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RANDOMIZED COMPARATIVE INTERVENTION STUDY OF HELICAL BLADE AND SCREW PROXIMAL FEMUR NAIL IN THE TREATMENT OF INTERTROCHANTERIC FEMUR FRACTURES.

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Abstract:

Introduction:

In the trochanteric region of the femur fractures are comparatively serious and their treatments can be done after hospitalization of the patient. The surgical procedure to fix the fractures helps in achieving mobilization of the bone. Intramedullary devices such as PFN and DHS are used for fixation.

Objective:

To compare the efficacy of Helical Blade PFN and Screw PFN for treating fractures in the intertrochanteric region.

Methods:

This study was randomized comparative research conducted among adults and elderly patients (Aged>50 years) during the study period from June 2018 to December 2020, where the patients were divided into two arms/groups where Group I patients (n=25) were treated with Helical PFN (PFNA2); Group II patients (n=25) were treated with Screw PFN and followed up prospectively.

Results:

Most of the patients in the present study were from the age group of more than 60 years. X-ray exposure shots during surgery were with mean of 36.08 in 25 patients of group I. The increase in X-ray exposure was due to the requirement of putting two screws in PFN rather than a single helical screw in PFNA2. Group I showed lower Singh's index with better results when compared with that of group II. Shortening of the limb by 3 cm (which is maximum shortening) was not found in any patient group I, whereas, in group II, 1 patient showed a maximum shortening of 3 cm.

Conclusion:

Based on this study's results, we can conclude that PFNA2 (Helical Blade PFN) is better than Screw PFN in the treatment of Intertrochanteric Femur Fractures. PFNA2 has a better contact area, lesser complications than Screw PFN in addition to lesser surgical duration and blood loss.

Recommendation:

Prosthetic replacement is recommended for unstable intertrochanteric fractures because of the complications that may occur after internal fixation.

Keywords: *Intertrochanteric femur fracture, Dynamic hip screw, Helical blade proximal femur nail, Surgical time, Blood loss*
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Introduction:

Fractures in the trochanteric region are serious and its treatments can be done after hospitalization of the patient. Amongst the fractures of the intertrochanteric region, the unstable fractures cannot be treated easily. The treatment methods in developing countries include immobilizing the region using plaster, traction of the bone, and close reduction, all these methods are associated with adverse complications. The surgical procedure to fix the fractures helps in achieving mobilization of the bone. Although weight bearing capacities of the patient are reduced significantly.

Another complication associated with the surgical [procedure in this region is severe blood loss. Even though the surgical procedure carried out to fix the bone in the

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trochanteric region is not invasive it requires a transfusion of blood [1]

There are various devices available for fixing the fracture internally like PFN, DHS, TFN, DCS, PFNA, Proximal Femoral Locking Plates, etc.[2] These devices can be used in the extramedullary region and intramedullary region. The proximal femoral nail is placed in the intramedullary region which provides stability to the bone. Dynamic hip screw provides power transmission and it is placed in the extramedullary region. Both are required to treat the trochanteric fractures to provide stability and mobility to the bone specifically for the geriatric population who have osteoporosis

Stable type of trochanteric fractures was previously treated by using dynamic hip screws as it is easier and economical to place this device. Arbeitsgemeinschaft fur Osteosynthesefragen (AO/ASIF), discovered a device known as the proximal femoral nail, it provides substantial strength it is rigid. It is placed in the intramedullary region compared to dynamic hip screw which is placed in the extramedullary region. [3]

Certain implantation failures associated with the proximal femoral screw include improper positioning of the screw and its movement from its fitted position, this is known as Z-effect. PFN has two types of screws, there is a de-rotation screw which migrates in the middle region and a lag screw which migrates in the backward region this effect is known as Z-effect. When the de-rotation screw migrates in the lateral region and the lag screw migrates in the medial region it is known as the reverse Z-effect. A study reported amongst the 45 patients 5 had Z-effect while implanting the PFN and 1 of them had reverse Z-effect. [4]

AO/ASIF 2003 developed a new version of PFN, PFNA-2.[5] It had a single screw which provided angular stability and improved the rotation had a helical blade that held the contacting bone and cancellous bone together which improved the surface of the content between the PFN screw and bone [6] These nails act like internal splints and helps in healing the fracture internally. The intramedullary nail does not disturb the vascular supply.[7] PFNA-2 improves the fixation stability by reducing the widening of the bone which is done in PFN. It does not require another screw it is proven that with a single screw, PFNA-2 is strong and rigid.[8]

Implanting the device in the intramedullary region has the following advantages:-

The implantation is such that it prevents the movement of the nail in lateral and backward positions.

The implantation takes place in the intramedullary region which makes it mechanically stronger to resist the forces binding them.

The nail of the implantation has a short lever arm comparatively which decreases the strain on the implant and prevents failures of implantation.

Nail acts as a sharing device and DHS acts as load bearing device. Since the implant is in the intramedullary region it bears the bending load by making contact with the medullary canal.

Nails aid in the indirect healing of the fracture by acting as a splint preserving the biological property of fracture and decreasing blood loss compared to DHS. Because in PFN minor surgical incisions as compared to DHS which cause less infection and less implant failure in PFN as compared to DHS.

This study was carried out to compare the efficiency of Helical Blade PFN (PFNA2) and Screw PFN (PFN) in the treatment of unstable intertrochanteric fracture femur.

Objectives:

To assess results of unstable intertrochanteric femur fracture treated with helical blade PFN and screw PFN, with regards to:

- Duration of surgery.
- Loss of blood during surgery (by surgical gauze).
- Radiological outcome.
- Functional outcome.
- Implant-related complications.

Subjects and methods:

Study Design:

This study was carried out prospectively in a randomized manner to compare the efficiency of the screw and proximal femoral nails with helical blades in treating unstable intertrochanteric fractures in the geriatric population.

Study Location and Duration:

The study was conducted in the Department of Orthopaedics at Government Medical College & Attached Group of Hospitals, Kota, Rajasthan, India prospectively during the study period from June 2018 to December 2020, after receiving the approval from Departmental Research Committee and Institutional Ethical Committee of the same institute.

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Methodology:

Two groups were formed amongst the participating patients Group I-Patients were treated with Helical Blade PFN and Group II-Patients were treated with Screw PFN Randomization was done by the envelop method.[9]

Before surgery, informed written consent was obtained from all the patients. All the patients were evaluated medically. Patients participating in the study underwent the following test as per the protocol:

· CBC, Blood sugar level, ESR, Blood urea level, Serum Bilirubin, Serum Electrolytes, Prothrombin Time, InternationalNormalization Ratio(INR), HIV, and HBsAg.

- ABO-Rh blood grouping and arrangement of blood unit to manage emergency conditions of heavy blood loss, if occurs.
- Chest X-ray and 12 Lead ECG.
- Inj. Tetanus toxoid 0.5cc IM and Inj. Ceftriaxone-salbactum1.5gm IV was administered preoperatively (Within 30 min. from the time of incision). A xylocaine sensitivity test was done.

Technique:

Position of the patient - the patient was operated in the supine position on the fracture table. The fractured limb & internal rotation of the affected hip were adducted at 15 to 30 degrees.

Reduction: The nature of the fracture was confirmed by viewing it on an image intensifier in posterior, anterior, and lateral views. The reduction of the fracture was carried out by pulling and rotating the bone externally and internally. The reduction was done to regain the weight-bearing ability and correct the abnormalities and damage to the rotation of the bone due to fractures. In the intertrochanteric stable type of fracture, the reduction is achieved by movement of the calcar femoral.

The method employed for the fixation of the bone

1. Helical blade PFN (PFNA-2) Technique

- An image intensifier is used to monitor the anatomical region where reduction is carried out.
- In the greater trochanter region, an incision of 4 cm is made. The Awl is placed in the greater trochanter region and then moved into the canal towards the lesser trochanter regions there is angulation of six degrees in the proximal part of PFNA2.
- In PFNA2 a single nail is introduced in the head of the femur. Then a rod is moved in the medullary canal which widens the canal. Once the nail is placed in the intramedullary region. A 2 cm incision is made by a stab using a targeting device.
- The helical screw is placed in the center of the head or the inferior region by hammering it 5-10 mm deep in the bone. The PFNA blade is tightened by rotating it clockwise.
- Distal locking screws are placed through the zig.
- According to the anatomy of the patients the screw should move to different angles of 125 and 135 degrees. The angles will depend on the reduction achieved.

· To allow better rotation and impaction it is preferable to place at least one screw. If the fracture is very unstable then placing two screws will impart better fixation. The screws should be shorter in length as they are easier in locking.

2. Proximal Femoral Nail (PFN) Technique:

- An image intensifier is used to monitor the anatomical region where reduction is carried out.
- An incision of 4 cm is done in the proximal region of the greater trochanter. An awl is positioned in the greater trochanter in the medial region and then it is inserted further in the canal towards the lesser trochanter.
- A guide rod is inserted in the canal due to which the canal is reamed. As soon as the screw is placed appropriately 2 cm incision is made by using a targeting device for neck screws.
- The length of the guide pin is measured by using a reamer and then the guide pin is introduced in the head of the femur
- In the center of the head or the inferior region of bone, the screw is placed. Distal locking screws are placed through the zig.
- According to the anatomy of the patients the screw should move to different angles of 125

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and 135 degrees. The angles will depend on the reduction achieved

- The nail is such that it can enter from the more anterior portal of the greater trochanter region
- To allow better rotation and impaction it is preferable to place at least one screw. If the fracture is very unstable then placing two screws will impart better fixation. The screws should be shorter in length as they are easier in locking.

Data Collection and Analysis:

The time required for the surgery was recorded. The starting point was the time during which incision was made and the end point was when the wound was closed. A proforma was prepared for recording information on the parameters before the surgery. The condition during and after the surgery was also recorded in the proforma. The records of the monthly follow-up up to six months were recorded.

The data obtained was subjected to statistical analysis using SPSS software version 21. The categorical data was put in the form of percentages the data from both groups was compared by using the chi-square test. The p-value of less than 0.05 for the difference in the data of both groups was considered to be significant.

Fig 1: Positioning of patient with proper painting & draping

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Fig 2: Inserting lag screw in screw PFN

Bias*:*

There was a chance that bias would arise when the study first started, but we avoided it by giving all participants the identical information and hiding the group allocation from the nurses who collected the data.

Ethical considerations:

The ethical aspects of the research were carefully thought out to preserve patient privacy and confidentiality.

Results:

Participants:

The majority of the patients in this study were above sixty years. A maximum number of patients were in the range of 61 to 70 years of age in both groups, and in group I two patient`s ages were above 80 years. Among the total subjects, 46 per cent were males and 54 per cent were females.

Most of the patients of both groups were affected by trivial injuries. In the present study, an equal number of cases were reduced open (22/25) and closed (3/25) among both groups. The average time required for the fixation surgery was 66.60 + 8.22 min and 87.92+ 13.83 min respectively. Subjects in group II required more time for surgery compared to group I. The difference was observed to be statistically significant (p=0.0004) (Table no. 1).

Table 1: Duration of surgery in both the groups

	Average	Standard deviation	p-value	Significance
Group I	66.60	8.22	0.0004	Significant
Group II	87.92	13.83		

Table 2: Average loss of blood recorded in both the groups

	Average	Standard deviation	p-value	Significance
Group I	171.80	39.29	0.0024	Significant
Group II	209.60	44.02		

Table 3: X-ray exposure shots among the subjects of study groups

	Average	Standard deviation	p-value	Significance
Group I	36.08	5.63	0.0006	Significant
Group II	72.08	12.55		

Table 4: Singh's Index among the study groups

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	Average	Standard deviation	p-value	Significance
Group I	2.24	0.778	0.035	Significant
Group II	2.72	0.79		

Table no.2 shows blood loss during surgery among the two study groups. Mean blood loss was 171.80 ml among the 25 patients of group I while mean blood loss was 209.60 ml among the 25 patients of group II. The difference in the mean±sd of blood loss (171.80±39 & 209.60±44.02 ml among group I & group II respectively) was observed to be statistically significant (p=0.0024).

Table no.3 shows the mean X-ray exposure shots during surgery among the study groups. Mean± SD was 36.08±5.63 & 72.08±12.55 among group I & group II respectively, the difference being statistically significant (p=0.0006). The increased x-ray exposure was due to the requirement of putting two Screws in PFN rather than a single helical screw in PFNA2.

Table no.4 shows group I having lower Singh's index with better results when compared with that among the subjects of group II.

Distribution according to LLD of Group I& Group II subjects at 24 weeks:

Table no.5 shows that 60% of patients of Group I and 48% of Group II had no LLD (limb length discrepancy). A shortening of 3cm of the limb is the maximum shortening. This shortening of limbs is found in group I patients and not in group II patients.

Table 5: Limb Length Discrepancy (LLD) among the study groups

LLD	Group I		Group II	
	No	**%**	**No**	**%**
0 cm	15	60%	12	48%
1 cm	5	20%	8	32%
2 cm	5	20%	4	16%
3 cm	-	-	1	4%
Total	**25**	**100%**	**25**	**100%**

Table 6: Complications observed among the two study groups

Associated difficulties	**Group I (N=25)**	**Group II (N=25)**
Screw cut out	1	-
Z Effect	-	2
Non union	1	-
Failure of the implant	1	2
Superficial infection	-	1
Total	3	5

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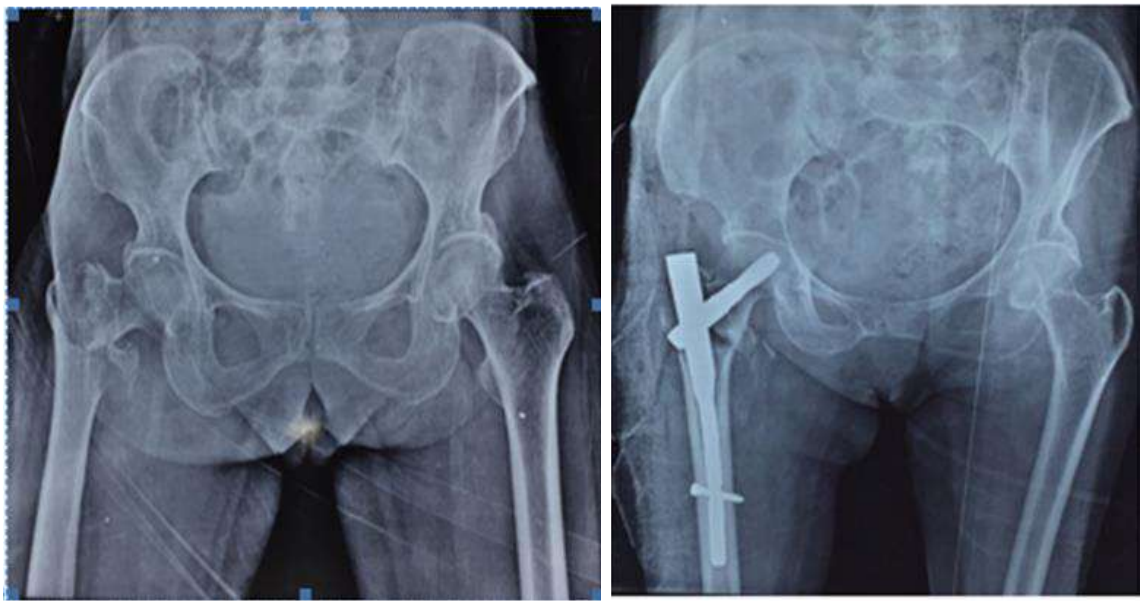

Fig 3: Preoperative and Postoperative x-rays of PFNA2 Fixation

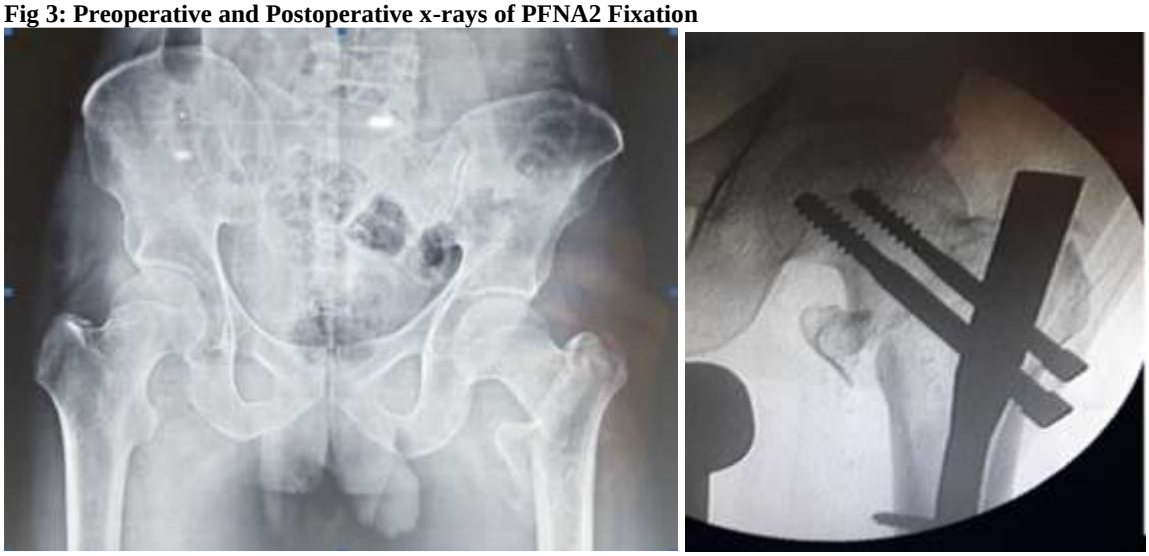

Fig 4: Preoperative and post-operative x-rays of PFN Fixation

Discussion:

Fractures within the intertrochanteric femur are considered a significant difficulty to treat by the Orthopaedic surgeons. This is not only due to the complexity of attaining fracture union, but also the need to restore optimum function as quickly as possible, while minimizing sequelae. The objective of management has shifted towards attaining prompt mobilization, swift rehabilitation, and speedy reintegration of persons into their pre-existing schedule as an autonomous individual.

Surgical intervention with internal fixation allows for prompt rehabilitation and provides the highest likelihood of functional restoration. As a result, it has become the preferred therapy for almost all fractures in the trochanteric area. Among the several kinds of implants, such as sliding nail/screw plates, fixed nail plate devices, and intramedullary devices, the hip screw for compression n is popular and efficient. However, closed intramedullary nailing methods have gained significance in treating intertrochanteric fractures.

As per **Mervyn Evans (1951)[10]** the intactness of the posteromedial cortex located in the lesser trochanteric region determines the stability of the intertrochanteric fractures. If it is intact the fracture is stable if it is not intact the fracture is not stable. .[10] In 1980 **Jacobs and co-workers** [11] reported an increase in intertrochanteric fractures.

The current research observed that the PFN group had more blood loss and longer operating time compared to the PFNA2 group. This may be attributed to more surgical exposure, which potentially prolongs the operative time

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and increases blood loss. The statistical analysis confirmed the significance of these findings, as shown by the p-value.

Manoj R. Kashid, Tushar Gogia et al. (2016)[12] demonstrated that the duration of the surgery was more in the case of PFN group compared to PFNA2 group (35.20 ± 6.03 minutes vs. 43.32 ± 8.20 minutes, and the difference was significant (p<0.001avaerage loss of blood in PFNA2 group was much lesser in compared to the PFN owing to lesser surgical duration (59.80 ± 14.96 ml vs. 77.80 ± 17.39 ml, (p<0.001). Jung Ho Park et al 2010[13] Reported that the duration of the surgery was 86.12 min and the loss of blood was 424 ml in the case of the helical femoral nail group the time required for the surgery was 83.3 min and the blood loss was 331.22 ml. In this study, the difference in the time required for the surgery was not significant

In the present study mean X-ray exposure shots were 36.08 in the PFNA group. Mean 72.08 shots were taken PFN group. Mean±sd was 36.08±5.63 & 72.08±12.55 in group I & group II respectively the difference was substantial (p<.0006). The duration of surgery in the PFN group may be attributed to meticulous procedure and it requires two screws to be placed. Manoj R. Kasid et al 2016[12] stated that the number of pictures taken during PFN surgery was lesser in comparison to the pictures taken during the PFNA2 surgery (18.60 ± 3.12 vs 29.52± 4.85 (p <0.001).

The claimed advantage of the Helical Blade Proximal Femoral Nail (PFNA2) is that it has only one neck screw and it does not require drilling. The neck gives more area of contact which subsequently reduces the chances of complications such as Z-effect in patients having osteoporosis as compared to screw PFN. Helical blade Proximal Femoral Nail (PFNA2) is associated with shorter operating time, lesser blood loss, and less morbidity as compared to screw PFN.

The reduction in hemorrhage in the helical PFN group can be explained by the lesser time required for surgery and the lesser size of the incision needed for surgery. This is because of the utilization of single drilling for the placement of the helical blade, as opposed to the prolonged time required for surgery and wider incision needed for the introduction of the lag screw and de-rotation screw in the PFN group.

Mean Singh`s indexes of the helical proximal femoral nail groups and PFN groups were 2.24 and 2.72 respectively, the difference in the group was significant (p =0.035). It can be derived that the patients with osteoporosis were more in the physical femoral nail group. Jung Ho Park et al 2010[13] indexes of the helical proximal femoral nail groups and PFN groups were 2.45 and 2.66, respectively the difference was not significant statistically (p =0.59). Significant shortening (≥3 cm) was not found in any case in group I & it was found in 1 case (4%) in group II.

Manoj R. Kasid et al 2016[12] The incomplete reduction, shortening of the limb more than 1 cm (p=0.684), and the occurrence of deformity malalignment (p =0.552were comparable in both groups. The PFNA group had fewer such instances compared to the PFN group. The change in mean neck shaft angle ± SD in the screw proximal femoral nail was 4.44±2.10 and in the helical proximal femoral nail was 3.69±2.16 which was not significantly different. Jung ho park et al 2010[13] Change in mean neck-shaft angles in the screw proximal femoral nail 4.31* and in the helical proximal femoral nail 3.481* which is not significantly different.

INFECTION: Superficial wound infection at the suture line was seen in 1 case which was operated by PFN. The increased tissue exposure in instances performed by PFN and the patient's poor immune state, due to their asthenic build and low socioeconomic level, may contribute to this. The patient had an extended course of intravenous antibiotics, lasting for 10 days. As per the procedure, we implemented intravenous antibiotics for 5 days. This research encountered a single instance of fixation failure with the PFNA implant. This failure was attributed to the patient's lack of cooperation, resulting in the cutting out of the screw of the helical blade. Subsequently, a re-operation was performed.

Various studies stated that there are complications associated with intramedullary nails [14, 15], in contrast, the current study did not have any such complications. In all the studies the minimum period of follow-up was six months in the current study the follow-up period was six months. Group I had one patient with a screw cut out, the same patient goes to non-union and implant failure, and a second surgery was in the form of bipolar hemiarthroplasty. In Group II, two patients had Z effect, and two patients had implant failure. One patient went for revised screw PFN, and in 2nd patient preferred bipolar hemiarthroplasty. In another study, Manoj R. Kasid 2016.[12] reported that one of the patients did not have satisfactory reunion and required re-operation and the incidences of complications were similar in both groups. One case (4%) of non-union was found in group I and two (4%) cases in group II, which is not significant. Non-union was treated by bipolar hemiarthroplasty.

Helical proximal femoral nails as an implant for intertrochanteric fractures in the femur has a functional advantage and it is associated with lesser complications. Jung Ho Park et al 2010[13] Stated that PFN had more complications. Lateral protrusion (12.5) of a lag screw occurred in 1 patient, and distal displacement of an anti-rotation pin (reverse Z effect) also occurred in 1 patient in PFN (screw proximal femoral nail) group. A fixation fracture resulted in refracture in 1 patient in the PFN (screw proximal femoral nail) group. This patient

underwent bipolar hemiarthroplasty. In another study, Manoj R. Kasid in 2016 [12] Noticed that two patients had infections after surgery both the growth was managed with antibiotics.

Conclusion:

Based on this analysis, the use of helical blade PFN is unequivocally superior to screw PFN in cases of Intertrochanteric Femur Fractures. The purported benefit of using a helical blade PFN is that it allows for the use of a single neck screw without the need to drill into bone, especially in patients with osteoporosis. This results in a surface area of contact for the blade and the bone, reducing the risk of complications. Another benefit of using helical blade PFN is reduced operating time, decreased fluoroscopy time, low surgical hemorrhage, and improved functionality and radiographic results.

Limitations

The limitations of this study include a small sample population who were included in this study. The findings of this study cannot be generalized for a larger sample population.

Recommendation

Prosthetic replacement is recommended for unstable intertrochanteric fractures because of the complications that may occur after internal fixation.

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Conflict of interest:

The authors report no conflicts of interest in this work.

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