

## **Clinical Trial of a New Device for Real-Time Muscle Pressure Measurements in Patients with an Upper or Lower Extremity Fracture at Risk for Acute Compartment Syndrome**

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**INTRODUCTION:** Acute Compartment Syndrome (ACS) is an orthopaedic emergency. In this study a continuous compartmental pressure monitor (“the device”) was assessed for its ease of use and ability to continuously reflect the intracompartmental pressure (ICP) in real time. This preliminary data is from four sites which are presently expanding data collection to two other sites as part of a multi-center study.

**METHODS:** Patients with long bone trauma of extremities risking developing compartment syndrome were enrolled. Informed consent was obtained from the patients. An FDA-cleared continuous compartmental pressure monitor was inserted in the compartment that was deemed most likely to develop ACS and ICP was continuously measured for up to 18 hours. Fractures were classified according to the AO/OTA classification. Patient clinical signs and pain levels were recorded by healthcare staff during routine in-patient monitoring.

### **RESULTS:**

Seventy-four patients were enrolled from November 2020 through May 2022: 49 males and 25 females. The median age was 41 years (range, 17–80). Sixty-five patients received the device post-operatively and nine received it pre-operatively. Preliminary results show that post-operative ICPs tend to be significantly higher than pre-operative ICPs but tend to trend downwards very quickly. The trend in this measurement appears to be more significant than absolute numbers. One patient pre-operatively illustrated a steep trend upwards with minimal clinical symptoms but required compartment release at the time of surgery that exhibited no muscle necrosis. There were no amputations, no surgical site infections, and no missed cases of ACS.

### **DISCUSSION AND CONCLUSION:**

Preliminary results suggest that this device is reliable and relatively easy to use. In addition, our results suggest that intracompartmental pressures can be higher immediately post-op but lower rapidly when the patient does not develop ACS.

Further elucidation of the pressure thresholds plus the added value of continuous trends in the pressure, upwards or downwards, will aid in preventing muscle necrosis during our management of these difficult long bone fractures. It may change the way we measure and treat compartment syndrome.