

## Original Research Article

# Treatment of humerus fracture with wise-lock implants

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## ABSTRACT

**Background:** Humerus fracture is a common fracture in aging population mainly occurring due to fall, high energy trauma and sports injury. Locking plate treatment is showing good results in stabilization of the fracture. The purpose of this study is to showcase the surgical treatment and results by using Auxein locking implants for the treatment of proximal humeral fracture.

**Methods:** Prospectively 13 patients were treated with ORIF treatment (6 males, 7 females with an average age of 43.6years). Fracture type is classified as per the Muller AO classification of fracture, 6 patients had type 11-A1 and 7 patients had type 11-A2. 1 patient were felt under American Society of Anesthesiologists grade 2 have mild systemic disease. Clinical outcomes were assessed at 1year follow-up with visual analogue scale score at 4 week, 16 week, 24 week and 1 year.

**Results:** The follow-up of patients was taken at 4<sup>th</sup>, 16<sup>th</sup>, 24<sup>th</sup> and 1 year bearing good clinical results. 2 patients were encountered with pain, these were elderly patients of the age 58 and 62 and had a history of other medical commodities. One patient reported of less weigh bearing ability which was relieved with physiotherapy.

**Conclusions:** Open reduction internal fixation treatment with Pheelos 3.5 mm wise lock proximal humerus plate showed good results with improved performance and negligible complications.

**Keywords:** Humerus fracture, Proximal humerus fracture, Long and short Pheelos plate, Locking implants

## INTRODUCTION

Humerus fracture also known as broken arm fracture, classified in to different classes based on the anatomy/location of fracture (proximal, shaft and distal) mainly occurs due to fall, road accident and sports injury. Four fracture parts are basis for Neer classification namely the humeral head, the lesser tuberosity, the greater tuberosity, the humeral shaft. Practically the basic concept of the discussion of these fractures by the number of parts involved in Neer classification. If the separation of the fragment is more than 1 cm or at an angle greater than 45°, it is considered displaced.

Among all type of humerus fracture, proximal humerus fracture is the 3<sup>rd</sup> most common fracture, it concludes 45% of humerus fracture and comprise 4-5% of all fracture.<sup>1,2</sup> Proximal fractures are the common fractures in older adult population, occurs due to low-energy fall onto an stretched out arm.<sup>3</sup> Approximately 80% of proximal humeral fracture are minimal or non-displaced fracture can be treated non-operatively, but in case of severe injury surgical procedure preferred. Open reduction and internal fixation has become a treatment option in displaced fractures to allow rigid fixation for early mobilization. Locking plate fixation appears to be a standard treatment, despite its association with a complication rate as high as 36% to 49%. Secondary loss

of reduction and screw perforation are common complications.<sup>4</sup>

This was a prospective study, the main concern of this study is to treat the proximal humerus fracture with indigenously prepared wise lock implants manufactured by Auxein, to reduce complication rate associated with the implants.

## METHODS

This was a prospective study, between August 2016 to April 2018, 13 patients with humerus fracture (proximal humerus fracture) were treated at Mesoamerican University, Quetzaltenango, Guatemala with Auxein implants (plates and screws). Enrolled patients were classified according to Muller AO classification of fractures- long bones with 6 patients having 11-A1, 7 with 11-A2. Only patients with good fracture reduction were included in the study. Average year of patients were 43.6 years, ranges from 26-62 years. 13 patients were observed with proximal humerus fracture treated with Pheelos-3.5mm wise lock proximal humerus plate. All surgeons included in the study were trained orthopedic surgeons. Patients underwent treatment with Pheelos-3.5 mm wise-lock proximal humerus plate were compared and analyzed with the literature of same implants from different manufacturer.

The American society of Anesthesiologists (ASA) grade was used for the categorization of patient's clinical status, 11 patients (6 females and 6 males) were categorized in grade 1 indicates a normal healthy patient. 1 patients (1 female) were categorized in grade 2 indicates a patient with a mild systemic disease. Patients with ASA grade 3 has been excluded from the study.

### *Implant characteristics*

The Pheelos-3.5 mm wise-lock proximal humerus plate (Figure 1 (a) and (b)) is made of titanium alloy with 9 head holes, 3, 4, 5 and 5, 6, 8, 10, 12 shaft holes and 3.5 mm in diameter for locking screws. 3.5 mm wise lock screw and 3.5 mm cortical screws were used for the fixation of implant.

### *Surgical technique*

Implants enable the surgeon to select the appropriate surgical approach for fracture and patient. Anatomic reduction is achieved according to fracture pattern and approach, either directly or indirectly, and can be stabilized with temporary metal wires while the plate is applied. Elongated holes in the shaft of the plates are used to bring the plate to the bone with wise lock and cortical screws and allow the adjustment of the plate position.

The surgery was performed under general anesthesia. After the surgery, follow-up of patients were taken at 4<sup>th</sup>

week, 16<sup>th</sup> week, 24<sup>th</sup> week and 1 year. Clinical outcomes were assessed using the 10 point score info system named as visual analogue scale (VAS) score. Performance of implant was evaluated by using radiography (X-ray). X-ray observed at 16<sup>th</sup> week showing good position of implants with recommendation of physical exercise for hand movement. All surgery was performed by same surgeon. X-ray reports were used for examined bony union, non-union, implant failure and plate migration. All radiographic measurements were evaluated by same surgeon.



**Figure 1: Pheelos 3.5 mm wise lock proximal humerus, (A) short and (B) long.**

## RESULTS

The outcome of the surgery was examined on 13 patients. With an average age of 43.6 years, ranging between 26-62 years, 6 patients were male while the remaining 7 were females. As per the classification described by Muller AO classification of fracture-Long bones with 6 patients having 11-A1 (46.15%), 7 with 11-A2 (53.85%) as described in the Table 1. All the identified subjects underwent open reduction internal fixation (ORIF) with no closed reduction without internal fixation. All the fractures were open fractures with no close fracture category. Cause of injuries is shown in Table 2.

Clinical evaluation for pain, aesthetic appearance and satisfaction with treatment was rated by patients on a VAS score (maximum score, 10 points) at the final follow-up. The mean VAS score (maximum score, 10 points) at the final follow-up is shown in Table 3. The follow-up of patients was taken at 4<sup>th</sup>, 16<sup>th</sup>, 24<sup>th</sup> and 1 year showed good clinical results. The maximum VAS score was 0.17 for 5 patients and the lowest was 0.15 for 1 patient. At the end of the 4<sup>th</sup> week the VAS score was 6 for 1 patient which is the highest and the 16<sup>th</sup> week the highest score was 3 for 4 patients at the 24<sup>th</sup> week it was 2 for 5 patients and on completion of 1 year it was 1 for 5 patients. As described in the Table 4, 2 patients out of 13 complained about pain. These were elderly patients of the age 58 and 62 and had a history of other medical commodities. One patient reported of less weigh bearing ability which was relieved with physiotherapy and two

were less satisfied with the aesthetic appearance after the surgery.

The inclusion criteria for all the patients were met after they all agreed to be interviewed. Some accepted it to be taken through telephonic conversation, few through video calling and the remaining to meet personally. The Pheelos plates were used for the treatment of the fractures. Observation beard good result. The patients were suggested general exercises and physiotherapy. With every follow the results were pleasing with no requirement of recurrence off surgery and complaints. There was no report of fixture failure, infection and non-union.

**Table 1: Demographic data and fracture type.**

Demographic data	
Average age in years (range)	43.6 (26-62)
Gender, N (%)	
Male	6 (46.15)
Female	7 (53.85)
Fracture type (Muller AO classification), N (%)	
11-A1: Left-Right	6 (46.15)
11-A2: Left-Right	7 (53.85)

**Table 2: Cause of injury.**

Injury mechanism	No. of patients
Fall and slip	4
Road accident	3
Sport injury	6

**Table 3: VAS score.**

Follow-up time	VAS score (%)
4 week	43.85
16 week	22.31
24 week	13.9
1 year	3.84

**Table 4: Evaluation parameter.**

Parameter	Satisfied	Not satisfied
Pain	11	2
Weight bearing	12	1
Aesthetics	11	2

## DISCUSSION

The treatment of the proximal humerus fractures is a complicated subject. Some denote it as controversial trial due to insufficient availability of evidence which could provide recommendations, thereby showing heterogeneity among studies.<sup>5</sup> For the rehabilitatization of these fractures use of locking plate fixation system has been used for cases discussed and can be attributed as a standard treatment. Some studies have acknowledged the

use of locking plates thereby accepting it the best prospect of treatment as its impact on the post-operative result is significantly high.<sup>6</sup> Using the demographic attributes of the patients, VAS score can become a medium that can decide the standards of the surgical outcome and the parameters to be adopted to make it successful. Considering pain scores and comparing the VAS outcome of different studies that also includes demographic data as well as biomechanics under controlled trials can be sufficient to recommend the treatment plans.<sup>7</sup> As for the present study the trial was conducted after every four weeks and the outcome was presented by calculating the VAS score. This has shown good acceptance outcomes. The assessment should include good tissue growth followed by bone quality, aesthetics with independence in the society and low risk of the surgery. With a follow up of 17 months the study stressed upon bone growth to be a major aspect for the satiability of the plating system.<sup>8</sup>

With ORIF major attention should be paid to medical communication, angulations of varus and calcar restoration. ORIF utilizations have increased as patients taking it have resulted in return to work quickly, rehabilitation of the elbow and shoulder and low rates of brace wearing during the recovery time.

With all fracture categories being open and none being closed the subjects of this study were able to adapt their routine life after the braces were removed in the 19-21 weeks of the surgery. Finding from some studies suggest that the removal of the brace and union of the segments clinically takes 11.5 weeks on an average ranging between 4-22 weeks. Thereby also comparing it with function bracing with 6.3-9.8 weeks. Using nailing system, intramedullary nailing and compression plates it takes 8.9-10.4 weeks.<sup>9-11</sup> Therefore, for such category of fractures functional outcome is associated with high rate of union after removal of braces.

Weight bearing is a major concern of the outcome of the complete surgical procedure. Elderly patients can face the restriction of weight if the union is not proper. Young patients on the other hand may not face the problem of weight bearing, but management being non operative can reduce their ability to reduce the ability to return to work due to delay. With skin also involved its related complications cannot be ignored which carries 1-95% of functional bracing.<sup>12-14</sup> 90% of the subjects were satisfied with load bearing ability after the surgery and rehabilitation period the use of locking system can be recommended. A comparative study between the operative and non-operative side shows no sign of complications or difference in terms of appearance. The study bared good results for the younger patients as for the elders frequent consequences were abserved.<sup>8</sup>

Using the present study represents the treatment of proximal humerus fractures surgically by using Pheelos-3.5 mm wise-lock proximal humerus plate, which are

designed and manufactured in house by Auxein Medical Pvt. Limited. Major complications like nerve palsy and infection has been reported by many studies but none was reflected in the outcome of our evaluation.

## CONCLUSION

The use of indigenously designed and manufactures locking system for the treatment of proximal humerus fractures demonstrates successful surgical outcome thereby attributing it to be suitable for open reduction internal fixation. For the validation of the results VAS can be used to subjectively assess the outcome by recording patient's response. The outcome of the surgery in terms of functionality and complications can be compared with the literature.

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## REFERENCES

1. Chen JL, Chang FC, Lin SJ, Chuang PY, Peng KT, Huang KC, Huang TW. The outcome of surgical management of proximal humeral fractures using locking plates: comparison between locking plates with different geometry. *J Shoulder Elb Surg.* 2018;12:2159-66.
2. Vijayvargiya M, Pathak A, Gaur S. Outcome analysis of locking plate fixation in proximal humerus fracture. *JCDR.* 2016;10(8):01.
3. Iannotti JP, Ramsey ML, Williams JG, Warner JJ. Nonprosthetic management of proximal humeral fractures. Instructional course lectures. 2004;53:403-16.
4. Müller ME, Nazarian S, Koch P, Schatzker J. The comprehensive classification of fractures of long bones. Springer Science and Business Media. 2012.
5. Handoll HH, Brorson S. Interventions for treating proximal humeral fractures in adults. *Cochrane Database of Systematic Reviews.* 2015:11.
6. Röderer G, Erhardt J, Kuster M, Vegt P, Bahrs C, Kinzl L, et al. Second generation locked plating of proximal humerus fractures—a prospective multicentre observational study. *Int Orthopaed.* 2011;35(3):425-32.
7. Zarezadeh A, Mamelson K, Thomas WC, Schoch BS, Wright TW, King JJ. Outcomes of distal humerus fractures: What are we measuring? *Orthopaed Traumatol Surg Res.* 2018;104(8):1253-8.
8. Wachtl SW, Marti CB, Hoogewoud HM, Jakob RP, Gautier E. Treatment of proximal humerus fracture using multiple intramedullary flexible nails. *Archiv Orthopaed Trauma Surg.* 2000;120(3-4):171-5.
9. Sarmiento A, Zagorski JB, Zych GA, Latta LL, Capps CA. Functional bracing for the treatment of fractures of the humeral diaphysis. *JBJS.* 2000;82(4):478.
10. Changulani M, Jain UK, Keswani T. Comparison of the use of the humerus intramedullary nail and dynamic compression plate for the management of diaphyseal fractures of the humerus. A randomised controlled study. *Int Orthopaed.* 2007;31(3):391-5.
11. Chapman JR, Henley MB, Agel J, Benca PJ. Randomized prospective study of humeral shaft fracture fixation: intramedullary nails versus plates. *J Orthopaed Trauma.* 2000;14(3):162-6.
12. Jawa A, McCarty P, Doornberg J, Harris M, Ring D. Extra-articular distal-third diaphyseal fractures of the humerus: a comparison of functional bracing and plate fixation. *JBJS.* 2006;88(11):2343-7.
13. Koch PP, Gross DF, Gerber C. The results of functional (Sarmiento) bracing of humeral shaft fractures. *J Shoulder Elbow Surg.* 2002;11(2):143-50.
14. Woon CYL. Cutaneous complications of functional bracing of the humerus: a case report and literature review. *JBJS.* 2010;92(8):1786-9.

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