

A Prospective, Randomized Comparison of Functional Bracing and Spica Casting for Femoral Fractures Showed Equivalent Early Outcomes

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Background: AAOS Clinical Practice Guidelines recommend spica casting for the treatment of most femoral fractures in children 6 months to 5 years of age. The purpose of the present study was to compare the outcomes of treatment with prefabricated braces with those of spica casting.

Methods: We performed a randomized prospective study of patients 6 months to 5 years of age who were managed with functional bracing or spica casting for the treatment of diaphyseal femoral fractures at 2 pediatric trauma centers. Patients with polytrauma, medical comorbidities impacting fracture-healing, or <6 weeks of follow-up were excluded. Spica casts were placed in the operating room with the patient under anesthesia. Functional braces were placed at bedside.

Results: Eighty patients (40 in the spica casting group and 40 in the functional bracing group) met the inclusion criteria and were analyzed. The mean age was 2.0 years in the casting group and 2.3 years in the bracing group ($p = 0.15$). Radiographs demonstrated similar shortening (9.0 ± 7.6 mm in the casting group and 6.8 ± 8.2 mm in the bracing group; $p = 0.21$), varus angulation ($9.0^\circ \pm 11.9^\circ$ in the casting group and $5.6^\circ \pm 9.4^\circ$ in the bracing group; $p = 0.19$), and procurvatum ($9.4^\circ \pm 12.9^\circ$ in the casting group and $6.7^\circ \pm 8.4^\circ$ in the bracing group; $p = 0.31$). At 6 weeks, there were no differences in shortening (13.1 ± 9.4 mm in the casting group and 11.0 ± 10.0 mm in the bracing group; $p = 0.35$), varus angulation ($2.4^\circ \pm 7.3^\circ$ in the casting group and $5.3^\circ \pm 6.3^\circ$ in the bracing group, $p = 0.06$), or procurvatum ($12.3^\circ \pm 9.8^\circ$ in the casting group and $9.1^\circ \pm 8.1^\circ$ in the bracing group; $p = 0.11$). Fifty-one patients (24 in the casting group and 27 in the bracing group) had 1 year of follow-up. There were no differences between the groups in terms of shortening (4.9 ± 5.4 mm in the casting group and 3.0 ± 6.9 mm in the bracing group; $p = 0.23$) or varus angulation ($1.8^\circ \pm 3.5^\circ$ in the casting group and $1.2^\circ \pm 4.1^\circ$ in the bracing group; $p = 0.56$), but there was a slight difference in procurvatum ($11.7^\circ \pm 8.3^\circ$ in the casting group and $5.1^\circ \pm 5.8^\circ$ in the bracing group; $p < 0.01$). More superficial skin issues were observed in the bracing group than in the casting group (9 compared with 1; $p = 0.02$), but all skin issues resolved with local wound care. Patients in the casting group had more difficulty moving independently (median score, 8 of 10 in the casting group and 5 of 10 in the bracing group; $p = 0.05$). Patients in the bracing group were more likely to fit into their car seat (40% in the casting group versus 86% in the bracing group; $p < 0.01$).

Conclusions: In this prospective randomized trial, patients who were treated with functional bracing had equivalent outcomes to those who were treated with spica casting. Prefabricated functional braces provided a viable alternative, avoiding the cost and anesthesia associated with cast placement.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

Disclosure: This study was funded by a POSNA Clinical Research Grant, and some authors have a related conflict of interest with OrthoPediatrics for brace development. The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (<http://links.lww.com/JBJS/I689>).

A **data-sharing statement** is provided with the online version of the article (<http://links.lww.com/JBJS/I676>).

Femoral fractures are 1 of the 2 most common orthopaedic injuries for which children are hospitalized¹. For patients 6 months to 5 years of age with diaphyseal femoral fractures and <2 cm of shortening, the American Academy of Orthopaedic Surgeons (AAOS) Clinical Practice Guidelines recommend immediate or delayed spica casting². While this has become standard treatment, caring for a child in a spica cast presents challenges related to hygiene and transportation³. Additionally, the rate of skin complications associated with spica treatment is reportedly as high as 28%⁴.

For the nonoperative treatment of other long-bone fractures, functional braces offer the advantages of being lightweight, being easily applied, and allowing improved access for skin care. Kramer et al. suggested that custom-made braces have clinical and financial benefits when compared with spica casting for femoral fractures⁵. While those authors demonstrated the potential advantages of bracing versus spica casting, the ability to generalize their technique was limited because the process of making custom braces in a timely fashion was reliant on an orthotist with a carver. As the high cost and limited availability of a carver limited adoption, we questioned whether similar results could be obtained with prefabricated braces. We proposed the development of 4 standardized sizes of braces that could be stocked and fitted, rather than being custom-made, to improve both cost and efficiency.

The use of a prefabricated brace has the advantage of avoiding anesthetic exposure and the need to wait for operating room availability. The objective of this prospective, multicenter, randomized controlled trial was to compare functional bracing (using prefabricated braces) with spica casting for the treatment of pediatric femoral fractures. We hypothesized that bracing and casting would perform equivalently with regard to radiographic and functional outcomes.

Materials and Methods

Institutional review board approval was obtained for this randomized prospective study, which was performed at 2 pediatric centers, and the study was registered at ClinicalTrials.gov (NCT03948139). Patients 6 months to 5 years of age with diaphyseal femoral fractures and characteristics amenable to spica casting were enrolled. Patients with comminuted and/or high-energy fractures, polytrauma, or medical comorbidities impacting fracture-healing were excluded. Randomization was performed at each site from a sequence of randomization assignments determined prior to the start of the study with use of electronically generated random numbers. These assignments were stored and utilized consecutively on the basis of each subject's site-specific enrollment number.

Spica casts were placed in the operating room by an attending surgeon, with the patient under general anesthesia; braces were placed at bedside by the orthotist and a member of the orthopaedic team (a resident, fellow, physician's assistant, or attending surgeon). The attending surgeon subsequently evaluated the brace if they had not been present for placement. Four standardized sizes were developed on the basis of measurements from prior patients who had been managed with

custom-made braces (Fig. 1). Prefabricated braces were stocked at both institutions and were modified by local orthotists to optimize fit. The protocols for each group are shown in Tables I and II.

A brace of the appropriate size and side was selected to fit the patient. Adjustments to the length or width of the cuff were made prior to application, templating from the contralateral leg.

The hip joint of the brace allows flexion and abduction, and the knee is supported in slight flexion (around 20°). The foot plate allows flexion and extension of the ankle but limits rotation and can be removed for easier ambulation when there is early callus. At 4 weeks, the hip joint is unlocked to allow more motion and ease of ambulation.

Braces were applied in the emergency department or hospital ward. Although an anesthetic or sedative was not used, weight-based analgesia (typically morphine) with or without a muscle relaxant (such as Valium [diazepam]) were utilized. Stockinette was cut to the length of the leg and was placed while applying gentle traction for stabilization through the foot. The brace was then slid under the torso and leg, which were then lowered into the brace. To allow for sitting, flexion at the hip was fixed between 30° and 60°. Abduction was fixed between 20° and 40° to prevent slippage⁶.

Radiographic union was defined as callus that bridged the fracture at ≥3 cortices. Nonunion was diagnosed if bridging callus at 3 cortices was not evident by 12 weeks. Malunion was defined as >30° of varus or valgus, >30° of procurvatum, or >15 mm of shortening in a patient aged 6 months to ≤2 years, and as >15° of varus or valgus, >20° of procurvatum, or >20 mm of shortening in a patient aged >2 years to 5 years.

The PODCI (Pediatric Outcomes Data Collection Instrument) and an additional custom questionnaire were used to assess functional outcomes and satisfaction at 6 weeks and 1 year after the injury (see Appendix).

A target sample size of 40 per group was based on data reported by DiFazio et al.⁴, a 28% versus 5% rate of skin problems (a dichotomous end point reflecting their presence versus absence), 2 independent samples, $\alpha = 0.05$, and $\beta = 0.80$. Patients with <6 weeks of follow-up were excluded from the analysis. Continuous outcome variables were reported as the mean and the standard deviation (SD) and were compared with use of the Student t test. Ordinal variables were reported as the median and interquartile range width (IQR) and were compared with use of the Mann-Whitney rank sum test or Fisher exact test. The level of significance was set at $p < 0.05$. Statistical analysis was performed with use of STATA/IC 14.0 (Stata Statistical Software, Release 14, 2015; StataCorp LP).

Results

Initial Fracture Characteristics

Ninety patients were initially randomized to treatment with a brace (45 patients) or a spica cast (45 patients). Nine patients did not complete the 6-week follow-up, and 1 was excluded because of a neuromuscular condition, leaving 80 patients for analysis (Fig. 2). One hundred and fifteen patients (36 at Center A



Fig. 1
An example of the functional femoral brace.

and 79 at Center B) declined participation. Of the 80 patients who were analyzed, 40 (22 at Center A and 18 at Center B) were randomized to treatment with a spica cast and 40 (16 at Center A and 24 at Center B) were randomized to bracing. The mean ages were similar (2.0 ± 0.8 years for the casting group and 2.3 ± 1.1 years for the bracing group; $p = 0.15$). Radiographic characteristics at the time of injury were also similar, including shortening (9.0 ± 7.6 mm for the casting group and 6.8 ± 8.2 mm for the bracing group; $p = 0.21$), varus ($9.0^\circ \pm 11.9^\circ$ for the casting group and $5.6^\circ \pm 9.4^\circ$ for the bracing group; $p = 0.19$), and procurvatum ($9.4^\circ \pm 12.9^\circ$ for the casting group and $6.7^\circ \pm 8.4^\circ$ for the bracing group; $p = 0.31$) (Table III).

No intraoperative complications occurred during spica cast placement. All braces were successfully placed at bedside. Six patients experienced brace issues, including unlocking of the brace at the hip (1 patient), loosening (1 patient), exchange of the brace for a larger size at the time of follow-up (1 patient), mold development (1 patient), and screw fall-out (2 patients). An additional patient removed the brace at 4 weeks at home without authorization. No complications or change in outcomes were encountered as a result of these issues.

Follow-up at 6 Weeks

Radiographic Findings

At the 6-week visit, all 80 fractures had healed. There were no differences between the groups in terms of femoral shortening (13.1 ± 9.4 mm in the casting group and 11.0 ± 10.0 mm in the bracing group; $p = 0.35$), varus angulation ($2.4^\circ \pm 7.3^\circ$ in the casting group and $5.3^\circ \pm 6.3^\circ$ in the bracing group; $p = 0.06$), or procurvatum ($12.3^\circ \pm 9.8^\circ$ in the casting group and $9.1^\circ \pm 8.1^\circ$ in the bracing group; $p = 0.11$).

Complications

No patient had a nonunion. One patient in the bracing group experienced malunion due to shortening that was 4 mm greater than criteria for malunion, but the 6-month hip-to-ankle radiograph demonstrated that the leg-length discrepancy was <1 cm.

Rashes and mild skin breakdown were observed in 1 patient in the casting group and 9 patients in the bracing group ($p = 0.02$). One patient who was started on oral antibiotics developed a rash. One patient experienced skin irritation and had a screw replaced in the brace. All skin issues resolved with local wound care. Two spica casts were soiled, and 3 needed cast-wedging.

Parent Questionnaire

Although 80 patients had radiographic follow-up at 6 weeks, the parents of only 54 patients completed the 6-week surveys. Parent satisfaction with treatment was high for both groups,

TABLE I Spica Casting Protocol*

Diagnosis and admission
Patient taken to OR for spica cast placement
Fluoroscopy used in OR to evaluate fracture alignment
Follow-up in 1 week in office
Wedge/adjust as needed based on radiographs
Follow-up in 2 weeks
Wedge/adjust as needed based on radiographs
Follow-up in 3-4 weeks
Wedge/adjust as needed based on radiographs
Follow-up in 6 weeks
Repeat radiographs†
Follow-up in 8 weeks
Repeat radiographs
Discontinue spica if adequate callus bridging of all 4 cortices
Follow-up radiographs at 3 months: follow-up and gait check
Follow-up radiographs at 1 year (including hip to ankle): follow-up and gait check

*OR = operating room. †If adequate callus bridging is observed at all 4 cortices, casting may be discontinued at this point.

TABLE II Functional Bracing Protocol

Diagnosis and admission
Measure uninvolved side and determine which of the 4 standard sizes is most appropriate
Orthotist to fit brace from standardized sizes within 24 hours
Radiographs obtained following brace placement to verify adequate fracture alignment
Follow-up in 1 week in office
Adjust as needed based on radiographs
Increase abduction if needed
Follow-up in 2 weeks
Change sock
Adjust as needed based on radiographs
Follow-up in 3-4 weeks
Parents start changing sock daily as needed
May remove for bathing if stable
Follow-up in 6 weeks
Repeat radiographs*
If braces are not discontinued at this point, hinge can be unlocked to allow range of motion and facilitate mobility
Follow-up in 8 weeks
Repeat radiographs
Discontinue spica if adequate callus bridging of all 4 cortices
Follow-up radiographs at 3 months: follow-up and gait check
Follow-up radiographs at 1 year (including hip to ankle): follow-up and gait check

*If adequate callus bridging is observed at all 4 cortices, bracing may be discontinued at this point.

with 84% (21) of 25 parents in the casting group and 76% (22) of 29 parents in the bracing group reporting scores of 10 of 10 ($p = 0.52$). There was no difference between the groups in terms of the perception of the stressfulness of the experience ($p = 0.73$). The ability to use the child's regular car seat was more limited in the casting group than in the bracing group (40% [10 of 25] in the casting group and 86% [25 of 29] in the bracing group; $p < 0.01$). If the number of days that the parent reported missing work exceeded the time from the injury to survey completion, the data were excluded. For parents reporting missing work, the median number of missed days was 17 days (IQR, 26 days) for the casting group and 5 days (IQR, 9 days) for the bracing group ($p = 0.14$). Parents reported that patients in the casting group had more difficulty moving independently (median score, 8 [IQR, 6] of 10 for the casting group and 5 [IQR, 5.5] of 10 for the bracing group; $p = 0.05$).

Follow-up at 1 Year

Radiographic Findings

Of the 51 patients with a follow-up visit at or after 1 year, 44 (21 in the casting group and 23 in the bracing group) had hip-to-ankle radiographs. The mean follow-up was 15.5 ± 6.5 months for the casting group, compared with 12.6 ± 2.0 months for the

bracing group ($p = 0.04$). There were no differences between the groups in terms of varus angulation ($1.8^\circ \pm 3.5^\circ$ in the casting group and $1.2^\circ \pm 4.1^\circ$ in the bracing group; $p = 0.56$) or femoral shortening (4.9 ± 5.4 mm in the casting group and 3.0 ± 6.9 mm in the bracing group; $p = 0.23$) (Figs. 3 and 4). No patient had a leg-length discrepancy of >1 cm.

Thirty-four patients (14 in the casting group and 20 in the bracing group) also had lateral femoral radiographs. The mean procurvatum was slightly greater in the casting group than in the bracing group ($11.7^\circ \pm 8.3^\circ$ compared with $5.1^\circ \pm 5.8^\circ$, respectively; $p < 0.01$). All patients were ambulatory and were able to participate in activities without restrictions, with the exception of 1 patient who had sustained a new and unrelated ankle fracture.

Parent Questionnaire

Fifty-one patients had ≥ 1 year of radiographic follow-up, and the parents of 30 of those patients completed the surveys. Parent satisfaction with treatment remained high for both groups, with 75% (9) of 12 parents in the casting group and 83% (15) of 18 parents in the bracing group reporting a score of 10 of 10 ($p = 0.66$).

PODCI Questionnaire

With regard to PODCI scores at ≥ 1 year, the bracing group reported almost no pain, with a mean score of 99.5 ± 2.4 of 100. That score was better than the score of 89.4 ± 19.0 for the casting group ($p = 0.02$). No other significant differences between the groups were observed in PODCI scores.

Discussion

Both the 2009 and 2015 AAOS Clinical Practice Guidelines recommend spica casting for the treatment of pediatric femoral fractures in patients between 6 months and 5 years of age with <2 cm of shortening^{2,7}. Nevertheless, the challenges of spica casting are well known. Nearly 10% of patients need to return to the operating room, and skin complications have been reported in up to 28% of patients⁴. Interestingly, in the present series, few skin issues and no returns to the operating room were reported in the casting group. It is notable that there were more superficial skin issues in the bracing group than the casting group, although all resolved with local wound care. While it is possible that this finding represented a real difference between the groups, it may instead have reflected the ability to detect these issues more easily in the bracing group. One important learning point during the study was having nursing staff provide education on bracing care similar to instructions for spica care, such as keeping the brace or cast clean and dry and avoiding environments with high exposure to water, sun, and sand. In the early portion of the study, training was provided for families in spica management but not bracing, which also may have contributed to those issues.

The radiographic outcomes were similar in both groups, although there was slightly more procurvatum in the casting group. This difference was small and, although significant, likely was not clinically relevant. One patient in the bracing

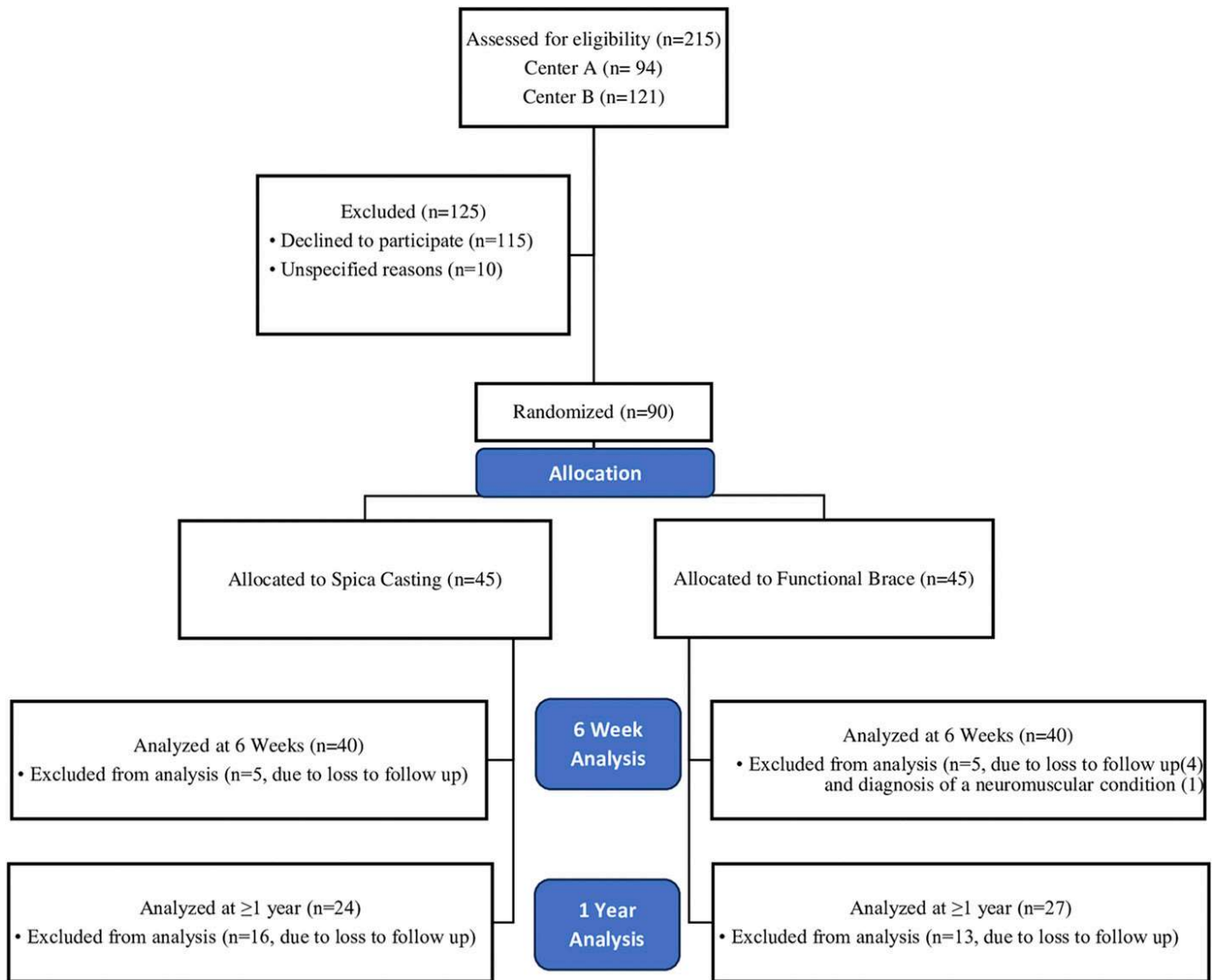


Fig. 2
Flowchart of study enrollment.

TABLE III Patient Characteristics

Patient Characteristics	Spica Cast (N = 40)	Functional Brace (N = 40)	P Value
Sex (<i>no. of patients</i>)			
Male	29 (72.5%)	31 (77.5%)	
Female	11 (27.5%)	9 (22.5%)	
Age* (<i>yr</i>)	2.0 ± 0.8	2.3 ± 1.1	0.15
Preop. radiographic measurements*			
Femoral shortening (<i>mm</i>)	9.0 ± 7.6	6.8 ± 8.2	0.21
Varus angulation (<i>deg</i>)	9.0 ± 11.9	5.6 ± 9.4	0.19
Procurvatum (<i>deg</i>)	9.4 ± 12.9	6.7 ± 8.4	0.31

*The values are given as the mean and the standard deviation.

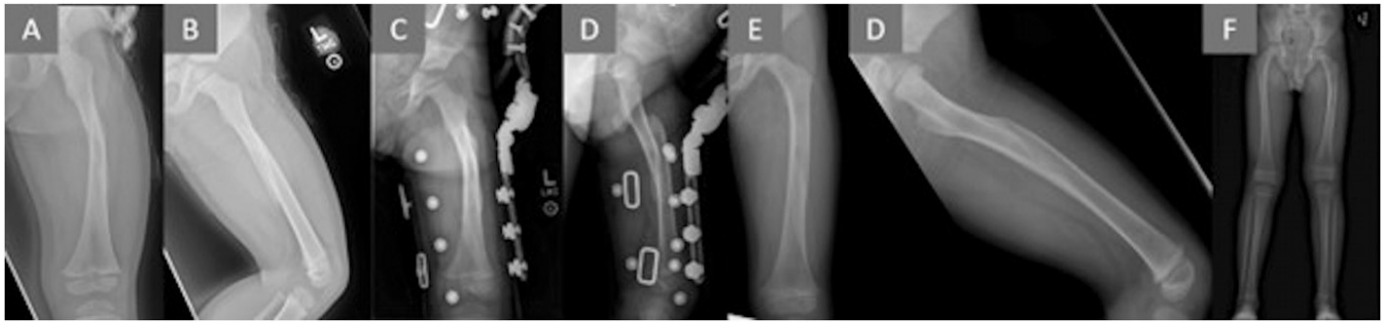


Fig. 3

Figs. 3-A through 3-F A 3-year-old boy sustained a left femoral fracture and was randomized to the functional bracing group. Radiographs were made at the time of the injury (**Figs. 3-A and 3-B**), at 6 weeks (**Figs. 3-C and 3-D**), and at 1 year (**Figs. 3-E and 3-F**).

group met the criteria for malunion due to shortening alone, which by 6 months had corrected to a leg-length discrepancy of <1 cm. As anticipated, we saw similar osseous remodeling in both groups and recommend using the same criteria for fracture alignment in patients treated with bracing as those that have been established for spica casting.

Caregiver burden associated with spica can be substantial. Safe transport is challenging, as the child can have difficulty fitting into a regular car seat⁸. Additionally, alternative car seats may not provide equivalent protection in the event of a collision⁹. Most patients (86%) in the bracing group fit into their own car seat, compared with only 40% in the casting group ($p < 0.01$). The socioeconomic impacts of spica casting, including days of school and work missed, are well documented^{3,10}. Hefernan et al. surveyed daycare facilities and found that only 22% allowed children to return in spica casts¹¹. For working parents, there was a trend toward more days off work in the casting group as compared with the bracing group (17 compared with 5 days, respectively; $p = 0.14$), although the difference was not significant.

Other attempts to minimize the impact of spica casting have been seen in single-leg “walking” spica studies^{12,13}. Flynn et al.¹² demonstrated improvement in care burden on the Impact on Family Scale in association with the walking spica (43.3 for traditional spica compared with 35.6 for walking

spica; $p = 0.04$). However, that difference represented only a 17% decrease in family burden. As multiple attending surgeons participated at each institution, the spica type was left to the discretion of the treating physician in that study. Nevertheless, that variability perhaps provides a more “real world” comparison of the brace to current practices.

One confounding variable in the present study is that it represented the first experience at both institutions with bracing for femoral fractures and therefore reflected the initial learning curve. In contrast, both attendings and institutions had many years, if not decades, of experience with spica casts, with established preferences and protocols in place. Attending surgeons were present for all spica cast placements, while braces were placed by the orthotist and another team member with subsequent evaluation by the attending surgeon. Additionally, both centers had experienced orthotists applying and adjusting the braces.

The ability to place the brace without a trip to the operating room or general anesthesia benefits patients and providers and avoids the cost and inconvenience of performing a procedure in the operating room. Furthermore, bracing avoids the risks of potential acute and chronic complications of general anesthesia in young children. Although the Food and Drug Administration recommendation for anesthesia in children <3

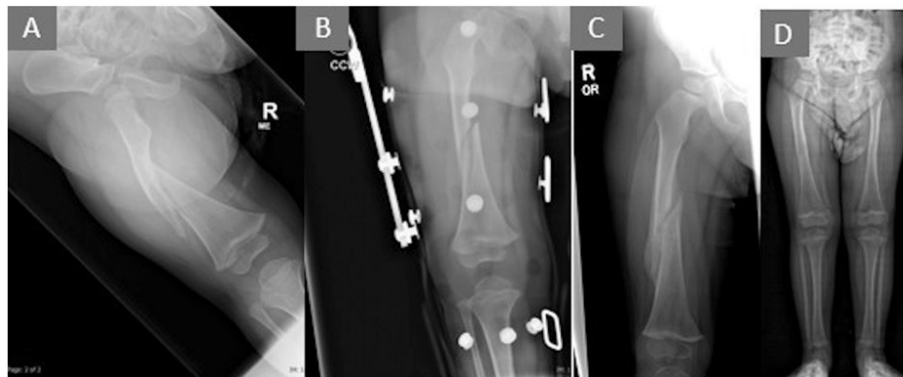


Fig. 4

Figs. 4-A through 4-D A 2-year-old boy sustained a left femoral fracture and was randomized to the functional bracing group. Radiographs were made at the time of injury (**Fig. 4-A**), after brace application (**Fig. 4-B**), at 6 weeks (**Fig. 4-C**), and at 1 year (**Fig. 4-D**).

years old pertains to >3 hours of anesthesia, the effect is thought to be cumulative and there are concerns about the potential for neurotoxicity resulting from anesthetic agents¹⁴. Another bothersome aspect of spica cast placement in the operating room is that it often requires young children to spend a prolonged time unable to eat or drink while awaiting operating room availability, which is avoided with brace placement at bedside. Bracing is also advantageous when compared with the use of flexible intramedullary nails, which are sometimes used for patients at the older end of the age range in the present series. While the use of flexible intramedullary nails provides some advantages in terms of ease of care, it typically requires a trip to the operating room for placement and for removal.

In the present series, we achieved the same outcomes with prefabricated braces as with spica casts, and we are optimistic that our findings will provide more institutions with the opportunity to adopt the bracing technique. The use of prefabricated braces represents a major advancement, as the use of custom-made braces for each patient was a limitation to the adoption of bracing and created an inevitable delay and logistical challenges during brace construction. A handful of mechanical issues were noted with the brace initially, but these issues decreased with verification that the screws were secure during routine visits. It is notable that, during the study period, the availability of prefabricated braces was limited, as their construction was supported by grant funding. Consequently, those who declined participation in the study received spica casting, although that did not necessarily reflect parent or provider preference.

This study is not without limitations. The casting group included a combination of one-half, one-quarter, and single-leg spica casts. Both centers had experienced orthotists applying and adjusting the braces, which was likely advantageous. A large number of families declined participation, an issue that has come to attention in association with other randomized controlled trials, although such trials remain the research gold standard. Additionally, ethnicity data were not routinely collected at all centers, which may limit the generalizability of these results. Lim et al.¹⁵ found that multicenter studies comparing operative and nonoperative treatments had the lowest enrollment among orthopaedic randomized controlled trials, and the present study falls in that category. This limitation introduces potential selection bias, as socioeconomic background and health literacy may contribute to patient willingness to participate, although recent research has suggested that most eligible patients, regardless of level of knowledge, have difficulty with decisions regarding randomized trial participa-

tion^{15,16}. While a small number of patients were lost before 6 weeks, many were lost before 1 year despite attempts to contact them, and the 1-year follow-up time was relatively short. Despite the intent to document all skin issues, it is possible, particularly in the casting group, that a portion of the minor issues that were noted at removal were not recorded if no additional treatment was required. However, those minor issues may be of little impact to patient, parent, and provider satisfaction. Of note, subsequent to the study, we have used a more absorbent stockinette or brace liner that has resulted in fewer skin issues.

In summary, in this prospective randomized trial, patients who were treated with bracing and those who were treated with spica casting had equivalent clinical and radiographic outcomes. Standardized functional braces provide a viable alternative to spica casting and have the potential to lessen the burden on patients, families, and the health-care system.

Appendix

 Supporting material provided by the authors is posted with the online version of this article as a data supplement at jbj.org (<http://links.lww.com/JBJS/I675>). ■

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