A determination of sterilization efficacy and bacterial pathogenicity regarding dental implant osteotomy burs.

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A determination of sterilization efficacy and bacterial pathogenicity regarding dental implant osteotomy burs.

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Abstract

Introduction: The practice of dentistry relies on comprehensive sterilization techniques for the use and reuse of dental instruments. Many of these critical devices can be used for multiple surgeries, as per the manufacturer's recommendations. However, current Army Infection Control Policy mandates that burs used in the placement of dental implants be discarded after a single use. If sterility could be achieved after each use, and the policy updated, the reuse of these burs alone could yield a $1 million savings annually. The specific aim of this study was to determine if the current sterilization methods implemented within military dental treatment facilities are as effective in the removal of aerobic bacteria as the manufacturer's recommended sterilization protocols.

Methods and Materials: The two sterilization methods assessed in this study were obtained from the 3i T3 Implant Surgical Manual, as well as Appendix J from the Army's Infection Control Policy. Implant osteotomy burs included pilot, 2mm twist, and 3.25mm, 4.1mm, and 5.0mm quad shaping burs. A total of 150 osteotomy burs per experimental group were swabbed for the evaluation of aerobic bacterial growth at three time points: pre-surgery, post-surgery, and post-sterilization. All swabs were subcultured onto blood agar plates within 48 hours of collection, incubated at 37℃ for 24-48 hours, and subsequently examined to determine the number of colony forming units (CFUs) present.

Results: A positive culture was detected for 4 samples (1.3%) at time point 1 (pre-surgery). At time point 2 (post-surgery), CFUs were detected in 77 percent of samples, with 10 percent >100 CFUs. Overall, bacteria were found in 3 of 300 samples
(1.0%, 95% CI: 0.2-2.9%) at time point 3, post-sterilization. No difference was found between sterilization protocols (p=1.00), but among bur types all 3 positives after sterilization were associated with the 2 mm twist bur. Rates of detection were 4.2% for the 2mm twist bur compared to 0% for other bur types (p=0.013).

Conclusion: Based on our results, there was no statistically significant difference between the two sterilization methods. When individual bur types were examined, the 2mm twist osteotomy bur was the only bur type to show positive post-sterilization cultures. However, due to such low CFU values, contamination cannot be ruled out. Therefore, we can confidently say that both sterilization protocols are effective at the sterilization of aerobic bacteria.

Introduction

Dental implants are a restorative modality used to treat partial and complete edentulism. The majority of these implants are made of titanium, and are fabricated during a precise manufacturing process. The placement of these endosteal dental implants is technique sensitive, and therefore requires thorough preparation and precise surgical skills. The instruments used to prepare a patient's bone for an implant include specialized surgical burs that directly correlate to the exact size of implant being placed. This study aimed to compare two different sterilization methods of implant osteotomy preparation burs: the 3i recommended sterilization method, and the Army Infection Control sterilization protocol.

In the modern era of dentistry, there have been a multitude of studies that have sought to investigate the efficacy of various sterilization procedures. Many of these studies have utilized endodontic files and diamond burs as their test subjects due to their intricate nature and design which makes them difficult to clean.[1-12] Modern implant osteotomy burs fall into the same category, with multiple flutes and bevels necessary for the precision required when placing endosteal dental implants. In the past, many of these studies have come to the conclusion that these burs are unable to be completely debrided of particulate prior to sterilization.[1-12] Other studies have shown that instruments not labeled as "sterile" from the manufacturer contain debris and therefore must be sterilized prior to use.[11,13-16] This has caused the Department of Veterans Affairs as well as the US Army to implement a single use policy in regards to dental implant osteotomy burs.[17,18]

Recently, the Food and Drug Administration has published new recommendations directed at manufacturers for validation of cleaning protocols regarding reusable medical devices.[19] The Centers for Disease Control and Prevention (CDC) classify patient-care items into three categories: critical, semicritical, and noncritical.[23] In this paper they classify implant osteotomy burs as critical devices, based on the Spaulding Classification for surgical and medical devices developed in 1957.[24] The definition of a critical item is one that is "intended to contact normally sterile tissue or body spaces during use and present the greatest risk of disease transmission." However, if the flow chart provided by the FDA is followed, it becomes clear that the implant osteotomy burs fall under the category of low risk of infection due to the presence of a reusable device that has an equivalent design and the same intended use as the single use device. Further research also shows that there is no evidence of implant complications as a direct result of contaminated (or reused) drill surfaces.[20]

Based on clinical data from 2016, Army clinics worldwide place an average of 1.64 implants per surgical visit.[17] Instrument cost analysis using government pricing for the surgical procedure (starter drill, 2mm twist, and osteotomy burs) totals $1.1M per year. According to several manufacturers' recommendations, these implant osteotomy burs are manufactured to maintain their structural stability and cutting efficiency for up to 15 cycles. While infection control and patient safety are two essential features to any dental practice, cost effectiveness and timely turn-around are also important considerations for a successful and productive practice. If these devices could be properly sterilized and reused without increased risk to the patient, there could be a significant financial savings on the part of the US Army and the Federal government.

No published studies were found comparing a manufacturer's recommended sterilization protocol to the Army infection control sterilization protocol in regards to dental implant osteotomy burs. Most studies relating to this topic have been completed utilizing endodontic files and diamond burs as the subjects of the experiments.[1-12] The results have then been extrapolated to include implant osteotomy burs. Few studies have actually used implant burs as the object of the experiment. One study by Parnia et al. investigated the cleansability of lumen free implant burs by exposing them to radioactively marked blood. Their results showed that predictable complete removal of all blood was impossible, and therefore the devices should be considered for single use.[21] However, it is worth noting that the researchers did not include an enzymatic wash in their cleaning and sterilization protocol, which could explain the incomplete removal of the radioactive blood.

Another study that directly looked at the sterilization of dental implant osteotomy burs was completed by Price in 2016.[22] This study utilized porcine mandibles as the subject in which the osteotomies were prepared. The aim was to

Figure 1: 3i Implant Osteotomy Burs (from left to right): pilot, 2mm twist, 3.25mm quad shaping, 4.1mm quad shaping, 5.0mm quad shaping.

determine if particulate and debris could be adequately removed from implant osteotomy burs during the cleaning and sterilization process. This was verified with SEM micrographs of 4 test groups; unused burs, unused and cleaned burs, used/cleaned/sterilized burs, and used/sterilized burs. Results showed that all bur groups showed signs of debris, even those that were not used and directly imaged. This shows that even sterile burs straight from the manufacturer have particulate in their grooves, most likely from the manufacturing process.

While these studies provide quality insight into the processing of contaminated dental implant osteotomy burs, as well as the outcomes of certain aspects of the sterilization process, they fail to address important key factors. Firstly, neither study compares the manufacturer's recommended sterilization protocol to the sterilization method they used in their research. Secondly, neither study further clarifies if the processed burs have any microbial bioburden present after sterilization that could potentially harm or infect patients. Therefore, we hypothesize that there will be no difference in CFUs between the burs sterilized following the manufacturer's recommendations and the burs sterilized following the Army Infection Control sterilization protocol.

Methods

During the course of this study, 3i implant osteotomy burs were sampled by swabbing them directly out of the sterilization pouch, after surgery but prior to sterilization, and after sterilization. All procedures were previously treatment planned and were in no way performed solely for research purposes. No personally identifiable information, patient race, ethnicity, or age was collected or attached to the dental implant osteotomy preparation burs.

The burs collected in this study were 3i tapered implant osteotomy burs. Throughout the surgical placement of the implant, multiple burs were used to create the intended osteotomy. Those burs included a pilot drill, a 2mm twist drill, and a combination of multiple quad shaping burs dependent on the size of implant being placed. A total of 300 implant osteotomy burs were sampled, 150 per experimental sterilization protocol. The burs arrived unsterile when purchased from the manufacturer, and therefore were sterilized prior to the start of the procedure via steam gravity sterilization (Getinge Model 533HC) at 275℃ for 25 minutes. The burs were swabbed (BD BBL CultureSwab Transport Systems: Liquid Amies) for aerobic bacteria at three time points: directly out of the package and prior to surgery (Time Point 1), immediately after the surgical procedure (Time Point

2), and after sterilization (Time Point 3). All burs were swabbed on a sterile field with sterile gloves. Between Time Point 2 and Time Point 3, burs were subjected to either the 3i recommended cleaning and sterilization protocol or the Army's infection control sterilization protocol. The 3i T3 Implant Surgical Manual lists a specific method for the sterilization and reprocessing of implant osteotomy preparation burs.

3i Recommended Cleaning and Sterilization Protocol:

1. After use, place drills into a beaker of plain water, mild soap or specialized cleaning solution.
2. Rinse with tap water for a minimum of two minutes while brushing with a soft bristled brush to remove visible debris. Clean the interior lumen with a thin wire to remove any remaining debris.
3. Place instruments in an ultrasonic bath containing enzymatic detergent for five minutes. Scrub the instruments again with a soft bristled brush and ream the interior lumen to remove any remaining debris.
4. Rinse and flush the instruments for one minute using tap water.
5. Inspect visually for any remaining bone fragments or debris and scrub as necessary.
6. Remove the bur block from the surgical tray. Scrub the surgical tray and block with a soft bristle brush and mild soap. Rinse thoroughly.
7. Place the components into the surgical tray and pour ethyl alcohol (do not use rubbing alcohol) over the burs and tray to remove soap residue and minerals from the water. Let the components dry before wrapping.
8. Wrap the surgical tray in paper or autoclave-approved bags twice to prevent a tear of the outer packaging from contaminating sterile instruments.
9. Steam Gravity Sterilization for a minimum of twenty minutes at a temperature of 270-275°F
10. Post sterilization, devices should be thoroughly dried to mitigate the risk of stainless corrosion (30 minutes is typical).

A slightly different sterilization method can be found in the Army's Infection Control Policy, Appendix J. The Army Dental Corps' policy on Infection Control/Exposure Control and Sterilization is based on the Centers for Disease Control & Prevention Guidelines for Infection Control in Dental Healthcare Settings (MMWR 2003), the CDC Summary of Infection Prevention Practices in Dental Settings (2015), the CDC Guideline for Disinfection and Sterilization in Healthcare Facilities (2008), and Dental Directorate policies.

Army's Infection Control Sterilization Protocol:

1. After use, place osteotomy burs in a stainless steel surgical cup of sterile saline.
2. Return used burs to bur block and place in sterilization room on unsterile side.
3. Prepare ultrasonic cleaner (Biosonic UC300, Whaledent, Cuyahoga Falls, OH) by rinsing, filling with fresh water, and run at 80°C for 45 minutes with enzyme tablets (Maxizyme, Henry Schein, Melville, NY).
4. Empty ultrasonic cleaner, rinse, and refill with fresh water.
5. Place each bur block individually in the ultrasonic cleaner and run at 80°C for 45 minutes with detergent solution (MPUS Plus, Dentronix, Cuyahoga Falls, OH).

Figure 2: swabbing of a 5.0mm quad shaping bur

Figure 3: BD BBL CultureSwab Transport Systems: Liquid Amies

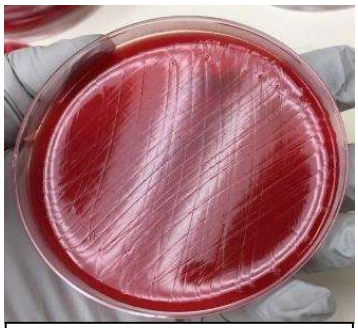

Figure 4: Inoculated plate (Trypticase Soy Agar (TSA II) with 5% Sheep Blood)

6. Rinse bur block with fresh water for 2 minutes and place in a thermal washer disinfector cycle (Getinge86, Rochester, NY) for 50 minutes.
7. Place burrs in a vacuum steam autoclave for 5 minutes at 273°F with a 20 minute dry time (Getinge 533HC, Rochester, NY).

All swabs were then transported to the Department of Clinical Investigation (DCI) at Tripler Army Medical Center for processing. Aerobic swabs were inoculated on blood agar plates (Trypticase Soy Agar (TSA II) with 5% Sheep Blood) under a Biological Safety Cabinet and subsequently incubated at 37˚C in ambient air for 24-48 hours. After appropriate incubation, the plates were examined to determine the number of colony forming units (CFUs). Samples were randomized by the principal investigator, and the associate investigator was blinded with regards to experimental group of each sample. Chi-square tests and Fisher's exact tests were used to assess whether rates of detection were associated with sterilization method or bur type. Nonparametric Kruskal-Wallis tests were used to evaluate whether CFU levels at time point 2, post-surgery, differed by method or bur type.

Results

While we hypothesized that we would see zero growth of bacteria on agar plates from burs swabbed at Time Point 1 (Pre-use), bacterial growth was observed on 4/300 plates (1.3%). These positive findings were evenly distributed among bur types, with one being from a pilot drill, and three from various quad shaping burs. All positive findings at Time Point 1 occurred on burs that were subsequently sterilized following the manufacturer's recommended sterilization protocol. At Time Point 2, we saw bacterial growth on 232/300 plates (77%) with 10% of the plates showing greater than 100 CFU values (31/300). Levels tended to be higher for the samples that were subsequently sterilized following the Army protocol vs. those following the manufacturer's method (p=0.017). Overall, bacteria were found in 3 of 300 samples (1.0%, 95% CI: 0.2-2.9%) at Time Point 3, after sterilization. There was no difference in methods (p=1.00), as two of the positives followed the Army sterilization protocol and 1 followed the manufacturer's guidelines. CFUs were very low for all three positive plates with growth (1, 2, and 3 CFUs), and corresponding growth at time point 2 was also very low (2, 1, 0 CFUs, respectively). No difference was found between cleaning protocols, but among bur types all 3 positives after sterilization were associated with the 2 mm bur. Rates of detects were 4.2% for the 2mm bur compared to 0% for other bur types (p=0.013).

Comment

The primary aim of this study was to compare the current sterilization methods implemented within military dental treatment facilities to evaluate if it is as effective in the removal of bacteria as the manufacturer's recommended sterilization protocol.

		Time Point 1 (pre-use)			Time Point 2 (post-surgery)								Time Point 3 (after sterilization)			
		>0 CFU			0 CFU		1-100 CFU		>100 CFU		p-value*	Median (IQR)	p-value**	>0 CFU			
	N	n	%	p-value*	n	%	n	%	n	%				n	%	95% CI	p-value*
All	300	4	1.33		68	23	201	67	31	10		4 (1-25)		3	1.00	(0.2-2.9)	
Method				0.123							0.006		0.017				1.000
Army	150	0	0.00		24	16	105	70	21	14		6 (1-32)		2	1.33	(0.2-4.7)	
3i	150	4	2.67		44	29	96	64	10	7		3 (0-23)		1	0.67	(0.02-3.7)	
Bur type				0.400							0.204		0.428				0.044
2mm	71	0	0.00		15	21	51	72	5	7		3 (1-19)		3	4.23		
3.25	55	1	1.82		16	29	31	56	8	15		7 (0-41)		0	0.00		
4.1	55	0	0.00		13	24	40	73	2	4		3 (1-21)		0	0.00		
5	55	2	3.64		9	16	36	65	10	18		6 (1-73)		0	0.00		
pilot	64	1	1.56		15	23	43	67	6	9		3 (1-15)		0	0.00		
Bur type				0.576							0.498		0.503				0.013
2mm	71	0	0.00		15	21	51	72	5	7		3 (1-19)		3	4.23	(0.9-11.9)	
Other	229	4	1.75		53	23	150	66	26	11		4(1-25)		0	0.00	(0-1.6)	

*P-value based on chi-square or Fisher's exact test for categorical counts.
**P-value based on Wilcoxon rank sum test or Kruskal-Wallis for actual counts.

Table 1: Data collection

Figure 5: (From left to right) Plates showing no bacterial growth, minimal growth (<100 CFU's), and >100 CFU's.

The secondary aim of the study was to determine if there could be any cost savings to the Army if both sterilization methods were equally effective. Based on our results, both methods are equally effective at sterilizing the implant osteotomy burs with regards to aerobic bacterial growth. There was no statistically significant difference between the Army Infection Control sterilization protocol and the 3i manufacturer's recommended sterilization protocol. It is noteworthy that all positive findings associated with Time Point 3 occurred on 2mm twist burs ($p=0.013$). This could be due to the unique anatomy of the bur itself, as it has a helical flute that is more difficult to clean when compared to the quad shaping burs. Additionally, all 3 positive findings showed single digit CFUs. With recovery that low, we cannot rule out potential cross contamination during the plating procedures.

In 2016, Army Dentistry placed around 5,600 dental implants. The implant osteotomy burs used during the surgery cost approximately $36 per bur. On average, 5 burs are used per surgery. When summed, the cost of burs alone totals around $1 million. If the burs were to be used up to 15 times as the manufacturer states, the bur cost drops to $67,000 annually. The proper sterilization and safe reuse ofimplant osteotomy burs could save the Army around $933 thousand annually. These numbers reflect only changing the single use policy for implant osteotomy burs. There are multiple other types of burs used in dentistry that are required single use as well, such as prosthodontic acrylic burs and polishing burs. Further investigation and evaluation of different bur types is necessary to determine if the new policy could be applied to all burs. The potential cost savings either way is significant but could be much higher if all bur types are included.

Several key studies regarding sterility and implant placement are important to consider when attempting to change policy. Pye et al. showed that there is no evidence of implant complications as a direct result of contaminated or reused drill surfaces.[20] The mouth is not a sterile environment, while the bone that the implant is being placed in is sterile prior to the surgery. The osteotomy field is immediately contaminated with bacteria from saliva after reflection of the tissue. However, Scharf and Tarnow reported that there are no differences in success rates of implant therapy when placed in "sterile" or "clean" environments.[25]

Our study has several limitations. Due to limited time and resources, only aerobic organisms able to grow in the 48 hour incubation time were studied. There are certain organisms more resistant to conventional sterilization methods than others, such as spore-forming bacteria that were not present in our study. Another limitation was that swabs in some instances were held for up to 48 hours before subculturing to media which surely impacted organism recovery. Nevertheless, further research with implant osteotomy burs needs to be performed to determine the sterilization efficacy in regards to anaerobic bacteria, viruses, prions, and fungi. To implement policy changes, investigation will need to be conducted supporting the sterilization efficacy of burs after repeated use.

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