EVALUATION OF CHANGES IN RESTING AND SWALLOWING TONGUE PRESSURE FOLLOWING TONGUE CRIB THERAPY IN TONGUE THRUSTERS.

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ORTHODONTICS AND DENTOFACIAL ORTHOPAEDICS

By

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Dr. Sanaf Zaman

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ABBREVIATIONS

S.No	Abbreviations	Full Form
1.	N/cm^2	Newton per centimeter square
2.	SD	Standard Deviation
3.	SE	Standard Error
4.	g/cm^2	Gram per centi meter square

Aim: Evaluation of changes in resting and swallowing tongue pressure following tongue crib therapy in tongue thrusters.

Material and method: This study was conducted on 40 subjects of 13-20 years, divided in two groups. Each group having 20 subjects named as group I (tongue thrusters) and group II (non tongue thrusters). Sensor holding device and Palatal crib was fabricated and placed in tongue thrusters and tongue pressure was measured over a interval of time. For group I and group II, the initial tongue pressure before crib placement was measured as T0. After placement of crib, T1 was measured, after 3 months T2, and after removal of tongue crib T3 was measured. Recordings were performed three times, both resting and swallowing using pressure sensor placed on sensor holding device, which was fabricated for each patient to hold the sensor tip efficiently.Out of the three readings, the mean was calculated and used as the final value and data thus obtained was recorded in excel sheet, later subject to statistical analysis.

Result: On comparison of the mean resting and swallowing tongue pressure among group I and group II, significant difference was observed.The tongue pressure comparatively reduced over a period of time. Statistically highly significant difference in tongue pressure was observed between group I and group II.

Conclusion: Tongue crib was efficient in reducing tongue pressure among tongue thrusters over interval of time**.** Resting and swallowing tongue pressure reduced significantly after tongue crib therapy in patients having tongue thrusting habit. Measurements performed before and after the tongue crib therapy in patients having tongue thrusting habit confirms that tongue responds adequately to environmental changes and adapts well to the new position. Tongue crib appliance was found effective to break the tongue thrusting habit and guides the tongue to adapt itself to a new normal position in the oral cavity.

Keyword: tongue thrust, Tongue pressure, tongue crib, sensor holding device, pressure sensor.

The teeth and supporting structures are constantly under the influence of the musculature, that is, orbicularis oris, buccinator, superior constrictor and tongue. These perioral muscles exert force on the dentoalveolar structures, which is counteracted by the forces exerted by tongue intraorally, thus keeping stomatognathic system in balance[1].

The tongue is a powerful muscular organ which has a natural or optimum position during rest as well as during function, and exerts varied pressure at frequent intervals[2]. The tongue at relaxed state lies in the floor of mouth, at that time dorsum of the tongue touches the hard palate while tongue tip is placed at the lingual aspect of mandibular incisors[3].During normal deglutition the anterior tip of the tongue comes forward to make contact at the retro incisal area of the palate, directly behind the maxillary anterior teeth.[4]

The equilibrium of the stomatognathic system can be disturbed by disturbance in function caused by abnormal habits ach as tongue thrust, tongue biting, mouth breathing, thumb sucking, unilateral chewing etc[5].

According to Functional matrix theory[6], form and function are related, so forces exerted due these unintended and aberrant functions constantly delivered on the maxillofacial and alveolar regions are able to deform bony structures gradually leading to jaw deformity and malocclusions.

The relationship between form and function of the stomatognathic system were previously investigated by several authors suggesting that the size, shape and posture of the tongue is able to affect the oral environment[7]. It is nonetheless an extended debatable issue whether or not unusual tongue morphology and function leads to malocclusion or conversely it only adapts itself to the local changes of the occlusion.

Tongue thrust is defined as an oral habit supposed to be due to persistence of a retained infantile swallow during childhood and adolescence, in which the tongue tip is forced forward between the anterior teeth.[8]

Tongue thrust can also be acquired as a habit in response to various predisposing factors like improper bottle feeding, prolonged thumb sucking, prolonged tonsillar and upper respiratory tract infections, tender gum or teeth that can result in the change in swallowing pattern to avoid pressure on the effected region.[9]Tongue thrust can be classified into simple and complex thrust depending upon the severity of the habit. In simple tongue thrust a normal tooth contact occurs during the act of swallowing and an open bite may be present. In simple tongue thrust, patients have good intercuspation of posterior teeth in contrast to patients having complex tongue thrust. Complex tongue thrust is defined as tongue thrust with teeth apart swallow which is most often associated with chronic nasorespiratory problems, mouth breathing habit, tonsillitis and pharyngitis.[10]

Graber[11] narrated the deleterious consequences of the tongue on the dentition leading to development of malocclusion because of its extraordinary size, abnormal posture or function. The impact of tongue thrust on dentofacial development relies upon numerous factors as the frequency of swallowing or how many times the tongue exerts pressure on the teeth, the severity of force exerted, the counteraction of tongue forces by other muscular structures together with the lips, the resistance of dentoalveolar structure to displacement and also on the resting pressure of the tongue when there is no swallowing.

Tongue thrust during swallowing may result in labial inclination of incisors, increased overjet, open bite, over eruption of posterior teeth leading to elimination of interocclusal clearance, spacing problems, bilateral narrowing of maxillary arch leading to crossbite and relapse after orthodontic treatment.[12]

The tongue pressure during swallowing has been found to be several times higher than the lip or cheek pressure.[13] The abnormal swallowing pattern with incompetent lips or lip trap might increase the tongue pressure with no corresponding strain from the lips and cheeks. In tongue thruster's duration and amount of tongue pressure on dentition was found to be more as compared to non-thrusters.[14]

Winders[15] stated that in all malocclusions the lingual musculature is far more active than the perioral musculature during speech and swallowing. According to him tongue pressure during deglutition ranges from 41 to 709 g/cm2 (0.40-6.95 N/cm2).

Kydd and Toda[16]also reported that tongue pressure during deglutition had a range of 37 to 240 wan' (0.36-2.35 N/cm2) and 112 g/cm2 (1.10 N/cm2) on an average. . Thereby it can be concluded that tongue is able to deliver forces of considerable magnitude and duration that can be a potent etiologic factor in development of malocclusion.

Richard L. Christiansen et al[17] measured the tongue pressure with 4.9 mm diameter sensor and found the average resting pressure of the tongue as 0.039g/mm^2.He stated that due to this high frequency of deglutition per day, the tongue pressure exerted is quite high and this pressure that is experienced per deglutition can be utilized in correction of malocclusions.

Lear, Flanagan and Moorreesi[18]observed more frequent swallowing pattern in children ranging 800-1200 swallows per 24 hours as compared to 233-1008 swallows per 24 hours in young adults. Thus, it can be concluded from this that tongue can deliver forces at considerable frequency throughout the day thereby influencing the dentofacial morphology. Investigators have been concerned principally with the magnitude and duration of force exerted by tongue during normal or abnormal deglutition. As the tongue plays an important role by contacting the palate during swallowing, numerous investigations have been performed to evaluate tongue pressure on contact between the tongue and hard palate during swallowing.[19,20]

Assuming the deleterious effects of abnormal tongue pressure, several modalities have been used to correct tongue thrust with variable success which include myofunctional therapy, habit control, exercises, habit breaking appliances[21]. Both fixed and removable cribs can be fabricated to aid in breaking the habit of tongue thrusting.[22] The tongue crib is an appliance that is designed to modify the tongue behaviour and break the tongue thrusting habit that is supposed to be responsible for the proclination of incisors in bimaxillary protrusion case and open bite.[23]Huang GJ et al [24]evaluated the effectiveness of crib therapy in open bite cases (4-8 mm open bite) exhibiting a significant increase in mean overbite after crib therapy for 10 months in

both growing and nongrowing patients and the patients who had achieved a positive overbite after crib therapy had a good chance to maintain it after completion of the treatment. They evaluated the role of the palatal crib and bonded lingual spur in correction of open bite during mixed dentition stage. Many investigators found significant decrease in resting and swallowing tongue pressure on anterior teeth and maxillary first molar area after application of crib appliance for 10 months in open bite patients.[25]

Cheng etal[26] suggested that each tongue dysfunction should be corrected during treatment if long term stability of the treatment outcome is required Tongue pressure can be measured by using sensing probes, sensor attached to palatal plate, sensor sheet system and pressure sensors [27]. Availability of ready to use mini sensors gives the freedom to the researchers to install them in experimental palatal plates or directly to the dentition with minimum discomfort to the patient. As these sensors are easy to place in patient's mouth and are very thin, so the patient compliance is more hence it was decided to use the same sensors in our study.

Tongue mass being constant, the tongue pressure might be redistributed in the oral cavity after application of tongue crib so this could be the concerning factor for the net result obtained by tongue crib therapy[28]Researches have emphasized the importance of intraoral tongue pressure but very few studies have evaluated the adaptive capability of tongue in response to environment changes in terms of changes in tongue pressure.[29]

Considering this, the present study was designed to evaluate changes in resting and swallowing tongue pressure on anterior dentition in oral cavity following tongue crib therapy in patients with tongue thrusting habit.

AIM: Evaluation of changes in resting and swallowing tongue pressure following tongue crib therapy in tongue thrusters.

OBJECTIVES:

1) To evaluate the resting and swallowing tongue pressure on anterior dentition in oral cavity in patients with tongue thrusting habit.

2) To evaluate the resting and swallowing tongue pressure on anterior dentition in oral cavity in patients without tongue thrusting habit.

3) To evaluate the resting and swallowing tongue pressure on anterior dentition in oral cavity after crib therapy in patients with tongue thrusting habit.

4) To compare the resting and swallowing tongue pressure on anterior dentition in oral cavity between non tongue thrusters and tongue thrusters before placement of crib.

5) To compare the resting and swallowing tongue pressure in tongue thrusters on anterior dentition in oral cavity before and after tongue crib therapy.

6) To compare the resting and swallowing tongue pressure of tongue thrusters after crib therapy with that of resting and swallowing tongue pressure of non tongue thrusters.

McKee TL (1956)[34]studied the position of tongue in individuals with Cleft Palate deformity. He described the normal position of tongue as being either high or low in relation to the mandibular denture, forward in the oral cavity, or well back in the pharynx. He concluded that at physiologic rest the apex of the tongue is generally against the lingual surfaces of the mandibular incisors, slightly below their incisal edges, the tongue is usually most convex in the non-cleft subjects, less convex in the unilateral cleft subjects and least convex in the bilateral cleft subjects, the dorsum of the tongue is superior to the occlusal surfaces of the mandibular posterior teeth in the non-cleft subjects and also in most of the cleft subjects and the soft palate and palatine uvula, unless disturbed by surgery as during cleft palate closure, or by growth aberrations, is against the dorsum of the tongue at the junction of the pharyngeal and palatine portions of the tongue.

Winders RV (1958)[36]conducted a study on 25 healthy subjects and studied forces exerted on the dentition by the perioral and lingual musculature during swallowing .He constructed transducers employing A-1 9, A-18 strain guage and measured perioral and lingual myometric pressures in the interproximal area between different teeth. He found absence of resting pressure on the lingual surfaces of maxillary central incisors during rest, except in Class III and some anterior open bite cases. Lingual pressure during swallowing ranges from 0.581 psi to 10.138 psi. In function the tongue exerts a much greater force on dentition than does the perioral musculature.

Kydd and Toda (1962)[29]studied fifteen subjects with various palatal shapes. They recorded the maximum tongue pressure during swallowing. After all the readings,he found mean swallowing pressure 109g/cm^2 in subjects with peaked palate,78 g/cm^2 in round palate and 89 g/cm^2 subjects of flat palate.He concluded that the mean swallowing tongue pressure among various palatal shapes were variably recorded and the maximum tongue pressure during swallowing was seen in subjects with peaked palate in comparison with round palate and flat palate.

Kydd WL, Akamine JS, Mendel RA, Kraus BS (1963)[33]measured the forces exerted by the lingual and perioral musculature on the anterior dentition during the act of swallowing. The devices employed in this study consisted of pressure

transducers utilizing resistance-strain gauges. Simultaneous recording of tongue and lip pressure on the maxillary central incisor during swallowing was registered on two sample populations. Group A consisted of 5 cases, at least 1 year out of the retention phase of treatment, who exhibited good occlusions. Group B was made up of 6 patients who had been treated and relapsed into an anterior open bite and who clinically exhibited a tongue thrust. All of the subjects ranged from fourteen to twenty years of age. The following results were observed: (1) The mean tongue pressure of the anterior open-bite sample was twice that of the controls. These differences were statistically significant. (2) Anterior open-bite subjects, i.e., tongue thrusters, exerted both tongue and lip pressures for a longer duration than did the non-open-bite subjects. (3) There was a lip-tongue synergy in the oral stage of swallowing for all subjects. The lip always applied pressure prior to the tongue. However, a difference did exist in duration of pressure and magnitude of pressure applied to the teeth by tongue and lip during swallowing. (4) The tongue did not protrude past the labial edge of the upper central incisors during swallowing among the anterior open-bite subjects, i.e., tongue thrusters.

Kydd WL ,Neff CW (1964)[5] conducted a study to determine the frequency of deglutition in a group of tongue thrusters and non tongue thrusters on 150 children seeking orthodontic treatment .He divided the subjects into two groups ,i.e, the control group and the abnormal swallower group. Both the groups were equally divided with age range of 9-15 years. The strain guage was placed on the patients neck and lightly taped. The record was evaluated by marking each swallow, recording the count and interpolating all results to the hourly rate. the findings of the study revealed that there exists a difference between the frequency of deglutition among normal and abnormal swallowers. He found that the non thrusters swallow at a mean rate of 61.4 times per hour,while the thrusters swallowed at slower mean rate of 37.25 times per hour .

Fishman (1969)[24] described the postural and dimensional changes in the tongue from rest position to occlusion, by taking three series of cephalograhs of 27 children who were having various malocclusions including Class II Div 1, Class I, pseudo Class III and Class II Div 2 cases, 29 normal children with no speech

defects or habits and 27 children who underwent speech evaluations and were categorized as lispers. To facilitate tracing of the tongue, a thin coating of tantalum powder mixed with gum acacia and water was painted on the median sulcus and tip of the dorsum on the majority of the patients. He concluded that in general the tip of the tongue contacted the lingual surfaces of the lower incisors, the dorsum of the tongue was superior to the occlusal plane and the posterior area of the dorsum contacted the soft palate in both rest and occlusion. In patients with lisping problem the anterior tongue movement was more posteriorly directed and the tongue posture for the posterior aspect of the tongue was more anteriorly related and the tongue increased in height from rest position to occlusion.

Proffit W (1978)[18] described the equilibrium theory concerning the factors influencing the position of the teeth.He described the primary and secondary factors that influenced the dental equilibrium. The primary factors which directly influenced the dental equilibrium are;intrinsic forces by tongue and lips, extrinsic forces:habits,orthodonticappliances,fprces from dental occlusion and forces from periodontal membrane.and the secondary factors are:postural relationship and erupting forces.he concluded that the position of the teeth and harmony is interplay of the above mentioned factors.

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Christiansen RL, Evans CA, Sue SK (1979)[4] conducted a study to measure lateral resting tongue pressure in 23 subjects. Among them 17 subjects had normal occlusion and 6 had a dental open-bite condition. Three sensing tips with different contact areas were used to study the relationship between sensor area and measured force. The average force of the resting tongue was 0.8 gm when measured with a 4.9mm diameter sensor (pressure = 0.039gm/mm2). When the

size of the sensor tip was increased, the force of the tongue increased in a non-linear manner. The mean stiffness of lingual musculature was 2.30 gm/mm. A correlation of r = -0.4 was found between resting tongue pressure and mandibular inter-canine width.

Christiansen RL,Evans CA, Sue SK(1979)[4] conducted a study to measure the lateral resting tongue pressure in 23 subjects. Among them 17 subjects had normal occlusion and 6 had a dental open bite malocclusion. Three sensing tips with different contact areas were used to study the relationship between the sensing areas and measured force.the average force of the resting tongue was 0.8gm when measured with a 4.9 mm diameter sensor(pressure =0.039 g/mm2). When the size of the sensor tip was increased ,the force of the tongue increased in a non linearmanner.the mean stiffness of lingual musculature was 2.30g/mm.

Huang GJ, Roberto J, Kennedy DB, Kokich VG (1989)[11] evaluated the effectiveness of crib therapy in 33openbite patients (7 -33 years) pre-treatment (T1), immediately post treatment (T2), and a minimum of one year after appliance removal (T3). Significant increase in mean T1 versus T2 overbite whereas no significant difference between mean T2 and T3 overbite for growing group. Significant differences in mean T1 versus T2 overbite (x=+4.2 mm, $p<0.001$) and in mean T2 versus T3 overbite (x=+0.8 mm, $p< 0.005$) for non growing groups.The findings suggested that patients who achieved a positive overbite with crib therapy had good chances of maintaining this correction after the treatment is completed, in both growing and nongrowing individuals. The reason for increased stability can be attributed to the modified tongue position or posture.

Hori K et al (1993) [48]conducted a study on 15 healthy subjects to clarify the physiological mechanisms of tongue pressure and to investigate the temporal relationship among tongue pressure, supra-hyoid muscle activity and video fluorographic (VF) images during swallowing, it was concluded that the tongue pressure was produced for bolus propulsion and was closely related to hyoid movement temporally during swallowing.

Takahashi et al, (1999) [12]**:** Examined the reliability of measurements using a newly developed perioral muscle pressure measuring device with a lip piece in

healthy adults. subjects were 40 healthy men (25.8 years) with normal stomatognathic function. Perioral muscle
pressure measuring device with a lip piece was used to measure upper lip, lower lip and tongue pressure, and a balloon-based measurement device was used to measure tongue and cheek pressure. Each measurement was taken twice with a 1-min interval between the two measurements. they determined intra-rater reliability by using the intra-class correlation coefficient as a test of relative reliability. As a test of absolute reliability, Bland-Altman analysis was used to assess systematic bias and the 95% confidence interval of the minimal detectable change was calculated. Additionally, the coefficient of variation was calculated. The Spearman-Brown formula was calculated the number of measurements needed to achieve a confidence coefficient 20.9. Each set of measurements was followed by a second set that were taken 1 week later. All measurements showed high values of intra-class correlation coefficient. Upper lip, tongue, and cheek pressure can be determined based on a single measurement, while lower lip pressure requires averaging twice. No systematic bias was observed. The coefficients of variation of measurements were almost the same between the two devices. Measurements were highly reliable regardless of the type of perioral muscles. Their findings suggest that the method described in this study is useful as a quantitative chair side method for examining perioral muscle pressure.

Hitoshi et al (2001)[21]: They treated a 21-year-old woman with a severe open bite and macroglossia with a standard edgewise appliance and without partial glossectomy. This was followed by retention using a Begg-type plate retainer for the upper dental arch and a fixed canine-to-canine for the lower arch. A crib was added to the upper plate retainer for suppression of a tongue thrust. The lower arch relapsed during the retention period, with a widening of the intermolar distance, flaring of the anterior teeth, and increased mobility of the teeth.they chose tongue reduction to resolve these problems and one-third of the middle dorsal part of the tongue was excised. After the tongue reduction, the patient experienced no functional problem in mastication, swallowing, and gustation, but she complained of mild speech difficulty and slight pain on the dorsal portion of her tongue. These symptoms disappeared 6 months after surgery. At this time, the

mandibular dental arch was markedly improved. The flared lower dental arch had returned to an upright position and the tooth mobility reduced to normal. No appliance was used after surgery. Most of the recovery changes occurred within 4 months. This case highlights the importance of the teeth tending to move toward a balance between the tongue pressure from the inside and labio-buccal pressure from the outside.

Yamaguchi H, Sueishi K (2003)[31]reported the association of abnormal posture with malocclusion, they stressed on the role of musculature and abnormal habits in the development of malocclusion. They concluded that maxillary protrusion and open bite in children are related to abnormal habits of digital sucking, tongue thrust, lip licking, lip sucking and mouth breathing. The development of malocclusion depends on the frequency, amount of pressure, duration and method of the habits. They concluded that the three factors of morphology, function and posture influence each other, contributing greatly to the continued growth and development of normal occlusion and a balance face.

Yuki Chiba, Mitsuru Motoyoshi, , and Shinkichi Namura(2003)[49]

The purpose of this study was to measure tongue pressure exerted on the loop of the transpalatal arch (TPA) during deglutition and to consider the influence of the distance of the loop of the TPA from the palatal mucosa and the anteroposterior position of the loop. Tongue pressures of 4 subjects with normal occlusion were measured with subminiature pressure sensors fixed on the TPA. The distances from the palatal mucosa to the surface of the pressure sensor were set at 2, 4, and 6 mm. The loop of the TPA was placed at the level of the middle of the maxillary second premolars (P), first molars (M1), or second molars (M2). Nine types of TPA devices were measured for each subject. The maximum recorded tongue pressure was taken from each act of deglutition. The minimum pressure value was exerted at position P when the distance from the palatal mucosa to the surface c the pressure sensor was 2 mm. The maximum value was obtained at position M2 and a distance of 6 mm from the palatal mucosa. When distances of 2, 4, and 6 mm were compared, significant differences between 2 and 4 mm, and between 2 and 6 mm were found. Significant differences were observed in comparisons between the positions P and M1, M1 and M2, and P and M2.

Shigeki et al (2004)[12]The purpose of this study was to test whether the tongue position affects the electromyo graphic (EMG) activities of masticatory muscles.they recorded the EMG activities of the masseter and anterior temporalis muscles in 10 skeletal Class I adults. Tongue position was monitored by two pressure transducers embedded in the midpalatal region and the lingual flange of a custom-made acrylic monoblock.they instructed subjects to assume three different tongue positions: rest, superior, and anterior. Friedman's test and Sheffe's F-test were used to statistically examine differences in muscle activities induced by changes in tongue position. Significant differences were found in masseter muscle activity between the rest and anterior positions and in anterior temporalis muscle activity between the rest and both the anterior and the superior tongue positions. They concluded that masticatory muscle activity is affected by tongue position.

Wen-hua et al (2005)[44]**:**This study evaluated the distributing characteristic of the forces exerting on the nor mal deciduous dentition and the relationship between the muscular forces, sex, and oral function. The pressure measurements were made with a computer-aided perioral force-measuring system designed by the authors. The forces were measured when the subject's head position was in a state of natural head position and oral function was at rest or with swallowing. The results indicated that the forces from lips, cheeks, and tongue at rest were about 37-208 N/m², whereas the pressure during swallowing was about 1009-1679 N/m². At rest, the pressure from lips and cheeks was higher than that from tongue ($P<.05$), whereas during swallowing, the lingual pressure was statistically larger ($P < .001$). A significant correlation existed between the muscular pressure and sex. When at rest, the boy's force from cheeks was higher than that of the girl's ($P<.05$) but during swallowing the boy's labial pressure was statistically higher than that of the girl's ($P<.01$). It was concluded that (1) the deciduous teeth are not in a state of absolute balance between external and internal forces, (2) the distributing manner and unbalanced mode of the forces are different with the different oral functions, (3) the lingual side of the mandibular anterior teeth endures great differences during oral functions and it may account for high

incidence of malocclusion in this segment, and (4) a statistical difference between muscular forces and sex exists.

Hori K, Ono T, Nokubi T (2006)[48]described the role of tongue in mastication and swallovving by its contact with the hard palate. Using an experimental palatal plate with 7 pressure sensors, and recording jaw movement using mandibular kinesiography, they assessed, in healthy subjects, the coordination of tongue and jaw movements during the entire masticatory sequence of solids, by measuring tongue pressure against the hard palate. Tongue pressure appeared during the occlusal phase, reached a peak near the start of opening, and disappeared during opening. Specific patterns in order, duration, and magnitude of tongue pressure were seen at the 7 pressure sensors in each chewing stroke. Magnitude and duration were significantly larger in the late stage of chewing (8 strokes before initial swallowing) than in the early stage (until 8 strokes after starting mastication). It was concluded that contact between the tongue and the hard palate in each chewing cycle was short in duration and low in magnitude during the early stage of mastication. Statistically significant changes in duration and magnitude of tongue pressure was found during the late stage of mastication suggest that later stages required long and close contact between the tongue and the hard palate.

Sayın et al (2006)[9]

The objective of this study was to investigate the initial effects of a tongue crib on tongue movements during deglutition by using real time balanced turbo field echo (B-TFE) CineMR imaging. A total of 21 patients were evaluated in this study. The open-bite group (OBG)consisted of 11 patients (seven girls, four boys) who had a mean age of 11 a mean overbite of -5.14 ± 1.83 mm. These patients were evaluated initially (T1) and whilewearing a tongue crib (T2). A total of 10 patients (five girls, five boys) with a mean age of 14.5+2.6 years and with a mean overbite of 1.6 ± 0.5 mm served as controls (CG), and only initial records were obtained from these patients. T2 was compared with T1 and CG. T1 was also compared with CG. they evaluated deglutition during three stages matching oral (1), pharyngeal (2), and esophageal (3) stages. Our results indicated that the tongue's

tip positioned more posteriorly when the crib was in place (T2) compared with both T1 and CG; the anterior portion of
the tongue's dorsum was at a lower position in T2 compared with both T1 and CG at stage 3;the midportion of the tongue's dorsum was at a lower position in T2 than in 11 and CG at stages1 and 2. To compensate for the posterior position of the tongue's tip (caused by the tongue crib),adaptive changes occurred in the anterior and midportions of the dorsum of the tongue.

Premkumar et al (2007)[15]:

The aim of this study was to evaluate oral sensory perception in patients with an anterior open bite (AOB) and associated tongue thrusting activity. This study was performed in the Department of Orthodontics, Government Dental Hospital, Chennai, on 30 subjects (16 females and 14 males) aged from 12 to 17 years with an AOB associated with a tongue thrust and in a control group of 100 subjects (53 Termates and 47 males aged from 12 to 17 years) with a normal occlusion and no oral habits. Stereognosis and two-point discrimination (2PD) were employed for evaluation of oral sensory perception. Statistical comparison was undertaken using a Student's t-test.Stereognostic ability was altered in children with an AOB associated with a tongue thrust ($t = 15.2$, probability of occurrence $P < 0.01$). The mean oral stereognostic score in the control group was 31.8 and in tongue thrusters 25.3, The AOB group also showed a diminished 2PD threshold at the tip of the tongue [control group 1.08 mm, tongue thrusters with an AQB 1.64 mm ($t=7.3$, $P<0.01$)].

Utanohara V et al (2008) [31]conducted a study to evaluate the Maximum Tongue Pressure in different age range and gender during the act of swallowing Using a Newly Developed Disposable Tongue Pressure Measurement Device. They developed a disposable tongue pressure measurement device designed for clinical use in adult Japanese. Eight hundred fifty-three subjects (408 male, 445 female; 20-79 years) were selected for this study. A balloon type disposable oral probe was used to measure tongue pressure by asking subjects to compress it onto the palate for 7 s with maximum voluntary effort. Values were recorded three times

for each subject, and the mean values Were defined as maximum tongue pressure. They concluded that males in the twenties, thirties, and forties showed higher tongue pressure than the females.

Chui shan et al(2008)[14]found that the multifactorial nature of anterior open bite makes its management difficult and various treatment modalities are being used. Clinicians must be able to diagnose the problem and choose the best treatment.

Successful treatment of anterior open bite greatly relies on both diagnosis and therapeutics. Although there are many different treatment modalities available, stability after treatment is still a critical issue as evidence on long term stability of various treatment options is lacking. Thus,clinicians should pay more attention during retention phase and long-term studies on post-treatment changes and stability should be encouraged.

Jalay T,Ahrari F (2009)[1] :studied effect of tongue thrust swallowing on position of anterior teeth in 193 growing children with age range of 9 to 13 years (99 girls,94 boys) with Angle's class 1 malocclusion and complete eruption of upper and lower incisors. The control group consisted of 36 subjects (18 girls , 18 boys, average age 11.2+-2.1 years) with Angle's class 1 malocclusion , normal overjet and overbite, normal sagittal and vertical skeletal relationships. Among 193 subject , 10 cases (5 %) were diagnosed to be tongue thrusters. Comparison of dental features between tongue thrusting and control subjects showed that overjet was significantly greater in tongue thrusting individuals ($P< 0.05$), while the mean overbite , upper incisor inclination , lower incisor inclination and interincisal angle was not statistically different between the two groups ($P > 0.05$). The results showed that overjet is the only variable which significantly increases in tongue thrust individuals compared to control subjects and tongue thrust may have an environmental effect on dentofacial structures.

Lambrechts H ,Baets E, Fieuws S, Willems G(2010)[3] conducted a cross sectional study comprising 107 subjects (63 females and 44 males) , between 7 and 45 years of age (median 15.2 years),seeking orthodontic treatment with the aim to determine the differences in lip and tongue pressure as a function of gender ,age, Angle's classification , occlusion and oral habits.No evidence was found for

a relationship between lip pressure and occlusion (P = 0.17). No statistical difference in tongue pressure existed between males and females or between angle classes was found where as significant difference (higher in males) was found in lip pressure.

Kennedy D, Kieser J, Bolter C,Swain M ,Singh B, Waddell JN(2010)[19] conducted a study examined how pressure is generated by the tongue against the hard palate differ between three points along the midline of the tongue, using a metal appliance described previously, they measured absolute pressure during water swallows in six healthy volunteres (4 males,2 females) with an age range of 25-35 years. participants performed three 10 ml swallows from a small cup on five separate days, thus providing a data of total 15 water swallows. In all subjects, pressure at the anterior and hind palate tended to be negative to the pre swallow value ;at mid palate however, pressure changes were less consistent between individuals. When the pressure differences between the sites were calculated ,it was that during the swallow a net negative pressure difference developed between the anterior and mid palate and a net positive pressure difference developed between mid palate and hind palate.overall,the most effort appears to have occurred at the front of the palate and the least at the mid palate. The result also showed that some participants exerted a small amount of mid line pressure when swallowing.

Taslan S, Biren S, Ceylanoglu C (2010)[2] : Evaluated the tongue pressure changes before ,during and after crib appliance therapy in 13 patients (age range : 7 years 11 months -12 years 1 month) and control group of 6 patients(age range : 7 years 7 months-9 years 11 months) was compared in mixed dentition open bite cases. Resting tongue pressure in the study group on the upper molar increased and continued increasing during first week. After the first week, the values showed a gradual decrease and even at the 10th month when the appliance was removed.The initial resting tongue pressure measured for upper central incisor at the 10th month and at the 12th month remained same in the control group. Swallowing tongue pressure in the study group showed a decrease at the end of the 10th month and it remained lower than initial values the following 2 months. found initial resting tongue pressure on central incisors as 16.42± gm/cm^2 and

swallowing tongue pressure 154.12± 41.12gm/cm^2 respectively in study group(Open bite). In control group resting tongue pressure on central incisors was 19.5± gm/cm^2 and swallowing tongue pressure 148.53± 23.09 gm/cm^2 .The resting tongue pressure for lower central incisor decreased after 10 month of appliance wear. Significant decrease in resting pressure on the crib appliance in the study group suggested tongue adaptation to the new position created by the appliance due to disturbance in intraoral pressure equilibrium.

LadanEslamian and Amir Peyman Leilazpour(2011)[16]:

The aims of this study were to determine the location and movements of the tongue on the palate during pronunciation of Persian consonants and selected words in subjects with and without a tonque thrust (TT). Ten patients with a TT and 10 control subjects, 9-13 years of age, matched for age, gender, ethnicity, type and severity of malocclusion, with no history of orthodontic treatment, surgery, or systemic disease were selected. Maxillary alginate impressions were taken to construct upper removable appliances with 12 electrodes. Fine wires connected the electrodes to a specially designed electropalatovision (EPU) device. The removable appliance was inserted in the upper arch and then the Persian consonants and some selected words were pronounced by both groups. An electromechanical marker was included on each electrode which showed the tongue movements on the palate. Tongue movements, the quantity of the tongue contacts, and the location of the tongue were compared using t- and Chi-square tests. In the TT group, the tongue had mor contact with the palate on six electrodes ($P<0.001$). When pronouncing the consonants, the tongue made contact anteriorly on the palate in the TT group. The quantity of tongue contacts with the palate was similar in both groups. During pronunciation of selected words, the contact points of the tongue to the palate were similar in both groups.

Stöhr, Ingmar(2011)[28]: In this paper they describe a wireless sensor system for measuring the spatially resolved pressure of the tongue against the upper palate. The system consists of eight piezoresistive absolute pressure sensors,a signal conditioning and data acquisition electronics, a wireless transceiver module and a LiPo-battery. A novel encapsulation protects the sensing elements during the

manual mounting process, while taking into account the sensibility of the tongue. The implemented technique of switched excitation voltage to reduce the power consumption of the sensors by 97 % is discussed. The design of the signal conditioning and data acquisition electronics is presented. Tongue pressure is sampled with 30 Hz per sensor and with a resolution of 0.25 mbar. The sensor systems overall power consumption with working transceiver is 56 mW. enabling a running time of more than two hours out of the integrated 60 mAh LiPo-battery. First measurement results of the working sensor system in the oral cavity are given.

Subramanya RM ,Gupta S (2014)[20] studied the posture of tongue in individuals with different skeletal pattern,to understand the relationship between the tongue posture and growth pattern of an individual. Sixty subjects in the age group 16-20 years were selected and divided according to vertical or horizontal growth pattern into two groups. They studied the subjects cephalometrically and concluded that the dorsum of the tongue was significantly higher in vertical skeletal pattern at all the points. They did not observe any significant difference between the position of the tip of the tongue and the distance between the soft palate and the roof of the tongue in horizontal and vertical pattern. They also observed that in normodivergent facial pattern;the tongue rests at the corrugated transverse ridges present on the palate,the tip of the tongue behind the anterior teeth.

Suchita Madhukar Tarvade, Sheetal Ramkrishna(2015)[20]

Oral habits are learned patterns of muscle contraction and have a very complex nature. They are associated with anger, hunger, sleep, tooth eruption and fear. Some children even display oral habits for release of mental tension. These habits might be non-nutritive sucking (thumb, finger, pacifier and/or tongue), lip biting and bruxism events. Tongue thrust is the most common of them, these habits can result in damage to dento-alveolar structure hence causes and its management plan is important to every clinician.

Maurya G.S., Bharadwaj A., Makhija P.G, Thukral R(2015)[17]

This case report is focused on the correction of tongue thrusting habit which causes the proclination of maxillary anterior segment of teeth and hence results in an open bite. The undue pressure on teeth tends to move them in the direction of force applied and if the force is due to some deleterious habit the ill effects presented are severe as the habit is puts a continuous force on the dentition. The aim is to correct the swallowing habit and hence help in bringing out faster and stable corrections. This requires a set of instructions with good patient education and motivation.

LeiteaJS ,Matiussib LB, Salemc AC, Provenzanod MGA, Ramose AL (2016) [10] evaluated the overbite correction of fixed palatal crib (FPC) and bonded lingual spur (BLS) in the early treatment of anterior open bite (AOB) in mixed dentition (primary outcome) as well as its influence on dental and skeletal cephalometric measurements (secondary outcome), control (n =13), palatal crib (n = 13), and spur (n = 13). Data from the lateral tele-radiography was obtained at the beginning, at 6 months, and after 1 year. At 6 months and then after 1 year all groups showed improvement in the overbite. However, only the crib and spur groups showed positive overbite.

In this study the overbite was reduced on average 2.33 mm in the control group and 3.95 mm in the crib group.Nasolabial angle, ANB, and SNB also presented minor changes without significance, reflecting individual variability in such ages.

Chawla h. , Suri s, Utreja a.(2016)[13]

The role of tongue thrust has often been suspected, long debated and largely dispelled as a primary etiological factor of malocclusion. However, tongue thrust may contribute to poor occlusal intercuspation both during and after treatment. A tongue thrust may also develop during orthodontic mechanotherapy as a result of the transient creation of intra and interarch spaces and this little recognized phenomenon was found to occur in many randomly followed cases. In many instances, this seemingly adaptive and secondary response of the tongue posture and function may persist and thereafter impede the resolution of intra and interarch problems.

Shwetha G.[1], Ashmitha K. Shetty[2], Usha R.3 and PushpalathaC(2017)[15]

Digit sucking is the most commonly seen oral habit and one of the most common learned patterns of behaviours seen in children of preschool age and is a habit of concern as it is an important etiological factor in the development of malocclusion, a secondary tongue thrust develops leading to the exaggeration of the condition. To plan an appropriate treatment it is important to understand the etiology, which includes psychological, physiological and anatomical and planning for behavior eradication is critical for the positive outcomes. Starting from counselling to appliance therapy, ample treatment modalities have been reported in the literature. Many appliances have been developed for habit correction and have been modified depending on the patient compliance. Palatal crib is one such appliance for treating digit sucking habit and tongue thrusting. This case report describes a 12-year-old girl who reported to our department with a history of digit sucking habit which was intervened using modified palatal crib appliance.

Irmak Partal and MugeAksu(2017)[22]

The etiology of Class II division 2 (CII/2) malocclusion focuses on heredity; however lip, cheek, and tongue pressures that are associated with the environmental effect are considered to have an effect. The aim of this study was to evaluate the relation between perioral pressures and the upper incisor inclination in CII/2 malocclusion.

Twenty patients (8 females, 12 males; mean age 10.29 ± 0.90 years) with CII/2 malocclusion were included in the study group, and 15 patients (5 females, 10 males; mean age 10.56 ± 1.06 years) with Class I malocclusion were included. The upper incisors were protruded with a utility arch (0.016 x 0.022 in. blue elgiloy wire). Perioral pressure assessment was made with the lowa Oral Pressure Instrument. Upper lip pressure, lower lip pressure, vertical lip pressure, left-right buccal pressures, swallowing, and maximum tongue pressures were measured. Repeated measure ANOVA was used to test the intragroup differences. Intergroup comparisons were made using two-way repeated measure ANOVA with Bonferroni correction. Relationships between the variables were analyzed using rank correlation (Spearman's rho). The significance for all statistical tests was

predetermined at $p < 0.05$. A significant change occurred in the upper lip pressure, lower lip pressure, and vertical lip pressure; however, significant difference was not found between the groups. Upper lip pressure increased significantly in both groups. In the CII/2 group, lower lip pressure increased after protrusion and decreased after retention, while vertical lip pressure decreased and then increased significantly. Left buccal pressure changes between the groups were not parallel. Right buccal pressure, swallowing, and maximum tongue pressure changes were not statistically significant. Statistically significant correlation was found between U1-NA (mm) and vertical lip pressure (r-0.467).In the CII/2 group, upper lip pressure increased only in retention. Lower lip pressure increased and vertical lip pressure decreased after protrusion. Nevertheless, these changes did not remain stable after the retention period. The difference between groups was not statistically significant at the end of retention.

This cross- sectional clinical study was conducted in the Department of Orthodontics and Dentofacial Orthopaedics, BBD CODS, LUCKNOW, to evaluate the changes in resting and swallowing tongue pressure following tongue crib therapy in patients with tongue thrusting habit.

Patients reporting to the Department of Orthodontics and Dentofacial Orthopaedics, BBDCODS , LUCKNOW for fixed orthodontic treatment were thoroughly examined and after proper investigations and diagnosis, suitable patients with and without tongue thrusting habit were included in the study.

Study Sample and size:

20 patients with tongue thrusting habit requiring fixed orthodontic treatment comprises the study group), whereas 20 patients without tongue thrusting habit requiring fixed orthodontic treatment were included in the control group (Table 1).

- **Eligibility Criteria:**

  - Inclusion criteria :

1)Patients having full completement of teeth except third molar.

2) Patients in the age range of 13-20 years.

3) Patients who never had undergone orthodontic treatment.

4) Patients with tongue thrusting habit were included in study group and patients not having tongue thrusting habit were included in control group.

  - Exclusion Criteria:

1) Patients with poor periodontal status, missing teeth.

2) Medically compromised patients.

3) Patients not willing to participate in the study.

Table 1: shows the sample distribution between groups:

N=40	No.of subjects	%
Group I (study group – patients with Tongue thrusting habit)	N=20	50 %
Group II (control group -patients without tongue thrusting habit)	N=20	50 %

The approval from the Ethical and Research Committee of Babu Banarasi Das College of Dental Sciences is obtained before conducting the study. A signed informed consent form as per the guidelines of University was taken from the patients.

Materials and Equipment's used: The following materials and equipment were used in the present study (Fig 1-Fig 5)

(i) For clinical diagnosis of tongue thrusting patient (Fig 1)

- Mouth mirror
- Dental probe
- Tweezer
- Water syringe
- Cotton rolls

(ii) For study model preparation (Fig 2)

- Gloves, Masks
- Cotton and cotton holder
- Plastic impression trays
- Alginate impression material with measuring cup
- Rubber bowl and spatula

- Cold water
- Dental plaster (type II)

(iii)For fabrication of sensor holding device (Fig 3)

- 21-gauge SS wire
- Working model
- Universal plier
- Adams plier
- Wire cutter

(iv)For fabrication of palatal crib (Fig 4)

- 19-gauge ss wire
- Adams plier
- Universal plier
- Wire cutter
- Molar bands
- Spot welder
- Lingual sheath

(v) For recording tongue pressure (Fig 5)

- FRS 400 sensor
- Connecting wires
- Sensor unit and tip

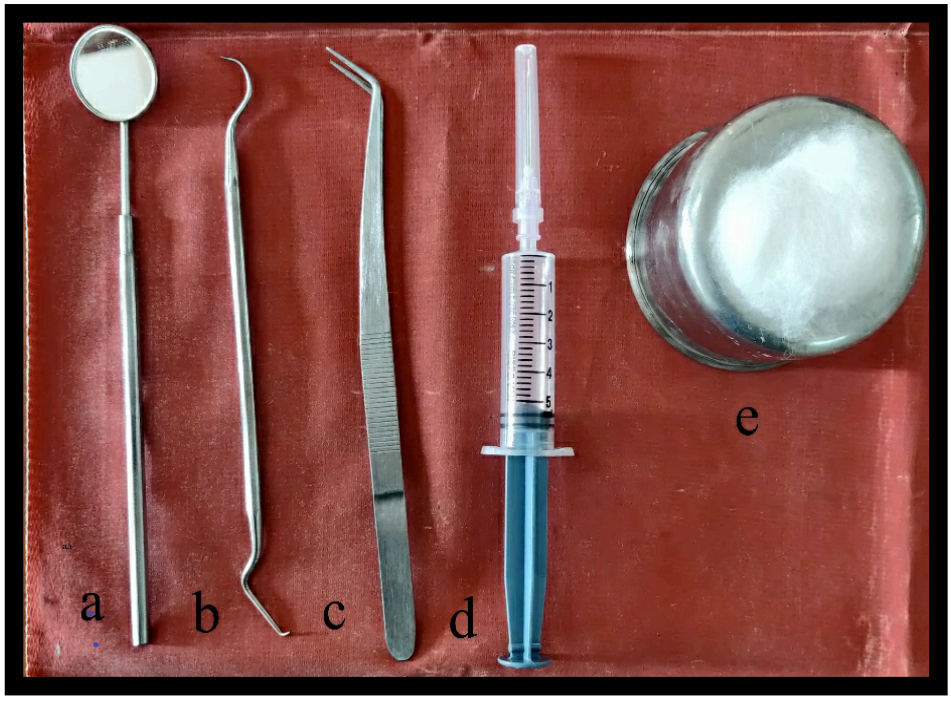


Fig 1: Armamentarium used for clinical diagnosis of tongue thrusting patient.

a. Mouth mirror
b. Dental probe
c. Tweezer
d. Water syringe
e. Cotton rolls

Fig 2: Material used for study model preparation.

A. Gloves
B. Masks
C. Rubber bowl and spatula
D. Cold water
E. Plastic impression trays
F. Alginate impression material
G. Spatula
H. Spatula
I. Dental plaster (type II)

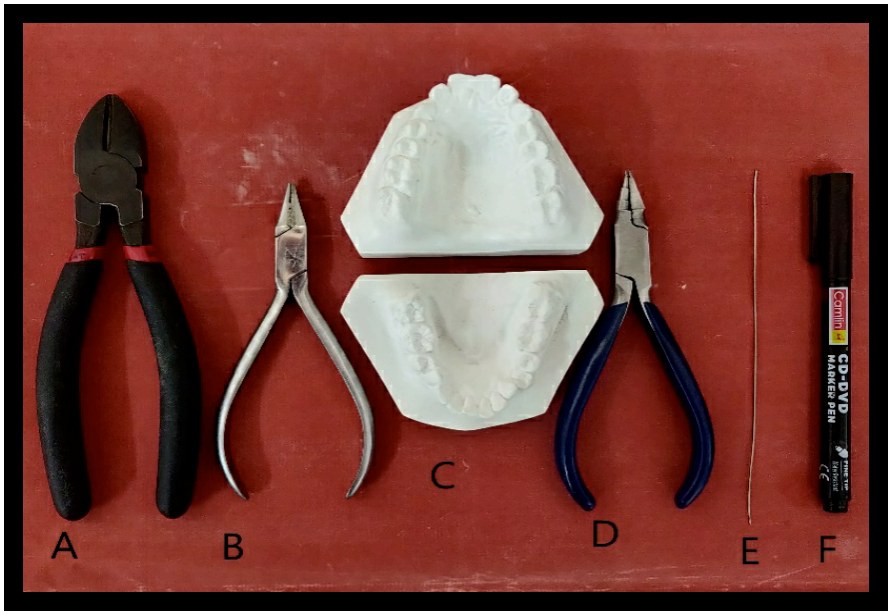


Fig 3: Armamentarium used for fabrication of sensor holding device.

A. wire cutter
B. Adams plier
C. Working model
D. Universal plier
E. 21-gauge SS wire
F. marker

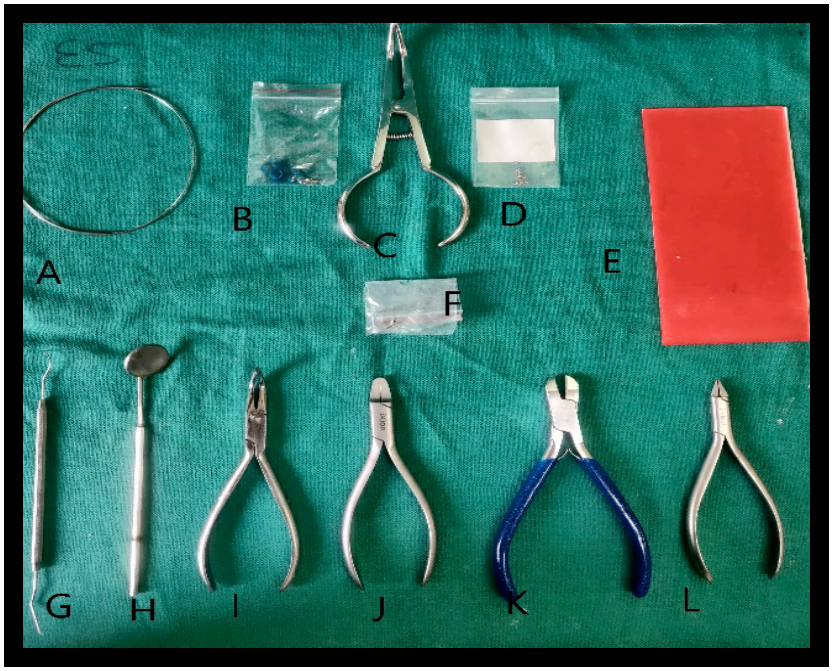


Fig 4: Armamentarium used for fabrication of palatal crib

A. 19-gauge SS wire
B. Separators
C. Separator placing plier
D. Lingual sheath
E. Modelling wax
F. Molar bands
G. Dental explorer
H. Mouth mirror
I. Band forming plier
J. Adams plier
K. Wire cutter
L. Universal plier

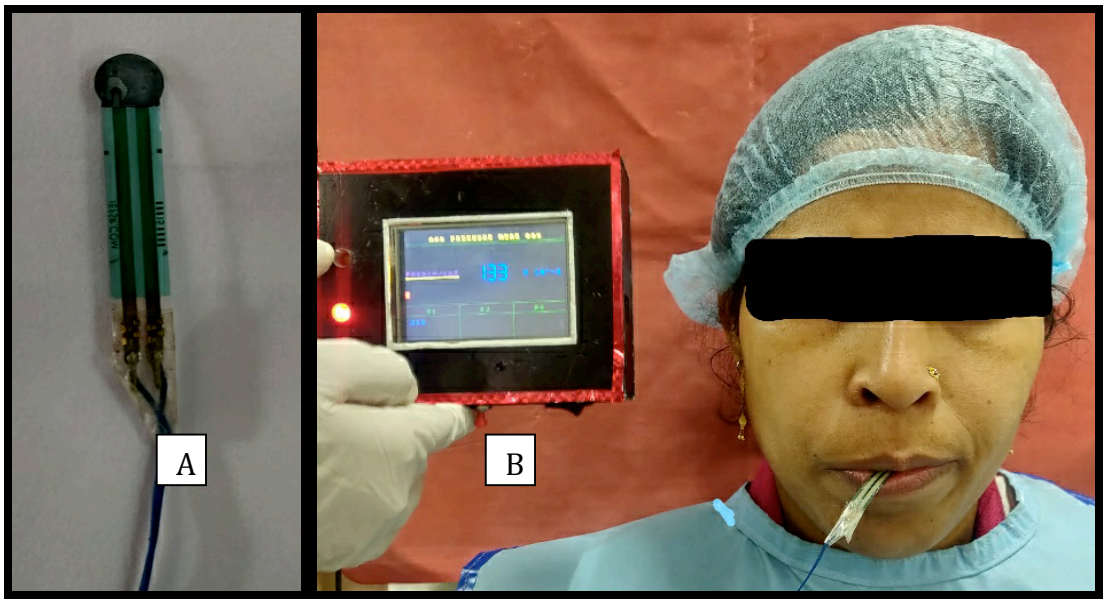


Fig 5: Shows recording of tongue pressure.

A. A: FRS 400 sensor andConnecting wires
B. Sensor unit and tip placed in patient's mouth

Methodology:

Patient coming to the Department of Orthodontics and dentofacial orthopaedics for fixed orthodontic treatment were screened and clinically examined for tongue thrusting habit and those patients who fulfilled the inclusion criteria were included in the study.

For confirming the tongue thrust habit patient was asked to sit up righted on the dental chair.The lower lip of the patient was held cautiously down to squirt water in to the mouth with water syringe then patient was asked to swallow. During normal swallow tip of the tongue touches interdental papillae behind maxillary central incisor and is able to swallow without difficulty, whereas in tongue thrusters the tip of the tongue sticks out between the teeth, whether the child is resting, swallowing or speaking.

To observe the position of tongue, lower lip was held carefully down and patient was asked to swallow, if tip was found to be sticking out between teeth, patient was

considered as tongue thruster and was included in the study group. Patients who were not tongue thrusters but fulfilled other inclusion criteria were included in the control group.

Working model preparations:

After appropriate impression tray selection, alginate was mixed in the rubber bowl with proper water powder ratio following manufacturer instructions. A proper mix was made using spatula in figure of eight motion. The patient was asked to sit in upright position on dental chair and impression tray was loaded with the material and placed in patient's mouth. After the impression was made, dental stone was poured and cast was fabricated.

Maxillary arch study model was prepared to make removable palatal crib of adequate length for each patient. A preformed band for maxillary right and left first molar were selected and lingual sheath welded on palatal side of molar band for insertion of distal extension of palatal crib.

Fabrication of sensor holding device:

For each patient a wire framework was fabricated to hold the sensor tip on the palatal aspect of maxillary anterior teeth while recording the tongue pressure and named as sensor holding device. The framework was made in such a way that it allows hindrance free placement of the sensor and its wire components. 21 gauge stainless steel wire segment was adapted on the palatal aspect of maxillary anterior teeth. The adapted wire was marked at the distal aspect of canine on both the sides. A 90 degree bend was made occlusally and the wire was bent at canine region to bring it labially. On labial side wire was adapted and secured in the interdental region between lateral incisor and canine like a pinhead . (Fig 6).

Figure 6: sensor holding device

- Separators were placed in the upper and lower first molar tooth mesially and distally. After 3-5 days interval patient was recalled and separators were removed. Pre -fabricated molar bands with lingual sheath were placed.

- Maxillary and mandibular working models were mounted on hinge articulator for fabrication of palatal crib for each patient. Height of the palatal crib was so decided that it would not encroach lower vestibular space after insertion in patients' mouth.

Fabrication of Palatal Crib

A 19gauge SS wire, with the help of universal and adams plier, long vertical crib made in the anterior palatal aspect resting lingually. The distal arm of the crib was extended to be filled snugly in lingual sheath.

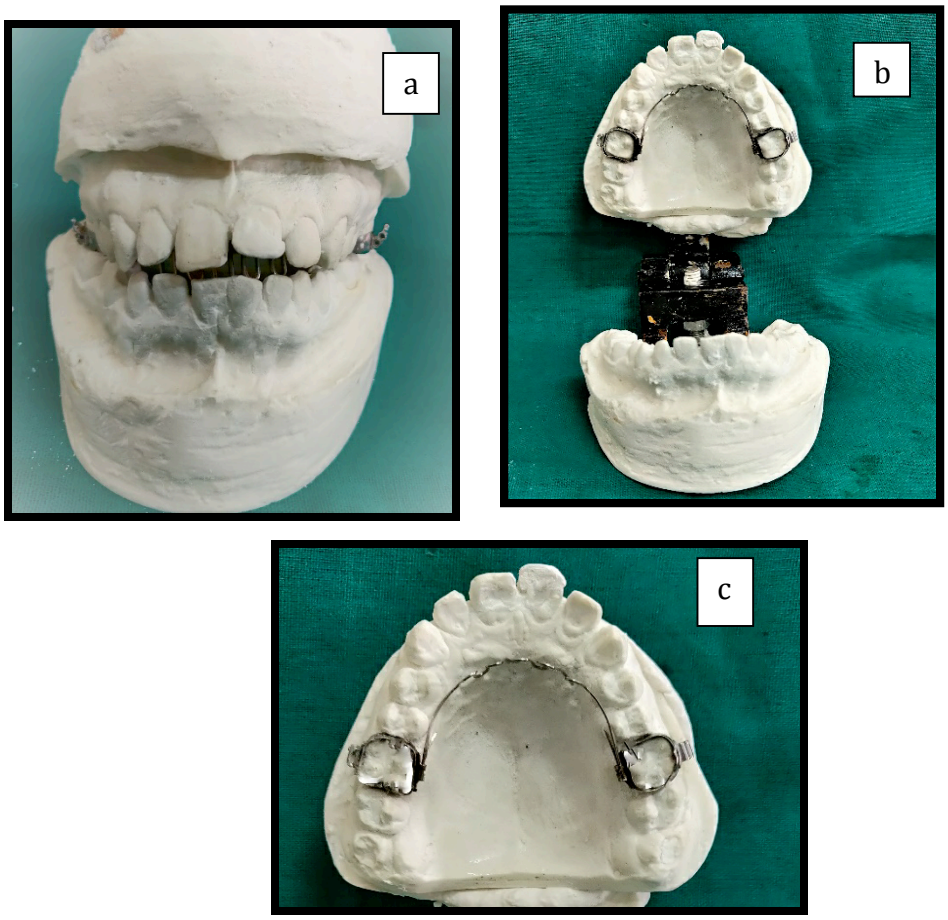


Figure 7a: Showing frontal view of mounted maxillary and mandibular working model.
Figure 7b: Maxillary and mandibular working models mounted on articulator after fabrication of palatal crib.
Figure 7c: Maxillary working model after fabrication of palatal crib.

was used. The force sensitivity is optimized for use in human touch control, sensitivity range up to 10N. The sensor has ultra-thin, small size and high sensing precision. Sensor along with unit, CIP and connecting wires is used for recording tongue pressure. A tongue pressure measuring assembly including, pressure sensor based on the principle of force sensitive resistor, a connector, amplifier and recording device was used to record tongue pressure. Before going into details of methodology a brief introduction about FSR (force sensitive resistors) and their mode of functioning is discussed as follows:

PRESSURE SENSOR:

A tongue pressure measuring assembly, including pressure sensor, based on the principle of force sensitive resistor, a connector, amplifier and recording device was used to record tongue pressure. Before going into details of methodology a brief introduction about FSR (force sensitive resistors) and their mode of functioning is discussed as follows:

Overview:

A force-sensitive resistor (force-sensing resistor or simply an FSR) has a variable resistance as a function of applied pressure. FSR are robust polymer thick film (PTF) devices that exhibit a decrease in resistance with increase in force applied to the surface of the sensor. This force sensitivity is optimized for use in human touch control of electronic devices such as automotive electronics, medical systems, and in industrial and robotics applications. The standard 400 sensor is a round sensor 7.62mm in diameter.

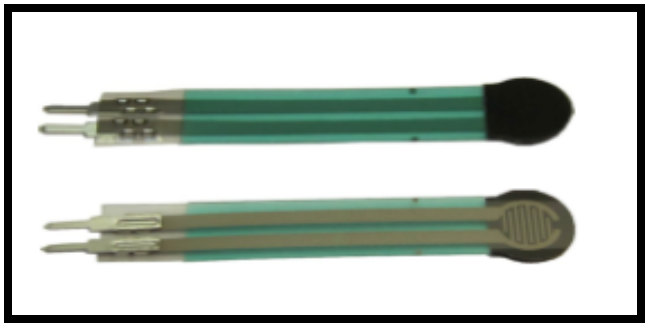


Fig 8: FSR 400 (5mm Circle) x 38mm

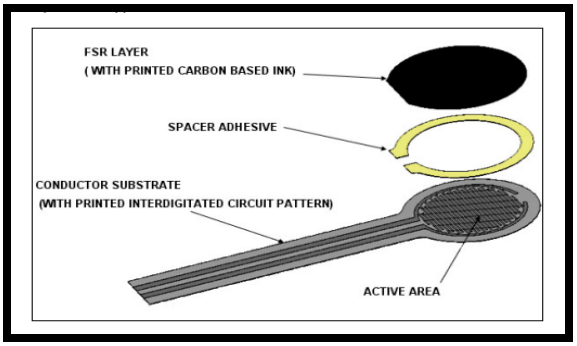


Fig 9: Exploded view of sensor

Theory of Operation

FSR consists of two membranes separated by a thin air gap. The air gap is maintained by a spacer around the edges and by the rigidity of the two membranes. One of the membranes has two sets of interdigitated fingers that are electrically distinct, with each set connecting to one trace on a tail. The other membrane is coated with FSR ink when pressed, the FSR ink shorts the two traces together with a resistance that depends on applied force.

Around the perimeter of the sensor is a spacer adhesive that serves both to separate the two substrates and hold the sensor together. This spacer typically has a thickness between 0.03mm and 0.15mm. This spacer may be screen printed of a pressure sensitive adhesive, may be cut from a film pressure sensitive adhesive, or may be built up using any combination of materials that can both separate and adhere to the two substrates. Both membranes are typically formed on flexible polymer sheets such as PET, polyimide, or any other film material.

At low forces only, the tallest protrusions make contact. At higher forces more and more points make contact. The result is that the resistance between the conducting fingers is inversely proportional to the applied force.

Table 2: Specification of FSR

General PARAMETER	**VALUE**	**NOTES**
Force Sensitivity Range	~ 0.2 to 20N	Dependent on mechanics
Break Force (Activation Force)	~ 0.2N min	Dependent on mechanics and FSR build
Part-to-Part Force Repeatability	± 6% of established nominal	With a repeatable actuation system, single lot.
Single Part Force Repeatability	± 2% of initial reading	With a repeatable actuation system
Hysteresis	+ 10% Average	$(R_F + R_F)/ R_{F+}$
Long Term Drift	< 5% per $\log_{10}$ (time)	Tested to 35 days, 1kg load

Force Resolution	Continuous	Depends on measurement electronics
Stand-Off Resistance	>10MΩ	Unloaded, unbent
Switch Travel	0.05mm	Typical; depends on design
Device Rise Time	<3 microseconds	Measured with drop of steel
Maximum Current	1 mA/cm^2 of applied force	

Measurement Techniques

FSR Voltage Divider for a simple force-to-voltage conversion, the FSR device is tied to a measuring resistor in a voltage divider (see figure below) and the output is described by the following equation:

$$V_{out} = \frac{R_M V+}{(R_M + R_{FSR})}$$

In the shown configuration, the output voltage increases with increasing force. If R_{FSR} and R_M are swapped, the output swing will decrease with increasing force. The measuring resistor, R_M, is chosen to maximize the desired force sensitivity range and to limit current. Depending on the impedance requirements of the measuring circuit, the voltage divider could be followed by an op-amp A family of Force vs. V_{OUT} curves is shown on the graph above for a standard FSR in a voltage divider configuration with various RM resistors. A (V+) of +5V was used for these examples.

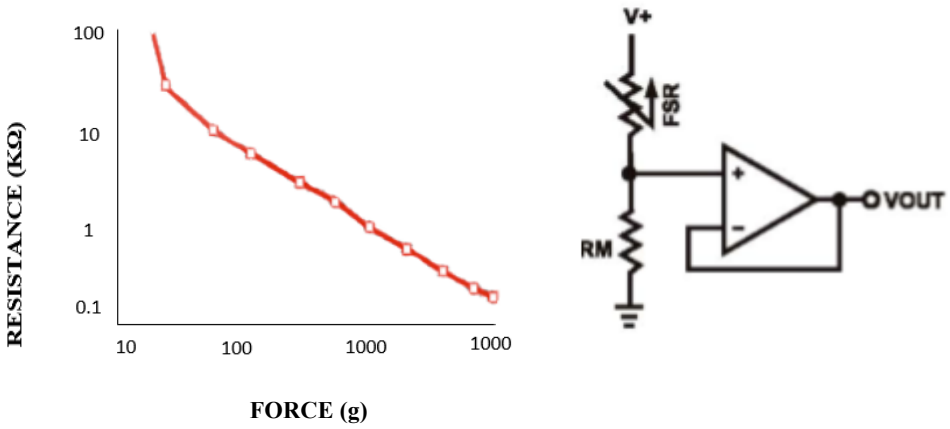


Fig 10: (A) Typical Force graph (B) Circuit diagram

Table 3: measurement of reliability:

test:

	Group I	Group II
Resting tongue pressure ($N/cm^{2)}$	**1.768 ($N/cm^{2)}$**	**1.189($N/cm^{2)}$**
Swallowing tongue pressure ($N/cm^{2)}$	**2.353 ($N/cm^{2)}$**	**1.988($N/cm^{2)}$**
Mean difference	**0.579**	**0.3645**
P value	**<0.001***	**<0.001***

BEFORE CRIB PLACEMENT

Recording of resting tongue pressure on anterior teeth: the resting tongue pressure was recorded with the subject sitting and head unsupported. The FSR sensor was adapted to the palatal aspect of central incisors with the help of customized sensor holding device for each patient.

Three readings for resting tongue pressure were measured at an interval of 1 minute and mean of the three were considered as resting tongue pressure of that patient. The same procedure was performed for all the patients. (T0)

Recording of swallowing tongue pressure on anterior teeth: The tongue pressure was recorded with the subject sitting in upright position and head unsupported. They were asked to swallow 15ml of water at room temperature to minimize the influence of temperature change.

RECORDING OF RESTING AND SWALLOWING TONGUE PRESSURE AFTER CRIB PLACEMENT (T1, T2, T3)

Recording of resting and swallowing tongue pressure on anterior teeth:

The patient was recalled after 3 months interval, crib was removed, and the resting and swallowing tongue pressure was measured in the same manner as previously described. The maximum pressure of three readings at each position was recorded. Out of these three, the mean was calculated and was used as the final value. 3 consecutive measurements for resting and swallowing tongue pressure were taken at every 3 months interval as T1, T2, T3. T1 represents the measurements taken after three months of the tongue crib therapy, T2 represents the measurements taken after six months of the tongue crib therapy and T3 represents the measurements taken after nine months of the tongue crib therapy.

The same procedure was carried out with all the subjects and the data thus obtained were recorded in excel sheet later subjected to appropriate statistical analysis.

The present clinical study was conducted to evaluate the changes in resting and swallowing tongue pressure following tongue crib therapy in patients with tongue thrusting habit. From the patients coming to the Department of Orthodontics and Dentofacial Orthopaedics for fixed Orthodontic treatment forty patients who fulfilled the inclusion criteria were selected and divided in two groups. Group I was experimental group with 20 patients having tongue thrusting habit and group II was control group who did not have habit of tongue thrusting.

Initial resting and swallowing tongue pressure (T0) on anterior dentition were evaluated for group I and Group II. In group I resting and swallowing tongue pressure after crib therapy were measured at intervals of 3 months (T1, T2, T3). The data thus recorded was tabulated and analysed in the following manner.

1. Evaluation of resting and swallowing tongue pressure on anterior dentition in the oral cavity before tongue crib therapy (T0) in Group I patient **(Table 4).**

2. Evaluation of resting and swallowing tongue pressure on anterior dentition in the oral cavity before tongue crib therapy (T0) in Group II patients **(Table 5).**

3. Evaluation of resting and swallowing tongue pressure on anterior dentition in the oral cavity at different time interval (T1, T2, T3) after placement of tongue crib in Group I patients **(Table 6).**

4. comparison of resting and swallowing tongue pressure on anterior dentition in the oral cavity at different time interval (T1, T2, T3) after placement of tongue crib in Group I patients **(Table 7and 8).**

5. Comparison of resting and swallowing tongue pressure (T0) between Group I andII **(Table 9)**

6. Comparison of resting and swallowing tongue pressure of group I (T3) to resting and swallowing tongue pressure of group II (T0) **(Table 10).**

The observations of the present study are displayed in following tables-

Table 4: Descriptive statistics of resting and swallowing tongue pressure before tongue crib therapy in group I(T0).

Resting tongue pressure (in Newton/cm^2)				Swallowing tongue pressure (in Newton/cm^2)		
N=20	Mean	Std.deviation(SD)	Std.error (SE)	mean	Std.deviation(SD)	Std.error(SE)
T0	1.768	.2131	.0476	2.353	.2722	.0609

Table4 shows descriptive statistics of measured resting and swallowing tongue pressure values in group I during at T0. The mean resting tongue pressure at before tongue crib placement (T0) was found 1.768 ±.2131N /cm^2). The mean swallowing tongue pressure before tongue crib placement (T0) was found 2.353± .2722 Newton/cm^2.

Table 5: Descriptive statistics of resting and swallowing tongue pressure in group II (T0).

N=20	**Resting Tongue Pressure (Newton/$cm^{2)}$)**			**Swallowing Tongue Pressure (Newton/$cm^{2)}$)**		
	Mean	Standard. Deviation (SD)	Standard. Error (SE)	Mean	Standard. Deviation (SD)	Standard error (SE)
T0	1.1899	.2194	.0476	1.988	. 115	.0609

Table 5 shows descriptive statistics of measured tongue pressure values in group II during resting and swallowing (T0). The mean values for resting and swallowing tongue pressure was found to be 1.768± .2131N and 2.353± .2722 N respectively.

Table 6: Descriptive statistics of resting and swallowing tongue pressure after tongue crib therapy in group I (T1, T2, T3).

Resting tongue pressure (in Newton/cm^2)				Swallowing tongue pressure (in Newton/cm^2)		
N=20	Mean	Standard. Deviation (SD)	Standard. Error (SE)	Mean	Standard deviation (SD)	Standard. Error (SE)
T1	1.561	.2363	.0528	2.187	.2082	.0466
T2	1.326	.1642	.0367	1.838	.3159	.0706
T3	1.322	.2763	.0618	2.353	.2423	.2423

Table6 shows descriptive statistics of measured resting and swallowing tongue pressure values in group I during at time intervals T1, T2, T3. The mean resting tongue pressure after three months of crib therapy at T1 was (1.561± .2363 Newton/cm^2). A progressive decrease in resting tongue pressure was observed, at T2 (1.326± .1642 Newton/cm^2) and at T3 the mean was 1.322± .2763 Newton/cm^2.

The mean swallowing tongue pressure after tongue crib placement at T1 the mean was 2.187± .2082, At T2, the mean calculated was 1.838±.3159 and at T3, the mean was 2.353±.2423 respectively).

Table 7: shows intragroup statistical inference of resting tongue pressure using Paired t test, at different time intervals before and after tongue crib therapy in Group I

Resting tongue pressure Mean($N/cm^{2)}$) ± SD		Mean difference	P value
T0 Vs T1	T0-1.768±.2131 T1 -1.561±.2363	0.207	<0.001*
T0 Vs T2	T0 -1.768±.2131 T2 -1.326±.1642	0.442	<0.001*
T0 Vs T3	T0-1.768±.2131 T3-1.322±.2763	0.446	<0.001*
T1 Vs T2	T1-1.561±.2363 T2-1.326±.1642	0.0528	< 0.01*
T2 Vs T3	T2-1.326±.1642 T3-1.322±.2763	0.0045	0.943
T1 VsT3	T1-1.561±.2363 T3-1.322±.2763	0.3224	<0.004*

p > 0.05 = Not Significant, p < 0.05 = Just Significant*, p < 0.01 = Significant **, p ≤ 0.001 = Highly Significant***

Table 7 shows descriptive statistics of resting tongue pressure at different time intervals in group I. resting tongue pressure reduced significantly from T0 to T1, from T0-T2 and from T0-T3 when compared using Paired t test as p<0.05.The mean resting tongue pressure before crib therapy(T0) was 1.768±.2131N/cm^2 which showed statistically significant reduction(p<.001) after three months of crib therapy (T1)1.561±.2363N/cm^2 which further decreased to1.326±.1642 N/cm^2 after six months of crib therapy (T2) and became1.322±.2763N/cm^2after nine months(T3) respectively and the changes were highly significant(p<.001) except for the T2 Vs T3 measurements.

Table 8: Shows intragroup statistical inference of swallowing tongue pressure using Paired t test, at different time intervals before and after tongue crib therapy in Group I:

swallowing tongue pressure (Mean ±SD(N/cm^2)		Mean Difference	P value
T0 Vs T1	T0-2.353±.2722 T1 -2.187±.2082	0.166	<0.001*
T0 Vs T2	T0 -2.353± .2722 T2 -1.838± .3159	0.515	<0.001*
T0 Vs T3	T0-2.353±.2722 T3-1.875±.2423	0.478	<0.001*
T1 vs T2	T1-2.187±.2082 T2-1.838±.3159	.3495	<0.001*
T2 vs T3	T2-1.838±.3159 T3-1.875±.2423	.0370	0.626
T1 vs T3	T1-2.187±.2082 T3-1.875±.2423	.3125	<0.001*

p > 0.05 = Not Significant, p < 0.05 = Just Significant*, p < 0.01 = Significant **, p ≤ 0.001 = Highly Significant***

Table8 describes intergroup statistical inference of swallowing tongue pressure using Paired t test, at different time intervals before and after tongue crib therapy in Group I .Significant reduction (<0.001)in swallowing tongue pressure was observed between the measurements taken before(T0) and after the crib therapy (T1,T2,T3) when compared using Paired t test as p<0.05.The mean swallowing tongue pressure at T0 (2.353±.2722)was reduced progressively from T1(2.187± .2082 N/cm^2),T2 (1.838± .3159 N/cm^2)andT3(1.875 ± .2423 N/cm^2)and the difference was statistically significant in all comparison groups i.e. fromT0 to T1, from T0-T2 and from T0-T3 when Paired t test was applied as p<0.05 .

After crib placement mean swallowing tongue pressure initially showed significant decrease (T1-T2) p<0.001where calculated mean difference was.3495 N/cm^2.

Similarly, when the mean swallowing tongue pressure at T2(1.838 N/cm^2) was compared with the mean swallowing pressure at T3(1.875 N/cm^2) the calculated mean difference was .0370 N/cm^2 and it was statistically nonsignificant. Although overall difference in swallowing tongue pressure after crib therapy from T1(2.187± .2082 N/cm$^{2)}$ to T3 (1.875 ± .2423 N/cm^2) was highly significant($p<0.001$).

Table 9: shows intergroup statistical inference of resting and swallowing tongue pressure using Paired t test between group I and Group II at T0.

		Mean ±SD (N/cm $^{2)}$	Mean Difference	P value
Resting Tongue pressure	Group I(T0) Group II (T0)	1.768±.2131 1.189±.2194	.5795	<0.001*
Swallowing tongue pressure	Group I(T0) Group II (T0)	2.353± .2722 1.988±.1151	.3645	<0.001*

p > 0.05 = Not Significant, p < 0.05 = Just Significant* , p < 0.01 = Significant **, p ≤ 0.001 = Highly Significant***

Table 9 shows intergroup statistical inference of resting and swallowing tongue pressure using Paired t test between group I and Group II at T0. The mean resting tongue pressure before tongue crib therapy of group I at T0 was 1.768±.2131N/cm ^{2} whereas initial mean resting tongue pressure (T0) in group II was 1.189±.2194N/cm ^{2}with the mean difference of 0.5795 N/cm ^{2} which was statistically significant($p<0.001$). The mean swallowing tongue pressure after tongue crib therapy of group I (T0) was 2. 353±.2722 N/cm ^{2}and the mean initial swallowing tongue pressure of group II(T0) was found to be 1.9880 N/cm ^{2} with the mean difference was 0.3645 which was statistically significant ($p<0.001$).

Table 10: shows intergroup statistical inference of resting and swallowing tongue pressure using Paired t test between group I (T3) and Group II(T0).

		Mean (Newton/cm$^{2)}$ ± Std. Deviation (SD)	Mean difference	P value
Resting tongue pressure	Group I (T3) Group II (T0)	1.3215±.27632 1.1885±.21941	0.5635	0.100
Swallowing tongue pressure	Group I (T3) Group II (T0)	1.8745±.24235 1.9880±.11510	0.1135	0.066

p > 0.05 = Not Significant , p < 0.05 = Just Significant* , p < 0.01 = Significant **, p ≤ 0.001 = Highly Significant***

Table 10 shows comparison of resting and swallowing tongue pressure of group I at T3 and group II at T0. The mean resting tongue pressure after tongue crib therapy of group I at T3 was 1.3215±.27632 N/cm ^{2} whereas initial mean resting tongue pressure (T0) in group II was 1885±.21941 N/cm ^{2}with the mean difference of 0.5635 N/cm ^{2} which was statistically nonsignificant. The mean swallowing tongue pressure after tongue crib therapy of group I (T3) was1.1885±.21941 N/cm ^{2}and the mean initial swallowing tongue pressure of group II(T0) was found to be 1.9880 N/cm ^{2} with the mean difference was 0.1135 which was statistically nonsignificant.

Development of abnormalities in dentoskeletal may occur due to various etiologic factors, usually functional forces which are unbalanced are supposed to be potential etiologic factors in malocclusion. This fact is based on the "Functional matrix theory" of craniofacial growth proposed by Melvin Moss in which he stated that growth of the face occurs in response to the functional needs and also effects of the soft tissues which is surrounding the bony structures of the maxilla and the mandible[3]. Graber[8] and Moyers also suggested that the activity of the masticatory muscles, the tongue and the muscles of the cheeks and lips have a major role in the developing occlusion as well as in relapse after the orthodontic treatment. Therefore, it seems mandatory to assess the abnormal function of different soft tissues including the tongue when studying the dental malocclusion related to oral habits. The tongue is a complex soft tissue structure which consists of multiple muscles that are well coordinated to produce very complex movements during speech, mastication and swallowing[2]. Because of this complexity and the nature of the tongue ,it is difficult to study it objectively using regular orthodontic techniques. However, prior to treatment planning of a malocclusion, it is always necessary to obtain more information and access about soft tissue changes because uneven pressure from lip,cheek, and tongue .Oral habits like tongue thrusting are considered as key factors in the occurrence and development of malocclusion.[13] Functional analysis of tongue movement is also equally important to the establishment of orthodontic treatment plan and retention.

Tongue size, posture and dysfunction along with other local and environmental factors can cause various dentofacial abnormalities. Tongue-thrust habit which is also called tongue-thrust swallow, visceral swallow, infantile swallow, reverse swallow, deviant swallow, perverted swallow, tongue-thrust syndrome and atypical swallow was defined by various authors as persistent infantile swallow caused by delayed maturation[7].Tulley [32](1969) defined tongue thrust as a forward movement of the anterior tongue between the teeth to contact the lower lip during swallowing and in speech[32]. However, he did not include the abnormal forward tongue rest position in his definition, whereas Proffit and Mason[27] (1975) defined the tongue-thrust as the protrusion of the tongue against or in between the anterior dentition with excessive circumoral muscle activity during swallowing, in addition one or more of the following conditions should exist to define the thrust ,first, the tongue should move forward to contact the lower lip during swallowing and secondly, the forward

movement of the tongue between the anterior teeth during speech may be observed. A forward positioning of the tongue with the tip of the tongue positioned between or against the anterior teeth at rest. Brauer and Holt [26](1965) defined it as any movement in the lips of during swallowing; they confirmed this by observing the position of the tongue during swallowing. If the tongue was thrusting in between the teeth and the teeth were not in centric occlusion then they marked this as a tongue-thrust.

The effect of tongue thrust on dentofacial development depends on several factors as the frequency of swallowing ,how often the tongue exerts force on the teeth, the severity of the force exerted on the teeth, the counteraction of these factors by other muscular structures such as the lips, the resistance of dentoalveolar structures to displacement,and finally the resting posture of the tongue when no swallowing is occurring.[1] It is also important to note that tongue tip protrusion is sometimes associated with a low forward posture of the tongue. Even if the amount of force is very low, this can influence tooth position horizontally or vertically since the duration of force is long. It has been demonstrated that prolonged low tongue position during the growth period in children may result in excessive molar eruption causing a clockwise rotation of the mandible, a disproportionate increase in lower anterior face height, retrognathia and open bite. A low tongue position may also prevent lateral expansion and anterior development of maxilla.

The frequency of swallowing, according to distinctive authors varies from 1000 to 2000 time in a day. Graber[8] reported on an average frequency of deglutition one in a minute between meals and around nine times a minute while eating. Kinkaid reported average frequency of deglutition about 1600 times per day while Staub[5] stated around 2400 somatic and visceral swallow per day.

Lear, Flanagan and Moorrees[6] observed more frequent swallowing pattern in children ranging 800-1200 swallows per 24 hours as compared to 233-1008 swallows per 24 hours in young adults. Thus, it can be concluded from this that tongue can deliver forces at considerable frequency throughout the day thereby influencing the dentofacial morphology.

During the adult swallowing, the tongue apex touches the hard palate, next to the incisive papilla. It should not touch the palatal surface of either upper or lower incisors

while during infantile swallow the tongue apex is placed between the incisors and press them around 1-3 seconds.[10]

Kennedy et al[19] reported that the duration of swallowing was between 1.7 and 3.4 seconds for swallowing saliva. Based on frequency of deglutition in a day if we calculate the total duration of time, to which tongue exerts pressure on dentition during swallowing it comes around 60-90 seconds in a day. Justus explained that this amount of time is fair enough to become a causative factor for malocclusion.

Winders[13] stated that in all malocclusions the lingual musculature is far more active than the perioral musculature during speech and swallowing.

Feu et al[28] states that abnormal forces even if small volume but of frequent occurrence are able to create dental abnormalities hence it is mandatory to modify the tongue position if stability of treatment results is required. However, evidence that tongue dynamics and resting postures are functional factors is still scarce, because it is not an easy task to achieve real-time parameterization of intraoral soft tissues.

Opposite to the above researchers Proffit [18] negates the impact of abnormal swallowing pattern for the development of any Orthodontic problem because of limited time of contact between teeth and the tongue during swallowing act ,instead he perceived resting tongue position more responsible for any deforming affect of tongue.

.The strength of the tongue can be assessed both qualitatively or quantitatively. Qualitative assessment is the most commonly used by professionals in their clinical practice, as this method is subjective and invariably dependent on the professional's experience and common sense, so it is subjected to uncertainties. The quantitative evaluation is performed through various instruments that gives the tongue strength of an individual in terms of numerical value. Thus, quantitative assessment of tongue dysfunction either in form or function increases the probability of appropriate diagnosis and treatment planning of a clinical in cases.

In an attempt to quantify the force/pressure put by the tongue within the oral cavity various devices are used by different researchers. Dynamometers, Mouth piece with gauge, mouthpiece containing load cells, mouth piece containing force sensing resisters, or pressure sensors connected on teeth or on palatal plate, bulb pressure sensors, Myometer 160 with probe are few devices used by researchers, each having its own advantage and disadvantage. Bulb pressure sensors are costly, requiring

numerous connective components and air-filled bulbs are prone to leaks, while the material properties can change with use and deformation.

The problem of the bulb is the issue of positioning and reproducibility within the oral cavity. Air-filled bulb positions are laborious to change because it slides too effortlessly on the tongue surface, and the connected tube is not scaled to demonstrate things of the bulb with lips closure. The primary disadvantage of dynamometers is not being sensitive to very little changes and at times, the measures do not seem to be reliable.

Sangave *et al*.[33] used piezoresistive FlexiForce sensors with measuring range from 0 to 110 N. Every sensing element was mounted to a stainless-steel plate connected to the mouthpiece.

Xu *et* [a4l]. used the pressure sensors to measure the tongue pressure exerted on the surface and the acrylic pads at three distances to the palatal mucosa during swallowing. Hori et al used seven pressure sensors installed in palatal plate to measure tongue pressure during mastication and swallowing. [41]

FSR sensors were successfully used to measure the tongue pressure in different areas of the oral cavity by many more researchers and found easy to place in patient's mouth and more patient compliant due to thinness so similar FSR sensors was used in the present study.

For correction of the tongue-thrust habit different methods have been attempted with variable success. The management of the tongue-thrusting habit may include simple habit control, habit-breaking appliances, myofunctional therapy, orthodontics and possible surgery. In tongue-thrusting subjects strong relation between the position of the mandible, occlusal contact and tongue activity was suggested by Dohan and Lalang. He suggested that enhancement of patient awareness of occlusion might aid in controlling tongue-thrust during different activities. Tongue crib appliances were found extremely effective in breaking the tongue thrust habit by several authors who suggested that tongue crib appliance create a mechanical barrier and prevent the tongue from thrusting between the incisors.

Andrianopoulos and Hanson[7] (1987) conducted a longitudinal study of tongue-thrust patients undergoing orthodontic treatment, and found that overjet correction was less stable in patients who received orthodontic treatment without myofunctional therapy for their tongue-thrust as compared to patients who received the therapy. Proffit and

Ackerman (1994), Cleall[29] (1965) suggested that correction of the malocclusion in patients with open bite malocclusion will lead to elimination of abnormal swallowing. Their finding were not in concordance with Subtelny and Subtelny[31] (1973) who used a tongue crib to treat patients with tongue-thrust activities and found that while in place the tongue is confined lingually to the crib, but once the crib is removed, the protrusive tongue returned to the previous activity. He did not find tongue crib beneficial for tongue thrust treatment.

Researchers have emphasized the importance of intraoral tongue pressure but very few studies have evaluated the adaptive capability of tongue in response to environment changes in terms of changes in tongue pressure. The employment of quantitative ways to measure tongue force can help the researchers in the evaluation of orofacial physiology, making the diagnosis of tongue force more reliable, particularly in those subjects having dentofacial deformities with altered soft tissue function, which are difficult to be noted by clinical evaluation.

Considering the above facts the present study was designed to evaluate changes in resting and swallowing tongue pressure on anterior dentition following tongue crib therapy in patients with tongue thrusting habit.20 patients with tongue thrusting habit requiring fixed orthodontic treatment comprises the study group(group I),whereas 20 patients without tongue thrusting habit requiring fixed orthodontic treatment were included in the control group (group II). Initial resting and swallowing tongue pressure (T0) on anterior dentition were evaluated for group I and Group II. In group I during the nine months of crib therapy resting and swallowing tongue pressure were measured at every 3 months (T1,T2,T3).

The data thus recorded was tabulated and analysed in the following manner.

1. Evaluation of resting and swallowing tongue pressure on anterior dentition in the oral cavity before tongue crib therapy (T0) in Group I patient **(Table 4).**

2. Evaluation of resting and swallowing tongue pressure on anterior dentition in the oral cavity before tongue crib therapy (T0) in Group II patients**(Table 5).**

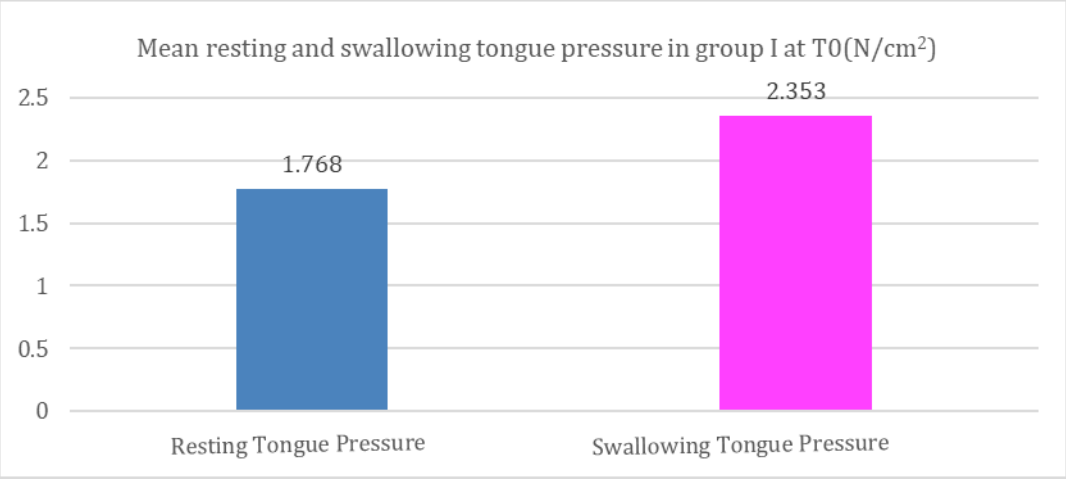
3. Evaluation of resting and swallowing tongue pressure on anterior dentition in the oral cavity at different time interval (T1,T2,T3) after placement of tongue crib in Group I patients**(Table 6).**

4. Comparison of resting and swallowing tongue pressure on anterior dentition in the oral cavity at different time interval (T1,T2,T3) after placement of tongue crib in Group I patients**(Table 7and 8).**

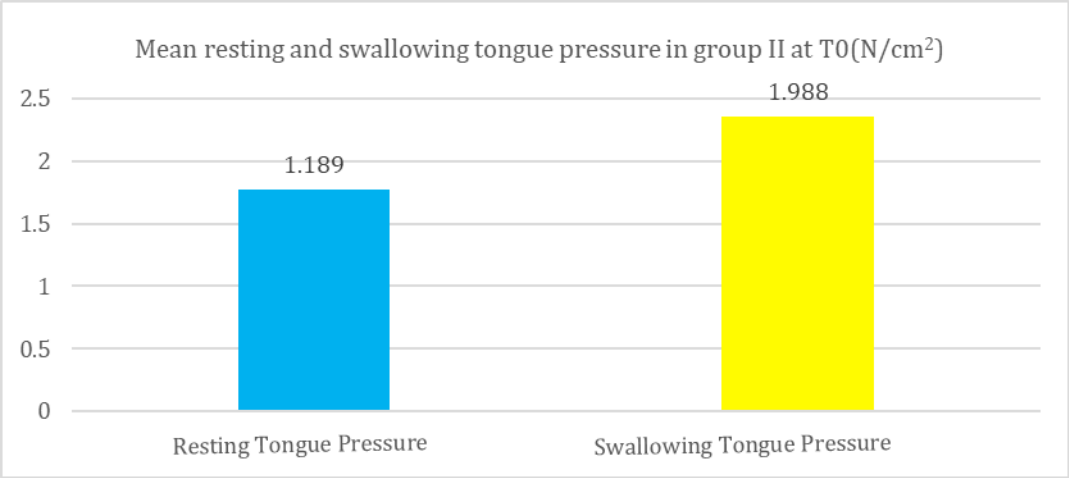
5. Comparison of resting and swallowing tongue pressure (T0) between Group I and II**(Table 9)**

6. Comparison of resting and swallowing tongue pressure of group I (T3)to resting and swallowing tongue pressure of group II (T0)**(Table 10).**

In the present study for group, I initial mean resting tongue pressure (T0) was 1.768 N/cm^2 and swallowing tongue pressure was 2.353 N/cm^2. In group II initial mean resting tongue pressure (T0) was 1.189 N/cm^2. whereas measured swallowing tongue pressure was 1.988 N/cm^2. (Table 4,5, graph 1).



Graph 1A: Bar diagram showing mean resting and swallowing tongue pressure in group I at T0.



Graph 1B: Bar diagram showing mean resting and swallowing tongue pressure in group II at T0.

Findings of the present study was supported by Kydd WL, Akamine et al.[5] Kydd studied fifteen subjects with various palatal shapes and maximum tongue pressure during swallowing were recorded he found mean swallowing pressure 109g/cm^2 in subjects with peaked palate,78 g/cm^2 in round palate and 89 g/cm^2 subjects of flat palate ,which was on an average similar to finding of the group II of the present study. Hori et al (2009) showed pressure 0.99 N/cm^2, which is seems lesser than the findings of the present study but difference in the pressure range could be due to the direct placement of pressure sensor or due to the position of the sensor tip, which was placed at slight posterior region.

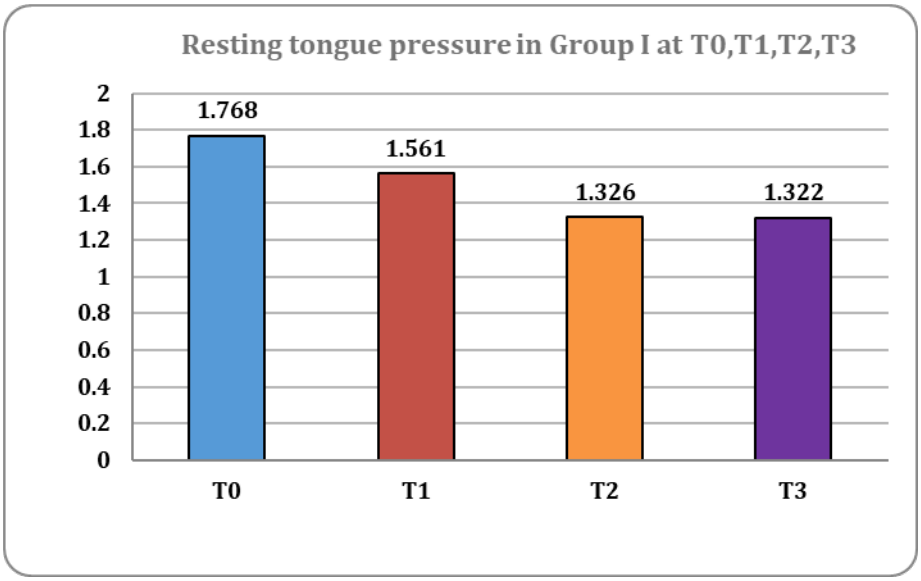
Kydd WL, Akamine etal [5]measured the forces exerted by the lingual and perioral musculature on the anterior dentition during the act of swallowing in two groups Group A exhibited good occlusions. Group B had anterior open bite and who clinically exhibited a tongue thrust. They found mean tongue pressure of the anterior open-bite sample was twice (285gm/cm^2)that of the controls(123gm/cm^2) and the differences were statistically significant.

Contrary to the findings of present study Winders RV[8],found absence of resting pressure on the lingual surfaces of maxillary central incisors during rest, except in Class III and some anterior open bite cases. In open bite cases tongue pressure during rest was in the range of 0.689 N/cm^2. Christainsen,Evans and Sue[4] also found very less forces as compared to our study. They evaluated the average force of resting tongue (pressure =0.039 g/mm^2) when measured with a 4.9 mm diameter sensor.

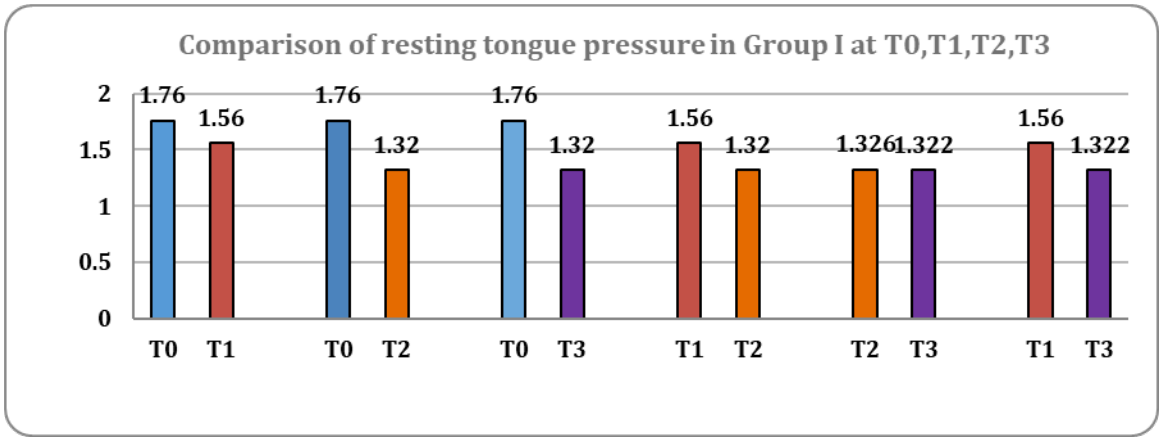
Taslan S et al[2] also found initial resting tongue pressure on central incisors as 16.42± gm/cm^2 and swallowing tongue pressure 154.12± 41.12gm/cm^2 respectively in study group(Open bite). In control group resting tongue pressure on central incisors was 19.5± gm/cm^2 and swallowing tongue pressure 148.53± 23.09 gm/cm^2 .Yoshikawa et al[41] evaluated the maximum Tongue Pressure in different age range and gender during the act of swallowing used disposable pressure sensing probe to compare with manometer .The average maximum tongue pressure in the twenties was found 41.7± 9.7 KPa gm/cm^2 .

Some previous studies done by Thuer U[49](1986) Lindemann[35](1990), Kucukkeles[34](2003), Frohlich[33](1994), tongue pressure during swallowing was reported much higher than those created during rest and phonation. The findings of the above studies are not in concordance to the findings of the present study. Variation in the amount of pressure recorded between present and other relevant studies were expected due to methodological difference regarding type, position, fixing of the sensor or due to variation of malocclusion.

On evaluating the changes occurred in resting and swallowing tongue pressure in group I , a regular decrease was observed during nine months of crib therapy. The difference from initial to final tongue pressure was statistically significant ($p<.001$) for both resting and swallowing tongue pressure. In group I The mean resting tongue pressure before crib therapy (T0) was 1.768±.2131N/cm^2 which showed statistically significant reduction($p<.001$) after three months of crib therapy (T1)1.561±.2363N/cm^2 which further decreased to1.326±.1642 N/cm^2 after six months of crib therapy (T2) and became1.322±.2763N/cm^{2}after nine months(T3) respectively and the changes were highly significant($p<.001$)(Table 6) except for the T2 Vs T3 measurements.(table 6,graph2 and 3).

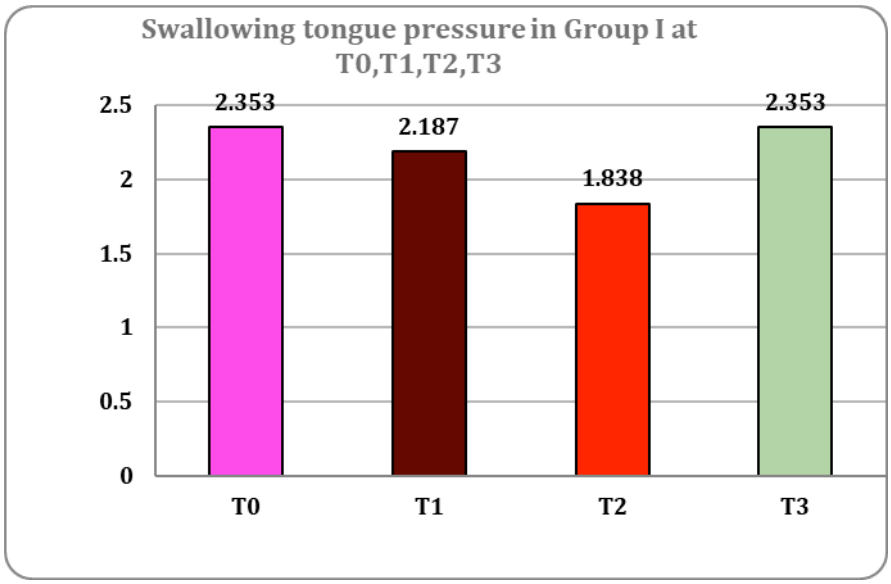


Graph 2: Bar diagram showing resting tongue pressure among group I before and after tongue crib therapy (T0,T1,T2,T3).

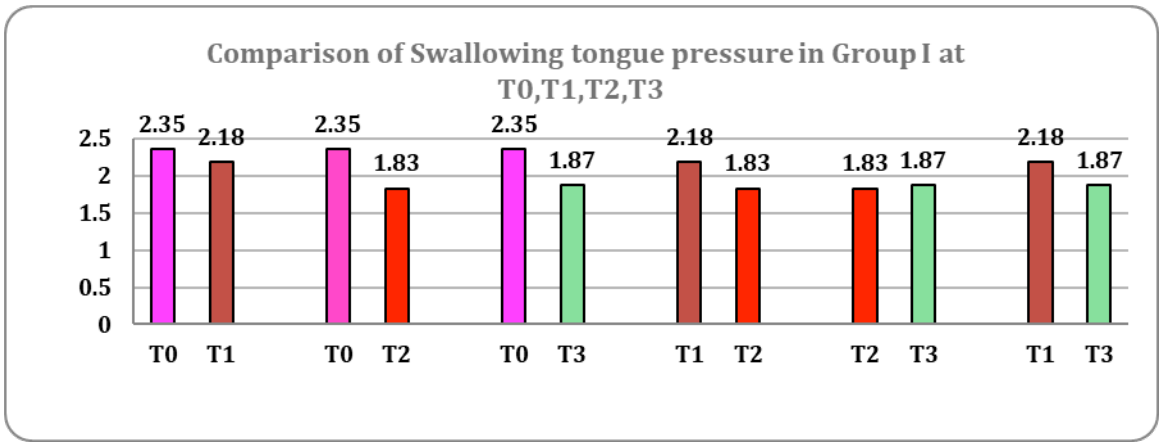


Graph 3: Comparison of resting tongue pressure among group I over interval of time (T0,T1,T2,T3)

Similarly The mean swallowing tongue pressure at T0 (2.353±.2722) was reduced progressively from T1(2.187± .2082 N/cm^2),T2 (1.838± .3159 N/cm^2)andT3(1.875 ± .2423 N/cm^2)and the difference was statistically significant in all comparison groups except T2 Vs T3 measurements.(table 7 and 8,graph 4 and 5)



Graph 4: Bar diagram showing swallowing tongue pressure among group I before and after tongue crib therapy (T0,T1,T2,T3)



Graph 5: Bar diagram showing Comparison of swallowing tongue pressure among group I over interval of time (T0,T1,T2,T3)

There are very few studies who quantified the tongue pressure on anterior dentition after orthodontic intervention, so direct comparison in this regard are not possible. However, decrease in tongue pressure can be assumed as effect of crib therapy in

qualitative manner supporting the soft tissue adaptation hypothesis. In that way findings of the present study are in agreement with the previous studies done by Taslan S[2], Sayın MO et al[9], Cleall etal[29] etc.

Taslan and his colleagues found that resting tongue pressure remained significantly lower than initial values at the 12th month of crib wearing. They evaluated the tongue pressure changes before ,during and after crib appliance therapy in 13 patients in mixed dentition open bite cases. The initial resting tongue pressure measured for upper central incisor at the 10th month and at the 12th month remained same in the control group. Swallowing tongue pressure in the study group showed a decrease at the end of the 10th month and it remained lower than initial values the following 2 months. Significant decrease in resting pressure on the crib appliance in the study group suggested tongue adaptation to the new position created by the appliance due to disturbance in intraoral pressure equilibrium. Their findings clearly suggested that the tongue adapts to the new position guided by the appliance. They suggested that the concerned patient should use the crib long enough to produce definitive behavioural changes.

Subtelny and Sakuda[31] reported an unsuccessful redirection of tongue position in open-bite treatment when the fixed palatal crib was worn for less than six months. There is now a consensus that these appliances should be fixed with the objective of bringing the dentition into normal function until spontaneous favourable movement is achieved.Huang GJ et al[11] evaluated the effectiveness of crib therapy in open bite cases (4-8 mm open bite) exhibiting a significant increase in mean overbite after crib therapy for 10 months in both growing and nongrowing patients. They also stated that the patients who achieved a positive overbite with crib therapy had a good chance of maintaining the correction after the treatment is completed.

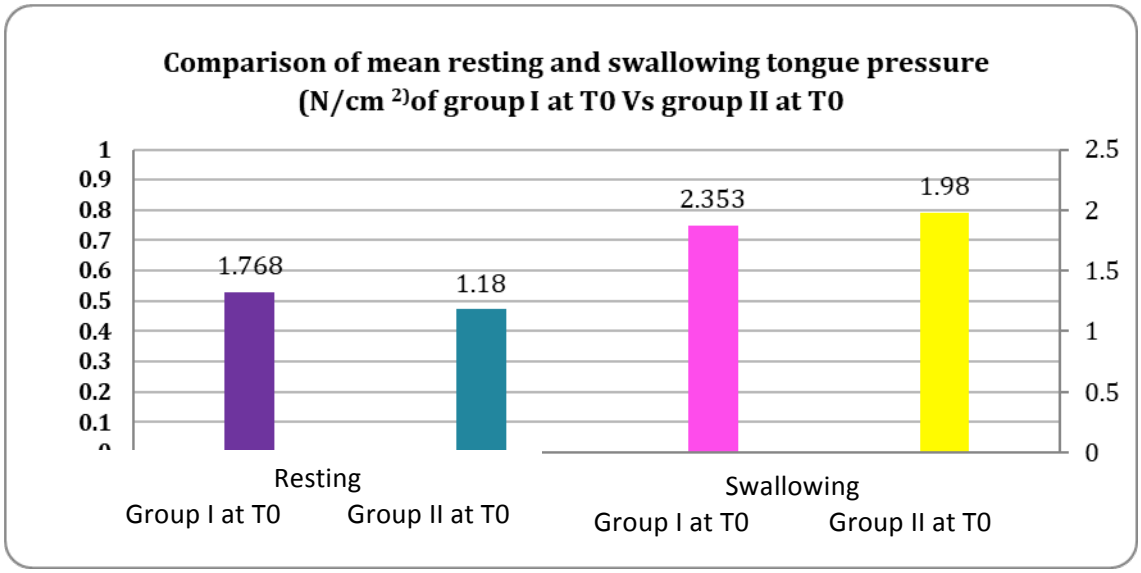
Sayın MO et al.[9], studied the initial effects of the tongue crib by means of Magnetic Resonance Imaging and found more posteriorly positioned tongue tip when the crib was in place which can be interpreted as reduced tongue pressure on anterior dentition suggesting, adaptive changes occurred in the anterior and midportions of the tongue's dorsum after tongue crib placement.

Further, cleall et al [29] also stated that the tongue crib limited the forward movement of the tongue and prompted the tongue tip to feature greater posteriorly in the course of

deglutition.He recommended that the glossopharyngeal structures at rest and in the course of swallowing adapted well to the modifications in sensory stimuli afforded through the insertion of the tongue crib.

CozzaP, Guitini V [22]reported that using a compliance-free, fixed appliance for the correction of open bite and inhibition of habits produces more favourable results.Juliana S. et al[10] evaluated the role of the palatal crib and bonded lingual spur in early treatment of anterior open bite in mixed dentition cases. Leitea et al[10] (2016) evaluated the overbite correction of fixed palatal crib (FPC) and bonded lingual spur (BLS) in the early treatment of anterior open bite (AOB) in mixed dentition (primary outcome) as well as its influence on dental and skeletal cephalometric measurements (secondary outcome), control (n =13), palatal crib (n = 13), and spur (n = 13). Data from the lateral tele-radiography was obtained at the beginning, at 6 months, and after 1 year. At 6 months and then after 1 year all groups showed improvement in the overbite. However, only the crib and spur groups showed positive overbite.

Comparison of resting and swallowing tongue pressure before tongue crib therapy (T0)in group I (1.768 N/cm^2 and 2.353 N/cm^2) and Group II(1.189 N/cm^2 and 1.988 N/cm^2) showed higher tongue pressure values in group I as compared to group II and the difference was statistically significant (p<0.001)(table 9,graph 6).



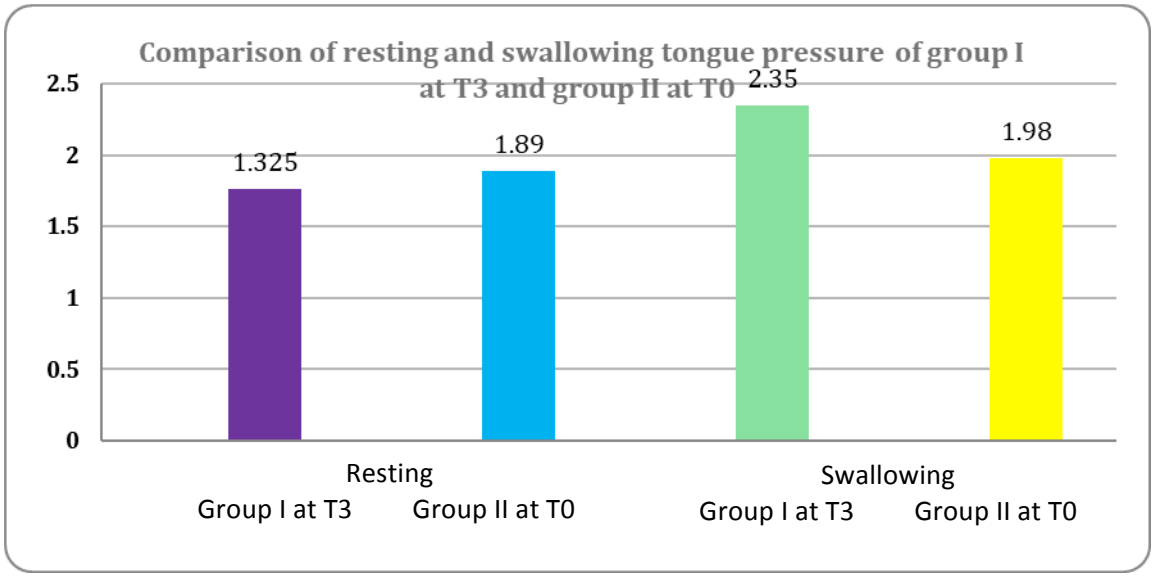
Graph 6: Bar diagram showing comparison of resting and swallowing tongue pressure of group I Vs group II at T0.

In contradiction to the present study, Posen (1972) concluded that the maximum tongue pressure remained the same, not being highly significant or lower when compared with the normal group (18 yrs. above-1700-2500g) or those with malocclusions (900-2300g).

Lambrecht's et al[3] also found no significant difference in tongue pressure among the type of malocclusion.

Proffit[18] also believed horizontally directed force of the tongue and lips during functional activity such as swallowing or speaking are not strong enough to effect either the shape of the dental arches or position of the teeth although he claimed that resting tongue pressure had more impact over the position of teeth. He proposed, tongue pressures decrease as the dimensions of the dental arch increases; this is the opposite of what might be expected if tongue pressure someway pushed the tooth into a new function.

When the resting and swallowing tongue pressure of group I after nine months of tongue crib therapy (T3) was compared to initial resting and swallowing tongue pressure of group II (T0) we found that resting and swallowing tongue pressure of group I at T3 was decreased and came up to approximately comparable measurements to initial values of group II making the difference between them nonsignificant. (Table 10 , graph 7).



Graph 7: Bar diagram showing comparison among resting and swallowing tongue pressure of group I at T3 and group II at T0.

Decrease in resting and swallowing tongue pressure of group I by crib therapy suggest tongue adaptation to new position created by the appliance. Similar to the findings of the present study effectiveness of crib appliance in repositioning the tongue is proved by previous studies as well., but the quantitative comparison of the measurements are not possible due to scarcity of the relevant studies.

The findings of the present study suggest that palatal crib is successful in discouraging tongue thrusting habit, In addition, it prevents the tongue from resting on maxillary incisors and help in correcting of proclination of the teeth.

With the results of the present study it is possible to enrich the literature with quantitative data on tongue pressure in anterior dentition in patients with tongue thrusting habit before and after crib therapy, contributing to functional evaluation and complementation of the diagnosis in orthodontics to draw specific therapy plans. This will make the therapy more stimulating for the patient, increasing their adherence to treatment.

Further studies of quantitative measurement of tongue pressure after orthodontic intervention can be done in different malocclusion groups including cleft cases. Studies can also be planned to evaluate post retention stability in terms of tongue pressure of treatment outcome.

Present cross sectional clinical study was conducted to evaluate the changes in resting and swallowing tongue pressure following tongue crib therapy in patients with tongue thrusting habit.

Following conclusion can be drawn from the present study:

1. Resting and swallowing tongue pressure reduced significantly after tongue crib therapy in patients having tongue thrusting habit.
2. Measurements performed before and after the tongue crib therapy in patients having tongue thrusting habit confirms that tongue responds adequately to environmental changes and adapts well to the new position.
3. Tongue crib appliance was found effective to break the tongue thrusting habit and guides the tongue to adapt itself to a new normal position in the oral cavity.

The clinical implication of the present study is that the tongue crib therapy is effective in reducing tongue thrust habit which is a potent factor causing malocclusion. Also, it is a major cause of relapse after fixed orthodontic treatment

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APPENDIX - I

BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES (FACULTY OF BBD UNIVERSITY), LUCKNOW

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled **"Evaluation of Changes in Resting & Swallowing Tongue Pressure Following Tongue Crib Therapy in Tongue Thrusters."** submitted by **Dr Sanaf Zaman** Post graduate student from the **Department of Orthodontics & Dentofacial Orthopedics** as part of MDS Curriculum for the academic year 2018-2021 with the accompanying proforma was reviewed by the Institutional Research Committee present on **27th November 2018** at BBDCODS.

The Committee has granted approval on the scientific content of the project. The proposal may now be reviewed by the Institutional Ethics Committee for granting ethical approval.

Prof. Vandana A Pant
Co-Chairperson

Prof. B. Rajkumar
Chairperson

APPENDIX - II

Babu Banarasi Das University
Babu Banarasi Das College of Dental Sciences,
BBD City, Faizabad Road, Lucknow – 226028 (INDIA)

Dr. Lakshmi Bala
Professor and Head Biochemistry and
Member-Secretary, Institutional Ethics Committee

Communication of the Decision of the VIIth Institutional Ethics Sub-Committee

IEC Code: 12 **BBDCODS/01/2019**

Title of the Project: Evaluation of Changes in Resting & Swallowing Tongue Pressure Following Tongue Crib Therapy in Tongue Thrusters.

Principal Investigator: Dr. Sanaf Zaman **Department:** Orthodontics & Dentofacial Orthopedics

Name and Address of the Institution: BBD College of Dental Sciences Lucknow.

Type of Submission: New, MDS Project Protocol

Dear Dr. Sanaf Zaman,

The Institutional Ethics Sub-Committee meeting comprising following four members was held on 10th January 2019.

1.	Dr. Lakshmi Bala Member Secretary	Prof. and Head, Department of Biochemistry, BBDCODS, Lucknow
2.	Dr. Amrit Tandan Member	Prof. & Head, Department of Prosthodontics and Crown & Bridge, BBDCODS, Lucknow
3.	Dr. Rana Pratap Maurya Member	Reader, Department of Orthodontics & Dentofacial Orthopedics, BBDCODS, Lucknow
4.	Dr. Sumalatha M.N. Member	Reader, Department of Oral Medicine & Radiology, BBDCODS, Lucknow

The committee reviewed and discussed your submitted documents of the current MDS Project Protocol in the meeting.
The comments were communicated to PI thereafter it was revised.

Decisions: The committee approved the above protocol from ethics point of view.

Forwarded by:

Lakshmi Bala 22/01/19

(Dr. Lakshmi Bala)
Member-Secretary
IEC

Member-Secretary
Institutional Ethic Committee
BBD College of Dental Sciences
BBD University
Faizabad Road, Lucknow-226028

(Dr. B. Rajkumar)
Principal
BBDCODS

PRINCIPAL
Babu Banarasi Das College of Dental Sciences
(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow-226028

APPENDIX - III

Consent Form (English)

Title of the Study -: EVALUATION OF CHANGES IN RESTING AND SWALLOWING TONGUE PRESSURE FOLLOWING TONGUE CRIB THERAPY IN TONGUE THRUSTERS.
Study Number……..
Subject's Full Name…….
Date of Birth/Age ……
Address of the Subject…….
Phone no. and e-mail address……
Qualification ……
Occupation: Student / Self Employed / Service / Housewife/ Other (Please tick as appropriate)
Annual income of the Subject……
Name and of the nominees(s) and his relation to the subject…… (For the purpose of compensation in case of trial related death).

1. I confirm that I have read and understood the Participant Information Document dated ……..for the above study and have had the opportunity to ask questions. OR I have been explained the nature of the study by the Investigator and had the opportunity to ask questions.
2. I understand that my participation in the study is voluntary and given with free will without any duress and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.
3. I understand that the sponsor of the project, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. However, I understand that my Identity will not be revealed in any information released to third parties or published.
4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).
5. I permit the use of stored sample (tooth/tissue/blood) for future research. Yes [ ] No [ ] Not Applicable [ ]
6. I agree to participate in the above study. I have been explained about the complications and side effects, if any, and have fully understood them. I have also read and understood the participant/volunteer's Information document given to me.

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:……..
Signatory's Name……. Date …….
Signature of the Investigator…… Date……..

Study Investigator‘s Name..... Date……..
Signature of the witness…… Date……..
Name of the witness……
Received a signed copy of the PID and duly filled consent form Signature/thumb impression of the subject or legally Date……

APPENDIX - IV

Babu Banarasi Das College of Dental Sciences
(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

सहमति पत्र

अध्ययन शीर्षक.....
अध्ययन संख्या.....
प्रतिभागी के पूर्ण नाम.....
जन्म तिथि / आयु.....
प्रतिभागी का पता .....
फोन नं. और ई-मेल पता .....
योग्यता .....
व्यवसाय: छात्र / स्व कार्यरत / सेवा / ग्रहिणी .....
अन्य (उचित रुप मे टिक करें) .....
प्रतिभागी की वार्षिक आय .....
प्रत्याशीयो के नाम और प्रतिभागी से संबंध...(परीक्षण से संबंधित मौत के मामले मे मुआवजे के प्रयोजन के लिए)

1. मेरी पुष्टि है कि मैने अध्ययन हेतु सुचना पत्र दिनांक ..... को पढ व समझ लिया तथा मुझे प्रश्न पुछने या मुझे अध्ययन अन्वेषक ने सभी तथ्यों को समझा दिया है तथा मुझे प्रश्न पुछने के समान अवसर प्रदान किए गये।

2. मैंने यहॉ समझ लिया कि अध्ययन में मेरी भागीदारी पूर्णतः स्वैच्छिक है और किसी भी दबाव के बिना स्वतंत्र इच्छा के साथ दिया है किसी भी समय किसी भी कारण के बिना , मेरे इलाज या कानूनी अधिकारो को प्रभावित किए बिना , अध्ययन में भाग न लेने के लिए स्वतंत्र हुँ ।

3. मैंने यह समझ लिया है कि अध्ययन के प्रायोजक , प्रायोजक की तरफ से काम करने वाले लोग, आचार समिति और नियामक अधिकारियों को मेरे स्वास्थ्य रिकार्ड को वर्तमान अध्ययन या आगे के अध्ययन के सन्दर्भ देखने के लिए मेरी अनुमति की जरूरत नही है, चाहे मैने इस अध्ययन से नाम वापस ले लिया है। हॉलाकि मै यह समझता हुँ कि मेरी पहचान को किसी भी तीसरे पक्ष या प्रकाशित माध्यम में नही दी जायेगी।

4. मै इससे सहमत हूँ कि कोई भी डेटा या परिणाम जो इस अध्ययन से प्राप्त होता है उसका वैज्ञानिक उद्देश्य (ओं) के उपयोग के लिए मेरी तरफ से कोई प्रतिबंध नही है।
5. भविष्य के अनुसंधान के लिए भंडारित नमूना (ऊतक/रक्त) पर अध्ययन के लिए अपनी सहमति देता हुँ।

हॉ [ ] नही [ ] अनउपयुक्त [ ]

APPENDIX - V

Babu Banarasi Das College of Dental Sciences

(A constituent institution of Babu Banarasi Das University)

BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

Participant Information Document (PID)

1. **Study title**

   EVALUATION OF CHANGES IN RESTING AND SWALLOWING TONGUE PRESSURE FOLLOWING TONGUE CRIB THERAPY IN TONGUE THRUSTERS.

2. **Invitation paragraph**

   You are being invited to take part in a research study, it is therefore important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully. Ask us for any clarifications or further information. Whether or not you wish to take part is your decision.

3. **What is the purpose of the study?**

   The purpose of this study is to evaluate the changes in resting and swallowing tongue pressure following tongue crib therapy in tongue thrusters.

4. **Why have I been chosen?**

   You have been chosen for this study as you are fulfilling the required criteria for this study.

5. **Do I have to take part?**

   Your participation in the research is entirely voluntary. If you do, you will be given this information sheet to keep and will be asked to sign a consent form. During the study you still are free to withdraw at any time and without giving a reason.

6. **What will happen to me if I take part?**

   You will have to wear the tongue crib appliance during the treatment.

7. **What do I have to do?**

   You do not have to change your regular lifestyles for the investigation of the study.

8. What is the procedure that is being tested?

This study consists of study subjectsof Angle 's Class I bimaxillary protrusion or Class II division 1 malocclusion patients with tongue thrusting habit. Tongue pressure will be measured before and after tongue crib therapy.

9. What are the interventions for the study?

Tongue pressure will be evaluated and compared before and after tongue crib therapy in tongue crib thrusters. However you will not have any side effect on your health. This will be done only once in the study.

10. What are the side effects of taking part?

There are no side effects on patients of this study.

11. What are the possible disadvantages and risks of taking part?

There are no risk or disadvantages of taking part in this study.

12. What are the possible benefits of taking part?

This study will help us to know that whether the tongue pressure can be decreased using tongue crib therapy in tongue thrusters. Thereby evaluating the efficiency of tongue crib appliance.

13. What if new information becomes available?

If additional information becomes available during the course of the research you will be told about these and you are free to discuss it with your researcher, your researcher will tell you whether you want to continue in the study. If you decide to withdraw, your researcher will make arrangements for your withdrawal. If you decide to continue in the study, you may be asked to sign an updated consent form.

14. What happens when the research study stops?

If the study stops/finishes before the stipulated time, this will be explained to the patient/volunteer.

15. What if something goes wrong?

If any severe adverse event occurs, or something goes wrong during the study, the complaints will be handled by reporting to the institution (s), and Institutional ethical community.

16. Will my taking part in this study be kept confidential?

Yes it will be kept confidential.

17. What will happen to the results of the research study?

The results of the study will be expected that Tongue crib appliance is efficacious in modifying pressure exerted by tongue on dentition.

It is assumed that the pressure recorded after tongue crib appliance therapy will be less compared to previous value. identity will be kept confidential in case of any report/publications.

18. Who is organizing the research?

This research study is organized by the academic institution (BBDCODS).

19. Will the results of the study be made available after study is over?

Yes.

20. Who has reviewed the study?

The study has been reviewed and approved by the Head of the Dept, and the IEC/IRC of the institution.

21. Contact for further information

Dr. Sanaf Zaman
Department of Orthodontics and Dentofacial Orthopedics
Babu Banarasi College of Dental Sciences.
Dr.Tripti Tikku (HOD)
Department of Orthodontics and Dentofacial Orthopedics
Babu Banarasi College of Dental Sciences.
Lucknow-227105
Dr. Laxmi Bala,
Member Secretary,
Babu Banarasi College of Dental Sciences.
Lucknow
bbdcods.iec@gmail.com

Signature of PI…….

Name……

APPENDIX - VI

बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज
(बाबू बनारसी दास विश्वविद्यालय का एक घटक संस्थान)
बीबीडी सिटी, फैजाबाद रोड, लखनऊ - 227105 (INDIA)

प्रतिभागी सूचना दस्तावेज (पीआईडी)

1. अध्ययन शीर्षक

जीभ के थ्रस्ट में जीभ के क्रिब ट्रीटमेंट के बाद आराम और निगलने वाली दबाव में बदलाव का मूल्यांकन।

2. निमंत्रण पैराग्राफ

आपको एक शोध अध्ययन में भाग लेने के लिए आमंत्रित किया जा रहा है, इसलिए आपके लिए यह समझना महत्वपूर्ण है कि अध्ययन क्यों किया जा रहा है और इसमें क्या शामिल होगा। कृपया निम्नलिखित जानकारी को ध्यान से पढ़ने के लिए समय निकालें। हमसे कोई स्पष्टीकरण या अधिक जानकारी के लिए पूछें। आप हिस्सा लेना चाहते हैं या नहीं यह आपका निर्णय है।

3. अध्ययन का उद्देश्य क्या है?

इस अध्ययन का उद्देश्य जीभ के थ्रस्ट में जीभ के क्रिब उपचार के बाद जीभ के दबाव को कम करने और निगलने में परिवर्तन का मूल्यांकन और तुलना करना है।

4. मुझे क्यों चुना गया है?

आपको इस अध्ययन के लिए चुना गया है क्योंकि आप इस अध्ययन के लिए आवश्यक मानदंडों को पूरा कर रहे हैं।

5. क्या मुझे भाग लेना है?

अनुसंधान में आपकी भागीदारी पूरी तरह से स्वैच्छिक है। यदि आप करते हैं, तो आपको रखने के लिए यह सूचना पत्र दिया जाएगा और सहमति पत्र पर हस्ताक्षर करने के लिए कहा जाएगा। अध्ययन के दौरान आप बिना किसी कारण के किसी भी समय वापस लेने के लिए स्वतंत्र हैं।

6. भाग लेने पर मेरा क्या होगा?

उपचार के दौरान आपको जीभ के क्रिब के उपकरण पहनने होंगे।

7. मुझे क्या करना है?

अध्ययन की जांच के लिए आपको अपनी नियमित जीवन शैली को बदलने की आवश्यकता नहीं है।

8. वह प्रक्रिया क्या है जिसका परीक्षण किया जा रहा है?

इस प्रक्रिया में जीभ के क्रिब पहनना और जीभ के थ्रस्ट में जीभ के क्रिब ट्रीटमेंट के बाद जीभ के आराम और निगलने के परिवर्तनों का मूल्यांकन और तुलना करना शामिल होगा।

9. अध्ययन के लिए हस्तक्षेप क्या हैं?

जीभ के थ्रस्ट में जीभ के क्रिब ट्रीटमेंट के बाद जीभ के दबाव को आराम और निगलने में परिवर्तन का मूल्यांकन और तुलना करना। हालाँकि आपके स्वास्थ्य पर इसका कोई दुष्प्रभाव नहीं होगा।

10. भाग लेने के दुष्प्रभाव क्या हैं?
इस अध्ययन के रोगियों पर कोई दुष्प्रभाव नहीं हैं।

11. भाग लेने के संभावित नुकसान और जोखिम क्या हैं?
इस अध्ययन में भाग लेने का कोई जोखिम या नुकसान नहीं हैं।

12. भाग लेने के संभावित लाभ क्या हैं?
यह अध्ययन हमें यह जानने में मदद करेगा कि जीभ के थ्रस्टरों में जीभ की आदत का इलाज करने और आराम करने और निगलने वाली जीभ के दबाव की तुलना करने में कुशल है।

13. यदि नई जानकारी उपलब्ध हो जाए तो क्या होगा?
यदि अनुसंधान के दौरान अतिरिक्त जानकारी उपलब्ध हो जाती है, तो आपको इन के बारे में बताया जाएगा और आप अपने शोधकर्ता के साथ इस पर चर्चा करने के लिए स्वतंत्र हैं, आपका शोधकर्ता आपको बताएगा कि क्या आप अध्ययन जारी रखना चाहते हैं। यदि आप वापस लेने का निर्णय लेते हैं, तो आपका शोधकर्ता आपकी वापसी की व्यवस्था करेगा। यदि आप अध्ययन जारी रखने का निर्णय लेते हैं, तो आपको एक अद्यतन सहमति पत्र पर हस्ताक्षर करने के लिए कहा जा सकता है।

14. जब शोध अध्ययन रुक जाता है तो क्या होता है?
यदि अध्ययन निर्धारित समय से पहले बंद / खत्म हो जाता है, तो यह रोगी / स्वयंसेवक को समझाया जाएगा।

15. अगर कुछ गलत हो जाए तो क्या होगा?
यदि कोई गंभीर प्रतिकूल घटना होती है, या अध्ययन के दौरान कुछ गलत हो जाता है, तो संस्थान (एस), और संस्थागत नैतिक समुदाय को रिपोर्ट करके शिकायतों को नियंत्रित किया जाएगा।

16. क्या इस अध्ययन में भाग लेने को गोपनीय रखा जाएगा?
हां इसे गोपनीय रखा जाएगा।

17. शोध अध्ययन के परिणामों का क्या होगा?
अध्ययन के परिणामों का उपयोग जीभ थ्रस्टरों में जीभ के क्रिब उपचार के बाद आराम और निगलने वाली जीभ के दबाव का मूल्यांकन करने के लिए किया जाएगा। किसी भी रिपोर्ट / प्रकाशन के मामले में आपकी पहचान गोपनीय रखी जाएगी।

18. अनुसंधान का आयोजन कौन कर रहा है?
यह शोध अध्ययन शैक्षणिक संस्थान (BBDCODS) द्वारा आयोजित किया जाता है।

19. क्या अध्ययन के परिणाम अध्ययन के बाद उपलब्ध कराए जाएंगे?
हाँ।

20. अध्ययन की समीक्षा किसने की?

अध्ययन की समीक्षा की गई है और संस्थान के प्रमुख, और आईईसी / आईआरसी द्वारा अनुमोदित किया गया है।

21. अधिक जानकारी के लिए संपर्क करें

डॉ। सनफ ज़मां

ऑर्थोडॉन्टिक्स और डेंटोफेशियल ऑर्थोपेडिक्स विभाग

बाबू बनारसी कॉलेज ऑफ डेंटल साइंसेज।

लखनऊ-227,105

मोब- 8658395767

डॉ। तृप्ति टिक्कू (HOD)

ऑर्थोडॉन्टिक्स और डेंटोफेशियल ऑर्थोपेडिक्स विभाग

बाबू बनारसी कॉलेज ऑफ डेंटल साइंसेज।

लखनऊ-227,105

मोब- 9554832799

डॉ। लक्ष्मी बाला,

सदस्य सचिव,

बाबू बनारसी कॉलेज ऑफ डेंटल साइंसेज।

लखनऊ

bbdcods.iec@gmail.com

पीआई का हस्ताक्षर .....।

नाम .....

दिनांक .....।

APPENDIX - VII
Child Assent Form

Study Title -:Evaluation of changes in resting and swallowing tongue pressure following tongue crib therapy in tongue thrusters.

Study Number _____

Subject's Full Name _____

Date of Birth/Age_____

Address_____

_____

I_____, exercising my free power of choice, hereby give my consent for participation in the study entitled: "Evaluation of changes in resting and swallowing tongue pressure following tongue crib therapy in tongue thrusters". I have been informed, to my satisfaction, by the attending physician, about the purpose of the study and the nature of the procedure to be done. I am aware that my parents/guardians do not have to bear the expenses of the treatment if I suffer from any trial related injury, which has causal relationship with the said trial drug. I am also aware of right to opt out of the trial, at any time during the course of the trial, without having to give reasons for doing so

Signature of the study participant _____

Date:_____

Name of the study participant_____

Signature of the Witness _____

Date_____

Name of the Witness _____

Signature of the attending Physician _____

Date _____

Name of the attending Physician _____

APPENDIX - VIII

Babu Banarasi Das College of Dental Sciences
(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

शिशु सहमति पत्र

मैं _____में भाग लेने के लिए अपनी सहमति प्रदान करता हूँ | मुझे इस अध्ययन के हेतु और उसमे की जाने वाली प्रक्रिया के बारे में चिकिस्तक द्वारा बता दिया गया है| मुझे पता है कि अध्ययन सम्बन्धी किसी हानि जिसका अध्ययन की दावा से सम्बन्ध है उसका खर्च मेरे माता पिता अथवा अभिवाहक को नहीं वहां करना है | मुझे यह भी पता है कि मैं इस अध्ययन से किसी समय बिना कोई कारण बताये बाहर हो सकता हूँ |

अध्ययन में भाग लेने वाले का नाम और हस्ताक्षर
_____दिनांक_____

गवाह के हस्ताक्षर _____दिनांक _____

गवाह का नाम _____

चिकिस्तक का नाम और हस्ताक्षर_____दिनांक_____

APPENDIX - IX

Statistical tools used in the present study:

Data was entered into Microsoft Excel spreadsheet and was checked for any discrepancies. Summarized data was presented using Tables and Graphs. The data was analysed by SPSS (21.0 version). Shapiro Wilk test was used to check which all variables were following normal distribution. Data was normally distributed (p-value was more than 0.05). *p*- value less than 0.05 was considered as statistically significant.

TOOLS FOR STATISTICAL ANALYSIS

The following statistical formulas were used in the analysis of present study:

1) MEAN: To obtain the mean of values, the individual observations were first added together and then divided by a number of observations. The operations of adding together or summation is denoted by the sign ∑.

   ∑= summation

   n= the number of observations

2) STANDARD DEVIATION: As every set of data is distributed randomly about the arithmetic mean, the standard deviation is the measure of dispersion of data about its arithmetic mean. It is the root of sum of the squares of the difference of each observation from the mentioned arithmetic mean, divided by total number of values.

$$\bar{x} = \frac{\sum x_i}{n}$$

Where:

S= standard deviation

X= the mean or average

n= the number of values

∑ means we sum across the values

TYPES OF T TESTS INDICATIONS.

a) Paired T Test

The paired t test is used to decide whether the differences between variables measured on the same or similarly matched individual are on average zero. As the data are matched there must be an equal number of observations in each sample.

Assumption. The paired t-test assumes that the differences in scores between pairs are approximately normally distributed, although the two sets of data under scrutiny do not need to be normally distributed.

b) Unpaired or two-sample t test (equal variance assumed)

The unpaired t test is used for comparing two independent groups of observations when no suitable pairing of the observations is possible. The samples do not need to be of equal sizes.

Assumptions. The test requires the populations to be normally distributed with equal variance, though the test is relatively robust to deviations from these assumptions.

Unpaired t test or two-sample t test (unequal variance)

When the variances of the two groups differ and transformation does not produce equal variance, the calculation of the t test becomes more complex. Instead of using the pooled variance, estimates of the individual population variances are used

Formula:

$$s = \sqrt{\frac{\sum (X - \bar{X})^2}{n - 1}} \qquad t = \frac{M_x - M_y}{\sqrt{\frac{S_x^2}{n_x} + \frac{S_y^2}{n_y}}}$$

M =mean

$$S^2 = \frac{\sum (x - M)^2}{n - 1}$$

n = number of scores per group

x = individual scores

M = mean

n= number of scores in group

- Define the problem
- State null hypothesis(H_0) and alternate hypothesis(H_1)
- Find t value, Find (X_1 - X_2)
- Calculate SE of difference between two means

SE = $\sigma\sqrt{1/n_1+1/n_2}$ or

t = (X_1 - X_2) / SE

- Calculate degree of freedom = n_1 + n_2 - 2
- Fix the level of significance (0.05)
- Compare calculated value with table value at corresponding degrees of freedom and significance level
- If observed t value is greater than theoretical t value, t is significant, reject null hypothesis and accept alternate hypothesis.

Statistical significance:

Level of significance "***p"*** signifies as below

p>0.05 not significant

p<0.05 Significant (*)

Measurement of tongue pressure

Tongue thrusting patients (Study Group) GROUP I

T(0)

	Mean		**Mean**
Resting (N/cm²)	**Resting (N/cm²)**	Swallowing (N/cm²)	**Swallowing (N/cm²)**
1.92	1.69	3.00	2.83
1.75		2.86	
1.40		2.63	
1.93	1.80	2.80	2.65
1.90		2.70	
1.57		2.45	
2.14	1.99	2.70	2.56
2.06		2.62	
1.77		2.36	
1.97	1.82	3.06	2.91
1.94		2.96	
1.55		2.71	
2.13	1.97	3.00	2.83
2.06		2.86	
1.72		2.63	
2.20	1.96	2.56	2.38
2.03		2.40	
1.65		2.18	
2.03	1.85	2.40	2.21
1.90		2.22	
1.62		2.01	
1.56	1.36	2.58	2.38
1.36		2.38	
1.16		2.18	
2.05	1.88	2.33	2.21
2.00		2.29	
1.59		2.01	
1.65	1.46	2.45	2.29
1.50		2.33	
1.23		2.09	
2.19	1.95	2.49	2.27
1.95		2.25	
1.71		2.07	
1.99	1.80	2.48	2.33
1.88		2.38	
1.53		2.13	

T(1)

	Mean		**Mean**
Resting (N/cm²)	**Resting (N/cm²)**	Swallowing (N/cm²)	**Swallowing (N/cm²)**
1.53	1.36	2.80	2.63
1.39		2.66	
1.16		2.43	
1.68	1.53	2.70	2.55
1.58		2.60	
1.33		2.35	
2.03	1.89	2.65	2.51
1.95		2.57	
1.69		2.31	
1.75	1.60	2.60	2.45
1.65		2.50	
1.40		2.25	
1.78	1.61	2.58	2.41
1.64		2.44	
1.41		2.21	
1.87	1.69	2.39	2.21
1.71		2.23	
1.49		2.01	
1.77	1.58	2.38	2.19
1.59		2.20	
1.38		1.99	
1.51	1.31	2.38	2.18
1.31		2.18	
1.11		1.98	
1.80	1.68	2.29	2.17
1.76		2.25	
1.48		1.97	
1.40	1.24	2.30	2.14
1.28		2.18	
1.04		1.94	
2.12	1.90	2.35	2.13
1.88		2.11	
1.70		1.93	
1.94	1.79	2.26	2.11
1.84		2.16	
1.59		1.91	

1.96		2.52		1.75		2.19	
1.89	1.82	2.40	2.36	1.63	1.59	2.07	2.03
1.61		2.16		1.39		1.83	
2.18		2.51		2.07		2.21	
2.08	1.98	2.35	2.33	1.91	1.89	2.05	2.03
1.68		2.13		1.69		1.83	
1.88		2.29		1.50		2.19	
1.71	1.66	2.15	2.12	1.36	1.33	2.05	2.02
1.39		1.92		1.13		1.82	
2.09		2.21		1.47		2.17	
1.94	1.89	2.09	2.05	1.35	1.31	2.05	2.01
1.64		1.85		1.11		1.81	
1.78		2.36		1.73		2.15	
1.68	1.60	2.26	2.21	1.63	1.58	2.05	2.00
1.34		2.01		1.38		1.80	
2.05		2.21		1.80		2.19	
1.94	1.85	2.03	2.02	1.62	1.61	2.01	2.00
1.56		1.82		1.41		1.80	
2.01		2.29		1.91		2.19	
1.87	1.81	2.09	2.09	1.71	1.71	1.99	1.99
1.55		1.89		1.51		1.79	
1.35		2.14		1.14		2.10	
1.37	1.22	2.10	2.02	1.10	1.02	2.06	1.98
0.94		1.82		0.82		1.78	

(T2)

	Mean		**Mean**
Resting (N/cm²)	**Resting (N/cm²)**	Swallowing (N/cm²)	**Swallowing (N/cm²)**
1.61	1.44	1.63	1.46
1.47		1.49	
1.24		1.26	
1.29	1.14	2.38	2.23
1.19		2.28	
0.94		2.03	
1.15	1.01	1.69	1.55
1.07		1.61	
0.81		1.35	
1.50	1.35	2.17	2.02
1.40		2.07	
1.15		1.82	
1.62	1.45	2.19	2.02
1.48		2.05	
1.25		1.82	
1.69	1.51	2.24	2.06
1.53		2.08	
1.31		1.86	
1.63	1.44	1.85	1.66
1.45		1.67	

(T3)

	Mean		**Mean**
Resting (N/cm²)	**Resting (N/cm²)**	Swallowing (N/cm²)	**Swallowing (N/cm²)**
1.38	1.21	2.28	2.11
1.24		2.14	
1.01		1.91	
2.06	1.91	2.22	2.07
1.96		2.12	
1.71		1.87	
1.23	1.09	2.16	2.02
1.15		2.08	
0.89		1.82	
1.94	1.79	2.16	2.01
1.84		2.06	
1.59		1.81	
1.83	1.66	2.18	2.01
1.69		2.04	
1.46		1.81	
1.36	1.18	2.19	2.00
1.20		2.03	
0.98		1.77	
1.80	1.61	2.18	1.99
1.62		2.00	

1.24		1.46		1.41		1.79	
1.49	1.29	1.52	1.32	1.46		2.18	
1.29		1.32		1.26	1.26	1.98	1.98
1.09		1.12		1.06		1.78	
1.26	1.14	2.22	2.10	1.20		2.10	
1.22		2.18		1.16	1.08	2.06	1.98
0.94		1.90		0.88		1.78	
1.68	1.52	2.27	2.11	1.63		2.13	
1.56		2.15		1.51	1.47	2.01	1.97
1.32		1.91		1.27		1.77	
1.54	1.32	2.34	2.12	1.53		2.21	
1.30		2.10		1.29	1.31	1.98	1.97
1.12		1.92		1.11		1.72	
1.26	1.11	2.14	1.99	1.20		2.11	
1.16		2.04		1.10	1.05	2.01	1.96
0.91		1.79		0.85		1.76	
1.32	1.16	2.13	1.97	1.25		2.07	
1.20		2.01		1.13	1.09	1.95	1.91
0.96		1.77		0.89		1.71	
1.52	1.34	1.70	1.52	1.81		2.06	
1.36		1.54		1.65	1.63	1.90	1.88
1.14		1.32		1.43		1.68	
1.35	1.18	1.93	1.76	1.21	1.04	2.05	1.88

1.21		1.79		1.07		1.91	
0.98		1.56		0.84		1.68	
1.42	1.26	2.25	2.09	1.19		1.99	
1.30		2.13		1.07	1.03	1.87	1.83
1.06		1.89		0.83		1.63	
1.69	1.54	1.67	1.52	1.56		1.94	
1.59		1.57		1.46	1.41	1.84	1.79
1.34		1.32		1.21		1.59	
1.73	1.54	2.20	2.01	1.60	1.41	1.72	
1.55		2.02		1.42		1.54	1.53
1.34		1.81		1.21		1.33	
1.71	1.51	2.29	2.09	1.21	1.01	1.70	
1.51		2.09		1.01		1.50	1.50
1.31		1.89		0.81		1.30	
1.39		1.27		1.31		1.21	
1.35		1.23	1.15	1.27	1.19	1.17	1.09
1.07	1.27	0.95		0.99		0.89	

2. Non tongue thrusting patients (Control Group)

T(0)

	Mean		**Mean**
Resting (N/cm²)	**Resting (N/cm²)**	Swallowing (N/cm²)	**Swallowing (N/cm²)**
1.37	1.20	2.18	2.01
1.23		2.04	
1.00		1.81	
1.37	1.21	2.14	1.98
1.27		2.04	
0.99		1.76	
1.19	1.03	2.15	1.99
1.11		2.07	
0.79		1.75	
1.62	1.44	2.19	2.01
1.52		2.09	
1.18		1.75	
1.31	1.10	2.18	1.97
1.16		2.03	
0.83		1.70	
1.26	1.03	2.24	2.01
1.09		2.07	
0.74		1.72	
1.36	1.11	2.23	1.98
1.17		2.04	
0.80		1.67	
2.02	1.82	2.23	2.03
1.88		2.09	
1.56		1.77	
1.30	1.17	2.14	2.01
1.32		2.16	
0.89		1.73	
1.14	0.96	2.17	1.99
1.08		2.11	
0.66		1.69	
1.73	1.48	2.32	2.07
1.46		2.05	
1.25		1.84	
1.64	1.45	2.17	1.98
1.51		2.04	

1.20		1.73	
1.42	1.21	2.34	2.13
1.27		2.19	
0.94		1.86	
1.33	1.09	2.32	2.08
1.14		2.13	
0.80		1.79	
1.35	1.20	1.68	1.53
1.26		1.59	
0.99		1.32	
1.25	1.10	2.17	2.02
1.18		2.10	
0.87		1.79	
1.25	1.12	2.11	1.98
1.22		2.08	
0.89		1.75	
1.40	1.22	2.19	2.01
1.29		2.08	
0.97		1.76	
1.05	0.85	2.17	1.97
0.92		2.04	
0.58		1.70	
1.11	0.98	2.14	2.01
1.14		2.17	
0.69		1.72	

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