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Research Paper

Efficacy of low-dose gamma radiation sterilization of polyethylene acetabular components used in hip replacements.

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ABSTRACT

Objective: To evaluate the efficacy of sterilization of the surface and deep layers of polyethylene acetabular components used in hip arthroplasties by the exposure to low doses of gamma radiation.
Material and Methods: 15 acetabular components, made of ultrahigh molecular weight polyethylene (UHMWPE) produced by domestic industry were tested in two phases: in the first phase, the surface's sterility was studied by incubation of the components in Trypticase Soy Broth (DIFCO®). In the second phase, the sterility of the deep layer of the acetabular component was evaluated by incubation of samples of this layer, collected from regions in which there is usually greater prosthetic wear.
Results: On all the samples evaluated, both the superficial and deep layers of the acetabular component showed no evidence of bacterial growth.
Conclusion: Low-dose gamma radiation sterilization is effective in sterilizing both the superficial and deep layers of acetabular components used in hip replacements.

Keywords: Hip, Arthroplasty, Infection, UHMWPE, Trypticase Soy Broth (DIFCO®).

INTRODUCTION

Infection in hip arthroplasties is a devastating clinical condition, which significantly increases the morbidity of this surgery. Its incidence ranges from 0.2% to 1% of arthroplasties performed, representing two thousand new cases of arthroplasty infection per year in the United States.[1] Some factors may contribute to the increase or decrease in the incidence of infection in hip arthroplasty, and these are divided into intrinsic and extrinsic relative to the patient.[2]

Among the relevant intrinsic factors are: obesity, diabetes mellitus, chronic renal disease, malnutrition, immunosuppression, AIDS, ASA score > II and advanced age. In most cases, these conditions favor an increased infection rate. Therefore, adequate preoperative preparation of the patient is the best attitude that can be taken to reduce the influence of intrinsic factors in the incidence of postoperative infection. [2,3]. Considering the factors extrinsic to the patient, the most common are: antibiotic prophylaxis, aseptic surgical technique and adequate antiseptic methods, as the use of laminar flow in the operating room and proper sterilization of surgical instruments and implants.[3,4]

Ultrahigh molecular weight polyethylene (UHMWPE) is a hydrophobic polymer from the class of the polyolefins and has been successfully used in various types of orthopedic applications, due to its unique combination of physical and mechanical properties, attributed mainly to its high molecular weight. The polymer can be synthesized under controlled conditions to produce a microporous solid material, either in the form of billets (by extrusion), plates (by molding) or even directly into the implant (by compression molding). [5] The UHMWPE can be sterilized by exposure to gamma radiation at doses ranging from 25 to 40 kGy, where sterilization occurs in its surface and subsurface. [6]

When confronted with hostile environments, some bacteria transform to a latent form, which substantially diminishes its metabolic and replicative capacity. As conditions become more favorable, those bacteria can resume their activities and pathogenic capacity[7]. Considering such latent form of bacterial survival, the presence of micropores in the UHMWPE, as well as the lack of information about the depth of sterilization reached by low-dose gamma radiation in UHMWPE, the authors proposed to evaluate the efficacy of such sterilization on the surface and deep layers of

UHMWPE acetabular components used in hip arthroplasty. In order to achieve this, industry standard polyethylene acetabular components, previously sterilized by low dose gamma radiation and sealed, were used.

MATERIALS AND METHOD

The methodology had two distinct phases: the first, which considered the possibility of contamination on the external surface of the UHMWPE acetabular component, and the second, which considered the possibility of contamination of the deep layer of the UHMWPE acetabular component.

FIRST PHASE

This phase was held in an aseptic chamber, cleaned and further sterilized by UV light of 260 nm wavelength, for an hour. During the completion of all trials, good laboratory procedures were followed to minimize the risk of contamination. The opening of the 15 sealed packages containing the UHMWPE acetabular components sterilized by low-dose gamma radiation (n = 15) was accomplished with the aid of sterile scissors. Once opened, the acetabular components were removed by means of sterile forceps and placed in 250 ml of Trypticase Soy Broth (DIFCO ®) contained in a sterile polyethylene packaging. This was followed by incubation in a bacteriological incubator - BOD at the temperature of 35ºC ± 1,0ºC for 10 days, as this temperature resembles that of the human body (Figure. 1).

Figure 1. Incubation of polyethylene acetabular component in Trypticase Soy Broth (first phase).

Broth sterility control was performed by incubating, under the same conditions, packaging containing the broth, but without inoculation with the acetabular components. On day 10, visual observation, phase contrast microscopy, and Gram stain were made in order to find any possible bacterial growth.

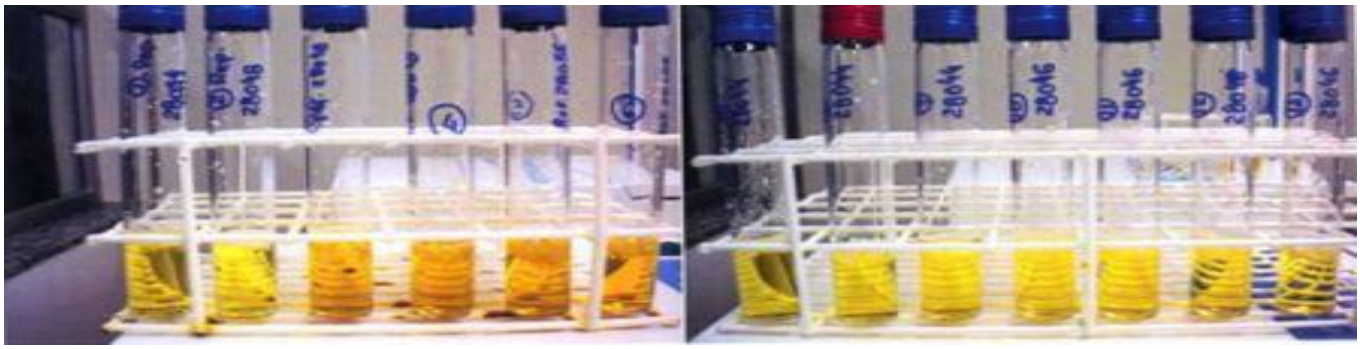
SECOND PHASE

This phase was held in an aseptic chamber, cleaned and further sterilized by UV light of 260 nm wavelength, for an hour. During the completion of all trials, good laboratory procedures were followed to minimize the risk of contamination. The opening of the package containing the UHMWPE acetabular component was accomplished with the aid of sterile forceps and scissors. To test deep layer sterility, material collection was made by drilling the polyethylene acetabular component's deep layer with the aid of an orthopedic surgical drill and a 3.0 mm drill bit previously sterilized (Figure. 2). The drilling was held on the inside of the concave region of the acetabular component and spanned its entire thickness.

Figure 2. Collection of material from the deep layer of the polyethylene acetabular component (second phase).

After these samples were collected, the UHMWPE fragments were transferred, with the aid of sterile forceps, to test tubes containing 10 mL of Trypticase Soy Broth (DIFCO ®), previously identified with the product's reference number. This was followed by incubation in a bacteriological incubator - BOD at a temperature of 35ºC ± 1,0ºC for 10 days (Figure. 3).

Figure 3. Incubation in Trypticase Soy Broth (second phase) of the material collected from the deep layers of the polyethylene acetabular components.



Broth sterility control was also carried out by incubating, under the same conditions, tubes containing the broth, but not inoculated with the fragments. On the tenth day, visual observation, phase contrast microscopy and Gram stain were made in order to find any possible bacterial growth.

RESULTS

After the incubation period under aerobic or facultative anaerobic conditions, neither broths containing the samples used for verifying neither the surface's sterility, nor those destined for checking the sterility of the deep layers, presented with turbidity at visual observation. There was also no evidence of bacterial growth or presence of viable facultative microorganisms after the phase-contrast microscopy and the Gram stain analysis.

DISCUSSION

Infection in hip arthroplasty has already been defined by Fitzgerald, dividing the infection in stage I (acute), stage II (indolent) and stage III (hematogenous or late), with stages II and III having a more difficult diagnosis. [8,9]

The most frequent microorganisms related to hip arthroplasty infections are gram-positive bacteria (66%), being *Staphylococcus epidermidis* (47%) and *Staphylococcus aureus* (23%) the most prevalent. The other 34% are divided among gram-negative bacteria such as *Escherichia coli*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, and gram-positive anaerobes such as *Clostridium bifermentans, Propionibacterium acnes*[10]. Noting that these microorganisms are commonly found in a latent form in our environment.[7]

The diagnosis of infection in arthroplasty can be straightforward, as seen in stage I, which occurs over a period of up to twelve weeks postoperatively and is characterized by pain, heat, redness, and possible purulent wound drainage in the operated hip. However, stages II and III, which usually occur six to twenty-four months postoperatively, can be more difficult to diagnose. In these cases, tests such as erythrocyte sedimentation rate, C-reactive protein, scintillography, arthrography and articular aspirates are used, along with the patient's clinical status and radiological follow-up, in the diagnosis of infection.[2,3] Of these, the articular aspirate has the highest sensitivity and specificity for confirming infection of arthroplasties. Nevertheless, it has up to 16% rate of false-positives.[1,9] New studies have shown an increase in both sensitivity and specificity from the association between preoperative articular aspirate and histopathologic analysis of intraoperative biopsy.[1,9] Thus demonstrating that local studies from the infection site have higher sensitivity and specificity for the diagnosis of infection.

Sochard describes the existence of polyethylene particles in the periprosthetic medium of hip arthroplasties, deposited after its wear over the years, as the cause of periprosthetic osteolysis and aseptic loosening. [(11)]

On the other hand, Kobayashi describes the detection of bacterial genes using polymerase chain reaction (PCR) in arthroplasties without clinical or laboratory evidence of infection, demonstrating an incidence of 12% positivity for bacterial DNA. This puts into question the fact that these are truly aseptic loosening and casts doubt on the mechanism by which the microorganisms infect the prosthetic .[(12)]

Crowninshield states that UHMWPE can be sterilized by exposure to gamma radiation at a dose of 25 to 40 kGy, in which sterilization occurs at its surface and subsurface, however, the extension of the subsurface is not clearly defined. [6]

The present study adds further evidence for the efficacy of low-dose gamma radiation in the sterilization, not only of the surface and subsurface, but also of the deep layer of the UHMWPE acetabular component.

Ainscow describes the hematogenous route as the most common for late infections. [8] However, to rule out the presence of microorganisms in a state of latency in the body of the polyethylene is an important step in tracking the site that originates the infection, since there is no description in the literature of the possibility of microorganisms under latent form being found in the body of the polyethylene.

In the present study there was no motivation to carry out a control group, because the sterilization method tested is not being compared to another and the formulation of a control group in this case should contain polyethylene non-sterilized, which obviously make positive our culture, but without comparison value, except that it had occurred a bacterial growth in the sterile group during our study. Yet the fact that there would never be in practical life the use of a non-sterilized polyethylene in a hip replacement surgery.

CONCLUSION

Under the conditions observed on this study, sterilization by low-dose gamma radiation is effective in sterilizing both the superficial and deep layers of the polyethylene acetabular components used in hip arthroplasties.

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