COMPARATIVE EVALUATION OF THE EFFECT OF CALCULUS IN THE EFFICIENCY OF SHUTTERS IN PASSIVE SELF-LIGATING BRACKETS:

AN IN-VITRO STUDY

By

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Dissertation submitted to the

Kerala University of Health Sciences, Thrissur

In partial fulfillment of the requirements of the degree of

MASTER OF DENTAL SURGERY

IN

ORTHODONTICS AND DENTOFACIAL ORTHOPAEDICS

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ABSTRACT

Self-ligating brackets do not require an elastomeric or stainless-steel ligature but have an inbuilt mechanism utilizing a permanently installed movable component that can be opened or closed to secure the arch wire into an edgewise slot. This study was designed to evaluate the effect of calculus in the efficiency of shutters in passive self-ligating brackets by measuring the force required to open the shutter at different intervals after immersing in artificial saliva with calcifying solution.

Background & Objectives:

To estimate the amount of force required to open the shutter initially (0 month) and after 1 month, 2 months and 4 months of immersing in artificial saliva with calcifying solution and to compare the change in force between 0 month and 1-, 2- and 4-months intervals.

Materials and Methods:

Four different passive self-ligating brackets (Damon, J J, Modern and Koden) were used for this study. Each group had 40 samples thus total 160 samples were used. Each group is divided to 4 subgroups a, b, c and d of 10 samples representing 0-month, 1 month, 2 months and 4 months interval respectively. Subgroup b, c, and d were immersed in artificial saliva with calcifying solution for respective period. The force required to open the shutters for all groups were measured using an Instron Universal Testing Machine.

Results

There was an increase in the amount of force required to open the shutter as the interval increases in all the 4 group of SLB's. Comparing the force between 0 month with 1 month, 2 months and 4 months interval, 4 months interval showed significant increase in force in all the 4 groups.

Conclusion

Since the force required to open the shutter increases with each interval it is concluded that calculus has an effect in the efficiency of shutter.

Keywords:

Artificial saliva, Calculus, Self-ligating brackets, Shutter.

TABLE OF CONTENTS

Sl. No	Title	Page No.
1	Abstract	vi
2	List of tables	viii-x
3	List of figures	xi-xii
4	List of graphs	xiii
5	Introduction	1-6
6	Objectives	7-8
7	Background & Review of Literature	9-24
8	Relevance	25-26
9	Methodology	27-45
10	Results	46-60
11	Discussion	61-71
12	Conclusion	72-73
13	References	74-90
14	Annexures	91-102

LIST OF TABLES

Sl. No	Tables	Page No.
1.	Table 1: Materials used for the preparation of 250ml of artificial saliva.	34
2.	Table 2: Comparison of force required to open the shutter between subgroups in Damon-Ormco	48
3.	Table 3: Posthoc comparison by TUKEY'S HSD TEST- Damon Ormco	48
4.	Table 4: Comparison of force required to open the shutter between subgroups in JJ Orthodontics	49
5.	Table 5: Posthoc comparison by TUKEY'S HSD TEST- JJ Orthodontics	49
6.	Table 6: Comparison of force required to open the shutter between subgroups in At-Ease Modern Orthodontics	50
7.	Table 7: Posthoc comparison by TUKEY'S HSD TEST- Modern Orthodontics	50
8.	Table 8: Comparison of force required to open the shutter between subgroups in Ez-Lock Koden Orthodontics	51

9	Table 9: Posthoc comparison by TUKEY'S HSD TEST- Koden Orthodontics	51
10	Table 10: Comparison of force of different subgroups between 4 different groups.	52
11	Table 11: Measurement of shutter opening force in group 1: Damon -Ormco	59
12	Table 12: Measurement of shutter opening force in group 2: Selfy-JJ Orthodontics	59
13	Table 13: Measurement of shutter opening force in group 3: At-Ease Modern Orthodontics	60
14	Table 14: Measurement of shutter opening force in group 4: Ez-Lock Koden	60
15	Table 15: MASTER CHART: Shutter opening force group 1: Damon Ormco	92
16	Table 16: MASTER CHART: Shutter opening force group 2: Selfy JJ Orthodontics	93
17	Table 17: MASTER CHART: Shutter opening force group 3: At-Ease Modern Orthodontics.	94

18	Table 18: MASTER CHART: Shutter opening force group 4: Ez-Lock Koden Orthodontics	95

LIST OF FIGURES

Sl. No	Figures	Page No.
1.	Figure 1: Passive Self ligating bracket – Damon Ormco	32
2.	Figure 2: Passive self-ligating brackets – Selfy JJ Orthodontics	32
3.	Figure 3: Passive self-ligating brackets – At-Ease Modern Orthodontics	33
4.	Figure 4: Passive self-ligating bracket – Ez-Lock Koden Orthodontics	33
5.	Figure 5: Instruments	34
6.	Figure 6: Artificial saliva with calcifying solution	35
7.	Figure 7: Incubator	36

8.	Figure 8: Autoclave	37
9.	Figure 9: Universal Testing Machine -JJ Murphy Research Centre	37
10.	Figure 10: Collecting plaque sample with celluloid strip	39
11	Figure 11: Total 160 samples (10 sample arranged in each block)	40
12	Figure 12: Samples in beaker immersed in artificial saliva with calcifying solution	42
13	Figure 13: Upper and Lower jaw of Universal Testing Machine	43
14	Figure 14: Experimental set up in Universal Testing Machine (front view)	44
15	Figure 15: Experimental set up in Universal Testing Machine (side view)	45

LIST OF GRAPHS

Sl. No	Graphs	Page No.
1.	Graph 1: Comparison of force required to open the shutter between subgroups in Damon-Ormco	53
2.	Graph 2: Comparison of force required to open the shutter between subgroups in JJ Orthodontics	54
3.	Graph 3: Comparison of force required to open the shutter between subgroups in At-Ease Modern Orthodontics	55
4.	Graph 4: Comparison of force required to open the shutter between subgroups in Ez-Lock Koden Orthodontics	56
5.	Graph 5: Comparison of force of different subgroups between 4 different groups.	57

Introduction

INTRODUCTION

Self-ligating brackets do not require an elastomeric or stainless-steel ligature but have an inbuilt mechanism utilizing a permanently installed movable component that can be opened or closed to secure the arch wire into an edgewise slot[1]. In majority of designs this mechanism has a metal labial face to the bracket slot which is opened and closed with an instrument or finger-tip. Self-ligating brackets were developed in 1930's and different types have been commercially available till date.

The first design of self-ligating brackets was introduced in 1930 by Charles E Boydd.[2] Charles E Boyd filed the first patent for self-ligating brackets in 1933.[2] The production was abandoned because the design proved to be too expensive and bulky to be commercially viable. The first self-ligating bracket, the Russel attachment was developed by New York Orthodontic pioneer Dr. Jacob Stolzenberg in early 1930's.[3]

In 1971 Dr. Jim Wildman of Eugene developed the Edge-lock Bracket System.[45] Edge-lock bracket was the first commercially successful bracket.[45] The introduction of SPEED bracket which was the first active self-ligating bracket in 1976 was considered as a revolutionary invention in the field of orthodontics by Dr G. Herbert Hanson of Hamilton.[47] More recently other designs have appeared including self-ligating Activa bracket in 1986 designed by Dr. Erwin Peter, the Time brackets in 1994 by Dr. Wolfgang Heiser of Innsbruck, Australia, Damon SL brackets in 1996 by Dwight Daman, Twin-lock brackets in 1998 by Gim Wildman, Damon 2 and Innovation brackets in 2000. The recent additions are Damon 3, Damon 3MX and Smart clip in 2004.[4]

Self-ligating brackets are broadly classified into Active and Passive Self-ligating brackets, depending on the design of the locking mechanism.

Active self-ligating brackets: Active brackets, with the labial fourth wall consist of a flexible but resilient spring clip in contact with the arch wire. Pressure is exerted on the arch wire against slot base.[5] Automatic seating of either a round or a rectangular

arch wire at the base of the slot is responsible for the light, continuous force.[6] These brackets express greater torque control.[7] In the active self-ligating system, friction is produced as a result of the clip pressing against the arch wire. E.g., SPEED, Sigma, Time brackets have active clip.

Passive self-ligating brackets: In passive self-ligating brackets, the slot is transformed into a tube by means of a labial "fourth wall" that does not contact the archwire.[8] The full expression of bracket properties is achieved only when higher dimensional wires are used and the rotation control is efficiently achieved only by using larger rectangular archwires.[9,10] Once it is engaged, the bracket is effectively turned into a tube, ideally allowing arch wires to slide freely within the tube.
E.g., Damon System, Ormco Corporation, Discovery SL, Dentaurum Ltd., Edge lock, Twin lock have passive slides.

In the recent years, self-ligating brackets have been gaining popularity and there has been a significant increase in number of self-ligating bracket systems available to orthodontists. Some of the claimed advantages of self-ligating brackets include reduced frictional resistance, less chair side assistance, faster arch alignment, reduction in overall treatment time, improved periodontal health and better patient comfort[11]

Another advantage of self-ligating brackets is their treatment efficiency. It was claimed that orthodontic treatment is faster in self -ligating brackets.[18] It was found that in one of the clinical studies there was a mean reduction of four months in treatment time and four visits during active treatment time.[12] In another clinical study in three practices, it was found that an average reduction in treatment time of six months and seven visits for Damon SL cases compared to conventional ligation.[13]

They are generally smoother for the patients because of the absence of wire ligature and also do not require as much chair time.[14-16] The shutter accurately locks the arch wire within the dimensions of the slot providing robust ligation and controlled tooth movement. Retrospective studies by Eberting et al and Harradine found significantly decreased total treatment time and fewer visits with self-ligating

brackets.[17,18] However, a large retrospective study by Hamilton et al.[19] and prospective studies by DiBase et al.[20] and Fleming et al.[21], have found no measurable advantages in orthodontic treatment time, the number of treatment visits, and time spent in initial alignment with self-ligating brackets over conventional brackets.

The claim of reduced friction with self-ligating brackets is often cited as a primary advantage over conventional brackets.[22,23] This occurs because the usual steel or elastomeric ligatures are not necessary. It was found that in one of the study by Khambey et al. that Damon (SLB) brackets showed the lowest friction for all dimensions of wires followed by the Time (SLB) bracket. The "A" company standard twin brackets produced the highest friction with all dimensions checked followed by tip edge bracket.[24] With reduced friction and hence less force needed to produce tooth movement, self-ligating brackets are proposed to have the potential advantages of producing more physiologically harmonious tooth movement by not overpowering the musculature and interrupting the periodontal vascular supply.[25]

Self-ligating brackets are designed with a concise configuration claiming to reduce the microbial colonization and plaque retention due to the absence of elastomeric modules[33.] Because of their design and lack of metal and elastomeric ligatures, self-ligating brackets, according to the producers, are less prone to bacterial colonization.[26,27] Some studies affirm that self-ligating brackets have an advantage over the conventional system in retaining a lower amount of biofilm, which would facilitate the maintenance of periodontal health in orthodontic patients.[28-30]

However, it is controversial if using self-ligating systems opening and closing mechanisms and removing the ligatures and modules from conventional brackets can lessen the adherence of microbes and the formation of biofilm.[31] In everyday orthodontic treatment, the issue of plaque buildup around brackets persists despite advancements in bracket technology.[26] Some studies suggest that self-ligating brackets provide greater bacterial accumulation when compared to the conventional appliances[31,32], leading to clinical uncertainty regarding the choice of orthodontic system. Previous studies have failed to show a difference in the streptococcus mutans

count between patients with conventional and self-ligating brackets and hence in conclusive till date.

Regardless of the bracket system orthodontic full-fixed appliances may complicate oral hygiene[34-36], resulting in significant biofilm accumulation around the brackets bases.[37-39] There is certainly some diversity in the results of investigations that have compared the influence of SLBs and conventional brackets on plaque accumulation, gingival and periodontal health. However, two recently published systematic reviews have gone some way in showing that SLBs do not seem to perform any better than conventional brackets in terms of these variables.[40]

The retention of dental biofilm and formation of plaque is favored when brackets are used during orthodontic therapy [41,42] and ageing of these plaques occur in oral cavity and calcification of these adsorbed complexes of ions and proteinaceous matter might alter the morphological, structural, compositional and mechanical properties of shutters.[27] This can adversely affect the effectiveness of the ligating mechanism of self-ligating brackets.[35]

As the wire is engaged in a self- ligating bracket and shutters are closed it becomes a complex shape, proper cleaning becomes a challenge to the patient as well as the clinician.

Ideally the shutter should be freely sliding and opened with ease in every appointment. For this easy opening of shutter, the force required to open the shutter even after some intervals of appointment should be the same as the force required at first appointment or at the time of bonding. But in certain patients with poor oral hygiene or due to salivary composition promoting easy calculus formation the plaque buildup that get calcified around the shutter can lead to obstruction in the free sliding of the shutter and forceful opening can even damage the shutter affecting the ligation mechanism, which hinders all the benefits of self- ligating brackets.

Currently no material is available in literature which elaborates the effect of calculus in the efficiency of shutters in self-ligating brackets. Hence the study was

taken up to evaluate the effect of calculus in the efficiency of shutters in Passive Self ligating brackets as an In-Vitro study and to compare the force required to open the shutters at 0 month i.e. initial opening force with 3 intervals (1 month, 2 months and 4 months) in 4 different passive self-ligating brackets after immersing in artificial saliva with calcifying solution.

Aims & Objectives

AIMS AND OBJECTIVES

Aim

To compare the force required to open the shutters at 4 intervals in 4 different passive self-ligating brackets after immersing in artificial saliva with calcifying solution.

Objectives

1) To quantify the force required to open the shutter at 0 month i.e. before immersing in artificial saliva with calcifying solution.

2) To quantify the force required to open the shutter after immersing the brackets 1 month, 2 months and 4 months in the artificial saliva with calcifying solution.

3) To compare the amount of force required to open the shutters at 0 month (before immersing in the solution) with 1 month, 2 months and 4 months after immersing in the solution of 4 different passive self -ligating brackets.

4) To compare the amount of force required to open the shutters at 0-month between 4 different passive self -ligating brackets.

Background & Review of literature

BACKGROUND OF THE STUDY

Some of the claimed advantages of self-ligating system include decreased resistance to sliding mechanics, minimizes the chair side time due to less time-consuming arch wire changes, precise control of tooth translation, greater inter bracket span of arch wire available without binding of ligature wire or elastomeric modules, hygienic, esthetic and comfortable and ligation stability, retains the original form throughout treatment.[11]

The oral and gingival tissues will always become colonized by microbes as a result of orthodontic treatment.[43] Because of their design and lack of metal and elastomeric ligatures, self-liagting brackets, according to the producers, are less prone to bacterial colonization.[26,27] However, it is controversial if using self-ligating systems opening and closing mechanisms and removing the ligatures from conventional brackets can lessen the adherence of microbes and the formation of biofilm. In everyday orthodontic treatment, the issue of plaque buildup around brackets persists despite advancements in bracket technology.[26]

An undeniable difference between all self-ligating brackets and their conventional counterparts is the lack of an elastomeric or metal ligature wire to keep the arch wire in place. This presents some obvious potential advantages, not least in terms of maintaining oral hygiene as the opening and closing mechanism associated with SLBs can make the bracket slot to act like a box that may itself have some impact on plaque retention, and when the inter appointment interval is increased this plaque can get calcified and affect the normal free sliding and opening of the shutter.

But currently there is very little data relating to how SLBs perform in relation to these parameters. This study aims to evaluate whether the calculus deposition has an effect in the efficiency of shutters in passive self-ligating brackets.

REVIEW OF LITERATURE

In 1935 Jacob Stolzenburg[3] first introduced the self-ligating bracket system and the features of Russell Lock attachment were explained. This system was considered to be more patient friendly as there was no need for steel ligatures, and the fourth sliding wall completely secures the arch wire within the slot providing a secured ligation mechanism and controlled tooth movement.

In 1972 Zachrisson S[44] stated that that gingival condition worsened within one or two months of fixed appliance placement and Periodontal condition worsened in posterior segment more and in interproximal areas. He concludes that this condition resolved once appliance were removed.

In 1972 Wildman AJ[45] introduced Edge lock self-ligating bracket which is the first self-ligating bracket to be produced in bulk quantities.

In 1994 Shivapuja[46] compared the work between self-ligation bracket and conventional brackets showed that the self-ligating brackets showed a significantly lower degree of frictional resistance, less chair side time and improved infection control compared to conventional ceramic or metal brackets.

In 1980 Hanson GH[47] introduced the Speed bracket.

In 1991 Menzaghi N et al.[48] analyzed the modifications of some components of salivary microflora (S. mutans, Lactobacillus and yeasts) induced by orthodontic treatment. He concluded that orthodontic treatment can modify the oral microflora, increasing the concentrations of cariogenic microorganisms in plaque and saliva.

In 1991 Davies TM[49] studied the effects of orthodontic treatment on plaque and gingivitis indicates that there were differences with respect to plaque accumulation and gingivitis at the baseline examinations between children who were receiving orthodontic treatment and those not receiving.

In 1994 Shiva puja, Jeff Berger et al.[50] compared frictional resistance in conventional and self-ligation bracket systems. They found a decrease in frictional resistance (both dynamic and static) in SLB's. Time taken for arch wire removal and for insertion were also found to be less in SLB's when compared with conventional brackets. Improved oral hygiene were found in SLB's when compared with conventional elastic modules which sticks food debris. They also found out significant less treatment time in SLB's compared with conventional bracket system.

In 1996 Harradine[51] described the potential benefits of the Activa bracket are the rapid alignment of very irregular teeth, lower anchorage requirements, and facilitation of sliding mechanics. Several problems arise from the unfamiliarity of a bracket without tie-wings, but the most significant drawback is the bond failure rate which is currently higher than with conventional brackets from the same manufacturer.

In 1998 Damon[22] introduced the Damon self-ligating bracket. The Damon philosophy states that light forces cause more physiologic tooth movement without interrupting blood supply. Teeth align by moving through least path of resistance. Orbicularis oris and the mentalis muscle act as lip bumper and reduce the proclination of incisors. Therefore, more alveolar bone generation, lateral expansion of arch, less proclination of anterior teeth because of lip bumper effect, and less need for extractions due to increase in arch length and width are claimed to be possible with self-ligating brackets.

In 1998 Dwight H Damon[8] compared the friction produced among the conventional twin brackets with three of the self-ligating brackets, which are one active (Sigma) and two Passive (Damon SL and Wildman Twin Lock). It was found that the conventional twin brackets with metal ligatures had friction values approximately 300 times greater compared to that of the passive self-ligating brackets. Likewise, the active brackets produced 216 times more friction compared to passive self-ligating brackets.

In 1998 Pizzoni L, Raunholt G, Melsen B et al.[9] studied the frictional forces related to self-ligating brackets and concluded that selection of bracket design, wire material, and wire cross-section significantly influences the forces acting in a continuous arch system.

In 2001 N.W.T Harradine[18] compared the treatment efficiency with conventional fully programmed brackets and Damon SL brackets. He concluded that Damon SLB's produced statistically and clinically significant reduction in treatment time and number of visits. Damon SL brackets showed significant levels of technical failures of ligation mechanism.

In 2002 Macchi et al.[52] described about the Philippe self-ligating lingual brackets for the first time.

In 2003 Harradine Nigel et al.[4] explained that currently available self-ligating brackets offer a valuable combination of low friction and secure full bracket engagement. These developments offer the possibility of a significant reduction in treatment time.

In 2004 Khambay B, Millett D, McHugh S et al.[24] evaluated methods of arch wire ligation on frictional resistance. There was no consistent pattern in the mean frictional forces across the various combinations of wire type, size and ligation method under the conditions of this experiment the use of passive self-ligating brackets is the only method of almost eliminating friction.

In 2004 Henao and Kusy[53] studied frictional characteristics of 4 self-ligation (Damon 2, In-Ovation, SPEED, and Time) and 4 conventional elastomeric ligations (respective conventional elastomeric MBT bracket types) in typodonts. They found less friction with self-ligation group.

In 2005 Miles et al.[54] conducted a retrospective cohort study to find the alignment efficiency between self-ligation smart clip and conventional bracket design victory

series and arrived at a conclusion that there is no difference between both the bracket systems.

In 2005 Theodore Eliades and Christoph Bourauel[55] studied the variety and potency of various aging factors affecting the morphology, structure and mechanical properties of polymeric and metallic orthodontic materials. They displayed force transferred from the activated arch wire to a pre-adjusted bracket slot, as well as friction during free sliding. They declared that the chance for aging on spring component of self-ligating brackets, adversely affect the ligation force while considering the intra oral surroundings. They demand more studies needed on these topics before establishing the advantages of self-ligating brackets.

In 2006 Miles et al[56] conducted a retrospective cohort study to find the alignment efficiency between 58 patients with Damon 2 brackets and 58 patients with conventional victory series and found no difference.

In 2007 Daniel J. Rinchusea and Peter G. Miles[57] stated that although SL brackets might have an impact on our profession, this should be tempered by remarks by Dr Peter Vig, who said that we should consider ourselves as craniofacial biologists. Too many orthodontists have a mechanistic view of orthodontics. In this regard, SL bracket systems are only a tool that we use today; therefore, they are just a component of orthodontics.

In 2007 Nikolaous Pandis, Christoph Bouravel and Theodore Eliades[58] evaluated the effect of intra oral aging on the force exerted during engagement of a wire in to the slot in active SLB's. They found that there is extensive relaxation of clip in some groups throughout the treatment but no permanent deformation. Their study described degradation in the ligating mechanism of brackets, resulting in the loss of stiffness of the clip which seems to be vary between products depending on the mechanotherapy and potential implications for the arch wire engagement in to the bracket slot.

In 2008 Steven Budd et al.[59] performed a study of the frictional characteristics of four commercially available self-ligating bracket systems the self-ligation design (passive versus active) appeared to be the primary variable responsible for resistance to movement generated in self-ligating brackets. Passively ligated brackets produced decreased amounts of resistance. Arch wire size and shape appeared to have a more profound influence on mean resistance force increased with increases in arch wire dimension and/or changes in cross-sectional shape of the arch wire (from round to rectangular). The Bucco-lingual dimension (thickness) of the wire appeared to be a more important factor than the occluso-gingival dimension in determining the frictional resistance of self-ligating brackets under the conditions of the study.

In 2008 Trevisi[60] described the smart clip self-ligating appliance features that it contains wire retaining nitinol clips with features of conventional twin brackets. It is a passive self-ligating appliance system with MBT prescription.

In 2008 Lorenzo Franchi, Tiziano Baccetti et al[61] evaluated the frictional forces produced by 4 types of passive stainless steel SLB‟S and by non-conventional elastomeric ligatures (NCEL) and conventional elastomeric ligatures (CEL) during sliding mechanics. They found out that significantly smaller static and kinetic forces were produced by the SLB‟S and NCEL (< 2g) compared with CEL (> 500g). Finally, they concluded that SLB‟S and NCEL are better alternatives for low friction during sliding mechanics.

In 2008 Harradine[4] found that self-ligating brackets do not require an elastic or wire ligature system, but have an inbuilt mechanism that can be opened and closed to secure the arch wire. Various advantages were found which includes full arch wire engagement, reduced friction between the bracket and the arch wire, optimal oral hygiene, less chair side assistance and faster arch wire removal and no special ligation method. Most of the brackets have a metal face to the bracket slot that is opened and closed with an instrument or using fingertip. The difference between active and passive clips in terms of alloy of which it’s made, alters the treatment efficiency by friction and torque.

In 2008 Pandis et al.[62] evaluated the use of self-ligating brackets and conventional brackets associated with periodontal condition on mandibular anterior dentition. 50 patients were selected and were allocated between the 2 groups. Concluded that there is no advantage with the use of self-ligating brackets over conventional brackets irrespective of periodontal status of mandibular anterior teeth.

In 2008 Ristic M[63] in his study on effects of fixed orthodontic appliances on subgingival microflora substantiates that fixed appliances transitionally increases the growth of pathogenic bacteria and hence result in gingival inflammatory response.

In 2009 Pellegrini et al.[30] reported that self-ligating appliances promote less retention of oral bacteria and patients bonded with self-ligating bracket had fewer bacteria in plaque.

In 2009 Fleming, DiBiase and Lee et al.[64] did a prospective randomized clinical trial to find out treatment efficiency with respect to duration between smart clip self-ligating bracket and victory series conventional MBT bracket and found no difference.

In 2010 Padhriag, Fleming, Ama Johal[21] evaluated the clinical difference in use of SLB's over conventional brackets. One of their studies, reported that less pain experienced with Damon SL III SLB's. it was found that during initial stages of treatment there was lower bacterial and streptococcal loads surrounding SLB's compared with conventional brackets. SLB's don't have any particular advantage regarding pain experience. there is insufficient evidence suggesting that orthodontic treatment is more or less efficient with SLB.

In 2010 Stephanie shih- Hsuan chen, Geoffrey Michael Greenlee et al[65] undertook a systematic review to recognize and review the orthodontic literature considering the efficiency, effectiveness and stability of treatment with SLBs compared with conventional brackets. They concluded that shorter chair time and slightly less incisor

proclination found to be the only significant advantages of SLBs over conventional systems which are supported by current evidence.

In 2011 Lindel et al[66] have evaluated stainless steel and ceramic brackets form biofilm adhesion in 20 adolescent subjects. They found that total biofilm formation was 12.5% on the surface of metal and 5.6% on ceramic brackets. Their results indicated that ceramic brackets exhibit less long-term biofilm accumulation than metal brackets.

In 2011 Kaklamanos, Chen and Athanasiou[67] conducted a meta-analysis and arrived at a conclusion that there is insufficient evidence for the faster treatment time of self-ligation bracket compared to conventional brackets except for shorter appointment timing and incisor proclination.

In 2012 Johansson and Lundstrom[68] conducted a randomized prospective clinical trial in 44 patients with Time self-ligation bracket and in 46 patients with 3M Gemini bracket to evaluate the efficiency of Time self-ligation bracket. There were no statistically significant differences between the groups in terms of mean treatment time in months and mean number of visits.

In 2013 Paola GANDINI, Linda ORSI et al[69] mentioned the opening and closure forces of sliding mechanisms of different SLBs using Instron Universal Testing machine. Opening forces were observed between 1.1 N and 5.6 N whereas the closure forces were observed between 1.57N and 4.87N. Significant differences were recognized among different brackets and between two prescriptions tested. They concluded that knowledge of different opening and closure forces of self-ligating brackets can help the orthodontist in the clinical management of these brackets.

In 2013 Nigel Harradine[70] summarized the advantages of self-ligation system thus, contributing to increased efficiency of the brackets. The advantages included full secured ligation without the problems of force decay in elastomeric modules, faster ligation and arch wire removal which saves up to 9 minutes per visit compared to the

conventional, rapidity of treatment due to lower resistance to sliding inside the bracket slot.

In 2013 Slavica Pejda et al.[71] determined the effect of different bracket design on periodontal clinical parameters. Periodontal parameters were recorded before start of treatment (T0) and after 6 weeks of start of treatment (T1) and 12 weeks (T2) and 18

weeks (T3). Bracket types did not show statistically significant differences in periodontal clinical parameters. He concluded that the bracket design does not have any strong influence on periodontal clinical parameters.

In 2013 Padhraig S, Fleming and Kevin O'Brien[72] contradicted the advantages put forth by other authors saying that there was no significant time difference for slide closure and replacement of ligatures and it is controversial to say that self-ligating brackets helps in faster alignment or in rapid space closure.

In 2013 Baka et al[73] have evaluated the effects of self-ligating brackets and conventional brackets ligated with stainless steel ligatures on dental plaque retention and microbial flora. They obtained supragingival plaque samples at baseline and 3 months after bonding for the detection of bacteria and used quantitative analysis for Streptococcus mutans, Streptococcus sobrinus, Lactobacillus casei, and Lactobacillus acidophilus using real-time polymerase chain reaction and concluded that Self-ligating brackets and conventional brackets ligated with stainless steel ligatures do not differ with regard to dental plaque retention.

In 2013 Michael H Bertl[74] did a Meta-analysis of differences between conventional and self-ligating brackets concerning pain during tooth movement, number of patient visits, total treatment duration, and ligation times. Pain levels did not differ significantly between patients treated with conventional or self-ligating brackets after 4 hours, 24 hours, 3 and 7 days. The number of appointments and total treatment time revealed no significant differences between self-ligating and conventional brackets The lack of significant overall effects apparent in this meta-analysis contradicts

evidence-based statements on the advantages of self-ligating brackets over conventional ones regarding discomfort during initial orthodontic therapy, number of appointments, and total treatment time.

In 2014 Nascimento et al.[75] have published a systematic review on whether the design of brackets (conventional or self-ligating) influences adhesion and formation of Streptococcus mutans colonies. They concluded that there is no evidence for a

possible influence of the design of the brackets (conventional or self-ligating) over colony formation and adhesion of Streptococcus mutans. This implies that it is the material aspect but not the design aspect that favor's or impedes colony formation.

In 2015 Megha Anand et al.[76] conducted a retrospective cohort study from 2 clinicians to assess differences between self-ligation and conventional bracket group with respect to treatment time, transverse dimension, arch length, lower incisor inclination, Peer Assessment Score, number of visits and number of emergencies. Though clinician 1 can find significant difference with respect to reduced treatment time in self-ligation group, clinician 2 did not find any difference. They concluded that there is no difference between groups.

In 2015 Raíssa Costa Araújo et al.[77] compared the degree of debris and friction of conventional and self-ligating orthodontic brackets before and after clinical use and concluded that after the intraoral exposure, there was a significant increase of debris accumulation in both systems of brackets. However, the self-ligating brackets showed a higher amount of debris compared with the conventional brackets. The frictional force in conventional brackets was significantly higher when compared with self-ligating brackets before clinical use.

In 2016 Bergamo et al.[78] evaluated the alterations on plaque index (PI), gingival index (GI), gingival bleeding index, and gingival crevicular fluid (GCF) volume after use of three different bracket types for 60 days. Patients were bonded with 3 different brackets – conventional (Gemini™, 3M Unitek), active self-ligating (In-Ovation®R;

Dentsply GAC) and passive self-ligating (Smart Clip™; 3M Unitek). The result of the study showed was no statistically significant correlation between tooth crowding, overjet, and overbite and the PI, GI, GBI scores, and GCF volume before bonding, indicating no influence of malocclusion on the clinical parameters regardless of the bracket design, no statistically significant difference was found for GI, GBI scores. PI and GCF volume showed a significant difference among the brackets in different periods. There was an increase in PI score and GCF volume 60 days after bonding of Smart Clip™ self-ligating brackets, indicating the influence of bracket design on these clinical parameters.

In 2016 Yang et al.[33] compared plaque indices associated with passive Self Ligating Brackets and conventional brackets and found no significant differences.

In 2016 Woo-SunJung, Kyungsun Kim et al.[79] studied the adhesion of periodontopathogens to self-ligating brackets (Clarity-SL, Clippy-C and Damon Q) and keyed out the relationships between bacterial adhesion and oral hygiene indexes. Adhesions of Aggregatibacter actinomycetemcomitans, Porphyromonas gingivalis, Prevotella intermedia, Fusobacterium nucleatum and Tannerella forsythia were quantitatively determined using real-time polymerase chain reactions. Greater quantities of bacteria were detected in the mandibular bracket than that of the maxillary bracket. The plaque and gingival indexes were not strongly correlated with bacterial adhesion to the brackets. Because Aa, Pg, and Pi adhered more to the DQ brackets in the mandibular area, orthodontic patients with periodontal problems should be carefully monitored in the mandibular incisor region where the distance between the bracket and the gingiva is small, especially when DQ brackets are used.

In 2017 Mezeg U, Primozic J et al.[80] assessed the influence of long-term in vivo exposure, debris accumulation and arch wire material on static and kinetic friction force among different types of brackets and arch wires couples. A significant correlation was seen between friction force and bracket type, while treatment duration, amount of debris accumulation, arch wire material or their manufacturer

was not significantly correlated to it. Nevertheless, higher friction forces were measured among in vivo aged SL brackets in comparison with as-received ones.

In 2017 Longoni JN, Lopes BM V, Freires IA, et al.[26] conducted a systematic review and based on the limited evidence concluded that self-ligating metallic brackets accumulate less *S. mutans* than conventional ones. However, these findings must be interpreted in conjunction with particularities individual for each patient – such as hygiene and dietary habits, which are components of the multifactorial environment that enables S. Mutans to proliferate and keep retained in the oral cavity.

In 2017 Eleftherios G. Kaklamanosin[81] compared the duration of orthodontic treatment and Gingival Index (GI) scores in Class I malocclusion patients treated with a conventional square-wire method or the Damon technique (DT). The study did not reveal any statistically significant differences between the compared conventional straight-wire method and Damon technique groups as regardless to total treatment duration and GI scores.

In 2017 Loli D[82] done a systematic review on fixed orthodontic therapy and plaque formation and concluded that during fixed orthodontic treatment, increased plaque formation with risk of periodontal diseases is common but transient and reversible with appliance removal. At this time, there are no documented difference in plaque formation between metallic brackets and esthetic brackets and between self-ligating brackets and elastomeric ligature brackets.

In 2017 Aditya Chhibber et al.[83] done a study on which orthodontic appliance is best for oral hygiene? and found no evidence of any significant difference in the oral hygiene levels among clear aligners, self-ligated brackets, and conventional (elastomeric-ligated) brackets after 18 months of active orthodontic treatment. However, in the short term, the CLA group participants had better GI and PBI scores than the fixed appliance groups.

In 2019 Gulbahar Ustaoglu et al.[84] done a comparison on effects of bracket types and treatment duration on periodontal health of adult patients concluded Although SLBs do not require ligatures that may facilitate plaque accumulation, our findings showed that SLB's were not advantageous over CB's in terms of periodontal health. Our findings also showed that gingival health deteriorated as the duration of the treatment increased.

In 2021 Pranshu Mathur et al.[85] concluded in his study that currently available self-ligating brackets offer the very valuable combination of extremely low friction and secure full bracket engagement and at last they are sufficiently robust and user-friendly to deliver most of the potential advantages of this type of bracket. The core advantages of self-ligation are now established and readily available. These developments offer the possibility of a significant reduction in average treatment times and maybe also in anchorage requirements, particularly in cases requiring large tooth movements. Evidence of better treatment effectiveness exists but is incomplete. While further refinements are desirable and further studies essential, current brackets appear able to deliver measurable benefit with good robustness and ease of use.

In 2021 Feres MF, Vicioni-Marques F et al.[27] studied Streptococcus mutans adherence to conventional and self-ligating brackets and concluded that Self-ligating brackets are likely to present lower rates of biofilm adhesion. Particularly, Abzil® and GAC® self-ligating brackets are less likely to accumulate biofilm. Although such results are derived from an in vitro study, practitioners might acknowledge findings concerning bacterial adhesion as one of the relevant features to be considered during bracket selection.

In 2022 Alexandru Mester[87] undertook a study on the periodontal health in patients with Self-Ligating brackets. Their findings indicated that SLB's are not superior to CBs in terms of periodontal health.

In 2022 Bergamo AZ, Casarin RC, et al.[88] mentioned that Self-ligating brackets exhibit accumulation of high levels of periodontopathogens in gingival crevicular

fluid. Some kinds of brackets could provide more retentive sites than others, and it seems to modulate the subgingival microbiota, since, in this study, we could observe the increase of the species associated with periodontal disease. Preventive protocols should be adopted in the use of self-ligating brackets.

In 2023 Ina Hendiani[86] inspected the effects of Using Conventional and Self-Ligating Brackets on Oral Hygiene and Periodontal Health Status and concluded that the effects of using CB and SLB were similar in increasing oral hygiene (PI) and periodontal health status (GI and bleeding index) in patients with mild to moderate crowding, although 3 articles revealed contradictive effects.

In 2023 Gracia Costa Lopes[89] did research and concluded that Self-ligating brackets do not reduce discomfort or pain when compared to conventional orthodontic appliances in Class I patients. There was no difference between conventional and self-ligating appliances in the parameters of pain: substance P and pressure. Functional aspects, such as pain, discomfort, and masticatory efficiency, should not be considered when making a therapeutic decision regarding the use of self-ligating vs conventional orthodontic appliances.

1n 2023 Eduard Radu Cernei[90] conducted review on Passive Self-Ligating Bracket Systems: A Scoping Review of Their Claims Regarding Efficiency and Effectiveness in orthodontic treatment alignment stage, space closure, patient comfort, arch development, stability of the results, periodontal health, and apical root resorption and found mixed evidence regarding the superiority of PSLB's over CB's and ASLB's in terms of efficiency and effectiveness. Still, most of the variables examined did not exhibit any notable variations among the three bracket types. Overall, more research is needed to fully understand the differences between PSLB's and other types of bracket systems and determine the most appropriate use in clinical practice.

In 2024 Diyan Ricky Warizgo, Shirley Gautamaetal et al.[91] conducted a study on Bacterial biofilm accumulation on self-ligating vs. elastomeric metal brackets: A review and concluded that the decision utilized by orthodontists to substitute self-ligating brackets for elastomeric ones in their clinical practice with the goal of

enhancing hygiene and reducing plaque accumulation is not yet supported by scientific data.

Relevance Of the study

RELEVANCE OF THE STUDY

Self-ligating brackets (SLB's) have gained popularity in recent years due to claims of improved orthodontic efficiency and effectiveness compared to the traditional or classical bracket system (CB). There has been a significant increase in number of self-ligating bracket systems available to orthodontists.

The retention of dental biofilm is favored when brackets are used during orthodontic therapy, irrespective of the bracket system. Orthodontic full-fixed appliances may also complicate oral hygiene, resulting in significant biofilm accumulation around the brackets.[35-39]

In SLB's due to its complex shape, proper cleaning becomes a challenge to the patient as well as the clinician. Ideally the shutter should be freely sliding to open in every appointment but in certain patients with poor oral hygiene or due to salivary composition promoting easy calculus formation, when interappointment interval is increased the plaque buildup get calcified around the shutter and lead to obstruction in the free sliding of the shutter.

But currently there is very little data relating to how SLBs perform in relation to these parameters. This study aims to evaluate whether the calculus deposition has an effect in the efficiency of shutters in passive self-ligating brackets so that the clinicians can take the necessary precaution to maintain free sliding of shutter throughout the treatment.

Materials & methods

STUDY DESIGN

This study was designed as an invitro study in laboratory conditions.

STUDY SETTINGS

- Department of Orthodontics and Dentofacial Orthopaedics, St. Gregorios Dental College, Kothamangalam, Kerala.
- UniBiosys Biotech Research lab CUSAT, Kalamaserry, Ernakulam, Kerala.
- J J Murphy Rubber Testing and Research Centre, Muvattupuzha, Ernakulam, Kerala.

SAMPLING

SAMPLE SIZE CALCULATION

$$n = 2 \times \frac{(\frac{Z\alpha}{2} + Z\beta)^2}{(d1-d2)^2} \times SD^2$$

Z α/2 =Type 1 error (5%) =1.96

Z β = Type1 error (20%) =0.84(Power of the study 80%)

SD =Standard deviation =0.9 (From literature)

d1-d2=difference in mean=0.8

$$n = 2 \times \frac{(1.96+0.84)^2 \times 0.9^2}{0.8^2}$$

$$n = 2 \times \frac{7.8 \times 0.81}{0.64} = 19.74 \approx 20 \text{ samples (per group)}$$

Sample size of minimum 20 per group is needed.

For this study sample size is taken as 40 × 4 groups = 160

SORTING OF SAMPLES

The sample size of the study was taken as 160.

Passive self-ligating brackets of 4 different company are selected as 4 groups.

The samples were divided into 4 groups of 40 each.

- Group 1- 40 samples of Damon-Ormco
- Group 2- 40 samples of JJ Orthodontics
- Group 3- 40 samples of Modern Orthodontics
- Group 4- 40 samples of Koden Orthodontics

Each group is divided into subgroup a, subgroup b, subgroup c, subgroup d of 10 samples each.

Control group

- Subgroup A - 10 samples of each group of 0-month interval (force measured before immersing in the solution).

Experimental group

- Subgroup B - 10 samples of each group of 1 month interval (force measured after 1 month of immersing in the solution).
- Subgroup C - 10 samples of each group of 2 months interval (force measured after 2 months of immersing in the solution).
- Subgroup D - 10 samples of each group of 4 months interval (force measured after 4 months of immersing in the solution).

INCLUSION CRITERIA

- Passive self-ligating brackets.
- Lower anterior brackets.
- Plaque sample from patient wearing self-ligating bracket with OHI −S score > 3.

EXCLUSION CRITERIA

- Active self-ligating brackets.
- All bracket other than lower anterior bracket.
- Plaque sample from patient wearing self-ligating bracket with OHI-S score < 3.
- Plaque sample from patient with blood disorders, cardio vascular disorders, neurological disorders.

MATERIALS

- Orthodontic lower incisor metal brackets- 0.022 x 0.028 SWA of MBT prescription.
    - Passive self-ligating lower incisor brackets - Damon-Ormco. (Figure 1)
    - Passive self-ligating lower incisor brackets - Selfy-JJ Orthodontics. (Figure 2)
    - Passive self -ligating lower incisor brackets - Ez-Lock Koden Orthodontics. (Figure 3)
    - Passive self- ligating lower incisor brackets - At-ease Modern Orthodontics. (Figure 4)
- Stainless steel wire – 0.017 *0.025 (American Orthodontics) (Figure 5)
- Celluloid strip (Figure 5)
- Borosilicate laboratory Beaker 50ml (OCTA Corp.) (Figure 5)
- Bracket holder (Figure 5)
- Stainless steel Explorer (Figure 5)
- Tweezer (Figure 5)
- Heavy wire cutter (Figure 5)
- Mouth mirror (Figure 5)
- Key of self-ligating bracket system (Damon) (Figure 5)
- Heat cure acrylic blocks (Figure 5)
- Glue (Figure 5)
- Artificial saliva with calcifying solution (UniBiosys Biotech Research lab, CUSAT, Kalamaserry, Ernakulam, Kerala.) (Figure 6)

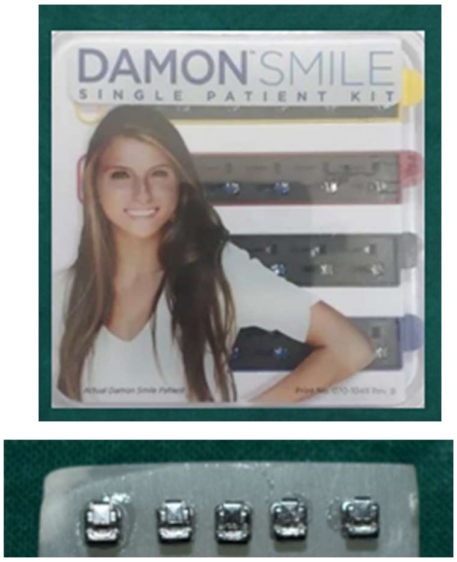


Figure 1: Passive Self ligating bracket – Damon Ormco

Figure 2: Passive self-ligating brackets – Selfy JJ Orthodontics

Figure 3: Passive self-ligating brackets – At-Ease Modern Orthodontics

Figure 4: Passive self-ligating bracket – Ez-Lock Koden Orthodontics

Figure 5: Instruments: Hard wire cutter, bracket holder, tweezer, key of self-ligating system, Stainless steel wire, celluloid strip, mouth mirror, probe, heat cure acrylic block, beaker, glue.

Artificial saliva with calcifying solution

Fusayama Artificial Saliva[94] was the medium used in this study to simulate the intraoral salivary conditions. Wasserman[95] calcifying solution was added to this artificial saliva to promote In-vitro calcification.

Sodium chloride	100 mg
Potassium chloride	100 mg
Calcium chloride dihydrate	199 mg
Sodium hydrogen phosphate 1 hydrate	172.5mg
Potassium thiocyanate	75 mg
Sodium sulfide 1.25	1.25 mg
Urea	250 mg
Distilled water	250 ml

TABLE 1: Materials used for the preparation of 250ml of artificial saliva.

The calcifying solution used throughout was prepared from a sterilized basal salt solution containing 0.7M NaCl, 0.05M KCl and 0.22M $NaHC0_3$. This stock solution was diluted tenfold by the addition of sterile water, and K_2HPO_4 was added to make a final concentration of 12 mg% of pCO_2 was bubbled through the solution to depress the pH to 6.0. $CaCl_2$ was then added to make a final concentration of 4 mg% of Ca. The pH was adjusted to 7.0 by passing compressed air through the solution. The calcium and phosphorus levels were comparable to the ionic concentration of these elements in saliva.

Figure 6: Artificial saliva with calcifying solution

EQUIPMENTS

- Incubator (UniBiosys Biotech Research lab, CUSAT, Kalamaserry, Ernakulam, Kerala.) (Figure 10)

- Universal testing machine – (INSTRON 6800 series, Shimadzu AG -1, capacity range of 0.02N to 300KN. (J J Murphy Rubber Testing and Research Centre, Muvattupuzha, Ernakulam, Kerala) (Figure 12)

- Autoclave (UniBiosys Biotech Research lab, CUSAT, Kalamaserry, Ernakulam, Kerala.) (Figure 11)

Figure 7: Incubator

Figure 8: Autoclave

Figure 9: Universal Testing Machine -JJ Murphy Research Centre

INSTRUMENT FOR MEASURING FORCE

Universal testing machine (INSTRON)

Autograph AGS-J Series- SHIMADZU Corporation-Japan)

Capacity range of 0.02N(2gm) to 5kN

Crosshead speed of 1 mm/minute

Crosshead speed accuracy of ±0.5% or ±0.025mm/min (0.001in/min)

METHODOLOGY

Preparation of artificial saliva with calcifying solution

The study is carried out after obtaining clearance from institutional ethical committee. Ethical clearance certificate no: SGDC/152/2022/4345.

Celluloid strips were placed around the lower anterior teeth of patient, undergoing orthodontic treatment with SLB's and an OHI-S score > 3, in the department of orthodontics, St Gregorios dental college after obtaining informed consent from the participants. Strips with adherent bacterial plaque was removed from the mouth after 72 hours (figure 10). The bacterial plaque, formed on these strips are the first stage in calculus formation. The celluloid strips were then transferred to artificial saliva with calcifying solution prepared from UniBiosys Biotech Research lab which was then kept in an incubator at the lab (figure 7).

Figure 10: Collecting plaque sample with celluloid strip.

Preparation of the sample

Rectangle blocks were made from heat cure acrylic.

The brackets with arch wire of each subgroup of 4 different groups were bonded to color coded heat cure acrylic blocks (figure 11).

- 10 brackets of subgroup A (0 months) of each group were bonded to grey color acrylic block.
- 10 brackets of subgroup B (1 month) of each group were bonded to red color acrylic block.
- 10 brackets of subgroup C (2 months) of each group were bonded to blue color acrylic block.
- 10 brackets of subgroup D (4 months) of each group were bonded to pink color acrylic block.

Figure 11: Total 160 samples (10 sample arranged in each block)

Control group

Subgroup A acrylic blocks of 0-month interval is not immersed in the solution, and the force required to open the shutter is measured using an Instron universal testing machine.

Experimental group invitro setup (figure 12)

Subgroup B acrylic blocks of each group are immersed into 50ml beakers containing 50ml of artificial saliva with calcifying solution and is kept in an incubator for a period of 1month. After 1 month the brackets are taken out and the force required to open the shutter is measured.

Subgroup C acrylic blocks of each group are immersed into 50ml beakers containing 50ml of artificial saliva with calcifying solution and is kept in an incubator for a period of 2 months. After 2 months the brackets are taken out and the force required to open the shutter is measured.

Subgroup D acrylic blocks of each group are immersed into 50ml beakers containing 50ml of artificial saliva with calcifying solution and is kept in an incubator for a period of 4 months. After 4 months the brackets are taken out and the force required to open the shutter is measured.

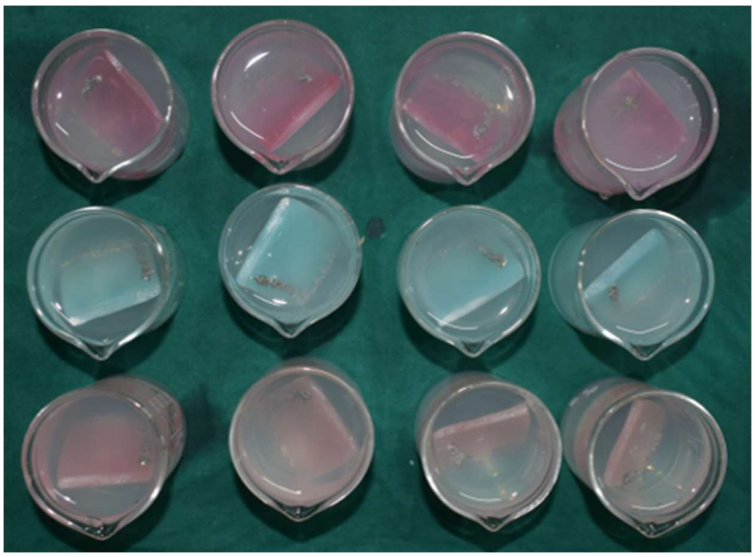


Figure 12: Samples in beaker immersed in artificial saliva with calcifying solution

All the blocks taken out at different period from the solution were autoclaved to disinfect the blocks and the force required to open the shutter of the self-ligating brackets were calculated with the help of a Universal testing machine (figure 13).

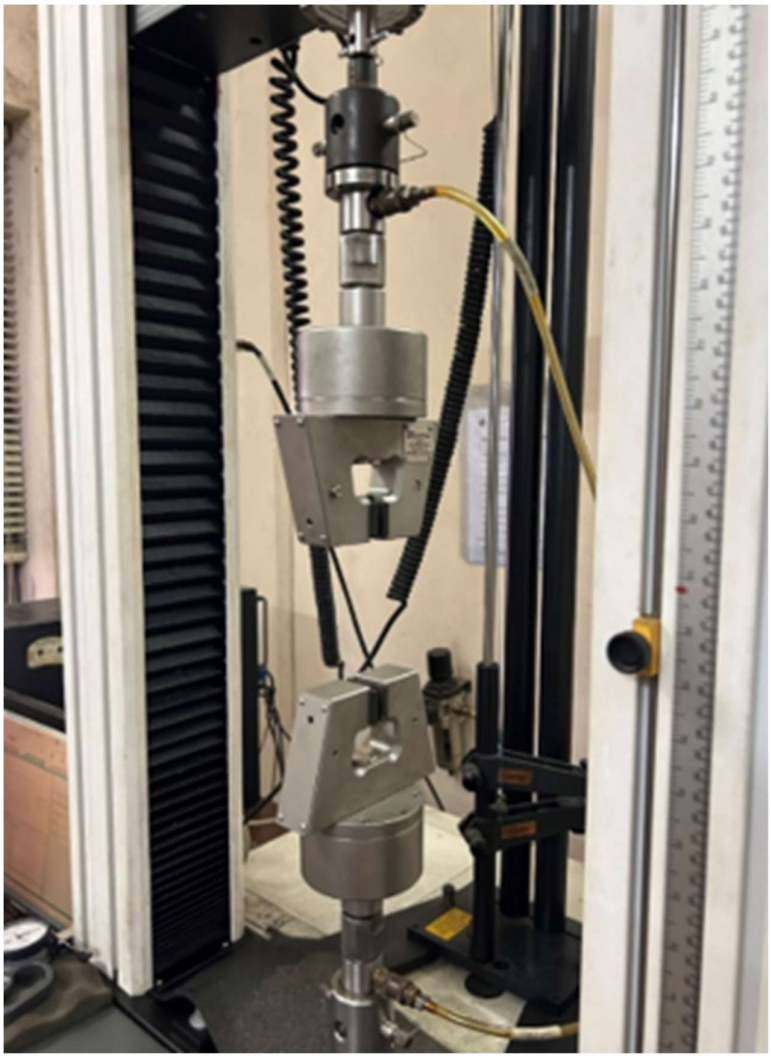


Figure 13: Upper and Lower jaw of Universal Testing Machine

Experimental set up in universal testing machine (figure 14, figure 15)

The acrylic block was fixed in the lower jaw of an Instron Universal testing machine. An explorer was fixed to the upper part of the Universal testing machine. The edge of the explorer hook was inserted in the hole of the shutter of a closed bracket. The explorer hook was then moved upward in a vertical direction at a cross head speed of 1mm /min until the shutter was completely opened. Maximum opening force value in Newton was recorded for each sample.

All the readings were recorded in a tabular column during the experiment for each group and subgroups separately.

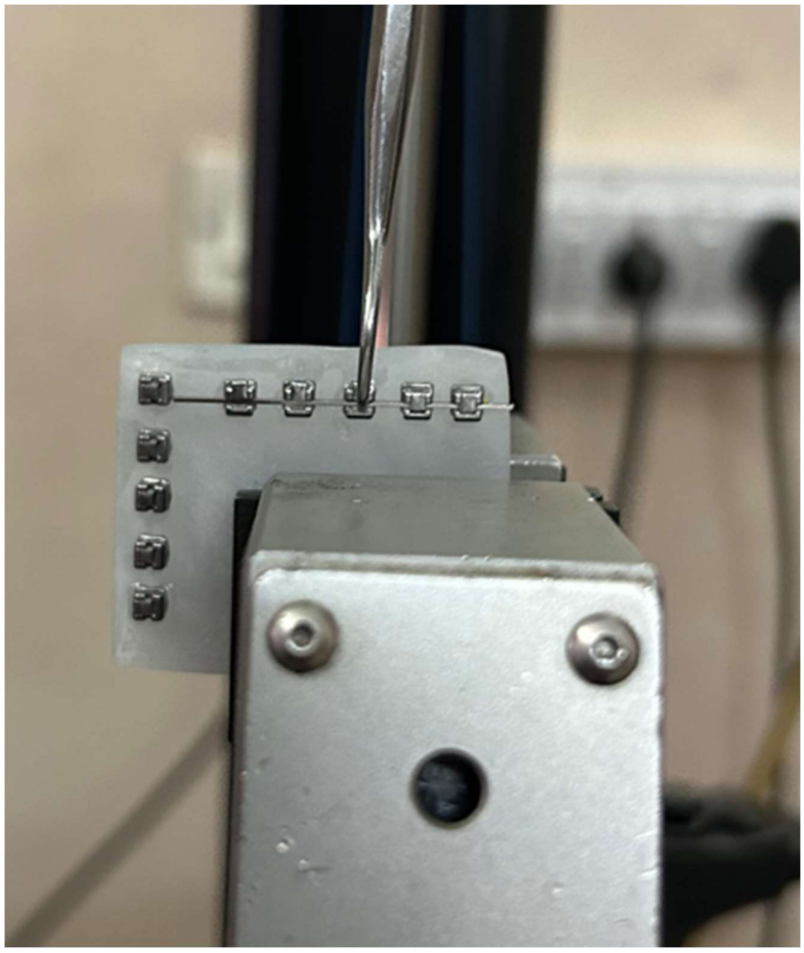


Figure 14: Experimental set up in Universal Testing Machine (front view)

Figure 15: Experimental set up in Universal Testing Machine (side view)

Results

STATISTICAL ANALYSIS

Data was analyzed using the statistical package - SPSS **26.0** (SPSS Inc., Chicago, IL) and level of significance was set at **$p<0.05$**. **Descriptive statistics** was performed to assess the mean and standard deviation of the respective groups. Normality of the data was assessed using **Shapiro Wilkinson test**. **Inferential statistics** to find out the difference within the group was done using **REPEATED MEASURES OF ANOVA followed by BONFERRONI POSTHOC TEST.**

RESULTS

COMPARISON OF THE MEAN FORCE OF 4 GROUPS BETWEEN DIFFERENT INTERVALS

		MEAN	SD
0 MONTH		2.67	0.40
1 MONTHS		2.75	0.45
2 MONTHS		3.17	0.44
4 MONTHS		3.63	0.41
P VALUE (REPEATED MEASURES OF ANOVA TEST)		0.0001*	
P VALUE (Boneferroni) POSTHOC TEST)	0 MONTH vs 1 MONTH	0.97	
	0 MONTH vs 2 MONTH	0.05	
	0 MONTH vs 4 MONTH	0.0001*	
OVERALL MEAN CHANGE		0.96±0.40	
PERCENTAGE OF CHANGE		35.95%	

***P<0.05 is statistically significant (Shapiro Wilkinson test, P>0.05)**

TABLE 2- Comparison of force required to open the shutter between subgroups DAMON - ORMCO

Groups	Difference	95% Confidence Interval		P value
0 MONTH vs 1 MONTH	0.08±0.40	-0.43	0.59	0.97
0 MONTH vs 2 MONTH	0.50±0.42	-0.01	1.01	0.05
0 MONTH vs 4 MONTH	0.96±0.43	0.44	1.47	0.0001*

P<0.05 is statistically significant

TABLE 3- POSTHOC COMPARISON BY TUKEY'S HSD TEST- DAMON - ORMCO

INFERENCE: Shapiro wilkinson test for normality did not report significant difference(P>0.05), Hence Parametric tests are used for the analysis. Regarding 'Comparison of force- Ormco Damon' within group analysis by Repeated Measures of ANOVA Test reported Statistically Significant Difference with a P value of 0.0001 (P<0.05). Bonferroni posthoc test reported significant difference between 0 month-4 months interval (0.0001). The percentage change in force between 0-4 months is 35.95%. The overall mean change is 0.96±0.40.

		MEAN	SD
0 MONTH		4.59	0.43
1 MONTHS		4.65	0.47
2 MONTHS		4.97	0.46
4 MONTHS		5.49	0.47
P VALUE (REPEATED MEASURES OF ANOVA TEST)		0.0003*	
P VALUE (Boneferroni) POSTHOC TEST)	0 MONTH vs 1 MONTH	0.99	
	0 MONTH vs 2 MONTH	0.26	
	0 MONTH vs 4 MONTH	0.0005*	
OVERALL MEAN CHANGE		0.9±0.45	
PERCENTAGE OF CHANGE		19.60%	

***P<0.05 is statistically significant (Shapiro Wilkinson test, P>0.05)**

TABLE 4- Comparison of force required to open the shutter between subgroups in JJ Orthodontics

Groups	Difference	95% Confidence Interval		P value
0 MONTH vs 1 MONTH	0.06±0.44	-0.49	0.61	0.99
0 MONTH vs 2 MONTH	0.38±0.45	-0.17	0.93	0.26
0 MONTH vs 4 MONTH	0.90±0.43	0.34	1.45	0.0005*

P<0.05 is statistically significant

TABLE 5- POSTHOC COMPARISON BY TUKEY'S HSD TEST- JJ ORTHODONTICS

INFERENCE: Shapiro wilkinson test for normality did not report significant difference(p>0.05), Hence Parametric tests are used for the analysis. Regarding 'Comparison of force- JJ orthodontics' within group analysis by Repeated measures of ANOVA Test Reported Statistically Significant Difference with a P value of 0.0003 (P<0.05). Bonferroni posthoc test reported significant difference between 0 month-4 months interval (0.0005). The percentage change in force between 0-4 months is 19.60%. The overall mean change is **0.9±0.45**

		MEAN	SD
0 MONTH		2.13	0.55
1 MONTHS		2.24	0.49
2 MONTHS		2.55	0.55
4 MONTHS		3.22	0.50
P VALUE (REPEATED MEASURES OF ANOVA TEST)		0.0002*	
P VALUE (Boneferroni) POSTHOC TEST)	0 MONTH vs 1 MONTH	0.96	
	0 MONTH vs 2 MONTH	0.29	
	0 MONTH vs 4 MONTH	0.0002*	
OVERALL MEAN CHANGE		1.09±0.53	
PERCENTAGE OF CHANGE		51.17%	

***P<0.05 is statistically significant (Shapiro Wilkinson test, P>0.05)**

TABLE 6- Comparison of force required to open the shutter between subgroups in At-Ease Modern Orthodontics

Groups	Difference	95% Confidence Interval		P value
0 MONTH vs 1 MONTH	0.11±0.50	-0.52	0.74	0.96
0 MONTH vs 2 MONTH	0.42±0.51	-0.21	1.05	0.29
0 MONTH vs 4 MONTH	1.09±0.53	0.45	1.72	0.0002*

P<0.05 is statistically significant

TABLE 7- POSTHOC COMPARISON BY TUKEY'S HSD TEST-MODERN ORTHODONTICS

INFERENCE: Shapiro wilkinson test for normality did not report significant difference(p>0.05), Hence Parametric tests are used for the analysis. Regarding 'Comparison of force- Modern orthodontics' within group analysis by REPEATED MEASURES OF ANOVA Test Reported Statistically Significant Difference with a P value of 0.0002 (P<0.05). Bonferroni posthoc test reported significant difference between 0 month-4 months interval (0.0002). The percentage change in force between 0-4 months is 51.17%%. The overall mean change is 1.09±0.53

		MEAN	SD
0 MONTH		3.79	0.45
1 MONTHS		3.91	0.42
2 MONTHS		4.26	0.41
4 MONTHS		4.82	0.58
P VALUE (REPEATED MEASURES OF ANOVA TEST)		0.0001*	
P VALUE (Boneferroni) POSTHOC TEST)	0 MONTH vs 1 MONTH	0.94	
	0 MONTH vs 2 MONTH	0.13	
	0 MONTH vs 4 MONTH	0.0001*	
OVERALL MEAN CHANGE		1.03±0.49	
PERCENTAGE OF CHANGE		27.17%	

***P<0.05 is statistically significant (Shapiro Wilkinson test, P>0.05)**

TABLE 8- Comparison of force required to open the shutter between subgroups in Ez-Lock Koden Orthodontics

Groups	Difference	95% Confidence Interval		P value
0 MONTH vs 1 MONTH	0.12±0.43	-0.44	0.68	0.94
0 MONTH vs 2 MONTH	0.47±0.42	-0.09	1.03	0.13
0 MONTH vs 4 MONTH	1.03±0.47	0.46	1.59	0.0001*

P<0.05 is statistically significant

TABLE 9- POSTHOC COMPARISON BY TUKEY'S HSD TEST-KODEN ORTHODONTICS

INFERENCE: Shapiro wilkinson test for normality did not report significant difference(p>0.05), Hence Parametric tests are used for the analysis. Regarding 'Comparison of force- Koden orthodontics' within group analysis by REPEATED MEASURES OF ANOVA Test Reported Statistically Significant Difference with a P value of 0.0001(P<0.05). Bonferroni posthoc test reported significant difference between 0 month-4 months interval (0.0001). The percentage change in force between 0-4 months is **27.17%.** The overall mean change is **1.03±0.49.**

	ORMCO DAMON	JJ	MODERN	KODEN	P VALUE	POSTHOC P VALUE	
0 MONTH	2.67±0.40	4.59±0.43	2.13±0.55	3.79±0.45	0.0001*	O vs J	0.0001*
						O vs M	0.05*
						O vs K	0.0001*
						J vs M	0.0001*
						J vs K	0.002*
						M vs K	0.0001*
1 MONTHS	2.75±0.45	4.65±0.47	2.24±0.49	3.91±0.42	0.0001*	O vs J	0.0001*
						O vs M	0.07
						O vs K	0.0001*
						J vs M	0.0001*
						J vs K	0.004*
						M vs K	0.0001*
2 MONTHS	3.17±0.44	4.97±0.46	2.55±0.55	4.26±0.41	0.0001*	O vs J	0.0001*
						O vs M	0.02*
						O vs K	0.0001*
						J vs M	0.0001*
						J vs K	0.008*
						M vs K	0.0001*
4 MONTHS	3.63±0.41	5.49±0.47	3.22±0.50	4.82±0.58	0.0001*	O vs J	0.0001*
						O vs M	0.26
						O vs K	0.0001*
						J vs M	0.0001*
						J vs K	0.02*
						M vs K	0.0001*

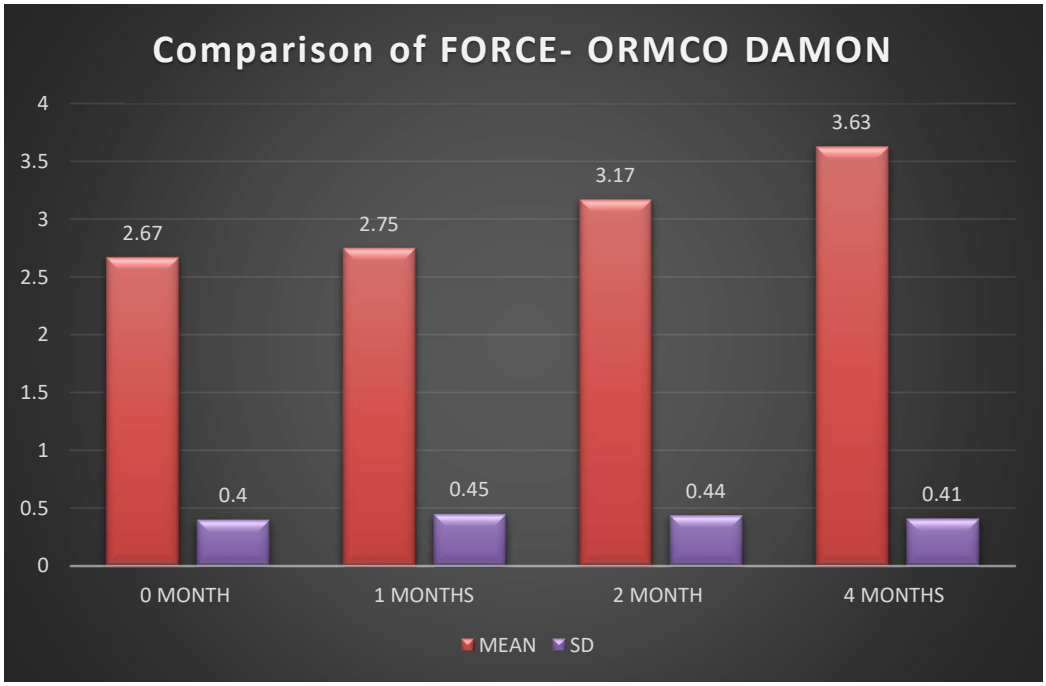
P<0.05 is statistically significant

TABLE 10- Comparison of force of different subgroups between 4 different groups.

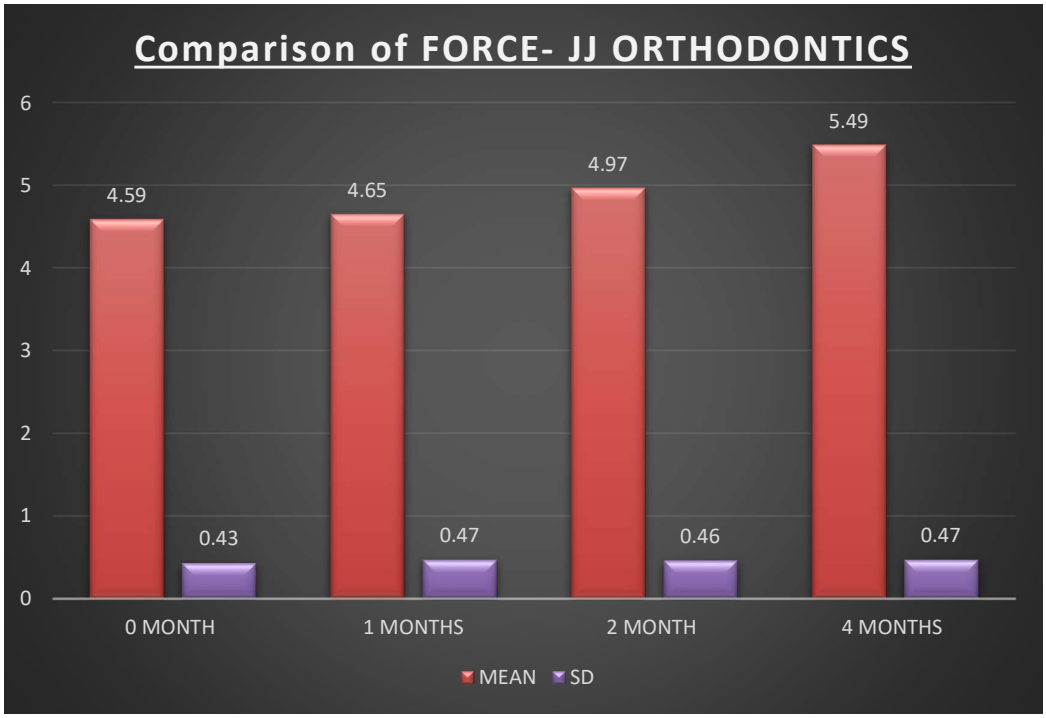
INFERENCE: Shapiro wilkinson test for normality did not report significant difference($p>0.05$), Hence Parametric tests are used for the analysis. Regarding 'Comparison of force-Between group analysis by ONE ANOVA Test Reported Statistically Significant Difference regarding all the 4 intervals. Boneferroni post test reported significant difference between all the pair groups at 0 months & 2 months. ($P<0.05$). Regarding 1 month & 4 months significant difference between most of the pair groups except Damon vs Modern ($P>0.05$) which reported non significant difference.

GRAPHS

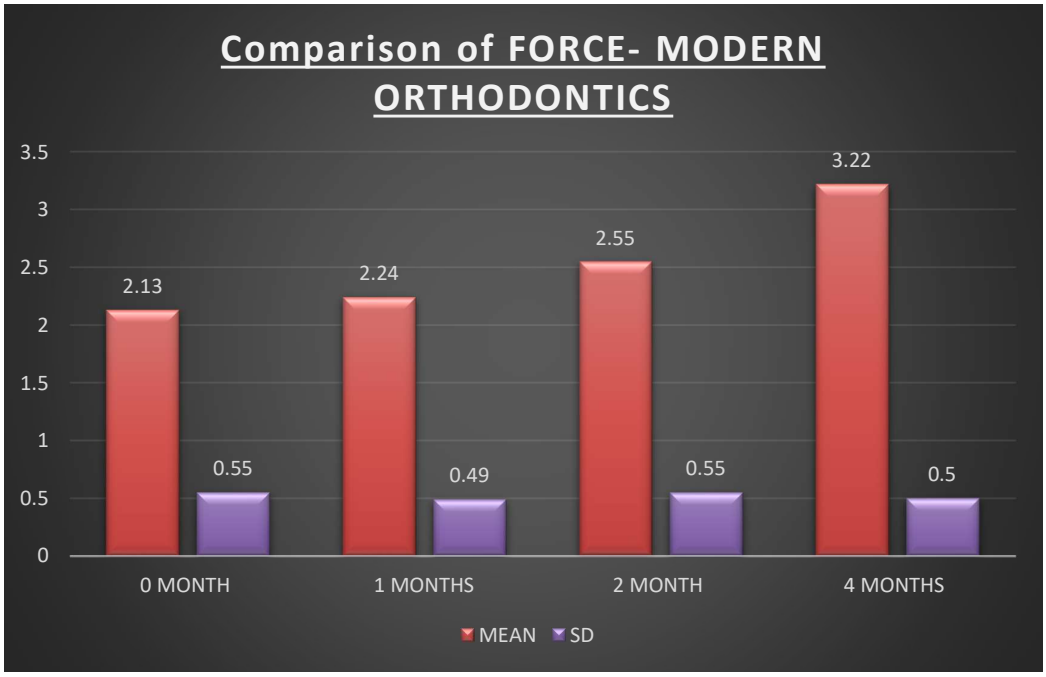
COMPARISON OF FORCE REQUIRED TO OPEN THE SHUTTER BETWEEN SUBGROUPS



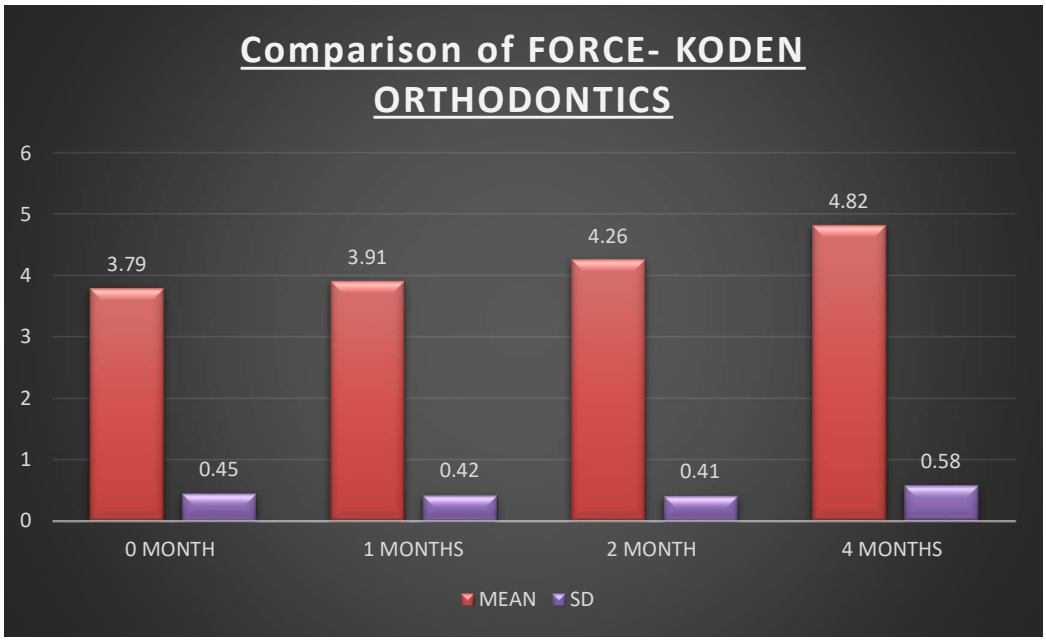
Graph 1: Comparison of force required to open the shutter between subgroups in Damon- Ormco



Graph 2: Comparison of force required to open the shutter between subgroups in JJ Orthodontics

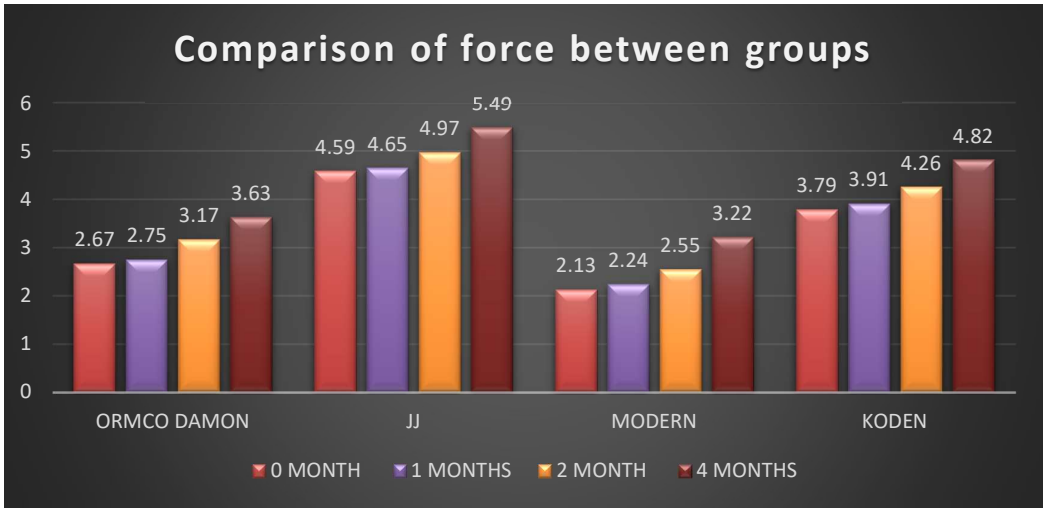


Graph 3: Comparison of force required to open the shutter between subgroups in At-Ease Modern Orthodontics



Graph 4: Comparison of force required to open the shutter between subgroups in Ez-Lock Koden Orthodontics

COMPARISON OF FORCE REQUIRED TO OPEN THE SHUTTER AT DIFFERENT INTERVALS BETWEEN THE 4 GROUPS



Graph 5: Comparison of force of different subgroups between 4 different groups.

RESULTS

The present study evaluated the force required to open the shutters at 4 intervals (0, 1 month, 2 months and 4 months) in 4 different passive self-ligating brackets. Table 11 to 14 represent the overall results. These tables show the experimentally observed force magnitude in all 4 intervals, of 4 groups of SLB's. Table 2 to 9 shows the statistical interpretation of comparison of force required to open the shutter at 0 month with 1 month, 2 months and 4 months interval in all 4 groups. Table 10 represent the comparison of force at different intervals between the groups. Graph 1 to 4 represent the graphical representation of comparison of force at different interval of 4 groups.

The results showed an increase in the amount of the magnitudes of forces within the experimental subgroups as the interval increases and were also higher when compared to the control group. When comparing the Damon Ormco group statistical test reported significant difference between 0 month-4 months interval (0.0001). The percentage change in force between 0-4 months was 35.95%. The overall mean change was 0.96±0.40N. Selfy- JJ group reported significant difference between 0 month-4 months interval (0.0005). The percentage change in force between 0-4 months was 19.60%. The overall mean change was 0.9±0.45N. On comparing the At-Ease Modern group a significant difference between 0 month-4 months interval (0.0002) was found. The percentage change in force between 0-4 months was 51.17%. The overall mean change was 1.09±0.53N. The Ez-Lock Koden group also reported significant difference between 0 month-4 months interval (0.0001). The percentage change in force between 0-4 months was 7.17%. The overall mean change was 1.03±0.49N. Comparison of force between 4 different groups reported a significant difference between all the pair groups at 0 months & 2 months. ($P<0.05$). Regarding 1 month & 4 months, significant difference between most of the pair groups except Damon vs Modern ($P>0.05$) was reported.

	FORCE AT 0 MONTH(N) (Subgroup A)	FORCE AT 1 MONTH INTERVAL(N) (Subgroup B)	FORCE AT 2 MONTHS INTERVAL(N) (Subgroup C)	FORCE AT 4 MONTHS INTERVAL(N) (Subgroup D)
	CONTROL	**EXPERIMENTAL**		
MEAN (N)	2.67	2.75	3.17	3.63
SD	0.40	0.45	0.44	0.41

TABLE 11: Measurement of shutter opening force in **GROUP 1: DAMON – ORMCO**

	FORCE AT 0 MONTH(N) (Subgroup A)	FORCE AT 1 MONTH INTERVAL(N) (Subgroup B)	FORCE AT 2 MONTHS INTERVAL(N) (Subgroup C)	FORCE AT 4 MONTHS INTERVAL(N) (Subgroup D)
	CONTROL	**EXPERIMENTAL**		
MEAN (N)	4.59	4.65	4.97	5.49
SD	0.43	0.47	0.46	0.47

TABLE 12: Measurement of shutter opening force in **GROUP 2: SELFY - J J Orthodontics**

	FORCE AT 0 MONTH(N) (Subgroup A)	FORCE AT 1 MONTH INTERVAL(N) (Subgroup B)	FORCE AT 2 MONTHS INTERVAL(N) (Subgroup C)	FORCE AT 4 MONTHS INTERVAL(N) (Subgroup D)
	CONTROL	**EXPERIMENTAL**		
MEAN (N)	2.13	2.24	2.55	3.22
SD	0.55	0.49	0.55	0.50

TABLE 13: Measurement of shutter opening force in **GROUP 3: AT-EASE - MODERN Orthodontics**

	FORCE AT 0 MONTH(N) (Subgroup A)	FORCE AT 1 MONTH INTERVAL(N) (Subgroup B)	FORCE AT 2 MONTHS INTERVAL(N) (Subgroup C)	FORCE AT 4 MONTHS INTERVAL(N) (Subgroup D)
	CONTROL	**EXPERIMENTAL**		
MEAN (N)	3.79	3.91	4.26	4.82
SD	0.45	0.42	0.41	0.58

TABLE 14: Measurement of shutter opening force in **GROUP 4: EZ-LOCK - KODEN Orthodontics**

Discussion

DISCUSSION

Self-ligating brackets introduced by **Dr. Jacob Stolzenberg** are bracket systems that do not use ligature wires or elastic ligatures to engage arch wires into their bracket slots. Rather they have their own locking mechanics incorporated into the bracket itself. The primary motive for introducing the Self-ligating brackets was to quicken the process of arch wire removal and placement but the manufacturers claim that one of its main advantages is reduced friction thereby leading to low force values which accelerate tooth movement.[18] Brackets act as handles for the arch wire to transfer the force in any fixed appliance system. Hence the shutters in the SLB's play an important role in the self-ligating system.[70]

Ideally, a shutter should be free to slide during opening for a smooth and fast appointment and easy engagement of arch wire in the slot, throughout the treatment. The evaluation of force needed to open the shutter is essential because discomfort is a potential problem during fixed appliance orthodontic treatment. Due to this reason opening forces should not exceed the normal in order to reduce discomfort in changing the arch wire or during the reactivation time.

As it is of complex shape, proper cleaning becomes a challenge to the patient as well as the clinician. Many clinicians have come up with the argument, that they face difficulty in opening the shutter due to debris and calculus buildup especially in patients with poor oral hygiene, but there is lack of evidence for this. No study has been done to find out the effect of debris and calculus in the efficiency of shutters in self- ligating brackets.

The hypothesis tested in this study was whether the calculus has an effect in the efficiency of shutters in passive self-ligating brackets. The study had 4 main groups of 4 different self-ligating brackets (Damon- Ormco, Selfy – JJ Orthodontics, At-Ease Modern and Ez-Lock Koden). Each group was divided into 4 subgroups of 10 sample each. Subgroup A, the control subgroup where force of opening the shutter (initial opening force) is measured before immersing in artificial

saliva with calcifying solution. Experimental subgroups, included the subgroup B, subgroup C and subgroup D where the force to open the shutter was measured after immersing in artificial saliva with calcifying solution after 1 month, 2 months and 4 months interval respectively, using Instron Universal Testing Machine.

The effect of calculus in the efficiency of the shutter was assessed by comparing the initial shutter opening force i.e. force at 0 month with force required to open the shutter at 1 month, 2 months and 4 months interval.

The initial mean force to open the shutter i.e. at 0-month N for Damon brackets was 2.67±0.40N, 2.75±0.45N for 1 month, 3.17±0.44N for 2 months and 3.63±0.41N for 4 months interval. We can see the force level increase gradually as the interval increases. The initial mean force to open the shutter for JJ brackets were 4.59±0.43N, 4.65±0.47N for 1 month, 4.97±0.46N for 2 months and 5.49±0.47N for 4 months. Similar to Damon brackets, JJ brackets also showed an increase in force as the interval increases. The initial mean force to open the shutter for Modern brackets were 2.13±0.55N, 2.24±0.49N for 1 month, 2.55±0.55N for 2 months, 3.22±0.50N for 4 months. Similar to Damon and JJ brackets, Modern brackets also showed an increase as the interval increases. The initial mean force to open the shutter for Koden brackets were 3.79±0.45N, 3.91±0.42N for 1 month, 4.26±0.41N for 2 months and 4.82±0.58N for 4 months. Similar to Damon, JJ and Modern brackets, Koden brackets also showed an increase as the interval increases.

Hence, when comparing the initial opening force with 1 month, 2 months and 4 months interval of each bracket group, there was an increase in the amount of force required to open the shutter as the interval increases in all the 4 groups of SLB's. Comparing the 0 month and 1 month, interval increase in force was seen in all the 4 groups but there was no significant difference in any group. Comparing the 0 month and 2 months interval increase in force was seen in all the 4 groups but there was no significant difference in any group.

On comparing the 0 month and 4 months interval, significant increase in force was seen in all the groups, increase of about 0.96N in Damon, 0.90N in JJ, 1.09N in Modern and 1.03N in Koden, where Modern brackets showed the highest increase and JJ brackets the least. The result shows that plaque and their calcification have an effect in the efficiency of shutters of self-ligating brackets by increasing the amount of force required to open the shutter.

Comparing the initial force required to open the shutter between the groups mean was measured 2.67N for Damon brackets, 4.57N for JJ brackets, 2.13N for Modern brackets and 3.79N for Koden brackets. Thus, results show initial opening is greatest for JJ brackets followed by Koden brackets, Damon brackets and least for Modern brackets.

According to study by Eliades[58] when these materials are exposed in the oral cavity, properties of the shutter might get changed. Material composition of clip used in SLB's such as metals, alloys, Niti and ceramics may undergo degradation in the oral cavity. This might adversely affect the effectiveness of the ligating mechanism of self-ligating brackets.[58] In a study by Harradine[11] aging of these materials in oral cavity occurs by calcification of adsorbed complexes of ions and proteinaceous matter which might alter the morphological, structural, compositional and mechanical properties of orthodontic alloys and polymers. The precipitation of ion occurs followed by protein adsorption and formation of a biofilm which later calcifies.[11] These studies are in concordance with the result obtained in this study.

An undeniable difference between all SLBs and their conventional counterparts is the lack of an elastomeric to keep the arch wire in place. This presents some obvious potential advantages, but not in terms of maintaining oral hygiene and promoting both gingival and periodontal health during treatment. However, the opening and closing mechanism associated with SLBs may itself have some impact on plaque retention, depending upon the design, but currently there is very little data relating to how SLB's perform in relation to these parameters.[96]

Orthodontic full-fixed appliance therapy may complicate oral hygiene[26,27] resulting in significant biofilm accumulation around the brackets bases.[36] Studies by Longoni and Ren et al.[26] showed that because of their design and lack of metal and elastomeric ligatures, self-ligating brackets, according to the producers, are less prone to bacterial colonization [26,27]. However, it is controversial if using self-ligating systems' opening and closing mechanisms and removing the ligatures from conventional brackets can lessen the adherence of microbes and the formation of biofilm[27]. In everyday orthodontic treatment, the issue of plaque buildup around brackets persists despite advancements in bracket technology,[26] which is in support to our study.

Furthermore, several studies by Chang and Scheie et al.[98,99] have already observed that SM levels significantly increase during orthodontic treatment.[98,99] However, according to data collected by a systematic review by Arnold et al.[100], the periodontal status of orthodontic patients seems to remain equally altered, whether by the use of conventional or self-ligating brackets.

Systematic review by Arnold et al.[100]compared the influence of SLBs and conventional brackets on plaque accumulation, gingival and periodontal health, have gone some way in showing that SLBs do not seem to perform any better than conventional brackets in terms of these variables which gives a similar result to our study.

Different studies by Gwinnett[101], do Nascimento[102] and Pandis[103] have suggested that the scientific literature has no consensus affirming whether the choice of self-ligating or conventional brackets should be made to avoid the increase in biofilm formation and adhesion of Streptococcus mutans to the dental surface.[103]

Paola Gandhini et al.[69] evaluated the opening and closure forces of sliding mechanisms of different SLB’s using Instron Universal Testing machine. They used Carrnere LX- ortho organizers; F1000, Leone; Damon-Q, Ormco) in their study.

Opening forces were registered between 1.1 N and 5.6 N. Significant differences were found among different brackets and between two prescriptions tested in their study.

There is a variability in the force needed to open or close the bracket for each tooth in the same appliance type used. This may be due to the different bracket shape and size and also depends on the tooth position in the mouth, The values were almost similar to the opening force for brackets used in this study, so clinician should consider this information when treating each patient.

Other factors which can alter the stiffness variation may be oxidation of material exposed to the oral environment for a long time. Theodore Eliades and Christoph Bourauel[58] analyzed the variety and potency of various aging variables affecting the morphology, structure and mechanical properties of polymeric and metallic orthodontic materials. They stated that the chance for ageing on spring component of self-ligating brackets adversely affect the ligation force while considering the intra oral environment giving a result similar to our study.

Grace Kelly, Martins Carneiro et al.[97] in a study concluded that there were significant changes in the stiffness of the clip among the various self-ligating brackets after repetitive opening and closure movements. But repetitive opening and closure movements of the clip did not cause plastic deformation. Their results were comparable to our results.

Recent studies by Smith, Hain, Nascimento and Pithon et al.[106] have demonstrated that self-ligating brackets favor a higher colonization of Streptococcus mutans and accumulate more biofilm compared with conventional brackets with steel wire ligation[75,105,106]. The result obtained were in concordance with our results.

Raıssa Costa Araujoa[108] compared the degree of debris and friction of conventional and self-ligating brackets. Self-ligating and conventional brackets, when exposed to the intraoral environment, showed a significant increase in frictional force during the sliding mechanics since debris accumulation was higher for the self-

ligating system[107,108], giving a result supportive giving a result which is supportive to our study.

Retrospective studies by Eberting et al.[17], Harradine[18] and Fleming et al.[109] found significantly decreased total treatment time and fewer visits with self-ligating brackets. With reduced friction and hence less force needed to produce tooth movement, self-ligating brackets are proposed to have the potential advantages of producing more physiologically harmonious tooth movement by not overpowering the musculature and interrupting the periodontal vascular supply, which was not in accordance with our study, may be because of a good oral hygiene maintenance by the patients.

However, in support to our study, a large retrospective study by Harradine [51] and prospective studies by Harradine and Pandis[18], have found no measurable advantages in orthodontic treatment time, the number of treatment visits, and time spent in initial alignment with self-ligating bracket over conventional brackets.

The shutter should never open accidently, leading to loss of tooth control, the SLB's should have a ligating mechanism that never breaks or distorts throughout the treatment. It should have a properly open clip or slide position so that clip or slide does not hinder the view of bracket slot over actual placement of the arch wire. A damaged clip especially in active /interactive types, affects the magnitude of force applied on the arch wire which hinders all the benefits of self-ligating brackets.[97]

It is of importance to discuss the possible consequences of increase in the force required to open the shutter. Breakage or deformation of the shutter that may further inhibit tooth movement, requiring larger retraction forces and leading to anchorage taxation is an important consequence. Debonding of the bracket due to excess force and slippage of the key that is used to open the shutter, causing injury to the oral tissues are some of the possible consequences. Owing to the high cost of the self-ligating brackets such consequences are a major drawback to the system.

Formation of calculus deposit around the brackets as the inter appointment interval increases can thus increase the force required to open the shutter causing deformation and breakage of the shutter and even inadvertent slippage of the instrument leading to injury to the patient. Regular monthly appointment and periodic opening and closing of the shutter can prevent the calculus buildup along with proper oral hygiene measures. So, the clinician should consider all these factors during the treatment and selecting an appliance system.

Thus, evidence on the advantages of self-ligation appears to be mixed and other well conducted studies are needed to evaluate the various claims made by the proponents of self-ligating bracket system. The literature is less about the degradation of the clip and effect of debris, plaque and calculus in the efficiency of shutter and their possible effect on friction during the orthodontic treatment, so, more studies should be done on this topic. Further researches should be conducted to test other clinical features that might compromise the clip integrity.

The great technological advancements that have occurred in the last years have brought research-based findings that have constantly led to the development of new materials and techniques.[110] These improvements are claimed to simplify the clinical procedures, but many commercially available orthodontic materials have been experimentally evaluated in laboratories[112] but not all aspects were tested to confirm their efficiency and effectiveness.

The evaluation of the opening and closure forces necessary to allow the slide of the mechanism is necessary because discomfort is a potential side effect during fixed appliance orthodontic therapy[114]. This can negatively influence the desire to undergo treatment[113], compliance, and treatment outcome[115]. For these reasons, opening and closure forces should not be excessive in order to reduce discomfort when changing the arch wire or reactivating the appliance.

Mechanistic view of orthodontics is misleading and so self-ligating brackets and their peculiar characteristics are only a component of orthodontics. We suggest

further studies to evaluate the long-term effects of intraoral aging on self-ligating brackets. Further studies are necessary to evaluate the effect of increase in force to open the shutter on friction and sliding mechanics in self-ligating brackets.

This study gives an insight into the importance of regular monthly appointments and maintaining a good oral hygiene even with self-ligating brackets.

LIMITATIONS OF THE STUDY

1) As this study was done in an In-Vitro setup, the results cannot be conclusive as the intra oral environment is different.

2) All the investigations have been conducted under ideal laboratory conditions, where as in oral cavity the factors like natural saliva, mastication, food habits, oral hygiene measures and other variables can influence the shutter sliding force.
3) In In-Vitro setup, the artificial saliva is in a static state whereas intraorally the saliva is in a dynamic flowing state that can influence the calcification process.

FUTURE SCOPE OF THE STUDY

- For better and accurate measurements of the force required to open the shutter after each interval, the study has to be conducted in an In-Vivo environment.

- It would be helpful to perform the same research in terms of effect of calculus in the friction in sliding mechanics in self-ligating brackets.

Conclusion

CONCLUSION

This in vitro study evaluated the effect of calculus in the efficiency of shutters in passive self-ligating brackets by comparing the change in amount of force required to open the shutter after immersing the brackets in artificial saliva with calcifying solution at 3 intervals (1 month, 2 months and 4 months) among 4 different self-ligating bracket types such as Damon brackets, JJ brackets, Modern brackets and Koden brackets.

From the results obtained from the study, following conclusions were drawn.

1) There was an increase in the amount of force required to open the shutter as the interval increases.
2) Comparing the initial opening force (0 month) with 1 month and 2 months interval, increase in force was seen but was not significant.
3) Comparing the 0 month and 4 months interval, significant increase in force was seen.

From the study it is concluded that as the interval of opening the shutter increases in self-ligating brackets in patients with poor oral hygiene or in patients with salivary composition favoring rapid calculus formation, the force required to open the shutter will also increase and a significant increase was seen in a 3-month gap between the appointments. The findings of this study indicate that the opening and closing mechanism associated with SLBs may itself have some impact on plaque retention that later calcify as the appointment interval increases and affect the efficiency of shutter. Hence similar to conventional bracket, patients having SLB's should also be instructed with monthly visit and oral hygiene measures.

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Annexures

Annexure 1: MASTER CHART

SHUTTER OPENING FORCE - GROUP 1: DAMON –ORMCO

SAMPLE NUMBER	OPENING FORCE AT 0 MONTH (N) (Subgroup A)	OPENING FORCE AT 1 MONTH INTERVAL (N) (Subgroup B)	OPENING FORCE AT 2 MONTHS INTERVAL (N) (Subgroup C)	OPENING FORCE AT 4 MONTHS INTERVAL (N) (Subgroup D)
1	2.3	2.3	2.7	3.6
2	3.2	3.3	3.5	4.2
3	2.2	2.2	2.8	2.9
4	2.6	2.6	3	3.3
5	3	3.1	3.8	4
6	2.8	2.8	3.3	3.6
7	3	3.1	3.5	4.1
8	2.3	2.3	2.7	3.5
9	2.1	2.3	2.6	3.1
10	3.2	3.5	3.8	4

Annexure 2: MASTER CHART

SHUTTER OPENING FORCE - GROUP 2: SELFY- JJ ORTHODONTICS

SAMPLE NUMBER	OPENING FORCE AT 0 MONTH (N) (Subgroup A)	OPENING FORCE AT 1 MONTH INTERVAL (N) (Subgroup B)	OPENING FORCE AT 2 MONTHS INTERVAL (N) (Subgroup C)	OPENING FORCE AT 4 MONTHS INTERVAL (N) (Subgroup D)
1	4.3	4.4	4.8	4.9
2	5	5.2	5.6	5.9
3	5.1	5.1	5.3	5.9
4	4.7	4.8	5	5.8
5	4	4	4.4	5
6	4.3	4.3	4.8	5.4
7	5.2	5.2	5.6	6.1
8	5	5.2	5.4	6
9	4.3	4.3	4.4	5
10	4	4	4.4	4.9

Annexure 3: MASTER CHART

SHUTTER OPENING FORCE - GROUP 3: AT-EASE-MODERN

SAMPLE NUMBER	OPENING FORCE AT 0 MONTH (N) (Subgroup A)	OPENING FORCE AT 1 MONTH INTERVAL (N) (Subgroup B)	OPENING FORCE AT 2 MONTHS INTERVAL (N) (Subgroup C)	OPENING FORCE AT 4 MONTHS INTERVAL (N) (Subgroup D)
1	2.4	2.4	2.8	3
2	1.1	1.3	1.8	2.5
3	3	3	3.6	4.1
4	2.5	2.6	3	3.9
5	1.7	1.9	2	2.8
6	1.8	1.8	2	2.9
7	2	2.2	2.2	3
8	2.6	2.6	2.8	3.5
9	2.4	2.6	2.8	3
10	1.8	2	2.5	3.5

Annexure 4: MASTER CHART

SHUTTER OPENING FORCE - GROUP 4: EZ-LOCK - KODEN

SAMPLE NUMBER	OPENING FORCE AT 0 MONTH (N) (Subgroup A)	OPENING FORCE AT 1 MONTH INTERVAL (N) (Subgroup B)	OPENING FORCE AT 2 MONTHS INTERVAL (N) (Subgroup C)	OPENING FORCE AT 4 MONTHS INTERVAL (N) (Subgroup D)
1	3.2	3.3	3.5	4
2	4.6	4.6	4.9	5.5
3	4.1	4.2	4.6	5.1
4	3.5	3.6	4	4.8
5	3.5	3.5	4	4
6	4	4.3	4.7	5.5
7	3.6	3.8	4.1	5
8	3.2	3.5	4	4.1
9	4.1	4.1	4.4	5.2
10	4.1	4.2	4.4	5

Annexure 5: Informed Consent (English)

I hereby give consent for my son/daughter…….to be part of the study "Comparative Evaluation of the Effect of Calculus in the Efficiency of Shutters in Passive Self ligating brackets: An In Vitro Study″, held at the Department of Orthodontics, St. Gregorios Dental college, Kothamangalam. I have been informed in detail in the language known to me, about the study. My son/daughter's participation in the study is entirely voluntary & our decision to discontinue the participation will not have any negative effect on child's dental care. I understand that our details will be kept confidential & I hereby grant permission /consent to Department of orthodontics & dentofacial orthopaedics to take plaque sample from my son/daughter's mouth for using in dissertation and for academic publications.

Parent signature/Thumb impression with date:

Patients signature/Thumb impression with date:
Address:
Contact number:
Witness name & signature
1.
2.

DR…….
Post graduate student)

DR……
(Professor& guide)

Annexure 6: Informed Consent (Malayalam)

സമ്മതപത്രം

സെന്റ് ഗ്രിഗോറിയസ് ഡെന്റെൽ കോളേജിലെ, ഓർത്തോഡോണ്ടിക്സ് വിഭാഗം നടത്തുന്ന "പാസിവ സെൽഫ് ലൈഗേറ്റ്ബ്രാക്കറ്റ്ൻറെ ഷട്ടറുകളിൽ അഴുക്ക് അടിഞ്ഞുകൂടുന്നതിൻറെ ഫലമായി അതിൻറെ കാര്യക്ഷമതയിൽ ഉണ്ടാകാവുന്ന വ്യതിയാനത്തിൻറ താരതമ്യ മൂല്യനിർണയ പഠനത്തിൽ" എന്റെ മകൾ/മകന്..... പങ്കെടുക്കാൻ എനിക്ക് സമ്മതമാണ്. പഠനത്തെക്കുറിച്ചുള്ള എല്ലാ വിവരങ്ങളും എനിക്ക് അറിയാവുന്ന ഭാഷയിൽ എന്നോട് വിവരിച്ചിട്ടുണ്ട്. ഏത് നിമിഷവും പഠനത്തിൽ നിന്നും പിന്മാറാം എന്നും, ഇത് തുടർന്നുള്ള എന്റെ മകളുടെ / മകന്റെ ചികിത്സയെ ബാധിക്കില്ലെന്നും, ചികിത്സാ വിവരങ്ങളുടെ സ്വകാര്യത നഷ്ടപ്പെടുത്താതെ സൂക്ഷിക്കുമെന്നു ഉറപ്പ് നൽകിയിട്ടുണ്ട്. ഇതിന്റെ ഭാഗമായി വായിൽനിന്നും അഴുക്ക് ശേഖരിക്കുന്നതിന് എനിക്ക് സമ്മതമാണ്.

പേര്

ഒപ്പ്/വിരലടയാളം

രക്ഷകർത്താവിന്റെ പേര്
ഒപ്പ്/വിരലടയാളം

തിയതി

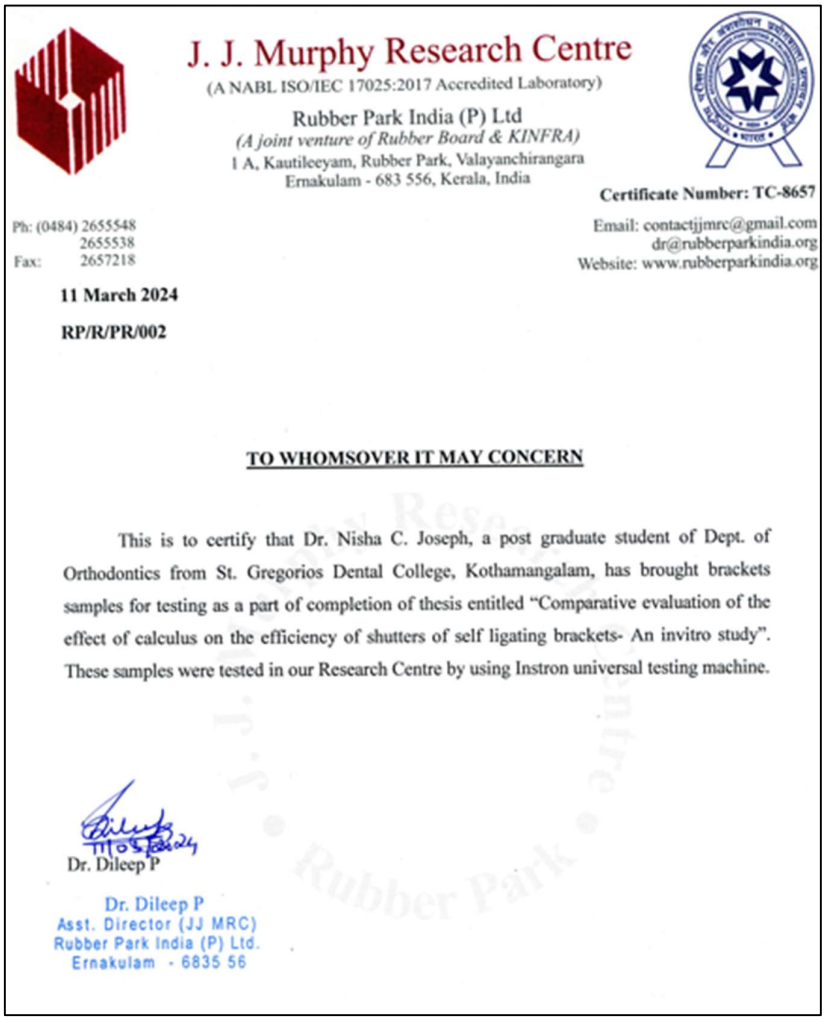
വിലാസം

സാക്ഷിയുടെ പേര്
ഒപ്പ്/വിരലടയാളം

ഡോക്ടർ.....
പി ജി സ്റ്റുഡന്റ്

ഡോക്ടർ.....
പ്രൊഫസർ/ഗൈഡ്

Annexure 7: Certificate



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11 March 2024

RP/R/PR/002

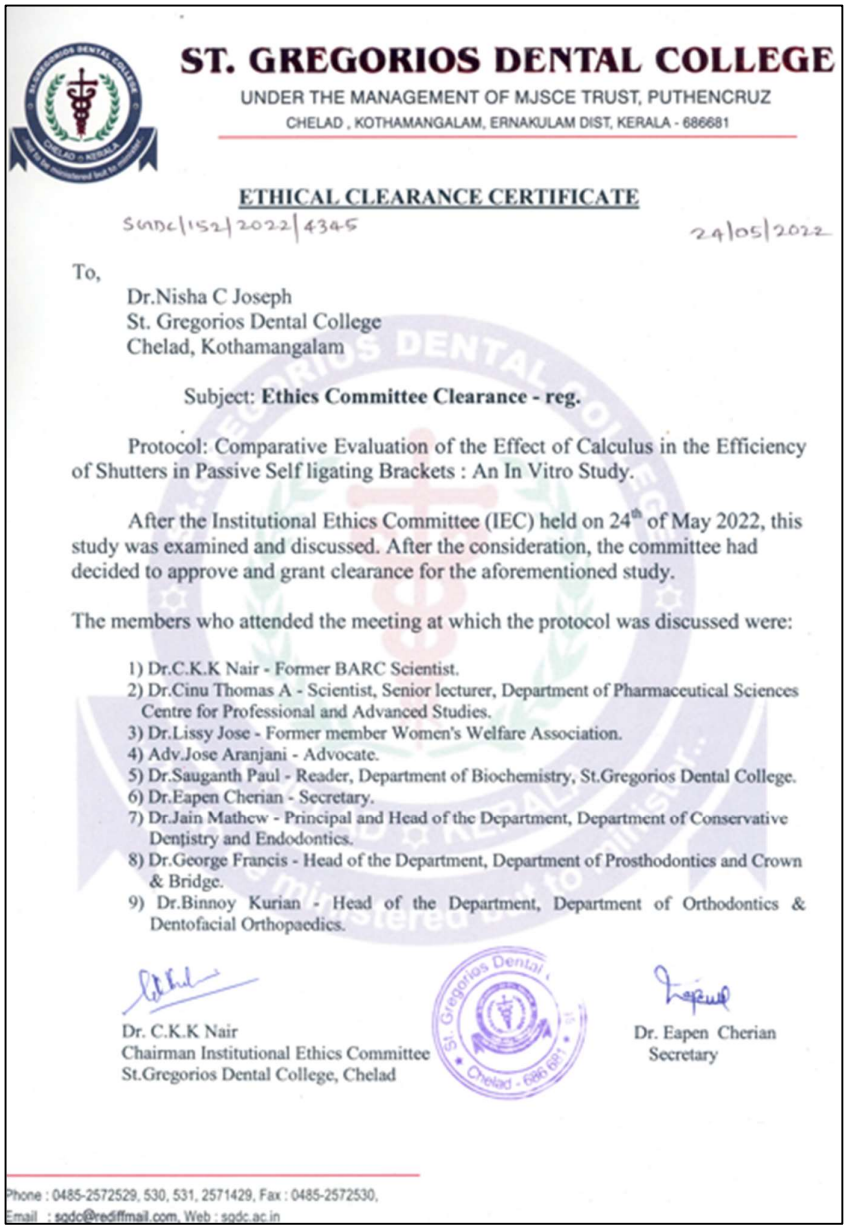
TO WHOMSOVER IT MAY CONCERN

This is to certify that Dr. Nisha C. Joseph, a post graduate student of Dept. of Orthodontics from St. Gregorios Dental College, Kothamangalam, has brought brackets samples for testing as a part of completion of thesis entitled "Comparative evaluation of the effect of calculus on the efficiency of shutters of self ligating brackets- An invitro study". These samples were tested in our Research Centre by using Instron universal testing machine.

Dr. Dileep P

Dr. Dileep P
Asst. Director (JJ MRC)
Rubber Park India (P) Ltd.
Ernakulam - 6835 56

Annexure 8: Ethical Clearance Certificate



ST. GREGORIOS DENTAL COLLEGE

UNDER THE MANAGEMENT OF MJSCE TRUST, PUTHENCRUZ

CHELAD , KOTHAMANGALAM, ERNAKULAM DIST, KERALA - 686681

ETHICAL CLEARANCE CERTIFICATE

SGDC/152/2022/4345 24/05/2022

To,

Dr.Nisha C Joseph
St. Gregorios Dental College
Chelad, Kothamangalam

Subject: **Ethics Committee Clearance - reg.**

Protocol: Comparative Evaluation of the Effect of Calculus in the Efficiency of Shutters in Passive Self ligating Brackets : An In Vitro Study.

After the Institutional Ethics Committee (IEC) held on 24th of May 2022, this study was examined and discussed. After the consideration, the committee had decided to approve and grant clearance for the aforementioned study.

The members who attended the meeting at which the protocol was discussed were:

1) Dr.C.K.K Nair - Former BARC Scientist.
2) Dr.Cinu Thomas A - Scientist, Senior lecturer, Department of Pharmaceutical Sciences Centre for Professional and Advanced Studies.
3) Dr.Lissy Jose - Former member Women's Welfare Association.
4) Adv.Jose Aranjani - Advocate.
5) Dr.Sauganth Paul - Reader, Department of Biochemistry, St.Gregorios Dental College.
6) Dr.Eapen Cherian - Secretary.
7) Dr.Jain Mathew - Principal and Head of the Department, Department of Conservative Dentistry and Endodontics.
8) Dr.George Francis - Head of the Department, Department of Prosthodontics and Crown & Bridge.
9) Dr.Binnoy Kurian - Head of the Department, Department of Orthodontics & Dentofacial Orthopaedics.

Dr. C.K.K Nair
Chairman Institutional Ethics Committee
St.Gregorios Dental College, Chelad

Dr. Eapen Cherian
Secretary

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Annexure 9: ACKNOWLEDGEMENT

I want to offer this endeavor to **God Almighty,** to the wisdom he bestowed upon me, the strength, peace of mind and good health to finish this research.

Expressing my infinite gratitude and indebtedness to my esteemed HOD, Professor, **Dr. Binnoy Kurian,** Department of Orthodontics and Dentofacial Orthopaedics, my inspiration for undertaking this study and for his constant support, immense knowledge, guidance and motivation throughout the course of my training as a post graduate student.

I sincerely thank **Dr. Tony Michael**, Professor, Department of Orthodontics and Dentofacial Orthopaedics for his noble support and advices which helped me throughout this study.

My Heartfelt thanks to our esteemed Principal **Dr. Jain Mathew** for his encouragement and support.

Extending my gratitude to my beloved teachers, **Dr. Renji K Paul, Dr. Abraham George, Dr. Deaby Miriam** and **Dr. Monisha J** for their continuous support to finish the work with perfection on time.

I am extremely thankful to **Dr. Anila S**, HOD, Professor Department of periodontology for sharing her knowledge and expertise in this study.

My most sincere gratitude to **Dr. Nandakumar**, HOD, Professor, Department of Orthodontics and Dentofacial Orthopaedics, Government Dental College, Kannur, as well as the other faculty members, **Dr. Ranjith Raveendran**, **Dr. Tradib Jayapal, Dr. Ashil Mohandas** who instilled a love for Orthodontics in me and trained me during my undergraduate days to be where I am today.

Thanking **Dr. Abdul Saheer**, HOD, Professor, Department of Public Health Dentistry, Malabar Dental College, for the statistical works and sharing his knowledge.

Thanking my friends **Dr. Neena Rahman**, **Dr. Athira Satheesan** and **Dr. Ruksana** for being my constant support and unfailing help in times of need.

Special Thanks to my batch mates **Dr. Vidhya K** and **Dr. Vidya SL** and to my seniors **Dr. Lisie P Mathew**, **Dr. Sreenath U P**, **Dr. Sarjin**, **Dr. Jose Nelson**, **Dr. Jishnu S** and **Dr. Kareena Kafeel** for their support.

I also thank my juniors **Dr. Sunil**, **Dr. Dhanya**, **Dr. Shikha** and mysub-juniors **Dr. Albert**, **Dr. Sreelakshmi** and **Dr. Sreeba** for their cooperation.

Above ground, indebted forever to my parents **Ouseph C C** and **Salikutty Ouseph**, my roots and wings, and my brother**, Nibin C Joseph** for his valuable support.

Words may fail to express the gratitude I have for my husband, **Capt. Joice K Joy** for being so understanding and putting up with me through the toughest times, pushing me farther than I thought I could go and being there for me at the end of the day.

I thank my little one, **Joanna Maria Joice** whose smile alone is enough to cheer me up. I hope I have been a good mother and that I have not lost too much during the tenure of my study.

Dr. NISHA C JOSEPH

Annexure 10: LIST OF ABBREVIATIONS

Sl.no	Abbreviation	Full form
1.	ASLB	Active Self ligating Bracket
2.	CB	Conventional Bracket
3.	DQ	Damon Q
4.	GBI	Gingival Bleeding Index
5.	GI	Gingival Index
6.	MBT	Mclaughlin Bennett Trevisi
7.	N	Newton
8.	OHI-S	Oral Hygiene Index -Simplified
9.	PI	Plaque Index
10.	PSLB	Passive Self ligating Bracket
11.	SLB	Self-ligating bracket
12.	SM	Streptococcus mutans
13	SWA	Straight Wire Appliance