A Novel Acoustic Emission Technology for Assessing Osseointegration in Bone-Anchored Implants

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INTRODUCTION: Bone-anchored limb prostheses (or osseointegrated implants) offer improved mobility, range of motion, and comfort compared to socket-based prosthetic legs. However, it is often associated with post-op complications, such as infection and aseptic loosening, necessitating revision surgeries. Current imaging modalities (e.g., CT, radiographs, bone scans) lack sensitivity to early loosening at the bone-implant interface, and acoustic emission (AE) technology may provide a sensitive, non-invasive tool for monitoring instability. This process involves the analysis of transient sound waves generated by the rapid releases of stress and energy in material. While it has shown promise in the evaluation of structural stability in other medical applications, uncertainty remains regarding the optimal sensor frequency in orthopedics and osseointegration. The objective of this study was to (1) evaluate if AE technology can adequately monitor implant stability under systematically controlled implant looseness conditions and (2) determine which sensor achieves the most reliable results. We hypothesized that AE parameters would correlate with varying implant loosening states and that high-frequency sensors would outperform low-frequency sensors in detecting instability.

METHODS: Eighteen human cadaveric femurs (N=18; 9 pairs) were cleaned of soft tissue and cut transversally to simulate above-knee amputations. The screw-type OPRA Implant System was implanted into each femur with standard surgical tools and techniques (Integrum). Tight versus intentionally loose initial fixation was achieved by varying canal diameter prior to placement of the implant. In each specimen, the OPRA implant was progressively loosened by unthreading 1, 2, and 5 full 360 degree turns. At each condition, a 20 N impact force was delivered into the distal abutment and side surface using a stainless-steel ball bearing on a 3D printed customized ramp (Figure 1). Acoustic emission signals were recorded during each impact using a high-frequency (300-1800kHz, PAC S225) and a low-frequency (100-450 kHz, PAC PK15I) sensor. AEwin64 software (PAC, v1.0) was used for waveform acquisition. The output variables included amplitude, energy, AE counts, duration, rise times, and multiple frequency components. RA (risetime/amplitude) and FA (AE counts/duration) were calculated to compare differences in high and low frequency data. Inter-specimen comparisons (tight vs. loose pairs) were assessed with paired t-tests, and differences in AE signals after progressive loosening was analyzed with repeated measures ANOVA.

RESULTS: RA-FA mapping demonstrated a distinguishable trend with loosening, characterized by an increase in RA and decrease in FA. This finding was confirmed by comparing 0 and 5 turn treatments, which revealed significant increases in RA (3 of 9 femurs, $p<0.01$) and decreases in FA (6 of 9 femurs, $p<0.05$). The low frequency sensor showed no significant relationship with loosening. The tight versus loose pair comparison at 0 turns and 2 turns demonstrated significantly higher AE amplitude, AE counts, and duration compared to tight controls at baseline ($p <0.05$). Progressive loosening in specimens with tight fixation produced significant differences in AE counts, energy, and average frequency ($p<0.03$, Figure 2). Duration and amplitude were also significant when comparing initial tightness to 1 turn and 5 turns loose ($p<0.05$).

DISCUSSION: This work demonstrates that AE technology is a viable solution for measuring the fixation stability of osseointegrated prostheses, thus, it has significant clinical potential for micromotion monitoring. The next step is to translate these findings from a static, cadaveric model to allow for validation under physiologic loading and the development of a standardized diagnostic loosening score.

SIGNIFICANCE/CLINICAL RELEVANCE: AE offers a novel, non-invasive, real-time method for detecting early implant loosening in bone-anchored prostheses, with potential to monitor early loosening, reduce revision rates, and improve long-term outcomes.

IMAGES AND TABLES:

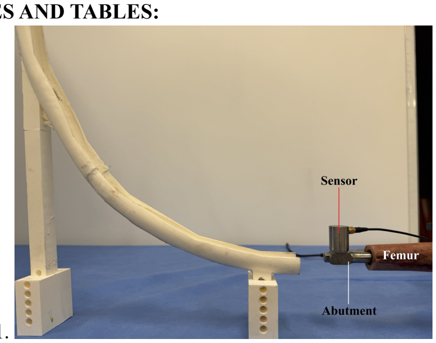

Figure 1.
A side view of the experimental setup. A 3D printed ramp was used to produce a 20N impact using a ball bearing. The AE sensors were attached to the osseointegrated implant using silicone grease (not pictured). The femur was held stable by a vice.

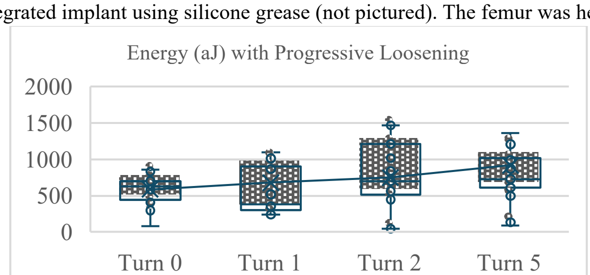

Figure 2.
A significant increase in AE energy ($p=0.0248$) was observed as implant loosening progressed from an initial state (0 turns) to gross instability (5 turns). This demonstrates a direct relationship between the degree of implant micromotion and the magnitude of energy released.