A Smart, Fully-Implantable Craniomaxillofacial Distractor

CLINICAL NEED

Distraction osteogenesis (DO) is a technique used to generate new bone at the site of a surgical cut by slowly separating plates attached to two opposing fragments. While the procedure is increasingly used in the treatment of various congenital craniomaxillofacial (CMF) deformities including undergrowth of the mandible in patients with disease such as, craniosynostosis or hemifacial microsomia, limitations exist in its current form, including the component that protrudes through the skin for manual engagement of the device.

SOLUTION

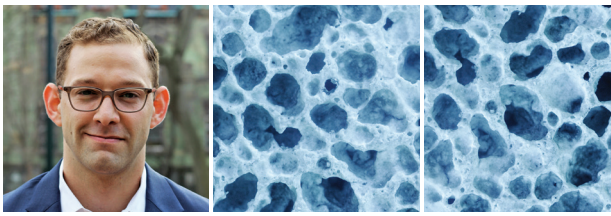
Ostiio is developing a fully-buried, remote-controlled DO system for the craniomaxillofacial skeleton. This device is intended to be applicable to all patients who would be treated with traditional DO systems, but is completely implanted under the soft tissue, without any external components protruding through the skin. The distraction is actuated through a magnetically driven external controller that can implement physician-defined distraction protocols.

COMPETITIVE ADVANTAGE

As the device has no parts protruding the skin, it is expected to decrease morbidity such as soft tissue infection and scarring associated with the current device form factor. In addition, as the manipulation will be remotely-controlled and software-driven, patient non-compliance and inaccuracies are also expected to be decreased.

ITP SUPPORT

With support from the ITP program, Ostiio will be developing device prototypes and performing mechanical and biocompatibility testing.



ARI M WES, MD, MSC

Ostiio LLC

"Ostiio is trying to alleviate the stress felt by parents of children undergoing CMF distraction, while giving control back to the surgeon."

http://pennhealthx.com/ostiio

CLINICAL TRANSLATION PATHWAY

Publications:
Complications in Posterior Cranial Vault Distraction. Ann Plast Surg. 2016.

Precision of the PRECICE internal bone lengthening nail. Clin Orthop Relat Res. 2014.

Intellectual Property:
PCT/US2018/021269 Systems and Methods for Contactless Cranio-maxillo-facial distraction

Regulatory Pathway:
Anticipated: Device, 510(k)

Commercialization Strategy:
Ostiio plans on bringing their device through the FDA. After clearance, the team will assess the different options for driving adoption by hospitals and patients.

Product Launch Strategy:
Following FDA clearance, Ostiio will explore partnerships with prominent players already in the CMF space to drive adoption.

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