Integrity of Craniofacial Plating Systems After Multiple Sterilization Procedures

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Purpose: To determine the effect of multiple autoclave sterilization cycles on the integrity of titanium plates and screws used in craniofacial reconstruction.

Materials and Methods: Torque to fracture was evaluated for 36 titanium 6AL-4V (Ti 6/4) screws divided evenly into 3 groups and tested as machined (control), after 10 cycles of autoclaving or after 50 cycles of autoclaving. Sterilization was carried out by autoclaving for 15 minutes followed by 8 minutes of drying at 270° to 272°F. The maximum torque attained before fracture was recorded. Rotating beam specimens were crafted from single lots of Ti 6/4, commercially pure titanium grade 4 (CP4) and commercially pure titanium grade 2 (CP2), and then subjected to testing in a standard rotating beam device as machined (control), after 10 cycles of autoclaving or after 50 cycles of autoclaving. The cycles required to fracture the specimen at a given applied stress were recorded for each material and for the number of autoclavings carried out before testing.

Results: Although there was a trend toward decreased strength and increased ability to fracture with increased number of autoclave cycles, this did not reach statistical significance. Torque to fracture testing for 7 mm Ti 6/4 screws showed no significant difference in the maximum torque reached before fracture between controls, those screws that had been autoclaved 10 times ($P < .500 \pm 5.70$) and those that had been autoclaved 50 times ($P < .398 \pm 4.08$). Rotating beam specimens of Ti 6/4, CP4, and CP2 showed no significant difference in cycles to fracture regardless of the number of sterilization cycles to which the material was subjected.

Conclusions: Repeated cycles of autoclaving had no significant effect on the integrity of titanium plates and screws routinely used in craniofacial surgery.

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As our experience in craniofacial surgery expands, so must our understanding of the tools of our trade. Our interest in the structural integrity of craniofacial plating system components was piqued by an anecdotal observance: the fracture of screw heads and plates from older instrument sets that had been used and autoclaved numerous times previously. In discussing this unusual event we realized that no readily available method is used to determine the duration of time a single plate or screw has spent in a given plating system or the total number of sterilization procedures each plate or screw has experienced. Furthermore, the individual components of a craniofacial plating system can undergo numerous sterilization procedures before a given plate or screw is implanted into the body, yet the literature contains no published reports documenting the material integrity of these multiply autoclaved materials.

With the advent of expensive titanium alloy arch wires, orthodontists began to investigate the feasibility of clinical recycling of orthodontic wires after sterilization. Single autoclave sterilization cycles of arch wires composed of either stainless-steel or various titanium alloy combinations had no adverse effects on the measured mechanical parameters for each material.[1] Similarly, other authors have shown

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single sterilization cycles of both new and clinically used titanium alloy arch wires, with a variety of approved cleaning modalities, to have no significant harmful effect on the mechanical properties of such orthodontic wires.[2-5]

Although arch wires are subject typically to the stresses of sterilization only once, endodontic files are sterilized repeatedly, providing a closer analogy to the focus of our study. Rapisarda et al[6] showed a reduction in the cutting efficiency of rotary nickel-titanium files that correlated with increased numbers of autoclave cycles, similar to the effect reported by Cooley et al[7] of steam autoclave sterilization on stainless steel drills. The effect of multiple sterilizations on endodontic files has not been resolved definitively. Hilt et al[8] investigated the mechanical properties of endodontic files subject to multiple autoclave sterilizations and found no relationship between the number of sterilization cycles and the tested properties of stainless steel or nickel-titanium files.

Immediately relevant to our hypothesis is an internal report by Zardiackas (University of Mississippi Medical Center, 2003) regarding the effect of repeated steam autoclave sterilization on the tensile properties of Ti-15Mo (titanium-molybdenum alloy).[9] The material properties of Ti-15Mo implants were not altered significantly after multiple sterilizations, although it is recommended that implants composed of this alloy not be subjected to more than 10 steam autoclave cycles.[9]

Given our uncertainty regarding the number of autoclave cycles experienced by any individual component of a craniofacial plating set and the absence of information in the literature on this topic, we endeavored to determine the effect, if any, of repeated autoclave cycles on the material properties of titanium implants used commonly in craniofacial surgery.

Materials and Methods

Titanium implants of various compositions were tested in 2 separate experiments: torque to fracture of titanium screws and rotating beam fatigue. All materials and testing procedures were made available through research support from Walter Lorenz Surgical, Inc (Jacksonville, FL).

The first experiment evaluated the torque to fracture of standard craniofacial screws composed of an alloy of 90% titanium, 6% aluminum, and 4% vanadium (Ti 6/4). From a single manufacturing lot, 36 2.0-mm diameter by 7 mm long high torque screws (Walter Lorenz part number 91-2007) were divided into 3 sets of 12 parts and each group was subjected to torque to fracture testing after a variable number of autoclave cycles. Each autoclave cycle was carried out for 15 minutes followed by 8 minutes of drying at 270° to 272°F. The control group was tested without autoclaving, the second set was tested after 10 consecutive cycles of autoclaving, and the third set was tested after 50 consecutive cycles of autoclaving.

Torque to fracture testing was carried out by loading a screw onto the appropriate blade and chuck and opposing the screw to an aluminum block with 1.6-mm diameter holes. The screw was allowed to engage the aluminum block at 20 rpm and the maximum torque (in-oz) reached before fracture of the screw was recorded. Two-tailed t tests with unequal variance were used to compare each of the experimental groups with the control as well as with each other.

Rotating beam fatigue was assessed for specimens of Ti (Ti, titanium) 6/4, commercially pure titanium grade 4 (CP4), and commercially pure titanium grade 2 (CP2). A single lot of each raw material was used as a standard rotating beam specimen for study in this experiment. Ti 6/4 and CP4 were tested as machined, after 10 autoclaving cycles and after 50 autoclaving cycles. CP2 was tested as machined and after 10 autoclaving cycles. Rotating beam fatigue was assessed at 4,000 Hz using a standard rotating beam machine. Variances were made in the applied cyclic stress level according to an experimental protocol designed to initiate fatigue fracture at approximately 1,000,000 cycles in the control group for each material. The number of the cycles required to initiate fracture was recorded and 2-tailed t tests with unequal variance were used to compare each experimental group with the control for their respective material.

Results

Torque to fracture was assessed, after multiple autoclaving cycles, for each of 3 sets of 12 7-mm high torque screws composed of Ti 6/4 (Walter Lorenz part number 91-2007). Although there was a trend toward decreased strength, the 2-tailed t test showed no significant difference between either the control group of screws and those that were subjected to 10 autoclaving cycles ($P < .500 \pm 5.70$) or those that were subjected to 50 autoclaving cycles before testing ($P < .398 \pm 4.08$) (Fig 1). These findings are further confirmed by t test analysis finding no significant difference in the torque to fracture between screws autoclaved for 10 cycles and those autoclaved for 50 cycles before testing ($P < .803 \pm 2.71$).

Rotating beam fatigue was determined as the cycles required to initiate fatigue fracture in a standard rotating beam testing protocol. Ti 6/4 rotating beam samples were tested as machined (n = 3), after 10 autoclave cycles (n = 3), and after 50 autoclave cycles (n = 5).

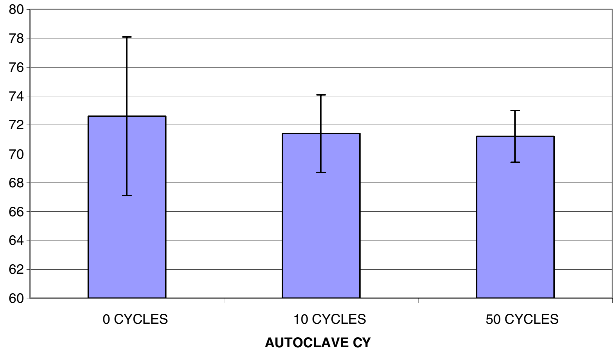

FIGURE 1. Torque to fracture testing of 7-mm Ti 6/4 screws.

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Again, although there was a trend to increased fatigue fracture with increasing number of autoclave cycles, this did not reach statistical significance. *T* testing indicated no significant difference in the cycles to fracture of Ti 6/4 when compared with the control after 10 autoclave cycles ($P < .555 \pm 643{,}705$) or after 50 cycles ($P < .567 \pm 395{,}941$) (Fig 2). Similarly, there was no difference in cycles to fracture when comparing the specimens treated by 10 cycles with those treated by 50 cycles of autoclaving ($P < .963 \pm 466{,}019$).

CP4, which is used in mandible plates and in other cases in which the implant will be relied upon for considerable load bearing, was not affected significantly by multiple sterilization procedures. Ten cycles (n = 5) of autoclaving were found to have no significant difference in the cycles to fracture for CP4 when compared with control (n = 3) ($P < .374 \pm 368{,}144$), and similar results were found for specimens subjected to 50 autoclave cycles (n = 4) ($P < .204 \pm 7{,}566$) (Fig 3). Comparison between the 2 experimental groups of CP4 also showed no significant difference in cycles to fracture ($P < .423 \pm 129{,}847$).

The final studied material, CP2, was tested as a control specimen (n = 4) and then after 10 autoclave cycles (n = 5). Experimental protocols and available machined specimens of single lot material precluded rotating beam testing after 50 autoclave cycles; therefore, results at the present time are available for the control group and those specimens tested after 10 autoclave cycles. The more malleable craniofacial plates have a higher proportion of CP2. No significant difference in the cycles to fracture is shown between control specimens of CP2 and those specimens that had been autoclaved ten times ($P < .809 \pm 51{,}212$) (Fig 4).

Discussion

An unusual clinical event, the intraoperative fracture of screws and plates used routinely, provided us with the impetus to seek an explanation for this occurrence so that it may be understood and avoided in the future. We recognized that the individual components of a craniofacial plating system are replaced as they are used and that it would stand to reason that some implants, especially those plate shapes and screw lengths used less frequently, might spend a disproportionately long time in the set and therefore be exposed to many more sterilization procedures than the manufacturer had otherwise intended. We hypothesized that multiple autoclave sterilization cy-

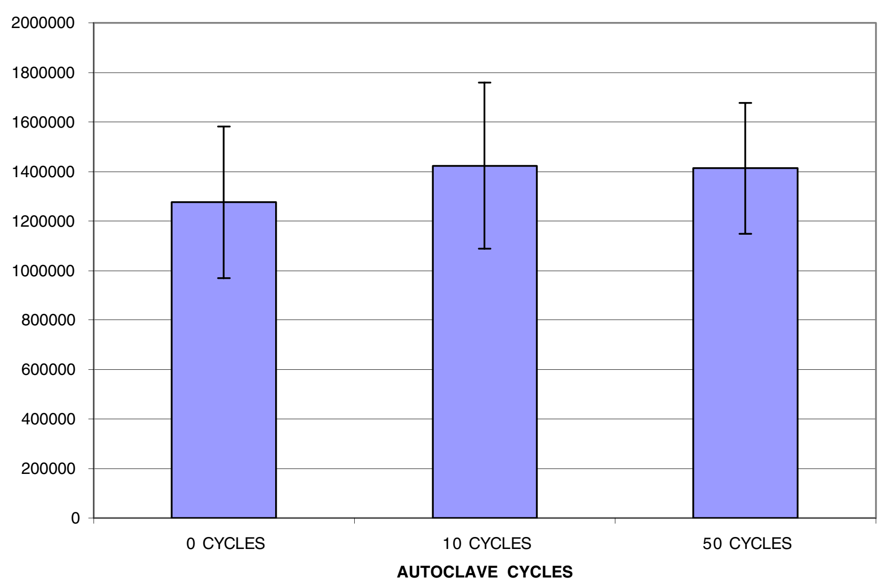

FIGURE 2. Rotating beam fatigue testing of Ti 6/4 specimens.

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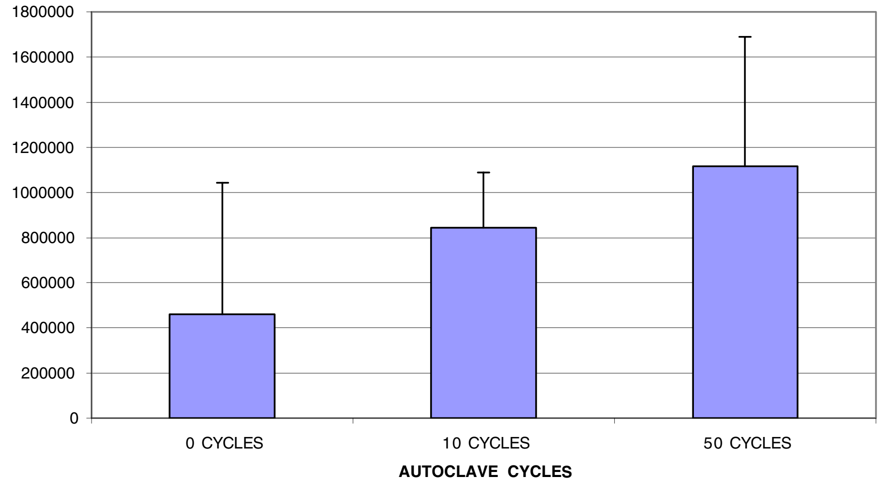

FIGURE 3. Rotating beam fatigue testing of CP4 specimens.

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cles may have deleterious effects on the integrity of the plates and screws used routinely in craniofacial surgery. Rigorous testing of the materials used in craniofacial plates and screws found no significant change in the examined material properties after at least 50 cycles of autoclave sterilization. Based on the results of the present study, we cannot recommend changes to the established and customary protocols for storing or autoclaving craniofacial plating systems.

Although the gross integrity of the tested materials seems unaffected, studying a different aspect of the implants, its biocompatibility, may expose the clinical consequences of multiple sterilizations. Several authors have examined the effect of multiple sterilizations on the surface characteristics of implantable metal alloys, and their findings may provide evidence for altering the manner in which titanium implants are prepared and sterilized.

A single cycle of heat sterilization has been shown to increase significantly the surface roughness of nickel-titanium disks, and nearly identical findings were noted after autoclave sterilization of clinically recycled nickel-titanium arch wires.[2,10] Vezeau et al[11] studied the effects of multiple sterilizations with different regimens on the surface characteristics of commercially pure titanium and found significant unfavorable consequences for future biocompatibility of the implanted material. Among the tested sterilization methods, steam autoclave produced the greatest discoloration and heaviest particulate contamination of

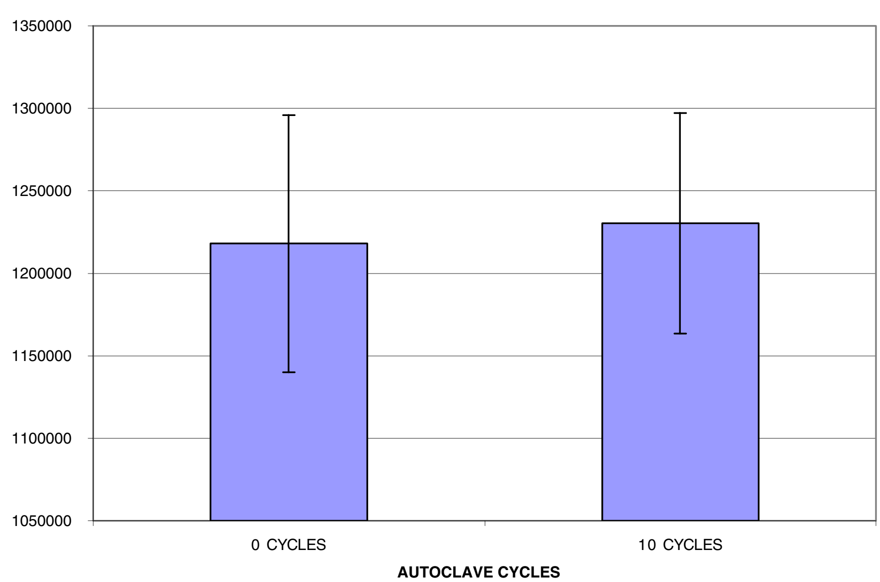

FIGURE 4. Rotating beam fatigue testing of CP2 specimens.

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the implant surface.[11] Importantly, cell-attachment and cell-spreading along the biomaterial was inhibited most significantly in the group exposed to the greatest number of steam autoclave cycles (10).[11] Multiple autoclave cycles may not impact significantly the material properties of craniofacial plates and screws, yet the clinical impact of repeated sterilization procedures on the biocompatibility of titanium remains an unanswered question. In vivo studies of the biointegration of titanium alloys that have been subject to different sterilization regimens is the next step in furthering our understanding of the clinical consequences of present equipment protocols.

Should in vivo studies show multiple autoclave cycles to impair significantly the biointegration of titanium implants, this would necessitate a change in the packaging and preparation of craniofacial plating systems. The expectation of enhanced biointegration and improved clinical outcomes would encourage either limiting the number of sterilization procedures for any implant or favor sterilization modalities that do not alter the surface properties of titanium alloys. Individual packaging of implants through bundling of plates and screws used typically in a given case, or custom ordering sterile packages of hardware a particular surgeon uses customarily might enhance the biocompatibility of existing craniofacial plating systems by simply avoiding additional sterilization procedures.

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