

Resorbable osteosynthetic devices in pediatric traumatology: a prospective series of 24 cases

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Abstract Bioresorbable devices are commonly used in traumatology. The biomechanical stability of these materials has improved in the past decade, and they have proven to be biologically non-hazardous, while their main advantage is that their use avoids reintervention for removal of the device. A prospective monocentric study was conducted: 24 patients presenting with a fracture that was amenable to osteosynthesis by small-diameter screws were included. These comprised ten tibial spine fractures, four osteochondritis dissecans of the distal femur, eight fractures of the medial epicondyle of the distal humerus, and two distal tibial apophyseal fractures. One or more screws were used that were made of a copolymer of poly-L-lactide-poly-D-lactide acid and trimethylene carbonate with a diameter of 2.8 mm. All patients were immobilized with a cast. Clinical and radiographic monitoring was conducted every month. The entire follow-up protocol had a duration of 24 months. One patient with osteochondritis dissecans presented with joint effusion. Joint stiffness at the time of cast removal resolved completely after 4 months, except

for with three children (one epicondyle fracture, two tibial spine fractures). No subjective or objective instability could be detected by clinical examination. Radiographic follow-up revealed no secondary displacement, and all of the fractures had healed. No osteolysis was seen around the screws. No growth disturbances were noticed. Bioresorbable materials thus appear to be a suitable alternative approach for certain pediatric fractures. Their use resulted in outcomes similar to traditional techniques in terms of functional properties and bone healing. Although initial costs are presumably slightly higher, by avoiding a removal operation the total financial burden is most likely reduced. *Level of evidence* III.

Keywords Resorbable device · Osteosynthesis · Pediatric traumatology

Introduction

In pediatric trauma, stabilization of a fracture involves use of osteosynthetic devices made of stainless steel, or more recently titanium. Use of devices made from these materials can entail complications (e.g., hematomas, healing problems, local sepsis) and requires reintervention, often under general anesthesia, for removal of the device.

Resorbable or biodegradable materials are polymers that have been used for more than 30 years in surgical applications [1]. Initially used just for sutures, they are now commonly used in maxillofacial surgery, such as the use of resorbable plates and screws for osteotomy syntheses or mandibular fractures [2–6].

These materials are currently being used in a broader range of applications, such as in orthopedics, where interference screws and absorbable anchors are being used with

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increasing frequency. In the field of adult trauma, some teams use absorbable screws and plates for internal fixation of ankle fractures [7–11]. The biomechanical stability of these materials has improved, and they have been shown to have no hazardous biological properties [12]. Their main advantage, however, is the absence of the need for further surgery to remove the device. We hence decided to clinically and radiographically evaluate this type of pediatric trauma material in a prospective study.

Materials and methods

Starting in 2010, we performed a monocentric and multi-operator prospective study over a 2-year period that involved 24 patients who were examined repeatedly and whose clinical data were subsequently analyzed.

Materials

The criteria for inclusion were a fracture that was amenable to osteosynthesis with small-diameter screws or pins only for patients with open physes. Our series currently

comprises twenty-eight patients, but this study excluded patients for whom we do not have at least 4 months of follow-up.

Twenty-four patients were retained, of which 15 were boys and nine were girls, with an average age of 12.5 years at the time of the accident. The lesion was on the left side in fifteen cases and on the right side for nine cases (Table 1).

Three lesion groups were defined for inclusion: extra-articular apophyseal fractures, intra-articular fractures, and degenerative intra-articular lesions. We have hence retained eight cases of medial epicondyle distal humerus fractures and two cases of distal tibial McFarland fractures for the extra-articular lesions, ten cases of avulsion fractures of the tibial spines that were type 2 or higher according to the classification of Meyers and McKeever [13, 14] for the intra-articular fractures, and four cases of distal femur condyle osteochondritis dissecans as models for degenerative lesions that require fixation.

The imaging set comprised front and lateral view radiography of the joint or the affected segment, complemented by an ultrasound for three of the patients presenting with tibial spine fractures to more accurately analyze the displacement so as to confirm the surgical indication, and

Table 1 Epidemiological data for the operated series

Number	Gender	Lesion	Side	Age	Number of screws
1	M	Tibial spine	L	9.19	4
2	M	Medial epicondyle	L	9.99	1
3	M	Medial epicondyle	R	13.15	1
4	F	Tibial spine	L	9.30	2
5	M	Tibial spine	R	18.87	1
6	M	Medial epicondyle	R	8.54	2
7	M	Tibial spine	L	8.01	2
8	M	Tibial spine	L	13.74	2
9	F	Salter II of the distal tibia	L	5.71	3
10	F	Tibial spine	R	10.71	2
11	M	Lateral femur condyle osteochondritis	L	16.72	2
12	F	Lateral femur condyle osteochondritis	L	15.02	1
13	M	Medial epicondyle	R	13.93	1
14	M	Tibial spine	L	11.59	2
15	F	Medial epicondyle	L	12.80	2
16	F	Medial epicondyle	R	14.10	2
17	M	Lateral femur condyle osteochondritis	R	14.16	3
18	F	Medial epicondyle	L	8.12	1
19	M	Tibial spine	L	16.22	3
20	M	Lateral femur condyle osteochondritis	L	16.44	1
21	F	McFarland fracture	L	11.00	2
22	M	Tibial spine	R	15.09	3
23	F	Medial epicondyle	R	12.53	1
24	M	Tibial spine	L	14.93	3

an MRI for all the patients presenting with an osteochondritis.

All interventions were performed by one of the senior surgeons in the team. The delay in surgical treatment did not exceed 24 h. We systematically performed an open reduction for intra- and extra-articular fractures and in the case of two tibial spine fractures also a complementary suturing of the anterior cruciate ligament. For condyle osteochondritis dissecans, the extent of the lesion was assessed by arthroscopy, while the placement of the osteosynthetic device was performed by a complementary arthrotomy.

The items used were one or more screws made of a copolymer of poly-L-lactic-poly-D-lactide acid and trimethylene carbonate (Inion OTPS[®]) that has seen prior use in pediatric orthopedics [15] and in traumatology [16], and that were 2.8 mm in diameter and 40 mm in length. These screws were custom-cut to the required length using the utensils provided with the product kit, and this is an inherent aspect of working with this material. For each intervention, one to four items were implanted.

The patients were all immobilized by use of a postoperative cast for which the type and the duration were customary for pediatric traumatology in terms of the lesion being treated, irrespective of the osteosynthetic material that was used. Thus, with a long leg cast for tibial spine fractures, the duration was 6 weeks, while with an arm cylinder cast for medial epicondyle fractures, the duration was 4 weeks. Patients treated for an osteochondral knee lesion were discharged with a protective splint that was to be worn for 6 weeks, and minor limb use was permitted once the intra-articular effusion had dissipated.

Methods

The surgeon who performed the osteosynthesis monitored all of the patients by successive radio-clinical checkups at 4–6 weeks (depending on the duration of the immobilization by the cast), at 2 and 4 months, and at the last follow-up clinical examination. The three lesion groups described previously were separated for the analysis.

The clinical evaluation at each examination entailed the criteria inherent for the fracture, such as the level of pain and the recovery of joint movement, and those that could potentially be related to the materials used, such as cutaneous or subcutaneous inflammatory reaction or an articular effusion.

At each examination, the radiological assessment comprised a front view and lateral view centered on the lesion, to discern aspects and timing of the consolidation, the occurrence of a secondary displacement, and the development of an osteolytic response at the level of the osteosynthetic device, as has been described previously

with certain polyglycolic acid materials [17, 18]. Furthermore, patients being monitored for osteochondritis dissecans lesions received an MRI checkup in order to monitor the integration and vitality of the fragment.

The minimal follow-up for inclusion had to be at least 4 months from the last visit. Hence, the only variable for this series was the use of a resorbable osteosynthetic material, as all other criteria for the treatment remained unchanged.

Ethics

The study was performed in accordance with the guidelines of the national ethics committee in charge of clinical research with humans, and it was in accordance with the Declaration of Helsinki of 1975, as revised in 2000.

Results

With the exception of one individual (who was not a local resident), all of the patients received a follow-up examination of their injury. At this final examination, clinical healing of the injury was achieved in all cases, and we did not observe any infectious complications. Our average clinical follow-up is 10 months, with a maximal follow-up of 2 years (based on final communication with the patient and/or their guardian).

Extra-articular apophyseal fracture

Upon removal of the cast, the patients who were treated for a medial epicondyle or McFarland fracture did not experience any pain. There was no sign of a local subcutaneous inflammatory reaction to the device. At the last visit, all elbows were stable in the frontal plane, but they also all exhibited an extension impairment amounting to between 5° and 30°. One patient presented an asymptomatic protrusion of the medial epicondyle. Until now, we have yet to encounter a local reaction to the device. On the other hand, three patients had a subcutaneous mobile fragment corresponding with a loose screw head once the body of the screw had been resorbed, but they had no other local symptoms. These loose screw heads were noted at the very last follow-up clinical examination, and they were by then already undergoing resorption themselves. The final patient interview, at approximately 24 months, indicated that the screw heads had essentially disappeared by then, without having caused any noticeable adverse effects.

From the radiographs, no secondary displacement could be discerned during the follow-up clinical examination. The consolidation was progressive and occurred without delay. The path of the screws remained more or less

visible, but we did not notice any osteolytic reaction surrounding the material (Fig. 1).

Intra-articular fracture

Out of ten patients treated for tibial spine fractures, two exhibited an impaired extension of 5° – 10° , and one other patient presented with algodystrophy and a lack of full recovery that prompted treatment at a rehabilitation center. The pain progressively disappeared and no persistent joint effusions were encountered that would be indicative of a reaction to the material. At their last clinical examination, all of the patients who were treated for a tibial spine fracture had a knee that was stable in the sagittal plane.

No secondary displacement could be discerned from the radiographs in the follow-up clinical examinations. The consolidation was progressive and occurred in the expected time frame. The path of the screws remained more or less visible, but we did not notice any abnormal reaction surrounding the material. The channel that could be seen was of the same diameter as that specified for the embedded screws, thereby ruling out all abnormal manifestations of extensive bone lysis (Fig. 2).

Degenerative intra-articular lesions

After 4 months of follow-up, two patients who were treated for osteochondral lesions had achieved normal joint movements without pain or effusion. Only one still had some movement-associated pain due to slight effusion. Ultimately, this last patient required specialized treatment by a physical medicine and rehabilitation team because, due to their aversion to pain, they refused to reapply weight. Their clinical progression was then favorable.

Follow-up by MRI showed consolidation of the osteochondral fragment for one patient, while the other three retained a viable fragment during the integration due to a shorter follow-up period with these three patients (Fig. 3).

Discussion

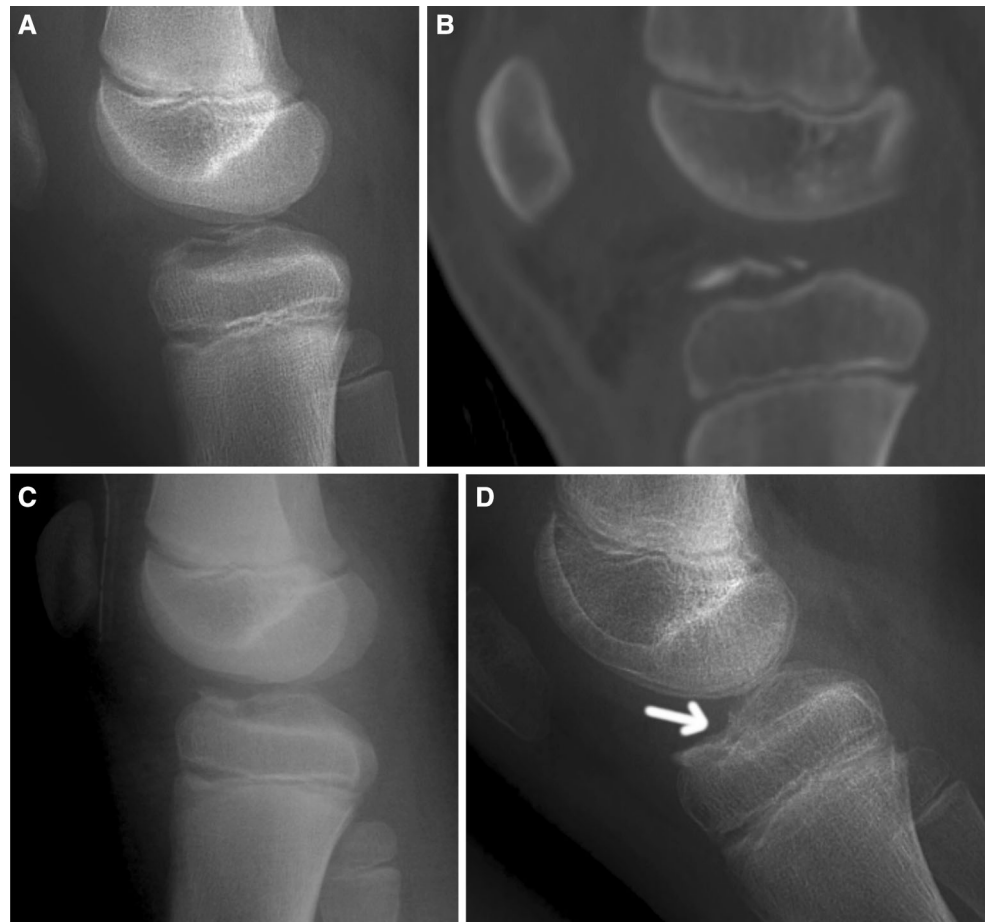
The use of resorbable materials in traumatology dates back to 1987. Rokkanen was the first to use it in Finland [19]. This initially only amounted to use of resorbable pins made from polyglycolic acid (PGA). Aside from issues inherent to osteosynthetic procedures, such as infection and



Fig. 1 Young girl, aged 14, presenting with a medial epicondyle fracture (**a**), treated by open reduction using a resorbable screw (**b**), for which the consolidation is readily visible after 6 weeks (**c**), and

the radiographic aspect is shown at a follow-up of 1 year (**d**). The visible path of the screw (*arrow*) disappears progressively

Fig. 2 Child, aged 11, who presented with an apparently displaced fracture of the tibial spines (a), for which the ultrasound image confirms the displacement and multi-fragmented nature (b). The osteosynthesis is ensured by two resorbable screws (c). The path of the screws is barely visible after 4 months (arrow), and without impairment of growth at the level of the tibial physis. The screws were strictly intra-apophyseal (d)



pseudarthrosis, the main disadvantage of these first-generation resorbable materials was the occurrence of local inflammatory reactions. In a series of nineteen ankle fractures, Eitenmuller [20] used plates and screws made of poly-L-lactide (PLLA). He reported a 52 % incidence of such inflammatory reactions. He did, however, come to the conclusion that there was a correlation between the volume of the device and the incidence of this reaction. In a series of more than 2000 patients, Böstman encountered a 5.3 % incidence of such inflammatory reactions [21]. He also concluded that a large area of resorbable material was a risk factor for an inflammatory reaction, which according to these studies occurred, on average, 8–18 months following the surgical procedure.

Since then, these materials have been perfected both at the mechanical level and at the chemical level. In 2008, Nieminen [12] studied a new resorbable material in animals that was used for maxillofacial surgery. This is the same copolymer that we used in our study. They found 100 % degradation without an inflammatory reaction after twenty-four months.

Among the more recent studies, Kukk [16] used this same material and encountered only a 2 % incidence of

inflammatory reactions. In our cases, no local inflammatory reaction and no other specific complications (e.g., allergies) were found after an average clinical follow-up of 10 months.

There are few reports in the literature of pediatric use of these materials. Only Mavrogenis [15] has reported a recent series on the use of a resorbable implant for children. This implant was of the same composition as that used in our study. This study comprised a heterogeneous cohort of nine patients who were treated for issues relating to trauma or deformities. Fifty-two devices were implanted. Generally speaking, the incidence of complications that they encountered was similar to those reported in the literature, but they did not detect any inflammatory reaction. More specifically, they did not see any growth impairment over an average follow-up period of 17 months. To our knowledge, no other study has reported a series identical to ours.

Aside from these considerations, the principal advantage of this resorbable material is the lack of need for additional surgery to remove the device. Indeed, the morbidity of reintervention is obvious. There are inherent risks with anesthesia, although we do not address these further here.

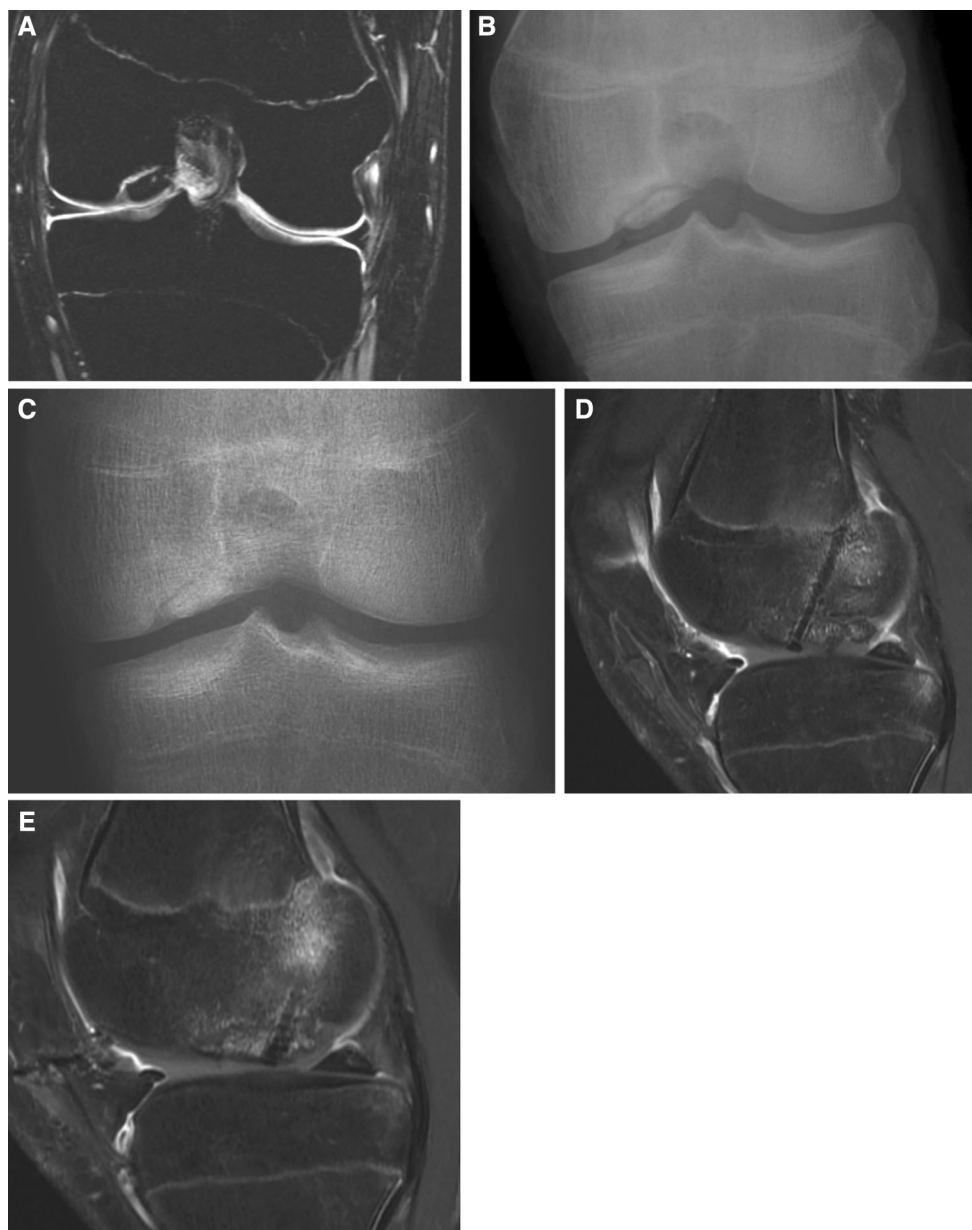


Fig. 3 T2 echo-gradient MRI (**a**) of a class 2 internal condyle osteochondritis, according to the SOFCOT classification (30) in a young man, aged 14, who was treated by insertion of two screws for which the radiographic image is shown immediately postoperatively (**b**) and at 6 weeks (**c**). The follow-up MRI at 3 months (sequence in

T1 with fat saturation and injection of gadolinium) displays a reintegration of the fragment, without an inflammatory reaction at neither of the two screws nor an idiosyncratic articular effusion (**d** and **e**)

The surgical intervention also has its own inherent risks. In 2008, Raney [22] performed a literature review regarding complications related to removal of the devices in children. The principal complications were fractures, infections, hematomas, problems with healing and failure to remove part of or all of the material. Furthermore, they reported several series that entailed complications due to an item being left behind (e.g., allergic reactions and induced tumors). The other advantage stems from cost savings. Indeed, the initial expense of the device is largely

compensated for by the savings gained by avoiding renewed intervention, as well as by being able to avoid having to treat potential specific complications. This was also demonstrated by Böstman, even though this was not a pediatric study [23].

Nonetheless, this technique does have some drawbacks. The radio-transparency of the material does not allow visualization of a possible movement of the screw or a fragment that has become detached, as was the case with three of our patients. On the other hand, this radio-

transparency is an advantage for postoperative monitoring by tomodensitometry or MRI, since it reduces artifacts. The other difficulty is the learning curve to master the skills required to work with these materials. Indeed, the material has a lower resistance to torsion, and it is not designed to allow application of considerable compression of the fragments. Rather, the material is meant to be used for osteosynthesis without compression, once the anatomical reduction has been made and firmly maintained during the placement of the implant in keeping with the specific properties of the ancillary device. This is also what Mavrogenis noted: In his study he encountered six broken screws [15]. He attributed these mechanical failures to inadequate drilling and tapping prior to insertion of the screws.

Lastly, and more specific to traumatology, for each of our lesion groups, our clinical and radiological results at the last visit were comparable to those found in the literature when a different type of metallic material was employed.

Louahem et al. [24] reported a series of 139 fractures of the medial epicondyle that were followed up, on average, for 3.9 years. The treatment was surgical regardless of the displacement, and the open reduction was systematic, as with us. They obtained 100 % consolidation, an absence of cubitus valgus, and an impairment of extension that was less than twenty-five degrees among 4 % of the patients. In our series, use of resorbable material allowed us to obtain results identical these at the last follow-up clinical examination.

Tibial spine fractures have mainly been documented by long-term studies like that of Casalonga et al. [25] who retrospectively reviewed thirteen patients for more than 2 years. Seven presented with a fracture of at least type 2 according to the classification of Meyers and McKeever [13, 14]. They were treated by suturing or direct attachment of the fragment with screws. They encountered no infectious complication or fault with the consolidation. We did not encounter instability or clinical looseness either, without, however, having performed objective measurements of the forward drawer test using a specific tool like the KT 1000®.

Lastly, use of resorbable materials for the fixation of osteochondral fragments dates back to 1997 when Tuompo used resorbable pins for a cohort of twenty-four patients [26]. It was only in 2005 that Larsen [27] presented a series of fixations by screws made of copolymer. No inflammatory reaction was encountered, contrary to prior studies that had reported several cases of synovitis in relation to the use of resorbable material made from PLLA [28, 29]. In our case, we only had to contend with one case of a recidivist effusion, for which it was not possible to know the contribution of an eventual inflammatory reaction. The most important series of relevance to functional outcomes is that

of the 2006 SOFCOT symposium which performed ninety-five surgical treatments on a cohort of 892 patients with osteochondritis dissecans [30]. A resorbable material was used with 25 % of the patients, with screws and pins being used equally. The authors noted good functional outcomes for 67 % of the interventions, without obtaining evidence for significant differences between each technique.

Conclusions

Resorbable materials have been used for surgical applications over the past 30 years. They have evolved progressively so as to exhibit a better biological tolerance and to attain better mechanical properties. In the last decade, they have seen routine applications in maxillofacial trauma and in orthopedics (e.g., interference screws for ligament grafts and resorbable anchors in rotor cuff surgery as well as in meniscal reinsertions).

The consolidation outcomes in this study were comparable to those seen with surgical techniques that use metallic devices. The clinical outcomes fully matched those obtained using conventional osteosynthesis techniques. Furthermore, at the biochemical level, it is worth noting that improvements in these materials tend to eliminate their principal drawback of non-specific inflammatory reactions. It remains to be seen, however, whether a sensitization to the different components may not nonetheless occur eventually and hence lead to a possible reaction in case of repeated use of these materials.

One of the principal advantages of this type of material lies with the lack of a requirement for additional surgical intervention to remove the item. This represents a major benefit to the patient since all surgical procedures under anesthesia entail a degree of risk. Furthermore, repeated surgical intervention can result in psychological stress, particularly in the pediatric setting. The other advantage that needs to be taken into account is the significant reduction in healthcare costs. Thus, while these materials have a higher initial cost, savings made by being able to avoid a day of hospitalization and additional interventions largely make up for the initial expense.

Conflict of interest None.

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