

Acoustic Emission Monitoring

Technology Abstract

A provisional patent ("AE stimulation of biological tissue structures," Winder, 2006) was filed with the U.S. Patent and Trademark Office, which describes an ultrasound device that employs nonlinear acoustics to stimulate biological tissue (such as bone tissue), for producing acoustic emissions. The use of nonlinear acoustics in an ultrasound projector is a key requirement for developing a commercially viable AEM device for medical applications. This technology will be used with [U.S. Patent 6,213,958](#) ("Method and apparatus for the acoustic emission monitoring detection, localization, and classification of metabolic bone disease," Winder, 2001) to create a diagnostic system for Acoustic Emission Monitoring (AEM). The proposed systems approach employs an acoustic model originally developed (and successfully used by the author) for various military sonar applications.

Commercial Potential

There is substantial scientific evidence suggesting that AEM can be used to describe the strength and quality of bone tissue. This will provide a means for the early detection, localization and characterization of metabolic bone disease and bone cancer. The ultimate goal is to build a database of *acoustic fingerprints* of specific pathological bone conditions, such as osteoporosis.

Osteoporosis is a major public health problem, which will affect even larger numbers of people as our population continues to age and life spans have been extended. It has been estimated that over 1.5 million osteoporotic fractures occur annually in the United States [1]. As new treatments for osteoporosis become available, the challenge will be to improve the ability to identify those with decreased bone quality and increased risk of osteoporotic fracture, so that effective interventions can be instituted. It is estimated that, in the United States, about 28 million patients will be candidates for yearly bone disease examinations [2-4]. These exams are typically conducted in the office of the primary physician or orthopedist.

The proposed product will therefore include a physician-operated device, plus a diagnostic service. The device can be sold or leased to each doctors' office. The results of each individual study will be transferred via modem or secure Internet connection, for real-time diagnosis at a central processing center, against a database of AEM signatures.

In the U.S. there are a total of ~15,000 physician and orthopedist private practices, plus ~5,000 eligible hospitals. Not including clinics and research centers, this suggests a total market for about 20,000 devices, at around \$10k/device, for a total of \$200 million. This closed-end revenue is dwarfed, however, by the associated service fees: the total U.S. market is approximately \$1.68 billion PER YEAR (assuming a fee of \$60 per study, times about 28 million patients per year), with a gross profit margin between 65-80%.

Epidemiology

Although the proposed technology and multi-phase program are relevant to *any* metabolic bone disease, such as osteoporosis, osteopenia, and osteosarcoma, this discussion will address osteoporosis – by far the most common type of bone disease. Osteoporosis has been generally considered to be a disorder primarily affecting post menopausal women. However, there are other large groups of the population at increased risk for osteoporosis and osteoporotic fractures, including those receiving steroid and immunosuppressive therapy, as well as elderly men.

Osteoporosis is a disorder currently characterized by a decrease in bone mass and a propensity to develop fractures. Osteoporosis tends to remain asymptomatic, and often unrecognized, until the development of the first fracture. One of the major challenges in treating osteoporosis is therefore the ability to identify those at increased risk of future fracture and to intervene with an effective therapy. Diagnostic complexity is added by the variety of different (and sometimes disabling) fractures from which patients may suffer:

- The most common osteoporotic fractures are those of the distal forearm, thoracic and lumbar vertebrae, and the proximal femur. The occurrence of any one of these fractures can cause significant morbidity and alteration in lifestyle (including cost of care).
- Vertebral fractures may be either asymptomatic, or may lead to disabling back pain and nerve compression.
- The morbidity, mortality, and costs associated with hip fractures are also substantial: of those able to walk at the time of the hip fracture, nearly half will not be able to ambulate without assistance following the fracture [5]. Both the short term and long term costs of caring for hip fracture patients alone have a tremendous impact on health care expenditures. Recent estimates of hip fracture rates per year in the United States are greater than 250,000; the direct and indirect annual costs range between \$7-10 billion. Estimates for the year 2020, due to the growing size of the elderly population, are between \$31-62 billion [6].

Current Diagnostic Mechanisms

The availability of improved methods of measuring bone mineral density (BMD), such as dual photon absorptiometry (DPA) and dual energy X-ray absorptiometry (DEXA), has greatly improved the ability to identify people at increased risk of developing osteoporotic fractures. BMD is an indirect measure of bone strength. However, it has been recognized that a segment of the population will develop osteoporotic fractures despite a normal BMD [7,8]. In addition, not all patients with decreased BMDs will develop osteoporotic fractures. Other factors, such as bone microarchitecture, accumulation of microfractures, and skeletal aging itself are likely to contribute to reduction in bone strength and risk of fracture.

A non-invasive, safe, and reliable technique to determine bone quality would substantially improve our ability to detect those at risk for the development of fractures, and would be an invaluable technique to monitor response to therapy. Such a technique must improve upon the results of BMD measurements in the prediction of fracture risk, if

it is to substantially improve our ability to diagnose osteoporosis [9]. Acoustic Emission Monitoring (AEM) is proposed as such a technique.

Acoustic Emission (AE) Principles

The foundation of Acoustic Emission (AE) physics is based on what is referred to as the “Kaiser Effect” and the “Felicity Effect.” [10]

The *Kaiser Principle* states that materials present acoustic emissions only under unprecedented stress. Acoustic emissions are attributed to frictional rubbing of grains against each other in polycrystalline materials and also from intergranular fractures. The *Kaiser Effect* states that many materials show low levels of acoustic emissions beginning at very low stress levels (less than 0.7 MPa or 100 psi), which are detectable under increased stress levels, all the way through to final failure. The Kaiser Effect has been tested to be valid for various materials, including metals, woods and other mineral composites. The *Felicity Effect* is the exception to the Kaiser Principle. It states that when an acoustic emission occurs at stresses lower than the peak stress of the previous acoustic emission, it typically indicates significant permanent damage in the material.

Acoustic Emission Monitoring (AEM)

Sudden localized changes of stress or strain in bone tissue produce wideband acoustic emissions that are uniquely related to the location and type of structural changes in bone mass, strength, and architecture (i.e., “bone quality”). Acoustic Emission Monitoring (AEM) could therefore provide a means for the early detection, localization and characterization of metabolic bone diseases and bone cancers. Ultimately, such a system might not only determine bone quality, but also lead to a point where an *acoustic fingerprint* of specific pathological bone conditions can be developed.

[U.S. Patent 6,213,958](#) (“Method and apparatus for the acoustic emission monitoring detection, localization, and classification of metabolic bone disease,” Winder, 2001) describes a diagnostic system to detect, localize, and characterize the acoustic emissions produced by applying noninvasive mechanical stimulation to the musculoskeletal system. These wideband acoustic emissions are extremely rich with information on tissue composition and structure that has not yet been explored by investigators. Although it is not known with 100% certainty whether the AE method actually works for bone tissue, all the work performed for the past twenty-five years in the field of AE materials testing overwhelmingly supports the concept. In particular:

AEM technology has been investigated by several researchers in the 1970's as a diagnostic tool for osteoporosis. Hanagud, Clinton and associates [11-13] showed that the acoustic emission rate from cattle femurs subjected to bending loads is greater for low density specimens as compared to those with normal density. These emissions were detected well before the actual bone failure. In a fairly recent study, Leichter and associates [14] examined the acoustic emissions from cancellous bone under compression. They also found that the post-yield acoustic emission rates were significantly higher in both osteoporotic and osteoarthritic bone specimens, compared to normal bone. In an earlier study, Katz and Yoon [15] related ultrasonic wave propagation measurements to the structure and anisotropic mechanical properties of osteoporotic and osteopetrotic bone. Their results showed that osteoporosis is characterized by increased porosity or decreased density, while osteopetrosis forms calcified cartilage in bone and affects the elastic stiffness and Young's modulus of bone

tissue. To briefly summarize our overall confidence in the clinical significance of the AE method:

- The Kaiser and Felicity Effects, coupled with the growing body of work of many investigators on cadaver bone specimens, indicate that this approach has a very high probability of success.
- AE patterns have also been successfully measured for fiber-reinforced composites [16] and composite motor cases [17], which further suggests that AE signals are appropriate for determining the integrity and the behavioral characteristics of the extracellular matrix of bone tissue.
- The AE method of determining strength of complex structures has been successfully used in the overall field of non-destructive testing [18-20] – it simply has not yet been applied to this particular problem.

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