Mechanically Active Bone Fixation Device: Design and Characterization

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Abstract

Mechanical stimulus in the form of exercise is known to improve bone formation during fracture healing. At a scale orders of magnitude smaller than this functional loading, mechanical stimulus delivered at high frequency (~30 Hz) can also enhance bone regeneration. External delivery of mechanical stimulus is used in many of the studies that demonstrate the positive effects of this low magnitude, high frequency (LMHF) stimulus, but these modes of delivery are challenging to translate into clinical settings. In this study, we fabricated and tested an internal delivery system comprised of a bone fixation device embedded with a magnetoelastic actuator which will change physical dimension in response to an applied magnetic field. Load transferred from the mechanically active device to a rodent femoral fracture provides local LMHF stimulus. The bone fixation device was characterized by off-axis compressive and torsional stiffness tests and accelerated fatigue tests. Iterative design produced a fixation device with the required stiffness parameters for *in vivo* validation.

What are the optimal mechanical properties for fracture stabilization and stimulation?

Methods

	Compressive stiffness	Torsional stiffness	Accelerated compressive fatigue	Accelerated torsional fatigue
Displace-ment	0 to -0.5 mm	5° to -5°	0 to -0.3 mm	2.5° to -2.5°
Frequency (Hz)	0.1	0.1	10	10
Cycles	4	4	100,000	100,000

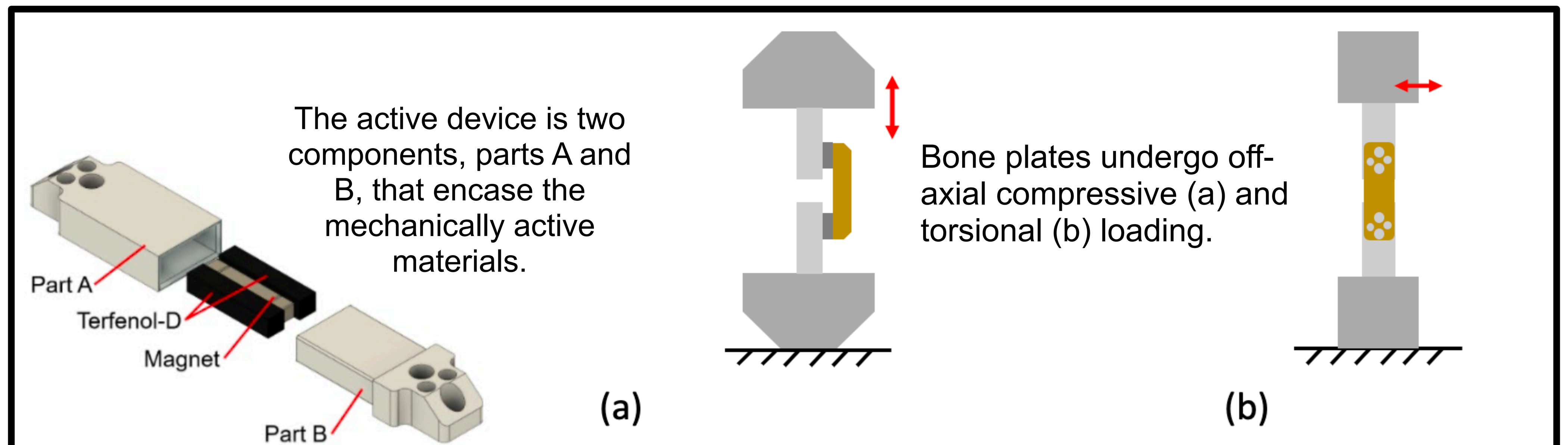
Table 1. Mechanical testing paramenters.

Design of the bone fixation device

The fixation device was redesigned while maintaining the fixation features of the device (Fig. 1a) to have additional features that helped in load sharing (Fig. 1b,c). The redesigned device was 3D printed using different photopolymer resins (BioMed Clear, Dental LT, Clear, Tough and Durable, Formlabs).

Characterization of designs

Mechanical characterization of these devices was based mainly on two major mechanical loads observed in the fixation device during implantation: compressive and torsional loads. The testing parameters (Table 1) were determined based on a previously established protocol on a mechanical tester.



Results

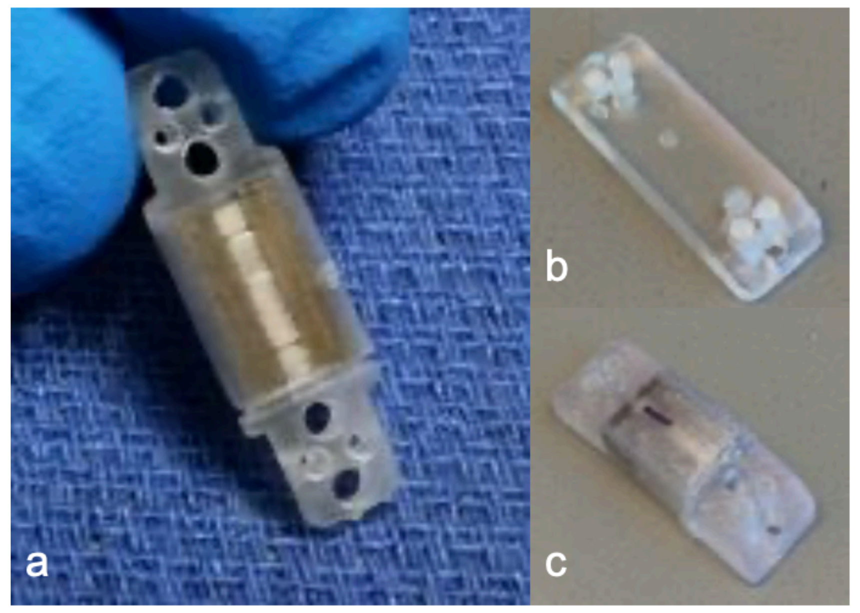


Figure 1. (a) Initial fixation device design with magnetoelastic material, **(b & c)** passive and active redesigned devices fabricated from BioMed clear resin. Devices are 24 mm × 6 mm.

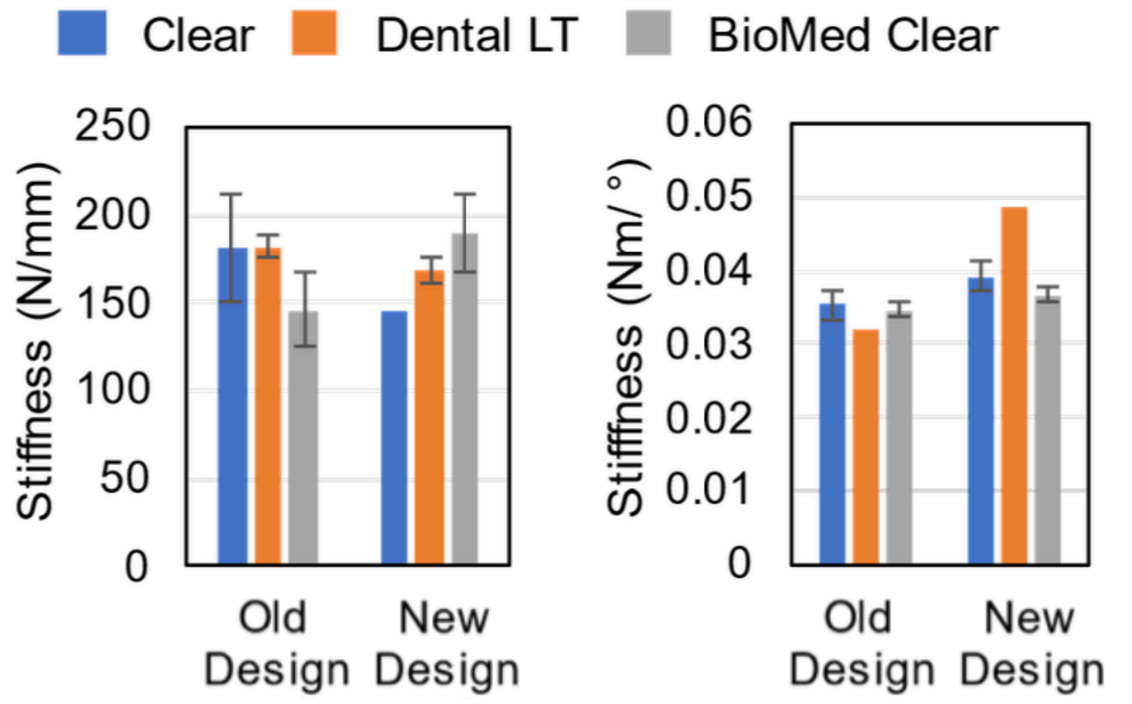


Figure 2. Mechanical test results **(a)** compressive stiffness and **(b)** torsional stiffness of passive model of the fixation device. Data is mean and SD of 4 samples.

- Analysis of the raw mechanical displacement vs load data determined the compressive stiffness and the relative rotation vs torque data to determine torsional stiffness.
- Mechanical testing results showed that Tough and Durable resins with 63.071± 6.013 and 31.306 ± 2.027 N/mm compressive stiffness would not provide enough fixation stability (<100 N/mm).
- Three other resins were further evaluated for their stiffnesses in the passive design as shown in figure 2a. The other three materials demonstrated compressive stiffness higher than the required 100 N/mm.
- My redesigned devices did not improve axial compression which was anticipated but the torsional stiffness of the device was quantitatively higher for the redesigned devices in comparison to initial device design as represented in 2b. Further mechanical tests to assess redesigned active devices will be performed.
- New designs in the BioMed Clear resin maintained mechanical integrity during fatigue testing.

Further Research

Since my work on this project in 2020, Dr. Karipott has continued to characterize the device:

- Establishing the controllability of mechanical activation using strain gauge testing
- Characterizing the device in vitro to demonstrate biocompatibility
- Completing in vivo trials using the segmented rodent femoral fracture model

Conclusions

In this project, we investigated an internal delivery system comprised of a bone fixation device embedded with a magnetoelastic actuator, allowing for mechanical activation. With load transferred from the mechanically active device to a rodent femoral fracture shown to apply local LMHF stimulus and iterative design completed to produce a fixation device with the required performance and safety parameters, *in vivo* validation was able to be pursued. Ultimately, the process of designing bone fixation devices and fabrication tools in CAD software, designing print orientation and supports for optimal plate outcome and performance, fabricating multi-component active plates, and organizing and analyzing data has allowed me to implement engineering principles from coursework, literature, and training.

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