The Product Design Specification

An MR-Compatible Device for Imaging the Lower Extremity During Movement and Under Load

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Function: MR imaging can provide clinicians and researchers valuable insights into the morphology of musculoskeletal structures. However, most current imaging techniques in use are static and do not provide direct measurements of biomechanical function. Recent breakthroughs in magnet strength, acquisition speed and processing of MR data have enabled imaging to be used to measure in-vivo muscle motion and joint kinematics during movement, and cartilage contact area under load. These applications require the use of a non-magnetic device for loading or guiding the limb through a desired, repeatable movement. The goal of this design project is to develop and build such a device for use in the Radiology clinic of the UW Hospital. Our initial applications are to:

1) Use Cine-PC (Phase Contrast) imaging to measure in-vivo musculotendon motion of the hamstrings during a stretch-shortening cycle. Cine-PC requires multiple cycles of motion, necessitating that the device guide the limb through a repeatable motion at relatively low loads.
2) Use VIPR imaging to measure knee cartilage contact area under various static load levels.

Client requirements:

- Provide repeatable, harmonic motion
- Same start and end points
- Constrain endpoints based on bore size
- Generate physiological load on hamstring
- Simulate swing phase of running
- Support thigh—limit movement
- Movement of shank provides force
- Provide compressive force to measure cartilage contact area
- Image near center of magnet
- Non-metallic, non-ferrous materials

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: The device should fit the dimensions of a standard MRI machine and provide a physiological load to the hamstring under repeated, harmonic motion. The endpoints should be constrained so as to start and stop the motion in the same position. If applicable, the device should also provide a compressive load on the knee to measure cartilage contact area.

b. *Safety*: The load on the patient must not injure the limb under any conditions. The device must not contain metal due to effects of the strong magnet in the MRI.

c. *Accuracy and Reliability*: Motion of the path should be accurate to +/- 1° at the start and end point, and +/- 3° at any point throughout the cycle. The same amount of force should be delivered during each motion within +/-5%.

d. *Life in Service*: This is a research device that will be periodically used 2-3 times per week imaging 10-20 subjects at a time. The device may sit for a couple months between research dates. The device will be used for about three years.

e. *Shelf Life*: Device will be stored in hospital storage cabinets. Shelf life should be about 5 years.

f. *Operating Environment*: The device will be stored at and used at room temperature in a hospital environment. It need not be sterile, but should be easily cleanable.

g. *Ergonomics*: The force that the device applies to the patient must not exceed normal physiological loads for the individual. Device should also be easy to assemble and disassemble for technicians.

h. *Size*: Size of the device is limited by the size of the MRI bore which is 60cm. Device should not take up unnecessary space around the MRI machine and not interfere with the technician's pathway to the machine.

i. *Weight*: Device should weigh about 25lbs, adequate enough to transport from location to location. Device should also be able to be disassembled for easy transport.

j. *Materials*: No metallic or ferrous materials can be used in our device. UW Hospital has a list of unacceptable MR materials we have already requested.

k. *Aesthetics, Appearance, and Finish*: No special finishes are needed. Device should not be cumbersome to the patient.

2. Production Characteristics

a. *Quantity*: One prototype is requested at this time

b. *Target Product Cost*: $300-400

3. Miscellaneous

a. *Standards and Specifications*: The only standard is that the device cannot contain metallic or ferrous materials. The device also must not cause any harm to the patient.

b. *Customer*: The client would prefer to have a variable physiological force, so the use of a combination of force producers can be used.

c. *Patient-related concerns*: Device does not need to be sterilized. Should be accommodating to all patients, but some size restraints may exclude some patients.

d. *Competition*: There exist a number of devices that apply a load to the knee for imaging under MRI, however our device will be the first to mimic physiological loading during swing phase while taking dynamic images of the knee under this load.