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RESEARCH

Polyethylene particles in synovial fluid after knee arthroplasty with a conventional or highly cross-linked polyethylene. Preliminary study☆

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KEYWORDS
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Abstract
Aim of the study: In recent years cross-linked polyethylenes have been developed in an attempt to reduce the wear, as has been demonstrated in knee simulators. The aim is to assess, by counting particles of polyethylene in synovial fluid, whether the reduction in wear is confirmed in patients with a highly crosslinked polyethylene prosthesis.
Material and methods: A prospective randomised study was designed. During the implantation of a knee prosthesis, one group of patients was assigned the use of a conventional polyethylene (group A), and the other group a highly crosslinked polyethylene (X3®, Stryker Orthopaedics) (group B). At 12 months after surgery a knee arthrocentesis was performed, and the number of polyethylene particles was counted in a scanning electron microscopy. Fourteen samples from each group were studied.
Results: Both groups were comparable in all study variables. We found no significant differences in the concentration of polyethylene particles/ml (1.49 ± 0.85 million in group A *vs* 1.42 ± 0.91 million in group B, $P = 0.60$) or the total number of isolated particles. We found no differences either in size or morphology of particles between both groups.
Discussion and conclusions: Although several *in vitro* studies *in vitro* using different types of highly crosslinked polyethylene found a significant reduction, we did not find that that wear was reduced in the knees of these patients. The great variability in the number of particles between individuals suggests that polyethylene wear *in vivo* depends on many factors, so perhaps the type of polyethylene is not the most significant factor.

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PALABRAS CLAVE
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Partículas de polietileno en líquido sinovial tras artroplastia de rodilla con un polietileno convencional o uno altamente entrecruzado. Estudio preliminar

Resumen
Objetivo: En los últimos años han aparecido polietilenos altamente entrecruzados para intentar disminuir el desgaste, tal como se ha demostrado en simuladores de rodilla. El objetivo es evaluar mediante el recuento de partículas de polietileno en líquido sinovial, si se confirma un menor desgaste en pacientes con prótesis de polietileno altamente entrecruzado.
Material y método: Estudio prospectivo aleatorizado, en el que durante la implantación de una prótesis de rodilla se asignó a un grupo de pacientes la colocación de un polietileno convencional (grupo A), y a otro grupo un polietileno altamente entrecruzado (X3® de Stryker Orthopaedics) (grupo B). A los 12 meses tras la cirugía se practicó una artrocentesis de rodilla y se hizo un recuento de partículas de polietileno en el líquido sinovial mediante microscopio electrónico de barrido. Se han analizado 14 muestras en cada grupo.
Resultados: Ambos grupos son comparables en todas las variables estudiadas. No hemos hallado diferencias significativas en la concentración de partículas de polietileno/ml ($1{,}49 \pm 0{,}85$ millones grupo A *vs.* $1{,}42 \pm 0{,}91$ millones grupo B; $p = 0{,}60$) ni en el número total de partículas aisladas entre ambos grupos. Tampoco hemos hallado diferencias en el tamaño ni la morfología de partículas entre ambos grupos.
Discusión y conclusiones: Aunque diversos trabajos *in vitro* han hallado una reducción muy significativa del desgaste del polietileno altamente entrecruzado, no se ha hallado que en las prótesis de rodilla implantadas en pacientes este desgaste se vea reducido. La gran variabilidad del número de partículas entre individuos sugiere que el desgaste de polietileno *in vivo* depende de muchos factores y probablemente el tipo de polietileno no sea el más determinante.

Introduction

Osteolysis is one of the main causes of failure in total knee arthroplasty. Consequently, osteolysis secondary to polyethylene wear and aseptic loosening is the principle cause of revision starting from 5 years after the index operation.[1,2]

In knee arthroplasty, the chief wear mechanism is fatigue. It produces larger particles than those produced in hip arthroplasty, in which wear occurs from abrasion and adhesion.[3] The size of the particles is important, given that the smaller ones have greater biological activity and producer greater osteolysis.[3] Particles >10 μm are not very pro-inflammatory because they are not susceptible to phagocytosis.[4]

Osteolysis is the result of a foreign-body reaction, induced by the particles generated by polyethylene wear.[5] These particles are phagocytosed by macrophages and giant cells, which are activated and liberate cytokines. Interleukins IL-1β, IL-6 and tumour necrosis factor alpha produce inflammation and stimulate the osteoclast; the activated osteoclast is the cell responsible for the osteolysis[6–8]; however, the cytokines also inhibit bone formation by the osteoblasts.[9]

To decrease polyethylene particle release, the industry has introduced different improvements over the last decades: improving the polyethylene sterilisation processes, using gamma radiation in an oxygen-free medium,[10] introducing new friction pairs and developing highly cross-linked polyethylene (XLPE).[11,12] Among these XLPE is the X3® (Stryker Orthopaedics, Mahwah, NJ).

The XLPE have been used for over 10 years in total hip arthroplasty, where they have shown better *in vivo* wear results than conventional polyethylene.[13–15] However, the studies carried on knee arthroplasty, and in those based on current use in this joint, are *in vitro* studies on a simulator.[16,17] In one study, Wang[6] found a reduction in polyethylene wear of 68% and 64% in standard arthroplasties with posterior cruciate ligament retention (CR) and posterior-stabilised (PS) total knee prosthesis (TKP) respectively, comparing polyethylene X3® to conventional polyethylene.[1] However, we know that simulator and *in vitro* studies do not always faithfully reproduce the conditions found in clinical practice.

The hypothesis of this study was that using XLPE X3® would reduce the number of polyethylene particles from wear, compared to conventional polyethylene conventional in an *in vivo* context. The main study objective was to compare the number of polyethylene particles isolated in synovial fluid following primary total knee arthroplasty, as based on using a conventional or XLPE polyethylene. The secondary objective was comparing particle size and morphology in both groups.

Material and methods

We designed a random, prospective study. The study protocol was approved by the local Ethics Committee. Patients gave informed consent for their inclusion in the study, which covered synovial fluid extraction by arthrocentesis at 12 months.