TITLE

COMPARISON OF EFFICACY OF SELF LIGATING PITTS21® AND CONVENTIONAL PREADJUSTED EDGEWISE TECHNIQUE (MCLAUGHLIN BENNETT TREVISI) IN ALIGNMENT AND SMILE ARC CORRECTION: A RANDOMIZED CLINICAL TRIAL

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NEED FOR THE STUDY

Any deviation from the normal occlusion of the teeth is termed as malocclusion.[1] Malocclusion is considered as one of the most important oral health problems by the WHO having a prevalence of 39% and 93% in children and adolescents.[2] In India the most prevalent malocclusion is Class I malocclusion followed by Class II and Class III malocclusions.[1] The prevalence of crowding was found to be 44.1%.[2] The most common feature associated with Class I malocclusion is crowded anterior teeth. A more ideal positioning of the teeth can be achieved by the orthodontist via mechanical therapy for improving the esthetics and function.[3]

Conventional orthodontic treatment uses arch wires that are secured within the bracket slot using elastomeric or metal ligatures to regulate the forces exerted on the teeth. Whereas self-ligated bracket system has an integrated specialized mechanism where they eliminate or minimize the need for an external ligature. Self-ligating bracket is faster in alignment and de-crowding. [4] MacLaughlin, Bennet, and Trevisi in 1998 introduced the MBT ™ appliance. MBT™ is a version of preadjusted bracket system for the use with light continuous force, lacebacks, and bendbacks designed ideally to work with sliding mechanism and friction. Response to clinical experience and clinical inputs MBT ™ system has been evolving and improving.[7]

The reduced frictional resistance during the initial stages of orthodontic treatment and stimulating the tooth movement without completely disrupting the vascular supply makes self-ligating brackets more efficient and physiologic than conventional bracket system.[5,6] Literature reveals that the

	Self ligated brackets have an advantage over conventional due to less subjective discomfort, reduced overall treatment time and superior torque expression.[6] Modern orthodontics does not deal only with the dental and skeletal aspects but also with facial proportions and the role of the dentition on facial appearance.[8] One of the main objectives of orthodontic treatment is to restore the esthetics and increase the self- confidence and self-esteem of the patients. "The smile arc is the relationship between the curvature of the incisal edges of maxillary anterior teeth (upper incisal line) and the curvature formed by the lower lip when smiling".[9,10,11]Today's esthetic philosophy of compensation for greater width in the upper posterior teeth, with minimal negative space in the buccal corridors is supported by Smile Arc Protection bracket positioning.[11] In comparison to the traditional techniques the maxillary anterior brackets are placed more gingivally in Smile Arc Protection for attaining a more pleasant smile arc and to positively affect the anterior portion of the upper occlusal plane cant.[12] The most recent advances in self-ligating bracket system is Pitts 21®. The Pitts 21® provides exceptional control of the anterior teeth while allowing for increased freedom of movement on the posterior teeth. The Pitts 21® system saves the time of the orthodontist. [12] Treatment planning for esthetic smile design will become more predictable as it helps orthodontists to open up "the art of the possible". [12] As we know there is lack of literature about the comparison between the conventional bracket system (MBT) and the self-ligating system the Pitts 21® system. Our study would be the first study to compare the initial alignment and treatment outcomes of the above bracket systems with the smile arc protection.

Malocclusion is one of the most important oral health problems. Reduced treatment time, better patient comfort and lesser pain is patients choice to treat malocclusion. The self- ligating bracket system claims to provide the above and claims to be faster in initial alignment and decrowding. This study aims to know the relationship between MBT bracket system and Pitts21® bracket system and their contribution to smile arc protection, initial alignment and decrowding. Literature reveals that Pitts21® fastens treatment plan and saves time. The Pitts21® bracket system is more expensive than MBT system, so we are conducting this study to understand and evaluate the initial alignment of the latest self-ligating bracket system Pitts21® along with its role in smile arc protection.

REVIEW OF LITERATURE

1. Sarver (2001) 13 conducted a study where the concepts of smile arc and its relation to orthodontics are discussed. This article gives an insight on the importance of smile arc in orthodontic treatment planning and how the procedures and the mechanics are adapted to optimize the appearance of the smile. The author illustrates three cases on how the treatment is directed and how the facial and the smile goal settings are related to each other. This study recognised the importance and the impact of smile parameters on orthodontic outcomes. It was mainly aimed at the importance of incisor positioning for achieving aesthetic smile. The author concludes by stating that if should reconsider and rethink some of the orthodontic mechanics and concepts of

	treatment to consistently build this smile arc into our diagnostic, treatment planning, and treatment regimens. 2. Pandiset al (2007)[17] conducted a study to investigate the duration of mandibular-crowding alleviation with self-ligating brackets compared with conventional appliances and the accompanying dental effects. Fifty-four subjects were selected from a pool of patients satisfying the following inclusion criteria: non-extraction treatment in the mandibular or maxillary arches; eruption of all mandibular teeth; no spaces in the mandibular arch; irregularity index greater than 2 in the mandibular arch; and no therapeutic intervention planned with any extraoral or intraoral appliance. The patients were randomly assigned to 2 groups: 1 group received treatment with a self-ligating bracket (Damon 2, Ormco, Glendora, Calif) and the other with a conventional edgewise appliance (Microarch, GAC, Central Islip, NY), both with 0.022-in slots. The irregularity index of the mandibular arch was normalized between the groups, and the time to alignment was estimated in days. Treatment duration was assessed by data modeling with the Cox proportional hazard regression. Lateral cephalometric radiographs were used to assess the alteration of mandibular incisor position before and after alignment. Measurements of intercanine and intermolar widths were also made on dental casts to determine changes associated with correction.Study reported no difference in the time required to correct mandibular crowding with Damon 2 and conventional brackets was observed. For 15 moderate crowding (irregularity index <5), however, the self-ligating group had 2.7 times faster correction. Greater crowding prolonged treatment by an additional 20% for each irregularity index unit. Increases in intercanine and intermolar widths associated with crowding correction regardless of bracket

	group were noted. The self-ligating group showed a statistically greater intermolar width increase than the conventional group. 3. Prettymana et al., (2012)[4] conducted a study to determine if there are significant clinical differences between self-ligating brackets (SLB) and conventional brackets. They conducted a survey to evaluate how SLB compare to CB in terms of orthodontists' perceptions. Orthodontists reported a perceived clinical difference between SLB and CB with regard to orthodontic treatment. SLB were preferred by orthodontists more often than CB for the majority of the treatment factors evaluated. The orthodontists' bracket preference was significantly influenced by the proportion of patients they treated with SLB, the number of cases it took them to become accustomed to SLB, and the average appointment intervals for both SLB and CB. 4. Pitts(2017)[16] has mentioned in his article about the philosophy and the protocols for positioning the brackets and other biomechanics that contribute in enhancing and protecting the smile arc in orthodontics. A lot of clinical case study and experimentation with Smile Arc Protection led to the development of the protocols. In this article the author has discussed six cases where the pre-treatment and post treatment results of the Smile Arc Protection were assessed. The study reveals that occlusal plane, gingival display and the smile arc which is positively affected by SAP and the Active early approach. 5. Bhardwaj, et al., (2017) conducted a pilot study to evaluate the clinical efficiency of 0.018″/0.022″ slot self-ligating (SL) bracket system (standard and tandem mechanics) in terms of rate of alignment by comparing it with a 0.022″ slot conventional ligating appliance system (MBT). Forty patients

	having Little irregularity index (II) of 6-15 mm, treated by all first premolars extractions, were randomly allocated to 0.022″ slot conventional ligating bracket system, 0.018″ slot SL bracket system, 0.018″ slot SL bracket system (tandem archwires), 0.022″ slot SL bracket system, and 0.022″ slot SL bracket system. The rate of alignment for each bracket system was measured from the difference in the II of serial casts taken at pre- treatment and at the end of alignment, divided by the number of days between the two measurements. Study concluded that the alignment efficiency was not different between SL versus conventional ligating group, the 0.018″ slot versus 0.022″ slot and tandem versus standard mechanics.

AIM OF THE STUDY:

This study aims to evaluate the relationship between MBT bracket system and Pitts21® bracket system and their contribution to initial alignment of maxillary anteriors - de crowding, smile arc protection

OBJECTIVES OF THE STUDY:

- To assess the initial alignment and decrowding of maxillary anteriors along with smile arc correction in MBT bracket system
- To assess the initial alignment and decrowding of maxillary anteriors along with smile arc correction in Pitts21® bracket system
- Comparing the efficacy of initial alignment and smile arc correction between MBT and Pitts21® bracket system.

MATERIALS AND METHODS

SOURCE OF DATA

Study design- Randomized Clinical Trial

Study settings- Department of Orthodontics and Dentofacial Orthopedics, Srinivas Dental College Mukka Suratkal.

Ethical Approval- Will be taken from the Institutional Ethics Committee.

Informed consent- A written informed consent will be obtained from the individual before participating in the study.

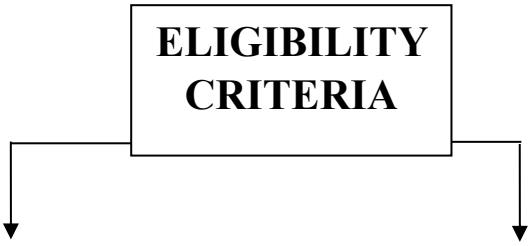
METHOD OF COLLECTION OF DATA

SOURCE OF DATA

30 subjects will be allocated into 2 groups. Group 1 would consist of patients with conventional MBT brackets (3M Unitek) and Group 2 will consist of patients with PITTS 21 bracket system cases from the Department of Orthodontics and Dentofacial Orthopaedics, Srinivas Institute of Dental Sciences, Mukka, Mangalore.

METHOD OF COLLECTION OF DATA

The study will include selection of Subjects with mild to moderate dental irregularity with a Littles index score (SCORE 3-6) for the two groups



INCLUSION CRITERIA

- Mild to moderate(3-6) dental irregularity according to Modified Little's irregularity index
- Non-extraction treatment
- Presence of all the permanent teeth at least up to the first molars
- Good oral hygiene and periodontal health.
- Males and female 13-40 years of age.

EXCLUSION CRITERIA

- History of craniofacial disorders, hypodontia, or hyperdontia.
- History of systemic and bone disease
- Tooth size anomalies
- Required orthognathic surgery to correct skeletal discrepancies.

MATERIALS TO BE USED-

Camera, lens and flash, Callipers, MBT Brackets(3M Unitek), Pitts21 brackets, Digital caliper, Impression materials, Impression Trays, Mouth mirror, Cheek retractor**.**

METHODOLOGY

Simple randomization without any stratification will be carried out using the Excel computer program with a 1:1 allocation ratio. Patients will be selected randomly based on the inclusion and exclusion criteria.

30 Subjects with mild to moderate dental irregularity with a Littles index score (SCORE 3-6) will be selected for the study. Modified Little's irregularity index[14,15] will be used to assess the changes in dental alignment throughout the study. The subjects will be allocated into 2 groups. Group 1 would consist of patients with conventional MBT brackets (3M Unitek) and Group 2 will consist of patients with PITTS 21 bracket system. The conventional MBT brackets will be fully ligated using elastomeric ligatures. In both the groups, before bonding the brackets, the impressions will be taken using alginate impression material (T0).

ALIGNMENT ASSESSMENT:

- The initial alignment will be assessed by taking impression for evaluation in the 2^{nd}, $4^{th}$and 6^{th} month (T1,T2,T3) .
- The casts will be disinfected and poured with dental stone.
- Each stone cast will be assessed for the initial alignment and decrowding using a Digital caliper. (Dentaurum, Inspringen, Germany).
- The intra examiner will examine the casts to check for the change in initial alignment and tooth contact after 6 months of treatment.

SMILE ARC ASSESSMENT:

- Before the start of the treatment the pre-treatment frontal smile photographs of both the groups will be recorded. (S1)
- Frontal smile photographs of both the groups will be taken after 6 months. (S2)
- Developing smile arc will be assessed after 6 months of treatment using frontal smile photographs of the patient(S2). A panel of 10 aesthetic specialists consisting of 5 orthodontists and 5 prosthodontists will be assessing the smile arc after 6 months of treatment. They will be provided with the photographs at (S1) and (S2) for the assessment.
- Visual assessment will be used to Grade the improvement of the smile arc from 0-10 and the difference will be assessed depending on if there is improvement or not.

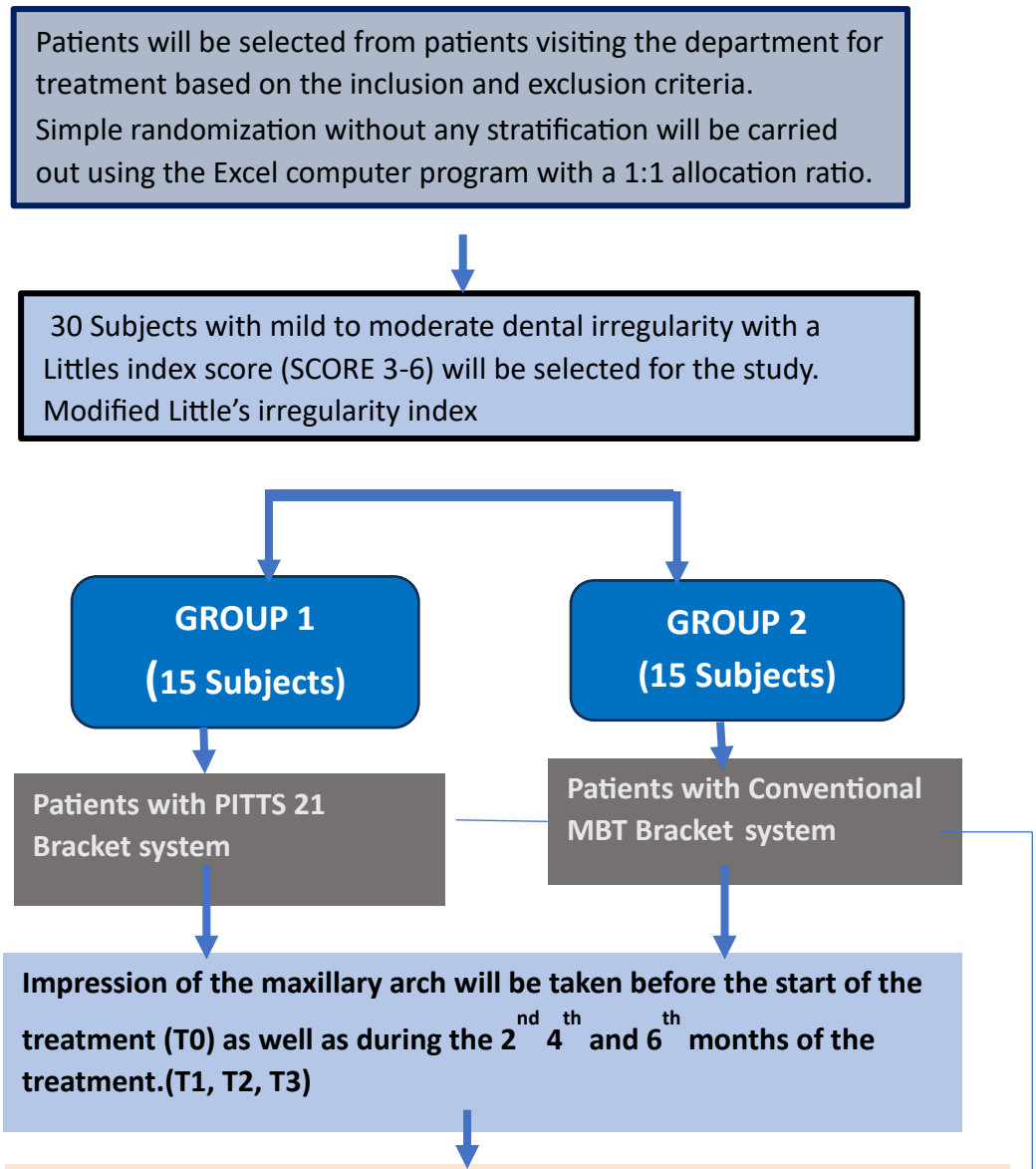
SAMPLE SIZE DETERMINATION:

The sample size was calculated using G*Power software (v3.1.9.7) 15 based on the mean difference and standard deviation of mandibular alignment rate reported in a randomized trial by Jahanbin et al. 16 With an alpha level of 5% and a study power of 80% ($\beta = 20\%$), the minimum sample size required was determined to be 26 subjects (13 per group). To account for a potential dropout rate of approximately 10%, the final sample size was increased to 30 participants, with 15 allocated to each group.

STATISTICAL ANALYSIS

Sampling ratio is taken as 1:1. α=5% and β= 20% Allowing a mean difference of (0.64-0.57). The standard deviation is 0.5. The marginal difference is calculated as 0.6 with a drop rate of 10%. Data will be entered and analysed using Statistical Package for Social Science (SPSS), version 17 (SPSS Inc. Chicago, IL, USA).

INVESTIGATION DESIGN:



The intra examiner will examine the digital casts after 6 months of treatment.

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Frontal smile photographs of both the groups will be taken before the start of the treatment (S1) as well as after 6 months (S2) to check for the developing smile arc

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A panel of 10 aesthetic specialists consisting of 5 orthodontists and 5 prosthodontists will be assessing the smile arc after 6 months of treatment

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- Visual assessment will be used to Grade the improvement of the smile arc and the difference will be assessed.

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INFORMED CONSENT FORM

Study title: Comparison Of Efficacy Of Self Ligating Pitts21® And Conventional preadjusted edgewise technique(MBT) In Alignment And Smile Arc Correction: A Randomized Clinical Trial.

Participant name: Date of birth/ Age:

I confirm that I have read and understood the information sheet for the above study and have the opportunity to ask questions.

I. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving reasons, without any medical care or legal rights being affected.

II. I understand that the sponsor of the study, 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 current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access.

III. 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.

IV. I acknowledge the intention to capture photographs, which could potentially serve for data dissemination and be utilized in discussions among subject experts during panel sessions.

V. I agree to take part in this study.

Name of the Participant:

Signature of the Participant:

Date:
Place:

Name of the investigator:

Signature of the investigator:

Date:
Place:

NON-DISCLOSURE AGREEMENT

_____(please enter first and last name, degree or title), understands and agrees that any and all information provided to _____ (last name) by Dr. Mahen Naik, regarding the thesis panel discussion, at any time is confidential ("Confidential Information") and may not be used in any manner by the panel member or his agents. I agree that I will not directly or indirectly, in whole or in part, disclose, use, disseminate, or in any manner publish to any person, firm, partnership, association, corporation or business organization, entity or enterprise regarding the demographic details of the subjects and the photographs for any reason or purpose whatsoever said Confidential Information, nor shall I make any claim or right or ownership to any Confidential Information.

If you agree to the foregoing, please confirm this by signing and returning to Dr. Mahen Naik, the principal investigator, this Agreement.

Name of the panel member:

Signature of the panel member:

Date:

Place: