

# EVIDENCE MATTERS

## RESEARCH BULLETIN

### Biosteon Screw Two to Five-Year Data Shows Full Screw Resorption Between 2 and 4 Years with Excellent Tunnel Remodeling

#### TOP-LEVEL SUMMARY

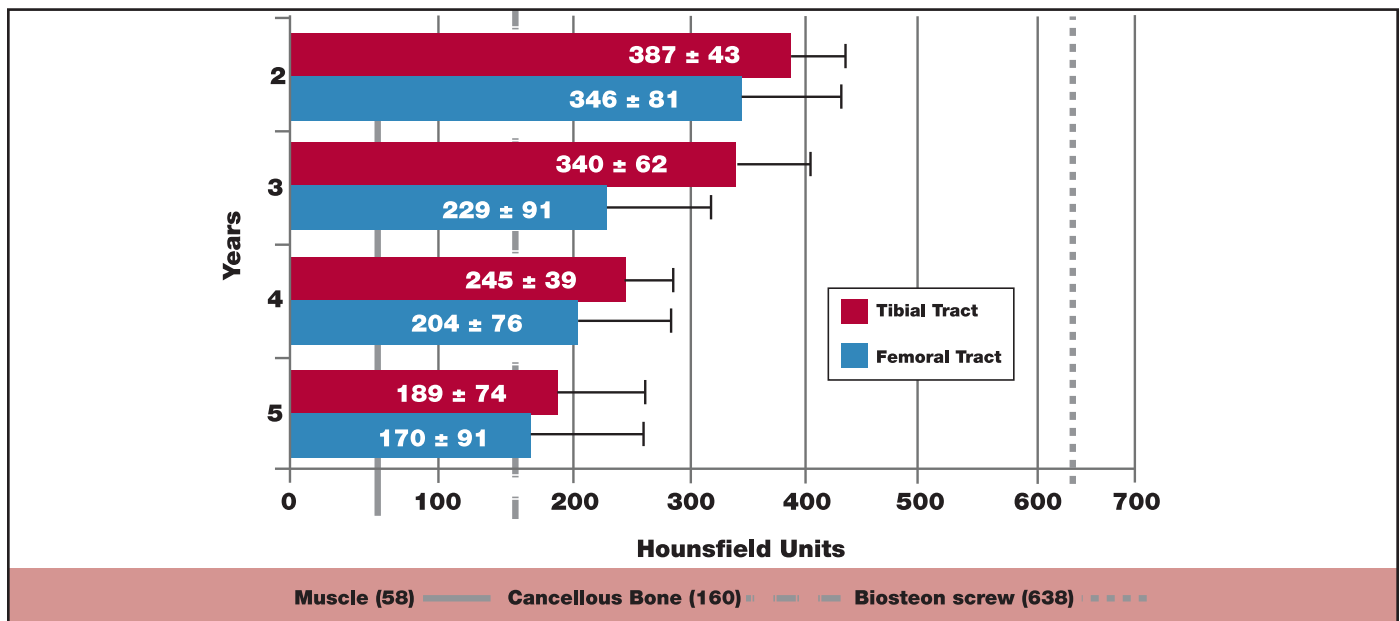
Surgeons at Florida Orthopaedic Institute<sup>1</sup> have been implanting Biosteon interference screws in their B-T-B (allograft and autograft) ACL reconstructions since 2003. Sixty-five patients were recruited for this retrospective evaluation; ten patients each were evaluated at 2, 3 and 4 years, and 35 patients at 5 years post-operatively. A physical examination and CT analysis was obtained. CT analyses provided comparison of density (Hounsfield Units) between the screw tract and the surrounding bone.

#### RESULTS

The density of a Biosteon screw is 638 HU, the surrounding cancellous bone is approximately 155 HU and the surrounding muscle is approximately 58 HU.

By 2 years, the screws have begun to resorb and all were fully resorbed at 5 years at which time there was no difference in density between the tunnels and the surrounding bone. Full resorption occurred between 2 and 4 years.

Clinically, there were no patients with greater than a trace Lachman test, and no positive pivot shift tests. The average KT-1000 manual maximum side-to-side difference was 0.73mm with no differences greater than 5mm. The average Lysholm score was 84.5 and the average difference in the single-leg hop test was 0.37 ft. The mean VAS score on the operative side was 1.39.<sup>2</sup>

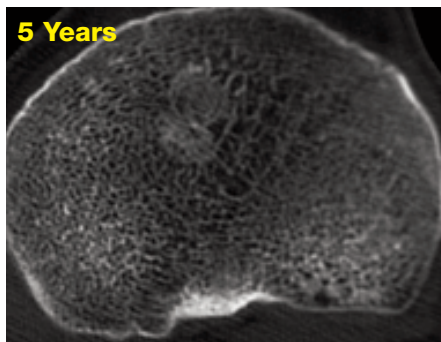
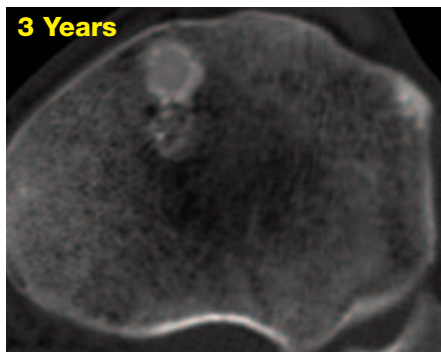


#### CONCLUSION FROM FOI

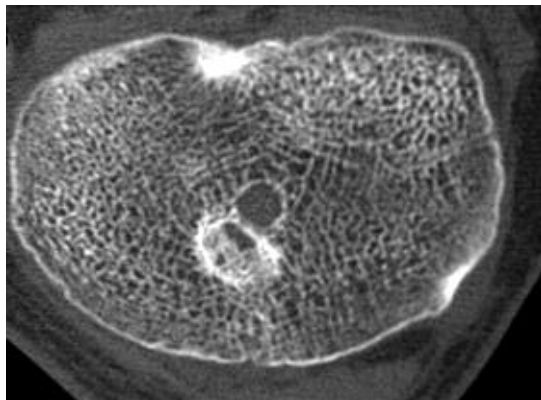
“The HA-PLLA Biosteon interference screw slowly resorbs over time. Eighty to 90% are completely resorbed between 3 and 4 years post-ACL reconstruction with patellar tendon autograft or allograft. Resorption and remodeling were confirmed by CT scans. No tunnel widening, sclerosis, cysts, or inflammatory changes were observed. The addition of HA to PLLA interference screws results in a composite screw with excellent strength, no adverse reactions, predictable resorption, and remodeling of the screw tract. Remodeling of the tunnel to fill with cancellous bone provides a more favorable situation in cases where future revision surgery may be required.”<sup>2</sup>

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The CT scans above show the progression of **resorption and remodeling** of the HA/PLLA composite Biosteon screw over time.



By comparison, the CT scan to the left is from a **PLLA screw** which had been implanted for **4 years**. According to Barber, the screw tract “is now empty of any biodegradable material and shows no evidence of bone ingrowth.” Density in Hounsfield units was reported as 47 indicating the tract was probably filled with fibrous scar tissue.<sup>3</sup>

### References:

1. Dr. Seth Gasser and Dr. Adam Morse, Florida Orthopaedic Institute, Tampa, FL.
2. Gasser, S et al. “Resorption and Remodeling of Biosteon® HA-PLLA Composite ACL Interference Screws: A Five Year Cohort Study” submitted: *Arthroscopy*.
3. Barber, FA, Dockery WD “Long-Term Absorption of Poly-L-Lactic Acid Interference Screws” *Arthroscopy* 2006; 22:820-826.

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