BLUETOOTH ENABLED SYSTEM FOR IN VIVO MONITORING AND LOGGING OF BIOMECHANICAL LOADS IN EXTERNAL FIXATORS

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Abstract: External fixators are widely used for treatment of fractures, deformities and bone defects. Monitoring of the bone neoformation is routinely accomplished by X-ray examinations. Still the estimation of the mechanical callus properties and the identification of healing problems depend largely on the surgeon's expertise. Callus assessment by in-vivo measurements of biomechanical loads can lead to impartial therapeutic decisions as shown in several studies. A lightweight yet powerful monitoring and logging system for mechanical callus assessment has been developed and the adaptation to the Ilizarov ring fixator and the hexapod external fixator is shown; the system can easily be transferred to other modifications of external fixators. The system consists of two parts, a control unit and force sensors with embedded signal processing capabilities. The control unit is equipped with a FLASH memory and a Bluetooth wireless data link for cable-free and telemedical application. The system has been successfully applied to clinical long term monitoring of distraction osteogenesis. The adaptation of the current system to the hexapod external fixator serves as base for the development of a medical robot fixed to the patient's extremity for optimized clinical, self-sufficient ambulatory or telemedicinally controlled fracture treatment.

Introduction

External fixation is a commonly used technique for stabilizing bone fragments in fracture fixation and distraction osteogenesis. A number of different systems that differ largely in size, material and geometry according to their purpose are currently in clinical use. Radiographic examinations are most suited to allow for an exact reduction of the fracture yet only form and intensity of callus calcification are accessible directly. However, therapeutic decisions during the course of healing are mainly determined by the mechanical properties of the osteosynthesis, which are estimated from radiological images; this method depends largely on the surgeon's expertise and is prone to inaccuracy.

Numerous studies show that in vivo measurements of the biomechanical loads acting on the callus provide means to assess significant mechanical properties that can be used to control the distraction osteogenesis and osteosynthesis [1-10]. The analysis of various assemblies of fixators and modes of measurement including torsion stiffness, bending stiffness and measurement of traction force shows that results obtained from callus assessment by mechanical measurements are superior or comparable to the radiographic determination of callus properties while the radiation exposure is minimized.

Despite its benefits, the application of in vivo measurements for mechanical callus assessment is still limited mainly to clinical studies and is not yet part of clinical routine.

Therefore the task was to develop a system for monitoring fracture healing by mechanical callus assessment that is suitable to become standard practice during treatment with external fixators. The system consists of force transducers and a control unit that should be adaptable to different fixator geometries and mechanisms of distraction. Furthermore, easy use and maintainance by the surgeon as well as the patient and the ability to supervise the full course of healing are mandatory.

Materials and Methods

The system consists of two main parts, the control unit and the sensors with embedded signal processing capability integrated into the geometry of the external fixators.

Control unit: The control unit is based upon a 32Bit RISC Microcontroller that provides a fair amount of processing power beyond what is necessary for a data logging system and thus is able to serve several peripherals located on-chip and in-system.

The system is powered by a lithium polymer battery as used in mobile phones, which provides a higher energy density than other types of batteries; the applied model holds a capacity of 1.2Ah.

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Safety concerns common to lithium batteries are met with dedicated circuitry for security, charging and load switching that constantly checks the battery for erroneous conditions and can disconnect the battery instantly from the rest of the system to avoid dangerous malfunctions.

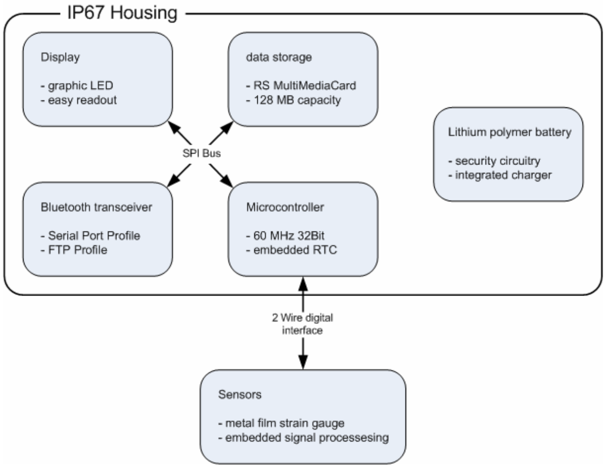

Figure 1: Block diagram of the control unit

The data acquired during the course of healing is stored on an embedded FLASH memory card (reduced size multi-media card); the smallest capacity available during development of the system still provides 128MB of memory, which is sufficient even for future enhancements of the control unit.

As cable-bound connections are usually unfavorable for use in mobile devices, a Bluetooth transceiver is integrated into the system; it provides encrypted cable-free access to all of the control unit's capabilities in a minimum range of ten meters. Standard Bluetooth profiles are employed: the FTP profile allows easy integration of the embedded memory as an additional drive into the file browser of a Bluetooth compatible operating system (i.e. Microsoft Windows together with the WIDCOMM Bluetooth stack), a terminal program (i.e. HyperTerminal) allows full access to the system's functions and parameters by use of the serial port profile.

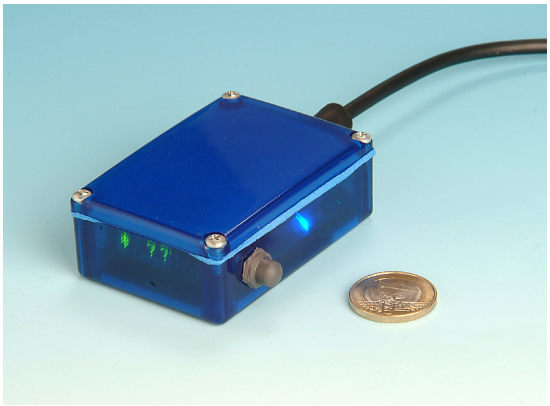

Figure 2: Prototype of the control unit

The immediate user interface is very simple, one button and a small display allow a quick check by the patient; the full amount of data taken by the device is available for further analysis to the surgeon.

The system shown in figure 2 has primarily been developed for the use in external fixators, the current size of 70*50*25mm and weight of 80g is sufficiently small, but further reduction of space and weight is feasible.

Sensors: Up to now the system has been adapted to the hexapod external fixator and to the Ilizarov fixator with traction cables. The attachment and design of the sensors and embedded electronics differ for the two external fixators, but still the basic design is common to both.

The longitudinal forces are measured by resistive strain gages in a Wheatstone bridge configuration. The voltage output of the force transducer is pre-processed in the analog domain by a digitally programmable sensor signal conditioning IC to achieve an output signal appropriate for a full-scale load of +/-1000N.

The pre-processed voltage output is sampled by the 14Bit A/D-converter of a mixed-signal microcontroller and the transducer output is further processed in the digital domain. The actual force can be read out via a two-wire digital interface in conjunction with information like the actual temperature of the sensor, identification number and possible error states.

Figure 3: Hexapod external fixator with manual control

Adaptation for the hexapod external fixator: The hexapod external fixator (see figure 3) is an external ring fixator system. Instead of parallel interconnecting longitudinal bars usually found in Ilizarov ring fixators, six linear actuator elements ("distractors") are attached to the rings. The distractors are connected to the rings via three pairs of ball joints creating the form of circularly arranged triangles. The ball joints are not blocked, therefore only an axial load is transferred along the distractors and thus exactly six independent degrees of freedom are allowed; this mechanism is known as hexapod or Stewart platform [11]. The hexapod mechanism is suited for universal computer assisted three dimensional fracture reduction and deformity correction [12].

Thus the hexapod external fixator is suited to gain access to all spatial forces and moments acting on the callus during the bone neoformation [1].

The distractors of the hexapod external fixator are equipped with longitudinal force sensors based on two resistive half-bridge strain gages directly applied to the outmost tube of the telescopic distractor. The resulting full-bridge is self-compensated for bending strain and temperature deviation. The transducer delivers an output voltage of approximately 0.5µV per Newton and Volt.

As shown in figure 4 the analog and digital signal processing circuitry is directly attached to each of the six distractors of the hexapod.

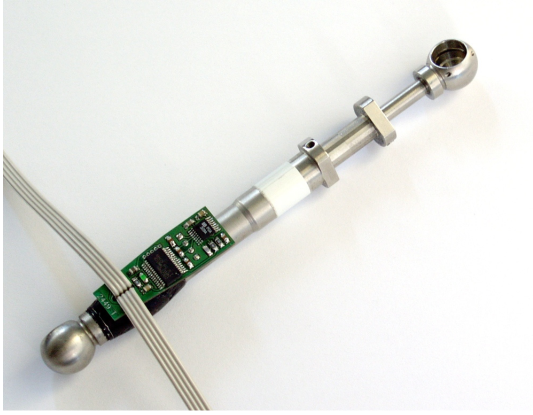

Figure 4: Distractor rod with force sensor and embedded signal processing circuitry

The distractors are interconnected with a four-wire cable, it is used to power the electronics and the transducers and it contains the serial two-wire digital interface used for data communication between the control unit and the distractors.

Force transducers using resistive strain gages usually require bridge balance adjustment by applying iterative abrasion of balancing resistors integrated intro the transducer bridge. The embedded signal processing capabilities of the instrumented disctractor rod renders analogue trimming unnecessary. The transducers are calibrated for gage factor and zero-offset by two semi-automatic calibration steps, the zero-offset is determined in a resting position and the gage factor is acquired by applying a known force in a material testing machine or a similar setup capable of providing an accurate force. The necessary measurements and calculations to obtain the calibration factors are carried out by the embedded electronics; the determined parameters are stored in "on-transducer" FLASH memory for later readout and use.

Adaptation for the Ilizarov fixator: The system has also been adapted to a special geometry of the Ilizarov fixator (see figure 5), which performs bone transport applying the principle of distraction osteogenesis. In this assembly the bone segment transport is driven by two tows under tension that are fixed at the bone segment and at the upper fixator ring. The tension force of the bone segment correlates to the strain in the cables and is an appropriate indicator to monitor the distraction osteogenesis [7, 13].

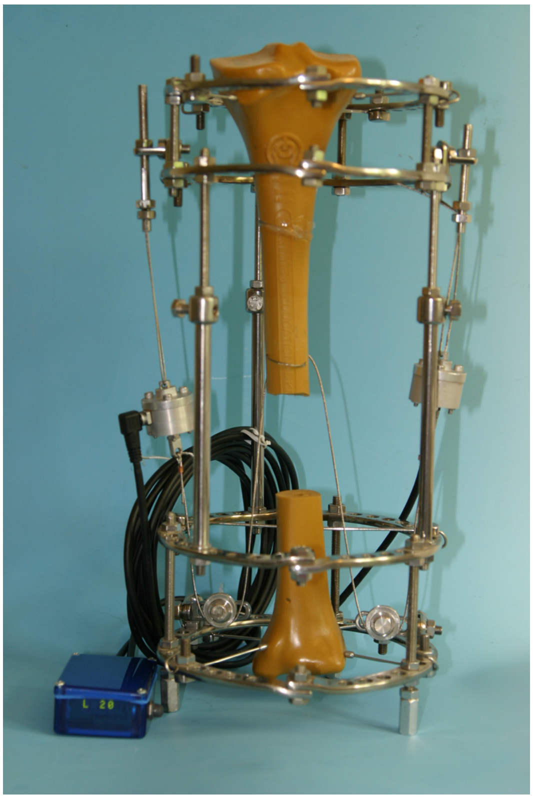

Figure 5: External fixator for bone segment transport equipped with the monitoring system and two force sensors

Commercially available force sensors are inserted in the tows to measure the force. To maintain overall system compatibility the cable setup shown in figure 6 is used to connect the force sensors to the control unit. Similar to the distractors of the hexapod external fixator, the output signal of the force transducers is pre-processed and converted into the digital domain by electronic circuitry embedded in the cable.

This adaptor cable uses the same electronic components as employed for the distractors of the hexapod external fixator in order to simplify maintenance of the different systems.

Figure 6: Cable assembly with embedded signal processing for two force sensors

As zero-offset and gage factor of the commercially available force sensors are usually provided by the manufacturer a semi-automatic calibration of the transducers can be skipped by manual entry.

Results

Before clinical application of the system, several tests were carried out. After the calibration of the sensors for the bone segment transport with the Ilizarov fixator the accuracy of the setup was determined to better than one Newton over the full load range (measurement with Zwick 1455 material testing machine). It was shown that the Bluetooth link provides stable transmissions up to 30m, more than expected from the Class II transceiver and the compact meander line antenna. Encrypted data transmissions utilizing the FTP profile were performed at a speed of about eight kBytes per second. Thus the limiting factor for the sample rate during live monitoring via the Bluetooth link is not the wireless data link but the restricted speed of the embedded signal processing; due to the high system gain of 2000 thorough filtering is necessary to provide stable and accurate force readings. The accuracy of one Newton over the full load range limits the sampling frequency to ten measurements per second. A sample rate of one measurement per minute was found to be appropriate for long-term data logging to accomplish a good balance between accuracy of the measured force variation over the course of healing and energy consumption.

Due to the use of the RS MMC FLASH memory card this data logging system is not constricted by the capacity and cost of integrated memory, it provides space for several years of measurement despite the additional overhead caused by the FAT32 file system.

Immersion tests have shown no intrusion of water into the control unit.

The system was applied successfully to monitor the forces acting on the tractive cables for a distraction osteogenesis with an Ilizarov ring fixator. The bone segment transport was carried out on the lower left leg of a 63-year-old male patient to treat a bone defect of 80mm due to osteomyelitis. Figure 6 shows the measured force progression during the first ten weeks of the bone segment transport.

During this long-term application of the system, the energy consumption of the device could be determined under real-life conditions; the lithium battery used in the control unit provided sufficient energy for about four weeks.

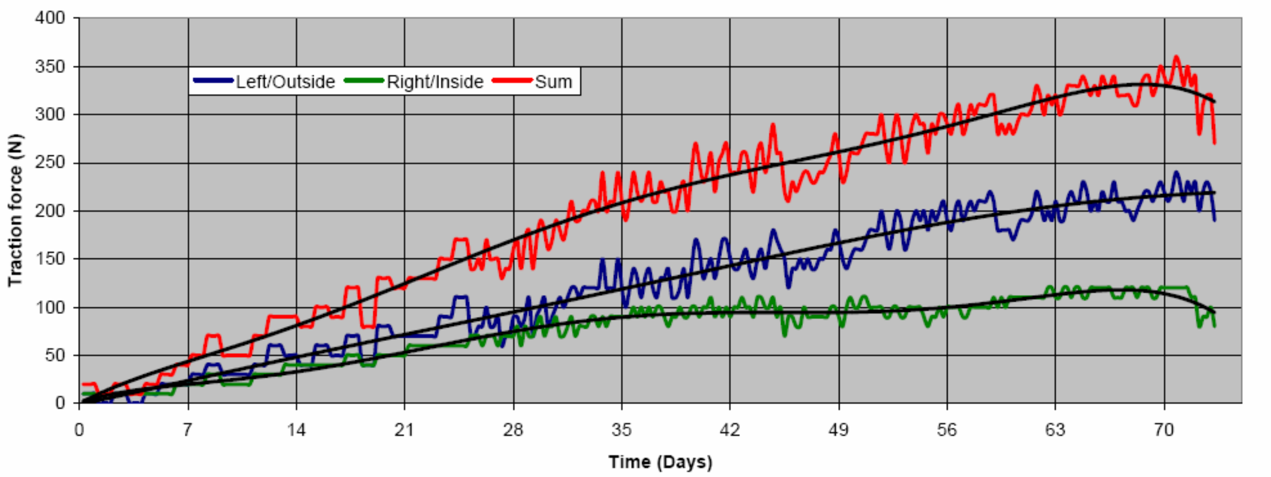

Figure 6: Traction force acting on the cable assembly of the bone segment transport during the first 10 weeks (polynomial interpolation shown in black)

Discussion

The data logging and monitoring system presented in this paper was successfully applied for long-term monitoring of the forces acting on the tows of a distraction osteogenesis on a first patient. Apart from fulfilling the intended purpose – long-term data logging and monitoring the biomechanical loads – several additional benefits were observed during system operation.

As the system is an integral and rugged part of the external fixator it can be left with the patient during the treatment, this renders manipulations at the fixator as usually required when force measurements are done unnecessary; the resulting gain in stability improves the patient's comfort during the treatment. The possibility to quickly check the actual strain in the tows proved as very efficient to keep it constant over modifications of the fixator during the treatment.

The lifetime of the battery limited to four weeks remains to be improved by optimized battery management hardware to enable continuous monitoring over the full course of healing.

Apart from the measurement of the biomechanical loads, which is done by the device autonomously, the acquired data has to be converted from device into Cartesian coordinates during the readout of the stored data. For the case of the bone segment transport with the Ilizarov ring fixator the angle of the cables fixed to the bone segment changes versus time, i.e. the tractive force acting on the bone segment differs from the sum of the strains measured in the tows.

Conclusions

As the data logging system is completely protected against intrusion of dust and water and can be firmly mounted to the fixator, continuous monitoring of biomechanical data can be accomplished during the full course of healing without disturbing the patient. The use of the device in clinical routine would provide means to lower the radiation exposure of the patient as the number of radiographs taken during the treatment could be reduced.

The split-up system approach – the control unit and the transducers with embedded signal processing – is favorable for adaptation to other assemblies of fixators. Only the transducers have to be adjusted for the specific fixator, the control unit can be used for any type of assembly, thus the system provides a persistent callus assessment platform for routine clinical application.

Due to the six independent degrees of freedom for measurement as well as for movement the hexapod external fixator is suited to serve as basis of a universal fracture reduction robot, the "intelligent" hexapod external fixator [14,15], which is currently in development by the authors.

Since the system can also be interfaced with a cell phone utilizing the Bluetooth wireless data link it completely liberates from personal attendance. Thus this principle can be used for numerous telemedical and remote sensing applications.

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