The Journal of Arthroplasty xxx (2017) 1–7

Contents lists available at ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

Is Cross-Linked Polyethylene an Improvement Over Conventional Ultra-High Molecular Weight Polyethylene in Total Knee Arthroplasty?

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ARTICLE INFO

Article history:
Received 5 July 2017
Received in revised form
28 September 2017
Accepted 3 October 2017
Available online xxx

Level of Evidence:
Level II
cohort study

Keywords:
total knee
XLPE
registry
survival
UHMWPE
manufacturing process

ABSTRACT

Background: Reducing polyethylene (PE) wear by increasing the cross-linking encouraged surgeons to hope for increased total knee arthroplasty (TKA) survival rates. Different methods of manufacturing cross-linked polyethylene (XLPE) were introduced, following promising in vitro results. Is there a measurable effect of cross-linking on TKA survival?
Methods: A registry study was conducted, focusing on fixed tibial inserts in primary TKA. Conventional PE represented 87% of the liners, 10% were cross-linked and 2% were antioxidant PE. Sixty-four percent of the liners were posterior-stabilized (PS). Survival of the different PE groups and survival of the main XLPE available were successively compared. We also looked for differences in the same brand implant groups with regard to PE type, as well as differences between cruciate retaining and PS knees.
Results: No differences were found when looking at survival for any cause or for aseptic loosening only ($P = .96$). When comparing the XLPE available, X3 was found to have a better survival than Prolong or Smith & Nephew XLPE ($P = .036$). When the same implants and X3 or conventional PE were used, no difference could reach a statistical significance. With Zimmer LPS Flex, Prolong XLPE was even associated with a lower survival compared with conventional PE. On Stryker implants, only the Cox regression model allowed highlighting a difference between X3 XLPE and conventional PE, only in PS knees.
Conclusion: Increasing the cross-linking seems to only have a low effect, if any, on knee arthroplasty survival. Differences between brands could be found; the manufacturing process could play a role.

Although total knee arthroplasty (TKA) survival is multifactorial, younger patients tend to have a lower survival [1]. Reducing polyethylene (PE) wear would seem beneficial, thus prompting a quest for better wear-resistant bearings. One of the answers resulted in increasing the cross-linking [2] of ultra-high molecular weight polyethylene, defining a new entity, cross-linked polyethylene (XLPE) [3].

As a polymer, PE [4] could be defined as a perfect composite of 2 phases. The amorphous phase represents the naked polymer strands that can be linked together via covalent bonds (in the process known as cross-linking), to increase the strength and the molecular weight of the polymer. The second phase is composed of polymer strands folding on themselves, producing the crystalline phase, responsible for most of the mechanical properties of the polymer. As cross-linking is usually performed by radiation, increasing the cross-linking also produces deleterious free radicals. To get rid of the free radicals, 2 processes were advocated [5]. The remelting process, implying to heat the polymer over the fusion point, was the oldest and most effective. But as it also strongly

One or more of the authors of this paper have disclosed potential or pertinent conflicts of interest, which may include receipt of payment, either direct or indirect, institutional support, or association with an entity in the biomedical field which may be perceived to have potential conflict of interest with this work. For full disclosure statements refer to https://doi.org/10.1016/j.arth.2017.10.005.

Investigation performed at IOR, Bologna, Italy.

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https://doi.org/10.1016/j.arth.2017.10.005
0883-5403/

Table 1
The 3 Populations of Polyethylene Tibial Inserts Were Comparable in Terms of Gender Ratio and Age at Implantation.

Polyethylene Type	Female				Male			
	No. of Patients	%	Mean Age	Range	No. of Patients	%	Mean Age	Range
Conventional	15,110	72.1	72.0	21-95	5845	27.9	71.0	24-92
Cross-linked	1858	70.4	70.8	31-88	783	29.6	70.1	34-90
Antioxidant	423	67.2	71.5	39-90	206	32.8	70.2	44-85
Total	17,391	71.8	71.9	21-95	6834	28.2	70.9	24-92

impacts the crystalline phase, thus reducing the mechanical properties, an alternative was offered. Annealing is made by several heating processes below the melting point, thus lowering the amount of free radicals without degrading the crystalline phase. Vitamin E was also introduced to lower free radicals, with different ways of incorporating it inside the polymer. As all these products were defined as XLPE, studying the impact of cross-linking is becoming increasingly difficult, from a clinical point of view. Registries offer a reliable mean to compare the survival of different implants and to look for influencing factors.

The Australian registry was analyzed by de Steiger et al [6], concluding on the apparent role of cross-linking in the reduction of revision rates. But they mentioned a possible bias, linked to the fact that brands often offer an XLPE with a new knee implant and/or a new ancillary. When looking at specific implants having been implanted with either a conventional or an XLPE, differences were not always found. Other registry studies also did not find an effect of cross-linking on survival [7,8]. The manufacturing process of XLPE was also not investigated.

A registry was used to select brands with the same insert philosophy but different PE types, to look for the specific effect of cross-linking on implant survival.

The goal of our study is to measure the effect of cross-linking on TKA survival. As cross-linking was introduced in that purpose, our hypothesis was that it has a beneficial effect on implant survival.

Methods

Study Design and Setting

This study was designed as a registry study. Since 2000, the Emilia-Romagna Italian registry (Register of Prosthetic Orthopedic Implants [RIPO]) has been following all orthopedic implants in the region, on about 4.5 million inhabitants. Patients were included from January 7, 2000 to December 12, 2015.

Participants/Study Subjects

All analyses presented in this study are based on 27,661 primary operations in 24,225 patients (3436 bilateral).

The inclusion criteria were implants in primary knee surgery on patients living in the region, having a fixed tibial insert with known material, posterior or minimally stabilized. Implants with incomplete data were excluded from the study.

The exclusion criteria were a mobile tibial insert or a hinged knee implant. Mobile inserts have been excluded to avoid a confusion bias linked to different wear behavior. It has already been demonstrated [9] that mobile inserts could have more wear than fixed inserts. Hinged implants also might show different wear characteristics than less constrained implants. Overall, the most homogeneous population possible was chosen.

PE inserts were categorized as conventional polyethylene (conventional PE), XLPE, or vitamin E impregnated polyethylene (antioxidant PE), as found in producer catalogs. The manufacturing process of the XLPE (remelting or annealing) was also recorded via the same means.

XLPE was first being used in 2007, while polyethylene with antioxidant (“antioxidant PE”) implantations started in 2012.

Table 1 shows the patient characteristics according to PE type. The 3 populations were comparable.

Table 2 focused on the repartition of the etiologies having led to the arthroplasty, also by PE type.

Repartition of implant characteristics by PE type showed similar features in conventional and XLPE, while PE with vitamin E was not associated with a cementless or hybrid fixation (Table 3).

Description of Experiment, Treatment, or Surgery

Survival curves of conventional, cross-linked, and vitamin E PEs were plotted against each other, looking for significance, with revision for any cause as an endpoint. As other causes of revision

Table 2
The Diagnoses Before Surgery by Polyethylene Type Did Not Show Differences Between the 3 Populations.

Diagnosis	Conventional PE	Cross-Linked PE	Antioxidant PE
Primary arthritis	21,406	2046	572
Deformity	1339	633	50
Rheumatic arthritis	282	30	4
Post-traumatic arthritis	286	44	7
Sequelae of fracture	268	45	4
Necrosis of the condyle	160	30	5
Sequelae of osteotomy	164	22	2
Post-traumatic necrosis	33	9	
Idiopathic necrosis	18		
Sequelae of septic arthritis	17	6	
Sequelae of poliomyelitis	2		
Chondrocalcinosis	10	3	
Other	143	17	4
Total	24,128	2885	648

Table 3
Repartition of Implant Characteristics by Polyethylene Type Showed Similar Features in CPE and Cross-Linked Polyethylene, While Polyethylene With Vitamin E Were Not Associated With a Cementless or Hybrid Fixation.

	CPE	XLPE	Antioxidant PE
Type of knee arthroplasty			
Bicompartmental	19,445	2448	338
Tricompartmental	4683	437	310
Stabilization of the insert			
Minimally stabilized	8630	1292	71
Posterior stabilized	15,498	1593	577
Cementation			
Cemented	22,589	2828	647
Cementless	955	46	
Femur cementless + tibia cemented	405	8	
Femur cemented + tibia cementless	173	3	
Total[a]	24,122	2885	647

CPE, conventional polyethylene.
[a] Seven missing data regarding the cementation.