**TRAUMA SURGERY** 



# Comparison of percutaneous compression plate to parallel screws in the treatment of nondisplaced femoral neck fractures in elderly patients: a prospective, randomized study

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#### Abstract

**Background** The optimal internal fixation for non-displaced femoral neck fractures remains controversial. This study aimed to compare the clinical results of the percutaneous compression plate (PCCP) with parallel screws (PS) in treating femoral neck fractures in elderly patients.

**Materials and methods** A total of 218 patients who underwent internal fixation were randomized to receive either a percutaneous compression plate (PCCP group) or parallel screws (PS group) using a computerized random sequence generator which was used to assign the order of randomization. Patients were assessed by the operating time, intraoperative blood loss, hemoglobin level drop, postoperative hospital stay, the time to full weight-bearing, reduction quality, fracture healing time, Harris hip score, and postoperative complications.

**Results** There was no significant difference between PCCP and PS groups regarding operative time, intraoperative blood loss, hemoglobin level drop, postoperative hospital stays, reduction quality, and Harris hip score (p > 0.05). The time to full weight-bearing and the fracture healing time in the PCCP group were shorter than those in the PS group (p < 0.05). The overall complication rates were slightly lower in the PCCP compared to the PS patients, but there was no significant difference (p > 0.05). However, the implant failure rate was significantly higher in the PS group compared to the PCCP group (p < 0.05). **Conclusions** The present study suggests that the PCCP is superior to the parallel screws fixation in the treatment of non-displaced elderly femoral neck fractures in terms of earlier full weight-bearing, shorter fracture healing time, and lower implant failure rate. Therefore, it may be a better therapeutic strategy for non-displaced femoral neck fractures in elderly patients.

**Keywords** Non-displaced femoral neck fractures · Percutaneous compression plate · Parallel screws · Minimally invasive surgical technique · Complication

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# Introduction

Femoral neck fractures in the elderly are the most common hip injury and account for 3.13% of all fractures and nearly half of the hip fractures in adults [1, 2]. It is estimated that the number of femoral neck fractures worldwide will reach 4.5 million by the year 2050 [3], seriously impacting the living quality of elderly patients and bringing a substantial economic burden to society [3, 4]. It is generally recommended that hemiarthroplasty or total hip arthroplasty be used for displaced femoral neck fractures in elderly patients [5]. However, the optimal care for non-displaced elderly femoral neck fractures (Garden I, II) is controversial [6]. Some authors suggest the non-operative treatment for Garden type I or II femoral neck fractures because the fractures are acceptably stable [7, 8]. However, outcomes following this strategy are not uniformly satisfactory, as prior studies have documented rates of postoperative secondary displacement ranging from 33 to 44% [6], and the rate of fracture healing was only 44.3% [9]. Subsequently, other authors have recommended surgical strategies, including hemiarthroplasty, total hip arthroplasty, and internal fixation, for non-displaced femoral neck fractures in the elderly to reduce various complications and mortality rates. Although arthroplasty improves mobility and reduces major reoperations, it is more invasive, bleeding, and expensive. Moreover, there was no significant difference between internal fixation and arthroplasty in long-term mortality and reconstructive hip functions. Therefore, internal fixation is currently considered the standard management for elderly patients with Garden I and II fractures [1, 8, 10, 11]. Internal fixation, including hip screw system (e.g., sliding hip screw, dynamic hip screws) and parallel screws for non-displaced femoral neck fractures, is recommended in elderly patients because of its minimal invasiveness, cost-effectiveness, and comparable clinical outcome with hip arthroplasty [12, 13]. Some previously reported that sliding hip screws or dynamic hip screw fixation required larger skin incisions, more soft tissue dissection, more blood loss, and longer length of hospital stay when compared with parallel screws [12, 14]. Although sliding hip screw or dynamic hip screw provides more biomechanical stability, what's more, avascular necrosis occurred more frequently in patients receiving sliding hip screw or dynamic hip screw than parallel screws [15, 16]. Under this consideration, the parallel screw is a preferred option compared with sliding hip screws or dynamic hip screws for osteosynthesis [17]. Although parallel screw is the most common treatment for non-displaced elderly femoral neck fractures [18], there was still a 4.8–11% implant failure rate [18, 19] and a 3.9–5% femoral head necrosis rate [19, 20]. Therefore, the optimal internal fixation strategy remains controversial, and the high complication rate after parallel screws has led surgeons to explore a better internal fixation strategy for non-displaced femoral neck fractures in elderly patients.

Recently, some researchers reported that percutaneous compression plate (PCCP) for femoral neck fractures in young adults obtained favorable short-term and longerterm outcomes [21–23]. Besides, Brandt et al. performed a biomechanical test and demonstrated that PCCP possessed distinguished rotational stability and higher maximum load failure for both stable and unstable intracapsular hip fractures than sliding hip screws [24]. And they also reported in another study that PCCP had some advantages, including less minimally invasive, fewer complications, and earlier full weight-bearing compared with dynamic hip screws [25]. However, it is still unclear whether PCCP is superior to parallel screws for non-displaced femoral neck fractures in elderly patients. Accordingly, the current prospective randomized comparative study compared the clinical outcomes of non-displaced elderly femoral neck fractures treated with PCCP or parallel screws. We hypothesized that PCCP may be a simple and efficient surgical procedure for non-displaced femoral neck fractures in elderly patients with a shorter fracture healing time, earlier full weight-bearing, and a lower implant failure rate.

# **Material and methods**

#### Inclusion and exclusion criteria

The inclusion criteria included: (1) over 60 years of age, (2) closed non-displaced femoral neck fractures (Garden I and II type), (3) capable of walking independently or with aids before the injury, (4) American Society of Anesthesiologists (ASA) classification between level 1–3, (5) time of injury to surgery was less than 72 h.

The exclusion criteria included: (1) patients with a mental disorder or mental illness, (2) patients with symptomatic arthritis before hip fracture, (3) displaced femoral neck fractures (Garden III and IV type), (4) posterior tilt of femoral neck fractures, (5) multiple fractures (combined with femoral head fracture, femoral shaft fracture, or femoral intertrochanteric fracture) or old fractures, and (6) pathology fractures.

#### Method of randomization and blinding

In an operating theater, all 218 patients were assigned to PCCP (PCCP group) or parallel screws (PS group) for nondisplaced elderly femoral neck fractures using a computerized random sequence generator which was used to assign the order of randomization. The sequence was concealed until the allocation was assigned via an opaque envelope (Fig. 1).

#### Surgical procedure

All surgeries were performed by a senior author. Patients were operated on under general anesthesia and were positioned supine on the traction table. Under the C-arm fluoroscopic guidance, closed reduction was performed until satisfactory fracture reduction quality was achieved. The osteosynthesis was achieved with the PCCP (Ortho-fix Orthopedics International, Bussolengo, Italy) or three parallel cannulated screws (Synthes Inc., West Chester, PA, USA). For the PCCP group, the surgical procedures of PCCP are described in detail previously [21]. For the PS group, the operative procedure of PS was standard and followed the three-point principle, with the insertion of three 6.5 mm [26]. After ensuring the quality of reduction and irrigating

study



the wound, the incision was closed without a wound drain. The reduction quality was checked by radiograph with the first postoperative radiographs (anterior-posterior and lateral views) according to the Garden alignment index and Dong [26].

#### **Perioperative regimen**

All patients received antibiotic prophylaxis with cefuroxime (1.5 g) 30 min before the skin incision and consecutively for 24 h after the operation. All patients were managed with a standardized postoperative rehabilitation program. Patients were encouraged to do active knee range of motion, quadriceps, hamstring strengthening, and standing exercises with a tilting table. All patients were allowed to ambulate with partial weight-bearing with walker assistance within 4 weeks after surgery. Full weight-bearing without any assistance was gradually permitted 6 weeks after the operation according to the patient's tolerance.

# **Outcomes of interest**

Clinical and radiographic examinations were scheduled at 6 weeks, 3 months, 6 months, 9 months, and 1 year after surgery, and fresh radiographs: anteroposterior and lateral views of the operated hip were assessed for the fracture healing, implant position, avascular necrosis, implant failure at each visit. Fracture healing was defined as the presence of bridging callus and the absence of the fracture line on both AP and lateral views. The implant failure was defined as the presence of re-displacement, loosening of the implant, and cut-out of the femoral head. Serial radiographs were analyzed by an independent observer.

The clinical data were recorded, including operating time, intraoperative blood loss, hemoglobin level at postoperative 24 h, hemoglobin level drop (preoperative hemoglobin level-hemoglobin level at postoperative 24 h), postoperative hospital stay, the time to full weight-bearing, fracture healing time, Harris hip scores (HHS), and postoperative complications (incision infection, implant failure, non-union, avascular necrosis). The Harris score was used to evaluate the hip joint function. The hip function was assessed using the HHS (0~100 points), and HHS of the two groups was evaluated at 12 months after surgery. The clinical outcomes and HHS were recorded by one of the surgeons at the patients' respective follow-up visits.

#### Follow-up

At the 12-months follow-up, 24 patients (12 in the PCCP) group and 12 in the PS group) had been dead for reasons irrelevant to the surgery. These 24 patients were excluded. The remaining 194 patients (97 patients in the PCCP group and 97 patients in the PS group) are available for analysis.

The detailed distribution of the 194 patients' demographics is shown in Table 1. The institutional review board approved the study, and informed consent was obtained from all patients.

#### **Statistical analysis**

SPSS version 18.0 for Windows (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. The randomization sequence was generated using SPSS. Data were presented as the mean  $\pm$  standard deviation (SD). A *t*-test was used for statistical comparisons between the two groups. The continuous data of the two groups of patients were analyzed with a two-tailed, unpaired *t*-test. Chi-square analysis or Fischer's exact test was used to test for statistically significant differences in the frequencies between the two groups. Differences between the two groups were considered significant when the *p*-value was less than 0.05.

## Results

**Table 1**The preoperative dataand demographics in the two

groups

As shown in Table 1, the PCCP group consisted of 97 patients (21 males and 76 females) with a mean age of 70.2 ± 6.3 years; the PS group consisted of 97 patients (29 males and 68 females) with a mean age of 71.7 ± 7.4 years (p=0.130). The BMI was 22.3 ± 1.9 kg/m<sup>2</sup> and 22.7 ± 2.1 kg/m<sup>2</sup> in the PCCP and PS groups, respectively (p=0.258). Besides, there was no statistical difference between the two groups in injury mechanism (p=0.868), fracture classification (p=0.461), ASA (p=0.190), injury-surgery interval (p=0.402), and preoperative Hb (p=0.552).

#### **Clinical results**

There was no significant difference between the two groups in terms of operative time (p = 0.082), intraoperative blood loss (p = 0.774), hemoglobin at postoperative 24 h (p = 0.779), hemoglobin level drop (p = 0.057), rate of blood transfusion (p = 0.368), postoperative hospital stays (p = 0.533), and Harris hip score (p = 0.228) (Table 2). Compared to the PS group, however, the time to full weight-bearing in the PCCP group was distinctly shorter ( $6.4 \pm 1.2$  vs  $8.2 \pm 1.6$  weeks, p < 0.001, Table 2). Meanwhile, the fracture healing time was significantly shorter in the PCCP group ( $13.9 \pm 2.9$  weeks) than in the PS group ( $14.8 \pm 2.7$  weeks) (p = 0.014, Table 2, Figs. 2, 3), suggesting the PCCP could promote bone healing.

#### Complications

Overall, the total complication rates were slightly lower in the PCCP than in the PS patients, but there was no significant difference (2 vs 8, p = 0.100, Table 2). Specifically, eight patients had relevant complications, including six who underwent implant failure and two avascular necrosis in the PS group while two patients had avascular necrosis in the PCCP group. Complete fracture union was confirmed through X-ray reexamination. Moreover, no patients experienced non-union or infection at the incision site. In addition, implant positionings were satisfactory in both groups after internal fixation. There was no significant difference (p=1.0) regarding the satisfactory reduction rates between the two groups (Table 2). Furthermore, the mean HHS for the PCCP and PS groups were  $88.5 \pm 6.3$  and  $87.3 \pm 7.4$ , respectively. Thus, there was satisfactory recovery after

	PCCP group $(n=97)$	PS group $(n=97)$	р
Gender			
Male/female	21/76	29/68	0.188
Age (years)	$70.2 \pm 6.3$ (range, 61–88)	71.7±7.4 (range, 61–90)	0.130
BMI (kg/m <sup>2</sup> )	$22.3 \pm 1.9$ (range, 17.8–26.8)	22.7±2.1 (range, 17.4–27.6)	0.258
Injury mechanism			0.868
Simple fall	52	55	
Vehicular trauma	24	21	
Fall from a height	21	21	
Garden type			0.461
Garden I	35	40	
Garden II	62	57	
ASA	$2.0 \pm 0.7$ (range, 1–3)	$1.9 \pm 0.8$ (range, 1–3)	0.190
Injury-surgery interval (h)	55.9±16.8 (range, 36–72)	57.9±16.1 (range, 36–72)	0.402
preoperative Hb (g/L)	115.4±14.2 (range, 89–142)	114.2 ± 14.9 (range, 91–140)	0.552

BMI Body Mass Index, ASA American Society of Anesthesiologists

Data are presented as mean  $\pm$  s.d. (range) or number (%)

Table 2	Clinical	results	in	the
two grou	ups			

PCCP group $(n=97)$	PS group $(n=97)$	р
40.9±5.7 (range, 25–50)	39.5±5.9 (range, 25–50)	0.082
80.2±11.5 (range, 55-100)	79.7 ± 10.9 (range, 50–95)	0.774
102.1 ± 14.1 (range, 76–130)	101.5±14.5 (range, 76–130)	0.779
13.4±2.0 (range, 10–18)	7–15 (12.7 $\pm$ 2.8)	0.057
4 (4.1%)	1 (1.0%)	0.368
$4.1 \pm 1.1$ (range, 3–6)	$3.9 \pm 1.2$ (range, 3–6)	0.533
$6.4 \pm 1.2$ (range, 5–8)	$8.2 \pm 1.6$ (range, 6–11)	0.000
13.9±2.9 (range, 10–18)	14.8±2.7 (range, 10–19)	0.014
97/97	97/97	1.0
88.5±6.3 (range, 68–98)	87.3±7.4 (range, 65–95)	0.228
2 (2.1%)	8 (8.2%)	0.100
0	0	_
0	6 (6.2%)	0.029
0	0	_
2 (2.1%)	2 (2.1%)	_
	PCCP group $(n = 97)$ $40.9 \pm 5.7$ (range, 25–50) $80.2 \pm 11.5$ (range, 55–100) $102.1 \pm 14.1$ (range, 76–130) $13.4 \pm 2.0$ (range, 10–18) 4 (4.1%) $4.1 \pm 1.1$ (range, 3–6) $6.4 \pm 1.2$ (range, 5–8) $13.9 \pm 2.9$ (range, 10–18) 97/97 $88.5 \pm 6.3$ (range, 68–98) 2 (2.1%) 0 0 2 (2.1%)	PCCP group $(n=97)$ PS group $(n=97)$ $40.9 \pm 5.7$ (range, 25–50) $39.5 \pm 5.9$ (range, 25–50) $80.2 \pm 11.5$ (range, 55–100) $79.7 \pm 10.9$ (range, 50–95) $102.1 \pm 14.1$ (range, 76–130) $101.5 \pm 14.5$ (range, 76–130) $13.4 \pm 2.0$ (range, 10–18) $7-15$ (12.7 $\pm 2.8$ ) $4$ (4.1%) $1$ (1.0%) $4.1 \pm 1.1$ (range, 3–6) $3.9 \pm 1.2$ (range, 3–6) $6.4 \pm 1.2$ (range, 5–8) $8.2 \pm 1.6$ (range, 6–11) $13.9 \pm 2.9$ (range, 10–18) $14.8 \pm 2.7$ (range, 10–19) $97/97$ $97/97$ $88.5 \pm 6.3$ (range, 68–98) $87.3 \pm 7.4$ (range, 65–95) $2$ (2.1%) $0$ $0$ $0$ $2$ (2.1%) $2$ (2.1%)

AVN Avascular necrosis

Data are presented as mean  $\pm$  s.d. (range) or number (%)

Bold *p* values indicated that groups were significantly different (p < 0.05)

Fig. 2 Radiographs of a 70-year-old female patient with a non-displaced femoral neck fracture were treated with PCCP. A1, A2 pre-operatively. B1, B2 Anteroposterior radiograph 2-day postoperative shows a satisfactory position of fracture and implants. C1, C2 Anteroposterior radiograph 12-week postoperative shows successful fracture healing



Fig. 3 Radiographs of an 78-year-old female patient with non-displaced femoral neck fracture was treated with three parallel screws. A1, A2 pre-operatively. B1, B2 Anteroposterior radiograph 2-day postoperative shows a satisfactory position of fracture and implants. C1, C2 Anteroposterior radiograph 15-week postoperative shows successful fracture healing



fixation with PCCP or PS for femoral neck fractures in elderly patients. However, the rate of implant failure was significantly higher in the PS group (6.2%) compared to the PCCP group (0%) (p = 0.029, Table 2). However, none of the patients required reoperation in either group during the 12-months follow-up period.

# Discussion

Femoral neck fractures have continued to increase among elderly patients along with increasing life expectancies in our community and have become a common cause of morbidity and mortality. Among femoral neck fractures, the non-displaced femoral neck fracture represents approximately 20% [27, 28]. Previously, parallel screws or hip screw systems have used to be the mainstream internal fixations strategy for non-displaced femoral neck fractures in the elderly population [12, 29]. Due to minimally invasive, shorter surgical time, and less intraoperative blood loss, many authors suggested that the preferred surgical method for non-displaced elderly femoral neck fractures was the internal fixation with parallel screws. However, higher rates of implant failure and femoral head necrosis were reported in elderly patients treated with internal fixation with parallel screws due to the lack of biomechanical stability [19, 30–32]. A biomechanical study shows that a stable angular plate (DHS-Screw, DHS-Blade, or FNS) provided superior stability compared to three parallel screws [31]. Hence, if an internal fixation can be placed using a minimally invasive surgical technique and provide good biomechanical stability, it will be a better choice for treating femoral neck fractures.

It is well known that PCCP is used initially to treat pertrochanteric fractures due to the advantages of percutaneous insertion and the principles of DHS [33]. Many orthopedic surgeons have attempted to fix femoral neck fractures with PCCP and obtained satisfactory healing with fewer complications [21, 23]. To our knowledge, there are no related reports comparing the PCCP and parallel screws fixation methods for treating non-displaced femoral neck fractures in the elderly. Therefore, in the current study, we compared the short-term outcomes of the PCCP and parallel screws in treating non-displaced elderly femoral neck fractures. Our findings showed no significant difference in the operative time, intraoperative blood loss, Hb level at postoperative 24 h, Hb level drop, and rate of blood transfusion between PCCP and parallel screws treating non-displaced femoral neck fractures in the elderly population. In our study, the average surgical time was shorter than previously reported with PCCP implants [21, 23], primarily because the non-displaced femoral neck fractures were relatively stable and easy to reduce. A shorter surgical time reduces the risk of intraoperative and the risk of damage attributed to anesthesia, representing less invasion [2]. From this perspective, these results indicated that the PCCP for elderly nondisplaced femoral neck fractures has a minimal invasion and less blood loss, resulting in faster recovery and satisfactory function. Therefore, the PCCP may be a better option for elderly non-displaced femoral neck fractures due to minimal invasiveness with less soft tissue dissection. Furthermore, incision within the safe vascular zone reduces blood loss and operative time.

There is still no consensus or preferred protocol for weight-bearing after internal fixation of non-displaced elderly femoral neck fractures. Some authors suggested that early full weight-bearing was associated with positive postoperative outcomes after internal fixation of the elderly femoral neck fractures, including decreased mortality, functional outcomes, and improved bone healing [34–36]. In contrast, others believed that early weight-bearing could increase the reoperation rate, and elderly patients with non-displaced femoral neck fractures would benefit from delayed weight-bearing postoperatively [37, 38]. In this study, the time to full weight-bearing was  $6.4 \pm 1.2$  weeks in the PCCP group, which was significantly shorter than in the PS group (8.2  $\pm$  1.6 weeks, p < 0.001). However, the postoperative complications were similar in both groups (2.1% vs 8.2%, p=0.100). Thus, it can be seen that early weight-bearing does not increase the rate of complications. A biomechanical study demonstrated that the composite force of anti-compression and anti-rotation of PCCP was superior to DHS [24], and DHS was more biomechanically stable than parallel screws [31, 39]. The PCCP is designed to combine the advantages of DHS and PS. Therefore, we assume PCCP provides more robust mechanical stability and guarantees postoperative rehabilitation and early full weight-bearing without fixation failure. Besides, immediate mobilization and early full weight-bearing are crucial rehabilitation strategies in the elderly, which are beneficial to regaining preoperative ambulatory status and decreasing morbidity and mortality. Hence, the PCCP as internal fixators will be a promising strategy for non-displaced femoral neck fractures in elderly patients due to the advantage of percutaneous insertion and reliable biomechanical features. It can not only allow patients to be fully weight-bearing early but also does not increase the incidence of complications.

Fracture non-union and avascular necrosis of the femoral head are regarded as the two severe complications following internal fixation of femoral neck fractures [26]. Garden classification is a determining factor in developing avascular necrosis of the femoral head following femoral neck fractures. Adequate fracture reduction is conducive to fracture healing due to restoring biomechanical stability, protecting the residual blood supply around the femoral head, and reducing the intracapsular pressure ("tamponade effect"), ultimately determining the fate of the femoral head [17, 26]. In our study, PCCP and parallel screws for non-displaced femoral neck fractures had a 100% union rate and a lower occurrence of avascular necrosis (2.1%). It was probably why all femoral neck fractures were stable (Garden I and II), and the reduction quality was excellent in the present study. In addition, PCCP internal fixation for non-displaced elderly femoral neck fractures had a shorter fracture healing time and a lower implant failure rate compared to the parallel screws. These positive results were attributed to the rational design and stable biomechanical features [23, 40]. PCCP implant has two thicker screws in the neck-head and an angular locking connection between the screw and plate. This design possesses reliable stability in all directions and dynamic compression ability [23, 40]. The marked compressive effect for the fracture ends affords better fixation stability and facilitates fracture healing under external force loading [29]. Therefore, short fracture healing time and the predominant anti-shear and anti-rotation features could reduce implant failure rates in elderly femoral neck fractures [41], achieving satisfactory fracture healing and functional recovery. Consistent with our study, Zhu et al. [21] and Jin et al. [23] have reported satisfactory healing with fewer complications in femoral neck fractures treated with PCCP implants.

In addition, we found that PCCP and parallel screws have similar postoperative hospital stays and Harris hip scores for treating non-displaced femoral neck fractures in elderly patients (p > 0.05). From this perspective, the therapeutic outcomes of PCCP were not superior to that of the parallel screws in terms of hospital stays and hip function. Postoperative hospital stays are mainly determined by surgical trauma and individual physical quality; hip function is mainly related to the joint condition, fracture union, and postoperative rehabilitation exercises. As mentioned above, PCCP and PS had a similar minimal invasion and less blood loss when treated with non-displaced elderly femoral neck fractures, resulting in faster recovery and satisfactory function. Furthermore, our results suggested that the Harris hip score was significantly higher in elderly patients in both groups. Previous studies have shown that a stable angular plate (dynamic locking plate or sliding hip screw) was not better than parallel screws in terms of the score [12, 42].

The present study has several limitations. Firstly, the trial was conducted at a single center, and the sample size was relatively small. We suggest that further studies with a greater number of patients should be done to consolidate our findings. Secondly, the fixation operations (PCCP and PS) were performed by the same surgeon in our study. The same surgeon could ensure consistency in surgical technique, which could reduce a potential bias influencing the final

operational outcomes. However, the surgeon independently selected the implants, leading to potential selection bias. In this study, all patients were randomly assigned by a computerized random sequence generator to minimize selection bias in our study. Thirdly, we did not consider the positioning of implants between both groups. Although it could potentially increase the risk of nonunion and implant failure, it was difficult to compare the placement of two different implants. Fourthly, mortality was not evaluated in the present study. In the study, there were 24 deaths (12 in the PCCP group and 12 in the PS group) for reasons irrelevant to the surgery during 12 months of follow-up. We assumed that the mortality was primarily related to patients' physical quality and that there was little correlation with the implants. A short follow-up time could be likely to underestimate mortality, reoperation rate, and implant failure in both groups.

# Conclusions

In conclusion, the present study suggests that the PCCP is superior to the parallel screws fixation in the treatment of non-displaced elderly femoral neck fractures in terms of earlier full weight-bearing, shorter fracture healing time, and lower implant failure rate. Therefore, the PCCP may be a better therapeutic strategy for non-displaced femoral neck fractures in elderly patients.

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**Data availability** The data that support the findings of this study are available from the corresponding author upon reasonable request.

## Declarations

**Conflict of interest** All the authors declared that no conflicts of interest specifically relevant to this study.

**Ethical approval** The study was approved by Affiliated Hospital of Jiangnan University.

**Informed consent** Informed consent was obtained from all individual participants included in the study.

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