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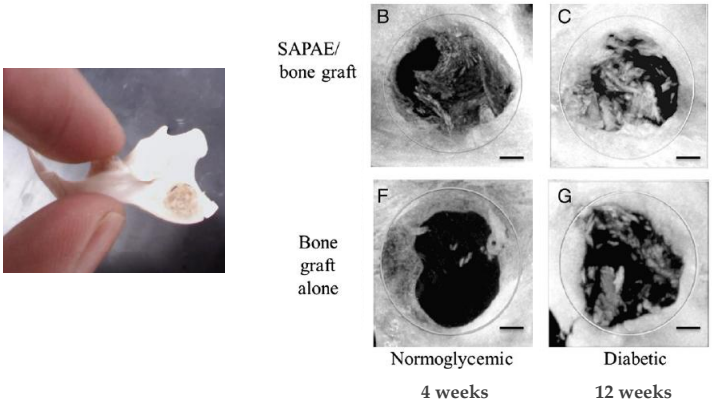

Left panel: Formulated polymer placed into a rat mandible defect. Right panel: Representative micro-CT images of mineralized bone formation in defect region in normoglycemic and diabetic rats. The polymers are shown to accelerate bone regeneration in normal animals at 4 weeks, and lead to greater bone formation in diabetic ones at 12 weeks.

Biodegradable and Biocompatible Salicylic Acid Releasing Polymer to Enhance Diabetic Bone Regeneration

Invention Summary:

Nearly 300 million people suffer from diabetes mellitus worldwide, with 25 million diabetics in the U.S. alone. Patients with diabetes are more prone to fractures, periodontitis, and other bone related issues as compared to healthy individuals and are typically characterized by increased inflammation and susceptibility to infection. They also experience decreased rates of repair/resolution for these problems. Current bone healing materials are less efficacious in diabetic patients than in non-diabetic patients; increased inflammation in diabetic patients is believed to be one of the causes. This inflammation can inhibit bone growth and exacerbate bone resorption. Currently there is a lack of effective strategies for diabetic bone regeneration. BMPs, or bone morphogenetic proteins, are widely investigated as a possible solution, but it's expensive and of questionable safety.

A novel technology developed by our scientists has specifically addressed this complication in diabetic bone repair. A polymer comprised of poly(anhydride-esters) with the NSAID salicylic acid chemically incorporated into the polymer backbone allows for **controlled release of drug over an extended period of time. The surface eroding polymer releases salicylic acid locally at a bone defect site to accelerate and enhance bone regeneration. The polymer also exhibits high biocompatibility *in vivo*. In a rat diabetic model, this technology achieved an 80-90% increase in bone regeneration over traditional bone grafts.**

In addition, Polymers containing other NSAIDs, antioxidants, antibiotics and analgesics can also be added to the polymer matrix to achieve a synergistic effect for promoting wound healing. The localized release of antimicrobials can also prevent the inflammation associated with bacterial infections.

Market Applications:

- Novel material to promote bone regeneration particularly in conditions where bone formation is impaired such as diabetic patients.
- This technology can be used alone or as device coatings for dental implants, bone grafts and other orthopedic and other surgical applications.

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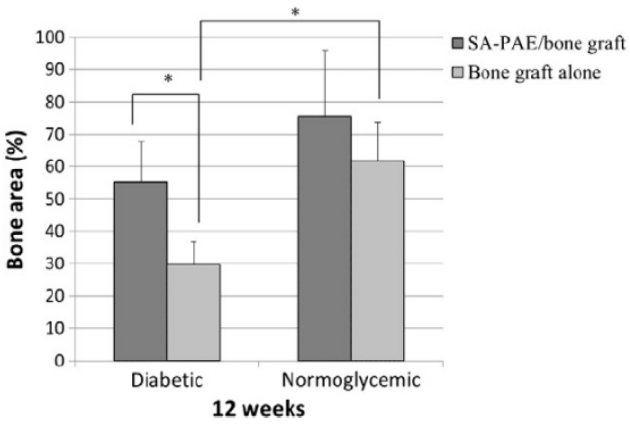
Advantages:

- Strong efficacy seen with *in vivo* bone regeneration studies
- Controlled and localized release of salicylic acid for over two weeks
- Tunable dose and release profiles
- Versatile formulations
- High biocompatibility and biodegradability
- Reduced cost (relative to recombinant growth factors such as bone morphogenetic proteins)
- Ease of manufacturing (relative to BMPs)
- Possibility to incorporate other active agents (e.g. other NSAIDs, antioxidants, and antibiotics) for synergistic effect, and can be used in combination with other polymers or drugs



Histomorphometric comparison of new bone percentage within the defects at 12 weeks in rats.

Intellectual Property & Development Status:
Patent pending. Available for licensing and/or research collaboration.