Original Article

A bone graft substitute is effective for posterior spinal fusion in patients with juvenile or adolescent idiopathic scoliosis: a retrospective study

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Background: Bone grafting is used to achieve fusion during surgical treatment of scoliosis. While both iliac crest autografts and allografts are effective options, each has associated risks. Synthetic alternatives without added biologics may achieve fusion while reducing or avoiding many of the risks associated with other bone graft options. However, there is lack of evidence for use of synthetic bone graft products in pediatric patients. The purpose of this study is to determine the efficacy of a commercially available biphasic beta-tricalcium phosphate and hydroxyapatite synthetic bone graft substitute for posterior spinal fusion (PSF) in patients with juvenile or adolescent idiopathic scoliosis (JIS or AIS).

Methods: We retrospectively identified patients with JIS or AIS who underwent PSF using a synthetic bone graft substitute (Mastergraft™; Medtronic, Minneapolis, MN, USA) at Akron Children's Hospital between 2015 and 2022. Patients with <23 months clinical and radiographic follow-up were excluded. Patient demographics, deformity metrics, and surgical data were collected. The primary outcome measure was fusion. Secondary outcome measures included intra-operative and post-operative complications, revision surgeries, and readmissions within 30 and 90 days.

Results: A total of 179 patients were included (mean age, 14.7 years; 72.1% female). A total of 60 cc of synthetic bone graft substitute was used in the majority (91.6%) of cases. At mean 40.9 months (range, 23–98 months) follow-up, 98.9% of patients successfully achieved fusion. There were 7 reoperations (3.9%), including 2 patients with pseudarthroses (1.1%), one of which manifested after a high-energy trauma.

Conclusions: A commercially available calcium phosphate and hydroxyapatite bone graft substitute, used in conjunction with locally obtained autograft, safely achieved fusion in 98.9% of patients with JIS or AIS.

Keywords: Scoliosis; fusion; pseudarthrosis; bone graft substitute

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Introduction

Pseudarthrosis is a rare but serious complication following posterior spinal fusion (PSF) for patients with juvenile or adolescent idiopathic scoliosis (JIS or AIS). Advances in surgical techniques and instrumentation have substantially lowered pseudarthrosis rates to approximately 0–1.4% (1-9). Locally harvested autograft is performed using all fragments of the spinous processes, transverse processes, facets, and/or laminae routinely collected during PSF. Augmentation with iliac crest autograft is the historical standard of care to maximize fusion rates; however, this is associated with potential donor-site morbidity, including pain, infection, bleeding, and longer operative times (10,11).

Cancellous allograft is another option for supplementation, but poses the potential risk for disease transmission, and many patients express resistance to cadaveric product, citing social/ethnic concerns. Other options include various derivative products such as demineralized bone matrix (DBM), synthetic proteins such as recombinant human bone morphogenetic proteins (rhBMPs) or other synthetic peptides, but these options may be prohibitively expensive, increase risk of complications (12), and are typically not approved for routine PSF in pediatric patients (13-16). Ceramics like beta-tricalcium phosphate, coralline hydroxyapatite, silicate calcium phosphate, and bioactive glass are alternative bone graft substitutes due to their osteoconductive and bioinert properties. However, without the necessary scaffold, ceramics lack osteoinductive potential (17,18).

At Akron Children's Hospital, all pediatric orthopedic spine surgeons elected to transition away from allograft for routine spinal fusions, seeking a cost-effective synthetic option free of any biologic derivative. Upon surgeon consensus, a commercially available synthetic bone graft substitute consisting of biphasic calcium phosphate (85% beta-tricalcium phosphate) and 15% hydroxyapatite was chosen for all routine spinal fusions. This is a resorbable scaffold with both osteoconductive and osteoinductive properties that is available in multiple consistencies, including porous granules, malleable putty, or flexible strips for coverage of posterior column osteotomy sites. Its efficacy and safety have been validated in animal (19-21) and adult human studies (22-27); however, its use in pediatric patients with JIS or AIS has not been extensively studied.

The purpose of this study is to determine the efficacy of a commercially available biphasic beta-tricalcium phosphate and hydroxyapatite synthetic bone graft substitute for PSF in adolescent patients. We hypothesized that the use of this synthetic bone graft substitute, in conjunction with locally harvested autograft, would result in high rates of fusion with low complication rates in this population. We present this article in accordance with the STROBE reporting checklist (available at https://jss.amegroups.com/article/view/10.21037/jss-2026-1-0047/rc).

Highlight box

Key findings

- In patients with juvenile or adolescent idiopathic scoliosis (JIS or AIS), posterior spinal fusion (PSF) can be safely achieved with a commercially available, synthetic calcium phosphate and hydroxyapatite bone graft substitute, used in conjunction with locally obtained autograft.

What is known and what is new?

- Iliac crest autograft has historically been used to augment local autograft but is associated with donor-site morbidity. Allograft and/or derivative biologic products pose potential risk for disease transmission and/or social/ethnic concerns.
- In this study, we show that a biphasic calcium phosphate synthetic bone graft substitute, used alongside locally harvested autograft in pediatric spine fusion, achieves high fusion rates with low complication rates, adding meaningful clinical evidence in a population where such data have been limited.

What is the implication, and what should change now?

- Synthetic biphasic calcium phosphate is a reliable adjunct to local autograft in PSF for JIS and AIS, achieving fusion and complication rates comparable to historical standards.
- Routine PSF for JIS or AIS can be performed using locally harvested autograft augmented with a biphasic calcium phosphate synthetic bone graft substitute, without the need for iliac crest autograft or allograft.

Methods

The study was conducted in accordance with the Declaration of Helsinki and its subsequent amendments. This study was approved by the Institutional Review Board of Akron Children's Hospital (#2024-061). Informed consent was not required because this was a retrospective study.

We retrospectively identified patients through an electronic medical record search using procedural current procedural terminology (CPT) codes for spinal fusion (22802 and 22804) and diagnostic International Classification of Diseases (ICD) codes for idiopathic scoliosis (M41.1) at Akron Children's Hospital, a high-volume tertiary care pediatric spine center. Inclusion

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criteria were all patients with diagnoses of JIS or AIS who underwent primary posterior-only instrumented spinal fusion with use of Mastergraft™ (Medtronic, Minneapolis, MN, USA) synthetic bone graft substitute from 2015 to 2022. Exclusion criteria were <23 months clinical and radiographic follow-up, concomitant anterior spinal surgery, prior spinal surgery, non-idiopathic scoliosis diagnoses, and lack of pre-operative or post-operative radiographs.

Patient demographics [age, sex, comorbidities, American Society of Anesthesiologists (ASA) classification] and preoperative radiographic deformity metrics (coronal curve magnitude and Lenke classification, as measured and determined by the primary surgeon) were recorded. Surgical variables included number of fused/instrumented levels, operative time, estimated blood loss (EBL), and osteotomies performed. Bone graft type and quantity were recorded, including quantity of morselized synthetic bone graft granules (cc), length of synthetic bone graft strips (cm), and total quantity of graft using the following volume-based equation: total graft (cc) = morselized cc + length × 0.6 × 2.

The primary outcome measure was fusion rate; pseudarthrosis was defined as lack of fusion mass spanning any instrumented level. This was assessed directly with advanced imaging when available or upon direct visualization at the time of reoperation if performed. When these modalities were not utilized during routine postoperative patient care, then fusion was determined indirectly using methodology as previously described (13,28), with a successful fusion defined as absence of postoperative pain, loss of correction, and/or implant failure. Secondary outcomes included intra- and post-operative complications, 30-day emergency department (ED) visits, readmissions within 30 and 90 days, and revision surgeries.

In terms of surgical technique, all patients underwent a standard posterior approach with subperiosteal dissection. Inferior facetectomies were performed at all fusion levels. Site and number of Ponte osteotomies, as well as pedicle screw placement techniques, were performed at the discretion of the operating surgeon. Instrumentation, deformity correction, irrigation, and decortication were then performed, using a high-speed burr at the upper and lower instrumented vertebrae and a Capener gouge at all intervening levels. Next, any Ponte osteotomy sites were covered centrally with synthetic bone graft strips for protection of the exposed spinal cord against compression from particulate graft. Then, locally harvested autograft was combined with additional morselized synthetic bone graft substitute and vancomycin powder and dispersed centrally along the wound bed.

Four fellowship-trained pediatric spine surgeons operated on subjects reported in this study. The choice of bone graft volume and consistency was decided at the discretion of the operating surgeon; all surgeons had standard practice of placing strips of synthetic bone graft over the exposed spinal canal at Ponte osteotomy sites; 3 of 4 surgeons then distributed morselized synthetic bone graft granules, while 1 of the 4 surgeons routinely placed synthetic bone graft strips longitudinally along the entire fusion bed in all cases.

Statistical analysis

Quantitative data were described statistically using means, medians, standard deviations, interquartile ranges (IQRs), and ranges (minimum, maximum). Categorical data were summarized using absolute frequencies and percentages. These analyses were performed using JMP Pro v.17 statistical software (JMP Statistical Discovery, LLC, Cary, NC, USA).

Results

A total of 179 patients met the inclusion criteria (*Figure 1*). The mean age was 14.7 years (range, 10.5–21.2 years); 72.1% were female and 27.9% were male. Most patients had a Lenke classification of 1 or 2 (74.9%) and an ASA classification of 2 (69.8%) or 3 (27.2%) (*Table 1*). The mean operative time was 228 minutes (range, 137–357 minutes). The mean EBL was 601.5 cc, and hospital length of stay ranged from 2 to 6 days, with a median length of stay of 3 days (*Table 2*).

Most cases (91.6%) used a total volume of 60 cc morselized synthetic bone graft granules, while 6.7% had a volume of <60 cc and 1.7% had >60 cc (*Table 3*). Synthetic bone graft strips were used in 68 patients (38.0%), with a median length of 20 cm. Ponte osteotomies were performed on 54 patients (30.2%), and synthetic bone graft strips were used in 98.1% of these patients to cover the osteotomy sites (*Table 3*, *Figure 2*).

Outcomes

At mean 40.9 months (range, 23–98 months) follow-up, 98.9% of patients had successfully achieved fusion (*Table 4*). There were no intraoperative or early complications directly attributable to the synthetic bone graft substitute. Ten

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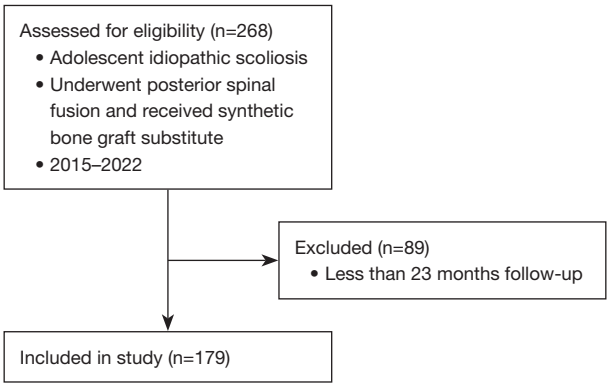


Figure 1 Study population flowchart.

patients (5.6%) had all-cause ED visits within 30 days, all due to pain and/or vomiting that resolved with conservative treatment (*Table 4*). Three of these patients (1.7%) were readmitted for viral gastroenteritis, opiate-induced nausea, and viral febrile illness. An additional 4 patients (2.2%) were subsequently readmitted within 90 days, including one pilonidal cyst with associated abscess away from the surgical wound, two deep surgical site infections, and one distal junctional failure with L4 Chance fracture and kyphosis that occurred 2.4 months postoperatively (*Table 4*).

Unplanned reoperations

Seven patients (3.9%) underwent unplanned reoperations (*Table 5*), including 3 deep infections (1.7%), 2 patients with pseudarthrosis (1.1%), 1 adding-on phenomenon (0.6%), and 1 distal junctional failure with an L4 bony Chance fracture that occurred 2.4 months after surgery (0.6%).

Pseudarthroses

The first patient with a pseudarthrosis was a 15-year-old female who initially underwent T9–L4 posterior spinal instrumentation and fusion (PSIF) with 60 cc of morselized synthetic bone graft substitute for a progressive 49-degree Lenke 5 curve with apex at L2–3. At 8.6 months postoperatively, the patient was asymptomatic but routine radiographs demonstrated a loose left L4 screw. Six months later (14.6 months postoperatively), she developed back pain and underwent exploration of the fusion mass with revision instrumentation, at which time a L2–3 pseudarthrosis was confirmed. This was treated with debridement of fibrous tissue, exchange of the loose screw, autologous iliac crest bone grafting (ICBG), and compression across the site. At 3.7 years following the revision procedure, she was asymptomatic with no clinical or radiographic evidence of pseudarthrosis.

The second pseudarthrosis also occurred in a 15-year-old female patient with a Lenke 6 AIS curve with a 58-degree left thoracolumbar curve and 44-degree right main thoracic curve. This patient underwent T3–L4 PSIF with 60 cc of morselized synthetic bone graft substitute. The patient did well initially, but 5 years after surgery, she was involved in a high-velocity pedestrian versus automobile collision with subsequent traumatic L1–2 fusion mass fracture, breakage of left rod below L1, and uncoupling of the L4 set screws, with computed tomography (CT) scan also demonstrating L3–4 pseudarthrosis. Over the following year, she remained minimally symptomatic but follow-up imaging demonstrating loosening of left L3 pedicle screw and caudal migration of the fractured rod. Due to irritation of lumbar paraspinal musculature from the migrating rod, she underwent revision L1–4 instrumentation at 76.8 months after index surgery, with ICBG, locally obtained autograft, 30 cc morselized synthetic bone graft substitute, and a 10 cm strip of synthetic bone graft substitute. At her latest follow-up 2.1 years after revision surgery, she was asymptomatic with no clinical or radiographic evidence of pseudarthrosis.

Discussion

In this study, we found that use of a commercially available synthetic bone graft substitute combined with locally harvested autograft during PSIF achieved successful fusion in 98.9% of patients with JIS or AIS. Synthetic bone graft

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Table 1 Preoperative characteristics, to include demographics and radiographic features

Characteristics	Data analysis
Age (years)	
Number	179
Mean ± SD	14.7±2.03
Median ± IQR	14.6±2.9
Range	10.5–21.2
Coronal curve magnitude (°)	
Number	177
Mean ± SD	58.9±11.15
Median ± IQR	56±12
Range	43–123
Length of follow-up (months)	
Number	179
Mean ± SD	40.9±19.18
Median ± IQR	33±32
Range	23–98
Sex, n (%)	
Female	129 (72.1)
Male	50 (27.9)
ASA, n (%)	
1	5 (3.1)
2	113 (69.8)
3	44 (27.2)
Lenke classification, n (%)	
1	81 (49.1)
2	41 (24.8)
3	13 (7.9)
4	2 (1.2)
5	15 (9.1)
6	13 (7.9)

ASA, American Society of Anesthesiologists; IQR, interquartile range; SD, standard deviation.

granules were used routinely to augment locally collected autograft, while prefabricated strips were placed over Ponte osteotomy sites to protect the spinal cord from impact by particulate bone graft. Two of 179 patients (1.1%) experienced postoperative pseudarthrosis, one of which manifested after a high-energy traumatic event. Other complications in this series were similar to published rates, including deep infection (1.7%), adding-on (0.6%), and distal junctional failure (0.6%) (17,29-35). For instance, Luhmann *et al.* reviewed a series of 1,057 AIS patients and found a 3.9% risk of reoperation, with a 1.3% rate of infection, 1.1% pseudarthrosis, and 0.6% adding-on, all

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Table 2 Surgical characteristics

Characteristics	Data analysis
Fusion levels	
Number	179
Mean ± SD	10.4±2.02
Median ± IQR	10±3
Range	5–22
EBL (mL)	
Number	178
Mean ± SD	601.5±420.19
Median ± IQR	500±450
Range	90–2,400
Cell salvage amount (mL)	
Number	171
Mean ± SD	197.5±149.39
Median ± IQR	164±150
Range	20–1,050
Operative time (minutes)	
Number	179
Mean ± SD	228±54.4
Median ± IQR	221±76
Range	137–357
Length of stay (days)	
Number	179
Mean ± SD	3.2±0.80
Median ± IQR	3±1
Range	2–6
Pontes, n (%)	
Y	54 (30.2)
N	125 (69.8)

EBL, estimated blood loss; IQR, interquartile range; SD, standard deviation.

similar to the rates in the current series (30). Other large series of AIS patients (5,17,29-35) report similar results in terms of total complications and reoperations.

This 1.1% rate of pseudarthrosis is comparable to existing published rates (4,5,17,29-31). Historically, rates of pseudarthrosis were much higher, and have declined over time with advancements in surgical technique (8). Pseudarthrosis and reoperation were regular occurrences after early fusions (36). This markedly decreased in the 1950s in the era of Harrington (37). Pseudarthrosis rates have continued to drop, with Ramo *et al.* reporting a decrease from 2.9% during 1988–2002 to 0.4% during 2003–2007 with newer generation implants at a single institution (9). Larger multicenter series have consistently

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Table 3 Bone graft characteristics (index surgery)

Characteristics	Data analysis
Total bone graft volume[†] (cc)	
Number	179
Mean ± SD	69.9±16.99
Median ± IQR	60±24
Range	30–133.2
Volume of granules (cc)	
Number	179
Mean ± SD	58.9±7.11
Median ± IQR	60±0
Range	30–90
Length of strip (cm)	
Number	68
Mean ± SD	24±9.5
Median ± IQR	20±16
Range	10–40
Granule density (cc/fusion level)	
Number	179
Mean ± SD	5.9±1.13
Median ± IQR	5.5±1.7
Range	3.7–12
Total graft density[‡] (cc/fusion level)	
Number	179
Mean ± SD	6.9±1.88
Median ± IQR	6.7±2.8
Range	3.8–16.8
Quantity of granules used categories (cc), n (%)	
<60	12 (6.7)
60	164 (91.6)
>60	3 (1.7)
Strips used (% yes), n (%)	
Total cohort (n=179)	68 (38.0)
Patients with Ponte osteotomies (n=54)	53 (98.1)
Length of strip used (cm), n (%)	
10	10 (14.7)
20	34 (50.0)
36	23 (33.8)
40	1 (1.5)

[†], total bone graft volume was calculated as (morselized cc + length × 0.6 × 2). [‡], total graft density (cc/fusion level) was calculated as total bone graft volume/number of fusion levels. IQR, interquartile range; SD, standard deviation.

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Figure 2 Strips of synthetic bone graft substitute overlying posterior column osteotomy sites to protect the spinal cord from particulate bone graft.

Table 4 Early outcomes following index surgery

Outcomes	Category		Complication	
	Type	N (%)	Type	N (%)
Fusion	Yes	177 (98.9)	–	–
	No	2 (1.1)	Pseudarthrosis	2 (100.0)
<30-day ED visit	Yes	10 (5.6)	Pain and/or vomiting	10 (100.0)
<30-day readmission	Yes	3 (1.7)	Viral gastroenteritis	1 (33.3)
			Nausea	1 (33.3)
			Viral febrile illness	1 (33.3)
30–90-day readmission	Yes	4 (2.2)	Deep surgical site infection	2 (50.0)
			Infected pilonidal cyst	1 (25.0)
			Distal junctional failure	1 (25.0)

ED, emergency department.

demonstrated pseudarthrosis rates in AIS ranging from 0% to 1.4% (1-6,8,9,17,29-31), so the 1.1% pseudarthrosis rate in this series (one of which occurred traumatically) is consistent with these outcomes.

Some authors have suggested that no adjunct is needed beyond the locally harvested autograft that is obtained as part of standard surgical technique (28,38-42). For instance, smaller series have demonstrated pseudarthrosis rates of 0–1.9% using locally collected autograft alone. Despite these limited results, most surgeons prefer some form of bone

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Table 5 Reoperations

Outcomes	N (%)	Indication	Revision surgery	Timing post-index surgery (months)
Reoperations	7 (3.9%)	Deep SSI	I&D	2.5
		Deep SSI	I&D	8.9
			I&D, implant removal	27.8
		Deep SSI	I&D, implant removal	16.1
		Pseudarthrosis	Revision fusion	14.6
		Pseudarthrosis	Revision fusion	76.8
		Distal junctional failure with L4 bony Chance fracture	Revise fusion to pelvis	2.4
		Adding on, thoracic curve	Extend fusion from T10 up to T3	60.9

I&D, irrigation and debridement; SSI, surgical site infection.

graft augmentation to increase bone graft quantity along the length of the fusion to feel confident in maximizing rates of successful fusion. Historically, locally harvested autograft with ICBG has been the standard of care (10). However, due to the frequent need for a separate incision for graft harvest, as well as increased blood loss, infection risk, operative time, and donor-site pain, this technique is now generally avoided since alternative products can achieve similar rates of fusion (13). Allograft is a potential alternative (17), functioning as an osteoconductive scaffold; however, it lacks osteogenic potential, poses risk of transmitted infection such as hepatitis and human immunodeficiency virus (HIV), albeit exceedingly rare (16,38), and some families express resistance to the use of cadaveric product. DBM is an allogeneic bone-derived material, processed to remove its mineral content while retaining bone collagen and embedded proteins, with osteoinductive properties (17). However, there is variability in growth factor concentrations, lack of evidence supporting its effectiveness as a standalone osteobiologic material, and it may not be cost-effective at many institutions (17,43,44). rhBMP has potent osteoinductive properties but has limited use in the pediatric population with concerns regarding oncogenic potential, high cost, and other potential complications such as inflammatory edema, heterotopic ossification, and radiculitis (13,17,45).

For these reasons, synthetic bone graft substitutes have become an attractive alternative. Ceramic materials such as hydroxyapatite, tricalcium phosphate, and bioactive glass are frequently used in spinal fusions for their low cost, biologic inertness, and osteoconductive properties (17). Hydroxyapatite has chemical similarities to bone minerals and high osteoconductivity with similar fusion rates to ICBG (46,47). Tricalcium phosphate also exhibits similar osteoconductivity, but undergoes rapid resorption, typically within 6 weeks, so commonly serves as a bone graft substitute and extender to augment autograft (17,48,49). The bone graft substitute utilized in this report is a synthetic osteoconductive, resorbable scaffold option comprised of biphasic calcium phosphate, 85% beta-tricalcium phosphate and 15% hydroxyapatite, engineered to balance new bone formation while remodeling into the patient's own bone. This has been studied in animal models with high efficacy attributed to its osteoconductive properties (16-18). Smucker *et al.* performed a randomized controlled trial in a rabbit model comparing various ratios of the bone graft substitute used in the current study to ICBG and found no difference in fusion rates (21). There have been additional reports of utilization of this synthetic bone graft substitute in adult patients (23,26,27), but lack of reported usage and outcomes in pediatric patients.

Likewise, there is a paucity of data with few reports of other bone graft substitute utilization in children and adolescents. Harshavardhana *et al.* compared silicate calcium phosphate and ICBG in AIS and found equivalent fusion rates without complications (15). Theologis *et al.* compared patients receiving ICBG (n=152), allograft (n=199), or five separate bone graft substitutes (total n=110, including DBM, beta-tricalcium phosphate, rhBMP, coralline hydroxyapatite, and bone marrow aspirate combined with a matrix) and found shorter operative time in the bone graft substitute group, with no differences in fusion rates,

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complications, or patient-reported outcomes between groups (13). Despite these reports of successful fusion, more data are necessary to demonstrate the safety and efficacy of bone graft substitutes in pediatric patients, as a cost-effective option with avoidance of potential risks associated with ICBG or allograft.

Limitations

There are several limitations to this study that should be considered. First is the retrospective design, which may introduce selection bias. A control group was not included, and the volume and consistency of the material used were not standardized but were decided at the discretion of the operating surgeon. As such, this represents an "as-treated" cohort without direct comparison other than to historical controls, which limits conclusions regarding efficacy. Additionally, other changes coinciding with the synthetic bone graft transition, such as implant materials and technique, could have skewed results. Since it is not clear whether autograft and/or volume or type of bone graft is the main determinant for fusion, there is a risk for confounding bias. However, there are large series with well-documented pseudarthrosis rates in the AIS/JIS patient population that allow indirect comparison to population norms (4,5,17,29-31). Another limitation is that we did not have advanced imaging available for all patients to directly assess fusion, so we relied on indirect measures, such as the absence of clinical symptoms and radiographic abnormalities, as utilized in prior studies (13,28). While this indirect method of assessing fusion is common practice in retrospective studies due to the low rate of routine postoperative CT scans due to radiation exposure and cost concerns, it is possible that the "true" fusion rate could be lower if determined on CT scan in all cases. Additionally, this is a single-institution study of a select pediatric patient population, so results may not be generalizable. Finally, although we considered cost in the decision to use the bone graft substitute, as 60 cc of this synthetic graft material cost was 79% cheaper than an equivalent quantity of DBM graft and 8.6% cheaper than allograft cancellous chips, it is probable that these cost differences vary widely at other institutions.

Conclusions

In this study, the use of a synthetic bone graft substitute at Akron Children's Hospital was associated with a low pseudarthrosis rate and an acceptable complication profile for achieving PSF in patients with JIS or AIS.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://jss.amegroups.com/article/view/10.21037/jss-2026-1-0047/rc

Data Sharing Statement: Available at https://jss.amegroups.com/article/view/10.21037/jss-2026-1-0047/dss

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki and its subsequent amendments. This study was approved by the Institutional Review Board of Akron Children's Hospital (#2024-061). Informed consent was not required because this was a retrospective study.

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