

**COMPARATIVE EVALUATION OF THE LATERAL THROAT FORMAND
THE BORDER EXTENSION OF MANDIBULAR COMPLETE DENTURE IN
THE DISTOLINGUAL REGION OF MODERATELY RESORBED RIDGES:**

AN In Vivo STUDY

Dissertation

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By

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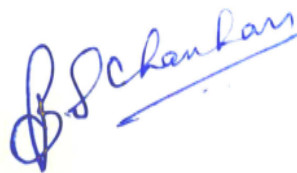
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“The single greatest cause of happiness is gratitude”

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List of Abbreviations	Stands For
OPG	Orthopantomograph
LTF	Lateral Throat Form
SD	Standard Deviation
et al.	et alia (and others)

ABSTRACT

1. **Introduction:** Retromylohyoid fossa (LTF) can prove to be an outstanding area to attain positive retention while extending the denture particularly in the condition where the extensions cannot be extended to sublingual fossa. This area was classified by Neil in three different types based on tonicity, activity and attachment of the adjacent structures, according to which even the dentures given to the patients could also have three different length and width distolingually.

Materials and Method: Equipment used in the study were Panoramic radiograph (OPG) of the patient, divider, HB pencil, metallic scale, cephalometric tracing sheet, gloves, head cap, mouth mask, mouth mirror and UNC-15 periodontal probe. 50 subjects were selected on the basis of their OPG they were divided into 25 subjects with mild ridges resorption and 25 subjects with moderate ridge resorption. Patients with mild resorption were classified under Wical and Swoope class I and patients with moderate resorption were classified under Wical and Swoope class II. The depth lateral form and denture flange of patients were measured using A UNC 15 probe and compared. Patients in each class were further classified according to Neil's classification.

Result: For both Wical and Swoope classes I and II, the border extensions of mandibular complete denture were found be significantly shorter than the available space in patient's mouth. It was found that in Wical and Swoope class I, the majority of patients fell under Neil's class I (80%), followed by class II (16%) and class III (4%). For Wical and Swoope Class II, 76% fell under Neil's class I, 20% in class II and 4% in class III.

Conclusion: The lateral throat form's depth should be measured and recorded in order to decide the stock tray for primary impression and in conjunction the extension of custom tray.

INTRODUCTION

A successful complete denture depends upon the relation of the dentures to the anatomy and structures which limit and support them.¹ When talking about mandibular complete denture, retention and stability is difficult to achieve due to atrophic mandibular ridge or incorrect extension of buccal or lingual flanges or poorly adapted fitting surface.

Denture's fabrication, usage and wearing instructions play an important role in denture's success. Sometimes patients may not fully comprehend the reasons behind lack of retention of a new mandibular denture. Such type of patients require more explanation, advice, and more instruction. A phonetic training technique may then be required to facilitate retention and stabilization of the mandibular dentures²³.

A thorough knowledge of the structures present in the mandibular lingual sulcus area is required by the clinician in order to carry forward or modify the steps and procedures required for fabrication of a complete denture which provides excellent retention, stability, and support⁴.

The correct positioning of lingual borders of mandibular denture is challenging. A proper border seal is achieved by the contact of borders with the soft tissue. The tongue restricts the direct visibility of lingual borders. The influence of so many muscles on the borders of the denture makes the understanding of lingual borders more complicated.

The method for increasing the stability and retention is, including as much denture bearing area as available which can be done by incorporating the distal part of the alveolingual sulcus. The lateral throat form is situated at the distal end of the alveolingual sulcus. It is also known as retro-mylohyoid fossa. It plays an important role in attaining a better peripheral seal in mandibular complete denture. Extending the mandibular denture into this area helps to resist horizontal forces along with increasing the border seal.⁵

The method for increasing the stability and retention is including as much denture bearing area as available. This is done by incorporating the distal part of the alveolingual sulcus.

INTRODUCTION

Retromylohyoid fossa (LTF) can prove to be an outstanding area to attain positive retention while extending the denture particularly in the condition where the extensions cannot be extended to sublingual fossa. The space, lateral throat form is surrounded by various other structures. Lateral to it, lies retromolar pad, posteriolaterally to the LTF is superior constrictor muscle, posteriomediaally to it is palatoglossus muscle and mylohyoid ridge is present anteriorly.⁵

This area was classified by Neil in three different types based on tonicity, activity and attachment of the adjacent structures, according to which even the dentures given to the patients could also have three different length and width distolingually. Neil's method is used for determining the lateral Throat Form of a patient which depends on the forces applied by the floor of mouth when the tongue protrudes out⁶.

A prosthodontist should have thorough knowledge of the anatomy of the intraoral tissues before proceeding to the construction of a proper prosthesis for moderately to severely resorbed mandibular ridges in edentulous patients to achieve maximum retention, stability and support. The denture must be closely adapted to the underlying structures on which it rests, and the occlusion with the opposing denture must be accurate. It is equally important that it should be intimately adapted to the cheeks, tongue, and lips with which it is constantly in close contact and with which it must function in harmony^{7,8}.

Hence, the present study is to investigate the accurate proportions of lateral throat form according to Neil's classification in completely edentulous patients with class I and class II mandibular ridges (Wical and Swoope)⁹ and also to compare the depth of lateral throat form in patient's mouth to that of their existing dentures.

AIM AND OBJECTIVES

AIM:

To classify the patients in class I & class II mandibular ridges, classified by Wical and Swoope, to determine the proportions of the three classes of Neil's classification of lateral throat form and to later match the difference in depth of the lateral throat form between the dentures and patient's actual mandibular anatomy.

Objectives:

- TO evaluate accurate proportions of lateral throat form (Neil's classification) in mandibular class I & class II ridges (Wical and Swoope classification)
- To measure the mean lengths of lateral throat form in mandibular class I and class II edentulous ridges
- To measure the mean lengths of lateral throat form in mandibular dentures of patients having class I and class II edentulous ridges
- Comparing the differences found in the mean length of lateral throat form in patient's mouth and denture flange of class I and class II of edentulous ridges

REVIEW OF THE LITERATURE

Linden F. Edwards and Carl O. Boucher (1942)¹ evaluated the correlation of the anatomy of the mouth with prosthetic dentistry. The study evaluated the anatomic structures which are good to bear the dentures in the mouth. Also, it was able to evaluate the structures that allow additional pressure, the structures that require relief and able to determine the structures that put a restriction on the periphery of the dentures.

Carl O. Boucher(1944)⁴ advocated that the success in attaining retention, stability, support, esthetics and preservation of residual ridges, depends on the dentist's knowledge of the anatomy of the mouth, and his skill in the use of an impression technique to establish the desired relationship between these objectives and the anatomic structure of the mouth . The plastic molding of the soft tissues, which is around the polished surfaces of dentures, helps to perfect the peripheral seal.

Tilton G E(1952)¹⁰ said that every step in denture construction should be stopped to perfection. Many dentures are worn which have imperfections built into them, provided they have peripheral seal sufficient to hold them in place. He concluded by saying that the impression base, needs the addition of a peripheral seal to stabilize and sustain the denture while lateral strains are being applied during mastication and while the explosive functions of border tissues are taking place.

Craddock F W(1953)¹¹ coined the term Retromolar pad. He stated that retromolar triangle is a small and shallow but clearly defined depression. It lies at the posterior termination of the alveolar process. The apex of the triangle points backwards just reaches the antero-internal surface of the ascending ramus of the mandible. The base of the triangle is in contact with the distal root of the third molar, and its lateral and medial borders blend anteriorly into the buccal and lingual crest of 3rd molar alveolus . It holds its importance in deciding the distal termination of a lower denture.

Lewis E T(1958)¹² reported about the anterior sublingual area anatomy, problems and some solutions for it. The floor of the mouth on the lingual side of the ridge is movable in function. By placing a mucous membrane graft in this area makes it much easier. Constructing the lower denture with adhesion, horizontal stability, and a completely functional border, it will not require much time to instruct the patient in its use, and the

REVIEW OF THE LITERATURE

struggle by the patient to control the dentures during function will be eliminated. Insufficient space in the sublingual fold causes dentures to failure.

Alan Lawson(1961)¹³ studied that, to achieve the correct form of the anterior lingual denture border , the denture base (or special tray) should be extended downward with stick modelling compound while the tongue is retracted . This achieves the correct degree of downward extension. The posterior border of this extension is trimmed until the sublingual fold just makes contact with the border when the tongue is relaxed

It was found that the size and position of sublingual folds is variable in different patients. They can range from large and well developed to much smaller, particularly in elderly patients in whom degenerative changes have occurred. Smaller the fold, poorer are the chances of success and greater becomes the care required to achieve the necessary contact with the mucosa of the floor of the mouth.

Barrett S G and Haines R W(1962)¹⁴ discussed about the main areas in an edentulous mouth on which the posterior part of the lower denture must rest. A constrictor square is present which is over the part of the superior constrictor. Superior to it is the palate and medially lies the anterior pillar of the fauces. It was concluded that the mandibular denture rests on the residual ridges of the mucoperiosteum and the flanges on the origins of the mylohyoid and buccinator. Posteriorly, it and crosses the retromolar pad. The retromylohyoid extension of the denture, the pad and the construction of a small post dam ,give an excellent seal. The extension of the denture into the constrictor square is prevented by the medial pterygoid.

Giglio JJ, Lace WP and Adren H (1962)⁸ studied the method for increasing retention and concluded that any procedure which increases the fluid film thickness, such as utilization of relief spaces, thin borders, under extension, and an insufficient posterior palatal seal, should be avoided.

Brill N, Tryde G, Cantor R (1965)¹⁵ discussed the challenges faced by dentists in making a good retentive lower denture. Lower dentures are subjected to conditions such as resorbed ridges and muscle activity that hampers the stability of the denture.

The anatomical foundations on the basis of which the lower dentures will be fabricated were discussed.

REVIEW OF THE LITERATURE

Lott F, Levin B (1966)¹⁶ introduced an impression making technique of soft tissues of mouth adjacent to the buccal, lingual, labial, palatal surface and incorporating the resulting extension in the denture. Flange wax was used from retromolar pad to sublingual region and patient was asked to perform functions of swallowing etc. This technique increased the area of intimate contact of dentures to tissues improving the stability, function, comfort and appearance of the complete denture.

Kolb H R(1966)⁷ described how limiting structures influence the shape of the mandibular denture borders. The variables considered in this article were: (1) the effect of tongue movement on the shape of the sublingual crescent space, (2) the prominence of the genioglossus attachment, (3) the prominence of the lingual ledge, (4) the proximity of the retromolar pad to the maxillary tuberosity at the established interr ridge distance, (5) the position of the external oblique ridge in relation to the residual ridge crest, (6) the positions of the buccinator and mylohyoid muscle attachments in relation to the ridge crest, (7) the activity of the mentalis muscle, and (8) habits and degree of neuromuscular control. It was concluded that the denture in contact with these structures helps in attaining retention and stability.

Preiskel, H. W. (1968)¹⁷ stated that the mylohyoid and retromylohyoid regions are key areas to the successful extension of complete lower dentures and the knowledge of the anatomy of this region along with an impression technique that makes best, possible use of the space are required. A method was described for correcting the form of the distal end of the lingual flange of complete dentures

Atwood DA (1971)¹⁸ stated that reduction of residual ridges (RRR) needs should be recognized as it causes physical, psychologic, and economic problems for millions of people all over the world. RRR is a chronic, progressive, irreversible, and disabling disease which has multifactorial origin. He researched about residual ridge resorption to find better methods of prevention or control of the disease. The result stated that the rate of resorption is slow and varies at different times and in different sites within an individual. The cofactors such as metabolic (sex, hormonal balance, osteoporosis,etc.),the functional (frequency, direction, and amount of force applied to

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the ridge) and the prosthetic factors (the type of denture base, the form and type of teeth, the interocclusal distance) together result in a more rapid rate of RRR.

Kenneth E. Wical(1974)¹⁹ studied in his 44 complete denture patients about the systemic conditions that play an important in the etiology of residual ridge resorption. The resistance of bone to mechanical stresses depends on its physiologic condition. Nutritional deficiencies and imbalances, as well as mechanical factors, are considerations in diagnosis and treatment planning for prosthodontic patients. It was concluded that there was a correlation among low calcium intake, low calcium/phosphorus ratios, and alveolar bone resorption. These elements appear to be contributing factors in bone resistance to resorption. The “recommended daily allowances” serve as useful guides in nutritional counselling.

Kenneth E. Wical(1974)⁹ in his 260 subjects described a method of estimating the severity of mandibular bone resorption by using the mental foramen and treat the inferior border of the mandible, as they appear in panoramic radiographs, as reference points the severity of mandibular bone resorption can be estimated by using the mental foramen and the inferior border of the mandible, as they appear in panoramic radiographs, as reference points. The approximate ratio of 3:1, the original height of the mandible can be conveniently estimated from the height of the lower edge of the foramen above the inferior border of the mandible. It was concluded that this method of estimating and describing the degree of bone resorption facilitated the study of this disease by providing an anatomic basis for classifying or grouping patients affected to varying degrees.

Bocage M, Lehrhaupt J (1977)²⁰ studied about a technique which involves a lingual wing (horizontal extension of the lingual flange). In this technique, after the final impression has been made, the surface should be coated with a suitable adhesive and loaded with a medium- or light-bodied silicone or rubber-base impression material. With light biting pressure, the patient was instructed to swallow several times during setting. The result indicated that on completion of the denture, there were no

REVIEW OF THE LITERATURE

interferences with lingual function, along with stability and increased comfort were present.

Krammer R V, Dentista C (1982)²¹ stated that sublingual flange extension improves the retention and stability of complete lower dentures. Independent of the technique used for the construction of a complete lower denture, a normal tongue position is important for its success. Abnormal swallowing habits may also alter the success of a complete lower denture and must be corrected before treatment begins.

Jacobson T E (1983)²² demonstrated that stability in a complete denture is the resistance to horizontal or rotational forces. It resists forces in the horizontal plane. Stability ensures the physiologic comfort of the patient. The factors affecting it involve the tissue, occlusal, and polished surfaces of the denture. It was concluded that any disharmony in these factors would affect the stability of the lower complete denture.

Kotkin H (1987)²³ described an impression technique that would provide a mandibular denture base with contours encouraging anterior positioning of the tongue for effective harnessing of the stabilizing and retentive forces exerted in this forward position. The guiding ramp is formed under the influence of controlled muscular activity in the region of the mandibular anterior teeth against it. Under the influence of the guiding ramp, the tongue is encouraged to assume a normal position where the tip is in contact with the mandibular incisors while its distal margins are related to the lingual surfaces of the posterior teeth. Tongue position in control during impressionmaking produces a mandibular denture base with a form more acceptable to the patient with advanced resorption of the mandibular residual ridge.

Jennings D E(1989)² explained that the simplest approach is to extend the denture base adequately for proper use of all available supporting tissues. If the patient is unable to wear a conventional denture, the surgical approach becomes necessary. Surgical procedures include vestibular extension that increase vestibular depth and augmentation procedures, which include (1) overlay grafts of rib or the crest of the ilium, (2) osteotomy grafts to include the visor osteotomy and the interpositional bone graft, (3)

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alloplastic grafts of which hydroxyapatite augmentation is the most common, and (4) various types of implants to restore the compromised ridge. The goal, is to restore the patient to perform masticatory function.

Azzam M K , Yurkstaas A A, Kronman J(1992)²⁴ studied about the extension of the flange in the sublingual crescent region as it is an important factor for mandibular denture stability and retention . An impression made with minimal pressure on the floor of the mouth while the tongue is at rest leads to greater mobility of the underlying muscles without denture dislodgment and without occlusion of the sublingual gland ducts. The evidence of enhanced resistance to dislodgment was achieved and the denture was more stable during normal tongue movements such as swallowing, speaking, and eating.

DeFranco RL, Sallustio A (1995)²⁵ developed a physiologic impression with maximum support of both hard and soft tissues. A procedure was described for the final impression of the severely atrophied mandible. The final impression was developed by using open- and closed-mouth procedures. The final impression was made after several appointments for reapplication of tissue-conditioning material and after the patient was comfortable enough. The method was developed to maximize the supportive aspect of the available denture foundation by two approaches, functional and anatomic. Peripheral borders developed functionally with the mouth closed, and the final phase of the impression made with the mouth open. This technique was developed as it will provide the patient with a denture that has function with maximum support and stability.

McCord JF, Tyson K W(1997)²⁶ evaluated the clinical problems encountered in the treatment of edentulous patients with atrophic (flat) mandibular ridges. An impression technique was described and illustrated. The objective of the technique was for the patients, for whom implant treatment is not a realistic option, may have improved denture function of their lower complete dentures.

Miller WP, Monteith B, Heath M R(1998)²⁷ investigated the effect of two different lingual shapes of lower dentures on patients ability to resist lifting forces. Two

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experimental prostheses were fabricated for each patient: one conventionally contoured, the other formed by piezography . Lower denture with a piezographically produced lingual surface displayed enhanced tongue retentive ability over a conventional design. It is reasonable to maximise retentive potential with oblique sublingual polished surfaces and minimise the adaptive demand, particularly for older patients, by using a piezographic technique which "customises" the contour and prevents over-extension.

Kikuchi M, Ghani F, Watanabe M(1999)²⁸ examined the effect of the texture of the fitting surface on the retention of the denture. Physical retention of denture depends on adhesion of salivary film to its fitting surface and supporting tissues. The mean retention of the bases increases by more than 2-fold when the fitting surface is airparticle abraded.

Huang P-S, Chou T-M, Chang H-P, et al (2007)⁶ investigated the proportion of 3 Neil's classifications of lateral throat forms and the difference in the length of the lateral throat form between the dentures and the patient's actual anatomy. The classification of lateral throat form was determined by the functional movements of the patients, and an implant depth gauge was used to measure the length of the lateral throat form in the patient's mouth and compare it to that of the dentures. There was a statistically significant difference in length between the ridge height of the mouth and the denture.

Bohnenkamp DM, Garcia LT. P (2007)³ reported the clinical use of phonetics and its effect on tongue position to improve the retention and stability of a mandibular complete denture. the wide range of movements of the mandible, tongue, and facial musculature, the mandibular denture presents the greatest difficulty in learning to use complete dentures. The patient should be instructed

to pronounce the sound "e" to help train and coordinate the positions of the tongue and buccinator muscles.

Parajuli PK , Shetty TB , Shenoy VK , Rodrigues SJ(2010)⁵ conducted a study in 30 patients in the south coastal region of Karnataka to investigate the proportions of Neil's 3 classes of lateral throat form and to evaluate the difference in the length of the lateral throat form of the patients denture and its actual anatomy. A significant difference was found between the two.

Chang J.J(2011)²⁹

The discrepancies between the depth and width of the mandibular denture anterior lingual flange and the alveolingual sulcus lead to decreased retention . Following functional border moulding, the mean retention of the mandibular denture increases in a significant manner.

A Abdul Gafoor, VV Harish Kumar, M Sheejith, C Swapna(2012)³⁰ studied about how to achieve retention in severely resorbed mandibular ridges during impression making and to maintain the retention and stability of these dentures during function. For this the anterior lingual border of the impression was then extended sublingually without interfering with the tongue function or blocking the opening of the ducts of the sublingual gland. This concluded into maintaining contact with the surrounding sublingual tissue in both protruded and retruded positions of the tongue, creating good peripheral seal.

Gandage Dhananjay S (2013)³¹ correlated the clinical anatomy of the lingual vestibule and its influence on denture borders by dissecting the of the floor of the mouth being carried out on cadaver through an intra oral approach. A proper border seal was achieved by the contact of borders with the soft tissue. It was concluded that the final lingual border should be so shaped in a way that it guides the tongue into the same position as it will occupy in relation to the finished denture. The tray should not dislodge when the tip of the tongue is in contact with the vermilion border of the lips.

Rastogi I (2014)³² evaluated relative proportion of the lateral throat form in 74 dentulous subjects between the age of 18-45 years. A customized instrument was used to measure the depth of the lateral throat form. An intraoral evaluation of the LTF using single method and the instrument was done. The study concluded that the majority of the lateral throat formed among the patients was of Class-I and then followed by Class-II and III. It was concluded that lateral throat formed plays an important role in providing retention and stability to the prosthesis.

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33 evaluated the lingual

Denizoğlu S, Yanikoglu N, Yilmaz B, Kürklu D(2014)

sulcus depths of the pair casts which was obtained with swallowing and excessive movements of the tongue. It was concluded that lingual sulcus depth is vertically and horizontally higher in the casts obtained with swallowing than those with excessive movements.

Nishna Pradeep and Jinsa P Devassy(2015)³⁴ introduced a simple technique for loose lower denture which could give excellent retention and stability to normal or medium height ridges and satisfactory retention in severely resorbed ridges, where otherwise retention was difficult to achieve. At the premylohyoid region, a layer of impression compound was added and patient was asked to carry out movements. It was concluded that this layer stays in contact with the sublingual fold and helps in retention and stability of the mandibular denture.

Mustafa AZ (2015)³⁵ examined the effect of lingual ledge on complete denture retention and stability for atrophied mandibular ridge in 10 patients who were complaining about retention in mandibular complete denture. Complete dentures were fabricated according to neutral zone technique, but the difference between the 2 sets were the denture base contours and the presence or absence of lingual ledge. In conclusion, lingual ledge developed during physiologic recording the denture space enhanced the mandibular denture retention and stability.

Yu-Ri Heo, Hee-Jung Kim, Mee-Kyoung Son, Chae-Heon Chung(2016)³⁶ analyzed the shapes of lingual polished surfaces in lower complete dentures which were formed by polished surface impressions. It was found that the height of the contour of the lingual polished surface at the lingual frenum was halfway between the occlusal plane and lingual border, it moved gradually in a downward direction. The angle from the occlusal plane to the height of the contour of the lingual polished surface increased as it progressed from the lingual frenum towards the retromolar pads. The shape of the mandibular lingual polished surface is convex at the lingual frenum, lateral incisors and gradually flattened towards the first molars and retromolar pads.

Kalavathy N, Kumar PR, Gupta S, Sridevi J, Shetty M, Sanketh AK(2016)³⁷ measured the exact depth of LTF using customized gauge and proposed a classification

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based on the measured depth. The customized gauge was inserted into the alveolo-lingual sulcus to measure the depth. The new classification for LTF gave consistent results and it was easier to use with less variability when compared to the Neil's classification.

Sharma A. (2016)³⁸ carried a study on 30 edentulous patients and measured the Lateral depth by customized tool and also by Neil's method. The customized tool was a hollow „L“ shaped pipe which was fabricated with acrylic resin with a flexible wrought wire inserted inside it. The result concluded that the fabricated instrument gave consistent result which helps in the proper selection of stock tray which in turn results in the proper extension of custom tray.

Sabina Poudel , Minu Dhungana , Rajani Karki ,Prabhat Shrestha(2016)³⁹ compared the inter-observer accuracy between Neil's method of classification and classification done by a customized gauze. It concluded that the method of measuring the depth of LTF with fabricated instrument was more accurate and reliable than Neil's method

MATERIAL AND METHODS

The materials and equipment used for the study were

- Panoramic radiograph of the patient
- Divider
- Hb pencil
- Metallic scale
- Cephalometric tracing sheet
- Gloves, Head cap, Mouth mask
- Mouth mirror
- UNC-15 periodontal probe.



Fig. 1 OPG of a patient



Fig. 2 Fig. Divider

MATERIAL AND METHODS



Fig. 3 Hb Pencil



Fig. 4 Metallic Scale

MATERIAL AND METHODS

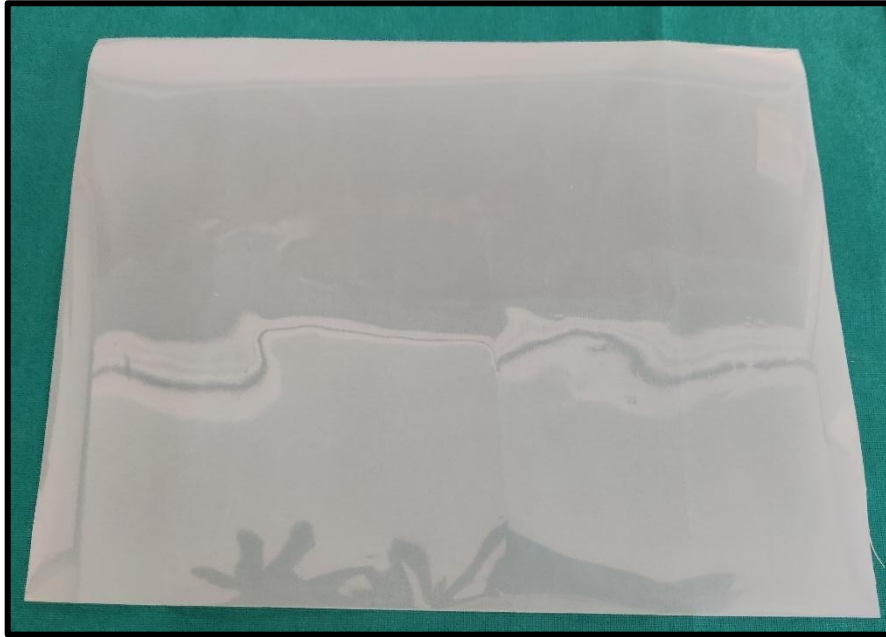


Fig. 5 Cephalometric tracing sheet



Fig. 6 Gloves

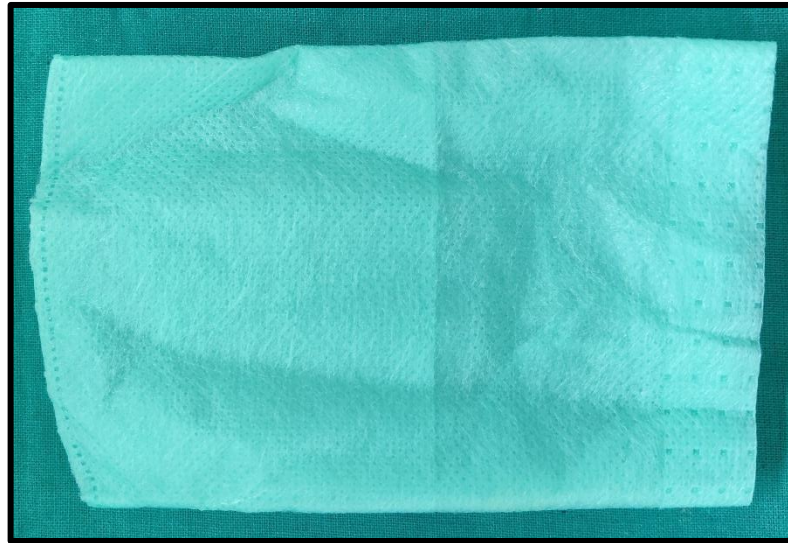


Fig. 7 Head cap



Fig. 8 Mouth Mirror

MATERIAL AND METHODS



Fig. 9 UNC 15 Periodontal Probe

MATERIAL AND METHODS

METHODOLOGY

Completely edentulous patients reported to the Department of Prosthodontics Crown and Bridge and Implantology, Babu Banarasi Das College of Dental Sciences, BBD University, Faizabad Road, Lucknow. Completely edentulous patients with mild to moderate mandibular resorbed ridges (Wical and Swoope) were selected for the study.

Total no. of specimens selected for the study were 50 which were further divided into 25 patients in each class. The eligibility criteria for patients was kept between the age group of 45-75 years.

Eligibility Criteria

- Inclusion Criteria was kept 25 patients with class I residual ridges (WICAL AND SWOOPE), 25 patients with class II residual ridges (WICAL AND SWOOPE), Proper neuromuscular co-ordination.
- Exclusion Criteria was patients with severely resorbed ridges (class III), patients with poor neuromuscular co-ordination, patients with degenerative or fibrotic conditions, that restricted movement of floor of mouth.

Sampling method was Stratified sampling. An oral examination of the patients reporting at UG and PG clinic of Department of Prosthodontics and Crown and Bridge was conducted and the patients with class I and Class II mandibular resorbed ridges were selected. To check the amount of bone resorption compared to the original height of the ridge, an OPG of the patient was taken and later were grouped under class I and class II category (25 in each group) according to WICAL AND SWOOPE classification.⁹

The amount of resorption was checked by the formula presented below:-

$$R = 3x - L$$

MATERIAL AND METHODS

Here, R signifies the amount of mandibular residual ridge resorption, x denotes the distance between the inferior border of the mandible and the inferior border of mental foramen; L signifies the height of the mandibular residual ridge.⁹

GROUPING

Subjects were divided according to Wical and Swoope

WICAL and SWOOPE CLASSIFICATION	NUMBER OF PATIENTS
Class I	25
Class II	25

After the final selection of the patient was done, they were asked to sit straight position and rest their back on the chair and place their tongue in a relaxed state. Later the clinician placed his finger in the direction of the distal alveololingual sulcus towards the lateral throat form. The patient was instructed to protrude the tongue up to 06 mm, beyond vermilion border of the lower lip.

Based on the magnitude of displacement of the tongue, the lateral throat form was classified for a specific patient and the patient were classified as class I, class II and class III according to Neil's classification. The proportions found in each class were recorded.

WICAL	NEIL'S CLASS I
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CLASS I	NEIL'S CLASS II
	NEIL'S CLASS III

WICAL CLASS II	NEIL'S CLASS I
	NEIL'S CLASS II
	NEIL'S CLASS III

Later, a well calibrated UNC-15 periodontal probe was inserted in the patient's mouth to measure the patient's lateral throat form depth. Using a mouth mirror the tongue was then displaced and the patient was then instructed to protrude the tongue 06 millimetres beyond lower lips' vermillion borer. The probe was used to measure the depth, both on right and left sides, of the anterior and posterior edges of the retro molar pad. The readings were recorded. After the fabrication of mandibular denture, the corresponding areas were measured on the denture.

The readings were compared statistically by an intra and intergroup comparison, Students paired 't' test and unpaired 't'- test.

MATERIAL AND METHODS

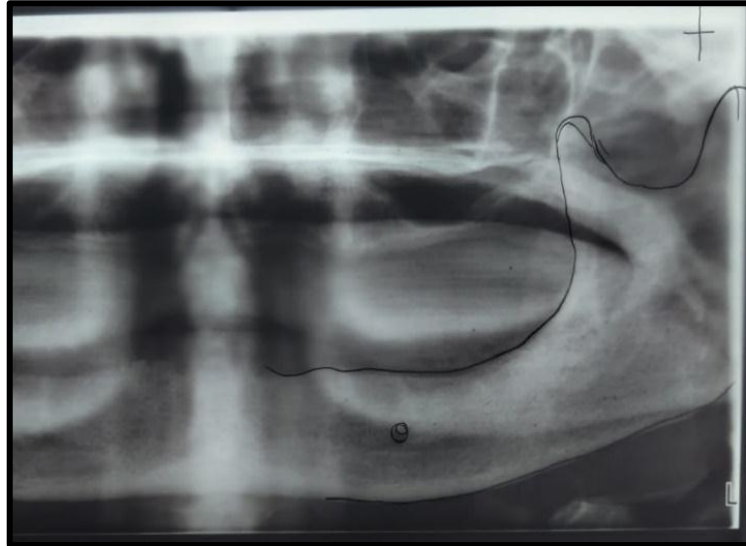


Fig. 10 Tracing of OPG done

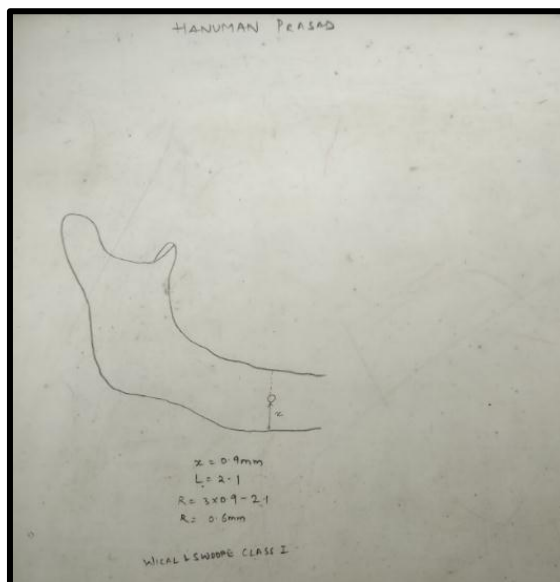


Fig 11 Tracing done of Wical and Swoope Class I

MATERIAL AND METHODS

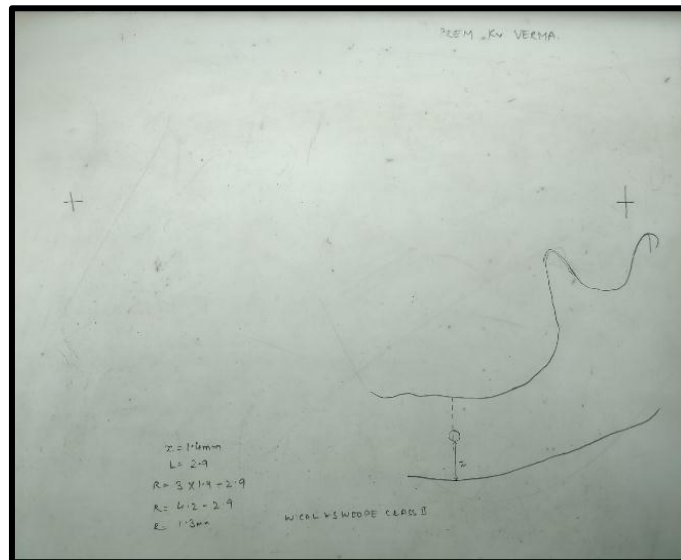


Fig 12 Tracing done of Wical and Swoope Class II

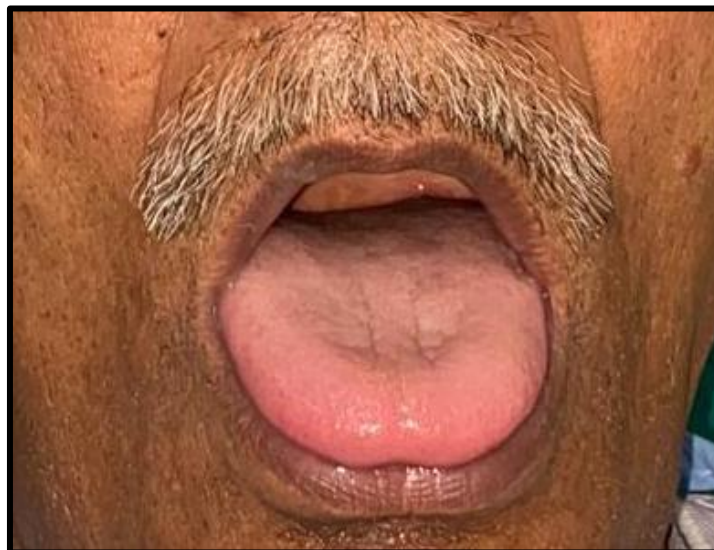


Fig. 13 Protruding the tongue up to 6mm beyond vermilion border

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Fig 14 Identifying Neil's classification



Fig. 15 Depth of lateral throat form on posterior aspect of retro molar pad of left side recorded



Fig.16 Depth of lateral throat form on anterior aspect of retro molar pad of left side recorded

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Fig. 17 Depth of lateral throat form on posterior aspect of retro molar pad of right side recorded



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Fig.18 Depth of lateral throat form on anterior aspect of retro molar pad of right side recorded

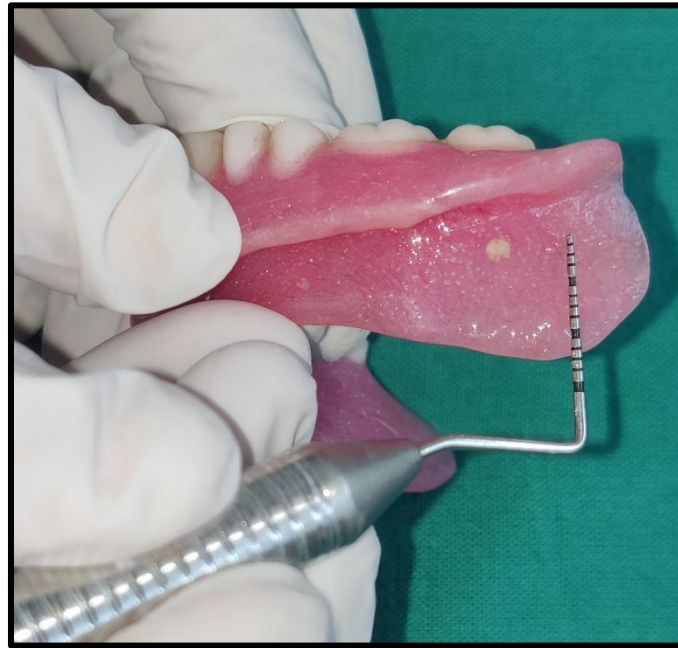


Fig.19 Depth of denture flange on posterior aspect of retro molar pad recorded



Fig. 20 Depth of denture flange on anterior aspect of retro molar pad recorded

RESULT

Table 1 Patients data for Wical and Swoope Class I

<i>Wical Class I</i>	Ant_ R_Pat	Pos_ R_Pa t	Ant_ L_Pat	Pos_ L_Pa t	Ant_R _Den	Pos_R _Den	Ant_L _Den	Pos_L _Den	Ant_R_Pat- Ant_R_Den	Pos_R_Pat- Pos_R_Den	Ant_L_Pat- Ant_L_Den	Pos_L_Pat- Pos_L_Den
Patient 1	10	12.5	11	13	9	12	9	11.5	1	0.5	2	1.5
Patient 2	8	10	11	12.5	7	7.5	9	10.5	1	2.5	2	2
Patient 3	13.5	15	12	14	12	14	10.5	11.5	1.5	1	1.5	2.5
Patient 4	11	14	13	15	11	12.5	10.5	13	0	1.5	2.5	2
Patient 5	9	11	9	14	8	11	9	12	1	0	0	2
Patient 6	17	18	14	17	8	11	12	17	9	7	2	0

RESULT

Patient 7	14	16	17	21	10	15	10	13	4	1	7	8
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Patient 8	14	16	16	17	12	11	14	16	2	5	2	1
Patient 9	12	14	12	17	11	14	10	16	1	0	2	1
Patient 10	16	16	12	19	15	11	12	16	1	5	0	3
Patient 11	9	14	14	20	7	12	10	17	2	2	4	3
Patient 12	9	10	15	20	8	9	14	15	1	1	1	5
Patient 13	10	16	16	18	9	13	12	12	1	3	4	6
Patient 14	18	16	17	13	11	10	9	12	7	6	8	1

RESULT

Patient 15	14	17	12	15	8	17	12	14	6	0	0	1
Patient 16	12	14	11	21	10	12	11	11	2	2	0	10
Patient 17	10	13	12	16	9	10	11	11	1	3	1	5
Patient 18	16	11	8	18	7	11	7	12	9	0	1	6
Patient 19	17	16	9	15	15	14	8	14	2	2	1	1
Patient 20	17	15	9	13	12	11	9	11	5	4	0	2
Patient 21	10	12	13	15	9	12	10	13	1	0	3	2
Patient 22	9	16	15	21	8	14	11	11	1	2	4	10
Patient 23	14	19	14	19	10	17	11	15	4	2	3	4

RESULT

Patient 24	10	20	18	16	8	14	15	13	2	6	3	3
Patient 25	14	18	13	21	10	10	12	13	4	8	1	8

Table 2 Patients data for Wical and Swoope Class II

<i>Wical Class II</i>	Ant_R_Pat	Pos_R_Pat	Ant_L_Pat	Pos_L_Pat	Ant_R_Den	Pos_R_Den	Ant_L_Den	Pos_L_Den	Ant_R_Pat-Ant_R_Den	Pos_R_Pat-Pos_R_Den	Ant_L_Pat-Ant_L_Den	Pos_L_Pat-Pos_L_Den
Patient 26	11	14	11	13	10	13	9	13	1	1	2	0
Patient 27	14	15	10	12	11	14	9	11	3	1	1	1
Patient 28	10	11	10	13	8	10	9	12	2	1	1	1
Patient 29	9	15	10	14	7	14	9	12	2	1	1	2
Patient 30	11	14	11	15	10	9	9	12	1	5	2	3
Patient 31	14	21	16	22	12	16	15	20	2	5	1	2
Patient 32	15	13	12	13	11	11	11	12	4	2	1	1

RESULT

Patient 33	9	17	14	18.5	8	13	13	18	1	4	1	0.5
Patient 34	20	14	18	19	19	14	16	17	1	0	2	2
Patient 35	8	14	18	15	8	13	17	14	0	1	1	1
Patient 36	9	20	17	15	8	18	15	12	1	2	2	3
Patient 36	12	20	15	20	8	18	12	14	4	2	3	6
Patient 37	13	21	17	21.5	13	10	13	18	0	11	4	3.5
Patient 38	19	17	15	22	12	11	12	20	7	6	3	2
Patient 39	20	19	14	17	20	17	12	16	0	2	2	1
Patient 40	21	17	14	18	20	17	12	16	1	0	2	2
Patient 41	16	21	16	20	12	20	15	15	4	1	1	5
Patient 42	16	20	15	21	15	19	9	17	1	1	6	4
Patient 43	15	19	13	20	15	18	12	12	0	1	1	8

RESULT

Patient 44	20	22	19	23	16	19	14	21	4	3	5	2
Patient 45	20	16	19	22	8	16	19	21	12	0	0	1
Patient 46	14	16	11	21	13	11	9	12	1	5	2	9
Patient 47	19	22	18	17	18	13	16	17	1	9	2	0
Patient 48	20	20	20	23	17	19	19	17	3	1	1	6
Patient 49	21	17	16	20	19	15	14	15	2	2	2	5
Patient 50												

RESULT

The results of the present study conducted in Department of prosthodontics and crown and bridge, BBDCODS show that patients classified in Wical and Swoope, 80% of them can be classified under Niels class I, about 16% were classified under Neil's class II and Neil's class III was the rarest to be found, only 4% patients classified under this class. (*Table 1*)

Similar result was found in Wical and Swoope, 76% of them can be classified under Niels class I, about 20% were classified under Neil's class II and Neil's class III was the rarest to be found, only 4% patients classified under this class. (*Table 2*)

It was observed that in Wical and Swoope class I, the lateral throat form's average length at right-hand side anterior aspect was 12.54mm with a standard deviation of 3.1 and lateral throat form's average length at left-hand side anterior aspect was found to be 12.92mm with a standard deviation of 2.7. Similarly, the lateral throat form's average length at the right-hand side posterior aspect was 14.78 mm with a standard deviation of 2.7, while on the lefthand side posterior aspect was 16.82mm with a standard deviation of 2.9. (*Table 3*)

Measuring the corresponding lengths of the denture flanges in Wical and Swoope class I, it was found that the average length at the right-hand side corresponding anterior aspect was 9.76mm with a standard deviation of 2.2, while the average length of denture flange at the left-hand side anterior aspect was 10.72mm with a standard deviation of 1.9. Similarly, the corresponding measurements of denture flanges posterior aspect are – on the right hand side posterior aspect the average length was found to be 12.2mm with a standard deviation of 2.3, while on the left-hand side posterior aspect the average length was 13.22mm with a standard deviation of 2.0.

(*Table 4*)

Similarly, in Wical and Swoope class II it was observed that, the lateral throat form's average length at right-hand side anterior aspect was 12.4mm with a standard deviation of 2.7 and lateral throat form's average length at left-hand side anterior aspect was found to be 12.36mm with a standard deviation of 2.4. Similarly, the lateral throat form's average length at the right-hand side posterior aspect was 14.6 mm with a

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standard deviation of 2.8, while on the lefthand side posterior aspect was 14.64mm with a standard deviation of 3.2. (*Table 5*)

Measuring the corresponding lengths of the denture flanges in Wical and Swoope class II, it was found that the average length at the right-hand side corresponding anterior aspect was 12.12mm with a standard deviation of 2.9, while the average length of denture flange at the left-hand side anterior aspect was 11.84mm with a standard deviation of 2.2. Similarly, the corresponding measurements of denture flanges posterior aspect are – on the right hand side posterior aspect the average length was found to be 13.2mm with a standard deviation of 2.8, while on the lefthand side posterior aspect the average length was 14.88mm with a standard deviation of 2.2. (*Table 6*)

Comparing the mean length of the lateral throat forms and the denture flanges in both Wical and Swoope class I and class II, it was found that the denture flanges in both the classes and at both anterior and posterior aspects were significantly shorter ($p < 0.001$) than the corresponding lateral throat forms of the patients.

In Wical and Swoope class I, the denture flange at the right-hand side anterior aspect was on an average 2.8 mm shorter than the lateral throat form at the anterior aspect with a standard deviation of 2.6, while the denture flange at the right-hand side posterior aspect was on an average 2.6mm shorter than the lateral throat form at the anterior aspect with a standard deviation of 2.4. Similarly on the left-hand side anterior aspect the denture flange was on an average 2.2mm shorter with a standard deviation of 2 than the corresponding lateral throat form, while on the left-hand side posterior aspect the denture flange was on an average 3.6mm with a standard deviation of 2.9 shorter than corresponding lateral throat form. (*Table 7 and Graph 1*)

Similarly, in Wical and Swoope class II, the denture flange at the right-hand side anterior aspect was on an average 2.32 mm shorter than the lateral throat form at the anterior aspect with a standard deviation of 2.6, while the denture flange at the righthand side posterior aspect was on an average 2.68mm shorter than the lateral throat form at the anterior aspect with a standard deviation of 2.8. Similarly on the left-hand side anterior aspect the denture flange was on an average 1.96mm shorter with a standard deviation of 1.4 than the corresponding lateral throat form, while on the lefthand side

RESULT

posterior aspect the denture flange was on an average 2.84mm with a standard deviation of 2.4 shorter than corresponding lateral throat form. (*Table 8 and*

Graph 2)

Table 3 : Proportion of Neil's classification in Wical and Swoope Class I

WICAL CLASS I	No. of Patients	Percentage %
Neil's Class I	20	80%
Neil's Class II	4	16%
Neil's Class III	1	4%
Total	25	100%

Table 4: Proportion of Neil's classification in Wical and Swoope Class II

WICAL CLASS II	No. of Patients	Percentage %
Neil's Class I	19	76%
Neil's Class II	5	20%
Neil's Class III	1	4%
Total	25	100%

Table 5 : Length of lateral throat forms in patients in Wical and Swoope Class I

Particulars	No. of Patients	Mean(mm)	Standard Deviation	Median(mm)	Mode(mm)
Ant_R_Pat	25	12.54	3.1	12.0	10.0
Pos_R_Pat	25	14.78	2.7	15.0	16.0
Ant_L_Pat	25	12.92	2.7	13.0	12.0
Pos_L_Pat	25	16.82	2.9	17.0	15.0

Ant_L_Pat - Length of Lateral Throat Form at Left Anterior Aspect

Ant_R_Pat - Length of Lateral Throat Form at Right Anterior Aspect

Pos_R_Pat - Length of Lateral Throat Form at Right Posterior Aspect

Pos_L_Pat - Length of Lateral Throat Form at Left Posterior Aspect

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Table 6 : Length of Denture flanges in patients in Wical and Swoope Class I

Particulars	No. of Patients	Mean(mm)	Standard Deviation	Median(mm)	Mode(mm)
Ant_R_Den	25	9.76	2.2	9.0	8.0
Pos_R_Den	25	12.2	2.3	12.0	11.0
Ant_L_Den	25	10.72	1.9	10.5	9.0
Pos_L_Den	25	13.22	2.0	13.0	13.0

Ant_R_Den - Length of Denture Flange at Right Anterior Aspect

Ant_L_Den - Length of Denture Flange at Left Anterior Aspect

Pos_R_Den - Length of Denture Flange at Right Posterior Aspect

Pos_L_Den - Length of Denture Flange at Left Posterior Aspect

Table 7: Length of lateral throat forms in patients in Wical and Swoope Class II

Particulars	No. of Patients	Mean(mm)	Standard Deviation	Median(mm)	Mode(mm)
Ant_R_Pat	25	12.4	2.7	15.0	20.0
Pos_R_Pat	25	14.6	2.8	17.0	14.0
Ant_L_Pat	25	12.36	2.4	15.0	11.0
Pos_L_Pat	25	14.64	3.2	19.0	15.0

Ant_L_Pat - Length of Lateral Throat Form at Left Anterior Aspect

Ant_R_Pat - Length of Lateral Throat Form at Right Anterior Aspect

Pos_R_Pat - Length of Lateral Throat Form at Right Posterior Aspect

Pos_L_Pat - Length of Lateral Throat Form at Left Posterior Aspect

Table 8 : Length of Denture flanges in patients in Wical and Swoope Class II

Particulars	No. of Patients	Mean(mm)	Standard Deviation	Median(mm)	Mode(mm)
Ant_R_Den	25	12.12	2.9	14.0	8.0
Pos_R_Den	25	13.2	2.8	14.0	13.0
Ant_L_Den	25	11.84	2.2	12.0	9.0
Pos_L_Den	25	14.88	2.2	15.0	12.0

Ant_R_Den - Length of Denture Flange at Right Anterior Aspect

Ant_L_Den - Length of Denture Flange at Left Anterior Aspect

Pos_R_Den - Length of Denture Flange at Right Posterior Aspect

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Pos_L_Den - Length of Denture Flange at Left Posterior Aspect

Table 9 : below is the mean lengths comparison of the Lateral throat form and the patient's Denture flanges for Wical and Swoope Class I

Particulars	Mean Difference (mm)	Standard Deviation	t Stat	t critical	p Value
Ant_R_Pat-Ant_R_Den	2.8	2.6	5.400	2.064	0.000
Pos_R_Pat-Pos_R_Den	2.6	2.4	5.452	2.064	0.000
Ant_L_Pat-Ant_L_Den	2.2	2.0	5.375	2.064	0.000
Pos_L_Pat-Pos_L_Den	3.6	2.9	6.197	2.064	0.000

Ant_L_Pat - Length of Lateral Throat Form at Left Anterior Aspect

Ant_R_Pat - Length of Lateral Throat Form at Right Anterior Aspect

Pos_R_Pat - Length of Lateral Throat Form at Right Posterior Aspect

Pos_L_Pat - Length of Lateral Throat Form at Left Posterior Aspect

Ant_R_Den - Length of Denture Flange at Right Anterior Aspect

Ant_L_Den - Length of Denture Flange at Left Anterior Aspect

Pos_R_Den - Length of Denture Flange at Right Posterior Aspect

Pos_L_Den - Length of Denture Flange at Left Posterior Aspect

Table 10: Below is the mean lengths comparison of the Lateral throat form and the patient's Denture flanges for Wical and Swoope Class II

Particulars	Mean Difference (mm)	Standard Deviation	t Stat	t critical	p Value
Ant_R_Pat-Ant_R_Den	2.32	2.6	4.418	2.064	0.000
Pos_R_Pat-Pos_R_Den	2.68	2.8	4.795	2.064	0.000
Ant_L_Pat-Ant_L_Den	1.96	1.4	7.160	2.064	0.000
Pos_L_Pat-Pos_L_Den	2.84	2.4	5.841	2.064	0.000

Ant_L_Pat - Length of Lateral Throat Form at Left Anterior Aspect

Ant_R_Pat - Length of Lateral Throat Form at Right Anterior Aspect

Pos_R_Pat - Length of Lateral Throat Form at Right Posterior Aspect

Pos_L_Pat - Length of Lateral Throat Form at Left Posterior Aspect

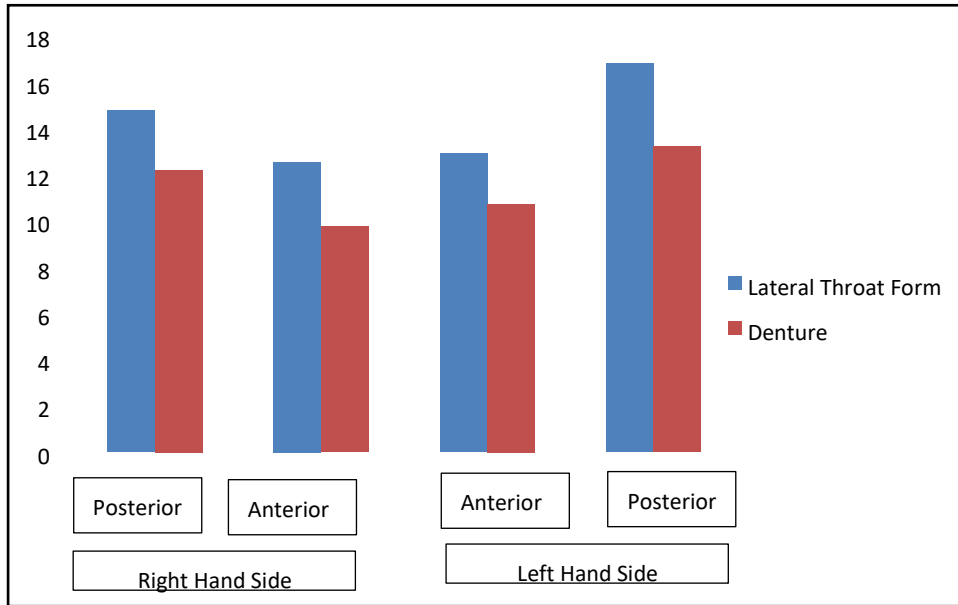
Ant_R_Den - Length of Denture Flange at Right Anterior Aspect

Ant_L_Den - Length of Denture Flange at Left Anterior Aspect

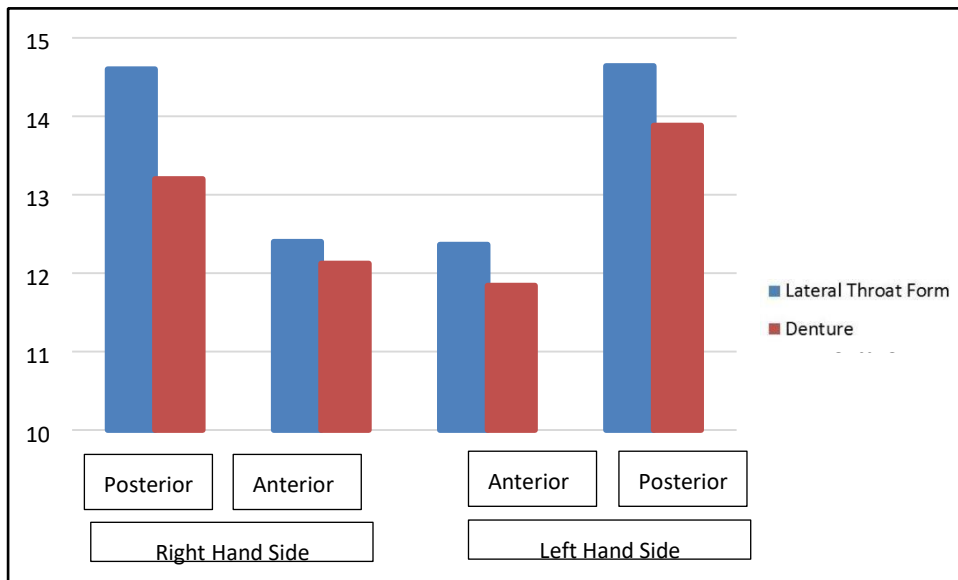
Pos_R_Den - Length of Denture Flange at Right Posterior Aspect

Pos_L_Den - Length of Denture Flange at Left Posterior Aspect

RESULT



Graph 1: Comparison between Lateral Throat Form and corresponding Denture flange at anterior and posterior aspect in Wical and Swoope class I



Graph 2: Comparison between Lateral Throat Form and corresponding Denture flange at anterior and posterior aspect in Wical and Swoope class II

DISCUSSION

The Retromylohyoid fossa, also known as Lateral throat form, is a structure located at the distal end of the alveolingual sulcus⁵. It is the distal most part of the sulcus, that plays an important role in maintaining the peripheral seal of the mandibular denture. The structures present in this area should be well understood to carry out further procedures of fabricating a well-functioning mandibular denture. The depth of the alveolingual sulcus and its correlation with the denture flange of the mandibular denture is an important study to understand and then act upon the correct procedure of fabricating a mandibular denture that will provide retention and stability.¹⁴

As the studies by Jacobson have shown that a mandibular denture provides stability to the denture due to its oro- facial musculature present around it, so it becomes an important aspect of the prosthesis as it provides physiologic comfort to the patient. The stability depends upon the amount of surface area present for the proper seating of the prosthesis.²²

The space (Lateral throat form) becomes an important subject to understand for a Prosthodontist, as this space aids in providing comfort and satisfaction to the denture wearer. A complete denture being an alien to the oral cavity, requires time to get adapted and stay in harmony with the oral mucosa and musculature and the structures on which it rests. A well trained clinician can help in this procedure by providing the patient with a complete denture prosthesis which is compatible and work in unison, failing to do so will not serve its purpose. Resorbed ridge leads to decreased retention and support of the mandibular denture.¹⁵

The above study was performed to compare and evaluate the depth of the Lateral throat form in patients with mild and moderately resorbed ridges with mandibular denture. Patients with neuromuscular diseases were not considered for the study as the retention and stability of the prosthesis would already be lost due to irregular movement of the mandible. Patients with degenerative or fibrotic conditions were also not made a part of the study as they had a restricted mouth opening which would lead to insufficient reading.

DISCUSSION

The age group considered for the study was from 45 years of age to 75 years as patients assistance above this age group would decrease. The distolingual sulcus depth and the later fabricated mandibular denture flange area were compared to check for the accuracy in there readings in both anterior and posterior, and either side of the sulcus depth. As the sulcus plays an important role in the retention and stability of the denture, it was checked weather the prosthesis is of the same level or short of it.

The study provided us with data, that the clinician can consider and be more careful while carrying out various procedure of denture fabrication that will help in making dentures which aids in providing retention and stability.

The study was done in completely edentulous patients having different level of resorbed mandibular ridge. The variation in the depth of the depth of the lateral throat form of these patients were investigated. Patients having a sound neuromuscular coordination were considered. The first step was to measure the amount of mandibular ridge resorption. The established method of calculating the amount of ridge resorption by Wical and Swoope was proposed. A panoramic radiograph of a completely edentulous patient was taken. With the help of a tracing sheet and a pencil, the level of ridge resorption was calculated. Based on the results attained, the patient was placed under the Wical and Swoope classification I, II, III. Patients with mild resorbed ridge than the original height were placed under class I, moderately resorbed as class II and severely resorbed as class III. Patients divided under this classification were grouped according to the amount of vertical loss of the bone. Class I patients had vertical bone loss which was upto one-third of the original. Class II had the vertical height loss which was between one third to two third of the original and Class III had two third or more of the mandibular height loss.

Other than this method, there were many authors which classified the bone loss according to the type of resorption. Glickman classified horizontal bone loss in dentulous patients into four grades. Where Grade I was incipient bone loss, Grade IV indicated total bone loss with gingival recession and furcation involvement.⁴⁰

DISCUSSION

T J Mc Garry et al in 1999 classified the edentulous mandible based on the bone height. A panoramic radiograph was taken of the patients and readings were recorded. Type I was the height of the bone 21mm or greater measured from the least vertical height of the mandible. For Type II it was 16 – 20mm, Type III was 11 – 15 mm and Type IV was 10mm or less measured from the area of least vertical height of the mandible.⁴¹

Branemark classified the resorbed ridge into Class A to Class E. The most alveolar bone is present in Class A, Class B represents moderate ridge resorption, Class C represents advanced ridge resorption, Class D and Class E are moderate to extreme resorption of the basal bone respectively.

Neil classified the residual ridge into Class I to Class III. Class I was if there was 0.5 inch of the space between mylohyoid ridge and floor of the mouth. Class II being less than 0.5 inch space and Class III denoted that the mylohyoid muscle is at the exact same level as the mylohyoid ridge.

Carl E Misch determined the density of the bone by taking radiographs and CT scans. The data was provided in Hounsfield units. D1 was most dense (>1250) and D4 was least dense (130 – 350).⁴²

The 2 classes were segregated with 25 completely edentulous patients each. The patient was asked to sit in an erect position. He was then asked to protrude his tongue to the vermilion border of the lower lip. While the patient is in this position, the clinician will retract the tongue using a mouth mirror and with the help of a UNC15 probe, measure the depth of the alveolingual sulcus from the anterior and the posterior end of the retromolar pad of left and right side of the oral cavity. A UNC 15 probe was used for the study as it provides us with the ease of its use and is used for conventional probing. The colour coding on the probe makes it easier for the clinician to identify the depth. The depth was calculated for the either side of the alveolingual sulcus. Later, a conventional complete denture was fabricated for each patient. In our study we incorporate the use of a UNC 15 probe, on which we completely rely as it is universally used for conventional probing

The length of the denture flange area of the denture was recorded using the same

DISCUSSION

UNC 15 probe on either side of the denture. The length of the sulcus was measured from the anterior aspect of the retromolar pad to the posterior aspect of the retromolar pad. This procedure was carried out individually for each patient from Wical and Swoope classified Class I and Class II patients. Patients belonging to Class III classification were not considered in the study. The patients under class III were the one with severely resorbed ridge or a negative ridge.

As the level of ridge resorption increases, the amount of retention and stability is lost inversely. Considering the patients with a severely resorbed ridge would not have given accurate result, hence results would have been unclear.

Once the readings were recorded, each class was individually checked for the accurate lateral throat form and the amount of displacement of the tongue and were placed in Neil's class I, II, III.

It was further statistically calculated. As stated by Carl O Boucher, it was of great importance for the denture flange to be of the same depth as that of the alveolingual sulcus in the oral cavity. Failing to do so would lead to altered retention and stability provided by the mandibular denture.⁴

Earlier, various methods of calculating the depth of the alveolingual sulcus have been described. In 2014, customized instruments were used to calculate the depth of the sulcus by Isha Rastogi. To a divider at its one end, a round wire was adapted. Opening and closing stops were attached to it. Between the two stops, a small portion of the scale was attached. The rounded end rested on the retromolar pad and the stop was opened till it touched the floor of the mouth. A limitation of this study was, it could only be used to verify the readings.³²

N.Kalawathy in 2016 designed a customized instrument to measure the exact depth of the Lateral Throat Form. An instrument which was customized into a hollow 'L' shaped had a copper pipe with a flexible wire passing through it. The wire was allowed to move freely movable within. One end of the extension would aid in measurement while the

DISCUSSION

other end moves on a metal scale which gets attached to the copper pipe. A stopper was made horizontally to make it movable on either side. A scale was attached to the horizontal arm.³⁷

Another method of calculating the lateral throat form was done in 2018 by S. Poudel in which a customized instrument was designed. A hollow 'L' shaped pipe was fabricated using acrylic resin through which a flexible wrought wire was passed. At one end of the pipe, a small acrylic ball that would rest on the floor of the mouth was attached. The other end would move on the scale attached to the acrylic pipe. The readings on the customized instrument were compared with that of the periodontal probe. It was concluded that the result on the customized instrument were more accurate and trustworthy.³⁹

Various methods of calculating the depth of the sulcus were demonstrated as the exact depth was required for its correlation to the denture flange. Any discrepancy in the reading would lead to incorrect data.

In both Wical and Swoope class I & class II we found that the number of patients classified under Neil's class I were about 5 times more common than class II & class III. In Wical and Swoope Class I, we had 80% of the patients classified under Neil's Class I and 16% & 4% respectively in class II & class III. Similarly, in Wical and Swoope Class II, we found that 76% of the patients were classified under Neil's Class I and 20% & 4% respectively for class II & class III.

In this study, we found that for patients classified in Wical and Swoope class 1, the average length of the lateral throat form of retro molar pad on the anterior edge was 12.54 mm and 12.92mm on the right and left-hand side respectively. The denture flange had the average length at the anterior edge as 9.76mm at the right side with 10.72mm at the left side, clearly depicting that the mandibular denture was less in length than the lateral throat form.

These results correspond to a study by Parajuli PK, Shetty TB , Shenoy VK and Rodrigues SJ et al, where they found that the corresponding mean lengths of the lateral

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throat forms were 15.1mm & 15.2 mm on the right and left-hand side respectively, and that of denture flange were 11.6mm and 12.06mm on the right and left-hand side respectively.⁵

Similarly, we found that the mean length at the posterior edge in the lateral throat form was 14.75mm and 16.82mm on the right-hand side and left-hand side respectively, while the mean length at the posterior edge in denture flange are 12.2mm and 13.22mm at the right hand and left-hand side respectively.

These results correspond to a study by Parajuli PK , Shetty TB , Shenoy VK and Rodrigues SJ et al, where we found that the corresponding mean lengths of the lateral throat forms were 17.2mm & 17.4 mm on the right and left-hand side respectively, and that of denture flange were 10.4mm and 10.6mm on the right and left-hand side respectively.

A very similar trend was found in Wical and Swoope class II patients as well. The average length of the lateral throat form of retro molar pad was 12.4 mm and 12.36mm on the anterior edge on right-hand side and left hand side respectively. While the average length of denture flange at the anterior edge was 12.12mm at the right hand side and 11.84mm at the left hand side, clearly showcasing that the denture was shorter than the lateral throat form.

Similarly, we found that the mean length at the posterior edge in the lateral throat form was 14.6mm and 14.64mm on the right hand side and left hand side respectively, while the mean length at the posterior edge in denture flange are 13.2mm and 14.88mm at the right hand and left hand side respectively.

In another study by N Kalavathy in 2016, they proposed a new way of classifying the LTF against Neil's classification. The proposed classification was divided into three classes. Class A was 2.5 – 4.1cm depth of the LTF. Class B was 1.5 - 2.4 cm and Class C was 0.5 – 1.4 cm. The inter-observer agreement for the depth of LTF was assessed by Cohen's kappa value, with $P < 0.001$. The mean depth of the sulcus as calculated by observers 1 and 2 was compared with ANOVA test and found to be significant with $P < 0.001$. It was concluded in there study that the customized method of measurement was much more reliable.³⁷

DISCUSSION

A study performed by Isha Rastogi in 2014 demonstrated intraoral proportions of Niels classification. It was found that on the right hand side 85.1% were class I, 9.5% class II and 5.4% class III and on the left hand side 81.1% were class I, 13.5% class II and 5.4% class III.³²

Present study stated that in Wical and Swoope Class I and II, there was a relative difference in the length of the LTF in anterior posterior left and right side of the sulcus to that of the length of the anterior posterior left and right side of the denture flange. . For Wical and Swoope Class I ,at the anterior edge of right retromolar pad, the length had mean of 2.78mm (SD – 2.6), on the left hand side was 2.2mm (SD – 2.0).Similarly, the mean difference in the length was 2.58 mm (SD- 2.4mm) in the right side and 3.6 mm (SD- 2.9 mm) in the left side at the posterior edge of the retromolar pad.

For Wical and Swoope Class II, at the anterior edge of right retromolar pad, the length had shown the mean difference to be 2.32mm with a standard deviation of 2.

6, while on the left hand side was 1.96mm with a standard deviation of 1.

4. Similarly, the average difference in length was 2.68 mm with a standard deviation of 2.8 in the right hand side and 2.84 mm with a standard deviation of 2.

4 in the left hand side of the retromolar pad at its posterior edge.

For both Wical and Swoope classes I and II, the border extensions of mandibular complete denture were found be significantly shorter than the available space in patient's mouth.

In the study done by Parajuli P K, the average difference in between length of the LTF and denture flange was found to be 3.5 mm with a standard deviation of 1. 2 in the right side and 3.2 mm with a standard deviation of 1.3 in the left side of retromolar pad at the anterior edge. Likewise, the mean difference between length was found to be 6.8 mm with a standard deviation of 1.7 in the right side and 6.8 mm with a standard deviation of 1.6 in the left side of retromolar pad at the posterior edge.

There was a significant difference ($p < 0.001$) between the lengths of lateral throat form and the mandibular complete denture.

DISCUSSION

This can be attributed to improper making of an impression and border moulding along with the over-reduced or under manipulated borders on the custom tray. While fabricating a conventional complete denture, each procedure should be carried out in proper manner. Lott F and Levin B discussed about the importance of impression making and its effect on stability by using flange wax for making a sublingual impression.¹⁶

The steps starting from the primary impression followed by border moulding and secondary impression and at last the finishing of the denture should be carried out with utmost care, as a little discrepancy in these procedures will lead to a shift in the depth of the denture flange and the lateral throat form. Bocage M stated that after the final impression was made, the lingual surface was coated with adhesive along with light body silicon over it and then asked to bite. The result indicated properly recorded lingual sulcus providing greater stability.²⁰

Kotkin discussed about an impression technique in which a ramp was made, for effective anterior position of the tongue. This technique would help in making impression with tongue in position which will cause a denture to be stable.²³

An Abdul Gafoor stated that for achieving the stability and retention of a mandibular denture, special care must be given while making an impression. He extended the anterior lingual border of the impression sublingually without interfering with the tongue function or blocking the opening of the ducts of the sublingual gland.³⁰

The authors stated the importance of each procedure and the effect it puts on the fabricated denture. The study discussed above plays an important role for a clinician to understand what small details should be looked upon carefully. While making the primary impression, if we use softer material rather than a medium fusing impression compound, it will lead to less amount of displaced tissue causing under extended borders. An under extended sulcus area will lead to reduced extension of stock tray. This will cause the cast to be short of the distolingual sulcus. Including this space with proper border extensions will lead to added retention, stability and support to the

DISCUSSION

denture. Patient visiting the clinic will be more satisfied and welcoming to the new denture.^{30,34}

Carl O Boucher stated that a clinician should have a thorough knowledge about the anatomical structures and should be skilful enough to transfer that knowledge over the prosthesis being fabricated. He stated that the success in attaining the retention, stability and support depends upon this knowledge.⁴

The Lateral throat form located on the distal end of the alveolingual sulcus is an important structure as it aids in providing retention and stability to the denture by increasing the peripheral seal of the area.³⁰ To record this region, the patient is asked to protrude his tongue 6mm touching the vermilion border of the lower lip

The correct positioning of lingual borders of mandibular denture is challenging. A proper border seal is achieved by the contact of borders with the soft tissue.³¹ the tongue restricts the direct visibility of lingual borders.

Earlier studies about the comparison between the LTF and the denture flange had shown a significant amount of difference between the two depths. It was also evident that the variable depth of the LTF of patients had Neil's class I to be the most common among all others.^{32,37,38,39}

Several studies about calculating the exact depth of LTF of the patient using various customized instrument had shown the importance of knowing the depth of the sulcus.

The decreased depth of the LTF on to the flange area gave us an insight on how a clinician should be careful enough while making a primary impression , and how this improper impression might lead to a decreased depth of the alveolingual sulcus. A well measured LTF in a patient can help us fabricate a denture which provides greatest retention and stability to the patient.

LIMITATIONS OF THE STUDY

The present study conducted was completely subjective. The inclusion criteria of including a healthy ridge and excluding a severely resorbed ridge may not give an insight into what is the retentive and stability condition in such cases. Patients with diseases such as oral sub mucous fibrosis and degenerative and fibrotic condition which restrict the movement of the floor of the mouth and the oral cavity were excluded.

The sample size collected due to the Covid – 19 conditions and time constraints is not enough to give completely error free result.

CONCLUSION

The present study was carried out in the Department of Prosthodontics, Crown and Bridge, BBDCODS Lucknow. The following conclusions were drawn along with limitations of the study.

- It was found that in Wical and Swoope class I, the majority of patients fell under Neil's class I (80%), followed by class II (16%) and class III (4%).
- For Wical and Swoope Class II, 76% fell under Neil's class I, 20% in class II and 4% in class III.
- In Wical and Swoope Class I, the mean length of lateral throat form in mandible at anterior edge of retromolar pad on right and left side was 12.54mm (SD – 3.1) and 12.92mm (SD – 2.7) respectively.
- Likewise, the mean length of lateral throat form at posterior edge of right and left side was 14.75mm (SD – 2.7) and 16.82mm (SD – 2.9) respectively.
- In Wical and Swoope Class II, the mean length of lateral throat form at anterior edge of retromolar pad for right and left side was found 12.4mm (SD – 2.7) and 12.36mm (SD – 2.4) respectively.
- Similarly the mean length of lateral throat form at posterior edge on right and left side was 14.6mm (SD – 2.8) and 14.64mm (SD – 3.2) respectively.
- In Wical and Swoope class I, the mean length of denture flange at anterior edge of retromolar pad on right and left side was 9.76mm (SD – 2.2) and 10.72mm (SD – 1.9) respectively.
- Similarly the mean length of denture flange at posterior edge on right and left side was 12.2mm (SD – 2.3) and 13.22mm (SD – 2.0) respectively.

CONCLUSION

- In Wical and Swoope class II, the mean length of denture flange at anterior edge of retromolar pad on right and left side was 12.12mm (SD – 2.9) and 11.84mm (SD – 2.2) respectively.
- The mean length of denture flange at posterior edge on right and left side was 13.2mm (SD – 2.8) and 14.88mm (SD – 2.2) respectively.
- In Wical and Swoope Class I and Class II, the comparison between the mean length of lateral throat form and the mean length of denture flanges in corresponding regions showed statistically significant difference.
- At the anterior edge of retromolar pad, the mean difference in length on right and left side was 2.78mm (SD – 2.6) and 2.2mm (SD – 2.0) respectively.
- At the posterior edge of retromolar pad, the mean difference in length on right and left side was 2.58 mm (SD- 2.4mm) and 3.6 mm (SD- 2.9 mm) respectively.
- For Wical and Swoope Class II, at the anterior edge of retromolar pad, the mean difference in length for right and left side 2.32mm (SD – 2.6) and 1.96mm (SD – 1.4) respectively.
- Similarly, the mean difference in length on right and left side was 2.68 mm (SD- 2.8mm) and 2.84 mm (SD- 2.4 mm) respectively .

For both Wical and Swoope classes I and II, the border extensions of mandibular complete denture were found be significantly shorter than the available space in patient's mouth.

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

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled “Comparative Evaluation of the Lateral Throat form and the Border Extension of Mandibular Complete Denture in the Distolingual Region of Moderately Resorbed Ridges: An In Vivo Study” submitted by **Dr Bhumika Singh Chauhan** Post graduate student from the **Department of Prosthodontics & Crown and Bridge** as part of MDS Curriculum for the academic year 2019-2022 with the accompanying proforma was reviewed by the Institutional Research Committee present on **19th December 2019** 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

ANNEXURE

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 VIIIth Institutional Ethics Sub-Committee

IEC Code: 15

BBDCODS/03/2020

Title of the Project: Comparative Evaluation of the Lateral Throat form and the Border Extension of Mandibular Complete Denture in the Distolingual Region of Moderately Resorbed Ridges: An In Vivo Study.

Principal Investigator: Dr. Bhumika Singh Chauhan **Department:** Prosthodontics & Crown and Bridge

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

Type of Submission: New, MDS Project Protocol

Dear Dr. Bhumika Singh Chauhan,

The Institutional Ethics Sub-Committee meeting comprising following four members was held on 18th March, 2020.

- | | |
|-----------------------------------------|------------------------------------------------------------------------------------|
| 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. Sahana S.
Member | Reader, Department of Public Health Dentistry, 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
18/03/20

(Dr. Lakshmi Bala)
Member-Secretary
IEC Member-Secretary
Institutional Ethic Committee
BBD College of Dental Sciences
BBD University
Faizabad Road, Lucknow-226028

B. Rajkumar

(Dr. B. Rajkumar)
Principal
BBDCODS

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

Proforma of project to be submitted to BBDCODS Institutional Ethical Subcommittee

ANNEXURE

Title of the project: Comparative Evaluation of the lateral throat form and the border extension of mandibular complete denture in the distolingual region of moderately resorbed ridges

An In Vivo study

1) Name of the Department: Department of Prosthodontics, Crown and Bridge / Address of the investigator: Bhumika Singh Chauhan, D/O J S Chauhan, Lucknow, Uttar Pradesh.

2) Name of the Faculties

a) Name and Designation of the Guide

Dr. Garima Agarwal

Reader

Department of Prosthodontics Crown and Bridge

BBDCODS

3) Date of approval by Institutional Research Committee (IRC): 19 December 2019.

4) Source of funding: Self

5) Study related information:

a. Place of Study

i. Babu Banarasi Das College of Dental Sciences, BBDU.

b. In-vitro studies on human subjects:

Please specify if it is body fluid blood/tissues/teeth, please specify

ANNEXURE

- i. Bile, Saliva etc ii. Teeth, Please specify iii. Tissue, please specify
iv. Use of stored or left over specimens iv. v. Any Other

c. In-vivo study on human subjects:

Please specify if any

- i. Intervention ii. Drugs iii. Implants iv. Any other e.g: X-rays/Ultrasound/etc

d. Vulnerable subjects:

Please specify if any

- i. Pregnant Woman ii. Elderly iii. Terminally ill iv. Physically/
mentally challenged v. Children under 18 vi. Students vii. Orphans

e. Survey of human subject:

- i. Verbal Questionnaire ii. Non-
invasive examination iii.
Invasive procedures

f. SEA (Severe Adverse Events) Reporting

- i. Is there a plan for reporting

8) Ethical issues involved in the study: of adverse events:

9) Do you need exemption from obtaining Informed Consent from subject- No

10) The Consent forms and Participant Information Documents are enclosed

11) Conflict of interest for any other investigator:

We the undersigned have read and understood this protocol and hereby agree to conduct the study accordance with this protocol and comply with all requirements the ICMR guidelines (2006)

Signature the Investigator:

Date:

Signature of the Guide:

Date:

ANNEXURE

Dr Garima Agarwal

ANNEXURE

Signature of the Head of the Department:

Dr.Amrit Tandan

Date:

**Babu Banarnsi 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

Comparative Evaluation of the lateral throat form and the border extension of mandibular complete denture in the distolingual region of moderately resorbed ridges : An In Vivo study

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?

To Investigate the accurate proportions of lateral throat form according to Neil's classification in completely edentulous patients with class I and class II mandibular ridges (Wical and Swoope) and also to compare the depth of lateral throat from in patient's mouth to that of their dentures.

4. Why have I been chosen?

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

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?

An OPG will be taken and later using a UNC-15 periodontal probe depth of alveolo-lingual sulcus will be measured.

7. What do I have to do

You do not have to change your regular lifestyles for the investigation of the study. This research study is self-sponsored by the candidate. You do not have to pay for any procedures involved.

8. What is the procedure that is being tested?

Procedure includes collection of data by examining your oral cavity by a single examiner with the help of sterilized diagnostic instrument.

9. What are the interventions for the study?" No interventions are required for 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 possible disadvantages for the patients of this study.

12. What are the possible benefits of taking part?

If we measure the actual depth of the Class I lateral throat form and then extend the lingual border of the mandibular denture to the depth recorded; this will help us in establishing a better retention and stability form thus providing physical and physiological comfort to the patient.

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. 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 during the study, or something goes wrong during the study, the complaints will be handled by reporting to institution(s) and IEC. **16. Will my taking part in this study be kept confidential?**

Yes, it will be kept confidential.

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

The results the study will be used to assess and determine the prosthetic treatment need elderly people in Lucknow city.

18. Who is organizing the research?

The research study self-sponsored by the candidate under the guidance of college and IEC. You do not have to pay for procedures involved.

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

Yes, you can contact your researcher and institute.

20. Who has reviewed the study?

The study has been reviewed and approved by the Head of Department and the IEC of the institution.

21. Contact for further information

Dr. Bhumika Singh Chauhan

Babu Banarasi Das College of Dental Sciences, BBDU

Lucknow

Mail Id – bhunikachauhan680@gmail.com

Mobile number- 9956036543

OR

Dr. Lakshmi Bala

Member Secretary,

Babu Banarasi College of Dental Sciences

Lucknow

Mail id-bbdcods lec@gmail.com

Mobile number

Thank you for taking part in the study

Signature of PI

Name

Date

बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज
(बाबू बनारसी दास विश्वविद्यालय का एक घटक संस्थान)
बीबीडी ससटी, फैजाबाद रोड, खनऊ-227105 (INDIA)
प्रतिभागी सचनारू दस्िािेज (पीआईडी)

1. भजफतू शीर्कष नार्शरू गरा रून का तरनात्मकु भलमांकनू औय भाभरीू ननरूकषु सित रकीये के डडस्टोसरगांअरु क्षेत्र में जफड़े के नरूरूस्ताय की िीभा रूस्ताय एन इनूीूो अधमन
2. ननभत्रां रू अनच्छेदु
आनको एक शोध अधमन में बाग रेने के सरए आभत्रांतरत ककमा जा यहा है, इसरए आनके सरए मह िभझना भहत्नरू है कक अधमन क्मों ककमा जा यहा है औय इिं क्मा शासभर होगा। कृनमा ननम्रसरखित जानकायी को धमान िे नदने के सरए िभम ननकारे। हभि कोई स्नष्टीकयर् मा अधधक जानकायी के सरए नछे। रू आन हहस्िाि रेना चाहते हैं मा नहीं मह आनका ननर्मष है।
3. अधमन का उदेशरू क्मा है? कक्षा औय ःगष ॥ अनन्ामष रकीये (Wical औय Swoope) के िाथ नयीू तयह िे edentulous योधगमों में नौर के ःगीकयर् के अनियु नार्शरू गरा रून के िही अननातु की जांच कयने के सरए औय योगी के भहांु िे नार्शरू गरा की फगहयाई की तरनाु उनके डने चय िे कयने के सरए बी।
4. भझे क्मों चनाु गमा है? आनको इि अधमन के सरए चनाु गमा है क्मोंकक आन आशमक भानदांडों को नयारू कय यह है।
5. क्मा भझे बाग रेना है?
अनिधांु ान में आनकी बागीदायी नयीू तयह िे स्ूचैच्छक है। महद आन कयते हैं, तो आनको यिने के सरए मह िचनाू न हदमा जाएगा औय िहभनत नत्र नय हस्ताक्षय कयने के सरए कहा जाएगा। अधमन के दौयान आन अबी बी ककिी बी िभम औय त्रफना कायर् फताए ःानि रेने के सरए स्ूत्रां है।

6. भये बाग रेने नय क्मा होगा?

एक OPG सरमा जाएगा औय फाद भें एक मएरीरू 15 आधधक जांच गहयाई का उन्नमोग कयते हुए
एिसरगांअरु
िलकि को भाना जाएगा।

7. भझे क्मा कयना है। अधमन की जांच के सरए आनको अननी ननमसभत जीन शरै ी को फदरने की
आशमकता नहीं है। मह शोध अधमन उम्भीदाय द्ाया स्-प्रामोच्चत है। आनको शासभर
ककी बी प्रकिमा के सरए बगतानु कयने की आशमकता नहीं है।

8. ह प्रकिमा क्मा है च्जिका नयीक्षर ककमा जा यहा है?
प्रकिमा भें ननषर नदै ाननक उन्नकयर् की िहामता िे एकर नयीक्षक द्ाया अनने भौखिक गहा
की जांच कयके डटे ा का िग्रां ह शासभर है।

9. अधमन के सरए हस्तक्षेन क्मा है?
अधमन के सरए ककी बी हस्तक्षेन की आशमकता नहीं है।

10. बाग रेने के दष्रबाु क्मा है?
इ अधमन के योधगमों नय कोई दष्रबाु नहीं हैं।

11. बाग रेने के िबां ार्त नकानु औय जोखिभ क्मा है?
इ अधमन के योधगमों के सरए कोई िबां ार्त नकानु नहीं है।

12. बाग रेने के िबां ार्त राब क्मा है?

महद हभ कक्षा नाश्र् गरा रून्न की ास्त्र्क गहयाई को भानते हैं औय कपय अनन्ामष दातों की रफां त िीभा को गहयाई तक दजष कयते हैं, डििे हभें एक फेहतय अधायर् औय च्स्थयता के रून्न भें स्थान्त कयने भें भदद सभरेगी, च्जििे योगी को शायीरयक औय शायीरयक आयाभ सभरेगा।

13. महद नई जानकायी उन्नरब्ध हो जाए तो क्मा होगा?

महद अनिधांु ान के दौयान अनतरयक्त जानकायी उन्नरब्ध हो जाती है, तो आन्नको इनके फाये भें फतामा जाएगा औय आन्न अन्नने शोधकताष के िाथ डि नय चचाष कयने के सरए स्त्रां है। महद आन्न ानि रेने का ननर्मष रेते हैं, तो आन्नका शोधकताष आन्नकी ानी की व्स्था कयेगा। महद आन्न अन्नतन िहभनत नय हस्ताक्षय कयने सरए कहा िकता है।

14. शोध अधममन रुक जाता क्मा महद अधममन ननधाषरयत िभम नहरे फदां ित्भ जाता है, मह योगी स्मिंेक को िभझामा जाएगा।

15. अगय कुछ गरत जाए क्मा होगा?

कोई घटना होती दौयान आईडिी रयन्नोटष कयके सशकामतों ननमत्रांत्रत ककमा

16. क्मा अधममन भें हा गोननीम यिा जाएगा।

17. शोध अधममन नरयर्ाभों क्मा होगा।

अधमन के नरयर्ाभो का इस्तभे ार रिनऊ शहय भें फजुुगष रोगो के कृत्रत्रभ उन्नचाय की ज़रूयत के सरए ककमा जाएगा

18. अनशधांु ान का आमोजन कौन कय यहा है? मह अधममन कौरेज औय IEC के भागदष शनष भें उम्पीदाय द्ाया स्-प्रामोच्चत आन्नको शासभर ककी बी प्रकिमा के बगतानु कयने की आशमकता नहीं

ANNEXURE

19. अधममन नरयर्ाभ अधममन के फाद उनरब्ध कयाए जाएंगे? हा आन शोधकताष औय िस्ां थान िे िनां कष कय िकते

20. अधममन िभीक्षा ककिने की?

र्बाग प्रभु द्ाया अधममन की िभीक्षा औय अनभोदनु गमा है औय िस्ां थान आई.ई.िी. 21. जानकायी सरए िनां कष कयें

बसभकाू चौहान फाफ ूफनायी दाि करैज
ऑप डेंटर िांइांिेज, BBDUI
रिनऊ

भेर आईडी bhumikachauhan680@gmail.com

भोफाइर नफां य 9956036543

मा

डॉ. रक्ष्मी फारा

िदस्म िधच्,
फाफ ूफनायी करैज ऑप डेंटर िांइांिेज

रिनऊ

भेर आईडी bbdcods_jec@gmail.com. भोफाइर

नफां य

अधममन भें बाग रेने के सरए धन्म्ाद

नीआई का हस्ताक्षय.

ANNEXURE

नाभ

हदनांक

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University)

BBD City, Faizabad Road, Lucknow - 227105 (INDIA) Form (English)

Consent Form (English)

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).

ANNEXURE

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.

Signatory's Name.....

Date:

Signature of the Investigator.....

Date:

Study Investigator Name.....

Date:

Signature of the witness.....

Date:

Name of the witness.....

Date:

Received a signed copy of the PID and duly filled consent form

Signature/thumb impression of the subject or legally

Date:

Acceptable representative

बाबनारसीदासकॉरजू ऑफडेंटर साइंसेज

(बाबनारसीदासविश्विद्यालय)

बीबीडीससटी, फै जाबादरोड, रखनऊ 227105 (भारि) फॉमम (अग्रंेजी)

सहमतिफॉमम

अधमनिखां मा

रुमकानयानाभू ..

जन्मनतधथ/आम.ु

रुमकानता.....

.....

.....

पोननां, औयई-भेरनता.....

मोगमता.....

व्मिाम: छात्र/स्योजगाय/िे्ा/गहहर्ी/अन्म (कृन्माउन्मक्तु के रून्भेहटक)

रुमकीर्कष आम:

नाभ औय प्रत्मासशमों (एि) औयरुमकेसरएअननेिफां धां ।

(नयीक्षरिे िफांधधतभांत्म् केभाभरेभेभु आजके ेउद्देशम के सरए)।

1. भनैचुकयताहु ूककभनैेप्रनतबागी िचनादस्ताेजकोू नढा औय िभज्ञा है ऊनयकेअधमनकोपोआयऔय प्रर्शननछनेकाू अिय सभरा है। माभै अन्ेर्कद्ाया अधमनकीप्रकृन्तिभ ज्ञामागमा है औय ि्ार नछनेू का अिय सभरामा।

2. भि भइता हूकक अधमनभैभयी बागीदायी स्च्चैच्छक है औय त्रफना ककीदफ् के स्त्रां इच्छा के िाथ दी गई है हदनाकोईकायर्हदए औय अननी धचककत्िादेिबारमाकाननीू अधधकायीको प्रबार्त्तककएर्नानिरेनेक सरएस्त्रांहां।

3. भिभइताहूककनरयमोजना के प्रामोजक, प्रामोजककी ओय िे काभकययहेदियोंू , ननैतकतािसभनतऔय ननमाभक अधधकारयमोकोत्भष ान अधमन औय ककी बी जागेअनिधांु ान के िफां धां भें येस्ास्मरयकाडकष ोदेिने के सरए भयी अनभनतकीु आशमकता नहीं होगी इके िफां धां भें आमोच्चत ककमा, बरेहीभनयीक्षर् िे्ानिरेरी हारांकक, भिभइता हूककभीनहचानतीियेनक्षकोजायीमाप्रकासशत ककी बी जानकायी भेंप्रकटनहीं ककमा जाएगा।

4, भइै ि अधमन िे उलत्र होनेरे ककी बी डटे ामानरयर्ाभों के उनमोगकोप्रनतफधांधत कयने के सरए िहभतन

हीफशतोककडितयहकाउनमोगकेर्ज्ञे ाननक उद्देशम (ओ) केसरएहो ।

5. भबै र्ष्भ के अनिधांु ान के सरएिग्रांहहतनभनु (दात ऊतक/यक्त) के उनमोगकी अनभनतु देताहां।हा[] नहीं।[रागनहीू ।

6. भउै नयोक्त अधमन भें बाग रेने के सरए िहभत हूं। भइजे हटरताओं औय दष्रबाु के फाये भें िभइामा गमा है, महद कोई हो.

औय उन्हें नयीू तयह िे िभइसरमा है। भनैभइेहदए

गएप्रनतबागी/स्मिििककेिचनादस्ताेजकोू बी नढा औय िभइा है।

हस्ताक्षयकताकष ानाभ.....

हदनांक....

अन्ेर्ककेहस्ताक्षय...

ANNEXURE

हदनांक.....

अधमनअन्ेर्क नाभ

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..... हदनांक.....

•िाक्षीकेहस्ताक्षय

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..... हदनांक

ग्ाहकानाभ

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नीआईडी औय र्धधतबयेगएिहभनतपाभकै िहस्ताक्षरयतप्रनतप्राप्तकी

हस्ताक्षय/र्मेके अगांठे का ननशानमाकाननीरून्नितायीि।ू

स्ीकामप्रष नतननधध

STATISTICAL ANALYSIS

Statistical analysis: Data was tabulated using Ms Excel 2013 and analyzed using MS Excel's data analysis tool pack names 'Analyzer Tool Pak'. After tabulating the data appropriately and naming the variables, descriptive analysis was carried out to calculate Mean, standard deviation, Median and Mode of the data. Post descriptive

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analysis, hypothesis was developed and Student's t-test was carried out with significance level $\alpha = 0.05$ to determine the difference between the means of two groups. Significance level of $p < 0.001$ was considered for the hypothesis.

Descriptive analysis was performed using the following formulae -

1. Mean – The most popular and most common measure of central tendency is the mean. The mean is calculated by dividing the summation of the values by the number of values. For example, if we have a data set with values $x_1, x_2, x_3, \dots, x_n$, the mean of the set can be calculated by the formula –

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

Where -

\bar{x} – Mean of the data

$\sum x$ – Summation of all values of x

n – Number of data items

2. Standard Deviation – Standard deviation is a measure used to indicate the spread or amount of variation in the data relative to its mean. A low standard deviation means that the data is rather concentrated around the mean and there is less deviation from the mean, while a higher amount indicates that there is a greater spread in the data relative to the mean. Generally, it is denoted by SD or σ .

Standard Deviation is calculated using the following formula

$$\sigma = \sqrt{\frac{\sum (x - \bar{x})^2}{n}}$$

Where – σ – Standard Deviation of the data set

$\sum (x - \bar{x})^2$ – Summation of square of difference of data point from the mean

n – Number of data items

3. Median – Median is another popular and common measure of central tendency. It is the middle value of the data set, when the data set is arranged in ascending or descending order of the value. It can also be versioned as the data halfway in the data set.

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Median can be calculated using the following formulae –

If the no. of observations is ODD –

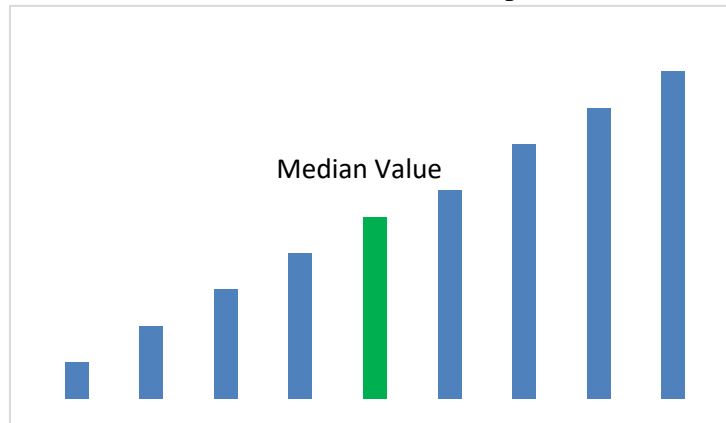
$$\text{Median} = \{(n + 1)th/2\}$$

Where n is the number of data points

If the no. of observations is EVEN –

$$\text{Median} = \{(n/2)th + ((n/2) + 1)th\}/2$$

Where n is the number of data points



4. Mode – Mode is the value that has the highest frequency of occurrence in the data set. In other words, it is the value that is repeated the most in the data set .
5. Student's t-test – Student's t-test is defined as a statistical hypothesis test, where the test statistic supports the t-test, once the Null hypothesis is established. The number of observations in the t-test should be less than 30. Paired t-test is used to compare the means of two different data sets. The formula for paired t stat value is defined as the summation of the difference between each set of data point divided by square root of n times the square of the sum of the differences and squared sum of differences wholly divide by n1.

$$t = \frac{\sum d}{\sqrt{(n(\sum d)^2 - \sum(d^2))/n-1}}$$

Where d – Difference between the two
data pair n – Number of observations






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