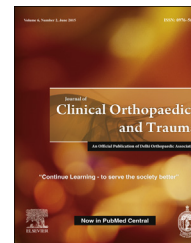


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## Review Article

## Polyethylene in knee arthroplasty: A review



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## ABSTRACT

Polyethylene (PE) has been used extensively in knee arthroplasty since the mid 20th century. Progress in material manufacturing and processing has led to newer polyethylenes over last few decades with different material properties. It has been established that PE wear in knee arthroplasty causes particle induced osteolysis which is the main reason for late failure and requires revision surgery. Although there are various causes of wear, the properties of PE have long been a matter of investigation as a contributory factor. The advent of newer highly cross linked PE has been shown to improve wear rates in hip arthroplasty but the benefits have not been shown to be of the same degree in knee arthroplasty. The laboratory and clinical studies so far are limited and slightly conflicting in their conclusions. The risks of using highly cross linked PE in knee arthroplasty include tibial post fracture, disruption of locking mechanism, liner fracture which can lead to increased wear and osteolysis. The current evidence suggests that highly cross linked polyethylenes should be used with caution and only considered in younger active patients. The results of a recently completed randomized trial to compare the conventional with high molecular weight PE in knee arthroplasty are awaited.

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## 1. History of polyethylene

Polyethylene is a commonly used plastic with millions of tonnes produced annually.<sup>1</sup> The generic chemical composition of PE is denoted by the formula (C<sub>2</sub>H<sub>4</sub>)<sub>n</sub>. The value of 'n' can

differ depending on the molecular size. The history of PE dates back to 1898 when German scientist Hans von Pechman prepared it serendipitously while heating diazomethane.<sup>2</sup> This new waxy substance was highly unstable and therefore not used industrially. It was in Northwich, England in 1933 that Eric Fawcett and Reginald Gibson synthesized the first

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industrially useful PE, again serendipitously when they applied extremely high pressure to a mixture of ethylene and benzaldehyde.<sup>3</sup> Unfortunately, their accidental discovery was not easily reproducible due to initiation of reaction by trace oxygen contamination. Later in 1935, Michael Perrin developed a reproducible method to synthesize PE.<sup>4</sup> This laid the foundation of industrial scale production of PE in subsequent years.

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## 2. Polyethylene manufacturing processes

Polyethylene components are manufactured by either machining or compression molding. Machined components are made from either a sheet or bar whereas compression moulded ones are made by powder compressed into the desired shape.<sup>5</sup> Arthroplasty components manufactured from compression moulded polyethylene have been shown to exhibit less wear and may be preferable for clinical use.<sup>6</sup>

The manufacturing processes directly affect the material characteristics and include irradiation dose, types of post irradiation thermal processing and end point sterilization.<sup>7</sup> Ultra high molecular weight polyethylene (UHMWPE) is a subset of polyethylene materials with extremely long chains and a molecular weight between 2 and 6 million units. In order to manufacture highly cross linked polyethylene (HXLPE), UHMWPE is irradiated with gamma or electron beam to break the carbon–hydrogen chains. This produces free radicals, which in the presence of oxygen facilitate degradation of the polymer. These free radicals also help to form cross-links. An increase in the radiation dose, increases the cross linking which confers an increase in wear resistance.<sup>7,8</sup> It is therefore expected that this would lead to improved clinical performance. However this does not seem to be the case because there is a corresponding decrease in mechanical properties like tensile strength and resistance to fatigue crack propagation.<sup>9</sup> In order to reduce the concentration of free radicals in irradiated PE, a process of post irradiated melting or annealing is performed. The melting point of PE is 135 °C. Melting changes PE structure from a crystalline to an amorphous solid and allows access to free radicals by unfolding polymer chains while the cross links act as molecular constraints. This reduction in crystallinity reduces mechanical properties like crack resistance and fracture toughness.<sup>7,9,10</sup> In contrast to melting, annealing involves heating the PE to below its melting point. This leads to less efficient removal of free radicals but preserves more mechanical properties.<sup>8</sup> Overall, a method which would not reduce the crystallinity and remove free radicals would be ideal. This has led to the development of 2nd generation highly cross linked polyethylenes.<sup>7</sup> Their manufacture uses other methods to extinguish free radicals which include soaking in vitamin E (alpha tocopherol, an antioxidant) or irradiating in 3 sequential doses with annealing after each radiation dose to reduce free radicals. Preliminary in vitro testing indicates good wear and improved mechanical and fatigue properties<sup>7</sup> in this group.

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## 3. Sterilization of polyethylene

The type of sterilization process is also reported to affect the characteristics of PE and its shelf life.<sup>11</sup> Sterilization using

gamma radiation in air makes PE susceptible to oxygenation. Ethylene oxide or gas plasma are used for sterilization without radiation to avoid free radical production, but this produces no cross linking directly affecting the mechanical properties.<sup>11</sup> In the second generation HXLPE, sterilization is performed with ethylene oxide or gas plasma to avoid reintroduction of free radicals.<sup>7</sup>

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## 4. Polyethylene in arthroplasty

UHMWPE was introduced by Sir John Charnley in 1960s in hip replacement surgery.<sup>12</sup> His development of a low friction arthroplasty with a metallic femoral head and an all PE cup was a milestone in orthopaedic surgery. This was achieved after an in depth research into cemented implant fixation and bearing surfaces. After an unhappy experience with teflon cups, he used a high density PE cup. Since then, PE has been used for almost half a century and remains a frequent bearing surface in total joint replacement.

The earliest attempt at a knee replacement dates back to 1890s and is accredited to Theophilus Gluck who used an ivory hinge prosthesis.<sup>13</sup> The early condylar designs came in vogue in 1960s which used PE tibial component.<sup>13</sup>

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## 5. Wear and osteolysis in arthroplasty

While PE has been an indispensable part of the evolution of joint arthroplasty surgery, its wear has been of as much interest. It has been established that PE wear in arthroplasty causes particle induced osteolysis which is the main reason for late failure and requires revision surgery.<sup>14</sup> Although there are various causes of wear, the properties of the PE have long been a matter of investigation as a contributory factor. Other factors include implant design, surgical technique and patient factors. The conventional PE used in hip arthroplasty was sterilized by gamma radiation in air, which offered the benefit of cross linking.<sup>11</sup> But at the same time, this process produced free radicals that oxidize in air and thus decrease resistance of this biomaterial leading to increased wear.<sup>11</sup> The need for improved implant durability stemmed from the fact that in the past decade, the indications for hip arthroplasty have changed to include younger, higher demand patients with increased life expectancy.<sup>7,15</sup> The subsequent development of new highly cross linked polyethylene (HXLPE) in 1990s was aimed at decreasing wear resistance whilst not compromising on material properties.<sup>16</sup> The basis of HXLPE production process has been cross linking, heat treatment and sterilization with avoidance of oxygen exposure.<sup>16</sup> The preclinical laboratory testing demonstrated the newer cross linked polyethylenes to have significantly less wear than conventional PE.<sup>7</sup> In published literature, there is evidence that these first generation HXLPE have decreased wear rates in vivo with reduction in the prevalence and severity of osteolysis. However, it has been shown that these HXLPEs may be more susceptible to fatigue fracture.<sup>7</sup> Currently, second generation HXLPEs have been developed as discussed previously in the manufacturing process. Mid term results of new HXLPEs indicate that it is one of the materials of choice in hip

arthroplasty surgery especially in young active patients with a long life expectancy.<sup>17</sup>

## 6. Polyethylene challenges in knee

Osteolysis was initially reported in knee implants as bone resorption associated with uncemented implants. It was realized later that this could also occur in cemented implants. Small particulate debris stimulates a foreign body cellular response leading to periprosthetic osteolysis.<sup>18</sup> These particles can be of polyethylene, cement (poly methyl methacrylate) and metal. It is recognized that failed total knee prostheses have larger flake-shaped debris, which elicits a tissue response characterized by fewer macrophages.<sup>19</sup> This is different from failed total hip prosthesis. This larger particle debris may be associated with delamination, pitting and fatigue wear. The prevalence of osteolysis after knee arthroplasty has been reported at 5%–20% at follow up times of <5 years–15 years.<sup>20</sup>

There are two methods of tibial and patella component wear in knee prosthesis, namely fatigue damage (pitting and delamination) and adhesive and abrasive wear.<sup>20,21</sup> Of these, pitting and delamination are accelerated by presence of free radicals which cause oxidation. Adhesive and abrasive wear are the main processes responsible for most of wear debris, late osteolysis and loosening.

Wear is affected by several factors which can be patient, technique or implant associated.<sup>5,20</sup> Patient factors include age, size and activity level. The surgical technique must focus on reducing wear by focussing on correct implant alignment and restoring mechanical axis of the joint. Implant factors in knee arthroplasty include component design (both bearing surface and backside) and polyethylene insert characteristics. These include the structure and thickness of the insert. The structure is closely related to the manufacturing processes used as well as the post manufacturing sterilization and packaging. The minimum recommended thickness of a PE insert is 8 mm.<sup>5</sup>

## 7. Difference between hip and knee

The knee differs from the highly congruent ball and socket articulation of the hip joint. Wear in knee arthroplasty occurs due to complex geometry of the articulation which involves rolling, sliding and rotational motion at the bearing surface. This can cause delamination, pitting and fatigue failure of the PE surface.<sup>22</sup> In contrast, wear in hip arthroplasty occurs mainly due to micro-adhesion and micro-abrasion.<sup>23</sup> Apart from the bearing surface, backside wear of a modular tibial insert is an additional problem. This PE wear is associated with osteolysis which is a major challenge and limitation of the success of knee arthroplasty surgery.<sup>22</sup>

## 8. Highly cross linked polyethylene in knee arthroplasty

Since the use of HXLPE liners for hip arthroplasty has been widely accepted due to decreased wear in medium term,<sup>24</sup> the

use of same has been proposed in knee arthroplasty surgery. This has however not been widely accepted due to concerns regarding HXLPE. These include reduced strength, fatigue resistance and fracture toughness due to additional irradiation and thermal treatment. The above has been demonstrated on laboratory testing of UHMWPE.<sup>9</sup> These factors may have an affect on the locking mechanism of the modular tibial components. In posterior stabilized knee prosthesis, there is concern regarding the strength of the tibial post. Similar concerns exist for the patellar prosthesis made of HXLPE, as well as regarding liner fracture, dislodgement or disruption of the locking mechanism. Vitamin E treatment in second generation HXLPEs supposedly has more strength but there are no clinical studies reported to document the efficacy of this process.<sup>20,25</sup>

In the last decade, there has been extensive laboratory testing of HXLPEs in simulation studies. The results of these in vitro studies provide a useful insight for the orthopaedic surgeon in the absence of robust clinical data. The knee simulation studies have several models with their main strengths being comparisons of modern and conventional polyethylenes as well as ability to test various altered clinical situations like malalignment and soft tissue imbalances. However, some studies are also limited by assumptions like the absence of third body wear. Moreover, knee motion is complex and may not have been exactly reproduced in the laboratory.

In one simulator study performed at the University of Leeds to investigate wear rates, wear debris and biological reactivity of non cross linked, cross linked and highly cross linked polyethylenes,<sup>26</sup> it has been found that wear rates are reduced with moderately and highly cross linked polyethylenes. This is consistent with similar reports in hip studies in the past.<sup>27,28</sup> The amount of wear reduction however was found to be less than in the hip with cross linked PE (33% as compared to 73% in hip). The conventional PE wear in the knee was found to be lower than in the hip due to kinematic conditions that induce less cross shear. This study also showed that increased molecular weight and increased cross linking reduced the size of the debris in the knee simulation, which increased the biologic activity due to increased percentage volume of submicron particles. This makes the low molecular weight conventional PE appear more promising in knee due to better fracture toughness and less reactive wear particles. The fact that knee joint has high stress levels and is historically known to have fatigue failure with implants makes this finding more interesting. This study has limitations which include use of different molecular weight polyethylenes for conventional, moderately and highly cross linked polyethylenes.

Murtaglou et al.<sup>29</sup> reported that during 5 million cycles of simulated gait, the aged conventional PE tibial component showed large areas of delamination while the unaged and aged HXLPE component showed none. They also showed that the aged HXLPE liner had wear rate that was a third of the aged and unaged conventional polyethylene liner. The study was however limited by a small sample size and the operation of knee simulator at a non-physiologic frequency.

Hermida et al.<sup>30</sup> compared conventional PE that was gamma irradiated (in air) to HXLPE that was annealed and

sequentially irradiated, and HXLPE that was electron beam irradiated, remelted and gas plasma sterilized in simulator after accelerated ageing. They tested the components in two malalignment conditions (7° varus, 80:20 medial lateral load distribution, 9° tibial internal rotation AND 5° varus, 70:30 medial lateral load distribution, 4° tibial internal rotation). Over 5 million cycles, none of the HXLPE aged liners showed visible delamination or severe wear. In addition, the wear in both types of HXLPE was less than the control. Between the 2 types of HXLPE, the sequentially irradiated and annealed PE wore less than the electron beam irradiated, remelted PE.

In one study, Muratoglu et al tested explanted and artificially roughened femoral components against unaged polyethylenes for 2 million cycles.<sup>31</sup> They found wear rate that was 80% less for the HXLPE liners as compared to conventional liners. In another study by Muratoglu et al<sup>32</sup> the simulator had the femoral component set to resemble a tight, unbalanced posterior cruciate ligament. There was no delamination shown after 0.5 million cycles in the aged HXLPE and unaged conventional PE liners. However, the aged conventional PE liner showed delamination at 50,000 cycles.

Several other simulator studies<sup>25,33,34</sup> involving sequentially irradiated and annealed HXLPE tibial liner found that the wear rates were significantly less with HXLPE and best with sequentially irradiated and annealed PE. Wang et al<sup>25</sup> studied both cruciate retaining and posterior stabilized liners to 5 million cycles and found that the wear was respectively 68% and 64% less for the HXLPE cruciate retaining and posterior stabilized liners as compared to conventional unaged PE. In addition, there was no difference in the mean size or morphology of wear particles produced between the conventional PE and the highly cross linked one.

Clinical studies comparing use of conventional versus highly cross linked PE are few and limited due to being non-randomized. These have reported a non significant decrease in radiolucent lines in medium term.<sup>35,36</sup> In the retrospective cohort study by Hodrick et al,<sup>35</sup> 100 cruciate retaining and sacrificing total knee arthroplasty patients with a gamma irradiated (in nitrogen) conventional PE liners were compared with 100 knees with HXLPE liners. The patient groups were similar and mean follow up was 91 and 75 months respectively for the conventional and HXLPE groups. There was no significant difference between the two groups in the number of revisions for tibial component loosening. There was no catastrophic failure in either groups. This study reported 20 tibial radiolucent lines (20 patients) in the conventional PE group as compared to 2 radiolucent lines (2 patients) in the HXLPE group. Activity level was not considered in the study. It can be assumed from these results that the HXLPE liner is safe for use for the mean follow up period but confers no advantage to conventional PE. Minoda et al compared 113 cruciate retaining knees (conventional PE liners) with 89 cruciate retaining knees (HXLPE liners) in a prospective consecutive series<sup>36</sup> with a 2 year follow up, and found no significant clinical or radiologic difference between the two groups. Tibial radiolucent lines were seen in 9.7% of conventional PE group versus 4.5% in the HXLPE group. The strength of this study is a reasonable comparability in the two groups. The limitations are a lack of randomization and a relatively short follow up time. In another study by Muratoglu et al,<sup>37</sup> retrieved liners

were compared (8 HXLPE versus 71 conventional PE). Both of these showed substantial scratching and surface changes. The total optical damage score showed no significant difference in the 2 groups. However, this study only evaluated a small sample size of HXLPE liners that had been in vivo for less than 1 year.

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## 9. Future research

A more definitive demonstration of the suggested advantage of HXLPE use in knee prosthesis will only be possible with properly designed and executed randomized controlled studies. One such trial has recently been completed in Korea at the Ewha Woman's University with results awaiting publication ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)). This trial (Comparison of Highly Cross-Linked and Conventional Polyethylene in Total Knee Arthroplasty) is a prospective randomized controlled trial and has finished in September 2013. This is expected to throw light on this issue and is also interesting given the fact that it will compare posterior stabilized implants.

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## 10. Summary

Given the current understanding based on published literature, a cautious approach is recommended as far as use of highly cross linked polyethylene in knee arthroplasty is concerned. So far, the data from simulation studies has shown a reduction in wear under normal kinematics with slightly conflicting results. The Leeds study has shown that the HXLPE wear particles are smaller and possibly more biologically active. The clinical studies are limited in availability and quality but indicate the safety of at least two types of HXLPE at 2 and 5 years. The results of the Korean randomized controlled trial are awaited and should help the clinical decision making regarding the choice of polyethylene in knee arthroplasty. It can be considered in younger, active patients and while using a congruent cruciate retaining design. Use of thick tibial inserts and posterior stabilized components made of HXLPE is currently not recommended due to concerns expressed earlier. As is true with the use of any implant, accurate surgical technique will help prevent load imbalance in knee arthroplasty and prevent failure. This area needs more research with appropriately powered prospective randomized controlled trials with sufficient follow up.

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## Conflicts of interest

All authors have none to declare.

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