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KNEE ARTHROPLASTY

# Highly cross-linked polyethylene in primary total knee arthroplasty is associated with a lower rate of revision for aseptic loosening: a meta-analysis of 962,467 cases

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## Abstract
**Background** The evolution in total knee arthroplasty (TKA) includes the highly cross-linked polyethylene (HXLPE) which has been reported as an effective manner to reduce the wear of the polyethylene and the osteolysis. The purpose of the present study is to synthesize the results of comparative studies between HXLPE and conventional polyethylenes and determine their effect in primary TKA.
**Methods** The US National Library of Medicine (PubMed/MEDLINE) and the Cochrane Database of Systematic Reviews were queried for publications utilizing the following keywords: "cross-linked", "polyethylene", "HXLPE", "conventional", "total knee arthroplasty", "TKA", "total knee replacement" and "TKR" combined with Boolean operators AND and OR.
**Results** Ten studies met the inclusion criteria and were included in the present meta-analysis with 962,467 patients. No significant difference was found regarding the revision rate for any reason between the patients who received HXLPE and those with conventional liner (OR 0.67; 95% CI 0.39–1.18; $I^2$: 97.7%). In addition, there was no difference regarding the radiolucent lines between the two types of liners (OR 0.54; 95% CI 0.20–1.49; $I^2$: 69.4%). However, with data coming from seven studies enrolling a total of 411,543 patients, it was demonstrated that patients who received HXLPE were less likely to be revised due to aseptic loosening compared to the patients with conventional liners (OR 0.35; 95% CI 0.31–0.39; $I^2$: 0.0%).
**Conclusion** The present meta-analysis showed that regarding the overall revision rate and radiographic outcomes there was no significant difference between the two types of liners. On the other hand, the significantly less revision rate due to loosening supports the routine continued use of HXLPE in primary TKA.

**Keywords** Total knee arthroplasty · Liner · Polyethylene · Highly cross linked

## Introduction

Total knee arthroplasty (TKA) remains a successful and durable procedure with its incidence growing in the United States (US). A recent study revealed a 46% increase in the rate of primary total hip arthroplasty (THA) and tripling of the rate of TKAs in a 13-year period [1]. It is estimated that more than 670,000 TKAs were performed in the United States in 2012 alone [2]. However, two of the most common indications for revision TKA historically have been polyethylene wear and osteolysis leading to aseptic loosening with conventional polyethylene [3].

As such, great effort has been given to improve the quality and longevity of polyethylene. In 1963, high density polyethylene was introduced as a way to improve component survival and wear profile [4]. Ultra-high molecular weight polyethylene (UHMWPE) has a high molecular weight, which is thought to result in increased longevity and less wear [5]. UHMWPE has been used in total joint arthroplasty in recent years after highly cross-linked polyethylene (HXPLE) was introduced to the arthroplasty market in the late 1990s [6].

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Manufacturing of HXLPE is done by exposing UHMWPE to gamma radiation [7], which breaks up intramolecular bonds and produces free radicals that promote cross-linking across multiple polymer chains [6]. The increased cross-linking of PE chains dramatically improves wear resistance but correspondingly diminishes the toughness of the polyethylene [8, 9].

The use of HXLPE in THA has been shown to decrease liner wear and has demonstrated significantly less osteolysis in comparison to conventional polyethylene liners [10, 11]. The reported incidence of failure due to wear has seen a sharp decline over time, dropping from 12% of all causes of revision TKAs in 2002 to 2% in 2010 [12]. On the other hand, particle-induced osteolysis induced by microscopic debridement of polyethylene components can have significant implications earlier on. The polyethylene particles shed during this process have been well studied as inducers of osteoclasts and inflammatory mediators. These cause subsequent resorption of bone surrounding the implant, which can result in aseptic loosening requiring revision surgery [13, 14]. Aseptic loosening remains a major issue in revision TKA, with the Australian Orthopaedic Association National Joint Replacement Registry reporting it to have accounted for 25% of revision TKAs performed in 2019, which led all causes of revision [15]. Radiographically, aseptic loosening can be seen in the form of radiolucent lines that indicate widening of the bone-cement interface [16, 17].

Thus, promising results seen with osteolysis rates in THA have led to the use of HXLPE in TKA as well. However, its use in TKA has been questioned due to the unique biomechanical environment of the artificial knee joint, which is characterized by greater contact stresses and shear forces compared to the hip [18].

Therefore, the purpose of this meta-analysis was to compare the rates of revision for aseptic loosening, all-cause revision, and presence of radiolucent lines between conventional polyethylene and HXLPE in primary TKA. Our hypothesis was that the use of HXLPE would be associated with lower revision rates compared to conventional polyethylene, especially revision for aseptic loosening given its close association with osteolysis.

## Methods

This systematic review and meta-analysis was performed according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines [19].

### Search strategy and search eligibility criteria

A comprehensive search was systematically conducted in Medline/PubMed and Cochrane Central databases. The following terms were utilized in the search algorithm: “cross-linked”, “polyethylene”, “HXLPE”, “conventional”, “total knee arthroplasty”, “TKA”, “total knee replacement” and “TKR” combined with Boolean operators AND and OR. The search was performed by two independent investigators and was reupdated just before the final analyses on June 25, 2020. The detailed PICO (population, intervention, comparison, outcomes) format strategy applied to this clinical scenario is presented in Supplementary Table 1.

A study was included in this meta-analysis if it fulfilled the following predefined criteria: (i) randomized controlled trials (RCTs) or observational analyses comparing HXLPE versus conventional polyethylene in patients undergoing primary TKA, (ii) studies that reported quantitative clinical outcomes data, and (iii) studies published in English language.

The predefined exclusion criteria were: (1) single arm studies reporting only on HXLPE or conventional polyethylene, (2) studies including patients undergoing revision TKAs, (3) case series/case reports, (4) cadaveric, laboratory or animal studies, and v) secondary research articles (e.g., systematic reviews, meta-analyses, letters to the editor or commentaries).

### Study selection

Two investigators (blinded for peer-review) assessed the titles and abstracts of all identified records independently. The same investigators independently screened the full texts of all potentially eligible studies, according to the inclusion criteria. Additionally, the references of the included studies were retrieved and manually reviewed to identify further eligible articles, according to the Snowball method. Investigators were blinded to each other throughout the study selection and data extraction processes. Any disagreements or discrepancies were resolved by consensus.

### Data extraction and outcomes

Two investigators independently extracted the relevant data from the eligible studies. All disagreements were resolved after discussion and the final decision was reached by consensus. Data were retrieved from all eligible studies in a predefined Microsoft Excel spreadsheet and included study characteristics (first author, year of publication, country of origin, enrollment period), number of patients in each group, sex, age, body mass index (BMI), follow-up duration and polyethylene type used. The primary outcome measure was total number of revision surgeries, and the secondary outcome measures were revisions due to loosening and report of a radiolucent line.

### Risk of bias assessment

Risk of bias was assessed in the included studies by two investigators with the Cochrane tool for RCTs and the ROBINS-I (Risk Of Bias in Non-randomized Studies – of Interventions) tool for nonrandomized studies [20, 21]. The Cochrane tool evaluates the following areas: adequate sequence generation, allocation concealment, blinding, baseline characteristics imbalance, patients lost to follow-up, measurement of data, and attrition bias. The following domains for the nonrandomized eligible studies were evaluated: confounding, selection of participants, departure from intended intervention, missing data, measurement of outcomes, and selective reporting. Any discrepancies in quality assessment were resolved via consensus.

### Statistical synthesis and analysis

Continuous variables were estimated as mean ± standard deviation (SD), while categorical variables were reported with absolute and relative frequencies. Odds ratios (ORs) with the corresponding 95% confidence intervals (CIs) were synthesized for the outcomes, using a random effects model. Heterogeneity was assessed with the $I^2$ statistic. $I^2$ greater than 75% indicated statistically significant heterogeneity [22]. A forest plot was used to graphically display the effect size in each study and the pooled estimates. A p value $< 0.05$ was considered statistically significant. STATA 14.1 (StataCorp LLC, College Station, Texas, USA) was used as statistical software.

## Results

### Literature search and eligible studies

The literature search yielded 189 potentially relevant records, after duplicates were removed. After screening titles and abstracts, 43 articles were retrieved for full-text evaluation. Inclusion and exclusion criteria were then applied to full-texts and 33 studies were excluded for the following reasons: (a) studies with no HXLPE group, (b) secondary review papers and (c) studies including patients undergoing revision TKAs. Ten studies met the predetermined eligibility criteria and were included in this meta-analysis. The PRISMA flowchart was applied to illustrate the step-by-step selection process (Fig. 1).

### Characteristics of the eligible studies and patients

Three RCTs [23–25], two observational prospective [26, 27] and five observational retrospective [6, 28–31] studies were included in this meta-analysis. A total of 962,467 patients, who underwent primary TKA with the use of either HXLPE (12.9%, $N = 124{,}653$) or conventional polyethylene (87.1%, $N = 838{,}152$) were enrolled. The mean overall duration of follow-up was 4.9 ± 1.6 years, ranging from 2 to 7 years. four studies [24, 27, 28, 30] reported separate follow-up durations for both polyethylene types, with similar mean follow-ups of 4.6 years for HXLPE and 5.02 years for conventional polyethylene. The mean patient age was 68.7 ± 5.1 (range: 60–78) years and 27.4% of the included patients were male. Significant baseline characteristics of all patients enrolled are summarized in Table 1. No study was assessed as having high risk of bias, while a detailed assessment of risk of bias for the included studies is available in Supplementary Table 2. The vast majority of the preoperative diagnosis was osteoarthritis (99.7%, $N = 411{,}695/412{,}884$). In two studies, [6, 27] the preoperative diagnosis is not mentioned.

### All-cause Revision TKA

All 10 eligible studies [6, 23–31], enrolling a total of 962,467 patients, reported data on total number of revision TKAs needed during their follow-up period. The random effects model meta-analysis demonstrated no significant difference between HXLPE and conventional polyethylene group (OR 0.67; 95% CI 0.39–1.18; $I^2$: 97.7%; $P$: 0.165) (Fig. 2).

### Revision TKA for Aseptic Loosening

Data about revision TKAs due to prosthesis loosening were provided by seven studies [23–26, 28, 30, 31], enrolling a total of 411,543 patients. Patients in HXLPE group were less likely to undergo revision operation due to loosening compared to the conventional polyethylene group (OR 0.35; 95% CI 0.31–0.39; $I^2$: 0.0%; $P < 0.001$) (Fig. 3).

### Radiolucent Lines

A total of 4 studies [24, 28–30], including 1495 patients, recorded the presence or absence of a radiolucent line. Results showed no superiority between HXLPE and conventional polyethylene in terms of this variable (OR 0.54; 95% CI 0.20–1.49; $I^2$: 69.4%; $P$: 0.235) (Fig. 4). In two of the studies [29, 30] radiolucencies greater than 1 mm were taken into consideration whereas in one study [24], the threshold was greater than 2 mm. Additionally, another study [28] did not note a specific definition for radiolucency.

## Discussion

Despite the success and effectiveness of TKA, aseptic loosening and osteolysis are major complications affecting long-term survival of the prostheses. This meta-analysis

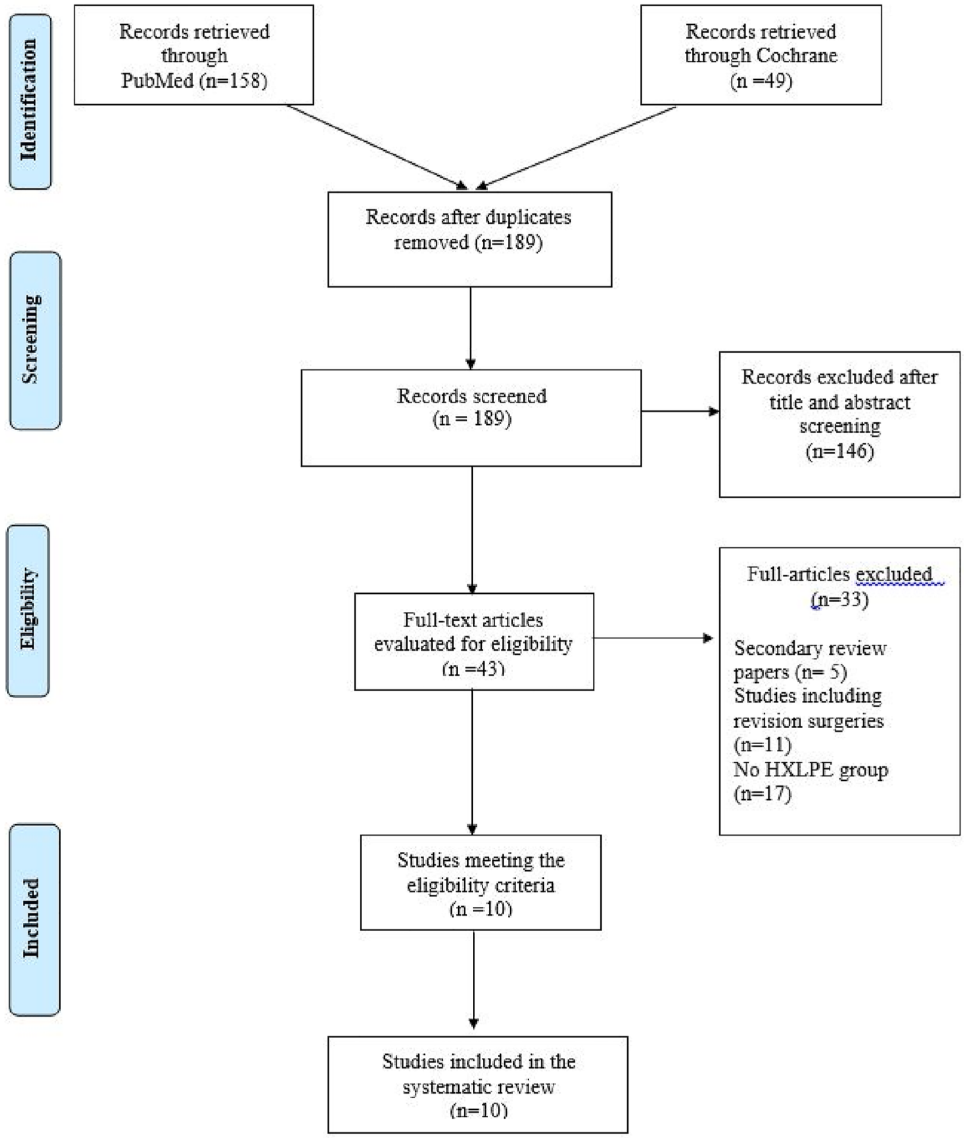


**Fig. 1** Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) search flow diagram

demonstrates that although the overall revision rates between HXLPE and conventional polyethylene were statistically similar, patients with a conventional polyethylene were more likely to be revised due to loosening. Wear of the polyethylene component in TKA continues to serve as a concern for surgeons since the particles created as a result of the wear can induce osteolysis and subsequently result in aseptic loosening, which remains a leading cause of revision TKA [15, 32]. Evidence has shown that particles generated from HXLPE are fewer due to the gamma or electron beam radiation, which increases the number of cross-links between the polymer chain [11, 33].

In THA, there have been some concerns about the biological response to polyethylene wear particles stemming from HXLPE. However, in a recent meta-analysis [34], which included 14 studies, eight of which were RCTs, it was shown that HXLPE is a more reliable choice relative to conventional liners in regards to revision rates, osteolysis, and polyethylene wear. More specifically, the authors concluded that the use of HXLPE was more effective in reducing the revision incidence caused by wear with a risk reduction of 91%, which theoretically demonstrates that HXLPE may decrease revision rates by reducing polyethylene wear and associated osteolysis [35].

The use of HXLPE in primary TKA remains controversial. The manufacturing process to produce crosslinking lowers the mechanical properties, making the polyethylene potentially more susceptible to fracture or catastrophic failure [8, 9]. In vitro studies have demonstrated reduced fracture toughness and crack propagation of highly cross-linked specimens compared with conventional polyethylene [36, 37]. It has been claimed that the additional irradiation and thermal stabilization comes with potential risks for reduced strength and fatigue resistance [38, 39]. Several case reports

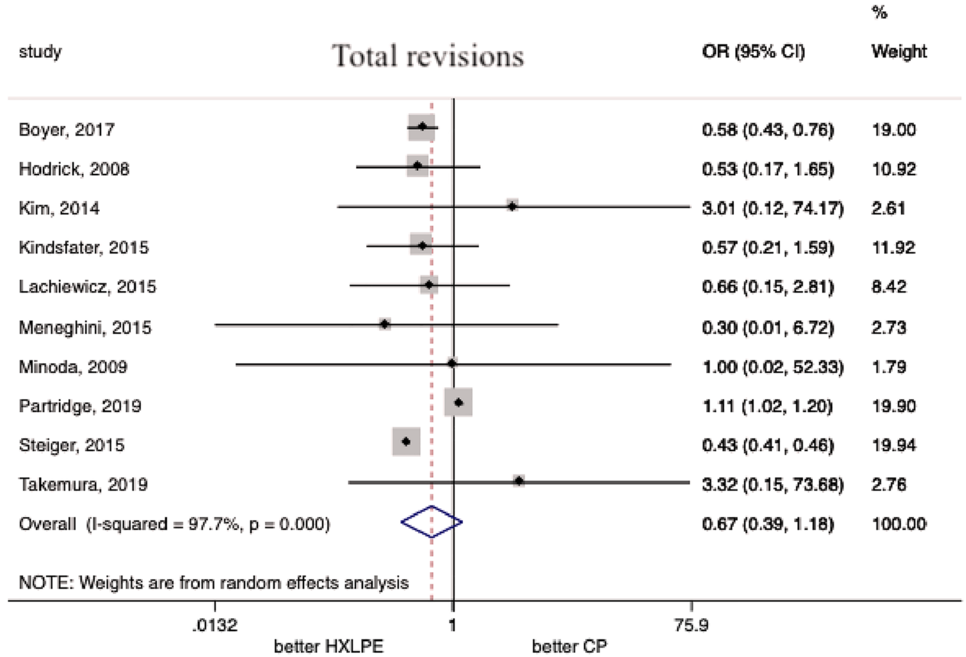


**Fig. 2** Forest plot comparing total revision rates in the utilization of HXLPE and conventional polyethylene

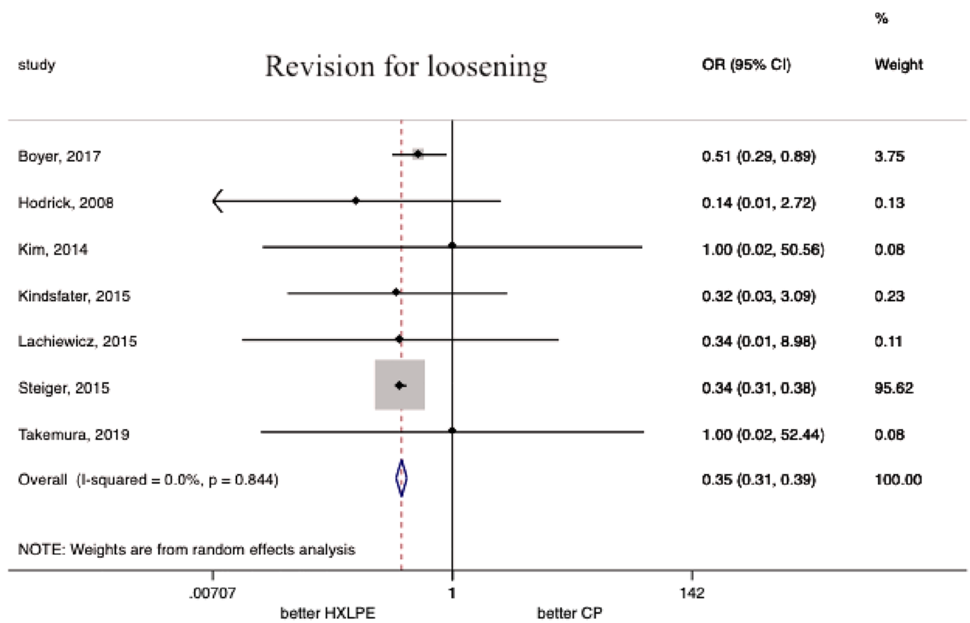


**Fig. 3** Forest plot comparing revision rates for loosening in the utilization of HXLPE and conventional polyethylene

or case series throughout the literature describe HXLPE tibial post fracture, which is an uncommon but severe complication [38, 40–42]. Diamond et al. [41] reported five fracture cases from a series of 955 TKAs with an estimated post fracture frequency of 0.5%. However, the failure mechanism still remains unclear and most likely involves multiple factors like patient's weight and activity and HXLPE material [43]. It should be noted that there are also cohort studies that presented no polyethylene post fractures [23, 28, 29, 43]. In our meta-analysis we did not have enough data available to synthesize and compare fracture or failure rates. Large scale studies with long-term follow-up are warranted to document these complications.

Moreover, the free radicals generated may lead to in vivo oxidation [44]. Because of this, there has been interest in adding Vitamin E, an antioxidant, to polyethylene liners. In vitro studies have confirmed that Vitamin E-infused polyethylene imparts higher oxidative resistance, but definitive clinical superiority has yet to be established [45, 46]. Only two studies in this review mentioned the use of Vitamin E-infused polyethylene, with one finding no difference in implant survival compared to HXLPE [26] and the other

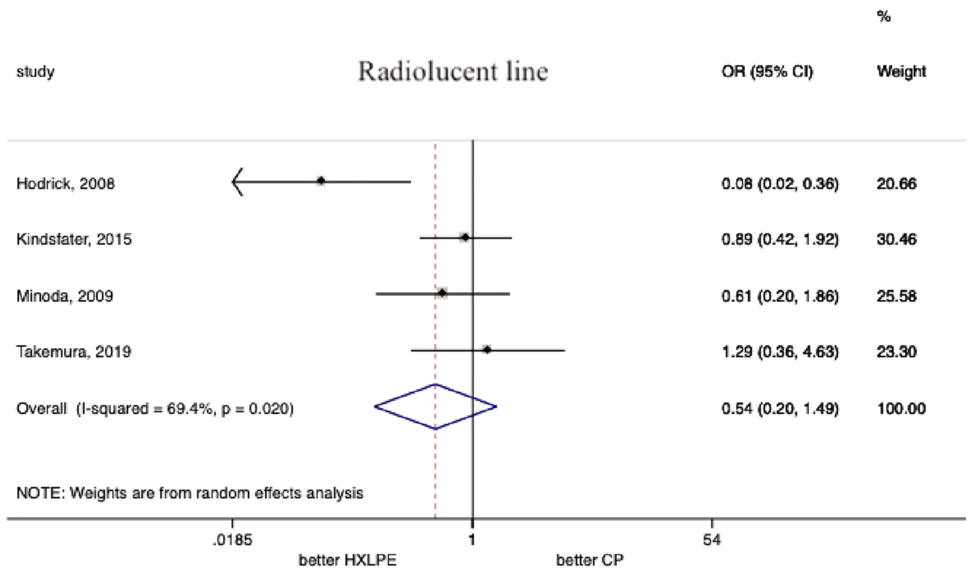


**Fig. 4** Forest plot comparing radiolucent lines in the utilization of HXLPE and conventional polyethylene

not reporting separate outcomes for Vitamin E-infused and non-infused HXLPE [31]. In the present meta-analysis, there was no difference in radiolucency between the two different types of liners, but no data directly comparing the wear rate between HXLPE and conventional liners was reported.

There are in vitro studies [47, 48] aimed at identifying the superiority of HXLPE use in TKA. In 2002, Muratoglu et al.[47] published an in vitro study simulating a tight posterior cruciate ligament balance during stair climbing. The authors compared the conventional polyethylenes with highly cross-linked ones and found that the performance of the highly cross-linked polyethylene inserts during this rigorous examination was identical to that of un-aged conventional polyethylene. Another in vitro study [48] evaluated the hypothesis of higher wear rates with highly cross-linked polyethylenes compared to unirradiated polyethylene tibial inserts. The authors conclude that during in vivo use, scratches that are generated on the femoral components are likely to produce a higher wear rate with both cross-linked and conventional polyethylene when compared to a smooth femoral component, but that this wear rate was likely to be higher with conventional polyethylene.

In a large retrospective study published from the Australian Orthopaedic Association National Joint Replacement Registry [49], Lewis et al. tried to examine if the revision rates for wear of TKA with different polyethylene types was improved with evolution of the implants. The authors report that only the Scorpio posterior stabilized (PS) to Triathlon PS comparison demonstrated any improvement in survivorship for both HXLPE and UHMWPE, compared to the comparison between Scorpio cruciate retaining (CR) to Triathlon CR, Genesis II PS to Legion PS, and Genesis II CR to Legion CR, which showed increased survival only with the use of UHMWPE.

In a previous meta-analysis published in 2016 [32], comparing HLXPE with conventional polyethylene, the authors did not find statistically significant differences between these two different types of polyethylenes. The present meta-analysis includes four additional studies, three of which were published after 2016. Additionally, the study population is a lot larger than the previous meta-analysis. Our analysis revealed a statistically significant reduction in revision due to aseptic loosening with the use of HXLPE inserts relative to the conventional ones (OR 0.35; 95% CI 0.31–0.39; $I^2$: 0.0%; $P < 0.001$).

The findings of this meta-analysis should be interpreted in the context of the following limitations. First, six of the included studies were not RCTs, which limits the external validity of our results due to potential selection bias. Second, rates of polyethylene post fractures, revisions specifically for wear, and osteolysis were not reported in any studies, preventing direct assessment of these outcomes. However, aseptic loosening, which is closely associated with osteolysis, was included and revealed a significant difference between the HXLPE and conventional polyethylene groups. We were also unable to assess publication bias for outcomes of interest due to the fact that < 10 studies were synthesized for each outcome [50]. Finally, not having access to patient-level data prevented further analysis of clinical outcomes or adverse events, other than those reported in the results section.

## Conclusion

In this meta-analysis of over 900,000 primary TKAs, the use of HXLPE was found to be associated with a similar overall rate of revision compared to conventional polyethylene. Furthermore, there was no difference in the presence or absence of radiolucent lines a mid-term follow-up. Notably, analysis of comparative data for 411,543 patients showed that the use of HXLPE was associated with a lower rate of revision for prosthetic aseptic loosening. This data support the routine continued use of HXLPE in primary TKA.

**Supplementary Information** The online version contains supplementary material available at https://doi.org/10.1007/s00402-021-03887-z.

## Declarations

**Conflict of interest** The senior author is a paid consultant of Depuy Synthes, Intellijoint Surgical and EOS Imaging. The rest of the authors declare that they have no conflict of interest.

**Ethical approval** This article does not contain any studies with human participants or animals performed by any of the authors.

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