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Bone&JointScience

Our Innovation in Focus

BIOSURE◇ REGENESORB Interference Screw: Rapid bone ingrowth and tendon-bone healing at 12 weeks in an ovine anterior cruciate ligament reconstruction model.

John Watson[1]; Nick Cotton, PhD[2]

1. Smith & Nephew, Inc., Baar, Switzerland
2. Smith & Nephew, Inc., Mansfield, Massachusetts, USA

1 Research goal

To measure bone ingrowth into BIOSURE◇ REGENESORB Interference Screws and assess bone-tendon integration in an ovine anterior cruciate ligament (ACL) reconstruction model.[1]

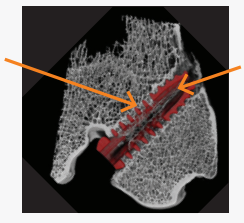
2 Type of evidence

3 Clinical relevance

- There has been a steady rise in ACL reconstruction procedures performed in recent decades, particularly in female patients and those younger than 20 or older than 40 years of age.[2]
- Globally, bioabsorbable interference screws are routinely used as fixation devices for reattaching soft tissue to bone in ACL reconstruction.[3]
- BIOSURE◇ REGENESORB Interference Screws (Smith & Nephew, Inc.; **Figure 1**) have an open architecture, and six times more surface area for bone ingrowth than conventional solid interference screws.[4] REGENESORB is an advanced biocomposite material that utilizes two osteoconductive components: calcium sulfate and beta-tricalcium phosphate (ß-TCP). These materials aid in the bone healing process at both early (4–12 weeks) and late (up to 18 months) time points.[5–8]

Figure 1:
BIOSURE REGENESORB Interference Screw.

Figure 2:
Bone ingrowth in the central cannulation of the BIOSURE REGENESORB Interference Screw at 12 weeks.[1]



4 Key results

- At 12 weeks, the mean volume of bone restored within the open cannulation of the interference screws was 50% and 44% in the femoral and tibial tunnel sites, respectively (**Figure 2**).[1]
- Tendon remodeling was observed within the tunnels, usually together with ossification and/or bone integration.[1]

5 Important considerations

- Although encouraging, animal study outcomes do not necessarily correlate with human outcomes.

Background

ACL injuries have become increasingly common in recent decades as greater numbers of younger people participate in high-level sports and older individuals maintain active lifestyles for longer.[2] This has led to a corresponding rise in ACL reconstruction procedures performed, particularly in female patients and those younger than 20 or older than 40 years of age.[2] Global survey data indicate that bioresorbable interference screws are routinely used as fixation devices for reattaching soft tissue to bone during these procedures.[3]

The graft fixation point is vulnerable following ACL reconstruction. Therefore, achieving tendon integration with the bone is critical for providing fixation, stability, and long-term graft survival.[9–11] It is thought that obtaining a direct bone-tendon interface, without a fibrous intermediate layer, is only possible with an anatomic interference fixation and its ability to prevent micromovement.[11]

The BIOSURE® REGENESORB Interference Screw (Smith & Nephew, Inc., Andover, MA, USA; **Figure 3**) has an open architecture for use for the reattachment of ligament, tendon, soft tissue, or bone-tendon-bone grafts. Micro-computed tomography (µCT) analysis[4] indicates that BIOSURE® REGENESORB has six-times the available surface area for bone ingrowth compared with conventional solid interference screws.*

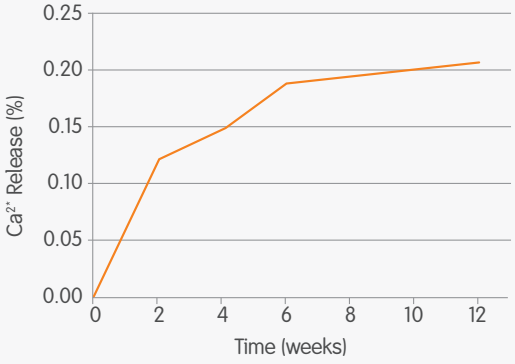
REGENESORB is an advanced biocomposite material comprised of the co-polymer poly (l-lactide co-glycolide) combined with two components, calcium sulfate and ß-TCP, which have different mechanisms of action but have each been demonstrated to be osteoconductive.[5–8] ß-TCP provides sustained bone formation over 18 months[5] and acts primarily as a scaffold for enhancing bone formation.[8] The REGENESORB material also delivers an early release of calcium[12] (**Figure 4**), which works in the early stages of bone healing (4–12 weeks)[5] and is associated with increased levels of local growth factors.[13] REGENESORB is designed to remain mechanically stable for a minimum of six months before being absorbed and replaced by bone within 24 months.[14]

Tendon-to-bone interface healing is important in the early 6- to 12-week post-operative period,[10,11] which correlates with critical time points in post-ACL reconstruction rehabilitation protocols, such as achieving full weight bearing by eight to 10 weeks. The current study was undertaken to measure bone ingrowth into BIOSURE® REGENESORB Interference Screws and concurrent tendon integration after the critical 12-week implantation period in an ovine ACL reconstruction model.[1]

*As compared with BioComposite (Arthrex, Inc.) and MILAGRO (DePuy Synthes Mitek Sports Medicine)

Figure 3:
BIOSURE® REGENESORB Interference Screw.

Figure 4:
Calcium release from a 6 x 25mm BIOSURE® REGENESORB screw.[12]



Methods

- Twelve sheep underwent unilateral excisional ACL reconstruction. One animal was excluded due to tunnel breaching the medullary canal in the tibia, possibly compromising the implant security. This left 11 animals for which tibial and femoral samples were available for analysis.
- BIOSURE® REGENESORB Interference Screws (7 x 25mm) were implanted in both the femoral and tibial bone tunnels in this ovine model of ACL reconstruction. A digital extensor tendon was used as the replacement ligament.
- At 12-weeks post-implantation the animals were euthanized and the implants and surrounding tissue were harvested for analysis.
- Bone ingrowth into defined volumes of interest around the femoral and tibial screws was determined by µCT. The percentage of bone in a defined volume adjacent to the implanted screws was also determined by µCT.
- To evaluate bone and tendon integration, histological specimens of distal femur and proximal tibia were resin embedded and thick sections cut and ground using the EXAKT system. An observational assessment of the slides was performed and images captured to determine local bone reaction and inflammation at the implantation site.

Results

- At 12 weeks, the mean volume of new bone restored within the center cannulation of the interference screws was 50% (standard deviation (SD): ±12) and 44% (SD: ±11), in the femoral and tibial tunnel sites, respectively (**Figure 5**).
- Histological assessment confirmed bone growth into the screw threads/fenestrations, and through the center cannulation and threads/fenestrations adjacent to the tendon. An example of bone integration and ingrowth at 12 weeks appears in **Figure 6**.
- Evidence of the tendon graft was seen in all the tunnels with the exception of one specimen. Tendon remodeling was observed usually together with ossification and/or bone ingrowth (**Figure 7**).

Figure 5:
Mean bone volume restored in samples receiving BIOSURE® REGENESORB, as compared with normalized bone samples.[1]

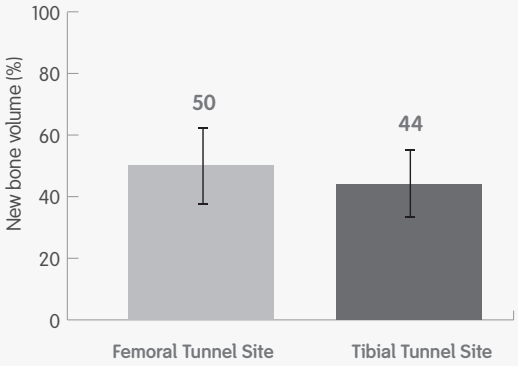


Figure 6:
Rapid bone integration and ingrowth in the central cannulation of the BIOSURE® REGENESORB Screw through the fenestrations.[1]

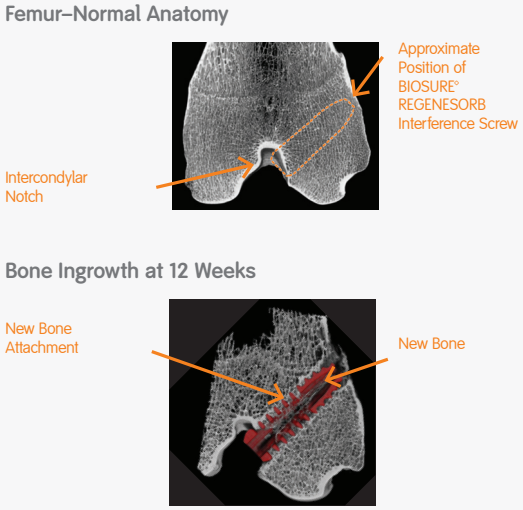
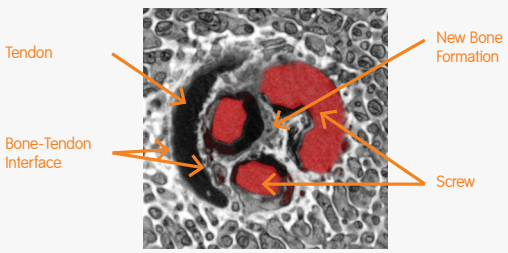


Figure 7:
Cross section of screw at 12 weeks. New bone formation within the screw and new bone surrounding and integrating with the graft on all surfaces.[1]



Conclusions

At 12 weeks, the BIOSURE® REGENESORB Interference Screw facilitates bone-tendon integration and bone-screw attachment. The open architecture provides channels and open space, which allows for the formation of new bone. Histological and radiographic evidence from an ovine ACL reconstruction study at 12 weeks indicates that bone can penetrate through the implant and form direct attachment to the tendon surface abutting the BIOSURE® REGENESORB Interference Screw. To our knowledge, this is the first time circumferential tendon-bone healing has been demonstrated in combination with an advanced biocomposite material using an interference screw fixation in pre-clinical results. Although encouraging, animal study outcomes do not necessarily correlate with human outcomes.

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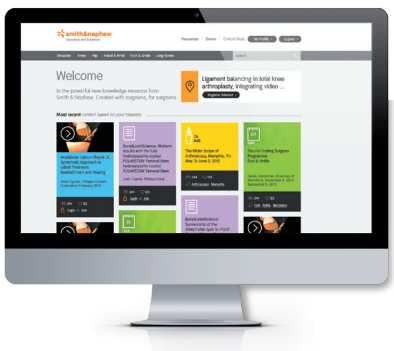
Notes



Smith & Nephew Pty Ltd
Australia
T +61 2 9857 3999
F +61 2 9857 3900
www.smith-nephew.com/australia

Smith & Nephew Ltd
New Zealand
T +64 9 820 2840
F +64 9 820 2841
www.smith-nephew.com/newzealand

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