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Investigators Brochure for Investigational Medical Device:

Gravitational Magnetic Resonance Elastography Transducer

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What is magnetic resonance (MR) elastography?

- MR elastography is an imaging technique that can be used when performing MRI scanning.
- MR elastography is a non-standard protocol, which is increasing in use as a clinical tool.
- It is **safe**, **non-invasive** and **painless**.
- The way that our body's tissues transmit vibration tells us something about their mechanical properties, such as their stiffness.
- During MR elastography, a person lies within the MRI machine (called the MR scanner) and has gentle vibration transmitted into whichever body tissue is being investigated, such as the brain, muscle, or abdominal organs.
- The MR scanner takes pictures of how the vibration travels through the tissue.
- After the scan using our analysis software, we can calculate the stiffness of the tissue from those pictures.
- An example of the result looks like this:

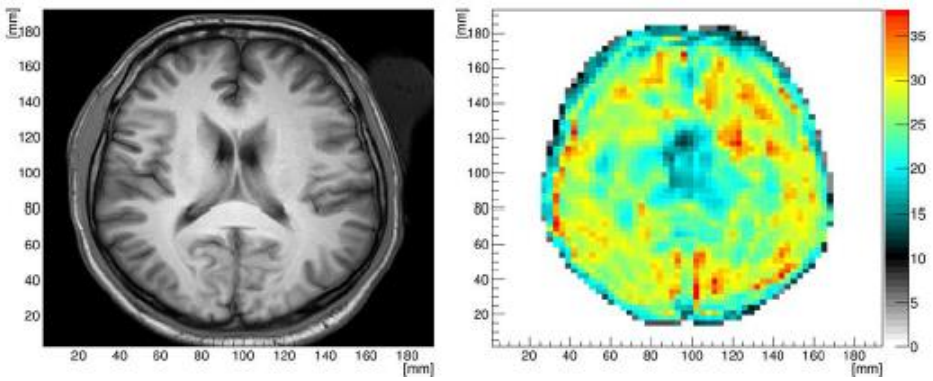

FIGURE 1. A) BRAIN ANATOMY. B) WAVELENGTH OF VIBRATION

What is the MR elastography transducer?

- The MR elastography transducer is the device that delivers the vibration to the body.
- The vibration feels similar to that of an electric toothbrush and is not painful in any way.
- The transducer is connected to the MR scanner so that the vibration can be synchronized to when the pictures are captured.
- Due to the strong magnetic field of the MR scanner, the transducer needs to be made of materials that are not magnetic.
- The MR elastography transducer that we will use in this study is called the *gravitational MR elastography transducer*. For simplicity, we will just call it the ***Gravitational Transducer***.

What is the Gravitational Transducer?

- The Gravitational Transducer is a type of magnetic resonance transducer that creates vibration through the rotation of a little mass inside a plastic housing.
- The Gravitational Transducer is a new type of transducer that is being used safely and successfully internationally.
- The part of the transducer that will come into contact with you looks like this:

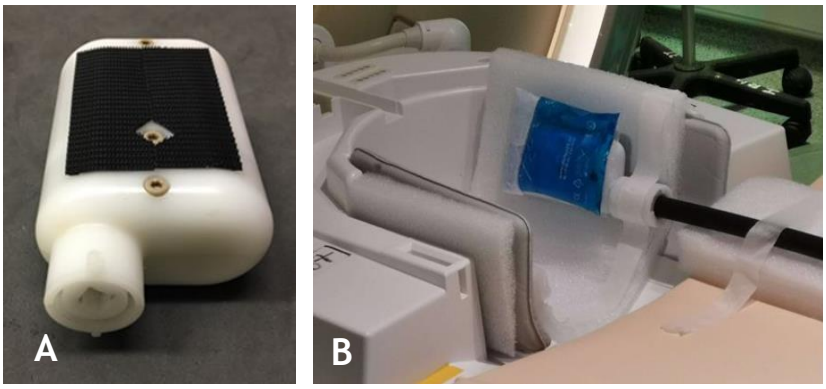

FIGURE 2. A) COMPONENT OF THE GRAVITATIONAL TRANSDUCER THAT WILL BE IN CONTACT WITH YOU; B) PICTURE SHOWING THE TRANSDUCER CUSHIONED IN THE MR IMAGING COIL BY A GEL PAD.

- It will either be strapped onto your body, or positioned underneath it. A gel pad will be placed between it and you for your comfort.

How does the device work?

- The transducer consists of a small, rectangular plastic box that will be either strapped or placed on their body.
- Inside the box is a small belt connecting two rotating shafts.

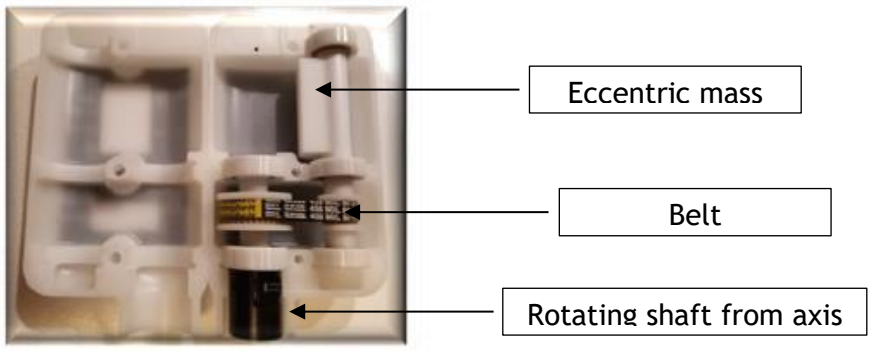

FIGURE 3. INTERNAL COMPONENTS OF THE GRAVITATIONAL TRANSDUCER.

- One of the shafts has a small weight attached to one side.
- When the shafts spin, the weight spins around and the changing position of the mass makes the transducer vibrate.
- Connected to the transducer is a long rubber hose. Inside the hose is a plastic core which rotates. We call this the axis.
- We connect the axis to the purpose built motor, which transmits the rotation to the transducer, rotating the eccentric mass to produce the vibration frequency that we need.

FIGURE 4. A) SECTIONS OF THE FLEXIBLE AXIS; B) PICTURE SHOWING HOW THE TRANSDUCER CONNECTS FROM INSIDE THE MRI TO THE MOTOR IN THE EQUIPMENT ROOM THROUGH THE FLEXIBLE AXIS.

Where was it created?

- The device was designed and created by a team of biomedical engineers at the English university, Kings College London.
- The head of this team is Professor Ralph Sinkus, a biomedical engineering professor and an expert in the field of MR elastography with more than 20 years' experience.
- https://kclpure.kcl.ac.uk/portal/ralph.sinkus.html
- Multiple gravitational transducers have been built at KCL and are in use safely and successfully around the world.

Why am I being asked to participate in a clinical trial?

- The Therapeutic Goods Administration (TGA) is the governmental agency that regulates the approval of medicines and medical devices that are available in Australia.
- The TGA maintain a list called the Australian Register of Therapeutic Goods (ARTG) which all medicines and medical devices available for sale must be approved on.
- The **Gravitational Transducer has not been registered on the ARTG** because it is not available for sale commercially, due to its specialized use.
- The Gravitational Transducer is therefore what is known as an ***investigational medical device***.
- The conduct of all human studies involving investigational medical devices (such as this one) must be reviewed as a clinical trial.
- The conduct of this trial has received ethical approval from the UNSW Human Research Ethics Committee (approval reference XXX) and the device has been registered with the Therapeutic Goods Administration (reference CT-2021-CTN-01514-1).
- This study is NOT a study of the safety or efficacy of the Gravitational Transducer, but must be run as clinical trial due to the investigational medical device.

Is it safe?

- The device is classified as 'low risk'.
- The components of the transducer that are in contact with you are non-conductive, non-magnetic and spill-proof, meaning there is no risk to you of magnetisation, heating or electric shock.
- The transducer casing consists of a hardy plastic box that has been designed to be very strong and resistant to shock or damage.
- The amplitude of the vibrations that the transducer is capable of supplying are well below any safety limits for the safe exposure level of workers to vibration.
- The control system of the device is equipped with a safety system that monitors the current provided to the motor, and shuts it down in the event of a malfunction.
- In the event of any adverse effect related to the device, the conduct of the study is covered by insurance.

What are the risks related to the device?

- There is a risk of tripping over some of the equipment. This equipment will be placed out of your way and taped down.
- There is a risk of bruising or mild friction burns if the transducer is placed directly over a bony region. For this reason, we will position a gel pad between you and the transducer.

What should I do if I have any questions about the device?

- If you have further questions relating to the device, please direct them to the people listed below:

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