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Ramiro Ramirez, Lucideon

Ambiguous standards

As the materials in hip and knee replacements continue to move forward, the standards for tests are distinctly lacking. *Engineering Materials* takes a look at what the ISO standards don't tell you.

Materials test firm, Lucideon, has carried out work looking into the testing standards used to access hip and knee prosthetic joint replacements.

In its white paper, *Hip and Knee Wear Testing – what the standards don't tell you,* it highlights areas that remain ambiguous within ISO standards when it comes to characterising wear. It goes on to offer advice to designers and manufacturers about best practice and how to go about navigating compliance during development.

Ramiro Ramirez, a wear test engineer at Lucideon, says: "We do a lot of non-standardised testing for our orthopaedic partners. But, while we find that the ISO standards offer a lot of detail, they are not always easy to apply to every test. We often need to adapt test rigs and develop new methods to suit the implant in question."

The current ISO standards for both hip (ISO 14242) and knee (ISO 14243) wear simulation provide well defined loading and displacement conditions for anatomical joints, which simulate the typical force and motion that a prosthetic joint is likely to experience during its operational life.

However, a few areas in the standards lack clarity, making it a challenging area for engineers as they look to implement a comprehensive pre-clinical wear testing program. The ISO standards recommend that the design of the implant must represent the worst case, which corresponds to the design that will see the highest stress and greatest damage. For wear testing, this 'worst case' is often decided by the material thickness (normally polyethylene) and implant size.

"We are used to designing customised testing methods that both fit within the requirements of the ISO standards and show the fitness of the implant when it comes to regulatory submission," explains Ramirez. "This white paper highlights the need for this kind of testing and will give manufacturers of hip and knee implants an insight into the kind of things that must be taken into consideration."

It wants to avoid situations where engineers devise tailored wear testing programs themselves. Lack of knowledge here may reflect badly during regulatory submission. For example, tests such as polyethylene aging and abrasive testing are becoming popular with the development of alternative bearing materials.

Implants and the materials used continue to advance the field of orthopaedics at speed. However, this is currently outpacing the development of new standards making testing and regulatory submission a potential grey area for many. It therefore requires innovative, thoughtful and scientific approaches to preclinical evaluations as the standards only explain and outline so much.

For more information and to download the white paper on *Hip and Knee Wear Testing – what the standards don't tell you,* go to the Lucideon website where there is an accompanying webinar available.
www.lucideon.com