

New Approach to Knee Implants Set to Begin Clinical Trials

Researchers at Englewood Health are studying a biomaterial called PEEK-OPTIMA™ (polyetheretherketone; Invibio), which may fundamentally transform the image of joint replacement technology with flexible, lifelike alternatives to metal and ceramics. The purpose is to enhance biology instead of rigidly imitate it.

Asit K. Shah, MD, PhD, the chief of orthopedic surgery at Englewood Health, likened the upcoming change in orthopedics to the automobile industry of the 1960s and 1970s, when carbon fiber supplanted metal and led to high-performance supercars.

"We've reached the limitations of arthroplasty design because of the materials we're working with," said Dr. Shah, who has been experimenting with implants made from PEEK-OPTIMA polymer for the past decade. "We can only make metal a certain thickness and mold it in a certain way. High-performance plastics, on the other hand, will open up a brand-new window of design considerations."

The advantage is not limited to design. As Dr. Shah explained, increased metallic load in



Asit K. Shah, MD, PhD
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the body has been linked to side effects, and a percentage of the population has metal allergies.¹

Ceramics have gradually replaced metal parts where possible, and there are nickel-free implants for patients with allergies, but complications can occur. Despite successful implantation, up to 20% of people who have undergone total knee replacement are unhappy with the result. "There could be something in the material that is causing pain in

this group," Dr. Shah said.

Dr. Shah is collaborating with Invibio Biomaterial Solutions and Maxx Orthopedics to develop a new generation of metal-free knee implants that are lightweight and show equivalent rates of wear to its metallic counterpart. Because it is more like the bone it is replacing, it may help maintain the health of the remaining bone. The goal is less fatigue, less cracking and increased flexibility.

It can also be manufactured less expensively and quickly. "While a metallic knee can take upwards of three months to make, implants made from this plastic can be produced in only three minutes because they're

injection molded, and they're user-ready in a week," Dr. Shah said. "Given the cost savings in manufacturing and inventory load, you can imagine how much cheaper these implants can be."

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Dr. Shah and his colleagues have published extensively on this biomaterial,²⁻⁴ which has shown promising wear resistance in simulations. The sponsor, Maxx Orthopedics, will soon begin a pilot clinical investigation in Europe of total knee replacements in approximately 34 patients.

"If this implant reacts the way we think it will in the body, it will open up the possibility for revolutionary design changes—not just incremental ones—and completely reshape the way we think about knees," he said. "The technology is there. We just need this next-generation material to push our design ideas further."

References

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