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Optimising the tip-apex-distance in trochanteric femoral fracture fixation using the ADAPT-navigated technique, a longitudinal matched cohort study

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ABSTRACT

Introduction: The annual incidence of proximal femoral fractures is 100–150/100,000 and continues to increase with an aging population. Cut-out of hip screws after fracture fixation has been quoted as 8% in the literature. The tip-apex distance (TAD) is the strongest predictor for cut-out after operative fracture stabilisation.
The aim of this study was to evaluate the novel ADAPT system (Adaptive Positioning Technology, Stryker, USA), a navigation device for intramedullary nailing of trochanteric fractures and its effect on optimising the TAD. This is the first clinical study to evaluate this new technology.
Methods: The study group of 36 consecutive patients with a pertrochanteric fracture underwent intramedullary nailing for fracture fixation using ADAPT technology, while the matched control group underwent conventional Gamma-3-nailing. Matching criteria included fracture classification, gender and age. We measured the operative time and the postoperative TAD in anteroposterior (AP) and lateral radiographs of the 72 patients.
Results: The mean TAD using ADAPT was 16.9 mm (range 8.4–33.7 mm) compared with 24.9 mm (range 14.6–40.2 mm) in the reference group treated without ADAPT. Using the ADAPT system significantly improved ($p < 0.0005$) the accuracy of lag screw placement but had no effect on operating time in fixation of femoral pertrochanteric fractures.
Conclusion: Working with the novel ADAPT system for positioning the lag screw using the Gamma-3-nail led to a statistically highly significant reduction of the TAD compared to the reference group ($p < 0.001$). The ADAPT system proved to be a very useful device in achieving higher surgical standards for the treatment of trochanteric fractures with intramedullary nailing. It enables higher accuracy in screw positioning and therefore better placement of the implant.

Introduction

Proximal femoral fractures are among the most common type of fractures requiring surgical intervention with an incidence of 100–150/100,000 worldwide resulting in a significant socio-economic burden in an ageing population [1]. Failure of fixation attributable to screw cut-out has an incidence rate of 8% [2–4].

The TAD is the strongest predictor of a cut-out after extramedullary and intramedullary stabilisation in intertrochanteric fractures, where the critical threshold is 25 mm [5–7]. However, there are also other factors that affect cut-out rate. A fracture reduction with an increased neck-shaft angle of 5-10° leads to a lower cut-out rate. Moreover, central-posterior placement of the hip screw in the lateral radiograph and a central inferior position in the AP view reduces the risk of cut out [8–11], while an anterior placement of the screw increases cut-out incidence [5].

The ADAPT-technology provides three-dimensional (3D) information based on two-dimensional (2D) fluoroscopic images

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[12,13]. The system (Fig. 1) is connected to a conventional C-arm by video cable. In order to correct the distortion in the C-arm images, a radiolucent disc that contains a defined pattern of metallic markers is attached to the image intensifier (named fluorodisc, Fig. 2) by velcro. A reference clip, which also contains metallic markers, is mounted to the targeting device (Fig. 3) of the implant and provides the system with spatial information. This enables the system to calculate a virtual 3D reconstruction of the femoral head without additional invasive markers or radiation. It automatically detects the used implant and its position relative to the femoral head. Thus, it helps the surgeon achieve the optimum lag screw position in the femoral head with the end point of screw insertion still being determined by guide wire position and the operating surgeon. A screenshot sequence of AP and lateral views using ADAPT is shown in Fig. 4. The final implant position calculation is shown in Fig. 5. The system offers the benefits of classical computer assisted surgery without any of the typical drawbacks like preoperative CT, invasive tracker fixation, instrument calibration, or patient registration. 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 aim of this study was to evaluate whether the use of the fluoroscopy-based 3D-navigation system ADAPT yields a smaller, optimised TAD.

Fig. 1. ADAPT-System.

Fig. 2. Fluorodisc attached to image intensifier by Velcro/.

Material and methods

A retrospective analysis was performed of 72 patients with trochanteric fractures who were treated with intramedullary stabilization using the Gamma-3-nail (Stryker, Mahwah, New Jersey, USA) at a level 1 trauma centre. The study group of 36 consecutive patients was treated using the ADAPT system.

A control group of 36 patients with trochanteric fractures treated with the Gamma-3-nail was matched using fracture classification (Müllers AO-classification for long bones [14]), including only 31 A.1–31 A.3 type fractures, gender and age at the date of surgery in that order out of our database of all 157 trochanteric fractures treated with Gamma-3-nail (Table 1). ERB Board approval was granted (No. AZ09-051).

There were no pathological fractures included in this study. No patients were excluded based on age or comorbidities.

Fig. 3. ADAPT-Clip mounted on standard Gamma-3-nail targeting device.

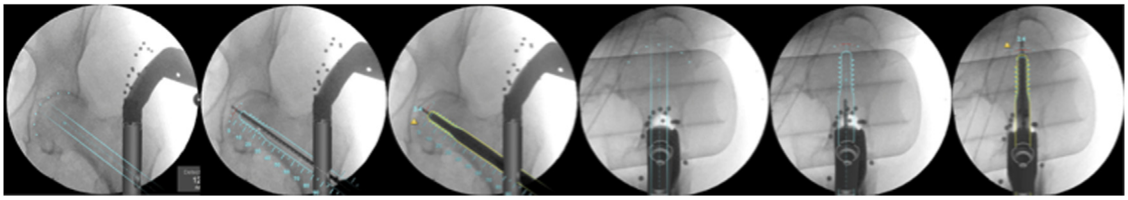

Fig. 4. Intraoperative screenshot sequence ap and lateral using ADAPT-technology.

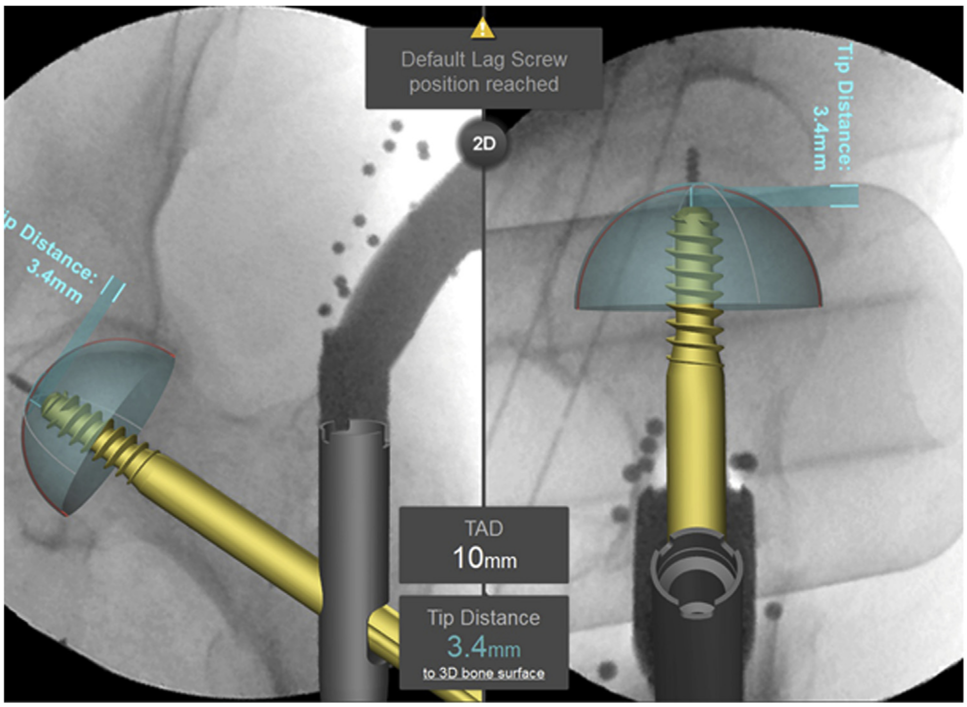

Fig. 5. Final screenshot showing lag screw position as 3D-calculation, indicating Tip Apex Distance and Tip Surface Distance in both, ap. and lateral plane. TAD calculated as 10 mm, Tip Surface Distance (TSD) 3,4 mm.

All 72 patients were treated with a Gamma-3-nail, using nails ranging from 180 mm to 440 mm (180 mm to 440 mm in the ADAPT group and 180 mm to 380 mm in the reference group). Patients were operated on by a team of five consultant trauma surgeons, either by the consultant surgeon himself or a surgical trainee, under direct consultant supervision.

There were no changes in technique between the ADAPT and the control group. The ADAPT-system solely provided additional 3D information to support the surgeon's way of proceeding.

The general approach in placing the lag screw was to aim for a position slightly inferior in the centre of the femoral head and neck. This approach remained unchanged in both groups.

The position of the hip screw was assessed, analysing postoperative radiographs in AP and lateral views in all 72 patients, and then TAD of the hip screw was determined as described by Baumgaertner et al. [6]. The TAD was defined as the sum of the distance in millimetres from the tip of the lag screw to the apex of the femoral head, as measured in an AP radiograph (named Xap), and that same distance as measured in a lateral radiograph (named Xlat), after correction has been made for magnification (Fig. 6). The apex of the femoral head was defined as the point of intersection between the subchondral bone and a line in the centre of and parallel to the femoral neck [6]. TAD was then compared between the two groups.

The two parameters Xap and Xlat (after correction has been made for magnification) were individually compared to see whether or not there was an advantage or disadvantage of the ADAPT-system in one of the two planes, specifically compared with the conventional surgical method without ADAPT.

In a subgroup analysis, the operating time was measured to determine whether or not using the ADAPT system has an impact on the operation time. For this purpose, the "knife to skin" to "end of suture" time was used, which was electronically documented for every procedure. Only cases were included where a standard nail (180–200 mm length) with instrumented distal locking was used. There were 28 patients in the ADAPT group and 26 patients in the reference group that underwent intramedullary nailing with the standard (180 mm or 200 mm length) nail.

Statistics

Based on TAD measurements of patients treated conventionally with the Gamma-3-nail before the ADAPT system was installed (23.7 ± 6.5 mm, $n = 20$) and a hypothesized reduction of the TAD with the use of the ADAPT system of 5 mm we calculated a required sample size of 28 patients per treatment group (significance level of $\alpha = 0.05$ and statistical power of 0.8). Allowing for an uncertainty

Table 1
Matched cohorts, using Fracture Classification, Gender and Age at Surgery.

	ADAPT Group					Matched Control Group				
	AO-Classification	Gender	Age	Implant Length in mm	OP-Time in min	AO-Classification	Gender	Age	Implant Length in mm	OP-Time in min
1	31-A.1	female	86	180	69	31-A.1	female	80	180	55
2	31-A.1	female	88	180	55	31-A.1	female	88	180	30
3	31-A.1	female	78	(380)	(75)	31-A.1	female	65	180	41
4	31-A.1	female	88	180	46	31-A.1	female	83	180	75
5	31-A.1	male	39	200	57	31-A.1	male	60	180	40
6	31-A.1	female	75	180	49	31-A.1	female	86	180	62
7	31-A.1	female	73	200	91	31-A.1	female	75	180	70
8	31-A.1	male	76	180	62	31-A.1	female	93	180	56
9	31-A.1	female	81	200	24	31-A.1	female	78	180	36
10	31-A.1	male	84	180	18	31-A.1	male	82	180	55
11	31-A.1	male	71	200	54	31-A.1	male	71	180	44
12	31-A.1	female	88	180	30	31-A.1	female	89	180	37
13	31-A.1	female	83	180	45	31-A.1	female	74	180	50
14	31-A.1	female	94	180	55	31-A.1	female	63	(360)	(33)
15	31-A.1	female	65	180	47	31-A.1	female	88	180	43
16	31-A.1	female	63	180	54	31-A.1	male	75	180	57
17	31-A.2	male	56	200	25	31-A.2	female	83	(320)	(89)
18	31-A.2	female	84	180	73	31-A.2	female	84	180	59
19	31-A.2	female	56	180	71	31-A.2	male	58	180	50
20	31-A.2	female	73	200	44	31-A.2	female	88	(360)	(138)
21	31-A.2	male	73	(280)	(94)	31-A.2	female	60	180	85
22	31-A.2	female	90	(280)	(44)	31-A.2	female	93	180	55
23	31-A.2	female	96	180	63	31-A.2	female	83	(320)	(87)
24	31-A.2	female	85	(320)	(155)	31-A.2	female	84	180	65
25	31-A.2	female	88	(240)	(85)	31-A.2	female	88	180	35
26	31-A.2	female	83	180	40	31-A.2	female	91	(360)	(70)
27	31-A.2	female	53	(260)	(243)	31-A.2	female	73	180	54
28	31-A.2	female	91	180	38	31-A.2	male	74	(380)	(80)
29	31-A.2	female	83	200	33	31-A.2	female	91	180	47
30	31-A.2	female	92	180	55	31-A.2	female	85	180	60
31	31-A.2	female	88	180	72	31-A.2	male	72	180	50
32	31-A.2	female	91	180	21	31-A.2	female	89	180	99
33	31-A.2	male	71	180	39	31-A.2	female	61	(280)	(82)
34	31-A.2	female	83	200	33	31-A.2	female	98	(320)	(48)
35	31-A.3	female	74	(320)	(154)	31-A.3	male	67	(320)	(100)
36	31-A.3	male	79	(440)	(143)	31-A.3	female	82	(320)	(51)
Σ	16xA.1,18xA.2,2xA.3	f/m = 28/8	78		49	16xA.1,18xA.2,2xA.3	f/m = 28/8	79		54

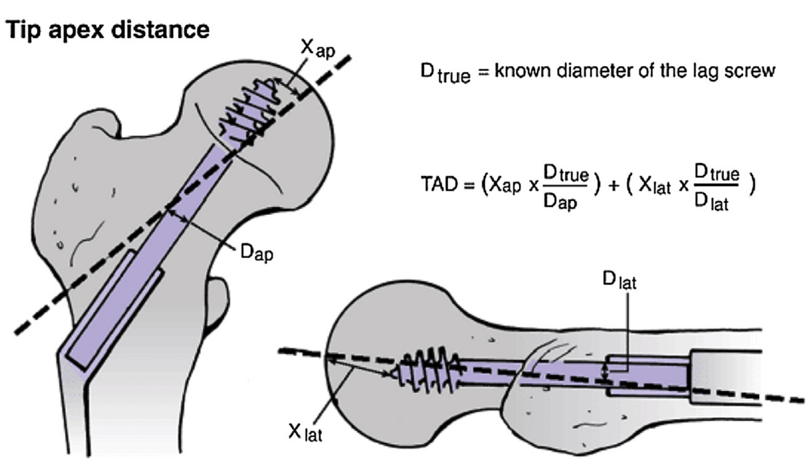

Fig. 6. Calculation of the tip-apex-distance using ap. and lateral radiographs (after Baumgaertner, 1995, JBJS [6]).

and possible dropouts we increased the number of patients by 30%–36 patients per group.

Normal distribution of the data (TAD, Xap, Xlat of the ADAPT (n = 36) and the reference group (n = 36); OP-time of the subgroups with standard nail length (ADAPT: n = 28; reference: n = 26)) was assured with the One-Sample Kolmogorov-Smirnov Test before the data was analysed using independent samples, two-tailed t-test. The level of significance was set to $\alpha = 0.05$ for all tests.

Results

All 72 patients were classified as AO 31-A-fracture with 32 fractures being 31-A.1, 36 fractures 31-A.2 and four fractures 31-A.3 showing equal distribution in both groups. Both the study and control groups consisted of 28 women and 8 men. The mean age was 79 years (standard deviation, SD ± 11.78) with the mean age in the ADAPT group being 78 years (SD ± 12.83) and 79 years (SD ± 10.80) in the reference group (Table 1).

The mean TAD in the ADAPT group was 16.9 mm, ranging from 8.4 mm to 33.7 mm (+/- 6.30), compared with 24.9 mm in the reference group treated without the ADAPT device, where the range was from 14.6 mm to 40.2 mm (+/- 6.68) (Fig. 7). Thus, the ADAPT group benefitted from a highly significant reduction of the TAD, compared to the reference group ($p < 0.001$).

The analysis of the individual parameters Xap and Xlat revealed a mean Xap of 8.1 mm in the ADAPT group compared to 11.7 mm in the reference group (Fig. 8), and a mean Xlat (in the lateral radiograph) of 8.8 mm in the ADAPT group compared to 13.2 mm in the reference group (Fig. 9). The difference between the two groups was shown to be statistically significant ($p < 0.001$ for Xap and $p < 0.001$ for Xlat).

For the standard nail (180 mm or 200 mm, n = 54), a mean operating time of 49 min (SD ± 18) in the ADAPT group (n = 28) compared to 54 min ± 16 min in the reference group (n = 26) was observed. No statistically significant difference was found between these groups ($p = 0.231$).

Discussion

The importance of correctly positioning the lag screw within the femoral head has been well demonstrated in the current literature. Several factors have been revealed to predict failure of intra- or extramedullary osteosynthesis of trochanteric fractures, such as an increased age of patient, an unstable fracture pattern and an anterior position of the hip screw in the femoral head [5], whereas placement in the centre-centre zone was found to be a negative predictor for failure of the osteosynthesis [5]. Most authors therefore have favoured a centre-centre position [15–27] or an inferior position [10,13,28–33], and biomechanical studies have further supported the use of these positions [34,35]

Most importantly, however, an increased TAD was found to be the strongest predictor ($p < 0.001$) of failure of the osteosynthesis due to cut-out, with a tolerable threshold of 25 mm [5–7].

Several factors have been identified as influencing and predicting successful treatment for trochanteric fractures using intramedullary nailing. It is key for surgeons to consider these factors in order to achieve the best possible results. However, in clinical practice, it appears to be hard to anticipate the outcome of

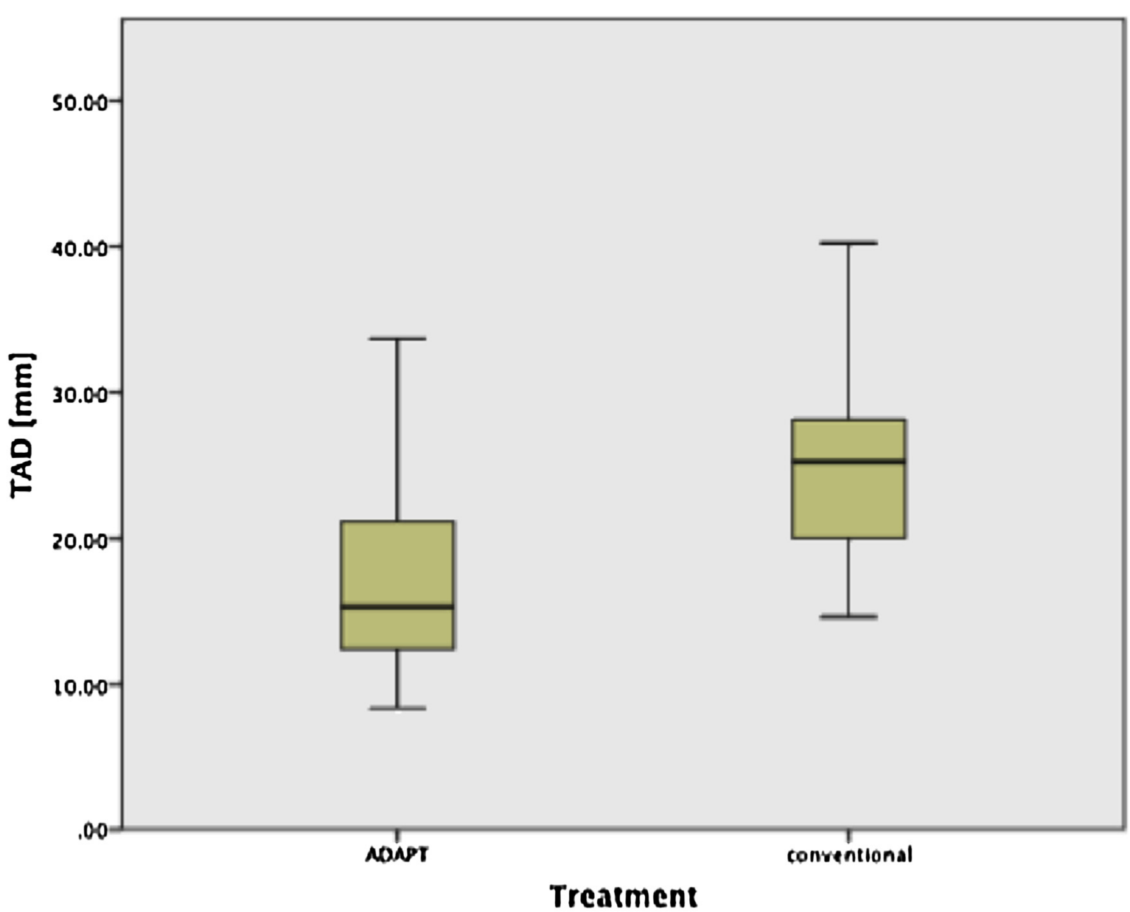

Fig. 7. Mean TAD ADAPT vs. Conventional, box plot.

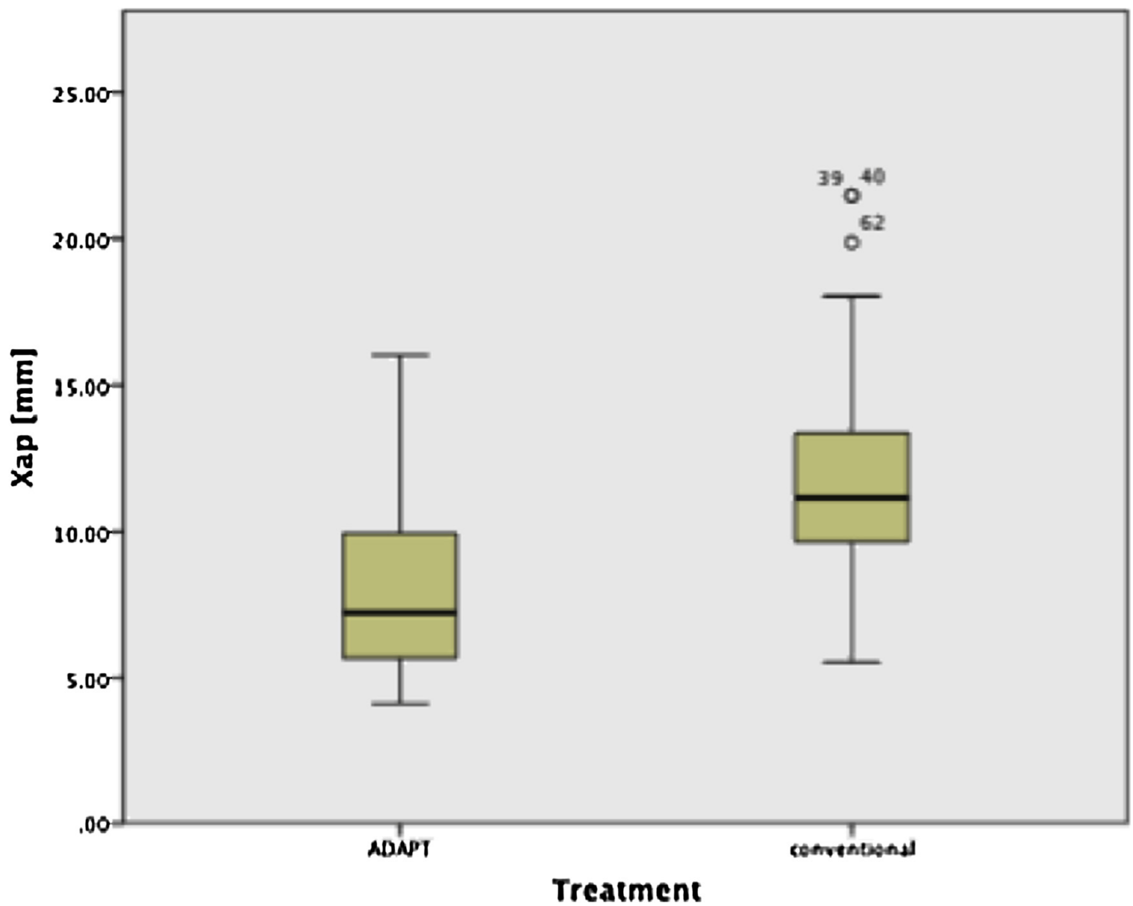

Fig. 8. Mean Xap ADAPT vs. Conventional, box plot.

the expected lag screw position, as operating technique and surgical set-up leave surgeons with only two-dimensional fluoroscopic views at the area of interest.

Although the ADAPT system has shown superior results compared to conventional implantation in cadaveric studies [36], this is the first trial reporting in-vivo data. This study shows that the new ADAPT-positioning technology is a useful device to achieve higher surgical standards and improve the outcome by supplying a 3D view of the neck of the femur, the femoral head and guiding the screw insertion while placing the screw into the femoral head, without changing the operative procedure itself. There was a significant reduction of the TAD, which is the strongest predictor for postoperative failure of osteosynthesis due to cut-out.

It was shown that, especially in the lateral view (which from a surgeon's point of view is harder to estimate in the conventional technique), using ADAPT is superior to conventional fluoroscopy as it allows a 3D view of the area of interest. ADAPT is therefore a useful additional tool to improve surgical performance.

This study has also demonstrated that there is no statistically significant difference in operating time with the ADAPT system when using standard length nails. This was in line with findings from a previous cadaveric study [36].

However, there are some limitations to this study, which should be mentioned. Operating time has been recorded as cut to suture time with no statistical difference revealed but the ADAPT system requires approximately 5 min of set up time in the preoperative setting. This was not recorded in this study.

In addition, analysis of the fluoroscopy time would have been desirable but could not be performed due to incomplete documentation.

Also, we are aware that a prospective randomised study design would have been favourable to a retrospective design with a matched reference sample. The use of a complete new technology without previous experience demanded a retrospective design but this will be considered for further trials.

With a mean TAD of 24.9 mm in our matched reference group, we represent the expected mean TAD shown in previous literature using intra- or extramedullary devices for treatment of trochanteric fractures without use of a navigation device in conventional technique under C-arm guidance. Baumgaertner et al. reported a mean TAD of 25 mm (198 cases) [6], Andruszkow et al. 19.7 mm (226 cases) [5], Sedighi et al. 23.5 mm (100 cases) [1],Geller at al. 20 mm (82 cases) [7] and Kraus et al. 26,7 mm (195 cases) [37].

In conclusion, using Stryker's ADAPT system for positioning the lag screw using the Gamma-3-nail led to a statistically highly significant reduction of the TAD compared to the reference group ($p < 0.001$).

We believe ADAPT to be a very useful device to achieve higher surgical standards for the treatment of trochanteric fractures with intramedullary nailing. There is a statistically significant decrease of the TAD. Especially in the lateral plane, it enables us to achieve higher accuracy in screw positioning and therefore better placement of the implant. As this system is currently not available for extramedullary treatment or intramedullary implants with two hip screws, we cannot conclude about results with such devices.

It will have to be shown in further follow up studies if this 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.

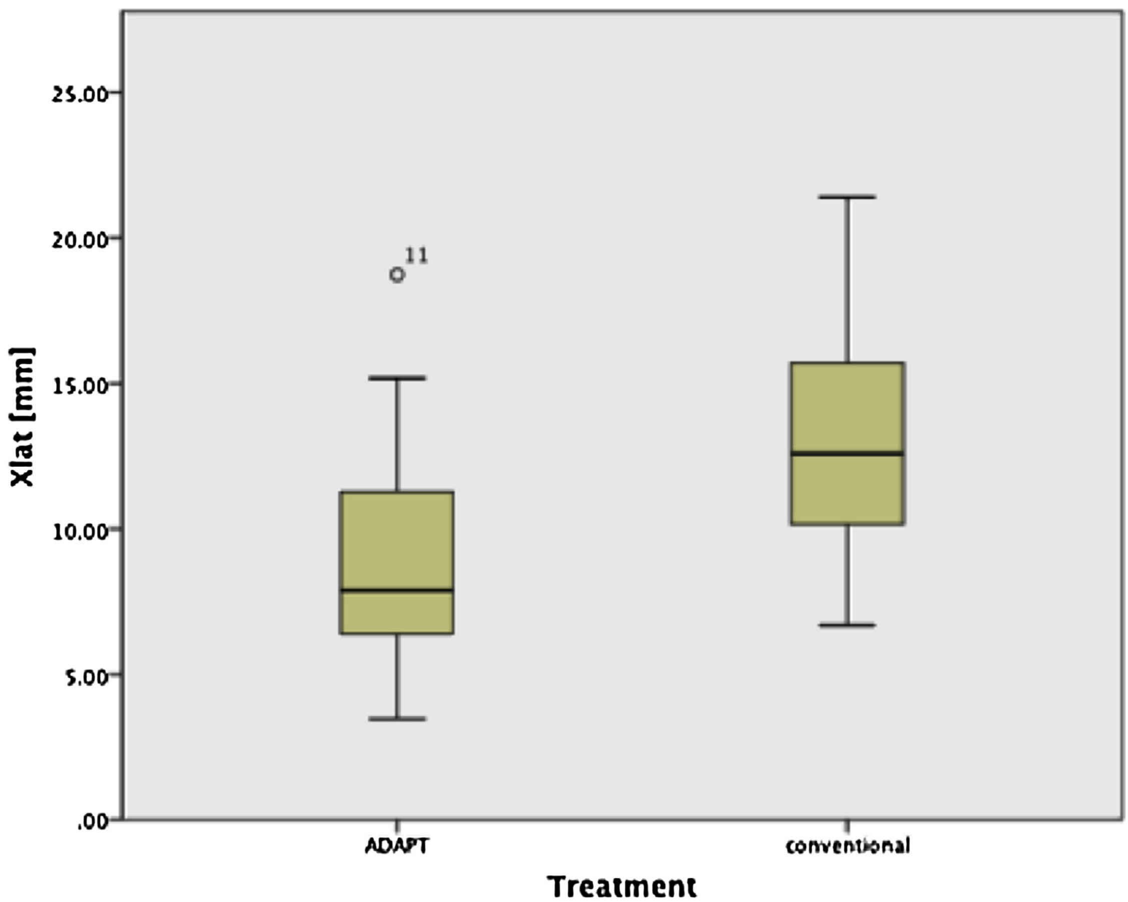

Fig. 9. Mean Xlat ADAPT vs. Conventional, box plot.

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