



Title:

An Osteoinductive Composite Scaffold Material Incorporating Phytoestrogenic and Osteoinductive Molecule Icaritin for Treatment of Bone Defect

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US Patent Pending

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Non-confidential abstract:

Bone defect repair is popular yet a challenging orthopaedic surgery involving trauma, osteoporotic fracture, or osteonecrosis (ON). In the United States, steroid-associated ON alone affects approximately 20,000 new patients per year, whereas the prevalence of ON patients in China may be 5 or more times of that in USA.

Prevention of steroid-associated ON is essential. HOWEVER, Patients only come to our orthopaedic clinics for ON diagnosis with symptoms, such as joint pain where they are mostly already at ON stage II or even stage III. In order to prevent joint collapse and joint replacement surgery, the current consensus is an early surgical intervention for stage II/III ON patients.

Osteogenic factors, gene or cell therapy alone or incorporated into porous scaffold material are used for achieving better surgical outcome. Bone morphogenetic proteins (BMPs) are osteoinductive agents. But the limitations in using BMPs may include: (i) high dose is essential due to its rapid degradation of unprotected protein(s) and effective concentration is also species-dependent; in humans much higher concentrations are needed than in rodents and dogs; (ii) difficulties with the incorporation of these proteins in proper vehicles due to their unstable chemistry; (iii) short time of residence at the site of the lesion; (iv) severe limitations in the gene therapy approaches apart from the direct cell transduction or the delivery of DNA by gene activated matrices. The applicants newly identified a small molecule icaritin as an intestinal metabolite of a parent ring similar to phytoestrogen. Our in vivo studies suggested that these phytoestrogenic molecules were able to keep the marrow stem cell (MSC)'s osteogenic ability and facilitated bone MSCs differentiate into osteoblasts. By incorporating icaritin into a porous osteoconductive PLGA/TCP (poly lactic-co-glycolic acid / tricalcium phosphate) using rapid prototyping technique and we demonstrated its good osteoinduction with slow release of the incorporated osteoinductive icaritin. Our novel composite material can be effectively used for bone defect repair, including as a novel, biologically stable, easily applicable, and cost-effective osteoinductive composite porous scaffold implant for effective core decompression to improve early surgical repair of ON lesions and avoid subsequent joint collapse for future clinical practice.

The applicants of this invention developed a novel osteoinductive composite scaffold material composed of PLGA/TCP incorporating phytoestrogenic and osteoinductive molecule icaritin. This novel composite implant material will have broad application, especially for treatment of bone defects.

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