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Comparative Results From a National Joint Registry Hip Data Set of a New Cross-Linked Annealed Polyethylene vs Both Conventional Polyethylene and Ceramic Bearings

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ABSTRACT

Background: Major concerns in hip arthroplasty concern the fate of bearing surfaces. Highly cross-linked polyethylene materials (HXLPE) currently demonstrate successful in vitro results with new technical procedures of cross-linking the polyethylene material, whereas processing the polyethylene below its melting temperature to produce so-called "annealed HXLPE" would allow retention of important mechanical properties.
Methods: Data released by the National Joint Registry of England and Wales addressing in 45,877 hips the same Trident uncemented cup, allowed us to compare the performance of a consecutive cohort of patients implanted with the newest generation of annealed HXLPE acetabular bearings (X3: 21,470) vs 2 consecutive nonselected cohorts, one with conventional polyethylene (N2vac: 8225) and one with ceramic-on-ceramic (CoC) hip bearings (AL: 16,182). The main end point in survivorship has been first defined as revision for any cause, then for any cause which could be related to a failure of the bearing couple.
Results: At 6-year follow-up, all Trident cups demonstrated encouraging global survival cumulative rates all between 95% and 99%. A first study demonstrated better survivorship with X3-HXLPE liners vs conventional ultrahigh molecular weight polyethylene. On the second parallel study, the cumulative survival rates were better for X3 liners as compared to CoC bearings. Moreover, when ranking the yearly cumulative percent revision rates, again the best results were obtained with X3 liners with small alumina heads (cumulative percent revision rate at 0.298).
Conclusion: Within the frame of this Trident study, the use of this X3 highly cross-linked annealed polyethylene could be considered as a reliable alternate solution to CoC bearings.
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For the last 2 decades, major concerns in hip arthroplasty have concerned the fate of bearing surfaces. Wear and osteolytic responses to particles with so-called "conventional" ultrahigh molecular weight polyethylene UHMWPE (PE) have led to wide spread use of current "hard-on-hard" (HoH) bearing couples, especially ceramic-on-ceramic (CoC) bearings. Apart from these

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HoH materials, highly cross-linked polyethylene materials (HXLPE) have also come a long way and currently demonstrate successful in vitro results with new technical procedures of cross-linking the polyethylene material [1-7]. Callary et al [8] reported on a 5-year radiostereometric analysis study (RSA) about a sequentially irradiated and annealed, second-generation highly cross-linked polyethylene (XLPE) liner and concluded that the mean proximal, 2-dimensional, and 3-dimensional wear rates calculated between 1 year and 5 years were all less than 0.001 mm/y with no patient recording a wear rate of more than 0.040 mm/y. Bascarevic et al [9] evaluated the reliability and durability of CoC in comparison to metal-on-HXLPE bearing couples in a prospective randomized study involving 150 patients (157 hips) with no statistically significant changes at a mean 50.4-month follow-up period in clinical and radiographic parameters between the 2 groups.

Some researchers suggested that processing the material below its melting temperature to produce so-called "annealed HXLPE," allows retention of important mechanical properties [10,11]. In particular, wear, oxidation, and mechanical properties of a sequentially irradiated and annealed UHMWPE in total joint arthroplasty have been reported by Wang et al [12]. According to these authors, the first-generation HXPE materials were produced by irradiation followed by heating below the melting temperature (annealing) or above the melting temperature (remelting). Both classes of HXPE material have demonstrated greatly, reduced wear, however, remelted HXPE materials have reduced fatigue strength, whereas annealed HXPE materials may oxidize when exposed to oxygen. A second-generation HXPE material was produced using a sequential irradiation and annealing process (SXL); SXL materials have cross-linking levels equivalent to those of first-generation HXPE materials, have fatigue and mechanical strength characteristics of first-generation annealed HXPE material, and have an oxidation resistance equivalent to that of virgin (unprocessed) UHMWPE. For such reasons, we have focused on sequentially annealed HXLPE through the present study.

The goal of the current project was therefore to compare, through 2 separate parallel studies, the performance of a consecutive nonselected cohort of patients implanted with a second-generation sequentially annealed HXLPE acetabular bearings vs 2 consecutive nonselected cohorts one implanted with conventional polyethylene (study A) and one implanted with contemporary alumina on alumina COC hip bearings (study B). These 3 types of bearings, all matched with the same acetabular shell, were analyzed from data released by the National Joint Registry (NJR) of England and Wales, through their 2012 annual report [13] allowing comparison of the outcome and results of more than 45,000 bearings belonging to these 3 different types of liners.

The study hypothesis of this retrospective case–control study was that sequentially annealed HXLPE liners could perform significantly better or worse than either the "conventional" PE or the CoC bearings control cohorts through a 2-tailed hypothesis. Conversely, the null-hypothesis was that no difference has been shown with respect to clinical outcome for these bearings, taking into account the various cumulative survival rates.

Material and Methods

Implants

The NJR has assimilated data on patients, surgeons, and implants performed in both the private and public sector (National Health Service) in England and Wales since 2003. According to the 2013 NJR Annual Report, in 51,185 cases, the acetabular shell was the hydroxyapatite (HA)-coated Trident uncemented cup (Stryker Orthopaedics, Mahwah, NJ), which features various bearing surface options and can be matched with either a polyethylene or ceramic liner into the same metallic shell. The study group consisted of second-generation sequentially irradiated and annealed X3 HXLPE liners, whereas the 2 control groups were, for the first group, gamma-in-nitrogen sterilized polyethylene (N2vac) "conventional" polyethylene liners and, for the second group, bulk Biolox Forte pure AL liners (Ceramtec, Plochingen, Germany). The head was either a CrCo head or an AL head for all PE liners, whereas only AL heads were coupled with the AL liners. The head diameters ranged from 22.2 mm up to 28 and 32 mm for N2vac liners and from 22.2 up to 28, 32, 36, 40, and 44 for X3 liners, whereas the ceramic system did not feature 22.2-mm heads. All acetabular components were manufactured by Stryker Orthopaedics.

Inclusion Criteria

Data recorded in the NJR database had collected information for all Trident acetabular system variations between April 2003 and March 2013. Several groups were defined with regard to the head material, that is, metal (MET) or alumina (AL) in the first instance, and head diameter, that is, less or equal to 32 mm as "small (S)" and over 32 mm as "large (L)."

Inclusion and exclusion criteria were selected to match, as much as possible, the functional environment of the prosthesis. From a total number of 51,185 Trident cases reported in the NJR annual report, and to minimize any potential bias, we included only cases, which fulfilled the following criteria:

- Primary hip arthroplasty.
- Complete data about material and diameter of head and material and diameter of implanted liner.
- Metal or alumina head featuring a 22.2 mm diameter or over.
- Fixed, nonconstrained liner, excluding both mobile bearings and constrained liners.
- Either X3, N2vac, or AL liners. Other types of HXLPE liners, which were not sequentially irradiated and annealed were excluded (namely Crossfire liners).
- Osteoarthritis as the only indication.
- HA-coated Trident as the metallic shell.

According to these inclusion criteria, data being available for comparison were 45,877 hips. In such a way,

- 21,470 X3 liners were available against 8225 N2Vac conventional PE liners for the first comparison as X3 vs N2vac (study A),
- 16,182 AL bearings for the second comparison as X3 vs CoC bearings (study B; Fig. 1).

Depending on both type of bearing and type and head diameter, 4 groups got defined for the first comparative study involving N2vac PE (only with small heads as large heads were not available with N2vac liners) and 4 groups for the second study (S and L metallic heads of X3 couples could obviously not be compared to CoC bearings).

Statistical Analysis

As the dependent variable, in accordance with Kaplan–Meier methods, cumulative survival curves have been computed between X3 liners and both N2vac (study A) and AL liners (study B) on various end points and subgroups. Statistical significance was set at $P < .05$. Statistical methods for clinical data used chi-square tests (including the Monte Carlo method to enhance sensitivity for small samples), nonparametric tests (Kruskall–Wallis), parametric tests (analysis of variance, Student *t*-test), and the Mantel–Haenszel and

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