A study into the effects of different ligation techniques on mandibular incisor alignment

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A thesis submitted to the University of Birmingham

for the degree of Master of Philosophy

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February 2016

Abstract

Aims

To determine whether ligation with figure of eight modules affects the rate of lower incisor alignment compared with conventionally tied modules and to establish whether there are any differences in the number of bracket failures between the two groups.

Methods

Ethical approval was obtained. Participants were randomly allocated to conventional module or figure of eight module groups, stratified for extraction or non extraction treatment. Lower labial segment alignment was measured on study models using Little's Irregularity Index at the start (T0) of treatment, at 6 weeks (T1) and 12 weeks (T2). Case records were analysed to assess the number of bracket failures per patient.

Results

100 subjects participated. In both groups the fastest rate of alignment was between T0 and T1; 3.20mm/month and 3.54mm/month in the conventional and figure of eight module groups respectively. The difference between the groups was not statistically significant. The bracket failure rate was also similar in both test groups; 4.4% for conventional and 3.6% for figure of eight ligation.

Conclusions

Ligation with the tighter figure of eight module configuration has no clinically significant effect on the rate of lower incisor alignment. Therefore it seems that figure of eight ligation does not hinder the alignment of the teeth. There were no differences in the average number of bracket failures per person.

Acknowledgements

I would like to express my heartfelt thanks to Mr D Spary, for the initial idea of the study, for his assistance in recruitment of patients and carrying out the orthodontic treatment, and his continuous support and encouragement.

I would like to thank Dr A Dhopatkar for his support and guidance during the course of this research and in the preparation of this thesis.

I am grateful to Professor T Dietrich and Mr A Cutts for their assistance with statistical analysis.

I wish to express my gratitude to Dr J Harrison for all her support and guidance.

I would like to thank all of the operators who undertook the orthodontic treatment for the clinical trial and the laboratory staff who produced all of the study models.

CONTENTS

CHAPTER 1: LITERATURE REVIEW

CHAPTER 2: MATERIALS AND METHODS

CHAPTER 3: RESULTS

CHAPTER 4: DISCUSSION

CHAPTER 5: CONCLUSIONS

CHAPTER 6: APPENDICES

LIST OF FIGURES

LIST OF TABLES

Chapter 1

LITERATURE REVIEW

CHAPTER 1: LITERATURE REVIEW

1.1 Introduction

The edgewise appliance (Angle, 1928) and its modern day derivative, the ubiquitous pre-adjusted edgewise appliance rely on secure ligation of the archwires into the brackets. Stainless steel ligatures, pins, elastomeric modules and self ligating spring clips or slides have been used successfully for many years. Since their introduction in the 1960s elastomeric modules have become the most popular choice with clinicians due to their ease of use, quick application and removal. Patients can also find them attractive by virtue of the many colours available.

Friction in orthodontics has long been a topic for debate. It is generally believed that frictional resistance must be minimised during sliding mechanics so that tooth movement can be generated through light optimal forces. Sliding mechanics is impossible when using standard edgewise appliances as numerous bends are required to finalise tooth positioning. In pre-adjusted edgewise appliances, first, second and third order movements are incorporated within the bracket system so that the archwire is flat and straight following tooth alignment. This facilitates space closure by allowing the teeth to slide along the archwire. Sliding mechanics reduce the need for wire bending, ensure lower forces are required and provide good labial torque control. If frictional forces are high, the efficiency of the system is affected and the treatment time may be extended or the outcome compromised (Drescher *et al.*, 1989).

The nature of ligation is an important contributor to frictional force. Ideal requirements of a ligating system are that it must be robust, ensure full bracket engagement, exhibit low friction between the archwire and bracket, be quick and easy to use, permit high friction when required, assist good oral hygiene and be comfortable for the patient (Harradine, 2003). Although elastomeric modules are the most commonly used ligation method, they have been found to produce higher frictional forces than other methods (Ireland *et al.*, 1991; Shivapuja *et al.*, 1994; Griffiths *et al.*, 2005). Elastomeric modules may also encourage plaque accumulation around the bracket archwire interface, predisposing to decalcification or periodontal disease (Taloumis *et al.*, 1997). Stainless steel ligatures are more time consuming to apply, produce variable ligation forces and pose the risk of soft tissue laceration to the patient and the orthodontist (Shivapuja and Berger 1994; Hain *et al.*, 2006; Maijer and Smith, 1990). Studies on self-ligating bracket systems have shown considerable reductions in friction (Berger, 1990; Maijer and Smith, 1990), but they are more costly and conflicting evidence has been published on whether this bracket system clinically quickens treatment time.

1.2 Elastomeric modules: composition and form

Elastomeric orthodontic modules are polyurethanes, which are thermosetting polymer products of a step-reaction polymerisation process (Eliades *et al.*, 1999). Even though it is know that elastomeric modules are polyurethane-based, their exact composition is patent-protected. They can be fabricated either by injection moulding or by cutting from elastomeric tubing (Chimenti *et al.*, 2005). An *ex vivo* study found that stretched die-cut stamped elastomeric chains maintained a higher level of remaining force than the injection moulded chains (Hershey and Reynolds, 1975). A more recent *in vivo* study comparing the force decay between the two types of elastomers has shown that there is no clinical difference (Bousquet *et al.*, 2006).

Elastomeric modules are composed of either poly(ether)urethanes or poly(ester)urethanes. Polyurethane elastomers are a product of the rearrangement polymerisation of diisocyanates and polyols. The three principal constituents that react are (1) a diisocyanate (Ar-NCO); (2) a long chain hydroxy-terminated polyol, either as a polyether or a polyester (R-OH); and (3) a chain extender which is either a short chain or a diamine. These polymers contain short rigid portions (aromatic rings and ureas) joined by short flexible 'hinges' (diamine linker and CH_2 group between the aromatic ring) and long very flexible portions (polyether) whose length can be adjusted. The elastomeric polymer can be easily stretched and largely regains its shape on relaxation (Eliades *et al.*, 2005). At rest polymer chains are randomly coiled and upon extension the chains are elongated into an ordered structure. When the elongation stress is removed, the chains exhibit elastic behaviour and tend to revert back to their original disorganised state (Wong, 1976).

Polyurethane elastomers possess a reasonable degree of stability in aqueous environments; however the presence of ester or ether backbone linkages increases the susceptibility to hydrolytic attack (Huget *et al.*, 1990). Despite most orthodontic elastomeric modules sharing a similar manufacturing process, significant variations in their force decay characteristics and force relaxation patterns have been reported (De Genova *et al.*, 1985; Kuster *et al.*, 1986). These difference may be attributed to (a) processing techniques (injection moulding or cutting); (b) additives included into the final product; (c) different dimensional (presence or absence of inter-modular link) or morphological (ellipsoid or circular modules) characteristics of the chains (Eliades *et al.*, 1999).

1.2.1 *In vivo* effects on polyurethanes

Polyurethane elastomeric modules do not exhibit perfect elastic behaviour as their mechanical properties are affected by temperature and time (De Genova *et al.*, 1985). The major limitation of *ex vivo* experiments is the inability to accurately replicate the dynamic conditions of the oral cavity. The main distinguishing factor is the presence of complex oral flora and their by-products, as well as the accumulation of plaque (Eliades and Bourauel, 2005). Other factors to consider *in vivo* that may alter the elastic properties of elastomers are chemicals from the saliva, food or oral hygiene products, thermal effects due to the ingestion of hot and cold foods, and mechanical effects, due to mastication and oral hygiene techniques (Ash and Nikolai, 1978; Kuster *et al.*, 1986; De Genova *et al.*, 1985).

The majority of studies undertaken on polyurethanes have used *ex vivo* testing. Experiments are standardised in an attempt to replicate the oral environment but it is impossible to control all of the factors that may have an impact in a clinical situation (Rock *et al.*, 1986). It is important not to overlook the effects of an *in vivo* environment on the clinical properties of a material (Ash and Nikolai, 1978; Kuster *et al.*, 1986; De Genova *et al.*, 1985; Ferriter *et al.*, 1990; Taloumis *et al.*, 1997).

Elastic polymers are relatively unaffected by short exposures to water but under prolonged contact with water, dilute acids or moist heat, decomposition occurs along with swelling of the material and slow hydrolysis. The staining of these polymers in the oral cavity can be attributed to filling of the voids in the rubber matrix by fluids and bacterial debris (Wong, 1976). They are also degraded by ozone through an autocatalytic process, which decreases their tensile strength and flexibility (Young and Sandrik, 1979). The absorption of lipids has been shown to cause structural alterations to the polyurethanes; these complexes act as a nuclei for calcification, lower the glass transitional temperature of the polymer and induce a plasticising effect (Eliades and Bourauel, 2005). Molecular chain stretching, slippage between adjacent molecular chains and molecular chain breakage can all cause permanent deformation of polymeric materials (Eliades *et al.*, 2004). If polymer chains slip past one another, viscous behaviour can occur that is slow and irreversible; if the chains stretch and uncoil, elastic behaviour is demonstrated that is quick and reversible (De Genova *et al.*, 1985).

The force delivered by polyurethane materials is related to their molecular structure; the glass transition temperature indicates the rigidity of a material. The higher the temperature range, the more rigid the polymer is. Higher glass transition temperatures are found with polyurethanes that contain more covalent bonds or cross-linking than those with a greater proportion of secondary interatomic bonds, such as hydrogen bonds, ionic bonds or van der Waals bonds. A study was conducted to compare glass transition temperatures for different brands and colours of orthodontic elastomeric chains before and after clinical use. Rocky Mountain Orthodontics (Denver, Colorado) chains had considerably higher glass transition temperatures than those of Ormco (Glendora, California) and G&H (Greenwood, Indiana) before use, indicating that the latter products should have greater flexibility. After four weeks of clinical use the glass transition temperatures decreased for the Ormco and RMO products but unusually increased for the G&H purple chains. Pigment had no significant effect on glass transition temperatures on products by RMO or Ormco (Renwick *et al.*, 2004).

The majority of research on elastomeric polymers has focused on chains or threads. Elastomeric ligatures are composed of the same material but the clinical applications are different, therefore the response may also be altered. This must be borne in mind when interpreting the results of studies (Taloumis *et al.*, 1997). A potential source of variation between *in vivo* studies with elastomeric chains is the span of the chain and the presence or absence of spacing between adjacent teeth.

During the initial aligning and levelling phase elastomeric ligatures are useful (Taloumis *et al.*, 1997). Mechanics that require complete engagement of the bracket slot, such as correction of rotations or torque expression, elastomeric ligatures may not be as effective due to rapid force loss and deformation. A bench study conducted showed that elastomeric ligatures were not effective in holding arch wires into the bracket when rotational moments were applied (Bednar and Gruendeman, 1993). The preadjusted edgewise appliance compromises on the expression of prescribed torque and this may be further reduced by elastomeric modules, that undergo stress relaxation (Gioka and Eliades, 2004). It may be preferable to shorten the time between appointments or use alternative ligation methods such as steel ligatures (Eliades and Bourauel, 2005).

Plastic deformation is the inability of a material to return its original shape after it has been stretched (Bishara and Andreasen, 1970). It begins at the original stretch and increases with time; also the smaller the original stretch, the smaller the deformity (Andreasen and Bishara, 1970).

Elastomeric chains submerged in a 37˚C water bath for 6 weeks showed that the most force decay occurred during the first hour and that the greater the initial force, the greater the decay (Chau Lu et al., 1993). However De Genova *et al.* (1985) found that the opposite; the higher the initial force, the smaller the force decay. An ex vivo study investigating the force loss of elastomeric ligatures found that the mean percentage loss was 53% to 68% in the first 24 hours (Taloumis *et* *al.*, 1997). It is recommended that elastomeric modules are replaced at each routine appointment due to the reduction in failure load strengths between visits (Dowling *et al.*, 1998).

A study by Ash and Nikolai (1978) found that the degradation rate of elastics was substantial immediately after activation but decreased gradually during a three week period. The decay in the oral cavity was significantly greater than in the water after one day for the elastic chain and for the module, after approximately ten days. A subsequent *in vivo* study showed a force reduction of 50% for elastomeric chains over a four week period (Rock *et al.*, 1986).

A unique study of parallel laboratory and intraoral experiments was conducted to determine whether the testing environments affected friction, using elastomeric ligation. Intraoral friction values were significantly higher than *ex vivo* values and the authors attributed this to possible lower ligation forces due to compositional changes of the elastomeric modules intraorally from water sorption (Iwasaki *et al.*, 2003). This is in variance with previous work concluding that pre-stretching elastomeric modules reduces friction by means of lower ligation forces. A pre-stretched elastomeric module reduces friction by 40% for 0.018 inch round wires (Taylor *et al.*, 1996).

The opinions in the literature on the effect of pre-stretching elastomeric modules on their force loss are markedly varied. Young and Sandrik (1979) reported that pre-stretching elastomeric chain in air significantly increased the remaining force by 17% to 25% after 24 hours. Brantley (1979) reported a 4.5% force loss in modules pre-stretched for 3 weeks in water compared to 65% in the control group. Baty *et al.* (1994) concluded any benefits from pre-stretching were minimal and probably of no clinical benefit. A more recent study found that the effects of pre-stretching elastomeric modules on force decay were noted mainly in the first hour, and thus questioned the clinical value of it (Kim *et al.*, 2005). Modules placed in a figure of eight configuration will undoubtedly be stretched to a greater extent than modules placed in the conventional manner.

The effects of water absorption on elastomeric modules include slippage of molecules or polymer chains past one another, thus accelerating the force decay of these materials. Unstretched modules placed in a synthetic saliva bath at 37˚C, pH 6.84 for 28 days absorbed moisture in the range of 0.06% to 3.15% (Taloumis *et al.*, 1997). The pH of the oral cavity affects orthodontic elastomerics; the pH of saliva ranges from 5.6 to 7.6, with a mean of 6.75. An acidic test solution (pH 4.95) induced a significantly smaller rate of decay in orthodontic polyurethane chain elastics when compared with a neutral solution (pH 7.26) (Ferriter *et al.*, 1990).

A wide range of orthodontic modules are available on the market, differing by dimension, colour, and the addition of fluoride or lubricants.

1.2.2 Dimensions of an elastomeric module

Elastomeric modules are marketed according to dimensions of wall thickness (WT), outside diameter (OD) and inside diameter (ID) (Figure 1.1).

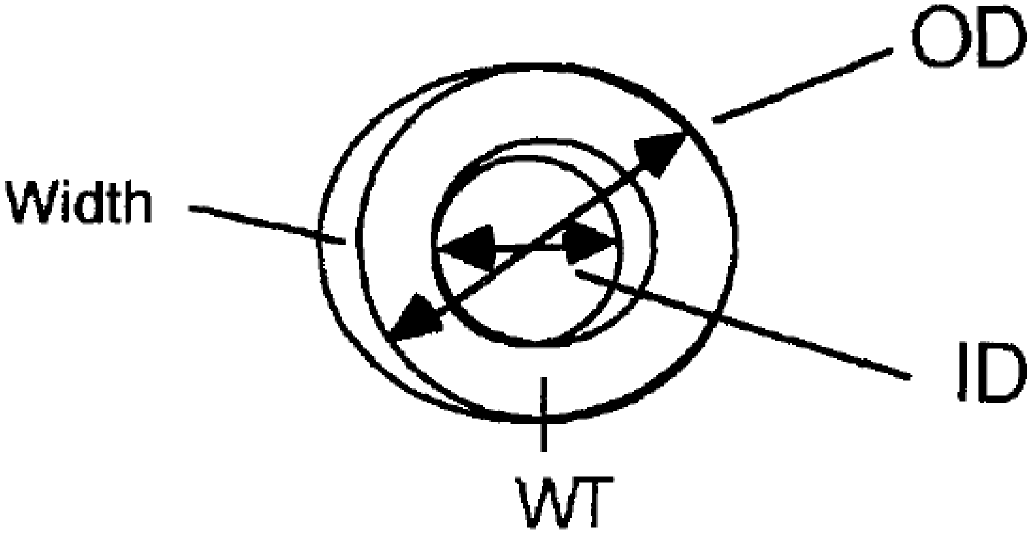

Figure 1.1 Dimensions of an elastomeric module (Taloumis *et al.*, 1997)

Each manufacturer produces modules of differing dimensions. Moisture and heat decrease the force levels and dimensional stability of elastomeric materials. The greater the wall thickness and the smaller the inside diameter, the greater the force the elastomeric ligature produces. However the outside diameter is poorly linked with the forces generated. It would be helpful if the modules were all marketed according to the inside diameter as this is most clinically useful

(Taloumis *et al.*, 1997). These findings concur with a more current study; the smaller the inside diameter of an elastomeric module, the greater the resistance to sliding (Griffiths *et al.*, 2005).

It had been proposed that small and medium elastomeric ligatures produce a significant decrease (13 to 17%) in frictional forces when compared with large ligatures, and this can be ascribed mainly to the wall thickness (Chimenti *et al.*, 2005). A more recent study contradicts this finding; they found no statistically significant difference in the friction generated by ligatures of different sizes (Arun and Vaz, 2011).

Elastomeric ligatures have varying degrees of excess material (flash) at their inner and outer edges. Taloumis *et al.* (1997) commented that the manufacturer Ormco consistently had the least amount of flash, along with the most consistent force measurements. No studies have been undertaken to assess if the amount of flash has any effects clinically.

1.2.3 The effect of colour on an elastomeric module

The addition of colouring additives to elastomeric ligatures may have a significant effect on their tensile strength properties. Tensile strength is the maximum stress (N) a material can withstand before fracturing or alternatively it can be measured as the extension to tensile strength (mm); this provides an indirect measure of the toughness of the ligatures. The extension to tensile strength of all the coloured Ormco ligatures was higher than that of the clear modules from the same manufacturer. However there was no significant difference between clear and coloured modules from Unitek in this *ex vivo* study. The mean tensile strength of all the ligatures tested decreased by 7 to 22% at four weeks, but their extension to tensile strength had almost increased by the same percentage, therefore it is suggested that the toughness remained roughly the same (Lam *et al.*, 2002). The addition of colour to modules can affect the friction; clear modules exhibited significantly lower friction than the other modules from the same proprietary group and they also demonstrated the lowest failure forces (Dowling *et al.*, 1998).

It has been postulated that the force delivery of elastomeric chains is affected by the filler material used in tinting the chains. Baty *et al.* (1994) found that coloured chains of a certain manufacturer behaved similarly to the grey chain from the same company, with the exception of purple and green chains from Ormco that required more extension to deliver the same force as the grey chain.

1.2.4 Addition of lubricants to elastomeric modules

Super Slick modules were introduced by TP Orthodontics (LaPorte, Ind) in 2000. They have a covalently bonded Metafix coating, which the company claim decreases friction by more than 70%. This claim was confirmed by findings of Hain *et al.* (2003;2006), who found that coated modules reduced friction by 60%

and 50% respectively, and also by Chimenti *et al.* (2005) and Arun and Vaz (2011). Other studies have found contradictory results (Khambay *et al.*, 2004; Griffiths *et al.*, 2005; Edwards *et al.*, 2012). Furthermore one study found no difference in the frictional forces between Super Slick modules and uncoated modules (Crawford *et al.*, 2010).

Hain *et al.* (2006) found that frictional resistance increases by approximately 80% if the coated modules are not pre-soaked in saliva. The presence or absence of saliva has a proportionally bigger effect on coated modules than on uncoated modules (Hain *et al.*, 2003).

1.3 Friction

1.3.1 Background

The first recorded experiments on friction were undertaken by Leonardo da Vinci approximately 475 years ago (Garner *et al.*, 1986). Friction in the orthodontic literature was been recognised for some time; Stoner (1960) identified that appliance inefficiency was due to dissipation of forces by friction or improper application. Frictional forces are encountered in an opposite direction to the moving body, therefore it is important that these forces are eliminated or at least minimised when orthodontic tooth movement is planned (Drescher *et al.*, 1989), otherwise tooth movement may be entirely inhibited or anchorage jeopardised (Edwards *et al.*, 1995). In the fixed appliance system, 12-60% of applied force may be lost due to friction (Kusy and Whitley, 1997). Low friction is particularly advantageous in extraction cases where sliding mechanics are required to achieve translatory movements (Cacciafesta *et al.*, 2003).

Friction is defined as “the force tangential to the common boundary of two bodies in contact that resists the motion of one relative to the other; it is proportional to the force with which the two surfaces are pressed together and dependent on the nature of the surfaces in contact” (Drescher *et al.*, 1989). It is independent of the area of contact and sliding velocity (O’Reilly *et al.*, 1999). The friction between two or more materials can be represented as $F_F = \mu\Sigma N$, where ΣN is the sum of the contacting (or normal) forces in all planes of space, and μ is the coefficient of friction between materials (De Franco *et al.*, 1995). The coefficient of friction is a constant for a given material and is dependent upon surface roughness, texture or hardness (Loftus and Årtun, 2001). The classic laws of friction are applicable to metals under normal conditions, but for other materials or extreme conditions, such as the intraoral environment, these laws are less reliable (O’Reilly *et al.*, 1999).

Friction reduces the efficiency of the fixed appliance system, resulting in an increased force required to achieve the desired result (Articolo and Kusy, 1999), however low forces are preferable to prevent anchorage loss (Quinn and Yoshikawa, 1985) and facilitate sliding mechanics. Additionally, low forces may increase patient comfort (Kusy and Whitley, 1997) and reduce the risk of root resorption (Harry and Sims, 1982).

During orthodontic tooth movement, the friction encountered can be divided into two separate entities:

1) Static friction – The resistance that prevents initial tooth movement (or force required to initiate tooth movement);
2) Kinetic friction – The force that resists tooth movement.

The coefficients of static and kinetic friction depend upon the relative roughness of the contacting surfaces and are determined in lab based experiments. The static coefficient is always larger than its kinetic counterpart (Frank and Nikolai, 1980). A stainless steel couple (brackets and archwires) produces the lowest coefficients of friction (Kusy and Whitley, 1989).

Clinically tooth movement occurs as a series of short steps rather than a smooth continuous motion. To begin with static friction between the bracket and archwire must be overcome to initiate tooth movement. Kinetic friction arises as the crown of the tooth tips in the direction of the applied force. The crown inevitably tips before the root does, creating a couple between the bracket and the archwire; this stops crown movement and acts to upright the root. Bony and periodontal remodelling ensues along the root surface and then the cycle continues (Frank and Nikolai, 1980). Drescher *et al.* (1989) reported that the retarding force or biologic resistance is the most important factor affecting friction in tooth-guided archwire mechanics. Even though the importance of biological variables has been recognised, few studies have investigated them (O'Reilly *et al.*, 1999).

Although the present literature review has focused on the factors most relevant to this study a plethora of factors can influence the forces exerted by an orthodontic fixed appliance (Table 1.1). The friction in the system may not always be predictable.

Bracket	**Archwire**	**Archwire/bracket interaction**	**Intra-oral factors**
Material	Material	Archwire/slot dimensions	Saliva
Type	Cross-sectional shape and size	Angulation of archwire relative to bracket slot	Masticatory function
Width	Stiffness	- First order bends	Sliding velocity
Inter-bracket distance		- Second order bends	
Prescription		- Third order torque	
		Method of ligation	

Table 1.1 Summary of factors affecting friction during fixed appliance therapy

1.3.2 Bracket material

Friction at the interface between two objects causes resistance to the direction of movement. As previously mentioned the frictional force is proportional to the force with which the surfaces are pressed together and the by the nature of the surface at the interface. Friction however is independent of the area of contact and this is due to surface irregularities known as asperities. Real contact only occurs at a limited number of small spots at the peaks of these asperities (Proffit *et al.* 2007). Surfaces with a greater number of asperities have a greater surface roughness and thus more force is needed to overcome the interlocking of these irregularities. Surface roughness is determined by the type of material the bracket (or wire) is produced from, the manufacturing process (e.g. heat treatment, polishing), and shelf life properties (e.g. corrosion, creep) (Frank and Nikolai, 1980).

Vaughan *et al.* (1995) demonstrated that sintered stainless steel brackets generated 40% less friction than cast stainless steel brackets. Sintering allows compression of stainless steel particles into a smooth contoured shape, unlike the casting process which requires milling, creating sharp angular brackets. These findings were echoed by Ogata *et al.* (1996).

Ceramic brackets have become increasingly popular over recent years due to their superior aesthetics over metal brackets. Tanne *et al.* (1991) concluded that the amount of tooth movement with three ceramic brackets was significantly less than with the metal bracket. They discovered that the slot surfaces and edges of ceramic brackets were rougher and more porous than those of a metal bracket and thus the wire surfaces were scratched by the ceramic brackets, whereas only minor scratches were observed with the metal bracket. Tooth movement was less efficient with the ceramic brackets and this was attributed to increased frictional resistance. Keith *et al.* (1993), in an *ex vivo* experiment, similarly found that ceramic brackets produced greater frictional resistance than stainless steel brackets. Abrasive wear of the archwires caused by the ceramic brackets and the subsequent wear debris may have contributed to the differences in frictional resistance. Clinically this has important implications when utilising sliding mechanics; increased force or decreased ligation force would be required to overcome both the static and kinetic coefficients of friction.

In general, polycarbonate brackets show higher frictional values than stainless steel brackets. An *ex vivo* experiment under dry conditions using a stainless steel archwire and bracket to archwire angulation of 0˚, ranked stainless steel brackets as having the least friction, followed by polycarbonate, sapphire, or porcelain (Tselepis *et al.*, 1994). This supported the work of Riley *et al.* (1979), Popli *et al.* (1989), Berger (1990), and Angolkar *et al.* (1990).

1.3.3 Archwire material

The pre-adjusted edgewise appliance relies on the ability of orthodontic wires to slide through brackets and tubes. Friction at this interface resists tooth movement and the higher the friction, the greater the force that is needed to overcome this and a greater anchorage need exists.

There is a general consensus that stainless steel wires demonstrate the least resistance to sliding, followed by nickel-titanium and then β-titanium (Frank and Nikolai, 1980; Garner *et al.*, 1986; Drescher, 1989; Tidy, 1989; Angolkar *et al.*, 1990; Kusy and Whitley, 1990; Pratten *et al.*, 1990; Ireland *et al.*, 1991). Kusy *et al.* (1988) used specular reflectance to analyse the surface roughness of orthodontic archwires and ranked stainless steel as the smoothest, followed by cobalt-chrome, β-titanium, and nickel-titanium. Higher frictional forces were also observed with nickel-titanium and β-titanium wires in a study by Kapila *et al.* (1990). They implied that this is due to the greater surface roughness of these alloys than the smoother stainless steel and cobalt-chrome wires, which demonstrated lower frictional forces.

On the contrary, Prososki *et al.* (1991) showed that stainless steel and β-titanium alloy wires had the highest frictional resistance, despite stainless steel being the smoothest, and that cobalt-chromium and nickel-titanium alloy wires exhibited the lowest frictional resistance, despite nickel-titanium being the roughest. No significant correlation could be established between average roughness and frictional force values. It has been postulated that the interlocking of asperities could result in a positive correlation with increased frictional resistance, but this effect was not seen in this study. Interestingly the opposite argument was not demonstrated either i.e. a very smooth surface would result in greater surface area in contact, thus a greater force would be required to overcome the friction. They proposed that there is an intermediate range of surface roughness that has no effect on the frictional properties. This theory was in agreement with Kusy and Whitley (1988) who suggested that low surface roughness did not necessarily result in low frictional coefficients. It was proposed that surface chemistry and chemical affinity played the most significant role.

Surface coated archwires have been developed to improve aesthetics and/or performance but the coating is frequently stripped away from the wire leading to greater binding and hence more friction (Dickson *et al.*, 1994). Zufall and Kusy (2000) investigated the frictional properties of an aesthetic fibre reinforced composite wire with a polymeric coating and found that the kinetic coefficient of friction was much greater than stainless steel wires.

Ion implantation of orthodontic archwires can be used to alter the hardness, friction, wear resistance, and surface colour (Burstone and Farzin-Nia, 1995). Studies by Kusy *et al.* (1992) and Burstone and Farzin-Nia (1995) have both shown that nitrogen ion implantation of beta titanium archwires significantly reduces the frictional resistance to values comparable with equivalent sized stainless steel wires. Ryan *et al.* (1997) reported that nitrogen ion implantation into nickel titanium and beta titanium wires produced significantly more tooth movement than their untreated counterparts.

1.3.4 Archwire cross-sectional shape and size

It is generally agreed that as wire sizes increases, so does the frictional force between bracket and wire (Riley *et al.*, 1979; Frank and Nikolai, 1980; Garner *et al.*, 1986; Tanne *at al.* 1991; Sims *et al.*, 1993; Ogata *et al.*, 1996; Thomas *et al.*, 1998). However Peterson *et al.* (1982) and Vaughan *et al.* (1995) felt that nickel-titanium did not follow this rule. They both reported that an increase in the size of nickel-titanium wire did not necessarily cause an increase in the frictional resistance, possibly owing to the flexibility of nickel-titanium.

It has been established that frictional forces increase not only with larger diameter wires, but with rectangular wires. Larger rectangular wires increase the bracket-wire interface, affecting the frictional forces (Angolkar *et al.*, 1990; Kapila *et al.*, 1990; Vaughan *et al.*, 1995; Ogata *et al.*, 1996; Taylor and Ison, 1996), especially at small bracket-archwire angulations (Frank and Nikolai, 1980). On the contrary, other studies have found that increasing archwire dimensions does not affect friction (Peterson *et al.*, 1982; Tidy, 1989); others have found that smaller dimension archwires produce the highest friction (Ireland *et al.*, 1991; Baker *et al.*, 1987). They postulated that this was due to greater tipping and thus increased binding.

The effect of cross-sectional archwire shape may be related to the bracket system used. In a study comparing various bracket-archwire combinations, it was shown that Damon SL II self-ligating brackets generated significantly lower friction when tested with round wires and significantly higher friction when tested with rectangular wires, compared to another brand of self-ligating brackets and conventional stainless steel brackets (Tecco *et al.*, 2005).

In another comparative study by Cacciafesta *et al.* (2003) of stainless steel and polycarbonate self-ligating brackets, the results revealed higher static and kinetic frictional forces as the wire size increased, regardless of archwire material.

1.3.5 Method of ligation

Harradine (2003) formulated a list of the ideal properties of a ligation system:

- Secure and robust;
- Ability to ensure full bracket archwire engagement;
- Low friction;
- Quick and simple to use;
- Allow maintenance of good oral hygiene;
- Comfortable for the patient;
- Permit easy attachment of elastic chain.

Friction of a ligature depends upon its coefficient of friction and the force that it exerts upon the bracket and archwire (De Franco *et al.*, 1995). The first law of friction states that frictional force between two bodies is proportional to the normal load between them. Thus the force of ligation directly influences the frictional resistance between the bracket and archwire by altering the normal force (Keith *et al.*, 1993).

Reported ligation forces are highly variable and can range from 50g to 300g. Comparisons between different studies can be difficult unless a consistent ligation force and methodology have been stated and employed (Articolo and Kusy, 1999).

Echols (1975) suggested that elastomeric module ligation produced frictional forces in the range of 39-133g. Much of the literature states that elastomeric modules produce higher frictional forces than other types of ligation (Ireland *et al.*, 1991; Shivapuja *et al.*, 1994; Griffiths *et al.*, 2005). Ideally, elastomeric modules should not be used in conjunction with flexible wires as too much of the active force is needed to overcome friction; the ligature may act as a restraint limiting the superelasticity of the nickel-titanium wire. A better alternative would be a loosely tied stainless steel ligature (Meling *et al.*, 1997; Kasuya *et al.*, 2007).

The frictional forces that are produced by stainless steel ligatures are sensitive to the method of application (Tidy, 1989). These differences can be attributed to the force used to tie the ligature. There is a general consensus among most authors that loosely tied stainless steel ligatures produce less friction than conventional elastomeric ligatures (Bednar *et al.*, 1991; Taylor and Ison, 1996; Hain *et al.*, 2003; Thorstenson and Kusy, 2003; Khambay *et al.*, 2004; Khambay *et al.*, 2005). According to other studies, frictional forces created by elastomeric and stainless steel ligatures are similar (Frank and Nikolai, 1980; Edwards *et al.*, 1995; Bazakidou *et al.*, 1997), whereas others found that elastomeric ligatures produced less friction than stainless steel ties (Riley *et al.*, 1979; Schumacher *et al.*, 1990). Although more evidence has shown that stainless steel ligatures produce less friction, the convenience and the speed of application of elastomeric modules will ensure their continued popularity (Maijer and Smith, 1990; Shivapuja and Berger, 1994). Furthermore loosely tied stainless steels may impart insufficient force to ensure complete engagement of the archwire in the bracket slot, thus torque expression could be impaired (Hain *et al.*, 2003).

Teflon-coated stainless steel ligatures were introduced to be used with ceramic brackets. Teflon has a low coefficient of friction and it has been shown to produce less friction than elastomeric modules and plain stainless steel ligatures (De Franco *et al.*, 1995; Edwards *et al.*, 1995). McKamey and Kusy (1999) developed a composite ligature which exhibited a tensile strength more than twice that of a dead-soft stainless steel ligature and had significantly greater stress-relaxation decay. It was proposed that this aesthetic composite ligature would be beneficial when tooth movement with negligible friction was required.

Elastomeric modules tied in a ‘figure of eight’ pattern produce significantly more friction than conventionally tied elastomerics or stainless steel ligatures (Edwards *et al.*, 1995; Voudouris, 1997; Hain *et al.*, 2003). Sims *et al.* (1993) demonstrated that ‘figure of eight’ elastomeric modules increased frictional resistance, when compared with conventionally tied modules, by a factor of 70-220 percent depending on the archwire size. A study comparing eight different types of ligation concluded that frictional resistance to sliding was the lowest when stainless steel ligatures were twisted in a figure of eight pattern until taut then untwisted one quarter turn and the greatest when elastomeric modules were tied in a figure of eight configuration (Sirisaowaluk *et al.*, 2006). If sliding mechanics are to be employed, elastomeric modules tied in a figure of eight pattern should be avoided as this may jeopardise anchorage (Edwards *et al.*, 1995).

In recent years an innovative ligature has been manufactured by Leone Orthodontic Products. The “nonconventional” elastomeric ligature is applied to a conventional bracket but the interaction forms a tube-like structure, which allows the archwire to slide freely, similar to a passive self-ligating bracket. It is claimed that these modules produce significantly lower levels of frictional forces than conventional elastomeric ligatures (Baccetti and Franchi, 2006; Gandini *et al.*, 2008).

In an aqueous environment elastomeric modules can degrade and if left too long, insufficient seating forces may result in poor tooth control and rotations occurring

(Harradine, 2003). Edwards *et al.* (1995) studied the degradation of elastomers in an aqueous environment and the effects upon ligation force. Storage of modules in artificial saliva increased the frictional resistance and the authors suggested that the effects of saliva acting as an adhesive outweigh the influence of force degradation of the elastomeric modules.

In an attempt to eliminate the effects of elastomeric and stainless steel ligatures, self-ligating brackets were introduced, which have been shown to generate very low frictional forces (Griffiths *et al.*, 2005). Self-ligating brackets are more expensive than conventional brackets but this is counterbalanced by advantages such as reductions in chairside time, treatment duration and the absence of bio-hostable elastic modules (Turnbull and Birnie, 2007).

1.3.5.1 Bracket failures in relation to ligation method

Very few studies have investigated the relationship between bracket failure rate and the method of ligation. A recent randomised controlled trial compared self-ligating and conventional brackets, both using a standardised etch and bond procedure. It was reported that there was no significant difference between the overall bond failure rates; 6.6% for SmartClip brackets and 7.2% for Victory brackets (O'Dywer *et al.,* 2015). Pandis *et al.* (2006) also found no difference in the bracket failure rates between self-ligating and edgewise brackets when bonded using both conventional acid etching and self-etching primer. A study comparing bond failure rates of an active (In-Ovation R) and passive (SmartClip) self-ligation system found that the bond failure rate was significantly lower with SmartClip brackets, but overall both brackets had clinically acceptable bond failure rates (Chapman, 2011).

Table 1.2 lists other potential causes of bracket failure, excluding ligation method.

Operator Factors	**Patient Factors**
Concentration of etch	Gender
Etching time	Age
Isolation technique	Presenting malocclusion
Bonding agent	Diet
Bonding technique	Care of appliance
Bracket type/base	Masticatory force
Mechanical force	Habits
Occlusal interference	Trauma

Table 1.2 Summary of operator and patient factors that can cause bracket failure

1.3.6 Saliva

The question as to whether saliva acts as a lubricant to reduce frictional resistance or as an adhesive which binds the archwire and bracket, preventing sliding mechanics, is contentious. Baker *et al.* (1987) reported that saliva substitute acted as a lubricant and reduced frictional forces by 15% to 19% when testing stainless steel wires and brackets.

Downing *et al.* (1994) examined the effects of frictional forces of stainless steel and ceramic brackets, combined with stainless steel, nickel-titanium and beta-titanium archwire materials. For all pairings, artificial saliva had the effect of increasing the frictional force when compared with the dry state. These findings were in agreement with Stannard *et al.* (1986), Pratten *et al.* (1990), and Kusy *et al.* (1991) that artificial saliva did not appear to act as a lubricant.

Kusy *et al.* (1991) concluded that saliva may promote lubricous and adhesive behaviour, depending on which archwire bracket couple is investigated. They found that in the dry state, stainless steel couples exhibited the lowest coefficients of friction and β–titanium couples the highest. Conversely in the wet state, saliva behaves like a lubricant with β–titanium couples and as an adhesive with stainless steel couples.

Pratten *et al.* (1990) explained that the discrepancies may be due to the loading forces used between the arch wire and the brackets. At low levels saliva acts like a lubricant but at high levels saliva may increase friction if it is forced out from between the contacts. However, engineering literature states that it is impossible to completely force out an oil film between two plane surfaces, no matter how heavy the load (Tselepis *et al.*, 1994).

Others have shown that saliva plays an insignificant role in lubrication and thus has a negligible impact on friction (Andreasen and Quevedo, 1970; Rucker and Kusy, 2002). The latter study explained that sliding occurs mainly in the dry state for single stranded wires, even in the mouth, as saliva is squeezed out from between the contacting smooth surfaces. With multi stranded wires, they suggest that there is a combination of an adhesive film covering the sliding surfaces and some surface contact.

Ireland *et al.* (1991) found that the influence of friction in a wet or dry environment on stainless steel and ceramic brackets using larger dimensional wires was minimal. A wet environment was created by pre-soaking elastomeric modules for 24 hours in a water bath at 37˚C then pouring the same water over the brackets during testing. With the smaller wires, a significant reduction in frictional resistance was seen with the ceramic brackets under a wet testing environment.

Tests performed to quantify friction using a saliva substitute should be treated with caution; human saliva would be the gold standard (Kusy and Whitley, 1992). The results from the literature are markedly varied, probably because no one factor dictates entirely the friction within the system. Friction is dependent on a wide range of factors, saliva being only one of them (Ireland *et al.*, 1991).

1.3.7 Masticatory function

An *in vivo* experiment was performed to determine if vibration caused by mastication reduced friction in an orthodontic appliance. Subjects were asked to chew softened gum with a measuring device in situ. The results showed that mastication did not significantly reduce frictional forces in an appliance consisting of stainless steel brackets with a 0.022 x 0.028 inch slot ligated to a 0.019 x 0.025 inch stainless steel archwire with a 0.010 inch diameter stainless steel or elastomeric ligature (Iwasaki *et al.*, 2003).

O'Reilly *et al.* (1999) attempted to replicate masticatory function *ex vivo* by repeated vertical displacement of a bracket under a constant load, testing multiple archwires. It was discovered that there was a 10% decrease in resistance to sliding for a 0.25mm displacement, 47% for 0.5mm, and 80% for 1mm of vertical wire displacement. There was also a significant reduction in sliding resistance, which differed depending on the archwire. There was an 85%, 80% and 16% reduction associated with 0.021 x 0.025 inch, 0.019 x 0.025 inch and 0.016 inch stainless wires respectively. For 0.019 x 0.025 inch β–titanium archwires, there was a reduction of 27%. It was concluded that given the likelihood of bracket and/or archwire displacements intra orally, the importance of true friction may be lessened; this was echoed by Braun *et al.* (1999).

In a similar *ex vivo* study by Olson *et al.* (2012) it was reported that frictional resistances were not significantly affected by the frequency of the archwire vibrations, but were significantly reduced by a least 17% when medium (150mV) and high (190mV) amplitude of vibration were used, compared with a low (110mV) amplitude. They deduced that the stick-slip behaviour at the bracket archwire interface is more influenced by vibration amplitude/amount of vertical displacement of the archwire, than vibration frequency.

1.3.8 Sliding velocity

At a slow sliding speed the oxide layer on an archwire is removed at a rate less than or equal to the rate at which it is formed. This is referred to as ‘corrosive wear’ (Kusy and Whitley, 1989). Frictional forces increase with time and immersion in water due to corrosion (Riley *et al.*, 1979). At a faster sliding speed adhesive wear from cold welding may occur as the time interval is too short for the protective oxide layer to reform. There is very little published data on the effects of sliding velocity but the third law of friction states that the coefficient is independent of relative velocity. Whether this can be applied to orthodontic archwires which are made of various alloys is uncertain. The coefficients of friction of cobalt chromium archwires decreased with increasing sliding velocity; however the coefficients of β–titanium archwires increased with sliding velocity (Kusy and Whitley, 1989).

1.4 Rate of tooth movement and force magnitude

The rate of tooth movement is affected by varying the force magnitude applied. There is an ideal force that will move a particular tooth, at the maximum rate (Quinn and Yoshikawa, 1985). Numerous studies, both animal and human, have presented conflicting results about the optimum force for orthodontic tooth movement (Table 1.3).

Author	Year	Force (cN)	Tooth Movement
Storey and Smith	1952	175-300 400-600	Optimum force range for maximum rate of movement is 150-200 cN for canines
Burstone and Groves	1961	25-150	50-75 cN caused optimal tooth movement. Increased force did not increase movement
Lee	1964	450	Optimum force level between 150 and 260 cN
Andreasen and Johnson	1967	200 400	Average 2.5 times faster with higher force
Hixon *et al.*	1969	300 0-1500	Higher forces per unit root area increase the rate of tooth movement
Hixon *et al.*	1972	300 0-1000	Higher forces produce more rapid tooth movement
Boester and Johnston	1974	55 140 225 300	55cN force yielded less space closure than 140, 225, and 300cN, which all produced the same amount of space closure
Andreasen and Zwanziger	1980	100-150 400-500	Greater forces produced greater rates of tooth movement
Lee	1995	35-450	Maximum rates of tooth movement are 0.78-1.34mm/wk for tipping movement with average force of 337-388cN, and 0.86-1.37mm/wk for bodily movement with average force of 354-375cN
Owman-Moll *et al.*	1996a	50 100	No difference in tooth movement between forces
Owman-Moll *et al.*	1996b	50 200	Tooth movement increased by 50% with 200cN, compared to 50cN
Lundgren *et al.*	1996	50	Horizontal movement of tooth crown was 0.8mm during first week and 3.7mm after week 7
Iwasaki *et al.*	2000	18 60	18cN could produce effective tooth movement
Yee *et al.*	2009	50 300	Amount of initial tooth movement not related to force magnitude, however from 4-12wks, increased force produced faster rates of tooth movement
Karadeniz *et al.*	2011	25 225	Average rate of tooth movement greater with higher force

Table 1.3 Summary of human *in vivo* studies investigating the rate of tooth movement and the amount of force delivered (Owman-Moll *et al.,* 1996a; Ren *et al.,* 2003)

Earlier studies suggested that increased force did not increase tooth movement (Burstone and Groves, 1961; Owman-Moll *et al.*, 1996a), but the majority of subsequent studies have shown the opposite (Andreasen and Johnson, 1967; Hixon *et al.*, 1972; Andreasen and Zwanziger, 1980; Karadeniz *et al.*, 2011).

A broad range of orthodontic forces can be used to induce tooth movement but it has been concluded that the rate is mainly based upon patient characteristics. A number of factors including age, medications, diet, systemic conditions and genetics, have all been shown to affect tooth movement (Ren *et al.,* 2003; Davidovitch and Krishnan, 2009).

1.5 Rate of alignment

Table 1.4 shows a summary of clinical trials investigating the rate of orthodontic alignment. The initial average contact point displacement in the study by O'Brien *et al.* (1990) was greater than in the other studies, but it was not stated whether Little's Irregularity Index was used, and the measurements were undertaken on computerised digital models unlike the other papers which used plaster study models.

From the available literature summarised in table 1.4, when lower arch extractions were carried out, the rate of lower incisor alignment per month seemed to be faster (Scott *et al.,* 2008; Ong *et al.,* 2010). Scott *et al.* (2008) concluded that the initial rate of incisor alignment is significantly influenced by the degree of initial irregularity; age, sex and bracket type were not statistically significant. Teeth therefore seem to align faster when they are more displaced at the start.

Author (Year)	**Upper or lower arch**	**Mean age (years)**	**Extraction or non extraction (2 premolars)**	**Pre-treatment irregularity (mm)**	**Rate of tooth alignment per 30 days (study time period)**	**Archwire Sequence**
O'Brien *et al.* (1990)[a]	Upper	12.95	Non extraction	15.61	1.5mm (0-34 days)	0.016" super-elastic Titanol
Miles (2005)[b]	Lower	17.1	Non extraction	5.8	1.8mm (0-10wks) 0.09mm (10-20wks) 0.94 mm (0-20wks)	0.014" Damon CuNiTi, 0.016"x0.025" Damon CuNiTi
Scott *et al.* (2008)[c]	Lower	16.38	Extraction	12.44	4.05mm (not stated)	0.014" CuNiTi, 0.014"x0.025" CuNiTi
Ong *et al.* (2010)[d]	Lower	10-18	Extraction	12.52	3.6mm (0-10wks) 0.72mm (10-20wks) 2.16mm (0-20wks)	0.014" CuNiTi, 0.014"x0.025" CuNiTi
Wahab *et al.* (2012)[e]	Upper	19.5	Extraction	12.9	3.46mm (0-16wks)	0.014" NiTi

Table 1.4 Summary of papers investigating rate of tooth alignment

Method of determining irregularity: [a] – Superimpositions of digitised study models, [b-e] – Little's Irregularity Index on plaster casts

No studies could be identified in the orthodontic literature that investigated the rate of incisor alignment using figure of eight module ligation, or which made a comparison with the rate of alignment with conventional module ligation.

1.6 Little's Irregularity Index

The irregularity index provides an objective measure of mandibular incisor crowding by measuring the contact point displacements of the anterior teeth. The index can sometimes provide higher values than the actual arch length deficiency if the anterior teeth are markedly displaced. Conversely, the index score can be lower than the actual arch length deficiency e.g. cases when the anatomic contact points are touching interproximally but the pattern of malalignment could be a 'zig-zag' type (Little, 1975).

In the literature, significant intra-class correlation coefficients (>0.9) have been reported for inter-examiner variability of the Little's Irregularity Index (Bernabé and Flores-Mir, 2006; Almasoud and Bearn, 2009; Wahab *et al.*, 2012). Sjögren *et al.* (2010) warned that these high correlation coefficients are misleading for assessing inter-examiner variability, as correlation coefficients are not a direct measure of agreement between two measurements. They are a measure of linear association between two measurements. Macauley *et al.* (2012) investigated the inter-examiner reproducibility of individual contact point displacement measurements in the maxillary arch, rather than the summed irregularity score.

They found poor reproducibility of the index, with 516 out of 600 measurements differing by greater than 20% of the mean. The same team explored the use of three dimensional intra-oral scanning machines to investigate if that improved the accuracy and precision of individual contact point displacement measurements between examiners. 348 of the 600 measurements differed by more than 20% of the mean, and they concluded that neither method of using Little's Irregularity Index was appropriate for orthodontic research purposes, especially for small contact point displacements (Burns *et al.*, 2014).

However, Little's Irregularity Index is still the most commonly used tool in the orthodontic literature to simply and reliably quantify mandibular crowding (Little, 1975) and to measure resolution of mandibular incisor crowding (Miles *et al.,* 2006; Scott *et al.,* 2008; Ong *et al.,* 2010). It provides a measurement that can be compared to data from other studies and to base sample size calculations. The index has also been used as the methodological approach for the Cochrane Collaboration review on retention procedures (Littlewood *et al., 2006)*, as it is an accepted and valid outcome measure.

1.7 Aims

The method of archwire ligation is thought to be an important factor that influences the rate of orthodontic tooth movement.

The aims of this study were:

(i) To determine whether ligation with figure of eight modules affects the rate of lower incisor alignment when compared with conventionally configured modules.

(ii) To establish whether there are any differences in the number of bracket failures between the conventional and figure of eight module groups.

1.8 Null hypothesis

There is no difference in the rate of mandibular incisor alignment between brackets ligated with either conventional modules or figure of modules.

Chapter 2

MATERIALS AND METHODS

CHAPTER 2: MATERIALS AND METHODS

2.1 Study design

The study was designed as a prospective randomised controlled clinical trial undertaken from May 2013 to January 2015. Patients requiring treatment with fixed orthodontic appliances in the orthodontic department at Queen's Hospital, Burton upon Trent were invited to take part in the study.

Subjects were randomly assigned to either conventional or figure of eight module groups. It was felt that extractions in the lower arch would be a confounding variable; therefore patients were randomly allocated to either group based on whether extraction or non extraction treatment was undertaken. The subjects were included in the trial for 12 weeks and seen every 6 weeks after bonding the fixed appliances. At each visit impressions of the lower arch were taken to allow measurements of irregularity to be made on study models.

2.2 Ethical approval and Research and Development approval

Ethical approval was obtained from the West Midlands Research Ethics Committee. Reference number: 12/WM/0368. Approval was also obtained from the Burton Hospitals Research and Development department.

The trial was registered on clinicaltrials.gov. Reference number: NCT01771692.

2.3 Participants

All potential participants were approached at their new patient appointment and invited to participate. The purpose of the trial was outlined and both children's and parent/guardian information sheets were given to them to read at their own leisure. It was made clear to the patient that there would be no additional stages in their treatment, and that if they did not agree to participate then it would not affect their future treatment in any way. They were given at least 1 week to consider whether or not to participate. At a subsequent review appointment, written consent was obtained from those who agreed to take part and they were randomly allocated.

2.3.1 Inclusion criteria

- Informed consent gained
- 12-15 years of age at the start of treatment (records appointment)
- Permanent dentition
- Mandibular incisor irregularity of 5-10mm (clinical observation)

2.3.2 Exclusion criteria

- Medical contraindications
- Oral hygiene of insufficient standard for orthodontic treatment
- Unwilling or unable to consent to the trial

2.4 Method

Informed consent was obtained and the subjects were randomly allocated to one of two groups, conventional module ligation or figure of eight module ligation, stratified for whether the treatment involved extractions or not in the lower arch.

At the bond up appointment the same MBT brackets (Victory™ Twin series, 3M Unitek) and standardised bonding procedure were used. Cheek retractors and a saliva ejector were placed to isolate the teeth. The teeth were etched for 15 seconds with 37% phosphoric acid (Bossklein) and washed and dried for 15 seconds with oil-free compressed air from a 3:1 syringe. A microbrush was used to apply a thin, uniform layer of bonding agent (light bond sealant, Reliance Orthodontics) to the teeth and light cure adhesive (light bond paste, Reliance Orthodontics) was placed on the bracket bases. Excess composite was removed after positioning the brackets and the adhesive was polymerised with a light curing unit according to the manufacturer's guidelines. The starting archwire was 0.014" NiTi and after 6 weeks this was changed to the largest NiTi wire than could be used to fully engage the bracket slots, frequently a 0.016" or 0.018" NiTi wire (Orthodontic Supplies Ltd). Unstretched Super Slick grey elastomeric modules (TP Orthodontics, LaPorte, Ind) were applied in either a conventional pattern or figure of eight pattern. A small amount of zinc polycarboxylate cement was placed on the lower first molars if there was occlusal interference.

The subjects were given two subsequent appointments at six weekly intervals. This time frame was chosen as this was the routine interval between orthodontic appointments and it would not cause any additional burden to the patients and parents/guardians. Impressions were undertaken for study casts pre-treatment (T0), 6 weeks (T1), and 12 weeks after starting fixed appliance treatment (T2).

Only superficial impressions were taken of the teeth, not including the full sulcus depth, to increase patient comfort and acceptability. All impressions were taken after the archwires were removed and they were cast immediately in the on-site laboratory. The white stone study models were stored separately.

The patients were treated by a mixture of operator grades; consultant, specialty registrar, FTTA and clinical assistants.

All the study models were evaluated using the standardised Little's Irregularity Index (Little, 1975) to quantify the degree of crowding of the lower anterior teeth. The study models were measured with digital callipers with sharpened tips that were accurate to 0.01mm. All measurements were undertaken by the author (RL), who was blinded to the intervention groups. To ensure reproducibility of the measurements, 30 measurements were repeated three months apart and assessed using the intraclass correlation coefficient and the Bland and Altman plot (Bland and Altman, 1986).

At a departmental meeting the trial was explained to all of the reception and nursing staff. The importance of arranging three appointments at the start of fixed appliance therapy at 6 weekly intervals was stressed. If patients missed an appointment or needed to reschedule one of the two review appointments, it was emphasised that this needed to be rearranged promptly to try to minimise different duration intervals between appointments.

The nurses were advised to fill out the lab prescription cards instructing the lab that the impression was for the trial so that they could be stored separately and cast immediately to ensure dimensional stability.

2.5 Outcomes

2.5.1 Primary outcome

The primary outcome measure was the rate of lower incisor alignment, specifically between three time periods; T0-T1 (0-6 weeks), T1-T2 (6-12 weeks), and T0-T2 (0-12 weeks).

2.5.2 Secondary outcome

The secondary outcome measure was bracket failure rate. Data for the participants were gathered from the clinical notes after all the irregularity measurements had been undertaken and thus, the patient had finished in the trial.

2.6 Sample size

The sample size calculation was based on the data from Ong *et al.* (2010). The sample size calculation for the number of patients necessary to achieve 80% power with an alpha of 0.05 was based on a clinically meaningful difference in Little's Irregularity Index of 1mm between the groups. The calculation showed that it would be necessary to recruit 50 patients into each group and that any drop outs would require further recruitment.

2.7 Randomisation process

www.randomization.com was used to perform the randomisation process. Block randomisation was used, in block sizes of six, and patients were stratified for extraction and non extraction treatment.

Sealed opaque, sequentially numbered envelopes were used to conceal the group to which the participant had been assigned. The envelopes were kept in a locked filing cabinet and opened by an independent individual when each participant was recruited to the study and had signed the consent, prior to the bond up process. The generator of the randomisation did not participate in patient recruitment, treatment or measurements. Once the participant had been randomised, based on the principles of an intention-to-treat analysis, any data generated was included in the final results.

2.8 Blinding

It was not possible to blind the clinician or the patient to the ligation method, however all the measurements were undertaken by the author (RL), who was blinded to the intervention groups. When measuring the study models, it was not possible to blind the measurer as to whether the treatment involved extractions or not.

2.9 Statistical data analysis

Descriptive statistics (mean, standard deviation) were calculated for all variables for the entire sample and each group separately using IBM SPSS Statistics for Windows (v22, IBM Corp, Armonk, NY).

A Shapiro-Wilk test was used to determine the normality of distribution for the irregularity and the bracket failure data. For the irregularity data, a third of the data were deemed non-normal therefore logarithmic transformations were taken to reduce the impact of outliers. Further Shapiro-Wilk tests were performed, which confirmed the transformed data were normally distributed. The bracket failure data were not normally distributed.

Independent samples t-tests were used to compare groups for the irregularity data. Mann-Whitney U tests were used to compare groups for the bracket failure data. All tests were two-sided at a significance level of alpha=0.05. The multiple imputation procedure was used to account for missing data using SAS (v9.3, SAS Institute, Cary, NC).

The intra-examiner reliability for the study model irregularity measurements was calculated using intraclass correlation and a Bland and Altman plot, following re-measurement of 30 study models, three months after the initial measurements were undertaken. The study models were selected randomly by a member of staff from the laboratory department, who was not involved in the study.

Chapter 3

RESULTS

CHAPTER 3: RESULTS

3.1 Baseline results

The results presented in this thesis are the preliminary results of an on-going clinical trial. At the time of writing up, 100 patients had been recruited; with 23 in the extraction conventional module group, 27 in the extraction figure of eight module group, 25 in the non extraction conventional module group, and 25 in the non extraction figure of eight module group (Figure 3.1). The baseline data for each group are presented in Table 3.1.

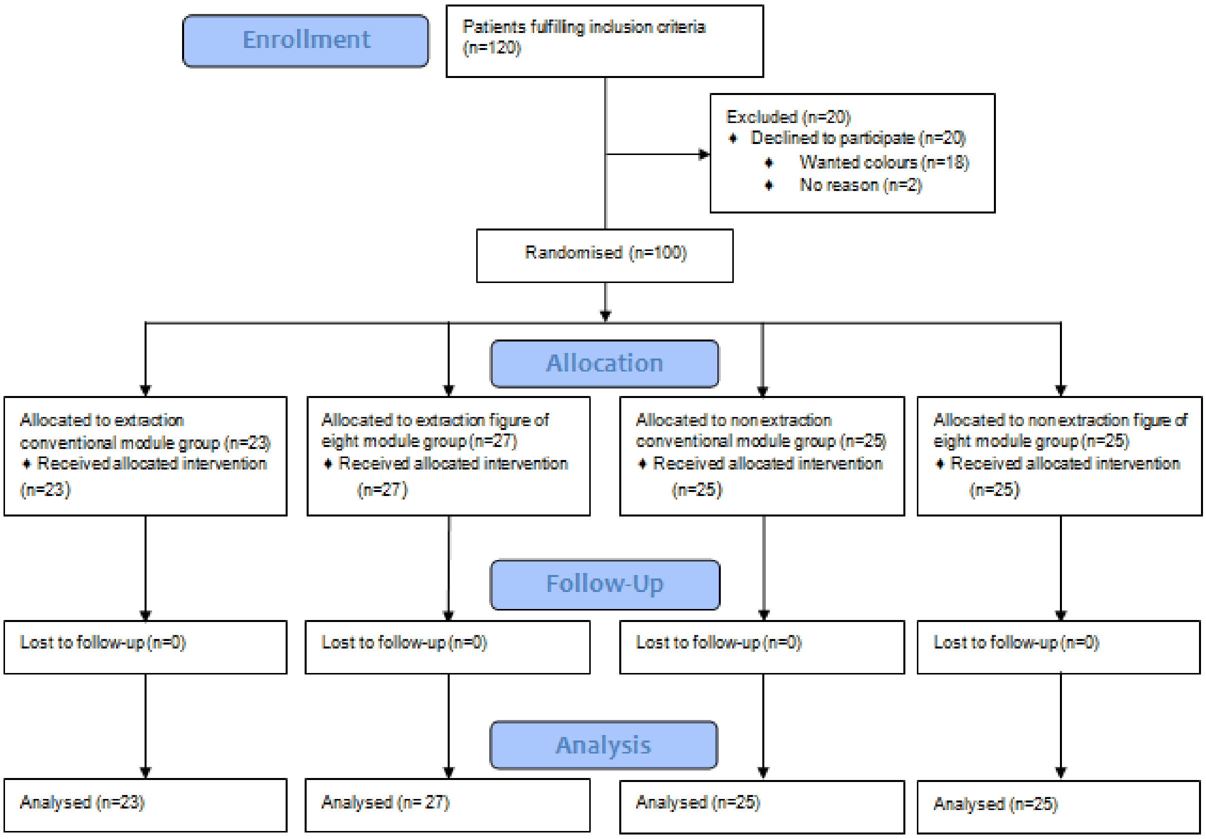

Figure 3.1 CONSORT flow diagram for patients through the trial

		Extraction Conventional Modules n = 23	Extraction Figure of 8 Modules n = 27	Non Extraction Conventional Modules n = 25	Non Extraction Figure of 8 Modules n = 25	Total n=100
Gender	Male (%)	8 (35)	12 (44)	10 (40)	12 (48)	42 (42)
	Female (%)	15 (65)	15 (56)	15 (60)	13 (52)	58 (58)
Age (years)	Mean (SD)	14.07 (1.37)	14.17 (1.34)	13.83 (1.11)	13.93 (1.10)	14.00 (1.22)
	Minimum	12	12	12	12	12
	Maximum	16	16	16	16	16
Little's Irregularity Index (mm)	Mean (SD)	9.33 (2.70)	9.25 (2.50)	8.50 (2.76)	7.84 (2.46)	8.73 (2.64)

Table 3.1 Baseline data

Overall and in each separate group there was a female majority. The age of participant at the commencement of orthodontic treatment ranged from 12 to 16 years with a mean age of 14 years. The groups were all evenly matched for age. At T0 Little's Irregularity Index was higher in both the extraction groups, and within the non extraction groups, the conventional module group had a higher starting index score.

3.2 Results

3.2.1 Alignment

The degree of crowding improved throughout the study for all groups but a small amount of crowding was still present at 12 weeks (T2) after the start of orthodontic treatment. The irregularity scores at T2 were greatest in the non extraction conventional module group and very similar for both figure of eight module groups (Table 3.2).

		Extraction Conventional Modules	Extraction Figure of 8 Modules	Non Extraction Conventional Modules	Non Extraction Figure of 8 Modules
Irregularity Index (mm) – Mean (SD)	T0	9.33 (2.70)	9.25 (2.50)	8.50 (2.76)	7.84 (2.86)
	T1	4.05 (3.30)	3.53 (2.94)	4.19 (3.19)	3.26 (2.53)
	T2	2.18 (2.88)	1.78 (2.15)	2.47 (3.25)	1.73 (1.97)

Table 3.2 Irregularity scores (T0-T2)

The mean changes in irregularity were alike in the extraction and non extraction groups respectively, but were both better in the figure of eight module groups from T0-T1 and T0-T2 (Table 3.3).

		Extraction Conventional Modules	Extraction Figure of 8 Modules	Non Extraction Conventional Modules	Non Extraction Figure of 8 Modules
Irregularity Index (mm) – Mean (SD)	T0-T1	5.28 (2.63)	5.72 (2.53)	4.31 (2.67)	4.57 (2.49)
	T1-T2	1.87 (1.09)	1.75 (1.44)	1.72 (1.70)	1.53 (1.47)
	T0-T2	7.15 (2.88)	7.47 (2.41)	6.03 (2.85)	6.11 (2.81)

Table 3.3 Mean changes in irregularity between time periods

Table 3.4 shows the irregularity scores (T0-T2) after combining the extraction and non extraction data. The conventional modules group had a greater irregularity index score at each time point.

		Conventional Modules	Figure of 8 Modules
Irregularity Index (mm) – Mean (SD)	T0	8.90 (2.74)	8.57 (2.56)
	T1	4.12 (3.21)	3.40 (2.73)
	T2	2.33 (3.05)	1.75 (2.05)

Table 3.4 Irregularity scores (T0-T2) for combined extraction and non extraction groups

The mean change in irregularity scores, for combined extraction and non extraction data, shows that the figure of eight module group aligned better from T0-T1 and T0-T2, but the conventional module group alignment was greater from T1-T2 (Table 3.5).

		Conventional Modules	Figure of 8 Modules
Irregularity Index (mm) – Mean (SD)	T0-T1	4.78 (2.66)	5.17 (2.55)
	T1-T2	1.79 (1.42)	1.65 (1.45)
	T0-T2	6.57 (2.89)	6.82 (2.67)

Table 3.5 Mean changes in irregularity between time periods for combined extraction and non extraction groups

3.2.2 Rate of lower incisor alignment

The rate of lower incisor alignment was calculated for each patient based on the exact number of days in between their scheduled six weekly visits, and the mean values are shown in Table 3.6. The rate of alignment was faster in the extraction groups, and within the extraction and non extraction groups, the figure of eight modules aligned the lower teeth quicker compared to conventional modules, for the time periods T0-T1 and T0-T2. In each of the four groups, the greatest irregularity improvement was seen between the start of treatment and six weeks (T0-T1).

		Extraction Conventional Modules	Extraction Figure of 8 Modules	Non Extraction Conventional Modules	Non Extraction Figure of 8 Modules
Irregularity Change (mm) – Mean (SD)	T0-T1	3.46 (1.84)	4.03 (2.01)	2.95 (1.78)	3.01 (1.61)
	T1-T2	1.35 (0.96)	1.21 (0.98)	1.16 (1.19)	1.14 (1.05)
	T0-T2	2.37 (1.21)	2.60 (0.88)	2.07 (1.07)	2.12 (0.96)

Table 3.6 Rate of alignment (mm per month) between time periods

The combined extraction and non extraction data demonstrated that the figure of eight modules aligned the teeth faster during T0-T1 and overall, between the start and the end of the study period. The conventional modules aligned the lower teeth quicker between T1 and T2 (Table 3.7).

		Conventional Modules	Figure of 8 Modules
Irregularity Change (mm) – Mean (SD)	T0-T1	3.20 (1.81)	3.54 (1.89)
	T1-T2	1.25 (1.08)	1.17 (1.01)
	T0-T2	2.21 (1.14)	2.37 (0.94)

Table 3.7 Rate of alignment (mm per month) between time periods for combined extraction and non extraction groups

3.2.3 Number of bracket failures

The mean number of recorded bracket failures for all groups was less than 0.5, and it was particularly low in the extraction figure of eight module group (0.19). The number of bond failures were skewed toward zero as 70% of participants experienced no failures during the trial period (Table 3.8).

	Number of bracket failures		
Group	**0**	**1**	**2**
Extraction Conventional Modules	16	6	1
Extraction Figure of 8 Modules	22	5	0
Non Extraction Conventional Modules	17	5	3
Non Extraction Figure of 8 Modules	15	8	2

Table 3.8 Number of bracket failures in each group

The average number of bracket failures per person was calculated to account for the fact that the patients in the extraction group had less brackets bonded. A similar trend was observed; the extraction figure of eight module group had the lowest bracket failure rate and the other three groups were very similar (Table 3.9).

		Extraction Conventional Modules	Extraction Figure of 8 Modules	Non Extraction Conventional Modules	Non Extraction Figure of 8 Modules
Number of Bracket Failures	Mean (SD)	0.35 (0.57)	0.19 (0.40)	0.44 (0.71)	0.48 (0.65)
Average Number of Bracket Failures Per Person	Mean (SD)	0.04 (0.07)	0.02 (0.05)	0.04 (0.07)	0.05 (0.07)

Table 3.9 Number of bracket failures and average number of bracket failures per person

Table 3.10 shows the bracket failure rate after combining the extraction and non extraction data. The results of the conventional module and figure of eight module groups are comparable.

		Conventional Modules	Figure of 8 Modules
Number of Bracket Failures	Mean (SD)	0.40 (0.64)	0.33 (0.55)
Average Number of Bracket Failures Per Person	Mean (SD)	0.04 (0.07)	0.04 (0.06)

Table 3.10 Number of bracket failures and average number of bracket failures per person for combined extraction and non extraction groups

The overall bracket failure in the lower arch for the 900 brackets used in the trial was 4%. The bond failure rate for the conventional module groups was 4.4% and 3.6% for the figure of eight module groups.

3.2.4 Distribution of bracket failures

Table 3.11 shows that there was a wide distribution of bracket failures, and that there were more failures in the non extraction groups.

Bracket	Extraction Conventional Modules	Extraction Figure of 8 Modules	Non Extraction Conventional Modules	Non Extraction Figure of 8 Modules	Total
LR1	1	1	1	1	4
LL1	0	0	1	1	2
LR2	2	0	3	2	7
LL2	1	1	2	0	4
LR3	0	0	1	2	3
LL3	0	1	0	1	2
LR4	2	2	1	0	5
LL4	1	0	0	1	2
LR5	1	0	1	2	4
LL5	0	0	1	2	3
	8	5	11	12	36

Table 3.11 Distribution of bracket failures

The time period when the bracket failures occurred was similar in the non extraction groups and the extraction figure of eight module group. In the extraction conventional module group, 87.5% of brackets failed between T0 and T1 (Table 3.12).

Time Period	Extraction Conventional Modules	Extraction Figure of 8 Modules	Non Extraction Conventional Modules	Non Extraction Figure of 8 Modules
T0-T1	7	2	7	7
T1-T2	1	3	4	5

Table 3.12 Time period when bracket failures occurred

Bond failures were highest on the lateral incisors followed by the premolars, central incisor, and canine. The most frequently debonded bracket was the lateral incisor on the right hand side. For all bracket types there were more bracket failures on the right hand side (Table 3.13).

Bracket Type	Right	Left	Total
Central Incisor	4	2	6
Lateral Incisor	7	4	11
Canine	3	2	5
First Premolar	5	2	7
Second Premolar	4	3	7

Table 3.13 Distribution of bracket failures according to bracket type and side

3.3 Analysis of results

Analysis was undertaken on an intention-to treat basis.

3.3.1 Independent samples t-tests

Independent samples t-tests were used on the parametric irregularity data. The effect of extraction and non extraction treatment on the rate of alignment (per month) was tested for the conventional module groups. There were no statistically significant differences between all three time periods (Table 3.14).

	t value	df	p value	95% Confidence Interval	Statistical significance?
T0-T1	1.622	45	0.112	-0.042, 0.390	No
T1-T2	0.713	44	0.480	-0.149, 0.312	No
T0-T2	0.775	46	0.442	-0.096, 0.217	No

Table 3.14 Independent samples t-tests to compare the effect of extraction and non extraction treatment for the conventional module groups between each time period

The effect of extraction and non extraction treatment on the rate of alignment (per month) was tested for the figure of eight module groups. There were no statistically significant differences between T1-T2 and T0-T2. However, the lower teeth aligned significantly faster in the extraction group between the time period T0-T1, $p = 0.05$ (Table 3.15).

	t value	Df	p value	95% Confidence Interval	Statistical significance?
T0-T1	2.005	50	0.050	-0.000, 0.281	Yes
T1-T2	-0.413	48	0.682	-0.245, 0.161	No
T0-T2	1.597	49	0.117	-0.021, 0.182	No

Table 3.15 Independent samples t-tests to compare the effect of extraction and non extraction treatment for the figure of eight module groups between each time period

The effect of conventional module and figure of eight module ligation on the rate of alignment (per month) was tested for the extraction treatment group. There were no statistically significant differences between the all three time periods (Table 3.16).

	t value	df	p value	95% Confidence Interval	Statistical significance?
T0-T1	-0.707	47	0.483	-0.186, 0.089	No
T1-T2	0.770	48	0.445	-0.123, 0.275	No
T0-T2	-1.288	48	0.204	-0.206, 0.045	No

Table 3.16 Independent samples t-tests to compare the effect of conventional module and figure of eight module ligation for the extraction treatment group between each time period

The effect of conventional module and figure of eight module ligation on the rate of alignment (per month) was tested for the non extraction treatment group. There were no statistically significant differences between the all three time periods (Table 3.17).

	t value	df	p value	95% Confidence Interval	Statistical significance?
T0-T1	-0.779	48	0.440	-0.292, 0.129	No
T1-T2	-0.404	44	0.688	-0.282, 0.188	No
T0-T2	-0.899	47	0.373	-0.195, 0.075	No

Table 3.17 Independent samples t-tests to compare the effect of conventional module and figure of eight module ligation for the non extraction treatment group between each time period

The effect of conventional module and figure of eight module ligation on the rate of alignment (per month) was tested for the combined extraction and non extraction data. There were no statistically significant differences between the all three time periods (Table 3.18).

	t value	Df	p value	95% Confidence Interval	Statistical significance?
T0-T1	-1.142	97	0.256	-0.201, 0.054	No
T1-T2	0.215	94	0.831	-0.133, 0.166	No
T0-T2	-1.597	82.280	0.114	-0.166, 0.018	No

Table 3.18 Independent samples t-tests to compare the effect of conventional module and figure of eight module ligation for the combined extraction and non extraction data between each time period

3.3.2 Mann-Whitney U tests

Mann-Whitney U tests were used on the non-parametric bracket failure data. The effect of extraction and non extraction treatment on the average number of bracket failures per person was tested for the conventional module and figure of eight module groups. There were no statistically significant differences (Table 3.19).

	U statistic	p value	Statistical significance?
Conventional Modules	282	0.892	No
Figure of 8 Modules	280	0.186	No

Table 3.19 Mann-Whitney U tests to compare the effect of extraction and non extraction treatment, for the conventional module and figure of eight module groups, on the bracket failure rate

The effect of conventional module and figure of eight module ligation on the average number of bracket failures per person was tested for the extraction and non extraction groups. There were no statistically significant differences (Table 3.20).

	U statistic	p value	Statistical significance?
Extraction	271	0.300	No
Non Extraction	294.5	0.681	No

Table 3.20 Mann-Whitney U tests to compare the effect of conventional modules and figure of eight modules, for the extraction and non extraction treatment groups, on the bracket failure rate

Furthermore, there was no statistically significant difference between conventional module and figure of eight module ligation, for the combined extraction and non extraction data, on the bracket failure rate ($U = 1190.5$, $p = 0.624$).

3.4 Intra-examiner reliability

Intra-examiner reliability was tested using a Bland and Altman plot (Figure 3.2) and also the intraclass correlation coefficient, which produced a value of 0.999, with 95% CI (0.998, 1.000). Both methods indicated excellent reliability for the study model measurements.

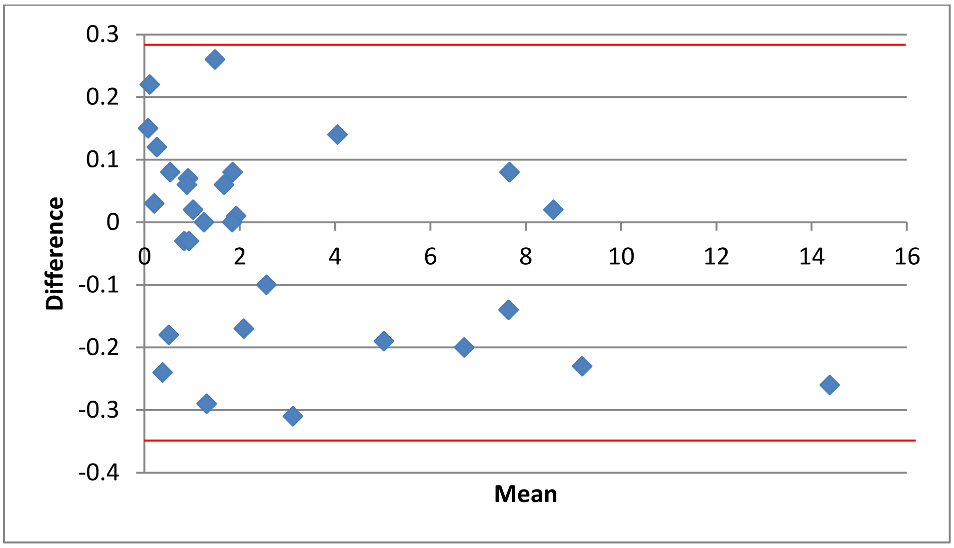

Figure 3.2 Bland and Altman plot for intra-examiner reliability

Chapter 4

DISCUSSION

CHAPTER 4: DISCUSSION

4.1 Study design

4.1.1 Treatment variation

Attempts were made to ensure a standardised protocol of appointment intervals at 6 weeks (T1) and 12 weeks (T2) after bonding the fixed appliances (T0). Unfortunately it was not possible for all patients to attend every 42 days exactly. Therefore the average daily irregularity change was calculated according to the dates the patients attended their appointments. This was then multiplied by 30 to achieve the standardised rate of irregularity change per month.

Patients in our unit attend routine orthodontic appointments at the standard interval of 6-8 weeks, therefore 6 weeks was chosen as the interval, to increase the external validity of the study. Shorter appointment intervals may have been better to more accurately assess the rate of initial alignment and bracket failure rate, but this would have caused an additional burden to participants and their parents/guardians.

One participant included in this study had wrongly been allocated to the extraction group, when extractions had only been carried out in the upper arch. As the subject had been randomised, they were included in accordance with the intention-to-treat analysis.

The force used to apply the elastomeric ligatures to the brackets in either a conventional pattern or figure of eight pattern would have varied for each operator. Reported ligation forces are highly variable and sensitive to the method of application (Tidy, 1989). Unstretched modules were used to help minimise this inconsistency.

4.1.2 Operators

The patients were treated by a mixture of operator grades; consultant, specialty registrar, FTTA and clinical assistants. All grades were competent in bonding fixed appliances and ligating the archwire with modules of either configuration. Reducing the number of operators would have minimised inter-operator variability, but this would have decreased the external validity of the study.

In this study, only one researcher (RL) measured the study casts, therefore the limitations concerning the wide variation of inter-examiner reliability (Sjögren *et al.,* 2010) are not applicable.

4.2 Baseline results

One hundred patients were recruited into the study and within the sample there were more females than males. This is a reflection of the female predilection in the orthodontic population at Queen’s Hospital Burton upon Trent, at the time of this trial. Fortunately gender has not been proven to be a factor related to orthodontically induced tooth movement (Dudic *et al.,* 2013).

The mean age of the participant in the study was 14 years, which reflects the typical age of patients being treated at the hospital participating in the study. Patients over the age of 16 years were excluded, to minimise any effect of age on the results. Dudic *et al.* (2013) concluded that younger patients (<16 years) showed greater tooth movement velocity than older ones, and Karadeniz *et al.,* (2011) found that age was negatively correlated with the rate of orthodontic tooth movement.

The ages presented were calculated using the bond up date. The inclusion criteria stated that a patient must be 12-15 years old at the records appointment, when the impressions for the pre-treatment study models and consent forms were completed. Some patients were 16 years old at the time of bond up due to the time interval from the records appointment. This was usually within a couple of months but some patients had been referred to the oral surgery department for extractions and/or exposures, which considerably increased the time frame to the start of fixed appliance treatment.

At T0 the irregularity was higher in both the extraction groups. This would be expected as patients who are more severely crowded, are more likely to have extractions as part of their orthodontic treatment plan. In the non extraction groups, the conventional module group had a higher starting index score compared to the figure of eight module group (8.50mm cf. 7.84mm). No previous studies have compared the interaction between the degree of crowding and the configuration of the elastomeric module, on the rate of tooth alignment. The rate of change in irregularity was calculated for all the participants, which should have minimised any small differences between the groups.

4.3 Results

4.3.1 Rate of alignment

Traditionally the rate of tooth movement is thought to be approximately 1mm per month. In this study the average rates of tooth movement per month ranged from 1.14mm (non extraction, figure of eight module group, T1-T2) to 4.03mm (extraction, figure of eight module group, T0-T1).

Miles *et al.* (2005) found a rate of alignment of 1.8mm per month in the initial 10 week period, in non extraction cases. This was slower than that found in this study, in the non extraction conventional module group; 2.95mm per month (T0-T1) and 2.07mm per month (T0-T2). However the pre-treatment irregularity index was lower in their study, 5.8mm versus 8.5mm.

The rate of lower incisor alignment was found to be faster when lower arch extractions were carried out. Over a 10 week period Ong *et al. (*2010) found that the rate of orthodontic tooth alignment was 3.3mm per month, compared to a slower 2.37mm per month and 2.60mm per month for the conventional module and figure of 8 module groups respectively. However the results from this study were over a longer 12 week period and the pre-treatment irregularity index was smaller (12.52mm versus 9.33mm). Teeth therefore seem to align quicker when they are more displaced at the start of treatment.

The results of this study suggest that there is no difference in the rate of mandibular incisor alignment between brackets ligated with conventional modules or modules ligated in a figure of eight configuration. The figure of eight module groups did align the lower teeth faster but this was not statistically significant. The groups were stratified before randomisation for extraction or non extraction treatment as this was thought to be a potential confounding variable. The results demonstrate that when comparing the ligation method, there were no statistically significant differences in the rate of alignment between treatment with or without extractions. However in the figure of eight modules groups, there was a significant difference between the extraction and non extraction groups for the time period T0-T1 ($p = 0.05$), indicating that the rate of alignment is significantly quicker in the extraction group.

Other potential confounding factors including malocclusion type, operator grade and bone density were not investigated. The type of malocclusion would be unlikely to affect the rate of lower incisor alignment as cement was placed onto the occlusal surfaces of the lower first molars if any occlusal interference was identified, thus freeing the occlusion. The patients in the trial were treated by a range of operators but all had considerable experience in bonding fixed appliances therefore this was not deemed to be a significant confounder. The bone density of the mandible was not considered but this may have been a confounding variable, which could possibly be investigated in future studies.

It is generally believed that frictional resistance must be minimised during alignment so that tooth movement can be generated through light optimal forces. The nature of ligation is an important contributor to frictional force. Elastomeric modules tied in a figure of eight pattern produce significantly more friction than conventionally tied elastomerics (Sims *et al.,* 1993; Edwards *et al.,* 1995; Voudouris, 1997; Hain *et al.,* 2003).

The results of this trial agree with the null hypothesis that figure of eight modules have no effect on the speed of alignment of the lower anterior teeth. As figure of 8 ties might be expected to increase friction and active alignment force, this is not in concordance with the majority of the literature that states that friction slows down orthodontic tooth movement. Neither has it shown that teeth move quicker with figure of eight modules, due to the increased force and more certain bracket slot engagement. Perhaps the increased friction from figure of eight modules is overcome intra orally by the masticatory forces, which are hundreds of times greater than the forces derived from the archwires, lessening the importance of true friction (O’Reilly *et al.,* 1999).

4.3.2 Bracket failures

The bracket failure rate was very similar between the two different ligation methods, and overall there was a bracket failure rate of 4% over the 12 week trial period, which is in line with other studies. Pandis *et al.* (2006) found a lower bracket failure rate of 3% over a 12 month observation period. Conversely O'Dywer *et al.* (2015) reported a bond failure rate of 7.2% over the entire orthodontic treatment period.

Ligation method is one factor that can affect the bracket failure rate, but there are a multitude of other factors that are involved. These include bonding material, bonding technique and procedure, diet, masticatory forces, mechanics and occlusal interference.

In the present study, bond failures were highest on the lower incisors (47%), followed by the lower premolars (39%). Previous studies have reported the highest bond failure rates on the premolars (Kula *et al.,* 2002; Sunna and Rock, 2008). A more recent study had an equal bracket failure rate between lower incisors and lower premolars (O'Dywer *et al.,* 2015). Lower incisors may be more prone to debonding due to their greater initial displacement from the line of the arch, and thus a greater ligation force is needed to engage the archwire into the bracket slot (O'Dywer *et al.,* 2015). This may be the reason why the majority of bonds failed between T0 and T1. The high failure rates of premolar brackets may be related to bonding problems, moisture control and greater masticatory forces (Zachrisson, 1977).

Nearly two thirds of all lower bond failures occurred on the right hand side, in concurrence with previous studies (Pandis *et al.,* 2006; O'Dywer *et al.,* 2015). This difference may be attributed to masticatory habits (Pandis *et al.,* 2006).

Chapter 5

CONCLUSIONS

CHAPTER 5: CONCLUSIONS

5.1 Conclusions

- Ligation with figure of eight modules has no effect on the rate of lower incisor alignment. Therefore figure of eight ligation does not seem to hinder the alignment of the teeth.

- There were no differences in the average number of bracket failures per person between conventional module and figure of eight module ligation.

5.2 Null hypothesis

There is no difference in the rate of mandibular incisor alignment between brackets ligated with either conventional modules or figure of modules.

- Accepted

5.3 Recommendations for clinical practice

In the initial alignment phase of fixed orthodontic treatment, clinicians should be confident that the utilisation of figure eight module ligation will not slow down the rate of lower incisor alignment, even though they do exert an increased frictional force on the archwire. Figure of eight modules ensure a more secure engagement of the archwire into the bracket slot compared to conventional modules but they may cause increased discomfort for the patient. Ultimately the choice of ligation rests with the individual clinician.

5.4 Further research

The fastest rate of lower incisor alignment was during the first six weeks after bonding the fixed appliances. Further research could be undertaken to investigate more accurately how the rate of alignment varies in this period of greatest tooth movement, by conducting another clinical trial with more regular appointment intervals.

Chapter 6

APPENDICES

CHAPTER 6: APPENDICES

1. Search strategy

The PubMed and Cochrane databases were searched for literature published up until January 2016. The Mesh term "orthodontic*" was crossed with a combination of the following terms: "ligation", "friction", "brackets", "elastomeric modules", "rate of alignment", "rate of tooth movement", "bracket failure", and "Little's irregularity index". The results were limited to English language. To complete the search, reference lists of the included studies were manually checked.

2. Patient information sheets and consent forms

CHILDREN'S INFORMATION SHEET v2.0 21/11/12

Title: A study to look at the factors that affect how the lower teeth straighten

PART 1: The project

We are asking if you would take part in a research project to look at the factors associated with how quickly the lower teeth straighten with fixed braces.
Before you decide if you want to join in it's important to understand why the research is being done and what it will involve for you. So please consider this fact sheet carefully.

Why are we doing this research?

There has been a lot of research into the factors that can affect the speed of alignment of teeth but there has been very little research on how different techniques of wire attachment to the brace can affect this.

The ability of orthodontic wires to slide freely through the brackets determines to a great extent the success of the brace. The major disadvantage with the use of sliding mechanics is the friction that is generated between the bracket and the wire during orthodontic tooth movement.

Why have I been invited to take part?

You have been asked to take part as part of your normal brace treatment. Other children with will also be asked to take part.

Do I have to take part?

No. It is up to you. If you do I will ask you to sign a form saying you are happy to take part. You will be given a copy of this information sheet and your signed form to keep. You are free to stop taking part at any time during the research without giving a reason. If you decide to stop, this will not affect the treatment you are receiving.

What will happen to me if I take part?

You will be randomly allocated to one of two different methods of attaching the wire to the bracket; either a figure of 0 or a figure of 8 (see photograph).

If you agree to take part, the only differences to your normal treatment would be that you will not be able to choose a colour on your lower brace for the first twelve weeks and it would require two additional moulds/impressions of your lower teeth at the first two appointments after your brace has been stuck on. No extra appointments will be needed.

Contact details

If you have any questions you can ask Mr Spary

Thank you for reading so far – if you are still interested, please go to Part 2*:*

PART 2: More information

What happens following completion of the study?

Your involvement in the study will be for the first twelve weeks that you have your fixed braces on, and then you will complete your orthodontic treatment as normal. So you will be able to choose a colour for your lower brace if you wish.

What if there is a problem or something goes wrong?

If you have any problems these will be seen to immediately. If you are worried about the way you have been treated then you may contact the study team. If you wish to complain then you can contact the people on the numbers below.

Confidentiality

You will not need to provide any personal details and you will not be identified in the report of the findings, but you may receive a copy of the results upon your request.

Who is organising this research?

This research is organised and supported by the University of Birmingham.

Who has reviewed the study?

Before any research goes ahead it has to be checked by a Research Ethics Committee. They make sure that the research is fair.

Questions & Complaints:

If you have any questions you can ask:

Rachel Little (Specialty Registrar)

Mr Spary (Consultant on the clinic)

If you want to seek impartial study advice or complain you can speak to:

Janet Cort (Complaints and PALS manager) Tel: [redacted] extension [redacted]

Thank you for reading this – please ask any questions that you want to

PARENT/GUARDIAN INFORMATION SHEET v2.0 21/11/12

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish.
(Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study).

Title: A study to investigate the factors affecting the speed of alignment of the lower front teeth

PART 1: The project

Why are we doing this research?

There has been a lot of research into the factors that can affect the speed of alignment of teeth but there has been very little research on how different techniques of wire attachment to the brace can affect this.

The ability of orthodontic wires to slide freely through the brackets determines to a great extent the success of the brace. The major disadvantage with the use of sliding mechanics is the friction that is generated between the bracket and the wire during orthodontic tooth movement.

Why have we asked your child to participate?

We are inviting you and your child to take part in this study as they are shortly due to commence orthodontic treatment. Participation is entirely voluntary and your child's treatment will not be affected if you decide not to participate.

What is involved?

Once you have verbally agreed to participate we will obtain written consent from you and your child. Your child will be randomly allocated to one of two different methods of attaching the wire to the bracket; either a figure of 0 or a figure of 8 (see photograph).

If you agree to take part, the only differences from standard orthodontic treatment would be that your child will not be able to choose a colour on their lower brace for the first twelve weeks and it would require two additional moulds/impressions of their lower teeth at the first two appointments after the brace has been fixed to the teeth.

No additional appointments are required.

At no point will any treatment be withheld. You may withdraw your child from the study at any time without consequence to the quality of care your child will receive.

Contact Details:

For further information about the study or for any concerns please contact:

Miss Rachel Little Tel: [redacted] extension [redacted]

Mr David Spary Tel: [redacted] extension [redacted]

Part 2: Additional information

What happens following completion of the study?

Your child's involvement in the study will be for the first twelve weeks that they have their fixed braces on, and then they will complete your orthodontic treatment as normal. So then they would be able to choose a colour for their lower brace if they wished.

What if there is a problem or something goes wrong?

If you have any problems these will be seen to immediately. If you are worried about the treatment received or the way you have been treated then you may contact the study team or speak to the consultant at any time.

Confidentiality

All of the information that is collected regarding the participants, during the course of the research, will be kept strictly confidential. You will not be asked to provide any personal details. Information that has been provided will be anonymised so you and your child cannot be identified from it. Participants will not be identified in the report of the findings and you may receive a copy of the results upon your request.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This group has approved this piece of research.

Organisation and funding

This study is being funded by the University of Birmingham.

Impartial advice and complaints

If you require further advice or have concerns, independent of the research team, then you may contact the Patient Advice and Liaison Service in the first instance. They can give advice, provide information on NHS services, listen to your concerns and help to sort out problems on your behalf.

Your PALS representative is:

Janet Cort (Burton Hospital) Tel: [redacted] extension [redacted]

Thank you for reading this – please ask if you have any questions.

Patient identification number

CHILDREN'S ASSENT FORM v2.0 21/11/12

(For participant)

<u>A study to investigate the factors that affect how quickly teeth straighten</u>

Please answer the following:	Please initial box
Have you read about this project?	
Has somebody explained this project to you?	
Do you understand what this project is about?	
Have you asked all the questions you want?	
Have you had your questions answered in a way you understand?	
Do you understand it's OK to stop taking part at any time?	

If you are happy to take part, please write your name and today's date

Your name ....

Date ....

Name of person/doctor who explained this project to you needs to sign too:

Print Name ______________________________

Sign ______________________________

Date ______________________________

Thank you for your help.

1 copy for patient; 1 for researcher site file; 1 (original) to be kept in hospital notes

Patient identification number:

PARENTAL RESEARCH PROJECT CONSENT FORM v1.0 30/05/12

(For parent/guardian of patient)

A randomised clinical trial to investigate the effects of ligation techniques on mandibular incisor alignment (a study to investigate the factors affecting the speed of alignment of the lower front teeth)

Please initial box

- I confirm that I have read and understand the information sheet about the above study. ☐
- I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
- I understand that my child's participation is voluntary and that I am free to withdraw consent at any time without giving any reason, and that my child's dental care or legal rights would not be affected. ☐
- I understand that sections of the dental notes may be looked at by responsible individuals or regulatory authorities taking part in this research. I give permission for these individuals to have access to my child's records. ☐
- I consent to my child completing the questionnaire. ☐
- I agree for my child to take part in the above study. ☐

.... Name of Parent/Legal Guardian	.... Relationship to child
.... Date	.... Signature

.... Name of Researcher taking consent	.... Date	.... Signature

1 copy for parent/guardian; 1 for researcher site file; 1 (original) to be kept in hospital notes

3. Raw data

Extraction group

Subject number	Age	Gender	Ligation Method	T0 Little's Irregularity Index	T1 Little's Irregularity Index	T2 Little's Irregularity Index
1	12	F	Figure of 8	8.93	2.22	1.25
2	14	M	Conventional	12.09	6.61	2.32
3	12	F	Figure of 8	7.7	1.64	0.68
4	13	F	Conventional	11.91	2.3	0.53
5	15	M	Figure of 8	10.42	5.12	1.72
6	16	M	Conventional	14.57	5.55	1.51
7	16	F	Figure of 8	10.4	2.39	1.44
8	14	F	Conventional	8.31	4.04	1.23
9	13	F	Figure of 8	6.51	2.7	2.14
10	12	M	Conventional	10.13	3.32	1.34
11	15	M	Conventional	11.38	8.39	7.27
12	14	M	Figure of 8	11.43	6.05	2.81
13	16	M	Conventional	6.13	0.89	0.2
14	12	F	Conventional	7.1	1.97	0.88
15	16	M	Figure of 8	11.35	4.03	1.09
16	14	F	Figure of 8	6.48	1.92	0.15
17	15	F	Figure of 8	11.93	9.06	8.57
18	12	F	Conventional	10.54	7.64	4.04
19	14	F	Conventional	11.67	3.83	0.86
20	13	M	Figure of 8	10.04	0.72	0.22
21	13	F	Conventional	4.84	0.86	0
22	13	M	Figure of 8	13.17	0.79	0.38
23	12	F	Conventional	12.26	1.84	0.85
24	14	F	Figure of 8	6.63	1.28	0.6
25	16	F	Conventional	7.12	4.49	3.28
26	13	M	Figure of 8	12.06	1.39	0.74
27	15	M	Figure of 8	8.72	5.12	1.58
28	15	F	Conventional	6.95	2.31	0.32
29	13	F	Conventional	9.02	1.26	0
30	12	F	Figure of 8	15.15	12.2	6.47
31	13	F	Figure of 8	9.14	1.24	0.32
32	14	F	Conventional	7.52	3.64	2.3
33	13	M	Figure of 8	9.55	3.85	0.82
34	16	F	Conventional	8.24	1.37	0
35	15	M	Figure of 8	10.54	4.85	2.3
36	12	M	Conventional	8.05	2.92	1.94
37	14	M	Conventional	8.72	9.04	7.97
38	14	F	Conventional	7.81	2.59	1.18
39	12	F	Figure of 8	10.03	4.05	1.35
40	13	F	Figure of 8	7.8	0.25	0
41	13	M	Conventional	7.86	1.97	0.86
42	14	F	Figure of 8	9.32	8.36	6.81

43	14	F	Conventional	7.08	1.76	0.19
44	15	M	Figure of 8	4.13	1.19	0
45	14	F	Figure of 8	7.1	3.57	1.71
46	12	M	Figure of 8	11.19	6.86	2.32
47	13	F	Conventional	15.31	14.51	11.1
48	14	F	Figure of 8	6.63	1.28	0.6
49	13	M	Figure of 8	6.41	2.66	1.64
50	16	F	Figure of 8	6.92	0.5	0.22

Subject number	Rate of change T0-T1/month	Rate of change T1-T2/month	Rate of change T0-T2/month	Number of bracket failures	Location and time period of bracket failure
1	3.59	0.69	2.25	1	LL3 T1-T2
2	3.91	3.48	3.71	0	
3	2.89	0.69	2.01	0	
4	5.15	1.52	3.75	1	LL4 T0-T1
5	4.54	2.49	3.43	0	
6	6.57	3.39	5.09	0	
7	4.9	0.68	2.95	1	LL2 T1-T2
8	3.05	2.01	2.53	0	
9	2.47	0.45	1.56	1	LR1 T1-T2
10	4.86	1.21	2.9	1	LR4 T0-T1
11	1.60	0.8	1.26	0	
12	4.61	1.59	2.69	0	
13	2.35	0.24	1.15	0	
14	3.58	0.25	1.06	0	
15	6.46	1.66	3.54	0	
16	3.18	1.21	2.18	0	
17	2.05	0.35	1.2	0	
18	2.12	2.51	2.32	1	LR2 T0-T1
19	5.22	2.79	4.21	0	
20	7.36	0.35	3.64	0	
21	2.84	0.44	1.43	1	LR5 T0-T1
22	10.32	0.26	4.57	0	
23	7.44	0.71	4.08	0	
24	3.82	0.49	2.15	0	
25	1.88	0.86	1.37	1	LR2 T0-T1
26	5.93	0.63	4	0	
27	3	2.47	2.71	0	
28	3.31	1.22	2.19	1	LR4 T0-T1
29	5.54	1.08	3.51	0	
30	2.06	4.09	3.06	0	
31	4.64	0.84	3.15	0	
32	1.79	0.82	1.37	0	
33	4.89	2.16	3.4	0	
34	4.91	0.53	2.08	0	
35	4.06	1.82	2.94	0	
36	2.85	1.18	2.32	2	LL2 T0-T1,LR1 T1-T2

37	-0.23	0.82	0.28	0	
38	3.2	1.21	2.37	0	
39	2.76	1.35	2.08	0	
40	6.47	0.18	3.08	1	LR4 T0-T1
41	3.61	0.4	1.58	0	
42	0.69	1.11	0.9	0	
43	3.55	1.12	2.38	0	
44	2.15	0.83	1.48	1	LR4 T0-T1
45	2.35	1.47	1.95	0	
46	2.76	3.24	2.99	0	
47	0.57	2.44	1.5	0	
48	3.82	0.49	2.15	0	
49	2.56	0.77	1.7	0	
50	4.59	0.2	2.39	0	

Non extraction group

Subject number	**Age**	**Gender**	**Ligation Method**	**T0 Little's Irregularity Index**	**T1 Little's Irregularity Index**	**T2 Little's Irregularity Index**
1	14	M	Figure of 8	9.02	5.19	1.96
2	13	F	Conventional	7.36	1.51	0.56
3	12	F	Conventional	5.09	2.11	1.3
4	14	M	Figure of 8	11.5	1.55	0
5	14	F	Conventional	10.44	2.72	0.7
6	13	M	Conventional	7.43	5.67	3.41
7	14	M	Conventional	8.95	1.92	0.41
8	16	M	Conventional	9.46	0.93	1.25
9	15	M	Figure of 8	12.52	7.59	4.55
10	15	F	Figure of 8	4.43	2.01	2.47
11	15	F	Conventional	9.29	4.79	1.78
12	12	F	Figure of 8	10.04	9.3	7.71
13	15	F	Figure of 8	11.37	6.04	2.17
14	12	M	Conventional	8.53	8.1	4.87
15	14	M	Conventional	10.15	1.01	0
16	13	F	Conventional	8.45	1.02	0.73
17	13	F	Figure of 8	7.22	1.61	0
18	12	F	Figure of 8	3.67	0.88	0.36
19	15	M	Figure of 8	7.18	1.36	0.73
20	13	M	Conventional	9.87	3.98	0
21	12	F	Conventional	12.53	10.16	11.11
22	14	M	Figure of 8	7.64	5.31	2.61
23	14	F	Conventional	5	1.81	0.2
25	14	M	Figure of 8	6.57	0.83	0
26	13	F	Conventional	7.77	3.27	1.45
27	12	F	Conventional	8.67	0.85	0.75
28	12	F	Conventional	8.99	5.75	5.33
29	12	F	Figure of 8	7.76	0.5	0
30	13	M	Figure of 8	3.38	1.85	0.89
31	13	M	Conventional	4.1	1.84	0.46

32	13	F	Conventional	13.58	7.42	6.95
33	14	F	Figure of 8	4.67	2.11	0.95
34	15	F	Figure of 8	10.01	7.62	3.87
35	12	F	Figure of 8	5.55	4.57	6.02
36	15	F	Conventional	4.14	3.18	0.67
37	13	F	Conventional	14.29	13.63	11.71
38	13	F	Figure of 8	5.64	3.24	2.07
39	12	M	Figure of 8	7.81	5.19	1.76
40	12	M	Conventional	11.55	6.58	0
41	13	M	Figure of 8	10.09	1.43	1.01
42	14	M	Conventional	9.26	6.08	0.92
43	14	M	Figure of 8	9.71	3.24	1.16
44	14	M	Figure of 8	9.1	0.89	0.15
46	12	F	Figure of 8	7.55	1.8	1.33
47	12	M	Conventional	5.35	5.22	3.82
49	12	F	Figure of 8	6.7	1.97	1.05
50	14	M	Figure of 8	9.64	5.1	0.47
52	15	F	Conventional	5.29	2.56	0.99
53	13	F	Figure of 8	7.16	0.38	0
54	13	F	Conventional	7.08	2.75	2.46

Subject number	**Rate of change T0-T1/month**	**Rate of change T1-T2/month**	**Rate of change T0-T2/month**	**Number of bracket failures**	**Location and time period of bracket failure**
1	2.74	2.36	2.55	0	
2	4.18	0.68	2.43	0	
3	1.81	0.29	0.85	0	
4	7.11	1.13	4.16	0	
5	3.31	1.44	2.61	0	
6	1.17	1.74	1.44	1	LR3 T0-T1
7	6.03	1.29	3.66	0	
8	6.09	-0.23	2.93	0	
9	2.64	2.68	2.66	0	
10	1.77	-0.33	0.71	0	
11	2.93	2.66	2.82	0	
12	0.53	1.36	0.91	0	
13	3.81	2.76	3.29	0	
14	0.26	0.93	0.71	2	LL2, LR2 T1-T2
15	4.9	0.72	3.11	2	LR2, LR4 T0-T1
16	4.55	0.21	2.55	0	
17	4.01	1.15	2.58	0	
18	1.99	0.37	1.18	0	
19	4.16	0.45	2.3	1	LL4 T0-T1
20	4.21	2.3	3.15	0	
21	1.69	-0.58	0.47	1	LL2 T1-T2
22	1.66	1.93	1.8	1	LR5 T0-T1
23	2.28	0.69	1.29	0	
25	3.51	0.59	2.17	1	LL5 T0-T1
26	3.21	0.98	1.93	0	

27	5.59	0.07	2.83	0	
28	2.31	0.3	1.31	0	
29	5.19	0.36	2.77	0	
30	1.09	0.82	0.97	1	LL5 T1-T2
31	1.74	1.09	1.42	1	LL1 T0-T1
32	4.4	0.4	2.58	1	LR5 T0-T1
33	1.83	0.83	1.33	0	
34	1.79	2.56	2.19	2	LL1 T0-T1, LR1 T1-T2
35	0.7	-0.78	-0.14	1	LR3 T1-T2
36	0.78	1.34	1.12	0	
37	0.47	1.48	0.96	0	
38	1.64	0.88	1.28	1	LR5 T1-T2
39	1.87	2.45	2.16	0	
40	4.26	4.7	4.5	2	LR1, LR2 T0-T1
41	5.3	0.33	3.13	0	
42	2.73	3.69	3.25	0	
43	3.88	1.49	2.79	0	
44	4.4	0.53	2.74	1	LR2 T1-T2
46	2.46	0.37	1.73	1	LR2 T0-T1
47	0.09	1	0.55	0	
49	3.38	0.66	2.02	2	LL3, LR3 T0-T1
50	2.96	3.31	3.13	0	
52	1.64	1.57	1.61	0	
53	4.84	0.28	2.59	0	
54	3.09	0.21	1.65	1	LL5 T1-T2

Reliability

Subject number	**Little's Irregularity Index measurement 1**	**Little's Irregularity Index measurement 2**
1	1.25	1.25
2	0.5	0.26
3	7.62	7.7
4	1.81	1.89
5	0.2	0.32
6	1.92	1.93
7	3.27	2.96
8	1.84	1.84
9	0.85	0.82
10	14.51	14.25
11	1.35	1.61
12	6.81	6.61
13	0.95	0.92
14	9.3	9.07
15	7.71	7.57
16	8.57	8.59
17	0.5	0.58
18	1.45	1.16
19	1.01	1.03
20	2.61	2.51
21	5.12	4.93
22	0.88	0.95
23	0	0.15
24	0.19	0.22
25	0.86	0.92
26	0.6	0.42
27	2.17	2
28	3.98	4.12
29	0	0.22
30	1.64	1.7

Chapter 7

LIST OF REFERENCES

CHAPTER 7: LIST OF REFERENCES

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