EFFECT OF COMPONENT MALALIGNMENT AND AGING ON SEQUENTIALLY CROSSLINKED POLYETHYLENE KNEE ARTHROPLASTY INSERTS

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ABSTRACT

Malalignment of tibial components in knee arthroplasty increases the local stresses on the articular surfaces and the implant–bone interface. This can result in increased wear and in reduced implant survivorship. Computer-assisted surgical navigation has been shown to reduce implant malalignment. However, the benefit of improved alignment in terms of implant wear has not been quantified.

Crosslinking polyethylene (UHMWPE) dramatically reduces wear but has not gained widespread acceptance in knee arthroplasty. Reasons typically cited are the increased potential for failure under the high stresses present at the knee and the increased risk for oxidative damage as a result of in vivo aging. Recently, sequential crosslinking of UHMWPE has been shown to be resistant to oxidative aging. The sequential irradiation and annealing processes substantially reduce the level of free radicals. An advantage of annealing over remelting is better preservation of mechanical properties. To determine if this crosslinking process could withstand clinical conditions in the knee, sequentially crosslinking UHMWPE inserts were aged and tested under high stress conditions induced by component malalignment.

METHODS

Data from a published report of computer-assisted surgical navigation versus conventional alignment techniques were obtained. To simulate malalignment conditions we chose varus and axial tibial rotation values that were 2 standard deviations from the mean for each of these alignment techniques (conventional and navigation).

<table>
<thead>
<tr>
<th>TABLE I: MALALIGNMENT CONDITIONS</th>
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<tbody>
<tr>
<td>Conventional</td>
</tr>
<tr>
<td>Alignment</td>
</tr>
<tr>
<td>Mediolateral Load</td>
</tr>
<tr>
<td>Distribution</td>
</tr>
<tr>
<td>Tibial Internal Rotation</td>
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</tbody>
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UHMWPE inserts were tested in an AMTI displacement-controlled knee wear simulator. To simulate varus malalignment the mediolateral distribution of vertical load for the appropriate varus angle was computed using the mechanical axis of the lower limb. The malalignment of the tibial tray in axial rotation was simulated by offsetting the tray relative to the femoral component in axial rotation.

Three groups of inserts were tested: Gamma-irradiated in air and artificially aged (GAA), sequentially crosslinked (SQXL), and sequentially crosslinked and artificially aged (SQXL-Aged). Sequential crosslinking was performed by gamma-irradiating compression molded GUR 1020 UHMWPE to 30 kGy followed by annealing. This process was repeated two more times for a total dose of 90 kGy. Accelerated aging was carried out in an oxygen bomb under 5 atm at 70°C for 14 days (as per ASTM F2003). Wear was measured by visual inspection and the gravimetric method.

RESULTS

Fig 1: Photograph of aged gamma-irradiated in air (GAA) insert after 1 million cycles of testing. GAA inserts began delaminating under both malalignment conditions as early as 500,000 cycles.

DISCUSSION

Gamma-irradiation in air generates substantial free radicals. These radicals dramatically increase the susceptibility for oxidative damage of polyethylene on exposure to oxygen during storage or in vivo. Several reports have linked polyethylene gamma-irradiated in air with delamination and severe damage. Our findings of delamination of aged gamma-irradiated in air inserts validated the conditions of high stresses generated under the malalignment conditions. As expected, unaged, sequentially crosslinked inserts (not subjected to oxidative damage) wore substantially less under the same conditions, which indicates that the sequentially crosslinked process preserved the mechanical properties of the insert to an extent sufficient to sustain the high stresses generated by malalignment conditions at least 2 standard deviations from the mean. In a normally distributed population, approximately 95% of the knees would be aligned within the ranges represented by these outliers.

No detectable effects of aging-induced oxidation on wear were found on the sequentially crosslinked inserts. These data support the reported low levels of free radicals and preservation of mechanical properties. Clinical outcome studies are necessary to confirm these in vitro findings and to support the use of sequentially crosslinked polyethylene in knee arthroplasty.


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