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Prospective Randomised Study Comparing Functional and Radiological Outcomes of Fracture Neck of Femur Fixation Using Poly-Axial Screw in Bolt Construct Versus Multiple Cancellous Screws

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Abstract: ***Background: Hip fractures in the elderly pose a serious health risk, especially in elderly people. In the younger generation, however, these fractures are associated with high - velocity trauma in RTA (Road traffic accidents) or falls from great heights. A sedentary lifestyle, females and an osteoporotic femur are common risk factors for the incidence of such fractures. Currently, 6% of men and 18% of women worldwide suffer from hip fractures. According to epidemiological studies, the hip fracture incidence will climb to 2.6 million by 2025 as life ex pectancy rises and the senior population continues to expand. Methods: This randomized, prospective study comprised eighty - four patients. The patients were randomly assigned to one of the two groups. Group A patients were treated by a poly - axial screw in bolt construct commonly known as Femoral Neck System (FNS) and Group B patients were treated with Multiple Cancellous Screws (MCS). The fracture was classified based on the AO/OTA classification. The first clinical follow - up was done on the 15th day and then at one month, three months and six months intervals post - operatively. Assessment of the outcome, both radiological and functional (as per modified Harris Hip Score), was done and recorded. Results: The mean Garden alignment index in Group A was 164.67 in the AP view and 164.52 in the lateral view and Group B, it was 163.90 in the AP view and 165.00 in the lateral view which was also found to be non significant (p > 0.05). Mean blood loss in Group A was 75.71 ml with an overall ranging from 40 to 120 ml whereas in Group B, mean blood was 63.81 ml with an overall ranging from 40 to 100 ml. Neck shortening was present in 14.28% of patients in Group A whereas 23.81% in Group B at 6 months post - surgery. The mean time of the procedure in Group A was 54.19 minutes with an overall range from 32 to 95 minutes whereas in Group B mean time of the procedure was 59.24 minutes with an overall range from 32 to 98 minutes. After the final follow - up, with mean HHS was 87.71 in Group A and the mean HHS was 82.24 in Group B which is significant (p < 0.05). Conclusion: Fracture Neck of Femur fixation using poly - axial screw in bolt construct has axial and rotational stability superior to traditional Multiple Cancellous Screws. It offers the mechanical benefit of reducing the deleterious effects of rotational displacement while yet allowing for dynamic compression of the fracture with weight - bearing. Being bio - mechanically superior, the poly - axial screw in bolt construct is on the verge of solving the unsolved mystery of fracture neck femur fixation.***

Keywords: Femoral neck fracture, hip fixation, poly-axial screw, cancellous screws, Harris Hip Score

1. Introduction

The hip joint is a diarthrodial type of joint. The rounded surface of * Corresponding author. the femur fits into the cup - like acetabulum making it a ball and socket type of joint. The angle formed by the neck of the femur and the medial portion of the shaft of the femur is roughly 130 ◦. The calcar femorale links the femur's posteromedial proximal diaphysis to the neck. This structure is an essential component because it supports and distributes the tension equally among the head, neck and the proximal shaft of the femur. Hence, the presence of calcar femorale is a deciding factor in selecting an appropriate implant for the neck of femur fractures.1–4 Hip fractures in the elderly pose a serious health risk, especially in elderly people. In the younger generation, however, these fractures are associated with high - velocity trauma in RTA (Road traffic accidents) or falls from great heights. A sedentary lifestyle, females and an osteoporotic femur are common risk factors for the incidence of such fractures.5 Currently, 6% of men and 18% of women worldwide suffer from hip fractures. According to epidemiological studies, the hip fracture incidence will climb to 2.6 million by 2025 as life expectancy rises and the senior population continues to expand.6, 7 The medial femoral circumflex artery, which extends from the femoral neck to the head, provides the major circulatory supply to the femoral head. Asa result, in displaced neck fractures, the blood supply is impaired. This puts the fracture healing at risk eventually causing non union or osteonecrosis. The treatment of this fracture becomes crucial in the younger age group of the population where hip replacement is considered inappropriate. Avascular necrosis remains the major complication in the ORIF (open reduction internal fixation) procedure.8–10 11, 12 Early mobilization is the primary goal of neck fracture treatment to decrease the complications likely to be encountered after surgery. Hence it is always advised to go with surgical options unless the patient presents with various other multiple co - morbidities posing unnecessary risk. Femoral Neck System, sliding hip screws, or multiple cancellous lag screws can be used to manage the fixation technique.

2. Materials and Methods

This prospective study was conducted at a tertiary care postgraduate teaching hospital, comprising eighty - four patients after approval from the ethical committee of the institution. Informed written consent was taken from every patient before the surgery. Primary evaluations of the patients were conducted regarding the presence of other injuries and associated complications. Complete data of the patients were recorded, detailed history taken and examination done. Routine investigations were done and initial radiographic

images were obtained in anteroposterior and lateral views. The fracture was then classified based on the AO/OTA classification.17 All necessary pre - operative investigations were done and the patient was planned for surgery as soon as they obtained an anaesthetic fitness. The patients were divided into 2 groups at random (using computer - generated random numbers). Group A i. e. the first group of patients in the study were managed by a poly - axial screw in bolt construct commonly known as Femoral Neck System (FNS) and Group B patients were treated with Multiple Cancellous Screws (MCS). The Operating Team for both procedures was the same, working in the same institute under the identical OT setup and environment.

3. Operative Steps

The procedure for group A (poly - axial screw - in bolt construct surgery) began with regional anaesthesia. After that, the patient was positioned supine over the table, and the image intensifier was adjusted such that the proximal femur could be viewed in both the lateral and anteroposterior planes. Moderate traction or flexion, adduction or abduction, and internal rotation of roughly 15 ◦ were used to align the femoral neck parallelly with the operating table. The reduction was assessed in two planes under an image intensifier. An open reduction was carried out in case the reduction was inadequate. At this point, a wire was then inserted into the superior or anterior portion of the femoral neck, to act as an anti - rotation wire. A straight lateral skin incision of 6 cm was made, commencing two to 3 cm from the midpoint of the axis of the neck of the femur. The lateral femoral surface was evaluated and appropriately exposed to ensure appropriate hardware installation. The 130 ◦ angled guide was used to insert the next guide wire as the center guide wire. Using the image intensification, this wire was positioned into the subchondral bone on the AP view, somewhat inferior to the femoral head's apex. The guide wire was centered on the femoral neck and head in the lateral view. The direct measuring device was slided over the guide wire in the centre and its depth was measured with the direct measuring instrument. The calculated construct size was produced by deducting 5 mm from the measured depth when the wire was infixed into the subchondral bone and selecting the next smaller construct size. The reamer was now slid onto the drill bit until it clicked into place at the expected build size. It was then held in place and locked by adding and fully tightening the nut and reaming down until the reamer stopped on the bone. Without tightening the block screw, the insert was pushed into the insertion handle. The bolt was fully placed into the plate using the computed construct size. The implant was now placed onto the insertion handle, and it was attached by manually tightening the block screw. The implant was placed into the pre - reamed hole over the central guide wire. Finally, image intensification was used to validate the depth of insertion and that the plate is aligned with the axis of the shaft of the femur and down to the bone. To prevent loss of reduction and head rotation, the central guide was removed while maintaining the anti rotation wire. The protective sleeve was now fastened to the insertion handle, and a hole was bored through it to accommodate the bi - cortical locking screw. The length of the screw was directly measured using the drill bit's marking. The depth gauge or drill bit was used to determine the length of the locking screw, which was then inserted. Using the screwdriver shaft, the 4 Nm torque limiter, and the proper handle, the final tightening was done carefully by hand. By pushing and pressing the sleeve's head together, the protective sleeve was taken off. The fixing sleeve was now examined after being passed over the drill bit's rear end. The bolt was fastened, and the setting was adjusted to match its size. Drilling continued until the fixing sleeve stopped on the insert guide. The anti - rotation screw was inserted. The length of the bolt was used as a reference for this screw. Insertion instruments were removed by fully releasing the insert's screw and unscrewing it (counter - clockwise) from the insertion handle. It was now time to withdraw the insert from the insertion handle. In group B (Multiple Canulated Screw Surgery), the process begins with regional anaesthesia. The image intensifier was then positioned so that the proximal femur could be viewed in both the AP and lateral planes on each patient while they lay supine on the surgical table. Moderate traction or flexion, adduction or abduction, and internal rotation of roughly 15 ◦ were used to align the femoral neck parallelly with the operating table. The reduction was assessed in two planes under an image intensifier. A lateral approach was used for closed reduction and fixation in this operation. Three cancellous screws were used in an inverted triangle fashion. The calcar supported the inferior screw. The wires were drilled using a 3.6 mm drill bit that was cannulated to insert the cannulated screws. Three cannulated cancellous screws (7.0 mm or 7.3 mm) were infixed over the wires. The wound was stitched in layers under a drain, and covered with crepe bandages.

4. Post- Operative Protocol

All patients were advised, the hip and knee exercises following three to five days postoperatively including hip abduction and adduction, gluteal sets, quadriceps sets, straight leg raise, hip and knee flexion, short arc quadriceps, internal and external rotation in the supine position and long arc quadriceps, hip flexion, ankle pumps in sitting position. The severity level was increased accordingly using either a TheraBand or weights. The first clinical follow - up was done on the 15th day and then at one - month, three months and six months intervals post operatively. Assessment of the outcome, both radiological and functional as per the modified Harris Hip Score was done and recorded [the Modified Harris Hip Score covers the domains in terms of - pain (severity and its effect on activities and the need for pain medication), function (including daily activity and gait), Absence of deformity (accounting hip adduction, flexion, internal rotation and limb length discrepancy), Range of motion. Depending on the overall scoring, further categories the hip status in four groups - Excellent, Good, Fair and Poor]. Complications such as non - union, malunion, hardware prominence, soft tissue irritation, and superficial skin infection were assessed and documented.

5. Observations and Results

This prospective randomised analytical study involved eighty - four subjects with fracture neck of the femur. In the present study, patients were in the age group with an overall range of 20–60 years and a mean of 44.90 years in Group A and a mean age of 44.57 years in Group B which is not significant ($p > 0.05$). There was a slight male prepon derance with 61.90%

of subjects being male in Group A and 57.14% in Group B which is not significant (p>0.05). Most patients sustained neck femur fractures following RTA. Others sustained due to slips and falls. The majority of patients had no comorbidities though diabetes mellitus and hypertension were observed to be the most common co morbidity.3 patients from group A and 1 patient from group B had both co - morbidities. As per the radiological classification of fracture neck of femur fractures (Fig.1) by Garden, type III was observed to be most common in the present study in both Groups. The mean incision length is 4.05cm in Group A and 3.80cm in Group B which is non - significant (p - Value >0.05). Hence, it was neither in favour nor against the Polyaxial screw in bolt construct. The intra operative reduction was checked over the image intensifier and found to be satisfactory in all patients in both groups. The mean Garden alignment index in Group A was 164.67 in the AP view and 164.52 in the lateral view and in Group B, it was 163.90 in the AP view and 165.00 in the lateral view which was also found to be non - significant (p > 0.05). Neck shortening was present in 14.28% of patients in Group A whereas 23.81% in Group B at 6 months post - surgery. Mean blood loss in Group A was found to be 75.71 mL with an overall ranging from 40 to 120 ml whereas in Group B, mean blood was 63.81 mL with an overall ranging from 40 to 100 ml. Postoperative pain was compared with vas score and found to be lower in Group A with a mean of 3.24 than in Group B with a mean of 4.14. All these observations are found to be significant as the p - value is less than 0.05. The mean time of the procedure in Group A was 54.19 minutes with an overall range from 32 to 95minutes whereas in Group B mean time of the procedure was 59.24 minutes with an overall range from 32 to 98 minutes. The mean hospital stay in Group A was 5 days whereas 6 days in Group B. All were operated on within 4 days of the injury with mean days being 2.57 in group A and in group B 2.43 days. All these findings are observed to be insignificant (p > 0.05). None of our patients had Implant irritation, post - operative neuro logical deficit or numbness. No complication was observed in the pre sent study in 95.23% of the cases in Group A whereas 85.71% of subjects observed no complication in Group B which is significant (p < 0.05). It was observed that a total of 40 patients got radiological union within a mean union time of 13.90 weeks ranging from 12 to 18 weeks in group A whereas a total of 38 patients got radiological union within a mean union time of 14.58 weeks ranging from 12to18 weeks in group B which is not significant (p > 0.05). The distribution of union time as observed in the present study is represented in Fig.2. After the final follow - up, with mean HHS was 87.71 in Group A and the mean HHS was 82.24 in Group B which is significant (p < 0.05). Excellent results were found in 19.05% of patients in Group A whereas 9.52% achieved in Group B. Good results were established in 66.67% of patients in Group A whereas 57.14% were achieved in Group B. Fair results were found in 9.52% of patients in Group A whereas 23.81% were achieved in Group B. Poor results were observed in 4.76% of patients in Group A whereas 9.52% in Group B. Fig.3 shows the modified HHS. One of the patients, operated using poly - axial screw in bolt construct developed an Infected non - union for which implant removal with antibiotic beads insertion was done and that patient got lost to follow - up subsequently.

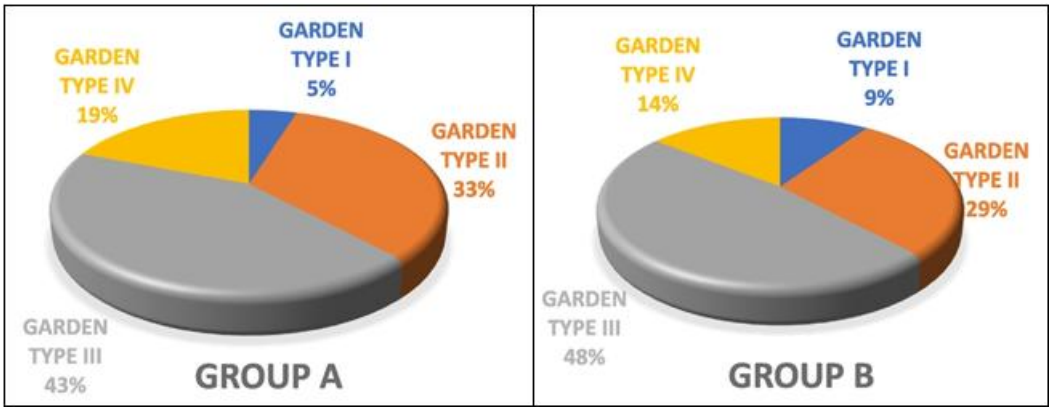

Figure 1: Radiological Pattern of Fracture in both groups per Garden Classification

6. Discussion

Femoral neck fractures are intrasynovial in nature. Also, the absence of the cambium layer in its periosteum makes it harder to heal. In fractures of the diaphyseal region, a hematoma is encased inside the periosteum. This helps in the production of pluripotent cells by the periosteum's cambium layer that aids in the creation of callus. Pluripotent cells are less abundant in intracapsular fractures, and synovial fluid continuously washes the fracture hematoma away. Thus, there is no promotion of subsequent fracture healing. Instead, the only kind of fracture repair that may occur is direct ostional remodelling. Anatomic compression and reduction are necessary for this kind of bone repair. If there is a tiny break in the healing process, primary healing could take place. However, there is not much room for forgiveness in the high tangential stress setting of neck femur fractures. Without causing the femoral neck to shorten or the femoral head to tilt or rotate, the optimal minimally invasive implant ensures stable internal fixation. Maintaining complete rotational stability as well as the stability of the fracture site in the sagittal and coronal planes is essential for the healing of fractures of the femoral neck. To warrant that the fracture heals, the internal fixation device must be able to endure the everyday load, maintain solid stability, and keep the fracture end reduced. Fixed - angle sliding hip screws and locking plates and complete or partly threaded cannulated screws are examples of implants that are currently readily accessible. Screws are devices with non - fixed angles. Partially threaded screws, as opposed to completely threaded screws, enable the fracture to be better compressed. A fixed - angle tool that permits compression is a sliding hip screw. A locking plate

with a set angle prevents compression. Fixed - angle locking plates are not advised for fractures of the neck femur because of the danger of a disastrous failure. The ideal situation would be to anatomically reduce and fix these fractures at length; however, the biological bridge that unites treating these fractures at length has not been created to date. The Lower Extremity Expert Group, DePuySynthes, and Products the Association for the Study of Internal Fixation collaborated to create a novel poly - axial screw in bolt design [femoral neck system (FNS)] to repair neck of femur fractures. There were no differences with regard to Implant irritation, post - operative scar/scar irritation, or Post- operative numbness between these two implants. Mean blood loss was less in MCS probably because of a percutaneous mode of insertion of screws, particularly in un - displaced fractures. Due to a dearth of prospective clinical studies, disagreements persist on the best implant architecture, scheduling of surgery, and surgical technique. Neck of femur fractures in individuals below 50 years tallies roughly around 5% of all hip fractures. Because of younger age, high demand individuals are not subjects for arthroplasty, preserving the native hip joint is crucial. When an intracapsular fracture is displaced and vertical, the biological context becomes less favourable for the surgeon.

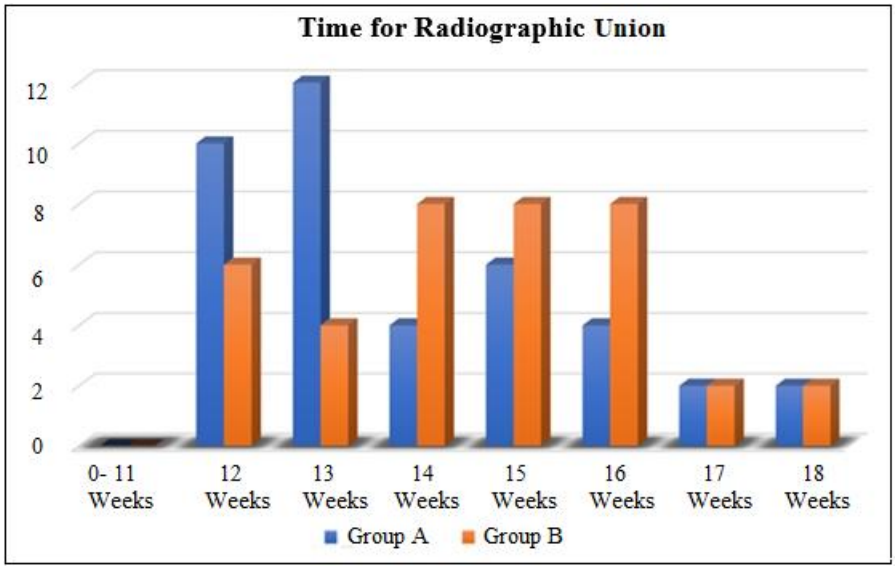

Figure 2: Comparison of time for Radiographic Union in both study groups

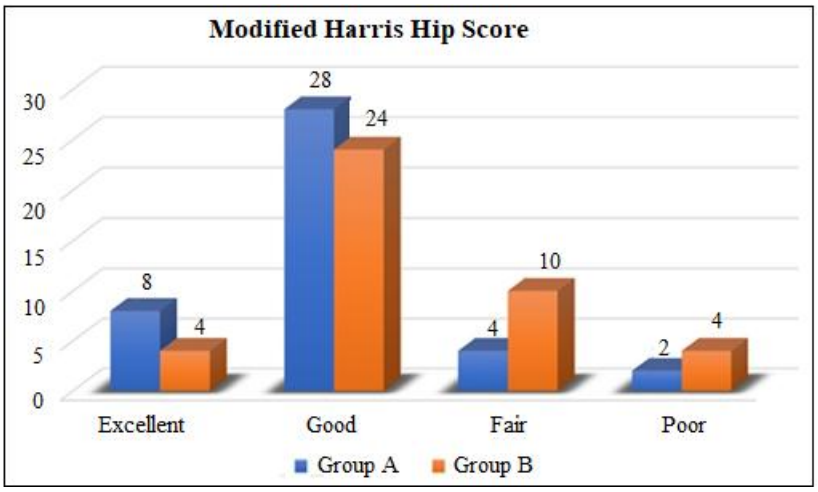

Figure 3: Comparison of Clinical Outcome in terms of Harris Hip Score

To get the desired outcome performing osteosynthesis in the fractured neck of the femur, angular stability can be obtained with less invasive techniques using poly - axial screw in bolt construct. By connecting a small side plate implant to the shaft of the femur, one may reduce the implant's footprint while also supporting the femoral head using a screw and bolt. By combining the stability of the dynamic hip screw with minimally invasive insertion technology, this design retains as much of the femoral head function as possible. Interestingly, poly axial screw in bolt construct uses compression at the fracture end to emphasize the biological properties of fracture healing. Treatment for femoral neck fractures may significantly improve with this innovative implant.24–27 In the present study, the earlier union was achieved in Group A treated with poly - axial screw in bolt construct. On the assessment of functional outcomes, 92.86% of the patients had excellent to fair out comes at the end of six months with poly - axial screw in bolt construct showing better functional results than MCS. Overall complication rate, Non - union, AVN, Cut - out, Radiographic union time, functional outcome, post - operative pain, Neck shortening, Hospital stay, and duration of procedure are in favour of poly - axial screw in bolt construct compared to MCS and comparison of Incision size remained insignificant. The

newer implant poly - axial screw in bolt construct shows better radiological and functional outcomes with lesser complications compared to traditional implants However, a large study with a longer follow - up is desirable to conclude it emphatically.

7. Conclusion

Femur fixation using poly - axial screw in bolt construct has axial and rotational stability superior to traditional Multiple Cancellous Screws. The poly - axial screw in the bolt construction prevents rotational movement on the head and protects against an anatomic reduction. It offers the benefit of reducing the deleterious effects of rotational displacement while yet allowing for the femoral neck fracture's dynamic compression with weight - bearing. MCS is advantageous in terms of not disrupting a good provisional reduction, and can also improve a provisional reduction. The MCS fixation, on the other hand, has a disadvantage in preserving the femoral neck - shaft angle. Furthermore, this screw build is ineffective in fighting shear stresses and cannot prevent varus collapse or retroversion. Being bio - mechanically superior, the poly - axial screw in bolt construct is on the verge of solving the unsolved mystery of fracture neck femur fixation in young patients. This construct is showing promising results in terms of union rate, union time, osteonecrosis of the head of the femur, cutout or implant loosening and an overall low complication rate compared to traditional implants.

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