

Implantable Magneto-hydrodynamics Pump to Generate Fluid Flow at a Femur Fracture

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Disclosures: Authors have no conflicts to disclose relevant to this abstract.

INTRODUCTION: Fracture non-union and delayed union significantly complicate fracture treatment and affect the patient's quality of life. About 5 -10 % of fractures fail to bridge in the appropriate time, thus necessitating the development of a more effective treatment approach. To accomplish this, it's essential to gain a deeper understanding of the physiological processes involved in bone regeneration. Investigators have been studying the role of fluid flow and fluid shear stress on bone regeneration using *in vitro* and computational models, and there is increasing evidence showing that fluid shear stress, in addition to strain, are involved in bone tissue growth and maintenance as well as in cell differentiation following fracture formation. Furthermore, increased fluid flow in femoral fractures can increase nutrient transport and improve the healing process. However, there hasn't been an *in vivo* study that has directly linked fluid flow to bone regeneration owing to technological limitations. Therefore, there is a need to develop a device that can do just that. One way to achieve this is by using a magneto-hydrodynamics (MHD) pump, a device that utilizes the interaction of electric current and DC magnetic flux to generate a force that propels fluid across a channel, which in this case, the fractured bone gap. The ultimate goal of this project is to develop a MHD-based implantable fixation device that can generate fluid flow at a bone fracture site and show that fluid flow and fluid shear stress in the absence of compression can influence bone regeneration. In this abstract, we present the design of the MHD-based fixation device for a rat segmental bone defect, as well as preliminary data showing the efficacy of the device *in vivo*.

METHODS: The developed device (**Fig. 1**) consists of an implantable bone plate, a pair of electrodes, a battery-powered circuit board, and external magnets placed on a 3D-printed platform. Prior to *in vivo* study, the system was tested through benchtop experiments to characterize electrochemical and flow properties. To explore how fluid flow affects bone healing, we conducted a pilot study using the fabricated device and compared changes in volume between a control and a flow group. Upon creation of the segmental defects, femurs were stabilized with internal PEEK fixation plates with electrodes attached, while the circuit board and battery were implanted in the abdominal cavity. The use of mechanically stiff PEEK as the fixation device results in low compressive strain on the healing callus, thus allowing fluid flow to be the dominant effect on bone healing. The fluid flow at the fracture site was controlled by placing magnets around the injured leg and activating the implanted electrodes wirelessly via Bluetooth (**Fig 2**). The control group ($n = 2$) received both an electric field and magnetic field without the generation of fluid flow, while the flow group ($n = 3$) received an electric field and magnetic field simultaneously resulting in flow. Rats were subject to treatment every three days for twenty minutes one week after surgery for a total duration of 4 weeks. Bone healing was monitored via *in vivo* radiograph and *ex vivo* μ CT quantification. The range of fluid flow generated is between 3 - 5 μ m/ sec at 0.4 Hz. All work was approved by IACUC.

RESULTS SECTION: Benchtop experiments showed that the velocity of fluid flow can be controlled by varying the input voltage or changing the magnetic field strength. The fabricated device can deliver flow in the range of 1 μ m/sec to 1 mm/sec by varying the applied electric field and magnetic field. The preliminary data (**Fig.3**) from this *in vivo* study showed that on average, the flow group had more bone volume at week 4 compared to the control group.

DISCUSSION: We present a novel device that generates fluid flow in bone defect to allows us to study the role of fluid flow on bone regeneration. The pilot study validated the ability of the device to be used *in vivo* and demonstrated the influence of fluid flow on bone regeneration in the relative absence of compression. The stiffness of the PEEK bone plate is much higher than similar bone plates fabricated using polysulfone or UHMWPE used on similar bone defect models. It has been previously shown that a stiff fixation plate reduces bone regeneration by decreasing strain applied on the healing callus. Therefore, the high stiffness of the PEEK fixation plate allows us to effectively reduce the effects of compressive strain and study only the influence of fluid flow-induced shear on bone regeneration. The *ex vivo* μ CT measurement of the defect tissue shows that the flow group regenerated more bone volume than the control group with 1/3 of subjects showing callus bridging. While the study's limited sample size precludes statistical analysis, the observable variation in bone volume between the control and flow groups underscores the effectiveness of the developed device, motivating future experiments.

SIGNIFICANCE/CLINICAL RELEVANCE: Subsequent investigations involving larger cohorts will be essential; however, the potential of a fluid-flow-inducing device holds great significance for researchers, addressing a notable knowledge gap regarding the impact of fluid flow on healing callus. In addition, it provides a platform to develop a fracture treatment regimen that will greatly benefit diverse patient populations, particularly those who may have limited ambulatory capabilities such as the elderly and individuals with multiple traumas.

IMAGES AND TABLES:

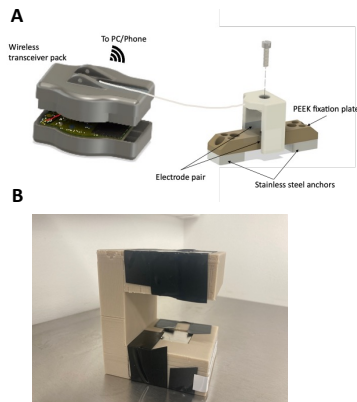


Fig.1. An exploded view of the components of the fabricated device (A). Picture of the external magnets on a platform (B).

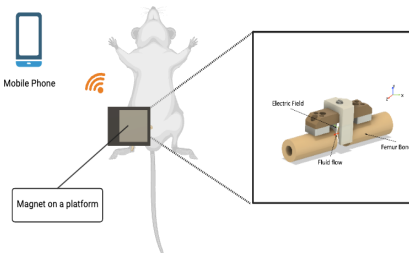


Fig. 2. Illustration of the experimental setup; the prone position of a rat with a magnet surrounding the femur and exploded view of the femur showcasing the implanted device.

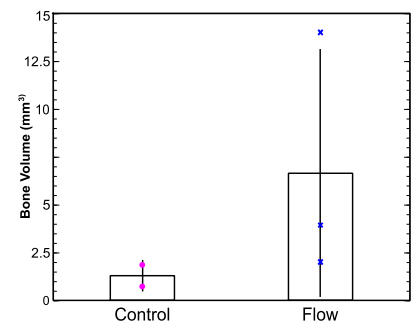


Fig. 3. Bar chart displaying bone volume data for the Control Group and the Flow Group, with data points indicating individual measurements.