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Outcome of dynamic locked plate in treatment of intracapsular femur neck fracture

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ABSTRACT

Background: The ideal surgical treatment of femoral neck fractures is still debatable. When internal fixation is used, many implants are available. This study aimed to evaluate the outcome following fixation of intracapsular femur neck fractures using the Targon-FN system (B. Braun, AG. Melsungen, Germany) comparing the results with a similar study done by the manufacturer and to assess risk factors associated with complications.
Methods: A prospective interventional case series involved 30 consecutive patients aged from 23 to 82 (Mean 49 years) treated at Al-Jalaa trauma hospital in Benghazi- Libya in period from January 2016 to July 2017, for an intracapsular femur neck fracture with Targon-FN system. According to Garden classification 9 fractures (30%) undisplaced and 21 (70%) were displaced fractures, with 2 patients (6.7%) had type I, 7 patients (23.3%) had type II, 7 patients (23.3%) had type III and 14 patients (46.7%) had type IV fracture. Epidemiological data were collected. Patients were followed-up for 2 years (average 16 months). Joint function was assessed clinically by using Harris hip score (HHS) and fracture healing by radiological assessment at sex weeks, 3 months, 6 months, 1 year and finally at 2 years. Complications were recorded. Statistical analysis done to predict risk factors associated with reoperation and complications.
Results: Sixteen patients (53.3%) developed one or more complications. Complications were higher than those of manufacturer's study and included avascular necrosis (53.3%, n=16), nonunion (30%, n=9), blown out implant (16.66%, n=5), loosening screw (3.3%, n=1), and deep infection (3.3%, n=1). In total, 5 patients required total hip replacements. At end of 2 years 19 patients (63%) had poor result, one patient (3.3%) had fair result, 1 patient (3.3%) had good result and 9 patients (30%) had excellent result according to HHS. Delayed surgery, fracture displacement, surgeon's experience, age ≥40 years and time to postop weight bearing recognized as risk factors for complications.
Conclusions: A minimally-invasive surgery of Targon FN justifies use of this system for the preservation of the patient's hip joint, early rehabilitation and mobilization. Complications and re-operation could be minimized by performing surgery within 24-48 hours, provision of skillful surgeons, and proper timing of postoperative weight bearing. The main limitation is the small number of cases and short follow-up averaged at 16 months.

Keywords: Intracapsular femur neck fracture, Internal fixation, Targon FN, Garden classification, HHS

INTRODUCTION

Hip fractures occur in the proximal femur and can involve the femoral neck, trochanteric, and subtrochanteric regions, the most common being intertrochanteric and femur neck fracture. After a simple fall intracapsular hip fracture is prevalent in the senior population and can cause severe morbidity and mortality if not treated adequately.[1,2] Closed reduction and internal fixation, open reduction and internal fixation, hemiarthroplasty and total hip arthroplasty are all surgical options.[3] Age, function, concurrent medical comorbidities, bone quality, and fracture characteristics all influence management indications.[4] Femur neck fractures are one of the biggest diseases of modern times, with lifetime incidences of

approximately 1 in 4 for women and 1 in 10 for men.[5] They are the most expensive fractures to treat.[6] Complications remain common given the spectrum of different fracture patterns and the baseline functions of the population affected, and if reoperations are required, mortality rates and financial costs rise considerably.[7] Most hip fractures are intracapsular; and this entails specific difficulties due to high risk of femur head avascular necrosis compared to extra capsular fractures so the outcome is potentially more dependent on the type and quality of the surgical treatment focusing on intra capsular fracture types. Hemiarthroplasty or total hip replacement are typical procedures frequently done to treat displaced intracapsular femoral neck fractures in the elderly, non-displaced fractures can be managed with joint preserving surgery with different types of internal fixation procedures. Conservative treatment is rarely indicated due to potentially high complication rates except for subgroup of non-ambulatory patients with severe medical comorbidities. The aim of treatment is always to outweigh the risks and benefits of surgical and conservative management which is associated with an increased risk of comorbidities such as pulmonary dysfunction, pneumonia, urinary tract infections, pressure sores, and venous thromboembolism.[8] Various guidelines exist regarding the management of hip fracture e.g. SIGN, Mak, NICE, and AAOS, with a consensus that early surgical management, usually within 24 to 48 hours, is the cornerstone of care for most hip fractures, with ultimate goal is to expedite early rehabilitation, which eases early ambulation and return to pre-morbid function while minimizing the complication risk, this approach has been associated with decreased mortality in many worldwide registries.[9-14] Displacement of the fracture is the main complication associated with reduction and fixation of intracapsular fractures, this accounts for 5% of un-displaced fractures and 30% of displaced fractures, this mainly is mechanical complication, with the traditional implants failing to hold the fracture in a stable configuration. Multiple parallel screws have inadequate purchase on the lateral femoral cortex so that the forces acting around the hip cause the fracture to collapse into a varus position and the fixation fails. The Targon ® FN has been designed with these specific problems in mind. The tele screws allow a controlled collapse of the fracture along the line of the femoral neck without any backing out of the screws into the soft tissues. Linking these distal and proximal screws with a locking plate gives a much more stable construction with superior rotational stability than would be found with either method of fixation, specific instruments have been designed to make the procedure easier to undertake using minimally invasive surgery. The surgical technique allows the surgeon to achieve an easy fixation whilst at the same time avoid potential complications such a bending of the guide wires or pushing of the guide wires into the pelvis. The initial positive experience with the Targon ® FN suggests this implant may be a major advance in the management of the intracapsular fracture and a possible solution to the dilemma of the “unsolved fracture”.

METHODS

This study was a prospective interventional case series of 30 consecutive patients aged from 23 to 82 years (Mean 49 years) treated for an intracapsular femur neck fracture with closed reduction and internal fixation using dynamic locking plate (Targon® FN system B. Braun AG, Melsungen, Germany) from January 2016 to July 2017 at Al-Jalaa trauma hospital, a level 1 trauma center in Benghazi, Libya. Patients with extracapsular neck femur fractures, pathologic fractures, or missing imaging and medical data were excluded. All grades of surgeons under supervision as appropriate participated in surgery which was done within two to ten days from day of trauma. Surgery was done under general anesthesia and fluoroscopic control in the supine position. A single dose of IV prophylactic antibiotic was given 30 min. before surgery. Closed reduction on traction table was done in all cases. The recommended surgical technique for the implant system was done according to the description of Parker et al.[15] The postoperative rehabilitation consisted of early active range of motion exercises of the hip. Elderly patients with stable fractures (Garden I and II) were allowed immediate, full weight bearing as tolerated as they are not able to cope with restricted weight bearing, while younger patients and those with displaced fractures (Garden III and IV), were allowed a 6 to 12-week period of partial weight bearing. All patients used axillary crutches for a minimum of six weeks then allowed to gradually discontinue crutches according to clinical and radiological assessment at follow-up. Patients were assessed postoperatively by x-rays and clinically according to HHS at six weeks, three months, six months, and one year after surgery. Follow up was extended longer when clinically necessary up to two years. Total range of motion was assessed as follows: 211°-300°=5 points, 161-210°=4 points 101-160°=3 points, 61-100°=2 points, 31-60°=1 point, and 0-30°=0 points. The lateral view X-ray was used to pick up residual anterior or posterior angulation at the fracture site after fixation. The tip-apex distance (TAD) was measured between the tip of the nearest tele screw to the apex of the femoral head in anteroposterior and axial view. The average TAD was considered 24 mm (range 9-36 mm). The result was standardized by the known lateral diameter (6.5 mm) of the tele screw. The time at which full weight bearing was allowed described as: immediately, 6 weeks, 12 weeks, or greater than 12 weeks. Any intraoperative complications or intraoperative additional step was recorded. Postoperative complications directly related to the surgical site were collected from the medical records and x-rays at the follow-up. A diagnosis of avascular necrosis was defined by Steinberg stage two or greater on any of the follow up x-rays.[16] Implant failure was defined by any damage of the implants noted on radiographs including breakage of the plate or breakage or loosening of any screws. Non-union was defined if the fracture showed no evidence of bony union of at least 2 cortices on plain X-rays in two planes after 6 months. Any revision surgery, including implant removal, was recorded.

Statistical analysis

Percent of categorical variables were compared using chi-square and Pearson correlation tests to examine the relationships of variables. Data analysis was done using Microsoft excel worksheet and the statistics package social science (SPSS) program version 23.

RESULTS

The follow up period continued to two years (Average16 months). All patients were available for follow up. The mean age was 49.00 years with range of 23-82 years, and maximum age interval was 41-60 years (Table 1).

Table 1: Age statistics.

Age (In years)	N
Total number	30
Mean	49
Median	49
Mode	40
Std. deviation	13.235
Minimum	23
Maximum	82
Range	23-82

The sex incidence was 63.3% males and 36.7% females (Figure 1). The left femur was more affected than the right femur with percentage of 56.7% and 43.3% respectively. According to garden classification 46.7% of fractures were type IV, 23.3% type III, 23.3% type II, and 6.7% type I (Figure 2). With respect to anatomical classification 33.3% were sub-capital fractures, 46.7% were transcervical fractures, and 20% were baso-cervical fractures (Figure 3).

The score for range of hip motion in all patients according to HHS at 6 weeks and at 3 months after surgery ranged between 2 points to 5 points. At 6 months range was zero to 5 points with 2 cases had 0 points and 16 cases had 5 point, 9 cases had 3 points and 3 cases had 1,2, and 4 points retrospectively. At 1 year and at 2 years patients scored 0, 2, 3, 4 and 5 points, most of them scored at 3-5 points, the total hip score for all patients and at all periods of the follow up ranged from zero to 99 with almost equal distribution in all cases (Table 2 and Figure 4).

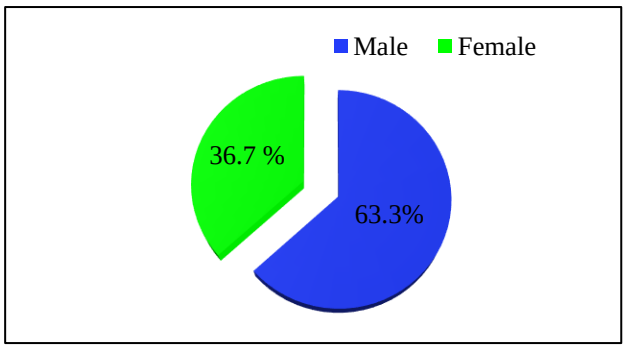

Figure 1: Sex incidence.

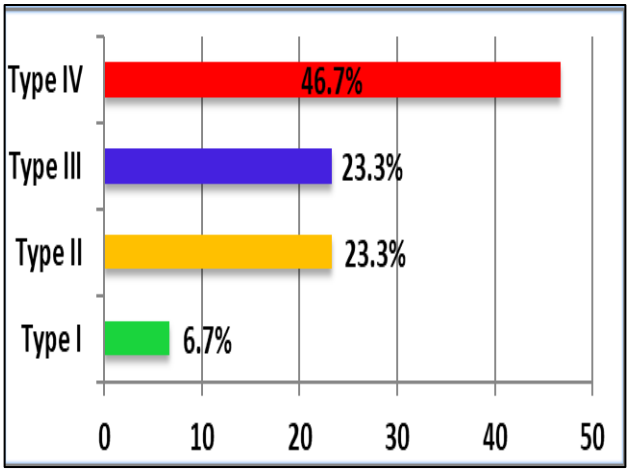

Figure 2: Percentage of patients according to garden classification.

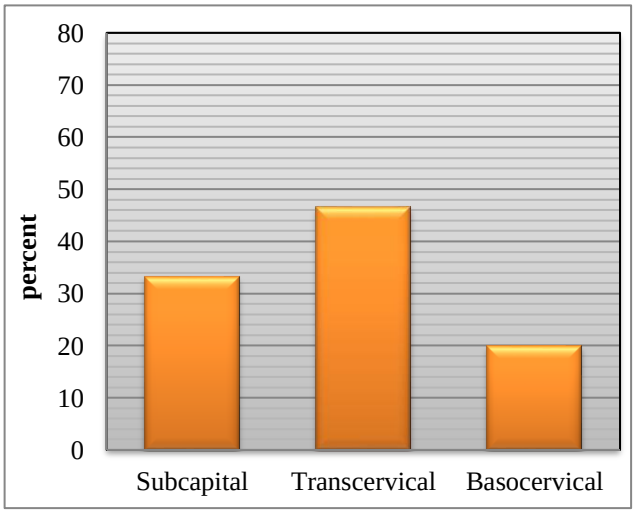

Figure 3: Percentage of patients according to the anatomical classification.

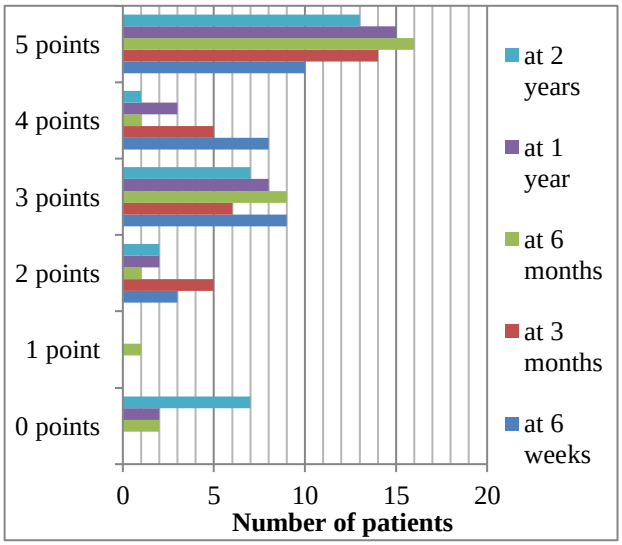

Figure 4: Number of patients with range of motion points at each period.

Table 2: Score for range of motion after 2 years.

HHS		N	Percent (%)	Valid percent	Cumulative percent
Valid	0	7	23.3	23.3	23.3
	2	2	6.7	6.7	30.0
	3	7	23.3	23.3	53.3
	4	1	3.3	3.3	56.7
	5	13	43.3	43.3	100.0
	Total	30	100.0	100.0	

Table 3: HHS at 2 years.

HHS		Frequency	Percent (%)	Valid percent	Cumulative percent
Valid	0	7	23.3	23.3	23.3
	12	1	3.3	3.3	26.7
	13	1	3.3	3.3	30.0
	16	1	3.3	3.3	33.3
	18	1	3.3	3.3	36.7
	19	4	13.3	13.3	50.0
	26	1	3.3	3.3	53.3
	35	1	3.3	3.3	56.7
	47	1	3.3	3.3	60.0
	67	1	3.3	3.3	63.3
	75	1	3.3	3.3	66.7
	82	1	3.3	3.3	70.0
	88	1	3.3	3.3	73.3
	91	1	3.3	3.3	76.7
	93	1	3.3	3.3	80.0
	95	5	16.7	16.7	96.7
	99	1	3.3	3.3	100.0
	Total	30	100.0	100.0	

The HHS evaluation was performed at 6 weeks, 3 months, 6 months, one year, and 2 years. The interpretation of HHS is: <70 (poor result), 70-79 (fair result), 80-89 (good result) and >90 (excellent result). At the end of 2 years follow up 19 patients (63%) had poor result, one patient (3.3%) had fair result, one patient (3.3%) had good result and 9 patients (30%) had excellent result (Table 3).

Complications

Among 30 patients enrolled in the study 16 patients (53.3) developed at least one complication each (Figure 5), eight of them were younger than 40 years and 8 were older than 40 years. Fourteen patients (46.7%) recovered without any complications and needed no intervention during the 2 years follow-up period (Figure 6), they were aged >40 years, this result was highly significant (p=0.008) and 12 of them were males and only 2 were females.

The patients who developed complications all had avascular necrosis (Figure 7), 9 patients (30%) had nonunion, and 5 patients (16.66%) had implant failure (Figure 8), and there was one patient (3.3%) with screw backing out and another patient (3.3%) with deep infection. Five patients (16.66%) had revision to total hip replacement.

Analyzing our findings after two years of follow up using Pearson correlation, there was no significant relationship between patients' sex and age, fracture classifications and complications' incidence as p>0.05 (Table 4).

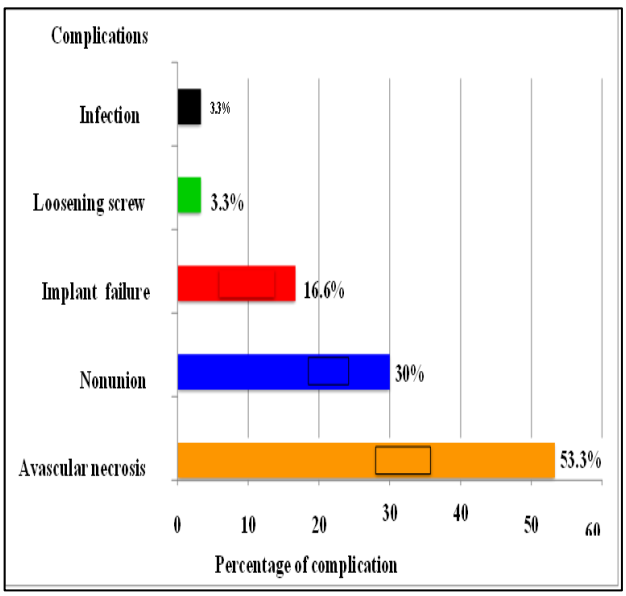

Figure 5: Type of complications.

Figure 6: Neck of femur fracture treated with Targon FN plate with sound union and no complications.

Figure 7: X-Ray of Lt. femur neck fracture treated with Targon FN united with avascular necrosis.

Table 4: Pearson correlation of patients age with sex and complication.

Variables	Age (In years)				N	Pearson correlation	P value
	≤40, n=9		>40, n=21				
	N	%	N	%			
Sex of patients							
Male	7	23.33	12	40	19	-0.048-	0.802
Female	2	6.66	9	30	11		
Avascular necrosis + non union							
Yes	8	26.66	8	26.66	16	-478-**	0.008
No	1	3.33	13	43.33	14		
Implant failure							
Yes	4	13.33	1	3.33	5	-426-**	0.019
No	5	16.66	20	66.66	25		

Pearson Correlation is not significant at the > 0.05 level (2-tailed *. Pearson Correlation is significant at the 0.05 level (2-tailed). **. Pearson Correlation is highly significant at the 0.01 level (2-tailed).

Figure 8: Implant failure with cutting through of screws and nonunion.

DISCUSSION

All patients were operated on by close reduction and fixed by the Targon FN plate within 2-10 days from the day of trauma, which caused a delay in surgeries that had an effect on clinical outcome. This was revealed by a study by Jan Poszepczyński et al from Poland to identify relationships between the outcome of femur neck fracture treated with the Targon FN system manufactured by Aesculap, patient's body mass, length of the period between the moment of injury and surgery, age, and prescribed medications.[17] They confirmed that the most serious complications occurred in patients who had a postponed surgery, i.e., over 4 days after injury involving a 31B3 fracture and no relationship between the outcome of treatment and the patient's age, body mass or received medications. The best results of treatment were obtained in the patients operated on the first or second day after injury. Operative procedure adjusted to the local and general condition of the patient is the only option that allows for the restoration of mobility after treatment of the femur neck fractures. Early reduction and fixation using the Targon FN system is an effective method of treatment of the femur neck fracture.

With regard to the present study, the functionality of the hip joint was tested by HHS, the total hip score for all patients and at all periods of the follow up ranged from zero to 99 score with almost equal distribution in all cases. According to HHS at 2 years follow up, 10 patients (33.3%) had excellent and good results. Out of 30 patients enrolled in the study 14 patients (46.7%) had no

complications and they did not need further intervention, while 16 patients (53.3%) had complications, there was no relationship between age and non-union rate, while relationship between age and avascular necrosis and implant failure was highly significant as $p<0.01$, also patients age and no complications showed highly significant results, these results show high percentage of complications compared to other studies.

In disagreement to our results Matar et al from United Kingdom conducted a retrospective study in 2018 that included 43 patients with intracapsular hip fractures treated with Targon® FN system, the method of this study is identical to our study, only 5 patients developed complications of those patients 3 had revision to arthroplasty and one had the implant removed with overall re-operation rate of 9.3%.[18] The study concluded that intracapsular hip fracture fixation using the Targon® FN locking plate system has an excellent outcome with low rate of complications. Our study revealed high complication rate.

The study financed and supported by the manufacturer of Targon® FN locking plate system (B-Braun company), and published in 2010 by Parker et al to evaluate 83 patients revealed complications in 14 patients (16.86%), 8 had non-union and 4 developed avascular necrosis, 1 had the implant removed due to fracture around the distal screws, and the last developed deep wound infection.[15] The most common complications encountered were avascular necrosis and non-union and this matches our findings despite the higher rate of complications in our series. Complications similar to those occurred in our study were seen in British study conducted by Aggarwal et al that involved 43 cases of intracapsular neck femur fracture who underwent fixation with Targon® FN system at Queen Elizabeth hospital in London, they had one case of nonunion (2.32%), and 3 cases of avascular necrosis (6.97%) these 4 patients had revision to THR.[19]

We had much higher complication rate (53.3%) than other studies including study of the place of the origin, this might be attributed to delayed surgery as main risk factor (2-10 days in our study), several studies recommended against delaying this type of surgery beyond maximum of 48 hours, another independent potential factor which has an impact on the result is surgeons' experience along with proper supervision as needed, and most importantly patients compliance and adherence to physical therapy protocol which is lacking in our environment, all these were contributory factors that caused the high rate of complications in this study.

CONCLUSION

This study revealed complication rate higher than any other study included that conducted by the place of origin. A critical factor with a negative impact on the functional and radiological outcome is delayed treatment of the fracture, especially with a significant fragment displacement. Measures to improve outcome should include early surgical intervention within 48 hours, surgery executed by average experienced surgeon, and appropriate post operative rehabilitation protocol with good patient compliance.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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