# Can Sequentially-irradiated and Annealed Highly Cross-linked Polyethylene Inserts Thinner than Eight-millimeters Be Utilized in Total Knee Arthroplasty?

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## ABSTRACT

The routine use of highly cross-linked ultra-high molecular weight polyethylene (UHMWPE) has remained controversial secondary to the possibility of decreased material properties when compared to conventional UHMWPE. The aim of the present study was to evaluate if thin, sequentially-irradiated, and annealed highly cross-linked UHMWPE tibial inserts would have improved wear properties, while maintaining mechanical integrity, compared to conventional UHMWPE during biomechanical testing under

**aligned and malaligned conditions. Polyethylene inserts (4.27 and 6.27mm) manufactured from GUR 1020-UHMWPE were cyclically loaded to analyze for wear. All wear scars were visually examined after loading using scanning electron microscopy (SEM). Volume loss was plotted versus cycle count with linear regression analysis yielding wear rates. There was no statistical difference in wear between both thicknesses for all testing conditions. During aligned condition testing, the volumetric wear rate for sequentially-irradiated and annealed polyethylene thicknesses of 4.27 and 6.27mm was 4.0 and 4.4mm3/million cycles; and during malaligned conditions, it was 13.9 and 15.1mm3/million cycles. For conventional polyethylene during aligned conditions, the volumetric wear rate was 33.0 and 22.8mm3/million cycles; and during malaligned conditions it was 50.0 and 50.8mm3/million cycles. By SEM evaluation, condylar wear surfaces for conventional and sequentially-irradiated and annealed polyethylene displayed surface ripples typical of adhesive wear. There were no observed visible differences between the wear scars for conventional compared to sequentially-irradiated and annealed polyethylene with no evidence of fatigue failure. This study demonstrated no differences between polyethylenes with thicknesses of 4.27 and 6.27mm. This strengthens the conclusion that sequentially-irradiated and annealed highly cross-linked UHMWPE can be utilized in total knee arthroplasty. The successful wear properties of 4.27mm liners could mean that smaller tibial resections leading to bone stock preservation could be utilized in patients undergoing total knee arthroplasty, although further in-vivo studies are needed.**

## INTRODUCTION

There has been a projected six-fold increase in the number of revision total knee arthroplasties (TKAs) performed by the year 2030.[1,2] Improved implant longevity is one of the key factors involved in addressing this high demand and therefore reducing the costs on the healthcare system.[2,1] Specific implant designs, patient factors, and technical issues have been linked to wear and osteolysis.[3,4] Thus, manufacturers and surgeons are continuously focusing on improving implant designs and polyethylene bearing surfaces. In the past, ultra-high molecular weight polyethylene (UHMWPE) had been used in TKA, but had the potential for increased wear.[4,5]

Multiple factors have been associated to prosthetic failure due to polyethylene wear in TKA, among these, the thickness of the tibial insert, the relative alignment of the tibial tray to the mechanical axis, and the material properties of the polyethylene.[6-9] Due to the high stresses placed on knee polyethylene bearings when compared to their hip counterpart, previous studies have recommended the use of polyethylene inserts with a minimum thickness of 8 to 10mm.[7] Also, conditions such as malalignment of 3 + degrees have been associated to increased wear and early prosthetic knee failures.[8-13] Given the historical experience with older generation polyethylene trays, the recent focus of bearing research has shifted to newer, potentially highly wear-resistant materials for TKA that could be used in the clinical setting.

The first generation highly cross-linked UHMWPE was introduced for clinical use as a bearing surface in the hip arthroplasty world over a decade and a half ago.[14] When compared to conventional UHMWPE, highly cross-linked UHMWPE displayed improved wear characteristics, however, the mechanical strength (fatigue fracture) may be decreased, making it a controversial bearing surface for TKA.[15,16] Exposing UHMWPE to ionizing radiation, like that used for historical sterilization, induces bond cleavage. These now unsaturated bonds may react in subsequent covalent bonding across the polymer chains linking them together, this is known as cross-linking. By tying the chains together, liberation of discreet micro pieces of material becomes more difficult and thereby wear resistance improves. However, this change in molecular structure can affect other properties of the material. Any associated change in the crystalline phase can alter strength and plasticity. More recently, the second generation highly cross-linked UHMWPE have been introduced into clinical practice.[17,18] These polyethylenes are either sequentially irradiated and annealed or supplemented with an anti-oxidant such as vitamin E, to improve their mechanical integrity and/or wear properties.[17,19] Free radicals left within the structure of polyethylene after cross-linking may allow for an increase in the oxidation potential. Possibly leading to a decrease in the oxidation potential and/or improvement in the wear properties of the polyethylene. Sequentially-irradiated and annealed polyethylene has been shown to maintain mechanical strength and oxidative resistance comparable to virgin UHMWPE while reducing wear.[19,20]

The routine use of these later generation polyethylene liners has remained controversial secondary to concerns related to the material properties of the first generation highly cross-linked UHMWPE.[18] However, we hypothesized that sequentially-irradiated and annealed highly cross-linked UHMWPE would retain improved wear resistance compared to conventional UHMWPE during biomechanical testing under severe (malaligned) conditions. Thus, the purposes of this study were three-fold: 1) to analyze the effect of tibial insert thickness on wear performance; 2) to analyze the effect of coronal alignment on wear performance; and 3) to evaluate fatigue failure during cyclic testing of sequentially-irradiated and annealed, highly cross-linked UHMWPE compared to conventional UHMWPE.

## MATERIALS AND METHODS

We utilized a wear simulator to assess and to compare the wear properties of polyethylene liners exposed to simulated normal aligned and malaligned conditions. The knee wear simulator utilized cobalt-chromium femoral and tibial components mated against polyethylene in a six-station machine (MTS, Eden Prairie, Minnesota). The polyethylene inserts were manufactured from compression molded GUR® 1020 UHMWPE (Ticona, Florence, Kentucky) that were either sequentially-irradiated then, annealed three times, and then gas plasma sterilized (SXL), or packaged in a nitrogen environment and irradiated to 30 kGy (conventional UHMWPE).[18] These polyethylene inserts had a true nominal thicknesses of 4.27 or 6.27mm (labeled as 7 or 9mm; Fig. 1).

Normal gait kinematics were simulated for testing following the ISO 14243-3 and 21536 protocols.[21,22] All motion and loading was computer-controlled and testing was conducted at a peak load of 2,600 N at a frequency of 1 Hz for two million cycles of normal gait with a maximum flexion angle of 58 degrees. Malalignment was simulated by tilting the femoral components 5 degrees. Separate polyethylene inserts were independently tested under intended neutral alignment (aligned) and malaligned conditions. The lubricant used was Hyclone™ Alpha Calf Fraction serum (Hyclone Labs, Logan, Utah) diluted to 50% with a pH-balanced 20mmole solution of deionized water and EDTA (protein level = 20 g/l). The serum solution was replaced and inserts were weighed for gravimetric wear at least every 0.5 million cycles. Standard test protocols were used for cleaning, weighing, and assessing the wear loss of the tibial inserts (ASTM F2025).[23] In addition, loaded soak control specimens were used to correct for fluid absorption with weight loss data converted to volumetric data. The volume loss was then plotted versus cycle count with linear regression analysis yielding wear rates.

All polyethylene inserts were visually examined, before and after wear testing, to determine the mode of wear and the macroscopic extent of damage. Further analysis of the wear scars after gold coating, using scanning electron microscopy (SEM), was conducted on all polyethylene components after testing to assess the extent of wear and microscopic damage that may have occurred to the articulating surface. In order to evaluate microscopic damage, the wear scars were evaluated at 5,000 times magnification utilizing SEM (Philips, Eindhoven, Netherlands).

Total volume loss and volumetric wear rates were determined for both SXL and conventional UHMWPE, with thicknesses of 4.27 and 6.27mm, and tested under aligned and malaligned testing conditions. Comparisons were made between varying thicknesses of SXL and conventional UHMWPE. In addition, a direct comparison was made between 4.27 and 6.27mm SXL with conventional UHMWPE. Statistical analysis was performed using a paired, two-tailed student's t-test. A p-value of less than 0.05 was considered significant.

## RESULTS

During aligned conditions, the total volume loss at two million cycles for SXL thicknesses of 4.27 and 6.27mm was 8.4 ± 3.1mm³ and 9.6 ± 2.4mm³. For conventional UHMWPE, the volume loss for both thicknesses was 48.4 ± 6.8mm³ and 43.6 ± 3.0mm³. The volumetric wear rate for SXL thicknesses of 4.27 and 6.27mm was 4.0 ± 1.9mm³/10⁶ cycles and 4.4 ± 0.8mm³/10⁶ cycles. For conventional

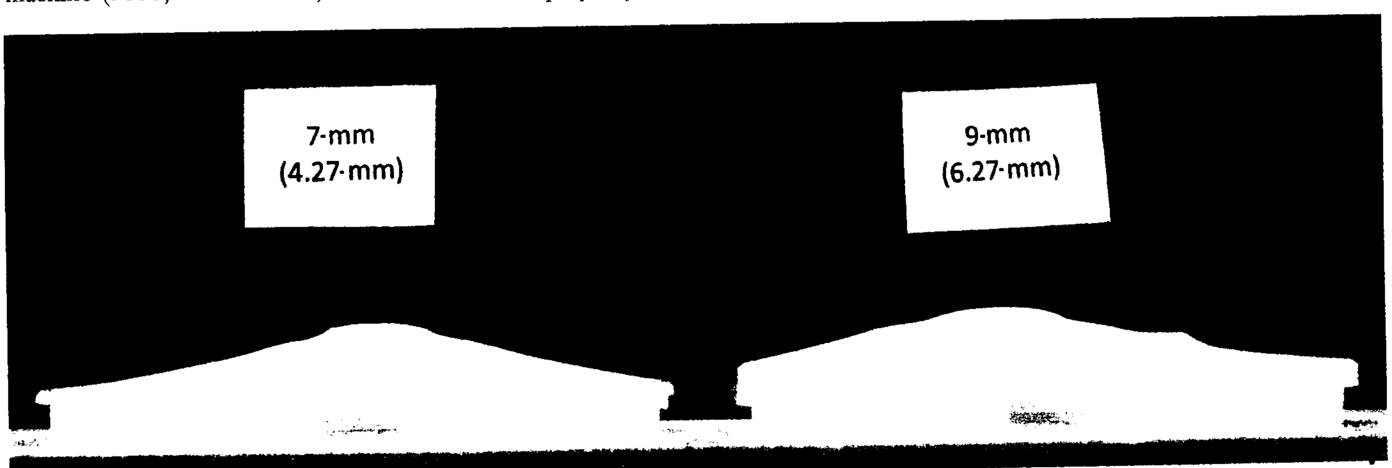


**Figure 1. Company-labeled 7- or 9mm X3 polyethylene CR inserts, corresponding to true nominal polyethylene thicknesses of 4.27- and 6.27mm.**

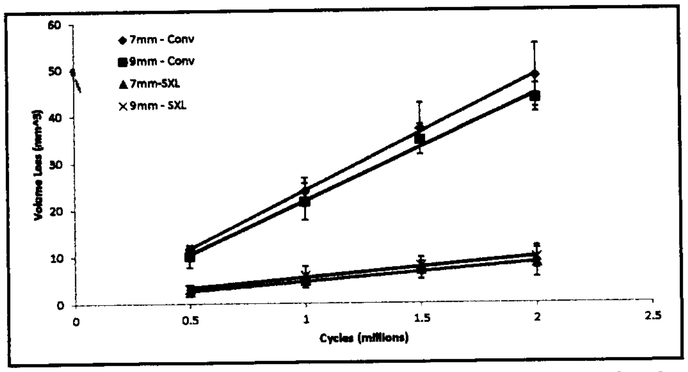


**Figure 2. Plot of volumetric wear results as a function of number of cycles under aligned conditions with the company-labeled 7- or 9mm X3 polyethylene CR inserts (Stryker Orthopaedics, Mahwah, New Jersey), corresponding to true nominal polyethylene thicknesses of 4.27- and 6.27mm.**

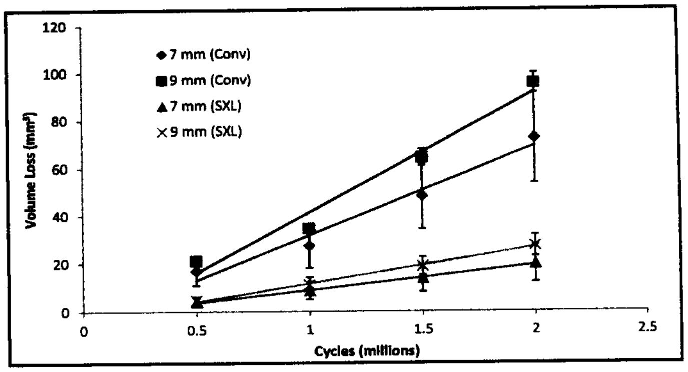


**Figure 3. Plot of volumetric wear results as a function of number of cycles under malaligned conditions with the company-labeled 7- or 9mm X3 polyethylene CR inserts, corresponding to true nominal polyethylene thicknesses of 4.27- and 6.27mm.**

UHMWPE, the volumetric wear for both liners was 33.0 ± 4.8mm$^3$/10$^6$ cycles and 22.8 ± 0.5mm$^3$/10$^6$ cycles (Fig. 2). No statistical differences were observed in the wear rate between the two polyethylene thicknesses for either material (p-value > 0.05). However, when compared to conventional UHMWPE, SXL liners had a reduction in wear rate of at least 81% (Table I).

During malaligned conditions, the wear rate expectedly increased when compared to aligned conditions. This test condition resulted in primarily medial condylar contact. The total volume loss at two million cycles for SXL thicknesses was 4.27 and 6.27mm was 19.7 ± 7.7mm$^3$ and 27.3 ± 4.5mm$^3$. For conventional UHMWPE, it was 72.4 ± 18.9mm$^3$ and 95.5 ± 4.2mm$^3$. The volumetric wear rate for SXL thicknesses of 4.27 and 6.27mm was 13.9 ± 4.1mm$^3$/million cycles and 15.1 ± 2.4mm$^3$/million cycles, and was 50.0 ± 8.8mm$^3$/million cycles and 50.8 ± 2.2mm$^3$/million cycles, for conventional UHMWPE (Fig. 3). There was no statistical difference in the wear rate between the two polyethylene thicknesses for either material (p-value > 0.05). Compared to conventional UHMWPE, there was a reduction in wear rate of at least 70% (Table I).

Visual inspection of conventional UHMWPE and SXL inserts of both thicknesses tested under aligned and malaligned conditions showed wear scars in areas of contact including burnishing, striations, and occasional scratches (Figs. 4 and 5). Electron microscopy images of condylar wear surfaces displayed surface ripples typical of adhesive wear. There were no observed visible differences in the wear scars and condylar wear surfaces between aligned and malaligned polyethylene inserts (Figs. 6 and 7). In addition, there were no differences in the wear scars when comparing 4.27 and 6.27mm polyethylene inserts.

None of the specimens, for both conventional UHMWPE and SXL had any evidence of macroscopic or microscopic fatigue failure during cyclic testing under aligned and malaligned conditions after two million cycles.

**Table I**
**Summary of volume loss and wear rates under aligned and malaligned conditions**

| Measure | Alignment and type of polyethylene | Polyethylene thickness: 4.27mm | Polyethylene thickness: 6.27mm | p-Value |
|---|---|---|---|---|
| Volume Loss (cubicmm) | Aligned SXL | 8.4 ± 3.1 | 9.6 ± 2.4 | 0.62 |
| | Aligned Conventional | 48.4 ± 6.8 | 43.6 ± 3.0 | 0.02 |
| | Malaligned SXL | 19.7 ± 7.7 | 27.3 ± 4.5 | 0.86 |
| | Malaligned Conventional | 72.4 ± 18.9 | 95.5 ± 4.2 | 0.58 |
| Wear Rate (cubicmm/million cycles) | Aligned SXL | 4.0 ± 1.9 | 4.4 ± 0.8 | 0.80 |
| | Aligned Conventional | 33.0 ± 4.8 | 22.8 ± 0.5 | <0.01 |
| | Malaligned SXL | 13.9 ± 4.1 | 15.1 ± 2.4 | 0.70 |
| | Malaligned Conventional | 50.0 ± 8.8 | 50.8 ± 2.2 | 0.63 |

*SXL, ultra-high molecular weight polyethylene that is sequentially-irradiated, annealed three times, and then gas plasma sterilized.*

## DISCUSSION

Since the introduction of sequentially-irradiated and annealed, highly cross-linked UHMWPE into the TKA world, successful 10-year survival rates of over 95% have been reported.[24] This material uses annealing to maintain the microstructure applied after each dose of irradiation is repeated. While annealing benefits the structural integrity, the small irradiation dose (30 kGy) leaves ample space between free radicals and the resulting cross-links. Steric hindrance (decreased molecular mobility) is also minimized, which also results in a minimal level of unreacted free radicals. Repeated increments result in a high level of cross-links, benefitting wear resistance.[18] The retention in mechanical properties combined with the preservation of wear reduction, up to 68% compared to conventional UHMWPE, has made this type of polyethylene an attractive option utilized for modern bearing surfaces.[19] To prove its ability to withstand adverse conditions in vivo, thin, sequentially-annealed highly cross-linked UHMWPE polyethylene bearings were first in-vitro tested under severe malaligned conditions. We found no statistical difference in wear between the two thicknesses for all testing conditions and polyethylene types without observing any fatigue failures.

Thin polyethylene bearings, less than 8mm in thickness, are presently not commonly used in clinical practice. The finite element analysis study conducted by Bartel et al. approximately 30 years ago led manufacturers to produce polyethylene bearings with at least this nominal threshold.[7] However, the analysis and focus at the time of that study was on stresses. The polyethylene utilized was predominantly gamma-in-air sterilized, which could potentially oxidize and consequently cause delamination of the material.[25] Modern materials, manufacturing processes, and total knee arthroplasty designs have attempted to address the issue of high stresses, and the focus of research now has shifted to materials that can potentially decrease wear. To the author's knowledge, only one clinical study has been conducted with a polyethylene less than the recommended 8mm thickness. At an average 10.7 year follow-up, these authors reported excellent mid-term clinical and radiographic results with a 4.4mm thick polyethylene. The 15-year Kaplan-Meier survival rate was 94.3%. A subset of patients in the study had bilateral total knee arthroplasties performed with one side having 4.4mm thick polyethylene and the other side having 6.4mm thick polyethylene. There were no significant differences in Knee Society knee and pain scores between the two groups of knees. Radiographically, no focal osteolytic lesions were observed at final follow-up and no polyethylene thickness changes consistent with measurable tibial component wear were identified in any knee.

A recent study by Bruni et al. also assessed the use of thin polyethylene all polyethylene-tibia unicompartmental knee arthroplasties in a cohort of 30 consecutive patients.[26] At eight-year follow-up, the all cause Kaplan-Meier survivorship was 83%. The authors concluded that this study failed to demonstrate an increased revision rate in these patients utilizing the minimum thickness of all polyethylene tibial implants. Our biomechanical study differs from the two prior studies by utilizing modern, modular, second-generation highly cross-linked compared to conventional UHMWPE and by simulating total instead of unicompartmental knee arthroplasties.

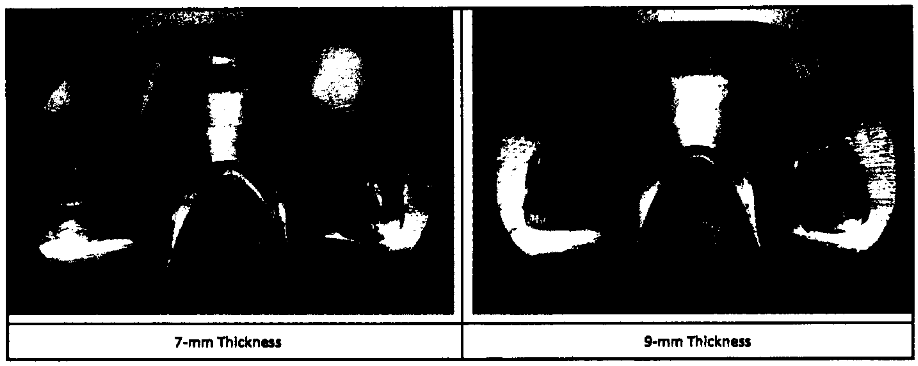


**Figure 4. Company-labeled X3 polyethylene CR inserts after non-malaligned wear testing and gold coating displaying burnishing, striations, and occasional scratches.**

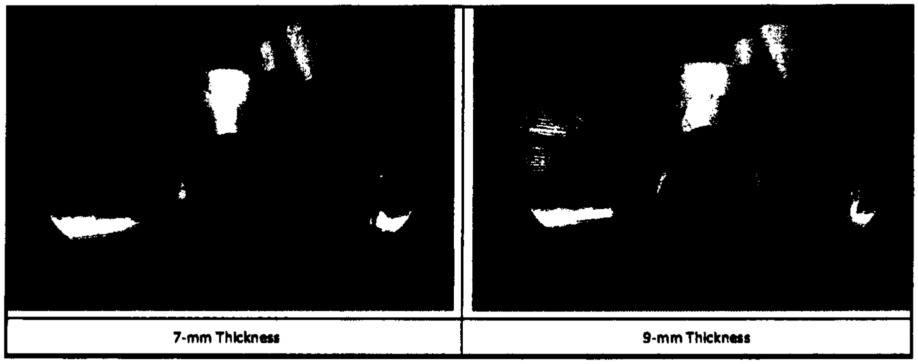


**Figure 5. Company-labeled X3 polyethylene CR inserts after malaligned wear testing and gold coating displaying burnishing, striations, and occasional scratches.**

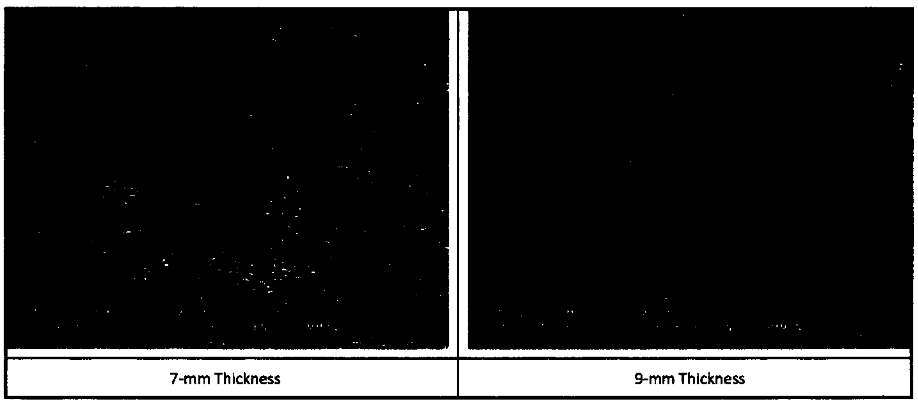


**Figure 6. Scanning electron micrographs (5,000x) of wear scars of the sequentially annealed and irradiated UHMWPE showing surface ripples typical of adhesive wear.**

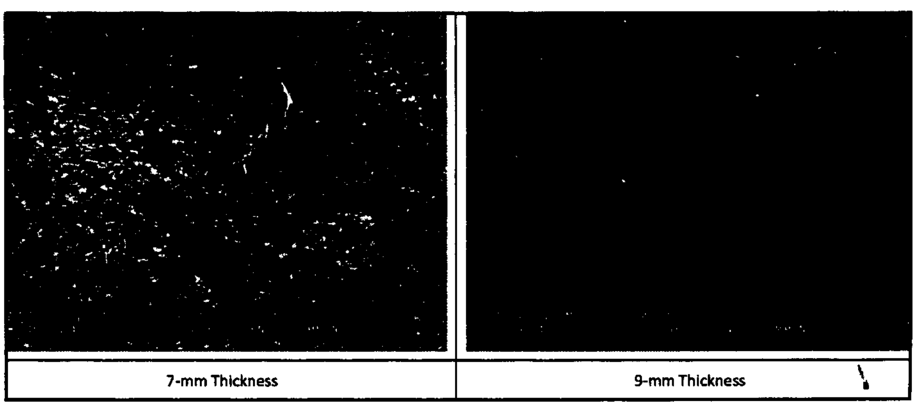


**Figure 7. Scanning electron micrographs (5,000x) of wear scars of the conventional UHMWPE showing surface ripples typical of adhesive wear.**

There was no observed fatigue failure of the thin polyethylene in the current study, with a greater than 70% wear reduction compared to conventional UHMWPE. This amount of wear reduction is consistent with the 68% wear reduction that was previously reported for sequentially-irradiated and annealed, highly cross-linked UHMWPE.[19] After five million cycles of wear simulator testing, Wang et al. found that the total volume loss for conventional UHMWPE was 20.0 ± 3.0mm³ and 6.4 ± 2.6mm³ for SXL.[19]

In terms of alignment in TKA, several studies have shown the deleterious effects of greater than 3 degrees of coronal plane malalignment.[8-10] With coronal plane malalignment relative to the mechanical axis, conformity in the TKA is potentially reduced. This loss of conformity can ultimately lead to increased stresses placed on the polyethylene bearing surface.[7] Previous reports describe that contact stresses can be increased by 25 to 150% for a varus tilt of only 5 degrees.[27,28] This increased contact stress can lead to stress overload in the polyethylene which could increase wear and cause mechanical failure.[8] In our biomechanical testing, we assumed a worse-case scenario of 5 degrees of malalignment. As expected, the wear rate in the malaligned polyethylene increased compared to the aligned polyethylene. It appears that the contact became somewhat isolated on the medial condyle. Although the specific clinical relevance of this is difficult to determine, it certainly concentrated stress in that region. Although the volumetric wear rate tripled, there was no fatigue failure noted and the SEM analysis of the wear scars of 4.27 and 6.27mm aligned and malaligned polyethylene inserts. Similar results were found for the volumetric wear rate for conventional polyethylene. In addition, the wear reduction of sequentially-irradiated and annealed, highly cross-linked UHMWPE compared to conventional UHMWPE was maintained in malaligned testing (Table I).

It is important to note that this study is a biomechanical testing study of the polyethylene bearing surface. Given that a knee simulator was used for testing, the complex motions of the knee, including rolling, rotation, and sliding, may not be accurately reproduced, thus possibly underestimating wear. More specifically, the *in vivo* environment can be extremely variable depending on activity, as well as patient factors and surgical factors. This variability was not exhaustively studied here. In addition, we assumed no third body debris in the lubricant solution which would give us a best-case scenario when performing these measurements. When compared to other studies, we only ran our simulator for a total of two million cycles; however, our findings comparing the two thicknesses showed no differences in different time points; therefore, we chose the two million-cycle mark as our endpoint. Also, other studies have assessed the multifactorial nature of delamination, wear, and fatigue during activities of daily living and they have also assessed aged components;[29,30] however, in an attempt to diminish the number of variables, we did not perform these comparisons. We acknowledge that aging our components (by utilizing an "oxygen bomb") and including other movements rather than normal gait should be further investigated. Even with these limitations, the study was performed under strict testing protocols which have been validated and previously reported.[18-23] These wear results are quite comparable to previous publications regarding the amount of wear reduction when comparing sequentially-irradiated and annealed, highly cross-linked UHMWPE to conventional UHMWPE.[19,20] Wang et al. found that, at five million cycles of wear testing, there was an observed 68% decrease in the wear rate of sequentially-irradiated and annealed, highly cross-linked UHMWPE, 5.7 ± 1.5mm³/10⁶, compared to conventional UHMWPE, 17.7 ± 2.2mm³/10⁶.[19] In the current study, wear reduction was greater than 70%. It has been reported previously that 25% of total knee arthroplasty revisions are secondary to polyethylene wear.[4,2] With the expected 601% increase in the revision burden for total knee arthroplasties by the year 2030, a 70% decrease in polyethylene wear rates could drastically reduce the number of revisions in the future.[2]

## CONCLUSION

The results of this study demonstrate that sequentially-irradiated and annealed, highly cross-linked UHMWPE polyethylene used in knee arthroplasty provides the opportunity for reducing thickness while maintaining wear properties. The differences in the volumetric wear rate for 4.27mm thick polyethylene have been shown to not be statistically significant when compared to 6.27mm thick polyethylene under aligned and malaligned testing conditions. This represents at least a 70% reduction in wear when compared to conventional UHMWPE (p-value = 0.01). The 4.27mm-thick polyethylene did not display fatigue failure under aligned and malaligned testing. This provides strength to the conclusion that sequentially-irradiated and annealed, highly cross-linked UHMWPE can be utilized as a bearing surface for TKA. In addition, the potential clinical application of thin, 4.27mm sequentially-irradiated and annealed, highly cross-linked UHMWPE would mean a smaller tibial resection in TKA procedures. This might lead to a preservation of bone stock while maintaining superior wear properties when compared to conventional UHMWPE. Further testing and clinical studies will need to be performed on thinner polyethylene bearings before advocating their routine use in TKAs. However, 6.27mm thick sequentially-irradiated and annealed, highly cross-linked polyethylene bearings, corresponding to the company-labeled 9mm thick bearings, should be considered safe for clinical applications based on the results of this study. STI

## AUTHORS' DISCLOSURES

Dr. Sayeed is a consultant for Medtronic. Ms. Korduba and Mr. Essner are paid employees for Stryker Inc. Dr. Harwin is a consultant and is on the speakers' bureau for Stryker Inc. He is also a consultant for Convatec, is a shareholder for Stryker Inc., and receives publishing royalties from SLACK Incorporated, Thieme Inc., and the Journal of Knee Surgery. Dr. Delanois is a consultant and is on the speakers' bureau for Stryker Inc. Dr. Mont receives grant/research support from Stryker Inc., DJ Orthopaedic, Sage Products, Inc., and the National Institutes of Health (NIAMS & NICHD). He is also a consultant for Stryker Inc., DJ Orthopaedic, Sage Products, Inc., and Medical Compression Systems.

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