The Journal of Arthroplasty 30 (2015) 1458–1463

Contents lists available at ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

The Divergence of Wear Propagation and Stress at Steep Acetabular Cup Positions Using Ceramic Heads and Sequentially Cross-Linked Polyethylene Liners

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ARTICLE INFO

Article history:
Received 30 December 2014
Accepted 23 February 2015

Keywords:
hip replacement
wear
finite element analysis
cross-linked polyethylene
implant position

ABSTRACT

The aim of the present wear simulator study was to assess the effect of steep acetabular cup positions on the wear propagation of highly cross-linked-PE (HX-PE) liners. Furthermore, a finite element analysis (FEA) was performed in order to calculate the stress within the HX-PE material in case of steep cup positions under physiological loadings. The higher stress in the HX-PE at a steep acetabular cup position did not result in increased wear in the present wear simulator study. The gravimetrical wear rates at normal (45°) and steep cup inclinations (75°) showed wear amounts of 3.15 ± 0.27 mg and 2.18 ± 0.31 mg per million cycles ($p = 0.028$), respectively. However, FEA revealed clear increase in stress at the HX-PE liners with respect to steep cup positions.

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Wear debris from the articulating partners of the total hip replacement (THR) is responsible for inflammatory reactions in the periprosthetic tissue, causing osteolysis and aseptic implant loosening [1,2]. Cross-linking the ultra-high molecular weight polyethylene (UHMWPE) clinically reduces the wear between the liner and femoral head [3,4] and could lead to longer implant durability. Experimental wear simulator studies with highly cross-linked polyethylene (HX-PE) demonstrated the reduction of wear compared to conventional non-cross-linked UHMWPE [5–7]. Moreover, the wear rate should be largely independent from the femoral head size that is used [8]. This opens up the possibility of using larger femoral heads, which in turn improve the range of motion and decrease the risk of impingement and dislocation [9].

However, in order to use larger femoral heads with a constant cup size, the liner thickness has to be reduced, which leads to higher stresses in the polyethylene [10]. The reduced mechanical properties of HX-PE [11,12] should be critically examined, especially with regard to low thickness of the liner. ISO 21535 [13] defines a minimum wall thickness of 5 mm for metal-backed UHMWPE liners. However, there are specifications missing concerning type of polyethylene material used (standard, cross-linked, Vitamine E doped).

Wang et al. [14] described a combined cross-linking and annealing process (sequentially highly cross-linked polyethylene: sequentially HX-PE) to increase the wear resistance and, furthermore, to maintain the mechanical properties of the polyethylene, which allow a liner thickness of less than 4 mm. Wear simulator studies with the sequentially HX-PE showed a reduction of wear compared to conventional polyethylene [5,15] and the clinical results are promising so far [16,17].

Because of anatomical circumstances or inaccurate implantation, an inappropriate acetabular cup position may be established and therefore the stress in the polyethylene may be increased *in situ*. Clinical failures of HX-PE were described at high stress situations caused by the implant position [18,19].

Experimental wear simulator studies usually mimic loads during normal levels of walking according to ISO 14242-1:2012. However, other patient activities will cause more severe stresses, e.g. stair climbing, sitting down/standing up, or other movements, which cannot be recreated in most hip simulators. As a result, wear patterns observed at retrievals, or excessive wear as seen in clinical failures cannot be reproduced in wear simulator tests [19,20]. Therefore, finite element analyses are advantageous for demonstrating critical stress in the implant components under various load conditions and implant positions [21,22].

Regarding thin-walled sequentially HX-PE liners used in combination with large endoprosthetic heads, it remains unclear if, (1) the bearing is forgiving towards steep cup placement with regards to wear, and (2) if critical stresses may occur in the liner under different loads and cup positions.

Therefore, the objective of the present study was to experimentally compare the wear behavior of thin sequentially HX-PE liners in a hip

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 doi: http://dx.doi.org/10.1016/j.arth.2015.02.025.

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http://dx.doi.org/10.1016/j.arth.2015.02.025
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simulator at a normal implant position and during a high stress situation, i.e. steep cup position. Furthermore, the influence of different patient activities on stress in the sequentially HX-PE liner at normal and steep cup positions was investigated by means of computational finite element analysis (FEA).

Materials and Methods

Wear Simulator Test

The sequentially HX-PE liner (X3™, Stryker GmbH & Co. KG, Duisburg, Germany) used for this study had an inner diameter of 44 mm and a wall thickness of 3.8 mm and it was made of compression-molded GUR 1020 resin sheets. High cross-linking is achieved by means of three alternate bouts of irradiation of the sheets with 3 Mrads and then annealing below the melting temperature. Gas plasma sterilization is then performed, after machining the liner geometry [12]. For wear testing, the liners were seated in 56 mm Trident® PSL acetabular cups (Stryker GmbH & Co. KG, Duisburg, Germany) and were combined with 44 mm alumina ceramic ball heads (BIOLOX®*forte*, CeramTec GmbH, Plochingen, Germany).

The acetabular cups were orientated in the wear simulator at two different inclination angles: at 30° (n = 3), which corresponds to an *in vivo* cup inclination of 45°, and at 60° (n = 3), which corresponds to an *in vivo* cup inclination of 75° (Fig. 1). For each combination, one loaded soak control was used to control liquid absorption of the liner.

The wear tests were performed over 5 million load cycles in a hip wear simulator (EndoLab GmbH, Rosenheim, Germany) according to ISO 14242-1:2012. All samples were axially loaded to a maximum of 3 kN; performed movements were flexion/extension, adduction/abduction and internal/external rotation. Loads and movements during one gait cycle were applied according to the range shown in Table 1. Tests were performed in temperature-controlled chambers at 37 °C ± 2 °C. Bovine serum (PAA Laboratories GmbH, Pasching, Austria) with a protein concentration of 20 g/l, containing sodium acid and ethylenediamine-tetraacetic acid, was used as medium for the wear tests. The amount of wear was determined gravimetrically every 0.5 million cycles using a high-precision balance (Sartorius ME235S, Sartorius AG, Goettingen, Germany).

Statistical significance between groups was calculated with the independent T-test using IBM® SPSS® Statistics Version 20 (IBM Corporation, New York, USA). Data were presented as mean value ± standard deviation and p-values of $p < 0.05$ were considered as significant.

Table 1
Range of Test Parameters of Wear Simulation According to ISO14242-1.

Test Frequency	1 Hz	
	Min	Max
(-) Extension and (+) Flexion angle	- 18°	+25°
Axial force	0.3 kN	3 kN
(-) Abduction and (+) Adduction angle	- 4°	+7°
Rotation angle	- 10°	+2°

Finite Element Analysis (FEA)

Finite element models of the same THR system at normal and steep cup positions were created by Abaqus/CAE Version 6.12 (Dassault Systemes Providence, USA). For geometric modelling of the hip cup, a CAD model from a 56 mm Trident® PSL acetabular cup (Stryker GmbH & Co. KG, Duisburg, Germany) was used. The geometry of the liner was modelled using the inner geometry of the hip cup and manual registration of measurements. The locking mechanism of the liner was removed in the CAD model to avoid contact problems and stress peaks. The radius of the femoral head amounted to 21.95 mm in order to achieve a clearance of 0.05 mm [23].

The hip cup and liner were meshed with hexahedral elements (ABAQUS element type C3D8R). The femoral head was defined as rigid due to the difference in stiffness compared to the polyethylene liner. The final meshes consisted of each approx. 74,000 elements representing the hip cup and liner. The total number of nodes was approx. 114,000. Material properties of the implant components are derived from literature data [11,24,25]. Linear elastic material behavior of the meshed components was assumed. Contact conditions were assigned both between the hip cup and liner as well as between the liner and femoral head. For both pairs, hard contact was chosen to avoid penetration of the components. Friction coefficients of 0.16 [23] and 0.06 [26] were defined for the combination of the hip cup against the liner (Ti6Al4V/X3) and for the liner against the femoral head (X3/ceramic), respectively.

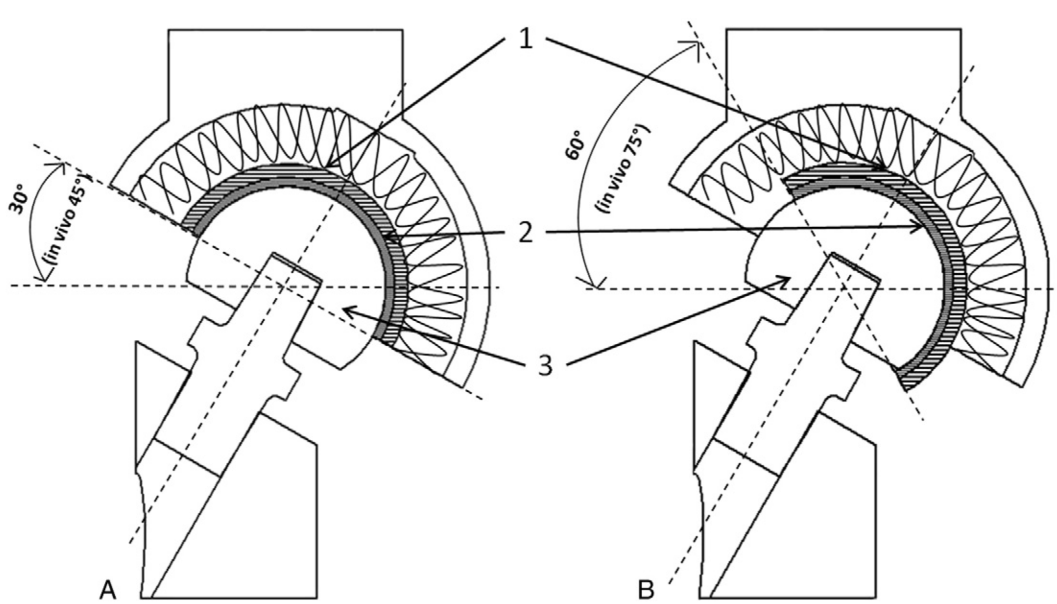

Fig. 1. Acetabular cup orientationin the wear test simulator, A: 30° cup inclination (45° *in vivo*), B: 60° cup inclination (75° *in vivo*), 1: acetabular shell, 2: sequentially HX-PE, 3: femoral head.

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