Valve or No Valve: A Prospective Randomized Controlled Trial of Casting Options for Pediatric Forearm Fractures

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Abstract

The purpose of this study was to determine the rate of cast-related complications when using split or intact casts. A total of 60 patients aged 3 to 13 years with closed shaft or distal third radius and ulna fractures requiring reduction were recruited for this study. Patients underwent closed reduction under sedation and were placed into a long-arm fiberglass cast with 1 of 3 modifications: no valve, univalve, or bivalve. Patients were followed to 6 weeks after reduction or surgical treatment if required. The frequency of neurovascular injury, cast saw injury, unplanned office visits, and cast modifications, the need for operative intervention, and pain levels through the follow-up period were recorded. The results showed no incidents of compartment syndrome or neurovascular injury. Additionally, there were no differences between complications associated with cast type ($P=0.266$), frequency of cast modifications ($P=0.185$), or subsequent need for surgical stabilization ($P=0.361$). Therefore, cast splitting following closed reduction of low-energy pediatric forearm fractures does not change clinical outcomes with respect to neurovascular complications, cast modifications, pain levels, or the need for repeat reduction. Consideration should be given to minimizing cast splitting after reduction of low-energy pediatric forearm fractures for practice efficiency and to potentially decrease saw-related injury. [Orthopedics. 2017; 40(5):e849-e854.]

Fractures of the forearm are the most common reason children seek orthopedic care. The initial management of those fractures with unacceptable displacement and/or angulation typically involves closed reduction, with or without sedation, and immobilization with a cast or a splint. If a cast is applied, significant variation exists among institutions nationally regarding the acute management of the cast. There are no consensus data on the type of cast material used, whether the cast ends above or below the elbow, and whether the cast is split at the time of application. Splitting of a circumferential upper extremity cast after its application is known to dissipate intra-cast pressures by up to 60% to 77%, theoretically reducing the risk of complications such as compartment syndrome, neurovascular injury, and pressure necrosis of skin. A previous retrospective study suggested that 16% of children placed into a circumferential forearm cast following reduction of a displaced fracture require cast modification for complications associated with soft tissue swelling, supporting the notion that circumferential casts should be split after fracture reduction. However, the act of splitting a cast is not without risk. Iatro...
genic cast saw abrasions and thermal burns occur with a frequency of 0.72% and are common sources of litigation, accounting for up to 4.7% of filed claims and having reported settlements greater than $12,000 per patient. Further, a split cast may result in loss of fracture reduction, requiring either additional manipulation of the cast, repeat reduction under sedation, or surgical stabilization.

The objectives of this single-center, prospective randomized controlled study of pediatric forearm fractures requiring acute reduction and casting were to examine the impact of cast valving on the rates of (1) cast-related complications such as compartment syndrome or cast saw injury and (2) fracture remanipulation or the need for subsequent operative intervention.

**Materials and Methods**

A prospective, nonblinded randomized controlled trial examining acute cast management following closed reduction of pediatric forearm fractures was initiated at a single pediatric level I trauma center. The study received institutional review board approval and was registered at ClinicalTrials.gov (NCT02614690).

Patients were included if they were between 3 and 13 years old and presented to the emergency department with a radius and ulnar shaft or distal radius and ulna fracture necessitating reduction under sedation. Reduction was considered when the coronal or sagittal plane angulation or displacement exceeded accepted standards for age and anatomic location of the injury. Patients were excluded from the study if the fracture was open; was pathologic; was associated with a neurovascular injury, joint injury, or other fracture; required operative treatment after initial evaluation; or involved the distal radial or ulnar physis. Intubated patients, patients with preexisting musculoskeletal pathologies, and patients who were unable to verbalize symptoms of discomfort were also excluded.

Informed consent was obtained from the patient’s legal guardian. All eligible patients underwent closed reduction of the forearm fracture in the emergency department by a third-year orthopedic resident or qualified physician’s assistant with at least 2 years of experience in managing pediatric fractures. The emergency department physicians used intravenous ketamine, intravenous ketamine and propofol, or intranasal fentanyl as sedation for reduction. Fracture manipulation and reduction was performed with the assistance of mini C-arm fluoroscopic imaging. A molded long-arm cast, composed of stockinette, cotton cast padding, and rigid fiberglass cast tape (Scotchcast; 3M, St Paul, Minnesota), was applied during reduction.

After cast application, patients were randomized using a card draw method. The orthopedic resident or physician’s assistant working with the patient drew a study card, sealed in an envelope, from a bin. The study card indicated the type of modification to be used. Patients were randomized into 1 of 3 groups: (1) intact (no valve); (2) a single dorsal or volar valve (univalve); or (3) a dorsal and volar valve (bivalve) (Figures 1-2). A cast saw with vacuum (986 Cast Vac; Stryker, Mahwah, New Jersey) was used to create split casts, and a cast spreader was used to ensure that the casts were fully split. All split casts had 2 to 3 pieces of silk tape (Durapore; 3M, St Paul, Minnesota) placed to secure them. Nonvalved casts were left intact. All patients were provided a cast-care instruction sheet describing how to address cast-related pain issues. The treating emergency department provider dispensed a narcotic pain medication prescription on discharge to home. Patients were scheduled for follow-up 5 to 10 days after the initial cast application and subsequently at the discretion of the provider. Study endpoints consisted of follow-up to 6 weeks.
after the initial reduction or subsequent operative intervention. At each office visit, a follow-up form consisting of the Wong-Baker FACES visual pain rating scale and a question asking about any unplanned visits to the office or emergency department for cast-related issues\textsuperscript{14,15} was completed by the patient’s legal guardian. In cases where the form was not completed, the patient’s medical record was reviewed to determine pain levels and document unplanned office or emergency department visits. In addition to the form, a new radiograph was obtained at each office visit, and information for cast modification (ie, cast wedging or fracture remanipulation) was recorded. A cast index, defined as the ratio of the sagittal cast width to the coronal cast width at the level of the fracture, was calculated from the initial follow-up radiographs to evaluate the uniformity and quality of applied casts.\textsuperscript{16}

**Statistical Methods**

Power analysis for the study was based on the incidence of cast-associated complications described by Nietosvaara et al\textsuperscript{8} and suggested that a sample size of 60 patients, with 20 patients in each of the 3 casting groups, was required to identify a significant difference. The 3 cast treatment groups were compared using a single-factor analysis of variance with a Tukey honest significant difference post hoc test to determine significant differences for all continuous variables. Chi-square contingency tables were used for discrete variables. Intraclass correlation coefficients were calculated to test reliability for cast index between providers using a subset of 15 patients. \( P \leq 0.05 \) was considered statistically significant, and an intraclass correlation coefficient of 0.85 or greater was considered good agreement. All statistics were calculated using SAS version 9.3 software (SAS, Cary, North Carolina).

**RESULTS**

Sixty patients were enrolled during a 26-month period from 2013 to 2015 (Figure 3). There were no significant differences in demographics between the study groups (Table 1). All patients reached the defined endpoints of surgical intervention or 6-week follow-up after initial reduction. The first follow-up appointment occurred at a mean of 6±2 days, and the mean number of follow-up visits during the 6-week period was 3±1.

Fractures of the distal radius and ulna comprised 52% of all fractures in the study; the remaining fractures included distal one-third (23%), midshaft (18%), and proximal one-third (7%) radius and ulna fractures. No significant difference existed between groups for fracture location. Low-energy injury mechanisms (97%) included fall from standing height (42%), playground fall (27%), and sports-related injury (28%). High-energy injuries (3%) consisted of trauma from motorized vehicle accidents. A significant difference was noted between groups in terms of injury mechanism (\( P = 0.006 \)). More falls from standing occurred in the no valve group than in the univalve and bivalve groups.

**Figure 3:** Consolidated Standards of Reporting Trials 2010 flow diagram of trial enrollment.

<table>
<thead>
<tr>
<th>Table 1: Patient Demographics</th>
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<tr>
<td>Characteristic</td>
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<tr>
<td>Age, mean (range), y</td>
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<tr>
<td>Sex, No. (%)</td>
</tr>
<tr>
<td>Male</td>
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<tr>
<td>Female</td>
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groups, while more sports-related injuries occurred in the univalve and bivalve groups (Table 2).

Cast index calculations showed an intraclass correlation coefficient of 0.91. The mean cast index for all casts in the study was 0.87±0.09 (no valve, 0.88±0.11; univalve, 0.90±0.09; bivalve, 0.83±0.05). A significant difference was noted between the bivalve and univalve groups (P=.039).

No significant difference in pain level among the 3 cast groups was identified (P=.266) (Table 3). No incidents of compartment syndrome or neurovascular injury were identified during the study. Similarly, there were no cast saw–related abrasions or thermal injuries. A total of 4 unplanned cast modification visits occurred for cast discomfort or paresthesias: 3 in the no valve group and 1 in the bivalve group. One of the visits in the no valve group required bivalve splitting of the cast for pain and swelling, while the other 2 required trimming of the cast for thumb irritation. The 1 unplanned visit in the bivalve group required further splitting of the cast because of pain and swelling. No significant difference in frequency of cast modification for discomfort or paresthesia was noted between groups (P=.185).

Four additional unplanned office visits occurred for other cast-related complaints (2 in the no valve, 1 in the univalve, and 1 in the bivalve groups). The frequency of these visits was not significantly different among the groups (P=.808). In the no valve group, 1 patient required a cast change for a wet cast, and 1 patient had a cast that was pulled off at school. In the univalve group, the lone visit was for concern over cast loosening, which required examination and reassurance. In the bivalve cast group, 1 patient was concerned about motion at the fracture site but was reassured with clinical and radiographic examination (Table 4).

During the follow-up period, a total of 20 casts were wedged for loss of reduction at the discretion of the orthopedic provider (4 no valve, 10 univalve, and 6 bivalve). There was no significant difference in the rate of wedging among the 3 cast groups (P=.122). There was no significant difference regarding subsequent need for surgical stabilization (P=.361), with only 1 patient (univalve group) requiring operative intervention for displacement of a proximal one-third radius and ulna fracture. None of the 60 patients required formal rereduction of the fractures during the study period (Table 4).

**Discussion**

Modifications to a circumferential upper extremity cast applied after reduction of a pediatric forearm fracture remain inconsistent throughout treating institutions, with poor guidance from the available literature. The retrospective study by Nietosvaara et al of 109 pediatric patients undergoing closed reduction for physeal level distal radius fractures is the largest clinical study available to address this issue and suggested a 16% complication rate related to swelling following reduction and application of a circumferential cast. In contrast, a recent prospective study of 100 pediatric patients with forearm fractures randomized to either an intact cast or a bivalve cast group showed no significant complications related to swelling and no differences in maintenance of
fracture position. However, postreduction pain levels were not assessed, and the option of a single split and the quality of the applied casts were not considered.

The current study offered a prospective randomized controlled evaluation of the range of postreduction circumferential cast management practices at a single institution. The study showed no statistically significant difference in potential cast-related complications due to swelling, with no episodes of compartment syndrome or post-casting neurovascular injury identified. In addition, there existed no significant difference between groups in the rate of unplanned patient visits to the office for cast modifications as a result of pain or paresthesias.

The authors did not find a statistically significant difference in patient-reported pain levels, using both a binary (pain or no pain) and a 4-level analysis, across the 3 cast groups during the 6-week follow-up period. This indicates that no specific benefit for pain management was conferred by creating a single or dual valve in the cast in the early postreduction period.

Loss of fracture reduction is reported to occur in 4% to 38% of pediatric patients undergoing closed management of forearm fractures and is related to the quality of the applied cast, as measured by the cast index. In this regard, cast splitting is thought to potentially lead to a greater need for repeat fracture manipulation. The current study showed no difference between groups in the rate of cast modifications for fracture manipulation (wedging) or the need for surgical intervention. Although more patients in the univalve and bivalve groups tended to undergo cast wedging when compared with patients in the no valve group, the differences did not reach statistical significance even when the univalve and bivalve groups were combined. None of the 60 study groups were identified.

These results challenge the clinical practice of routinely splitting fiberglass

<table>
<thead>
<tr>
<th>Table 4</th>
<th>Cast-Related Complications and Cast Modifications</th>
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<tr>
<td>Variable</td>
<td>No Valve</td>
</tr>
<tr>
<td>Complication</td>
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<tr>
<td>Compartment syndrome/neurological injury</td>
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<tr>
<td>Cast saw abrasions/thermal injury</td>
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<td>Unplanned cast modification visits</td>
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<tr>
<td>Modification</td>
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<td>Surgical stabilization</td>
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<tr>
<td>Cast wedged</td>
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</table>

*Dashes indicate cannot be calculated.*

However, no significant differences in cast indices were observed when comparing the no valve group with the univalve and bivalve groups, suggesting that the crucial comparison between a patient with a maintained cast and a patient with an altered cast involved a cast that was uniformly applied.

**Conclusions**

In the acute treatment of pediatric forearm fractures, there was no difference between study groups. Circumferential intact casts (no valve) were shown to be safe and effective treatment options with respect to cast-associated complications and fracture stability when compared with univalve and bivalve casts. Based on the results of this study, single or double splitting of a long-arm fiberglass cast in a pediatric patient with an isolated forearm fracture sustained in a low-energy environment provided no clinical benefit in reducing the incidence of cast-related complications. In fact, no differences in compartment syndrome, post-casting neurovascular injury, need for fracture manipulation, or post-procedure pain levels were identified.

These results challenge the clinical practice of routinely splitting fiberglass
casts after closed reduction of pediatric forearm fractures to prevent complications related to swelling from the injury. Selective maintenance of circumferential casts for pediatric patients with low-energy injuries requiring reduction could decrease the potential morbidity and additional procedural time of fracture reduction as well as the potential for cast saw injury from repeated cast splitting procedures.

REFERENCES