A Wearable Ultrasound Device for the Monitoring and Acceleration of Bone Fracture Healing

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Introduction
Several methods for the acceleration of the healing process have been used, including electrical stimulation. Electromagnetic fields (EMFs) have direct biological effects on endochondrial cells and enhance the formation of callus (Gupta et al., 1991). Ultrasound is currently used for the diagnosis of osteoporosis (R. Strelitzki et. al., 1996). In this case, two ultrasound transducers are placed on the skin, on opposite sites of the bone sample and the transition time of ultrasound waves is measured. In a recent study (C. Malizos et. Al., 1999) the use of ultrasound waves was proposed to enhance callus formation. In this work, the architectural design of a personalized wearable device for the monitoring and acceleration of bone fracture healing using ultrasound signals is presented. The proposed wearable device is plugged onto an external fixator and the traducers are placed directly on the surface of the bone. The proposed system can be used for the acceleration, as well as the monitoring of the healing progress. In comparison with currently used techniques, such as X-rays and manual sensing, the proposed device provides accurate information on the progress of healing and can recognize possible problems or non-union quite early in the process. In addition, it provides with several support services, such as communication of information to the doctor, intelligent data processing and generation of alerts when it is needed.

Methods
The proposed wearable system addresses the monitoring and acceleration of maturation of callus in bone healing when an external fixator is used. With the existing methods, it is possible to recognize the formation of callus only at its final stage, when the cartilage tissue starts to calcify and therefore becomes visible on X-rays film. However, following the fracture of a long bone, a sequence of cellular and molecular events is responsible for the joining of the broken ends and the reshaping of the bone to obtain the original structure. Failure to heal or non-union can be caused by several factors including surgery. In current practice, this can be recognized at least 3 weeks after the surgery when the formed callus becomes visible on X-rays. Our aim is to develop a method to replace today’s used techniques and provide a quantitative monitoring tool as well as an acceleration mechanism of the healing process using ultrasound signals. The system consists of a sensing module, a pre-processing and feature extraction module along with a decision support module, a communication module, an alerting mechanism and a centralized data repository. Fig. 1, shows the systems’ architecture.
The sensing system is based on the transmission of ultrasound waves through the fracture site (Fig. 2(b)). Two broadband, unfocused disk transducers (5mm in diameter) with nominal frequency of 500kHz are used, one acting as transmitter and the other as receiver. The transducers are placed on opposite sites of the fracture and form direct contact with the bone (see Fig. 2(a)).

Figure 1: System’s Architecture

Figure 2: (a) External fixator setting, (b) Sensing System

Both the ultrasound propagation velocity and the signal distortion are used to quantify callus maturation. Ultrasound wave propagation velocity is strongly associated with bone elasticity (i.e. strength) and density. Callus developed at the fracture site possesses different properties, and thus the ultrasound velocity is substantially lower. The transmitter sends out a pulse, and when the receiver detects this signal, the transition time is recorded. Measurements at different stages of the healing period provide
information on the healing progress. Velocity measurements however, cannot provide any information on the changes in the architectural microstructure of the repairing bone. Therefore, the spectral distortion of the propagating signal is investigated as well. The bone, as most biological tissues, is a dispersive material, and thus spectral analysis of the received signal captures microstructural changes, which take place at the fracture site. Bone and callus microstructural properties are investigated using the ultrasound signal in the frequency range of 0.2-1 MHz. The transmitter sends out a pulse and the spectrum of this signal is selected to have a central frequency of 0.5 MHz. Fig. 3 shows the spectrum of the transmitted signal, and the spectrum of the received signal at different stages of the healing progress.

Signals corresponding to various stages of osteogenesis are recorded to be used in a data-driven intelligent engine after the feature extraction stage for diagnosis. Different classification methods are used. The system provides with quantitative information on the formation of the callus and the healing process, even at its early stages, allowing orthopaedicians to take appropriate actions in changing the prescribed therapy immediately after the identification of a problem. At the same time ultrasound signals in different frequencies can be utilized for the acceleration of the healing process (C. Malizos et al., 1999).

Each time a measurement is performed, the received signal is rectified, filtered, windowed and feature extracted and it passes through a preliminary decision support module located on the patient’s wearable device. All recorded signals, the extracted features, the result from the preliminary diagnosis module, as well as other measurements such as local temperature and heart rate are wirelessly transferred to the centralized system. The procedure is handled by the communication module that certifies the secure transferring of the patients’ data to the centralized system. A second decision support module operates also in the centralized system, exploiting additional information on the patient’s history and health status to support doctors’ decision on the fracture healing process. Doctors are notified on possible problems and they are able to monitor the healing process and define actions that will resolve unwanted situations and accelerate the healing process. After recognizing a possible problem in the healing procedure, the alerting mechanism informs the responsible doctor, who bears full responsibility in communicating the result through the centralized system to the patient. Doctors are able to change the programming of the monitoring and acceleration procedures at any time during the healing process and monitor each patient’s progress and expected result. The centralized decision support system is updated regularly with information taken from the centralized repository for the treated patients, providing thus an evolving diagnostic system.

Results & Discussion
The proposed wearable device engages data collection for the maturation of the bone healing interacting with the human bone, tracking and recording ultrasound measurements. It is used for the monitoring and for the acceleration of the fracture healing activating low-pulsed ultrasound, proved to accelerate the healing process significantly. For this purpose, the transducers have direct contact with the bone, avoiding signal distortion from other tissues. The proposed device is still at an experimental stage and clinical trials are foreseen to verify the results. However, fast and accurate decisions can be made without using conventional methods. In fact, possible problems and non-unions in the fracture healing process can be recognised at an earlier stage.

References
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