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ADAPT System Assisted Gamma Nails Internal Fixation Versus Conventional Gamma Nails Internal Fixation for Intertrochanteric Fractures: A Systematic Review and Meta- Analysis

Jiang Xiaole[1], Lin Dongze[1], Lin Chaohui[2], Chen Peisheng[2], Zheng Ke[2], Liu Jiajie[3] and Lin Fengfei[1]*

[1]*Department of Orthopaedics, Fuzhou Second General Hospital, Fujian Provincial Clinical Medical Research Center for First Aid and Rehabilitation in Orthopedic Trauma, China*

[2]*School of Clinical Medicine, Fujian Medical University, China*

***Corresponding author:** Lin Fengfei, Department of Orthopaedics, Fuzhou Second General Hospital, Fujian Provincial Clinical Medical Research Center for First Aid and Rehabilitation in Orthopedic Trauma, Fuzhou 350007, China

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ABSTRACT

Purpose: The purpose was to compare the efficacy of ADAPT system-assisted gamma nail internal fixation with conventional gamma nail internal fixation in the treatment of intertrochanteric fractures.

Materials and Methods: A systematic literature search was conducted in December 2023 using three databases: PubMed, Embase and Web of Science. The language was limited to English. A meta-analysis was performed using RevMan 5.4 software provided by the International Cochrane Group to compare perioperative outcomes between ADAPT system-assisted gamma nailing internal fixation and conventional gamma nailing internal fixation: operative time, intraoperative fluoroscopy time, tip distance, and tip-to-cephalad distance.

Results: Seven studies involving 548 patients were included. Primary outcome indicators: Intraoperative fluoroscopy time was shorter in the ADAPT system group compared with the conventional approach group. The difference in operative time between the two groups was not statistically significant. Secondary outcome indicators: The ADAPT system group had a smaller tip distance compared to the traditional approach group. ADAPT accurately measured the tip-to- surface distance (TSD).

Conclusion: Compared to traditional gamma nail internal fixation for intertrochanteric fractures, the ADAPT system reduces X-ray exposure to healthcare professionals and helps patients achieve better outcomes. Therefore, ADAPT system-assisted gamma nail internal fixation is a preferable choice for the treatment of intertrochanteric fractures.

Keywords: Intertrochanteric Hip Fractures; ADAPTS; Systematic Review and Meta-Analysis

Abbreviations: TSD: Total Screw Displacement; TAD: Tip-Apex Distance; WMD: Weighted Mean Differences; CI: Confidence Intervals; OR: Odds Ratios; NOS: Newcastle- Ottawa Scale; RCTs: Randomized Controlled Trials; CCTs: Comparative Controlled Trials; PCSs: Prospective Cohort Studies; PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses; CAS: Computer-Assisted Surgery: MSH: Medical Subject Headings

Introduction

Intertrochanteric femoral fracture is the most common type of hip fracture in clinical practice. especially among elderly patients. [1,2] Global projections indicate a rising trend in the total number of intertrochanteric femur fractures, posing challenges to medical care systems. Currently, most scholars believe that unstable fractures are more inclined to be fixed with intramedullary nails [3]. Gamma nail internal fixation is one of the commonly used surgical treatment modalities for intertrochanteric fractures of the femur [4]. Due to the advantages of minimally invasive, less bleeding, and reliable fixation, it has become a common method of internal fixation involving unstable

intertrochanteric femoral fractures [5]. The management of intertrochanteric femoral fractures is continuously evolving to meet the demands of efficacy and awareness of the disease [6,7]. In recent years, navigation systems have become increasingly available and their use in orthopedic surgery is becoming more and more important. Computer-assisted surgery (CAS) has been evolving since the early 1990s, and over the past 30 years, CAS technology has been applied in the fields of arthroplasty, spine surgery, oncologic surgery, and trauma surgery [8]. This computer-assisted surgical system has made a significant advance in the field of surgery. This computer-assisted surgical system has been described in detail in previously published cadaveric studies [9].

While traditional intramedullary nailing surgery requires precise preoperative planning and hardware placement, this computer- assisted system helps orthopedic surgeons to navigate and position the nails during the procedure, thereby improving the safety of the procedure and reducing the complication rate, and increasing the precision of the procedure [10]. The ADAPT system is a computerized navigation system used to assist surgeons in operating on proximal femoral fractures using the Stryker Gamma3 coarse augmentation nails. ADAPT was developed to improve the positioning of intramedullary nails. ADAPT is capable of displaying the distance from the tip of the screw to the surface of the femoral head intraoperatively, such as the tip-apical distance (TAD) as proposed by Baumgaertner et al. [11] TSD is the original concept of ADAPT, which estimates the position of the screw in three dimensions [12]. As a result, more and more orthopedic surgeons are accepting it [13]. There is evidence-based evidence comparing conventional Gamma nail internal fixation with ADAPT system-assisted Gamma nail internal fixation for intertrochanteric femoral fractures. However, the important metric of TSD was not included in the analysis as well as some of the included metrics were not further analyzed. We performed this meta-analysis to explore the clinical outcomes of traditional manipulation and ADAPT system-assisted Gamma nail internal fixation for intertrochanteric femoral fractures based on previous articles.

Materials and Methods

This study adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. The research protocol for this study was registered with PROSPERO (CRD42024501479).

Search Strategy and Eligibility Criteria

We searched Embase, PubMed, Web of Science, and the search period from build to January 2024. We used the PubMed search strategy as an example, combining Medical Subject Headings (MSH) subject terms and free words: ((“Hip Fractures” [Mesh]) OR (((((Intertrochanteric Fractures) OR (Trochanteric Fractures)) OR (Intertrochanteric Hip Fractures)) OR (extracapsular hip fracture)) OR (peritrochanteric fracture))) AND ((((((“Surgery, Computer-Assisted”[Mesh]) OR (Computer Assisted Surgery)) OR (computer aided surgery)) OR (image guided surgery)) OR (Surgical Navigation)) OR (Navigation, Surgical))

Inclusion and Exclusion Criteria

The inclusion criteria were as follows:

1. Participants All patients were definitively diagnosed with intertrochanteric femoral fractures.
2. Interventions The experimental group used the ADAPT system to assist internal fixation with Gamma nails.
3. The control group was internally fixed with conventional Gamma nails.
4. Outcomes were reported for at least one of the following outcome metrics: operative time, intraoperative fluoroscopy time, TAD, TSD.
5. Study design: Randomized controlled trials (RCTs), retrospective comparative controlled trials (CCTs) and prospective cohort studies (PCSs) were included.

Exclusion Criteria

Duplicate publications, case reports, letters, reviews, conference abstracts, studies from which data could not be extracted, non-human and physical experimental studies, systematic evaluations and meta-analyses, excluding femoral neck fractures.

Data Extraction

Two reviewers, Lin Dongze and Chen Peisheng, screened all the literature according to the inclusion and exclusion criteria. The following information was extracted independently by 2 evaluators: authors, year of publication, study design, mean age, sex, type of fracture and duration of follow-up, quality assessment results, and general information on outcomes. The primary outcome indicators included in the study were: time to surgery and time to radiation. Secondary outcome indicators include TAD, TSD. Another investigator will resolve any disagreements.

Quality Assessment

RCT risk of bias was assessed by two reviewers, Lin Dongze and Chen Peisheng, respectively, according to the Cochrane Collaboration Tool. The Cochrane Collaboration Tool has seven domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete results, selective reporting of results and other sources of bias. Each domain was categorized as low, high, and unclear risk of bias. The Newcastle- Ottawa Scale (NOS) was used to assess the quality of the included non-randomized controlled trials (non-RCTs). The assessment scale consists of 3 domains: selection of study groups, comparability and exposure (case-control studies), or outcome (cohort studies). 1 star

indicates a score of 1 out of a total of up to 9 points. Total scores of 0-3, 4-6, and 7-9 are categorized as low, medium, or high quality.

Statistical Analysis

Statistical analyses were performed using Review Manager 5.4 (Cochrane Collaboration, Oxford, UK) and STATA 12.0 (Stata Corp LP, College Station, Texas). Odds ratios (OR) and 95% confidence intervals (CI) were used for comparison of binary variables. Weighted mean differences (WMD) and 95% CIs were calculated for continuous outcomes. Median and interquartile ranges of continuous data were converted to means and standard deviations according to the method described by Wan et al. All meta-analyses were tested for heterogeneity using Cochrane Q p-values and I^2 statistics. When the p-value was <0.05 or I^2 >50%, heterogeneity was significant and the results were combined using a random effects model. Otherwise, a fixed-effects model was used. p-values less than 0.05 were considered statistically significant. We performed the egger test to assess publication bias (only for results that included 10 or more studies).

Overview of Search Results

A total of 2236 documents were retrieved by searching the 3 databases, and 226 duplicates were excluded using Endnote20 software. Titles and abstracts were read to exclude 1594 irrelevant studies. The full texts of 27 literatures were read carefully. Four literatures were excluded due to in vitro studies, four literatures were excluded due to physical research experiments, five literatures were excluded due to unavailability of data extraction, nine did not use the ADAPT system, and finally seven literatures were included in this study. Information about the search process is presented in Figure 1. This study followed the PRISMA 2009 checklist.

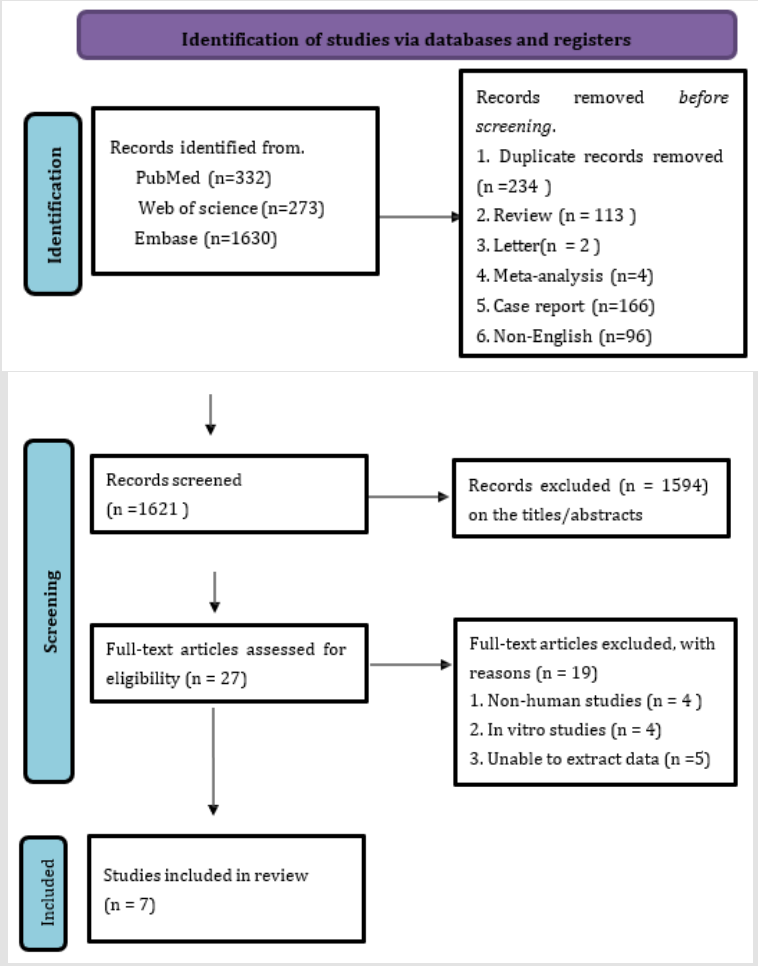

Figure 1: Flowchart of PRISMA.

Characteristics of the Study

Inclusion of 7 studies published in 2018-2023 [12, 14-19], a total of 548 patients with intertrochanteric femoral fractures, of which 288 patients were treated with ADAPT-assisted approach and 260 patients were treated with conventional surgical approach.5 studies reported operative time and 4 studies reported postoperative fluoroscopy time. Secondary outcome indicators such as TAD, TSD, 6 studies reported TAD. 2 studies reported TSD. ADAPT was chosen as the computerized navigation software in all seven selected papers. The study characteristics of these studies are shown in (Table 1).

Table 1: Characteristics of the included studies.

Study	Year	Study design	Group	Simple size	Age (year)	Gender (F)	Fracture Classification (n)
H. Takai	2018	CCT	ADAPT	55	85.7	45	AO: 19A.1/30A.2/3A.3/3B.2
			Conventional surgery				
Ryan J. Lilly	2018	RCT	ADAPT	26	82±11	19	AO:10A.1/14A.2
			Conventioal surgery	24	81±9	15	AO:8A.1/18A.2
Simon Weidert	2019	RCT	ADAPT	18	NA	NA	NA
			Conventional surgery	13	NA	NA	NA
Jan Herzog	2019	CCT	ADAPT	36	78±12.83	28	AO:16A.1/18A.2/2A.3
			Conventional surgery	36	79±10.80	28	AO:16A.1/18A.2/2A.3
Hirokazu Takai	2020	CCT	ADAPT	32	87.4±5.0	85	AO:38A.1/48A.2/11A.3/4B.2
			Conventioal surgery	26			
Tomotoshi Murakami	2021	PCS	ADAPT	20	85.9	18	Jensen:2Type1/6Type2/9Type3/ 2Type4/2T
			Conventioal surgery	20	83.5	18	Jensen:4Type1/9Type2/4Type3/ 2Type4/1T
Trevor Simcox	2021	CCT	ADAPT	41	84.4±11.8	33	Jensen:2Type1/9Type2/0Type3/ 21Type4/7
			Conventioal surgery	41	84.8±8.5	33	Jensen:4Type1/8Type2/3Type3/ 16Type4/7

Quality Assessment

A total of seven studies were included, including two randomized controlled trials [14,17] and 5 retrospective studies [12,15,16,18,19]. The Publication risk randomized controlled trial bias was assessed by the Cochrane Collaboration risk of bias tool. In terms of sequence generation, 2 studies were at low risk of bias. In terms of allocation concealment, blinding of participants and personnel, and other biases, all studies were at low risk of bias. In terms of incomplete outcome data, all studies had a high risk of bias. In terms of selective reporting, all studies had a low risk of bias. Therefore, all studies were considered to be of high quality. The Newcastle-Ottawa scale assessed the quality of non-randomized controlled trials.1 study [19] scored 8 and 2 studies [15,16] Score of 7, 2 studies [12,18] scored 4. The final 2 studies [12,18] were considered to be of moderate quality and 3 studies [15,16,19] were considered high quality (Table 2).

Table 2: Quality assessment by the Newcastle-Ottawa Scale for cohort study.

Study ID	Selection	Comparability	Exposure or Outcome	Total Score
Hirokazu Takai 2020	★★★	★	★★★	7
Trevor Simcox 2021	★★★★	★	★★★	8
JanHerzog 2019	★★★	★★	★★★	7
Tomotoshi Murakami 2021	★	-	★★★	4
H. Takai2018	★	-	★★★	4

Results

Operation Time

Five studies reported operation time data, including two RCTs [14,17] and three non-RCTs [16,18,19] A total of 261 patients were enrolled, including 261 in the ADAPT group and 26 in the conventional surgery group. Overall heterogeneity between studies was high (I2 = 0% in randomized controlled trials, I2 = 69% in non-randomized controlled trials, and I2 = 75% in 5 studies), and using a random-effects model, the results showed that there was no statistically significant difference in operation time in the ADAPT-assisted group compared with that in the traditional approach group (MD = 0.24, 95% CI: -6.12 to -6.61; P = 0.003). The results of the randomized controlled trial showed a significant reduction in operation time in the ADAPT-assisted group compared with the traditional approach group (MD = -6.54, 95% CI: 1.92 to 11.17; P = 0.34), and the results of the non-randomized controlled trial showed no statistically significant difference between the computer-assisted group and the traditional approach group (MD = - 3.38, 95% CI: - 11.09 to 4.33; P = 0.04) (Figure 2).

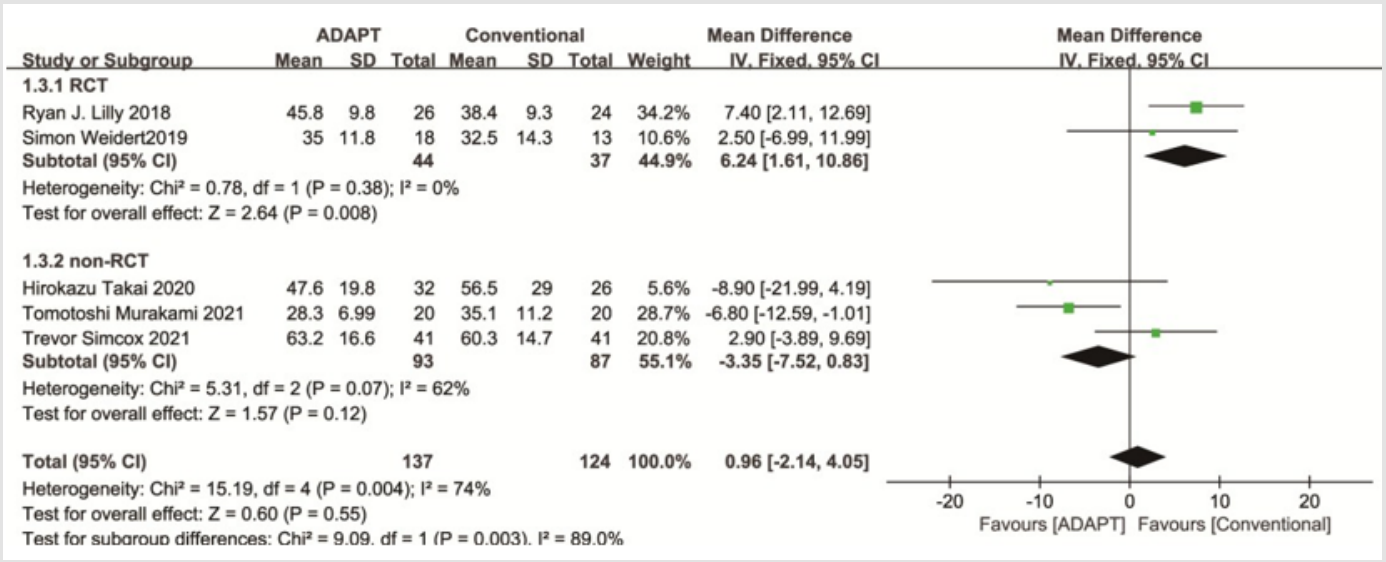

Figure 2: Forest plot diagram of compared operation time between traditional method group and computer-assisted group.

Intraoperative Fluoroscopy Time

Four studies reported intraoperative fluoroscopy time, including one RCTs [14] and three non- RCTs [16,18,19]. A total of 230 patients were included, including 119 in the ADAPT group and 111 in the conventional surgery group. The data were pooled using a random-effects model based on the test for heterogeneity, and the pooled analysis of the studies showed a significant reduction in intraoperative fluoroscopy time in the ADAPT-assisted group compared with the conventional approach group (MD = -75.29s; 95% CI:-131.88 to 18.70s; P = 0.80; Heterogeneity: I2 = 95%; P < 0.00001) (Figure 3).

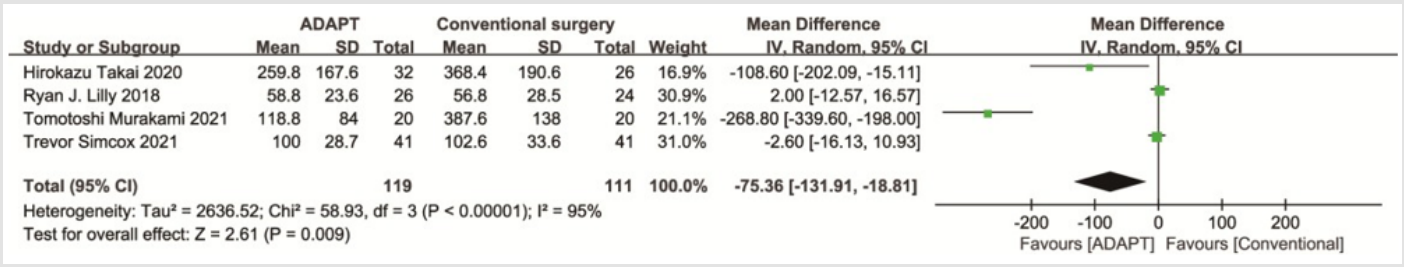

Figure 3: Forest plot diagram of compared Intraoperative fluoroscopy time between traditional method group and computer-assisted group.

TAD

Six studies provided data on TAD. Two of these were randomized controlled trials [14,17] and 4 were non-randomized controlled trials [15,16,18,19]. A total of 333 patients were included, including 173 in the ADAPT group and 160 in the conventional surgery group. The data were pooled using a random-effects model according to the heterogeneity test, and the results showed that the TAD in the ADAPT group was significantly smaller than that in the conventional surgery group (MD = -4.13; 95% CI -6.23 to -2.02; P < 0.0001; Heterogeneity: I2 = 86%; P <0.00001) (Figure 4).

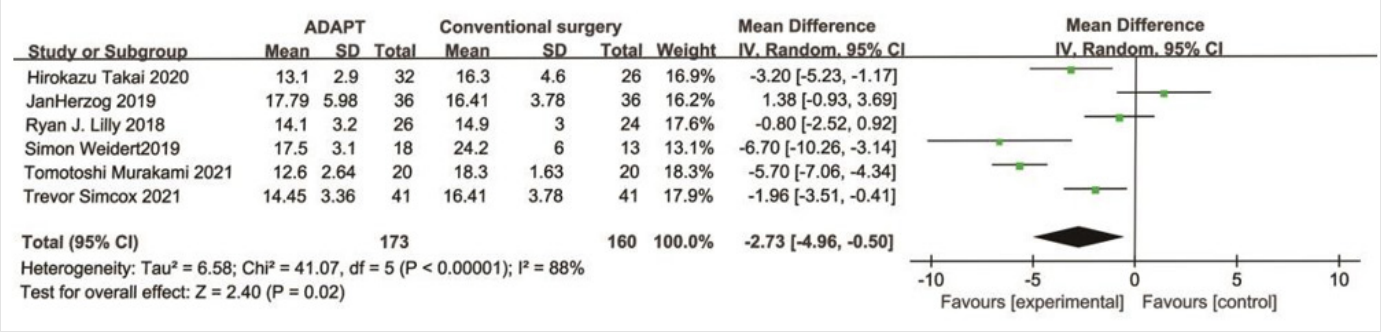

Figure 4: Forest plot diagram of compared TAD between traditional method group and computer-assisted group.

Tip-To-Head-Surface Distance

TSD was reported in two studies. Two were non-randomized controlled trials. [12,18] A total of 75 patients were included, and meta-analysis showed no statistically significant difference between intraoperative ADAPT-measured TSD and postoperative CT-measured TSD (MD = 0.23; 95% CI -0.02 to 0.48; P = 0.09; Heterogeneity:I2 = 5%; P = 0.3) (Figure 5).

Figure 5: Forest plot diagram of compared tip-to-head-surface distance between traditional method group and computer-assisted group.

Discussion

The rise in osteoporosis among the elderly population contributes to the increasing incidence of intertrochanteric femoral fractures [20] (Figure 6). Computer-assisted surgery, particularly the ADAPT system, offers potential benefits in terms of precision and ease of operation. However, the advantages and disadvantages of ADAPT system-assisted Gamma nail internal fixation versus conventional surgical Gamma nail internal fixation remain questionable due to the

lack of direct comparative evidence. Through a literature search, only a relatively small number of literature analyses have answered this question. In this meta-analysis, the analysis compares the efficacy of ADAPT system-assisted Gamma nailing in the treatment of intertrochanteric fractures of the femur with the efficacy of traditional surgical placement of Gamma nails. Seven papers were finally included. In this systematic review and meta-analysis, the efficacy of ADAPT-assisted Gamma nailing in treating intertrochanteric femur fractures was compared with that of traditional trepanning surgery. The primary findings of our analysis were that ADAPT resulted in a smaller Tip-Apex Distance (TAD) and reduced radiation exposure compared to conventional surgery, with no significant difference in operative time between the two approaches. This study also found that the use of ADAPT for measuring tip-to-head-surface distance (TSD) did not significantly differ from measurements obtained by postoperative CT scans. The analysis of this study indicates that incorporating ADAPT into intertrochanteric femoral surgery is linked with a decrease in TAD. Screw dislodgement represents a complication of intertrochanteric femur fractures (Figure 7).

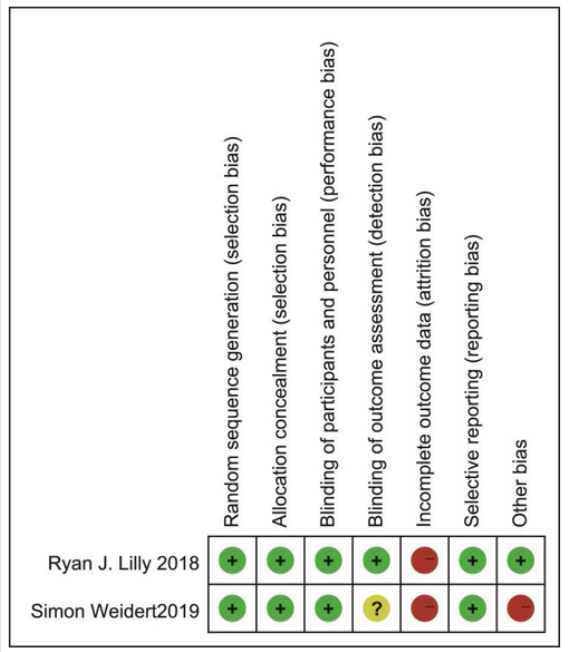

Figure 6: Risk of bias assessment of each included study: bias summary.

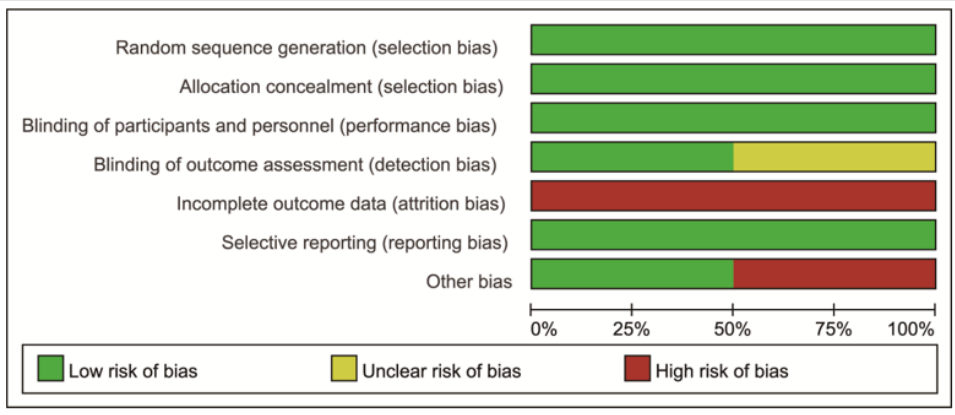

Figure 7: Risk of bias assessment of each included study: bias graph.

TAD serves as a highly predictive factor for failure in intramedullary nailing procedures and should ideally be less than 25 mm to mitigate the risk of screw dislodgement [11]. Analysis of prior cadaveric studies [21] has demonstrated a reduction in outliers of TAD in surgeries utilizing ADAPT, suggesting improved accuracy and stability. These conclusions align with our findings, indicating that the ADAPT system can construct a three- dimensional model of the femoral head using directional fluoroscopic views, enabling a more comprehensive view of the surgical site and screw placement. Traditional surgery, confined to two- dimensional space, presents challenges, particularly for less experienced orthopedic surgeons. There was no significant difference in operating time between the two groups. Despite ADAPT's initial aim to offer a convenient operational method, its total operative time fell short of expectations (Figure 8). The ADAPT system necessitates intraoperative programming of the machine and additional time for machine operation, which is particularly challenging for orthopedic surgeons newly acquainted with the system. Prolonged operating time can lead to decreased surgeon concentration and an elevated risk of physician operator error. Evaluation of the system revealed a 14% increase in the risk of complications for every 30-minute increase in operative time [22].

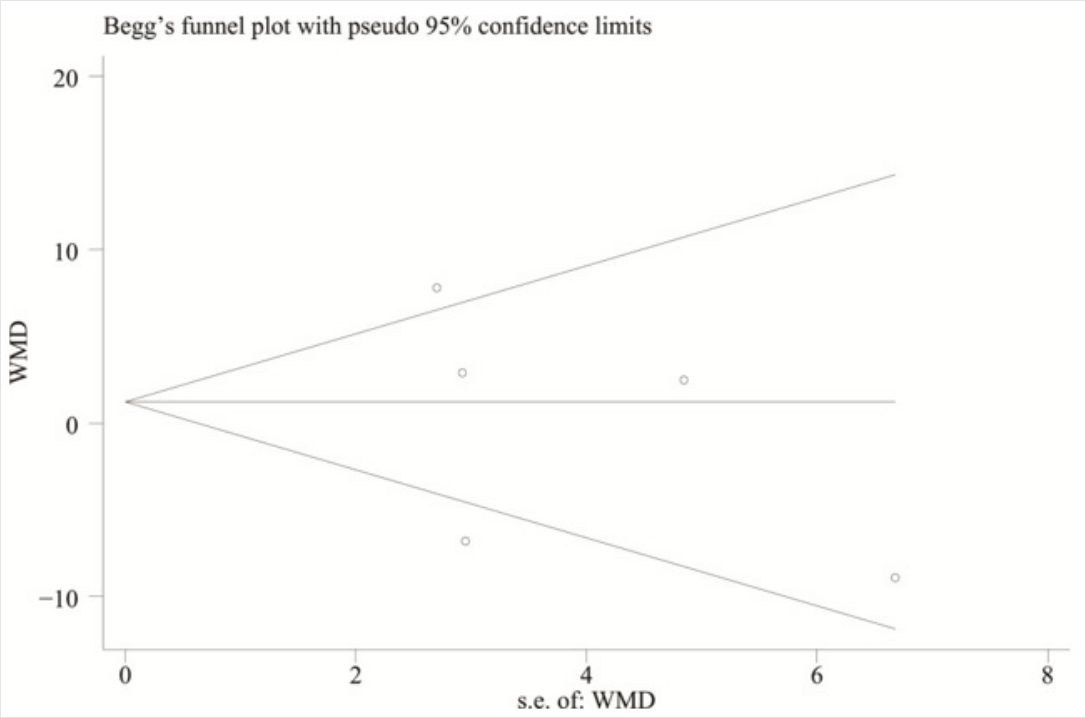

Figure 8: Funnel plot of operation time.

While unskilled orthopedic surgeons may not experience increased operating time with the ADAPT system, surgically skilled practitioners may encounter a lengthened operative duration due to the system's cumbersome machine operation. In orthopedic surgery, the placement of internal fixations necessitates continuous fluoroscopy by the physician. Despite wearing a lead jacket during the procedure, prolonged periods of fluoroscopy are common. It's generally accepted that minimizing radiation exposure is beneficial for both the surgeon and the patient, as it reduces the risk of adverse effects [23] (Figure 9). Previous cadaveric studies investigating surgeries using the ADAPT system have demonstrated a reduction in intraoperative fluoroscopy time compared to conventional surgery. This finding aligns with the results of the present study, as ADAPT can track screw positions, thereby minimizing the need for additional fluoroscopy. However, it's worth noting that some studies have suggested that ADAPT may not consistently reduce intraoperative fluoroscopy time. Lilly et al. concluded that [14] surgeons typically repeat fluoroscopy to confirm the position of screws due to their habitual practice. TSD, or Tip-to-head-surface distance, is a concept designed to measure the three-dimensional distance from the tip of a screw to the surface of the femoral head axially. It indicates how far a screw can be inserted before reaching or penetrating the femoral head surface.

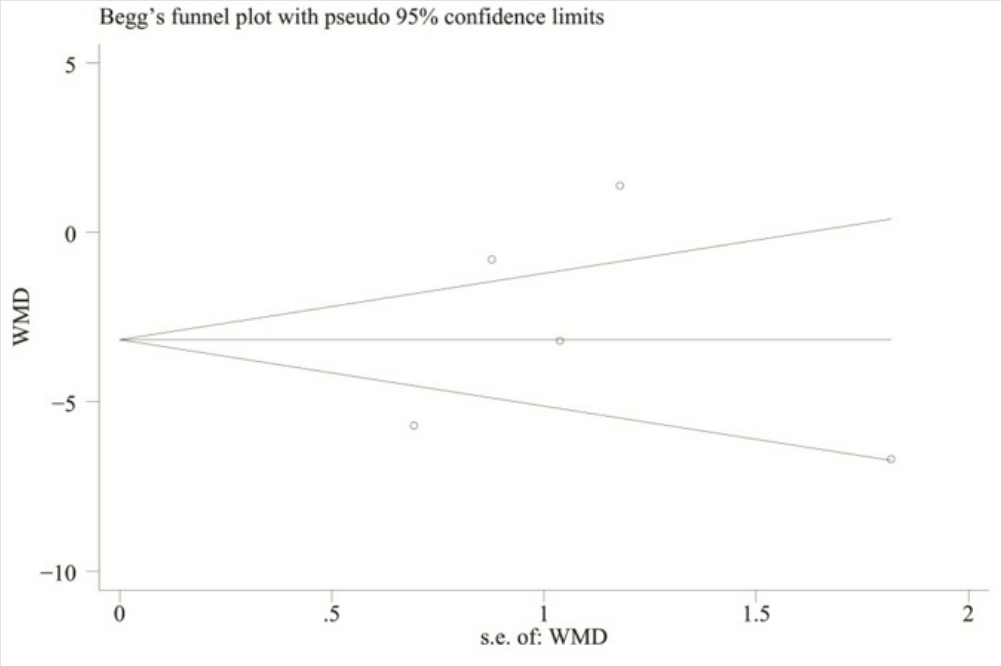

Figure 9: Funnel plot of TAD.

Both TAD and TSD are crucial in determining screw position. While TAD, within normal limits, might suggest proper screw placement, relying solely on 2D imaging may lead to screw penetration of the articular surface if the screw is in an eccentric position. TSD, however, offers a meaningful measurement regardless of screw position, as it calculates the true 3D distance from the screw tip to the femoral head surface [24]. Therefore, the concept of TSD is crucial for the measurement of screw placement position. In a cadaveric study of the ADAPT system it was shown that [21] less experienced surgeons could achieve equally accurate results as experienced surgeons with the introduction of the TSD concept. In the two articles we included, we compared intraoperative TSD values obtained using the ADAPT system with TSD values from postoperative CT scans. The results revealed no significant difference between the intraoperative and postoperative measurements, indicating that the ADAPT system offers high accuracy for intraoperative measurements. These findings highlight the ADAPT system as a computer-assisted tool with precise intraoperative measurements. By visualizing TSD and TAD through calculation, the ADAPT system provides surgeons with real-time information during surgery, facilitating rapid skill development.

Conclusion

The current evidence indicated that the ADAPT system allows for more accurate screw placement compared to conventional surgery. Reduced intraoperative radiation without reducing operative time. And the accuracy of ADAPT in measuring TSD intraoperatively was found. Future studies with more high-level evidence-based medical evidence and follow-up data are still needed.

Strengths and Limitations

Our study's analysis suggests several clinical advantages associated with the use of ADAPT. Firstly, it facilitates achieving a lower Tip-Apex Distance (TAD), which is critical for optimal outcomes. While an acceptable TAD can be attained through the freehand method, ADAPT offers enhanced accuracy in this regard. Secondly, the intraoperative Total Screw Displacement (TSD) measured by ADAPT closely correlates with TSD measured by postoperative CT scans, indicating comparable accuracy between ADAPT and CT imaging. This similarity enhances intraoperative safety. However, our systematic review and meta-analysis have several limitations worth noting. Firstly, there's a possibility of unavoidable omission bias in related studies, which may affect the overall findings. Additionally, the sample size of our study might not have been sufficient to mitigate potential biases, and the inclusion of studies with varying designs, such as retrospective cohort studies or randomized controlled trials (RCTs), might have weakened the evidence base. Moreover, few studies provided adequate follow-up data, potentially limiting the rigor of efficacy estimations. The scarcity of available studies also constrains the robustness of our conclusions. Furthermore, not all included studies clearly delineated all steps of the TAD measurement, which could introduce quantitative bias into the data. Lastly, insufficient information about nail length may have biased the pooled analysis. Despite these limitations, we made efforts to minimize bias by identifying and including all potentially eligible studies.

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Competing Interests

The authors declare that they have no competing interests.

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Lin Fengfei. Biomed J Sci & Tech Res

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