Comparison of the Failure Rate for Infra-Zygomatic Bone Screws Placed in Movable Mucosa or Attached Gingiva

Abstract

Objective: *Compare the six-month failure rates for infra-zygomatic crest (IZC) bone screws inserted into movable mucosa (MM) or attached gingiva (AG). The hypothesis was that MM would have a higher failure rate than AG.*

Materials and Methods: *A total of 386 patients (76 males and 310 females; mean age, 24.3 years; aged from 10 to 59 y/o) were treated with a 2x12mm IZC OBS (OrthoBoneScrew® Newton's A Ltd, Hsinchu City, Taiwan), bilaterally. Pairs of stainless steel (SS) and Ti alloy (TA) screws were randomly assigned as to side. All OBSs were positioned in the lateral aspect of the alveolar process, buccal to the upper first and second molar roots, by the same clinician (C.C.). All OBSs were placed at an angle of about 70 degrees above the horizontal (extra-alveolar approach) to achieve maximum bone engagement. Screw heads were positioned at least 5mm above the level of the soft tissue to facilitate oral hygiene. All OBSs were immediately loaded with pre-stretched elastomeric modules ranging from 8-oz to 14-oz (227–397 g or 223–389 cN), according to the patients' age and bone density. The clinician decided on the applied load according to clinical requirements, and the perception of the bone mass and density supporting the OBS. Six months after each screw was placed, it was routinely evaluated for mobility, ability to maintain continuous anchorage during the 6 month period, and type of mucosa penetrated by the tip of the OBS as it was installed. All 772 consecutively placed IZC OBSs in 386 patients were assessed for the soft tissue effect. SS vs. TA failure rate will be reported separately.*

Results: *387 were placed in MM and 385 were in AG. 49 out of 772 miniscrews failed (6.35%), 25 of which were in MM (6.46%), and 24 were in AG (6.23%); there was no statistically significant difference at the p<.05 level. There was no significant relationship between failure and the initial applied load. Failures were unilateral in 21 patients and bilateral in 14 patients. The failure rate on the right side (6.48%) was slightly higher than the left (6.22%), but the difference was not statistically significant. Patients with screw failures were 12-43 yr old, mean age of 24.2 yr, which was insignificant compared to the demographics of the entire sample.*

Conclusion: *IZC miniscrews were highly successful (93.65%), and there was no significant difference between MM and AG, or any other variable tested, i.e. age, side, asymmetry or initial applied load. (Int J Orthod Implantol 2017;47:96-106)*

Key words:

Infra-zygomatic crest, bone screws, skeletal anchorage, movable mucosa, attached gingiva, extra-alveolar orthodontic anchorage

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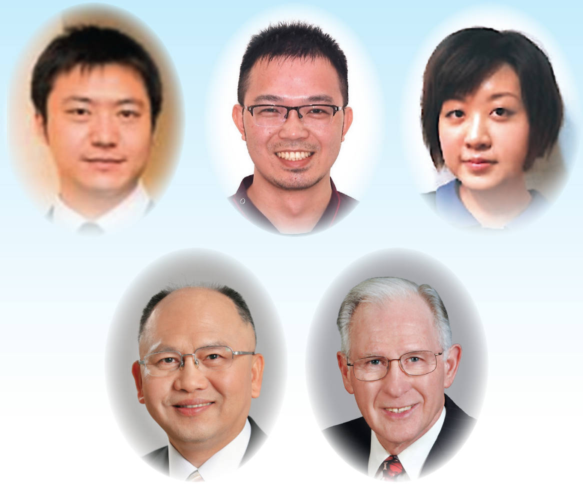


Introduction

Anchorage is one of the most important factors in orthodontic treatment. It is usually provided intraorally by other teeth or extraorally by headgear fitted to the head or neck.[1-3] Skeletal anchorage is provided by temporary anchorage devices (*TADs*): miniscrews[4] or osseointegrated implants.[5,6] Miniscrew anchorage was introduced in 1997 by Kanomi,[7] and gained wide acceptance in the orthodontic profession, particularly as more refined miniscrews were developed.[4,8] Miniscrews in interradicular and other intraoral sites provide anchorage for dental retraction, protraction, intrusion, and extrusion, for both erupted and impacted teeth.[9] Miniscrews have long suffered from a high failure particularly when they contact the periodontal ligament (*PDL*) adjacent to the roots of teeth.[10]

The infrazygomatic crest (*IZC*) is effective anchorage for many types of tooth movement including retraction of the entire upper dentition to correct Class II malocclusion,[11] excessive gingival exposure,[12]

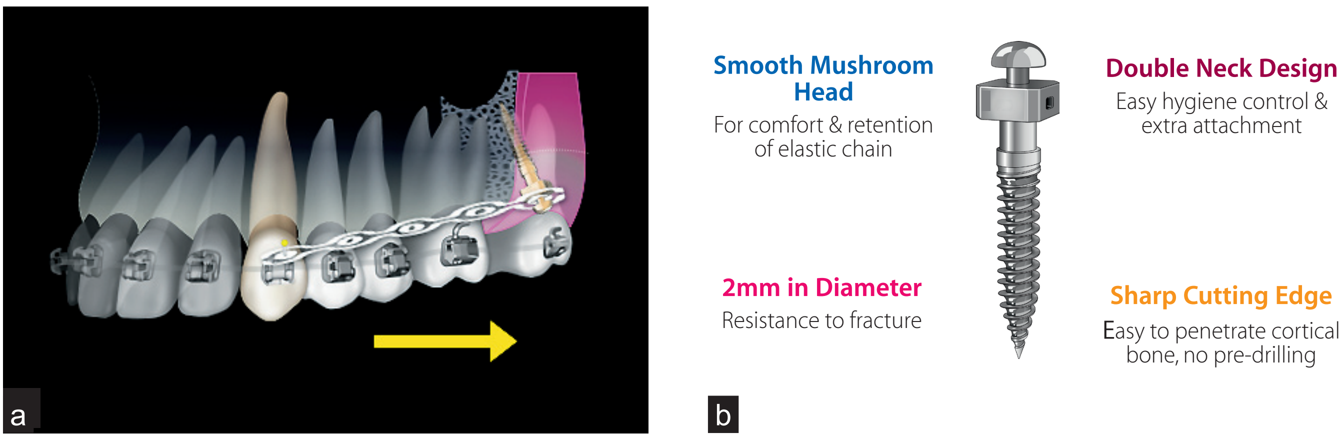


Fig. 1:

a. *The IZC bone screw mechanism that anchors the retraction of the entire maxillary arch (arrow) is illustrated by Dr. Rungsi Thavarungkul.*

b. *Specifications are shown for the 2x12mm SS bone screw designed to be inserted in the infra-zygomatic crest (IZC) as a self-drilling fixture.*

skeletal asymmetry,[13] maxillary canine-lateral incisor transposition,[14] and scissors bite.[15] It is vital to understand the failure rate of this relatively new method, relative to the type of soft tissue penetrated, age at failure, and initial applied load.

The primary aim of this research is to compare the failure rates of IZC screws inserted through movable mucosal (*MM*) as opposed to attached gingiva (*AG*). The hypothesis tested is that miniscrews placed in movable mucosa will have a higher failure rate (*<6 months*).

Material and Methods

The devices tested were 2x12mm stainless steel (*SS*) and Ti alloy ortho-bone-screws (*OBSs*) (*OrthoBoneScrew®, Newton's A Ltd, Hsinchu City, Taiwan*) randomly inserted according to side into the infra-zygomatic crest (*IZC*). A total of 772 IZC OBSs were placed bilaterally in 386 consecutive patients (*76 males and 310 females; mean age, 24.3 years*). All the screws were placed by the same orthodontist (*C.C.*) in the lateral aspect of the alveolar process, and buccal to the upper first and second molar roots. To permit efficient oral hygiene, all screw heads were at least 5mm superior to the soft tissue surface (*Fig. 2*).

There was a slight statistically significant, but clinically insignificant, difference in the failure rate (*<1%*) between SS and Ti alloy screws, that will be reported separately. The small overall number of failures (*<7%*) showed no significant relationship between the material and soft tissue site. The purpose for this report is to assess the effect of the soft site for all IZC bone screws (*n=772*) to compare to previous studies of mucosa effects. This research was conducted under Indiana University IRB Approval No. 1607517021.

Mucogingival junction (*MGJ*) was demarcated visually, and by manually moving the buccal mucosa. This method was previously shown to be as reliable as the Lugol's iodine technique.[16] Under local

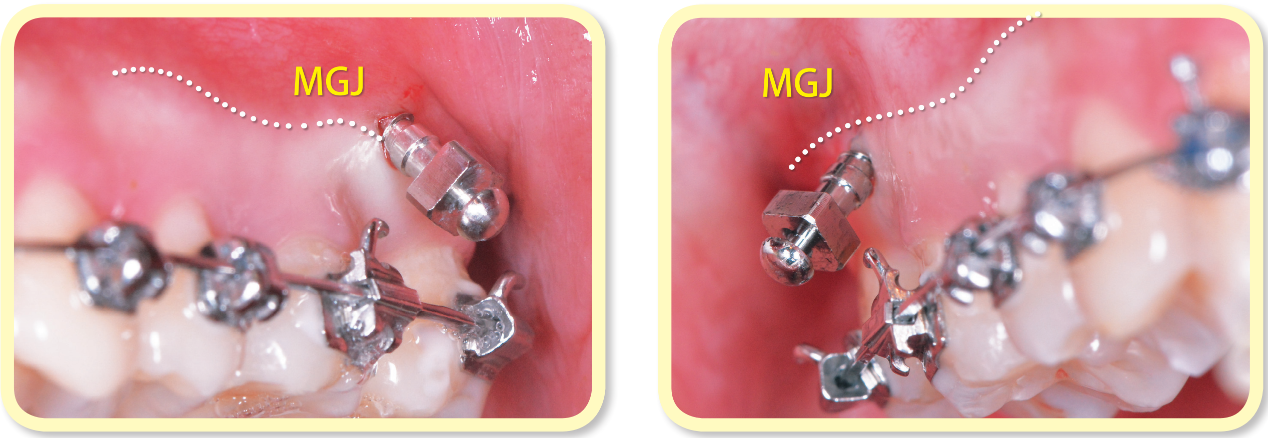
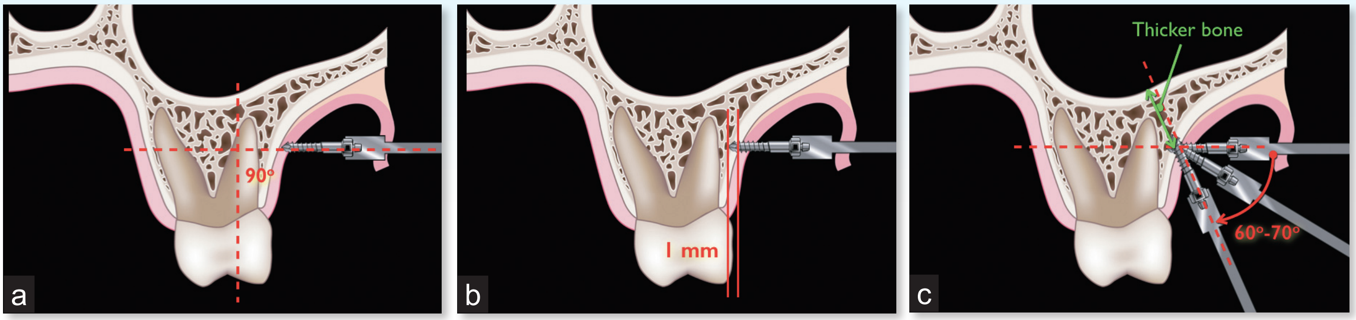
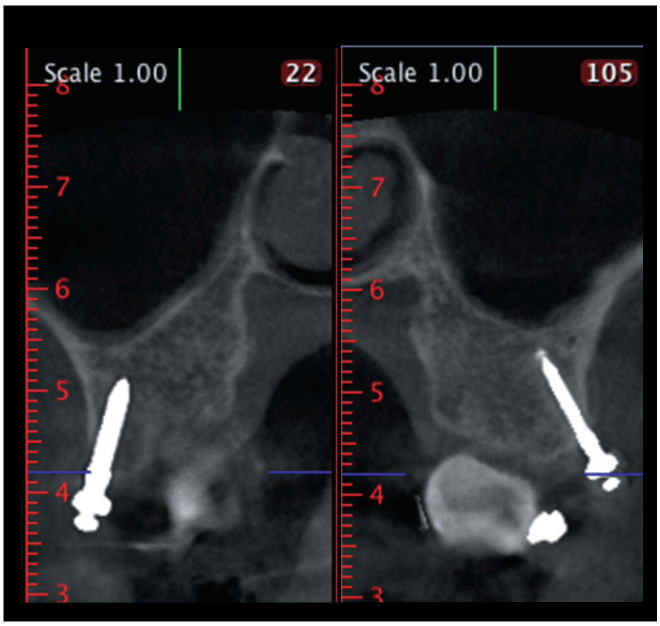


Fig. 2:
IZC OBSs placed in movable mucosa (left) and in attached gingiva (right). The white broken line is the mucogingival junction (MGJ).

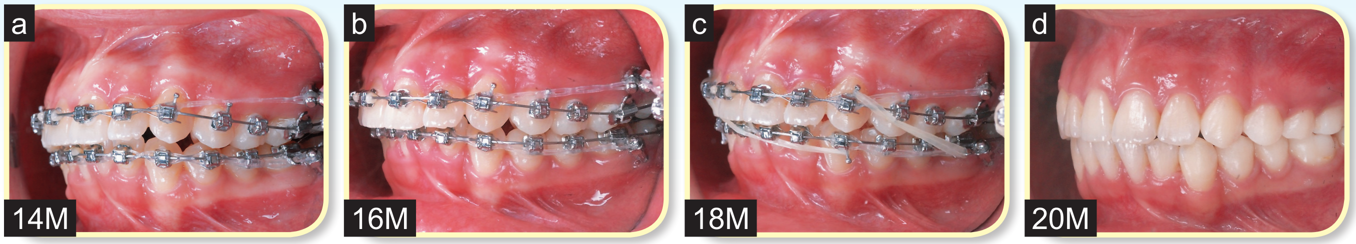


■ *Fig. 3: A 2x12mm IZC bone screw is inserted, as illustrated by Dr. Runsi Thavarungkul:*
a. Initial insertion of the screw tip is perpendicular (90°) to the bone surface.
b. The screw tip engages and penetrates an ~1mm bone cortex, buccal to the molar roots.
c. After the OBS penetrates the outer layer of cortical bone, the screw driver is turned clockwise, while rotating the angle of the screw about 60-70° in the frontal plane. This procedure achieves engagement of a thicker layer of bone at the base of the zygomatic process while avoiding the roots of the maxillary molars.

anesthesia, a sharp dental explorer was sounded through the soft tissue to mark the desired skeletal site for the bone screw without regard to the type of soft tissue at the site. No pilot drill or water cooling was needed. A self-drilling OBS was inserted into the wound and screwed into the bone perpendicular to the long axis of the adjacent teeth (*Fig. 3a*). After penetrating the cortical bone about 1mm (*Fig. 3b*), the driver was progressively rotated about 60°-70° to the occlusal plane to install the OBS in the thickest bone on the buccal surface of the maxillary molars (*Fig. 3c*). This method results in extra-alveolar (*E-A*) TADs that provide bilateral osseous anchorage in the posterior maxillary arch.[11-14] The final position of the screw head was just apical to the brackets on the molars (*Figs. 3-5*). Each OBS was immediately loaded from 8-14oz (*227g–397g or 223–389cN*), as needed relative to the bone mass and density supporting the OBS, as perceived by the clinician during the installation procedure. Pre-stretched elastomeric modules[17-19] were attached between the canine hook and the screw head to provide continuous anchorage for at least 6 months to retract the maxillary buccal segments. The installation protocol, and hygiene instruction to prevent soft tissue inflammation, were the same for all OBSs.



■ *Fig. 4:*
CBCT was taken after miniscrew insertion to make sure that the OBS is buccal to the molar roots, and to confirm that there is no root damage.



■ *Fig. 5:*

a. Correction of Class II occlusion with IZC anchorage commenced at 14 months (14M) into treatment.

b. As shown at 16 months (16M) most of the correction was achieved with an elastomeric chain anchored by the IZC OBS, and attached to the maxillary canines bilaterally.

c. A Class II elastic was initiated at 18 months (18M) to supplement the IZC anchorage.

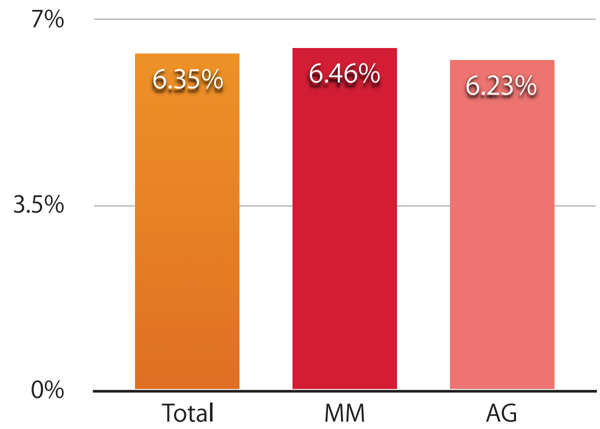
d. At 20 months (20M) the correction was complete and the fixed appliances were removed. Note the entire Class II correction was achieved in 6 months.

Pre-stretched power chains were replaced bilaterally every 4 weeks, and the stability of the IZC screws was tested. The 6 month test duration was selected for all IZC OBSs because that period of maxillary retraction is adequate for most Class II patients to achieve an acceptable occlusion and facial profile.

Results

All 772 OBSs placed bilaterally in 386 consecutive patients were carefully assessed every 4 weeks for the first six months of maxillary arch retraction. Depending on the position of the OBS tip at the time of installation, 387 bone screws were placed entirely or partially in MM (*scored as MM*), and 385 miniscrews were surrounded entirely by AG. Failure was defined as loose screws that exfoliated spontaneously or were removed by the clinician within 6 months of installation. Failure incidences were: 1. 49 of 772 (6.35%) overall, 25 of 387 (6.46%) for the MM group, and 3. 24 out of 385 (6.23%) for the AG group (*Fig. 6*). A Chi-square test showed there was no statistical significance between the failure rates between the two groups (*MM vs. AG*) so the hypothesis was rejected.

About 94% of the patients were anatomically symmetrical, so the OBS were in the same type of



■ *Fig. 6:*

Overall IZC OBS failure rate was 6.35% (total). There was slightly higher tendency for screws to fail in MM compared to AG, but the difference was not statistically significant.

mucosa on both sides. However, there were ~6% asymmetric patients (23/386), so one bone screw was in MM and the other was in AG. 3 of 23 asymmetric OBSs failed (~13%) when placed in MM, and 2 of 23 (~8.7%) failed in AG. This difference was not statistically significant because of the small sample sizes.

The average time to failure for the 49 failed IZC bone screws was 3.3 months. The average age of the patient at screw failure was 24.2 years (*Fig. 7*), compared to 24.3 years, the overall age of the entire sample (*n*=386). Out of 49 failures overall, the number of left side failures was 24, and right side failures was 25. There was no significant statistical relationship between the failure rate compared to age, left side or right side. However, there was an interesting difference in unilateral compared to bilateral failure. The 49 failed screws came from 35 patients; 21 individuals had a single screw failure and the other 14 lost screws on both sides.

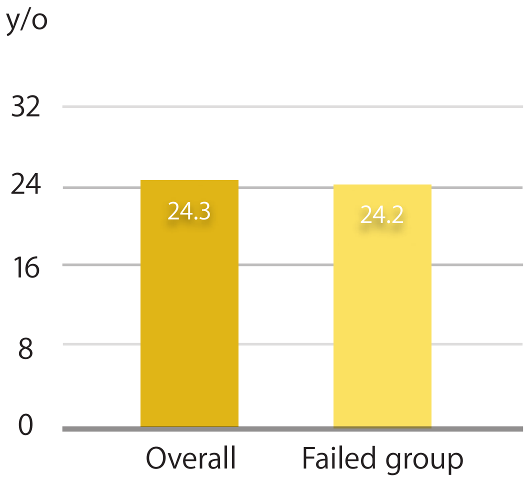


Fig. 7:
The age of patents for the overall sample (24.3yr) and the failure group (24.2yr) were nearly identical; there was no statistically significant difference.

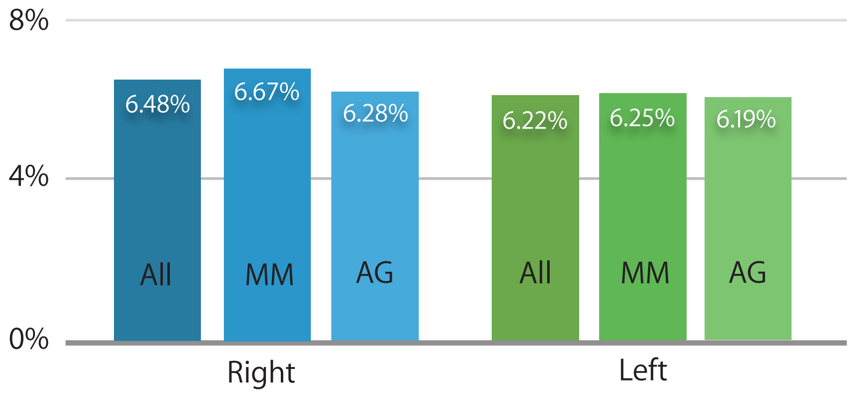
Discussion

All 772 SS bone screws were installed without fracture, and no root damage was noted for any adjacent teeth. The successful TADs (>93%) provided continuous anchorage throughout the study. All screws that failed were replaced with another IZC OBS in a nearby site, as needed. Thus, E-A IZC bone screws were successful anchorage for all patients, but it was necessary to replace the screws that failed. These highly predictable devices have a failure rate of only 6.35% and almost all patients have suitable sites for placement. The present data demonstrate that IZC OBSs are an important advance in E-A osseous anchorage to support orthodontics and dentofacial orthopedics therapy. There are many important advantages compared to inter-radicular (*I-R*) miniscrews:

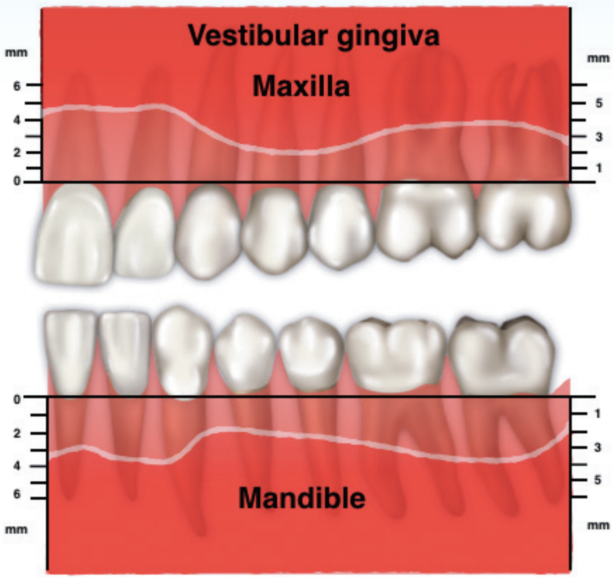
1. Less risk of tooth root damage
2. More abundant bone at the site of placement permits a larger screw diameter (*2mm*)
3. No interference with the path of tooth movement
4. Adequate anchorage for retracting the entire arch to reduce protrusion
5. Much lower failure rate
6. Fewer TADs are needed for comprehensive treatment of severe malocclusions

Clinical evaluation of I-R miniscrews has demonstrated that placing TADs in movable mucosa was problematic because of soft tissue irritation, inflammation, hyperplasia, and miniscrew loosening.[20] In addition, placing more than one I-R miniscrew reduces the chance of success by 67%.[20] The current study of 772 consecutive IZC bone screws in 386 patients documented bilateral failure in only 14 patients (*3.6%*).[21] A previous study of mandibular buccal shelf (*MBS*) bone screws documented a bilateral failure rate of only 16 of 840 (*1.9%*). Collectively, these data are more consistent with a genetic predisposition to OBS failure in a small fraction of patients[21] rather than a failure effect related to the number of TADs used per patient.[20]

Recent data reveal major advantages E-A compared to I-R TADs. The relatively low failure rate for IZC bone screws (*6.35%*), with no difference for MM or AG sites, is similar to outcomes for a larger study of 1680 consecutive MBS bone screws.[21] For the latter, there was an overall failure rate of 7.2%, but no significant difference for bone screws placed in MM (*7.31%*) or AG (*7.2%*). Thus, OBSs are equally reliable (*~93% or greater*) when placed in MM or AG at either the IZC or MBS sites. Attached gingiva in maxillary molar area is only 4mm wide on average[22] (*Fig. 9*), and the MM apical to the MGJ is what Sebastian and Terri[23] call the "*zone of opportunity*." Mucosa becomes firmly attached to the periosteum at the MGJ, and there is virtually no mobility, relative to underlying bone, so MM is an ideal site for I-R mini-implant or miniscrew insertion.[20,23] Since recent studies have noted that cortical bone thickness increases in the apical direction,[24-26] the MM apical to the MGJ offers TAD sites with more space between the conical dental roots because they usually diverge in an apical direction. Anatomically more apical positioning of the I-R miniscrew sites reduces the risk of root contact, a common factor in mini-



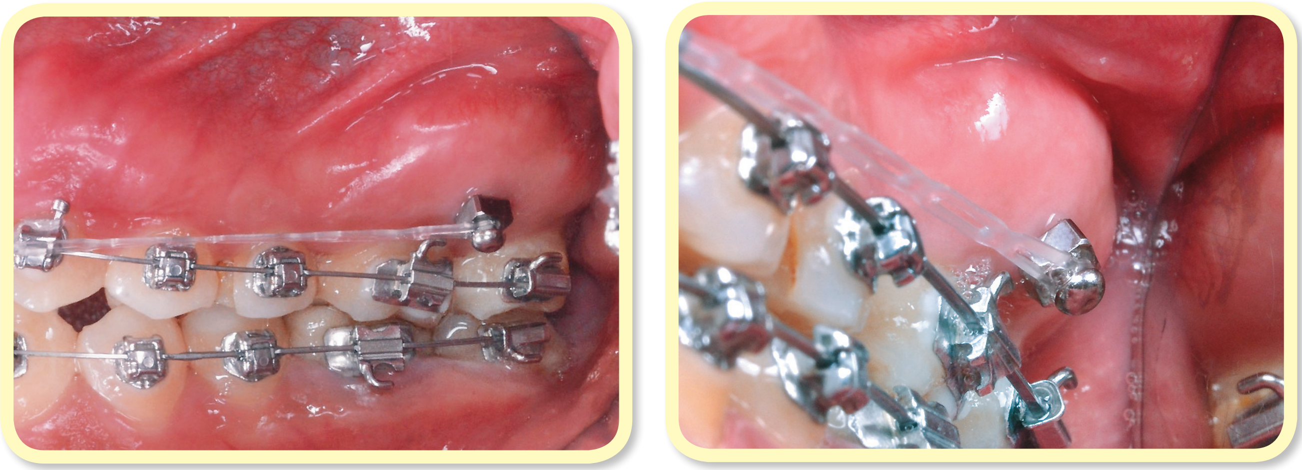
■ *Fig. 8:*
There was a slightly higher tendency for failure on the right compared to the left side, and MM failure was slightly elevated in both groups, but none of the differences were statistically significant between or within the groups.



■ *Fig. 9*:
The average width of attached gingiva on buccal side is illustrated for the maxillary and mandibular arches. Adapted from Clinical Periodontology and Implant Dentistry 2008, Reference 22.

implant failure,[10,27,28] but the MM covering the more apical sites is a higher risk site for I-R TADs. Mucosa covering is not a significant risk factor for OBSs, which is a major advantage for E-A TADs in the IZC (*Fig. 6*) or MBS sites.[21]

Some patients with excellent AG width for OBS placement had exostosis (*Fig. 10*). The large mass of bone buccal to the molars was covered wth AG, which was convenient for IZC bone screw placement, but the internal bone density was poor. To engage as much bone as possible, the OBSs were screwed in deeper than 5mm relative to the soft tissue surface. Soft tissue irritation was not a problem despite the screw platform being near the mucosa, probably because it was easier to keep the OBSs on exostoses clean compared to sites closer to the molars (*Fig. 10*).



■ *Fig. 10*:
Some patients in the sample had exostoses on the buccal surface of the maxillary molars that were covered with attached gingiva. See text for details.

The failure rates for many types of I-R miniscrews are relatively high, so many authors report the clinical experience as a "*success rate*" from 57-95%, with an average of about 84%.[29-31] The failure rate for the current E-A bone screws in the IZC area based was 6.35%, which is comparable to MBS OBSs (*7.2%*),[21] but is considerably less for I-R miniscrews in the mandible (*19.3%*) or the maxilla (*12.0%*).[32,33]

Within the restraints of this study, the failure rates (*Fig. 6*) of IZC bone screws in either MM (*6.46%*) or AG (*6.23%*) are the lowest rates for non-integrated TAD failure reported for any large patient sample (*≥50*). The consecutive patient sample size (*n=386*) is only exceeded by a study of MBS OBSs (*n=1680*) in 840 consecutive patients.[21] It is clear that E-A OBSs inserted in the buccal surface of either the posterior mandible (*MBS*) or the posterior maxilla (*IZC*) are the most reliable TADs currently available for orthodontic anchorage.

Furthermore, E-A OBSs offer new horizons for dentofacial orthopedics because the location of the TADs, buccal to the roots of the molars, is advantageous for moving the entire dental arch relative to the apical base of bone with determinate mechanics.[34] Thus, conservative dentofacial orthopedics, with no extractions or orthognathic surgery, is capable of managing severe skeletal malocclusions by moving entire arches as segments. Modest bilateral forces of 200cN, applied to an entire arch as a segment, results in relatively uniform PDL stress below the necrotic threshold. Avoiding PDL necrosis enhances the rate of tooth movement and reduces the risk of root resorption.[35-36]

The excellent success with E-A bone screw anchorage in the IZC (*Figs. 6-8*) and in the MBS has considerably expanded the therapeutic scope for conservative treatment of severe skeletal malocclusion: Class II[37,38] and Class III.[39] These E-A devices have also provided effective anchorage to manage vertical dimension problems in the maxilla[40] and mandible.[41] In addition, E-A anchorage in the posterior aspect of the arch is advantageous for severe dentoalveolar crowding.[37,42] CBCT imaging is not essential for utilizing OBSs, but the 3D image is useful for confirming the buccal clearance of the screws relative to the adjacent molar roots.[43]

Conclusions

1. E-A bone screws placed in the IZC have a low failure rate (*6.35%*) over 6 months, and there is no statistically significant difference for sites covered with movable mucosa or attached gingiva.

2. The 2mm diameter bone screws placed in the IZC were not susceptible to fracture, and they offer distinct advantages compared to miniscrews placed near the roots of teeth: lower failure rate, no interference with the path of tooth movement. Furthermore, they offer adequate anchorage to retract the entire maxillary arch, retract molars for non-extraction alignment of a crowded dentition, and present less potential for root damage.

3. E-A bone screws placed buccal to the molars in both arches have ~93% success rate. OBS skeletal anchorage lateral to the dental arches has proven effective for conservative management of many severe skeletal and dental malocclusions.

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