
[All ETDs from UAB](#)

[UAB Theses & Dissertations](#)

2007

A Comparative Study of Nonextraction Treatment Efficiency Using Conventional Edgewise Brackets and Self-Ligating Brackets

Chad R. Reddick
University of Alabama at Birmingham

Follow this and additional works at: <https://digitalcommons.library.uab.edu/etd-collection>

Recommended Citation

Reddick, Chad R., "A Comparative Study of Nonextraction Treatment Efficiency Using Conventional Edgewise Brackets and Self-Ligating Brackets" (2007). *All ETDs from UAB*. 6702.
<https://digitalcommons.library.uab.edu/etd-collection/6702>

This content has been accepted for inclusion by an authorized administrator of the UAB Digital Commons, and is provided as a free open access item. All inquiries regarding this item or the UAB Digital Commons should be directed to the [UAB Libraries Office of Scholarly Communication](#).

A COMPARATIVE STUDY OF NONEXTRACTION TREATMENT EFFICIENCY
USING CONVENTIONAL EDGEWISE BRACKETS AND SELF-LIGATING
BRACKETS

by

CHAD R. REDDICK

P. LIONEL SADOWSKY, COMMITTEE CHAIR

ALEX JACOBSON

SANDRE MCNEAL

A THESIS

Submitted to the graduate faculty of the University of Alabama at Birmingham,
in partial fulfillment of the requirements for the degree of
Master of Science

BIRMINGHAM, ALABAMA

2007

A COMPARATIVE STUDY OF NONEXTRACTION TREATMENT EFFICIENCY
USING CONVENTIONAL EDGEWISE BRACKETS AND SELF-LIGATING
BRACKETS

CHAD REDDICK

ORTHODONTICS

ABSTRACT

Although there is a long history of self-ligating brackets in orthodontics, their popularity has peaked in recent years. Many private practice orthodontists have begun using these brackets because of perceived advantages they may offer. It is widely believed that the design features of most self-ligating brackets produce less friction between wire and bracket, faster archwire removal and ligation, better bracket engagement, and improved oral hygiene. If self-ligating brackets truly offer these benefits, their use may lead to more efficient treatment. The purpose of this study was to evaluate the nonextraction treatment efficiency of one self-ligating bracket system (In-Ovation™, GAC International, Bohemia, NY) versus conventional twin edgewise brackets (Ovation™, GAC International, Bohemia, NY) used in the same practice. Treatment duration, number of appointments, and number of archwires used per patient were compared within one private orthodontic practice. The total sample included 120 patients consecutively finished with each bracket type. After exclusions, there were 75 patients in the self-ligating (SL) group and 70 patients in the conventionally-ligated (CL) group. Overall, significantly fewer total appointments, scheduled appointments, and archwires were necessary to finish the SL patients compared to the CL patients. Following adjustment for age, gender, and Angle classification, scheduled appointments was the only parameter that remained significantly different between bracket groups.

When the bracket types were separated by Angle classification, Class I SL patients required significantly fewer total appointments, scheduled appointments, and archwires than Class I CL patients. No statistical differences were found for Class II or Class III patients for any efficiency measure. These results indicate that there is promise for self-ligation leading to more efficient orthodontic treatment. This study also suggests that Class I cases benefit more from the advantages of this bracket design.

ACKNOWLEDGEMENTS

The authors thank Drs. Stephen Sherman, Glen Cowan, Andre Ferreira, Firoz Rahemtulla, Mark Litaker, and the faculty members and residents of the Department of Orthodontics, University of Alabama School of Dentistry, Birmingham, Alabama.

TABLE OF CONTENTS

	<i>Page</i>
ABSTRACT.....	ii
ACKNOWLEDGEMENTS.....	iv
LIST OF TABLES.....	vi
LIST OF FIGURES.....	vii
INTRODUCTION.....	1
LITERATURE REVIEW.....	5
History.....	5
Advantages of Self-ligation.....	17
Frictional Characteristics.....	17
Chairtime requirements.....	35
Bracket Engagement.....	38
Oral Hygiene.....	39
Infection Control.....	40
Treatment Efficiency.....	41
A COMPARATIVE STUDY OF TREATMENT EFFICIENCY USING CONVENTIONAL EDGEWISE BRACKETS AND SELF-LIGATING BRACKETS.....	45
CONCLUSIONS.....	68
GENERAL LIST OF REFERENCES.....	69
APPENDIX	
A INSTITUTIONAL REVIEW BOARD FOR HUMAN USE APPROVAL FORM.....	73
B INSTITUTIONAL REVIEW BOARD WAIVER OF INFORMED CONSENT.....	74

LIST OF TABLES

<i>Table</i>	<i>Page</i>
1 Sample characteristics.....	54
2 Regression models adjusted for gender, age, and Angle classification	56

LIST OF FIGURES

<i>Figure</i>	<i>Page</i>
1 Russell attachment in the open position.....	6
2 Russell attachment in the closed position.....	6
3 Edgelok bracket in the open position.....	7
4 Edgelok bracket in the closed position.....	7
5 Mobil-lock bracket in the open position.....	8
6 Mobil-lock bracket in the closed position.....	8
7 SPEED bracket in the open position.....	9
8 SPEED bracket in the closed position.....	10
9 Time bracket in the open position.....	11
10 Time bracket in the closed position.....	11
11 Damon SL bracket in the open position.....	12
12 Damon SL bracket in the closed position.....	13
13 Damon 3 bracket in the closed position.....	13
14 Damon 3 MX bracket in the closed position.....	14
15 Twin Lock bracket in the open position.....	15
16 Twin Lock bracket in the closed position.....	15
17 Frontal view of the In-Ovation R bracket in the closed position.....	16
18 Side view of the In-Ovation R bracket in the closed position.....	17

INTRODUCTION

Self-ligating brackets have become much more popular in recent years. Many private practice orthodontists have found their advantages to be so beneficial to their practices, a large number of clinicians have begun using these brackets exclusively. It is widely believed that the design features of most self-ligating brackets produce less friction between the wire and the brackets, faster archwire removal and ligation, better bracket engagement, and improved oral hygiene. If self-ligating brackets truly offer these benefits, their use may lead to more efficient treatment.

Some treatment efficiency measures include total duration of orthodontic treatment, number of appointments necessary to complete treatment, and the amount of supplies necessary to complete treatment. After analyzing these factors, it may be accurately determined whether the use of these appliances leads to an increase in treatment efficiency.

Friction plays an important role in orthodontic treatment. When using certain types of mechanics, it has been estimated that 50% of the orthodontic force applied is used purely to overcome the friction of the system.¹ Although the total friction of the system is dependent on a number of factors, friction from ligation (classical friction) is an important component. Stainless steel ligatures can be loosely tied to lower the level of classical friction, but this is at the expense of chairside time by the operator. Elastomeric ligation is very fast, but disadvantages include permanent deformation, decomposition, and force decay.²

According to Kusy and Whitley,³ classical friction may not be the primary contributor of this resistance to sliding. Another parameter that becomes important when the bracket and archwire are not passive is binding. Binding is increasingly important as the stiffness of the wire and the angle of entry into the bracket slot increase.⁴ Some frictional studies use a passive system that eliminates binding as a factor, while other investigations increase the angles of entry of the wire so binding becomes more of a factor. The overwhelming majority of frictional studies support the notion that friction decreases with the use of self-ligating brackets versus conventional edgewise brackets.⁴⁻²³ However, frictional differences depend on the bracket designs, methods of testing, and the binding introduced into the system. At large angles of entry, the effects from ligation method are diminished due to the increase in the binding variable.^{13,14,16,21,22}

Friction plays a role in routine orthodontic treatment, but it varies on the type of mechanics used. For space closure, friction-independent mechanics may be used (i.e. closing loops). Sliding mechanics involves sliding brackets along the archwire and friction plays an important role in this type of space closure.²⁴ Although friction-independent mechanics may be employed for space closure, the initial stages of leveling and aligning still rely heavily on the ability of the archwire to slide freely through the bracket, making friction an important aspect of every edgewise appliance, at least in the early phases of treatment.

In the early development of self-ligating brackets, the principal aim was faster ligation of the archwire into the bracket. With the invention of elastomeric ligatures, this advantage has probably diminished somewhat.²⁵ However, a number of studies have investigated the speed of ligation for self-ligating brackets compared with conventional

brackets and most investigations support the idea that using self-ligating bracket systems saves chairside time for the operator, at least to some extent.^{15,25-27}

While it has been suggested that self-ligating brackets have numerous advantages, it is still unclear whether these bracket design differences yield clinical improvements in treatment outcome or speed. If one bracket system is to be considered superior to another, it must produce higher quality results or it must be more efficient in treatment. Efficiency can be measured as cost to the patient and the clinician (time and money) to yield a result of equal quality for one appliance compared with another. This question has been investigated in only two studies, both involving comparisons of conventional twin brackets with Damon self-ligating brackets.

Harradine²⁵ compared thirty consecutively-treated Damon SL cases with thirty matched cases treated with conventional fully programmed brackets. One measure of treatment efficiency used in his study was the treatment time in months from first placement of fixed appliance to removal of fixed appliances. The other measure used was the number of appointments required during this time, including unscheduled appointments. The Damon SL and conventionally ligated bracket groups were essentially the same with regard to initial dental irregularity, and they also finished with very similar quality of treatment outcome. The Damon group spent an average of four fewer months in treatment. The Damon group also required an average of four less visits to complete active treatment.

In a study by Eberting et al,²⁸ cases treated with Damon brackets and those treated with conventional brackets were evaluated. This study not only compared the treatment time and number of appointments, but also assessed the quality of the treatment outcome

employing the American Board of Orthodontics (ABO) grading scale. In addition, a survey was sent to each of the 215 patients in the study to obtain the patient perceptions of how their treatment progressed and finished. The total sample of 215 was selected randomly from a pool of available patients treated with either Damon brackets or conventional brackets from three orthodontic practices.

Damon patients reported that their length of treatment was slightly shorter than expected whereas non-Damon patients perceived their treatment took longer than expected. With respect to treatment time, the patients in each of the three practices showed a significantly lower treatment time when treated with Damon brackets. The Damon patients were treated in significantly fewer appointments for completion in each of the three practices as well. For the combined samples, there was a difference of about six months and seven appointments per treatment. Damon patients also had significantly better ABO scores than patients with conventional brackets in the three practices combined.²⁸

The purpose of the present study is to evaluate nonextraction treatment efficiency of one self-ligating bracket system compared to a non self-ligating bracket system used in the same practice. Treatment duration, number of appointments, and number of archwires used per patient were compared within one private orthodontic practice to determine whether the change to self-ligation was beneficial with respect to efficiency measures for the clinician. Although it is only a sample of one orthodontic practice, the present study evaluated the self-ligating bracket system to further substantiate or refute the manufacturers' claims of increased treatment efficiency.

LITERATURE REVIEW

Orthodontic treatment efficiency has been a primary focus of clinicians and manufacturers in recent years. With this in mind, some clinicians have begun using self-ligating brackets because of the anticipated benefits. Some of the possible benefits include reduced frictional resistance, reduced chair time, and the promotion of better oral hygiene. Although success of self-ligation with respect to bracket sales is relatively recent, various self-ligating bracket designs have been introduced since the Russell attachment was first described in the early 1900's.²⁹

History

The first self-ligating appliance was introduced in 1935 and was composed of bands with Russell attachments. The attachments consisted of flat screws that fit into the faces of the brackets. This bracket was markedly different than contemporary self-ligating brackets in two ways. First, the slot cover was separated from the rest of the body each time a wire was to be replaced. Secondly, the cover, in this case a screw, could also be adjusted for tightness to make the bracket completely passive or active with the archwire.²⁹ The screw can even be tightened to the point of total binding, if desired. The developer of this bracket, Dr. Jacob Stolzenberg, found that the patients treated with this system were considerably more comfortable, with shorter office visits and shorter treatment time. It was developed with two distinct types: one, a 0.022 by 0.028-inch

channeled block for the edgewise technique; and the other, a 0.022 by 0.036-inch channel for the ribbon arch wire.³⁰

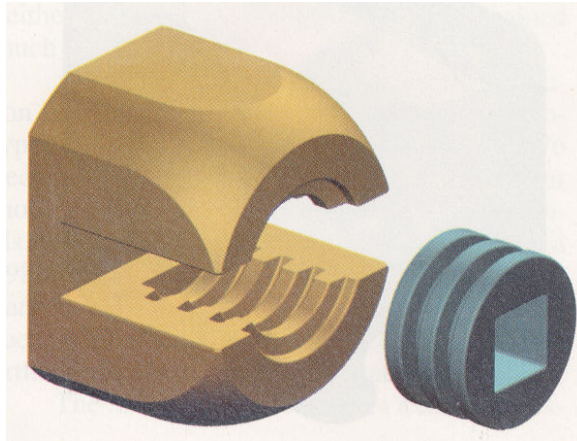


FIGURE 1. Russell attachment in the open position.

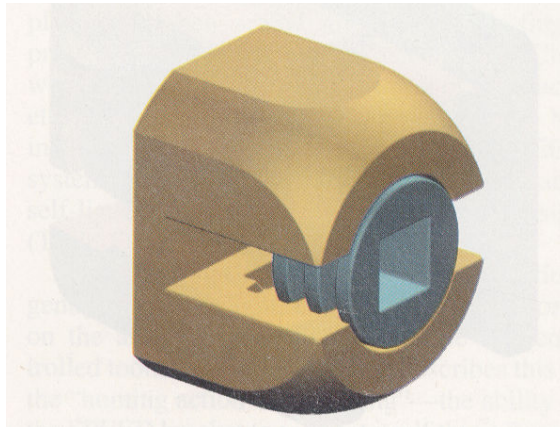


FIGURE 2. Russell attachment in the closed position.

There were various self-ligating bracket designs introduced in the following years, but none were commercially successful. In 1972, Ormco became the first large manufacturer to introduce a self-ligating bracket. The Edgelok bracket was welded to

bands like the Russell attachment. The bracket had a round body with a rigid labial sliding cap. After closure, the bracket was converted to a passive tube. The Edgelok was the first self-ligating bracket to enjoy any sort of commercial success.³¹ Its inventor, Dr. Jim Wildman, believed its automatic locking and unlocking, reliable action, complete control in all three planes of space and complete bracket engagement made this bracket superior to other brackets available at this time.³²

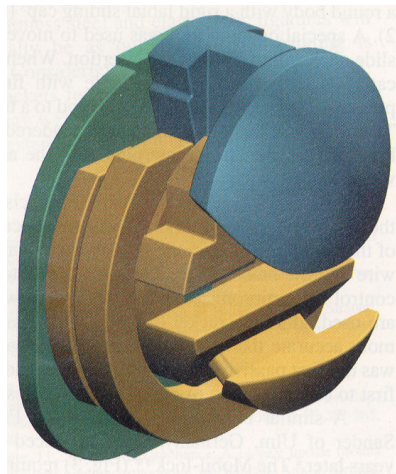


FIGURE 3. Edgelok bracket in the open position.

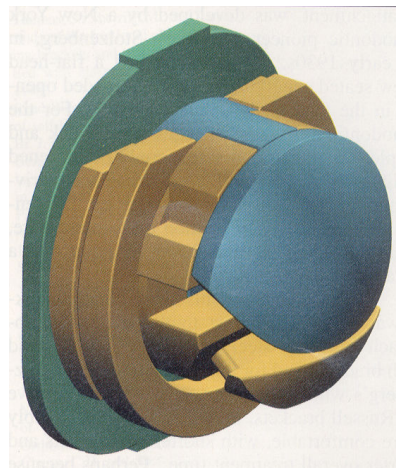


FIGURE 4. Edgelok bracket in the closed position.

Three self-ligating brackets of significance were introduced in the 1980s. The Forestadent Mobil-lock bracket had a similar design to the passive Edgelok bracket and was introduced in 1980.³¹ The bracket cover was a semicircular disk which was rotated into the closed position. The cover could be rotated enough to engage a larger diameter archwire, making it active in this configuration.

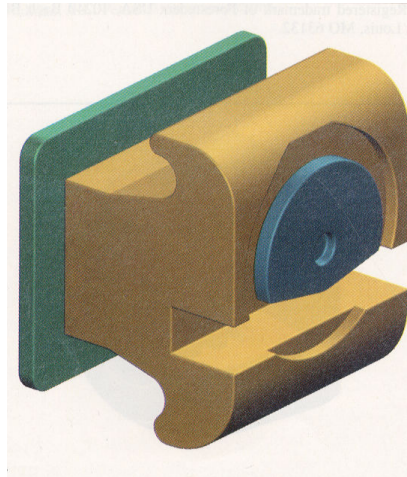


FIGURE 5. Mobil-lock bracket in the open position.

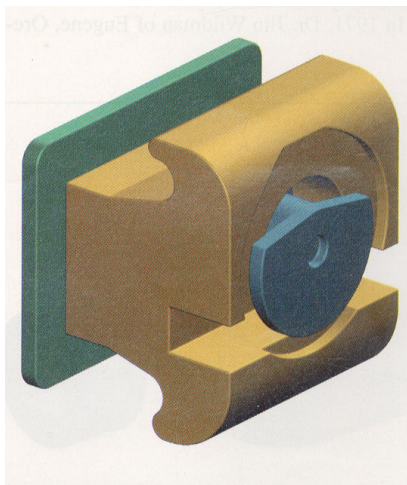


FIGURE 6. Mobil-lock bracket in the closed position.

At about the same time, the SPEED bracket was introduced to the market. SPEED is an acronym which stands the descriptive terms spring-loaded, precision, edgewise, energy, and delivery. This bracket was quite different than previous designs. Most notably, it employed a flexible spring clip that becomes active when it is displaced from its rest position. The force applied to the archwire by the flexible clip is more constant and resilient than that imparted by steel or elastic ligatures.³³ The clip of the SPEED bracket may be slid occlusally from the gingival side of the bracket with a scaler or ligature director.³⁴ According to Dr. G. Herbert Hanson, the bracket's inventor, the light forces lead to more patient comfort and improve the efficiency of tooth movement while decreasing treatment time.³³

Over the years, numerous design modifications and improvements of the SPEED bracket have led to commercial success. One modification was the introduction of mushroom hooks on posterior brackets to lessen the need for auxiliary tube hooks. A spring retainer slot was also added to hold the spring mechanism in the closed position.³⁵

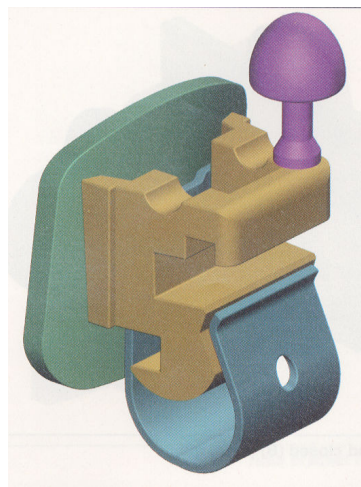


FIGURE 7. SPEED bracket in the open position.

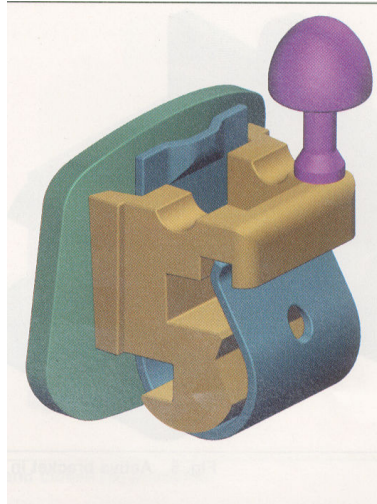


FIGURE 8. SPEED bracket in the closed position.

The Activa bracket was introduced by “A” Company in 1986. Its design included a rounded rigid arm that rotated occlusogingivally around the cylindrical bracket body.³¹ This bracket was passive like most of its predecessors and did not have any interaction with the archwire. Harradine and Birnie³⁶ believed the clinical advantages of this bracket were low friction, more certain archwire engagement, less chairside assistance, and the inclusion of a vertical slot for hooks and auxiliaries. It was thought the low friction was by far the largest advantage and it led to faster alignment and more certain space closure.

Disadvantages that have been suggested with the Activa bracket use include: higher bond failure rate, less convenience with elastomeric chain, unfamiliarity with the bracket, difficulty in holding and seating during bonding, impossibility of partial slot engagement, retaining clip breakage, and wire displacement due to the low friction.³⁶ Another author stated that the Activa brackets were so easy to open and close, patients were able to disengage the archwire and this led to the commercial failure of this bracket.³¹

In 1995, another self-ligating bracket was introduced, the Adenta Time bracket. In appearance, it is very similar to the SPEED bracket, but its ligating mechanism is very different. The slot cover is a rigid curved arm that originates on the gingival side of the bracket. This arm pivots occlusally into the closed position with the use of a special instrument. The rigidity of the slot cover is the main difference between the Time and SPEED brackets.³¹

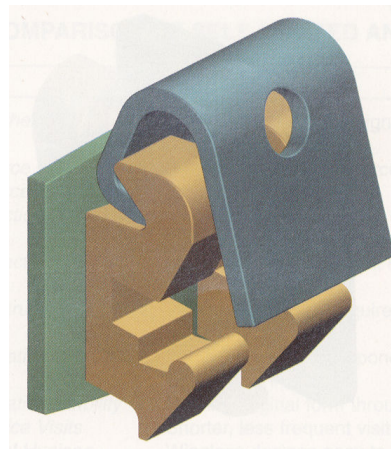


FIGURE 9. Time bracket in the open position.

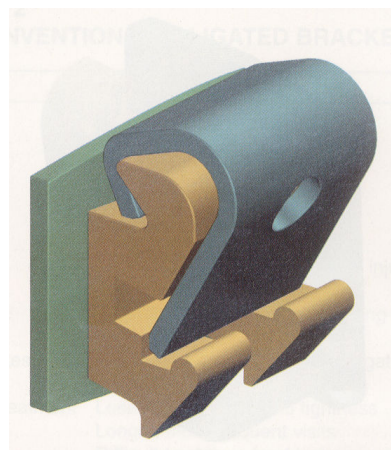


FIGURE 10. Time bracket in the closed position.

Dr. Dwight Damon invented the most commercially successful line of self-ligating brackets to date, the Damon brackets. The Damon SL I and SL II were introduced by “A” Company in 1996 and 1999, respectively. The only difference between these twin edgewise brackets is that the SL I featured a labial cover that straddled the tie wings and the SL II incorporated a flat slide between the tie wings. Both passive brackets incorporate a slide that moves incisally on the maxillary teeth and gingivally on mandibular teeth. Special opening and closing pliers were required to move the slide.³¹

The design criteria which were determined for the Damon SL bracket were: adherence to Larry Andrews’s straight-wire principles, twin bracket configuration, tube formation upon closure, downward opening slide mechanism, and a passive ligation mechanism. The advantage of a twin configuration is the easy bracket placement characteristics. Forming a passive tube has been thought to enhance torque by some. A bracket with downward opening slides allows the clinician and assistant enhanced visualization when engaging the archwire.³⁷

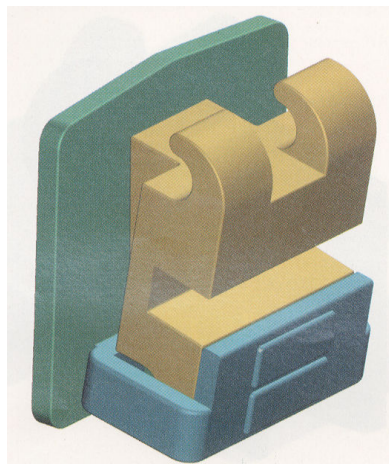


FIGURE 11. Damon SL bracket in the open position.

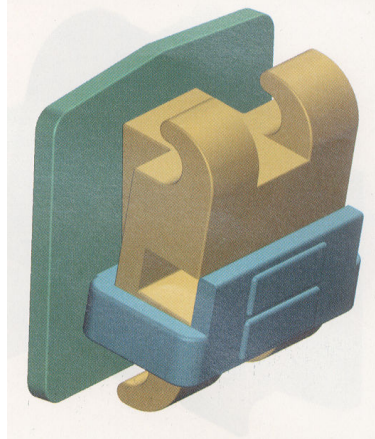


FIGURE 12. Damon SL bracket in the closed position.

Recently, the Damon 2, Damon 3, and Damon 3 MX brackets have been introduced. The Damon SL brackets were the predecessors of the Damon 2 brackets (introduced in 2000) and further improvements were made before the introduction of the Damon 3 MX brackets in 2005. All three of these are stainless steel brackets. The Damon 3 bracket, launched in 2004, is a combination of clear composite resin and stainless steel to provide a more esthetic alternative to self-ligation.

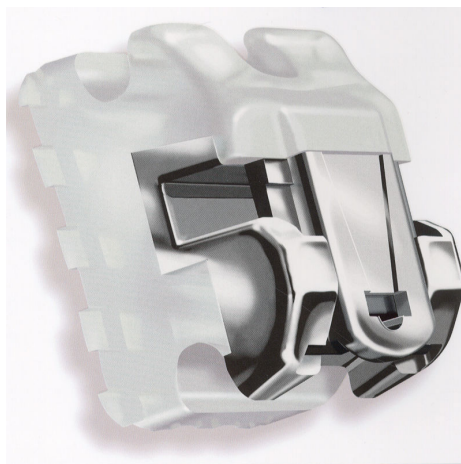


FIGURE 13. Damon 3 bracket in the closed position.



FIGURE 14. Damon 3 MX bracket in the closed position.

Damon³⁷ has found that teeth move more efficiently when they move individually. Passive self-ligating bracket systems are thought to allow low forces, low friction, and small dimension wires to be used early in treatment to permit the teeth to move on a more individual basis. The idea behind the Damon system is to allow optimum force levels for tooth movement and to allow the teeth to find their “physiologic” tooth position.

Proffit¹ suggested that optimum levels for tooth movement would be high enough to stimulate cell activity without completely stopping the blood supply to the periodontal ligament. Pain is related to the development of ischemic areas and inflammation in the periodontium. Using the Damon system, archwire changes and appointment intervals are timed to allow uninterrupted vascular supply to the periodontal ligament and surrounding bone.³⁸

Twenty-seven years after his first endeavor, the Edgelok bracket, Dr. Jim Wildman introduced the Twin Lock bracket. Starting in 1997, this bracket was manufactured by Ormco, as was Wildman’s previous bracket. The Twin Lock had a

rectangular slide that was occlusal when open and it was slid gingivally upon closure. The slide was housed between the tie wings of a twin edgewise bracket.³¹ The Twin Lock was a passive bracket as was Wildman's previous invention. Although this bracket did not achieve much success in sales, it did serve as the basis for the Damon 2 bracket, which also had its slide housed between the tie wings.

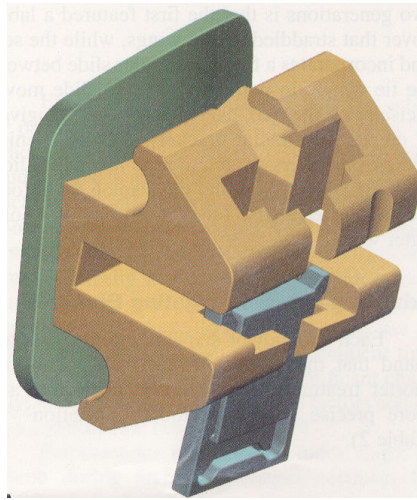


FIGURE 15. Twin Lock bracket in the open position.

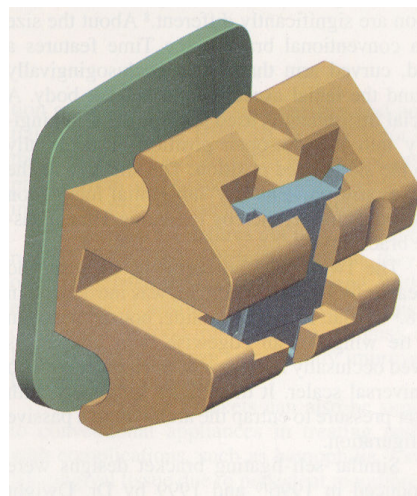


FIGURE 16. Twin Lock bracket in the closed position.

GAC introduced its first self-ligating bracket, In-Ovation, in 1999, with the smaller version for anterior teeth becoming available in 2001. After improvements in design the brackets are now manufactured under the name In-Ovation R. Clip failure had been a problem with past brackets,³⁹ but the In-Ovation bracket is easily converted to a traditional twin bracket if the clip fails. The standard sized bracket also has an additional horizontal slot which may be used for severely displaced or ectopic teeth with the use of a “piggy-back” technique. Distinguishing itself from other self-ligating brackets, In-Ovation is passive with smaller archwires, but begins actively engaging larger archwires. A 0.022 x 0.028-inch slot bracket first interacts with the archwire when the diameter exceeds 0.019-inch round or 0.018 x 0.025-inch rectangular wire. According to Parkin,³⁹ System-R combines fast and reliable ligation, low friction in the early stages of treatment, and precise control in later stages without compromising the final result. He has also found the security of ligation and absence of decaying forces allows for longer treatment intervals. Increased treatment intervals, along with reduced chair time for the patient and the operator result in an overall time savings.



FIGURE 17. Frontal view of the In-Ovation R bracket in the closed position.



FIGURE 18. Side view of the In-Ovation R bracket in the closed position.

Advantages of Self-Ligation

Frictional Characteristics

Laws of friction state that a frictional force is: 1) proportional to the force acting perpendicularly to the contact, 2) independent of the area of contact, and 3) independent of sliding velocity.⁴⁰ These “laws” do not always hold true. Considering the materials used in orthodontics, the first two may be considered accurate, but the relationship between friction and sliding velocity has not been validated.³

There are a number of other situations that must be considered when calculating friction in an archwire-bracket-ligature system. Friction may be affected by the direction and magnitude of the relative motion between the surfaces in contact, externally applied loads and/or displacements which can be due to orthodontic ligation, environmental conditions such as temperature and lubricants, surface characteristics, and material properties.¹⁴

Surface roughness may increase the amount of friction between bracket and archwire. Among wire alloys, stainless steel wires consistently outperform both nickel-titanium and beta-titanium (TMA) wires. Also, stainless steel brackets show lower friction than ceramic brackets when coupled with the same archwire.⁴¹

There are two types of friction. Static friction is the force to initiate movement, and kinetic friction is the force that resists movement already initiated. Most deem static friction as most important in orthodontics because tooth movement is not believed to be fluid. It is more likely that movement occurs in short tipping and uprighting movements.¹⁴

Force systems can be designed for space closure in two ways: with friction-independent mechanics or sliding mechanics. Using loops or levers, a force system may be employed that circumvents the need for limiting friction or applying large amounts of force to overcome friction. Teeth can also be moved by translation along the archwire with sliding mechanics, which can be largely affected by friction present in the system.²⁴ Although friction-independent mechanics may be employed for space closure, the initial stages of leveling and aligning still rely heavily on the ability of the archwire to slide freely through the brackets.

Frictional resistance occurs when sliding occurs between the bracket, wire, and ligature. It has been estimated that 50% of the orthodontic force applied is used purely to overcome the friction of the system.¹ This force is largely unknown; however, it is well established that the use of a ligature adds friction to the system. Elastomeric ligatures have also shown permanent deformation, decomposition, and force decay.²

Attempts have been made to create elastic ligatures that reduce the resistance to sliding normally attributable to the ligatures. Recently, Slide elastic ligatures have been developed by Leone Orthodontic Products. The innovative design allows the elastomeric ligature to form a tube-like structure with the slot, instead of actively pressing the wire into the bracket slot. This ligature has been found to significantly lower the amount of static and kinetic friction when compared with conventional elastomeric ligatures.⁴² The research investigating the frictional benefits of Super Slick modules (TP Orthodontics), a polymeric-coated ligature, has not been conclusive.^{8,9}

When speaking of a bracket-wire-ligature combination's resistance to sliding, conventional friction is not the only element that needs to be considered. According to Kusy and Whitley,³ classical friction may not even be the primary contributor of this resistance to sliding. Another parameter that becomes important when the bracket and archwire are not passive is binding. Binding becomes increasingly important as the angle of entry of the wire into the bracket slot increases. When the archwire contacts both edges of the slot walls as the bracket is angled relative to the archwire, the binding component begins to contribute to the resistance to sliding. The angle at which the archwire first contacts the edges of the slot walls is called the critical angle for binding.²² A third phenomenon called notching can occur, at which point all sliding motion ceases. Notching is especially important when the bracket is made of much harder material than the archwire. Each of these factors may affect the ability to carry out orthodontic tooth movement, but it is impossible to measure how much each contributes. Frictional studies usually measure the additive effects of all of these parameters.

The frictional characteristics of self-ligating brackets are probably the most notable advantages of using one of these appliance systems. Frictional resistance to archwire sliding is also one of the most studied areas of these brackets. Almost all related studies support the notion that there is reduced friction to sliding with self-ligating brackets when compared with conventionally ligated brackets.⁴⁻²³

The majority of published research on the resistance to archwire sliding uses a passive bracket set-up, where the brackets are already leveled and aligned. This design minimizes binding and pure friction should dominate the resistance. One such study by Sims and colleagues¹⁷ evaluated 0.022 x 0.028-inch slot Minitwin, Activa, and SPEED brackets. Four different dimensions of rectangular archwire were tested, and two types of polyurethane ligation were used on the conventional twin brackets (“O” and “figure 8”). This study concluded that there was a significant reduction in frictional resistance in the Activa brackets compared with the SPEED brackets. The passive Activa brackets demonstrated friction values of close to zero with all archwires. The SPEED brackets showed a reduction in friction of 50-70 percent when compared with the Minitwin brackets using elastomeric ties of the “O” configuration. The placing of “figure 8” ties increased friction by a factor of 70-220 percent compared to conventional ties. The results from this study could be expected because the SPEED bracket has some archwire interaction with its flexible arm, while the Activa bracket is passive. The normal force of ligation is also increased as the elastomeric ties are ligated in a “figure 8” pattern. This would increase the frictional resistance.

The Damon SL and Minitwin brackets were compared in a similar study by Kapur and colleagues.¹¹ The bracket slots were 0.0225 x 0.030-inch maxillary first premolar

brackets with standard Andrews prescription. Both brackets were mounted passively and the conventional brackets were ligated with elastic ligatures. The wires tested were 0.018 x 0.025-inch nickel-titanium and 0.019 x 0.025-inch stainless steel. With both archwires, the Damon SL bracket demonstrated significantly less kinetic friction than the Minitwin bracket; the difference being much more pronounced with the stainless steel wire. The frictional forces were about 2.5 times as great for the Minitwin bracket with nickel-titanium wire, but the forces were close to 20 times as great with the stainless steel wire. As would be expected, the friction was much greater with the nickel-titanium wire than stainless steel for the Damon SL bracket, most likely due to the material properties.³ However, this trend was unexplainably reversed for the Minitwin bracket.

Tecco et al⁴³ used an investigational design that incorporated 10 aligned brackets and tested the frictional resistance generated by conventional stainless steel (Victory Series, 3M Unitek), Time Plus (American Orthodontics), and Damon SL II brackets (SDS,Ormco). Archwire alloys of stainless steel, nickel-titanium, and beta-titanium were used in five different sizes (0.014, 0.016, 0.018, 0.016 x 0.022, 0.017 x 0.025, and 0.019 x 0.025-inch) with a total of 10 different archwires. This study found that Time Plus brackets generated significantly lower friction than both the Damon SL II brackets and the conventional brackets. However, Damon SL II brackets generated significantly lower friction with round wires when compared to the other brackets. The Damon SL II brackets had significantly higher friction than the Time Plus brackets when tested with rectangular wires. Beta-titanium wires showed higher frictional forces than the other alloys. As expected, all brackets had higher frictional values as the wire size increased.

In a 1998 investigation, Thomas et al²⁰ found Damon SL brackets to be superior to Adenta Time, TP Tip-Edge and “A” Company Standard Twin brackets with respect to frictional characteristics. This study used 5 different types of wires (0.014-inch nickel-titanium, 0.0175-inch multistrand stainless steel, 0.016 x 0.022-inch nickel-titanium, 0.016 x 0.022-inch stainless steel, and 0.019 x 0.025-inch stainless steel). The Damon SL bracket was found to have the lowest amount of friction with all wires, followed by the Time bracket, Tip-Edge bracket, and Standard Twin bracket. The 0.016 x 0.022-inch nickel-titanium wires produced higher frictional resistance than the same dimension stainless steel wires with all brackets.

In another investigation, Griffiths and colleagues⁸ studied the resistance to sliding of 3 types of elastomeric modules, self-ligating brackets, and monocrystalline brackets with 0.022-inch slots. The investigators used a passive design with straight lengths of 0.018-inch and 0.019 x 0.025-inch stainless steel wires in wet and dry states. The brackets used were Ormco’s Damon 2 and Inspire ceramic brackets. The Damon 2 brackets were evaluated with slide closed, as well as with the slide open with three different elastomeric ligatures (super-slick, round, and rectangular modules). The Inspire brackets were also tested with the different types of elastomeric ligatures. The results showed that the self-ligating brackets demonstrated virtually zero friction with each combination of wire and environmental condition. In all but two combinations, round modules provided the least resistance to sliding and rectangular modules the greatest, with super-slick modules in between the two. The monocrystalline ceramic brackets demonstrated greater resistance to sliding than stainless steel brackets. Testing in the wet

(lubricated) state, friction was reduced with .018-inch wires, but it increased for the 0.019 x 0.025-inch wires.

Hain and colleagues⁹ also studied the effect of ligation method on friction in sliding mechanics. They compared super-slick modules, regular modules in normal configuration and “figure 8”, stainless steel ligatures, and the SPEED self-ligating bracket. The 0.022-inch slot twin brackets evaluated were Victory Series, Minitwin and Clarity (metal-reinforced ceramic), all manufactured by 3M Unitek. The static friction was evaluated using 0.019 x 0.025-inch stainless steel archwires, in the dry and saliva-lubricated states. The investigators determined that the loosely tied steel ligatures were found to generate the least friction, followed by the super-slick modules, SPEED brackets, regular elastomeric ligation, and “figure 8” elastomeric ligation. These results differed somewhat from those of Griffiths et al,⁸ which showed the super-slick modules to be inferior to regular round elastomeric ligatures. It is also unexpected that the super-slick modules performed better than the self-ligating SPEED bracket, but the active arm of the SPEED bracket could have accounted for this difference.

In a recent study, Cacciafesta and colleagues⁷ evaluated friction of stainless steel and esthetic self-ligating brackets in various bracket-archwire combinations. The brackets compared included Ormco Damon SL II, Gestenco Oyster polycarbonate self-ligating brackets, and 3M Unitek Victory Series conventional stainless steel brackets. Conventional brackets were ligated with elastic ligatures. Three different orthodontic alloys (stainless steel, nickel-titanium, and beta-titanium) of three different dimensions (0.016-inch, 0.017 x 0.025-inch, and 0.019 x 0.025-inch) were investigated, for a total of 27 bracket-archwire combinations. The investigators found that the stainless steel self-

ligating brackets (Damon SL II) generated significantly lower static and kinetic frictional forces than both conventional stainless steel and polycarbonate self-ligating brackets, which showed no significant differences between them. All brackets displayed higher static and kinetic frictional forces as the wire size increased. Beta-titanium archwires were found to have significantly more frictional resistance than stainless steel and nickel-titanium archwires, but no differences were found between stainless steel and nickel-titanium archwires. This is somewhat surprising as most studies have shown stainless steel to be superior to nickel-titanium in this respect.³

Three separate parameters were evaluated in a 1994 study by Shivapuja and Berger.¹⁵ Frictional resistance, both static and kinetic, was evaluated in three self-ligating brackets, stainless steel twin brackets, and ceramic brackets. The self-ligating brackets tested were the Edgelok, Aactiva, and SPEED brackets. Both steel ligation (approximately 150 grams of ligation force) and elastomeric ligation were evaluated on the metal and ceramic twin brackets. In addition, the investigators studied the frictional resistance when using power modules, and the chair time requirements for ligating and removing archwires using each type of bracket.

The investigators did not find a significant difference in the static resistance of the three self-ligating brackets and the twin bracket with metal tie. Similarly, the twin metal bracket with the elastomeric ligature and the ceramic brackets with either the steel ligature or the elastomeric ligature showed greater kinetic resistance than the other four groups. When using elastic power modules, the SPEED bracket system displayed significantly greater frictional resistance than either the Aactiva bracket system or the Edgelok bracket system. The authors believe this is due to the extended contact between

the archwire and the power module with the design of the SPEED bracket. The investigators also note, however, that a mushroom hook has since been added to the bracket design, and this should improve its frictional characteristics with the use of power modules. The study also confirmed that an archwire could be tied and untied significantly faster with any of the self-ligating brackets when compared to elastomeric or steel ligatures. As expected, the discrepancy was much larger with steel ligatures.¹⁵

In 1990, Berger⁶ studied the force levels necessary to draw four different archwires through four ligated bracket systems and the self-ligated SPEED bracket system. The archwires evaluated were 0.016-inch round stainless steel, 0.0175-inch round braided stainless steel, 0.018-inch round stainless steel, and 0.016 x 0.022-inch rectangular stainless steel. The bracket-ligature combinations compared included an American Orthodontics plastic bracket ligated with elastomeric ligatures and stainless steel ligatures, an “A” Company steel twin bracket ligated with both types of ligatures, and the SPEED self-ligating bracket. The author found that there was a significant reduction in the level of force required to move each of the wires through the SPEED bracket system when compared to the other four bracket systems. The reduction was even more significant when the rectangular steel and round braided archwires were used.

In a 1994 study, Taylor and Ison¹⁹ evaluated frictional forces in different types of brackets with various stainless steel archwires (0.018, 0.020, 0.016 x 0.022, 0.018 x 0.025, and 0.019 x 0.025-inch). “A” Company preadjusted stainless steel brackets, “A” Company Activa self-ligating brackets, and Strite SPEED self-ligating brackets were compared. Six different model setups were used, two with each type of bracket. The models included one molar tube and either one or two of the brackets being evaluated.

Standard brackets were ligated with elastomeric modules. The investigators concluded that the Activa brackets produced the least friction for all wires tested. SPEED brackets with round wires showed little frictional force, while rectangular wires gave rise to higher forces close to those recorded with two standard steel brackets. In a separate component of this study, stainless steel ligatures, stretched, and unstretched elastomeric modules were investigated to determine frictional values for different types of ligation. It was found that loosely tied ligatures or stretched modules reduced frictional forces in the standard steel brackets, with the reduction being greatest for round archwires. It was also determined that frictional forces steadily declined over a 3-week period when archwires were secured with elastomeric ligatures.

In 1997, Voudouris²⁷ investigated three “interactive” twin brackets and compared them with three conventional twin brackets with respect to dynamic frictional resistance. The three systems tested were the Sigma System (American), the Interactwin (Ormco), and the Damon System (“A” Company). The conventional twin counterparts used were American Master Series, Ormco Diamond, and “A” Company Twin. All brackets had 0.022 x 0.028-inch slots and were tested using 0.018-inch, 0.020-inch, and 0.019 x 0.025-inch stainless steel archwires. Elastomeric ligatures were used for the conventional bracket systems. In addition, figure eight elastomer patterns and 0.011-inch metal ligatures were tested with the 0.018-inch archwire size and one of the conventional brackets.

The author found that the frictional resistance was significantly reduced in all three interactive brackets compared to the conventional twin brackets with elastomeric ligation. Friction also increased as the wire dimensions increased. Since the Sigma

System uses an active mechanism, it was found to have a larger frictional resistance than the two passive self-ligating brackets. However, the Sigma bracket still displayed lower friction than the stainless steel ligation method (intermediate), elastomeric ligation (high friction), and figure eight elastomeric ligation (highest friction).²⁷

In a different type of study, Loftus and colleagues¹² used a model that allowed tooth tipping and rotation as the archwire was slid through brackets. This was done in order to test a more clinically representative condition. Conventional and self-ligating stainless steel brackets and ceramic brackets with and without stainless steel slots were investigated. All wires tested were 0.019 x 0.025-inch rectangular wires, made of stainless steel, nickel-titanium, and beta-titanium. There were no significant differences found between conventional and self-ligating stainless steel brackets and ceramic brackets with stainless steel slots. The conventional ceramic brackets generated significantly higher friction than the other brackets tested.

The results of this study differ from those found in most other studies. However, loosely tied stainless steel ligatures generate very little normal force on the archwire, yielding almost no friction due to the method of ligation. This would lessen any differences between archwires and bracket slots of similar materials, regardless of the ligation method in this study. With regards to archwire material, the study concluded that beta-titanium archwires produced higher frictional forces than nickel-titanium arch wires, but no differences were found between either of the titanium alloys and stainless steel arch wires.¹²

Henao and Kusy¹⁰ investigated the frictional resistance of conventional and self-ligating brackets using standardized archwires and dental typodonts. This study differed

in that it used pretreatment typodonts of an oral cavity with progressively maloccluded quadrants. The examination compared four self-ligating brackets (Damon 2, In-Ovation, SPEED, and Time) and four conventional brackets (one from each corresponding manufacturer). The drawing force values were compared from each of the four quadrants with three different austenitic nickel titanium (NiTi A) archwires (0.014-inch, 0.016 x 0.022-inch, and 0.019 x 0.025-inch). Tests were run in the dry state and at an oral ambient temperature. The self-ligating In-Ovation brackets and conventional Mini Diamond SDS (Ormco) brackets were also tested in the wet state at the same temperature using only the 0.014-inch archwire. Elastic modules were used for the ligation of the conventional brackets.

It was concluded that self-ligating brackets outperformed conventional brackets when coupled with small archwires, which would be comparable to the early stages of treatment. With larger archwires, force values of conventional brackets were comparable with those of self-ligating brackets. The authors believe that this outcome emphasizes the importance of leveling before using larger wires and sliding mechanics. The investigators also noticed a slight increase in force values from quadrant to quadrant, which corresponded to an increase in malocclusion. This increase related to the effects of decreasing clearances and interbracket distances in the more maloccluded quadrants.¹⁰

In a similarly designed study, Henao and Kusy⁴⁴ used duplicate dental typodonts with progressively maloccluded quadrants to test four self-ligating brackets with three manufacturer-suggested archwires. The SPEED, Time, In-Ovation, and Damon 2 brackets were tested with wires that represented three stages of orthodontic treatment. Conventional Mini Diamond brackets manufactured by Ormco were used as a control. A

second portion of the study used the same archwires that were successfully tested in the first experiment. The same wires were used for each type of bracket in the upper quadrants only.

The self-ligating bracket designs yielded lower frictional values than the control design in 49 of 56 cases in the first experiment. The P_{\max} (maximum drawing force necessary to pull the archwires through the brackets) values were lower for the self-ligating designs when coupled with up to 0.020 x 0.020-inch archwires. The P_{\max} values were similar with this wire size and greater. Overall, the Time brackets had higher frictional values than those of the other self-ligating designs for 10 of the 14 cases in the second experiment.⁴⁴ These results confirm that active clips usually exhibit higher frictional values than brackets with slides, when the second-order angulations are below the critical angle.²¹ Statistically, the four designs were different, with the Damon 2 (passive slide) being the outlier of the group, with the other three designs using clips for ligation.⁴⁴

It was demonstrated that with the appropriate bracket-archwire combination, the effects of increased levels of malocclusion may be minimized. Frictional values were dictated by archwire size, malocclusion, bracket design, and bending stiffness of the archwire. When clearance was significant, brackets with slides outperformed those with clip designs. However, as malocclusion increased and archwire size reduced clearance, brackets with slides and clips became similar in frictional characteristics.⁴⁴

Efforts have been made to measure the effects of second-order angulation (tipping) on the resistance to sliding of self-ligating brackets. One such study by Thorstenson and Kusy⁴ also investigated the effects of archwire size and material on

frictional resistance. The authors used four different designs of self-ligating brackets. The Damon 2, In-Ovation, SPEED, and Time brackets were coupled with five different archwires (0.014-inch NiTi A [austenitic nickel-titanium], 0.016 x 0.022-inch NiTi A, 0.019 x 0.025-inch NiTi A, 0.019 x 0.025-inch NiTi M [martensitic nickel-titanium], and 0.019 x 0.025-inch stainless steel). Only the effects of second-order angulation were considered; first- and third-order angulations were not included in this study. The second-order angulations evaluated ranged from -9° to 9° .

From the results of this study, the investigators concluded that when clearance between the archwire and bracket exist, the resistance to sliding is almost negligible for self-ligating brackets with slides (Damon 2) coupled to any size wire or self-ligating brackets with clips (SPEED, In-Ovation, Time) with wires that do not contact the clip. If a wire large enough to contact the clip is used, the resistance depends on the archwire size, the bracket design, and the materials of the couple. This resistance has a frictional component (dependent on the ligation force and the coefficient of friction of the materials) and a binding component, which is increased with an increased angulation and wire stiffness. With the 0.019 x 0.025-inch stainless steel archwires, which were the stiffest, the resistance to sliding increased at rates from 75 to 84 g/degree. For the least stiff wire, the 0.014-inch NiTi A, the rates of increase ranged from 2.6 to 5.4 g/degree, exemplifying the large variations associated with different wire stiffness.⁴

In a separate investigation, Thorstenson and Kusy²² evaluated the resistance to sliding of self-ligating brackets and conventional stainless steel brackets with second-order angulations. This study took into account both wet (saliva) and dry environments, as well as different steel ligation forces. Two brackets were evaluated: the Mini

Diamond Twin bracket and the Damon SL bracket, each manufactured by Ormco. The twin brackets were ligated with steel ligatures at different forces, while the self-ligating brackets were tested with the slide closed and with the slide removed. With the slide removed, the archwire was ligated with a steel ligature at various forces. All measurements were made using 0.018 x 0.025-inch stainless steel archwires. The angulation values ranged from -9° to 9° and the normal force values applied by steel ligation were 200, 300, 400, 500, and 600 cN (1 cN = 1 g). The tests were repeated in the wet state, using the operator's saliva. Different normal forces were not applied to the closed self-ligating bracket, its ligation was passive.

The investigators found that the resistance to sliding for the conventional bracket in the dry state is a constant value for any given normal force at angulation values below the critical angle for binding, but increases as the angle goes beyond the critical point. The wet state follows a similar trend, but higher resistance to sliding was encountered than in the dry state. This tendency has been noted for similar materials in a past study.¹⁴ The authors of this study also found that opened self-ligating brackets are comparable to conventional stainless steel brackets when they are ligated with steel ligatures at the same force level. Overall, the resistance to sliding was lower for the self-ligating brackets than the conventional brackets at any angle. This was likely due to the lower value of the classic frictional component and the lower level of normal force placed on the archwire.²²

In a very similar study, Thorstenson and Kusy²¹ sought to compare the resistance to sliding between different self-ligating brackets with second-order angulation in the dry and saliva states. The authors used 6 self-ligating bracket designs (Damon, Activa, Twinlock, SPEED, In-Ovation, and Time). Three of the bracket designs had passive

slides and three had active clips. Resistances to sliding and critical angles were studied for use with a 0.018 x 0.025-inch stainless steel archwire. Below each critical angle, passive brackets (Damon, Aactiva, and Twinlock) exhibited negligible friction and brackets with active clips (In-Ovation, SPEED, and Time) exhibited frictional forces up to 50g. Above the critical angle, all brackets had elastic binding forces that increased at similar rates as angulation increased and were independent of bracket design. Generally, brackets with a lower critical angle displayed higher resistance to sliding; the passive brackets with high critical angles exhibited the lowest resistance. This, however, would be at a cost of some lost control, according to the investigators.

In 1994, Sims and colleagues¹⁶ compared the resistance to sliding of one self-ligating bracket and two conventional twin brackets when subjected to select tip and torque values. The investigators determined that the self-ligating Aactiva brackets consistently produced less friction than the conventionally-ligated brackets (Minitwin and Standard Straight Wire). Minitwin brackets were slightly more resistant to movement than the Standard Straight Wire brackets during torquing, but the opposite was true for tipping movements. Increasing tip and torque values produced almost linear increases in friction for all brackets, but tip had a much more profound effect on friction. Because of this, the authors recommend that prior to sliding on rectangular wires, full alignment of the bracketed teeth should occur to eliminate second and third order effects that may add to anchorage requirements.

Four bracket designs were evaluated in a variable angulation study by Pizzoni et al¹³ in 1998. The brackets included conventional twin brackets manufactured by Dentaaurum and “A” Company, as well as the self-ligating Damon SL and SPEED

brackets. All brackets had 0.022-inch slots. For the conventional brackets, two lengths of 0.010-inch stainless steel were placed perpendicularly to the archwire so that a normal force of 2N was applied. Archwires evaluated included 0.018-inch round TMA and stainless steel, in addition to 0.017 x 0.025-inch rectangular TMA and stainless steel. Each bracket-wire combination was evaluated at angulations of 0°, 3°, 6°, 9°, and 12°. From this investigation, the authors concluded that round wires had lower friction values than rectangular wires, the beta-titanium wires had significantly higher friction values than stainless steel wires, and friction increased with angulation for all bracket-wire combinations. The self-ligating brackets performed better than traditional brackets, but the Damon SL brackets (passive ligation) showed significantly lower friction than the SPEED bracket (active spring ligation). These results corroborate those of similar studies.

Read-Ward and colleagues¹⁴ compared the static frictional resistance of three self-ligating brackets (Mobil-Lock, Activa, and SPEED) versus a conventional steel ligated Ultratrim bracket (Dentaurum). The effects of archwire size (0.020, 0.019 x 0.025, and 0.021 x 0.025-inch stainless steel), bracket/archwire angulation (0, 5, and 10 degrees), and the presence of a lubricant (unstimulated human saliva) were investigated. It was demonstrated that increases in wire size and bracket-archwire angulation resulted in increased friction for all bracket types, with the presence of a wet environment having an inconsistent effect. For zero angulation, self-ligating brackets displayed significantly lower static frictional resistance in comparison to conventional brackets for the 0.020-inch wires, but for the larger rectangular wires, the differences were less significant.

Conventional Ultratrim brackets produced large variation, which the authors believed to be related to a non-standardized ligation force.

Miles and colleagues⁴⁵ compared the effectiveness and comfort of Damon 2 brackets (Ormco) and conventional Victory Series brackets (3M Unitek) using a split-mouth design. The alignment was compared using the irregularity index (II) as proposed by Little.⁴⁶ Two archwires were used, a 0.014-inch Damon copper NiTi and a 0.016 x 0.025-inch Damon copper NiTi wire, to achieve initial alignment. The II was measured following each archwire removal at ten weeks. The conventional brackets were ligated with elastomeric ligatures and they were tied in a “figure 8” configuration if the brackets were not fully engaged with normal ligation. No steel ligatures were used. The patients were recalled within the first few days of bracket placement to find the discomfort levels on each side and to determine which brackets were more comfortable to the lips. Discomfort was assessed again at the first wire change as to which brackets were more comfortable when the new wire was ligated. Patients were also asked which brackets they preferred in appearance. Bracket failure rates were recorded for each group over the 20 weeks of the study.

The results did not show a clinically significant difference in alignment between the two types of brackets. However, the difference was statistically significant (0.2 mm) with the conventional brackets achieving a lower II than the Damon 2 brackets. The conventional twin brackets were more uncomfortable with the initial wire ligation, but substantially more patients reported discomfort with the Damon 2 brackets when the second archwire was engaged. Patients preferred the look of the twin brackets over the Damon 2 brackets and the Damon brackets had a higher bond failure rate.⁴⁵

Manufacturers have claimed that some brackets other than self-ligating brackets also have reduced friction. This assertion was investigated by Redlich et al⁴⁷ in a recent study. The investigators tested Nu Edge (TP Orthodontics), Discovery (Dentaurum), Synergy (Rocky Mountain Orthodontics), and Friction Free brackets (American Orthodontics), all “reduced friction” brackets. Additionally, Time (American Orthodontics), a self-ligating bracket, and Omni Arch (GAC) conventional brackets were compared. Angulations of 0°, 5°, and 10° with 0.018-inch, 0.018 x 0.025-inch, and 0.019 x 0.025-inch stainless steel archwires were tested. In all of the brackets examined, the friction force increased as the angulation and the wire size increased. Two of the brackets tested were ligated on only a single pair of wings with elastomeric ligatures. Each of these brackets (Friction Free and Synergy) yielded lower friction than that of the self-ligation group (Time). The Friction Free brackets had significantly lower friction measurements for each wire size and angulation than all other brackets. Interestingly, a significantly higher friction level for each wire and angulation was generated by the self-ligating brackets when compared with all the other groups. This result is somewhat surprising, but the active clip of the Time brackets has been found to place significant force on engaged archwires.²¹

Chairtime requirements

In the early development of self-ligating brackets, the principal aim was faster ligation. With the invention of elastomeric ligatures, this advantage has diminished somewhat.²⁵ However, a number of studies have investigated this facet of self-ligation

and most support the idea that using these bracket systems saves chair time, at least to some extent.^{15,25-27}

In 2001, Harradine²⁵ investigated the treatment efficiency of self-ligating brackets, primarily that of the Damon SL bracket (“A” Company) compared to the efficiency of conventional brackets. A portion of this study compared the speed of the author in ligation/slide closing as well as the speed of ligature removal/slide opening. With both comparisons, a significant decrease in time was needed to open or close the slides of the Damon SL brackets when compared to placing or removing elastomeric ligatures on conventional brackets. The time savings was about 9 seconds for one archwire placement and about 16 seconds for archwire removal. Although these savings were statistically significant, the author felt that it was of very little clinical significance. The investigator did note however, that there was a greatly reduced need for chairside assistance during the procedures when using self-ligation.

In a previously mentioned study by Voudouris,²⁷ archwire change time requirements were studied in addition to the frictional characteristics of self-ligating (interactive twin) brackets. The clinical time to disengage and remove 0.018-inch stainless steel mandibular archwires, and the time to engage 0.020-inch stainless steel arch wires by three different orthodontic operators was measured. Each operator used 25 mandibular arches. Ligation in each conventional twin sample arch included four metal ligatures placed on all mandibular canine and lateral incisor brackets with a total of six elastomers for the remaining brackets. This investigation demonstrated that the time involved with disengaging and engaging archwires of the interactive twin brackets was

significantly reduced by a factor of approximately four when compared to the combined elastomeric and metal ligation methods.

In one phase of a 1994 study by Shivapuja and Berger,¹⁵ the time required to remove and replace the mode of ligation was evaluated. The time recorded involved either the maxillary or the mandibular arch from second premolar to second premolar and did not involve any archwire manipulation. The results of this study showed significantly less time was necessary to open or close the self-ligating brackets (Activa, SPEED, and Edgelok) than conventional brackets with either elastomeric or stainless steel ligatures.

A study by Maijer and Smith²⁶ aimed to determine whether the clinical time involved in using a self-ligating bracket (Activa) was less than that when using a conventional edgewise bracket (Straight Wire). One certified dental assistant was assigned to a group of patients with self-ligating brackets and one assistant was assigned to a group of patients with conventional brackets. The assistants each had more experience with the brackets of the group to which they were assigned. The groups included 26 patients, the first 14 of which were excluded to eliminate the possibility of nervousness affecting the results. Each patient had to have a minimum of 20 brackets and four molar bands in place. The assistants had to announce the start and completion of archwire removal and insertion and these times were recorded by an independent operator. The orthodontist's adjustments were also timed with each appliance. The two operators' tasks were then reversed, so that the more inexperienced operator was manipulating each appliance. In this case, however, only the anterior teeth were timed to eliminate posterior wire removal and cinching.

It was found that more than triple the time was required for an experienced operator to remove and ligate a complete edgewise arch, compared to the self-ligating appliance. The difference was larger for securing the archwire than for removing it. Even when the assistants' roles were reversed, the operator using the self-ligating appliance was about four times as fast as the operator using the edgewise appliance. The orthodontist's adjustments averaged about six minutes with either appliance.²⁶

Bracket Engagement

Ideal bracket/ligature properties in the opinion of Harradine⁴⁸ include secure, robust ligation and full bracket engagement of the archwire. Secure ligation can be obtained readily with the use of stainless steel ligatures, although they have other drawbacks including the speed of ligation. Elastomeric ligatures are mediocre, especially with increased treatment intervals. This weakness is due to the force decay, which has been documented by Taloumis et al.⁴⁹ Secure ligation is a large advantage of self-ligating brackets regardless of whether the bracket is active or passive. There is a difference between active and passive systems, however. The active self-ligating brackets begin full engagement with smaller diameter archwires when flexion of the active arm of the bracket places an engagement force on the archwire. With passive systems, the archwire is predictably contained within the slot, but first-order control is inferior until full-thickness archwires are used.

In an evaluation of the Activa bracket by Harradine and Birnie,³⁶ it was proposed that the combination of low friction and secure archwire engagement are only possible with a self-ligating bracket. They also believe that these are by far the most beneficial

features of the Activa brackets under investigation. The authors believe this combination allows the teeth to be slid along the archwire with lower and more predictable forces with almost none of the tooth rotation afforded by a deformable mode of ligation. Hence, anchorage is conserved because of lower reciprocal forces and the ability to slide one tooth at a time along the archwire. The combination is also very helpful in situations where teeth are severely rotated and irregular.

Oral Hygiene

A number of authors have suggested that self-ligating brackets are superior to those using conventional elastomeric ligation with respect to oral hygiene,^{28,48} but this has not been extensively investigated. One relevant study, however, was published by Voudouris in 1997.²⁷ A portion of this investigation evaluated the bracket hygiene using three-dimensional measurement of scanning electron microscope pictures. Views of the contact areas and where the seating force was applied over a 0.020-inch archwire were compared under magnification. The brackets evaluated were the American Sigma self-ligating bracket and the American Master Series conventional twin bracket. Each bracket was compared for size and shape of contact areas contributing to bracket hygiene with 0.020-inch stainless steel archwires. The self-ligating brackets demonstrated labial archwire contact with either a narrow interface area or arm contact that was near zero. The use of a single, internally located and linear contact area of the interactive brackets was less than 25% of the contact area of the conventional twin brackets ligated with elastomers. The contact area is not the only important factor in hygiene, as it is widely believed that elastomeric ligatures absorb and retain more plaque than stainless steel.

One study⁵⁰ evaluated the method of ligation as a factor affecting changes in microbial flora and periodontal status after orthodontic bonding. A total of 21 orthodontic patients scheduled for fixed orthodontic treatment were selected for this split-mouth study. Two commonly used auxiliaries (elastomeric rings and ligature wires) for tying archwires were tested. Microbial and periodontal records were obtained before bonding (T0), one week later (T1), and five weeks after bonding (T2). Although teeth ligated with elastomeric rings exhibited slightly greater numbers of microorganisms than teeth ligated with steel ligature wires, the differences were not statistically significant. The two archwire ligation techniques showed no significant differences in the gingival index, bonded bracket plaque index, or pocket depths of the bonded teeth. The teeth ligated with elastic ligatures were more prone to bleeding, however. Therefore, it was the authors' opinion that elastomeric rings should not be used in patients with poor oral hygiene. Although self-ligating brackets were not compared, it is likely that they would perform similarly to the wire ligatures in this investigation.

Infection Control

Some publications and manufacturers have claimed that there may be advantages relating to infection control when using self-ligating brackets as opposed to traditional brackets and ligatures.^{15,28} It is assumed that self-ligation would be preferred only to steel ligatures in this respect, because of the sharp ends present after cutting. Elastomeric ligatures do not pose any risk.

Two investigations have surveyed the percutaneous injuries occurring in orthodontic offices. The first, published in 1998 by Bagramian and McNamara,⁵¹ found

the prevalence of percutaneous injuries to private practice orthodontists. The sample reflected a similar geographic distribution of the population as a whole and most of the practitioners surveyed were in solo full-time practice, averaging 35 hours per week, and treating patients for 47 weeks per year. A 20-day prospective period was used to collect data. There was an injury rate that would equate to approximately one percutaneous injury per orthodontist per year. Although 84% of these injuries occurred outside the mouth, over 50% of these injuries were associated with an orthodontic wire. This category would include wire ligatures and archwires, and the use of steel ligatures could increase the risk of this type of injury.

In a similar study by McNamara and Bagramian,⁵² chairside assistants were surveyed prospectively concerning the occurrence of percutaneous injury during a 20-day period. The study identified a percutaneous injury rate that could be extrapolated to about 1.4 episodes of percutaneous injury per year per assistant. The majority of these injuries occurred outside the mouth and assistants with more orthodontic experience had a lower injury rate. When grouped together, sharp instruments including explorers and scalers accounted for 42.3% of injuries, while orthodontic wires accounted for 29.5%. This significant portion of injuries related to wires cannot be discounted.

Treatment efficiency

While it has been suggested that self-ligating brackets have numerous advantages, it is still unclear whether these bracket design differences yield clinical improvements in treatment. If one bracket system is to be considered superior to another, it must produce higher quality results or it must be more efficient in treatment. Efficiency can be

measured as cost to the patient and the clinician (time and money) to yield a result of equal quality. This question has been investigated in only two studies.

Harradine²⁵ compared thirty consecutively-treated Damon SL cases with thirty matched cases treated with conventional fully programmed brackets. Each pair of cases had the same incisor classification of malocclusion, a similar age at the start of treatment, Peer Assessment Rating (PAR) scores at the start of treatment differing by eight or less, and similar extraction patterns. Cases with palatally ectopic canine teeth or cases involving orthognathic surgery were matched for these attributes. The PAR scores were included because of their relationship with treatment complexity, as well as their value in assessing the measure of treatment result quality. One measure of treatment efficiency used in this study was the treatment time in months from first placement of fixed appliance to removal of fixed appliances. The other measure used was the number of appointments required during this time, including unscheduled appointments. In another portion of this study, the incidence of bracket complications was measured for both bracket types on 25 consecutively seen cases who had been in treatment by the author with full fixed appliances a minimum of 12 months.

As expected from patient selection, the two groups were essentially the same with regard to initial dental irregularity, but they also finished with very similar average dental irregularity indices. The Damon group spent an average of four fewer months in treatment. The Damon group also required an average of four less visits to complete active treatment. Bracket problems associated with the Damon SL brackets were considerable and most were related to slide breakage and inadvertent slide opening. Slide failures have been one of the primary areas the manufacturer's focus in improvement of

the Damon system. Each type of bracket showed similar numbers of debonded brackets during treatment.²⁵

In a study by Eberting et al,²⁸ cases treated with Damon brackets and those treated with conventional brackets were evaluated. This study not only compared the treatment time and number of appointments, but also assessed the quality of the treatment outcome with the American Board of Orthodontics (ABO) grading scale. In addition, a survey was sent to each of the 215 patients in the study to obtain the patient perceptions of how their treatment progressed and finished. The sample was selected randomly from a pool of available patients treated with Damon brackets and those patients treated with conventional brackets from three practices. For inclusion, the patients must have been started and completed using the same method of ligation (Damon or conventional) and an even distribution of extraction and nonextraction cases be maintained for each patient group.

The results of the survey showed that the Damon responses were very similar to the non-Damon responses for eight of the nine questions. There were significant differences, however, for the question concerning perceived treatment length. The question asked patients whether they felt their length of treatment was shorter, longer, or exactly what was expected. Damon patients thought their length of treatment was slightly shorter than expected whereas non-Damon patients perceived their treatment took longer than expected. With respect to treatment time, each of the three practices showed a significantly lower treatment time for Damon cases. For the three practices combined, Damon cases were also found take significantly less time to complete. The Damon cases took a significantly fewer number of appointments for completion in each of the three

practices and for all three practices combined. For the entire sample, there was a difference of about six months and seven appointments per treatment. This investigation showed that two of the three practices had significantly better ABO scores for the Damon patients. For the three practices combined, there were significantly better ABO scores for the Damon patients as well.²⁸

A COMPARATIVE STUDY OF NONEXTRACTION TREATMENT EFFICIENCY
USING CONVENTIONAL EDGEWISE BRACKETS AND SELF-LIGATING
BRACKETS

by

CHAD R. REDDICK, P. LIONEL SADOWSKY, ALEX JACOBSON,
AND SANDRE MCNEAL

In preparation for *The Angle Orthodontist*

Format adapted for thesis

ABSTRACT

Although there is a long history of self-ligating brackets in orthodontics, their popularity has peaked in recent years. Many private practice orthodontists have begun using these brackets because of perceived advantages that they may offer. It is widely believed that the design features of most self-ligating brackets produce less friction between the wire and bracket, faster archwire removal and ligation, better bracket engagement, and improved oral hygiene. If self-ligating brackets truly offer these benefits, their use may lead to more efficient treatment.

The purpose of this study was to evaluate nonextraction treatment efficiency of one self-ligating bracket system (In-Ovation, GAC International, Bohemia, NY) compared to conventional twin edgewise brackets (Ovation, GAC International, Bohemia, NY) used in the same practice. Treatment duration, number of appointments, and number of archwires used per patient were compared within one private orthodontic practice. The total sample included 120 patients consecutively finished with each bracket type for a total of 240 patients. After applying the exclusion criteria, there were 75 patients in the self-ligated (SL) group and 70 patients in the conventionally-ligated (CL) group.

Overall, significantly fewer total appointments, scheduled appointments, and archwires were necessary to finish the SL patients compared to the CL patients. All patients included in the present study were deemed to have quality results by the principal investigator. Following adjustment for age, gender, and Angle classification, scheduled

appointments was the only parameter that remained significantly different between the groups of patients treated with different brackets. When the patient groups were separated by Angle classification, Class I SL patients required significantly fewer total appointments, scheduled appointments, and archwires than Class I CL patients. No statistical differences were found for Class II or Class III patients for any efficiency measure. These results indicate that there is promise for self-ligation leading to more efficient orthodontic treatment, at least in Class I patients. The design of the Ovation self-ligating bracket may benefit Class I cases more due to the frictional advantages of the self-ligating brackets during the leveling and aligning phase of treatment. This phase of treatment is normally a larger proportion of total treatment time for Class I patients, compared with Class II and Class III patients.

INTRODUCTION

Self-ligating brackets have become much more popular in recent years. Many private practice orthodontists have found their advantages to be so beneficial to their practices, a large number of clinicians have begun using these brackets exclusively. It is widely believed that the design features of most self-ligating brackets produce less friction between the wire and the brackets, faster archwire removal and ligation, better bracket engagement, and improved oral hygiene. If self-ligating brackets truly offer these benefits, their use may lead to more efficient treatment.

Some treatment efficiency measures include total duration of orthodontic treatment, number of appointments necessary to complete treatment, and the amount of supplies necessary to complete treatment. After analyzing these factors, it may be accurately determined whether the use of these appliances leads to an increase in treatment efficiency.

Friction plays an important role in orthodontic treatment. When using certain types of mechanics, it has been estimated that 50% of the orthodontic force applied is used purely to overcome the friction of the system.¹ Although the total friction of the system is dependent on a number of factors, friction from ligation (classical friction) is an important component. Stainless steel ligatures can be loosely tied to lower the level of classical friction, but this is at the expense of chairside time by the operator. Elastomeric ligation is very fast, but disadvantages include permanent deformation, decomposition, and force decay.²

According to Kusy and Whitley,³ classical friction may not be the primary contributor of this resistance to sliding. Another parameter that becomes important when the bracket and archwire are not passive is binding. Binding is increasingly important as the stiffness of the wire and the angle of entry into the bracket slot increase.⁴ Some frictional studies use a passive system that eliminates binding as a factor, while other investigations increase the angles of entry of the wire so binding becomes more of a factor. The overwhelming majority of frictional studies support the notion that friction decreases with the use of self-ligating brackets versus conventional edgewise brackets.⁴⁻²³ However, frictional differences depend on the bracket designs, methods of testing, and the binding introduced into the system. At large angles of entry, the effects from ligation method are diminished due to the increase in the binding variable.^{13,14,16,21,22}

Friction plays a role in routine orthodontic treatment, but it varies on the type of mechanics used. For space closure, friction-independent mechanics may be used (i.e. closing loops). Sliding mechanics involves sliding brackets along the archwire and friction plays an important role in this type of space closure.²⁴ Although friction-independent mechanics may be employed for space closure, the initial stages of leveling and aligning still rely heavily on the ability of the archwire to slide freely through the bracket, making friction an important aspect of every edgewise appliance, at least in the early phases of treatment.

In the early development of self-ligating brackets, the principal aim was faster ligation of the archwire into the bracket. With the invention of elastomeric ligatures, this advantage has probably diminished somewhat.²⁵ However, a number of studies have investigated the speed of ligation for self-ligating brackets compared with conventional

brackets and most investigations support the idea that using self-ligating bracket systems saves chairside time for the operator, at least to some extent.^{15,25-27}

While it has been suggested that self-ligating brackets have numerous advantages, it is still unclear whether these bracket design differences yield clinical improvements in treatment outcome or speed. If one bracket system is to be considered superior to another, it must produce higher quality results or it must be more efficient in treatment. Efficiency can be measured as cost to the patient and the clinician (time and money) to yield a result of equal quality for one appliance compared with another. This question has been investigated in only two studies, both involving comparisons of conventional twin brackets with Damon self-ligating brackets.

Harradine²⁵ compared thirty consecutively-treated Damon SL cases with thirty matched cases treated with conventional fully programmed brackets. One measure of treatment efficiency used in his study was the treatment time in months from first placement of fixed appliance to removal of fixed appliances. The other measure used was the number of appointments required during this time, including unscheduled appointments. The Damon SL and conventionally ligated bracket groups were essentially the same with regard to initial dental irregularity, and they also finished with very similar quality of treatment outcome. The Damon group spent an average of four fewer months in treatment. The Damon group also required an average of four less visits to complete active treatment.

In a study by Eberting et al,²⁸ cases treated with Damon brackets and those treated with conventional brackets were evaluated. This study not only compared the treatment time and number of appointments, but also assessed the quality of the treatment outcome

employing the American Board of Orthodontics (ABO) grading scale. In addition, a survey was sent to each of the 215 patients in the study to obtain the patient perceptions of how their treatment progressed and finished. The total sample of 215 was selected randomly from a pool of available patients treated with either Damon brackets or conventional brackets from three orthodontic practices.

Damon patients reported that their length of treatment was slightly shorter than expected whereas non-Damon patients perceived their treatment took longer than expected. With respect to treatment time, the patients in each of the three practices showed a significantly lower treatment time when treated with Damon brackets. The Damon patients were treated in significantly fewer appointments for completion in each of the three practices as well. For the combined samples, there was a difference of about six months and seven appointments per treatment. Damon patients also had significantly better ABO scores than patients with conventional brackets in the three practices combined.²⁸

The purpose of the present study is to evaluate nonextraction treatment efficiency of one self-ligating bracket system compared to a non self-ligating bracket system used in the same practice. Treatment duration, number of appointments, and number of archwires used per patient were compared within one private orthodontic practice to determine whether the change to self-ligation was beneficial with respect to efficiency measures for the clinician. Although it is only a sample of one orthodontic practice, the present study evaluated the self-ligating bracket system to further substantiate or refute the manufacturers' claims of increased treatment efficiency.

MATERIALS AND METHODS

The sample was selected from consecutively finished cases with GAC In-Ovation self-ligating brackets and GAC Ovation conventional twin edgewise brackets in a single private orthodontic practice in Baton Rouge, Louisiana. Patients were excluded from the sample if any permanent teeth other than third molars had been extracted, records were inadequate, or a surgical treatment plan had been used. Limited treatment patients, transfer patients, and two-phase treatments were also excluded from the study sample. In addition, patients deemed uncooperative and patients with less than acceptable results were excluded. Uncooperative patients were designated based on the total number of broken brackets and broken appointments equaling seven or greater. Acceptable results were judged by the principal investigator as a Class I buccal occlusion, good alignment, and good overbite/overjet relationship.

The following information was gathered using the patients' treatment records, personal histories and pre- and post-treatment photographs: birth date, gender, treatment start date, treatment completion date, number of broken brackets, number of broken appointments, total archwires used, number of emergency appointments, total number of appointments, initial molar classification, initial canine classification, final molar classification, and final canine classification. From this information, the start age, treatment duration in months, and the scheduled appointments (total appointments minus emergency appointments) were calculated. Each patient was categorized as dental Class I, II, or III based on the initial molar and canine classifications.

For the conventionally-ligated (CL) sample, the first 120 patients who had their treatment completed in 2003 using Ovation conventional twin brackets were selected. After applying the exclusion criteria, the sample was reduced to 70 patients for the conventionally-ligated group. The CL group included 22 males and 48 females and the average age was 15.0 years at the start of treatment. The CL group consisted of 40 Class I (57.1%), 25 Class II (35.7%), and 5 Class III patients (7.1%). In the self-ligated (SL) sample, the first 120 patients who had their treatment completed in 2006 with In-Ovation self-ligating brackets were selected. After applying the exclusion criteria, the SL group was reduced to 75 patients. The self-ligated group included 32 males and 43 females and the average age at the start of treatment was 17.1 years. The SL group was comprised of 45 Class I (60.0%), 23 Class II (30.7%), and 7 Class III patients (9.3%).

Statistical Analysis

Categorical variables for the sample (Angle classification and gender) were compared between bracket types using a chi-square analysis. Means and standard deviations were calculated for the treatment duration, total appointments, scheduled appointments, emergency appointments, number of archwires used for each bracket type, and were compared using t-tests. ANOVAs, adjusting for gender, age and Angle classification, were used to compare the adjusted means for each bracket type. P-values were determined at the 95% confidence level. All analysis was performed using SAS v 9.1.3.

RESULTS

The sample characteristics of the self-ligated (SL) and conventionally-ligated (CL) groups can be found in Table 1. With respect to Angle classification, there was no statistical difference between the group of SL subjects and the CL group. The average age at the start of treatment and the gender composition of the two groups were also not significantly different.

TABLE 1. Sample characteristics (* statistically significant at $p < 0.05$)

N (%)	Overall	Bracket Type		p-value
		Self-ligated (SL)	Conventionally Ligated (CL)	
Class				
I	85 (58.6)	45 (60.0)	40 (57.1)	0.7638
II	48 (33.1)	23 (30.7)	25 (35.7)	
III	12 (8.3)	7 (9.3)	5 (7.1)	
Gender				
Male	54 (37.2)	32 (42.7)	22 (31.4)	0.1619
Female	91 (62.7)	43 (57.3)	48 (68.6)	
Mean, (S.D.)				
Age	16.2 (10.3)	17.3 (11.0)	15.0 (9.4)	0.1778
Duration (months)	21.4 (6.0)	20.6 (6.5)	22.2 (5.3)	0.1078
Total appointments	16.3 (4.4)	15.4 (4.6)	17.3 (4.0)	0.0087*
Scheduled appointments	15.0 (3.8)	14.1 (3.7)	16.0 (3.7)	0.0016*
Emergency appointments	1.3 (1.5)	1.4 (1.7)	1.3 (1.4)	0.7752
Arch wires	13.8 (3.0)	13.2 (3.1)	14.5 (2.8)	0.0062*

The average treatment duration for the SL group was 20.6 months (S.D. 6.5). The average treatment duration for the CL group was 22.2 months (S.D. 5.3). The difference of 1.6 months was not statistically significant.

The total appointments required to complete treatment in the SL group averaged 15.4 (S.D. 4.6). The average for the CL group was 17.3 (S.D. 4.0). The SL group required an average of 1.9 fewer appointments than the CL group and this difference was statistically significant ($p=0.0087$). The average number of scheduled appointments for the SL group was 14.1 (S.D. 3.7). The CL group required an average of 16.0 appointments (S.D. 3.7), and the difference between the groups was significant ($p=0.0016$). The emergency appointments for the two groups were almost identical: 1.4 (S.D. 1.7) for the SL group and 1.3 (S.D. 1.4) for the CL group.

The SL group required significantly fewer archwires throughout the course of treatment ($p=0.0062$). The SL subjects were treated with an average of 13.2 (S.D. 3.1) archwires, while the CL subjects required 14.5 (S.D. 2.8) archwires.

Since the groups differed somewhat in Angle classification, gender, and age, they were adjusted accordingly. The regression models with adjusted means and p-values are shown in Table 2. Overall, the treatment duration was not statistically different between bracket types. When the groups were divided into Angle classifications, the treatment duration again did not differ statistically.

With respect to the total appointments per patient, there was no significant difference between the bracket types overall. When the bracket groups were separated by Angle classification, the Class I SL group required significantly fewer appointments (14.1) than the corresponding group of CL patients (16.2). For the scheduled

appointments per patient (total appointments minus emergency appointments), there was a significant difference between bracket types. The mean number of scheduled appointments for the SL group was 14.8, while the CL group averaged 16.4

TABLE 2. Regression models adjusted for gender, age, and Angle classification (* statistically significant at $p < 0.05$)

	Bracket Type		p-value
	Self-ligated (SL)	Conventionally Ligated (CL)	
Adjusted Means			
Duration (months)			
Overall	22.1	22.5	0.7227
Class I	18.6	20.1	0.2025
II	24.5	25.3	0.6015
III	23.0	22.1	0.7682
Total appointments			
Overall	16.2	17.5	0.1855
Class I	14.1	16.2	0.0245*
II	17.8	19.5	0.1444
III	16.7	16.8	0.9668
Scheduled appointments			
Overall	14.8	16.4	0.0423*
Class I	12.9	14.9	0.0088*
II	16.2	18.1	0.0647
III	15.1	16.3	0.5768
Emergency appointments			
Overall	1.4	1.0	0.3003
Class I	1.2	1.2	0.9389
II	1.6	1.4	0.7868
III	1.5	0.5	0.2621
Arch Wires			
Overall	13.5	14.5	0.1716
Class I	12.5	14.1	0.0128*
II	14.6	15.2	0.4628
III	13.5	14.1	0.7214

appointments. This difference totaled 1.6 appointments per subject ($p=0.0423$). For the Class I subgroup, the SL group averaged 12.9 appointments and the CL group averaged 14.9 appointments, for a difference of 2.0 appointments. This difference was also statistically significant ($p=0.0088$). The number of scheduled appointments was not statistically different for the Class II and Class III subgroups for the different bracket types. Emergency appointments did not differ overall or with respect to classification groups between bracket types.

The number of archwires used per patient was not statistically different for all three classifications combined. However, for the Class I patients alone, statistically fewer archwires were used per patient treated with the SL brackets than for those treated with the CL brackets. Patients treated with SL brackets required an average of 12.5 archwires while patients treated with CL brackets required an average of 14.1 archwires. This difference of 1.6 archwires was statistically significant ($p=0.0116$).

DISCUSSION

The purpose of this study was to evaluate the nonextraction treatment efficiency of the In-Ovation self-ligating brackets compared to the Ovation conventionally-ligated twin edgewise brackets. This comparison was accomplished by finding the treatment duration, number of appointments, and number of archwires used for each patient in the sample. In addition, bracket groups were divided into Angle classifications to find if efficiency differences were more apparent in one classification group compared to another.

One private practice was used to evaluate treatment efficiency measures before and after changing systems from a conventionally-ligated appliance to a self-ligating appliance. All patients were treated by the same orthodontist. All brackets used had 0.022 x 0.028-inch slots. The orthodontist had approximately fifteen years experience with conventional twin brackets prior to the year 2000, when most of the conventionally-ligated (CL) patients were started. In 2003, when most of the self-ligated (SL) patients began treatment, the orthodontist had less than one year experience using the self-ligating brackets.

The total sample size was 240 patients, 120 consecutively finished with conventionally-ligated Ovation brackets and 120 consecutively finished with In-Ovation self-ligating brackets. Since the aim of this study was to determine nonextraction treatment efficiency, all patients that had any teeth other than third molars removed for orthodontic reasons were excluded from the sample. To get a more homogeneous sample

and to eliminate outliers with respect to efficiency measures, patients requiring orthognathic surgery, limited treatment, two-phase treatment and transfer patients were also excluded. Uncooperative patients, judged by number of broken appointments and broken brackets, were excluded as well. To assure that high treatment standards were maintained for both groups, any patients who had less than adequate results were removed from the sample at the discretion of the principal investigator. After applying the exclusion criteria, the CL group included 70 patients, while the SL group consisted of 75 patients.

Treatment duration is one of the most important facets of orthodontic treatment for the patient and the orthodontist. Patients are anxious to have their malocclusion corrected and they normally look forward to the day that the appliances will be removed. Concerns about oral hygiene, practice management, and practice reputation in the community drive the orthodontist to try to decrease treatment time for the patient. Claims of decreased treatment time by the orthodontic manufacturers and in the literature^{25,28,29} have increased interest in self-ligating brackets with a number of designs.

The present study evaluated one self-ligating bracket design, GAC In-Ovation, which has a passive clip at small archwire sizes, but an active clip at larger archwire sizes. The results of this study did not show a difference in treatment time between self-ligating brackets and traditional brackets, and therefore did not support the findings of other studies.^{25,28} However, these studies evaluated a different bracket design, the Damon SL. Harradine²⁵ found about a four month reduction in treatment time with self-ligating brackets compared to twin brackets and this difference was significant. The study by Harradine²⁵ differed from the present study in that it evaluated 30 consecutive

finished cases matched for age, treatment plan, and PAR index. It included various types of cases including surgical and extraction treatment, as well as nonextraction treatment. Eberling et al²⁸ also found a significant treatment duration difference in the Damon SL cases and the conventional edgewise cases. The investigators found a six month decrease in treatment time in the self-ligating group. The study by Eberling et al²⁸ also included both extraction and nonextraction cases, but the present study investigated the nonextraction cases only.

In addition to treatment duration, the number of patient visits per treatment is an important indicator of treatment efficiency. Having fewer appointments is more convenient for the patient, and it opens up the schedule for the clinician. Overall, the present study did find that significantly fewer appointments were necessary for SL patients (1.9 appointments), but this difference was no longer found to be significant following adjustment for age, gender, and Angle classification. There was a significant difference, however, in the adjusted number of appointments for Class I SL patients compared to Class I CL patients (2.1 appointments). No statistical differences were found for Class II or Class III patients. Treatment efficiency measures for different Angle classifications have not been investigated previously.

In the present investigation, the total appointments were categorized as scheduled appointments and emergency appointments to determine if any intergroup differences would be found. The separation of appointments into different types had not been investigated in previous studies. In this study, emergency appointments did not differ between groups overall, after adjustment, or within any Angle classification group. This is promising for self-ligating brackets, specifically the In-Ovation bracket, because clip

failures in past designs have been reported,³⁰ possibly increasing the number of emergency appointments.

For all Angle classifications combined, the number of scheduled appointments was significantly less for the SL group before and after adjustment (1.9 and 1.6 appointments, respectively). The Class I SL group also required significantly fewer scheduled appointments than the Class I CL group (2.0 appointments). There were no statistical differences found in the Class II or Class III subgroups.

It has been claimed by some manufacturing companies that the use of self-ligating brackets may decrease the number of archwires used per patient. Because of this claim, the number of archwires used per patient was also analyzed in the present investigation. No previous investigations have compared the number of archwires used with conventionally-ligated and self-ligated appliances.

For all three Angle classes combined, there were significantly fewer archwires used in the SL group (1.3 archwires). However, after the means were adjusted for age, gender, and Angle classification, the difference was no longer significant. For the Class I patients alone, there were statistically fewer archwires used for the SL patients compared to the CL patients (1.6 archwires). Any difference in the number of archwires used can be important in two ways. First, it may decrease the practice supply costs, especially if high-technology, high-cost wires are used. Secondly, it could decrease the chair time necessary for adjustment appointments. Each of these benefits would increase practice efficiency.

When comparing the number of appointments and number of archwires used for different groups of patients, some factors should be considered. Both elements are

largely under the control of the clinician. Patients might normally be seen more often than necessary, especially when working with light, flexible archwires used for leveling and aligning. In many instances, archwires are also changed more often than necessary because the orthodontist is impatient. The clinician may also feel inclined to see patients less frequently and change archwires less frequently because these are the expected benefits of self-ligating brackets.

The number of archwires used is dependent upon the treatment philosophy of the orthodontist as well. The philosophy of the clinician includes the stage of dental development of patients at treatment initiation. In the practice where the records for the present study were gathered, patients are commonly started in the late mixed dentition, before second molars are fully erupted. Dropping in wire size to engage newly banded or bonded second molars in the late stages of treatment can cause an increase in archwires used. Broken brackets may cause similar problems, leading to a higher than expected average of about fourteen archwires per patient in the present sample. A change in treatment philosophy could lead to increased treatment intervals and fewer archwire changes. A different appliance is not necessarily the cause of changes in these areas, so the results of any study of this type should be interpreted with caution.

The significant differences found between bracket groups appeared to be due to the differences in the Class I subgroups. There were significantly fewer total appointments, scheduled appointments, and archwires used for the Class I patients in the SL group compared to the Class I patients in the CL group. Treatment duration in the Class I subgroup was not statistically different, but the SL group did average 1.5 fewer months in treatment than the CL group.

One explanation for these findings is that reduced friction would benefit Class I patients to a greater degree than Class II or Class III patients. A reduction in friction would theoretically allow brackets to slide more freely along the archwire. Since this is a nonextraction study, the majority of sliding occurs in the leveling and aligning phase of treatment. Anteroposterior correction, including elastic wear, would be less affected. Since a larger proportion of time and effort is spent leveling and aligning Class I cases, it would follow that Class I cases would benefit more from reduced friction and reduced friction brackets in nonextraction treatment.

There are weaknesses in the design of this study that should be mentioned. The most obvious weakness is the control of result quality. The principal investigator critically viewed final photographs for a Class I occlusion, good alignment, and good overbite/overjet relationship. Less than adequate results were excluded from the sample at the discretion of the investigator. Ideally, each set of patient records would have been graded by American Board of Orthodontics standards and scored to compare quality of result. Locating adequate records including final models would have made a study of this size difficult and the sample size would have been diminished accordingly. Another factor that could not be controlled in the present study is the difference in experience levels of the clinician with the SL and CL brackets. As mentioned earlier, the clinician had less than one year experience with the SL bracket when these cases were started, compared to about 15 years experience with the CL brackets. Although both brackets have similar prescriptions, unfamiliarity with subtle nuances in bracket positioning and clinical use may have led to less efficient treatment than may be possible with In-Ovation self-ligating brackets in the future.

CONCLUSIONS

The results of the present study support the belief that self-ligating brackets can increase treatment efficiency when compared to conventionally-ligated brackets, at least to some extent. After group adjustments for age, gender, and Angle classification, the SL and CL groups only differed significantly with respect to scheduled appointments. However, Class I patients appeared to benefit more from the advantages of self-ligation. The SL patients required fewer total appointments, fewer scheduled appointments, and fewer archwires to complete treatment than the CL patients.

A concern when interpreting the results of this study is that the clinician controls the number of appointments scheduled for the patient and the number of archwires used during treatment, two parameters which were found to be significantly different in the present study. This may be due to the clinician expecting these advantages and treating patients accordingly. It should also be noted that the treating orthodontist in this investigation had less than one year experience using the self-ligating In-Ovation bracket. The efficiency of treatment with self-ligating brackets should improve as the clinician becomes more accustomed to the brackets. The findings in this study do not suggest the change to self-ligating brackets would be advantageous for all orthodontic practices. The results do, however, show that some practice management benefits may result from the use of self-ligating brackets. Additional advantages that may be offered by self-ligation, such as oral hygiene improvement, should also be investigated.

REFERENCES

1. Proffit WR, Fields HW. The biologic basis of orthodontic therapy, in *Contemporary Orthodontics*, C.V. Mosby Co., St. Louis, 1993: 266-288.
2. Voudouris JC. Seven clinical principles of interactive twin mechanisms. *J Clin Orthod* 1997; 31: 55-65.
3. Kusy RP, Whitley JQ. Friction between different wire-bracket configurations and materials. *Sem in Orthod* 1997; 3: 166-177.
4. Thorstenson BS, Kusy RP. Effect of archwire size and material on the resistance to sliding of self-ligating brackets with second-order angulation in the dry state. *Am J Orthod Dentofacial Orthop* 2002; 122: 295-305.
5. Articolo LC, Kusy RP. Influence of angulation on the resistance to sliding in fixed appliances. *Am J Orthod Dentofacial Orthop* 1999; 115: 39-51.
6. Berger J. The influence of the SPEED bracket's self-ligating design on force levels in tooth movement: A comparative in vitro study. *Am J Orthod Dentofac Orthop* 1990; 97: 219-228.
7. Cacciafesta V, Sfondrini MF, Ricciardi A, Scribante A, Klersy C, Auricchio F. Evaluation of friction of stainless steel and esthetic self-ligating brackets in various bracket-archwire combinations. *Am J Orthod Dentofac Orthop* 2003; 124: 395-402.
8. Griffiths HS, Sherriff M, Ireland AJ. Resistance to sliding with 3 types of elastomeric modules. *Am J Orthod Dentofac Orthop* 2005; 127: 670-675.
9. Hain M, Dhopatkar A, Rock P. The effect of ligation method on friction in sliding mechanics. *Am J Orthod Dentofac Orthop* 2003; 123: 416-422.
10. Henao SP, Kusy RP. Evaluation of the frictional resistance of conventional and self-ligating bracket designs using standardized archwires and dental typodonts. *Angle Orthod* 2004; 74: 202-211.
11. Kapur R, Sinha PK, Nanda RS. Frictional resistance of the Damon SL bracket. *J Clin Orthod* 1998; 32: 485-489.

12. Loftus BP, Årtun J, Nicholls JJ, Alonzo TA, Stoner JA. Evaluation of friction during sliding tooth movement in various bracket-archwire combinations. *Am J Orthod Dentofac Orthop* 1999; 116: 336–345.
13. Pizzoni L, Raunholt G, Melsen B. Frictional forces related to self-ligating brackets. *Eur J Orthod* 1998; 20: 283–291.
14. Read-Ward GE, Jones SP, Davies EH. A comparison of self-ligating and conventional orthodontic bracket systems. *Br J Orthod* 1997; 24: 309-317.
15. Shivapuja PK, Berger J. A comparative study of conventional ligation and self-ligation bracket systems. *Am J Orthod Dentofac Orthop* 1994; 106: 472-480.
16. Sims APT, Waters NE, Birnie DJ. A comparison of the forces required to produce tooth movement *ex vivo* through three types of preadjusted brackets when subjected to determined tip or torque values. *Br J Orthod* 1994; 21: 367–373.
17. Sims APT, Waters NE, Birnie DJ, Pethybridge RJ. A comparison of the forces required to produce tooth movement *in vitro* using two self-ligating brackets and a pre-adjusted bracket employing two types of ligation. *Eur J Orthod* 1993; 15: 377–385.
18. Spiller RE, DeFranco DJ, Story RJ, von Fraunhofer JA. Friction forces in bracket-wire-ligature combinations. *J Dent Res* 1990; 69: 155.
19. Taylor NG, Ison K. Frictional resistance between orthodontic brackets and archwires in the buccal segments. *Angle Orthod* 1996; 66: 215-22.
20. Thomas S, Birnie DJ, Sherriff M. A comparative *in vitro* study of the frictional characteristics of two types of self-ligating brackets and two types of preadjusted edgewise brackets tied with elastomeric ligatures. *Eur J Orthod* 1998; 20: 589–596.
21. Thorstenson BS, Kusy RP. Comparison of resistance to sliding between different self-ligating brackets with second-order angulation in the dry and saliva states. *Am J Orthod Dentofac Orthop* 2002; 121: 472–482.
22. Thorstenson BS, Kusy RP. Resistance to sliding of self-ligating brackets versus conventional stainless steel twin brackets with second-order angulation in the dry and wet (saliva) states. *Am J Orthod Dentofac Orthop* 2001; 120: 361–370.
23. Tidy DC. Frictional forces in fixed appliances. *Am J Orthod Dentofacial Orthop* 1989; 96: 249-254.
24. Andreasen GF, Quevedo FR. Evaluation of friction forces in the 0.022 X 0.028 edgewise bracket *in vitro*. *J Biomechanics* 1970; 3: 151-160.

25. Harradine NWT. Self-ligating brackets and treatment efficiency. *Clin Orthod Res* 2001; 4: 220–227.
26. Maijer R, Smith DC. Time saving with self-ligating brackets. *J Clin Orthod* 1990; 24: 29-31.
27. Voudouris JC. Interactive edgewise mechanisms: form and function comparison with conventional edgewise brackets. *Am J Orthod Dentofacial Orthop* 1997; 111: 119-40.
28. Eberting JJ, Straja SR, Tuncay OC. Treatment time, outcome and patient satisfaction comparisons of Damon and conventional brackets. *Clin Orthod Res* 2001; 4: 228–234.
29. Hanson GH. JCO interviews Dr. G. Herbert Hanson on the SPEED bracket. *J Clin Orthod* 1986; 10: 183-189.
30. Parkin N. Clinical pearl: clinical tips with System-R. *J Orthod* 2005; 32: 244-246.

CONCLUSIONS

The results of the present study support the belief that self-ligating brackets can increase treatment efficiency when compared to conventionally-ligated brackets, at least to some extent. After group adjustments for age, gender, and Angle classification, the SL and CL groups only differed significantly with respect to scheduled appointments. However, Class I patients appeared to benefit more from the advantages of self-ligation. The SL patients required fewer total appointments, fewer scheduled appointments, and fewer archwires to complete treatment than the CL patients.

A concern when interpreting the results of this study is that the clinician controls the number of appointments scheduled for the patient and the number of archwires used during treatment, two parameters which were found to be significantly different in the present study. This may be due to the clinician expecting these advantages and treating patients accordingly. It should also be noted that the treating orthodontist in this investigation had less than one year experience using the self-ligating In-Ovation bracket. The efficiency of treatment with self-ligating brackets should improve as the clinician becomes more accustomed to the brackets. The findings in this study do not suggest the change to self-ligating brackets would be advantageous for all orthodontic practices. The results do, however, show that some practice management benefits may result from the use of self-ligating brackets. Additional advantages that may be offered by self-ligation, such as oral hygiene improvement, should also be investigated.

GENERAL LIST OF REFERENCES

1. Proffit WR, Fields HW. The biologic basis of orthodontic therapy, in *Contemporary Orthodontics*, C.V. Mosby Co., St. Louis, 1993: 266-288.
2. Voudouris JC. Seven clinical principles of interactive twin mechanisms. *J Clin Orthod* 1997; 31: 55-65.
3. Kusy RP, Whitley JQ. Friction between different wire-bracket configurations and materials. *Sem in Orthod* 1997; 3: 166-177.
4. Thorstenson BS, Kusy RP. Effect of archwire size and material on the resistance to sliding of self-ligating brackets with second-order angulation in the dry state. *Am J Orthod Dentofacial Orthop* 2002; 122: 295-305.
5. Articolo LC, Kusy RP. Influence of angulation on the resistance to sliding in fixed appliances. *Am J Orthod Dentofacial Orthop* 1999; 115: 39-51.
6. Berger J. The influence of the SPEED bracket's self-ligating design on force levels in tooth movement: A comparative in vitro study. *Am J Orthod Dentofac Orthop* 1990; 97: 219-228.
7. Cacciafesta V, Sfondrini MF, Ricciardi A, Scribante A, Klersy C, Auricchio F. Evaluation of friction of stainless steel and esthetic self-ligating brackets in various bracket-archwire combinations. *Am J Orthod Dentofac Orthop* 2003; 124: 395-402.
8. Griffiths HS, Sherriff M, Ireland AJ. Resistance to sliding with 3 types of elastomeric modules. *Am J Orthod Dentofac Orthop* 2005; 127: 670-675.
9. Hain M, Dhopatkar A, Rock P. The effect of ligation method on friction in sliding mechanics. *Am J Orthod Dentofac Orthop* 2003; 123: 416-422.
10. Henao SP, Kusy RP. Evaluation of the frictional resistance of conventional and self-ligating bracket designs using standardized archwires and dental typodonts. *Angle Orthod* 2004; 74: 202-211.
11. Kapur R, Sinha PK, Nanda RS. Frictional resistance of the Damon SL bracket. *J Clin Orthod* 1998; 32: 485-489.

12. Loftus BP, Årtun J, Nicholls JJ, Alonzo TA, Stoner JA. Evaluation of friction during sliding tooth movement in various bracket-archwire combinations. *Am J Orthod Dentofac Orthop* 1999; 116: 336–345.
13. Pizzoni L, Raunholt G, Melsen B. Frictional forces related to self-ligating brackets. *Eur J Orthod* 1998; 20: 283–291.
14. Read-Ward GE, Jones SP, Davies EH. A comparison of self-ligating and conventional orthodontic bracket systems. *Br J Orthod* 1997; 24: 309-317.
15. Shivapuja PK, Berger J. A comparative study of conventional ligation and self-ligation bracket systems. *Am J Orthod Dentofac Orthop* 1994; 106: 472-480.
16. Sims APT, Waters NE, Birnie DJ. A comparison of the forces required to produce tooth movement *ex vivo* through three types of preadjusted brackets when subjected to determined tip or torque values. *Br J Orthod* 1994; 21: 367–373.
17. Sims APT, Waters NE, Birnie DJ, Pethybridge RJ. A comparison of the forces required to produce tooth movement *in vitro* using two self-ligating brackets and a pre-adjusted bracket employing two types of ligation. *Eur J Orthod* 1993; 15: 377–385.
18. Spiller RE, DeFranco DJ, Story RJ, von Fraunhofer JA. Friction forces in bracket-wire-ligature combinations. *J Dent Res* 1990; 69: 155.
19. Taylor NG, Ison K. Frictional resistance between orthodontic brackets and archwires in the buccal segments. *Angle Orthod* 1996; 66: 215-22.
20. Thomas S, Birnie DJ, Sherriff M. A comparative *in vitro* study of the frictional characteristics of two types of self-ligating brackets and two types of preadjusted edgewise brackets tied with elastomeric ligatures. *Eur J Orthod* 1998; 20: 589–596.
21. Thorstenson BS, Kusy RP. Comparison of resistance to sliding between different self-ligating brackets with second-order angulation in the dry and saliva states. *Am J Orthod Dentofac Orthop* 2002; 121: 472–482.
22. Thorstenson BS, Kusy RP. Resistance to sliding of self-ligating brackets versus conventional stainless steel twin brackets with second-order angulation in the dry and wet (saliva) states. *Am J Orthod Dentofac Orthop* 2001; 120: 361–370.
23. Tidy DC. Frictional forces in fixed appliances. *Am J Orthod Dentofacial Orthop* 1989; 96: 249-254.
24. Andreasen GF, Quevedo FR. Evaluation of friction forces in the 0.022 X 0.028 edgewise bracket *in vitro*. *J Biomechanics* 1970; 3: 151-160.

25. Harradine NWT. Self-ligating brackets and treatment efficiency. *Clin Orthod Res* 2001; 4: 220–227.
26. Maijer R, Smith DC. Time saving with self-ligating brackets. *J Clin Orthod* 1990; 24: 29-31.
27. Voudouris JC. Interactive edgewise mechanisms: form and function comparison with conventional edgewise brackets. *Am J Orthod Dentofacial Orthop* 1997; 111: 119-40.
28. Eberting JJ, Straja SR, Tuncay OC. Treatment time, outcome and patient satisfaction comparisons of Damon and conventional brackets. *Clin Orthod Res* 2001; 4: 228–234.
29. Stolzenberg J. The Russell attachment and its improved advantages. *Int J Orthod Dent Children* 1935; 21: 837-840.
30. Stolzenberg J. The efficiency of the Russell attachment. *Am J Orthod Oral Surg* 1946; 32: 572-582.
31. Berger J. Self-ligation in the year 2000. *J Clin Orthod* 2000; 34: 74-81.
32. Gottlieb EL, Wildman AJ, Hice TL, Lang HM, Lee IF, Strauch EC Jr. The Edgelok bracket. *J Clin Orthod* 1972; 6: 613-623.
33. Hanson GH. JCO interviews Dr. G. Herbert Hanson on the SPEED bracket. *J Clin Orthod* 1986; 10: 183-189.
34. Hanson H. The SPEED system: A report on the development of a new edgewise appliance. *Am J Orthod* 1980; 78: 243-265.
35. Berger J. The SPEED appliance: a 14-year update on this unique self-ligating orthodontic mechanism. *Am J Orthod Dentofac Orthop* 1994; 105: 217-223.
36. Harradine NWT, Birnie DJ. The clinical use of Activa self-ligating brackets. *Am J Orthod Dentofac Orthop* 1996; 109: 319-328.
37. Damon DH. The rationale, evolution and clinical application of the self-ligating bracket. *Clin Orthod Res* 1998; 1: 52-61.
38. Damon DH. The Damon low-friction bracket: a biologically compatible straight-wire system. *J Clin Orthod* 1998; 32: 670-680.
39. Parkin N. Clinical pearl: clinical tips with System-R. *J Orthod* 2005; 32: 244-246.

40. Jastrzebski ZD. *The Nature and Properties of Engineering Materials* (ed 2). New York: Wiley and Sons, 1976: 182-185.
41. Kusy RP. Materials and appliances in orthodontics: brackets, arch wires, and friction. *Curr Opin Dent* 1991; 1: 634-644.
42. Baccetti T, Franchi L. Friction produced by types of elastomeric ligatures in treatment mechanics with the preadjusted appliance. *Angle Orthod* 2006; 76: 211-216.
43. Tecco S, Festa F, Caputi S, Traini T, Di Iorio D, D'Attilio M. Friction of conventional and self-ligating brackets using a 10 bracket model. *Angle Orthod* 2005; 75: 1041-1045.
44. Henao SP, Kusy RP. Frictional evaluations of dental typodont models using four self-ligating designs and a conventional design. *Angle Orthod* 2005; 75: 75-85.
45. Miles PG, Weyant RJ, Rustveld L. A clinical trial of Damon 2 vs conventional twin brackets during initial alignment. *Angle Orthod* 2006; 76: 480-485.
46. Little RM. The irregularity index: a quantitative score of mandibular anterior alignment. *Am J Orthod* 1975; 68: 554-563.
47. Redlich M, Mayer Y, Harari D, Lewinstein I. In vitro study of frictional forces during sliding mechanics of "reduced-friction" brackets. *Am J Orthod Dentofac Orthop* 2003; 124: 69-73.
48. Harradine NWT. Self-ligating brackets: where are we now? *J Orthod* 2003; 30: 262-273.
49. Taloumis LF, Smith TM, Hondrum SO, Lorton L. Force decay and deformation of orthodontic elastomeric ligatures. *Am J Orthod Dentofac Orthop* 1997; 111: 1-11.
50. Turkkahraman H. Archwire ligation techniques, microbial colonization, and periodontal status in orthodontically treated patients. *Angle Orthod* 2005; 75: 231-236.
51. Bagramian RA, McNamara JA Jr. A prospective survey of percutaneous injuries in orthodontists. *Am J Orthod Dentofacial Orthop* 1998; 114: 654-658.
52. McNamara JA Jr, Bagramian RA. Prospective survey of percutaneous injuries in orthodontic assistants. *Am J Orthod Dentofacial Orthop* 1999; 115: 72-76.

APPENDIX A

INSTITUTIONAL REVIEW BOARD FOR HUMAN USE APPROVAL FORM

UAB THE UNIVERSITY OF
ALABAMA AT BIRMINGHAM
Institutional Review Board for Human Use

Form 4: IRB Approval Form
Identification and Certification of Research
Projects Involving Human Subjects

UAB's Institutional Review Boards for Human Use (IRBs) have an approved Federalwide Assurance with the Office for Human Research Protections (OHRP). The UAB IRBs are also in compliance with 21 CFR Parts 50 and 56 and ICH GCP Guidelines. The Assurance became effective on November 24, 2003 and expires on February 14, 2009. The Assurance number is FWA00005960.

Principal Investigator: REDDICK, CHAD RUSSELL
Co-Investigator(s):
Protocol Number: **X060601002**
Protocol Title: *A Comparative Study of Non-Extraction Treatment Efficiency Using Conventional Edgewise Brackets and Self-Ligating Brackets*

The IRB reviewed and approved the above named project on 09/19/06. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services. This Project will be subject to Annual continuing review as provided in that Assurance.

This project received EXPEDITED review.

IRB Approval Date: 9-19-06
Date IRB Approval Issued: 09/19/06

HIPAA Waiver Approved?: Yes

Marilyn Doss
Marilyn Doss, M.A.
Vice Chair of the Institutional Review Board for Human Use (IRB)

Investigators please note:

The IRB approved consent form used in the study must contain the IRB approval date and expiration date.

IRB approval is given for one year unless otherwise noted. For projects subject to annual review research activities may not continue past the one year anniversary of the IRB approval date.

Any modifications in the study methodology, protocol and/or consent form must be submitted for review and approval to the IRB prior to implementation.


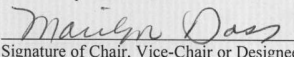
Adverse Events and/or unanticipated risks to subjects or others at UAB or other participating institutions must be reported promptly to the IRB.

470 Administration Building
701 20th Street South
205.934.3789
Fax 205.934.1301
irb@uab.edu

The University of
Alabama at Birmingham
Mailing Address:
AB 470
1530 3RD AVE S
BIRMINGHAM AL 35294-0104

APPENDIX B

INSTITUTIONAL REVIEW BOARD WAIVER OF INFORMED CONSENT

 THE UNIVERSITY OF ALABAMA AT BIRMINGHAM Institutional Review Board for Human Use		PI: REDDICK, CHAD RUSSELL Protocol # X060601002
UAB IRB Approval of Waiver of Informed Consent and/or Waiver of Patient Authorization		
<input checked="" type="checkbox"/> Approval of Waiver of Informed Consent to Participate in Research. The IRB reviewed the proposed research and granted the request for waiver of informed consent to participate in research, based on the following findings: <ol style="list-style-type: none"> 1. The research involves no more than minimal risk to the subjects. 2. The research cannot practicably be carried out without the waiver. 3. The waiver will not adversely affect the rights and welfare of the subjects. 4. When appropriate, the subjects will be provided with additional pertinent information after participation. 		
Check one: <input type="checkbox"/> and Waiver of Authorization (below) <input type="checkbox"/> or Waiver of Authorization (below) <input type="checkbox"/> Waiver of Authorization not applicable		
<input type="checkbox"/> Approval of Waiver of Patient Authorization to Use PHI in Research. The IRB reviewed the proposed research and granted the request for waiver of patient authorization to use PHI in research, based on the following findings: <ol style="list-style-type: none"> 1. The use/disclosure of PHI involves no more than minimal risk to the privacy of individuals <ol style="list-style-type: none"> i. There is an adequate plan to protect the identifiers from improper use and disclosure. ii. There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention that is otherwise required by law. iii. There is an assurance that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted. 2. The research cannot practicably be conducted without the waiver or alteration. 3. The research cannot practicably be conducted without access to and use of the PHI. 		
—OR—		
<input type="checkbox"/> Full Review The IRB reviewed the proposed research at a convened meeting at which a majority of the IRB was present, including one member who is not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any of such entities. The partial waiver of authorization for screening was approved by the majority of the IRB members present at the meeting.	<input checked="" type="checkbox"/> Expedited Review The IRB used an expedited review procedure because the research involves no more than minimal risk to the privacy of the individuals who are the subject of the PHI for which use or disclosure is being sought. The review and approval of the partial waiver of authorization for screening was carried out by the Chair of the IRB, or by one of the Vice-Chairs of the IRB as designated by the Chair of the IRB.	
_____ Date of Meeting	9-19-06 Date of Expedited Review	
_____ Signature of Chair, Vice-Chair or Designee	 Signature of Chair, Vice-Chair or Designee	
_____ Date	09/19/06 Date	
Rev. 12/08/2005	470 Administration Building 701 20th Street South 205.934.3789 Fax 205.934.1301 irb@uab.edu	The University of Alabama at Birmingham Mailing Address: AB 470 1530 3RD AVE S BIRMINGHAM AL 35294-0104
		Page 1 of 1

