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Proximal femoral nails compared with reverse distal femoral locking plates in intertrochanteric fractures with a compromised lateral wall; a randomised controlled trial

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Abstract

Purpose There is no consensus about the best option of internal fixation for unstable intertrochanteric fractures. The aim of the present study was to compare proximal femoral nail (PFN) with contralateral reverse distal femoral locking compression plate (reverse-DFLCP) in the management of unstable intertrochanteric fractures with compromised lateral wall.

Method In a randomized controlled study, from November 2011 to October 2012, 40 patients with unstable intertrochanteric fractures with compromised lateral wall (AO 31A 2.2 to 3.3) had osteosynthesis by PFN (n=20) or reverse-DFLCP (n=20). Intra-operative variables compared were duration of surgery, blood loss during surgery, fluoroscopy time and surgeons perception of the surgery. Patients were followed up clinically for a minimum of one year. Functional outcome was assessed by Parker Palmer mobility score (PPMS), Harris hip score (HHS), and Short Form-12. Failure was defined as any condition which would necessitate revision surgery with change of implant.

Results Duration of surgery (p=0.022), blood loss during surgery (p=0.008) and fluoroscopy time (p=0.0001) were significantly less in the PFN group than in the reverse-DFLCP group. No significant difference was found in type of reduction, difficulty in reduction and surgeon's perception of surgery. The PFN group had better functional outcome than the reverse-DFLCP group. HHS for the PFN group was 81.53±13.21 and for the reverse-DFLCP group it was 68.43±14.36 (p=0.018). SF-12 physical (p=0.002) and mental component (p=0.007) scores in the PFN group was significantly better than in the reverse-DFLCP group. There was one failure in the PFN group as compared to six in the reverse-DFLCP group (p=0.036).

Conclusion Due to favourable intra-operative variables, better functional outcome and lower failure rates, we conclude that PFN is a better implant than reverse-DFLCP for intertrochanteric fractures with compromised lateral wall.

Introduction

The sliding hip screw (SHS) is the most widely used implant for stabilization of intertrochanteric fractures [1]. Despite the general success of SHS for stabilization of stable intertrochanteric fractures, there is dissatisfaction with its use in case of unstable fracture patterns. Excessive sliding of the lag screw results in limb shortening and medialization of the femoral shaft and high chances of implant failure and poorer functional outcome [2–5].

Cephalomedullary devices, with their course of evolution and improvement of implant designs, have been demonstrated to be useful in the management of unstable fractures [6–8]. But they are associated with intra-operative technical and mechanical complications [9, 10]. Moreover, geometrical mismatch between proximal femoral nail and the femora of Asians make surgery more difficult and complicated [11, 12].

Pre contoured locking plates were introduced in the last decade as angular stable devices to provide rigid fixation of communited proximal femur fractures [13]. Due to higher failure rates of proximal femoral locking compression plate [13, 14], some authors advocated the use of reverse distal femoral locking compression plate (reverse-DFLCP) of the

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contralateral side for intertrochanteric fractures, as it provided an added number of screw options for proximal femoral fracture fragments, thus resulting in a more stable construct with higher pull out resistance [15–17]. Clinical studies have also showed good results of reverse-DFLCP when compared to intramedullary devices [15–17].

The aim of the present study was to compare proximal femoral nail (PFN) with reverse-DFLCP in the management of unstable intertrochanteric fractures with compromised lateral wall.

Materials and methods

Between November 2011 and October 2012, 40 consecutive patients with intertrochanteric femoral fractures who fulfilled the inclusion criteria were randomized to be treated with either PFN (Green Surgicals, Gujarat, India) or contralateral reverse-DFLCP (Green Surgicals, Gujarat, India). The ethical committee of our hospital approved the study plan and informed consent was obtained from all patients before the operation. Patients (age > 18) presenting to our department with an unstable intertrochanteric fracture with compromised lateral wall (AO 31A 2.2 to 3.3) and operated within three weeks were included in the study. Patients with a pathological fracture, multiple injuries, fractures with significant subtrochanteric extension (>3 cm), or those who were unable to give informed consent or refused to participate and those unfit for surgical intervention, were excluded.

Plain radiographs in the anteroposterior (AP) view of the pelvis with both hips with 15 degrees of internal rotation and cross-table lateral view were obtained on admission, and all fractures were categorized according to the AO/ASIF classification [18]. The patients were allocated to one of the two groups as determined by the unique randomization table generated by www.randomization.com. Allocation concealment was done by opaque envelope technique. The envelope was opened 24 hours before surgical intervention by the treating surgeon.

Surgical techniques

Standard operative technique was used for PFN [19]. The surgical technique for reverse-DFLCP was as follows:

The patient was placed in supine position on the fracture table. Closed reduction was attempted and checked under image intensifier in both anteroposterior (AP) and lateral views. If acceptable, part was cleaned, painted and draped. An incision of size about 5 cm was made over the greater trochanter and fascia of the vastus lateralis muscle was incised at its proximal insertion and flipped anteriorly to visualize the bone. The plate was introduced through the proximal incision

and slid down distally beneath the muscle tissue without stripping the periosteum off the lateral femur. The plate was maneuvered onto the distal fragment through a short distal incision, using bone holding forceps. In this position, proper placement of the plate was checked. Four to six proximal locking screws were passed through threaded screw hole up to the centre of the neck. Satisfactory position of screw was checked in AP and the lateral planes. Following this, distal fixation was performed with three to four screws through the distal incision. In cases where closed reduction was not possible, a mini open or open reduction was done and the rest of the steps were the same. The wound was irrigated and closed in layers.

Intra-operative variables that were recorded were: duration of surgery, blood loss during surgery, fluoroscopy time, type of reduction, difficulty in reduction and surgeon's perception of surgery. Plain AP and lateral radiographs were obtained on the first post-operative day, and analysed for reduction of the fracture and position of the implant. The patient was allowed to sit up in bed the day after surgery, and active exercises of the operated hip and knee were started. Depending on the patient's condition and the stability of the internal fixation, weight-bearing was started using axillary crutches or walking frame as soon as possible. Sutures were removed at post op day 14.

Patients were advised to come for follow up at two weeks, six weeks, three months, six months and one year. Patients with a minimum follow up of one year were included in the final analysis. Union was defined as bridging callus in three or more cortices on AP and lateral radiographs with ability to bear full weight on the extremity. However with this protocol it was not possible to know when exactly the union occurred in each individual patient.

Functional outcome was assessed by Parker Palmer mobility score (PPMS), Harris hip score (HHS), and Short Form-12 (SF-12). The SF-12 measures the general health status from the patient's point of view and results are expressed in terms of two meta-scores: the physical component summary (PCS) and the mental component summary (MCS). HHS of 90–100 was considered as excellent, 80–89 as good, 70–79 fair and < 60 as poor. Failure was defined as any condition which would necessitate revision surgery with change of implant. All other complications were noted.

Statistical analysis

Keeping HHS as the primary variable, 80 % as power of study, 10 % as loss to follow up and 10 % anticipated mortality rate, we got 40 as the sample size for our study. Mann–Whitney U test was used to compare parametric variables between two groups. Chi-square test was used for categorical variables. A p value of less than 0.05 was taken as significant.

Table 1 Demographic profile of the patients

Study group		PFN (n=20)	DFLCP (n=20)	Total (n=40)	p value
Age (mean ± SD) in years		55.55±17.09	53.95±14.75	54.7	0.400[a]
Sex	Male	10	18	28	0.013[b]
	Female	10	2	12	
Fracture classification (AO type)	31 A 2.2–2.3	9	12	21	0.342[b]
	31 A3.1–3.3	11	8	19	
ASA grade	I	8	9	17	0.288[b]
	II	12	9	21	
	III	0	2	2	
Quality of bone (Singh's index grade)	≤3	7	4	11	0.4[b]
	>3	13	16	29	

PFN proximal femoral nail, *DFLCP* distal femoral locking compression plate

[a] *P* value as calculated by Mann-Whitney *U* test

[b] *P* value as calculated by chi-square test

Results

Both the groups were comparable for demographic data except for sex distribution (Table 1). Intra-operative variables, i.e. duration of surgery, blood loss during surgery and fluoroscopy time were significantly less in the PFN group than in the reverse-DFLCP group (Table 2). No statistically significant difference was found in type of reduction, difficulty in reduction and surgeon's perception of surgery (Table 3). Although there was no statistical difference in the surgeons perception of the difficulty of surgery, surgeons found doing the reverse-DFLCP moderately difficult or difficult 15 of 20 times, as compared to PFN where it was eight of 20 times.

Most patients started walking with support within the first week of surgery. It was a general observation that the patients with PFN were more comfortable during early mobilization as compared to the patients with reverse-DFLCP.

At one year functional outcome was assessed in 17 patients of the PFN group and 14 patients of the reverse-DFLCP group. No significant statistical difference was found in the PPMS between the two groups but the mean HHS for the PFN group was significantly higher than the reverse-DFLCP group (Table 4). More patients had excellent or good HHS (Table 4). There was a significant difference in the mean PCS and MCS of the SF-12 score between the groups (Table 4).

In the PFN group at one-year follow-up 17 patients had fracture union (Fig. 1). One patient had failure due to technical reasons for which revision surgery was done, while the other two were lost to follow up. No patient had a malunion or nonunion. In reverse-DFLCP group 11 patients had fracture union (Fig. 2), two had non union while one had malunion in 100° coxa vara. Three patients had loss of reduction with varus collapse for which revision surgery was done (Fig. 3), while three were lost to follow-up. Thus there were a total of six failures in reverse-DFLCP (two nonunions, one malunion, and three loss of reductions with varus collapse). The failure rate was significantly higher in the reverse-DFLCP group (p= 0.036). With the numbers available, it was not possible to do a subgroup analysis to correlate the type of reduction (closed/ open) in the two groups with the failure rates. All three patients with varus collapse were treated with removal of implant, refixation with dynamic hip screw (DHS) and bone grafting. One patient had fracture healing with a shortening of 2.5 cm. He had a fair HHS. The second patient died five months after the DHS surgery due to other medical reasons, i.e. chronic liver failure. The fracture had not united till then. The third patient had deep infection with DHS cutout for which implant removal and excision arthroplasty was done. The two patients with non union refused any form of surgery till the last follow-up. Both patients had a poor HHS score (58 and 45). Both used a support for mobilization.

Table 2 Comparison of intraoperative variables between the two groups

Intraoperative variables	PFN	DFLCP	p-value
Duration of surgery(min)	64.30±21.40	80.95±22.57	0.022
Blood loss (ml)	316±143.98	441±131.34	0.008
Fluoroscopy time (sec)	22.75±16.02	35.68±8.70	0.00001

PFN proximal femoral nail, *DFLCP* distal femoral locking compression plate

Table 3 Comparison of intraoperative variables between the two groups

Intra-operative variables		PFN	DFLCP	P-value
Type of reduction	Closed	11	10	0.766
	Mini-open	3	2	
	Open	6	8	
Difficulty in reduction	Easy	15	14	1
	Moderately difficult	5	6	
	Difficult	0	0	
Surgeon perception for surgery	Easy	12	5	0.063
	Moderately difficult	8	14	
	Difficult	0	1	

PFN proximal femoral nail, *DFLCP* distal femoral locking compression plate

Table 4 Functional outcome at one-year follow up

Functional outcome variables		PFN (mean ± SD) (n=17)	DFLCP (mean±SD) (n=17)	p value[*]
Parker Palmer mobility score		7.53±1.807	6.86±1.40	0.140
Harris hip score		81.53±13.21	68.43±14.36	0.018
Excellent		4	1	
Good		6	4	
Fair		4	4	
Poor		3	5	
SF-12[a]	PCS[b]	41.83±12.28	31.18±9.99	0.002
	MCS[b]	57.52±3.99	53.74±3.87	0.007

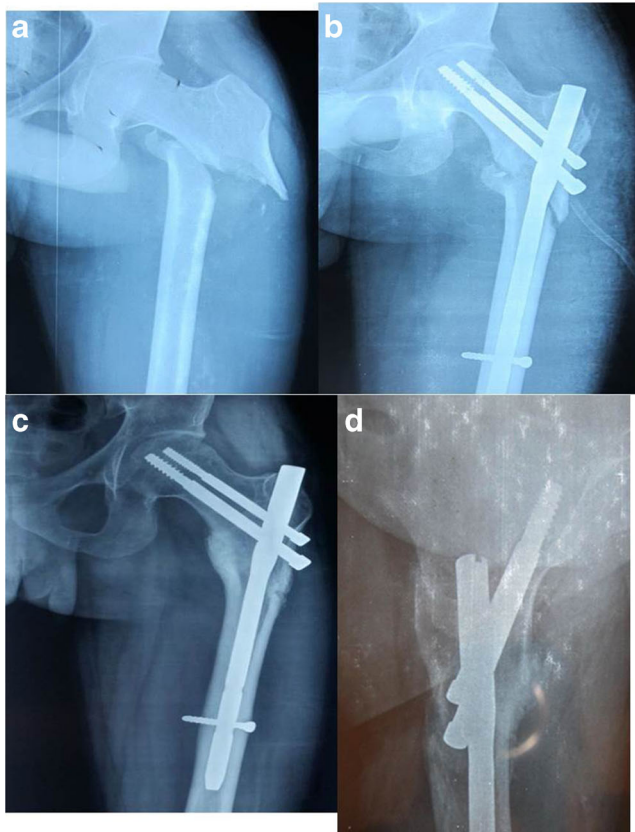*PFN* proximal femoral nail, *DFLCP* distal femoral locking compression plate

[*] *P* value as calculated by Mann–Whitney *U* test

[a] Short Form-12

[b] Physical component summary, mental component summary

Discussion

The lateral trochanteric wall has been recognized as an important predictor of stability in intertrochanteric fractures


Fig. 1 a Radiograph of left hip showing AO 31A 3.1 fracture. **b** Immediate postoperative radiograph showing good reduction and proper implant placement. **c**, **d** Six-months follow-up radiograph showing union
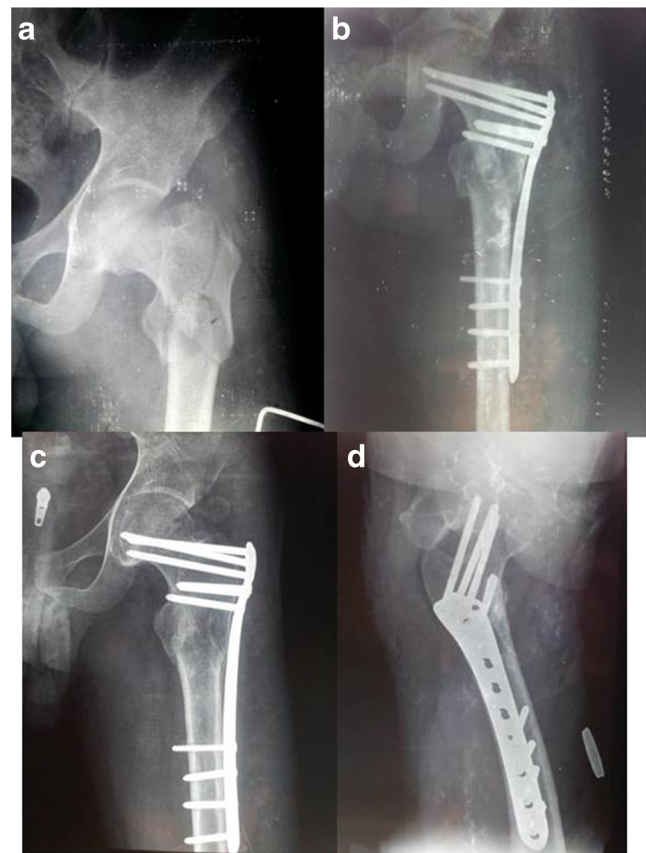
Fig. 2 a Radiograph of left hip showing AO 31A 3.3 fracture. **b** Immediate postoperative radiograph showing good reduction and proper implant placement. **c**, **d** Six-months follow-up radiograph showing union

[20–22]. The SHS which is considered as the gold standard in the management of intertrochanteric fracture works on the principle of controlled collapse at the fracture site [2, 20, 23]. However, to achieve this phenomena the lateral wall must be intact. If SHS is used in fractures with broken lateral wall (AO31A3.1 to 3.3), there is uncontrolled collapse, resulting in union with limb length shortening and poorer functional outcome [3, 23]. Moreover the large diameter drilling for the barrel of the SHS also increases the chances of breaking the lateral wall intra-operatively in AO31A2.2–2.3 fractures, leading to poorer outcomes [20, 21, 23]. In spite of this general consensus about the importance of the lateral wall the literature is not clear about the exact area of the proximal femur which constitutes the lateral wall. Gotfried defined it as the proximal extension of the femoral shaft [20], while Palm et al. defined it as the lateral femoral cortex distal to the vastus ridge [21]. In our opinion if we draw two lines, one as a tangent to the superior femoral neck and the other as a tangent to the inferior femoral neck, the part of the lateral femoral cortex which lies between these two lines is the lateral femoral wall (Fig. 4). If on an anteroposterior view this area is broken

Fig. 3 **a** Radiograph of left hip showing AO 31A 3.2 fracture. **b** Immediate postoperative radiograph showing reduction in slight varus. **c** Six-months follow-up radiograph showing screw loosening and back out with varus collapse
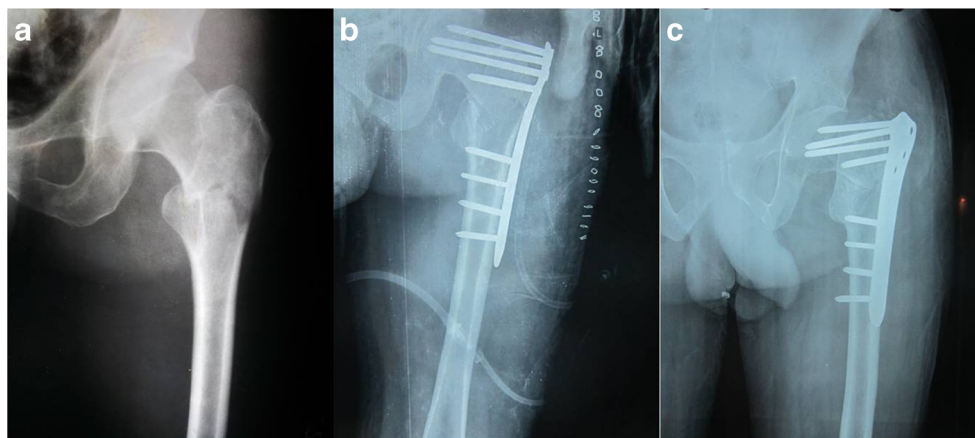
or is very delicate and vulnerable to get fractured during surgery, like in osteoporotic patients with the fracture exiting lateral to the greater trochanter, the SHS alone must not be used.

If the patient has a compromised lateral wall, there are two ways to reconstruct it; one is to use an intramedullary nail, because it bypasses the lateral wall and acts as a prosthetic lateral cortice medial to the broken lateral wall. The other way is to use an extramedullary device which can act as a fixation devise as well as reconstruct the lateral wall, i.e. SHS with trochanteric stabilization plate, condylar blade plate, DCS, proximal femoral locking compression (PFLCP), reverse-DFLCP plates, etc. There are proponents and opponents of both these methods but there is lack of consensus about the best way to manage these fractures. Moreover, there are few studies which compare these two techniques [24–26].

Early designs of intramedullary nails, e.g. Gamma nail, were associated with high intraoperative technical and

mechanical difficulties due to their short length (20 cm), large diameter (17 mm proximal and 12-, 13-, 14- and 16-mm distal) and 10 degree of valgus curvature which created stress at the tip of the nail on lateral cortex of femur resulting in femoral shaft fractures. Newer designs like proximal femoral nail (PFN) with less valgus curvature (6 degrees), longer length, smaller diameter (9, 10 and 11 mm) and additional antirotation screw are associated with less complication rates and better results [26–28]. They act as load sharing devices. In contrast to this the PFLCP act as angular stable devices and provide rigid fixation. But they are associated with a higher number of varus collapse and implant failure [13, 14]. To overcome this problem the reverse-DFLCP of the contralateral side has been advocated by some authors, as it provides an added number of screw options for proximal femoral fracture fragment, resulting in a more stable construct [15–17]. They are anatomically suitable for proximal femoral fractures because the shape of the lateral condyle of the femur is similar to the greater trochanter, and the plate of the contralateral side follows the physical curve of the femoral shaft. They can be done by minimally invasive methods. Clinical studies have also shown good or equivalent results of reverse-DFLCP compared to intramedullary devices [15–17, 26].

We found that the duration of surgery, blood loss during surgery and fluoroscopy time were significantly less in the PFN group than in the reverse-DFLCP group. Other authors who have studied these factors have reported mixed results (Table 5). Although there was no statistical difference in the surgeons perception of the difficulty of surgery, surgeons found doing the reverse-DFLCP moderately difficult or difficult 15 of 20 times, as compared to PFN where it was eight of 20 times. It was especially difficult and time consuming to put multiple locking screws into the femoral head through the neck and required multiple AP and lateral images. This was in spite the fact that the surgeons doing the procedure were adequately trained in both the procedures and had been doing it regularly before the start of the trial. We also observed that although theoretically it is possible to put a locking bolt in
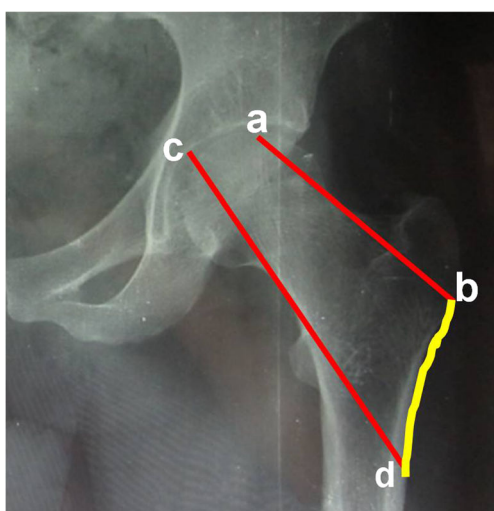
Fig. 4 If two lines, one as a tangent to the superior femoral neck (**a–b**) and the other as a tangent to the inferior femoral neck (**c–d**) are drawn, the part of the lateral femoral cortex which lies between these two lines (**b–d**) is the lateral femoral wall

Table 5 Comparison of our results with other studies

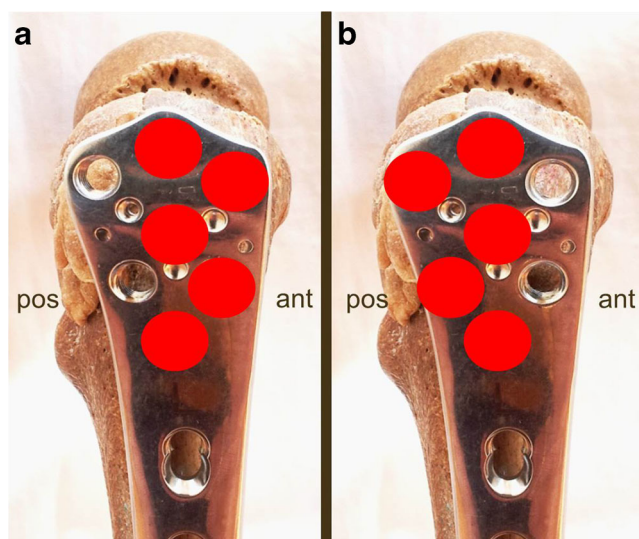| Parameter		Zhou et al. [16]	Yao et al. [15]	Han et al. [26]	Tao et al. [17]	Present study
Duration of surgery (min)	PFN	65.36	51.8	67.36	61	64.30
	DFLCP	98.25	48	69.47	87.2	80.95
	P-value	0.006	0.383	>.05	0.0001	0.022
Amount of blood loss (ml)	PFN	115.28	176.4	146.82	228	316
	DFLCP	157.86	149.45	150.79	242	442
	P-value	0.179	0.071	>.05	0.565	0.007
Fluoroscopy time (sec)	PFN	–	–	–	140±63.5	22.75±7.87
	DFLCP	–	–	–	196±85.0	35.65±8.70
	P-value	–	–	–	0.001	0.0001
Functional outcome	PFN	84.09	75.5	–	82.8	81.53
	DFLCP	86.04	72.9	–	82.0	68.43
	P-value	0.247	0.128	–	0.717	0.013

PFN proximal femoral nail, *DFLCP* distal femoral locking compression plate

each of the seven proximal holes of the reverse-DFLCP, in practice one can usually put a maximum of five (three central and two either anterior or posterior) bolts (Fig. 5). There is probably a need for defining and refining the technique of reverse-DFLCP if it is to be used for this group of fractures.

The functional outcome as assessed by PPMS was comparable but the HHS was significantly greater for the PFN group than the reverse-DFLCP group. This was in contrast to other studies where authors have reported comparable results (Table 5). One reason for this was that three patients with anticipated poor outcome (two nonunions and one malunion) who refused resurgery were included in the analysis. There was no difference once these patients were

excluded. This only reiterates the fact that in intertrochanteric fractures like other fractures, sound union in correct position is paramount and the implant must serve that purpose. We believe that more sensitive score, like HHS, provides better information regarding hip function than PPMS. This was also reflected in better SF-12 results in the PFN group.

There was significant difference in the number of failures in the PFN group ($n=1$) as compared to the reverse DFLCP group ($n=6$). The single failure in the PFN group was due to technical reasons as the implant had been put without adequately reducing the fracture. In the reverse-DFLCP group, except for one patient who had a technical failure, all the other five patients had failure despite the implant being in the correct position and fracture reduced adequately initially. When we analysed these patients we found that in all these patients there was failure of the locking mechanism of the proximal screws with the plate, which resulted in screw loosening and backout and varus collapse. This pattern of failure is quite different from those reported by other authors who have reported screw breakage and cut out as the main modes of failure. We believe that the engineering of these implants need to be improved so that the locking mechanism does not fail and the implant continues to act as angle stable device.

Conclusion

In summary, the results of our study show that duration of surgery, blood loss during surgery and fluoroscopy time was less in the PFN group compared to the reverse-DFLCP group. At one-year follow up, the PFN group had better functional outcome than the reverse-DFLCP group as assessed by Harris hip score and Short Form-12. Moreover, there were significantly higher failures in the reverse-DFLCP group than the

Fig. 5 Of the seven proximal holes of the reverse-DFLCP one can usually put a maximum of five (three central and two either anterior **a** or posterior **b**) bolts

PFN group. Based on these findings, we conclude that PFN is a better implant than reverse-DFLCP for intertrochanteric fractures with compromised lateral wall.

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