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Effect of Physical and Chemical Sterilization on the Fracture Resistance of Orthodontic Mini-implants: An In-vitro Study

Sherin Johnson[1*], Sameena Begum[1], Laxmikanth S.M.[1], Raghunandan Chunduri[1], Khadeer Riyaz[1], Anju Varughese[1]

[1]Department of Orthodontics and Dentofacial Orthopedics, The Oxford Dental College, Bengaluru, Karnataka, India

***Corresponding author:** Sherin Johnson

Address: Department of Orthodontics and Dentofacial Orthopedics, The Oxford Dental College, Bengaluru, Karnataka, India.

E-mail: sherinjn126@gmail.com

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Abstract

Aim: This study evaluated the effect of physical and chemical sterilization techniques on the fracture resistance of mini-implants.
Methods: Thirty-two titanium mini-implants of 1.5 x 8 mm were randomly divided into four groups: control, steam sterilized, dry heat sterilized, and chemically sterilized. The samples were then tested in the air for fracture resistance using a universal testing machine. A tangential load was applied to the head of the mini-implant with a 1 mm/min crosshead speed after blocking each of them in the machine. Also, the maximum load was recorded previous to screw fracture. he Kruskal-Wallis test and Mann-Whitney post hoc test were used for data analysis.
Results: The results of this study demonstrated the mean fracture resistance difference between the four groups was statistically significant at $p<0.001$. Moreover it was showed the control group had significantly higher mean fracture resistance compared to dry heat and chemically sterilized groups at $p=0.001$ and $p=0.009$ respectively. This was followed by the stem sterilized group demonstrating significantly higher mean fracture resistance as compared to dry heat and chemically sterilized groups at $p=0.001$ and $p=0.01$ respectively. Later, the chemically sterilized group also showed significantly higher mean fracture resistance as compared to the dry heat group at $p=0.002$. However, no significant difference was observed between the control and stem sterilized groups ($p=0.29$).
Conclusion: The steam sterilized group demonstrated the highest fracture resistance that was followed by the chemically sterilized group, and the least with the dry heat sterilized group.
Keywords*:* Fracture Resistance, Mini-Implants, Orthodontics, Sterilization, Temporary Anchorage Devices

Background

Orthodontic mini-implants are frequently utilized for skeletal anchorage in orthodontics to reduce complications arising from anchorage loss and patient compliance issues. Due to their small size and ability to be inserted into a variety of alveolar bone locations, they are immediately load-bearing, and the insertion method does not cause significant damage (1).

Titanium mini-implants exhibit great corrosion resistance, good compatibility with hard tissues, high performance, high specific strength, and strong chemical and interfacial compatibility with tissues. This alloy's mechanical strength is greater than that of pure titanium, making it more suitable for mini-implants because they have a smaller diameter. Additionally, because it is less bioactive than pure titanium, it is easier to remove and encourages less osseointegration (2). However, the mechanism underlying titanium's superior biocompatibility compared to other metals is not fully known.

In clinical treatment, titanium mini-implants with lower diameters and lengths are routinely used. However, larger-diameter screws often exhibit greater anchoring resistance and lower breakage risk (3). On the other hand, radicular injury is less likely when smaller-diameter screws are easily placed between the radicles (4). Clinicians can choose the material and diameter of mini-implants correctly by understanding the impact of the maximum load of various types of mini-implants.

Mini-implant success is primarily influenced by insertion location and technique, orthodontic

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loads, and patient-related factors (5, 6). Principal stability is also affected by the quality of the bone, as well as the geometrical layout of the implant, the method of placement, the distance from the root, and periodontal inflammation (7). The initial stability of a mini-implant is crucial since early orthodontic mini-implant failure occurs in the majority of cases. Weak bone-mini-implant integration may be the cause of early failure and hence the resistance to fracture must be evaluated (8). However, orthodontic forces are typically not sufficiently strong to break the implants. This is especially true if there is high bone consistency or partial integration has already taken place. An intervention that must be performed to remove a fractured mini-implant from the bone is neither simple nor always effective. Due to these factors, shattered mini-implants are occasionally still present in the bone (4).

Orthodontic mini-implants are sold on the market as single units, single dosage sterile packages, or clinical kits. Before implantation, sterile mini-implants may become contaminated through non-sterile tray coverings or gloves. Another factor contributing to implant infection is improper insertion methodology. In response to such contamination, an osseous infection could develop. Mini-implants that become contaminated by contact with non-sterile surfaces before being inserted into the bone, hence require further sterilization. Guidelines from the Centers for Disease Control state that sterilizing is a difficult process. Fast-paced orthodontic teams must clean and disinfect 500–1000 equipment each day while seeing 80–120 patients per day (9).

As a result, dental offices use autoclaves as the gold standard for sterilizing. Unfortunately, not many dental practices have the ability to heat sterilize instruments. As a result, certain professionals often utilize chemical solutions for sterilization and disinfection. Mini-implants' surface hardness and roughness may alter as a result of sterilization. Orthodontic bands, arch wires, and ligatures have all been studied for their reactions to various sterilizing methods (10, 11). However, there is not enough information in the literature about its effects on mini-implants.

This study aimed to assess how different sterilizing methods — physical and chemical — affect the fracture resistance of mini-implants used in orthodontic treatment.

Methods

Sample size estimation

The sample size has been estimated using the software GPower v. 3.1.9.4

Considering the effect size to be measured (f) at 65%, the power of the study at 80%, and the alpha error at 5%, the total sample size needed is 32. Hence, each study group will comprise eight samples [8 samples x 4 groups = 32 samples].

Thirty-two Abso anchor titanium mini-implants from Dentos India Pvt. Ltd., measuring 1.5 mm in diameter and 8 mm in length, were employed in this in vitro study. They were split into four groups of eight mini-implants each at random. The study excluded mini-implants with flaws or ones that have been previously utilized. The first group was considered as the control. According to the American Dental Association's recommendations for sterilizing important equipment, the second group was sterilized in an autoclave for 15 minutes at 120°C and 15 psi using the Unique Clave C-79 (Genist Technocracy Pvt. Ltd., Bengaluru, India). Samples in the third group were sterilized under dry heat using the Melag Sterilizer 75 (MELAG Medizintechnik, Berlin, Germany) at 161°C for two hours. Mini-implants in the fourth group were chemically sterilized using 2% glutaraldehyde (Cidex) for 10 hours.

The samples were subsequently delivered to a mechanical testing facility where a universal testing machine (The Nano Plug 'n' Play, DTech, Haryana, India) was used to assess the fracture resistance.

Analysis	A priori	Compute required sample size
Input	Effect size f	0.65
	α err prob	0.05
	Power (1-β err prob)	0.80
	Number of groups	4
Output	Non-centrality parameter λ	13.5200000
	Critical F	2.9466853
	Numerator df	3
	Denominator df	28
	Total sample size	32
	Actual power	0.8315831

After blocking each of them in the lower jaw of the machine, a tangential load was applied to the head of the mini-implant (between the endosseous thread and transmucosal collar) with a 1 mm/min crosshead speed (Figs. 1, 2, and 3). Additionally, the highest load was previously applied to it and the fracture was noted. The reported load values were in Newtons. Statistical analysis was used to analyze the data.

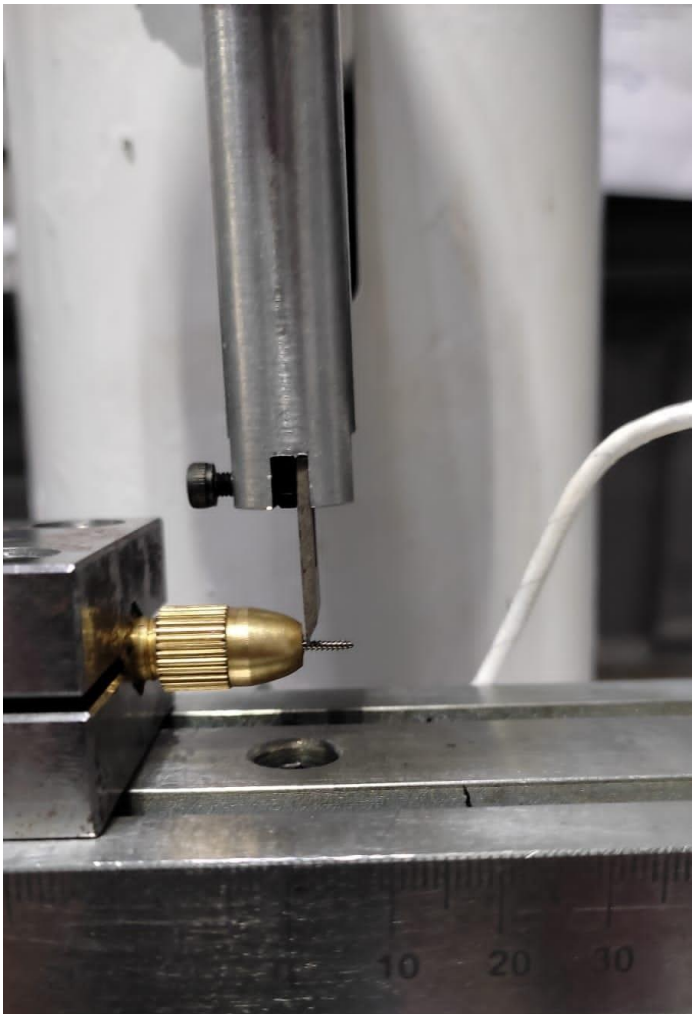


Figure 1. Blocking of the mini-implant head

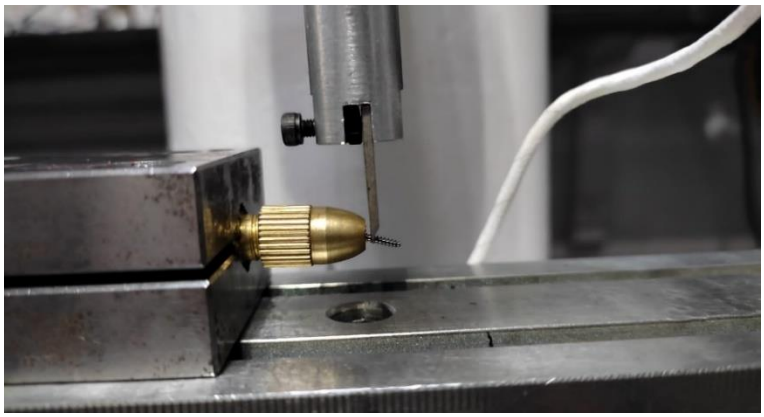


Figure 2. Application of load on the mini-implant



Figure 3. Fractured mini-implant after load application

Statistical analysis

Statistical Package for Social Sciences [SPSS] (for Windows, version 22.0, released 2013 Armonk, NY: IBM Corp.) was used to perform statistical analyses.

Descriptive Statistics

Mean and standard deviation for quantitative variables, and frequency, and proportions for categorical variables were utilized for descriptive analysis of all the explanatory and outcome parameters.

Inferential Statistics

The comparison of the mean fracture resistance (in N) among titanium mini-implants sterilized under four different protocols was done by using the Kruskal Wallis test followed by the Mann-Whitney post hoc test. Kruskal Wallis test is a nonparametric test to determine if there are statistically significant differences between two or more groups of an independent variable on a continuous or ordinal dependent variable. Mann-Whitney U test compares the difference between two independent groups when the dependent variable is either ordinal or continuous, but not normally distributed. The level of significance was set at $p<0.05$.

Results

The Kruskal Wallis test result shows the mean fracture resistance between the four groups [Table 1]. The mean fracture resistance for the control group was 419.858±60.240, for the steam sterilized group was 390.345±39.607, for the dry heat sterilized group was 254.459±21.160 and for the chemically sterilized group was 322.989±47.036. This difference in the mean fracture resistance was statistically significant at $p<0.001$ (Fig. 4).

Multiple pairwise comparisons of mean difference in the fracture resistance between the four groups using the Mann-Whitney post hoc test revealed that the control group showed significantly higher mean fracture resistance as compared to the dry heat sterilized and the chemically sterilized groups at $p=0.001$ and $p=0.009$ respectively [Table 2]. This was followed by the steam sterilized group demonstrating significantly higher mean fracture resistance as compared to the dry heat sterilized and the chemically sterilized groups at $p=0.001$ and $p=0.01$ respectively. Later,

Table 1. Fracture resistance (N) by sterilization method (Kruskal-Wallis test)

Groups	N	Mean	SD	Min	Max	P-Value
Group 1	8	419.858	60.240	332.92	508.35	<0.001*
Group 2	8	390.345	39.607	305.14	423.15	
Group 3	8	254.459	21.160	226.76	283.43	
Group 4	8	322.989	47.036	279.00	390.89	

* - Statistically Significant

Note: Group 1 – Control Group; Group 2 – Steam Sterilized Group; Group 3 – Dry Heat Sterilized Group; Group 4 – Chemically Sterilized Group

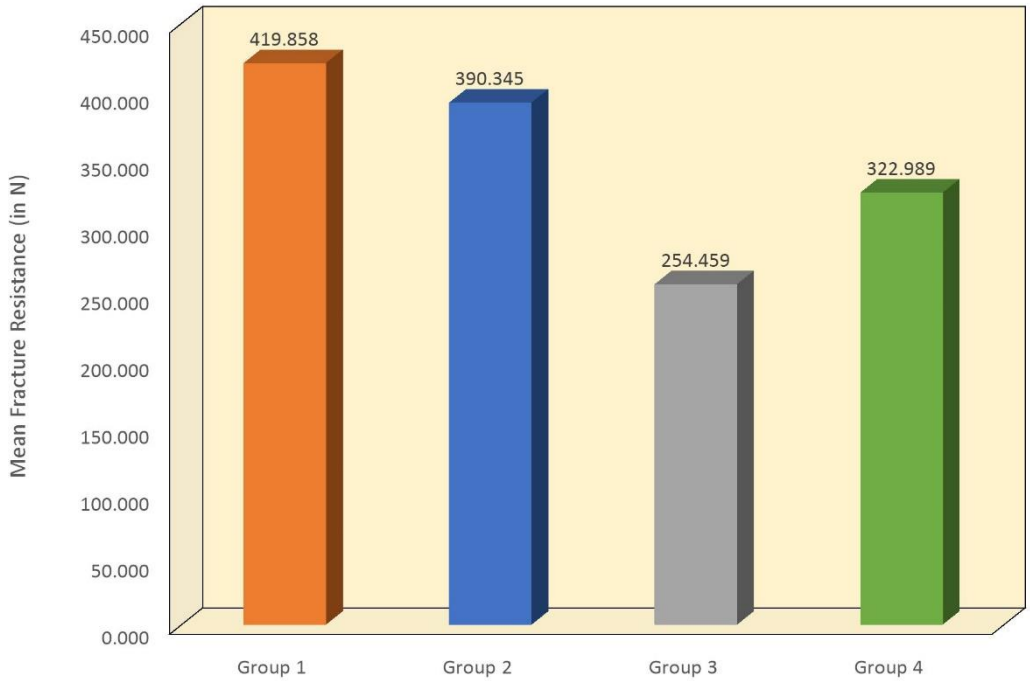


Figure 4. Mean Fracture Resistance (in N) between different groups

Table 2. Pairwise comparisons of fracture resistance (Mann-Whitney U test)

(I) Groups	(J) Groups	Mean Diff. (I-J)	95% CI for the Difference		P-Value
			Lower	Upper	
Group 1	Group 2	29.513	-30.994	90.019	0.29
	Group 3	165.399	104.892	225.905	0.001*
	Group 4	96.869	36.362	157.375	0.009*
Group 2	Group 3	135.886	75.380	196.393	0.001*
	Group 4	67.356	6.850	127.863	0.01*
Group 3	Group 4	-68.530	-129.036	-8.024	0.002*

* Statistically Significant

Note: CI : Confidence Interval, Group 1 : Control Group; Group 2 : Steam Sterilized Group; Group 3 : Dry Heat Sterilized Group; Group 4 : Chemically Sterilized Group

the chemically sterilized group also showed significantly higher mean fracture resistance as compared to the dry heat sterilized group at p=0.002. However, no significant difference was observed between the control and the steam sterilized groups (p=0.29). This infers that the control group showed the significantly highest fracture resistance that was followed by the steam sterilized and the chemically sterilized groups and the least with the dry heat sterilized group.

Discussion

Orthodontic mini-implants, which were used as temporary anchorage devices, have gained popularity over the past 20 years due to their lower price, easier installation, less painful operation, and reduced patient discomfort (12). They reduce the problems brought on by anchorage loss by enabling the utilization of skeletal anchoring for tooth

motions. Mini-implants must, however, be sterilized before insertion.

The tensile strength of orthodontic wires (SS, TMA, and Co-Cr wires) is influenced by sterilization and disinfection techniques such as the autoclave, hot air oven, glutaraldehyde, and UV light, but there is no degrading effect, according to studies (13, 14, 15). Therefore, to ensure the highest level of patient safety, orthodontists can sterilize orthodontic wires ahead of implantation because does not impact the tensile strength or surface roughness of the alloys.

The selection of titanium mini-implants for our study was driven by their well-established biocompatibility and the documented minimal adverse effects in comparison to stainless steel mini-implants. Although stainless steel mini-implants showed greater resilience to failure, titanium nevertheless outperformed stainless steel in terms of overall performance for orthodontic mini-implants (16).

Orthodontic mini-implants are obtainable on the market in many lengths, often ranging from 5.0 mm to 10.0 mm and diameters from 1.2 mm to 2.5 mm. The selection of 1.5 mm diameter mini-implants for our study was based on their widespread use in orthodontics. This diameter offers a balance of benefits, combining the advantages of larger-diameter implants, such as enhanced anchoring resistance and reduced risk of breakage, with the benefits of smaller diameters, including ease of placement and a lower risk of causing damage to adjacent structures, especially in tight spaces (5).

In our study, we deliberately subjected the head of the mini-implant (between the endosseous thread and transmucosal collar) to fracture loading. This choice was based on the widely accepted notion that this region is often regarded as the weakest part of the entire mini-implant structure (17), as detailed in the methods section and the collar region of the mini-implant was fractured due to the experiment.

The study found that fracture values, measured at a crosshead speed of 1 mm/min, varied between 254.45 and 419.85 N. In contrast, traditional clinical applications typically report fracture values well below 5N. Conversely, in non-standard applications, mini-implants face higher forces, leading to an elevated risk of fracture (4).

The factors influencing the stability of mini-implants include insertion site and procedure, orthodontic loading and patient-related factors (18). Furthermore, the diameter, shape, length, depth of screw thread and chemical factors such as microstructure and the processing of the mini-implant affect the insertion and fracture torques (5, 8). Concerning the study conducted by Manni et al., the success rate of mini-implants is better in male patients (88.1%) when compared to females. Insertion of mini-implants is most favorable in the attached gingiva (success rate 85.4%) directly followed by insertion in the mucogingival line (84.2%). A higher success rate is demonstrated when mini-implants are inserted in the maxilla (86.9%) compared to those inserted in the mandible (76.1%). The most favorable position relative to the root is in the coronal third (success rate 82.8%) and loading not exceeding 150–250 g should be applied to the screw immediately (6).

According to Mattos et al. (19), the fracture torque values of the mini-implants sold by various manufacturers varies. The fracture torques of the tip and neck were greater than the torque needed to place mini-implants of five different brands of orthodontic mini-implants, according to Assad-Loss et al.'s (2) research. The fracture torque of orthodontic mini-implants from five different manufacturers was examined by Dalla Rosa et al. (20), who found that the fracture torque was higher for mini-implants with larger dimensions. The air bending or fracture stresses of mini-implants, studied by Scribante et al. (4) demonstrated that larger-diameter mini-implants showed greater values, while smaller-diameter mini-implants showed lower forces. This is consistent with the current investigation's assessment of the fracture resistance following the application of shear stress.

Orthodontists are constantly looking for solutions to this problem because of rising overhead expenses, worries about waste management, and environmental harm. According to Buckthal and Kusy (21), 52% of orthodontists recycle and reuse nickel-titanium wires to lower the overall cost of the orthodontic treatment. Studies on retrieved implants were seldom ever done in the past. In addition, when recycled mini-implants were examined, morphological alterations mostly happened at the screw tip. All of the mini-implants analyzed in this in vitro investigation were brand-new and free of flaws.

According to some authors, numerous sterilization cycles changed the mini-screws' surface properties (22). While Adelson et al. (23) claimed that after 10 and 50 cycles of autoclaving, no statistically significant difference existed regarding the integrity of titanium plates and screws utilized in craniofacial reconstruction. Manufacturers frequently recommend steam sterilizing to sterilize orthodontic materials in clinical settings because it has been shown to have no impact on their mechanical qualities. Proteins

and enzymes produced by bacteria are denatured and coagulated during moist heat sterilization. Different approaches must be researched because it can be challenging for certain doctors to set them up in their clinics.

Dry heat sterilization is currently hardly employed due to the possibility of structural alterations. Dry sterilization did not have a negative impact on the fracture of nickel-titanium endodontic files according to Testarelli et al. (24) and Silvaggio and Hicks (25). Dry heat causes the components to oxidize destructively and denatures the proteins of bacteria that produce oxidative damage and harmful consequences on the bacterium (5).

In contrast to the sterilization methods by heat, orthodontists regularly employ cold sterilization and disinfection techniques in the dental office. Chlorine dioxide and 2% glutaraldehyde are some of the common disinfectants and sterilants approved by the American Dental Association (26). The 2% acidic glutaraldehyde (Banicide) requires 10 hours to completely sterilize. The majority of these chemical solutions may corrode and damage the metallic materials that are submerged in them. However, due to the oral environment and 2% glutaraldehyde sterilizing process, there was no evidence of rusting (10).

Our ability to compare several sterilizing techniques to determine the most effective one for surgical and orthodontic goods is the strong feature of this study. Testing miniature implants made of various materials but with the same geometric design would be a benefit that is suggested to be included in the design of future research. Additionally, research might be done to determine how sterilizing affects the other characteristics of titanium mini-implants.

The study's disadvantage is that it only looked at fracture resistance to see if sterilizing affected the mechanical characteristics of the mini-implants. Hardness testing and surface modifications were excluded from this investigation. Reused mini-implants were also not included in this study. Therefore, in the current in vitro study, the impact of repeated cycles of various sterilization procedures was not assessed.

Conclusion

After one cycle of autoclave sterilization, no statistically significant effects on the fracture resistance of titanium mini-implants were found within the study's constraints.

According to the study of the various sterilizing methods, dry heat sterilization showed the most detrimental effects on the fracture resistance of mini-implants, chemical sterilization showed intermediate effects and steam sterilization showed the least ill effects.

In conclusion, dental offices can safely disinfect titanium mini-implants using an autoclave or a solution of 2% glutaraldehyde.

Conflicts of interest: None to declare.

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