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Time Dependent Fixation and Implantation Forces for a Femoral Knee Component: An In Vitro Study

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Time Dependent Fixation and Implantation Forces for a Femoral Knee Component: An *In Vitro* Study

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Abstract

Implant survival rate is a primary concern for individuals receiving a primary total knee arthroplasty. Loosening is the primary reason for revision surgery and was therefore the focus of the current study. To better understand the mechanics of implant fixation, the time-dependent fixation of a femoral knee component was measured in vitro on three cadaveric femurs. The fixation of each femoral knee component was measured with strain gauged implants for at least 10 minutes on each femoral component. Additionally, impaction forces were measured during the implantation of each component. These forces were 2–6 times less than previously reported. The implantation impact forces were higher for the bones with higher bone density. Power law regressions were fit to the absolute value of the principal strains measured on the components over time to quantify the relaxation of the bone. The average power coefficient value for the three bones was lower for the bones with higher bone density. The average power coefficient value for the maximum principal strains was significantly higher than that of the minimum principal strains in each bone. The results were extrapolated to approximate the fixation strength at nine months after implantation. In this time period the strain was predicted to decrease to between 78 and 91% of the strain one second after implantation where those with lower bone density will have decreased fixation strength.

Introduction

Implant survival rate is a primary concern for individuals receiving primary total knee arthroplasty. Loosening is the primary reason for revision surgery [1] and was therefore the focus of the current study. The fixation immediately after implantation was assessed in previous work by the authors with *in vitro* testing and FE modeling [2]. But bone is a viscoelastic material and thus will experience stress relaxation [3-6]. Stress relaxation will decrease the pressure at the press-fit bone-implant interface which will in turn decrease the press-fit fixation. The goal of this study was to quantify the decrease in fixation due to the relaxation of bone.

Surgical implantation forces are also of interest because of the possibility of damaging the bone [7], implant [8] or surgical tools. Implantation forces have been measured in the past, but primarily on hip components [9-11].

Primarily, this study intends to answer the question: How much does the strength of the fixation at a bone-femoral knee component interface decrease due to the relaxation of bone; and, does the relaxation depend on bone density? Secondarily, this study intends to answer the question: What are the impaction forces on the femoral knee component during implantation; and, do these forces depend on bone density?

Materials and Methods

Three left human cadaveric femurs were obtained from a major regional university through the Uniform Anatomical Gift Act. The femurs were received with the soft tissue removed. Each had been wrapped in saline-saturated gauze, sealed in an airtight plastic bag and frozen to -20 °C. Radiographic analysis showed that two femurs had normal bone density and the other had low bone density. The femurs used are listed in Table 1 with the corresponding implant, mean Hounsfield units from the computed tomography (CT) data (Mimics 10, Materialise, Ann Arbor, MI) of the surgically prepared distal femurs and relative density rank among the three bones.

Table 1: Relative Density Ranking of Femurs used for In Vitro Experiment.

Bone ID	Density	Relative density rank	Implant
F-1	Normal bone density	1	NexGen size F
D-1	Normal bone density	2	NexGen size D
D-2	Low bone density	3	NexGen size D

The NexGen® Complete Knee Solution (Zimmer, Inc., Warsaw, IN) cementless femoral knee component was chosen for this study. Figure 1 shows a photograph of the implanted component on the femur with the anterior shield, posterior condyles and implant tapered (4° each side) box region labeled. Initial fixation for this implant is caused by a press-fit. According to the manufacturer's described surgical technique, the bone is surgically cut so that the anterior-posterior (AP) dimension of the femur is larger than that of the box by 3 to 4 mm. The interference was confirmed using CT data of the surgically prepared bone and the computer aided design models of the implant (Siemens NX 6, Plano, TX). Upon implantation, the bone compresses in the AP direction to fit inside the implant. This causes a press-fit force between the bone and the implant. This force also causes the implant to deform, primarily with the shield and condyles bending outward in the sagittal plane [2].

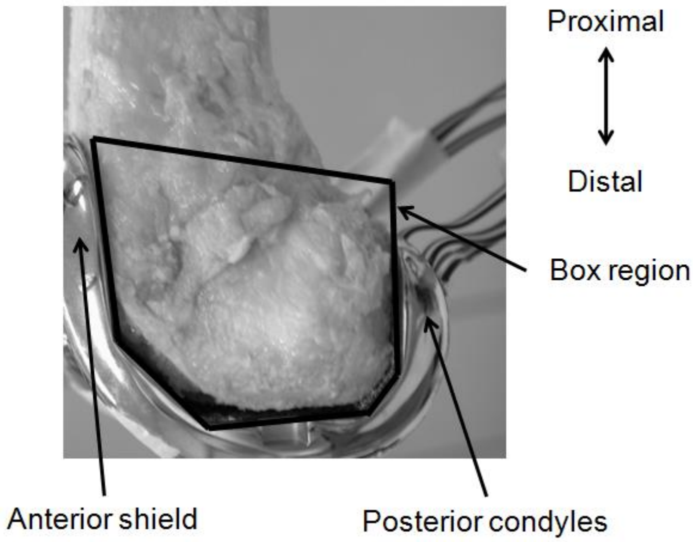

Figure 1: Sagittal View of Implanted Femoral Knee Component. The anterior shield, posterior condyles and implant box region are labeled.

Four triaxial strain gauge rosettes (CEA-06-062UR-250, Measurements Group Inc., Raleigh, NC) were bonded to each of the implants. Two strain rosettes were attached to the anterior shield and one on each posterior condyle (Figure 2). Due to the press-fit with the flange and condyles bending outward, the primary strains on the external face are compressive strains. Thus the magnitude of the minimum principal strain is expected to be larger than that of the maximum principal strain [2]. Based on the results of a preliminary FE analysis of the implant, the specific locations for the strain gauge rosettes were chosen to be in regions with a relatively high strain magnitude and low strain gradient. The locations were restricted to surfaces which would not be in contact with the bone or be impacted during the implantation procedure.

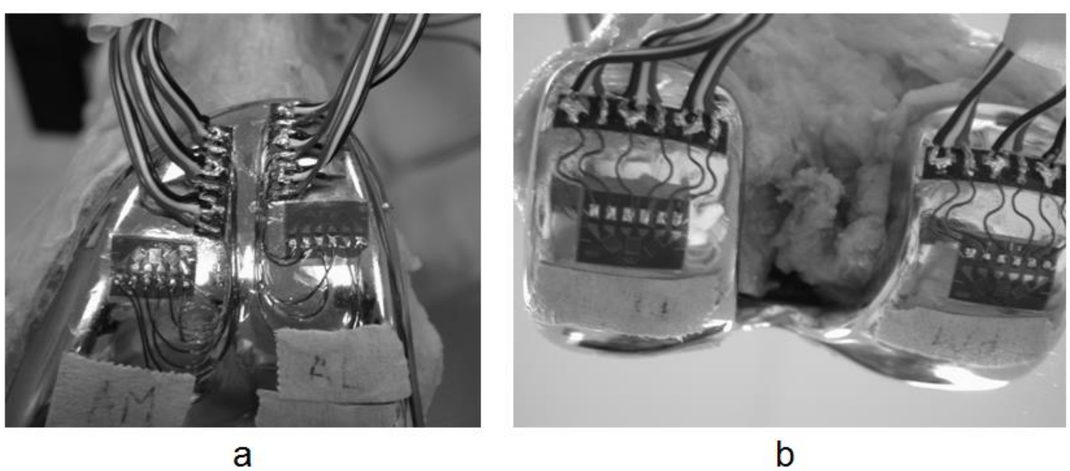

Figure 2: Photographs of Strain Rosette Locations. a) Anterior view showing rosettes on anterior shield, b) Posterior view showing rosettes on each posterior condyle.

The implant size for each bone was determined (Table 1), and surgical cuts were made on each femur according to the manufacturer's recommended surgical technique. The surgical technique was performed by the first author (TB) after first being trained in the same way the manufacturer trains its surgeons. Practice surgeries were performed with composite bones and then at least a dozen similar cadaveric bones. The femurs were thawed at room temperature for a minimum of six hours and the femoral knee components were implanted onto the bones using surgical tools and methods. During implantation the impaction tool was held in the left (non-dominant) hand and the surgical mallet in the right (dominant) hand. The surgical mallet was instrumented with an impact load cell (model 200C20, PCB Piezotronics, Depew, NY) that was calibrated by the manufacturer annually and has been previously used to measure skull impact fracture forces [12-14]. The femurs were clamped at midshaft so that the anatomical axis was horizontal to the surgical table (see Figure 3), thus a horizontal stroke was used instead of a vertical one that might be used for maximum impaction force. The impaction tool was struck as hard as possible in this manner. Impaction strikes were applied until the femoral component could not be pressed any farther onto the bone. For the F-1 bone this required 20 strikes. As the strike number increased the strikes became more frequent and likely approached the maximum force of the author (TB) for the horizontal implantation setup. The impaction force was recorded at 10 kHz using a LabVIEW (National Instruments, Austin, TX) data acquisition system during each mallet strike with the impact load cell attached to the surgical mallet. A t-test was performed to determine if the impaction forces differed between bones.

Figure 3: Photograph of the D-1 Bone Clamped Horizontally, with Strain Gauged Femoral Component Implanted.

The strains in each rosette were recorded using LabVIEW at 100 Hz for approximately five seconds before and immediately after implantation and at one minute intervals for 10 minutes on each bone. Additionally, strains were recorded every five minutes between 10 and 25 minutes for the F-1 bone. Previous studies on the viscoelastic behavior of cancellous bone have been performed to 10–420 seconds [3-6]. These have reported that the behavior "leveled off" in this time [5]. A 5 Hz, third order Butterworth low pass filter was used to reduce the signal noise. The mean and standard deviation of the filtered data were calculated and used to find the principal strains for each strain rosette. The difference between the pre- and post-implantation strains was calculated. The fixation strength was determined using these strains and compared between bones.

A power law regression ($\varepsilon = At^{-n}$) was fit to each strain versus time (relaxation) data set. Power law regression was chosen because a long term creep experiment on cortical bone did not approach an asymptote even after six weeks of creep [15]. The power law coefficient (n) was determined for the maximum and minimum principal strains at each strain gauge rosette location for each bone. For negative strains like the minimum principal strain, this was done by fitting the curve to the absolute value of the data. In this step if the negative of the multiplicative constant was used with the unchanged power coefficient, the calculated best fit line matched the original (negative valued) data set. For example, the power law regression fit to the absolute value of the D-1 AL minimum principal strain data set is $\varepsilon = 352\ t^{-0.0115}$. The equation $\varepsilon = -352\ t^{-0.0115}$ fits the D-1 AL data set. This is shown in Figure 4.

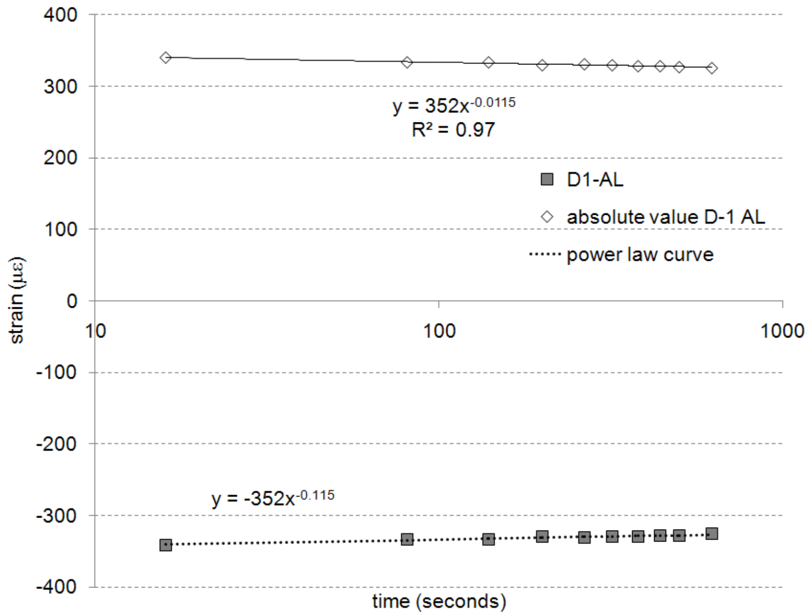

Figure 4: Example of Fitting a Power Law Regression to the Minimum Principal Strain Relaxation of the D-1 AL Data Set. A power law regression was fit to the absolute value of the data. The negative of the multiplicative constant from this regression was used to fit to the D1-AL data.

Results

The principal strain found on the external face of the femoral component for up to 25 minutes after implantation is plotted in Figure 5 and Figure 6. The four strain rosette locations for each of the three bones is shown.

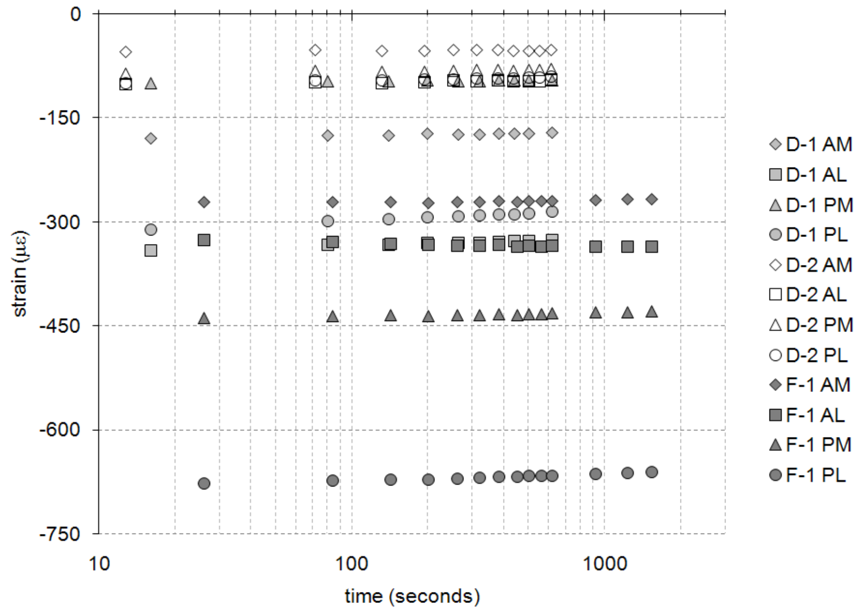

Figure 5: Relaxation of Minimum Principal Strain. Four locations from each of the three bones are shown. PM – posterior medial, PL – posterior lateral, AM – anterior medial, AL – anterior lateral.

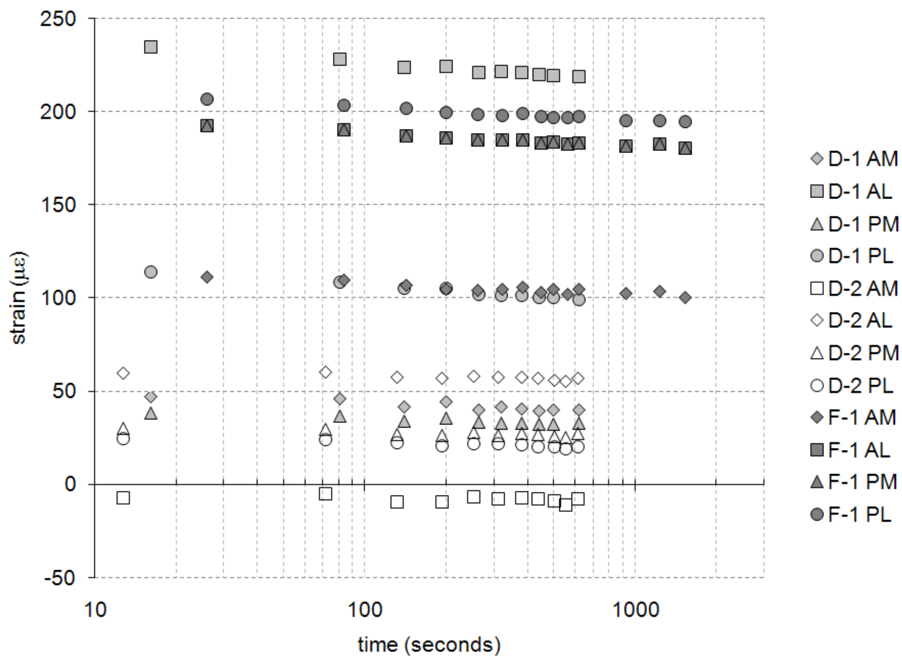

Figure 6: Relaxation of Maximum Principal Strain. Four locations from each of the three bones are shown.

The power law coefficient for the maximum and minimum principal strains at each location for each bone is shown in Table 2. The average power coefficient value for the three bones decreased with increasing bone density. The power coefficient value for the maximum principal strains was significantly higher (p = 0.002) than that of the minimum principal strains.

Table 2: Power Coefficient (n) Values for the Four Locations of the Three Bones.

Location	max principal strain	min principal strain
D-1 AM	0.0524	0.0103
D-1 AL	0.0196	0.0115
D-1 PM	0.0518	0.0112
D-1 PL	0.0393	0.0228
D-2 AM	0.0630	0.00694
D-2 AL	0.0173	0.0144
D-2 PM	0.0395	0.0179
D-2 PL	0.0600	0.0223
F-1 AM	0.0229	0.00385
F-1 AL	0.00404	0.00711
F-1 PM	0.0159	0.00504
F-1 PL	0.0152	0.00582
Average D-1	0.0408	0.0140
Average D-2	0.0450	0.0154
Average F-1	0.0145	0.00546
Average AM	0.0461	0.00702
Average AL	0.0137	0.0110
Average PM	0.0357	0.0114
Average PL	0.0382	0.0170

A representative impaction force versus time curve for a mallet stroke during impaction is shown in Figure 7. The maximum impaction forces for the strokes to implant each one of the femoral knee components are shown in Figures 8–10. The average and standard deviation for each bone is shown in Table 3. The impaction force of F-1 was significantly different (p = 0.001) from D-1 and D-2, but D-1 and D-2 were not significantly (p < 0.05) different from each other.

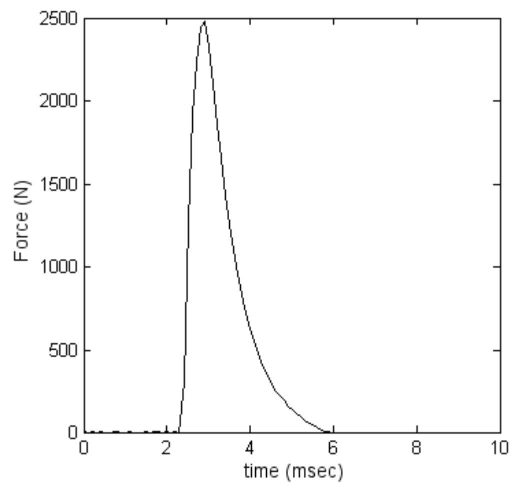

Figure 7: Example of Impaction Strike Force versus Time. F-1 strike number eight. The impaction force peaks within 1 msec and lasts less than 4 msec.

Figure 8: Maximum Impact Forces of the Strikes for the D-1 Implantation.

Figure 9: Maximum Impaction Forces of the Strikes for the D-2 Implantation.

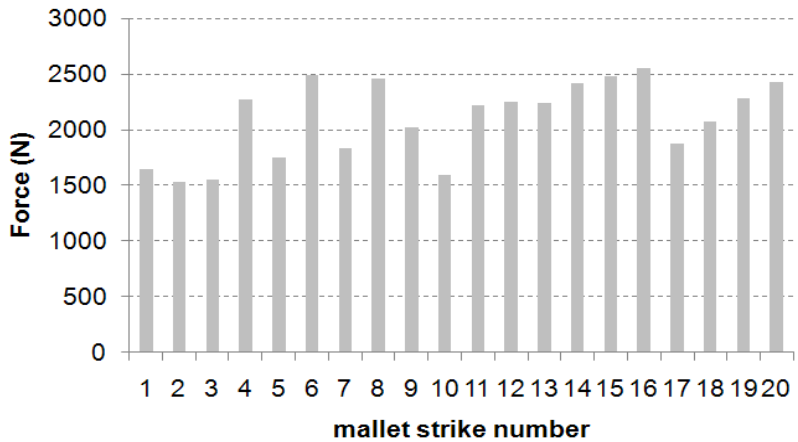

Figure 10: Maximum Impaction Force of the Strikes for the F-1 Implantation.

Table 3: Mallet Strike Average and Standard Deviation

Bone	D-1	D-2	F-1
Average (N)	1630	1580	2100
Standard deviation (N)	227	184	346

F-1 was significantly different ($p = 0.001$) from D-1 and D-2. D-1 and D-2 were not significantly ($p < 0.05$) different.

Discussion

Due to the lack of time-dependent fixation data, this study intends to quantify how much the strength of the fixation at a bone-femoral knee component interface decreases due to the relaxation of bone. For press-fit fixation the bone is cut to a larger AP dimension than the femoral component's inside AP dimension. This causes the bone to compress for the press-fit. This geometrical interference causes a stress in the bone and a pressure at the bone-implant interface [2]. The press-fit of the implant causes the anterior flange and posterior condyles to bend outward. This bending causes the primary strains on the external face to be compressive strains. Thus the strain measured on the implant is a result of the stress in the bone. The measurement of femoral component strain as a function of time is therefore a measure of the stress relaxation behavior of the bone and not of its creep deformation behavior. The decrease in strain measured over time also indicates a decrease in the pressure and fixation strength of the bone-implant interface.

The average power coefficient values for the maximum principal strains were similar to the published results of previous studies that tested in the elastic region of human cancellous bone. The D-1 and D-2 bones (0.041 and 0.045) were 3.8% less and 6.1%, respectively, more than the power coefficient from Bredbenner and Davy (0.042) [4], who tested vertebral bone. They were 6.3% and 17%, respectively, more than that of Deligianni et al. (0.038 in Direction 3) [5] for the proximal femur, respectively. The coefficient from the F-1 bone (0.015) was 20% less than that of Zilch et al. for the proximal femur (0.018) [3]. A finite element model was created of the press-fit interface and the cancellous bone was found to be plastically strained [2]. This result coupled with the fact that power coefficient values were found to increase with plastic strain in bovine bone suggests that the power coefficient should be larger than the measured results [16]. This assumes that the power coefficient of cancellous bone in the AP direction of the distal femur has similar values to those measured in the principal material directions of the proximal femur and the spine. This assumption may not be true since Deligianni et al. showed that tan δ (viscoelastic damping) is anisotropic within anatomical location [5] and that the power coefficient may be dependent on anatomical location. Additionally, this assumes that since the power coefficient (stress-relaxation) increased with strain in bovine bone it will also increase with strain in human bone.

The exact time from surgery for full secondary fixation strength is unknown, but is likely to be within a broad window from six weeks to nine months [17, 18]. The shorter limit is from a study that reported in six weeks there was enough bone ingrowth into titanium porous coated implants in the distal femur of canines to determine significant differences in torsional stability due to relative motion [17]. The longer limit is from a study that showed that there was statistically significant bone increase in bone ingrowth into titanium porous coated cylindrical implants after nine months of implantation time in humans [18]. Figure 11 shows the relaxation data extrapolated from the first three decades of time measured here to nine months. This is a useful initial estimate for the decrease in fixation strength in time because similar data has not been reported. Note that this extrapolation is four decades of time longer than the experiment and can be used only as an estimation because of the assumption that bone will continue to follow the same relaxation power law for this period of time. Previous long term viscoelastic studies on cortical bone suggest that assuming the behavior to follow a power law for long time periods is reasonable [15, 19] because even after six weeks (over five decades of time) the behavior does not approach an asymptote [15]. This extrapolation as an initial estimate of the change in fixation over time also motivates the need for further studies to describe long-term, time-dependent fixation.

As previously discussed, the minimum principal strain is the better indicator of fixation because the component is expected to have a compressive strain due to bending of the anterior shield and posterior condyles. According to the extrapolation, the minimum principal strain for the F-1, D-1 and D-2 bones is predicted to decrease to 91%, 79% and 78% at nine months, respectively, where a larger power coefficient means the fixation decays faster. The maximum principal strains will decrease to 78%, 50% and 47% at nine months, respectively. This decrease in fixation is an approximation of the worst-case scenario because bone ingrowth will occur over the same duration and will increase the strength of the fixation at the interface. Clinically, this approximation indicates that a press-fit component will not be as stable long term for individuals with lower bone density due to stress relaxation and that a clinician may need to consider a different fixation option for patients with lower bone density.

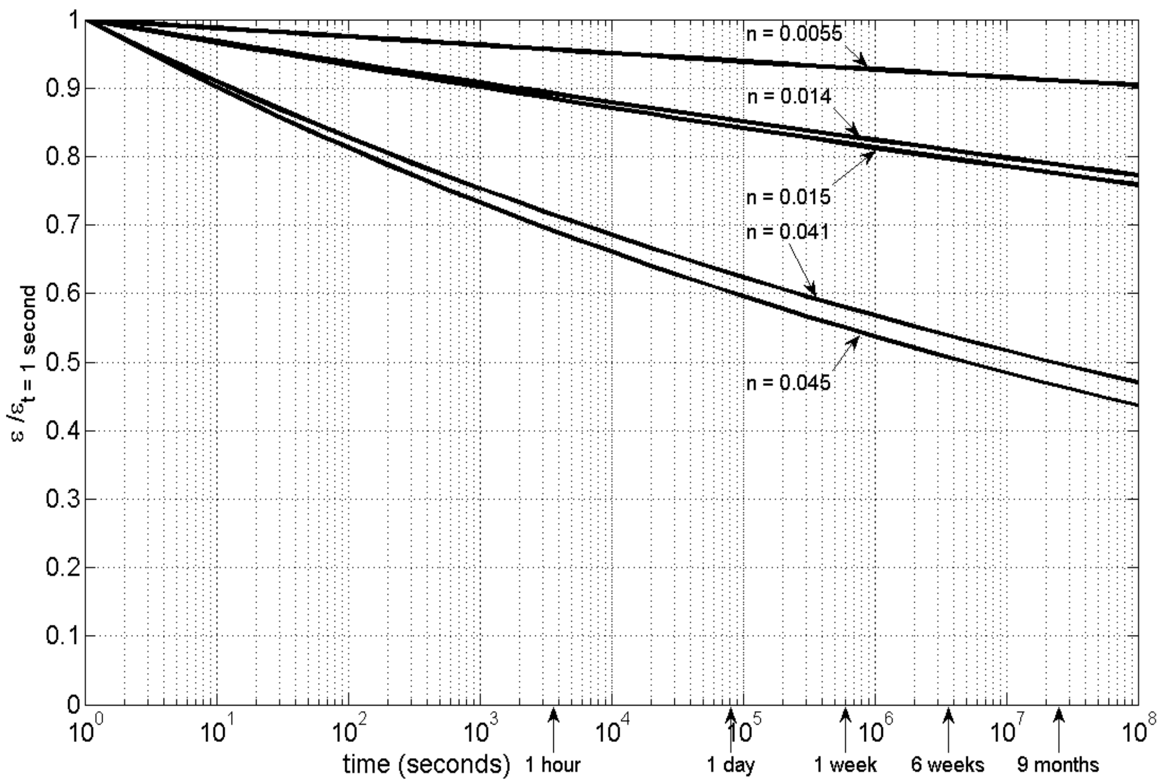

Figure 11: Power Law Decay for Minimum and Maximum Principal Strains for Each Bone to Approximate Long-Term Cancellous Bone Relaxation.

The average power coefficients for the minimum and maximum principal strains for each bone are shown: F-1 min (0.0055), D-1 min (0.014), D-2 min (0.015); F-1 max (0.015), D-1 max (0.041), D-2 max (0.045).

In addition to the limitations discussed above, in the current study it was assumed that the power coefficient was completely due to the relaxation of the bone and the relaxation of the metals in the orthopedic implant are negligible. The power coefficient value of the minimum principal strain in the F-1 bone (0.0055) approached the same order of magnitude as some metals used in orthopedic devices (steel: 3×10^{-4} [20]; stainless steel: 1×10^{-3} – 6×10^{-3} [21]; Ti: 6×10^{-5} [22]) and it is possible that since the power coefficient value was so low that the power coefficient of the metals did contribute to the power coefficient measurement.

This study also quantified the impaction forces on the femoral knee component during implantation. Impaction forces are dependent on implant systems, surgical tools, patients and surgeons. Each of these factors will affect the impaction force. Implant systems differ in geometry and material. For example, the amount of interference in the press-fit has been shown to affect the removal load [23]. The density, and therefore modulus of elasticity, of the bone onto which the component is being implanted will also have an effect on the force. The more dense the bone, the more force will be required for implantation. This was demonstrated by the results that found the F-1 bone required significantly more impaction force than the D-1 and D-2 bones.

The implant size (D vs. F) may have had a small effect on the force required, but this was not expected to be a confounding factor because the components were the same type and each bone had the same initial geometric interference [2]. Finally, the strength and technique of the surgeon will affect the implantation forces [8]. Because of all these differences it is difficult to compare exact impaction forces from one study to another, but general trends can be observed.

Other authors have reported impaction forces to implant different orthopedic implants. Kroeber et al. measured impaction forces of 3.1–4.0 kN implanting a press-fit acetabular component [9]. Maharaj and Jamison measured mean peak impact forces of 5.83 and 6.20 kN implanting a carbon-fiber laminated composite hip into embalmed femurs and polyurethane foam, respectively, using drop-weight testing [8]. Blevins et al. used impaction forces of 1.5–9.0 kN at rates of 0.8, 120 and 200 kN/sec to implant a hip stem and measured the removal forces [10] based on cited implantation forces. Ries et al. measured impaction forces of 12.5–13.2 kN to implant two porous coated hip stems into cadaveric femurs [11]. Visnic et al. created an axisymmetric FE model of a press-fit acetabular cup and calculated implantation loads of 0.9–1.9 kN [24]. They cited Brown et al. who experimentally implanted acetabular cups with measured forces of 2–3 kN [25]. The impaction forces measured here were on the same order as Visnic et al. [24] citing Brown et al. [25] for an acetabular component, slightly less than those measured for by Kroeber et al. for an acetabular component [9] and less than half those measured by Maharaj and Jamison for the composite hip stem [8] and less than one sixth measured by Ries et al. [11]. The horizontal impact required due to the setup of this experiment likely reduced the impaction forces. The cited results suggest that higher impaction forces are likely applied during implantation of the femoral knee component, although the effect of the horizontal impact was not likely 2–6 times greater than what was measured in the current study.

In summary, the time-dependent fixation of femoral knee components was measured in vitro on three cadaveric femurs in this study. The average relaxation power coefficient value for the three bones decreased with increasing bone density. The results were extrapolated to approximate the fixation strength at nine months after implantation and suggest that those with lower bone density will have decreased fixation due to stress relaxation over time. In this time period the strain decreased to between 78 and 91% of the strain one second after implantation. Additionally, impaction forces were measured during the implantation of each component. These forces were 2–6 times less than previously reported. The implantation impact forces increased with increasing bone density. Clinically, the results of this study indicate a press-fit component will not be as stable long term for individuals with lower bone density due to stress relaxation and that a clinician may need to consider a different fixation option for patients with lower bone density.

Conflict of Interest Statement

Each author (TB, JM) certifies that he or she has or may receive payments or benefits from a commercial entity (Zimmer) related to this work. One or more of the authors (HP) has received funding from Zimmer.

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