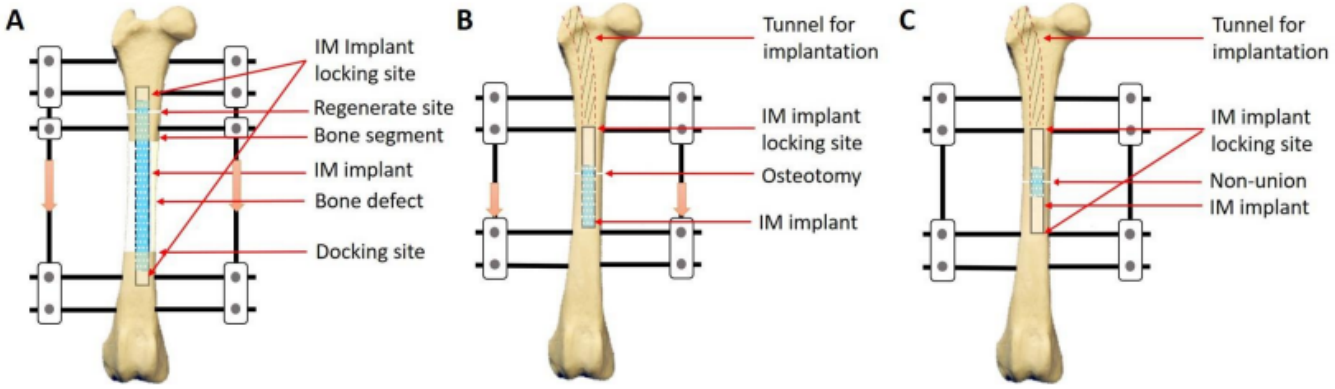
Docket #: S20-459

Bioactive Implant for Reconstruction of Bone Defect, Deformity and Nonunion

Based on their proprietary HyTEC tissue engineering platform, researchers at Stanford have developed an osteoinductive intramedullary implant (IM) device for improved bone healing. The novel, bioactive device can used as an adjunctive therapy to distraction osteogenesis for (1) bone transport over an IM implant; (2) bone lengthening over an IM implant, or (3) bone healing over an IM implant for the treatment of nonunion. The device can effectively accelerate bone consolidation in bone lengthening and prevent docking site nonunion when patients are subjected to bone transport surgery. It can also effectively promote bony fusion in the treatment of nonunion. The devices comprise core scaffolds (polymer, ceramic, metal or composite) and bioactive hydrogel coatings. The core scaffolds can be porous/non-porous and degradable/non-degradable. The hydrogels can be interpenetrating networks of a physically crosslinked gel and a covalently crosslinked gel. Small molecular weight crosslinkers can be added to the hydrogel to increase the crosslink density. The bioactive materials include drugs and growth factors (such as BMP-2, PDGF and IGF-1), which are loaded into the hydrogel and exhibit a tunable or sustained-release pattern.

Figure



Schematic representation of the bioactive IM implant device for bone healing under three conditions. Blue color represents the hydrogel coating. White dots in the implant device represent porous structure. (A) Bone transport over an IM implant. Two ends of IM implant are anchored by two fixative pins. (B) Bone lengthening over an IM implant. The implant can be inserted through a bone tunnel. One end of IM implant is anchored by one fixative pin. (C) Non-union treated with an IM implant. Two ends of IM implant are anchored by fixative pins. (image credit: the inventors)

Related Technology

For more about the researchers' HyTEC tissue engineering platform and its applications in regenerative medicine and therapeutic delivery, see S20-459.

Applications

- The intramedullary implant devices (metallic, polymeric or composite) are used for delivery of growth factors in bone healing. Examples include:
  - Treatment of long bone defect adjunctive to bone transport technique
  - Correction of bone deformity adjunctive to bone lengthening technique
  - Treatment or prevention of nonunion
  - Antibiotic-laden metallic, polymeric, or composite IM implant for bone transport or bone lengthening

Advantages

- Compatible with current surgical treatment and can be easily adapted by orthopedic surgeons – the end users

- Can be implanted in a single surgery that is needed for defect or facture fixation for the treatment of long bone defects, bone deformities or nonunion
- Device can be inserted to the proximal and distal ends of bone segments or inserted through a bone tunnel in a minimally invasive way. The devices can be anchored in site by the fixative pins.
- No secondary surgery needed for removing the tissue at the nonunion site and implant allograft in bone transport DO
- No allograft is needed during surgery for nonunion
- Can be biodegradable. Could also provide mechanical support if using metallic materials
- Convenient storage and transportation conditions for manufacturers, distributors and surgeons

Patents

- Published Application: WO2023114104
- Published Application: 20240416014
- Issued: 12,678,543 (USA)

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