquita Filho": meus queridos **Lidinho e Bertolina**, pelo carinho e prontidão sempre oferecidos com carinho.

Ao Prof. Dr. Paulo Henrique dos Santos pela amizade, carinho e atenção. Muito obrigado pelas palavras de incentivo.

À **coordenadora do Programa de Pós-Graduação em Odontologia**, da Faculdade de Odontologia de Araçatuba, da Universidade Estadual Paulista "Júlio de Mesquita Filho" **Profa. Dra. Maria José Hitomi Nagata**, pela gentileza, acessibilidade e comprometimento com nosso Programa.

Aos **Funcionários** da Seção de Pós-Graduação: **Valéria, Lilian e Cristiane**, pela prestatividade e atenção a mim dispensada.

Á **Coordenação de Aperfeiçoamento de Nível Superior (CAPES)** e ao **Programa de Pós Graduação em Odontologia da Faculdade de Odontologia** de Araçatuba, da Universidade Estadual paulista "Julio de Mesquita Filho" pela concessão das bolsas **PROAP** viabilizando as apresentações nos congressos internacionais do **IADR 2011** e **EOS 2012.**

Os meus queridos colegas de Pós-Graduação **Carla, Lídia, Ana Carolina, Aubrey,** em especial **Laercio, Yesselin, Éverton, Kelly e Juliana** pelo carinho, companheirismo e ajuda em tantos percalços dessa pós-graduação.

Aos meus amigos **Erivan e Laércio** por tanto me ajudarem nesses anos de convivência saudável e prazerosa em nossa casa de Araçatuba.

A equipe de Professores da Disciplina de Clinica Infantil - Ortodontia da Universidade Paulista - UNIP campus de Sorocaba: **Rodolfo, Jefferson, Paulo, Aline, Roberta, Tatiana e Lucila,** que por sua dedicação e companheirismo, que tornaram viável minha ausência nesses anos.

Aos **Professores James A. McNamara** (University of Michigan) **e Lorenzo Franchi** (Università degli Studi di Firenze), pela inestimável ajuda na seleção e aquisição das imagens telerradiográficas do grupo controle usado nesta Tese.

Á **Universidade Paulista – UNIP** e ao diretor do Instituto de Ciências da Saúde**, Prof. Dr. Pascoal Laercio Armonia** por tornarem possível essa importante etapa de minha vida profissional.

A **todas as pessoas**, que direta ou diretamente, me auxiliaram na execução deste trabalho.

Resumo

RESUMO

Bigliazzi R. **Estudo longitudinal das alterações dentoesqueléticas à longo prazo da má oclusão de classe II, divisão 1ª tratada com o bionator de Balters utilizando-se a cefalometria radiográfica e a morfometria geométrica** [tese]. Araçatuba: Faculdade de Odontologia da Universidade Estadual Paulista; 2013.

Objetivo: Avaliar os efeitos à longo prazo do tratamento com o bionator base (Classe II) de Balters de pacientes com maloclusão de Classe II e retrusão mandibular em crescimento usando-se a morfometria (análise de thin-plate spline [TPS]). **Materiais e Métodos:** Vinte e três pacientes (8 meninos e 15 meninas) foram consecutivamente tratados com o bionator de Balters (grupo bionator). A amostra foi avaliada em T0, início do tratamento; em T1, final da terapia com o Bionator; e em T2, na observação à longo prazo (incluindo uma fase com aparelhos fixos). A idade média ao início do tratamento foi de 10 anos e 2 meses (T0); no pós-tratamento foi de 12 anos e 3 meses; e no acompanhamento à longo prazo de 18 anos e 2 meses (CVM 6). O grupo controle constou de 22 indivíduos (11 meninos e 11 meninas) sem tratamento da maloclusão de Classe II. As radiografias cefalométricas foram analisadas nos três tempos de observação para todos os grupos. A análise TPS avaliou estatisticamente (testes de permutação) as diferenças na forma e tamanho craniofacial entre os grupos bionator e controle. **Resultados:** A análise TPS mostrou que o tratamento com o bionator foi capaz de produzir alterações favoráveis na forma mandibular (deslocamento para frente e para baixo) que contribuiu significantemente para a correção da desarmonia dentoesquelética de classe II, e esses resultados observados à longo prazo são mantidos após cessar o crescimento. O grupo controle não apresentou diferenças estatísticamente significantes no sentido da correção da Classe II. **Conclusões:** Este estudo sugere que o tratamento com o bionator na Classe II mantém resultados favoráveis à longo prazo na forma craniofacial com a combinação de alterações dentoalveolares e esqueléticas.

Palavras-chave: Má oclusão de Angle Classe II; Aparelhos ortopédicos; Crescimento.

Abstract

ABSTRACT

Bigliazzi R. **Morphometric analysis of long-term dentoskeletal effects induced by Balters Bionator Therapy** [Thesis] Araçatuba: Univ Estadual Paulista; 2013.

Objective: To evaluate the long-term effects of the standard (Class II) Balters bionator in growing patients with Class II malocclusion with mandibular retrusion by using morphometrics (thin-plate spline [TPS] analysis). **Material and Methods:** Twenty-tree Class II patients (8 male and 15 female) were treated consecutively with the Balters bionator (bionator group). The sample was evaluated at T0, start of treatment; T1, end of bionator therapy; and T2, long-term observation (including fixed appliances). Mean age at the start of treatment was 10 years 2 months (T0); at posttreatment, 12 years 3 months (T1); and at long-term follow-up, 18 years 2 months (CS 6). The control group consisted of 22 subjects (11 males and 11 females) with untreated Class II malocclusions. Lateral cephalograms were analyzed at the three time points for all groups. TPS analysis evaluated statistical (permutation tests) differences in the craniofacial shape and size between the bionator and control groups. **Results:** TPS analysis showed that treatment with the bionator is able to produce favorable mandibular shape changes (forward and downward displacement) that contribute significantly to the correction of the Class II dentoskeletal imbalance and these results are maintained at long-term observation after completion of growth. The control group showed no statistically significant differences in the correction of Class II malocclusion. **Conclusions:** This study suggests that bionator treatment of Class II malocclusion maintains shape favorable results over the long-term with a combination of skeletal and dentoalveolar changes.

Keywords: Malocclusion, Angle Class II; Orthotic Devices; Acromegaly

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Lista de Abreviaturas

LISTA DE ABREVIATURAS

BG	= Balters bionator group
CCA	= Convencional cephalometric analysis
CG	= Control group
CS	= Cervical vertebra maturation
F	= The critical value of F-destribution
f	= females
FJO	= Funcional jaw orthopedics
m	= males
n	= number
P	= Probability value
RCTs	= Randomized clinical trials
SD	= Standard deviation
TPS	= Thin-plate spline
T	= Observation intervals
X	= Magnification fator
y	= years

Sumário

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Introdução Geral

1 INTRODUÇÃO GERAL*

A possibilidade de modificação ortopédica do crescimento facial é um tópico de grande interesse para os ortodontistas clínicos e pesquisadores já que os fatores específicos envolvidos no desenvolvimento de tais discrepâncias é ainda assunto de considerável debate.

A compreensão da relação entre a forma facial, o crescimento e as maloclusões é um importante aspecto do tratamento ortodôntico-ortopêdico. A correção das maloclusões está necessariamente relacionada ao conhecimento dos eventos inerentes ao crescimento e desenvolvimento craniofacial, em função da observação dos locais e períodos em que se desencadeiam.[1] São requisitos fundamentais para o êxito terapêutico, o diagnóstico preciso, um planejamento adequado e um tratamento eficiente e estes se encontram dependentes do conhecimento sobre as inúmeras alterações dentoesqueléticas que ocorrem durante os diferentes períodos do crescimento craniofacial. O crescimento facial não é meramente um processo de aumento de tamanho e a face da criança não é uma miniatura da face do adulto.[1] Ele não acontece num padrão constante especialmente em crianças mais jovens. Cada criança numa mesma idade cronológica não apresenta necessariamente a mesma equivalência na maturidade esquelética ou mesmo no seu potencial de crescimento.[2]

Os estudos cefalométricos vêm sendo utilizados na pesquisa do relacionamento dos diferentes tecidos que compõem o esqueleto facial, bem como ao trabalho clínico, especialmente ao diagnóstico, ao plano de tratamento e à reavaliação do tratamento relacionada às alterações craniofaciais. A cefalometria radiográfica convencional vem sendo utilizada também para descrever e predizer o crescimento, que é relacionado à alteração na morfologia.

Dentre as várias possibilidades terapêuticas existentes, os aparelhos ortopédicos faciais funcionais ganharam grande destaque a partir dos anos 30 na Europa[3,4] e agora assumem posição de destaque no tratamento das discrepâncias

*Lista de referências no Anexo A

anteroposteriores e verticais no mundo todo.[3,5-8]

Vários autores se preocuparam em identificar os componentes chaves que caracterizam as más oclusões de Classe II,[9-17] como essas más oclusões não são uma entidade clínica única, sendo o retrognatismo mandibular o seu componente mais frequente[14,15,18,19] e sabendo-se que a correção espontânea desta entidade clínica é muito pouco provável,[20-22] aparelhos como o bionator de Balters que propiciam o avanço mandibular são amplamente usados em nossa especialidade.[22]

Um grande número de considerações tem sido propostas para explicar o sucesso na correção das Classes II pela terapia funcional. Estas incluem: a melhora dos padrões funcionais, [23-26] o aumento na quantidade do crescimento mandibular como resposta secundária ao avanço da mordida de construção propiciada pelo uso do aparelho,[4,6,18,27-34] o redirecionamento e inibição do crescimento da maxila,[5,22,33,35,36] a remodelação do côndilo e da articulação têmporo mandibular [22,31,37-39] e alterações dentoalveolares tanto maxilares quanto mandibulares.[29,39-46]

Depois de entendido o mecanismo de ação dos aparelhos o desafio seguinte é conhecer a estabilidade dos resultados alcançados. Devido à necessidade de acompanhamento à longo prazo dos pacientes tratados e da inerente dificuldade dessa realização, essa linha de pesquisa é uma das mais carentes da literatura ortodôntica. Especificamente sobre o bionator de Balters menos trabalhos ainda são identificados na literatura.[31,34,44,46]

O trabalho de Keeling et al.[31] demonstrou que não houve significante recidiva esquelética depois do tratamento ativo, mas houve recidiva dos molares e incisivos superiores. Concluem sugerindo que a contenção deve ser utilizada até que seja iniciada a segunda fase de tratamento com o aparelho fixo para prevenir a recidiva dentária. Contudo o período de observação após a terapia com o bionator foi de apenas um ano. Por outro lado Tulloch et al.[34] não encontraram a

mesma estabilidade identificada no estudo anterior acompanhando os pacientes durante o período de troca de todos os dentes decíduos até a fase com aparelho fixo. Identificaram que o sucesso ou a falha do tratamento nem sempre pode ser explicado pela colaboração do paciente ou abordagem terapêutica e que as diferenças individuais do crescimento seriam o fator mais importante. Rudzki-Janson, Noachtar[46] acompanharam pacientes tratados exclusivamente com bionator com pacientes tratados com bionator e retratados posteriormente com extra-bucal associado ao aparelho fixo, até 5 anos após o tratamento. Concluíram que os pacientes que foram tratados exclusivamente com o bionator apresentaram rotação anterior da mandíbula e rotação normal da maxila, demonstrando que quanto maior a rotação para anterior da mandíbula maior a probabilidade de sucesso da terapia ortopédica. A maior limitação desse estudo contudo foi a falta de comparação com um grupo controle.

Faltin et al.[44] acompanharam 23 pacientes, tratados com bionator e subsequente fase com aparelho fixo, até o final do crescimento com um grupo controle com as mesmas características de Classe II e retrusão mandibular. Identificaram que as mudanças esqueléticas mandibulares obtidas com o bionator persistiam mais nos pacientes que foram tratados durante o surto de crescimento que naqueles tratados antes do surto. A maior limitação do estudo de Faltin et al foi o pequeno número de indivíduos que foram incluídos tanto no grupo pré-pico puberal (13 pacientes) quanto no grupo durante o pico (10 pacientes). A metodologia empregada também não avaliou de maneira abrangente aspectos do relacionamento das bases ósseas no sentido anteroposterior e vertical, dentoalveolares e os tegumentares. Neste sentido Malta et al.[47] se propuseram a estudar as alterações esqueléticas e do perfil facial à longo prazo em 20 pacientes tratados com o bionator de Balters com um grupo sem tratamento e puderam verificar que o bionator não influenciou o crescimento da maxila, enquanto produziu significante efeito estimulador da mandíbula (3.3 mm mais que no grupo classe II controle). Perceberam significante melhora do trespasse horizontal e da relação molar, com significante melhora do trespasse vertical associado ao aumento da altura facial anterior inferior. Constataram alterações

favoráveis do perfil facial com o bionator à longo prazo pois o mento avançou 2,5 mm mais quando comparados ao controle.

A despeito de seus resultados clínicos, a capacidade dos aparelhos ortopédicos em modificar o crescimento facial ainda é muito discutida, assim como seu modo de ação.[3,4,8,22] A variabilidade dos resultados na literatura são muitos e em relação ao bionator de Balters não é exceção.[6,22,29,30,32,34,35,37,38,40-42,46,48,50,51]

Alguns autores como Tullock et al.[34], Martins[39] e Keeling et al.[31] verificaram, assim como nesta revisão bibliográfica, a dificuldade em analisar essa variabilidade de resultados ao se comparar esse tipo de modalidade terapêutica. Três aspectos foram os mais frequentes: o metodológico, o prático e o clínico. Os problemas metodológicos foram normalmente relacionados ao desenho da investigação, seleção da amostra, a presença e a relevância de grupos controle e a habilidade de controle das variáveis. Os problemas práticos dizem respeito a coleta da documentação e observação com tempo suficiente de intervalo. Os clínicos envolveram às variações no desenho dos aparelhos e fatores como cooperação dos pacientes e variação dos profissionais envolvidos.

As análises cefalométricas tem sido a metodologia mais utilizada para demonstrar os resultados e benefícios terapêuticos da ortodontia e da ortopedia facial, porém, Moyers, Bookstein[52] criticaram as análises cefalométricas por não estarem baseadas na real biologia do crescimento craniofacial, falhando na representação da forma (tamanho e formato) das estruturas faciais e consequentemente de suas alterações.

Os problemas não só estão relacionados ao fato da cefalometria radiográfica tradicional ser uma representação bidimensional de estruturas na realidade tridimensionais,[53-55] mas também nos métodos usados para analisar esses dados.[53-59] O erro metodológico mais evidente é o sistema de comparações ser totalmente dependente aos planos de referência.[55,58,60] A forma das estruturas anatômicas são descritas através de distâncias e ângulos, mas o crescimento

craniofacial ocorre em algum lugar entre os pontos anatômicos, não estando necessariamente nestes pontos. Para entender as alterações de crescimento e remodelação é necessário saber de que forma cada ponto afastou-se dos outros. Dessa maneira a análise do crescimento não seria compatível com a cefalometria tradicional, porque os pontos anatômicos sofrem uma deformação espacial, que não pode ser resumida por distâncias e ângulos.[52-55,57,60]

As análises morfométricas vêm sendo utilizadas como método alternativo e muitas vezes complementar para superar as dificuldades analíticas da cefalometria tradicional.[3,6,53-56,60,62-66] O desenvolvimento da Morfometria Geométrica tem sido acompanhado pela introdução de uma série de termos que não são familiares para a maioria dos ortodontistas.[67] Morfometria é uma palavra derivada do grego “morph” que significa formato e “mentron” que significa mensuração, usadas de maneira contemporânea para definir tamanho (size) e formato (shape).[67,68] Alteração de tamanho (size changes) refere-se ao aumento ou diminuição proporcional em todas as dimensões da forma (estrutura anatômica) que esta sobre investigação, frequentemente acompanhada pela alteração de formato (shape changes). Alterações de formato de estruturas biológicas requerem alterações de contorno da forma investigada, frequentemente resultante de alterações localizadas de tamanho.[69] Formato foi definido por Kendall[70] como “a informação remanescente quando a localização, tamanho e fatores rotacionais são todos removidos“ Esta definição também é relacionada com o princípio da invariância dos métodos morfométricos enunciado por Lele[69] que diz que qualquer método morfométrico deve ser invariante a efeitos de tamanho, orientação e posição.

As sofisticadas técnicas morfométricas como as sobreposições de Procrustes, Análise da Matriz de Distâncias Euclideanas (EDMA), Análise de Deformações (Thin-plate Splines), Análise Escalar de Elementos Finitos entre outras, através de seu rigor e sofisticação matemática, evitam a necessidade de registro e sobreposição, pré requisito quando se usa a análise cefalométrica tradicional.[63,64,71,72]

Dentre as análises morfométricas destaca-se a Análise de Deformações (Thin-plate Splines)[63,64,71] desenvolvida por Bookstein[73] que permite a comparação de marcos anatômicos (landmarks) em dois ou mais espécimes (indivíduos). Este método permite a construção de grades de transformação que capturam as mudanças de forma, com grande interpretação visual.[74] Recentemente tem se tornado um método importante na literatura ortodôntica internacional como um meio de investigação das modificações relacionadas ao crescimento facial e do tratamento ortodôntico.[63,64,72]

Recentemente no intuito de verificar as alterações á curto prazo de tamanho e forma sobre as estruturas craniofaciais em pacientes submetidos ao tratamento com o bionator base de Balters, Antunes et al.,[75] concluiram que o bionator foi capaz de induzir siginificantes alterações que levaram a correção da desarmonia dentoesqueletal da classe II de Angle.

Em função de todos os fatores discorridos anteriormente que ainda estimulam assíduos debates e devido ao diminuto número de investigações à longo prazo dessa modalidade terapêutica, este trabalho teve como objetivo avaliar através da associação da cefalometria convencional e da morfometria geométrica os efeitos à longo prazo do tratamento da má oclusão de Classe II com retrognatismo mandibular com o bionator de Balters na fase de crescimento puberal contribuindo para uma melhor comprensão terapêutica.

Artigo

2 ARTIGO*

Morphometric analysis of long-term dentoskeletal effects induced by Balters Bionator Therapy.

Renato Bigliazzi[a]; Francisco Antonio Bertoz[b]

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ABSTRACT

Objective: To evaluate the long-term effects of the standard (Class II) Balters bionator in growing patients with Class II malocclusion with mandibular retrusion by using morphometrics (thin-plate spline [TPS] analysis).

Material and Methods: Twenty-tree Class II patients (8 male and 15 female) were treated consecutively with the Balters bionator (bionator group). The sample was evaluated at T0, start of treatment; T1, end of bionator therapy; and T2, long-term observation (including fixed appliances). Mean age at the start of treatment was 10 years 2 months (T0); at posttreatment, 12 years 3 months (T1); and at long-term follow-up, 18 years 2 months (CS 6). The control group consisted of 22 subjects (11 males and 11 females) with untreated Class II malocclusions. Lateral cephalograms were analyzed at the three time points for all groups. TPS analysis evaluated statistical (permutation tests) differences in the craniofacial shape and

*Este artigo será submetido a revista The Angle Orthodontist conforme normas no Anexo C

size between the bionator and control groups.

Results: TPS analysis showed that treatment with the bionator is able to produce favorable mandibular shape changes (forward and downward displacement) that contribute significantly to the correction of the Class II dentoskeletal imbalance and these results are maintained at long-term observation after completion of growth. The control group showed no statistically significant differences in the correction of Class II malocclusion.

Conclusions: This study suggests that bionator treatment of Class II malocclusion maintains shape favorable results over the long-term with a combination of skeletal and dentoalveolar changes.

KEY WORDS: Functional jaw orthopedics; Class II malocclusion; Morphometric analysis; Thin-plate spline analysis

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2.1 INTRODUCTION

Funcional Jaw Orthopedics (FJO) at the pubertal spurt followed by fixed appliances is a viable therapeutic option in patients with unfavorable Class II malocclusions.[1] Among different FJO available to treat Class II malocclusion, the Balters bionator is a tooth-borne (passive) functional appliance designed and introduced by Wilhelm Balters in the 1960s.[2,3] The bionator moves the mandible anteriorly so that over time a new postural position of the lower arch is achieved, producing significant changes in dental and skeletal facial structures,[2-7] and improvement of the facial profile.[7,8]

In the literature,[9,10] the bionator has shown moderate effectiveness and efficiency in inducing supplementary growth of the mandible in treated subjects vs untreated Class II controls. On the other hand, therapeutic effectiveness of the most functional appliances is greatest when these appliances are used during the period of the individual pubertal growth spurt.[11-15] Faltin et al.[15] and Franchi et al[16] reported the significant impact of treatment timing on the changes induced by the standart (class II) bionator and activator appliances, since treatment at puberty was found to produce significantly greater increases in mandibular total and ramus lengths when compared with controls long-term. But there are still controversies concerning the effects of FJO on the maxilla and the mandible.[10,17-23] All the conflicting findings could be attributable to discrepancies in age selection, skeletal age as a common factor, lack of control matching group, treatment duration and the great variability in the cephalometric variables and referent points adopted by the investigators.[10,16,22,23] Some variables are affected by the forward and downward posture of the condyles after functional appliance therapy (eg. articulare) and it could be interpreted as an increase in mandibular length.[10,22,23] With regard to the changes in sagittal mandibular position, It should be noted, however, that the marked changes in positions of sella and nasion along with growth limit the adequacy of SNB as a cephalometric indicator of sagittal mandibular position.[7,10] Furthermore conventional cephalometric analysis (CCA) despite of being individualized, does not always prove effective in determining

accurately the location and mode in which changes in shape and size occur within the craniofacial complex.[24] Thus, CCA is rather governed by conventions involving points and planes, which fail to capture curvilinear forms and changes in these forms.[25]

Bookstein[26] introduced thin-plate spline (TPS) analysis as a morphometric tool for the comparison of configuration landmarks. It is a descriptive method of shape (or shape change) independently from size that has been developed and implemented as major improvement when compared with conventional cephalometrics.[26,27] It also allows the construction of transformation grids that capture differences in form, enabling a more effective visual interpretation and mathematical representations of the treatment effects.[28-30]

Antunes at al.[31] analyzed using TPS analysis the short-term effects of the standard Balters bionator in growing patients with Class II malocclusion with mandibular retrusion. TPS analysis showed that treatment with the bionator is able to produce favorable mandibular shape changes that contribute significantly to the correction of the Class II dentoskeletal imbalance. No data are available in the literature with regard to the long-term dentoskeletal changes produced by orthopedic treatment of Class II malocclusion and assessed with a geometric morphometric analysis.

The aim of this study, therefore, was to investigate the long-term effects of the standard (Class II) Balters bionator in the treatment of patients with Class II malocclusion with mandibular retrusion using TPS analysis.

2.2 MATERIALS AND METHODS

Cephalometric records of 23 white patients (15 females and 8 males) with Class II division 1 malocclusion with mandibular retrusion determined by cephalometric analysis of Ricketts et al.[32] and Schwarz, modified by Faltin et al.,[33] consecutively treated with the Balters bionator (BG group; Figure 1) were collected from a single orthodontic practice (Kurt Faltin Jr.) The treatment protocol consisted of a bionator, constructed without coverage of the lower incisors, to be worn 16-18 hours a day and followed by approximately 1 year of fixed appliance therapy to refine occlusion. Those patients still in the mixed dentition phase by the end of bionator treatment were instructed to wear the appliance only at night until complete eruption of the premolars and permanent canines. After the comprehensive phase of treatment, each patient was given a lower incisor fixed retainer. Lateral cephalograms were obtained at three time periods: T0, at the start of treatment; T1, at the end of bionator therapy; and T2, at long-term observation after completion of growth,[34] including the phase with fixed appliances. Patient compliance and treatment success were not considered as inclusion criteria so that sample selection was conducted irrespective of clinical results.

The control group (CG group) consisted of 22 white subjects (11 females and 11 males) with untreated Class II division 1 malocclusions. Cephalograms of the untreated subjects were obtained from University of Michigan Growth Study and the Denver Child Growth Study. Significant effort was directed toward matching the CG to the BG as closely as possible with respect to dentoskeletal features (Class II with mandibular retrusion) at T0, gender distribution (for the effect this variable would have on head size), age at all observation periods, duration of observation intervals (T0–T1, T1–T2, and T0–T2), and skeletal maturity at all-time points.

All treated and control subjects were either in CS1, CS2 or CS3 in cervical vertebral maturation at T0 and in either CS3, CS4 and CS5 at T1. All treated and untreated patients had completed active growth (CS6) at T2.[34] Institutional review

board approval was obtained before the study (418/10/CEP/ICS/UNIP). Demographic data of the samples are reported in Table 1.

The following homologous landmarks were digitized on the lateral films using TPS software (tpsDig2 version 2.16, Ecology & Evolution, SUNY, Stonybrook, NY): point Se (sella turcica), point Na (nasion), point Po (porion), point Co (condylion), point Pt (superior pterygoid point), point Or (orbitale), point ANS (anterior nasal spine), point PNS (posterior nasal spine), point A (A), point A1 (incisal of upper central incisor), point B1 (incisal of lower central incisor) , point AR1 (apex of the root of the upper central incisor), point BR1 (apex of the root of the lower central incisor), point B (B), point Pg (pogonion), point Go (gonion), point A6 (distal upper first molar superior), point B6 (distal lower first molar), and point Me (menton) (Figure 2). TPS software (tpsRegr version 1.38, Ecology & Evolution) computed the orthogonal least-squares Procustes average configuration of craniofacial landmarks in both the BG and CG at T0, T1 and T2, using the generalized orthogonal leastsquares procedures described by Rohlf and Slice.[35] This is a superimposition method where shapes defined by the configuration of anatomic homologous landmarks are compared through various optimization criteria. It involves translation, rotation, and scaling. Superimposition parameters are determined so as to minimize the sum of squares of distances between points in each configuration and their corresponding reference points. Therefore, all configurations are scaled to an equivalent size (centroid size = 1) and registered with respect to one another. The average craniofacial configurations were subjected to TPS analysis to compare the longitudinal differences in shape within the treated and control groups. The smoothing effect of the TPS also gives some idea of shape changes in regions between landmarks. The matrix of Procrustes residuals can be used for any statistical procedure.[31,35]

Statistical analysis of shape differences was performed by means of permutation tests with 1000 random permutations on Goodall F statistics (tpsRegr version 1.38, Ecology & Evolution). Differences in size (centroid size analysis) at the tree developmental phases (T0-T1, T1-T2 and T0-T2) were tested by means of

Mann-Whitney U-test for longitudinal comparisons. For those comparisons showing significant shape differences, a test for allometry, checking for shape depending on size, was carried out (tpsRegr version 1.38, Ecology & Evolution).

To estimate operator reliability, 30 randomly selected records were reevaluated after a week of preliminary data collection. Intraobserver precision was calculated on distances between landmark positions between the first tracing and the second tracing cephalograms in both groups by the same operator, using Dahlberg formula.[36] The average method error for landmark identification was 0.9 mm (SD = 0.4).

2.3 RESULTS

No significant shape differences were found between the BG and CG at T0 (*P* = .431). The results from centroid size analysis did not reveal any significant difference in size difference between the BG and CG at T0 (*P* = .125). At T1 and T2 significant shape (*P* = 0.001) and size differences (*P* = .0004 and *P* = 0.000) were found between the BG and CG.

The analysis of longitudinal dentoskeletal shape changes in the BG showed significant T0–T1 differences (*P* = 0.000; Figure 3). This difference could be described graphically by an expressive extension in the horizontal axis in the region of the mandibular symphysis and in the middle portion of the mandible between the condyle and the symphysis. A slight extension on both the horizontal and vertical axes could be recorded at the gonial angle. A marked constriction on the horizontal axis in the region of the upper incisors was also evident, reflecting dental changes. The results from centroid size analysis showed significant size differences from T0 to T1 in the BG (*P* = .0001). Allometry was significant for the bionator sample (*F* = 3.526; *P* = 0.015), thus indicating dependence of size differences on shape differences in the treated group. Whereas no significant shape differences were obtained for the same interval in the control group (*P* = 0.293; Figure 4). Centroid size longitudinal analysis showed statistically significant size differences from T0 to T1 in the CG (*P* = 0.017).

Posttreatment shape changes could be detected in the BG (*P* = 0.000, Figure 5). This longitudinal T1-T2 shape differences could be described graphically by a slight extension in the horizontal axis in the region of the mandibular symphysis and a evident extension in the middle portion of the mandible between the condyle and the symphysis. A marked extension could be visualized also in the vertical and horizontal extension in the ramus. The results from centroid size analysis showed significant size differences from T1 to T2 in the BG (*P* = 0.000). The influence of size on shape changes (allometry) was detected for the bionator sample (*F* = 2.543; *P* = 0.05) In the CG no significant shape

differences could be detected (*P* = 0.923; Figure 6). Centroid size longitudinal analysis showed statistically significant size differences from T1 to T2 in the CG (*P* = 0.020).

The treatment and posttreatment (long-term) changes in BG reveled the overall graphically significant (*P* = 0.000; Figure 7) extension in horizontal and vertical directions of the mandible with a grid constriction in the horizontal axis in the region of the upper incisors. Centroid size analysis showed significant size differences from T0 to T2 in the BG (*P* < 0.0001). Allometry was significant (*F* = 1.728; *P* = 0.013), thus indicating dependence of size differences on shape differences in the treated group. No significant long-term shape differences could be detected in CG (*P* = 0.999; Figure 8). Centroid size longitudinal analysis showed statistically significant size differences from T0 to T1 in the CG (*P* = 0.0007).

2.4 DISCUSSION

The literature contains conflicting reports with regard to how growth can be influenced by FJO. Some of these conflicting reports could be done in conducting clinical researches with methodological bias. The lack of sufficient numbers of patients, age selection, the pairing of skeletal age control groups, the discrepancies in the time of the observation periods and the variability of cephalometric analyses used in these studies are the most common factors of conflicting results. Chen et al.[22] and Marcico et al.[23] emphasize the need to conduct more randomized clinical trials (RCTs) to reduce the methodological limitations when analyzing the efficacy of FJO on mandibular growth. But the difficulty in gathering many patients with a specific occlusion deviation and the ethical issue of leaving a group of patients untreated for a rather long-time are the main substantial reasons for the paucity of RCTs in orthodontics.[10]

Most of the investigations concerning the treatment of Class II with functional appliances especially with the bionator are short term in nature. Many studies of the clinical trials on bionator treatment recorded the dentoskeletal changes in the long term.[7,15-17] but they all used CCA. The CCA methods used in those studies do now allow understanding of the changes in mandibular morphology (shape) that occur with bionator therapy. New methods of geometric morphometrics, based on the analysis of landmark configurations, allow further in-depth investigation of morphological processes evolved with facial orthopedic treatment.[26,28-30] Among these new alternatives, TPS analysis allows the possibility of extracting size and successive analysis of morphology in a “size-free” shape space.[26,27] It enables easy, comprehensible viewing of changes in shape while clearly highlighting the region where these changes occur. TPS analysis expresses the difference between two average landmark configurations through transformation grids and continuously models the deformation of a given shape into another using a regression function.[31] Projected into a linear tangent space, the shape variables can then be used in further conventional statistical procedures.[35]

The present study compared the long-term effects of the standard (Class II) Balters bionator in the treatment of patients with Class II malocclusion with mandibular retrusion vs an untreated Class II control group by using TPS and centroid size analyses. Control matching enabled separation of growth and bionator treatment effects. No short or long-term sagittal maxillary shape effects were assessed as a consequence of bionator therapy in the Class II patients. As in Antunes et al.,[31] a constriction in the region of the upper incisors indicating a retroclination of these teeth were found in short-term. On the other hand no significant changes could be detected comparing T1-T2 postreatment effects in dentoalveolar component. The vestibular wire is a basic feature of the Balters bionator. It stimulates the lip closure with favorable negative pressure, thereby helping the mandible find its anterior position in the appliance with a concomitant effect on lip and cheek musculature.[17] The dentoalveolar compensation in the BG was probably related to lip closure and improvement of tongue position (a new neuromuscular pattern) induced by the appliance.[31] In the standard Balters bionator used in our study, the buccal shield does not touch the upper incisors and does not have inferior incisal coverage which can play a role in dental compensation rather than orthopedic correction[16,31]. Consequently, the presence of absence of the coverage of the lower incisors did not affect significantly their inclination.[6,15,16] The bionator induced significant short and long-term shape changes in the mandible that could be described as a mandibular forward and downward displacement. This mandibular displacement was more evident at the mandibular symphysis as it was associated with a mandibular elongation that was depicted by a horizontal extension of the grid in the middle portion of the mandible between the condyle and the symphysis. These changes contributed significantly to the sagittal and vertical correction of the dentoskeletal Class II relationships during the treatment period with the bionator (T0-T1).[31]

The second part of this study analyzed the long-term overall effects of bionator therapy. The bionator induced a significant supplementary elongation of the mandible over controls and was associated with vertical displacement of the gonial angle and a change in the direction of condylar growth (more posterior)

during the postreatment period (T1-T2). The results of current study differ from those reported by Malta et al[6] and Franchi et al[16], who using CCA found that the significant elongation of the mandible was not associated with a significant advancement of the chin (Pg to Nasion perpendicular) both in the short term and in the long term. These are probably related with the fact that CCA measure linear distances or angles but do not relate distance or angle changes to whole form changes, leading to certain limitations for shape assessment.[24,27] In the current investigation, allometry (shape depending on size differences) was significant for the BG in all time periods studied and no significant shape change could be recorded in the CG. Consequently, no significant improvement in the dentoskeletal Class II relationships was evident in the CG. The present investigation showed that the favorable mandibular modifications induced by pubertal treatment are stable in the long term.

TPS analysis showed that treatment with the bionator is able to produce favorable mandibular shape changes that contribute significantly to the correction of the Class II dentoskeletal imbalance reported in previous studies [6,7,10,16,31] and these results are maintained at long-term observation after completion of growth.[6,7,16] More studies are needed to determine the extents to which these mandibular dentoskeletal shape changes can influence on facial esthetics.

2.5 CONCLUSIONS

- The bionator appliance did not induce a restraining shape effect on the maxilla, while is able to produce significant shape changes that are characterized by a forward and downward displacement of the mandible associated with mandibular elongation. These shape changes contributed significantly to the dentoskeletal correction of the Class II dentoskeletal imbalance and these results are maintained at long-term observation after completion of growth.

- These short and long-term findings confirm the effectiveness of functional jaw orthopedics in the treatment of patients with Class II malocclusion associated with mandibular retrusion.

2.6 REFERENCES

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TABLE

Table 1. Demographics for the Treatment and Control Groups

Groups	Age at T0, y		Age at T1, y		Age at T2, y		T0-T1 interval, y		T1-T2 interval, y		T0-T2 interval, y	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Bionator group (n=23, 15f, 8m)	10.2	1.5	12.3	1.8	18.2	2.1	2.1	1.0	5.11	1.7	7.1	2.1
Control group (n=22, 11f, 11m)	10.3	1.4	12.1	1.6	16.8	1.5	2.0	0.8	4.6	2.0	6.5	1.8

FIGURES

Figure 1. Bionator in the oral cavity

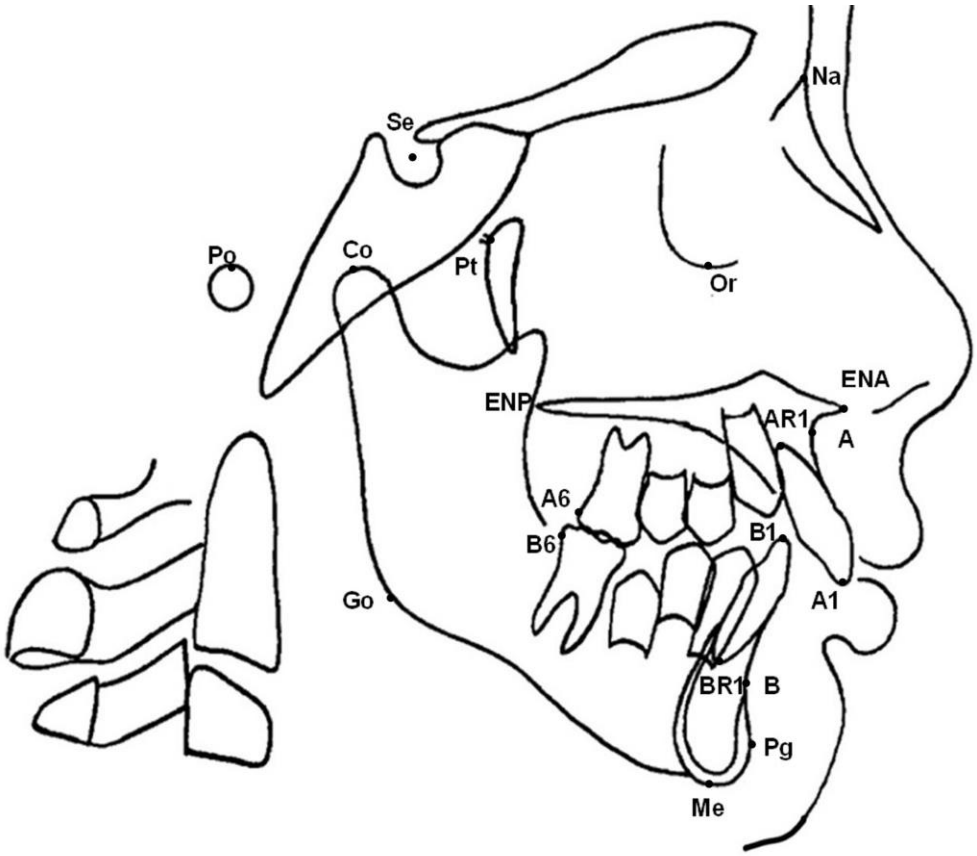

Figure 2. Landmarks used for morphometric analysis.

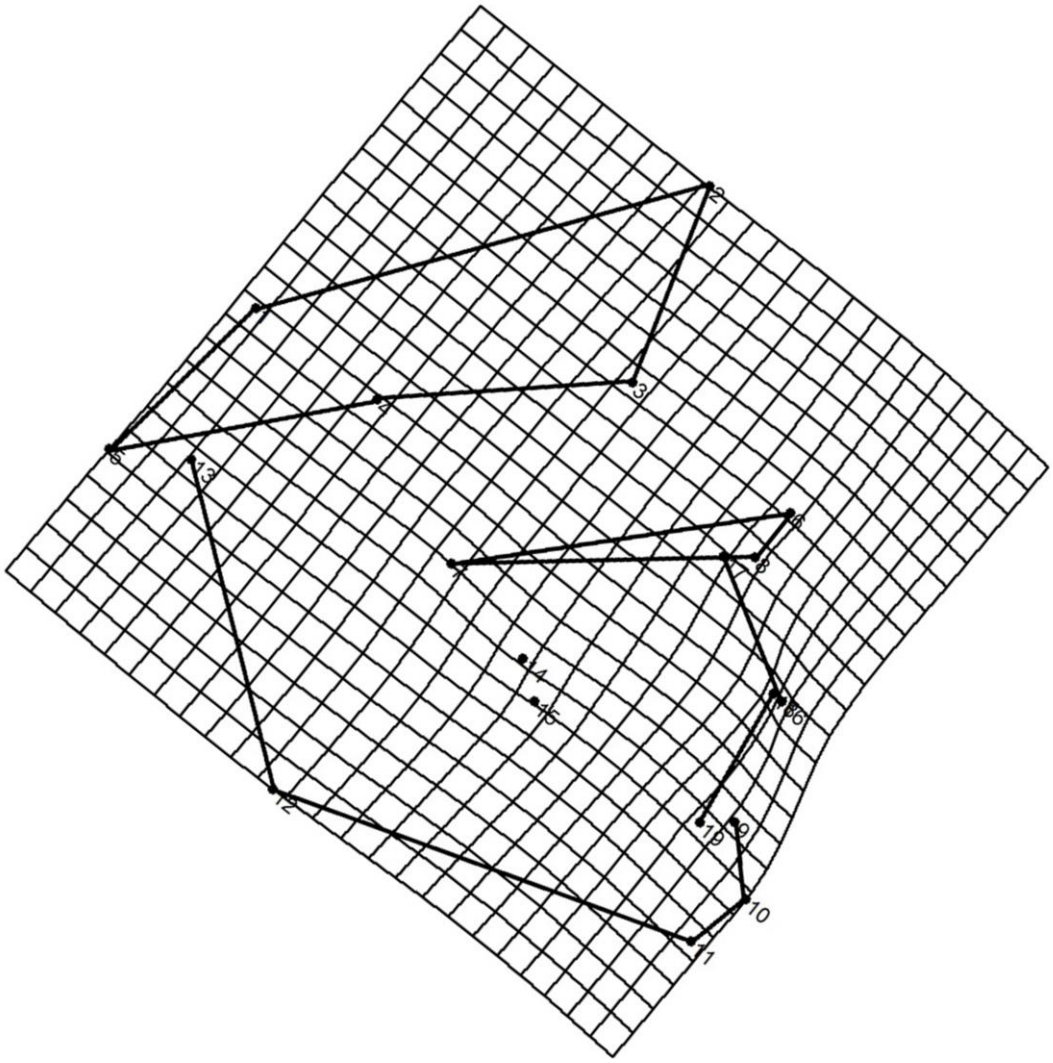

Figure 3. TPS graphical display of shape differences between T0 and T1 in the bionator group (magnification factor 3X).

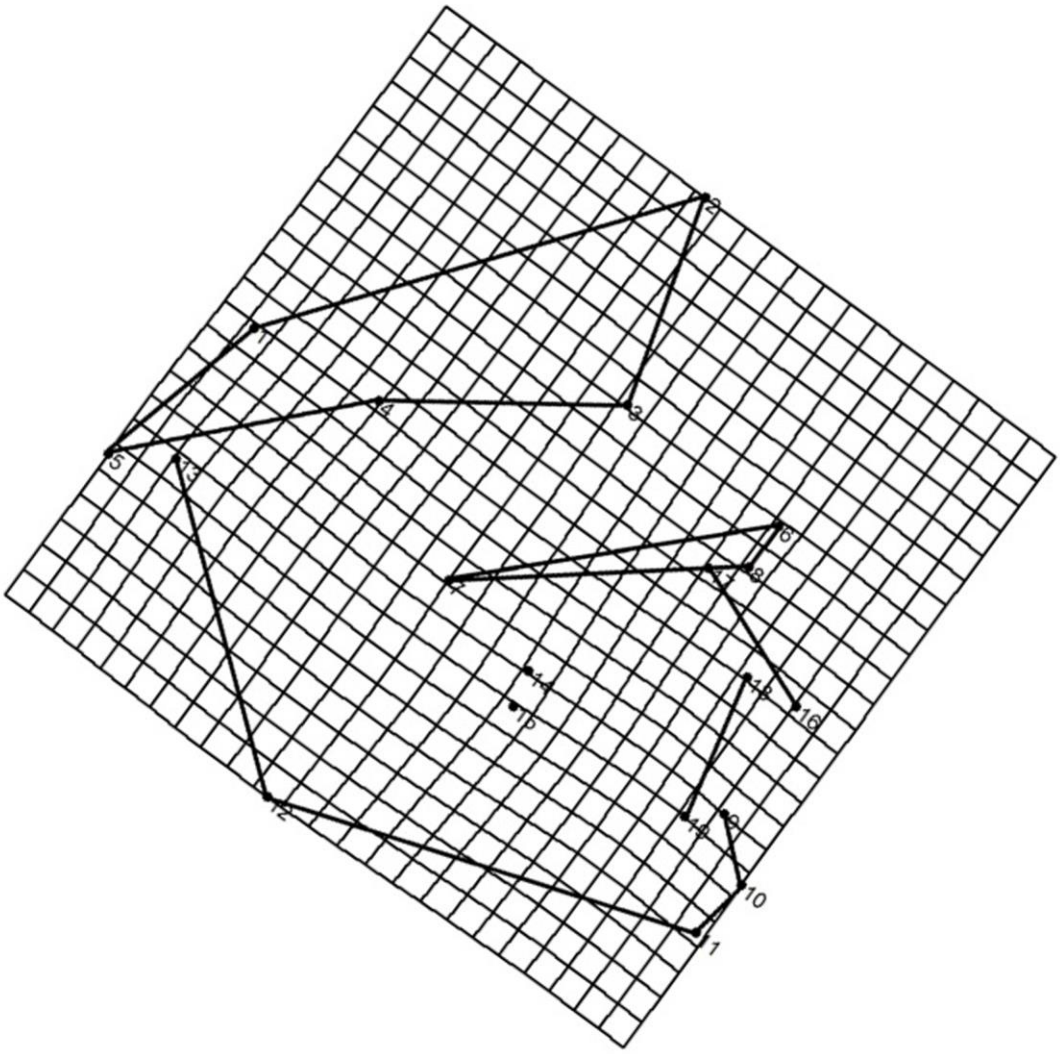

Figure 4. TPS graphical display of shape differences between T0 and T1 in the control group (magnification factor 3X).

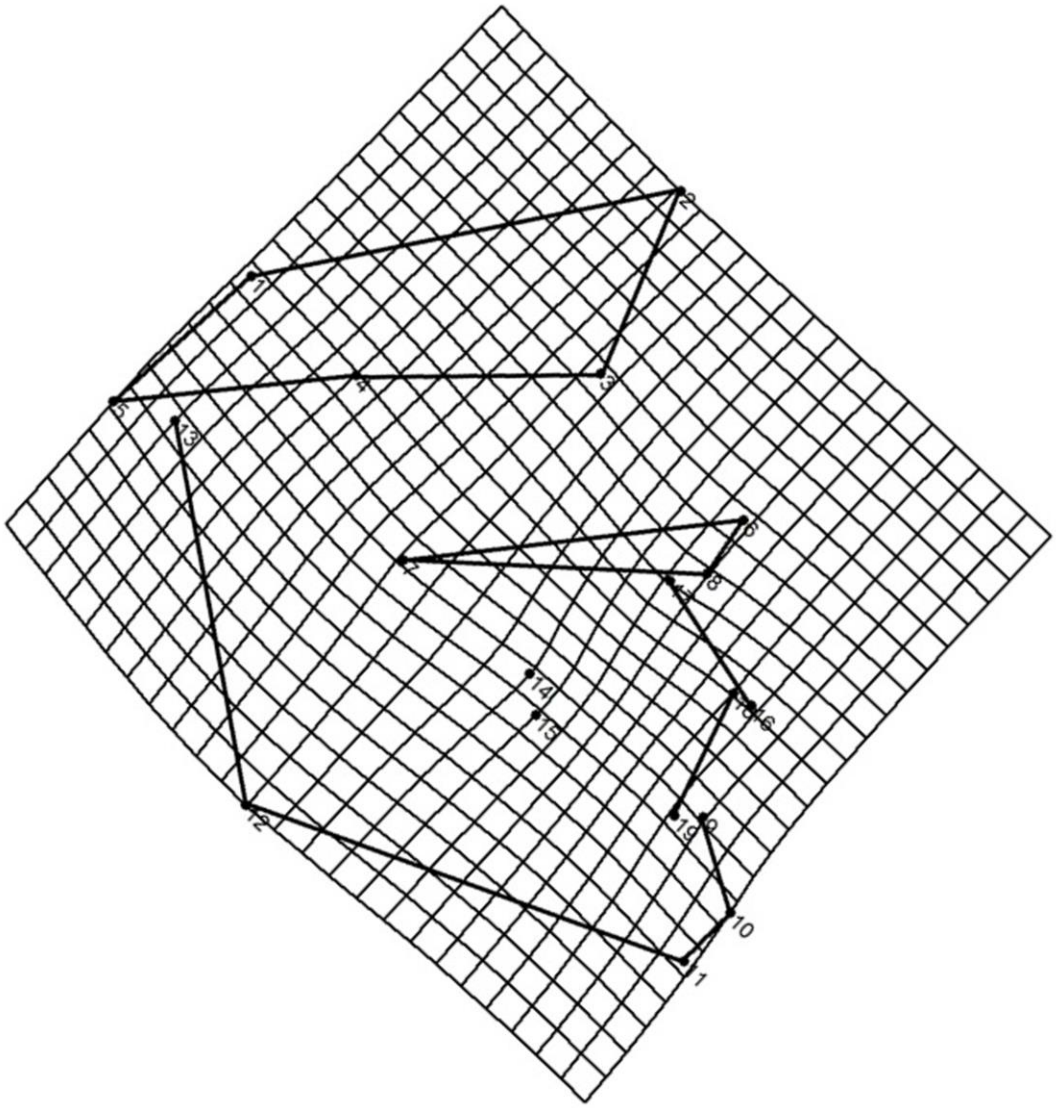

Figure 5. TPS graphical display of shape differences between T1 and T2 in the bionator group (magnification factor 3X).

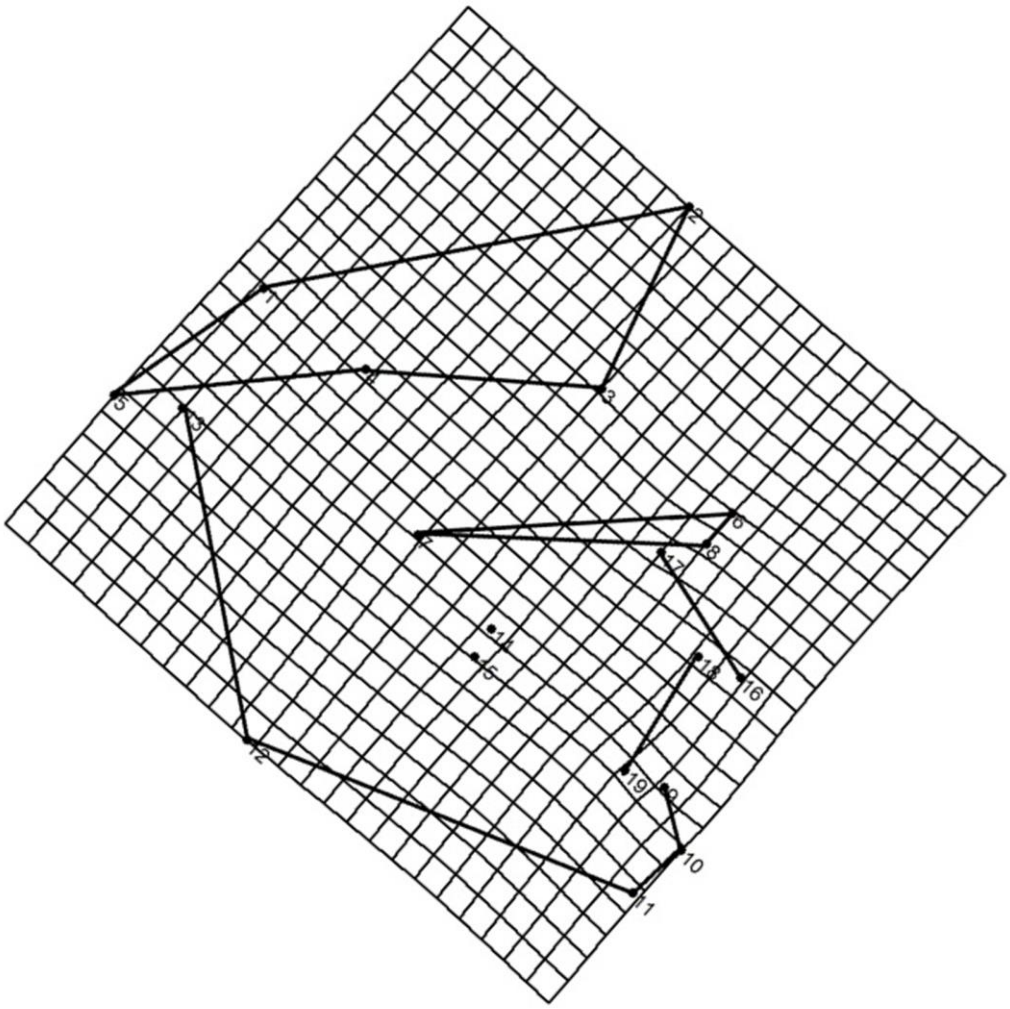

Figure 6. TPS graphical display of shape differences between T1 and T2 in the control group (magnification factor 3X).

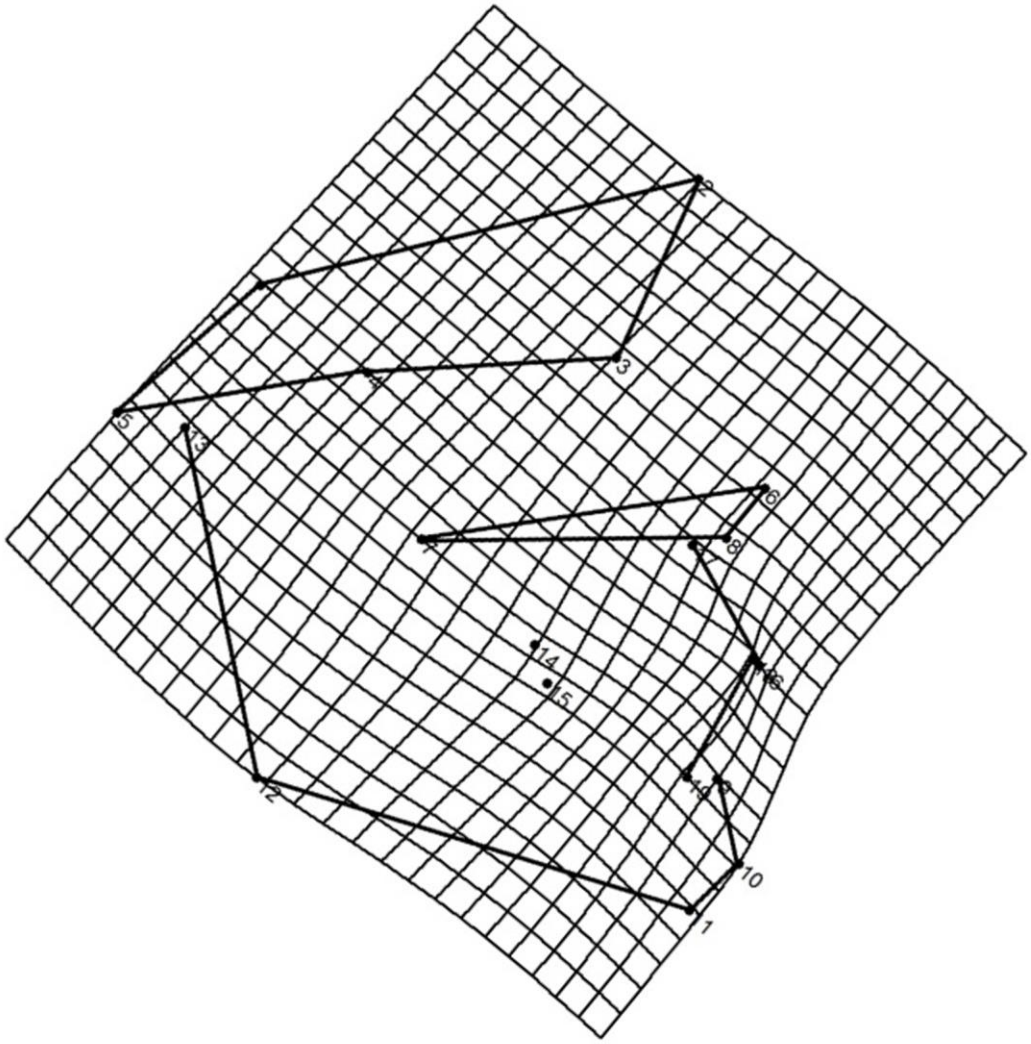

Figure 7. TPS graphical display of shape differences between T0 and T2 in the bionator group (magnification factor 3X).

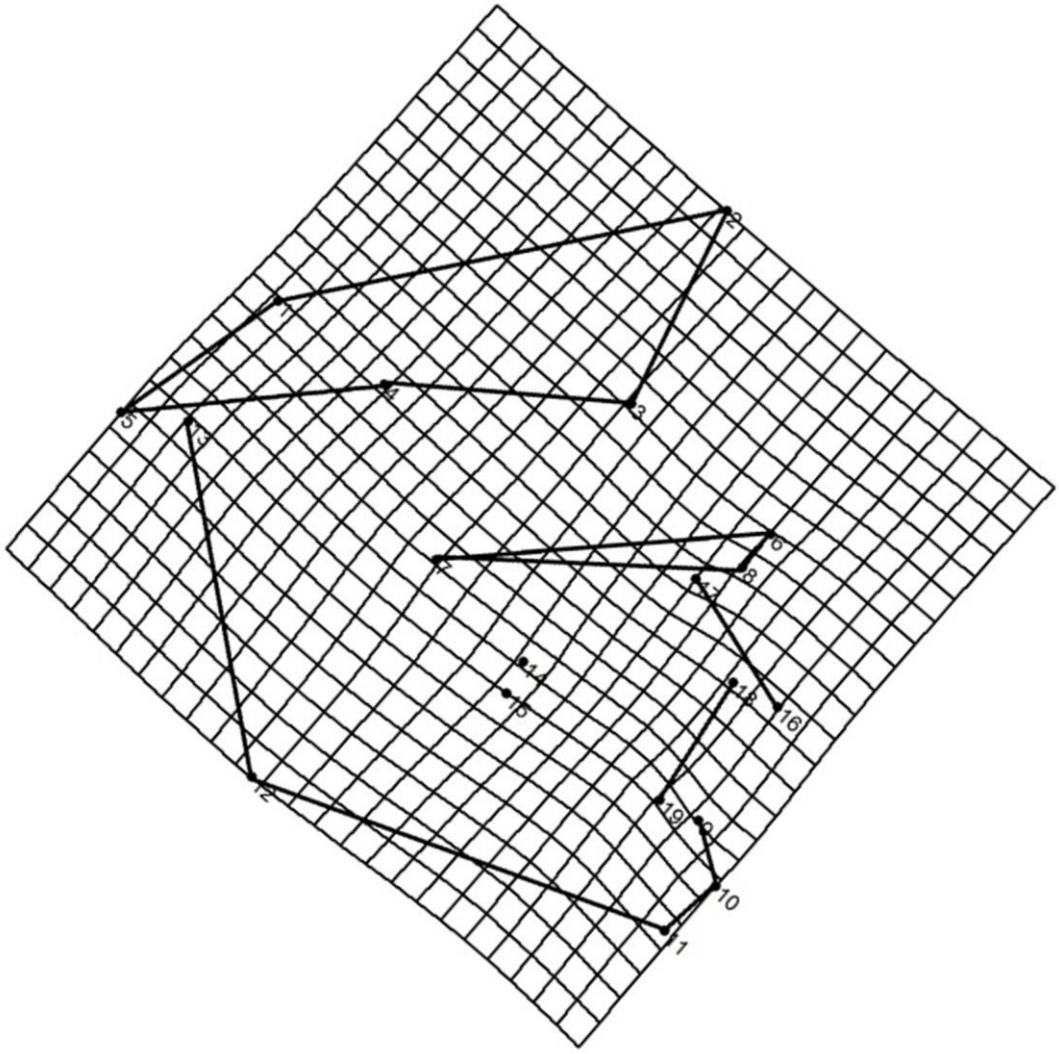

Figure 8. TPS graphical display of shape differences between T0 and T2 in the control group (magnification factor 3X).

Anexos

ANEXO A. Referências da Introdução Geral

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ANEXO B. Aprovação do Comitê de Ética em Pesquisa em seres Humanos

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CERTIFICADO

CERTIFICAMOS, que o protocolo nº 418/10 CEP/ICS/UNIP, sobre o projeto de pesquisa intitulado "Estudo longitudinal das alterações dento-esqueléticas à longo prazo da má oclusão de Classe II, divisão 1ª tratada com o Bionator de Balters utilizando-se a cefalometria radiográfica e a morfometria geométrica", sob a responsabilidade, RENATO BIGLIAZZI, está de acordo com os Princípios Éticos, seguindo diretrizes e normas regulamentadoras de pesquisa envolvendo seres humanos, conforme a Resolução nº 196/96 do Conselho Nacional de Saúde e foi aprovado por este Comitê de Ética em Pesquisa.

Universidade Paulista, em São Paulo-SP, aos 16 dias do mês de setembro de 2010.

Luciene Tauil
Secretária do Comitê de Ética
em Pesquisa da UNIP

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ANEXO C. Normas para publicação do periódico **THE ANGLE ORTHODONTIST.**

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Frequência: Bimensal

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