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The Clinical Relevance of Hip Simulator Testing of High Performance Implants

Aiguo Wang, PhD, Aaron Essner, MSc, and Joe Cooper, BA

Effective in vitro hip simulation testing should reproduce clinical failures, clinical wear mechanisms, and clinical successes. These validated test outcomes are the only criteria for predicting the failures and successes of new bearing surfaces and geometries. The authors have successfully reproduced the clinical failures of Charnley's polytetrafluoroethylene (PTFE) and Hylame polyethylene, and successfully predicted clinical successes, including first generation highly crosslinked UHMWPE (Crossfire) over gamma-inert sterilized conventional UHMWPE (N2vac). When approached with new implant technologies, surgeons must know how to evaluate the validation of testing methods used by manufacturers, to ensure the test outcomes of these products predict good survivorship.
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Today's total hip arthroplasty patients comprise a changing population that grows younger and more active every year. As patients' expectations increase, so does the demand for new bearing technologies capable of long-term wear under harsh conditions.

Testing is a crucial phase in the development of these new technologies, and there are many parameters affecting the validity and predictive potential of implant testing. Any new bearing technologies must be subjected to rigorous and exacting in vitro testing, to meet the implant demands of present and future patient populations. The clinical relevance of this testing is critical.

There is a long clinical history of bearing material failure in acetabular components. A study by Min and coworkers on the Harris-Galante cup (Harris-Galante II, Zimmer, Warsaw, IN) revealed a 17.3% failure rate of the polyethelene liner after 8 years.[1] Previous clinical failures include the early failure of Hylamer polyethelene (DePuy, Warsaw, IN) in total hip[2] arthroplasty. Teflon and polyester are two other bearing surfaces used in total hip arthroplasty, both having poor clinical histories.[3]

New bearing technologies face not only the failures of past generations, but also the increasing patient demand for better implant performance. Disease also challenges implant performance, such as obesity, as well as diseases linked to obesity such as diabetes and hypertension.[4] Other challenges include suboptimal implant placement (sometimes because of new trends or surgical technique) such as minimally invasive surgery (MIS), and establishing realistic patient expectations.

Laboratory in vitro simulation testing must reproduce the mechanisms, rate, and total magnitude of wear. The ultimate goal of these reproductions is the accurate prediction of the clinical failure or success of bearing surfaces and design. As bearing surface technologies advance to meet increasing patient expectations, a validated simulation testing model with a clinical history of predictive success must be used to effectively analyze and develop these technologies. The objective of this paper is to review the criteria for effective simulation testing and provide the reader with the background necessary for the investigation of the testing methods of new implant technologies.

Wear Study Parameters

When designing a wear study, several investigational parameters must be considered. Lubrication is critical to the simulation of physical joints, and its composition is a determinant of the testing result. Lubricants for simulator testing need careful consideration regarding protein content. Previous research has found that protein in water-based lubricants promotes the wear rate of ultra-high molecular weight polyethylene (UHMWPE) in artificial joint testing.[5] However, soluble proteins can denature as a result of frictional heating and produce a "solid." This solid is generally com-

Biomechanics and Tribology Laboratory, Stryker Orthopaedics, Mahwah, NJ.

Address reprint requests to Aiguo Wang, PhD, Science and Clinical Studies, Stryker Orthopaedics, 325 Corporate Drive, Mahwah, NJ 07430; aiguo.2ang@stryker.com.

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posed of albumin and globulin, similar to cooked egg-white in texture, and was found to be an effective solid lubricant for UHMWPE.[6] In conducting simulation tests on polyethylene, the highest wear rate occurs with the lubricant containing an intermediate concentration of proteins, above and below which, wear will decrease.[7] That is, with inadequate lubricant protein levels, UHMWPE wear is minimal. Conversely, with elevated protein levels, denaturing occurs, thereby artificially protecting articular surfaces again reducing UHMWPE wear. Therefore protein must be at or slightly below physiological levels to accurately simulate in vitro polyethelene wear.[8]

A significant consideration is the turnover of lubricants used in testing. Local frictional heating between a head and cup will denature proteins. This logically occurs in the body as well as the laboratory. The major difference is the ability of the body to remove this debris and supply fresh proteins/lubricant. In vitro simulators are "dead men walking." Turnover must be accounted for, either by frequent lubricant changes or a sufficient volume to minimize degradation, yet supply fresh proteins.[9]

The albumin:globulin ratio in lubrication is another important consideration. An increased albumin:globulin ratio has been shown to significantly reduce wear in both UHMWPE and polytetrafluoroethylene (PTFE).[8] In a study by the authors, 32 mm cups and cobalt-chrome heads were tested with different albumin:globulin ratios for 1 million cycles. It was found that the wear rate for UHMWPE decreased almost linearly as the albumin:globulin ratio increased.[10] This is because of the preferential denaturing of albumin. The ideal ratio should be as close to joint fluid as possible, something generally not found in the ordinary bovine serum normally used. Fetal bovine serum has a consistency much closer to joint fluid.[8] It must also be noted that synovial fluid is usually the intended lubricant for simulation purposes, but post total joint replacement (TJR) joint fluid is actually a more accurate target.

Clinically relevant loading must be applied in conjunction with multi-directional motion for accurate wear studies. Achieving loading that mimics a variety of joint reaction forces for in vivo activities will provide a more accurate reflection of clinical outcomes.

Motion pattern is another parameter important to the accuracy of a wear study. The direction and pattern of motion will determine an in vitro simulation's accuracy when compared with in vivo outcomes. Wear rates and rankings of wear resistance for various UHMWPE materials are very different under unidirectional and multi-axial motion conditions. UHMWPE strain-hardens under unidirectional motion but strain-softens under multi-directional motion because of molecular orientation-induced anisotropy at the wear surface. Unidirectional wear testing machines are not sufficient for the evaluation of polyethelene bearing materials because they do not simulate the wear created by real joints.[6,11] Multidirectional wear testing is essential to a successful artificial joint simulation.

Simply applying cross-path motion and clinically relevant forces is not enough. The motions and forces must be applied in a clinically relevant manner in terms of relative point of application. Acetabular inserts should be mounted superiorly to femoral heads, as occurs anatomically. In other words, cross-shear motion and force should be applied through the femoral head as in a hip joint (anatomy must be replicated in simulation). If force and motion are not applied anatomically, clinical results will be inaccurate. This is partly because of the concentrated location of force application on a stationary insert that results when a femoral head is articulated within it. If the cup is moved with the head remaining stationary, stresses and motions are distributed around the cup, altering the anisotropic orientation mechanism mentioned earlier. Components must be anatomically placed during testing to replicate the anatomy of the hip joint. By placing the component correctly, applying superior force to the cup, and simulating anatomic motion of the femoral head, test results will more effectively predict clinical outcomes.

Standardization and Current Practices

The American Society of Testing and Materials (ASTM) has attempted to establish testing standards. It is generally difficult to achieve consensus on these standards, however, due mostly to varied individual laboratory experiences and equipment. A particular set of conditions may not be possible to enact on all equipment in the research community, and even if this were possible, it may not produce the same results. For this reason, as well as political concerns regarding historical data, a unified standard has been very difficult to establish. It seems that clinically relevant hip simulation models, and therefore standards, must account for the issues as opposed to rote following of a prescribed test standard. Individual adjustment of lubricants and other test factors may be necessary to achieve clinical relevance and accuracy. A standard has been provided by the International Standards Organization (ISO) but this does not precisely account for lubricant details. Further improvement appears necessary.

The authors have made significant contributions to the development of ASTM and ISO standards regarding lubrication, component positioning, and other testing issues. Wang and co-workers established an in vitro lubricant formulation to closely observe clinical wear rates.[8] They have also determined requirements for in vitro hip-simulator testing and based them on clinical results: wear rates, wear rate rankings, and wear debris size and morphology must agree with reported clinical results.[12]

The satisfaction of these standards, and other requirements such as 510(k) clearance from the FDA, do not guarantee clinical success. Determining the safety of a medical device and predicting its long-term wear are two very different objectives. Surgeons must possess a background knowledge of wear testing and its importance to effectively investigate the validation of the testing used by the manufacturers whose products they use.

Laboratory hip joint simulator testing is required to accurately predict wear rates and magnitudes of new bearing sur-