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Abstract: Introduction
Humeral shaft fractures are a common injury. Non-operative treatment in the form of functional bracing is the mainstay of management. The prefabricated humeral brace is the most popular and commonly used design. Since it was first described by Sarmiento in 1977 there has been little evolution in the design of the humeral brace. We provide the first evaluative study on the efficacy of the Clasby brace. This is a novel design which, unlike the Sarmiento design, utilises Charnley's principles of 3 point fixation to achieve and maintain fracture reduction. We compare this to those of other studies exploring the efficacy of the prefabricated humeral brace. In addition we determine patient satisfaction and pain control within the brace.

Methods
All patients presenting to our orthopaedic fracture clinic with a humeral shaft fracture, between August 2010 and February 2011, were managed in the brace.

Results
26 patients were included in the study. The mean age was 61. There was a 96% union rate. Mean time to union was 11 weeks. There were no cases of mal-union (defined as angulation of greater than 25o in any plane.) The mean satisfaction score was 8.3 (out of 10)

Conclusion
The Clasby brace is efficacious at managing humeral shaft fractures. In our study of a contiguous series of patients, its use resulted in an excellent rate of union with associated low rates of mal-union. It is effective at controlling pain and is associated with high patient satisfaction scores.

Suggested Reviewers:

Dear Editor,

Thank you for considering our submission for inclusion in your journal. Since Sarmiento developed the prefabricated humeral brace for the management of humeral shaft fractures, over 33 years ago, - there has been little work done to improve this or develop new designs. We evaluate the efficacy a novel humeral brace the Clasby brace for the management of humeral shaft fractures.

The Authors

Evaluation of the Clasby: A New Brace, Based on Charnley's Principle of 3-Point Fixation, for the Management of Humeral Shaft Fractures

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Keywords: humeral shaft fracture, brace, non-operative management.

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Introduction

Humeral shaft fractures are not uncommon injuries. They account for 1-3% of all fractures[1,2]. Given the shape of the arm, patients often experience discomfort with the forms of plaster cast immobilisation which have traditionally been utilised: namely the U-slab or hanging cast methods[2]. Although these can be effective treatment modalities, the splints can be challenging to apply in more distal and proximal fractures and also in large patients. In addition, both splints are also associated with significant elbow and shoulder stiffness once immobilisation has been discontinued[3].

The prefabricated humeral brace, as popularised by Sarmiento, has, to some degree, circumvented this problem[4]. Pre-contouring to the shape of the arm allows for greater comfort and also allows for movement at the elbow. Having said this, it does not restore alignment and so has been associated with varus, anterio-posterior and rotational mal-

alignments[5]. When compared to operative fixation, the complication rate of the prefabricated functional humeral brace is low[4]. However, given the full contact of the rigid brace with the arm's contours soft tissue complications may arise. These have been reported at a frequency of between 1 to 5%[67].

The Clasby brace is a recent addition to the pantheon of treatment options available and has been designed specifically to treat humeral shaft fractures. It was designed to addresses some of the weaknesses of the traditional bracing options. The brace is a flexible neoprene construct with well-padded rigid struts. The proximal part of the brace mounts the shoulder and divides into two padded straps which wind around the contra-lateral axilla and fasten anterior to the chest (Figure 1). We report the first results from the use of the Clasby brace in the management of humeral shaft fractures, with the study endpoint being fracture union.

Methods

All patients presenting to the orthopaedic fracture clinic with humeral shaft fractures, between August 2010 and February 2011, were enrolled in the study. In the accident and emergency department patients were initially placed in a U-slab, in one case, in a collar and cuff and then referred to the fracture clinic. As the study progressed the Clasby became available to patients on initial presentation to the accident and emergency department. Patients were asked to rate their pain control and overall satisfaction with the U-slab or collar and cuff using visual analogue scores. In fracture clinic the Clasby brace

was applied. Pre and post brace application radiographs were taken. Patients were seen at 2 weeks and then 4 weekly intervals with plain radiographs taken at each presentation. Patients were asked to rate their pain control and overall satisfaction with the Clasby using visual analogue scores. Patients were kept in the brace until both clinical and radiographic union were achieved. With regard to the satisfaction scores the 0 and 10 anchor points were “not at all satisfied” and “very satisfied” respectively. With regard to the visual analogue pain scores the 0 and 10 anchor points were “no pain” and “pain as bad as it could be”. Radiographic union was defined as the presence of bridging callus on at least one view of the humerus. Clinical union was defined as the absence of movement or pain at the fracture site.

Statistical Analysis

Shapiro-Wilk test was performed to determine the distribution of the data. Pain and satisfaction scores were found to be non-normally distributed. Wilcoxon-rank test was performed to compare these paired non-parametric data. Age and union times were found to be normally distributed and compared with the findings of other studies using the one sample t-test. Gender and laterality frequency were compared using two-tailed binomial distribution test. Categorical (proportions) data were compared using Fisher’s exact test.

Results

26 patients presented to our unit with humeral shaft fractures between August 2010 and February 2011. 20 patients were placed in a U-slab on initial presentation. In 5 cases the Clasby brace was applied at the time of injury. 1 patient was placed in a collar and cuff. The mean age was 61.5 (range: 11.5 -95.7). There was a slight male preponderance with 17 male and 9 female patients. This was not statistically significant. (p= 0.16 two-tailed binomial distribution test). Left-sided injuries were more common than right (left 17 vs right 9). The difference was not statistically significant (p=0.17 two-tailed binomial distribution test). The median and modal times in U-slab/collar and cuff were 12 and 0 days respectively. 20% (5/26) were applied at the time of injury. The mean time within the brace was 59.3 days. The most common mechanism of injury was a fall from standing, which accounted for 70% (19/26) of cases. The commonest precipitants for fall were ice and alcohol causing 37% and 16% of falls. One fracture occurred following weight lifting (table 1).

The commonest distribution and pattern of fracture is shown in table 2.Middle third fractures were the most common site of injury with spiral fractures being the most frequently observed fracture pattern.

All fractures were closed injuries. There were two cases of associated radial nerve palsy occurring at the time of the fracture. One resolved spontaneously. The second failed to respond and the patient underwent surgical exploration and operative fixation of the fracture. One patient was lost to follow-up. Neither the patient who underwent operative fixation nor the patient who was lost to follow-up could be included in the time to union

analysis. At the time of the study one patient had been in the brace for the less than four weeks hence definitive determination of union could not be made. The patient was however included in the patient satisfaction and pain control analysis. One patient passed away from an unrelated medical condition after fracture union. One patient was non-compliant with the brace. He was included in the analysis on an intention to treat basis. There was a 96% (23/24) union rate. The mean time to union was 11 weeks (range: 3-22 weeks).

There were no cases of varus-valgus deformity of greater than 25^{o}. 90% had less than 5^{o} anterior-posterior angulation deformity. There were no cases of anterior-posterior malunion of greater than 20^{o}. Table 3 shows our study results compared to the findings of other studies using the prefabricated Sarmiento humeral brace.

There were 19 and 18 responses to the satisfaction and pain visual analogue questionnaires respectively. Satisfaction was rated from 0 to 10; 0 representing a perception of being "not at all satisfied" and 10 being "very satisfied". Pain was graded a scale of 0 to 10; a response of 0 constituting "no pain" and 10 constituting "pain as bad as it could be". The results are shown in table 4. The Clasby brace was associated with a statistically significant improvement in pain control and satisfaction scores when compared with U-slab plaster.

Discussion

The Edwin *Smith Papyrus*, dating from around 1600BC and as such the earliest surviving surgical text, details management of humeral shaft fractures in ancient Egypt.

Patients' arms were bound in cloth bathed in alum to increase the rigidity of the material[8]. To this day, splinting of the humerus remains the first line management for fractures of the humeral shaft[9]. Current methods of immobilisation include the U-slab plaster and the prefabricated humeral brace popularised by Sarmiento. The U-slab represents little improvement on the alum soaked cloth design used by the Ancient Egyptians over 3,500 years ago. Although the U-slab plaster can achieve good fracture reduction in the initial stages of treatment, application of the plaster is a costly and time consuming process which requires a high degree of expertise. Several re-applications are often required over the treatment period. Patients often find it an uncomfortable form of treatment[2]. In comparison, the pre-fabricated humeral brace is quicker and easier to apply, being easily adjustable if required. In addition it permits early mobilisation of the elbow and shoulder which avoids later stiffness and may facilitate and expedite the healing process. A number of studies have shown that humeral shaft fractures treated in the brace have high union rates and low rates of mal-union. These traits have given it ascendancy over operative modes of fixation for a number of years[10]. The largest study evaluating the efficacy of the pre-fabricated humeral brace was conducted by Sarmiento and observed union rates of 98% for closed humeral shaft fractures. However, in the literature as a whole, non-union rates of between 2% and 23% have been reported[5-9]. The disparity between the results observed by Sarmiento's group and those at other centres may be due lack of expertise when compared to the centre of origin of the prefabricated humeral brace.

In the current study the Clasby brace showed very good union rates and low rates of mal-union. A union rate of 96% was observed**.** The results were comparable to union

and varus/valgus deformity rates observed in Sarmiento's study of his humeral brace[5]. The cohort using the Clasby brace were significantly older than that in Sarmiento's, with mean ages being 61 and 36 respectivley. The difference reached statistical significance. Age has been shown to influence the likelihood of union in humeral shaft fractures, with older patients more likely to suffer from non-union[7]. When compared with studies matched for age; the Clasby brace outperformed the prefabricated humeral brace with regard to union rates. However the difference did not reach statistical significance.

$25^{o}$of varus/valgus deformity is generally regarded as the limit of cosmetic and functional acceptability[5,9,10]. There were no cases of angular deformity greater than 25^{o} in any plane in patients using the Clasby brace. Anterior-posterior deformity is less well tolerated than a valgus/varus deformity. The former is cosmetically more apparent and functionally more disabling at lesser degrees of angulation when compared to a valgus/varus deformity[11,12]. The acceptable limit of angulation in this plane is reported at 20^{o} [11,12]. The Clasby brace was particularly effective at maintaining anatomical anterior-posterior alignment (lateral radiographs). 10% of patients had an anterior-posterior mal-alignment of greater than 5 degrees. There were no cases of anterior-posterior malunion of greater than 20^{o}. These results are superior to the most comprehensive results reported for the prefabricated humeral brace[4]; where 30% have anterior-posterior mal-alignment of greater than 5%. This difference reached statistical significance ($p<0.05$). The mean time to union was shorter for the Clasby brace (11 weeks) compared with the humeral brace (11.5 weeks) but this did not display statistical significance.

The pre-fabricated humeral brace is based on Sarmiento plastering/splinting techniques[13]. Its efficacy is dependent upon effective moulding of the plaster such that it

matches the contours of the limb to which the brace is applied. This plastering technique is effective in the lower limb in the form of the Sarmiento cast whereby the contouring facilitates weight-bearing at the patella. However, in the humerus this plastering paradigm is not necessarily conducive to maintenance of fracture alignment in the upper limb and nor is it able to restore or reduce the fracture pattern to achieve and maintain anatomical alignment[5].

In contrast, the Clasby brace is designed to function according to Charnley's principles of three-point moulding. As such, it aims to not only maintain fracture position but also has a greater propensity to restore anatomical alignment (figure 2c, 2g; 3c, 3g)[14]. The difference in principle is significant. As the humeral brace functions by matching the contour of the arm, it is recommended that it is not applied while the swelling remains significant as at this stage the contouring is imperfect[4]. However, given its mode of action, the Clasby brace can be applied immediately following injury, so dispensing with the need for initial U-slab or hanging cast treatment and their potential difficulties.

The Clasby brace consists of two continuous elements (Fig 1). The first is the brace moiety which encases the arm. This contains 3 padded longitudinal struts which lie against the lateral, anterior-lateral and posterior-lateral aspect of humeral head proximally and lateral epicondyle distally. Two medial straps tighten the brace against the arm and provide medial points of fixation resisting deformity. This construct observes Charnley's principle of three-point moulding in a number of plains. The proximal segment of the arm brace mounts the shoulder before diverging into the straps, which are the second component of the brace. The straps wrap under the contralateral axilla. This provides support to the injured limb and prevents hunching of the ipsilateral shoulder through the

action of trapezius and levator scapulae. Satisfaction scores were significantly higher and pain score significantly lower within the brace compared to the U-slab. The design modifications in this study translated to good union and anatomical alignment rates.

Conclusion

Like the Sarmiento Pre-fabricated Humeral Brace, the Clasby Brace offers significant advantages over traditional U-slab management including, ease and speed of application, ease and speed of adjustment, improved patient comfort and water tolerance that allows a patient to bathe with the brace on. Our study indicates it has potential advantages over the Sarmiento humeral brace which includes the ability to be used from day one, hence obviating the need for initial U-slab management with its associated difficulties. Its apparent better performance at preventing mal-union may be due to its ability to not only hold but reduce fractures (figure 2c, 2g; 3c, 3g). With the Sarmiento method the initial reduction relies on the more technically demanding application of the U-Slab. As our study shows, the disadvantage with a removable brace centres around the potential for non-compliance and thus more time may be needed to focus on patient education in order to optimise results. As a result of the findings from this study, the Clasby brace has now been made available for first line management of these fractures in our institution's accident and emergency department.

Our results on a contiguous series of patients show that The Clasby Brace, which utilises Charnley's principles of 3 point moulding, is an effective way of treating humeral shaft fractures. It is associated with low rates of mal-union and high rates of union,

patient satisfaction and pain control. These outcomes are comparable to other studies which have managed these fractures according to Sarmiento's paradigm of total-contact bracing and utilised a pre-fabricated humeral brace. However, due to its ability to reduce the fracture and be applied from day one, the Clasby Brace potentially offers improved clinical outcome, time and cost saving advantages.

Conflicts of Interests

The Authors confirm that there is no conflict of interests.

Figure 1: Clasby brace being worn by a model.

Figure 2: Radiographs of humeral shaft fracture managed in the brace: a-d: AP, e-g: Lateral

a/e: radiograph at the time of fracture

b/f: radiograph in the u-slab

c/g: radiograph in Clasby brace

d/h: radiograph at union

Figure 3: Radiographs of humeral shaft fracture managed in the brace: a-d: AP, e-g: Lateral

a/e: radiograph at the time of fracture

b/f: radiograph in the u-slab

c/g: radiograph in Clasby brace

d/h: radiograph at union

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Table 1

The table shows the mechanisms of humeral shaft fractures.

Mechanism	Per Centage of pt (No pts)
Fall	70% (19)
due to ice	(6)
due to alcohol	(3)
Sport & Recreation	19% (5)
Pushbike	(1)
Weight-lifting	(1)
Football	(1)
Ice Skating	(1)
Walking Dog	(1)
Household accident	(1)

Table 2

The table shows the commonest sites and patterns of fracture.

Site	Per centage (No Patients) This Study
Upper Third	7.7% (2)
Upper-Middle Third Junction	23.1% (6)
Middle Third	5.7% (15)
Mid-lower Third Junction	11.5% (3)
Lower Third	0 % (0)
Pattern	
Spiral/Oblique	53.8% (14)
Transverse	30.8% (8)
Comminuted	15.4% (4)

Table 3

The table shows the results of fractures managed in the Clasby brace and those from studies involving the use of the pre-fabricated humeral brace as popularised by Sarmiento. P-values are determined relative to the Clasby results (one sample t-test). The values in bold represent statistically significant p-values.

	Clasby	Sarmiento *et al* 2000[5]	Toivanen *et al* 2005[7]	Ekholm *et al* 2006[2]	Denard *et al* 2011[9]
Mean Age yrs	**61**	**36 p<0.001**	53	58	**36 p<0.001**
Commonest Site	Middle 1/3	Middle 1/3	Middle1/3	Middle 1/3	Middle 1/3
Union rate (%)	92	98	77	90	79
Union time (wks)	1l	11.5	N/A	N/A	**20 p<0.001**
Malunion (%) (>25^{o} Any Plane)	0	3.3	0	N/A	N/A
≤5^{o} ant-post (%)	**90**	**70 (p<0.05)**	N/A	N/A	N/A

Table 4

Pains and satisfaction scores for the Clasby brace compared with scores given for the U-slab/collar & cuff. Satisfaction was rated from 0 to 10; 0 representing a perception of being "not at all satisfied" and 10 being "very satisfied". Pain was graded a scale of 0 to 10; a response of 0 constituting "no pain" and 10 constituting "pain as bad as it could be. The values in bold represent statistically significant p-values.

	U-slab/collar & cuff	**Clasby**	
Mean Pain Score (range)	7 (1-10)	4 (2-10)	**p=0.01**
Mean Satisfaction Score (range)	5.7(0-10)	8.3 (5-10)	**p<0.005**

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