Continuous and objective monitoring of fracture healing progression using the AO Fracture Monitor – preliminary evidence from the first-in-human investigation

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ABSTRACT INTRODUCTION: Plain radiography is the current gold standard for clinical assessment of fracture healing progression. However, healing assessment through conventional X-rays is limited to single-time-point (snapshot) measurements, and their interpretation can be highly subjective. Addressing these shortcomings, an implantable implant load sensor – AO Fracture Monitor [1] (Figure 1a) – was developed at the AO Research Institute Davos that continuously measures the load on the bone plate under physiological loading, thereby providing a quantitative measure of healing progression. This study aims to evaluate the safety and clinical performance of this novel device.

METHODS: The clinical study is currently ongoing in four medical centers in Germany (ClinicalTrials.gov ID NCT05410587). In this abstract, we present preliminary results obtained from eight patients across two centers with a monitoring period of at least 16 weeks to date (data acquisition still ongoing in one patient). The enrolled patients suffered from fractures of the distal femur. The fractures were fixed using a locking plate which was equipped with the implantable load sensor during surgery (Figure 1b). Based on the loading of the plate, the Fracture Monitor autonomously measures patient activity (number of loading events per day) and relative implant load – that is, the load on the implant normalized to the maximum value recorded postoperatively. On a daily basis, the Fracture Monitor transmits the recorded data via the accompanying smartphone application on the patient's phone to a central cloud server. Patients are following standard of care rehabilitation protocols and both patients and medical staff are blinded to the data acquired by the Fracture Monitor.

RESULTS SECTION: Implantation and data acquisition by the fracture monitor has been working flawless so far, and no device-related adverse events were recorded. Following the surgery, patient activity gradually increased and saturated around 60 days post-op at the level of approximately 4000 loading events per day (Figure 1c). We observed substantial differences in activity levels among included patients, with an average standard deviation of 1710 loading events per day. The peak of relative implant load occurred on average at 69±49 days post-surgery. Subsequently, the relative implant load dropped by 32±24% until the end of the monitoring period.

DISCUSSION: In this work, we present the preliminary results from the first-in-human application of the Fracture Monitor. The gradually increasing activity levels demonstrate the progressive recovery after a distal femur fracture. Furthermore, in comparison to preclinical data acquired with the fracture monitor with immediate full weight-bearing [1], initial partial weight-bearing prescribed as per standard of care appears to delay the maximum implant load. The timing of peak implant load and the extent of its subsequent decrease however varies widely between patients and may indicate differences in their healing progress. A larger patient sample and correlation with the clinical healing outcomes are required to confirm the diagnostic relevance of this parameter.

SIGNIFICANCE/CLINICAL RELEVANCE: Our technology allows for X-ray-free, continuous and objective monitoring of fracture recovery, which spot-targets the limitations of current radiological examinations. Provisional findings from the first clinical patients confirm the clinical feasibility of the device to be used in distal femur fractures. The combination of remote monitoring and quantitative feedback on patient activity and implant loading could enable more personalized and efficient rehabilitation, thereby significantly improving fracture aftercare.

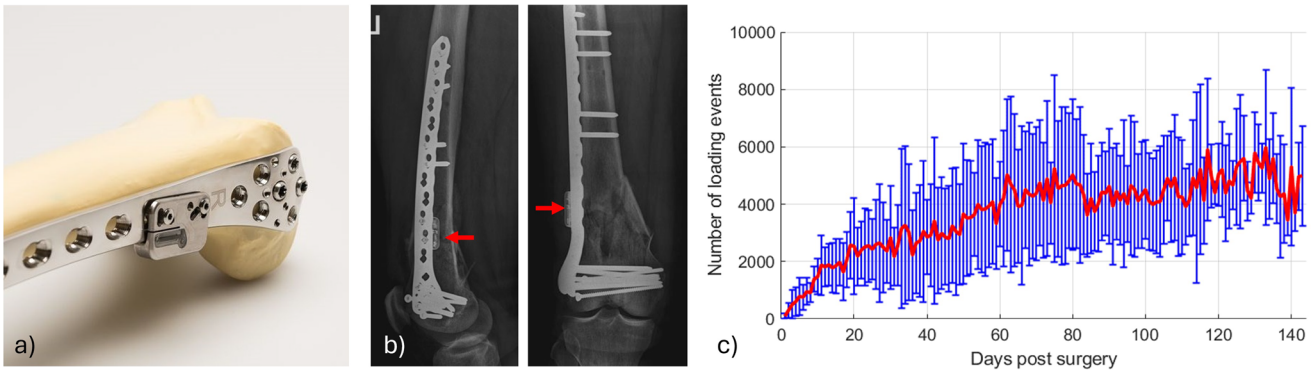

Figure 1. a) Plate with Fracture Monitor mounted on an artificial femur; b) fracture of distal femur treated with locking plate that was equipped with the Fracture Monitor (red arrows); c) average number of loading events for all included patients for the entire monitoring period—blue bars represent standard deviation.

REFERENCES:

[1] Windolf, Markus, et al. "Continuous implant load monitoring to assess bone healing status—evidence from animal testing." Medicina 58.7 (2022): 858.

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