Biomechanical Evaluation of the ODI Hip Screw System

Research Report for Compression and Torsion Biomechanical Tests

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BIOMECHANICAL EVALUATION OF A NEW TYPE OF HIP COMPRESSION SCREW WITH RETRACTABLE TANGS

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The advantages of treatment by open reduction and internal fixation for intertrochanteric, subtrochanteric, and some femoral neck fractures of the proximal femur has been well known to orthopedic surgeons for several decades. Rigid internal fixation with interfragmentary compression permits early mobilization and reduces patient morbidity and mortality. Initial results with the Jewett triflanged nails were dampened when long term reports revealed as high as a 26% failure rate commonly associated with varus displacement and joint penetration with these devices. The introduction of a sliding hip compression screw lowered these complications by allowing the fracture site to collapse upon itself as patients ambulated rather than having the lag screw erode through the bone and penetrate into the hip joint. Technical failure, defined as loss of fixation, loosening of the lag screw and/or cut out of the screw with hip joint penetration has still been reported in from 4 - 19% of cases.

Unstable fractures with a large posterior spike of bone and/or medial comminution are particularly challenging and both medial displacement and valgus osteotomies have been proposed for restoring stability to this fracture pattern. Other authors have advocated the use of methylmethacrylate as an adjunct to internal fixation with intertrochanteric fractures in osteoporotic patients. Anatomic reduction and rigid internal fixation with a compression screw – plate system is the preferred technique by the majority of current authors. Restoring a stable fracture pattern is fundamental to obtaining a high union rate of these challenging fractures and reoperation following nonunion of intertrochanteric fractures that fail to unite with primary treatment is uniformly advocated. In many series, from 30 to 65% of all intertrochanteric fractures are classified as unstable. With weak osteoporotic bone and in unstable, comminuted 3 and 4 part intertrochanteric fractures of the proximal femur, varus angulation of the fracture fragments and joint penetration rates of from 8 - 34% have been reported. A high grade of osteoporosis or the presence of osteomyelitis have been shown to be the important predisposing factors in the spontaneous development of a subcapital femoral neck fracture after a healed intertrochanteric hip fracture.

While some authors have advocated the use of intramedullary nails instead of hip compression screws for intertrochanteric fractures, the compression hip screw remains the most popular method for treatment of these sometimes challenging fractures. Intramedullary hip - screws have been shown to have significantly less sliding of the lag-screw, effectively converting these into fixed angle devices with the attendant risks of cut-out, distal cortical hypertrophy or fracture, and limb shortening, especially in unstable fractures. Furthermore, intramedullary devices are technically more demanding with higher intra-operative and post-operative complications and inferior return of mobility.

Several commercially available hip compression screw systems are “keyed” whereby they have a design fit between the lag screw and side plate that minimizes torque or
rotation forces from occurring at the fracture site by limiting rotation between the lag screw and the barrel of the side plate. These systems still allow sliding to occur between the lag screw and side plate, enabling fracture fragments to settle into a stable pattern as the patient walks. A compression screw at the time of internal fixation can be utilized to apply compression forces across the fracture site. This minimizes the potential for excessive lag screw slide and subsequent impingement of the threads of the lag screw against the barrel, effectively converting a sliding screw into a fixed angle device.

Sliding occurs mainly during the first 2 weeks post-operatively and excessive sliding has been associated with a delay in union of the fracture and lag screw cut-out. In cases of severe osteoporosis, excessive tightening of the compression screw can lead to a stripping out of the thread “purchase” within the bone of the femoral head and a subsequent loss of fixation. Increasing the strength of attachment of the lag screw within the femoral head (or the “purchase” of the lag screw) can enable greater compressive forces to be applied across the fracture site. With appropriate lag screw length choice, initial compression at the fracture site should result in less settling of the lag screw, and thus less chance of lag screw thread-barrel engagement.

We tested a new type of hip compression screw incorporating a reversibly deployable series of four tangs (Figures 1 and 2) that protrude from the base of the threads of the lag screw. The tangs are designed to engage into the cortical bone at the base of the femoral head-neck junction in the inferior portion of the femoral head. We hypothesized that the engagement of the tangs into the dense cortical bone serves three purposes. First, they increase the “purchase strength” of the lag screw within the femoral head, enabling the surgeon to tighten the compression screw with greater force without the lag screw stripping out. Second, the tangs resist torque forces between the femoral head and the lag screw by counteracting rotational forces occurring at this interface. Third, by increasing the amount of bone engaged by the screw, particularly the dense cortical bone at the base of the femoral neck, it theoretically should resist joint penetration by increasing the column of bone necessary for a lag screw to penetrate through prior to perforating through the femoral head and entering into the hip joint space. This paper reports the results of testing the first two of our three hypotheses.

Because the final location of the lag screw relative to the femoral head geometry has been shown to be significant in terms of failure, we chose to test the central versus the inferior head position of the lag screw and its relationship to purchase within the femoral head. Furthermore, we hypothesized that resistance to torque forces is a critical factor leading to the failure of hip pins in osteoporotic bone. As the patient ambulates in the early post-operative period, the repetitive torque and loading forces are paramount in leading to a wedge effect of the lag screw in the minimally dense femoral head. Therefore, we chose to test the torque or rotational strength of the talon hip pin.

Compression at the fracture site is critical to preventing subsequent excessive slide of the lag screw as the patient ambulates in the post-operative period. We therefore chose to test compressive forces across the fracture site utilizing the Talon hip pin.

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1. Talon Dynamic Compression Hip Pinning System (ODi: Orthopedic Designs Inc., P. O Box 7778 St. Petersburg, FL 33734)
Materials and Methods

A total of 25 matched pairs of embalmed adult cadaveric femurs were obtained and the soft tissue removed. Radiographs were taken of each femur to assure symmetry between right and left limbs, rule out bone pathology and assess femoral anatomy. Dual energy x-ray absorptiometry (DEXA) (Lunar Corporation, Madison, WI) was used to quantify the bone mineral density (BMD) of each femoral pair at the region of Ward’s triangle. Femoral pairs were excluded from the study if there was: (1) asymmetry between right and left femurs; (2) a pathological condition; or (3) bone mineral density difference greater than 15% between right and left femurs.

In order to maintain alignment and assist reduction, the femoral heads were drilled and tapped for implantation of hip pins prior to creation of intertrochanteric fractures. A pneumatic saw was used to score the femur in a circumferential manner extending from the proximal superior aspect of the greater trochanter to the inferior aspect of the femoral neck, just superior to the lesser trochanter. The fracture was then completed with an osteotome.

In all studies, for one side of each pair of femurs, an ODI compression hip screw system with a 4-hole side plate was surgically implanted using the procedure recommended by the manufacturer. The tangs (Figure 2) of the ODI lag screw were deployed in one femur from each pair (tang) while the tangs remained retracted in the contralateral femur (screw). The femurs receiving the tang treatment were alternatively placed in the higher BMD bone of a pair and then the lower BMD bone of the next pair. All femurs were fixed with a standard barrel (38 mm)/standard barrel angle (135°) plate. The lag screw length was determined by the femoral neck length and set as specified by the manufacturer. Radiographs were taken after implantation to document tang deployment and lag screw position. All surgical implantations were conducted by two orthopaedic surgeons.

Torsional Stability

Eight pairs of embalmed, adult cadaveric femora were used for this phase of the investigation. All femoral pairs underwent cyclic torsional loading followed by a torsional load to failure. Femoral heads were potted in dental stone (Snap Stone, Whip Mix, Louisville, KY) in such a way that the fracture would be perpendicular to the axis of rotation. Each femur was mounted on a custom made jig that held the shaft at approximately 45° (Figure 3). A torsional load was applied to the femur using an Instron materials testing system (Instron Corp, Canton, MA). The cyclic torsional load applied to the femur was ramped between 1 and 11 N-m in a clockwise direction (tightening action). Torsional loading was applied to the femurs at 1 Hz for 5000 cycles. Angular displacement and torque were collected during cycling to determine rotational stability of the construct. All femurs underwent cyclic testing prior to torque to failure.

After cycling, the compression screw was removed from the lag screw and the femoral head fragment removed from the lag screw barrel of the side plate and the femoral shaft. The lag screw was securely mounted to the materials testing equipment using a 4-jaw Jacobs chuck. The femoral head, mounted in dental stone and reinforced with k-wires, was mounted to the actuator of the materials testing equipment. The construct was loaded to failure in torque at a loading rate of 1 degree/sec to a maximum rotation of 90 degrees in a clockwise direction.
Statistical analyses involved an analysis of variance (ANOVA) with a complete block design (paired samples) evaluating the effects of bone mineral density and treatment (tang or screw). All statistical tests were run using SAS statistical software at a significance level of $\alpha = 0.05$.

**Interfragment Compression**

Seventeen pairs of embalmed, adult cadaveric femora were assigned for this phase of the investigation. Intertrochanteric osteotomies were performed, instead of ostectomies, to provide space between fracture fragments for the compression transducer. Care was taken to assure parallel fragment surfaces for uniform load distribution to the interposed ring load transducer. The load transducer placed between intertranchanteric fragments is shown in Figure 4.

Four pairs of specimens were tested with the lag screw in the central aspect of the femoral neck (center). The lag screw was placed in the inferior position (IP) for the remaining femoral pair to provide better cortical purchase. Both center and IP positions were tested to determine if lag screw position affected compressive characteristics.

A 4400 N (1000 lb) capacity ring load cell (Transducer Techniques, Inc, Temacula, CA) was used to monitor the compression of intertrochanteric fragments. The calibrated load cell was placed between the fracture fragments prior to insertion of the device lag screw. For each quarter turn of the compression screw, the interfragment compression and torque applied to the compression screw were recorded in a systematic fashion. Compression force and torque were recorded for a total of 15 complete turns of the compression screw. Failure was defined as a drop in compression of more than 50% within one turn of the compression screw. Data was acquired 5 screw turns beyond peak compression. Radiographs were acquired following testing to document the device position at failure.

Statistical analyses involved an analysis of variance (ANOVA) with a complete block design (paired samples) evaluating the effects of bone mineral density, lag screw position (center or IP) and treatment (tang or screw). If a significant effect of position was found, the effects of treatment by position were determined. Similarly, if a significant effect of position by treatment was determined. All statistical tests were run using SAS statistical software at a significance level of $\alpha = 0.05$. 
Results

Torsional Stability

Table 1 summarizes the results of the cyclic torsional and torque to failure tests. The relative rotational displacement during cyclic testing from preload to maximum load was defined as amplitude. The absolute rotational displacement from beginning to end of cycling (5000 cycles) was defined as migration. The amplitude during cyclic loading for the **tang** and **screw** groups was not significantly different. However, the femurs fixed with the **tang** treatment had significantly less rotational migration during 5000 torsional cycles than the **screw** group ($p = 0.023$), with angular values of $1.59 \pm 3.15$ degrees and $2.11 \pm 2.97$ degrees, respectively. The peak torque for the **tang** device was significantly greater than the torque for the **screw** device ($p = 0.00016$) with torque values of $6.48 \pm 1.73$ N-m and $1.92 \pm 1.71$ N-m, respectively. The average rotational displacement occurring prior to peak torque was $27.13 \pm 18.20$ degrees for the **tang** group and $30.13 \pm 19.38$ degrees for the **screw** group. The rotational displacement at peak was not different between the **tang** and **screw** groups. The torque at 15 degrees of rotation, a more clinically relevant value, was also significantly greater for the **tang** compared to the **screw** device ($p=0.0028$) with torque values of $4.185 \pm 2.002$ N-m and $1.21 \pm 1.15$ N-m, respectively. Peak torque and torque at 15 degrees of rotation are presented graphically in Figure 5.

Interfragment Compression

Of the 17 paired specimens assigned to compression testing, 5 pairs of specimens were deleted from the analysis. The specimens were eliminated due to testing errors (n=2), implantation errors (n=1), and BMD differences between contralateral femurs greater than 15% (n=2). The remaining 12 femur pairs were evaluated for interfragment compression as a function of compression screw rotation. Table 2 and Figures 6 – 9 summarize the results from the compression test. The peak compressive forces generated by the **tang** treatment group were significantly greater than the **screw** group in the inferior position ($p = 0.0046$) with compression values of $1398.41 \pm 466.84$ N and $712.83 \pm 322.77$ N, respectively (Figures 7 & 9). No differences between **tang** and **screw** treatments were noted when the device was implanted in the central position (Figures 8 & 9). The compression was significantly greater for the **tang** group when the lag screw was placed in the inferior position compared to the central position ($p=0.011$) but no difference in the **screw** group was noted (Figure 10). The **tang** group produced significantly greater compression than the screw group in the inferior position ($p=0.036$) but no difference in the central position (Figure 7). The BMD did not have a significant effect on interfragment compression for the **screw** or **tang** group ($p > 0.05$).
Discussion

Numerous papers have addressed the ideal positioning of the lag screw within the femoral head to maximize purchase of the screw and to minimize the risk of cut out. Our data clearly demonstrates that an inferior placement of the lag screw within the lower portions of the femoral head results in greater purchase of the lag screw regardless of whether the tangs are deployed. However, with tang deployment, a 96% greater peak compression strength is obtained prior to failure when compressive forces are applied across the fracture site. These results were statistically significant [Figures 7 & 9; \( p=0.0046 \)]

Our results show that one of the critical factors maximizing the purchase of the lag screw within the femoral head is to engage the tangs within the dense cortical bone at the junction between the femoral head and the neck. If a central location is chosen and the bone is weak and osteoporotic, deployment of the tangs provides no further increase in purchase resistance to compressive forces within the femoral head (Figure 8). If the tangs are engaged within the dense cortical bone provided by an inferior lag screw axis, then a statistically significant \( (p=0.036) \) increase in compressive force across the fracture site can be produced (Figure 10) prior to lag screw failure.

Regardless of tang deployment, an inferior position is supported by this study. With both the torque testing and the compression testing, at the extremes of testing, representing non-physiologic loads, radiographs revealed gross tang deformity. In all instances, when the actuator retrieval mechanism was utilized, the tangs fully retracted and no tangs broke or failed to retract.

We believe that the mechanism of failure accounting for lag screw cut out and subsequent pin penetration so commonly reported is multifactorial. Gill J. et al reported that high stresses in the surrounding cancellous bone contribute to the failure of repairs. Failure to compress the fracture site fully has been noted clinically to be accompanied by excessive slide of the lag screw, which has been shown to be associated with a poor functional outcome. The advantage of enhanced compression across the fracture site has been advocated by numerous authors. Indeed, excessive slide, presumably associated with poor initial compression has been shown to prolong time to union of operatively treated intertrochanteric fractures. Prior to the introduction of the talon hip pinning system, few hip pinning systems were designed to prevent rotation forces between the lag screw and the proximal femoral bone. While hip bolt procedures have been advocated by some authors to increase the purchase of the device within the femoral head, most authors have favored use of the hip compression screw. Our results clearly demonstrate an approximately three times greater peak rotational purchase of the Talon lag screw within the femoral head compared to those lag screws wherein the tangs were not deployed (Figure 5). There are no comparative studies to date testing different commercially available hip pinning systems with the Talon hip pin. Thread length and screw designs vary between manufacturers.
Most current hip pinning systems fail to adequately address rotational or torque forces that occur between the femoral head and the lag screw as the patient ambulates and arises from or resumes the sitting position. We postulate that with weakened osteoporotic bone, the lag screw acts like a wedge, slowly working its way upward as the patient ambulates and subjects their recently fractured hip to rotational forces. This is particularly a problem in the non-compliant and slightly demented patients who nevertheless remain ambulatory. Many authors have noted the extreme resorption of bone in the femoral head and metaphyseal regions of the proximal femur and torsional forces have been implicated in implant failure. Enlarged threads patterns or expansile devices such as molley-bolt designed hip lag screws fail to reach to the dense remaining cortical bone that we believe holds the greatest promise for maximizing purchase of the lag screw within the femoral head.

Our prior experience has shown great difficulty in experimental models for reproducing “cut-out” of the femoral head. Investigators have difficulty obtaining only osteoporotic femurs for testing, and many matched specimens vary in bone density even in the same person. We alternated between most and least dense femurs for deployment of our tang-deployed and control lag screws, but a better test design would be to have matched controls that were tested in only osteoporotic femurs. Furthermore, our fracture design was a stable model whereby a simple 2 part intertrochanteric fracture was created. This insured a stable reconstruction of the fracture pattern simulating a reproducible construct expected after open reduction internal fixation. Clinical experience dictates that unstable and multipart fractures are those most at risk for cut-out, in addition to the extremely osteoporotic. Furthermore, in vivo experience would suggest greater extremes of fracture site bone interdigitation depending upon the extremes of fracture comminution and the success of the fracture site reduction.

Our results clearly demonstrate that with a stable 2 part intertrochanteric fracture of the proximal femur treated with a Talon lag screw with tangs fully deployed, the resistance to torque forces (Table 1, p=0.0028) in our experimental model were greater with tangs deployed that with comparable lag screws wherein the tangs were not deployed. Many manufacturers and numerous studies have attempted to prevent or reduce the incidence of cut out of the lag screw by enlarging the threads of the lag screw or by expanding a molley-bolt type device within the head of the femoral head. An association with overreaming and weak osteoporotic bone have been shown to be significant risk factors.

We believe that the unique combination of deployable tangs within the femoral head has been shown to be superior to resisting rotational forces than a comparable lag screw without tangs deployed. Furthermore, the tangs deploy a full 1 inch at maximum deployment. Most standard lag screws have an external thread diameter of approximately ½ in. The column of bone that a lag screw must erode through to penetrate through the superior cortex of the femoral head is thus doubled with the talon hip pin with tangs deployed.
The peak compressive forces generated by the **tang** treatment group were significantly greater than the **screw** group in the inferior position ($p = 0.0046$) with compression values of $1398.41 \pm 466.84$ N and $712.83 \pm 322.77$ N, respectively (Figures 7 & 9). No differences between **tang** and **screw** treatments were noted when the device was implanted in the central position (Figures 8 & 9). The compression was significantly greater for the **tang** group when the lag screw was placed in the inferior position compared to the central position ($p=0.011$) but no difference in the **screw** group was noted (Figure 10). The **tang** group produced significantly greater compression than the **screw** group in the inferior position ($p=0.036$) but no difference in the central position (Figure 7). The BMD did not have a significant effect on interfragment compression for the **screw** or **tang** group ($p > 0.05$).

In summary, the talon hip pinning system in our matched cadaveric model provided a two fold increase of purchase of the lag screw when tangs were deployed within the femoral head when compressed to failure at the fracture site. Optimal location of any lag screw with an axis inferior to the center of the femoral head as advocated by Wu, C. et al$^{104}$ in supported by our results in this study. This leads to greater purchase of the lag screw within the femoral head in an area that presumably has more dense bone and thus theoretically should resist cut-out. Deployment of the tangs into or through the cortical endosteal surface increases the purchase strength of the lag screw in this inferior position.

Furthermore, tang deployment appears to be the critical factor in resisting rotational torque forces about the femoral head in our test model. After cyclical testing of the fracture construct, peak torque for the **tang** device was significantly greater than the torque for the **screw** device ($p = 0.00016$) with torque values of $6.48 \pm 1.73$ N-m and $1.92 \pm 1.71$ N-m, respectively. Our results support our hypotheses that the Talon hip pin system with tangs deployed provides significantly increased purchase of the lag screw within the proximal femoral head and will allow greater compression forces to be applied across the fracture site. The increased purchase afforded by the tangs within the femoral head counteracts rotational forces and provides a greater column of bone that must be eroded through prior to lag screw penetration in our model. While our results did not address the degree of tang penetration into the dense cortical bone, we believe from our experience with this device that engagement or penetration into or through the cortical bone at the base of the femoral head-neck junction is the critical technical step to maximize the tang purchase within the femoral head.
### Table 1. Results of Torsional Biomechanical Tests

<table>
<thead>
<tr>
<th>Implantation Location</th>
<th>Measurement</th>
<th>Screw</th>
<th>Tang</th>
<th>Screw vs Tang (p-value)</th>
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<td></td>
<td>Peak Compression (N)</td>
<td>712.83 ± 322.77</td>
<td>1398.41 ± 466.84</td>
<td>*p = 0.0046</td>
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<td>(n = 8)</td>
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<td></td>
<td>Peak + 1 turn (N)</td>
<td>380.88 ± 196.64</td>
<td>1033.47 ± 451.37</td>
<td>*p = 0.021</td>
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<td>Peak + 3 turn (N)</td>
<td>343.90 ± 192.90</td>
<td>712.46 ± 384.01</td>
<td>*p = 0.024</td>
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<td></td>
<td>Peak + 5 turn (N)</td>
<td>258.55 ± 132.22</td>
<td>472.99 ± 215.43</td>
<td>p = 0.078</td>
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<td>(n = 6)</td>
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<td>Central</td>
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<td></td>
<td>Peak + 5 turn (N)</td>
<td>71.73 ± 55.42</td>
<td>180.15 ± 30.55</td>
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### Table 2. Results of Interfragmentary Compression Tests

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<th>Tang</th>
<th>Screw vs Tang (p-value)</th>
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Figure 1. *Talon Hip Compression Screw System*
Figure 2. *Talons fully deployed*
Figure 3. Specimen in Test Fixture for Cyclic Torsional Loading
Figure 4. Specimen with Load Transducer Interposed between Intertrochanteric Fragments to Measure Compression
Figure 5. Peak Torque and Torque at 15 Degrees

Tang > Screw (p = 0.00016)

Tang > Screw (p = 0.0028)
Figure 6. *Interfragment Compression for Each Femur Pair in the Inferior and Central Lag Screw Positions*

![Graph showing interfragment compression for each femur pair in the inferior and central lag screw positions.](image-url)
Figure 7. *Peak & Post-Peak Compressive Forces*
*Inferior Postion*

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<th>Force (N)</th>
<th>Screw &lt; Tang (p = 0.0046)</th>
<th>Screw &lt; Tang (p = 0.021)</th>
<th>Screw &lt; Tang (p = 0.024)</th>
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- Screw < Tang for Peak (p = 0.0046)
- Screw < Tang for Peak + 1 turn (p = 0.021)
- Screw < Tang for Peak + 3 turn (p = 0.024)
- Screw = Tang for Peak + 5 turn (p = 0.078)
Figure 8. Peak and Post-Peak Compressive Forces
Central Postion

- Screw = Tang ($p = 0.853$)
- Screw = Tang ($p = 0.905$)
- Screw = Tang ($p = 0.396$)
- Screw < Tang ($p = 0.024$)
Figure 9. *Peak Interfragment Compression for Inferior and Central Lag Screw Placement*

- **Inferior:** Screw < Tang ($p = 0.0046$)
- **Central:** Screw = Tang ($p = 0.853$)
Figure 10. *Inferior versus Central Placement of Lag Screw*

- Inferior = Central  
  \( p = 0.3635 \)
- Inferior > Central  
  \( p = 0.0110 \)
Bibliography


