Original Article

Failure rates for stainless steel versus titanium alloy infrazygomatic crest bone screws:

A single-center, randomized double-blind clinical trial

Chris H. Chang[a]; Joshua S. Lin[b]; W. Eugene Roberts[c]

ABSTRACT

Objectives: To compare failure rates for stainless steel (SS) and titanium alloy (TiA) bone screws (BSs) placed in the infrazygomatic crest (IZC).

Materials and Methods: A total of 386 consecutive patients (76 male, 310 female; mean age 24.3 years, range 10.3–59.4 years) received IZC BSs (SS or TiA) via a double-blind, split-mouth design. BSs penetrated attached gingiva (AG) or moveable mucosa (MM) with 5 mm of soft tissue clearance. All BSs were immediately loaded and reactivated monthly with $\leq$14 oz (397 g or 389 cN) applied directly to the upper archwire bilaterally for 6 months to retract the maxilla to correct Class II or bimaxillary protrusion.

Results: Of the 772 devices, there were 49 (6.3%) failures: 27 SS (7.0%) and 22 TiA (5.7%). The 1.3% difference was not statistically significant ($P = .07$). There was no significant relationship between SS or TiA failures relative to (1) right vs left side, (2) unilateral vs bilateral, or (3) age at failure. Significantly ($P < .05$) increased failure rates were noted for SS screws in only two subgroups: AG site (7.4%) and right side (7.8%). Unilateral failure occurred in 21 patients (5.4%), and bilateral failures occurred in 14 of the total 772 patients (1.8%).

Conclusions: The overall success rate of 93.7% indicates that both SS and TiA are clinically acceptable for IZC BSs. (*Angle Orthod.* 2019;89:40–46.)

KEY WORDS: Infrazygomatic crest; Bone screws; Skeletal anchorage; Stainless steel; Titanium alloy; Randomized clinical trial; Double blind; Split-mouth design; Predisposition to failure

INTRODUCTION

Retromolar osseointegrated implants are efficient extra-alveolar (E-A) temporary anchorage devices (TADs) in the posterior mandible,[1] but they are expensive, require space in the arch, and are difficult to remove. Kanomi[2] attempted to simplify the TAD concept by placing stainless steel (SS) interradicular (I-R) "mini-implants" between the roots of teeth. This approach was mimicked by many other types of small I-R titanium (Ti) or Ti alloy (TiA) miniscrews,[3–5] but the I-R positioning of the devices interfered with the path of tooth movement[6] and precluded routine movement of an entire dental arch as a segment.[6,7] To conservatively manage skeletal malocclusions without extractions or orthognathic surgery, Chang et al.[8] revived the E-A TAD concept by placing self-drilling SS bone screws (BSs) in the mandibular buccal shelf (MBS). SS was selected as the material rather than Ti or TiA because of its toughness (resistance to fracture) when placed in the dense cortical bone. None of 1680 MBS BSs fractured, and only 7.2% failed, but 1.9% of all patients experienced bilateral failures.[8] Thus, 26.4% (1.9/7.2) of the overall failure experience suggested a genetic predisposition[9] and/or a biomaterials problem, possibly related to SS (nickel) sensitivity.[10]

Success with the MBS stimulated interest in developing TADs for E-A anchorage in the posterior maxilla. The same 2×12-mm SS BSs (Figure 1) were installed

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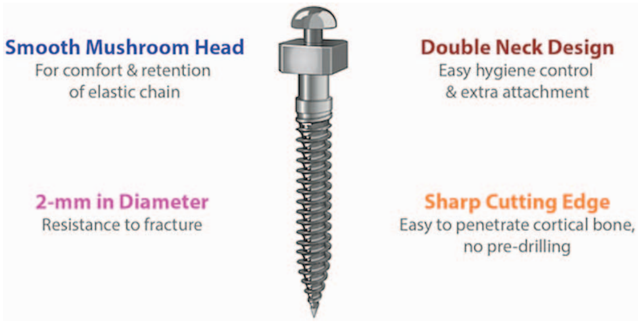

Figure 1. Bone screw specifications (SS or TiA).

at the base of the infrazygomatic crest (IZC; Figure 2), with a rotating screwdriver method (Figure 3).[11–13] This unique surgical approach resulted in a TAD buccal to the roots of the maxillary molars, which was capable of providing extra-radicular (E-R) anchorage for retraction of individual maxillary teeth or the entire upper arch (Figure 4). Maxillary bone is less dense (Figures 3 and 4) than in the mandible,[8] so the strength of SS may not be necessary for the posterior maxilla. It was hypothesized that TiA has adequate strength for the IZC, and the absence of nickel[10] would result in a lower failure rate compared with SS, particularly for patients predisposed to failure. Therefore, the current research objectives were to assess unilateral and bilateral failure rates relative to (1) material (SS or TiA), (2) side of placement (right vs left), and (3) type of soft tissue at the site (ie, attached gingiva [AG] vs movable mucosa [MM]).

MATERIALS AND METHODS

This clinical research project was approved by the Indiana University Institutional Review Board (approval No. 1607517021) to compare identical BSs made of SS and TiA (Figure 1). A sample of 386 consecutive patients requiring bilateral IZC anchorage to retract the maxillary teeth agreed to participate. A total of 772 consecutive 2 × 12-mm OrthoBoneScrew TADs (Newton's A Ltd, Hsinchu City, Taiwan) were placed bilaterally in the IZCs of 76 males and 310 females, with a mean age of 24.3 years and a range of 10.3–59.4 years. According to a randomized split-mouth design (Figure 5), half of the IZC BSs (386) were made of 316LVM surgical SS, and the other half were composed of Ti6Al4V TiA. Pairs of SS and TiA screws were coded for the right and left sides and arranged in an alternating order, to ensure that equal numbers of each type were tested on the right and left sides in a uniform manner.

All screws were placed buccal to the roots of the maxillary molars (Figure 4) by the same clinician who had placed >1000 IZC BSs with a well-established, multicenter clinical procedure.[11–16] After achieving local

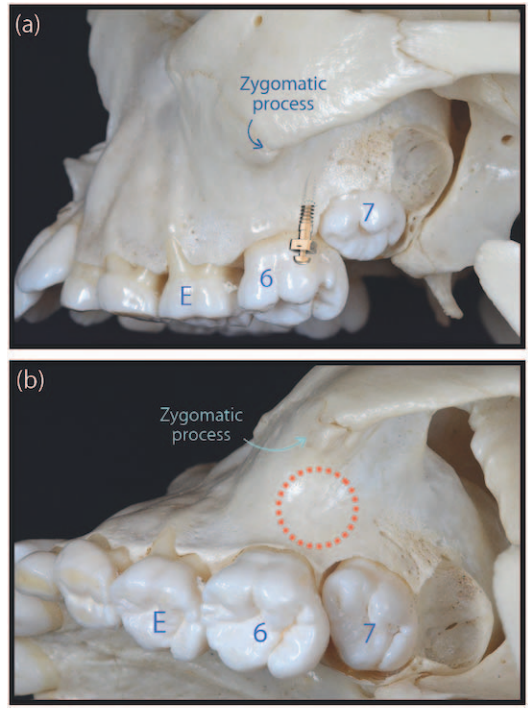

Figure 2. (a) An IZC bone screw (gold) is placed inferior to the zygomatic process relative to the second deciduous molar (E), first molar (6), and second molar (7). (b) Occlusal view of the maxilla shows the preferred site for an IZC BS (red dotted circle).

anesthesia, a sharp dental explorer was sounded through the soft tissue to mark the desired skeletal site, which is independent of the mucogingival junction (Figure 6). The type of soft tissue penetrated by the screw tip was scored as either AG or MM. The self-drilling BS (Figure 1) was oriented perpendicular to the buccal plate, and the screwdriver was turned clockwise to penetrate the approximately 1-mm-thick cortical plate (Figure 3a). As the screw penetrated the cortical plate (Figure 3b), the screwdriver was gradually rotated inferiorly about 60–70° to achieve a final insertion position buccal to the roots of the molars (Figure 3c). The final position of the screw head was about 5 mm superior to the soft tissue (Figure 6a), which was at about the level of the gingival crest or hooks of the buccal tubes as viewed from the buccal (Figure 6b).

For the present study, the maxillary teeth of each patient were retracted (Figures 7a–d). All BSs were immediately loaded and reactivated every 4 weeks with prestretched power chains,[17] within the well-established force range for IZC BSs under routine conditions: 8–14 oz (227–397 g or 223–389 cN).[11–16] As previously defined,[11–16] the treatment force varied within the prescribed range according to the clinician's perception of bone density at the time of BS placement and the specific biomechanics required.

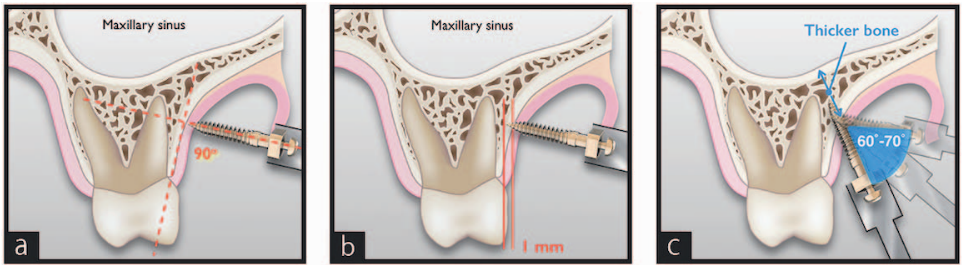

Figure 3. (a) Orientation of the BS at the start of the installation procedure. (b) Penetration of the approximately 1-mm bone plate on the buccal surface. (c) Change in orientation in the frontal plane as the BS is rotated to place.

All IZC BSs in this study were used as anchorage to retract the entire maxillary arch for at least 6 months (Figure 7c) to achieve a Class I occlusion (Figure 7d).[12–16] According to a double-blind design, neither the patient, clinician, nor staff member was aware of the composition of any of the TADs until the code was broken at the end of the study. Once decoded, the TADs were sorted into four groups of 193 IZC BSs each: left SS, left Ti, right SS, and right Ti. Failure rates were calculated for each group and subgroup and tested for statistical significance with the chi-square test.

RESULTS

Table 1 shows the overall failure incidence divided into SS and TiA groups vs age, sex, and clinical characteristics. A total of 49 of 772 (6.3%) BSs failed within 6 months. The distribution for materials (n = 386 each) was 27 SS (7.0%) and 22 TiA (5.7%; Tables 1 and 2); the difference of 1.3% was not statistically significant ($P = .07$; Figure 8). Collectively, there was no significant difference at the $P < .05$ probability level between SS and TiA for any of the following: (1) right (6.5%) vs left (6.2%) side, (2) unilateral (21 patients, 5.4%) vs bilateral (14 patients, 1.8% of 772 patients), or (3) age. The 35 patients experiencing failure had a mean age of 24.2 years (range 12.2–43.3 years) compared with the mean age of 24.3 years (range 10.3–59.4 years) for all subjects in the sample. The only significant differences in failure rates ($P < .05$) were SS in AG (7.4%) vs TiA in AG (5.1%), and SS on the right side (7.8%) vs TiA on the right side (5.2%; Table 2; Figure 9).

DISCUSSION

I-R miniscrews made of TiA have relatively high failure rates, so the data have often been reported as "success rates" from 57%–95%, with an average of about 84%.[18–21] The most common E-R TADs are made of SS, and they are used as anchorage in the MBS and IZC regions to treat a broad variety of malocclusions.[8,11–16] Most studies of I-R miniscrews had a higher failure rate in the mandible (19.3%) than in the maxilla (12.0%).[18–21] In comparison, there was no significant difference between the failure rates for E-A BSs: 7.2% for MBS BSs in the posterior mandible[8] compared with 7.0% for IZC BSs in the posterior maxilla (Figure 8).

Predisposition to failure[8] appears to affect all types of nonintegrated TADs. Uesugi et al.[21] reported that the primary success rate for the initial insertion of I-R miniscrews was 80.4% (maxilla 82.6%, mandible 71.0%), but the secondary insertion success was only 44.2% (maxilla 46.6%, mandible 36.8%). These data support a predisposition to failure, particularly in the mandible, but the data are not directly comparable to E-A TADs because neither bilateral nor multiple failures were reported. Although E-A TADs had a much higher success rate (>92%), and there was little difference between the maxilla and mandible, predis-

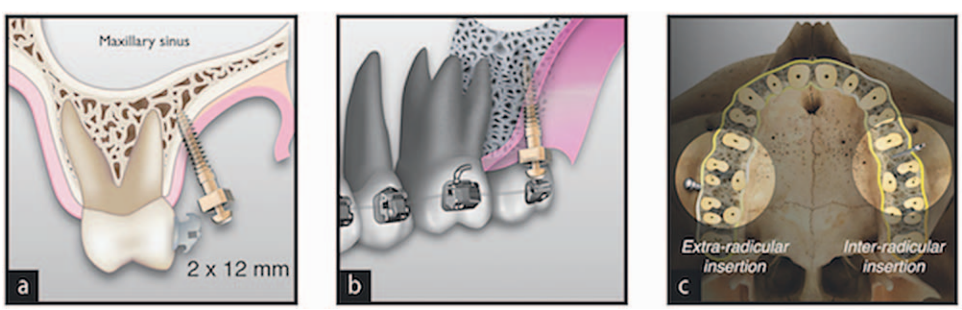

Figure 4. (a) The completed installation procedure as illustrated in Figure 2. (b) The TAD is buccal to the roots of the maxillary molars. (c) A transverse cross section of the maxilla distinguishes between an extra-radicular vs interradicular insertion of a TAD. See text for details.

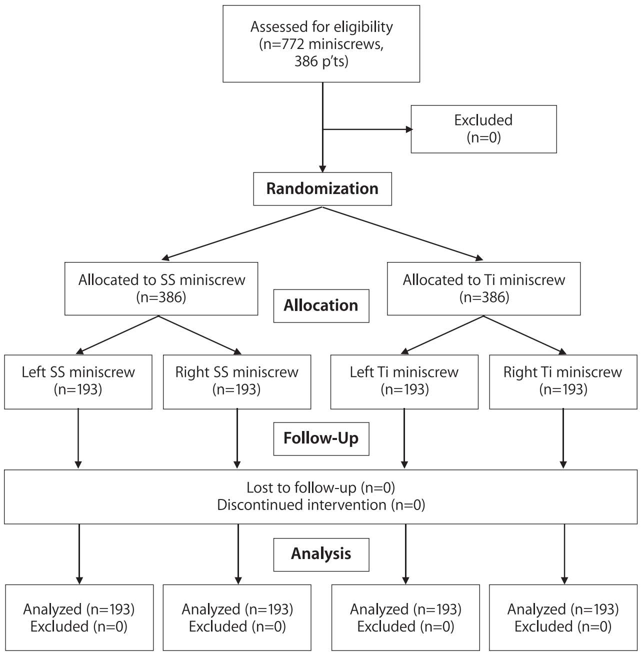

Figure 5. Flow chart for the randomized clinical trial.

position to failure persists as evidenced by bilateral failures of 1.9% in the MBS[8] and 3.6% for the IZC (present study). In the absence of a significant materials effect (present study), predisposition to failure appears to be predominantly genetic, which is similar to fracture nonunions[9] and external apical root resorption.[22] This potential complication is an important consideration for informed consent because alternate treatment methods may be desirable: extractions, headgear, and/or orthognathic surgery.

IZC Screw Failure

In several case reports,[12–16] IZC screws were used as anchorage for retraction of the entire maxilla to correct Class II malocclusion and/or bimaxillary protrusion. Failure was defined as the inability of an IZC BS to serve as adequate anchorage to accomplish the intended orthodontic purpose for 6 months. This interval was the minimal anchorage requirement to retract the maxilla in the present sample. Additional study is indicated to determine the long-term failure rate relative to the overall anchorage needs for specific patients (Figure 7). Movement of an IZC BS within bone[23,24] was not considered a failure if the device continued to provide the anchorage intended. TAD failures may include screw fracture, mobility, uncontrollable soft tissue inflammation, and/or host factors (pain or root damage). In this study, the only type of TAD failure was a loose (mobile) screw that exfoliated or was deemed too loose to provide effective anchorage.

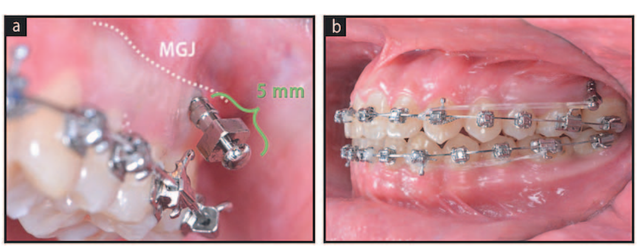

Figure 6. (a) About 5 mm of clearance from the head of the BS to the soft tissue surface is needed for effective hygiene. The mucogingival junction separates the AG from the MM. (b) An IZC bone screw anchors an elastomeric chain that is attached to the archwire mesial to the maxillary canine bracket.

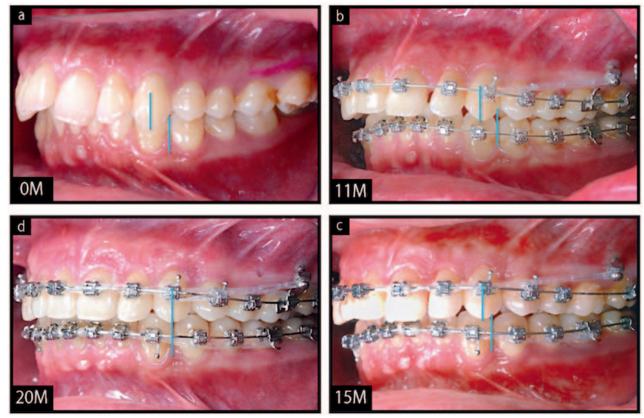

Figure 7. (a) 0M: Left buccal view of a severe Class II malocclusion at the start of treatment. The canine discrepancy is marked with vertical lines. (b) 11M: Initiation of maxillary retraction with IZC anchorage. (c) 15M: Progress after 4 months of maxillary retraction. (d) 20M: Class I occlusion is achieved after 9 months of maxillary retraction.

SS vs TiA

SS has long been the material of choice for orthopedic applications requiring sharp self-drilling screws that are tough (resistant to fracture). In vivo comparison of SS and TiA (Ti) for nonintegrated TADs revealed there were no significant differences in the bone response.[25,26] To avoid BS fractures, SS continues to be the preferred material for the MBS.[8,23] TiA

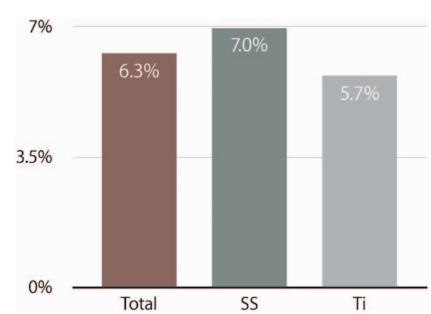

Figure 8. Overall failure rate (6.3%) is partitioned into SS (7.0%) and Ti (5.7%). The 1.3% difference between SS and Ti (TiA) was not significant ($P = .07$).

Table 1. Baseline Characteristics of Patients: Sample Size and Number of Failures in the Stainless Steel (SS) and Titanium (Ti) Alloy Groups

	Total		SS		Ti Alloy	
		Failure		Failure		Failure
	N = 772	n = 49	n = 386	n = 27	n = 386	n = 22
Age (mean, range)	24.3 (10.3, 59.4)	24.2 (12.2, 43.3)	24.3 (10.3, 59.4)	23.6 (12.2, 39.1)	24.3 (10.3, 59.4)	24.9 (12.2, 43.3)
Sex						
Male	76 subjects n = 152	n = 10	n = 76	n = 4	n = 76	n = 6
Female	310 subjects n = 620	n = 39	n = 310	n = 23	n = 310	n = 16
Mucosal type						
Right	386	25	193	15	193	10
AG	191	12	92	7	99	5
MM	195	13	101	8	94	5
Left	386	24	193	12	193	12
AG	194	12	96	7	98	5
MM	192	12	97	5	95	7

may be an adequate material for the MBS, but a specific fracture study is needed. In comparison with SS, TiA offered a slightly lower failure rate in AG and on the right side (Figure 9). Small differences in materials and site-specific failure rates may seem trivial, but they are important data for perfecting manufacturing and surgical procedures. The overall success rates for E-A TADs made of both materials exceeded 92%, so either SS or TiA are suitable for most clinical applications.

Chang et al.[8] studied the role of soft tissue type (AG or MM) and sidedness on the failure of MBS BSs made of SS. There was no significant difference between AG and MM, but the overall failure rate was significantly greater on the left side (9.29%, $P < .001$). That problem was attributed to increased difficulty in placing an MBS screw on the left side for a right-handed surgeon. For the IZC, there were more SS failures on the right (15) compared with the left (12) side, but TiA failures were greater on the left (12) compared with the right (10) side. These small differences were not clinically relevant. Relative to E-R TAD sites, both SS and TiA have a high success rate (>92%), but continued study of other materials, screw design, and surgical methods are indicated because each variable may be relevant to specific sites under different conditions.

Stability of TADs

In addition to a high failure rate,[18–21] I-R TADs may interfere with the desired path of tooth movement.[6] E-A TADs avoid these problems, so they have evolved into a superior anchorage mechanism for the conservative management of severe skeletal malocclusion.[7,8,23] However, the stability of nonintegrated TADs when loaded is problematic. In distinction to osseointegrated fixtures,[27,28] nonintegrated screws move relative to basal bone when used for orthodontic anchorage.[23,24] Bone labels for loaded TADs in monkeys (Melsen B. and Roberts WE., unpublished data) documented that firm, nonintegrated screws drifted within bone via a bone-modeling and remodeling mechanism similar to tooth movement.[28] Remodeling of the cortical bone, supporting loaded 1.6-mm TiA screws, was much less compared with BSs with a larger diameter (3–3.5 mm).[29] The latter are consistent with the dimensions of osseointegrated dental implants, which have a high remodeling rate (>300%/y) and that may be related to flexure at the bone-screw interface as a functional shear plane.[27,28] Long-term osseointegration of prosthetic implants (>3 mm in diameter) is based on the biomechanics of interface flexure due to a mismatch in the modulus of elasticity of Ti or TiA and cortical

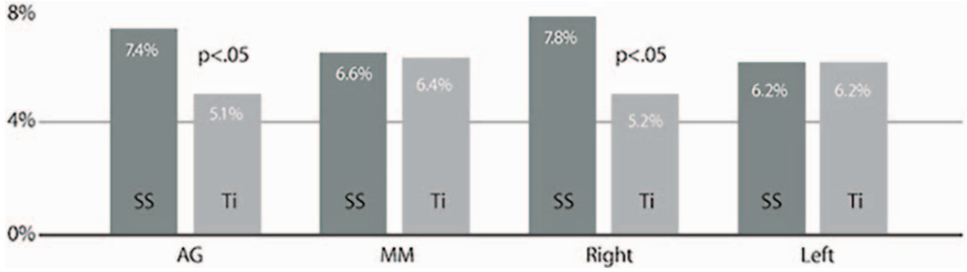

Figure 9. Failure rates are shown for IZC bone screws placed in AG, MM, as well as on the right or left side. The only significant differences ($P <$ .05) were for SS screws placed in AG and on the right side.

Table 2. With a Split-Mouth Design, Failure Rates (%) per Group Are Given According to Mucosal Type: Attached Gingiva (AG), Moveable Mucosa (MM), Right Side (R't), and Left Side (L't)

Failure Rate (%)	AG (6.2)	MM (6.5)	R't (6.5)	L't (6.2)
SS (7.0)	7.4	6.6	7.8	6.2
Ti (5.7)	5.1	6.4	5.2	6.2

bone.[27,28] Additional research is needed to produce TADs <3 mm in diameter that heal with a modest degree of osseointegration to resist movement within supporting bone but still be easily removed with a conservative procedure after treatment.

CONCLUSIONS

- Both SS and TiA are clinically acceptable materials for IZC BSs because the overall success rate was 93.7%.
- Compared with TiA, SS IZC BSs have an insignificantly ($P = .07$) higher failure rate of 1.3%.
- SS screws placed in the AG and on the right side had a slight but significantly higher ($P < .05$) failure rate compared with TiA.
- None of the 772 IZC BSs fractured or resulted in appreciable pain.

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