EVALUATION OF FRACTURE TORQUE RESISTANCE IN MINISCREWS AFTER MULTIPLE REUSE CYCLES

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SUMMARY: Orthodontists are increasingly reusing miniscrews used as anchorage devices, either when they fail after insertion or when they need to be installed in a new site due to changed mechanical needs. The objective of this study was to simulate the reuse of miniscrews up to three times and evaluate their resistance to fracture. To achieve this objective, 48 miniscrews (Morelli - Sorocaba - SP, Brazil) were used; these were divided into the following four groups: C = Control, G1 = one reuse, G2 = two reuses, and G3 = three reuses. To simulate the insertion in the patient's oral cavity, swine iliac bones were used. After insertion of the miniscrews into the bone specimens, they were removed, cleaned, and sterilized by autoclaving. With a reference in the device, it was possible to standardize the insertions. After all groups had undergone the corresponding reuse cycles, the miniscrews were submitted to fracture, and the maximum force required for fracturing was measured using a digital axial torque wrench. Bovine tibia specimens were used for this step because they have higher bone density and cortical thickness. The average values of the groups were analyzed using a one-way ANOVA test with the Bonferroni post-hoc test. A statistically significant difference in fracture resistance between group G3 and the other groups was noted. However, all groups required higher mean strengths for fracture than those recommended for miniscrew insertion in patients.

KEYWORDS: Orthodontics. Orthodontic anchoring procedures. Recycling.

INTRODUCTION

Miniscrews, which are composed of either titanium alloys or stainless steel[1], constitute an important group of intraoral bone anchorages. Owing to their intraosseous stability, it is possible to

eliminate the side effects in the anchorage unit; they can also be installed in several areas of the alveolar bone and be used for various types of movements [2,3,4,5,6,7,8]

Miniscrews have gained popularity because they can be inserted easily by a minimally invasive procedure, and cause little trauma and discomfort to the patient [9,10]. Furthermore, this form of anchorage reinforcement does not require patient cooperation, avoiding prolonged treatment and delayed results. With an increased need for rigid anchorage in current orthodontics, screw technology has been evolving [11], but even so, the reported failure rate of miniscrews post-installation, at approximately 13.5%, is still high. Besides failure, another event that may require the relocation of miniscrews is the mechanics used, as the root of a tooth gets closer to it or new mechanics are required[13,14].

In their efforts to reduce costs and make treatment time-efficient, some orthodontists have been reusing miniscrews in the same patient. It remains unknown as to exactly how much this affects the structure and properties of the screw, each time it goes through the processes of insertion in the bone plate, removal, and sterilization. A study has indicated that invasive medical instruments can be reused in the same patient if their integrity and mechanical properties are maintained after use and sterilization[15]. In some areas of medicine, the reuse of devices, such as pacemakers[16] and catheters[17], has been studied. This is also the case in dentistry, more specifically in orthodontics, where there has been research on reuse and sterilization of brackets[18], orthodontic wires[19,20,21] and, more recently, miniscrews[22,23,24,25].

However, no study has evaluated the reuse of miniscrews more than once, undergoing the processes of cleaning, sterilization, and reinsertion repeatedly; there is little scientific evidence regarding this real-world possibility of reusing miniscrews. Therefore, this study aimed to evaluate the occurrence or non-occurrence of miniscrew embrittlement in terms of fracture resistance after being reused for up to three times.

MATERIALS AND METHODS

MINISCREW TEST SAMPLES

The study used 48 self-drilling titanium alloy Morelli miniscrews (Sorocaba, São Paulo, Brazil), 1.5 mm in diameter, 6.0 mm in length with a 1.0 mm transmucosal portion. The implants were pre-sterilized by the manufacturer with gamma rays. They were divided into 4 groups of 12 miniscrews each: Control (C), 1 reuse cycle (G1), 2 cycles (G2), and 3 cycles (G3).

Group C comprised miniscrews that were subjected to fracture testing without being used. Other groups went through cycles that simulated reuse, which consisted of insertion in swine iliac bone specimens, removal, cleaning, and sterilization. Group G1 underwent

the reuse cycle once before being submitted to fracture testing, whereas groups G2 and G3 underwent the reuse cycle two and three times, respectively.

SWINE ILIAC BONES

To simulate the reuse of miniscrews, we used swine iliac bone specimens (Figure 1), from recently slaughtered animals because their properties, such as density and cortical bone thickness, are very similar to human bones[26].

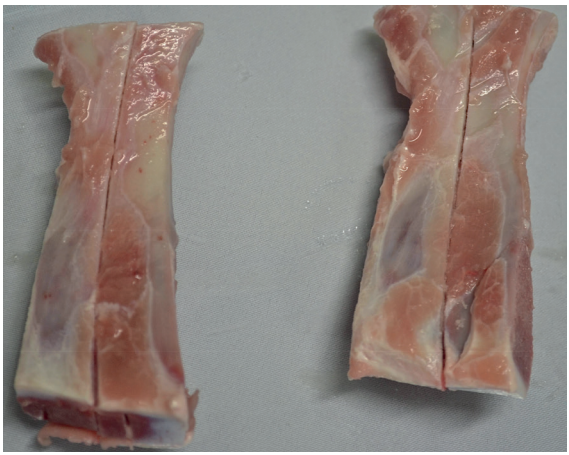


Figure 1 – Swine iliac bone specimen.

In order to standardize the specimens, they were cut longitudinally in the middle to allow visual access to the cortical bone. A caliper rule was used to select bone samples with a cortical thickness between 1.7 mm and 2 mm, excluding those that did not match this criterion (Figures 2 and 3). This range of cortical thickness was adopted because, according to Baumgaertel and Hans (2009)[27], the posterior region of the human mandible has a cortical bone thickness that varies, on average, between 1.87 mm and 1.98 mm.

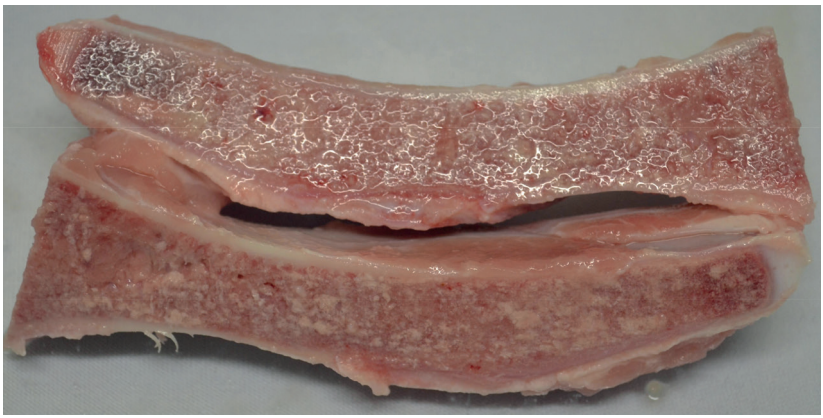


Figure 2 – Swine iliac bone cut longitudinally, allowing visual access to cortical thickness.

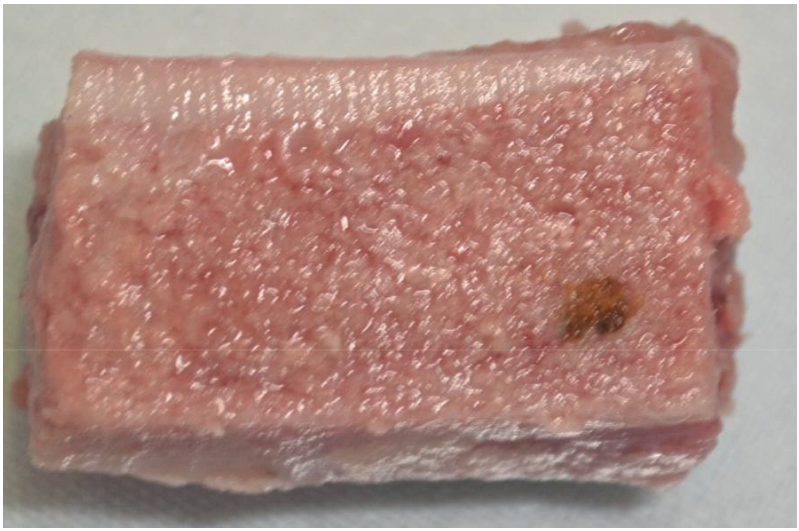


Figure 3 – Selection of parts with bone cortical thickness ranging between 1.7 and 2 mm and elimination of specimens with thicknesses outside this range.

CREATION OF PROTECTION FOR THE BONE SPECIMENS

A plaster mold (ASFER Indústria Química Ltda., São Caetano do Sul, São Paulo, Brazil) was created based on a rectangular model (Figure 4) so that specimens selected for the study could be inserted into a JET self-polymerizing acrylic resin base (CLÁSSICO - Artigos Odontológicos Ltda, São Paulo, São Paulo, Brazil). The plaster mold was isolated with foil and resin was poured in the corresponding space. At the beginning of polymerization, a bone cube was placed in the resin with only a part of it immersed, enough to fix the bone without covering the part where miniscrews would be inserted (Figure 5).

Figure 4 – Finished plaster model.

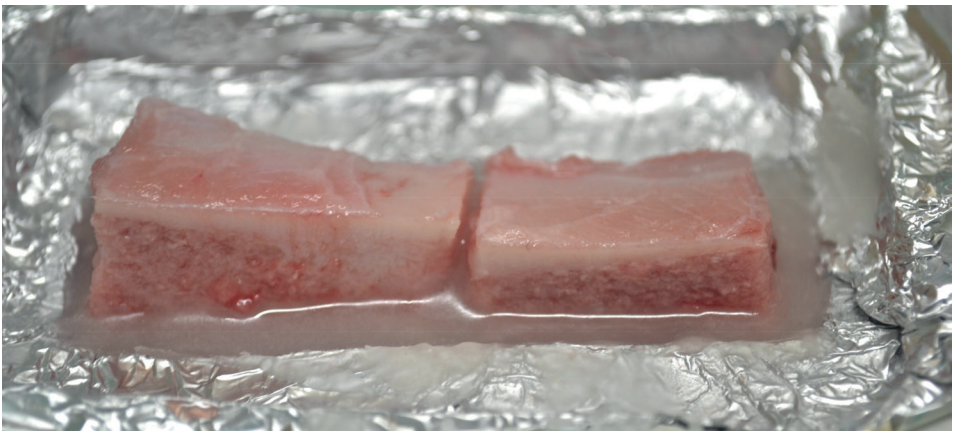


Figure 5 – Swine iliac bone specimens positioned on resin during the polymerization process.

This process was carried out to avoid transmission of the compressive force, caused by the vise located in the installation device during attachment, to the bone specimen, limiting it to the acrylic resin.

After completion of the polymerization process, the specimens were removed from the mold and excessive aluminum foil was removed so that they could be transferred to the seizure device located in the miniscrew insertion device (Figure 6).

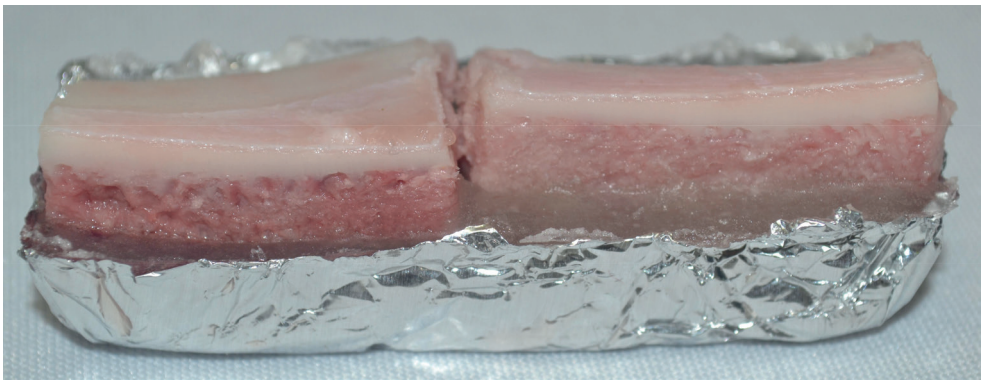


Figure 6 – Specimens ready for miniscrew insertion.

INSERTION DEVICE:

To standardize the miniscrew insertion procedure, we used a device that has a base to guide the installation wrench attached to the TQ 680 axial digital torque wrench (Instrutherm; Instrumentos de Medição Ltda., São Paulo, São Paulo, Brazil) (Fig. 7).

The goal was to prevent unplanned movements, such as inclination, from being incorporated during the procedure and adding one more variable to the experiment, given that the objective of the study was to analyze exclusively if the reuse process affected the structure of the miniscrew with regard to fracture resistance.

In addition, with the base acting as a reference for insertions, the operator had greater control during installation, allowing for insertion of a fixed, uniform length of the screw into the specimen. A vise, located exactly in front of the reference, was responsible for seizure and stabilization of the specimen across the installation wrench, allowing total immobilization of the kit.

A torque sensor allowed adjustment of the measurement units for strength and measurement of the peak strength in addition to digitally displaying the values obtained in the experiment.

Figure 7 – Device used for inserting the miniscrews in swine iliac and bovine tibia specimens. 1 - Insertion reference; 2 - Digital axial torque wrench (torque sensor) with attached miniscrew wrench; 3 - Torque sensor display; 4 - Vise for seizure and stabilizing specimens for inserting miniscrews.

PROCEDURE FOR INSERTION OF MICROSCREWS:

In order to minimize the effect of the quality of bones in terms of, for example, higher density or age, which could result in a greater insertion force and, consequently, greater embrittlement after reuse, the swine iliac bone specimens were randomized for inclusion in the different groups using the www.random.org website. Before each miniscrew installation, the digital torque wrench was calibrated, set, and reset to measure the maximum power peaks in N.cm units in high resolution mode (Figure 8).

Figure 8 – Torque meter adjusted for insertions.

Specimens were stabilized across the installation wrench with the vise, and insertions were performed simulating clinical situations. To ensure that all miniscrews are inserted in a standardized manner, we defined a distance of 1 mm between the beginning of the screw head and the cortical bone as the end-point of the insertion procedure, the length corresponding to the end of the screw thread and, consequently, the beginning of transmucosal section (Figure 9).

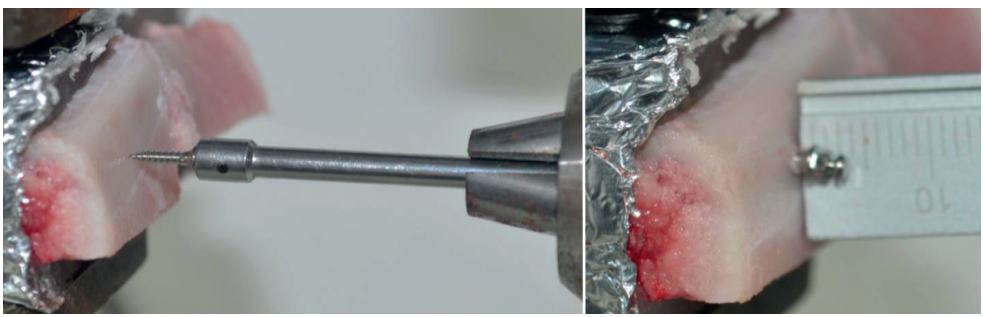


Figure 9 - Stabilized specimen on the vise and wrench with attached miniscrews for beginning the installation process; fully installed miniscrews with 1 mm distance between screw head and cortical bone.

The final torque strength of each installation was noted so that the average strength of each group at the time of reuse could be compared later to confirm that all groups of miniscrews underwent similar stresses at each reuse.

PROCEDURE FOR CLEANING AND STERILIZATION:

Between reuses and before the fracture test, the miniscrews were cleaned with a sponge and a neutral detergent to remove superficial residue. After cleaning, they were individually wrapped, tagged with an identification label of the group they belonged to (Figure 10), and sterilized in standard single cycles at a temperature between 126 and 129 ºC and a pressure of 1.7 to 1.8 kgf/cm², for 16 minutes. A Cristofoli Vitale 12 (Cristófoli Biosecurity Equipment, Campo Mourão, Paraná, Brazil) autoclave was used for this process.

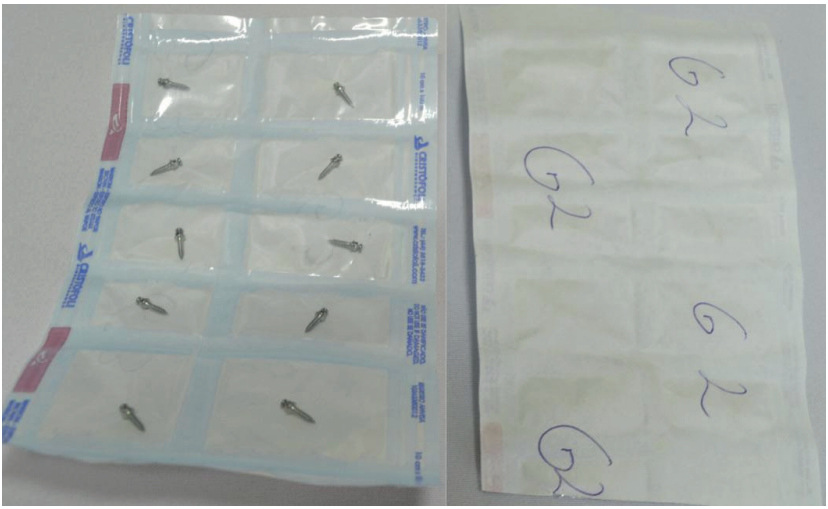


Figure 10 – Miniscrews wrapped individually and identified by group, ready for sterilization.

PROCEDURE FOR MINISCREW FRACTURE:

After all miniscrews underwent reuse cycles corresponding to each group (G1 = 1 reuse, G2 = 2 reuses, G3 = 3 reuses), group C was used in the test procedure. To perform the miniscrew fracture without the risk of the bone not being dense enough to cause it, cross-cut bovine tibia specimens were used (Figure 11). Bovine tibia has a higher density than the swine iliac bone (around 1 g/cm^3 [28] compared to 2 g/cm^3 for bovine tibia); the former may also have a cortical bone thickness of approximately 6 mm[26]. Before each test, the torque wrench was set and reset. All miniscrews fractured during the test (Figure 12) and the required strength values were noted.

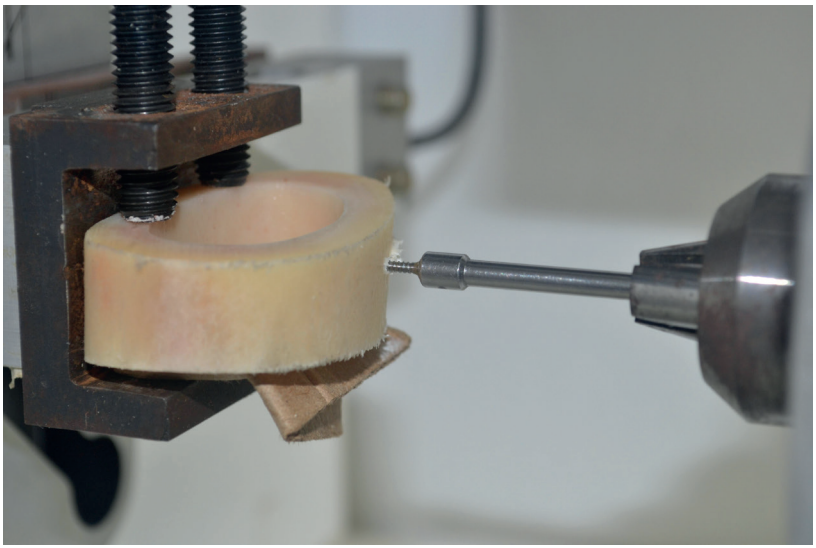


Figure 11 – Miniscrews being installed in bovine tibia specimen to perform fracture.

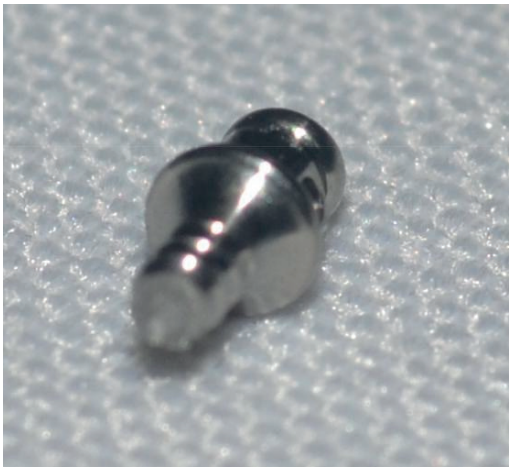


Figure 12 – Fractured miniscrews.

SAMPLE SIZE CALCULATION

Sample size calculation was performed using the OpenEpi- Version 3 program with the following parameters: power, 80%; significance level, 5%; ratio between groups, 1:1; and a difference of means of 1 point with standard deviation of 0.71 and 0.95 for each group, respectively[23]. This resulted in a minimum sample size of 12 specimens per group.

STATISTICAL ANALYSIS

Data were analyzed using the statistical program STATA 12.0 (StataCorp, College Station, TX, USA). The mean and standard deviation values for each group were obtained. The distribution of outcome variables was verified using the Shapiro-Wilk test in order to confirm normality of the data distribution. To verify possible differences between study groups, we used a one-factor ANOVA (Analysis of Variance) test with the Bonferroni post-hoc test to identify any statistical differences between the groups.

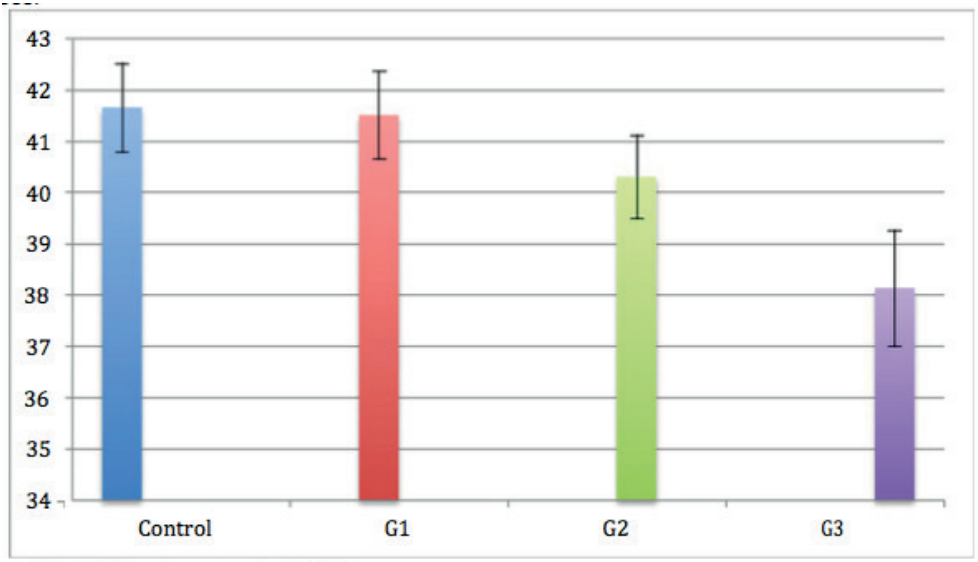
RESULTS

There was a statistically significant difference in terms of fracture resistance between study groups ($p < 0.001$). Table 1 shows the mean values and respective standard deviations of the strength required for fracture for all groups. The control group recorded the highest mean force required for miniscrew fracture, while the group with three reuses recorded the lowest mean force. The Bonferroni post-hoc test showed that the difference in force was significant for group G3 (3 reuses). There was no statistically significant difference between groups G1 and G2, and the Control group. Graph 1 shows a graphical representation of the mean values and standard deviations of each group.

Group	Means	Standard deviations	P
C	41,65[a]	1,73	
G1	41,50[a]	1,70	
G2	40,30[a]	1,63	
G3	38,13[b]	2,26	<0,001

Control group “C”, group with 1 reuse “G1”, group with 2 reuses “G2”, and group with 3 reuses “G3”. Different letters indicate statistically significant differences according to the Bonferroni post-hoc test.

Table 1: Means, standard deviations, and statistically significant differences according to a one-way ANOVA test with the Bonferroni post-hoc test.



**Strengths in N.cm

Chart 1: Comparison of average values and standard deviations for the groups.

DISCUSSION

Often, during the course of orthodontic treatment, miniscrews require repositioning, either because of high failure rate[12], or because there is need for insertion at a better location to continue treatment[13,14]. Based on medicine, where the possibility of reusing certain instruments in the same patient, as long as their mechanical properties are maintained[15,16,17] has been studied, dentistry, more specifically orthodontics, has begun studying this aspect as well. Mattos et al., (2010)[23] compared the strength required for torsional fracture of new, same brand miniscrews (group 1), autoclaved miniscrews (group 2), and those returned after use in patients (group 3). There was a statistically significant difference in strength required for fracture only between groups 1 and 3, suggesting that sterilization alone was not a debilitating factor for miniscrews and that reuse - in which the screw is submitted to insertion and removal forces - may have some effect on fracture resistance. Similarly, the present study also showed that reused miniscrews were more fragile in relation to fractures, but showed that a statistically significant difference was only found in the group that had undergone three reuse cycles.

It is worth noting the differences in the methodologies used in the two studies, though the aforementioned study evaluated miniscrews that underwent the stress of insertion and removal, as did those in the present study; however, the miniscrews in the former study also remained in the oral cavity of the patients for a certain period, suffering local biological reaction and orthodontic mechanical stress, and were submitted to fracture testing after removal, without being sterilized again. In contrast, in the present study, the miniscrews

were only installed and removed, without facing the vicissitudes of the oral environment or any applied mechanical stresses, and were sterilized in an autoclave before being submitted to fracture testing.

Mattos et al. (2011)[22] compared the fracture resistance during insertion of miniscrews between manufacturer's originals and autoclaved groups. No statistically significant difference in the strengths was observed when comparing original and autoclaved miniscrews of the same brand. This agrees with the previous study by Mattos et al. (2010)[23], which found no difference between manufacturer's originals and autoclaved groups of miniscrews with regard to the strength necessary to cause torsion fracture. It is important to note that, according to the manufacturer of the Morelli miniscrews (Sorocaba-SP - Brazil), Gamma-Co 60 irradiation is used for sterilization; this involves exposure of miniscrews to short electromagnetic waves (high frequency) with high penetration power that rupture the DNA strands of the microorganisms, either killing them or rendering them incapable of replication. This process is validated by ABNT (Brazilian Association of Technical Norms) in NBR (Brazilian Standard) 15729:2009. The manufacturer's sterilization process does not, at any time, subject the miniscrews to the sudden changes of temperature experienced during autoclaving, which could theoretically lead to a structural defect and consequently, to embrittlement. However, as shown in previous studies, such embrittlement is not seen to occur, so the only remaining concern is about the quality of sterilization; is the autoclave able to provide a sterilization as effective as the manufacturer's, preventing contamination in future insertions or impairing screw stability?

Estelita et al., (2014)[24] compared fracture strengths in same brand miniscrews divided into 4 groups: control (original from manufacturer); group 1, inserted and removed from a swine iliac bone specimen; group 2, inserted, removed from bone, and recycled through ultrasonic cleaning and autoclaving; group 3, same process as group 2, but included addition of an aluminum oxide sandblast. No statistically significant difference was found when comparing the fracture resistance of all three groups, with the control group. This study is similar to the present one, wherein fracture resistance of reused miniscrews were compared using swine iliac bones to simulate installation in patients. However, the objective of this study was to compare the effect of several post-use cleaning methods on miniscrew fracture resistance after a single use, while we aimed at evaluating if repeated reuse can weaken the screw, using the same cleaning and sterilization method. Therefore, they evaluated only one reuse for each cleaning method and also did not find a statistically significant difference in fracture strengths. A statistically significant difference was revealed only when we simulated three reuses.

The objective of the present study contrasts with those of previous studies that have solely evaluated resistance to torsion fracture of miniscrews, which were returned after use in patients, submitted only to autoclave sterilization, or submitted to reuse simulation only once; the present study's methodology evaluated their resistance when reused up to three

times.

This change in methodology was proposed to progressively evaluate the extent to which the screw structure is affected as it repeatedly goes through the reuse cycle.

It should be noted that, in patients, a procedure is performed prior to the installation of self-drilling miniscrews in which the cortical bone is drilled with the spearhead adapted to the insertion wrench. This procedure can sometimes cause a small bone gap where the screw will be installed, facilitating the initial drilling of the screw. This step was not performed in the simulation, but even so, during all insertions, miniscrews maintained their self-drilling capacity in all groups.

Previous studies that evaluated strengths required for torsional fracture of unused miniscrews of two different brands showed mean values of 29.72 and 58.33 N.cm for miniscrews that were 1.6 mm in diameter[1]. The mean strength required for fracture of the control group in our study was within this range, at 41.53 N.cm; however, forces required for fracture in both studies were higher than the recommended insertion strength of 5 to 10 N [29] and removal strength of 10.78 to 21.07 N [30].

It is clear that even miniscrews reused thrice, although requiring less strength to fracture, are still strong enough to undergo insertion and removal, given that mean strength for fracture for all groups was higher than that indicated for installation, and practically impossible to reach manually in patients, only being possible in the study due to the support provided by the device and the larger diameter of the torque meter in relation to the wrench, which facilitated the application of greater force.

Further studies are required to evaluate the efficacy of cleaning and autoclave sterilization to ensure that they do not, in any way, cause the miniscrews to fail and potentially harm the patient. In addition, an alternative methodology, in which the miniscrews are submitted to conditions that simulate time spent in the oral environment, in contact with intra-osseous fluids and undergoing orthodontic mechanical stress would be of great value.

CONCLUSION

In conclusion, the study showed that as the miniscrews were progressively reused, their resistance to fracture decreased. However, a statistically significant decrease in fracture resistance compared to the control group was noted only after three reuses. Moreover, even the group that presented the lowest resistance to fracture, still required a considerably greater force to fracture than what is indicated for miniscrew insertion in patients.

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