Minimum 10-Year Follow Up of Vitamin-E Diffused and Highly Crosslinked Polyethylene Liners in Total Hip Arthroplasty: Comparative Evaluation from a Prospective, International, Multicenter Study of 977 Patients

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INTRODUCTION:

Total hip arthroplasty (THA) is a proven, effective treatment for end-stage osteoarthritis. The success of THA is due in part to the advent of highly crosslinked (XL) polyethylene implants. In 2007, a new generation of polyethylene liners entered clinical use. The new liners infused polyethylene with vitamin E (EP). The EP liner was hypothesized to prevent the loss of mechanical properties caused by in vivo oxidation, thus extending the lifetime of the implant. This study aimed to quantify implant longevity by comparing the wear rate and patient-reported outcome measures (PROMs) between EP and XL liners. The international prospective study reported the clinical outcomes of a 977-patient cohort with minimum follow up ten years after surgery.

METHODS:

The prospective cohort study began in 2007, including eight countries and seventeen centers. The centers were randomly assigned to implant combinations. The final cohort included 977 patients (EP liner: n=520; XL liner: n=457). Demographic information included age, gender, race, and body mass index was collected at time of surgery.

Patients were followed preoperatively, postoperatively, and at 1, 3, 5, 7, and 10 years after surgery. Each follow-up visit involved clinical evaluation, radiography, and PROM collection. Radiographs were evaluated for implant wear using the Martell method (Figure 1). PROMs included the Harris Hip Score (HHS), the Short-Form 36 (SF-36), the EuroQol 5-dimension (EQ-5D), and the University of California, Los Angeles Activity Score (UCLA). Revisions were also recorded. Mann-Whitney U tests were used to evaluate statistical differences between implant cohorts. P-values of <0.05 were considered significant.

RESULTS:

At ten years following surgery, 534 patients were eligible for follow up. Of those eligible, 352 patients returned for clinical evaluation (65.9% eligible; 36.0% overall). No statistical differences were found (P >0.05) in the demographics of the followed-up cohort (Table 1).

With the numbers available for study, the mean femoral penetration rate was -0.009 mm/year and 0.024 mm/year for EP and XL liners, respectively (Figure 2). The EP liner exhibited significantly lower wear (P=0.0100) than the XL liner. The negative rate reflects the orientation of vector wear, which was inferior to the acetabular center.

PROMs suggested no significant difference between EP and XL liner cohorts (Table 2). However, compared to previous follow-up periods, mean 10-year scores decreased across all measures (Figure 3). The overall incidence of revision was 2.3% for EP and 2.0% for XL liners.

No significant difference arose in liner type and primary indication among the 352 patients represented in the 10-year cohort and those lost to follow up. However, there was a statistical difference in age (P=0.0452) as well as ethnicity (P=0.0002) in patients lost to follow up (Table 3).

DISCUSSION AND CONCLUSION:

Our study demonstrated no significant difference in PROM scores relative to current XL technology and a significantly lower wear rate. The reduction in wear rate seen in EP liners relative to XL liners is promising, as this is the most crucial characteristic that impacts long-term survival of polyethylene implants.

The principal limitation of this study concerns the patients lost to follow up. Pandemic-related site closures account for the statistical differences in study demographics (ethnicity and age). No other significant difference arose in demographics and liner type among the patients lost to follow up compared to patients returning for 10-year follow up. Thus, results may be generalizable to the study population.

Increasingly, THA patients constitute a younger demographic. The EP liner may improve the lifetime performance of THA implants, ensuring arthroplasty outcomes meet the needs of an increasingly active population.

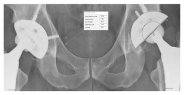

Figure 1: Example of two-dimensional wear analysis as calculated by the Martell method.

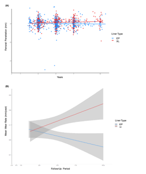

Figure 2: Two-dimensional liner wear as defined by the (A) raw femoral penetration relative to the 1-year radiograph and (B) the mean wear rate, or femoral penetration (mm) over time (years). Note: the sign of the wear rate reflects position of the wear vector relative to the acetabular center (e.g., negative rate indicates wear vector inferior to center). EP = vitamin-E infused polyethylene; XL = crosslinked polyethylene.

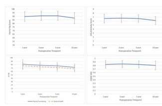

Figure 3: Mean patient reported outcome measures (PROMs) at each follow-up period, including standard deviation. HHS = Harris Hip Score; UCLA = University of California, Los Angeles Activity Score; SF-36 = Short-Form 36; EQ-5D-VAS = EuroQol 5-dimension visual analog scale.

Table 1: Demographics of the patient population followed-up at 10-years, including liner type and *P*-values.

	All (n=352)	XL Liner (n=179)	EP Liner (n=173)	*P*-value
Mean Age	74.80 (47-89)	74.80 (47-89)	74.79 (47-89)	0.7566
Women	173	90	83	0.6658
Ethnicity				
White	333	171	162	0.4330
African American	3	0	3	0.1177
Hispanic Latino	5	3	2	1.0000
Other	11	5	6	0.7675
Mean BMI	28.31±5.07	28.60±5.10	28.05±5.05	0.3320
Indication				
Primary Coxarthrosis	253	124	129	0.2875
Dysplastic coxarthrosis	29	16	13	0.7002
Secondary Coxarthrosis	14	5	9	0.2849
Unspecified Coxarthrosis	56	34	22	0.1118

*Statistically significant P-values <0.05

XL = crosslinked polyethylene; EP = vitamin-E infused polyethylene; BMI = body mass index.

Table 2: Summary of mean patient-reported outcome measures (PROMs) at 10-year follow up, including liner type and *P*-value.

Mean Score	XL Liner (n=143)	EP Liner (n=147)	*P*-value
HHS	87.20%	87.72%	0.7716
UCLA (out of 10)	5.95	6.29	0.1808
SF-36			
Physical Functioning	70.82%	72.76%	0.5170
General Health	66.80%	68.97%	0.4090
EQ-5D-3L			
Mobility: no problems	64.34%	65.31%	0.8638
Mobility: some problems	35.66%	34.69%	0.9046
Selfcare: no problems	89.51%	88.44%	0.7702
Selfcare: some problems	9.79%	10.88%	0.7827
Selfcare: unable	0.70%	0.68%	0.9845
Usual activities: no problems	65.03%	72.10%	0.1943
Usual activities: some problems	31.47%	26.53%	0.4916
Usual activities: unable	3.50%	1.36%	0.2475
Pain/Discomfort: none	53.15%	56.46%	0.5705
Pain/Discomfort: moderate	43.36%	36.73%	0.4512
Pain/Discomfort: severe	3.50%	6.80%	0.2273
Anxiety/Depression: none	84.62%	85.03%	0.9209
Anxiety/Depression: moderate	13.29%	12.93%	0.9363
Anxiety/Depression: severe	2.10%	2.04%	0.9733
EQ-5D-VAS	75.12%	76.50%	0.5527

*Statistically significant *P*-values <0.05

XL = crosslinked polyethylene; EP = vitamin-E infused polyethylene; HHS = Harris Hip Score; UCLA = University of California, Los Angeles Activity Score; SF-36 = Short-Form 36; EQ-5E-3L = EuroQol 5-dimension 3-level version; EQ-5D-VAS = EuroQol 5-dimension visual analog scale.

Table 3: Demographics of the followed-up patient population compared to those lost to follow-up at 10-years after surgery, including liner type and *P*-value.

	All (n=977)	Followed Up (n=352)	Lost to Follow Up (n=625)	*P*-value
Mean Age	73.96 (37-90)	74.8 (47-89)	73.5 (37-90)	**0.0452***
Women	484	173	311	0.8542
Ethnicity				
White	89.87	94.60	87.20	**0.0002***
African American	2.46	1.42	3.36	0.0706
Hispanic Latino	6.04	0.85	8.64	**<0.0001***
Other	1.64	3.13	0.80	**0.0060***
Mean BMI	28.44±5.08	28.33±5.07	28.5±5.08	0.5530
EP Liner	53.02	49.15	55.20	0.0688
Indication				
Primary Coxarthrosis	73.90	71.88	75.04	0.2795
Dysplastic coxarthrosis	6.24	8.24	5.12	0.0531
Secondary Coxarthrosis (including trauma)	4.09	3.98	4.16	0.8899
Unspecified Coxarthrosis	15.76	15.91	15.68	0.9248

*Statistically significant P-values <0.05

BMI = body mass index; EP = vitamin-E infused polyethylene.