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CORR Insights®: Are PEEK-on-Ceramic Bearings an Option for Total Disc Arthroplasty? An In Vitro Tribology Study

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Where Are We Now?

The study by Siskey and colleagues is novel in that it addresses several aspects of wear and damage to the surfaces of a cervical disc replacement. Specifically, the authors have evaluated wear of PEEK-on-ceramic bearings not only under idealized conditions, but also

under simulated impingement and “abrasive” conditions, simulating the effects of third-body damage on wear. The study is masterfully conducted and pushes the envelope on wear evaluation of total disc replacements beyond current ASTM and ISO requirements. As the authors indicate, disc replacements currently on the market were approved using only idealized conditions.

The authors conclude that PEEK-on-ceramic bearings may be a reasonable alternative to polyethylene-on-CoCr or metal-on-metal bearing for cervical disc replacements. However, in drawing this conclusion, one must take the specifics of the design into account. It is difficult from this wear simulation alone to make general

conclusions regarding the tribological behavior of PEEK-on-ceramic bearings, since the ceramic core may not have had predictable types of motion against each of the superior and inferior PEEK components.

Where Do We Need To Go?

Ideally, preclinical experiments should predict the clinical performance of a cervical disc replacement with high certainty. In this regard, the current study serves as an important reminder that ASTM, ISO, or other currently required tests alone are insufficient to predict the short-term clinical performance, let alone the longer-term performance, of these devices. Specifically, while total disc replacement wear simulations are necessary for the complete preclinical evaluation of a disc replacement, they certainly are not sufficient.

Generally, testing standards seek to assure the safety of a device, but they do not necessarily assess the clinical performance. Engineering tools have become more widely available to

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conduct preclinical evaluations of many different aspects of disc replacement performance. These include finite element modeling, material testing, wear simulation, fatigue testing, and benchtop models for evaluation of fixation. While the perception of some in the implant-design community is that new or novel implants are often required to undergo too many tests, or that preclinical testing is an expensive burden, the cost and effort of such testing pale in comparison to the costs of the surgical procedures, let alone the costs of litigation, should the device fail to perform as expected.

Rather than testing only wear performance under ideal conditions or fatigue strength, implant performance should be evaluated in a multifaceted fashion that targets its weaknesses and challenges the demands under worst-case-scenarios that will occur clinically. While the current study is a great example, other examples include simulation of the performance under poor bone quality

fixation conditions, overweight patients, and professional athletes.

How Do We Get There?

As the authors of the current study indicate, cervical disc replacements now use bearing surface materials that were previously established in total hip replacements. However, the success of total hip replacements today is in large part owed to the vast number of in vitro studies performed over several decades. Clinicians, industry, and regulatory agencies should work more closely with independent researchers and academic institutions in developing elaborate methods and approaches for preclinical evaluation of novel designs of disc replacements. Clinically, failures of disc replacement are attributed, in large part, to fixation issues, dislodgement, and impingement. Laboratory cadaver or synthetic models could be used to study and address many of these issues. These

types of studies and experimentation would be facilitated if regulatory agencies require, or at least encourage, these prior to the approval of an implant.

At present, most journals consider randomized clinical trials as the gold standard for novel implant evaluation. In the same way that we have varying levels of evidence for clinical trials, similar progressive levels to grade preclinical evaluation studies may serve to rank them in terms of quality. Most preclinical studies use a model of some sort to evaluate an implant; however, every model requires a certain level of validation to provide convincing evidence. Cross-platform validation, such as wear studies validated by retrieval analysis, can be used as an important criterion to judge the level of evidence provided by a model. Ultimately, however, it is in the best interest of the community to spend more time and resources for evaluating new implants or materials for the spine prior to clinical trials.