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The goal of this project is test the performance of set screws used in prosthesis under chewing simulation.

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American Academy of Fixed Prosthodontics poster competition, Chicago

ABSTRACT

Title: The Effect of Bar Design and Repetitive Loading on the Reverse Torque Values of Lateral Set Screws

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Statement of problem: Implant-supported prostheses can be secured to implants with screws (screw-retained) or they can be cemented to abutments. In clinical situations where neither design is recommended, utilizing set screws allows easy retrieval of the prostheses with minimum cost and satisfies esthetic requirements. Set screws use is mostly governed by retrospective, anecdotal and clinical reports. There is no information on loosening or fatigue of set screws and how often they should be maintained and replaced. The shape of the prosthesis, the number of set screws used and dynamic loading are all factors that can affect the clinical performance of the set screws.

Purpose: The purpose of this study was to investigate the difference in reverse torque values of fatigued one set screw or two set screws used to retain straight or curved implant prostheses in vitro.

Materials and methods: This study was conducted in vitro using a milled substructure with two designs (straight and curved) and cast superstructures retained by one or two set screws. There were 8 specimens in each of the four groups, with a total sample size of 32. Set screws in the four groups were tested for changes in reverse torque values using a torque meter after simulated chewing of six months. Data (Ncm) was analyzed using 2-way ANOVA ($p \leq 0.05$). Data are reported as mean (standard deviation).

Results: Data obtained in this study revealed no statistically significant difference in the reverse torque values between prostheses retained by one set screw and two set screws ($F = 0.18$, $p = 0.67$) or between prosthesis retained on curved bars and straight bars ($F = 0.42$, $p = 0.52$). The mean reverse torque in the one set screw group was 12.13 (1.06) Ncm, in the two set screws group 11.99 (0.58) Ncm, in the straight bar group 11.96 (0.52) Ncm and in the curved group was 12.16 (1.08) Ncm. In addition, no significant interaction was found in the reverse torque values between the number of set screws and substructure design ($F = 0.32$, $p = 0.58$).

Conclusions: Within the limitations of this in vitro study, it can be concluded that under functional loading the reverse torque values are not affected by the design of the prosthesis or the number of set screws used to retain the prosthesis.

The Effect of Bar Design and Repetitive Loading on the Reverse Torque Values of
Lateral Set Screws

By
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Thesis submitted to the Faculty of the Graduate School of the
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Introduction

Historians agree that screws were first invented in ancient Greece. However, they are split as to whether it was invented by Archytas of Tarentum (400-350 B.C) or later (287 BC – 212 BC) by Archimedes (Woods & Woods, 2000).

Screws are heavily utilized in various aspects of dentistry and many treatment modalities are made possible by the employment of screw mechanics. In oral surgery, fixation screws along with plates are used to stabilize osteotomies and fractures (Ochs, 2003). In orthodontics, screw-shaped mini-implants are placed in the bone to gain the anchorage needed to align teeth. Many orthodontic appliances utilize expansion screws as an active component to achieve the desired tooth movement (Reynders *et al.*, 2009). In prosthodontics, tenting screws are used to stabilize membranes over bone grafts. Screws are also used to retain the restorative components of implants (GPT8, 2005).

Basics of screws

The screw, a simple machine, is an inclined plane wrapped around a cylinder, used either as a fastener or as a force and motion modifier. Screws take many forms; the most common form consists of a cylindrical shaft with helical grooves or ridges called threads on the external surface. The screw acts as a mechanism that converts rotational motion to linear motion, and a torque (rotational force) to a linear force (Bhandari, 2010).

Many attempts have been made to standardize screw types and designs. The International Association for Standardization standard (ISO-68-1:1998) is one of the most common standardizations existing for screw threads. Another system for standardization, the Unified Thread Standard (UTS), commonly used in the United States, is a non metric inch-sized thread type standardization. Both systems share the same thread geometry but not the absolute dimensions. Both use similar parameters to describe screws. The shaft of the screw has two diameters: Major and minor. The major diameter is measured between the crests of the threads. The minor diameter is measured between the roots of the threads (Fig. 1 and Fig. 2). Other parameters include the lead and the pitch. The lead is the linear distance the screw travels axially in one complete revolution (360°) of the shaft. The pitch is the axial distance between the crests of adjacent threads measured parallel to the axis (Bhandari, 2010). Coarse threads are those with larger pitch and fine threads are those with smaller pitch. An additional category in (ISO-68-1:1998) includes extra fine, with a very fine pitch thread. Extra fine pitch metric threads are more resistant to becoming loose from vibration (Juvinal & Marshek, 2011). The lead and the pitch determine the mechanical advantage of the screw; the smaller the lead and/or pitch, the higher the mechanical advantage (Bhandari, 2010).

Figure 1. Geometric parameters of retaining screws
(Al Jabbari *et al.*, 2008)

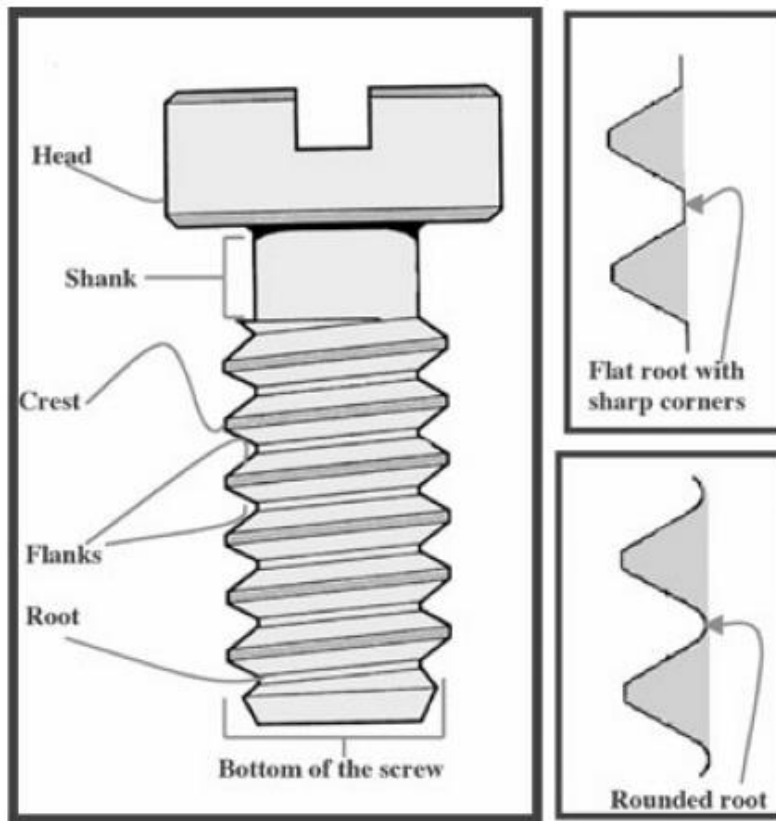
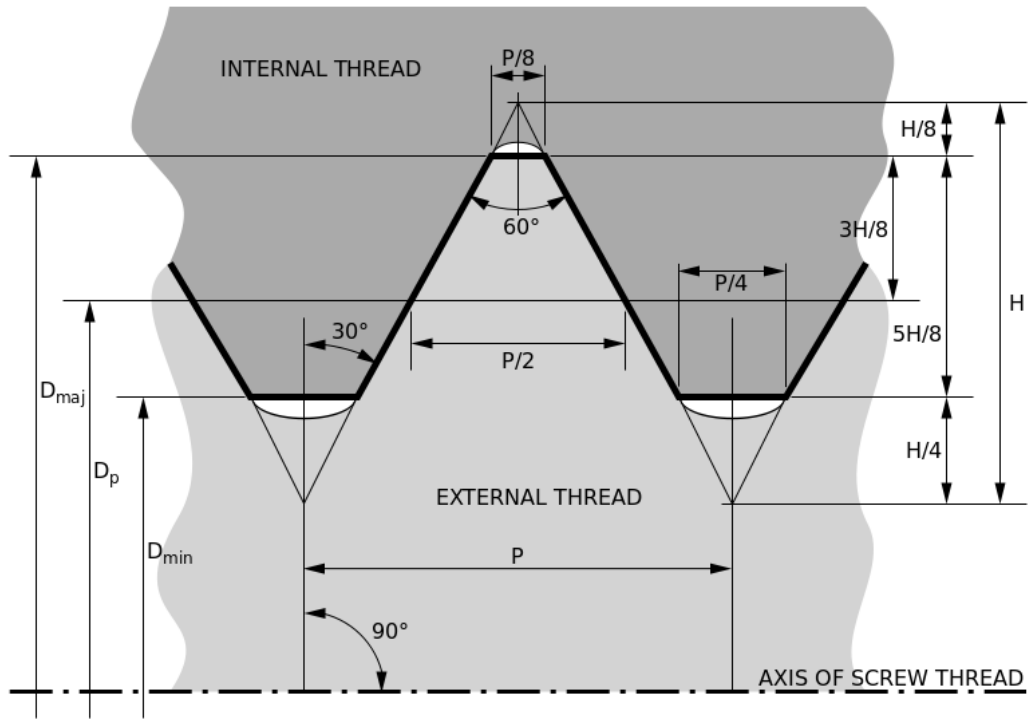


Figure 1: Geometric retaining screw parameters. Al Jabbari et al

Figure 2. ISO (ISO-68-1:1998) and UTS thread dimensions



ISO and UTS Thread Dimensions.

P: Pitch, H: Thread height, Dmaj: Major diameter, Dmin: Minor diameter, Dp: Effective pitch diameter.

The helix of a screw's thread can turn in two possible directions. This is known as handedness. Most screws are right-handed; the screw is tightened when turned in a clockwise direction. The root of the threads can be rounded or flat (Fig. 1). The thread angle of a screw is the angle between the threads. Both ISO (ISO-68-1:1998) and UTS screws have V thread design. Other designs in other standardizations include: Whitworth threads, Pipe thread, Acme thread, Buttress and Square (ISO-68-1:1998).

Screw threads may have different cross-sectional shape/thread forms; square, triangular, trapezoidal, or other shapes. The V-thread (60 degree angled sides extended to a sharp point at the crest of the thread), where there is no truncation, is seldom used because the threads are vulnerable to damage and the sharp point causes severe stress concentration (Juvinal & Marshek, 2011). Most triangle threads are truncated to various degrees affecting the thread depth. The most optimal is 60-75% of the original depth (Juvinal & Marshek, 2011).

Screw threads are described as being Single Start or Double Start (Fig. 3). Most screw thread forms are Single Start (only one ridge wraps around the cylindrical body) resulting in the lead and pitch having the same value (Juvinal & Marshek, 2011). ISO describes many variations in screw head design: hexagon, square, pan, countersunk/flat, fillister, oval, cheese, hexagon socket and hex socket headless set screw carriage bolt among others (Juvinal & Marshek, 2011).

Figure 3. Single thread, double thread.
(Juvinall & Marshek, 2011)

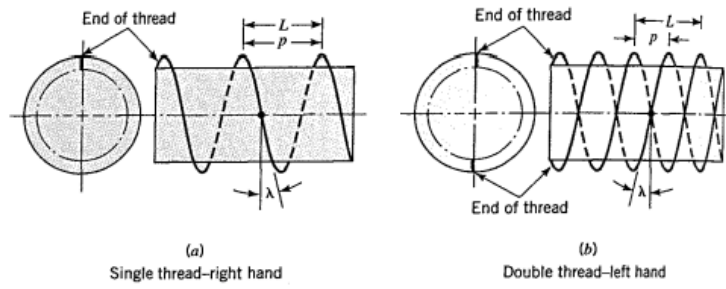


FIGURE 10.1
Helical threads of pitch p , lead L , and lead angle λ .

Implant screw mechanics

The screw joint consists of the two parts tightened together by a screw, such as an abutment and an implant being held together by a screw. The interplay of screw joint separating forces (external) and clamping forces (internal) affect screw joint stability. The screw loosens when the separating forces are greater than the clamping forces. To achieve secure rigid joint assembly, the clamping force should be greater than the separating forces (McGlumphy *et al.*, 1998).

The initial clamping force is achieved with the tightening of the screw and is proportional to the tightening torque. Small torque does not achieve joint stability and large torque leads to screw fatigue or stripping of screws (Burguete *et al.*, 1994). The contact force, the initial tension on the screw, clamps together the assembly components of the screw joint is known as the preload (explained below) (Fig. 4). These forces are generated within the screw when torqued. The tightening torque is applied to the head of the abutment screw as a moment, transformed along the interface of the screw thread surfaces and the implant threaded surfaces. The tensile forces forming within the screw stretches the screw causing frictional forces to develop between the engaging threads leading to compressive forces building up and securing the joint parts tightly against each other (Burguete *et al.*, 1994).

Figure 4. Clamping forces.
(McGlumphy *et al.*, 1998)

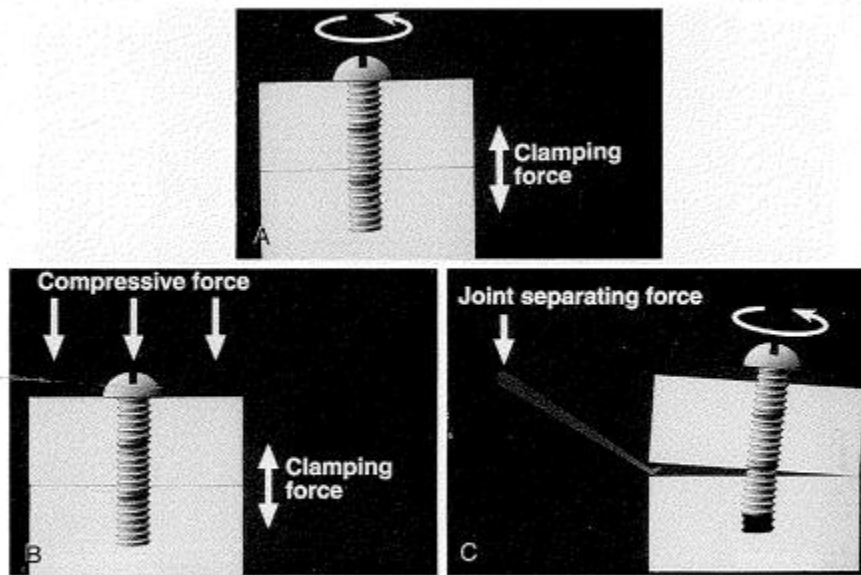


Figure 11. A, Torque applied to a screw develops a clamping force. B, Forces along the same axis of the screw maintain the tight connection. C, A force sufficient to separate the two components will cause the screw to loosen. (Adapted from Block MS, Kent JN: Maxillofacial Reconstruction. Philadelphia, WB Saunders, 1995, p 154; with permission.)

Preload

Preload is the tension created in a screw, especially in the fluted threadings, when tightened (GPT8, 2005). Preload is the contact force that clamps the abutment and the implant as that tightening torque is increased above the initial contact. The optimum preload force recommended for any implant screw is 75% of the yield strength of the abutment screw (Lang *et al.*, 2003). Preload is not only affected by the amount of torque applied but also the design of the screw.

The threads of the screw and the internal threads of the implant cannot be machined smooth perfectly. The only contacting surfaces are the high spots when the initial torque is applied. That leads to the development of preload. These high spots wear with under loading and 2-10% of the initial preload will be lost. This is a mechanical engineering principle known as embedment relaxation. The amount of embedment relaxation is dependant on the roughness of the surface of threads, the surface hardness of the materials and the amount of load subjected (Sakaguchi & Borgersen, 1995; Siamos *et al.*, 2002).

Differences in screw material affect the preload due to differences in the coefficient of friction, the yield strength and the fracture resistance. Gold screws can be tightened more effectively than titanium ones and therefore will provide better retention (Dixon *et al.*, 1995).

The success of the implant assembly depends on achieving an optimum preload (Lang *et al.*, 2003). The coefficient of friction between the components of the implant assembly can significantly influence the level of preload attained in screw tightening. Lang, Kang et al. used finite element analysis to evaluate the effect of the coefficient of friction on the

amount of preload developed in the implant complex during and after abutment screw tightening (Lang *et al.*, 2003). They determined that increasing the amount of tightening torque may not achieve the desired outcome (the optimum preload). However, lowering the coefficient of friction may be an efficient way to increase the preload. The coefficient of friction is dependent on the hardness of the threads, the surface finish, lubricants (such as saliva), the speed of tightening, fit between threads, fit (at the abutment/implant interface), and screw and screw hole tolerances. By varying any of these factors, the coefficient of friction and the preload achieved in screw joint assembly will be affected.

The bigger the screw diameter, the higher the preload. However, the size of the screw intraorally is limited by the size of the teeth. Screw head design affects the preload as well. Screw heads with an internal hexagon are tighter than those with slots allowing better control while tightening and preventing slippage by the clinician (Kallus & Bessing, 1994). Flat head screws have less strains on the interface compared to cone-shaped head screws and thus are less susceptible to screw loosening due to an improved head to shaft ratio (4:1) in tapered versus (1:1) in flat head (Patterson & Johns, 1992). However, Norton *et al.* showed that a cone shaped screw head diminishes micromovement and reduces loosening and fracture (Norton, 1997). There has been concerns about the lack of retrievability due to the possibility of cold welding of cone-screw joints. However, it is mostly based on anecdotal evidence (Norton, 1999). Norton defined cold welding as an increase in reverse torque with respect to tightening torque and results in a lack of retrievability. Norton investigated the reverse torque for the ITI Straumann and Astra Tech implant system under a range of tightening torques. It was shown that an increase in the reverse torque in cone-shaped screws only occurs with high tightening torque values above clinical relevant levels

of torque when plastic deformation is expected. The reverse torque values were 80% to 90% of tightening torque (Norton, 1999).

Torque

The higher the torque, the higher the preload attained. However the amount of the torque that can be applied is restricted by the strength of the implant-bone interface and the fracture point of the screw material. The optimum preload force recommended for any implant screw is 75% of the yield strength of the abutment screw (Lang *et al.*, 2003).

The torque removal value is used to establish the optimum torque that can be used without disturbing the osseointegration of the implant. Animal studies that have been conducted suggest a torque value not greater than 30-35 Ncm should be applied to the implant bone interface (Carr *et al.*, 1995; McGlumphy *et al.*, 1998). Carr *et al.* studied torque removal values of Hydroxyapatite-coated (HA) implants, commercially pure titanium (CP) and Ti-6Al-4V implants in the maxilla and mandible of baboons after 3-4 months of placement. They showed that HA coated had higher torque removal values (186.0 Ncm) than CP Ti (74.0 Ncm) and Ti-6Al-4V (78.6 Ncm). Carr *et al.* also showed that the values in the mandible were greater than the maxilla although the difference was not significant (Carr *et al.*, 1995). Johansson studied the removal torque value of implants placed in rabbit tibia and found an average removal torque value of 68 Ncm (Johansson & Albrektsson, 1987). Sennerby found the torque removal value in the tibia of rabbits to be 36.5 Ncm after 6 months of placement (Sennerby *et al.*, 1992). Tjellstrom conducted an in vivo human study and showed that the average removal torque value of titanium implants placed in the mastoid region was 42.7 Ncm after 4 months (Tjellstrom *et al.*, 1988). Higher

torques are generally found in animals than humans. The results from animal studies should not be inferred to humans without caution (Carr *et al.*, 1995).

Screw loosening

Screw loosening occurs because the external forces acting on the screw joint cause erosion and a small amount of slippage between threads. This releases some of the stretching and continual loss of the preload until the preload reaches a level where the preload/clamping force is below the critical value to resist external forces, leading the engaging threads to turn and loosen (McGlumphy *et al.*, 1998). The fatigue of the screw occurs when the total summation of forces acting on the screw (preload/ clamping force and external separating forces) exceeds the yield strength of the screw. Screw loosening occurs most often with single crown restorations on molars. This is because of the wider crown dimensions relative to the implant diameter that creates off axis forces that acts to separate the screw joint (McGlumphy *et al.*, 1998). Bakaeen, Winkler et al. found that screw loosening can be reduced by narrowing the occlusal table of molar single tooth implants when one implant is used for support.

Screw loosening is more likely to occur when passive fit of the multiunit framework to the implants is not achieved. Screw loosening is one of the issues leading to loss of retention in a screw-retained prosthesis. Screw loosening can be considered an early sign of inadequate design and occlusal overloading (Bakaeen *et al.*, 2001).

Dixon discussed the factors that contribute to screw loosening. First, inadequate clamping force (screws must be torqued 50% to 75% of maximum preload as mentioned earlier). Second, biomechanical overload that occurs when the compressive forces are

greater than the preload and disengage the threads. The tensile forces will lead to plastic deformation of the screw, reducing the clamping forces. Third, off-axis centric forces (excessive implant angles, cantilever prosthesis, and connecting implants to natural teeth using fixed partial dentures) should be avoided. Lastly, implant components and prosthesis misfit contribute to screw loosening (Dixon *et al.*, 1995).

Bakaeen et al. showed that prosthetic gold screws become loose with an applied torque that was approximately 2-3 N less than the tightening torque (Bakaeen *et al.*, 2001). Sakaguchi et al. reported that embedment relaxation happens shortly after screw tightening and 2% to 10% of the initial preload is lost (Sakaguchi & Borgersen, 1995). They proposed to routinely retighten abutment screws ten minutes after initial torque is applied. The screw loosening is less when abutment screws are torqued above 30 Ncm. Screw loosening can occur in the prosthetic screw or in the abutment screw for screw-retained prostheses. However, it is more likely to occur in the prosthetic screw as it is the weakest component within the assembly. Screw loosening is a potential problem for screw-retained restorations at the level of the abutment screw and prosthetic screw and also with cement-retained restorations at the level of the abutment screw (Sakaguchi & Borgersen, 1995).

Screw material

Screws are primarily made of gold or titanium alloy. The gold content of gold screws ranges from 2% to 64% depending on the manufacturer (Martin *et al.*, 2001). Titanium alloy (90% Ti, 6% Al, 4% Vn) is widely used for screws to achieve high stability of the screw joint assembly and due to its lower cost (Spazzin *et al.*, 2009). Spazzin et al, examined the influence of the screw material on joint stability at two levels of fit. They showed that Ti screws provided higher joint stability than gold screws, however, titanium

screws could get loose more easily under dynamic stresses in misfit prostheses. Titanium has lower malleability and higher friction resistance that will lead to smaller contact area between threads on initial tightening (Spazzin *et al.*, 2009).

Guda *et al.* examined the preload and material properties of abutment screws using finite element analysis. They suggested that materials with a higher elastic modulus should be used for manufacturing abutment screws to achieve higher preload (Guda *et al.*, 2008).

Martin *et al.* examined the amount of preload generated at 20 Ncm and 32 Ncm in four types of screws; gold, titanium, Gold-Tite (palladium coated with gold) and TorqTite (Ti with proprietary surface treatment). They showed that abutment screws with enhanced surfaces have lower coefficient of friction that reduces loosening by generating a higher preload torque value than traditional gold and titanium screws (Martin *et al.*, 2001). Byrne *et al.* also showed that gold-coated screws had the highest preloads for all torques (10, 20 and 35 Ncm) compared to gold and titanium screws (Byrne *et al.*, 2006).

Farina *et al.* examined the reverse torque of gold and titanium prosthetic screws with two levels of prosthesis fit under dynamic loading. They showed that titanium and gold screws had no significant difference in the reverse torque and higher values were found after the retorque application (Farina *et al.*, 2014).

Torque and chewing simulation

Several studies have investigated the effect of cyclic fatigue loading on the reverse torque values of different screws used in implant dentistry. Farina *et al.* investigated the effect of masticatory function on the screw joint stability of implant-supported prostheses with four different torquing protocols (Farina *et al.*, 2014). Implant-supported prosthesis

with passive fit and misfit were subjected to one year of chewing simulation using either gold or titanium screws. They showed that misfit caused a significant reduction in the reverse torque regardless of the tightening technique and re-torquing increased screw joint stability for misfit groups.

Bakaeen et al. showed the effect of chewing simulation and untightening torques on the loosening of gold screws for implant crowns with varying occlusal table widths and implant diameters (Bakaeen *et al.*, 2001). Their study showed that prosthetic gold screws became loose with applied torque that was about 2-3 Ncm less than the tightening torque. Screw loosening can be reduced by narrowing the occlusal table of molar single tooth implants. Siamos et al. tested the effect of simulated loading in implant prostheses with varying preloads on the screw loosening (Bakaeen *et al.*, 2001). They recommended to routinely retighten abutment screws ten minutes after initial torque applications and that increasing the torque value above 30 Ncm could be beneficial for abutment-implant stability and decrease screw loosening.

Screw-retained versus cement-retained implant prostheses

Implant-supported prostheses can be secured to implants with screws (screw-retained) or they can be cemented to abutments which are attached to implants with screws (cement-retained). Several arguments have been made to support each prosthesis design to achieve maximum clinical success rates, however, the best type of implant prosthesis remains controversial.

Each method of retention has certain advantages and disadvantages depending on the specific clinical situation. A major drawback of the screw-retained restoration is that the screw access channel might be positioned in an esthetic area when the implant's position is less than ideal. In patients with a limited jaw opening, cement-retained restorations offer easier access to the posterior aspect of the mouth. A screw access hole in a screw-retained prosthesis may interfere with achieving ideal and stable occlusal contacts. Then, occlusal restorative material will be required to cover the screw access channel (Hebel & Gajjar, 1997). This restorative material is susceptible to wear under mastication forces which may result in the loss of occlusal contacts compared to cement-retained restorations with intact occlusal surface (Vigolo *et al.*, 2012). Porcelain fracture is commonly observed in screw-retained restorations because the screw access hole disrupts the structural continuity of the porcelain leaving some unsupported porcelain at the screw access hole (Agar *et al.*, 1997; Shadid & Sadaqa, 2012; Vigolo *et al.*, 2012).

The retention of cement-retained restorations is affected by the taper of the abutment, surface area, the height, the surface roughness and the type of cement. Most prefabricated machined abutments have six degrees of taper. A five mm abutment height is required for predictable retention of cement-retained restorations. Screw-retained restorations should

be used when an interocclusal space of four mm or less is present (Shadid & Sadaqa, 2012). The type of cement is also an important factor affecting the amount of retention that might be accomplished for cement-retained restorations. Cement can be either permanent or provisional. Provisional cement allows restoration retrieval. However, there have been reports of gingival inflammation when using cement-retained prostheses because of the difficulty in removing the excess cement and the risk of scratching the abutments (Agar *et al.*, 1997; Bernal *et al.*, 2003).

One of the major factors in determining the use of cement-retained or screw-retained restorations is the predictability of retrieval when biologic or technical complications occur. Screw-retained prostheses have the advantage of potential retrieval that obviates damaging the restoration or implant. Several suggestions and techniques have been introduced to facilitate the removal of cement-retained restorations. One is using provisional cement. Some techniques have been suggested to allow retrieval of cement-retained prostheses, which depend on locating the screw access opening, such as placing a small ceramic stain on the occlusal surface of the restoration as a guide to the location (Schwedhelm & Raigrodski, 2006).

Set screws

Set screws (also referred to as lingual locking screws, lateral fixation screws, cross pins) are small, transverse screws used to secure a prosthesis to a preset recess or hole on the palatal or lingual cervical aspect of the implant abutment or substructure, thereby allowing retrieval of the prosthesis.

Set screw assembly consists of a small precision screw (commonly 1.4 -1.6 mm in diameter) with or without a pre-threaded housing integrated into the prosthesis. Designs of commercially available set screws (Table 1) vary between unthreaded apex screws, which accurately engage the recess in the supporting structure (abutment or substructure) and threaded lingual locking screws or cross pins, which are screwed transversely into a hole made in the abutment or the substructure (Gervais *et al.*, 2008).

Set screws are most commonly made of titanium alloy or gold. The housing of the screw can be made of a pre-threaded gold housing or a cast-on titanium matrix sleeve. The screw passes through the prosthesis to engage the abutment or substructure. The housing of the screw is incorporated within the prosthesis either by tapping in the sleeve, using adhesive for the sleeve housing, or utilizing a wax pattern that is incorporated within the wax-up of the prosthesis. When the set screw used does not have any housing, a hole is drilled into the abutment using cutting instruments with a slightly smaller diameter than that of the screw. Then the screw is tapped into the abutment (Clausen, 1995).

Set screws are used to prevent the prosthesis (single crown, short span FDP or superstructure) from being dislodged during function while allowing retrieval if needed. Once the screw engages its hole, it prevents the vertical and rotational displacement of the

prosthesis. Set screws can be used with custom abutments or with available abutments of various implant systems if the abutment meets certain requirements (sufficient bulk and favorable taper for optimum resistance form). These abutments must be milled or prepared, with the hole or recess, to receive the set screw at the planned site. Resistance form is the feature of an implant abutment shape that prevents dislodgment of the prosthesis along an axis other than its path of insertion (Clausen, 1995; Gervais *et al.*, 2008). Gervais et al suggested that abutment walls should be milled with zero degree taper for single crowns and at least two degrees taper for multi-unit prostheses. (Gervais *et al.*, 2008)

Set screws can prove to be advantageous when there is limited occlusal clearance, insufficient retention forms or when access of the abutment screw is in an esthetic area because of unfavorable axial alignment of a dental implant. The use of set screws in conjunction with angled abutments solves the problem of screws emerging through the esthetic surface, for example, the labial surface of incisors. Utilizing set screws allows easy retrieval of the prostheses with minimum cost and maintains the basic principle of esthetics. In addition, set screws allow passively fitting superstructures to be constructed and provision of positive retention (Sethi & Sochor, 2000).

Potential disadvantages stem from the fact that set screws are typically much smaller than abutment screws and are not able to withstand occlusal forces without protection from the crown-abutment complex. Overall retention of the prosthesis is gained from the parallelism of the abutment crown assembly (0-2 degrees taper) irrespective of the use of set screws. There is dead space at the prosthesis and abutment interface, which may permit fluid percolation and biofilm formation in this space and be a source of malodor. Sethi et

al. suggested the use of a 'soft cement' to provide a biological seal and yet allow the retrieval of the prosthesis (Sethi & Sochor, 2000).







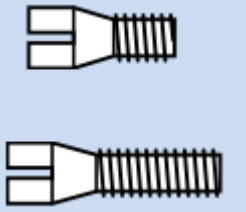
The use of set screws requires that the prosthesis be of sufficient thickness. The resultant thicker contour may affect patient comfort and phonetics (Lee *et al.*, 2007). A set screw should be designed so that it engages the recess or hole when the prosthesis fits passively on the abutment or substructure. Discrepancies of fit between these components might result in excessively large stresses being transmitted to the supporting components. This may lead to cold working of the set screw threads, making the retrieval of the prosthesis challenging.



Accurate fit, with a ten microns gap tolerance, can be difficult to achieve considering potential sources of inaccuracy associated with impression materials, casts and fabrication of metal frameworks. In addition, clinical accessibility to tighten these screws can be difficult intraorally, making the proper positioning of the access holes on the prosthesis critical. For example, a mandibular molar set screw should be placed into the mesio-lingual angle of the crown, rather than perpendicular to its lingual face because of the presence of the tongue and arch shape of the mandible (Sethi & Sochor, 2000).

Set screws are commonly used for retaining the substructure and superstructure prosthesis. A substructure is a metal framework connecting the retainers and supporting the fixed or removable prosthesis. The superstructure is the superior part of a fixed or removable dental prosthesis that includes the replacement teeth and associated gingival/alveolar structures (GPT8, 2005). The use of this design requires adequate inter-occlusal space for the prosthesis. The substructure-superstructure can be used when the

alignment of the implants is unfavorable and may replace lost bone and soft tissue structures as well as teeth (Rodriguez-Tizcareno, 1996; Sethi & Sochor, 2000; Lee *et al.*, 2007).

Table 1. Commercially available set screws

Manufacturer	Product	Housing	Screw Head design	Apex design	
Nobel Biocare (Gothenburg, Sweden) (Yorba Linda, CA)	1.4 mm prosthetic screw multi-unit	No	Round, straight, cylindrical	Threaded	
Bredent screws (Senden, Germany)	Security-Lock-Ceramic 1.4 mm	Wax	No head	Unthreaded	
	Security-Lock-adhesive sleeve 1.4 mm	Titanium sleeve	No head	Unthreaded	
	Security-Lock 1.0, 1.4, 1.8 mm	High-melting cast-on alloy sleeve	No head	Unthreaded	
	Titanium lingual screw 1.4, 1.6 mm	Titanium screw	Conical head	Threaded	
Attachment International (Calabasas Hills, CA)	1.4 mm Hex Set screw 1.6 mm Hex Set screw	Yes	No head	Unthreaded	
DeguDent, Dentsply (York, PA)	Precision screws: 1.0 mm, short 1.0 mm, Long 1.2 mm, short 1.2 mm, Long 1.4 mm, short 1.4 mm, Long	Yes	Round, straight, cylindrical	Threaded	

Cendres+Metau x (Biel/Bienne, Switzerland)	Ipsoclip RE (operator removable retentive element) Ipsoclip SE (screw- retained retentive element)	Yes	No head	Unthreaded	
Staumann ITI dental implant system (Andover, MA)	Tansversal Fixation System® in combination with Octa® abutment	Yes	Round, straight, cylindrical	Threaded	 <p>(Sutter <i>et al.</i>, 1996)</p>

Current literature on set screws

A search of the dental literature resulted in five clinical reports (Clausen, 1995; Rodriguez-Tizcareno, 1996; Sethi & Sochor, 2000; Lee *et al.*, 2007; Gervais *et al.*, 2008). Set screws use is mostly discussed in retrospective, anecdotal and clinical reports. The information and potential functions of the set screws in prosthesis retention are not evidence based. Sutter *et al.* discussed the technique for using Octa abutment manufactured by International Team for Implantology ITI (Sutter *et al.*, 1996). No research has been reported to supports that set screws are sufficient to provide retention for prostheses and resistance to lateral forces or rotational dislodgment. In addition, there are no published guidelines for the number of set screws needed for retaining a full arch prosthesis, the optimal distribution and locations or the difference found when using a hole or recess in the abutment. There is no research data on the loosening or fatigue of set screws and how often they should be maintained and/or replaced. Furthermore, no research has been done that compares the performance of different set screws available in the market.

Purpose

The Purpose of this study is to investigate the difference in reverse torque values of fatigued one set screw or two set screws used to retain straight or curved implant retained prostheses in vitro.

Hypotheses

Null hypotheses

There is no significant difference in the reverse torque values of set screws between prostheses retained using one fatigued set screw or two fatigued set screws.

There is no significant difference in the reverse torque values of set screws between straight or curved prostheses retained by fatigued set screws.

There is no significant interaction in the reverse torque value of set screws between the number of set screws and prostheses curvature.

Research hypotheses

Specific research hypotheses

Prostheses retained using two fatigued set screws will have a significantly higher reverse torque value than prostheses retained using one fatigued set screw.

Curved prostheses retained by fatigued set screws will have a significantly higher reverse torque value than straight prostheses retained by fatigued set screws will.

General research hypothesis

There is a significant interaction in the reverse torque value of set screws between the number of set screws and the prostheses curvature.

Materials and methods

An in vitro study was performed to compare the reverse torque value after fatigue of straight and curved substructure/superstructure prostheses retained by either one set screw or two set screws. Each specimen will simulate a six unit fixed dental prosthesis (FDP) in a substructure (bar) and superstructure design (see Introduction). Specimens will be divided into four groups (8 specimens/group, see Table 2 and power analysis).

Table 2. Experimental groups.

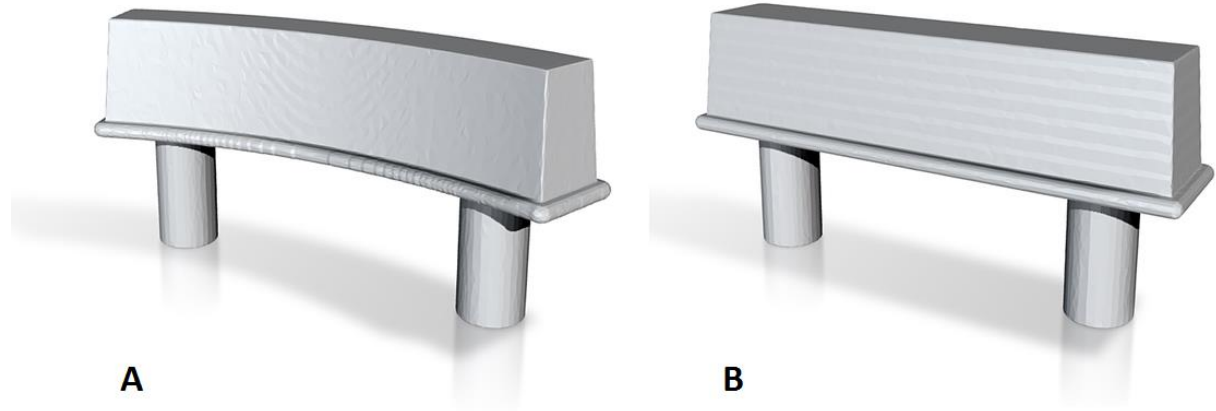
Experimental group	Bar Design	Retention	Screw location
1	Straight	One set screw	Center of the prosthesis, on the lingual surface, midway occluso-gingivally and mesio-distally
2	Straight	Two set screws	On the lingual surface, midway occluso-gingivally and 10 mm lateral to the midline
3	Curved	One set screw	Center of the prosthesis, on the lingual surface, midway occluso-gingivally and mesio-distally
4	Curved	Two set screws	On the lingual surface, midway occluso-gingivally and 10 mm lateral to the midline

Bar fabrication

Substructures were 3D designed digitally using GibbsCAM® CAD/CAM software, (Gibbs and Associates, Moorpark, CA) creating x3d digital files for straight and curved bars. The straight bar used in this study was 30 mm in length, five mm in width and seven mm in height. The curved bar used in this study was five mm in width, seven mm in height, with an arch length of 30 mm, and conformed to a circle with a diameter of 45 mm. The bar was designed with a total convergence angle of eight degrees, a chamfer finish line 0.5 mm wide and had two rods on the intaglio surface which were embedded in auto-polymerizing acrylic resin blocks to retain the bar in the resin blocks (specimen holders). Image rendering of the x3d files and 3D printing with Stainless steel was done by Shapeways (Shapeways HQ, New York, NY) (Fig. 5). The bars were 3D printed in 420 Stainless Steel infused with bronze, and had a final composition of approximately 60% steel and 40% bronze. To build steel models, special 3D printers deposited small drops of glue onto layers of stainless steel powder, one layer at a time, until the print was completed. The models then went through an infusion process that replaced the glue with bronze, creating a full metal product. Models were then processed to the desired finish and sprayed with a sealant. A total of eight specimens were fabricated for each of the four groups.

Figure 5. Three dimensional bar design.

A: Curved (5 mm in width, 7 mm in height, arch length of 30 mm, and conforming to a circle with a diameter of 45mm). B: Straight (30 mm in length, 5 mm in width and 7 mm in height).



Superstructure fabrication

The printed bars were coated with one layer of die lube (Blue Dolphin Products, Morgan Hill, CA). A resin pattern (GC America) of a superstructure of two mm in thickness was made on the fabricated bars. A putty (Lab-Putty, Coltene) template was made of the first superstructure pattern and was used to fabricate all superstructure resin patterns by adding resin to the index before applying it on the corresponding bar. This was done to ensure that all superstructures are of the same size.

The resin pattern was sprued at the lingual surface with a connector bar (6 gauge rod Tri-Wax sprue system, Ivoclar Vivadent, Amherst, NY), and was weighed before being placed on a 5 cc rubber crucible former (Whip Mix Corporation, Louisville, KY). One layer of casting ring liner (Kaoliner Casting Ring Liner 2" x 0.40", Dentsply Caulk, Milford, DE) was used to line a 5 cc casting ring (Whip Mix). Surfactant (Smoothex debubblizing Solution, Whip Mix) was sprayed on the resin pattern. A rubber crucible former and casting ring was assembled and the resin pattern was invested with phosphate bonded investment material (Cera-Fina; Whip Mix). Sixty grams of powder were added to 14.5 mm of special liquid concentrate (Whip Mix) and was mixed according to the manufacturer's instructions in a vacuum mixer (VPM2 vacuum mixer, Whip Mix). After the investment was allowed to bench set for two hours, the ring and casting crucible (Bego Fornax T, Bego, Germany) was placed in a burnout furnace (Infinity L30, Jelrus, Whip Mix) and the temperature was increased in two stages. The first stage began at room temperature and raised to 800°F at a heat rate of 20°F /min. At 800°F, it was heat soaked for 30 minutes. In the second stage, the temperature increased from 800°F to 1600°F, at a heat rate of 30°F /min. At 1600°F it was heat soaked for three hours. The casting crucible

and ring were placed in a casting machine (Bego Fornax T, Bego) and pattern was casted with base metal alloy (Rexillium III, Pentron Laboratory Technologies, LLC, Wallingford, CT). The casting was removed from the investment and cleaned by placing it in an ultrasonic bath (Pro-Sonic 600; Sultan Healthcare, Hackensack, NJ) of distilled water at room temperature for five minutes, followed by steam cleaning (Portable Steamer; Belle De Saint Claire Inc, Chatsworth, Ca). All specimens were checked under magnification (Microscope, Nikon SMZ-2T) and with check-fitting spray (Occlude Aerosol Indicator Spray, Pascal Company Inc. Bellevue, WA) for surface irregularities and marginal fit.

Set screw placement

For the one set screw group, a screw hole was prepared in the center of the bar on the lingual surface, midway occluso-gingivally and mesio-distally. For the two set screw group, two holes were drilled. Both were placed on the lingual surface midway occluso-gingivally ten mm lateral to the midline. A clear laminate vacuum forming template (0.5mm Proform coping material, Keystone industries, PA) was made on the first specimen of each group. The vacuum form was trimmed and the holes were marked. This template was used to mark the location of the holes on the remaining specimens to ensure that the holes were placed in the same position.

The bar and superstructure for each specimen were assembled and a tungsten carbide center drill (provided in the Diatit-Multidrill kit, Bredent GmbH & Co. KG. Senden, Germany) were used to prepare a small groove on the superstructure in the site where the set screw was placed (Bredent). Bredent set screws (titanium set screw 1.4mm, Bredent GmbH) was utilized because they are the most commonly used by dental laboratories (data obtained using a telephone survey). A Multidrill 1.3 x 5 tool (Diatit-Multidrill kit, Bredent)

was used to prepare a core hole, approximately two mm deep into the superstructure while it was seated on the bar. A tap tool (Diatit-Multidrill kit, Bredent) was used to cut the thread into the bar (tapping) using clockwise rotation without exerting any pressure until the first tap reached the bottom of the core hole. A rich quantity of oil was used during this process. When the titanium screw (1.4mm: Ø 2.1 mm x 4.5 mm, length of screw head: 2.5 mm) was inserted through the superstructure alone, the screw head should protrude approximately 0.3 mm into the bar. The screw head was adapted by grinding it until it became flush with the surface of the superstructure using titanium processing kit burs (Bredent, Germany). After tapping, the specimens were steam cleaned to remove metal chips and oil residue from the core hole.

Specimen holder

Prefabricated plastic specimen holders (SD Mechatronic GmbH, Feldkirchen-Westerham, Germany) were used to retain the bar-superstructure assembly. Each holder was 34 mm in diameter and 17 mm in height. The holder was lubricated with petroleum jelly (Vaseline, Unilever, USA). Clear, auto-polymerizing acrylic resin (Ortho-Jet Clear, Lang Dental Manufacturing Co. Inc., Wheeling, IL) was poured into the holder. The bar-superstructure assembly was placed into the acrylic resin using a surveyor (A.M.D. Surveyor 102, A.M.D. Dental Mfg. Inc., Highland Park, NJ). The test specimens were placed perpendicular to the table. The finish line of the bar was 2 mm above the acrylic surface. The acrylic resin was allowed to set for 20 minutes and then the test assembly was placed in 100% humidity for 24 hours. A lateral pin traversing the diameter of the specimen holder will be used to retain the acrylic resin and the test assembly.

Dynamic loading

To simulate the chewing loads found intraorally, resin holders containing test specimens were attached to a Chewing Simulator (CS 4.2, SD Mechatronic GmbH, Feldkirchen-Westerham, Germany). Each specimen was subjected to a dynamic cyclic load with both vertical and lateral components (120,000 cycles, 5kg of weight, 3 mm height, 0.7 mm lateral movement, vertical and lateral speeds of 60 mm/s, frequency 1.6 hz) on the center of the occlusal aspect (Heintze, 2006). A chewing simulation of 120,000 cycles represented six months of clinical service (Sakaguchi *et al.*, 1986; Heintze, 2006; Rosentritt *et al.*, 2009; Steiner *et al.*, 2009). The load was applied with low impact to each specimen with a round stainless steel stylus (2.5 mm at tip, 6 mm in height, SD Mechatronic GmbH) at a 90 degree angle.

Reverse torque testing

The set screws were tightened according to the recommended torque values (15 Ncm) using an electronic torque gauge (Mark 10 Series TT03 torque meter, Mark-10 Corporation, Copiague, NY). The torque required to loosen the screws was measured using the torque gauge (Mark 10 Series TT03 torque meter, Mark-10 Corporation, Copiague, NY). This measurement was used to compare the torque required to loosen the screws after subjecting the specimens to dynamic loading. The reverse torque values were recorded as an indication of the fatigue of set screws in straight and curved specimens.

Statistical analysis

A difference of one Ncm of reverse torque values was found to be significant in previous studies between different groups (Bakaeen *et al.*, 2001).

An n of 13 per group provided adequate power. With an n of 13, using a two-way analysis of variance (ANOVA) and a 1-tailed test an effect size of 0.50 for both number of screws and design of prostheses, an effect size of 0.50 for their interaction, the power was equal to 0.93 for both number of screws and design of prosthesis and 0.79 for their interaction. In this study, a specimen size of eight per group was selected due to economic considerations.

Two-way analysis of variance (ANOVA) was used to test for any statistical differences in reverse torque value. A $p \leq 0.05$ was considered significant.

Results

Each set screw was torqued to 15 Ncm (Mark 10 Series TT03 torque meter). Following chewing simulation, the reverse torque was measured for set screws of each group. Data was collected using Mark 10 Software, MESUR Lite. Mean, Median range and standard deviation for each group can be seen in table 3.

Statistical analysis of the data revealed no significant difference in the reverse torque values between one set screw and two set screws ($F = 0.18$, $p = 0.67$). The mean reverse torque in the one set screw group was 12.13 (1.06) Ncm. The mean reverse torque in the two set screws group was 11.99 (0.58) Ncm (Table 4, Fig 6). The difference was not statistically significant.

No significant difference was found in the reverse torque values between curved bars and straight bars ($F = 0.42$, $p = 0.52$). The mean reverse torque in the straight bar group was 11.96 (0.52) Ncm. The mean reverse torque in the curved group was 12.16 (1.08) Ncm (Table 4, Fig 7). The difference was not statistically significant.

There was no significant interaction between the number of set screws and substructure design in the reverse torque values ($F = 0.32$, $p = 0.58$). The results can be seen in Table 4, Fig 8.

Table 3. Data collected for each group. Mean, Median, Range and Standard deviation.

Group	description	n	Mean	Median	Range	SD
1	Straight bar with 1 set screw	8	11.94	11.85	11.3-12.6	0.49
2	Straight bar with 2 set screws	8	11.98	11.98	11.4-12.75	0.58
3	Curved bar with 1 set screw	8	12.31	12.35	9.4-13.9	1.44
4	Curved bar with 2 set screws	8	12.01	11.95	11.25-13.1	0.62

Table 4. ANOVA table for difference in reverse torque (Ncm).

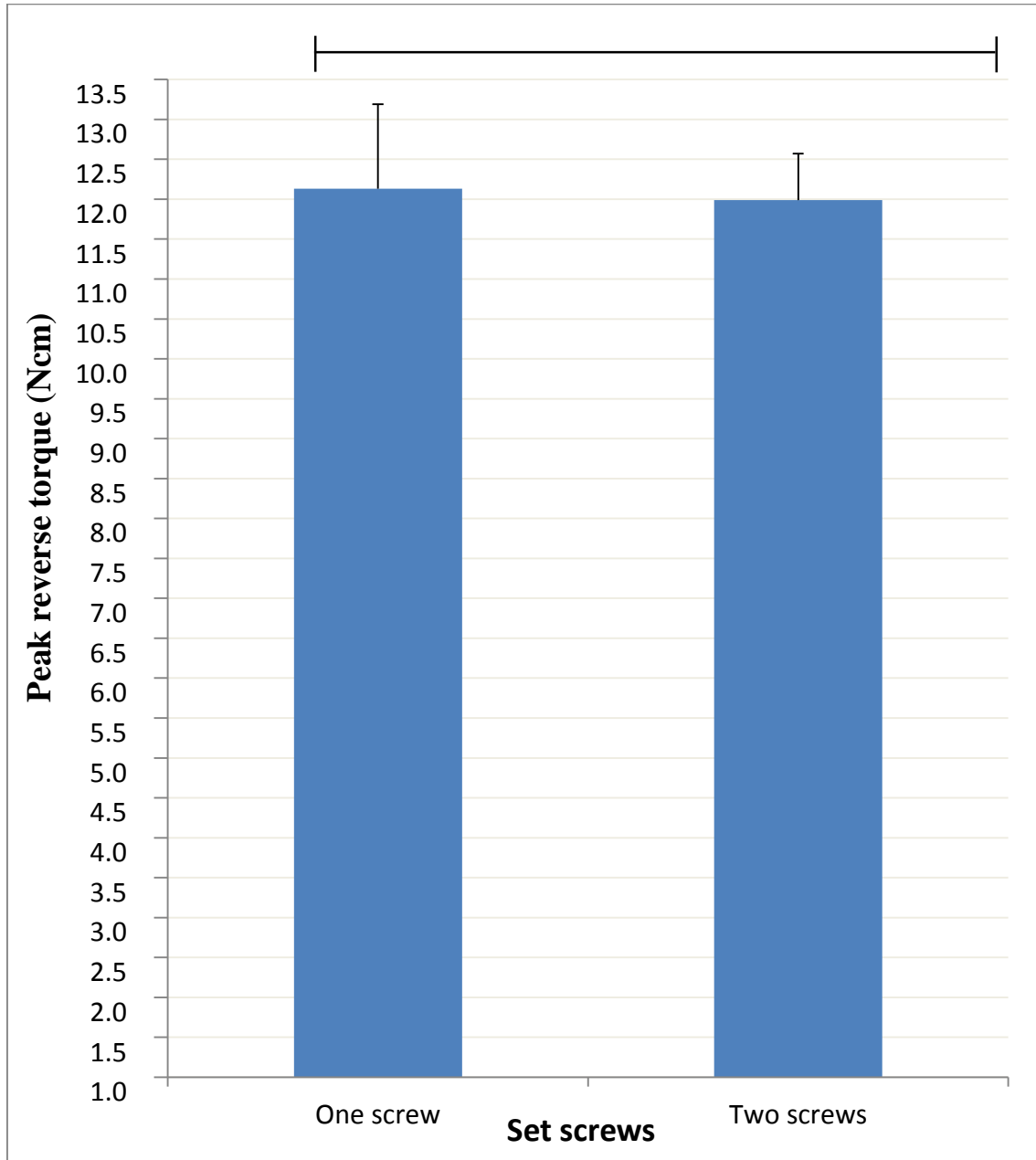
Source	df	N	Mean	SD	F	p
Set screws	1				0.18	0.674*
One		16	12.13	1.06		
Two		16	11.99	0.58		
Bar Design	1				0.42	0.52*
Straight		16	11.96	0.52		
Curve		16	12.16	1.08		
Interaction	1				0.322	0.575*

*Non-significant

Table 5. Observed power and effect size.

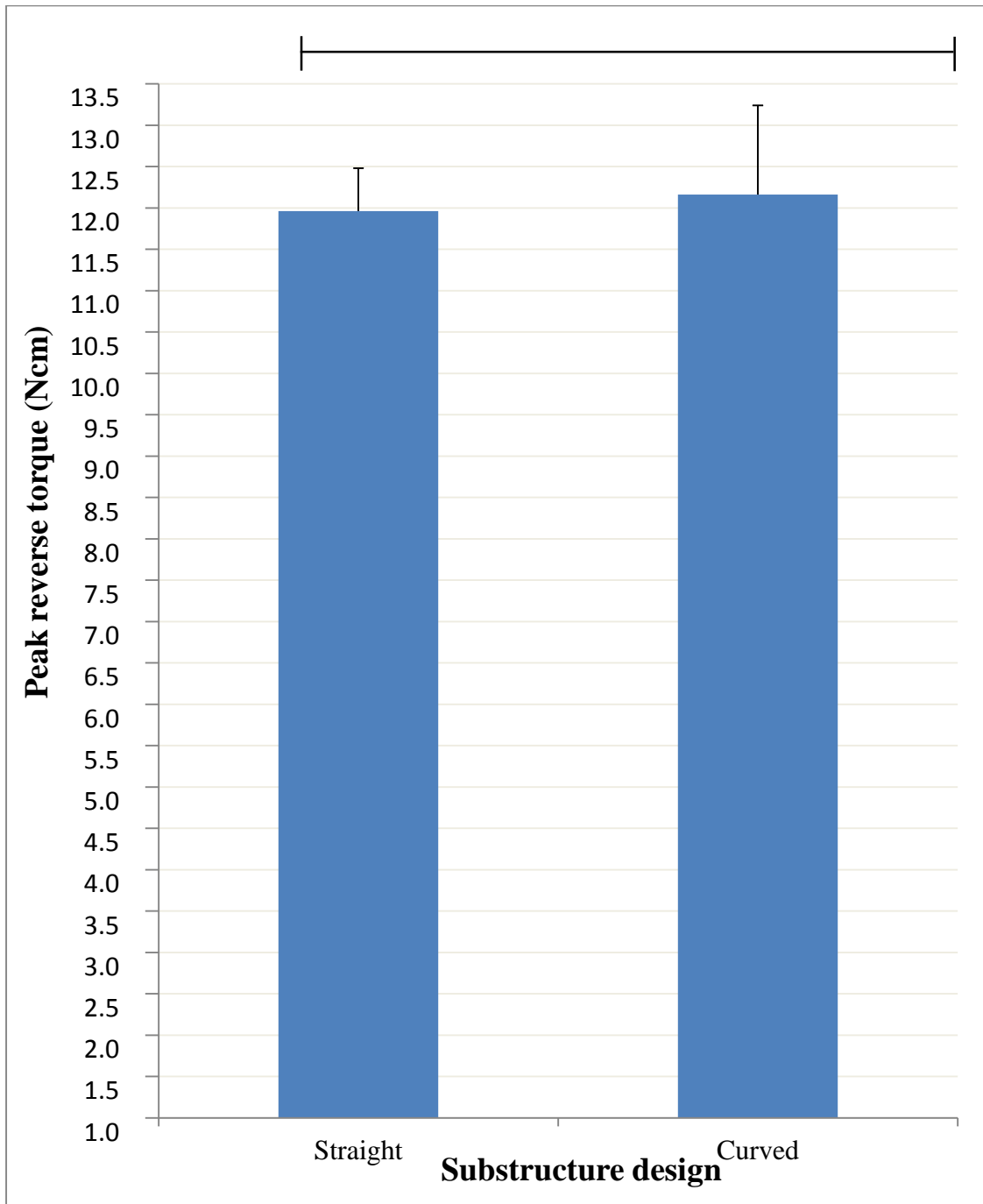
Source	Effect size	Observed power
Set screws	0.006	0.070
Bar design	0.015	0.096
Set screw * Bar design	0.011	0.085

Figure 6. Mean peak reverse torque (Ncm) for one screw and two set screw groups. Error bars represent standard deviation (SD) ($F = 0.18$, $p = 0.67$).



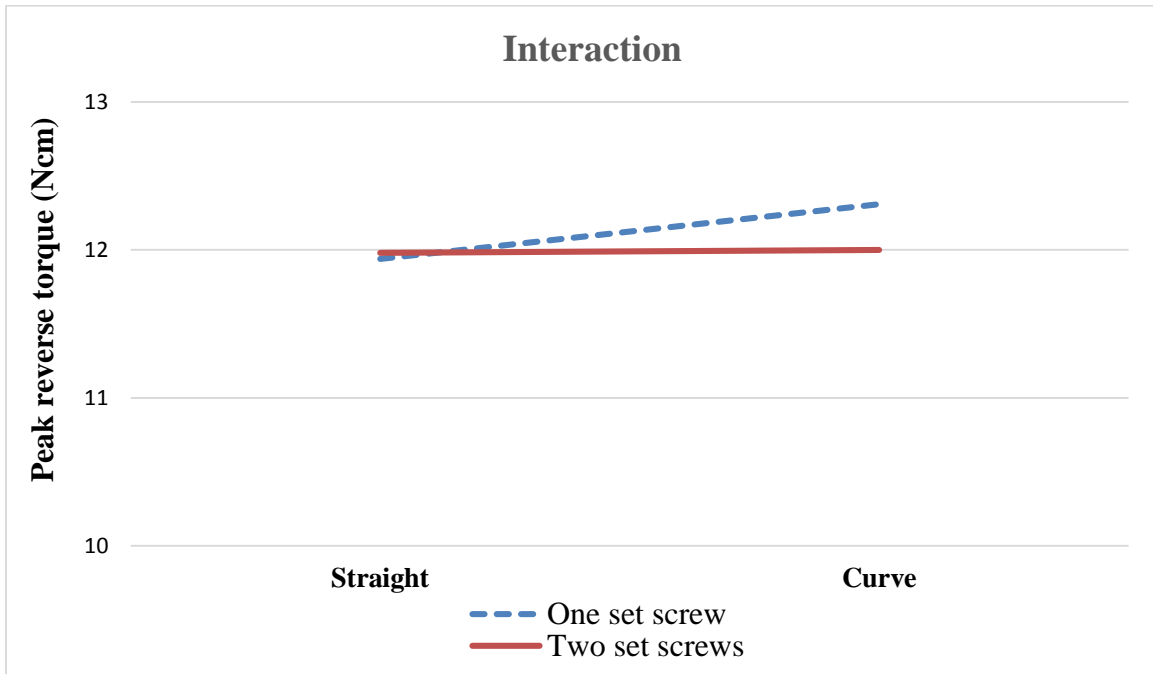
Groups under the same bar are not significantly different.

Figure 7. Mean peak reverse torque (Ncm) for substructure design groups. Error bars represent standard deviation (SD) ($F = 0.42$, $p = 0.52$).



Groups under the same bar are not significantly different.

Figure 8. Mean peak reverse torque (Ncm) set screws versus substructure design ($F = 0.32$, $p = 0.58$).



Discussion

The results of the present study supported the null hypotheses. The difference in the design of the substructure and the number of the set screws utilized did not result in significant reduction of reverse torques.

It was calculated that an n of 13 per group would provide adequate power. However, the number of specimens tested was reduced to 8 per group. The number was reduced due to economic considerations. The effect size was very small (0.006, 0.015, 0.011) suggesting that the set screws and substructure design had little effect on the reverse torque. Thus, the reduction in the number of specimens did not affect the lack of significance found in this research. Even if an n of 13 had been used, the results would not have been significant. In addition, even if statistical significance had been found in the recorded reverse torque values, the difference in the reverse torque value between one and two set screws and between straight and curved bars would not have been clinically relevant.

The resistance form is the feature of the abutment geometrical configuration that prevents dislodgment of the prosthesis. The design of the prosthesis provides resistance to lateral and anterior/posterior movements that could compromised stability by lateral loads, which in turn could be detrimental to the implants (Rodriguez-Tizcareno, 1996; Schwarz, 2000). A segmented full arch prosthesis would have straight and curved components. Two basic designs of the substructures were used in this study; straight and curved. The results of this study shows no significant reduction in the reverse torque recorded after dynamic loading between these two designs.

The reverse torque value between the one set screw and two set screws groups was not statistically significant nor clinically relevant. This might be explained by the following; Set screws serve to aid in the retention of the prosthesis and prevent dislodgment during function. The overall retention of the prosthesis is gained from the parallelism of the substructure-superstructure assembly and the friction between the superstructure and substructure (Rodriguez-Tizcareno, 1996; Sethi & Sochor, 2000). Thus, the number of set screws may not be critical for the retention of the designed prosthesis.

The specimens were subjected to dynamic loading equivalent of 6 months of function. It was hypothesized that the transmitted load would result in the reduction of the reverse torque of the screws. The longevity of the prosthesis, the stability of screw joint and the possibility to retrieve the prosthesis depends on the passive fit of the prosthesis (Spazzin *et al.*, 2009; Farina *et al.*, 2014). Mechanical complications might result from overloading dental implants and implant prostheses including; screw loosening and fracture, prosthesis fracture and implant fracture, potentially compromising implant longevity (Schwarz, 2000). Absolute passive fit is not critical for long-term success of clinically acceptable frameworks leading some authors to argue against its significance in implant treatment (Abduo *et al.*, 2010). Nonetheless, misfit may not have a direct effect on the health and stability of the osseointegration of implants as it has been shown to affect mechanical complications of the screw joint interface and the reduction of reverse torque (Taylor, 1998; Spazzin *et al.*, 2009; Farina *et al.*, 2014). These studies have demonstrated the effect of dynamic loading on the screw joint stability at the abutment-implant interface. This effect might be extrapolated to the set screw interface of substructure-superstructure

design. Excessive stresses can be transmitted to the set screw in poorly designed and misfit prosthesis and might lead to lower reverse torque of the set screws.

The results obtained in this in vitro study may not be directly extrapolated to the clinical setting. Only the design of the substructure and number of screws were investigated. In this study the specimens were subjected to six months of simulated function without thermal cycling. The increased exposure of set screws to functional loading or higher occlusal forces may affect the longevity of the screws and resistance to fatigue. This might adversely affect the loosening torques of set screws. Other factors that could affect the loosening torque of set screws and potentially influence the performance of the substructure/superstructure assembly under dynamic loading were the length of the prosthesis, the distribution of the set screws, and the angle of the screws. Further research is needed to investigate the performance of set screws under longer periods of chewing simulation, the effect of increased length of the prosthesis and whether it dictates the number of set screws needed for proper retention and the effect of the angulation at which the set screw engages the substructure which might limit clinical accessibility and may affect the resistance to occlusal forces and lead to altered reverse torque.

Conclusions

Within the limitations of this in vitro study, it can be concluded that under functional loading the reverse torque values were not affected by the design of the prosthesis or the number of set screws used to retain the prosthesis. In addition, for clinically relevant levels of tightening torque, no problems are anticipated with respect to retrievability of the prosthesis using set screws. The clinician can use a minimum number of set screws to retain a substructure-superstructure prosthesis. The results of this study suggest that the clinician has ample freedom for the substructure design.

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