

## OsteoMag: Novel Biodegradable Metal Alloys for Bone Fixation Plates and Screws

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**Technology:** The OsteoMag team is developing biodegradable metallic fixation plates and screws aimed at treating bone fractures by providing stability throughout the healing process while avoiding complications of permanent metallic implants, eliminating the need for secondary removal surgeries. The technology comprises two key aspects: alloy development and device development. Novel, patent-pending magnesium (Mg) based alloys and devices were developed to match the strength, degradation behavior, and biocompatibility vital for fixation plate and screws. Cell viability testing of the alloys has been performed using pre-osteoblast cells and human bone marrow stromal cells. Initial screening of the alloys shows promising results. It is hence anticipated that further optimization of the compositions and processing will lead to a suitable material for target craniofacial and orthopedic applications.

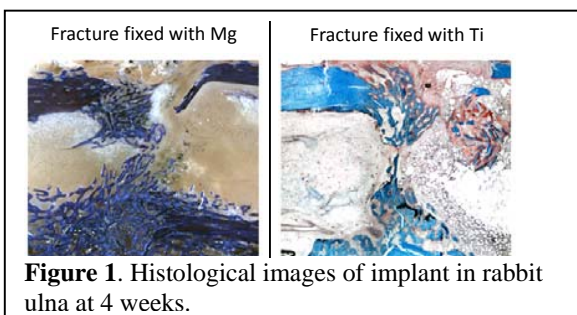
The first generation OsteoMag prototype screw and plate was tested in vivo in rabbit ulna fracture models using Ti plates as control. There were no complications, and bone

burden on patients' bodies and costs up to \$60,000, which will be obviated by our degradable metallic fixation devices. To better understand our targeted market, we obtained opinions from over a dozen craniofacial or orthopedic surgeons. Over 90% of surgeons use plates and screws made of "gold standard" non-degradable metals. However, 78% of surgeons complained about the need for secondary surgery. 75% of the surgeons would switch to our product from the current gold standard if they become commercially available, which clearly demonstrates the unmet clinical need and potential for market penetration. Current market leaders only provide non-degradable metal and degradable polymer devices giving OsteoMag a potential first mover advantage in the use of degradable metals.

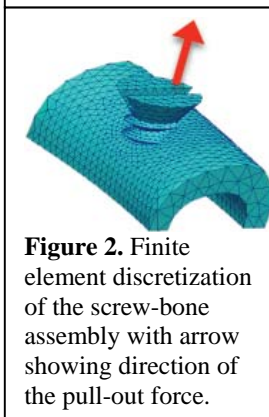
**Commercialization Strategy:** To ensure rapid and cost effective market entry, we plan to first target the craniofacial segment before entering the larger orthopedic market. We will target the craniofacial market first since these cases present reduced load-bearing requirements to lessen the amount of mechanical tests required for FDA approval. We anticipate that our product will qualify for 510(k) clearance with substantial equivalence to currently approved metallic and resorbable fixation devices. We expect OsteoMag to be reimbursed by CMS and private insurers through pre-established codes covering surgical devices and procedures used for fracture fixation.

Following current small animal feasibility tests, we will seek an additional ~\$300,000 in government grants (current funding is through NSF-ERC) to expand our studies to larger animal tests. Design verifications, and strategies for manufacturing, regulatory approval, and clinical trials will also be developed. We estimate that after 3-4 years we will require approximately \$3 million in Series-A investment through angel and venture investment. We are confident that our progressing IP portfolio and animal feasibility data will attract outside investment. Pre-clinical GLP study results under FDA guidelines would further support the submission of an IDE in Year 5 of the project.

As the safety and efficacy of OsteoMag is validated, we will pursue an exit strategy by licensing our technology to a market leader. Exiting after conducting pre-clinical GLP studies but before clinical trials will allow us to forgo the rigorous regulatory process and needing to generate \$20 million in Series-B funding to pursue clinical trials. It is anticipated that industry leaders with greater resources, marketing and manufacturing capabilities, and expertise in garnering FDA approval will transition OsteoMag to the clinical environment more smoothly. In the event of no satisfactory licensing offers based on market valuation, we will continue to raise Series-B funding for clinical trials to demonstrate the safety and efficacy of our plates and screws to the FDA.



**Figure 1.** Histological images of implant in rabbit ulna at 4 weeks.



**Figure 2.** Finite element discretization of the screw-bone assembly with arrow showing direction of the pull-out force.

healing was analyzed by micro-CT imaging and immunohistochemistry. The healing status was comparable to Ti controls (Fig. 1) and showed enhanced bone formation. After the pilot study, new plates and screws were designed using finite element analysis to optimize device stability and degradation rate (Fig. 2). Devices with the new design were

manufactured and used in the rabbit ulna model displaying reduced fracture during insertion.

**Market:** The fixation plate and screw market is growing in the U.S. at an annual rate of 14.3%. The market comprises two internal fixation segments: craniofacial (\$425M/year in US) and orthopedic (\$2.1B/year in US). Current commonly used materials often cause complications and require the removal of fixation devices. Secondary surgery for removal of devices imposes a