Effect of Fabrication Method and Resin Type on Performance of Tibial Bearings

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Abstract: Polyethylene has been used successfully for more than 30 years as an orthopedic bearing material. During this time, several polyethylene resins and fabrication methods have been used to produce bearings. Some bearings fail prematurely due to fatigue, which has been linked to oxidation and degradation of mechanical properties resulting from gamma sterilization in air. Fabrication method and/or resin have been hypothesized to govern whether oxidative degradation occurs in gamma-sterilized bearings. This study evaluates the effect of fabrication (machining/direct compression molding) and resin type on oxidation and the resulting mechanical properties for a large series of never-implanted bearings. While many molded bearings studied exhibit lower oxidation than machined bearings, fabrication method is not a significant predictor of oxidation. Resin type and shelf-age are found to be significant predictors of oxidation. Bearings fabricated from Himont 1900 exhibit lower oxidation than those from GUR 415/412 at comparable times after gamma in air. However, Himont 1900 bearings lose strength and elongation at lower oxidation levels than GUR 415/412 bearings. But since Himont 1900 oxidizes more slowly, Himont 1900 bearings retain mechanical properties for longer shelf times than comparable GUR 415/412 bearings. These effects are seen in retrievals as well. © 2000 John Wiley & Sons, Inc. J Biomed Mater Res (Appl Biomater) 53: 143–151, 2000

Keywords: polyethylene resin; polyethylene fabrication method; polyethylene oxidation; polyethylene mechanical properties; shelf aging

INTRODUCTION

Polyethylene has been used successfully for more than 30 years as an orthopedic bearing material. However, some polyethylene bearings fail early by fatigue, and the fatigue damage seen has been linked to gamma radiation sterilization performed in an air environment.[1,2] Sterilization by gamma irradiation in air has been documented to cause an increase in oxidation and degradation of mechanical properties that continues with time.[3–5] Because gamma irradiation breaks bonds and creates reactive sites within the polyethylene,[6] bearings that are gamma sterilized oxidize when exposed to an oxygen-rich environment, e.g., bearings gamma-sterilized in air oxidize while sitting in inventory before implantation. Shelf time before implantation can be a significant factor in the success or failure of bearings that are gamma-sterilized in air.[4]

Based on evaluation of a limited number of bearings, the material and/or fabrication method of bearings have been hypothesized to control oxidative degradation of polyethylene gamma-irradiated in air.[7,8] Historically, three types of resins have been used to fabricate implants: GUR 415, GUR 412, and Himont 1900.[9] These resin types differ in molecular weight, which affects the properties of the fabricated materials. The resins are either extruded into rod, molded into rod or sheet for machining, or are directly molded into bearings. The fabrication processes require heating the polyethylene resins above their melting points.[9] This heating increases the low molecular weight fraction of the UHMWPE resin, such that the molecular weight of the formed bearings is less than that of the original resin.[10] Gamma irradiation of the formed bearings induces free radicals, which can cross-link, recombine, or lead to oxidation and chain scission. While gamma irradiation causes substantial cross-linking, which increases the average total molecular weight of UHMWPE to almost infinity, it also increases the soluble constituents, thereby widening the molecular weight distribution.[11] This study attempts to evaluate the effect of fabrication method and resin type on oxidation and mechanical property changes over time in gamma-irradiated in air bearings on the shelf or *in vivo*.

MATERIALS AND METHODS

Sample Selection, Preparation, and Examination

Never implanted tibial bearings (100) of six designs from four manufacturers (Table I) were analyzed in this study. The

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TABLE I. Never Implanted Tibial Bearings Analyzed in this Study

Manufacturer/Design	Number Tested	Sterilization Method	Resin	Fabrication Method
A-1	22	Gamma in air	GUR 415 (21)	Machined
			Himont 1900 (1)	Machined
A-2	32	Gamma in air	GUR 412 (7)	Machined
			Himont 1900 (3)	Machined
			GUR 415 (11)	Molded
			Himont 1900 (11)	Molded
B	6	Gamma in air	GUR 412 (5)	Machined
			Himont 1900 (1)	Machined
C	10	Gamma in air	GUR 415	Machined
D-1	19	Gamma in air	Himont 1900	Molded
D-2	11	Gamma in air	GUR 415	Machined

method and date of sterilization, and method and material of fabrication for each bearing were determined from information on the implant package and discussions with the implant manufacturer. All bearings were gamma-irradiated in air and represented post-sterilization shelf-aging times of 2 months to 16.5 years. Of the 100 bearings, 58 were machined; 42 were direct compression molded (hereafter referred to as molded). Of these same 100 bearings, 53 were fabricated from GUR 415, 12 from GUR 412, and 35 from Himont 1900.

For comparison, 65 retrieved tibial bearings were included in this study. The retrieved polyethylene bearings were of the same design from one manufacturer with a range of *in vivo* duration from 5–99 months (Table II). Of the 65 retrieved bearings, 42 were molded from Himont 1900 and 23 were machined from GUR 415. The 65 retrieved bearings were from a patient population approximately evenly divided by gender (35 female, 30 male). The mean patient age for the Himont 1900 bearings was 67 years (range: 24–86 years), and the mean patient weight was 183 lb (range: 110–278 lb). The mean patient age for the GUR 415 bearings was 62 years (range: 39–92 years), and the mean patient weight was 193 lb (range: 119–315 lb).

Each retrieved tibial bearing was examined visually using a Nikon Binocular Dissecting Microscope (Nikon Corporation, Tokyo, Japan) with a magnification factor of 10. All 65 bearings were rated for clinical damage on a 0 (none) to 3 (severe) scale.[12] The clinical damage ratings for cracking and delamination were used to assess fatigue failure of the polyethylene in this set of retrievals.

To examine the material of the polyethylene bearings, one of two methods was used. One method was to cut the bearing with a band saw along a sagittal plane through a condyle exposing a vertical cross-section. Thin slices (approximately 200 μm thick) were removed parallel to the exposed cross-section using a Jung microtome (Jung, Heidelberg, Germany). The thin sections created by this technique, vertical cross-sections,[1] were used for microscopic examination.

Using the alternate method, a set of thin sections was prepared using a technique developed to permit static mechanical testing of the surface, subsurface, and center regions.[1] Two sagittal cuts, approximately 6 mm apart, were made from the anterior to the posterior surface of the tibial bearings using a band saw. Thin sections (approximately 200 μm thick) were cut parallel to the nonarticular surface using the microtome producing a series of horizontal sections.[1] A sequence of thin sections representing a depth to approximately 4 mm (20 sections) was taken from each sample.

Microscopy

Light microscopy was used to study the morphology of the polyethylene. The specimens used for microscopy were three-dimensional pieces of tibial bearings rather than microtomed thin sections, as were used in the other tests in this study. Images were taken of plan views of the articular surfaces. Light microscopy was done using a Nikon optical microscope with objective lens magnification up to 50×, using reflected and/or transmitted light, depending on the specimen. Images were taken digitally using a Sony digital camera (Model XC-75) (Tokyo, Japan), then processed using NIH Image 1.6 on a Macintosh computer (Cupertino, CA).

Fourier Transform Infrared Spectroscopy

Fourier Transform Infrared spectroscopy (FTIR) was used to determine the level of oxidation in each bearing. FTIR absorbance spectra were obtained using one of the following: a Digilab model 60A double beam spectrometer with a UMA 300 infrared microscope (Biorad Instruments, Cambridge,

TABLE II. Retrieved Tibial Bearings, Same Manufacturer, Same Design

Resin/Fabrication	Sterilization Method	Number Retrieved	% with Delamination or Cracking	Duration Range (mo.)
Himont 1900 Molded	Gamma in air	43	32	11–99
GUR 415 Machined	Gamma in air	22	36	23–61

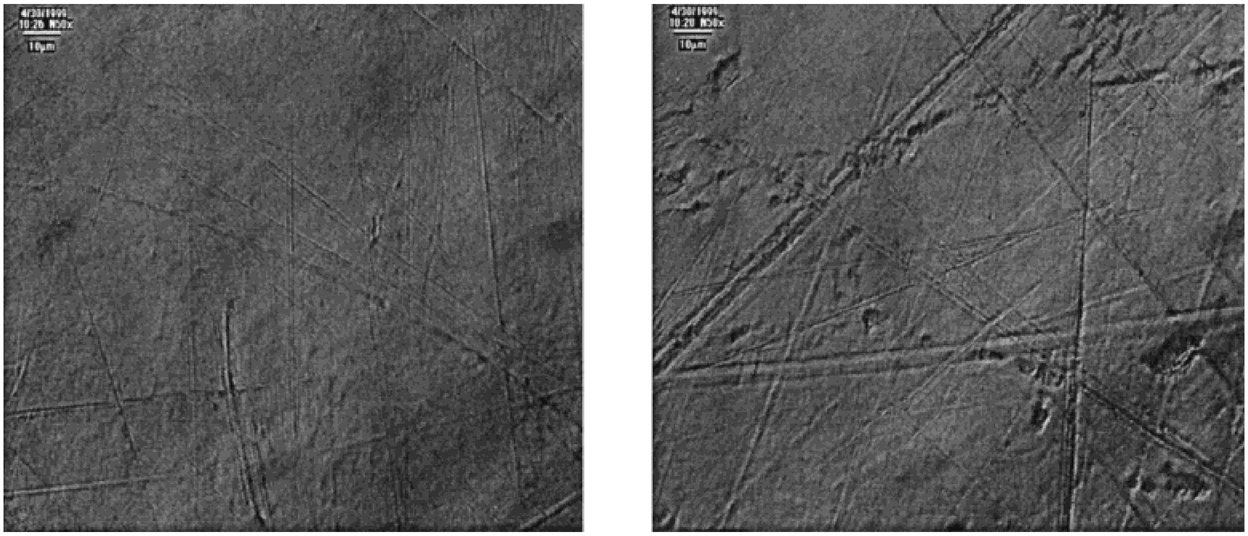


Figure 1. Light microscope images of articular surfaces from molded, never-implanted tibial bearings: (left) relatively smooth surface for molded Himont 1900; (right) more surface features for molded GUR 415. Scale bar 10 microns.

MA) with a 50 μm $\times$ 100 μm examining window, or a Perkin–Elmer Model 1605 FT-IR (Norwalk, CT), or a Perkin–Elmer Spectrum BXII (Norwalk, CT). Oxidation measurements using the infrared microscope were made vs. depth on a single vertical cross-section of each bearing. Oxidation measurements from the other two spectrometers were made on a series of horizontal thin sections, each representing a different depth into the tibial bearing.

This study focused on the incorporation of oxygen into the polyethylene by examining the carbonyl region of the FTIR spectra, wave numbers between 1800–1660 cm^{-1}. The carbonyl region, measuring carbon–oxygen double bonds, indicates the presence of ester, ketone, aldehyde, and carboxylic acid. The oxidation level of the bearing thin section was defined as the measured ketone peak height per measured thin section thickness (absorbance/mil).

Mechanical Testing

To measure the mechanical properties of each zone (surface, subsurface, and center) of a series of tibial bearings, up to 20 horizontal thin sections were taken from each bearing. Each horizontal section was stamped, using a metal die, into a dumbbell configuration suitable for mechanical testing (ASTM Type V sample because of bearing geometry limitations).[13] The gauge length was that of an ASTM Type V[13] sample, but with smaller gripping zones, again because of bearing geometry limitations. Uniaxial tension tests were performed using these dumbbell-shaped horizontal thin sections. Ultimate tensile strength and elongation at break were measured as a function of depth for these tibial bearings.

The apparatus used for the tensile testing consisted of a load frame (Model 8501 Instron Corp, Canton, MA), with a servo hydraulic actuator (Model 3398-341), and a 200 pound load cell (Model 2518-806). The thin sections were gripped by Instron Series 2712 pneumatic action grips. Specimen elongation was measured using an Instron noncontacting video extensometer (Model 2663-304) to accurately measure specimen strain. Instron Series IX Automated Materials Testing System software (Version 7.26) controlled testing and recorded output. A gauge length of 12.7 mm was used, and the samples were loaded at a nominal strain rate of 100% per min.

Statistical Methods

Several statistical methods were used for data analysis. Stata 5.0 (Stata Corp, College Station, TX), a statistics/data analysis package, was used to perform ANOVA, *t*-tests, and linear regression on selected subsets of data. ANOVA was used to determine what variables were significant predictors of oxidation level, UTS, and elongation in never-implanted bearings and in duration of retrieved bearings. Linear regression was used to determine if there was a linear relationship between oxidation and shelf age, and ultimate tensile strength (UTS) and shelf age for never-implanted bearings.

RESULTS

Light microscopy images showed that the articular surfaces of molded bearings (Fig. 1) appeared quite smooth. Machined bearing surfaces showed linear machining marks (Fig. 2) and appeared much rougher than the molded bearings.

Maximum oxidation vs. shelf age was plotted by method of fabrication and resin type for the never-implanted bearings (Fig. 3). The range of maximum oxidation for machined bearings was 0.01–0.22 absorbance units/mil for an age range of 2–198 months. The range of maximum oxidation for molded bearings was 0.009–0.194 absorbance units/mil for

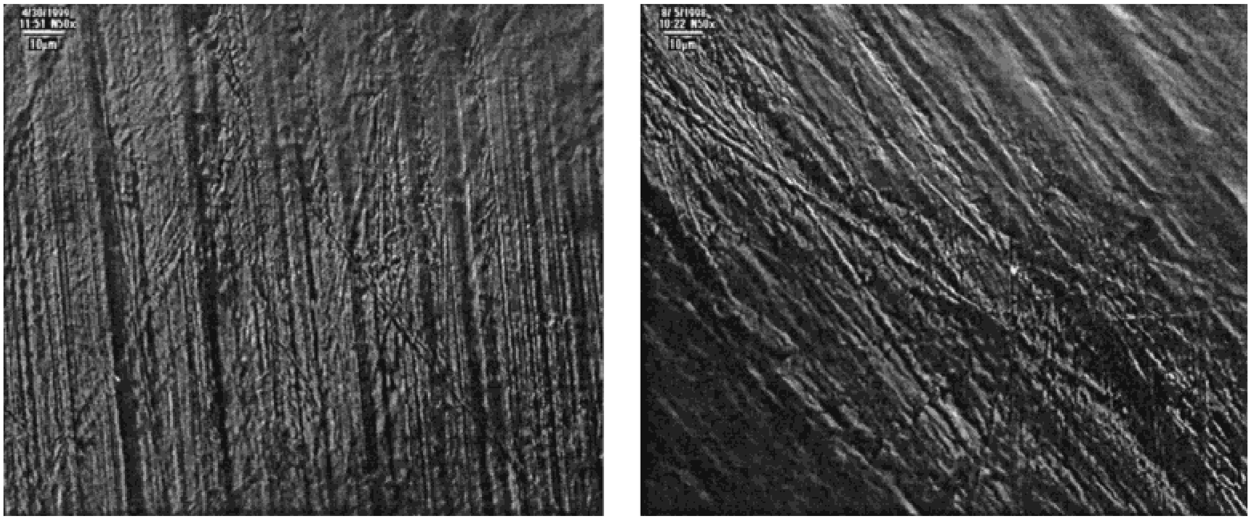


Figure 2. Light microscope images of articular surfaces from machined, never-implanted tibial bearings. Rough surfaces due to machining marks for both (left) Himont 1900 and (right) GUR 415. Scale bar 10 microns.

an age range of 14–172 months. The range of maximum oxidation for GUR 415 bearings was 0.01–0.194 absorbance units/mil for an age range of 2–106 months. The range of maximum oxidation for GUR 412 bearings was 0.022–0.22 absorbance units/mil for an age range of 44–129 months. The range of maximum oxidation for Himont 1900 bearings was 0.009–0.058 absorbance units/mil for an age range of 14–198 months. Multivariate ANOVA of these data showed that bearing age (p = 0.0000), resin type (p = 0.0000), and an interaction between resin type and fabrication method (p = 0.0000) are significant predictors of oxidation for this set of never-implanted bearings. Fabrication method was not a significant predictor of oxidation.

Linear regression of oxidation data vs. shelf age for the GUR (R^2 = 0.62) and Himont 1900 (R^2 = 0.50) resins showed that never-implanted bearings fabricated from each of the resins exhibited increasing oxidation with time. However, based on these linear regressions, bearings fabricated from GUR 415 and 412 resins oxidized at a higher rate (factor of 7) than bearings fabricated from Himont 1900 resin.

A comparison of two never-implanted, machined bearings, one GUR 412 and one Himont 1900, shows that the GUR 412

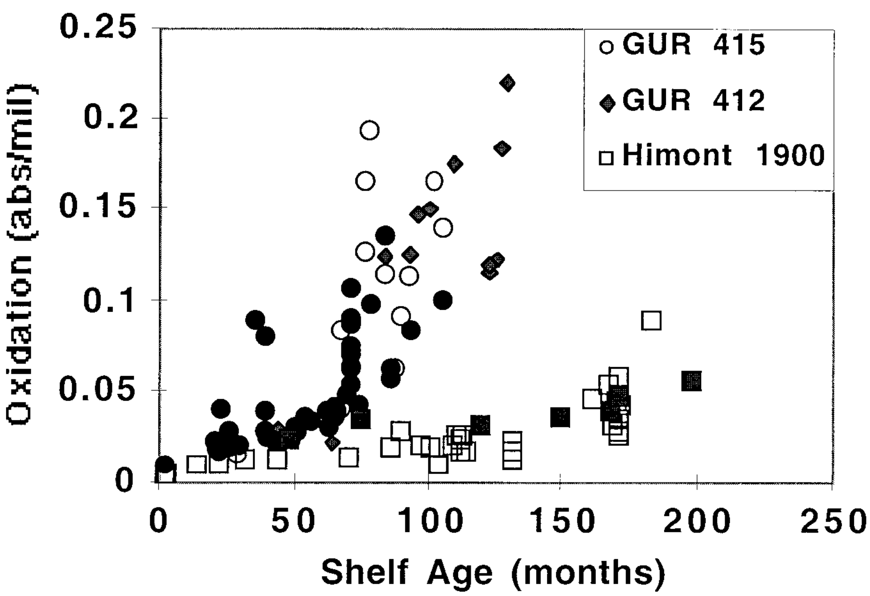
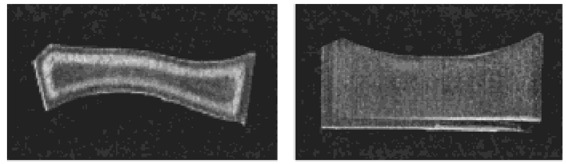


Figure 3. Oxidation (ketone peak height per mil thickness) vs. length of time on the shelf after gamma sterilization in air (shelf age) for never implanted tibial bearings. Bearings identified by resin and fabrication type (filled symbols — machined; open symbols — direct compression molded).



Resin	GUR 412	Himont 1900
Shelf Age (years)	10	12.5
Maximum Oxidation (abs/mil)	0.15	0.03
UTS @ Maximum Oxidation (MPa)	23	24
Elongation @ Maximum Oxidation (%)	10	33

Figure 4. Comparison of thin sections from tibial bearings machined from GUR 412 and Himont 1900. Visual evidence that Himont 1900 does not exhibit a subsurface white band, while newer GUR 412 has severe subsurface white band. While oxidation of GUR 412 is significantly higher, mechanical properties for bearings of both materials are similar.

bearing has much higher subsurface oxidation than does the Himont 1900 bearing, even at shorter time since gamma-sterilization in air. Microtomed cross-sections of these bearings show that the GUR 412 bearing exhibits a severe white band from microtoming, while the Himont 1900 bearing exhibits essentially no white band from microtoming (Fig. 4). The mechanical properties for both bearings are at or below ASTM minimum specifications.[14]

Ultimate tensile strength (UTS) and elongation at the depth of maximum oxidation were plotted as a function of time since sterilization for the three resin types. UTS of the GUR resins ($R^2 = 0.78$) and Himont 1900 resin ($R^2 = 0.69$) (Fig. 5) showed a linear decrease with time. Elongation (Fig. 6) decreased at shorter shelf times for tibial bearings fabricated from GUR 415 and GUR 412 resins than for bearings fabricated from Himont 1900 resin.

For bearings in which oxidation was measured from a series of horizontal sections, mechanical properties as a function of oxidation were evaluated. Multivariate ANOVA demonstrated that resin type ($p = 0.0000$) and oxidation level

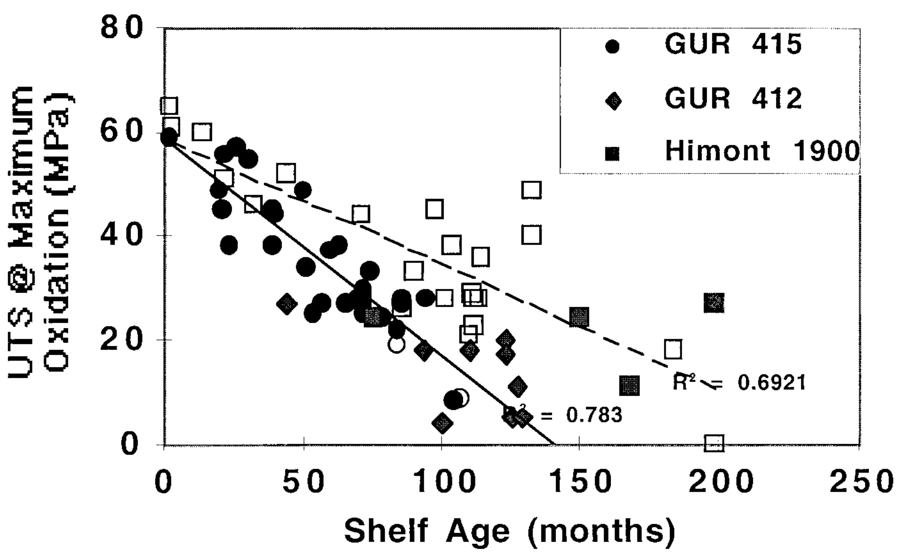


Figure 5. Ultimate tensile strength at the depth of maximum oxidation vs. shelf age for never implanted gamma-sterilized in air tibial bearings fabricated from three resins. Bearings identified by resin and fabrication type (filled symbols — machined; open symbols — direct compression molded). Tibial bearings from GUR 415 and GUR 412 lose UTS after shorter time on the shelf than bearings from Himont 1900.

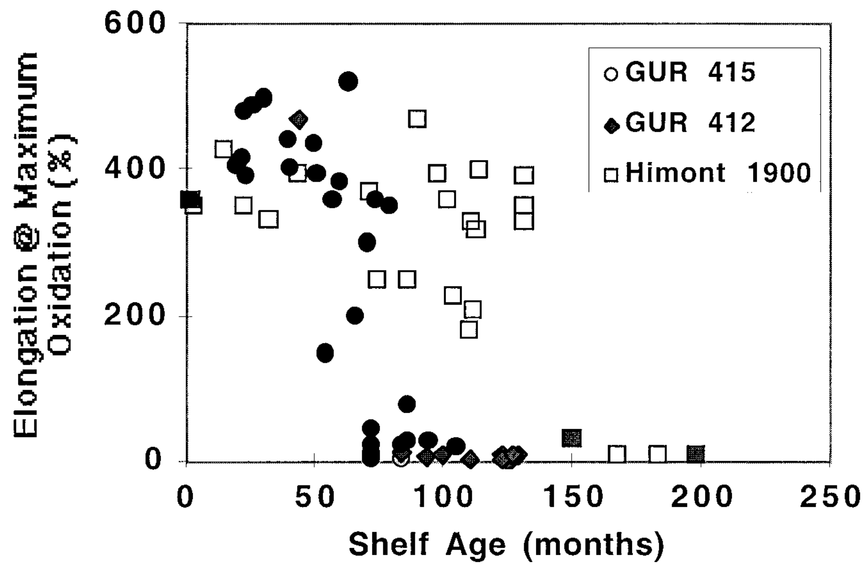


Figure 6. Elongation at the depth of maximum oxidation vs. shelf age for never-implanted gamma-sterilized in air tibial bearings fabricated from three resins. Bearings identified by resin and fabrication type (filled symbols — machined; open symbols — direct compression molded). Tibial bearings from GUR 415 and GUR 412 lose elongation after shorter time on the shelf than bearings from Himont 1900.

(p = 0.0000) are significant predictors of ultimate tensile strength (UTS) and elongation. UTS decreased as a function of increasing oxidation (Fig. 7), from a maximum of 66 MPa to a minimum of 14 MPa. Elongation first increased from around 400% to a maximum of 600% and then sharply decreased to near zero as oxidation increased (Fig. 8).

Multivariate ANOVA of the 65 retrieved tibial bearings showed that, for the retrieved bearings in this study, resin type was a significant predictor of *in vivo* duration (p = 0.0010), while patient age, weight, and gender were not. Patient activity level and pre-implantation shelf life were not evaluated as predictors of duration, because these data were not available for all 65 retrieved bearings. Only two of the 65 retrieved bearings (both molded Himont 1900) were retrieved for failure of the tibial bearing. Based on cracking and delamination ratings, 32% (14 of 43) of the bearings molded from Himont 1900 had some presence of delamination or cracking (delamination and/or cracking score of 1 or greater).

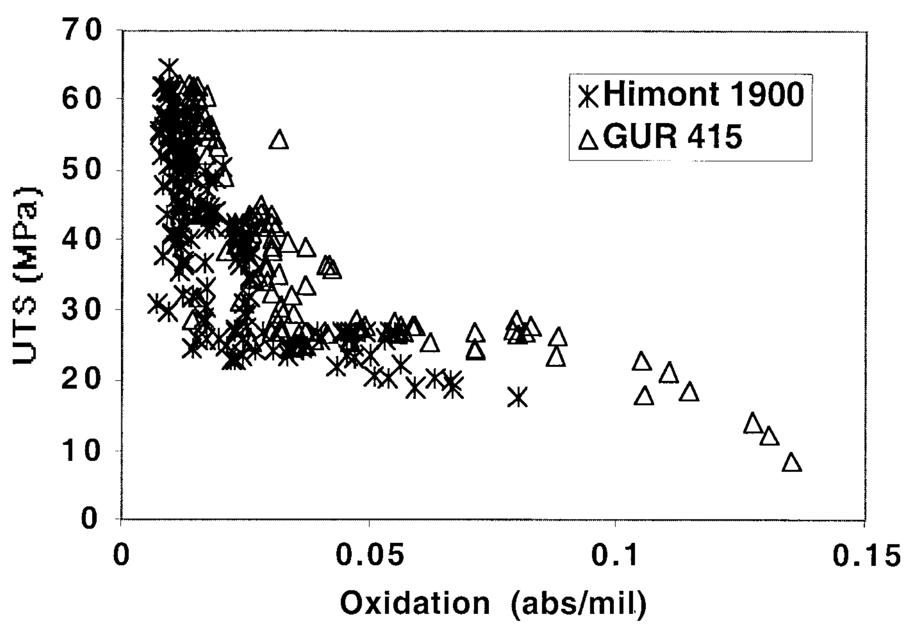


Figure 7. Ultimate tensile strength as a function of oxidation for tibial bearings from GUR 415 and Himont 1900. Bearings from Himont 1900 lose strength at lower oxidation levels than bearings from GUR 415.

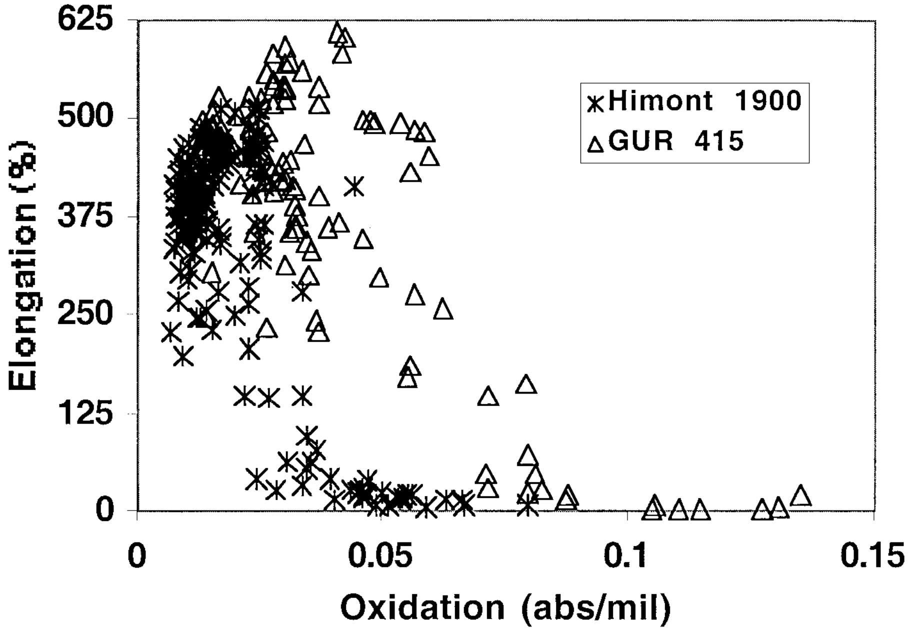


Figure 8. Elongation as a function of oxidation for tibial bearings from GUR 415 and Himont 1900. Bearings from Himont 1900 lose elongation at lower oxidation levels than bearings from GUR 415.

The *in vivo* duration of these 14 bearings ranged from 11–99 months. Of the 22 bearings machined from GUR 415, 8 (36%) had some presence of delamination or cracking. The *in vivo* duration of these 8 bearings ranged from 23–61 months (Fig. 9).

DISCUSSION

Performance of UHMWPE bearings is influenced by a variety of factors, both before and after implantation. Orthopedic implant manufacturers have control of most of the pre-implantation factors that influence performance. Two of these factors, fabrication method and resin type, have been studied for bearings that were sterilized by gamma irradiation in air. The analysis of the effect of these factors on never-implanted and retrieved tibial bearings is presented here.

The methods used to fabricate bearings are direct compression molding and machining (of either extruded bar or compression molded sheet or bar). Microscopic evaluation of molded and machined bearings would suggest that molding could have an impact on the ability of UHMWPE bearings to resist oxidation. The articular surfaces of molded bearings are much smoother than the articular surfaces of same-design, same-manufacturer, machined bearings. Additionally, data reported for USAXS (ultra-small-angle X-ray scattering)[15] suggest that ram-extruded bar stock may have spatial variations in consolidation along the radius of the bar, indicated by the presence of inter-particle regions. These inter-particle regions are most pronounced at the center of the bar. Inter-particle regions could lead to higher diffusion rates of oxygen in bearings machined from ram-extruded bar stock, potentially leading to higher oxidation rates in bearings gamma-sterilized in air. Fabrication method, however, is not found to be a significant predictor of oxidation for the series of never-implanted bearings in this study.

Resin type, along with shelf age, are significant predicators of the oxidation level measured in this series of never-implanted, shelf-aged bearings. Bearings either molded or machined from Himont 1900 have much lower oxidation levels over time on the shelf than do bearings fabricated from either GUR 415 or GUR 412. However, in contrast to suggestions in the literature that molded Himont 1900 does not oxidize significantly, if at all,[7] molded and machined Himont 1900 bearings in this study were found to oxidize at a measurable rate.

Oxidation alone, however, is not sufficient to predict the *in vivo* performance of tibial bearings in all cases. Comparison of thin sections from two never-implanted, machined bearings (one GUR 412 and one Himont 1900, Fig. 4) shows results consistent with others reported in the literature.[7] The GUR 412 bearing has a severe white band, consistent with its high oxidation. The Himont 1900 bearing has no white band and much lower oxidation, even though its shelf storage time is 2.5 years longer than the GUR 412 bearing. However, measured mechanical properties (UTS and elongation) at the depth of maximum oxidation are similar for the two bearings, even though the oxidation of the two bearings differs by almost a factor of 5. Neither bearing would meet the minimum specifications set by ASTM for implantable polyethylene bearings.[14] Based on this comparison, oxidation appears to affect the mechanical properties of the individual resins differently. The effect of oxidation on mechanical properties is key to the *in vivo* performance of bearings.[16]

While Himont 1900 oxidizes much more slowly than GUR 415 or 412, oxidation has much more of an effect on the mechanical properties of Himont 1900 than the GUR resins. Bearings fabricated from Himont 1900 lose strength at sig-

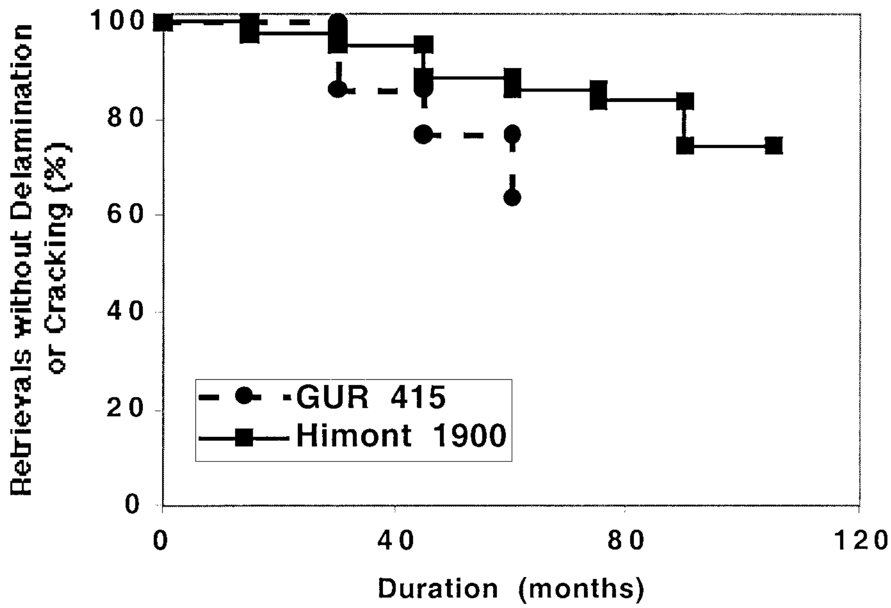


Figure 9. Percentage of retrieved bearings of same design, same manufacturer, fabricated from GUR 415 or Himont 1900 without delamination or cracking after a given duration *in vivo*. While retrieved bearings from both GUR 415 and Himont 1900 have similar ultimate percentage of retrievals with delamination or cracking, GUR 415 retrievals exhibit these fatigue wear modes after shorter duration *in vivo* than Himont 1900 retrievals.

nificantly lower oxidation levels than bearings fabricated from GUR 415. The difference in oxidation level at which UTS losses occur probably reflects the initial difference in molecular weight of the resins themselves. For both Himont 1900 and GUR resins, UTS drops to a value of around 25 MPa and plateaus at that level over a range of oxidation. The authors hypothesize that this plateau reflects the effect of increasing crystallinity on UTS that occurs as the polymer oxidizes. Increasing crystallinity, which increases UTS within a limited range, offsets the UTS losses due to increasing oxidation and decreasing molecular weight. However, as oxidation increases further, UTS again declines as the combined effects of lowered molecular weight and increased crystallinity result in a brittle material.

Elongation of UHMWPE initially increases as oxidation level increases, and then drops precipitously when a critical oxidation level is reached. This behavior is reported in thermal oxidation literature.[17] Elongation for GUR and Himont 1900 bearings follow the same increasing trend initially. However, as oxidation increases, bearings fabricated from Himont 1900 resin lose elongation at lower oxidation levels than bearings fabricated from GUR 415 resin. As in the case of UTS, the difference in oxidation level at which elongation losses occur probably reflects the initial difference in molecular weight of the resins themselves.

While Himont 1900 bearings lose strength and elongation at lower oxidation levels than GUR 415 bearings, the time for Himont 1900 bearings to reach lower mechanical properties is significantly longer than for GUR 415 bearings, by almost a factor of two. The trend of UTS and elongation with shelf time for GUR 415 resin shows a steeper decline than for Himont 1900 resin, suggesting that Himont 1900 bearings retain adequate UTS and elongation for acceptable performance longer than GUR 415 bearings during shelf storage.

The effect of oxidation on mechanical properties of shelf-aged bearings is important, especially when evaluating the efficacy of using gamma irradiated in air inventory that has been shelf stored for several years. However, the effects of oxidation on the retention of mechanical properties are seen in clinical performance as well. The performance of two groups of retrieved bearings (same design, same manufacturer, different starting resin and fabrication method) suggests that the mechanical property differences seen in the shelf-aged study carry over into *in vivo* performance. The bearings' ability to resist fatigue, determined by presence or absence of delamination or cracking, were essentially the same for the two groups of retrieved bearings in this study. The molded Himont 1900 bearings exhibited evidence of delamination or cracking in 32% of the retrieved bearings and the machined GUR 415 bearings exhibited evidence of delamination or cracking in 36% of the retrieved bearings. However, the difference in performance is apparent when comparing the duration *in vivo* prior to delamination or cracking. Figure 9 shows the difference between the molded Himont 1900 and machined GUR 415 bearings in terms of the percentage of the retrievals of each type that show no delamination or cracking at increasing duration. The percentage of "unfatigued" retrieved GUR 415 bearings (no delamination or cracking) drops sharply as duration *in vivo* increases. The percentage of "unfatigued" retrieved Himont 1900 bearings is higher than that of GUR 415 bearings for almost twice the *in vivo* duration of the GUR 415 retrievals. This difference in duration prior to the beginning of fatigue mirrors the differences in timing for loss of UTS and elongation between Himont 1900 and GUR 415 shelf-aged bearings.

These analyses have evaluated the effects of fabrication method and starting resin on the performance of bearings sitting in inventory and *in vivo*. Several factors are uncontrolled in these analyses that could have a measurable affect on oxidation: gamma dose, gamma dose rate, shelf aging environment, and individual patient variables. Resin type and shelf-time are found to be significant predictors of oxidation in bearings, while fabrication method is not. Large differences in oxidation rate between GUR 415/412 and Himont 1900 resins are found. However, these differences are offset substantially by the effect of oxidation on the mechanical properties of bearings fabricated from these resins. Bearings fabricated from Himont 1900 lose strength and elongation at lower oxidation levels than those fabricated from GUR 415. When this loss of mechanical properties is evaluated as a function of time, GUR 415/412 bearings are found to lose strength and elongation at shorter shelf storage times than Himont 1900 bearings. This difference is reflected also in the difference in duration prior to onset of delamination or cracking of retrieved GUR 415 and Himont 1900 bearings compared in this study. However, neither the GUR resins nor Himont 1900 should be considered immune to the effects of gamma irradiation, especially gamma irradiation in air. Oxidative degradation leading to mechanical property decline, and eventual bearing failure can and does occur in bearings fabricated from each of the resins studied.

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