# A comparative study of proximal femoral nail versus dynamic hip sliding plate and screw system for treatment of intertrochanteric hip fractures

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Abstract Background: Fracture of intertrochanteric femur has been recognised as a major challenge by the Orthopaedic community, not solely for achieving fracture union, but for restoration of optimal function in shortest possible time with minimal complications. Operative treatment in the form of internal fixation permits early rehabilitation and offers the best chance of functional recovery hence becomes the treatment of choice for virtually all fractures of trochanteric region. Among the various types of implant available i.e. fixed nail plate device, sliding screw plate and intramedullary devices, the compression hip screw is most commonly used but recent technique of closed intramedullary nailing is gaining popularity. The present study is to compare the results of Proximal femoral nailing (PFN) and Dynamic hip screw (DHS) in terms of effectiveness, strength of construct, early mobilisation of patients and their advantages / disadvantages when used to treat similar type of fractures. Material and methods: This prospective study was done at Government Medical college, Aurangabad between 2013-2016 under the guidance of its ethical committee. This study was conducted on 60 patients (30 patients were in PFN group and 30 patients were in DHS group). Clinical and radiological follow up of all patients were carried out regularly till the patients achieved maximum possible functions of injured limb. Results were evaluated using Harris hip scoring system. Results: Mean blood loss was 107ml. for PFN and 262ml. for DHS. Average surgical time was 79 minutes for PFN and 103 minutes for DHS. Average time of union was 12 weeks for PFN and 14.85 weeks in DHS. Conclusion: PFN has lesser operative time, lesser blood loss, early post-operative rehabilitation and better functional outcome especially in unstable fractures compared to DHS.

Key Word: Proximal femoral nail, Dynamic hip screw, Intertrochanteric femoral fractures.

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# INTRODUCTION

Intertrochanteric fractures are extra-capsular fractures extending from base of greater trochanter along intertrochanteric line to lesser trochanter just above medullary canal. Intertrochanteric fractures of femur are most commonly operated fractures. Intertrochanteric fractures are common in elderly people. The frequency of these fractures has increased primarily due to increased life span along with sedentary life due to urbanization. Trochanteric fractures when occur in younger population is due to high velocity trauma, whereas in elderly

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population it is mostly due to trivial trauma. Also, the geriatric age group (higher proportion in women) has a higher incidence of osteoporosis along with low energy falls from standing height accounts for approximately 90% of hip fractures in community. Higher velocity traumatic intertrochanteric fractures are relatively rare and are more common in men less than 40 years of age.<sup>1</sup> Intertrochanteric fractures can be managed by conservative or operative methods. Conservative methods were the treatment of choice until 1960 when  $Horowitz^2$ documented that the mortality rates in conservative methods were higher as compared to operative methods. The trochanteric fractures managed by conservative methods usually unite. If suitable precautions are not taken than fracture undergoes malunion, leading to varus and external rotation deformity at the fracture site and shortening and limitation of hip movement.<sup>2</sup> As conservative methods resulted in higher mortality rates and complications like decubitus ulcer, urinary tract infections, pneumonia, thromboembolic complications, these methods have been abandoned.

Conservative methods are now indicated only under 2 conditions,

- 1. Elderly person with high medical risk for anaesthesia and surgery
- 2. Non ambulatory patient with minimal discomfort following injury.

Since this fracture is more common in the elderly patients, the aim of treatment should be prevention of malunion, and early mobilization. Taking all the factors into consideration, surgery by internal fixation of the fracture is an ideal choice.<sup>3</sup> Factors determining the strength of fracture implant assembly depends on the bone quality, fragment geometry, fracture reduction, implant type and implant placement.<sup>4</sup> Surgeon can control only the quality of reduction, choice of implant and its placement. As intertrochanteric fractures have the highest post-operative fatality rate among surgically treated fractures, they have become an important health issue and is very important to study and compare different surgical options available for these fractures.

Implants for the fixation of intertrochanteric fractures can broadly be divided into

- 1. Extramedullary devices, example: D.H.S
- 2. Intramedullary devices, example: P.F.N.

The most commonly used device is the Dynamic Hip Screw with Side Plate (D.H.S). This is a collapsible fixation device, which permits the proximal fragment to collapse or settle on the fixation device, seeking its own position of stability. The latest implant for management of intertrochanteric fracture is P.F.N (Proximal Femoral Nail). This implant is a cephalo-medullary device and has many potential advantages like<sup>5</sup>

- 1. Being intramedullary, load transfer is more efficient.
- 2. Shorter lever arm results in less transfer of stress and less implant failures
- 3. Advantage of controlled impaction is maintained.
- 4. Sliding is limited by intramedullary location, so less shortening and deformity.
- 5. Shorter operative time, less soft tissue dissection and less blood loss.

In view of these conditions, this study is taken up to compare the results of D.H.S and P.F.N.

#### MATERIAL AND METHODS

This was a prospective, analytical study aimed to achieve fracture union by using two different kind of internal fixation modalities in similar type of fractures.

**Inclusion criteria:** includes recent traumatic history, isolated intertrochanteric fractures, stable and unstable fractures and the consent to participate in study.

**Exclusion criteria**: includes patients with multiple fractures, pathological fractures, old neglected fractures, paediatric age group, reverse intertrochanteric fractures and elderly patients with high medical risk for anaesthesia and surgery.

### **IMPLANT DETAILS:**

**Dynamic hip screw Components:** The implant consists of a lag screw, a compression screw and a barrel side plate attached to it. Lag Screw is available in lengths from 60-110mm.Compression Screw of 36 mm is used which allows compression at the fracture site. Barrel side plate are available in angles of 125<sup>0</sup>,130<sup>0</sup>, 135<sup>0</sup>, 140<sup>0</sup> and from 4-12 holes. 135<sup>0</sup> and 140<sup>0</sup> plates are more often used. 4.5 mm cortical screws are used to fix the side plate with shaft. In our study we used lag screw of 60-110 mm and a side plate that allowed a purchase of at least 8 cortices with shaft of femur and 130-140<sup>o</sup> angled plate depending upon the neck shaft angle determined pre-operatively.



Figure 1: 1 - Compression screw 2 - Richard's screw 3 - Barrel plate



1 - T Handle 2 - Angle guide 3 - Tap 4 - Guide wire



1 - Screw driver for Richard's screw 2 - Triple reamer

# PROXIMAL FEMORAL NAIL

**Components:** The implant consists of a Proximal Femoral Nail, a self-tapping de-rotation 6.5mm screw, a self-tapping 8mm femoral neck lag screw, 4.9mm distal locking screws and an end cap. PFN is made up of either 316L stainless steel or titanium alloy. PFN comes in following sizes: Length of standard PFN is 250 mm and available length of Long PFN is 340, 360, 380, 400 and 420 mm.

#### Diameter: 9, 10, 11, 12 mm

**Neck shaft angle range:**  $130^{\circ}$ ,  $135^{\circ}$  The nail is having 14 mm proximal diameter. This increases the stability of the implant. There is  $6^{\circ}$  medio-lateral valgus angle which prevents varus collapse of fracture, even when there is medial communition. The distal diameter is tapered to 9-12 mm, which also has a groove to prevent stress concentration at the end of the nail and avoids fracture of the shaft distal to the nail. Proximally it has two holes, the distal one for insertion of 8mm neck screw which acts as a sliding screw and the proximal one is for 6.5mm hip screw which helps to prevent the rotation. Distally the nail has two holes for insertion of 4.9mm locking screws of which one is static and the other one is dynamic hole

which allows dynamization. In our study we used the standard length PFN of 250mm with distal diameter of 9, 10 and 11mm. The common neck shaft angle used was 135° followed by 130°. End cap was not used.



Figure 4: 1 - Cannulated awl 2 - Proximal reamer 3 - T-handle



Figure 5:

1 - Proximal femoral nail with 14mm diameter with 6°mediolateral valgus and tapered tip.

2 - 6.5mm de-rotation screw.

3 - 8mm lag screw.

4 - 4.9mm locking bolt in static mode 5 - 4.9mm locking both in dynamic mode



Figure 6: 1. Hammer assembly 2. Zig



Figure 7:

1 - Solapur protection sleeve

2 and 3 - Sleeve for guide wire and reamer for proximal screw

4 - Reamer for 6.5 mm de-rotation screw

5 - Reamer for 8mm lag screw

Pre-operative routine investigations were done. Informed consent was obtained by patient for both surgical procedure and participation in the study. After anaesthetic fitness all cases were operated under combined spinal and epidural anaesthesia on fracture table using standard protocol. Post-operative antero-posterior and lateral view x-rays of the operated hip were taken. Post-operatively static exercise in bed for glutei, hamstrings, quadriceps and breathing exercises were started next day of surgery. Sitting was allowed on next day of surgery with passive exercises in bed. Drain if inserted was removed after 48 hours. ROM exercises were started actively. The protocol for weight bearing, in stable fractures is to start partial weight bearing next day after surgery and full weight bearing was started after 6 weeks, while in unstable fractures, non-weight bearing walking was allowed on operated side with the help of a walker or crutches next day after surgery, partial weight bearing after 6 weeks and full weight bearing was started after 3 months approximately. However, weight bearing was modified as per the type of fracture, stability of internal fixation, fracture union and tolerance of the patient. Postoperative dressings were done on 2<sup>nd</sup> and 5<sup>th</sup> day. Suture removal was done on or after 14 days. Follow up was done at 2<sup>nd</sup>, 4<sup>th</sup>, 6<sup>th</sup> week, 3 months, 6 months, and 1 year after the surgery. The patients were assessed functionally on the basis of Harris Hip Score and radiologically. The post-operative pain was assessed as per Hip Score criteria at the end of 1 year along with post-operative gait assessment. Union was decided on the basis of obliteration of fracture line with bridging callus so as to allow unprotected function of the limb.

**Harris Hip Scoring System:** Formulated by W. H. Harris<sup>6</sup> it incorporates all-important variables into single reliable figure, which is both reproducible and reasonably objective.

	Table 1: Point scale with max	imum of 1	00 points:					
	pain	44						
	Function	47						
	Range of Motion	05						
	Deformity	04						
	Total	100						
	Table 2: Harris hi	p score						
1	Pair	n		44				
1	Totally disabled, crippled,	pain in be	d, bedridden	00				
2	Severe pain, serious lin	nitation of	activities	10				
3	Moderate pain, tolerable but	makes co	ncession to pain	20				
4	Mild pain, no effect or	n average a	activities	30				
5	Slight, occasional, no co	Slight, occasional, no compromise in activity						
6	None, or ig	nores it		44				
	Tota	l.						
II	Functi	on		47				
Α	Distance v	valked						
1	Bed and ch	air only		00				
2	Two or thre	e blocks		05				
3	Six blo	Six blocks						
4	Unlimi	Unlimited						
В	Activit	ies						
	Shoes and	socks						
1	Unable to	wear		00				
2	With diff	iculty		02				
3	With e	With ease 04						

	Public transportation	
1	Unable to use Public transportation (Bus)	00
2	Able to use Public transportation (Bus)	01
	Limp	
1	Severe or unable to walk	00
2	Moderate	0
3	Slight	0
4	None	1
	Support	
1	Two crutches or not able to walk	0
2	Two canes	0
3	One crutch	0
4	Cane most of the time	0
5	Cane for long walks	0
6	None	1
	Stairs	
1	Unable to use stairs	0
2	In any manner	0
3	Normally using a railing	0
4	Normally without using railing	0
	Sitting	
1	Unable to sit in any chair comfortably	0
2	On a high chair for 30 min.	0
3	Comfortably on an ordinary chair for one hour	0
	Total	

Та	ble 3: The sco	ore is reported as <sup>6</sup>	
1	90-100	Excellent results	Г
2	80-89	Good	
3	70-79	Fair	
4	60-69	Poor	
5	Below 60	Failed result	

# **RESULTS**

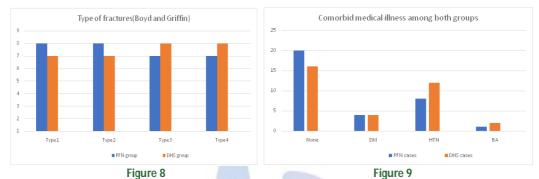
This study was conducted on 60 patients (30 patients were in PFN group and 30 patients were in DHS group). Male: Female ratio was 2.75:1 in PFN group and 9:1 in DHS group.

	Та	ble 1: Distrib	ution of ca	ses accordi	ng to gende	er among bo	oth groups	
Gender -	PFN c	ases	DHS c	ases	To	tal	Chi aguara taat	n voluo
Gender -	No.	%	No.	%	No.	%	Chi-square test	p-value
Male	22	73.33	27	90.0	49	81.67		
Female	08	26.67	03	10.0	11	18.33	2.78	P=0.095
Total	30	100	30	100	60	100	2.78	NS

	PFN	l cases	DHS	cases	То	otal	Chi-square	n voluo
Age group	No.	%	No.	%	No.	%	test	p-value
20-30	05	16.67	01	3.33	06	10.00		
30-40	03	10.0	05	16.67	08	13.33		
40-50	05	16.67	04	13.33	09	15.00		
50-60	05	16.67	03	10.00	08	13.33		P=0.613
60-70	07	23.33	10	33.33	17	28.33	1.78	NS
70-80	01	3.33	07	23.33	08	13.33		145
80-90	02	6.67	00	00	02	3.33		
>90	02	6.67	00	00	02	3.33		
Total	30	100	30	100	60	100		
Mean ±SD	52.70	)±20.49		55.1	7±15.11		t=0.531 p	=0.598

In PFN group 15 cases (50%) were having Right side involvement and remaining 15 cases (50%) were having Left side involvement whereas in DHS group 16 cases (53.33%) were having right side involvement and remaining 14 cases (46.67%) were having Left side involvement with p-value =0.796 (NS).

Table 3: demonstrates distribution of cases according to fracture											
Encoderno	PFN	cases	DHS	cases	Тс	otal	Chi-square	re			
Fracture	No.	%	No.	%	No.	%	test	p-value			
Stable	16	54.33	14	46.67	30	50.0		D 0 722			
Unstable	14	46.67	16	54.33	30	50.0	1.24	P=0.732			
Total	30	100	30	100	60	100		NS			





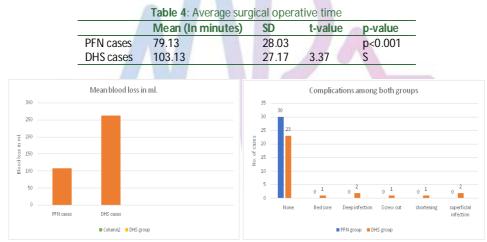


Figure 10: Average blood loss among both groups Figure 11: Shows complications among both groups

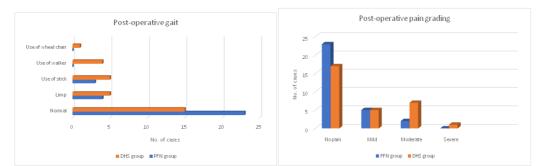


Figure 12: Shows post-operative gait among both groups Figure 13: Shows post-operative pain among both groups

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Table 5: Comparison of Mean Harris Hip score						
		N	Mean	SD	t-value	p-value
2 weeks	PFN group	30	49.80	13.18		
2 weeks	DHS group	30	49.76	12.74	0.010	0.992
4 weeks	PFN group	30	58.13	13.74		
4 Weeks	DHS group	30	57.56	13.01	0.194	0.870
6 weeks	PFN group	27	68.00	12.33		
0 weeks	DHS group	26	66.56	12.93	0.398	0.692
3 months	PFN group	27	74.87	11.01		
3 11011018	DHS group	26	74.20	11.32	0.211	0.833
(months	PFN group	27	79.08	10.98		
6 months	DHS group	26	80.96	9.65	0.636	0.528
1.000	PFN group	27	82.33	9.20		
1 year	DHS group	26	82.52	8.89	0.072	0.943

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Figure 14: Mean Harris hip score among both groups

Figure 15: Shows final outcome among both groups

Table 6: Association between final outcome and fracture outcome

			PFN	group					DHS g	roup		
Final outcome	St	able	Uns	stable	То	tal	Sta	ble	Uns	table	Тс	otal
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Excellent	08	100.0	00	00	80	100	07	100	00	00	07	100
Good	07	87.5	01	12.5	80	100	06	75.0	02	25.0	08	100
Fair	00	00	09	100	09	100	00	00	09	100	09	100
Poor	00	00	02	100	02	100	00	00	02	100	02	100
Total	15	55.55	12	44.45	27	100	13	50.0	13	50.0	26	100

Table 8: Comparison of Mean Harris Hip score in stable and unstable cases after 1 year

		Mean	SD	t-value	p-value
Stable	PFN cases	86.93	6.71	1.90	P=0.102
Stable	DHS cases	89.38	4.35	1.90	NS
Unstable	PFN cases	71.50	8.37	37 1 4 O P=	
Unstable	DHS cases	69.23	7.71	1.69	NS



Figure 16:

Figure 17:

Figure 18:

Figure 16: Pre-operative AP and Lateral radiographs; Figure 17: Post-operative AP and Lateral radiographs; Figure 18: Complication of excessive collapse of DHS screw leading to shortening of 3cms

A 41 - year old female with right sided stable intertrochanteric fracture treated with PFN. (Fig. 19)

- a) Pre-operative image
- b) and c) Immediate post-operative AP and Lateral radiograph
- d) Union at 6 weeks follow-up

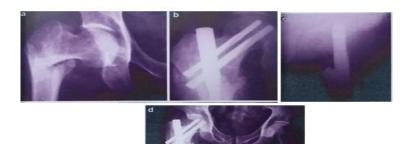


Figure 19

#### DISCUSSION

With all the advancement in the field of technology, the road traffic accidents are increasing day by day. With modern methods of treatment along with awareness of healthy living, average life expectancy of Indian population has almost doubled from 35 years to 64 years resulting in tremendous increase in osteoporotic population and osteoporotic fractures. Increasing life expectancy, sedentary and busy life style along with increasing traffic on road and lack of observing traffic rules result in increased incidence of fractures. Trochanteric fractures are most frequently encountered fractures by orthopedic surgeons worldwide. Before the invention of operative treatment, conservative treatment in the form of prolonged traction was preferred, however this treatment was associated with complications like bed sores, deep vein thrombosis, bronchopneumonia. Elderly people could not tolerate prolonged immobilization. This led to evolution of operative treatment. Operative treatment permits fixation of fracture, not only anatomical or in near anatomical position but also allowed rapid mobilization. Since 20th century numerous operative treatment modalities have been evolved like smith Peterson nail (S P Nail), Jewett nail, Enders nail, Asnis screw, Medoffs plate etc. amongst them Dynamic hip screw (DHS) is most frequently used device. Proximal femoral nail has been recently introduced in 1996 by AO/ASIF, has begun to compete with Dynamic hip screw in treatment of proximal femoral fractures. This intramedullary device has following advantages

- 1. Addition of 6.4mm anti-rotation screw.
- 2. Greater implant length.
- 3. Small valgus angle of 6 degrees.
- 4. Small diameter with fluffing tip reducing stress riser effect below distal tip of nail
- 5. More proximal positioning of distal lock to avoid abrupt changes in stiffness of implant constructs.

Sixty patients of trochanteric fractures managed operatively by internal fixation with Dynamic Hip Screw and Proximal Femoral Nail during the course of this study were sorted and each was followed for at least 1 year. Follow up of all patients in both groups were carried out regularly with clinical and radiological assessment at successive visits till patients achieved maximum possible functions of the injured limb. The data collected from patients of these two groups was analysed, evaluated and compared with each other. Age distribution Most of patients in present study were from age group of 6<sup>th</sup> to 8<sup>th</sup> decade. Mean age in years for group operated by PFN is 52.70. Mean age in years for group operated by DHS is 55.17. This signifies the fact that patients from these age groups are involved in low energy trauma like domestic fall (fall at home)<sup>4,7,8,9,10</sup> Gallaghar *et al*<sup>11</sup> (1980) reported an eight-fold increase in trochanteric fractures in men over 80 years and women over 50 years of age.

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Average age reported by other workers is as follows								
Name of the worker	Age in years							
Cleaveland and Thompson <sup>12</sup> , 1947	76.0							
Murray and Frew, 1949	62.5							
Boyd and Griffin <sup>3</sup> , 1949	69.7							
Scott, 1951	73.3							
Evans <sup>4</sup> 1951								
Males	62.6							
Females	74.3							
Wade and Campbell (1959)	72.0							
Sarmiento <sup>13</sup> , 1963	71.9							
Gupta, RC, 1974	51.2							

Cleveland *et al*<sup>12</sup> pointed out the inherent weakness of the bone structure of elderly, predisposing them to injury. More wide spread measures to correct or prevent osteoporosis should be instituted. The elderly should be freed from potential danger of poor lighting, slippery floor, wet slippers etc. For some patients whose general condition makes them vulnerable to fall and fracture, total restriction of independent ambulation is indicated. Due to early fixation of such fractures and early mobilization, these patients could gain full range of movement at an early date with minimal loss of productivity.

**Sex distribution:** Most of patients from present study were males. There was a male preponderance in our patients. The ratio of males to female was 2.75:1 in PFN group and 9:1 in DHS. This reflects the preference and

better acceptance of surgery by males and higher incidence of trochanteric fractures of femur in male population due to their more active lifestyles. David G. Lovelle<sup>14</sup> found trochanteric fractures more common in women than men by a margin of three to one. Melton J.L., Ilistrup DM, Riggs BL et al<sup>11</sup> (1982) released a study titled 'fifty years trend in Hip fracture incidence' and reported a female to male ratio of 1.8:1. This variation is probably because our study measured the male female ratio amongst operated fractures that reported for follow up and not the actual sex incidence for all trochanteric fractures. Majority of patients in this series were male as they are more outgoing and engaged in activities like agriculture, driving of motor vehicles and are more likely to be involved or prone to accidents/ fall. Females play a more dormant role and are involved more in household activities. B. B. Ohari and Hatim Shaikh from Indore (1957) also found males predominantly affected in their series.

Ratio of males: females in other series is given below							
Series	Males	Females					
Boyd and Griffith <sup>3</sup> (1949)	74	226					
Murray and Frew 1949	56	46					
Scott (1951)	35	65					
Robey 1956	46	53					
Clawson <sup>15</sup> 1957	75	102					

**Type of fractures:** In our present study, out of 60 intertrochanteric fractures, 30 cases were of unstable fracture pattern and 30 cases were of stable fracture pattern. Out of which 16 (54.33%) of stable and 14 (46.67%) of unstable fracture pattern are treated by PFN. 14 (46.67%) of stable and 16 (54.33%) of unstable fracture pattern are treated by DHS. According to Mervyn Evans<sup>4</sup> the Intertrochanteric fractures are considered as stable or unstable depending upon integrity of posteromedial cortex. Fractures with intact posteromedial cortex are considered as stable fractures while fractures with loss of posteromedial cortex are considered as unstable fractures. Postero medial cortex constitutes mainly the lesser trochanter.<sup>16,17,18,19</sup>

Wound complications: Superficial wound infection was seen in 2 cases operated by DHS whereas no cases operated by PFN were having it. These 2 cases had superficial wound infection at suture site. This may be attributed to low immunity status of patient as the patient was of asthenic built and belonging to low socioeconomic status with soft tissue exposure, which is more in cases operated by DHS. In all these patients, treatment of IV Antibiotics was prolonged, as per our protocol we gave IV antibiotics for 5 days but in presence of wound infection we continued its use for 10 days. Dressing of wounds were done as per necessity. In all these cases, the wound healed in the end. In the series of patients operated by DHS by Dr. G.S Kulkarni<sup>20</sup>, there were two cases of deep infections which were treated by removal of implant. The infected sinuses thus healed after implant removal.

Average time of Fracture Union: Average time of union was about 12 weeks in PFN and 14.85 weeks in DHS. We have used criteria for union as presence of bridging callus at fracture site. Clinically, absence of pain at fracture site.

R	Radiological time of union in other series							
Sr. No.	Series	Radiological union (In weeks)						
1	Kevin D. Harrington <sup>21</sup>	16						
2	Juluru-P. Rao	18						
3	Luis A. Flores <sup>22</sup>	13						
4	B. Ma11 <sup>23</sup>	14						
5	Present Series	12						

**Range of Movement (As per Harris Hip Scoring system):** The range of movement calculated by the Harris Hip Scoring system treated by both the implants i.e. PFN and DHS was good and almost same. The range of movements namely flexion, extension, external and internal rotation was good in most cases, excellent in a few. In very few cases, there were poor results. The poor result was attributed to other associated factors namely a long interval between trauma and surgery and development of post-operative infection.

Author	No. of	Type of	Technical	Cut	Implant	Fracture below	Z	Reverse	Reoperation
	Patients	fracture	failure	out	failure	tip of nail	effect	Z effect	rate
Simmermacher	191	A2(67%)	4.7%	1	1	-	-	-	7%
Domingo <sup>24</sup>	295	A2(59%)	12%	1	1	1	-	-	3%
Banan <sup>25</sup>	60	A2(83%)	8.7%	4	4	2	-	-	6.5%
Al-yassari <sup>26</sup>	76	A2(77%)	10.5%	4	4	1	-	-	7.1%
Werner	70	A2(54%)	25.7%	6	6	-	-	-	19%
Boldin	55	A3(62%)	18.7%	2	2	-	2	2	18%
Fogagnolo	46	A2(64%)	23.4%	5	5	1	5	5	19.1%

#### Technical and Mechanical complications of PFN published in the literature

In present study, Boyd and Griffin type I, II, III fractures were there. This classification is easy to understand, recollect and apply. We found no cases with screw cut out, fracture below the tip of nail and Z effect. There were 2 cases of reverse Z effect and 1 case of breakage of nail in between proximal screw and distal lock.

# CONCLUSION

PFN has following advantages over DHS in treatment of intertrochanteric fractures

- 1. Lesser operative time
- 2. Lesser blood loss
- 3. Early post-operative rehabilitation of patients
- 4. Better functional outcome

However, the difference in functional outcome is not statistically significant and thus requires a larger group of study to prove significance.

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