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Does an additional attachment plate improve fixation in Vancouver type B1 and C periprosthetic femoral fractures? A retrospective comparative study

Soo-Hwan Jung¹, Chul-Ho Kim², Jae Suk Chang³ and Ji Wan Kim^{2*}

Abstract

Introduction This study compared the clinical and radiologic outcomes of well-fixed periprosthetic femoral fractures after hip arthroplasty according to the use of single plate fixation with additional attachment plate device (group 1) or not (group 2).

Materials and methods Retrospective data were obtained from a single center by reviewing medical records of patients who underwent reduction and internal fixation of Vancouver type B1 and C periprosthetic femoral fractures between June 2006 and June 2021. The study analyzed patient demographics, fracture characteristics, surgical details, functional outcomes (Harris hip score [HHS] and Koval score at 1-year follow-up), reoperation rates, and radiologic findings. In this study, nonunion and malunion were defined as indicators of “healing problems.”

Results Among the 32 included patients (group 1: 15; group 2: 17), fractures resulted from high-energy (six cases) and low-energy (26 cases) injuries, with no open fractures. The fractures included 21 cases of Vancouver type B1 and 11 cases of type C. One patient (6.7%) in group 1 required revision surgery. Excellent or good outcomes were observed in 100% of group 1 and 88.2% of group 2 patients according to Beals–Tower criteria ($p=0.031$). Healing problems occurred in 6.7% and 41.2% of patients in groups 1 and 2, respectively ($p=0.03$). HHS score, Koval score, union time, or femoral alignment did not differ significantly between the two groups ($p>0.05$).

Conclusions Using an additional plate in the treatment of well-fixed periprosthetic femoral fractures yielded better clinical outcomes compared to cases without an additional plate. Lower rates of nonunion or delayed union and improved overall healing were observed in the augmented group.

Keywords Periprosthetic femoral fracture, Attachment plate, Healing problem, Total hip arthroplasty, Clinical outcome

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Introduction

Periprosthetic femoral fracture (PFF) is among the most serious complications after total hip arthroplasty (THA), and it is a major cause of early failure [1]. Treating PFFs presents a difficult challenge. The number of PFFs is increasing due to a rise in the elderly population worldwide and the increasing prevalence of hip arthroplasty [2]. PFF is the third most common cause (6%) of revision surgery after THA [3, 4]. The incidence of PFF is 0.4–1.1% after THA and 2.1–4% after revision hip arthroplasty [3, 5]. The Vancouver classification, the most widely used for PFF, classifies the fractures into three types—A, B, and C—based on the fracture location. Type B is defined as a fracture around the stem or just below its tip, and type C is defined as a fracture well below the stem tip. Type B is subdivided based on implant fixation status and bone loss. In B1 fractures, the implant is stable and well-fixed. B2 is associated with a loose stem and adequate bone stock, and B3 has a loose stem with inadequate bone stock [6]. In type B1 or C fractures with stable stems, the principle of management is open reduction and internal fixation. Several studies have reported satisfactory outcomes of internal fixation [1, 7]. Recently developed poly-axial plates or attachment plates reportedly provide satisfactory results in achieving sufficient stability at the proximal area of the femur with the stem [8, 9]. However, thus far, few studies have compared the outcomes of internal fixation between attachment plate use and non-use. We hypothesized that internal fixation augmented with additional plates would improve clinical and radiologic outcomes. Thus, this study evaluated whether the surgical outcomes of internal fixation with an attachment plate differed from those without this augmentation.

Materials and methods

This study was approved, and informed consent was waived due to the retrospective nature of the study and the analysis used anonymous clinical data, by the Ethics Committee of Institutional Review Board of Asan Medical Center, Seoul, Republic of Korea (IRB No. 2022–0862). All experiments were performed in accordance with relevant guidelines and regulations.

Patients and study design

After obtaining approval from the Institutional Review Board, we retrospectively reviewed data from patients who underwent internal fixation of Vancouver type B1 and C PFFs after hip arthroplasty between June 2006 and June 2021. Among these patients, we evaluated those who were followed up for at least 12 months at our institution. Two orthopedic surgeons performed all the surgeries. Both were fellowship-trained orthopedic trauma surgeons with extensive experience, currently serving as faculty members specializing in orthopedic hip and

trauma surgery at a university hospital. The inclusion criteria were: (1) patients diagnosed with PFF after THA or hemiarthroplasty (HA); (2) Vancouver type B1 or C1, well-fixed femoral stem; and (3) patients who received reduction and internal fixation. The exclusion criteria were: (1) intraoperative fractures; (2) concomitant infection; (3) concomitant acetabular fracture; and (4) incomplete medical records or follow-up of < 12 months. Among the 69 patients with PFF, 32 were finally enrolled. (Fig. 1).

We recorded patient information, including age at the time of PFF diagnosis, sex, injury mechanisms, body mass index (BMI), bone mineral density (BMD), smoking history, American Society of Anesthesiologists (ASA) classification [10], Charlson comorbidity index (CCI) [11], and follow-up periods. At our institution, BMD testing is routinely performed during the initial hospitalization period, typically within 4 days after surgical fixation of the fracture and before discharge. However, due to national health insurance guidelines in our country, BMD testing is usually reimbursed only once per year. As a result, in some cases—particularly when a prior BMD scan had been performed within the past year—the scan was not repeated at the time of the periprosthetic fracture but instead relied on the most recent available measurement. Additionally, we obtained surgery data from the medical records, including primary diagnosis (osteonecrosis, osteoarthritis, intertrochanteric fracture, or femur neck fracture), implant stem type (HA, THA, or revision THA), duration from hip arthroplasty to PFF diagnosis, fracture pattern including open fractures and Vancouver classification, number of cortices of screw purchase and wires according to the fracture site, and surgical method (minimally invasive plate osteosynthesis or open reduction and internal fixation), and estimated blood loss (EBL) between each group. Furthermore, we reviewed the need for reoperation. \pm .

Details of surgical procedure

In all cases, the surgical goal was to achieve direct reduction. The primary fixation was performed using a lateral plate, with the objective of securing six intact cortices each in the proximal and distal fracture fragments. However, due to the nature of periprosthetic fractures, it was often difficult to achieve six intact cortices because of the presence of a retained femoral stem. In such cases, an additional attachment plate was used to supplement fixation. For the lateral plate, either a femoral Locking Compression Plate 4.5/5.0 (DePuy Synthes, West Chester, PA, USA) or the NCB® Periprosthetic Femur System (Zimmer Inc., Warsaw, IN, USA) was utilized.

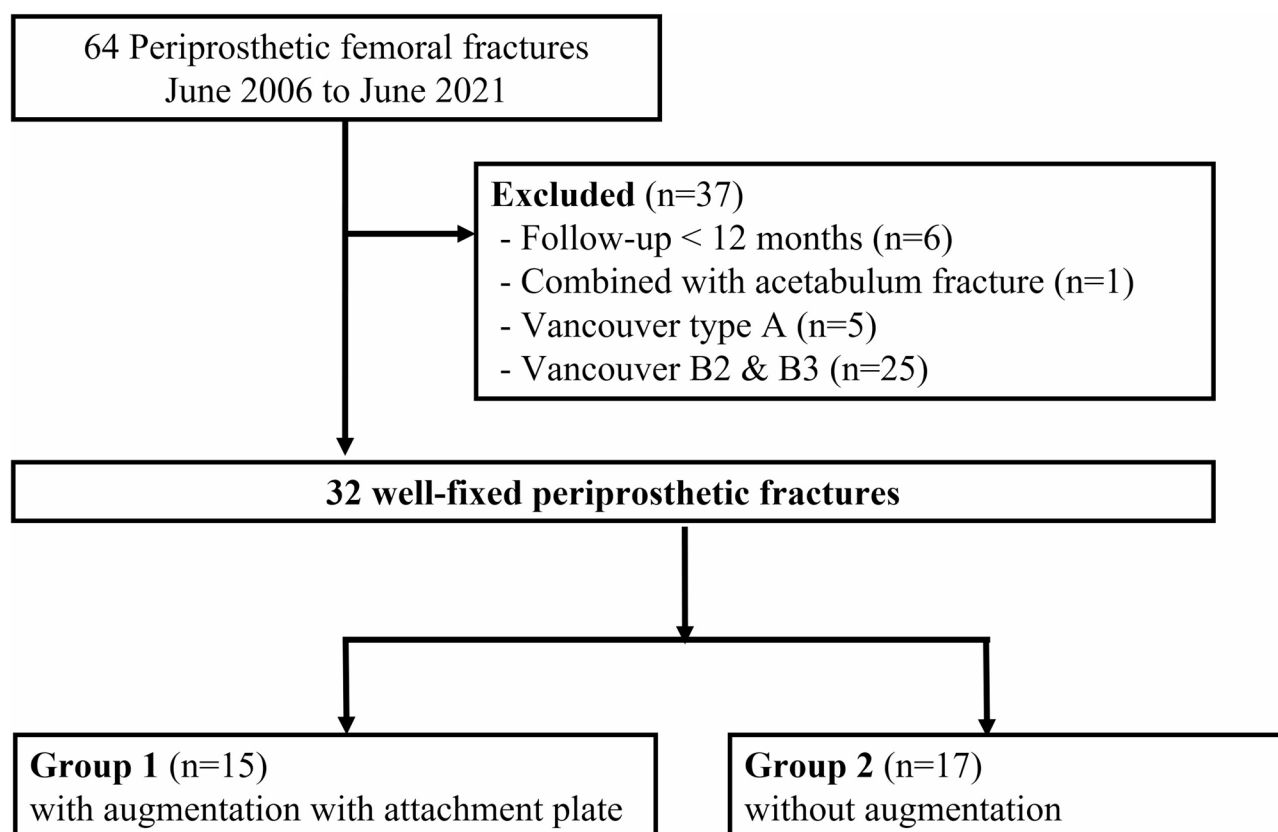


Fig. 1 Flow chart of patient selection

Additional attachment plates

Two types of additional attachment plates were used to achieve adequate screw fixation around the proximal part of the stem: Locking Attachment Plate (LAP, Depuy-Synthes, West Chester, PA, USA) and Non-Contact Bridging Periprosthetic Trochanter Plate (NCB PP, Zimmer Inc., Warsaw, IN, USA). Group I consisted of nine patients who received a LAP (Fig. 2), which is a clamp-on plate attached to a conventional locking compression plate (LCP, Depuy-Synthes, West Chester, PA, USA), which provides crossed arms on each side of the plate with 3.5 mm locking or cortical screws beside the prosthesis stem [12, 13]. Six patients received the NCB PP (Fig. 3), which is designed to reattach the greater trochanter in combination with a poly-axial NCB periprosthetic proximal femur plate, which enables the insertion of 3.5 mm locking screws around the stem [14].

Postoperative rehabilitation

All patients received the same postoperative rehabilitation protocol. Range of motion exercises within a tolerable level using continuous passive motion were allowed after internal fixation. Weight-bearing was restricted for 4 weeks postoperatively, and then partial weight-bearing within a tolerable range was allowed with a walker or crutches until bone union.

Radiologic evaluations

The radiologic findings included union rate, union time, anatomical alignment of femur and Beals and Tower's classification at the last radiologic follow-up. The radiological assessment included femur anteroposterior (AP) and lateral radiographs. Union was defined as the bridging of the fracture at three cortices on AP and lateral femur radiographs, and clinically as the absence of pain during weight-bearing [15]. However, delayed union was defined as a failure to reach bony union by 6 months postoperatively, whereas nonunion was defined as the absence of progressive fracture healing over 3 months, which extends beyond 9 months from the date of the operation [16, 17]. Furthermore, the degrees of alignment of the femur in the coronal and sagittal plane on radiographs of the AP and lateral femur were evaluated. In this study, anatomical alignment was categorized as good anatomical alignment; fair ($<5^\circ$ of malalignment), and poor ($>5^\circ$ of malalignment) [18, 19].

The Beals and Tower's criteria [20], which classify the clinical results as excellent (stable arthroplasty with minimal deformity), good (stable arthroplasty or with minimal subsidence and fracture healed with moderate deformity), or poor (loosening, nonunion, sepsis, severe deformity or new fracture), were applied at the final follow-up. Moreover, nonunion and malunion were

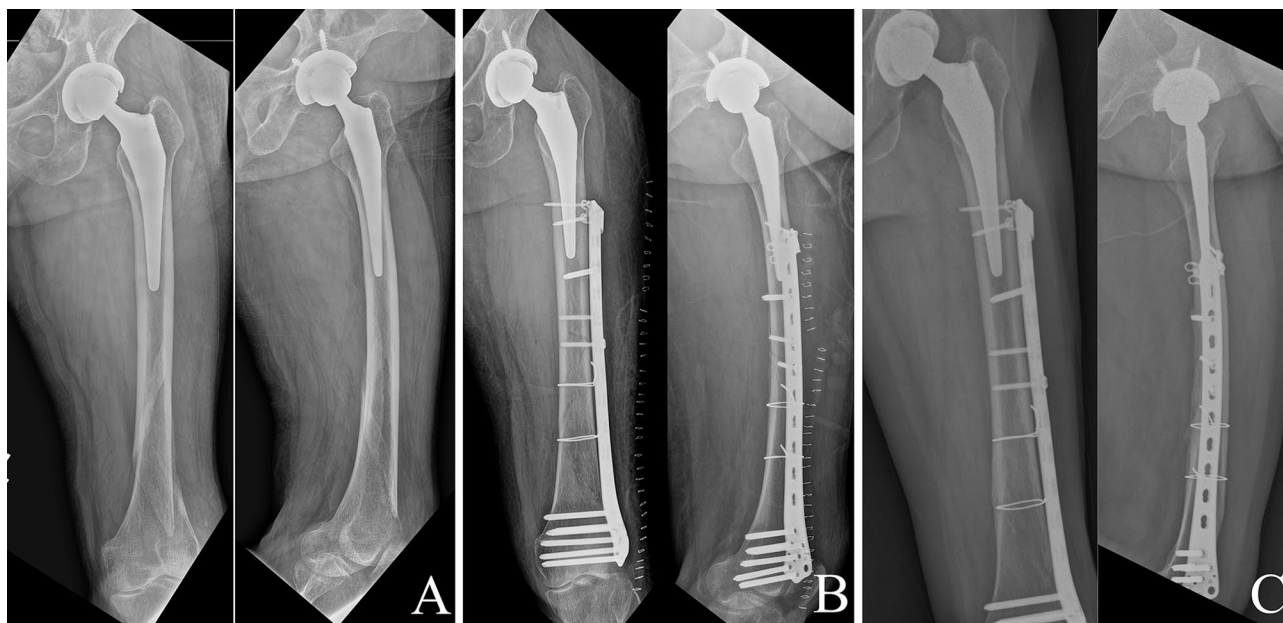


Fig. 2 (A) A 74-year-old woman with a left periprosthetic femur fracture (Vancouver type C). (B) Treatment with open reduction and internal fixation radiographs with the locking compression plate for distal femur (LCP-DF) proximally augmented with an attachment plate. (C) Six-month postoperative radiographs showing bone union with good alignment

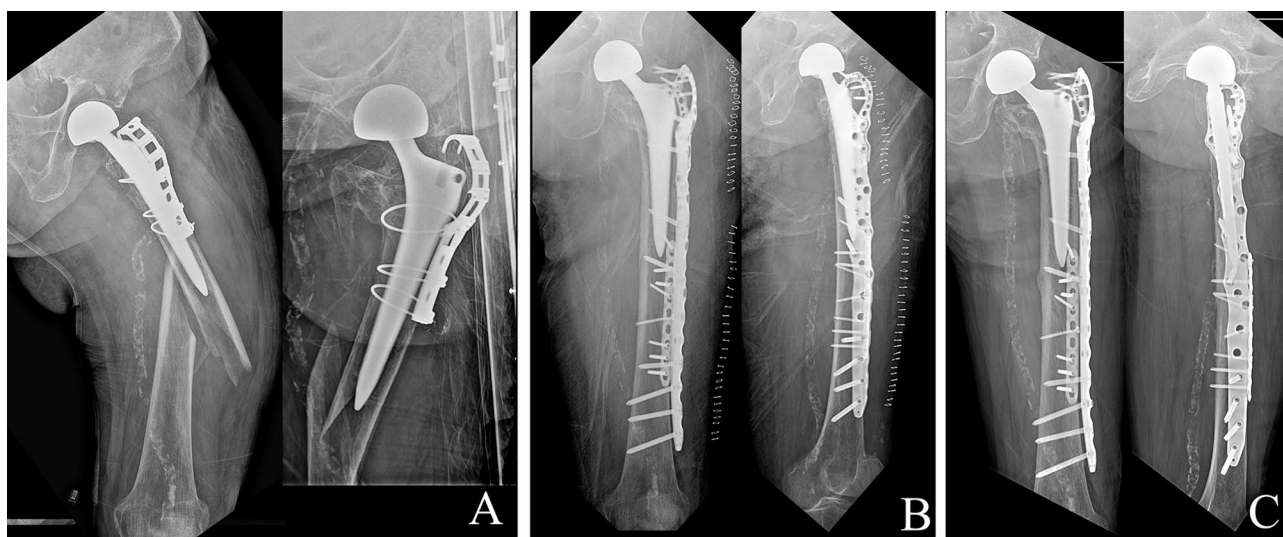


Fig. 3 (A) A 91-year-old woman with a left periprosthetic femur fracture (Vancouver type B1). (B) Osteosynthesis with a dual locking plate augmented with an attachment plate. (C) Six-month postoperative radiographs showing bone union with good alignment

considered healing problems. We investigated all additional surgeries related to the PFF operation, such as superficial or deep infection, refracture, dislocation, or aseptic loosening, for reoperation assessment.

Clinical evaluation

Functional outcomes were evaluated by Harris hip score (HHS) 1 year postoperatively. Ambulatory ability was assessed with the Koval's score (grade 1: independent community ambulator, grade 2: community ambulator with a cane, grade 3: community ambulator with

walker/crutches, grade 4: independent household ambulator, grade 5: household ambulator with a cane, grade 6: household ambulator with walker/crutches, grade 7: nonfunctional ambulator). HHS and Kovel scores were assessed via the medical records or a telephone interview.

Statistics

The demographic data, radiologic and clinical outcomes were compared between the two groups. Statistical evaluation was performed by a specialized statistician in our institution using IBM SPSS Statistics for Windows,

Table 1 Baseline demographics

	Group 1 (n = 15)	Group 2 (n = 17)	Pvalue
Female, n (%)	10 (66.7)	15 (88.2)	0.209
Male, n (%)	5 (33.3)	2 (11.8)	
Age at surgery (years)	78.1 ± 8.0	80.8 ± 10.1	0.425
BMI (kg/m ²)	22.7 ± 2.7	24.3 ± 4.5	0.216
BMD (T-score)	-2.1 ± 1.5	-3.0 ± 1.2	0.062
Smoking (packs × years)	5.8 ± 15.4	5.4 ± 15.0	0.765
ASA score	2.5 ± 0.5	2.3 ± 0.5	0.322
CCI	4.9 ± 1.1	4.5 ± 1.1	0.149

BMI, body mass index; BMD, bone mineral density; ASA, American Society of Anesthesiology; CCI, Charlson comorbidity index

Group 1, with attachment plate augmentation; Group 2, without attachment plate augmentation

version 25.0 (IBM Corp., Armonk, NY, USA). Independent *t*-tests or Mann–Whitney tests were used to compare continuous variables, whereas chi-square or Fisher's exact tests were used to compare categorical variables. All tests were analyzed with a 95% confidence level. The level of significance was set at 0.05.

Results

The fractures resulted from high-energy injuries, including high-energy falls, motor vehicle accidents (six cases), and low-energy injuries (26 cases). No cases involved open fractures. Additionally, in all enrolled cases, the index surgery was performed using a cementless stem. The mean age of the patients was 79.5 years (62–93 years) and the mean follow-up period was 18.8 months (12–118 months). Twenty-five of the fractures were in women (seven in men). Fifteen patients received an attachment plate (group 1), and 17 patients did not (group 2). Comparison of the patients' baseline demographics, BMI, BMD, smoking periods, ASA score, and CCI between groups 1 and 2 showed no statistically significant differences (Table 1).

The surgical details are summarized in Table 2. This study included 21 Vancouver type B1 fractures and 11 type C fractures. Four different types of plates were used in the surgeries: 14 cases with locking compression plates for the distal femur (LCP-DF), seven cases with 5.0 mm LCPs, eight cases with NCB plates, and three cases with the greater trochanteric reattachment (GTR, Zimmer Inc., Warsaw, IN, USA) cable-ready system. In group 1, LAPs were used in nine cases, and poly-axial NCB peri-prosthetic proximal femur plates were used in six cases. The number of cortices with purchase by the proximal screws was significantly higher in group 1 compared to group 2 (14.2 ± 4.1 vs. 3.4 ± 3.9 , $p < 0.001$). In contrast, the proximal wire was more frequently used in group 2 compared to group 1 (0.2 ± 0.4 vs. 1.3 ± 1.2 , $p = 0.004$). Group 1 also had a higher number of distal screws used compared to group 2 (13.5 ± 4.6 vs. 5.6 ± 4.6 , $p < 0.001$). The EBL was no differences between two groups (232.3 ± 201.4 vs. 214.6 ± 115.1 , $p = 0.546$).

The clinical and radiological outcomes are summarized in Table 3. The Koval scores and HHS did not differ significantly between the two groups. In group 1, one patient (6.7%) had nonunion, which was successfully treated with a bone graft. In group 2, seven patients (41.2%) had nonunion (five cases, Fig. 4) or delayed union (two cases), but this difference was not statistically significant ($p = 0.069$). There was no significant difference in union times between the two groups (24.0 ± 12.7 vs. 41.5 ± 53.2 weeks, group 1 and group 2, respectively). Group 1, had a significantly higher proportion of patients with good and fair alignment compared to group 2 (100% vs. 82.3%, $p = 0.031$), as determined by the Beals–Tower criteria. Group 2 had significantly more healing problems compared to group 1 (41.2% vs. 6.7%, $p = 0.03$). One patient (5.9%) in group 2 required reoperation due to a superficial surgical site infection, which was successfully

Table 2 Surgery data

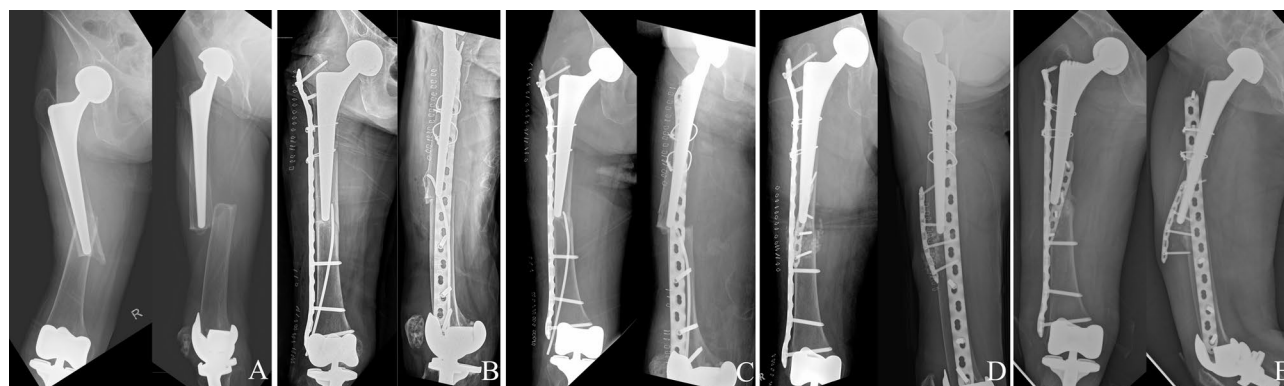
	Group 1 (n = 15)	Group 2 (n = 17)	Pvalue
Initial diagnosis (ONFH/OA/femur neck Fx./intertrochanteric Fx.), n (%)	4 (26.7%), 3 (20%), 7 (46.7%), 1 (6.7%)	3 (17.6%), 4 (23.5%), 8 (47.1%), 2 (11.8%)	> 0.999
Vancouver type (B1/C), n (%)	9 (60%), 6 (40%)	12 (70.6%), 5 (29.4%)	0.529
Initial operation (HA/THA/Revision)	3 (20%), 8 (53.3%), 4 (26.7%)	8 (47.1%), 6 (35.3%), 3 (17.6%)	0.282
Time interval (months) to Fx.	118.9 ± 114.6	78.7 ± 75.0	0.258
Number of cortices of proximal screw purchase	14.2 ± 4.1	3.4 ± 3.9	< 0.001*
Number of cortices of distal screw purchase	13.5 ± 4.6	5.6 ± 4.6	< 0.001*
Number of proximal wires	0.2 ± 0.4	1.3 ± 1.2	0.004*
Number of distal wires	0.3 ± 0.6	0.6 ± 0.9	0.503
Plate length (mm)	312.1 ± 61.2	208.4 ± 105.0	0.002*
MIPO vs. ORIF	9 (60%), 6 (40%)	6 (35.3%), 11 (64.7%)	0.162
Estimated blood loss, mL	232.3 ± 201.4	214.6 ± 115.1	0.546

Fx., fracture; ONFH, osteonecrosis of femoral head; OA, osteoarthritis; MIPO, minimally invasive plate osteosynthesis; ORIF, open reduction and internal fixation

Table 3 Comparison of the clinical and radiologic outcomes between the two groups

	Group 1 (n = 15)	Group 2 (n = 17)	Pvalue
Koval score	3.7 ± 2.3	3.9 ± 2.5	0.549
HHS	71.3 ± 13.3	65.0 ± 26.7	0.505
Union/delayed/nonunion, n (%)	14 (93.3%), 0 (0%), 1 (6.7%)	10 (58.8%), 2 (11.8%), 5 (29.4%)	0.069
Union time (weeks)	24.0 ± 12.7	41.5 ± 53.2	0.678
Beals–Tower criteria (excellent/good/poor), n (%)	14 (93.3%), 1 (6.7%), 0 (0%)	9 (52.9%), 6 (35.3%), 2 (11.8%)	0.031*
Alignment (good/fair/poor), n (%)	13 (86.7%), 2 (13.3%), 0 (0%)	10 (58.8%), 4 (23.5%), 3 (17.6%)	0.201
Healing problem	1 (6.7%)	7 (41.2%)	0.03*

HHS, Harris hip score

**Fig. 4** (A) A 70-year-old woman with a right periprosthetic femur fracture (Vancouver type B1). (B) Treatment with minimal invasive plate osteosynthesis showing good reduction. (C) Reduction loss at postoperative day 13. (D) Revision osteosynthesis with an anterior plate and bone substitute. (E) Two-year postoperative radiographs showing union with malalignment**Table 4** Comparison of the clinical and radiologic outcomes between the two kinds of plating technique (MIPO vs. ORIF)

	MIPO (n = 15)	ORIF (n = 17)	Pvalue
Koval score	3.6 ± 2.1	4.1 ± 2.6	0.615
HHS	72.2 ± 11.9	63.8 ± 27.1	0.378
Union/delayed/nonunion, n (%)	11 (73.4%), 2 (13.3%), 2 (13.3%)	13 (76.5%), 0 (0%), 4 (23.5%)	0.411
Union time (weeks)	44.4 ± 50.2	20.0 ± 8.4	0.135
Beals–Tower criteria (excellent/good/poor), n (%)	11 (73.3%), 4 (26.7%), 0 (0%)	12 (70.6%), 3 (17.6%), 2 (11.8%)	0.591
Alignment (good/fair/poor), n (%)	11 (73.3%), 4 (26.7%), 0 (0%)	12 (70.6%), 2 (11.8%), 3 (17.6%)	0.237
Healing problem	4 (26.7%)	4 (23.5%)	0.579

MIPO, minimally invasive plate osteosynthesis; ORIF, open reduction and internal fixation; HHS, Harris hip score

treated with antibiotics and debridement. Subgroup analyses based on the minimally invasive plate osteosynthesis (MIPO) and open reduction group did not demonstrate any significant difference in HSS, Koval score, union rate, union time, anatomical alignment of the femur, Beals and Tower's classification and healing problems (all $p > 0.05$) (Table 4).

Discussion

The main outcome of this study suggests that additional plate augmentation can lead to better clinical outcomes in patients with well-fixed PFF. The results demonstrated a significantly higher rate of satisfactory outcomes after

internal fixation in the augmented group. The surgical treatment of PFF is a challenging task that requires careful preoperative planning and expertise since most patients are elderly with osteoporosis, making fixation of the plate to the fracture fragment containing the intramedullary stem difficult. The reported overall union rate after internal fixation in well-fixed PFF (Vancouver type B1 or C) is $\geq 70\%$ in most literature, although this is still a topic of debate depending on the surgical technique. In the study by Froberg et al. [21] of 60 PFFs using an LCP, the average follow-up was 23 months, with a union rate of 71.6%. Hoffmann et al. [22] reported a union rate of 90.2% for LCP with an average follow-up of 25 months. In

this study, the overall union rate was 75%, which is consistent with previous findings. The union rate was higher in group 1 (93.3%) than in group 2 (58.8%), although the difference was not statistically significant.

The high union rate in group 1 in the present study compared to other published reports may be attributed to the increased stability resulting from the greater number of proximal and distal cortices of screw purchase. However, achieving proximal fixation in an osteoporotic bone with an intramedullary stem can be difficult and has been linked to fixation failure in elderly patients. Various techniques for plate fixation around the stem have been proposed, including screws, cerclage wires, and attachment plates. Although controversy exists regarding the preferred technique and optimal fracture management [1, 23], some studies have reported good results with the use of attachment plates. For example, Wall et al. [8] reported no failures of locking attachment plates or screws in their retrospective study of 28 PFFs treated with LCP-LAP. Kim et al. [9] similarly reported good outcomes in their retrospective study of 19 PFF patients treated with LCP-LAP. Conversely, the high rate of healing problems and nonunion/delayed union in group 2 in our study may suggest inadequate proximal fixation resulting in loss of stability and femoral malalignment. Supporting our findings, not only clinical but also biomechanical studies have demonstrated similar results. For instance, Lenz et al. [24] conducted a biomechanical study comparing cerclage wiring combined with LCP plates to locking attachment plates combined with LCP plates in the treatment of periprosthetic femoral fractures. Their study showed that locking attachment plates provided superior outcomes in terms of stiffness, anterior-posterior bending, axial translation, and number of cycles to failure. Moreover, we observed that group 1 had more distal cortices of screw purchase and greater coverage of the femur with the longer plate. The longer plate with an attachment plate may have increased the number of cortices of purchase in the both proximal and distal fragments. Several studies supported the necessity for longer plates, reporting that sufficient fixation in the proximal and distal portions of the fracture site spanning the prosthesis might be mandatory [25, 26]. The longer plate length is an important factor for stable fixation, as it increases the lever arm and the pull-out strength, preventing the failure of implant fixation such as pulled-out screws or cable breakage.

Furthermore, among the limited literature available on the biomechanical properties of attachment plates in PFFs, Lenz et al. [12] conducted a biomechanical study comparing LAP-LCP and cerclage-LCP. Their findings demonstrated that the LAP-LCP improved proximal fixation and showed superior biomechanical outcomes in terms of axial stiffness, relative movement for AP bending

and axial translation, and cycles to failure compared to the cerclage-LCP. Additionally, Wall et al. [8] assessed the clinical outcomes and characteristics of plates and screws surgically treated with LCP-LAP, in which they reported that LCP-LAP provided sufficient fixation and showed low failure rates in cases with well-fixed stems.

MIPO aims to preserve the periosteum and is combined with a locking screw fixation device to improve holding power in fragile bone. This technique is indicated for minimally displaced or comminuted fractures. Several studies reported good outcomes in well-fixed PFF with MIPO [21, 27, 28]. In the current study, the clinical and radiologic outcomes did not differ significantly between the two groups. However, among the complications recorded in our study, one patient (6.7%) in group 1 had nonunion after the MIPO technique with malreduction. This suggests that accurate fracture reduction is important for relative stability as well as the biology of fracture healing.

This study has several limitations. First, this was a retrospective study with a small number of sample sizes. The inclusion of a larger patient cohort would enhance the statistical power and reliability of the results. Secondly, the involvement of two different surgeons with potentially varied decision-making approaches and long study period might introduce bias or inconsistencies in the treatment and outcomes. Future studies could benefit from a standardized approach by a single surgeon or a team to minimize such variations. Third, most of the plates used in group 2 were conventional LCP, whereas group 1 received poly-axial or LCP-DF plates. This discrepancy in plate selection could introduce confounding factors that may influence the observed outcomes. Although no clinical studies have yet been published on this issue, a cadaveric study by Wähnert et al. [29] compared the locking attachment plate (LAP®, Depuy Synthes®, Solothurn, Switzerland) and the non-contact bridging plate (NCB®, Zimmer GmbH, Winterthur, Switzerland), reporting that axial stiffness and the number of cycles to failure were higher in the NCB group. A more uniform selection of plates across both groups would strengthen the study's conclusions. Fourth, BMD and quality were not evaluated, which could have affected the clinical outcomes.

Nevertheless, the strength of this study lies in its comparison of clinical outcomes based on the attachment plate. We hope that these results can guide surgeons in the treatment of well-fixed PFF after THA. Despite the limitations mentioned, this study offers valuable insights into the clinical outcomes associated with different attachment plates in the treatment of well-fixed PFFs following THA. The comparison of clinical outcomes provides valuable information to guide surgeons in making

informed decisions regarding the choice of attachment plate for these specific fracture types.

Conclusion

The use of an attachment plate improved the clinical outcomes of patients with well-fixed PFFs. We believe that the increased number of proximal cortices of screw purchase and longer plates provided adequate fixation, potentially leading to satisfactory outcomes. To improve patient outcomes, surgeons should consider the findings of this study when selecting an appropriate attachment plate for the treatment of well-fixed PFFs after THA.

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Author contributions

SHJ – data curation, formal statistical analysis, writing; CHK – editing, review; JSC – data collection, review; JWK – study design, writing, and editing. The author(s) read and approved the final manuscript.

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Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

This study was approved by the Institutional Review Board of Asan Medical Center (IRB No. 2022–0862) and waiver was received for the need to provide written informed consent. Data collection was performed in accordance with relevant guidelines and regulations of the committee.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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