# Removal torque of osseointegrated mini-implants: an *in vivo* evaluation

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SUMMARY The possibility of using osseointegrated implants for orthodontic anchorage is well known. When absolute orthodontic anchorage is needed, mini-implants can be inserted in the non-alveolar bone area (e.g. palatal process or retromolar areas of the mandible). However, what happens to these implants at the end of treatment can be a problem as neither trephine explantation nor simply leaving the subgingival part of the implant in the bone permanently are acceptable solutions.

In this investigation, 16 Exacta small screw titanium implants (Exacta MS series conical profile, with a diameter of 3.3 mm and a length of 7.0 mm) were used as indirect orthodontic anchorage in 16 adult patients. The site of implant placement was established based on radiological investigations. There were eight palatal and eight retromolar implants inserted in seven males and nine females (mean age 30.3 years). On completion of treatment, the implants were unscrewed to the maximum limits of their removal torque values (RTVs) and the obtained data were analysed using a *t*-test. An *in vitro* study before the clinical trial was also undertaken to determine the maximum mechanical resistance of the unscrewing system.

The clinical procedure and average RTV (67.91±12.47 N/cm) were considered compatible with safe, non-invasive removal of the implant followed by rapid anatomical reconstruction of the area involved.

## Introduction

In recent years, orthodontic treatment has been transformed by the introduction of skeletal anchorage. The biomechanical principles of this approach are the same as those applied in traditional anchorage. However, the possibility of using a stable anchorage point has extended the possibilities for orthodontic treatment in patients with a significant number of missing teeth, when existing bone support is inadequate, or in adult patients who would normally refuse to wear headgear. Various types of implants have been proposed depending on the clinical situation, the force applied, and the type of orthodontic movement needed. These include osseointegrated implants (Ödman et al., 1988; Roberts et al., 1990; Triaca et al., 1992; Wehrbein et al., 1996a), miniscrews and non-osseointegrated anchorage devices (Kanomi, 1997; Costa et al., 1998; Bae et al., 2002; Carano and Velo, 2004), mini-plates (Jenner and Fitzpatrick, 1985; Umemori et al., 1999), and onplants (Block and Hoffman, 1995). Intra-bone osseointegrated implants are the simplest in terms of surgical insertion and clinical reliability. However, the presence of a full dentition without edentulous spaces or spaces that need to be closed orthodontically require the use of smaller implants specifically designed for orthodontic purposes.

Different orthodontic endosseous implant systems are associated with varying clinical protocols (Wehrbein and Merz, 1998; Favero, 2000; Mura *et al.*, 2000). At the end of orthodontic treatment, Wehrbein *et al.* (1996b) suggested trephine explantation, while Mura *et al.* (2000) proposed leaving the implant in the bone indefinitely so as to avoid this invasive procedure. Both solutions leave much to be desired, which is why osseointegrated anchorage implants have been relatively limited in orthodontic use (Hohlt, 2004). The ideal situation would be removal of the implant by simply unscrewing it, followed by healing of the bone in which it was inserted. A fundamental condition to be able to do this is to have an osseointegrated implant that can withstand orthodontic loads but can also be removed at the end of the treatment with minimal trauma.

The removal torque value (RTV) is the torsion force required to remove an implant and this value has been widely used by a number of authors in order to find the relationship between the implant surface and bone (Gotfredsen *et al.*, 1992; Klokkevold *et al.*, 1997, 2001; Wennerberg *et al.*, 1997; Baker *et al.*, 1999). The force required for removal (Ivanoff *et al.*, 1997) increases in line with the torsion resistance of the bone–implant interface, and therefore the anchorage capability of the implant (Wennerberg *et al.*, 1997; Trisi *et al.*, 1999).

For osseointegrated implants designed for orthodontic anchorage, the torque used must allow easy implant removal, with no risk of breakage of instruments or damage to adjacent anatomical structure. Furthermore, determining the RTV provides further useful information related to the implant's tolerance range to orthodontic rotation, the identification of potential dangerous moments, the preparation of suitable connecting bars, and determining correct application of orthodontic loads.

The aim of this study was to establish the RTV of osseointegrated implants used for orthodontic anchorage

*in vivo* and to evaluate the possibility of their non-invasive removal after orthodontic treatment by manual unscrewing.

## Materials and methods

The implants used in the study were internal hexagonal screw implants (Exacta MS 7, Biaggini Medical Devices, La Spezia, Italia), with a conical shape and small size (diameter 3.3 mm, length 7 mm), made of commercially pure titanium in conformity with the American Society of Testing and Material (ASTM) directions (Trisi *et al.*, 1999). The implants were a grade 3 ASTM B348-90 type with a sandblasted endosseous surface with a machined mucous tunnel (Figure 1).

Ethical approval was granted by the Ethics Committee of the Institute of Dentistry, University of Brescia, and all patients signed a standard informed consent for the implant and orthodontic therapy. Given that the use of osseointergrated implants is a relatively new technique, on commencement of treatment, the patients were also told verbally and in writing that:

- 1. The positioning of implants in the palatal or retromolar region for orthodontic reasons was an experimental procedure.
- 2. After orthodontic treatment, given that the implant was not to be used for prosthetic purposes, it would ideally be unscrewed using an anti-clockwise rotation, or if this was considered inadvisable, then by trephine explantation. An alternative would be to leave the implant in position, once the connecting bar to the arch had been removed.



Figure 1 The Exacta MS 7 temporary orthodontic mini-implant used in this study.

3. The implants would be inserted fully respecting the principles laid out in the Declaration of Helsinki and its successive up-dates.

Sixteen healthy adults (seven males and nine females) agreed to participate in the study. The patients ranged in age from 19.4 to 54.5 years (mean age 32.7 years). Eight of the implants were placed in the anterior region of the hard palate (palatal process), and the remainder in the mandibular retromolar area, buccal to the base of the vertical ramus (Figure 2).

## Implant surgical insertion protocol

For the palatal implant patients (four males aged 20.3–52.1 years, mean age 32.3 years, and four females aged 19.4–48.3 years, mean age 33.2 years), a panoramic radiograph, lateral cephalometric radiograph, and computed axial tomograph of the palate were taken to measure the bone height available and the chosen insertion site (Wehrbein *et al.*, 1999; Bernhart *et al.*, 2000; Favero, 2000). For the retromolar patients (three males aged 32.2–45.6 years of age, mean age 32.9 years, and five females aged 23.4–54.5 years of age, mean age 32.5 years), only a panoramic radiograph was obtained.

The implant insertion point was established on the basis of clinical radiological data with the aid of transparencies of the orthodontic implants and, in the case of the palatal implants, of a surgical stent (Favero, 2000; Cousley and Parberry, 2005). One hour before surgery, a single dose of 2 g amoxicillin was administered and local anaesthesia was achieved using carbocain cloridrate 1:100 000 by local regional infiltration.

For the subjects having implants placed in the retromolar region, access was made possible with a triangular muco-periosteal flap distal and buccal to the terminal molar. All were placed in the para-median position and a mucous punch, using circular scalpels, was utilized. The implant bed



Figure 2 Radiographic image of lower retromolar implant for anchorage. Note the connecting bar between the implant and the molar.

was then prepared by creating a bone route 7 mm deep, using a cylindrical surgical drill, 2.35 mm in diameter. The bone route was then adjusted with a conical surgical drill measuring 3.3 mm at its widest diameter and 7 mm in length (Biaggini Medical Devices). The drills were used at low speed and well irrigated with sterile, chilled physiological solution. The bone density was rated by the surgeon, according to the resistance at the moment of surgical bone perforation (Table 1) and classified according to Lekholm and Zarb (1985).

The implants were then inserted manually taking care to ensure primary stability. The mandibular retromolar edges were sutured with 3.0 mm silk, submerging the implants. For the palatal implants, a titanium healing screw was inserted, high enough to encourage healing of the soft tissues. In the 2 day healing period, 2 g/day of amoxicillin and an anti-inflammatory (ibuprofen 1.200 mg/day) were administered. Chlorexidine mouthrinses (0.12%) were prescribed three times a day for 1 week. The border sutures were removed after 1 week, and weekly check-ups were carried out for 1 month after the procedure.

#### Loading the implants

After 3 months, the retromolar implants were surgically exposed and orthodontically loaded. For the palatal implants, orthodontic appliance was constructed 6 months after surgery. Before loading the implants, the arches were levelled and aligned to allow the desired dental movements to be commenced as soon as the implants were connected to the anchorage unit. The connection between implant and anchorage was made with fused titanium bars, rigidly connected through a system at the implant head (Favero, 2000). The connection to the arches was undertaken using a bonding technique, or through the use of bands cemented to the teeth and soldered to the bar, thus allowing different types of tooth movement (rotation, extrusion, intrusion,

Table 1Bone types found during implant insertion (according to<br/>Lekholm and Zarb, 1985\*).

Palatal implants		Mandibular retromolar implants	
Patient	Bone type	Patient	Bone type
1	D3	9	D2
2	D3	10	D1
3	D2	11	D1
4	D4	12	D2
5	D3	13	D3
6	D4	14	D2
7	D4	15	D2
8	D2	16	D1

\*Bone type D1: dense cortical bone; D2: thick layer of compact bone surrounding a core of dense trabecular bone; D3: thin layer of cortical bone surrounding a core of dense trabecular bone; D4: thin layer of cortical bone surrounding a core of lower density trabecular bone. tipping, torque, and bodily movements). The implants, as indirect anchorage units, were therefore subjected to orthodontic loading which was variable in intensity, duration, and method of application for a minimum period of 8 months and a maximum of 26 months. All implants were stable at the end of treatment.

### In vitro tension test

In order to establish the breaking points that would be used as a reference in the *in vivo* test, 10 implants (identical to those used in the in vivo study) were held in a clamp and the special hexagonal keys (Biaggini Medical Devices) fixed in each of the implant heads. On each key, a ratchet was inserted that was set to rotate anti-clockwise. At the nonengaged end of this ratchet, a digital traction dynamometer AIKOH 9020 B (Aikoh Engineering Co., Nagoya City, Japan) was connected (Figure 3). A gradually increasing tension was then applied to the dynamometer. This tension was directed on the key and therefore on the implants in an anti-clockwise direction to obtain the mechanical breaking point of the unscrewing system. The peak values of the linear tractions of maximum mechanical tolerances were then registered when the implants broke. For each linear peak, the corresponding torque value was calculated and expressed in Newtons per centimetre.

### In vivo screwing test

At the end of treatment, all patients had their orthodontic appliances and connecting bars removed. Following this, appropriate fixed and removable retainers were made and removal of the implants was undertaken under local anaesthetia. The loading method used in the *in vitro* test was reproduced *in vivo* using a new implant key for each patient. Anti-rotational torque was applied according to the data obtained *in vitro* and a torque limit of 150 N/cm was fixed to the implant keys for safety (Figures 4 and 5). Both objective and subjective clinical criteria were adopted during the traction to determine the adequacy of the tension applied in relation to the integrity of the peri-implant anatomical structures. When the maximum limit of traction



Figure 3 In vitro tension test: photograph showing the measurement of the implant unscrewing mechanical system breaking point.

tolerance on the skeletal-integrated surface was exceeded, the implants were manually removed. The extent of the unscrewing tension at implant removal was noted for each patient. The extent of the corresponding torsion moments, and consequently the relative RTV values, were calculated for each linear traction grade produced. In the two groups of patients, the data were statistically analysed, using a *t*-test.

## Results

## In vitro tension test

The maximum tolerance, and mean recorded values, in the tension test are shown in Table 2. In all tests, breakage of the unscrewing apparatus was evident at the level of the internal hexagon of the implant and was associated with distortion.

## In vivo reverse-torque test

All implants were easily removed without trauma by releasing the bone implant fastener after tension had been applied in an anti-clockwise direction. There were no complications during implant removal or the healing period. After removal, each implant underwent microscopic analysis, which showed no significant morphological alterations of the internal hexagonal cavities. Using the same analytical procedure, no significant deformation of the implant keys was found. One week after surgery, all patients who had received a palatal implant had complete recovery of the palatine mucosa (Figure 6a–c). Recovery in those patients who had received a retromolar implant occurred even earlier.

Data describing the extent of the RTV needed to unscrew the implants are summarized in Table 3, although it should be noted that these results are not necessarily transferable to all implant types and sizes.

## Discussion

The RTV of the palatal implants ranged from 53.0 to 82.3 N/ cm (mean value:  $67.2\pm9.4$  N/cm) and, for the retromolar implants, from 36.5 to 90.9 N/cm (mean value:  $68.6\pm15.6$ N/cm). These values are clearly lower than the maximum tension recorded in the *in vitro* strain test. There did not appear to be any relationship between the orthodontic movements, the extent and method of the load applied to the palatal or retromolar implant components, or the RTV recorded.

At the end of orthodontic treatment, the RTVs were notably lower than those in animal studies where standardsized implants were placed in the maxillary bone (Scarano *et al.*, 2002). This difference is principally attributable to the limited osseointegrated implant surface relative to the small size of the orthodontic implants used (Ivanoff *et al.*, 1997). The limitation of the small size of the implants, in terms of primary stability, percentage of osseointegrated surface, and response to the orthodontic load are, on the



Figure 4 In vivo removal test: the implant key.



Figure 5 Schematic drawing of the mechanical unscrewing system.

 
 Table 2
 In vitro test of maximum mechanical tolerance (anticlockwise rotational value).

Test	N/cm
1	215.2
1	215.3
2	213.2
3	203.4
4	207.6
5	209.3
6	210.4
7	205.0
8	217.1
9	218.4
10	208.4

Average anti-clockwise coupling toleration = 210.8 N/cm.

other hand, compensated for by their rough surfaces and conical shape. Previous studies have found that, independent of the dimensions of the implant, rough titanium surfaces have more contact between bone and implant and a higher RTV than machined surfaces (Buser *et al.*, 1991; Kieswetter *et al.*, 1996; Klokkevold *et al.*, 1997, 2001; Wennerberg *et al.*, 1997, 1998; Carlsson *et al.*, 1998; Cochran *et al.*,



**Figure 6** (a) Palatal implant linked to the transpalatal bar for orthodontic treatment; (b) after removal of the implant and orthodontic appliance; (c) 5 days after implant removal.

**Table 3** Removal torque value (RTV) at the end of orthodontic treatment.

Palatal implants		Mandibular retromolar implants	
Patient	RTV (N/cm)	Patient	RTV (N/cm)
1	64.0	9	36.5
2	65.0	10	69.1
3	82.3	11	90.9
4	58.7	12	73.9
5	76.6	13	77.1
6	53.0	14	67.4
7	66.1	15	60.8
8	71.1	16	72.9
Average value = $67.2 \pm 9.4$ N/cm		Average value=68.6±15.6 N/cm	

Average overall RTV (palatal implants + retromolar implants):  $67.91 \pm 12.47$  N/cm.

1998; Trisi *et al.*, 1999) and implants with a conical shape increase primary stability when compared with cylindrical implants (Saccone *et al.*, 2002). This has been confirmed in other dental fields in which the mechanical principle of conical coupling is exploited (Sutter *et al.*, 1993).

In all subjects, the maximum tolerance values of torque for *in vivo* unscrewing were greater compared with the higher torsion moments developed in orthodontic applications, which clinically can reach up to 20 N/cm (Pisoni, 2002).

Another element which can influence unscrewing tolerance of an implant is bone type. It is accepted that there is a significant relationship between the RTV and the thickness of the bone in which the implant is inserted (Bass and Triplett, 1991; Jaffin and Berman, 1991; Niimi *et al.*, 1997). In this study, the average RTV for the palatal implants was similar to that for the retromolar implants, despite the significant differences in bone density recorded in the former (Table 1). This may be due to the effect that an orthodontic load applied to an ankylosed implant might induce around the periimplant bone, giving rise to a bone thickening (Roberts *et al.*, 1984; Wehrbein and Diedrich, 1993; Trisi and Rebaudi, 2002).

## Conclusions

In spite of the small sample, the following conclusions can be made:

- 1. Exacta osseointegrated micro-implants can be removed at the end of treatment by a simple atraumatic unscrewing movement, without trephining.
- 2. The maximum traction tolerance on the skeletalintegrated surface of this implant is due to a considerably higher rotation compared with normal orthodontic appliances.
- 3. The unscrewing does not create undue strain on the mechanical components.

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