Smith+Nephew

REDAPT◊
Revision Acetabular System

Stiffness comparison of REDAPT Locking Screws and non-locking screws utilized with the REDAPT variable angle locking feature

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Introduction

The successful biological fixation of uncemented implants depends on friction between the porous structure and bone. If used, screws can provide the short-term minimization of stress and micromotion to allow for long-term fixation via biological fixation. Screws have been shown to provide adjunctive fixation to uncemented acetabular components, and constructs consisting of screws and acetabular shells have demonstrated clinical success.[1,2] However, traditional screw fixation relies on compression to provide fixation of the shell within the acetabular cavity.

For these challenging acetabular revision cases, Smith+Nephew has developed the REDAPT◊ Revision Acetabular System with a variable angle locking feature incorporated in the screw holes. This locking feature (Figures 1) can be used with traditional non-locking screws to provide compression to the acetabular shell within the cavity, and in conjunction with newly designed REDAPT Locking Screws which interface with the tabs in the locking feature and lock the shell in place. The REDAPT Locking Screw does not rely solely on compression into bone for fixation as is the case with traditional screws. Instead, it provides a rigid construct when interfaced with the locking feature of the acetabular shell.

The purpose of this study was to compare the cantilever bending stiffness of constructs consisting of 6.5mm REDAPT Locking Screws or non-locking screws assembled with coupons simulating the REDAPT variable angle locking feature.

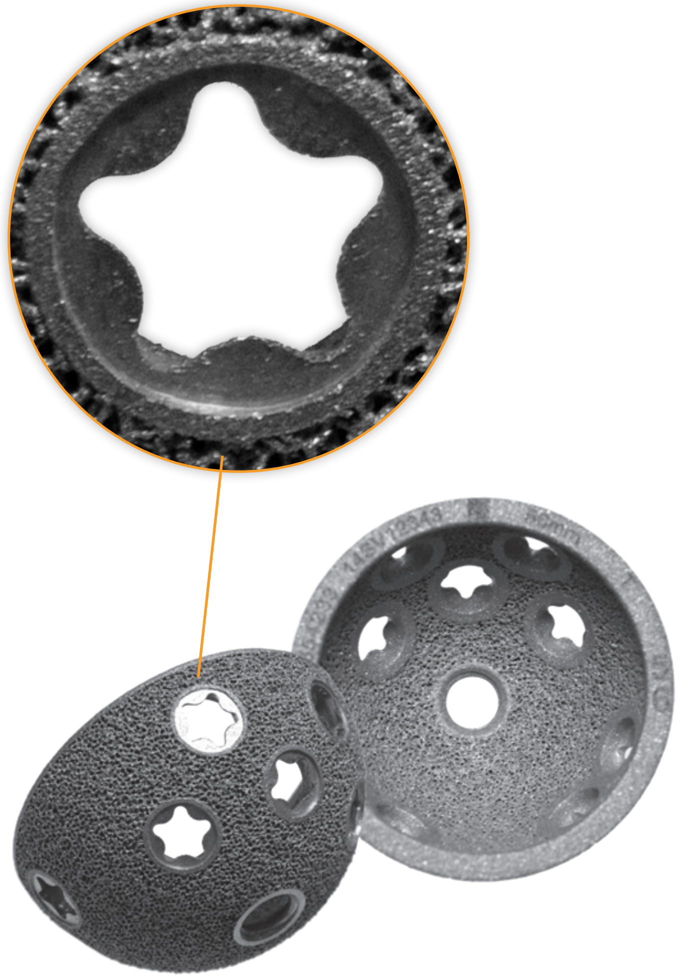

Figure 1: The REDAPT Revision Acetabular System locking feature incorporated into a REDAPT Revision Acetabular Fully Porous Shell.

Methods

Static cantilever bend testing was conducted on constructs consisting of a test coupon and a Ti-6Al-4V 6.5mm REFLECTION◊ spherical head non-locking screw or a Ti-6Al-4V 6.5mm REDAPT◊ Locking Screw. Both screws were inserted into test coupons made of additive manufactured (EOS) Ti-6Al-4V (Figure 2), which simulated the variable angle locking features in the REDAPT Revision Acetabular System. Non-locking screws were inserted on-axis (0°), while REDAPT Locking Screws were inserted at the maximum allowed of angle of 6° relative to the screw hole axis. Coupons were manufactured with the thinnest tab thickness allowable by print tolerances, which is considered worst case for this testing.

Test blocks of 15 lbf/in^3 (0.24 g/cm^3) polyurethane foam were utilized as the medium for screw insertion. REDAPT Locking Screws were tightened to 35 or 50 in-lbf (4.0 or 5.6 N-m). Non-locking screws were tightened until the tightening torque would not increase further. Constructs were fixed in a test frame (Figure 3), and the tip of the screw was loaded in displacement-control mode at 0.1 in/min (2.54mm/min) until failure of the construct.

The cantilever bending moment was calculated for each construct by multiplying the applied force by the moment arm, which was defined as the distance from the back of the test coupon to the loading location and measured with calipers. The applied moment was plotted against the change in displacement for each construct. The stiffness of the construct, defined as slope (inch-lbf/inch) of the linear portion of the resulting curve, was calculated. The stiffness of the locking screw constructs was compared to that of the non-locking constructs using a one-way analysis of variance (ANOVA). Post-hoc analyses were conducted using a Tukey test with a p-value < 0.05 considered significant.

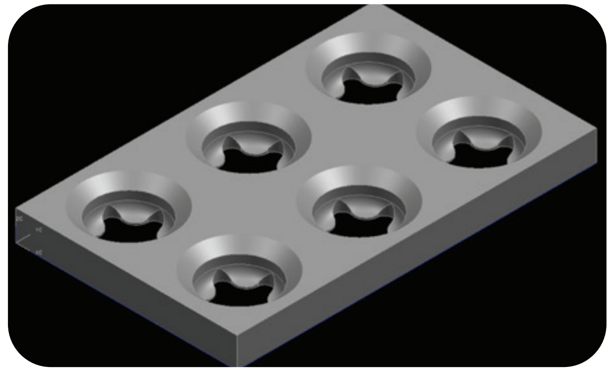

Figure 2: The test coupon used to simulate the locking tab features in the REDAPT Revision Acetabular System.

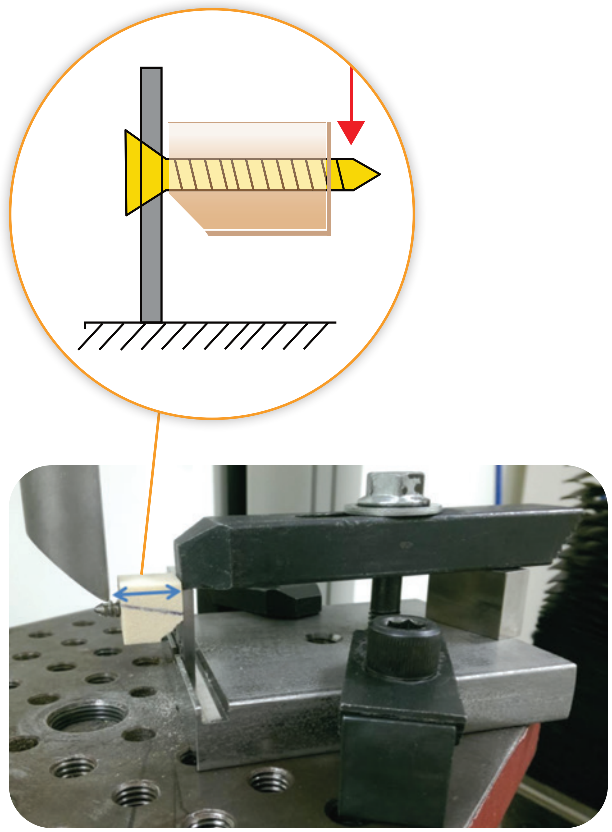

Figure 3: Static cantilever bending test setup. The test coupon is held in place and a load is applied to the end of the screw via the loading bar.

Results

REDAPT◊ Locking Screws tightened to 35 and 50 in-lbf (4.0 and 5.6 N-m) displayed a significant difference in cantilever bending stiffness when compared to non-locking screws ($p < 0.05$), with average values 682% and 888% higher, respectively (Figure 4).

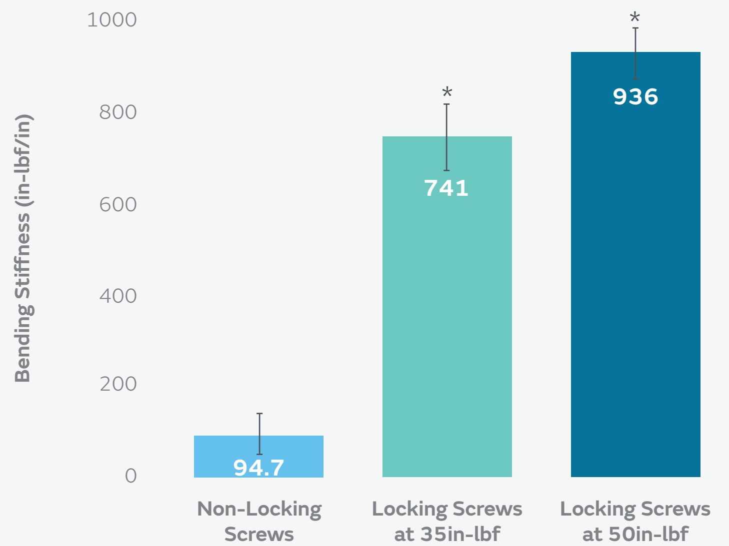

Figure 4: Mean (+/-SD) cantilever bending stiffness data for locking and non-locking screws. REDAPT Locking Screws tightened at a 6º angle to 35 and 50 in-lbf (4.0 and 5.6 N-m) were significantly stiffer than non-locking screws ($p < 0.05$). The error bars represent the standard deviations. Data is on file at Smith+Nephew.[5]

*Represents significant difference from non-locking screws.

Conclusions

Based on the results of the testing and the data analysis conducted, it can be concluded that using REDAPT Locking Screws results in a stiffer construct when subjected to cantilever bending. Previous testing of an acetabular shell modified to accept REDAPT Locking Screws showed that the modified construct provided greater resistance to lever-out and torque-out than a construct with non-locking screws.[3] It has been observed that even small motions (less than 150 µm) at the bone/implant interface can discourage biological fixation.[4] Therefore, the use of REDAPT Locking Screws to provide a more rigid construct may increase the probability of initial stability, leading to greater potential biological fixation and long-term clinical success.

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References

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