Early Outcomes of Sequentially Cross-Linked Thin Polyethylene Liners with Large Diameter Femoral Heads in Total Hip Arthroplasty

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Abstract

Two important issues affecting the outcome of total hip arthroplasty have been dislocation and wear, despite excellent clinical results. Larger femoral heads have had success in decreasing dislocation rates; however, there are concerns regarding the subsequent use of thinner polyethylene liners, and their effects on wear rates. Historically, high stresses on thin polyethylene bearings have caused concerns, including rim cracking and catastrophic implant failure with polyethylene thicknesses less than 5 millimeters. Recently, sequentially cross-linked and annealed polyethylene has been shown to reduce the wear rate significantly, compared to conventional ultra-high-molecular-weight polyethylene (UHMWPE) in vitro. The purpose of this study was to analyze the clinical and radiographic outcomes in a cohort of patients treated with sequentially cross-linked and annealed polyethylene bearings with a nominal thickness of 3.8 millimeters. Outcomes were compared to a similar cohort of patients who were treated with total hip arthroplasty during the same time period and utilizing the same polyethylene thickness of 5.8 millimeters or greater.

Materials and Methods: We identified 50 patients (53 hips) who had a minimum 2-year clinical and radiographic follow-up after a standard total hip arthroplasty, performed with a thin, sequentially cross-linked and annealed polyethylene bearing surface. There were 15 males and 35 females, with a a mean age of 60 years (range, 16 to 93 years) and a mean body mass index of 28.6 kg/m^2 (range, 17.2 to 47.5 kg/m^2). Overall survivorship was compared to a cohort of 50 patients (53 hips) treated with total hip arthroplasty during the same time period, utilizing the same polyethylene of 5.8 millimeters or greater thickness. Radiographic analysis of polyethylene wear was performed on a subset of 26 hips, using a previously validated two-dimensional computer-aided technique. Volumetric wear was calculated and subsequent annual volumetric and linear wear rates were derived for each patient in the study cohort. Additionally, radiographic analysis was performed to assess for any progressive radiolucencies or malalignment.

Results: The overall survivorship of the study cohort was 100%, compared to a 96% survivorship in the comparison group (two failures due to infection). The mean Harris hip scores in the thin polyethylene cohort improved from 43 points (range, 10 to 67 points) pre-operatively to 91 points (range, 69 to 100 points) postoperatively. Upon radiographic review, no malalignment, radiolucencies, or polyethylene fracture was noted in the study cohort. The mean volumetric wear rate was 0.4122 mm^3/year (range, 0.2311 to 0.7310 mm^3/year), and the mean linear wear rate was 0.0004 mm/year (range, 0.0002 to 0.0007 mm/year) for the thin polyethylene group. The mean volumetric wear was 0.8839 mm^3 (range, 0.4621 to 1.5839 mm^3) for this cohort. Excellent clinical and radiographic outcomes were found for patients treated with thin, sequentially cross-linked and annealed polyethylene bearings utilized in total hip arthroplasty, with a nominal thickness of 3.8 millimeters. We have not seen any failures with thin polyethylene liners that have undergone this manufacturing process, which is in contradistinction to results of previously reported thin polyethylene liners. Wear rates were lower than other bearing surfaces at similar periods.

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Conclusion: Although more follow-up is needed, it is hoped that these bearings will allow patients to have decreased dislocation rates associated with large femoral heads without the disadvantages reported with other types of thin polyethylene articulations or larger diameter metal-on-metal total hip arthroplasties.

As the demand for total hip arthroplasty increased in the USA, multiple attempts by surgeons and manufacturers have been made to decrease the need for and frequency of revision. A recent study examining 51,345 revisions in the Medicare population between 2005 and 2006 found that the primary causes were instability and dislocation (accounting for 22% of the total).[1] This was followed by mechanical loosening (19.7%), infection (14.8%), and osteolysis, with or without wear (11.6%). Attempts to decrease dislocation complications have often utilized increasing femoral head sizes with metal-on-metal bearings.[2-5] To attempt to reduce wear, both ceramic-on-ceramic and metal-on-metal bearings have been promulgated. However, ceramic components have their own inherent complications of squeaking and the potential for ceramic fracture and chipping. Metal-on-metal bearings have reported adverse local tissue reactions related to metal ions or hypersensitivity. Based on these problems, there may be a need for improved designs or techniques.

Currently, the most commonly used total hip arthroplasty interfaces are metal-on-polyethylene designs.[6] Earlier generation polyethylene bearings had high wear rates, often leading to osteolysis. Fortunately, new developments in highly cross-linked polyethylene have led to lower initial wear rates. Now there is also the potential to decrease the required polyethylene width to allow larger head sizes to reduce the risk of dislocation. This is still a controversial issue, since previously used earlier generation thinner polyethylene liners (less than 5 millimeters) were associated with high failure rates.[7-9] Failure often resulted from excessive wear or cracking at the rim of the liner, where it locked into the acetabular shell.

More recently, a newer generation of highly cross-linked ultra-high-molecular-weight polyethylene (UHMWPE) was released, which utilized a hybrid cross-linking technology, in which polyethylene was sequentially irradiated and annealed. This process preserved the mechanical strength associated with UHMWPE, while trying to avoid the problems of fatigue cracking and in vivo oxidation seen with previous generation models. Dumbleton and colleagues[10] tested these newer generation acetabular bearings in hip simulators with 32 millimeter femoral heads. They used conventional polyethylene and first generation UHMWPE (Crossfire®, Stryker Orthopaedics, Mahwah, New Jersey) as a control in comparing fatigue and wear data. They found that the newer UHMWPE bearing had lower wear rates than first-generation models (97% wear reduction from traditional UHMWPE and 62% reduction, compared to first-generation highly cross-linked UHMWPE).[10] The use of these new polyethylene components has led to the question of whether they can be employed in a thin design (less than 4 millimeters) but without the early failure rates previously seen.

Our purpose was to assess total hip arthroplasties that utilized larger diameter femoral head components (36 millimeters or greater) and thin newer generation highly cross-linked UHMWPE liners. Survivorship was compared to a cohort of patients undergoing standard total hip arthroplasty with the same generation polyethylene liners of standard thickness (5.8 millimeters or greater). Similarly, a comparison of clinical outcomes was done using Harris hip scores. Radiographic data was used to assess wear and to diagnose radiographic failures.

Materials and Methods

Fifty consecutive patients (53 hips) were identified during a 1-year period, from August 2007 to July 2008, who had undergone a total hip arthroplasty utilizing thin (3.8 millimeter) highly cross-linked and annealed polyethylene bearing surface liners (Trident®, X3®, Stryker Orthopaedics, Mahwah, New Jersey). All patients had a larger diameter femoral head component (36 millimeters or greater) (LFIT™ Anatomic) with an Accolade™ TMZF® stem and Trident® Hemispherical Acetabular Shell (all components, Stryker Orthopaedics, Mahwah, New Jersey). All patients were operated on at one of two high-volume joint arthroplasty centers. Total hip arthroplasties were performed through an anterolateral approach. Institutional review board (IRB) approval was granted for the use and study of these components.

There were 15 males and 35 females, who had a mean age of 60 years (range, 16 to 93 years) and a mean body mass index of 28.6 (range, 17.2 to 47.5). Patients were matched to a similar cohort that included patients who had undergone total hip arthroplasties during the same period and had the same generation polyethylene liners as the experimental cohort, but with standard thickness and with 32 or 36 millimeter femoral heads. Patients from both groups had similar pre-operative ages, and were of similar gender distribution, body mass index, and pre-operative Harris hip scores (see Table 1 for demographic characteristics of each cohort).

Clinical evaluations were made pre-operatively, and at 6, 12, 26, 52 weeks postoperatively, and yearly, thereafter. Data was compiled by three of the investigators (CC, AJ, QN) to assess for Harris hip scores and survivorship. Any peri-operative and postoperative medical and surgical complications were tabulated and assessed for the two patient cohorts.

Radiographs were evaluated at the same time as clinical evaluations. We examined wear rates of a subset of 26 patients utilizing a previously validated two-dimensional computer-aided technique.[11,12] Volumetric wear was calculated and subsequent annual volumetric and linear wear rates were derived for each patient in the study cohort. Additionally, radiographic zonal analysis was performed for both

Table 1 Preoperative Comparison of Thin Polyethylene Group to Matched Cohort

	Thin Polyethylene	Control
Total hips (patients)	53 (50)	53 (50)
Mean age in years (range)	60 (16-93)	61 (18-93)
Mean BMI (kg/m^2)(range)	28.6 (17.2-47.5)	29.3 (18.3-48.7)
Gender (female:male)	35:15	27:26
Side of surgery (left:right)	29:24	26:27
Mean preoperative Harris hip score points (range)	43 (10-67)	53 (36-73)

BMI, body mass index.

acetabular and femoral components, with assessment for any progressive radiolucencies, malalignment, or changes in component position.

Data was recorded to a Microsoft Excel spreadsheet (Microsoft Corp. Redmond, Washington) from patient charts and Harris hip score evaluation sheets. Additionally, medical records were checked for any additional surgeries to determine if patients had suffered complications related to their surgery. Postoperative radiographs were compared to most recent follow-up films, using specialized software (Hip Analysis Suite™, version 8.0.4.1, Chicago, Illinois) to determine volumetric and linear wear.

Results

The overall survivorship of the study cohort was 100%, compared to 96% (51 of 53 hips) in the matched group, at a mean follow-up of 26 months (range, 24 to 32 months). The two revised hips were both due to sepsis, which will be described later; therefore, none of the hips in either cohort were revised for aseptic failure. The Harris hip scores in the thin-polyethylene cohort improved from a mean of 43 points (range, 10 to 67 points) pre-operatively to 91 points (range, 69 to 100 points) postoperatively. In the matched cohort, the mean Harris hip score increased from 53 points (range, 36 to 73 points), to 90 points (range, 55 to 99 points).

Radiographic review showed no progressive radiolucencies or polyethylene fracture in either cohort. The subset of 26 patients from the thin polyethylene group, for which radiographic wear analysis revealed a mean volumetric wear rate of 0.4122 mm^3/year (range, 0.2311 to 0.7310 mm^3/year) and a mean linear wear rate of 0.0004 mm/year (range, 0.0002 to 0.0007 mm/year). The mean volumetric wear was 0.8839 mm^3 (range, 0.4621 to 1.5839 mm^3).

No complications were reported in the thin polyethylene cohort. A periprosthetic fracture occurred in one of the matched patients after a fall, which required open reduction and internal fixation (ORIF). However, both the femoral and acetabular components remained intact. Two of the matching patients required revision. Both had primary infections on their operated hip. One patient underwent revision with replacement of components approximately 6 months after the initial operation. Currently, this patient is doing well at a follow-up of 24 months, with a Harris hip score of 97 points. The other patient underwent multiple washouts between the time of the total hip arthroplasty in October 2007 to March 2009, which was then revised and re-implanted. This patient is doing well at the most recent follow-up of 13 months, with a Harris hip score of 99 points.

Discussion

Despite excellent long-term results, dislocation and late wear-related problems continue to be sources of concern for conventional total hip arthroplasty.[1] The first-generation polyethylenes, which had high wear rates, have been superseded by newer highly cross-linked UHMWPEs that have led to reduced wear by 40% to 100%.[13-18] These newer generation polyethylenes have decreased wear rates; seen as low as 0.003 mm/year in vivo, as compared to earlier generation polyethylene (0.051 mm/year).[19] These new, stronger liners have allowed for flexibility of design, such as thinner liners, which permits the use of larger diameter femoral heads. In the present study, excellent clinical and radiographic results were found for patients receiving total hip arthroplasty utilizing 3.8 millimeter thin highly cross-linked sequential

Table 2 In Vivo Wear Rates of Different Bearing Surfaces in Total Hip Arthroplasty

Study	Bearing Interface	Mean Linear Wear Rate (mm/year)	Hips Enrolled	Mean Follow-up (Months)
McCalden et al.[19]	Metal-on-conventional polyethylene	0.051	50	81
McCalden et al.[19]	Metal on XLPE	0.003	50	81
Olyslaegers et al.[20]	Metal on XLPE	0.050	60	60
Geller et al.[5]	Metal on XLPE	0.06	45	40
Schmalzried et al.[21]	MoM	0.0042	6	240
Schmidt et al.[22]	MoM	0.0035	44	—
Dorlot et al.[23]	CoC	0.000025	20	96
Current study	Metal-on-X3®	0.0004	53	26

XLPE, highly cross-linked polyethylene; MoM, metal-on-metal; CoC, ceramic-on-ceramic X3®, new generation ultra-high-molecular-weight polyethylene.

annealed UHMWPE. At short-term follow-up, there has been minimal wear without other complications, suggesting that the use of the new generation liners is safe to use with large diameter femoral heads.

The limitations of this study include the short-term follow-up and the small number of patients enrolled. Another limitation is the paucity of data of patients with the polyethylene wear-analysis software. In addition, various other matching cohorts could have been used, including earlier generation polyethylene patient groups, as well as other interfaces (ceramic-on-ceramic or ceramic-on-polyethylene). Nevertheless, we believe that, despite these limitations, this investigation provides valuable information about the early outcome of thinner polyethylene bearings.

The results of this study show excellent wear rates in the subset of 26 patients with the new generation polyethylene (X3®). Most current literature describes utilizing highly cross-linked ultra-high molecular-weight polyethylene (XLPE). A recent study performed by Geller and coworkers[5] describes wear results representative of these types of bearings. In 52 total hip arthroplasties performed with larger diameter femoral heads (32 millimeters or larger) on highly cross-linked polyethylene (Trilogy®, Zimmer Inc., Warsaw, Indiana), there were wear rates of 0.06 ± 0.41 mm/year at 3 years, with no polyethylene liner failures.[5] The main difference between this and the current study is that all of the patients in the Geller and associates[5] study had polyethylene thicknesses of 8 to 10 millimeters. However, they concluded that the use of highly cross-linked polyethylene with larger femoral heads could be used for patients at increased risk for dislocation. Comparison of the wear rates found in this study to other similar studies utilizing different bearing interfaces can be found in Table 2. The linear wear rate in this study was superior to the previously reported polyethylene bearings used and comparable to a ceramic-on-ceramic bearing interface.

There are few reports concerning the use of thin polyethylene liners; however, most investigators advise against their use. A recent case series examined four retrieved acetabular liners of an earlier generation polyethylene (Longevity®, Zimmer Inc., Warsaw, Indiana) that showed failure in all at an area of thickness less than 4 millimeters.[9] All the liners were of one brand of highly cross-linked ultra-high-molecular-weight models. The two patients in that study had reported early primary failure at less than 1 year. They concluded that the use of thin polyethylene may be more susceptible to fatigue and rim cracking, which, fortunately, was not found in the present study.

Conclusion

The use of thin (3.8 millimeter) polyethylene can provide successful results in concurrent use with large diameter femoral heads at short-term follow-up at a minimum of 2 years. Our results of thin polyethylene liners with large femoral heads showed similar wear rates to total hip arthroplasties utilizing larger thicknesses of polyethylene. Similarly, there was no evidence of failure or cracking of the polyethylene rim. Although more follow-up is needed, it is hoped that these bearings will allow patients to enjoy the benefit of decreased dislocation rates associated with large femoral heads but without the disadvantages reported with other types of thin polyethylene articulations.

Disclosure Statement

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