

Bone diagnostic instrument

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The bone diagnostic instrument is designed to measure materials properties of bone even if it is covered with soft tissue such as periosteum, connective tissue and skin. It uses (1) a probe assembly, consisting of a reference probe that penetrates soft tissue and stops on the surface of the bone and a test probe that is inserted into the bone, (2) an actuation system that can move the test probe, typically into and out of the bone, (3) a sensing system that can determine the dynamics of the test probe as it moves in the bone, and (4) a measurement system to record the data that is sensed during the motion. In our current prototype, a sharpened, solid test probe slides inside a sharpened hypodermic syringe that serves as the reference probe. A load cell senses the force as a function of the distance that the test probe is inserted into the bone relative to the position of the reference probe that rests on the surface of the bone, measured with a linear variable displacement transformer. Examples of the type of data that can be taken with this prototype include cyclic force versus distance curves that show differences in material properties of different types of bone. © 2006 American Institute of Physics. [DOI: [10.1063/1.2221506](https://doi.org/10.1063/1.2221506)]

I. INTRODUCTION

Recent measurements of materials properties of bone have demonstrated that there is substantial deterioration of these properties with aging. For example, Nalla *et al.* have shown that the stress necessary to initiate cracks in the bone, the initiation toughness, decreases by 40% over six decades from 40 to 100 years in human bone even without diagnosed bone disease. And, even more dramatically, the crack-growth toughness is effectively eliminated over the same age range.¹ This recent research extends and supports earlier research that showed a significant deterioration in another materials property, fracture toughness, with age.²⁻¹¹

These measurements suggest that deteriorating materials properties of bone due to aging or disease may play a role in bone fracture risk in addition to the well known factors of (1) decrease in bone mineral density and (2) deterioration of microarchitecture. Instruments already exist to clinically measure these two well known factors: for example, dual energy x-ray absorption (DEXA) and computerized tomography (CT), respectively. There exists, to our knowledge, no instrument that can clinically measure the material properties of bone relevant to fracture risk in living patients. Here we report a design concept for such an instrument. Furthermore, we present results from a prototype instrument based on this design concept and a few examples of the type of data that can be obtained. Further research, beyond the scope of this initial report, will be necessary to determine whether this instrument, or future instruments based on this design concept, will be useful for measuring materials properties of bone in living humans, animals, or cadavers.

II. DESCRIPTION

The design concept for the bone diagnostic instrument is that a probe assembly, consisting of a test probe and a reference probe which penetrates through the skin of a living person, animal, or cadaver so that the reference probe comes to rest on the surface of bone (Fig. 1). The test probe is then inserted into the bone to measure material properties. With a sharpened test probe (we typically use test probes sharpened to half angles of order 11°), it is possible to measure post-yield properties and detect irreversible changes in force versus distance curves. The force versus distance curves can be processed to give parameters such as (1) maximum insertion distance, (2) maximum force reached, and (3) change of these values after multiple cycles of insertion.

The test probe and reference probes may be sharpened asymmetrically, as shown in Fig. 1, to minimize the lateral offset between the tip of the test probe and the tip of the reference probe. This minimizes the zero offsets in the force versus distance curves that result from bone surfaces that are not completely perpendicular to the axis of the probe assembly. We also routinely use symmetrically sharpened test probes when these zero offsets in distance are unimportant, for example, when we are cycling to a fixed maximum force rather than a fixed maximum distance or when we sense the distance at a fixed threshold force and then insert to a constant distance beyond the distance corresponding to the fixed threshold force.

The prototype bone diagnostic instrument shown in Fig. 2, the Osteoprobe™ I, can be used in two different measurement modes: (1) force controlled or (2) distance controlled. In the first, the test probe gets inserted into the bone until a set force is reached and the measured parameter is the resulting insertion distance. In the second mode, the insertion force is increased until the test probe inserts a set distance.

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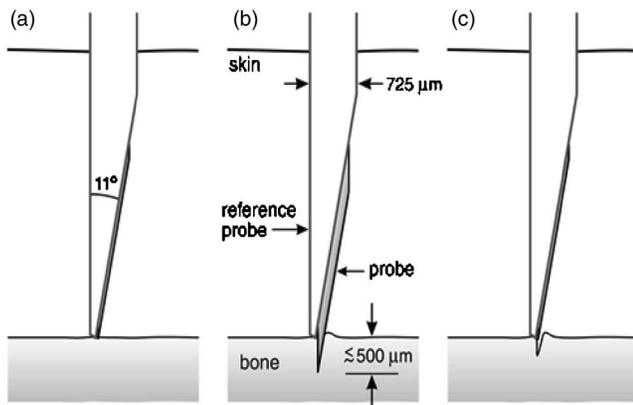


FIG. 1. (a) A typical probe assembly for a bone diagnostic instrument. It consists of a sharpened high speed steel rod as the test probe and a sharpened hypodermic needle, 22 gauge in our current prototype, as the reference probe. This panel shows the probe assembly on the surface of the bone just before test probe insertion. (b) The distance that the test probe is inserted into the bone is measured relative to the position of the reference probe on the surface of the bone. The force to insert and withdraw the test probe is also measured. (c) If the probe is cycled deeply enough into the bone, typically over a few microns, there will be postyield damage that can be sampled in subsequent cycles, which is visible in this panel as a hole remaining in the bone after the test probe was withdrawn.

Corresponding to these two modes, the Osteoprobe™ I can cycle the test probe into and out of the bone with two different actuation systems. One system, based on a solenoid, is most convenient for cycling to a fixed force. For this a current is supplied to the solenoid by a 0–2 A voltage controlled current source. For operation to a fixed force the current source supplies a current that increases to a fixed maximum. The other system, based on a motor and cam, is most convenient for cycling to a fixed distance. Figures 3 and 4 show results obtained using the solenoid system. Figure 5 shows results obtained using the motor and cam system.

Figure 3 shows that the Osteoprobe™ I can discriminate between baked bovine bone and unbaked, control, bovine bone. This model system of baked versus unbaked bone has been very useful in refining our prototypes because the bovine bone is easily and inexpensively obtained from a local grocer and because the baking is an easy way to degrade its fracture resistance. Differences in fracture properties become dramatic for bone baked at 250 °C. for 2.5 h.^{4,12} This is the treatment we used for the baked bone in this report. For testing, the bones are held in small machinist's vices in a glass bowl that is resting on a spring scale on a lab jack. The lab jack is used to raise the scale, bowl, vice, and bone until the bone contacts the probe assembly of the Osteoprobe™ I which is mounted on a support frame. The applied preload force with which the reference probe contacts the bone can be set by continued raising of the lab jack until the desired force is read on the scale. This preload force will set the maximum force that can be used during the testing cycles. If the preload force is exceeded by the insertion force during the test, the reference probe will lift off the bone. The tests are conducted with the bone immersed in Hank's balanced salt solution (HBSS) buffer to keep conditions as close as possible to *in vivo* measurements.

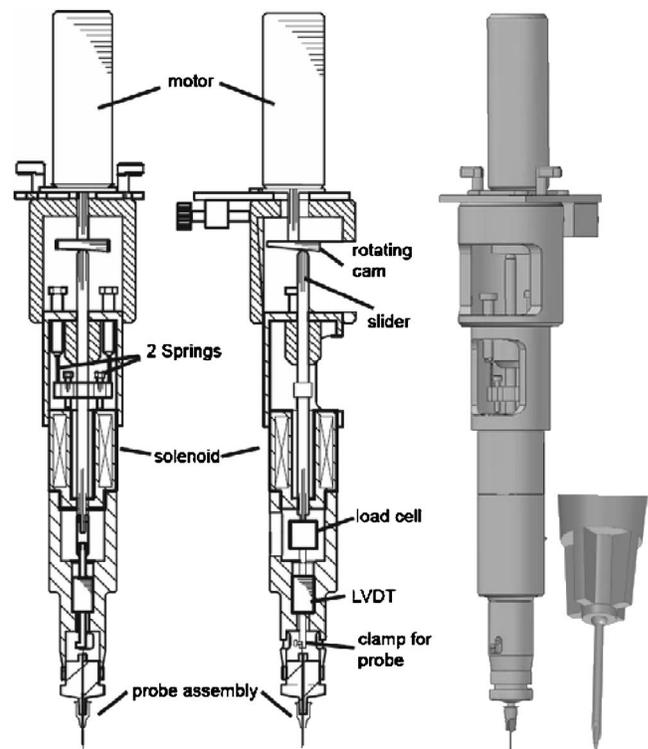


FIG. 2. This prototype bone diagnostic instrument, the Osteoprobe™ I, can sense force with a load cell, Futek model LSB200, and distance with a LVDT Macro Sensors model CD 375. One actuation system cycles the test probe into and out of the bone with forces generated by a solenoid in combination with two springs. This combination provides positive forces for insertion, when the force from the solenoid exceeds the force from the two springs and it provides negative forces to pull the test probe out of the bone when the force from the solenoid is less than the force from the two springs. The prototype instrument also has an additional actuation system consisting of motor drive for cycling to fixed maximum distances. In this case the solenoid need not be energized. The two springs, however, are still required to hold a slider, which is connected to the test probe, against a rotating cam.

For this model system, the Osteoprobe™ I can unambiguously and reproducibly distinguish the baked bone from the unbaked bone based on the expected differences in mechanical properties; see Fig. 3. The unbaked, control bone resists insertion of the test probe better: the distance of the test probe insertion at a fixed force is smaller. The unbaked, control bone also survives cycling better, i.e., repetitive loading to a fixed force. The maximum insertion distance that results from each cycle reaches a limit for the unbaked, control bone, while the maximum insertion distance continues to increase for the baked bone. Note that the maximum force for each cycle increases slightly, especially for the baked bone. This is because we are using open loop electronics that just cycles the current to a fixed maximum. The force from the solenoid is, however, dependent on not only the current, but also on the position of the ferromagnetic core in the solenoid coil. As the distance of insertion increases, the position of the core changes to a position that gives slightly more force for the same current. This could be cured by using feedback on the measured force in a closed loop system that controls the current.

Figure 4 demonstrates that the Osteoprobe™ I can discriminate between the bone material properties of two individual humans that could be expected, based on previous

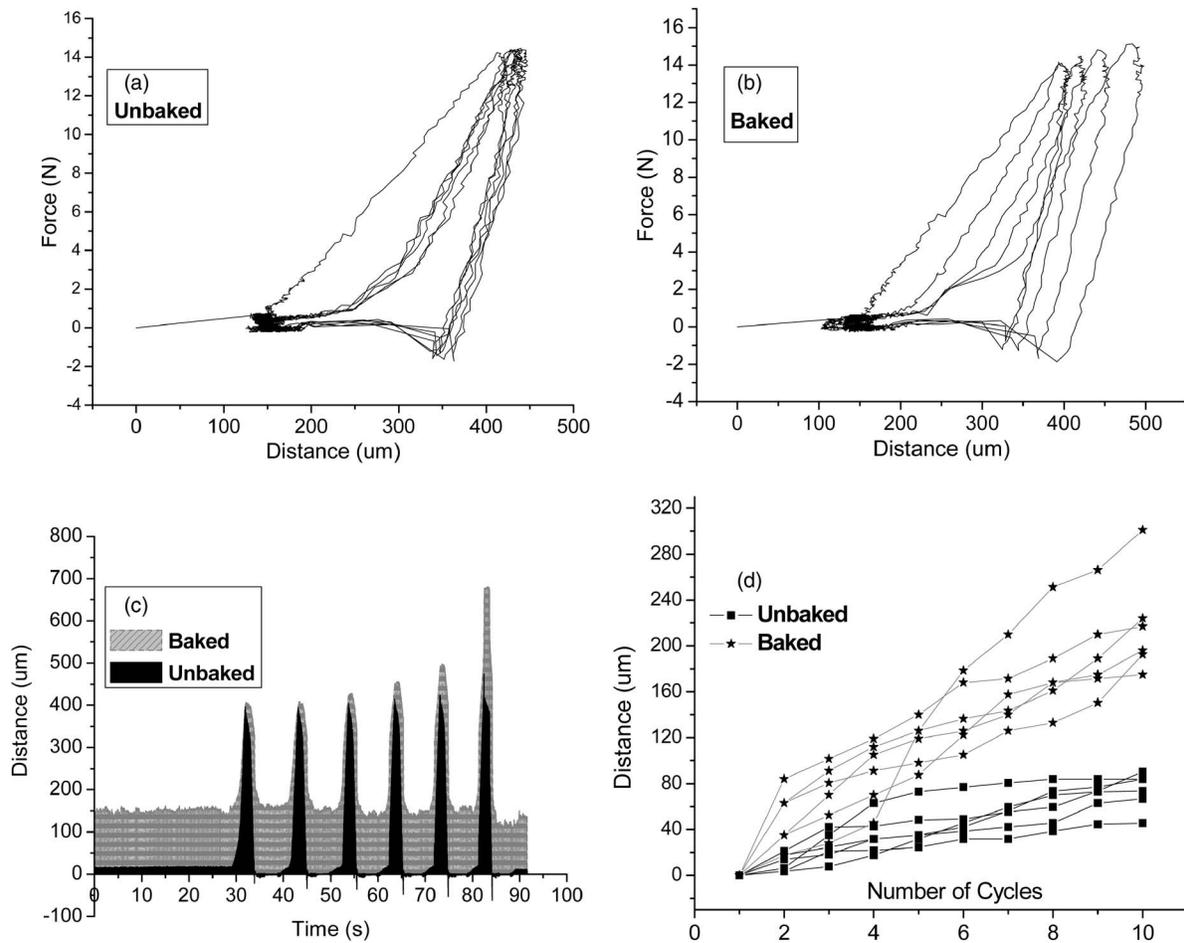


FIG. 3. Force vs distance curves obtained with the Osteoprobe™ I on (a) uncooked bovine bone and (b) cooked bovine bone samples that are submerged in buffer and cycled multiple times. The uncooked bone resists insertion of the test probe better. This can be seen more clearly in plots of distance vs time for the data of (a) and (b). (c) The maximum distance of insertion that results from each cycle reaches a limit for the uncooked bone, while the maximum distance of insertion continues to increase for the cooked bone as can be seen in this compilation of data from a total of 12 samples (six cooked and six uncooked) tested on different days (d). For these curves the force was controlled with the solenoid in the Osteoprobe™ I.

investigations,^{1,4,13} to have different fracture properties because one is young, 19 years old, and one is elderly, 59 years old. The bone of the younger individual survives cycling better. The maximum distance of insertion that results from each cycle reaches a limit for the bone from the younger individual, while the maximum insertion distance continues to increase for the bone from the older individual even though the bone from the younger individual is cycled to a larger fixed force (7 vs 5.5 N). This suggests that the bone from the older individual is less able to resist damage accumulation. Damage accumulation in the form of microcracks has been associated with increased fracture risk.^{14–17} We cannot, however, conclude that the Osteoprobe™ I has demonstrated a significant difference between the bone material properties of bone from younger versus older individuals. Demonstrating such a difference would require many measurements on bones from many individuals and is beyond the scope of this report for several reasons including the fact that we do not have available to us the bone of many young individuals.

Figure 5 demonstrates the use of the Osteoprobe™ I with the alternate actuation system involving a motor and cam rather than the solenoid used in the experiments of Figs.

3 and 4. In this case the distance of insertion is controlled with the motor and the force is measured with the load cell. The force necessary to insert the test probe to a fixed distance decreases as the bone is damaged. For the uncooked bovine bone, Fig. 5 also demonstrates the ability of the Osteoprobe™ I to penetrate soft tissue, even the tough periosteum that covers the bone surface, and still make measurements on the bone. Note that the curves of Fig. 5(b), measured with the uncooked bone covered with soft tissue, including the periosteum, are very similar to the uncooked bovine curves of Fig. 3, for which all soft tissue, including the periosteum, had been removed from the bone surface.

III. DISCUSSION

In recent years, the value of indentation techniques in the investigation of the mechanical properties of biological materials including bone, dentin and cartilage has been realized.^{5,18–27} Intrinsic toughness characterizes the resistance of mineralized tissues to cracking and fracture. Indentation protocols offer a means to quantify both the toughness and hardness of the biomaterials.¹ Examinations of the dentin-enamel junction (DEJ) of teeth further confirm the

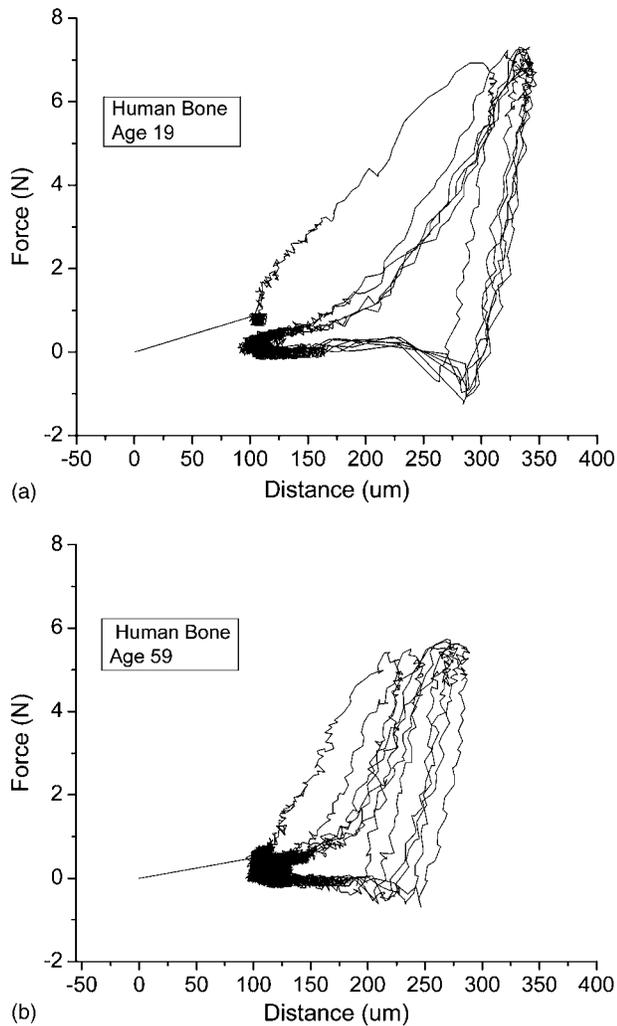


FIG. 4. Multiple force vs distance curves obtained with the Osteoprobe™ I on human bone samples from (a) a 19 years old male and (b) a 59 years old male. The samples were submerged in buffer and cycled multiple times. The younger bone resists insertion of the test probe better. The maximum distance of insertion that results from each cycle reaches a limit for the bone from the young donor while the maximum distance of insertion continues to increase for the bone from the more elderly donor even though the maximum force delivered was lower. For these curves the force was controlled with the solenoid in the Osteoprobe™ I.

value of indentation protocols for understanding crack propagation and fracture mechanics. Using a Vickers indentation instrument, Imbeni *et al.* were able to characterize how cracks propagate and where crack-arrest barriers appear. Toughness and hardness factors for the enamel, dentin, and the interface between the two were quantified.²⁸ Vickers indentation testing would, however, be difficult on a living patient because of the need to image, at high resolution, the indentations and the cracks that propagate from the corners of the indentations.

Indentation instruments also currently exist that are designed for use under surgical conditions. One such instrument has been designed to measure the stiffness of cartilage through arthroscopic surgical control.^{29,30} Biomechanical property changes in articular cartilage are early indicators of degeneration in the tissues. A reduction in compressive stiffness of articular cartilage is related primarily to the reduction

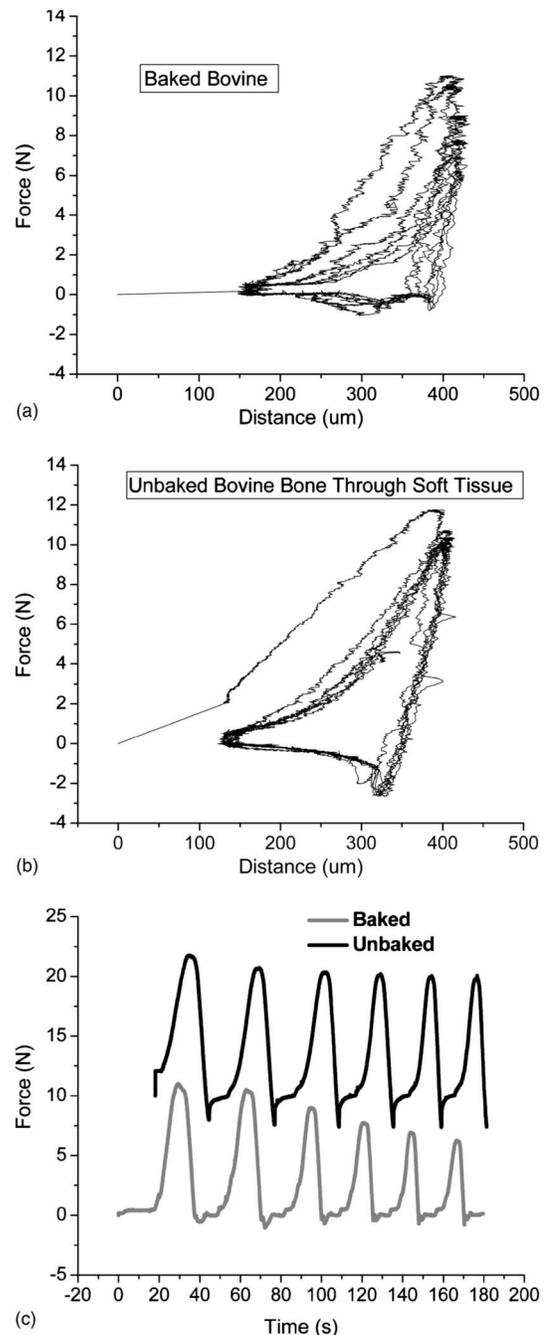


FIG. 5. Multiple force vs distance curves obtained with the Osteoprobe™ I on baked (a) and unbaked (b) bovine bone. The bone samples were submerged in buffer and cycled multiple times. For these curves the distance was controlled with a motor and cam. Again, as for the case of controlling the force with a solenoid (Fig. 3), the baked bovine bone noticeably deteriorates under cycling. But now, rather than seeing the deterioration as an increase in distance of insertion with repeated cycles of nearly constant maximum force, we see a decrease in the maximum force with repeated cycles to nearly constant maximum distance. That is, as the baked bovine bone is damaged with repeated cycles, it takes less and less force (as measured by the load cell) to insert the test probe to a fixed distance. The curves in panel (c) have been offset by 10 N to allow for better readability. The decrease in force required for insertion into baked bone is evident. In contrast, the unbaked bovine bone resists damage. The curves for the unbaked bovine bone (b) reach a limiting cycle that is very similar to the limiting cycle seen with controlling the force with a solenoid [Fig. 3(a)]. It is significant that this curve (b) was obtained from unbaked bovine bone that still had soft tissue, including the periosteum, covering it. The initial applied force, of order 15 N, was sufficient to have the probe assembly penetrate down to the bone.

of proteoglycan content and early detection offers possibilities for treatment to arrest the conditions leading to the degenerative process.²⁹ A similarly designed instrument was used for measurement of structural properties of the cartilage present near the metacarpal bones in equine species and the results correlated positively with glycosaminoglycan levels in the tissues.³¹ An arthroscopic cartilage indenter has been recently used to detect cartilage softening as the early mechanical sign of degradation not yet visible to the eye.³²

Another instrument, the Osteopenetrometer, was designed for *in vivo* testing of trabecular bone during surgical procedures. This instrument was developed to characterize the mechanical properties of trabecular bone to obtain information relevant to reducing the problem of implant loosening following total knee arthroplasty.³³ The Osteopenetrometer involved penetrations of lengths of order 8 mm and widths of order of millimeters in diameter at implant sites during surgery. The goal was to have large enough indentations to average over many trabeculae inside the trabecular bone.

The Osteoprobe™ is distinct from these previous instruments. It is designed to be used without surgically exposing the bone surface. The small diameter probe assembly is inserted through the skin down to the bone. It is not necessary to expose or visualize the bone surface. It is also distinct from the OsteoSonic™, developed by Tawackoli *et al.* at Rice University, which uses acoustic waves to measure the structural integrity of bone without penetrating the skin with any sort of probe.³⁴ The Osteoprobe™ is designed to probe not only preyield parameters such as elastic modulus, but also postyield parameters such as toughness by actually creating yield in a small probed volume of the bone.

Only further research will be able to determine the optimal probed volume for Osteoprobe™ and the optimal number of measurements per bone sample. One consideration is keeping the probed volume and the number of measurements small to minimize trauma to the bone and patient, at least for living patients. On the other hand, it is necessary to either have the probed volume large enough to average over relevant structures within the bone or to make multiple tests to average over relevant structures. We have tried insertion distances in the range of 2–1000 μm . Our initial results suggest that, if single tests are desired, it is necessary to average over osteons, which have typical dimensions of order 200 μm . Thus we have used insertion distances of order 500 μm in the data presented in this report. Another parameter that will be important to investigate is the speed of the testing. There is, of course, an advantage to running as fast as possible in terms of the time it takes to complete a test. We have explored cycle times in the range of 1–100 s, but selected cycle times of 10–30 s for the data presented in this report because of the relatively slow response of our linear variable displacement transformer (LVDT) distance sensor in our current prototype. Finally, the type of information that can be learned depends on the shape of the test probe. We have used spherical test probes, conical test probes with opening angles ranging from 5° to 90°, cube corner test probes, and other faceted test probes. In general, the sharper test probes give better differentiation, but if they are too sharp, they can break

or deform. Most of the data in this report came from rounded, beveled test probes with a bevel angle of roughly 11° as shown in Fig. 1. On the other hand, if it were desired to measure elastic modulus or hardness such as measured by conventional indentation techniques, it would be best to use tips with the same shapes as used in the conventional indentation techniques.^{5,18–26}

In summary, we report a new concept for a bone diagnostic instrument and initial results from a prototype instrument designed using this concept. It represents a step toward a long term goal of producing an instrument that could be clinically tested to see if it could help physicians assess overall fracture risk. Only further research can determine if the Osteoprobe™ I, or further iterations of bone diagnostic instruments, will be able to provide the level of consistency and discrimination needed for serious investigations of bone material properties in living humans, animals, or even cadavers.

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