Bioabsorbable Magnesium Alloy Doubles the Strength of Orthopedic Implants

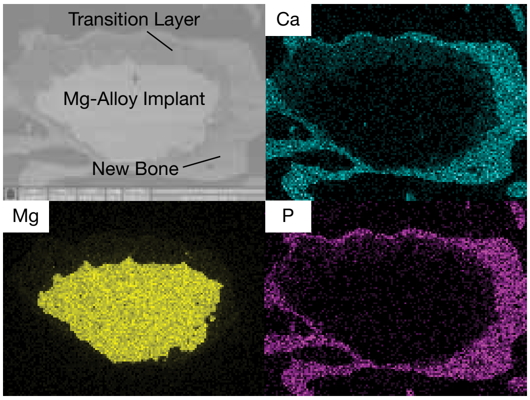
Every year, millions of patients suffer bone fractures that require surgical implants. Many of these patients face painful, costly secondary operations to remove these nonabsorbable implants, which are typically made of titanium or stainless steel. Nonabsorbable implants in infants who have undergone craniofacial reconstruction, for example, must be removed so that the infant's skull can grow unimpeded. Permanent implants put in to fix small bone fractures in adults, such as in toes and fingers, can leave stiffness and bulging and can also weaken the bone. The current annual market for implants exceeds $4 billion, and the costs of secondary operations exceed $500 million.

The use of implants made of bioabsorbable polymers could address the latter by enabling the implant to be absorbed by the body once it has served its purpose in assisting bone growth. Although such bioabsorbable polymers are currently available, they are not always strong enough to rigidly retain the bone geometries surgeons design and set.

With support from the National Science Foundation, Thixomat subsidiary nanoMAG, LLC, of Livonia, MI, has developed a novel alternative — a bioabsorbable alloy called BioMg 250 that has twice the strength of polymers used in commercial bioabsorbable implants. The company had previously developed lightweight magnesium-aluminum alloys for electronic devices. But those alloys contain ingredients such as aluminum and rare earth metals that are not biocompatible.

"We had to throw out the cookbook and start all over with a new alloy formula," explains Steve LeBeau, president of nanoMAG.

nanoMAG designed a material made of magnesium alloyed with small amounts of a ternary combination of elements that are naturally found in the body — zinc, calcium, and manganese. These essential nutrients stimulate new bone growth. Magnesium is typically alloyed with large amounts (7–10%) of one or two metals. In BioMg 250, the magnesium is microalloyed, *i.e.*, alloyed with small amounts (<3% total), of three additional components. This combination of elements has enabled superior strength and bioabsorption rates compared to magnesium alloys with larger amounts of one or two additional elements. Microalloying also prevents the formation of large intermetallic particles that can accelerate corrosion in the human body because of their anodic or cathodic relationship to the magnesium.



▲ Micrographs of *in vivo* implants (observed over 52 weeks) show bone growth and the distribution of calcium, phosphorous, and magnesium (clockwise from top right). Image courtesy of nanoMAG.

Keys to boosting the strength of the alloy are the size and electronegativity of the alloying metals. "We picked the three alloying elements to be 'odd,' in that their size and electronegativity are significantly larger or smaller than the size and electronegativity of the magnesium atom," says Ray Decker, vice president at Thixomat/nanoMAG. "Odd elements tend to reduce the grain (crystal) size during solidification of the alloy, which results in fine grains in the final processed alloy," Decker explains. "Most importantly, the odd elements are uncomfortable in the magnesium matrix and can reach a lower energy state by clustering with each other to form ordered second-phase particles during aging heat treatments — which further enhances the hardness, strength, and ductility of the alloy."

nanoMAG is continuing the development of the material in partnership with the Univ. of Michigan, the Univ. of Pittsburgh, and the NSF Engineering Research Center for Revolutionizing Biometallic Materials at North Carolina A&T Univ. (NCAT). Researchers at NCAT conducted *in vivo* studies over 52 weeks to measure the interaction of the BioMg 250 screws with bones and tissue and to assure nontoxicity. Histology studies revealed no sign of cell toxicity.

With double the tensile strength of commercial bioabsorbable polymer implants, BioMg 250 implants will enable practical use in load-bearing orthopedic applications. The proven stimulation of new bone growth will be an added advantage. nanoMAG anticipates applications such as screws and plates for craniofacial, finger, and toe bones and ligaments.

"This new class of materials could be a disruptive game changer for orthopedic surgery," say the Univ. of Michigan team leaders Steven Goldstein, emeritus professor and former Research Dean of the Medical School, and Ken Kozloff, associate professor of Orthopedic Surgery.

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