

THE STABILITY OF IMMEDIATELY LOADED 3 MM MINISCREW IMPLANTS:
A FEASIBILITY STUDY

A Thesis

by

DANIELLE RENEE GESHAY

Submitted to the Office of Graduate and Professional Studies of
Texas A&M University
in partial fulfillment of the requirements for the degree of

MASTER OF SCIENCE

Chair of Committee,	Peter H. Buschang
Committee Members,	Larry P. Tadlock
	Emet Schneiderman
	Phillip M. Campbell
Head of Department,	Larry Bellinger

May 2016

Major Subject: Oral Biology

Copyright 2016 Danielle Renee Geshay

ABSTRACT

Shorter miniscrew implants (MSIs) make it possible to reduce the risk of root damage, increase the number of buccal placement sites, and to treat patients during the mixed dentition. The purpose of the present study was to evaluate the stability of 3 mm long MSIs placed in humans by an inexperienced operator. A total of 82 MSIs were placed in the buccal maxillae of 26 adult subjects by one operator who had previously placed only 5 buccal MSIs. Pairs of adjacent implants were immediately loaded with a 100g nickel-titanium closed-coil spring. Subjects were recalled after 1, 3, 5, and 8 weeks, at which times stability was verified and questionnaires pertaining to MSI-related pain and discomfort were completed. All MSIs were removed after 8 weeks. The failure rates of MSIs in the anterior and posterior placement sites were 35.7% and 30.0% respectively. The overall failure rate was 32.9%. 10 of 27 failed MSIs (37%) were traumatically dislodged by the subjects. Excluding these incidental failures, the failure rate in the anterior and posterior sites were 31.6% and 15.2%, and the overall primary failure rate was 23.6%. Failures were significantly ($p=0.010$) greater among the first half (41 MSIs) placed than the last half (46.3% vs 19.5%). All primary failures occurred on or before day 42; on average, they failed on day 24.5. Subjects experienced very low pain (2.2% of maximum) and discomfort (5.5% of maximum) during the first week only. Shorter 3 mm MSIs placed by an inexperienced operator are highly likely to fail. With clinical experience, failure rates can be dramatically improved. Pain and discomfort experienced after MSI placement is minimal and temporary.

ACKNOWLEDGEMENTS

I would like to thank my committee chair, Dr. Buschang, and my committee members, Dr. Tadlock, Dr. Campbell, and Dr. Schneiderman, for their guidance and support throughout the course of this research.

Special recognition should be given to the dental students, orthodontic residents, and orthodontic staff that graciously volunteered to participate in this study. I also want to extend my gratitude to the Gaylord Endowed Chair for providing financial support for this and many other important research projects in the Baylor Orthodontics department.

Finally, I would like to thank my co-residents, Dr. Lauren Van Gemert, Dr. Kim Rogers, Dr. Kristina Christoph, Dr. Chris Cramer, and Dr. Alec Rice, with whom I have shared both the joys and hardships of residency. You are all outstanding clinician-researchers and equally amazing people, and have each impacted me in a unique and permanent way.

TABLE OF CONTENTS

	Page
ABSTRACT	ii
ACKNOWLEDGEMENTS	iii
TABLE OF CONTENTS	iv
LIST OF FIGURES	vi
LIST OF TABLES	vii
CHAPTER I INTRODUCTION AND LITERATURE REVIEW	1
MSI History	3
MSI Success and Failure Rates	5
Osseointegration	7
Primary and Secondary Stability	8
Insertion Torque	10
Removal Torque	12
Miniscrew Design Characteristics	14
Length.....	15
Shorter MSIs	17
Animal Studies on 3 mm MSIs	19
Potential Root Injuries with MSIs.....	20
Interradicular Distances.....	23
Gingival Thickness.....	24
Cortical Bone Thickness	25
Conclusion.....	27
CHAPTER II BACKGROUND.....	29
CHAPTER III MATERIALS AND METHODS.....	32
Subjects	32
Placement Protocol.....	33
Follow-up	34
Statistical Analysis	35

CHAPTER IV RESULTS	37
Failures	37
Insertion and Removal Torque	38
Gingival Thickness.....	39
MSI Tipping	39
Questionnaires.....	39
CHAPTER V DISCUSSION	41
Incidental Failures	41
MSI Failure Rate	42
Clinician Experience	44
Timing of Failures	45
Insertion and Removal Torque	45
MSI Tipping	48
Pain Questionnaires	48
Clinical Implications	49
CHAPTER VI CONCLUSIONS	51
REFERENCES	52
APPENDIX A FIGURES.....	63
APPENDIX B TABLES	71
APPENDIX C QUESTIONNAIRE	74

LIST OF FIGURES

		Page
Figure 1	Periapical radiographs taken on each side of the maxilla in order to visualize bone between posterior tooth roots.....	63
Figure 2	MSI placement protocol.....	64
Figure 3	Periapical radiographs taken after MSI placement to ensure that the MSIs were located in bone between tooth roots.....	65
Figure 4	Pairs of adjacent implants were immediately loaded with a nickel titanium closed-coil spring stretched to deliver a force of 100g.....	65
Figure 5	Percentages of MSI failures for the right and left sides.....	66
Figure 6A	Percentages of anterior and posterior MSI failures, out of all MSIs placed (i.e., 82 total)	67
Figure 6B	Percentages of anterior and posterior MSI failures, excluding incidental failures (i.e., 72 total)	67
Figure 7A	Percentages of MSI failures for those placed early (i.e., the first half of MSIs placed by investigator) and late (i.e., the last half placed), for all MSIs placed (82 total)	68
Figure 7B	Percentages of MSI failures for those placed early (i.e., the first half of MSIs placed by investigator) and late (i.e., the last half placed), excluding incidental failures (72 total).....	68
Figure 8	Day at which the primary and incidental failures occurred.....	69
Figure 9	Gingival thickness measurements (mean +/- SD) at the anterior and posterior MSI insertion sites.....	69
Figure 10	Mean change in distance between adjacent MSIs at each time interval (+/- standard error of the mean)	70

LIST OF TABLES

	Page
Table 1	Miniscrew failure rate.....71
Table 2	Factors potentially associated with MSI failure.....71
Table 3	Mean MSI insertion torque and removal torque at 56 days.....72
Table 4	Pain and discomfort [medians (Med) and interquartile ranges] associated with miniscrews at follow-up timepoints, measured on a Visual Analog Scale72
Table 5	Frequency of responses to the question, “Did you take medication to relieve pain or discomfort associated with miniscrews?”72
Table 6	Frequency of responses to the question, “Did you take medication to relieve pain or discomfort not associated with miniscrews?”73
Table 7	Frequency of responses to the question, “Have the miniscrews caused any type of injury?”73

CHAPTER I

INTRODUCTION AND LITERATURE REVIEW

Edward Angle used Newton's Third Law of Motion in 1907 to describe the concept of orthodontic anchorage: "According to the well-known law of physics, action and reaction are equal and opposite, hence it must follow that the resistance of the anchorage must be greater than that offered by the tooth to be moved, otherwise there will be displacement of the anchorage and failure in the movement of the teeth to the extent, or, possibly, in the direction desired. The sources at our disposal for securing anchorage or resistance are, first, the teeth themselves, and second, sources external to the teeth..."¹

Simply stated, anchorage allows for wanted tooth movements while minimizing undesired side effects. Traditional orthodontic systems employ a reactive unit (tooth/teeth acting as anchorage) against an active unit (tooth/teeth intended to undergo movement) using extraoral, intra-arch, or inter-arch mechanics. Even with perfect patient compliance, most traditional mechanics are subject to some form of anchorage loss during treatment.

The advent of mini-screw implants (MSIs) has provided orthodontists with a valuable tool for attaining maximum or near absolute anchorage. Once affixed in bone, they make it possible to manage the forces applied to teeth more precisely without adverse reciprocal tooth movements. Unlike bulkier traditional anchorage appliances, MSIs can be easily placed and removed in a virtually limitless number of intraoral

locations. MSIs have gained rapid popularity and acceptance for this reason, as well as for their affordability, minimal invasiveness, and patient acceptance.²⁻⁴ They are particularly advantageous when extraoral appliances are impractical and patient compliance is unreliable.^{2,4} Though patients initially presume MSIs to be painful and uncomfortable, they actually find them to be non-painful and less uncomfortable than other appliances, and they would recommend them as a treatment modality to their friends and relatives.⁵

Although MSIs are versatile and predictable tools for anchorage, the concern for root damage is a primary deterrent for many orthodontists.⁶ Although root injury caused by MSI placement usually heals unremarkably, it does have the potential to cause localized bone loss, ankylosis, and pulpal damage leading to devitalization of the tooth.⁷ It has been suggested that shorter MSIs might subject patients to less risk of root contact during placement than traditional 6 or 8 mm MSIs. With a reduced potential for tooth damage, orthodontists would have more options for MSI placement locations that were previously precluded by longer MSIs. Additional insertion sites could yield treatment alternatives with improved biomechanics and fewer unwanted side effects resulting from non-ideal MSI locations. Furthermore, shorter MSIs have implications for use in dentofacial orthopedics in younger patients where potential damage to tooth buds has precluded miniscrew placement. Several studies have shown 3 mm MSIs to be stable at various forces in animal models.⁸⁻¹³ However, no studies to date have examined the stability of 3 mm MSIs in humans.

Therefore, the purpose of this study is to assess the feasibility of using immediately loaded 3 mm miniscrew implants in human subjects.

The following review will first discuss the history and success rates of MSIs in order to lay a foundational knowledge of the subject. Osseointegration and primary and secondary stability will be explained, followed by a discussion of the biological factors and physical miniscrew characteristics that affect stability.

MSI History

The first reported attempt to use implants for orthodontic anchorage was 70 years ago by Gainsforth and Higley.¹⁴ The investigators placed modified 3.4 mm-diameter x 13 mm-long vitallium screws in the mandibular ascending rami of six dogs to serve as absolute anchorage during canine retraction. This study demonstrated, for the first time, that tooth movement using basal bone anchorage was possible. Unfortunately, effective orthodontic force could not be maintained for more than 31 days due to implant failure. The authors speculated that the prompt loosening of the screws was largely because of the communication with the oral cavity and the resulting contact with oral fluids and microorganisms.

Following the 1945 study by Gainsforth and Higley, there were no attempts to use bone implants to move teeth until the clinical case reports of Linkow^{15,16} in 1969, in which blade implants were used to retract teeth with rubber bands.

In the late 1970s and 1980s, several investigators thoroughly tested, in animals, the concept of using endosseous implants during orthodontic treatment. In the majority

of these studies, forces were applied from implant to implant to test their stability when loaded with various orthodontic forces.¹⁷⁻²⁰ Others used implants to facilitate the orthodontic movement of teeth,^{21,22} for maxillary expansion,²³ and for the orthopedic protraction of the maxilla.²⁴

In 1983, Creekmore and Eklund published the first clinical report of bone screw usage for orthodontic anchorage in humans.²⁵ A 13 mm vitallium screw was utilized in a 25-year-old female orthodontic patient exhibiting a deep impinging overbite. Placed immediately below the anterior nasal spine, the anchor was used to intrude the upper incisors approximately 6 mm and torque them lingually about 25 degrees using an elastic thread. Following this initial article, several more clinical reports described the use of endosseous implants for orthodontic purposes, with varying degrees of success.²⁶⁻²⁸ Though the use of endosseous dental implants for orthodontic anchorage was promising, several disadvantages became evident. The bulky implant size precluded placement in many intraoral sites. The invasiveness of surgical placement and removal procedures, discomfort of initial healing, and difficulty to maintain oral hygiene around implants were troublesome limitations for patients. In addition, the prolonged time before loading and high monetary expense prevented their widespread use. Recognizing the above-mentioned factors, Kanomi repurposed smaller, less invasive surgical bone plate fixation screws for orthodontic use.²⁹ At 1.2 mm wide and 6 mm in length, these miniscrews were small enough to be placed in the interradicular space between mandibular central incisors for successful intrusion of the lower anterior segment over a four-month period. Kanomi suggested that placement and removal procedures should be simple enough for

an orthodontist or general dentist to perform, and that healing following removal should be rapid and inconsequential. This development paved the way for numerous orthodontic companies to begin manufacturing smaller implants that provided minimal surgical invasiveness, greater versatility in orthodontic applications, and increased patient comfort and acceptance.

In 1998, Costa et al introduced a simplified placement and use protocol that prompted a more pervasive acceptance of miniscrews in orthodontics.³⁰ In 2008, a survey of members of the American Association of Orthodontists concluded that 80% of orthodontists had at least one current miniscrew case in their practice, and 54.4% had placed their own MSIs.⁶ A more recent survey in 2010 of 47 orthodontists in the northwest United States revealed that 91% of respondents reported treating at least one patient with miniscrews, though only 43% reported placing the devices personally.³¹ Most recently, a 2013 survey reported usage of temporary skeletal anchorage devices to be 77% among the 158 responding Australian orthodontists.³²

MSI Success and Failure Rates

While endosseous implants have a well-documented approximate success rate of 97%,^{33,34} the success rate for orthodontic miniscrew implants is more ambiguous. Numbers have ranged widely depending on the study. They vary due to differences in definitions of success, timing of assessment of primary outcomes, and methodologies that may allow for uncontrolled variables.³⁵ Though variation was substantial, 85% of orthodontists in a 2008 survey reported MSI failures of 25% or less in their practices.⁶ In

2009, Reynders et al reported in a systematic review of 19 studies that MSIs had failure rates that varied from 0-100%.³⁵ However, the study reported that most articles reported failure rates of less than 20% if usable mobile and displaced implants were included as successful. Schatzle et al performed a meta-analysis around the same time and found 27 studies that met their inclusion criteria.³⁶ The study analyzed a total of 2374 miniscrews inserted in 1196 patients with a total of 363 or 15.3% failure. In 2010, Crismani et al included 14 clinical trials in a systematic review analyzing 1419 MSIs in 452 patients.³⁷ The mean overall failure rate was 16.2% +/- 7.4%. Most recently, in 2012, Papageorgiou et al. systematically evaluated 52 studies and found, of the 4987 MSIs placed in 2281 patients, an overall failure rate of 13.5% (95% confidence interval 11.5-15.8%).³⁸

The failure to achieve the same success as observed in endosseous implants has prompted many studies aimed to determine the causal factors of MSI instability. Three contributing topics must be considered: physical features of the miniscrew, biological characteristics of the implant site, and insertion techniques of the orthodontist. Bony characteristics at the implant site, including cortical thickness and density, affect stability; however, at this time, little can be done to alter a patient's biology. Insertion techniques are also critical. Carrillo and Buschang described placement techniques that produced success rates above 90%.³⁹ The technique described emphasizes meticulous planning, maintenance of MSI position and orientation throughout insertion, evaluation of stability following MSI placement, and explanation of necessary post-op hygiene

protocol.³⁹ Perhaps the most investigated aspects related to MSI failure are the physical design traits of the implants.

Osseointegration

Before further discussion into the physical characteristics of MSIs, it is important to first recognize the basic mechanism through which implants are retained in bone. The process of osseointegration was defined by Branemark as a direct contact between living bone and implant, as evident under light microscopy.⁴⁰ Long-term evaluation of functional osseointegrated implants was completed by Albrektsson et al, who removed 38 stable and integrated screws from patients and used X-rays, SEM, TEM and histology to analyze the intimate relationship between implant and bone.⁴¹ The author described the process of osseointegration to be determined by the following parameters: (1) implant material, (2) implant design, (3) implant finish, (4) status of the bone, (5) surgical technique, and (6) implant loading conditions.

The amount of osseointegration that occurs around miniscrews is highly variable. Partial osseointegration denotes a distinct advantage in orthodontic applications, allowing effective anchorage to be combined with easy insertion and removal. It has been shown that bone-to-implant contact (BIC) of stable MSIs subjected to various loads in the mandible and maxilla can range from 2.2-94.8%.⁴² This is important to note because only small amounts of BIC may be required because orthodontic forces are substantially less than the occlusal loads placed on endosseous dental implants.

Primary and Secondary Stability

The clinical effectiveness of MSIs lies in their ability to maintain intimate bony contact, thus resisting reactive orthodontic forces.⁴³ Immediately following insertion, implant retention is entirely mechanical and related to the amount of bone contacting the surface of the MSI. This initial mechanical engagement and absence of mobility is defined as primary stability. Primary stability is largely important in orthodontic miniscrew success since there is not the same requirement for long-term stability and full osseointegration as in endosseous dental implants.⁴⁴ For orthodontists, primary stability is also a critical factor because it allows for immediate loading. Primary stability has been associated with many factors, including insertion site characteristics, root proximity, geometric design of the screw, soft tissue inflammation, operator insertion technique, and magnitude and loading time of an orthodontic force.⁴⁴ Cortical bone depth and density, in particular, are thought to be the most important patient factors for primary stability.⁴⁵

The initial stability of a miniscrew is important because most incidences of orthodontic MSI failure occur early.⁴⁶ Stability might be expected to decrease during the first week, when osteoclasts and mesenchymal cells, which appear by day four, begin removing bone damaged by MSI placement.⁴⁷ MSI insertion generates stresses and strains along the length of the implant that injures surrounding bone. Excessive damage may lead to micromotion between the implant body and the surrounding bone, and is considered to be a high risk factor for early implant loss as failure of osseointegration occurs.⁴⁸ Because of this, strategies to reduce trauma to bone during insertion should

produce greater MSI stability. Over time, there is a transition from primary mechanical stability, provided by the implant geometry engaging in cortical bone, to biologic stability, provided by newly formed bone in intimate contact with the screw surface as osseointegration occurs. This second phase of increasing stability is referred to as secondary stability. As new bone is formed around the MSI, secondary stability increases.

There is a period of time during healing in which osteoclastic activity has decreased the mechanical stability of the MSI, but the formation of new bone has not yet occurred to the level required to maintain implant stability. This “critical period” of decreased stability would theoretically be the time when an MSI is most at risk of relative motion and be most susceptible to failure.⁴⁸ Berglundh and coworkers used a dog model to describe the temporal phases of wound healing adjacent to endosseous implants.⁴⁷ Extrapolating these results to humans, the critical time frame for implant healing would be 2 to 3 weeks postplacement.⁴⁸

Ure et al described changes in overall MSI stability placed in the maxillae of beagle dogs over a period of eight weeks.⁴⁹ Resonance frequency analysis, which measures the vibrations of the implant within bone, was utilized to quantify the stiffness of bone surrounding the implants. MSIs placed into nonkeratinized tissue –most of which eventually failed – showed greater decreases in stability over the first three weeks compared with those placed in keratinized tissue. MSIs placed in keratinized tissue that remained stable over the 8-week period also showed significant decreases in stability in the first three weeks, followed by increases during the fourth and fifth weeks.

Importantly, this data corroborates the 3-week point as the critical period of transition previously identified for endosseous implants.

Primary stability decreases over time, and secondary increases over time, resulting in a set of characteristic curves that is often viewed in the literature. Clinically, orthodontists observe the overall net stability, which is a combination of both primary and secondary stability. The point at which the primary and secondary curves cross represents the point of least net stability, or the period that MSIs are most likely to fail. As per the studies above, this occurs approximately 3 weeks after placement. After this point, secondary stability continues to increase, resulting in an overall net stability increase.

While osseointegration cannot be evaluated directly in human studies due to an inability to obtain the bone-implant specimen for light microscopy or micro-computed tomography analysis, primary stability can be indirectly evaluated with insertion torque and removal torque measurements.

Insertion Torque

Placement torque is a common measurement used to evaluate the quality of the bone to implant interface. After revealing a statistically significant correlation between the implant placement resistance and bone density values, Friberg et al concluded that placement torque measurements were a reliable method for evaluation of bone quality.⁵⁰ Motoyoshi et al evaluated this concept in a clinical study by measuring the insertion torques and success rates of 124 pre-drilling orthodontic MSIs.⁵¹ The investigators determined that, for 8 mm long and 1.6 mm diameter implants, an insertion torque in the

range of 5 to 10 Ncm yielded the highest stability rate, at 96.2%. Success rate decreased to 72.7% with insertion torque values below 5 Ncm, and further decreased to 60.9% with values above 10 Ncm. They concluded that a lower insertion torque is suggestive of poor primary stability and potential failure. Conversely, excessive torque during placement can generate high levels of stress that result in degeneration of the bone at the implant-tissue interface.⁵² Compressive stresses can reach a sufficiently high level and result in necrosis and local ischemia of the bone surrounding the implant, which may result in failure. In addition, extensive crack formation and microdamage suggesting “very severe destruction” has been shown adjacent to MSIs to a distance of 200 µm after intentional overinsertion of orthodontic implants.⁵³

Suzuki et al placed 186 5, 6, and 7 mm pre-drilling MSIs between the second premolars and first molars in 105 consecutive patients and immediately loaded them with 50 to 100 g nickel-titanium closed-coil springs.⁵⁴ The average torque value was under 5 Ncm, which was lower than the previously mentioned study by Motoyoshi et al.⁵¹ The authors stated that the reason for this difference was the shorter screw length. They did, however, find a tendency for increasing torque value for longer and for mandibular screws, and found decreased stability when insertion torque exceeded 10.1 Ncm. The authors concluded that ideal torque value might differ according to the type of miniscrew and the placement method.

According to a recent systematic review, there is no strong evidence indicating that specific maximum insertion torque levels are associated with higher success rates for orthodontic MSIs.⁵⁵ The quality of the body of evidence for all seven studies

included in the review was relatively poor; all studies were non-randomized and subject to multiple biases.

Removal Torque

Removal torque can also be used as an indirect mechanical evaluation to infer stability and bony integration of an implant. Sullivan et al studied the removal torque of pure titanium screw-type implants and indicated that fully osseointegrated endosseous implants should have a removal torque greater than 20 Ncm.⁵⁶ Since orthodontic implants are not intended to fully osseointegrate, the removal torque of MSIs can be expected to be significantly less. Moreover, studies have shown that MSIs can fracture at removal if the removal torque exceeds the limits that the MSI can withstand.⁵⁷ Unfortunately, torque tests may not always be accurate due to the delicate nature of the implant interface. For example, variable forces that are not isolated along the long axis of the implant may be registered with any unintended tipping of the hand-held measurement device.⁵⁸

Only a few studies have been conducted to assess removal torque of MSIs, and the findings of these studies are inconsistent. Chen et al measured the removal torques of 46 MSIs in Chinese adults.⁵⁹ The screws used were titanium bone screws designed for fixation of fractures and measured 2 mm in diameter and 7, 11, 13, 15, or 17 mm in length. Removal torque values ranged from 2.35 to 21.08 Ncm, with a mean of 10.78 Ncm. Removal torque was significantly lower in the maxilla than the mandible. The effects of screw length on removal torque could not be fully determined, because shorter screw lengths were only used in the mandible. Because the removal torques were

significantly lower than the published reports of fully osseointegrated implants, the authors concluded that miniscrew retention was primarily mechanical and not due to osseointegration.

In an effort to further analyze MSI placement and removal torque, Suzuki and Suzuki placed 120 pre-drilling, cylindrical type MSIs and 160 self-drilling conical type MSIs in 95 patients.⁶⁰ In the buccal dentoalveolar bone of the maxilla and mandible, 8 mm long MSIs were placed, while 6 mm long MSIs were used in the midpalatal suture area. For both types of screws at all implant sites, removal torque values were significantly higher than the corresponding insertion torque values. MSIs in the maxilla had a significantly lower insertion torque (12.1 +/- 3.1 Ncm) and removal torque (15.8 +/- 3.6 Ncm) compared with the mandible and the palate. In addition, the self-drilling MSIs yielded significantly higher insertion torque (mean 14.5 Ncm) than the pre-drilling (mean 9.2 Ncm).

In a 2016 study, Migliorati et al measured the maximum insertion torque and maximum removal torque of 81 self-drilling MSIs in 51 patients.⁶¹ The MSIs used were either 8 or 10 mm in length, and were either immediately loaded or loaded after 1 week. The mean insertion torque at placement was 16.95 +/- 2.85 Ncm in the maxilla and 19.58 +/- 2.56 Ncm in the mandible, which are higher than those values previously recommended by Motoyoshi et al. The overall failure rate for the sample was 7.4%. The mean removal torque, 10.52 +/- 5.14 Ncm, was significantly lower than the insertion torque measurements. This result differs from that previously described by Suzuki et al,

who found that removal torque values were higher than corresponding insertion torque values.⁶⁰

Miniscrew Design Characteristics

The physical design of miniscrews can be altered to optimize both primary and secondary stability. Modifications in MSI length, diameter, pitch, fluting, thread design, shaft design, and surface treatment have all been investigated in order to determine what enhancements provide improved implant stability. Buschang and Kim recently reviewed the information currently known about each of these aspects.⁶² All other things being equal, the greater the surface area of bone in contact with a screw, the greater the primary stability. Two methods for maximizing screw surface area include increasing diameter or decreasing pitch (i.e., the distance between the threads). Increases in diameter have been shown to increase both insertion torque and pullout forces. Diameter is an important consideration because MSIs need to be wide enough to attain stability, but narrow enough to fit into interradicular spaces without causing undesirable root damage. Decreasing pitch increases the pullout forces of miniscrews, and this relationship is also associated with bone density. Studies on fluting are ambiguous; some show decreases in insertion torque due to the increased clearance of bone debris, while others show increases in insertion torque due to bone debris accumulating around the threads. Surface modification via sandblasting and acid etching has been shown to decrease insertion torque and increase removal torque, but studies remain limited. With

regards to shaft design, it remains unclear whether conical or cylindrical shapes are more successful.⁶²

Length

An increase in length is one of the most obvious ways to increase the surface area, and therefore the primary stability, of an MSI. Winkler et al demonstrated that shorter endosseous dental implants tended to fail significantly more often following uncovering and after loading than longer implants.⁶³ This might be expected because the holding power of a screw is proportional to the amount of the thread engagement.⁶⁴ The effects of length in orthodontic miniscrew research is more controversial, since many studies compare MSIs that differ in more than one characteristic, limiting their ability to evaluate the true consequences of variation in length.

While it is intuitive that primary stability increases with increased MSI length, it has been found that insertion torque also increases. In one report, three different lengths (6, 8, and 10 mm) of otherwise identical miniscrews were inserted into minipig osseous tissue of different cortical thicknesses (1-6 mm) in order to evaluate the influence of length on insertion torque and maximum fracture torque.⁶⁵ The results showed that insertion torque increased with increasing screw length and increasing cortical bone thickness. No differences were found between implant lengths with respect to force required to fracture. Lim et al also noted that insertion torque significantly increased with increasing screw length.⁶⁶

Shah et al experimentally studied the effects of altering several design factors, including implant length, on primary stability of miniscrews as determined by maximum insertion torque and pullout strength.⁶⁷ Theoretically, the ideal MSI should minimize insertion torque (less potential for bone damage) and maximize pullout strength (greater holding power). The author placed 6 mm-long x 1.75 mm-diameter MSIs and otherwise identical 3 mm-long MSIs that were either 1.75 or 2 mm in diameter MSIs in four different types of synthetic bone (i.e., two densities and two cortical thickness). The results showed that 6 mm MSIs displayed 1.3-1.5 times greater insertion torque and 3.2-3.6 times greater pullout strength than otherwise identical 3 mm MSIs. Intuitively, this result was expected, since longer implants might penetrate deeper into the bone and achieve a greater amount of mechanical engagement. However, the values for both parameters were consistently above the limits recommended for primary stability. Insertion torque for the 3 mm MSIs was consistently greater than 4 Ncm, and pullout forces were substantially above the ranges of orthodontic forces typically applied for tooth movements.

With regards to long-term stability in clinical situations, the data are more vague. Kuroda et al showed a tendency toward decreased stability with decreasing screw length (from 100% success with 12 mm to 69.2% success with 6 mm); however, this difference was not statistically significant.⁶⁸ Several other investigations have shown similar trends but yielded no statistically significant differences.^{46,69} Recently, Sarul et al completed a prospective clinical study in which 6 and 8 mm MSIs that were otherwise identical were

used to retract incisors and canines in mandibular extraction cases.⁷⁰ The shorter 6 mm screws had a lower success rate (66% vs 81.5%).

Shorter MSIs

Root proximity has been found to be a major factor for screw failure in orthodontic anchorage.⁷¹ One previous CBCT study indicated that MSI length of 6 mm or less and a diameter of 1.5 mm or less would be safest for avoiding root contact and unwanted damage.⁷² Shorter MSIs confer several advantages, including decreased risk of root damage, increased numbers of potential placement sites, and therefore improved biomechanics. Decreased treatment time can also be expected because orthodontic separation of teeth prior to MSI placement would no longer be necessary. To that end, several investigators have looked into the long-term success rates of shorter miniscrews.

In 2013, Suzuki et al placed 5, 6, and 7 mm miniscrews that were otherwise identical in 105 consecutive patients in order to determine optimal screw length.⁵⁴ CBCT scans were performed after miniscrew implantation in order to determine cortical bone thickness at the implant site and root proximity. Overall success rates in the maxilla and mandible were 93.4% and 70.3%, respectively. There were no significant differences found between differing screw lengths in the maxilla; in the mandible, the 5 mm screws were less successful than the 6 or 7 mm screws. Failed miniscrews exhibited significantly closer root proximity; however, there was no difference in root proximity between screws of all three lengths. This implies that root proximity is partially a function of operator technique and planning, rather than entirely a function of screw

length. These findings were corroborated by Watanabe et al, who found that root proximity was the factor that most affected MSI failure.⁷³

When Deguchi et al loaded 96 5 mm implants with 200-300 g of force in dogs, 93 were still stable after 3 months.⁷⁴ Ohmae et al placed 4 mm long MSI's into the jaws of beagles with 100% success after loading them with 150 g of force for 12 to 18 weeks.⁷⁵ Mortensen et al experimentally compared 6 mm long MSIs to identical 3 mm long MSIs.⁸ Success rates six weeks after immediate loading with either 600 g or 900 g of force were significantly higher for the 6 mm (100%) than the 3 mm (67%) MSIs. However, several of the 3 mm MSIs had tips that sheared off during placement, which might be expected to decrease stability. Also, 60% of the failed 3 mm MSIs were from a dog that was described as unusually active and was regularly observed chewing on his food bowl and on the run bars of the cage. Excluding the MSIs from that dog, as well as the sheared MSIs, the net success rate of the 3 mm MSIs was 90.6%. It should be noted that the miniscrews in this study were maintained at forces that represent extreme orthopedic levels, far from the light orthodontic forces needed for tooth movements.

Importantly, the length of the MSI shaft does not necessarily equal the depth of its placement. According to Kau et al, clinicians can expect 71.2% of the length of a screw section of an MSI to be embedded in the alveolar bone.³ This would suggest that a 3 mm screw could be expected to engage in only approximately 2 mm of bone. Postmortem evaluations of 42 successful MSIs revealed average insertion depths of 1.6 mm and 3.9 mm for 3 mm and 6 mm MSIs, respectively.⁷⁶ These findings suggest that

the effect of MSI length on long-term stability is relatively small and probably related to the primary stability that longer screws provide.

Animal Studies on 3 mm MSIs

A handful of reports can be found describing the use of 3 mm MSIs in animal research. The experiment by Mortensen et al⁸, comparing loaded 3 and 6 mm MSIs in beagle dogs, was described previously.

Liu et al performed several studies successfully utilizing 3 mm MSIs to investigate various aspects of sutural expansion in rabbits.⁹⁻¹² In order to determine optimal force levels to maximize sutural bone expansion, 74 total 3 mm long by 1.7 mm diameter MSIs were placed in 37 white rabbits and randomly loaded with force levels of 0, 50, 100, or 200 g delivered by nickel-titanium open-coil springs.⁹ A total of 9 MSIs failed within the first 2 weeks, yielding a success rate of 89% (65 of 74). A companion study used 28 of the same 3 mm long MSIs loaded with 50 g to compare continuous and intermittent forces during sutural expansion in 18 rabbits.¹⁰ One rabbit lost two MSIs between days 1 and 2; another rabbit lost two MSIs on day 18, resulting in a success rate of 86% (24 out of 28). A third rabbit study utilized 60 3 mm MSIs loaded with 100 g in order to understand the effects of rhBMP-2 on sutural expansion.¹¹ Only one MSI failed on day 10, resulting in a 98% success rate. Finally, another follow-up investigating whether there is a dose-dependent relationship between rhBMP-2 and bone formation during sutural expansion used 100 3 mm MSIs in 50 rabbits.¹² Five pairs of MSIs failed,

resulting in a 90% success rate. When the MSIs from these four experiments are pooled, 23 out of 262 total MSIs failed, for an overall success rate of 88%.

Recently, Truong et al placed 66 3 mm long by 1.6 mm diameter MSIs in 11 rabbits in order to evaluate the effects of fluting on primary stability.¹³ Loaded with 100g nickel-titanium open coil springs, the MSIs were evaluated at 2 and 6 weeks post-insertion. Both fluted and non-fluted MSIs produced equal success rates of 97% (32 out of 33 for each design). Insertion torque for both designs ranged from 1.5 to 7 Ncm, which is significantly lower than previously published values. The author stated this is likely due to both the shorter length of the screws and the lower bone density of the rabbit skulls. After 6 weeks, removal torque values were significantly higher for fluted (3.42 +/- 0.26 Ncm) than non-fluted (2.49 +/- 0.20 Ncm) MSIs.

Potential Root Injuries with MSIs

Though miniscrews have been shown to be relatively stable alternatives to more traditional anchorage devices, many orthodontists still do not use them on a regular basis. In a 2008 survey, 32.8% of orthodontist respondents cited fear of root damage as their primary deterrent for placement in their own practice.⁶ Loss of tooth vitality^{77,78} and transection of root apices⁷⁹ have been previously noted during the placement of endosseous implants and surgical fixation screws. Fortunately, the periodontal literature shows that repair can occur following tooth root and periodontal ligament damage. Hellden et al demonstrated in 1972 that new cementoid could be recognized on the surface of one injured tooth specimen after 23 days, and on almost all other injured teeth

by day 40.⁸⁰ Until recently, the root damage and the healing process for teeth injured during orthodontic miniscrew placement remained largely undetermined. Asscherickx et al showed that healing in beagles takes places approximately 12 weeks after root damage from MSIs; however, the study was limited to 6 screws placed unintentionally against roots, 3 of which became loose and had to be removed.⁸¹

Chen et al were the first to intentionally place MSIs in contact with roots in order to evaluate healing of PDL structures over varying time periods.⁸² A total of 72 MSIs were placed in the mandibles of 6 mongrel dogs, 47 of which were intentionally positioned in contact with tooth roots. The authors found that MSIs contacting the root were at greater risk of failure. Histologically, the failed MSIs appeared to be surrounded with a greater volume of soft tissue, with peri-implant inflammation present. It was also shown that the lesions created on the roots were repaired with a narrow zone of mineralized tissue deposited on the root surface after screw removal, indicating healing of the tooth and periodontium. In all cases, the periodontal ligament space was maintained.

In order to determine the extent of damage possible from MSI placement, Hembree et al evaluated the immediate, short-term (6 weeks) and long-term (12 weeks) damage to roots and periodontium of MSIs placed in 7 beagle maxillae and left in situ.⁸³ Six MSIs per dog were placed to intentionally contact tooth roots. They were placed interradicularly between the 2nd, 3rd, and 4th premolars and were randomly assigned to be either left in situ for 6 or 12 weeks, or placed immediately before sacrifice. Importantly, the author noted that the tactile resistance of the MSIs increased substantially and

noticeably with tooth contact. This tactile change may be used clinically as an indicator of possible root contact during MSI placement, and may be more a more reliable guide than radiographs. Of the 42 teeth examined histologically, 73.8% had been damaged by the MSI: 7.2% showed defects into the PDL, 19% into cementum, 26.2% into dentin, 7.2% into furcational bone, and 14.2% into the pulp. This study demonstrated the capability of miniscrews to cause immediate and extensive damage to teeth and the surrounding periodontal structures, with little to no differences apparent at 6- and 12-weeks. While some teeth showed evidence of healing at both time intervals, there were other areas where healing had not occurred.

In a companion study looking at the healing potential of injured teeth and periodontium, Brisceno et al used a randomized split-mouth design to intentionally injure roots during MSI placement in 7 beagle dogs.⁷ 56 self-tapping, 8 mm long implants were placed interradiarily to damage the distal or mesial roots of the mandibular 2nd, 3rd, and 4th premolars and 1st molar. They were immediately removed after roots were contacted. Approximately 67.9% of teeth showed defects into the dentin, 19.6% into cementum, and 12.5% into the pulp. Most teeth (64.3%) showed normal healing when damage was limited to the dentin or cementum. Healing was evident at both 6 and 12 weeks via a new cementum layer, PDL attachment, and bone regeneration. The amount of new cementum approximately doubled between the 6- and 12-week healing periods. Abnormal healing was found in 35.7% of teeth; there was lack of PDL and bone regeneration (10.7%), major furcational bone loss or destruction (9%), spot ankylosis (3.6%), and pulpal damage with inflammatory infiltrate (12.5%). Placement of

MSIs into the pulp produced irreversible damage. As in the previous study, it was noted that the insertion torque doubled with root contact (23.8 vs 50.7 Ncm).

Based on the evidence provided by both this and previously described studies, orthodontists should obtain thorough diagnostic records and radiographs, as well as a detailed informed consent from their patients, prior to an elective procedure such as MSI placement. It is also appropriate for orthodontists to have a thorough understanding of the depth of the roots in typical MSI placement sites. Important measurements to realize include average interradicular distances, soft tissue thickness, and cortical bone thickness.

Interradicular Distances

Aiming to provide an anatomical map to assist orthodontists in miniscrew placement in a safe location between dental roots, Poggio et al obtained volumetric tomographic images of 25 maxillae and 25 mandibles from the records of 2000 patients with no missing teeth or severe crowding.⁸⁴ The mesiodistal and buccolingual distances were measured for each interradicular space 2, 5, 8, and 11 mm from the alveolar crest. It was found that in the maxilla, there is greater mesiodistal interradicular width on the palatal side than the buccal. In the maxillary buccal segment, the greatest amount of mesiodistal bone was between the first and second premolars (3.5 ± 1.1 mm) and between the canine and first premolar (4.3 ± 1.1 mm). The mesiodistal space between the first and second maxillary molar on the buccal side was the narrowest of the arch (2.3-2.5 mm). In the mandible, the greatest amount of mesiodistal bone dimension was

between the first and second premolars (4.9 ± 1.0 mm, at 11 mm depth); the least was between the first premolar and canine (2.7 ± 0.7 mm, at 2 mm depth).

Several years later, Chaimanee et al updated the 'safe zone' idea by assessing the influence of different dentoskeletal patterns on the availability of interradicular spaces.⁸⁵ The investigators used periapicals instead of tomographic images to compare 60 subjects with skeletal Class I, II, or III patterns. It was shown that the availability of interradicular space was mainly influenced by the axial inclination of teeth, which changed due to dentoalveolar compensation to variations in sagittal skeletal discrepancies. For all skeletal patterns, the safest zone of the posterior maxilla was between the second premolar and first molar and the least safe was between the first and second molars. In the posterior mandible, the safer zones were located between the first and second premolars and between the first and second molars.

Gingival Thickness

In 1977, Goaslind et al measured gingival thickness on 10 male patients (age 25-36) with healthy gingiva using a transformer probe assembly excited by an oscillator and coupled to a digital voltmeter.⁸⁶ The mean thickness for the depth of the gingival sulcus (the free gingival measurement) for all teeth measured was 1.56 ± 0.39 mm. The mean thickness of the attached gingiva was 1.25 ± 0.42 mm. Thickness of attached gingiva increased from anterior to posterior in the mandible, and remained relatively constant in the maxilla.

More recently, Cha et al evaluated soft tissue thickness of the buccal attached gingiva of 61 young Korean adults using an ultrasonic gingival-thickness meter.⁸⁷ Measurements were made just adjacent to the mucogingival junction in the upper and lower arches. The buccal gingival thickness in the upper arch ranged from 1.05 to 1.84 mm, with a mean of 1.26 mm. The thickness on the lower arch ranged from 1.02 to 1.61 mm, with a mean of 1.17. These results corroborate the initial findings of Goaslind et al.⁸⁶

Cortical Bone Thickness

It has been suggested that initial MSI stability may be influenced more by cortical bone thickness than by implant length.⁸⁸ This was based on the fact that initial stability is achieved by mechanical retention in cortical bone rather than osseointegration. The bony surface must ideally be sufficiently thick to mechanically retain the miniscrew, but not so thick that insertion torque increases to the point that there is excessive stress at the implant-bone interface. As described previously, compressive stress that reaches a sufficiently high level may result in necrosis and local ischemia of the bone surrounding the implant.⁵²

Papageorgiou et al suggested that cortical bone thickness might be important for MSI success because, on the exploratory analysis of two studies in their meta-analysis, they found that a zone of cortical bone thickness of 1 mm or more was associated with fewer failures.³⁸

Because there was no comprehensive assessment of cortical bone thickness at common MSI placement sites, Farnsworth et al used CBCTs on 26 adolescents and 26 adults to analyze the thickness of the buccal cortical plates in both the mandible and the maxilla.⁸⁹ Thickness was greater in adults than adolescents in all locations except the infrazygomatic crest, posterior paramedian palate, and mandibular buccal site between the first and second molars. In the mandible, thickness increased from anterior to posterior; in the maxilla, thickness remained relatively consistent. Based on these results, one could expect interradicular cortical bone to average 0.8-2.5 mm thick in the mandible, and 0.8-1.4 mm in the maxilla.

In 2014, Cassetta et al looked at cortical bone thickness using 48 CT scans divided into groups based on age, gender, and sites at 2, 4, 6, and 8 mm apical to the gingival crest.⁹⁰ Generally, it is recommended to place MSIs about 4 mm apical to the alveolar crest, just below where the attached gingiva meets with the mucogingival junction. At this height, the researchers measured interradicular cortical bone thickness as ranging from 1.41-1.69 mm in the mandible, and 1.22-1.52 mm in the maxilla.

Horner et al looked at the differences in cortical bone thickness between hyper- and hypodivergent patients.⁹¹ Because cortical bone adapts to strains that are placed on it, and varying facial divergence results in differences in facial musculature and bite forces, they hypothesized that there may be a difference between high angle and low angle patients. Pre-treatment CBCTs of 57 patients were used to measure the buccal and lingual cortex thickness between each of the posterior teeth at approximately 5 mm apical to the alveolar crest. In general, cortical bone was thicker in hypodivergent

patients. Differences between groups were small in the maxilla. In the mandible, cortical bone thickness increased from anterior to posterior, probably due to increased bite force in the posterior. In both groups combined, mean mandibular buccal thickness ranged from 1.26-3.06 mm, and mean maxillary thickness ranged from 0.99-1.36 mm.

Conclusion

If one were to complete a risk analysis, there should be little to no risk of hitting a tooth root in the buccal posterior region when placing 3 mm miniscrews in interradicular spaces that are 3 mm wide, with 1-1.5 mm of attached gingival thickness, and 1-1.5 mm thick cortical bone.

As has become apparent in these studies, shorter MSIs have great potential to provide orthodontists superior versatility in terms of placement sites intraorally. With a reduced potential for tooth damage, orthodontists would have more options for MSI placement locations that were previously precluded by longer MSIs. Additional insertion sites could yield treatment alternatives with improved biomechanics and fewer unwanted side effects resulting from non-ideal MSI locations. Decreased insertion torque needed to place shorter implants may yield decreased microdamage at the bone-implant interface, thus resulting in quicker healing time. In addition, without a need for tooth root separation prior to insertion, total orthodontic treatment time would decrease.

Multiple studies have shown 3 mm MSIs to be stable at various forces in animal models.⁸⁻¹³ Unfortunately, data from animal studies cannot be extrapolated to direct application in humans. For example, there are differences in gingival thickness, bone

thickness, and bone density between rabbits, beagle dogs, and humans. To date, there are no studies evaluating the feasibility of the use of 3 mm miniscrew implants in humans.

CHAPTER II

BACKGROUND

The advent of mini-screw implants (MSIs) has provided orthodontists with a valuable tool for attaining maximum or near absolute anchorage. Once affixed in bone, mini-screws make it possible to manage the forces applied to teeth more precisely and without adverse reciprocal tooth movements. MSIs have gained rapid popularity and acceptance due to their easy placement and removal in a number of intraoral locations, as well as their affordability, minimal invasiveness, and patient acceptance.²⁻⁴ They are particularly advantageous when extraoral appliances are impractical and patient compliance is unreliable.^{2,4} Although patients initially presume that MSIs are painful and uncomfortable, it has been reported that they can be non-painful or less uncomfortable than other orthodontic appliances, and that patients would recommend them as a treatment modality to their friends and relatives.⁵

Although MSIs are a versatile tool for anchorage, they are not guaranteed to remain stable after placement. Systematic reviews report failure rates ranging between 13.5-20% when useable mobile and displaced MSIs are included.³⁵⁻³⁸ Failure rates reported by practicing orthodontists are similar: 85% of respondents to a 2008 survey reported MSI failures of 25% or less.⁶ In addition to stability concerns, the potential for root damage is a primary deterrent for many orthodontists.⁶ Although root injury caused by MSI placement usually heals unremarkably, it can cause localized bone loss, ankylosis, and pulpal damage leading to devitalization of the tooth.^{7,82,83}

The risk of root contact during placement would be substantially less for shorter 3 mm MSIs than for traditional 6 or 8 mm long MSIs. Interradicular spaces between tooth roots are, on average, 3 mm wide in the posterior segment.⁸⁴ Soft tissue thickness just adjacent to the mucogingival junction is approximately 1-1.5 mm thick,^{86,87} and interradicular cortical bone thickness has been reported to range from 0.8-3.06 mm in the mandible and 0.8-1.52 mm in the maxilla.⁸⁹⁻⁹¹ Taking these factors into consideration, there should be little to no risk of hitting a tooth root in the buccal posterior region when placing 3 mm MSIs. With a reduced potential for root damage, orthodontists would have more options for MSI placement locations, yielding treatment alternatives with improved biomechanics and fewer unwanted side effects. The need for root separation prior to insertion would be reduced, which would decrease total orthodontic treatment times. Furthermore, shorter MSIs could be used for dentofacial orthopedics in younger mixed dentition patients, for whom potential damage to tooth buds and erupting teeth has precluded miniscrew placement.

Experimental studies have shown that 3 mm MSIs loaded at various force levels are stable in different animal models.⁸⁻¹³ After problematic MSIs were excluded, an overall failure rate of 9.4% was reported for 3 mm MSIs placed in canine jaws and loaded with orthopedic level forces.⁸ Liu et al reported an overall 9.2% failure rate in a series of four studies that placed 3 mm MSIs in the cranium of rabbits and loaded them with various expansive forces.⁹⁻¹² Most recently, Truong et al reported a 3% failure rate for fluted and non-fluted 3 mm MSIs loaded with 100 g of force in rabbits.¹³

No studies to date have examined the stability of 3 mm MSIs in humans. In addition, no studies have evaluated the effect of experience on MSI failure rates. Therefore, the purpose of this study was to assess the stability of immediately loaded 3 mm miniscrew implants placed in human subjects by an inexperienced operator.

CHAPTER III

MATERIALS AND METHODS

Subjects

Adult subjects were recruited from a pool consisting of dental students, graduate students, and staff at Texas A&M University Baylor College of Dentistry. The project was approved by the Institutional Review Board (#2014-0849-BCD-FB) and informed consent was obtained from all of the patients. Exclusion criteria included: 1) pregnant females, 2) smokers, and 3), those taking medications that could affect bone metabolism. A clinical and radiological exam was performed in order to qualify subjects for the study. Periapical radiographs were taken on each side of the maxilla in order to visualize the bone between posterior tooth roots (Figure 1). An intraoral exam was completed to evaluate buccal frenum attachments, root eminences, and vestibular height. Subjects were excluded if there was inadequate space between tooth roots, or if buccal frenum attachment was located in site of miniscrew placement.

A power analysis indicated that 80 screws would be needed to establish an effect size of 15%, assuming a power of 95% and an alpha of 0.05. A total of 82 miniscrews were placed in 26 subjects (10 males, 16 females; age 22.6-45.7, mean 27.4 years). One subject withdrew from the study before the miniscrews had been placed. Seventeen subjects had four MSIs placed between the maxillary canines and first premolars, and between second premolars and first molars. Six subjects had only one side that qualified, and received two MSIs. Two subjects, who underwent previous orthodontic treatment

that included extraction of premolars, had the posterior MSIs placed between the first and second molars. Two subjects allowed only one MSI to be placed.

Placement Protocol

All measurements and procedures were performed by a single clinician using a standardized placement protocol (Figure 2). Subjects brushed their teeth with toothpaste and rinsed with Peridex chlorhexidine rinse (3M ESPE, Irvine, CA) for 45 seconds. Topical anesthesia (20% lidocaine, 4% tetracaine, 2% phenylephrine) was applied at each MSI site for 2 minutes and rinsed. Three subjects who experienced discomfort and requested further anesthesia received anesthetic infiltration with 1/8 carpule of 2% lidocaine with 1:100,000 epinephrine. After tissue numbness was verified, gingival thickness was measured at the insertion site using a sharp explorer with an endodontic rubber stop. The measurement was made perpendicular to the mucosal surface with light pressure through soft tissue until hard bony surface was contacted. This measurement, as well as all other measurements acquired throughout the study, was taken three times and an average was recorded.

Each 3 mm long, 1.7 mm wide MSI (Dentos, Seoul, Korea) was placed perpendicularly into bone using a manual driver. The MSIs were inserted until the screw threads were no longer visible and the base of the necks were flush with the gingiva. In subjects who had thicker than average gingiva (ie, greater than approximately 1 mm), additional turns were applied to compensate. After full insertion, a digital torque screwdriver (Imada, Northbrook, IL) was applied to each MSI for a half turn and the

resulting insertion torque was recorded. Constant communication was maintained with subjects during placement using a thumbs up/thumbs down system to ensure that they experienced minimal pain during MSI placement.

After placement, periapical radiographs were taken to ensure that the MSIs were located in bone between tooth roots (Figure 3). Pairs of adjacent implants were immediately loaded with a nickel titanium closed-coil spring (Ormco, Orange, CA) stretched to deliver a force of 100 g (Figure 4). Stainless steel ligature wires were threaded through the miniscrew heads and attached to the springs. Triad gel (Dentsply, York, PA) was applied and cured over the ligature ends to prevent potential wire abrasion to the cheeks or gingiva. The distance between each pair of screws was measured with calipers. Following placement, subjects rinsed with Peridex for an additional 45 seconds, and were instructed to rinse each night for 5-7 nights. Intraoral photos were taken, and oral hygiene and miniscrew care instructions were given. Orthodontic wax was given to each subject for use as needed to prevent cheek irritation.

Follow-up

Subjects were recalled after 1, 3, 5, and 8 weeks. At each appointment, miniscrew stability was verified and the distance between implants was measured. Subjects were also given a follow-up questionnaire relating to pain and discomfort experienced during the study (Appendix C). The first two questions were asked using a 10 cm Visual Analog Scale (VAS), with “No pain” and “Worst pain ever” as anchors. The first question was used as a baseline to verify consistency between timepoints. The

second question asked how much pain the patient was currently in. The third question, anchored with “No discomfort” and “Worst discomfort ever”, asked how much discomfort the patient was currently experiencing. The next two questions asked subjects whether they took medications to relieve pain or discomfort associated with the MSIs, and whether they took medications to relieve pain or discomfort not associated with MSIs. The final question asked if the miniscrew implants caused any type of injury.

Subjects were instructed to call the examiner if they experienced any problems or had loose screws. If one screw on one side failed, it was replaced when there was sufficient space intraorally to move the MSI more apically. In cases where vestibular height precluded MSI replacement apically or where the previous site was inflamed, the spring was removed and the MSI was not replaced. If both screws on one side failed, they were removed and not replaced. After 8 weeks, all remaining springs and screws were removed. Removal torque was recorded for the first counterclockwise turn of each MSI using the digital torque screwdriver.

Statistical Analysis

SPSS Version 22 (SPSS Inc, Chicago IL) was used for data analysis. Insertion torque, removal torque, and MSI distance data were analyzed using paired samples t-tests. Failed and not failed MSI groups were compared using Chi-Square tests. Timing of failures was evaluated using non-parametric Mann-Whitney tests. Significance was determined for survey responses using Friedman tests, and differences between timepoints were compared using 2-tailed Wilcoxon Signed Rank Tests. Significance for

all data was set at $p < 0.05$.

CHAPTER IV

RESULTS

Failures

An implant was considered a failure if it exhibited any degree of mobility upon examination (Table 1). The overall failure rate was 32.9% (27 out of 82 MSIs). The failure rate of the anterior screws was 35.7% (15 out of 42 MSIs) and of the posterior screws was 30.0% (12 out of 40 MSIs). Ten of the 27 failures were considered to be incidental failures, or failures where the MSIs were unintentionally but traumatically displaced by the subjects. Seven incidental failures (2 anterior, 5 posterior) occurred during meals, with subjects biting into large or hard foods (examples include apples, pears, and large hamburgers). One anterior screw was traumatically displaced when a subject was hit in the face by a cell phone. In two cases of anterior trauma, the subjects waited several days to have the failed MSI and attached spring removed. On exam, the adjacent posterior screws were also mobile. Due to the likelihood that the posterior MSI mobility was a consequence of either the initial trauma, or the instability of the loosened anterior MSI and attached spring that were not removed in a timely manner, these two failures were also considered incidental failures.

The remaining 17 failures were primary, or real, failures. The overall primary failure rate was 23.6% (17 out of 72 MSIs). The primary failure rate for the anterior screws was 31.6% (12 out of 38 MSIs) and the primary failure rate for the posterior screws was 15.2% (5 out of 33 MSIs).

There was no significant difference in failure rate between MSIs placed on the right and left sides (Table 2, Figure 5) or between anterior and posterior screws (Figure 6A and 6B). There were significantly more failures in the first half of the screws placed by the investigator than in the last half, when all screws were considered (Figure 7A) as well as when incidentally displaced screws were excluded (Figure 7B).

Three failed screws were replaced more apically within one week of reported failure. All three screws failed within 2 weeks of placement, and were not replaced again. The remaining subjects either had short vestibular heights or buccal frenum attachments that precluded MSI replacement more apically, or miniscrew sites that were inflamed from previously loosened screws. In these cases, MSIs were not replaced. All unloaded screws adjacent to failed MSIs (N = 15) maintained stability throughout the remainder of the study.

All primary failures occurred on or before day 42 (Figure 8); on average, they failed on day 24.5. Most failed between 15 and 26 days. Incidental failures, whose mean occurrence was day 36.5, displayed no clear pattern and continued throughout the full eight weeks of the study.

Insertion and Removal Torque

Insertion torque ranged from 2.3 to 10.7 Ncm, with a mean of 7.8 +/- 1.2 Ncm for the anterior screws and 7.4 +/- 1.9 Ncm for the posterior screws, with no statistically significant anteroposterior differences (Table 3). Removal torque ranged from 0.3 to 3.8 Ncm, with a mean of 1.7 +/- 0.9 Ncm for the anterior screws and 1.7 +/- 0.7 Ncm for the

posterior screws. There was no significant difference in removal torque between the anterior and posterior screws. Insertion torque was significantly ($p < 0.01$) larger than removal torque for both anterior and posterior screws.

Gingival Thickness

Mean gingival thickness was 1.08 ± 0.27 mm at the anterior insertion site, and 1.10 ± 0.05 mm at the posterior insertion site (Figure 9). There was no statistically significant difference in thickness between the anterior and posterior sites ($p = 0.745$).

MSI Tipping

The distances between pairs of adjacent MSIs decreased over time (Figure 10). Significant decreases occurred between placement and week 1 ($p < 0.01$), as well as between weeks 1 and 3 ($p = 0.027$). Decreases thereafter were small and not statistically significant.

Questionnaires

Median responses to the first question, regarding worst pain ever experienced, ranged from 74.0 to 76.9, with no statistically significant differences between the four time points (Table 4). There was a significant decrease ($p < 0.01$) in current pain reported between weeks 1 and 3, with median pain decreasing from 2.2 to 0.3. A significant decrease ($p < 0.01$) in current discomfort was also reported between weeks 1

and 3. No statistically significant difference in current pain or discomfort was reported after the first week.

The percentages of patients taking medication to relieve MSI-associated pain or discomfort decreased from 61.6% at week 1, to 4.2% at week 3 (Table 5). This represents a decrease of 57.4% between week 1 and 3, which was statistically significant ($p < 0.01$). One subject reported taking medication to relieve MSI-associated pain at week 8, due to gingival swelling and soreness at the MSI site. Upon exam on the day of removal (i.e., at 8 weeks), the MSI was found to be mobile. The percentage of subjects taking analgesics for pain unrelated to MSIs ranged from 20.8% to 29.2%, with no statistically significant differences between time points (Table 6).

When asked “Have the miniscrews caused any type of injury?”, 46.2% of respondents responded affirmatively at week 1 (Table 7). Reported injuries were due to cheek rubbing and mucosal ulceration from the MSI head (N=8), gingival sloughing due to topical anesthetic (N=2), and gingival irritation due to the coil spring (N=2). One subject reported injury on week 5, due to the recurrence of a small cheek ulceration that lasted for three days. Another subject, who had the previously mentioned mobile screw, reported painful and swollen gingiva at week 8.

CHAPTER V

DISCUSSION

Incidental Failures

There are two types of miniscrew failures: real, or primary failures, which are well-documented in the literature, and secondary or incidental failures, which are caused by direct trauma and generally avoidable. In the present study, a significant number of screws were traumatically dislodged by subjects. Most of these failures occurred when subjects bit into large or tough foods. While subjects were initially advised to avoid hard foods, these instructions were obviously ignored by some after they became acclimated to the MSIs. There is no literature attributing unintentional subject-inflicted trauma as a cause for miniscrew failure. In addition, MSI stability has not previously been assessed in subjects not undergoing orthodontic treatment. An informal survey of four clinical orthodontists, with a cumulative of 42 years of experience using MSIs in a private practice setting, showed that ‘none’, ‘maybe one’, and ‘very few, if any’ trauma-related failures occurred in their patients.

Decreased incidental failures might be expected among orthodontic patients because they are less likely to bite and chew harder foods, usually due to orthodontic pain and their tendency to choose a softer diet.⁹²⁻⁹⁵ This explains the significant reductions in maximum isometric bite forces that occur after presurgical orthodontics⁹⁶ and functional appliance therapy.⁹⁷ Furthermore, the profile of orthodontic brackets and wires provides a physical barrier that shields MSIs from forces delivered by food boluses

during mastication. The profile of braces also displaces the cheeks and lips off of the gingiva, which could provide a buffer to minimize muscular forces that would otherwise transfer directly onto the MSI. In addition, orthodontic patients are usually given dietary guidelines that restrict the consumption of hard or sticky foods that are difficult to eat and more likely to cause appliance breakage. Since incidental trauma-related failures are less likely among orthodontic patients, it is important to compare both the total failures and the primary, non-traumatic failures to the literature.

MSI Failure Rate

The failure rate of 3 mm MSIs placed in human subjects by an inexperienced operator is higher than previously reported rates for longer screws. The primary failure rate in the present study was 23.6%. The most recent comprehensive systematic review of the literature indicates that, on the basis of the 4987 MSIs placed in 2281 patients, approximately 13.5% (95% confidence interval 11.5-15.8%) might be expected to fail.³⁸ However, this review included studies with various screw designs (several as long as 17 mm), placed throughout the oral cavity (i.e., maxilla, mandible, palate, retromolar pad, etc.), and used for a variety of treatments. Due to the large variation in placement site characteristics, MSI design factors, insertion techniques, and loading protocol, definitive statements regarding causes of MSI failure could not be made, and larger prospective controlled trials were recommended.

While there are no human studies using 3 mm MSIs to compare with, experimental animal studies have reported good success rates. In canine jaws, Mortensen

et al reported an overall failure rate of 9.4% for 3 mm MSIs after problematic MSIs (i.e. those with broken tips and those that failed due to trauma) were excluded.⁸ Liu et al reported an overall 9.2% failure rate in a series of four studies that placed 3 mm MSIs in the cranium of rabbits and loaded with various expansive forces.⁹⁻¹² Most recently, Truong et al reported a 3% failure rate for fluted and non-fluted 3 mm MSIs loaded with 100 g of force in rabbits.¹³ The discrepancy between human and animal studies suggests that the stability of 3 mm MSIs is dependent on factors other than length.

Only two clinical studies have been published using shorter MSIs in the buccal maxillary posterior segment of humans, and their results differ significantly. Suzuki et al reported a failure rate of 6.6%, with no differences in stability between immediately-loaded 5, 6, and 7 mm MSIs.⁵⁴ Baek et al reported a much higher 24.8% failure rate for 5 mm MSIs that were loaded after two to three weeks.⁹⁸ These conflicting figures also suggest that there must be some other factor or factors besides length that account for 3 mm MSI instability.

One factor that was potentially important in the current study was the MSI insertion site. The primary failure rate for the anterior screws placed distal to the canine was twice (30.8 vs 15.2%) as high as the rate for those placed between the second premolar and first molar. This difference might be due to the anterior screws having often been required to be placed in non-keratinized moveable mucosa, which is a known risk factor for miniscrew failure.^{69,99-101} Buccal frenum attachments were also frequently located at varying heights distal to the canines, and may have placed intermittent forces on the MSIs. In addition, several participants with higher smile lines complained that the

corners of their upper lips “hooked” on the anterior MSIs when smiling. MSIs located between the second premolars and first molars, the most common insertion location documented in the literature, did not pose any of these issues.

Clinician Experience

Clinician experience is an important determinant for MSI success. One graduate orthodontic resident, who had previously placed only five buccal MSIs, purposefully placed all of the 3 mm MSIs in the current study, with significantly more of the screws failing during the first half of the study than the second (35.3% versus 13.2% failure). The primary failure rates during the last half of the experiment were 14.3% and 11.8% in the anterior and posterior sites respectively, which are similar to or less than failure rates reported for longer screws.^{36,38} Failure rates might have been further reduced with greater clinical experience, improved insertion techniques, and modification of the MSI design. It has been previously shown that MSI failure rates decrease during the course of investigations.^{102,103} A significant difference in failure rates between professors and postgraduate students (1.9% versus 29.2%) has been reported for buccal implants used for posterior tooth distalization.¹⁰⁴ In a study that evaluated operator learning curve in addition to various other factors related to MSI success, a novice operator’s failure rate with 5 mm MSIs placed in the midpalate decreased from 25% (9 out of 36 MSIs) during the first 18 months, to 8.8% (6 out of 68 MSIs) during the next 18 months, with further decreases thereafter.¹⁰⁵ Improved skills over time are important for success and must be a consideration for future MSI stability evaluations.

Timing of Failures

Failures of 3 mm miniscrews mostly occur between two to four weeks after insertion. On average, primary failure of MSIs in the current study occurred at 24.5 days. Multiple studies have reported that the majority of MSI failures occur within one month after placement.^{46,60,106-109} Longitudinal assessments of MSI stability in dogs reveal that stability decreases for 3 weeks, followed by increases thereafter.^{49,110,111} Following MSI insertion, damaged bone must be removed by osteoclasts during the initial stages of the healing process, which decreases primary stability. Following alveolar trauma, osteoclastic activity increases during the first week, and declines to control levels after approximately 3 to 4 weeks.^{112,113} Newly formed immature bone is evident around MSIs after 2 to 3 weeks.^{47,114} Stability increases are evident after 3-4 weeks as the deposition and remodeling of new bone around the implant over time (i.e., increased secondary stability) surpasses the resorption of the old bone.^{49,110,111} Strategies to reduce trauma to bone during insertion should produce greater MSI stability.

Insertion and Removal Torque

Insertion torque measurements indicate that the primary stability of 3 mm MSIs is similar to the primary stability of longer screws. In the present study, insertion torque ranged from 2.3 to 10.7 Ncm, with a mean of 7.8 and 7.4 Ncm in the anterior and posterior sites, respectively. These values are comparable to several previous reports using 8 mm MSIs.^{51,60,115-117} Considerably higher mean insertion torques, up to 16.95 Ncm, have been reported for longer self-drilling MSIs.⁶¹ Lower placement torque values,

under 5 Ncm, have been reported for 5, 6, and 7 mm MSIs placed between the maxillary and mandibular second premolars and first molars, with the greatest insertion torques measured for the longer length MSIs placed in the mandible.⁵⁴ Lower torque values may have been due to pre-drilling.^{60,118}

Importantly, insertion torque in the present study was within the range recommended by Motoyoshi et al, who reported significantly higher stability rates for MSIs (pre-drilled 8 mm screws) with maximum insertion torques ranging from 5 to 10 Ncm, than for those with maximum insertion torques less than 5 or greater than 10 Ncm.⁵¹ Suzuki et al also found decreased stability when insertion torque exceeded 10.1 Ncm.⁵⁴ Interestingly, a recent systematic review found no strong evidence linking specific insertion torque levels with higher success rates.⁵⁵

Shorter and longer screws likely exhibit comparable insertion torque because primary stability depends primarily on the cortical thickness and density.^{45,88} Cortical bone thickness of 1 mm or more has been associated with fewer miniscrew failures.³⁸ Similar insertion torque between short and long screws suggests similar primary stability, and will likely result in a similar healing process.

On the other hand, removal torque indicates that 3 mm MSIs may have decreased secondary stability compared with longer screws. The average removal torque for the 3 mm MSIs was 1.7 Ncm, with a range from 0.3 to 3.8 Ncm. These values are lower than mean removal torques reported by previous studies, which range from 4.4 to 16.4 Ncm.^{59-61,116,119} One explanation for lower removal torque is the significantly shorter healing time in the present study compared to others. The average healing times for the

previously mentioned studies ranged from approximately 6.5 to 23 months, while the maximum healing time for the 3 mm MSIs in the present study was 56 days. Since healing is a continual process, it is safe to assume that removal torque would increase with increased study duration. A second, more obvious reason for decreased removal torque is the simple fact that the previous reports used MSIs that were 8 mm or longer, and the present study used short 3 mm MSIs. Secondary stability increases as osseointegration occurs. Bone has been shown to form along the entire surface of MSIs during the healing phase.^{13,120,121} Since shorter screws have less surface area than longer screws, they would also have less bone-to-implant contact, and therefore decreased secondary stability.

It remains unknown how much osseointegration, or secondary stability, is “enough” with regards to MSI stability. Studies report a wide range of removal torque values, from 2.4 to 35.4, for stable MSIs.^{59,119} It has also been reported that MSIs can fracture at removal if the removal torque exceeds the limits that the MSI can withstand.⁵⁷ These reports demonstrate that higher, does not necessarily mean better. Importantly, though removal torque values were low in the present study, multiple screws exhibited bony fragments embedded in the threads upon MSI removal. This indicates that a functional connection was established between the bone and the 3 mm MSIs, beyond the bone-to-implant contact described by Brånemark⁴⁰ as osseointegration.

MSI Tipping

Miniscrew implants tip during the first few weeks after insertion. In the present study, the distances between pairs of implants decreased significantly during the first three weeks. Clinically, the change was minimal, with an average total decrease of approximately 0.5 mm between the screw heads (or 0.25 mm per MSI). Longer 17 mm MSIs placed in the zygomatic buttress have been reported to be displaced 0.4 mm.¹²² After 6 months of continuous loading, 7 mm MSIs have been shown to tip 1 mm at the screw head in the axial plane and 0.73 mm in the coronal plane.¹²³ Mortenson et al showed that, over a 6-week observation period, 6 mm MSIs moved 1.8 mm, and 3 mm MSIs moved 2.2 mm, with the amount of tipping that occurred being related to the applied forces.⁸ It is likely that the majority of miniscrew displacement occurs during the first few weeks before newly remodeled bone achieves intimate contact with the MSI threads.^{47,49} Importantly, the displaced and tipped MSIs reported in all studies were sufficiently stable to maintain orthodontic forces, indicating that MSIs do not have to remain absolutely stationary under orthodontic loading in order to achieved desired treatment effects.

Pain Questionnaires

Pain and discomfort experienced after MSI insertion was minimal and mild. Reported values (2.2% pain and 5.5% discomfort) in the present study peaked at one week, with little or no pain or discomfort thereafter. Buschang et al showed that, while 50% of patients expect MSIs to be moderately or very painful before placement, none

reported that they were moderately or very painful after treatment.⁵ Patients who had longer (6-12 mm) miniscrews placed reported peak pain (19.5%) one hour after MSI insertion, which was less than half of peak levels reported by patients with traditional orthodontic appliances.^{68,124} Subjects in the present study probably also experienced increased pain one hour after insertion. However, because shorter screws are situated further from the periodontal ligament surrounding the tooth roots, the subjects in the present study probably experienced less pain than if longer screws had been placed.

Though analgesic medication was recommended to all subjects immediately following implant placement, only 46% reported consuming medication to relieve MSI associated pain within the first week. Pain was attributed to injuries caused by MSI placement, including cheek rubbing, ulceration, gingival sloughing from topical anesthetic, and gingival irritation from the coil springs. Importantly, irritation in most subjects was resolved after 3-4 days, and not present at the one week recall. Oral ulceration has been reported in 42-76% of patients with traditional orthodontic appliances.^{125,126} Patients should not expect overall pain or discomfort with comprehensive orthodontic treatment to be any greater with the adjunct use of miniscrews.

Clinical Implications

Stable 3 mm MSIs provide numerous clinical advantages over longer screws. To minimize the potential for failure, shorter MSIs could be tied off with a light force for 6-8 weeks before applying higher forces. The increased potential for failure between 2-4

weeks should be emphasized when using 3 mm screws, perhaps with electronic reminders, so that the patients may exercise caution when eating and avoid harder foods during this time. Improvements to the MSI design may yield improved stability and patient acceptance. For example, the hexagonal head of the current design has sharp 90° edges that frequently irritated the subjects' cheeks. Increases in MSI diameter, fluting, and SLA surface treatment are all proven ways to increase the stability of 3 mm MSIs.^{67,127} Patients should be informed to expect pain and discomfort experienced initially to decline to minimal levels after 1 week. Orthodontic wax may be recommended to prevent mucosal irritation, which is likely in the first week. Perhaps most important, the MSIs need to be placed by experienced operators.

CHAPTER VI
CONCLUSIONS

- 1) 3 mm MSIs placed by an inexperienced operator in humans are more likely to fail.
With clinical experience, failure rates can be dramatically improved.
- 2) Failures of 3 mm MSIs occur mostly between 2-4 weeks after insertion.
- 3) 3 mm MSIs have acceptable levels of insertion torque but low removal torque.
- 4) 3 mm MSIs tip during the first few weeks after insertion.
- 5) Pain and discomfort experienced after 3 mm MSI placement is minimal and temporary.

REFERENCES

1. Angle EH. Treatment of Malocclusion of the Teeth: Angle's System. Philadelphia: White Dental Manufacturing Company; 1907.
2. Favero L, Brollo P, Bressan E. Orthodontic anchorage with specific fixtures: related study analysis. *Am J Orthod Dentofacial Orthop* 2002;122:84-94.
3. Kau CH, English JD, Muller-Delgado MG, Hamid H, Ellis RK, Winklemann S. Retrospective cone-beam computed tomography evaluation of temporary anchorage devices. *Am J Orthod Dentofacial Orthop* 2010;137:166.e161-165; discussion 166-167.
4. Prabhu J, Cousley RR. Current products and practice: bone anchorage devices in orthodontics. *J Orthod* 2006;33:288-307.
5. Buschang PH, Carrillo R, Rossouw PE. Orthopedic correction of growing hyperdivergent, retrognathic patients with miniscrew implants. *J Oral Maxillofac Surg* 2011;69:754-762.
6. Buschang PH, Carrillo R, Ozenbaugh B, Rossouw PE. 2008 survey of AAO members on miniscrew usage. *J Clin Orthod* 2008;42:513-518.
7. Brisceno CE, Rossouw PE, Carrillo R, Spears R, Buschang PH. Healing of the roots and surrounding structures after intentional damage with miniscrew implants. *Am J Orthod Dentofacial Orthop* 2009;135:292-301.
8. Mortensen MG, Buschang PH, Oliver DR, Kyung HM, Behrents RG. Stability of immediately loaded 3- and 6-mm miniscrew implants in beagle dogs--a pilot study. *Am J Orthod Dentofacial Orthop* 2009;136:251-259.
9. Liu SS, Opperman LA, Kyung HM, Buschang PH. Is there an optimal force level for sutural expansion? *Am J Orthod Dentofacial Orthop* 2011;139:446-455.
10. Liu SS, Kyung HM, Buschang PH. Continuous forces are more effective than intermittent forces in expanding sutures. *Eur J Orthod* 2010;32:371-380.
11. Liu SS, Opperman LA, Buschang PH. Effects of recombinant human bone morphogenetic protein-2 on midsagittal sutural bone formation during expansion. *Am J Orthod Dentofacial Orthop* 2009;136:768.e761-768; discussion 768-769.
12. Liu SS, Xu H, Sun J, Kontogiorgos E, Whittington PR, Misner KG et al. Recombinant human bone morphogenetic protein-2 stimulates bone formation during interfrontal suture expansion in rabbits. *Am J Orthod Dentofacial Orthop* 2013;144:210-217.

13. Truong P, Campbell PM, Kontogiorgos E, Taylor RW, Buschang PH. Master's Thesis: Stability and Three-Dimensional Analysis of Bone Formation in Longitudinally Fluted Miniscrew Implants Orthodontics. Dallas, Texas: Texas A&M University Baylor College of Dentistry; 2014: p. 67.
14. Gainforth B, Higley L. A study of orthodontic anchorage possibilities in basal bone. *American Journal of Orthodontics and Oral Surgery* 1945;31:406-417.
15. Linkow LI. The endosseous blade implant and its use in orthodontics. *Int J Orthod* 1969;7:149-154.
16. Linkow LI. Implant-orthodontics. *J Clin Orthod* 1970;4:685-690 passim.
17. Smith JR. Bone dynamics associated with the controlled loading of bioglass-coated aluminum oxide endosteal implants. *Am J Orthod* 1979;76:618-636.
18. Sherman AJ. Bone reaction to orthodontic forces on vitreous carbon dental implants. *Am J Orthod* 1978;74:79-87.
19. Gray JB, Steen ME, King GJ, Clark AE. Studies on the efficacy of implants as orthodontic anchorage. *Am J Orthod* 1983;83:311-317.
20. Roberts WE, Smith RK, Zilberman Y, Mozsary PG, Smith RS. Osseous adaptation to continuous loading of rigid endosseous implants. *Am J Orthod* 1984;86:95-111.
21. Linder-Aronson S, Nordenram A, Anneroth G. Titanium implant anchorage in orthodontic treatment an experimental investigation in monkeys. *Eur J Orthod* 1990;12:414-419.
22. Turley PK, Kean C, Schur J, Stefanac J, Gray J, Hennes J et al. Orthodontic Force Application to Titanium Endosseous Implants. *The Angle Orthodontist* 1988;58:151-162.
23. Turley PK, Shapiro PA, Moffett BC. The loading of bioglass-coated aluminium oxide implants to produce sutural expansion of the maxillary complex in the pigtail monkey (*Macaca nemestrina*). *Arch Oral Biol* 1980;25:459-469.
24. Smalley WM, Shapiro PA, Hohl TH, Kokich VG, Branemark PI. Osseointegrated titanium implants for maxillofacial protraction in monkeys. *Am J Orthod Dentofacial Orthop* 1988;94:285-295.
25. Creekmore TD, Eklund MK. The possibility of skeletal anchorage. *J Clin Orthod* 1983;17:266-269.

26. Roberts WE, Marshall KJ, Mozsary PG. Rigid endosseous implant utilized as anchorage to protract molars and close an atrophic extraction site. *The Angle Orthodontist* 1990;60:135-152.
27. Kokich VG. Managing complex orthodontic problems: the use of implants for anchorage. *Semin Orthod* 1996;2:153-160.
28. Wehrbein H, Merz BR, Diedrich P, Glatzmaier J. The use of palatal implants for orthodontic anchorage. Design and clinical application of the orthosystem. *Clin Oral Implants Res* 1996;7:410-416.
29. Kanomi R. Mini-implant for orthodontic anchorage. *J Clin Orthod* 1997;31:763-767.
30. Costa A, Raffainl M, Melsen B. Miniscrews as orthodontic anchorage: a preliminary report. *Int J Adult Orthodon Orthognath Surg* 1998;13:201-209.
31. Hyde JD, King GJ, Greenlee GM, Spiekerman C, Huang GJ. Survey of orthodontists' attitudes and experiences regarding miniscrew implants. *J Clin Orthod* 2010;44:481-486.
32. Miles P. 2013 survey of Australian orthodontists' procedures. *Aust Orthod J* 2013;29:170-175.
33. Orenstein IH, Tarnow DP, Morris HF, Ochi S. Factors affecting implant mobility at placement and integration of mobile implants at uncovering. *J Periodontol* 1998;69:1404-1412.
34. Esposito M, Grusovin MG, Willings M, Coulthard P, Worthington HV. The Effectiveness of Immediate, Early, and Conventional Loading of Dental Implants: A Cochrane Systematic Review of Randomized Controlled Clinical Trials. *International Journal of Oral & Maxillofacial Implants* 2007;22:893-904.
35. Reynders R, Ronchi L, Bipat S. Mini-implants in orthodontics: a systematic review of the literature. *Am J Orthod Dentofacial Orthop* 2009;135:564.e561-519; discussion 564-565.
36. Schatzle M, Mannchen R, Zwahlen M, Lang NP. Survival and failure rates of orthodontic temporary anchorage devices: a systematic review. *Clin Oral Implants Res* 2009;20:1351-1359.
37. Crismani AG, Bertl MH, Celar AG, Bantleon HP, Burstone CJ. Miniscrews in orthodontic treatment: review and analysis of published clinical trials. *Am J Orthod Dentofacial Orthop* 2010;137:108-113.

38. Papageorgiou SN, Zogakis IP, Papadopoulos MA. Failure rates and associated risk factors of orthodontic miniscrew implants: a meta-analysis. *Am J Orthod Dentofacial Orthop* 2012;142:577-595.e577.
39. Carrillo R, Buschang PH. Palatal and mandibular miniscrew implant placement techniques. *J Clin Orthod* 2013;47:737-743.
40. Branemark PI. Osseointegration and its experimental background. *J Prosthet Dent* 1983;50:399-410.
41. Albrektsson T, Branemark PI, Hansson HA, Lindstrom J. Osseointegrated titanium implants. Requirements for ensuring a long-lasting, direct bone-to-implant anchorage in man. *Acta Orthop Scand* 1981;52:155-170.
42. Woods PW, Buschang PH, Owens SE, Rossouw PE, Opperman LA. The effect of force, timing, and location on bone-to-implant contact of miniscrew implants. *Eur J Orthod* 2009;31:232-240.
43. Kim TW, Baek SH, Kim JW, Chang YI. Effects of microgrooves on the success rate and soft tissue adaptation of orthodontic miniscrews. *Angle Orthod* 2008;78:1057-1064.
44. Migliorati M, Benedicenti S, Signori A, Drago S, Barberis F, Tournier H et al. Miniscrew design and bone characteristics: an experimental study of primary stability. *Am J Orthod Dentofacial Orthop* 2012;142:228-234.
45. Huja SS, Litsky AS, Beck FM, Johnson KA, Larsen PE. Pull-out strength of monocortical screws placed in the maxillae and mandibles of dogs. *Am J Orthod Dentofacial Orthop* 2005;127:307-313.
46. Miyawaki S, Koyama I, Inoue M, Mishima K, Sugahara T, Takano-Yamamoto T. Factors associated with the stability of titanium screws placed in the posterior region for orthodontic anchorage. *Am J Orthod Dentofacial Orthop* 2003;124:373-378.
47. Berglundh T, Abrahamsson I, Lang NP, Lindhe J. De novo alveolar bone formation adjacent to endosseous implants. *Clin Oral Implants Res* 2003;14:251-262.
48. Raghavendra S, Wood MC, Taylor TD. Early Wound Healing Around Endosseous Implants: A Review of the Literature. *International Journal of Oral & Maxillofacial Implants* 2005;20:425-431.
49. Ure DS, Oliver DR, Kim KB, Melo AC, Buschang PH. Stability changes of miniscrew implants over time. *Angle Orthod* 2011;81:994-1000.

50. Friberg B, Sennerby L, Roos J, Lekholm U. Identification of bone quality in conjunction with insertion of titanium implants. A pilot study in jaw autopsy specimens. *Clin Oral Implants Res* 1995;6:213-219.
51. Motoyoshi M, Hirabayashi M, Uemura M, Shimizu N. Recommended placement torque when tightening an orthodontic mini-implant. *Clin Oral Implants Res* 2006;17:109-114.
52. Meredith N. Assessment of implant stability as a prognostic determinant. *Int J Prosthodont* 1998;11:491-501.
53. Wawrzinek C, Sommer T, Fischer-Brandies H. Microdamage in cortical bone due to the overtightening of orthodontic microscrews. *J Orofac Orthop* 2008;69:121-134.
54. Suzuki M, Deguchi T, Watanabe H, Seiryu M, Iikubo M, Sasano T et al. Evaluation of optimal length and insertion torque for miniscrews. *Am J Orthod Dentofacial Orthop* 2013;144:251-259.
55. Meursing Reynders RA, Ronchi L, Ladu L, van Etten-Jamaludin F, Bipat S. Insertion torque and success of orthodontic mini-implants: a systematic review. *Am J Orthod Dentofacial Orthop* 2012;142:596-614.e595.
56. Sullivan DY, Sherwood RL, Collins TA, Krogh PH. The reverse-torque test: a clinical report. *Int J Oral Maxillofac Implants* 1996;11:179-185.
57. Jolley TH, Chung CH. Peak torque values at fracture of orthodontic miniscrews. *J Clin Orthod* 2007;41:326-328.
58. Baker D, London RM, O'Neal R. Rate of pull-out strength gain of dual-etched titanium implants: a comparative study in rabbits. *Int J Oral Maxillofac Implants* 1999;14:722-728.
59. Chen YJ, Chen YH, Lin LD, Yao CC. Removal torque of miniscrews used for orthodontic anchorage--a preliminary report. *Int J Oral Maxillofac Implants* 2006;21:283-289.
60. Suzuki EY, Suzuki B. Placement and removal torque values of orthodontic miniscrew implants. *Am J Orthod Dentofacial Orthop* 2011;139:669-678.
61. Migliorati M, Drago S, Gallo F, Amorfini L, Dalessandri D, Benedicenti S et al. Immediate versus delayed loading: comparison of primary stability loss after miniscrew placement in orthodontic patients-a single-centre blinded randomized clinical trial. *Eur J Orthod* 2016.

62. Buschang PK, KB. Considerations for Optimizing the Use of Miniscrew Implants in Orthodontic Practice. In: Kim K, editor. Temporary Skeletal Anchorage Devices: Springer; 2014. p. 1-27.
63. Winkler S, Morris HF, Ochi S. Implant survival to 36 months as related to length and diameter. *Ann Periodontol* 2000;5:22-31.
64. Lyon WF, Cochran JR, Smith L. Actual Holding Power of Various Screws in Bone. *Ann Surg* 1941;114:376-384.
65. Pithon MM, Figueiredo DS, Oliveira DD. Mechanical evaluation of orthodontic mini-implants of different lengths. *J Oral Maxillofac Surg* 2013;71:479-486.
66. Lim SA, Cha JY, Hwang CJ. Insertion torque of orthodontic miniscrews according to changes in shape, diameter and length. *Angle Orthod* 2008;78:234-240.
67. Shah AH, Behrents RG, Kim KB, Kyung HM, Buschang PH. Effects of screw and host factors on insertion torque and pullout strength. *Angle Orthod* 2012;82:603-610.
68. Kuroda S, Sugawara Y, Deguchi T, Kyung HM, Takano-Yamamoto T. Clinical use of miniscrew implants as orthodontic anchorage: success rates and postoperative discomfort. *Am J Orthod Dentofacial Orthop* 2007;131:9-15.
69. Park HS, Jeong SH, Kwon OW. Factors affecting the clinical success of screw implants used as orthodontic anchorage. *Am J Orthod Dentofacial Orthop* 2006;130:18-25.
70. Sarul M, Minch L, Park HS, Antoszewska-Smith J. Effect of the length of orthodontic mini-screw implants on their long-term stability: A prospective study. *Angle Orthod* 2015;85:33-38.
71. Kuroda S, Yamada K, Deguchi T, Hashimoto T, Kyung HM, Takano-Yamamoto T. Root proximity is a major factor for screw failure in orthodontic anchorage. *Am J Orthod Dentofacial Orthop* 2007;131:S68-73.
72. Deguchi T, Nasu M, Murakami K, Yabuuchi T, Kamioka H, Takano-Yamamoto T. Quantitative evaluation of cortical bone thickness with computed tomographic scanning for orthodontic implants. *Am J Orthod Dentofacial Orthop* 2006;129:721.e727-712.
73. Watanabe H, Deguchi T, Hasegawa M, Ito M, Kim S, Takano-Yamamoto T. Orthodontic miniscrew failure rate and root proximity, insertion angle, bone contact length, and bone density. *Orthod Craniofac Res* 2013;16:44-55.

74. Deguchi T, Takano-Yamamoto T, Kanomi R, Hartsfield JK, Jr., Roberts WE, Garetto LP. The use of small titanium screws for orthodontic anchorage. *J Dent Res* 2003;82:377-381.
75. Ohmae M, Saito S, Morohashi T, Seki K, Qu H, Kanomi R et al. A clinical and histological evaluation of titanium mini-implants as anchors for orthodontic intrusion in the beagle dog. *Am J Orthod Dentofacial Orthop* 2001;119:489-497.
76. Caraway DM. Shear force at failure of immediately-loaded 3 mm and 6 mm miniscrew implants at six weeks post-insertion. Master's Thesis. Center for Advanced Dental Education. Saint Louis University. St. Louis, MO; 2007.
77. Margelos JT, Verdelis KG. Irreversible pulpal damage of teeth adjacent to recently placed osseointegrated implants. *J Endod* 1995;21:479-482.
78. Farr DR, Whear NM. Intermaxillary fixation screws and tooth damage. *Br J Oral Maxillofac Surg* 2002;40:84-85.
79. Rubenstein JE, Taylor TD. Apical nerve transection resulting from implant placement: a 10-year follow-up report. *J Prosthet Dent* 1997;78:537-541.
80. Hellden L. Periodontal healing following experimental injury to root surfaces of human teeth. *Scand J Dent Res* 1972;80:197-205.
81. Asscherickx K, Vannet BV, Wehrbein H, Sabzevar MM. Root repair after injury from mini-screw. *Clin Oral Implants Res* 2005;16:575-578.
82. Chen YH, Chang HH, Chen YJ, Lee D, Chiang HH, Yao CC. Root contact during insertion of miniscrews for orthodontic anchorage increases the failure rate: an animal study. *Clin Oral Implants Res* 2008;19:99-106.
83. Hembree M, Buschang PH, Carrillo R, Spears R, Rossouw PE. Effects of intentional damage of the roots and surrounding structures with miniscrew implants. *Am J Orthod Dentofacial Orthop* 2009;135:280.e281-289; discussion 280-281.
84. Poggio PM, Incorvati C, Velo S, Carano A. "Safe zones": a guide for miniscrew positioning in the maxillary and mandibular arch. *Angle Orthod* 2006;76:191-197.
85. Chaimanee P, Suzuki B, Suzuki EY. "Safe zones" for miniscrew implant placement in different dentoskeletal patterns. *Angle Orthod* 2011;81:397-403.
86. Goaslind GD, Robertson PB, Mahan CJ, Morrison WW, Olson JV. Thickness of facial gingiva. *J Periodontol* 1977;48:768-771.
87. Cha BK, Lee YH, Lee NK, Choi DS, Baek SH. Soft tissue thickness for placement of an orthodontic miniscrew using an ultrasonic device. *Angle Orthod* 2008;78:403-408.

88. Miyamoto I, Tsuboi Y, Wada E, Suwa H, Iizuka T. Influence of cortical bone thickness and implant length on implant stability at the time of surgery--clinical, prospective, biomechanical, and imaging study. *Bone* 2005;37:776-780.
89. Farnsworth D, Rossouw PE, Ceen RF, Buschang PH. Cortical bone thickness at common miniscrew implant placement sites. *Am J Orthod Dentofacial Orthop* 2011;139:495-503.
90. Cassetta M, Sofan AA, Altieri F, Barbato E. Evaluation of alveolar cortical bone thickness and density for orthodontic mini-implant placement. *J Clin Exp Dent* 2013;5:e245-252.
91. Horner KA, Behrents RG, Kim KB, Buschang PH. Cortical bone and ridge thickness of hyperdivergent and hypodivergent adults. *Am J Orthod Dentofacial Orthop* 2012;142:170-178.
92. Krishnan V. Orthodontic pain: from causes to management--a review. *Eur J Orthod* 2007;29:170-179.
93. Trein MP, Mundstock KS, Maciel L, Rachor J, Gameiro GH. Pain, masticatory performance and swallowing threshold in orthodontic patients. *Dental Press J Orthod* 2013;18:117-123.
94. Feldmann I, List T, Bondemark L. Orthodontic anchoring techniques and its influence on pain, discomfort, and jaw function--a randomized controlled trial. *Eur J Orthod* 2012;34:102-108.
95. Wiedel AP, Bondemark L. A randomized controlled trial of self-perceived pain, discomfort, and impairment of jaw function in children undergoing orthodontic treatment with fixed or removable appliances. *Angle Orthod* 2015.
96. Thomas GP, Throckmorton GS, Ellis E, 3rd, Sinn DP. The effects of orthodontic treatment on isometric bite forces and mandibular motion in patients before orthognathic surgery. *J Oral Maxillofac Surg* 1995;53:673-678; discussion 678-679.
97. Al-Khateeb SN, Abu Alhajja ES, Majzoub S. Occlusal bite force change after orthodontic treatment with Andresen functional appliance. *Eur J Orthod* 2015;37:142-146.
98. Baek SH, Kim BM, Kyung SH, Lim JK, Kim YH. Success rate and risk factors associated with mini-implants reinstalled in the maxilla. *Angle Orthod* 2008;78:895-901.
99. Viwattanatipa N, Thanakitcharu S, Uttraravichien A, Pitiphat W. Survival analyses of surgical miniscrews as orthodontic anchorage. *Am J Orthod Dentofacial Orthop* 2009;136:29-36.

100. Cheng SJ, Tseng IY, Lee JJ, Kok SH. A prospective study of the risk factors associated with failure of mini-implants used for orthodontic anchorage. *Int J Oral Maxillofac Implants* 2004;19:100-106.
101. Topouzelis N, Tsaousoglou P. Clinical factors correlated with the success rate of miniscrews in orthodontic treatment. *Int J Oral Sci* 2012;4:38-44.
102. Fritz U, Ehmer A, Diedrich P. Clinical suitability of titanium microscrews for orthodontic anchorage-preliminary experiences. *J Orofac Orthop* 2004;65:410-418.
103. Garfinkle JS, Cunningham LL, Jr., Beeman CS, Kluemper GT, Hicks EP, Kim MO. Evaluation of orthodontic mini-implant anchorage in premolar extraction therapy in adolescents. *Am J Orthod Dentofacial Orthop* 2008;133:642-653.
104. Oh YH, Park HS, Kwon TG. Treatment effects of microimplant-aided sliding mechanics on distal retraction of posterior teeth. *Am J Orthod Dentofacial Orthop* 2011;139:470-481.
105. Kim YH, Yang SM, Kim S, Lee JY, Kim KE, Gianelly AA et al. Midpalatal miniscrews for orthodontic anchorage: factors affecting clinical success. *Am J Orthod Dentofacial Orthop* 2010;137:66-72.
106. Aboul-Ela SM, El-Beialy AR, El-Sayed KM, Selim EM, El-Mangoury NH, Mostafa YA. Miniscrew implant-supported maxillary canine retraction with and without corticotomy-facilitated orthodontics. *Am J Orthod Dentofacial Orthop* 2011;139:252-259.
107. Basha AG, Shantaraj R, Moge Gowda SB. Comparative study between conventional en-masse retraction (sliding mechanics) and en-masse retraction using orthodontic micro implant. *Implant Dent* 2010;19:128-136.
108. Upadhyay M, Yadav S, Nagaraj K, Patil S. Treatment effects of mini-implants for en-masse retraction of anterior teeth in bialveolar dental protrusion patients: a randomized controlled trial. *Am J Orthod Dentofacial Orthop* 2008;134:18-29.e11.
109. Tseng YC, Hsieh CH, Chen CH, Shen YS, Huang IY, Chen CM. The application of mini-implants for orthodontic anchorage. *Int J Oral Maxillofac Surg* 2006;35:704-707.
110. Cuairan C, Campbell PM, Kontogiorgos E, Taylor RW, Melo AC, Buschang PH. Local application of zoledronate enhances miniscrew implant stability in dogs. *Am J Orthod Dentofacial Orthop* 2014;145:737-749.
111. Carney LO, Campbell PM, Spears R, Ceen RF, Melo AC, Buschang PH. Effects of pilot holes on longitudinal miniscrew stability and bony adaptation. *Am J Orthod Dentofacial Orthop* 2014;146:554-564.

112. Sebaoun JD, Kantarci A, Turner JW, Carvalho RS, Van Dyke TE, Ferguson DJ. Modeling of trabecular bone and lamina dura following selective alveolar decortication in rats. *J Periodontol* 2008;79:1679-1688.
113. Dibart S, Yee C, Surmenian J, Sebaoun JD, Baloul S, Goguet-Surmenian E et al. Tissue response during Piezocision-assisted tooth movement: a histological study in rats. *Eur J Orthod* 2014;36:457-464.
114. Kim S-J, Park Y-G, Kang S-G. Effects of Corticision on Paradental Remodeling in Orthodontic Tooth Movement. *The Angle Orthodontist* 2009;79:284-291.
115. Motoyoshi M, Matsuoka M, Shimizu N. Application of orthodontic mini-implants in adolescents. *Int J Oral Maxillofac Surg* 2007;36:695-699.
116. Motoyoshi M, Uemura M, Ono A, Okazaki K, Shigeeda T, Shimizu N. Factors affecting the long-term stability of orthodontic mini-implants. *Am J Orthod Dentofacial Orthop* 2010;137:588.e581-585; discussion 588-589.
117. Motoyoshi M, Yoshida T, Ono A, Shimizu N. Effect of cortical bone thickness and implant placement torque on stability of orthodontic mini-implants. *Int J Oral Maxillofac Implants* 2007;22:779-784.
118. Chen Y, Shin HI, Kyung HM. Biomechanical and histological comparison of self-drilling and self-tapping orthodontic microimplants in dogs. *Am J Orthod Dentofacial Orthop* 2008;133:44-50.
119. Kim SH, Cho JH, Chung KR, Kook YA, Nelson G. Removal torque values of surface-treated mini-implants after loading. *Am J Orthod Dentofacial Orthop* 2008;134:36-43.
120. Ikeda H, Rossouw PE, Campbell PM, Kontogiorgos E, Buschang PH. Three-dimensional analysis of peri-bone-implant contact of rough-surface miniscrew implants. *Am J Orthod Dentofacial Orthop* 2011;139:e153-163.
121. Massey CC, Kontogiorgos E, Taylor R, Opperman L, Dechow P, Buschang PH. Effect of force on alveolar bone surrounding miniscrew implants: a 3-dimensional microcomputed tomography study. *Am J Orthod Dentofacial Orthop* 2012;142:32-44.
122. Liou EJ, Pai BC, Lin JC. Do miniscrews remain stationary under orthodontic forces? *Am J Orthod Dentofacial Orthop* 2004;126:42-47.
123. Garg KK, Gupta M. Assessment of stability of orthodontic mini-implants under orthodontic loading: A computed tomography study. *Indian J Dent Res* 2015;26:237-243.

124. Scheurer PA, Firestone AR, Burgin WB. Perception of pain as a result of orthodontic treatment with fixed appliances. *Eur J Orthod* 1996;18:349-357.
125. Kvam E, Gjerdet NR, Bondevik O. Traumatic ulcers and pain during orthodontic treatment. *Community Dent Oral Epidemiol* 1987;15:104-107.
126. Otasevic M, Naini FB, Gill DS, Lee RT. Prospective randomized clinical trial comparing the effects of a masticatory bite wafer and avoidance of hard food on pain associated with initial orthodontic tooth movement. *Am J Orthod Dentofacial Orthop* 2006;130:6.e9-15.
127. Chang CS, Lee TM, Chang CH, Liu JK. The effect of microrough surface treatment on miniscrews used as orthodontic anchors. *Clin Oral Implants Res* 2009;20:1178-1184.

APPENDIX A

FIGURES

Figure 1. Periapical radiographs taken on each side of the maxilla in order to visualize bone between posterior tooth roots. Planned MSI sites (located between the upper canines and first premolars, and between second premolars and first molars) are indicated by black arrows.

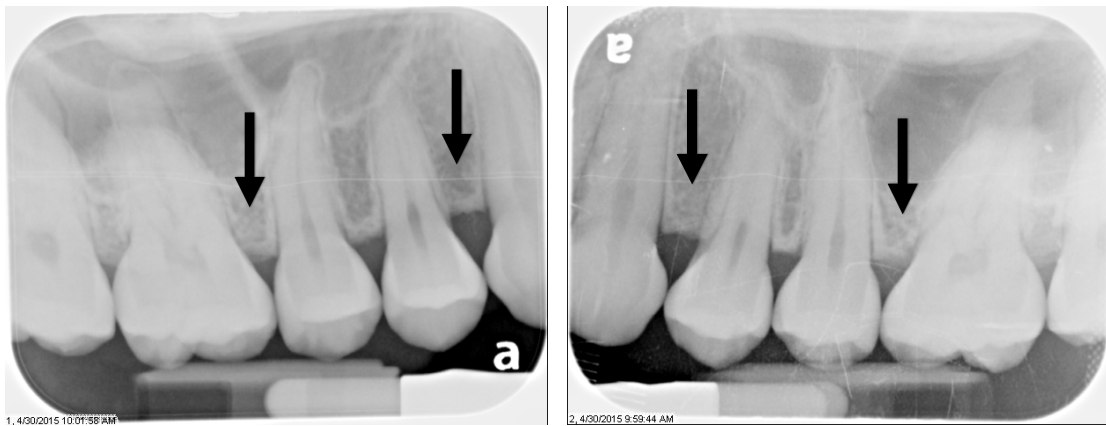


Figure 2. MSI placement protocol. A. Topical anesthesia was applied at each MSI site for 2 minutes and rinsed. B. After anesthesia was verified, gingival thickness was measured at the insertion site using a sharp explorer with an endodontic rubber stop placed perpendicular to the mucosal surface with light pressure through soft tissue until hard bony surface was contacted. C. 3 mm MSIs were inserted perpendicularly into bone using a manual driver. MSIs were inserted until screw threads were no longer visible and the base of the necks were flush with the gingiva. D. After full insertion, a digital torque screwdriver was applied to each MSI for a half turn and the resulting insertion torque was recorded.



Figure 3. Periapical radiographs taken after MSI placement to ensure that the MSIs were located in bone between tooth roots.

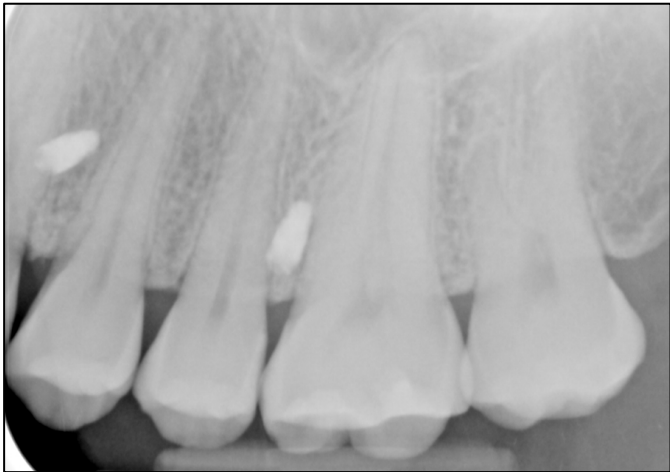


Figure 4. Pairs of adjacent implants were immediately loaded with a nickel titanium closed-coil spring stretched to deliver a force of 100g.



Figure 5. Percentages of MSI failures for the right and left sides.

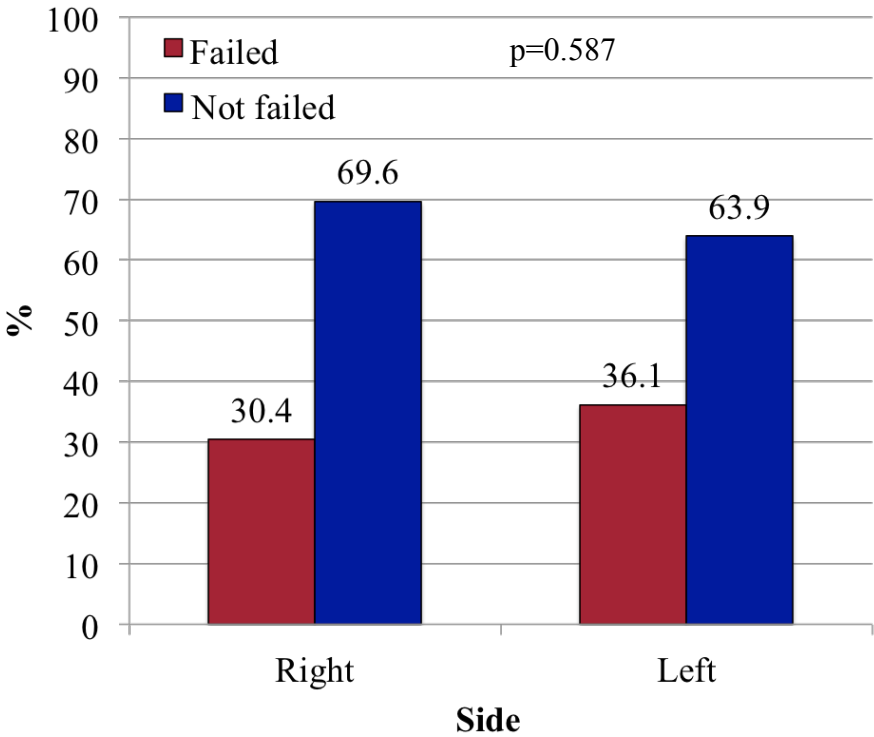


Figure 6A. Percentages of anterior and posterior MSI failures, out of all MSIs placed (i.e., 82 total).

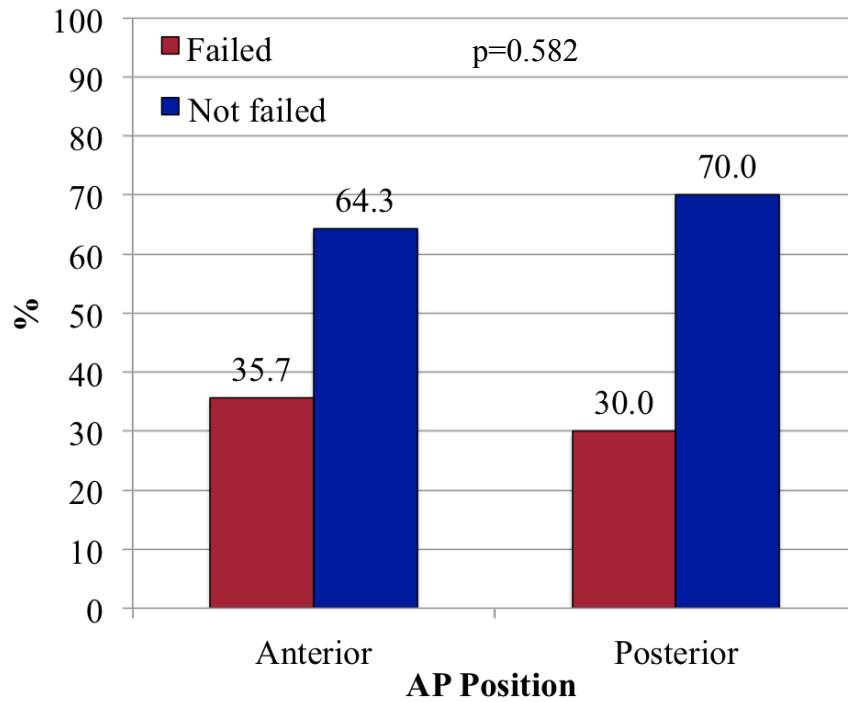


Figure 6B. Percentages of anterior and posterior MSI failures, excluding incidental failures (i.e., 72 total).

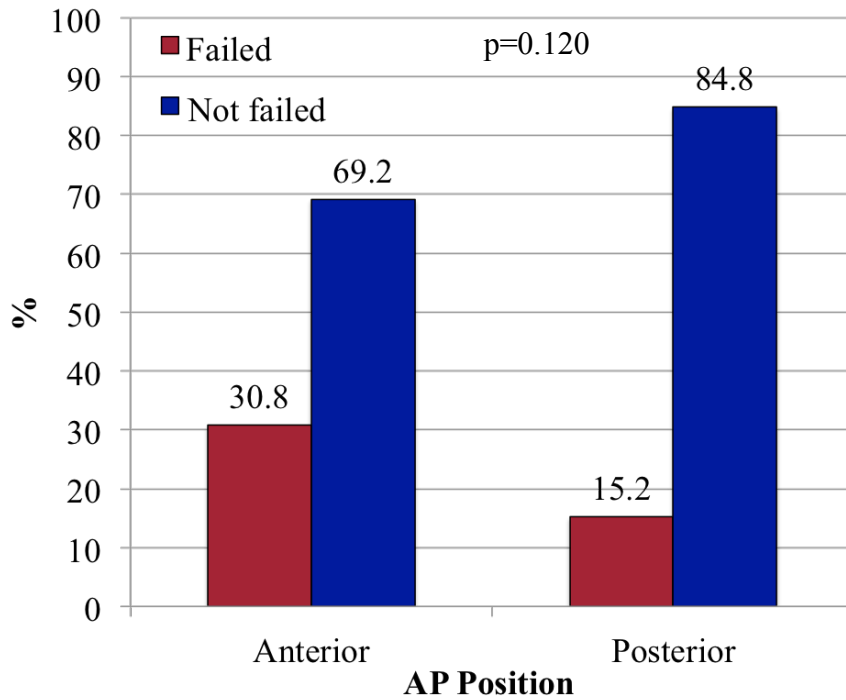


Figure 7A. Percentages of MSI failures for those placed early (i.e., the first half of MSIs placed by investigator) and late (i.e., the last half placed), for all MSIs placed (82 total).

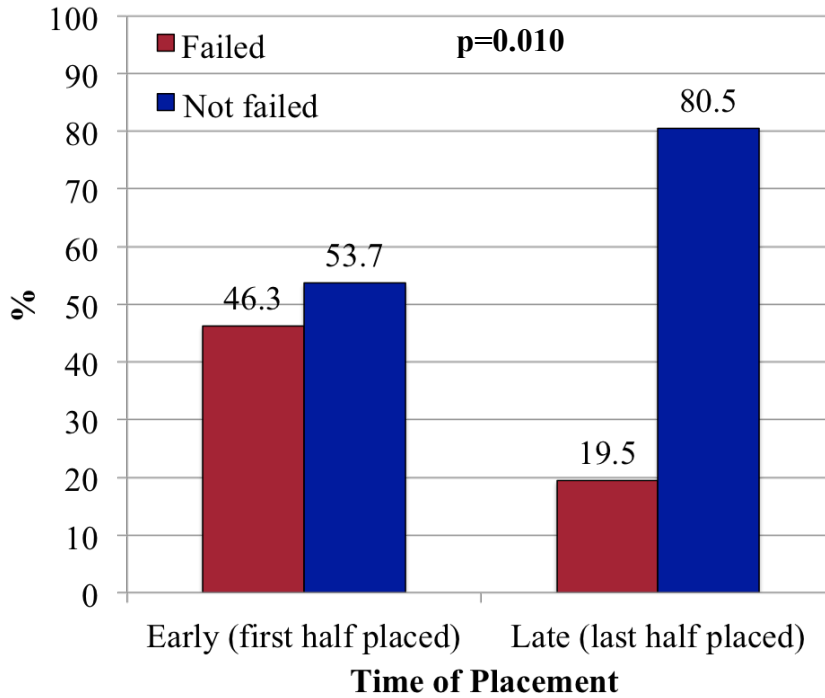


Figure 7B. Percentages of MSI failures for those placed early (i.e., the first half of MSIs placed by investigator) and late (i.e., the last half), excluding incidental failures (72 total).

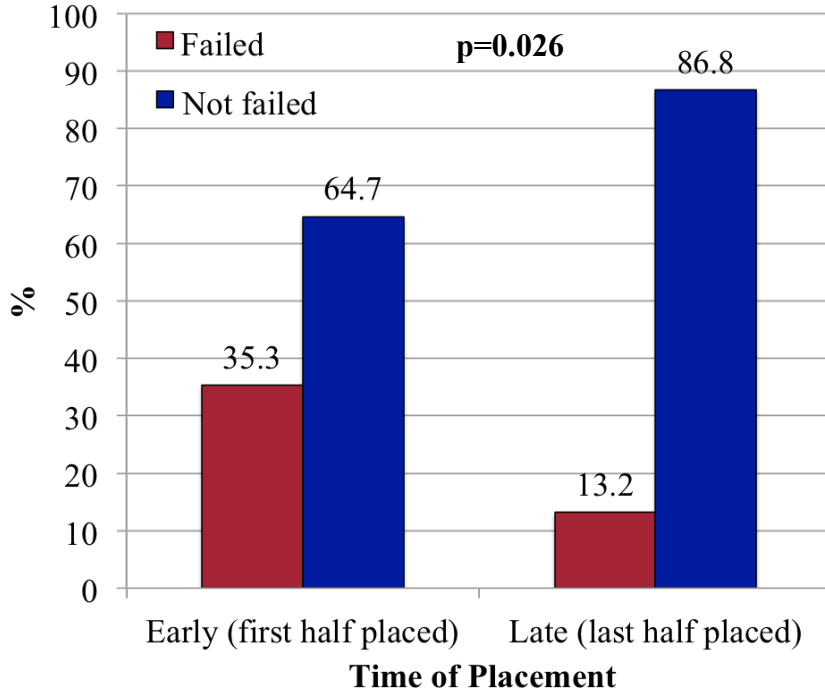


Figure 8. Day at which the primary and incidental failures occurred.

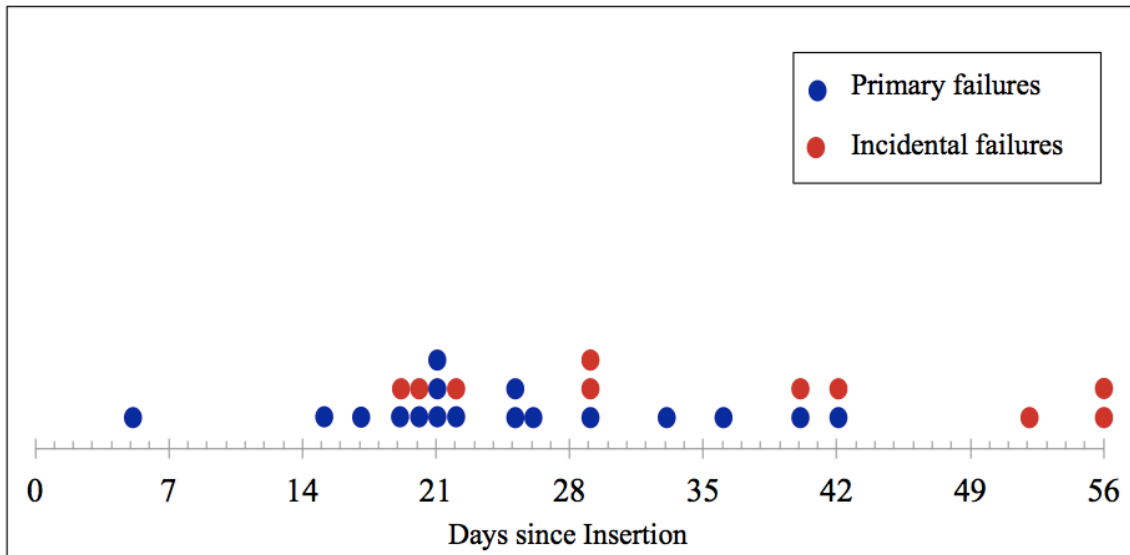


Figure 9. Gingival thickness measurements (mean +/- SD) at the anterior and posterior MSI insertion sites.

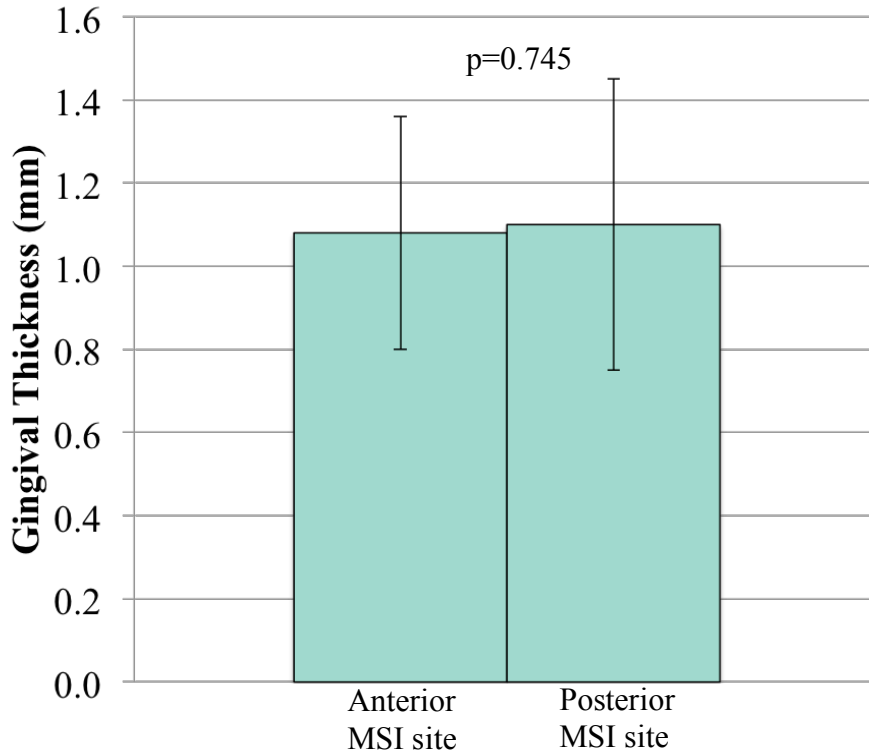
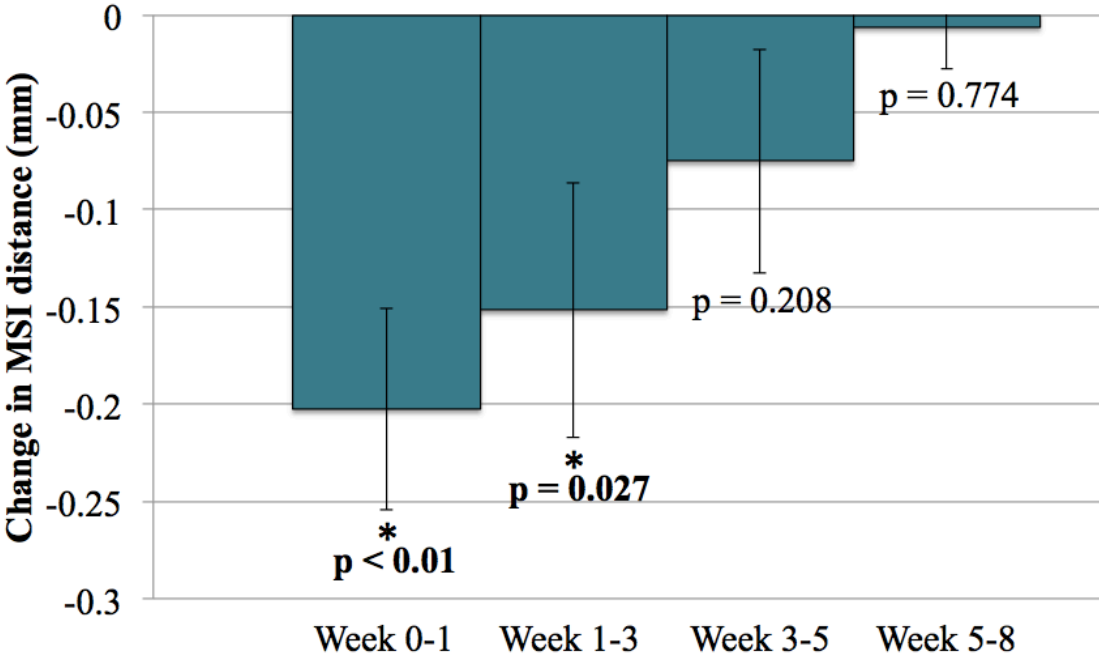


Figure 10. Mean change in distance between adjacent MSIs at each time interval (+/- standard error of the mean)



APPENDIX B

TABLES

Table 1. Miniscrew failure rate

	All Failures (primary and incidental fails)	Primary Failures (excluding incidental fails)
All MSIs	27/82 (32.9%)	17/72 (23.6%)
Anterior MSIs	15/42 (35.7%)	12/38 (31.6%)
Posterior MSIs	12/40 (30.0%)	5/33 (15.2%)

Table 2. Factors potentially associated with MSI failure

Factor		Failed	Not failed	Sig.
Side	Right	14/46 (30.4%)	32/46 (69.6%)	0.587
	Left	13/36 (36.1%)	23/36 (63.9%)	
AP (all screws - 82 total)	Anterior	15/42 (35.7%)	27/42 (64.3%)	0.582
	Posterior	12/40 (30%)	28/40 (70%)	
AP (excluding incidental fails – 72 total)	Anterior	12/39 (30.8%)	27/39 (69.2%)	0.120
	Posterior	5/33 (15.2%)	28/33 (84.8%)	
Time of placement (all screws – 82 total)	Early (first half placed)	19/41 (46.3%)	22/41 (53.7%)	0.010
	Late (last half placed)	8/41 (19.5%)	33/41 (80.5%)	
Time of placement (excluding incidental fails – 72 total)	Early (first half placed)	12/34 (35.3%)	22/34 (64.7%)	0.026
	Late (last half placed)	5/38 (13.2%)	33/38 (86.8%)	

Bold term indicates significance (p < 0.05)

Table 3. Mean MSI insertion torque and removal torque at 56 days

		Insertion Torque (Ncm)	Removal Torque (Ncm)	Diff.
Anterior MSIs	Mean	7.75	1.71	p < 0.01
	SD	1.24	0.94	
Posterior MSIs	Mean	7.39	1.69	p < 0.01
	SD	1.92	0.70	
Diff.		p = 0.193	p = 0.686	

Table 4. Pain and discomfort [medians (Med) and interquartile ranges] associated with miniscrews at follow-up timepoints, measured on a Visual Analog Scale

	Week 1			Week 3			Week 5			Week 8		
	25%	Med	75%	25%	Med	75%	25%	Med	75%	25%	Med	75%
Worst pain ever*	57.9	75.3	80.8	59.0	74.6	82.1	53.4	74.0	83.9	58.4	76.9	82.9
Current Pain	0.0	2.2	8.2	0.0	0.3	2.8	0.0	0.0	1.9	0.0	0.0	1.3
Current Discomfort	2.6	5.5	15.9	0.0	1.0	3.9	0.0	0.5	2.9	0.0	0.0	2.2

*Indicates the worst pain ever experienced by the subject prior to study participation

Table 5. Frequency of responses to the question, “Did you take medication to relieve pain or discomfort associated with miniscrews?”

	Never	Seldom	Frequently	Always
Week 1	10/26 (38.5%)	12/26 (46.2%)	4/26 (15.4%)	-
Week 3	23/24 (95.8%)	1/24 (4.2%)	-	-
Week 5	24/24 (100%)	-	-	-
Week 8	23/24 (95.8%)	1/24 (4.2%)	-	-

Table 6. Frequency of responses to the question, “Did you take medication to relieve pain or discomfort **not** associated with miniscrews?”

	Never	Seldom	Frequently	Always
Week 1	19/26 (73.1%)	7/26 (26.9%)	-	-
Week 3	17/24 (70.8%)	7/24 (29.2%)	-	-
Week 5	19/24 (79.2%)	5/24 (20.8%)	-	-
Week 8	19/24 (79.2%)	4/24 (16.7%)	1/24 (4.2%)	-

Table 7. Frequency of responses to the question, “Have the miniscrews caused any type of injury?”

	No	Yes
Week 1	14/26 (53.8%)	12/26 (46.2%)
Week 3	24/24 (100%)	-
Week 5	23/24 (95.8%)	1/24 (4.2%)
Week 8	23/24 (95.8%)	1/24 (4.2%)

APPENDIX C

**INSTRUCTIONS ON FILLING
OUT QUESTIONNAIRE**

TEXAS A&M UNIVERSITY
BAYLOR
COLLEGE OF DENTISTRY
Texas A&M Health Science Center

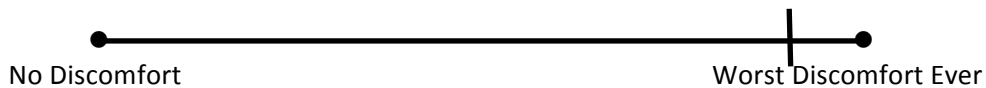
Patient # _____
Date _____

Each of the sheets that follow have 6 questions apiece. The 6 questions will ask you about discomfort you have previously experienced and are currently experiencing as well as about pain medications that you have taken.

The **first question** will ask you to remember the worst discomfort of your life and record the discomfort on the line between the phrases, “No Discomfort” and “Worst Discomfort Ever”

Example 1: Please rate the worst physical discomfort that you have ever experienced in your life on the following line.

Let’s say that the worst discomfort that I have ever experienced was a broken arm and nothing else that I have ever done has hurt that bad. I would mark this experience near the right end of the line near “Worst Discomfort Ever”



Example 2: In the past week, how often did you take medication to relieve pain or discomfort due to the miniscrews?

Please answer these questions with a 1 for never, 2 for seldom, 3 for often, and 4 for always by **CIRCLING** the appropriate response.

Ex. In the past 24 hours how often did you take medication to relieve pain or discomfort due to the miniscrews?

1 = NEVER 2 = SELDOM 3 = OFTEN 4 = ALWAYS

Example 3: Have the miniscrew implants caused any type of injury?

Please mark the appropriate answer with a **CHECK**, and include any additional information on the line.

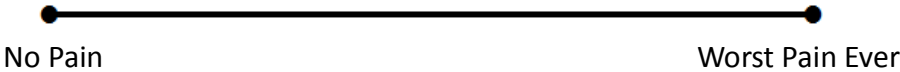
No Yes
If yes, describe the injury. _____

**PATIENT INFORMATION
AND SURVEY: WEEK 1**

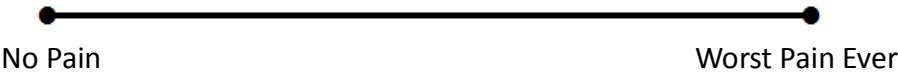
Patient # _____
Date _____

TEXAS A&M UNIVERSITY
BAYLOR
COLLEGE OF DENTISTRY
Texas A&M Health Science Center

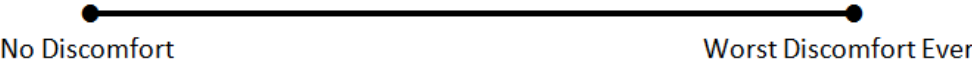
1. Please rate the worst physical pain that you have ever experienced in your life.



2. Rate the amount of pain that you are currently experiencing with your miniscrews.



3. Rate how much discomfort you are currently experiencing with your miniscrews.



In the past 1 week, how often:

4. Did you take medication to relieve pain or discomfort associated with miniscrews?
1 = NEVER 2 = SELDOM 3 = OFTEN 4 = ALWAYS

5. Did you take medication to relieve pain not associated with miniscrews?
1 = NEVER 2 = SELDOM 3 = OFTEN 4 = ALWAYS

6. Have the miniscrew implants caused any type of injury?
 No Yes
If yes, describe the injury. _____

PATIENT INFORMATION AND SURVEY: WEEK 3


Initials _____ Date _____

TEXAS A&M UNIVERSITY


BAYLOR
COLLEGE OF DENTISTRY

 Texas A&M Health Science Center


1. Please rate the worst physical pain that you have ever experienced in your life.


 No Pain Worst Pain Ever

2. Rate the amount of pain that you are currently experiencing with your miniscrews.


 No Pain Worst Pain Ever

3. Rate how much discomfort you are currently experiencing with your miniscrews.


 No Discomfort Worst Discomfort Ever

In the past 1 week, how often:

4. Did you take medication to relieve pain or discomfort associated with miniscrews?
 1 = NEVER 2 = SELDOM 3 = OFTEN 4 = ALWAYS

5. Did you take medication to relieve pain not associated with miniscrews?
 1 = NEVER 2 = SELDOM 3 = OFTEN 4 = ALWAYS

6. Have the miniscrew implants caused any type of injury?

[] No [] Yes

If yes, describe the injury. _____

PATIENT INFORMATION AND SURVEY: WEEK 5


Initials _____ Date _____

TEXAS A&M UNIVERSITY

BAYLOR
COLLEGE OF DENTISTRY


 Texas A&M Health Science Center

1. Please rate the worst physical pain that you have ever experienced in your life.




No Pain
Worst Pain Ever

2. Rate the amount of pain that you are currently experiencing with your miniscrews.



No Pain
Worst Pain Ever

3. Rate how much discomfort you are currently experiencing with your miniscrews.



No Discomfort
Worst Discomfort Ever

In the past 1 week, how often:

4. Did you take medication to relieve pain or discomfort associated with miniscrews?
 1 = NEVER 2 = SELDOM 3 = OFTEN 4 = ALWAYS

5. Did you take medication to relieve pain not associated with miniscrews?
 1 = NEVER 2 = SELDOM 3 = OFTEN 4 = ALWAYS

6. Have the miniscrew implants caused any type of injury?

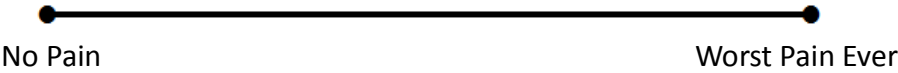
[] No [] Yes

If yes, describe the injury. _____

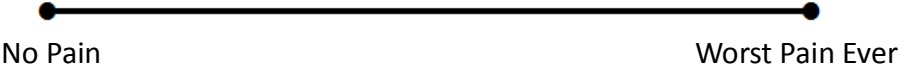
PATIENT INFORMATION AND SURVEY: WEEK 8

Initials _____ Date _____

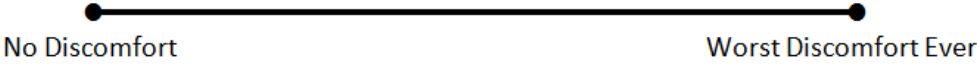
1. Please rate the worst physical pain that you have ever experienced in your life.



2. Rate the amount of pain that you are currently experiencing with your miniscrews.



3. Rate how much discomfort you are currently experiencing with your miniscrews.



In the past 1 week, how often:

4. Did you take medication to relieve pain or discomfort associated with miniscrews?
 1 = NEVER 2 = SELDOM 3 = OFTEN 4 = ALWAYS

5. Did you take medication to relieve pain not associated with miniscrews?
 1 = NEVER 2 = SELDOM 3 = OFTEN 4 = ALWAYS

6. Have the miniscrew implants caused any type of injury?
 No Yes
 If yes, describe the injury. _____