EFFICIENCY OF THE FLIP LOCK HERBST APPLIANCE IN MANAGEMENT OF ANGLE'S CLASS II DIVISION 1 MALOCCLUSION ON A CLASS II SKELETAL BASE DUE TO RETROGNATHIC MANDIBLE

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BRANCH – V

ORTHODONTICS AND DENTOFACIAL ORTHOPAEDICS

THE TAMILNADU DR. M.G.R MEDICAL UNIVERSITY

CHENNAI – 600 032

2015 – 2018

CERTIFICATE

This is to certify that **Dr.SUSHMITHA.R.IYER,** Postgraduate student (2015-2018), in the Department of Orthodontics and Dentofacial Orthopedics (branch V), Tamil Nadu Government Dental College and Hospital, Chennai-600 003, has done this dissertation titled **"Efficiency of the Flip lock Herbst appliance in management of Angle's class II division 1 malocclusion on a class II skeletal base due to retrognathic mandible"** under my direct guidance and supervision for partial fulfilment of the M.D.S. degree examination in May 2018 as per the regulations laid down by The **Tamil Nadu Dr. MGR Medical University, Chennai-600032** for **M.D.S Orthodontics and Dentofacial Orthopaedics (branch V)**degree examination.

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DECLARATION

I, **Dr.SUSHMITHA.R.IYER**, do hereby declare that the dissertation titled**“Efficiency of the Flip lock Herbst appliance in management of Angle's class II division 1 malocclusion on a class II skeletal base due to retrognathic mandible”**was done in the Department of Orthodontics, Tamil Nadu Government Dental College & Hospital, Chennai 600 003. I have utilized the facilities provided in the Government Dental College for the study in partial fulfilment of the requirements for the degree of Master of Dental Surgery in the specialty of Orthodontics and Dentofacial Orthopaedics (Branch V) during the course period **2015-2018** under the conceptualization and guidance of my dissertation guide, **Professor Dr.SRIDHAR PREMKUMAR,M.D.S.**

I declare that no part of the dissertation will be utilized for gaining financial assistance for research or other promotions without obtaining prior permission from The Tamil Nadu Government Dental College & Hospital.

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TRIPARTITE AGREEMENT

This agreement herein after the “Agreement” is entered into on this.............. day of January 2018 between the Tamil Nadu Government Dental College and Hospital represented by its **Principal** having address at Tamil Nadu Government Dental College and Hospital, Chennai-03, (hereafter referred to as, ‟ the college‟)

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Dr. SRIDHAR PREMKUMAR aged 50 years working as professor at the college, having residence address B-3, Block 2, Jains Ashraya Phase III, Arcot road, Virugambakkam, Chennai-92. (Herein after referred to as the ‘co-investigator)

And

Dr.SUSHMITHA.R.IYER aged 26 years currently studying as postgraduate student in department of Orthodontics in Tamil Nadu Government Dental College and Hospital (Herein after referred to as the “PG/Research student and Principal investigator”).

Whereas the, PG/Research student as part of her curriculum undertakes to research ***“Efficiency of the Flip lock Herbst appliance in management of Angle's class II division 1 malocclusion on a class II skeletal base due to retrognathic mandible.”*** for which purpose the co-investigator and the college shall provide the requisite infrastructure based on availability and also provide facility to the PG/Research student as to the extent possible as a Principal investigator.

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1.
2.

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Ref No: R. C. NO: 0420/DE/2016 date : 01-08-2016

Sub: IEC review of the research proposals,

Title of the work: Efficiency of the flip lock herbst appliance in the management of Angle's class II division 1 malocclusion attributed to retrognathic mandible.

Principal Investigator: Dr.Sushmitha.R.Iyer
IIyr PG student.

Department : Department of Orthodontics and dentofacial orthopaedics,
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Thank you for submitting your research proposal , which was considered at the Institutional Ethics Committee meeting held on the 01.07. 2016, at TN Govt. Dental College and the documents related to the study referred above were discussed and the modifications done as suggested and reported to us through your letter dated 30 - 07 -2016 have been reviewed. The decision of the members of the committee , the secretary and the Chairperson IEC of TN Govt. Dental College is here under:

Approved	Approved and advised to proceed with the study
Approved with suggestions	--
Revision	--

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LIST OF ABBREVIATIONS

FJO	-	Functional Jaw Orthopaedics
FFA	-	Fixed Functional Appliance
RFA	-	Removable Functional Appliance.
RCT	-	Randomised Clinical Trial
CCT	-	Controlled Clinical Trial
SR	-	Systematic Review
CVM	-	Cervical Vertebra Maturation
TMD	-	Temporomandibular Disorder
TMJ	-	Temporomandibular Joint
MRI	-	Magnetic Resonance Imaging
CBCT	-	Cone Beam Computed Tomography
VTO	-	Visual Treatment Objective
IMPA	-	Incisor Mandibular Plane Angle
SO	-	Saggital Occlusal
ABCH	-	Apical Base Change

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1.Participant Information sheet (English)

2. Informed consent (English)

3. Participant Information sheet (Tamil)

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INTRODUCTION

Class II malocclusion is the second most prevalent malocclusion after class I malocclusion encountered in an orthodontic practice. Skeletal class II malocclusion in a growing child with a retrognathic mandible is amenable to growth modification. Functional jaw orthopaedics (FJO) works by enhancing the forward mandibular growth by posturing it forward and or downward. There are various appliances to effect this. They can be either removable or fixed.

Growth modification is typically carried out during the adolescent period which is already rife with many social and developmental issues. Success of any treatment depends on patient compliance. Compliance encompasses elements relating to patients' self-care responsibilities, their role in the treatment process and collaboration with the care providers[1]. Patient compliance is difficult to predict and to some extent, depends on the degree of discomfort and treatment duration[2]. Fixed functional appliances (FFA) place the onus of treatment on the orthodontist, and are continuous in their mode of action with a short length of treatment time[3]. Comparative evidence from recent meta analyses conducted on removable appliances and fixed appliances show that significant changes do occur and the skeletal changes with fixed appliances are greater than the removable ones[4]. Patient perception of treatment is an important factor and this varies among the removable, fixed rigid and fixed flexible variants of functional appliances.[5]

Among the FFAs, there are three types – Rigid, Semi rigid and Flexible[1]. The Herbst appliance, introduced by Dr.Emil Herbst in 1909 and later reintroduced by Pancherz[6] in 1979, is a type of rigid fixed functional appliance.

It has shown consistent results in correction of class II malocclusion. The disadvantages of the Herbst appliance include chewing problems, soft tissue impingement, breakage or distortion of the appliance, bent rods, loose or broken bands and screws[6]. Following its revival, many modifications have come up to address some of these problems.

The Flip lock Herbst (TP Orthodontics Inc.) is a rigid fixed functional appliance, a variant of the Herbst appliance, introduced by Miller[7]. Unlike the Herbst appliance, which uses screws as locking mechanism, the Flip lock Herbst uses ball joints. It is claimed to have better patient comfort and acceptance due to its increased freedom for lateral movements in the mandible, fewer breakages and less chair side time[7].

Although several studies on the Herbst appliance have shown its effectiveness in correction of class II malocclusion, there are no studies till date on the Flip lock Herbst appliance.

AIMS AND OBJECTIVES

Aim:

To assess the efficiency of the Flip lock Herbst appliance in correction of Angle's class II division 1 malocclusion on a class II skeletal base attributed to retrognathic mandible during active growth period.

Objectives:

1. To estimate the skeletal , dentoalveolar, and soft tissue changes in patients treated with the Flip lock Herbst appliance (TP Orthodontics Inc).

2. To analyse the skeletal and dental contributions to the overall correction achieved.

3. To analyse the changes in the condylar region and glenoid fossa.

REVIEW OF LITERATURE

Since the time of its conception, Functional jaw orthopaedics (FJO) has been subjected to numerous evaluations.

CLASS II MALOCCLUSION

Class II malocclusion has a variety of skeletal and dental features and its successful treatment depends on proper diagnosis and treatment planning[8]. FJO is indicated in cases with retrognathic mandible. Earlier there was a philosophical divide concerning the treatment of class II malocclusion with proponents of FJO on one side and others who believed the growth of mandible cannot be altered.

McNamara Jr., (1981)[9] studied 277 subjects aged 8 to 10 years, with class II malocclusion in the mixed dentition period. Mandibular skeletal retrusion was the most common feature. Wide variation in vertical development was also noted with 30 to 50% of the subjects having excessive anterior face height.

Baccetti et al (1997)[10] analysed the position of glenoid fossa in a sample of 180 subjects with different sagittal and vertical problems and found out that in skeletal class II cases a more posterior position of the glenoid fossa is seen when compared to skeletal class III. In subjects with high mandibular plane angle the fossa was more cranial in position in relation to the cranial base when compared to cases with normal or low mandibular plane angle.

Bishara et al (1997)[11] longitudinally evaluated 65 subjects with class II division 1 malocclusion who did not receive treatment. Records were analysed at three stages - completion of deciduous dentition, eruption of first molars and complete eruption of permanent teeth. Significant difference in mandibular length between groups were observed and were more pronounced in the earlier stages. Significant difference was also noted in growth magnitude between groups with greater skeletal and soft tissue convexities in class II division 1 cases.

Ngan et al (1997)[12] studied growth changes in class I and class II cases with longitudinal records between the ages of seven and fourteen using tensor analysis. Most of the class II cases had a skeletal mandibular retrusion. Combination of horizontal and vertical abnormalities were noted rather than maxillary protrusion. An increase in mandibular angle was noted in class II subjects unlike class I subjects. Mandibular length and corpus length were shorter in the class II group. The skeletal differences were not resolved through puberty without treatment with class II subjects having a smaller rate with downward and backward direction.

Stahl et al (2008)[13] studied growth changes in untreated subjects with normal occlusion and class II division 1 through CVM stages CS1 to CS6. Craniofacial growth was assessed using lateral cephalograms and was similar in the two groups but with smaller increase in mandibular length in the class II division 1 group during CS3 to CS4. Class II dentoskeletal disharmony did not tend to self-correct with growth in association with worsening of the deficiency.

Jacob H , Buschang P (2014)[14] evaluated class and sex differences in mandibular growth and modelling among 130 untreated adolescents from records obtained at 10 and 15 years of age. Most of the subjects in class II group had retrusive mandible rather than protrusive maxilla. The group exhibited less vertical condylar growth and less gonial modelling than class I group. Overall mandibular length was shorter in the class II group due to condylar growth deficiencies. Boys had larger mandibles and exhibited greater size increases than girls.

SYSTEMATIC REVIEWS ON FUNCTIONAL THERAPY

Chen, et al (2002)[15] systematically reviewed RCTs from 1966 to 1999 to evaluate the efficacy of functional appliances in enhancement of mandibular growth. Linear and angular measurements were evaluated in treated and control group. Among the measurements only Ar-Pg and Ar-Gn showed significant difference among the treated and control groups. The results suggested that functional appliances had little clinical effect on mandibular length. .

Cozza et al (2006)[16] systematically reviewed the mandibular changes produced by functional appliances in the correction of class II malocclusion against untreated controls from 1966 to 2005 . Four RCTs and 18 CCTs were included in the study. Two thirds of the studies reported a clinically significant enhancement of total mandibular length. RCTs did not report the same. Four linear cephalometric variables and one angular measurement to depict the mandibular length were assessed. Efficiency was calculated by dividing the supplementary elongation of the mandible that was achieved by the treatment duration (number of months). The average coefficient of efficiency was 0.16 mm/month for seventeen months . The highest coefficient of efficiency was (0.28 mm/month) for the Herbst appliance followed by the Twin-block (0.23 mm/month). The short term effect on mandibular growth enhancement was significantly larger when the treatment was instituted at the adolescent growth spurt.

Marsico et al (2011)[17] reviewed RCTs on functional therapy which used anatomic condylion in their cephalometric assessment. Four linear cephalometric variables were considered to analyse mandibular changes . The included RCTs that had instituted functional therapy with removable appliances in the mixed dentition period with mean treatment duration of 15 to 18 months. The effect of functional therapy on mandibular growth in the short term was statistically significant but unlikely to be clinically significant.

D'Antò et al (2015)[18] systematically reviewed all systematic reviews and meta analyses on functional orthopaedic treatment. Fourteen SRs were included . Various appliances were evaluated - headgear (3 studies), Herbst (2) , activator (2) Twin block (4) Jasper jumper (1) Bionator (1) and FR2 (1). The authors concluded that in general there is not enough evidence to support or discourage orthopaedic functional treatment. Reduction in overjet was observed in several functional appliances except Herbst due to poor quality of literature. There was some evidence of mandibular length enhancement after treatment with functional appliances, except Herbst appliance, which presented poor quality of literature. The effect of treatment on soft tissue lacked sufficient evidence, Further implications was on need for long term effects of functional treatment.

SYSTEMATIC REVIEWS ON EFFECTS OF FIXED FUNCTIONAL APPLIANCES

Perinetti et al (2015)[19] conducted a systematic review and meta-analysis on the skeletal and dentoalveolar effects of fixed functional appliances on class II malocclusion in pubertal and post pubertal patients .Out of twelve studies included, eight included patients in the pubertal period and four in the post pubertal period. For the functional therapy alone, supplemental mandibular elongation was 1.95 mm among pubertal and 1.73 mm among post pubertal patients. Functional with multibracket appliance therapy showed 2.22 mm elongation in pubertal patients and 0.44 mm in post pubertal patients. Both mandibular elongation and maxillary growth restraint were seen with skeletal effects more pronounced in pubertal phase. Fixed functional treatment was effective in treatment of class II malocclusion with some dentoalveolar effects and more skeletal effects when performed during puberty.

Bock et al (2016)[20] performed a systematic review and meta-analysis on stability of fixed functional appliance treatment. Twenty studies were included, all on the Herbst appliance except one study , which was on the Twin force bite corrector. Post treatment relapse for ANB , molar relationship, overjet, overbite, soft tissue profile were appraised. The scientific evidence concerning the stability of treatment results was not available for most fixed functional appliances except for Herbst appliance.

The quality of most studies was rather low (evidence level III), but good dentoskeletal stability without clinically relevant changes was found for most variables.

Ishaq et al (2016)[21] studied the effect of fixed functional appliances installed on multibracket appliances against untreated controls. Seven articles were selected based on inclusion criteria. The treatment duration ranged from 4.8 to 7 months. All studies included except one used a flexible or semi rigid variant of fixed functional appliances Level of evidence was weak and based on that no difference was noted for SNB and effective mandibular length. A slightly greater skeletal effect was seen in pubertal subgroup than post pubertal. The vertical dimension was not influenced by the treatment.

STUDIES ON THE HERBST APPLIANCE

Dr.Emil Herbst developed the Okklusionsscharnier or Retentionsscharnier otherwise known as the Herbst appliance[22]. He presented his invention at the 5th International Dental Congress in Berlin in 1909 and published reports about the appliance in 1934. However after that period research on the appliance was dormant until 1979 when Dr Hans Pancherz revived it.

Pancherz (1979)[6] studied twenty boys with class II division 1 malocclusion , out of which 10 were treated with the Herbst appliance, the other 10 served as control. Patient age ranged from 10 to 13 yrs. Treatment duration was 6 months .The anchorage design consisted of wire reinforcement between bands on upper first premolars and first molars and lower lingual arch from first premolar on one side to the other. Construction bite was taken in an edge to edge position of incisors.

Dental casts, cephalometric radiographs and TMJ radiographs were analysed before and after treatment. Treatment resulted in normal occlusion, restriction of maxillary growth with reduction of SNA, increase in mandibular growth and lower facial height but no change in the mandibular plane angle. There was reduction in profile convexity. However during first month of treatment breakage of the appliance and loosened bands were noted.

Pancherz (1981)[23] followed up the cases from his previous research and analysed the records 12 months post-treatment. Partial relapse occurred because of unstable cuspal interdigitations in only 3 cases. Maxillary restraint was seen only during treatment period, with return of SNA values to almost pre-treatment levels after removal of appliance.

Pancherz (1982)[24] analysed skeletal and dental changes in 22 patients treated with the Herbst appliance for 6 months. Two designs for mandibular anchorage was followed for 18 and 4 cases respectively. All the cases achieved the desired correction. The contribution of skeletal and dental changes to molar correction were 43% and 53% respectively. Overjet correction was mainly because of skeletal (56%) and dental (44%) changes. Overall mandibular skeletal changes predominated. No difference was seen in between two groups pertaining to anchorage design. Favourable changes in the mandibular position was mainly due to increase in mandibular length. In few cases it was displaced anteriorly by treatment. This was ascribed to the remodelling processes in the fossa as demonstrated in animal studies or functional adaptation to the advanced position. But the latter was ruled out by careful evaluation of the TMJ radiographs which demonstrated an unchanged condyle fossa relationship.

Pancherz (1982)[25] studied changes in vertical dimension with the use of Herbst appliance. Twenty two patients with class II malocclusion and deep bite were treated with the Herbst appliance and compared against 20 untreated controls. The upper incisors and molars were intruded during treatment and lower molars were allowed to erupt which resulted in correction of deep bite with limited changes in the upper and lower jaws bases. However in four cases, posterior rotation of jaw bases were observed.

Pancherz H and **Anehus-Pancherz M (1993)**[26] studied the short and long term effects of the Herbst appliance on the maxillary complex. Short term effects after therapy for 7 months were assessed. In 69% of the treatment sample, upper molars were intruded during treatment. In 96%, upper molars moved distally. Palatal plane was tipped downward by therapy. Maxillary position in the sagittal dimension was unaffected. Long term effects assessed 6.4 years after treatment most of the changes reverted as normal growth changes occurred. A high pull like headgear effect was seen on the maxillary complex. In long term basis, no difference was seen pertaining to Influence of retention on treatment change and presence or absence of third molars.

Ruf S and Pancherz H (1998)[27] studied long term effect of the Herbst appliance on the TMJ in 20 patients. MRI of the left and right joints along with clinical examination and an anamnestic questionnaire were used. The findings were within the normal range. Five cases showed moderate signs of TMD. Incidence of TMD in the patients were similar to untreated population. The findings were within the normal range

Ruf S and **Pancherz H (1999)**[28] studied 25 adolescent and 14 young adult cases with Class II malocclusions treated with the Herbst appliance. Magnetic resonance imaging (MRI) was used to analyse the remodelling of the temporomandibular joint (TMJ). MRI images were taken at four intervals, before treatment, at the start of treatment , during treatment and after treatment. Condylar and fossa remodelling and changes in the condyle-fossa relationship were analysed. After 6-12 weeks of treatment, signs of remodelling at the postero-superior border of the condyle was noted in most of the cases. Only 3 of the treated patients , demonstrated signs of ramus remodelling. At the anterior surface of the postglenoid spine, signs of glenoid fossa remodelling were noted . Effective TMJ changes were more horizontally directed, compared to untreated controls. Condylar and glenoid fossa remodelling contribute to the enhancement of mandibular growth accomplished by the Herbst.

Manfredi et al (2001)[29] investigated the skeletal effects of Herbst appliance on 25 boys and 25 girls . Conventional cephalometric analyses with European norms were used to study the effects. Paired t test was used to evaluate pre- and post-treatment cephalometric variables. Effects of growth were counteracted by comparison with age and sex matched norms of Bhatia-Leighton standards in terms of z scores. They used a statistical procedure to counteract the effect of growth and sex on the results. Favourable sagittal and vertical jaw base position was found only in males. In both sexes, forward repositioning and mandibular body length increase was noted.

Hagg et al (2002)[30] analysed treatment changes and complications with Acrylic splint Herbst and banded Herbst. 28 children with class II division 1 malocclusion were treated with either banded Herbst appliance or cast metal splint Herbst appliance. Treatment changes were evaluated with lateral cephalograms. The frequency of clinical problems such as fracture and dislodgment were recorded. Both appliances showed similar changes with treatment. For the banded appliances, dislodgement occurred in a few cases and fracture occurred in a relatively large number of cases. For the splinted appliances, among the complications few fractures and more dislodgements occurred. Splinted type showed reduction of clinical and laboratory time spent in mending appliances.

McNamara, Jr et al (2003)[31] studied the changes in condyle, glenoid fossa and ramus of 7 young adult rhesus monkey, treated with the acrylic splint Herbst appliance. 7 monkeys served as controls. The animals were terminated and the TMJ regions of the animals were analysed histologically at 3, 6, 12, and 24-week intervals after placement of the appliance. Adaptive changes in the condylar cartilage were evident at 3 weeks, with the gradual increase in the thickness of the condylar cartilage throughout the experimental period. Minor changes were noted in the articular tissue. All adult control animals had a bony cap that persisted in the experimental animals. Along the anterior surface of the postglenoid spine significant bone deposition occurred only in the 6- and 12-week experimental groups. On the posterior border of the ramus, no evidence of apposition or resorption was seen. Structural adaptations occurred with treatment.

Popowich et al (2003)[32] systematically evaluated the effect of Herbst appliance therapy on temporomandibular joint (TMJ) morphology. 5 studies were selected, out of which 4 used MRI and 1 study used tomograms to evaluate TMJ changes. Conclusive evidence regarding osseous remodelling or condyle position change could not be elicited by the MRI studies. Minor condyle position change was observed in the tomogram study. The minor changes in condyle position relative to the glenoid fossa are clinically not significant. Regarding the disc position, methodological deficiencies hampered consensus.

Pancherz and Michailidou (2004)[33] studied the amount and direction of glenoid fossa displacement, condylar growth and effective TMJ changes in class II division 1 patients treated with the Herbst appliance. Comparison were made among groups based on vertical growth pattern. Cephalograms were examined before, after and 5 years after treatment. In all the groups the fossa was displaced anteriorly and inferiorly. Condylar growth was directed posteriorly and vertically. In the hyperdivergent group, growth was more posteriorly directed than hypodivergent.

DeAlmeida et al (2005)[34] compared 30 untreated controls against 30 cases treated with the Herbst appliance in the mixed dentition period. Treatment duration was 12 months and resulted in significant dental changes. The treatment group showed correction by more dentoalveolar changes than skeletal changes . There was no difference with respect to forward maxillary growth. Statistically significant Increase in mandibular growth was noted with treatment . There was increase in posterior facial height with restriction of vertical development of upper molars and eruption of lower molars. The skeletal changes found in this study were less in comparison to previous studies on Herbst performed in adolescent subjects.

Barnett et al (2007)[35] systematically reviewed the skeletal and dental effects of the crown or banded type of Herbst appliance in cases with class II division 1 malocclusion. Only three studies met the criteria . Findings revealed that there were more dental than skeletal changes in the correction. There was proclination of lower incisors and mesial movement of lower molars and. Upper molars demonstrated significant distal movement and intrusion. Regarding the effects on mandibular sagittal position and length , mixed findings were observed depending on the type of measurement used .Effects on the maxilla were not statistically significant and demonstrated a lack of headgear effect.

Serbesis-Tsarudis and Pancherz (2008)[36] evaluated the effective TMJ and chin position changes in patients with class II division 1 malocclusion. One group consisted of 24 patients treated with fixed orthodontics (Tip Edge) and class II elastics and the other consisted of 40 patients treated with Herbst appliance. Bolton standards were used as control. Orthodontic therapy and class II elastics had less favourable sagittal changes on effective TMJ growth and chin position compared to Herbst treatment.

Wigal et al (2011)[37] studied remodelling of both condyle and glenoid fossa by examining lateral cephalometric radiographs of 22 subjects in the mixed dentition period treated with the crown Herbst appliance. Both condyle and glenoid fossa underwent significant remodelling in forward direction in comparison to the control group. In the treatment group both fossa and condyle were in an anterior position compared to the continued backward changes in the controls.

Jakobsone et al (2013)[38] studied skeletal and dental effects of crown Herbst appliance in 40 patients. Before treatment , after treatment and 1 year follow up lateral cephalometric records were studied. Both dental (66%) and skeletal (34%) changes accounted for class II correction with limited skeletal change. The mandible increased in length 1.5 mm more than the control group. However this change was not statistically significant .During the follow up, rebound changes occurred in the upper molars and lower incisors causing slight increase in overbite and overjet.

LeCornu et al (2013)[39] conducted a pilot study on the three dimensional effects of the Herbst appliance. Seven patients with class II malocclusion were treated with fixed orthodontic treatment and the Herbst appliance in a step wise advancement for 6 to 9 months. Retention period was 3 to 4 months. The control group consisted of class II malocclusion treated with elastics and fixed orthodontic treatment. Cone-beam computed tomography scans (CBCT) were taken before and after treatment. The generated three dimensional models were registered on the anterior cranial bases. Anterior translation of both condyles and glenoid fossa were noted, whereas the controls demonstrated backward movement. Also the A point in controls moved forward in comparison to treatment group. There was no difference in terms of mandibular length, ramal height and gonial angle between the groups. Translation of the glenoid fossa contributed to mandibular positional changes.

Yang et al (2015)[40] systematically reviewed the effects of the Herbst appliance in treatment of Class II malocclusion. Twelve clinical controlled trials were included. All studies had eleven measurements (linear and angular) taken during both active treatment and long term period. Consistent results were seen in meta analysis for all measurements except SNA, ANB and overbite. SNB, mandibular plane angle, and A point-OLp showed publication bias. Significant increase in SNB, decrease in SNA occurred . Both Pg-OLp and Co-Gn were increased following treatment which indicated changes in condylar position and mandibular length. Skeletal and dental changes occurred but their relative contributions was not able to be assessed. Treatment with the Herbst appliance had no effect on the mandibular plane angle. There was also an increase in Co-Go which could have offset the increase observed in mandibular plane angle. Sub group analysis among types of Herbst appliances showed that the banded type had significant changes in SNA, SNB and Pg-OLp. The Herbst appliance was found to be effective for patients with class II malocclusion.

Marchi et al (2016)[41] compared stainless steel crown Herbst appliance with acrylic splint Herbst appliance. Similar sagittal changes were noted in both the groups. Control of Vertical growth pattern was also similar. Crown Herbst showed a slightly increased skeletal contribution to correction and was effective in cases with lack of space in the upper arch.

Souki et al (2017)[42] compared three dimensional effects Herbst appliance on 25 patients in pubertal phase against control group treated with non-orthopaedic treatment modalities. Pre- and post-treatment CBCT scans were taken. Anterior cranial base and regional mandibular registration was done to assess mandibular displacement and mandibular growth. Downward displacement of mandible was seen in both groups; 2.4 mm in Herbst and 1.5 mm in control. Mandible was displaced significantly forward in Herbst group by 1.7 mm. Also in the group, ramal and condylar remodelling was observed.

Nunes do Rego et al (2017)[43] compared profile silhouettes of 21 patients treated with the Herbst appliance for 1 year. Silhouettes taken Before treatment, after treatment and 2 years after treatment were evaluated by orthodontists, lay persons and general dentists . All groups appreciated the profile changes at three stages and preferred the post treatment profiles, however the magnitude of changes in profile were small .Lay persons quantified the greatest magnitude of change.

THE FLIP LOCK HERBST APPLIANCE:

Robert Miller (1996)[7] introduced a variant of the Herbst appliance - The Flip lock Herbst appliance. It had a ball-joint connector instead of screws and reduced the number of moving parts hence reducing the chance of breakage. Improved patient comfort was attributed to its low profile and smooth contour .The soldered ball joint provided for adequate strength and a wide range of motion. The proposed advantages of the Flip lock Herbst appliance were postulated as - Improved patient comfort and acceptance; Fewer clinical problems; Less chairside time for reactivation and less frequent emergency appointments.

STUDIES COMPARING FIXED VERSUS REMOVABLE FUNCTIONAL APPLIANCES

McNamara Jr., **et al (1990)**[44] compared untreated class II malocclusion cases against cases treated with acrylic splint Herbst, and Frankel appliances. Significant skeletal changes were seen in both treatment groups pertaining to mandibular length and lower facial height. Mean mandibular length (Co-Gn) increase was greater for Herbst (4.8 mm/year) followed by Frankel (4.3 mm/year) compared to 2.1 mm/year increase of the control group. They found out a greater increase in lower anterior facial height with Frankel group (2.2 mm) than Herbst (1.8 mm). Greater dentoalveolar effects were seen with the Herbst group.

Kevin O'Brien et al (2003)[45] conducted a multi-centre randomized clinical trial in the United Kingdom on 215 subjects. Age of the subjects ranged from 11 to 14 years at the start of treatment. Either the Herbst or Twin block appliance was used. There was no difference in treatment duration or skeletal and dental effects between the appliances. But Herbst (12.9%) presented with a lower failure to completion rate than twin block (33.6%) at a cost of more appointments for repair due to frequent de-bonding and breakages. Co-operation with the Herbst was better than with twin block. The twin block had a more negative effect on speech, sleep patterns and school work. Phase I functional treatment was rapid with Herbst but phase II was prolonged, hence the overall treatment duration was similar to twin block. The prolonged phase II was attributed to the fact that occlusal settling occurred with selective trimming of the twin block appliance, however the same could not be performed in the fitted Herbst appliance. Girls had a better response to treatment than boys, probably due to differing levels of co-operation. Severity of the initial skeletal discrepancy influenced the outcome, however mandibular plane angle did not influence the treatment outcome. This was contrary to the clinical perception that patients with reduced facial height or larger skeletal discrepancy respond better to functional therapy.

Schaefer et al (2004)[46] compared treatment with stainless steel crown Herbst and twin block appliances. Treatment was carried out in two phases, functional followed by fixed orthodontic treatment. Both groups had similar treatment duration [phase I of 14 months and phase II of 15 months]. Both groups were similar at the start of treatment except for the posterior facial height, which was increased in the twin block group. Also the group had greater overjet with increased maxillary dental proclination and mandibular dental retroclination. Both appliances produced similar effects with minor changes pertaining to mandibular length increase. But the Twin block group underwent greater mandibular advancement evident with changes in SNB and projection of chin to N perpendicular. A significantly larger increase in the nasolabial angle occurred with twin block group. The authors concluded that twin block seemed to be slightly more efficient in correcting molar relationship, sagittal maxillomandibular skeletal differential with greater increase of ramal height.

Baysal A and **Uysal T (2014)**[47] studied the dentoskeletal effects of the twin block and the Herbst appliance in skeletal class II malocclusion with 20 subjects in each group and 20 in the control group. Treatment duration was similar in the Herbst group (15 months) and in the twin block (16 months). No significant differences occurred but greater mandibular skeletal changes were seen in the twin block group. In the control group , changes occurred with growth but the skeletal discrepancy and overjet remained. In the Herbst group, both skeletal and dental changes contributed to correction but significant upper arch distalisation and lower incisor protrusion was noted .

Vaid et al (2014)[48] conducted a meta-analysis of short term treatment effects of functional appliances. 24 articles on RFA and 7 on FFA were included in the review. 1469 (780 treated and 689 control) cases were evaluated in the RFA group and 353 (219 treated and 134 control) in the

FFA group. Statistically and clinically significant effects were seen for mandibular length (2.29 mm) and maxillary dental changes in FFA. RFA on the other hand had 1.61 mm increase in mandibular length which was not clinically significant. Only FFAs had a significant effect on mandibular length but at the cost of anchorage loss by lower incisor procumbency.

Koretsi V et al (2014)[49] published a systematic review and meta-analysis on the effects of removable functional appliances in subjects with class II malocclusion. 1031 subjects were evaluated for skeletal dental and soft tissue changes which were annualised to short term and long term effects. Compared to untreated controls, treatment resulted in modest reduction of SNA, minimal increase in SNB, .Short term evidence indicated that RFA were effective with mainly dentoalveolar effects rather than skeletal. When compared with untreated control, skeletal effects of RFAs were minimal and of negligible clinical importance. Annual increase of SNB was 0.62/year. Regarding long term effects, evidence was inadequate for assessment. This study was followed up by a similar study on FFA .

Zymperdikas et al (2015)[50] conducted a systematic review and meta-analysis on the treatment effects of fixed FFAs in class II malocclusion against untreated class II patients. In the short term, FFA was effective in correction of class II malocclusion with mainly dentoalveolar effects rather than skeletal. However annual increase in SNB (0.87/year) was found to be greater for the FFA than the previous study which reported on RFA (42). Skeletal effects were more pronounced in patients treated before or during growth peak. Compared to single step advancement, stepwise mandibular advancement was associated with greater proclination of the lower incisors and greater retroclination of the upper . Growth pattern on treatment outcome was not assessed due to insufficient data.

Pacha et al (2015)[51] reviewed four articles in their systematic review comparing the efficacy of FFAs versus RFAs in correction of class II malocclusion. Skeletal, dentoalveolar and soft tissue effects were assessed. Controls were not included. Studies on FFAs reported shorter duration of treatment time. The review also focussed on patient centred outcomes. All functional devices irrespective of their type successfully corrected the overjet. The skeletal and dental effects in the sagittal plane were also proportionally similar in between appliance types. But there was little evidence regarding the relative effectiveness of FFA and functional appliances or in relation to patient perception and experiences.

MATERIALS AND METHODS

SELECTION OF SUBJECTS

Ten consecutive patients with class II division 1 malocclusion who reported to the Department of Orthodontics and Dentofacial orthopaedics, Tamilnadu Government Dental College and Hospital, Chennai were included in the study based on inclusion and exclusion criteria.

Inclusion criteria:

1) Patients willing for participation.
2) Permanent dentition with class II division 1 malocclusion.
3) Bilateral full cusp class II molar relationship.
4) Positive VTO (Visual treatment objective) with mandibular advancement.
5) Overjet of 7 to 9 mm.
6) Patients in active growth period [stage : fourth or fifth according to Bjork (1972)[52], Grave and Brown method (1976)][53].
7) Retrognathic mandible (SNB 74°-77°; Nasion perpendicular to Pogonion; Co-Gn).
8) Orthognathic maxilla (SNA 82°$\pm$ 2 ; Point A to Nasion perpendicular; Co – A).
9) Horizontal or average growth pattern.

Exclusion criteria:

1. Patients who have proclined lower incisors (IMPA more than 110°).
2. Patients who have prognathic maxilla.
3. Patients with upper and lower incisor crowding.

4. Presence of midline deviation.
5. Previous history of orthodontic treatment.
6. Previous history of trauma.
7. Presence of systemic diseases.
8. Presence of periodontal disorders.

RECORDS

Following sets of records were taken at T1 (before start of treatment) and T2 (after completion of functional therapy)

- Standardized lateral Cephalometric radiographs in centric occlusion.
- Standardized lateral Cephalometric radiographs in open mouth position to get an unobstructed view of the condylar head [6] .
- Hand wrist radiographs to assess skeletal maturity.
- Photographs.
- Study models

STUDY POPULATION:

Lateral cephalometric records at T1 were hand traced on matte acetate tracing sheets and hand wrist radiographs were examined and patients who fulfilled the inclusion and exclusion criteria were included in the study

Out of 10 patients, two patients dropped out of treatment. The final sample consisted of 8 patients.

MATERIALS FOR APPLIANCE FABRICATION AND APPLICATION:

Flip lock Herbst appliance **(** TP Orthodontics Inc) .

Molar band material (RMO Inc)

Stainless steel wire 0.032”

Silver Solder

Flux

Glass Ionomer Cement

METHODOLOGY

APPLIANCE DESIGN AND BITE JUMPING

- Functional mandibular advancement was done with the Flip lock Herbst appliance (TP Orthodontics Inc) . It consists of two ball connectors, a tube and a plunger on each side[7]
- Upper first molars and first premolars were banded and anchorage was reinforced with a 0.032” stainless steel lingual wire soldered to the first molar and first premolar on each side[6] .
- Lower first molars and first premolars were banded and stabilized with a 0.032” stainless steel lingual wire soldered to the first molar and first premolar from one side to the other side.
- The ball joint connectors for the appliance were soldered on to the buccal surfaces of the bands on upper first molars and lower first premolars.
- The framework was cemented to the upper and lower arches. The tube was connected to the upper ball joint member. Right and left sides are distinguished by red and green dots scribed on the upper head of the tube (Figure 8).

- The plunger length was measured in accordance to the advancement needed to achieve class I molar relation (5 mm). The plunger was then cut to the appropriate length. Plunger was inserted into the tube and the patient was asked to advance the mandible so that the plunger end can be fitted on to the ball joint connector in the lower first premolar.
- The tubes and plungers are fitted on to their respective ball joint connectors and snap fit established.
- Follow-up of all the patients was carried out. For the first month, patients were reviewed once in a week. From the next month onwards, they were reviewed once in a month. Change in molar relationship was checked in the monthly reviews by removing the plunger and tube.
- When class I molar relationship was achieved, the appliance was debanded and records for T2 were taken.

CEPHALOMETRIC ANALYSES

Following cephaometric analyses were performed on pre- (T1) and post-treatment lateral cephalometric records (T2) .

Cephalometric variables definition[54]:

S- Geometric centre of the pituitary fossa .

N- The most anterior point on the frontonasal suture in the sagittal plane

A-The most posterior midline point in the concavity of the maxillary base between anterior nasal spine and prosthion.

B- The most posterior midline point in the concavity of the mandibular base between the infradentale and pogonion.

SNA– Angular relationship of maxilla to cranial base

SNB- Angular relationship of mandible to cranial base

ANB- Angular relationship of maxilla and mandible

SO-ANALYSIS

The Sagittal – Occlusal analysis (SO- ANALYSIS)[24] given by Pancherz was used to study the skeletal and dental effects of the functional therapy. Reference planes for the analysis were :

NSL - line joining the nasion and sella.

OL (occlusal line) – Line connecting upper incisor and distobuccal cusp of the upper permanent first molar.

OLp, (occlusal line perpendiculare) - A line perpendicular to OL through S

MP- Tangential line to the mandibular base.

The occlusal line (OL) and the occlusal line perpendiculare (OLp) from T1 lateral cephalogram were used as a reference plane and was transferred to T2 by superimposition of the tracings on the NSL with S as registration point. The following landmarks were identified and parameters measured.

ii - The incisal tip of the lower central incisor.

is - The incisal tip of the upper central incisor.

mi- The contact point of the mesial suface of lower permanent first molar.

ms- The contact point of the mesial suface of upper permanent first molar.

ss – The deepest point in the concavity of the upper alveolar process.

pg - The anterior most point on the chin.

ar- The intersection of posterior ramal border with the inferior border of the posterior cranial base.

ss/OLp- Position of the maxilla in the sagittal plane.

pg/OLp- Position of the mandible in the sagittal plane.

ar/OLp- Position of the condyle

pg/OLp+ar/OLp – Effective mandibular length.

NSL/MP - Growth pattern of the lower jaw.

is/OLp - Position of the upper central incisor.

ii/OLp - Position of the lower central incisor.

is/OLp-ii/OLp – Overjet.

ms/OLp – Position of the upper first molar.

mi/OLp - Position of the lower first molar.

ms/OLp-mi/OLp - Molar relationship

is/OLp-ss/OLp - Position of the upper central incisor within the maxilla

ii/OLp-pg/OLp - Position of the lower central incisor within the mandible

ms/OLp-ss/OLp -Position of the upper molar within the maxilla

mi/OLp-pg/OLp -Position of the lower molar within the mandible

SOFT TISSUE ANALYSIS :

Effects on the soft tissues were studied by the following variables.

UL STRAIN - Upper lip strain measured as the horizontal distance between the vermilion border of the upper lip and the labial surface of upper central incisor[55]

UL THICKNESS - Upper lip thickness measured as the horizontal distance between the outer border of the upper lip to a point 2 mm below point A.

NLB ANGLE- Nasolabial angle measured as the angle between columella tangent and tangent to the upper lip.

Ns-Ss-Pg[24] – Angle between soft tissue nasion (Ns), Subspinale (Ss) and soft tissue Pogonion (Pg)

E- LL[56] - Lower lip to Ricketts Esthetic plane E, calculated as distance of lower lip from the reference plane E (from tip of nose to the soft tissue pogonion).

BUSCHANG AND SANTOS -PINTO ANALYSIS

Changes in the gleniod fossa and condylar position was assessed by Buschang and Santos Pinto analysis[33]

Reference planes and points :

RL - A line connecting the incisal edge of the lower incisor and the distobuccal cusp tip of the lower first permanent molar.

RLp- A line perpendicular to RL through S.

Co- the most superior and posterior point of the condylar head. This point was marked by transferring the outline of the condylar head from mouth open radiographs to radiographs taken in habitual occlusion.

Fossa position:

Position of the glenoid fossa at T1 and T2 was assessed by superimposition of films on cranial base as described by Bjork and Skeiller[57].

SAGITTAL - Distance between Co and RLp.

VERTICAL - Distance between Co and RL.

Condyle position:

Position of the condyle at T1 and T2 was assessed by superimposition of films on mandible as described by Bjork and Skeiller.

SAGITTAL - Distance between Co and RLp.

VERTICAL - Distance between Co and RL.

Displacement of the glenoid fossa was analysed by comparing T1 (pre-) and T2 (post treatment) values. A positive value indicates forward remodeling and negative value indicates posterior remodeling.

PITCHFORK ANALYSIS :

The Pitchfork analysis[58] was used to quantify the skeletal and dental contribution to the changes observed.

Reference lines and points:

MFOP - Mean functional occlusal plane is determined by averaging the functional occlusal planes on T1 and T2 through regional maxillary superimpositions and transferred through both films .

Fiducial lines – Maxillary and mandibular, help in superimposition of films. They are arbitrary lines marked on each head film corresponding to the superimposition done.

W Point – Wing point is the intersection of greater wing with jugum. Cranial base reference point from which maxillary change is measured.

D point – Centre of the bony symphysis.

Skeletal and dental parameters:

MAXILLA- Skeletal changes in the maxilla (Positive sign denotes distal movement and negative value denotes forward movement)

MANDIBLE- Skeletal change in the mandible (Negative sign denotes distal movement and positive value denotes forward movement). Value derived from formula (MANDIBLE= ABCH - MAXILLA)

ABCH- Sum of maxillary and mandibular skeletal changes as Apical base change.

6/6 – Molar relationship change

U6- Upper molar changes

L6- Lower molar changes

1/1 – Overjet change

U1- Upper incisor change

L1- Lower incisor change

SIGN CONVENTION – Changes favoring correction of class II malocclusion were assigned positive value and changes worsening class II relation were assigned negative values**.**

COLOR CONVENTION - Pre-treatment (T1) tracing was done in black and post functional treatment in red (T2).

Area 1: T1 and T2 films were superimposed by the maxillary regional superimposition on the nasal line, palatal curvature and anterior contour of key ridge. Superimposition was recorded by fiducial line. Maxillary displacement was measured at the W points, ABCH (Apical Base Change) as the displacement of D-points, and upper molar change (U6) at their mesial contact points and upper incisor change (U1) at the incisal edge. All measurements were made parallel to the MFOP.

Area 2: T1 and T2 films were superimposed on natural reference structures of mandible. Lower molar change (L6) was measured at the mesial contact points and lower incisor change (L1) incisor change at the incisal edges.

Area 3: The tracings were registered on the mesial contact points of the upper molars and oriented along the MFOP. Separation of the mesial contact points of the lower molars were measured to calculate molar relationship change (6/6).

Area 4: The tracings were registered on the upper incisors and oriented along the MFOP. Separation of the lower incisor tips were measured to calculate overjet change (1/1).

Formulas to quantify changes :

1) ABCH= MAXILLA + MANDIBLE

Apical base change as sum of maxillary and mandibular skeletal changes.

2) 6/6 = ABCH + U6 + L6

Molar relation change as sum of skeletal (ABCH) and dental changes (U6 +L6)

3) 1/1= ABCH + U1 + L1

Overjet change as sum skeletal (ABCH) and dental changes (U1 +L1)

The results of the analysis will be given in its classical Pitchfork diagram.

Skeletal and dental contributions to molar relationship (6/6) and overjet change (1/1) will be evaluated from the findings of the pitchfork analysis.

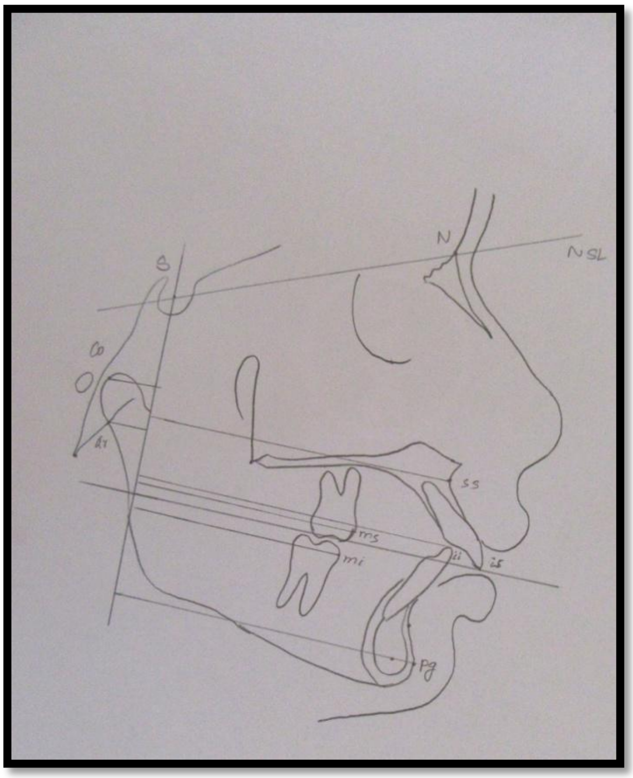
ANALYSIS OF DATA:

Results for T1 and T2 records were calculated and tabulated. Statistical analysis was performed using the Statistical Package for the Social Sciences computer software (SPSS version 22.0) to analyze the data. The Normality tests Kolmogorov-Smirnov and Shapiro-Wilks test was carried out to assess the normality of variables in the study.

COLOR PLATES

1. LATERAL CEPHALOGRAM IN OCCLUSION AND OPEN MOUTH POSITION (T1)

2. SO- ANALYSIS (T1)



3. **HAND WRIST RADIOGRAPH**

4. **EXTRA ORAL PHOTOGRAPHS -PROFILE VIEW WITH VTO (T1)**

5. EXTRA ORAL PHOTOGRAPH-FRONTAL VIEW (T1)

6. INTRA ORAL PHOTOGRAPHS (T1)

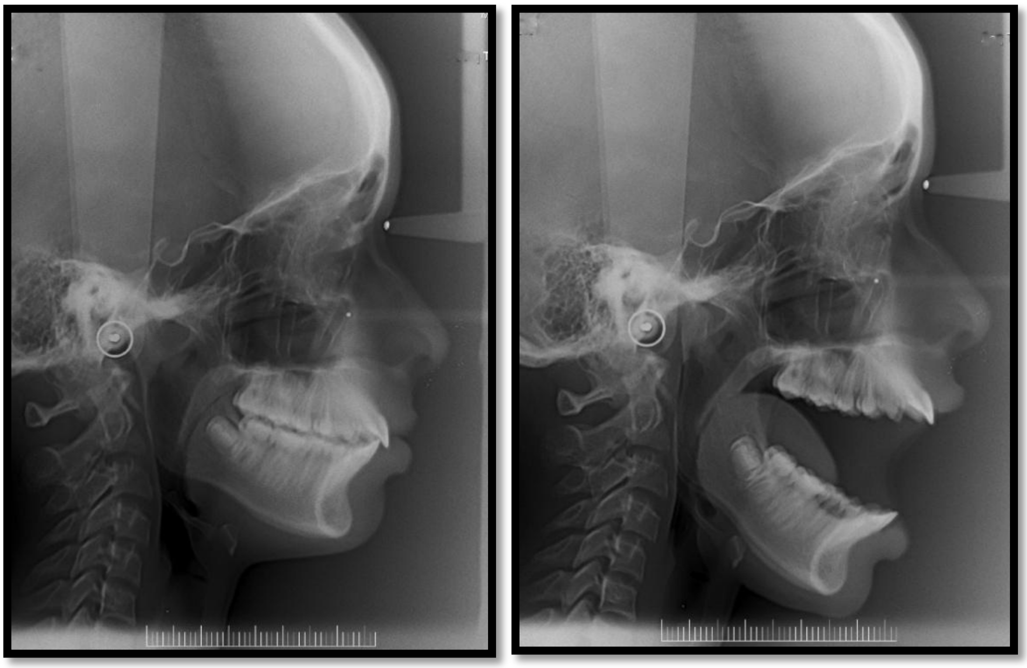
7. APPLIANCE FABRICATION

8. APPLIANCE COMPONENTS AND INSERTION:

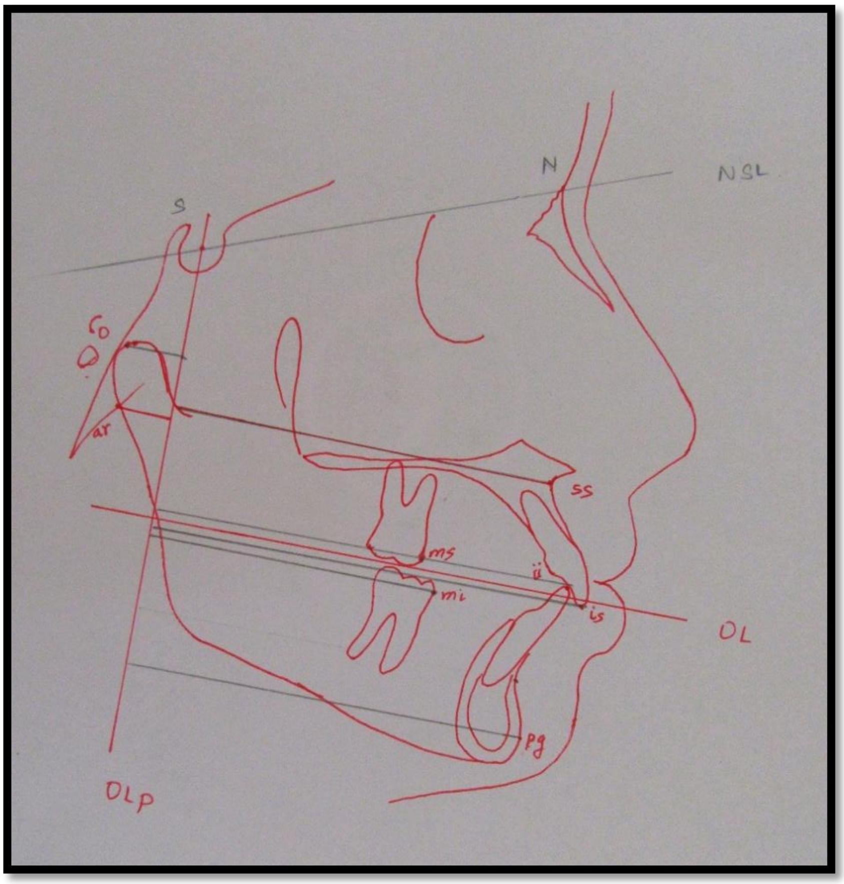
9. INTRA ORAL PHOTOGRAPHS (T2)

10. EXTRA ORAL PHOTOGRAPHS (T2)

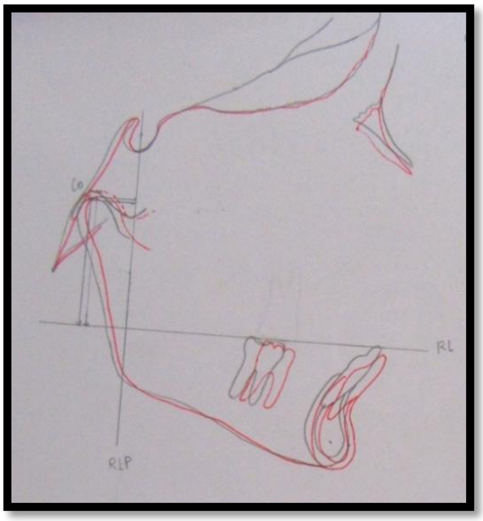
11. LATERAL CEPHALOGRAM IN HABITUAL OCCLUSION AND OPEN MOUTH POSITION (T2)

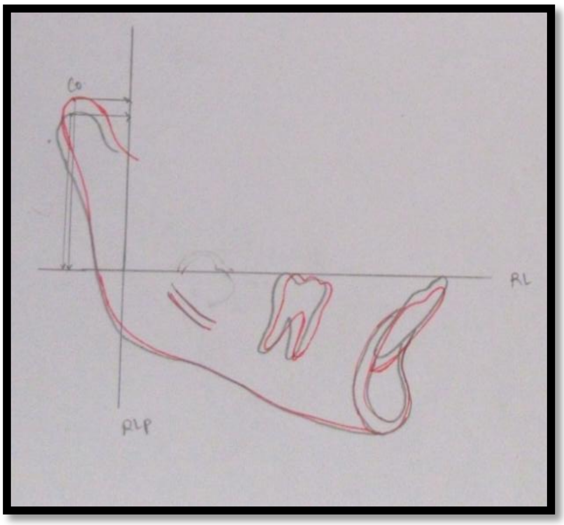


12. SO-ANALYSIS (T2)

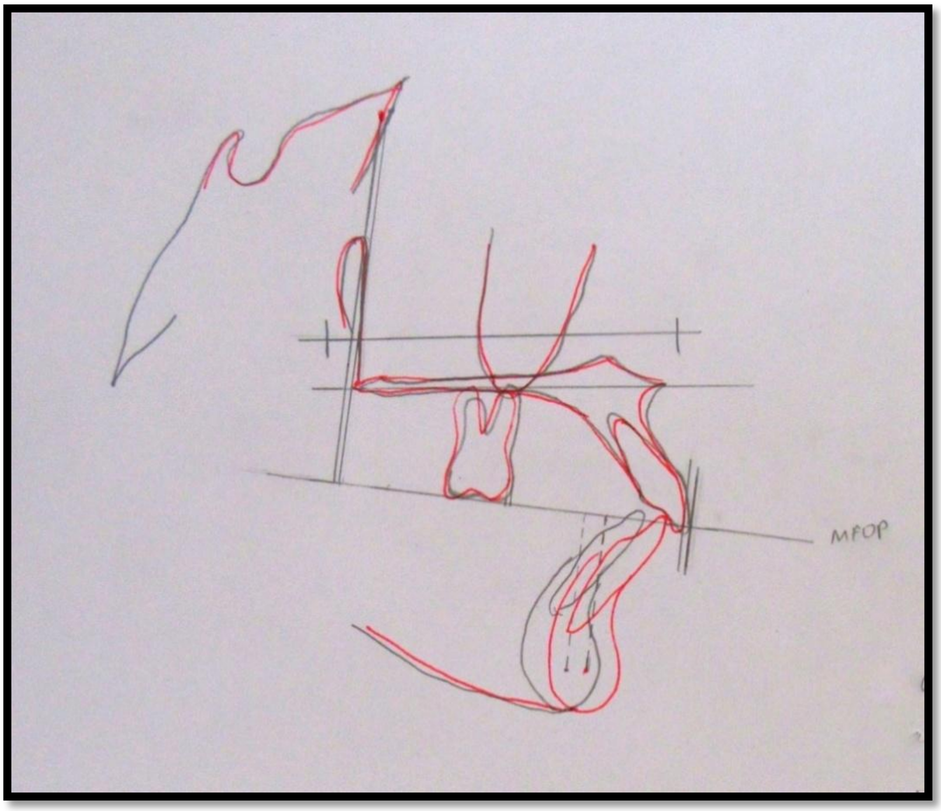


13. BUSCHANG AND SANTOS-PINTO ANALYSIS- GLENOID FOSSADISPLACEMENT AND CONDYLAR GROWTH

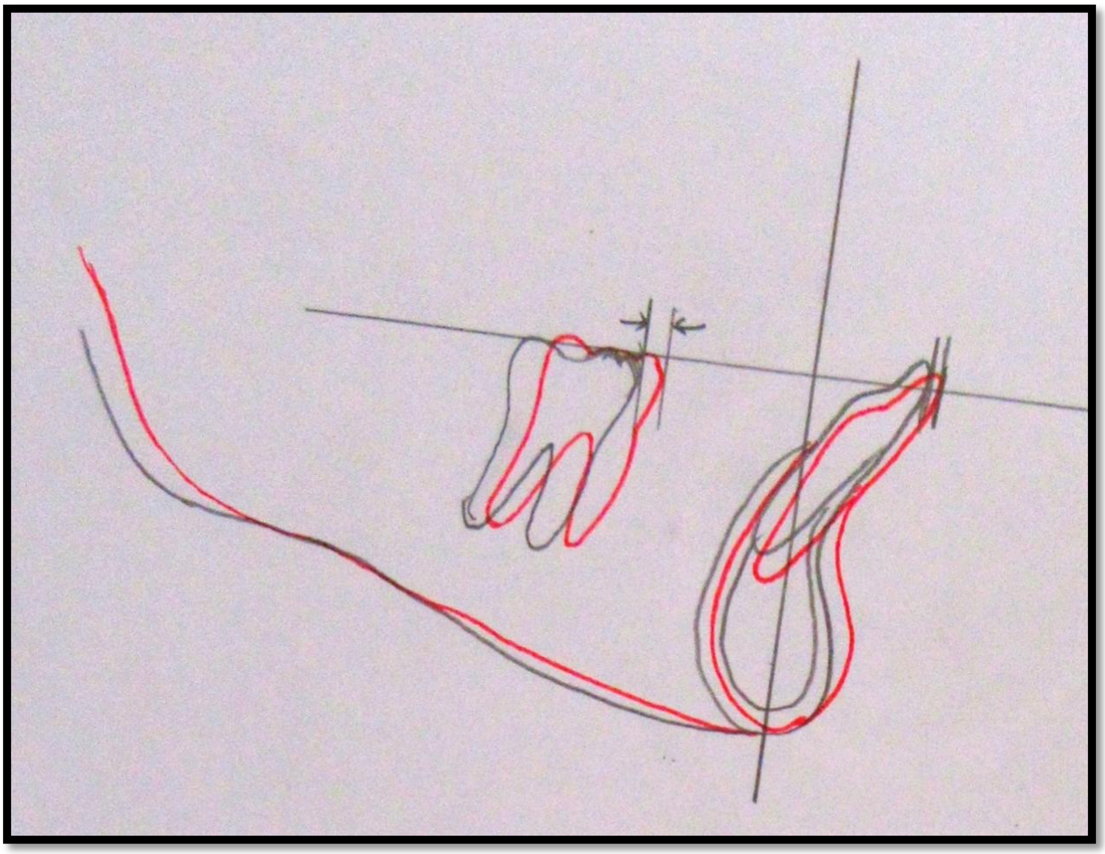




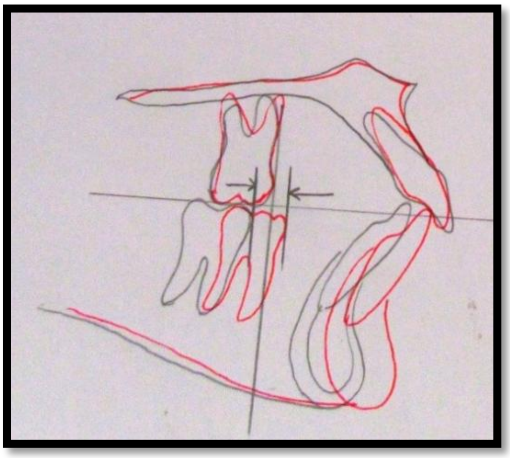
14. PITCHFORK ANALYSIS – SUPERIMPOSITION AREA 1

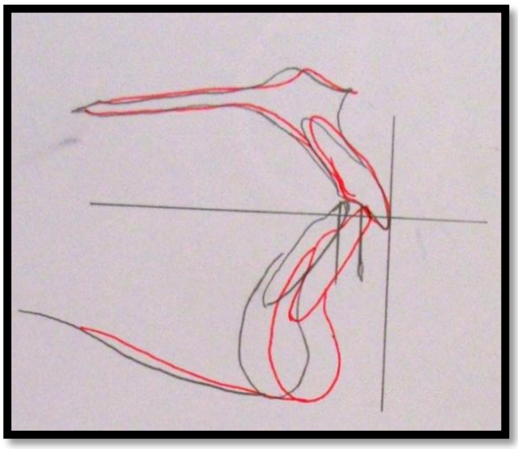


15. PITCHFORK ANALYSIS – SUPERIMPOSITION AREA 2

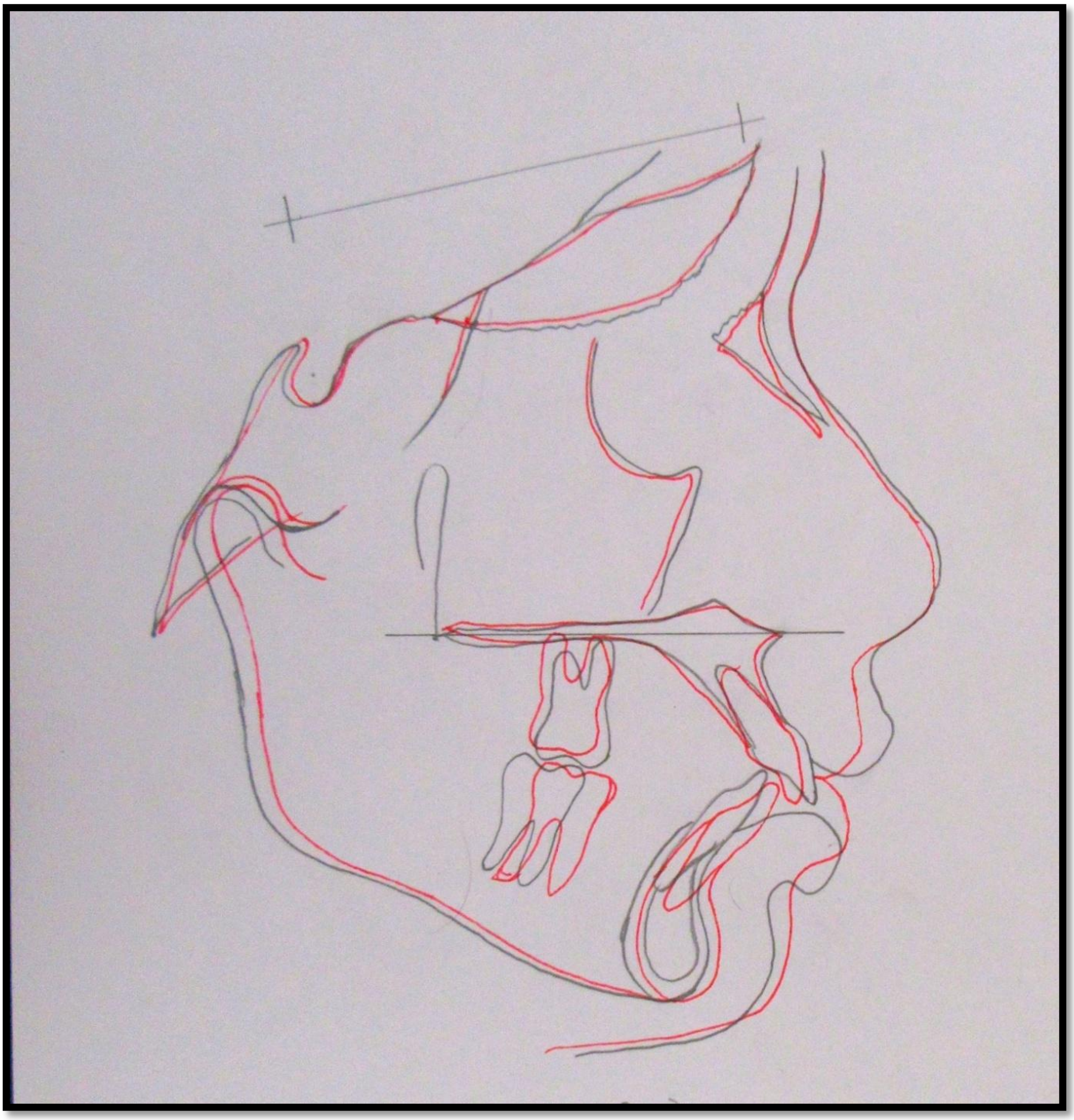


16. PITCHFORK ANALYSIS – SUPERIMPOSITION AREA 3 AND 4





17. CRANIAL BASE SUPERIMPOSITION



18. RANGE OF MOVEMENTS WITH FLIP LOCK HERBST

RESULTS

Four male subjects and four female subjects were included in the study. Details of the patients are summarised in table-1. Pre-treatment (T1) and post-treatment (T2) values were calculated for skeletal, dental and soft tissue cephalometric variables and tabulated (Table -2).

The mean age of the subjects included in the study was 13 years with a range from 12 years to 15. 8 years. The treatment duration lasted for 7.9 months on an average, ranging from 6.1 to 10.3 months (Table -3).

The Normality tests Kolmogorov-Smirnov and Shapiro-Wilks tests results revealed that the variables followed Normal distribution. Therefore, to analyse the data parametric methods were applied. To compare the mean values between pre-treatment and post-treatment, paired samples t-test was applied. To analyse the data SPSS (IBM SPSS Statistics for Windows, Version 22.0, Armonk, NY: IBM Corp. Released 2013) was used. Significance level was fixed as 5% ($\alpha = 0.05$).

SKELETAL EFFCTS :

Comparison of mean values of pre- and post-treatment skeletal parameters (Table 4) showed significant skeletal in the maxilla and mandible.

There was a statistically significant increase ($p= 0.001$) in mandibular length measurement pg/OLp from 71.2 mm to 72.5 mm.

Highly significant increase ($p= 0.015$) in effective mandibular length measurement pg/OLp+ar/OLp from 80.7 mm to 81.8 mm.

Sagittal position of the mandible (SNB) showed highly significant increase from 75.4° to 78.1° ($p<0.001$).

Maxillary position (SNA and ss/OLp) showed a statistically significant decrease. ANB values decreased significantly from 6.3° to 2.8°.

Mandibular plane underwent small but significant counterclockwise rotation from 30° to 29.1°.

DENTAL EFFCTS :

Evaluation of mean values of pre- and post-treatment dental parameters showed that the dental effects were contributory to class II correction.

Reduction in overjet was highly significant ($p<0.001$) from 7.3 mm to 2.6 mm (Table 5).

Molar relationship correction (ms/OLp-mi/OLp) showed highly significant changes (Table 2, 5).

Upper molar (ms/OLp) moved distally and lower molar (mi/OLp) moved mesially and these changes were highly significant. These parameters reflect a combination of skeletal and dental changes.

Upper molar (ms/OLp-ss/OLp) moved distally by 1.5 mm within the upper jaw ($p=0.058$).

Position of the lower molar within the lower jaw was also significant ($p=0.002$) and changed from 22 mm to 20.5 mm depicting favourable movement of lower molar.

Position of the upper incisor within the maxilla was significant ($p<0.001$) and changed from 11.1 mm to 9.3mm denoting retraction of upper incisors

Position of the lower incisor within the mandible was unchanged.

SOFT TISSUE CHANGES :

Statistically significant decrease in upper lip strain was noted.

Slight but statistically insignificant increase in the upper lip thickness.

Nasolabial angle showed significant increase from 99° to 107° and so did soft tissue convexity from 150° to 156°

Position of the lower lip to Ricketts E plane decreased by 0.6 mm but this was not statistically significant. (Table 6)

SKELETAL AND DENTAL CONTRIBUTIONS TO TREATMENT CHANGES :

Skeletal and dental variables contributing to treatment change showed slight inter-individual variation. (Table 9)

Pooled values of Pitchfork analysis is represented as the classic diagram to gain a differential insight into treatment changes. (Chart-26 and Table- 10)

The upper fork represented by skeletal changes in the maxilla. Maxillary growth was restricted by 0.3 mm. The lower fork represents skeletal changes in mandible with 2.8 mm forward growth. The molar relationship change (5.125 mm) at the centre is net result of skeletal contribution (ABCH) and backward movement of upper molar by 0.8 mm. The overjet change (4.938 mm) is net result of skeletal contribution (ABCH) and backward movement of upper incisor by 1 mm and mesial movement of lower incisor by 0.83 mm. Skeletal and dental contributions to molar correction was 61% and 39% respectively. Skeletal and dental contributions to overjet correction was 63% and 37% respectively. (Charts- 24, 25).

CHANGES IN CONDYLAR AND GLENOID FOSSA POSITION:

There was significant difference (p=0.002) in the mean values of sagittal position of the glenoid fossa from 13.18 mm to 13.81 mm. On an average the fossa underwent an anterior relocation by 0.63 mm (Table 8).

There was significant difference (p=0.002) in the mean values of the vertical position of the glenoid fossa from 34 mm to 34.8 mm. On an average the fossa underwent an inferior relocation by 0.8 mm.

Highly significant differences (p<0.001) for condyle position in the sagittal and vertical planes were noted. Sagittal condyle position changed from 12.62 mm to 14.06 mm, denoting an increase in condylar growth by 1.44 mm in the sagittal direction.

Vertical position of the condyle changed from 33.25 mm to 35.31 mm, denoting an increase in vertical growth of the condyle by 2.06 mm.

TABLE 1: SUMMARY OF DETAILS OF PATIENTS TREATED FOR THE STUDY

	1	2	3	4	5	6	7	8
T1	09/07/2016	30/12/2016	02/09/2016	20/02/2017	05/12/2016	30/07/2016	29/12/2016	10/11/2016
T2	13/03/2017	10/10/2017	30/05/2017	24/08/2017	19/08/2017	11/02/2017	21/07/2017	14/07/2017
Age	12 years 4 months	12 years 3 months	15 years one month	13 years 5 months	13 years 9 months	13 year 2 months	12 years	12 years 10 months
Sex	Female	Female	Male	Female	Male	Male	Female	Male
Hand wrist stage	Stage 4	Stage 5	Stage 5	Stage 5	Stage 4	Stage 4	Stage 4	Stage 4

TABLE 2: PRE- AND POST-TREATMENT VALUES OF SKELETAL, DENTAL AND SOFT TISSUE PARAMETERS.

VARIABLES/SUBJECTS	1		2		3		4		5		6		7		8	
SKELETAL	PRE	POST	PRE	POST	PRE	POST	PRE	POST	PRE	POST	PRE	POST	PRE	POST	PRE	POST
SNA	82	80	83	82	82	81	80	80	82	82	81.5	81	83	81	81	81
SNB	74	78	76	78	76	77.5	75	78	75	78.5	76.5	78	75	79	76	78
ANB	8	2	7	4	6	3.5	5	2	7	3.5	5	3	8	2	5	3
ss/OLp	72	69	72	70	73	71	70	70	72.5	69.5	73	72	73	70	73.5	71
pg/OLp	72	73	71	71.5	70	71.5	69	71	72	73.5	73	73.5	73	74	70	72.5
ar/OLp	10	9	9	9	10	10	10	10	9	9.5	9	8.5	10	9.5	9	9
pg/OLp+ar/OLp	82	82	80	80.5	80	81.5	79	81	81	83	82	82	83	83.5	79	81.5
NSL/MP	32	31	29	29	26	24	32	32	29	27	30	29.5	30	30	32	30.5
DENTAL																
is/OLp	84	79	85	79	84	80	81.5	79.5	83.5	79	82	80	85	80	83	81
ii/OLp	76	76	77	77	77	77	74	76	76	77	73	78	77	77	75.5	78
is/OLp-ii/OLp	8	3	8	2	7	3	7.5	3	7.5	2	5.5	2	8	3	7.5	3
ms/OLp	52	49	52.5	48	53	51.5	53	51.5	53	49	49	44.5	53	50	51	48
mi/OLp	50	52	50	52.5	51	53	50	54	50	52.5	45	48	50	53	48	51
ms/OLp-mi/OLp	2	-3	2.5	-4.5	2	-1.5	3	-2.5	3	-3.5	4	-3.5	3	-3	3	-3
is/OLp-ss/OLp	12	10	13	9	11	9	11.5	9.5	11	9.5	9	8	12	10	9.5	10
ii/OLp-pg/OLp	4	3	6	5.5	7	6.5	5	5	4	3.5	3.5	4.5	4	3	5.5	5.5
ms/OLp-ss/OLp	20	20	19.5	22	20	19.5	17	18.5	19.5	24.5	24	27.5	20	20	22.5	23
mi/OLp-pg/OLp	22	21	21	19.5	19	18.5	19	17	22	21	28	25	23	21	22	21.5
SOFT TISSUE																
UL STRAIN	13	14	11.5	13	14	14	12	13.5	12.5	13.5	11	13.5	11	12	11	12
UL THICKNESS	15	15	14	14	16	16	15	15	14	14	13	14	13.5	14	13	13.5
NLB ANGLE	100	100	111	118	95	100	102	108	98	107	99	112	95	105	97	110
Ns-Ss-Pg	153	157	155	160	148	154	153	156	150	155	148	159	146	155	152	154
E- LL	2	0	-2	-1	1.5	0	0	0	2	1	-2	1	3	1	2	0

TABLE 3: DESCRIPTIVE STATISTICS

TREATMENT DURATION AND AGE

	TIME DURATION	**Age**
N	8	8
Mean	7.913	13.1038
Std. Dev.	1.4197	1.00345
Minimum	6.1	12.00
1^{st} Quartile	6.500	12.2700
Median	8.100	13.0000
3^{rd} Quartile	8.875	13.6675
Maximum	10.3	15.08

TABLE 4: PAIRED SAMPLE T-TEST TO COMPARE MEAN VALUES OF SKELETAL PARAMETERS BETWEEN PRE- AND POST-TREATMENT.

Variables		N	Mean	Std. Dev.	t-Value	p-Value
SNA	Pre	8	81.813	.9978	2.728	0.029
	Post	8	81.000	.7559		
SNB	Pre	8	75.438	.8210	7.124	<0.001
	Post	8	78.125	.4432		
ANB	Pre	8	6.375	1.3025	6.089	<0.001
	Post	8	2.875	.7906		
ss/Olp	Pre	8	72.375	1.0938	5.384	0.001
	Post	8	70.313	.9613		
pg/OLp	Pre	8	71.250	1.4880	5.274	0.001
	Post	8	72.563	1.1160		
ar/OLp	Pre	8	9.500	.5345	1.158	0.285
	Post	8	9.313	.5303		
pg/OLp+ar/OLp	Pre	8	80.750	1.4880	3.211	0.015
	Post	8	81.875	.9910		
NSL/MP	Pre	8	30.000	2.0702	2.824	0.026
	Post	8	29.125	2.5460		

TABLE 5: PAIRED SAMPLE T-TEST TO COMPARE MEAN VALUES OF DENTAL PARAMETERS BETWEEN PRE- AND POST TREATMENT.

Variables		N	Mean	Std. Dev.	t-Value	p-Value
is/OLp	Pre	8	83.500	1.2817	6.730	<0.001
	Post	8	79.688	.7039		
ii/OLp	Pre	8	75.688	1.4865	2.072	0.077
	Post	8	77.000	.7559		
is/OLp-ii/OLp	Pre	8	7.375	.8345	16.756	<0.001
	Post	8	2.625	.5175		
ms/OLp	Pre	8	52.063	1.4252	7.442	<0.001
	Post	8	48.938	2.2589		
mi/OLp	Pre	8	49.250	1.9086	11.881	<0.001
	Post	8	52.000	1.8323		
ms/OLp-mi/OLp	Pre	8	2.813	.6512	13.332	<0.001
	Post	8	-3.063	.8634		
is/OLp-ss/OLp	Pre	8	11.125	1.3296	3.949	0.006
	Post	8	9.375	.6944		
ii/OLp-pg/OLp	Pre	8	4.875	1.2174	1.357	0.217
	Post	8	4.563	1.2939		
ms/OLp-ss/OLp	Pre	8	20.313	2.1034	2.262	0.058
	Post	8	21.875	3.0208		
mi/OLp-pg/OLp	Pre	8	22.000	2.8284	4.709	0.002
	Post	8	20.563	2.3670		

TABLE 6: PAIRED SAMPLE T-TEST TO COMPARE MEAN VALUES OF SOFT TISSUE PARAMETERS BETWEEN PRE- AND POST TREATMENT.

Variables		N	Mean	Std. Dev.	t-Value	p-Value
UL STRAIN	Pre	8	12.000	1.1019	4.771	0.002
	Post	8	13.188	.7990		
UL THICKNESS	Pre	8	14.188	1.0670	1.871	0.104
	Post	8	14.438	.8210		
NLB ANGLE	Pre	8	99.625	5.1807	5.112	0.001
	Post	8	107.500	6.0474		
Ns-Ss-Pg	Pre	8	150.625	3.1139	5.112	0.001
	Post	8	156.250	2.2520		
E- LL	Pre	8	.813	1.9261	0.883	0.406
	Post	8	.250	.7071		

TABLE 7: CHANGES IN CONDYLAR AND GLENOID FOSSA POSITION

Sagittal	GLENOID FOSSA			CONDYLE		
SUBJECT	T1	T2	T2-T1	T1	T2	T2-T1
1	12	13	1	12	13.5	1.5
2	13	13.5	0.5	12.5	13	0.5
3	13.5	14	0.5	12.5	14.5	2
4	12.5	12.5	0	12	12.5	0.5
5	14	14.5	0.5	12.5	14.5	2
6	13.5	14.5	1	13.5	15	1.5
7	14	15	1	13	14.5	1.5
8	13	13.5	0.5	13	15	2

Vertical	GLENOID FOSSA			CONDYLE		
SUBJECT	T1	T2	T2-T1	T1	T2	T2-T1
1	34	35	1	33	35.5	2.5
2	33	34.5	1.5	32	33.5	1.5
3	34	35	1	33.5	36.5	3
4	33.5	34	0.5	33	35	2
5	36	36.5	0.5	35	36.5	1.5
6	33	34.5	1.5	32.5	35	2.5
7	34	34	0	33	34.5	1.5
8	34.5	35	0.5	34	36	2

TABLE 8: PAIRED SAMPLE T-TEST TO COMPARE MEAN VALUES OF GLENOID FOSSA AND CONDYLAR POSITION CHANGES

Variables		N	Mean	Std. Dev.	t-Value	p-Value
FOSSA POSITION SAGITTAL	Pre	8	13.188	.7039	5.000	0.002
	Post	8	13.813	.8425		
FOSSA POSITION VERTICAL	Pre	8	34.000	.9636	4.333	0.003
	Post	8	34.813	.7990		
CONDYLE POSITION SAGITTAL	Pre	8	12.625	.5175	6.524	<0.001
	Post	8	14.063	.9425		
CONDYLE POSITION VERTICAL	Pre	8	33.250	.9258	10.362	<0.001
	Post	8	35.313	1.0329		

TABLE 9: PITCHFORK ANALYSIS

VARIABLES	1	2	3	4	5	6	7	8
MAXILLA	0.5	1	1	0	-0.5	-0.5	0	1
MANDIBLE	2.5	1.5	3	3.5	3.5	2.5	3.5	2.5
ABCH	3	2.5	4	3.5	3	2	3.5	3.5
6/6	5	6	6	5	4	5.5	5	4.5
U6	0.5	2	1	0.5	-0.5	2.5	0.5	0
L6	1.5	1.5	1	1	1.5	1	1	1
1/1	4	5	5	4	5.5	4.5	6	5.5
U1	0.5	2	0.5	0	1.5	1	1.5	1
L1	0.5	0.5	0.5	0.5	1	1.5	1	1

TABLE 10: MEAN VALUES FOR PITCHFORK VARIABLES

PITCHFORK	MEAN	STD.DEV.
MAXILLA	.313	.6512
MANDIBLE	2.813	.7039
ABCH	3.125	.6409
6/6	5.125	.6944
U6	.813	.9978
L6	1.188	.2588
1/1	4.938	.7289
U1	1.000	.6547
L1	.813	.3720

CHARTS

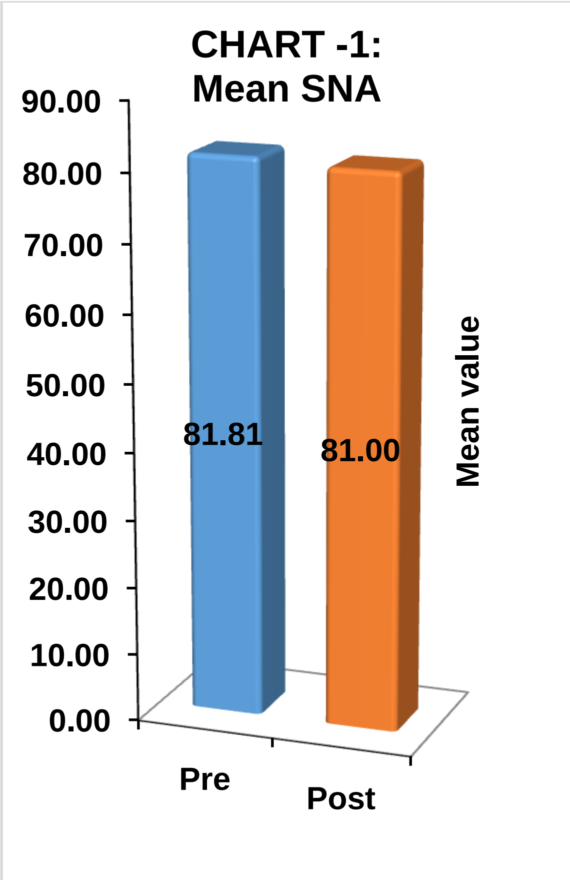


CHART -1:
Mean SNA
90.00
80.00
70.00
60.00
50.00
40.00
30.00
20.00
10.00
0.00
81.81
81.00
Mean value
Pre
Post

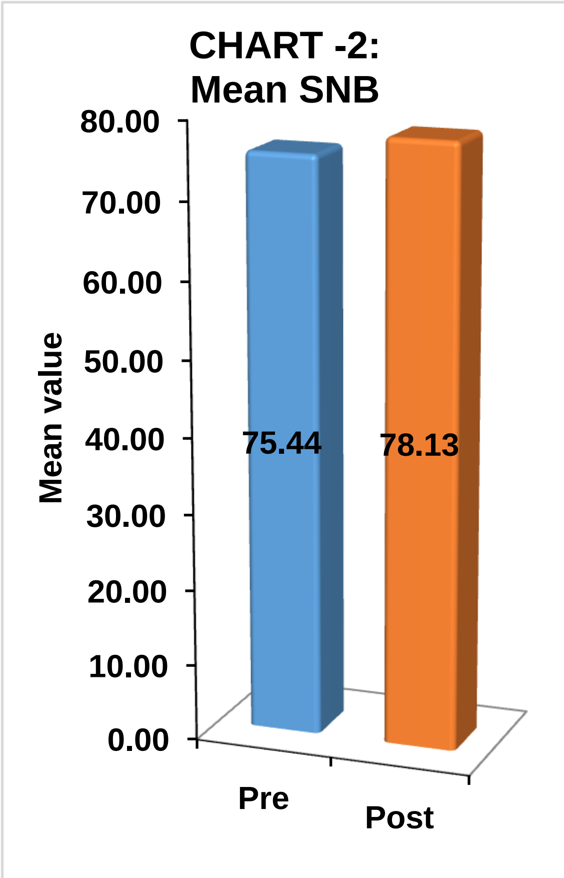


CHART -2:
Mean SNB
80.00
70.00
60.00
50.00
40.00
30.00
20.00
10.00
0.00
Mean value
75.44
78.13
Pre
Post

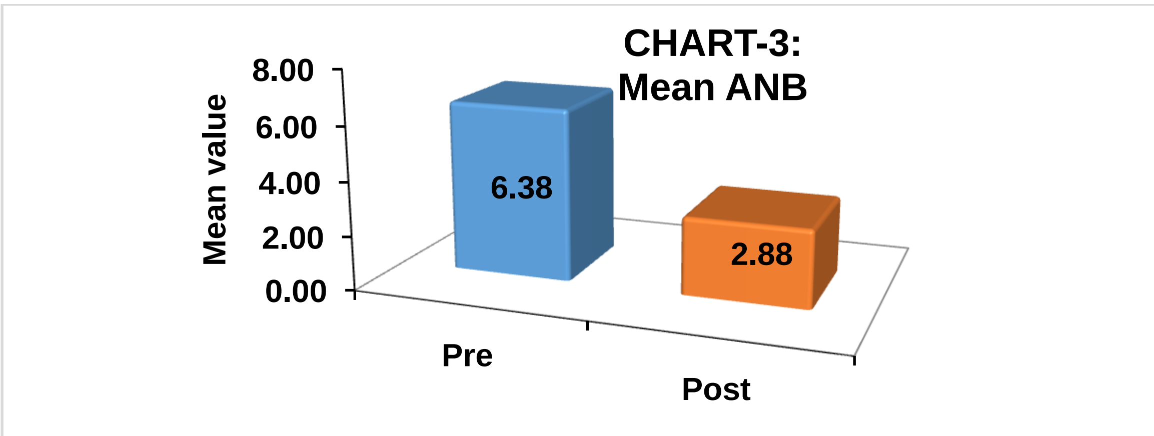


CHART-3:
Mean ANB
8.00
6.00
4.00
2.00
0.00
Mean value
6.38
2.88
Pre
Post

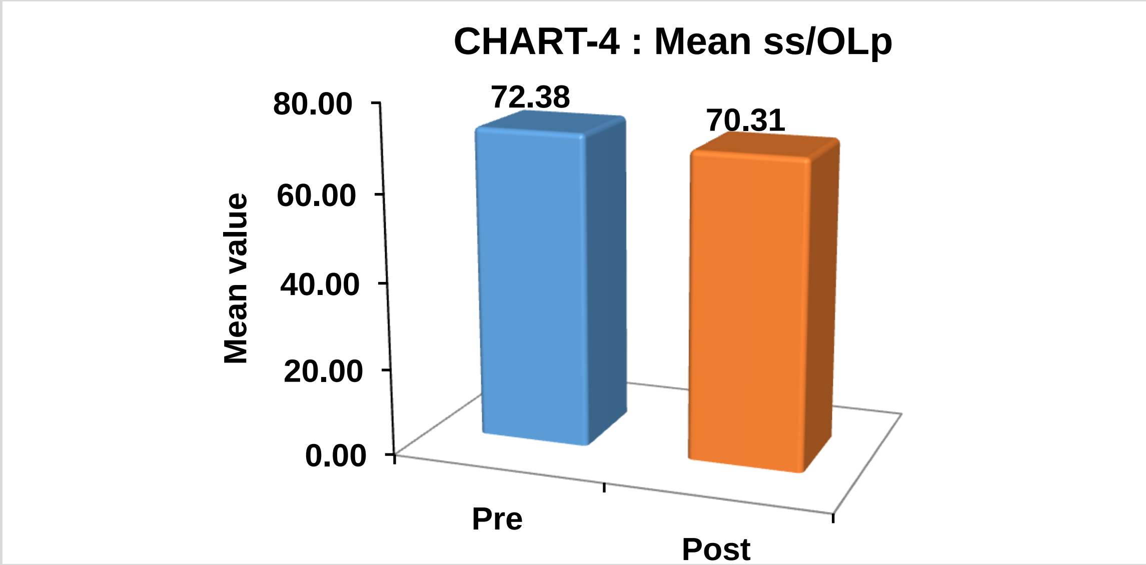


CHART-4 : Mean ss/OLp
Mean value
80.00
60.00
40.00
20.00
0.00
72.38
70.31
Pre
Post

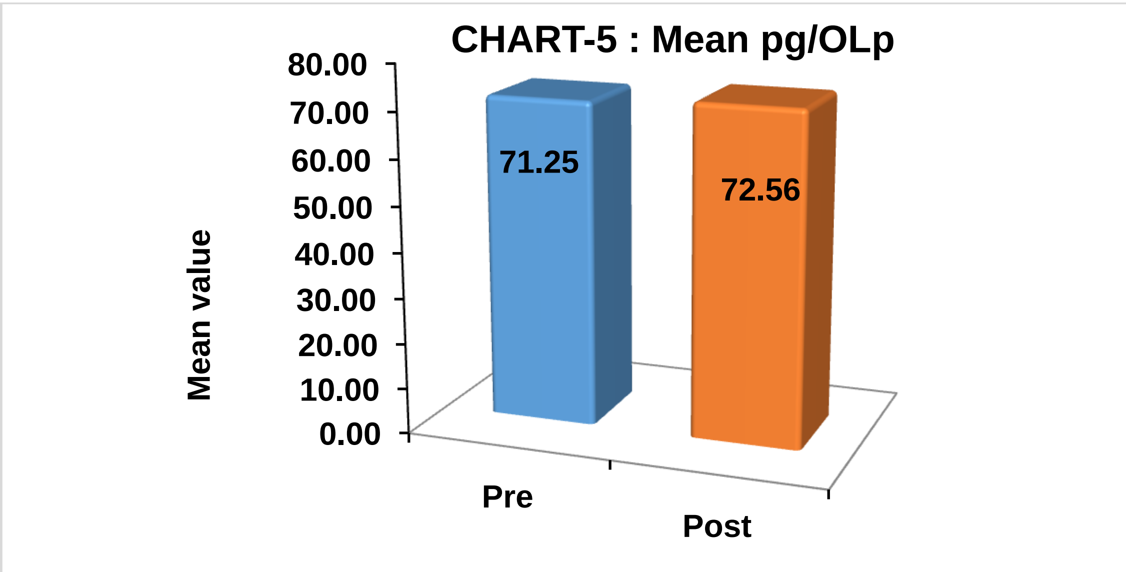


CHART-5 : Mean pg/OLp
Mean value
80.00
70.00
60.00
50.00
40.00
30.00
20.00
10.00
0.00
71.25
72.56
Pre
Post

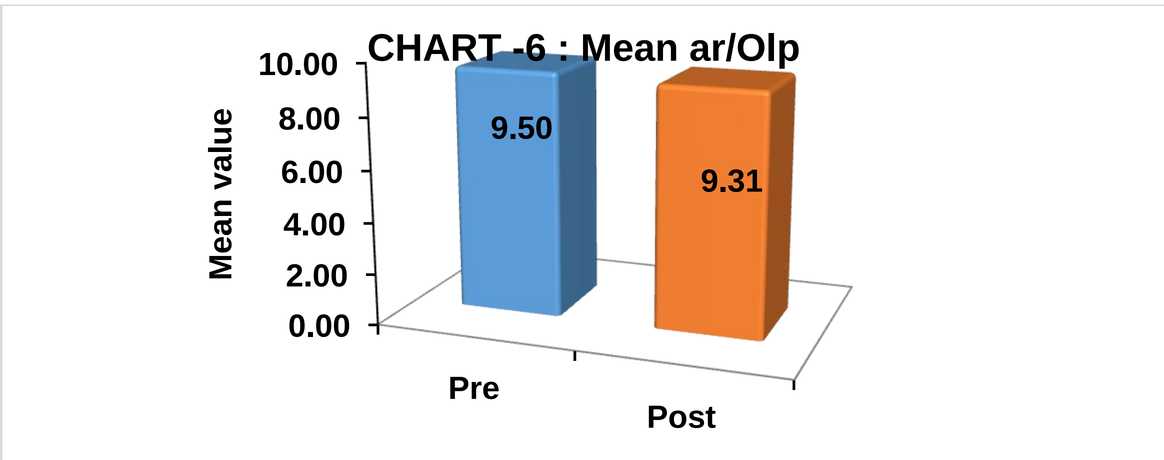


CHART -6 : Mean ar/Olp
Mean value
10.00
8.00
6.00
4.00
2.00
0.00
9.50
9.31
Pre
Post

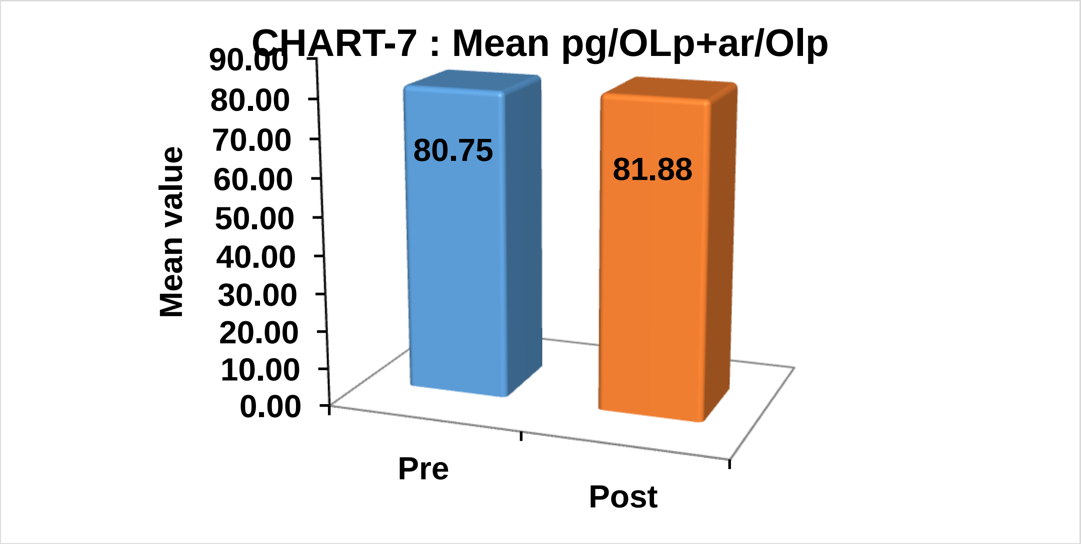


CHART-7 : Mean pg/OLp+ar/Olp
Mean value
90.00
80.00
70.00
60.00
50.00
40.00
30.00
20.00
10.00
0.00
80.75
81.88
Pre
Post

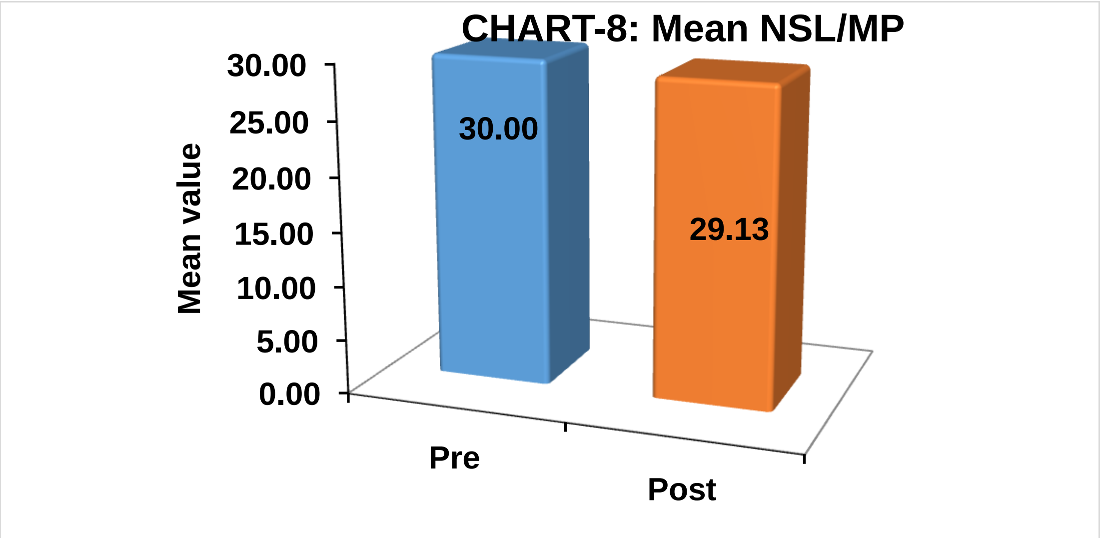


CHART-8: Mean NSL/MP
Mean value
30.00
25.00
20.00
15.00
10.00
5.00
0.00
30.00
29.13
Pre
Post

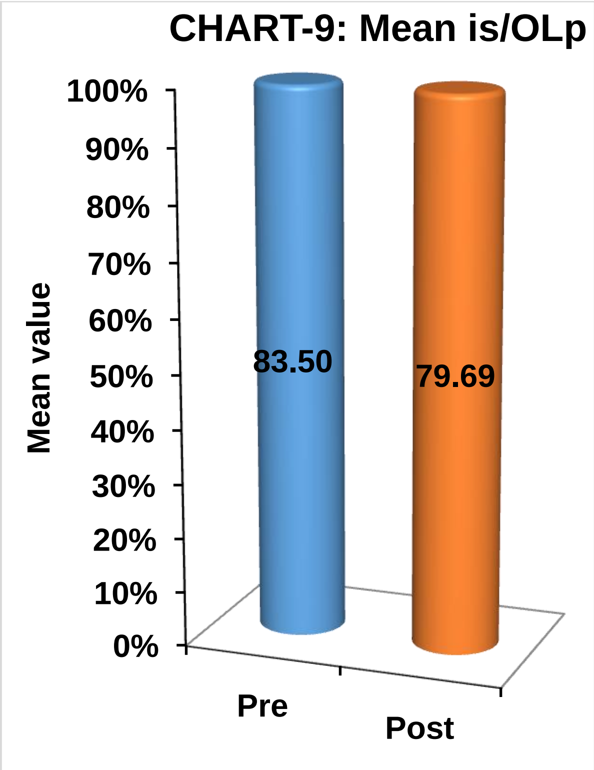


CHART-9: Mean is/OLp
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
Mean value
83.50
79.69
Pre
Post

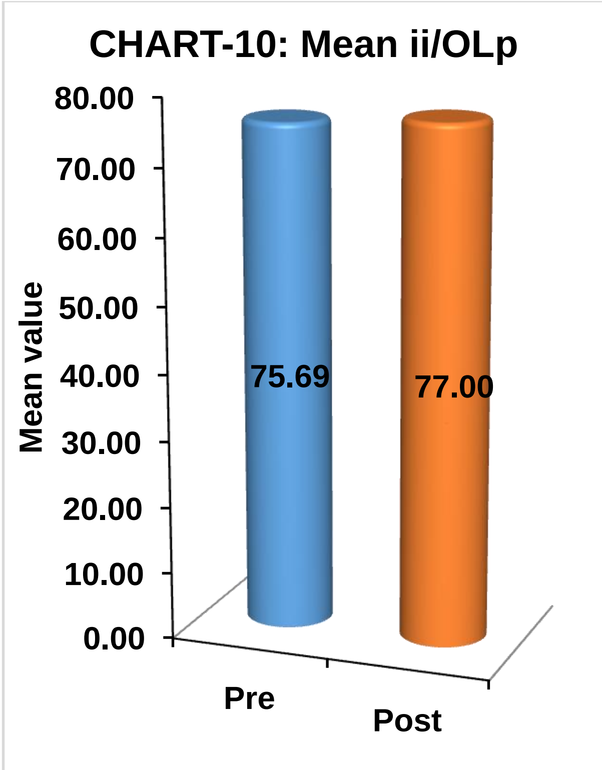


CHART-10: Mean ii/OLp
80.00
70.00
60.00
50.00
40.00
30.00
20.00
10.00
0.00
Mean value
75.69
77.00
Pre
Post

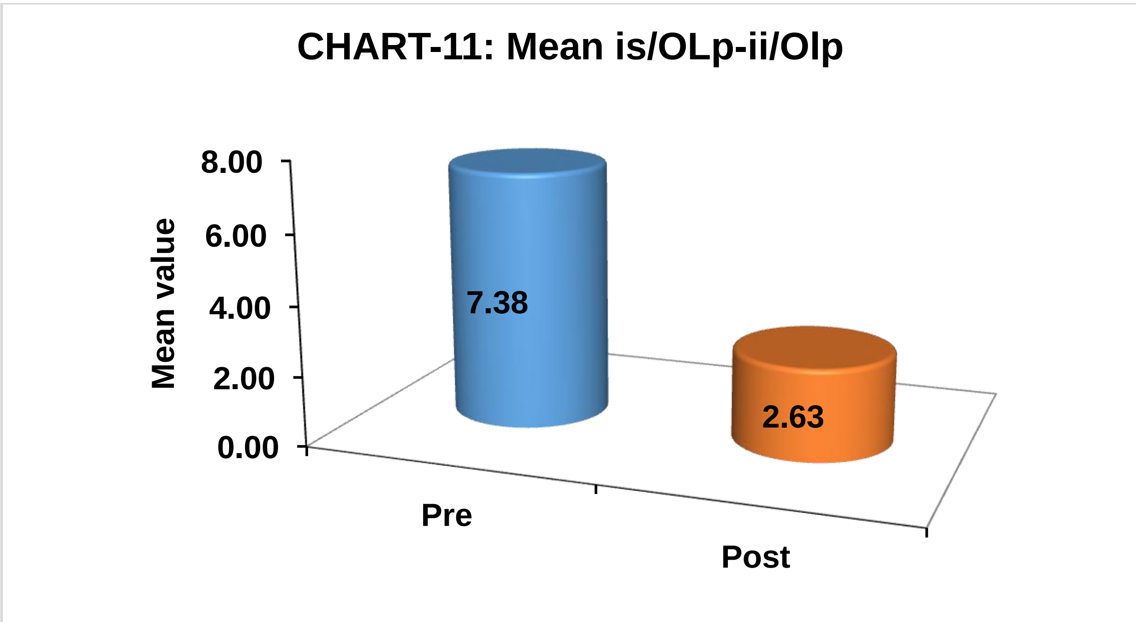


CHART-11: Mean is/OLp-ii/Olp
8.00
6.00
4.00
2.00
0.00
Mean value
7.38
2.63
Pre
Post

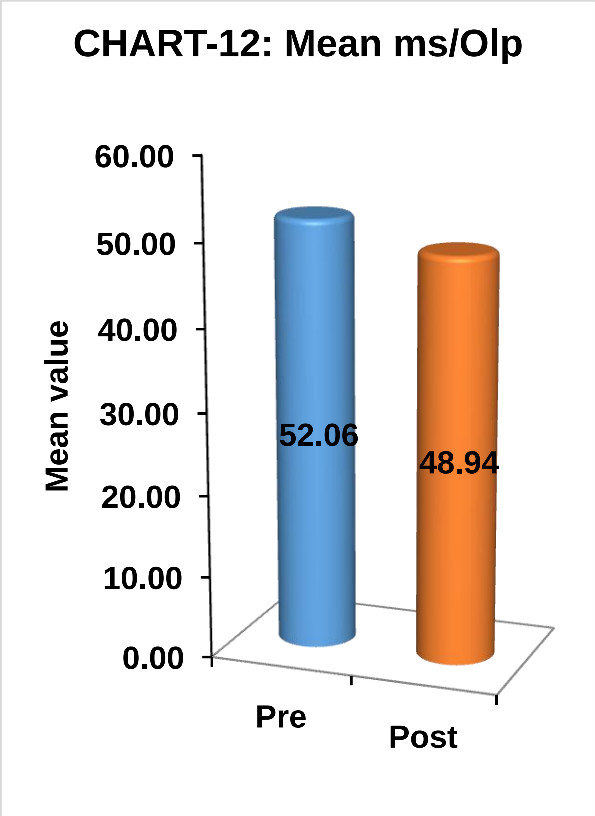


CHART-12: Mean ms/Olp
60.00
50.00
40.00
30.00
20.00
10.00
0.00
Mean value
52.06
48.94
Pre
Post

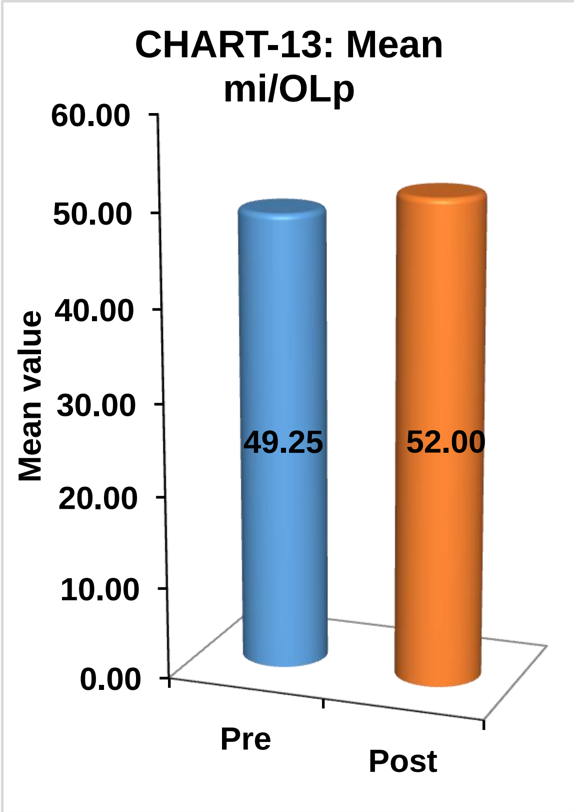


CHART-13: Mean mi/OLp
60.00
50.00
40.00
30.00
20.00
10.00
0.00
Mean value
49.25
52.00
Pre
Post

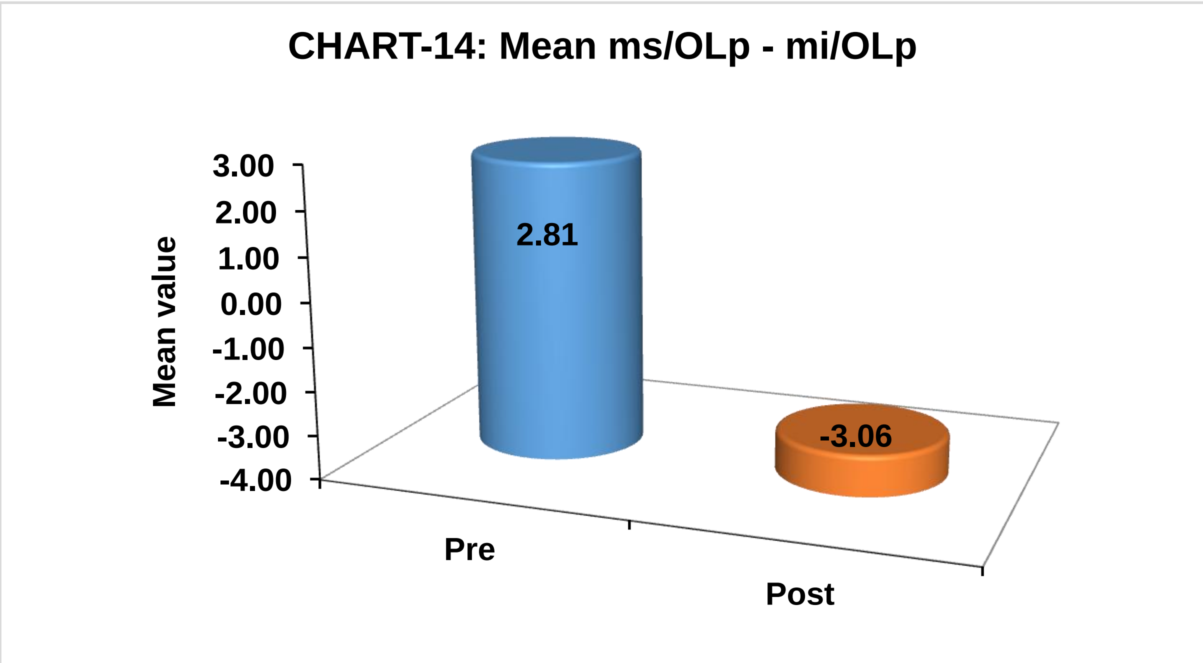


CHART-14: Mean ms/OLp - mi/OLp
3.00
2.00
1.00
0.00
-1.00
-2.00
-3.00
-4.00
Mean value
2.81
-3.06
Pre
Post

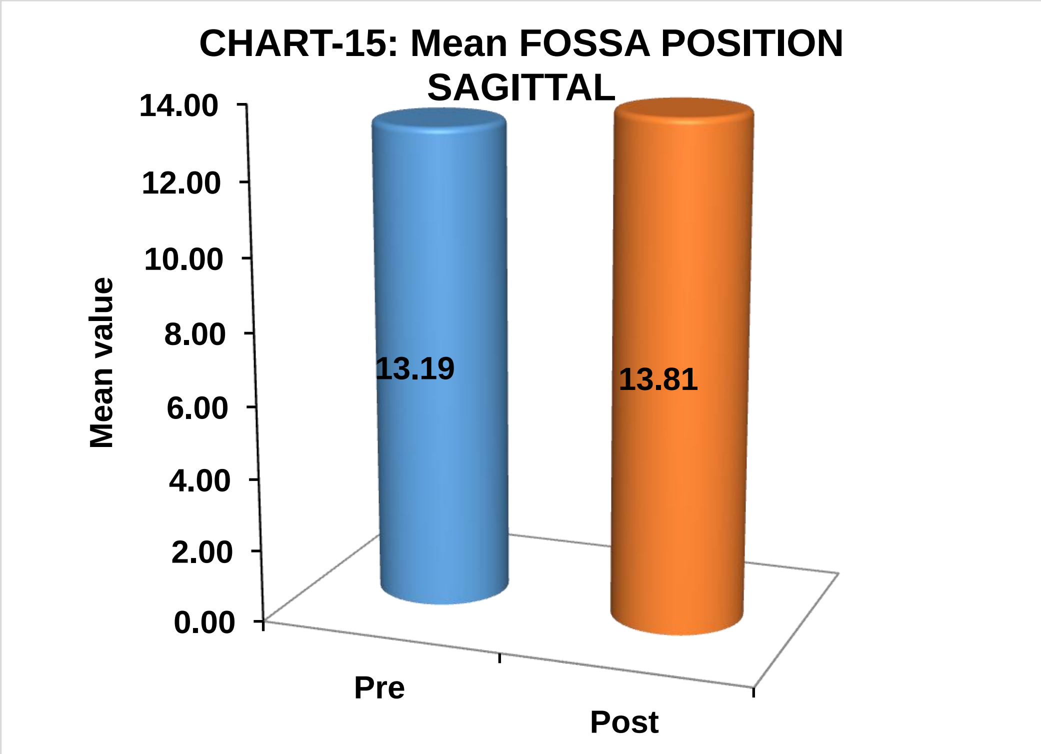


CHART-15: Mean FOSSA POSITION SAGITTAL
Mean value
14.00
12.00
10.00
8.00
6.00
4.00
2.00
0.00
13.19
13.81
Pre
Post

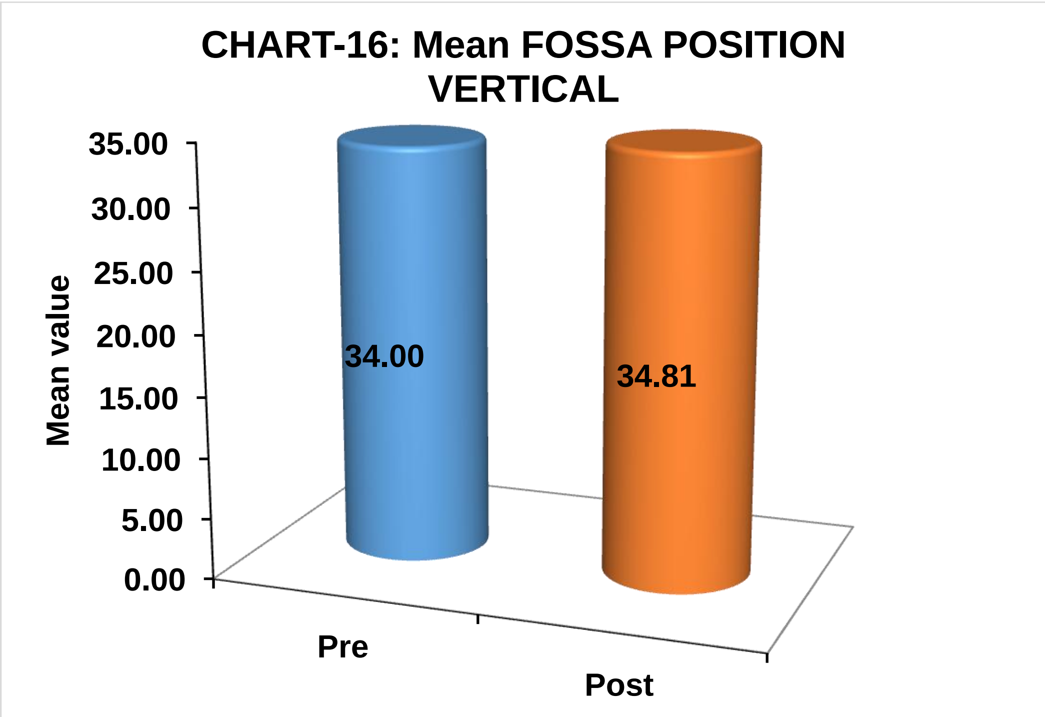


CHART-16: Mean FOSSA POSITION VERTICAL
Mean value
35.00
30.00
25.00
20.00
15.00
10.00
5.00
0.00
34.00
34.81
Pre
Post

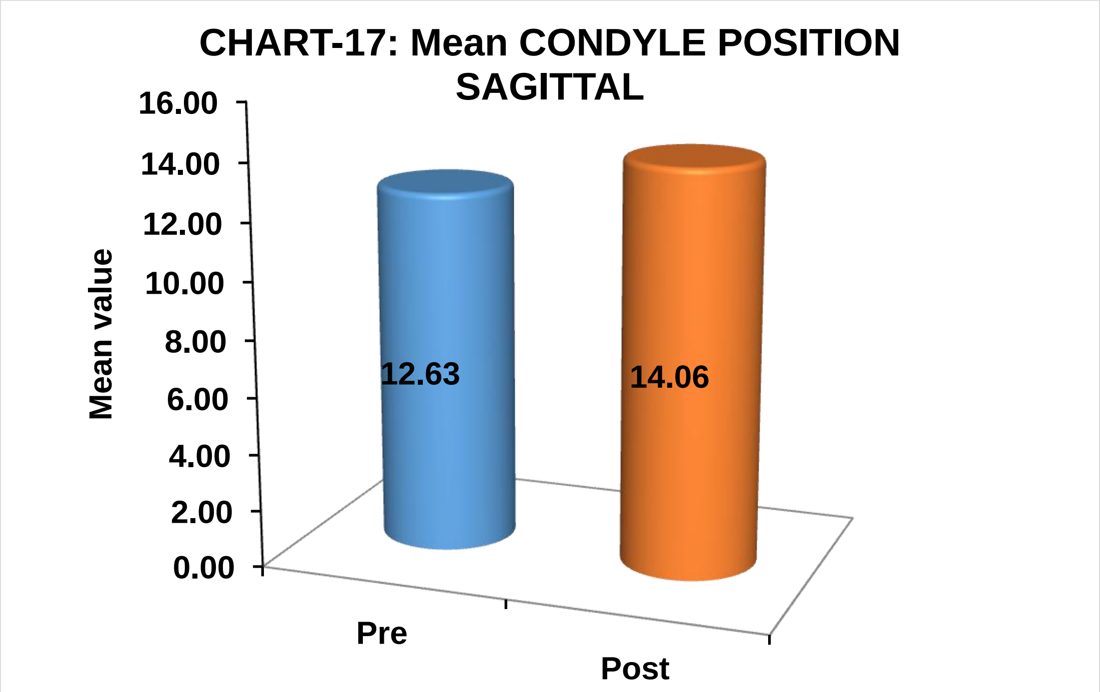


CHART-17: Mean CONDYLE POSITION
SAGITTAL
Mean value
16.00
14.00
12.00
10.00
8.00
6.00
4.00
2.00
0.00
12.63
14.06
Pre
Post

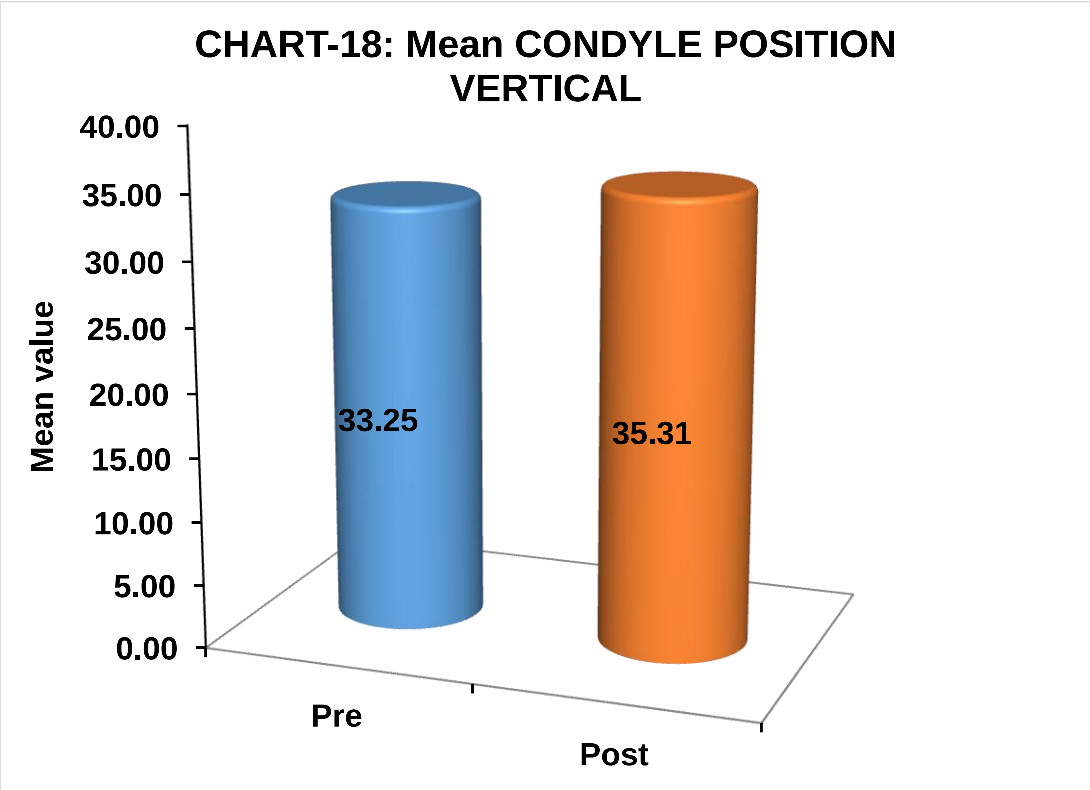


CHART-18: Mean CONDYLE POSITION
VERTICAL
Mean value
40.00
35.00
30.00
25.00
20.00
15.00
10.00
5.00
0.00
33.25
35.31
Pre
Post

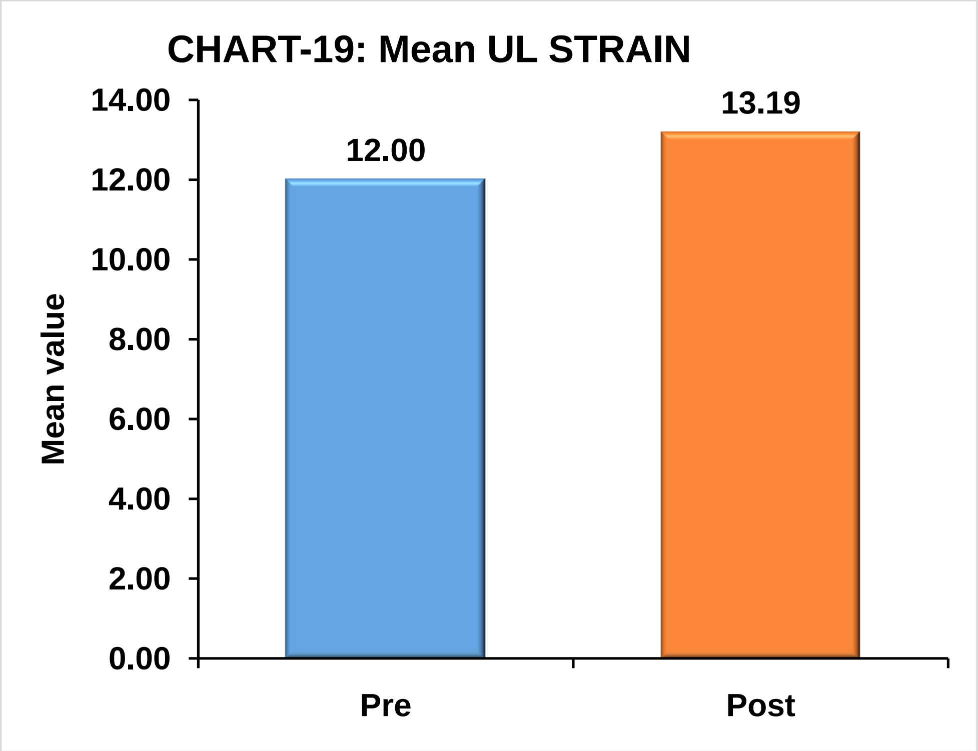


CHART-19: Mean UL STRAIN
Mean value
14.00
12.00
10.00
8.00
6.00
4.00
2.00
0.00
12.00
13.19
Pre
Post

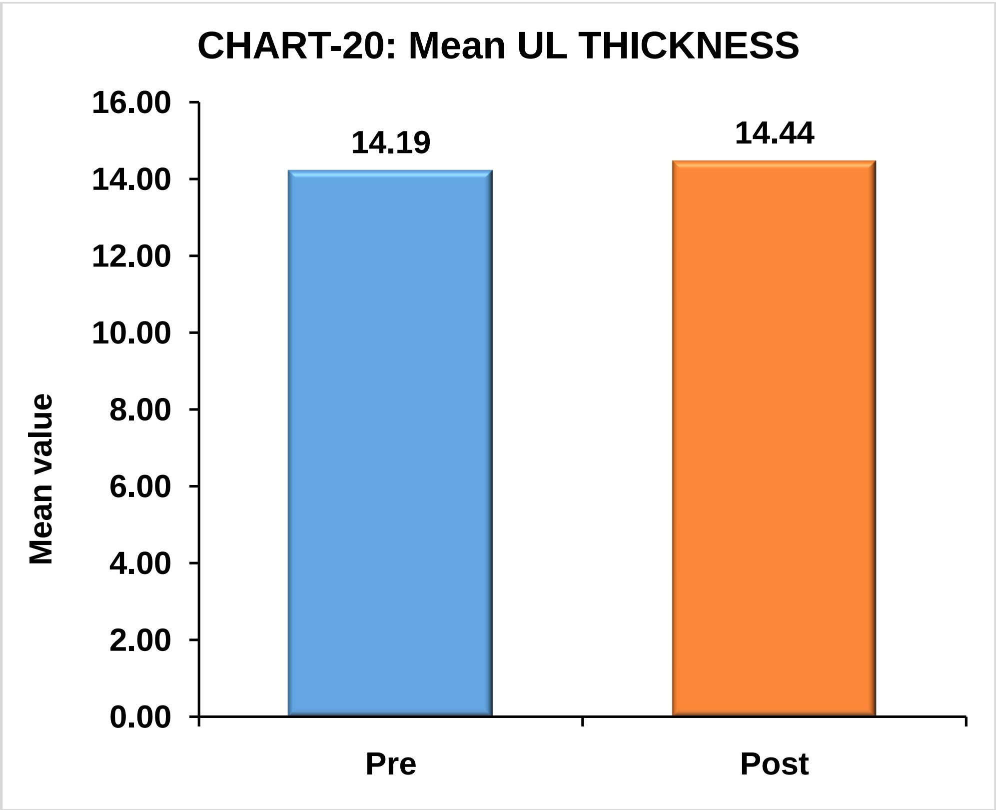


CHART-20: Mean UL THICKNESS
Mean value
16.00
14.00
12.00
10.00
8.00
6.00
4.00
2.00
0.00
14.19
14.44
Pre
Post

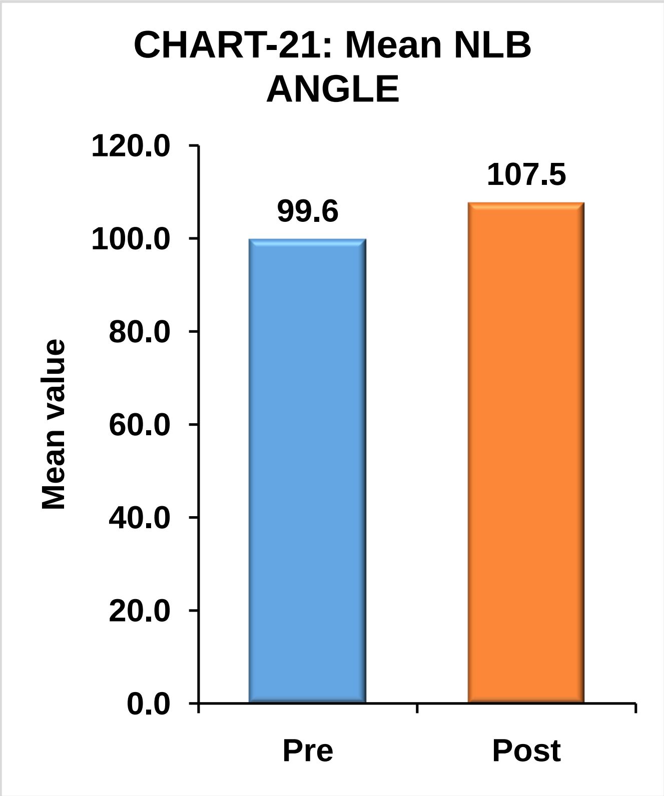


CHART-21: Mean NLB ANGLE
Mean value
120.0
100.0
80.0
60.0
40.0
20.0
0.0
99.6
107.5
Pre
Post

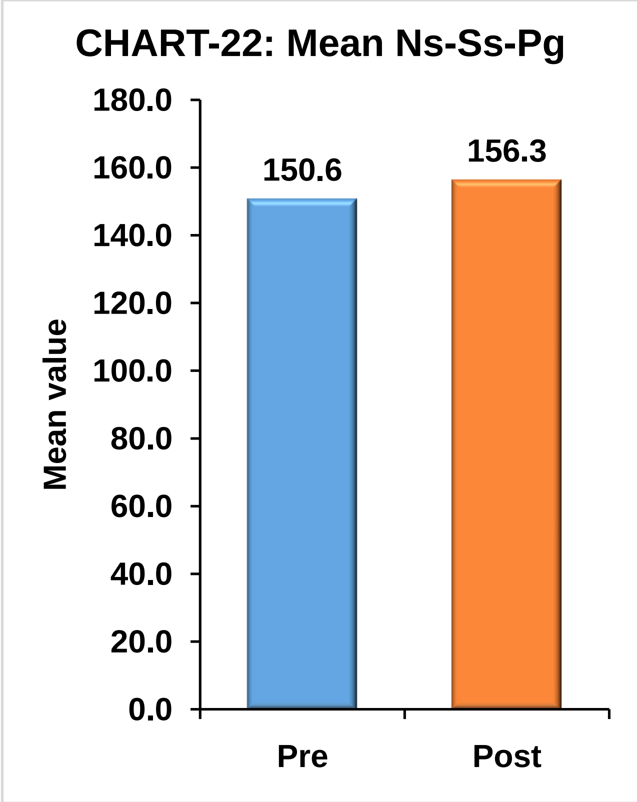


CHART-22: Mean Ns-Ss-Pg
Mean value
180.0
160.0
140.0
120.0
100.0
80.0
60.0
40.0
20.0
0.0
150.6
156.3
Pre
Post

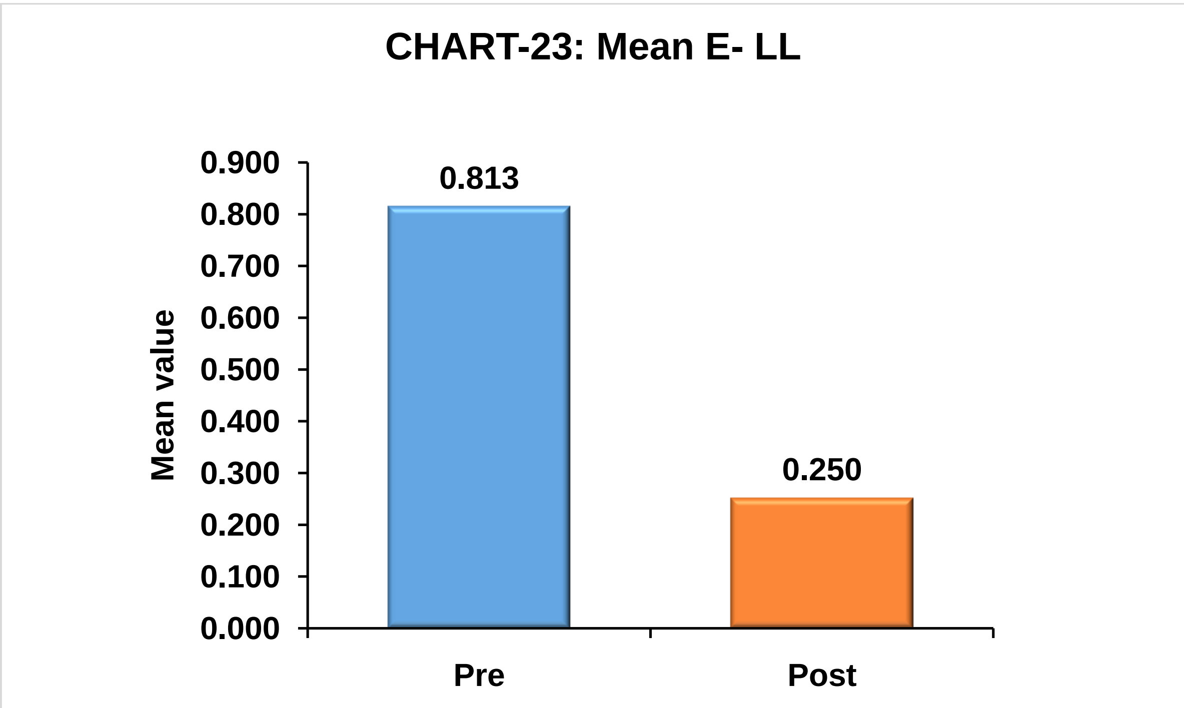


CHART-23: Mean E- LL
Mean value
0.900
0.800
0.700
0.600
0.500
0.400
0.300
0.200
0.100
0.000
0.813
0.250
Pre
Post

CHART-24 :SKELETALAND DENTAL CONTRIBUTION TO MOLAR CORRECTION

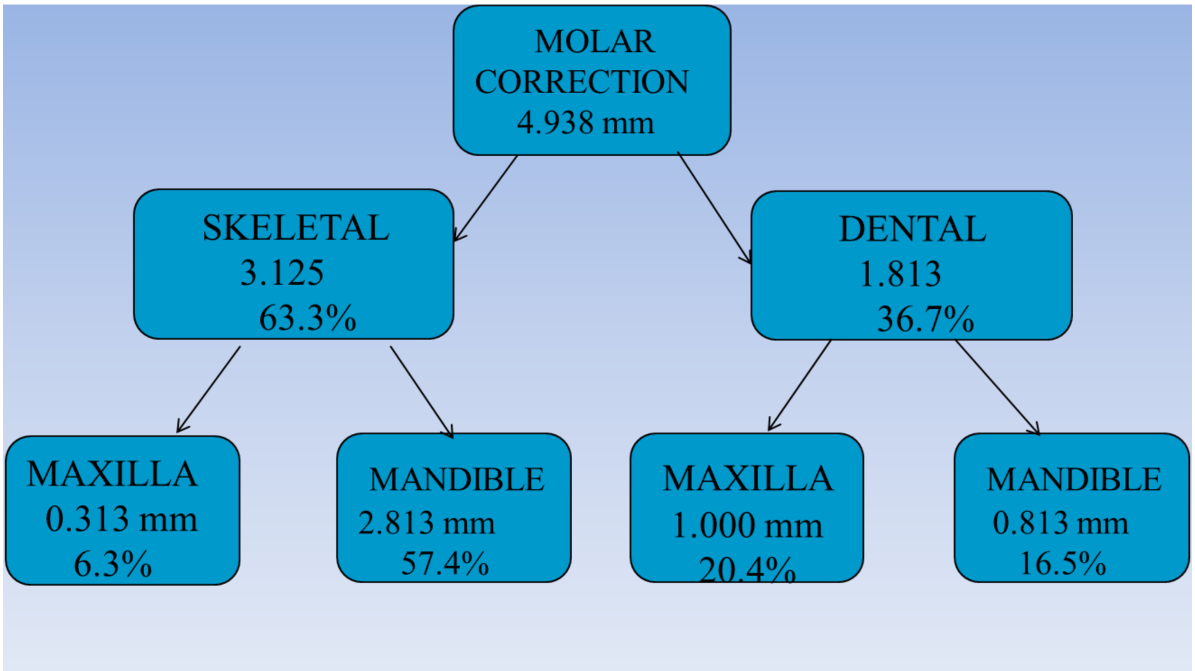


CHART-25 :SKELETAL AND DENTAL CONTRIBUTION TO OVERJET CORRECTION

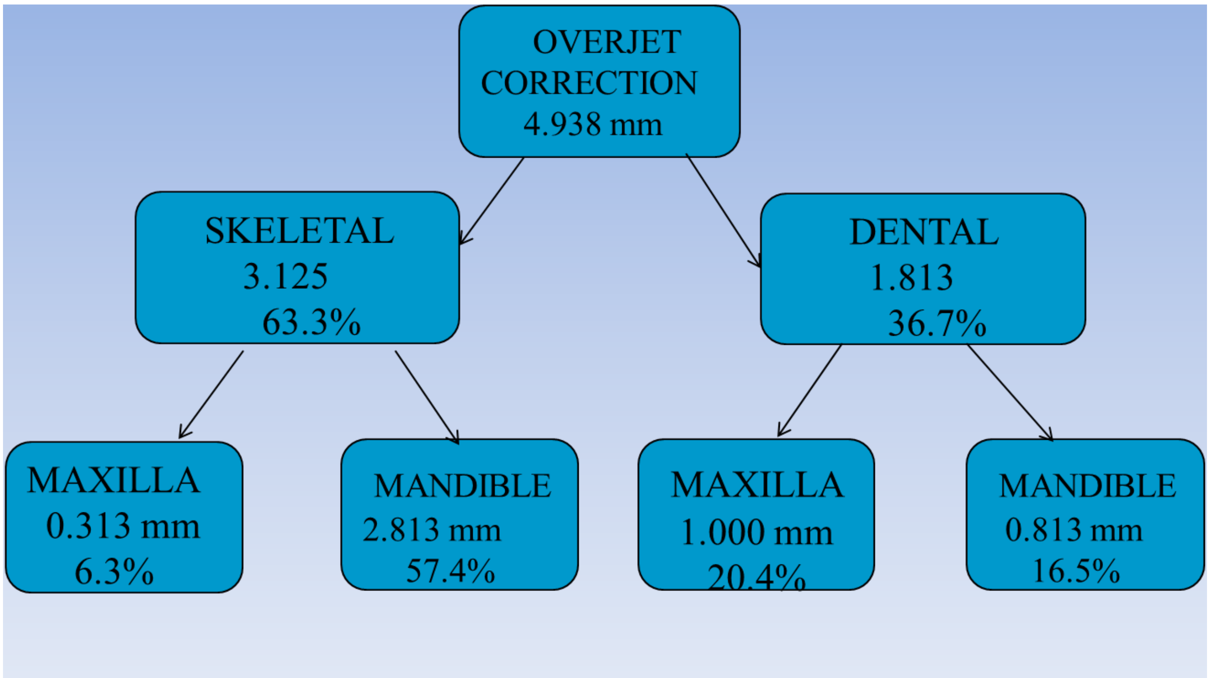
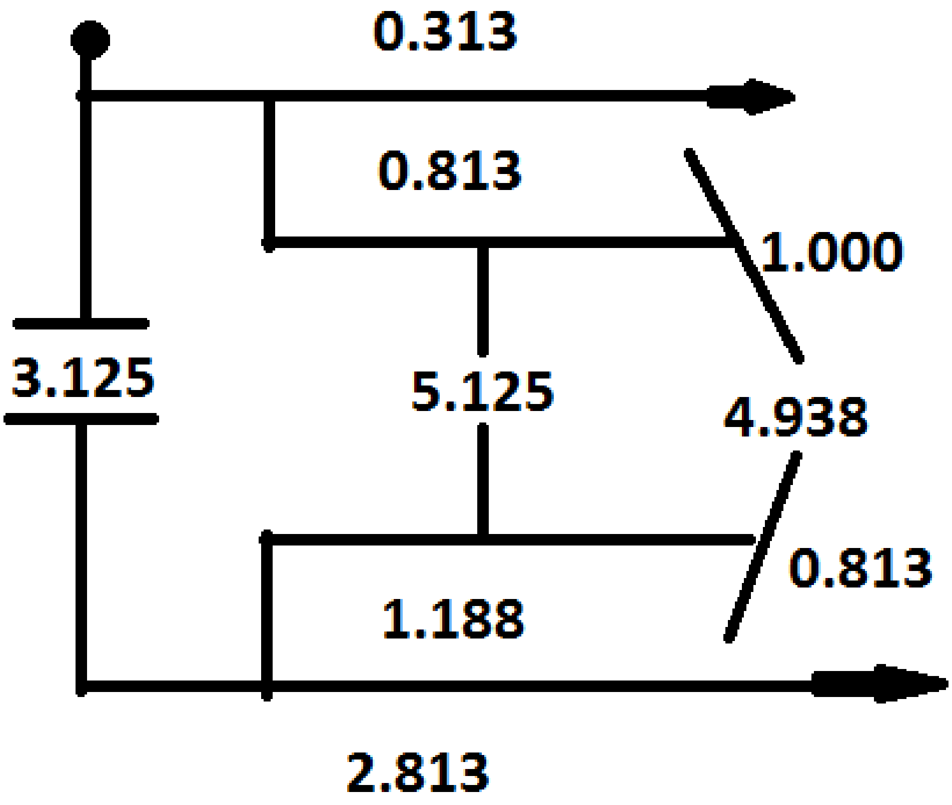


CHART-26: PITCHFORK DIAGRAM



DISCUSSION

Class II malocclusion, most frequently presents with retrognathic mandible[9] and it is amenable to correction in the growing period with Functional Jaw Orthopaedics (FJO). Although both, Fixed Functional Appliances (FFA) and Removable functional appliances (RFA) are used for correction, FFAs have the advantage of compliance free, continuous bite jumping by full time action and shorter treatment duration[3,59,60]. Among the FFAs, the Herbst appliance, a rigid type of FFA has shown consistent results. However, the drawbacks of Herbst appliance are, it is more prone to breakage[6,29] and has less freedom of lateral mandibular movements[7].

In this study, a variant of the Herbst appliance – the Flip lock Herbst appliance was used in treatment of class II malocclusion. This appliance has a ball joint instead of screws which connect the appliance to the upper and lower member (figure – 8). The proposed advantages of flip lock as quoted by the company includes, an increased range of lateral movements, less bulky and increased comfort for the patient[7]. Patient perception of treatment, though overlooked is an important factor in treatment success[44]. In this study only patients who volunteered for functional therapy were selected.

Ten consecutive patients were selected who fulfilled the inclusion and exclusion criteria. Consecutive selection of samples is a better alternative than other non-randomised trial designs[61]. Skeletal criteria for selection was orthognathic maxilla (as assessed by cephalometric variables SNA, Point A to Nasion perpendicular, Co – A) and retrognathic mandible (assessed by SNB, Nasion perpendicular to Pogonion, Co-Gn). Patients with orthognathic maxilla were included so that the effect of the appliance primarily on retrognathic mandible can be assessed. Cases with mild to moderate mandibular retrognathia (SNB value of 74°-77°) were selected. The skeletal criteria reflects the regard for phenotype of class II malocclusion[62], herein this study mandibular retrognathia. Because of the dental criteria for selection (Permanent dentition with no crowding in the upper and lower arches), functional phase was directly started without the need for pre-functional fixed appliance treatment which is the usual norm when using a FFA. Subjects with overjet within the range of 7 to 9 mm were included to have a uniform protocol of single step advancement.

The anchorage design for the appliance consisted of total anchorage in lower arch by inclusion of teeth from first molar on one side to contralateral in the lower arch; partial anchorage in upper arch by inclusion of first premolar to first molar on each side (figure-8). Achievement of class I molar relationship marked the end of functional phase and change in the molar relationship was assessed by easy removal of the tubes and plunger. Since it works by snap fit over the ball joints, removal and insertion are quite easy.

FJO literature is laden with controversies with some studies showing promising results[16,19,21], inadequate effects[15,17] or partial[49] .These differences can be partly attributed to the skeletal maturity at which the treatment was instituted[63].So this study was performed at or slightly before the pubertal growth spurt. Use of a reliable skeletal maturity indicator is essential. Here skeletal maturity was assessed with HWR (Hand Wrist Radiograph) by Bjork (1972) and Grave and Brown (1976) technique[52,53]. Accordingly, patients in stage 4 and 5 were chosen (figure-2).

Out of the 10 patients selected for study, two patients (one female, one male) were dropped out of the study, owing to failure to report at the monthly intervals. Treatment was not forced upon patients, though we used a non-compliant appliance. Only patients who were willing to participate in the therapy were recruited. The two drop outs may be explained by O'Brien et al's conjecture[44] that payment of fees as opposed to free treatment (which was carried out in this present study), might ensure co-operation.

Skeletal and dental changes were appraised through the SO analysis (sagittal occlusal analysis) developed by Pancherz[24](figures- 2 , 12). This analysis was done in addition to traditional jaw base parameters like SNA, SNB and ANB. The SO analysis also facilitates comparison between the present study on the Flip lock Herbst appliance and previous studies on the Herbst appliance.

The effects of the Herbst appliance on the maxillary jaw has been documented as a head gear effect with tipping of the palatal plane, intrusion and distal movement of molars, but no change in the sagittal maxillary position [64,24]. In these studies, the phenotype of the malocclusion wasn't mentioned[6]. In the present study, only class II malocclusion due to orthognathic maxilla and retrognathic mandible were included. Sagittal maxillary position revealed a small change as appraised by changes in SNA from 81.8° to 81°. But maxillary position as described by ss/OLp showed a significant decrease (P= 0.001) from 72.3 mm to 70.3 mm. Thus, angular changes (SNA) showed minimal decrease whereas linear measurement (ss/OLp) showed significant decrease. Overall a maxillary restraining effect was appreciable. This effect was more pronounced than previous studies which showed a maxillary restraint effect as assessed by SNA reduction of

0.5 degrees[24]. However the phenotype of the skeletal malocclusion was not revealed in those studies. This study was carried out with a strict inclusion criteria including orthognathic maxilla. The effect of FFA on patients with prognathic maxilla versus orthognathic maxilla need to be distinguished.

The changes in the position of mandible were assessed by SNB and pg/OLp values, both of which showed significant increase statistically ($P<0.001$ and $P=0.001$ respectively) in agreement with previous studies[23,24]. A small but significant counterclockwise rotation from 30° to 29.1 in the mandibular plane was observed comparable to previous studies[24,38,40]. Changes in the mandible position with functional therapy can be due to sum of all changes such as positional change from correction of functional retrusion, anterior relocation of the fossa and accompanying condylar growth in the sagittal direction, dual bite or an actual increase in mandibular length. The effective mandibular length as a sum of positional changes and length changes is a better alternative than other linear measurements. In this study, the effective mandibular length (pg/OLp+ar/OLp) increased by 1.1 mm. This is a mean value and inter individual variation existed in the changes ranging from 0 to 2.5 mm. This can be ascribed to the biological variation in response to treatment[65].

To understand growth changes of the mandible, condylar growth and fossa displacement must be evaluated [66]. This was evaluated using Buschang and Santos-Pinto method. This analysis can be done on lateral cephalogram itself, which is routinely taken for orthopaedic cases (figure-16). The condylar outline was viewed from an open mouth cephalogram and transferred to the standard lateral cephalogram. In this study, the position of condyle in the sagittal direction changed favourably by 1.44 mm. The position of the condyle in the vertical direction changed favourably by 2.06 mm in this study, comparable to the previous studies ranging from 2.7 mm to 3.1 mm[24,33]. In previous studies with the Herbst appliance, change in the condyle position ranged from 1.7 mm to 3.1 mm[27,33,37,67]. Pancherz et al[67] showed 3.1 mm upward and 2.8 mm forward change in the condyle position with the banded Herbst appliance. Their study population consisted of 15 subjects with mean age of 13 years and treatment duration of 7 months. The increased values found in that study can be attributed to their gender distribution in the study population which consisted of 4 females and 11 males, whereas in this study gender distribution was equal. Another factor might be the accompanying increased lateral movements with the Flip lock Herbst appliance. Although classified under a rigid FFA, this increase in flexibility with movements should be considered.

The glenoid fossa also remodelled favourably during treatment (figure-16). An anterior relocation of 0.62 mm and inferior relocation of 0.8 mm was observed, which correlates with the results of previous study on the Herbst appliance[33]. This increase in vertical condylar growth along with counter clockwise movement of mandible as denoted by changes in the NSL/MP values and an anteriorly relocated glenoid fossa, have a synergistic effect with mandibular length. These changes can be appraised as the effective mandibular length.

Inter-individual variations were observed in relation to condyle and glenoid fossa changes (table 7). The impact of viscoelastic tissues should be considered along with standard skeletal, dental, neuromuscular and age factors that influence condyle-glenoid fossa growth with orthopaedic advancement[68]. In this study the skeletal, dental and age factors were comparable between patients. Biological variability can be understood by further research on this hypothesis by strict inclusion criteria and evaluation of changes with advanced techniques.

FFAs are fixed to the teeth, and invariably some amount of dental changes occur, and the total therapeutic change in any functional therapy is a result of combination of skeletal and dental correction that takes place. Achievement of class I molar relationship marked the end of functional phase in this study. Dental changes observed in the present study were favourable towards class II correction, upper molars and incisors moved backwards; lower molars and incisors forwards.

Position of upper incisor (is/OLp) changed significantly from 83.5 mm to 79.6 mm ($P<0.001$). Position of the upper incisor within the maxilla (is/OLp-ss/OLp) decreased from 11 to 9 mm ($P=0.006$) suggesting a retroclination of upper incisors. Dental changes with the maxillary incisor were more pronounced when compared to other studies[24,45]. This can be attributed to the anchorage design consisting of total anchorage in the mandible with partial in the maxilla. Upper molar position within the maxilla moved distally by 1.5 mm ($P=0.058$) comparable to previous studies.

Lower incisor position changes (in total and within the mandible), though favourable were not significant. Lower molar changes were highly significant ($P<0.001$). Lower molar position within lower jaw changed significantly (0.002). Overall dental changes in maxilla were more than mandible indicating a loss of anchor in the upper arch alone owing to the design of the anchorage.

Molar relationship change (is/OLp-ii/OLp) and overjet (ms/OLp-mi/OLp) changes were highly significant. Skeletal and dental contributions to these changes were analysed with Pitchfork analysis.

The pitchfork analysis was used to distinguish skeletal and dental changes and represented as pitchfork diagrams to permit comparisons[59.] In a recent study of the effects of forsus[69], the authors used pitchfork analysis. Although the setting of that study was different (Fixed orthodontic treatment followed by fixed functional) , the pitchfork diagrams (chart-26) of treatment effects of these two appliances show a greater apical base change with the Flip lock Herbst appliance (3.1 mm) as opposed to Forsus (2.9mm) in a short span of time. This is partly due to the effects of the appliances on the maxillary jaw. The Herbst appliance showed restriction of growth (0.3 mm) unlike the Forsus (-0.3 mm).

For molar correction and overjet correction skeletal changes predominated with 61% and 63% respectively. This favourable orthopaedic outcome is due to selection of patients in pre-pubertal and circum-pubertal period. The dental changes accounted for 39% for molar correction and 36% for overjet correction. These findings are similar to the effect produced by the Herbst appliance[24]. Among the dental changes, maxillary dentition showed more changes than mandibular dentition. (Charts- 24,25)

The anchorage design can also influence the degree of maxillary and mandibular dental changes. This study used design consisting of total anchorage in the mandible with partial in the maxillary part. Accordingly more dental changes were observed in the maxilla than mandible and more skeletal changes in the mandible. By varying the anchorage design, tailor made approach can be used in accordance to the phenotype of the malocclusion. This type of component approach by varying the number of teeth included is an advantage specific to FFA. Anchorage can also be maximised with the help of miniscrews thereby increasing the orthopaedic effect[70].

Pancherz stressed on the importance of proper occlusal interdigitation as the key to post treatment stability. Although the present study is short term, it was found that with correction of molar relationship at T2, posterior interdigitation was also improved in few cases. This can be achieved only when the teeth are free to erupt without any occlusal coverage which in turn depends on the design of the appliance. Johnston[71] recounts that this interdigitation with functional correction "locks" the mandible to the maxilla. Hence during the postfunctional period, the growth of the maxilla controls mandibular displacement and both grow in unison, whereas in the functional phase, maxillary growth is restricted and mandibular growth is enhanced.

Favourable but variable soft tissue effects have been documented with the Herbst appliance as reduction in facial convexity and upper lip retrusion[72]. In this study, there was significant reduction in upper lip strain by 1.1 mm. This might suggest that there was a change in upper anterior inclination with treatment. But there was also a concomitant increase in upper lip thickness by 0.3 mm indicative of soft tissue changes occurring at the adolescent period.

The nasolabial angle, increased from 99° to 107°. The lower lip moved back with respect to the esthetic plane by 0.6 mm. The profile changes in the soft tissue silhouette was analysed by changes in the Ns-Ss-Pg value. There was a significant decrease in soft tissue convexity from 150° to 156°. Similar degree of change was also seen in a previous study[73] on facial profile change of adolescents and young adults.

The present study on the Flip lock Herbst appliance showed favourable skeletal, dental and soft tissue changes. These changes were similar to the effect produced by the Herbst appliance in previous studies[24,37,40] with an added advantage of comfort and ease of lateral mandibular movements enabled by the ball joint type of connector (figure 18).

Breakages were noted in all patients ranging from one to three incidents during the whole course of treatment. These incidents occurred most during the first month and near the band solder junction and not with the appliance components. A phased activation might help in reducing these incidents as the patient gets accustomed to the high forces produced in a rigid system. Ease of movements of the mandible were seen clinically and none of the patients reported any difficulties with mastication or speech with the appliance except for the occasional breakage.

SUMMARY AND CONCLUSION

SUMMARY :

Treatment of class II division 1 malocclusion with orthognathic maxilla and retrognathic mandible was carried out with a modification of the Herbst appliance namely Flip Lock Herbst appliance in this study. It differs from the former in having a ball joint type of attachment which enables easier and comfortable movements of the mandible. Correction was done during the active growth period with patients corresponding to stages 4 and 5 of Bjork, Grave and Brown method of assessment of skeletal maturity. The present study was done in the department of Orthodontics and Dentofacial Orthopaedics, Tamil Nadu government dental college and hospital, Chennai. A total of 8 patients in the active growth period with the age range of 12 – 15 years of both genders were included in this study based on inclusion and exclusion criteria. Functional phase lasted for 7.9 months in average ranging from 6.1 to 10.3 months. Pre-treatment and post-functional treatment lateral cephalometric radiographs were used to evaluate skeletal, dental and soft tissue changes.

Following conclusions are derived from this study,

1. Statistically significant inhibition of the maxillary growth occurred.
2. Statistically significant changes in mandibular position occurred with considerable inter-individual variation.
3. Among the skeletal changes, mandibular changes predominated.

4. Statistically significant increase in the condylar growth in the vertical and sagittal direction was observed with anterior and inferior relocation of the glenoid fossa. These changes also showed inter-individual variation.
5. Dental changes occurred in both maxilla and mandible. Significant dental changes were seen in upper incisors and lower molars with distal movement of upper incisors and mesial movement of lower molars. Overall maxillary dental changes predominated.
6. Evaluation of lower incisor position using SO analysis showed minimal changes with regard to positional changes within the mandible
7. Overjet and molar relationship changes were statistically significant.
8. Significant reduction in profile convexity and upper lip strain.
9. There was a significant increase in the nasolabial angle within the normal range.
10. With regards to treatment efficiency of the Flip lock Herbst appliance in molar correction , skeletal changes accounted for 61% and dental changes for 39% of the total correction. For overjet correction skeletal changes contributed to 63% and dental changes to 37% of the total correction.

CONCLUSION:

The Flip lock Herbst appliance has proved to be efficient in correction of Angle’s class II division I malocclusion on a class II skeletal base due to orthognathic maxilla and retrognathic mandible. Significant changes were achieved in both maxilla and mandible. Both skeletal and dental changes occurred with the former predominating (60:40).

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ANNEXURE - I

Participant Information Sheet

Title of the study :EFFICIENCY OF THE FLIP LOCK HERBST APPLIANCE IN MANAGEMENT OF ANGLE'S CLASS II DIVISION 1 MALOCCLUSION ON A CLASS II SKELETAL BASE DUE TO RETROGNATHIC MANDIBLE.

Name of the research institution: Tamilnadu government dental College & hospital

Purpose and procedure of the study:

Functional orthodopaedic treatment is done to improve facial, dental esthetics and oral function by correction of underlying skeletal problem in the growing years. It helps in improving the growth of the lower jaw by placing it forward. For any patient undergoing this treatment, a fixed functional appliance is fitted on to the teeth which will cause the lower jaw to be placed forward. The appliance will be fixed on the molar teeth on the upper and lower jaw.

After a few months(6-9months) when the desired changes have taken place,, it will be removed and orthodontic treatment to align the teeth will be done as a second phase. For this treatment, small buttons called “Orthodontic brackets” are fixed on each tooth to cause tooth movement

Like all orthodontic patients, subjects in this study will have a usual treatment planning .Orthodontic treatment will be undertaken as is done routinely.To assess the efficiency of the above said functional appliance, measurements will be taken in their routine records . The Lateral cephalogram Radiographs will be taken before treatment and after completion of the first phase of treatment.

Risk of participation: Apart from radiation exposure while taking lateral cephalograms, which is within acceptable limits taken for this study, no other risk is anticipated.

Benefits of participation : Patient gets benefit of functional orthopedic & orthodontic treatment.

1. **Confidentiality:**

The privacy of the patients in the research will be maintained throughout the study. In the event of any publication or presentation resulting from the research , no personally identifiable information will be shared.

2. Participant's rights:

Taking part in the study is voluntary. You are free to decide whether to participate in the study or to withdraw at any time. Your decision will not result in any loss of benefits to which you are otherwise entitled.

3. Compensation: NIL

Contacts:

For queries related to the study:

PRMARY INVESTIGATOR: DR.SUSHMITHA.R.IYER

CONTACT DETAILS:PG SECTION,DEPT OF ORTHODONTICS,
TAMILNADU GOVT DENTAL COLLEGE
& HOSPITAL,
FRAZER BRIDGE ,Chennai-600003.
PHONE NUMBER: 9600090801

For queries related to the rights as a study participant, please write to:

The Chairperson,
NIE-IHEC, National Institute of Epidemiology (ICMR),
2nd Main Road,
Ayapakkam,
Chennai – 600077,
Ph: 044-26136234)

ANNEXURE - II

Annexure: AF 06/004/01.0

Informed Consent Form

"EFFICIENCY OF THE FLIP LOCK HERBST APPLIANCE IN MANAGEMENT OF ANGLE'S CLASS II DIVISION 1 MALOCCLUSION ON A CLASS II SKELETAL BASE DUE TO RETROGNATHIC MANDIBLE. ".

Participant ID No:

"I have read the foregoing information sheet given to me about the methods and procedures to be followed for the study, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this study and understand that I have the right to withdraw from the study at any time without in any way it affecting my further medical care."

Date

[The literate witness selected by the participant must sign the informed consent form. The witness should not have any relationship with the research team; If the participant doesn't want to disclose his / her participation details to others, in view of respecting the wishes of the participan t, he / she can be allowed to waive from the witness procedure (This is applicable to literate participant ONLY). This should be documented by the study staff by getting signature from the prospective participant]

"I have witnessed the accurate reading of the consent form to the potential participant and the individual has had opportunity to ask questions. I confirm that the individual has given consent freely"

Date Name of the witness Signature of the witness

Date Name of the interviewer

ANNEXURE - III

தகவல் அறிவிப்பு படிவம்

நாங்கள் தமிழ்நாடு அரசு பல் மருத்துவமனை மற்றும் கல்லூரியின் நோயாளிகளும் முகம் மற்றும் பல் சீரமைப்பிற்காக பற்களின் மேல் பொருத்தப்படும் தாடை முன்னிழுப்பான் (Fixed Functional Appliance) கொண்டு கீழ் தாடை வளர்ச்சியை அதிகரிக்கும் செயல் திறன் பற்றிய ஆய்வு செய்ய இருக்கிறோம்.

இந்த சிகிச்சை கீழ்தாடை வளர்ச்சி குறைபாட்டை வளரும் பருவத்திலேயே சரி செய்கிறேது.

இந்த தாடை முன்னிழுப்பான் மேல் மற்றும் கீழ் பகுதியில் உள்ள கடைவாய் பற்களின் மேல் பொருத்தப்படும்.

தாடை சிகிச்சைக்குப் பிறகு பற்களின் சீரமைப்பிற்காக உலோக பொத்தான்கள் பொருத்தப்படும்.

இந்த சிகிச்சைக்காக எடுக்கப்படும் பல் அளவு மற்றும் நான்கு கதிர் வரை படங்களின் அளவுகளே இந்த ஆய்விற்கும் உட்படுத்தப்படும்.

இந்த ஆராய்ச்சியில் பங்கேற்கும் நோயாளிகளின் விவரங்கள் ஆய்வு முடியும் வரை இரகசியமாக வைக்கப்படும். ஆராய்ச்சியின் முடிவு பற்றிய பதிப்புகள் அல்லது வெளியீடுகளில் யாருடைய தனிப்பட்ட விவரங்களும் பகிர்ந்து கொள்ளப்பட மாட்டாது ஆராய்ச்சியில் பங்கேற்பது நோயாளிகளின் தன்னிச்சையாக முடிவாகும். மற்றும் எந்த நேரத்திலம்

இந்த ஆய்விலிருந்து சட்ட உரிமைகள் பாதிக்கப்படாமல் விலகிக் கொள்ளலாம்.

இந்த சிறப்பு ஆய்வின் முடிவு இந்த ஆய்வின் போதோ அல்லது ஆய்வின் முடிவிலோ தங்களுக்கு தெரிவிக்கப்படும்.

நோயாளியின் பெயர்	கையொப்பம் / பெருவில்ரேகை	தேதி
ஆராய்ச்சியாளரின் பெயர்	கையொப்பம்	தேதி

ANNEXURE - IV

ஒப்புதல் படிவம்

"முகம் மற்றும் பல் சிரமைப்பிற்காக பற்களின் மேல் பொருத்தப்படும் தாடை முன்னிழுப்பான் (Fixed Functional Appliance) கொண்டு கீழ் தாடை வளர்ச்சியை அதிகரிக்கும் செயல்திறன் பற்றிய ஆய்வு"

பெயர் : புற நோயாளி எண்:

முகவரி: எண்:

தொலைபேசி எண் : வயது / பால் :

நான் வயது வருடம் என்னுடைய சுய நினைவுடனும் மற்றும் முழு சுதந்திரத்துடனும் "முகம் மற்றும் பல் சிரமைப்பிற்காக பற்களின் மேல் பொருத்தப்படும் தாடை முன்னிழுப்பான் (Fixed Functional Appliance) கொண்டு கீழ் தாடை வளர்ச்சியை அதிகரிக்கும் செயல் திறன் பற்றிய ஆய்வில் என்னை சேர்த்துக்கொள்ள சம்மதிக்கிறேன்.

இந்த ஆராய்ச்சியின் நோக்கம், மருத்துவு முறைகள் மற்றும் பரிசோதனை முறைகள் எனக்கு திருப்தியூட்டும் வகையில் விளக்கப் பட்டன.

இந்த ஆராய்ச்சியின் செயல்முறைகளில் என்னை உட்படுத்திக் கொள்ள சம்மதிக்கிறேன்.

இந்த ஆராய்ச்சியின் முடிவு வரை ஒத்துழைக்க சம்மதிக்கிறேன்.

என்னுடைய மருத்துவ குறிப்பேடுகளை இந்த ஆராய்ச்சியில் பயன்படுத்திக்கொள்ள சம்மதிக்கிறேன்.

நோயாளியின் பெயர் கையொப்பம் / பெருவிரல் ரேகை தேதி

ஆராய்ச்சியாளரின் பெயர் கையொப்பம் தேதி