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Load Monitoring System for Partial Weight Bearing Therapy for Rehabilitation of Lower Extremity Fractures

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Abstract— **Partial Weight Bearing Therapy (PWB) is used during in rehabilitation of lower-extremity fractures, but optimal outcomes are limited by the paucity of data supporting the current standard of care, the inability of clinicians to assess patients' compliance to the prescribed therapy, and by the patient's inability to apply clinical loading guidelines. To address these needs a Load Monitoring System (LMS) was developed using a novel long-term load measuring technology coupled with consumer electronics for storing and reporting of patient limb loading data. The project was planned as a staged effort and the results of the first stage development are presented here. During the first stage of this project, the LMS insole load sensor was developed for 6-week standalone operation. The LMS was subjected to bench-testing, demonstrating low static and dynamic drift.**

I. INTRODUCTION

The merging of consumer electronics and physiologic monitoring is transforming the field of healthcare. Current technology now provides clinicians and patients with real time feedback for evaluating pathologies from diabetes and cardiovascular disease to monitoring daily physical activity. The result is a paradigm shift in healthcare practices towards unbiased, evidence based care where patients are continuously monitored in order to improve the treatment process.

Our research group proposes to bring personalized physiologic monitoring to lower extremity fracture care through the development of a Load Monitoring System. Treatment of lower extremity fractures, such as the fractures of the tibia, is currently limited to immobilization and limb loading restrictions until bone healing is complete. [1] Limb loading is discouraged in order to prevent premature displacement of fractured segments. However, controlled loading is critical for proper bone healing as controlled levels of stress and strain are necessary to activate osteogenic cells and induce the creation of new bone and bone union. [2] Applying controlled loading to a fractured limb to accelerate healing is known as Partial Weight Bearing (PWB) therapy. Although PWB is the current standard of care for lower extremity fractures, PWB prescriptions are based on experience of the prescribing clinician and not on objective data. Additionally, the success of the PWB therapy is entirely dependent on patients' strict compliance with the prescribed loading regimen, to which clinicians have no means of assessing. Therefore an accurate, practical, and cost effective means of continuous limb load monitoring would enable data based therapy to improve lower extremity fracture outcomes.

Coupling such a load-monitoring technology with available electronic components for recording and reporting patient limb-loading would allow clinicians to monitor patient compliance and make appropriate interventions.

Previously our group presented a novel load-measuring technology that overcomes the current technological limitations in long term limb load monitoring.[3], [4] Long-term load-load monitoring is made possible by a micromachined piezoresistive pressure sensor (MPPS). MPPSs have high linearity, high strength, high mechanical repeatability, high stiffness, little to no hysteresis, and can be cycled almost indefinitely without failure. These properties coupled with their low cost and small size have made the MPPS sensor particularly well suited for this application. MPPS can be adapted for continuous force measurements by packaging in a constrained silicone gel. This novel approach to measuring force using a well understood, widely available and inexpensive sensor technology can meet the performance and cost requirements for continuous clinical measurements of patient limb loading.

The work presented here couples this novel long-term limb loading technology with consumer electronics to enable continuous patient limb-load monitoring and clinical feedback. The Load Monitoring System (LMS) presented here was designed for the specific application of PWB monitoring following tibial fracture rehabilitation. The LMS was developed in collaboration with the University of Utah Orthopaedic Center in Salt Lake City, UT. Our goal was to design the overall LMS sensor and signal conditioning circuitry and to evaluate the functional performance of the system on the bench through long term cycle testing. The results presented here verify important design specifications and represent an important milestone prior to clinical testing.

II. METHODS

A. *System functions*

The function of the LMS is to measure and store limb loading data during PWB therapy. Measured data is periodically retrieved and stored in the physician database, where it is available for review and interpretation. Target LMS specifications are listed in Table 1. The LMS comprises two modules (Figure 1):

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1. Insole Assembly (IA) module, which is a load-measuring portion of the LMS, located in the sole of a CAM walker. The IA load force is measured by 2 or 3 transducers, located in the heel and metatarsal positions. The transducers provide both analog sensor signal and digital data. Components of the IA include MPPS, integrated signal conditioners analog-to-digital converters, and analog instrumentation amplifiers.
2. Instrumentation module (IM) for collecting and storing load sensor data and performing control and supervisory functions, including: sampling, time and power management, and data storage in a removable SD card.

The major System Requirements are summarized in Table 1.

Table 1. Stage 1 System Requirements summary.

Record weight bearing (limb loading)	• Capture the amount of weight placed on limb from within standard CAM walkers as CAM walkers are used for limb immobilization during PWB therapy. • Operate in an external environment with fluctuations in temperature and humidity. • Record loading of 110N to 1110N with a max overload of 2224N.
Record temporal parameters of gait	• Record a time stamp with millisecond resolution in order to permit identification of rise and fall of loading events.
Accuracy	• Transducer accuracy must remain within ±5% of full scale over 6 weeks of continual use (6 weeks is the maximum time period between follow up visits during standard tibial fracture rehabilitation)
Direct clinical implementation	• Intuitive placement as an insole insert (less than 2 minutes to place in shoe). • Simple operation (less than 1 minute to start recording from device). • Pre-calibrated.
Transparent to patient	• 3-months of standalone battery and memory capabilities. • No interference with Activities of Daily Living (ADLs).
Convenient data retrieval	• Less than 2 min time of data upload from the LMS.
Cost effective	• Cost must not preclude large scale implementation of device.

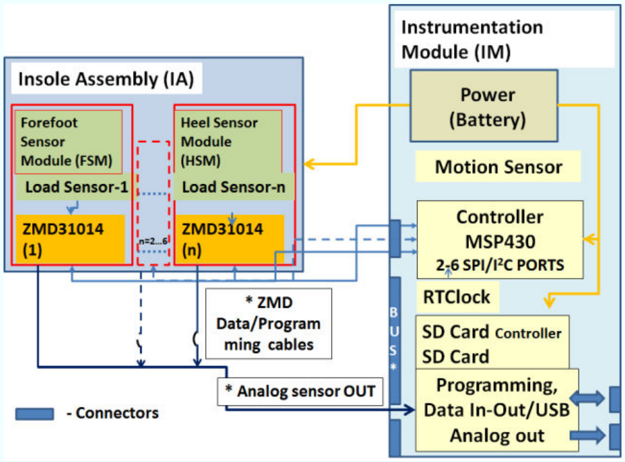

Figure 1. Functional block diagram of LMS

B. Insole Assembly (IA)

The IA contains the transducer assembly and sensor signal conditioning circuitry. The transducer assembly enables longer-term limb-load recording and the basic design of the load transducer using a micromachined silicon pressure sensor constrained in silicone gel has been discussed in detail in previous publications. [3], [4]

In order to achieve accuracy, reproducibility and long-term stability of load measurement, the MPPS has been integrated with a signal acquisition and conditioning circuit. The ZMD 31014 CMOS sensor signal conditioner with I2C output is a highly accurate amplification and 14-bit analog-to-digital conversion (ADC) circuit for the acquisition of differential bridge input signals with on the chip temperature compensation. [5] The ZMD 31014 provides on-chip digital compensation of signal offset, sensitivity, temperature drift and non-linearity via an internal correction algorithm with calibration coefficients stored in a non-volatile EEPROM. The circuit is individually addressable, allowing for the placement of multiple transducers on a common data/programming bus. Additionally, the prototype insole transducers are equipped with a micropower instrumentation amplifier (INA126) that provides direct access to the analog output of the transducer for development circuit optimization purposes. [6]

C. Instrumentation Module (IM)

The IM component collects, stores, and communicates limb-loading data collected from the IA. The design focuses on minimizing power consumption, maximizing the duration of data collection periods between battery changes, and minimizing size and weight, while maintaining small size and low cost of the module.

The IM comprises the following functional components.

Microcontroller module.

MSP430 microcontroller module provides programming, power management, data flow control, and real-time synchronization

Data collection.

The IM initializes data collection cycle by addressing individual IA transducer modules and establishing I2C communication with the ZMD devices. After the data uploading is completed, the processor samples the battery voltage and acquires the date and time stamp from the real time controller (RTC) chip, forms a data record and writes it into the SD flash memory. After the data collection cycle is completed, the microcontroller turns off the ZMD module and switches into sleep mode to conserve power, maintaining only active clock monitoring function.

Real Time Clock (RTC)

The IM uses an RTC module for maintaining date and time count during active part of the device lifecycle. The clock is powered by an on-board battery, and is initialized with current date/time during the IM programming at the end of the module assembly process.

Communication with a PC

The MSP430 uses a USB for programming and for transferring data for processing, storage and display, etc. This system is activated upon connecting the USB cable between each module and a PC. The USB is also used for necessary programming and performance (error) diagnostic tasks, as well as the initial clock synchronization and activation/programming of the ZMD signal conditioning and analog-to digital (ADC) conversion modules.

Data storage

A removable 8 GB SD card is used for data storage. In order to protect the card against tampering, the card is not accessible by the user without opening the IM case.

Power supply and management.

Both IA and IM modules are powered by a common 3.3 V Li ion battery (CR2054). Active power management by the MSP430 (duty cycle control) permits continuous system operation for up to 6 weeks of therapy. The power management module monitors battery status, controls charging and provide battery status information to the microcontroller.

IM placement.

The IM is placed externally to the load measurement transducer, usually on the tibial part of the cast.

D. Bench Testing

For continuous long-term limb-load monitoring the LMS needs to have low static and dynamic drift. Both static and dynamic drift were analyzed using a custom built load simulator. The load simulator has two steel plates (15.24x30.5x1.27 cm) seperated by threaded rods (1.27cm x 15.24cm) on the four corners. Anchored to the top plate are three single acting acting air cylinders (3.81cm bore size, McMaster-Carr). Plungers were machined to attach to the threaded rod of the air cylinder, plungers were machined from 1.27cm thick aluminum sheets to be 5.08cm diameter circles. The air cylinders were connected to a solenoid (McMaster-Carr) that was activated by a circuit containing: a 12V power supply, NPT transitor, and a NI-USB-6211 DAQ. The DAQ produced an anologue output to activate the solenoid as dictated by custom LabView VI's. An inhouse airs supply was connected to a filter/regulator (McMaster-Carr) then to the solenoid. The air cylinders were calibrated to coordinate the input pressure to output force. LMS IA components were anchored on the bottom plate and the hieght between the top of the sensor and the aluminum plunger was adjusted to 12.7 mm by changing the distance between the two steel plates. The analogue output from the IA was collected by the same DAQ that activate the solenoid which also powered the sensors with a 5V DC.

During static testing the loading protocol was as follows: ~ 350 N for 2, no load for 2 hours, ~ 425 N for 2 hours, no load for 2 hours. Output from the IA was collected at 2 Hz. During dynamic testing a load of 450 N was applied 100,000 times at 2 Hz while the IA were sampled at 100 Hz. Data from the IA was saved to text files and the percent of full scale (450N) drift was calculated using both MATLAB and Excel.

III. RESULTS AND DISCUSSION

A. LMS System Design

Figure 1. shows a block diagram of the LMS system including the IA and IM components. A study conducted by our group demonstrated that peak loading occurs in the heel and forefoot regions of the plantar surface[7]. Therefore force transducers were placed in the insole region of both the heel and the metartasal head, or forefoot, region. Figure 2 displays the insole insert outside and within a standard CAM walker. The LMS insole insert is easily incorporated into the standard CAM-walkers employed at the University of Utah. Figure 3 provides a schematic of the circuitry within both transducers showing the ZMD chip and anolgue amplifier. Notice, that due to ZMD addressability, a common data and programming bus can be used for signal and data transfer between the IA and the Instrumentation module.

Figure 2. Insole Assembly (IA) component of the LMS both as the insole insert and inserted within a standard CAM walker. In the image of the insole insert the two transducers located under the heel and metatarsal head region are visible.

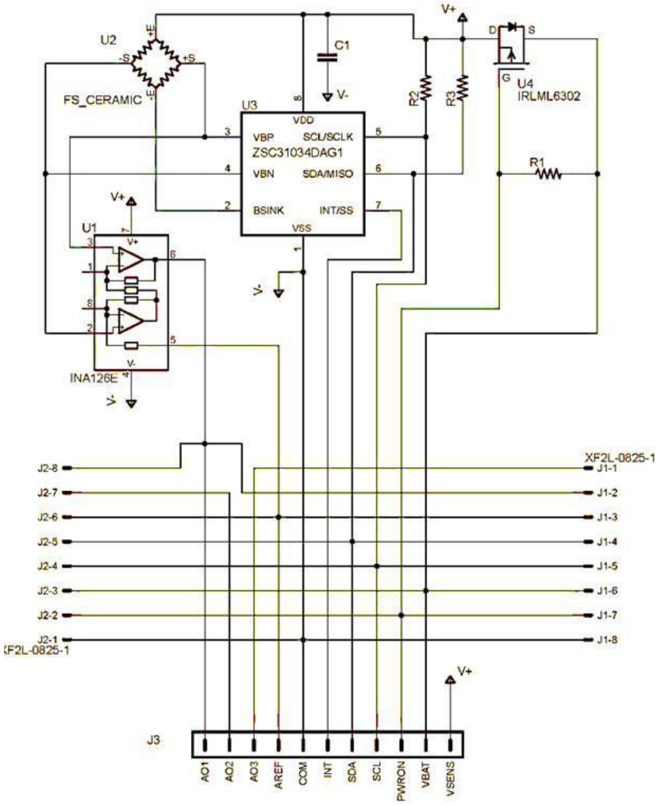

Figure 3. Schematic of circuitry for IA

B. Bench Testing

Static testing on the LMS had an overall full scale drift of 0.27%. The drift was greater for the loading conditions (average of 0.44(+0.50)for the 350N load and 0.55(+0.53)% for the 425N load) than for the unloading condition (0.04(+0.03)% and 0.05(+0.05)% respectively.) The maximum drift was observed 4.8% when the 450N was first applied which diminished quickly. Figure 4 shows the IA transducer output during testing. Dynamic testing on the LMS never exceeded 3% full scale drift. The static and dynamic tesing combined tests the LMS beyond what would be expected during PWB therapy for a 6 week period. Currently available insole monitoring system Pedar® demonstrated a 17% drift after 3 hours of dynamic loading [8] and an error of 34% after 7 hours of a static loading. [9] Another avaialble system, F-Scan demonstrated a 19% drift after 15 minutes of static loading. [10]

IV. CONCLUSION

To address the limitations in patient monitoring during PWB therapy we have developed a novel, inexpensive load sensing technology that is couple with consumer electronics to enable continuous limb load monitoring and clinical feedback. The developed LMS performed well during bench testing demonstrating low static and dynamic drift. The LMS system is easily incorporated into standard CAM walkers used during PWB therapy. The electronics within the LMS were designed for 6 weeks of standalone operation. Currently, clinicians have access to the limb-loading data via SD card during follow-up visits. The work presented was in preparation for use in patients with tibial fractures to produce data driven PWB therapy protocols.

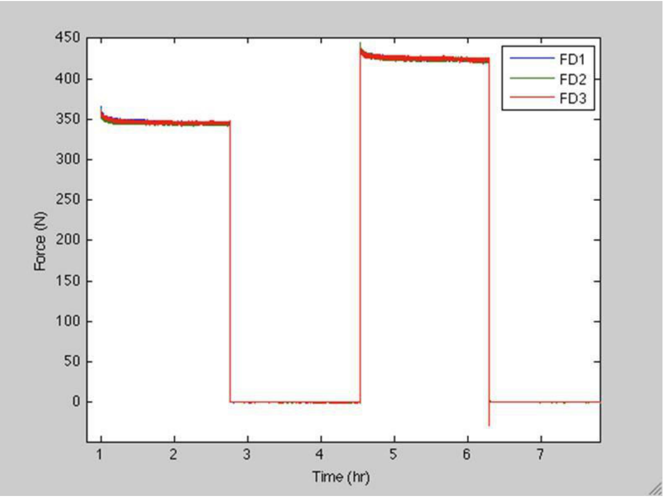

Figure 4. Load output recording during static drift testing. Maximum drift was 4.8% after a force of 425N was applied.

In the future we envision the LMS being used for all lower-extremity fracture care that rely on PWB therapy. Additionally, we plan to expand the technological capabilities of the reporting mechanism to enable on-demand access to limb-loading data to both clinicians and to the patients.

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REFERENCES

[1] C. N. Cornell and J. M. Lane, “Newest factors in fracture healing,” *Clin Orthop Relat Res*, no. 277, pp. 297–311, 1992.

[2] J.-H. Chen, C. Liu, L. You, and C. A. Simmons, “Boning up on Wolff’s Law: mechanical regulation of the cells that make and maintain bone,” *J Biomech*, vol. 43, no. 1, pp. 108–118, Jan. 2010.

[3] K. North, S. D. Maass, and R. W. Hitchcock, “An insole sensor for recording weight bearing behavior during tibial fracture rehabilitation,” *Conf Proc IEEE Eng Med Biol Soc*, p. 1856–9, 2010.

[4] K. North, E. N. Kubiak, and R. W. Hitchcock, “Sensor packaging design for continuous underfoot load monitoring,” *Biomed Microdevices*, vol. 14, no. 1, p. 217–24, Feb. 2012.

[5] “ZMD31014 Low-Cost Sensor Signal Conditioner, www.zmdi.com.”

[6] “Micropower Instrumentation Amplifier INA126, Texas Instruments Publ.#SBOS062A, Aug 2005.” .

[7] K. North, M. Q. Potter, E. N. Kubiak, S. J. M. Bamberg, and R. W. Hitchcock, “The effect of partial weight bearing in a walking boot on plantar pressure distribution and center of pressure,” *Gait & Posture*, vol. 36, no. 3, pp. 646–649, Jul. 2012.

[8] A. Arndt, “Correction for sensor creep in the evaluation of long-term plantar pressure data,” *J Biomech*, vol. 36, no. 12, p. 1813–7, 2003.

[9] H. L. Hurkmans, J. B. Bussmann, E. Benda, J. A. Verhaar, and H. J. Stam, “Accuracy and repeatability of the Pedar Mobile system in long-term vertical force measurements,” *Gait Posture*, vol. 23, no. 1, p. 118–25, 2006.

[10] J. Woodburn and P. Helliwell, “Observations on the F-Scan in-shoe pressure measuring system,” *Clin Biomech (Bristol, Avon)*, vol. 12, no. 3, p. S16, 1997.