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A minimally invasive approach to osseo-disintegrate implants via thermal energy. An *in-vivo* pilot study

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ABSTRACT

Aim This pilot preclinical study assessed applying thermal energy to osseo-disintegrate dental implants, minimizing collateral damage.
Materials and methods Two experiments were designed. In the first one, thermal energy from a commercially available dental monopolar electro-scalpel (PerFect® TCS II) was applied to 55 Neodent® Titamax implants inserted in pig ribs (*ex vivo*), assessing temperature rise on the surrounding bone. The second one used the same thermal energy source and dental implants on an *in vivo* rabbit tibiae model (8 rabbits, 2 implants per tibiae, 5 months healing). Osseointegration measurements were ISQ, and removal torque values (RTV). After healing, implants from the first 5 rabbits were randomly treated with no thermal energy, 5 and 10s application. Seven days later, implants were measured, rabbits euthanized, and histology samples obtained. Three rabbits went through a second thermal application (15s).
Results Temperatures after 5s were 84.6 ± 18.6°C, and 94.3 ± 22.0°C for 10s application ($p<0.001$). RTV and ISQ remained unchanged after 5s or 10s of thermal energy application. Nevertheless, after 15s, a tendency for a lower RTV could be observed. Histology confirmed an area of bone destruction.
Conclusions Temperatures produced by different thermal application protocols are reported, thus filling a knowledge void. Extended time applications, monocortical insertion, and waiting more than one week for bone necrosis could decrease RTV in further studies. These data are essential in developing safe clinical implant removal tools.

KEYWORDS Explantation, Device Removal, Osseointegration, Temperature.

INTRODUCTION

Dental implants are currently one of the most common treatment strategies for rehabilitating partial/full edentulism. Reasons for their massive use are their high survival and success rates. A recent systematic review reported dental implant survival rates of 94.6% for the treatment of full or partially edentulous patients followed for at least ten years (1). Nowadays, titanium implants are commonly used by other medical disciplines such as traumatology, otorhinolaryngology, and neurosurgery (2). The biological phenomenon that explains this success is known as osseointegration, a term introduced by Brånemark defined as "the direct, structural and functional connection between living bone and the surface of an implant, under a functional load" (3). The implant-bone interface's microscopic nature has four layers: Haversian bone, a layer of proteoglycans of about 100Å, followed by a layer of titanium oxide equal to or greater than 100Å, and the implant's surface (3). This close union allows chewing forces transmission to the surrounding bone without detectable movement of this interface. That is why the prosthetic supra-structure anchored to the implants can successfully resist axial, lateral, and rotational loads, as long as they remain within physiological limits.

Even though improvements in implant design, surface characteristics, and maintenance protocols in recent years have resulted in increased success rates, still 3-10% of oral implants fail (4,5). With approximately 2 million new implants being placed worldwide each year, and tens of millions of dental implants currently in function, it is estimated that the number of implants that are failing per year could be in the range of 200,000 - 250,000 units (6). An implant has to be removed in some situations, even if it is still partially anchored to the bone. These situations include extreme bone loss, implant fracture, severe peri-implantitis, and malpositioning (7,8). When the implant cannot be unscrewed, the removal often becomes highly invasive (using trephines, burs, and/or chisels) with severe bone damage and sometimes a high risk of compromising neighboring teeth. Recently, a systematic review searched for the different techniques applied for implant removal on humans, showing that the most

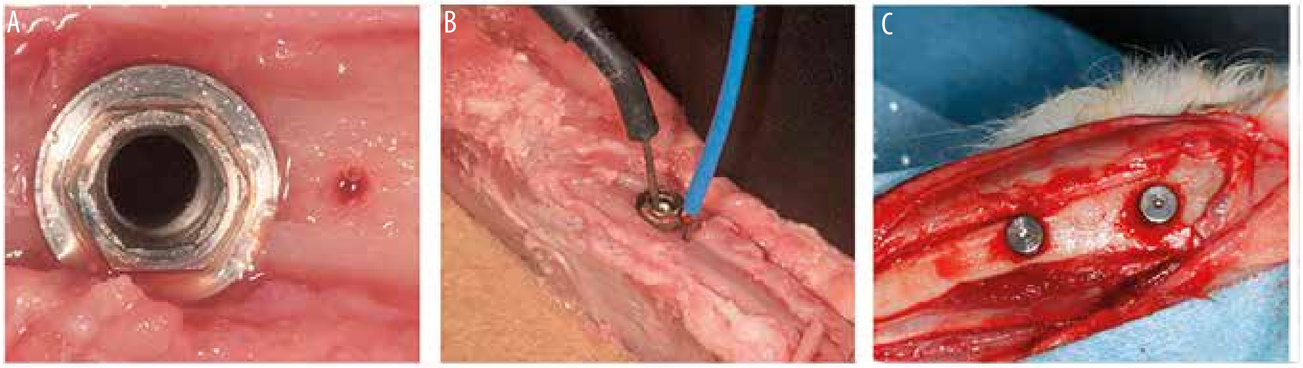

FIG. 1 Images from the experimental procedure.
A: Implant (Ø 3.75 mm) inserted (ex vivo) in pig rib with at 1 mm distance a narrow tunnel (parallel to the implant, 3 mm in depth) in the bone to insert the thermocouple to measure the temperature.
B: The complete set-up with a thermocouple in the tunnel and the active tip of the monopolar electric scalpel in the implant's lumen, the latter to create thermal energy.
C: Two implants (Ø 3.75 mm, length = 9 mm) in a rabbit tibia, at a distance of 15-18 from each other. All implants had bicortical anchorage.

common techniques were reverse torque removal, followed by burs and trephines, piezosurgery, and Er:Cr:YSGG laser (9).

Currently, there are no commercially available validated products that can successfully and safely remove different dental implants. For this reason, it is essential to search for new techniques and instruments that can fulfill this void.

One promising approach is the use of high temperatures near the bone-implant interphace. The impact of heat produced during the preparation of an osteotomy has been examined in several studies (10–16). Heating can lead to hyperemia, necrosis, fibrosis, osteocyte degeneration, and increased osteoclastic activity (10–18).

Some papers empirically explored using an electro-scalpel to apply heat to an osseointegrated implant causing thermo-necrosis in the peri-implant bone to facilitate implant removal (19,20). However, the concern when using electro-scalpel is the risk of exaggerated osteonecrosis (19).

Considering these data, we proposed using a clinical available dental electric scalpel as a dental implant removal tool. This pilot preclinical study aimed to determine if the application of a thermal energy protocol (using a monopolar electric scalpel) to osseointegrated implants could facilitate their removal, causing minimal damage to the peri-implant tissues.

MATERIALS AND METHODS

This pilot animal study protocol was approved by the Universidad de los Andes' Ethical Committee. The design considered two experimental phases. The first one was an *ex vivo* testing (pig ribs for validation of the technique and measurements of the thermal energy in the peri-implant tissues generated by an electric scalpel), followed by an *in vivo* rabbit model for exploring the clinical applicability on osseointegrated implants.

Titamax Ti implants (Neodent, Curitiba, Brazil) 3.75 mm in diameter and 9 mm in length were used for both experimental phases. These titanium implants are screw-shaped with external hexagon connection, sand blasted, and acid-etched surface consisting of oxidized titanium (mainly TiO2) C, O, and a few amounts of contaminants like N, P, and S.

Ex vivo phase

According to manufacturer guidelines, 55 dental implants (Titamax Ti medullary, Neodent, Curitiba, Brazil), 3.75 mm in diameter and 9 mm in length, were inserted in fresh pig ribs with an insertion torque of 40N. A 0.2 mm diameter tunnel (2-3 mm in depth) was made in the cortical bone at 1 mm distance from the implant to insert a thermocouple (Fig. 1a). The ribs were fixed in a holder in contact with the counter electrode of an adjustable monopolar electric scalpel Perfect TCS II (Coltene Whaledent Inc., Mahwah, NJ, USA) (Fig. 1b). According to previous papers, thermal energy was applied by placing the active tip using 3.69 MHz frequency, 45 W, at maximum power (cut mode) inside the implant lumen as far as the tip could go (19,20). The temperature generated in the peri-implant bone was recorded via a digital multi-meter (UT60E, UNI-T, China) able to measure temperatures ranging from -40°C to +1000°C. For each of the 55 preparations, two temperatures were recorded, after 5s and 10s of energy application. Both the initial and the maximum temperature were registered.

In vivo phase

Eight New Zealand rabbits (≥ 12 months in age with a weight of 3.8 - 4.5 kg) were enrolled for this part of the study. They lived in individual cages with an ad libitum regimen for feeding. All surgical interventions were conducted under 10% Ketamine (Ketamil®, Agrovet) and 2% Xylazine (Centrovet®) in 35 and 5 mg/kg doses respectively.

Implant insertion

Both tibiae of each rabbit were shaved, and the skin was disinfected with a 10% povidone-iodine solution (Hofsa® Line, Difem Pharma). After applying 3% mepivacaine locally (Mepisv® 3%, DFL, Brazil), the medial face of the proximal metaphysis of the tibia was exposed (21). According to the manufacturer's protocol, two osteotomies were prepared (15-18 mm apart from each other) to insert Neodent® Titamax Ti medullary implants (3.75 x 9 mm), using an insertion torque of 40N (4 implants per rabbit) (Fig. 1c). Immediately after insertion (T1), ISQ T1 values were recorded using a resonance frequency analysis device (Osstell ISQ, Osstell AB, Göteborg, Sweden). Values were recorded from 2 different directions (proximal and distal) considering the mean value. Finally, the periosteum and muscular plane were closed with 3-0 resorbable suture material (Vicryl®, Ethicon, USA), and the skin with 3-0 non-resorbable monofilament nylon sutures (Mononylon Ethilon®, Ethicon, USA).

Implant osseo-disintegration

After five months of healing (T2), the implants were exposed and the ISQ measurements were repeated (ISQ T2). The implants were randomly allocated to one of the following 3 treatment groups (random distribution protocol obtained via the program Stata 14.2):

- Control group: without thermal energy application.
- Test group 1: 5s of thermal energy application.
- Test group 2: 10s of thermal energy application.

Finally, the cover screw was reconnected, and the wound closed (as mentioned before). The implants were again exposed seven days later (T3), and the ISQ measurements were repeated (ISQ T3).

In 5 rabbits, RTV was recorded with a torque wrench (Tohnichi BTG,150CN-S, Japan). The rabbits were sacrificed with a T61 Euthanasia Solution (Intervet International GMBH Germany), in an approximate volume of 0.5-1 ml per rabbit. The tibias were immediately removed and immersed in a 3.7% formalin solution for fixation and sent for histological analysis.

Since the small effect on RTV observed in the first 5 rabbits, it was decided to prolong the last 3 rabbits' test period. Their implants (n = 12) were randomly distributed for an extra application of energy, now for 15s, and for an additional healing time of 1 week (T4), after which the ISQ values were again recorded (ISQ T4), the removal torque was scored, and rabbits were sacrificed for histological examination. For these 3 specimens, the following groups were created.

- Control group (n = 4): without thermal energy application.
- "Pseudo" control group (n = 2): single thermal energy application of 5 or 10 seconds.
- Test group 1: with 2 thermal applications, the 1st time 5s (n=3), and the 2nd 15s.
- Test group 2: with 2 thermal applications, the 1st time 10s (n=3), and the 2nd 15s.

Histological evaluation

All samples were decalcified using Ana Morse solution (Merck, NJ, USA) for 17 days. Dehydration with 70°, 80° and 90° ethanol were performed to embed them in paraffin (Paraplast, Sigma Aldrich, St. Louis, Missouri, USA). Three µm samples were obtained and used for histological examination after staining with hematoxylin-eosin (Merck, KGaA, Darmstadt Germany).

Statistical analysis

All data descriptions and analyses were done using Stata® 14.2 (StataCorp, Texas, USA) software. For descriptive statistics, measures of central tendency and dispersion were used. We built a linear multilevel regression model searching for possible differences between thermal energy protocols at the *ex vivo* phase using $p<0.05$ as the significance level. For group comparison on the *in vivo* phase, a random-effects model was estimated using the regression estimator, considering each rabbit's nesting. Finally, the graph was made using GraphPad Prism 8.2.1 software (San Diego, CA, USA).

RESULTS

Ex-vivo phase

After 5 seconds of thermal energy application, the bone's mean temperature was 84.6 ± 18.6°C. After 10 seconds of application, higher temperatures were reached (94.3 ± 22.0°C) been statistically different ($p< 0.001$) (Fig. 2).

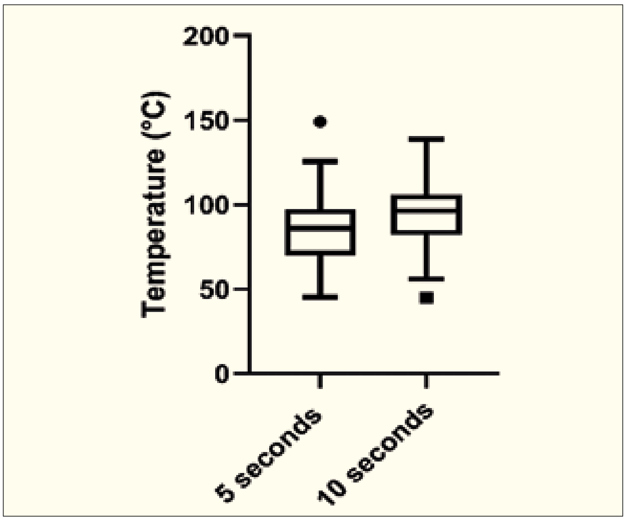

FIG. 2 Whiskers box-plot for temperature measurements after 5s or 10s of thermal energy application via a monopolar electric scalpel inserted into the implant lumen (*ex vivo* experiment).

	No heat			5s			10s		
Variable	P50 (IQR)	min-max	N	P50 (IQR)	min-max	N	P50 (IQR)	min-max	N
ISQ t1	74.5 (5)	71.5 - 80	6	80 (5.5)	73 - 81	7	80 (8.5)	70 - 81	7
ISQ t2	84 (3.5)	80 - 85	6	84 (8)	79 - 90	7	86 (3)	83 - 90	7
ISQ t3	84.5 (2)	80 - 87	6	85 (5)	80 - 89	7	85 (4)	80 - 89	7
R.Torque (Ncm)	103 (66)	60 - 140	6	130 (20)	80 - 150	6*	117 (50)	70 - 130	6**

*No heat: control group; 5S: test group 1; 10s: test group 2; t1: implant insertion; t2: after 5 months of submerged healing, before applying thermal energy; t3: one week after the application of thermal energy; P50: median; IQR: interquartile range; min-max: minimum and maximum values; N: number of observations; * one implant from the 5s group could not be removed; ** one implant form the 10s group could not be removed.*

TABLE 1 Results from the first part of the *in vivo* phase (20 implants from the first 5 rabbits). ISQ and removal torque values for control (no heat), 5s and 10s groups of thermal energy application.

	No heat, 5s or 10s			5s and another 15s of heat			10s and another 15s of heat		
Variable	P50 (IQR)	min-max	N	P50 (IQR)	min-max	N	P50 (IQR)	min-max	N
ISQ t1	74 (3)	71 - 77	6	74 (1)	74 - 75	3	71 (6)	70 - 76	3
ISQ t2	81.5 (5)	80 - 89	6	87 (7)	81 - 88	3	86 (4)	83 - 87	3
ISQ t3	84 (6)	80 - 88	6	85 (7)	80 - 87	3	85 (2)	84 - 86	3
ISQ t4	83.5 (6)	80 - 89	6	85 (8)	81 - 89	3	86 (3)	84 - 87	3
R. Torque (Ncm)	110 (34)	90 - 140	5*	100 (20)	90 – 110**	2	120 (65)	55 - 120	3

*No heat, 5s and 10s: control and pseudo control group; 5s and another 15s of heat: test group 1; 10s and another 15s of heat: test group 2; t1: implant insertion; t2: after 5 months of submerged healing, before applying thermal energy; t3: one week after the application of thermal energy; t4: one week after the second application of a thermal energy (no application for the control group) P50: median; IQR: interquartile range; min-max: minimum and maximum values; N: number of observations; * one implant from the 5s group could not be removed; ** one implant form the 10s group could not be removed.*

TABLE 2: Results from the second part of the *in vivo* phase (12 implants from the last 3 rabbits). ISQ and removal torque values for control (no heat, 5s or 10s), 5s + 15s, and 10s + 15s groups of thermal energy application.

In vivo phase: ISQ values and removal torque

ISQ values increased between implant insertion (T1) and re-entry after 5 months (T2) with an overall mean increase of 8.5 ± 4.3 (Table 1, 2). After applying thermal energy, values remained unchanged with a mean reduction of 0.2 ± 3.5 after a first application (Table 1) and no reduction (0.0 ± 1.1) after the 2nd application (Table 2). This lack of change was despite the different thermal protocols used.

No statistically significant results could be obtained for the removal torque when thermal energy was applied for 5 or 10s (Table 1). However, after the 2nd application of thermal energy, now for 15s, the removal torque tended to decrease, although not statistically significant ($p = 0.27$).

Histological examinations

In the 5s group sample, alterations of the cortical and medullary bone tissue could be observed, with inflammatory and necrotic tissue areas showing no

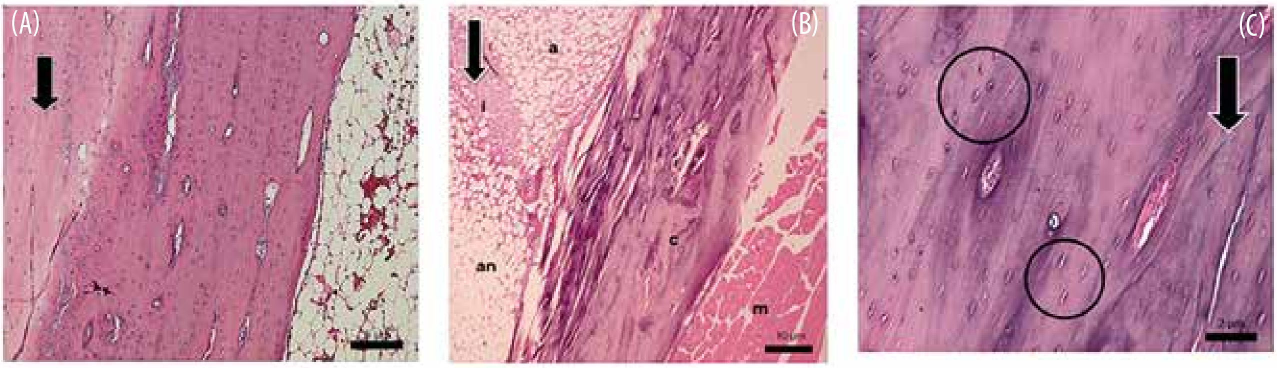

FIG. 3 Histological pictures of the peri-implant bone. Black arrows indicate the position of the removed implant. A:Control implant. B: Test implant after applying thermal energy for 5s. Alterations of the cortical and medullary bone tissue can be observed, ranging from inflammatory tissue to necrotic adipose tissue areas. m: muscle; c: cortical bone; a: adipose tissue; i: inflammatory tissue; an: necrotic adipose tissue. C: Test implant after 10s of thermal application. Osteocyte lacunae in the bone close to the test implants (compare upper with lower circle) became empty.

particular distribution around the removed implant (Fig. 3b). No evident histological differences could be identified between test groups.

DISCUSSION

In contrast with previous studies, our study's findings indicate that thermal energy application in osseointegrated implants placed in rabbit tibia does not decrease its removal torque (19,20).

Thermal energy from electric scalpels has been proposed as a safe and atraumatic technique for implant removal (19,20). There are two types of electric scalpels: monopolar and bipolar. Both are widely used in medicine, with the monopolar type being the most employed in dentistry (19). This encouraged us to investigate the possible applications of a monopolar one for implant removal.

There is little research on the biological damage after an accidental touching of a dental implant with an electric scalpel. Wilcox and co-workers studied the temperature changes when an electric scalpel or laser got in direct contact with a dental implant, using a bovine model (22). The bipolar unit did not produce cumulative temperature increases above 5°C, whereas the monopolar electrosurgical unit regularly produced temperature increases above 10°C. The authors concluded that using a monopolar electric scalpel during plastic or flap surgery should be avoided since it could generate a temperature increase higher than 10°C when getting in direct contact with the implant, causing unforeseen damage to the peri-implant tissues. The bipolar unit, in contrast, was considered to be safe.

Previous studies on the use of an electric scalpel to remove osseointegrated implants were case reports only (19,20). The authors could not find a paper on the generated temperatures and/or on the extent of the peri-implant tissue damage. In 2004, Massei and Szmukler-Moncler used an ultra-high frequency (UHF) electric scalpel for 3 seconds to remove 20 implants (fractured or post orthodontic treatment) (20). The generated temperatures were, however, not mentioned. Cunliffe and Barclay in 2011 reported on 1 case where they applied a monopolar ultra-high frequency (UHF) electric scalpel on the implant neck for 15 seconds (19). After 1 week, the implant could be removed with a torque of less than 30 Ncm, with minimal bone destruction and no macroscopic evidence of necrosis. This information helped us to decide time frames to remove the implants after heat treatment. Given the limited information provided by the existing literature (19,20), we developed an *ex vivo* experiment to systematically evaluate the temperature rise inside fresh ribs bone, 1 mm from the implant surface, during the thermal energy application (19,20). When the electrode comes in contact with the implant, the high-frequency alternating current, generated by the electric scalpel, is transmitted to the bone tissue, generating heat. Two-time intervals were analyzed: 5 and 10 seconds, based on previously published data trying to do the lowest possible damage to the peri-implant bone (19,20). The temperature increased to ± 82°C for the 5-seconds application and 95 °C for the 10-seconds application at the *ex vivo* phase, giving theoretical support to the *in vivo* phase

In our experiment, ISQ values increased during the five months of healing, which agrees with the literature regarding ISQ data after osseointegration (23). Following the application of thermal energy, the ISQ values did not change. The reason could be that small changes in the peri-implant bone cannot be detected by ISQ measurements, as shown by Merheb and co-workers (24).

The thermal energy application for 5 or 10s also did not affect the osseointegrated implants' removal torque values. However, when the thermal energy was applied for 15s a tendency towards decreased removal torque values could be observed. Nevertheless, removal torques observed in our specimens were too high. The latter might be explained by the implants' bi-cortical positioning, a situation known to increase the torque resistance. Ivanoff and co-workers indeed observed that bi-cortical implants had twice higher removal torque values at 6 weeks and three times higher at 12 weeks compared to implants anchored only in one cortex (25). Since today, most implants in humans are placed mono-cortically, new experimental trials should perhaps consider mono-cortical implants.

Most relevant explanations for the difference between our studies and the previous literature can be the following.

1. The positioning of the active electrode inside the implant, transforming the latter into an electrode of larger diameter, generating a lower current density, given that current density is defined by the interaction between intensity and electrode section (mm^2); nevertheless, this issue did not affect the results of two previously published articles that used electro-scalpel (19,20).
2. The interval between energy application and implant removal might have been too short; Eriksson and co-workers showed that bone resorption started only from the 3rd week after the heat was applied (10).
3. The duration of the peak temperature which was only for some seconds; Eriksson and Albrektsson in their work applied 47°C for one minute (10); and Li and co-workers as long as 10 minutes (12).
4. The cortical bone thickness around the neck and apex of the implant.
5. The frequency of our electro-scalpel (3.69 MHz, high frequency) was seven times lower than the one used by Massei and Szmukler-Moncler (20), at 27 MHz and ultra-high frequency, or by Cunliffe and Barclay (also ultra-high frequency) (19). The latter appears to be the main reason for our high RTV after thermal energy application.

Our data, therefore, seem to indicate that when applying a high-frequency electro-scalpel instead of an ultra-high frequency, one should increase the time of application or apply several cycles of 15 seconds to compensate for the lower AC frequency.

The present results do not confirm that the application of thermal energy through a monopolar electro-scalpel diminishes the removal torque of an osseointegrated implant. Only in the last series of applications (15s) a tendency of lower removal torque values could be observed.

CONCLUSIONS

We demonstrated the mean temperatures produced by different thermal application time protocols, filling a critical knowledge void in the literature. Considering our overall results, we believe that using more extended time applications (e.g., 25s - 60s), mono cortical implant insertion, and waiting longer than one week after thermal application for implant removal (e.g., 2 or 3 weeks) should decrease removal torque values. These data are crucial in developing a safe clinical implant removal tool based on monopolar high-frequency electric-scalpels, considering that ~25% of the failed implants are challenging to remove with traditional methods.

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