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Closed Treatment of Humeral Shaft Fractures by Functional Bracing using Polyvinyl Chloride versus Plaster-of-Paris Cast: A Randomized Clinical Trial

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Introduction: This study compared Polyvinyl Chloride (PVC) made vs Plaster of Paris (POP) made functional braces in the closed treatment of fractures of the humeral shaft. Outcomes examined were the rate of fracture union, radiographic alignment, DASH scores and the range of motion of the shoulder and elbow.

Methods: This was a parallel randomized clinical trial conducted at the Corazon Locsin-Montelibano Memorial Regional Hospital from July 2016 to July 2017. All eligible patients were included and randomly allocated into PVC and POP treatment groups. All patients were followed-up on the 3rd, 6th, 10th, and 14th week for clinical and radiographic evaluation.

Results: There were 31 patients, 14 and 17 in the PVC and POP groups, respectively. The median rate of union in the PVC and POP groups were 10.50 and 10.00 weeks, respectively. The median varus and valgus angulation in the PVC and POP groups were 15.75° and 16.5°, respectively. The median anterior and posterior alignment in the PVC group was 1.7° and POP group was 9.6°. The median DASH score of the PVC and POP groups were 7.1 and 12.5, respectively. The median range of motion in the elbow was 135° for both groups. The median range of motion in the shoulder in the PVC group was 150° and POP group was 140°.

Conclusions: There was a high rate of union of humeral shaft fractures with acceptable functional outcome with the use of the PVC made functional brace compared to the traditional POP made functional brace.

Keywords: Humeral shaft fracture, functional brace, polyvinyl chloride brace

Fractures in the humeral shaft is around 3% of all shaft fractures.[1] Clinical experience has shown that these fractures have a higher rate of healing with excellent return of function and most will heal with non-surgical management.[2,3] Functional bracing has been widely accepted on its conservative treatment.[4,5,6,7] Moreover, it is an ideal candidate for functional fracture bracing because minor angular deformities do not affect functional activity and accurate anatomic reduction is often not necessary.

Fracture bracing stabilizes long bone fractures of the humerus by compressing surrounding muscle and soft tissue. The cylinder-shaped brace provides a stabilizing force equal in all directions, which limits motion at the fractured site while shoulder and distal joint motion is maintained.[8] As muscles contract, it produces a pseudohydraulic environment wherein the increase in size is converted into compressive forces within the cylinder.[9]

Functional bracing can be done with the use of the traditional plaster of Paris (POP) or other pre-fabricated commercially-available cast brace which is considerably more expensive and not widely available. This study was done to evaluate effectiveness of using PVC as an innovative option which relatively widely available but requires craftsmanship.

The PVC-made cylinder will allow the application of the principles of functional bracing that is consistent pressure exerted on the fracture during active muscle contraction. Thus, it is the soft-tissue compression, not the stiffness of the material in the brace or cast, which provides stabilization.[10] Moreover, the shape of the soft tissue containment does not depend on the strength of the cylinder material, but rather on the size and shape of the cylinder. Therefore, the internal force mechanically stabilizes the fracture and with the careful development of prefabricated fracture braces, the technique has become more practical and acceptable.

The humerus is not a weight-bearing bone and compressive forces are not as significant a factor in healing as in other long bones. Rigid immobilization of the shoulder therefore is not necessary because the glenohumeral articulation allows significant mobility with minimal torsional stress. Also, the physiologic-dependent position of the upper arm uses gravitational forces to realign the fracture fragments.[11]

Zagorski, et al. stated that patients had excellent or a good functional result with full range of motion of the extremity.[12] In another study, they concluded that the treatment of choice for diaphyseal fractures of the humerus is the prefabricated brace.[13]

Camden, et al., compared functional bracing with the traditional method of plaster U-slab immobilization and noted that there was no difference between groups for healing time and final alignment of the fracture.[14] However, Herkert, et al. found out that even if there is a perfect primary reposition, impossibility of proper retention in the plaster cast may lead to post-primary osteosyntheses.[15] Balfour, et al. emphasized the use of a humeral fracture brace requires attention to and comprehension of proper technique.[16,17] The Sarmiento brace remains the treatment of choice, in spite of newer intramedullary operations that are allegedly minimally invasive and technically less complicated.[18]

Toivanen, et al. found that by applying a functional brace immediately after injury, there was no significant difference found in respect to healing between different AO-type fractures.[19] Ekholm, et al. contradicts that in simple (type A) fractures, the non-union rate seems to be higher, and patients with healed non-unions after revision surgery reported worse functional outcomes.[20] In another study by Sarmiento, et al., 2.5% required operative intervention because of a non-union.[21]

Ozkurt, et al. noted that based on proper indications, functional bracing applied after regression of edema may be the treatment of choice.[22] Papasoulis, et al. found that fractures treated with functional bracing heal in an average of 10.7 weeks at 94.5% union rate.[23,24]

Modified functional cast brace can be applied on the 1st day of the presentation in most of the situations.[25] There was no available literature regarding the use of PVC as an innovative option being a material used for crafting a functional brace for the closed treatment of humeral shaft fractures.

The study was done to evaluate the efficacy of the PVC made brace based on: the rate of healing as determined by the rate of union and radiographic alignment; functional outcome quantified by Disabilities of the Arm, Shoulder and Hand (DASH) Score and return of movement at the shoulder and elbow measured by the range of motion at 14 weeks post injury.

Methods

This study was a parallel randomized clinical trial conducted in Corazon Locsin Montelibano Memorial Regional Hospital, Bacolod City, Negros Occidental, Philippines. The study was approved by the institution's Ethics Review Committee, CLMMRH RERC 2016-11.

Inclusion Criteria

All patients eighteen years of age and/or older, with closed humeral shaft fractures (between 4 cm distal to the surgical neck of the humerus and 4 cm proximal to the superior border of the olecranon fossa), cooperative and mobile patient who gave consent were included.

Exclusion Criteria

Patients with multiple injuries, pathologic or open fractures, with neurovascular-associated injury and those who refused were excluded.

Treatment Protocol

All patients included in the study underwent close reduction and initial immobilization with a coaptation splint placed from the axilla to the elbow, ending in the deltoid. The injured extremity was stabilized with the elbow in 90º of flexion for 7 days. Patients were re-evaluated in the outpatient department one week after the initial injury for the swelling, skin conditions and loosening of the splint. The procedures were done by the principal investigators and treated patients according to the treatment group determined by randomization.

Treatment Groups

PVC Group

The coaptation splint was removed and the upper extremity was cleaned with sterile gauze soaked in 70% alcohol. With the patient upright and the limb hanging free, cast padding was applied followed by the brace. The brace consisted of two sleeves cut from a PVC pipe. The brace encircled the patient's arm. It had adjustable Velcro straps to hold the sleeves together. The brace extended from approximately 5cm distal to the axilla to 5cm proximal to the olecranon. Patients were given instructions on how to adjust the brace and tighten the Velcro straps several times a day to accommodate the changes in the girth of the extremity that occurred as the swelling subsided. Patients were also instructed to wear the brace at all times. The PVC brace set-up and size templates are shown in Figure 1.

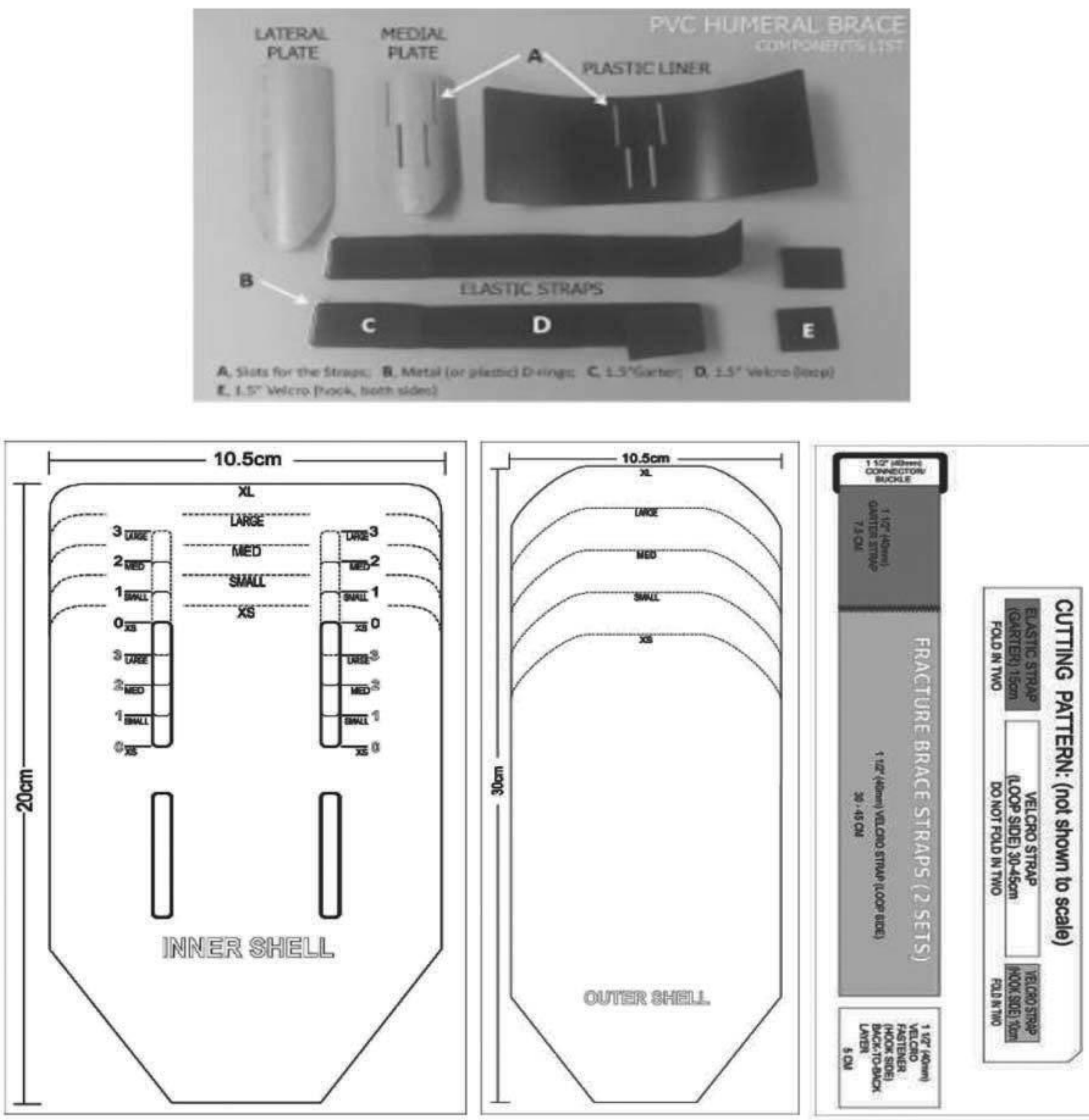

Figure 1. The PVC brace components and size templates.

POP Group

The initially applied coaptation splint was removed and the upper extremity was cleaned with sterile gauze soaked in 70% alcohol. With the patient sitting and leaning slightly to the injured side, cast padding was applied and functional brace using Plaster of Paris was wrapped around the upper arm from axilla to elbow. The sleeve was worn at all times except for bathing. The brace also had a collar and cuff for comfort.

Outcomes

Treatment groups were followed-up on the 3rd, 6th, 10th and 14th week where radiographic measurements and clinical assessments on the fitting of the braces were done. The functional braces were removed in the 14th week of follow-up with adequate bony union. Bone fracture healing, union, was assessed radiographically with the development of adequate callus formation; clinically with the absence of motion and pain on the fracture site. Bone alignment was measured, in degrees, in AP and lateral radiographs. Functional outcome measurement utilized the DASH score instrument which was performed by the principal investigators, where a 0-100 scale where 100 indicated most disability.[31] Return of movement was measured as range of motion measured in degrees, using a goniometer centered in the axis of rotation of the joint being examined at the 14th week. Sample cases, with patients' permission, on PVC brace are shown in Figure 2.

Figure 2. Sample cases, with patients' permission, on PVC brace.

Sample Size

Eligible patients who satisfied the inclusion criteria of the study, consulting at the Emergency Department (ED) and the Out Patient Department (OPD), during the accrual period from July 2016 to July 2017, were recruited. No sample size calculation was performed.

Randomization

Randomization into two clinical groups was done through fishbowl technique, wherein the investigator draws from a container with rolled papers containing the words "Plaster of Paris" or "Polyvinyl Chloride" and then returned the rolled paper in the container after determining the treatment group of the patient. The principal investigators generated the random allocation sequence with 50% chance for each treatment group and a third person, who was not part of the study, was asked to verify the randomization, check the measurements, assessment findings to reduce bias.

Statistical Analysis

Descriptive statistics summarized the demographic data. A T-test was used to compare the mean scores of measurements of angulation, time to union, measurement of humeral length and elbow ROM outcomes. If data were not normally distributed, a non-parametric test (Mann-Whitney U) was used to explore the sample populations.

Results

A total of 31 eligible patients were included in the study. They were randomly allocated to the PVC group which had 14 patients and POP group which had 17 patients. All patients received the interventions stated in the protocol and none was lost to follow-up or withdrew from the study (Figure 3).

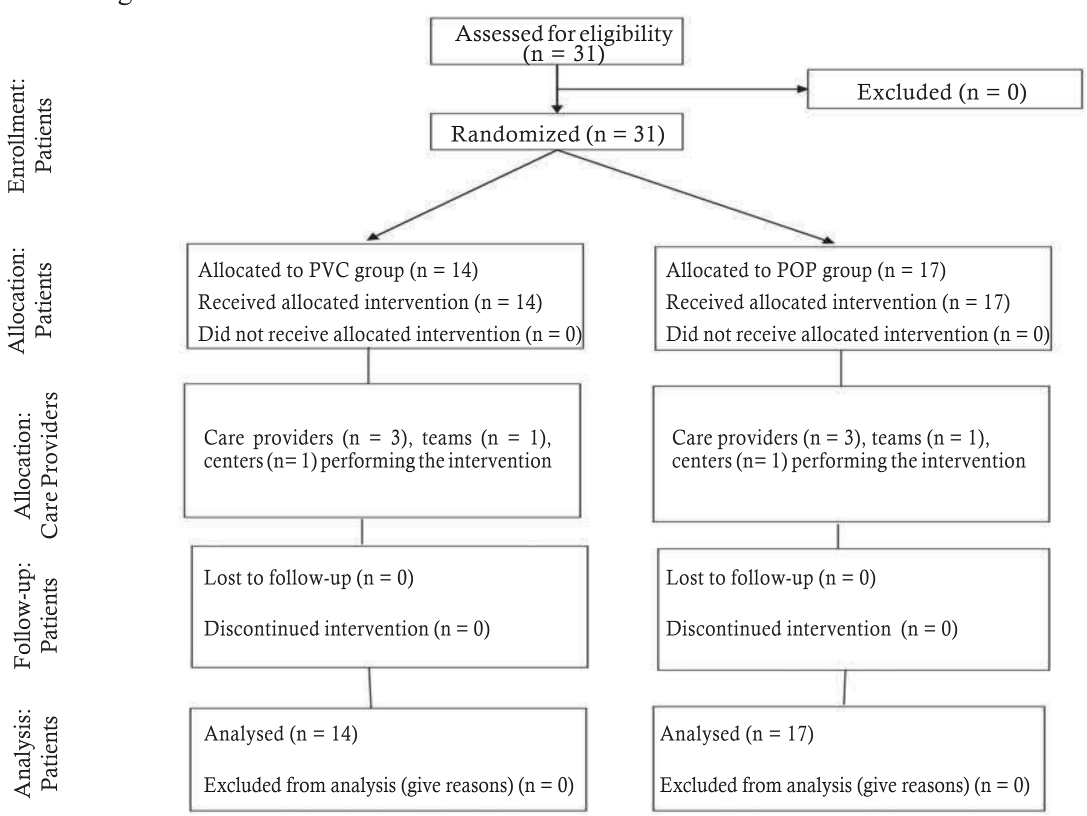

Figure 3. CONSORT[32] flow diagram.

Most of the patients in the PVC and POP groups were between 18-37 years old at 92.8% and 64.7%, respectively. They were predominantly males in the PVC and POP groups at 85.7% and 70.6%, respectively. The laterality of the extremity involved was equally distributed in the PVC group while mostly the right was involved in the POP group at 70.6%. The injuries in the PVC and POP groups were due to vehicular accident at 71.4% and 58.8%, respectively. Most of the fractures AO classifications in the PVC and POP groups were 12-A2 at 42.9% and 41.2%, respectively. The demographic profiles of patients are shown in Table 1.

Table 1. Demographic profiles of patients.

Variable	Classification	PVC Group (n=14)		POP Group (n=17)	
		Frequency	Percentage (%)	Frequency	Percentage (%)
Age	18-27	6	42.8	4	23.5
	28-37	7	50	7	41.2
	38-47	0	0	1	5.9
	48-57	0	0	0	0
	>58	1	7.1	3	17.6
Sex	Male	12	85.7	12	70.6
	Female	2	14.2	5	29.4
Extremity Involved	Right	7	50.0	12	70.6
	Left	7	50.0	5	29.4
Mechanism of Injury	Fall	4	28.5	7	41.2
	Vehicular Accident	10	71.4	10	58.8
AO/OTA Classification	12-A1	0	0	2	11.7
	12-A2	6	42.9	7	41.2
	12-A3	5	35.7	5	29.4
	12-B1	1	7.1	2	11.7
	12-B2	1	7.1	1	5.9
	12-B3	0	0	0	0
	12-C1	0	0	0	0
	12-C2	0	0	0	0
	32-C3	1	7.1	0	0
Total		14	100	17	100

The median rate of union in the PVC and POP groups were 10.50 and 10.00 weeks, respectively. There was no significant difference when grouped according to PVC (Sum of ranks=219.50) and POP (Sum of ranks=276.50), U=114.500, p=.857.

Radiographic measurements were done on the 14th week of follow-up. The highest varus and valgus angulation in the PVC and POP group were 25.00° and 30.20°, respectively. The median varus and valgus alignment in the PVC and POP group were 15.75° and 16.50°, respectively. There was no significant difference when grouped according to PVC (Sum of ranks=195.00) and POP (Sum of ranks=301.00), U=90.000, p=.249. The highest anterior and posterior alignment in the PVC and POP group were 23.00° and 19.60°, respectively. The median anterior and posterior alignment in the PVC and POP group were 1.70° and 9.60°, respectively. There was a significant difference when grouped according to PVC (Sum of ranks=168.00) and POP (Sum of ranks=328.00), U=63.000, p=.025.

Functional outcome and range of motion measurements were done at the 14th week follow-up schedule, corresponding to the removal of the braces. The highest DASH score in the PVC and POP group were 35.80 and 66.70, respectively. The median DASH scores of the PVC and POP groups were 7.10 and 12.50, respectively. There was no significant difference when grouped according to PVC (Sum of ranks=223.50) and POP (Sum of ranks=272.50), U=118.500, p=.984.

The median range of motion in the elbow of the PVC and POP groups was 135°. Though the medians were identical, there was a significant difference in the distributions of the two groups (PVC (Sum of Ranks=273.00) and POP (Sum of Ranks=223.00), U=70.000, p=.008). The median range of motion in the shoulder in the PVC and POP group were 150.00° and 140.00°, respectively. There was a statistically significant difference detected between both groups (PVC (Sum of Rank=274.50) and POP (Sum of Rank=221.50) U=68.500, p=.019). Fracture healing and functional outcome results are shown in Table 2.

Discussion

The main limitations of the study were a small sample size and a single center study design, although, it included all eligible patients who satisfied the inclusion criteria

Table 2. Fracture healing and functional outcome results.

Variables	GROUPS	N	Median	Average Deviation	Sum of ranks	U	Z	p-value
Rate of Union (weeks)	PVC	14	10.50	2.8	219.50	114.500	-.180	.857
	POP	17	10.00	3.1	276.50			
Varus/Valgus Alignment (degrees)	PVC	14	15.75	4.5	195.00	90.000	-1.152	.249
	POP	17	16.50	5.0	301.00			
Anterior/ Posterior Alignment (degrees)	PVC	14	1.70	5.1	168.00	63.000	-2.236	.025
	POP	17	9.60	4.2	328.00			
DASH (score)	PVC	14	7.10	9.6	223.50	118.500	-.020	.984
	POP	17	12.50	17.3	272.50			
Range of motion in the elbow joint (degrees)	PVC	14	135.00	0.0	273.00	70.000	-2.658	.008
	POP	17	135.00	15.6	223.00			
Range of motion in the shoulder joint (degrees)	PVC	14	150.00	5.0	274.50	68.500	-2.345	.019
	POP	17	140.00	32.9	221.50			

and consulted the ER and OPD of the institution in 1 year. Random allocation, use of uniform treatment protocols and use of a third person to verify measurements and findings were done to minimize bias.

Most of the patients included were 18-37 years old, predominantly males and the patients' injuries were mostly due to vehicular accidents. These were associated with the rising number of young men using cheap and affordable motorcycles as the primary mode of transportation. The union rate was noted at 100% with the median time to union in 10-10.50 weeks. The results were better as compared to Gelder, et al. with 96 % and the mean time to union at 11 weeks and Sarmiento, et al. with 97.5% and the mean time to union at 11.5 weeks.[21,26] Moreover, study results were better compared to Koch, et al. Rutgers, et al. and Ali, et al. at 87% healed clinically at a mean of 10 weeks, 90% union rate, and 83%, respectively.[18,27,28]

The median varus and valgus alignment in PVC and POP groups were 15.75° and 16.50°, respectively. The study showed statistically significant difference in the anterior and posterior alignment in the PVC and POP groups with 1.70° and 9.60°, respectively. Study results were within the acceptable criteria and these results support the results of Papasoulis, et al. where the mal-alignment was noted within the acceptable range, Wallny, et al. with 12.6% of patients had more than 10° of mal-alignment, and Ozkurt, et al. with 6° varus and valgus, and 8° anterior and posterior angulation.[17,22,23] The study has shown better results with the use of functional bracing compared to Sarmiento, et al., where fractures treated with prefabricated brace and 87% patients had angulation less than 16% in anteroposterior view and 81% patients healed with less than 16% angulation in lateral view.[9]

The functional outcome results measured using the DASH score of patients in the PVC and POP groups were 7.10 and 12.50, respectively, which show a generally good clinical outcome with minimal disability. These findings were better than Toivanen, et al. where 72 of 93 (77%) patients' fractures healed without problems.[19] Moreover, the outcomes agree with the results of Ekholm, et al. and Kapil, et al. which confirm an acceptable functional outcome after successful fracture-brace treatment with a high rate of union with nearly normal elbow motion and some restriction of shoulder motion.[20, 24]

Statistically, there is a significant difference in the range of motion in the elbow and shoulder joint, wherein, the PVC group has better range of motion. This may be due to the less weight, thinner, ease of adjustment and better comfort in the PVC group. The difference in the range of motion of the elbow and shoulder may be small but clinically significant, since, there will be a wider range of motion to accommodate free joint motion for better function. These results are consistent with the findings of Zagorski, et al. and Camden, et al. using prefabricated brace and found a good functional result with full range of motion of the extremity.[12,13,14] In contrast, Rosenberg, et al. revealed an impaired functional outcome in the shoulders after humeral shaft fracture. Although, the fracture union is usually achieved following the functional bracing of humeral shaft fractures, the shoulder function in the injured limb may remain impaired.[29] In addition, Fjalestad, et al. found loss of external rotation in the shoulder, being present in (38%) of the fractures.[30] Finally, these findings support Herkert, et al. Balfour, et al. and Pal, et al. wherein the use of functional bracing including modifications and innovations remains a viable option for the treatment of humeral shaft fractures. It, however, requires a very close, carefully observing aftercare, attention and comprehension of proper technique.[15,16,25]

In summary, no difference was detected between the two study groups with respect to the rate of union, varus and valgus alignment and DASH scores. However, results showed a difference between the two groups where the PVC group had better results in the anterior and posterior alignment, and range of motion in the elbow and shoulder joints.

Conclusion

This study suggests that fractures of the humeral shaft can be adequately treated with a functional brace made with PVC. In this study, there is a high overall rate of union of humeral shaft fractures with good alignment and functional outcome after successful functional fracture brace treatment. The modified functional cast brace made with PVC is an option in the treatment of humeral shaft fractures which, when used appropriately, is safe, and offers better comfort and functional outcomes.

Recommendation

The authors recommend the use of PVC pipe as an novel material for functional bracing of the fractures of the humeral shaft. Also, further studies utilizing such a modified PVC brace with a larger population, multicenter settings and long-term follow-up are needed.

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