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2010 Volume 2
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Albany Medical College Orthopaedic Journal

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Comparison of Computer Monitors in Evaluating Digital Radiographs for the Diagnosis of Scaphoid Fractures

Justin M. Ferrara, MD, Paul Hospodar, MD, Richard L. Uhl, MD, Erin L. Kaufman, MPH
Division of Orthopaedic Surgery, Albany Medical College, Albany, NY

Presented at the 2008 AMC Orthopaedic Surgery Annual Resident Thesis Day

Background: The diagnosis of acute scaphoid fractures can be a challenge. Advances in technology have lead to the increased use of digital radiographs as opposed to actual radiographs in the evaluation of musculoskeletal injury. There is much variation in the quality of the monitors used to evaluate these studies. This study compares personal computer (PC) monitors and picture archiving and communication system (PACS) monitors in the evaluation of non-displaced scaphoid fractures. The purpose of this study is to retrospectively compare the ability of orthopaedic surgeons to identify scaphoid fractures on digital radiographs using a PC and a PACS monitor.

Methods: Twenty-five patients who had previously been diagnosed in an outpatient orthopaedic setting with an acute, non-displaced scaphoid fracture were identified from a review of patient charts. A control group of twenty-five subjects with a diagnosis of wrist sprain who had wrist radiographs taken were also identified. All subjects had wrist radiographs that included a posterioanterior view, a posterioanterior view with ulnar deviation, and a lateral view. Two orthopaedic attending surgeons reviewed the radiographs of both groups while being blinded to the diagnoses. The reviewers evaluated for the presence or absence of scaphoid fracture.

Results: The reviewers correctly identified a non-displaced scaphoid fracture in 44 of 50 radiographic images using the PC monitors. The reviewers correctly identified a negative radiographic image (no fracture) in 46 of 50 radiographic images using the PC monitors. This represents a sensitivity of 0.88 and a specificity of 0.92 for the PC monitor. Using the PACS monitors, the reviewers correctly identified a non-displaced scaphoid fracture in 39 of 50 radiographic images. The reviewers correctly identified a negative radiographic image (no fracture) in 45 of 50 radiographic images using the PACS monitors. This represents a sensitivity of 0.78 and a specificity of 0.90 for the PACS monitors.

Conclusions: Orthopaedic surgeons are justified in their use of PC monitors in the evaluation of non-displaced scaphoid fractures. PACS monitors do not offer the orthopaedic surgeon additional diagnostic power.

Introduction
The diagnosis of acute scaphoid fractures can be a challenge.2,8,11 There may not be obvious radiological evidence of fracture until several weeks after the initial injury, and ultimately additional radiographic studies may be required to make a diagnosis.1 Non-displaced scaphoid fractures can be subtle, even when being evaluated with the highest quality monitors used by radiologists.2,4,8 According to Pillai and Jain, the incidence of true scaphoid fractures with initially negative radiographs is 6.66%.8 Conventional x-rays miss these types of fractures on the patient’s initial presentation.7

Advances in technology have lead to the increased use of digital radiographs as opposed to actual radiographs in the evaluation of musculoskeletal injury.4 There is much variation in the quality of the monitors used to evaluate these studies.4,6 Radiologists tend to utilize higher quality monitors, which optimize brightness, luminance, and resolution. Radiologists’ monitors generally either undergo periodic self-checks or have formal quality assurance evaluation performed by the radiology staff. Many orthopaedic offices use personal computer monitors as opposed to a picture archiving and communication system (PACS) used by radiologists. Currently there are no formally defined standards or specific guidelines for the type of monitor used in the evaluation of digital radiological studies.4,6,8 There are significant differences in quality of monitor used in the orthopaedic outpatient setting compared to those used by radiologists.4,6

There are varying opinions as to the optimal number of views that need to be taken to diagnose a scaphoid fracture.7,10 When consulting orthopaedic surgeons, 57.5% preferred four views, while 33.3% preferred three views.7,10 The majority of consulted radiologists preferred four views (68.4%) while 15.8% preferred three views.7,10 There is no known literature that evaluates the number of views preferred in America. Our study will utilize three views: posterioanterior, lateral, and posterioanterior with ulnar deviation.

The PACS system has several qualities that make it unique. It is composed of several components which include a digital device, a network with a bandwidth be-
tween 10 and 50 megabytes/study, an archiving device, diagnostic workstations and software that has archiving and routing features. The benefits of having a PACS system include, cost savings as compared to conventional radiographs, productivity improvements, superior image quality, decreased interpretation time, and an avenue for rapid consultation with other specialists. The PACS system can be expanded to include additional workstations and may utilize the Internet to allow the films to be accessed outside of the facility by other consultants. Several studies have demonstrated no statistical diagnostic difference between the PACS workstation and personal computer monitors. The PACS monitors are not routinely utilized in the outpatient orthopaedic settings likely due to the additional cost associated with such systems.

An acute scaphoid fracture is a diagnosis that is commonly made in the orthopaedic office setting, without the assistance of a radiologist and/or the PACS monitor. The recent trend is for offices to become “filmless” as computer technology improves to the point of digital radiograph quality rivaling that of the printed radiograph. Prior study has demonstrated that the benefit of routine duplicate radiograph interpretation by both an orthopaedist and a radiologist does not justify its cost. Our study compared two systems (PC and PACS monitors) in the evaluation of non-displaced scaphoid fractures. The null hypothesis was that there was no statistically significant difference in the identification of scaphoid fractures in digital radiographs evaluated by attending orthopaedic surgeons using either a PC monitor or the PACS monitor. The purpose of this study was to retrospectively compare the ability of orthopaedic surgeons to identify non-displaced scaphoid fractures on digital radiographs using PC and PACS monitors.

Materials and Methods
The study population consisted of adults aged 18 and older. The experimental group consisted of 25 patients who were identified with a diagnosis of an acute non-displaced scaphoid fractures at their initial visit (ICD-9 code 814.00). The control group consisted of 25 subjects who ruled out for scaphoid fractures (wrist sprain diagnosis) but had wrist radiographs taken at their initial visit (ICD-9 code 842.00). All subjects had wrist radiographs that included a posteroanterior view of the wrist, a posteroanterior view of the wrist with ulnar deviation, and a lateral view of the wrist.

A fifth year orthopaedic resident selected subjects and radiographic images (JMF). The patient database used to identify the subjects came from the Capital Region Orthopaedic Group billing office (Albany, NY). The database included all patients with the diagnosis of a scaphoid fracture and wrist sprain in the last four years, the beginning of the utilization of digital imaging at this facility. Fractures deemed to be acute, non-displaced, and without concomitant pathology in skeletally mature patients were included. All radiographs were taken at the Bone and Joint Center. The Bone and Joint Center/ Capital Region Orthopaedic Group is a private, outpatient facility closely affiliated with Albany Medical Center Division of Orthopaedics. Typical radiographs used in the study are shown in Figure 1A, 1B, and 1C.

Two orthopaedic attending surgeons (RLU, PH) reviewed the radiographs of both groups while being blinded to the subjects’ diagnoses. Each subject was randomly assigned a number and the subject’s name and sex were removed from the radiograph. The radiographs were evaluated for the presence or absence of scaphoid fracture. Both reviewers evaluated all subjects first on the PC monitor and then on the PACS monitor. The order of the cases was random. The reviewers were allowed to magnify the digital images as each monitor’s system allowed.

The data was calculated for the positive and negative predicted value, sensitivity, and specificity. A chi-square was used to determine the significance of the variables. Power was recalculated at the end of the study to determine the true statistical power of the study.

The study protocol was approved by the Albany Medical Center’s Institutional Review Board and carried out in accordance with the Declaration of Helsinki of the World Medical Association. Informed consent was not required.

![Figure 1A, 1B, and 1C](image-url)

1A- P/A wrist, 1B-P/A wrist with ulnar deviation, 1C-lateral wrist in a study subject with scaphoid fracture.
Results
The radiographic images were evaluated by the two reviewers separately on both the PC and the PACS monitors. There were twenty-five subjects with non-displaced scaphoid fractures and twenty-five subjects without a scaphoid fracture (wrist sprain). The mean age for the subjects in the fracture group is 33 years. The mean age for the subjects in the non-fractured group is 39 years. There are 17 male subjects and 8 female subjects in the fracture group. There are 9 male subjects and 16 female subjects in the non-fractured group. The subject characteristics can be seen in Table 1.

The data from the two reviewers were combined such that for each system evaluation (PC or PACS) there were data from fifty images demonstrating a scaphoid fracture and fifty images without a scaphoid fracture. The reviewers correctly identified a non-displaced scaphoid fracture in 44 of 50 radiographs using the PC monitors. The reviewers correctly identified a negative radiographic image (no fracture) in 46 of 50 radiographs using the PC monitors. This represents a sensitivity of 0.88 and a specificity of 0.92 for the PC monitor. Using the PACS monitors, the reviewers correctly identified a non-displaced scaphoid fracture in 39 of 50 radiographs. The reviewers correctly identified a negative radiographic image (no fracture) in 45 of 50 radiographs using the PACS monitors. This represents a sensitivity of 0.78 and a specificity of 0.90 for the PACS monitors. This information is represented in Table 2.

Further extrapolating these data gives a positive predictive value of 0.89 and a negative predictive value of 0.80. The positive predictive value is the proportion of patients with positive test results who are correctly diagnosed. The negative predictive value is the proportion of patients with negative test results who are correctly diagnosed.

There were a total of 26 of 100 images that were evaluated and diagnosed incorrectly. The data collection sheet contained a question regarding the recommended treatment based on the diagnosis, either conservative or surgical management. An incorrect diagnosis resulted in a change in the treatment recommendation in only one case. The radiograph was incorrectly read as showing a scaphoid fracture using the PACS monitor and surgical intervention was recommended. Surgical intervention was recommended in only 5 other cases, all of whom were correctly diagnosed with a scaphoid fracture. Three of these recommendations were made when evaluating the images with the PACS monitor and two were made using the PC monitor.

The data collection sheet used by the reviewers contained a question regarding the desire for additional imaging to further clarify the diagnosis. The reviewers would have liked to have reviewed additional images for diagnostic purposes in 84 of 100 in the non-fractured group and in 72 of 100 in the fracture group.

The data collection sheet also asked the reviewers their opinion of the quality of the radiographic image. The image was judged as good, fair, or poor. Of the PC images, 46 were rated as good, 47 as fair, and 7 as poor. Of the PACS images 87 were rated as good, 12 as fair, and 1 as poor (see Table 3).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Scaphoid fracture group (N=25)</th>
<th>Non-fractured group (N=25)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Mean)</td>
<td>33</td>
<td>39</td>
<td>0.27</td>
</tr>
<tr>
<td>Sex (M:F)</td>
<td>17:8</td>
<td>9:16</td>
<td>&lt;0.0001, 0.007</td>
</tr>
<tr>
<td>Wrist laterality (R:L)</td>
<td>15:10</td>
<td>14:11</td>
<td>0.057, 0.271</td>
</tr>
</tbody>
</table>

Table 1: Subject Characteristics for the Two Groups

<table>
<thead>
<tr>
<th></th>
<th>Scaphoid fracture group</th>
<th>Non-fractured group</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correct Reading</td>
<td>PC 44 (88%)</td>
<td>46 (92%)</td>
<td>0.88</td>
<td>0.92</td>
</tr>
<tr>
<td>Incorrect Reading</td>
<td>6 (12%)</td>
<td>4 (8%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PACS 39 (78%)</td>
<td>11 (22%)</td>
<td>45 (90%)</td>
<td>0.78</td>
<td>0.90</td>
</tr>
</tbody>
</table>

Table 2: Results of the Radiographic Image Review Using PC and PACS Monitors
Discussion
Prior investigation in the radiology literature demonstrated no difference in the detection of wrist fractures with PC compared to PACS. In that study, Doyle et al. evaluated the ability of radiologists to detect wrist fractures. However, Liang et al. demonstrated a significant difference in the ability of radiologists to detect fractures on digital radiographs using two different monitors. There currently remains no formally defined standards or specifications for the types of monitors used to read digital radiographic images. Brem et al. demonstrated that low-cost computer monitors could be safely used to detect cervical spine fractures in the emergency department.

In the orthopaedic clinic setting, it is common practice for orthopaedic surgeons to evaluate the radiographs taken in their office. Prior study has demonstrated that the benefit of routine duplicate radiograph interpretation by both an orthopaedist and a radiologist does not justify its cost. Routine radiological consultation of radiographs in the orthopaedic setting is unnecessary. Major savings in health-care costs can be seen by not routinely undertaking radiological consultation for elective orthopaedic problems. In many office settings plain radiographs are no longer printed, but rather are digitally stored and evaluated via computer by the orthopaedic surgeon.

This study demonstrates that there was no clear advantage in using the PACS by orthopaedic surgeons to evaluate wrist radiographs for scaphoid fractures. There was no significant difference in the ability of the reviewers to determine the presence of a non-displaced scaphoid fracture using the conventional PC monitor or the PACS monitor. Using the PC monitor a sensitivity of 0.88 and a specificity of 0.92 were demonstrated. The PACS monitors demonstrated a sensitivity of 0.78 and a specificity of 0.90 in the identification of the scaphoid fractures. While the sample size was not sufficient enough to give this study adequate power, there was no meaningful difference between the two systems evaluated.

Over the course of this study, the reviewers did occasionally arrive at the wrong diagnosis. This occurred in 26 of 100 radiographs. The largest percentage of these occurred using the PACS monitors in a group of subjects that had scaphoid fractures, but were diagnosed as having no fracture. This inability to diagnose a fracture did change the treatment that was recommended based on the radiographic evaluation in one case.

This study lends evidence to the notion that orthopaedic surgeons are justified in their use of PC monitors in the evaluation of digital imaging for the purpose of identifying fractures. With a sensitivity of 0.88, the reviewers were able to diagnose non-displaced scaphoid fractures using a PC monitor to evaluate digital images without difficulty.

This study has several limitations. Recall bias cannot be excluded in the reviewers’ interpretation of the images even though they were presented in random order each time. They may have recognized the images in the second evaluation, however the reviewer would still have been blinded to the true diagnosis. There was a lack of power in this study making it difficult to generalize the results to a broader population. The focus of this study was on the presence of a scaphoid fracture therefore it is difficult to generalize to a wider variety of fractures. Bias may have been introduced by the fact that one of the systems to be evaluated by the study (the PC monitor) was used to make the original diagnosis.

This study represents further justification for the use of personal computer monitors in the evaluation of skeletal fractures by the orthopaedic surgeon. PACS monitors do not offer the orthopaedic surgeon additional diagnostic power.

References


The Effects of Non-enzymatic Glycation on Cancellous Bone: A Comparison between Hip Osteoarthritis and Hip Fractures

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Presented at the 2008 AMC Orthopaedic Surgery Annual Resident Thesis Day

**Background:** The non-enzymatic glycation (NEG) of tissue has been shown to occur as a normal consequence of aging. Whether the accumulation of advanced glycation end products (AGEs) contributes clinically to osteoporotic fragility fractures is not well understood. We hypothesized that cancellous bone from individuals who sustained a hip fracture would have higher levels of AGEs than patients without fractures, and that these samples would fail under less biomechanical compression.

**Methods:** A total of eighteen femoral heads were used. One group consisted of nine patients with hip osteoarthritis undergoing total hip arthroplasty, and a second group contained nine patients who sustained a femoral neck fracture requiring hip hemiarthroplasty. Cores of bone were mechanically tested to determine stress/strain properties. Non-enzymatic glycation was measured through described methods utilizing photochemistry.

**Results:** The bone from the hip fracture group was an average of 54% weaker than the bone from the osteoarthritic group (p<0.05). The NEG content was nearly 12% higher in the hip fracture group, but this value was not statistically significant.

**Conclusions:** This study demonstrates the phenomenon of NEG occurs in the cancellous bone collagenous matrix of both osteoarthritic and osteoporotic patients and may contribute in different ways to these disease processes. Based on previous research, the increase in NEG within fractured bone helps explain that under compression it behaved in a significantly more brittle manner. If further data shows a significant increase in AGE levels in osteoporotic patients compared to others of similar ages, then we may have another target for the treatment of osteoporosis and the prevention of fragility fractures.

**Introduction**

Hip fractures and their associated morbidity are a significant public health care concern in this country. In older patients, hip fractures often occur as a result of increased fragility of the proximal femur due to osteoporosis, defined as a “systemic skeletal disorder characterized by a quantitative deficit of bone mass and micro-architectural breakdown of bone tissue”°. We are an ever-aging society, with the elderly population being the fastest growing segment. It is predicted that worldwide hip fractures will reach epidemic proportions; rising from about 1.7 million in 1990 to 6.3 million in the next forty years. It is estimated 1 in 3 women and 1 in 12 men will suffer a hip fracture during their lifetime°. The impact here goes well beyond the health care system’s ability to handle this growing census of patients, as research indicates that only about 50% of these patients are able to regain their pre-fracture ambulatory status°. An alarming financial burden is also on the horizon, with costs of over $20,000 per patient for the first year after fracture alone and an estimated $131,500 million total cost by the year 2050°.

It has been shown that as a natural consequence of aging, a gradual decline in bone mass occurs on the order of 0.3 to 0.5% a year starting by the age of 30°. Human bone is in a constant state of remodeling secondary to a delicate coupling at the cellular level of osteoblast mediated bone formation and osteoclast mediated bone resorption. In comparing the main types of human adult bone, the turnover rate of cancellous bone is approximately eight times that of cortical bone. This is because cancellous bone occupies a larger amount of surface area in the human skeleton, and thus it is this type of bone which is affected most by osteoporosis. While this loss of bone mass over time occurs macroscopically, it is also well established that there are corresponding changes within bone at the molecular level. Specifically, the collagen matrix undergoes various biochemical reactions as the body ages. Numerous studies support the concept that collagen plays a substantial role in the ability of bone to absorb energy, defined as its toughness. Collagen makes up 90% of the organic phase of bone and subsequently undergoes a variety of biosynthetic events which alter its...
properties\textsuperscript{4}. In particular, advanced glycation end products (AGEs) can be made as posttranslational modifications to collagen when reducing sugars react non-enzymatically with free amino groups in lysine, hydroxylysine or arginine residues. These products can act as adducts to proteins or even create covalently bonded collagen cross-links\textsuperscript{5}. Previous research has documented that this process of non-enzymatic glycation (NEG) occurs in the extra-cellular matrix of many human tissues, including bone. Investigators have shown that NEG of collagen, not only increases with age, but also has a negative impact on the mechanical properties of both cortical and cancellous bone\textsuperscript{6,7}. In vitro models of NEG demonstrate a change in post-yield properties such that the altered bone has a decreased capacity to accumulate damage and dissipate energy\textsuperscript{8}. Recent utilization of 3D Cat Scan and finite element analysis to measure bone geometry and trabecular connectivity has called into question our current methods of calculating bone mass and mineral density, citing their inconsistent predictions of bone strength\textsuperscript{1}. Given that most fragility fractures secondary to osteoporosis are of cancellous bone, a more complete understanding of cancellous bone fragility at the molecular level would allow us to better assess the risk of age-related osteoporotic fractures. The goal of this study is to examine the NEG process in vivo as it pertains to the clinical entities of degenerative hip arthritis and femoral neck fractures. We hypothesize that, with controlling for age, cancellous bone samples from individuals who sustain hip fractures will (1) have higher concentrations of NEG compared to patients without fractures and will (2) fail under less biomechanical compression than those samples from individuals who have osteoarthritis.

**Materials and Methods**

**Sample Selection**

After Institutional Review Board approval was granted and informed consent was obtained from each study participant, the entire femoral head including a portion of the femoral neck was taken from patients undergoing both total hip arthroplasty procedures and hip hemiarthroplasties. All surgeries were completed at Albany Medical Center (Albany, NY) between the periods of October 2006 through November 2007. Care was taken intra-operatively in order to minimize damage to the cancellous bone within the bone sample as it was removed from the patient. A section of bone was taken from the portion of the femoral neck in each case so that it could be evaluated by the pathology department per standard protocol. The remaining bone was preserved in saline soaked gauze and deep frozen at -80°C until it was time for specimen preparation and mechanical testing. A total of eighteen femoral heads were used for this study. The first experimental group consisted of nine patients with degenerative hip disease having total hip replacement surgery. The second group was composed of nine patients who sustained a displaced femoral neck fracture requiring hip hemiarthroplasty. Of note, all cases of femoral neck fracture occurred from a fall from standing height, which is defined by the literature as fragility fracture\textsuperscript{1}. Patients with rheumatoid arthritis, congenital or acquired dysplasia, or other inflammatory arthropathy were excluded from the study. Blood samples were collected from each patient in accordance with the requirements for human tissue handling at Rensselaer Polytechnic Institute (RPI) in Troy, NY. Hemoglobin A1c (HbA\textsubscript{1c}) levels, which are proportional to a patient’s average blood glucose concentration over the previous four weeks to three months, were also drawn.

**Mechanical Testing**

A drill press with a modified jig was used to obtain multiple cores of cancellous bone from each femoral head. The cores measured approximately 8mm in diameter and 20mm in length. They were taken in line with the principal compressive trabeculae orientation of the bone. This orientation was pre-determined using plain radiographs of the femoral heads. The cores were then cut into 8-10mm sections under constant hydration (ISOMET 11-1180, Buehler Corp., Lake Bluff, IL). The final core measurements averaged 7.6±0.3mm in diameter and 8.6±0.9mm in length. Between testing, samples were submerged in normal saline and stored at -80°C.

Mechanical testing of cores from degenerative and fractured femoral heads was conducted using an MTS Bionix 858 hydraulic servo mechanical testing station (MTS, Eden Prairie, MN). Each specimen was glued to brass endcaps and loaded to failure in unconfined compression at 833 microstrains/second at 37 degrees Celsius under constant hydration. Load-displacement data was collected during testing, and stress-strain curves were created. The following parameters were then calculated: (1) elastic modulus; (2) yield stress and strain (determined using the 2% offset method); (3) ultimate stress and strain (defined as the point of maximal load); and (4) post-yield strain (defined as the difference between the ultimate and yield strain values). Student t-tests were used to evaluate the differences due to the underlying disease process of each experimental group, with the level of significance set at P=0.05.

**Determination of NEG**

After completing the mechanical testing, the nine cancellous bone specimens from each experimental group were decalcified with a 20% solution of 90% formic acid diluted
with deionized water. The solution was changed daily until the presence of calcium was no longer detected by a calcium determination assay. The specimens were then digested with papain collagenase (0.4 mg/ml in 0.1 mM sodium acetate buffer, pH 6.0, 16 h, 65 degrees Celsius). NEG content was quantified using fluorescence readings taken with a Synergy-HT Microplate reader at wavelengths of 360nm excitation and 460nm emission (BioTek USA, Winooski, VT) against a quinine sulfate standard. The amount of collagen in each cancellous bone sample was estimated based on the level of hydroxyproline. The content of hydroxyproline was determined by recording the absorbance of digested specimens against a standard at 570nm wavelength using a Dynatech MR-600 Microplate reader (Dynatech Inc., Alexandria, VA).

**Results**

**Patient Demographics**

In the degenerative hip disease group, there were five males and four females, with an average overall age of 78. In the hip fracture group, there were three males and six females, with an average overall age of 82. The two experimental groups were not significantly different with respect to age (Figure 1).

**Hemoglobin A1c Levels**

The mean HbA1c level from blood samples of the nine patents undergoing total hip arthroplasty for degenerative joint disease was 5.79. The average level from blood samples of the nine patients sustaining a femoral neck fracture was 6.32. Both of these values were within normal reference ranges for our lab (4.1-6.5), and no statistical difference between the two groups was found (Figure 2).

**Mechanical Testing**

In comparison to bone taken from patients who sustained a hip fracture, there was about a 54% average increase in elastic modulus (stiffness) for the bone taken from patients with osteoarthritis; however, this difference was not statistically significant (p=0.20). In addition, no significant differences were found between the groups with respect to yield stress, yield strain, ultimate stress or ultimate strain (Table 1). The data for post yield strain demonstrated an average 116% increase within the osteoarthritic bone, which resulted in a statistically significant difference between experimental groups (Figure 3).

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<tbody>
<tr>
<td>Arthritis</td>
<td>531±315</td>
<td>5.72±3.4</td>
<td>1.13±0.43</td>
<td>6.54±3.5</td>
<td>2.02±0.59</td>
<td>0.887±0.41</td>
</tr>
<tr>
<td>Fracture</td>
<td>344±283</td>
<td>3.98±2.5</td>
<td>1.30±0.71</td>
<td>4.29±2.6</td>
<td>1.71±0.79</td>
<td>0.411±0.12</td>
</tr>
</tbody>
</table>

*Denotes statistical significance (Student’s t-test, p<.05).
Figure 3. Comparison of post yield strain between hip osteoarthritis and femoral neck fracture groups. Results are statistically significant (p<0.05).

**AGE Quantification**
Compared to cancellous bone cores from patients with degenerative hip disease, calculations for the content of NEG were nearly 12% higher in the hip fracture group (Figure 4). This difference was not statistically significant. Upon further analysis, no significant difference was found between the NEG content in males and females, either within each group or across groups.

**Discussion**
Osteoarthritis (OA) and osteoporosis (OP) are the two most common musculoskeletal disorders found in the elderly population. Over the last thirty years, the prevailing theory in the literature was that these two disease entities were mutually exclusive. This largely stemmed from work by Foss and Byers which studied 140 patients with hip fractures and found only 3 with radiographic evidence of osteoarthritis. The prevailing opinion was that the presence of hip OA was protective against OP and helped to

Figure 4. AGE content was higher in the fracture group than in the osteoarthritis group, but this increase was not statistically significant (p=0.52).
prevent osteoporotic hip fractures. This inverse relationship has been called into question over the past decade, with studies suggesting an underappreciated number of patients with concomitant OA and OP, especially in the female, post-menopausal population. Glowacki et al. found that 25% of a cohort of post-menopausal women with degenerative joint disease (DJD) scheduled for elective total hip arthroplasty also had occult osteoporosis. A more recent study by Mäkinen et al. saw that nearly 73% of their cohort of female patients with OA undergoing hip replacement were either osteopenic or osteoporotic based on bone mineral density. Our study attempts to better understand both the biomechanics and biochemistry of cancellous bone samples taken from patients at the clinic endpoint of these two disorders. The phenomenon of NEG has already been shown in our lab to increase with age and results in a decrease in the mechanical properties of bone. These resulting advanced glycation end products have been implicated as a pathogenic factor in a variety of diseases, including the articular cartilage degeneration seen in osteoarthritis. To our knowledge, this is only the second study to examine the NEG process in patients with fractured cancellous bone and the first study to quantify AGE levels in the underlying bone of osteoarthritic patients.

Other studies have performed mechanical testing on both osteoporotic and osteoarthritic bone. The values for elastic modulus in our study revealed a 36% increase in stiffness for the OA bone. Although the result is not statistically significant, this trend is consistent with work done by Li and Aspen, who compared subchondral and cancellous bone samples in OA and OP hips to age- and gender-matched controls and demonstrated an increase in stiffness for the OA group compared to OP. These results support the idea that the underlying bone indeed plays some role in the pathogenesis of OA. In a recent report, Sun et al. compared seven femoral heads taken from fractured hips with seven femoral heads from total hip replacements due to degenerative joint disease. Also lacking a control group, they found a significantly higher elastic modulus and yield stress in the osteoarthritic bone. Unlike our study, Sun et al. did not examine post-yield properties, which are clinically more relevant when determining the toughness of bone. They postulated the increase in stiffness and yield stress may explain why several aforementioned epidemiological reports have shown fractures to be rare in the OA population. The data in our study reveals a significant reduction in post-yield strain in the fracture group, supporting our hypothesis that the fractured bone would undergo less compression prior to failure.

Saito et al. reported an increase in advanced glycation end products (AGE) within cancellous bone in cases of hip fractures compared to age- and gender-matched non-fractured controls. Within the control group of their study, osteoarthritic cases were excluded. In our study, quantifiable AGE levels were found in cancellous bone from both hip fracture and osteoarthritic patients. While the amount of NEG we measured was not compared against a cadaver control group, it is important to acknowledge the inherent difficulties of controlling for age with the possibility of sub-clinical OA and OP acting as a confounding variable. We have also shown previously in our lab that increasing age has a significant positive effect on the accumulation of AGEs in cortical and cancellous bone. It is thus important that the experimental groups in this study were of similar ages in order to make a fair assessment of NEG in each separate disease cohort. Also, in order to eliminate the possibility of any poorly controlled diabetic patients affecting the AGE content of the cancellous bone, HbA1c levels were found to be similar between experimental groups. Overall, there was indeed a slight trend in our data towards more AGEs in the hip fracture group by 12%. Although this difference was not statistically significant, it is possible that an increase in sample size may yield results to support our original hypothesis. The increase in NEG also helps to explain the fact that under compression the fractured bone was found to behave in a significantly more brittle manner than the osteoarthritic bone, especially considering our previous work that has shown NEG to have detrimental effects on the post-yield properties of cancellous bone.

At a minimum, it cannot be discounted that this study demonstrates that the phenomenon of NEG is occurring in the cancellous bone collagenous matrix of both osteoarthritic and osteoporotic patients and may be contributing in different ways to these disease processes. Whether the mechanical alterations found in arthritic bone in our study are primary or secondary to degenerative changes in the overlying cartilage, and whether the accumulation of AGEs, which is known to occur at the articular surface, also affects the NEG process within bone warrants future research. If further data collection shows a significant increase in AGE levels in osteoporotic patients compared to others of similar ages, then we may have another target in the treatment of osteoporosis and the prevention of fragility fractures. Recent advances in pharmaceutical research proposing “AGE inhibitors” and “AGE breakers” offer much potential promise as additional weapons against the increasing health care burden of osteoporotic hip fractures.

Acknowledgements
This work was supported by NIH grant AG20618. Thanks to Howie Morris of Albany Medical Center in the Department of Radiology for assistance with the x-rays.
References


How Much Motion is There in the Normal Scapholunate Joint?

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This study was undertaken to evaluate motion which occurs in the normal scapholunate joint, as the wrist moves from extension to flexion, and to compare that motion to the radiocarpal (radiolunate) and midcarpal (lunocapitate) motion occurring at the same time. We found that there was an average of 32 degrees of motion at the scapholunate joint. This represented 52% of the midcarpal motion, with 29 degrees of scaphocapitate motion accounting for the remaining 48% of midcarpal motion. Midcarpal motion averaged 54% of total wrist motion, thus for each 4 degrees of wrist motion, approximately 2 degrees occurred at the midcarpal joint, with 1 degree of motion occurring at the scapholunate joint. Motion outside the range described may indicate wrist pathology.

Introduction

The scaphoid plays a unique role in carpal mechanics, acting as a linkage to stabilize the midcarpal joint.1,5 Although reports of the ratio of radiocarpal to midcarpal motion vary, both joints contribute to total wrist motion.3,4,6,7 Since the scaphoid is attached by ligaments to both the lunate and capitate, the scapholunate and scaphocapitate joints each must contribute to the total midcarpal motion. In this study we used plain X-rays to evaluate the normal motion of the scapholunate, scaphocapitate, and lunocapitate joints while the wrist moves from extension to flexion.

Materials and Methods

Thirty volunteers, without wrist problems, had plain lateral X-rays taken with their wrists in extension, neutral and flexion (Figure 1). Each was asked to hold their wrist in maximum extension and flexion; no attempt to passively bend the wrist further was made. Each wrist was carefully positioned with the radius and ulna superimposed to minimize variation.

The X-rays were then digitized, at 150 dots per inch, 256 shades of gray, using a transilluminated radiograph scanner (XRS Company, San Jose, CA). During scanning, the image was adjusted to compensate for X-ray technique differences. The digitized images were displayed on a high resolution computer monitor at 8 to 10X zoom. Computer software was used to adjust the level (brightness) and window (contrast) of the images so that the outlines of the overlapped carpal bones could be clearly distinguished on the lateral X-ray (Image Systems, Troy, NY).

Standard radiographic axes of the scaphoid, lunate, capitate, and radius were plotted over the digitized X-ray image, using a computer assisted drafting (CAD) program (Image Meterology, Ballston Spa, NY).2,4,7 Angles between each axis were measured using the CAD program and recorded (Figures 2 and 3). The average angle and standard deviation were determined for each wrist position, and the motion and contribution to total wrist motion for each joint calculated.

Results

Active wrist motion averaged 64 degrees extension and 50 degrees flexion, for a total active motion of 114 degrees (+/- 22 degrees). The average midcarpal (lunocapitate) motion was 61 degrees (+/- 18 degrees). This accounted for 54% of the total wrist motion.
The scapholunate angle changed from 37 degrees (+/- 10 degrees) in extension to 69 degrees (+/- 10 degrees) in flexion. The scaphocapitate angle changed from 72 degrees (+/- 8 degrees) in extension to 43 degrees (+/- 12 degrees in flexion).

The 32 degrees of scapholunate motion accounted for 52% of the total midcarpal motion. The 29 degrees of scaphocapitate motion accounted for the remaining 48% of midcarpal motion.

Fifty-five of the average 64 degrees of extension occurred at the midcarpal joint, however individual variation was wide from 17 percent to 76 percent. Likewise, of the 50 degrees of average flexion, 48% occurred at the midcarpal joint, but again, individual variation was wide (14% to 80%).

Discussion
Wrist motion is the result of complex 3-dimensional motion of the carpal bones as they interact with each other. The scaphoid stabilizes the midcarpal joint, it also allows midcarpal motion. This study examines only the motion of flexion and extension as it projects on the lateral X-ray. Motion of the scaphoid also involves rotation under the capitate, which cannot be adequately analyzed by this simple method.

Based on the data presented, for every 4 degrees of wrist motion, there is approximately 2 degrees of midcarpal motion, and approximately 1 degree of motion at the scapholunate joint. Any efforts to reconstruct the scapholunate joint must allow a similar degree of motion or midcarpal stiffness will result. Fusion of the scaphocapitate joint will eliminate approximately 50% of midcarpal and 25% of total wrist motion. Ligament reconstruction that allows motion at the scapholunate joint may help to increase the resulting motion.

Motion at the midcarpal joint varied considerably among the volunteers, which may account for the wide variation of the contribution of this joint in previously published reports. Motion outside the range described may indicate pathology, but, for evaluation of the individual patient, comparison views my be needed to determine normal for that patient, rather than using a published range of values.

References


Displaced Intra-articular Calcaneal Fractures Comparison of Two Different Surgical Techniques: Modified Palmer’s Approach and Extensile Lateral Approach: Early Complications, Radiographic Findings and Outcomes

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Presented at the 2009 AMC Orthopaedic Surgery Annual Resident Thesis Day

Background: Intra-articular calcaneal fractures remain a challenging group of injuries to manage. Recent studies have suggested operative intervention provides advantages over non-operative treatment, albeit with an increased risk of wound complications. Varying surgical approaches have been advocated, and selecting one which minimizes the risk to the soft-tissue envelope would provide a significant advantage in maximizing the patient’s post-operative outcome. This study was undertaken to examine the differences in radiographic and functional outcomes, as well as in rates of soft-tissue complications associated with intra-articular calcaneal fractures treated surgically using either an extensile lateral or a modified Palmer’s approach.

Methods: We retrospectively reviewed surgically treated calcaneal fractures treated at a level I trauma center over a period of 4.5 years. Twenty-two fractures were treated with a modified Palmer’s approach and 52 fractures were treated with an extensile lateral approach. Functional outcomes were evaluated using the AAOS foot and ankle questionnaire administered at office visits or by telephone interviews.

Results: Sixty-eight patients with 74 displaced intra-articular fractures, were followed for an average of 20 months. The population skewed predominantly male (76%; p<0.001). Mean age at time of injury was found to be 38.5 years (range, 15 to 70) with no significant differences noted between the extensile lateral and the modified Palmer groups. The single largest mechanism of injury was fall from height (66.7%) with motor vehicle accident the second most common (25.3%). Severity of initial injury, as evaluated by Sander’s classification, was not found to be significantly different between groups. Two patients (9%) treated with the modified Palmer’s approach developed wound complications that were successfully managed with wound care, while 24 patients (46%) treated with the extensile lateral approach developed wound complications.

Conclusions: There was no significant difference in outcomes between the two groups. Our data would support a decrease in the rate of wound complications associated with a modified Palmer’s approach as compared to the extensile lateral approach without a significant change in the patient’s functional outcome or in the degree of radiographic improvement.

Introduction
Calcaneal fractures account for 60% of fractures of the tarsal bones and 2% of all fractures. These fractures can be classified broadly into intra-articular and extra-articular types, with the intra-articular variant being more common, representing 70-75% of all fractures of the os calcis, frequently resulting from axial loading with varying degrees of shear force. Despite their frequency, advances in diagnostic imaging and methods of internal fixation, their management remains challenging and controversial.

Treatment goals focus on the minimization of pain and the maximization of functional use of the foot in performance of activities of daily living. Current recommendations for treatment range from nonoperative to operative intervention, including primary arthrodesis, closed reduction and percutaneous pinning, and open reduction with internal fixation (ORIF). Open technique was described by Lenormant and Wilmot in 1932 and popularized by Palmer in 1948. However, inability to reproduce Palmer’s results led to a decline in the use of this method.

During the last decade there has been renewed enthusiasm for the operative treatment of intra-articular calcaneal fractures. Thordarson, in a prospective, randomized study comparing operative and nonoperative treatment of calcaneal fractures, found that functional scores were better for fractures treated surgically than for those managed by nonoperative methods. Buckley, in another prospective study, demonstrated similar results, but in a select group of patients. The meta-analysis by Randle et al. also reported a tendency for better results with operative treatment.

There remains, however, no consensus regarding the surgical approach, with many having been described, including medial, lateral, combined medial and lateral, extended lateral, and sinus tarsi approaches. Further, the
method of fixation remains a point of debate, with various proponents advocating fixation with pins, screws, or plate fixation with screws. While the literature suggests significant benefit from operative management of these fractures, complications have been shown to be a common problem in many studies, with some series reporting up to 33% incidence of surgical wound breakdown, a finding that has prompted interest in minimally invasive techniques, including the use of a modified Palmer’s approach, that offer the potential to avoid compromising the already damaged soft tissue envelope.

The purpose of this study was to review differences in outcomes and early wound complication between patients with intra-articular calcaneal fractures treated with a modified Palmer’s approach and the extensile lateral approach.

Materials and Methods
A retrospective review was done of all calcaneal fractures treated at a level I trauma center over a period of 4.5 years. This study was given full approval from the local Institutional Review Board and ethics committee.

Inclusion criteria for the entry into the study consisted of adult patients older than 17 years of age, with a diagnosis of displaced intra-articular calcaneal fractures treated surgically, and with fractures meeting Sanders II classification or greater, as defined by the findings in the CT scan. Patient selection was restricted to those treated by either a trauma surgeon or an orthopaedic foot specialist. Patient with concomitant injuries to the ipsilateral foot were excluded.

Between Sept 2002 and April 2007, 72 patients with 78 intra-articular calcaneal fractures underwent surgical management. Four patients were excluded because a primary fusion was done at the time of the initial treatment. This resulted in a study population of 74 displaced intra-articular fractures of the os calci in 68 patients. The patients were divided into two groups: Group 1 consisted of 22 fractures that were treated with the sinus tarsi approach; Group 2 included 52 fractures treated with the extended lateral approach. Patients were initially treated with ice and elevation. Timing for the surgical intervention was delayed until soft tissue swelling had adequately subsided and skin wrinkling was apparent.

Operative Technique
All the patients in this study underwent open reduction and internal fixation through either an extensile lateral or sinus tarsi approach, which are described in detail below.

Modified Palmer Lateral (Sinus Tarsi) Approach: In this approach, a straight incision is made on the lateral side of the foot, approximately 1 to 1.5 cm distal to the tip of the fibula and roughly perpendicular to the long axis of the fibula. The incision starts approximately 1 cm posterior to the fibula and continues distally for a total length of 3 to 4 cm. The incision is more transverse than that used by Palmer. We have found that this technique facilitates excellent visualization of the posterior facet. The peroneal tendons are identified and the distal portion of the retinaculum is released. The tendons are mobilized and retracted anteriorly. The fat pad in the sinus tarsi is mobilized proximal to distal, and the capsule of the posterior talocalcaneal joint is opened if the capsule is intact. An elevator is used to align the posterior facet with the medial sustentaculum fragment, and the depressed posterior facet is reduced to the talus. Kirschner wires are used to provisionally fix the posterior facet to the medial fragment, and one or two lag screws are passed across the fracture site from lateral to medial. Once this posterior facet fragment is fixed to the medial fragment and the joint has been successfully elevated, correction of the varus deformity of the posterior tuberosity is performed. A Schantz pin is inserted into the lateral aspect of the calcaneus tuberosity. This pin is then pulled downward to recreate the calcaneal height and to correct the varus alignment. Often a laminar spreader is placed between the tuberosity and posterior facet fragments to help maintain height. K-wires are then passed from the heel into the posterior facet fragment to provisionally stabilize the tuberosity fragment. A 6.5 cannulated screw is used to complete the fixation. Finally, bone grafting of the defect below the posterior facet is performed by either bone grafting with cancellous bone chips or with calcium pyrophosphate bone cement. The wound is irrigated prior to closure and closed with deep 2-0 absorbable sutures. Skin closure is performed with 4-0 nylon sutures.

Extensile Lateral Approach: Described by Benirschke et al., a modification of the techniques described by Palmer and Letournel was used. This is an extensile, L-shaped lateral incision. The vertical part of the incision parallels the long axis of the limb, the horizontal part roughly parallels the plantar surface of the foot. A full thickness flap is raised containing the peroneal tendons, sural nerve and calcaneofibular ligament. This exposure allows visualization from the tuberosity to the calcaneo-cuboid joint. Kirschner wires are placed in the fibula, talar neck and cuboid. These are bent to minimize retraction on the wound edges, using a so-called “no touch” technique. Fracture reduction is initiated with elevation of the expanded lateral wall, disimpaction of the posterior facet and lag screw fixation of the facet to the sustentacular segment. The tuberosity malalignment is then corrected, as is the height. Provisional K wire fixation is utilized. Fluoroscopic imaging with lateral, axial and Broden’s projection are analyzed to assess reduction. Plate fixation is then applied in the tuberosity, beneath the posterior facet.
and along the anterior calcaneus. The surgical wound is closed over an eighth-inch Hemovac drain. Wound closure is accomplished with inverted 2-0 absorbable sutures to close the subcutaneous layer and 3-0 nylon horizontal mattress sutures for the skin.

Post-Operative Management
Postoperatively the management for the two groups was similar; the patients were placed in a ‘bulky Jones’ dressing with the extremity elevated for 48 hours. Intravenous antibiotics were continued for 24-48 hours. When the soft tissue swelling had abated, the patient was allowed to begin active range of motion of the ankle and subtalar joints. Walking on the injured foot was not permitted for twelve weeks. Resumption of weight-bearing was initiated at that time to patient tolerance. Individuals with unilateral fractures were instructed to bear weight on the forefoot initially, with gradual resumption of heel-to-toe ambulation. For the group treated with the modified Palmer’s approach, 25% weight bearing was allowed at eight weeks, which was incremented by 25% for every week thereafter, by twelve weeks the patient was full weight bearing.

Medical records and radiographs were retrospectively reviewed. Wound complications were defined using clinical criteria, specifically persistent drainage, inflammatory signs, events requiring unplanned procedure (i.e. debridement), need for additional special wound care and patients requiring treatment with antibiotics beyond two weeks postoperatively.

Radiographic Data
The preoperative radiograph and computer tomography (CT) scans were used to evaluate and classify the fracture. All patients had displacement greater than 2mm from anatomic position. Sander’s classification\(^8,31\), without subclasses, was utilized in order to describe the fracture. Lateral radiographs immediately after the surgery and during the last clinic follow-up visit were also evaluated. The angles of Gissane and Böhler, as measured on these three sets of radiographs, were compared.

Functional Outcome
The AAOS foot and ankle questionnaire was used as a measure of functional outcome. This is a patient-reported, foot-specific instrument. The questionnaire has twenty items that, combined, form the Foot and Ankle Core Scale and an additional five questions that form the Shoe Comfort Scale. The Core Scale can be further subdivided into four subscales: Pain (nine items), Function (six items), Stiffness and Swelling (two items) and Giving Way (three items)\(^22\). Patients with bilateral fracture were asked to complete the questionnaire for the foot with the most complaints and functional disability. For purposes of comparison, the AAOS Foot and Ankle scores were divided into the same groups used for the Maryland Foot and Ankle score (MFS): a score of 90-100 was graded as an excellent result; 75-89 as good; 50-74 as fair, and less than 49 was graded as a failure. Patients were evaluated during an office visit, or by telephone interview.

Results
Sixty-eight patients with 74 displaced intra-articular calcaneal fractures treated surgically were registered in the study. Patients were followed on average for 20 months. There were 50 (74%) men and 18 (26%) women (p<0.001). The age of the patients at the time of injury was a mean of 39 (range, 15 to 70) (Table 1). Twenty-five fractures (33%) were due to polytrauma and fifty (67%) fractures due to isolated trauma. The trauma mechanism was a motor vehicle accident in 19 fractures (25.3%), fall from height represented 50 fractures (66.7%), and 6 (8%) fractures were the result of other type of mechanism.

No significant differences between the groups treated with the modified Palmer’s approach (Group 1) and extensile lateral approach (Group 2) were detected with regard to the age at the time of injury, mechanism of injuries, or type of fracture classifications. Any wound that did not heal primarily, required dressing changes, local wound care, further surgery, became infected with discharge, exhibited any signs of skin necrosis, or that required antibiotics was recorded as wound complication (Table 2). Two patients (9%) of Group 1 developed wound complications, compared to twenty-four patients (46%) in Group 2.

Further description of this subgroup of patients was performed, examining these patients for additional factors such as smoking history and diabetes. In the univariate analysis, there were seven smokers in Group 1, one diabetic, four worker’s compensation patients, and two patients who experienced some type of wound problem.

In Group 2, there were nineteen smokers, eight diabetics, twelve patients with worker’s compensation, and twenty-four who experienced some type of wound problem. Of note, all surgical wounds healed and no major complications, such as deep infections or amputations, were documented. Incision and drainage was required in only three patients (5.7%) in Group 2, none in Group 1, and no patients were noted to have developed osteomyelitis. Using the Pearson’s Chi-Square, in Group 2 it was shown that smoking was significantly related to wound problems (p=0.025), and diabetes trended towards, but was not significantly related to, wound problems (p=0.067). In Group 2 smoking trended towards, but was not significantly related to, wound problems (p=0.075).

Four patients, one (4.5%) from Group 1 and three (5.6%) from Group 2 had hardware removal at the time of most recent follow up. Removal of the hardware was carried out at the patient request, or if there was found to be
scar tethering and pain at the site of hardware insertion. No significant difference was found between the two groups. Late fusion was performed in one (4.5%) patient from the sinus tarsi approach and in three (5.6%) from the lateral extensile approach at the time of final follow-up.

Forty-four fractures (60%) were classified as Sanders’s II, twenty-six (35%) as Sanders’s III and four (5%) as Sanders’s IV. No significant difference was found between the groups (Table 3). Information on the Böhler’s angle was available for fifty-nine cases. There were no differences between the two groups at the time of last follow-up (34° Group 1 vs. 31° Group 2) (Table 3).

Six patients had a bilateral injury; three in each group. Sixty-nine was the maximum possible number of recorded the AAOS foot and ankle scores. Eighty-four percent of Group 1 subjects and seventy percent of Group 2 subjects were able to answer the questionnaire. The four patients who had already undergone arthrodesis did not complete the questionnaire and were considered to have a poor result from the primary treatment. The functional outcomes are presented in Table 4. In Group 1, 69% of patients had a good to excellent result compared to 66% in Group 2.

Discussion
Debate on the treatment of calcaneal fractures continues despite numerous published series. Recent retrospective and small prospective studies have suggested that operative care of displaced intra-articular calcaneal fractures had an advantage over non-operative care6,13,31,32,38,40. The largest prospective, randomized, multicenter study of Buckley et al7 showed benefit of surgical over conservative treatment in a selected number of patients, specifically those who are younger, female, have a light-to-moderate workload involving the foot, and those who are not receiving Worker’s Compensation do well with operative care. Another study suggests that patients treated operatively are 5.5 times less likely to need a subtalar arthrodesis3.

Open reduction procedures have the main advantage of an anatomic reduction, restoring the subtalar joint congruity, arch height, heel width and decreased the possibility of lateral impingement. Proponents of this approach emphasize that this anatomic restoration, with a limited period of immobilization, lead to superior functional results5,8,14,29.

Despite the high enthusiasm in recent years for the operative treatment of intra-articular calcaneal fractures, the soft tissue problems associated with it 15,16,17,18,19.

<table>
<thead>
<tr>
<th>Table 1. Patient Demographics</th>
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<tbody>
<tr>
<td>Total 68 Patients 74 Fractures</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
</tr>
<tr>
<td>• Male</td>
</tr>
<tr>
<td>• Female</td>
</tr>
<tr>
<td><strong>Age/mean (years)</strong></td>
</tr>
<tr>
<td><strong>Other Factors</strong></td>
</tr>
<tr>
<td>✓ Smoker</td>
</tr>
<tr>
<td>✓ Diabetes</td>
</tr>
<tr>
<td>Worker’s Compensation Injury</td>
</tr>
<tr>
<td><strong>Wound Complications</strong></td>
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<td></td>
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</table>

<table>
<thead>
<tr>
<th>Table 2. Treatment of Wound Complications</th>
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<tr>
<td>Modified Palmer’s Approach (Group 1) 22 fractures</td>
</tr>
<tr>
<td><strong>Wound Complications</strong></td>
</tr>
<tr>
<td>I &amp; D</td>
</tr>
<tr>
<td>Wound Care</td>
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<tr>
<td>Antibiotics Only</td>
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</table>
Table 3. Radiographic Evaluation

<table>
<thead>
<tr>
<th>Sander’s Classification</th>
<th>Total Cases</th>
<th>Modified Palmer’s (Group 1)</th>
<th>Extensile Lateral (Group 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sanders II</td>
<td>44 (60%)</td>
<td>13 (59%)</td>
<td>31 (60%)</td>
</tr>
<tr>
<td>Sanders III</td>
<td>26 (35%)</td>
<td>6 (27%)</td>
<td>20 (38%)</td>
</tr>
<tr>
<td>Sanders IV</td>
<td>4 (5%)</td>
<td>3 (14%)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Böhler’s Angle</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(mean ± SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial</td>
<td>15.5° ± 16.5</td>
<td>12.4° ± 14.8</td>
<td></td>
</tr>
<tr>
<td>Immediate Post-operative</td>
<td>36.8° ± 6</td>
<td>31.1° ± 7.8</td>
<td></td>
</tr>
<tr>
<td>Last Follow-up</td>
<td>34.1° ± 6.1</td>
<td>30.9° ± 8.2</td>
<td></td>
</tr>
</tbody>
</table>

Table 4. Outcome according to AAOS foot and ankle score. Bilateral injuries were counted once. Patients who had subtalar fusion after the initial treatment were considered poor outcome.

<table>
<thead>
<tr>
<th>Number of patients evaluated</th>
<th>Modified Palmer’s Approach</th>
<th>Extensile Lateral Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group 1</td>
<td>Group 2</td>
</tr>
<tr>
<td></td>
<td>16 (84%)</td>
<td>35 (71%)</td>
</tr>
<tr>
<td>AAOS Score Average ± SD</td>
<td>82.6 ± 10.9</td>
<td>77.5 ± 14.9</td>
</tr>
<tr>
<td>• Excellent</td>
<td>31%</td>
<td>20%</td>
</tr>
<tr>
<td>• Good</td>
<td>38%</td>
<td>46%</td>
</tr>
<tr>
<td>• Fair</td>
<td>25%</td>
<td>20%</td>
</tr>
<tr>
<td>• Poor</td>
<td>6%</td>
<td>9%</td>
</tr>
</tbody>
</table>

Wound complications have proven to be a problem: Stephenson et al. report an incidence of wound breakdown of 27% while Benirschke et al. report 11% rate of wound complications using the lateral approach. The high incidence of wound complications in our series may reflect the broad criteria that were used to define them. Our results should be carefully analyzed as the disparity in wound complications between the two groups may somehow be attributed to the difference in the number of patients (22 vs. 53), the disproportionate number of ipsilateral injuries (9% vs. 21%) and number of patients that sustained other, significant musculoskeletal injuries (18% vs. 40%), (Group 1 modified Palmer’s approach vs. Group 2 extensile lateral approach, respectively). Our analysis, however, suggests that there is no significant difference between patients with isolated injuries and polytrauma injury.

Aktugle et al. in a study of 36 displaced intra-articular calcaneal fractures, showed poorer outcomes for those patients who sustained polytrauma when compared with patients with isolated injuries, independent of the type of treatment chosen. This may be accounted for given the tendency for polytrauma patients to have been subject to...
higher energy mechanisms of trauma, and the understanding that the additional injury to other systems, in addition to their significant orthopaedic injuries, leads to a major catabolic response that has the potential for impairment of soft tissue healing.

Radiographic findings demonstrated equivalent improvement for the two groups, improving Böhler’s angle, restoring measured values to within a normal range. Because Group 1 subjects received only screw fixation and bone graft or calcium pyrophosphate, there was a concern during follow-up that a loss of reduction might result, due to the poorer biomechanical advantages of this type of fixation as compared to the use of plate and screw fixation. Our data demonstrate that at the time of final radiographic evaluation there was no evidence of further collapse or change in Böhler’s angle. These findings are in line with those reported by Gupta et al. 21, where the use of the modified Palmer lateral approach, demonstrated significant improvement in mean values of Böhler’s angle, posterior facet angle, posterior facet depression, heel width and calcaneal height on CT scans post-operatively.

At last follow-up the American Orthopaedic Foot and Ankle score was classified as good to excellent in 66% to 69%, with no difference found between groups. The rate of late fusion similarly showed no difference and its incidence was found to be similar to what has described in the literature. Buckley et al. 3 found that the need for arthrodesis was 4% in a series of patients treated with ORIF. Csizy et al. 3 in a review of a prospective randomized database, found a subtalar fusion rate of 9.8%.

In summary, this retrospective review study comparing two different techniques for the treatment of intra-articular calcaneal fractures found similar results in outcome measures and improvement of radiographic criteria. However, a lower rate of wound complications was observed with the group of patients treated with the modified Palmer’s approach. Differences may be attributed to decreased operative time and dissection required. The modified Palmer’s approach is more distal to the lateral calcaneal artery and thus appears to avoid injury to this artery, implicated as a cause of wound complications with the extended lateral approach. Smoking seems to be the other only factor associated with wound complications. However, our results should be evaluated carefully. There are limitations of our study. First, this is a retrospective review, and is limited accordingly. Secondly, the number of patients treated in the extensile lateral approach outnumber those treated with the modified Palmer’s approach by a ratio of 2:1. This disparity may have limited the ability of this study to clearly identify significant differences. Thirdly, we have used broad criteria to define wound complications. In our series only three patients (5.7%) had a severe infection that required additional intervention and no patient required reconstruction with a flap, was diagnosed with osteomyelitis, or required amputation. These findings are closer to what has been published in the recent literature. Of all the patients treated in our institution with the diagnosis of intra-articular calcaneal fracture, only one required reconstruction with a flap, and of note, this patient had initially been treated at another institution.

We conclude that both techniques are equally successful at improving radiographic parameters. Outcomes were similar for the two groups. Although there was a difference in the rate of wound complications, there was no significant difference in the incidence of severe complications. There is a learning curve for both techniques. In our study the surgical intervention was performed by either an orthopaedic foot specialist or a trauma specialist, and at least one study has suggested there is a significant relationship between the deep infection rate, traumatic subtalar arthritis and the institutional fracture load42. Smoking seems to be the other only factor associated with wound complications.

References


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<tr>
<td>41.</td>
<td>Aktuglu K, Aydogan U. The functional outcome of displaced intra-articular calcaneal fractures: a comparison between isolated cases and polytrauma patients.</td>
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</table>
Comparison of Endoscopic and Open Carpal Tunnel Release in the Same Patient

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Presented at the 2009 AMC Orthopaedic Surgery Annual Resident Thesis Day

Background: Considerable debate still exists over whether endoscopic carpal tunnel release is superior to conventional open carpal tunnel release. The aim of this study is to retrospectively review a set of patients who have had bilateral carpal tunnel surgery, open on one hand and endoscopic on the other hand, and look at their overall function, satisfaction and return to activities.

Methods: Of 550 endoscopic releases done from December 2003 to October 2008, 33 patients had had previous open carpal tunnel releases performed in the opposite hand prior to the endoscopic release. Of these 33 patients, 22 patients were evaluated for this study.

Results: Seventeen of 22 patients enrolled in this study had the initial (open) procedure performed in the dominant hand. The average return to ADLs (Activities of Daily Living) and work was shorter for the endoscopic procedure. There were no wound healing problems noted with either procedure. There were no significant differences in grip strength or pinch strength in the 2 groups. DASH (Disabilities of the Arm, Shoulder and Hand) scores were also similar in both groups. Twenty of the 22 patients surveyed would recommend endoscopic surgery over open carpal tunnel surgery to a family member or friend.

Conclusions: Patients who have undergone bilateral carpal tunnel surgery with one side done endoscopically and one side open greatly favor the endoscopic surgery side from an overall satisfaction standpoint. This study supports previous prospective studies that demonstrate faster short term return of function in the endoscopic group compared to the open group.

Introduction
Median nerve compression at the wrist is the most common compression neuropathy of the upper extremity. Annually, an estimated 1 million American adults have CTS requiring carpal tunnel release. The cost of this has been estimated to be over 2 billion dollars per year. Median nerve compression at the wrist was first described by Sir James Paget in 1854 following a distal radius fracture. In 1880 James Putnam described the first series of patients with classical carpal tunnel symptoms with pain and paresthesia in the median nerve distribution of the hand. The first carpal tunnel release was reportedly performed by Herbert Galloway in 1924. Endoscopic techniques were introduced to reduce the length of incision thereby decreasing postoperative pain. There is still considerable debate over the efficacy of endoscopic carpal tunnel versus open in regards to postoperative morbidity and complications. The first endoscopic carpal tunnel release was performed by Okutsu et al in 1987 in Japan. The 2 portal endoscopic technique was introduced by Chow in 1989 and the one incision was described by Agee in 1992. Several studies have been performed in order to compare endoscopic and open carpal tunnel release but controversy still exists over which procedure is superior. One study in the British JBJS by Ferdinando et al in 2002 was a prospective randomized study of patients with bilateral carpal tunnel syndrome.

Each patient had undergone an open carpal tunnel release on one hand and a one incision endoscopic release on the other hand. The results of this study showed no advantage of the endoscopic release over open release in terms of patient satisfaction and return to normal function. Trumble et al in 2002 did a prospective randomized study of 192 hands in 147 patients comparing the single incision endoscopic release and the open release. The study found that good functional outcomes and patient satisfaction are achieved more quickly in the endoscopic group of patients. This study also found that there was no significant cost difference in the two procedures.

The purpose of this study is to evaluate patients who have had bilateral carpal tunnel surgery with one side done endoscopically and the other open. Complications, resolution time of symptoms, DASH scores, grip strength, pinch strength, length of time to return to ADLs and work and overall patient satisfaction will be recorded for these patients.

Materials and Methods
In order to qualify for this study a patient would have bilateral carpal tunnel surgery, one which was performed open (by various surgeons) and one which was performed via a single incision endoscopic technique by a single surgeon (R.W). Patients that had any type of revision surgery
were disqualified. Prior to chart review, IRB approval was obtained for the study. Overall, 550 patients qualified for chart review. Of these, 33 were disqualified for the study. Of these 33, only 22 could be included either because of refusal to enroll in the study or inability to contact patient.

Prior to examining the patient, the examiner was not told which hand was done endoscopically. Each patient was examined for: grip strength, tip pinch and key pinch strength, 2 point discrimination, carpal tunnel provocative testing (Tinel’s, Phalen’s, Compression), abductor pollicis brevis strength, numbness in the palmar cutaneous branch distribution, and scar length. Grip strength was measured using a Jamar dynamometer. Pinch strength was measured using a pinch gauge. Abductor pollicis brevis strength was determined to be strong or weak based on exam and relative to the contralateral side. Pillar pain was also recorded for each patient. When there was a radial sided pillar pain, thumb CMC testing and extensor tendon tenosynovitis testing was performed to rule out these pathologies. Range of motion deficits for each hand and wrist were also documented.

Each patient was asked to rank, on a scale of 1-5, their impression of each side. Patients also noted the time it took to return to work and return to ADLs after each surgery. The total number of postoperative visits to physical therapy were recorded for each patient. Patients were also asked if they had any residual symptoms such as numbness, weakness, scar tenderness, swelling, and loss of coordination on each side using a 0–5 scale. The time to resolution of symptoms such as numbness, palm tenderness, and hand weakness was also recorded for each hand. Finally, the patients filled out a DASH form for each extremity.

Results
Of the 22 open procedures, 17 were done on the dominant hand. Of the 22 endoscopic procedures, 5 were done on the dominant hand. There was a mean of 9 years between open and endoscopic surgeries. The average return to work for the endoscopic side was 21 days and for the open side it was 25 days (p value = .195). The average return to ADLs for the endoscopic side was 15 days, and for the open side 34 days (p value < .001). The average DASH score for the endoscopic side was 20 and for the open side it was 16 (p value = .665). Mean grip strength for the endoscopic side was 21 and for the open side 20 kg (p value = .61).

Seventeen of the 22 patients had comorbid conditions such as diabetes (3 patients), thyroid disease (6 patients), hypertension (4 patients), and other medical comorbidities (4 patients). One patient had a cervical spine fusion after her carpal tunnel surgeries. She stated that her median nerve symptoms had resolved after each hand procedure. Of the patients that went to physical therapy, the endoscopic group averaged 7 total visits, and the open side averaged 13 visits. The average length of the endoscopic scar was .94 cm, and the average length of scar for the open side was 3.3 cm. There were no wound healing complications in either group.

There were 6 cutaneous nerve complications as defined by a patch area of numbness over or near the thenar eminence. Three of these were endoscopic and the other three were from the open group. Six patients reported residual paresthesias in their hands, five of these were in the open group. Of the 4 hands that had weakness in APB testing, 2 were endoscopic and 2 were open. Of the 4 hands that failed 2-point discrimination testing, 2 were endoscopic and 2 were open. During provocative testing, 5 of the open procedure hands recreated symptoms of carpal tunnel syndrome and 4 of the endoscopic hands exhibited signs of carpal tunnel syndrome. Ten patients demonstrated symptoms of pillar pain. Of these, 7 hands were done endoscopically.

When patients were asked which surgery they would recommend for a family member or friend, 20 of 22 patients recommended the endoscopic surgery. The most common response for why was that it was a faster recovery, less pain and a smaller scar.

Discussion
From the results of this study it appears that the single incision endoscopic carpal tunnel surgery offers a shorter recovery time and better overall satisfaction for the patient when compared to conventional open carpal tunnel release. While the short term results appear to be improved for the endoscopic group, the data does not appear to demonstrate that the long term results of these two techniques are any different as evidenced by similar motor strengths and DASH scores. This study offers a unique perspective for the patient and the examiner when comparing both hands. Furthermore there does not seem to be a significant increase in complications associated with either surgery in this particular study.

There are several limitations to this study. This is not a randomized, prospective study with a large number of patients which certainly can question the statistical significance of the results. While the endoscopic surgery was done by a single surgeon, the open sides were done by various surgeons with different surgical training (Neurosurgery, Orthopaedic Surgery, and Plastic surgery). Moreover there may have been bias in the endoscopic group. These patients may have selected the endoscopic procedure after their open procedure because of their level of dissatisfaction with their previous surgeon. Another source of bias in this study is the fact that more open procedures were done on the dominant hand of the patient. In this scenario the patient is more likely to use the dominant hand more compared to the non-dominant, which could delay the recovery time compared to the endoscopic side.
References


Total Shoulder Arthroplasty vs. Hemiarthroplasty for Osteoarthritis: A Retrospective Review of Clinical Outcomes

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Presented at the 2010 AMC Orthopaedic Surgery Annual Resident Thesis Day

**Background**: Osteoarthritis of the shoulder can be treated by either total arthroplasty or hemiarthroplasty. Several studies comparing the two techniques have found either slightly better results for total arthroplasty at short-term follow-up or no difference. The purpose of this study was to compare the outcomes of hemiarthroplasty and total shoulder arthroplasty in patients with osteoarthritis and an intact rotator cuff.

**Methods**: Thirty-four shoulders with osteoarthritis and an intact rotator cuff, who had received a total or hemiarthroplasty, were clinically evaluated with range of motion, strength, University of California at Los Angeles (UCLA) shoulder scale and the Western Ontario Osteoarthritis of the Shoulder (WOOS) index.

**Results**: No significant differences were found between total shoulder arthroplasty and hemiarthroplasty regarding shoulder scores, strength, flexion, abduction or internal rotation at an average 39 months follow-up (15-145 months). A difference in external rotation was found favoring total shoulder arthroplasty (140: p = 0.03).

**Conclusions**: At an average 39 months follow-up, the results of primary total shoulder arthroplasty and hemiarthroplasty for osteoarthritis with an intact rotator cuff are similar for range of motion, strength, and quality of life.

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**Introduction**

Charles Neer II designed the first modern shoulder hemiarthroplasty in 1951. Although it was initially designed for fracture-dislocations and avascular necrosis, it was also used for arthritis. Problems using the prosthesis in rotator-cuff deficient shoulders and with glenoid erosions prompted Neer’s next design, the total shoulder arthroplasty, in 1974. Since that time, both general shoulder design types have been used for glenohumeral arthritis.

Significant controversy still exists, however, in patients with osteoarthritis and an intact rotator cuff. Several studies have compared outcomes after total and hemiarthroplasty for osteoarthritis and have found either slight favor for total arthroplasty regarding pain relief and flexion at short-term follow-up or no difference. Their heterogeneity, inconsistent use of shoulder scores, occasional use of patients with rotator cuff tears, and short-term follow-up make it difficult to reach a conclusion on the subject.

Further, failed hemiarthroplasties are often revised to total shoulders and failed total arthroplasties often convert to hemiarthroplasties. Whether these revised shoulders are clinically similar to primary arthroplasties is also debated. This is important, as some may claim that a benefit of hemiarthroplasty is the easy conversion to total arthroplasty at a later date, for example. The purpose of this study, was to compare the outcomes of hemiarthroplasty and total shoulder arthroplasty in patients with osteoarthritis and an intact rotator cuff.

**Materials and Methods**

**Patient Selection**

The billing records of a large orthopaedic group (Capital Region Orthopaedics in Albany, NY) were searched for all cases of shoulder hemiarthroplasty and total shoulder replacement since 2000. Search criteria were shoulder arthroplasty for reason other than fracture (CPT 23470, 23472) and surgery performed by an orthopaedist performing more than one arthroplasty per year. Charts were then reviewed to identify patients for inclusion.

**Inclusion criteria:**

- Diagnosis of osteoarthritis in clinical or operative notes.
- Intact rotator cuff in operative note.
- Surgery performed greater than one year prior to study.

**Exclusion criteria:**

- Other arthritic diagnosis such as rheumatoid arthritis, gouty arthritis, cuff tear arthropathy or avascular necrosis of the humeral head.
- Diagnosis of rotator cuff tear or lack of rotator cuff notation in chart.
- Less than one year follow up.
- Revision of primary arthroplasty.

Seventy seven shoulders (33 hemiarthroplasties and 44 total arthroplasties) performed by 6 surgeons fit the criteria for inclusion in the study. Thirty-four shoulders...
in 33 patients were available for clinical evaluation, and form the study group.

**Clinical Evaluation**
Patients were asked to return to the office for a physical exam, evaluation by the UCLA Shoulder Scale, and completion of a questionnaire. Range of motion and strength were tested through flexion, abduction, internal rotation and external rotation. The questionnaire was the WOOS Index, a validated scoring system for quality of life assessment.

**Consent**
Our study protocol was approved by our facility’s Institutional Review Board. All patients provided consent for participation.

**Data Analysis**
T-tests and ranksum analysis were used to compare the two groups regarding range of motion, strength, the UCLA scale and the WOOS index.

**Results**
Of the 34 shoulders studied, 13 received hemiarthroplasty and 21 received total arthroplasty. The average follow-up was 39 months and the median was 31 months (range 14-145 months).

Within the hemiarthroplasty group, the average age of patients was 63 years. Average follow-up was 48 months and median was 39 months (range 15-145 months). There were 9 men and 4 women. Three shoulders had undergone a previous procedure. One received a labral debridement, one a debridement and excision of loose bodies, and one had excision of loose bodies, acromioplasty and open distal clavicle excision.

Within the total arthroplasty group, the average age of patients was 68 years. Average follow-up was 32 months and median was 28 months (range 14-79 months). There were 15 men and 5 women. Two shoulders had previously undergone arthroscopic labral debridement.

**Range of Motion**
There was no significant difference in range of motion between the two groups for flexion, abduction, or internal rotation using t-test or ranksum analysis. There was significantly better external rotation with total arthroplasty, 47° vs. 33° (p=0.03) using the t-test. Ranksum analysis found no significant difference in external rotation (z=0.0676) (Table 1).

**Strength**
No differences were found comparing strength of flexion, abduction, internal rotation or external rotation for the primary or revision groups using either t-test or ranksum analysis (Table 2).

### Table 1: Range of Motion for Primary Shoulder Arthroplasty

<table>
<thead>
<tr>
<th>Motion Type</th>
<th>Hemi (avg)</th>
<th>TSA (avg)</th>
<th>Difference (CI)</th>
<th>p-value</th>
<th>z-score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion</td>
<td>123°</td>
<td>132°</td>
<td>9° (-29 to 11)</td>
<td>0.3641</td>
<td>0.3850</td>
</tr>
<tr>
<td>Abduction</td>
<td>104°</td>
<td>115°</td>
<td>11° (-36 to 15)</td>
<td>0.4114</td>
<td>0.5235</td>
</tr>
<tr>
<td>Int. Rotation</td>
<td>65°</td>
<td>60°</td>
<td>5° (-8 to 19)</td>
<td>0.4459</td>
<td>0.3652</td>
</tr>
<tr>
<td>Ext. Rotation</td>
<td>33°</td>
<td>47°</td>
<td>14° (-26 to -1)</td>
<td><strong>0.0300</strong></td>
<td>0.0676</td>
</tr>
</tbody>
</table>

TSA = Total Shoulder Arthroplasty, CI = Confidence Interval

### Table 2: Strength for Primary Shoulder Arthroplasty

<table>
<thead>
<tr>
<th>Strength Type</th>
<th>Hemi (avg)</th>
<th>TSA (avg)</th>
<th>Difference (CI)</th>
<th>p-value</th>
<th>z-score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion</td>
<td>4.76</td>
<td>4.61</td>
<td>0.15 (-0.23 to 0.54)</td>
<td>0.4347</td>
<td>0.4890</td>
</tr>
<tr>
<td>Abduction</td>
<td>4.53</td>
<td>4.76</td>
<td>0.23 (-0.60 to 0.15)</td>
<td>0.2423</td>
<td>0.3152</td>
</tr>
<tr>
<td>Int. Rotation</td>
<td>4.38</td>
<td>4.33</td>
<td>0.05 (-0.35 to 0.45)</td>
<td>0.7940</td>
<td>0.8530</td>
</tr>
<tr>
<td>Ext. Rotation</td>
<td>4.53</td>
<td>4.67</td>
<td>0.14 (-0.49 to 0.23)</td>
<td>0.4699</td>
<td>0.4614</td>
</tr>
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TSA = Total Shoulder Arthroplasty, CI = Confidence Interval
Shoulder Scores

No difference was found in either the UCLA scale or WOOS index between the primary arthroplasty groups using t-test and ranksum analysis (Table 3).

Discussion

Our study showed little difference between primary total shoulder arthroplasty and hemiarthroplasty for osteoarthritis with an intact rotator cuff. While no differences were found in strength or the motions of flexion, abduction or internal rotation, a 14° difference in external rotation in favor of total arthroplasty was significant. It is possible that the exposure of the glenoid in total shoulders may lead some surgeons to also release the subscapularis off of the anterior scapula, leading to greater external rotation postoperatively. The z-score of the ranksum analysis did not show significance for external rotation, but showed a trend toward significance, and the confidence interval for the t-test was large, suggesting a large variability in data. Flexion and external rotation were also found to be better in total shoulders at 4 years in another study, but that study included patients with rotator cuff tears in the hemiarthroplasty group, introducing bias in favor of the total shoulder group.

As with another study comparing WOOS index scores, we found no difference between the primary arthroplasty groups. While the previous study found no difference at 2 years, our findings are at an average of 3.25 years. The WOOS index measures quality of life through physical symptoms, recreation/work, lifestyle, and emotions. The score is given as a number out of 100, with 100 being a completely unaffected quality of life as relates to the shoulder. This index was developed specifically for shoulder osteoarthritis and consists of 19 questions.

We also included the UCLA shoulder score which, unlike the Constant, ASES, SPADI or SST, was designed to assess outcome after shoulder arthroplasty. While many studies utilize other shoulder scores or several scores for comparison, only the UCLA score assesses pain, function, ROM, strength and patient satisfaction. We found no significant difference in UCLA score between the two groups.

This study included only patients with an intact rotator cuff noted at the time of surgery. Large rotator cuff tears in total shoulder arthroplasty are associated with less postoperative motion, more pain, and loose components. This is likely due to a “rocking horse effect” of the head on the glenoid and, thus, stress on the glenoid component/glenoid bone interface. Despite this knowledge, several studies investigating differences between total and hemiarthroplasty for shoulder osteoarthritis have failed to exclude patients with rotator cuff tears from the study population.

In conclusion, primary total shoulder arthroplasty and hemiarthroplasty for osteoarthritis with an intact rotator cuff are similar in range of motion, strength, and quality of life at an average 3.25 years follow-up. The statistically significant difference found for external rotation favoring total shoulder arthroplasty may not be clinically relevant.

Table 3: Shoulder Scores for Primary Shoulder Arthroplasty

<table>
<thead>
<tr>
<th>Shoulder Score</th>
<th>Hemi (avg)</th>
<th>TSA (avg)</th>
<th>Difference (CI)</th>
<th>p-value</th>
<th>z-score</th>
</tr>
</thead>
<tbody>
<tr>
<td>UCLA</td>
<td>28.1</td>
<td>30.0</td>
<td>1.9 (-5.3 to 1.5)</td>
<td>0.2711</td>
<td>0.0840</td>
</tr>
<tr>
<td>WOOS</td>
<td>79</td>
<td>88</td>
<td>9 (-424 to 89)</td>
<td>0.1937</td>
<td>0.0956</td>
</tr>
</tbody>
</table>

TSA = Total Shoulder Arthroplasty, CI = Confidence Interval

References


Adjacency effects: A novel in vivo/in vitro, active/passive protocol for assessing redistribution of motion of the entire thoracolumbar spine following surgical intervention

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Adjacent segment disease is recognized as a potential complication of spinal fusion. In vitro testing and finite element analyses largely indicates that fusion instrumentation placed at one level significantly changes the stress and motion at adjacent levels. However, advances in dynamic stabilization systems and motion preserving technologies show promise for minimizing adjacent level effects. The purpose of this study was to use a new in vivo/in vitro active/passive biomechanical testing method to quantitatively assess the three-dimensional motion redistribution of the entire thoracolumbar spine following surgical intervention during full dynamic range of motion based on in vivo kinematics, without the confounding factors inherent in a clinical trial.

Whole bony-ligamentous thoracolumbar spines (C7 through S1) were harvested from cadavers. C7 was attached to the end-effector of the six degree-of-freedom robot and three-dimensional in vivo kinematic data from normal healthy volunteers was loaded into the robot controller. The three-dimensional motion of 11 vertebrae were simultaneously measured during replication of in vivo motion. After completion of the intact motion assessment, specimens were then subjected to surgical interventions at the L4-L5 level including laminotomy, laminectomy, discectomy, facetectomy, facet screw fixation, and then pedicle screw fixation, followed by two level pedicle fixation at L3-L5. The range of motion testing was repeated and recorded between each intervention.

With successive interventions (laminotomy, laminectomy, discectomy, facetectomy), intersegmental motion at the L4-5 level increased and there was a redistribution of motion at adjacent levels. Pedicle screw fixation at the L4-5 level resulted in a reduction in motion at L4-5 and a reduction at L3-4 with concomitant increases in motion at all other levels relative to the intact state. These preliminary data indicate that surgical interventions at the L4-5 level affect motion at all other levels of the spine (from S1 up to at least T7). There is a redistribution of motion at adjacent levels following surgical intervention that compensates for the changes in motion at the index level. These results suggest that an intervention at one level does not strongly predispose the immediate super- and sub-adjacent levels to substantially altered kinematics while sparing other levels, but rather that all levels are subjected to some redistribution.

Introduction

Single and multi-segment spinal fusions have been used to treat spinal instability and chronic pain. Relatively high rates of success have been reported and fusion remains a good option after failure of conservative treatment. Surgeons and researchers as early as five decades ago began to describe what has become known as adjacent level disease. Clinical follow-up of fusion patients has led to the publication of numerous scientific articles documenting changes at levels adjacent to fused segments. These largely radiographic changes have been linked to poor outcomes and to time-dependant symptoms, thus adjacent segment disease is recognized as a potential complication of spinal fusion.

Adjacent segment disease is a term with broad meaning. It encompasses any changes that occur in a mobile segment adjacent to a spinal fusion. Some of the most common changes include; disc degeneration, listhesis, instability, disc herniation, facet hypertrophy, and osteophyte formation. The ambiguity of the definition of this degenerative process has made the study of its etiology difficult.

Although many reports have correlated adjacent level disease to poor functional outcomes and to the need for further surgical intervention, others have doubted the cause and effect relationship. Some report earlier degeneration in patients with fusions while others fail to find differences between ongoing degenerative processes and problems caused by surgery.

In vitro testing and finite element analyses largely indicates that fusion instrumentation placed at one level significantly changes the stress and motion at adjacent levels. Other studies have shown that
instrumented fusion causes an increase in intradiscal pressure\textsuperscript{14-17}. Some reports indicate an increase in adjacent level motion following fusion\textsuperscript{18,19} while others report a decrease\textsuperscript{20}.

There are many reasons for the disparity in results. Clinical studies are fraught with the difficulty of discerning the difference between pathology at adjacent levels whose progression was inherent, versus pathology that was initiated or exacerbated by fusion at an adjacent level. In vitro testing and finite element models afford the luxury of eliminating the confounding effects of natural disease progression, yet, ex vivo models are generally based on application of arbitrary loads or motions that may have limited clinical relevance.

Advanced image analysis techniques have become available for use in quantifying motion of the spine using plain radiographs. This has allowed quantitative analysis of range of motion and center of rotation of patients before and after treatment and over time following treatment\textsuperscript{21}. The comparison of before and after data allows quantification of spinal motion redistribution. However, this valuable technology is limited to analysis of static images and also is limited to analyzing the number of levels that are captured on a plain film.

In vitro mechanical testing has also been used to assess adjacent level effects. The most recent techniques have moved beyond the “flexibility” and “stiffness” protocols originally proposed by Panjabi\textsuperscript{22,23}. The newer “hybrid” protocol encompasses the concepts of the flexibility and stiffness protocols but is based on a recently posed theorem: that the overall range of motion of the spine does not change (relative to its intact state) as a result of surgical intervention, even if that surgical intervention affects motion at a treated level\textsuperscript{24}. Thus, the overall range of motion of the trunk will remain the same even if a surgical intervention (such as fusion in the lumbar spine) alters the kinematics of one level. Likewise, the overall range of motion of the head and neck will remain the same following a cervical spine intervention. The theoretical basis for this is that muscles, tendons, ligaments, and other intact tissues are trained to achieve an inherent range of motion and by replacing one component of the system (such as replacing an intervertebral disc with an implant) the inherent range of motion does not necessarily change. Although this theory has not yet explicitly been proven, there is evidence to support it\textsuperscript{25,26} and it is now a widely accepted basis for in vitro biomechanical testing\textsuperscript{27,28}.

Advances in dynamic stabilization systems and motion preserving technologies show promise for minimizing adjacent level effects, however this remains controversial\textsuperscript{29-32}. Data from in vitro testing and finite element models are only able to predict clinical adjacent level effects to the extent that the experimental or simulated mechanical and kinematic environment mimics in vivo conditions. When in vitro testing is conducted on specimens consisting of three motion segments or fewer, additional artifact is introduced because the redistribution of stress and motion is constrained at the super and subadjacent levels.

The purpose of this study was to use a new in vivo/in vitro, active/passive biomechanical testing method to quantitatively assess the three-dimensional motion re-distribution of the entire thoracolumbar spine following surgical intervention during full dynamic range of motion based on in vivo kinematics.

**Materials and Methods**

We have previously conducted work to develop a hybrid in vivo to in vitro methodology for quantifying adjacent level effects. The method is based on whole spine, three dimensional kinematic data collected from volunteer subjects performing voluntary trunk range of motion activities. The data were collected using three dimensional motion tracking sensors (Flock of Birds, Ascension Technology, Burlington, VT) which were mounted on the skin superficial to C7, T12, and S1. The data were collected at over 100 samples per second throughout range of motion to the maximum extent achievable by the subjects. Subject motion was also recorded on high definition video during the course of data acquisition. Previous radiographic studies have shown less than 2° of difference between superficial sensors mounted on the skin in this fashion and actual vertebral movement\textsuperscript{33}. Data were collected during flexion, extension, right and left lateral bending, and rotation as shown in Figure 1.

Following in vivo data collection, each data set recorded from the volunteers was reduced to command set to drive a robotic simulator (Puma 560, Rensselaer Polytechnic Institute, Troy, NY). The robotic system was used for in vitro testing.

**Specimen Preparation**

In this pilot study, three whole bony-ligamentous thoracolumbar spines (C\textsubscript{7} through S\textsubscript{1}) were harvested from male cadavers within 24 hours of death. Specimens were harvested by transection through the C\textsubscript{6}-C\textsubscript{7} disc space followed by circumferential release of extraneous soft tissue, osteotomies through each rib approximately 10 cm lateral to the vertebrocostal joint, and transection through the sacrum caudal to S\textsubscript{1} with a reciprocating saw. Care was taken not to disrupt the facet capsules, ligaments, or intervertebral discs of all levels. Once excised, the bony-ligamentous spines were wrapped in saline soaked gauze and stored frozen at -20° C in plastic bags until the time of use.

The skeletal dimensions of the cadaver (head to toe length) and the C\textsubscript{7} to S\textsubscript{1} length were measured at the time of harvest. Prior to in vitro testing, the dimensions of
the cadaver and spine were compared to those in the database of in vivo subjects and the most appropriate in vivo data set (with the closest spinal and skeletal dimensions to the cadaveric spine) was retrieved for testing.

**Intact Motion Assessment**

At the time of testing, each cadaveric spine was thawed to room temperature and kept moist throughout the experiment by saline spray. The caudal end of the spine was potted in a cup fixture with Low (47° C) Melting temperature Alloy (LMA). Screws were placed in the sacrum to facilitate rigid fixation of the sacrum in the LMA. Once potted in LMA, the caudal end of the spine and fixture were fixed to a platform rigidly attached to the floor. The cranial end of the spine, (C7), was attached to the end-effector of the six degree-of-freedom robot using a custom clamp, as shown in Figure 2.

The three-dimensional kinematic data from the appropriate in vivo subject was loaded into the robot controller. The data are used to control the end-effector relative to the sacrum such that the position and orientation of the C7 vertebra relative to the sacrum precisely matches that of the position and orientation of the volunteer. The robot control is maintained throughout all range of motion maneuvers (flexion/extension, lateral bending, torsion).

Position and orientation sensors (Flock of Birds, Ascension Technology, Burlington, VT) were mounted to 11 vertebrae (T7 to L5) using polycarbonate mounting fixtures and screws (Figure 3). The robot then moved C7, relative to S1, in an identical fashion to the active motion of the in vivo volunteer in left and right lateral bending. The three-dimensional motion of the 11 vertebrae were simultaneously measured at a rate of approximately 60 samples per second during spine maneuvers with the spine in its intact state as a baseline measurement. The spine was moved at 50% of the speed of the volunteers to eliminate any inertial effects. The spine was moved through three sets of lateral bending motion and the data from the 3rd set was used for comparison.

**Figure 1:** Three-dimensional data were previously collected from volunteers during flexion, extension, lateral bending, and torsion.

**Figure 2:** C7 was fixed to the end-effector of the robot using a custom clamp.

**Figure 3:** Eleven sensors were mounted to thoracic and lumbar vertebrae (left) to track three-dimensional motion during lateral bending (right).
Clinical Therapeutic Interventions

After completion of the intact motion assessment, specimens were then subjected to surgical interventions at the L4-L5 level. Each spine then underwent a successive laminotomy, laminectomy, discectomy, facetectomy, facet screw fixation, and then pedicle screw fixation, followed by two level pedicle fixation at L5-S1. The range of motion testing was repeated and recorded between each intervention. The range of motion for each vertebra was compared to the intact state. Changes in range of motion at each level were calculated and were used to calculate the redistribution of motion at adjacent levels.

Motion Redistribution Assessment

For each treatment, at each of the 11 recorded levels of the spine, the intact state and post-intervention three dimensional kinematic data were compared quantitatively. These data were used to quantify the redistribution of motion (if any), and thus quantify the adjacent level effects of each treatment.

Results

Representation of the typical flexion/extension motion for the volunteers is shown in Figure 4. All previously collected data sets were successfully converted to command sets for the robotic motion simulator. Preliminary data from in vitro testing of the intact spines showed a pattern of increasing intersegmental motion from caudal to cranial with peaks at T11-T12 and T7-8 as shown in Figure 5. The patterns in intersegmental motion are consistent with previous reports from in vivo studies.

With successive interventions (laminotomy, laminectomy, discectomy, facetectomy), intersegmental motion at the L4-5 level increased and there was a redistribution of motion at adjacent levels. Instrumentation reduced motion at the index level with a redistribution at adjacent levels as shown in Figures 6 and 7. Pedicle screw fixation at the L4-5 level resulted in a reduction in motion at L4-5 and a reduction at L3-4 with concomitant increases in motion at all other levels relative to the intact state.

Discussion

In this pilot study, we have introduced a novel methods for quantitatively evaluating the effects of surgical intervention at one level of the lumbar spine on the kinematics of the entire thoracolumbar spine. The model is novel in that in vitro spine motion is based on in vivo active voluntary motion, not arbitrary motions or moments applied to the spine. As such, the fidelity with which in vivo motion is reproduced is higher than other in vitro testing protocols and intuitively the predictive value of in vivo effects from in vitro testing is also high.

The intersegmental distribution of motion of the intact specimens in vitro is consistent with previous

Figure 4: The data previously collected from normal healthy volunteers during flexion/extension, lateral bending, and torsion were converted to a command set for the robotic motion simulator.
Figure 5: Mean intersegmental motion of intact in vitro specimens increased from caudal to cranial with characteristic peaks at T11-12.

Figure 6: Frontal plane motion was captured during lateral bending.
This validates the model with respect to reproduction of in vivo motion in vitro. This indicates that although in vitro motion of the entire thoracolumbar spine is only controlled by manipulating C7 relative to S1, the passive intersegmental motion at all levels of the spine during in vitro testing is similar to in vivo active motion.

These preliminary data indicate that surgical interventions at the L4-5 level affect motion at all other levels of the spine (from S1 up to at least T7). There is a redistribution of motion at adjacent levels following surgical intervention that compensates for the changes in motion at the index level. Relative to an intact state, fusion at the L4-5 level reduced motion at L4-5 and L3-4 and increased motion at all other levels. The extent of redistribution of motion was small, less than 1° of motion in most cases, but was consistent at all levels. Importantly, these results suggest that an intervention at one level does not strongly predispose the immediate super- and sub-adjacent levels to substantially altered kinematics while sparing other levels, but rather that all levels are subjected to some redistribution.

As with all new models, there are associated strengths and limitations using this technique. This model allows each individual vertebral segment to be studied both before and after surgical interventions to identify any changes in motion at a given level. The motions during in vitro testing are based on active in vivo motion under voluntary control of the paraspinal muscles. The motion of the spine in vitro is representative of active physiologic range of motion. The effects of the rib cage in stabilizing the spinal column has also been taken into account at least in part as rib cage was left intact and the vertebrocostal joints left undisturbed.

While our technique focuses on reproduction of the three-dimensional kinematics of the thoracolumbar spine, the protocol does not necessitate application of an axial preload or follower load to the in vitro specimens. The reported advantage of applying a follower load to specimens in vitro is to stabilize the spine and foster higher fidelity reproduction of spine motion when the specimen is tested in unconstrained motion. Using the in vivo/in vitro active/passive protocol, it is not clear that application of a follower load would add to the fidelity of the kinematics or mechanics of the specimens in vitro.

The novel method described facilitates comprehensive evaluation of the entire thoracolumbar spine for adjacent level effects following surgical intervention. Preliminary data indicate that motion is redistributed throughout the spine and not just at the levels immediately adjacent to the intervention. Future work will include evaluations of motion sparing and dynamic stabilization therapies and the effects of an axial preload on spine kinematics.
References


Introduction:
It is estimated that up to 80% of the general population will experience at least one significant bout of low back pain (LBP) in their lifetime\(^1\),\(^2\). LBP had the highest prevalence of any reported medical condition in 2005, with up to 40% of the United States adult population stating that they had experienced low back pain in the previous 3 months. This is more than two times the incidence of other common maladies including pain in other joints such as the hip, knee, or shoulder (8%, 15%, and 12% respectively)\(^3\). The leading known cause of low back pain is degenerative disc disease (DDD)\(^3\),\(^4\),\(^5\).

Over the past decade, mechanical, genetic, and psychosocial factors have been linked to the onset of disc degeneration, and it has been further shown that these risk factors are cumulative\(^6\),\(^7\),\(^8\). The majority of the well-established risk factors for LBP are mechanical in nature, and are often related to activities of daily living and everyday work activities such as poor postural control, experiencing whole-body vibrations, and frequent lifting. Despite these correlations, the underlying mechanism by which DDD and LBP develop remains unclear.

One common link between these activities is that they can cause prolonged submaximal muscle activity in the primary spinal extensor muscles. Intuitively, muscle fatigue may play a role in the development of DDD and LBP. Poor posture forces the extensor muscles to work harder to support the spine, and thus causes fatigue over time\(^9\),\(^10\),\(^11\),\(^12\). Similarly, whole-body vibration causes instability of the spine as well as fatigue in the spinal musculature, especially at its resonant frequency of 5 Hz\(^13\),\(^14\),\(^15\),\(^16\). Additionally, frequent and heavy lifting, in itself has been shown to cause fatigue in the primary spinal extensors\(^17\),\(^18\).

Primary extensor muscle fatigue initiates recruitment of secondary agonistic muscles to help support the spine\(^19\),\(^20\),\(^21\),\(^22\),\(^23\). For example, when the erector spinae complex is fatigued, it will recruit the multifidus muscles. However, unlike the primary extensor muscles, these secondary muscles are normally much shorter and less optimized for supporting the spine. In addition to these secondary muscles, the body will also recruit antagonistic muscles to prevent spine instability. Although normally categorized as a primary spinal flexor, the activity of the rectus abdominus muscles has been shown to increase following erector spinae fatigue\(^24\). Appropriately, the correlation between patients with low back pain and an increased recruitment of agonistic and antagonistic muscles has also been demonstrated\(^25\),\(^26\),\(^27\).

Primary extensor muscle fatigue causes altered spinal recruitment patterns. The link between altered muscle activity and spinal degeneration may be the result of a net increase in force across the disc space\(^28\),\(^29\). However, this has not yet been proven experimentally.

Several types of these mathematical models have been developed and the process of estimating spinal...
loads has become increasingly complex through the use of multiple technologies, such as electromyography (EMG) and finite element analysis (FEA)\textsuperscript{30,31,32}. However, these techniques have not been verified by direct in vivo data.

Limited in vivo studies using instrumented interbody implants and posterior implants have been conducted to monitor loads in the spine\textsuperscript{33,34}. While these instrumented implants have collected data which provide insight into the changing forces as a function of activities, they have been limited because they are designed around fusion devices. These implants inhibit the natural motion at the level of interest and therefore cause an artifact in the data. As an alternative, a multi-axial articulating force-sensing implant overcomes this limitation. Furthermore, current research with these force-sensing implants has been limited to brief sessions recording load data during normal activities, such as sitting and standing, while changes in disc space forces as a function of primary muscle fatigue have never before been measured. The purpose of this study was: 1) to develop and test a wireless force-sensing interbody implant, and 2) to create an in vivo large animal model to study primary extensor muscle fatigue. Using the combination of these tools, changes in multi-axial forces in the disc space can be measured in vivo prior to and following muscle fatigue, thereby providing data on an incompletely understood step in the disc degeneration process.

**Materials and Methods**

**Implant Design**

We developed a novel wireless force-sensing implant similar to many current total disc replacements. The implant has distinct superior and inferior articulating components to allow for vertebral motion and the collection of multi-axial force data through wireless sensors, as shown in Figure 1. During articulation of adjacent vertebrae in flexion, extension, lateral bending, or a combination of these movements, the superior concave component of the implant articulates on the three force transfer struts arranged convexly in the inferior component assembly. Embedded below the force transfer struts are three capacitive wireless sensors. The orientation and geometry of the struts ensures that they remain normal to the contacting surface of the superior component during articulation. A single strut is centered anteriorly, while the remaining two are located posterolaterally, equidistant from the centerline and each 110 degrees from the anterior strut in the axial plane. These struts allow the entire load seen in the anterior and middle columns of the spine to be transferred to the three sensors in a unique distribution dependent upon the positioning of the adjacent vertebrae.

The distribution of forces measured by the three sensors facilitates calculation of the multi-axial forces being applied to the implant, including the axial compressive force, the anterior/posterior shear force, and the left/right lateral shear force. An analytical model was developed wherein once the sensors are experimentally calibrated such that a voltage-force relationship is determined, the three forces measured by the sensors can be used, along with their constant orientation parameters, to determine the three components of the load being applied as is shown in Figure 2.

When taking readings from the implant, each sensor’s force is used in combination with the following equations to calculate the axial compressive and shear forces.

\begin{equation}
\vec{F}_j = \vec{F}_{AxialComp} = [F_1 \cos \theta + F_2 \cos \theta + F_3 \cos \theta]j
\end{equation}

\begin{equation}
\vec{F}_x = \vec{F}_{LateralShear} = [-F_2 \sin \theta \cos \varphi + F_3 \sin \theta \cos \varphi]j
\end{equation}

\begin{equation}
\vec{F}_y = \vec{F}_{PShear} = [F_1 \sin \theta - F_2 \sin \theta \sin \varphi - F_3 \sin \theta \sin \varphi]k
\end{equation}
Implant Experimental Model
To experimentally validate our implant design, a functional, scaled model of the implant was created into which three subminiature button load cells were integrated. The model was assessed by applying both axial and eccentric loads up to 445 N using a custom-built seven degree of freedom spine testing machine, as shown in Figure 3 below. The forces measured by the button load cells were used to back-calculate the applied load via the analytical model (Equations 1-3). The calculated values were then compared to the actual applied load.

Implant Computational Model and Finite Element Analysis
Validation of the implant design was also achieved using finite element analyses (FEA). A computer generated model of the implant was created using SolidWorks (Dassault Systèmes SolidWorks Corporation, Concord, MA) and analyzed using CosmosWorks (Dassault Systèmes SolidWorks Corporation, Concord, MA). This analysis included loading the implant both axially, as well as in flexion, lateral bending, and combinations thereof. The loads transferred to the sensors were again used to calculate the applied loads, and these computed values were compared to the actual applied loads.

Fatigue Animal Model
The goat cervical spine is a well established analog to the human lumbar spine because it has a similar structure and loading pattern and is oriented vertically. The splenius is the most superficial of the intrinsic muscles in the goat cervical spine and is primarily responsible for extension of the neck. It is an analog to the human erector spinae complex which is primarily responsible for trunk extension in the lumbar spine.

Following IACUC approval, four skeletally mature male Alpine-Nubian cross-bred goats were used in this study. To develop the fatigue model, the goats were anesthetized and needle electrical stimulation was employed bilaterally to repeatedly activate the splenius. The goats were placed in a sling such that its body was supported in a prone position with legs suspended, as shown in Figure 4. Two cables were attached to either side of a halter and were extended downward to attach in series with a miniature load cell. Needle electrodes were placed bilaterally in the splenius to stimulate it while minimizing co-contraction of adjacent muscle groups. During stimulation of the splenius, the load cell-halter system was used to monitor and record the head extensile force elicited by the stimulation. These data were used to determine the extent of fatigue.

Results

Implant Experimental Model
Results of the experimental model of our articulating multi-axial implant demonstrated excellent agreement with experimental results. The calculated forces were in close agreement with the applied loads, validating the design and proving its functionality.
between the calculated and actual applied loads. The implant was first loaded in neutral compression with a maximum load of 445 N. With six trials completed in this orientation, the mean axial, A/P shear, and lateral shear forces calculated using the button load cell results and the analytical model had errors less than ±22 N (or 5% error), when compared to their respective applied loads. When subjected to eccentric loading, the mean error in measured loads was also less than ±22 N.

**Implant Computation Model and Finite Element Analysis (FEA)**

Table 1 shows the results of the finite element analysis. The implant underwent loading in the neutral position via an applied axial load and in the flexed and laterally bent positions via off-axis loads. All of the loads were calculated within 0.3% error of the applied loads and the angles within 0.2 degrees.

**Fatigue Animal Model**

The optimal electrical stimulation parameters were determined iteratively and consisted of a frequency of 1 Hz with a 200 μs duration and an amplitude of 300 volts. This combination provided the low frequency stimulation desired to mimic low frequency fatigue in humans, while also providing a duration and amplitude with enough force to cause a visible movement of the head with each stimulation, but not cause co-contraction of nearby muscles. The elapsed time between the onset of stimulation (baseline reading) and muscle exhaustion was approximately 2 hours. The initial baseline reading illustrated distinct peaks with consistent magnitudes averaging approximately 37 N. The first sign of fatigue detected was variability in the force magnitude of each peak, and an increasing standard deviation within each 10 second segment was observed as the test progressed. The decrease in average amplitude over the 2 hours was linear with a correlation coefficient of 0.81, as shown in Figure 5. The last data set before a ten minute pause at the end of the study exhibited only four of the ten expected response peaks with an overall average magnitude for the set just over 5 N. After the ten minute pause at the end of the study, the first ten second data set demonstrated that the mean peak amplitude was still indistinguishable from noise and that the muscles had not recovered from the fatigue.

![Figure 4](https://via.placeholder.com/150)

*Figure 4 – A diagram of the goat during fatigue testing illustrates the head halter which is in series with the load cell (a) and the needle electrodes, a close-up of which is shown in (b).*

![Table 1](https://via.placeholder.com/150)

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Discussion

We have designed a wireless, articulating, multi-axial load cell implant. Both scaled functional models and computational models have been tested for this implant, and the results of this study demonstrate that our implant is sufficiently sensitive to measure axial and shear forces. Initial muscle fatigue testing showed that the use of electrical stimulation was effective in isolating the primary extensor muscles of the caprine cervical spine and creating low frequency fatigue. In addition, we showed that using electrical stimulation at the specified parameters to stimulate the caprine cervical primary extensors can result in a 100% decrease in force over a 2 hour time period.

In this study, the novelty of the implant is two-fold: the implant-sensor design itself and the unique data it will provide. The multi-axial force sensing implant allows for the measurement of loads directly imposed on the vertebral bodies and discs in real-time throughout a wide range of motion. In this way, the data will more closely reflect actual in vivo loading relative to previous estimates. In addition, much of the current data available on spinal loading focuses on axial compressive forces. Although the compressive force is the major component of spinal loading, A/P and lateral shear forces are also present in the disc space and may play a significant role in the development of degenerative disc disease. While the concentric layers of the annulus fibrosis provide excellent support with respect to axial forces, the orientation of the collagen fibers within the annulus fibrosis provide no ability to resist shear forces. Furthermore, there is an increased risk of disc injury when compressive forces are combined with shear forces in activities such as flexion and lateral bending. Therefore, an increase in A/P and lateral shear forces due to fatigue could be significant in the development of degenerative disc disease.

There are currently no experimental data which relate fatigue in the primary spinal extensor musculature to the magnitude of force across the intervertebral disc. If muscle fatigue does in fact increase forces across the disc, it is a potential initiator for degenerative disc disease, as increased loading is a known precursor to low back pain. We predict that increased muscle recruitment is the primary mechanism through which fatigue in the primary spinal extensors causes an increase in interbody forces. There is an increased recruitment of secondary agonistic muscles upon fatigue. However, the secondary agonists in the back support one or at most a few levels within the spine. Thus, the insertion and origins of these muscles are not as optimized as the primary extensors for supporting large structures. Their recruitment as an adjunct to support the spine once the primary extensors fatigue may be causing more harm than good. In addition,
although counterintuitive, there are several examples in the body other than the spine where fatigue in a primary agonistic muscle results in recruitment of antagonistic muscles for support. This antagonistic recruitment may prevent injury in the short term by stabilizing the joint, but like the secondary agonists, the antagonists provide suboptimal support which may further increase the joint loading.

Epidemiologic data indicate correlations between activities which cause fatigue in the primary spinal extensors and the onset of low back pain. The overlying process through which degenerative disc disease develops is multi-faceted and not well understood. Therefore, a better understanding of this link can help to prevent the onset of disc degeneration, treat patients, and elucidate the mechanism through which everyday activities cause low back pain.

References


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Introduction
Low back pain is a leading cause of disability, lost wages, and physician office visits.1-3 The causes of low back pain are complex and not fully understood, but epidemiologic data indicate a strong correlation between repeated mechanical loading of the lumbar spine and painful degenerative intervertebral disc disease.4-8

In Vivo Effects of Cyclic Compression on the Intervertebral Disc and Endplates of the Lumbar Spine: A Pilot Study With a Novel Animal Model

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Background: Epidemiologic data indicate a correlation between repeated mechanical loading of the lumbar spine and painful degenerative intervertebral disc disease. Clinically, sclerotic changes of the vertebral endplates and subchondral bone are often observed comitant to intervertebral disc degeneration, however the temporal relationship between endplate sclerosis and disc degeneration is not well characterized. The lumbar spine of the New Zealand white rabbit is a promising model to study the response of the lumbar spine to dynamic mechanical loading. Unlike the mouse and rat tail models however, no cyclic loading model exists for the rabbit lumbar spine.

Purpose: The purpose of this study was to characterize the correlation between cyclic axial loading and the initiation and propagation of (a) intervertebral disc degeneration and (b) endplate sclerosis in our model.

Methods: Following surgical placement of transfixing pins and dorsally extending percutaneous posts, the lumbar spines of 11 New Zealand white rabbits were loaded cyclically via an external apparatus for two hours per day, five days per week. Loads were applied at 5 x BW at either 0.5 Hz for 10 weeks (n=4), 0.5 Hz for 26 weeks (n=2), 5 Hz for 8 weeks (n=2), or 5 Hz for 30 weeks (n=2). One animal (n=1) was designated as a surgical control animal and underwent the identical surgical procedure as the other animals but received no daily loading. Serial plain radiographs were used to monitor changes in the spine. Spines were harvested and diffusion and disc health were analyzed using post-contrast enhanced MRI imaging. Endplate thickness and bone density were quantified via microCT analysis. Disc and endplate changes were characterized by gene expression analysis and histopathology.

Results: Results indicate that the disc, endplates, and subchondral bone degenerate in response to cyclic mechanical loading. Endplate cartilage thins and calcifies, resulting in thickened sclerotic subchondral bone. Diffusion to the disc is reduced proportionally to the extent of sclerosis. The disc becomes fibrotic and disorganized, the extent of which is proportional to load exposure. The observed trends in gene expression analysis suggest that the slower accumulation of load cycles in the low frequency group may have a beneficial effect on matrix homeostasis and inflammation in our model, whereas the rapid accumulation of cycles in our high frequency group may stimulate matrix synthesis accompanied by pro-inflammatory and catabolic activity.

Conclusions: We have developed an apparatus, a technique, and an animal model to study the long-term effects of mechanical loading on the intervertebral disc, endplates, and subchondral bone in the lumbar spine in vivo. Physiologic mechanical loading alone will initiate degenerative changes in the intervertebral disc and sclerotic changes in the endplates accompanied by a reduction in passive diffusion from the subchondral bone to the disc. Rapid accumulation of cycles stimulated matrix synthesis accompanied by pro-inflammatory and catabolic activity, whereas the slower accumulation of cycles may have a beneficial effect on matrix homeostasis and inflammation in our model. Results indicate that mechanisms affecting subchondral bone density also affect disc diffusion and homeostasis.
temporal relationship between endplate sclerosis and disc degeneration is not well characterized. The endplates and subchondral bone play a critical role in intervertebral disc homeostasis via regulation of small molecule diffusion to and from the avascular disc.\textsuperscript{9-12} There is evidence to suggest that bony endplate sclerosis occurs secondary to disc degeneration as a result of altered loading distributions relative to a healthy disc.\textsuperscript{13} Yet, there is also evidence indicating that the temporal sequence is reversed, and that sclerotic endplates initiate disc degeneration via a reduction in diffusion to and from the disc.\textsuperscript{14}

In diarthrodial joints, subchondral bone remodels in response to mechanical loading.\textsuperscript{15} Increasing bone density and reduction in porosity correlate to exposure to cyclic loading. These changes have been indicated as a possible initiator of osteoarthritis via a reduction in diffusion to the articular cartilage.\textsuperscript{16} Changes in vertebral subchondral bone are common,\textsuperscript{17} but the correlation to cyclic mechanical spinal loading has received little attention.

The response of the intervertebral disc (both anulus fibrosis and nucleus pulposus) to repeated mechanical loading has been studied previously, primarily through utilization of the rat caudal (tail) vertebrae model.\textsuperscript{18-21} Using this in vivo model, the metabolic response of the disc to loads of varying magnitude, frequency, and duration have been described. The rat tail model is unique in that it allows for study of the gradual onset of chronic disc degeneration resulting from mechanical loading, whereas other common animal models utilize iatrogenic anular disruption or chemical alteration to initiate disc degeneration.\textsuperscript{22-24} While the rat tail model has yielded valuable data for characterizing the response of the disc to loading, the effect of loading on the endplates and subchondral bone have not been studied in this model. Rat vertebral physes remain open throughout adulthood\textsuperscript{25,26} and caudal motion segments lack posterior elements and zygapophysseal joints, potential confounding factors for elucidating the critical role of the endplates and subchondral bone in the degenerative process.

The lumbar spine of the New Zealand white (NZW) rabbit is a promising alternative model. The vertebral physes close at skeletal maturity and there remain only sparse cells of the notochord phenotype in the disc.\textsuperscript{27-29} With respect to dynamic loading, the resonant frequency of the rabbit spine is 4.5 Hz, similar to that of the human spine.\textsuperscript{30,31} Pressures in the human intervertebral disc have been measured at 2.6 MPa during activities of daily living at forces that correspond to approximately 6 times body-weight.\textsuperscript{32-33} Based on the morphology and cross-sectional area of the skeletally mature NZW rabbit lumbar intervertebral disc, an axial load of approximately 6 times body weight corresponds to a stress of approximately 2.6 MPa in the disc.\textsuperscript{34,35} These properties and the larger physical size of the rabbit lumbar spine relative to the rat and mouse suggest its utility as a model to study the response of dynamic mechanical loading. Unlike the mouse and rat tail models however, no cyclic loading model exists for the rabbit lumbar spine.

To comprehensively characterize the complex interplay between the intervertebral disc, vertebral endplates, and subchondral bone in response to repeated mechanical loading, we have developed a novel in vivo animal model. The purpose of this study was to characterize the correlation between cyclic axial loading and the initiation and propagation of intervertebral disc degeneration and endplate degeneration in our model.

**Materials and Methods**

We have developed an external apparatus for applying chronic, cyclic, compressive, axial-only loads to the lumbar spine of a live animal. The loading apparatus ("The Degenerator") is a novel portable external apparatus capable of applying axial compressive forces at controlled magnitudes and frequencies. The Degenerator interfaces with the spine to apply loads by engaging four percutaneous posts that extend dorsally from the vertebral bodies. During loading, the Degenerator is attached to the posts, and following loading, it is disengaged. The four percutaneous posts are attached to two adjacent lumbar vertebrae via two transfixing pins that extend bilaterally from the vertebral bodies (one per vertebra). During loading, the animals are placed into the apparatus awake, and unrestrained.

In this study, we utilized 11 skeletally mature (>4.5 kg) New Zealand White (NZW) rabbits to test our apparatus and to characterize the effects of cyclic loading on the intervertebral disc and endplates.

**Apparatus**

The Degenerator utilizes a single linear actuator (Mirai Inter-Technologies, Rochester, NY) which interfaces with a personal computer and moves under closed-loop control. Through a series of bearings, the motion of the actuator is transferred to a clamping mechanism which secures the Degenerator to the percutaneous posts (and thus the spine). By aligning the actuator with the long axis of the spine, it applies an axial-only load (no bending or torsion) to the spine even if the percutaneous posts are not perpendicular to the spine or parallel to each other. The Degenerator allows for control of load frequency, duration, magnitude, and displacement. The apparatus is mounted to a cart and extends below to the top of a rabbit restrainer system (Plas Labs, Lansing, MI) mounted directly underneath. The animal is placed in a restrainer and the clamping mechanism is attached to the percutaneous posts.
Apparatus-Spine Interface

For interfacing the loading system with the lumbar spine, we chose to modify the technique described by Kroeber et al.\textsuperscript{42} where transfixing pins are placed transversely through adjacent vertebral bodies and attached to dorsally extending percutaneous posts. After IACUC approval, using general anesthesia standard aseptic techniques, sharp and blunt dissection were used to expose the lateral aspect of the lumbar spine via a single 10 cm lateral incision to facilitate placement of the transfixing pins. The anatomic landmark for caudal pin insertion is 3 mm from the caudal endplate of the caudal vertebral body at the interface of the transverse process and vertebral body. The landmark on the cranial vertebra is approximately 3 mm from the cranial endplate and 1 mm ventral to the ridge where the transverse process transitions into the vertebral body, as shown in Figure 1.

A 1 mm k-wire was drilled through the vertebral body at each location. The k-wires were then removed and a 2 mm transfixing pin with 2.5 mm central threaded region (IMEX Veterinary, Inc., Longview, TX) was placed into the pre-drilled hole. The threaded region of each pin was coated with nanophase hydroxyapatite (Spire, Corp., Bedford, MA) to facilitate rapid osseointegration.

Four stab incisions were then made dorsal to the spine to facilitate placement of each post. Incisions were made just cranial to the L5-S facet joints and just caudal to the L3-4 facet joints. The 6 mm stainless steel posts were placed blindly through the two left incisions and guided onto the left lateral aspect of the caudal and cranial transfixing pins. The right side of the transfixing pins were then trimmed using pin cutters through the lateral incision and the right posts were placed percutaneously onto the pins through the two right stab incisions. The lateral incision was then closed in layers. Sutures were used as necessary to close the dorsal incisions around the posts. The posts were cleaned daily with betadine and antibiotic ointment for at least two weeks following surgery. Animals were allowed a four week quiescent period following surgery to allow for bony ingrowth into the pins during which their acclimation to the apparatuses was continued.

Loading Regimen

One animal (n=1) was designated as a surgical control animal and underwent the identical surgical procedure as the other animals but received no daily loading. At approximately 4 weeks post-operatively, the other animals began their daily loading regimen for 2 hours, five days per week. Animals were loaded cyclically from no load to 220 N at either 0.5 Hz for 10 weeks (n=4), 0.5 Hz for 26 weeks (n=2), 5 Hz for 8 weeks (n=2), or 5 Hz for 30 weeks (n=2). A 220 N load is approximately 5 x BW for the 4.5 kg animals. This is within the range of estimated physiologic loading in the lumbar spine of humans during activities of daily living\textsuperscript{36-38} and similar to force levels used in other models.\textsuperscript{39-43} Based on our previous work measuring the morphometric properties of the rabbit intervertebral disc, the mean cross-sectional area of the disc is approximately 95 mm\textsuperscript{2} resulting in a disc space stress of approximately 2.3 MPa.\textsuperscript{34,35} Five times body weight applied to a typical human lumbar intervertebral disc of cross-sectional area 1,800 mm\textsuperscript{2} results in a stress of approximately 2 MPa.\textsuperscript{44} This is consistent with intradiscal pressure measurements taken from human discs during lifting (2.3 MPa)\textsuperscript{33,45} and sitting while holding a weight (2.6 MPa).\textsuperscript{33,45} Based on mean stiffness of the NZW lumbar motion segment, application of 220 N results in compression of the disc of approximately 25%. By comparison, at 5.7 X BW, the human disc space narrows by approximately 25%.\textsuperscript{46} Loading frequencies were chosen to mimic exposure in occupations which correlate to disc degeneration such as truck drivers, operators of heavy machinery (5 Hz)\textsuperscript{47-49} and manual laborers (0.5 Hz).

Serial Plain Radiographs

Disc space narrowing, osteophyte formation, and endplate sclerosis are clinical indicators of disc degeneration. During the time course of loading, plain x-rays were used
to measure these parameters. Lateral plain radiographs were taken every two weeks and digitized for analysis. Standardized exposure times and intensities (64 kVp 2 MA) were used. Disc Height Index (DHI) was measured at each time point and changes in loaded levels were compared to unloaded adjacent levels. The presence or absence of osteophytes and changes in lucency of the endplates were graded by a single blinded investigator. Time-point radiographs were compared to baseline films to assess changes.

Administration of Contrast Agent/Euthanasia
Forty-five minutes prior to euthanizing each animal at its designated time point, gadodiamide (Omniscan, Amersham Health, Princeton, NJ) was administered (0.3 ml/kg BW, IV) to assess diffusion into the intervertebral disc. Forty-five minutes after administration of the gadodiamide, animals were euthanized (Pentobarbital 100 mg/kg BW IV). The entire lumbar spine was harvested en bloc, and the pins and posts carefully removed. The spine was sectioned into individual motion segments and temporarily stored in Fomblin (Sovay Solexis, West Deptford, NJ) to prevent dehydration and facilitate high quality MRI images. The super-adjacent, loaded level, and sub-adjacent motion segments were harvested as a basis for intra-subject normalization.

Post Contrast Enhanced T1 and T2 Mapping
Diminished diffusion through the vertebral endplates is associated with degenerative disc disease. In this study, measurement of gadodiamide in the disc via post contrast enhanced MRI was the primary means by which diffusion was quantified. A series of T1 and T2-weighted images were taken of the lumbar spine using a 7T MRI scanner (Bruker Biospin, Billerica, MA) equipped with a 9 cm actively shielded gradient set capable of generating magnetic field strengths of 300 mT/m and a 62 mm circularly polarized quadrature volume coil. Sagittal images for T1 relaxation mapping were acquired using a RARE sequence. MSME sequence scans were used for obtaining T2 relaxation values. Regions-of-interest (ROIs) were created in the nucleus pulposus, anterior and posterior anulus, superior and inferior vertebral bodies, and superior and inferior endplates. Data for measuring effective T1 and T2 relaxation constants were calculated from a series of images acquired with a minimum of 8 relaxation delays. In each ROI, T1 and T2 values were computed as quantitative measures of small molecule (gadodiamide) diffusion through the endplates into the intervertebral disc and water content, respectively. Values from loaded discs were compared to non-loaded adjacent levels and aged matched controls.

Micro CT Analysis
Osteophytes and subchondral sclerosis are features common to disc degeneration. Subchondral bone volume and bone mineral content were quantified to assess ectopic mineralization and subchondral sclerosis. A μCT analysis (SCANCO, vivaCT 40, Bassersdorf, Switzerland) was performed on loaded and adjacent unloaded levels. Following reconstruction of 19 μm sagittal sections, a volume-of-interest (VOI) was established which included a 2 mm deep region of subchondral bone at the central 1/3 of the endplate as shown in Figure 2. VOIs were created for both the cranial and caudal endplates. Bone density of the VOI was quantified at the loaded level and compared to the adjacent unloaded levels. Mid-sagittal slices were also used to measure endplate thickness and intervertebral disc height. Values from loaded levels were compared to non-loaded adjacent levels and aged matched controls.

Gene Expression Analysis
Immediately following post-mortem imaging, specimens were either designated for gene expression analysis or histopathology. Experimental and adjacent unloaded motion segments designated for gene expression analysis were transected through the intervertebral disc using standard aseptic technique. Samples of nucleus pulposus (NP) and anulus fibrosis (AF) were harvested via sharp dissection then snap frozen and stored at -80° C. At the time of analysis, mRNA was isolated separately from AF

Figure 2: Mid-sagittal μCT scans were used to measure disc space height, endplate thickness, and subchondral bone density in all specimens.
and NP tissue using trizol extraction followed by Qiagen mini-prep kit utilizing a DNAse step to remove genomic DNA. Gene expression analysis (real time PCR) was performed on the NP and AF using custom designed, validated primers to compare expression of inflammatory genes (TNF-α, and IL-1β) and genes involved in matrix homeostasis (Col I, Col II, aggrecan, versican, TIMP-1 and MMP-3). The ∆∆Ct method was utilized to calculate relative gene expression after normalizing to the housekeeping gene GAPDH.

**Histopathology**

Histologic analyses were used to assess cellular and tissue level indicators of disc health and degeneration. Experimental and adjacent unloaded motion segments were fixed in 10% neutral buffered formalin and decalcified using a 7 day protocol (Formical 2000, Decal Chemical Corp., Tallman, NY). Decalcified specimens were routinely processed, paraffin embedded, and sectioned serially in the mid-sagittal and lateral para-sagittal planes. Specimens were stained with either hematoxylin and eosin or safranin-O and fast green. Discs were assessed qualitatively for lamellar organization and changes in structural properties, proteoglycan content, cell morphology, cell distribution, and fibrosis. The cartilaginous endplates were assessed for thinning, ossification, disruption, and fracture. Chondrocyte disorganization, clumping, and hypertrophy were also assessed.

**Results**

Of the 11 animals in the study, all animals tolerated the surgical procedure well. All were sufficiently acclimated to the Degenerator so that none showed signs of distress during loading and none required restraining. One poorly placed transfixing pin failed at approximately 750,000 cycles (4 weeks) in the high frequency 8 week group and the data from the animal were not included in subsequent analyses. There were no other study related complications. The mean disc cross-sectional area and corresponding disc space stress for each group are shown in Table 1.

**Table 1: Transverse axial MRI images were used to measure intervertebral disc cross-sectional area. Based on slight variations in disc size, mean applied stress ranged from 2.56 to 2.95 MPa.**

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Applied Load (N)</th>
<th>Mean Disc Area (cm²)</th>
<th>Calculated Stress (MPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sx Control</td>
<td>0</td>
<td>0.86</td>
<td>Not Loaded</td>
</tr>
<tr>
<td>0.5 Hz 10 wk</td>
<td>220</td>
<td>0.86</td>
<td>2.56</td>
</tr>
<tr>
<td>0.5 Hz 26 wk</td>
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<td>2.95</td>
</tr>
<tr>
<td>5.0 Hz 8 wk</td>
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<tr>
<td>5.0 Hz 30 wk</td>
<td>220</td>
<td>0.79</td>
<td>2.74</td>
</tr>
</tbody>
</table>

**Serial Plain Radiographs**

Plain radiographs proved to have limited sensitivity for subtle changes in disc space height. There were no statistically significant changes (p>0.05) in DHI discernable from plain x-rays in either the high or low frequency loaded discs at any time point relative to baseline. In all loaded levels, the mean change in disc height up to 30 weeks was less than 10%. X-rays did indicate osteophyte formation adjacent to the endplates of some animals subjected to long term (30 weeks) high frequency (5.0 Hz) loading as shown in Figure 3.

**Post Contrast Enhanced T1 and T2 Mapping**

T1 constants were higher (indicative of less gadodiamide diffusion) in loaded intervertebral discs relative to adjacent control levels. Data indicate increased T1 constants in the nucleus and anterior annulus of high frequency long
Term animals, but no differences were detected in the posterior annulus. More subtle differences were detected in low frequency long term animals. Analysis of endplates indicated a 10.5% decrease in T1 constants (increase in gadodiamide) in the caudal endplate relative to the non-loaded surgical control, as shown in Figure 4. The high frequency long term group also showed trends of decreased T2 constant in the nucleus, indicative of a reduction in water as shown in Figure 5.

**Micro CT Analysis**
CT analysis revealed that cyclic loading resulted in an increase in subchondral bone density at loaded levels proposal to duration and frequency of exposure. After 10 weeks of low frequency loading, subchondral bone density increased by a mean of 11.9% and by 30 weeks of high frequency loading, bone density increased by 20.6% compared to the sub-adjacent unloaded level as shown in Figure 6.

**Gene Expression Analysis**
Data from a limited sample of NPs indicate a frequency effect and duration effect with early (10 week) low frequency (0.5 Hz) samples illustrating a reduction in expression

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**Figure 4:** Post contrast enhanced MRI indicated diminished diffusion in loaded levels (lower) relative to unloaded adjacent levels (upper).

**Figure 5:** Post-contrast enhanced MRI imaging normalized to the sub-adjacent level indicated an increase in the T1 constant (decrease in gadodiamide) following 30 weeks of high frequency loading (top). The corresponding T2 constants were reduced (bottom).

**Figure 6:** There was a 12% increase in caudal endplate subchondral bone density resulting from 10 weeks of low frequency cyclic loading (left). Bone density increased by 21% in motion segments exposed to high frequency loading for 30 weeks (right).
of versican and an increase in Col II accompanied by a dramatic reduction in Col I, TNF-α, IL-1β, MMP-3 and TIMP-1 relative to unloaded levels. Early (8 week) high frequency (5.0 Hz) samples illustrated a slight increase in expression of IL-1β and TIMP-1, with a slight reduction in COX-2, ADAMTS5, and MMP-3. Late (26 week) low frequency samples indicate an increase in versican and Col II. In contrast, late (30 week) high frequency (5.0 Hz) samples express an increase in aggrecan and Col II accompanied by an increase in TNF-α, MMP-3, and TIMP-1.

Data from the low frequency AF samples indicate an initial pro-inflammatory response with dramatic increases in iNOS and IL-1β expression at 10 weeks, followed by apparent remodeling at 26 weeks as indicated by a decrease in all pro-inflammatory markers and a sharp increase in Col II expression. Relative to unloaded adjacent controls, high frequency AF samples indicated an early reduction in expression of all inflammatory and homeostatic genes followed by an upregulation in expression of all measured in the 30 week high frequency loaded discs with the most substantial increase in expression of Col II.

Histopathology

The NP of unloaded age-matched surgical control sections were sparsely cellular with a gelatinous extracellular matrix. Twenty-six week loaded low frequency sections indicated fibrosis and increased cell density in the NP. Thirty week loaded high frequency sections showed advanced fibrosis, cell clustering, significant matrix disorganization, and disc space narrowing.

As shown in Figure 7, relative to an age-matched unloaded surgical control disc, 30 weeks of high frequency loading has a deleterious effect on the disc. Loaded discs exhibited substantial fibrosis and increased cell number and clustering in the nucleus, accompanied by matrix disorganization and a loss in disc height.

Analysis of endplate cartilage and subchondral bone indicated that unloaded surgical control endplates have a distinct border with the adjacent subchondral bone. There are resting chondrocytes near the nucleus side and relatively sparse hypertrophic chondrocytes on the bone side. With loading, there is evidence of chondrocyte cloning and hypertrophy. The cartilaginous endplates are thinned while the subchondral bone is thickened. As shown in Figure 8, the bony side of the cartilage is more diffusely integrated with bone and there are more numerous hypertrophic chondrocytes present.

Discussion

We have developed an apparatus, a technique, and an animal model to study the long-term effects of mechanical loading on the intervertebral disc, endplates, and subchondral bone in the lumbar spine in vivo. The model allows us to apply physiologic loading to an individual motion segment of the NZW rabbit and can be used to characterize the effects of load magnitude, frequency, and duration on the health and degeneration of the spine. For the current study, we utilized the NZW rabbit, but the technique is potentially scalable to other species using a modified apparatus. The model is unique in that it facilitates investigation of the earliest effects of mechanical loading at the molecular, cellular, tissue, and global scale of both the intervertebral disc and endplates in the lumbar spine.

Unlike anular puncture models and chemonucleolysis models which presuppose that degeneration is initiated by anular failure or disc matrix changes, respectively, the model utilized in the current study is based on mechanical loading alone with no assumptions on the mechanism of degeneration. Likewise, previous models
for studying the role of endplate diffusion in disc degenera-
tion are based on iatrogenic alteration of the endplates or
subchondral bone.56,57 In the current study, no disruptions
were made to the loaded disc, endplates, or subchondral
bone, which uniquely facilitated study of the early effects
of mechanical loading on the lumbar spine.

Like the rat caudal vertebrae model, our results
indicate that physiologic mechanical loading alone
will initiate degenerative changes in the intervertebral
disc.18-21 Unique to our model, we have also shown that
the endplates respond to loading with increasing bone
density and endplate thickness. Because of the critical
role of the endplates in disc homeostasis, characterizing
the complex interrelationship between disc and endplate
pathology is critical in defining the mechanism of spinal
degeneration.

In this pilot study, the significance of the results
is hampered by the small sample size. In cyclically loaded
specimens, we measured an increase in subchondral bone
density and an increase in uptake of MRI contrast agent in
the subchondral bone, indicative of sclerotic changes to the
endplates in response to loading. In the same specimens,
there was a decrease in contrast agent into the disc. This
suggests a reduction in passive diffusion from the subchon-
dral capillaries to the disc. Endplate histology corroborated
these findings, indicating thickened mineralized endplates
in specimens exposed to prolonged loading. As shown in
Figure 9, the correlation suggests that mechanisms affect-
ing subchondral bone density also potentially affect disc
diffusion and homeostasis. This has been demonstrated
previously in an unstable cervical spine injury model.58

Gene analyses demonstrated substantial changes
in expression of loaded levels compared to adjacent
unloaded controls in the NP and AF. Although the exact
interpretation of these results is hampered by the small
sample size, the observed trends suggest that the slower

Figure 8: In unloaded levels (left), the disc side of the cartilaginous endplate is comprised primarily of resting
articular chondrocytes (RC). In loaded levels (right), there is evidence of clustered hypertrophic chondrocytes (HC)
and endochondral bone formation with no distinct tidemark. 20X.

Figure 9: Among all surgical levels, there is a correlation between T1 constant and subchondral bone density.
accumulation of load cycles in the low frequency group may have a beneficial effect on matrix homeostasis and inflammation in our model, whereas the rapid accumulation of cycles in our high frequency group may stimulate matrix synthesis accompanied by pro-inflammatory and catabolic activity. Loading at specific frequencies and magnitudes may have a protective effect, upregulating anabolic activity and initiating remodeling rather than chronic degeneration.41,43,59

Based on our preliminary data, the mechanism of disc degeneration and the relationship between cyclic loading, diffusion, and disc degeneration remains unclear. But our preliminary data support the hypothesis that loading results in subchondral sclerosis, decreased diffusion, and ultimately disc degeneration. Characterization of the temporal sequence of these events, the mechanism underlying degeneration, and the dose response of the spine to mechanical loading may provide insights into future strategies for novel preventative measures, diagnostic assessments, and therapies targeting low back pain. The novel we have developed can uniquely facilitate future work in these critical areas.

References


The Effect of Anti-Rotation and Anti-Cutout Features in Cephalomedullary Nail Fixation of Intertrochanteric Femur Fractures: An Acute Biomechanical Study

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† Orthopaedic Associates, LLP, Bellaire, TX.

Background: Extra-capsular hip fractures are common in the elderly population. Cutout, loss of fixation, and proximal fragment rotation remain as possible complications of treatment with cephalomedullary nails. The purpose of this study was to biomechanically compare two cephalomedullary nails that incorporate anti-rotation and/or anti-cutout features to a previous generation nail with no such features.

Methods: The Gamma 3 Nail with standard lag screw was used as the benchmark for comparison to the Gamma 3 RC Clip nail and the Trigen InterTAN nail, both of which incorporate anti-cutout and anti-rotation features. An intertrochanteric fracture was created in composite bone models. Each specimen was loaded to simulating single leg stance 1,000 times while stiffness, migration (cutout), compressive force across the fracture site, and distal fragment rotation were monitored.

Results: Maximum lag force during compression was very dynamic, highly variable, and decreased rapidly. Stiffness was highest in the Trigen InterTAN group and mean migration of the proximal fragment was maximum in the InterTAN group and least in the Gamma 3 group. Proximal fragment rotation was small for all constructs.

Conclusions: In the dense bone of the composite specimens, the enhanced designs of the Gamma 3 RC and the InterTAN yielded little improvement relative to the Gamma 3. The stiffer InterTAN resulted in higher migration likely because a stiffer construct will cause compaction of bone around the lag screw. Additional research in osteopenic bone is necessary to comprehensively characterize the effects of the design enhancements of these implants.

Introduction:
Extracapsular hip fractures are common in the elderly population. In 2004, an estimated 756,000 proximal femur fractures occurred in the United States.¹ That number is increasing, and estimates suggest that four out of ten women over age 50 in the United States are likely to experience a hip, spine, or wrist fracture sometime during the remainder of their lives.² Hip fractures in the elderly population are associated with a three times greater risk of mortality during the first three months after fracture compared to non-fractured cohorts.³,⁴ Nearly one in five hip fracture patients ends up in a nursing home and mortality after hip fracture is around 30% at one year.⁵ Prevention and treatment of hip fractures has thus become a national priority.⁶

Despite significant improvements in both surgery and rehabilitation in recent decades, hip fracture treatment remains a challenge. Treatment options for extracapsular hip fractures include intramedullary devices such as compression hip screws or cephalomedullary devices. Until recently, the compression hip screw was the gold standard for intertrochanteric fractures, both stable and unstable. Cephalomedullary devices initially gained popularity for treatment of unstable fractures but have now become a suitable option for even the stable intertrochanteric fracture. Mechanically, implant strains are decreased with intramedullary fixation of intertrochanteric fractures relative to dynamic side plates and sliding screw fixation.⁷ However, cutout, loss of fixation, and proximal fragment rotation remain as potential complications of treatment with cephalomedullary nails.⁸⁻¹¹ The latest generation of nails are designed to minimize cutout and incorporate anti-rotation features in the design. These design features purport to minimize loss of fixation and result in better outcomes. Several intramedullary products are currently available to the orthopaedic surgeon, however, the relative performance characteristics of these implants have not been reported and to date there have been no comprehensive reports on the biomechanics of the latest generation nails compared to previous designs.

The purpose of this study was to compare two cephalomedullary nails that incorporate anti-rotation and/or anti-cutout features to a previous generation nail with no such features with respect to fracture compressive lag

Acknowledgements: This study was funded by an institutional grant from Stryker.
force, bending stiffness, migration, cutout, and proximal fragment rotation using biomechanical testing in an intertrochanteric in vitro fracture model.

**Materials and Methods**

The Gamma 3 Nail with standard lag screw (Stryker, Mahwah, NJ) was used as the benchmark for comparison to the Gamma 3 RC Clip nail (Stryker, Mahwah, NJ) and the Trigen InterTAN nail with compression screw (Smith & Nephew, Memphis, TN). As shown in Figure 1, both the Gamma 3 RC Clip nail and the Trigen InterTAN nail incorporate anti-rotation and/or anti-cutout features not found in previous nail designs.

To evaluate the biomechanical performance of the nails, Evans Type I stable intertrochanteric fractures were created in fourth-generation composite Sawbone left femurs (Pacific Research Laboratories, Vashon, WA). The composite bones have similar properties to healthy human bone.12-14

All specimens were prepared in identical fashion. Using a jig for repeatability, a bandsaw was used to create a partial intertrochanteric osteotomy centered proximally in the greater trochanter and extending distally to the center of the lesser trochanter.

Before completing the osteotomy, the femurs were randomly assigned to receive either the 125° Gamma 3 Nail (180 mm long with 10.5 mm φ x 95 mm standard lag screw) in the “G3S” group, the 125° Gamma 3 RC Clip Nail (180 mm long with 10.5 mm φ x 95 mm lag screw and clip) in the “G3RC” group, or the 125° InterTAN Nail with compression screw (180 mm long with 11 mm φ x 95 mm lag screw and 7 mm φ x 90 mm compression screw) in the “ITI” group. A sample size of six (n=6) was used for each treatment group for a total of 18 specimens.

Implants were placed according to each manufacturer’s recommended technique with every attempt made to position the lag screws so that the final tip to apex distance was less than 25 mm as recommended by Baumgaertner.9 Pilot holes for placement of the nails and the lag screws were drilled using a drill press and custom jigs to minimize variability in placement technique. Subsequently, implants were placed using standard techniques with each manufacturer’s instruments. The lag screws were placed across the partial osteotomy extending several turns into the femoral head but were not advanced completely into the proximal fragment. Using a bandsaw, the osteotomies were then completed without the blade touching the lag screw. The proximal fragment was then removed by carefully unscrewing it from the lag screw. A second osteotomy was cut from the proximal fragment.

**Figure 1:** The lag screws used with the Gamma 3 RC Clip nail (center) and the Trigen InterTAN nail (right) incorporate anti-rotation and/or anti-cutout features not found in previous nail designs such as the Gamma 3 nail (left).
parallel to the first resulting in a 5 mm thick section of intertrochanteric bone being removed. The proximal fragment was then carefully placed back onto the lag screw in a position identical to when it was removed. This facilitated anatomic reduction of each fracture with a 5 mm osteotomy and minimized variation between specimens as shown in Figure 2.

To measure compressive lag force across the osteotomy site, an array load cells was placed in the osteotomy gap. Three 3.5 mm thick button load cells (Futek Advanced Sensor Technology, Inc., Irvine, CA) were fixed between two aluminum plates so that the overall thickness of the sensor array was 5 mm. The sensor array was placed into the osteotomy gap around the lag screw so that the three sensors were located proximal to the screw, anterodistal to the screw, and posterodistal to the screw. The sensor array allowed free passage of the lag screw into the femoral head, as shown in Figure 3.

Before tightening the lag screws, the distal third of each femur was cut off, the nails were locked distally, and the specimen was potted vertically using quick setting epoxy (Bondo, Atlanta, GA) in an aluminum cup. The cup was mounted to a fixture and placed in a mechanical testing machine (MTS Systems, Carry, NC) so that it was oriented at 25° adduction in the coronal plane and neutral in the sagittal plane.15-17

Once mounted in the mechanical testing machine, the lag screws were inserted completely into the distal fragment, extending through the sensor array into the femoral head. The lag screws were then compressed 2.5 mm one half screw turn at a time while compressive force data were recorded from the sensor array at a rate of at least 10 samples per second.

Figure 2: All specimens underwent an identical procedure to create a 5 mm osteotomy.

Figure 3: Posterior view images were used to gauge movement of the proximal fragment relative the femoral shaft. Compression forces across the fracture site (indicated by arrows) were measured via a load cell array placed in the osteotomy gap.

After a one minute quiescent period, a high resolution digital photograph was taken of the proximal femur from a posterior view with a scale marker positioned within the image for reference, as shown in Figure 3. Additional “flag” pins were placed in the proximal and distal fragments extending posteriorly to monitor any rotation of the proximal fragment during loading. A high resolution digital photograph was taken of the femur from a lateral view with the markers positioned within the image for reference, as shown in Figure 4.

After baseline (no load) images were taken, the crosshead of the mechanical testing machine was lowered and zeroed at the point of contact with the femoral head. A flat loading platen attached to the crosshead was used to apply a vertical compressive load to the femoral head. The platen was attached to a roller plate to allow unconstrained motion of the femoral head under axial loading. The specimen was then loaded to 750 N simulating single leg stance17-19 and unloaded back to zero at a rate of 25 mm per minute while fracture compression force data, mechanical testing machine force data, and crosshead displacement data were collected. At peak load, posterior and lateral view photographs were taken for later assessment of deformation/relative motion. After unloading, the specimen was again photographed from both posterior and lateral directions. Each specimen was then cycled 1,000 times from 50 to 750 N. At 10, 100, 250, 500, 750, and 1,000 cycles, data were recorded and each specimen was photographed at peak load and after unloading to monitor stiffness, changes in femoral head displacement (migration), compressive force across the fracture site, and distal fragment rotation.
Migration, defined as extent of the residual collapse of the proximal fragment after removal of load at each cycle, was measured using the crosshead of the mechanical testing machine. After completion of each measured loading cycle, the difference between the baseline location of the crosshead and the femoral head was measured. Residual femoral head displacement (migration) was compared between treatment groups at all loading cycles.

After completion of cyclic testing, the sensor array was removed and the proximal fragment was unscrewed from the lag screw. The proximal fragment was sectioned using a bandsaw and the tip to apex distance was measured using a caliper, as shown in Figure 5. Photographs were analyzed digitally (ImageJ, NIH) to determine proximal fragment rotation about the lag screw. Compressive lag force across the osteotomy was analyzed at cycles 1 through 100. Stiffness of each construct was calculated from the linear region of the force-displacement curves from the mechanical testing machine. Quantitative data were compared between the three treatment groups using an ANOVA and Games-Howell post-hoc testing with values considered statistically significant at p<0.05.

**Results**

All of the implants were placed in a similar fashion using the custom jigs. Due to the density of the composite bone models (simulating healthy bone), compression of the lag screws was very difficult in all specimens and hand tools (pliers) were necessary to rotate the lagging apparatus. Compression beyond 2.5 mm would likely have been impossible in this model. One specimen (in the G3S group) cracked during testing. This specimen was the first tested and an initial attempt had been made to compress it beyond 2.5 mm. The specimen was likely damaged during compression and subsequently it was not used in the analysis after it cracked. All other specimens were compressed to 2.5 mm and completed the testing protocol with no device related complications.

**Compressive Lag Force**

Maximum lag force during compression was very dynamic and highly variable. As shown in Figure 6, the force was highly time dependent and decreased rapidly. The mean maximum compressive force during lagging was highest in the G3S group followed by the G3RC group followed the ITI group, as shown in Figure 7. There was no significant difference in mean maximum force between G3S and G3RC groups after compression, but both were significantly higher than the ITI group (p<0.002).

After a single loading cycle, there was a substantial loss in compressive force in all treatment groups. The compressive force across the osteotomy gap dropped to less than 10% of the peak value by completion of the first cycle. The ITI and G3RC groups maintained the highest forces after the first cycle, with the G3S group dropping to near zero by cycle 100. There were no statistically significant differences between treatment groups at any time after the initial lag likely due to the high variability in the readings, as shown in Figure 7. Continued cyclic loading did affect the magnitude of the compressive force across the osteotomy with some cycles resulting in a slight increase in force.

**Construct Stiffness**

Construct stiffness was calculated from the linear portion of the load/crosshead displacement curve. The mean stiffness was highest in the ITI treatment group at all cycles, as shown in Figure 8. The mean stiffness of all constructs increased with cycles. The differences in stiffness between treatment groups were not significant at the first cycle of testing, but the difference between the ITI stiffness and the other two treatments approached significance by the 10th cycle (p<0.09). Mean ITI stiffness became significantly

![Figure 4: Image analysis and two pins were used to determine the amount of proximal fragment rotation relative to the fixed distal component.](image1)

![Figure 5: Tip to apex distance (arrow) was measured from the proximal fragment using the technique proposed by Baumgaertner after sectioning with a bandsaw.](image2)
Figure 6: Compressive force was measured as the lag screw was used to compress the osteotomy.

Figure 7: The mean maximum compressive force during lagging was significantly higher in the G3S and G3RC groups compared to the ITI group, but the force diminished substantially for all groups by completion of the first cycle of loading. Error bars indicate on standard deviation.
higher from the 100th to 1,000th cycle (p<0.038). There were no significant differences between the G3S and G3RC groups at any cycle.

**Proximal Fragment Rotation**
The proximal fragment rotation was small for all constructs. The maximum mean rotation of any construct was 1.8°, measured in the G3S group after cycle 250. Although the rotation of the G3S group was at least three times higher than the other groups at every measured cycle, the differences between groups were not statistically significantly different at any cycle number, likely due to the high variation in specimens, as shown in Table 1.

**Migration**
There was no cutout in any specimen and migration of the lag screw within the femoral head was minimal for all treatment groups. At every measured cycle, mean migration was maximum in the ITI group and least in the G3S group. Mean migration ranged from 1.2 to 2.3 mm as shown in Figure 9. There were no statistically significant differences in cutout between any treatments at any measured cycle.

**Tip to Apex Distance**
Mean tip to apex distance for each treatment group is shown in Table 1. The tip to apex distance was statistically significantly (p<0.002) lower in the ITI group compared to the other two treatment groups, but there were no significant differences between the G3S and G3RC groups.

**Discussion**
The Gamma 3 RC nail incorporates a clip that slides over the lag screw and flares out at the medial end of the screw after it has been placed. The Trigen InterTAN nail incorporates a second compression screw that interlocks with the lag screw. The addition of these features is intended to reduce proximal fragment rotation and cutout. Both designs add to the complexity and cost of the systems relative to more traditional nails that do not incorporate such features. In this study, we evaluated the effects of the enhanced design features of the latest generation of cephalomedullary nails relative to the more traditional design of the Gamma 3 Nail. To evaluate the effects on the biomechanical properties, we used a physiologically relevant model of hip biomechanics to simulate the acute post-operative phase of loading.

Our results indicate that all of the systems are capable of generating substantial compressive force to lag a fracture intra-operatively. The G3S and G3RC nails generated over 800 N of compressive force in the dense bone of the composite models. This force is ample for reduction and compression of most intertrochanteric fractures. However, the compressive force was immediately lost and dropped to less than 10% of its peak after a single cycle of loading. This indicates that while the
implants are effective at lagging the proximal fragment intra-operatively, none are capable of maintaining the compression under the loads associated with single leg stance. The G3S system was able to generate the highest mean compressive force, but resulted in the lowest compressive force following one cycle of loading and dropped to zero compressive force by cycle 100. The other two systems were not able to generate as much compression, but were able to maintain some compression through the first 100 cycles of loading.

Like the sliding hip screw, the cephalomedullary nail is designed to allow shortening of the fracture under load to allow bone impaction and facilitate increased stability at the fracture site. All three implants used in this study have set screws which hold the lag screw in the nail. While the set screws appear to be effective at preventing rotation of the lag screw relative to the nail, all three systems allow dynamic sliding of the screw when the femur is loaded, even when the set screws are tightened. Our results indicate that the set screws are sufficient to maintain the relative position of the lag screw while the proximal fragment is lagged into place, but the set screws

<table>
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<th>G3S</th>
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<td>1.2</td>
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<tr>
<td>TAD [mm]</td>
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<td>16.9</td>
<td>33.4</td>
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</tbody>
</table>

TAD, tip to apex distance.

Figure 9: Mean migration in all treatment groups was less than 2.5 mm and reached a plateau by 750 cycles.
do not facilitate “locking” of the lag screw relative to the nail. Our results also indicate that the ability of each system to lag the proximal fragment is not dependent on the novel design features (the clip or interlocking compression screw), however the new designs do appear to facilitate some retention of compression under load. It is not clear from this study what feature in the new designs enhances maintenance of fracture compression.

Proximal fragment rotation was small for all constructs. The amount of friction between the lag screw and the proximal fragment was high for all specimens based subjectively on the amount of torque necessary to advance and compress the lag screw. Mean proximal fragment rotation was highest in the Gamma 3 Nail group. However, the maximum rotation in this group was 1.8° and is still within an acceptable range for clinical practice. The enhanced designs of the Gamma 3 RC and the Trigen InterTAN resulted in negligible rotation in all specimens (mean less than 0.5°), a substantial reduction in rotation relative to the traditional design. In osteopenic bone, it is likely that proximal fragment rotation would be greater in all cases and that the advantages of the enhanced designs would be more prominent.17

Rigid fixation and ample implant stiffness are critical for minimizing interfragmentary motion and maintaining fracture reduction under load.22 In this study, the InterTAN nail constructs had the highest stiffness of the three implants. The addition of the interlocking compression screw inferior to the lag screw increases the moment of inertia of the construct and subsequently enhances its bending stiffness.23 There was little difference in the stiffness between the Gamma 3 and the Gamma 3 RC nails indicating that the addition of the clip to the nail does not significantly enhance bending stiffness. In all treatment groups, the mean stiffness increased with loading cycles, likely due to settling and compaction of the bone around the tip of the lag screw.

The trends in migration of the three treatment groups mirror the trends in stiffness with highest migration in the InterTAN group. This is likely because a stiffer construct will cause compaction of bone around the lag screw. A large mismatch in stiffness between the bone and the implant will result in the bone deforming more than the screw under load and local compaction of the bone around the screw. Compaction of the bone results in a void adjacent to the screw and settling.21 The more stiff the lag screw is relative to the adjacent bone, the more relative deformation will occur and the more compaction and migration will result. As the bone becomes compacted, its local stiffness increases and migration plateaus with increasing cycles. In osteopenic bone, the effects of a mismatch in stiffness will be increased and further migration or cutout is more likely.

Among other factors, the likelihood of cutout in the treatment of peritrochanteric fractures is dependent on surgical technique.8,9 Tip to apex distance is strongly correlated to incidence of cutout with 25 mm being a threshold value above which cutout is more likely.9 In this study, every attempt was made to size and place the implants to achieve a tip to apex distance of less than 25 mm. However, a post-hoc measurement revealed that the mean tip to apex distance in two of the three treatment groups (G3S and G3RC) was greater than 25 mm while the third group (ITI) was less than 25 mm. This inherently predisposes two treatment groups to a higher likelihood of cutout and thus is a confounding factor in this study. However, as shown in Figure 10, a regression analysis of all specimens correlating tip to apex distance and migration indicated only a very weak correlation (R2=0.10) indicating that either the composite model bones or the implant systems were insensitive to tip to apex distance within the range of our testing.

In this study, we used composite models to simulate bone of normal density. In osteopenic bone, the likelihood of cutout and proximal fragment rotation are higher and the benefit of the design features of the nails warrants further assessment. The addition of the interlocking compression screw in the Trigen InterTAN implant appears to primarily increase the stiffness of the device, whereas the addition of the clip in the Gamma 3 RC implant appears to primarily reduce proximal fragment rotation. In this study, both implants performed well with clinically acceptable levels of cutout and rotation. However, additional research in osteopenic bone is necessary to comprehensively characterize the effects of the design enhancements of these implants.
Figure 10: A regression analysis of all specimens indicates only a weak correlation (R²=0.10) between tip to apex distance and migration.

References


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ric Force measurements across the hip after total arthro-


22. Kraemer WJ, Hearn TC, Powell JN, Mohamed N. Fixation of segmental subtrochanteric frac-

A New ACL Guide for Accurate Tunnel Placement

Jason Wong, Rachel Michos, Ryan Harting, Whitney Naslund
Advisors: R. Maxwell Alley, MD, Eric H. Ledet, Ph.D,

2010 Senior Design Showcase Finalist, Rensselaer Polytechnic Institute

The Problem:
The accepted method of tunnel placement for ACL reconstruction involves drilling a guide pin after locating the exit point on the tibial plateau. If the original tibial guide pin was placed too vertically, there will be a misalignment as the pin is drilled through the femur.

Design Goals:
Design a guide that allows the position of the tibial tunnel to be determined using landmarks on both the tibia and the femur simultaneously prior to choosing the path through for the guide through the tibia.

Design alternatives:
- Hinge design
- Nitinol (shape memory metal)

Final design concept:
Slider design
- Marks the femoral and tibial ACL footprint simultaneously
- Sliding track mechanism
- Lever system
- Angle adjustment preserves linearity

Figure 1: Concept drawing of the ACL guide.

Figure 2: Prototype of the hinged ACL guide.

Figure 3: Placement of the guide on a saw bones model.
**Minimally Invasive Reusable Carpal Tunnel Release System**

Jonathan Chung, Matthew Connelly, Courtney Dumont, Alyssa Kowcz, Jason Taylor, Jeffrey Teixeira, Samantha Wozniak
Advisors: David E. Quinn, MD, Richard R. Whipple, MD, Eric H. Ledet, Ph.D

2010 Senior Design Showcase Finalist, Rensselaer Polytechnic Institute

**The Problem:**
Current endoscopic carpal tunnel release systems exhibit limitations including having a limited range of view, reduced visualization due to fogging and difficulty separating the tenosynovium.

**Design Goals:**
- Improve the visualization throughout the procedure
- Maintain alignment with the ring finger axis
- Minimize the number of non-reusable parts
- Reduce the number of procedure steps

**Design alternatives:**
Three tip designs considered before the final design are presented in Figure 1.

**Final Design Concept:**
- Replaceable blade
- Enhanced field of view
- Improved tenosynovium stripping capabilities (Figures 2 and 3)

*Figure 1: Tip design evolution prior to the final design choice.*

*Figure 2: The final design choice showing the enhanced tenosynovium stripping edge.*

*Figure 3: Profile of the final design choice.*
Grand Rounds for the Division of Orthopaedic Surgery are presented every Wednesday (except the first Wednesday of the month), 7 AM to 8 AM EST (EDT), from the auditorium at the Bone and Joint Center, 1367 Washington Avenue, Albany, NY.

Grand Rounds speakers include Division of Orthopaedic Surgery faculty and residents, and guest lecturers. Topics are chosen to provide a broad coverage of current orthopaedic treatment as well as relevant clinical and basic science topics.

### Grand Rounds Schedule for 2010

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<td>William Lavelle, MD</td>
<td>Adult Lumbar Scoliosis</td>
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<td>6/30/10</td>
<td>Bruce White, MD</td>
<td>Ethical Dilemmas in Orthopaedics</td>
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Rensselaer Polytechnic Institute Department of Biomedical Engineering Musculoskeletal Research Team

- **Deepak Vashisht, Ph.D.**
  Professor & Dept. Head Fragility Fractures

- **Robert Spilker, Sc.D.**
  Professor Soft Tissue Modeling

- **Hiroki Yokota, Ph.D.**
  Professor Bone & Joint Biomechanics

- **Shiva Kotha, Ph.D.**
  Associate Professor Bone Biomechanics

- **Eric Ledet, Ph.D.**
  Assistant Professor Spinal Degeneration

- **David Corr, Ph.D.**
  Assistant Professor Soft Tissue Engineering

- **James Cooper, Ph.D.**
  Assistant Professor Soft Tissue Engineering
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As pioneers in spine surgery, our comprehensive range of products has been the most trusted and respected in the world for years. Yet our experience shows that what matters goes far beyond the technologies we produce. DePuy Spine is more than a spine implant company. We're here to help you provide the best care possible.
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