Proposed Aggressive Cleaning and Sterilization Procedure To Be Used on Orthopaedic Surgical Instruments

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INTRODUCTION
Sterilization of orthopaedic instruments tends to be more aggressive at European hospitals when compared to hospitals in the United States. This is due to the potential of prion associated infectious diseases such as Creutzfeldt-Jakob and spongiform encephalopathy (mad cow disease). The stability of prions make them difficult to destroy by standard steam autoclaving methods. It would be useful to develop a standard sterilization procedure aggressive enough to eliminate the risk of prions and that could be used in all hospital settings.

The World Health Organization has proposed a procedure which includes immersing the instruments in 1N NaOH followed by gravity-displacement autoclaving. Although aggressive, this method is damaging to the instruments and potentially unsafe to the operators. It would be ideal to develop a method that can reduce the infectiveness of the prion without the adverse consequences to the instruments and operator. It has been suggested that successful autoclave parameters for a pre-vacuum setting are a temperature of 134-137°C for 18 minutes. Using these settings in combination with initial cleaning must be first tested on the surgical instruments to determine its effects.

The purpose of this study was to propose an aggressive cleaning and sterilization method based on previous research that would be more effective in Europe. This method was tested on an existing orthopaedic instrument to determine if the parameters used would be tolerated by surgical instruments.

METHODS
Test Samples
Offset Adapters (Stryker, NJ, n=9), size 8mm, were tested to determine their mechanical and structural durability after aggressive cleaning and sterilization procedures.

Mechanical Testing
The offset adapters were assembled onto a Triathlon Tibial Baseplate (Stryker, NJ), size 8, during testing. A worst-case loading condition was enforced by orienting the offset adapters to produce increased moment forces and leaving internal compression springs unlubricated to produce higher frictional forces. A customized shaft and spring (Fig. 1, A) were attached to the offset adapter/tibial baseplate construct during testing to apply a force. A wrench was then used to push against the toggle pin of the offset adapter and disengage it from the tibial baseplate. Component failure was defined as disassembly not occurring.

Cleaning
An Ultrasonic Cleaner (VWR, PA, model 250HT) was used with an alkaline solution, MetriClean 2 Detergent (Metrex Corp., CA), with a pH of 13-14. This detergent was chosen because it has the highest possible pH concentration used in surveyed hospitals. The cleaner was run for 10 minutes at 98°C. The components were then rinsed with deionized water at room temperature.

Sterilization
An autoclave (Stryker Century Sterilizer, Mentor OH, model SV-1263) was used to sterilize the components. The offset adapters were tested using a pre-vacuum setting with a maximum temperature of 137°C, a steam time of 18 minutes and a dry time of 30 minutes.

RESULTS
During mechanical testing it was found that all test samples were able to disengage from the tibial baseplate. This indicated that the highly aggressive cleaning and autoclaving procedure did not compromise the integrity of the instrument. The pin protrusion length varied between 1.29-1.38mm before testing and 1.33-1.38mm after testing (Graph 1). This minimal change in length did not affect the functionality of the component and therefore all offset adapters were functional after testing. A paired t-test with a 95% confidence interval showed there was no significant difference between the initial and final pin protrusion lengths (p=0.55).

DISCUSSION
Although rare, prions pose a dangerous risk when using reusable surgical instruments. Research has been done to develop cleaning and sterilization protocols but to date there is no generalized hospital procedure that includes these aggressive parameters and do not damage the surgical instruments. We suggested a cleaning and sterilization procedure based on existing hospital practice (based on survey of several hospitals) and proven effective sterilization parameters. Literature shows that autoclaving on a pre-vacuum setting with a temperature of 134°C for ≥18 minutes results in a prion decrease of 5 logs. This study we increased this temperature and kept the recommended time the same, assuming this would provide similar elimination of prions.

This protocol was tested on offset adapters to determine its influence on the functionality of this instrument. The offset adapters demonstrated that they were able to endure this aggressive testing for simulated 10 year duration without compromising mechanical or structural integrity. Therefore, this procedure should be considered when developing an aggressive cleaning and sterilization standard.

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REFERENCES

Figure 1. The testing apparatus applied a moment force to the offset adapter using a spring and customized shaft (A). The pin protrusion length of the offset adapter was measured before and after testing (B).

The components were tested for 240 cycles to simulate 10 years of use with a safety factor of 2. For the first 48 cycles, the components were mechanically tested, cleaned and sterilized for each cycle. During the following 144 cycles, the components were tested in 36 cycle increments. Performing 36 mechanical tests, 360 minutes of cleaning completed with 36 sterilization cycles. The final 48 cycles were treated the same as the initial 48 cycles. In addition, pin protrusion length (Fig. 1, B), the length correlating to how much locking surface area there is with the mating part, was measured before the initial cycle and after all 240 cycles were completed.