Bioresorbable Electrical Stimulator for Improved Bone Regeneration

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Introduction

>Delayed healing or non-union (pseudo-arthrosis) remains a common, costly, and morbid complication after spinal fusion surgery.
>Direct current electrical stimulation (DCES) of bone growth represents a unique surgical adjunct to promote bone formation and facilitate healing.
>Unfortunately, existing spinal fusion DCES systems utilize permanent electronic components, are increasingly invasive, and carry significant safety risks.

Objectives

1) To describe the design and implementation of a novel implantable bone healing system that utilizes a biodegradable DC electrical stimulation contact interface.
2) To determine if the in vivo application of our novel device is capable of accelerating the time course to bone repair in a non-critical sized rat femoral defect model.
3) To identify the bio-compatibility and safety profile of the stimulator-bone interface.

Methods

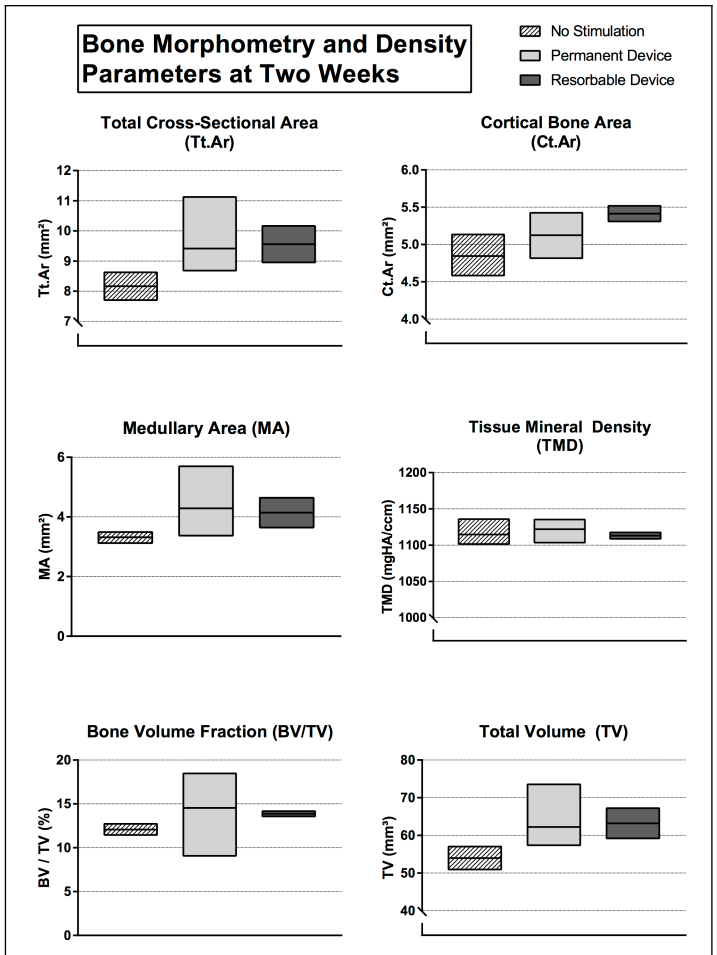
> Non-critical femoral defects were created in 15 Lewis rats.
> Animals were randomized into three treatment groups (n=5 each).

- Group I did not receive any stimulation
- Groups II and III received daily continuous 50uA DCES through permanent and bioresorbable femoral electrodes, respectively.

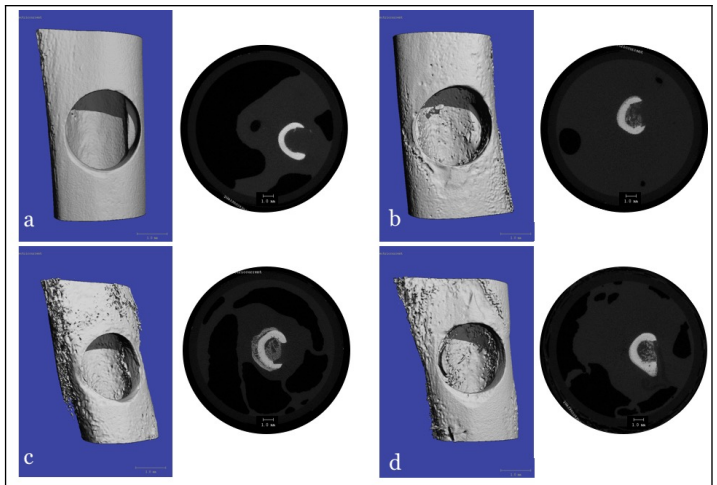
> All animals were euthanized two weeks post implantation and the injured femurs were harvested.

Results

> Micro-CT morphometric analysis demonstrated a trend towards increased overall bone formation, total tissue and bone volume, bone volume fraction, cross-sectional area, and cortical bone area after two weeks of DCES (Figure 1).
> The performance of bioresorbable stimulators compared favorably with that of permanent devices.



Bone Morphometric and Density Parameters, as assessed by high resolution Micro-CT.



3D reconstructions and cross-sectional images of femoral defects at day 0 (a), and after 2 weeks of treatment (b,c,d). b) Group I, c) & d) Groups II and III.

Conclusions

> The results of the study suggest a trend toward increased bone formation with DCES in line with previous work, and highlight the possibility for integrating implantable bioresorbable technology to enhance bone healing.
> Further work is needed to examine the impact of varying DCES on osteogenesis and the optimization of bio-degradable hardware systems.