



This is an enhanced PDF from The Journal of Bone and Joint Surgery

The PDF of the article you requested follows this cover page.

Rapid Polyethylene Failure of Unicondylar Tibial Components Sterilized with Gamma Irradiation in Air and Implanted After a Long Shelf Life

Thomas F. McGovern, Deborah J. Ammeen, John P. Collier, Barbara H. Currier and Gerard A. Engh
J Bone Joint Surg Am. 2002;84:901-906.

This information is current as of December 11, 2009

Supplementary material

Commentary and Perspective, data tables, additional images, video clips and/or translated abstracts are available for this article. This information can be accessed at <http://www.ejbjs.org/cgi/content/full/84/6/901/DC1>

Letters to The Editor are available at
<http://www.ejbjs.org/cgi/content/full/84/6/901#responses>

Reprints and Permissions

Click here to [order reprints or request permission](#) to use material from this article, or locate the article citation on jbjs.org and click on the [Reprints and Permissions] link.

Publisher Information

The Journal of Bone and Joint Surgery
20 Pickering Street, Needham, MA 02492-3157
www.jbjs.org

RAPID POLYETHYLENE FAILURE OF UNICONDYLAR TIBIAL COMPONENTS STERILIZED WITH GAMMA IRRADIATION IN AIR AND IMPLANTED AFTER A LONG SHELF LIFE

BY THOMAS F. MCGOVERN, MD, DEBORAH J. AMMEEN, BS, JOHN P. COLLIER, DE,
BARBARA H. CURRIER, MChE, AND GERARD A. ENGH, MD

Investigation performed at Anderson Orthopaedic Research Institute, Alexandria, Virginia

Background: The mechanical toughness of polyethylene that has been sterilized by gamma irradiation in air decreases after a long shelf life. The purpose of the present study is to report the high failure rate after unicondylar knee replacements performed with polyethylene bearings that had been sterilized with gamma irradiation in air and implanted after a shelf life of ≥ 4.4 years.

Methods: Between December 1997 and January 2000, seventy-five unicondylar knee replacements were performed in sixty-two patients. All patients were followed both clinically and radiographically. A revision operation was offered when the patient had pain, swelling, and radiographic evidence of rapid polyethylene wear. The effect of aging of the polyethylene during storage was evaluated by dividing the knees into three groups on the basis of shelf life and comparing them with regard to the rate of revision and the observed wear of the polyethylene. Four retrieved components were examined for the presence of oxidation.

Results: At a mean of eighteen months after the arthroplasty, thirty knees had been revised and seven were scheduled for revision. The rate of polyethylene wear increased as the shelf life increased. There was a significant inverse linear correlation between the shelf life of the polyethylene and the time to revision ($p < 0.01$, $r^2 = 0.64$). All retrieved components had greater-than-expected wear with pitting and delamination of the surface. Seven components had fractured, and ten had both fractured and fragmented. Analysis of four components confirmed severe oxidation of the polyethylene.

Conclusion: The present study demonstrated early, severe wear of tibial polyethylene bearings that had been sterilized by gamma irradiation in air and stored for ≥ 4.4 years. This risk can be minimized by ensuring that implants have not been sterilized with gamma irradiation in air and stored for several years.

For almost twenty years, gamma irradiation in air was the industry standard for the sterilization of ultra-high molecular weight polyethylene implants used for knee arthroplasty. Implant manufacturers discontinued this method of sterilization after laboratory investigations demonstrated that free radicals are created by gamma irradiation in air, making the polyethylene prone to oxidation and decreasing its mechanical toughness¹⁻⁴. The level of oxidation before implantation is directly related to the duration of exposure to oxygen before implantation (the shelf life of the bearing). Despite the discontinuation of this method, many implants that have been sterilized by gamma irradiation in air remain available in the inventories of manufacturers, company representatives, and

hospitals. In addition, the method and date of sterilization of some of these implants is not readily accessible to the orthopaedic surgeon.

In the course of routine postoperative surveillance, the senior author (G.A.E.) noted a pattern of early failure and observed severe polyethylene wear at the time of revision among patients who had received the same type of bearing. These findings prompted a more in-depth review of the patients in whom this type of prosthesis had been used. The present study was designed to test the hypothesis that the duration of storage of a polyethylene bearing after gamma irradiation in air has a strong direct correlation with the wear properties of the bearing and with the rate of failure of the arthroplasty.

TABLE I Shelf Life and Wear Category of Retrieved Bearings*

Shelf Life	No. Revised	Wear Category		
		Grade I	Grade II	Grade III
≥4 yr (range, 53 to 59 mo) (n = 8)	1	1	0	0
≥5 yr (range, 60 to 71 mo) (n = 36)	15	7	5	3
≥6 yr (range, 72 to 83 mo) (n = 29)	12	3	2	7

*The data are given as the number of bearings.

Materials and Methods

Between December 1997 and January 2000, a single surgeon (G.A.E.) performed unicondylar knee arthroplasty for the treatment of medial compartment osteoarthritis in sixty-two consecutive patients (seventy-five knees). Thirteen patients had a bilateral procedure. The Duracon unicompartmental implant system (Stryker Osteonics Howmedica, Rutherford, New Jersey) was used exclusively during this period. The tibial components were all-polyethylene, nonmodular implants that were sterilized with use of gamma irradiation in air. At the time of implantation, the surgeon was not aware of the method of sterilization or the shelf life of the tibial components.

All patients had a routine clinical and radiographic follow-up evaluation at six weeks, four months, and annually thereafter. An anteroposterior weight-bearing radiograph and a 90° flexed lateral radiograph were made at each interval. The occurrence of early clinical failure (within two years after the arthroplasty) in several patients and the discovery of severe polyethylene wear at the time of revision surgery led to an investigation into the shelf life of the tibial bearing.

The product lot number and the catalog number of the seventy-five implants were identified from the operative record of each patient. The lot number was used to determine the sterilization date and to calculate the shelf life of the bearing. Two tibial bearings had a shelf life of less than two years, whereas the others had a shelf life of 4.4 to 6.9 years.

When the investigation revealed that the tibial bearing had a prolonged shelf life, clinical and radiographic evaluation was performed every six months rather than annually. To identify polyethylene wear, the anteroposterior weight-bearing radiographs made at each follow-up examination were compared with those made six weeks after implantation (Figs. 1-A and 1-B).

A revision operation was offered when the patient had pain, swelling, and radiographic evidence of accelerated polyethylene wear.

All revised tibial bearings were examined visually in the laboratory and were categorized according to the severity of wear. Grade-I wear was characterized by extensive regions of delamination and deep pitting; grade-II wear, by delamination, pitting, and at least one full-thickness fracture extending from the bearing surface to the cement mantle; and grade-III wear, by several full-thickness fractures that had re-

sulted in fragmentation of the bearing in situ. The laboratory examination also included measurement of the minimum implant thickness of the nonfragmented bearings with use of digital calipers.

Radiographic Measurements of Wear

The radiographs of fifty-nine knees were available for analysis of the wear rate. The remaining sixteen knees were excluded from this analysis: four had radiographs of poor quality, three had severe fragmentation of the component, seven had been lost to follow-up, and two had received an implant with a shelf life of less than two years. The standing anteroposterior radiograph that had been made nearest to the one-year postoperative interval (mean, 13.6 months; range, twelve to seventeen months) was used to measure the polyethylene thickness and to calculate the reduction in thickness during the first postoperative year. The bearing thickness was measured from the distal apex of the femoral component to the plane formed by four tantalum beads that had been embedded by the manufacturer at a position 2 mm from the bottom of the tibial component. The thickness measurements were corrected for magnification and the apparent tilt of the component. The same surgeon (T.F.M.) measured all radiographs. The accuracy of the measurement technique was evaluated by comparing the radiographic and actual measurements of the minimum implant thickness of the eighteen nonfragmented components that were retrieved at the time of revision.

Statistical Analysis

The seventy-three implants that had a prolonged shelf life were divided into three groups: those with a shelf life of at least four years (range, fifty-three to fifty-nine months), those with a shelf life of at least five years (range, sixty to seventy-one months), and those with a shelf life of at least six years (range, seventy-two to eighty-three months). The age and weight of the patient and the initial polyethylene thickness were recorded. The differences in wear rates, patient age and weight, and initial polyethylene thickness among the three groups were tested with analysis of variance and the Tukey post hoc test. The relationship between the time to revision and the shelf life was examined with regression analysis.

Documentation of Oxidation

The first four retrieved tibial components were sent to the

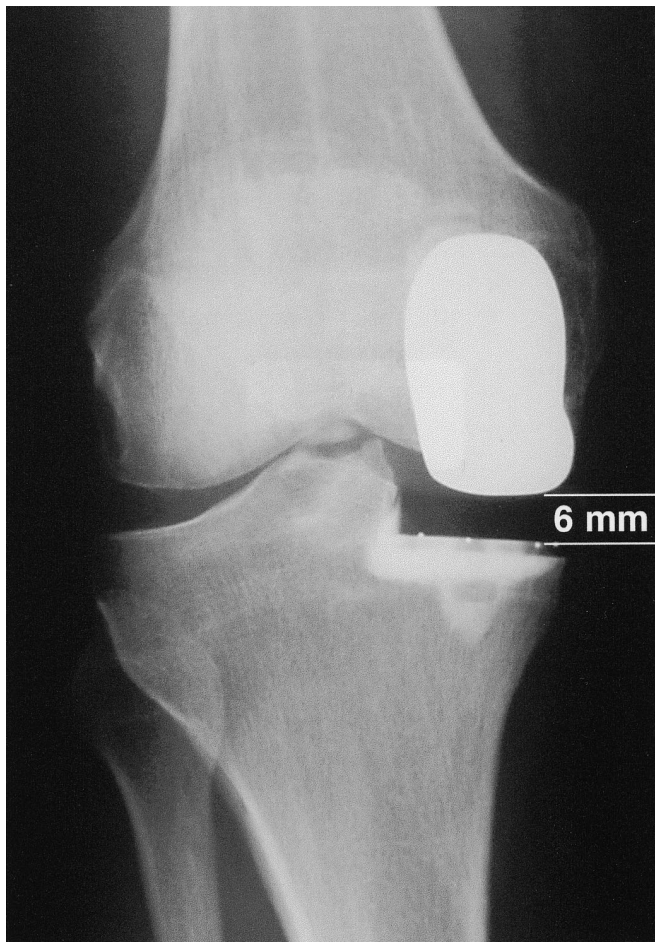


Fig. 1-A
Weight-bearing anteroposterior radiograph, made six weeks postoperatively, showing an 8-mm-thick polyethylene tibial bearing. (The marker beads are embedded 2 mm from the inferior surface of the bearing.)

Dartmouth Biomedical Engineering Center for Fourier transform infrared spectroscopy to determine the level of oxidation of each bearing. A set of thin sections of each tibial component was prepared with use of a technique that was developed to permit testing of material properties as a function of depth into the bearing⁵. A series of thin (200- μ m) horizontal sections was cut with use of a microtome⁵. A sequence of these sections, representing a depth of approximately 1 to 1.5 mm from the surface of the bearing, was taken from each sample. These sections were analyzed with Fourier transform infrared spectroscopy to measure oxidation⁵.

Results

The early postoperative course following the initial unicompartmental arthroplasty was uneventful for all patients. A pain-free, functional range of motion was achieved and lower extremity strength and gait were improving as expected with postoperative rehabilitation activities. However, within the first eighteen months, some patients began to have increased swelling and discomfort and exhibited radiographic

signs of tibial component wear. A revision operation was recommended when activity-limiting pain was not relieved with anti-inflammatory medication and accelerated polyethylene wear (>1 mm/year) was confirmed on radiographs.

The two patients in whom the tibial bearing had had a shelf life of less than two years continued to do well at the time of the latest follow-up. Of the sixty patients (seventy-three knees) in whom the bearing had had a shelf life of more than four years, thirty-two patients (thirty-seven knees; 51%) had had or were scheduled to have a revision at a mean of eighteen months after the arthroplasty. This group included twenty-five patients (twenty-eight knees; 38%) who had had a revision at our institution, five patients (six knees; 8%) who were scheduled to have a revision at our institution, and two patients (three knees; 4%) who had had or were scheduled to have a revision at an outside institution. The remaining patients continued to be monitored carefully.

With the numbers available, there were no significant differences among the three shelf-life groups with regard to the age or weight of the patients or the initial thickness of the polyethylene bearing.

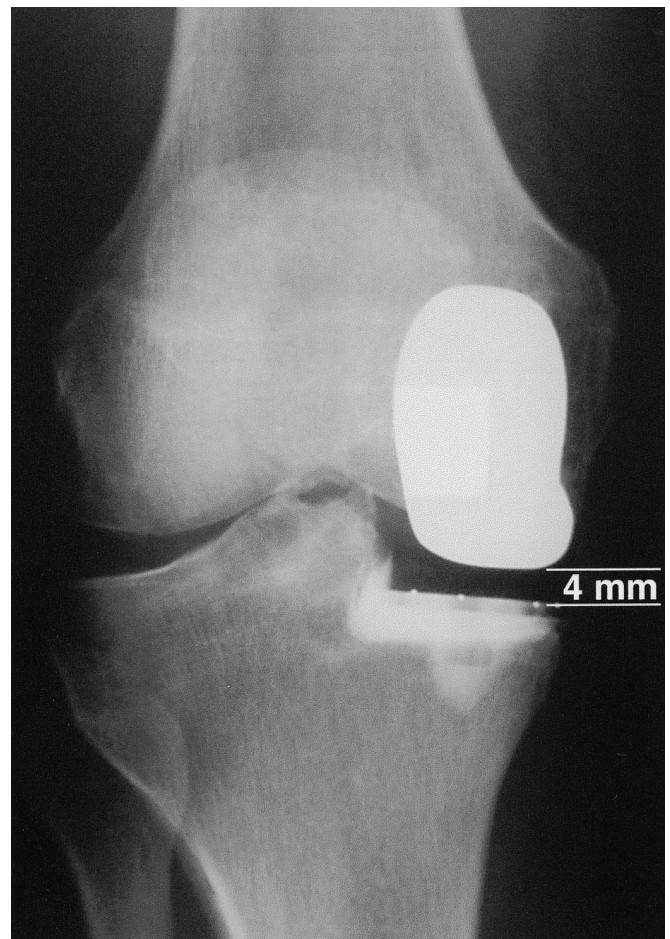


Fig. 1-B
Radiograph, made thirteen months postoperatively, showing 2 mm of polyethylene wear.

Revisions

The mean time to revision arthroplasty for the twenty-eight knees that were revised at our institution was eighteen months (range, seven to thirty months). The intraoperative findings in all knees included a large effusion, hypertrophic synovial tissue, loose fragments of delaminated polyethylene, and a visibly worn tibial component. There was no evidence of osteolysis in the distal part of the femur or the proximal part of the tibia. The femoral component was well fixed in all knees. The deepest wear was noted in the region where the polyethylene bearing surface was in contact with the femoral component with the knee in full extension. The bearings without full-thickness cracks or fragmentation remained fixed to the proximal part of the tibia, the bearings with full-thickness cracks but without fragmentation were easily removed along with the attached polymethylmethacrylate, and the fragmented bearings were grossly loose.

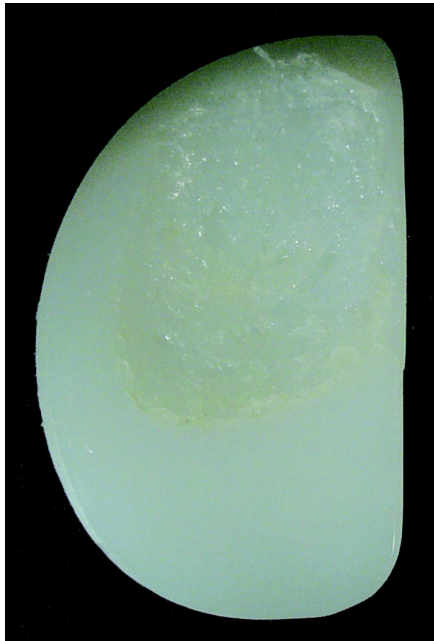


Fig. 2-A

Grade-I wear. This bearing had a shelf life of seventy-eight months and was retrieved twelve months after implantation. The bearing surface has extensive delamination and pitting.

Inspection of Retrieved Implants

Twenty-eight retrieved polyethylene tibial bearings were examined and categorized for wear. All bearings had clearly visible fatigue wear (Table I). Eleven components had grade-I wear (Fig. 2-A), seven had grade-II wear (Fig. 2-B), and ten had grade-III wear (Fig. 2-C). There was a significant inverse linear correlation between the shelf life of the implant and the time to revision ($p < 0.01$, $r^2 = 0.64$) (Fig. 3).

The four retrieved tibial bearings that were analyzed with Fourier transform infrared spectroscopy were found to be highly oxidized. The oxidation level of the bearings in this study was of the same magnitude (3.4 to 4.4) as that of the tibial bearings in the study by Currier et al.⁶, which had been sterilized with gamma irradiation in air and had a shelf life of six to nine years.

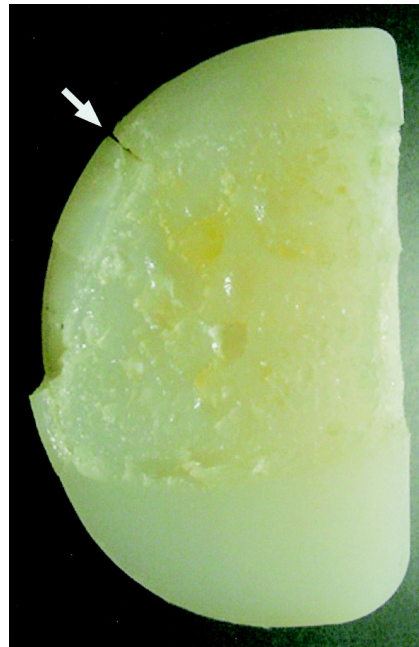


Fig. 2-B

Grade-II wear. This component had a shelf life of sixty-five months and was revised twenty-one months after surgery. The bearing surface has severe delamination, pitting, and a full-thickness crack (arrow) that extended into the cement mantle.

Polyethylene Wear Rate

There was a strong linear correlation between the actual and radiographic measurements of the minimum thickness of the eighteen bearings that had been retrieved intact ($p < 0.01$; $r^2 = 0.93$). The mean difference (and standard deviation) was -0.13 ± 0.32 mm (range, -0.8 mm to 0.4 mm).

The wear rate increased as the shelf life increased. The mean wear rate was 0.9 mm/year for the implants with a shelf life of at least four years, 1.6 mm/year for those with a shelf life of at least five years, and 1.7 mm/year for those with a

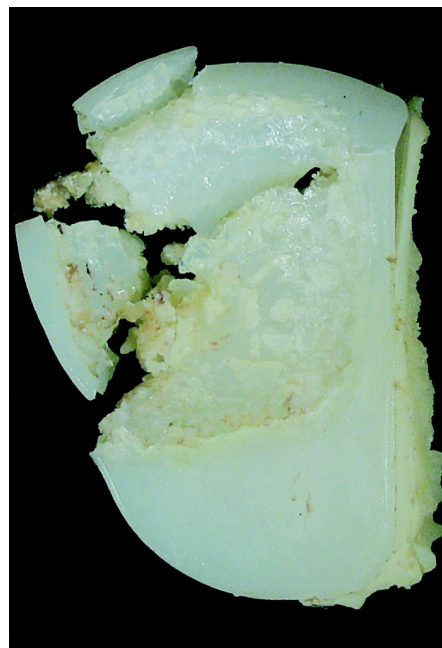


Fig. 2-C

Grade-III wear. This component had a shelf life of seventy-three months and was revised seventeen months after surgery. The bearing has severe fatigue wear with fragmentation of the polyethylene.

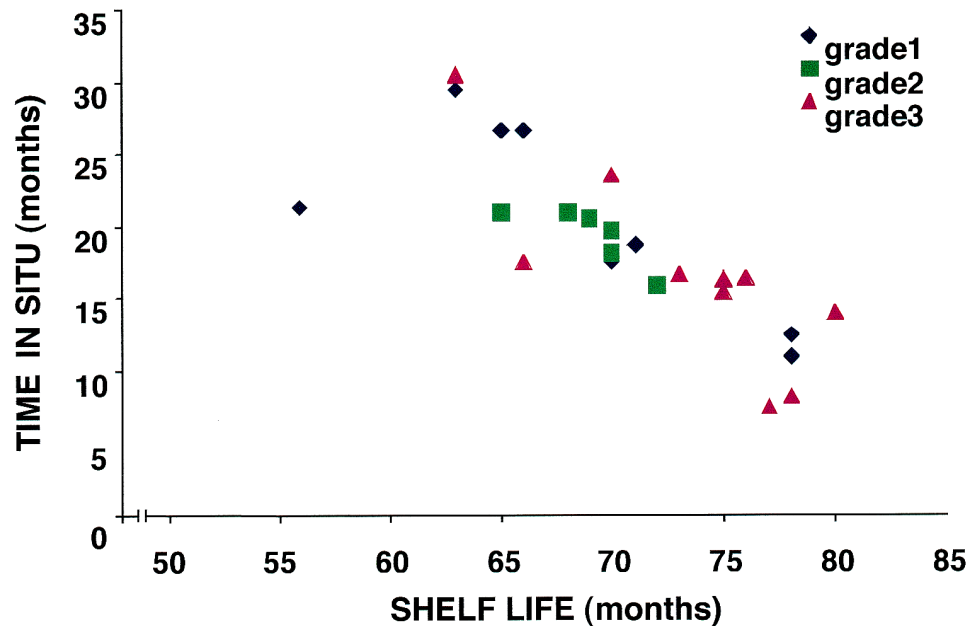


Fig. 3

Illustration depicting the relationship between the time in situ and the shelf life of revised tibial bearings.

shelf life of at least six years. The mean wear rate in the four-year group was significantly different from that in the six-year group ($p = 0.045$).

Discussion

Deterioration of the mechanical toughness of polyethylene bearing surfaces has been demonstrated *in vitro*^{2,4}, and accelerated wear of highly oxidized ultra-high molecular weight polyethylene bearings has been described in anecdotal reports². The findings of the present study demonstrate that accelerated wear and failure can occur *in vivo* as a result of a loss of mechanical toughness secondary to the oxidation of this material.

Bearing surface wear is unavoidable, and multiple factors contribute to the wear rate after knee arthroplasty. The alterations of the mechanical properties of polyethylene associated with gamma irradiation in air and shelf life have been demonstrated in the laboratory⁶⁻⁸ as well as in case studies⁹. All four of the tibial bearings that were analyzed with spectroscopy in the present study exhibited extremely high levels of oxidation. The findings of previous studies⁶ suggest that these levels of oxidation were sufficient to alter the mechanical properties of the polyethylene and to lead to rapid failure under load. Two of these bearings had been stored for long enough (>6.5 years) to have reached an oxidation level that was sufficient to reduce the toughness of the polyethylene to <10% of its original value. The almost immediate failure of these bearings *in vivo* was consistent with deterioration of the mechanical properties. The other two bearings, which had a somewhat shorter shelf life before implantation (4.5 and 5.5 years), would be expected to have a somewhat lower level of oxidation and slightly better mechanical properties at the time of implantation. However, *in vivo* oxidation may have further reduced their mechanical

properties to a level that caused them to fail less than two years after implantation.

Examination of the retrieved tibial bearings in the present study showed accelerated fatigue wear and early rapid failure with early delamination, and, in some cases, fracture and fragmentation. In the multicenter study by Lindstrand et al.¹⁰, acceptable clinical results were reported in association with the Duracon unicondylar implant after a follow-up interval of one to six years. Those authors did not report early wear and rapid failure of the tibial bearing as a reason for revision in their study, which suggests that shelf life was not an issue.

In the present study, thirty-seven (51%) of the seventy-three tibial bearings with a prolonged shelf life had been revised or were scheduled for revision at a mean of eighteen months (range, seven to thirty months) after implantation. We anticipate that all such bearings will need to be revised eventually because of premature fatigue failure of the polyethylene. On the basis of these preliminary data, we recommend that surgeons maintain a heightened awareness of the potential for rapid failure of knee bearings that were sterilized by gamma irradiation in air and were subjected to a prolonged shelf life. In the current study, the surgeon could not determine the shelf lives of the bearings on the basis of the component packaging. Although the information was present in the product lot number, the meaning of the code was not known.

Furthermore, we recommend that if a patient presents with radiographic evidence of accelerated wear within the first few years after an arthroplasty, he or she should be monitored on a regular basis both clinically and radiographically. The surgeon should contact the manufacturer to obtain the sterilization method and the shelf life of the implant as part of the diagnostic workup. If the polyethylene bearing was sterilized

with gamma irradiation in air and remained unimplanted and exposed to oxygen for several years before implantation, the surgeon and the patient should discuss the likely need for early revision of the bearing. Finally, the surgeon should be aware of the potential for implants that were sterilized with gamma irradiation in air to remain undetected in inventory. Preoperative verification that the polyethylene was not sterilized with gamma irradiation in air could safeguard against this type of early fatigue failure in the future. ■

Thomas F. McGovern, MD
Deborah J. Ammeen, BS
Gerard A. Engh, MD

Anderson Orthopaedic Research Institute, 2501 Parker's Lane, Suite 200, Alexandria, VA 22306. E-mail address for T.F. McGovern, D.J. Ammeen, and G.A. Engh: ammeen@aori.org

John P. Collier, DE
Barbara H. Currier, MChE
Thayer School of Engineering, Dartmouth College, 8000 Cummings Hall, Hanover, NH 03755

The authors did not receive grants or outside funding in support of their research or preparation of this manuscript. They did not receive payments or other benefits or a commitment or agreement to provide such benefits from a commercial entity. No commercial entity paid or directed, or agreed to pay or direct, any benefits to any research fund, foundation, educational institution, or other charitable or nonprofit organization with which the authors are affiliated or associated.

References

1. **Bargmann LS, Bargmann BC, Collier JP, Currier BH, Mayor MB.** Current sterilization and packaging methods for polyethylene. *Clin Orthop.* 1999; 369:49-58.
2. **Currier BH, Currier JH, Collier JP, Mayor MB, Scott RD.** Shelf life and in vivo duration. Impacts on performance of tibial bearings. *Clin Orthop.* 1997;342:111-22.
3. **McKellop H, Shen FW, Ota T, Lu B, Wiser H, Yu E.** Wear of UHMWPE acetabular cups after gamma sterilization in nitrogen, thermal stabilization and artificial aging. *Trans Soc Biomaterials.* 1997;23:45.
4. **McNulty DE, Hastings RS, Swope SW, Huston DE.** Sterilization methods and artificial aging of UHMWPE resins: the relation between resilience and oxidation. *Trans Orthop Res Soc.* 1999;24:821.
5. **Collier JP, Sperling DK, Currier JH, Sutula LC, Saum KA, Mayor MB.** Impact of gamma sterilization on clinical performance of polyethylene in the knee. *J Arthroplasty.* 1996;11:377-89.
6. **Currier BH, Currier JH, Collier JP, Mayor MB.** Effect of fabrication method and resin type on performance of tibial bearings. *J Biomed Mater Res.* 2000;53:143-51.
7. **Collier JP, Sutula LC, Currier BH, Currier JH, Wooding RE, Williams IR, Farber KB, Mayor MB.** Overview of polyethylene as a bearing material: comparison of sterilization methods. *Clin Orthop.* 1996;333:76-86.
8. **Williams IR, Mayor MB, Collier JP.** The impact of sterilization method on wear in knee arthroplasty. *Clin Orthop.* 1998;356:170-80.
9. **Bohl JR, Bohl WR, Postak PD, Greenwald AS.** The Coventry Award. The effects of shelf life on clinical outcome for gamma sterilized polyethylene tibial components. *Clin Orthop.* 1999;367:28-38.
10. **Lindstrand A, Stenstrom A, Ryd L, Toksvig-Larsen S.** The introduction period of unicompartmental knee arthroplasty is critical: a clinical, clinical multicentered, and radiostereometric study of 251 Duracon unicompartmental knee arthroplasties. *J Arthroplasty.* 2000;15:608-16.