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ORIGINAL PAPER

A systematic review of radiological outcomes of highly cross-linked polyethylene versus conventional polyethylene in total hip arthroplasty

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Abstract The purpose of this study was to summarise the best evidence to assess radiological outcomes of highly cross-linked polyethylene compared with conventional polyethylene in total hip arthroplasty. All randomised, controlled clinical trials comparing highly cross-linked polyethylene with conventional polyethylene were sought and then analysed by two independent reviewers using the Cochrane collaboration guidelines. Eight studies in seven articles were identified as eligible for inclusion. Due to the clinical and methodological heterogeneity, data from the studies included could not be pooled. No failures related to highly cross-linked polyethylene were reported. All highly cross-linked polyethylene groups had a significantly lower wear or penetration than conventional polyethylene groups. This preliminary result suggests that highly cross-linked polyethylene has significantly less wear than conventional polyethylene.

Résumé Le but de cette étude est de résumer les données indiscutables dans les prothèses totales de hanche concernant l'évaluation du devenir radiologique du polyéthylène hautement réticulé comparé au polyéthylène conventionnel. Tous les essais contrôlés, randomisés comparant le polyéthylène hautement réticulé au polyéthylène conventionnel ont été analysés par deux reviewers indépendants à partir de la base de Cochrane. 8 études dont 7 articles ont été identifiés et inclus dans ce travail. Du fait de l'hétérogénéicité clinique et méthodologique de ces études, toutes les données n'ont pu être regroupées. Aucun échec du polyéthylène hautement réticulé n'a été rapporté. Dans ces études, tous les groupes concernant le polyéthylène hautement réticulé et ont une usure et une pénétration plus basses que le polyéthylène conventionnel ceci de façon significative. Ces données préliminaires permettent de penser que le polyéthylène hautement réticulé a de façon significative moins d'usure que le polyéthylène conventionnel.

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Introduction

The metal-on-polyethylene bearing surface remains the most common articulation in total hip arthroplasty and has provided satisfactory results [1, 2, 24]. However, polyethylene wear, leading to periprosthetic osteolysis, is one of the most important causes of aseptic loosening and revision total hip arthroplasty [11, 18, 21].

To reduce wear and improve longevity of total hip arthroplasty procedures, highly cross-linked polyethylenes have emerged as an alternative bearing. In vitro studies have shown that these materials show great improvements in resistance to wear [13, 16, 20]. Nevertheless, hip simulator data is not always consistent with clinical findings [10, 14].

Since 1998, highly cross-linked polyethylene has been introduced for clinical use in total hip arthroplasty.

Although many clinical studies reported dramatic wear reduction, most of them were not randomised, controlled trials and lacked high-level clinical evidence. Moreover, no systematic review or meta-analysis has been published on this matter.

We therefore performed this systematic review to summarise the best evidence in the literature to assess wear performance of highly cross-linked polyethylene acetabular liners compared with conventional polyethylene liners. We postulated that highly cross-linked polyethylene should have a significantly lower wear than conventional polyethylene.

Materials and methods

Search strategy

We searched Medline, EMBASE, Cochrane Central Register of Controlled Trials, and ISI Web of Science, with no restrictions on date of publication or language. The search strategy employed the following terms: highly cross-linked; polyethylene; randomised. The reference list of published trials was manually examined to find additional relevant studies. We also contacted experts in the field to identify additional studies. The closing date for retrieval of studies was 13 October 2008.

Selection criteria

We included randomised total hip arthroplasty clinical trials comparing highly cross-linked polyethylene liners with conventional polyethylene liners and excluded those trials which were only reported in proceedings with the full text unavailable. When data in studies was presented repeatedly, we included the longest follow-up outcomes.

One reviewer performed an initial title and abstract screening of articles to discard those which were clearly ineligible, then two reviewers independently examined the full article to assess the trials for eligibility for inclusion, with disagreements resolved by discussion. If necessary, we attempted to contact the author of the original reports to obtain further details.

Data extraction and assessment of risk of bias

Two reviewers independently extracted data from each trial including the location of the trial, study design, participants, liner type, methods of fixation, outcomes, follow-up duration, dropout or lost to follow-up data, and conflict of interest by using standardised forms. Risk of bias in the studies was assessed independently by at least two reviewers according to the criteria [12, 25]. The criteria involved the judgement for four features of interest including sequence generation, allocation sequence concealment, blinding, and incomplete outcome data. Any disagreements between reviewers arising at any stage were resolved by discussion when necessary with the help of a third reviewer.

Data analysis

Data could not be analysed using a meta-analysis due to the clinical and methodological heterogeneity in the available studies. They were expressed as mean and standard deviation.

Results

The search strategy generated 18 articles from Medline, 13 from EMBASE, 17 from Cochrane Central Register of Controlled Trials, and 18 from ISI Web of Science. Due to two studies reported by the same article [5], eight studies in seven articles [4, 5, 7–9, 15, 23] were identified as eligible for inclusion (Fig. 1). Four highly cross-linked polyethylene liners were used: Marathon in two studies [4, 7], Longevity in two [5, 9], Durasul in three [5, 8, 23], and Crossfire in one [15]. The types of hip implant and fixation method were different among studies.

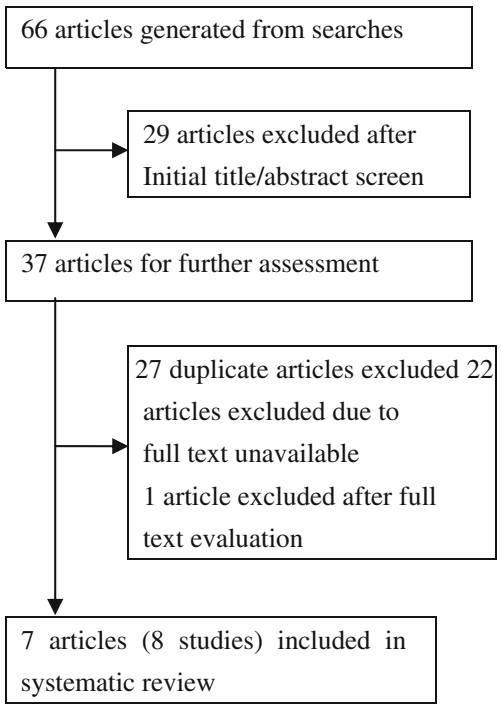

Fig. 1 Flow diagram showing selection process of studies included in systematic review

The randomisation process was described and appropriate for three studies [4, 9, 23]; the other studies mentioned randomisation allocation but lacked a description of the randomisation method [5, 7, 8, 15]. With respect to allocation concealment, four studies [4, 9, 15, 23] were adequate and four [5, 7, 8] were unclear. Regarding blinding of outcome assessment, six studies [4, 7–9, 15, 23] were adequate and two [5] were unclear. Four studies [5, 7, 15, 23] reported the rate of exclusion were greater than 15% and one study [4] did not describe the exact number of participants in both groups.

Characteristic details and risk of bias of seven of the studies are summarised in Tables 1 and 2, respectively. Table 3 shows the results of radiological evaluation of highly cross-linked polyethylene compared with conventional polyethylene. Due to clinical and methodological heterogeneity, data from the studies which included comparison of highly cross-linked polyethylene with conventional polyethylene could not be pooled and thus are described individually according to the polyethylene liners used.

No failures related to polyethylene liners were reported in the studies included. Two studies compared wear of Marathon polyethylene liners with that of Enduron liners. Clavert et al. [4] reported significant differences between the two groups in linear ($p=0.002$), 3D linear ($p=0.012$), and volumetric wear rate ($p=0.017$). Similarly, Engh et al. [7] reported that the Marathon group was significantly lower in the 2D linear and volumetric wear rate than those in the Enduron group ($p<0.001$ and $p<0.001$). Meanwhile, they found significantly lower incidence of any osteolysis ($p<0.001$) and osteolysis more than 1 cm^2 ($p=0.002$) in the Marathon group.

Three studies reported the penetration results of Durasul polyethylene liners compared with Sulene liners. Digas et al. [5] found that the Durasul group was significantly lower in proximal and total head penetration ($p<0.001$ and $p<0.001$), not in medial and anterior head penetration ($p=0.3$ and $p=0.5$). In another randomised trial, Garcia-Rey et al. [8] reported that there was a significant difference in penetration rate ($p<0.001$) in favour of the Durasul group. Similarly, Triclot et al. [23] described that the Durasul group had significantly lower linear and volumetric penetration rate ($p=0.0027$ and $p=0.0058$).

Two studies compared penetration of Longevity polyethylene liners with that of conventional liners. Digas et al. [5] found that the Durasul group was significantly lower in proximal and total head penetration ($p<0.001$ and $p<0.001$), but not in medial and anterior head penetration ($p=0.2$ and $p=0.4$). Gly-Jones et al. [9] reported that the Longevity group was significantly superior to the control group in linear wear rate ($p=0.012$) and total penetration ($p=0.0184$).

Comparing Crossfire polyethylene liners with conventional liners, Martell et al. [15] reported significantly lower penetration rates in 2D linear ($p=0.001$), 2D volumetric ($p=0.049$), and 3D linear ($p=0.005$) types. They also noted that the Crossfire group had showed a trend for reduction in 3D volumetric wear rate.

Table 1 Characteristics of the studies included

Study	Design	Participants analysed	Linear	Fixation	Follow-up (y)	Notes
Clavert et al. [4]	RCT	Unclear	Marathon Enduron	Hybrid	4	Two participants died of causes unrelated to surgery. Evidence of conflict of interests
Digas et al. [5][a]	RCT	HXLPE=28 CPE=27	Durasul Sulene	Cemented	5	Five participants did not attend the follow-up. Evidence of conflict of intrests
Digas et al. [5][a]	RCT	HXLPE=19 CPE=19	Longevity CPE	Hybrid	5	13 participants (26 hips) could not be evaluated. Evidence of conflict of intrests
Engh et al. [7]	RCT	HXLPE=76 CPE=72	Marathon Enduron	Cementless	4.3	226 participants included, 148 measured wear rate, 186 identified osteolysis Incidence. Evidence of conflict of intrests
Garcia-Rey et al. [8]	RCT	HXLPE=45 CPE=45	Durasul Sulene	Cementless	5.5	No osteolysis. No conflict of intrests
Glyn-Jones et al. [9]	RCT	HXLPE=26 CPE=25	Longevity CPE	Hybrid	3	Three participants excluded. Evidence of conflict of intrests
Martell et al. [15]	RCT	HXLPE=24 CPE=22	Crossfire N_2/Vac	Cementless	2.3	97 hips included, only 46 hips measured 2D wear and 29 hips 3D wear. Evidence of conflict of intrests
Triclot et al. [23]	RCT	HXLPE=33 CPE=34	Durasul Sulene	Hybrid	4.9	35 participants excluded. Evidence of conflict of intrests

RCT randomised, controlled trial, *HXLPE* highly cross-linked polyethylene, *CPE* conventional polyethylene
[a] Data from two studies reported in one article

Table 2 Risk of bias of the studies included

Study	Randomisation process	Allocation concealment	Blinding	Incomplete outcome data addressed
Clavert et al. [4]	Low	Low	Low	High
Digas et al. [5][a]	Unclear	Unclear	Unclear	Low
Digas et al. [5][a]	Unclear	Unclear	Unclear	High
Engh et al. [7]	Unclear	Unclear	Low	High
Garcia-Rey et al. [8]	Unclear	Unclear	Low	Low
Glyn-Jones et al. [9]	Low	Low	Low	Low
Martell et al. [15]	Unclear	Low	Low	High
Triclot et al. [23]	Low	Low	Low	High

"High" indicates high risk of bias in the according stage; "Low" indicates low risk of bias in the according stage; "Unclear" indicates either lack of information or uncertainty over the potential for bias

[a] Data from two studies reported in one article

Discussion

We have summarised the best evidence from randomised, controlled trials comparing highly cross-linked polyethylene with conventional polyethylene in total hip arthroplasty. Although the quality of the trials included were different, all highly cross-linked polyethylene groups had a significantly lower wear or penetration than conventional polyethylene

Table 3 Results of radiological evaluation of highly cross-linked polyethylene compared with conventional polyethylene

Study	Outcomes				
Clavert et al. [4][a]	Wear rate	Linear (mm/y)	3D linear (mm/y)	Volume (mm^3/y)	
		p=0.002	p=0.012	p=0.017	
		HXLPE=0.0239	0.0242	13.741	
		CPE=0.1276	0.1109	60.24	
Digas et al. [5][b]	Penetration	M/L (mm)	P/D (mm)	A/P (mm)	Total (mm)
		p=0.3	p<0.001	p =0.5	p<0.001
		HXPEL=−0.019±0.021	0.15±0.030	−0.01±0.026	0.23±0.030
		CPE=−0.05±0.020	0.36±0.046	0.02±0.026	0.41±0.046
Digas et al. [5][b]	Penetration	M/L (mm)	P/D (mm)	A/P (mm)	Total (mm)
		p=0.2	p<0.001	p=0.4	p<0.001
		HXLPE=0.001±0.0261	0.08±0.020	0.09±0.036	0.20±0.026
		CPE=−0.04±0.015	0.34±0.067	0.03±0.036	0.41±0.056
Engh et al. [7]	Wear rateOsteolysis	Linear 2D (mm/y)	Volume(mm^3/y)	Osteolysis	Osteolysis>1cm^2
		p<0.001	p<0.001	p<0.001	p=0.002
		HXLPE=0.01±0.07	5±22	23(96)	6(96)
		CPE=0.20±0.13	107±76	52(90)	20(90)
Garcia-Rey et al. [8]	Penetration rate	Linear (mm/y)			
		p<0.001			
		HXLPE=0.006±0.007			
		CPE=0.038±0.013			
Glyn-Jones et al. [9]	Wear ratePenetration	Linear wear (mm/y)	Total penetration (mm)		
		p=0.012	p=0.0184		
		HXLPE=0.03±0.06	0.35±0.14		
		CPE=0.07±0.05	0.45±0.19		
Martell et al. [15]	Penetration rate	2D linear (mm/y)	2D volume (mm^3/y)	3D linear	3D volume
		p=0.001	p=0.049	p=0.005	p=0.199
		HXLPE=0.12±0.05	62.07±34.15	0.14±0.07	62.72±30.48
		CPE=0.20±0.10	90.89±52.74	0.29±0.17	101.77±62.71
Triclot et al. [23]	Penetration rate	Linear (mm/y)	Volume (mm^3/y)		
		p=0.0027	p=0.0058		
		HXLPE=0.025±0.128	29.24±44.08		
		CPE=0.106±0.109	53.32±48.68		

HXLPE highly cross-linked polyethylene, *CPE* conventional polyethylene, *M/L* medial(+)/lateral(-), *P/D* proximal(+)/distal(-), *A/P* anterior(+)/posterior(-)

[a] The outcomes can not be expressed as mean and standard deviation due to lack of the exact number of participants analysed in the study

[b] Data from two studies reported in one article

groups. This shows that highly cross-linked polyethylene can significantly reduce wear.

In a prospective non-randomised study, Dorr et al. [6] reported a significantly lower linear wear rate of 0.029 ±0.02 mm/y in the Durasul group compared with 0.065± 0.03 mm/y in the Sulene group after the initial bedding-in penetration. This was consistent with the results from this systematic review. Similarly, in two retrospective comparative studies with five-year follow-up, Olyslaegers et al. [17] and Rajadhyaksha et al. [19] reported an almost 51% and 74% reduction of wear rate, respectively, for highly cross-linked polyethylene after the bedding-in period.

There are some important limitations to note in our work. First, there was significant clinical and methodological heterogeneity between the studies included. They differed with respect to outcomes, methods of radiological evaluation, methodological quality, manufacturing process of highly cross-linked polyethylene, implants, fixation methods and surgical techniques, which prevented data from being pooled. Second, due to the novelty of highly cross-linked polyethylene, the follow-up periods were short, which prevented us from making firm decisions about some important results such as incidence of osteolysis and revision total hip arthroplasty. Third, conflict of interest is an issue that requires special consideration. In this review, authors in seven studies received or will receive benefits from commercial parties. Some studies [3, 22] reported that the research more likely favoured the sponsor's product when an investigator had a financial interest in or funding from companies.

Conclusions

This systematic preliminary review suggests that highly cross-linked polyethylene has significantly less wear than conventional polyethylene. Further follow-up is necessary to determine the safety and incidence of osteolysis of highly cross-linked polyethylene.

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