

OSSIOfiber® Compression Screw Performance in a Load Bearing In Vivo Model

Objective

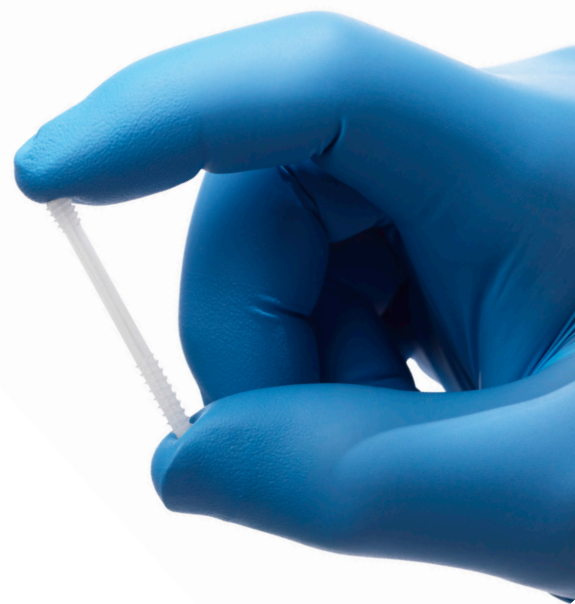
The objective of this study was to evaluate the performance and mechanical integrity of OSSIOfiber® Compression Screw in a full load-bearing osteotomy fixation in an ovine model.

Methods

Lateral Femur Condyle Wedge Osteotomy was performed by intersecting transverse cuts along the lateral aspect of the right distal femur in 5 mature female sheep. Each osteotomy was reduced and fixated using two 3.5mm X 26mm OSSIOfiber® Compression Screws. No additional external immobilization was applied to the operated limbs and animals were allowed to fully load bear immediately following surgery. Lateral (L) and Anteroposterior (AP) digital X-Rays of the implanted sites were performed at time 0 and 2 weeks following the procedure, to evaluate osteotomy fixation and maintenance of bone reduction and alignment. Computed Tomography (CT) scans were performed at 3 and 6-months post-operative and Histopathology evaluation was conducted at 6 months, to further evaluate bone remodeling, healing progress, and any potential adverse

Test Device: OSSIOfiber® Compression Screws

- Bio-Integrative, headless, cannulated OSSIOfiber® Compression Screws with 3.5mm diameter*



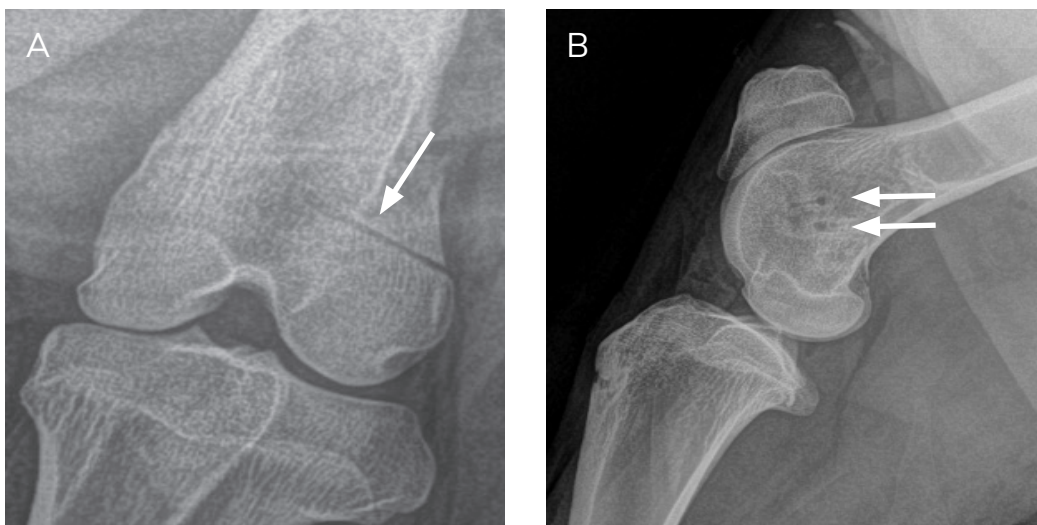
*OSSIOfiber® Compression Screws are FDA cleared and pending commercial availability

2-Weeks Post-Operative Results

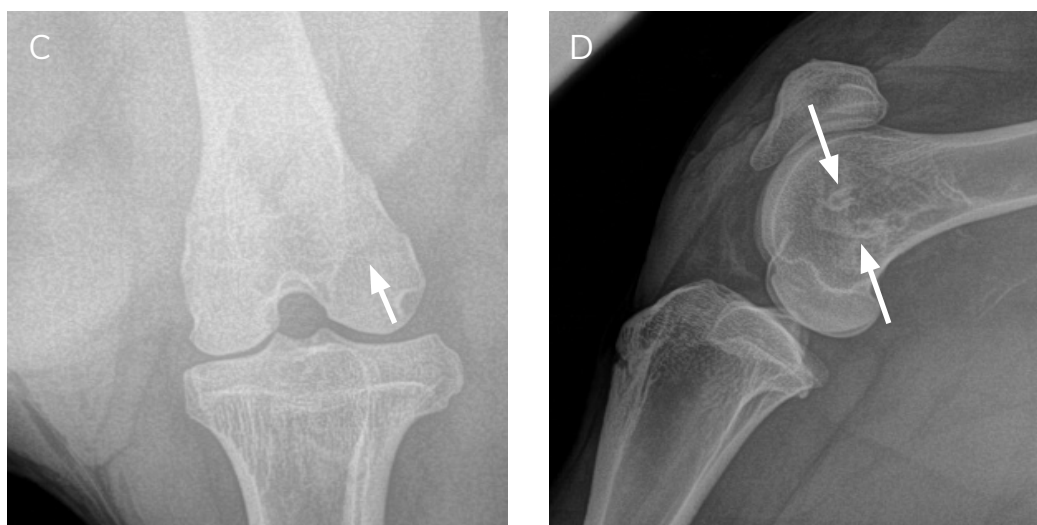
- All animals presented uneventful and complete recovery, reaching lameness score of 0 within two weeks of surgery, with normal gait and function.
- X-Rays demonstrate stable fixation of the wedge osteotomy, in a good anatomical alignment, suggesting the OSSIOfiber[®] Compression Screws' desired performance in a load bearing environment.

Figure 1: X-Rays at Time 0 and 2 Weeks Post-Operative showcasing OSSIOfiber[®] Compression Screws maintaining a stable, well-aligned osteotomy under early full load bearing conditions

Time 0



Two-Weeks Post-Operative



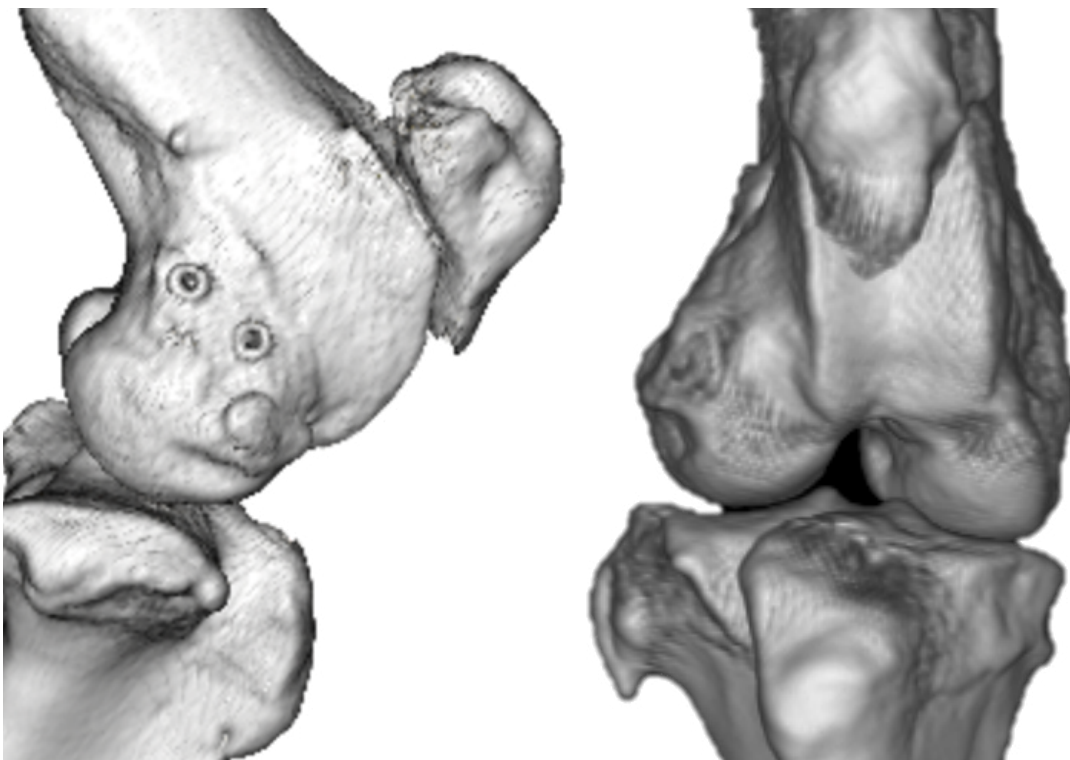
- A:** AP radiograph of the right distal femur, demonstrating a well-aligned osteotomy line
B: Lateral radiograph with visible insertion sites of two OSSIOfiber[®] Compression Screws
C: AP radiograph showing sustained anatomical reduction with osteotomy lines not visible
D: Lateral radiograph showing intact OSSIOfiber[®] Compression Screws

3 Months Post-Operative Results

- CT scans confirmed well-maintained reduction of the osteotomy sites with no evidence of implant migration or failure
- All animals demonstrated bony fusion. The osteotomy fragments were found to be completely integrated with the surrounding bone, with 100% bone bridging across the osteotomy sites.

Figure 2: CT scan at 3 Months showcasing complete bony healing and bridging across osteotomy site

3 Months



"...All animals demonstrated bony fusion...with 100% bone bridging across the osteotomy sites."

6 Months Post-Operative Results

- All the implanted animals healed uneventfully, without signs that might indicate possible clinical concerns.
- Osteotomy well reduced and completely healed. OSSIOfiber® Compression Screws maintained their structural integrity following 6 months of full load bearing, as demonstrated well by Micro CT
- The implanted sites showed no signs of local bone resorption or osteolysis, providing further evidence of excellent biocompatibility.

Figure 3: CT scan at 6 Months showcasing the mechanical integrity of OSSIOfiber® Compression Screws, as it maintains its structure and withstands the forces applied by full load bearing

6 Months

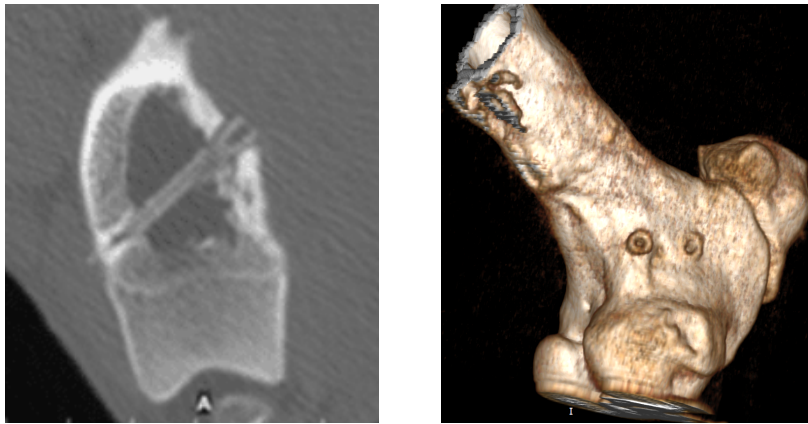
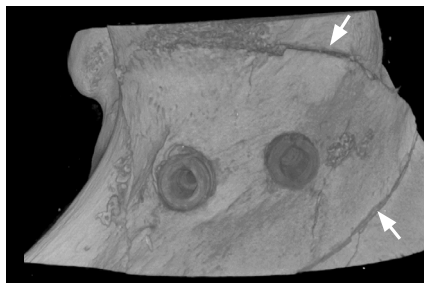


Figure 4: Micro CT Imaging – Time 0 compared to 6-months post-operative demonstrate accurate reduction and excellent bone healing and fusion

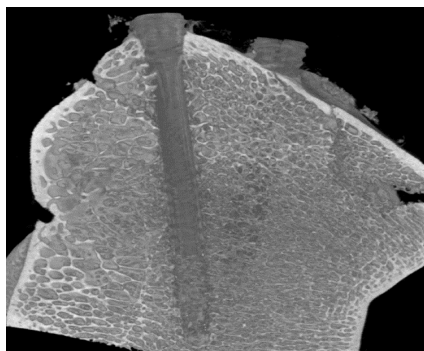
Time 0
Arrows indicate osteotomy lines



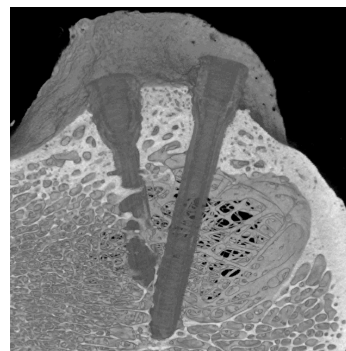
6 Months
Osteotomy lines completely healed



Time 0
Arrows indicate osteotomy lines



6 Months
Bone bridges and matured across fracture site

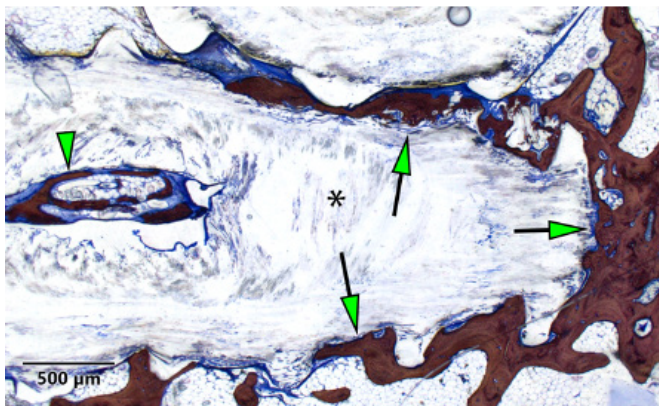


6 months Histopathology Results

- Excellent bone-implant interface demonstrated in both cancellous and cortical bone
- Optimal apposition and osteotomy bridging with complete remodeling of the osteotomy sites into mature cancellous and cortical bone
- Absence of callus formation, representing healing by first intention, was indicative of a very stable construct, with no signs of implant loosening or migration
- Optimal biocompatibility with no signs of inflammatory response, osteolysis, necrosis or fibrotic encapsulation
- OSSIOfiber[®] Compression Screws overall bio-integration demonstrated by evidence of phagocytic activity focally at the implant interface with early mesenchymal cellular investment into implant wall

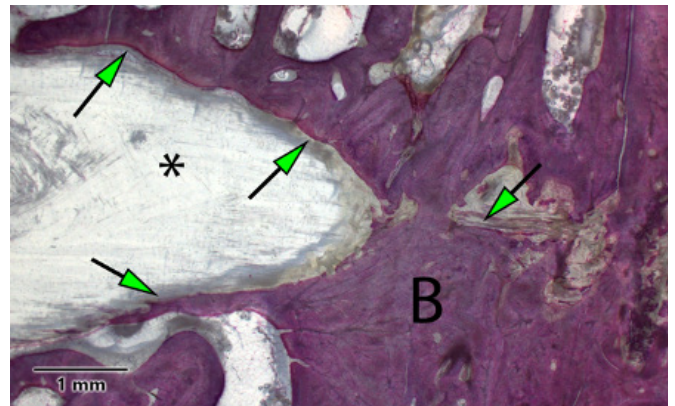
Figure 5: Histopathology evaluation of the osteotomy sites at 6-months, indicates excellent bone-implant interface with extensive cortical and cancellous bone attachment

A: 6 Month Histology in Distal Femur Cancellous Bone



A: Oblique section of the OSSIOfiber[®] Compression Screw (asterisk) in cancellous bone, showing excellent integration with moderate bone in contact (green arrows) and bone formation within the central canal of the screw (green arrowhead). There is no fibrous sequestration of the screw and integration is optimal.

B: 6 Month Histology in Distal Femur Cortex



B: Oblique cut of the OSSIOfiber[®] Compression Screw (asterisk) in cortical bone showing extensive bone-in-contact (green arrows); there is no inflammatory response and integration of the screw is optimal.

Discussion

Mechanical stability of fracture repair is a critical factor influencing the process of bone healing. It is well established that stability provided by compression screw fixation enhances the healing process. In this study, the initial healing response was evident as early as two weeks, with well reduced osteotomy sites and sustained bone alignment. By three months, consistent with appropriate fixation of the osteotomy, successful bone healing was observed in CT scans of all treated animals. The absence of prominent callus formation was further indicative of a very stable construct, which ultimately lead to the uneventful bone remodeling. The phagocytic cellular activity at the implant interface, combined with early mesenchymal cell infiltrating within the implant wall and complete absence of adverse inflammatory response, further promotes bone healing and demonstrates the excellent bio-integrative properties of the OSSIOfiber® Compression Screw.

"...initial healing response was evident as early as two weeks with well reduced osteotomy sites and sustained bone alignment."

Conclusion

In this study, the performance of the bio-integrative OSSIOfiber® Compression Screw was evaluated in the full load-bearing ovine osteotomy model, through 6-months follow up. The preserved mechanical integrity of the OSSIOfiber® Compression Screw enabled adequate reduction, maintenance of anatomical alignment and complete bone fusion. Combined with the unique bio-integrative properties, these results demonstrate the OSSIOfiber® Compression Screws as a promising strong fixation alternative to metal hardware for surgeons and patients.



Data on File at OSSIO.
OSSIOfiber Compression Screws are not yet available for sale.
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