Advancing Minimally Invasive Fracture Fixation Technology

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Immediate
Post-operative weight bearing achieved

Zero
Adverse immune or foreign-body reactions

5 weeks
Earliest radiographic fracture bridging

13 weeks
Follow-up with excellent osseous integration

Background

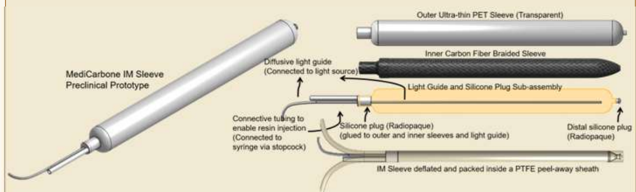
Combat and civilian long-bone fractures represent a major medical burden, with over **six million fractures annually** in the U.S. and more than **250,000 intramedullary (IM) nailing procedures** performed each year. Conventional metallic nails and fixators are standard of care at Role II and higher military facilities, these implants provide stabilization but have persistent limitations: difficult removal, infection risk, stress shielding, poor adaptability to complex injuries, and reduced performance in compromised bone. These challenges are amplified in **austere, resource-limited military environments**, where rapid stabilization, evacuation, and re-intervention are critical.

MediCarbone's intramedullary sleeve system (TRL 4) offers a next-generation alternative. The flexible sleeve is inserted minimally invasively and filled with a **biocompatible, in-situ photopolymerizing polymer** that cures into a rigid fixation device. Uniquely, the polymer can be **depolymerized and safely removed** once healing is complete or when corrective surgery is required, addressing one of the most significant limitations of metal implants.

Study Objective

The objective of this study is to evaluate the surgical feasibility, biocompatibility, and fracture-stabilization performance of the MediCarbone carbon-fiber composite intramedullary sleeve system as an advanced alternative to traditional metallic fixation methods. Through controlled implantation in sheep tibia using both non-fracture and fracture models, the study aims to determine the device's ability to provide biomechanically compatible, radiolucent, customizable, and easily removable fixation that supports rapid stabilization, early weight-bearing, and accelerated healing.

MediCarbone Intramedullary Sleeve System



MediCarbone Intramedullary Sleeve System

In situ Photocurable Resin System

Methods

In Vivo Biocompatibility in Sheep Tibia: Non-Fracture vs Fracture Model
This study evaluated **(A) surgical placement**, **(B) biocompatibility**, and **(C) fracture-stabilization capability** of the **MediCarbone Intramedullary Sleeve System** in skeletally mature sheep (*Ovis aries*). All procedures were followed as approved by the IACUC protocol at the University of Arizona.

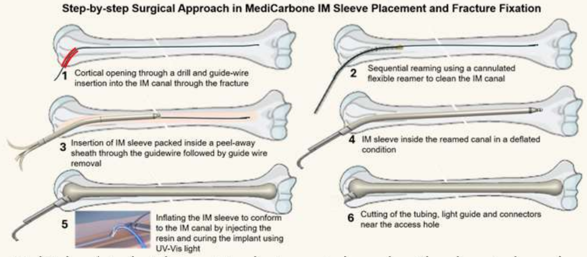
Methods

Non-Fracture Model: A 1 cm incision was made at the anterior tibial plateau, and a 1.2 mm guide wire was placed into the medullary canal under fluoroscopy. The canal was sequentially reamed (5–7 mm), marrow removed, and the canal cleaned. A 170 mm MediCarbone sleeve was inserted and filled with **Photocure Injectable Resin System (PIRS)**, then cured for **20 minutes** with 405 nm light. The incision was closed, and animals were euthanized at 3 months.

Fracture Model: A controlled tibial fracture was created under strict aseptic conditions. A 5 cm anteroposterior incision exposed the proximal tibial periosteum, and a temporary **4.3 × 13.5 × 142 mm surgical plate** was applied with **3.7 mm unicortical screws** to maintain alignment during fracture creation. A precise mid-diaphyseal fracture was produced using a **Gigli saw**, with the plate ensuring stable reduction throughout. A **170 mm MediCarbone intramedullary sleeve** was inserted under fluoroscopy, filled with **Photocure Injectable Resin**, and cured for **20 minutes at 405 nm**. After curing, all unicortical screws were replaced with **4.5 mm bicortical locking screws**, and the incision was closed.
Animals was monitored for **13 weeks**, with serial radiographs to assess implant position and healing. After euthanasia, tibiae will undergo **µCT and histological analysis**.

Histology: Post-mortem tibiae were harvested, fixed in 10% NBF, processed undecalcified, resin-embedded, stained with Villanueva, and imaged for biocompatibility assessment.

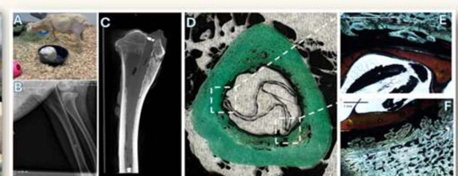
Step-by-step Surgical Approach in MediCarbone IM Sleeve Placement and Fracture Fixation



MediCarbone's implant placement step-by-step surgical procedure. The schematic shows a human humerus bone with oblique mid-diaphyseal fracture as a sketch based on an identical transverse fracture fixation that was successfully performed in a pilot sheep tibia

Results

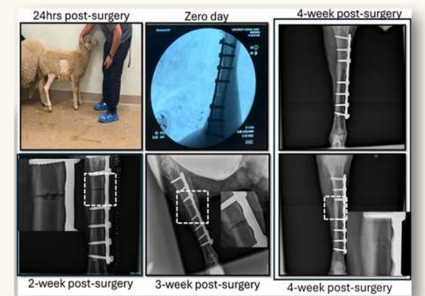
- **Non-fracture model:** At 13 weeks, radiological and histological analyses showed excellent integration and biocompatibility with no adverse reactions.
- **Fracture model:** The sheep bore weight immediately after surgery on the stabilized limb.
- **Early healing:** Radiographic analysis revealed fracture bridging as early as 5 weeks post-operatively.
- **Biocompatibility:** Histology confirmed the device did not elicit an immune response or impede fracture healing.



Non-Fracture Model Data. Figure 1. **A.** The sheep bore weight immediately after tibia implantation. **B and C.** Imaging at 91 days shows the implant intact and well-positioned in the medullary canal. **D, E, and F.** Histology confirms close implant contact with the endosteum without inflammation.

Results

Fracture Model



Fracture Model Data. Twenty-four hours after surgery, the sheep was weight-bearing without external support. The tibia X-ray shows an internally stabilized diaphyseal fracture using a MediCarbone intramedullary nail, fracture plates, and cortical nails. Early callus and bone-bridging is visible by 4 weeks, with detailed views at 2, 3, and 4 weeks.

At 24 hours post-operation, the sheep is fully weight-bearing without external fixators or casting. Radiographs show a diaphyseal fracture stabilized internally using the **MediCarbone in situ–cure intramedullary nail**, supported by reduction plates and cortical screws. **Fracture bridging and early callus formation appear as soon as four weeks**, indicating rapid biological response and stable fixation.

This early mobility and accelerated healing suggest that the MediCarbone system may reduce immobilization time, improve functional recovery, and lower complication rates compared with traditional external fixation or casting, positioning in situ cure IM nailing as a strong alternative in modern orthopedic care.

Conclusions

The MediCarbone IM nail improves fracture fixation, healing, and mobility in a preclinical ovine model. Radiolucent, removable, and customizable fixation is well suited to austere and military surgical settings. Immediate weight bearing and early bridging support faster recovery and a quicker return to duty. Findings position the device as a promising alternative to traditional metallic fixators for complex extremity fractures.

Carbon-Fiber Composite IM Nail : Key Advantages

- **Biomechanically compatible fixation** that better matches natural bone stiffness
- **Radiolucent construction** enabling clear intra-operative and post-operative imaging
- **Customizable composite architecture** adaptable to varied fracture patterns
- **Supports natural bone healing** through load-sharing mechanics

Benefits for Service Members

- **Faster functional recovery**, enabling earlier mobilization
- **Lower infection risk** due to composite materials and reduced thermal conductivity
- **Reduced implant-failure risk** from high fatigue resistance
- **Simplified removal** with lightweight, radiolucent design
- **Adaptability across fracture types**, including complex or multi-segment injuries
- **Quicker return to duty**, improving readiness and operational continuity

Acknowledgement

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