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 concerns, 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 cumulative percent 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.
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-XLPE 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 HXPE,” 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 HXPE 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,

- 2,1470 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
log-rank in survival rates. With regard to survivorship analysis while performing the log-rank tests, a valuable strength of the analysis was insured by a minimum of 30 cases remaining at risk at longest follow-up; moreover, a value greater than or equal to 0.50 for correlation tests (alpha set at 0.05; effect size set at 0.02) was considered as valid. All statistical analyses were performed with XLSTATS (Addinsoft, New York, NY), version 2013.3.01. Because the time after index surgery was different among the 3 groups, as the X3 Trident device has only been available since 2006, the comparative survival rates have been analyzed for all available combinations at the same maximum follow-up period useable for each group. When the number of cases in any subgroup did not allow for consistent comparison with regard to various types and diameters of head vs types of liners, the related comparative analyses were excluded because of low statistical power.

Analyses for the 3 groups have been completed by assessment of the related yearly cumulative percent revision rates (CPRs). Statistical tests were carried out by the authors and validated by a Statistician Engineer.

The main end point has been first defined as revision for any cause for the entire cohort of each group in each of the 2 case–control studies A and B, then as a second step for each subgroup of paired implants according to the related subgroup (based on type of liner, type of head, and head size). An additional analysis has been carried out by selecting the end point as any cause, which could be related to a failure of the bearing couple itself according to the NJR tables. Out of 28 potential causes of revision as recorded in the NJR database, 12 were selected as bearing-related: dislocation, fracture of the socket, fracture of the head, head socket mismatch (socket), head socket mismatch (head), head socket mismatch (global), lysis around stem, lysis around socket, wear of acetabular component, wear of PE component, dissociation of the liner, and adverse soft tissue reaction.

In addition to survivorship analyses, the yearly CPR has been analyzed for all cohorts as the ratio of revisions/100 implanted prostheses during the global number of follow-up period. This ratio can be illustrated by the following formula as “revisions/100 obs. years = N revised hips/(N primary hips × mean follow-up in years)/100.” The cumulative percentage revision, generically a “cumulative failure rate,” accounts for right censoring due to death and “closure” of the database at the time of analysis and in primary hips is generally considered as correctly performing under the “warning” value of 1.

Demographics

CoC bearings were mainly indicated in younger patients, which explained some discrepancies in mean ages which were significantly higher (Kruskal–Wallis; P < .0001) for N2vac and X3
Type of surgery was mainly recorded as “hip primary” in all groups (97.0% for N2vac, 99.8% in X3, and 97.3 in the AL group) and less than 3% for “hip complex primary.” Approach was mainly posterior for the 3 groups (49.8% N2vac, 73.3% X3, and 69.1% AL), followed by lateral, including Hardinge (43.1% N2vac, 26.2% X3, and 28.8% AL), being said that anterior approach was less than 7% for the 3 groups (74.7% N2vac, 99.8% X3, and 97.3% AL).

Mostly used stems (N2vac, X3, and AL, respectively) were Exeter at 74.3% against 16.0% for 36 mm and 9.7% for 28 mm. The 5 cases mainly used stems (N2vac, X3, and AL, respectively) were Exeter V40 (68.9%, 52.3%, and 52.8%), Accolade I (16.9%, 41.6%, and 38.1%), then HA-coated ABG II (2.5%, 13%, and 5.3%), HA-coated Omnifit (4.8%, 0.4%, and 2.7%), and Corail (0.3%, 2.8%, and 0%).

In fact, only 2 variables could potentially demonstrate a statistically significant difference between the paired studied groups, that is, patient’s age (t-test with \(P < .001\)) and head diameter (chi-square <0.0001). The mean ages of patients at surgery were higher for N2vac and X3 groups vs AL group. However, when age and ASA score were included in a Cox proportional hazards regression analysis of the various bearings, there were no groups, which had significant differences from the basis, apart from the subgroup of small metalic heads while comparing N2vac vs X3 liners. These variables could thus be considered as introducing no potential bias in the analysis (all \(P > .05\)), whereas the subgroup of small metalic heads (N2vac vs X3) has been specifically analyzed within the related section.

### Global Outcomes and Complications Leading to Revision

#### Comparative Factors in Unrevised vs Revised Hips

Average age of patients within the revised hips (N at 703) was significantly lower (Kruskal–Wallis with \(P = .005\)) at 65.62 years (18.5-97.6; standard deviation [SD] 11.137) vs unrevised ones (N at 43,084) at 66.94 years (15.4-100.6; SD 10.504). Conversely, comparative variables were not significantly different (chi-square) for ASA scores (\(P = .252\)) as well as gender (\(P = .914\)). The “hip complex surgery” was significantly more frequent (chi-square with \(P < .0001\)) vs “hip primary” within the revised group (3.70%) vs unrevised (1.42%).

The size of cup for revised and unrevised groups was mainly 50 mm, 52 mm, and 54 mm (with, respectively, 17.5%, 22.9%, and 19.3% for revised, against 20.9%, 23.6%, and 18.7% for unrevised hips). No significant difference according to the outcome of hips could be demonstrated according to the diameter of cups with \(P = .886\) by chi-square test. Head diameters were (for both revised vs unrevised groups) mainly 32 mm (40.4% vs 46.6%), 28 mm (26.2% vs 20.9%), and 36 mm (24.2% vs 25.6%) with no significant difference at \(P = .809\) (chi-square). The rate of revised hips according to the mode of fixation was not significantly (chi-square with \(P = .021\)) different with 1.14% for cemented vs 2.18% for HA-coated stems. Rates of revised hips vs unrevised for the 5 mostly used stems (ie, Exeter V40, Accolade I, ABG II, HA Omnifit, and Corail) were not significantly different at \(P = .147\) (chi-square).

#### Comparative Factors Between the 3 Groups of Bearings Within the Revised Hips Cohort vs Unrevised

Average ages for revised patients were lower in the AL group at 60.13 years (18.5-87; SD 11.311), than for N2vac at 68.83 years (42-91; SD 9.236) and X3 at 69.30 (37-98; SD 9.716). Interestingly, a comparison of ages within the 3 groups according to revised patients vs unrevised could not demonstrate statistical difference at \(P = .991\) (chi-square). Patients’ gender was not significant at \(P = .350\) (chi-square); comparative statistical values according to the outcome of “hip complex primaries” vs “hip primaries” did not demonstrate any difference between revised and unrevised hips (N2vac at 0.299; AL at 0.238; and X3 at 0.718). Similarly, the size of the cup was not significant for the outcome within the 3 groups (N2vac at P with .896; AL at P with .999; and X3 at P with .985). So was the diameter of the head as a not confounding variable for N2vac (P with .738), AL (P with .806), and X3 (P with .218).

Comparatively, the mode of fixation (cemented vs HA-coated stems) was statistically significant in favor of the cemented ones for the 3 types of bearings (N2vac P with .008; AL P with .037; and X3 P with .002).

The revision period after surgery was significantly different for the bearings with the shortest period for X3 at 1.12 years (0-5, SD: 1.111), followed by AL at 1.91 years (0-8.4, SD 1.899) and N2vac (0-7.9, SD 1.993). Among these revised hips, the rate of bearing-related causes was significantly higher for N2vac at 40.45%, then AL at 22.34%, and X3 at 14.29% (chi-square with \(P < .0001\)).

#### Comparative Factors Within the Bearing-Related Failures Cohort

Two variables could be taken into account for any bearing-related failure, that is, cup size and head diameter. With regard to cup sizes, none of the 3 studied bearings demonstrated a significant difference between revised vs unrevised hips, according to the size from 46 to 66 mm, that is, \(P\) value (chi-square) at 0.552 for N2vac, 0.562 for AL, and 0.314 for X3. Conversely, a significant difference within the N2vac cohort (at .043) was found between revised vs unrevised hips according to head diameter, whereas such a significance was not observed for AL (at .598) and X3 (at .809).

With respect to the causes of bearing-related failures, the detailed causes recorded through the registry would allow for some comparisons, being said that the mode of gathering data does not provide exact circumstances of the need for revision regarding each specific case, with frequent multiple recorded causes, whereas some records could be seen as questionable (eg, wear of acetabular components with ceramic liners). In addition, the high percentage of recurrent dislocations in each group prevents from any analysis in depth for other comparative bearing-related causes. Anyway, the revision rates according to the various liners for bearing-related revisions other than recurrent dislocations was 0.26% with N2vac, against 0.19% with CoC, and the lowest rate at 0.07% for X3 liners (Table 1).

### Survivorship in Study A Comparing X3 vs N2vac Liners

Global results, survival rates, and comparisons are listed in Table 2.
End Point: Revision for Any Cause

Comparative Global Survival Rates

For a global cohort of 21,470 X3 liners, with a maximum available period of follow-up at 6.2 years, the cumulative survival rate was 98.0% (0.976-0.983), whereas in the 8225 N2vac liners group, with a maximum available period of follow-up at 9.5 years, the cumulative survival rate was 96.7% (0.960-0.973; Fig. 2).

At a similar period of 6.2 years for each group, the cumulative survival rate was thus 98.0% (X3) against 97.3% (0.969-0.977) for the N2vac group. No statistically significant difference was recorded at log-rank test with a P value at .072 between these 2 groups.

Comparative Survival Rates for Specific Subgroups According to Various Types and Diameters of Heads

- Small metallic heads (MET-S): At a similar period of 5.9 years for each group, the cumulative survival rate was 98.5% (0.979-0.991) in the X3 study cohort (N at 6695) against 97.4% (0.970-0.979) in the N2vac control group (N at 7435). A statistically significant difference was recorded with better results for X3 liners at log-rank test with a P value at .014 between these 2 MET-S groups (Fig. 3). When age and ASA score were included in a Cox proportional hazards regression analysis of the 2 bearings, X3 liners were significantly better as compared to N2vac.

- Small alumina heads (AL-S): At a similar period of 5.7 years for each group, the cumulative survival rate was 99.1% (0.985-0.996) in the X3 study cohort (N at 2521) against 97.5% (0.964-0.987) for the N2vac group (N at 798). A statistically significant difference was recorded with better results for X3 liners at log-rank test with a P value at .002 between these 2 AL-S groups (Fig. 4).

Large heads (MET-L and AL-L): Because of the lack of diameter greater than 32 mm in N2vac liners, no statistical test could be carried out between N2vac and X3 liners coupled with large heads. Nevertheless, survival rates have been computed for X3 liners, coupled with large metallic heads (MET-L), which demonstrated a cumulative rate at 6.1 years of 97.5% (0.969-0.980) for a study cohort of 9543 X3 liners, with 151 revisions. When large alumina heads were used, at a 5.7-year period, the cumulative survival rate was 98.3% (0.975-0.991) in the X3 study cohort (N at 2711).

End Point: Revision for Bearing-Related Failures

Comparative Global Survival Rates

For a global cohort of 21,470 X3 liners, with a maximum available period of follow-up at 6.2 years, the cumulative survival rate was 99.6% (0.994-0.998), whereas in the 8388 N2vac liners, with a maximum available period of follow-up at 9.5 years, the cumulative survival rate was 98.3% (0.977-0.988). At a similar period of 6.2 years, the cumulative survival rate was thus 98.0% (X3) against 97.3% (0.969-0.977) for the N2vac group. No statistically significant difference was recorded at log-rank test with a P value at .072 between these 2 groups.

Table 1
Breakdown of Bearing-Related Failures According to the 3 Groups of Bearings.

<table>
<thead>
<tr>
<th>Bearings</th>
<th>AL</th>
<th>N2vac</th>
<th>X3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dislocation subluxation</td>
<td>30</td>
<td>51</td>
<td>21</td>
</tr>
<tr>
<td>Dissociation of liner</td>
<td>9</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Wear of acetabular component</td>
<td>9</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Adverse soft tissue reaction</td>
<td>5</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Lysis stem</td>
<td>3</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Head socket mismatch head</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Implant fracture head</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Lysis socket</td>
<td>1</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Head socket mismatch socket</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Implant fracture socket</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>61</td>
<td>72</td>
<td>36</td>
</tr>
</tbody>
</table>

AL, alumina.

Table 2
Comparative Survival Rates at 6 Years in Study A (X3 vs N2vac Liners).

<table>
<thead>
<tr>
<th>End Point Cohorts</th>
<th>X3</th>
<th>N2vac</th>
<th>Rank</th>
<th>Log-Rank; P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any cause</td>
<td>21,470</td>
<td>8525</td>
<td>97.3</td>
<td>X3 &gt; N2vac; NS, P = .072</td>
</tr>
<tr>
<td>MET-S</td>
<td>6695</td>
<td>7429</td>
<td>97.4</td>
<td>X3 &gt; N2vac; S, P = .014</td>
</tr>
<tr>
<td>AL-S</td>
<td>2521</td>
<td>796</td>
<td>96.9</td>
<td>X3 &gt; N2vac; S*, P = .002</td>
</tr>
<tr>
<td>Bearing related</td>
<td>21,470</td>
<td>8525</td>
<td>98.8</td>
<td>X3 &gt; N2vac; S**, P = .001</td>
</tr>
<tr>
<td>MET-S</td>
<td>6695</td>
<td>7429</td>
<td>98.9</td>
<td>X3 &gt; N2vac; S**, P = .002</td>
</tr>
<tr>
<td>AL-S</td>
<td>2521</td>
<td>796</td>
<td>98.7</td>
<td>X3 &gt; N2vac; S***, P = .000</td>
</tr>
</tbody>
</table>

Significant (P < .05); **highly significant (P < .01); ***very highly significant (P < .001).

Values in bold correspond to statistically significant differences.

AL, alumina; L, large; MET, metal; NS, not significant (P > .05); S, small.
years for each group, the cumulative survival rate was thus 99.6% (0.994-0.998), for X3 against 98.8% (0.985-0.991) for the N2vac group. A highly significant statistical difference was recorded at log-rank test with a \( P \) value <.0001 between these 2 groups.

**Comparative Survival Rates for Specific Subgroups According to Various Types and Diameters of Heads**

- **MET-S:** At a similar period of 5.9 years for each group, the cumulative survival rate was 99.7% (0.995-0.999) in the X3 group (N at 6695) against 98.9% (0.986-0.992) in the N2vac group (N at 7435). A highly significant statistical difference was recorded with better results for X3 liners at log-rank test with a \( P \) value at .002 between these 2 MET-S groups.
- **AL-S:** At a similar period of 5.7 years for each group, the cumulative survival rate was 99.9% (0.998-1) in the X3 study cohort (N at 2711) against 99.8% (0.997-0.999) for the N2vac group (N at 2588). Again, although comparative survival rates were better for X3 bearings, however, no statistically significant difference was recorded at log-rank test with a \( P \) value at .187 between these 2 groups considered as a whole.
- **AL-L:** At a similar period of 5.7 years for each group, the cumulative survival rate was 99.9% (0.993-1) in the X3 study cohort (N at 2521) against 99.4% (0.993-0.996) for the CoC group. Comparative survival rates were better for X3 bearings; however, no statistically significant difference was recorded at log-rank test with a \( P \) value at .045 between these 2 groups.
- **Large heads (MET-L, AL-L):** Because of the lack of diameter greater than 32 mm in N2vac liners, no statistical test could be carried out between N2vac and X3 liners coupled with large heads. Nevertheless, survival rates have been computed for X3 liners, coupled with large metallic heads (MET-L), which demonstrated a cumulative rate at 6.1 years of 99.5% (0.992-0.998) for a study cohort of 9543 X3 liners, with 25 revisions. When AL-Ls were used, at a 5.7-year period, the cumulative survival rate was 99.7% (0.995-1) in the X3 study cohort (N at 2711).

**Survivorship in Study B Comparing X3 Matched with Alumina Heads vs CoC Bearings**

Global results, survival rates, and comparisons are listed in Table 3.

**End Point: Revision for Any Cause**

**Comparative Global Survival Rates**

For a global cohort of 5232 X3 liners coupled with alumina heads, with a maximum available period of follow-up at 5.9 years, the cumulative survival rate was 98.6% (0.981-0.991), whereas in the 16,182 CoC group, with a maximum available period of follow-up at 9.7 years, the cumulative survival rate was 96.9% (0.962-0.976; Fig. 5). At a similar period of 5.9 years for each group, the cumulative survival rate was thus 98.6% (0.981-0.991) X3 against 97.6% (0.973-0.979) for the CoC group. Comparative survival rates were better for X3 bearings; however, no statistically significant difference was recorded at log-rank test with a \( P \) value at .187 between these 2 groups considered as a whole.

**Comparative Survival Rates for Specific Subgroups According to Various Types and Diameters of Heads**

- **AL-S:** At a similar period of 5.7 years for each group, the cumulative survival rate was 99.1% (0.985-0.996) in the X3 study cohort (N at 2521) against 97.8% (0.974-0.981) for the CoC bearings group (N at 13,594). Comparative survival rates were in favor of X3 bearings, however, no statistically significant difference was recorded at log-rank test with a \( P \) value at .058 between these 2 groups AL-S (Fig. 6).
- **AL-L:** At a similar period of 5.7 years for each group, the cumulative survival rate was 98.3% (0.975-0.991) in the X3 study cohort (N at 2711) against 97.4% (0.966-0.982) for the CoC bearings group (N at 2588). Again, although comparative survival rates were better for X3 bearings, no statistically significant difference was recorded at log-rank test with a \( P \) value at .564 between these 2 groups AL-L (Fig. 7).

**End Point: Revision for Bearing-Related Failures**

**Comparative Global Survival Rates**

For a global cohort of 5232 X3 liners, with a maximum available period of follow-up at 5.9 years, the cumulative survival rate was 99.8% (0.997-1), whereas in the 16,182 CoC bearings group, with a maximum available period of follow-up at 9.7 years, the cumulative survival rate was 99.1% (0.985-0.996). At a similar period of 5.9 years for each group, the cumulative survival rate was thus 99.8% (X3) against 99.4% (0.992-0.996) for the CoC group. A statistically significant with better results with X3 liners was recorded at log-rank test with a \( P \) value at .045 between these 2 groups considered as a whole.

Table 3
Comparative Survival Rates at 6 Years in Study B (X3 vs CoC Bearings).

<table>
<thead>
<tr>
<th>End Point</th>
<th>Cohorts</th>
<th>X3</th>
<th>CoC</th>
<th>Rank</th>
<th>Log-Rank Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Survival (%)</td>
<td>N</td>
<td>Survival (%)</td>
<td>( P )</td>
</tr>
<tr>
<td>Any cause</td>
<td>Global</td>
<td>5232</td>
<td>98.6</td>
<td>16,182</td>
<td>97.6</td>
</tr>
<tr>
<td>AL-S</td>
<td>2521</td>
<td>99.0</td>
<td>13,594</td>
<td>97.8</td>
<td>X3 &gt; CoC</td>
</tr>
<tr>
<td>AL-L</td>
<td>2711</td>
<td>98.3</td>
<td>2588</td>
<td>97.4</td>
<td>X3 &gt; CoC</td>
</tr>
<tr>
<td>Bearing related</td>
<td>Global</td>
<td>5232</td>
<td>99.8</td>
<td>16,182</td>
<td>99.4</td>
</tr>
<tr>
<td>AL-S</td>
<td>2521</td>
<td>99.9</td>
<td>13,594</td>
<td>99.4</td>
<td>X3 &gt; CoC</td>
</tr>
<tr>
<td>AL-L</td>
<td>2711</td>
<td>99.7</td>
<td>2588</td>
<td>99.3</td>
<td>X3 &gt; CoC</td>
</tr>
</tbody>
</table>

Values in bold indicate statistical significance.

AL, alumina; CoC, ceramic-on-ceramic; L, large; NS, not significant; S, small.
Comparative survival rates were better for X3 bearings; however, no statistically significant difference was recorded at log-rank test with a $P$ value at .086 between these 2 groups of AL-S.

- AL-L: At a similar period of 5.7 years for each group, the cumulative survival rate was 99.7% (0.995-1.0) in the X3 study cohort (N at 2711) against 99.3% (0.989-0.997) for the CoC bearings group (N at 2588). Again, although comparative survival rates were better for X3 bearings, no statistically significant difference was recorded at log-rank test with a $P$ value at 0.118 between these 2 groups of AL-L.

**Breakdown of Comparative Yearly CPR According to the 3 Groups**

The CPR allows for comparison of several cohorts although the numbers of cases and follow-up can be different. When comparing the 8 combinations between liner, type of head, and head size, a ranking can be obtained between the various groups. The best results from our NJR Trident series were obtained by X3 HXLPE bearings matched with a small alumina head (28 or 32 mm) with a CPR of 0.298, followed by both the X3 liners matched with small metallic heads and CoC bearings with small heads (CPR of 0.431).

Roughly speaking, large heads, be they metal or alumina, have performed at a lower level than the 28 and 32 mm, with all types of bearings, apart from small alumina heads marched with N2vac liners. Anyway, all the Trident variants indices were encouraging at a rate below the “warning” value of 1 (Table 4).

**Discussion**

Data from the NJR 9th Annual Report allowed us to analyze a large cohort of acetabular cups of similar design, featuring 3 different liners. The study hypothesis of this retrospective case–control study was that the new generation of sequentially annealed HXLPE X3 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. Our study hypothesis through a first comparison was confirmed for HXLPE liners, which performed significantly better than “conventional” PE. Conversely, a second study comparing HXLPE against CoC bearings could not reject the null-hypothesis based on the frame of the related cohorts.

At a similar follow-up period of around 6 years, all Trident cups demonstrated, in all combinations of liners and heads, encouraging global survivorship with cumulative rates all between 95% and 99%. The first study demonstrated that X3 liners performed significantly better than N2vac PE within all subgroups of small heads (metal and alumina). When taking into account only the potential bearing-related failures as the end point, a very high level of statistical significance was observed in all subgroups, confirming within the frame of the study, the superiority in terms of survivorship of X3 HXLPE liners vs conventional UHMPE components. On the second parallel study, for the whole group or for any subgroup of head sizes, the cumulative survival rates at the sixth year were better for X3 liners as compared to CoC bearings. Similar comparative analyses were carried out while taking into account only the potential bearing-related causes for revision, and
confirmed a statistically significant better outcome with X3 than CoC for the whole group. However, this was not statistically confirmed among the 2 subgroups of small and large alumina heads. Moreover, CPR rates allowed for ranking the index of revisions/100 observed, with again the best result obtained when matching X3 liners with small alumina heads (CPR of 0.298), followed by both X3 liners with small metallic heads and CoC bearings with small heads (both had a CPR of 0.431). All the Trident combinations for this index remained under the “warning” limit of 1 in terms of CPR analyses.

Adverse tissue response to wear particles released from UHMWPE hip bearings stimulated laboratory studies in the 1990s that suggested conventional polyethylene can be highly cross-linked during the manufacturing process to provide a 3-dimensional structure that is intrinsically resistant to wear. As confirmed by Röhrl et al [9] in an RSA study, wear for annealed highly cross-linked PE was extremely low up to 10 years. Callary et al [8] reported on a 5-year RSA about a sequentially irradiated and annealed, second-generation highly crosslinked 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.

According to Wang et al [12], a second-generation HXPE material was produced using a SXL. Dumbleton et al [14], described this X3 material as “the basis for a second-generation HLXPE,” created by a sequential irradiation and annealing process. This process, according to these authors, preserves mechanical strength properties and has the highest survivorship in functional fatigue testing, while demonstrating a low free radical content, and performance under accelerated aging being the same as virgin UHMWPE. In such a way, “modern” highly cross-linked PEs have become true competitors of H0H bearings. To our knowledge, no article has been previously published about in vivo comparison between alumina bearings and HLXPE liners except an article in 2010 by Bascarevic et al [9], concluding that alumina bearing couples at 4 years had proved to be as reliable as CoCr/HXLPE, and on similar findings a personal series by Epinette and Manley in 2014 [15] reporting no differences found in bearing-related hip survivorship at 10- to 12-year follow-up between patients with ceramic on highly cross-linked polyethylene bearings compared to patients with CoC bearings.

There are some shortcomings in the data collected from these 3 cohorts that could compromise the analysis. The periods of follow-up differed slightly between the cohorts, the number of cups in some subgroups were very low, and above all, causes for revisions can be extremely variable and address confounding, non-bearing-related events. This discrepancy in follow-up periods was addressed by selecting all survival analyses in the same 6-year follow-up, which is the maximum period available for X3 implants. No specific analysis related to any potential temporal effect in the comparative outcome of the 3 cohorts has been carried out because of the relatively short time for the X3 liners at 6 years. Such an additional investigation defining different steps of comparative outcomes will have to be performed within a further study at 10 years of follow-up period for X3 liners. With respect to end points, in addition to the revisions for any cause, which was our first primary dependent variable, we also computed all survival rates in all groups and subgroups on the 12 potential bearing-related causes (of the 28 various events) extracted from the NJR database report. The additional use of these bearing-related end points seems consistent for additional assessment and, given the huge number of analyzed NJR data using the same component, may help to draw valuable information, although the period of follow-up was relatively short and a high level of recurrent dislocations recorded in all groups of these fixed bearings. Anyway the percentage of bearing-related causes, in not dislocated hips, was in favor of X3 bearings with 0.07% vs 0.19% for CoC and 0.26% with N2vac. The encouraging results provided by the present study have naturally to be confirmed by further similar comparative analyses at longer follow-up, and namely, specific studies focusing in depth on the negative impact of dislocations on the global outcomes of bearings.

However, and within the frame of this double-parallel Trident acetabular study, the findings suggested that X3 liners performed significantly better than conventional polyethylene and at least as well as the CoC bearings, if not better. Hence, the conclusions of the present study at mid-term follow-up would give support to the use of polyethylene bearings in this specific X3 highly cross-linked sequentially and annealed formulation as a reliable alternate solution to CoC bearings.

Acknowledgments

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References

15. Epinette JA, Manley MT. No differences found in bearing related hip survivorship at 10-12 years follow-up between patients with ceramic on highly cross-linked polyethylene bearings compared to patients with ceramic on ceramic bearings. J Arthroplasty 2014;29(7):1369.