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Review article

Importance of preclinical evaluation of wear in hip implant designs using simulator machines☆

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ABSTRACT

Total hip arthroplasty (THA) is a surgical procedure that involves the replacement of the damaged joint of the hip by an artificial device. Despite the recognized clinical success of hip implants, wear of the articulating surfaces remains as one of the critical issues influencing performance. Common material combinations used in hip designs comprise metal-on-polymer (MoP), ceramic-on-polymer (CoP), metal-on-metal (MoM), and ceramic-on-ceramic (CoC). However, when the design of the hip implant is concerned besides the materials used, several parameters can influence its wear performance. In this scenario, where the safety and efficacy for the patient are the main issues, it is fundamental to evaluate and predict the wear rate of the hip implant design before its use in THA. This is one of the issues that should be taken into account in the preclinical evaluation step of the product, in which simulated laboratory tests are necessary. However, it is fundamental that the applied motions and loads can reproduce the wear mechanisms physiologically observed in the patient. To replicate the *in vivo* angular displacements and loadings, special machines known as joint simulators are employed. This article focuses on the main characteristics related to the wear simulation of hip implants using mechanical simulators, giving information to surgeons, researchers, regulatory bodies, etc., about the importance of preclinical wear evaluation. A critical analysis is performed on the differences in the principles of operation of simulators and their effects on the final results, and about future trends in wear simulation.

☆ Study conducted at the Instituto Nacional de Metrologia, Qualidade e Tecnologia (Inmetro), Divisão de Metrologia de Materiais, Duque de Caxias, RJ, Brazil.

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Importância da avaliação pré-clínica do desgaste em projetos de implantes de quadril usando máquinas simuladoras

Palavras-chave:
Artroplastia, substituição, quadril
Prótese do quadril
Desenho de prótese

RESUMO

A artroplastia total do quadril (ATQ) é um procedimento cirúrgico que envolve a substituição da articulação danificada por um dispositivo artificial. Apesar do reconhecido sucesso clínico dos implantes de quadril, o desgaste das superfícies articulares ainda é uma das questões críticas que influenciam o desempenho. As combinações de materiais comuns usadas nas próteses incluem metal sobre polímero (MsP), cerâmica sobre polímero (CsP), metal sobre metal (MsM) e cerâmica sobre cerâmica (CsC). No entanto, em relação ao desenho do implante de quadril, além dos materiais utilizados, vários parâmetros podem influenciar o seu desgaste. Neste cenário, onde a segurança e eficácia para o paciente são as principais questões, é fundamental avaliar e prever a taxa de desgaste do modelo de implante de quadril antes de sua utilização em ATQ. Esta é uma das questões que devem ser levadas em conta na etapa de avaliação pré-clínica do produto, na qual testes de simulação em laboratórios são necessários. No entanto, é fundamental que os movimentos e cargas aplicados possam reproduzir os mecanismos de desgaste fisiologicamente observados no paciente. Máquinas especiais, conhecidas como simuladores de articulação, são utilizadas pra replicar os deslocamentos angulares e cargas *in vivo*. Este artigo enfoca as principais características relacionadas à simulação de desgaste de implantes de quadril por meio de simuladores mecânicos, fornecendo informações a cirurgiões, pesquisadores e órgãos reguladores, dentre outros, sobre a importância da avaliação pré-clínica do desgaste. Foi feita análise crítica sobre as diferenças nos princípios de funcionamento dos simuladores e seus efeitos nos resultados finais, bem como sobre as tendências futuras na simulação de desgaste.

Introduction

The replacement of the damaged hip joint by an artificial device, known as Total Hip Replacement (THR), is a surgical procedure widely performed in Orthopedics in the last decades.[1] THR has an excellent cost/effectiveness ratio, once it improves the functional state and quality of life of the patients in a reliable way.[2] The hip implant designs often use a combination of metal-on-polymer (MoP), metal-on-metal (MoM), ceramic-on-ceramic (CoC) or ceramic-on-polymer (CoP) as the materials of the femoral head and liner. Although the clinical success and great technological advances in hip implants are well recognized, the materials used in THR systems have been continuously subject of research and development.[3] The wear of the articulating components, causing the primary failure of the implant due to osteolysis and aseptic loosening, remains as an important drawback.[4–6] The main problem related to wear is the generation of debris, which can incite a highly inflammatory biological response that can lead to subsequent localized periprosthetic bone loss, and consequently, re-surgery is required.[7] Particularly for ultra-high molecular weight polyethylene (UHMWPE) cup liners, high wear occurs mostly in the superior-lateral portion of the liner,[8] and the consequent debris generation into the body becomes a main factor to limiting the life of the implant.[1]

Tribology (friction and wear) of the bearing surfaces, associated with biocompatibility, are two critical aspects responsible for the clinical success of a hip implant. Research and development of new materials of hip implants is a fundamental key in reducing wear. It is important to keep in mind that when a new design (including materials, geometry, etc.) is being considered to be used in a THR system, the components will be exposed to several loadings and movements, giving origin to a wide range of mechanical contact stresses during the daily activities.[6] It makes the pre-clinical validation a critical stage in the development of a new design. Pre-clinical validation is considered by some researchers and manufacturers as an extension in the risk analysis task.[9]

The most accepted preclinical method to evaluate the wear performance of a hip implant design in laboratory comprises the use of singular machines that simulates the physiological loadings and movements clinically observed. These machines are known as hip joint simulators, and provide important outcomes about the expected behavior of a hip implant in clinical use.

This work reviews the main characteristics of the wear behavior of hip implants obtained through the results from simulator tests performed under standard protocols, and explains the importance in the preclinical evaluation of new hip implant designs before its clinical use.

Why simulate wear in a hip implant?

Before the introduction in the market, usually every product under development goes through a stage of assessment, aiming to determine its performance and possible modes of failure. Especially for hip implant designs, considering the

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