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Original Article

Effect of repeated cycles of steam sterilization on the integrity of cannulated surgical screws

Kelly Capuder, Christopher Gill, Jawdat Hafez, Jill Kawalec, Vincent Hetherington*

Kent State University College of Podiatric Medicine, United States

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ABSTRACT

The process of repeated handling and steam sterilization of bone screws and allows debris to deposit on the surface and inside cannulated screws. Individually packaged screws could alleviate these potential problems. This research intended to evaluate the effect that multiple cycles of sterilization may have, if any, on the mechanical integrity of cannulated screws. The results indicate that the mechanical integrity of the screws tested was not compromised.

1. Introduction

Surgical screws are one of the most common implantable devices used today for reliable and stable bone alignment following a surgery. The primary function of a surgical bone screw is to fixate osteotomies and fracture fragments together providing stability and compression between bone. Therefore, the integrity of the screws is an important concept in ensuring patient safety.

Several authors have demonstrated that steam sterilization and reprocessing can affect the surface properties of titanium including the presence of extraneous materials, alterations in cellular response and biocompatibility [1–4]. Previous research has shown that there is a direct correlation between repeated cycles of steam sterilization and the oxidation properties of surgical screws. As the number of cycles of steam sterilization increases, the oxidation layer of the screws thickens [5]. A presentation on randomly selected reprocessed bone screws from orthopedic fixation set by McAuley [6] visually demonstrates these findings. Costa et al. [7] reported that contamination occurs with reprocessed flexible intermediary reamers, depth gauges, and screws used for intramedullary nailing of the femur. Smith et al. [8] reported that retained bio-debris might not be sterile after steam sterilization.

Steam sterilization did not effect fracture resistance of miniplates made from a titanium alloy from several manufacturers following one cycle of steam sterilization [9,10]. Adelson et al. [11] found a trend that repeated cycles of steam autoclaving titanium screws when comparing three groups, controls as machined, and after ten cycles and after 50 cycles no significant effect for either experimental group.

The purpose of this study was to test if the mechanical integrity of cannulated screws is compromised after repeated cycles of steam sterilization. The specific aims of this study are to determine if the strength, reflected by changes in the flexural strength of cannulated screws, changed in 3-point bending after repeated cycles of steam sterilization. It is hypothesized that as a result of repeated sterilization the integrity of the screws is compromised with increasing cycles of steam sterilization. It is expected that the strength of the screw will decrease.

2. Materials and methods

2.1. Screws

The screws used in this study were GO-EZ™ partially threaded, cannulated titanium compression screws (BioPro, Inc., Port Huron, MI). Two different screw sizes were evaluated: 3.0 × 28 mm (n = 80) and 3.0 × 40 mm (n = 80). The screw sizes selected are commonly used in foot surgery. For each screw size (Fig. 1),the screws were divided into two groups: (1) control (n = 40) and (2) sterilized (n = 40). Screws in the control group were not sterilized beyond processing before packaging. Screws in the sterilized group underwent 30 cycles of steam sterilization. For each cycle, the screws were sterilized at 250 °F for 15 min with a drying time of 30 min in an autoclave (Mark II model SSR-3A-PB, Consolidated Stills and Sterilizers, Boston, MA).

Between each cycle of sterilization the screws were removed from the caddie using pickups and placed back in the caddie once. The cycle of sterilization used was based on the recommendation of the Center for disease contril and prevention (Table 1).

* Corresponding author.
E-mail address: vhetheri@kent.edu (V. Hetherington).

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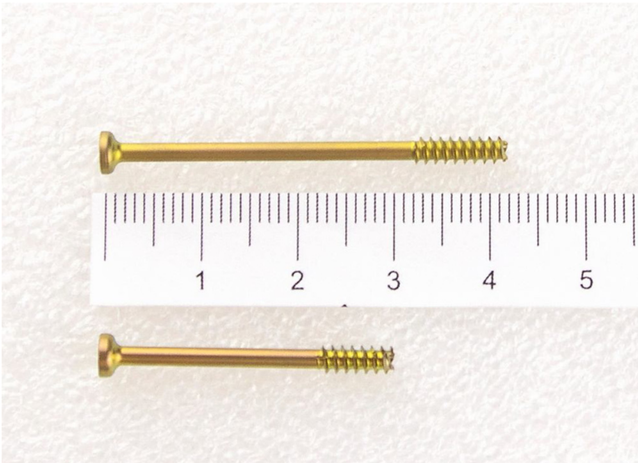

Fig. 1. The screws used in this study were partially threaded, cannulated titanium compression screws (BioPro, Inc., Port Huron, MI). Two different screw sizes were evaluated: 3.0 × 28 mm and 3.0 × 40 mm.

2.2. Mechanical testing procedures

Three-point bend tests were conducted on all screws to determine the flexural strength at yield and the maximum flexural strength. Flexural strength at yield was the strength at the yield point or the point at which permanent deformation occurs in the screws. Flexural strength at yield was considered the failure point of the screw — the maximum flexural strength as defined as the maximum flexural strength obtained during testing. Mechanical testing was completed using an MTS Model 858 Mini Bionix biomechanical test system (MTS, Eden Prairie, MN).

Three-point bend tests were conducted using methods adapted from ASTM C1684-13e1, "Standard Test Method for Flexural Strength of Advanced Ceramics at Ambient Temperature — Cylindrical Rod Strength." The cylindrical surfaces of the nose and supports of the three-point bend fixture had a diameter of 3 mm. Each screw was positioned on the test fixture such that there was 5 mm of overhang of the test specimen beyond the outer rollers on each side and that the screw was directly centered below the axis of the applied load (Fig. 2). The screw was then loaded at a rate of 5 mm/min. During the test, the load and actuator displacement was recorded, and a load versus displacement curve generated. The flexural load at failure was measured as the yield point, or the load at which the linear portion of the load-displacement curve (elastic deformation) ends and plastic deformation begins. The maximum flexural load was determined as the maximum load attained during testing (Fig. 3). The flexural strength at yield and the maximum flexural strength of each screw was calculated using flexural loads in the following formula:

$\sigma = (8FL)/(\pi d^3)$where:
σ = flexural strength (MPa)
F = flexural load (N)
L = distance between outer supports (mm)
d = diameter of screw (mm)

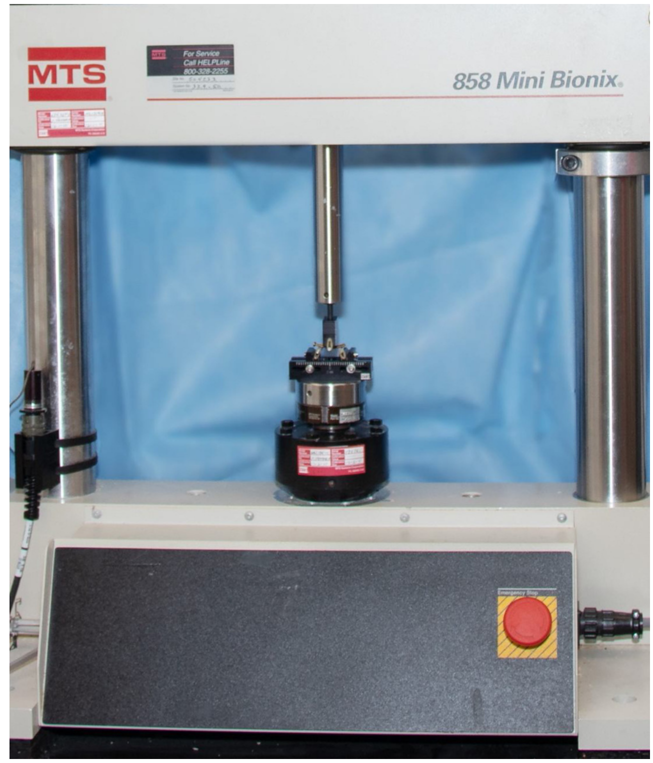

Fig. 2. Each screw was positioned on the test fixture such that there was 5 mm of overhang of the test specimen beyond the outer rollers on each side and that the screw was directly centered below the axis of the applied load.

2.3. Statistical analysis

The mean and standard deviation of the flexural strength at yield and the maximum flexural strength for each group calculated, and the differences between control and sterilized groups statistically analyzed for each screw size using a two-tailed Student's t-test with significance defined as $p < 0.05$.

3. Results

3.1. 3.0 × 28 mm screws

The mean flexural strengths at yield for the 3.0 × 28 mm screws are presented in Fig. 4. The average strength for the control group (C28) was 335.2 ± 24.1 MPa, while that for the sterilized group (S28) was 336.6 ± 31.2 MPa. There was no significant difference between groups ($p = 0.827$).

The mean maximum flexural strengths for the 3.0 × 28 mm screws are presented in Fig. 5. The average strength for the C28 group was 454.4 ± 21.6 MPa, while that for the S28 group was 458.8 ± 25.8 MPa. There was no significant difference between

Table 1
Centers of disease control and prevention, the minimum cycle times for steam sterilization, William A. Rutala, David J. Weber, Healthcare Infection Control Practices Advisory Committee (HICPAC). "Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008, Update February 15, 2017.
Source: Centers of disease control and prevention.

Type of sterilizer	*Item*	*Exposure time at 250 °F (121 °C)*	*Exposure time at 270 °F (132 °C)*	*Drying time*
Gravity displacement	Wrapped instruments	30 min	15 min	15–30 min
	Textile packs	30 min	25 min	15 min
	Wrapped utensils	30 min	15 min	15–30 min
Dynamic-air-removal (e.g., prevacuum)	Wrapped instruments		4 min	20–30 min
	Textile packs		4 min	5–20 min
	Wrapped utensils		4 min	20 min

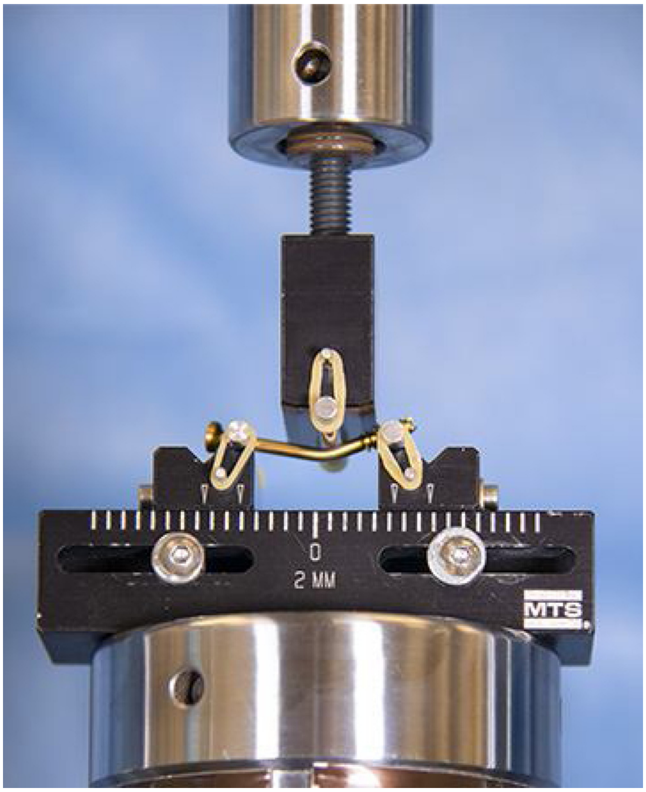

Fig. 3. The maximum flexural load was determined as the maximum load that is reached during testing.

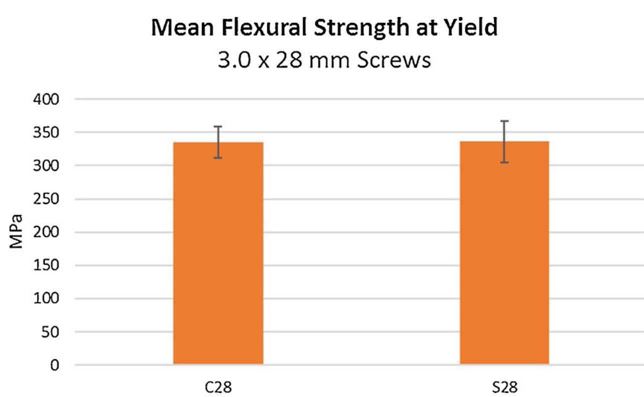

Fig. 4. The average strength for the control group (C28) was 335.2 ± 24.1 MPa, while that for the sterilized group (S28) was 336.6 ± 31.2 MPa.

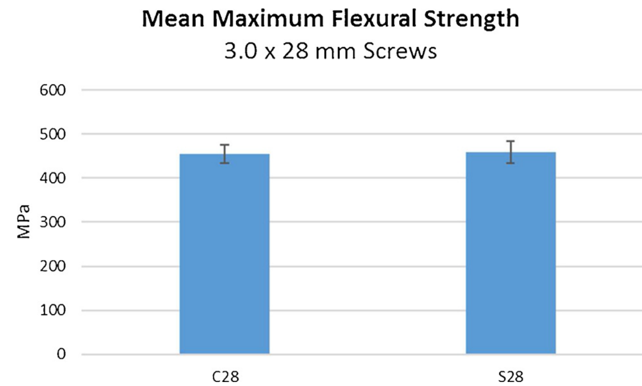

Fig. 5. The average strength for the C28 group was 454.4 ± 21.6 MPa, while that for the S28 group was 458.8 ± 25.8 MPa.

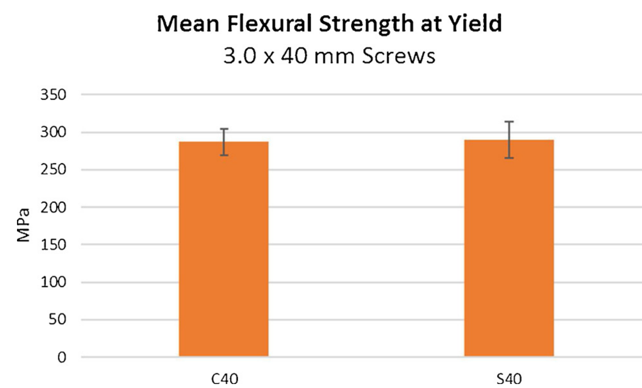

Fig. 6. The average strength for the control group (C40) was 287.0 ± 17.6 MPa, while that for the sterilized group (S40) was 289.7 ± 23.9 MPa.

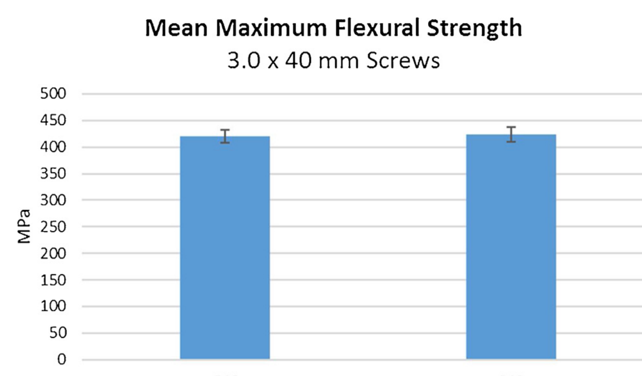

Fig. 7. The average strength for the C40 group was 420.0 ± 12.6 MPa, while that for the S40 group was 423.3 ± 13.9 MPa.

groups ($p = 0.408$).

The mean flexural strengths at yield for the 3.0 × 40 mm screws are presented in Fig. 6. The average strength for the control group (C40) was 287.0 ± 17.6 MPa, while that for the sterilized group (S40) was 289.7 ± 23.9 MPa. There was no significant difference between groups ($p = 0.564$).

The mean maximum flexural strengths for the 3.0 × 40 mm screws are presented in Fig. 7. The average strength for the C40 group was 420.0 ± 12.6 MPa, while that for the S40 group was 423.3 ± 13.9 MPa. There was no significant difference between groups ($p = 0.266$).

4. Discussion

These results are of particular interest in foot and ankle surgery as cannulated screws are increasingly used in many surgical procedures. The screws selected are sizes used in foot surgery. Screws may be provided packaged and sterilized individually. However, individual packaging may not be the case in all countries and institutions where screws are still stored and sterilized in trays or caddies, subjected to repeated sterilization. The purpose of this study was to determine whether the integrity of selected cannulated screws is maintained after multiple trials of steam sterilization. Changes in the mechanical properties are of interest to foot surgeons due to loading forces that the screws may be subjected. Our data shows that the repetitive cycles of steam sterilization do not affect the mean flexural strength of the surgical screw.

Limitations of this study includes that the number of steam sterilization cycles, limited number, and sizes of screws. The number of cycles used may be less than the number of cycles screws are subjected to in hospitals or surgery centers that could result in greater wear and tear occurring in this study. Further research should see a greater number of screws and screw sizes, increases in the number of sterilization exposures and examination of the surface of the screws for deleterious effects.

5. Conclusion

In conclusion, the data found in this study is consistent with previous studies. The results showed no statistical significance between the control and sterilized groups for both screw sizes. The outcome of this study is important because it shows the resilience of the screws to steam sterilization allowing the screws to undergo multiple rounds of reprocessing while preserving patient safety.

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