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Titanium alloy *vs.* stainless steel miniscrews: an *in vivo* split-mouth study

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Abstract. – OBJECTIVE: To compare *in vivo* Titanium Alloy (TiA) with Stainless Steel (SS) miniscrews Temporary Anchorage Devices (TADs) using removal torque and Scanning Electron Microscopic (SEM) analysis.

PATIENTS AND METHODS: 15 subjects (6 males and 9 females) who required maximum anchorage were recruited. For each patient, a TiA TAD and a SS TAD with same length and width were implanted following a randomized split-mouth study design. Retraction was carried out with nickel-titanium spring ligated directly from the anterior hooks of the archwire to the TADs to produce 90 to 100 g of force. When no further anchorage supplementation was needed, the TADs were removed. The removal torque values were registered with a digital screwdriver. After removal, the TADs were collected in a fixed solution and examined using SEM and X-ray microanalysis.

RESULTS: All TADs remained intact, with a 100% success rate. There was no difference in removal torque between TiA and SS miniscrews (4.4 ± 1.3 N-cm and 5.1 ± 0.7 N-cm, respectively). All specimens' loss of gloss with signs of biological contaminations resulted in a dull implant surface. SEM photomicrographs of TiA miniscrews showed predominantly blood cells while SS miniscrews showed the precipitation of an amorphous layer with low cellular component. There was no difference in spectroscopic analysis between TiA and SS miniscrews.

CONCLUSIONS: TiA and SS miniscrews had comparable removal torque values. SEM photomicrographs showed no evidence of osteointegration with both TADs having similar biological responses.

Key Words
Titanium alloy miniscrew, Stainless steel miniscrew, SEM analysis, Removal torque.

Introduction

The anchorage unit's stability, defined as the amount of allowed movement of the reactive unit, plays a very important role in the management of orthodontic treatment. Controlled tooth movements during space closure, without undesirable reciprocal movement in the anchorage unit are very difficult to achieve[1]. To reinforce anchorage, adjunctive extra-oral or intraoral appliances such as transpalatal bar, nance holding arch, or extra-oral traction, are usually necessary[2]. However, these methods tend to cause discomfort, leading to a lower patient's compliance [3].

The orthodontic miniscrews have been introduced as new devices for anchorage reinforcement[4]. Orthodontic miniscrews offer various advantages to both the orthodontist and the patient: simple insertion and removal, increased patient comfort, and favorable cost-benefit ratio[5,6].

Miniscrews are also called "Temporary Anchorage Devices" (TADs)[7,8] because they are designed to be removed after orthodontic treatment[9]. Miniscrews are generally made of Titanium Alloys (TiA) or surgical Stainless Steel (SS) that are both highly biocompatible materials[10]. TiA allows for direct bone contact (osteo-integration) between endosseous dental implants and the host bone[11]. Contrary, SS miniscrews tend to develop a fibrous tissue interface between the screw and bone[12,13]. Despite of the differences between TiA and SS, both materials provide relatively predictable clinical outcomes. They offer similar success in fulfilling the biomechanical requirement of stability[14-16]. A recent meta-analysis by Papado-

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poulos et al[17] reported success rates of 87.7% for both TiA and SS. The main difference between the two materials is that SS provides greater mechanical characteristics[18,19], when the insertion or removal torque exceeds the torsional strength[20,21]. Thus SS, because it is stronger than the traditional TiA, would reduce the risk of breakage[22,23]. The information gathered may help orthodontists to understand the intricacies of success or failure of miniscrews related to their material composition. Gritsch et al[24] in 2013 evaluated the use of immediate loaded TiA and SS screws in pigs growing model. They studied the specific bone response in the vicinity of the devices (test-zone) compared to a control zone. No significant differences between the materials were found regarding the percentage of "bone-to-implant contact" or the static and dynamic bone parameters. However, 5% threshold of "bone-to-implant contact" was obtained after 4 weeks with the SS devices, leading to increased survival rate values.

Brown et al[22] in 2014 compared TiA miniscrews with identically sized SS implants, which were inserted into the tibias of 12 rabbits. All miniscrews demonstrated mechanical stability after 6 weeks with no mobility. No significant differences in micro damage or bone-to-implant contact were found between the tension and compression sides of the implants. TiA and SS miniscrews showed similar total micro damage burden values when subjected to 100 g of loading. This work showed a 100% success rate in rabbit tibias, suggesting that SS can be used as TADs with at least the same efficacy of TiA miniscrews.

To our knowledge, no study analyzed *in vivo* the biological response of the TiA and SS miniscrews with immediate orthodontic loading. In the present investigation, we compared TiA and SS miniscrews by analyzing: 1) the insertion and removal torque; 2) the morphological, structural, and compositional alterations in used orthodontic miniscrews derived from Scanning Electron Microscopic (SEM).

Patients and Methods

Patients

15 subjects (6 males and 9 females with a mean age 16.2 ± 4.6), who required maxillary first premolar extractions and canine distalization, were recruited in the study. Before starting the research, we estimated that a sample of 15 subjects would give 80% power to detect at least 0.7 N-cm differences in removal torque between the two miniscrewers, with a standard deviation of 0.4 N-cm[22] (SigmaStat 3.5, Systat Software, Point Richmond, CA, USA). Participants were recruited at the Department of Orthodontics at the University of Rome "Tor Vergata" (Rome, Italy). All patients were in good general health with healthy periodontium, generalized probing depths not exceeding 3 mm, and no radiographic evidence of periodontal bone loss. An experienced clinician who assessed them as needing maximum anchorage treated patients. This was defined as "no mesial movement of the molars during the period of anchorage supplementation". No attempt was made to achieve distal molar movement since this was not clinically required. Patients who required functional appliance therapy, those who had previous orthodontic treatment or extraction, hypodontia, craniofacial syndromes or cleft, antibiotic therapy within the past six months, and anti-inflammatory drugs within the past month, were excluded.

All patients were fitted with Straight Wire Mirabella prescription (Sweden&Martina, Due Carrare, Padoa, Italy) maxillary and mandibular pre-adjusted edgewise appliances and the necessary extractions were performed. Before placing the TADs, the maxillary arch was aligned and leveled by using 3 archwires (0.016 NiTi, 0.019x0.025 NiTi, 0.019x0.025 posted Stainless Steel).

For each patient, a TiA miniscrew (Spider Screw, Sarcedo, Vicenza, Italy) and a SS miniscrew (Leone, Florence, Italy) were placed following a randomized split-mouth study design. All TADs had the same length (8 mm) and width (1.5 mm). TiA TADs were self-drilling and inserted directly with a hand screwdriver without making a pilot hole with a hand piece. SS miniscrews required a pilot drill (1.2 mm in diameter). Both types of miniscrews were implanted buccally in the posterior alveolar crest.

To avoid the risk of root proximity during the TADs placement, an accurate radiological examination was performed and surgical templates were used. Surgical template was made with orthodontic wire and acrylic resin in order to precisely locate the insertion point to avoid damage to the adjacent structures. The acrylic fits over the occlusal surfaces of the teeth near the surgical site, and the wire was inserted in the acrylic and bent so that it was corresponded to the point of screw placement. The distance from this point to the adjacent anatomic structures was determined radiographically using the long-cone parallel technique. The TADs were placed under local anesthesia, at the junction of the attached gingiva with the reflected mucosa and mesial to the maxillary molars. The insertion torque for both types of TADs was assessed, despite TiA miniscrews being self-drilling (while SS miniscrews were not), and the difference in the shape of the final portion of the tip. The mean value of Implant Placement Torque (IPT) when tightening the mini-implant into the bone was measured using a torque dynamometer (HTG-2N, IMADA, Toyohashi, Japan). The miniscrews were placed before any retraction force was applied on the archwire with anterior hooks placed distal to the lateral incisors. Retraction was carried out with nickel titanium spring ligated directly from the anterior hooks of the archwire to the TADs to produce 90 to 100 g of force. Anchorage supplementation was discontinued once the canines were in Class I and Overjet reduction completed. At this point the operator judged that no further anchorage supplementation was needed and the TADs were removed. The mobility of each screw was measured by using Periotest (Siemens AG, Bensheim, Germany) before removing the TADs. The following guidelines were used to obtain a reproducible registration: (1) the calibration of the device was checked; (2) the handpiece of the periotest was held in the horizontal position; (3) the handpiece was applied perpendicularly to the screw, which was perpendicular to the floor; (4) the tip of the handpiece was less than 4 mm from the screw.

The maximal torque values required to loosen the miniscrews were registered with a digital torque dynamometer (HTG-2N, IMADA, Toyohashi, Japan). After removal, miniscrews were immediately fixed in Karnovsky solution (paraformaldehyde and glutaraldehyde) and were collected to evaluate the bone-miniscrew interface using SEM (FEI, Quanta 200, Florence, Italy) analysis.

Each retrieved miniscrew was analyzed at three magnification of 85X, 200X, 600X focusing on orthodontic head, transmucosal collar and bony portion. Greater magnifications of 3000-10000X were necessary to detect bony islands.

Furthermore, the retrieved TADs were subjected to energy-dispersive X-ray microanalysis to investigate their elemental composition with a silicon- lithium energy dispersive microanalysis (EDS) detector (Sapphire CDU, EDAX, Mahwah, NJ, USA) equipped with a super ultrathin beryllium window. Elemental microanalysis was performed at many times the original magnification window, 200-second acquisition time, and 30-33% dead time. The quantitative analysis of the percentage of weight concentration of the probed elements was performed by nonstandard analysis and ZAF routines by using TEAM software (version 4.2.2, EDAX, Florence, Italy).

This project was approved by the Ethical Committee of the University of Rome "Tor Vergata" (Rome, Italy) (Protocol number: 134/15). Written informed consents were obtained from all patients or the parents of those under 18 years of age.

Statistical Analysis

Statistical analysis was performed using SPSS (Statistical Package for the Social Sciences; SPSS, Version 12, Chicago, IL, USA). Mean values and standard deviations were calculated for insertion torque, removal torque, and periotest value (PTV) testing. Any difference in the periotest value (PTV) was detected by means of *t*-test for independent samples. The maximum insertion torque, removal torque, and EDS values were not normally distributed (Kolmogorov-Smirnov test) with unequal of variance (Levene's test). The Wilcoxon Signed Rank test was used for comparing TiA and SS miniscrews. Results were considered significant if $p < 0.05$.

Results

No complication occurred operatively or post-operatively and no infection was detected in any of the patients throughout the study. All TADs remained intact with a 100% success rate. The mean period of TADs function as an anchorage unit was 160.8 ± 23 days. The periotest value recorded before removal of 8.8 for TiA TADs and 9.1 for SS TADs, indicated mechanical stability for both types of miniscrews with no statistical differences ($p > 0.05$). There was no statistical difference in insertion and removal torque between TiA and SS miniscrews. The mean insertion torque for TiA was 3.2 ± 1.1 N-cm while for SS miniscrews was 2.9 ± 0.9 N-cm. The mean removal torque for TiA was 4.4 ± 1.3 N-cm while for SS miniscrews was 5.1 ± 0.7 N-cm. Figure 1 shows optical microscopic image of TiA and SS miniscrews before and after their removal. Fractured screw tips and stripped screw threads after clinical use were not observed. All specimens' loss of gloss with signs of biological contaminations resulted in a dull implant surface.

At higher magnification, SEM photomicrographs of TiA miniscrews showed predominantly blood cells covering most of the surface. SS miniscrews showed the precipitation of an amorphous layer with low cellular component (Figures 2,3,4). Randomly organized osteo-integration islets on both types of miniscrew surfaces were found.

Finally, there was no statistically difference in spectroscopic analysis between TiA and SS miniscrews. Elements such as carbon, oxygen, and sodium, were found. EDS indicated the presence of Titanium (Ti), Aluminum (Al), and Vanadium (V) as the main elements on the surfaces of all TiA miniscrews and it was the only statistically significant difference (Table I).

Discussion

We aimed to compare *in vivo*, immediately loaded orthodontic TiA *vs.* SS TADs analyzing the removal torque and the morphological, structural, and compositional alterations by means of SEM. The split-mouth study design involved for each subject the use of TADs of two different materials presenting with the same length (8 mm) and diameter (1.5 mm). There is clinical evidence from dental implantology that bone quality and oral hygiene influence TADs prognosis. Randomized split-mouth study design minimized the effect of all the inter-individual variables such as age, sex, periodontal health, and duration of load, reducing the need of a larger sample. The trial showed a 100% success rate for both types of miniscrews. No TADs fractured during placement, clinical use, or removal, suggesting that TiA miniscrews can be used as temporary orthodontic anchorage with at least the same efficacy than SS miniscrews. Indeed, the high degree of osteo-integration required for dental implants is not a requirement for orthodontic TADs to function as anchorage devices [22,25].

Not the material, but insertion technique, thread design, and dimension of TADs are the essential factors affecting implant primary stability[26]. A valid method to assess the primary stability of implants quantitatively is the measurement of insertion torques[26-28]. Motoyoshi et al[28] examined the insertion placement torques of mini-implants and recommended torque values of 5-10 N-cm. Higher values may result in higher failure rates because of distinctive bone compression with micro damages or may even cause mini-implant fracture[29,30].

Figure 1. Optical microscopic image of TiA and SS miniscrews before (**A** and **C**) and after (**B** and **D**) their removal. The retrieved ones have lost of gloss with signs of biological contaminations.

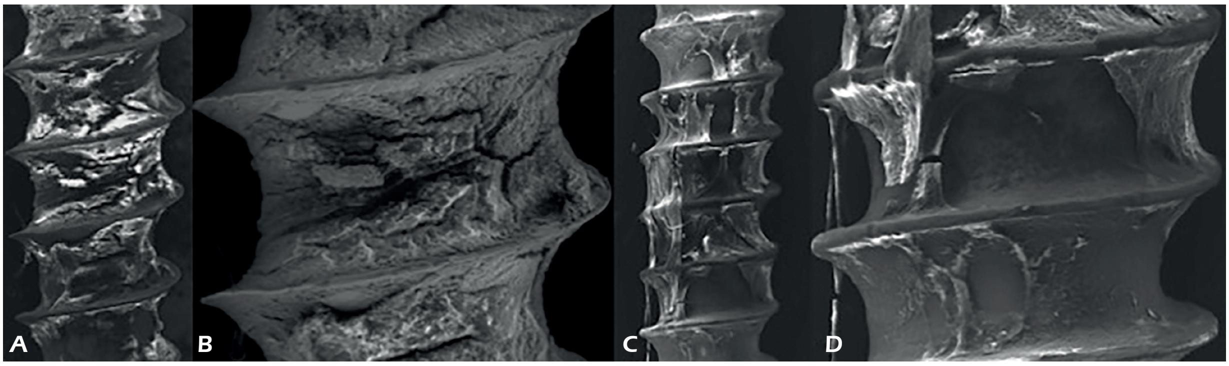

Figure 2. SEM photomicrographs of bony portion of TiA and SS miniscrews after clinical use. **A, C**, TiA miniscrew 85X. **B, D**, SS miniscrew (200x).

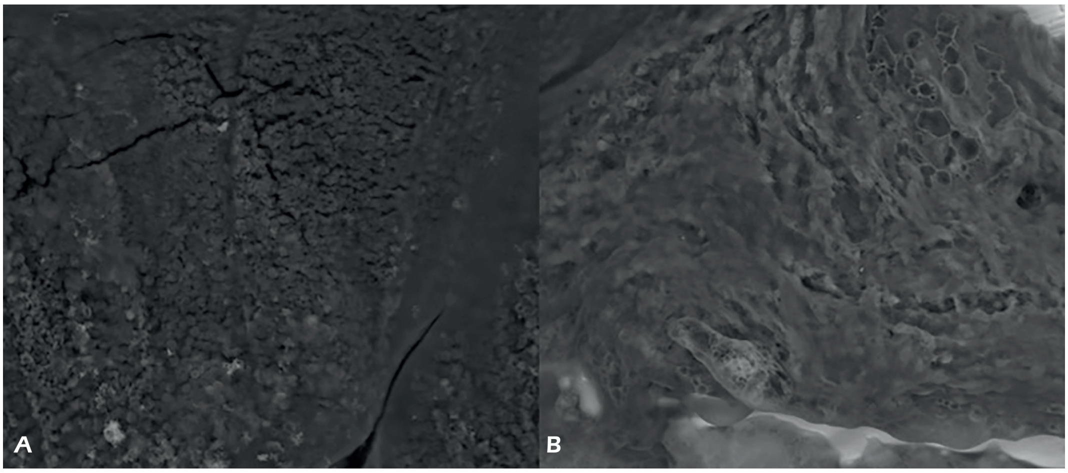

Figure 3. SEM photomicrographs of bony portion of TiA miniscrews after clinical use with red blood cells, (1200x).

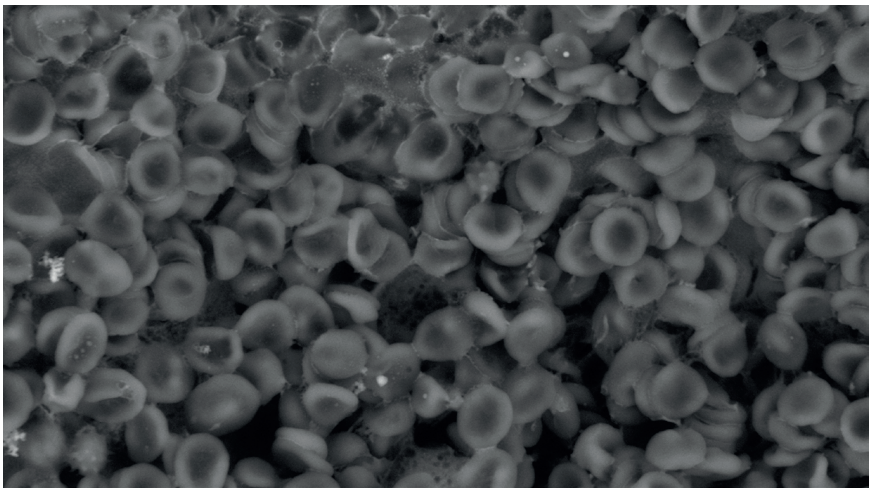

Figure 4. SEM photomicrographs of bony portion of TiA and SS miniscrews after clinical use. **A**, TiA miniscrew 600X. **B**, SS miniscrew (600x).

Table I. Chemical composition of the biological material on TiA and SS miniscrew surfaces as highlited by EDS analysis (Wilcoxon Signed Rank Test, $p<0.05$).

Elements	Weight % SS	Error % SS	Weight % TiA	Error % TiA	Difference	*p*-value
Carbon (C)	56.1	6.4	51.4	7,2	4.7	NS
Nitrogen (N)	2.0	33.8	0	0	2	NS
Oxygen (O)	32.8	9.9	34.6	9.7	-1.8	NS
Sodium (Na)	5.8	8.6	0	0	5.8	NS
Silicon (Si)	0.1	8.6	0.2	20.9	-0.1	NS
Phosphorus (P)	1.9	3.1	5.4	4	-3.5	NS
Sulphur (S)	0.4	4.7	0	0	0.4	NS
Calcium (Ca)	0	27.2	0	0	0	NS
Chromium (Cr)	0.2	8.1	0	0	0.2	NS
Manganese (Mn)	0	54.4	0	0	0	NS
Iron (Fe)	0.6	4.3	0.5	16.8	0.1	NS
Nickel (Ni)	0.1	12.1	0.2	30	-0.1	NS
Aluminium (Al)	0	0	0.3	9.8	-0.3	**
Strontium (Sr)	0	0	0.2	6	-0.2	NS
Titanium (Ti)	0	0	12.4	1.2	-12.4	**
Vanadium (V)	0	0	0.5	4.8	-0.5	**

NS: Not significant; **$p<0.01$.

To avoid the risk of root proximity during the TADs placement, an accurate radiological examination was performed and surgical templates were used. Kuronda et al[31] suggested that the proximity of miniscrews to the adjacent tooth roots is one of the major risk factors for failure of screw anchorage. Considering that the width of periodontal ligament is approximately 0.25 mm, Poggio et al[32] reported that a minimum clearance of 1 mm of alveolar bone around the screw is sufficient for periodontal health. No gingival inflammation was observed in the treated subjects. According to Miyawaki et al[33], the risk of tissue inflammation is lessened when the miniscrews are inserted into keratinized attached gingiva avoiding areas of frenulum, muscle tissues and mobile mucosa (non-attached gingiva). In addition to histological evaluation, a non-invasive method for determining implant stability and the extent of osteo-integration is the measurement of removal torque. The removal torque reflects the characteristics of the implant-bone interface during and after their usage[34]. Partial osteo-integration can increase the torque values and complicate the removal of TADs[22]. In the present study, TiA and SS TADs resulted both not osteo-integrated. The interaction between bone and mini-implant was mainly due to mechanical interlocking. These results are in agreement with those reported by previous researches[22,33,35]. Brown et al[22] compared TiA miniscrews with identically sized SS mini-implants (length: 6 mm; diameter: 1.6 mm), inserted into the tibias of 12 rabbits reporting no differences in removal torque between TiA and SS TADs (4.4 ± 1.7 N-cm and 4.4 ± 2.3 N-cm, respectively). We did not evaluate the insertion torque since the two miniscrews presented different tip designs that might influence a greater torque resistance during the insertion of SS TADs. After clinical use, fractured screw tips and stripped screw threads were not observed by means of optical microscope. All retrieved TADs showed signs of biological contaminations on their surfaces (Figure 1). The SEM analysis showed the presence of biological materials on the surfaces of retrieved TADs (Figure 2). Particularly, at higher magnification, SEM photomicrographs of TiA TADs showed predominantly blood cells covering most of the surface (Figure 3). SS TADs showed the precipitation of an amorphous layer with low cellular component (Figure 4). These results are consistent with those reported by Albrektsson et al[12] and Gotman et al[13] who observed that SS tends to develop a fibrous tissue interface between the screw and the bone.

Finally, the EDS microanalysis detected statistically significant differences only in the percentages of titanium, aluminum, and vanadium. The presence of iron was similar in both miniscrews. However, the results should be carefully interpreted. The iron in the TiA TADs is a consequence of the presence of blood cells, while the iron in SS TADs represents the material of the specimens itself[34]. A limit of our investigation was the different shape of the final portion between Tia and SS TADs. The selected TADs resulted the most similar available miniscrews for diameter, length and thread interval. However, all the other limits, such as the difference in soft tissue thickness, oral hygiene, periodontal health, age, sex, and duration of load, have been overcome by the split mouth study design.

Conclusions

TiA and SS miniscrews showed similar removal torque values. SEM photomicrographs of TiA TADs demonstrated blood cells covering most of the surface. SEM photomicrographs of SS TADs showed the precipitation of an amorphous layer with low cellular component. No evidence of osteo-integration was detected.

Conflict of Interest:
The Authors declare that they have no conflict of interests.

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