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Final Technical Report

DEVELOPMENT OF A NEW NONINVASIVE METHOD TO DETERMINE THE INTEGRITY OF BONE IN VIVO

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by

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The main objective of this project is to develop a safe, noninvasive technique to determine the properties of bone in-vivo. During the initial phase of this project (1974-1978), we showed that the dynamic stress in a bone as measured by bonded strain gages could also be detected by vibrating traction pins attached to the bone and placed in a magnetic field (Saha & Pelker, 1975). We also demonstrated that the characteristics of the stress wave propagating in a bone as monitored by traction pins could be correlated to the degree of simulated fracture heating and porosity of bone (Saha & Pelker, 1976; 1980).

Although the method of vibrating traction pins could potentially be used as a method of measuring the rate of fracture healing, such method was applicable only for patients who already had traction pins in their bones as a part of their fracture treatment. This is because few surgeons would be inclined to introduce pins in their patient's bones unless it is needed for traction purpose. Moreover, with one traction pin, the wave shapes proximal and distal to the site of fracture could not be compared. Therefore, a concerted effort was undertaken towards developing a new technique of detecting the stress-waves noninvasively without the use of a traction pin. As a result of this, we have developed an electromagnetic device for monitoring elastic waves in bone which does not require the use of traction pins and the output of which is also not affected by soft tissue properties, a difficulty commonly encountered by other authors who attempted to use ultrasonic and vibration methods to determine the in-vivo properties of bone (Doherty et al, 1974; Saha and Lakes, 1977a, b).

Due to the piezoelectric nature of bone (Cochran et al, 1968), a propagating stress wave also generates a magnetic field extending outside the bone. The propagation of an elastic wave along a long bone can therefore be detected by monitoring the resulting magnetic field, and this is the principle behind this newly developed electromagnetic sensor. Sensors were constructed by winding 4,500 turns of fine (no. 38) wire around a ferrite core, the permeability of which was about 2200. To minimize capacitive loading, a specially designed pre-amplifier was mounted directly above the sensor. Sensor output was conditioned using an active filter which removed the strong 60 cycle "hum" component of the signal and restricted to bandwidth to 80 kHz.

A driver for the excitation of stress waves was made by constructing a stack of lead-titanate zirconate piezoelectric elements. A pulse amplifier was designed to energize the driver and to match its impedance. The input of the amplifier was provided by a Tektronix type 505 pulse generator. The pulse amplifier was designed to be compact so that the effect of external electromagnetic interference was minimized and further reduction of such interference by layers of μ metal shielding was facilitated.

Pulsed bending waves of small amplitude were generated in both dry and wet embalmed, human femora using the configuration shown in Fig. 1. An identical set-up was used in tests for artifacts, using ½ in. diameter rods of (non-piezoelectric) aluminum and plexiglas in place of a bone. Electrical pulses supplied to the driver were 10 μsec in duration and were separated by an interval of 10,000 μsec, corresponding to a repetition rate 100/sec. This interval was sufficient for reflected waves to be damped out before the arrival of the next pulse. The stress waves were also monitored by semiconductor strain gages bonded to the bone.

Typical sensor and strain gage and a surface electrode outputs from an embalmed femur are shown in Fig. 2. Some dissimilarities between the magnetic

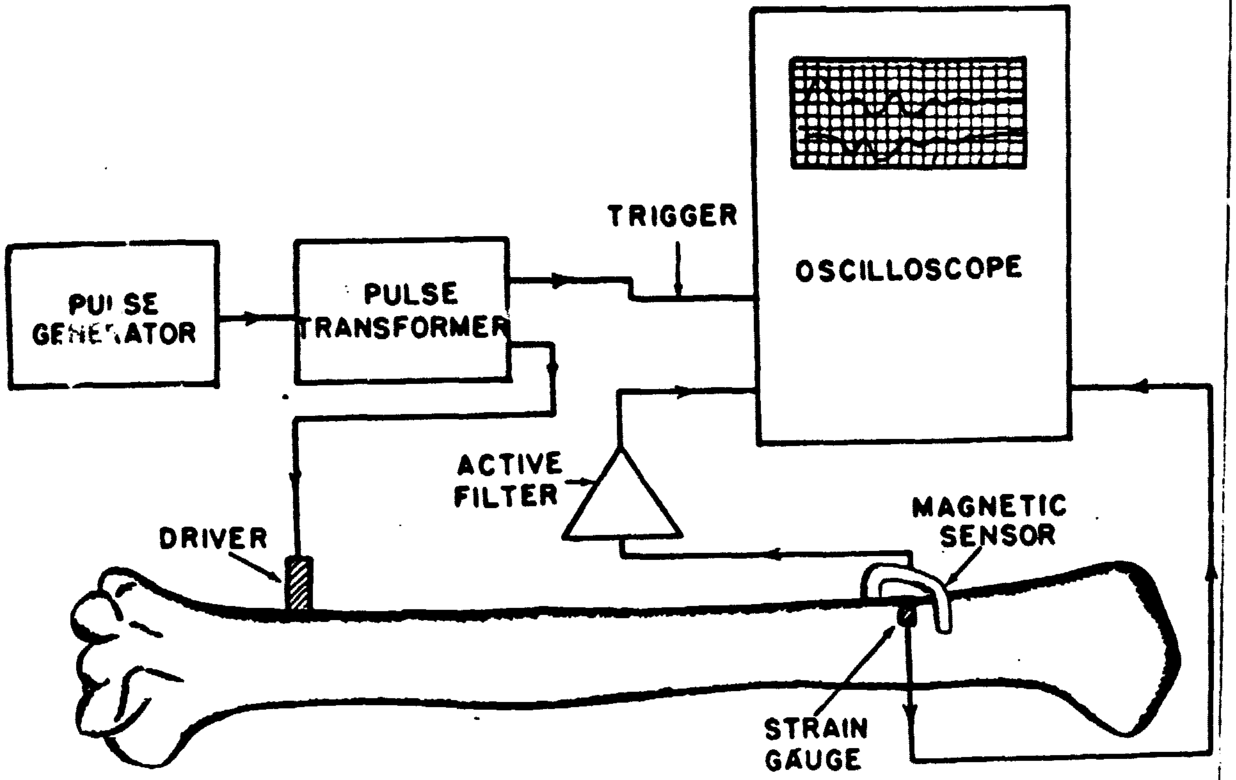

Figure 1. Experimental set-up of the wave propagation test using a long bone, the waveforms being monitored by a bonded strain gauge and by the non-contacting electromagnetic sensor.

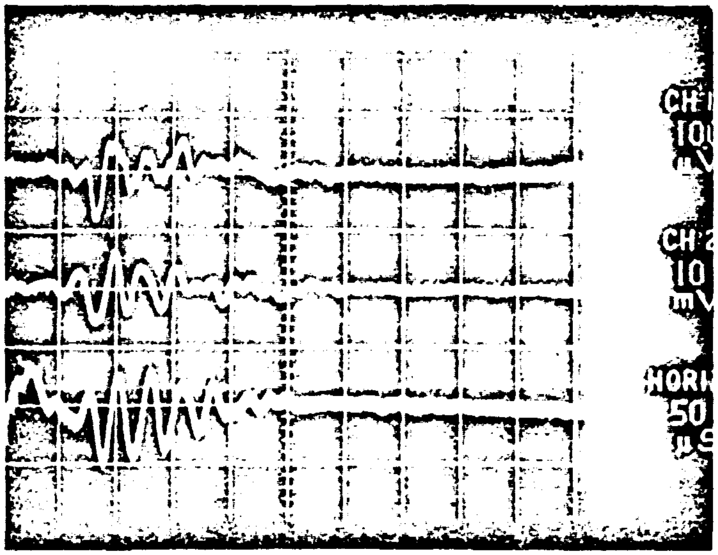

Figure 2. A comparison of typical waveforms in a human femur (dry) as detected by a bonded strain gauge (top trace), a surface electrode (middle trace) and the magnetic detector (bottom trace). The waves were generated by a transverse impulse of 10 microsecond duration using a set-up as shown in Figure 1.

sensor and strain gage outputs are to be expected since the strain is measured at a point on the surface while the sensor responds to strain-generated polarization in a stressed region of the bone in close proximity to the sensor. Nevertheless, the device produces a signal which is proportional to the strain amplitude and the surface charge in the bone. Note that the maximum strain amplitude in the bone is of the order 1.4×10^{-6}, which is less than 0.5 percent of the strain typically measured in the leg bones of walking animals (Lanyon and Smith, 1969).

In tests upon human volunteers, the driver was pressed to the skin over the anterior portion of the tibia, and the sensor was placed distal to the driver, 0.5 cm above the skin over the anterior portion of the tibia. Signals obtained using wet bones in vitro or in vivo were significantly weaker than signals from dry bones, therefore a signal averager (Princeton Applied Research, model TDH9) was used to extract the repetitive signals from random noise in the sensor.

During these tests, the output of the electromagnetic detector was stored on floppy discs in a digital oscilloscope (Nicolet, Explorer model III) and the frequency components of the wave forms were analyzed in a spectrum analyzer (Hewlett Packard, model 3582A). After wave propagation studies were completed on excised whole bones, simulated fractures were experimentally induced in the samples by making serial cuts of increasing depth into the bone cortex. The wave propagation studies were then repeated on each sample. When the whole bone was separated into two parts, they were joined by a soft silastic cement, simulating the initial stages of fracture healing, and the wave propagation study was repeated on each bone. The silastic was then removed and the bones were joined by acrylic bone cement, simulating the final stages of bone healing and the stress waves were monitored at two points as before.

A preliminary result of this study indicates that the changing characteristics of the stress waves as it propagates along the bone could be correlated to the degree of union at the point of simulated fracture. There was also a shift in the dominant frequency with increasing depth of cut in the cortex. Therefore spectrum analysis could be an additional means for monitoring the degree of fracture union.

For intact bones, the decrease in the amplitude of the wave also had a significant correlation with the mass per unit length of the bone. At each cross-section of the bone examined, the magnetic detector was rotated circumferentially and its outputs were recorded at every 15° interval. To ensure that the measured outputs were independent of the ultrasonic transducer orientation, the readings were repeated for several different transducer positions at the same cross-section of the bone. After completion of the magnetic detector readings at several sections along the length of the bone, the bone was machined at each section and the actual thickness of the cortex at each point was measured by a micrometer.

Due to the viscoelastic nature of bone, there is a decay in the amplitude of stress wave as it propagates along the length of the bone. Therefore the output from the magnetic detector was normalized by dividing with the maximum reading at the cross-section, and the same was done for the cortical thickness. Figure 3 shows the close correspondence between the magnetic detector output and the actual cortical thickness at one cross-section. This is not unexpected, because the measured magnetic field is highly dependent on the amount of stressed bone nearest

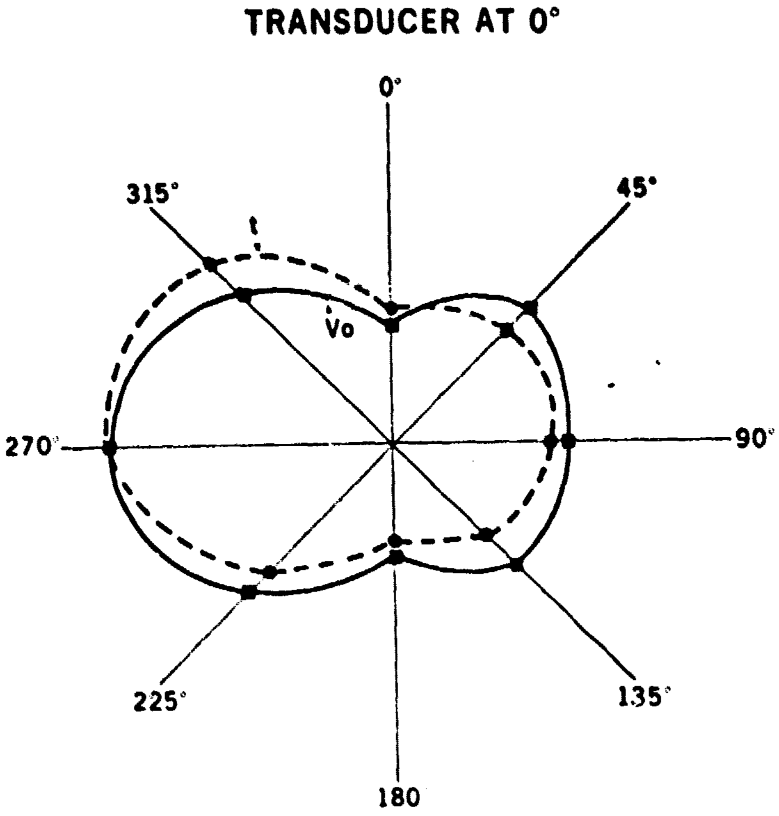

Figure 3. Comparisons of normalized outputs from electromagnetic detector (Solid Line, Vo) and bone cortical thickness (dashed line, t) for various circumferencial angles.

the detector. For most cross-sections, the correspondence between the electromagnetic detector output and cortical thickness was highly significant. The slight scatter in the data is due to the fact that the measured magnetic field is not only a function of the bone thickness at a point, but is also weakly affected by the whole bone mass near the detector.

This result indicates that this newly developed electromagnetic detector can measure cortical bone thickness non-invasively (Saha & Reddy, 1981). By moving this detector along the length and circumference of a long bone, it may be possible to more objectively ascertain the change in cortical thickness than is presently possible.

During long-term space flights, disuse osteoporosis is the main problem affecting the skeletal system of astronauts. Therefore, monitoring the skeletal status of the astronauts is of vital medical importance during these manned space programs. Results of our experiments suggest that the electro-magnetic device, when fully developed, could be a valuable tool in providing quantitative information regarding the bone loss of the astronauts during prolonged space flights.

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