EFFECT OF MINISCREW IMPLANT DESIGN CHARACTERISTICS AND BONE PROPERTIES ON INSERTION TORQUE FOR PRIMARY STABILITY - AN INVITRO STUDY

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CHENNAI

DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation titled **"EFFECT OF MINISCREW IMPLANT DESIGN CHARACTERISTICSAND BONE PROPERTIES ON INSERTION TORQUE FOR PRIMARY STABILITY-AN INVITRO STUDY"** is a bonafide and genuine research work carried out by me under the guidance of **Prof. Dr. V.K. Shakeel Ahmed M.D.S, Diplomate of Indian board of Orthodontics,** Professor, Department of Orthodontics and Dentofacial Orthopedics, Ragas Dental College and Hospital, Chennai.

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CERTIFICATE

This is to certify that this dissertation titled **"EFFECT OF MINISCREW IMPLANT DESIGN CHARACTERISTICSAND BONE PROPERTIES ON INSERTION TORQUE FOR PRIMARY STABILITY- AN INVITRO STUDY"** is a bonafide record work done by **Dr. Mathew S Chericken** under my guidance during his post graduate study period 2015-2018.

This dissertation is submitted to **THE TAMILNADU Dr.M.G.R. MEDICAL UNIVERSITY,** in partial fulfillment for the degree **of MASTER OF DENTAL SURGERY in BRANCH V** - Orthodontics and Dentofacial Orthopedics. It has not been submitted (partially or fully) for the award of any other degree or diploma.

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ABSTRACT

AIM:

The aim of our study was to evaluate the geometrical design characteristics (lead angle of thread, pitch, depth, taper, number of threads, surface area, thread length, diameter, thread type) of 2 commercially available self drilling tapered miniscrew implants using scanning electron microscopy (SEM) and to evaluate the effects of each geometrical design parameters of MSI's on primary stability using insertion torque in different cortical bone thickness.

MATERIAL AND METHOD:

A total of 60 titanium miniscrew implants (MSI's) were used in this study,consisting of 30 MSI's each from two different manufacturers (Dentos Korea, SK Surgicals India). MSI's were grouped into small, medium and large according to their diameters as 1.3mm, 1.5mm and 1.8mm respectively. All MSI's had a standard length of 8mm. All the MSI's used in this study were tapered and self-drilling type. Precise measurement of all MSI geometric design parameters were evaluated using scanning electron microscopy (SEM) and Image J software. Mechanical evaluation of insertion torque was done to evaluate primary stability.

RESULTS:

Geometric design characteristics like decreasing the MSI pitch distance, increasing the number of threads, maintaining a uniform MSI taper and increasing the surface area of MSI's plays an important role to achieve optimal insertion torque and thereby enhancing primary stability.An increase in lead angle increases the cutting efficiency of MSI. Therefore MSI's with higher lead angles are recommended for easy insertion of MSI in thick cortical areas.Increase in MSI depth reduces the core diameter of the MSI and are more prone to fracture. An increase in the diameter of the MSI and cortical bone thickness which increases the insertion torque will enhances the primary stability

CONCLUSIONS:

A great variability in the geometric design characteristics of MSI was observed. On the basis of the present outcomes it is assumed that MSI design parameters could be strategically matched, in order to improve its performance, according to insertion site characteristics and clinical demands concerning the directions of the forces applied. So, the clinicians must know these geometric design characteristics of MSI's in order to increase the success rates of their procedures.

KEY WORDS: Miniscrew implant, Geometric design parameters, Insertion torque, Miniscrew implant stability, Scanning electron microscope, Cortical bone thickness.

CONTENTS

Introduction

INTRODUCTION

Anchorage control is one of the major factor for the success of orthodontic treatment and for this reason, efforts have been made to develop appropriate anchorage methods[61]. Miniscrew implants (MSI's) has received great attention in the orthodontic literature and among the orthodontists as a true source of skeletal anchorage. Since their first clinical use almost three decades ago, MSI's have been investigated extensively and adopted worldwide.[2]

Scientific and clinical studies on MSI's have reported mechanical and biological factors as well as clinical applications[2] including the intrusion, extrusion, uprighting of impacted teeth, distalization of the maxillary and/or mandibular teeth, en-masse retraction of the anterior teeth, management of sagittal, transverse and vertical discrepancies.[8,87,88,89]

Despite the great progress made so far, improvements in the clinical performance of MSI's is still a major topic of interest. MSI's may present episodes of loosening, mobility or displacement, and may be associated with injury to the adjacent structures and inflammation or infection of the surrounding tissue.[65,63] The factors which might have an impact on early MSI loss and how relevant these factors are, is not well understood.

Hence, stability is one of the essential factors related to MSI permanence at the site of insertion. Primary stability is regarded as the key factor for MSI success[95]. This is initially represented by the mechanical interaction between the MSI surface and surrounding bone. It varies according to individual patient factors such as bone properties (bone quantity and bone quality)[80,81], implant site[113,114], miniscrew implant geometry[59,105,81](diameter, length), surgical technique and insertion torque.

The stability of miniscrew implants can be quantified by the insertion torque[70].Insertion torque[69] is the measure of the rotational force needed to insert the MSI into the bone for primary stability and is represented as Newton centimetre (Ncm). Maximum insertion torque (MIT) values in the range of 5 to 10 Ncm has been considered as the gold standard for success of MSI's[82]. Due to the difference in the properties of bone throughout the maxillo-facial complex, there is a variation in the mean MSI insertion torque values in maxilla and mandible which has been reported in literature[80].Low insertion torque increases the possibility of loosening of the MSI at the bone interface thus compromising the primary stability[37], while excessive insertion torque over the threshold range can cause bone cracks and bone necrosis[105].Another probable consequence of excess insertion torque is failure within the miniscrew implant itself via its bending, fracture or its failure[93].

Since there is considerable variation in bone quality, the type and design of MSI that is most suitable for the host bone site available for insertion to enhance primary stability has not been reported in the literature. Therefore, when a clinician chooses an MSI for use in practice, he/she is presented with the difficult task of selecting which MSI would be best suited for each clinical situation. Many studies have been conducted to analyze primary stability with regards to bone quality, MSI length, MSI diameter and operator factors. There has been little attention paid to miniscrew implant design and its effect on primary stability. Hence, other geometric characteristics of MSI that might enhance the primary stability remains to be fully understood. Since no optimal design has been defined yet, each parameter could contribute to upgrading miniscrew implant performance, thereby enhancing mechanical stability, strength and load transfer.

Therefore the aim of our study were as follows:

- To evaluate the geometrical design characteristics (pitch, depth, taper, number of threads, lead angle of thread, thread types, thread length, diameter) of two commercially available self drilling tapered miniscrew implants using scanning electron microscopy (SEM) and were measured using Image J software. The surface area of MSI's were calculated with the help of mathematical formula.
- To evaluate the effects of each geometrical design parameters of MSI's on primary stability using insertion torque in different cortical bone thickness.

Review of Literature

REVIEW OF LITERATURE

Anchorage in orthodontics is the resistance to unwanted tooth movement. In the field of orthodontics, several methods have been developed to overcome the critical problem of anchorage. Among them, skeletal anchorage systems have gained increasing interest.

Currently, many MSI manufacturers exist yet they not all share the same design. MSI's are often described by four main characteristics:

1) The alloy or metal used;
2) The dimensions and design of the threaded portion or shaft
3) The screw head or attachment design and
4) The insertion methodology.

Most of today's orthodontic miniscrew simplants are fabricated from polished, bio-inert titanium alloys (TiAl6V4) except the orthodontic miniscrew implant (Leone S.p.A.) which is fabricated from stainless steel. Though these alloys are usually classified as type IV or V titanium, orthodontic miniscrew implants manufacturers do not readily divulge their unique manufacturing information or material composition data. Addition of aluminum to titanium increases the tensile strength, creep strength and elastics modulus and also will expand the alpha phase and increase the strength. A beta-stabilized (β alloy) titanium alloy will have vanadium, molybdenum, iron, chromium and zirconium added to stabilize the phase. It has higher yield and ultimate tensile strength than all alpha-alloys. One of the most successful alpha-beta alloys is Ti-6Al-4V, which has an excellent combination of strength, toughness and corrosion resistance.

The threaded portions of contemporary MSI's are engineered to be long enough to trespass soft tissues and gain anchorage in cortical and alveolar bone while also being narrow enough in diameter to avoid penetration or damage to tooth roots when placed adjacent to these structures. The design of the shaft is classified as cylindrical or tapered.

Insertion methods among MSI's may be categorized as either drill-free or non drill-free, depending on the thread design. Drill-free MSIs feature a cutting tip which does not require that a pilot hole be created before insertion, while non drill-free designs commonly require a soft-tissue punch and a pilot hole to be drilled in bone before placement.

The effects of implant length and diameter on insertion torque and pullout strength have been reviewed, but the interrelationship between various diameters, cortical bone thickness and other geometric design parameters like pitch, lead angle, depth, taper, number of threads and surface area on the insertion torque of these MSI systems are not widely published.

Anatomic Location Of Bone Parameters

MSI's can be placed both in maxilla and mandible, but investigators have shown that placement site may influence their performance. Possible sites in the maxilla are the nasal spine, the palate, the infra-zygomatic crest, the maxillary tuberosities and the alveolar process. In mandible insertions have been reported in the symphysis, the alveolar process and the retro-molar area.

Berens et al (2006)[11] warned not to place MSI's in the lingual side of the lower jaw, due to the technical demand during insertion and the patients tongue interference and observed quite high loss rates on the palatal side of the upper jaw where according to them the mucosal thickness came into play. The palatal mucosa they reported is 5mm thick in some parts which automatically leads to a long lever arm, which is a decisive factor in the loss of the MSI.

Park et al (2006)[91] on 227 MSI's showed higher failure rate in the mandible (13.6% for the mandible and 4% for the maxilla).

Poggio et al(2006)[97] discussed that in maxilla, the best insertion sites are in the anterior and apical portion and in the mandible and the safest sites are between first and second molars and premolars. In the mandible the safest sites are mesial or distal to the first molar according to **Deguchi et al(2006)**[32].

Conical vs cylindrical MSI's

The conical MSIs show greater primary stability compared to the cylindrical ones as found in a study of **Wilmes et al (2008)**[116]**.** He compared the Dual Top MSI and the Tomas pin and found that despite having the same dimensions the Tomas pin types showed less primary stability than the Dual Top MSI. One apparent reason for that is the intra-osseous part of the Tomas pin which is cylindrical, which seems inferior to those having a conical shape.

Kim et al (2008)[58]showed in his mechanical study that the conical group of MSIs showed significantly higher maximum insertion torque (MIT) and maximum removal torque (MRT) than the cylindrical group. He concludes that although the conical shaped MSI could induce tight contact to the adjacent bone tissue and might produce good primary stability, the conical shape may need modification of the thread structure and insertion technique to reduce the excessive insertion torque while maintaining the high resistance to removal.

Kim et al (2009)[59]compared cylindrical, taper shaped and dual thread MSIs and said that the cylindrical shape had the lowest MIT and MRT in each length. Although taper shape showed the highest MIT in each length, when the values of insertion and removal angular momentum were analysed (IAM and RAM), dual-thread shape showed significantly higher MRT and RAM in each length.

Self drilling vs self tapping MSI

Thread designs of MSI have evolved over the years. Original self tapping designs, otherwise known as “non-drill-free” screws, require pilot hole preparation prior to insertion. Today, most manufacturers are promoting the advancement of self-drilling or “drill free” designs where MSIs are placed in a one-step procedure eliminating the need for pre-drilling. There are several advantages to using MSIs that do not require a pilot hole.

Buschang et al. 2008[14]According to a 2008 American Association of Orthodontics (AAO) survey, the majority of orthodontists never drill a pilot hole prior to MSI placement, indicating a strong preference for the self-drilling design due to its versatility and ease of placement.

Chen Y et al(2008)[21]**, Kim JW et al(2009)**[60] **.** The drill-free method results in higher insertion torques than the pre-drilling method, which can lead to greater primary stability and success rates as a result of increased bone-to-implant contact ratio.

Dao et al (2009)[31]Since the self-drilling design obviates the need for pre-drilling with a motorized hand-piece, it also significantly reduces root damage risks due to better tactile feedback during manual insertion.

Baumgartel S et al (2010)[10]An important element affecting MSI secondary stability is the amount of mechanical damage induced to the tissues upon MSI placement, and its effect on satisfactory healing of the site**.** The self-drilling technique is thought to cause a reduced amount of damage by eliminating overheating of adjacent bone during the self-drilling process.

Miniscrew Implant Length

Hitchon et al (2003)[44]examined the effects of MSI length (12mm, 14mm and 16mm) by testing 201 MSI-type MSIs in fresh human cadaver specimens. Length was shown to have a statistically significant effect on pull out strength, with longer MSI having a higher resistance to displacement. This might be expected because holding power is directly proportional to the amount of thread engagement as reported by **Lyon et al (1941)[68].**

Chen et al (2006)[22]studied, retrospectively, the relationship between MSI length and the retention rate. Fifty-nine MSIs, either 8mm or 6 mm in length, with a diameter of 1.2mm, were placed in 29 patients for orthodontic anchorage. A statistically significant difference was found between the two groups. The success rates of the 8mm MSIs and 6mm MSIs were 90.2% and 72.2%, respectively.

Lim et al (2008)[66]examined the effects of MSI length, diameter and shape on insertion torque. Cylindrical and taper type MSIs with different lengths, diameters, and pitches were tested by placing them in synthetic bone. Their results showed that increasing MSI length resulted in greater insertion torque, suggesting that greater stability could be achieved.

Miniscrew Implant Diameter

Hughes et al(1972)[47]recommended using MSI with a larger outer diameter when greater holding power is desired. The major diameter is the diameter as determined by the outer diameter of the threads. Outer diameters vary widely among and within different manufacturers. MSIs currently available in the market have outer diameters ranging between 1.2 mm and 2mm.

Miyawaki et al (2003)[79]all reported that the 1.0mm outer diameter screws failed, while the 1.5mm and 2.3mm diameter screws showed success rates of 83.9% and 85%, respectively. The authors concluded that a diameter of less than 1.0mm was a significant criterion associated with failure. The advantage of a thinner screw is that it can be placed in more locations, such as between the roots of teeth. The drawback, however, is the greater potential for screw fracture.

Wilmes et al(2008)[113]studied various parameters affecting the primary stability of orthodontic MSIs. Outer diameter was one of the parameters determined to have an influence on primary stability. Insertion torques of five different MSI types, tomas-pin (Dentaurum, Ispringen, Germany) 08 and 10mm, and Dual Top (Jeil Medical Corporation, Seoul, Korea) 1.6 × 8 and 10mm plus 2 × 10mm, were measured to determine their primary stability. The Dual Top MSI with a diameter of 2mm achieved the greatest primary stability followed by the Dual Top MSI with a smaller diameter of 1.6mm.

Pitch of MSI

Brinley, Behrents, Kim, Condoor, Kyung and Buschang et al (2009)[24]tested the hypotheses that pitch and fluting have no effect on the primary stability of miniscrew implants (MSIs). MSIs with 0.75mm pitch provided greater primary stability than was provided by 1.0mm pitch MSIs. Pullout strength significantly increases as pitch decreases from 1.0mm to 0.75mm. No significant difference in placement torque or pullout strength has been noted between MSIs with a 1.0mm and a 1.25mm pitch. MSIs with flutes have significantly higher placement torque and pullout strength than MSIs without flutes. A positive correlation between placement torque and pullout strength has been noted.

Abu hussein et al (2010)[1] stated that pitch of the MSI is inversely related to the number of threads in the unit area. When the threads are spaced far apart, the MSI's have a high pitch; conversely, when the threads are spaced close together, the MSI's have a low pitch

Ashish Handa et al (2011)[7] aimed to study the impact of thread pitch of orthodontic mini-implant on the maximum effective stress in the surrounding jaw bone, using the three dimensional finite element method. There is a tendency of the maximum stresses to decrease as the pitch of the screw decreases and vice versa. Stress increased with increasing screw pitch but there was no significant influence of thread pitch on the pattern of stress distribution.

According to **Santos et al (2014)**[99]as the number of MSI's thread increases the pitch value is reduced and this results in increased insertion torque.

Cunha AC, Freitas AOA, Marquezan M, Nojima LI (2015)[28]evaluated the effect of pitch distance on the primary stability (PS) of orthodontic mini-implants (MIs) in artificial bone. Thread depth and pitch have been associated with the possibility of enhancing the cutting efficiency of the mini-implant, by providing a lower insertion torque. The mini-implants with a shorter pitch distance and an insertion angle of 30° presented better primary stability in artificial bone of greater density. The mini-implants with a longer pitch distance and an insertion angle of 45° were found to be more stable in artificial bone of lower density.

Depth of MSI

M Migliorati et al (2012)[71] in his in vitro experimental study with 30 different MSI's evaluated geometrical design characteristics and their relationship between mechanical properties of MSI's. The authors concluded that the bigger the depth of the thread of MSI, bigger was the insertion torque.

Walter et al (2013)[108]in his in vitro study investigated the effects of MSI design characteristics on the mechanical properties in artificial bone. As the depth of MSI increases the core diameter decreases and MSI are more prone to fracture.

Marigo et al (2016)[70]analysed the design and surface of two brands of MSI before and after 12 to 18 months of clinical use. He stated that as the depth of the thread increases the insertion thread into bone increases which increases the primary stability of MSI's.

Abdelgader et al (2016)[52] in his FEM study investigated the effect on thread design on primary stability of MSI. According to him, the deeper the thread, the more intraosseous surface area of MSI. When the threads are deep, MSI's are more stable as they offer more resistance to displacement.

Cunha AC et al (2017)[29] in his in vitro study evaluated primary stability of MSI's of different geometrical designs. His study was carried out in two stages. First evaluation of geometric design characteristics using SEM.

Second insertion torque measurement to evaluate primary stability. His result suggests that MSI with higher thread depths show less mobility. MSI with higher thread depth showed greater insertion torque.

Taper of MSI

Motoyashi et al (2006)[82] in his in vivo study to determine adequate insertion torque for better success of MSI's demonstrated that taper shaped MSI's can be loaded immediately. This may be due to rigid mechanical contact between the MSI and the bone.

Song Cha, Hwang et al (2007)[105] in his in vitro study evaluated the effect of MSI design on insertion torque and removal torque. He concluded that a tapered form MSI especially with increasing outer diameter is the design that increases the torque the most.

Lim et al (2008)[103] determined the variation in the insertion torque of MSI's according to length, diameter and shape in his in vitro study. He concluded that insertion torque was increased mainly in taper type MSI's.

Kim et al (2008)[55] in his study on beagle dogs investigated the mechanical and histological properties of conical and cylindrical shaped MSI's in terms of success rate. He concluded that conical shaped MSI had tight contact to adjacent bone tissue that resulted in good primary stability. It also showed high insertion torque which could affect adjacent tissue healing.

Chang et al (2012)[54] in his finite element study (FEM) study investigated the influence of various MSI's design factors affecting the mechanical properties of MSI's. He showed that increasing the core diameter of uppermost threads of MSI's to create tapered core design could reduce stress concentration effects at the neck while improving pull out resistance. Improvement in mechanical properties from a tapered core occur only when there is sufficient cortical bone thickness.

Lead angle of MSI

Kithara et al (2013)[61] in his study evaluated morphologically active tip of six different self drilling MSI’s. Images of the active tips of the mini-implants were obtained with a Zeiss optical microscope, Stemi 200-C with magnification of 1.6X. The images of the surface were viewed with the Axio Vision program (Zeiss, Jena, Germany) to calculate linear and angular measures. Mini-implant morphology and the details of tips and threads were also evaluated through Scanning Electronic Microscopy (SEM). He concluded that reduced angles could complicate insertion of the MSI leading to high values of insertion torque , increasing the risk of fracture.

Katie et al (2014)[57] in his in vitro study determined the unique contribution of geometrical design characteristics of orthodontic MSI's on insertion torque while controlling the influence of cortical bone thickness. A total number of 100 cylindrical MSI's was used. He concluded that insertion torque are best controlled by choosing an MSI diameter and lead angle according to the assessed cortical bone thickness. Higher lead angle improves cutting efficiency during implantation.

Cunha AC et al (2017)[29] in his in vitro study evaluated primary stability of MSI's of different geometrical designs. His study was carried out in two stages. First evaluation of geometric design characteristics using SEM. Second insertion torque measurement to evaluate primary stability. He concluded that lower thread angles should be considered when a higher insertion torque is necessary.

Thread type

Obaidi et al (2016)[50] in his study evaluated the insertion torque for drill and non drill techniques. He showed many causes make Dentos MSI's give low insertion torque and it may include knife edge of thread pattern, best pitch and self drilling shape of tip of MSI's.

Surface area of MSI

Steigenga et al (2003)[53] showed that the shape of the implant determines the surface area available for stress transfer and governs the initial stability of the implant. A change in implant diameter and thread design could increase surface area by more than 300%. Such increases in surface area could decrease stresses to the crestal bone regions and reduce both crestal bone loss and early loading implant failure. In areas with poorer bone quality and density (notably the posterior maxillary areas), emphasis should be given to maximizing implant surface area contact with available bone.

Nelson et al (2014)[17] in his study showed that the thread geometry of the conical MSI increases the implant surface area in contact with the host tissue. The lessening of pitch of the conical MSI thread enhance its contact area as compared to the cylindrical MSI. As surface area increases, the friction surface between the MSI and the site wall increases, demanding a larger insertion torque. It is expected that the increased surface area of the MSI, enhance the number of sites to bind to cells, helps in tissue growth and improve the mechanical stability.

Testing primary stability

The various methods available to test implant stability can be divided into invasive and non-invasive methods. The non invasive methods include percussion testing, radiographic methods, resonance frequency analysis and placement torque **Meredith et al (1998)**[76].

One invasive method used to evaluate primary stability measures cutting torque resistance. This technique measures the energy needed to remove bone prior to implant placement. **Friberg et al (1999)**[37] showed a positive correlation between cutting torque resistance and bone density, which is one of the factors that determines stability. The limitation of this method of measurement is that repeated measures cannot be made; it is only useful to estimate the implant stability prior to placement. It is used most frequently for prosthetic dental implants where the larger size of the implant necessitates the removal of bone prior to placement. Bone removal prior to placement of orthodontic mini-screw implants is often not needed due to their small size.

This factor also limits the importance of this method for orthodontic applications.

As such, tests are typically performed during or immediately after implant insertion **Huja et al (2005)**[49]. In situations where non-viable tissues are being tested, primary stability can be measured at any time. For the analysis of primary stability, insertion torque is perhaps the best and most commonly used method.

Insertion torque of Miniscrew Implant

Bowman et al (2008)[12] reported that the force used to insert the MSI is transferred through the screw and produces a compressive force on the adjacent bone. A minimal level of insertion torque is required to achieve an adequate amount of stability. However, too much torque during placement may cause damage to the adjacent bone and eventually result in screw failure.

Insertion torque is an objective method of measuring implant stability that was originally introduced by **Hughes and Jordan et al (1972)**[47]**.** This is probably the most often used method to evaluate primary stability. It describes the rotational force required to insert a screw into bone **Collinge et al (2000)**[26]**.**

O'Sullivan et al (2004)[84] reported that insertion torque values differ according to MSI type and higher values of insertion torque show higher interfacial stiffness at the MSI-bone interface. Placement torque correlates directly with cortical bone thickness. Other aspects influencing IT are the bone quality and quantity, the drilling hole, MSI characteristics and insertion technique, continuous or intermittent rotation and dry or wet conditions.

Insertion torque is said to determine primary stability **Deguchi et al (2006)[32], Wilmes et al (2008)[116].** And as known, a sufficient primary stability measured by insertion torque seems to play a major role for the treatment time survival rate **Motoyoshi et al (2009)[80].** This is also proven in dental implantology. Insertion torque levels must range between certain limits, since very low or very high values can be critical for MSI success.

Motoyoshi et al (2006)[82]reported higher loss rates when the insertion torque exceeds 10Ncm for MSIs with a diameter of 1.6mm. A torque value of more than 15Ncm recorded at the time of insertion appears to be one of the critical variables for MSI survival under immediate loading according to **Chaddad et al (2008)[19].** The high torque values may result in higher failure rates due to bone compression, local ischemia, necrosis and micro damages **Wawrzinek et al (2008)[110].**

Thickness of cortical bone

Ansell et al (1968)[6]reported retention depends on the bone-to-screw contact, better bone quantity should result in better primary stability.

Dalstra et al (2004)[30]showed that the maximum stress occurs at the cortical bone level when an implant is loaded. Using a finite element model, they showed that increasing cortical bone thickness drastically reduced the peak strain development in the peri-implant bone tissue. This inverse correlation amid cortical bone thickness and peak strain development suggests that cortical bone thickness is a key determinant of preliminary stability.

Huja et al (2005)[48]performed pull-out tests by placing 56 MSIs in the maxilla's and mandibles of beagle dogs. They found a positive correlation between cortical bone thickness and the maximum force at pull-out (Fmax). Fmax was reported to be 134.5 N in the anterior mandible and 388.3 N in the posterior regions of the mandible. They also showed that the posterior regions of the jaws had thicker cortical plates and greater pull-out values. In another study, **Huja et al (2006)**[49]**,** found peak pull-out strength to be directly related with cortical bone thickness at 6 weeks post-insertion in a canine model.

Motoyoshi et al (2006)[82]recommend that the prepared site should have a cortical bone that is more than 1.0 mm thick. They stated that individuals with greater MSI success had significantly higher cortical bone thickness. Cortical bone thickness and insertion torque were significantly greater in the mandible than in the maxilla.

Salmoria et al (2008)[102]in his study reported that cortical thickness is one of the main factors influencing insertion torque and, consequently, primary stability and failure rate. More screw threads are able to engage into thicker cortical bone which, in turn, translates into greater primary stability.

Failure rates and understanding MSI failure

Loss of miniscrew stability limits their usefulness. The ultimate cause of implant failure is a lack of bone to implant contact. A number of factors have been suggested as possible reasons for implant loss. Peri-implantitis when inserted in the unattached mucosa, **Cheng et al (2004)**[20] application of excessive forces on the miniscrew implant, **Buchter et al (2005)**[15] insufficient primary stability, **Motoyoshi et al (2006)**[82] bone damage during insertion due to compression or over-heating, **Wilmes et al (2006)**[113] and excessively large lever arms (thick mucosa), **Wiechmann et al (2007)**[111], are just some of the implicated factors.

Miyawaki et al (2003)[79]suggested that factors associated with failure were the implant's diameter, inflammation of the peri-implant tissue and the mandibular plane angle. They found that screws with 1.0mm diameters had success rates of 0%, but screws with 1.5mm and 2.3mm diameters had success rates of 83.9% and 85%, respectively. They also showed that patients with high mandibular plane angles tended to have thinner buccal cortical bone

and may lack sufficient mechanical interdigitation. Inflammation can increase the risk of miniscrew failure due to bone damage around the neck of the MSI. Over time, inflammation may lead to progressive loss of bone. This could cause the screw to lose its mechanical grip and fail. Park et al. attributed the greater success of miniscrews placed on the left than the right side to the fact that the majority of the patients were right-handed and might be expected to have better hygiene on the left side. Better hygiene results in less inflammation and possibly promotes greater success of miniscrew stability. It, thus, becomes imperative to gain an understanding of the MSI stability and the factors determining it.

Materials and Methods

MATERIALS AND METHODS

The present *in vitro* study was carried out in the Department of Orthodontics and Dentofacial Orthopaedics, Ragas Dental College and Hospital, Chennai.

Miniscrew Implants

A total of 60 titanium miniscrew implants (MSI's) were used in this study, consisting of 30 MSI's each from two different manufacturers: Dentos, Korea **(Fig 1)** and SK Surgicals, India **(Fig 2)**. Ten MSI's from each manufacturer were further grouped into small, medium and large according to their diameters as 1.3mm, 1.5mm and 1.8mm respectively. Out of ten MSI's from each diameter five MSI's were inserted into 1mm cortical bone thickness and another five MSI's into 2mm cortical bone thickness. All the MSI's were tapered, self-drilling and had a standard length of 8mm.

Miniscrew implants, stratified into three groups by diameter, length, type and manufacture are shown in**Table 1.**

This study was carried out in two stages: firstly by a detailed study of the geometric design characteristics of the two as-received miniscrew implants commonly used (Dentos, Korea and SK Surgical, India) and secondly by evaluating the effect of each geometric design characteristics of MSI's on insertion torque for determining the primary stability by inserting MSI's into synthetic sawbones.

EVALUATION OF MINISCREW IMPLANT GEOMETRIC DESIGN USING SCANNING ELECTRON MICROSCOPY (SEM)

MSI's from both the manufacturers were subjected to scanning electron microscope (SEM) analysis Zeiss Supra 55VP **(Fig 3**). SEM evaluation was done with the MSI's fixed in the same orientation and mounted on aluminium sample holders with the use of double-adhesive carbon tape. SEM was performed at 20 kV acceleration voltage. Digital images were acquired by SEM**.**

Evaluation of geometrical characteristics of MSIs

Digital images at 10x and 15x magnifications were taken in order to obtain the measurable images of all the MSI's. Precise measurement of all MSI geometric design parameters were done using Image J software (NIH, Bethesda, Md)[25]. The parameters measured were pitch, depth, lead angle, taper, number of threads and thread type of all the MSI's **(Fig 4)**. Lead angle was measured in degree. The pitch and depth of the MSI thread were obtained in millimetres.

Surface area of the entire length of threaded portion of the miniscrew implant (excluding the MSI head) was calculated with the equation 1 and 2.[34]

$$\Gamma_3 = \Gamma_b + 2\pi \frac{(L_T - l_{tip})}{\rho}\left[(r_D + r_K)\sqrt{(r_D - r_K)^2 + t_w^2/4} - r_K t_w\right]\frac{\sqrt{(2\pi r_D)^2 + \rho^2}}{2\pi r_D}$$

(Equation 1)

$$\Gamma_b = \pi r_K \sqrt{r_K^2 + l_{tip}^2} + 2\pi r_K (L_T - l_{tip})$$

(Equation 2)

l_{tip} - distance from tip of fastener to intersection of conical core section

L_T- distance from tip of fastener to end of threaded fastener section

r_K-root radius of fastener

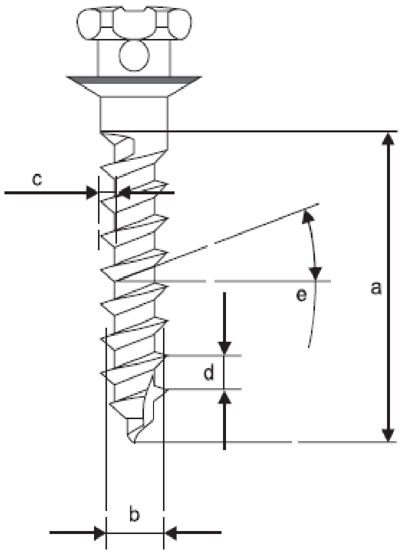
r_D-crest radius of fastener

t_w-thread width at root diameter

ρ -distance between thread crests

Γ -surface area

Geometrical design characteristics



a- Length

b- Diameter

c- Depth

d- Pitch

e- Lead angle

EVALUATION OF MINISCREW IMPLANT INSERTION TORQUE

Synthetic Bone Model

In this study, artificial bone blocks (Sawbones®, A Division of Pacific Research Laboratories Inc, Vashon, Wash, USA) was selected because it met the requirements of the American Society for Testing and Materials (F-1839-08)[58,66]and has been successfully used for biomechanical tests of MSI's **(Fig5)**. The bone block consisted of two layers that simulated cortical and cancellous bones. The fibre-filled epoxy sheets and solid rigid polyurethane foam block were used as alternate experimental materials for cortical and cancellous bones respectively. The artificial bone block had a cortical bone thickness of 1mm and 2mm **(Fig 6)**. The bone block measured 170mm in length, 120mm in width and 40mm in height. The high upper layer simulated the cortical bone and had a density of 0.80 g/cc (50 per cubic feet). The lower layer simulated the cancellous bone and had a density of 0.48 g/cc (30 per cubic feet). The artificial bone block was sectioned into four smaller sized rectangular blocks of 170 X 40 X 15mm dimensions each, for ease of placement and testing in the custom-made apparatus. A graph sheet was stuck over the cortical surface of each bone block. Using the graph sheet, the bone blocks were divided into three different columns for the three different diameters of MSI's used.

(Table 2, 3)

Custom-made Aluminium Apparatus for measuring Maximum Insertion Torque (MIT)

A custom-made aluminium apparatus **(Fig 7)** consisting of a clamp which stabilized the bone blocks and a guide which allowed the placement of the digital torque driver to measure the maximum insertion torque of MSI's were used in this study. This custom-made device design was based on the study done by **Pithon et al** (2013)[94].

Digital Torque Meter

Lutron TQ-8800 digital torque meter (Taiwan) **(Fig 8)** was used in this study to evaluate the insertion torque (MIT) of miniscrew implants. The torque meter driver guide allowed forward and backward movement of the digital torque driver in horizontal direction, which prevented wobbling or oblique forces during using MSIs. The digital torque driver consisted of a torque sensor which minimizes reading error.

Evaluation of Maximum Insertion Torque of MSIs

Each sectioned rectangular bone block was placed in the slider and secured with the clamps of the custom-made aluminium apparatus. **(Fig 9)** The head of a miniscrew implant was securely held with the help of an inbuilt chuck in the torque driver. This helped to stabilize the MSI's perpendicular to the cortical bone surface and to insert MSI at a predetermined point on the graph. The MSI's were inserted into the bone block using finger pressure in a clockwise rotational axis without predrilling pilot hole. **(Fig 10)** The maximum insertion torque of all the MSIs were recorded in Newton centimetres (Ncm) using the digital torque meter.

STATISTICAL ANALYSIS:

Data entry and statistical analysis was performed with using the SPSSv.19 software (SPSS Inc., Chicago, Illinois, USA). Descriptive statistics and statistical analysis, including calculation of the mean and standard deviation were performed for two different MSI's to evaluate the effects of individual geometric design characteristics such as the lead angle, pitch, depth, taper, surface area, number of threads, diameter and length influencing the insertion torque. Using insertion torque as the outcome, Pearson Correlation coefficient was done to measure the strength of the association between geometric design parameters of MSIs and cortical bone thickness. A multiple linear regression model was used to determine the unique contribution of individual geometric design characteristics of MSI's for prediction of insertion torque while controlling cortical bone thickness.

Tables & Figures

Table 1. Description of miniscrew implants used in this study.

Diameter (mm)	Length (mm)	Type	Manufacturer
1.3(small)	8	Taper Self drilling	Dentos, Daegu, Korea SK Surgicals, Pune, India
1.5(medium)	8	Taper Self drilling	Dentos, Daegu, Korea SK Surgicals, Pune, India
1.8(large)	8	Taper Self drilling	Dentos, Daegu, Korea SK Surgicals, Pune, India

Table 2. Mechanical properties of synthetic bone block.(cancellous area)

Density		Compressive		Tensile		Shear	
		Strength	Modulus	Strength	Modulus	Strength	Modulus
Pcf*	g/cc	Mpa	Mpa	Mpa	Mpa	Mpa	Mpa
30	0.5	18	445	12	592	7.6	87

***Pcf-per cubic foot**

Table 3. Mechanical properties of epoxy sheet (cortical area)

Density		Compressive		Tensile		
		Strength	Modulus	Strength	modulus	strain
Pcf	g/cm^3	Mpa	Gpa	Mpa	Gpa	%
102	1.64	157	16.7	106	16.0	0.80

Fig 1. Miniscrew implants of varying diameters (Dentos, Korea).
A. 1.3x8mm (small sized MSI), B. 1.5x8mm (medium sized MSI),
C. 1.8x8mm (large sized MSI).

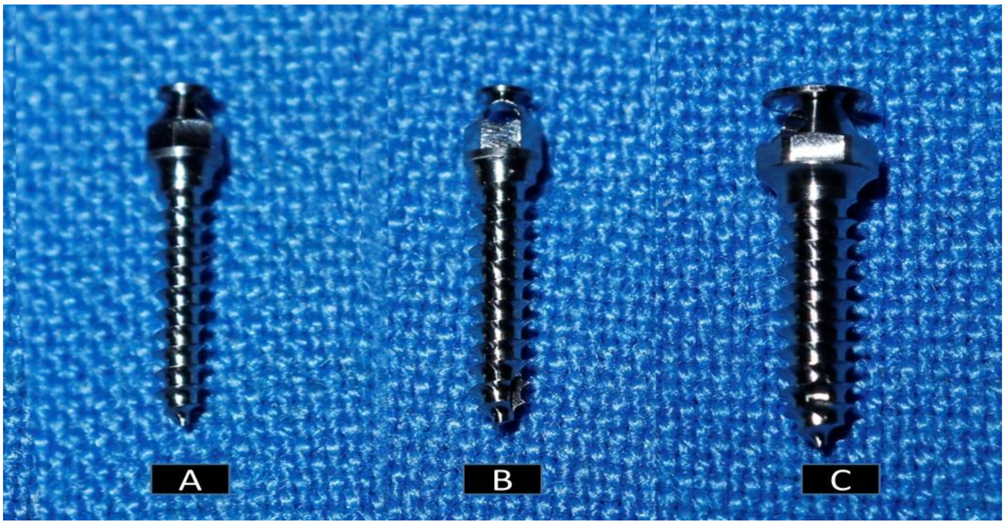


Fig 2. Miniscrew implant of varying diameters (SK Surgicals, India).
A.1.3x8 mm (small sized MSI), B. 1.5x8mm (medium sized MSI),
C. 1.8x8mm (large sized MSI).

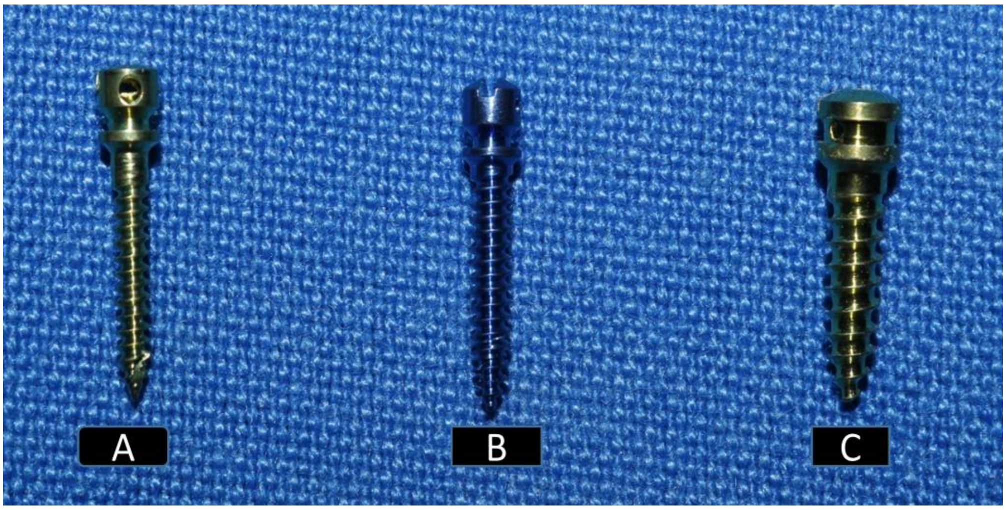


Fig 3. Scanning Electron Microscope (Zeiss Supra 55VP) for scanning all miniscrew implants.

Fig 4. SEM image of as-received MSI's (10x) for evaluating geometric design parameters with Image J software.

1.8x8 mm (large size MSI)

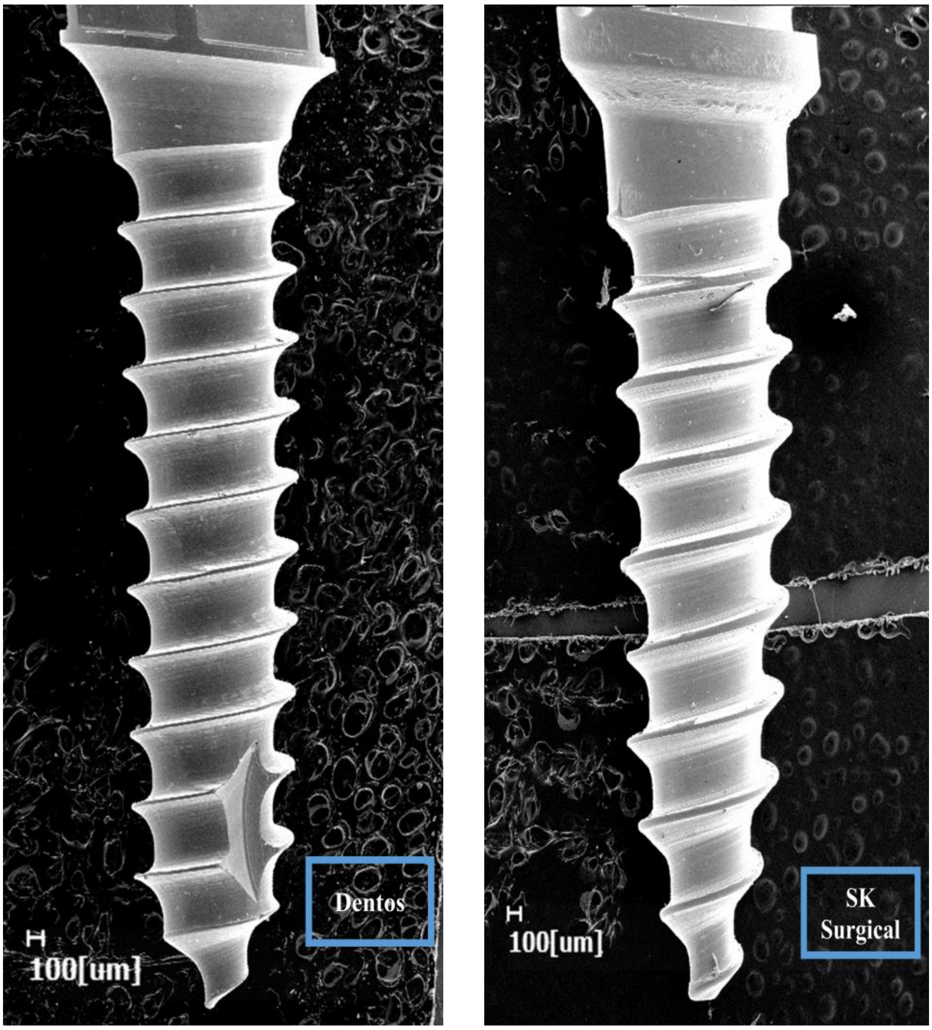


Fig 4 continued

1.5x8mm (medium size MSI)

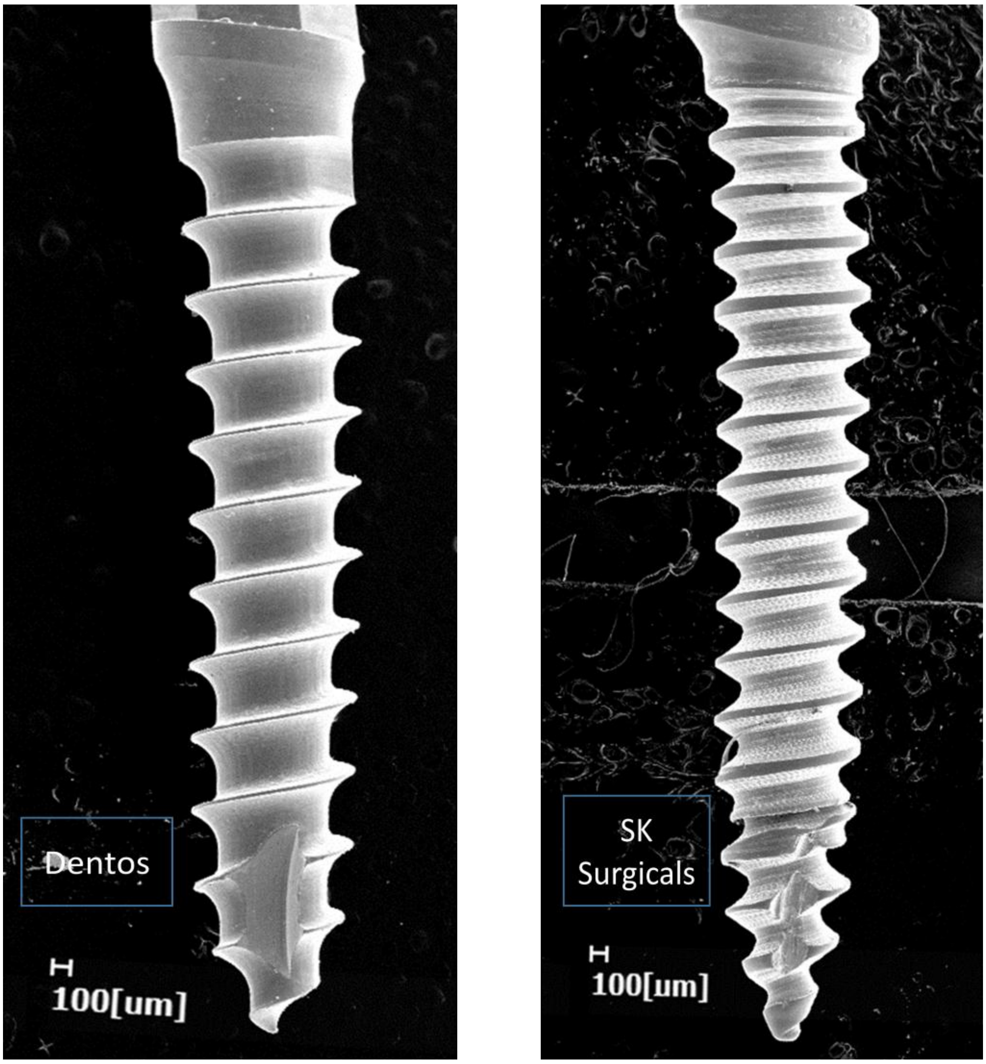


Fig 4 continued

1.3x8mm (small size MSI)

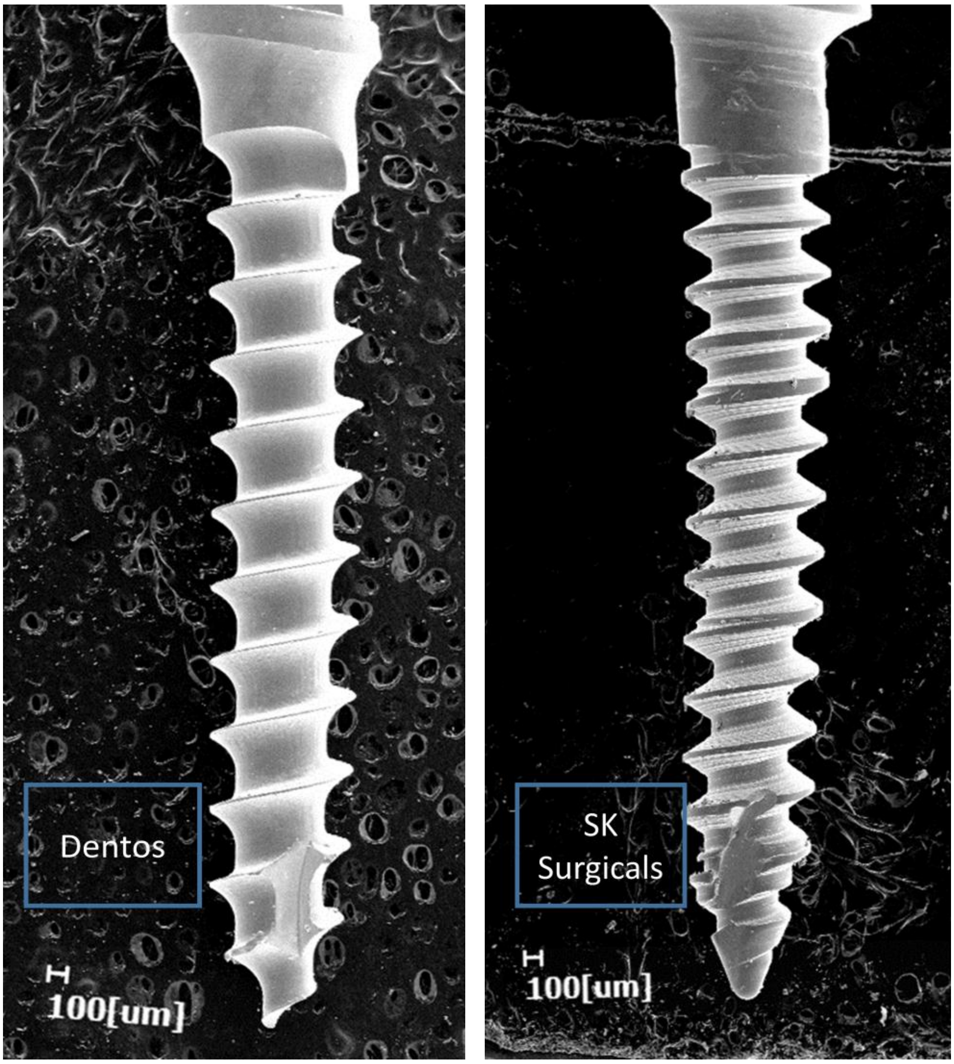


Fig 5. Artificial bone block (Sawbones® A Division of Pacific Research Laboratories Inc, Vashon, Wash, USA) with fiber filled epoxy sheets and solid rigid polyurethane foam with bone density of 30 pcf.

Fig 6. Sectioned Bone block with 1mm and 2mm fiber filled epoxy sheets cut into rectangular blocks of dimensions 170 X 40 X 15 mm.

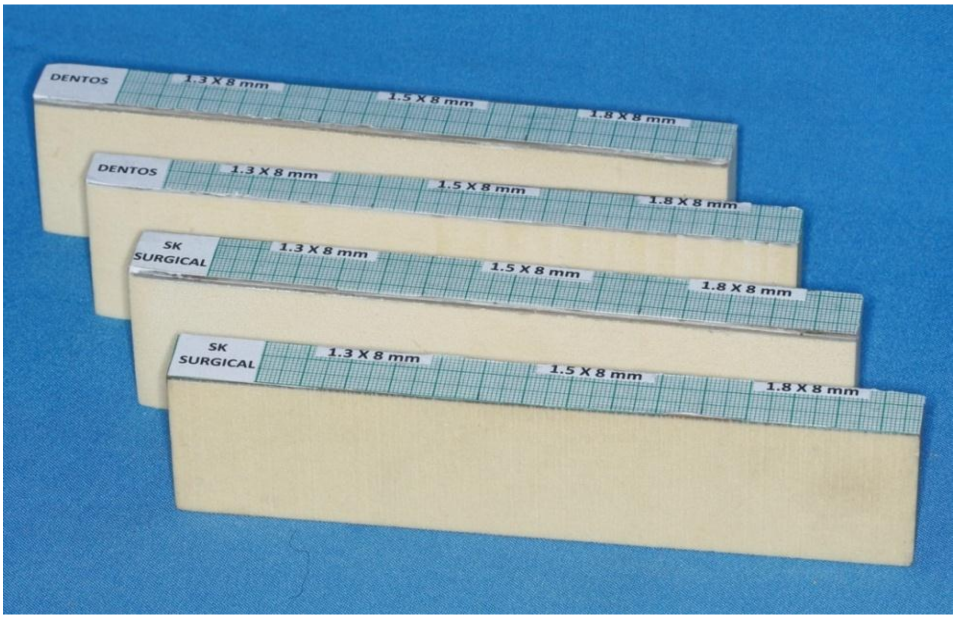
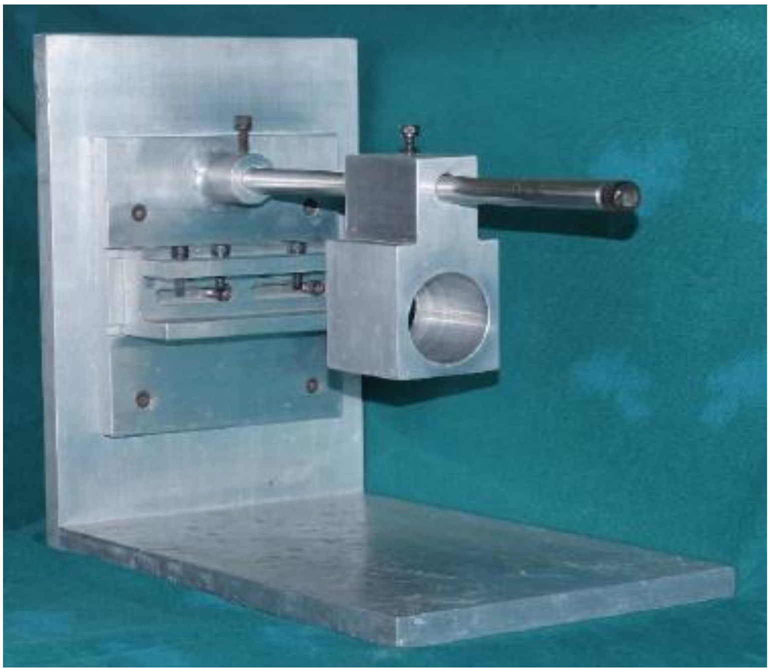


Fig 7. Custom-made Aluminium apparatus to receive the bone block and to guide the torque driver.



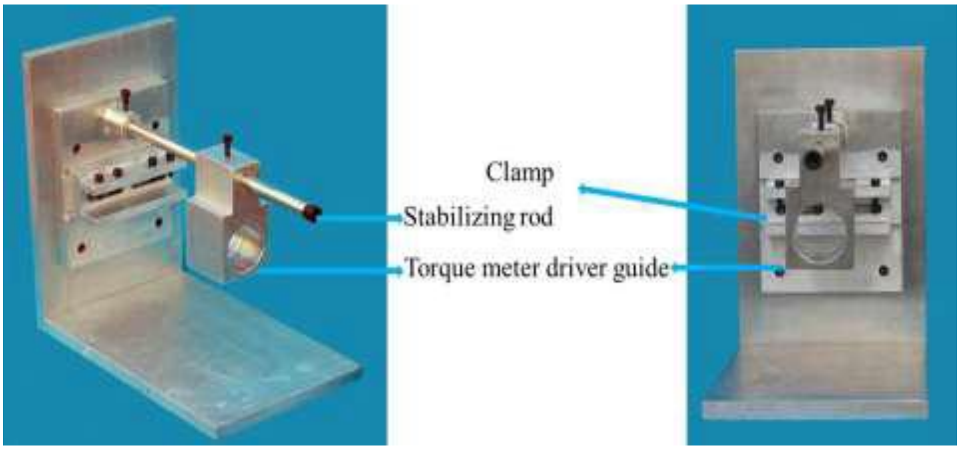
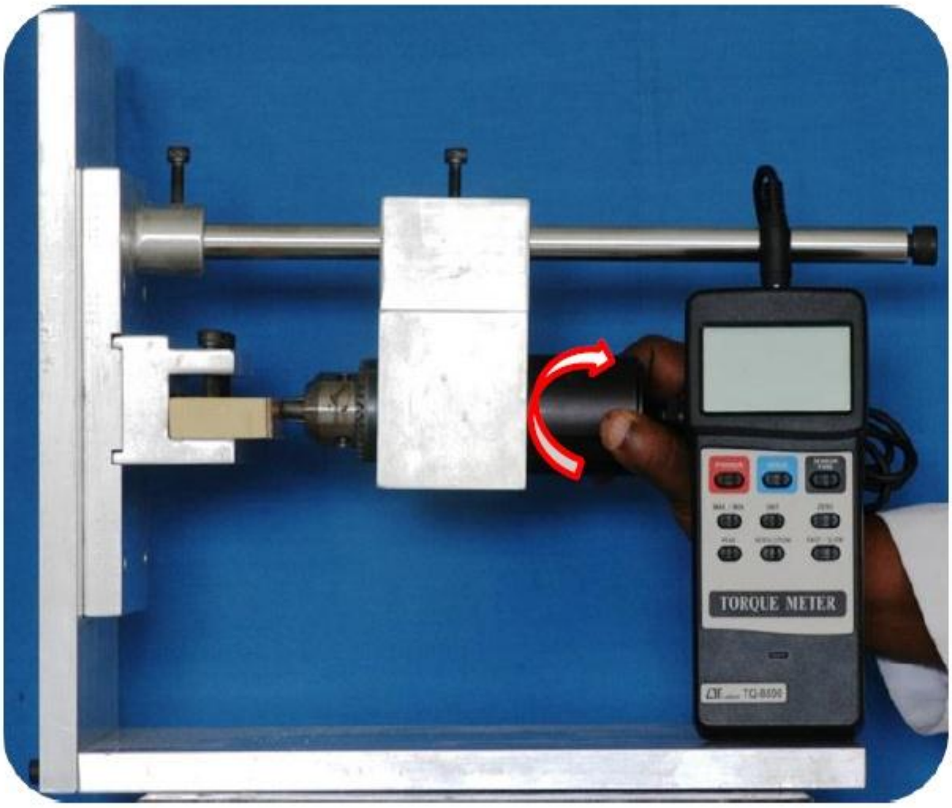


Fig 8. Lutron TQ 8800 digital torque meter (Taiwan) with torque driver to measure insertion torque.

Fig 9. Aluminium apparatus with torque meter driver guide containing torque driver with MSI. Slider clamp containing bone block for insertion of MSI to quantify insertion torque.

Fig10. MSI's inserted into the bone blocks using finger pressure in a clockwise rotational axis.



Results

RESULTS

This in vitro study was done to evaluate the geometric design of two commercially available self-drilling miniscrew implants using scanning electron microscopy (SEM, Zeiss Supra 55VP). SEM images of MSI's were used to evaluate the individual geometric design parameter such as pitch, depth, taper, lead angle, number of threads using the image J software (NIH, Bethesda, Md). Surface area of the MSI's were calculated using a mathematical formula. After evaluating the individual geometric design of all the as received MSI's of varying diameters, they were inserted into the synthetic bone block to evaluate the insertion torque using Lutron TQ-8800 digital torque meter (Taiwan) with established test procedures.

DESCRIPTIVE STATISTICS

Evaluation Of Geometric Design Parameters

Geometrical design parameters of all the miniscrew implants (Dentos MSI's, SK Surgical MSI's) were assessed using the scanning electron microscopy and are shown in (**Table 4 and 5).**

Small diameter MSI (1.3x8mm)

Among the smaller diameter of two different MSI's tested for geometrical design parameters, Dentos MSI's had higher lead angle of $9.48^{\circ} \pm 0.15^{\circ}$ when compared with SK Surgical MSI's lead angle of $6.42^{\circ} \pm 0.32^{\circ}$.

Dentos MSI's showed highest pitch value of 0.53 ± 0.04 mm when compared with SK Surgical MSI's pitch of 0.42 ± 0.03mm.

Whereas SK Surgical MSI's had highest depth value of 0.19 ± 0.01 mm when compared with Dentos MSI's having a depth of 0.17 ± 0.01mm. The SK Surgical MSI's had highest taper value of 0.03 ± 0.01 when compared with Dentos MSI's taper of 0.01 ± 0.01. The Dentos MSI's showed highest surface area of 39.73 ± 0mm^2 using mathematical formula when compared with SK Surgical MSI's surface area of 34.23 ± 0mm^2. The number of threads were more in SK Surgical MSI's (14 threads) when compared with Dentos MSI's (11 threads) of the same diameter.

Medium diameter MSI (1.5x8mm)

Among the medium diameter of two different MSI's tested for geometrical design parameters, Dentos MSI's had higher lead angle of 10.14° ± 0.08° when compared with SK Surgical MSI's lead angle of 7.34° ± 0.11°. Dentos MSI's had highest pitch value of 0.63 ± 0.02mm when compared with SK Surgical MSI's of 0.51 ± 0.02mm.

Whereas, SK Surgical MSI's had highest depth value of 0.20 ± 0.01 mm when compared with Dentos MSI's depth of 0.18 ± 0.01mm. The SK Surgical MSI's had highest taper value of 0.08 ± 0.0 when compared with Dentos MSI's taper of 0.04 ± 0.01. The Dentos MSI's showed highest surface area of 48.27 ± 0mm^2 using mathematical formula followed by SK Surgical MSI's surface area of 41.05 ± 0mm^2. The number of threads were more in SK

Surgical MSI's (14 threads) when compared with Dentos MSI's (11 threads) of the same diameter.

Large diameter MSI (1.8x8mm)

Among the larger diameter of two different MSI's tested for geometrical design parameters, Dentos MSI's showed higher lead angle of $10.65^{\circ} \pm 0.04^{\circ}$ when compared with SK Surgical MSI's having a lead angle of $9.97^{\circ} \pm 0.13^{\circ}$. SK Surgical MSI's showed highest pitch value of 0.73 ± 0.02 mm when compared with Dentos MSI's of 0.65 ± 0.03mm.

Whereas, SK Surgical MSI's had same depth value of 0.19 ± 0.01mm when compared with Dentos MSI's depth of 0.19 ± 0.01mm. The SK Surgical MSI's showed highest taper value of 0.11 ± 0.01 when compared with Dentos MSI's taper of 0.05 ± 0.01. The Dentos MSI's showed highest surface area of $67.74 \pm 0mm^2$ using the mathematical formula followed by SK Surgical MSI's surface area of $45.71 \pm 0mm^2$. In contrast, the number of threads were more in Dentos MSI's (11 threads) when compared with SK Surgical MSI's (8 threads) of the same diameter.

Geometric design characteristics mean values for the total number of MSIs from the two manufacturers (Dentos, SK Surgical) (Table 6)

The descriptive statistics of geometric design characteristics of total number of MSIs from two manufacturers (Dentos , SK Surgical) are shown in **(Table 6).**

Among the three varying diameters of MSI's studied from the two manufacturers (Dentos, SK Surgicals), our results showed an increase in mean lead angle and mean pitch values with the increase in diameter.

Whereas MSI depth was similar for both the MSI's (Dentos, SK Surgical).

There was a gradual increase in MSI taper values when the diameter of MSI's increased from 1.3mm to 1.8mm among the two tested MSI's.

It was also observed in our study that there was an increase in surface area with the increase in diameter of MSI's and MSI's taper.

Evaluation Of Insertion Torque In Cortical Bone Thickness Of 1mm

The maximum insertion torque of varying diameters of MSI’s (1.3mm,1.5mm,1.8mm) in 1mm cortical bone thickness were evaluated and descriptive statistics are given in **(Table 7)**.

The mean maximum insertion torque of 1.3mm diameter Dentos MSI's was 12.52 ± 0.27 Ncm and SK Surgical MSI's was 13.64 ± 0.21Ncm.The mean maximum insertion torque of 1.5mm diameter Dentos MSI's was 15.30 ± 0.19Ncm and SK Surgical MSI's was 16.34 ± 0.21Ncm. The mean maximum insertion torque for 1.8mm diameter Dentos MSI's was 32.50 ± 0.41Ncm and SK Surgical MSI's was 30.74 ± 0.37Ncm.

There was consistent increase in insertion torque with increase in the diameter of miniscrew implant.

Evaluation of insertion torque in Cortical bone thickness of 2mm

The maximum insertion torque of varying diameters of MSI's (1.3mm,1.5mm,1.8mm) in 2mm cortical bone thickness were evaluated and descriptive statistics are given in **(Table 7)**.

The mean maximum insertion torque of 1.3mm diameter Dentos MSI's was 21.32 ± 0.29Ncm and SK Surgical MSI was 24.26 ± 0.31Ncm. The mean maximum insertion torque of 1.5mm diameter Dentos MSI's was 24.10 ± 0.34 Ncm and 30.32 ± 0.88Ncm for SK Surgical MSI. The mean maximum insertion torque of 1.8mm diameter Dentos MSI's was 41.36 ± 0.24Ncm and 39.64 ± 0.51Ncm for SK Surgical MSI's.

There was consistent increase in insertion torque with increase in the diameter of MSI and thickness of the cortical bone.

The results showed as the diameter of MSI's increased it resulted in increase in insertion torque which was statistically significant. The results of peak insertion torque values for MSI's inserted into different cortical bone thickness showed, with increase in the cortical bone thickness, there was a proportionate increase in the peak insertion torque values which was statistically significant.

Pearson's bivariate correlation coefficient

Using maximum insertion torque (MIT) as the outcome, Pearson's bivariate correlation coefficient was used to measure the strength of the association between geometric design parameters and cortical bone thickness.**(Table 8)**

In bivariate correlations, MIT was significantly positively correlated with the lead angle of the MSI thread (r = 0.428; p = 0.001), the pitch of the MSI thread (r = 0.581; p = 0.001), depth of the MSI thread (r = 0.381; p = 0.003), the taper of the MSI thread (r = 0.589; p = 0.000), number of threads of MSI (r =- 0.465; p = 0.000), surface area of MSI (r =- 0.621; p = 0.000), diameter of MSI (r = 0.763; p = 0.000) and cortical bone thickness (r = 0.529; p = 0.000), whereas it was not significantly correlated with the type of MSI used whether Dentos or SK Surgical (r = 0.069; p = 0.599).

Lead angle of MSI, pitch of MSI, depth of MSI, taper of MSI, number of threads of MSI, surface area of MSI, diameter of MSI and cortical bone thickness were statistically significant and had association with insertion torque.

In our study lead angle was more for all the Dentos MSI's than SK Surgical MSI's of varying diameters studied, so the cutting efficiency of Dentos MSI's was increased which reduced the insertion torque. Whereas, pitch values for 1.3x8mm and 1.5x8mm SK Surgical MSI's were less when compared with Dentos MSI's of same diameter which increased the insertion torque of SK Surgical MSI's when compared with Dentos MSI's. A decrease in pitch is thought to increase the screw purchase to increase the primary stability. The thread depth was slightly more for SK Surgical MSI's than

Dentos MSI's, which resulted in increased in insertion torque for SK Surgical MSI's.

When number of threads increased distance between threads reduced (pitch), which eventually lead to increase in insertion torque.

In our study SK Surgical MSI's of 1.3mm and 1.5mm diameter had 14 thread numbers when compared with Dentos MSI's of 1.3mm and 1.5mm diameter having 11 threads. In contrast 1.8mm Dentos MSI's had 11 thread numbers when compared with 1.8mm SK Surgical MSI's having 8 thread numbers. This can be the probable reason for increase in insertion torque in Dentos MSI in 1.8mm diameter.

The Dentos MSI's with diameter of 1.3mm, 1.5mm and 1.8mm showed more surface area as compared to SK Surgical MSI's having diameter of 1.3mm, 1.5mm and 1.8mm. Increase in surface area also lead to increase in the insertion torque. SK Surgical MSI's showed higher taper length value compared to Dentos MSI's, increasing taper length which improves the mechanical properties like insertion torque and pull out strength.

Multiple linear regression model

A multiple linear regression analysis was used to determine the unique contribution of individual geometrical design characteristics of miniscrew implants in predicting the maximum insertion torque while controlling cortical bone thickness. **(Table 9)**

The multiple linear regression model showed that significant predictors of higher MIT were for taper of MSI ($p=0.008$), number of threads of MSI ($p=0.000$), surface area of MSI threads ($p=0.000$) , type of MSI used whether Dentos or SK Surgical ($p=0.000$), cortical bone thickness ($p=0.000$)and MSI diameter ($p = 0.000$). Lead angle ($p = 0.004$), pitch ($p = 0.224$).and depth ($p=0.488$) were not statistically significant parameters for maximum insertion torque.

Though there was statistical significant correlation for pitch, depth and lead angle with primary stability, on multiple regression analysis for this particular study pitch, depth and lead angle of MSI showed no significance.

A multiple regression analysis was run to predict maximum insertion torque from lead angle, pitch, depth, taper, number of threads, surface area external diameter cortical bone thickness. There was linearity assessed by partial regression plots and a plot of studentized residuals against the predicted values. There was independence of residuals, as assessed by a Durbin- Watson statistic of 0.778.

There was homoscedasticity, as assessed by visual inspection of a plot of studentized residuals versus unstandardized predicted values. There was no evidence of multicollinearity, as assessed by tolerance values greater than 0.1. There was no studentized deleted residuals $\geq \pm 3$ standard deviations, no leverage Q plot. The multiple regression model statistically significantly predicted survival $F(9, 50) = 398.50$, $p < 0.0005$,adjusted $R^2 = 0.986$. All variables added statistically significantly to the prediction, $p \leq 0.05$.

Tables & Figures

Table 4. Geometric design characteristics of Dentos MSI's with varying diameters.

Mean± SD values

Type	Dimension (mm)	Lead angle (Degree)	Pitch (mm)	Depth (mm)	Taper	No. Of threads	Surface area (mm^2)
Dentos	1.3x8	9.48±0.15	0.53±0.04	0.17±0.01	0.01±0.01	11	39.73
	1.5x8	10.14±0.08	0.63±0.02	0.18±0.01	0.04±0.01	11	48.27
	1.8x8	10.65±0.04	0.65±0.03	0.19±0.01	0.05±0.01	11	67.74

Table 5. Geometric design characteristics of SK Surgical MSI's with varying diameters.

Mean± SD values

Type	Dimension (mm)	Lead angle (Degree)	Pitch (mm)	Depth (mm)	Taper	No. Of threads	Surface area (mm^2)
SK Surgicals	1.3x8	6.42±0.32	0.42±0.03	0.19±0.01	0.03±0.01	14	34.23
	1.5x8	7.34±0.11	0.51±0.02	0.20±0.01	0.08±0.01	14	41.05
	1.8x8	9.97±0.13	0.73±0.02	0.19±0.01	0.11±0.01	8	45.71

Table 6. Geometric design characteristics mean values for the all number of MSIs from the two manufacturers (Dentos, SK Surgicals)

Parameters	Dimension	N	Mean ±SD
Lead angle (degree)	1.3 x 8	20	7.95 ± 1.59
	1.5 x 8	20	8.76 ± 1.41
	1.8 x 8	20	10.30 ± 0.36
Pitch (mm)	1.3 x 8	20	0.48 ± 0.07
	1.5 x 8	20	0.57 ± 0.07
	1.8 x 8	20	0.69 ± 0.05
Depth (mm)	1.3 x 8	20	0.18 ± 0.01
	1.5 x 8	20	0.19 ± 0.01
	1.8 x 8	20	0.19 ± 0.01
Taper	1.3 x 8	20	0.02 ± 0.01
	1.5 x 8	20	0.06 ± 0.02
	1.8 x 8	20	0.08 ± 0.03
Number of threads	1.3 x 8	20	12.50 ± 1.53
	1.5 x 8	20	12.50 ± 1.53
	1.8 x 8	20	9.50 ± 1.53
Surface area (mm^2)	1.3 x 8	20	36.98 ± 2.82
	1.5 x 8	20	44.66 ± 3.70
	1.8 x 8	20	56.72 ± 11.30
Insertion torque (Ncm)*	1.3 x 8	20	17.93 ± 5.12
	1.5 x 8	20	21.51 ± 6.30
	1.8 x 8	20	36.06 ± 4.66

Ncm*- Newton centimeter

Table 7. Descriptive statistics of maximun insertion torque for varying diameters of miniscrew implants from 2 manufacturers (Dentos, SK Surgicals) in 1mm and 2mm cortical bone thickness.

Diameter	Type	Maximum insertion torque (Ncm)*	
		Cortical bone thickness 1mm	Cortical bone Thickness 2 mm
1.3 x 8 mm	Dentos	12.52 ± 0.27	21.32 ± 0.29
1.3x 8 mm	SK Surgicals	13.64 ± 0.21	24.26 ± 0.31
1.5x 8 mm	Dentos	15.30 ± 0.19	24.10 ± 0.34
1.5x 8 mm	SK Surgicals	16.34 ± 0.21	30.32 ± 0.88
1.8x 8 mm	Dentos	32.50 ± 0.41	41.36 ± 0.24
1.8x 8 mm	SK Surgicals	30.74 ± 0.37	39.64 ± 0.51

***Ncm- Newton Centimeter**

Table 8. Pearson Bivariate Correlation test between mean insertion torque and geometric design parameters for total number of MSIs from two manufacturers (Dentos, SK Surgicals)

Parameters	N	Insertion torque Pearson corelation (r)	Significance(p)
Lead angle	60	0.43	0.001
Pitch (mm)	60	0.58	0.000
Depth (mm)	60	0.38	0.003
Taper (mm)	60	0.59	0.000
No . of threads	60	-0.46	0.000
Surface area (mm^2)	60	0.62	0.000
Diameter(mm)	60	0.76	0.000
Manufacturer	60	0.07	0.60
Cortical bone thickness	60	0.529	0.000

P value < 0.05

Table 9. Multiple linear regression model for prediction of maximum insertion torque.

	Unstandardized coefficients		Standardized coefficients	95.0% confidence interval for B		correlations			Significance
	B	Std error	Beta	Lower bound	Upper bound	Zero	partial	part	
(Constant)	-51.67	17.07		-85.96	-17.38				0.004
Lead angle(degree)	1.24	1.01	0.20	-0.78	3.27	0.43	0.17	0.02	0.224
Pitch(mm)	-11.03	5.95	-0.12	-22.98	0.93	0.58	-0.25	-0.03	0.070
Depth(mm)	-15.55	22.26	-0.02	-60.24	29.15	0.38	-0.09	-0.01	0.488
Taper	59.56	21.72	0.21	15.93	103.20	0.59	0.36	0.04	0.008

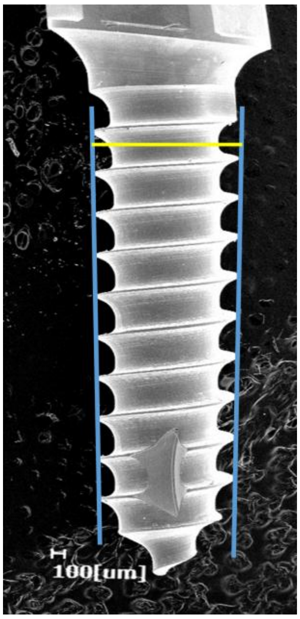
Table 9 continued

	Unstandardized coefficients		Standardized coefficients	95.0% confidence interval for B		correlations			Significance
	B	Std error	Beta	Lower bound	Upper bound	Zero	partial	part	
No . of theads	-1.9	0.34	-0.42	-2.60	-1.26	-0.46	-0.40	-0.05	0.003
Surface area (mm^2)	1.20	0.09	1.36	1.01	1.40	0.62	0.87	0.20	0.000
Company	19.32	2.93	1.02	13.43	25.20	0.07	0.68	0.11	0.000
Cortical bone thickness	9.10	0.31	0.53	9.36	10.62	0.53	0.98	0.53	0.000
Diameter	-3.904	0.939	-0.617	-5.790	-2.018	0.763	-0.507	-0.069	0.000

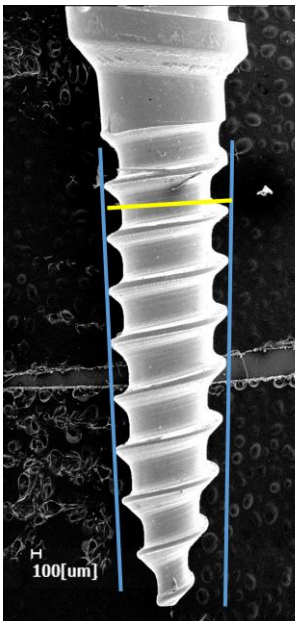
(P value < 0.05)

Fig 12. Parameters of MSI's measured.

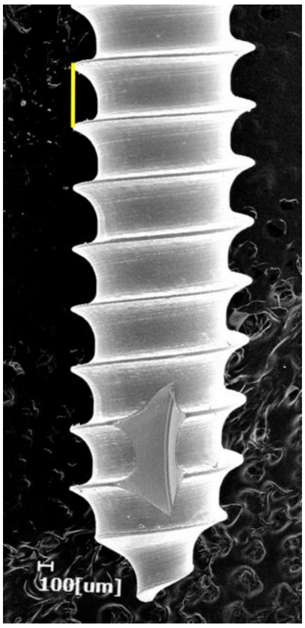
<u>1.8x8mm MSI's</u>
(Large size)



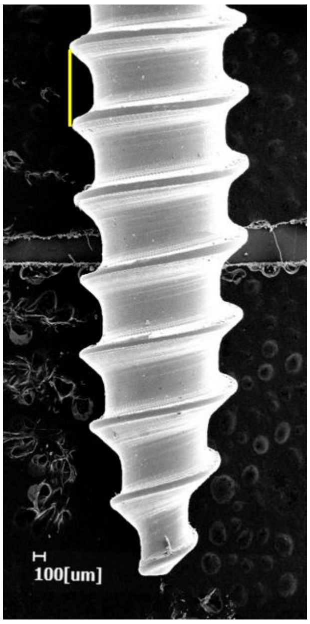
Diameter of Dentos MSI



Diameter of SK Surgical MSI

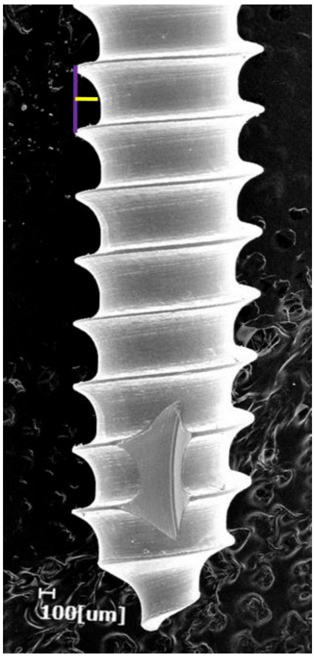


Pitch of Dentos MSI

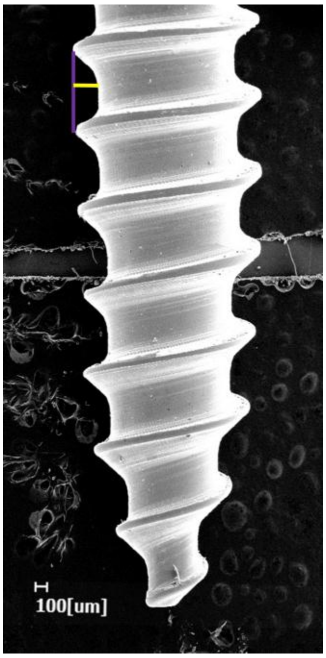


Pitch of SK Surgical MSI

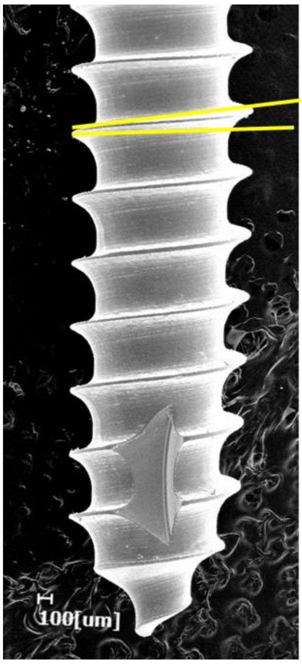
Fig 12 continued



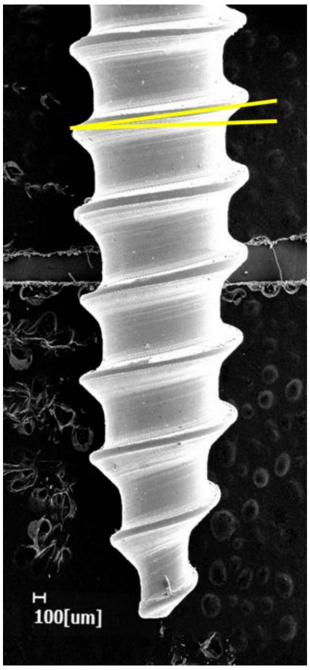
Depth of Dentos MSI



Depth of SK Surgical MSI

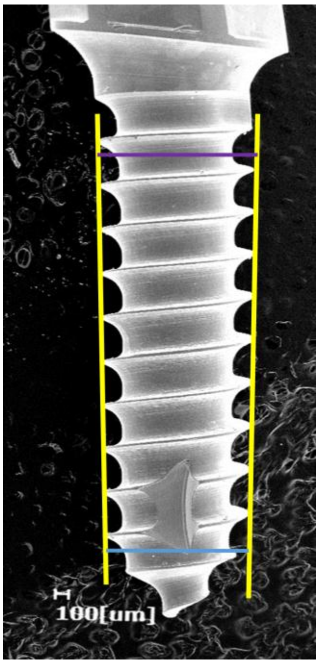


Lead angle of Dentos MSI

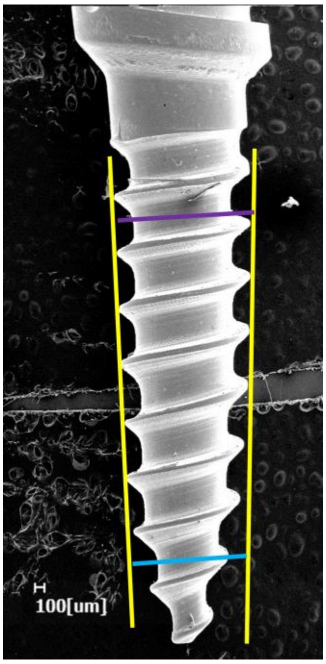


Lead angle of SK Surgical MSI

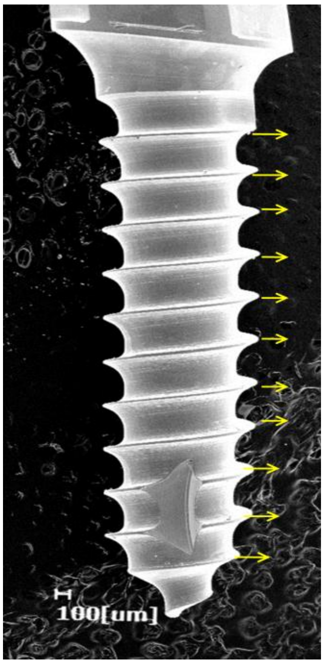
Fig 12 continued



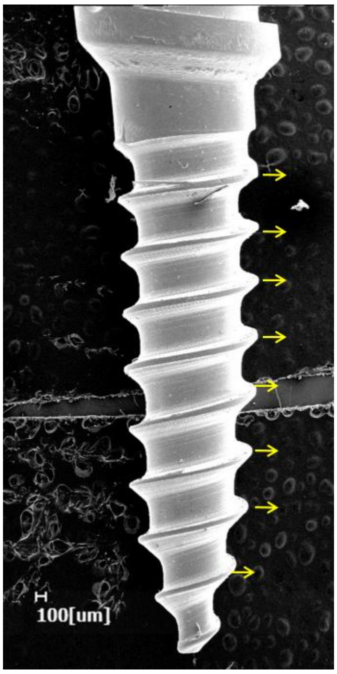
Taper of Dentos MSI



Taper of SK Surgical MSI



Number of threads of MSI

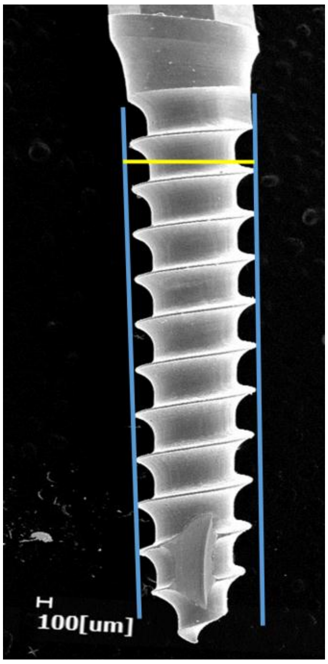


Number of threads of MSI

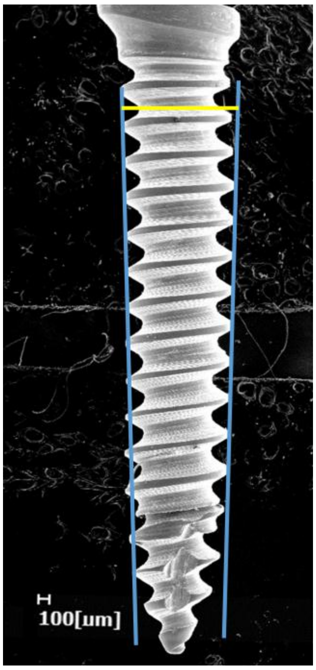
Fig 12 continued

<u>1.5x8mm MSI's</u>

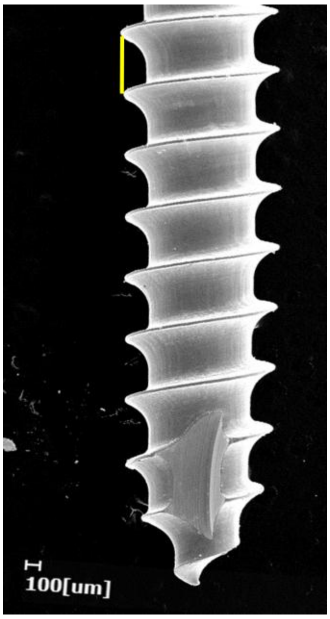
(Medium size)



Diameter of Dentos MSI



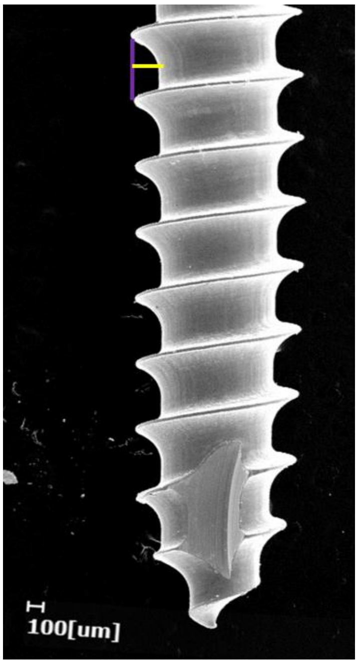
Diameter of SK Surgical MSI



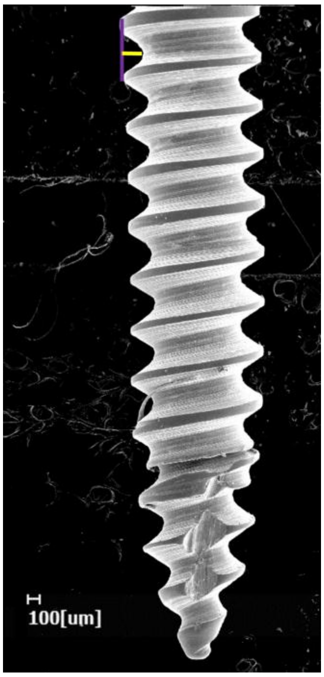
Pitch of Dentos MSI

Pitch of SK Surgical MSI

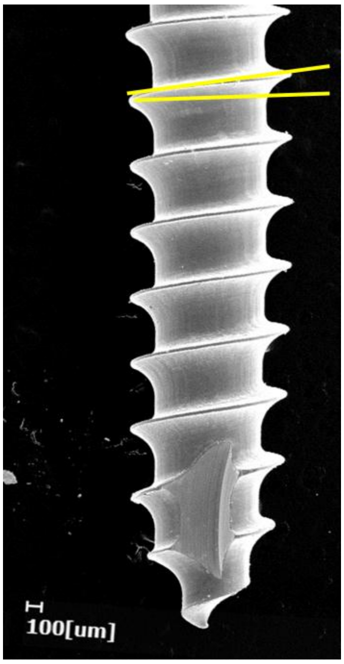
Fig 12 continued



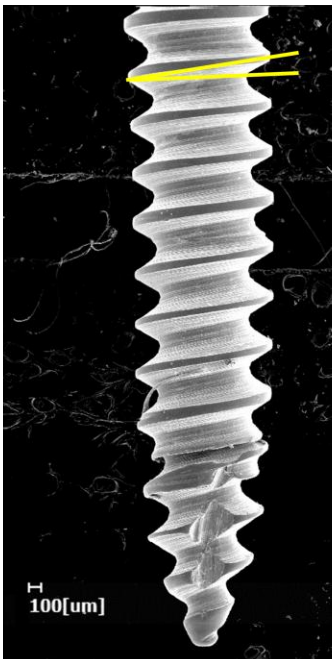
Depth of Dentos MSI



Depth of SK Surgical MSI

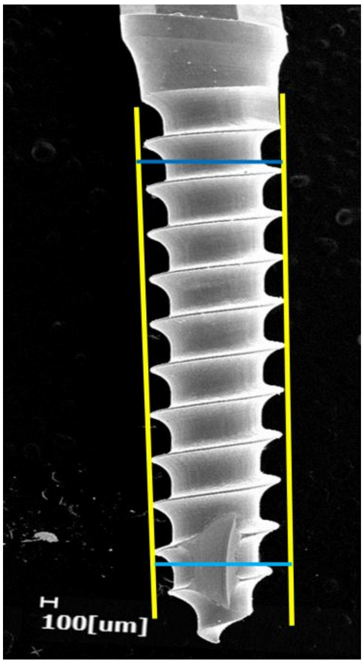


Lead angle of Dentos MSI

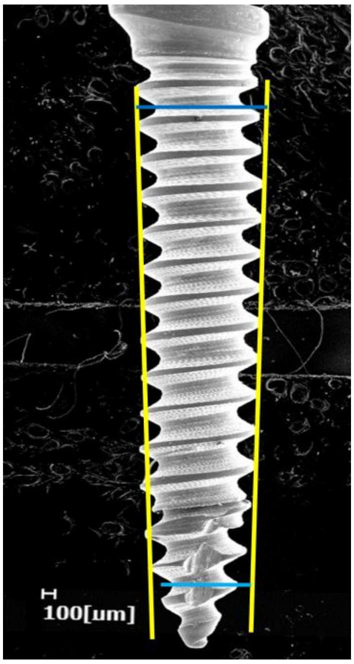


Lead angle of SK Surgical MSI

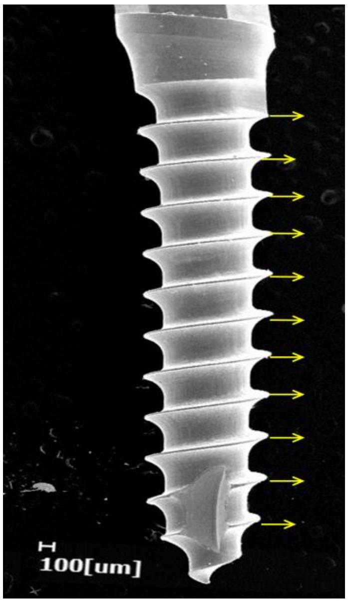
Fig 12 continued



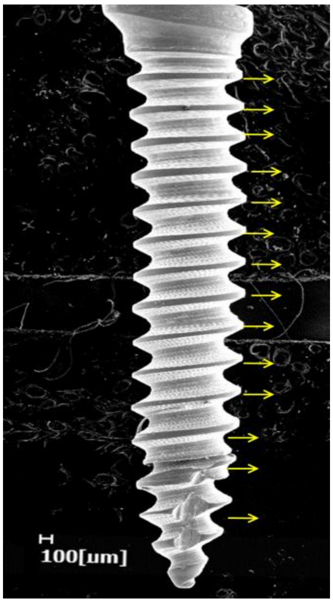
Taper of Dentos MSI



Taper of SK Surgical MSI



Number of threads of Dentos MSI

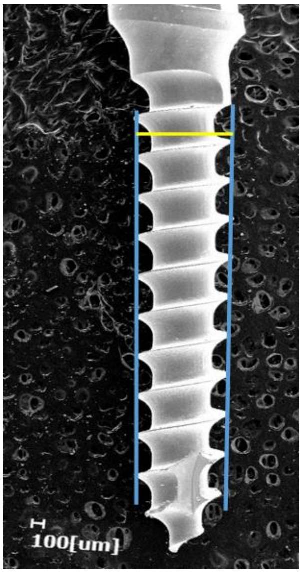


Number of threads of SK Surgical MSI

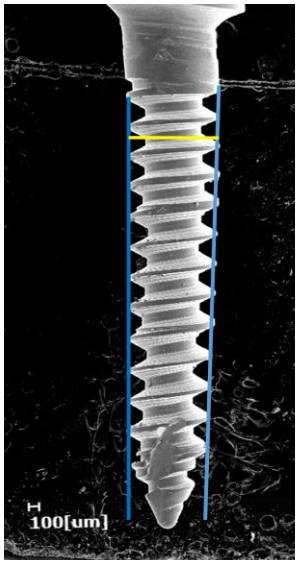
Fig 12 continued

1.3x8mm MSI's

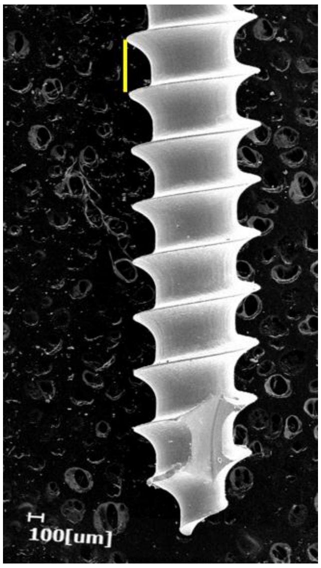
(Small Size)



Diameter of Dentos MSI



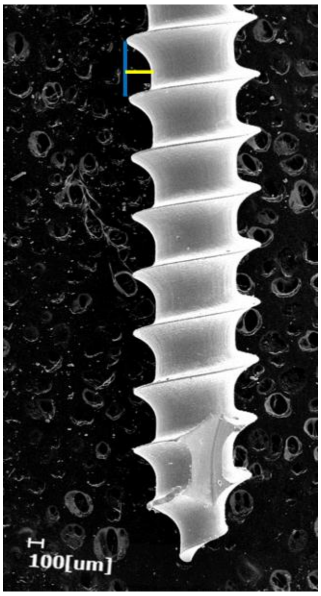
Diameter of SK Surgical MSI



Pitch of Dentos MSI

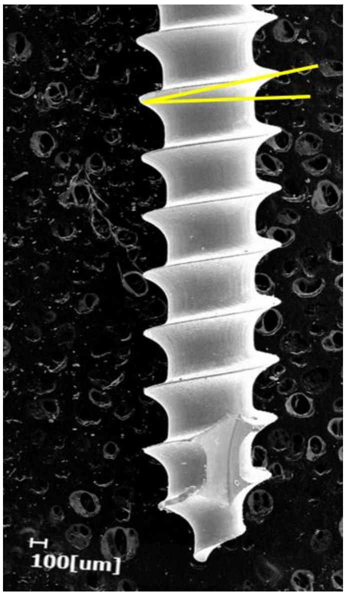
Pitch of SK Surgical MSI

Fig 12 continued



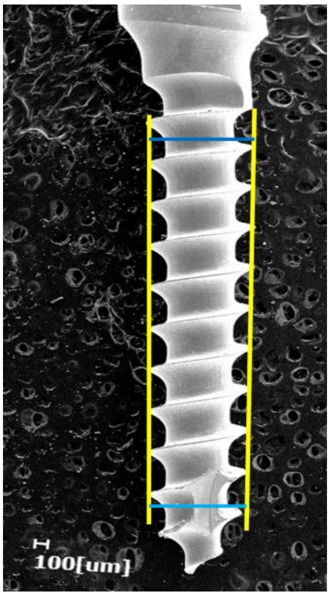
Depth of Dentos MSI

Depth of SK Surgical MSI

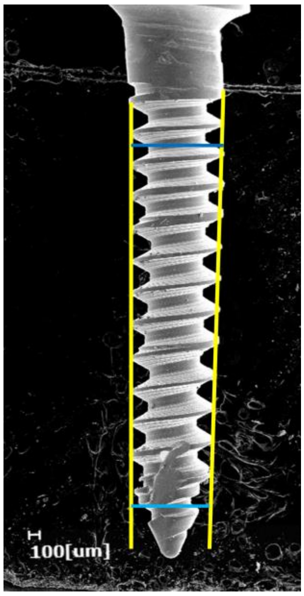


Lead angle of Dentos MSI

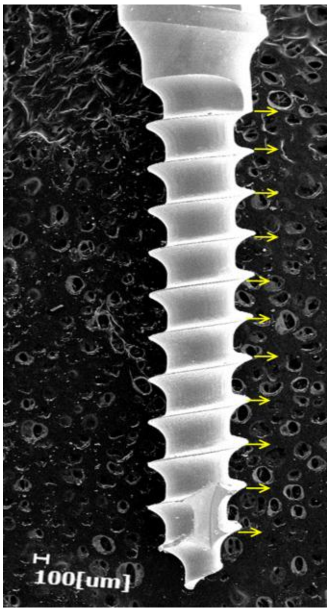
Lead angle of SK Surgical MSI



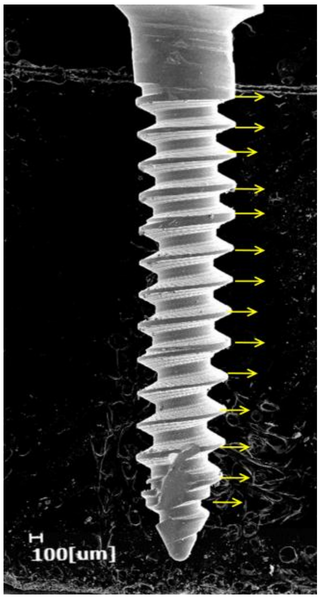
Taper of Dentos MSI



Taper of SK Surgical MSI



Number of threads Dentos of MSI



Number of threads of SK Surgical MSI

Figure 13. Comparison of lead angle (degree) of various diameters of MSI's (Dentos, SK Surgical).

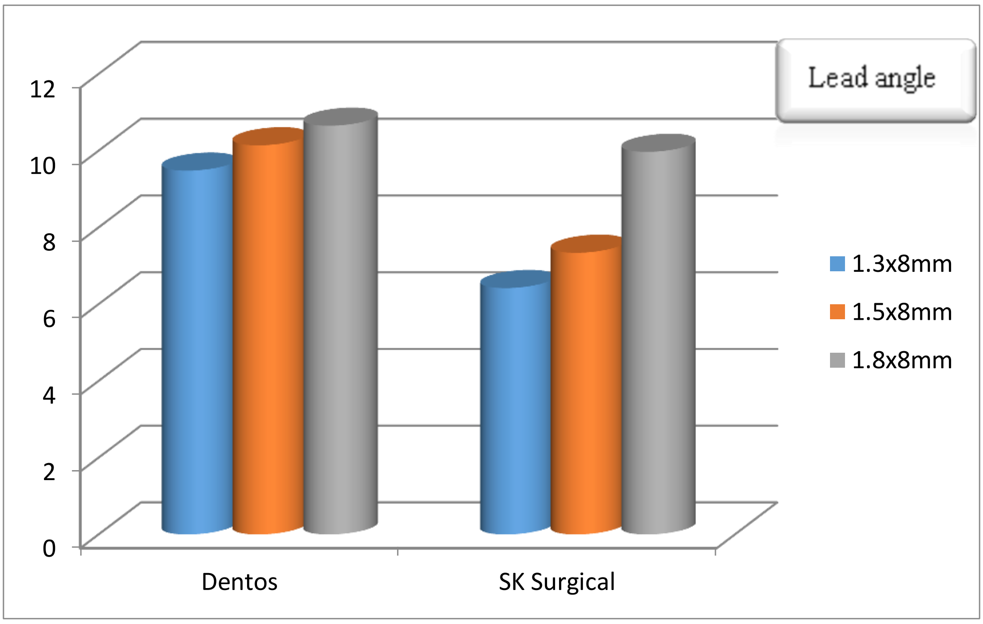


Figure 14. Comparison of pitch (mm) of various diameters of MSI's (Dentos, SK Surgical).

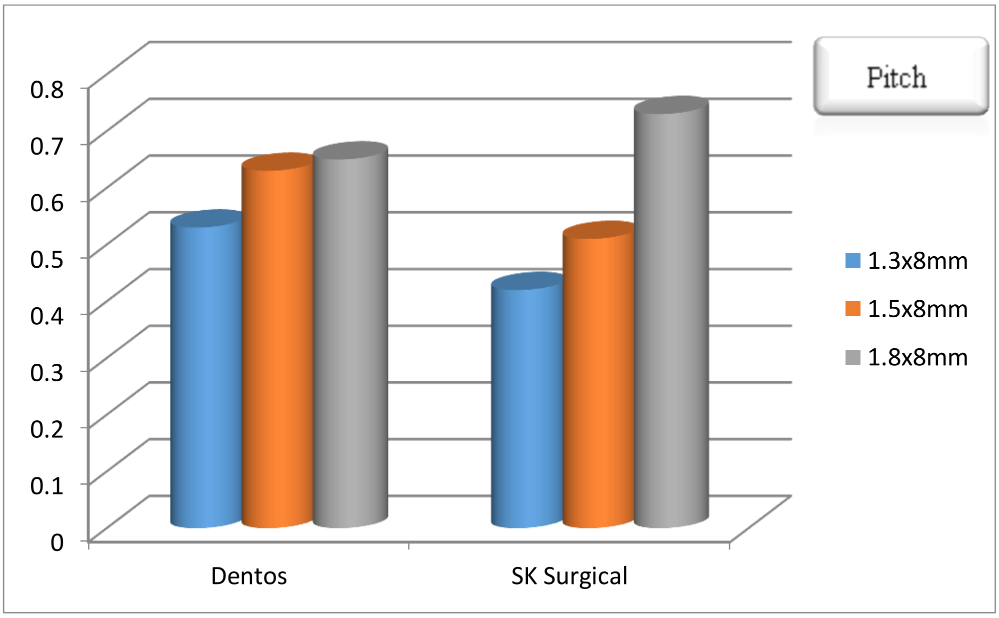


Figure 15. Comparison of depth (mm) of various diameters of MSI's (Dentos, SK Surgical).

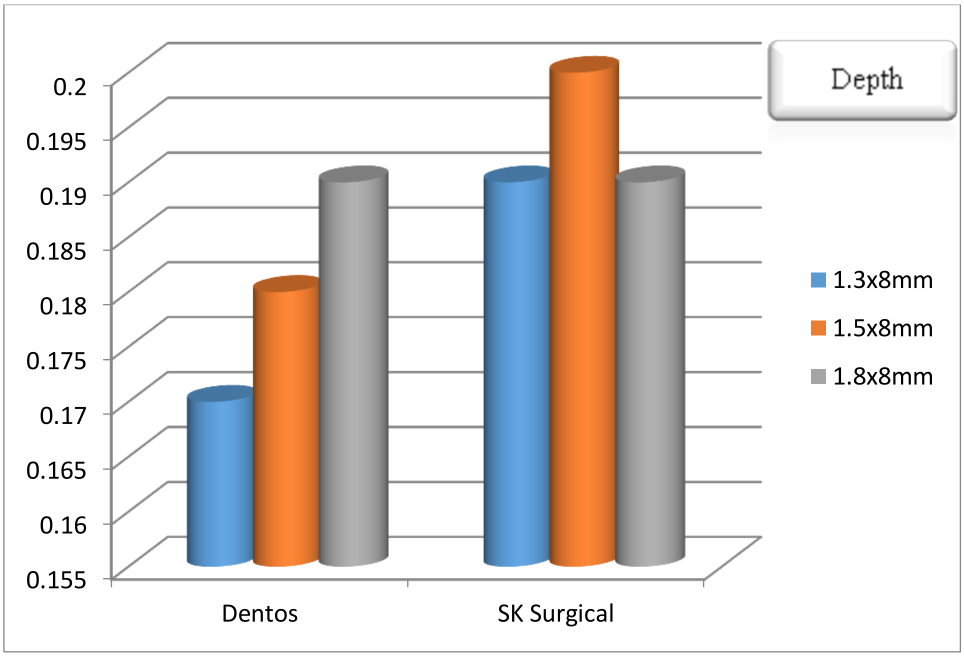


Figure 16. Comparison of taper of various diameters of MSI's (Dentos, SK Surgical).

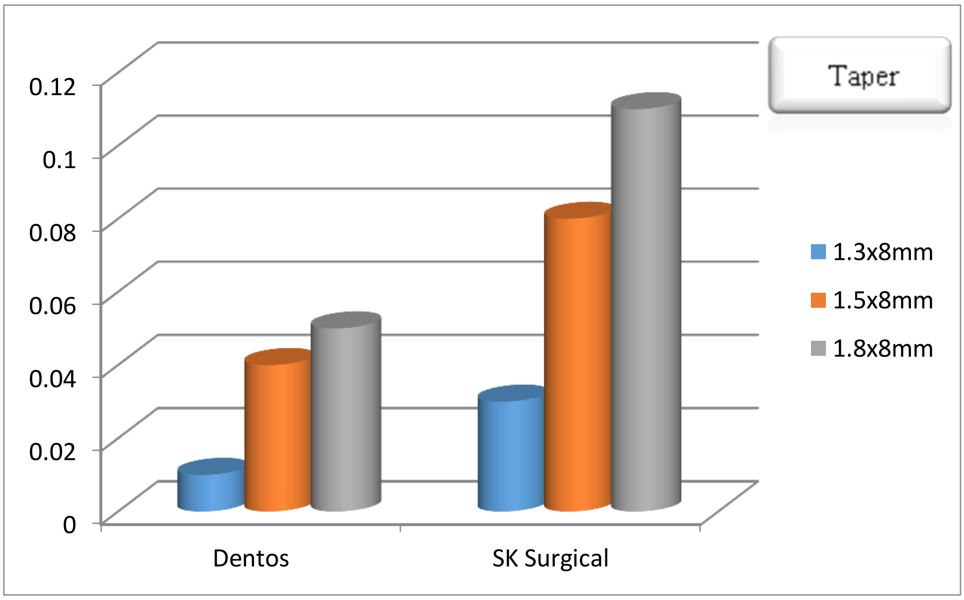


Figure 17. Comparison of surface area (mm^2) of various diameters of MSI's (Dentos, SK Surgical).

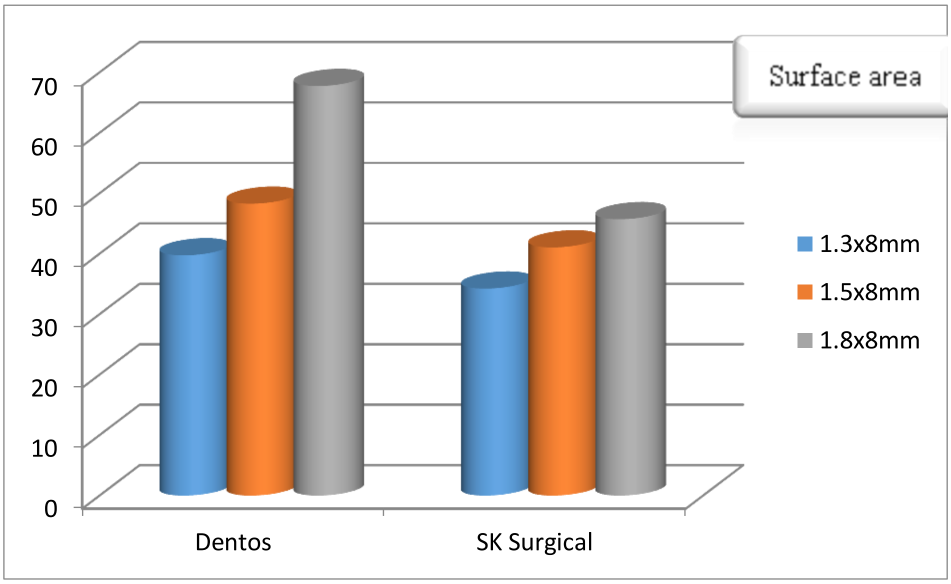


Figure 18. Mean Insertion Torque (Ncm) of Dentos MSI's and SK Surgical MSI's in 1mm cortical bone thickness.

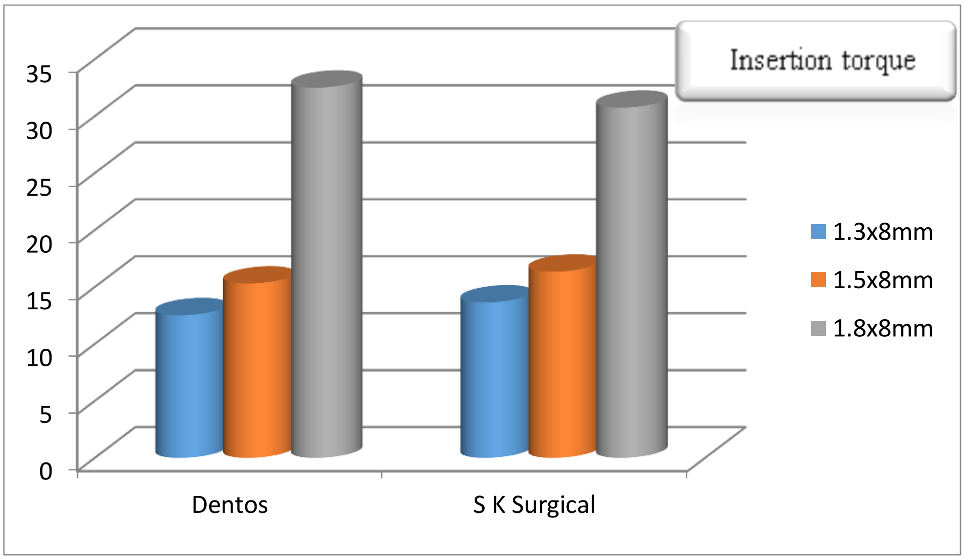
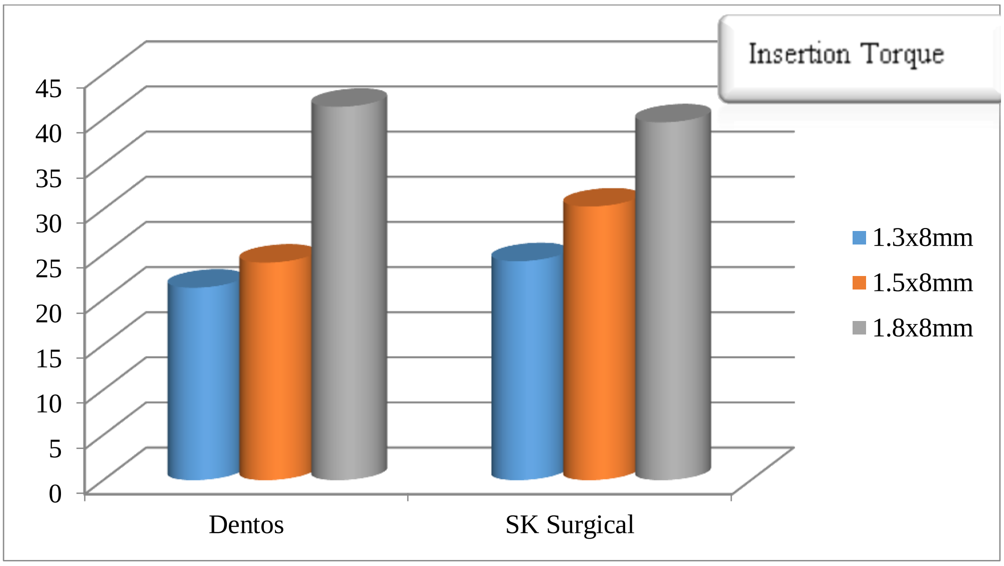


Figure 19. Mean Insertion Torque (Ncm) of Dentos MSI's and SK Surgical MSI's in 2mm cortical bone thickness.



Discussion

DISCUSSION

Successful orthodontic treatment greatly depends on appropriate, stable anchorage. In order to be considered clinically effective, miniscrew implants (MSI's) must provide resistance to orthodontic forces for the entire period in which anchorage reinforcement is required during treatment.[86] However, MSI's may present episodes of loosening, mobility or displacement[109,65] and may be associated with injury to the adjacent structures and inflammation or infection of the surrounding tissues[79,63]. **Cheng et al** has reported that miniscrew implants have a lower success rate (80-85%) than osseointegrated implants (91% and 97.8%, for maxilla and mandible, respectively).[20] Therefore, obtaining an efficient interface between MSI and bone tissue continues to be the key point to achieve higher success rate.

Stability is one of the essential factors related to MSI permanence at the site of insertion[2]. This is initially represented by the mechanical interaction between the MSI surface and surrounding bone, referred to as primary stability, and is followed by a biological bone healing process, which represents secondary stability.[38,39]

The initial MSI stability is important for clinical success if MSI's are to be loaded immediately.[76]A lack of primary stability frequently leads to MSI mobility and subsequent loss. In cases where primary stability is not achieved during insertion, the MSI cannot be engaged in therapy for the next 6−8 weeks, which prolongs orthodontic treatment.

Primary stability of miniscrew implants has been associated with many factors, including insertion site, root proximity, soft-tissue inflammation, operator technique, magnitude and loading time of the orthodontic force.[45,74]Some studies have shown that the MSI primary stability is a more important factor on its survival rate and reliability than other factors such as bone quality and quantity, so primary stability is a critical factor in implant failures.[79] It has also been reported in the literature that bone properties, MSI design (diameter, length) and surgical technique have a great impact on primary stability.[59,105]

Some of the qualitative and objective methods to determine the primary stability of MSI's are noninvasive clinical test methods (ie, insertion torque, radiographs, percussion test, periotest and resonance frequency measurement)[76] and invasive research test methods (ie, Pull Out Test and removal torque).Some of these non invasive methods (radiographs, percussion test, periotest)can be unreliable due to operator sensitivity, errors and deliver results with low accuracy. Radiographs are problematic because they are a two-dimensional and not easily standardized. Percussion is also not reliable because the test results can differ depending upon the vertical position and angle of the testing instrument as it strikes the MSI[4]. Measurements of insertion torque using Osstell's resonance frequency analysis (RFA) is a reliable examination methods[51]to assess primary stability. Since miniscrew implants are much smaller than dental implants, this measurement method is not currently applicable, according to the manufacturer. In addition, resonance frequency tests are not very accurate because the ear is not sensitive enough to discriminate such frequencies[76]. Although reverse torque is typically classified as a non-invasive test, arguments can be made that such a test is in fact quite invasive because damage can occur at the bone-to-implant interface.

Thus the only feasible means of quantitatively assessing the primary stability of miniscrew implants is to measure insertion torque. **Motoyoshi et al** recommended optimal maximum insertion torque (MIT) values between 5-10 Newton centimeter (Ncm) for MSI's which help clinicians improve clinical results[82].

Many studies have been conducted to analyze the impact of primary stability with respect to the diameter and length of the MSI's[96,115,66]. There has been little attention paid to miniscrew implant design and its effect on stability. Hence, other geometric characteristics of MSI's that might enhance the primary stability remains to be fully understood.

Some of the other factors not disclosed by the manufacturers that were tested in this study were geometrical design of MSI's parameters such as pitch, depth, lead angle, taper, number of threads and surface area. Relationship between MSI geometric design and stability are yet to be answered.

Hence, this study was carried out in two stages: firstly by a detailed study of the geometric design characteristics of the two as-received miniscrew implants (Dentos, Korea and SK Surgical, India) using scanning electron microscopy (SEM) analysis and secondly by evaluating the effects of each geometrical design parameters of MSI's on primary stability using insertion torque in different cortical bone thickness.

According to **Goldstein et al**, scanning electron microscopy and energy dispersive X-ray microanalyses are well established methods for studying morphological features and elemental composition in relation to specimen topography and structure[40]. According to **Casaglia et al** SEM analysis has permitted calculation with extreme precision of the occupied space by the body of MSI, the extension of thread and the amplitude of the head[18].

Therefore in our study geometric design of two brands of as received MSI's of varying diameters were assessed using scanning electron microscopy (SEM) imaging (Zeiss Supra 55VP). The digital images of MSI's at 10x and 15x magnification were taken in order to obtain general information (shape, diameter and length). Other geometric design characteristics of MSI's were measured using the Image J software (NIH, Bethesda, Md).[25]

In a study by **Handa et al**, it was shown that the pattern of stress distribution is maximally concentrated at the point of entry of the MSI into the bone that is concentrated near neck of the MSI away from the direction of force application where the tractional force would be maximally experienced.[7] **Chang et al** in his studies showed strain surrounding MSI's was concentrated at the uppermost threads[54]. Thus all the geometric design parameters were measured in uppermost threads of the MSI's.

Self-Drilling Vs Self Tapping MSI's

According to a 2008 American Association of Orthodontics (AAO) survey, the majority of orthodontists never drill a pilot hole prior to MSI placement, indicating a strong preference for the self-drilling design due to its versatility and ease of placement.[14] It has been shown by various clinical and histological studies that pre-drilling prior to MSI placement is a significant factor in failures associated with MSI insertion procedures. The drill-free method results in higher MSI insertion torques than the pre-drilling method which can lead to superior primary stability and success rates as an outcome of increased bone-to-implant contact ratio.[21,60] The self-drilling design obviates the need for pre-drilling with a motorized hand-piece; it also has a better tactile feedback during manual insertion which significantly reduces root damage risks.[31]

Heidemann et al found that, when pre-drilling of the implant site is performed, the pilot hole should not have a diameter greater than 80% of that of the screw in order to maintain good primary stability and an ideal insertion torque.[43]

Therefore MSIs of self-drilling type were chosen in our study, which is in concurrence to the above mentioned studies.

Titanium and stainless steel miniscrew implants are commonly used in clinical practice. In our study titanium MSI's were used as titanium alloys offers more advantages over stainless steel due to enhanced biocompatibility corrosion resistance, and bacteriostatic action, all attributed to the surface titanium oxide film formed, as well as in mechanical strength.[42,98]

1. EVALUATION OF GEOMETRIC DESIGN PARAMETERS OF TWO SELF DRILLING MSI's.

a. Pitch of the MSI

Jones et al defined thread pitch as the distance from the center of the thread to the center of the next thread, measured parallel to the axis of a MSI[36]. MSI pitch determines how much the screw advances with each turn with greater amount of advancement. **Abuhussein et al** stated that pitch of the MSI is inversely related to the number of threads in the unit area[1]. When the threads are spaced far apart, the MSI's have a high pitch; conversely, when the threads are spaced close together, the MSI's have a low pitch. **Kong et al** claims under or oversized thread pitches being less appropriate for clinical use.[62] However in a study by **Hong et al** MSI's with double thread with a decreasing pitch in the neck may counteract this disadvantage by increasing the stability by enhancing the interlock between MSI and bone.[46]

It has been suggested that MSI pitch is clinically more important than MSI diameter because the MSI diameter is limited by the bone site and space available.[119]Whereas,pitch is not limited by available space and its effect on primary stability has been noted.

According to **Christine et al** greater primary stability was shown by MSI's with 0.75 mm pitch than MSI's with 1mm pitch.[24]**Gracco et al**[41] and **Chang et al**[54] have said that pitch values are important for primary stability.

Cunha et al concluded that the MSI's with a shorter pitch distance and an insertion angle of 30 degree presented better primary stability in artificial bone of greater density.[28]

In our study the pitch of 1.3x8mm Dentos MSI's were 0.53 ± 0.04, 1.5x8mm MSI's were 0.63 ± 0.02mm and for 1.8x8mm MSI's 0.65 ± 0.03 mm.

In our study the pitch of 1.3x8mm SK Surgical MSI's were 0.42 ± 0.03, 1.5x8 mm MSI's were 0.51 ± 0.02mm for and for 1.8x8 mm MSI's 0.73 ± 0.02mm.

The pitch of Dentos MSI's was more than SK Surgical MSI's for 1.3x8mm and 1.5x8mm MSI's. The pitch of SK Surgical MSI was more for 1.8x8mm MSI than Dentos MSI of same diameter. **(Table 4,5) (Fig 14)**

The primary stability of 1.3x8mm and 1.5x8mm SK Surgical MSI's would be high compared to Dentos MSI's of same diameter as pitch values were less for SK Surgical MSI's. Contrary the primary stability of 1.8x8mm Dentos MSI's would be high compared to SK Surgical MSI's of same diameter as pitch values were less for Dentos MSI's.

Results of our study are in concurrence with the study of **Christine et al**.

Since the significance of the bone to miniscrew implant contact has been established; the thickness of the cortical bone in which a MSI is to be inserted must be taken into consideration when choosing a pitch. In bone that has only 1 mm cortical bone thickness, a MSI with a pitch of 0.4-1.0mm will only have 1-2 threads in contact with cortical bone. Whereas in bone that has

2-3mm cortical bone thickness with a pitch of 0.4 to 1mm will have 2 to 4 threads in contact with the cortical bone. A decrease in pitch is thought to increase the screw purchase to increase the primary stability.[120] If the cortical bone thickness is less or pitch distance of MSI's is more, it may lead to micro movements, bone resorption which leads to decreased primary stability and MSI failure.[93]

Though there was statistical significant correlation for pitch with primary stability, on multiple regression analysis for this particular study, pitch value showed no significance.

b. Depth of the MSI

Misch et al defined thread depth as the distance between the major and minor diameter of the MSI's.[78] **Wilmes et al** suggested that the ideal thread depth to outer diameter ratio should be around 30 % or less to avoid weakness of shank.[113] According to **Abdelgader et al** the deeper the thread, the greater the intraosseous surface area of an MSI.[52] Given the same implant body, insertion of miniscrew implant is easier with a shallow thread depth. Hence, it is agreed that 'the deeper the threads, the wider the surface area of the implant.' Greater thread depth may be an advantage in areas of softer bone and higher occlusal force because of the higher functional surface area in contact with bone. On the other hand, shallow thread depth permits easier insertion into denser bone with no need for tapping (**Misch et al**).[78]

The miniscrew implant becomes fragile and the core diameter decreases as the thread depth increases.[52] According to **Walter et al** deeper the threads more stable the miniscrew implants as they offer more resistance to displacement and can be used in poorer bone quality situations.[108] Mean insertion torque (MIT) is strictly correlated to MSI geometry, the bigger the depth of the thread the bigger was the MIT. According to **Gracco et al** MSI with greater thread depth presented higher insertion torque.[41]

Marigo et al in a surface analysis study of two brands of MSI's using SEM with same external diameter, demonstrated when the depth of the thread increases the mechanical stability also increases[70]. Finite element study by **Chang et al** showed that MSI's generate higher stresses on the bone and thread elements by increasing thread depth.[54] In another study by **Cunha et al** comparing two MSI's with SEM study stated that MSI with higher thread depth present lower mobility.[29] MSI mobility may be reduced if the thread depth is increased which is extremely relevant from clinical point of view.[29]

In our study the mean depth of 1.3x8mm Dentos MSI's were 0.17 ± 0.01mm, 1.5x8mm MSI's were 0.18 ± 0.0 mm and 1.8x8mm MSI's were 0.19 ± 0.01mm **(Table 4,5) (Fig 15)**.

The mean depth 1.3x8mm SK Surgical MSI's were 0.19 ± 0.01mm, 1.5x8mm MSI's were 0.20 ± 0.01mm and 1.8x8mm MSI's were 0.19 ± 0.01 mm. **(Table 4,5) (Fig 15).**

On comparing MSI depth, SK Surgical MSI's of 1.3 x 8mm and 1.5x8 mm showed increased depth values than Dentos MSI's of the same diameter. Depth values for both the MSI's were same for 1.8x8mm diameter. MSI's with greater depth can be used in poor quality bones.

Findings of our study are in concurrence with data by **Walter et al**[108] who showed a tendency towards increased fracture risk in small, medium and large MSI's when the thread depth to outer diameter ratio reaches about 40% (reflecting a shank loss of 0.1 or 0.3 mm).

The findings of our study are in concurrence with the study done by **Marigo et al**[70] which states increase in depth enhance primary stability of MSI's.

Though there was statistical significant correlation for depth for primary stability, on multiple regression analysis for this particular study, depth value showed no significance.

c. Lead angle of the MSI

Lead, which is the distance from the center of the thread to the center of the same thread after one turn or, more accurately, the distance that a MSI would advance in the axial direction if turned one complete revolution[1]. With a smaller lead angle and more number of threads, increases the surface area of the screw, thereby enhance primary stability[52]. The angle selected for miniscrew implants should be optimization of the need for a larger surface and a smallest amount of trauma. According to **Katie et al** higher the lead angle, improves the cutting efficiency during implantation because lead defines the axial travel for a single revolution[57]. According to **Kithara et al** reduced angles could complicate the insertion of MSI's leading to high values of insertion torque, increasing risk of fracture.[61]

The lead angle of 1.3x8mm Dentos MSI 's were 9.48±0.15, 1.5x8mm MSI's were 10.14±0.08 and 1.8x8mm MSI's were 10.65±0.04.

The lead angle of 1.3x8mm SK Surgical MSI's were 6.42±0.32, 1.5x8 mm MSI's were 7.34±0.11 and 1.8x8mm MSI's were 9.97±0.13. **(Table 4,5) (Fig 13).**

Dentos MSI's with high lead angle show better success rate due to high cutting efficiency compared to SK Surgical MSI's with less lead angle.

The results of our study showed that lead angle was more for Dentos MSI compared to SK Surgicals and it was in concurrence with the study by **Katie et al**.[57]

d. Number of threads of MSI

The thread is a key part of the miniscrew implant. Miniscrew implants are anchored in bone by mechanical fit (or press-fit), and the fit quality and stability are largely determined by the thread.

The presence of threads with smaller thread pitch increases the number of threads per length unit and increases the contact area of MSI with the bone. This change in MSI design will increase primary stability measured by insertion torque.[107]

Insertion torque value and bone implant contact area was increased when number of threads of MSI's were increased. This increased primary stability.[99] As the number of threads increased, the MSI bone contact, resistance to displacement and primary stability increases[70]. According to **Kithara et al** increased number of threads and reduced distance between the threads leads to greater resistance to insertion of the MSI into the bone.[61]

Thread shapes can vary according to the manufacturer as V shape, Square shape, Buttress shape, Reverse buttress and Spiral shape. Dentos MSI have knife edge threads, that results in low insertion torque[50]. In contrast SK Surgical MSI's have spiral type thread which shows high insertion torque.

The number of threads were 11 for all diameters of Dentos MSI's. The number of threads for SK Surgical MSI's were 14 for 1.3x8mm and 1.5x8mm diameters. The number of threads were 8 for 1.8x8mm SK Surgical MSI's. The number of threads were standard for Dentos MSI's. In contrast number of threads were varying for SK Surgical MSI's. Insertion torque value and bone implant contact area was increased when number of threads of MSI's were increased. This increased primary stability **(Table 4,5).**

e. Taper of MSI

According to **Marigo et al** taper is calculated as the difference between the largest and smallest diameters of the thread divided by the length of active part.[70] A significant increase in insertion torque was observed mainly in the taper type miniscrew implant. MSI with higher taper values showed increased insertion torque according to studies by Kim et al and Lim et al.[55]

Differences have been reported between conical and cylindrical shaped MSIs regarding their retention in bone, with the first ones tending to be in an advantageous position. The conical MSI's show greater primary stability compared to the cylindrical ones as found in a study of **Wilmes et al.**[116]

Kim et al[55]showed in his mechanical study that the conical group of MSI's showed significantly higher maximum insertion torque (MIT) and maximum removal torque (MRT) than the cylindrical group. He concludes that although the conical shaped MSI's could induce tight contact to the adjacent bone tissue and might produce good primary stability, the conical shape may need modification of the thread structure and insertion technique to reduce the excessive insertion torque while maintaining the high resistance to removal.

The taper 1.3x8mm Dentos MSI's were 0.01±0.01, 1.5x8mm MSI's were 0.04±0.01 and 1.8x8mm MSI's were 0.05±0.01. **(Table 4,5) (Fig 16)**

The taper of 1.3x8mm SK Surgical MSI's were 0.03±0.01, 1.5x8mm MSI's were 0.08±0.01 and 1.8x8mm MSI's were 0.11±0.01. **(Table 4,5) (Fig 16)**

Taper values was more for SK Surgical MSI's than Dentos MSI's. SK Surgical MSI's showed lack of uniform taper. Taper was steep from fifth thread to the tip whereas in Dentos MSI, taper was uniform.

f. Surface area of MSI

Various MSI's shapes were developed to improve the interaction between bone and miniscrew implant, increase the surface area, distribution of forces to the bone and achieve a better primary stability.[17] The screw shape provides a large contact area between MSI and bone, increases primary stability, reduces the shear stress in the bone-MSI interface. By varying the profile of fillets of tapered threads is possible to increase the surface area of the conical MSI's relative to cylindrical MSI's with the same diameter and length. The fillet can be triangular, square, V-shaped, rounded or trapezoidal. MSI's with rough surfaces permit a firmer mechanical link to the nearby tissues and are considered to increase primary stability as they present a larger surface area (**Romanos et al**).[100] The thread geometry of the conical MSI's increases the implant surface area in contact with the host tissue. The lessening of pitch of the conical MSI thread enhance its contact area as compared to the cylindrical MSI's. As surface area increases, the friction surface between the MSI and the site wall increases, demanding a larger insertion torque. It is expected that the increased surface area of the MSI, enhance the number of sites to bind to cells, helps in tissue growth and improve the mechanical stability.

The surface area of 1.3x8mm Dentos MSI's were 39.73 mm^2, 1.5x8 mm MSI's were 48.27 mm^2 and 1.8x8mm MSI's were 67.74 mm^2. **(Table 4,5) (Fig 17)**

The surface area of 1.3x8mm SK Surgical MSI's were 34.23 mm^2, 1.5x8mm MSI's were 41.05 mm^2 and 1.8x8mm MSI's were 45.71 mm^2. **(Table 4,5) (Fig 17)**

The surface area is directly related to the number of threads. Inspite of more number of threads in SK Surgical MSI's, surface area is less compared to Dentos MSI's because taper was steep from fifth thread to the tip in SK Surgical MSI's whereas in Dentos MSI's, taper was uniform.

This was the probable reason for more surface area in Dentos MSI's which enhance primary stability when compared with SK Surgical MSI's.

g. Diameter of MSI

Miyawaki et al showed that diameter of the MSI is significantly associated with its stability.[79] **Miyawaki et al** also found MSI with 1mm diameter is at risk of more failure and 0 % success rate. However, the 1.2 mm, 1.3mm and 1.5mm diameter MSI's had higher success rates than the 1.6mm MSI's. Though thinner MSI’s are easier to place in most inter-dental locations, the drawback of thinner MSI’s is the greater potential for screw fracture. **Kuroda et al** also agrees with the findings that smaller MSI's tend to break during placement and removal.[64] According to **Kuroda et al**, 1.5mm diameter MSI's offered a 96.5% success rate compared to other MSI's such as the 1.3mm, 1.4mm, 1.6mm or 2.0mm which offered success rates of 95.1%, 89.4%, 93.2% and 88.7%.

The external diameter of the threads of most MSI's varies between 1.2mm and 2.3mm. The MSI must be of sufficient structural diameter to resist breakage under load, yet narrow enough to fit into typical inter-radicular spaces to prevent damage of vital structures.

Poggio et al after studying the safe zone for MSI also concluded that the diameter of MSI's should not exceed 1.5mm[97]. **Deguchi et al**, also agree in their 3D CT study that MSI's with diameters of 1.3 to 1.5mm are recommended for skeletal anchorage in inter-radicular areas.[32] Small increase in the outer diameter of MSI, greater than 1.5mm diameter, increases the chances of potential root contact.

Hence, in accordance with the above mentioned studies, the MSI's tested in our study were selected according to the anatomic variations in various locations in the maxilla and the mandible. Since most of the clinical application of the MSI's are for the anchorage purposes, and due to the variations in the anatomy of buccal, the lingual inter-radicular spaces and non tooth bearing araeas the MSI's of varying diameters selected for this study were 1.3mm, 1.5mm and 1.8 mm respectively.

h. Length of MSI

The length of a miniscrew implant is defined as the length of the threaded body and not the length of the entire MSI.

Tseng et al emphasized that the actual depth of insertion of MSI was more important than its length[106]. **Deguchi et al** recommends MSIs of 6 to 8mm in length for skeletal anchorage in inter-radicular areas.[32]

Miyawakiet al[79]do not associate the length of the MSI with its stability if the MSI was at least 5mm long. Studies by **Park et al**[91]and **Kuroda et al**[64]have also shown higher success rates by increasing the length of the MSI's with the same diameter, but the differences were not statistically significant.

According to a study by **Kuroda et al**[64] the 8mm long MSI returned a success rate of 93.3% compared to the 6mm, 7mm and 10mm long MSI's which had a success rate of 89.2%, 83.3% and 91.7% respectively.

Hence, 8mm length MSI's were used in our study, which is in concurrence with the above mentioned studies.

2. EVALUATION OF INSERTION TORQUE OF TWO MSI'S

Cortical Bone Thickness

Cortical bone thickness is one of the most significant factors determining primary stability and consequently playing an important role in the success or failure of the MSI’s. **Ansell et al**[5] reported stability of the MSI’s depends on the bone-to-screw contact, better bone quantity should result in better primary stability. Areas with thick cortex are considered to be better for miniscrew placement.[79,49]Cortical bone thickness seems to play a key role in primary stability, a mechanical interlock between the thread of the MSI's and high density cortical bone permits a high value of interconnection.

Ono et al[85] reported that the average thickness of the maxillary cortical bone is approximately 1.2mm. **Kanazawa et al** and **Kasai et al** measured the mandibular cortical bone and found that the thickness was between 2.0mm-2.2mm.[56]

Park et al and **Cho et al** reported that the average buccal cortical bone thickness was 1.17 to 1.31mm and the average buccal mandibular cortical bone thickness was 1.26 to 2.91mm and the average cortical bone thickness in the maxillary palatal alveolar process was 1.15 to 1.25mm and the retromolar pad area showed abundant cortical bone thickness of 1.96 to 2.06mm.[23,90]

Since there are variations in the cortical bone thickness of the human maxilla and the mandible, which widely ranges from 1.17 to 2.91mm, synthetic bones were selected in this study with different cortical bone thickness of 1mm and 2mm.

Hence, 1mm cortical bone served as a model for the thin human maxillary cortical bone, 2mm cortical bone thickness served as the model for the thicker human mandibular cortical bone.

According to **Yuehuei H et al**. & **Draughnet al** synthetic bone offers the following advantages over the cadaveric bone.[117]

- The quality of cadaver bone varies widely, requiring large number of specimens to be tested per configuration to establish significant differences.

- Miniscrew implants are often used in relatively young patients whose bone quality can be poorly presented by the often fragile, osteoporotic bone characteristic of the elderly donors from whom most cadaver bone is derived.
- Cadaver bone is typically obtained "fresh-frozen" hence not sterilized creating stringent handling requirements for the prevention of disease transmission.
- For a long term in vitro study to be performed, deterioration of the properties of the cadaver bone over time must be considered.

According to **Burkhart et al** the axial stiffness of formalin fixed cadaveric bone increased by 14.1%, whereas torsional stiffness increased by 14.3% and they conclude that formalin fixation significantly influences the stiffness of human cadaveric bones[13]. According to **Wilke et al** formalin fixed specimens of cadaveric bone are not representative of the in- vivo conditions for biomechanical testing[112].

A study on interspecies differences in bone composition, density, and quality by **Aerssens et al** found that none of the animal bone with regard to bone composition, bone density, and bone mechanical competence were similar to the humans.[3] According to **Bagi et al** the direct comparisons between anatomic and structural characteristics of bone in animals and humans are difficult and extrapolating the data obtained from animals to humans can be complex.[9]

Human cadavers and animal bones were not chosen for our study to avoid natural variations in bone.

Hence in our study we used synthetic bone blocks (Sawbones®, Pacific Research Laboratories, Inc., Vashon, WA, USA) which had a uniform bone density and met the American Society for Testing and Materials (ASTM F-1839-08) regulations on mechanical studies of metal bone screws. According to Kim et al synthetic bone has shown to be a good substitute for real bone.

Miniscrew Implant Placement Methods

There are two methods of MSI insertion: MSI's placed by hand driver (manually) and MSI's placed with the help of machine (reduction gear hand piece). All MSI systems feature at least one instrument for manual insertion but not all have one for use with a hand-piece.

According to **Soon-Seop Woo et al** the machine driven MSI's exhibited high failure rate of 28% compared to manually inserted MSI's, which had 11% failure rate.[104]This can be attributed to engine driven drilling causing more frictional heat and thereby resulting in more injury to the bone tissue and cells.

Manual insertion of a MSI permits the user to get a feeling of the osseous quality at the insertion point and in turn the necessary torque. Depending on the resistance of the bone the torque applied to the MSI's can be varied or controlled by the user. Whereas the disadvantage of machine driven MSI insertion is that there is no tactile feeling of resistance of the bone or load application to the miniscrew implant.

Hence the MSI insertion procedure used in our study was manual, to mimic clinical scenario.

Mechanical evaluation of insertion torque

The second part of our study consisted of mechanical evaluation of insertion torque. The as received MSI's after SEM study were inserted into artificial bone blocks and insertion torque was measured using digital torque meter. It is generally thought that adequate placement torque is one of the principal factors affecting the primary stability when tightening the miniscrew implant into the bone.

Motoyoshi et al found that the recommended placement torque was between 5Ncm – 10Ncm for successful implantation with the self-tapping MSI's in both the maxilla and the mandible.[82] They further recommended that, regardless of the self-drilling or the self-tapping MSI's, the adequate placement torque range of the MSI's should be between 5Ncm – 10Ncm, and a placement technique that used a torque within that range should be selected.

In our study, various diameters of MSI’s were selected and inserted into different cortical bone thickness using a custom-made apparatus, which consisted of torque meter driver guide, which allowed perpendicular path of MSI insertion. MSI’s were inserted into the bone blocks with the help of a digital torque driver using finger pressure. The peak insertion torque of varying diameters of MSI’s and different cortical bone thickness were measured.

Meredith et al recommended, of all the methods used to test the primary stability of the MSI’s, he found insertion torque and resonance frequency analysis as the most reliable examinations.[76]

Therefore, in concurrence with the recommendations by Meredith et al, insertion torque of varying diameters of MSI’s on insertion into different cortical bone thickness were measured.

The mechanical test results confirm that overall MSI design has an impact on the mechanical properties.

In our study all the MSI's were grouped into small, medium and large diameter MSI's based on their diameters as 1.3mm, 1.5mm and 1.8mm respectively.

<u>Evaluation of effect of MSI geometric design on insertion torque</u>

Small diameter MSI (1.3x8mm)

They are mainly suitable for narrow interradicular placement as required for simple tooth movements in maxilla and mandible.[108]

Dentos MSI's and SK Surgical MSI's having same diameter of 1.3mm, had significant difference in insertion torque. In 1mm cortical bone thickness the mean maximum insertion torque for 1.3mm diameter Dentos MSI's was 12.52 ± 0.27 Ncm and SK Surgical MSI's was 13.64 ± 0.21 Ncm.**(Table 7) (Fig 18)**

In 2mm cortical bone thickness the insertion torque values were increased close to two times. The mean insertion torque for Dentos MSI's was 21.32 ± 0.29 Ncm and for SK Surgical MSI's 24.26 ± 0.31 Ncm. **(Table 7) (Fig 19)**

SK Surgical MSI's were having very high insertion torque as compared to Dentos MSI's. Apart from diameter, length of the MSI's and cortical bone thickness, the variation in insertion torque could also be due to the following geometric design characteristic of MSI's.

1. The number of threads in Dentos MSI's were 11 compared to SK Surgical MSI's which were 14 **(Table 4 and 5)**. SK Surgical MSI's had more threads compared to Dentos MSI's. According to **Santos et al** as the number of MSI's thread increases the pitch value is reduced and this results in increased insertion torque.[99] This was the probable reason for Dentos MSI's to have optimum insertion torque as compared to SK Surgical MSI's having high insertion torque.

   According to study by **Marigo et al** as the number of threads increase the MSI bone contact increases, resistance to displacement increases and thereby increases the primary stability.[70] Thread pitch increases the cutting efficiency of the MSI's by providing lower insertion torque according to study by **Cunha et al**.[28] It's advisable to use a MSI with lesser pitch to decrease the level of stress generated in the bone surrounding the MSI as it provides more orthodontic forces during treatment according to a study by **Handa et al**[7]. Hence our study suggests SK Surgical MSI's will have increased primary stability than Dentos MSI's.

2. The taper for Dentos MSI's were 0.01±0.01 and for SK Surgical were 0.03±0.01 **(Table 4 and 5).** SK Surgical MSI's had slightly higher taper values than Dentos MSI's. According to **Sim et al** and **Lim et al** significant increase in mean insertion torque was observed mainly in the taper type MSI's. MSI's with higher taper values showed increased insertion torque.[103,58] A continuous increase of insertion torque in the taper group was probably due to a tighter contact to the surroundings than the cylindrical group due to difference in diameter between the upper and lower parts.[16] Hence in area or sites with soft bone tapered MSI's are preferable. Taper values was more for SK Surgical MSI's than Dentos MSI's. SK Surgical MSI's showed lack of uniform taper and taper was steep from fifth thread to the tip, whereas in Dentos MSI taper was uniform. This was the probable reason for increase in insertion torque and primary stability in SK surgical MSI's compared to Dentos MSI's.

3. The depth of SK Surgical MSI's were 0.19±0.01mm and Dentos MSI's were 0.17±0.01mm **(Table 4 and 5)**. According to **Walter et al** as the depth of MSI increases the core diameter decreases and MSI are more prone to fracture.[108] MSI's with increased depth and high insertion torque in MSI site with increased cortical bone thickness are prone to fracture. Hence SK Surgical MSI's with increased depth, reduced core diameter and high insertion torque are not recommended in areas of high cortical bone thickness. **Chen et al** also suggest that MSI's with smaller diameter(1.2mm and 1.3mm) are not suitable to be inserted into a bone with density greater than 40 pounds per cubic foot.[22] Hence in a narrow interdental area with increased cortical bone thickness MSI's with lesser depth are preferable.
4. The lead angle for Dentos MSI's were 9.48±0.15 and for SK Surgical MSI's were 6.42±0.32◦. **(Table 4 and 5)** Dentos MSI's had higher lead angle values than SK Surgical MSI's. According to **Katie et al** higher the lead angle improves the cutting efficiency during MSI insertion because lead defines the axial travel or a single revolution[57]. Reduced angles could complicate the insertion of MSI leading to high values of insertion torque, increasing risk of fracture. This was the probable reason Dentos MSI's had optimum insertion torque and SK Surgical MSI's had increased insertion torque. Hence in areas or sites with increased cortical bone thickness MSI's with high lead angle are preferable.

5. The surface area for Dentos MSI's were 39.73 mm^2 and for SK Surgical MSI's were 34.23 mm^2. (**Table 4 and 5)** The surface area of Dentos MSI's were more compared to SK Surgical MSI's. The probable reason for increased surface area in Dentos MSI's were due to lack of uniform taper and steep taper of SK Surgical MSI compared to uniform taper of Dentos MSI.[50] According to Romanos et al large surface area of MSI results in optimum insertion torque and better primary stability.[100]

Due to the proximity of MSI insertion sites to surrounding dental roots, periodontal ligament, nerves and blood vessels, it is important to consider the diameter of MSI's to prevent injuries.

Medium diameter MSI (1.5x8mm)

Medium diameter MSI's are preferred for en masse teeth movement or intrusion of teeth.[108] The greater the length and diameter of the medium MSI, the higher was the implant stability with increasing forces.[92]

Dentos MSI's and SK Surgical MSI's having same diameter of 1.5mm, there was a significant difference in insertion torque. In 1mm cortical bone thickness the mean maximum insertion torque for Dentos MSI's was 15.30 ± 0.19 Ncm and SK Surgical MSI's was 16.34 ± 0.21 Ncm. In 2mm cortical bone thickness the insertion torque values were increased close to two times. The mean insertion torque for Dentos MSI's was 24.10 ± 0.34 Ncm and for SK Surgical MSI's 30.32 ± 0.88 Ncm. **(Table 7) (Fig 17,18)**

The insertion torque for both MSI's were more than optimum insertion torque. In Dentos MSI the insertion torque was less as compared to SK Surgical MSI's.

The results of our study showed that, when the diameter of the MSI’s increases from 1.3mm to 1.5mm, the mean peak insertion torque values and primary stability also correspondingly increased. The probable reason could be because, as the wider outer diameter of MSI increases, more bone is displaced during insertion, producing greater torsional stress at the bone-screw interface, leading to increase in the peak insertion torque values.

Elias et al compared two types of MSI’s from the same manufacturer with different diameters, he found that, the greater the diameter, greater was the MSI insertion torque, since it was proportional to the contact area between MSI and the bone[35]. The results of this study were in concurrence with our findings.

Motoyoshi et al and co-workers evaluated a range of 5-10 Ncm as optimum insertion torque for pre-drilling MSI's in both, the maxilla and mandible.[82] For self-drilling MSI's, the adequate insertion torque may be somewhat higher. Using conical MSI's, a pilot drill is recommended to decrease the insertion torque for better secondary stability because high placement torques although they increase primary stability may not be favourable in the clinical setting.

The variation in insertion torque could also be due to the other geometric design characteristic of MSIs.

1. The number of threads in Dentos MSI's were 11 compared to SK Surgical MSI's which were 14. **(Table 4 and 5)** SK Surgical MSI's had more threads. The probable reason for Dentos MSI's to have less insertion torque as compared to SK Surgical MSI's was due to more number of threads in SK Surgical MSI's. According to study by **Marigo et al** as the number of threads increase the MSI bone contact increases, resistance to displacement increases and thereby increases the primary stability.[70] Hence our study suggests SK Surgical MSI's will have increased primary stability than Dentos MSI's.
2. The depth value for SK Surgical MSI's was 0.20±0.01mm and Dentos MSI's was 0.18±0.01mm. **(Table 4 and 5)** . According to **Marigo et al** as the depth of the thread increases the insertion thread into bone increases which increases the primary stability of MSI's.[70] Even if depth was more for the MSI's, the core diameter should be sufficient enough to resist fracture during MSI insertion. According to **Walter et al** ideal thread depth to outer diameter ratio should be around 30% or less to avoid weakness of the shank.[108] In our study both MSI's with 1.5mm diameter had ideal thread depth and core diameter, hence none of the MSI's fractured in spite of high insertion torque.
3. The lead angle value for Dentos MSI's were 10.14±0.08 and for SK Surgical MSI's were 7.34±0.11◦. **(Table 4 and 5)** Dentos MSI's had higher lead angle values than SK Surgical MSI's. Hence in cases of dense bone, a higher lead angle, less conical shape MSI's with sharp

threads are preferable to avoid excessive friction and compression.

4. The taper for Dentos MSI's were 0.04±0.01 and for SK Surgical MSI's were 0.08±0.01. SK Surgical MSI's had slightly higher taper values than Dentos MSI's. **(Table 4 and 5)** According to **Song et al** in his in vitro study demonstrated that tapered MSI with an increasing outer diameter increases the insertion torque.[105] Taper values was more for SK Surgical MSI's than Dentos MSI's. SK Surgical MSI's showed lack of uniform taper. Taper was steep from fifth thread to the tip whereas in Dentos MSI taper was uniform. This was the probable reason for increase in insertion torque in SK surgical MSI's compared to Dentos MSI's.

5. The surface area for Dentos MSI's were $48.27mm^2$ and for SK Surgical MSI's were $41.05mm^2$. **(Table 4 and 5)** The surface area of Dentos MSI's was more compared to SK Surgical MSI's.

MSI's with high lead angles, reduced taper, increased surface area and sharp threads are probably more appropriate for denser bone, e.g. the mandible or the palate.

Large diameter MSI (1.8x8mm)

Large diameter MSI's is used as anchorage for molar distalization or maxillary bone-borne hybrid hyrax expanders requiring higher loading forces.[67]

Dentos MSI's and SK Surgical MSI's having same diameter of 1.8mm, there was a significant difference in insertion torque. In 1mm cortical bone thickness the mean maximum insertion torque for 1.8mm diameter Dentos MSI's was 32.50 ± 0.41Ncm and SK Surgical MSI's was 30.74 ± 0.37Ncm. In 2mm cortical bone thickness the insertion torque values were increased close to one-third times. The mean insertion torque for Dentos MSI's was 41.36 ± 0.24 Ncm and for SK Surgical MSI's 39.64 ± 0.51 Ncm.**(Table7)** Both the MSI's had very high insertion torque.

The results of our study showed that, when the diameter of the MSI’s increases from 1.3mm to 1.5mm to 1.8mm the mean peak insertion torque values also correspondingly increased and was consistent.

In Dentos MSI's the insertion torque was more as compared to SK Surgical MSI's. The variation in insertion torque could also be due to the following geometric design characteristic of MSIs.

1. The number of threads in Dentos MSI's were 11 compared to SK Surgical MSI's which were 8. **(Table 4 and 5)** Dentos MSI's had more threads. Hence pitch value less for Dentos MSI's compared to SK Surgical MSI's. According to **Kithara et al** reduced pitch values increases insertion torque[61]. According to study by **Marigo et al** as the number of threads increase the MSI bone contact increases, resistance to displacement increases and thereby increases the primary stability.[70] Hence our study suggests Dentos MSI's will have increased primary stability than SK Surgical MSI's.
2. The depth value for SK Surgical MSI's was 0.19±0.01mm and Dentos MSI's was 0.19±0.01 mm. **(Table 4 and 5)** Both MSI's were having

same depth. According to **Marigo et al** as the depth of the thread increases the insertion thread into bone increases and the primary sttability of MSI's increases.[70]

3. The lead angle value for Dentos MSI's were 10.65±0.04◦ and for SK Surgical MSI's were 9.97±0.13◦. **(Table 4 and 5)** Dentos MSI had higher lead angle values than SK Surgical MSI's.
4. The taper for Dentos MSI's were 0.05±0.01 and or SK Surgical MSI's were 0.11±0.01.(**Table 4 and 5)** SK Surgical MSI's had slightly higher taper values than Dentos MSI's. According to **Song et al** in his in vitro study demonstrated that tapered MSI with an increasing outer diameter increases the insertion torque.[105]The higher insertion torque values of the taper shape are in general associated with higher compression forces during placement which may result in necrosis of osteocytes and bone resorption. Taper values was more for SK Surgical MSI's than Dentos MSI's. SK Surgical MSI's showed lack of uniform taper. Taper was steep from fifth thread to the tip whereas in Dentos MSI's taper was uniform.
5. The surface area for Dentos MSI's were $67.74mm^2$ and for SK Surgical MSI's were $45.71mm^2$.**(Table 4 and 5)** The surface area of Dentos MSI was more compared to SK Surgical MSI.

Longer length and larger diameter MSI's with increased lead angle, reduced taper, large surface area, less depth and sharp cutting threads can be used in buccal shelf area and infrazygomtic areas.

In maxilla bone is soft and spongy, self drilling MSI's without pilot hole can be used. In mandible bone thickness is more, so self drilling MSI's with a pre drilled pilot hole is recommended to reduce high insertion torque if required.

The levels of insertion torque obtained in our study exceeded the ideal range of insertion torque recommended for obtaining stability in human bone. This variance may be attributed to the physical characteristics inherent to artificial bone.[66] Predrilling of pilot hole for MSI insertion was not done in our study. Self drilling MSI's show statistically significant higher maximum insertion torque values than do predrilling MSI's in both maxillary and mandibular sites.

The major aim of clinical practice is to maintain the MSI fixed immediately after insertion and until the conclusion of orthodontic treatment mechanics. The achievement of satisfactory primary stability provides the ideal environment for tissue healing, increasing the chances of a successful treatment. This is the main reason that primary stability parameters such as insertion torque and pull-out values continue to be widely used as stability predictors.

Obtaining an efficient interface between MSI and bone tissue continues to be the key point to achieving higher success rates.

In-office decision making regarding selection of a specific miniscrew implant type is related to host characteristics namely, bone density and cortical bone thickness and choosing the most appropriate geometrical miniscrew design combination will enhance the primary stability of the MSI and thus, the success of orthodontic therapy.

The mechanical test results from our study confirm that overall MSI design has an impact on the mechanical properties. Manufacturers should therefore provide more information on other geometric design characteristics of MSI's than solely their lengths and outer diameter so that orthodontists can select the appropriate MSI for the desired procedure.

The progressive increase in the use of orthodontic MSI's has encouraged their large-scale production and consequently the development of a wide range of devices with distinct geometrical characteristics.

Even though this in vitro study with the two commercially available MSI's from Dentos and SK Surgical had differences in body dimensions, thread designs, and surface finishes, their differences between the evaluations should not compromise their use.

In clinical situations, these data could mean that orthodontists who have planned to place a miniscrew should consider not only the safe zones, but also site characteristics to obtain better primary stability as soon as possible.

Inspite of being an invitro experiment, our study had the following strength:

1. The study was designed to simulate the near clinical situation, controlling various variables, to evaluate the insertion torque.
2. The homogeneity of the synthetic bone allowed standardization and comparison among the different situations that were tested.

Limitation of the study

The primary limitation of this study pertains to the inability to directly transfer the effects identified into the clinical situation because polyurethane blocks were used. Evaluation of soft tissue health, bone stock and orthodontic forces were not considered. Further studies focussing on the dynamic and elastic response of the bone to MSI placement are required.

All the findings of our invitro study cannot be extrapolated to clinical situation and further clinical research should be done invivo to evaluate the results of this study.

Summary and conclusion

SUMMARY AND CONCLUSION

Effective anchorage by miniscrew implants has achieved widespread acceptance in orthodontic treatment. The primary stability of MSI is important for clinical success if MSI's are to be loaded immediately. However, miniscrew implant failure such as loosening, mobility, and displacement remains a very great concern for the clinicians.

Primary stability of miniscrew implants has been associated with many factors, including insertion site, cortical bone thickness, root proximity, soft-tissue inflammation, operator technique, magnitude and loading time of the orthodontic force. Many studies have been conducted to analyze the impact of primary stability with respect to the diameter and length of the MSI'S. There has been little attention paid to other geometrical design characteristics of MSI's and its effect on stability remains to be fully understood. However, because excellent stability is necessary for these devices, it is important to know how geometrical design characteristics and mechanical properties of MSI's helps to plan a successful orthodontic treatment.

However, literature is scant with studies which has evaluated the effect of each geometric design characteristics of the MSI’s when inserted into different cortical bone thickness and insertion torque was used in this study to evaluate primary stability.

Therefore this in vitro study was done to evaluate the detailed geometric design characteristics of two commercially available self-drilling miniscrew implants to obtain measurable images of MSI's using scanning electron microscopy (SEM) and to evaluate the effects of each geometrical design parameters of MSI's on primary stability using insertion torque in different cortical bone thickness.

Conclusions drawn from this study are

A. Geometric design characteristics like decreasing the MSI pitch distance, increasing the number of threads, maintaining a uniform MSI taper and increasing the surface area of MSI's plays an important role to achieve optimal insertion torque and thereby enhancing primary stability. However, incorporating micro threads with decreasing pitch in the cervical area of threaded MSI will enhance the primary stability.

B. An increase in lead angle increases the cutting efficiency of MSI. Therefore MSI's with higher lead angles are recommended for easy insertion of MSI in thick cortical areas.

C. Increase in MSI depth reduces the core diameter of the MSI and are more prone to fracture. Hence in interdental areas with high cortical bone thickness, 1.3 mm diameter MSI's with increase in depth are not indicated. However MSI's with 1.5mm and 1.8 mm diameter with deeper thread depth increases stability in poorer quality bones.

D. An increase in the diameter of the MSI and cortical bone thickness which increases the insertion torque will enhances the primary stability. It has been suggested that MSI pitch is clinically more important than MSI diameter because the MSI diameter is limited by the bone site and space available. Whereas, pitch is not limited by available space and its effect on primary stability has been noted.

E. Predrilling with pilot hole was not done in our study, but it is recommended when large diameter MSI's are placed into thick cortical bone areas to reduce high insertion torque.

A great variability in the geometric design characteristics of MSI was observed. On the basis of the present outcomes it is assumed that MSI design parameters could be strategically matched, in order to improve its performance, according to insertion site characteristics and clinical demands concerning the directions of the forces applied. So, the clinicians must know these geometric design characteristics of MSI's in order to increase the success rates of their procedures.

The purpose of the present study is to provide information about miniscrew implant design that might provide a foundation for the development of improved MSIs. Existing MSI designs are relatively similar and have remained basically unchanged since their introduction. New designs may lead to more creative anchorage possibilities

Are there design possibilities yet to be introduced that could improve on the basic designs presently available. Hence further research and clinical studies must demonstrate whether these results are relevant for both primary stability and long term stability during the entire time that MSI's are in use.

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Annexures

Annexure – I

RAGAS DENTAL COLLEGE & HOSPITAL
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TO WHOMSOEVER IT MAY CONCERN

Date: 18.12.2017
Place: Chennai

From
The Institutional Review Board,
Ragas Dental College and Hospital,
Uthandi,
Chennai – 600 119.

The dissertation topic titled **"EFFECT OF MINISCREW DESIGN CHARACTERISTICS AND BONE PROPERTIES ON INSERTION TORQUE FOR PRIMARY STABILITY."** submitted by **Dr. MATHEW S CHERICKEN.,** has been approved by the Institutional Review Board of Ragas Dental College and Hospital.

Dr. N.S. Azhagarasan M.D.S,
Member secretary,
Institution Ethics Board,
Ragas Dental College & Hospital
Uthandi, Chennai – 600 119.

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Annexure – II

URKUND

Urkund Analysis Result

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