Docket #: S15-027

Implant for improved treatment of early stage osteonecrosis of the hip

Drs. Shanjani, Yang and Goodman in the Department of Orthopaedic Surgery at Stanford University have developed an implant that promotes generation of natural bone and vasculature for use in the treatment of early stage osteonecrosis of the hip (ONH) also known as avascular necrosis (AVN) of the hip. The hip is a ball and socket joint with the head of the femur (thighbone) serving as the ball. ONH is a painful condition that occurs when blood supply to the ball (femoral head) is disrupted. This condition can lead to collapse of the ball, subsequent arthritis and eventual need for total hip replacement. Several surgical strategies, including core decompression of the necrotic segment of bone with or without local bone grafting , are strategies to try and preserve the hip during the early stages of the disease. However, these options are not always successful and total hip replacement may still be needed despite the early intervention. Thus, there is a need for improved treatment strategies for early stage ONH to provide both a biologically sound treatment and mechanical support.

To help meet this need the inventors have developed a biomimetic load-bearing and bioactive functionally-graded implant for reconstitution of the osteonecrotic area at early stages. This technology will prevent the progress of osteonecrosis by promoting generation of natural bone and vasculature and will eliminate the need for total hip replacement. The implant is made by additive manufacturing technology and can be customized in terms of geometrical dimensions and internal micro-structure for the individual patient. The manufacturing process is also very cost effective. Implantation of the device is fairly straightforward and comparable to current techniques.

Stage of research
The inventors have fabricated the implant and performed physical and mechanical characterization. In addition, preliminary animal studies have been conducted and

show the implant has great promise.

Related technology
Dr. Yang and colleagues have developed a new biodegradable, photocrosslinkable polymer (see Stanford Docket S14-265) that may be used as an alternative material to create the implant.

Applications

- Treatment of ONH at early stage (ARCO I and II, and early stage III)
- Research- tissue engineering studies
- The implant can be supplemented with other biologically based additions such as growth factors, small molecules, cells, etc.

Advantages

- Improves efficacy of treatment for early stage ONH
- Biodegradable- implant will be replaced by natural bone
- Geometrically customizable for the patient
- Improved integration capability compared to current treatments
- Easy to implant
- Eliminates need for autologous grafts
- Eliminates need for revision surgeries
- Avoids total hip replacement

Publications

- U.S. Patent Application Serial No.15/559,550
- Kawai et al. Customized, Degradable, Functionally Graded Scaffold for Potential Treatment of Early Stage Osteonecrosis of the Femoral Head *Journal of Orthopaedic Research* 21 August 2017

Patents

- Published Application: WO2016154063

- Published Application: 20180043062
- Issued: 10,729,816 (USA)

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