CALVARIAL BONE REGENERATION USING 3D-PRINTED SCAFFOLD AND BONE MARROW ASPIRATE

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CLINICAL NEED

Craniofacial bones play important roles in our daily lives as they protect vital organs, perform important physiological functions, and shape facial identity. Critical-size defects (CSDs) in calvarial bones caused by trauma, congenital defects, or tumor resections are a significant challenge for patients/physicians and can significantly compromise quality of life. Due to the lack of suitable autologous donor bone, metal and PEEK plates are often used to repair CSDs. The failure rate of cranial implants in children approaches 100% after 20 years, which demonstrates the dire need for a better solution for these young patients.

SOLUTION

Our product, bone marrow aspirate delivered on a custom 3D-printed, biodegradable scaffold, will provide a novel biological treatment for these patients that can generate new bone. Our regenerative approach can improve function by creating dense, high-quality bone that matches the properties of the calvaria and integrates seamlessly with native bone, thus reducing the risk of infection and surgical revision while creating a smooth bone surface for aesthetics. Our product will revolutionize treatment for pediatric patients in particular, because it will restore the ability of their skulls to grow in concert with their developing brains.

COMPETITIVE ADVANTAGE

We provide a novel biological solution to a biological problem. There are currently no cellularized scaffolds for bone regeneration on the market. Our team is led by craniofacial surgeons, scientists, and regulatory/industry experts who have a clear understanding of the urgent clinical needs, have developed an innovative approach to bone regeneration, and know how to deliver our products to patients with CSDs.

TARGET MARKET

Foresight Science & Technology estimated that the global market for cranial implants was ~$300 million in 2016 with a projected annual growth rate of 6.9%. Once we have secured FDA approval for the primary indication of CSDs in adult patients, we intend to pursue long bone regeneration (research is already underway) as well as a pediatric indication in craniosynostosis (1 in 1,800-3,000 live births). This will provide us with an entry into the larger global bone graft/substitutes market, which is valued by Foresight at ~$2.7 billion with a projected annual growth rate of 4.8% for the next 5-8 years. Our technology is also suitable for veterinary use in the large and growing pet care market.

REGULATORY PATHWAY

Confirmed via pre-Request for Designation to the FDA Office of Combination Products that the product will be regulated as a device through CDRH.

INTELLECTUAL PROPERTY

US patent 16/762.398. EU and China patents issued.

RELATED PUBLICATIONS

(1) Zhao H, Feng J, Ho TV, Grimes W, Urata M, Chai Y. The suture provides a niche for mesenchymal stem cells of craniofacial bones. Nat Cell Biol. 2015;17(4):386-396. **(2)** Park S, Zhao H, Urata M, Chai Y. Sutures Possess Strong Regenerative Capacity for Calvarial Bone Injury. Stem Cells Dev. 2016;25(23):1801-1807. **(3)** Li X, Yuan Y, Liu L, et al. 3D printing of hydroxyapatite/tricalcium phosphate scaffold with hierarchical porous structure for bone regeneration. Bio-des. Manuf. 2020;3:15–29. **(4)** Johnson ZM, Yuan Y, Li X, et al. Mesenchymal stem cells and three-dimensional-osteoconductive scaffold regenerate calvarial bone in critical size defects in swine. Stem Cells Transl Med. 2021;10(8):1170-1183.

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