What is going wrong with endoprosthetics?

Almost 400,000 hip and knee joints are replaced by prosthetic implants in Germany each year. However, the number of corrective operations is also high with just under 35,000 joint implants being substituted. Outside of normal replacements, such corrective intervention may become necessary prematurely if, for instance, dislocation or aseptic prosthetic loosening occurs. The new voluntary endoprosthesis register should ensure transparency for products and users.

German Summary

In Deutschland werden jedes Jahr fast 400 000 Hüft- und Kniegelenke durch Prothesen ersetzt. Auch die Zahl der Revisions-Operationen ist hoch: knapp 35 000 Gelenke werden ausgetauscht. Vom normalen Ersatz abgesehen, kann eine solche Revision frühzeitig notwendig werden, wenn es beispielsweise zu einer Luxation oder einer aseptischen Prothesenlockerung kommt. Wo liegen aber die Gründe, wenn etwas schief läuft? „Es gibt keine validen Studien aus denen sich das Verhältnis von Anwenderfehlern und Produktfehlern ergibt. Nach US-amerikanischen Angaben sind etwa zwei Drittel der Vorkommnisse auf Anwenderfehler zurückzuführen und ein Drittel auf Produktfehler – diese Angaben beziehen sich aber auf alle Medizinprodukte“, erklärt Rechtsanwalt Jörg F. Heynemann, der mit seiner Kanzlei ausschließlich geschädigte Patienten vertritt. Der deutschsprachige Beitrag ist nachzulesen auf www.meditec-international.com/medi0511endo

The fact that completely problem-free products exist is documented in Sweden where a mandatory prosthetic implant register has been kept for over 30 years. At total of 97% of some prosthetic hip replacements still work 20 years after being inserted. So what are the reasons when things go wrong?

Manufacturers and engineers developing new prosthetic products generally focus their efforts on resolving existing problems. The size of prosthetic heads has been increased, for instance, to prevent dislocation. Good results in standard tests are very important in the evaluation and control of such design modifications. Unfortunately it is increasingly clear that problems can still occur in clinical application despite top results in pre-clinical simulation under standard conditions. Patients do not move in a uniform way and nor are components fitted identically each time. Both factors have an enormous impact on the wear and performance of joint implants. However, these effects only become evident in clinical application. Manufacturers must therefore understand that good standard test results only constitute a minimum requirement.

Let us focus our attention on the users or in other words the consultants. Some products cause problems all the time in certain hospitals but do not occur elsewhere. "There are no valid studies which indicate the ratio of user errors to product errors. According to figures from the USA, around two-thirds of cases are a result of user errors and a third due to product errors. However, these figures apply to all medical products," explained the attorney Jörg F. Heynemann, whose firm exclusively represents patients who have suffered damages. He went on to add: "Serial damages caused by a faulty product can usually be settled easily because the manufacturer is actively interested in resolving the problems and often co-operates voluntarily. The register will make it easier to identify such serial patterns at an earlier stage and will make high correction rates on the user side transparent." He hopes the voluntary list will make it obvious who is not participating and that the resulting pressure will be sufficient to oblige all relevant participants to take part.

Patients need realistic explanations

Another reason for the premature failure of joint replacements can be overloading by patients. Many of the prosthetic product brochures produced by manufacturers and the advertising material of orthopedic clinics show sporty, fit elderly people implying that a hip replacement can turn people from coach potatoes into marathon runners. The force exerted on a hip joint can increase by up to five times the body weight with gentle jogging and over eight times when stumbling, according to studies by Georg Bergmann et al. More realistic explanations to patients of what is and is not possible will also help ensure that the target lifespan of a prosthetic joint is achieved. There is also a fine line between product failure and normal replacement. Heynemann would probably advise a patient with a 12-year-old prosthetic hip that has dislocated against taking legal action, at least if no serial pattern of damages exists. He explained: "If someone is very active and the joint is exposed to great stress, it is almost impossible to prove product failure."

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There are many reasons for the failure of prosthetic implants. The voluntary register is a step in the right direction towards identifying problematic products, users who do not work with sufficient care and any other factors. However, the objective should remain a mandatory register to record the widest possible cross-section of users and products, especially since all requirements for a mandatory register are already in place.

Ramona Riesterer ←

"One problem resolved usually gives rise to three new ones"

Three questions on the prosthetic joint replacement debate for Professor Michael M. Morlock Ph.D., Head of the Institute of Biomechanics at the Hamburg-Harburg University of Technology:

Professor Morlock, is it true that the premature failure of prosthetic joint replacements is occurring increasingly frequently?
This impression has arisen because the media frequently likes to report on such cases. Lots of patients believe that they will get something if they take action, so as a result they do. However, it is very clear that all established products actually produce fantastic clinical results and are very reliable. There tend to be cases more frequently with newer designs.

Why is that?
Major advancement in product development is practically unachievable now, and design modifications which resolve a problem usually give rise to three new ones. The larger heads that aim to prevent the need for corrective intervention owing to dislocation have the side-effect of causing increased abrasion. The exact positioning of the components is also very important here, as users are accustomed to greater tolerance from traditional products. Lots of cases are therefore due to components not being positioned exactly as specified by the manufacturer.

Is it the fault of users for not performing well enough or should the manufacturers communicate the lower tolerance of their products more clearly?
Compulsory user training, including the assessment of training results, would ensure that fewer problems occur. (rr)

Professor Michael M. Morlock Ph.D.: "Compulsory user training, including the assessment of training results, would ensure that fewer problems occur."