Hip operations are one of the most common medical procedures in Europe. But a significant number of replacements fail prematurely due to poor fitting and wear-and-tear issues. New non-metallic implants developed by European researchers potentially offer a longer lasting, less invasive, more biocompatible alternative which poses a lower risk to patients.

For people with irreparable damage to the joint, a hip replacement can make a huge difference, allowing them to lead active, less pain-filled lives. Around 800 000 hip procedures are carried out every year, costing some EUR 1.5 billion.

With the number of hip operations rising by around 15% annually, that cost is set to rise. For healthcare budgets already overstretched to cover the ageing European population, this is a worrying trend. And it is not the only one.

Currently, 10% of replacement hips are given to patients under 55 years’ old, which with the current metal-on-metal prosthetics and implant methods, results in 1 in 3 failing within 16 years of the operation.

For the over 55s, a further 20% of implants fail within 20 years, requiring corrective surgery costing an additional EUR 2.3 billion a year. While late-generation ‘Finsbury’ metal-on-metal total hip replacement designs, made from chromium-cobalt, have increased the survival rate of the implants significantly (by 93%), elevated levels of metal ions in the bloodstream of recipients has continued to concern physicians.

So researchers in the EU-funded ENDURE project have developed a new kind of hip implant that, unlike conventional replacements on the market today, provides a metal-free solution using ceramic and polymer parts for resurfacing the hip.

“Like the latest metal-on-metal prosthetic designs, this ceramic-on-polymer combination only covers the femoral head and, in addition, allows for a more natural remodelling of bone tissues, without the
negative effects associated with chromium and cobalt ions,” explains Dr Andy Taylor, managing director of Aurora Medical, the project’s lead partner.

Some researchers believe that metal ions in the blood and lymph could cause damage to organs and increased inflammation. There are also incidences of non-cancerous ‘pseudotumours’ in some patients.

Preserving bones … another innovation

The ENDURE project has developed and tested its innovative metal-free composite. The hip socket is made of a carbon-fibre-reinforced medical-grade material called PEEK. This is a very strong, plastic-like polymer composite which is wear-resistant and biocompatible, thus suitable for implanting in the body.

For the femoral head – the implant that articulates in the hip socket – ceramic was chosen for its strength and low wear. A special coating, called hydroxylapatite, was used in the joint to ensure that the bone tissue fuses thoroughly with the surface structure of the implant.

Researchers at the Fraunhofer Institute for Manufacturing Engineering and Automation IPA in Stuttgart, a project partner, were able to confirm the durability of ENDURE’s new prototype hip replacement during testing by using a robot that simulated various movements, such as walking and descending stairs.

Applying a ‘bone preserving’ approach, called hip resurfacing, the ENDURE implants minimise the amount of bone that potentially needs to be removed to accommodate the replacement. Hip resurfacing uses thin-walled shells instead of large metal stems – the traditional approach which can result in more bone loss during fitting.

Another innovation in the project, according to Dr Taylor, has been achieved in the way the prosthesis is mechanically attached to the bone without cement: “Using a purpose-engineered texture incorporating scaffolds on the surfaces of the implant in contact with the bone, the ball and socket are press-fitted onto the prepared femoral head and into the acetabulum – the natural, concave surface of the pelvis – and anchored in place.”

Meanwhile, physicians at the University of Newcastle in the UK tested the implant in operations performed on cadavers. The test demonstrated that, with instrumentation designed during the project, the new hip system can be successfully implanted and removed, if needed, without difficulties.

Preclinical studies were conducted during the project. Exploitation of the technology will be undertaken by DePuy orthopaedics after it purchased Finsbury.

“Successful completion of this technology could provide a way forward with the bone-preserving resurfacing approach to hip replacement,” concludes Dr Taylor.

See also:
CORDIS [2]

Project:
Enhanced durability resurfacing endoprosthesis

Project Acronym:
ENDURE