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**Dentoskeletal and soft tissue treatment effects of two different methods
for treating Class II malocclusions.**

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2010.

APPROVAL PAGE

Master of Dental Science Thesis

**Dentoskeletal and soft tissue treatment effects of two different methods
for treating Class II malocclusions.**

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Dentoskeletal and soft tissue treatment effects of two different methods for treating
Class II malocclusions.

Objectives: Moderate to severe Class II malocclusions can not only cause esthetic and functional problems but can also lead to psychological problems of varying intensity depending on the amount of anterior-posterior discrepancy and its interaction with the related soft tissue structures. Although there are several methods of treating such malocclusions (extractions, distalization, functional appliances etc), the final goal is always to provide acceptable esthetics and stability. The purpose of this clinical-cephalometric study was to examine the dentoskeletal and soft tissue treatment effects of maxillary anterior teeth retraction with mini-implant (MI) anchorage in young adults having Class II Division I malocclusion undergoing extraction of only the maxillary first premolars in comparison with patients undergoing treatment with a non-extraction approach i.e. using a fixed functional appliance. Methods: 35 patients (mean age 16.5 ± 3.2 years, overjet ≥ 6 mm) were assigned to group 1 (G1): correction of overjet with MIs as anchor units, or group 2 (G2): where fixed functional appliances were used. Dentoskeletal and soft tissue changes were analyzed on lateral cephalograms taken before and after the correction of overjet. Statistical analyses were performed using the Student's paired and unpaired 't tests.' Kolmogorov-Smirnoff tests and Q-Q plots were used to assess the normality of the data. Results: A statistically significant increase was noted in the facial vertical dimensions in G2, but the variables in G1 showed no significant differences ($P > 0.05$). Extrusion and mesialization of the lower molar was noted in G2, whereas G1 showed distalization (anchorage gain) and intrusion of the upper molar. Facial convexity angle, nasolabial angle, and lip protrusion did not show any significant differences. Conclusions: Both the treatment approaches provided adequate decompensation of the malocclusion but had minimum effect on the skeletal discrepancy. There was a dramatic improvement in the facial esthetics in both the groups however the different treatment methods used in the two groups did not yield any significant soft tissue differences. However the treatment time was significantly less with fixed functional appliances.

Key words: Overjet; Class II; Mini-implants; Fixed functional appliance.

INTRODUCTION

Objective of Research

There are numerous studies in the literature evaluating different methods for correcting a Class II malocclusion. No study to date, has investigated/compared the treatment results obtained by using mini-implant based space closure (maximum anchorage) and fixed functional appliance therapy. Such a study will not only help clinicians choose the appropriate modality of treatment for their patient but also provide a platform for future prospective investigations in similar areas. The purpose of this clinical-cephalometric study was to examine the dentoskeletal and soft tissue treatment effects of maxillary anterior teeth retraction with mini-implant anchorage in Class II Division I patients undergoing extraction of only the maxillary first premolars in comparison with patients undergoing treatment with a non-extraction approach using a fixed functional appliance. Lateral cephalograms were used to analyze the results.

Review of Literature

Class II malocclusions are frequently observed in orthodontic practice and are characterized by an incorrect relationship between the maxillary and mandibular arches because of skeletal or dental problems or a combination of both. Based on overjet greater than 4mm, the National Health and Nutrition Examination Survey (NHANES II)¹ data indicate an 11% prevalence of Class II malocclusion in the US population. It has been reported that mandibular retrusion is its most common characteristic with 80% of the Caucasian population displaying this trait as opposed to only 20% expressing excessive maxillary development.^{2, 3} In spite of such a predilection the majority of orthodontic

appliances/techniques focuses on the maxillary arch for treating /compensating the Class II malocclusions (upper premolar extractions, distalization). In contrast only functional appliances aim specifically at repositioning of the mandible and /or the mandibular arch in an anterior direction to address the above problem. Class II malocclusions can be treated using a variety of treatment protocols including extractions, functional appliances, maxillary molar distalization, and /or surgical –orthodontic procedures. The choice of treatment depends upon the characteristics associated with the malocclusion, such as the amount of anterior-posterior discrepancy, age, patient compliance, psychological implications, stability, financial conditions, treatment time and degree of treatment efficiency.⁴⁻⁸ Class II malocclusions are commonly treated during the growth period by either 1- phase treatment with fixed appliance therapy or 2 – phase treatment with the first phase (growth modification) usually followed by a second phase of fixed appliance therapy.⁹

Over the years numerous investigations have evaluated the possibility of growth modification with functional appliances. However the results are generally equivocal, with conflicting evidence as to their effectiveness. Several studies on growth modification were published recently.⁹⁻¹² These studies indicate that growth modifiers do have a modest effect on jaw growth initially, but the final outcome for patients after the second phase of treatment with fixed appliances is no different than for patients treated with fixed appliances only.⁹ Moreover, they are considered uncomfortable and unesthetic by many patients and require patient compliance because they are removable. Non-compliance of patients in general is increasing, a trend that does not exclude orthodontics. In such a scenario a fixed functional appliance can save both time and

trouble. Like any other functional appliance, it too follows a non-extraction approach; however, its primary effect is on the teeth and the adjoining dentoalveolar structures.

The appliance is effective 24 hours a day without being dependent on patient compliance. This is of particular interest in the case of non-motivated, non-compliant adolescents or of handicapped patients. This treatment effectively shortens the duration of therapy, and ideal use can be made of the remaining growth of a patient beyond the pubertal growth spurt. The most common fixed appliances are the Jasper Jumper, the Herbst, the Twin Force Bite Corrector¹³, the Eureka Spring, and Forsus Fatigue Resistant appliance.

The classic interarch fixed appliance for Class II correction is the Herbst appliance. It is reported to have a combination of orthopedic and dental effects.^{10,11} It was the first fixed functional appliance, developed as long ago as 1909 by Emil Herbst¹⁴ and is still in use today. However, it was not until about 1970 that Hans Pancherz, amongst others, re-introduced the Herbst appliance and set it on its way to success. In 1987 James J. Jasper¹⁵ developed and patented the so called Jasper Jumper™, a flexible helical compression spring in a gray plastic cover which is positioned between the upper and lower jaw during fixed orthodontic treatment. The Jasper Jumper delivers a constant light force to the upper molar and lower arch via a compressed coil within a plastic housing. The effects produced are very similar to those of Class II elastics, flaring of the lower incisors and retrusion of the upper incisors.¹⁵⁴⁻¹⁷ However the major problem with the Jasper Jumper has been breakage.

The Forsus Spring was developed from a combination of concepts from the Herbst and Jasper Jumper.¹⁸ The FRD (Forsus Fatigue Resistance Device) (3M Unitek

Corp, Monrovia, Calif) is a three-piece, semirigid telescoping system incorporating a superelastic nickel-titanium coil spring that can be assembled chair-side in a relatively short amount of time. It is compatible with complete fixed orthodontic appliances and can be incorporated into preexisting appliances. The FRD attaches at the maxillary first molar and onto the mandibular archwire, distal to either the canine or first premolar bracket. As the coil is compressed, opposing forces are transmitted to the sites of attachment. Investigations with FRD and other fixed functional appliances have shown that the changes observed in the overjet are primarily dentoalveolar in nature, with distalization of the maxillary dentoalveolar process and mesial displacement of the mandibular molars.

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Heinig and Goz¹⁸ used the Forsus Spring over a period of 4 months to treat 13 patients having an average age of 14.2 years. Evaluation of the lateral cephalograms showed that the sagittal occlusion relations were improved by approximately $\frac{3}{4}$ of a cusp width to the mesial on both the right and left side as a result of distal movement of the upper molars and mesial movement of the lower molars. Retrusion of the upper incisors and protrusion of the lower incisors reduced the overjet by 4.6 mm. Overall, two thirds of the patients found the Forsus spring to be more effective than the appliance previously used to correct their Class II malocclusion, such as headgear, activator or Class II elastics. They also stated that the older the patient to be treated, the less the condyle is subject to remodeling through forward displacement of the mandible and the more the correction is due to dentoalveolar changes.

The Forsus Fatigue Resistance appliance has some important features: easy chair side construction; no special bands, crowns or wire attachments; easily inserted, adjusted,

and removed. It can also be used for preserving maxillary molar and mandibular incisor anchorage. The fixed appliance is of minimal disturbance to the wearer since almost all oral functions are still possible.

Jones et al,²² while comparing Class II elastics and the Forsus spring, found greater skeletal advancement and dental movements in the mandible than in the maxilla which accounted for the Class II correction. Lower incisor proclination was evident in both the groups. Extrusion of the maxillary and mandibular molars was also seen. In a separate study De Vincenzo²³ quantified the skeletal and dental contributions to Class II correction with the Eureka spring. He showed distal movements of the maxillary molar and mesial movement of the mandibular molars contributing 33% and 60% respectively toward the correction of the Class II molar relation. Similarly Karacay et al²³ reported equal amounts of distal maxillary molar and mesial mandibular molar movement in patients treated with the Forsus Nitinol Flat Spring (NFS).

Treatment of Class II malocclusion in young adults can also be performed by distalization of the maxillary molars, or by maxillary premolar extractions. Tooth extraction is a common approach in orthodontic treatment to resolve dental crowding. Its frequency in orthodontic patients has been reported to be 42.1%.²⁵ The extraction of upper premolars is often chosen as an alternative in non-growing Class II patients, for some patients with significant overjet, or in cases in which there has been failure of attempted headgear or functional appliance treatment to achieve Class I canine relationships.²⁶ Extractions can involve 2 maxillary premolars or 2 maxillary and 2 mandibular premolars. The extraction of only 2 maxillary premolars and anterior teeth

retraction is generally indicated when there is no crowding or cephalometric discrepancy in the mandibular arch.^{27,28}

Besides selective removal of permanent teeth, followed by dental camouflage to mask for the skeletal discrepancy to provide a good facial balance, in severe malocclusions orthognathic surgery can also be an option. However, as with every invasive procedure, certain risks are involved and complications after orthognathic surgery can also be a matter of concern.^{29,30} Hence orthognathic treatment plans should be used judiciously. Johnston reported that 10% of patients ultimately experienced total condylar resorption after orthognathic surgery.³¹

While retracting the anterior teeth in a full cusp Class II malocclusion, anchorage control assumes profound importance because maintaining the posterior segment in place becomes very critical. A loss in molar anchorage can not only compromise correction of the antero-posterior discrepancy but can also affect the overall vertical dimension of the face. There have been numerous studies that have demonstrated that in the majority of maxillary premolar extraction cases there is a mesial movement of the upper buccal segments along with a slight opening rotation of the mandible.

In order to preserve anchorage numerous appliances and techniques have been devised; Nance holding arch, transpalatal bars, extraoral traction, use of multiple teeth at the anchorage segment and application of differential moments are some of the commonly used ones. However, all these methods have a few inherent disadvantages, like; complicated designs, need for exceptional patient cooperation, elaborate wire bending along with a good understanding of the underlying biomechanical principles, etc. With the introduction of dental implants,³² miniplates³³ and microscrews³⁴⁻³⁷ as anchorage

units, it has now become possible to obtain absolute anchorage for the posterior teeth and close the extraction spaces completely by anterior teeth retraction. However, there still seems to be a paucity of accurate scientific evidence pertaining to the treatment effects of skeletal anchorage in Class II malocclusions. Luecke and Johnston³⁸ treated 42 patients with Class II division 1 malocclusions with upper premolar extractions using Edgewise technique, and evaluated the mandibular position. They found that in non-growers the mandible rotated in a posterior direction thereby increasing the vertical dimension. In other studies no increases in the mandibular plane angle were reported.^{27,39}

In 1945, Gainsforth and Higley⁴⁰ were the first to mention orthodontic implants in print for augmentation of anchorage. They used Vitallium screws, which were inserted in the ramal area. They were immediately loaded and used for canine retraction in the upper arch. Unfortunately just in a month's time, after loading, all the implants were lost.

Bae et al⁴¹ inserted micro implants of 1.2mm in diameter and 10mm in length between the maxillary 1st and 2nd premolars, for retraction of the maxillary anterior teeth. The micro implants were stable for the entire length of treatment and were easily removed with a screw driver after debonding and debanding. Total treatment time was 26 months.

Wehrbein et al⁴² used a palatal mini-implant connected with a transpalatal arch to maxillary first molars as anchorage to retract canines and incisors. Dental class II patients that needed extraction of first premolars were selected. Each patient received one implant in the center of the anterior palate. The canine and incisors were retracted using traction springs with continuous force. The mean anchorage loss was 0.7 mm on the right and 1.1 mm on the left side. On average the right canine was retracted by 6.6 mm and the left by

6.4 mm. Overjet reduction was 6.2mm. However, there was some anchorage loss noted which was attributed to the bending of the transpalatal arch during retraction.

Upadhyay et al⁴³ (2007) in a prospective clinical trial showed that the maxillary anterior teeth were retracted bodily with slight intrusion and all the premolar extraction spaces were closed without loss of anchorage. Furthermore the maxillary posterior teeth showed distal movement. After achieving a good facial profile, the retraction forces from the miniscrew implants were discontinued. The screws remained immobile all throughout the treatment in all the cases.

There have been only a few reports in the literature elucidating the use of implants in Class II malocclusions involving the extraction of the upper first premolars. Nagaraj et al⁴⁴ in a case report described the treatment of an adult female with a severe Class II malocclusion and congenitally missing mandibular incisors by using mini-implants for en masse retraction of the maxillary anterior teeth. More than 13mm of maxillary incisor retraction was obtained. The patient's facial esthetics showed dramatic improvement. The upper and lower lips were retracted by 6mm and 7 mm, respectively.

In a separate case report Upadhyay and Yadav⁴⁵ demonstrated the clinical utility and versatility of mini-implants in carrying out different types of tooth movement in a 14-year-old boy with a 'severe' Class II division 1 malocclusion. Mini-implants were placed for 'en masse' retraction and intrusion of maxillary anterior teeth and for lower molar protraction. More than 11 mm of maxillary incisor retraction was achieved together with 3 mm of intrusion. There was significant reduction in the dentoalveolar protrusion and retraction of the upper lip, which resulted in decreased mentalis strain and improved chin

projection. Cephalometric superimposition and panoramic radiographs showed no anchorage loss and good occlusion at the end of treatment.

Rationale

The two different treatment protocols discussed above have the same treatment objective/goal: correction of the exaggerated overjet either by the retraction of the maxillary teeth or by the proclination /mesialization of the mandibular teeth or a combination in order to obtain optimal dentofacial esthetics. It can be assumed that the skeletal and dental changes produced by premolar extraction in the maxillary arch can be substantially different from those produced with interarch fixed functional appliances as the mechanism and point of application of force is different for both the treatment modalities. This in turn might have a bearing on the overall facial esthetics of the patient which by far is the most important objective of contemporary orthodontics.

There are no studies in the literature that have compared the dentoskeletal and soft tissue effects of the two techniques described above for treating Class II malocclusions. It would be interesting to observe the differences between these techniques as it may have a bearing on the overall treatment planning for Class II patients seeking orthodontic intervention for compensating their Class II malocclusions. Potential differences between appliance systems must be identified and understood, so that an appropriate decision can be made when deciding on treatment alternatives.

Null Hypothesis

General Null Hypothesis

There is no difference in the skeletal and soft tissue profile (lip protrusion and facial convexity) obtained after treatment with mini-implant based space closure and fixed functional appliance therapy in Class II malocclusion patients.

Specific Null Hypothesis

1. The dentoalveolar response (molars, incisors, overjet and molar discrepancy) in Class II malocclusion orthodontic patients treated with the aforementioned approaches are significantly different.
2. Extractions and/or fixed functional appliances do not cause a significant increase in the vertical dimensions of the face.

MATERIALS AND METHODS

The University of Connecticut Institutional Review Board (IRB) approval was obtained for the study and data analysis. The sample was retrospectively selected from the files of the Department of Orthodontics KLES Institute of Dental Sciences at Belgaum, India. The files included records of 202 patients treated in the last 4 years from the time of selection who were included in a clinical trial examining the effects of extraction and non-extraction fixed appliance treatment approaches to correct Class II malocclusions. The patient records were used to determine their initial age, gender, start of treatment and total treatment time.

To eliminate susceptibility bias, all the available patients from the archive who met the inclusion criteria, with matching ages in both the groups, were selected. Sample selection was based exclusively on the initial anteroposterior molar relationship, regardless of any other dentoalveolar or skeletal cephalometric characteristics. Only 32 patients met the following inclusion criteria:

- 1) Class II molar relation.
- 2) Overjet equal to or greater than 4mm.
- 3) Permanent dentition with all the teeth present. (excluding third molars)
- 4) Class II Division 1 malocclusion with no subdivision malocclusion
- 5) No craniofacial syndromes or systemic disease.
- 6) Minimal crowding in the dental arches.

Patients were rejected if any other method was employed to treat the Class II malocclusion. Except for the method of Class II correction employed, the treatment of both groups was similar, consisting of full, fixed orthodontic appliances. By limiting the

sample to three operators performing either of the treatments, variation in treatment technique was minimized.

Clinical set up:

Fixed Functional Appliance group (G1) (Fig 1)

In the Forsus group consisting of 18 patients, preadjusted edgewise appliance (PEA) brackets with a 0.022-inch slot were used. Leveling and aligning were done with nickel-titanium (NiTi) & stainless steel (SS) archwires. The leveling and aligning phase lasted approximately 6-9 months. The forsus appliance was placed only when 0.021 x 0.025-inch SS wires had been used for at least 2 weeks before insertion. The mandibular arch was tied back to the first or second molars. In the maxillary arch the forsus appliance was attached to the headgear tube of the banded first molar as prescribed by the manufacturer with a ball-pin attachment. In the mandibular arch, it was attached to the archwire distal to the canine on either side.

Extraction group (G2) (Fig 2)

This group had 14 patients. Preadjusted edgewise appliance (PEA) brackets with a 0.022-inch slot were used for all the patients. Once the initial leveling and aligning were over, 0.017 x 0.025 -inch stainless steel arch wire, with 'crimpable hooks' placed distal to lateral incisors, was inserted into the upper arch. To ensure that the wire was passive, it was left in place for at least 4 weeks before initiating retraction. Titanium mini-implants (1.3 mm in diameter and 8 mm in length) were inserted between the roots of the first molar and second premolar in both the upper quadrants. The surgical procedure for

implant placement involved incision of the overlying mucosae, preparing a hole with a pilot drill under constant irrigation with a coolant and placement of the mini-implants with a screw driver. The implants were checked for mobility (primary stability) and were ‘immediately’ loaded with precalibrated nickel-titanium ‘closed’ coil springs extending from the implant head to the crimpable hooks. A force of 150 g was applied bilaterally for ‘en masse’ retraction of the upper anterior teeth. Direction of the applied forces was upward and backward. Conventional mechanics was used for the lower arch.

Cephalometric Records

The cephalometric radiographs obtained were of good quality with hard and soft tissue structures clearly discernible. The length of time between the two cephalograms was not more than 14 months for any of the subjects. Radiographs for each patient were taken at two different time points:

T1: Before correction of the overjet.

T2: After overjet correction.

Data were monitored, coded, and entered as received. Each subject was assigned a unique identifier that was used on all experimental forms and samples. Regular backup of files was performed, and backup copies were housed in separate secure locations. Research personnel were trained in procedures designed to minimize missing data. All the cephalometric radiographs were hand-traced on acetate paper and included the cranial base, nasal complex, maxilla, mandible, orbit, pterygomaxillary fissure, dentition, and the entire soft tissue profile from glabella to cervicale. When the central incisors overlapped, both were traced, and an average of the two axial inclinations

was used. Linear and angular measurements were performed to the nearest 0.5 mm and 0.5 degrees respectively.

Cephalometric Landmarks used (Figure 3):

1. S (Sella): Geometric centre of the pituitary fossa.
2. N (Nasion): The most anterior point on the fronto-nasal suture on the mid sagittal plane.
3. A (A point): The most posterior midline in the concavity between the anterior nasal spine and the alveolar bone covering the maxillary incisors.
4. B (B point): The most posterior midline point in the concavity of the mandible between the most superior point on the alveolar bone covering the mandibular incisors and pogonion.
5. Go (Gonion): A point on the curvature of the angle of the mandible located by bisecting the angle formed by the lines tangent to the posterior ramus and the inferior border of the mandible.
6. Gn (Gnathion): A point located by taking the midpoint between the anterior and inferior points of the bony chin.
7. ANS (Anterior Nasal Spine): The anterior tip of the sharp bony process of the maxilla at the lower margin of the anterior nasal opening.
8. PNS (Posterior Nasal Spine): The posterior spine of the palatine bone constituting the hard palate.
9. Me (Menton): The lowest point on the symphyseal shadow of the mandible seen on a lateral cephalogram.

10. Pog (Pogonion): The most anterior point on the chin.
11. U1 (Upper Central Incisor): Incisal tip of the maxillary central incisor.
12. L1 (Lower Central Incisor): Incisal tip of the mandibular central incisor.
13. U6 (Upper 1st Molar): The anterior most point on the mesial outline of the crown of the maxillary 1st molar.
14. L6 (Lower 1st Molar): The anterior most point on the mesial outline of the crown of the mandibular 1st molar.
15. G (Glabella): The most prominent anterior point in the midsagittal plane of the forehead.
16. Sn. (Subnasale): Point at the junction of the columella and the upper lip.
17. Pog' (Soft tissue pogonion): The most anterior point on the soft tissue chin
18. Ls (Labrale Superius): The most anterior point on the convexity of the upper lip
19. Li (Labrale Inferius): The most anterior point on the convexity of the lower lip.
20. Nt: Most anterior point on the sagittal contour of the nose.

Cephalometric Planes used (Figure 4):

1. S-N plane.
2. Sella horizontal (Sh or Constructed FH plane or x axis).
3. Palatal plane (ANS-PNS).
4. Mandibular plane (Go-Gn).
5. Sella vertical (Sv or y axis).
6. Rickett's E-plane (Esthetic plane) (Nt-Pog').

Cephalometric Measurements Undertaken:

I. Skeletal Measurements (Figure 5):

A) Angular Measurements ($^{\circ}$):

1. SNA
2. SNB
3. ANB
4. Go-Gn-SN
5. PP-MP

B) Linear Measurements (in mm)

6. UFH
7. LFH
8. PFH
9. AFH

II. Dental Measurements (Figure 6):

A) Angular Measurements ($^{\circ}$):

1. U1-SN
2. IMPA
3. U1-L1

B) Linear Measurements (in mm):

4. U6-PP
5. U6-Sv

6. L6-MP
7. L6-Sv
8. U1-Sv
9. U1-PP
10. L1-Sv
11. L1-MP

III. Soft Tissue Measurements (Figure 7):

A) Angular Measurements (°):

1. G-Sn-Pg
2. Nasolabial angle

B) Linear Measurements (in mm):

3. E line-Ls
4. E line-Li

Superimpositions

In order to differentiate skeletal and dental changes, disregarding displacement of the nasion, total and local superimposition methods were carried out as described by Bjork and Skieller.⁴⁶ Within this method a coordinate system with the sella-nasion as the X-axis and a perpendicular to this through the sella as the Y-axis was constructed on the first cephalograms. For the total superimposition method, the first and second cephalograms of each subject were superimposed on stable bone structures in the anterior cranial base, and the coordinate system constructed on the first cephalograms was

transferred to the second cephalogram. For the local superimposition method, the same coordinate system constructed on the first cephalograms was transferred to the second by superimposing the two cephalograms on the maxillary and mandibular structures.

Statistical Method

All cephalometric and study cast measurements were transferred to an Excel spreadsheet (Excel Office 2003; Microsoft Corp, Seattle, WA)

.Mean changes occurring during treatment were then calculated, and the data were statistically analyzed using a commercially available statistical software package (SPSS Inc, Chicago, III). Mean and standard deviation were used to describe central tendencies and dispersion. Kolmogorov-Smirnoff tests and Q-Q plots were used to assess the normality of the data (Appendix). Comparisons between the two groups were undertaken using a two-tailed Mann-Whitney U-test. Pair wise comparison between related assessments made at the two time intervals were made using two-tailed Wilcoxon signed rank test.

Measurement error

In order to evaluate the individual error, either during tracing, superimposing or transferring the co-ordinate system from the first cephalogram to the second or measuring the parameters, the T1 and T2 cephalograms of all the subjects were retraced at least 3 months later. All radiographs were retraced by 1 operator (M.U). Systematic errors were estimated by paired t tests ($P < 0.05$) and causal errors were calculated according to

Dahlberg's formula, $Se^2 = \Sigma d^2/2n$, where d is the difference between duplicate measurements, and n is the number of double measurements.

RESULTS

The treatment changes for each measurement have been calculated by subtracting the pretreatment measurements from the post treatment. Linear measurements which show a negative sign are synonymous with a distal, backward or intrusive movement to a relevant reference line or a shortening of the vertical dimension, while a positive value indicates a forward, mesial or extrusive movement increase in the vertical dimension. A positive value for change in an angular measurement indicates that the measurement became more obtuse during treatment.

Pretreatment Comparisons:

The patient ages were similar in both the groups in that no statistically significant differences were observed between them ($P>0.05$) (Table I). Pretreatment differences among the variables for the groups are presented in Table II. The treatment intervention for G1 (4.01 ± 1.3 months) was significantly less ($P>0.05$) than G2 (9.94 ± 2.44 months), as there were two distinct modalities of treatment. The descriptive statistics containing means and standard deviations for the respective groups and the treatment changes have been highlighted through tables II-VII.

Skeletal changes:

No significant differences were observed between the groups for any of the skeletal parameters.

1. Anterio-posterior changes: G1 showed an overall increase in the SNB angle ($0.96\pm 1.55^\circ$) ($P<0.05$) and a decrease in the ANB angle ($-1.54\pm 1.05^\circ$) ($P<0.01$), while G2 showed a significant decrease only for the ANB angle ($-0.64\pm 0.98^\circ$) ($P<0.05$).

2. Vertical changes: G1 showed a significant increase only for PFH (1.96 ± 2.6 mm) while G2 in addition to the PFH (1.59 ± 0.94 mm) showed an increase in the PFH/AFH percentage ratio (1.23 ± 0.92). The UFH/LFH showed a decrease for G2 (-4.41 ± 5.73).

Dental changes:

1. Maxillary incisor movement: Clinically significant ($P < 0.05$) levels of retraction were achieved in the two groups for both angular (U1-SN) and linear (U1-Sv) measurements. Significant differences ($P < 0.05$) were also found when the groups were compared with each other with G2 showing greater incisor retraction than G1. In the vertical plane G2 showed a significant amount of intrusion (-1.32 ± 1.08 mm) ($P < 0.05$) while G1 showed relative extrusion (1.5 ± 0.98 mm) ($P < 0.05$).

2. Mandibular incisor changes: The lower incisors showed significant levels of proclination ($P < 0.05$) for G1 both for angular (IMPA) ($10.69 \pm 5.36^\circ$) and linear (L1-Sv) (3.96 ± 1.97 mm) measurements. In contrast, G2 showed significant ($P < 0.05$) amounts of up righting: IMPA ($-4.82 \pm 5.36^\circ$), L1-Sv (-1.77 ± 2.16 mm).

3. Maxillary first molar movements: There was significant intrusion ($P < 0.05$) of the maxillary molars (U6-PP) for both G1 (-1.08 ± 1.08 mm) and G2 (-0.64 ± 0.78 mm) however, the differences were not significant between the two groups ($P > 0.05$). Similarly both the groups showed a distalizing effect (U6-Sv) on the molars, however, the results were not significant ($P > 0.05$).

4. Mandibular first molar movements: There were significant ($P < 0.05$) amounts of extrusion of the mandibular molar (L6-MP) for both G1 (1.15 ± 0.72 mm) and G2 (0.82 ± 0.75 mm). The differences between the two were not significant ($P > 0.05$). In G1

there was a significant ($P<0.05$) amount of mesial movement (L6-Sv) of the molar (3.42 ± 2.62 mm) when compared to G2 (0.64 ± 1.1 mm). However, within G2 this movement was not significant ($P>0.05$).

Soft tissue changes:

1. Profile changes: A significant ($P<0.05$) decrease in the facial convexity angle (G-Sn-Pg) was noted for G2 ($-2.18\pm 1.33^\circ$). Although a decrease was also noted for G1 ($-0.77\pm 2.26^\circ$), it was not significant ($P>0.05$). Similarly, although there was a significant increase in the nasolabial angle for both the groups: G1 ($8.19\pm 8.06^\circ$) ($P<0.05$) and G2 ($11.55\pm 5.94^\circ$) ($P<0.05$), there were no significant differences noted when the groups were compared ($P<0.05$).

2. Upper lip changes: Statistically significant levels of upper lip retraction (E line-Ls) ($P<0.05$) were seen for both the groups (G1 = -1.19 ± 1.3 mm, G2 = -2.41 ± 1.22 mm) but the inter group differences were not statistically significant ($P>0.05$).

3. Lower lip changes: A significant increase was noted in the lower lip prominence for G1 (1.85 ± 1.39 mm) ($P<0.05$) while a decrease was noted for G2 (-2.73 ± 2.4 mm) ($P<0.05$). The differences were statistically significant when the groups were compared with each other ($P<0.05$).

DISCUSSION

The investigated cases were selected primarily on the basis of presenting a bilateral Class II malocclusion independent of the associated cephalometric characteristics. Originally G1 had 41 potential subjects treated without premolar extractions, and G2 had 23 subjects treated with 2-maxillary premolar extractions. However the strict inclusion criteria and the need to perfectly match the groups significantly reduced the group sizes. Prior to treatment , the 2 groups of Class II Division 1 malocclusions presented with almost identical hard and soft tissue profile characteristics with only two significant differences (Table IV).

Correction of the Class II malocclusion in G1 was achieved by the distalization of the upper molar and incisor retraction simultaneously with lower molar mesialization and incisor flaring. On the other hand in G2 the molar relation was maintained with complete retraction of the maxillary anterior teeth to correct the overjet problem. After successful correction of the malocclusion the comparisons revealed no differences in the skeletal parameters or the soft tissue parameters except the lower lip protrusion which was found to be significantly greater for G1 when compared to G2 or the pretreatment position. Overall the facial profiles of the extraction and non-extraction group were found to be similar after correction of the overjet.

Orthodontic treatment with either of these approaches is more comfortable for the patient than traditional reinforced anchorage such as multi-brackets combined with intraoral or extraoral anchorage, because there is no requirement for the patient's cooperation. This allows the orthodontist to make a more correct diagnosis and treatment plan, because the tooth movement does not depend on patient's cooperation and hence

can be relatively more predictable. However, the long-term stability after treatment for such mechanics is largely unknown, especially for mini-implant based anterior retraction. More relapse might be possible in implant-treated patients during the retention phase because all tooth movement to correct the overjet is carried out in the maxilla. With fixed functional appliances the tooth movement is divided between the arches, i.e there is simultaneous retraction of the upper incisors and flaring of the lower incisors to compensate for the overjet. This is a topic for future study. After treatment in both the groups it was observed that maxillary incisors were significantly retracted and adequate overjet was established. These results suggest that both methods are useful to improve maxillary dental protrusion and interincisal relationships, but the movement of the molars and the incisors were significantly different in the two groups.

The maxillary molars were slightly intruded in both the groups. In G1 the force exerted by the FRR was directly on the molars in the upper arch distal to the center of resistance of the upper arch; hence, besides the intrusive force on the maxillary molars there was also a moment which tipped the molar back (Fig 8). Similarly in G2, the force on the upper arch was acting upwards and backwards, but the point of attachment here was between the laterals and the canines producing a similar upward and backward movement but lesser in extent. Distal movements of the maxillary molars have been previously reported with the Forsus Nitinol Flat Spring (NFS) and similar appliances.⁴⁷⁻⁴⁹ The studies showing the greatest distal movements of the maxillary molars measured the effects immediately after interarch appliance removal.^{17,47,50} Mesial movement with growth and anchorage loss due to additional orthodontic treatment may mask or negate these distal movements. Therefore, strictly speaking this mesial movement does not

qualify as the treatment effects of the Forsus appliance but rather is a result of the treatment mechanics used during finishing and detailing. After Class I molar occlusion is achieved and appliances are removed, mesial maxillary molar movement might be expected to keep pace with the mandibular molars.

The mandibular molars were extruded in both the groups. However the extrusion was significantly more for G1. In spite of this, there was no increase in the mandibular plane angle. This can be explained by two factors. First, the extrusion of the lower molars was a compensation for the intrusion of their counterparts noted in the upper arch. Secondly, besides the extrusive movement of the lower molars they underwent significant forward movement in the A-P direction. These results suggest that the wedge effect caused by this mesial movement cancelled the opening rotation of the mandible. This rationale for extraction is sometimes referred to as the 'wedge hypothesis', which essentially suggests that orthodontic forward movement of posterior teeth leads to a reduction in the vertical dimension.⁵¹ Such treatment mechanics can be highly beneficial in treating high angle patients who require minimal clockwise rotation of the mandible.⁵²

One factor which may indirectly reduce the risk of posterior rotation of the mandible during treatment with a fixed functional appliance is intrusion of the incisors with fixed appliances which in our study was carried out before insertion of the Forsus appliance. This adjustment of the curve of Spee makes it possible to jump the mandible forward to an edge to edge incisor relationship with a small or negligible concomitant rotation of the mandible and opening of the bite in the lateral segments. Moreover, the vertical vector of the functional force which is transferred by the Forsus appliance to the teeth may have an intrusive effect on the posterior segments of the maxillary dentition.

This effect is beneficial and may also counteract the tendency of posterior mandibular rotation which has been reported in previous studies.⁵³⁻⁵⁵

Anchorage preservation is a key factor in treating full cusp Class II cases with extraction. In G2, small amounts of molar distalization (anchor gain) were noted although not statistically significant. In previous reports, 1.6 to 4mm of mesial molar movement has been reported while retracting the canine with traditional mechanics.^{56,57} With the use of adjuncts for anchor preservation up to 2.4 mm of anchor loss has been observed.^{58,59} After space closure the contact between the canine and second premolar was established. At this point any further continuation of the retraction force resulted in its transmission to the posterior segment through the interdental contacts. The coil springs in majority of the cases were left in place for at least a couple of months after space closure. This might have caused some distalization of the molars as observed cephalometrically. (Fig 9)

Overall, headgear, functional orthodontic appliances and extraction of teeth are valuable means of treating sagittal discrepancies between the upper and lower jaws. Fixed functional appliances and extractions are welcome aids when patient compliance is declining. They can be used to treat either dental or skeletal Class II malocclusions. The only contradiction cited to date has been a predisposition to root resorption. Unfortunately, we did not quantify this variable in this study.

Today's culture has an increased awareness and concern regarding facial esthetics. Orthodontic patients, their parents, and practitioners are more concerned with the effect treatment may have on the facial form and harmony. Hence, it is becoming

increasingly important to know the soft tissue effects of the method of treatment so that interventions can be used accordingly as best suited.

Consistent with other studies,⁶⁰⁻⁶⁴ large individual variation was found in the hard and soft tissue profile measurements. Specifically compared to skeletal and dental parameters, few soft-tissue parameters showed statistically significant differences between the two groups in spite of obtaining absolute anchorage in G1 and utilizing the complete extraction space for incisor retraction. This was especially true for lip position relative to the esthetic plane. This is in contrast with the findings of Lo and Hunter⁶⁵ who suggested that the soft-tissue profile followed closely the underlying skeletal framework. Oliver⁶⁶ found that patients with thin lips or high lip strain displayed a significant correlation between incisor retraction and lip retraction, but patients with thick lips or low lip strain displayed no such correlation. Lip tension will vary between individuals and between time periods for any one individual. Inability to control or quantify this variable remains a shortcoming of retrospective soft tissue cephalometric studies. Studies evaluating the soft tissue profile and lip thickness must also consider the effect of lip strain on the accuracy of measurements of static lip position and response. Additionally, it has been reported that lip response, as a proportion of incisor retraction, decreases as the amount of incisor retraction increases, indicating that the lips have some inherent support.⁶⁷ The mobile and flexible lip texture can also produce large variations of the lip position on the lateral cephalogram, even when patients are asked to keep their lips relaxed and their teeth in occlusion.⁶⁸ The more regional effect of incisor retraction should be expected because even with orthognathic surgery, the soft tissue change decreases as the distance from the surgical site increases.

One slight unexpected treatment result as discussed previously was the decrease in lower lip projection in G2. Typically one does not expect to see a decrease in lower lip projection if lower teeth are not extracted or moved. This decrease most likely resulted from an uprighing of the lower lip. With a deep overbite, an increased overjet, and a Class II dental relationship, the lower lip may be artificially held in a more forward position trapped in the space between the upper and lower incisors. As the bite opens and the maxillary incisors are retracted, the lip returns to its normal position resulting in a 'decreased' lower lip projection. In comparison G1 showed an increase in the lip protrusion after treatment primarily due to the fact that the lower incisors were considerably proclined during the application of the fixed functional appliance. Controlling the inclination of the lower incisors during treatment can possibly prevent lip protrusion if not desired in a treatment protocol.

Soft tissue profile must also consider the normal maturational changes that occur and the considerable individual variation. Growth of the nose and chin in untreated adolescents has been shown to far exceed concomitant changes in the lips.⁶⁹⁻⁷² This normal maturational change tends to continue postadolescence, resulting in further 'relative retraction' of the lips. Nose and chin growth have also been shown to exceed the lip changes observed in adolescents undergoing active treatment.^{60,73} However these variables at best should have a modest effect on our analysis because the treatment intervention in both the groups lasted only 4-10 months (Table I).

The nasolabial angle increased significantly for both the groups after treatment, however, no significant difference was found between the two although G2 showed a greater change. This study group also displayed a greater nasolabial angle change than

the previous studies. This is most likely because of the strict retraction requirements of this patient sample and the larger mean maxillary incisor retraction. A greater retraction of the incisors gives more opportunity for the soft tissue between subnasale and labrale superius to move posteriorly. However G1 showed significantly less increase in the nasolabial angle than G2.

The use of Ricketts' esthetic plane and other measurements to assess the profile in this study comes with the subtle implication that these standards may be good indicators of whether or not a face is esthetic. The perception of an esthetic face is much more than the sum of these sagittal measurements. The view of the entire face, the balance and harmony of the parts and the 3-dimensional character all play significant roles in each individual's perception of what constitutes a pleasing facial appearance.

A number of group differences appeared to be statistically significant but were not clinically significant or relevant. This was due to the amount of variation in treatment changes seen between subjects in each group. Large variation in treatment changes is a common finding among treated Class II patients and is likely due to the movements required to correct the different types and extents of dental and skeletal discrepancies.⁷⁴⁻

CONCLUSIONS

1. The results of our statistical tests and clinical observations show that in spite of some differences in the treatment outcome with these two approaches both provided adequate decompensation for the matched Class II Div 1 malocclusion patients but did not entirely correct the skeletal discrepancy.
2. Both the treatment approaches provided good control over the vertical dimension.
3. In terms of esthetic appearance, there were no differences in the soft tissue profile changes between the two groups although a lesser lower lip projection was noted for patients undergoing extraction.
4. Treatment time was significantly less with fixed functional appliances.
5. Caution needs to be exercised when extrapolating the results obtained to severe skeletal Class II malocclusions displaying significant amounts of overjet and /or inter jaw discrepancy. Further studies are recommended to provide more information regarding the hard and soft tissue response in such samples.

FIGURES

Figure 1: Clinical set up for a G1 patient.



Figure 2: Clinical set up for a G2 patient.



Figure 3: Cephalometric landmarks.

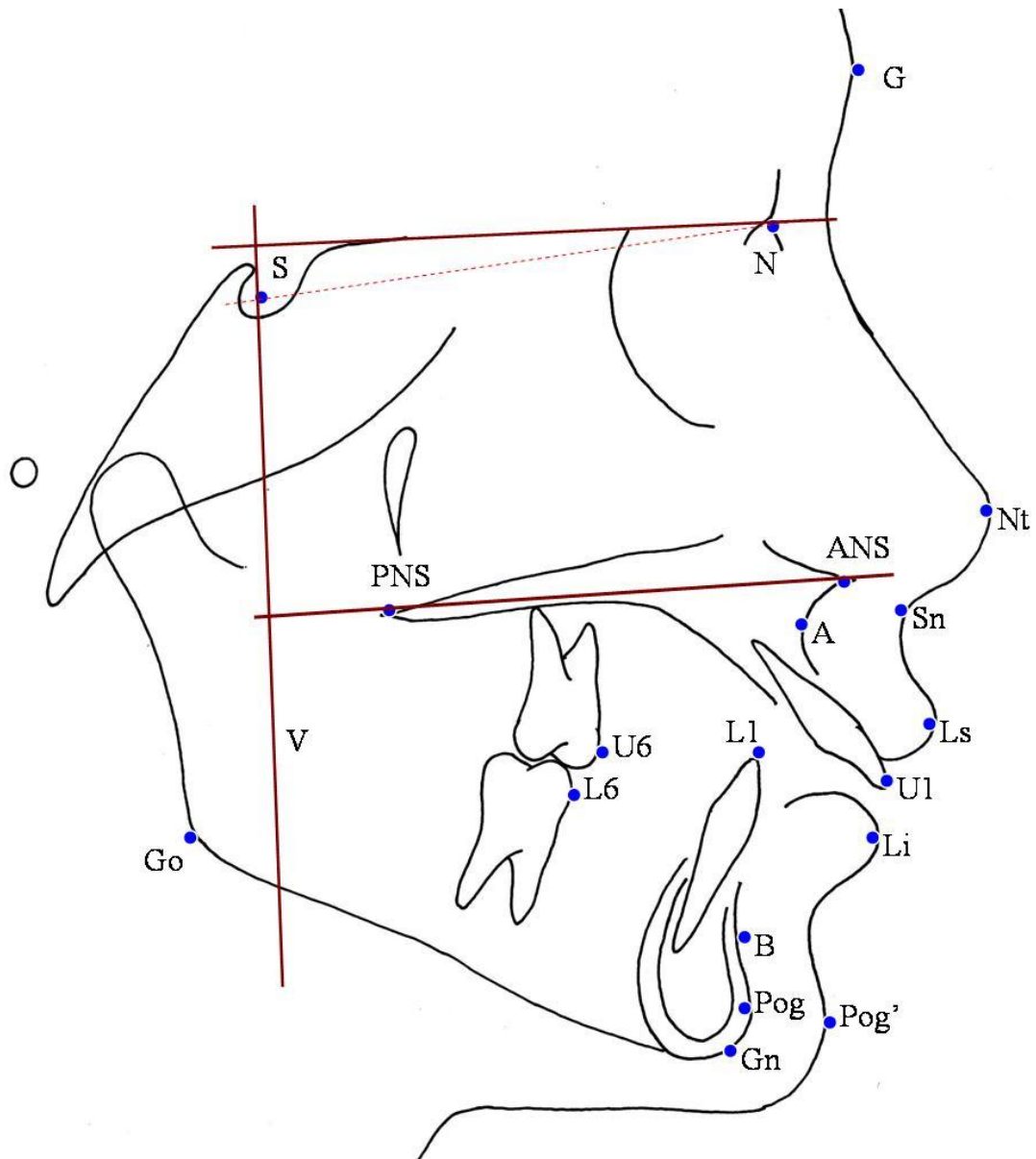


Figure 4: Cephalometric planes.

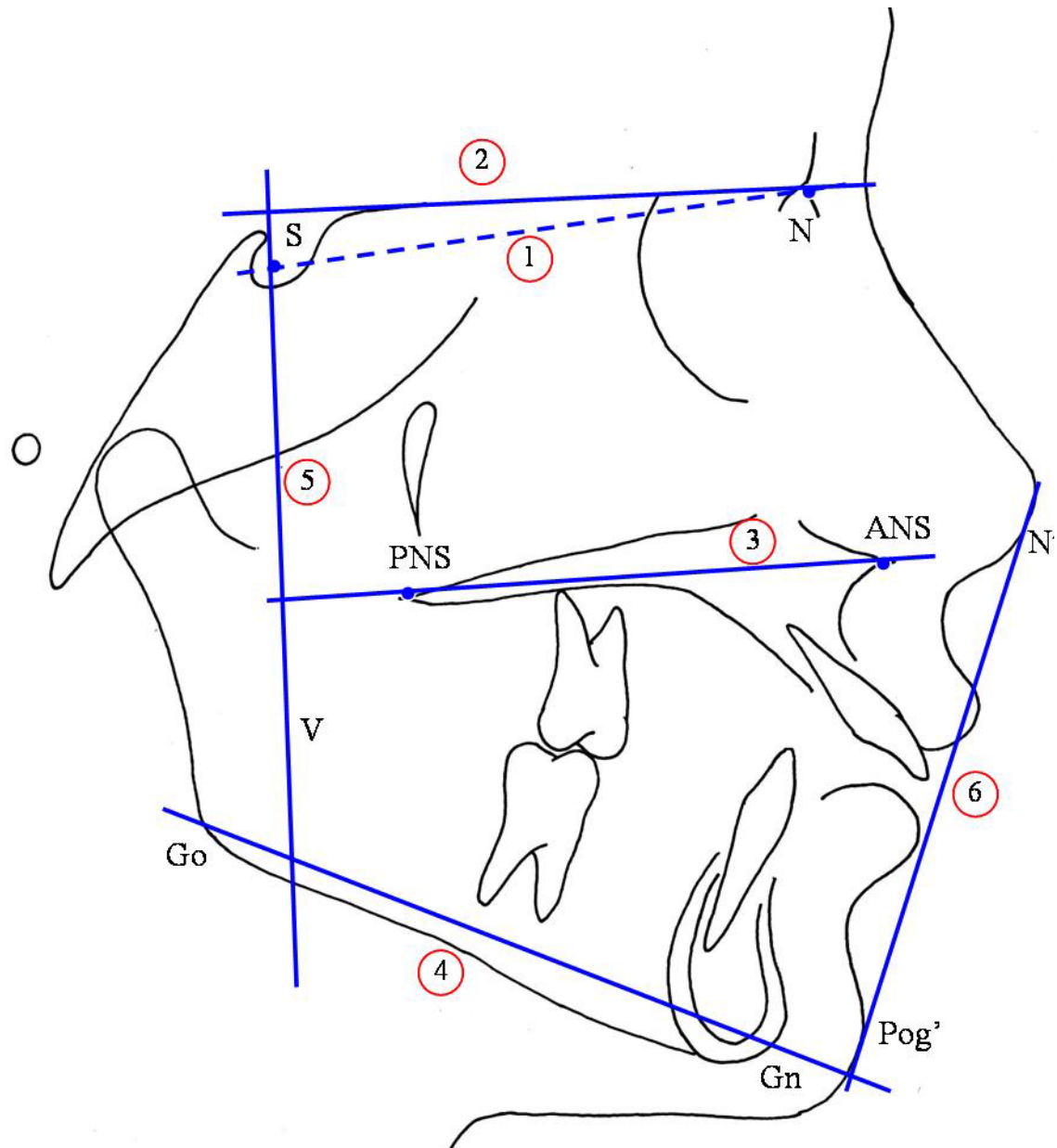


Figure 5: Skeletal parameters.

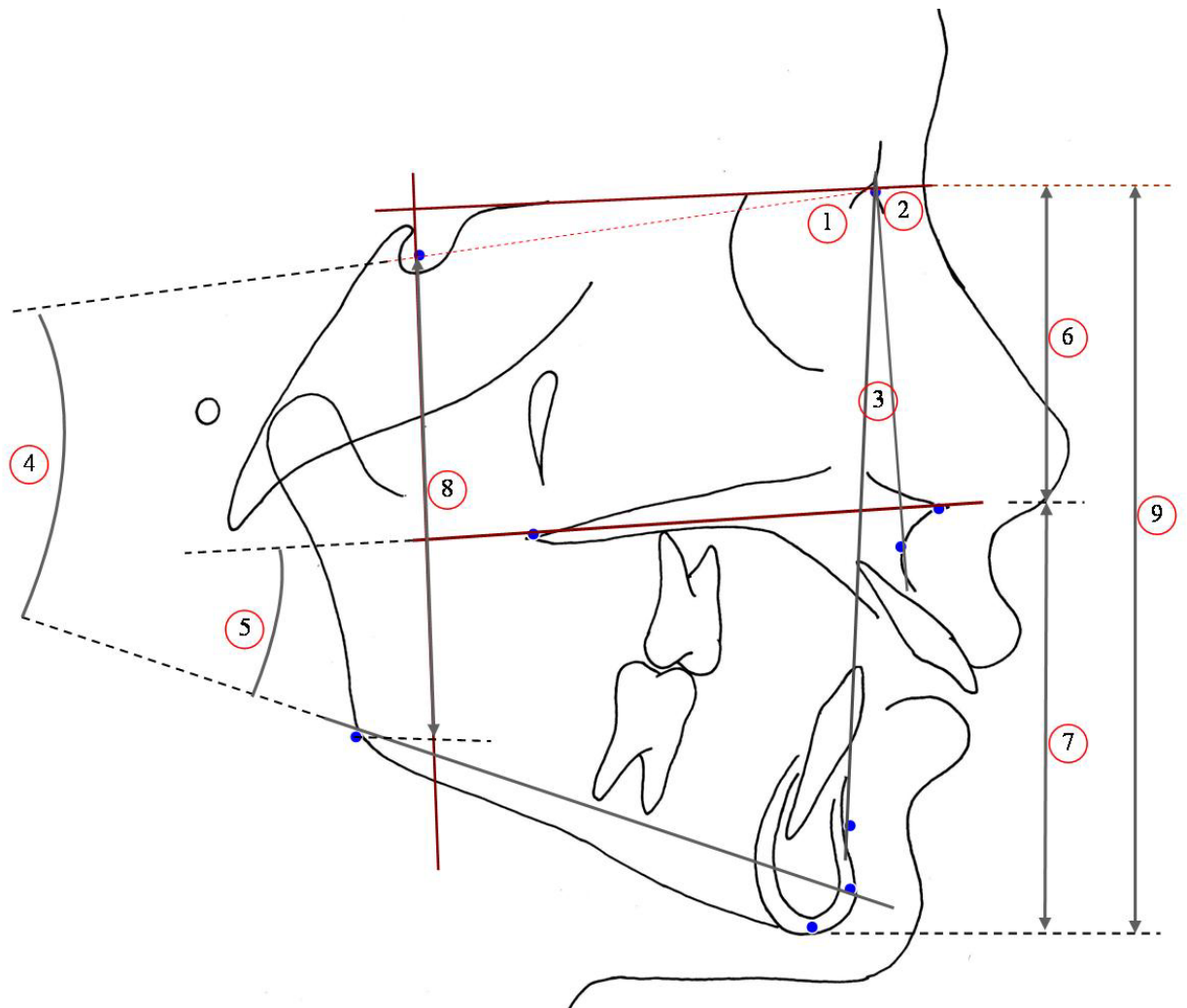


Figure 6: Dental parameters.

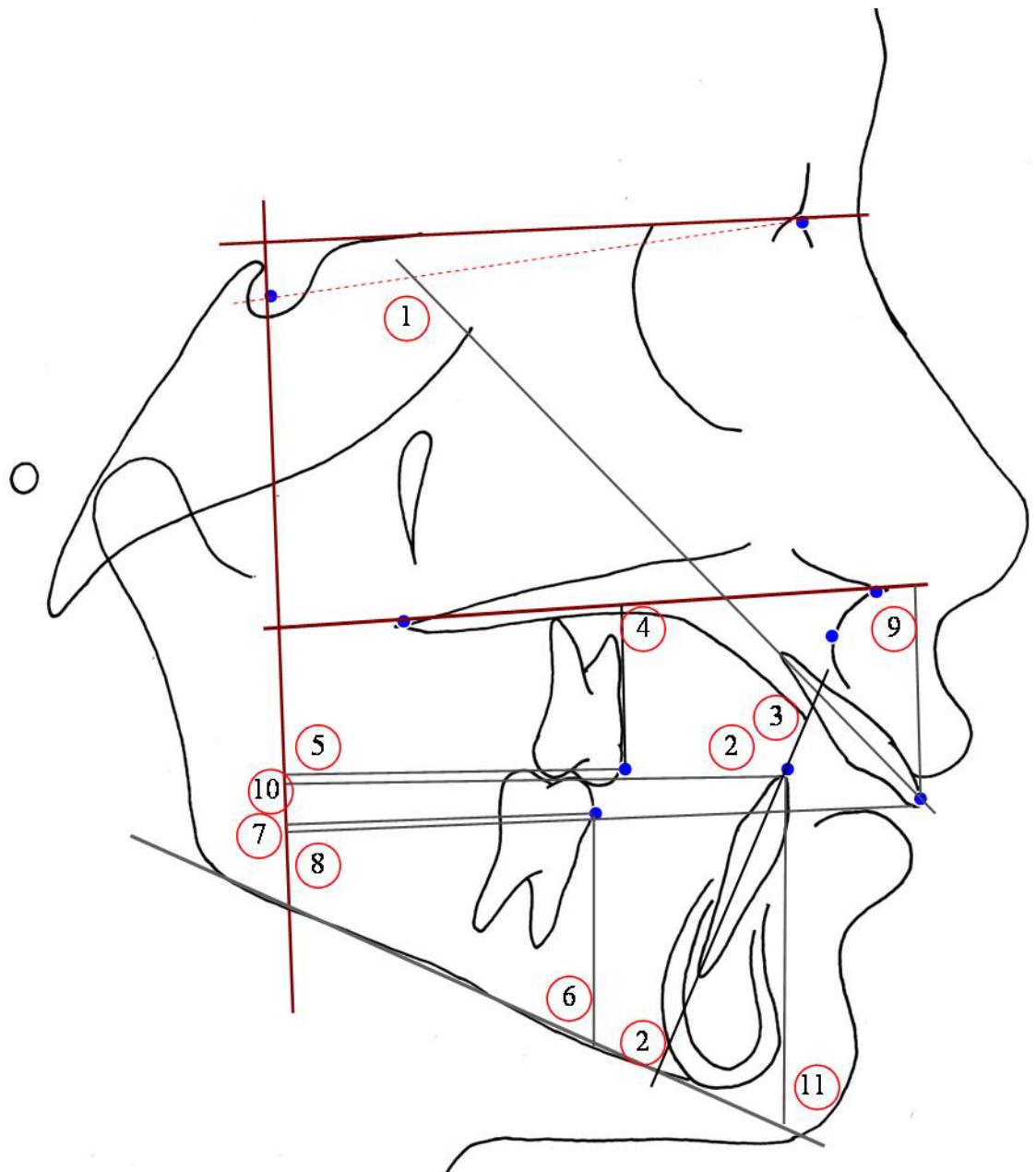


Figure 7: Soft-tissue parameters.

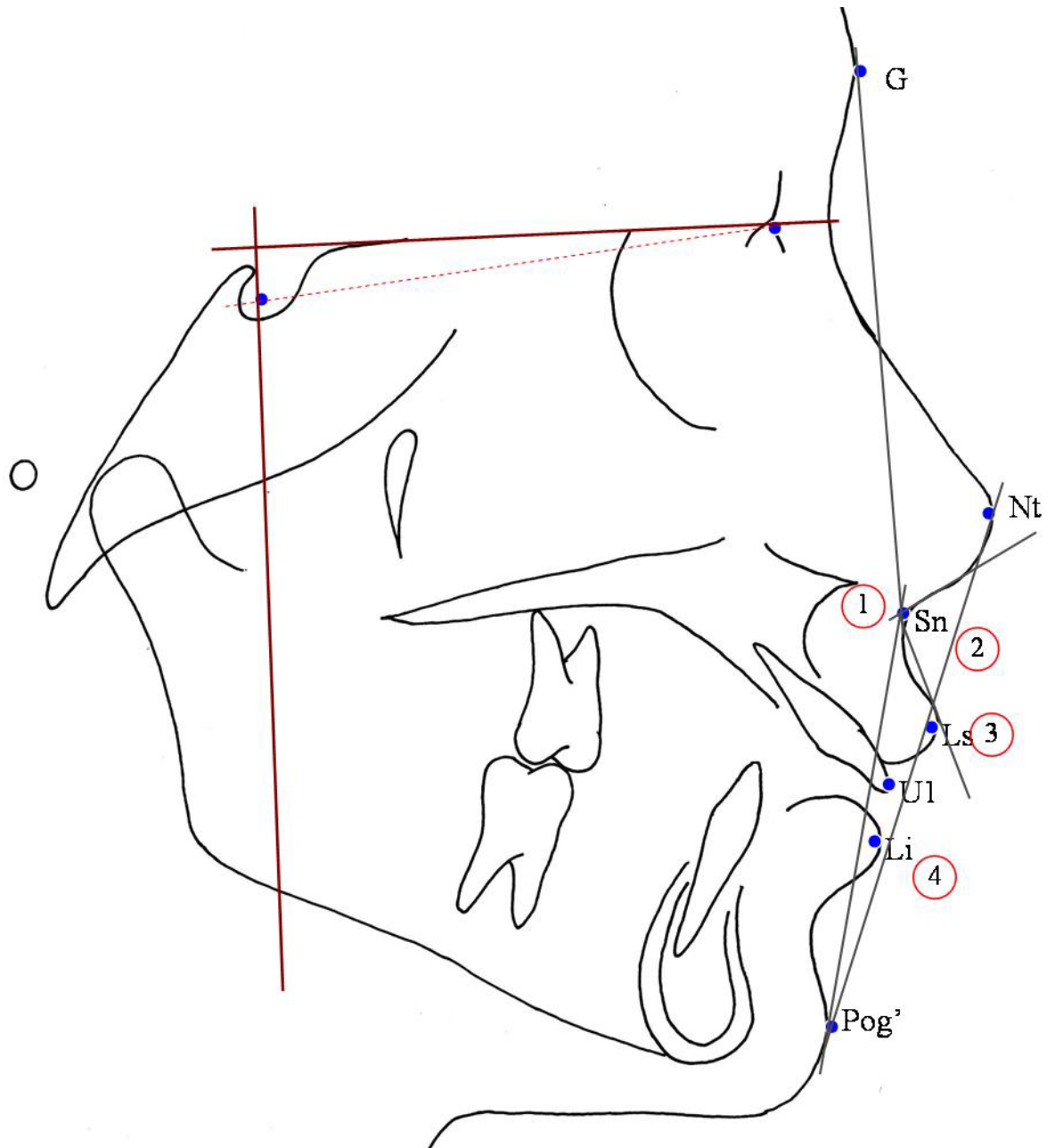
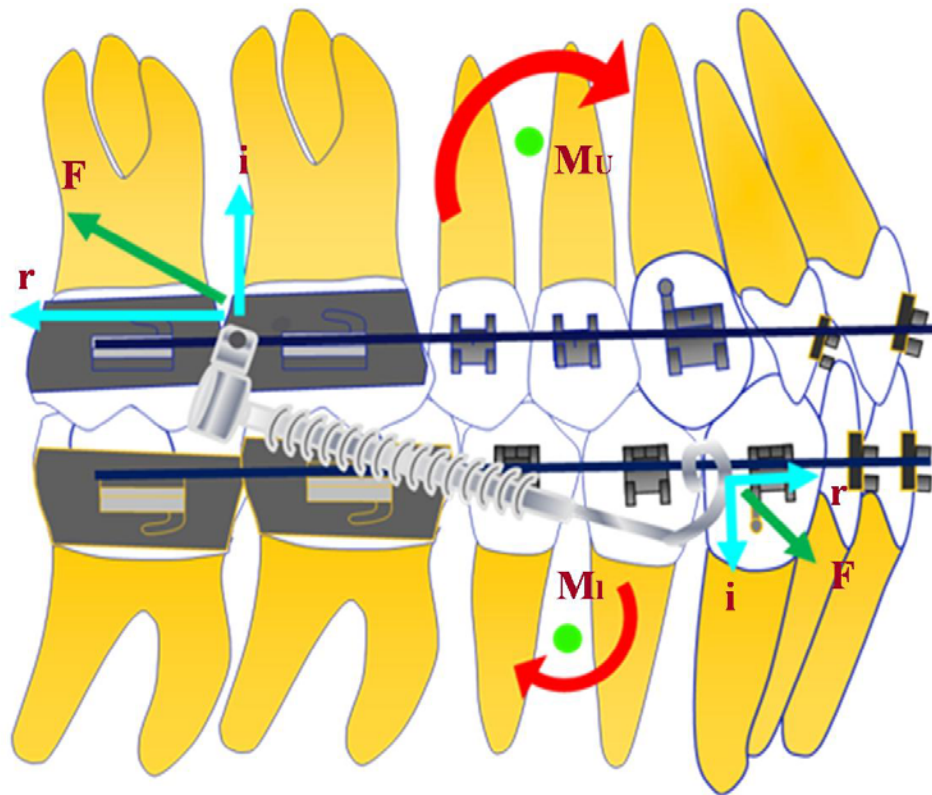
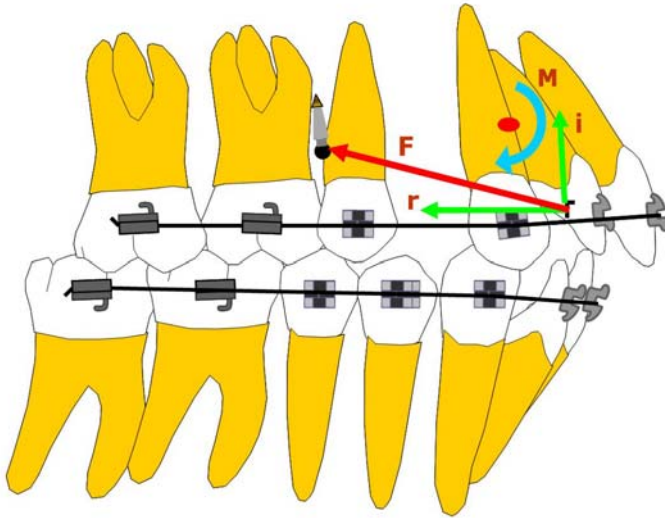


Figure 8: Biomechanical design of the force system involved in G1 patients having the fixed functional appliance.

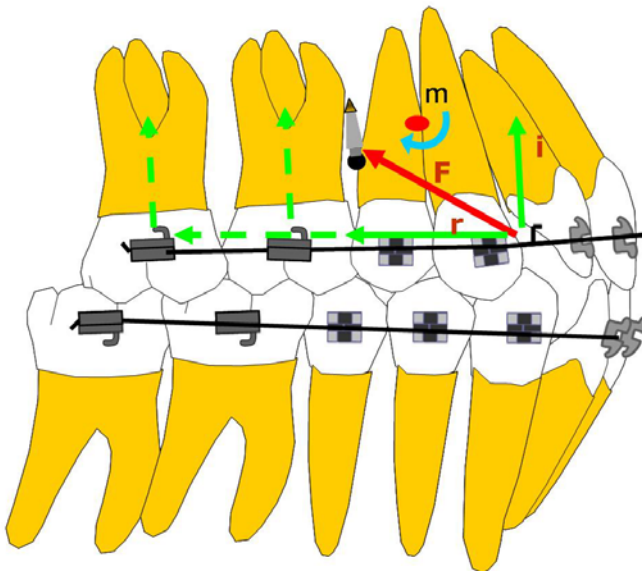


Here, F = Total force, i = vertical (intrusive) component, r = horizontal component, M_u = Moment created on the upper arch, M_l = moment created on the lower arch ($M_u > M_l$).

Figure 9: Biomechanical design of the force system involved in G2 patients having mini-implants for en masse retraction. B) Force system involved after space closure (m = total moment around the center of resistance of the maxillary arch).



A) Force system before space closure (F =total force, i = intrusive component, r =retractive component, M = moment around the anterior center of resistance)



B) Force system involved after space closure (m = total moment around the center of resistance of the maxillary arch).

TABLES

Table I. Details of the study sample (n=25)								
<i>Measurement</i>			<i>G1(n=18)</i>		<i>G2 (n=14)</i>			
			<i>Mean</i>	<i>S.D</i>	<i>Mean</i>	<i>S.D</i>	<i>P Value</i>	<i>Sign</i>
Age at T1(in years)			16.51	3.51	17.38	2.85	0.635	NS
Duration of Treatment Intervention (in months)			4.01	1.3	9.94	2.44	0	*
(T2-T1)								
NS indicates not significant; * P < 0.05,								

Table II- Dahlberg's Method Error						
	Forsus (G1)			Implant (G2)		
	T1	T 2	Change	T1	T2	Change
Skeletal Parameters						
SNA (°)	0.3922	0.3252	0.5801	0.4129	0.3371	0.533
SNB (°)	2.3717	0.2402	2.5702	0.282	0.1066	0.3015
ANB (°)	0.2402	0.1698	0.3252	0.2132	0	0.2132
Go-Gn-SN (°)	0.2594	0.2942	0.3669	0.3989	0	0.3989
PP-MP (°)	0.3252	0.3536	0.4385	0.3693	0	0.3693
UFH (N-ANS)	0.2942	0.4494	0.4599	0.3198	0	0.3198
LFH (ANS-Me)	0.2594	0.3101	0.4903	0.4395	0.2132	0.4885
UFH/LFH (%)	0.3101	0.3	0.4489	0.1895	0.2205	0.3606
PFH (S-Go)	0.3101	0.3922	0.5	0.3198	0.533	0.6216
AFH (N- Me)	0.2594	0.4043	0.3669	0.1066	0.282	0.3015
PFH/AFH (%)	0.1641	0.2725	0.3777	0	0.3268	0.3268
Pog-Sv	NA	NA	NA	43.1706	0.3198	43.0791
Dental Parameters						
U1-SN (°)	0.3101	0.3536	0.5633	0.282	0.2611	0.3844
IMPA (°)	0.4043	0.3101	0.3798	0.5839	0.2611	0.7385
U1-L1 (°)	0.2942	0.5095	0.7071	0.2132	0.3198	0.3844
U6-PP	0.3397	2.0709	1.8964	0.3371	0.4395	0.5539
U6-Sv	0.3101	0.3536	0.4703	0.4129	0.3371	0.5741
L6-MP	0.0981	0.2942	0.3101	0.2611	0.2611	0.3693
L6-Sv	1.197	0.3101	1.3265	0.3371	0.3371	0.4523
U1-Sv	0.3101	0.2402	0.4385	0.4129	0.3015	0.5112
U1-PP	1.7894	0.2942	1.8134	0.282	0.3989	0.2384
L1-Sv	0.2942	0.4494	0.6651	0.3198	0.2611	0.3536
L1-MP	0.2942	0.4043	0	NA	NA	NA
Soft Tissue Parameters						
G-Sn-Pg (°)	0.416	0.4599	0.7071	0.3371	0.5	0.5436
Nasolabial angle (°)	0.4043	0.2193	0.4385	0.3844	0.3371	0.4647
E line-Ls	0.4903	0.3101	0.546	0.3693	0.1508	0.3693
E line-Li	0.1961	0.2402	0.3101	0.2384	0.1066	0.2611

Table III. Pearson's Correlations for Two Separate Data Collections						
	Forsus			Implant		
	T1	T 2	Change	T1	T 2	Change
Skeletal Parameters						
SNA (°)	0.988	0.9869	0.8772	0.9832	0.9923	0.814
SNB (°)	0.5586	0.9965	-0.1301	0.994	0.9993	0.9477
ANB (°)	0.9843	0.9914	0.9001	0.9883	1	0.955
Go-Gn-SN (°)	0.9977	0.9976	0.9425	0.9962	1	0.9009
PP-MP (°)	0.9964	0.9956	0.9475	0.9966	1	0.9145
UFH (N-ANS)	0.9956	0.9881	0.8521	0.9839	1	0.8592
LFH (ANS-Me)	0.9953	0.9962	0.9697	0.9921	0.9986	0.6569
UFH/LFH (%)	0.998	0.9978	0.9765	0.9993	0.9992	0.9962
PFH (S-Go)	0.9978	0.9962	0.9614	0.9979	0.9947	0.7972
AFH (N- Me)	0.9978	0.9968	0.9822	0.9998	0.9981	0.9454
PFH/AFH (%)	0.9992	0.9977	0.9617	1	0.995	0.9143
Dental Parameters						
U1-SN (°)	0.9983	0.9978	0.9866	0.9989	0.9973	0.9954
IMPA (°)	0.998	0.9992	0.9954	0.9912	0.9985	0.981
U1-L1 (°)	0.9985	0.9937	0.9889	0.9994	0.9968	0.9976
U6-PP	0.9715	0.4788	0.5589	0.9781	0.9318	0.507
U6-Sv	0.9966	0.9964	0.921	0.9976	0.9969	0.8513
L6-MP	0.999	0.9938	0.8991	0.991	0.9886	0.8277
L6-Sv	0.9677	0.9974	0.8025	0.9986	0.9978	0.927
U1-Sv	0.9987	0.9986	0.9558	0.9978	0.9983	0.975
U1-PP	0.7254	0.9912	0.4165	0.9803	0.9677	0.9562
L1-Sv	0.9981	0.9948	0.8993	0.999	0.9994	0.9738
L1-MP	0.994	0.9874	0.9303	NA	NA	NA
Soft Tissue Parameters						
G-Sn-Pg (°)	0.9885	0.9764	0.8979	0.9948	0.986	0.8951
Nasolabial angle (°)	0.9988	0.9996	0.9971	0.9998	0.9996	0.9958
E line-Ls	0.9574	0.9922	0.8368	0.9781	0.9883	0.9418
E line-Li	0.9974	0.9942	0.9522	0.9973	0.9986	0.9904

Table IV. Comparison of morphologic characteristics of the patients treated with the Forsus appliance (G1) and with implants (G2) at T1 (in mm)						
	G1(n=18)		G2(n=14)			
	Mean	SD	Mean	SD	P Value	Sig
Skeletal Parameters						
SNA (°)	80.46	3.26	82.86	3.09	0.217	NS
SNB (°)	74.96	3.72	76.55	3.53	0.682	NS
ANB (°)	5.5	1.99	6.32	1.65	0.206	NS
Go-Gn-SN (°)	27.38	5.47	29.91	6.26	0.1	NS
PP-MP (°)	26.38	5.55	26.77	6.25	0.408	NS
UFH (N-ANS)	52.12	3.66	51.41	2.62	1	NS
LFH (ANS-Me)	62.92	3.9	65.09	4.91	0.682	NS
UFH/LFH (%)	82.96	6.97	79.37	6.19	1	NS
PFH (S-Go)	77.73	6.71	76.95	7.1	1	NS
AFH (N- Me)	114.58	5.69	116.32	6.25	0.414	NS
PFH/AFH (%)	67.73	5.55	66.16	4.84	1	NS
Dental Parameters						
U1-SN (°)	110.58	7.33	108.55	6.83	1	NS
IMPA (°)	99.15	8.32	97.91	4.95	1	NS
U1-L1 (°)	116.62	7.81	119.59		0.683	NS
U6-PP	21.58	2.05	21.91	2.12	1	NS
U6-Sv	44.62	5.48	49.82	6.54	0.12	*
L6-MP	33.92	2.86	27.45	2.62	0.001	*
L6-Sv	41.69	5.88	47.82	7.61	0.1	NS
U1-Sv	74.81	6.9	76.91	8.35	1	NS
U1-PP	28.27	3.21	30.45	2.07	0.206	NS
L1-Sv	65.96	6.7	68.5	10.55	0.217	NS
Soft Tissue Prameters						
G-Sn-Pg (°)	18.62	3.4	19.64	4.86	0.414	NS
Nasolabial angle (°)	93.85	11.89	92.18	17.33	0.444	NS
E line-Ls	-0.73	2.39	0.55	1.72	0.217	NS
E line-Li	-0.31	3.54	2.55	4.24	0.217	NS
NS indicates not significant; * P < 0.05						

Table V. Comparison of the treatment changes(T2-T1) between G1 and G2 (in mm)						
	G1(n=18)		G2(n=14)			
	Mean	SD	Mean	SD	P Value	Sig
Skeletal Parameters						
SNA (°)	-0.58	1.3	-0.18	1.23	0.357	NS
SNB (°)	0.96	1.55	0.45	1.19	0.679	NS
ANB (°)	-1.54	1.05	-0.64	0.98	0.182	NS
Go-Gn-SN (°)	-0.31	1.09	-0.5	1.26	0.414	NS
PP-MP (°)	-0.81	1.75	-0.41	1.26	0.682	NS
UFH (N-ANS)	0.46	1.16	-0.14	0.84	0.105	NS
LFH (ANS-Me)	0.96	2.46	0.36	0.95	1	NS
UFH/LFH (%)	0.03	2.58	-4.41	5.73	0.414	NS
PFH (S-Go)	1.96	2.6	1.59	0.94	1	NS
AFH (N- Me)	1.5	2.61	0.18	1.17	0.123	NS
PFH/AFH (%)	0.84	1.71	1.23	0.92	0.414	NS
Dental Parameters						
U1-SN (°)	-7.31	5.07	-12.41	5.76	0.01	*
IMPA (°)	10.69	5.36	-4.82	5.36	0	*
U1-L1 (°)	-2.35	6.97	16.59	6.67	0	*
U6-PP	-1.08	1.08	-0.64	0.78	1	NS
U6-Sv	-0.62	1.73	-0.45	0.79	1	NS
L6-MP	1.15	0.72	0.82	0.75	0.386	NS
L6-Sv	3.42	2.62	0.64	1.1	0.002	*
U1-Sv	-3.12	1.93	-5.18	2.74	0.123	NS
U1-PP	1.5	0.98	-1.32	1.08	0	*
L1-Sv	3.96	1.97	-1.77	2.16	0.001	*
Soft Tissue Parameters						
G-Sn-Pg (°)	-0.77	2.26	-2.18	1.33	0.123	NS
Nasolabial angle (°)	8.19	8.06	11.55	6.4	0.012	NS
E line-Ls	-1.19	1.3	-2.41	1.22	0.078	NS
E line-Li	1.85	1.39	-2.73	2.4	0.001	*
NS indicates not significant; * P < 0.05						

Table VI. Comparison of the treatment changes (in mm)(T2-T1) in patients treated with the Forsus appliance(G1)							
	T1			T2			
	Mean	SD		Mean	SD	P Value	Sig
Skeletal Parameters							
SNA (°)	80.46	3.26		79.88	2.85	0.118	NS
SNB (°)	74.96	3.72		75.92	3.1	0.048	*
ANB (°)	5.5	1.99		3.96	1.86	0.003	*
Go-Gn-SN (°)	27.38	5.47		27.08	5.45	0.356	NS
PP-MP (°)	26.38	5.55		25.58	5.35	0.125	NS
UFH (N-ANS)	52.12	3.66		52.58	3.14	0.136	NS
LFH (ANS-Me)	62.92	3.9		63.88	5.1	0.389	NS
UFH/LFH (%)	82.96	6.97		83	5.94	0.944	NS
PFH (S-Go)	77.73	6.71		79.69	6.46	0.025	*
AFH (N- Me)	114.58	5.69		116.08	7.34	0.085	NS
PFH/AFH (%)	67.73	5.55		68.58	5.09	0.116	NS
Dental Parameters							
U1-SN (°)	110.58	7.33		103.27	7.65	0.001	*
IMPA (°)	99.15	8.32		109.85	11.13	0.001	*
U1-L1 (°)	116.62	7.81		114.27	6.6	0.254	NS
U6-PP	21.58	2.05		20.5	1.84	0.012	*
U6-Sv	44.62	5.48		44	5.96	0.263	NS
L6-MP	33.92	2.86		35.08	2.85	0.003	*
L6-Sv	41.69	5.88		45.12	6.19	0.005	*
U1-Sv	74.81	6.9		71.69	6.39	0.002	*
U1-PP	28.27	3.21		29.77	3.08	0.002	*
L1-Sv	65.96	6.7		69.92	6.48	0.002	*
L1-Mp	45.88	3.73		45.88	3.73	0.001	*
Soft Tissue Parameters							
G-Sn-Pg (°)	18.62	3.4		17.85	3.11	0.254	NS
Nasolabial angle (°)	93.85	11.89		100.04	10.35	0.013	*
E line-Ls	-0.73	2.39		-1.92	3.05	0.013	*
E line-Li	-0.31	3.54		1.54	3.21	0.004	*
NS indicates not significant; * P < 0.05							

Table VII. Comparison of the treatment changes (in mm)(T2-T1) in patients treated with implants (G2)

	T1		T2				
	Mean	SD	Mean	SD	P Value	Sig	
Skeletal Parameters							
SNA (°)	82.86	3.09	82.68	3.36	0.571	NS	
SNB (°)	76.55	3.53	77	3.38	0.159	NS	
ANB (°)	6.32	1.65	5.68	1.91	0.049	*	
Go-Gn-SN (°)	29.91	6.26	29.41	5.87	0.207	NS	
PP-MP (°)	26.77	6.25	26.36	5.97	0.351	NS	
UFH (N-ANS)	51.41	2.62	51.27	2.11	0.739	NS	
LFH (ANS-Me)	65.09	4.91	65.45	4.92	0.169	NS	
UFH/LFH (%)	79.37	6.19	74.96	7.81	0.016	*	
PFH (S-Go)	76.95	7.1	78.55	7.05	0.004	*	
AFH (N- Me)	116.32	6.25	116.5	6.13	0.763	NS	
PFH/AFH (%)	66.16	4.84	67.39	4.51	0.007	*	
Dental Parameters							
U1-SN (°)	108.55	6.83	96.14	5.07	0.003	*	
IMPA (°)	97.91	4.95	93.09	6.63	0.008	*	
U1-L1 (°)	119.59	7.22	136.18	5.6	0.003	*	
U6-PP	21.91	2.12	21.27	1.78	0.041	*	
U6-Sv	49.82	6.54	49.36	6.25	0.101	NS	
L6-MP	27.45	2.62	28.27	2.45	0.014	*	
L6-Sv	47.82	7.61	48.45	7.51	0.072	NS	
U1-Sv	76.91	8.35	71.73	6.97	0.003	*	
U1-PP	30.45	2.07	29.14	2.18	0.011	*	
L1-Sv	68.5	10.55	66.73	10.12	0.022	*	
Soft Tissue Parameters							
G-Sn-Pg (°)	19.64	4.86	17.45	4.41	0.005	*	
Nasolabial angle (°)	92.18	17.33	103.73	14.42	0.003	*	
E line-Ls	0.55	1.72	-1.86	1.32	0.003	*	
E line-Li	2.55	4.24	-0.18	2.72	0.013	*	
NS indicates not significant; * P < 0.05							

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APPENDIX

This appendix contains the Kolmogorov-Smirnoff tests used to assess the normality of the observed data. Variables where the null hypothesis of normality is rejected are highlighted in **bold**.

Table A – Kolmogorov-Smirnoff Statistics - Time 1

	Forsus			Implant		
	Kolmogorov-Smirnov ^a			Kolmogorov-Smirnov ^a		
	Statistic	df	Sig.	Statistic	df	Sig.
SNA_1	.172	13	.200*	.175	11	.200*
SNB_1	.217	13	.094	.111	11	.200*
ANB_1	.170	13	.200*	.206	11	.200*
GoGnSN_1	.186	13	.200*	.328	11	.002
PPMP_1	.160	13	.200*	.366	11	.000
UFH_1	.187	13	.200*	.274	11	.021
LFH_1	.123	13	.200*	.144	11	.200*
UoverL_1	.247	13	.029	.192	11	.200*
PFH_1	.172	13	.200*	.202	11	.200*
AFH_1	.225	13	.072	.212	11	.179
PoverA_1	.221	13	.084	.277	11	.018
U1SN_1	.227	13	.066	.201	11	.200*
IMPA_1	.147	13	.200*	.168	11	.200*
U1L1_1	.187	13	.200*	.209	11	.194
U6PP_1	.144	13	.200*	.235	11	.090
U6Sv_1	.196	13	.183	.271	11	.024
L6MP_1	.126	13	.200*	.307	11	.005
L6Sv_1	.215	13	.103	.219	11	.147
U1Sv_1	.245	13	.032	.166	11	.200*
U1PP_1	.115	13	.200*	.227	11	.119
L1Sv_1	.178	13	.200*	.155	11	.200*
L1MP_1	.104	13	.200*	.262	11	.034
GSnPg_1	.221	13	.082	.188	11	.200*
Nangle_1	.144	13	.200*	.169	11	.200*
LineLs_1	.158	13	.200*	.238	11	.082
LineLi_1	.183	13	.200*	.225	11	.124

a. Lilliefors Significance Correction

*. This is a lower bound of the true significance.

Table B - Kolmogorov-Smirnoff Statistics - Time 2

	Forsus			Implant		
	Kolmogorov-Smirnov ^a			Kolmogorov-Smirnov ^a		
	Statistic	df	Sig.	Statistic	df	Sig.
SNA_2	.253	13	.022	.222	11	.136
SNB_2	.135	13	.200 [*]	.227	11	.117
ANB_2	.158	13	.200 [*]	.211	11	.185
GoGnSN_2	.150	13	.200 [*]	.267	11	.027
PPMP_2	.158	13	.200 [*]	.398	11	.000
UFH_2	.179	13	.200 [*]	.271	11	.023
LFH_2	.139	13	.200 [*]	.157	11	.200 [*]
UoverL_2	.183	13	.200 [*]	.194	11	.200 [*]
PFH_2	.176	13	.200 [*]	.196	11	.200 [*]
AFH_2	.174	13	.200 [*]	.221	11	.138
PoverA_2	.210	13	.122	.244	11	.065
U1SN_2	.116	13	.200 [*]	.217	11	.154
IMPA_2	.153	13	.200 [*]	.121	11	.200 [*]
U1L1_2	.173	13	.200 [*]	.233	11	.096
U6PP_2	.223	13	.077	.207	11	.200 [*]
U6Sv_2	.280	13	.006	.217	11	.154
L6MP_2	.182	13	.200 [*]	.278	11	.018
L6Sv_2	.277	13	.007	.253	11	.048
U1Sv_2	.253	13	.022	.251	11	.050
U1PP_2	.150	13	.200 [*]	.269	11	.025
L1Sv_2	.220	13	.084	.160	11	.200 [*]
L1MP_2	.191	13	.200 [*]	.256	11	.042
GSnPg_2	.217	13	.095	.186	11	.200 [*]
Nangle_2	.191	13	.200 [*]	.137	11	.200 [*]
LineLs_2	.110	13	.200 [*]	.168	11	.200 [*]
LineLi_2	.162	13	.200 [*]	.163	11	.200 [*]

a. Lilliefors Significance Correction

*. This is a lower bound of the true significance.

Table C - Kolmogorov-Smirnoff Statistics – (T2-T1)

	Forsus			Implant		
	Kolmogorov-Smirnov ^a			Kolmogorov-Smirnov ^a		
	Statistic	df	Sig.	Statistic	df	Sig.
SNA_D	.209	13	.123	.195	11	.200 [*]
SNB_D	.202	13	.149	.261	11	.035
ANB_D	.150	13	.200 [*]	.197	11	.200 [*]
GoGnSN_D	.226	13	.067	.164	11	.200 [*]
PPMP_D	.137	13	.200 [*]	.199	11	.200 [*]
UFH_D	.192	13	.200 [*]	.254	11	.046
LFH_D	.267	13	.012	.203	11	.200 [*]
UoverL_D	.136	13	.200 [*]	.233	11	.096
PFH_D	.174	13	.200 [*]	.280	11	.016
AFH_D	.268	13	.011	.208	11	.200 [*]
PoverA_D	.155	13	.200 [*]	.238	11	.083
U1SN_D	.291	13	.004	.160	11	.200 [*]
IMPA_D	.139	13	.200 [*]	.357	11	.000
U1L1_D	.189	13	.200 [*]	.186	11	.200 [*]
U6PP_D	.226	13	.068	.234	11	.092
U6Sv_D	.157	13	.200 [*]	.339	11	.001
L6MP_D	.200	13	.160	.191	11	.200 [*]
L6Sv_D	.171	13	.200 [*]	.232	11	.100
U1Sv_D	.103	13	.200 [*]	.175	11	.200 [*]
U1PP_D	.157	13	.200 [*]	.150	11	.200 [*]
L1Sv_D	.200	13	.161	.162	11	.200 [*]
L1MP_D	.202	13	.149	.276	11	.019
GSnPg_D	.156	13	.200 [*]	.191	11	.200 [*]
Nangle_D	.279	13	.007	.134	11	.200 [*]
LineLs_D	.133	13	.200 [*]	.268	11	.027
LineLi_D	.159	13	.200 [*]	.172	11	.200 [*]

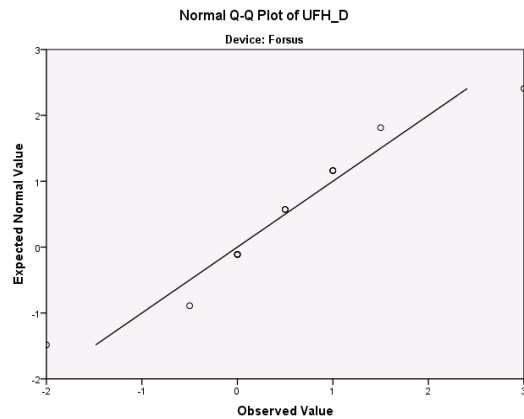
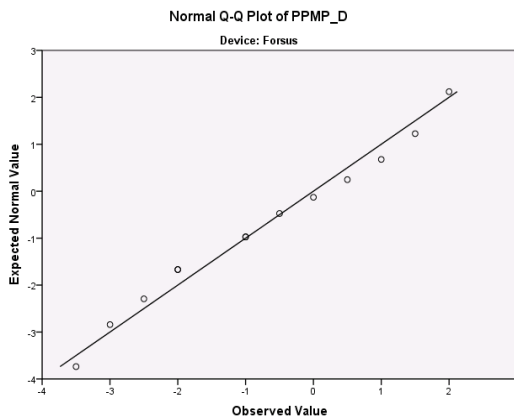
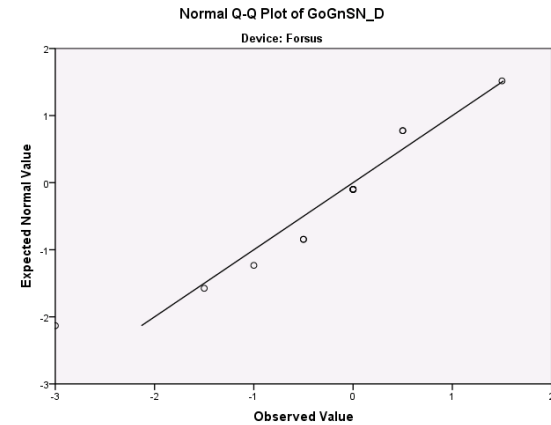
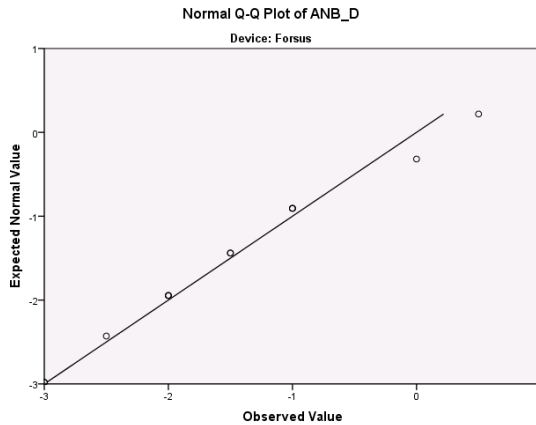
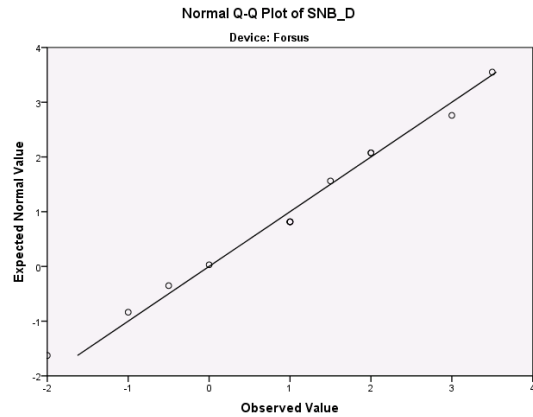
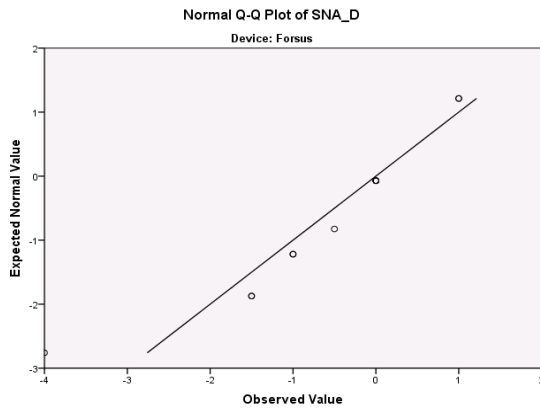
a. Lilliefors Significance Correction

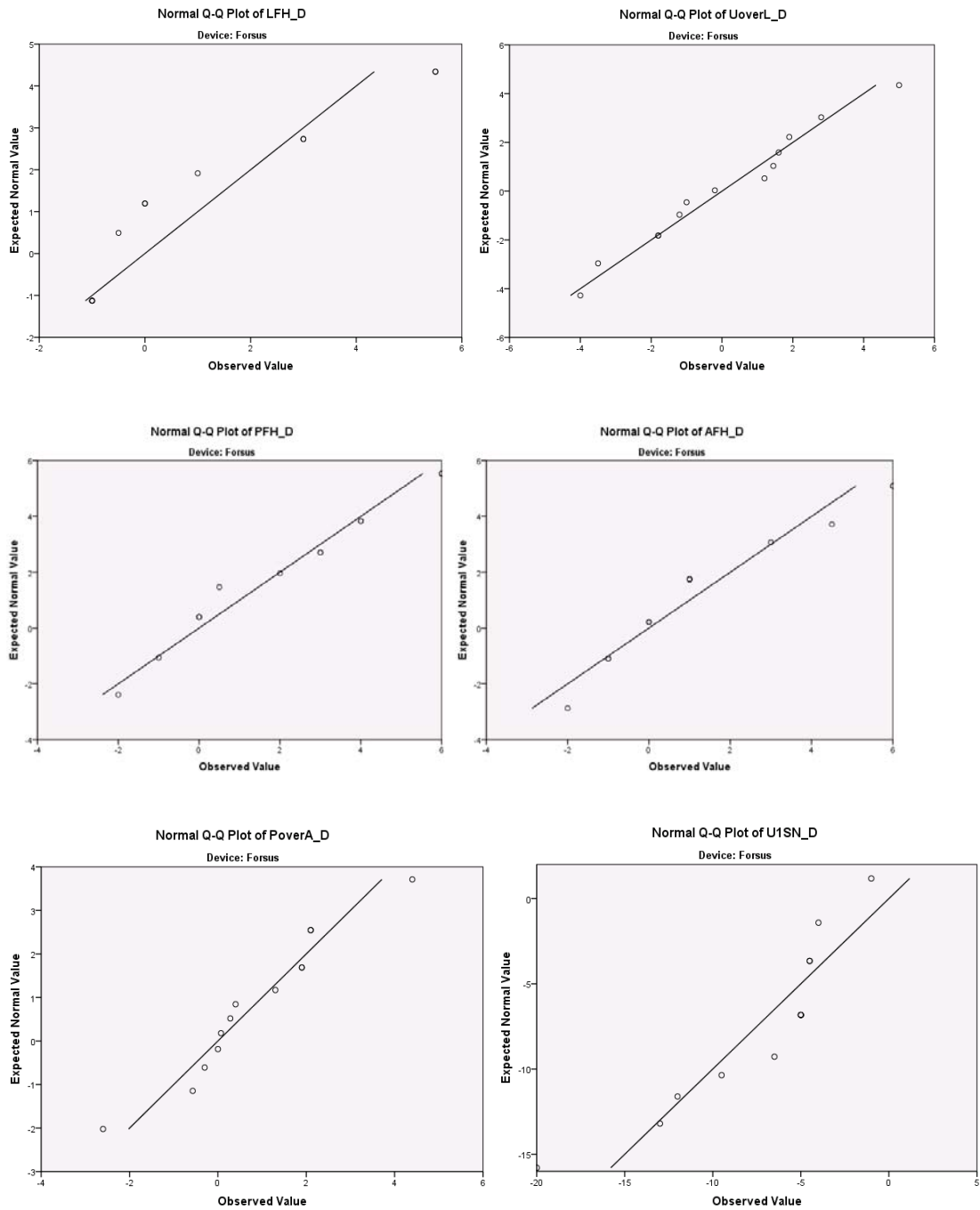
*. This is a lower bound of the true significance.

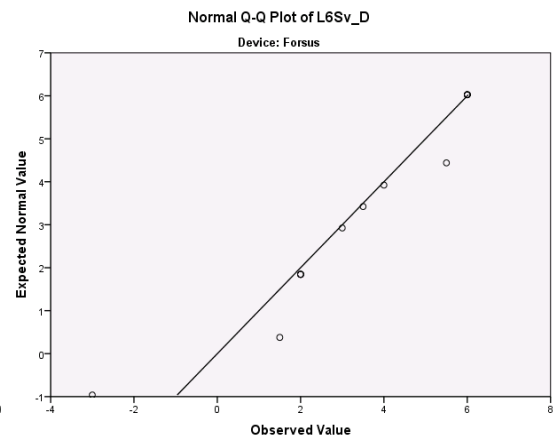
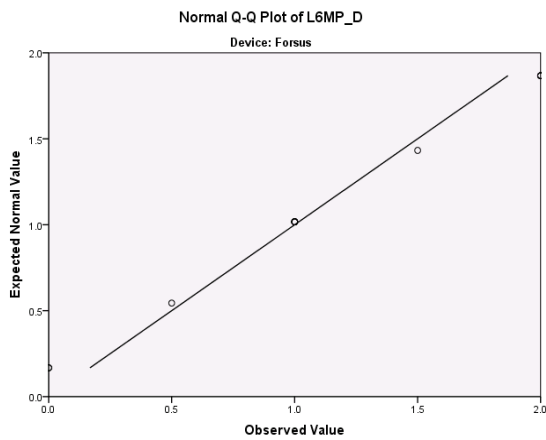
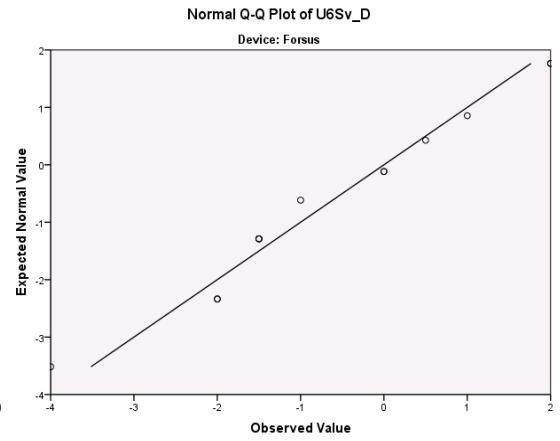
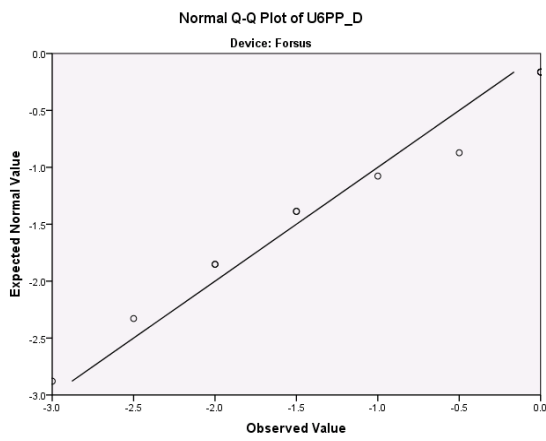
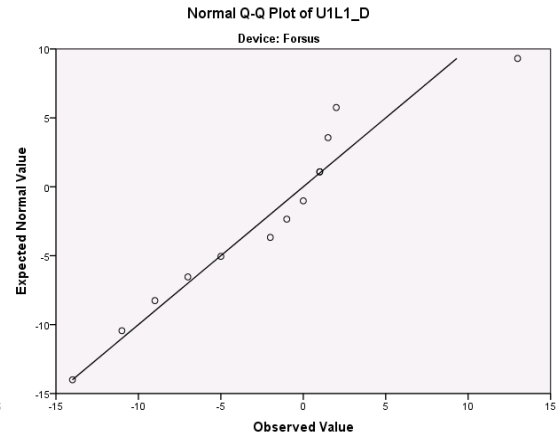
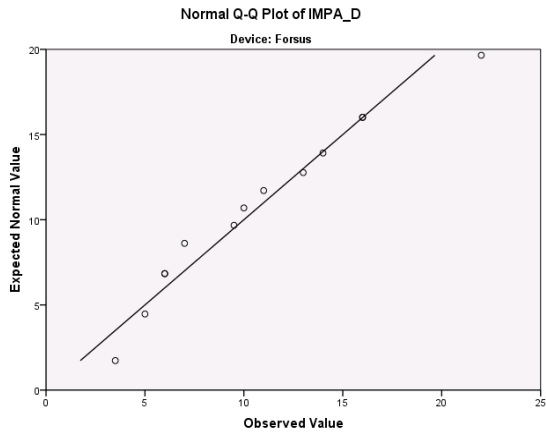
Checking Normality Graphically

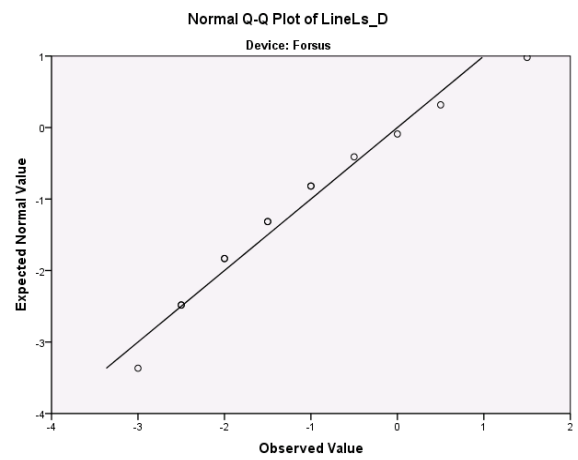
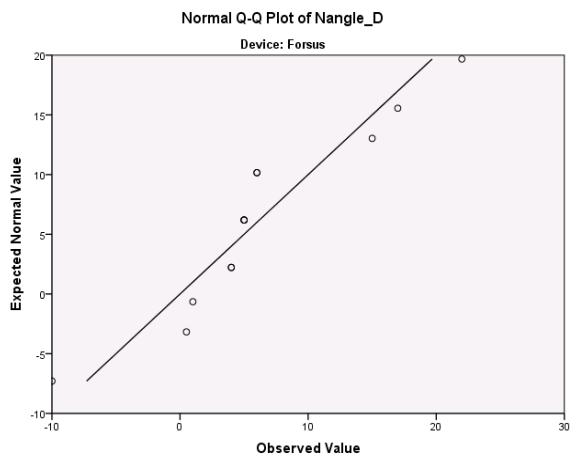
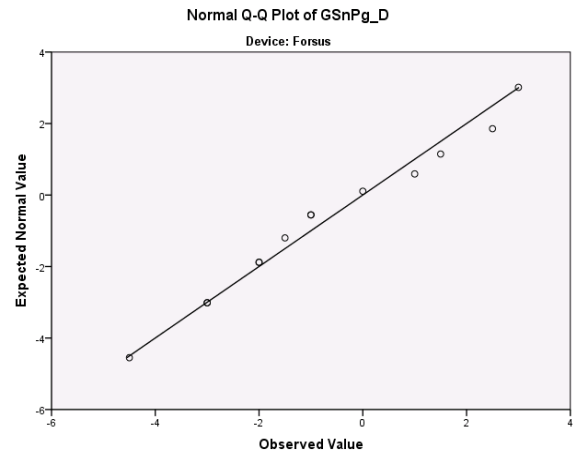
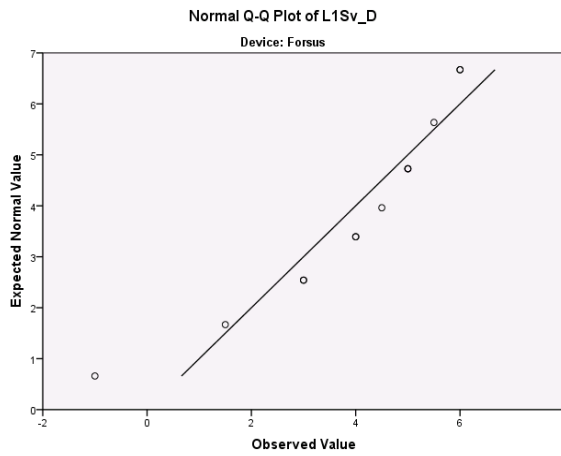
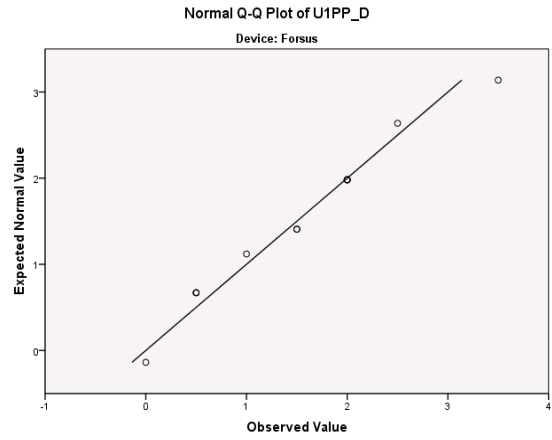
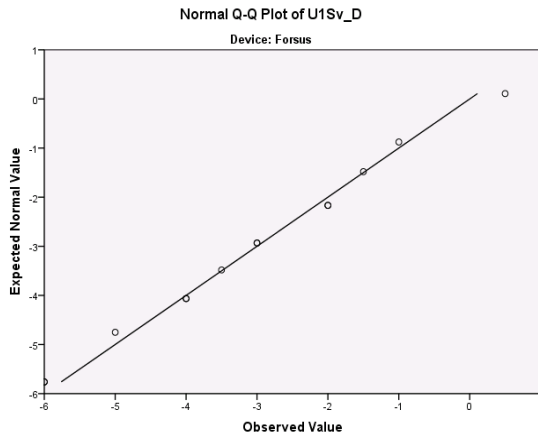
This appendix contains the Q-Q plots used to assess the normality assumption for the t -test.

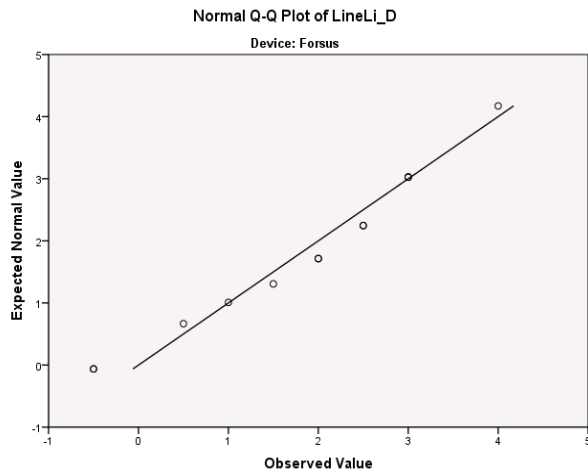
Device = Forsus











Device = Implant

