Smith+Nephew

REDAPT◊
Revision Acetabular System

CONCELOC◊
Advanced Porous Titanium

# Biologic fixation of additive manufactured CONCELOC Advanced Porous Titanium in a load-bearing animal model

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## Introduction

The successful fixation of cementless implants depends on the minimization of stress and micromotion at the bone/implant interface to allow for long-term fixation via bone ingrowth.[1] The short-term minimization of stress and micromotion can be achieved through friction between the porous structure and the bone as well as means of additional fixation such as screws, spikes or fins, for example.[2] Although standard porous coatings such as beads or fiber mesh have demonstrated clinical success,[3,4] advanced porous structures can provide enhanced friction and biological fixation that could be beneficial in more challenging cases involving compromised bone in acetabular revision arthroplasty.

For these challenging acetabular revision cases, Smith+Nephew has developed the REDAPT◊ Revision Acetabular System with CONCELOC◊ Advanced Porous Titanium. The REDAPT Fully Porous Shell (Figure 1) is fabricated through additive manufacturing, which permits greater design flexibility compared to standard, subtractive manufacturing (i.e., machining). Smith+Nephew has leveraged this design flexibility to produce a custom, randomized porous structure similar to cancellous bone (Figure 2) with a bone-interfacing surface with higher friction compared to beads.

The purpose of this study was to evaluate the biological fixation of the novel CONCELOC porous structure in a validated animal model[5] and to compare the results to a clinically successful (maximum revision rate of 5% at 10 years), sintered bead coating.[6,7]

**Figure 1:** The outer and inner surfaces of the REDAPT acetabular revision shell.

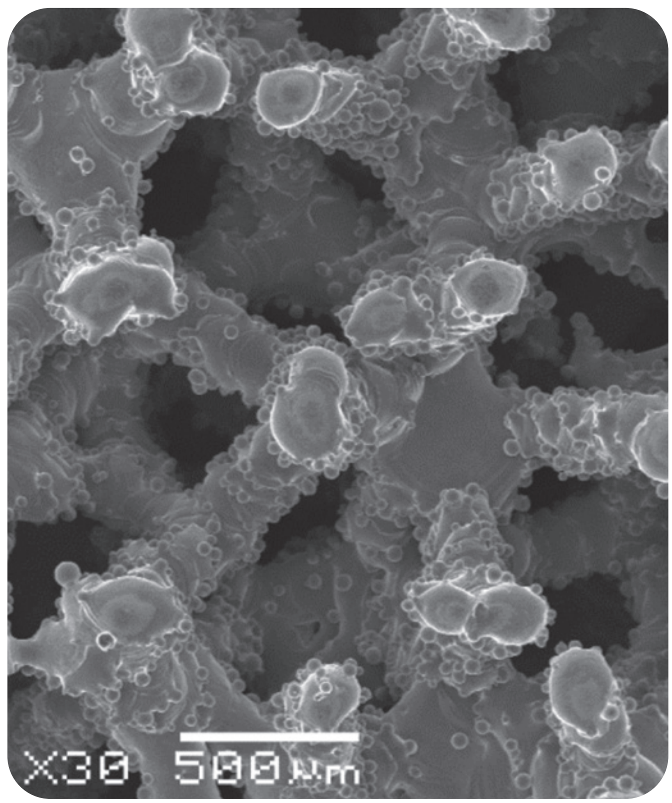


**Figure 2:** An SEM image of CONCELOC Advanced Porous titanium structure.

## Methods

Semi-circular implants were fabricated with one of two porous ingrowth structures on the top and bottom. Implants representing the CONCELOC◊ porous structure (Figure 3a) were fabricated by laser sintering of Ti-6Al-4V powder in an additive manufacturing system where both the solid and porous features were built layer-by-layer from a virtual model. For the control, sintered bead coatings were fabricated by sintering 2 – 3 layers of small, CP-Ti beads onto Ti-6Al-4V solid substrates (Figure 3b).

Biologic fixation was assessed using a previously validated, load-bearing ovine model.[5] This model was purposely developed as a more challenging ingrowth model due to the higher stresses and micromotions observed in the sub-articular region[5] compared to the more standard implantation sites into the femoral diaphysis or metaphysis.

Bilateral defects were created in the cancellous bone of the proximal tibias of adult sheep parallel to and approximately 3mm below the medial tibial plateaus (Figure 4a). One of each type of implant was randomly assigned to the left or right limb and press-fit into each bilateral defect (Figure 4b). After 12 weeks, the tibiae were harvested and subjected to biomechanical testing (n=8 per porous structure) to assess the force required to push the implants out of the bone.

**Figure 3a**

**Figure 3b**

**Figure 3:** Images of the (a) additive-manufactured CONCELOC implants and (b) CP-Ti bead sub-articular implants.

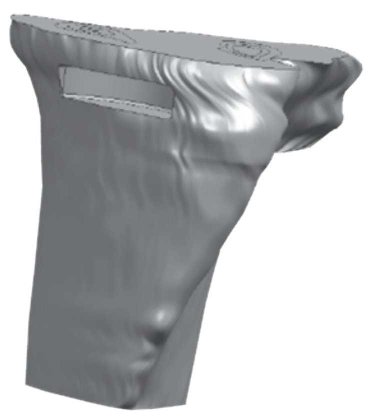

**Figure 4a**

**Figure 4b**

**Figure 4:** (a) A schematic illustration of the defect created in the proximal tibia below the tibial plateau and (b) an X-ray of one of the CONCELOC implants in the tibia.

## Results

All animals were fully weight bearing and had normal gait and ambulation, and there were no problems or concerns with animal welfare during the *in vivo* phase of the study. The mean push-out force for CONCELOC◊ implants was 23% more than that required for the CP-Ti bead implants (Figure 5), and this difference was statistically significant (p=0.013) when evaluated with a one-sided, paired t-test.

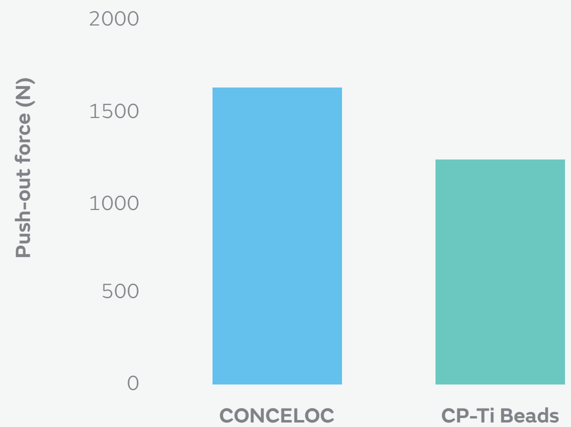


**Figure 5:** Mean (+/-SD) push-out force for CONCELOC and CP-Ti beaded implants after 12 weeks *in vivo* (p=0.013).

## Conclusions

The additive-manufactured CONCELOC Advanced Porous Titanium has been shown to provide good biological fixation in an aggressive, validated, ovine model. After 12 weeks *in vivo*, the push-out strength of the CONCELOC implants was significantly higher than that of clinically successful CP-Tibeads (p=0.013).[6,7] This difference is likely due to the combination of higher friction and the greater porosity of the CONCELOC porous structure.[8] As a result it may be reasonable to hypothesize that the REDAPT◊ Fully Porous Shell with CONCELOC structure may provide superior fixation and osseointegration. Further research is required to assess these parameters in compromised bone often encountered in acetabular component revision.


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**References**


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