PILOT STUDY: INTERNALLY COOLED ORTHOPEDIC DRILLS – STANDARD STERILIZATION IS NOT ENOUGH?

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SUMMARY – Bone drilling causes focal temperature rise due to metal-to-bone contact, which may result in thermal osteonecrosis. Newly constructed internally cooled medical drill of an open type decreases temperature rise at a point of metal-to-bone contact although standard sterilization of such a drill could be inadequate due to bacteria retention within the drill lumen. The aim of this pilot study was to examine the effectiveness of sterilization and to propose sterilization recommendations for internally cooled open type bone drills. Unused internally cooled medical steel bone drills were tested. Drills were contaminated with *Pseudomonas aeruginosa*, *Bacillus* sp., beta-hemolytic *Streptococcus* sp., *Enterobacter* sp. and methicillin-resistant *Staphylococcus pseudintermedius* and then incubated for 24 hours at 37 °C. Afterwards, drills were autoclaved for 15, 20 and 30 minutes at 132 °C and 2.6 bar. When 15-minute sterilization was used, one out of 16 drills was contaminated with *Pseudomonas aeruginosa*, while the other 15 drills were sterile. Extended cycle sterilization in autoclave lasting for 20 and 30 minutes resulted in 100% sterility of all drills tested. In conclusion, lumened drills should be exposed to extended sterilization times in autoclave. Minimal recommended time for sterilization of lumened drills is 20 minutes.

Key words: *Bone and bones – injuries; Osteonecrosis; Orthopedic procedures – adverse effects; Sterilization; Surgical wound infection*

Introduction

Many orthopedic procedures include bone drilling. When this procedure is performed, temperature rise develops due to metal-to-bone contact, which may result in thermal osteonecrosis[1,2]. The lowest temperature threshold for thermal osteonecrosis is 47 °C lasting for one minute[3-5]. Higher temperatures can cause irreversible enzyme disturbances even with shorter duration (50 °C in 30 seconds)[6]. Avoiding thermal damage to the surrounding bone is essential since osteonecrosis develops during subsequent 3-4 weeks and could lead to delayed loosening of screws and implants. During ambulation, screw loosening leads to implant failure and/or refractures[3]. Internally cooled bone drills (open system) conduct cooling fluid directly to the point of contact of cutting surface of the drill and the bone. These types of drills are in widespread use in dental surgery; however, they are still experimental in orthopedics. Augustin *et al.*[3] proved that internally cooled drill decreased temperature rise in porcine bone far below 47 °C using hard metal drills (tungsten cobalt carbide). Given that previous experiments were not

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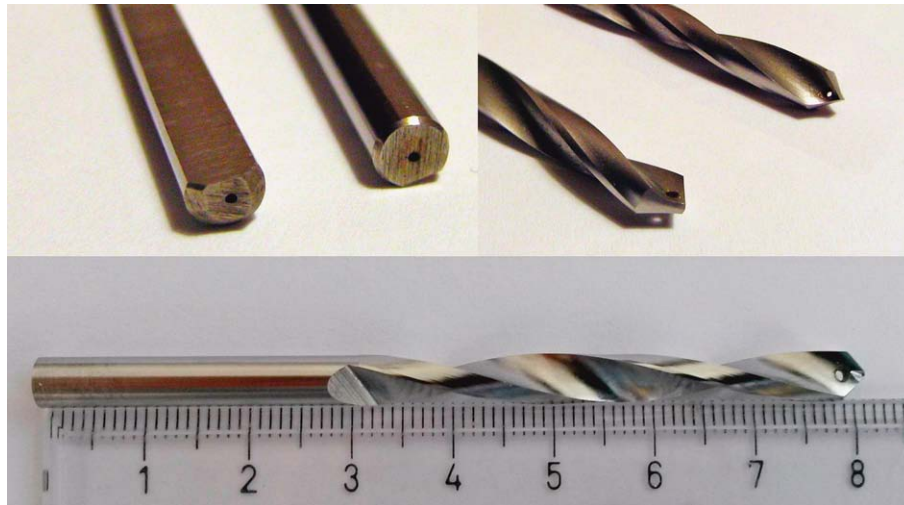
Fig. 1. Drill with open type internal cooling.

Table 1. Composition of the drills

Element	Handle	Middle	Cutting edge
Si	0.21	0.30	0.28
Cr	15.42	15.61	15.81
Mn	0.55	0.54	0.51
Fe	82.33	81.88	81.75
Ni	1.48	1.67	1.65

conducted with medical steel drills, the idea was to construct a medical steel bone drill with open type internal cooling. A possible disadvantage of the drills with narrow rinsing channels is the increased risk of bacterial contamination[7]; sterilization of such drills may be inadequate due to bacteria retention within the drill lumen.

Chan-Myers *et al.*[8] showed that bacterial burden recovered from the lumened medical devices used in routine surgeries was much higher in lumen than on the surface of the instruments. Bacterial contamination on instruments may differ in the type of bacteria immediately after the operation and after cleaning of the instruments. Also, the number of colonies on instruments can be higher than it was before cleaning[8,9]. The decontamination standards and guidelines are well documented and validated for conventional surgical instruments, but there is a general paucity of consolidated information relating to the microbiological decontamination of surgical power tools such as orthopedic surgical drills[10]. Also, sterilization parameters of surgical power tools are not well documented.

The aim of this study was to examine the effectiveness of sterilization and to propose sterilization recommendations for open type internally cooled bone drills that may become a standard in bone drilling.

Materials and Methods

Sixteen unused internally cooled medical steel bone drills (Komet Medical GmbH, Lemgo, Germany, S2727.098) were tested. The drills have two spiral channels and drill point angle of 90°. Dimensions of the drills are: length 8 cm, diameter 4.5 mm, and cylindrical channel diameter 0.3 mm with two side openings at the tip of the drill (Fig. 1). The composition of the drills is shown in Table 1.

All drills were immersed in the liquid culture medium Brain Heart Infusion Broth, Oxoid (BHI) that was previously inoculated with *Pseudomonas aeruginosa*, *Bacillus* sp., beta-hemolytic *Streptococcus* sp., *Enterobacter* sp. and methicillin-resistant *Staphylococcus pseudintermedius* (MRSP) (Fig. 2).

The drills were not sterilized prior to inoculation nor were handled aseptically. Incubation time was 24 hours at 37 °C. After these 24 hours, BHI was inoculated on a solid nutrient medium (Columbia agar, Merck, Burlington, Massachusetts, USA) as a control of bacterial growth of used strains (Fig. 3).

After the drills had been taken out of BHI, these were rinsed with distilled sterile water and cylindrical channels were flushed with fine needle with special attention to fluid passage through the whole channel

Fig. 2. Drills immersed in liquid culture medium Brain Heart Infusion Broth, Oxoid (BHI) that was previously inoculated with Pseudomonas aeruginosa, Bacillus sp., beta-hemolytic Streptococcus sp., Enterobacter sp. and methicillin-resistant Staphylococcus pseudintermedius (MRSP).

Fig. 3. After 24 hours, the used BHI was inoculated on a solid nutrient medium (Columbia agar, Merck, Burlington, Massachusetts, USA) as a control of bacterial growth of used strains.

and exiting on the other side. Drills were then autoclaved (gravity-displacement steam sterilization; Tuttenauer GS Hospital Autoclave) for 15 minutes at 132 °C and 2.6 bar[11-13]. Empty autoclave chamber was neither sterilized nor tested for sterility prior to the experiment. After 24-hour autoclaving the drills, they were taken out of the autoclave and again immersed in BHI and incubated for 24 hours at 37 °C. Liquid culture medium (BHI) used was then inoculated on solid nutrient medium (Columbia agar, Merck, with the ad-

dition of five percent defibrinated sheep blood) and incubated for 48 hours at 37 °C. Also, the same experiment was conducted with 20- and 30-minute autoclaving.

The above mentioned strains were isolated at Bacteriological Laboratory, Department of Microbiology and Infectious Diseases with Clinic, Faculty of Veterinary Medicine, University of Zagreb.

Results

In the part of the experiment with 15-minute sterilization in the autoclave, one out of 16 drills was contaminated with *Pseudomonas aeruginosa* (Fig. 4). The other 15 drills were sterile. In the extended cycle sterilization in the autoclave lasting for 20 and 30 minutes, all drills were sterile.
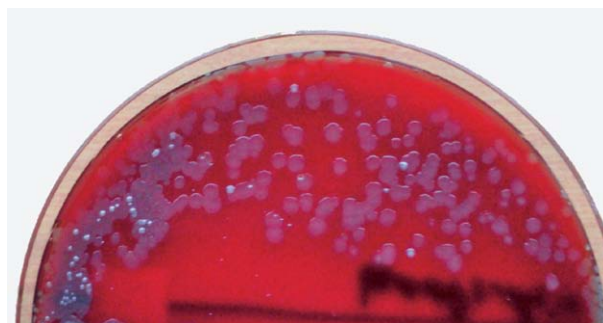

Fig. 4. One out of 16 drills was compromised with Pseudomonas aeruginosa.

Discussion

Bone drilling is the essential part of orthopedic surgery. During bone drilling, temperature rises on the bone-to-metal interface above 47 °C and could lead to thermal osteonecrosis[3-5] with its devastating consequences. Augustin *et al.*[14] showed that external irrigation reduced temperature rise during drilling. Later research[3] showed the internally cooled drill (open type) to be more efficient in decreasing temperature rise. Internally cooled drills were introduced in 1975 by Kirschner and Meyer in dental surgery[15]. Lavelle and Wedgwood also showed that internal cooling was superior to external one[16]. There are three mechanisms that contribute to minimization of temperature rise. First, the cooling agent, usually distilled saline at room temperature, is driven directly to the point of contact

Table 2. The risk of infection degree according to Spaulding[19]

Critical	Enters sterile tissue and must be sterile
Semicritical	Contacts mucous membranes and requires high-level disinfection
Noncritical	Comes in contact with intact skin and requires low-level disinfection

of cutting edge of the drill and the bone, where the temperature rise originates due to friction. External irrigation, on the contrary, cools only the part of the drill outside the bone, and also the surface of the bone, not deeper layers. This is especially important for the outer cortex that cannot be reached by external irrigation. Second, cooling fluid reduces friction, which is the main cause of temperature rise. Third, cooling fluid lubricates and cools off heated bone chips, which then are more easily removed.

Also, due to the lower consumption of the cooling agent with internal irrigation, the spillage of the cooling agent is lower[3]. Therefore, the sterile operative field contamination possibility due to cooling agent droplets bouncing from the potentially not sterile surrounding field is also lower. Many orthopedic procedures involve contact of a surgical instrument with patient sterile tissue. A major risk of such procedures, especially if reprocessed instruments are used, is the inoculation of pathogenic microbes, the situation that could lead to surgical site infection or even osteomyelitis. Noailles *et al.*[17] found the rate of surgical site infection after hip hemiarthroplasty to be 1.7%-7.3%. Failure of adequate sterilization may lead to transmission *via* contaminated medical and surgical devices[18]. According to Spaulding *et al.*[19], all surgical tools are in 'critical category' based on the degree of the risk of infection ('enters sterile tissue and must be sterile') (Table 2).

Despite multiple guidelines stating that the risk of infection transmission from reprocessed medical devices is exceedingly low, the high transmission rates during outbreaks are often overlooked[20]. Tosh *et al.*[21] showed that reprocessed arthroscopic equipment retained tissue in the lumen of both the inflow and outflow cannulae and was contaminated with *Pseudomonas aeruginosa*, responsible for surgical site infection. Blevins *et al.*[22] have described three patients having undergone meniscus repair within a four-day period and who developed surgical site infection due to coag-

ulase-negative *Staphylococcus* sp. Inspection of reprocessed arthroscopic inflow/outflow cannulae revealed dried organic matter within the lumen. The diameter of the lumen was not stated. Parada *et al.*[23] report on similar results with coagulase-negative *Staphylococcus* sp. as the etiologic agent due to residual bioburden in the cannulated portion of a tibial fixation hex driver.

Although many articles relate to improper disinfection and/or inadequate instrument care prior to the sterilization process, 'sterilization' itself is considered as self-explanatory and rarely investigated.

Since studies of dental high-speed handpieces using dye expulsion have confirmed the potential for retraction of oral fluids into internal lumened compartments of the device due to high-speed rotation[24], a similar phenomenon may be present with lumened drills. It is not clear whether retraction ensues during full speed rotation or during the slowdown. Chan-Myers *et al.*[8] examined the degree of microbial contamination associated with the use of rigid metal lumened medical devices without the use of sterilization, and the efficacy of standard cleaning techniques used to remove pathogenic microorganisms from lumen channels. The authors found that the total number of aerobic and anaerobic bacteria recovered from within the lumen was much higher than that recovered from the external surface of the device. The levels of bioburden found within lumened devices after cleaning were generally decreased, but on six out of 18 devices, increased level of bioburden was found. The unexpected result was explained as contamination from personnel handling the devices. This makes sterilization process even more important. This research was done in the field of general surgery, which included 'contaminated' procedures, unlike orthopedics where 'clean' operations are conducted.

It has also been proven that not only the number of colonies may be higher but the type of bacteria may also differ before and after cleaning[8,9]. This is explained as contamination by hospital environment, personnel instrument handling during surgery, and as personnel instrument handling while outside the sterile surgical field. Pinto *et al.*[25] analyzed microbial load in orthopedic surgical instruments. The predominance of gram-positive bacteria was observed in 'clean' operations. Although 'contaminated' operations had a relatively higher frequency of gram-negative bacteria, gram-positive bacteria still prevailed. In 'infected' operations,

Staphylococcus sp. accounted for 70% of the isolated microorganisms. Also, it has been proven that *Staphylococcus aureus* infections tend to have a worse outcome than, for example, *Streptococcus* sp.[26]. Of 18 species of microorganisms recovered from surgical instruments after orthopedic procedures, only one belonged to *Bacillus* sp. All the other microorganisms were those found in nature under vegetative form and being eliminated by heat at approximately 80 °C.

Surgical instruments used in sterile procedures have relatively low bioburden levels, averaging about 10^2 *per* instrument[9]. Reduction in the microbial load on medical devices during cleaning is an essential step that increases the safety and reliability of the sterilization process. Previous studies have demonstrated that the level of microbial contamination on surgical instruments after standard machine cleaning is very low, with 72% of instruments having 0-10 colony-forming units of relatively nonpathogenic bacteria (i.e. coagulase-negative bacteria, *S. aureus*, *Bacillus* sp., and diphtheroids)[27]. The exact time frame when to clean surgical instruments after usage is not well defined but it is recommended that it should be done as soon as possible after usage[28]. Low bioburden level after cleaning, which consists predominantly of vegetative microorganisms, presents a low challenge to sterilization and disinfection systems[9].

In this study, only bacterial contamination and not viral was used because enveloped viruses (such as hepatitis B, hepatitis C or HIV) are in general more susceptible to heat than vegetative bacteria[29,30]. Our research aimed to clarify the sterilization procedure for open type internally cooled bone drills. The results indicated that standard sterilization procedure was not sufficient and that longer duration of sterilization was mandatory. According to the literature, the need for additional processing times may be the result of the complex design of a device (e.g., very long or narrow lumens). This is commonly referred to as 'extended sterilization cycle time'[31]. In general, standard cycle times can range from 5 to 20 minutes of exposure in a dynamic air-removal sterilizer at 132 °C and as long as one hour in a gravity cycle at 121 °C[32]. The temperature for wrapped items (e.g., surgical drills) in a gravity-displacement cycle may be 121 °C for exposure time of 30 minutes, 132 °C for 15 minutes, or 135 °C for 10 minutes[11-13]. Sterilization should be done in the first six hours after use because bacterial count increases logarithmically after six hours[33].

To the authors' knowledge, the only similar research was performed by Proff *et al.*[7] but with notably smaller drills and with similar results. Drills were 11 mm in length, contamination was monobacterial, and time used for sterilization was only 5 minutes.

The results of our study pointed out that minimum recommended time for sterilization of orthopedic lumened drills was 20 minutes. Internally cooled bone drills should be cleaned and channel rinsed immediately after its use because drying of bioburden inside the lumen could cause obstruction of the cooling system. It should be noted that despite the fact that the authors of this study infected the tested drills with bacteria mentioned in most of the international literature, there is always the possibility of infection by other causes, and we believe that this study is a good pilot testing platform for a higher number of drills and microbial samples.

If the internally cooled drill enters the clinical use, the recommended cleaning procedure would be as follows: immediately after usage in the operating room, the drill should be rinsed with high-pressure distilled water while still connected on the system adapted to the drilling machine. In that case, the bioburden from the lumen would be flushed before drying and would make cleaning more efficient. Extended sterilization would follow after cleaning procedure.

In conclusion, lumened drills should be subjected to extended sterilization times in autoclave. Minimal recommended time for sterilization of lumened drills should be 20 minutes.

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Sažetak

PROBNO ISTRAŽIVANJE: ORTOPEDSKA SVRDLA S PROTOČNIM HLAĐENJEM OTVORENOG TIPA – JE LI STANDARDNA STERILIZACIJA DOVOLJNA?

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Bušenje kosti izaziva porast temperature na mjestu kontakta metala i kosti, što može rezultirati termičkom osteonekrozom. Novokonstruirano svrdlo s unutarnjim hlađenjem otvorenog tipa smanjuje porast temperature na mjestu kontakta metala i kosti, ali standardna sterilizacija takvog svrdla može biti nedovoljna zbog zadržavanja bakterija unutar kanala svrdla. Cilj ovog probnog istraživanja bila je procjena učinkovitosti sterilizacije te prijedlog preporuka za sterilizaciju medicinskog svrdla s unutarnjim hlađenjem otvorenog tipa. Testirana su nekorištena medicinska svrdla s unutarnjim hlađenjem otvorenog tipa. Svrdla su kontaminirana sljedećim bakterijama: *Pseudomonas aeruginosa*, *Bacillus* sp., beta-hemolitički *Streptococcus* sp., *Enterobacter* sp. i meticilin-rezistentni *Staphylococcus pseudintermedius*. Inkubacija je trajala 24 sata na temperaturi od 37 °C. Potom su svrdla sterilizirana u autoklavu 15, 20 i 30 minuta na temperaturi od 132 °C i tlaku od 2,6 bara. Kod sterilizacije u trajanju od 15 minuta jedno od 16 korištenih svrdla bilo je kontaminirano bakterijom *Pseudomonas aeruginosa*, dok su ostala svrdla bila sterilna. Produženi ciklus sterilizacije u autoklavu u trajanju od 20 odnosno 30 minuta rezultirao je sterilnošću svih svrdla. U zaključku, svrdla s lumenom je potrebno sterilizirati produženim ciklusom sterilizacije. Minimalno preporučeno trajanje sterilizacije je 20 minuta.

Ključne riječi: *Kosti – ozljede; Osteonekroza; Ortopedski postupci – štetna djelovanja; Sterilizacija; Kirurška rana, infekcija*