Humerus Fracture Bracing as a Solution

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Humerus shaft fractures account for 8% of all upper extremity fractures, around 640,000 per year. Since the 1980’s, – standard of care for treating the majority of humeral shaft fractures has been the use of the Sarmiento fracture brace. These fractures included mid-shaft and distal 1/3 diaphyseal extra-articular humerus fractures. The majority (50%) or 450,000 of humeral diaphyseal fractures are mid-shaft, with 8% or roughly 50,000 being distal 1/3 fractures. Sarmiento stated that fracture bracing for distal 1/3 extra-articular humerus fractures has a 95% union rate with an acceptable average varus deformity of 9 degrees. All had excellent functional results.

However, despite excellent results with fracture bracing of distal 1/3 extra-articular humerus fractures, there is still a preponderance of surgical treatment for these fractures. There are multiple studies demonstrating excellent results with surgical treatment of these fractures, with near 100% union rates and excellent functional outcomes. But there is very little difference between the results of fracture bracing versus surgical fixation. So why is fracture bracing being used less in the treatment of distal 1/3 humerus fractures, and humeral shaft fractures in general? The most cited reasons are pain, deformity and skin irritation.

Orthopaedic surgeons are taught in residency that to ensure proper immobilization of a fracture, the joint above and below the fracture needs to be immobilized. Currently there are no fracture braces on the market that provide immobilization of the joint above and below, including the Sarmiento. Due primarily to their location, distal 1/3 humerus fractures are more unstable than mid-shaft fractures. Since the conventional brace does not cross the elbow joint, the fracture is poorly controlled. That is, typical humeral fracture braces do not immobilize the elbow joint. As a result, patients often complain of motion and pain at the fracture site.

Secondly, patients and many surgeons are unaccepting of any bony deformity seen clinically and radiographically, even though the deformity does not produce dysfunction. As with supracondylar humerus fractures in children, there is an overwhelming prevalence of surgical fixation of these fractures to minimize/eliminate varus deformity. The majority of patients with this resulting “gun-stock” deformity have complete functional recovery, but are left with a cosmetic deformity. There is a paucity of literature suggesting that displaced and/or angulated supracondylar humerus fractures in children should be treated non-operatively. Our current society dissuades surgeons and patients from accepting deformity.

Lastly, humeral fracture bracing utilizes a fabric sleeve beneath the brace. Depending on temperature and humidity, these sleeves frequently become soiled and lead to skin breakdown. Both patients and physicians complain about odor, not mention the complications from skin breakdown.

However, surgical treatment of distal 1/3 humerus fractures is not without risks. The surgery takes a long time and is difficult to perform. There is also a risk of neurologic injury involving the radial nerve, and conventional fixation can fail. Jawa stated that in his series of surgical repair of distal third humerus shaft fractures, there was a 26% complication rate: 5% loss of fixation, 5% infection, 15% iatrogenic radial nerve palsy, and 5% joint stiffness. In Yang’s series, there was a 5% iatrogenic radial nerve palsy. Surgery for humerus fracture repair is expensive, costing around $15,000 to $25,000. (CMS)
The Aligner PHX Brace

Because of these stated issues, a varus/valgus-hinged humeral fracture brace with a forearm extension, dubbed the Aligner PHX Brace, was designed. Earlier versions included a humeral fracture brace coupled to a hinged elbow ROM brace to control the distal fracture fragment. Although the brace controlled the distal fracture fragment, the varus deformity could not be eliminated. Initial thoughts were to just bend the hinged portion of the hinged elbow brace into valgus, and this valgus bend to the fracture brace corrected the varus deformity. We have since developed and patented a specialized hinge that allows for in-situ anatomic reduction of the fracture.

This white paper will summarize outcomes of 24 patients treated in the Aligner PHX Brace from April 2013 to January 2015.

Materials and Methods:

24 consecutive patients from two surgeons (GG and JV) were included in this analysis. Inclusion criteria were the following: presence of a distal 1/3 extra-articular humerus fracture or a mid-shaft humerus fracture. Both pediatric and adult patients were considered. Patients with documented radial nerve injury prior to orthopedic evaluation were also included. Contraindications included intra-articular distal 1/3 humeral diaphyseal fractures, supracondylar humerus fractures, and combined proximal radius/ulna and distal 1/3 humeral diaphyseal fractures. The 24 patients are shown in Table 1.

Each patient was fitted with the Aligner PHX Brace within the first week of injury, often times in an office setting. Each arm was held by the orthopedic surgeon while the orthotist placed the brace onto the arm. Once the brace was adjusted, a gentle manipulation of the varus/valgus fracture hinge was performed by the orthopedic surgeon. The overwhelming majority of patients tolerated this reduction with minimal to no discomfort. Once the reduction was performed, the hinge was tightened and post-reduction radiographs were obtained. For patients with marked varus deformity (greater than 25 degrees), the reduction was accepted when the varus deformity was less than 10 degrees. The patients were then asked not to remove the brace and to follow-up within 5 – 7 days.

Upon the next appointment, each patient obtained new radiographs prior to being seen by the orthopedic surgeon. Any patients with residual varus deformity seen by radiographs underwent a second minor manipulation. For patients with initial deformity greater than 25 degrees, the majority of these patients had spontaneously corrected the deformity to less than 5 degrees and only minor manipulation was necessary. The skin about the fracture brace was also evaluated and noted for any breakdown.

The patients were followed on a weekly or biweekly basis until fracture callus was identified by radiographs. Once callus was noted, the varus/valgus hinge was returned to a neutral position and the elbow range-of-motion portion of the brace was unlocked to allow for full elbow range of motion. Patients were seen every two weeks once callus was demonstrated.
The Aligner PHX brace was discontinued once radiographs showed solid bridging callus.

Patients were followed afterward monthly until solid union was noted. Patients were left non-weightbearing until solid union was noted.

Table 1.

<table>
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% reduction in angulation

Average Angulation 19.7 5.0 74.8%

Results:

The Aligner PHX Brace has had excellent results. The initial angular deformity for the 24 patients in this study prior to brace placement was 19.7 degrees, and was corrected to an average of 5.0 degrees, an improvement of almost 75% reduction in the angulation. All patients were questioned once their fractures were healed and the Aligner PHX brace was discontinued. Patients reported good to excellent results with no patients experiencing dissatisfaction with their
clinical or radiographic results. Previously reported shoulder and elbow stiffness with use of conventional fracture bracing has been not encountered with the Aligner PHX Brace.

There were minor complications with the early prototypes that included skin breakdown from the stockinette/ humeral component of the fracture brace. Of note, there is a similar complication rate with conventional humeral fracture bracing. Skin liners were changed weekly and antifungal cream was placed on the skin. With the new lining developed for the Aligner PHX brace, the brace is fitted directly to skin without the need for stockinette. This made a vast improvement in the management of these fractures with little to no skin breakdown.

Other complications included initial loss of reduction because of noncompliance. This too has been improved with new figure of 8 strap configuration making the brace more comfortable to wear.

Patient #1 initially had anatomic alignment and callus on radiographs and the brace was removed prematurely. The patient resumed normal activities and noted increasing pain upon follow-up the following week.

Patient #12 was lost to follow-up and it is unknown how he ultimately healed.

Patient #17 had fractured the Aligner PHX Brace and delayed seeking medical advice for an extended period of time. He presented one month after initial placement of the Aligner PHX Brace not wearing the brace and with the brace in two pieces.

**Discussion:**

Humeral shaft fractures, and particularly extra-articular distal 1/3 humerus shaft fractures are difficult to treat, either operatively or non-operatively. To date, there is no fracture brace on the market that addresses angulated fractures. The Aligner PHX Brace is the first brace recognized by CMS to facilitate fracture reduction and to eliminate the inherent varus deformity seen in distal 1/3 humerus fractures thus lessening the need for surgical repair. The Aligner PHX Brace has also been shown to eliminate residual varus or valgus deformity in mid-shaft humerus fractures that failed conventional static fracture brace treatment. Prior to the advent of the Aligner PHX Brace, many of these fractures would have been left to heal angulated/displaced or required surgical repair.

Early versions of the Aligner PHX Brace, which included a humeral fracture cuff with elbow extension, and subsequent "bending" of the elbow hinge into valgus, showed promise in treating these fractures. However, the bending of the hinge was less reproducible and it was difficult to measure how much to bend the hinge. Incorporation of the varus/valgus hinge eliminated the guesswork. Measurements obtained from radiographs assisted in the determination of the position of the hinge.

There was some difficulty in deciding where the valgus hinge should be placed. In vitro analysis could not be reproducible in vivo. It was determined that best results occurred with the valgus
hinge placed at the fracture apex and the humeral cuff trimmed laterally to allow for the distal fracture to correct its alignment.

Skin problems were also noted. The majority of skin problems were related to the skin liner being wet with perspiration or from routine daily cleaning. Patients were followed weekly for skin checks and changing of the skin liner. Subsequent Aligner PHX Braces incorporated mesh-like interface that was placed directly against skin and skin pressure ulcerations and superficial infections were nearly completely eliminated.

Initial loss of reduction can occur if the Aligner PHX Brace was not kept snug against the proximal arm, which allowed the distal arm to deform into varus. A gunslinger-type shoulder harness was designed to keep the Aligner PHX Brace from lifting off the shoulder proximally. An abduction pillow has also been used in some patients to negate issues pertaining to body habitus.

The authors learned that initial callus was needed prior to allowing the elbow to start moving. Bridging callus was required before the brace could be removed. The Aligner PHX Brace was typically worn for 4 – 6 weeks, often times longer depending on radiographs.

Angular deformities in the sagittal plane were also corrected by flexing the elbow. The typical posterior angulation of the distal fragment was corrected by placing the elbow into flexion and locking the elbow ROM joint.

Patient satisfaction with the Aligner PHX Brace was overwhelmingly positive. Because of the design of the figure-of-8 straps, and control of motion of the elbow and forearm, nearly all patients felt much more stable in the brace.

In conclusion, the Aligner PHX Brace is an exciting, revolutionary new brace designed to eliminate the need for surgical treatment of distal 1/3 humeral shaft and mid-shaft humerus fractures. Early results from its use are very encouraging.*

*Dr. Grant receives royalties from and is a consultant for Medical Technology, Inc DBA Bledsoe Brace Systems regarding the Aligner PHX brace.
References
