ORIGINAL ARTICLE

Ten-year Successful Results of Primary Total Knee Arthroplasty Using Cross-linked Polyethylene

Philippe Massin[1], Pierre de Saint Hermine[2], Jean Marie Frin[2], Patrick Le Nay[2], Philippe Ridereau[2], Laurent Hubert[2]

[1]Department of Orthopedic Surgery, Angers University Hospital and Clinique Hartmann, Clinique Hartmann, 26 Boulevard Victor Hugo, 92200 Neuilly Sur Seine, France, [2]Department of Orthopedic Surgery, Angers University Hospital, 4 Rue Larrey, 49100 Angers, France

ABSTRACT

Introduction: Highly cross-linked polyethylene (HXLPE) has been used for over a decade in total hip arthroplasty and has been shown to significantly reduce wear phenomena. At the knee, data are rare and the advantage of HXLPE inserts remains hypothetical because the stress regimen and wear mechanism are different. HXLPE has been accused of notwithstanding shear and peak compressive stresses. Our assumption was that the use of HXLPE would not compromise 10-year results compared to standard polyethylene. We asked whether[1] it would affect 10-year survival of primary total knee arthroplasty; [2] it would impair 10-year radiographic and clinical results. **Methods:** We examined 97 patients (Group 1) who underwent total knee arthroplasty with HXLPE (Durasul) over 10 years ago. These patients were retrospectively compared to 50 patients operated on in the same period using the same implant (Natural Knee 2, Zimmer) with standard polyethylene (sterilized in inert atmosphere) by other surgeons from the same institution (Group 2). Functional and radiographic results (from standard radiographs) were compared in terms of survival, clinical outcomes, and osteolysis. Sixty-four patients from Group 1 and 30 patients from Group 2 were examined with a follow-up of more than 10 years. Seventeen of Groups 1 and 12 in Group 2 died. Five and 14 patients, respectively, were lost. **Results:** 10-year survival rates, including revision for any cause, were 97 ± 3 and 91 ± 10%, respectively ($P = 0.19$). Two patients in Group 1 were reviewed due to instability and stiffness of the knee, and three patients in Group 2 were reviewed due to infection, instability, and patellar pain. Otherwise, the International Knee Society, Knee injury and Osteoarthritis Outcome Score, and mobility interval scores were not significantly different (P-values of 0.6, 0.7, and 0.7, respectively). None of the radiographs of the two groups showed osteolysis or widening radiolucencies. **Conclusions:** 10-year functional and radiographic results were not compromised by the use of HXLPE in cemented primary knee arthroplasty. On the other hand, the advantage of using HCLP in total knee arthroplasty is not yet proven. Longer monitoring and more accurate wear assessment are needed.

Key words: Highly cross-linked polyethylene, long-term results, primary total knee arthroplasty

INTRODUCTION

Highly cross-linked polyethylene (HXLPE) has been used for over a decade in total hip arthroplasty. Indeed, it was demonstrated in the 1980s that the wear resistance of polyethylene increased with the level of irradiation, causing connections between monomer chains using these double vinyl links located at the end of the chain.[1]

Irradiation also releases free radicals which increase the risk of oxidative degradation. Therefore, irradiated polymers had to be subjected to high temperatures (above their melting point) to eliminate free radicals. However, the remelted materials

Address for correspondence:
Philippe Massin, Department of Orthopedic Surgery, Angers University Hospital, Clinique Hartmann, 26 Boulevard Victor Hugo, 92200 Neuilly Sur Seine, France. E-mail:phmassin@gmail.com

also showed a decrease in mechanical fatigue strength. Their tensile strength and tensile strength were lower.[2] As a result, these polymers were more affected by creep.[3]

At the hip, abrasion is predominant, resulting from contact between two congruent spherical surfaces. *In vitro* wear simulation of a highly cross-linked poly showed that gravimetric wear was lower than that of a conventional poly.[4] Clinical results confirmed a significant decrease in long-term wear.[5]

At the knee level, data are rare, and the advantage of HXLPE inserts remains hypothetical because the stress regimen and wear mechanism are different. The HXLPE was suspected of not resisting shear stresses and compression peaks, resulting from two incongruent surfaces sliding over each other. There were fears of rapid deterioration or breakage of the insert, especially with the thinner inserts. However, Muratoglu *et al.*[6,7] showed that *in vitro* tests on posterior cruciate retaining prostheses produced less adhesion and abrasive wear using aged HXLPE. Iwakiri *et al.*[8] found smaller and fewer particles in the synovial fluid of knee joints implanted with HXLPE at the early stage after surgery. On the contrary, Hinarejo *et al.*[9] found no significant difference in the number of particles in the synovial fluid of joints implanted with HXLPE compared to those implanted with conventional polyethylene.

Clinical trials[5] report results, to date, in the medium term. Using a moderately XLPE (subjected to 6.5 Mrad), Lachiewicz and Soileau[10] produced the 4.5-year results of a randomized comparison with conventional polyethylene and found no advantage but also no disadvantage in the use of HXLPE. Hodrick *et al.*[11] also failed to show a difference in survival between HXLPE (irradiated at 9.5 doses and remelted) and conventional polyethylene in a 5–7 years' retrospective survey.

Two senior authors have used this polyethylene with the same prosthesis (Natural Knee, Zimmer, Indiana) since 2003. Two other senior surgeons from the same institution performed several knee replacements during the same period with the same implant using conventional polyethylene (sterilized in an inert atmosphere under 2.2 Mrad gamma irradiation). The first 100 patients operated with HXLPE were compared to a group of patients implanted with conventional polyethylene during the same period. A 10-year retrospective comparison of results was undertaken.

Our assumption was that the use of HXLPE would not compromise 10-year results compared to standard polyethylene. We asked whether:

1. Survival in the two patient groups was different.
2. Radiographic and clinical results were similar.

METHODS

A retrospective comparison of 147 consecutive patients, who underwent total primary knee arthroplasty in the same establishment during 2003–2004 by 3 senior surgeons, using the ultracongruent NK2 prosthesis with fixed inserts of different types, was undertaken. The operations were carried out with conventional instruments using the measured gap resection technique. 97 patients were operated on by two surgeons using Durasul inserts (irradiated with 9.5 Mrad and subsequent melting and sterilized with ethylene dioxide), while the remaining 50 patients were operated on by a third and fourth surgeons using conventional polyethylene (irradiated with 2.5 Mrad in an inert atmosphere). The age, sex, and bone mass index (BMI) of the two populations were not significantly different [Table 1].

There were some differences in the surgical techniques because 48% of the tibial baseplate in Group 2 were fixed using additional screws whereas there was none in Group1 [Table 2]. The most frequent insert thickness was 9 mm in both groups, but the use of thicker inserts was more frequent in Group 1 (47% vs. 14% in Group 2; $P < 0.001$).

The patella was resurfaced selectively, in those patients complaining primarily of pre-operative patellar pain syndrome. Thus, 75 patients had their patella resurfaced in Group 1, while there were only 24 in Group 2 ($P = 0.003$).

Patients who had not passed their 10-year clinical examination were recalled and scheduled for clinical examination and guided fluoroscopic X-rays (standard X-rays, side views, AP, and skyline). 64 patients from Group 1 and 30 patients from Group 2 were examined with a follow-up of more than 10 years. Seventeen of Groups 1 and 12 in Group 2 died

Table 1: Demographic characteristics

Patient's description	HXLPE (*n*=97)	Standard (*n*=50)	*P* value
Sex ratio (male/female)	0.64	0.85	0.43
Age (years)	70	72	0.27
BMI	29.5	29.6	0.98
HKA preoperative (°)	176	177	0.47
Etiology			0.77
Primary osteoarthritis	87	46	
Post-traumatic	3	2	
Rheumatoid	6	2	
AVN	1	0	

HKA: Hip knee ankle angle, BMI: Bone mass index, AVN: Avascular necrosis

before the 10th post-operative year. Five and 14 patients, respectively, were lost [Table 3].

Functional and radiographic results were compared in terms of survival, clinical outcomes (International Knee Society [IKS];[12] Knee Injury and Osteoarthritis Outcome Score [KOOS] score;[13] and manual measurement of active bending amplitude), and osteolysis. The AP and X-ray-guided side views were examined in the Ewald[14] femoral zones and 3 and 5-tibial areas of the fixation interface (around the stem). The main criterion was survival, endpoint revision for any cause, or pending revision (radiographic loosening not revised at review date).

We calculated that the search for a 5% decrease in the number of Group 2 survivors compared to Group 1 would require at least 36 patients in each group, for an alpha risk of 0.05 and a power of 80%.

We compared continuous variables between the two groups using t-tests and categorical variables with Chi-square tests. Time to revision for wear, which was the primary outcome, was analyzed using a log-rank test with survival probabilities displayed using a Kaplan–Meier plot. All statistical tests were for a two-sided comparison with significance set at $P < 0.05$.

Table 2: Variations in the surgical technique

Surgical technique	HXLPE (*n*=97)	Standard (*n*=50)	*P* value
Fixation of the tibial baseplate using screws	0	24	<0.0001
Patellar resurfacing	75	24	0.0003
Insert thickness			<0.0001
9 mm	49	43	
11 mm	27	5	
13 mm	16	2	
16 mm	5		

RESULTS

The 10-year survival rates, including revision for any cause or pending revision, were 97 ± 3 and 91 ± 10%, respectively ($P = 0.19$). There was no revision due to wear and/or aseptic loosening. Two patients in Group 1 were reviewed due to instability and knee stiffness, respectively, and three patients in Group 2 were reviewed due to infection, instability, and patellar pain.

Otherwise, the IKS scores, KOOS scores, and mobility ranges were not significantly different (*P*-values of 0.6, 0.7, and 0.7, respectively) [Table 4]. None of the radiographs of the two groups showed osteolysis or widening radiolucencies [Figures 1 and 2].

DISCUSSION

While the results of total knee arthroplasty using HXLPE were, to date, only described at mid-point, here we present the results of a 10-year monocentric retrospective study and found that the use of HXLPE did not compromise survival or radiographic and clinical outcomes.

This study has limitations. (1) There was no randomization. Although the two groups were comparable for age and BMI, there were more women in Group 2, but there is still no evidence that gender would influence the occurrence of wear. (2) Four senior surgeons were involved, but they were trained for knee surgery and used the same implantation technique. However, several Group 2 tibial base plates were fixed with additional screws, which may have contributed to backside wear. (3) No tomodensitometry (TDM) was performed to detect osteolysis. It may, therefore, be underestimated. (4) No attempt was made to measure wear accurately. It is not possible to obtain accurate and reproducible wear measurements on standard radiographs. It has been shown that wear assessment would be possible if the inserts were provided with tantalum markers, which would allow

Table 3: Follow-up and causes for revisions

Patient's status at final review	HXLPE	Standard	*P* value
Follow-up for those patients reviewed after 10 years	11±0.5 (10.5–12.5)	11±0.5 (10.5–12.4)	0.6
Deceased (%)	17 (17)	12 (24)	0.3
Lost (%)	14 (14)	5 (11)	0.9
Survival (%)	97±3	91±10	0.2
Revision	2	3	0.3
Infection		1 (9 months)	
Instability	1 (36 months)	1 (12 months)	
Stiffness	1 (38 months)		
Patellar pain		1 (70 months)	

Table 4: 10-year clinical and radiographic results

10-year results	HXLPE (*n*=64)	Standard (*n*=30)	*P* value
IKS	138.8±14.3	135.9±28.4	0.51
KOOS	54.2±16.3	52.7±13.3	0.67
Flexion range (°)	110±9	109.1±19.8	0.69
Radiolucencies at the stem	0	0	
Osteolysis	0	0	

IKS: International knee society, KOOS: Knee injury and osteoarthritis outcome score

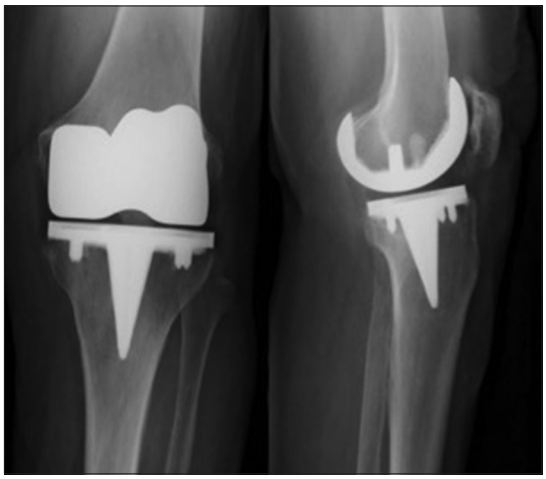

Figure 1: 11-year radiographic result of a 75-year-old patient of Group 1, showing no osteolysis and no radiolucency. The patient reported an 80% knee injury and osteoarthritis outcome score

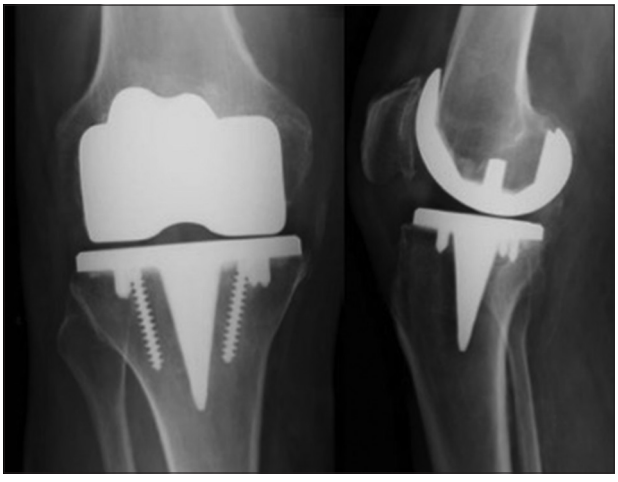

Figure 2: 11-year radiographic result of a 65-year-old patient of Group 1, showing no osteolysis and no radiolucency. The patient reported a 75% knee injury and osteoarthritis outcome score

incidence control.[15] It is regrettable that manufacturers who propose a new material for clinical use do not also provide the means to adjust the radiographic incidence, which would allow faster detection of abnormal deterioration of the inserts. (5) Several patients were lost due to the retrospective nature of this evaluation, which weakens the demonstration. (6) The thickness of the insert is a major parameter influencing the deterioration of the insert. Pijls *et al.*[16] showed that inserts smaller than 8 mm were not suitable for use. In the present study, only 53% of the HXLPE inserts were of the thinnest thickness (9 mm), while there were 86% on the conventional poly group, which may have favored the latter.

However, this is the first long-term monocentric evaluation of HXLPE in the knee. Hodrick *et al.*[11] reported results over 5–7 years of total knee replacement using the same implant and HXLPE. Although they did not provide information on the thickness of the insert, they came to similar conclusions in terms of survivors. They observed that radiolucencies were more frequent in the group of patients implanted with conventional polyethylene. Three revisions were required in the conventional poly group, while there were none in the XPLE group.

These studies may lack the power to achieve significance when comparing survivals. De Steiger *et al.*[17] concluded from a registry study of over 380,000 implants with follow-up of more than 5 years that the use of XLPE would decrease the 10-year revision rate from 5.8 to 3.5, particularly in those knees implanted with NK2 prostheses. In fact, looking for a 2%-difference between survival rates of 2 groups of patients requires at least 580 individuals in each group to reach a 80%-power. However, register studies may ignore other parameters such as shelf aging or other technical parameters that also influence wear resistance.

The tolerance to HXLPE may vary depending on the design of the insert. With postero-substituting devices, fractures of the post-cam have been described.[18] However, this was not the case in Kim and Park's series,[19] which also tested postero-substituted inserts in bilaterally operated patients. They found no post-cam fracture or osteolysis on either side at 5.9 years of average follow-up. In the case of posterior cruciate-retaining implants, Kim *et al.*[20] found no difference between the right and left sides of patients implanted bilaterally with HXLPE on one side and moderately cross-linked poly on the other side. The superiority of HXLPE is generally reported in series of patients implanted with ultracongruent implants. However, with this design, wear may be related to the surgical technique, in particular to residual laxity, producing a paradoxical forward rolling and subsequent delamination, as reported in a recent series showing 20% osteolysis at 7 years.[21] Therefore, it is difficult to compare different groups of patients who were not operated on by the same surgeon with the variable quality of polyethylene, as a substantial difference in residual anterior-posterior laxity may persist due to subtle interindividual variations in the assessment of ligament tension.[21]

The degree of cross-linking can also have an influence. In their registry study, de Steiger *et al.*[17] found a significant improvement in HXLPE implant survival if it was a highly irradiated and remelted insert. On the contrary, implants with a moderate level of cross-linking that had been annealed gave the same survival as those involving conventional poly. Meneghini *et al.*[21] failed to show any difference with conventional poly in 60 patients when using annealed XLPE after 5 years of use. Kindsfater *et al.*[22] reported the same results over 5 years using a moderately cross-linked poly in a randomized study involving groups of over 400 patients.

In conclusion, our 10-year study showed the absence of wear-related revisions using remelted HXLPE inserts including the thinnest ones. As far as the incidence of osteolysis is concerned, only powerful investigations involving hundreds of patients can demonstrate a positive effect. As with the hip, systematic, accurate, and successive measurements of medial and lateral tibial femoral width on AP fluoroscopic guided incidences would allow the *in vivo* wear rate to be calculated and the potential durability of HXLPE implants to be extrapolated.

REFERENCES

1. McKellop H, Shen FW, Lu B, Campbell P, Salovey R. Development of an extremely wear-resistant ultra high molecular weight polyethylene for total hip replacements. J Orthop Res 1999;17:157-67.
2. Baker DA, Hastings RS, Pruitt L. Study of fatigue resistance of chemical and radiation crosslinked medical grade ultrahigh molecular weight polyethylene. J Biomed Mater Res 1999;46:573-81.
3. Lewis G, Carroll M. Effect of crosslinking uhmwpe on its tensile and compressive creep performance. Biomed Mater Eng 2001;11:167-83.
4. D'Lima DD, Hermida JC, Chen PC, Colwell CW Jr. Polyethylene cross-linking by two different methods reduces acetabular liner wear in a hip joint wear simulator. J Orthop Res 2003;21:761-6.
5. Lachiewicz PF, Soileau ES. Highly cross-linked polyethylene provides decreased osteolysis and reoperation at minimum 10-year follow-up. J Arthroplasty 2016;31:1959-62.
6. Muratoglu OK, Bragdon CR, O'Connor DO, Perinchief RS, Jasty M, Harris WH, *et al.* Aggressive wear testing of a cross-linked polyethylene in total knee arthroplasty. Clin Orthop Relat Res 2002;404:89-95.
7. Muratoglu OK, Bragdon CR, Jasty M, O'Connor DO, Von Knoch RS, Harris WH, *et al.* Knee-simulator testing of conventional and cross-linked polyethylene tibial inserts. J Arthroplasty 2004;19:887-97.
8. Iwakiri K, Minoda Y, Kobayashi A, Sugama R, Iwaki H, Inori F, *et al. In vivo* comparison of wear particles between highly crosslinked polyethylene and conventional polyethylene in the same design of total knee arthroplasties. J Biomed Mater Res B Appl Biomater 2009;91:799-804.
9. Hinarejos P, Piñol I, Torres A, Prats E, Gil-Gómez G, Puig-Verdie L, *et al.* Highly crosslinked polyethylene does not reduce the wear in total knee arthroplasty: *In vivo* study of particles in synovial fluid. J Arthroplasty 2013;28:1333-7.
10. Lachiewicz PF, Soileau ES. Is there a benefit to highly crosslinked polyethylene in posterior-stabilized total knee arthroplasty? A randomized trial. Clin Orthop Relat Res 2016;474:88-95.
11. Hodrick JT, Severson EP, McAlister DS, Dahl B, Hofmann AA. Highly crosslinked polyethylene is safe for use in total knee arthroplasty. Clin Orthop Relat Res 2008;466:2806-12.
12. Insall JN, Dorr LD, Scott RD, Scott WN. Rationale of the knee society clinical rating system. Clin Orthop Relat Res 1989;248:13-4.
13. Roos EM, Lohmander LS. The knee injury and osteoarthritis outcome score (KOOS): From joint injury to osteoarthritis. Health Qual Life Outcomes 2003;1:64.
14. Ewald FC. The knee society total knee arthroplasty roentgenographic evaluation and scoring system. Clin Orthop Relat Res 1989;248:9-12.
15. Massin P, Heizmann J, Prove S, Dupuy FR, Ponthieux A. Accuracy and reproducibility of computer-assisted measurement of polyethylene wear in knee arthroplasty. Acta Orthop Belg 2008;74:72-82.
16. Pijls BG, Van der Linden-Van der Zwaag HM, Nelissen RG. Polyethylene thickness is a risk factor for wear necessitating insert exchange. Int Orthop 2012;36:1175-80.
17. de Steiger RN, Muratoglu O, Lorimer M, Cuthbert AR, Graves SE. Lower prosthesis-specific 10-year revision rate with crosslinked than with non-crosslinked polyethylene in primary total knee arthroplasty. Acta Orthop 2015;86:721-7.
18. Diamond OJ, Howard L, Masri B. Five cases of tibial post fracture in posterior stabilized total knee arthroplasty using prolong highly cross-linked polyethylene. Knee 2018;25:657-62.
19. Kim YH, Park JW. Comparison of highly cross-linked and conventional polyethylene in posterior cruciate-substituting total knee arthroplasty in the same patients. J Bone Joint Surg Am 2014;96:1807-13.
20. Kim YH, Park JW, Kim JS, Lee JH. Highly crosslinked-remelted versus less-crosslinked polyethylene in posterior cruciate-retaining TKAs in the same patients. Clin Orthop Relat Res 2015;473:3588-94.
21. Meneghini RM, Ireland PH, Bhowmik-Stoker M. Multicenter study of highly cross-linked vs conventional polyethylene in total knee arthroplasty. J Arthroplasty 2016;31:809-14.
22. Kindsfater KA, Pomeroy D, Clark CR, Gruen TA, Murphy J, Himden S. *In vivo* performance of moderately crosslinked, thermally treated polyethylene in a prospective randomized controlled primary total knee arthroplasty trial. J Arthroplasty 2015;30:1333-8.

How to cite this article: Massin P, Hermine PS, Frin JM, Nay PL, Ridereau P, Hubert L. Use of Highly Cross-linked Polyethylene in Primary Total Knee Arthroplasty Did Not Compromise 10-year Results. Clin Res Orthop 2018;1(2):1-5.