STABILITY OF TEMPORARY ANCHORAGE DEVICES IN VARYING PORCINE BONE DENSITIES

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by
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ABSTRACT

Objectives: Human bone density varies between areas of the maxilla and mandible. Orthodontists place Temporary Anchorage Devices (TADs) in all parts, guided by bone porosity and intra-oral location. These decisions may influence TAD stability, defined as the amount of interlocking between the TAD and bone immediately after insertion. The aim of the study was to evaluate the effect of bone mineral density (BMD) on TAD stability in vitro.

Methods: Porcine jawbone samples were collected from a local slaughterhouse and maintained hydrated. Samples were created by sectioning rectangular blocks of approximately $1.5 \times 1.5 \times 3$ cm^3 from different jaw locations and scanned using SkyScan 1127 with appropriate settings (16 mm pixel size, large camera, 100Kv, 100mA, 10W, 180° rotation, and 0.5Al filter). The BMD of the samples was quantified by converting the x-ray attenuation coefficients to BMD. Twenty (n=20) Rocky Mountain TADs of 1.6 mm × 8 mm were inserted perpendicular to the surface of the bone samples. To evaluate TAD stability, all TADs were subjected to a tangential force on an Instron machine until the TADs were displaced 2.5 mm. The force required to displace the TADs overtime was recorded, and the slope was calculated to determine resistance to displacement.

Results: The mean BMD, resistance to displacement and yield point were 1.20 g/cm^3 ± 0.12, 95.57 N/mm ± 29.14, and 29.04 N ± 10.78. Our results indicate no significant relationship between BMD and TAD resistance to displacement, and between BMD and yield point, as determined by Pearson correlation test (0.109, -0.188) and a two-tailed significance test ($p = 0.647$, $p = 0.428$), respectively.

Conclusion: Data from this study design did not reveal any association between BMD and TAD stability. Changes in the study protocol such as, bone harvesting from jaw sites with lower BMD, or alterations in TAD length might provide different results.

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TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

CHAPTER 1

INTRODUCTION

Temporary Anchorage Devices (TADs) are mini-screws inserted by the orthodontist to serve as skeletal anchorage in orthodontic tooth movement. Their principal clinical applications include retraction of anterior teeth, protraction of posterior teeth, molar or arch intrusion, and molar distalization (Papadopoulos, 2007). Commercial TADs are available with different screw characteristics such as length, diameter and shape (Singh, 2010). Even though the American Dental Association does not have official recommendations on TAD insertion protocol, there have been numerous studies providing guidelines on the intraoperative insertion technique such as the insertion method (self-tapping or self-drilling) as well as, the insertion angle of the screw. The same holds true for studies that provide guidelines for TAD selection regarding TAD length and diameter and the insertion torque (Singh, 2010). Another consideration of practitioners in choosing a TAD is the density of receiving bone. Longer length TADs are placed into the trabecular bone whereas, shorter TADs are chosen to be placed into cortical bone (Singh, 2010). There are no clear recommendations, however, on how to choose a TAD design and their insertion protocol based on bone properties; specifically, porosity and bone mineral density. On average, maxillary bone is two times less dense than mandibular bone (Gulsahi, 2010). Anterior regions of the mandible are denser than posterior; and the same is true for the maxilla (Devlin, 1998). Primary stability of mini-screws refers to the amount of mechanical interlocking between the mini-screw and the bone immediately after its insertion (Proffit, 2018). A recent report suggested that TADs are more stable in denser synthetic bone (0.64 g/cc) compared to less dense synthetic bone (0.56 g/cc) with an average reduced pull-out strength and insertion torque of around 15% for the mini-screws placed in the less dense bone (Shah, 2012). It should be noted, however, that study was conducted on synthetic bone samples, which may be unrealistic as it disregards the real human bone microstructures. Another study evaluated the effect of bone quality and quantity on TAD primary stability, but the study was only conducted using human cadaveric palatal bone and did not consider other intra-oral locations (Bourassa, 2018). Interestingly, most studies that evaluated TAD stability employed a pull-out or pure vertical force. TADs are known to fail due to loosening under constant orthodontic loading (Dalessandri, 2014). A vertical force pulling TADs is not commonly found in clinical scenarios except occasionally on the palate (Lee, 2013). To overcome limitations of reported studies, this study will investigate the stability of TADs in different densities of porcine bone that correlate with bone densities of regions of the human jawbones. TAD stability will be simulated via loosening through the measurement of force subjection over time to produce 2.5 mm of mini-screw deflection. Results from this investigation could provide new guidelines and protocols for practitioners in regard to TAD considerations to help improve their clinical success.

CHAPTER 2

REVIEW OF THE LITERATURE

2.1 Orthodontic Anchorage

Orthodontics is a specialty of dentistry that treats misaligned teeth. In order to achieve proper tooth position, forces are applied to the teeth via appliances such as, brackets and wires or clear aligners (Feldman, 2006). Orthodontic anchorage is the prevention of undesired tooth movement, and is employed to divert these reciprocal forces and help control wanted tooth movements during treatment (Daskalogiannakis, 2000). The teeth, the palate, the head/neck and by placing mini-screws (TADs) into bone can all provide anchorage.

In the process of deciding which type of anchorage to use for a case, there are multiple factors to consider such as the number of teeth being moved, the type of teeth being moved, the type of tooth movement, periodontal condition, duration of tooth movement and the anchorage value of each tooth, which is about equal to the tooth's root surface area (Krishna, 2016). There are three different types of anchorage defined as maximum, moderate and minimum anchorage as presented in Figure 1 (Gianelly, 1971). The difference is based on the extent of movement that occurs in both the active (tooth/teeth undergoing movement) and reactive units (tooth/teeth acting as anchorage during movement of the active unit) during force application when closing spaces (Gianelly, 1971).

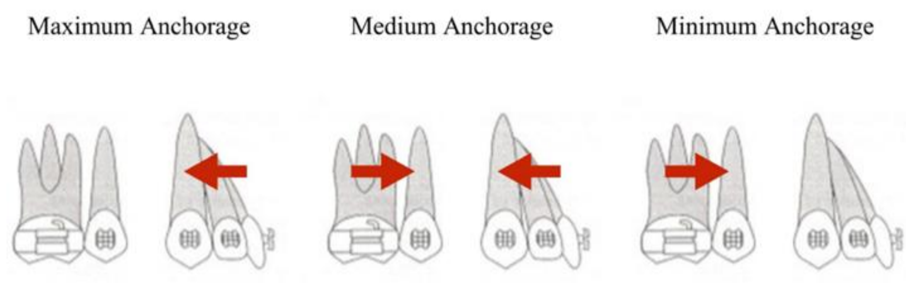

Figure 1. Orthodontic Anchorage. (Nanda, 2010)

Marcotte in 1990 defined space closure via maximum anchorage when there is 75% anterior retraction and 25% posterior protraction. Maximum anchorage is provided by different external appliances such as Nance appliance and a headgear. Moderate anchorage is about equal posterior and anterior movements to close spaces. Moderate anchorage can be supplied via a transpalatal arch, a lower lingual holding arch, or using multiple teeth together (tooth mass) to equally close spaces. Minimum anchorage is defined as 75% of space closure is achieved through mesial movement of posterior teeth and can be carried out by the use of a power chain to close spaces (Krishna, 2016). Without anchorage considerations, final treatment goals for the amount of relative protraction and retraction will not occur as planned. More recently, the idea of skeletal anchorage is considered. Skeletal anchorage uses the bone as anchorage support in order to obtain desired orthodontic tooth movements.

2.2 Orthodontic Mini Screws

Skeletal anchorage is achieved by the use of orthodontic mini-screws also known as temporary anchorage devices (TADs). A TAD is a mini-screw that is temporarily fixed into the bone enhancing orthodontic anchorage directly or indirectly (Singh, 2010).

Direct anchorage is when the TAD is the direct source of the anchorage and receives the reactive forces of the moving tooth or teeth (Holberg, 2013). The moving teeth can be attached to the TAD by a power chain or a coil spring. Indirect anchorage is when the TADs are connected via a bar or a wire to a stabilized tooth or teeth, which ultimately receive the reactive forces from the moving teeth (Holberg, 2013). An example is a TAD supporting a transpalatal arch appliance. The TADs' ability to provide anchorage allows orthodontic tooth movement to not only be more controlled but also more predictable, since there is less anchorage loss and less undesired tooth movements compared with non-skeletal anchorage (Barthélemi, 2019). The development of temporary anchorage devices was based on the combination of traditional orthodontic anchorage, dental implants and orthognathic fixation methods while employing the principles of osseointegration and orthodontic mechanics (Singh, 2010). In 1996, the first clinical implementation of TADs for anchorage was conducted on the palate to retract the upper anterior teeth in a Class II malocclusion. The result was 8 mm of anterior teeth retraction in order to correct the bite (Wehrbein, 1996).

TADs come in different shapes and sizes. They have lengths that range from 6-12 mm and diameters from 1-2 mm (Lyczek, 2017). They can also have varying thread shapes and be tapered or cylindrical in shape. Figure 2 shows different types of TADs. TADs can look very similar to implants in size and shape, however there are distinctions. First, Kanomi in 1997 described TADs to be tiny enough so they can be inserted in various locations within the jawbones and can be easily placed and removed by the orthodontist (Kanomi, 1997).

Figure 2. Rocky Mountain Orthodontics (RMO) Dual-Top TADs (Rocky Mountain Orthodontics)

Second, the desire for and the extent of osseointegration. Osseointegration is not desired in orthodontic mini-screws, as they are used temporarily for anchorage and will eventually be removed unlike dental implants (Kanomi, 1997). Dental implants and TADs are both made from titanium alloys due to its accepted biocompatibility. Titanium alloys normally form an oxide layer on the surface, which promotes osseointegration (Liu, 2017). However, the surface of TADs is smoothed (reduction of roughness), which helps deter and prevent any osseointegration up to a certain extent, depending on its insertion time (Singh, 2010). After microscopic examination of TADs placed in beagle dogs for a minimum of 6 months, however, Vannet showed that partial osseointegration of orthodontic mini-screws does occur (Vannet, 2007). Additional differences include that mini-screws can and are meant for immediate force application of up to 200 g; and their failure is dependent on their primary stability rather than the success of osseointegration (Lyczek, 2017).

2.3 TAD Primary Stability

Primary stability of TADs is determined by the mechanical retention of the screw in bone or bone to screw contact (Proffit, 2018). The primary stability of TADs in clinical studies was correlated with TAD success or failure (Dalessandri, 2014). Unfortunately, success and failure were not equally defined across studies, so it is difficult to concretely define TAD stability and success. Nevertheless, a common trend in the definitions was clinically detectable loosening of the TAD (Dalessandri, 2014).

There are several methods used to measure the primary stability of orthodontic mini-screws. It can be assessed qualitatively by the orthodontist or quantitatively using methods such as insertion/removal torque, resonance frequency analysis, the periotest, and the pull-out test (Tepedino, 2017). Insertion torque is the frictional resistance between the screw thread and its surrounding bone when inserting the mini-screw into bone. Maximum insertion torque, which is expressed in N·cm, is the maximum torque value recorded during the insertion of orthodontic mini-screws. Studies in dental implants have shown that insertion torque and implant micromotion are exponentially related. When there is micromotion, there is a decrease in stability and insertion torque (Brizeula-Velasco, 2015). In order to achieve primary stability of TADs, a certain level of maximum insertion torque is necessary to guarantee that the mini-screw has enough mechanical retention within the bone. It was demonstrated that this optimal insertion torque value is between 5-10 N·cm, independent of insertion location, because too low a torque indicates insufficient mechanical fixation of the mini-screw in bone and too high a torque reflects too strong of pressure exerted by the mini-screw on the bone, which may lead to ischemic osteonecrosis (Motoyoshi, 2006).

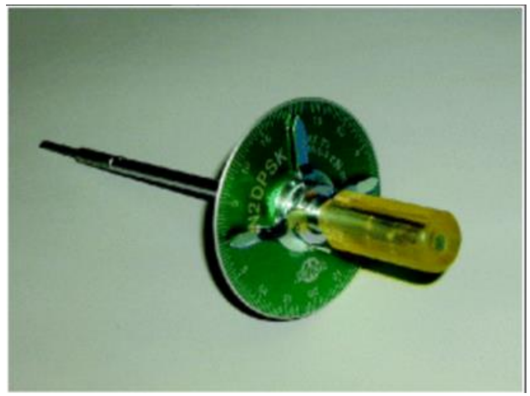

Figure 3. Torque Screwdriver. (Motoyoshi, 2006)

Insertion torque, as an indirect method to measure primary stability of mini-screws, is done by using either mechanical torque gauges or digital torque sensors (Reynders, 2012). An example of a torque screwdriver can be seen above in Figure 3. Removal torque has also been used, which records the force needed to remove the mini-screws (Chen, 2006). Due to the possibility of osseointegration, however, this method is less accurate since increased torque removal values can be a result of partial osseointegration.

Resonance frequency analysis (RFA) is a method used to assess the TAD stability by attaching a transducer directly to the mini-screw. Electromagnetic impulses are emitted from the mini-screw in order to detect its resonance frequency and translates it into an implant stability quotient (ISQ) value. The values tend to range between 40 and 80. The higher the ISQ value, the higher the stability. RFA has been shown to be an accurate and sensitive method to noninvasively measure stability throughout the life of the mini-screw (Seifi, 2016).

A periotest is another noninvasive method that has been shown to measure mini-screw stability (Seifi, 2016). The periotest device produces a transient vibration on the mini-screw via a periotest handpiece, which is electromagnetically accelerated. The device shows periotest values (PTV), where a more negative PTV corresponds with more stability of the mini-screw (Seifi, 2016). Reports have revealed that RFA and the periotest are both strong measures of stability with RFA being slightly more reliable (Al-Jetaily, 2011).

The pull-out test is an invasive method used to measure primary stability of TADs by recording the pure vertical force needed to pull-out the mini-screw from the bone (Yashwant, 2017). Higher pull-out forces are correlated with increased stability due to the better "attachment" of the TAD to bone. This evaluation method is usually employed in laboratory testing. A major limitation of this method is the lack of clinical replication. Orthodontic forces are usually directed in an oblique direction in relation to the mini-screw's long axis (Yashwant, 2017). Additionally, TADs are not subjected to high magnitude forces in clinical settings. Therefore, pull-out forces ignore realistic conditions, and their clinical correlation is more limited.

A variation of the pull-out tests is loading the mini-screw in a direction perpendicular to its axis, which represents a closer clinical scenario (Tepedino, 2017). For this evaluation method, TADs are displaced for 1.5 mm representing the amount of displacement that would lead to a clinically mobile mini-screw and lead to potential failure (Brettin, 2008). This method of measuring the primary stability of mini-screws will be used in this study, as it attempts to resemble a more clinical scenario.

The primary stability of TADs can be influenced by several factors including screw design (diameter, length, thread), placement technique (insertion angle and torque), and bone properties (quality and quantity) (Lyczek, 2017).

2.4 Mini-Screw Design Characteristics and Primary Stability

There are several different design characteristics of TADs that include the length, diameter, thread shape factor, and form that all influence its primary stability. Some examples of TADs of different diameters and lengths are seen in Figure 4.

Figure 4. Different Available TADs. (Dentist Skysea)

A recent study explored the influence of TAD length on stability. When TADs were placed in patients' mandibles, the 8 mm length mini-screws were more stable than 6 mm length screws, and a length of at least 8 mm was sufficient to achieve primary stability (Sarul, 2015). However, this study had a limited sample size, and the possibility of confounding factors such as the bone quality and quantity to make solid conclusions.

In discussing mini-screw diameter, Motoyoshi et al. suggested that screws with a diameter equal to or smaller than 1.0 mm should be avoided because of their significantly higher failure rate than larger diameter mini-screws (Motoyoshi, 2017). The overall recommendation is to use mini-screws with a diameter of at least 1-2 mm to improve their primary stability, and thus their mechanical retention.

The “thread shape factor” is the fraction of thread depth over thread pitch, denoted as a percent. A higher ratio significantly correlates with increased mini-screw primary stability by increasing the resistance of the screw to removal (Migliorati, 2013).

Lastly, one study explored the differences in primary stability for tapered versus cylindrical mini-screw designs in dogs (Cha, 2010). Results showed that the tapered design had an increased primary stability until 3 weeks after loading compared to the cylindrical design. At 12 weeks after loading, the design did not have any additional effects on the secondary stability (Cha, 2010).

It is important to note that all of these aforementioned studies, regarding TAD design, are merely references each examining one of several variables that factor into mini-screw stability. It is difficult to compare these studies as well as make a universal guideline for mini-screws. Nevertheless, it is important to understand how all of these different variables can influence stability.

2.5 Mini-Screw Placement Technique and Primary Stability

Not only do the mini-screw design features play a role in primary stability, but factors such as insertion method and operator skill play a role as well. Mini-screws can be inserted via either a self-tapping (pre-drilling with a pilot hole) or self-drilling (drill-free) method (Singh, 2010). According to a current systematic review and meta-analysis, clinical studies have shown similar success rates for self-drilling compared to self-tapping placed mini-screws (Yi, 2016). One might consider either no pilot hole or drilling a smaller one when placing mini-screws in the maxilla in order to promote more stability due to the maxilla's thin cortical and thick cancellous bone (Lyczek, 2017). Conversely, the mandible with its thick cortical bone might make one consider using the self-tapping method of insertion. It is because without pre-drilling, there is a higher risk for the operator to use excessive pressure on the bone leading to ischemia and necrosis (Lyczek, 2017).

The placement angle of the orthodontic mini-screw is another consideration for primary stability. Lee et al. placed TADs at various angles of insertion to see the angle's impact on TAD primary stability (Figure 5). The study showed that placement of mini-screws perpendicular to the cortical bone leads to the highest primary stability and that angles less than α=60 degrees can reduce the stability of the mini-screws when subjected to forces from various directions (Lee, 2013).

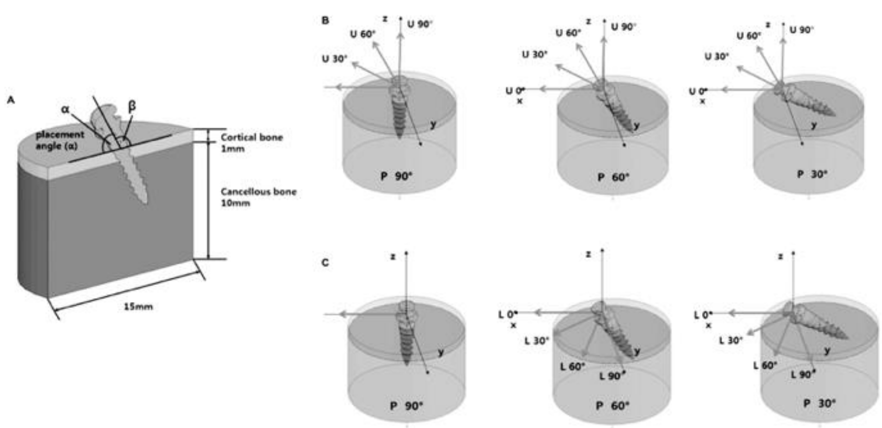

Figure 5. Angles of Insertion. (Lee, 2013)

Operator experience also plays a major role in mini-screw primary stability (Lee, 2013). Lim et al. reported that clinicians who inserted at least 20 mini-screws had a 3.6 times higher chance of achieving primary stability, compared to operators who had performed fewer procedures. However, some potential confounding factors were the insertion site and length and diameter of the mini-screw (Lim, 2011).

2.6 Bone Properties and Primary Stability

Bone quality and quantity play major roles in achieving primary stability of TADs (Wilmes, 2011). Reports of experimental studies have shown a positive correlation between both cortical bone thickness and density and increased primary stability of mini-screws (Wilmes, 2011). The cortical bone thickness varies depending on the area of the jaw. The maxilla had a buccal cortical thickness ranging from 1.59 to 2.23 mm and a lingual cortical thickness ranging from 1.95 to 2.35 mm (Katranji, 2007). In the mandible, these measurements were 0.99 to 1.98 mm and 1.24 to 2.51 mm for the buccal and lingual cortical thicknesses respectively (Katranji, 2007). A study by Baumgaertel found that the mean palatal cortical bone thickness was highest at the anatomic contact point of the canine and first premolar at 1.49 mm ± 1.16 mm and decreased going posteriorly to a mean of 1.00 mm ± 0.40 mm for the anatomic contact point between the first and second molars (Baumgaertel, 2009). These measurements are illustrated below in Figures 6A and 6B.

A) B)

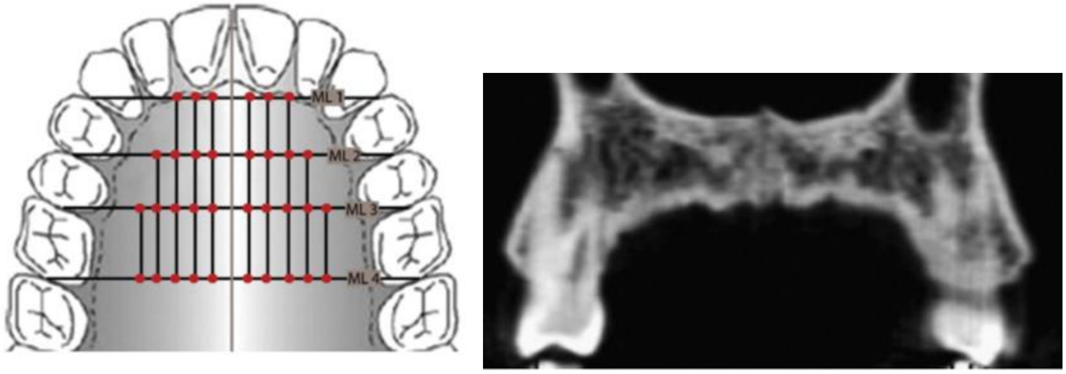

Figure 6. Measurements of Bone Thickness at Different Locations A) Anatomic Contact Points, B) Transverse Slice of Palate Between the Premolars. (Baumgartel, 2009)

General trends in the cortical bone thickness of the palate are higher in the anterior palate as compared to the middle and posterior palate. Additionally, the cortical bone thickness is higher for the midline as compared to the middle and lateral areas of the palate (Manjula, 2015). Motoyoshi et al. discovered that the critical thickness to ensure sufficient primary stability is 1 mm (Motoyoshi, 2007). Overall, mini-screws were 6.93 times more likely to fail when the cortical bone thickness was less than 1.0 mm compared to 1.0 mm or greater (Motoyoshi, 2007). Thus, thicker cortical plates promote increased stability of mini-screws.

Bone mineral density (BMD) is the quantity of bone tissue in a volume of bone, and it varies throughout different regions of the jaws. Lekholm and Zarb categorized human bone into 4 groups as seen in Figure 7. Type 1 is homogenous cortical bone primarily found in the anterior mandible and midpalatal region. Type 2 is a large layer of cortical bone around a core of dense trabecular bone primarily found in the anterior maxilla, the midpalatal region and the posterior mandible. Type 3 is a small layer of cortical bone around dense trabecular bone primarily found in the posterior maxilla and mandible. Type 4 is a small layer of cortical bone around a core of low-density trabecular bone primarily found in the posterior maxilla and tuberosity region (Lekholm, 1985).

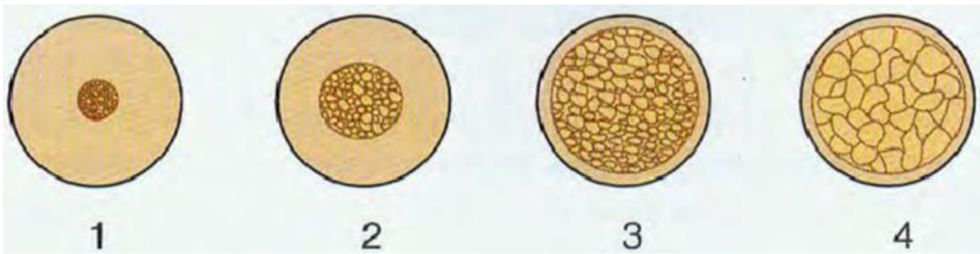

Figure 7. Different Types of Bone Quality. Type 1: Homogenous Cortical Bone, Type 2: Large Layer of Cortical Bone Around a Center of Dense Trabecular Bone, Type 3: Small Layer of Cortical Bone Around Dense Trabecular Bone, Type 4: Small Layer of Cortical Bone Around a Core of Low-Density Trabecular Bone. (Lekholm, 1985)

As seen in Table 1 below, the mean bone mineral density for the mandible is 1.11 g/cm^3 with the anterior mandible being denser than the posterior mandible. The mean bone mineral density of the anterior and posterior maxilla is 0.55 g/cm^3 and 0.31 g/cm^3 respectively; including the hard palate with a mean of 0.45 g/cm^3 (Devlin, 1998).

Table 1. *Mean Bone Mineral Densities of the Jaws* (Devlin, 1998)

Bone site	**Mean BMD**	**SD**
M_b	1.11	0.3
MX_a	0.55	0.14
MX_p	0.31	0.14
MX_{pp}	0.50	0.16

SD, Standard deviation; M_b, mandibular body; MX_a, anterior maxilla; MX_p, posterior maxilla; MX_{pp}, posterior maxilla including hard palate.

As bone density decreases, strength of the bone also decreases. Type 1-3 bone has been found to be adequate for mini-screw insertion but placement in type 4 bone is not recommended due to its higher failure rate (Chugh, 2013). Unfortunately, BMD and its exact relationship to TAD stability has not been thoroughly investigated. However, bone thickness and density can be accurately measured using micro-computed tomography.

2.7 Micro-Computed Tomography (Micro-CT)

Micro-computed tomography (micro-CT) is a non-destructive imaging tool for the production of high-resolution three-dimensional (3D) images composed of two-dimensional trans-axial projections, or slices, of a target specimen. In micro-CT, the sample rotates while x-rays pass through it, so multiple views can be acquired. The tissue samples absorb and deflect the x-rays at differing amounts, and the micro CT records these varying x-ray intensities (News Medical Life Sciences). The 2D images obtained are reconstructed into a 3D image with the help of a computer producing 3D images with voxel size of about 1 μm. This small voxel size provides an increased resolution image (Boerckel, 2014). Some advantages of micro-CT scanning are providing 3D images without altering or destroying the specimens, whether material or biological. Additionally, it provides x-ray imaging on a smaller scale and with increased resolution compared to medical CT scans. It is also a rapid technique where the reconstruction, analysis and interpretation of the images is easy. Some weaknesses of micro-CT are that the use of radiation can alter the size of some tissues and thus the results. Additionally, some types of tissues cannot be micro-CT, and micro-CT is not able to distinguish similar types of tissues (News Medical Life Sciences). Overall, micro-CT is useful to study bone, teeth, tissue and other materials (Micro Photonics). It can examine features such as bone structure and quality as well as the bone mineral density, which all play important roles in the primary stability and ultimate success of mini-screws. An article by Irie explains how BMD can be measured by the amount of hydroxyapatite in the bone. Additionally, the parameters for choosing the proper resolution, regions of interests and thresholds for bone analysis of the maxilla and mandible using micro-CT are also delineated (Irie, 2018). In this study, micro-CT is being used to evaluate the bone densities of the porcine jaws prior to TAD insertion.

2.8 Limitations of Past Studies Studying TAD stability

There have been several studies investigating the influence of bone mineral density on TAD stability with some significant shortcomings. In 2020, Elibol et al. placed orthodontic mini-screws into synthetic bone blocks, with varying densities that simulated cortical bone, to test the effects of bone density on the pull-out strength of TADs (Elibol, 2020). Elibol et al. found a statistically significant increase in the primary stability of the TADs placed in denser blocks (0.80 g/cm^3, 0.72 g/cm^3 and 0.64 g/cm^3). Shah et al. did a very similar study but tested insertion torque in addition to pull-out strength and found a statistically significantly higher maximum insertion torque and pull-out strength for TADs placed in higher density bone (0.64 g/cm^3 and 0.55 g/cm^3) (Shah, 2012). Pan et al. also used synthetic bone with different densities (0.64 g/cm^3, 0.32 g/cm^3 and 0.16 g/cm^3) but resonance frequency analysis was performed to measure stability (Pan, 2019). Pan et al. found a linear correlation between density and RFA. Overall, these studies found a positive correlation between bone density and their respective methods to measure stability. A major limitation of these studies was the use of artificial bone structures. Even though artificial bone structures can provide relatively repetitive and consistent results, real bone has viscoelastic properties that more accurately mimic true biological conditions (Elibol, 2020). Another study evaluated the effect of bone quality and quantity on TAD primary stability by measuring insertion torque, but the study was only conducted using human cadaveric palatal bone and did not examine the maxilla or mandible, which are primary locations for mini-screw anchorage (Bourassa, 2018). Additionally, all of the above-mentioned studies did not test the loosening of the screws to measure primary stability, which might represent a more clinical scenario.

To overcome the limitations of reported studies, this study will investigate the effect of BMD on TAD stability in vitro using porcine jaw bones rather than synthetic bone. TAD stability will be evaluated by applying a force perpendicular to bone blocks and measuring the force over time to produce 2.5 mm of mini-screw deflection.

CHAPTER 3

AIMS OF THE INVESTIGATION

The aim of the study is to evaluate the stability of TADs after insertion into porcine bone samples with different densities (porosities). Specific aims are:

- To collect and section samples of porcine bone with varying densities that correlate with various mini-screw insertion locations of the human jaw
- To determine if there is a significant difference between the primary stability of mini-screws in varying densities of bone

Significance

Evaluating the stability of TADs after inserted into real bone with varying densities will help determine the relevance of this parameter. If significant differences are found in the primary stability of the TADs, other TAD considerations (e.g., intraoral location of TAD placement) that help increase their clinical service, should be taken into account by orthodontists.

CHAPTER 4

MATERIALS AND METHODS

4.1 Sample Preparation

For this study, an adult porcine maxilla and 2 mandibles were procured from Clemens Food Group in Hatfield, PA. Figure 8A shows the two mandibles that were obtained for the study. These bones were manually cleansed of any soft tissue and hemi-sectioned using a low-speed precision cutting machine. Sixteen bone samples (N=16) of approximately 1.5x1.5x3 cm^3 were obtained, so they could fit into the micro-CT machine. Figure 8B outlines the cuts made on one of the mandibles to make the bone blocks for the study.

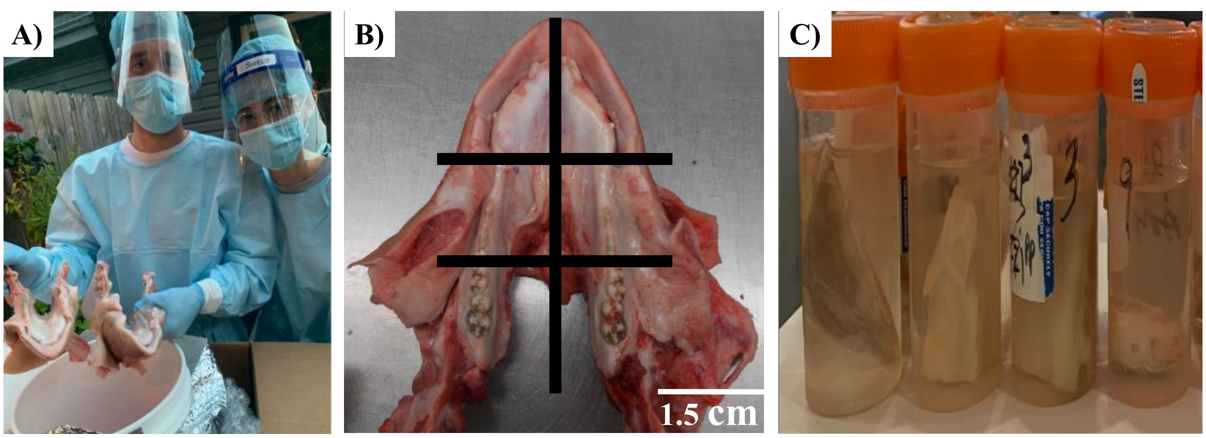

Figure 8. Sample preparation. A) Porcine bone collection, B) Porcine mandible, C) Sectioned samples from different locations

After sectioning, samples were immediately placed in a sample holder and submerged into phosphate-buffered saline (HBSS) to prevent de-hydration seen in Figure 8C. Samples were kept refrigerated at 4° Celsius before testing and evaluation to maintain their properties (Assad-Loss, 2017).

4.2 Micro-CT

Bone samples were placed in a holder with parafilm and scanned with the Skyscan Micro-CT machine (SkyScan 1172; Skyscan, Aartselaar, Belgium). An image of the SkyScan can be seen below in Figure 9. The scan specifications used were: 16 mm pixel size, large camera size, 100 Kv, 100 mA, 10 W, 180° rotation, and 0.5 Al filter. These parameters allowed the proper determination of the bone mineral density. In addition, these parameters were chosen due to the larger bone samples sizes. To allow an increased number of projections to be made in order to minimize noise, the scan settings were a frame averaging of 6, 0.4 degrees of rotation and random movement of 10.

Figure 9. Micro-CT machine (SkyScan)

Each scan was rebuilt using NRecon V1.6.10. For this reconstruction, the ring artifact was set to 10 and the smoothing was set to 2. Lastly, beam-hardening correction was set to 60%. Using Dataviewer V1.5.2, the rebuilt dataset of the bone samples was then reoriented in a transverse, coronal and sagittal view, seen in Figure 10A, in order to analyze the bone for insertion sites.

The appropriate regions of interest (ROI) were loaded into the CT-Analyzer V1.14.4.1 software. Twenty ROIs, which would be the TAD insertion sites, of 9x3x3 mm^3 were selected in the bone samples that had solid bone throughout. An example ROI is shown in Figure 10B. These dimensions were chosen to ensure there would be ample bone surrounding the 1.6 mm x 8 mm TADs when inserted in all dimensions. The cortical bone thickness and the mean bone mineral density of these ROIs were measured using the CT Analyzer software (Bouxsein, 2010). These twenty sites were located on the original sixteen bone samples for TAD placement.

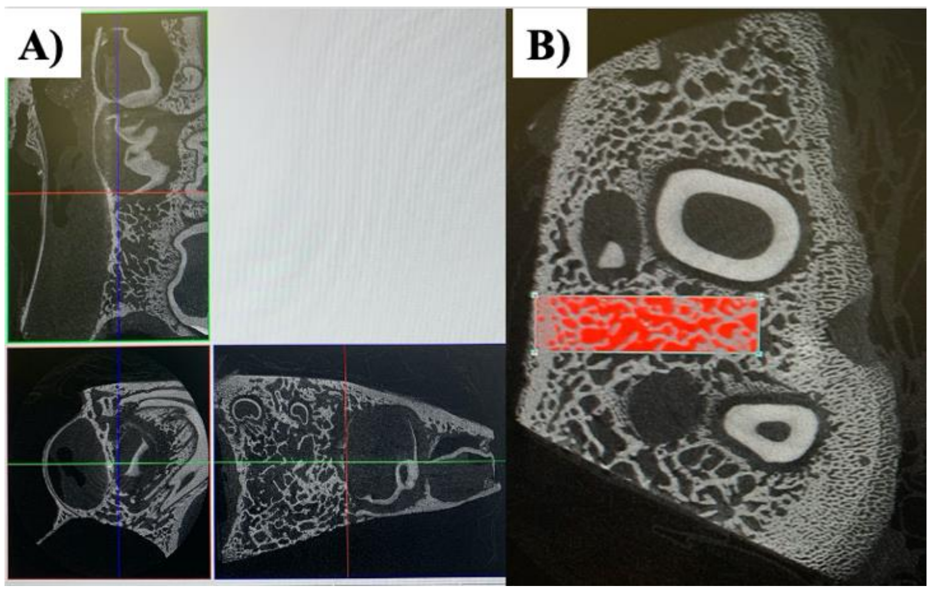

Figure 10. Micro-CT. A) Bone reorientation, B) Selecting the ROI

4.3 Mechanical Testing

Twenty 1.6 mm diameter and 8 mm length crosscut (Rocky Mountain Orthodontics) TADs were inserted into the bone samples corresponding with the twenty suitable sites determined from micro-CT. All TADs were placed with a manual digital torque screwdriver (Rocky Mountain Orthodontics) set to 10 N·cm and inserted until the collar was 1 mm from the bone surface to account for a 1 mm soft tissue thickness. The screws were placed at 90° to the bone surface and steel ligatures were tied around them. The bone samples were then placed in an Instron machine, which is a machine that measures the mechanical properties of materials. This setup can be seen in Figure 11. In this study, the actuator of the Instron machine pulled each TAD at a rate of 0.5 mm/sec for approximately 2.5 mm of deflection. This amount of displacement was selected to include the amount of movement that would result in a clinically mobile mini-screw and potential failure, which is around 1.5 mm (McManus, 2011). The force versus displacement of each TAD was recorded. The force over displacement data for each TAD was placed in an Excel spreadsheet and graphed. The data were visually cleaned by removing the beginning of each of the curves, which represents the elongation (pre-tension) of the stainless steel ligatures used. This filtration step enabled the recording of the real displacement of the TADs during tension. The force-displacement curves were also cut off at their yield points and this force for each TAD was identified. The slope of the linear portion of the curves (resistance to displacement) was calculated.

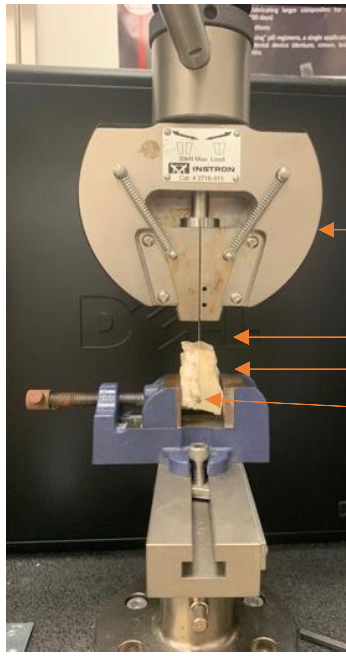

Figure 11: Mechanical Testing Set Up

4.4 Statistical Analysis

A Pearson correlation test and a two-tailed significance test using $p<0.01$, as a cutoff for significance, were conducted between the bone density, the slope of force over displacement (stability), cortical bone thickness and the yield point. This was performed in order to evaluate if there is a relationship between BMD and these respective factors.

CHAPTER 5

RESULTS

Of the twenty suitable sites in the bone samples, the micro-CT determined the mean BMD to be 1.20 g/cm^3 ± 0.12 g/cm^3 with a range of 0.995-1.41 g/cm^3. The BMD of all 20 sites can be seen below in Figure 12. The BMD of the suitable sites for bone placement were all relatively similar and toward the higher end of human jaw bone densities, most closely resembling the average BMD of the mandibular body between 1.11 g/cm^3 ± 0.3 g/cm^3 (Devlin, 1998).

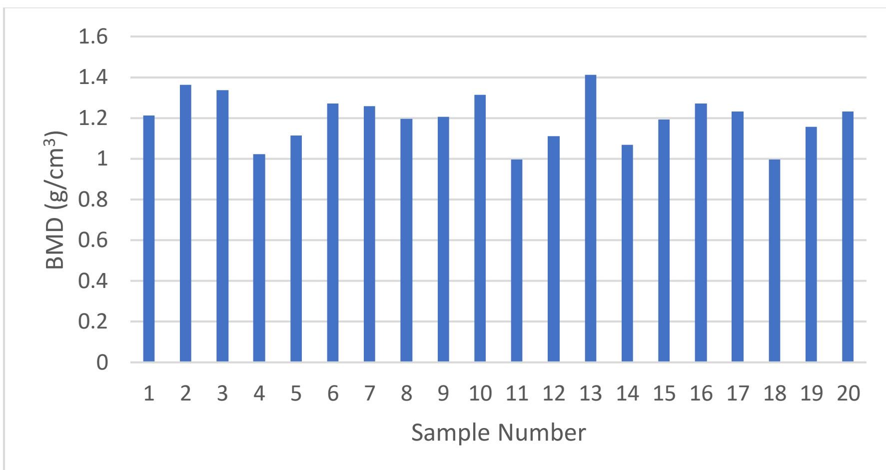

Figure 12: BMD for Different Bone Samples

A representative curve for TAD #3 is shown below in Figure 13 for the load vs displacement. The slope of this plot (resistance to displacement) is shown below at 140.46 N/mm and represents the resistance to displacement of the TAD. Additionally, the last point of the plot, at 22.5 N, represents the yield point of the curve.

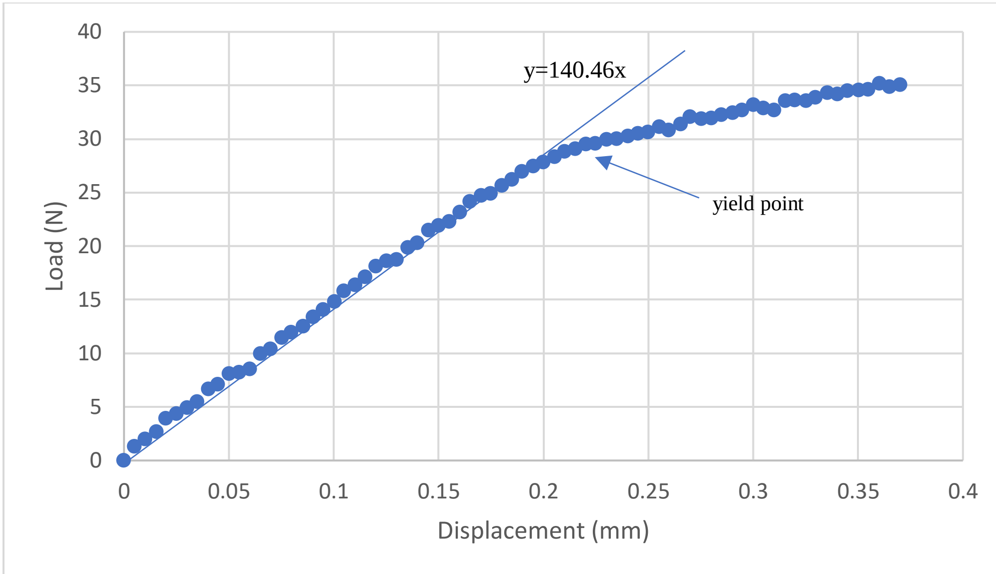

Figure 13: Force vs. Displacement Curve During Pulling of TAD #3

TADs #6, 8, 10, 13, 15 and 18 had significantly lower slopes than the rest of the TADs. This can be attributed to human error when either placing these TADs or during mechanical testing. Thus, they were removed from the dataset prior to statistical analysis. In Figure 14, the slopes of each TAD's resistance to displacement as well as their yield points can be observed. After evaluating all of the included TADs cleaned individual slopes, the mean slope of the force versus deflection curve was 95.57 N/mm ± 29.14 N/mm, and the mean yield point was 29.04 N ± 10.78 N. This raw data can be found in Appendix A.

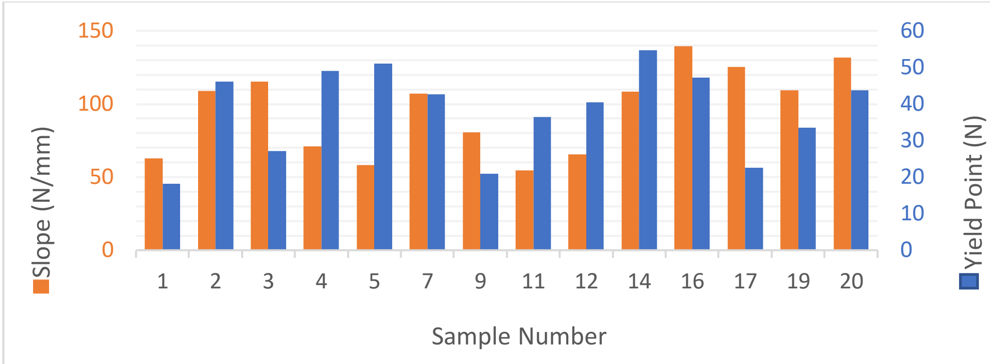

Figure 14: Slope of Force vs. Displacement and Yield Point

Our results indicate no significant relationship between BMD, TAD resistance to displacement (stability) and yield point, as determined by Pearson correlation test (0.109, -0.188) and a two-tailed significance test (0.647, 0.428, $p<0.01$), respectively, as seen in Appendix B. This indicates that BMD, with a range of 0.995-1.41 g/cm^3, does not significantly influence the stability of TADs under orthodontic load. Additionally, there were no significant differences found between the highest three and lowest three bone mass density sites in terms of average slope, thickness, or yield point as seen in Appendix C. This further indicates that there is no significant influence of BMD on TAD stability when comparing a BMD of approximately 1.0 g/cm^3 to 1.4 g/cm^3.

CHAPTER 6

DISCUSSION

6.1 Results in Comparison to Current Literature

With the growing implementation of TADs, it is important to know how to maximize their success. Bone mineral density of the TAD insertion location is one factor to consider for mini-screw stability and ultimately, their clinical success. The relationship between BMD and TAD primary stability has been investigated, but they have all used different methods.

Elibol et al. found a statistically significant increase in the pullout strength of 1.6 mm x 8 mm TADs placed in higher grade compared to lower grade density polyurethane blocks (0.80 g/cm^3, 0.72 g/cm^3 and 0.64 g/cm^3) with 3 varying cortical thicknesses (1, 2 and 3 mm) using pullout tests with a 5mm/min loading rate (Elibol, 2020). Small increases in density resulted in significant increases in the primary stability of the TADs as measured by pullout strength.

Pan et al. reported a highly linear correlation between trabecular bone density and resonance frequency analysis using polyurethane foam blocks of densities 0.16 g/cm^3, 0.32 g/cm^3 and 0.64 g/cm^3, thicknesses of 1, 2 and 3 mm and 2 mm x 10 mm TADs inserted at depths of 2, 4 and 6 mm (Pan, 2019). The average resonance frequency values, and thus the stability of TADs, increased as bone density increased.

Shah et al. also found a statistically significant higher maximum insertion torque and pullout strength for TADs placed in synthetic bone of 0.64 g/cm^3 compared to 0.55 g/cm^3 using 6 mm x 1.65 mm, 3 mm x 1.75 mm and 3 mm x 2 mm TADs and cortical thicknesses of 1 mm or 2 mm (Shah, 2012). Shah et al. found that a decrease in density from 0.64 g/cm^3 to 0.56 g/cm^3 decreased insertion torque by 12.5%–18.8% and pull out strength by 1.8–4.5 kg or 14.8%–16.1% and thus primary stability (Shah, 2012).

These aforementioned studies from Elibol, Pan and Shah et al. found significant differences in the pullout strengths, resonance frequencies and insertion torques versus BMD. However, these works used synthetic bone, and the BMD of these studies used bone blocks with much lower BMD (0.16-0.80 g/cm^3) compared to this study. All of these results differed from our study which utilized real bone and a BMD ranging from 0.995-1.41 g/cm^3 with varying cortical thicknesses ranging from 0.7 mm-3.6 mm. In contrast, we did not find a relationship between BMD and TAD stability as measured by resistance to displacement. Although not comparable methods, the differences in the study designs could explain the differing results regarding BMD and stability. Synthetic bone enables uniform and consistent BMD and the cortical thicknesses can be controlled. Our bone samples did not all have sites usable for the placement of TADs because the samples had areas that lacked uniform bone. As a result, the range of BMD ended up toward the higher end of human jaw BMD rather than incorporating a larger range of jaw BMD of 0.17-1.41 g/cm^3. The cortical thickness could not be controlled between insertion sites in our study as well. Additionally, BMD may only play a role on stability of TADs up to a certain BMD, which might have already been surpassed in the BMD range used in this study.

Bourassa et al. found that insertion torque, and therefore primary stability, was not significantly but moderately affected by BMD when comparing insertion torques while placing 1.4 mm x 6.0 mm TADs into human cadaveric maxillary hard palates with density sites ranging from 0.26 g/cm^3 to 0.44 g/cm^3 (Bourassa, 2018). The study found that the insertion torque, and thus primary stability, increased when placed in areas of increasing BMD (Bourassa, 2018).

In an ex vivo study by McManus et al., it was found that the mean resistance to movement of mini-screws, or primary stability, was moderately correlated with increasing insertion torque (McManus, 2011). 96 TADs (1.5 mm x 11 mm) were placed by a digital torque driver into sectioned maxillae and mandibles of cadavers. All screws were inserted at a depth of 6 mm and at 90 degrees to the bone surface and subjected to a force perpendicular to the TADs. McManus et al. found that the mean maximum insertion torque and screw resistance to movement were larger in the mandible compared to the maxilla, which corresponds with the higher BMD in the mandible than in the maxilla.

These two studies by Bourassa and McManus et al. found a moderate correlation between BMD and TAD primary stability. Their study designs more closely resemble our study by not using synthetic bone, but rather cadaveric bone. However, there were several differences including the BMD and bone thicknesses, TAD dimensions and insertion depths as well as the means of measuring primary stability via insertion torque. When all screws were considered together in the McManus et al. study, the resistance to displacement and yield point were approximately 77.27 N/mm and 37 N, respectively. These numbers were similar to the numbers found in this study with a resistance to displacement of 95.57 N/mm ± 29.14 N/mm, and a mean yield point of 29.04 N ± 10.78 N. Ultimately, these results, as well as ours, did not find a significant correlation between TAD primary stability and BMD.

For our study, 1.6 mm x 8 mm TADs were used based on results from Motoyoshi et al. and Sarul mentioned previously, to permit adequate dimensions to minimize chances of TAD failure. The same reasoning to minimize TAD failure was implemented when choosing an insertion torque and angulation of 10 N·cm and 90° respectively, supported by Motoyoshi and Lee et al. However, not all practitioners use the same type of TADs or insertion protocol, so that needs to be considered when interpreting results from any study whether synthetic or actual bone is used. Additionally, the TADs in this study were self-drilling, so a pilot hole was not needed. Yet, placing TADs into bone with a high cortical bone thickness and BMD could produce excessive heat from the increased pressure while inserting them leading to ischemic osteonecrosis and TAD failure (Motoyoshi, 2006). This is another factor to consider when placing TADs because the mandible has denser and thicker bone than the maxilla. Ultimately, there are several different factors dental practitioners must take into account when treatment planning which type of TADs and insertion protocol they are going to use, which are case dependent and based on clinician preference.

6.2 Limitations

Our results from this study design did not reveal any association between BMD and TAD stability using porcine jawbones with a BMD range of 0.995-1.41 g/cm^3. Even though the goal of this study design was to not use synthetic bone, using real bone had its limitations. There was only so much bone that could be collected and sectioned. Additionally, even though bone was collected from the maxilla and mandible, not all of the bone was solid. As a result, TADs could not be placed in these regions. The good bone samples that were tested ended up being only higher density bone rather than including the range of densities of the human jawbone of approximately 0.17-1.41 g/cm^3, which was the aim of the study. Lastly, only twenty mini-screws were able to be placed due to the cost.

6.3 Future Considerations

Future studies could expand on this study design by harvesting more mandibles and maxillas in order to ensure usable bone samples with a lower BMD (0.17- 1.00 g/cm^3) are collected, so a larger range of BMD (0.17-1.41 g/cm^3) can be compared within the same study. Additionally, different animal bone or human cadaveric bone could be used and more mini-screws could be placed. The TADs also could have been subjected to a smaller but more clinically relevant load such as 150 g or 1.47 N over a longer period of time (Tseng, 2006). This would more closely resemble orthodontic loading conditions, rather than using a larger load over a shorter period of time as in this study. These changes might have led to different results or made the conclusions from the study stronger. Alterations in any of the mini-screw characteristics, such as length or diameter, or in insertion technique, such as torque and angulation, might provide different results as well.

CHAPTER 7

CONCLUSIONS

Twenty (n=20) Rocky Mountain TADs of 1.6 mm × 8 mm were inserted into bone blocks with BMDs ranging from 0.995-1.41 g/cm^3. A tangential force, using an Instron machine, was applied to the TADs, and the force required to displace the TADs overtime was recorded. After statistical analysis, it was determined that within a BMD range of 0.995-1.41 g/cm^3, there is no statistically significant relationship between BMD and TAD stability, as measured by resistance to displacement. Using the same TAD diameter and length, the TADs were not any less stable in lower BMD (0.995-1.02 g/cm^3) as opposed to greater BMD (1.34-1.41 g/cm^3). Changes in the study protocol, however, such as altering any of the mini-screw characteristics or using a BMD range of 0.17-1.41 g/cm^3, might lead to different results. Overall, the bone density in the anterior maxilla and mandible as well as in the posterior mandible is adequate to promote TAD primary stability. When clinicians are placing TADs in the posterior maxilla, for an upper molar intrusion as an example, the bone is not as dense, and the TAD will be more prone to failure. Therefore, the clinician should consider placing longer or wider diameter TADs and try to insert the TAD at as close to a 90-degree angle as possible. These considerations will help increase TAD stability and success. Hopefully future studies continue to elucidate the relationship between BMD and TAD stability and help optimize TAD success.

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APPENDIX A

RAW DATA

	Slope of Force vs. Displacement	BMD	Thickness	Yield Point
1	62.93	1.213	2	17.09
2	108.7	1.364	3.2	43.27
3	115.5	1.335	2	25.50
4	71.12	1.021	2	45.99
5	58.04	1.113	1.3	47.85
6	2.013	1.270	1.4	3.106
7	107.0	1.257	1.7	39.97
8	31.43	1.194	1.2	7.518
9	80.40	1.205	1.2	19.60
10	33.77	1.315	1.4	36.96
11	54.63	0.9952	0.7	34.10
12	65.58	1.110	1.2	37.92
13	22.68	1.412	3.6	11.02
14	108.4	1.069	1	51.37
15	38.34	1.193	1	18.84
16	139.3	1.272	1.4	44.25
17	125.5	1.232	1.3	21.17
18	33.18	0.9974	0.8	14.24
19	109.2	1.157	2.7	31.46
20	131.6	1.232	2.7	40.99

APPENDIX B

OVERALL STATISTICAL ANALYSIS

		Density	Slope	Thickness	Yield Point
Density	Pearson Correlation	1	.109	.608**	-.188
	Sig. (2-tailed)		.647	.004	.428
	N	20	20	20	20
Slope	Pearson Correlation	.109	1	.216	.624**
	Sig. (2-tailed)	.647		.359	.003
	N	20	20	20	20
Thickness	Pearson Correlation	.608**	.216	1	.055
	Sig. (2-tailed)	.004	.359		.819
	N	20	20	20	20
Yield Point	Pearson Correlation	-.188	.624**	.055	1
	Sig. (2-tailed)	.428	.003	.819	
	N	20	20	20	20

**Correlation is significant at the 0.01 level (2-tailed).

APPENDIX C

STATISTICAL ANALYSIS OF TOP 3 AND BOTTOM 3 DENSITIES

	Sig. (2-tailed)		Std. Error Difference	95% Confidence Interval of the Difference	
				Lower	Upper
Slope	.409	-29.307	31.83	-117.7	59.04
Thickness	.050	-1.767	.6368	-3.535	.0015
Yield Point	.907	1.658	13.40	-35.53	38.85