

Original Research Article

In vitro biomechanical comparison of various implants in Pauwels type 3 fracture neck femur

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ABSTRACT

Background: The objective of this study was to find out the correlation among type of implant, type of fracture and quality of bone in a cadaveric model of unstable fracture neck of femur (Pauwels type 3) fixed with either; proximal femoral nail (PFN), dynamic hip screw (DHS), dynamic hip screw with an anti-rotation screw (DHS and ARS) or cannulated cancellous screws (CCS).

Methods: This study was conducted on 24 cadaveric bones (6 in each group) in which unstable fracture neck of femur (Pauwels type 3) were created and fractures in each group were fixed with different implants after creating a comparable group using DEXA scan. These were tested on a cyclic physiological loading machine at 2 cycles per second with a load of 200kg. The test was observed for 10,000 loading cycles or till failure whichever occurred earlier. Subsidence was measured and analyzed.

Results: Five specimens in the PFN group, 3 specimens in the DHS and ARS and DHS group completed 10,000 cycles while all the specimens in CCS group failed before 10000 cycles. Mean subsidence of the PFN group was significantly lower than the other groups.

Conclusions: PFN constructs were stronger than the other constructs. However, these data must be interpreted as strictly biomechanical, representing only part of the scenario at work *in vivo*. Nonetheless, the significant findings of increased strength of fixation over the DHS, DHS with ARS and CCS certainly appear to support the use of PFN clinically.

Keywords: Proximal femoral nail, Femoral neck fracture, Cadaveric model, Pauwels

INTRODUCTION

Neck of femur fractures are commonly encountered fractures around the hip and various modes of treatments are available. The mode of treatment depends on various factors like age of the patient, type of fracture pattern, quality of bone and other comorbidities.¹ Displaced intracapsular femoral neck fracture in young adults, continues to be a difficult problem to treat. They are associated with higher incidences of femoral head osteonecrosis and nonunion.²⁻⁴ The treatment available is

either internal fixation or hemi/total replacement arthroplasty. The Pauwels type 3 (unstable) fracture remains a difficult challenge. The dominant shear force with this high angle fracture pattern lends itself to higher rates of failure and nonunion. Failure of fixation in unstable fracture neck of femur is a frequently encountered complication leading to nonunion and femoral head osteonecrosis.^{4,5} Number of factors are responsible for failure of fixation in unstable fracture neck of femur.⁶ Biomechanical studies have shown the role of individual factors like type of implant, type of fracture and quality of

bone.⁷ Till now the method of fixation and the choice of implant is controversial.⁸⁻¹¹ We tried to find out the correlation among these factors in a cadaveric model of unstable fracture neck of femur (Pauwels type 3) fixed with either; proximal femoral nail, dynamic hip screw, dynamic hip screw with an anti-rotation screw or cannulated cancellous screws. This study was conducted on cadaveric bones in which the unstable fracture neck of femur (Pauwels type 3) were created using standard technique and these fractures were fixed with either proximal femoral nail (PFN), dynamic hip screw (DHS), dynamic hip screw with an anti-rotation screw (DHS and ARS) and cannulated cancellous screws (CCS) after creating a comparable group using DEXA scan.

METHODS

This research study was done in the Department of Orthopaedics, Institute Of Medical Sciences, Banaras Hindu University in collaboration with the Department of Metallurgical Engineering (IIT-BHU) between July 2012 to 2013 after approval from the ethical committee and institutional review board and was performed in accordance with the ethical standards of the 1964 declaration of Helsinki as revised in 2000.

The biomechanical cadaveric study was conducted on 24 dry cadaveric femoral specimens (6 specimens in each group). All the specimens were standardized using DEXA scan and made them comparable. 24 femoral dry cadaveric specimens were soaked in saline for 4-6 hours. Pauwels type 3 fracture neck femur was created in all the specimens maintaining the same angle in all specimens. PFN, DHS, DHS and ARS, and 3 CCS (7 mm, inverted triangle configuration) were implanted in 6 specimens of each group under image intensification maintaining anatomical reduction of the fracture site. After final fixation, implant position was checked under image intensifier and critically analyzed. Fresh implants of the same size and same manufacturer (Yogeshwar Private Limited, Mumbai, India), made up of stainless steel were used and these implants were FDA (food and drug administration) certified. All implants used were made of 316L stainless steel.

These were tested on a cyclic physiological loading machine at 2 cycles per second with a load of 200kg. Cyclic loading test and fatigue test of the implanted specimens were conducted using computer-controlled servo-hydraulic MTS testing machine (model 810) of ± 50 KN capacity. We tried to simulate the forces and stresses the construct would be subjected to during the regular walking. Studies of biomechanics of hip joint suggest that testing for 10,000-20,000 cycles simulates 2-6 months of *in vivo* cyclic loading of the femur.¹² The test was observed for 10,000 loading cycles or till failure whichever occurred earlier. The specimens to be tested were initially mounted on the base designed to fix the shaft of the femur using cement to reinforce the construct. The constructs were mounted in such a way that they represented the normal

anatomic loading conditions of the hip in stance phase. MTS was used to give the cyclic load to the head of the femoral construct. Tests were conducted under load control made in compression at the frequency of 2Hz using a triangular waveform. The constructs that survived 10,000 cycles were analyzed for any physical and radiological changes and were again tested till failure. After the specimens were tested, the axial displacement of the head at the fracture site (subsidence) with preload was again measured.

Subsidence was defined as “the difference between the displacement measured with preload applied, before cyclic loading and the displacement measured with preload applied, after cyclic loading.” Subsidence was measured with a direct measuring device (verniers calipers). All tested constructs were again checked physically and radiologically for implant bending, fracture, screw bending, screw back-out and screw cut out.

All the statistical analyses were performed using in stat software for windows (GraphPad version 3.00, San Diego, California, USA). The student's t test was used to analyze the difference of mean for bone mineral density (BMD), number of cycles sustained. standard deviation and standard error of mean for these variables were also calculated. The test was referenced for p value and 95% confidence interval was constructed around sensitivity proportion using the normal approximation method. A value of less than 0.05 was considered to be statistically significant.

RESULTS

Five out of 6 specimens in PFN group, 3 out of 6 specimens in DHS and DHS and ARS group completed 10,000 cycles while none out of six specimens in CCS group were able to complete 10000 cycles. Average DEXA for PFN, DHS, DHS and ARS, CCS was 0.87 gm/cm², 0.88 gm/cm², 0.86 gm/cm² and 0.88 gm/cm² respectively and there were no significant differences between four groups (p=0.992) (Table 1).

Average DEXA value of specimens that sustained 10,000 cycles in PFN group, DHS group, DHS and ARS group was 0.90 gm/cm², 0.97 gm/cm² and 0.95 gm/cm² respectively while average DEXA value of specimens that failed in PFN, DHS, DHS and ARS and CCS was 0.68 gm/cm², 0.79 gm/cm², 0.78 gm/cm² and 0.88 gm/cm² respectively, which showed that specimen with low BMD got failed early while specimen with high BMD sustained 10000 cycles (Table 2).

In PFN group 1 construct failed with cut out of screw, while the mode of failure in 2 constructs in the DHS group was due to loosening of screw and 1 construct failed with cut out of screw. In the DHS and ARS group 3 constructs failed due to loosening of screws while in CCS group 2 constructs failed with bending of screws and 4 failed due to bending along with back out of screws (Table 2).

PFN showed mean the subsidence of 8.26 mm and DHS showed a mean of 15.00 mm after cycling and this difference was statistically significant (p=0.012). Similarly, mean subsidence difference between PFN and DHS with ARS was statistically significant (p=0.025) while the mean subsidence difference between DHS and DHS with ARS was statistically insignificant (Table 3).

The mean cycles sustained by the PFN group was statistically significant in comparison to DHS (p=0.038), DHS with ARS (p=0.047) and CCS (p=0.001) group. However, the mean cycles sustained by DHS was statistically insignificant in comparison to DHS with ARS (p=1.000) and to CCS group (p=0.248) (Table 4 and 5).

Table 1: DEXA for measurement of bone quality in PFN, DHS, DHS WITH ARS and CCS group.

Specimen	PFN (DEXA gm/cm ²)	DHS (DEXA gm/cm ²)	DHS WITH ARS (DEXA gm/cm ²)	CCS (DEXA gm/cm ²)
1	1.00	0.98	0.96	0.98
2	0.98	0.99	0.97	0.96
3	0.96	0.94	0.92	0.98
4	0.82	0.86	0.88	0.84
5	0.78	0.80	0.76	0.79
6	0.68	0.72	0.70	0.74
Average	0.87	0.88	0.86	0.88

Table 2: Correlation with bone quality and modes of failure in PFN, DHS, DHS with ARS and CCS groups after 10,000 cycles.

Specimen	PFN (DEXA gm/cm ²)	Mode of failure	DHS (DEXA gm/cm ²)	Mode of failure	DHS and ARS (DEXA gm/cm ²)	Mode of failure	CCS (DEXA gm/cm ²)	Mode of failure
1	1.00	Stable	0.98	Stable	0.96	Stable	0.98	Bending of screws
2	0.98	Stable	0.99	Stable	0.97	Stable	0.96	Bending of screws
3	0.96	Stable	0.94	Stable	0.92	Stable	0.98	Bending and back out of screws
4	0.82	Stable	0.86	Loosenin g of screws	0.88	Loosen ing of screws	0.84	Bending and back out of screws
5	0.78	Stable	0.80	Loosenin g of screws	0.76	Loosen ing of screws	0.79	Bending and back out of screws
6	0.68	Cut out of screw	0.72	Cut out of screw	0.70	Loosen ing of screws	0.74	Bending and back out of screws

Table 3: Correlation and calculation of subsidence PFN, DHS and DHS with ARS group.

Specimen no.	Subsidence (mm) PFN	Subsidence (mm) DHS	Subsidence (mm) DHS with ARS
1	7.00	12	11.5
2	7.56	14.5	13.2
3	8.25	18.5	17.5
4	8.50	Implant failure	Implant failure
5	10.00	Implant failure	Implant failure
6	Implant failure	Implant failure	Implant failure
Average	8.26	15.00	14.06
SD	1.13	3.27	3.09

Table 4: Number of cycles sustained and modes of failure in PFN, DHS, DHS ARS and CCS group.

Specimen	Max. no. of cycles survived by PFN group	Mode of failure	Max no. of cycles survived by DHS group	Mode of failure	Max no. of cycles survived by DHS with ARS group	Mode of failure	Max no. of Cycles survived by CCS group	Mode of failure
1	68,000	Cut out of screw	45,000	Loosening of screws	47,000	Loosening of screws	2,500	Bending of screws
2	60,000	Cut out of screw	31,000	Loosening of screws	33,000	Loosening of screws	2,100	Bending of screws
3	58,000	Cut out of screw	20,000	Cut out of screw	21,000	Loosening of screws	1,800	Bending and back out of screws
4	47,000	Cut out of screw	8,200	Loosening of screws	8,000	Loosening of screws	1,500	Bending and back out of screws
5	35,000	Cut out of screw	6,400	Loosening of screws	7,000	Loosening of screws	1,200	Bending and back out of screws
6	9000	Cut out of screw	5,100	Cut out of screw	5,500	Loosening of screws	600	Bending and back out of screws

Table 5: Comparison of number of cycles completed by four groups.

Group	Cycles completed (mean±SD)	ANOVA (p value)
PFN	46167.0±21516.66	<0.001
DHS	19283.0±16056.95	
DHS with ARS	20250.0±16863.42	
CCS	1616.7±673.54	

DISCUSSION

Although there is a general consensus regarding the operative therapy of undisplaced femoral neck fractures, the management of unstable and displaced fractures remains controversial, particularly in the elderly.^{8,9,13} Also the fact that prompt reduction and stable fracture fixation in the treatment of femoral neck fractures with the hope that the metaphyseal vessels will promptly reestablish and restore circulation before late segmental collapse occurs is definitely there but, because of elevated osteosynthesis failure and an increased nonunion rate, hemi or total hip arthroplasty are preferred by the majority of surgeons when treating older persons.^{14,15}

Another factor which leads to implant failure is the quality of bone. It is well known that poor quality of bone (osteoporosis) affords poor implant purchase and consequent high fixation failure. A number of

experimental studies have been done so far to define the factors for failure of implant, but so far these factors have not been studied in combination.^{7,16-18} The aim of this study was to combine all the factors, namely the subsidence, osteoporosis and loading of the construct to stimulate physiological weight bearing and study the modes of failure of stability after 10,000 cycles or after maximum no. of cycles sustained by the specimen that survived 10,000 cycles. All the specimens were tested not only to failure but also cycled under constant loading.

Proper positioning of implants is of indisputable importance for high fracture strength after internal fixation of an unstable femoral neck fracture. Biomechanical essentials for anchoring osteosynthetic implants include placing screws through the midpoint of the femoral head (highest BMD) or just below (highest backing), monitoring the tip apex distance (TAD) and placing an additional lag screw to prevent rotation of the head-neck fragment.¹⁹⁻²¹

In our study, the stabilization of simulated unstable Pauwels type 3 fractures with the PFN had substantial biomechanical advantages. This might be because the PFN screws transferred the bending moments from the femoral head and neck to the cortical bone of the femoral shaft.²² In contrast to this, the CCS could only transfer moments by interactions between the screw and the cancellous bone.^{10,11,23} The closer positioning of the lag screw of PFN

to the inferior femoral neck (compared with the DHS) may be the reason for the displacement differences between the PFN and DHS groups. The hold and purchase of any screw in the bone is a combination of screw design and rigidity of the host bone. As such osteoporotic bone stock would theoretically have poor purchase with the same screw as compared to normal bones.²⁴ The demand for prompt mobilization with full loading of the affected limb becomes increasingly difficult to meet in aging patients with advanced osteoporosis.

In our study, the fixation strength and the force to failure of all four devices were slightly higher in the specimens with higher BMD. Independent from the BMD, the PFN constructs were stronger than the DHS, DHS with ARS and CCS constructs. However, the BMD of all specimens that failed during cyclical testing were significantly lower than that of the surviving femurs.

PFN constructs also sustained an average high no. maximum cycles till failure than did specimens stabilized with DHS and DHS with ARS (Table 5). Because none of the CCS specimens were available for failure testing, there was no power to detect a significant difference between the CCS and other groups. The finding that none of the CCS, 3 of the DHS and ARS and 3 of the DHS constructs could survive our cyclical loading test that has important clinical implications. Normal activities of daily living can produce upward of 1,400 N to 1,500 N across the hip. The average patient hip joint is loaded with 238% body weight when walking at 4km/h and with 251% when climbing up stairs. With full weight bearing in the immediate, postoperative period (corresponding to 1,400 N loads) and using 6 weeks as the healing time for a femoral neck fracture (corresponding to 10,000 cycles), five out of six specimens stabilized with the PFN survived till fracture union.¹² In contrast to this, 100% of the CCS, 50% of the DHS and 50% of the DHS with ARS constructs failed before the amount of cycles representing the time needed for osseous healing.

In our study, there was a clear difference in the failure mechanisms of the PFN and CS constructs. All of the six specimens stabilized with CCS failed as the screws got bent and got back out. The calcar screw was the most affected, because the more superior screws were supported by the trabecular bone of the femoral neck (Figure 1).

In clinical practice, the screws usually back out.^{6,9,13} Similar biomechanical failure could be observed in the DHS, but in the DHS group, the classical “cut out” appeared as well (Figure 2).

In the DHS and ARS group specimens failed due to loosening of screws (Figure 3). In the PFN group, no hardware bending or backing out occurred. PFN constructs failed because of cut out of screw and fracture in the trochanteric region (Figure 4).

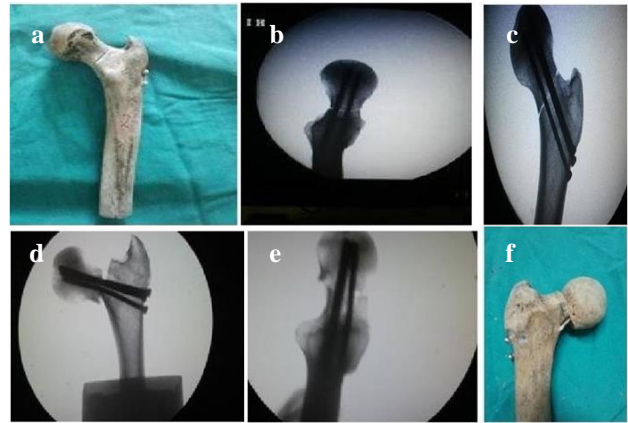


Figure 1: CCS specimen (a-c) before testing, (d-f) specimen after testing (2500 cycles) failed due to bending of screw before completing 10000 cycles.

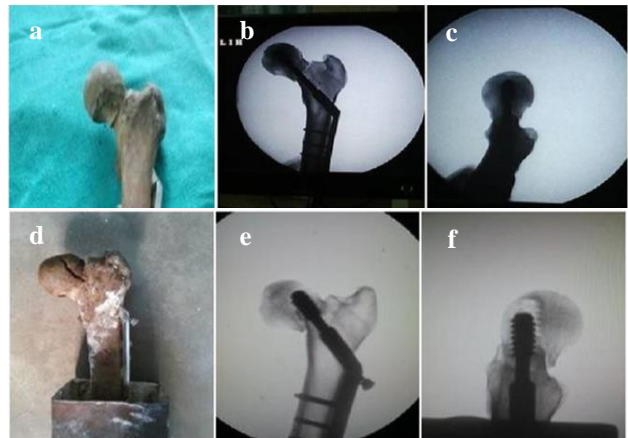


Figure 2: DHS specimen (a-c) before testing, (d-f) specimen after testing to failure 45,000 cycles, failed due to loosening of screw and cut out of screw.



Figure 3: DHS and ARS specimen (a-c) before testing, (d-f) specimen after testing to failure (47,000 cycles), failed due to loosening of screw.

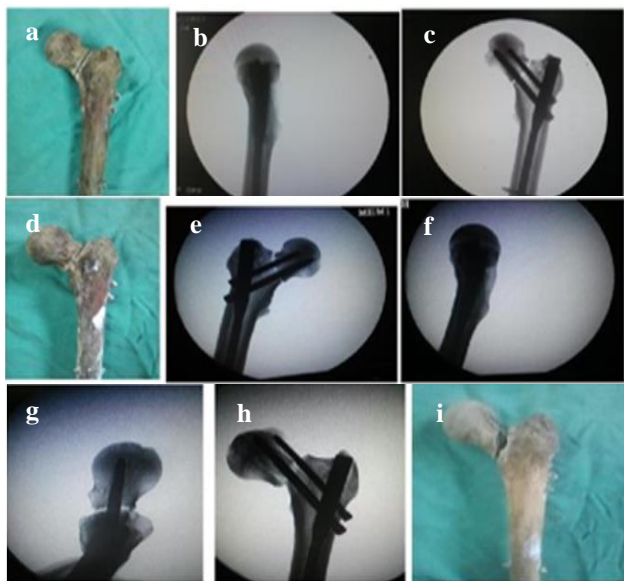


Figure 4: PFN specimen (a-c) before testing, (d-f) specimen after testing for 10,000 cycles (stable) and (g-i) specimen after testing to failure (68,000 cycles), failed due to cut out of screw.

As this implant has not been used much in humans to treat femoral neck fractures, it is difficult to draw conclusions on possible failure mechanisms *in vivo*.

There have been several studies in human cadavers comparing biomechanical properties of implants. To the best of our knowledge, there are not much previous studies to analyze the biomechanical performance of the PFN for stabilizing unstable femoral neck fractures. However, previous biomechanical studies compared other internal fixation devices for this fracture type.¹⁶⁻¹⁸ Some authors have already showed favorable results clinically with use of bi axial PFN in neck femur.²⁵

For patients aged between 60 years and 80 years, the consensus about the optimal treatment remains controversial.⁸ The mechanical advantages of internal fixation with intramedullary nails have now been proven in this biomechanical study however maintaining reduction while doing intramedullary nailing in fracture neck femur *in vivo* is a difficult task and requires technical expertise. Also lack of radiolucent jig for proximal screw insertion makes visualization of the screws on the lateral projection difficult and introduction of nail requires excessive adduction and flexion which can pose difficulty in fatty and obese patients. In cases with completely dislocated femoral neck fracture in which an anatomic reduction is not possible or in cases with severe arthrosis, there is a clear preference for joint replacement.^{14,15} In all other cases, especially in younger patients, an osteosynthesis should be considered after careful evaluation of individual circumstances that may limit the outcome of this treatment.^{19,26,27}

Possible limitations to our experiment lie in study design only axial loading was tested. Torsional stiffness, medial/lateral bending, and flexion/extension bending of the constructs were not tested. However, clinically and in previous biomechanical studies, this has been shown to not be the mode of failure. The cadaveric nature of this study is also a limitation. Ideally, to apply a realistic load to the proximal femur, we would simulate muscle forces in addition to axial loading. There is no accounting for the soft tissue envelope or bone healing, which is impossible to examine in the *in vitro* model. In our study, only a small number of samples were tested, which limited the statistical power, particularly in the subgroup analysis. If a construct failure occurs in an elderly patient, prosthetic replacement is nearly always necessary. After primary fixation with a DHS or multiple CS, the anatomic options for prosthetic fixation are good, because of preservation of the distal femoral neck and the trochanteric region. Because of the fractured trochanteric region after failure of the PFN constructs, the anchorage of a prosthetic stem in a revision operation could be complicated and associated with higher intra and postoperative risks such as prosthetic dislocation. Furthermore, in our study, the osteotomy was created by a saw, we did not take into account the effect of comminution and fracture irregularity on the stability of the implants. A major comminution of the posterior aspect of the femoral neck in garden stage III and IV fractures occurs in 70% of cases and is an important determinant of insecure fracture fixation.²⁸

Therefore, these data must be interpreted as strictly biomechanical, representing only part of the scenario at work in fixation and healing of these injuries *in vivo*.

CONCLUSION

The significant findings of increased strength of fixation of PFN over the DHS, DHS with ARS and CCS independent of BMD certainly appear to support the use of proximal femoral nail clinically in Pauwels type 3 fracture neck of femur.

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Ethical approval: The study was approved by the institutional ethics committee

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