Docket #: S19-096

Soft Tissue of Orbit Range of Motion (STORM) analysis

For orbital fractures, there are advanced solutions for the restoration of bony contour following trauma but the most debilitating functional consequences (pain and double vision) are due to soft tissue injury and entrapment rather than bony distortion.
However, there are no quantitative means of assessing soft tissue entrapment pre-, intra-, and postoperatively in order to guide clinical decision making. Addressing this issue, Stanford researchers have developed a device and descriptive system for quantitative assessment of orbital soft tissue restriction called **STORM**. This medical device measures resistance of eye movement to locate soft tissue impingement and adhesions in surgical and diagnostic settings. In addition, to more precisely measuring restrictions, the resulting heat map identifies the location of the adhesion/entrapment.

Stage of Development

- Prototype developed and tested on cadaver
- Plans for clinical tests

Applications

- **Orbital fractures** (especially complex repairs in conjunction with large and/or custom implants)
- Orbital reconstruction following skull base or sinus surgery
- Thyroid eye disease
- Congenital myopathy and fibrosis syndromes
- 3rd nerve palsy and other large angle strabismus syndromes

Advantages

- **Quantitative measurement** of orbital soft tissue restriction to locate soft tissue impingement and adhesions in surgical and diagnostic settings
- **Generates heat map** which identifies the location of the adhesion/entrapment
- **High clinical efficacy**
- **Easily applied by all surgeons** (majority of orbital fractures are also repaired by surgeons without ophthalmic training)
- **Addresses gap** in market space
- The closest competitor that we are aware of is a functional first generation prototype developed by our team that contains a load cell within force-sensing forceps manipulated by the surgeon, with translation of the instrument measured by an inertia monitoring unit (IMU) that combines the capacity of an accelerometer and gyroscope, theoretically permitting proxy positional assessment by measurement of speed and linear acceleration about three axes. In a cadaveric fracture model, this permits accurate assessment of peak soft tissue resistance but does not work accurately enough to produce a reliable resistance-versus-excursion map. The instrument also still requires precision grasping of the ocular surface at the corneoscleral limbus.

Publications

- Bair, Henry, and Benjamin P. Erickson. "A Device to Quantify Orbital Compliance and Soft-Tissue Restriction." *Journal of Neurological Surgery Part B: Skull Base* 82, no. S 02 (2021): OD024.

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