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What is the optimal protocol to decontaminate a dropped custom polyethylene component?

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ABSTRACT

Background: With advancements in manufacturing technology, custom orthopedic implants have become commercially available. A new concern with these implants is what to do when custom heat-sensitive components are contaminated. While intraoperative decontamination protocols for dropped autograft tissue have been described, no literature describes an intraoperative protocol for decontaminating one-of-a-kind polyethylene implants. The purpose of this work is to describe and evaluate polyethylene decontamination protocols using materials found in the average operating suite that could be used intraoperatively.
Methods: Sixteen custom polyethylene inserts were contaminated with potting soil and processed in one of four protocols: 1) hydrogen peroxide, 2) chlorhexidine gluconate, 3) povidone-iodine, or 4) control. Following processing, the implants were cultured with swabs or sonication. Each implant was evaluated with one aerobic, one anaerobic, and one fungal culture.
Results: All cultures from implants processed with both the chlorhexidine and povidone-iodine protocols were negative. One colony of *Ralstonia* species was isolated on the aerobic culture from one of the implants processed with hydrogen peroxide. The remainder of the cultures from implants processed with the hydrogen peroxide protocol were negative. All of the cultures for each culture modality from all of the control implants were positive with florid proliferation.
Conclusion: In the rare situation that a custom polyethylene insert becomes contaminated intraoperatively, the surgeon should consider all salvage options. Chlorhexidine and povidone-iodine decontamination protocols eliminated bacterial growth following culture swabs or sonicate taken from the contaminated polyethylene inserts while hydrogen peroxide failed in one case to completely eradicate growth.

1. Introduction

With improvements in manufacturing technology, one-of-a-kind, personalized orthopedic implants are now commercially available. Custom implants have been used in primary knee arthroplasty as well as in complex reconstructions for bone tumors and failed arthroplasty [1–3]. However, these technologies have also introduced new challenges. One challenge when working with one-of-a-kind implants is contamination. Traditionally, if an implant is dropped on the floor or otherwise becomes contam-

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inated, an identical implant could be used without delay or compromise in patient outcome. With custom implants, however, this is typically not an option.

The Centers for Disease Control (CDC) has published general guidelines for disinfection and sterilization in healthcare facilities [4]. Common protocols that would apply to custom polyethylene inserts include autoclave sterilization, ionizing radiation, ethylene oxide gas sterilization, hydrogen peroxide gas plasma sterilization, peracetic acid sterilization, and liquid chemical sterilization including hydrogen peroxide soaks. Commercially, polyethylene inserts are sterilized by gamma irradiation, hydrogen peroxide gas plasma, or ethylene oxide [5]. Of these methods, only autoclave sterilization and hydrogen peroxide soaks are readily available in the typical operative suite. Unfortunately, autoclave sterilization has been shown to change the surface properties of polyethylene [6] and the hydrogen peroxide soaks described by CDC require concentrated (seven percent) peroxide for six hours for sterilization [4], precluding the use of these methods intraoperatively.

The lack of established protocols to decontaminate contaminated polyethylene intraoperatively is similar to the challenge of interoperative decontamination for dropped autografts. Several groups have described solutions for successfully decontaminating dropped autografts [7–10]. These reported protocols for contaminated graft decontamination utilize chemicals commonly available in the operative suite, but their effectiveness has not been evaluated on polyethylene.

The purpose of this work is to determine the most effective decontamination technique for heat-sensitive custom implants. We hypothesize that custom, one-of-a-kind polyethylene implants can be effectively decontaminated using materials readily available in the typical operating room.

2. Materials and methods

2.1. Study design

Sixteen unique polyethylene inserts were divided into four groups consisting of 1) hydrogen peroxide, 2) chlorhexidine gluconate, 3) povidone-iodine, or 4) control. Each polyethylene for groups 1–3 was contaminated with potting soil, washed, decontaminated, rinsed, dried and then cultured (Figure 1). Controls were contaminated and then cultured immediately or after a tap water rinse. The experiments were divided between two days, one week apart such that two duplicate inserts for each group were processed on each day, for a total of four for each decontamination method. Factory sterilized and sealed knee polyethylene inserts (ConforMIS, Billerica, MA) were obtained by saving unused sizes from total knee arthroplasty surgeries at our institution.

2.2. Contamination

Each orthopedic device was dropped into a bag of organic garden soil (Nature's Care Organic & Natural Potting soil, Miracle Gro, Marysville, OH) and completely covered.

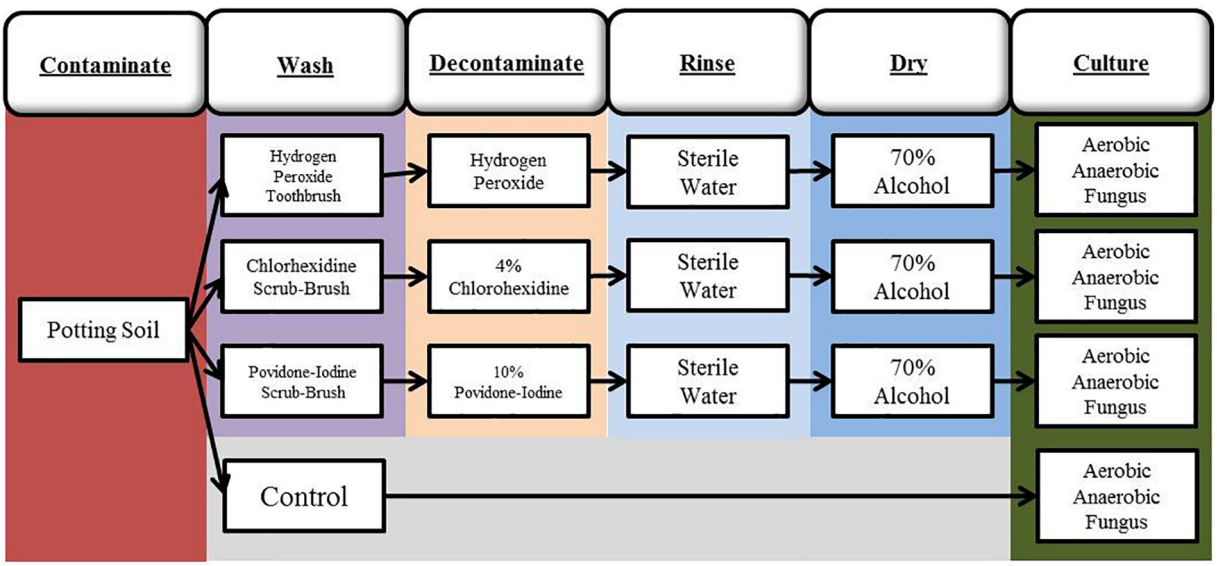

Figure 1. Diagram demonstrating workflow and experimental groups.

Figure 2. Photographs demonstrating contamination process of polyethylene.

2.3. Washing

Following contamination, each device was removed from the soil and was gently brushed with an unsterile, gloved hand to remove excess soil (Figure 2). The remainder of the visible contamination was removed by rinsing the device with tap water and scrubbing it for 30 s as would be done at a typical operating room scrub sink with either 1) three percent hydrogen peroxide (Hydrox Laboratories, Elgin, IL) and a sterile toothbrush, 2) four percent chlorhexidine scrub brush (BD E-Z Scrub 107, Becton Dickinson and Company, Franklin Lakes, NJ), or 3) eight percent povidone-iodine scrub brush (BD E-Z Scrub 245, Becton Dickinson and Company, Franklin Lakes, NJ) depending on the planned sterilization solution (Figure 1). The device was then rinsed with tap water and placed into a sterile specimen cup.

2.4. Decontamination

The sterile cup was filled with either 1) three percent hydrogen peroxide (Hydrox Laboratories, Elgin, IL), 2) four percent chlorhexidine gluconate (Hibiclens, Molnlycke Health Care, Norcross, GA), or 3) 10% povidone-iodine (Scrub Care, Care Fusion, Vernon Hills, IL) and sealed with a lid. Each specimen was agitated by manually vigorously shaking the container for 30 s after which time the lid was removed and the specimen was removed with a new set of sterile gloves and placed into a second sterile specimen cup.

2.5. Rinsing

The new sterile cup was then filled with sterile water and gently agitated by shaking the container. The chlorhexidine and povidone-iodine groups were rinsed three times (in the same container) to eliminate visible residual chemicals. The hydrogen peroxide group was rinsed once. New sterile gloves were again donned and each specimen was removed and placed into a third sterile specimen cup.

2.6. Drying

The third cup was then filled with 70% isopropyl rubbing alcohol (Hydrox Laboratories, Elgin, IL) and agitated. New gloves were donned and the polyethylene was placed on a sterile towel under a hood in the microbiology lab (Thermo Scientific 1300 series A2, Fisher Scientific, Marietta, OH) to allow the residual drying solution to evaporate.

2.7. Controls

One polyethylene insert from each day was contaminated and placed directly into the sterile hood for swabbing or sonication. A second insert was contaminated and then rinsed with tap water, but no other treatment prior to placement into the sterile hood for swabbing or sonicating. A total of four polyethylene inserts were cultured without decontamination. Two of the polyethylene inserts were cultured immediately and two were rinsed with tap water, dried, then sampled for culture. Three cultures (aerobic, anaerobic, and fungal) were taken for each of the four polyethylene inserts for a total of 12 control cultures.

2.8. Specimen cultures

On the first round of experiments, each polyethylene was swabbed and cultured for aerobic, anaerobic, and fungal cultures according to institutional protocols in the clinical microbiology laboratory. For the second round, each device was removed, placed into a 4th sterile specimen cup and was sonicated according to institutional standards. Specifically, each polyethylene was covered with sterile saline, vortexed for 30 s, sonicated for five minutes at 40 kHz (Branson 5510, Marshall Scientific, Hampton, NH), and vortexed for an additional 30 s. The saline was then transferred to 50 mL conical tubes and centrifuged at 4000 rpm for five minutes. The supernate was then removed and the sediment from each tube was combined prior to plating on culture plates. Aerobic cultures were held for three days, anaerobic cultures were held for 14 days, and fungal cultures were held for eight weeks.

2.9. Statistical analysis

The outcome variable of interest was a positive culture of any kind. The total proportion of positive cultures for each group was compared using the Fisher exact test. Statistical analysis was performed using RStudio software (RStudio, Inc., Boston, MA) [11].

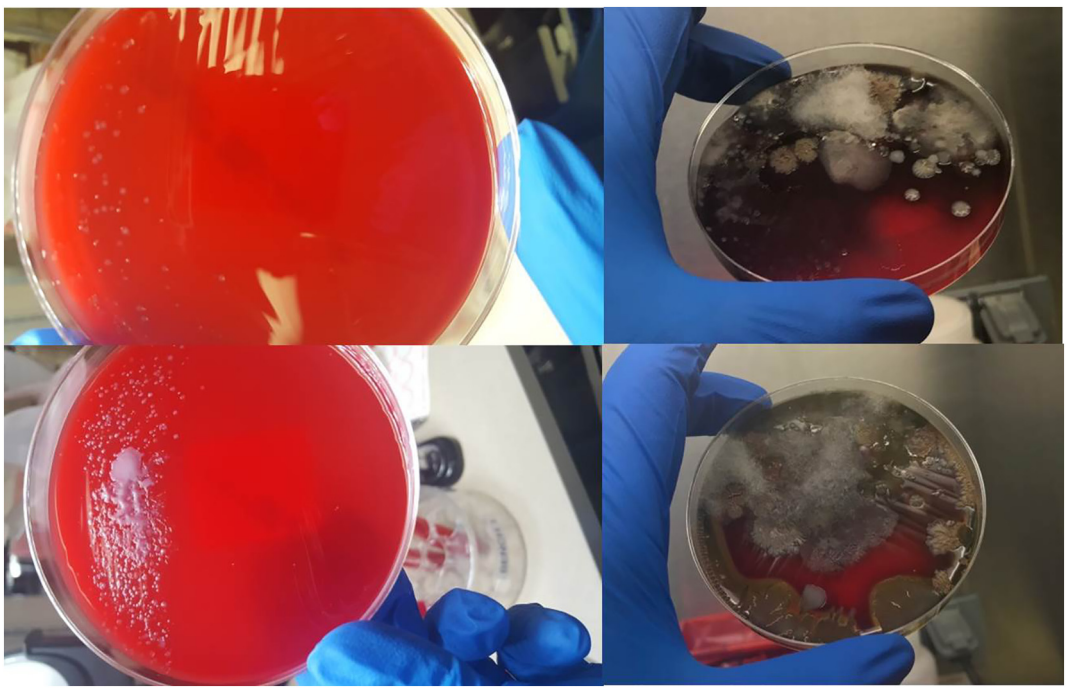

Figure 3. Photographs of the aerobic culture plates obtained by swabbing brushed and rinsed control polyethylene inserts (top row) or brushed alone polyethylene inserts (bottom row) at day one (left column) and two weeks (right column).

3. Results

3.1. Controls

All culture samples taken from the control polyethylene grew multiple colonies. Rinsed polyethylene had a qualitatively smaller density of colonies (Figure 3), but, both control protocols yielded florid, polymicrobial cultures.

3.2. Hydrogen peroxide

Neither of the two polyethylene insets processed with the hydrogen peroxide protocol and swabbed for culture grew organisms; however, one of the two polyethylene inserts processed with the hydrogen peroxide protocol and then sonicated grew a single colony of *Ralstonia* species on an aerobic culture medium. The remainder of the anaerobic and fungal cultures were negative. When compared to controls, there was a significant difference in total positive cultures in the hydrogen peroxide group (1/12 vs 12/12, $p < 0.001$, Table 1). When comparing the number of specimens with persistent contamination (any device with at least one positive culture), however, no significant difference between hydrogen peroxide and controls was observed (1/4 vs 4/4, $p = 0.1429$, Table 2).

3.3. Chlorhexidine

None of the four polyethylene inserts processed with the chlorohexidine protocol grew any organisms in aerobic, anaerobic, or fungal culture media. This was a significant difference from the controls with respect to both total positive cultures (0/12 vs 12/12, $p < 0.0001$) and persistent contamination of the polyethylene (0/4 vs 4/4, $p = 0.0286$).

3.4. Povidone-iodine

None of the four polyethylene inserts processed with the povidone-iodine protocol grew any organisms in aerobic, anaerobic, or fungal culture media. This was a significant difference from the controls with respect to both total positive cultures (0/12 vs 12/12, $p < 0.0001$) and persistent contamination of the polyethylene (0/4 vs 4/4, $p = 0.0286$).

4. Discussion

The purpose of this work is to establish a plausible intraoperative protocol to decontaminate contaminated polyethylene inserts, using materials typically available in the operating room (OR), in a time-frame that would not unnecessarily delay the surgical procedure. We have observed that the methods of processing contaminated autografts (chlorohexidine and povidone-iodine scrubs) appear to be effective in decontaminating polyethylene while our hydrogen peroxide protocol was unable to eliminate persistent contamination.

In the clinical setting, contamination should first be avoided. In the rare scenario of a dropped custom polyethylene insert, a number of options exist but all are associated with potential compromises. Choices include: use of a different thickness polyethylene insert; conversion to an off the shelf implant system; and intra-operative attempts to decontaminate the contaminated insert. Ultimately, each case of polyethylene contamination will be unique and the pros and cons should be weighed by the surgeon prior to proceeding with definitive management. The results of this study suggest that polyethylene inserts can be reliably decontaminated with materials readily available in the OR, in a reasonable period of time.

An understanding of the process for decontaminating dropped allografts is prudent for those attempting to decontaminate dropped polyethylene. In the contaminated autograft literature, both chlorhexidine gluconate and povidone-iodine effectively decontaminated autografts with post-processing cultures free of positive results [8–10]. Presnal and Kimbrough studied the degree of contamination of autografts after a fall on the floor [7]. They cultured 50 dropped specimens and found no positive cultures, leading them to advocate for less stringent and damaging decontamination methods for dropped autografts. Bauer et al. focused on decontamination procedures for contaminated grafts [8]. They found that autoclaving, two percent chlorhexidine gluconate washes, and 10% povidone-iodine washes were effective at decontaminating dropped grafts but that autoclaving and

Table 1
Culture results for each of the treatment modalities.[a]

	Positive cultures	Negative cultures	p-Value[b]
Hydrogen peroxide	1	11	<0.0001*
Chlorhexidine gluconate	0	12	<0.0001*
Povidone-iodine	0	12	<0.0001*
Control	12	0	–

Values marked with an asterisk were significantly different compared to controls.
[a] Each polyethylene underwent three cultures: aerobic, anaerobic, and fungal.
[b] p-Values reflect the proportion of positive cultures for each group compared to controls using the Fischer Exact test.

Table 2
Persistent contamination (one or more positive cultures from one polyethylene) for each of the treatment modalities.

	Persistent contamination	Culture negative	p-Value[a]
Hydrogen peroxide	1	3	0.14
Chlorhexidine gluconate	0	4	<0.05*
Povidone-iodine	0	4	<0.05*
Control	4	0	–

Values marked with an asterisk were significantly different compared to controls.
[a] p-Values reflect the proportion of cases with persistent contamination for each group compared to controls using the Fischer Exact test.

chlorhexidine gluconate also destroyed living cells. Bruce et al. found a contamination rate of 70% of dropped osteoarticular fragments [9]. They further explored using 10% povidone-iodine or four percent chlorhexidine to decontaminate contaminated grafts. When grafts were scrubbed with these solutions, all 56 of their post-treatment cultures remained negative. Additionally, chlorhexidine was shown to be more destructive to living cells on the graft than povidone-iodine. Campbell et al. studied varying concentrations of chlorhexidine on sterility and viable autograft cells [10]. They found that grafts cleansed with the lowest attempted concentration of chlorhexidine gluconate (0.002%) had the highest number of living autologous cells while maintaining sterile cultures.

In our work to decontaminate contaminated polyethylene, we used sonication to improve our sensitivity to detect contamination, yet we also achieved culture-negative results when using chlorhexidine gluconate and povidone-iodine surgical scrub brushes and prep solutions commonly available in the operative suite. We used a higher concentration of chlorhexidine than recommended by Campbell et al. for allografts [10] as polyethylene does not contain living cells, and residual chlorhexidine is removed prior to implantation.

In addition to allograft decontamination, povidone-iodine has been used in total joint arthroplasty in an attempt to decrease postoperative wound infections. Brown et al. first described a reduction in postoperative wound infections following total joint arthroplasty by utilizing a three minute dilute povidone-iodine (0.35%) soak prior to wound closure [12]. This time requirement appears to have been adopted from the work of Cheng et al. in the setting of spine surgery where a randomized controlled trial comparing low concentration povidone-iodine (0.35%) soak to saline lavage alone demonstrated a significantly lower infection rate [13]. In our study, we observed negative cultures in all four specimens following a 30 second povidone-iodine scrub followed by a 30 second povidone-iodine submersed agitation. This was one-third the exposure time used in the aforementioned studies, but the povidone-iodine was more than 20 times more concentrated.

We chose a third experimental arm consisting of hydrogen peroxide. This method has not been described in the autograft literature. Instead, hydrogen peroxide is described by the CDC as a valid sterilization chemical in the form of liquid soaks and gas plasma. Additionally, hydrogen peroxide gas plasma is commonly used for initial sterilization of polyethylene inserts commercially. Finally, hydrogen peroxide is readily available in most operating rooms. Unfortunately, one of the four polyethylene inserts had persistent contamination despite the hydrogen peroxide protocol. While disappointing, this is not completely unexpected. Gas plasma sterilization changes the physical properties of the hydrogen peroxide and should not be considered the same as a liquid soak. Liquid hydrogen peroxide soaks require seven percent hydrogen peroxide submersion for at least six hours at 20 °C [4]. Our protocol used three percent hydrogen peroxide for a 30 second scrub and 30 second submersed agitation for a total contact time of one minute. This is much different than the CDC guidelines. It should be noted, however, that while the hydrogen peroxide protocol failed to clear all contamination in one of four polyethylene inserts, the contamination burden was much lower than the controls. This may illustrate the importance of mechanical removal of the bacteria via scrubbing as advocated by Bruce et al. [9].

This study is not without limitations. The first is the lack of distinction between high-level decontamination and sterility. Sterility assurance level (SAL) is the "probability of a viable microorganism being present on a product unit after sterilization [4]." In general, a probability of less than one in one million of a single organism surviving the sterilization process, or SAL of 10^{-6}, is considered adequate sterilization for surgical instruments [4]. This work does not attempt to prove that these protocols approach a SAL of 10^{-6}, rather, we have shown that these simple protocols significantly reduce the chance of persistent organisms on the implant. The second limitation is that we made no attempt to evaluate the damage to the polyethylene in response to our protocols. Classically, gamma irradiation sterilization was found to change the physical properties of polyethylene leading to cross-linked polyethylene [14]. Additionally, other decontamination methods have also been shown to affect this material [12,15]. It is possible that the chemical and physical decontamination methods used in this study, all of which are essentially oxidizing agents, could alter the mechanical properties or wear of the polyethylene. A third potential criticism to this work is the contamination model. Previous autograft contamination studies report 0–70% contamination rate when live tissue is dropped on the floor [7,9] with coagulase-negative *Staphylococcus* representing the most prevalent organism [9]. In this work, we used potting soil to both reliably generate bacterial growth on the controls, as well as to provide a "worst-case" representation of organisms expected to be tracked into an operating room from shoes and other sources. However, this source of contamination may have excluded nosocomial organisms. It is plausible that having a larger variety of organisms contained in the soil is more important than narrowing the contamination to a few known species of contaminant. Additionally, it should be noted that several of the polyethylene inserts, were, in fact accidentally dropped on the floor and/or in the sink of the clinical microbiology lab during the contamination process, yet no nosocomial organisms were isolated. An additional limitation of the paper is that decontamination of the

samples took place in the microbiology lab, and drying of the inserts was done under an incubation hood, which may not accurately reflect the operating theater environment. In practice, we would suggest performing the initial rinse at the scrub sink, the decontamination in a sterile dish, the second rinse in another sterile dish, followed by the alcohol drying on a sterile towel in a low-activity area of the OR. Lastly, implants on the second day were sonicated while those on the first underwent swabs alone. Sonication has been shown to increase the sensitivity of cultures taken from explanted prosthesis [16–18]. However, cultures from all four controls on both the first and second days revealed florid growth, thus we do not believe that the lower sensitivity of the culture swabs on half of the implants materially affects the conclusions of the study.

5. Conclusions

Should a one-of-a-kind polyethylene component become contaminated, surgeons should use their best judgment in determining the best course of action. Options include using a different thickness of polyethylene insert or revising the knee to an off-the-shelf implant. In addition cleaning of the contaminated implant may be considered. Based upon the results of this study, protocols using chlorhexidine and povidone-iodine both successfully eliminated bacterial growth from the contaminated polyethylene inserts.

References

[1] Martin G, Swearingen A, Culler S. Hospital outcomes and cost for patients undergoing a customized individually made TKA vs off-the-shelf TKA. JISRF Reconstr Rev 2014;4(1):103.
[2] Kim D, Lim JY, Shim KW, Han JW, Yi S, Yoon DH, et al. Sacral reconstruction with a 3D-printed implant after hemisacrectomy in a patient with sacral osteosarcoma: 1-year follow-up result. Yonsei Med J 2017;58(2):453.
[3] Li X, Wang Y, Zhao Y, Liu J, Xiao S, Mao K. Multilevel 3D printing implant for reconstructing cervical spine with metastatic papillary thyroid carcino. Spine (Phila Pa 1976) 2017;42(22):E1326–30. https://doi.org/10.1097/BRS.0000000000002229.
[4] Rutala WA, Weber DJ. Guideline for disinfection and sterilization in healthcare facilities, 2008; 2008.
[5] Kurtz SM. UHMWPE biomaterials handbook: ultra high molecular weight polyethylene in total joint replacement and medical devices. Academic Press; 2009.
[6] Fuchs S, Linnenbecker S, Langenbrinck A, Chylarecki C. Oxidation of ultra high molecular weight polyethylene as a result of sterilization. Rev Chir Orthop Reparatrice Appar Mot 2000;86(1):15.
[7] Presnal BP, Kimbrough EE. What to do about a dropped bone graft. Clin Orthop Relat Res 1993(296):310.
[8] Bauer J, Liu RW, Kean TJ, Dennis JE, Petersilge W, Gilmore A. A comparison of five treatment protocols for contaminated bone grafts in reference to sterility and cell viability. J Bone Joint Surg Am 2011;93(5):439.
[9] Bruce B, Sheibani-Rad S, Appleyard D, Calfee RP, Reinert SE, Chapin KC, et al. Are dropped osteoarticular bone fragments safely reimplantable in vivo? J Bone Joint Surg Am 2011;93(5):430.
[10] Campbell J, Filardo G, Bruce B, Bajaj S, Friel N, Hakimiyan A, et al. Salvage of contaminated osteochondral allografts: the effects of chlorhexidine on human articular chondrocyte viability. Am J Sports Med 2014;42(4):973.
[11] Team R. RStudio: integrated development for R. Boston, MA: RStudio, Inc.2015 URL http://www.rstudio.com.
[12] Brown NM, Cipriano CA, Moric M, Sporer SM, Della Valle CJ. Dilute betadine lavage before closure for the prevention of acute postoperative deep periprosthetic joint infection. J Arthroplasty 2012;27(1):27.
[13] Cheng M-T, Chang M-C, Wang S-T, Yu W-K, Liu C-L, Chen T-H. Efficacy of dilute betadine solution irrigation in the prevention of postoperative infection of spinal surgery. Spine 2005;30(15):1689.
[14] Goldman M, Pruitt L. Comparison of the effects of gamma radiation and low temperature hydrogen peroxide gas plasma sterilization on the molecular structure, fatigue resistance, and wear behavior of UHMWPE. J Biomed Mater Res A 1998;40(3):378.
[15] Shigematsu M, Kitajima M, Ogawa K, Higo T, Hotokebuchi T. Effects of hydrogen peroxide solutions on artificial hip joint implants. J Arthroplasty 2005;20(5):639.
[16] Trampuz A, Piper KE, Jacobson MJ, Hanssen AD, Unni KK, Osmon DR, et al. Sonication of removed hip and knee prostheses for diagnosis of infection. N Engl J Med 2007;357(7):654.
[17] Janz V, Wassilew GI, Kribus M, Trampuz A, Perka C. Improved identification of polymicrobial infection in total knee arthroplasty through sonicate fluid cultures. Arch Orthop Trauma Surg 2015;135(10):1453.
[18] Rothenberg AC, Wilson AE, Hayes JP, O'Malley MJ, Klatt BA. Sonication of arthroplasty implants improves accuracy of periprosthetic joint infection cultures. Clin Orthop Relat Res 2017;475(7):1827.