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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

safety and efficacy of the patient, a deeper investigation of the performance of the product is even necessary.

It is not only the tribology performance of the hip design coupling, but also the fixation of the prosthetic components that influence the long-term clinical performance of artificial hip joints.[10] On the other hand, the arising of modern implants, in association with surgical technique refinements, also with cementless fixation methods, have moved to the wear properties of the materials of the bearings surfaces the main responsibility for the durability of the total hip arthroplasty.[11] For these reasons, wear of the hip implant is one of the design attributes widely investigated in laboratories and companies around the world, also clinically during the life of the patient, and in retrieved implants. The study of the performance of the implant in wear tests is a tool for the development of hip designs, once it allows assessing wear rates, debris sizes and shapes prior to implantation.[12] The simulation of wear in laboratory is mainly motivated by the possibility to assessing the performance of different hip implant designs by comparing their wear rates and wear mechanisms. Different types of material combinations may result in different wear mechanisms. There are several mechanisms of wear, such as abrasive, adhesive, fatigue and abrasive wear mechanism by third body particle. The wear mechanisms can be assessed after the wear tests by laboratory analyses with advanced techniques of materials characterization.

Considering the practical operation of the hip joint, it is well known that the wear is governed not only by the material properties and design, but also by the lubricant film.[13] Moreover, from the point of view of engineering, wear of a hip implant is also regarded as a function of the kinematics conditions,[14] which can also affect the lubrication film. The correct simulation of the kinematics environment is crucial in order to correctly reproduce the lubrication condition of the joint, and thus, the wear behavior of the hip implant.

Regarding the choice of the pair of materials of the joint, one shall consider the advantages and disadvantages (risks) related to the intended tribological performance of the hip implant. For example, combinations that use soft articulating material (such as UHMWPE) against a hard bearing surface (metallic alloy or ceramic) will produce specific wear rates, which are correlated to the specific properties of the materials, associated with the specific joint design (geometry). Therefore, it is essential to determine the acceptable level of wear of the material combination. It is at this level that the wear simulation in laboratory, using appropriate equipment and protocols, associated to a controlled environment that replicates the human musculoskeletal system and kinematics, is considered as a powerful tool for the correct evaluation of wear performance.

Preclinical wear tests also ensure that the hip implant design has a satisfactory performance and safety in terms of durability, which increases the confidence of the product to the patients and surgeons.[3] A further advantage that hip implant wear simulation can bring out is the possibility of assessing the engineering factors that would affect the wear of the implant *in vivo*. The surface finishing (roughness) of the bearing surfaces is regarded as a key parameter that influences the wear behavior of the implant.[15,16] For example, wear tests can be performed in simulators to compare the wear rate of the liner as a function of different surface roughness values of the femoral head.[17]

Simulated tests can also be performed to evaluate the effect of scratched femoral heads on the wear of the liner. The existence of scratches in the head is regarded as one of the mechanisms responsible for abrasive wear in UHMWPE.[14] Additionally, roughness and scratches on the femoral head surface are closely related to the type of material used. Metals such as stainless steel and CoCr alloy (CoCr) are more susceptible to scratching than ceramics, once these materials have lower hardness in comparison to ceramics.

The wear performance of the implant regarding the influence of using different materials in the femoral head, such as ceramics and metals, can also be evaluated from simulated wear tests. Simulators have been used since long date to evaluate the wear mechanisms of these materials, giving valuable information about the advantages and disadvantages of each material.[15,18,19]

The diameter of the hip joint is another design aspect critical to wear since it is related to the contact stress field produced during the hip operation. Wear tests can be performed in simulators to evaluate the influence of femoral head diameter on the wear rate of liners, mainly those fabricated with UHMWPE material. It is seen that, for UHMWPE, the volumetric wear can critically depend on the diameter of the femoral head.[19] For example, the wear of a UHMWPE liner articulating against a 32 mm-femoral head is higher than the wear observed for liners articulating against femoral heads with smaller diameters.[20] The advantage of using a higher diameter is related to the higher range of movement (ROM) obtained without impingement occurrence, leading to better stability of the implant and decrease of dislocation risk.[20–24] In opposite, increasing the femoral head size leads to an increase in the sliding distance and velocity, which are parameters recognized to have influence on wear.[22] However, tests using wear simulators have demonstrated that femoral heads with large diameters only cause wear when the liner is fabricated from non-crosslinked UHMWPE. In the case of crosslinked UHMWPE, wear simulated tests have shown that wear is not necessarily dependent on the size of the femoral head.[25]

Research and development on orthopedic artificial joints, making use of experiments in joint simulators, are vast. Regardless of the increasing use of diverse materials, UHMWPE is one of the most applied materials for implant joints, and has been used as bearing material for artificial joints since the 1960s.[17,26,27] Since the first generation of UHMWPE, the search of solutions for wear related problems has been focused in changing its mechanical properties. Modifications in the structure of UHMWPE have been made to improve the wear resistance of the hip implant material. One way to improve the mechanical properties of UHMWPE, whereas indirectly, is the sterilization by gamma irradiation in substitution of ethylene oxide (EtO). Such irradiation process leads to the crosslinking of the polymer chains and consequently increases the wear resistance of the material.[28] Highly cross-linked UHMWPE liners present low wear, by more than 50%, compared with noncrosslinked ones.[29] The disadvantage of using gamma radiation relies in the production of free radicals, which can cause oxidation of the polymer and, consequently, make the material more fragile.

It is now obvious that hip wear simulation tests are a powerful tool to confirm the improvement in wear resistance before clinical use. In fact, it was already verified that hip wear simulation associated with deep material analysis, from macro to micro/nano scale phenomena, are helpful to identify the amount of wear and the material loss mechanisms of UHMWPE applied in THR. Using advanced techniques for atomic level analyses of the UHMWPE can reveal aspects of material structure modifications related to wear performance. The wear performance can become worst if the UHMWPE material undergoes strain softening while running under multi-directional mechanical stress field.[30,31]

Hip simulators machines

The use of advanced materials, as well as improvements in the design of the hips, has been considered as alternatives to reduce the wear of implants. However, to confirm that a new material or design is effective to reduce wear, a reliable comparative procedure is required. Usually, a first evaluation involves simplified tests to assess the wear and coefficient of friction (COF) of the materials intended to be used as bearing materials. Briefly, the equipment used to perform simplified tests is a tribometer, and the main advantage of using this kind of machine is the low cost, simplicity and ready availability of results. It allows ranking different materials with respect to their wear rate and coefficient of friction. This represents tribological performance evaluation but only at a preliminary level; that is, it is not possible to evaluate the effect of some other important features, such as the design of the hip joint, on wear. This limitation is related to the elementary geometry employed to the contacting surfaces, the applied load ranges and the environmental conditions, which do not exactly reproduce *in vivo* conditions.[17]

Tests performed in suitable equipment, where both the design and the material wear properties can be simultaneously assessed by the use of real hip joint implants, can bring important pre-clinical outcomes about the wear performance of the implant. The worldwide accepted method to assess the design and material wear properties of hip implants involves the use of a simulator machine. As already is in its own name, a simulator replicates the conditions of loadings, angular displacements (abduction/adduction, internal/external rotation and flexion/extension) and environment, as observed in the human gait. In this way, the prediction of the *in vivo* wear rates of total joint replacements is obtained in a more clinically relevant way.[32,33] Nevertheless, although the attributes of the hip joint design are evaluated in the hip simulator test, it should be clear that the expertise of the surgeon as well as the clinical aspects of the patient cannot be taken into account.

Joint simulators have been widely used for a long time worldwide, not only to evaluate designs for wear performance, but also to conduct R&D in hip implants, and not only by laboratories but also by the manufacturing companies. In the last case, it means that it is possible to promptly evaluate the wear performance of a new hip design at the own site of the company. The interest in having a hip simulator on site is a good indicative that worldwide companies, especially the American and European ones, are making particular investments to improving the tribological performance in their own manufactured products.

In Brazil, the scenario is quite different. The hip joint simulators are mostly located in research institutes and universities, meaning that the evaluation of the wear rates of the hip implant designs cannot be promptly obtained at the company site. This fact can inhibit actions directed to R&D unless that the company is in connection to the tester entity in a well-established joint-work relationship. This kind of action should allow making innovative advancements in the orthopedic product sector in Brazil.

Several types of joint simulators are available in the market to perform wear tests. The main difference among the simulators is the mechanical principle of operation, leading to the existence of different models and manufacturers around the world.[28] To date, most of the hip simulator machines have hydraulic or electromechanical operation. An example of a hydraulic simulator is the one placed at the Materials Metrology Division (Dimat) in the National Institute of Metrology, Quality and Technology (Inmetro). It is presented in Fig. 1A, illustrating the general view of the machine and the detail of a work station (Fig. 1B) where the test specimens (femoral head and liner) are mounted.

This particular simulator has principles of operation based in hydraulic forces that are responsible to supply the required conditions to operate the loadings and angular displacements. One interesting feature of this equipment is the six-axis load cell installed in each work station, which allows measurement of forces and moments in *x*, *y* and *z* Cartesian coordinates. The set of forces and moments are produced as a result of the design of the hip implant when the load and displacement curves are applied during the test. Its assessment can give information on the resistive forces acting during the hip operation, such as those related to friction. It should be remembered that, as small is the friction force acting during the operation of the joint, better will be felt the implant inside the body.

Despite the existence of international standardized test methods describing the loadings and displacements, the principle of mechanical operation of the simulator plays an important role to the differences in the wear rates observed among different laboratories. Instead of the three types of angular motion performed by the joint, hip simulators can use simplified conditions. For example, only the flexion/extension and internal/external rotation can be applied to the test specimen in some simulators, being not able to apply the abduction/adduction. In this case, this type of simulator is usually known as biaxial rocking motion (BRM), where the motion is applied in the femoral head through the rotation of a block mounted under the femoral head with 23° of inclination.[32] BRM simulators, in some circumstances, apply only static load, but even with such diverse loading condition, they have shown to produce valid results.[18]

As the inputs (loadings and displacements) are different among hip simulators, the direct comparison between the wear rates, determined from different simulators for the same hip implant model, can become difficult. Thus care should be taken in order to accept and validate data for comparisons among experimental results.

Fig. 1 – (A) General view of a hydraulic multi-station hip simulator; (B) detail of a work station with a hip joint test specimen (without lubricant).

Hip wear simulation methodology

The *in vivo* tribological aspects of hip replacements are complex, highly variable and depend on several conditions inherently found in the patients. This makes a single standard pre-clinical test unable to simulate all the involved conditions in laboratory.[34] However, standardization is an issue to be considered so as to create a basis for quality determination. In terms of hip wear performance evaluation, it is necessary to establish a standard operational cycling concerning the angular movements and the loadings, having in mind the existence of different machines in several laboratories around the world. Theoretically, this would allow reproducibility among the international laboratories, and thus, make comparison of the wear rates of hip implant designs possible, independently of the characteristics of the tester. The ISO 14242 standard, in its parts 1 and 3,[35,36] specifies the conditions to be used for the wear testing of total hip-joint implants. It gives the ranges for the angular movements between the articulating components, the pattern of the applied load, the speed cycle, the testing duration, the sample configuration, and the test environment. The methods of wear assessment, based on gravimetric techniques and/or changes in dimensional form of the components, are also specified in the ISO 14242-2 standard.[37]

The ranges of the angular movements and the applied force specified in the ISO 14242-1 standard[35] were established with basis in the human gait and forces also considering the relative movement between the pelvic and the femoral components.[12,28] The applied force reported in this standardized protocol was defined based on simple activities of the daily life, for example, walking. It has been shown that during walking activity the load presents values between zero to four times the patient body, in that one cycle of testing comprises a compressive loading with a maximum value of 3000 N and minimum load of 300 N, angular displacements of flexion/extension (F/E), abduction/adduction (AB/AD) and internal/external rotation (IR/OR). The angles go to 2° IR, 10° ER, 25° F, 18° E, 4° AB and 7° AD, respectively.

Another important parameter specified in the ISO 14242-1 standard[35] is how the lubrication between the femoral head and the acetabular liner is promoted during the test. It is important to have in mind that the physiological condition of lubrication of the human joint is related to the synovial fluid. In the simulator wear test the *in vivo* lubrication condition is replicated by the use of calf serum diluted with deionized water. Particularly for this type of lubricant, it is important to pay attention to the protein mass concentration. A protein mass concentration of (30 ± 2) g/L had been specified in the ISO 14242-1 standard.[35] However, it has recently changed in the way that, if the wear mechanisms observed in the hip joint components tested in the simulator are not clinically reproducible as those observed in retrieved joints, a different protein mass concentration in the lubricant may be used. This highlights one of the main concerns of hip wear simulation, which is the reproduction of the clinical mechanisms as observed *in vivo*.

To predict the wear of the hip implant as it would be *in vivo*, it is specified a minimum of five million cycles, using the force and angular movement ranges according to the ISO 14242-1 standard.[35] It is assumed that one million of cycles of motion of the hip joint replicate approximately the average number of normal walking footsteps of an average patient in one year.[18,19,38]

Younger people have been also using hip implants; in this case, the daily life activities can be quite different. Consequently, the assumption that one million cycles of wear

test represents one year of clinical use of the hip prosthesis has been considered by many researchers as an old conjecture. This is true, especially for the so called hard-on-hard bearing combinations, such as CoC and MoM. These are THR alternatives that have been increasing in young and active patients.[39] To this case, the experts belonging to the standardization committees such as ISO and ASTM are nowadays making efforts to developing specific standardized test methods. The test procedures for hard-on-hard joints must anticipate the performance under more adverse working conditions, in order to be capable to discern the hip performance correctly. However, for the soft-on-hard combination of materials, which is one of the most employed worldwide, the test procedure established in the ISO 14242-1 standard[35] is considered adequate for performance evaluation of the hip joint.

The practical result of a wear test is the rate in which the hip component wears as a function of the number of running cycles under the angular movements and forces applied in the simulator. Usually, loss of material (in mass) is plotted as a function of specific intervals of testing, such as 500,000 cycles. An example of graphical representation of the cumulative mass loss as a function of the number of cycles is shown in Fig. 2. In this particular example, UHMWPE acetabular liners (components that lose material due to wear) articulated against a 28 mm femoral heads. The head was made of CoCrMo alloy (comprising three specimen pairs, results in Fig. 2A) and of stainless steel (three specimen pairs, results in Fig. 2B) up to five million cycles.[31] From the slope of the graphical representation, and assuming a linear curve using the least square method, it is possible to estimate the wear rate of each individual sample.[37] It can be seen from Fig. 2 that the average wear rate of the set of UHMWPE samples is approximately 48 mg/10^6 cycles (estimated as 51 mm^3/10^6 cycles), independent of the material used in the femoral head.

To highlight the importance of wear tests using simulators in order to compare the wear rates among different hip designs, an example is the hip design comprising the femoral head and liner (28 mm diameter) made from nanocrystalline diamond (NCD) on silicon nitride substrate, in which the wear rate was 0.02 mm^3/10^6 cycles.[40] Comparing the wear rates of the two hip designs above mentioned, it is possible to observe enormous difference in the wear rate among them.

The graphical plot is also useful to obtain information about the wear behavior of the hip implant design along the time of operation. Depending on the material combination, it is possible to observe two different behaviors: the run-in wear and the steady-state wear. The first one is characterized by the wear that occurs during the initial phase of the test, which is clinically equivalent to the initial running period of the *in vivo* implanted hip. In this phase, wear rates are usually high because the head and cup go into conformity with each other while wear occurs. The topography of real contacting surfaces is not ideal and some of the surface asperities can be initially high. These are worn away in the running-in period, thus making the surfaces conformal. After the transient period, the steady-state wear is attained, characterized by a constant wear rate, typically less than the run-in wear rate.

The determination of the wear rate plays an important role in the evaluation of hip designs, since it allows the direct

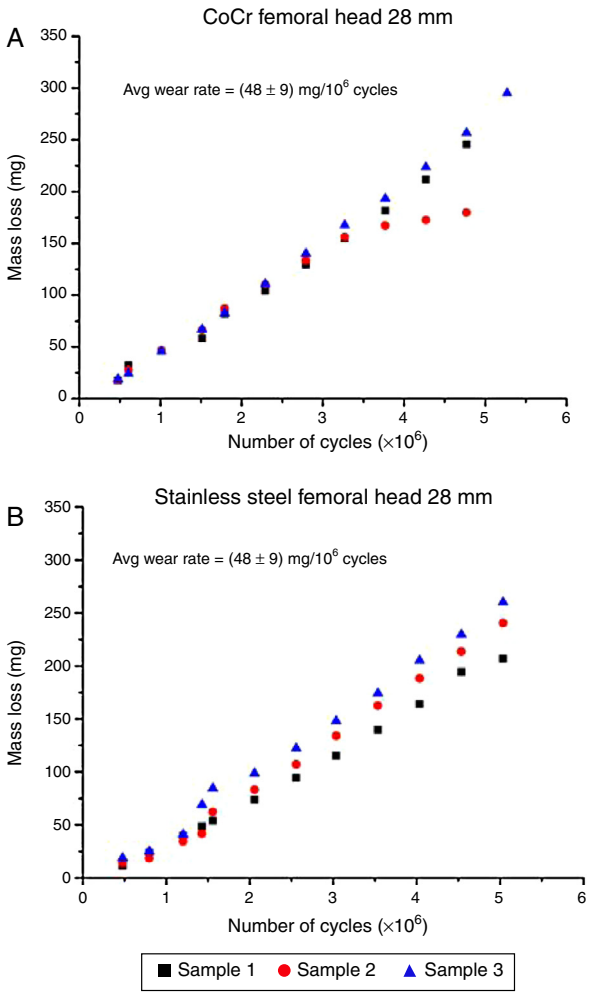

Fig. 2 – Example of wear plots as a function of number of cycles for UHMWPE acetabular liners that articulated against (A) CoCrMo alloy and (B) stainless steel.

ranking of material combinations intended to be used in hip implants. As specified in the ISO14242-2[37] standard, the wear behavior is obtained after fitting a line by least square method throughout the cumulative mass loss data, as a function of the number of loading cycles. The wear rate is then simply calculated as the angular coefficient (slope) of the fitted line. It has been seen that this procedure is quite convenient for the wear rate determination of hip implants made of conventional UHMWPE. However, some other aspects should be considered for the wear rate determination, as it has been seen worldwide, by well-established hip wear simulation players. It is especially critical in the case of wear with two distinct run-in and steady state behaviors. In this case, it is either possible to calculate a run-in wear rate separated from the steady-state wear rate, or a unique wear rate using the entire set of data. Clearly, the wear rates calculated in this particular situation can be quite different. Thus, care should be taken when reporting the average wear rate of a particular hip implant design.

After these points stated, one must have in mind the procedural dependent aspect of wear. That is, wear can result different not only due to the differences in the implant design,

but also as the effect of differences in test protocols, hardware setup and lubricant composition.[41] All these aspects must be considered when comparing results produced from different testing laboratories. The establishment of an individual database for each laboratory plays an important role in studying wear of hip implants. However, it is a hard task once the wear simulated test is expensive and time consuming, requiring several years to obtain a reliable and powerful database.

Moreover, it should be emphasized that, for precise evaluation of any implant design, one should consider several aspects of the materials used in the joint components, going from physical, chemical and mechanical characterizations, to the biocompatibility assessment, besides the preclinical tests for performance assessment of the product. However, in spite of the huge set of data obtained from the tests and analyses concerning the evaluation of the implant design, it is always important to call attention to the fact that these results are concerned to the evaluation of the product; that is, not considering the surgical performance and the patient health condition. Thus, they should be interpreted cautiously with respect to the direct applicability to clinical conditions, and cannot be assumed as a final decision on the success of a hip design after implantation.

Concerning the preclinical wear tests for performance assessment for the particular case of Brazil, the national literature only reports case studies of failed implanted prosthesis, the causes going from materials out of specification, through structural non-conformity of the components. Wear of implants is not reported, probably because the implants could not even reach to the stage to develop wear. However, problematic issues concerning material control and straight mechanical structure design verifications can be overcome with technological modernization of Brazilian implant manufacturers, also with the help of increasing number of specialized testing laboratories. In this way, failures coming from non-conformity in materials and structure designs can be surpassed by others, now coming from wear. In this way, the wear behavior can become a key factor for dictating the performance of the product. We call attention that performing tests to predict wear of hip implant designs should overcome the existing obstacles such as material control and straight mechanical structure design, in order to make advances on the safety and health of patients, and gaining benefit from the data obtained in the wear tests, to improve the implant's market.

Future of hip simulation wear tests

Testing of hip implants is a dynamic area. Recently, retrieved implants have provided information about the *in vivo* mechanisms of wear in hip implants. Several test protocols have also been developed in laboratories around the world, and the influence of design, as well as parameters of loading and movements on the wear performance, have been addressed. Furthermore, in the last decades, the tribological research of the material combinations used in total hip replacements has been considering a more simplified model of loads and movements than that established in the ISO 14242 standard, and based on a normal human gait.[12]

However, it is well known that, in many situations, the femoral head and acetabular cup are not submitted to the stresses observed in a normal gait only, since hip implants have been considered to be used in younger and more active patients. In addition, considering the developments of new materials (ceramics, UHMWPE with crosslinking, etc.) to improve wear resistance, the current loads and movements prescribed in ISO 14242-1 standard[35] for wear tests may become limited to evaluate wear of modern hip implants designs. The recent clinical failures by localized wear from edge loading and abnormal sounds (squeaking) identified in several hip implant designs have also contributed to the need of more aggressive hip wear test.[42] Also, increase in the lifespan of the hip implant is expected by both surgeons and patients; this leads to the need of improvements in the wear tests toward establishing higher levels of confidence of the devices against particular conditions of elevated working time. The time duration and the ranges of movements and loadings established in the ISO standard 14242-1[35] do not represent aspects of current everyday life activities of more active patients, thus the wear test protocol should be modified to meet the requirements of modern daily life activity.[12]

In this scenario, a new term in the area of hip wear simulation has been arising recently, named as "adverse conditions test". This includes steep inclination angle of the acetabular cup, higher loading level, higher motion speed, third body abrasion and microseparation.[43] Adverse conditions tests are powerful once it allows identification of materials with improved performance and the elimination of hip designs with inadequate wear resistance under more aggressive operation, prior to their clinical use.

Adverse conditions tests have been considered particularly for the evaluation CoC and MoM bearings, once the current ISO 14242-1[35] standard test protocol usually cannot distinguish different hard-on-hard designs concerning wear. Besides that, in some THR, it is possible that a perfect positioning of the implant cannot be achieved. This implicates in an adverse condition that can lead to increased wear of the articulating surface. Hip simulator machines can also be employed to evaluate the stability performance of the implant by replicating such adverse conditions related to incorrect positioning of the implant that may occur during the surgery.

Regarding the wear measurement, as discussed before, the wear rate is an important result obtained with hip simulation tests. However, inaccurate measurement of mass loss of the test specimens affects the confidence of the information disseminated about the wear quality of the prostheses being tested. To overcome this possible drawback, geometrical approaches using three-dimensional Coordinate-Measuring Machine (CMM) have been coupled to hip wear simulation tests to obtain more accurate measurement of wear.[31,44] Geometrical approaches have been considered as an additional analysis to hip wear simulation because it has the advantage of identification of the location of wear and its corresponding depth precisely.

Another issue is concerned to the increasing use of ceramic materials in total hip arthroplasty (THA). Both femoral heads and acetabular cups fabricated from ceramic materials

have been used, mainly due to the high hardness, chemical inertness, low coefficient of friction and tolerance by the organism.[45] It should be pointed out that, despite the expected superior wear performance, retrieved ceramic couples in some cases have shown a long, narrow area of damage, which has been called stripe wear.[46] Stripe wear is associated with edge loading, which is the contact between the head and the edge of the liner. This contact results from misalignment between the center of femoral head and the center of the acetabular cup. It is related to the migration of the femoral component, producing distal translation and internal rotation, in such way that the final position of the component is retroverted.[46] Variation in translational positioning of the centers of the head and cup, which is not detected on radiographs, is a frequent clinically occurrence and can result in substantial increase in wear rate.[35] Clinically, a loose soft tissue tension can allow separation of the bearing during the swing phase of gait, and when the heel strike occurs it can produce edge loading before relocation occurs.

However, CoC bearings have shown an excellent performance under standard hip simulator test conditions and do not present usual stripe pattern of wear as found in retrievals.[39] The wear identified under standard hip simulation tests is demonstrated to be very low in simulator studies.[45] Modification of the wear test protocol established in the ISO 14242-1 standard[35] has been considered by many researchers, to including micro-separation as an artificial feature of the wear test, in order to promote edge loading occurrence. In this way, it is expected that ceramic couples after the wear simulation in laboratory present stripe wear, which clinically replicates the wear feature as found *in vivo*.[35]

Final remarks

Hip simulator machines are a powerful tool for preclinical evaluation of hip designs, anticipating the intended wear performance of the bearing materials. There is need of deep studies concerning the wear performance of hip implants available in the Brazilian market.

Knowledge of tribological principles in association with hip simulator wear tests have contributed to the development and durability increase of artificial hip joints. Results of wear tests can contribute to increase the confidence of the surgeon on a specific hip design. However, even with the technological advances, the success of a total hip replacement device still depends on two important factors: the surgeon and the patient's physiological condition.

Conflicts of interest

The authors declare no conflicts of interest.

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