

General

One year “ADAPT system” use for proximal femoral fracture osteosynthesis with intramedullary nail . A case control study.

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Keywords: Computer-assisted surgery, femoral intertrochanteric fracture, tip-apex distance, cut-out, ADAPT System.

<https://doi.org/10.52965/001c.121094>

Orthopedic Reviews

Vol. 16, 2024

Introduction

Proximal femoral fractures (PFF) are a significant health concern among the elderly, often leading to complications and high mortality rates. Intramedullary nailing is widely considered the most effective treatment for lateral proximal femoral fractures (LPFF), with the Tip Apex Distance (TAD) being a crucial predictor of surgical success. This study aimed to compare outcomes between patients treated with and without the ADAPT (ADaptive Positioning Technology) system, which aids in the precise placement of the cephalic screw.

Materials and Methods

A retrospective analysis was conducted on 97 patients with intertrochanteric fractures treated in 2022. Patients were divided into two groups: those treated with the ADAPT system (group I, n=34) and those treated without it (group II, n=63). Fractures were classified according to AO/OTA classification. The primary outcomes measured were operative time, cephalic screw angle, TAD, and incidence of lag screw cut-out. Statistical analyses included chi-square tests and t-tests, with significance set at $P < 0.05$.

Results

The ADAPT system did not significantly reduce TAD (18.21 mm in the ADAPT group vs. 19.94 mm in the control group, $p=0.149$). Operative times were similar between the groups. The incidence of lag screw cut-out was low in both groups, with no significant differences. The study confirmed a strong correlation between higher TAD and increased risk of screw cut-out, underscoring the importance of precise screw placement.

Discussion

Computer-assisted surgery, such as the ADAPT system, aims to enhance the accuracy of cephalic screw placement. In this study, the ADAPT system didn't demonstrate a statistically significant advantage in reducing TAD or preventing screw cut-out. Nevertheless, the critical role of TAD in preventing fixation failure was reaffirmed, emphasising the need for precise surgical techniques.

Conclusion

While the ADAPT system did not show a significant advantage in reducing TAD or preventing screw cut-out in this study, the importance of achieving optimal TAD in cephalomedullary nailing was reinforced. Future research should continue to explore the role of computer-assisted systems in enhancing surgical accuracy and improving outcomes for patients with LPFF.

1. INTRODUCTION

Proximal femoral fractures (PFF) pose a formidable health challenge, representing one of the most common types of fracture in the elderly population¹: they have gained in-

creasing attention due to their association with age-related bone fragility and the growing aging population. As explored by Dhanwal et al. the epidemiology of hip fractures reflects a global diversity: genetic and environmental factors play a role in the etiology of hip fracture.² Understanding the etiology and finding predictable factors of different

types of hip fracture (femoral neck and trochanteric) can help with prevention and management.³

There have been ongoing discussions concerning optimal treatment of lateral proximal femoral fractures (LPFF): which one leads to the least amount of failures, quickest rehabilitation and, most importantly, lowest mortality. Intramedullary nailing is considered the most appropriate treatment option in LPFF.⁴ Literature considers different parameters in order to define which factors most influence the outcome of the surgery: on top of patient age and correct reduction of the fracture, but also failure of fixation due to cephalic screw cut-out is one of the most relevant factors.⁵ The correct positioning of the cephalic screw depends on 2 factors: the region of the femoral head where it is positioned in the antero-posterior (AP) and lateral view and the distance between the apex of the lag and the cortical of the femoral head. This latter parameter has been evaluated by Baumgartner et al, which defines it as the "tip apex distance" (TAD index) that represents the result of the sum of the distances between the apex of the nail and the external cortical in the AP and lateral view.⁶

TAD is the strongest predictor of a cut-out after intramedullary nailing in PLFF and the critical threshold is 25 mm.⁷ So, the ADAPT (ADaptive Positioning System) Stryker system (Stryker Leibinger GmbH & Co. KG, Freiburg, Germany) has been developed; it can intra-operatively calculate the TAD as well as the tip-surface distance, which is the 3D distance between the lag screw's tip and subchondral bone surface of the femoral head.

The ADAPT system is composed of a set of points of reference that are applied to the brilliance amplification device and to the external maniple of the Gamma nail (Stryker); this signal is then sent to an external device which uses an ad hoc software in order to determine the TAD index and the distance between the apex of the cephalic screw in the two view. It then suggests necessary adjustments to obtain a positioning within the optimal range.

The aim of this study was to compare the results obtained with the use of the ADAPT system with the results achieved in the patients where this system wasn't used.

2. MATERIALS AND METHODS

Our first approach to the surgical navigation platform goes back to the end of 2020 but we consider the period between January '22 and December '22 to mitigate bias related to the inability of the surgical team to fully use this system. A total of 97 patients with diagnosis of intertrochanteric fractures in 2022 were evaluated. A retrospective analysis was performed. We divided patients in two groups according to the osteosynthesis procedure: with (group I) or without (group II, control group) the Stryker ADAPT® system. Among the sample analysed, 34 patients were categorised under group I, 63 patients under group II. Orthopaedic Trauma Association (AO/OTA) fracture classification was used to evaluate fracture type: the fractures were grouped into classes 31A1, 31A2 and 31A3⁸ We included basicervical fractures (31B3) treated with cephalomedullary nail. The

treatment of basicervical femoral neck fractures remains a topic of interest and controversy. It is widely agreed that intramedullary fixation is more effective in preventing complications such as fixation failure.⁹ However, only few studies have focused on the outcomes of intramedullary nailing in treating basicervical fractures.^{10,11}

Two authors (G.G.M and S.C) independently collected data. Any discordance was resolved through consensus with a third author (L.C.). The study was conducted in a level -1 trauma centre and the surgery was performed by expert trauma surgeons (M.N., M.D.G., E.L.). All cases were operated on a fracture surgery traction table. In all patients the Gamma 3 (Stryker®) nail (170 length, 125° neck angle) was implanted, locked with a distal static screw. All the patients had antibiotic prophylaxis¹²; an urinary catheter was pre-operatively placed; postoperatively, anti-thrombotic stockings and low molecular weight heparin prophylaxis were used in order to avoid deep vein thrombosis; we collected pre and post-operative radiographies (AP pelvic view, AP and LL view of the affected hip) of all the patients.

We examined the operative time, the cephalic screw angle, the post operative cases of nail cut out and the use of the U-blade (Stryker®). It's a device occasionally applied to strengthen the lag screw and to avoid rotation of the femoral head over the femoral neck. As a main control criteria, we evaluated the tip apex distance (TAD) obtained. This value was calculated using the Baumgaertner's equation. When ADAPT was used, the system itself verified the TAD value.

We followed the patients for at least 1 year of follow-up. We performed postoperative x-rays, an x-rays at 1 month, 3 months, 6 months and a x-rays at 1 year after surgery.

Statistics were conducted using chi-square test to compare data between the two groups and t-student test for the continuous data. Data was processed by SPSS IBM software. Values of $P < 0.05$ were considered to be statistically significant.

3. RESULTS

3.1. DEMOGRAPHIC CHARACTERISTICS

We evaluated 97 patients, 18 (18.5%) were male and 79 (81.5%) were female. The mean age at diagnosis was 82.9 (standard deviation, σ 8.9) years. Concerning the type of fracture, 39 (40.2%) were classified as 31A1, 29 (29.9%) as 31A2, 12 (12.4%) as 31A3 and 17 (17.5%) were grouped into class 31B3. There were no significant differences in terms of type of fracture between two groups ($p=0.389$). Demographic and clinical data are presented in Table 1.

3.2. TREATMENT

Among the enrolled patients, 34 (35.1%) were treated with ADAPT System, 63 (64.9%) without it (control group). The mean age was 83.71 years (σ 8.062) in the ADAPT group and 82 years in the control group (σ 9.401), $p=0.373$.

Table 1. Demographic and Clinical Data

Adapt System	Gender	U-Blade	AO Classification	
				Basicervical fracture
Group 1	M=6 (17.1%) F=28(82.35%)	YES= 6 (18.1%) NO=27 (81.9%)	31A1=10 (29.4%) 31A2=11 (29.7%) 31A3=6 (17.6%) 31B3=7 (20.6%)	31B3=7 (21.2%) Others=27 (78.8%)
Group 2	M=12(19.1%) F=51(80.9%)	YES=9(12,7%) NO=55(87,3%)	31A1= 29 (46%) 31A2=18(28.6%) 31A3= 6 (9.5%) 31B3=10 (15.9%)	31B3=10 (25.9%) Others=53(84.1%)
Total	M=18 (18.5%) F=79 (81.5%)	YES=15 (15.5%) NO=82 (84.5%)	31A1=39 (40.2%) 31A2=29 (29.9%) 31A3= 12(12.4%) 31B3= 17(17.5%)	31B3=63(65%) Others=33(35%)
P-value	0.87	0.77	0.38	0.58

Table 2. Sample's features for continuous data. T-student analysis

	Number	Mean	Standard Deviation	Standard Error	P-Value
Age	Group 1=34 Group 2=63	Group 1=83.71 Group 2=82.00	Group 1=8.062 Group 2=9.401	Group 1=1.383 Group 2=1.184	0.373
Cephalic Screw Angle	Group 1=34 Group 2=63	Group 1=125.15 Group 2=125.24	Group 1=1.941 Group 2=1.663	Group 1=0.333 Group 2=0.209	0.809
TAD	Group 1=33 Group 2=63	Group 1=18.21 Group 2=19.94	Group 1=5.407 Group 2=5.570	Group 1=0.941 Group 2=0.702	0.149
TIN	Group 1=34 Group 2=63	Group 1=80.29 Group 2=70.65	Group 1=25.934 Group 2=26.735	Group 1=4.448 Group 2=3.368	0.090

The operative time was 48.88 min (σ 18.110) in the ADAPT group and 46.35 (σ 15.650) min in the control group ($p=0.09$)

The mean cephalic screw angle in the ADAPT group was 125.15° (σ 1.941), compared with 125.24° (σ 1.663) in the reference group treated without the ADAPT device, $p=0.809$.

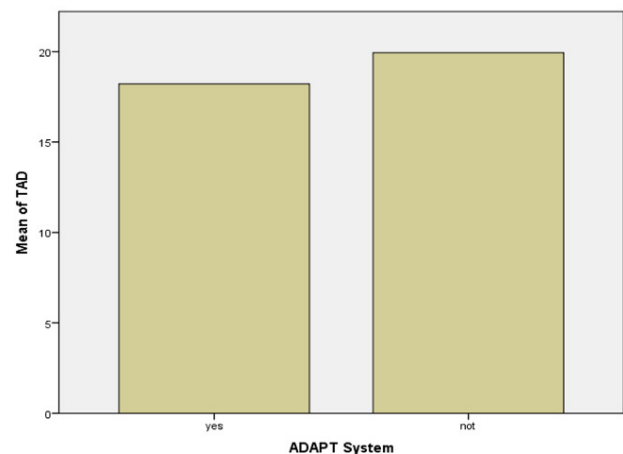
Regarding the TAD, it seems expected to be lower with the ADAPT system. TAD was 18.21mm (σ 5.407) in the ADAPT group and 19.94mm (σ 5.570) in the control group ($p=0.149$) as resumed in Table 2.

Thus, the ADAPT group didn't benefit from a statistically significant reduction of the TAD compared to the control group: T-student test proved it (Figure 1).

In a second phase of our analysis, we reported that 5 patients (5.15%) suffered from cut-out of lag screw, only one of them treated with ADAPT system ($p=0.47$).

16 patients (16.49%) underwent internal fixation using the U-Blade lag screw: we observed cut out in only one of them (6.25%). There were no significant differences with a p -value = 0.32 (Table 3).

The mean TAD was 18.9mm in the group of 92 patients (94.85%) without any mobilisation of lag screw (standard deviation, σ 5.190) and 27.40mm (standard deviation, σ 6.269) in the group of 5 patients who suffered from cut-out of lag screw. As shown in Table 4, a statistically significant difference was found between these groups ($p=0.037$).

**Figure 1. T-student test**

4. DISCUSSION

In recent years computer-assisted orthopaedics surgery has increased. The better efficiency and accuracy in device positioning leads to less failures of the implants and consequently second revision surgeries.¹³

Computer-assisted surgery has also been employed in femur traumatology as well. Our study aimed to show the impact of the ADAPT system in the surgical treatment of

Table 3.

Cut-out	Group	U-Blade	Ao Classification	
				Basicervical fracture
YES	Group 1= n.1 Group 2= n.4	Yes = n.1 Not= n.5	31A1 = 10 31A2 = 11 31A3 = 6 31B3 = 7	31B3= 1 Others= 4
NO	Group 1= n.33 Group 2= n.59	Yes = n.15 Not= n.76	31A1 = 38 31A2 = 26 31A3 = 12 31B3 = 16	31B3=16 Others=75
P-Value	0.47	0.32	0.42	0.89

Table 4.

Cut-off	Number	Mean	Standard Deviation	Standard Error	P-Value
Age	CoN=92 CoY=5	CoN=82.54 CoY=83.60	CoN=9.163 CoY=3.286	CoN=0.955 CoY=1.470	0.563
Cephalic Screw Angle	CoN=92 CoY=5	CoN=125.27 CoY=124.00	CoN=1.717 CoY=2.236	CoN=0.179 CoY=1.000	0.275
TIN	CoN=92 CoY=5	CoN=46.35 CoY=48.88	CoN=15.650 CoY=18.110	CoN=1.973 CoY=3.107	0.494
TAD	CoN=91 CoY=5	CoN=18.90 CoY=27.40	CoN=5.190 CoY=6.269	CoN=0.544 CoY=2.804	0.037

CoN= cut-out No

CoY=cut-out Yes

proximal femoral fractures. ADAPT system aims to help the surgeon to reduce the risk of misplacement of the lag screw.

The safety margin established by Baumgaertner et al.⁶ is correlated to the biomechanics of the hip and the transmission of forces from the load-bearing zone along the force lines of Ward, avoiding overloading of peripheral cephalic regions. Right at the base of the femoral neck, where Ward's triangle is situated, there are particularly intense forces of flexing strain, the degree of which is related to the length of the neck.¹⁴

Pervez H et al reported that the ideal measurement is 5mm < TAD < 20mm,¹⁵ Herman A et al and Hsueh KK et al reported that inferior-centre placement of lag screw is best although TAD is greater than 25mm.^{16,17} As Takai et al noticed in their study, TAD in the case of inferior-centre positioning is larger than that centre-centre positioning because the distance from the tip of the lag screw to the axis of the femoral neck is obviously longer in inferior-centre positioning.¹⁸ Baumgaertner MR et al and Galanakis IA et al claim that the centre-centre position of the lag screw is better.^{7,19}

The critical nature of TAD underscores the broader importance of precision in cephalomedullary nailing. Our data correlates with the literature, indicating that the placement of the lag screw must be as accurate as possible within the quadrants defined by Park et al.,²⁰ and its length carefully selected to prevent varus displacement of the femoral neck and migration of the screw itself.

In the literature It's still controversial if a higher TAD is a major risk of lag screw cut-out.

Andruszkow H et al and Geller JA et al support that increased TAD is one of the strongest predictors of failure of the osteosynthesis due to cut-out.^{21,22}

Our analysis reveals a strong correlation between the TAD and the incidence of cut-out. We found 5 patients who suffered from lag screw cut out (5.15%) with a mean TAD of 27.40mm; on the other side we reported a mean TAD of 18.9mm in the group of 92 patients (94.85%) without any mobilisation of lag screw.

As Kang et al reported in their study, mechanical instability of the lag screw could contribute to screw migration and consequent fixation failure.²³ The U-blade gamma nail has a screw-blade hybrid type device. Kwak et al. reported that the rotational stability of the proximal fragment was greater with the hip screw type than with the blade type and hybrid type in a biomechanical study.²⁴ We reported that 16 patients (16.49%) underwent internal fixation using the U-Blade lag screw: we observed cut out in only one of them (6.25%) although there were no significant differences.

In our series, the majority of patients were treated with nails with a cervicodiaphyseal angle of 125°, achieving often an optimal TAD. The mean cephalic screw angle in the ADAPT group was 125.15°, compared with 125.24° in the reference group treated without the ADAPT device.

The ADAPT system doesn't demonstrate a concrete advantage in our study regarding TAD and lag screw cut-out. TAD was 18.21mm (σ 5.407) in the ADAPT group and 19.94mm (σ 5.570) in the control group. Even if only one

patient treated with ADAPT system suffered from lag-screw cut out, it's not statistically significant ($p=0.47$)

In our study, in terms of intraoperative time, ADAPT System doesn't modify surgical time. Atesok K et al sustain that the disadvantages of computer-assisted trauma include a time-consuming to set up and an increased operating time.¹³ In our analysis the operative time was 48.88 (σ 18.110) min in the ADAPT group and 46.35 (σ 15.650) min in the control group ($p=0.09$).

The limitations of our study are represented by its retrospective nature and bias in patients recruitment. Unfortunately we also have lack of data on patients' bone quality. Moreover, our study doesn't consider radiation dose time. The literature argues that the ADAPT system reduces radiation exposure.^{25,26}

5. CONCLUSION

While the ADAPT system didn't exhibit advantages in our comparative analysis, the highlighted correlation underscores the fundamental importance of achieving optimal TAD in cephalomedullary nailing that the ADAPT System

ensures. As orthopaedic surgery continues to evolve, these insights pave the way for refined techniques and further exploration of computer-assisted systems to enhance precision and improve patient outcomes.

Our study reveals a strong correlation between the Tip Apex Distance (TAD) and the incidence of cut-out if LPFF.

It must be shown in further studies if it will lead to a decrease in postoperative complications and reduction of cut-out rate, but our results are promising and indicative of potentially improved surgical outcomes.

CONFLICTS OF INTEREST

Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article.

Submitted: June 20, 2024 EST, Accepted: July 03, 2024 EST

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