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Remote monitoring of bone healing via bending with direct electromagnetic coupling sensing in an exploratory tibial fracture study

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ABSTRACT

Objectives: The purpose of this study was to evaluate the feasibility and efficacy of longitudinal bending measurements to monitor the progression of fracture healing. Standard methods for evaluating bone healing rely on the assessment of radiographs, which is subjective in nature and intractable during the first several weeks of healing due to the delayed timeframe of radiographically visible mineralization. In contrast, bending measurements can provide a direct objective measurement of fracture stability that is sensitive to soft callus formation during the acute healing phase.

Methods: In this study, a direct electromagnetic coupling (DEC) sensing system, which measures bending compliance, was evaluated in an exploratory observational study of diaphyseal tibial fracture patients. Longitudinal measurements were obtained from five patients at their clinical visits and remotely from 14 patients in their homes.

Results: The DEC bending data satisfied repeatability criteria of less than 10 % precision error in 12 of 14 remote patients. As expected, bending compliance decreased with time for 17 of 18 fractures that resulted in union. One fracture resulted in non-union, and the corresponding bending compliance increased with time. The bending compliance rate of change, determined as early as 4 weeks post-injury, detected significant differences between patients with and without non-steroidal anti-inflammatory drug (NSAID) use and between patients with and without co-morbidities.

Conclusions: These results demonstrated the feasibility of remote bending measurements using DEC, which provide a precise metric of early fracture healing rate that may be invaluable for clinical patient management and as an outcome measure in clinical research.

Introduction

Monitoring bone healing progress is critical for the determination of successful bony union in fractures. Identifying non-unions is necessary to guide clinical decision-making for conducting revision surgeries or other secondary interventions to promote bony union. There is no gold standard for determining healing, but typical fracture care relies primarily on radiographic evidence to determine healing progress, and clinical information such as patient pain or manual palpation of the healing site may provide additional evidence [1,2]. However, two-dimensional radiographs and clinical information are subjective in nature and can be challenging to interpret [1,2]. Radiographic evaluations lack adequate sensitivity and specificity for determining clinical healing outcomes for the first 12 weeks post-injury due to the paucity of visible mineralized tissue during soft callus formation [3].

Mechanical loading methods to monitor bone healing are sensitive to earlier changes in the healing callus compared to radiographs due to the measurable changes in mechanical stiffness during soft callus formation. The phenomenon of early mechanical changes at the fracture site has been consistently demonstrated through computational simulations [4,

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5], large animal studies of bone healing [6–9], and clinical research studies using mechanical measurement devices [10–17].

Devices for mechanically monitoring healing have potential utility in clinical patient management. For example, return-to-weightbearing decisions based on external fixator load sharing resulted in earlier weightbearing and fewer re-fractures compared to standard clinical methods [12]. Mechanical measurements could also provide an indication for interventions, such as bone grafting or osteobiologics, to promote bone healing. These interventions are not often used in clinical fracture care due to a lack of definitive indications for their use, a limited understanding of their efficacy, and high costs [18,19]. Mechanical methods of monitoring healing have the potential to identify individuals early in the healing process who are at high risk of non-union, which may facilitate a more targeted and effective use of acute therapeutics to treat challenging fractures.

Mechanical measurements of healing can also be useful for clinical research purposes. There is no clear consensus for standardized outcome measures for comparison of treatments in clinical fracture repair trials [18]. Clinical research studies on bone healing currently assess study groups based on (1) radiographic measurements, which have poor sensitivity and specificity at early timepoints, and (2) clinical healing outcomes, which are heavily skewed to successful healing [1]. As a consequence, large sample sizes are required, and study durations are long. Longitudinal mechanical measurements of healing could provide an early measurement of healing rate, which could improve the feasibility and statistical power of clinical bone healing research.

Despite these advantages, current methods and devices for mechanically monitoring bone healing have not been adopted for widespread use. Previously used external measurement devices can be bulky and intricate to use, requiring clinical space, personnel expertise, and time to perform measurements during patient visits [10,13,15,17]. Implantable monitoring devices have the advantage of providing continuous remote measurements, producing a lower clinical burden and providing more data [16,20,21]. However, these implantable devices are compatible only with the fixation implants they are designed for, and they would raise the cost of the original fixation surgery.

To address these shortcomings, we have developed direct electromagnetic coupling (DEC) technology, which is external to the body and compatible with any method of fracture fixation. We integrated this technology into a device that patients can use themselves to continuously and remotely monitor the healing progress. DEC utilizes an external radio-frequency antenna to electromagnetically couple with the fractured bone, metal implant, and surrounding tissue and measure deflections of the bone-implant construct due to an applied load. The theoretical foundations of the DEC technology have been previously established [22,23], and the technique of using DEC to detect changes in fracture site compliance have been verified using in vitro, *in silico*, and in vivo animal models using plate and intramedullary nail fixation [4–7].

The purpose of this study was to assess the feasibility and efficacy of using DEC to monitor healing in a clinical fracture cohort. An exploratory observational study was completed on 18 patients with diaphyseal tibial fractures and intramedullary nail fixation. Diaphyseal tibial fractures are clinically challenging and return a relatively high non-union rate, reported to be 10–12 % [24,25]. Thus, diaphyseal tibial fractures represent an excellent evaluation platform for an initial clinical assessment of DEC.

Materials and methods

Study design

A total of 19 patients were enrolled in the study. A sample size of 16 was targeted based on power analysis of proportion statistics to assess DEC success rates of device usage and data variance. Longitudinal bending measurements of the fractures were obtained using the DEC measurement device. Five patients were enrolled in an *in-clinic* phase of the study in which measurements were acquired with the assistance of research personnel at the patients' standard clinical follow-up visits. Following the *in-clinic* phase, 14 patients were enrolled in a *remote monitoring* phase of the study, in which patients used the DEC device independently to collect bending measurements daily in their home from 2-weeks to 8-weeks post-injury. The *in-clinic* phase provided an opportunity to confirm the ability of fracture patients to position their leg into the device and operate it without assistance prior to implementation of the *remote monitoring* phase of the study. Successful DEC data collection was defined *a priori* as completion of data collection through the study period and a precision error of less than 10 %. Patient data failing to meet these prospective success criteria were excluded from subsequent analyses. Clinical healing outcomes and radiographic grading data were collected for comparison to DEC results. All study endpoints and data collection processes were prospectively determined. For this exploratory observational study, the standard of care was not altered for the patients. One patient was lost to follow-up in the *in-clinic* phase.

This study was conducted with approval from the Colorado Multiple Institutional Review Board under protocol number 19–3107. Patients presenting to a regional network of hospitals with diaphyseal tibial fractures and receiving intramedullary nail fixation were included for participation. Patients were screened and excluded if under 18 years of age, treated with more than one implant on the study extremity, unable to complete follow-up visits, classified as a special population such as prisoners, women who were pregnant, patients whose fractures were due to advanced pathology such as bone cancer, patients undergoing surgery for revision for malunion or infection, patients with a pacemaker, or patients experiencing homelessness or are otherwise unable to provide access to electricity for powering the DEC measurement device. The nature of the study and possible consequences were explained to all participants, and informed consent for study participation was acquired.

Direct electromagnetic coupling measurement device and data collection

The DEC measurement device consisted of a lower frame for positioning the patient's leg and an upper frame that opened on a hinge to allow the patient to lift their leg in and out of the device (Fig. 1A). The lower frame included a contoured leg-rest and foot-rest with adjustable placement to provide for precise and consistent positioning of the fractured leg in the device. The upper frame hinged closed and latched in place for the measurement (Fig. 1B). Within the upper frame were two outer loading points which were positioned to rest on the anterior aspect of the patient's tibia (Fig. 1C). A DEC antenna was used to measure bending deflections in the central region between the loading points, and two linear variable differential transformer (LVDT) displacement sensors contacted the leg to measure deflections adjacent to the outer loading points. A lower loading point within the center of the leg-rest was driven by a motor to apply load in a three-point bending configuration. A force transducer attached to the lower loading point measured the applied load. Three-point bending was utilized instead of four-point bending to simplify the device for more reliable loading and to maximize bending relative to the applied load. Bending moments were calculated at the fracture location, determined radiographically, to account for varying fracture locations.

A vector network analyzer within the device powered the DEC antenna and measured the S_{11} parameter, a measurement of the reflected power, over the range of 1600 to 2000 MHz. The application of the bending load caused a deflection of the fractured leg toward the antenna (Fig. 1D). This deflection was detected as a shift in the S_{11} parameter due to electromagnetic near field effects (Fig. 1E) [22]. Through a calibration procedure in which the antenna was moved a known displacement relative to the fractured leg, the S_{11} signal was converted to bending deflection [23]. The bending angle was calculated from the deflection measured by DEC antenna relative to the LVDTs, and the bending compliance was calculated as the slope of the bending angle-bending

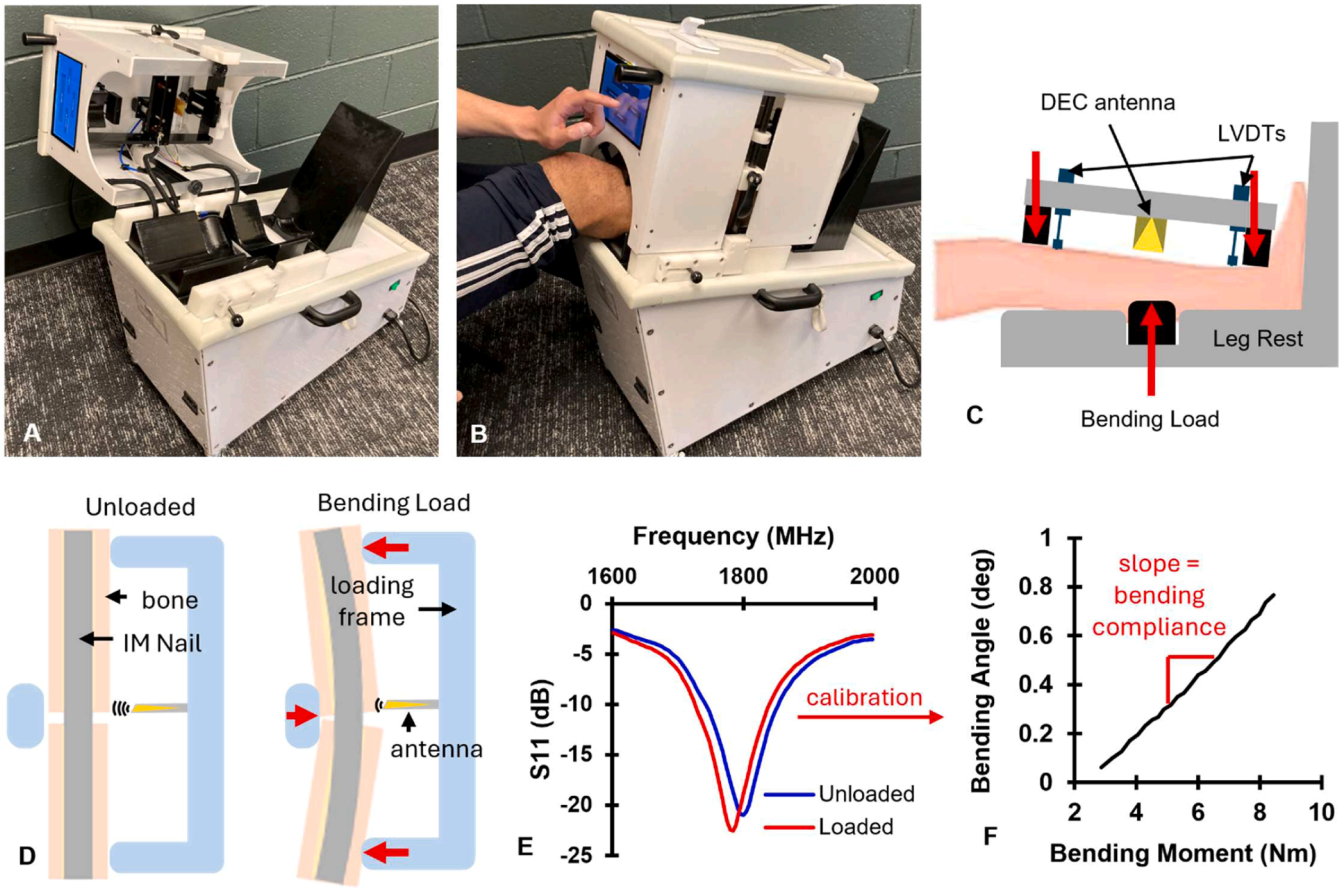


Fig. 1. DEC Remote monitoring device. (A) Schematic drawing demonstrating the use of DEC in three-point bending to measure bending deflections. (B) The bending deflection produces a shift in the DEC antenna's raw frequency versus S11 curve. (C) By calibrating the raw antenna data via an application of a standardized displacement, the bending angle is produced, and the bending compliance is calculated as the slope of the bending angle versus bending moment curve. (D) The DEC remote monitoring device opens on a hinge to a seated fracture patient to place the fractured tibia on the device. (E) The upper frame of the device closes over the fracture tibia for measurements. The device is operated by the patient through a simple touchscreen interface. (F) The functional structure of the device is shown. Three-point bending is applied to the fractured tibia, and a central DEC antenna measures bending deflections while 2 linear variable differential transformers (LVDTs) are used for additional displacement measurements near the outer loading points.

moment curve (Fig. 1F).

The measurement process was initiated by a user-controlled touchscreen interface. Computing hardware and software within the device automated the load application and data collection from the sensors. Each measurement consisted of five cycles of loading up to 80 N and unloading to 30 N applied at the lower loading point, which equated to a maximum bending moment of 11.8 Nm at the central span. Individual loading cycles were disregarded if the data exhibited artifacts due to patient movement, but all tests included at least three valid cycles. The calibration procedure immediately followed the load application. Following data collection, the deidentified data files were uploaded to a secure network server via wireless internet connection (Wi-Fi). The data files were accessed by the research team for compilation and analysis. Due to the exploratory nature of the study, the DEC data were not shared with the patients or their attending physicians.

Multiple displacement sensors were required for calculating bending angle because the soft tissue displacement at the loading points could cause an artifact in the deflection measurement of the DEC antenna. Therefore, LVDTs were included as additional sensors to correct this artifact, which was typically in the range of 0.5 to 2 mm. Following the initiation of this study, a multi-antenna DEC system was developed which eliminates the need for LVDT displacement sensors and improved the repeatability of the measurement system in cadaveric testing. This multi-antenna DEC system has also been implemented effectively in a large animal bone healing study [6].

Clinical data collection

Clinical data collection included the implant type and size, Müller AO fracture classification [26], comorbidities (obesity, diabetes, smoking, peripheral vascular disease, immunosuppression), NSAID use, BMI, and clinically-determined outcomes (non-union: requiring revision surgery, or union: no revision surgery). Weekly telephone interviews with patients were conducted to assess patient pain or any issues using the DEC measurement device.

Biplanar radiographs were collected from the patients' regular clinical follow-up examinations. Radiographs were evaluated following the semi-quantitative radiographic union scale in tibia (RUST) scoring system [27,28] by a single reviewer (JD) blinded to all other clinical and DEC data. Briefly, each of the four visible cortices in biplanar radiographs was assigned a score of 1 (visible fracture line without callus), 2 (visible fracture line with callus), or 3 (no fracture line with callus), and the four cortical scores were added for a total score ranging from 4 to 12.

Statistical analysis

The precision error, i.e. repeatability, of the raw bending compliance data was assessed as the mean of the absolute value of the residual error of spline-fitted compliance-time curves relative to the magnitude of the bending compliance, using a cubic smoothing spline (MATLAB function *csaps*, smoothing parameter = 0.8, MathWorks, Natick, MA, USA).

Precision error was not calculated for the *in*-clinic patients due to the limited time points. For each patient, the bending compliance rate of change was determined as the slope (mean and 95 % confidence interval) of the raw bending compliance versus time curve via linear regression. Correlations between DEC results and RUST scores, nail diameter, or BMI were assessed via linear regression with $\alpha = 0.05$. A one-way ANOVA was used to analyze potential differences in DEC results between Müller fracture classification categories with $\alpha = 0.05$. Two-sided Welch's *t*-tests with $\alpha = 0.05$ were used to analyze differences in DEC results between patients with and without co-morbidities, between patients with and without NSAID usage, and between sexes. Proportion tests used the Wilson/Brown method to calculate 95 % confidence intervals. All statistical analyses were conducted using Prism 10.2 (GraphPad, Boston, MA)

Results

Twelve males and seven females were enrolled. Fifteen patients identified their ethnicity as white non-Hispanic, two as Hispanic, one as Pacific Islander, and one as other. All patients were reamed and implanted with titanium interlocking intramedullary nails ranging from 8 mm to 13 mm diameters.

Bending measurements using direct electromagnetic coupling (DEC)

Study participants in the *remote monitoring* phase were instructed to use the DEC device every day for a 6-week period. All 14 patients used the device at least 2 days each week, and the mean and standard deviation of device usage was 6.1 ± 0.8 days per week. No patients reported pain or discomfort when using the device.

Among *remote monitoring* phase patients, the precision error of the bending compliance data was 6.4 % ± 8.1 % (mean and standard deviation). The bending compliance data from two patients, with precision errors of 20 % and 29 %, exceeded the acceptable threshold of 10 % and were excluded from subsequent analyses. The data from the remaining 12 patients exhibited a mean precision error of 3.3 % (range 1.8 % to 7.1 %). Thus, 86 % (95 % confidence interval of 60–97 %) of *remote monitoring* patients exhibited acceptable precision error enabling adequate analysis of the bending compliance data.

In the *in-clinic* phase, three fractures resulted in successful union, one fracture resulted in non-union requiring a revision surgery 6-months post-injury, and one patient was lost to follow up. In the *remote monitoring* phase, all 14 patients experienced successful union of their fractures. The fractures that resulted in union typically exhibited a trend of decreasing bending compliance over time as measured using DEC (Fig. 2), as expected for a developing callus which increases stability at the fracture site. The decrease in bending compliance corresponded to an increase in RUST scores over time (Fig. 2). However, at 6-weeks, all RUST scores except one were 8 or lower, indicating a visible callus at the fracture site but no osseous bridging across the fracture gap.

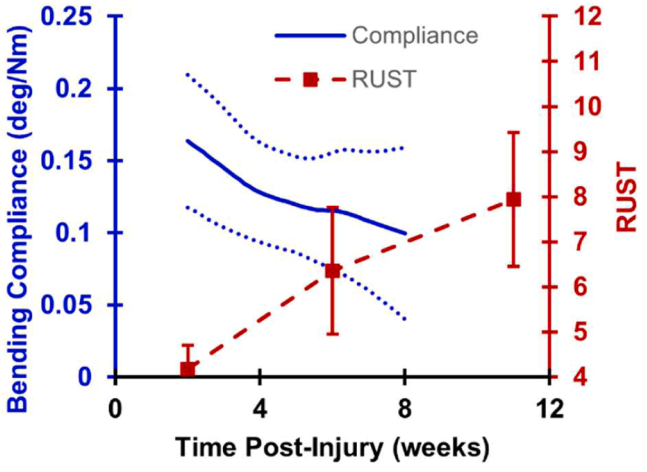


Fig. 2. Compiled bending compliance and RUST data. The longitudinal bending compliance and RUST data are summarized (mean and standard deviation) for all patients with clinical union from the remote monitoring phase of the study.

The temporal bending compliance curves exhibited a wide range of profiles. Qualitatively, among the *remote monitoring* patients, six fractures exhibited a sharp decrease in compliance over the first several weeks followed by a plateau (Fig. 3A), seven fractures exhibited a gradual decrease in compliance over the 2- to 8-week period (Fig. 3B), and one fracture unexpectedly exhibited an increase in compliance despite successfully healing (Fig. 3C). The fracture that resulted in non-union exhibited slightly increasing compliance over a 22-week follow-up period, as expected for a fracture with a failed healing response (Fig. 3D). Radiographs from all patients are available in the supplementary material (Figures S1-S18).

The rate of change of bending compliance was measured as the slope of linear regressions of the temporal DEC curves from *remote monitoring* patients (Fig. 4A). The compliance rate of change was measured from 2- to 4-weeks (4-week rate), 2- to 6-weeks (6-week rate) and 2- to 8-weeks (8-week rate). The rates of change were typically negative due to the decreasing compliance (i.e. increasing stiffness). The rate of change magnitude of the 4-week rate was greatest, followed by the 6-week rate and the 8-week rate (Fig. 4B-C). This trend was consistent with the shape of many compliance curves showing an early sharp drop in compliance followed by a plateau (e.g. Fig. 3A). In addition to the magnitude of the measured compliance rate of change decreasing over time, the 95 % confidence interval width also decreased over time because more datum points were obtained by the later time points, producing greater confidence in the measured slope. The ratio of the 95 % confidence interval to the magnitude of the compliance rate of change slope can be an overall indicator of how well the DEC data captured the healing rate. On average, this ratio was relatively constant at 44–45 % across the 4-week, 6-week, and 8-week measurements (Fig. 4C).

Radiographic evaluations of fracture healing

The RUST scores ranged from 4 to 9 for fractures that resulted in clinical union at 6 ± 1 weeks post-injury (Fig. 5A) and ranged from 5 to 10 at 11 ± 2 weeks post-injury (Fig. 5B). The fracture that resulted in non-union exhibited a RUST score of 4 at 2-, 6-, and 12-weeks and a score of 5 at 22-weeks.

There were no statistically significant correlations of the DEC-measured compliance rate of change at 4-weeks, 6-weeks, or 8-weeks to the RUST scores at 6-weeks or 11-weeks (Fig. 6). The strongest correlation was between DEC at 8-weeks and RUST at 11-weeks, with $R^2 = 0.24$ and $p = 0.07$ (Fig. 6F).

Clinical and device-use data

A summary of all DEC measurement results and clinical data collection are shown in Table 1. The fractures in this study were classified in the Müller AO system with 8 simple spiral, 1 simple oblique, 5 simple transverse, 2 wedge spiral, 1 wedge bending, and 2 complex irregular fractures. The fracture that resulted in non-union was a complex irregular fracture. There were no significant differences in DEC results between Müller AO fracture classification types ($p = 0.70$–0.84, Supplementary Figure S19). The initial magnitude of bending compliance showed a weak and non-significant trend of decreasing bending with increasing intramedullary nail diameter ($R^2 = 0.08$, $p = 0.28$, Supplementary Figure S20). There were no significant correlations of DEC compliance rate of change results with the intramedullary nail diameter ($p = 0.60$–0.76, Supplementary Figure S20).

The mean compliance rate of change was significantly lower in

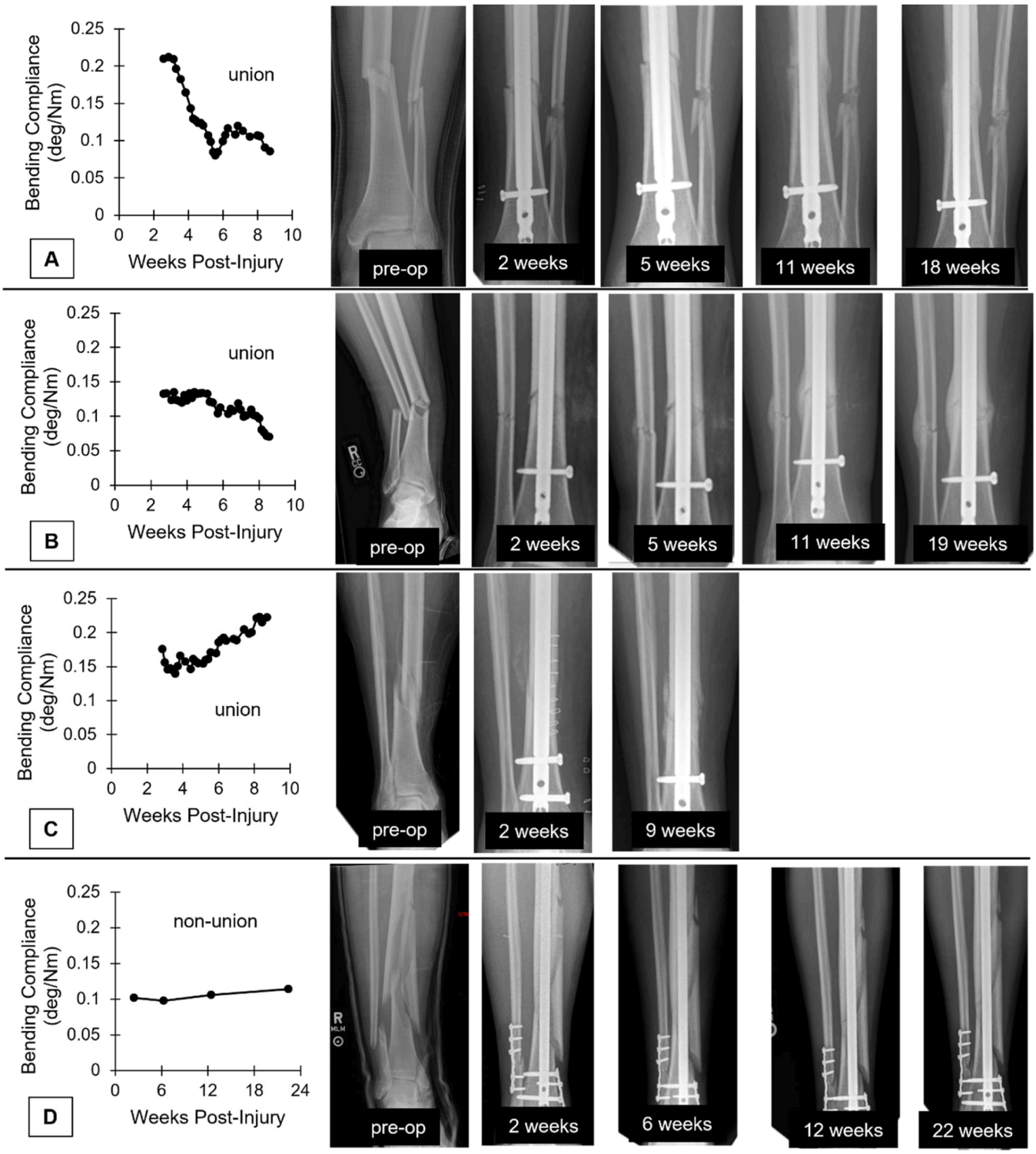
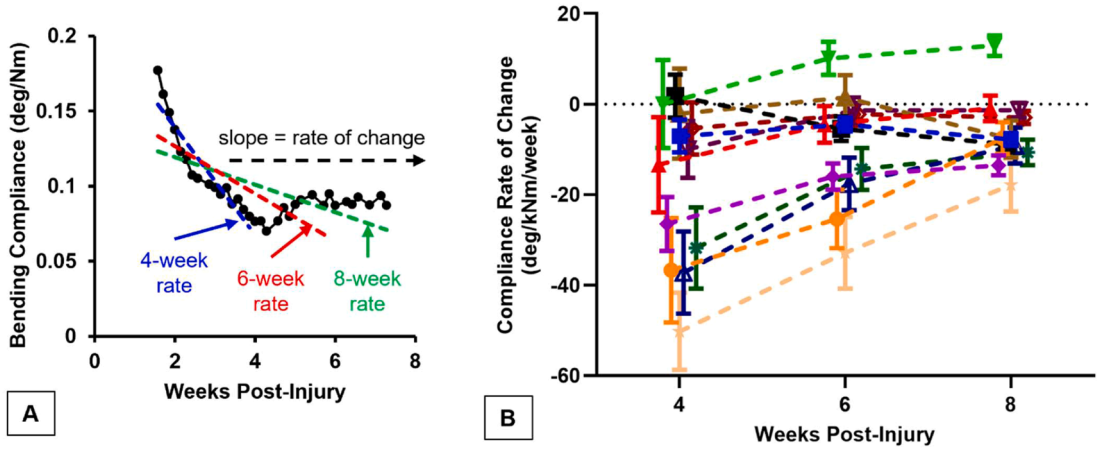


Fig. 3. Example DEC bending compliance curves and radiographs. Various temporal profiles of bending compliance are shown with corresponding longitudinal radiographs of the fractures. (A) Example compliance curve showing a sharp decrease during the first several weeks followed by a plateau. Five additional remote patients exhibited curves with similar trends. (B) Example compliance curve showing a slow gradual decrease. Six additional remote patients exhibited curves with similar trends. (C) Example compliance curve from the only patient with clinical union that exhibited an increase in compliance over time. (D) Example compliance curve from the only patient with clinical non-union. Data from this patient were only collected at regular clinical follow-up.

magnitude for patients with at least one co-morbidity, including smoking, obesity, and diabetes, for rates measured at 4-weeks ($\boldsymbol{p = 0.03}$) and 6-weeks ($\boldsymbol{p = 0.02}$) but not at 8-weeks ($p = 0.12$) (Supplementary Figure S21). Also, the mean compliance rate of change was significantly lower in magnitude for patients taking non-steroidal anti-inflammatory drugs (NSAIDs) for rates measured at 6-weeks ($\boldsymbol{p = 0.04}$) and 8-weeks ($\boldsymbol{p = 0.01}$) but not at 4-weeks ($p = 0.54$) (Supplementary Figure S22). There were no significant correlations between DEC data and body mass index (BMI, $p = 0.17$–0.27, Supplementary Figure S23) or sex ($p = 0.89$–0.96, Supplementary Figure S24).



C

	Compliance Rate of Change Slope [deg/kNm/week] Mean *(S.D.)*	95% C.I. Half-Width [deg/kNm/week] Mean *(S.D.)*	95% C.I. / Slope (%)
4-weeks	-18 *(17)*	7.9 *(2.5)*	44%
6-weeks	-9.4 *(12)*	4.2 *(1.9)*	45%
8-weeks	-6.3 *(7.7)*	2.8 *(1.3)*	44%

C.I. = Confidence Interval, S.D. = Standard Deviation

Fig. 4. Bending compliance rate of change. (A) The raw bending compliance data are shown from an example patient. The bending compliance rate of change was determined as the slope of the curve via linear regressions up to 4-weeks, 6-weeks, and 8-weeks. Due to the non-linearity of the curves, the slopes typically decreased from 4 to 8 weeks. (B) The bending compliance rates of change (slope and 95 % confidence interval from the linear regression) are shown for each remote monitoring patient determined at 4-weeks, 6-weeks, and 8-weeks. Each color represents an individual patient. (C) The bending compliance rate of change of all remote monitoring patients is summarized to show the means and standard deviations of the slopes and 95 % confidence intervals.

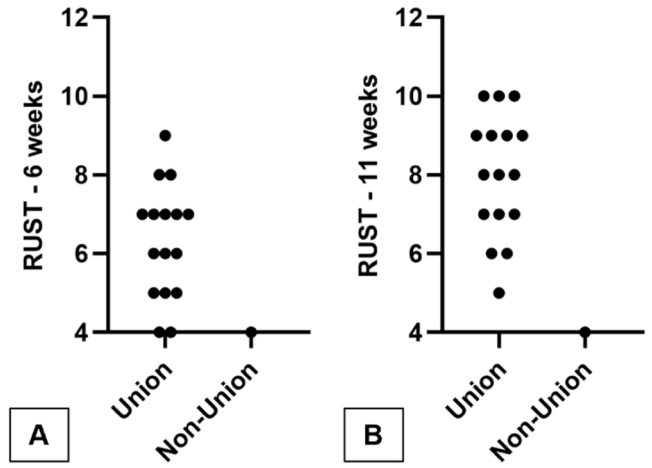


Fig. 5. Radiographic scoring results. (A) RUST scores at 6 ± 1 weeks for all patients separated by clinical outcome. (B) At 11±2 weeks, RUST scores showed greater separation between patients with clinical union and the patient with non-union.

Discussion and conclusions

Feasibility and efficacy of DEC for monitoring fracture healing

The goal of this study was to assess the feasibility and efficacy of the DEC system to remotely monitor fracture healing in an exploratory observational cohort of diaphyseal tibial fractures. DEC device usage and data collection were successful in all *remote monitoring* patients, and the collected bending data met quality standards of low precision error in 12 out of 14 patients monitored, demonstrating feasibility of the remote DEC system. Further, the DEC system effectively monitored temporal changes in the bending compliance of the fractured tibiae. The DEC data from fractures that healed consistently exhibited decreasing bending compliance over time, with the exception of just one fracture. This trend of decreasing compliance was the expected result to demonstrate the increasing mechanical stability associated with successfully healing fractures and was consistent with previous studies in which fractures were monitored via mechanical methods [6–17]. The DEC data collected from the fracture with non-union, which showed a relatively unchanging bending behavior over time, demonstrated the potential for the DEC system to distinguish non-union from union healing pathways.

The rate of change of bending compliance was more useful for monitoring healing compared to the magnitude of bending compliance, which was highly variable between patients and may depend on many variables, including implant size, screw configuration, anatomic dimensions, and bone quality. The 95 % confidence intervals on the bending compliance rate of change data were consistently lower than their magnitudes (Fig. 4), demonstrating high confidence in the overall temporal trends of compliance for each patient on an individual basis. However, the timeframe in which the temporal trend of bending compliance could be determined was variable between patients. For fractures that exhibited dramatic decreases in compliance indicative of rapid healing such as in Fig. 3A, there was high confidence in a decreasing compliance trend (negative rate of change) as early as 4-weeks post-injury (Fig. 4B). For fractures that showed more gradual changes, such as in Fig. 3B, the temporal changes in compliance were not clear until 6-weeks or 8-weeks post-injury (Fig. 4B). These results indicate that mechanical bending measurements may be effective at identifying patients during the acute healing phase whose fractures are on a pathway to rapid healing. However, distinguishing non-union healing pathways from slow healing or delayed union may be challenging during the acute timeframe.

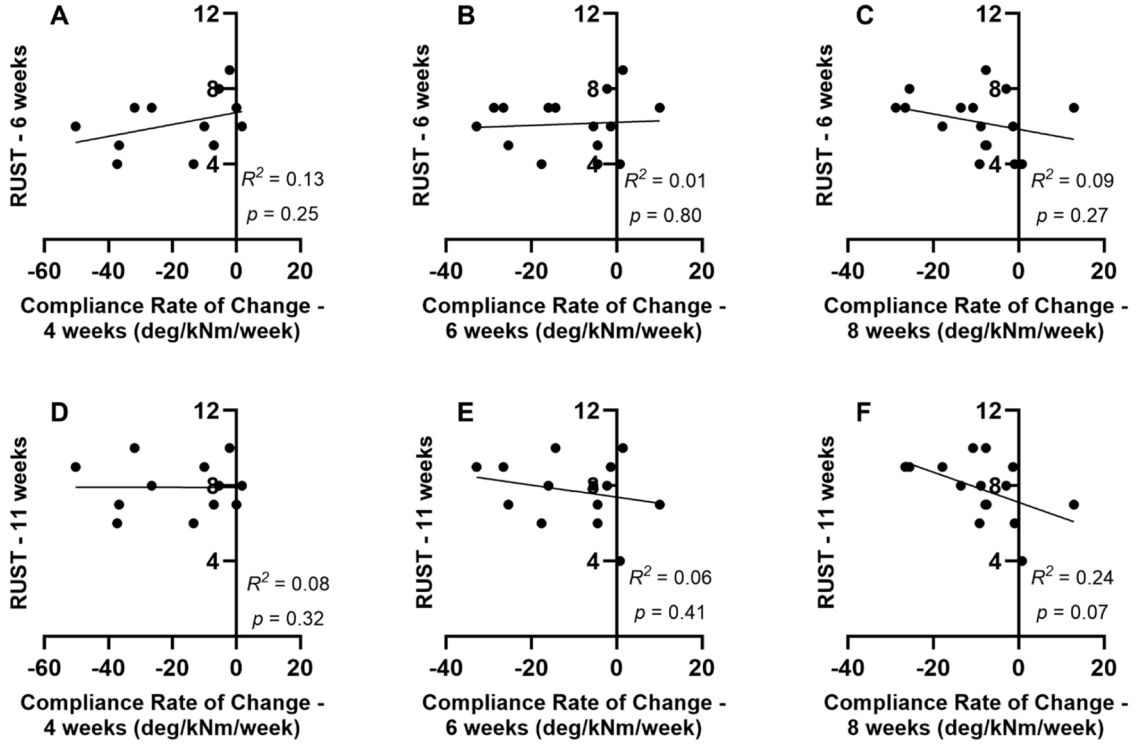


Fig. 6. Linear regression results correlating DEC data to radiographic scoring. Data were included from all in clinic and remote monitoring patients with union or non-union clinical outcomes. No statistically significant correlations were found ($\alpha = 0.05$). (A) Compliance rate of change at 4-weeks versus RUST at 6 ± 1 weeks, (B) Compliance rate of change at 6-weeks versus RUST at 6 ± 1 weeks, (C) Compliance rate of change at 8-weeks versus RUST at 6 ± 1 weeks, (D) Compliance rate of change at 4-weeks versus RUST at 11 ± 2 weeks, (E) Compliance rate of change at 6-weeks versus RUST at 11 ± 2 weeks, (F) Compliance rate of change at 8-weeks versus RUST at 11 ± 2 weeks.

Table 1
Full study data by patient. Full study data are presented including DEC results, RUST scores, and clinical data.

				DEC: Compliance Rate of Change (deg/kNm/week)											
Patient ID	Study phase	Clinical outcome	DEC Precision Error (%)	4-week	6-week	8-week	RUST at 6 ± 1 weeks	RUST at 11 ±2 weeks	Additional RUST score (weeks)	Nail Dia. (mm)	Müller Class.	Co-morbidities	NSAIDs	BMI	Gender
R01	remote	union	1.8	−7.1	−4.5	−7.8	5	7	8 (23)	12	A3	smoker	no	22.3	M
R02	remote	union	29.4				5	5		13	A1	obesity, smoker	no	29.8	M
R03	remote	union	4.3	−13	−4.5	−1.0	4	6		12	A1	none	yes	24.8	M
R04	remote	union	20.2					10		9	A1	smoker	no	29.8	F
R05	remote	union	3.7	0.026	10	13		7		10	A1	obesity, diabetes	yes	40.7	F
R06	remote	union	3.0	−27	−16	−14	7	8		10	A3	none	no	29.9	M
R07	remote	union	2.5	−37	−25	−7.5	5	7		10	A1	none	yes	25.9	M
R08	remote	union	3.7	1.8	−5.4	−8.9	6	8	8 (19)	9	A3	none	yes	31.2	M
R09	remote	union	7.1	−2.1	1.4	−7.7	9	10	11 (23)	13	A1	smoker	yes	33.7	M
R10	remote	union	2.3	−37	−18	−9.2	4	6		10	A1	none	no	23.6	F
R11	remote	union	4.0	−10	−1.4	−1.4	6	9	9 (27)	10	B1	none	yes	24.6	M
R12	remote	union	2.1	−5.4	−2.2	−3.0	8	8		8	A1	none	yes	37.6	F
R13	remote	union	2.7	−32	−14	−11	7	10		8	C3	none	yes	32.7	F
R14	remote	union	2.7	−50	−33	−18	6	9	9 (18)	11	A3	none	yes	28.5	M
C01	in clinic	union			−27	−27	7	9		9	B2	none	no	25.8	F
C02	in clinic	union			−26	−26	8	9		9	A2	none	no	27.5	F
C03	in clinic	non-union			0.80	0.80	4	4	5 (22)	10	C3	diabetes	yes	25.8	M
C04	in clinic	union			−29	−29	7			11	A3	none	no	30.6	M

Bending stiffness or compliance measurements are useful for demonstrating progress toward union during the acute phase of healing but may lack specificity for determining when a fracture is fully healed and consolidated. Bending measurements in an ovine healing model have demonstrated strong correlations between bending stiffness and strength at relatively low stiffness values (during early healing as the callus is developing), but at high stiffness magnitudes, it was a poor predictor of strength, as immature woven bone can exhibit similar stiffness but lower strength compared to mature lamellar bone [29]. This agrees with computational simulations that have found stiffness measurements to be most sensitive to changes that occur during soft callus development as compared to hard callus development and bone remodeling [4,5]. Similarly, other studies have concluded that mechanical measurements of healing are more useful when assessing the relative change or temporal progress rather than the isolated magnitude of the measurement [10,29]. This highlights the benefit of a longitudinal remote monitoring approach to obtaining mechanical measurements of bone healing.

DEC and radiographic evaluations for patient care

Mechanical methods for monitoring fracture healing such as DEC may provide a useful supplement to typical radiographic assessments, and the two methods complement each other well. Mechanical methods may be most useful at determining healing rates during the acute healing phase and identifying patients exhibiting a robust early healing response. In contrast, radiographic assessments are unreliable and inaccurate during the early phase of healing. However, radiographic scoring can have high sensitivity and specificity for determining healing at later time points, such as 24-weeks [3]. Nevertheless, radiographs provide limited evidence as an imaging modality. Since the DEC method directly measures the structural stability of the healing fracture site, it is possible this type of measurement would provide a more targeted metric of clinical healing compared to radiographic assessments. By providing additional information during the early phase of healing, DEC measurements could provide reassurance for patients identified to be healing well. Further, DEC could be used to identify patients at risk of delayed healing or non-union, and this could provide an indication for early intervention to promote bony healing, such as bone grafting or the use of osteobiologics.

The results of bending measurements using DEC did not correlate with radiographic assessments in this study. A decreasing (negative) compliance rate of change measured using DEC and an increasing RUST score are both expected to be associated with a greater healing response; therefore, it would be logical for these two metrics to be inversely correlated. However, a strong correlation was not expected considering the limitations of radiographs and the results of prior clinical and animal studies which found radiographic assessments to correlate weakly with mechanical outcomes [30,31]. Although, a RUST score of 10 or greater is a strong indicator of mechanically defined healing [31–34]. The strongest (but not statistically significant) correlation between DEC and RUST in this study was found when using the latest available timepoints for both DEC and RUST (Fig. 6F). A larger sample size would provide more confidence in conclusions regarding correlations of DEC bending measurements to RUST scores or in comparing the two methods for their efficacy to inform on clinical healing.

DEC as an endpoint for clinical fracture healing research

The DEC system has potential utility as an endpoint in clinical fracture healing research by providing a metric of healing rate during the early healing time period. This potential was demonstrated, in concept, by the results of this study. The bending data measured using DEC revealed significant differences between patients with and without co-morbidities known to impair fracture healing and between patients with and without NSAID use. Co-morbidities were associated with a slower healing rate in this study, which is in agreement with prior studies showing impaired healing associated with smoking [35,36] and diabetes [35,36]. NSAID use was associated with a slower healing rate, which is also in agreement with recent studies [37–39]. Notably, the results of the current study demonstrate correlation but not causality, and this study was not designed to assess the effects of these co-morbidities or NSAID use. However, these results demonstrate the potential for DEC to be used to detect meaningful differences in healing rate between groups, even with a low sample size in this exploratory study. This could have a substantial impact on clinical fracture healing research, which currently lacks consensus on defined endpoints for assessing healing outcomes [1].

Study limitations

This study was limited to the assessment of diaphyseal tibial fractures. It is unknown how the results would translate to other fracture locations. The time frame of DEC data collection was limited at two to eight weeks post-injury for *remote monitoring* patients. It was assumed that this time frame would be most useful for assessing bending, but no long-term DEC data were collected to assess this method during the late stages of healing. Also, data were not collected during the first two weeks post-injury, which typically consists of inflammation and hematoma formation that is not expected to substantially affect mechanical compliance, with callus formation initiating after this stage. However, it is possible early mechanical changes were occurring in some patients which were not captured by the DEC data collection time frame. Finally, the conclusions that can be drawn from the study are limited by the small sample size of this exploratory study.

Clinical application of DEC

The results of the current study demonstrated feasibility of both in-clinic and remote measurements of tibial fracture bending using DEC, good repeatability of the measurements, and the efficacy to track changes in bending over time. Accordingly, the DEC technology could be applied as a study endpoint in clinical research studies related to bone healing. In order for the DEC technology to be applied in clinical patient care for the monitoring and/or determination of healing, further testing with a larger sample size is required to assess the clinical usefulness of this method. Further, stakeholder involvement in testing and use would be required to identify barriers to clinical translation.

Ethics statement

This study was conducted with approval from the Colorado Multiple Institutional Review Board under protocol number 19–3107. The nature of the study and possible consequences were explained to all participants, and informed consent for study participation was acquired. Research was conducted in accordance with the principles embodied in the Declaration of Helsinki and in accordance with local statutory requirements.

CRediT authorship contribution statement

Kevin M. Labus: Writing – review & editing, Writing – original draft, Visualization, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Julie Dunn:** Writing – review & editing, Supervision, Project administration, Methodology, Investigation, Funding acquisition, Data curation. **Milan Ilić:** Writing – review & editing, Validation, Methodology, Investigation, Conceptualization. **Branislav M. Notaroš:** Writing – review & editing, Supervision, Resources, Methodology, Investigation, Funding acquisition, Conceptualization. **Kirk C. McGilvray:** Writing – review & editing, Methodology, Investigation, Conceptualization. **Christian M. Puttlitz:** Writing – review & editing, Supervision,

Resources, Methodology, Investigation, Funding acquisition, Conceptualization.

Declaration of competing interest

KML, KCM, and CMP are co-inventors on patent: US 10,641,664, "Displacement and deformation monitoring method and system without using any strain sensor, and components thereof."

KML and CMP are co-inventors on patent: US 10,674,954, "Loading device for measuring stiffness of structural member over time, monitoring system, and method thereof."

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.injury.2025.112771.

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