Granular crystal sensor and actuator for orthopaedic implant stability assessment
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ABSTRACT
We propose a new granular crystal sensor and actuator suite based on highly nonlinear solitary waves to offer a compact, inexpensive, and reliable diagnostic instrument for biomedical applications. A granular crystal sensor/actuator composed of tightly packed elastic particles is assembled to generate and retain self-reinforcing, nondispersive diagnostic solitary waves. Via direct contact, this device can nondestructively evaluate the mechanical integrity of biomedical structures, prosthesis in this study, based on the responsiveness of the solitary waves reflected from the interface between the granular crystal and inspection medium. Using a prototype of granular crystal sensor/actuator, we perform a pilot study to investigate the orthopaedic implant stability of artificial composite femurs in a noninvasive manner. For experimental tests we impose harsh mechanical loading to the artificial femoral implant samples using a femoral load simulator. Preliminary studies show promising results, demonstrating the proposed granular crystal sensor/actuator successfully detects fracture at the stem-bone interface of the composite femoral stem model. This study suggests the granular crystal sensor/actuator might be used as a novel diagnostic instrument for a nondestructive evaluation of mechanical integrity in biomedical implants through enhanced accessibility and reliability.

Keywords: Phononic/granular crystals, biomedical/orthopaedic implant, solitary waves, total hip arthroplasty

1. INTRODUCTION
Joint replacement surgeries are becoming widespread due to the aging of population and the advancement of medical technology [1, 2]. Among different types of joint replacement surgeries, including shoulder, wrist, knee, and ankle replacements, total hip arthroplasty (THA) is one of the most common joint replacement surgery with over 500,000 operations performed annually worldwide [3]. The THA operation involves the implant of an artificial metal stem into the femoral canal to construct prosthetic femoral joint. The implant configurations, such as stem dimensions, materials, and surface finishing, may vary depending on a series of clinical parameters. Unfortunately, these parameters have not yet been assessed objectively for the long-term stability of orthopaedic implants [4]. Furthermore, it has been reported that the usage of metal stems can cause a process called “stress shielding” around implants [5]. This is because a highly stiff metal stem shields the bone from mechanical stresses, which it would naturally be subjected to. The stress shielding phenomenon results in the eventual bone resorption, leading to the degradation of the mechanical integrity between prosthesis and bone. This loosening of implant is the most common mode of failure that often necessitates revision surgery [6]. Moreover, many peri-prosthetic fractures (fracture of the bone around the prosthetic implant) can also be attributed to gross loosening of implants, which results in eventual structural failure. Therefore, the ability to assess bone-stem mechanical integrity would be extremely advantageous in both a clinical setting for assuring proper fixation of stem, and the design of artificial stem for optimization purpose.

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Current techniques for inspecting the physical engagement between the implant and bone structure (herein, called implant stability) include radiographic imaging and vibration analysis techniques. Diagnostics based on medical imaging, generally radiography using ionizing X-radiation, is most common in assessing implant stability [7]. Radiographic imaging can help monitor the position of the implant and its movement during the healing process after surgery [8]. However, X-ray based techniques present sensitivity limits in detecting implant loosening and early stages of interface degradation. A vibration analysis (VA) technique, introduced originally for dental implants stability assessment, has been applied to joint implant analysis in preliminary studies [9]. This method uses shaker to excite the bending behavior of an implant-artificial bone system and analyses its physical stability by means of accelerometers [10]. The VA technique, however, is negatively affected by the intrinsic invasiveness and complexity of the testing apparatus. Overall, both radiographic imaging and VA technique exhibit limitations in the assessment of implant stability during surgical procedures or in the early detection of crack/debonding development after surgery [11-14].

In this study, we introduce and evaluate a novel method for a nondestructive evaluation of orthopaedic implant stability by using highly nonlinear solitary waves (HNSWs). We employ a phononic crystal made of a one dimensional chain of spherical particles (also called as a granular crystal), to generate and propagate HNSWs as input excitations sources. HNSWs are compactly-supported lumps of energy, which are formed by a balance between nonlinear and dispersive effects in intrinsically nonlinear media (e.g., granular, layered, fibrous, or porous materials) [15]. It has been shown that by hitting this granular crystal with a striker it is possible to generate HNSWs that propagate down the chain [15, 16]. Via direct contact, we transmit a single pulse of HNSW to the combined system of orthopaedic implant and artificial bone. In this paper, we limit our study to a standalone, exposed prosthesis structure, rather than treating more complicated implants embedded in soft tissues, such as muscle and flesh, for in-vivo testing.

The mechanism of HNSW interaction with an inspection specimen is significantly affected by its mechanical properties, geometry, and boundary condition, showing wave dynamics unseen in linear systems [17, 18]. In this study, therefore, we investigate the characteristics of HNSWs reflected from the implant structure to assess its mechanical stability. The robustness of HNSWs, as well as their sensitivity, makes them extremely useful as information carriers in nondestructive evaluation (NDE) applications. Using artificial femoral implant samples, we find that HNSWs are sensitive to the level of stem fixation within the femoral canal. Specifically, we show that the proposed sensing scheme successfully detects peri-prosthetic fracture at the stem-bone interface in a composite femoral stem model. This preliminary study suggests that a granular crystal sensor/actuator suite might be used as a portable and reliable sensing instrument for fast and reliable evaluation of orthopaedic implants stability.

2. MATERIALS AND METHODS

We prepared artificial THA samples, which exhibit different stem geometry and configurations of stem-bone interface. We first acquired baseline diagnostic data of these samples via the proposed granular crystal sensor/actuator suite. After the initial acquisition of the baseline data, we applied a dynamic joint reaction force to each sample to simulate the effects of highly intense patient activities via the servo-hydraulic femoral load simulator [14]. The samples underwent up-to eight sets of mechanical loading cycles, and in each set, we applied both axial force and torsion simultaneously in a time-incremental pattern. Between sets of physiological loading, diagnostic evaluation of the implant stability was performed via HNSWs to detect structural failure of the implant samples. Visual inspections were also carried out after each loading to find any noticeable defects (e.g., dislocation, cracks) developed at the stem-bone interface.

2.1. Specimen preparation

Three artificial femoral implant samples were assembled that combined metal stems and synthetic femurs [Table 1]. The metal stems were made of a CoCrMo (Cobalt-chromium-molybdenum) alloy [Zimmer Orthopedics, Inc., Austin, TX]. We used synthetic composite femurs for bone-like mechanical characteristics and configurations [Pacific Research Laboratories, Vashon Island, WA]. They featured an E-glass filled epoxy to mimic cortical bone and rigid polyurethane foam for cancellous regions. We used two different approaches to achieve fixation of metal stems into the artificial bone. The Samples 1 and 2 employed a traditional cemented configuration of the implanted stems, involving the use of simplex PMMA (Poly(methylmethacrylate) cement [Howmedica, Rutherford, New Jersey]. On the other hand, the metal stem in the Sample 3 was pressure-fitted into the femoral canal by means of hammer impact. The rationale for the use of both “cemented” and “non-cemented” prostheses was to assure the sensitivity of our diagnostic method to both implant configurations, all widely used in clinical practices. For the same reason, we built two samples (Samples 1 and 3) using
“collared” stems, while the Sample-2 adopted “non-collared” geometry of metal stem. The use of “collared” or “non-collared” stems is still a subject of debate from the perspective of the long-term implant stability [19-21].

Table 1. Specifications of artificial femoral implant specimens.

<table>
<thead>
<tr>
<th>No.</th>
<th>Stem Material</th>
<th>Geometry</th>
<th>Femur Stem-femur interface</th>
<th>Bonding material</th>
<th>Implant method</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>CoCrMo</td>
<td>Collared</td>
<td>Cortical bone</td>
<td>E-glass filled epoxy</td>
<td>Simplex PMMA cement</td>
</tr>
<tr>
<td>2</td>
<td>CoCrMo</td>
<td>Non-collared</td>
<td>Cancellous bone</td>
<td>Rigid polyurethane foam</td>
<td>Simplex PMMA cement</td>
</tr>
<tr>
<td>3</td>
<td>CoCrMo</td>
<td>Collared</td>
<td>Cancellous bone</td>
<td>E-glass filled epoxy</td>
<td>Simplex PMMA cement</td>
</tr>
</tbody>
</table>

2.2. Femoral load simulator

For the mechanical loading of the specimens, we used a servo-hydraulic femoral load simulator [14] to impose simultaneous axial and torsional loading on femoral implant samples. The specimen tested was mounted in an inverted position, and the root of the specimen (i.e., a distal part of the composite femur) was firmly fixed to an actuator, which applied axial force and angular torque in the vertical direction [Fig. 1 (a)]. The head part of the stem was rigidly fixed to a brass ball joint at the base of the femoral load simulator to resist the actuator-applied forces. The actuator was controlled to generate a user-defined profile of loading through a connected software interface. We repeated up-to eight sets of harsh mechanical loading for each specimen to develop mechanical degradation of the stem-bone interface [Table 2]. The experimental specifications of the loading profiles were altered to find efficient loading conditions for accelerating implant’s mechanical degradation. In each set, the loading intensity was increased gradually to impose harsher fatigue condition. The maximum axial loading was 3000 N, while the zero-to-peak amplitudes of maximum angular torques were 25 N-m. This is much severer loading than the actual physiological stresses applied to a femoral bone of a normal person. Applied loading and displacement profiles were acquired via the load cells embedded inside the actuating element of the femoral load simulator at a sampling frequency of 20 Hz. In particular, the measured axial and angular displacements can be translated into the relative motion of stem with respect to the composite femur, considering high rigidity of metal stem compared to that of the composite femur.

Table 2. Experimental specifications of loading profiles for the servo-hydraulic femoral load simulator.

<table>
<thead>
<tr>
<th>Set no.</th>
<th>Duration [s]</th>
<th>Axial loading [N]</th>
<th>Angular loading (0 to peak) [Nm]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Start</td>
<td>Increment</td>
</tr>
<tr>
<td>1</td>
<td>497</td>
<td>300</td>
<td>50</td>
</tr>
<tr>
<td>2</td>
<td>497</td>
<td>300</td>
<td>50</td>
</tr>
<tr>
<td>3</td>
<td>497</td>
<td>300</td>
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<tr>
<td>4</td>
<td>498</td>
<td>300</td>
<td>50</td>
</tr>
<tr>
<td>5</td>
<td>1100</td>
<td>300</td>
<td>100</td>
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<tr>
<td>6</td>
<td>1100</td>
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<tr>
<td>7</td>
<td>954</td>
<td>300</td>
<td>0</td>
</tr>
<tr>
<td>8</td>
<td>953</td>
<td>300</td>
<td>0</td>
</tr>
</tbody>
</table>

2.3. Granular crystal sensor/actuator

A granular crystal sensor/actuator was assembled using a vertically-aligned chain of 20 stainless-steel beads (type 440C with a 9.53-mm radius, McMaster-Carr) [Fig. 2(b)]. The spheres were constrained by four stainless steel rods to hold the particles vertically. In this study, we generated a single pulse of HNSW by releasing a striker bead (identical to the bead composing the chain) from a 1-cm drop height using an electrical solenoid [18]. The HNSW formed in the chain was transmitted to the implant structure via direct contact with the flat area of the stem top [Fig. 2(c)]. For the fixture of the implant specimen, we mounted firmly the distal portion of the implant using custom-designed clamps and fastening screws. We recorded both incident and reflected waves that convey diagnostic information about the bone-stem integrity using a sensor bead within the chain [15, 18]. We positioned the instrumented bead in the 7th particle site from the top of the chain, and the piezoelectric element inside the instrumented bead converted pressure waves in the chain into voltage signals. We acquired the signals using a data acquisition board (National Instrument PCI-6115), which were converted back to force profiles of the propagating waves using a calibration factor of the instrumented particle. The details on the
sensor manufacturing and calibration can be found in [22]. For each testing, we performed five measurements of HNSWs and analyzed the signals in MATLAB to extract features from the reflected HNSWs.

3. RESULTS AND DISCUSSION

In this section, we first described the response of artificial femoral implants under the simulated physiological loading. By analyzing the loading and displacement data obtained from the femoral loading simulator, we calculated the stiffness values of the implant specimens both in the axial and angular directions. Based on the calculated stiffness profiles, we detected any noticeable degradation of the stem-bone integrity. We then analyzed the HNSW measurements obtained from the identical samples. We compared the HNSW-based diagnostic results to those obtained from the mechanical loading analysis to verify both results are in agreement.

3.1. Mechanical loading results

Typical profiles of axial and angular loading are shown in Figs. 2 (a) and (c), respectively. These specific profiles are from the Loading-5 applied to the Sample-1 [Table 2]. As shown in the insets of Figs. 2 (a) and (c), the force and torque profiles exhibited sinusoidal waveform with a 1-s period. The maximum compressive force in the axial loading direction was gradually increased from 300 N to 3,000 N during 1,100-s testing period. The corresponding axial displacement history is shown in Fig. 2 (b), showing a similar trend to that of the axial loading. At the peak loading, the dynamic displacement in the axial direction was increased up to approximately 2 mm. However, as the axial loading returned to zero at the end of the testing, we found that the displacement of the fixed stem also recovered to its initial position without noticeable residual movement [see the average displacement curve, denoted in bold red line, in Fig. 2 (b)]. The torsional loading was simultaneously applied to the composite femur samples with its peak amplitude at 25 N-m. This corresponds to a 50 N-m torque in a peak-to-peak range [Fig. 2 (c)]. The angular displacement also followed the gradually increasing trend of the torque profile as shown in Fig. 2 (d). At the maximum torque, the peak-to-peak angular displacement was as high as 2.5 degrees.
Based on the loading and displacement measurements, we calculated axial and angular stiffness values per cycle to quantify the level of stem's fixation into a composite femur. In this study, we defined the axial stiffness at the $n$-th cycle, $k_{\text{axial}}^n$, as:

$$k_{\text{axial}}^n = \frac{F_{\text{avg}}^n}{u_{\text{avg}}^n} \approx \frac{F_{+\text{peak}}^n + F_{-\text{peak}}^n}{u_{+\text{peak}}^n + u_{-\text{peak}}^n},$$

(1)

where $F_{\text{avg}}^n$ is the average force during a single cycle (i.e., one second period), and $F_{+\text{peak}}^n$ and $F_{-\text{peak}}^n$ denote the force amplitudes at the positive and negative peak, respectively. The average value of the axial displacement is $u_{\text{avg}}^n$, which is approximately the mean of the maximum ($u_{+\text{peak}}^n$) and minimum ($u_{-\text{peak}}^n$) displacements within a cycle.

Unlike the axial loading profile, angular loading and displacement profiles are symmetric with respect to its undisturbed, neutral position [see Figs. 2 (c) and (d)]. Therefore, the derivation of angular stiffness based on average values results in trivial values. Hence, we defined the angular stiffness, $k_{\text{angular}}^n$, based on the peak-to-peak amplitudes of the torque and rotation:

$$k_{\text{angular}}^n = \frac{\Delta T^n}{\Delta \theta^n} \approx \frac{T_{+\text{peak}}^n - T_{-\text{peak}}^n}{\theta_{+\text{peak}}^n - \theta_{-\text{peak}}^n}.$$  

(2)

Here, $T_{+\text{peak}}^n$ and $T_{-\text{peak}}^n$ are the peak torque values in the clockwise and counter clockwise directions, and $\theta_{+\text{peak}}^n$ and $\theta_{-\text{peak}}^n$ are the corresponding angular rotations in the $n$-th cycle of the physiological loading.

Figure 3 shows the evolution of axial and angular stiffness values of three THA samples over the accumulated cycles of testing sets. The spikes observed in each set were trivial, because near-zero displacements at the beginning of loading tend to generate unstable and large stiffness values. We also found that the calculated stiffness values behaved nonlinearly, showing different stiffness values depending on the loading magnitudes. However, the stiffness values were
stabilized towards the end of each loading set. The noisy angular stiffness values in the early period for the samples 1 and 3 were due to the improper acquisition of angular loading data.

According to the calculated stiffness profiles, it is evident that both axial and angular stiffness of the sample-3 are significantly lower than those of the samples-1 and -2. This is because the pressure-fit fixation of metal stem into the composite femur was not as strong as the fixation achieved by the cemented interface. We also observed that even after the repeated sets of harsh fatigue loading, the composite femurs did not develop noticeable degradation of either axial or angular stiffness, particularly for the Samples-1 and -2. This high durability of composite femurs is in sharp contrast to the behavior of real human femurs, in which the mechanical integrity between the stem-bone interface is gradually degraded under fatigue due to the bone resorption caused by stress shielding [5].

Despite the unrealistically high stiffness of composite femurs, the Sample-3 with pressure-fit fixation showed a sudden change in its axial and angular stiffness values around the 2,000-cycle point [see the boxed areas in Figs. 3 (a) and (b), with their zoomed views in the insets of each figure]. The axial stiffness value was decreased by 48%, from $4.71 \times 10^5$ N/m [marked in a red triangle in the inset of Fig. 3 (a)] to $2.45 \times 10^5$ N/m [marked in blue circle]. To the contrary, we observed the angular stiffness increased from 446 N-m to 627 N-m, as marked in a circle and a triangle in the inset of Fig. 3 (b). Based on the displacement measurements acquired from the load cell, we found that the stem of the Sample-3 slipped abruptly into the femoral canal, with its axial displacement from 2.87 mm to 6.76 mm, at around the 2,000-cycle point.

We performed visual inspection of femoral implant specimens after the Loading-6. As a result, we found the peri-

![Figure 3](image.png)

Figure 3. (Color online) Axial and angular stiffness profiles of three samples during the accumulated loading cycles. (a) Axial stiffness as a function of a cycle number. The Sample-3 presents lower stiffness value than those of the Samples-1 and -2. The axial stiffness of the Sample-3 drops sharply around 2,000-cycle point (inset). (b) Angular stiffness as a function of a cycle number. The Sample-3 presents increased angular stiffness around 2,000-cycle point. The inset shows an abrupt increase of angular stiffness values around 2,000-cycle point.
prosthetic fracture as shown in Fig. 4. This means the sudden slippage of the stem into the femoral canal was probably caused by this peri-prosthetic fracture. In fact, the development of cracks around the corner of the prosthesis is very common in clinical situations due to the stress concentration [23]. In our analysis, the discontinuity of the stiffness values successfully captured the sudden development of fracture in the bone interface around the implant. The increase of the angular stiffness is probably due to the firmer grip of the stem, after the repositioning of the prosthesis into the femoral canal.

### 3.2. HNSW-based diagnostic results

After each set of fatigue testing, we nondestructively assessed the implant stability of the artificial femur specimens via the proposed HNSW-based diagnostic method. The diagnostic results of HNSWs are reported in Figs. 5 (a) and (b) for the Sample-1 and the Sample-3, respectively. We did not present the measured signals from the Sample-2, since the measurement results were almost identical to those from the Sample-1. In both figures, the first pulses represent the incident solitary waves felt by the instrumented sensor, while the subsequent pulses denote the waves arriving at the same sensor after being reflected from the sensor-stem interface. We observed that a single hump of incident HNSW was disintegrated into a chain of smaller HNSWs after its interaction with the implant structure. Previous studies have shown that this backscattering phenomenon of the reflected waves is strongly affected by material properties, geometry, and boundary condition of the inspection medium [17, 18]. Therefore, we carefully analyzed the signals that corresponded to the reflected HNSWs to inspect any changes of implant stability after loading.

For the Sample-1, we observed that the temporal profiles of reflected HNSWs remained constant, when the diagnostic waves were acquired after Loading-2 (blue line), Loading-6 (red line), and Loading-8 (green line). This implies that the Sample-1 exhibits no significant degradation of its mechanical integrity after repeated sets of fatigue testing. On the other hand, we found that the diagnostic results of the Sample-3 presented dissimilar patterns between acquired signals. When we measured the HNSWs after the Loading-6, we found that the arrival of the secondary reflected wave, as

![Figure 4. A photo of the Sample-3 that shows crack development at the interface between the metal stem and artificial bone.](image)

![Figure 5. (Color online) Diagnostic measurements of incident (first impulse) and reflected (subsequent impulses) HNSWs from the instrumented sensor located in the 7th particle from the top of the granular chain. (a) Force profiles from the Sample-1 after the Loadings-2, -6, and -8. (b) Force profiles from the Sample-3. The green line denotes a baseline data acquired before the loading cycles, while the red and blue lines correspond to the data taken after the Loading-2 and -6, respectively. We observe a change of secondary reflected solitary wave from the diagnostic wave from the Loading-6, compared to the other two sets of data.](image)
pointed by an arrow in Fig. 5 (b), was further delayed than the waves in the baseline and the Loading-2 data. We also observed that its amplitude was significantly reduced compared to those of the other two sets of reflected HNSWs. It has been reported that the delay and attenuation of the secondary reflected wave implies the degraded stiffness of the underlying layer in a composite medium [18]. In the case of the composite femur, this means the mechanical degradation of artificial bone layer that surrounds the femoral stem.

The point of HNSWs measurement after the Loading-6 corresponds to the 2,000 accumulated cycles of fatigue testing for the Sample-3. As verified from the mechanical loading analysis and visual inspection, a critical fracture at the bone-implant interface occurred around this point. Therefore, our findings from the HNSW-based diagnostic method are in agreement with the results obtained from the mechanical loading and visual inspection analysis. Due to the excessive durability of the composite femur, we could not obtain gradual degradation of stem-bone integrity throughout the repeated fatigue testing. This prevented us from quantifying the sensitivity of our proposed scheme to the continuous level of implant stability. However, our method proved to be responsive to an abrupt change of implant’s structural integrity, such as interfacial bone fracture, at the stem-bone interface.

4. CONCLUSION

We assembled a prototype of granular crystal sensor/actuator to assess the implant stability of artificial composite femurs via highly nonlinear solitary waves (HNSWs). To simulate physiological fatigue loading, composite femur samples were tested in the servo-hydraulic load frame using a custom proximal femoral load simulator. After each loading, diagnostic evaluation of the mechanical integrity of the stem-bone interface was performed using the proposed granular crystal sensor/actuator. Based on the HNSW-based diagnostic method, we investigated a variation of HNSWs reflected from composite femur specimens. Preliminary findings indicate that the proposed nondestructive evaluation scheme can detect severe damage of the stem-bone interface, by showing a drastic change in reflected HNSWs.

This study has been limited to the investigation of the implant stability via direct contact to the implant structure. Such site-specific measurements will be helpful in determining the primary implant stability during a total hip replacement surgery to prevent over- or under-insertion of prostheses that cause premature loosening or hoop stress-induced fracture of femoral bones. Also, our method can be used in the process of prosthesis design optimization by quantifying the stem fixation quality in a noninvasive and time-efficient manner. However, many challenges and further study remain for in-vivo testing of the granular crystal sensor/actuator in a clinical setting. For example, the effects of soft tissue layers (e.g., muscle, flesh) need to be addressed to use this device on the patient's skin surface. Furthermore, we dealt with only an experimental portion of the study in this paper. The numerical investigation of HNSWs’ interaction with implant structures will be treated in an upcoming publication.

Based on the attenuation and scattering patterns of the reflected HNSWs, the granular crystal sensor/actuator can examine various engineered structures and materials systems. For this reason, the HNSW-based diagnostic scheme using the phonic crystal sensor/actuator has high potentials to expand to a number of areas, including aerospace, mechanical and civil applications. The feasibility study of the proposed sensing instrument to different applications will be performed in the future.

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REFERENCES


