

## SONIC DIAGNOSIS OF BONE FRACTURE HEALING—A PRELIMINARY STUDY\*

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**Abstract**—The definition of bone fracture healing onset, progress and extent is a difficult clinical diagnosis. Available criteria of manual stability, X-ray appearance, symptomatic pain and passage of time are indeed valuable, but subjective in nature. This study explores the transmission and comparative measurement of stress wave disturbances across a fracture site as a technique of quantifying the union state. Results from laboratory animal experimentation and subsequent clinical usage indicate a potentially valuable method has been developed.

### INTRODUCTION

At the present time the determination of fractured bone union onset, progress, and return to a normal state is a subjective diagnosis. The clinician utilizes a manual examination for stability, X-ray evidence of healing, the empirical passage of time, and the patient's evaluation of symptomatic pain. The first of these, the manual examination for stability, appears to be a readily learned and consistently practiced technique by the orthopaedic surgeon (Matthews, Kaufer and Sonstegard, 1974). For bones deeply underlying muscular and subcutaneous tissue, such as the femur or humerus, the test is of qualified value. Similarly X-ray evidence may be of variable implication since in many fractures the bone is functionally normal long before the X-ray indicates obliteration of the fracture line (Mooney *et al.*, 1970). Consequently many fractures are perhaps maintained in casts several weeks longer than necessary. Conversely, the conventional methods do not indicate when the healing process has failed. Diagnosis of a non-union and the need for surgical intervention may thus be unduly postponed, although internal fixation and/or grafting should be initiated at the earliest possible time.

The dynamic structural response of long bones has been the subject of considerable investigation, including Jurist (1970), Brash and Skorecki (1970), Abendschein and Wyatt (1970), Campbell and Jurist (1971), Thompson (1973), Jurist and Kianian (1973), Lewis, Goldsmith and Wong (1973), and Doherty, Bovill and Wilson (1974). These studies have directioned emphasis toward characterization of material properties of normal bone as well as delineation of responses peculiar to the non-normal, such as osteoporotic or

fractured. Although these impact, impedance and resonance techniques have demonstrated a potential for bone healing diagnosis, widespread clinical acceptance and application has not yet evolved. Three factors appear to have limited the realization: 1. Clinical application has been restricted to those bones which present readily accessible landmarks for excitation and measurement, such as the tibia and ulna. 2. Electrical devices utilized are not placed in intimate contact with the bone but rather sense or excite through overlying tissue, an issue addressed by Orne (1974). 3. Response interpretation is tempered by influences of adjacent bones, muscle, ligaments and associated tissue (Lewis, 1975).

There thus exists the need for a quantitative technique for bone fracture healing diagnosis, and there has been demonstrated the potential of dynamic responses to provide same. This effort elaborates a technique which appears to have overcome the above mentioned factors limiting previously reported methods. Laboratory animal experimentation and subsequent clinical usage have yielded results which, although demanding of continued refinement, do harbor justification for continued investigation.

### LABORATORY METHODOLOGY

A guiding criterion in our design of a sonic diagnosis of bone fracture healing technique was the mitigation of surrounding tissue influences. Direct attachment to bone at excitation and sensing locales was thus desired, and was determined to be practical and feasible by means of standard hypodermic needles. Light tapping of a needle base yields tip penetration through the periosteum and into the immediately adjacent cortical surface. This fixation is adequate for needle position maintenance, measurement device support, and response detection.

A three needle configuration constitutes the measurement approach, (see Fig. 1). One needle attachment provides the source of disturbance excitation. Preliminary studies of the approach, using wood, brass and bone, indicated that provision of a planar stress wave travelling the specimen length provides advantages in theoretical considerations as well as sensor output sensitivity. Planar excitation is not generally possible in the clinical setting, however, and therefore the excitation needle has been oriented

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**BASIC APPROACH**

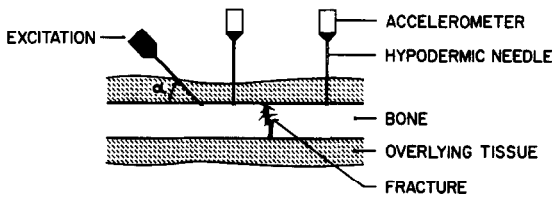


Fig. 1. Measurement technique utilizing an excitation needle and two sensing needles, each implaced in intimate contact with the bone surface.

at approx. 45 degrees to the long axis of the bone. Variations of the 45 degree angle through  $\pm 15$  degrees were observed not to appreciably influence the results to be discussed here. Two needles provide bone attachments at disturbance measurement sites. The needles are implaced perpendicular to the longitudinal bone axis at a predetermined separation distance which spans the fracture. The first of these needles provides a control measure of the incoming excitation disturbance. The second measures the disturbance character after fracture traverse.

As shown in Fig. 2, an impulsive or impact disturbance is provided at the excitation needle. In initial studies this disturbance was generated by a Ledex, Model 174543-033 solenoid at a force magnitude of approx. 1 kgf. Manual provision of this disturbance was found to be more convenient, and thus is the method now utilized. Although a precise definition of the force-time, spectral character of the excitation may seem in order, in fact use of the prefracture control measurement allows ready definition of a suitable input, i.e. tap. Unidirectional, piezoelectric accelerometers were attached in a vertical orientation to the measurement site needled. Wilcoxon Research, Model III, 1 g, 6 mv/g, 1.2 pc/g, 1-18,000 Hz devices were contact cemented to metal syringe end adaptors which enabled rapid and secure attachment to the needle bases.

Instrumentation for measurements is shown in Fig. 2. Triggering of a Textronic 564 Dual Channel Storage Oscilloscope is provided at the excitation source. Accelerometer outputs are conditioned by a two channel charge amplifier prior to scope input.

The left radius in each of seven dogs, aged 3-4 months, was studied in the laboratory. Following 15 mg/kg pentobarbotal anesthesia, measurement needles were implaced

**IMPULSE EXCITATION**

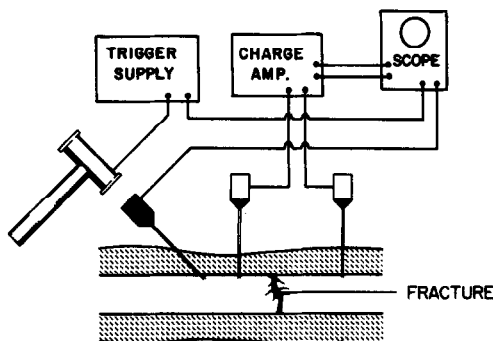


Fig. 2. Technique as utilized with an impulse source imparted at the excitation needle.

6 cm apart, and the excitation needle approx. 3 cm distal of the prefracture sensing site. The initial study session for each animal included a prefracture control measurement, a surgical exposure, a 0.5 mm wide transverse fracture of the radius imparted with an oscillating saw, wound closure, limb X-ray, and application of a full length limb cast. At succeeding weekly intervals the cast was removed, the animal anesthized, measurements made, an X-ray taken and the cast reapplied. This protocol was followed for six weeks post fracture with the exception that after 4 weeks a cast was not applied.

**LABORATORY STUDY RESULTS**

A representative, preoperative control measurement is shown in Fig. 3. At each scope gain and sweep setting the records include an output pair, the upper of which designates the measurement nearest the excitation source, the lower the measurement 6 cm further from the source. These results were reproducible when the excitation-sensing needles and accelerometers were removed and reapplied, and when excitation taps were successively applied. Laboratory studies were made using 1 1/2 in. long, 18 g excitation needles and 5/8 in., 25 g sensor needles. Data reduction considerations center upon the initial character of disturbances arriving at sensing sites. No significant differences in these results to be reported were observed for needle lengths from 1/2 to 3 in., or for gages from 15 to 25.

Control measurements as shown in Fig. 3 were immediately followed by a surgical fracture imposed

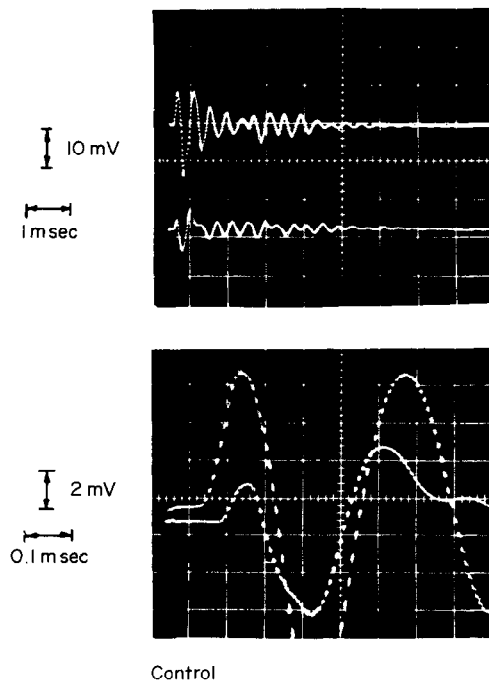


Fig. 3. Prefracture control measurements from dog radius. At each scope setting the records include an output pair, the upper of which is the measurement nearest the excitation source, the lower the measurement an additional 6 cm from the source.

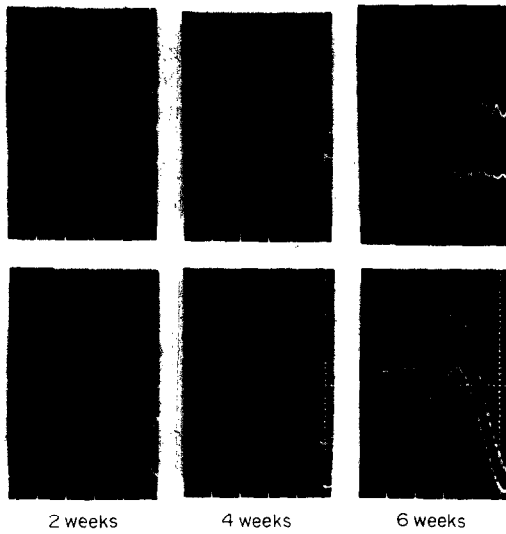


Fig. 4. Measurement results at 2, 4, and 6 weeks after surgically imposed transverse fracture of dog radius.

between the sensing sites. Subsequent measurements were made at 6 weekly intervals, with results representative of these observations shown in Fig. 4. Parameters considered in characterizing the pre- and post-fracture wave fronts were amplitude ratio, slope ratio and propagation velocity, Fig. 5. In order to more accurately define the velocity, scope settings of 1 mV/division and 20  $\mu$ sec/division were utilized. Parameter values, mean  $\pm$  1 S.D., are given in Fig. 6 for the seven animals studied. For each animal the criteria of manual stability and X-ray appearance indicated suitable fracture union progress at 4 weeks, at which time limb cast use was discontinued.

At six weeks the manual stability and X-ray criteria yielded a healed diagnosis. This subjective determination was confirmed by mechanical tests. Following the sixth and final measurement the animals were sacrificed. The normal front leg and the opposite used

IMPULSE RESULTS

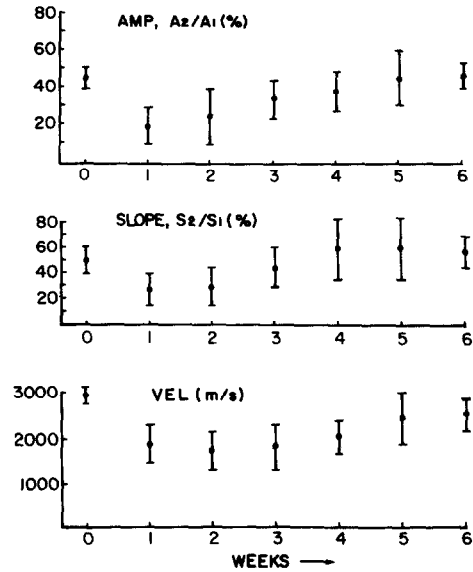


Fig. 6. Parameter values, mean  $\pm$  one standard deviation, for seven dog radii results.

in the fracture study were removed and frozen at  $-4^{\circ}\text{C}$ . The limbs were subsequently thawed, the radii dissected free of surrounding tissue and tested in center loaded, three-point bending in an Instron Machine. The 5 in. bone-beams were loaded at a 0.5 in./min midspan deflection rate. Load-deformation measurements for six bone pairs yielded the following, normal radii vs healed fracture radii:

- Maximum load sustained:  
120  $\pm$  77 lbs vs 113  $\pm$  77 lbs.
- Beam stiffness:  
520  $\pm$  181 lb/in. vs 542  $\pm$  184 lb/in.
- Deflection at maximum load:  
0.26  $\pm$  0.06 in. vs 0.21  $\pm$  0.09 in.

PARAMETER MEASURES

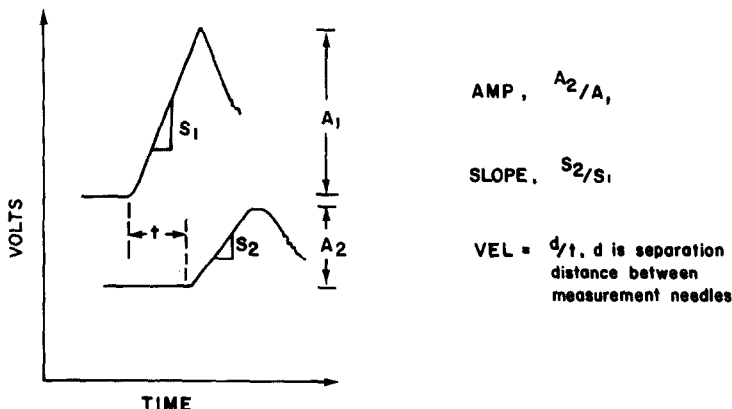


Fig. 5. Wave front parameters considered in pre- vs post-fracture site measurements.

Beam stiffness was taken from a linear force-deflection slope which followed a small, characteristic toe-in behavior. Paired Student *t*-tests show no significant difference ( $p > 0.1$ ) between the normal and healed fracture specimens for the 3 measures compared. The results thus provide objective confirmation of the end point measure of clinical healing as determined by the stress wave measurements.

#### LABORATORY STUDY CONCLUSIONS

Animal experimentation has demonstrated that a three needle excitation-sensory system enables measurement of response parameters which are sensitive to the union state of transverse surgical fractures of dog radii. Comparison of pre- and post-fracture wave fronts enables ready insight into the propagation and dispersive nature of fracture site material changes. Each of the parameters, amplitude ratio, slope ratio and propagation velocity, precipitously decrease at initial fracture, and monotonically increase as union progresses (Fig. 6). Results for the seven specimen studies have evidenced, however, an extent of parameter value scatter which to date precludes definitive conclusions with regard to the extent of healing. Given sequential measurements, as per Fig. 4 at 2, 4 and 6 weeks, a ready diagnosis of healing onset and progress may be made. In reference to Fig. 5, however, if a singular measurement yields an amplitude ratio of 26%, a slope ratio of 30% and a velocity of 1875 m/sec (a combination observed for one animal at 4 weeks), the data scatter overlap between no union (1-2 weeks) and satisfactory progress (3-4 weeks) precludes a definitive conclusion. This same animal yielded respective values of 11%, 27% and 770 m/sec at two weeks. We thus conclude, from this example and similar results for the other 6 animals, that given successive measurements the technique user can identify healing progress. Given a single measurement the user only can differentiate the gross nonunion from an essentially complete union.

#### CLINICAL EXPERIENCE

Eleven patients have undergone sonic diagnosis of bone fracture healing by the technique previously described. In each case the post fracture time was considered by the referring physician to be adequate for union onset. The conventional methods of manual stability, X-ray appearance and pain were inconclusive for a pending decision of surgical intervention. The following protocol and criteria were established.

1. The patient clearly understood the experimental nature of the measurement, appreciated the possibility of an inconclusive result, and signed a release permit to that effect.

2. If at any time during the measurement the patient experienced apprehension, pain or discomfort which he felt was unnecessary or unreasonable, the procedure was to be immediately terminated (none was).

3. A diagnosis of nonunion was to be made if measured parameters were each below the laboratory means at 2 weeks, namely an amplitude ratio of 26%, a slope ratio of 27% and a propagation velocity of 1700 m/sec.

4. A diagnosis of healed was to be made if measured parameters each exceeded the laboratory means at 5 weeks of 47%, 61% and 2400 m/sec respectively.

5. An inconclusive result was to be reported if criteria 3 or 4 were not satisfied.

6. A measurement was taken across the fracture site and, where appropriate, in a similar manner on the opposite limb.

7. An injection of 1% Xylocaine solution was administered to skin, soft tissue and the bone surface at each needle site prior to measurement apparatus attachment.

8. As in the laboratory studies, only sterile excitation and sensory needles, available as standard hospital supplies, were used. Lengths and gages were selected in view of the particular bone and extent of overlying soft tissue to be considered.

9. Measurement needles were inplaced so as to span the entire fracture in the minimum possible distance without compromising localized skin and wound conditions.

The eleven patient diagnoses included femoral, tibial, humeral, ulnar fractures and a spinal fusion. One case, representative of the technique and the results obtained, is that of a comminuted, left limb tibial fracture. This referral was 9 months post fracture. Prior to the sonic diagnosis the fracture treatment included cast immobilization for 4 months followed by partial weight bearing, cast mobilization. The protocol and measurement criteria given above were followed. Measurement needles of 1 in. length and 18 g were spaced at 15 cm. A 2 in., 18 g excitation needle was inplaced 4 cm distal of the prefracture measurement site. A similar needle placement was used for the right limb control measurement.

Results for the fractured limb are shown in Fig. 7. For the fracture, parameter values of an amplitude ratio 14%, slope ratio 14% and 940 m/sec propagation velocity were observed. Control results were 55%, 65% and 2800 m/sec respectively. Agreement of control values with similar laboratory results substantiated use of criterion 3 above, and a diagnosis of non-union made. This result was included in the considerations by the referring physician which led to surgical intervention. At surgery a nonunion was observed and treated.

Similar results were obtained for 8 other patients, namely a sonic study, a diagnosis of nonunion, surgical intervention and confirmation of the diagnosis. Two exceptions arose, the first being that of the spinal fusion. A sonic diagnosis of nonunion was made but surgical intervention was not elected. The patient remains nonunion symptomatic. The second exception was a femoral fracture for which prior treatment

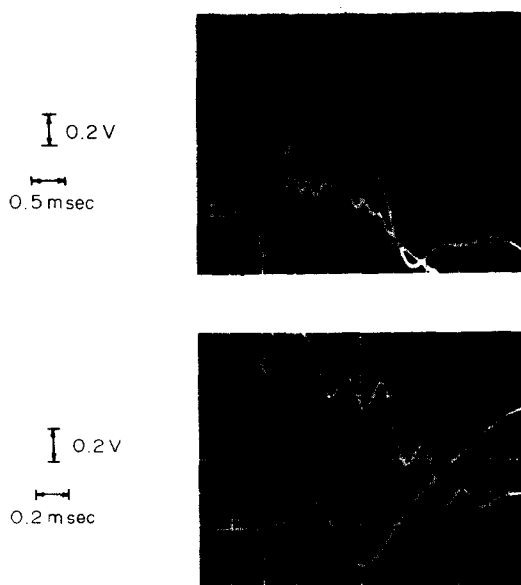


Fig. 7. Clinical measurements denoting diagnosis of nonunion.

included installation of an intramedullary nail. Measurement results for the fractured and control limb are shown in Fig. 8. By criterion 5 above an inconclusive result was reported. Subsequent surgery did disclose a nonunion, and thus the metallic fixation device across the fracture site did negate the technique applicability.

#### SUMMARY AND DISCUSSION

A technique for the sonic diagnosis of bone fracture healing has been developed. The method utilized

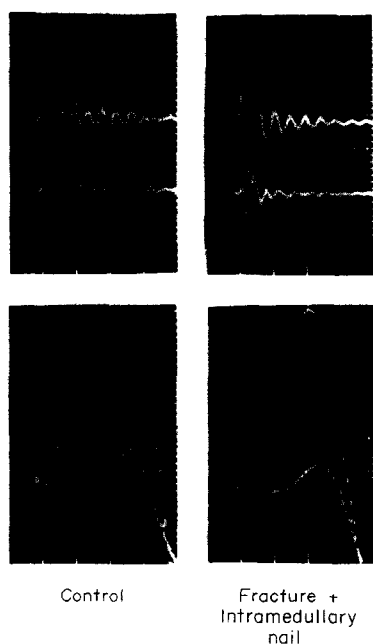


Fig. 8. Clinical measurement for femur with intramedullary nail which denoted an inconclusive diagnosis, subsequently shown at surgery to be a non-union.

three standard hypodermic needles, which are readily placed in secure, intimate contact with the bone surface. This approach circumvents limitations of methods previously described by other investigators in that influences of adjacent bone, connective tissue and overlying muscle, subcutaneous tissue and skin are effectively removed from measurement observations.

A laboratory study on seven dogs has demonstrated that readily determined and reproducible parameter values characterizing excitation disturbance wave fronts provide measures sensitive to the state of fracture union. When successive measures are made during healing the technique provides an indication of union onset and progress. Given but a single measurement of parameter values, however, the laboratory data scatter as observed to date precludes definite conclusions with regard to union progress. Various data reduction and comparative techniques are now being explored to determine if diagnosis refinement may be realized.

A study of 11 patients has explored the clinical suitability and potential of the technique. Although relatively crude diagnostic criteria were used, nine correct determinations of nonunion were made. A tenth nonunion diagnosis, in the case of a spinal fusion, has not been surgically confirmed but is substantiated by continued patient symptoms. One case yielded an inconclusive result, that of a femur with an intramedullary nail. The implant introduced a measurement artifact which precluded the correct conclusion, a nonunion.

This preliminary study has disclosed numerous topics germane to an understanding of the technique itself as well as the character of stress wave propagation in bone. For example, what is the nature of the measured phenomenon, an extensional, shear or surface wave or perhaps some combination thereof? Might better control and definition of the excitation "tap" yield less scattered measurements? Would use of a continuous or swept frequency excitation input provide amplitude and phasing differentials between pre- and post-fracture measurement sites which better enable union status diagnosis? The diagnostic potential of the technique has been demonstrated in both the laboratory and the clinic. Investigation of these questions is thus merited.

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