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# Evaluation of a novel functional orthotics device for managing proximal humerus fractures

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***Abstract*---** This study aims to evaluate the efficiency of an orthotic device in treating proximal humerus fractures. The following research methods were used Orthosis user group compare to the non-orthotic user group in terms of PHFs management. Physical function in daily activities and recovery were assessed using the DASH, SPADI, SST, Muscular Strength, and CONSTANT scores, radiological assessment, as well as the Orthosis questionnaire AND mathematically (statistical data processing). Based on the data normality results and clinical outcomes, a statistically significant difference between two groups was illustrate, the orthosis user group indicating a minimum level of inability, pain severity and a lack of functional skills to execute specific activities, had higher shoulder function and activity muscle strength recovered to a normal level, more effective in preserving and


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promoting arm function, as well as allowing for better functional mobility. Bone union indicating that the orthosis user group allowed the fracture to heal while providing sufficient support and stability. Furthermore, an orthosis satisfaction survey found that patients were fell protected and comfortable with the new orthosis.

***Keywords*---**Orthosis, Proximal Humeral Fractures, Rehabilitation, Assistive device, Physical therapy.

## 1 Introduction

Proximal humerus fractures have an early modest jump in incidence between certain ages of 10 and 14, followed by a return to reduced numbers in young adults, then an increase after 45 years, culminating at 70 years (Kim et al., 2012). A common injury, accounting for approximately 10% (Fjalestad et al., 2005) of all fractures and 70% of humeral fractures (Basti et al., 1994; Elkowitz et al., 2002). Those fractures can cause long-term disability and are typically misdiagnosed, When compared to hip fractures (Fink et al., 2003). Approximately 85 % of cases occur in adults over the age of 50, with a female to male ratio of 70:30 in the 60 years to 90 years old age group (Charles M Court-Brown & Caesar, 2006). PHFs caused by falls have increased in frequency since 1970 (Palvanen et al., 2006). Patients over 60 who have fallen from a standing height responsible for nearly 75% of all PHFs (Court-Brown CM, Garg A, 2001; Green et al., 2003). The vast majority of patients with these injuries are elderly and have poor therapeutic expectations. Where the surgery should only be performed on the very elderly above 85 years old, those with cognitive impairment, a non-functional limb, or those with major medical complications such as diabetes, smoking, drug and alcohol abuse, rheumatoid arthritis, immunocompromise including steroid treatment , and concurrent neoplasia have all been related to poor outcomes and an increase side effects of treatment (Murray et al., 2011). PHFs are caused by advanced age, low bone mineral density, impaired vision and balance, no history of hormone replacement therapy, more than 3 chronic illnesses, and previous fragility fractures (Court-Brown CM, Garg A, 2001; Huopio et al., 2000; Lin et al., 1998). The PHFs are more likely to occur in younger patients due to motor accidents, convulsions, electric shock, and falls from greater than a standing height (Huopio et al., 2000), and these injuries are more likely to produce extensive bone and soft tissue damage, needing surgical intervention (Green et al., 2003; Lin et al., 1998). There is a scarcity of high-quality data supporting PHFs treatment, particularly consensus based protocol driven treatment, rather than a larger prevalence of PHFs (Gibson et al., 2001; Lanting et al., 2008; Misra et al., 2001). The majority of patients with these injuries will be able to regain use of their shoulder without surgery. According to experts, only about 20% of people need undergo surgery (CHARLES S NEER, 1970). Treatment of humerus fractures can be surgical like pinning, plate and screws or conservative e.g., immobilization in a splint or orthotic device. Surgery is commonly recommended for patients with multiple fractures, vascular and nerve injury, bilateral humeral shaft fractures, pathological fractures, comminuted segmental fractures, and open fractures (Crenshaw Jr & Perez, 2007). To address these injuries, a growing number of reconstructive techniques are now available, each with their own set of benefits and drawbacks. They are more difficult to treat, whether because they require more powerful shoulder function or because their fracture is more complex (Murray et al., 2011). However, vascular necrosis, stiffness, rotator cuff dysfunction and non-union are all serious repercussions of non-operative therapy of PHFs (Gaebler et al., 2003; Hertel et al., 2004; Koval et al., 1997; McQueen, 2008).While problems are uncommon with non-operative treatment, they have a negative impact on outcomes and frequently necessitate extra therapy (Bosch et al., 1998; Leyshon, 1984; Olsson & Petersson, 2006; Serin et al., 1999). The majority of PHFs in this demographic are relatively non-displaced and can be successfully controlled without surgery nonetheless, whether surgical or nonsurgical procedures are used, accomplishing the goal is crucial. Treatment decisions are influenced by a variety of conditions, but all surgeons should strive for complication free healing in order to achieve a pain free, mobile, stable, and functioning shoulder. Patients who were given functional shoulder braces were educated on how to use the brace and told to wear it as much as possible throughout the day and, if comfortable, at night, a cotton sleeve and unique thermopile pads make up the majority of the shoulder braces, secured with two elastic velcro straps. Where a chronic tendinitis, bursitis, overuse injuries, impingement syndrome, and early degenerative arthritis are all indications for using the brace (Walther et al., 2004). The shoulder cast, conventional sling, hanging arm cast, and airplane splint are all choices for bracing. For all non-operatively treated PHFs, a typical sling offers appropriate immobilization (Hanson et al., 2009). The sling can provides a tiny gravitational distraction to the bone ends, which can help with pain alleviation in the short term (Depalma & CAUTILLI, 1961). A study by Likewise et al. found that patients who were treated with a hanging cast had inferior clinical outcomes (CHARLES S NEER, 1970). The hang arm casts offer no benefit over a regular sling, and excessive distraction of the bone ends by a hanging arm cast might lead to nonunion, whereas other immobilization treatments are incredibly badly tolerated (Leyshon, 1984; Rasmussen et al., 1992; Svend-Hansen, 1974). A commercially available orthosis that is frequently used in our practice for the treatment of PHFs has a number of documented disadvantages for the patient, such as comfort, skin sensitivity, a bascule with reduced fracture tolerance, bulkiness, and awkwardness in size are all factors to consider. This design should provide support while also promoting fracture union and allowing complete elbow and wrist movement. The advantages are expected to be light, adaptable, simple, beneficial for skincare, showering, easy to apply, made from locally available materials, and may be worn as outerwear. The use of this orthosis is to provide more support for static stability indices than traditional conservative treatments, resulting in speedier functional recovery and better outcomes in the elderly. The orthosis will take care of all of the aforementioned factors. The main aim of this study would be to see how effective the orthosis is within treating proximal humerus fractures.

*Literature review*

The clinical evaluation of PHFs begins with a complete assessment of the history and clinical diagnosis, physical examination begins with exposure and observation of the entire shoulder girdle and affected extremity. The whole shoulder girdle and affected extremity are exposed and observed during the medical assessment, clinical phase, it's critical to examine skin condition since any disturbances could indicate an open wound. In the absence of further injury, patients should be able to actively move their elbows, wrists, and fingers. Function outcome is evaluated by isometric deltoid contraction against resistance with the arm adducted and cutaneous sensation in the proximal lateral arm, albeit this method has been demonstrated to be unreliable when compared to electroencephalography (Visser et al., 1999).

Planning management, patient related factors such as age, medical comorbidities, functional expectations, mental status, prospective rehabilitation, and alcohol/substance misuse must all be taken into account. Therefore, patients with less demand and who are in poor health are better suited to non-operative therapy if the target is to regain painlessly and quickly function (Hodgson, 2006). Non-operatively managed patients fared poorly based on two factors: the degree of fracture displacement and age (C M Court-Brown et al., 2002). Historically, shoulder spica casts and airplane splints have been utilized in the past to counteract the deforming stresses of the proximal humeral shaft, These methods were not well accepted (Misra et al., 2001). The minimal displaced fractures of the proximal humerus comprise the majority of these fractures 50% to 65%, whereas the fractures of the tuberositys and the surgical neck are among them. These fractures usually respond favorably to non-operative treatment (Rasmussen et al., 1992). Although tuberosity displacement is difficult to treat without surgery, an unstable two-part PHFs can sometimes be stabilized with closed reduction (Twiss, 2015). A standard "collar and cuff" sling offers sufficient immobilization for all non-operatively treated PHFs. Ongoing care, you can use a hanging arm cast, regular sling, shoulder spica cast, or an airplane splint (Hanson et al., 2009). These methods allow for gravity distraction of the fracture ends, which may have an analgesic effect in and of itself, excessive distraction of the bone ends, in fact, can result in non-union. Therefore, casts with hanging arms have no advantage over slings. There are only a few studies that look at functional outcomes in fractures that are minimally displaced, such as a study followed a total of 104 patients for a year, documenting their functional outcomes. The shoulders pain, function, and range of ROM were all evaluated. A total of 80 patients 77% had a good or outstanding outcome and 94 individuals 90% reported no or little shoulder pain. Functional recovery was 94% on average, with 48 patients 46% achieving 100 percent recovery. Patients who began supervised PT during the first fourteen days of their injuries did better (Koval et al., 1997). The greater tuberosity fracture occurs infrequently on its own. Isolated fractures account for 14 to 20% of all GT fractures (C M Court-Brown et al., 2001). In addition, Some other studies have looked at the outcomes of patients with minimally displaced fractures and concluded that they can be treated without surgery (Jellad et al., 2012; Mattyasovszky et al., 2011; Rath et al., 2013). In a retrospective study of 114 patients with undisplaced or minimally displaced GT fractures by Schliemann et al. found that these fractures can be successfully treated non-operatively. Instead of additional displacements, surgery was most likely necessary for concomitant soft tissue injuries. Moreover , that even a 3-5mm displacement might cause impingement and increase the force required for abduction (Schliemann et al., 2018). The PHFs with two-part surgical neck fractures account for 20% to 30% of all proximal humeral fractures (Bergdahl et al., 2016), patients may respond to non-operative treatment if the fracture fragments are sufficiently reduced (Chun et al., 1994). Furthermore, a systematic review study focused on the subgroup of one- and two-part fractures and found that non-operative treatment resulted in an exceptional rate of radiographic union (100%) and good functional flexion range of motion 151 degrees. Non-operatively treated neck fractures may heal in a valgus or varus deformation. Where 3 and 4-part fractures, according to a Court-Brown and McQueen study the PHFs account for 21% to 23% of all fractures (Charles M Court-Brown et al., 2001). Depending on the patient and the fracture configuration, both operational and non-operative therapy options are available, closed reduction with non-operative management seems to have a negative functional outcome (Clement et al., 2014). A prospective RCT on 40 patients with 3 or 4-part proximal humeral fractures who were either treated with a tension band or conservatively, they found no differences in functional outcomes despite the fact that radiological outcomes had improved (Karol Zyto et al., 1997). There are multiple studies comparing operational and non-operative management of various levels and quality, but they are heterogeneous and therefore do not address specific fracture types in different cohorts.

To summarize, the majority of mildly displaced and fragile PHFs can be safely managed non-operatively using various treatments such as hinging casts, braces, or other orthotics devices, which can help to reduce the consequences of the fractures. Three- and four-part fractures can be managed and treated non-operatively with satisfactory results, depending on the age and fracture fragments. Before major conclusions about the management of these fractures can be reached, non-surgical management with specific operative approaches in specific patient groups with 3 or 4-part fractures must be studied. Physical therapy and rehabilitation programs are critical for restoring patients activity levels and should begin as soon as possible after the injury, followed by radiological photos to determine whether or not bone union has occurred.

## 2 Materials and Methods

*Study design*

A prospective cohort study, every patient will sign a written consent form when they are enrolled in, this study was conducted at AL-Yarmouk Teaching Hospital, AL-Krama Teaching Hospital, AL-Karkh General Hospital, and Institute of Medical Technology (IMT), Middle Technical University (MTU), Baghdad in collaboration with the Department of Rehabilitation Medicine and Physiotherapy, Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, China. The Ministry of Health/Environment, Health Department of Baghdad/ Al Karkh (Training and Human Development Center Research committee) (registration number: REC.2021057) of Iraq gave their approval to this study.

*Clinical characteristics and treatment evaluation*

The types of PHFs fractures will be determined using anteroposterior and axillary lateral views. The duration of time it will take for bone union to occur will be determined using radiography images. Age, gender, fracture type, first treatments, mechanism of fractures, duration of orthosis treatment, rehabilitation management, and complications (e.g. pressure areas, rash, skin injuries) were all examined as clinical outcomes. The assessment will include the DASH (Disabilities of the Arm, Shoulder, and Hand), SPADI (Shoulder Pain and Disability Index), CONSTANT score, SST (Simple Shoulder Test) examination of the shoulder joint, the Muscular Strength (MS), and the orthosis satisfaction questionnaire.

A total of 53 patients with PHFs were treated from February 2021 to February 2022. The inclusion criteria were patients with closed PHFs, subluxation, dislocation, or slight displacement, willingness for the follow-up a rehabilitation program and the exclusion criteria were the PHFs associated with humeral shaft fractures, vascular fractures, nerve injury, pathological fractures, and open fractures or patients having any previous neurologic disease that could affect the rehabilitation process. Throughout the treatment procedure, all patients were scanned with X-rays in the emergency room, as per our departments usual protocol.

Table 1
Demographic characteristics of the patients (N=53)

| Patients Characteristics | Non-orthosis users group | Orthosis users group | Statistical significance |
|---|---|---|---|
| Patient (n) | 26 | 27 | NS |
| Age | 51.1 ± 14.01 | 60.63 ± 11.83 | NS |
| Gender | | | |
| Male | 17 | 19 | NS |
| Female | 9 | 8 | NS |
| # Side | | | |
| Left | 11 | 10 | NS |
| Right | 15 | 17 | NS |
| Neer classification | | | |
| Type 1 | 6 (11.3 %) | 8 (15.0 %) | NS |
| Type 2 | 13 (24.5%) | 14 (26.4 %) | NS |
| Type 3 | 5 (9.43 %) | 4 (7.54 %) | NS |
| Type 4 | 2 (3.77) | 1 (1.88%) | NS |

*Note: *Fracture type:1=one part; 2 two-part; 3 = three-part; 4 = four-part. Data are mean ± SD or n; quantitative variables were analyzed using the Student's t test and Levene's Test for Equality of Variances , NS not statistically significant (p <0.0001).*

*Management procedure*

All of the patients were initially treated with a U-Slab before being referred to an outpatient clinic for further assessment. The orthosis users group will receive orthosis device for (4-6 weeks) during hospitalization, while passive activity beginning at 3 weeks, depending on the fracture state. Once their orthosis was taken down, patients underwent physical therapy for stretching and strengthening exercises. Then when the fracture has been confirmed to be healed radiographically, the orthosis will be removed as soon as possible. Radiographic union was defined as " presence of osseous bridging between the main fragments " on at least one radiograph, and the clinical union was defined as " no pain/tenderness at the fracture site"(Athreya et al., 2019) . Non-orthosis patients will be treated conservatively in the hospitals, with pain-free passive pendulum exercises conducted for 6 weeks while wearing a collar.cuff or/and a U.sling brace, followed by 6-12 weeks of physiotherapist-supervised active range of motion R.O.M exercises as pain allows. Finally, three X-rays were taken at each visit over the course of three months to assess for bone union during the treatment period.

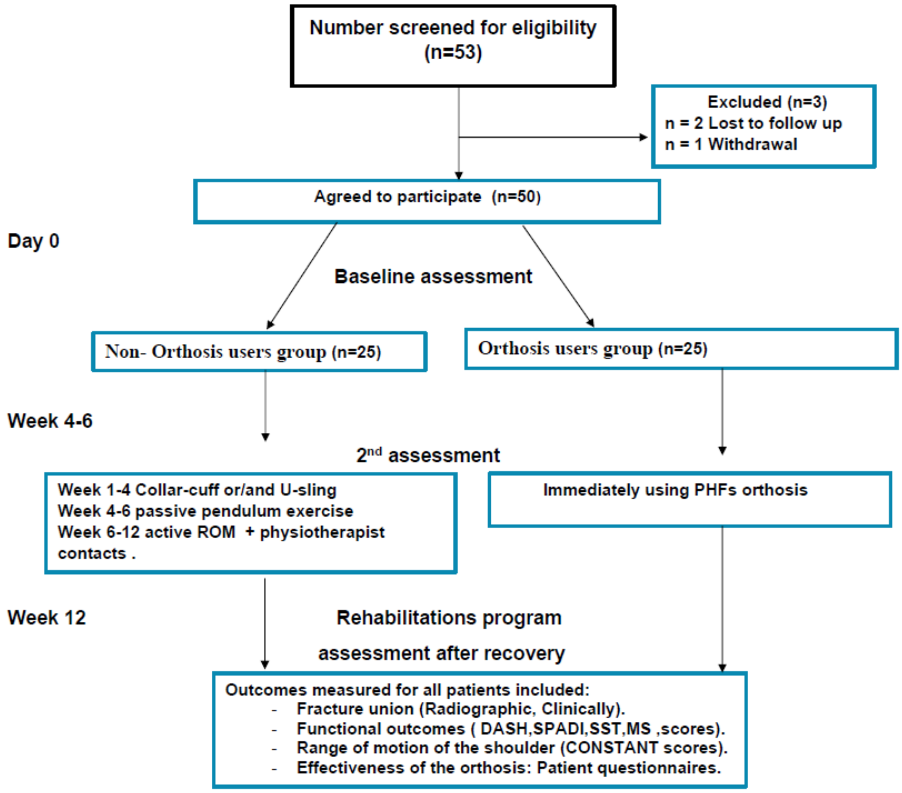


Figure 1. *Study flow diagram*

*Equipment produced for PHFs orthosis*

The following equipment is required to design and manufacture the PHFs orthosis: Plastic polypropylene 4mm-5mm, soft EVA 4mm-5mm covering, velcro, straps, and pelvic adjustable for negative and positive cast models. Before casting, should be aware of the following: Anatomy of a shoulder joint and upper extremity limb, biomechanics principles, and cast impression technology, as well as practical components such as orthosis fabrication, transfer of the correct alignment to the definitive orthosis, PHFs cosmetic finish, patient training and evaluation. The casting instructions are intended to assist in the creation of a well-fitting orthosis that includes basic equipment. It's also critical to construct a complete negative cast using the patient's upper-limb cast, which covers the shoulder in its usual position. Wrist and hand are in a normal position, with the elbow flexed at 90 degrees and a minor abduction.

*Simple biomechanical aspects of the model*

The anterior view covers the scapula and arm muscles, as well as the humerus bone and extends the orthosis shall with 90 degrees free spaces over the anterior portion of the radial and ulnar bones at pronation position of the forearm and wrist joint freely as function position hand. ***Therefore,*** extend the orthosis shall be covering the posterior region of the forearm 4 cm laterally ulnar bone and 4 cm medially radial bone, you can cover the muscles on the scapulas posterior surface and the arm, as well as the humerus bone. The medial view of the elbow joint will be 90 degrees flexion of the PP posterior shall, with a 5 cm wall spanning the radial bone area and 2 cm above the medial epicondyle depending on the design patent fattens and anatomical elbow joint. Whereas, lateral view the supraspinatous muscle is 2cm above the suprascapular notch and covers the glenohumeral and acromioclavicular joints on the anterior side. A flat molding for the scapula with an infraspinatus and teres minor on the posterior aspect and cover the scapula-associated distal head of the humerus bone until the elbow joint is completely covered lateral epicondyle and triam line 2 cm above medial epicondyle of elbow joint. finally, stretch the orthosis shall to cover the back of the forearm and extend the shall of the orthosis to encompass the posterior part of the forearm, 4 cm laterally ulnar bone and 4 cm medially radial bone.

*Fitting and finishing*

Accomplish the initial fitting according to P&O requirements, well modify the plastic as needed and smooth the trim line, cut off the excess and smooth the trim line, glue this throughout, then cut out the orthosis with an oscillating saw, going to follow the outline and remove the plastic shell from the plaster model and the stocking from within the shell. Checking the proper alignment and fit of the shoulder socket, making sure there is no overdone compression in the bone prominent to avoid any future complications, asking the patient about comfort in seating, the weight of the orthosis parallel with the adjustment of the straps fixation, during this time try to move their fingers freely and the proprioception is feeding back normally, and also checking the elbow area from the medial condyle to make sure it is free. Finally, the orthosis can be wrapped in a variety of pictures, forms, and drawings, depending on the patient's desire to choose something that matches their personal style while still being cosmetically pleasing.

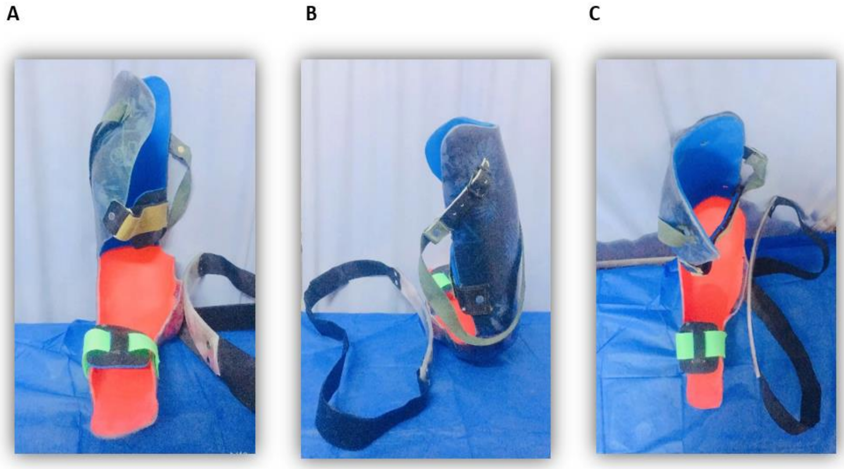


Figure 2. *(A), (B), (C) PHFs orthosis model design with the straps.*

## 3 Results and Discussions

*Characteristics of clinical manifestation*

Initially, 53 patients were enrolled in this study, with a mean age of 58.1 years (range 36–79), 36 males and 17 females, with left arm involvement in 21 cases and right arm involvement in 32 cases; mechanism of injury was fall from height 42 and high-energy trauma 11; and patients with associated problems were pelvis fractures (2 patients), shoulder dislocation (1 patient), and displacement (2 patients). According to Neer's classification patients had one-part fractures :14, two-part fractures: 27, three-part fractures: 9, and four-part fractures: 3. Therefore, 50 patients completed the trial, though. Two patients were not being followed up on, and one patient had dropped out. however, The Mean±SD for (DASH 26.24±13.12), (SPADI 5.06±2.35), (SST 65.00±23.21), (MS 3.80±0.98), (CS-AFL 76.04±10.93, CS-UAFL 83.16±11.27) and the Mean±SD for bone union was (17 patients) 53.06±5.48 (union) less than 60 days, (16 patient) 73.56 ± 8.84 (delayed union) between 61-89 days and (17 patients) 99.81±8.86 more than 90 days (non-union). Data were normality distributed assessed with normality test (Shapiro-Wilk test, Kolmogorov-Smirnov test) except for the fracture union (Shapiro-Wilk test 0.0151, Kolmogorov-Smirnov test 0.0488) duration, all other data were normally distributed.

*Consequences of the assessments and evaluations*

The orthosis users group consisted of (25 patients), with eight having type 1# fractures, fourteen having type 2# fractures, four having type 3# fractures, and one having type 4# fractures. The DASH score was 18.54(10.07), SPADI score was 3.66(1.83), SST score was 81.64(12.26), and the MS grade was 4.20 (0.76). The CS-AFL score of 83.76(6.43) and the CS-UAFL score of 89.08(4.97) are both "Excellent" scores. The average duration of bone union for (12 patients) was 52.08 (6.00) union takes less than 60 days, throughout (8 patients) was 67.25(4.02) delayed union occurs in 61-89 days and (5 patients) was 97.00(6.32) for more than 90 days are considered non-union. Whereas, the non-orthosis group of 25 patients, there are six patients with type 1# fractures, thirteen patients with type 2# fractures, five patients with type 3# fractures, and two patients with type 4# fractures. The DASH score was 33.94(11.26), the SPADI score was 6.46(1.95), the SST score was 48.33(19.24), and the MS grade was 3.40(1.04). The CS-AFL score of 68.32(8.85) and the CS-UAFL score of 77.24(12.72) both relate to a "Fair" score. The average duration of bone union for five patients was 55.40(3.36) union takes less than 60 days, throughout eight patients was 79.88(7.77) delayed union occurs in 61-89 days and twelve patients was 100.08(9.83) for more than 90 days are considered non-union. Based on the data normality results, the statistics for intergroup comparison were performed with either an unpaired t-test or a Mann-Whitney U test. An unpaired t-test revealed a statistically significant difference between the two groups' functional evaluations (DASH, SPADI, SST, MS, CONSTANT score).

The non-orthosis users group of mean±SD 33.94±11.26 reported a substantially higher DASH score (P-value <0.0001) than the orthosis group 18.54±10.07 indicating a greater level of inability to execute specific activities. Similarly, the mean SPADI score in the non-orthosis user group 6.461±1.959 and orthosis users group 3.663±1.834, (P-value <0.0001), report a high level of pain severity and a lack of functional skills. The SST in orthosis user group was 81.68±12.26 and in non-orthosis user group was 48.33±19.24, with a (P-value <0.0001), indicate that the orthotics user group had more shoulder function activity than the non-orthotics user group. Furthermore, the MS grade of the orthotic user group was 4.20±0.76, whereas the MS grade of non-orthotic users was 3.40±1.04, (P-value 0.003), signify that the orthotic user group muscle power strength recovered to a proximately normal level up to 5 grades higher than non-orthotic users. The orthosis user group had the highest level of ability to carry out normal daily activities in the affected limbs (CS affected limb, orthosis user group 83.76 ±6.437, P-value <0.0001) compared to the non-orthosis user group (CS affected limb, Non-orthosis group 68.32±8.85). All of these measures assessing upper limbs function reveal that the new orthosis was more effective in preserving and promoting arm function, as well as allowing for better functional mobility.

Table 2
Shows the effects of comparisons between groups

| Variable | t | df | P-value |
|---|---|---|---|
| **DASH** | -5.094 | 48 | 0.0001 |
| **SPADI** | -5.213 | 48 | 0.0001 |
| **SST** | 7.307 | 48 | 0.0001 |
| **MS** | 3.098 | 48 | 0.003 |
| **CS-AFL** | 7.050 | 48 | 0.0001 |
| **CS-UAFL** | 4.334 | 48 | 0.0001 |

*Note: *t- statistical , df - degrees of freedom , statistically significant (p <0.0001).*

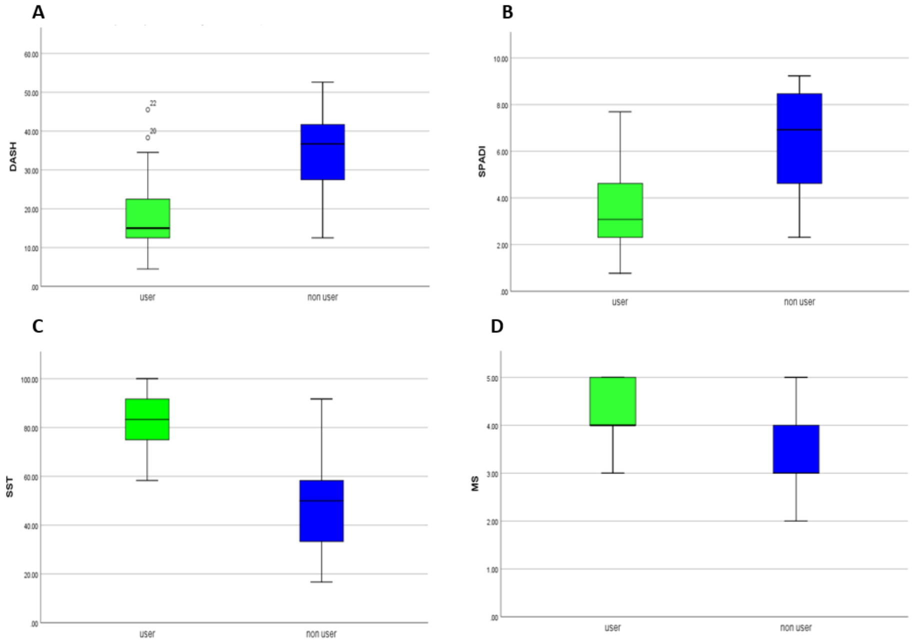


Figure 3. *(A) DASH, (B) SPADI, (C) SST, (D) MS The clinical outcomes for orthosis users and non-users.*

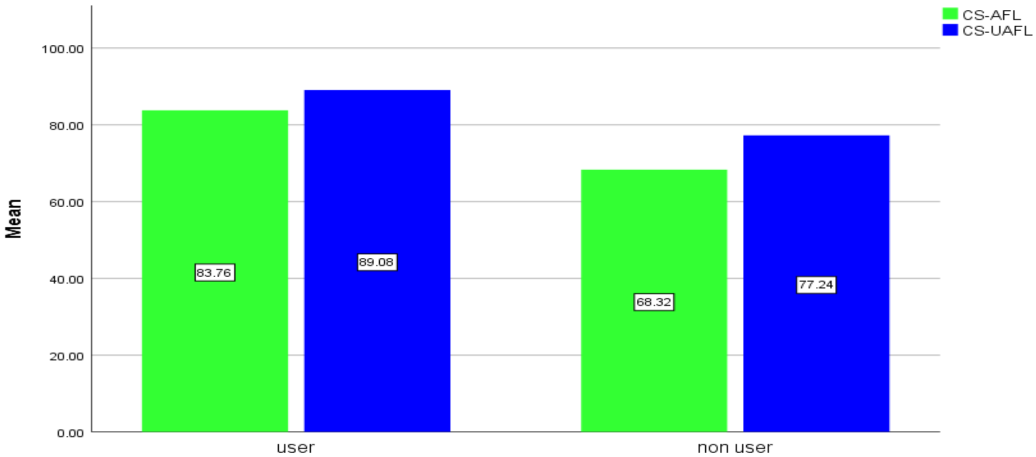


Figure 4. *Assessment function of normal daily activities in the affected and unaffected limbs for both groups.*

*Duration of bone union*

Finding that the bone union of 17 patients have a complete union, 16 patients have a delayed union, and 17 patients have a delay to non-union due to a long duration of follow-up of more than 90 days, implying that the majority of patients skip follow-up. As a result, patients with type two and type three fractures are more likely to wish to union, but fractures with more fragments and extensive displacement take longer to heal and are more likely to be associated with chronic disease. Therefore, Young patients with minor fractures and minimal displacement can be reunited faster than older patients. A consequence, the majority of patients are comfortable with their achievable rate, and surgical is not required. Where the shifting of the humeral head on the coronal plane has little effect on the eventual functional outcome. In practice, we recognize that the majority of non-unions in PHFs occur in surgical neck fractures, since the adhesion of fracture fragments may be diminished due to the tilted orientation. According to the median union time for oblique fracture line >30 degrees and transverse line 30 degrees fractures was 11 and 15 weeks, respectively. The humeral shaft was classified as delayed union at 24 weeks and non-union at 6 months (Mahabier et al., 2013). However, treatment for non-union, according to some study, should begin within three months (McQueen, 2008),(Norris, 1990). It would appear to be contradictory in this study, given that the majority of fractures healed within three months after injury. On (Fig.5), orthosis users had a substantially shorter fracture union duration (orthosis group 18.04 ± 20.01, non-orthosis group 65.92 ± 83.44, P-value 0.0054), indicating that the orthosis allowed the fracture to heal while providing sufficient support and stability. The orthosis user group timeframe for union, delayed union, and non-union are more dynamic than those who receive a conservative therapy non orthosis user. Furthermore, an orthosis satisfaction survey found that patients were fell protected and comfortable with the new orthosis.

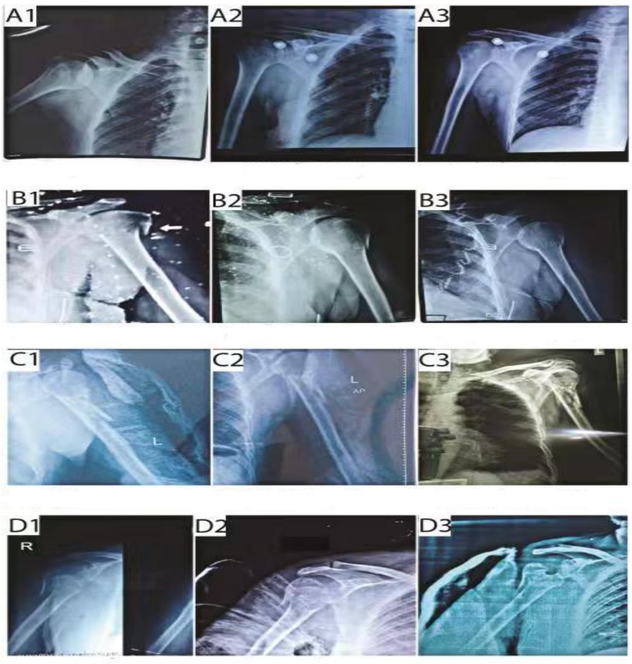


Figure 5. *Bone union is assessed via a radiographic picture. A1, A2, and A3, 43 years old, a male with part 2# right PHFs associated with shoulder dislocation using orthosis on the (55 days) of bone union. B1, B2, and B3, a 48-year-old woman's left PHFs, part 2#, using orthosis (54 days) of bone union.C1, C2, and C3, a 61-year-old male part 3# with left PHFs using orthosis 60 days of bone union. D1,*

*D2, and D3, a 60-year-old lady part 3# right PHFs non-user orthosis (109 days) bone of union delay.*

Table 3
Duration of bone union. (N=50)

| Duration | groups | N | Mean | SD | Minimum | Maximum | P-value |
|---|---|---|---|---|---|---|---|
| Less than 60 days | user | 12 | 52.08 | 6.007 | 43 | 60 | 0.269 |
| | non user | 5 | 55.40 | 3.362 | 50 | 59 | |
| 61-89 days | user | 8 | 67.25 | 4.027 | 63 | 75 | 0.001 |
| | non user | 8 | 79.88 | 7.772 | 69 | 88 | |
| More than 90 days | user | 5 | 97.00 | 91 | 91 | 107 | 0.531 |
| | non user | 12 | 100.08 | 90 | 90 | 120 | |

*Note: *N=50 , SD : stander deviations*

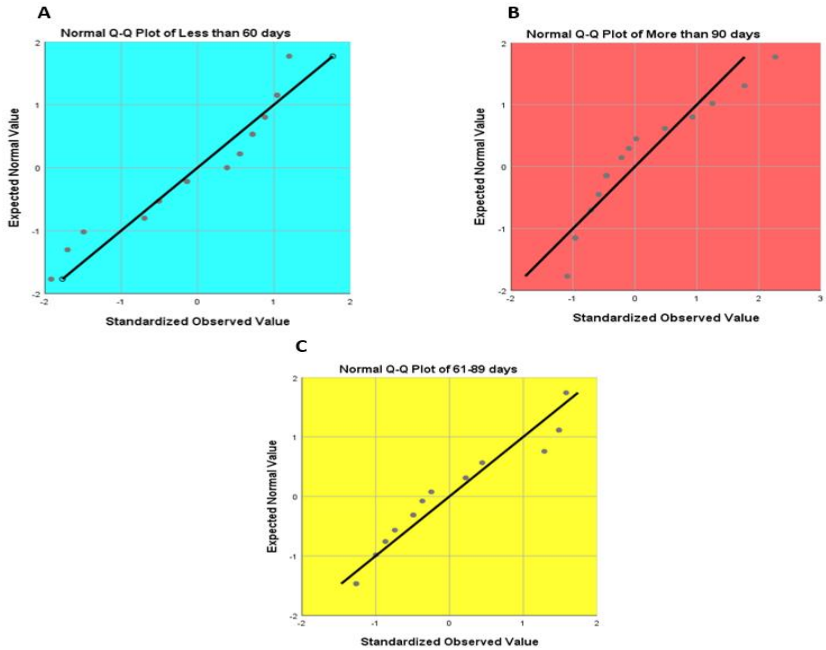


Figure 6. *(A), (B), (C) Display the period of bone union is distributed in a certain way.*

*The groups correlations*

Patients with a humeral head tilt of roughly 130°" relative to the shaft and 30°" retro torsion relative to the elbow condyles had acceptable range of motion. Three patients had restricted range of motion, making it difficult for them to button their shirts, carry a heavy object, wash their backs, push an object with their affected limb, and reach for an item on a high shelf. The introduction of the orthosis resulted in a speedier fracture union and functional recovery, according to functional evaluation methodologies. All of the patients experienced a minor loss of function, but there were no complications as a result of the orthosis treatment. In addition, according to a quantitative result report for each variable DASH, SPADI, SST, and MS, both groups have a substantial correlation coefficient that has been flagged as present = 1 perfect pearson correlation (significant at the 0.01 and 0.05 levels).

Table 4

*Orthosis and non-orthosis user (N=50 patients correlation).*

| **Variable** | **Matrix. COr** | **DASH** | **SPADI** | **SST** | **MS** |
|---|---|---|---|---|---|
| **DASH** | Pearson Correlation | 1 | .644** | -.490** | -.324* |
| | P-value | | .000 | .000 | .022 |
| **SPADI** | Pearson Correlation | .644** | 1 | -.585** | -.278 |
| | P-value | .000 | | .000 | .051 |
| **SST** | Pearson Correlation | -.490** | -.585** | 1 | .333* |
| | P-value | .000 | .000 | | .018 |
| **MS** | Pearson Correlation | -.324* | -.278 | .333* | 1 |
| | P-value | .022 | .051 | .018 | |

*Note: ***. Correlation is significant at the 0.01 level (2-tailed).*

**. Correlation is significant at the 0.05 level (2-tailed).*

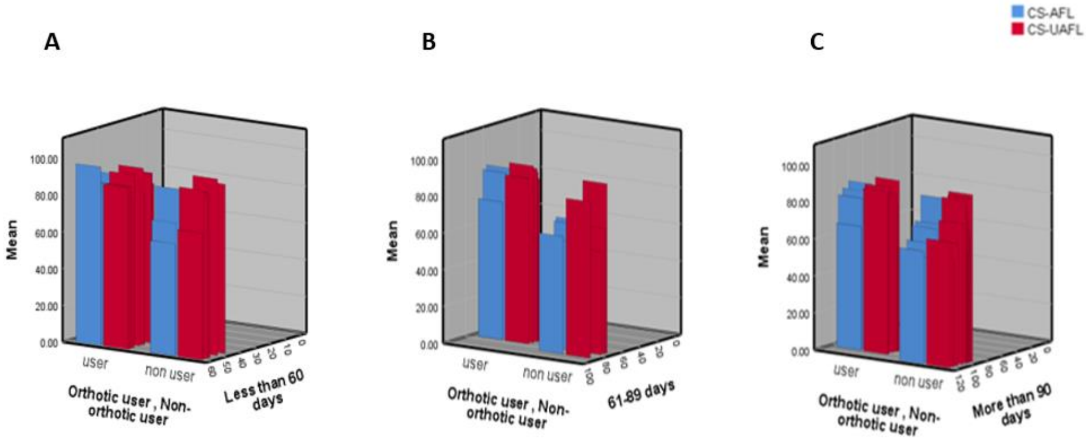


Figure 7. *(A) Bone union, (B) bone delay union, (C) bone delay or non-union using the CS-AFL and SC-UAFL relationships between the two groups.*

Figure 8. Models of PHFs orthotics devices

*3.2 Discussions*

The goal of PHFs should be to reduce pain and improve shoulder function (Parnes & Jupiter, 2010). However, as the number of fracture fragments rises, the functional prognosis worsens: whether treated operatively or conservatively, 4-fragment fractures perform substantially worse than 2- or 3-part fractures (Wolters et al., 1996). Despite this, research on the outcomes of displaced four-part PHFs shown that both operative and non-operative treatment can produce equal results. Furthermore, they discovered no evidence that surgical therapy with an angle-stable device were superior to conservative treatment in patients over 60 with three and four-part displaced fractures (Fjalestad et al., 2012). The hanging therapy could cause distractions and displacements at the fracture site, according to the researchers (Rees et al., 1998).Gardner and his colleagues, study (Gardner et al., 1997) elucidate that the muscle activity can generate five times the force generated by weight bearing. Were the PHFs orthosis has a triangle shoulder joint socket that effectively compresses the pectoralis major and infraspinatus muscles, with an anterior and posterior shell that is contoured to accommodate the shoulder musculature, while allowing early shoulder and elbow fixation. Clement et al. recently reported a research with 211 patients with mildly displaced proximal humerus fractures, ranging in age from 65 to 98. The average Constant-Murley score was 68.8 a score of better than 55 was considered excellent. At the eight to sixteen-weeks follow-ups, it was found that PHFs orthosis users had better shoulder function than non-users, as indicated by the Constant score. This, on the other hand, is likely to have clinical significance (Athreya et al., 2019).

During the healing process, there have been instances of non-union. Consider the fracture pattern, fracture displacement, bone quality, past rotator cuff disease or arthrosis, and patient function while developing a treatment plan. The most important goal is to build a strong skeleton that allows for early shoulder range of motion (C M Court-Brown et al., 2001; Keene et al., 1983; Mathews & Lobenhoffer, 2004; Olsson & Petersson, 2006; K Zyto et al., 1995; Karol Zyto et al., 1997). Several studies have demonstrated that applying micro-movement to fractures improves fracture healing. The application of gravity to the lower limb has traditionally been used to add micro-movement. In the upper limb, gravity is presumably less of a factor in creating micro-movement (Goodship & Kenwright, 1985; Kenwright et al., 1991; Rubin & Lanyon, 1987).

As a consequence, patients using the PHFs orthosis exhibited greater rates of union on radiographs and reduced anteroposterior tolerable residual angulation. Nonetheless, based on our clinical findings, founding that patients younger than 60 years old had much better functional results when compared to patients older than 60 years old. The pull of surviving muscle attachments would boost the possibility of a successful closed reduction in the three and four-part fractures which prove that the PHFs orthosis can be used to treat 3 and 4 part PHFs with minimal displacement, were the model cast design can be tweaked for each case and distribute the force on the muscles based on the severity of the case condition. Despite that our study did demonstrate benefits in both pain and functional outcomes, which reflects directly on the efficacy of the custom functional PHFs orthosis. The design allows easier inspection of the skin and soft tissue, elbow 90° flexion, shoulder in a natural position with slight abduction, and the wrist joint freely as function position hand. The benefits of this orthosis include satisfaction in a well-fitting and comfortable fit, less time-consuming, may be removed at any time when needed, such as for showering, and can be adjusted using velcro straps. In the present study, the non- operative treatment led to satisfactory functional results in elderly low-demand patients which supports our hypothesis. Age, fracture type, and radiologic findings did not influence functional results independently. Due to its low cost-effective features, this novel orthosis may be more appropriate in low-income countries which is soft cushioned and light in weight. Furthermore, the fabrication process is simple, time-saving, and requires less skilled orthotics professionals. Finally, will observe in this study that the benefits of online services often necessitate the employment of live service delivery mechanisms for supervising physical therapy to continue the rehabilitation process. Users are convinced that our orthosis will provide adequate fracture protection with practical evaluations.

There appeared to be some inevitable limitations to this study such as the COVID-19 epidemic occurred during the study period. Patients with these types of fractures are usually referred to supervised therapy. Surveillance rehabilitation, on the other hand, consumes a significant amount of healthcare resources, raising the question of whether patients benefit from supervised exercise treatment (Handoll et al., 2015; Mellstrand Navarro et al., 2019). The sample size was insufficient, patients were mostly over 30 years, it would have been better if included all possible ages. The length of follow-up and therapy varied, and data collection was limited during the pandemic, the current study did not receive adolescent and children patients with humerus fractures for unknown reason. To make meaningful conclusions about client compliance and satisfaction, a large sample size would be required. The majority of studies lack randomization, comparators, and independent evaluation, which makes it impossible to draw clinically meaningful conclusions. Patient compliance is the most crucial limiting factor, especially when it comes to velcro on the pelvis, therefore patients who do cooperate with their orthosis have a higher chance of success. In our experience, noncompliance has been attributable to concerns about comfort, a high-profile and weighty orthosis, and insufficient pain control due to incorrect shaping. The majority of the PHFs orthosis used in this study are commercial thermoplastic material designs, which specialists found limiting in clinical practice. Instead, it could explore lamination techniques using carbon fiber and thermosetting materials, which are commonly costed.

## 4 Conclusion

This device is encouraging since non-operative therapy is appropriate for the majority of proximal humerus fractures. The PHFs orthosis can be made in various sizes for both male and females, making it easy to use in community-based rehabilitation (CBR) outreach programs. The experiments prove that it is a favorable treatment option, as these conventional methods have few complications in rehabilitation services when undertaken with careful patient selection coupled with meticulous technique. For proximal humerus fractures, new orthosis outperformed existing conservative treatment choices. Whereas, comparing our orthosis to other products in therapeutic interventions, if available, in order to show that our bespoke functional orthosis is better tolerated by patients, and effective in treating proximal humerus fractures. Our new orthosis was superior to the traditional methods of conservative treatment for proximal humerus fracture (PHF).

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