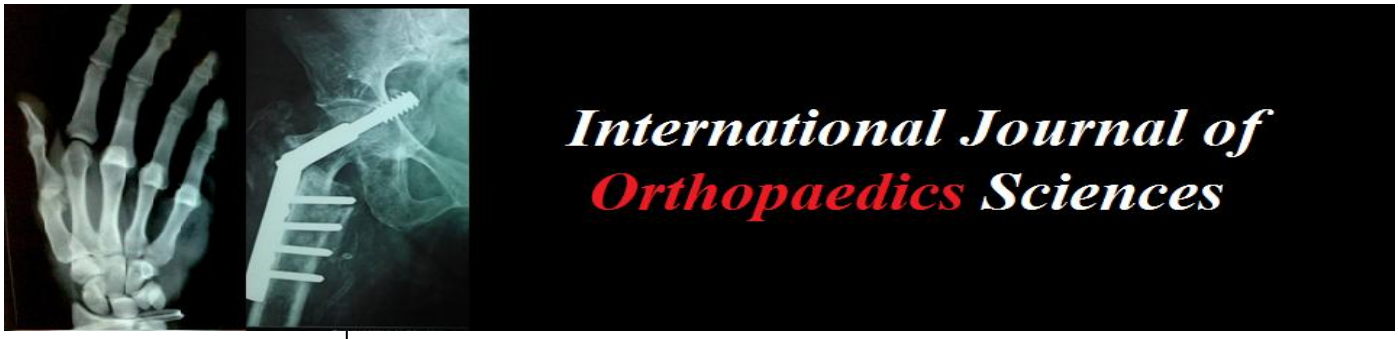

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Comparison of radiological outcome of unstable Intertrochanteric femur fractures in elderly patients treated with Indian and Foreign Cephalomedullary nails

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Abstract
Aim of study: Purpose of study was to compare the radiological outcome of unstable intertrochanteric fractures in the patients treated by Indian and Foreign Cephalomedullary nails.
Methods: 417 patients aged 65 years and above with unstable intertrochanteric fractures fixed with Cephalomedullary nails were analysed in two groups – {Group1-{-Indian (PFN, Gamma nail); Group-II Imported (PFNA2, AOAFN)}. Exclusion criteria included polytrauma, pathological fractures, open fractures. Data was collected from January 2011 to June 2015. Pre-op radiographs were analysed for preoperative comminution, lateral wall breach and osteoporosis (singh's index). Post operatively radiological outcome were analysed with respect to bony union in weeks. Also complications like cut-outs, varus collapse, implant failures, nonunion with both implants were analysed in immediate postop, 6weeks, 12weeks, 18weeks, 24weeks and upto 1year. Data was analysed by statistical methods.
Results: Out of 417 patients, 248were operated with Indian and 169 patients with foreign implants. Radiological union in Indian was 16.41 weeks and 15.27 weeks in Foreign (p=0.887). Varus collapse was seen in 3.6% vs 2.9% (p=0.407).Cutout in 2.4% of Indian and 2.3% in Foreign (p=0.493). Implant failures seen in 2.4% vs 1.8%. Nonunion seen in 0.8% and 1.8% (p= 0.372).Complication rates were 12.9% patients with Indian and 11.2% with Foreign implants (p=0.412).

Keywords: Unstable Hip fractures, Cephalomedullary nails, radiological outcome

1. Introduction
Intertrochanteric fractures are one of the most common fractures of the hip more so in the elderly with osteoporotic bones. Morbidity and mortality associated with these fractures are very high if left untreated. Hence surgery is the treatment of choice for such fractures. It is estimated that by 2020, almost 20% of the Indian population will be older than 60 years and the annual incidence of hip fractures will reach 6,00,000.90% of the intertrochanteric fractures arising from low-energy trauma, occur in patients older than 65 years [1]. However surgical stabilization of unstable intertrochanteric fractures in elderly is a challenge because of pre-operative comminution, lateral wall breach, Osteoporosis and comorbidities.
Although consistently good results are obtained while treating stable intertrochanteric fracture, treatment failure rates with unstable fracture are comparatively higher [2, 3].
The intramedullary device shows its advantage in fixing unstable intertrochanteric fractures and extramedullary device yielded good results in fixation of stable intertrochanteric fractures [4-9]. The fracture pattern, osteoporosis and comorbidities in the patients were the uncontrollable factors in reducing the surgery-related complication rate. However, the surgery-related complications could be reduced by the advanced surgical management utilizing the new fixation devices [10]. Biomechanically, large force required to produce medial migration of femoral shaft with intramedullary device which is a common complication of extramedullary devices [11].
According to AO classification, Intertrochanteric fractures are classified into stable and unstable fractures (AO 31A2.2-3.3).Unstable fractures are treated by nails.

The nail occupies the medullary canal, preventing excessive sliding and medialization of the shaft even in A3 fractures [12]. In our country, financial constraint is often a consideration for usage of Indian prototype stainless steel nails or synthes titanium nails. In todays literature, there are no studies analyzing the radiological outcome of unstable intertrochanteric fractures in elderly patients treated with indian and foreign Cephalomedullary nails. Hence in this study, we are analyzing the efficacy of both implants in terms of surgical fixation, fracture union, complications and cost effectiveness.

Materials and Methods

417 consecutively operated patients which include 248 patients operated with Indian implants and 169 operated with foreign implants with unstable intertrochanteric fractures fixed with Cephalomedullary nails between January 2011 and June 2015 were analysed retrospectively in two groups. Group 1(Indian implants) included fracture fixation with intramedullary devices like PFN and Gamma nails, the Indian implants were used from various manufacturers (Sharma, Pitkar and Coimbatore surgicals) and approved by drug controller of India. Group 2 (Foreign implants) include Synthes PFNA2 and AO AFN.

Indian implants used from more than one manufacturer-

-ISO Certified Vibash Coimbatore Surgicals No-AB13ISI42660/R1

-ISO Certified Sharma Surgicals No-MD-QMS/91/R/1718

-EC Certified S.H Pitkar Ortho tools Surgicals No-5678-2014-CE-IND-NA REV1

The inclusion criteria were all patients aged 65 years and above with unstable fractures treated with Indian and foreign Cephalomedullary nails. Patients with polytrauma, pathologic fractures, open fractures and ipsilateral fractures of femur were excluded. Domestic injury was the most common mode of injury in both groups. The approval was given by the Institutional Review Board of our institution prior to commencing the study, surgical procedure for the both implants and postoperative mobilization protocols were standardized.

Both short and long nails were used depending upon the bowing of femur implants were selected. Short and long nails in Indian implants were available from 180 mm-420 mm with diameter measuring 9mm,10mm and 11mm. Foreign nails were available from 240mm with diameter of short nails measuring 9mm,10mm,11mm,12mm and long nails upto 420mm measuring 9mm and 10mm in diameter. PFNA2 blade diameter measured 14mm.

Surgical technique of reduction included both closed and open reduction, closed reduction was done using traction and internal rotation and also with the aid of steinmann pin and homann retractor. Open reduction was done with help of pointed reduction forceps, towel clip and encerclage wiring. Final reduction attempted by all methods aimed at maintaining neck shaft angle with no varus angulation, posteromedial cortex continuity and lateral wall reconstruction using encerclage wiring /additional screws.

Radiological parameters were analysed preoperatively, immediate post operation and in last follow up X rays. Mean follow up was 6 months (4 months-2 yrs). Surgical technique was common to all patients and consisted of an indirect and direct reduction of the fracture and osteosynthesis in orthopedic table by the closed and open technique under imaging. Patient factors include pre op comminution, lateral wall breach which was classified using AO classification [13] (fig-2). Singh's index [14] (fig 1a, 1b) was used to grade preoperative osteoporosis in uninjured hip. Indian implant PFN protype (fig 1c) and foreign PFNA2 prototype (fig 1d) was used. Neck shaft angle was calculated in uninjured hip (fig-3).

In the immediate post-operative x ray surgical reduction factors like anatomical reduction (fig-4), proper screw/blade positioning (fig-5), tip apex distance [15, 16] (fig-6) and sliding length [17] (fig-7) were calculated. Reduction was good (0-5degree), acceptable (5-10 degree), poor (>10 degree) [18].

Reduction also was found to be anatomical if there was adequate posteromedial cortical contact, angulation <5 degree, no distraction in fracture fixation [19]. Screw positioning was appropriate if screw was placed into the lower half of the neck AP view, centrally on a lateral view [18] and PFNA2 blade was placed in to the center of the neck AP view and centrally on a lateral view. Tip apex distance of <25mm [16] for Indian implants and 20-30 mm for Foreign implants [15] was considered appropriate. Sliding length difference of 0-5mm between immediate and last follow up x rays for both implants was acceptable [19].

In the last follow up x rays, outcome was analysed for surgical fixation, union and complications. Fractures were judged to be united radiographically if bridging callus was evident on 3-4 cortices as noted on two views [18] (fig-8)

Last follow up x rays were analysed for complications like loss of reduction i.e, varus collapse (fig-9), cutouts (fig-10), joint penetration (fig-11), broken implants (fig-12), back outs (fig 13), nonunions (fig-14), peri implant fractures (fig-15).

Tip Apex Distance and Sliding length between immediate post op and last follow up were analysed for cut outs, backouts, joint penetration between both groups.

Statistical analysis of the failures was performed. Percentage was calculated for categorical variables. The pearson chisquare test was done to find association between the variables with the operative treatment and radiological analysis with Indian and Foreign implants.

P value of less than 0.05 was considered to be significant.

Results

Of the 417 patients 248 were operated with Indian implants and 169 were operated with foreign implants. Average age of the whole study group is 79.7 yrs (65- 104yrs) Indian implants and 77.2 yrs (65-101yrs) in foreign implants.263 were females and 154 were males. Most common mode of injury was domestic injury 83.45% of cases (206 cases 83.1% in Indian and 142 cases 84% in Foreign). Predominant fracture type was AO31 A2.2 according to AO classification accounting to 31.89%, followed by A2.3 26.37% and 31A3.3 24.22%. Pre op comminution was seen in 53.62% of group1 and 65.68 % in group2. Lateral wall breach was found in 46.37% in group1 and 34.31% in group 2. Osteoporosis was observed in 74.10% when both groups were combined.

Indian implants used were PFN (233/248) and gamma nails (15/248), foreign implants included PFNA 2 (162/169), AO AFN (6/169) and EXACTECH PFN (1/169). Closed surgical reduction was done in 203/248 indian implants and 148/169 foreign implants whereas open reduction was done in 45/248 indian implants and 21/169 foreign implants.

Satisfactory reduction was achieved in 221(89.1%) patients operated with group1 and 156 (92.3%) in group2. Satisfactory screw/blade positioning was performed in 231 (93.1%) group 1 and 155 (91.7%) group 2.

Neck shaft angle difference between preoperative and immediate post-operative x rays was 3.3 deg in group 1 and

2.1 degree in group 2 (Table-1). Neck shaft angle difference between immediate post operation and last follow up x rays was 4.7 degree in group 1and 3.1 degree in group 2. Tip Apex Distance was 22.30mm immediate post-operative and 24.97mm in last follow up in group 1 whereas 22.16mm and 23.78mm in group 2. Sliding Length difference in group1 was 4.21mm and 2.99mm in group 2 (Table-2).

Complication rates was seen in 12.9% patients operated with Indian implants and 11.2% patients operated with Foreign implants (p=0.412).Varus collapse was seen in 3.6% in Indian implants vs 2.9% of Foreign implants (p=0.407). Cutout was found in 2.4% of Indian and 2.3% in Foreign (p=0.493). Implant failures seen in 2.4% Indian implants vs 1.8% foreign implants. Nonunion seen in 0.8% in Group 1 and 1.8% in Group 2 (p= 0.372). Osteoporosis was found in 78.12% patients with complications in Indian implants and 84.21% in complicated cases of foreign implants (Table-3).

Discussion

Intertrochanteric fractures is one of the most common fractures of the hip especially in elderly with osteoporotic bones and it is usually due to low energy trauma like simple falls. Orthopaedic surgeons often have dilemma in choosing best implants for unstable intertrochanteric fractures in order to achieve favourable outcome which can be functional or radiological. Various treatment options include closed and open reduction, involve Cephalomedullary nails, extramedullary implants, bipolar hemireplacement, THR. Good fixation outcomes depend upon bone quality, fracture comminution, lateral wall breach and surgical technique. Cephalomedullary nails like PFN, PFNA2, AOAFN, Gamma nails have been extensively used for such fractures.

There are very few studies comparing Indian and foreign implants. Rawall *et al* in 2011 showed in their study that there is no statistical difference between outcomes of Indian and foreign implants (spinal pedicle screws) [20]. In our study we compared radiological outcomes in unstable Intertrochanteric fractures in elderly treated by Indian and foreign Cephalomedullary nails. In our study cost effectiveness of both implants were analysed, average cost of Indian nails were 7000 Rs and foreign nails was 37000 Rs which meant that there was a huge difference in cost factor. For poor patients this cost factor is an economic burden that can be imposed during payment of medical bills.

According to Russel *et al* in their study concluded that acceptable reduction is less than 5 degree of angulation in any plane. Malreduction more than 5 degree in 10% cases and acceptable reduction in 90% cases which is comparable to our study which showed malreduction more than 5 degree in 7% cases and acceptable reduction in 93% cases.

According to Kim *et al*. [21] in their study had 27.7% angular small malreduction when extramedullary implant was used in unstable trochanteric fracture, whereas in our study malreduction more than 5 degree was seen in 7% cases, thus from our study we can conclude that Cephalomedullary implant have less angular malreduction [21].

According to Suk Kyu Choo *et al*. [17] average sliding was 5.0 mm for lag screws of the PFN group and 2.8 mm for the helical blade of the PFNA group. In my study, average sliding between immediate post operation and last follow up x ray in Indian implants was 4.21mm and foreign implants was 2.99mm which was comparable with above study. Sliding of the lag screw/blade is purely because of the impaction of the fracture. This impaction of the proximal fragment leads to lateral slide of both the proximal screws and is an indirect measure of collapse of the fracture.

According to Amir Herman *et al*. [22] TAD was calculated for the lag screw in proximal femoral nails and found to be 20.7mm. In my study mean TAD in Indian study was 22.30mm (range 18.3mm-27.7mm) immediate post operation and 24.97mm (20.1mm-36.3mm) in the last follow up which was comparable to above study. According to Nikoloski *et al*, TAD rule of < 25 mm should not apply for the PFNA. They suggest avoiding a TAD < 20 mm due to possible axial cut-out and avoiding a TAD > 30 mm to avoid cephalad cut-out.

In my study mean TAD in foreign group was 22.16mm (range 18.7mm-28.3mm) immediate post operation and 23.78mm (21.1mm-31.5 mm) in last follow up which was comparable to above study.

The most common malreduction is a posteriorly sagging femur shaft with an anterior step off at the fracture site. This may not be reduced by closed means and Carr *et al*. [23] have described an open reduction maneuver where the shaft is first pulled laterally with a bone hook around the shaft to disimpact the fracture and then using a lever to push the head and neck fragment posteriorly to align with the shaft. This simple reduction maneuver is important to achieve anteromedial stability so as to allow immediate mobilization without putting excessive load on the implant.

Case example of Indian implant with poor outcome (fig-16).

Figure 16: (A) X ray pelvis with both hips –AP view 31 A2.3 Right intertrochanteric femur fracture. (B) Showing improper reduction of fracture immediate post op. (C) 1month after surgery showing varus collapse. (D) 2 months after surgery, varus collapse was observed with cut out of lag screws from femoral head requiring reoperation. (E) Underwent reoperation with bipolar hemireplacement of right hip.

Case example of foreign implant with poor outcome (fig-17).

Figure 17: (A) X ray pelvis with both hips –AP view 31A3.3 Left intertrochanteric femur fracture. (B) Showing improper reduction of fracture immediate post op.(C) 3 months after surgery shows no bridging callus. (D) 8 months after surgery showed medialisation of shaft with no callus formation going to nonunion (E) 2 ½ years post-surgery showed implant failure with varus collapse and broken nail due to nonunion. (F) Revised to THR left hip.

According to Gadegone and Salphale [24] in their study of nailing fixation for trochanteric fractures had union in all cases between 15 weeks to 21 weeks, which is comparable to our study (16.41 weeks in Indian and 15.27 weeks in foreign).

According to Schipper *et al*. [8] cut-out of the implant was 3 out of 211 PFN (1.42%) and 6 out of 213 Gamma nail (2.81%). In our study 2.39% indian implants and 2.36% foreign implants had cut outs which was comparable without statistical significance.

The mean time to union in my study was 16.41 weeks (10.5-26.5 weeks) in group1 and 15.27 weeks (10.2-25.4 weeks) in group2 (fig 18).

According to Haidukewych *et al*. [25] described good results in a series of 60 patients with failed intertrochanteric fractures that underwent revision to total hip replacement or bipolar hemiarthroplasty (2/60=3.3%). In our study, we had 8 revisions out of 417 patients, in which 1 patient was revised to THR and 4 with bipolar hemireplacement [5/417=1.19%], 2 patients underwent PFNA2, 1 patient underwent DCS fixation.

According to Megas P, Kaisidis *et al* and Papasimos, Koutsojannis *et al* the complication rates with the Cephalomedullary nail device range from 5% to 13%. In my study 12.9% Indian implants and 11.24% foreign implants

had complications which includes cut out, non-union, peri implant fracture, implant failures but without statistical significance. Breakage of Cephalomedullary implant is a rare but serious complication and has been reported to have an incidence of 2.9% in a series of 453 patients by Von Ruden *et al*. In our study, we had implant failure rate of 2.15% patients and 8 patients underwent reoperations.

Comparision of my study with other international studies as shown in (Table – 4), Varus collapse and cut outs were less in our study compared to other studies.

Conclusion

Proper reduction and screw positioning holds the key irrespective of implants, proper surgical reduction is equally achieved by both implants. Both Indian and foreign implants had similar bony union and complication rates with no statistically significant difference between both groups. Our study shows that failure rate is low in both Indian and foreign groups. The outcome depends on preoperative comminution, proper reduction, screw/blade positioning and osteoporosis rather than on the type of implant used. Properly performed, Indian implants are safe and viable option and inpar with Foreign implants.

Fig 1a: Singh's and maini index (osteoporosis grading).

Fig 1b: Grade 2 thinning of primary compressive trabeculae.

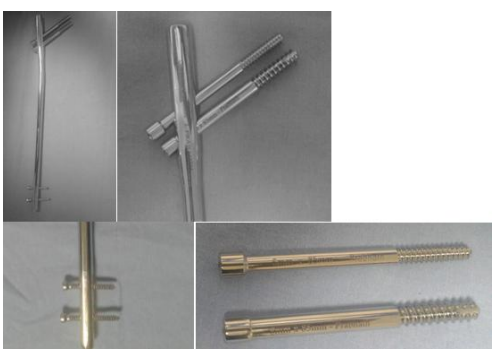

Fig 2: Ao classification for intertrochanteric femur fractures.

Fig 3: Neck shaft angle calculated in uninjured hip.

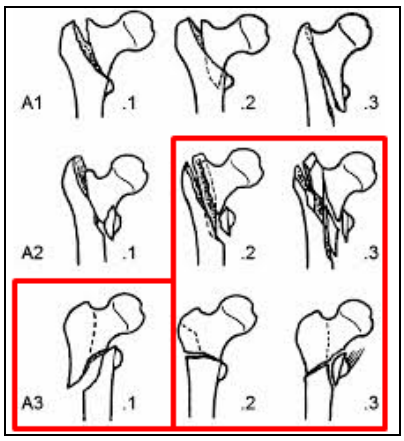

Fig 4: Anatomical reduction in immediate postoperative x ray.

Fig 5: Screw positioning in immediate post-operative x ray.

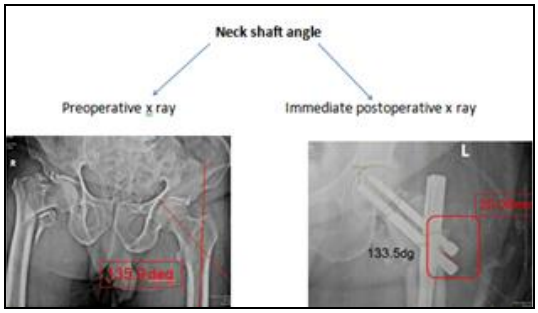

Fig 6: Calculating tip apex distance.

Fig 7: Sliding length in immediate post-operative x ray.

Fig 8: Bony union.

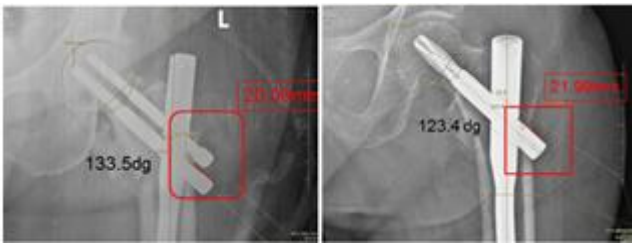

Fig 9: Complications like varus collapse.

Fig 10: Cut Outs.

Fig 11: Joint penetration.

Fig 12: Broken implants.

Fig 13: Back Outs.

Fig 14: Nonunions.

Fig 15: Peri implant fractures.

Fig 16: Case example of Indian implant with poor outcome.

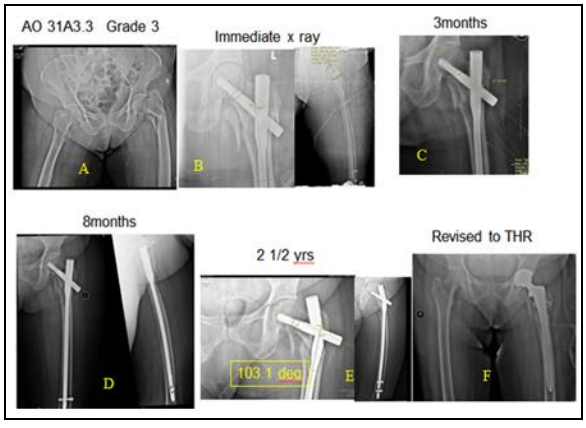

Fig 17: Case example of foreign implant with poor outcome.

Fig 18: Time for union in weeks in both groups.

Table 1: Neck shaft angle in preoperative and immediate post-operative x ray.

	Neck shaft angle		
	Preoperative in normal hip	**Immediate post-operative**	
Indian implants	133.7 deg	130.4 deg (121.7-141.5 deg)	3.3 deg
Foreign implants	131.3 deg (125.1-135.1 deg)	129.2 (122.9-139.7 deg)	2.1 deg
			Anatomical (0-5 degree)

Table 2: Neck shaft angle, tip apex distance and sliding length in immediate post-operative and last follow up x rays.

Parameters	**Indian implants**		**Foreign implants**	
	Immediate x	Last x ray	Immediate x rays	Last x ray
Neck shaft angle	130.4 deg (121.7-141.5 deg)	125.7 deg (105.7-139.2 deg)	129.2 deg (122.9-139.7)	126.1 deg (103.6-137.2 deg)
	4.7 degree (0-5 deg)		3.1 degree (0-5 deg)	
Tip apex distance	22.30mm (18.3-27.7 mm)	24.97mm (20.1mm-36.3mm)	22.16mm (18.7mm-28.3mm)	23.78 mm (21.1mm-31.5mm)
	(<25mm)		(20-30mm)	
Sliding length	23.84mm (18.9-27.2mm)	28.03mm (19.7-44.3mm)	24.77mm (19.5-28.1mm)	27.76mm (18.8-43.1mm)
	4.21mm (0-11mm)		2.99mm (0-11)	

Table 3: Distribution of complications in Indian and foreign implant groups.

Parameters	**Indian Implants**	**Osteoporosis**	**Foreign Implants**	**Osteoporosis**	**P Value**
Cutouts	10(4.03%)	7	7(2.%36)	4	0.292
Back Outs	5(3.22%)	4	3(2.37%)	2	0.368
Broken implants	7(2.41%)	5	3(1.78%)	3	0.369
Varus collapse	9(3.62%)	7	5(2.95%)	4	0.407
Peri implant fracture	-		1	1	
	32 (12.90%)	23	19 (11.24%)	14	0.435

Table 4: Table comparing my study complication rates with other studies.

	Indian Implants	**Foreign Implants**	
Bony Union	16.41 weeks	15.27 weeks	Gadegone and Saphale *et al* (24) (15-21 weeks) 2010
Varus collapse>10 deg	3.62%	2.95%	Jeetendra bajpai *et al* (28) (6.66%) 2014
Tip apex distance	24.97mm	23.78mm	Heman *et al* (22) (20.7mm) 2012
Sliding length	4.21mm	2.99mm	Suk Kvu choo *et al* (17)(0-5mm)2010
Cut outs	4.03%	2.36%	Schipper *et al* (8) (PFN 5.2%, Gamma nail 6.1%) 2004
Complication rates	12.09%	11.24%	Kaisidis *et al* (26) (5-13%) 2009
Reoperations	4.43%	2.36%	Haidukewych *et al* (25) (3.3%) 2003

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