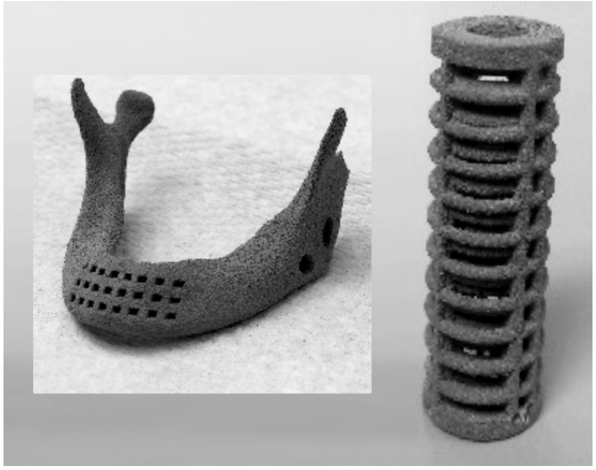
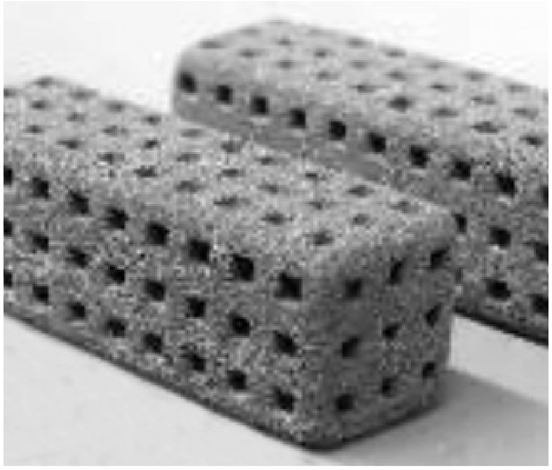
SUCCESS STORY

Using Additive Manufacturing (AM) Technology and Advanced Materials to Create Medical Implants

Reduce Healthcare Costs and Shorten Recovery Time for Patients Requiring Reconstruction Surgery





3D printed bone scaffolds were created with various designs to evaluate in vivo re-sorption, biocompatibility, and bone regeneration.

Models were constructed from novel biodegradable iron (Fe) based alloys as well as magnesium (Mg) based alloys.

PROBLEM

Current implants for craniomaxillofacial bone reconstruction often require secondary removal surgeries. There is a critical need to develop additive manufacturing (AM) methods to convert bioresorbable alloys into the required shapes, such as patient specific scaffolds for bone regeneration.

OBJECTIVE

The primary objective was to apply materials technology along with AM techniques to produce customized patient specific medical devices from novel biocompatible and bioresorbable iron (Fe) and manganese (Mg) based alloys having the desired materials and bio-functional properties such as mechanical strength, resorption rate, and cytocompatibility. A binder jetting AM technology (ExOne) was used to demonstrate the feasibility of manufacturing required shapes.

TECHNICAL APPROACH

Theoretical calculations were performed to predict the effects of introducing calcium (Ca) and Mg on corrosion behavior of biodegradable iron-manganese (Fe-Mn) alloys. Fe-Mn-Ca and Fe-Mn-Mg alloys were synthesized and the sintered pellets of the alloys were analyzed in terms of corrosion and cytotoxicity properties.
Fe-Mn and Fe-Mn-Ca exhibited good and favorable cytotoxicity results and thus were selected for binder-jet 3D printing studies.

- Demonstrate 3D printing of Fe and Mg based alloys
- Fabricate simple 3D printed constructs and extended to generation of plates, screws, and stents
- Characterize 3D printed Fe and Mg constructs for structure, corrosion, and biocompatibility

AMERICA MAKES TECHNOLOGY DEVELOPMENT ROADMAP

This project aligns to:

MATERIAL

ASTM PROCESS CATEGORY: Binder Jetting

EQUIPMENT: ProMetal RX-D

MATERIAL: Fe and Mg based alloys

ACCOMPLISHMENTS

- CALPHAD calculation exhibited an increase in corrosion rates of binary Fe-35Mn alloy by replacing Mn content with Ca and Mg. Synthesized powder of Fe-Mn-Ca and Fe-Mn-Mg exhibited gamma-phase austenite and epsilon-phase martensite solid solution without distinct Ca or Mg peaks in X-ray diffraction patterns.
- Theoretical calculation was performed to predict an effect of introducing Ca and Mg on corrosion behavior of biodegradable Fe-Mn alloy. Fe-Mn-Ca and Fe-Mn-Mg alloys were synthesized and the sintered pellets of the alloys were analyzed in terms of corrosion and cytotoxicity properties. Furthermore, Fe-Mn and Fe-Mn-Ca exhibited good and favorable cytotoxicity results and thus were selected for binder-jet 3D printing studies. Based on the results, the main conclusions drawn are listed as follows:
- Sintered pellets of Fe-Mn-Ca and Fe-Mn-Mg demonstrated that the corrosion current density increased with Ca or Mg content in the potentiodynamic polarization test studies validating the theoretical CALPHAD studies. The pellets exhibited good cytocompatibility after 1 and 3 days' culture of MC3T3 culture followed by live/dead cell viability assay.
- 3D-printed specimens of Fe-Mn and Fe-Mn-1Ca presented 39.1 and 52.1% open porosity respectively. Micro pores in size of ~5um diameter were observed under scanning electron microscopy analysis.
- The corrosion current density of 3D-printed Fe-Mn and Fe-Mn-1Ca was greater than that of sintered pellets. 3D-printed Fe-Mn-1Ca exhibited higher corrosion current density compared to 3D-printed Fe-Mn.
- 3D-printed Fe-Mn and Fe-Mn-1Ca also exhibited good cytocompatibility with MC3T3 cells assessed using both direct live/dead and indirect MTT cell viability assays. In terms of mechanical properties, Fe-Mn-1Ca exhibited higher stiffness and brittle failure in tensile testing but higher UTS was observed in comparison to Fe-Mn.
- Selective Laser Melting (SLM) of water-atomized Fe-Mn powder demonstrated the initial feasibility of the SLM process. However, several SLM related processing parameters and various characteristics of the starting Fe-Mn powder need to be optimized to generate defect free and phase pure Fe-Mn biodegradable scaffolds.
- The rotated plywood design resulted in more even distribution of buckling under compressive loading in the radial direction as well as increased ultimate compressive strength and elastic modulus demonstrating promise for use of these designs.

PROJECT END DATE

February 2016

DELIVERABLES

<u>AM of Fe and Fe-Based Alloy Components:</u>

- Demonstrate the feasibility of 3D printing of Fe-based alloys
- Fabricate Fe-based 3D constructs designed as medical devices
- Characterize Fe-based 3D printed constructs for structure, corrosion, and cytocompatibility
- Demonstrate faster corrosion of Fe-based alloys

<u>AM of Mg and Mg-Based Alloy Components:</u>

- Demonstrate the feasibility of 3D printing of Mg-based alloys
- Fabricate Mg-based 3D constructs designed as medical devices
- Characterize Mg-based 3D printed constructs for structure, corrosion, and biocompatibility
- Demonstrate faster corrosion of Mg-based alloys

All downloadable deliverables are available to America Makes members via the Digital Storefront

FUNDING

$647K total project budget
($295K public funding/$352K private funding)

PROJECT PARTICIPANTS

Project Principal:
University of Pittsburgh

Other Project Participants:
The ExOne Company
Magnesium Elektron Powders
McGowan Institute for Regenerative Medicine
University of Pittsburgh Medical Center
Reade Manufacturing Co.
North Carolina State University
Hoeganaes Corporation

Public Participants:
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U.S. Department of Energy

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