Failure Rates for SS and Ti-Alloy Incisal Anchorage Screws: Single-Center, Double Blind, Randomized Clinical Trial

Abstract

***Objective**: Compare the 6 month failure rates for stainless steel (SS) and titanium alloy (Ti) miniscrews placed between the roots of maxillary central and lateral incisors. The null hypothesis was that there is no statistical difference in the failure rates for screws made of SS or Ti.*

***Materials and Methods**: Over a three year period (2014-17), 320 consecutive 1.5x8mm miniscrews (OBS®, iNewton Dental Ltd, Hsinchu City, Taiwan) were placed bilaterally between central and lateral incisor roots in 160 consecutive patients (26 males,134 females, mean age 25.9 yr, range 10-58 yr). All of the screws served as temporary anchorage devices (TADs) to intrude the maxillary anterior dentition. Half the TADs were made of 316LVM surgical stainless steel (SS) and the other half (160) were composed of Ti6Al4V titanium alloy (Ti). All the miniscrews were placed by the same orthodontist with a double blind, split mouth design. Torque was measured when each screw was seated to provide an index of primary stability. All TADs were immediately loaded with 2-oz (57g, 55 cN), and used for at least 6 months as anchorage to intrude the maxillary anterior segment. Anchorage loss due to a loose screw was defined as a failure.*

***Results**: The overall failure rate was 7.2% for incisor anchorage screws placed in cortical bone about 0.6mm thick. For the right and left sides combined (n=160 for each material), 18/160 SS (11.25%) and 5/160 Ti (3.125%) failed. A chi-square test revealed the difference in failure rates was statistically significant (p≤0.05). Torque levels indicating primary stability were relatively consistent (5.8-6.1N-cm), and appear to be unrelated to TAD failure. The hypothesis was rejected because Ti alloy has a superior success rate to SS as a material for incisal miniscrews.*

***Conclusions**: TADs made of Ti alloy have a lower failure rate compared to SS when placed in thin cortical bone. These results are consistent with a biocompatibility-related tendency for less bone resorption at the bone screw interface. (J Digital Orthod 2018;52:70-79)*

***Key words**:*

Incisors screws, gummy smile correction, stainless steel, titanium alloy, randomized clinical trial, double blind, split mouth, failure rate, biocompatibility

Introduction

Gummy smile or excessive gingival exposure when smiling is a common chief complaint relative to dentofacial esthetics. Orthognathic surgery may be indicated for severe discrepancies, but orthodontic treatment with miniscrew anchorage and conservative periodontal surgery produces a desirable, less invasive outcome (*Fig. 1*).[1,2]

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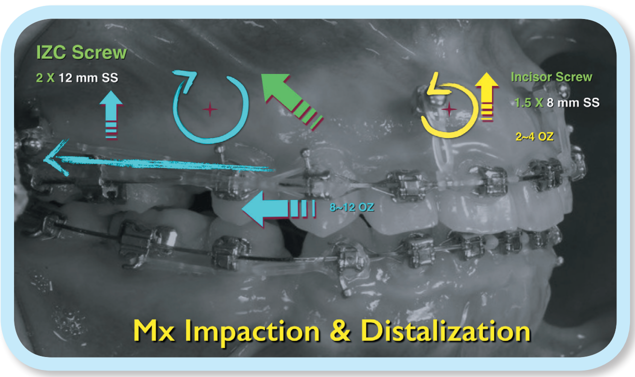
Temporary anchorage devices (*TADs*) are common sources for orthodontic anchorage,[3-9] but there is controversy over the most desirable material for a particular site. Incisal screws are a promising new approach for intrusive anchorage in the maxillary anterior region (*Figs. 2 and 3*). Stainless steel (*SS*) is a well established material for orthopedic devices, but titanium alloy (*Ti*) is recognized as a more bone biocompatible material for constructing osseointegrated implants.[7] If a TAD, not designed to integrate, is placed in thick bone, SS may be a superior material because it is stronger (*less brittle*) compared to Ti.[9] However, biocompatibility may be an issue for thin cortical bone sites. Ti may be preferred because of enhanced bone biocompatibility, particularly with respect to nickel sensitivity. There are no reported studies investigating the material of choice for maxillary anterior TADs. The null hypothesis was that there is no statistical difference in the failure rates between SS and Ti miniscrews.

Fig. 1:
Excessive gingival exposure when smiling (left) is conservatively corrected (right) with orthodontic intrusion, anchored with maxillary anterior incisal bone screws, and periodontal crown-lengthening surgery.

Materials and Methods

A total of 320 consecutive 1.5x8mm (*Fig. 3*) (*OBS®, iNewton Dental Ltd, Hsinchu City, Taiwan*) miniscrews were placed bilaterally between central and lateral incisor roots of 160 consecutive patients (*26 males and 134 females, mean age 25.9 yr, range 10-58 yr*). All the screws were placed in the same center by the same orthodontist over a three-year period (*2014-17*). The TADs were screwed to place with a torque wrench to standardize the engagement with supporting bone and ensure initial stability (*Fig. 4*).

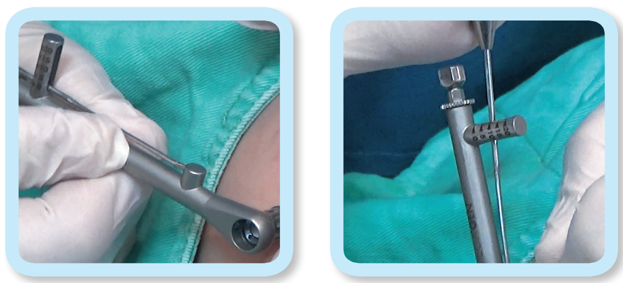


■ *Fig. 2:*
The chain of elastics from the infrazygomatic crest (IZC) bone screw to the cuspid bracket has distal and vertical components (blue arrows) that produce a clockwise moment (blue curved area) around the maxillary center of resistance (small red cross). The maxillary anterior miniscrew anchors an intrusive force (yellow arrow) that creates a counterclockwise moment (yellow curved arrow) tending to flare the maxillary incisors. The presumed resultant for all the applied loads is the green arrow to intrude and retract the entire maxillary arch.

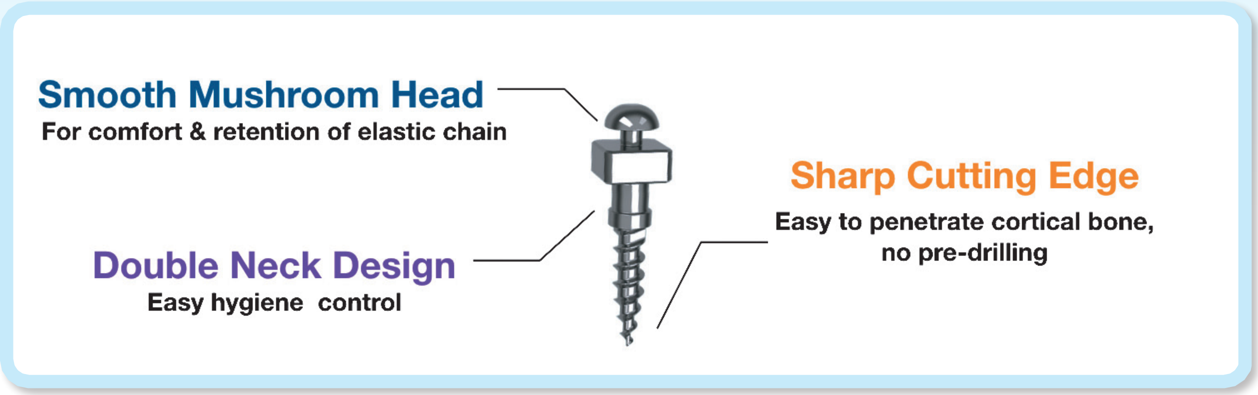
An alternating, randomized split mouth design was utilized for miniscrews as specified in Fig. 5. Half of the screws (*160*) were made of 316LVM surgical stainless steel (*SS*) and the other half (*160*) were composed of Ti6Al4V titanium alloy (*Ti*). Code numbers were assigned to pairs of miniscrews (*one SS and one Ti*), with a specification for which screw to install on each side. Only the data assessor (*statistician*) knew the actual code for each patient.

The blinded, alternating placement method insured that uniform numbers of screws of each type were tested on the right and left sides throughout the study. According to the code, one pair of screws was randomly selected for each patient. Neither the clinician, staff nor patient was aware of the screw composition for TADs placed on each side (*double blind randomized design*). At the end of the study the data were decoded according to side (*right or left*) and material type (*SS or Ti*), and were then sorted

■ *Fig. 3:*
A randomized split mouth design compared the failure rate for miniscrews made with SS and Ti alloy.



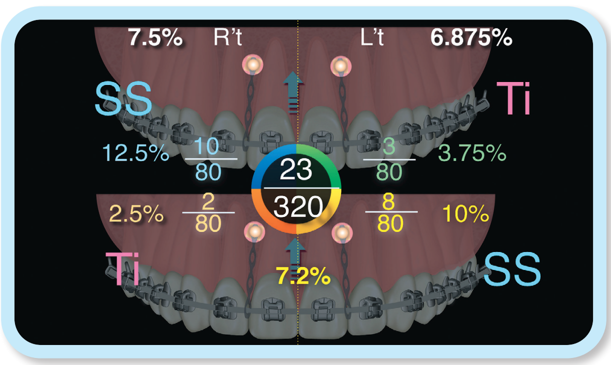
■ *Fig. 4:*
The torque value to seat each incisal bone screw was measured with a clinical torque wrench.



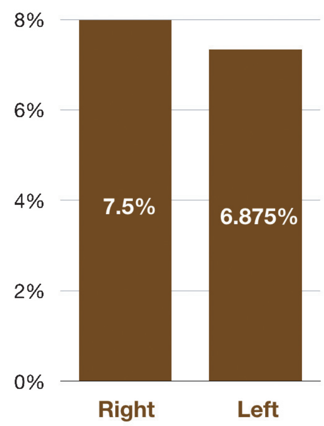
■ *Fig. 5:*
Specifications are illustrated for 1.5x8mm miniscrews designed to be inserted between central and lateral incisors with a self-drilling technique.

into four groups of 80 miniscrews each: left SS, left Ti, right SS, and right Ti. Failure rates were calculated for each of the four groups (*Fig. 6*), and tested for significant differences using a chi-square test, with $p<0.05$ as the minimum standard for significance. All failures were plotted according to the right and left sides (*Fig. 7*), divided according to material type (*Fig. 8*), and then subdivided according to side (*Fig. 9*).

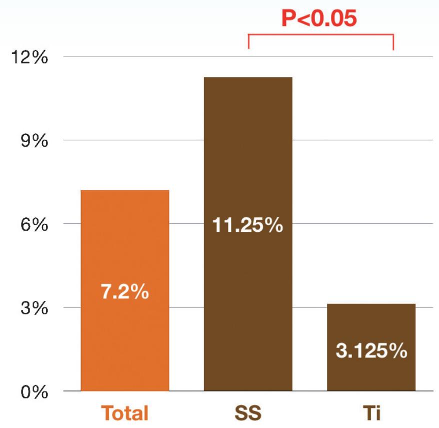
In Fig. 10, the average torque values are shown for all miniscrews (*Total*), for those that failed (*Failure*), as well as for screws placed on the right and left sides. In addition average torque levels are documented for all titanium alloy (*Ti*) miniscrews and for those that failed (*Failure Ti*). Furthermore, failure rates for all stainless steel (*SS*) TADs are compared to those that failed (*Failure SS*) (*Fig. 11*).



■ *Fig. 6:*
Failure rates of SS and Ti miniscrews are illustrated in multiple colors for the right and left sides respectively. The upper image is for SS on the right and Ti on the left. The lower image summarizes data for the opposite configuration. The overall data is shown in the center: 23 failures out of 320 miniscrews (7.2%).



■ *Fig. 7:*
The combined failure rate for the right side was 7.5% ($^{12}/_{160}$), and comparative data for the left side combined was 6.875% ($^{11}/_{160}$). The difference was not statistically significant.

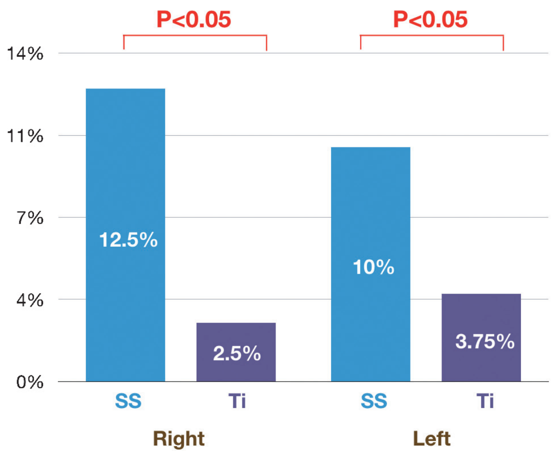


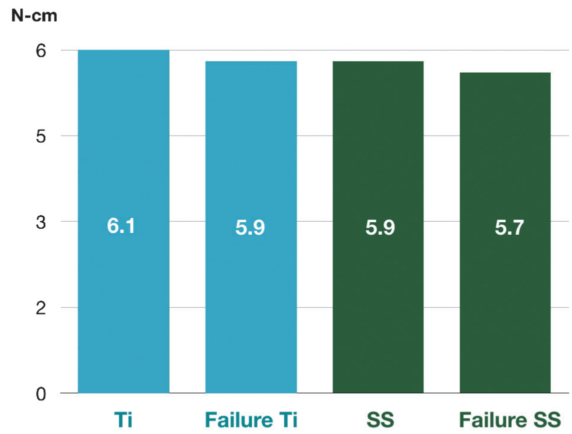
■ *Fig. 8:*

The overall failure rate for all screws was 7.2% (23/320), which was divided into 11.25% (18/160) for SS, and 3.125% (5/160) for Ti. The red bracket shows that the difference was statistically significant (P<0.05).

■ *Fig. 10:*

Average torque values were nearly equal: all miniscrews 6.0 N-cm, all failures 5.8 N-cm, all right side TADs 6.1 N-cm, and all left side TADs 6.0 N-cm. There were no statistically significant differences.





■ *Fig. 9:*

For the right side, 12.5% (10/80) SS screws failed, but only 2.5% (2/80) Ti screws failed. For the left side, 10% (8/80) SS screws failed, and 3.75% (3/80) Ti screws failed. The red brackets document the differences were statistically significant (P<0.05) on both sides.

■ *Fig. 11:*

Average torque values were sorted according to the material composition of the miniscrews: all Ti 6.1 N-cm, Failure Ti 5.9 N-cm, all SS 5.9 N-cm and Failure SS 5.7 N-cm. There were no statistically significant differences.

Because of anatomic limitations, most of the incisor screws (*95%*) were placed in movable mucosa, mucosal type was not considered as a variable. After achieving local anesthesia, a sharp dental explorer was sounded through the soft tissue to mark the desired skeletal site for the incisor miniscrew. A self-drilling TAD was inserted into the site with no pre-drilling or water cooling and was subsequently screwed into the bone perpendicular to the bone surface between the central and lateral incisors (*Figs. 3 and 12*). All final engagements of TADs into osseous sites were measured with a torque wrench (*iNewton Dental Ltd, Hsinchu City, Taiwan*) as shown in Fig. 4. The final position of the screw platform for all screws was in light-contact with the soft tissue. Pre-stretched elastomeric chains,[10-12] anchored by the incisal TADs, were applied to intrude the maxillary incisors (*Fig. 3*). To avoid iatrogenic problems, all miniscrews were immediately loaded with only about 2-oz (*57g, 55cN*) of force[13-15] for at least 6 months. Failure was defined as a lack of TAD anchorage due to a miniscrew coming loose within 6 months.

The patients were instructed in oral hygiene procedures to control inflammation. The pre-stretched power chains were replaced every 4 weeks. The stability of the incisor screws was tested at every appointment for 6 months. Consent for participation in this study was obtained from all patients (*and the parents if the patients were adolescents*) before their recruitment.

Results

Fig. 6 illustrates the regional differences in failure rates for each material: 1. overall 23/320 (*7.2%*), SS 10/80 (*12.5%*) on the right, SS 8/80 (*10%*) on the left, Ti 2/80 (*2.5%*) on the right, and Ti 3/80 (*3.75%*) on the left. For all failures combined (*n=320*), 7.5% were on the right and 6.875% were on the left (*Fig. 7*). Dividing the total failure data (*7.2%*) according to material type, revealed a statistically significant (*$P<0.05$*) increase in SS failures (*11.25%*) compared to Ti (*3.125%*) (*Fig. 8*). For TADs placed on the right side, failures were 10/80 (*12.5%*) SS and 2/80 (*2.5%*) Ti. Left side results were 8/80 (*10%*) SS and 3/80 (*3.75%*) Ti (*Fig. 9*). Chi-square analysis revealed that the lower failure rates for Ti compared to SS were statistically significant (*$p\leq.05$*) overall (*Fig. 8*) and on both sides (*Fig. 9*). These data indicate Ti is superior to SS as the material of choice, so the hypothesis was rejected.

The overall torque average value was 6.0 N-cm. The average torque for the right and left sides were 6.1 N-cm and 6.0 N-cm, respectively. The corresponding levels for screws that eventually failed was 5.8 N-cm, which was not a statistically significant difference (*Fig. 10*). Dividing the data according to material, there was a slight mean decrease of 0.2 N-cm between the average and failure TADS for each material (*Fig. 11*), but that small difference was not statistically significant. (*$P>0.05$*).

Discussion

Gummy smile refers to excessive gingival display during full smile. Orthodontic intrusion[16,17] with TAD anchorage and/or surgical crown lengthening improves the smile display.[1,2] Failure of TADs extends treatment time, increases clinical effort and is inconvenient for the patient. Potential factors that may explain the advantage of Ti over SS are:

1. **Screw specification**: A double neck design and with an insertion stop superior to the threads provides for optimal mucosal clearance to prevent food impaction and inflammation (*Fig. 5*).[18,19] Light contact of the alveolar mucosa allows for hygiene to remove plaque and food debris that would otherwise result in inflammation and swelling. The thick platform supporting the head of the TAD was designed to control overgrowth of inflamed mucosa. The design and installation procedure was identical for the SS and Ti screws, and no difference in tissue reactions was evident when the code was broke, so screw specification (*Fig. 3*) did not appear to be related to TAD failure with either material.

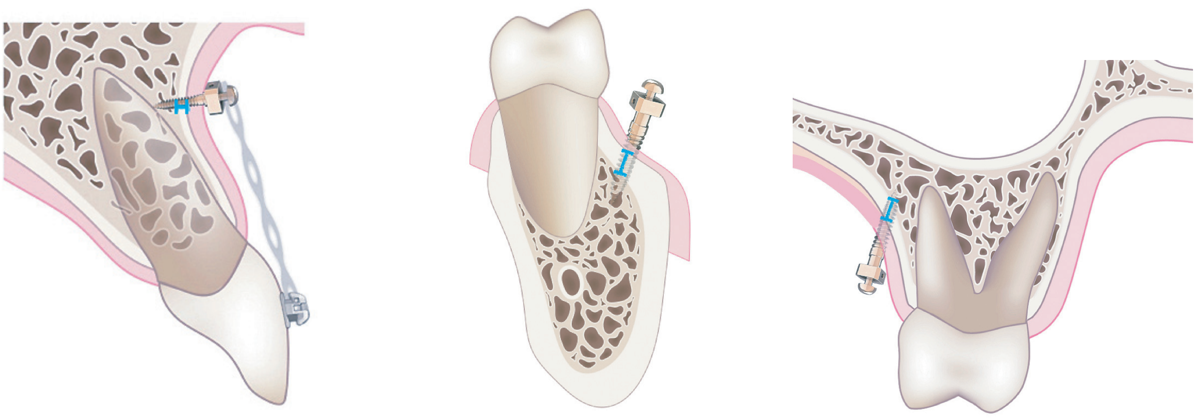
2. **Movable mucosa (MM) or attached gingiva (AG)**: Although AG is usually preferred when installing an interradicular TAD,[5,6,8] soft tissue type had no effect on the failure rate of extra-alveolar (*E-A*) TADs placed in the infra-zygomatic crest (*IZC*)[18] or mandibular buccal shelf (*MBS*).[19] Soft tissue clearance up to 5mm below the TAD platform is beneficial to prevent food impaction and permit optimal hygiene. However, such a large space between the mucosa and the base of the screw platform is inappropriate for incisal miniscrews because the TAD prominence would be uncomfortable for the patient. The double neck design (*Fig. 5*) with light contact of the alveolar mucosa proved adequate for oral hygiene and did not irritate the lip (*Fig. 12*). The vast majority (*95%*) of incisal TADs for this study were located in MM. Soft tissue irritation was minimal, so mucosal type did not appear to be an important factor relative to TAD failure.

3. **Insertion technique**: Indeed, a surgical technique can affect the failure rate.[19] The difference in failure rate between the right and left side was attributed to the doctor's hand position, especially for the hand approaching the posterior buccal shelf area of the mandible. It was more difficult to place a MBS screw on the left side for a right-handed surgeon. For the present study of maxillary incisal screws, the small difference between the right side 7.5% (*12/160*) and the left side 6.875% (*11/160*) was not statistically significant, and was probably due to the chance alone.

4. **Applied load**: According to Dellinger,[13] light force (*50-100g*) provided optimal intrusion of a tooth with minimal tissue damage, particularly root resorption.[14,15] All TADs (*SS and Ti*) in this study were loaded with similar forces (*2-oz, 57g, 55cN*). The applied load was adequate for dental intrusion, but did not appear to be a factor in TAD failure.

5. **Cortical bone engagement**: Screw torque values as fixtures are seated is an indirect measurement of primary stability[20] relative to cortical bone engagement.[21] When a TAD is installed at an angle to the supporting plate of cortical bone, there is increased bone contact at the screw interface, which enhances the mechanical interlocking.[21-23] The torque value in seating a fixture is directly related to cortical bone thickness, and 1mm of cortical bone engagement is sufficient for the primary stability of most TADs.[24,25] However, cortical bone thickness for the anterior buccal plate of bone is only about 0.5-0.6mm (*Figs. 12a*).[26,27] This is an important consideration because even a 0.5mm difference in cortical bone thickness (*interface bone contact*) can impact the success rate.[25] Cortical bone thickness for posterior teeth is >1mm (*Figs. 12b & c*),[28,29] and the failure rate for E-A bone screws is <10% at all sites. Since torque values were similar for all incisal TADs (*Figs. 10 and 11*), primary stability associated with cortical bone engagement does not appear to be an important factor in TAD failure.

6. **Material (SS or Ti)**: Maxillary incisal miniscrews made of SS rather than Ti alloy have higher failure rates (*Figs. 6, 8 and 9*). None of the five mechanical and tissue factors analyzed above appears to affect incisal screw failure, so a material affecting on bone physiology at the screw interface may favor Ti alloy. Huja et al.[30] documented intense bone remodeling (*>50%/yr*) within 1mm of a Ti miniscrew interface. Francis et al.[31] noted the intense remodeling within 1mm of the interface was inversely related to the diameter of the screw. Gabser et al. (*2007*)[32] noted a short term decrease in bone resorption at the osseous interface of Ti compared to SS screws, and there was a higher



■ *Fig. 12:*
Cortical bone thickness is demonstrated with blue bars for three bone screw sites:
Maxillary incisor area (left), Mandibular buccal shelf (middle), and Infrazygomatic crest (right).
The average thickness of cortical bone engaging the screw at each site is marked with blue bars. Note that bone thickness is considerably less in the maxillary anterior region (left).

prevalence of reactionary cells (*inflammation*) adjacent to SS screws. Furthermore, Ti screw fixation of a metatarsal fracture is more successful in achieving an osseous union compared to SS screws.[33] These data suggest that Ti alloy may have a slight advantage in bone biocompatibility compared to SS. When the bone is thick such as in the posterior maxilla, there was no significant difference in the failure rate between Ti and SS for infrazygomatic crest (*IZC*) bone screws.[34] However, when the bone site is thin, a slight advantage in resisting bone resorption at the miniscrew interface may explain the significantly enhanced short-term (*6 mo*) success rate for Ti alloy compared to SS (*Figs. 6, 8 and 9*).

Conclusion

1. Overall failure rate for incisal screws placed in the anterior maxilla was 7.2%, which is similar to the reliability of bone screws placed in either the mandibular buccal shelf or infrazygomatic crest.

2. There was a significantly lower failure rate for Ti alloy (*3.125%*) incisal bone screws, compared to identical screws made of SS (*11.25%*).

3. A slight biocompatibility advantage for resisting bone resorption at a miniscrew interface may explain the higher success rate of Ti alloy compared to SS in thin cortical bone.

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Reference

1. Lin C, Wu Y, Chang CH, Roberts WE. Simplified mechanics for gummy smile correction. Int J Orthod Implantol 2017;47:72–91.
2. Yeh HY, Chang CH, Roberts WE. Implant-orthodontic combined treatment for gummy smile with multiple missing teeth. Int J Orthod Implantol 2013;32:16–32.
3. Proffit WR. Biomechanics and mechanics. In: Contemporary Orthodontics. 3rd ed. St Louis, Mo: CV Mosby; 2000. p. 308–311.
4. Nanda R, Kuhlberg A. Biomechanical basis of extraction closures. In: Nanda R, Kuhlberg A, eds. Biomechanics in Clinical Orthodontics. Philadelphia, Pa: WB Saunders; 1996. p. 156–187.
5. Melsen B, Bosch C. Different approaches to anchorage: a survey and an evaluation. Angle Orthod 1997;67:23–30.
6. Melsen B, Costa A. Immediate loading of implants used for orthodontic anchorage. Clin Orthod Res 2000;3:23–28.
7. Roberts WE, Nelson, CL, Goodacre, CJ. Rigid implant anchorage to close a mandibular first molar extra ion site. J Clin Orthod 1994;28(12):693-704.
8. Kanomi R. Mini-implant for orthodontic anchorage. J Clin Orthod 1997;31:763–767.
9. Crismani AG, Bertl MH, Celar AG, Bantleon H-P, Burstone CJ. Miniscrews in orthodontic treatment: review and analysis of published clinical trials. Am J Orthod Dentofacial Orthop 2010;137(1):108-13.
10. Ash JL, Nikolai RJ. Relaxation of orthodontic elastomeric chains and modules in vitro and in vivo. J Dent Res 1978; 57:685–690.
11. Baty DL, Storie DJ, von Fraunhofer JA. Synthetic elastomeric chains: a literature review. Am J Orthod Dentofacial Orthop 1994;105:536–542.

12. Kin KH, Chung CH, Choy K, Lee JS, Vanarsdall RL. Effects of prestretching on force degradation of synthetic elastomeric chains. Am J Orthod Dentofacial Orthop 2005;128:477–482.
13. Dellinger EL. A histologic and cephalometric investigation of premolar intrusion in the Macaca speciosa monkey. Am J Orthod 1967;53(5):325–55.
14. Melsen B. Biological reaction of alveolar bone to orthodontic tooth movement. Angle Orthod 1999;69(2):151–8.
15. Sarikaya S, Haydar B, Ciğer S, Ariyürek M. Changes in alveolar bone thickness due to retraction of anterior teeth. Am J Orthod Dentofacial Orthop 2002;122(1):15–26.
16. Nanda R. Correction of deep overbite in adults. Dent Clin North Am 1997;41(1):67–87.
17. Burstone CR. Deep overbite correction by intrusion. Am J Orthod 1977;72(1):1–22.
18. Hsu E, Lin J, Yeh HY, Chang CH, Roberts WE. Comparison of the failure rate for infraygomatic bone screws placed in movable mucosa or attached gingiva. Int J Orthod Implantol 2017;47:96–106.
19. Chang CH, Liu Sean SY, Roberts WE. Primary failure rate for 1680 extra-alveolar mandibular buccal shelf mini-screws placed in movable mucosa or attached gingiva. Angle Orthod 2015;85:905-910.
20. Wilmes B, Rademacher C, Olthoff G, Drescher D. Parameters Affecting Primary Stability of Orthodontic Mini-implants. J Orofac Orthop / Fortschritte der Kieferorthopädie 2006;67(3):162-74.
21. Marquezan M, Mattos CT, Sant'nna EF, de Souza MM, Maia LC. Does cortical thickness infuence the primary stability of miniscrews? A systematic review and meta-analysis. Angle Orthod 2014;84(6):1093-103.
22. 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(1):18-25.
23. Motoyoshi M, Inaba M, Ono A., Ueno S, Shimizu N. The effect of cortical bone thickness on the stability of orthodontic mini-implants and on the stress distribution in surrounding bone. Int J Oral Maxillofac Surg 2009;38:13-8.
24. 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):779-84.
25. Motoyoshi M, Matsuoka M, Shimizu N. Application of orthodontic mini-implants in adolescents. Int J Oral Maxillofac Surg 2007;36(8):695-9.
26. Calvani L, Calvani L, Hirayama H, Pissiotis A, Michalakis K. Association between increased concavity of maxillary labial alveolar bone and decreased labial cortical bone thickness: a cone beam computed tomography aided retrospective cohort study. J Prosthodont 2017.
27. Baumgaertel S, Hans MG. Buccal cortical bone thickness for mini-implant placement. Am J Orthod Dentofacial Orthop 2009;136(2):230–5.
28. Huang C, Chang CH, Roberts WE. 3D cortical bone anatomy of the mandibular buccal shelf: a CBCT study to define sites for extra-alveolar bone screws to treat Class III malocclusion. Int J Orthod Implantol 2016;41:74–82.
29. Ono A, Motoyoshi M, Shimizu N. Cortical bone thickness in the buccal posterior region for orthodontic mini-implants. Int J Oral Maxillofac Surg 2008;37:334-340.
30. Huja SS, Kaya B, Mo X, D'Atri AM, Fernandez SA. Effect of zolendronic acid on bone healing subsequent to mini-implant insertion. Angle Orthod 2011;81:363-369.
31. Francis CF, Oz U, Cunningham LL, Huja PE, Kryscio RJ, Huja SS. Screw-type device diameter and orthodontic loading influence adjacent bone remodeling. Angle Orthod 2017;87:466-472.
32. Ganser A, Thompson RE, Tami I, Neuhoff D, Steiner A, Ito K. An in vivo experimental comparison of stainless steel and titanium Schranz screws for external fixation. Eur J Trauma Emerg Surg 2007;33(1):59-68.
33. DeVries JG, Cuttica DJ, Hyer CF. Cannulated screw fixation of Jones fifth metatarsal fractures: comparison of titanium and stainless steel screw fixation. J Foot Ankle Surg 2011;50(2):207-12.
34. Chang CH, Lin JS, Roberts WE. Failure rates for SS and Ti alloy infrazygomatic bone screws: single center, randomized and double blind clinical trial. Angle Orthod (accepted September 2018).