ผลของขนาดเส้นผ่านศูนย์กลางของร่องนำเจาะไว้ก่อนต่อเสถียรภาพปฐมภูมิของวัสดุฝังเกลียวขนาดเล็ก: การทดลองในห้องปฏิบัติการ

Effects of Pre-drilled Pilot-hole Diameters on Miniscrew Implant Primary Stability: An *In vitro* Study

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บทคัดย่อ

วัตถุประสงค์: เพื่อประเมินผลของขนาดเส้นผ่านศูนย์กลางของร่องนำเจาะไว้ก่อนต่อเสถียรภาพปฐมภูมิของวัสดุฝังเกลียวขนาดเล็กชนิดใช้กับเพดานปากในกระดูกสังเคราะห์คล้ายเพดาน โดยวัดแรงบิดหมุนในการใส่มากที่สุดและแรงต้านทานการดึงในแนวดิ่ง

วัสดุและวิธีการ: วัสดุฝังเกลียวขนาดเล็กไทเทเนียมอัลลอย ความยาว 6 มิลลิเมตร เส้นผ่านศูนย์กลาง 1.8 มิลลิเมตร จำนวน 60 ตัว ถูกแบ่งเป็น 6 กลุ่มๆ ละ 10 ตัว ทดสอบผลของร่องนำขนาดต่างๆ (1.1 มิลลิเมตร, 1.2 มิลลิเมตร, 1.3 มิลลิเมตร, 1.4 มิลลิเมตร, 1.5 มิลลิเมตร และ กลุ่มที่ไม่มีการเจาะร่องนำเป็นกลุ่มควบคุม) ร่องนำนี้

Abstract

Objective: To evaluate the effects of pre-drilled pilot-hole diameters on the primary stability of palatal miniscrew implants in synthetic composite palatal bone substitute using maximal insertion torque and pull-out strength measurements.

Materials and Methods: Sixty titanium alloy miniscrew implants, with a length of 6.0 mm and a diameter of 1.8 mm, were divided into six groups, 10 each, of different-sized pre-drilled pilot-hole (1.1-mm, 1.2-mm, 1.3-mm, 1.4-mm and

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ถูกเจาะในกระดูกสังเคราะห์คล้ายเพดาน (ความหนาแน่นของกระดูกพรุน 0.32 กรัม/ซีซี และของกระดูกทึบ 0.64 กรัม/ซีซี) บันทึกแรงบิดหมุนในการใส่มากที่สุดขณะไขหมุดเกลียวลงไปที่ความลึก 5.0 มิลลิเมตร หลังจากนั้นบันทึกแรงต้านการดึงในแนวดิ่งขณะที่วัสดุฝังเกลียวขนาดเล็กถูกดึงหลุดออกจากกระดูกสังเคราะห์คล้ายเพดานที่อัตราเร็ว 10.0 มิลลิเมตร ต่อนาที

ผลการศึกษา: ค่าเฉลี่ยแรงบิดหมุนในการใส่มากที่สุดแตกต่างกันอย่างมีนัยสำคัญทั้ง 6 กลุ่ม ($p<0.001$) โดยที่กลุ่มควบคุมให้ค่ามากที่สุด (11.58 นิวตันเซนติเมตร) และลดลงเมื่อขนาดของร่องนำใหญ่ขึ้น พบว่ามีค่าน้อยที่สุดเมื่อร่องนำขนาด 1.5 มิลลิเมตร (4.08 นิวตันเซนติเมตร) ไม่พบความแตกต่างอย่างมีนัยสำคัญของแรงต้านการดึงในแนวดิ่งระหว่างกลุ่มควบคุมกับกลุ่มร่องนำขนาด 1.1 มิลลิเมตร และ 1.2 มิลลิเมตร (ร้อยละ 61.1 และ ร้อยละ 66.7 ของขนาดเส้นผ่านศูนย์กลางด้านนอกของวัสดุฝังเกลียวขนาดเล็กขนาด 1.8 มิลลิเมตร ตามลำดับ) ($p>0.05$) แต่พบความแตกต่างอย่างมีนัยสำคัญระหว่างกลุ่มร่องนำขนาด 1.3 มิลลิเมตร, 1.4 มิลลิเมตร และ 1.5 มิลลิเมตร (ร้อยละ 72.2 , ร้อยละ 77.8 และ ร้อยละ 83.3 ตามลำดับ) ($p<0.001$)

บทสรุป: จากการวิจัยพบว่า แรงบิดหมุนในการใส่มากที่สุดและแรงต้านการดึงในแนวดิ่งมีค่าลดลง เมื่อร่องนำเจาะไว้ก่อนมีขนาดเส้นผ่านศูนย์กลางใหญ่ขึ้น ร่องนำขนาด 1.1 มิลลิเมตร และ 1.2 มิลลิเมตร ทำให้เกิดเสถียรภาพปฐมภูมิที่ดี เหมาะสำหรับการฝังวัสดุฝังเกลียวขนาดเล็กไทเทเนียมอัลลอยขนาด 1.8 มิลลิเมตร x 6 มิลลิเมตร ในกระดูกเพดานสังเคราะห์

คำสำคัญ: วัสดุฝังเกลียวขนาดเล็ก ร่องนำ แรงบิดหมุนในการใส่ แรงต้านการดึงออกแนวดิ่ง กระดูกเพดาน

1.5-mm diameters, and no pilot-hole as a negative control group). The different sizes of pre-drilled pilot holes were created in synthetic composite palatal bone blocks (bone density of 0.32 g/cc for cancellous bone, and 0.64 g/cc for cortical bone). The maximal insertion torque was recorded as the implant threads were engaged into the bone block at a depth of 5.0 mm. The vertical pull-out strength was measured at a 10 mm/min rate of removal until the implant was separated from the block.

Results: Mean maximal insertion torque showed significant differences ($p<0.001$) among the six groups. The control group showed the greatest maximal insertion torque (11.58 Ncm). This torque decreased with increased pilot-hole diameter. The 1.5-mm pilot-hole exhibited the least maximal insertion torque (4.08 Ncm). There were no significant differences in pull-out strength between the no-pilot-hole and 1.1-mm and 1.2-mm pre-drilled pilot-hole diameters (61.1% and 67.7% of the implant outer diameter, respectively) ($p>0.05$). However, the significant differences were found between 1.3-mm, 1.4-mm, and 1.5-mm pilot-hole diameters, (72.2%, 77.8%, and 83.3% the implant outer diameter, respectively) ($p<0.001$).

Conclusions: The maximal insertion torque and the pull-out strength decrease when pre-drilled pilot-hole diameter increases. The 1.1-mm- and 1.2-mm-diameter pre-drilled pilot-hole provide optimal primary stability and are suggested for 1.8 mm x 6 mm titanium alloy implant placement in synthetic palatal bone.

Keywords: miniscrew implant, pre-drilled pilot-hole, insertion torque, pull-out strength, palatal bone

Introduction

Over decades, miniscrew implants have been widely accepted as a reliable approach for providing a temporary anchorage-control device during orthodontic treatment.(1,2) Miniscrew implant placement has become a solution in case of either lack of dental support or absence of patient compliance.(3,4) Miniscrew implants are meant to be used for a certain period and are detached by the end of their application. Sufficient primary stability is, thus, an essential factor for miniscrew implant success.(5) Major factors affecting primary stability are cortical bone quality and quantity. This explains why palatal sites have been suggested as the most suitable placement sites(6), with thick and dense cortical bone, few vital anatomical structures and an abundance of keratinized tissue.

Pull-out strength testing is a standard method for assessing miniscrew implant mechanical properties, not only in orthodontics, but also in plastic and maxillofacial surgery, orthopedics and neurosurgery.(7) Pull-out strength is determined by the amount of force applied to remove a miniscrew implant from its placement site. Despite other factors, maximal insertion torque can also influence both the success and failure rate of miniscrew implants. Motoyoshi, *et al.*(8) investigated the success rate of miniscrew implant insertion and found significantly greater maximal insertion torque in the failure group than in the successful group. They recommended a maximal insertion torque range of 5.0 Ncm to 10.0 Ncm to increase percentage of implant success. Suzuki, *et al.*(9) agreed that a higher possibility of implant failure is associated with greater than 10.0 Ncm of maximal insertion torque.

The pre-drilling insertion system has been recommended for miniscrew placement into highly dense cortical bone to decrease compression along the bone-implant interface.(10) However, the larger the pre-drilled pilot-hole, the less insertion torque is required.(11) It has been suggested that pre-drilled pilot-hole diameters in the range of 70.0% - 85.0% of miniscrew implant outer diameter provide optimal primary stability.(12) Pre-drilled pilot-hole diameters for implant placement into bone with a highly dense cortical plate have not been adequately investigated. This laboratory investigation was aimed to determine the effects of pre-drilled pilot-hole diameters on implant primary stability.

Materials and Methods

Sixty titanium alloy, Ti-6Al-4V, miniscrew implants (Osstem Implant Co., Seoul, Korea: length, 6.0 mm: diameter, 1.8 mm) were randomly assigned to six groups. The first five groups were used to evaluate the effects of five pre-drilled hole diameters: 1.1 mm, 1.2 mm, 1.3 mm, 1.4 mm and 1.5 mm, and the other group was used as the negative control group with no pilot-hole for maximal insertion torque and vertical pull-out strength measurement.

Synthetic composite bone blocks (Sawbones® Pacific Research Laboratories, Inc., Vashon, WA, USA) were chosen over animal or cadaver bone because they have consistent physical properties and reliability for miniscrew comparative assessment.(13) To imitate human palatal bone(14), a 2.0 mm thick layer of 40 pcf (0.64 g/cc) epoxy-reinforced polyurethane (cortical bone) was attached to a 12.0 mm thick block of 20 pcf (0.32 g/cc) rigid polyurethane (cancellous bone). A custom-made instrument-holding system (Figure 1) was used to position the digital torque gauge (IMADA Inc., Northbrook, IL, USA) and the synthetic bone blocks to ensure the same direction of the pre-drilled pilot-hole line and implant insertion path.

A 1.1-mm pre-drilled pilot-hole with a depth of 5.0 mm was constructed manually using a drill-bit, which was housed in the chuck of the digital torque gauge. To control the pilot-hole depth, a color-code stop was placed at a distance of 5.0 mm from the drill-bit tip. The same protocol was run with all pre-drilled pilot-hole groups using 1.2-mm, 1.3-mm, 1.4-mm and 1.5-mm drill bits, respectively.

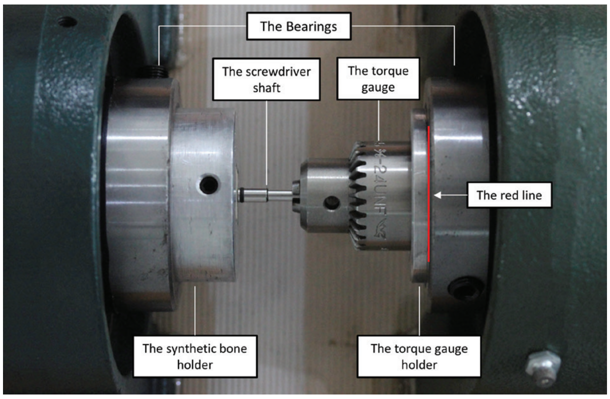
For the maximal insertion torque assessment, cubical 'Sawbones' blocks in the control group were fixed into the custom-made synthetic bone holder, which was rigidly fixed to one of the instrument-holding system's bearings. A miniscrew implant was attached to the digital torque gauge via the screwdriver shaft of the implant. A red line was drawn on the torque-gauge holder of the holding system 5 mm from its edge as a stop mark. The implant was driven 5.0 mm into the bone block (not the entire thread length) with a constant speed of twelve rotations per minute until the edge of the torque-gauge holder reached the red line (Figure 2). The maximal insertion torque was then recorded. The same protocol was run with the previously drilled synthetic bone.

After the maximal insertion torque tests, the synthetic bone cube was transferred and rigidly fixed to the inferior clamp of a Universal Testing Machine (Instron Corp., Canton, MA, USA). The miniscrew implant was fixed using a pulling apparatus which was attached to the superior clamp of the Universal Testing Machine (Figure 3). The test was run with load cell of 500 N. A vertical force with a 10 mm/min rate of removal was applied parallel to the implant long axis until the implant was detached from the block. The maximal force at the moment of implant detachment was determined as its pull-out strength.

Data were analyzed using SPSS 17.0 software (SPSS Inc., Chicago, Ill., USA). All data were tested for normality using the Shapiro-Wilk test. Means and standard deviations of maximal insertion torque and pull-out strength were measured and compared using one-way analysis of variance and Tukey's HSD post hoc comparison test. Results were considered statistically significant at $p<0.05$.

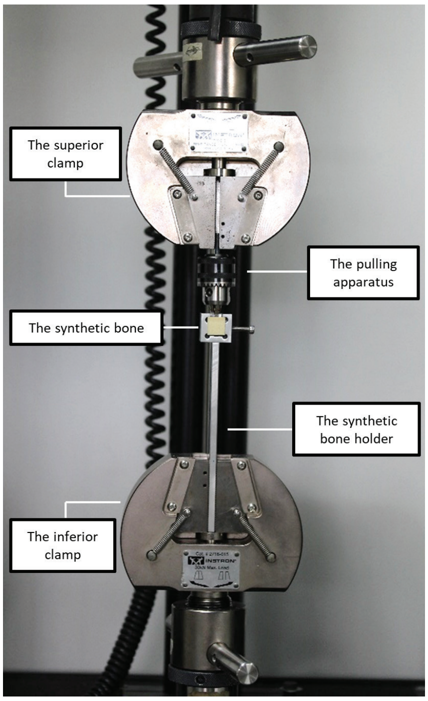
รูปที่ 1 *ระบบยึดเครื่องมือทำขึ้นเฉพาะเพื่อใช้ยึดมาตรวัดแรงบิดดิจิทัลและกระดูกสังเคราะห์*

Figure 1 *A custom-made instrument holding system was used to hold the digital torque gauge and a synthetic bone block.*



รูปที่ 2 *วัสดุฝังเกลียวขนาดเล็กถูกไขลงในกระดูกสังเคราะห์รูปลูกบาศก์ลึก 5 มิลลิเมตร โดยใช้เครื่องหมายเส้นสีแดงกำกับตำแหน่งหยุดการไขบนตัวยึดมาตรวัดแรงบิด*

Figure 2 *A miniscrew implant was driven 5 mm into the cubical bone block using the red line marked on the torque gauge holder as a stop point.*



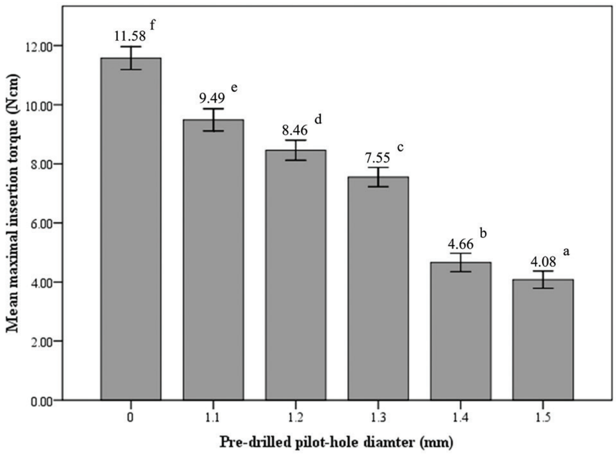
รูปที่ 3 *กระดูกสังเคราะห์ที่มีวัสดุฝังเกลียวขนาดเล็กฝังอยู่ถูกยึดกับตัวหนีบตัวล่างของเครื่องทดสอบอินสตรอนผ่านตัวยึดกระดูกสังเคราะห์ วัสดุฝังเกลียวขนาดเล็กถูกจับด้วยอุปกรณ์ดึงซึ่งติดอยู่กับตัวหนีบตัวบนของเครื่องทดสอบอินสตรอน*

Figure 3 *A synthetic composite bone cube with inserted miniscrew implant was rigidly fixed to the inferior clamp of the Universal Testing Machine via the synthetic bone holder. The miniscrew implant was fixed using a pulling apparatus which was attached to the superior clamp of the machine.*

Results

Maximal insertion torque

The mean maximal insertion torques are presented in Figure 4. The data satisfied the normality distribution, which meant that homogeneity of variance was found. One-way analysis of variance (ANOVA) revealed significant difference in mean maximal insertion torque (p<0.001) among all six groups of different pre-drilled pilot-hole diameters. Tukey's test showed that maximal insertion torque was significantly greater in the miniscrew implant inserted without using pilot-holes than in those inserted with pilot-holes. The differences between the control group and the groups with 1.1-mm, 1.2-mm, 1.3-mm, 1.4-mm and 1.5-mm pilot-hole diameters were also statistically significant (p<0.001). The post-hoc test also confirmed that there were significant differences in maximal insertion torque associated with pilot-hole diameters (p<0.001). The maximal insertion torque in implants placed in larger-diameter pilot holes was less than that in implants placed in smaller-diameter.



รูปที่ 4 *ค่าเฉลี่ยและส่วนเบี่ยงเบนมาตรฐานของแรงบิดหมุนในการใส่มากที่สุดของกลุ่มควบคุม 0 มิลลิเมตร, กลุ่มร่องนำขนาด 1.1, 1.2, 1.3, 1.4 และ 1.5 มิลลิเมตร ในกระดูกสังเคราะห์คล้ายเพดาน*

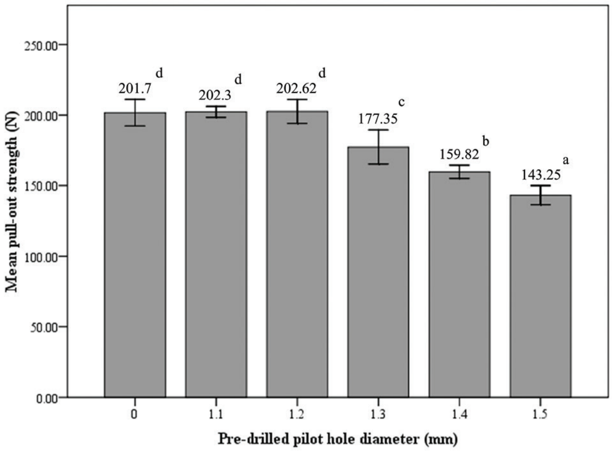
**ตัวอักษรยกที่กำกับไว้หลังค่าเฉลี่ย: อักษรที่แตกต่างกันบ่งชี้ว่ามีความแตกต่างกันอย่างมีนัยสำคัญของแรงบิดหมุนในการใส่มากที่สุดที่ (p<0.001)*

Figure 4 *Means and standard deviations of maximal insertion torque in implants placed in 0 mm (the control group), 1.1-mm, 1.2-mm 1.3-mm, 1.4-mm, 1.5-mm diameter pre-drilled pilot-holes in synthetic composite palatal bone.*

**Superscript letters following mean values: the different letters indicate significant difference in maximal insertion torque at p<0.001.*

Pull-out strength

The mean pull-out strengths are displayed in Figure 5. The implants placed in 1.1-mm and 1.2-mm diameter pilot holes exhibited insignificantly greater pull-out strength (202.30 N and 202.62 N, respectively) than did those in the control group (201.70 N). Tukey's test showed significantly greater pull-out strength in implants placed in smaller-diameter pilot holes than that in those in 1.3-mm, 1.4-mm, and 1.5-mm diameter pilot holes (177.35 N, 159.82 N, and 143.25 N, respectively). (p<0.001)



รูปที่ 5 *ค่าเฉลี่ยและส่วนเบี่ยงเบนมาตรฐานของแรงต้านการดึงในแนวดิ่งของกลุ่มควบคุม 0 มิลลิเมตร, กลุ่มร่องนำขนาด 1.1, 1.2, 1.3, 1.4 และ 1.5 มิลลิเมตร ในกระดูกสังเคราะห์คล้ายเพดาน*

**ตัวอักษรยกตามหลังค่าเฉลี่ย: อักษรที่เหมือนกันบ่งชี้ว่าไม่มีความแตกต่างอย่างมีนัยสำคัญของแรงต้านการดึงในแนวดิ่ง (p>0.05) แต่อักษรที่แตกต่างกันบ่งชี้ว่ามีความแตกต่างกันอย่างมีนัยสำคัญของของแรงต้านการดึงในแนวดิ่งที่ (p<0.001)*

Figure 5 *Means and standard deviations of pull-out strength in implants placed in 0-mm (the control group), 1.1-mm, 1.2-mm 1.3-mm, 1.4-mm, 1.5-mm diameter pre-drilled pilot-holes in synthetic composite palatal bone.*

**Superscript letters following mean values: the same letters indicate no significant difference in pull-out strength at p-value 0.05, but different letters indicate significant difference in pull-out strength at p<0.001*

Discussion

A success rate greater than 90% has been reported for palatal miniscrew implants in recent studies.[15-18] Mechanical retention between bone and the miniscrew implant appears to be the main factor affecting miniscrew implant stability rather than osseointegration during early loading.[19] Motoyoshi, *et al.*[20] have proved that the effective placement site should have more than 1 mm of cortical bone thickness to raise the success rate. Additionally, Winsauer, *et al.*[21] have suggested bony support of at least 5 mm to withstand rotational force and dynamic loads, contributing to implant stability. Suteerapongpun, *et al.*[22] also confirmed that paramedian areas of palatal bone have bone thickness of 5.0 mm to 8.0 mm and cortical bone thickness of 2.0 mm, findings which are consistent with those of Winsauer, *et al.*[21] and Motoyoshi, *et al.*[20] Information pertaining to the thickness and quality of palatal bone supports the selection of ideal miniscrew implant placement sites to secure miniscrew retention due to the great palatal bone thickness, and its lack of critical anatomical structures.

Significant decreases in mean maximal insertion torque were recorded with increased pre-drilled pilot-hole diameter because the larger the pre-drilled pilot-hole, the less adjacent bone needs to be displaced and compressed.[23] Motoyoshi, *et al.*[8] have recommended maximal insertion torque ranging from 5.0 Ncm to10.0 Ncm in the area of buccal alveolar bone using a pre-drilling miniscrew placement system. They observed greater insertion torque in failed rather than in successful miniscrew implants. Suzuki, *et al.*[9] have confirmed a higher failure with insertion torque greater than 10

Ncm, a finding corroborated by Nguyen, *et al.*(24) who found that large amounts of microdamage corresponded with an increase in the insertion torque. Yet, Suzuki, *et al.*(17) have reported the average maximal insertion torque of miniscrew implants in mid-palatal sites at 14.5 ± 1.6 Ncm and 21.1 ± 2.2 Ncm for the pre-drilling and self-drilling miniscrew implants, respectively. These findings are also supported by Di Leonardo, *et al.*(25) who found that maximal insertion torque of successful self-drilling implants placed in the palatal region ranges between 10 and 20 Ncm. However, no concrete recommendation was derived from their results.

Numerous investigations(10,12,21,23,26-29) on miniscrew implants with pre-drilled pilot-holes have indicated that the larger the pilot-hole, the less insertion torque and pull-out strength were recorded. In this investigation, there was no significant difference in pull-out strength between the control group and the groups with 1.1-mm-and 1.2-mm-diameter pilot-holes. This means that the implants in these three groups had the same holding power. However, pull-out strength significantly decreased in the group with 1.3-mm pre-drilled pilot-holes. Defino, *et al.*(26) have shown a similar trend, a finding which supports the idea a pilot-hole smaller than the inner diameter results in increased pull-out strength. The miniscrew thread depth, pitch and design are considered as crucial factors in determining pull-out strength. The association between implant stability and variations in thread pitch and depth is well-recognized.(30-34) Greater depth and smaller pitch show greater pull-out strength, which leads to greater primary stability. Scrutinized under a scanning electron microscope (SEM), the inner diameter, thread depth and thread pitch were measured as 1.30 mm, 0.25 mm and 0.77 mm, respectively. The miniscrews with no pilot-hole and those with 1.1-mm- and 1.2-mm-diameter pilot-holes engage their full thread of 0.25 mm into the cortical bone, whereas those with 1.4-mm and 1.5-mm pilot-holes had only 0.15 mm and 0.05 mm of engagement, respectively. This might explain why the miniscrew implants inserted with no pilot-hole and those with 1.1-mm and 1.2-mm pilot-holes produced similar strength.

In the past, palatal miniscrew implant placement required flap operations or soft tissue puncture due to the large diameter of implant.(4,35) However, smaller diameter implants have been recently developed to eradicate a flap-operation need. Kuroda, *et al.*(36) have also preferred a small miniscrew with a pilot-hole over palatal implant because it showed similar high success rate but less pain and discomfort for patients. Some studies have reported miniscrew implant fractures during insertion, which were strongly associated with maximal insertion torque.(37,38) The mid-palatal bone area also had a tendency to miniscrew implant fracture. One out of fifty-eight implants was reported to have fractured during self-drilling placement in the mid-palatal bone.(17)

Base on the result from this study, a pre-drilled pilot-hole is recommended for miniscrew implant placement in dense cortical bone resembling the palatal bone. Either 1.1-mm- or 1.2-mm-diameter pre-drilled pilot-holes (62% and 67% of implant outer diameter) should be the optimal size for 1.8 mm x 6 mm titanium alloy miniscrew implants. They decreased maximal insertion torque and produced great pull-out strength. This range was evidently lower than what was found in earlier studies.(12,27) The reason behind this finding might be that the instrument holding set-up allows for the same axis to be used for drilling the pilot hole and for inserting the miniscrew. On the other hand, it is possible that the largest pre-drilled pilot-hole diameter should be the size of the inner diameter of the miniscrew implant to provide optimal primary stability. However, these assumptions should be further investigated.

To date, no related study has provided details regarding the procedures for the pre-drilling of pilot-holes. This study used a rigid system to create all the pre-drilled pilot holes. However, in clinical situations, where the drilling is likely to be free-hand, the reliability and reproducibility of pilot-hole construction may be reduced because of variation in the insertion procedure. Variation in pilot-hole creation may result in an over-drilled hole or in mis-direction. In this experiment, the instrument holding system was designed to resolve those problems and eliminate confounding factors. Additionally, the instrument-holding system was created to imitate clinical drilling, because the miniscrew body should be drilled perpendicular to the palatal bone to achieve optimal retention.(39) Miniscrew implants can be inserted manually using a contra-angle hand piece or with a motorized implant driver to ensure perpendicularity. Nevertheless, the directions of clinical orthodontic force are most likely horizontal and tangential. Therefore, further clinical studies should be conducted to investigate the effects of different angles of force application.

The main limitation of this study was the inability to provide a direct reference to clinical practice. The synthetic composite bone in this study was well-selected for controlling the confounding factors, simulating palatal bone and focusing on the effect in the area of interest. However, actual human bone would be much more complicated and might be expected to result in different outcomes. Indeed, the patterns of difference associated with pre-drilled pilot-holes should be comparable for both synthetic and natural bone.

Conclusions

The maximal insertion torque and the pull-out strength decrease when pre-drilled pilot hole diameter increases. From the biomechanical point of view, the 1.1-mm- and 1.2-mm-diameter pre-drilled pilot-hole (62% and 67% of implant outer diameter) provide optimal primary stability and are suggested for 1.8 mm x 6 mm titanium alloy implant placement in synthetic palatal bone.

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References

1. Papadopoulos MA, Tarawneh F. The use of miniscrew implants for temporary skeletal anchorage in orthodontics: a comprehensive review. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2007; 103(5): e6-e15.
2. Cope JB. Temporary anchorage devices in orthodontics: a paradigm shift. *Semin Orthod* 2005; 11(1): 3-9.
3. Yao C-CJ, Lai EH-H, Chang JZ-C, Chen I, Chen YJ. Comparison of treatment outcomes between skeletal anchorage and extraoral anchorage in adults with maxillary dentoalveolar protrusion. *Am J Orthod Dentofacial Orthop* 2008; 134(5): 615-624.
4. Sandler J, Benson PE, Doyle P, et al. Palatal implants are a good alternative to headgear: a randomized trial. *Am J Orthod Dentofacial Orthop* 2008; 133(1): 51-57.

5. Melsen B, Costa A. Immediate loading of implants used for orthodontic anchorage. *Orthod Craniofac Res* 2000; 3(1): 23-28.
6. Asscherickx K, Vannet BV, Bottenberg P, Wehrbein H, Sabzevar MM. Clinical observations and success rates of palatal implants. *Am J Orthod Dentofacial Orthop* 2010; 137(1): 114-122.
7. 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(3): 307-313.
8. Motoyoshi M, Hirabayashi M, Uemura M, Shimizu N. Recommended placement torque when tightening an orthodontic mini-implant. *Clin Oral Implants Res* 2006; 17(1): 109-114.
9. Suzuki M, Deguchi T, Watanabe H, et al. Evaluation of optimal length and insertion torque for miniscrews. *Am J Orthod Dentofacial Orthop* 2013; 144(2): 251-259.
10. Heidemann W, Gerlach KL, Gröbel KH, Köllner HG. Influence of different pilot hole sizes on torque measurements and pullout analysis of osteosynthesis screws. *J Craniomaxillofac Surg* 1998; 26(1): 50-55.
11. Wilmes B, Rademacher C, Olthoff G, Drescher D. Parameters affecting primary stability of orthodontic mini-implants. *J Orofac Orthop* 2006; 67(3): 162-174.
12. Gantous A, Phillips JH. The effects of varying pilot hole size on the holding power of miniscrews and microscrews. *Plast Reconstr Surg* 1995; 95(7): 1165-1169.
13. Thompson MS, McCarthy ID, Lidgren L, Ryd L. Compressive and shear properties of commercially available polyurethane foams. *J Biomech Eng* 2003; 125(5): 732-734.
14. Wu JH, Wang HC, Chen CM , et al. Pullout strengths of orthodontic palatal mini-implants tested in vitro. *J Dent Sci* 2011; 6(4): 200-204.
15. Kakali L, Alharbi M, Pandis N, Gkantidis N, Kloukos D. Success of palatal implants or miniscrews placed median or paramedian for the reinforcement of anchorage during orthodontic treatment: a systematic review. *Eur J Orthod* 2019; 41(1): 9-20.
16. Rodriguez JC, Suarez F, Chan HL, Molina MP, Wang HL. Implants for orthodontic anchorage: success rates and reasons of failures. *Implant Dent* 2014(2); 23: 155-161.
17. Suzuki EY, Suzuki B. Placement and removal torque values of orthodontic miniscrew implants. *Am J Orthod Dentofacial Ortho*p 2011; 139(5): 669-678.
18. Karagkiolidou A, Ludwig B, Pazera P, Gkantidis N, Pandis N, Katsaros C. Survival of palatal miniscrews used for orthodontic appliance anchorage: a retrospective cohort study. *Am J Orthod Dentofacial Orthop* 2013; 143(6): 767-772.
19. 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(4): 373-378.
20. 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(5): 779-784.
21. Winsauer H, Vlachojannis C, Bumann A, Vlachojannis J, Chrubasik S. Paramedian vertical palatal bone height for mini-implant insertion: a systematic review. *Eur J Orthod* 2014; 36(5): 541-549.

22. Suteerapongpun P, Jotikasthira D, Janhom A, Wattanachai T. Palatal cortical bone thickness in thai patients with open vertical skeletal configuration, using cone-beam computed tomography. *CM Dent J* 2018; 39(1): 85-93.
23. Hung E, Oliver D, Kim KB, Kyung HM, Buschang PH. Effects of pilot hole size and bone density on miniscrew implants' stability. *Clin Implant Dent Relat Res* 2012; 14(3): 454-460.
24. Nguyen MV, Codrington J, Fletcher L, Dreyer CW, Sampson WJ. The influence of miniscrew insertion torque. *Eur J Orthod* 2018; 40(1): 37-44.
25. Leonardo BD, Ludwig B, Lisson JA, Contardo L, Mura R, Hourfar J. Insertion torque values and success rates for paramedian insertion of orthodontic mini-implants. *J Orofac Orthop* 2018; 79(2): 109-115.
26. Defino HL, Wichr CRG, Shimano AC, Kandziora F. The influence of pilot hole diameter on screw pullout resistance. *Acta Ortop Bras* 2007; 15(2): 76-79.
27. Uemura M, Motoyoshi M, Yano S, Sakaguchi M, Igarashi Y, Shimizu N. Orthodontic mini-implant stability and the ratio of pilot hole implant diameter. *Eur J Orthod* 2012; 34(1): 52-56.
28. Baumgaertel S. Predrilling of the implant site: Is it necessary for orthodontic mini-implants? . *Am J Orthod Dentofacial Orthop* 2010; 137(6): 825-829.
29. Buschang PH, Kim KB. Considerations for optimizing the use of miniscrew implants in orthodontic practice. In: Kim KB, ed: *Temporary Skeletal Anchorage Devices*, 1st ed, Berlin: Springer; 2014: 1-27.
30. Migliorati M, Signori A, Biavati AS. Temporary anchorage device stability: an evaluation of thread shape factor. *Eur J Orthod* 2012; 34(5): 582-586.
31. Gracco A, Giagnorio C, Incerti Parenti S, Alessandri Bonetti G, Siciliani G. Effects of thread shape on the pullout strength of miniscrews. *Am J Orthod Dentofacial Orthop* 2012; 142(2): 186-190.
32. Kim YK, Kim YJ, Yun PY, Kim JW. Effects of the taper shape, dual-thread, and length on the mechanical properties of mini-implants. *Angle Orthod* 2009; 79(5): 908-914.
33. Steigenga J, Al-Shammari K, Misch C, Nociti Jr FH, Wang HL. Effects of implant thread geometry on percentage of osseointegration and resistance to reverse torque in the tibia of rabbits. *J Periodontol* 2004; 75(9): 1233-1241.
34. Eraslan O, İnan Ö. The effect of thread design on stress distribution in a solid screw implant: a 3D finite element analysis. *Clin Oral Investig* 2010; 14(4): 411-416.
35. Creekmore TD, Eklund MK. The possibility of skeletal anchorage. *J Clin Orthod* 1983; 17(4): 266-269.
36. 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(1): 9-15.
37. Kuroda S, Tanaka E. Risks and complications of miniscrew anchorage in clinical orthodontics. *Jpn Dent Sci Rev* 2014; 50(4): 79-85.
38. Whang C, Bister D, Sherriff M. An *in vitro* investigation of peak insertion torque values of six commercially available mini-implants. *Eur J Orthod* 2011; 33(6): 660-666.
39. Wilmes B, Ludwig B, Vasudavan S, Nienkemper M, Drescher D. The T-zone: median vs. Paramedian insertion of palatal mini-implants. *J Clin Orthod* 2016; 50(9): 543-551.