IEEE Journal of Translational Engineering in Health and Medicine

Received 29 May 2023; revised 24 October 2023; accepted 7 November 2023.
Date of publication 16 November 2023; date of current version 24 November 2023.

Digital Object Identifier 10.1109/JTEHM.2023.3332453

A Novel Navigation Device for Precise Percutaneous Placement of the Guidewire in Femoral Neck Fracture Cannulated Screw Fixation Surgery

YUTAO CUI, GUANGKAI REN, CHUANGANG PENG, BAOMING YUAN, AND DANKAI WU

Orthopaedic Medical Center, The Second Hospital of Jilin University, Changchun 130041, China

(Yutao Cui and Guangkai Ren contributed equally to this work.) CORRESPONDING AUTHORS: B. YUAN (yuanbm@jlu.edu.cn) AND D. WU (wudk@jlu.edu.cn)

This work was supported by the Scientific Development Program of Jilin Province under Grant 20190304123YY.
This work involved human subjects or animals in its research. Approval of all ethical and experimental procedures and protocols was granted by the Ethics Committee of the Second Hospital of Jilin University under Authorization No. 2018303.

ABSTRACT The accuracy of screw placement is a key factor for the stability of the cannulated screws used in the fixation of femoral neck fractures. In this study we designed a navigation device for ensuring the screw reaches the ideal position for optimal fixation. From March 2019 to September 2020, 66 patients with femoral neck fracture were enrolled and divided into 2 groups, one group was treated using the traditional free-hand cannulated screw fixation and the other using the new navigation device with assisted fixation. The effectiveness of the 2 methods was compared based on surgery duration, intraoperative bleeding, number of fluoroscopic examination and guidewire insertion attempts, screw parallelism, and effective fixation area. Fracture healing, complications and hip joint function were assessed after operation. The new navigation device reduced the duration of surgery without causing additional intraoperative bleeding, and significantly reduced number of fluoroscopy examination and guidewire insertion attempts (4.00±1.58 vs. 6.09±1.94 with traditional surgery). The accuracy of screw implantation was improved, as demonstrated by increased screw parallelism (0.71±0.57° vs. 1.66 ±1.01° with traditional surgery) and higher effective fixed area (64.88±10.52 vs. 58.61±9.19 mm^2 with traditional surgery). In the postoperative follow-up, except for one case of femoral head necrosis and one case of bone nonunion in the traditional surgical group, the other patients showed fracture healing. There was no significant difference in hip joint function between the 2 groups. The new navigation device enables rapid and accurate guidewire positioning for cannulated screw fixation through simple operation procedures, resulting in good prospect for clinical transformation.

INDEX TERMS Femoral neck fracture, fracture fixation, cannulated screw, navigation device.

Clinical and Translational Impact Statement— This navigation device has translational significance of increasing the accuracy of screw placement in cannulated screw fixation of femoral neck fracture, reducing the operation difficulty and improving the cure rate.

I. INTRODUCTION

Femoral neck fractures are one of the most common types of hip fracture, accounting for nearly half of proximal femoral fractures [1], [2]. For patients—especially younger ones—without displaced or with partially displaced femoral neck fractures, closed reduction and internal fixation with preservation of the femoral head is a widely used surgical strategy [3], [4]. Fixation with 3 cannulated compression screws in an inverted triangle arrangement has excellent mechanical strength and local stability [5], [6]. With this method, optimal screw placement is critical for the stable healing of femoral neck fractures and contributes to the difficulty of the surgery. For this mission, the three screws should be located at the distal, proximal anterior and proximal posterior femoral neck, with the distal screw located at the calcar femorale and the other two screws located within 3mm

IEEE Journal of Translational Engineering in Health and Medicine

of the anterior and posterior cortical edge of the proximal end, respectively. The angles of the three screws should be parallel to femoral neck shaft angle and the anterior inclination angle of the femoral neck [7], [8]. To achieve optimal positioning of implanted screws, cannulated screw fixation is assisted by intraoperative C-arm fluoroscopy. The traditional surgical method mostly relies on the clinical experience of the surgeon to manipulate the position of the screw under fluoroscopic monitoring. However, this free-hand approach lacks accuracy, which results in repeated attempts to insert, remove and adjust the guiding Kirschner wire (K-wire). Additionally, multiple insertion attempts increase exposure of both the patient and surgeon to radiation from the fluoroscope as well as the risk of the K-wire damaging the blood supply to the femoral head while undermining the stability of the femoral neck, which can increase the incidence of femoral head necrosis and screw withdrawal [9], [10], [11].

Various devices have been developed to facilitate screw implantation including computer-assisted or robot-navigated implantation and physical guide devices [12], [13]. The computer or robotic navigation system significantly increases the accuracy of screw placement, decreases the number of K-wire placement attempts, and reduces local bone damage [14]. However, obtaining fluoroscopic imaging data with the computer navigation system is complicated and will prolong the operative time [15]. Moreover, computer-assisted systems and navigation robots are expensive and are not available in most hospitals. Physical guide devices improve traditional surgery and can not only increase the accuracy of screw placement but also shorten the operative time [16]. However, most existing physical guiding devices must be hand-held by the surgeon during the operation and have insufficient accuracy.

In this study, we designed a novel adjustable guide device with good clinical translational significance to assist with precise screw placement in cannulated screw fixation surgery of femoral neck fractures (Fig. 1). Clinical indices including operative time, intraoperative blood loss, frequency of intraoperative fluoroscopy, guidewire insertion attempts, accuracy of screw positioning, postoperative complications, and recovery of hip function were evaluated as measures of the clinical effectiveness of the new device.

II. MATERIALS AND METHODS

A. INCLUSION AND EXCLUSION CRITERIA

The inclusion criteria for patients in this study were as follows: 1) >18 and <65 years old; 2) clinically diagnosed with a unilateral femoral neck fracture; and 3) no lower limb fracture on the same side as the femoral neck fracture. Exclusion criteria were as follows: 1) patient was >65 years old with a Garden type IV fracture; 2) closed reduction could not be performed due to multiple injuries or severe trauma; 3) unable to tolerate surgery due to severe coexisting illness; 4) injury-to-surgery interval exceeded 72 h; and 5) patients had rheumatoid arthritis or osteoarthritis.

TABLE 1. General characteristics of the study population.

	Traditional surgery	Navigation device	P value
Sex, male/female	18/15	17/16	
Age, years	*53.48±6.87*	51.55±9.28,	0.338
Garden fracture classification			
I	*0*	0	
II	*23*	20	
III	10	13	
Injury-to-surgery interval, days	1.64±0.87	1.53±1.00	0.647

B. STUDY DESIGN AND PARTICIPANTS

The study was approved by the ethics committee of the Second Hospital of Jilin University (NO.2018303) and informed consent was taken from all individual participants. All patients who underwent closed reduction and cannulated screw fixation of femoral neck fractures were considered for recruitment in this trial. A total of 66 patients were included in this study according to the above criteria at the Second Hospital of Jilin University from March 2019 to September 2020. The mean age of patients was 52.5 years (range: 30–63 years), with 35 males and 31 females. There were 43 fractures classified as Garden type II and 23 as Garden type III. All patients enrolled in the study were randomized into 2 groups: one underwent traditional surgery and the other underwent surgery assisted by the new navigation device. The average injury-to-surgery interval in traditional surgery group and navigation device was 1.64±0.87 and 1.53±1.00 days respectively. All operations were performed by the same senior trauma orthopedic surgeon (D. Wu). Data collection, analysis and follow-up were conducted by another doctor who did not know the specific groups of patients. Each patient was followed for at least 1 year to evaluate fracture healing and functional recovery. General information on the patients in the 2 groups is provided in Table 1. There were no statistically significant differences in age, sex ratio, fracture patterns, or interval from injury to surgery between the 2 groups.

C. STRUCTURE OF THE NEW NAVIGATION DEVICE

The navigation device is made of 304 stainless steel material and has supporting, sliding adjustment, rotating adjustment, and aiming components (Fig 1 A, B). The supporting component provide mechanical support for the adjustment and aiming components so that the surgeon does not have to hold the navigation device during surgery. The sliding adjustment components can be operated to assist in locating the K-wire insertion position, while the rotating adjustment components is used to assist in locating

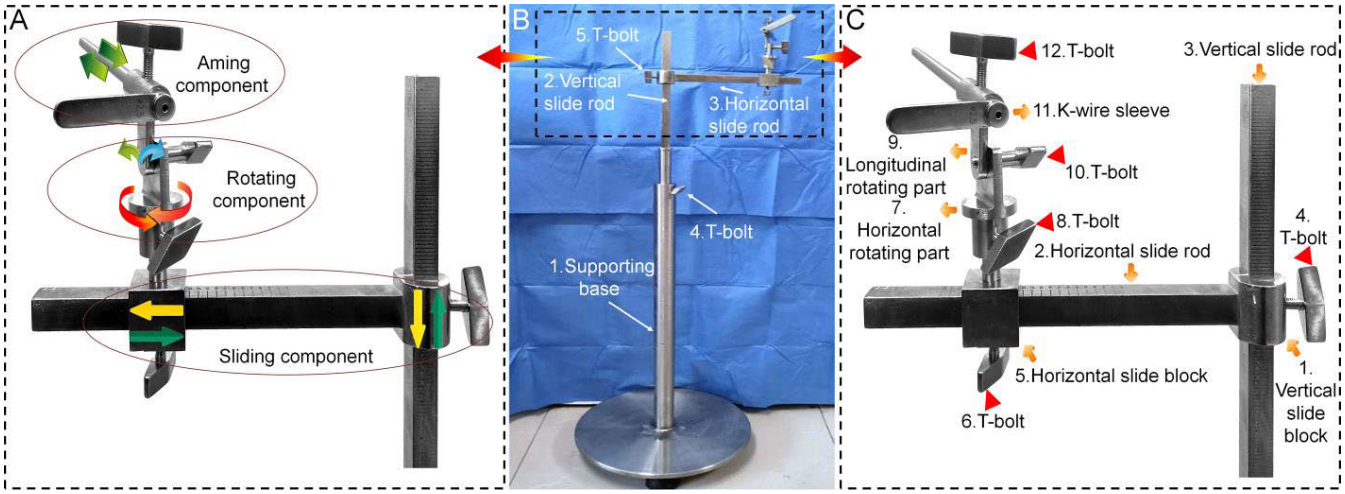

FIGURE 1. New navigation device for precise screw placement in cannulated screw fixation surgery of femoral neck fractures: A. Adjustment of sliding, rotating, and aiming components; B. Illustration of the overall appearance and supporting components; C. Illustration of sliding, rotating, and aiming components.

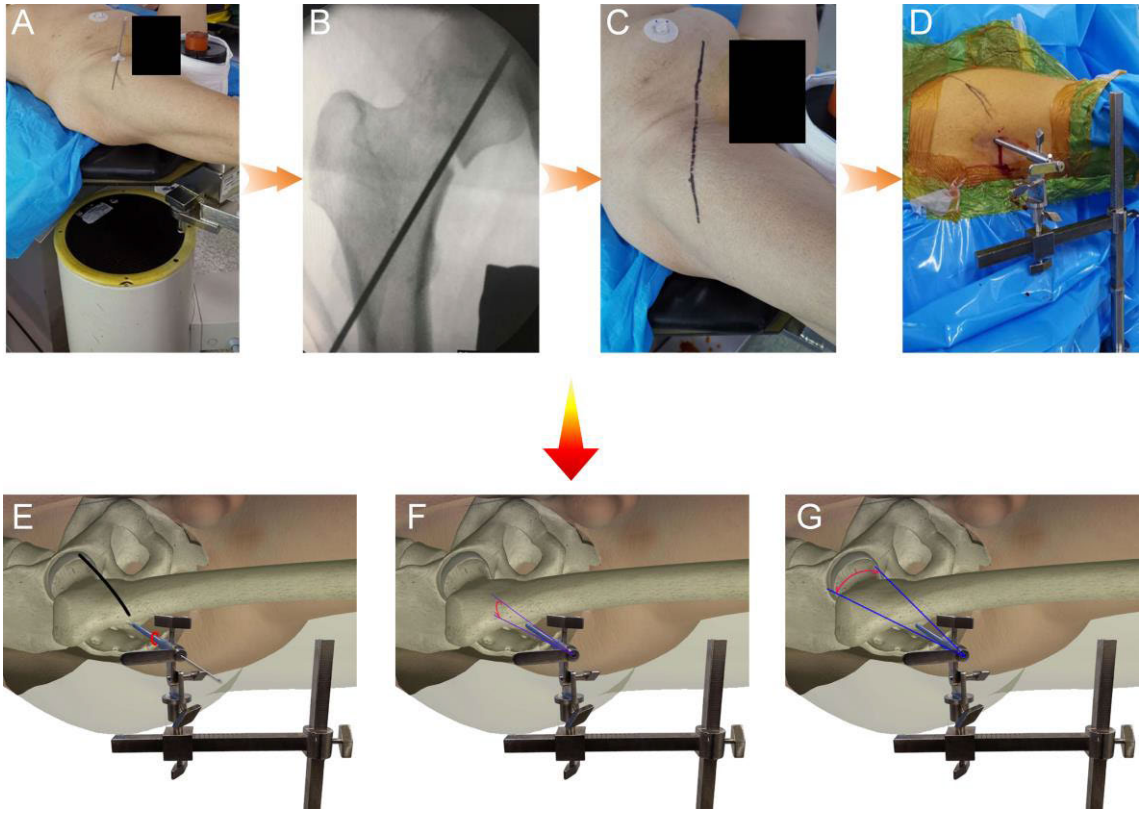

FIGURE 2. Intraoperative working diagram of the new navigation device. A–D. Body surface marking of femoral calcar location. E–G. Working principle of the new navigation device.

the insertion angle, and the aiming device is mainly used for fixing and implanting the guidewire. The surgeon can coordinate the use of these components, easily determine the optimal insertion position and angle under intraoperative fluoroscopy. The guidewire can be implanted according to the position and angle template provided by the navigation device.

The supporting component comprises a support base (Fig 1 B1) and vertical (Fig 1 B2) and horizontal slide rods (Fig 1 B3). The vertical slide rods can be connected with the supporting base and fixed by T-bolt (Fig 1 B4), and the horizontal sliding rods can be directly sleeved on the vertical slide rods and fixed by another T-bolt (Fig 1 B5), thus forming the main supporting structure of the navigation device.

IEEE Journal of Translational Engineering in Health and Medicine

The sliding adjustment component comprises vertical and horizontal slide block devices and 2 T-bolt locking devices. The vertical sliding block (Fig 1C1) is welded to the horizontal slide rod (Fig 1C2) and sleeved on the vertical slide rod (Fig 1C3) such that the horizontal slide rod can move on the vertical slide rod through the vertical sliding block and can be fixed by the T-bolt ((Fig 1C4). The horizontal sliding block (Fig 1C5) can be directly sleeved to the horizontal slide rod and fixed by T-bolt (Fig 1C6). The horizontal sliding block can then be connected with the horizontal rotating part (Fig 1C7) and fixed by a T-bolt (Fig 1C8). The horizontal rotating part is further connected with other rotating adjustment components and aiming adjustment components, so that these components can slide along with horizontal sliding block. Components connected to the sliding blocks can be controlled by moving the sliding block to adjust the position of K-wire insertion. After the optimal position is achieved, the horizontal and vertical sliding blocks can be fixed with T-bolts.

The rotating component consists of a horizontal rotating part connected to a longitudinal rotating part (Fig 1C9) and 2 T-bolt locking devices. The longitudinal rotating part is connected with the horizontal rotating part via a T-bolt (Fig 1C10) and can only swing relative to the horizontal rotating part. The rotating component allows adjustment of the K-wire insertion angle according to the collo-diaphyseal angle and femoral neck anteversion. After establishing the optimal angle, the rotating component is locked with T-bolts.

The aiming component consists of a K-wire sleeve (Fig 1C11) and a T-bolt locking device (Fig 1C12). The K-wire sleeve is driven by other components for direct adjustment of the K-wire positioned therein. The sleeve can also be locked by the T-bolt after length adjustment.

D. SURGICAL PROCEDURE

The surgery was performed under general or epidural anesthesia. Under anesthesia, closed reduction was performed with the aid of a traction bed and the reduction was confirmed by C-arm fluoroscopy. In the navigation device group, a K-wire was placed in front of the hip and its position was marked in the anteroposterior fluoroscopy image after adjustment to the level of the femoral calcar (Fig 2A-2C). The new navigation device was installed and placed on the outside of the hip after intraoperative disinfection and drape placement. According to the mark line on the hip, an incision of 1 cm was made on the proximal lateral part of the femur; the sleeve of the navigation device was inserted into the incision, and the first K-wire was placed in the sleeve in the approximate direction of the mark line (Fig 2D-2E). After the K-wire touched the bone surface, it was fixed by the T-bolt on the sleeve without implantation. According to the extension line of the K-wire on the fluoroscopic image, the expected position and angle could be judged, and the guidewire could be continuously adjusted through the navigation device to determine the optimal implantation (Fig 2F-2G).

The first guidewire was inserted to determine the distal screw implantation. After sleeve implantation, based on the lateral fluoroscopy image, the vertical rotating block was adjusted so that the insertion angle was consistent with the anterior inclination angle of the femoral neck (Fig 3A-B). After completing the adjustment, the vertical rotating component was locked through the T-bolt located on it. The inserting position of the guide wire was adjusted to the lateral central axis of the femoral neck through the vertical sliding block (Fig 3B). The position of the vertical slide component was also locked by the T-bolt located on it. Then, the intraoperative fluoroscopy was changed to anteroposterior perspective. Based on the anteroposterior fluoroscopy image, the insertion angle of the first guidewire was adjusted with the horizontal rotating block so that it conformed to the femoral neck shaft angle (Fig 3C). The insertion point of the first guidewire was then adjusted with the horizontal sliding block so that the first guidewire was positioned at the calcar femorale (Fig 3C). After the adjustment was completed, the positions of the horizontal rotating and the slide component were locked by the T-bolt located on them respectively. The first K-wire was finally implanted through the accurately positioned sleeve.

Since the three screws should all be implanted at angles consistent with the neck-shaft angle and anteversion angle, the second and third guide wires can be implanted according to the angles adjusted when the first guide wire is implanted. Therefore, when the second and third guidewires were implanted, the rotating components of the navigation device remained unchanged, and only the sliding components needed to be adjusted to find the insertion point. The second guidewire was adjusted to determine the proximal anterior screw implantation site. The sleeve of the second guidewire was inserted according to the angle determined by the first guidewire (Fig 3D). With the assistance of lateral fluoroscopy, the position of the second guidewire was adjusted to be close to the cortex of the anterior edge of the femoral neck by the vertical slide block, while avoiding the guide wire to penetrate (Fig 3E). With the assistance of anteroposterior fluoroscopic images, the position of the guidewire was adjusted to close to the upper edge of the femoral neck by a horizontal slide block, and the guide wire was also avoided to penetrate (Fig 3F). After the adjusted position was fixed by T-bolts at the vertical and horizontal slide block sites, respectively, the second guidewire was implanted.

The third guidewire was used to guide the proximal posterior screw. After insertion of the sleeve at the same angle determined by the first guidewire, the third guidewire was positioned close to the posterior edge of the femoral neck by the vertical slide block on the lateral fluoroscopic images and close to the upper edge by a horizontal slide block on the anteroposterior images (Fig 3G-I). Guidewire penetration also needed to be avoided. After fixing the position frame of the navigation device, the third guidewire was implanted.

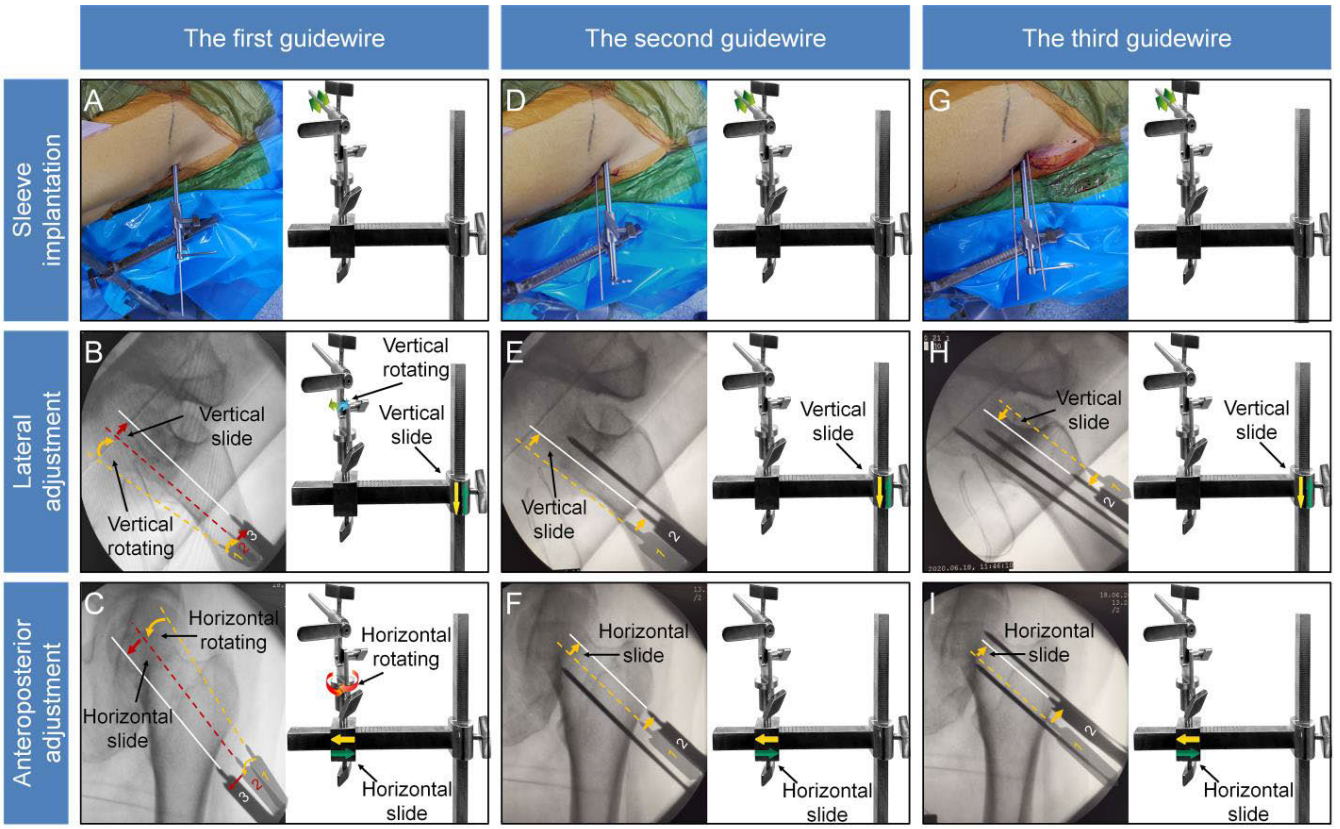

FIGURE 3. **Adjustment of the angles and positions of the 3 Kirschner wires (K-wires) through the new navigation device. A–C. The insertion of the sleeve (A), the angle and position adjustment under lateral (B) and anteroposterior perspective (C) for the first guide wire. D–F. The insertion of the sleeve(D), the position adjustment under lateral (E) and anteroposterior perspective (F) for the second guide wire. G–I. The insertion of the sleeve (G), the position adjustment under lateral (H) and anteroposterior (I) perspective for the third guide wire. The red and yellow dashed lines and numbers indicate the expected position of the K-wires before adjustment, while the white solid lines and numbers indicate the expected position of the K-wires after adjustment.**

After guidewire insertion, 3 cannulated screws were implanted and the position and depth of the screws were again confirmed by fluoroscopy.

In the traditional surgery group, screw implantation was performed by hand based on the clinical experience of the lead surgeon. Multiple C-arm fluoroscopy sessions were required to confirm the position of the guidewire during this process. If the position and angle were not satisfactory, the guidewire had to be withdrawn and adjusted for reinsertion. After multiple position adjustments under fluoroscopic imaging, the 3 cannulated screws were successively implanted.

E. CLINICAL EFFECTIVENESS STUDY

To evaluate the effectiveness of the new navigation device, we compared the surgical procedure between the traditional surgery and navigation device groups in terms of the duration of surgery, amount of intraoperative bleeding, number of intraoperative fluoroscopic examination, and intraoperative attempts to insert K-wires. Screw parallelism and effective fixation area were also examined to determine the accuracy of screw placement. Parallelism was calculated by measuring the average difference in angle between each of the 3 screws and the femoral shaft axis on the radiograph and using the formula $(|\theta1-\theta2| + |\theta1-\theta3| + |\theta2-\theta3|)/3$, where $\theta1$, $\theta2$, and $\theta3$ represent the angles of the distal femoral, proximal anterior, and proximal posterior screws relative to the femoral shaft axis, respectively (Fig 4A). The area of the triangle between the screws in the femoral neck was evaluated by postoperative computed tomography (CT) examination in the section perpendicular to the axis of the femoral neck (Fig 4B). Both the angle and area were measured by image J software.

Postoperative fracture healing time and complications were recorded. Hip joint function was evaluated with the Harris Hip Scoring system with a score of 90–100 considered as excellent, 80–89 as good, 70–79 as fair, and <70 as poor. All data were collected and analyzed by doctors who did not know the specific groups of patients.

F. STATISTICAL ANALYSIS

The guidewire insertion attempts were set as the primary outcome for power analysis. Based on previous study of computer-aided navigation device, we assumed that the primary endpoint in the navigation device group and traditional surgery group was 3.0±0.1 times and 4.8±1.6 times

IEEE Journal of Translational Engineering in Health and Medicine

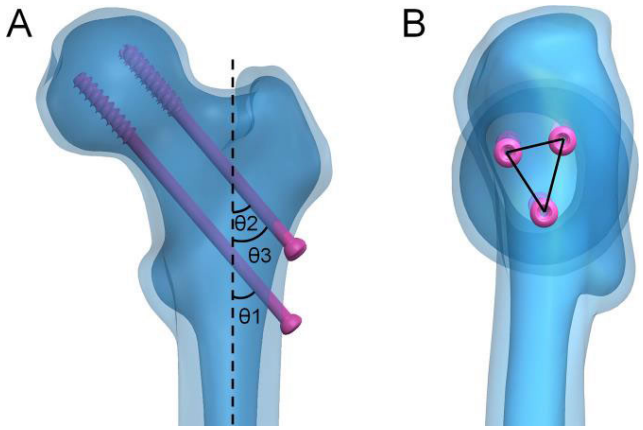

FIGURE 4. Evaluation of screw position accuracy. A. Illustration of screw parallelism measurement. B. Illustration of the measurement of the effective fixation area.

respectively [12]. Then, assuming 20% loss of the primary endpoint, 33 evaluable patients in each group (66 in total) were planned to be enrolled and randomly assigned in a 1:1 ratio, in order to provide 80% power to detect a statistical significance in navigation device group in comparison with traditional surgery group with a 2-sided type I error of 0.05. The data are presented as mean±standard deviation. Differences between groups were evaluated with the Student's t test. Statistical analyses were performed using SPSS v19.0 software (SPSS Inc., Chicago, IL, USA). The threshold for statistical significance was set at $p<0.05$.

III. RESULTS

A total of 66 cases of femoral neck fracture were included in the study (n=33 per group). The follow-up time ranged from 12 to 24 months, with an average of 15.73±3.39 months in traditional surgery group and 15.30±2.93 months in navigation device group. All patients achieved good reduction and fixation during surgery. Fig 5 shows the surgical process and follow-up results of a representative patient. The average operation time was significantly shorter in the navigation device group than in the traditional surgery group (42.62±9.99 vs. 50.19±7.77 min; Fig 6A). However, intraoperative bleeding volume was similar in the 2 groups (32.44±5.17 and 34.53±4.53 ml, respectively; Fig 6B). In the new navigation device group, the average number of intraoperative fluoroscopy was fewer than in the traditional surgery group (25.27±8.47 vs. 37.12±9.95; Fig 6C) and fewer drilling attempts were made (4.00±1.58 vs. 6.09±1.94; Fig 6D); the difference between groups was significant for both parameters. These results indicate that the new navigation device improved the surgical process by enhancing the accuracy of guidewire placement and reducing fluoroscopy time and number of guidewire insertion attempts.

To determine the accuracy of the angle and position of screw insertion, we evaluated screw parallelism and effective fixation area. Mean parallelism was 1.66±1.01° in the traditional surgical group and 0.71±0.57° in the navigation device group; that is, the angles between implanted screws were smaller in the latter group, indicating greater parallelism (Fig 6E). The mean effective fixed area was significantly larger in the navigation device group than in the traditional surgery group (64.88±10.52 vs. 58.61±9.19 mm^2; Fig 6F). Thus, the new navigation device enabled the screws to be implanted in a better position with superior fixation effect.

TABLE 2. Postoperative complications and outcomes.

	Traditional surgery	Navigation device
Follow-up period, months	15.73±3.39	15.30±2.93
Complications, numbers (rate)		
Femoral head necrosis	1 (3.03%)	0 (0%)
Bone nonunion	1 (3.03%)	0 (0%)
Joint function, numbers (rate)		
Excellent	17 (51.52%)	19 (57.58%)
Good	12 (36.36%)	12 (36.36%)
Fair	4 (12.12%)	2 (6.06%)
Poor	0 (0%)	0 (0%)
Scores of joint function	87.33±7.65	88.97±6.37

One patient in the traditional surgical group experienced femoral head necrosis in Ficat stage 2, which was performed without special treatment. One case of nonunion occurred in the traditional surgery group and the patient healed well after reinforcing internal fixation and promoting osteogenesis. The remaining patients achieved satisfactory fracture healing without postoperative infection, neurovascular injury and screw relaxation. Joint function was evaluated with the Harris Hip Scoring system at the 12-month follow-up. There was no statistically significant difference in hip joint function between the 2 groups. In the traditional surgery group, 17 patients had excellent hip joint function, 12 were good, and 4 were fair, with an average score of 87.33±7.65. In the navigation device group, 19 cases were excellent, 12 cases were good, and 2 cases were fair, with an average score of 88.97±6.37 (Table 2).

IV. DISCUSSIONS

In cannulated screw fixation surgery of femoral neck fractures, the appropriate position and screw angles are critical parameters that directly affect the stability of the fixation, fracture healing, and incidence of complications [17]. Given this mission, we have designed an economical and effective navigation device with translational impact that can pre-adjust the insertion angle of the guidewire through a rotating component and the insertion position through a sliding component to increase the accuracy of screw implantation and simplify the surgical procedure.

The cannulated screw fixation surgery is typically needs to be performed with the aid of C-arm fluoroscopy, and the attending surgeon is continuously exposed to radiation in traditional surgery as control must be maintained over the guidewire during positioning. The navigation device developed in this study has a support base and T-bolt fixation that allow the surgeon to withdraw from the radiation

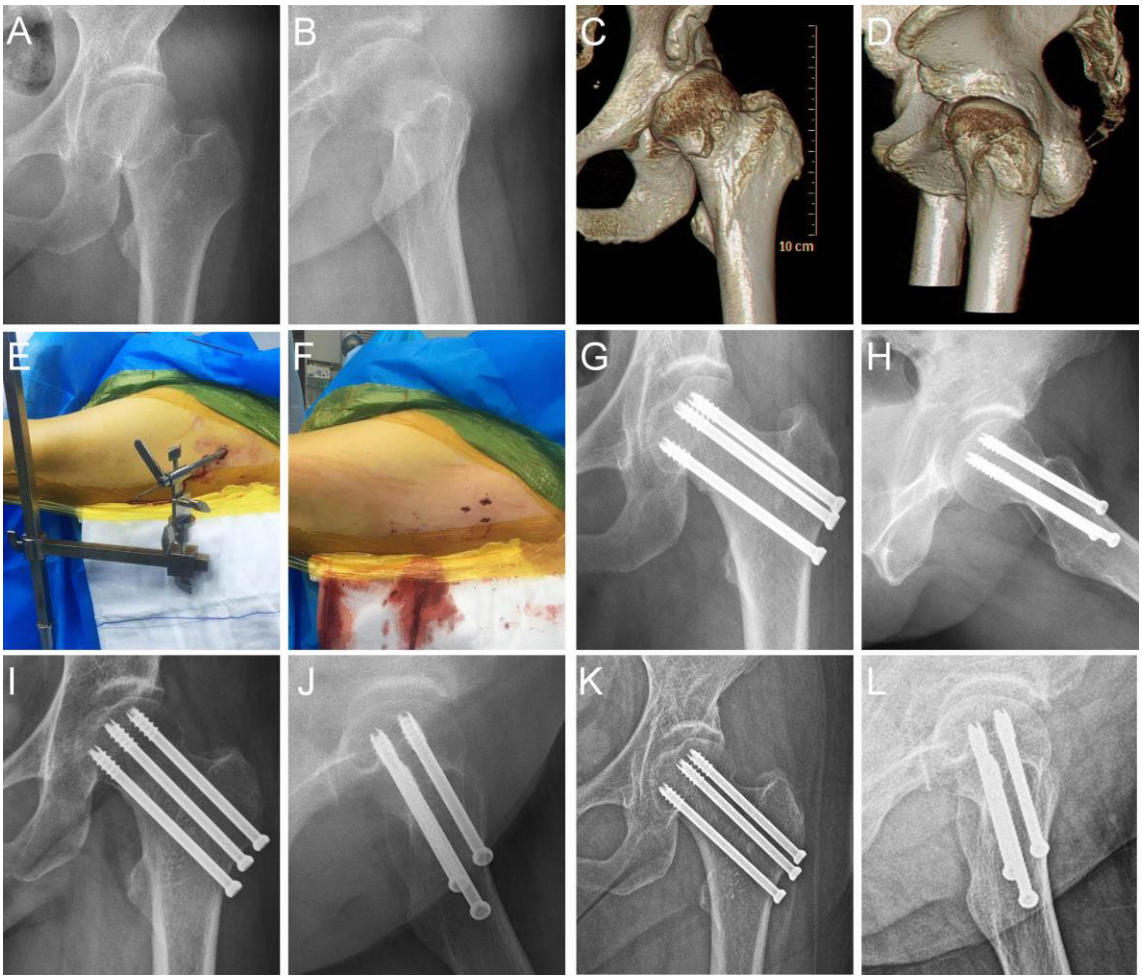

FIGURE 5. Surgical process and follow-up results of a representative patient. A–D. Anterior and lateral X-ray and CT reconstructions of femoral neck fractures. E, F. Intraoperative external image. G–L. Anterior and lateral radiographs of femoral neck fracture site after screw implantation (G, H), 3 months after surgery (I, J), and 12 months after surgery (K, L).

area when the fluoroscope is in use. As for the guidewire implantation, using the navigation device, the first distal femur guidewire can be inserted into the sleeve according to the preoperative marks on the inner edge of the femoral neck, and the optimal implantation site was confirmed through fine adjustment of the rotating and sliding adjustment component. Since all three guidewires should conform to the neck shaft and anterior inclination angles, after the first guidewire is implanted, the locking of the rotating component of the navigation device will directly provide the appropriate angle for the second and third guidewires, and the surgeon only needs to adjust the sliding component to determine the implantation position. The second or third guidewires can be easily located in the anterior and posterior cortices of the proximal femur, respectively. An in-out-in screw implantation pattern should be avoided where the screws penetrate the cortex [18], [19]. Thus, the new navigation device enabled rapid and accurate determination of the guidewire insertion site and simplified the surgical procedure, thereby significantly reducing the operative time. Additionally, preadjustment of the guide by the navigation device significantly reduced intraoperative fluoroscopy time and number of attempted guidewire insertions. This in turn decreased radiation exposure to the patient and surgeon, and also reduced damage to the bone at the fracture site that can be caused by repeated withdrawal and insertion of the guidewire. The safety of the new navigation device was evidenced by the fact that intraoperative bleeding volume with this method was comparable to that with traditional surgery.

Implanting the screws parallel to each other allows sliding compression of the femoral head to the neck of the femur during local bone resorption at the fracture site, decreasing the risk of nonunion and femoral head necrosis [20]. Additionally, a larger fixation area between screws in the lateral position increases fixation stability and reduces the occurrence of bone nonunion when the screws are located in the cortex [21], [22]. Compared to the traditional surgery group, the screws in the navigation device group were more parallel to each other and the triangular area

IEEE Journal of Translational Engineering in Health and Medicine

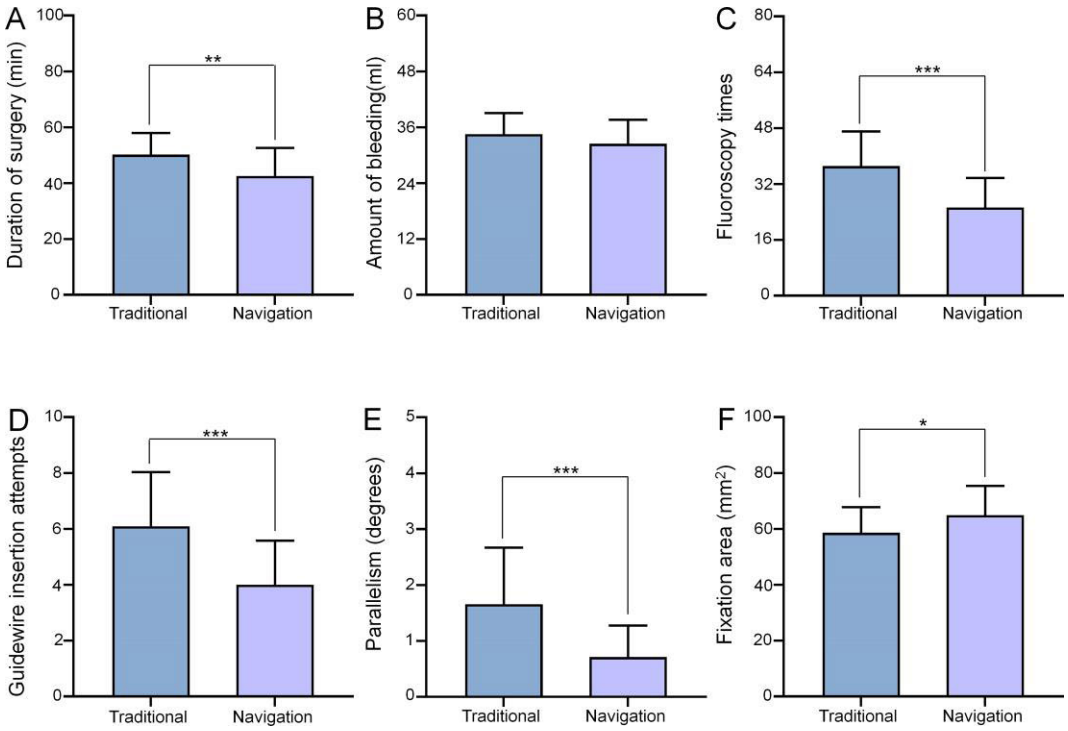

FIGURE 6. **Evaluation of the clinical effectiveness of the new navigation device. A–F. Duration of surgery (A), amount of intraoperative bleeding (B), fluoroscopy time (C), number of guidewire insertion attempts (D), parallelism between screws (E), and effective fixation area (F) were compared between the traditional surgery group (Traditional) and new navigation device group (Navigation) (n=33 per group). *p<0.05; **p<0.01; ***p<0.001.**

fixed by the screws in the lateral position was larger. Moreover, compared with the traditional operation group, all patients in the navigation device group achieved satisfactory fracture healing without complications such as femoral head necrosis and bone nonunion. Thus, the new navigation device increased the accuracy of screw placement and fixation stability while reducing the incidence of postoperative complications.

At present, there have been some studies on the development of navigation devices, and the therapeutic effect has been proved. Using a guidance module to assist with implantation is an option. The guidance module is a fixed module designed according to the structure of the femoral neck, which does not need to be adjusted, so that the guide wire can be positioned quickly [13], [23]. However, there are some differences in the local characteristics of patients, and the guide module can not be finely regulated, and the accuracy of screw implantation will be impaired. The new navigation device in this study can accurately locate the optimal implantation position and angle by sliding and rotating components. Furthermore, the support components of the new navigation device in our study significantly improve the guidance modules that still required constant intraoperative hold. Moreover, computer-aided navigation device is an emerging and effective strategy, which collects and calculates the local information of the patient through the computer to obtain the implantation position and assist the operation [24]. There is no doubt that it does greatly enhance the accuracy of guidewire implantation, but its treatment cost is high, and the operation process is complex, and the operation time is prolonged. In contrast, the navigation device in this study will have a lower cost, a simpler procedure, and a shorter operation time.

This study also has some limitations. The operations in this study were performed by surgeons who were familiar with the navigation device, which may lead to some inevitable bias in the data. For beginners, it may be necessary to learn the operation of the device periodically, so as to make it reach the appropriate state. In addition, a direct comparative study between this novel navigation device and existing navigation modules or computer-aided devices was not performed, which will be improved in future studies to promote the clinical translation and application of the device.

V. CONCLUSION

In this study, a new type of navigation device for femoral neck fracture cannulated screw surgery was designed and fabricated to aid intraoperative screw positioning and increase the accuracy of screw placement. Compared to the traditional surgical method, the new navigation device simplified the surgical procedure, reduced radiation exposure to the patient; moreover, repeated guidewire insertion and removal during the operation was reduced while the accuracy of screw positioning was improved. Our results demonstrate that the navigation device designed in this study is highly effective and safe for cannulated screw implantation in femoral neck

fracture surgery, and the clinical translation of this device will bring great convenience to the treatment of femoral neck fractures.

REFERENCES

[1] S. Duan, H. Liu, W. Wu, K. Yang, Z. Zhang, and S. Liu, "Robot-assisted percutaneous cannulated screw fixation of femoral neck fractures: Preliminary clinical results," *Orthopaedic Surg.*, vol. 11, no. 1, pp. 34–41, Feb. 2019.

[2] C. Long, J.-H. Liu, X.-P. Chai, X.-F. Liu, and Z.-X. Duan, "A novel 3D-printed device for precise percutaneous placement of cannulated compression screws in human femoral neck fractures," *BioMed Res. Int.*, vol. 2021, Jun. 2021, Art. no. 1308805.

[3] P. K. Cronin, D. M. Freccero, M. S. Kain, A. J. Marcantonio, D. S. Horwitz, and P. Tornetta, "Garden 1 and 2 femoral neck fractures collapse more than expected after closed reduction and percutaneous pinning," *J. Orthopaedic Trauma*, vol. 33, no. 3, pp. 116–119, Mar. 2019.

[4] L. Zhuang, L. Wang, D. Xu, and Z. Wang, "Anteromedial femoral neck plate with cannulated screws for the treatment of irreducible displaced femoral neck fracture in young patients: A preliminary study," *Eur. J. Trauma Emergency Surg.*, vol. 45, no. 6, pp. 995–1002, Dec. 2019.

[5] K. Ding et al., "Titanium alloy cannulated screws and biodegradable magnesium alloy bionic cannulated screws for treatment of femoral neck fractures: A finite element analysis," *J. Orthopaedic Surg. Res.*, vol. 16, no. 1, p. 511, Aug. 2021.

[6] Y. Tang, Z. Zhang, L. Wang, W. Xiong, Q. Fang, and G. Wang, "Femoral neck system versus inverted cannulated cancellous screw for the treatment of femoral neck fractures in adults: A preliminary comparative study," *J. Orthopaedic Surg. Res.*, vol. 16, no. 1, p. 504, Aug. 2021.

[7] S. Lindequist, "Cortical screw support in femoral neck fractures: A radiographic analysis of 87 fractures with a new mensuration technique," *Acta Orthopaedica Scandinavica*, vol. 64, no. 3, pp. 289–293, Jan. 1993.

[8] J. W. Oakey, M. D. Stover, H. D. Summers, M. Sartori, R. M. Havey, and A. G. Patwardhan, "Does screw configuration affect subtrochanteric fracture after femoral neck fixation?" *Clin. Orthopaedics Rel. Res.*, vol. 443, pp. 302–306, Feb. 2006.

[9] L. Wan et al., "Application of robot positioning for cannulated screw internal fixation in the treatment of femoral neck fracture: Retrospective study," *JMIR Med. Informat.*, vol. 9, no. 1, Jan. 2021, Art. no. e24164.

[10] M. He et al., "Evaluation of a bi-planar robot navigation system for insertion of cannulated screws in femoral neck fractures," *Orthopaedic Surg.*, vol. 11, no. 3, pp. 373–379, Jun. 2019.

[11] X. Wang, H. Lan, and K. Li, "Treatment of femoral neck fractures with cannulated screw invasive internal fixation assisted by orthopaedic surgery robot positioning system," *Orthopaedic Surg.*, vol. 11, no. 5, pp. 864–872, Oct. 2019.

[12] M. C. Müller et al., "Three-dimensional computer-assisted navigation for the placement of cannulated hip screws. A pilot study," *Int. Orthopaedics*, vol. 36, no. 7, pp. 1463–1469, Jul. 2012.

[13] W. Yin et al., "A novel guidewire aiming device to improve the accuracy of guidewire insertion in femoral neck fracture surgery using cannulated screw fixation," *Med. Sci. Monitor*, vol. 22, pp. 2893–2899, Aug. 2016.

[14] Q.-H. Cheng et al., "Computer-assisted cannulated screw internal fixation versus conventional cannulated screw internal fixation for femoral neck fractures: A systematic review and meta-analysis," *J. Orthopaedic Surg. Res.*, vol. 16, no. 1, p. 687, Nov. 2021.

[15] J.-Q. Wang et al., "Computer-assisted navigation systems for insertion of cannulated screws in femoral neck fractures: A comparison of bi-planar robot navigation with optoelectronic navigation in a Synbone hip model trial," *Chin. Med. J.*, vol. 124, no. 23, pp. 3906–3911, Dec. 2011.

[16] V. Yuenyongviwat, P. Tuntarattanapong, and B. Tangtrakulwanich, "A new adjustable parallel drill guide for internal fixation of femoral neck fracture: A developmental and experimental study," *BMC Musculoskeletal Disorders*, vol. 17, no. 1, p. 8, Jan. 2016.

[17] J.-J. Yang et al., "Risk factors for nonunion in patients with intracapsular femoral neck fractures treated with three cannulated screws placed in either a triangle or an inverted triangle configuration," *J. Bone Joint Surg.*, vol. 95, no. 1, pp. 61–69, Jan. 2013.

[18] J. D. Adams, J. B. Walker, and M. Loeffler, "Avoid the in-out-in posterosuperior femoral neck screw: The use of the piriformis fossa radiographic landmark," *J. Orthopaedic Trauma*, vol. 36, no. 5, pp. 224–227, May 2022.

[19] B. J. Yuan et al., "High incidence of 'in-out-in' posterosuperior screws after cannulated screw fixation femoral neck fractures," *Eur. J. Orthopaedic Surg. Traumatol.*, vol. 30, no. 8, pp. 1417–1420, Dec. 2020.

[20] V. T. Selvan, M. J. Oakley, A. Rangan, and M. K. Al-Lami, "Optimum configuration of cannulated hip screws for the fixation of intracapsular hip fractures: A biomechanical study," *Injury*, vol. 35, no. 2, pp. 136–141, Feb. 2004.

[21] M. Todkar, "The complications of displaced intracapsular fractures of the hip," *J. Bone Joint Surg., Brit. volume*, vol. 87, no. 11, p. 1584, Nov. 2005.

[22] H. K. M. Hamelinck, M. Haagmans, M. M. Snoeren, J. Biert, A. B. van Vugt, and J. P. M. Frölke, "Safety of computer-assisted surgery for cannulated hip screws," *Clin. Orthopaedics Rel. Res.*, vol. 455, pp. 241–245, Feb. 2007.

[23] B.-F. Ren, G. Li, Q.-P. Ma, X. Lv, and J. Sun, "Quick and accurate placement of cannulated screws to internal fixation of femoral neck fractures using a novel guide device," *Adv. Therapy*, vol. 40, no. 3, pp. 844–852, Mar. 2023.

[24] M. Liebergall, D. Ben-David, Y. Weil, A. Peyser, and R. Mosheiff, "Computerized navigation for the internal fixation of femoral neck fractures," *J. Bone Joint Surg.*, vol. 88, no. 8, pp. 1748–1754, Aug. 2006.