ORIGINAL RESEARCH

Effects of Repeated Sterilization Cycles on Primary Stability of Orthodonic Mini-Plates

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ABSTRACT

Objective: To evaluate if repeated sterilization has deleterious effects on the clinical stability of mini-plates. **Materials and Methods:** Thirty samples of three different groups of the following mini-plates were tested. Mini-plates were divided into three groups, group-I control (n = 10), group-II (n=10), group-III (n = 10). Test groups were sterilized one, five and ten times respectively. **Results:** student t-test showed no statistically significant difference in Tensile bond strength (Mpa) measured in the three study groups and Comparison of roughness (µm) showed that there was statistical significance between the three study groups. **Conclusion:** Repeated sterilization for 5 and 10 times on mini plates did not affect Tensile strength but led to increased roughness that could affect the stability of mini plates.

KEYWORDS: Sterlization, Mini plates, Orthodontics

INTRODUCTION

Temporary anchorage devices (TADs) are a fundamental part of orthodontic treatment planning and subsequent treatment delivery. These anchorage devices are commonly used to facilitate movement of teeth within the upper and lower jaws, when a large amount of tooth movement is required or dental anchorage is insufficient because of missing teeth or poor periodontal condition.[1]

Since its introduction to orthodontics, the use of mini plates has increased significantly in practice. It is important to understand the advances in biomaterials, biomechanical properties, protocols for proper infection control and sterilization before placement of mini plates .[2]

Temporary anchorage device products are available in single-dose unit sterile packages or as part of a clinician's kit, which includes a variety of plates of multiple lengths and diameters, and these require prior sterilization. The TADs may have to be sterilized when exposed to non-sterile environment. This may alter their physical and biomechanical characteristics which could, in turn, affect their stability during use.[3]

Although, the literature contains a number of studies on the effects of sterilization on stainless steel, Nickel-titanium arch wires and various pliers, there is a lack of data in regard to sterilization effects on, titanium alloy mini-plates and subsequent changes in their mechanical properties and clinical function. The Aim of this study was to determine if repeated sterilization had deleterious effects on the stability of titanium mini-plates.

MATERIALS AND METHODS

The study was conducted in the Department of Orthodontics and Dentofacial Orthopedics, GITAM Dental College and Hospital, Visakhapatnam, Andhra Pradesh, India. A total sample of sixty mini-plates (Ti6Al4V) of orthomax manufacturer was tested; they were randomly categorized into three groups:

Sample	Sample Size	Autoclaved
GROUP I	20	One Time
GROUP II	20	Five Times
GROUP III	20	Ten Times

Table 1: Different Groups

Mini-plates in group-I, II, III were inserted in an individual auto-sealing envelope and then subjected to one, five, ten sterilization cycles respectively for 28 minutes at 121ºC and 1.2Kg pressure, as per the recommendations of the manufacturer. The autoclave used was Dental autoclave sterilizer Unique Clave model no. C-79 B. The group-I set of 20 mini plates served as a control group. The mini plates were tested for tensile strength in megapascals using universal testing machine. Strength versus deformation graph was obtained from which the flow limit was observed in a specific elongation using the Universal testing machine (INSTRON, 8801: u.k) at the mechanical department of GITAM engineering College, Visakhapatnam, Andhra Pradesh.

Surface roughness was measured in micrometers using Hommel profiler. The measured length was 1.00 mm, cut-off was 0.08 mm and the radius tip was 5 mm (according to ISO 11562). The measurements were done in randomly selected regions and three measurements were done in each region.

Statistical analysis: Mean and Standard deviation was

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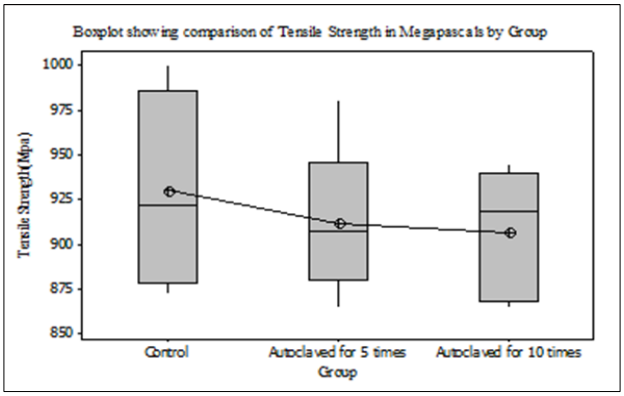
calculated from data obtained and a Student T-test was performed to know the difference between the groups with $p \leq 0.05$ showing any statistically significant difference.

MATERIALS AND METHODS

The Mean Tensile strength was 907Mpa in group-I, 912Mpa in group-II, 930 Mpa in group-III. The following table shows that there was no statistically significant (p = 0.703) difference when the three study groups were compared using student T-test.

Group	Mean	SD	F-value	P-Value	Decision
Control	930.2000	54.58663	0.363	0.703	Not Significant
Autoclaved for 5 times	912.2000	42.64622			
Autoclaved for 10 times	907.0000	36.53081			

Table 1: Tensile strength (Mpa) measured in the three study groups



Graph 1: Graphical representation of the Mean Tensile strength recorded in the three study groups.

Group	Mean	SD	F-value	P-Value	Decision
Group-I	1.1160	.30411	2017.492	0.000	Significant
Group-II	5.3000	.17903			
Group-III	9.8280	.12892			

Table 2: Comparison of roughness (µm) between the three study groups using student t-test. (p ≤ 0.05 shows statistically significant)

The Mean roughness was 1.1µm in group-I, 5.3µm in group-II, and 9.8 µm in group-III. The following table shows that there was statistically significant (p = 0.703) difference when the three study groups were compared using student T-test.

DISCUSSION

Mini plates are widely used as anchorage units in orthodontic treatment. The surgical use demands sterilization of the material. Michael Tet al, Huang et al suggested Tensile forces acting on the mini plate are important as they determine the stability.[4,5]

Motyka et al studied the microstructure of titanium alloys. They found that transition phase of α and β phases in the alloy was above 850ºc to produce any deformation in thermomechanical process.[6] In the present study, the temperature used for sterilization was 121ºc which is far below the range mentioned by Motyka et al to produce any change in tensile properties. The result from present study suggested that repeated sterilization on miniplates did not affect the tensile strength.

Giuseppe et al studied mechanical characteristics of titanium miniplates for osteosynthesis using Finite element analysis (FEA), Experimental static tests have shown that all tested miniplates did not have notable differences, and this suggests that sterilization cycles do not affect mechanical characteristics.[7] The present study correlates with the above findings suggesting that repeated sterilization on miniplates do not affect the mechanical properties of titanium mini plates.

The study conducted by Schiff et al on the corrosion potential of different Titanium alloys in orthodontics wires suggested that fluoride environment at pH of 4.2 enhanced corrosion.[8] Vani et al suggested that mechanical properties of the beta titanium wires were decreased using topical fluoride agents due to the dissolution of the passive layer of titanium due to oxidation reduction phenomenon.[9] The present study is in contrary to the studies done by Schiff, Vani et al as there were no specific conditions to accumulate H, F,O ions or decreased pH in the autoclave to enhance corrosion and decrease mechanical properties of miniplates.[8,9]

Mattos et al in their study compared the surface morphology and fracture torque resistance of retrieved and As-received mini-implants. The surface morphology when viewed under Scanning Electron Microscopy presented without corrosion and hence they recommended re-use of retrieved mini-implants after autoclave sterilization. The above study suggested the reuse of As-received mini plates when mechanically clean and re-sterilized without potential loss of form or function.[10]

According to International Organization for Standard-ization (ISO 5832:5) and American Society of the International Association for Testing and Materials (ASTM F136) the tensile strength for Ti-6AL-4 V is 850-1250Mpa, The mean tensile strength of group-I,II,III are 907,912,930 Mpa respectively, which is within the standard range suggesting that tensile strength did not change significantly to alter the mechanical properties.

Stanford et al emphasized that clean and sterile layers of oxide are the most important issue in implants than other biological aspects.[11] Mabboux F. et al in 2005 studied surface characteristics of titanium implants and suggested that with increased roughness there was more surface free energy which lead to bacterial accumulation.[11,12]

Eugenio et al studied cytotoxicity and genotoxicity of a commercial titanium alloy material using bacterial and cell-mutation assays and concluded that roughness characteristics of 1.73±0.16 µm were not genotoxic. In

the present study, the roughness in group II and group III is above 3 µm suggesting that this increase in roughness could be genotoxic.[13]

Albrektsson and Wennerberg have shown that a moderate roughness of 1-2um may limit peri-implantitis and ionic leakage which is optimal surface roughness for good clinical performance. In the present study surface roughness in group-I was found to be between 1-2µm, which is within the optimal range for clinical performance, while group II had range between 3-6µm and group III had values between 6-9µm. The roughness in group II and group III was found to be above the optimal surface roughness for good clinical performance. This increased roughness suggests that there is an increased chance for bacterial accumulation which leads to failure of miniplates when sterilized for 5 to 10 times.[14]

CONCLUSION

- Repeated sterilization for 5 to 10 times on mini plates did not affect the Tensile strength.
- Repeated sterilization leads to increased roughness and can affect stability of mini plates.

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