学位論文

Biomechanical evaluation of extramedullary versus intramedullary reduction in unstable femoral trochanteric fractures

(不安定型大腿骨転子部骨折における髄外型整復と髄内型整復の力学的評価)

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著者の宣言

本学位論文は、著者の責任において実験を遂行し、得られた真実の結果に基づいて正確に作成したものに相違ないことをここに宣言する。

【序論】

大腿骨転子部骨折は、骨粗鬆症を有する高齢者の転倒によって多く発生する骨折である。同骨折を受傷した場合、早期離床、死亡率低下を目的として、速やかな骨折整復固定術が必要となる。最近では、術後合併症が少ないと言われる髄内釘固定が多く行われているが、それでも骨折部の粉砕を伴う不安定型の骨折では術後合併症が3～12%の確率で生じると言われている。術後合併症には、ブレードのカットアウト、過度のスライディングなどがある。骨折の整復位とインプラントの設置位置は、手術成功のための重要な因子であり、骨折部の安定性が向上すると術後合併症を軽減できる。以前の研究では、前後像で近位骨片の内側骨皮質を遠位骨片のわずかに内側に整復し固定する「髄外型」が、逆の整復位である「髄内型」と比べて、骨折治癒環境が優れており、さらに、側面像でも同様に、近位骨片が遠位骨片に比べて前方にある整復位が、後方にあるものと比べて成績が良いと報告されている。ただし、これらは臨床的な報告であり、上記を裏付ける生体力学的実験の報告はなかった。そこで、骨折部の圧縮剛性、ブレードのスライディング量およびインプラントの骨内制動に関して、「髄外型」は「髄内型」よりも優れていると仮定し実験を行った。

【方法】

骨粗鬆症骨として模擬大腿骨を使用し不安定大腿骨転子部骨折モデルを作成した。後方骨片を除去し骨性サポートがない状態とする。2つの異なる整復位で固定した後に、力学的安定性を比較した。近位骨片の半骨皮質分を、正面像で遠位骨片の内側かつ側面像で遠位骨片の前方整復したものを「髄外型」、一方、正面像の遠位骨片の外側かつ側面像の遠位骨片の後方に整復したものを「髄内型」とした。「髄外型」と「髄内型」をそれぞれ11個ずつ、合計22個のモデルを作成した。すべてをDePuy Synthes社の髄内釘であるTFNAを使用した。このインプラントの特徴として、骨折部での力学的負荷の分散と、骨折部の圧着を目的にブレードが髄内釘内でスライドするように設計されている。ブレード挿入位置の指標としてブレード先端と骨頭との距離（TAD）を測定した。骨折モデルを正面像で内転20° に固定し、10mm / minの速度で0～2000Nまで、電気機械式万能試験機を使用して軸圧負荷をかけた。荷重-変位曲線の傾きを圧縮剛性とし、髄内釘の大腿骨内での動きの指標として、頚体角、ブレードのスライディング量および遠位ネジ穴直径の変化を測定し、2種類の骨折モデル間のパラメーターを比較した。統計分析にはマンホイットニーU検定を使用し、$p < 0.05$を有意差ありとした。

【結果】

「髄外型」は「髄内型」よりもTADは有意に大きかった（$p = 0.001$）が、臨床的に許容できる範囲内(<20mm)であった。圧縮剛性（$p = 0.804$）と頚体角の変化（$p = 0.678$）に有意差はなかった。圧縮後のブレードスライディング量は、「髄内型」が「髄外型」よりも有意に多かった（$p < 0.01$）。遠位ネジ穴の直径も、「髄内型」の方が「髄外型」よりも有意に大きかった（$p = 0.019$）。我々の仮説に反して、圧縮剛性と頚体角に有意差は見られなかったが、「髄内型」は「髄外型」よりも有意に大きなブレードスライディング量と遠位ネジ穴径の拡大を示した。

【考察】

大腿骨転子部は前方骨皮質が厚く硬いため前面は単純な骨折線となる一方、後方は粉砕することが多い。従って、不安定大腿骨転子部骨折では、インプラント以外では骨片同士の前内側骨皮質の接触のみで荷重を支えることになる。ただし、骨片間で効果的な荷重支持がなされない場合、ブレードの過度なスライディングが発生し、ブレードのカットアウトや偽関節などの術後合併症を引き起こす可能性がある。本研究では、「髄内型」のブレードのスライディング量は負荷増大とともに増加し、髄内釘に到達するまで停止しなかった。しかし、「髄外型」では前内側骨皮質が接触した段階で骨性支持が得られスライディングは停止した。これは、「髄内型」は過度なスライディングを伴うという臨床報告と一致していた。頚部の内反変形がブレードカットアウトのリスクを増加させるとの報告もある。本実験では、頚体角の変化に有意差は見られなかったが、遠位ネジ穴径は「髄内型」が「髄外型」よりも有意に大きかった。遠位ネジ穴径の拡大は、圧縮中の大腿骨内反負荷の増強を示す。「髄外型」では、近位骨片、髄内釘、および遠位骨片の3つの部位で構成されていたが、「髄内型」は前内側に骨性接触がないため、近位骨片-髄内釘および髄内釘-遠位骨片という2つの部位で構成されることになる。この状態では、荷重は近位骨片を介して直接、髄内釘そして遠位ネジに負荷が集中することになる。髄内釘および遠位ネジへの応力集中を防ぐために、前内側骨皮質の接触が不可欠である。

目次 頁

Abstract

Introduction

The failure rate of operations involving the cephalomedullary nail technique for unstable femoral trochanteric fractures is 3–12%. Changing the reduction strategy may improve the stability. This study aimed to confirm whether reducing the proximal fragment with the medial calcar contact, as opposed to utilizing an intramedullary reduction, would improve the stability of such fractures.

Materials and Methods

The unstable femoral trochanteric fracture model was created with fixation by cephalomedullary nails in 22 imitation bones. The two reduction patterns were as follows: one was with the proximal head-neck fragment external to the distal bone in the frontal plane and anterior in the sagittal plane as "Extramedullary", while the other was the opposite reduction position, that is, bone in the frontal plane and sagittal plane as "Intramedullary". We evaluated the tip-apex distance, compression stiffness, change in femoral neck-shaft angle, amount of blade telescoping, and diameter of the distal screw hole after the compression test. Statistical analysis was conducted using the Mann–Whitney U test.

Results

No significant differences were seen in compression stiffness ($p = 0.804$) and femoral neck-shaft angle change ($p = 0.644$). Although the "Extramedullary" tip-apex distance was larger than the "Intramedullary" distance ($p = 0.001$), it indicated clinically acceptable lengths. The amount of blade telescoping and the distal screw hole diameter were significantly larger in "Intramedullary" than in "Extramedullary" ($p < 0.001$, $p = 0.019$, respectively). Our results showed that "Intramedullary" had significantly larger blade telescoping and distal screw hole diameters than “Extramedullary”, and contrary to our hypothesis, no significant differences were seen in compression stiffness and femoral neck-shaft angle change.

Conclusions

As opposed to the “Intramedullary” reduction pattern, the biomechanical properties of the “Extramedullary” reduction pattern improved stability during testing and decreased sliding.

1. Introduction

Femoral trochanteric fractures often occur in elderly people owing to osteoporosis. In such instances, immediate surgery is required to improve their quality of life and decrease the mortality rate after injury.[1] Two types of implants can be utilized during surgery, i.e., cephalomedullary nails and sliding hip screws. Given that cephalomedullary nailing is associated with a lower risk of postoperative complications,[2-4] this technique is often preferred by surgeons when performing fixations. However, the overall failure rate of fixation operations for unstable femoral trochanteric fractures is 3–12%.[5–7]

Postoperative complications include blade/screw cutout, excessive blade/screw sliding, and broken implants.[8] Excessive blade/screw telescoping and varus collapse, which might have caused implant failure, occurred in unstable femoral trochanteric fractures,[7,9] and the combination of critical factors, including incorrect reduction, non-optimal blade/screw position, and characteristic fracture pattern, could lead to blade/screw cut-out.[10] Among these critical factors, we can only control the reduction position and the blade/screw position. Therefore, fracture reduction and placement of the implant are crucial for a successful surgery. A previous study suggested that when the fragment was reduced and fixed by placing the medial cortex of the head-neck fragment slightly medial to the medial cortex of the femur shaft in AP view ("Extramedullary" reduction), the mechanical environment for fracture healing was better than that when the head-neck fragmented was fixed laterally to the upper medial edge of the femur shaft ("Intramedullary" reduction).[11] In addition, the anterior femoral neck cortex posterior to the distal fragment in the lateral view shows a higher risk of excessive sliding of the lag screws than does that located anterior to the distal fragment.[12,13] During the reduction procedure in the operating room, elevators and Kirschner wires are usually used as levers while the lesser trochanter represents the landmark. Briefly, a small incision is made above the lesser trochanter using fluoroscopy, which is followed by the insertion of the elevators into the fracture line to conduct reduction. However, no biomechanical evidence is available to support these clinical advantages.

Considering that these reduction patterns might have different biomechanical properties, we hypothesized that “Extramedullary” reduction is superior to “Intramedullary” reduction regarding the compression stiffness and the blocking capability of blade/screw sliding and implant movement inside the femur.

2. Materials and Methods

In this study, we created unstable femoral trochanteric fracture models and compared their mechanical stability based on the two different reduction patterns. We used imitation bone as an osteoporotic model (#1111, Sawbones; Pacific Research Laboratories, Vashon, WA, USA) to compare the two types of reduction patterns. Using an oscillating saw, we created the AO Foundation/Orthopedic Trauma Association (AO/OTA) classification 31A2.3 type unstable femoral trochanteric fracture models, with no support posteromedially and posterolaterally. The landmarks were the tip of the greater trochanter and the bottom of the lesser trochanter. While we first cut the imitation bone along the intertrochanteric crest using the bone saw, we then hollowed out the posterior wall fragment, so this fracture had a large defect posteriorly, including the greater and lesser trochanters (Fig. 1-a). We controlled variability by marking the same points and cutting at the same places on each bone with precision.

We placed the medial cortex of the proximal head-neck fragment “half of the cortex thickness” medial to the distal bone fragment in the frontal plane and anterior to the distal fragment in the sagittal plane as “Extramedullary” (Fig. 1-b, c).

We placed the medial cortex of the proximal head-neck fragment “half of the cortex thickness” inside the distal bone fragment in the frontal plane and posterior to the distal fragment in the sagittal plane as “Intramedullary”. (Fig. 1-d, e).

We created 11 “Extramedullary” and 11 “Intramedullary” models, totaling 22 models.

We used an extra-short TFNA™ implant (DePuy Synthes, West Chester, PA, USA) with a 100-mm helical blade, a femoral neck angle of 130°, and a 5.0-mm distal locking screw for internal fixation in all 22 cases. The blade component in this implant was designed to slide within the nail for compression while maintaining the load-sharing characteristics at the fracture site. We positioned the entry point of the implant at the tip of the greater trochanter, placed the guide of the nail, reamed the femur, and inserted the interlocking nail into it. We then situated the guide of the helical blade toward the apex of the femoral head and placed the helical blade while maintaining each reduction pattern, at the site where the penetration was confirmed to be safe by fluoroscopy. Finally, we placed one locking screw at the distal femur. After the operation, we measured the tip-apex distance (TAD)[14] as an indicator of the blade insertion position.

We performed a compression test on the prepared fracture models using an electromechanical universal testing machine (Instron model no. 33R4467; Instron Corporation, Norwood, MA, USA). The fractures of the models were reduced by both patterns to examine the mechanical stability of each and compared. Each specimen was fixed using a hand-made fixing stand to ensure the 20° adduction of the femur in the frontal plane. Adduction angles of 15°–25° have been shown to simulate the physiological loading of the proximal femur in the single-leg stance phase of the gait and have been used in other related biomechanical research studies.[15–17] We applied an axial pressure load at 10 mm/min from zero up to

2000 N. Load-displacement curves were collected and compression stiffness was calculated for each femur as the slope of the load-displacement curve. We also measured the change in the femoral neck-shaft angle, amount of blade telescoping, and distal screw hole diameter as indicators of nail motion in the femur and compared the parameters between the two different reduction patterns.

The Mann–Whitney U test was used for statistical analysis and the threshold for significance was $p < 0.05$. All statistical analyses were performed using SPSS software (version 19.0; SPSS, Chicago, IL, USA).

3. Results

We found that “Extramedullary” (17.5 ± 1.5 mm, range = 8.0–24.2 mm) showed larger TAD than did “Intramedullary” (10.1 ± 1.1 mm, range = 6.3–18.8 mm) (p = 0.001). There were no significant differences in compression stiffness (p = 0.804) and the change in the femoral neck-shaft angle (p = 0.678). The amount of blade telescoping after the compression test was significantly greater in “Intramedullary” (3.2 ± 0.4 mm, range = 2.0–6.9 mm) than in “Extramedullary” (0.19 ± 0.14 mm, range = -0.76–0.82 mm) ($p < 0.01$). In all “Intramedullary” specimens, the proximal head-neck fragment slid to the lateral side after the compression test (Fig. 2). The distal screw hole diameter was also significantly larger in “Intramedullary” (6.7 ± 0.4 mm, range = 4.7–8.0 mm) than in “Extramedullary” (5.2 ± 0.19 mm, range = 4.7–6.4 mm) (p = 0.019). “Intramedullary” models showed enlargement of the distal screw hole after the compression test.(table 1)

4. Discussion

This study showed that “Extramedullary” had significantly lower blade telescoping and distal screw hole diameter than “Intramedullary” after the compression test. To our knowledge, this is the first study to examine and compare biomechanical properties of two different reduction patterns for the treatment of unstable femoral trochanteric fractures.

In the case of AO/OTA classification 31A2.3 type fracture, the fracture line in the anterior aspect of the trochanter occurs simply because the anterior component of the trochanter has a thick and strong bone cortex, while the fracture line in the posterior aspect collapses owing to the cancellous bone in the posterior component of the trochanter.[18] The thickness and bone quality of the anteromedial bone cortex are maintained even in elderly patients because the loading force while walking is transmitted through the anteromedial bone cortex of the proximal bone fragment.[19] Therefore, contact with the anterior medial cortex between the proximal head-neck fragment and distal fragment alone can support the loading force except in an implant in an unstable femoral trochanteric fracture. This is also an important factor in terms of load tolerance.

If effective bone-on-bone impaction is not applied, however, excessive sliding can occur. A previous study reported that excessive blade/screw telescoping often occurred[7] and caused postoperative complications such as blade/screw cutout and pseudoarthrosis in unstable femoral trochanteric fractures.[9] Excessive sliding indicates that the intended compression was not obtained and has been shown to predict clinical failure of the surgery.[20–22] In our study, the proximal head-neck fragment sliding increased with the loading force and did not stop until the proximal head-neck fragment reached the nail in “Intramedullary”; however, bone support was obtained early in the anterior medial cortex in “Extramedullary”(Fig. 2). These findings indicated that when an excessive load was applied, the proximal head-neck fragment moved to the lateral side easily, and excessive telescoping occurred because there was no bone support of the anteromedial cortex in the “Intramedullary” pattern. In the results of our study, the amount of blade telescoping after the compression test was found to be significantly greater in “Intramedullary” than in “Extramedullary”; this finding was in accordance with that of previous clinical reports, which showed Intramedullary pattern with excessive blade telescoping.[12,13].

Pervez et al. reported that the varus reduction position increased the risk of blade cutout.[23] In our experiment, although no significant differences were seen in the neck-shaft angle change, the distal screw hole diameter was larger in “Intramedullary” than in “Extramedullary”. Enlargement of the distal screw hole indicated that the nail varus movement occurred in the femur during axial compression. In the “Extramedullary” pattern, the nail-bone construct consisted of three parts: the proximal head-neck fragment, intramedullary nail, and distal fragment. In contrast, the “Intramedullary” pattern showed that the nail-bone construct consisted of these three factors separately following two parts, proximal head-neck fragment-cephalomedullary nail and cephalomedullary nail-distal fragment, owing to the absence of bony contact in the anteromedial area between the proximal head-neck fragment and distal bone. In this condition, the axial compression load was concentrated on the distal screw through the head-neck fragment to the cephalomedullary nail; the nail varus movement occurred in the femur in the “Intramedullary” pattern under a high loading force. To prevent the concentration of stress at the site of the distal screw, which might cause nail varus movement in the femur, the anterior medial bone contact was essential to share the loading force in unstable femoral trochanteric fractures.

The location of the implant after the operation also affected the frequency of implant failure. Baumgaertner et al. mentioned that the TAD played an important role in preventing implant failure.[14,24] Brujin et al. reported that TAD > 25 mm was related to the risk of screw cutout.[25]

As shown by our results, TAD in “Extramedullary” and “Intramedullary” reductions did not exceed the recommended standard value of 20 mm.[26] Although TAD in “Intramedullary” was significantly lower than that in “Extramedullary”,” Intramedullary” showed a significantly greater amount of blade telescoping and distal screw hole diameter than did “Extramedullary”. Thus, the “Extramedullary” reduction pattern was preferable in unstable femoral trochanteric fractures.

There were a few limitations to this study. First, we used imitation osteoporotic bone model material that might not have replicated the biomechanical properties of human bone exactly. However, synthetic bone is easy to handle without interspecies variability, indicating that the differences among the groups were due to the reduction pattern itself. Second, we could not consider the condition of the soft tissue, including muscles and ligaments, which may affect the reduction pattern. Third, we evaluated just two-dimensional displacements; we could not assess the rotation of the proximal fragment. Fourth, only axial loading force could be reproduced; the stress on the hip joint during walking, which might be measured using the cyclic-load test, was not reproducible. However, we showed that “Intramedullary” reduction was less stable than was “Extramedullary” reduction in the femur even by a single axial compression load. We believe that our biomechanical results support previous clinical studies.[12,13] Further experiments, such as 3D evaluation and fatigue testing using cadaveric bone should be conducted to explore the differences in the biomechanical properties between the two reduction patterns.

5. Conclusions

The “Extramedullary” reduction pattern provides anterior medial bone support and is biomechanically superior to the “Intramedullary” reduction pattern. Anterior medial bone contact is necessary for the treatment of unstable trochanteric femoral fracture to avoid postoperative complications following excessive telescoping or varus collapse. There is a scope for future studies on human models to verify our findings.

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Table 1 Results of the biomechanical test series for two different reduction patterns (mean ± SE)

Variables	Extramedullary with Subtype A (n = 11)	Intramedullary with Subtype P (n = 11)	*p* value
Tip-apex distance (mm)	17.5 ± 1.5	10.1 ± 1.1	**0.001**
Compression stiffness (N)	212 ± 8.6	214 ± 6.9	0.804
Change in femoral neck-shaft angle (degrees)	7.9 ± 0.73	7.4 ± 0.84	0.678
Blade telescoping (mm)	0.19 ± 0.14	3.2 ± 0.41	**< 0.001**
Diameter of the distal screw hole (mm)	5.2 ± 0.19	6.7 ± 0.37	**0.019**

Mann–Whitney U test.

Figure 1

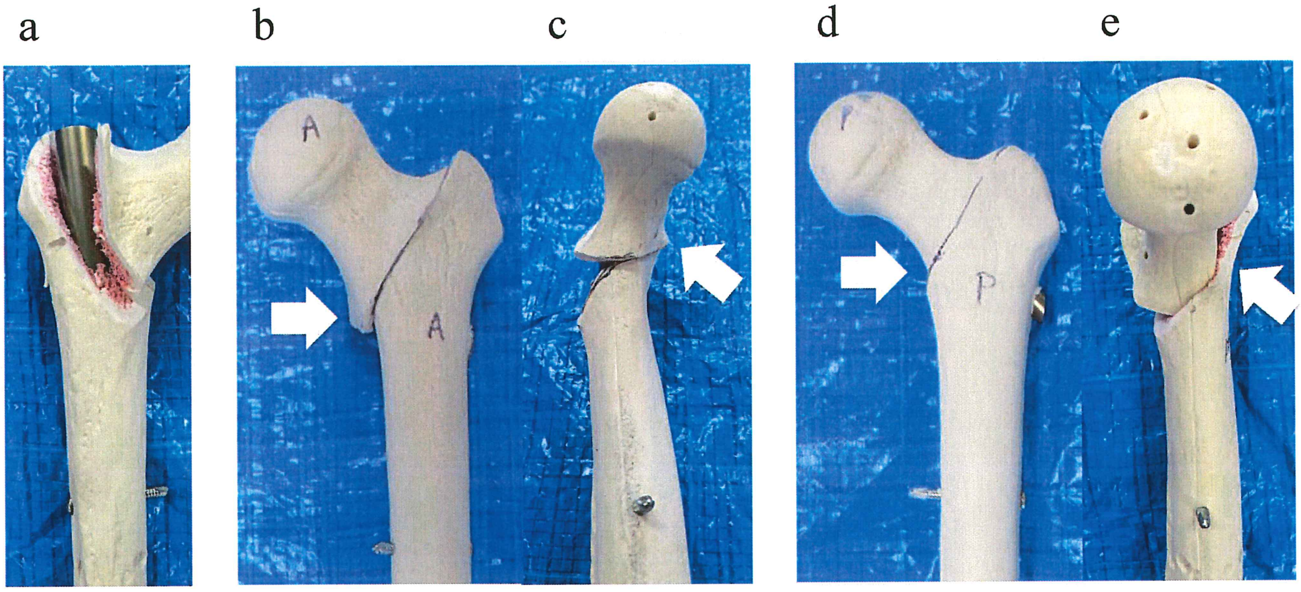

Figure 2

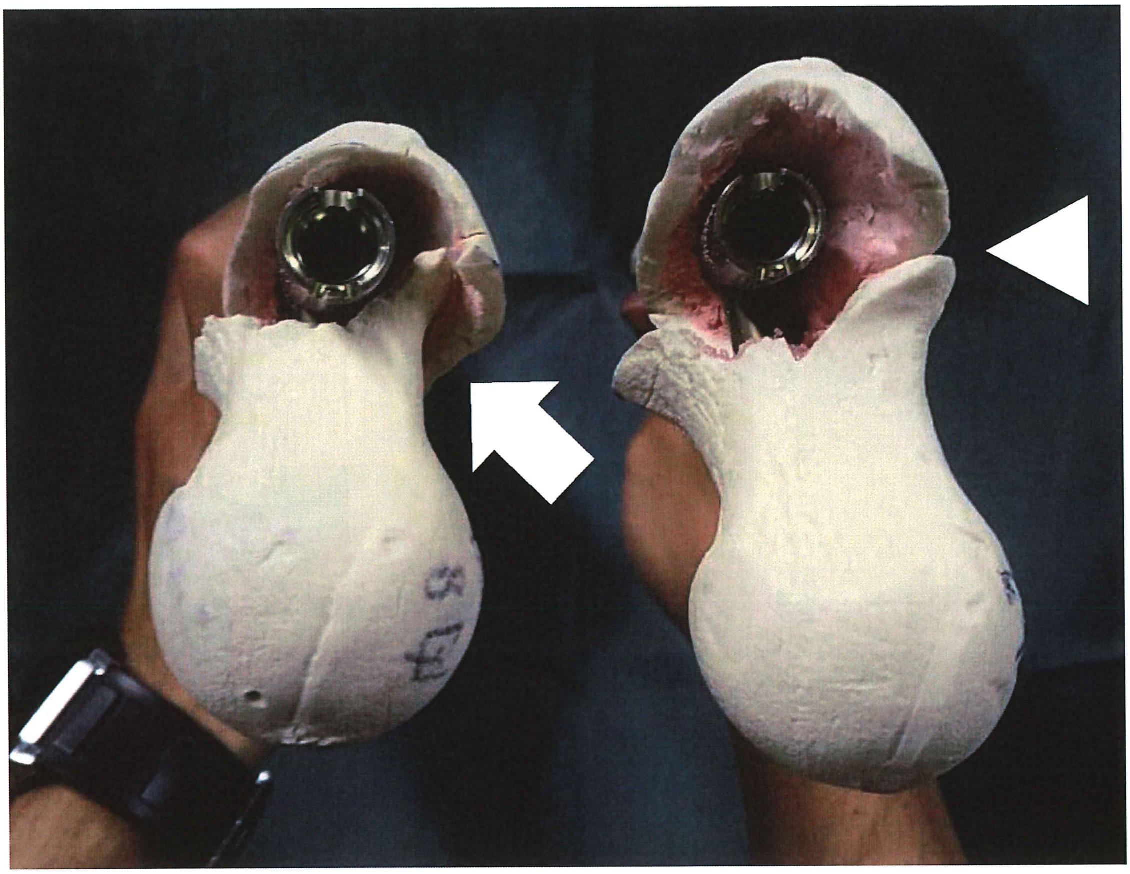

Figure legends

Fig. 1. Reduction patterns for unstable femoral trochanteric fractures.

Both types had a large posterior defect including greater and lesser trochanters (a). “Extramedullary” pattern(b)(c)and “Intramedullary” pattern.(d)(e)

Fig. 2. Movement of proximal head-neck fragment after compression testing for the two different reduction patterns in unstable femoral trochanteric fracture.

“Intramedullary” pattern showed neck shortening without anterior bone contact (white arrow), while “Extramedullary” pattern showed anterior bone contact without neck shortening (white arrowhead).