Outcomes analysis after routine removal of implants in healthy pediatric patients

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Routine removal of nonspinal, orthopedic implants from pediatric patients is a debated practice. The purpose of this study was to compare preremoval and postremoval outcome measures in children. Twenty-five patients, mean age 11.6 years, completed a pain scale and the Pediatric Outcomes Data Collection Instrument (PODCI). Many patients scored in the normal range of the PODCI before and after removal. Higher postoperative PODCI scores were found in patients without preoperative pain, and in patients with upper extremity versus lower extremity implants. In summary, routine removal of implants in children was carried out without complications and with some functional benefits. ***J Pediatr Orthop B*** **18:381–387** © **2009 Wolters Kluwer Health | Lippincott Williams & Wilkins.**

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Introduction

The indications for removing orthopedic implants from children are not clearly understood. Some authors have advocated routine removal of implants (ROI) from pediatric patients [1], whereas others have discouraged that procedure [2]. Peterson [3] provided a list of proposed indications, including removal of all Kirschner wires, Steinman pins, implants from the lower extremities, and patients wishing to participate in contact sports. The risk of complications associated with ROI in children has been reported to be as high as 27% [4]. Aside from the avoidance of anecdotally reported adverse complications, such as late infection or fractures secondary to stress shielding, the benefits from ROI remain largely unknown.

To the best of our knowledge, no prospective studies have looked at healthy pediatric patients to assess the effects of routine ROI. Most studies are retrospective and focus primarily upon the type and frequency of postoperative complications [1,2,4–8]. Although these papers provide valuable insight into the possible risks of ROI (including those specific for certain implants), they focus on only one aspect of the argument, for or against ROI. As stated by Becker *et al.* [8], '…to address the question of routine blade-plate removal, we must evaluate all the patients who had blade plates inserted over a similar time span and determine their rate of problems related to the retained hardware'. However, this would be difficult to establish as the rate of unfavorable effects related to retained implants is low [3] and the follow-up period is potentially the lifetime of the patient.

We examined the short-term effects of routine, nonspinal implant removal from a healthy pediatric population using outcomes analysis. The purpose of this study was to prospectively compare pre-ROI and follow-up ROI outcome measures, using a pain assessment scale and the Pediatric Outcomes Data Collection Instrument (PODCI) version 2.0 [9] to evaluate functional and psychosocial status.

Materials and methods

Between November 2005 and May 2007, 36 consecutive patients with a mean age of 11.5 years (range, 3–18 years) were identified as healthy children undergoing elective orthopedic ROI. Patients were included if they were between the ages of 2 and 18 years, had no major comorbidities or diagnoses causing limited mobility, and had achieved full activity status before routine ROI. All fractures or osteotomies were united radiographically and the surgeries were performed under general anesthesia on an outpatient basis. One patient had his index surgery at an outside institution. The study protocol had institutional review board approval.

All patients were examined by the treating physician to rule out other indications for ROI such as infection, neurogenic pain, or nonunion. Even when asymptomatic, no patients refused elective removal. Charts were reviewed for age, sex, medical comorbidities, initial diagnosis, implant type, and post-ROI complications. A 10-point pain scale (0 = no pain; 10 = worst possible pain) and PODCI questionnaires were completed

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in-person pre-ROI and through phone at follow-up. The PODCI for pediatric patients between the ages of 2 and 10 years has a parent-reported form, and the PODCI for adolescents between the ages of 11 and 18 years has both self-reported and parent-reported forms. The PODCI has six scales: upper extremity (UE) function, transfer and basic mobility, sports and physical functioning, comfort/pain, global functioning, and happiness. Global functioning encompasses all scales with the exception of happiness.

Table 1 Frequency of implant type and diagnosis

Implant type (*n*)	Diagnosis	*n*
Flexible nail (10)	Both bone forearm fracture	5
	Elbow fracture	3
	Wrist fracture	1
	Tibia fracture	1
Plate/screws (7)	Legg–Calve–Perthes	4
	Both bone forearm fracture	1
	DDH	1
	Femur fracture	1
Screws (4)	Ankle fracture	2
	DDH	1
	Tibia fracture	1
Staples (2)	Cavus foot	1
	Genu valgum	1
Screws/rush rod (1)	Ankle fracture	1
Staples/Steinman pin (1)	Cavus foot	1

DDH, developmental dysplasia of the hip.

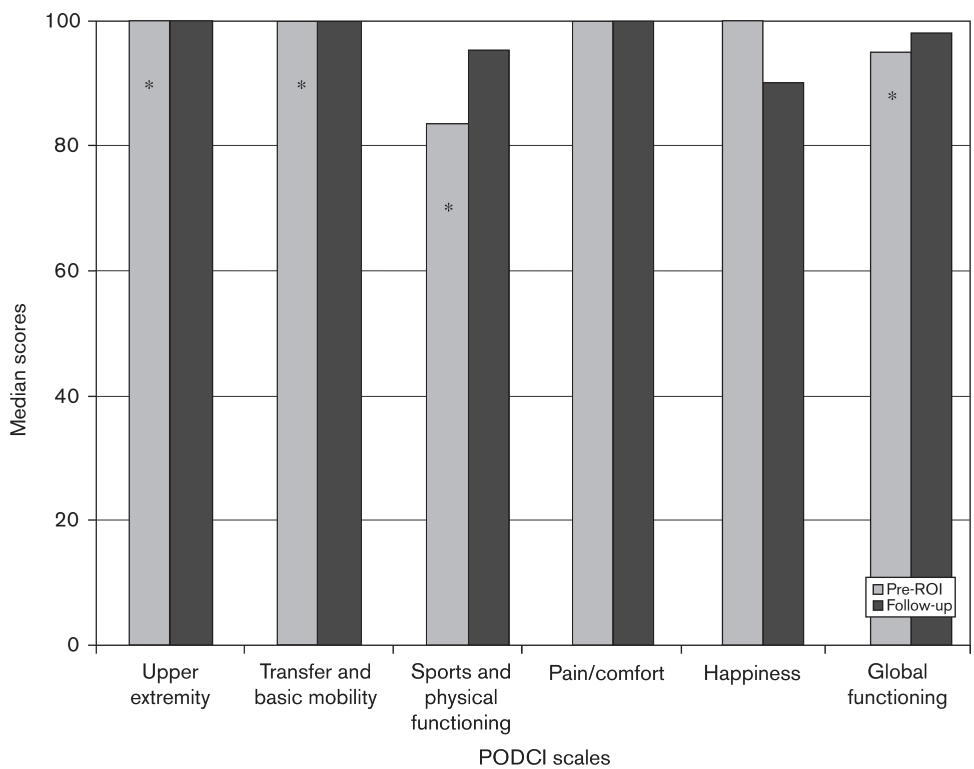
Statistical analysis

The *t*-test for independent samples was used to compare the age, and the Fisher exact test was used to compare the proportions in which pre-ROI pain was present or absent, of the group that completed both the pre-ROI and the follow-up ROI PODCIs with the group that was lost to follow-up. As the PODCI scores were negatively skewed, comparisons were made using nonparametric statistics, the Wilcoxon signed ranks test for related samples, and the Mann–Whitney *U* test for unrelated samples. For the group of patients with pre-ROI pain, the *t*-test for related samples was used to compare pre-ROI and follow-up pain scores. For all analyses, *P* value of less than 0.05 was considered statistically significant. Statistical analyses were performed using SPSS 10.0 (SPSS Inc., Chicago, Illinois, USA).

Results

Of the 36 patients, three were excluded. One patient's parent refused to sign consent and two patients underwent additional surgery on the affected extremity before follow-up. Eight other patients were unreachable. In total, 25 patients (69%) had complete pre-ROI and follow-up data at a mean of 16.5 months (range, 8.5–30.5 months).

Fig. 1



Median Pediatric Outcomes Data Collection Instrument (PODCI) scores pre-removal of implants (ROI) and at follow-up for the entire sample ($n=25$). $^*P<0.05$.

The comparison of the eight patients lost to follow-up with the ones retained for the study showed no statistically significant difference in age, presence of pre-ROI pain, and pre-ROI PODCI scores on all six scales.

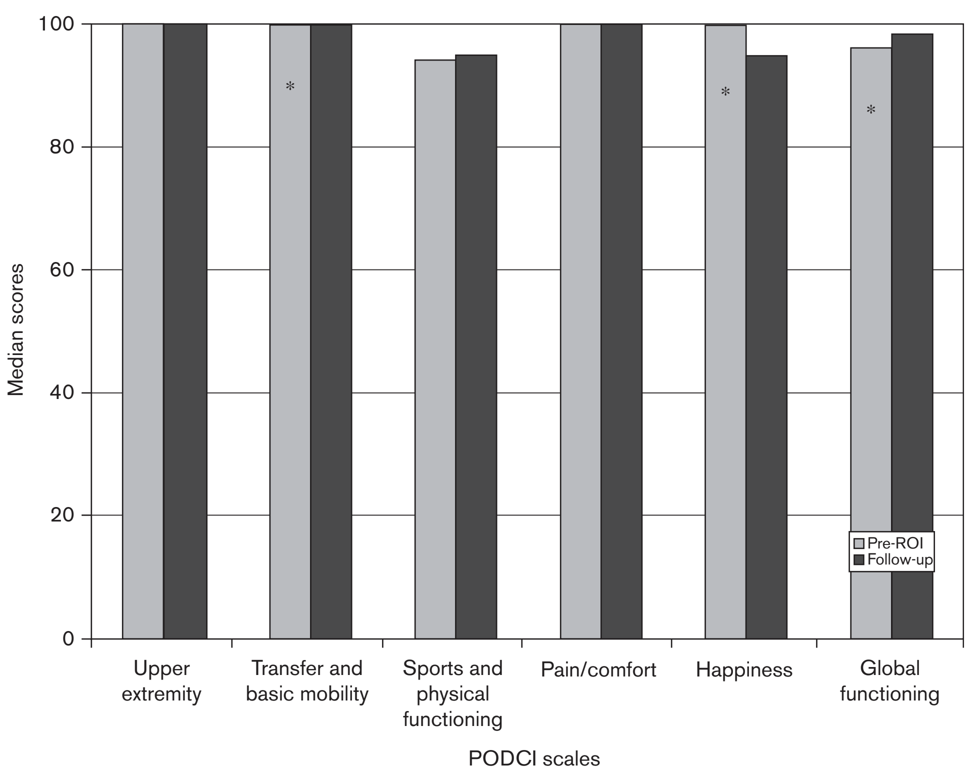
The 16 boys and nine girls enrolled in this study had a mean age of 11.6 years (range, 3–18 years). Although none had any major medical comorbidities, three had diagnoses of very mild cerebral palsy, low-level lipomeningocele, and Ehlers-Danlos syndrome. The mean length of time that the implant had been in place was 8.3 months (range, 2–31 months). The implants were in the UE in 11 patients and the lower extremity (LE) in 14 patients. Implant type and initial diagnosis are listed in Table 1. No intraoperative or postoperative complications were associated with implant removal surgery.

In reference to the PODCI forms, the follow-up group consisted of 10 pediatric and 15 adolescent patients. Three adolescent patients only had self-reported follow-up PODCI scores. A statistically significant improvement from pre-ROI to follow-up was found in four scales: UE ($P = 0.033$), transfer/basic mobility ($P = 0.014$), sports ($P = 0.017$), and global functioning ($P = 0.012$) (Fig. 1). Three of the four significant scales had median scores in the mid-90s to 100 at pre-ROI and at follow-up. The only scale, which had a median score below the 90s was sports, in which the score was 83 (range, 70.50–100) pre-ROI versus 95.00 (range, 85.00–98.50) at follow-up.

Preoperatively, seven patients (28%) reported having symptomatic pain at the area of the implant with a mean pain score of 1.9 (range, 0.6–2.9) pre-ROI and 1.8 (range, 0–5.0) at follow-up, which were not significantly different ($P = 0.92$). At follow-up, four of these patients (57%) had complete relief of pain with ROI. In spite of successful surgery, the remaining three (43%) patients still reported pain. No patients without pre-ROI pain developed pain at follow-up.

The PODCI scores for the seven patients with reported pre-ROI pain showed no significant difference between pre-ROI and follow-up scores. In the 18 patients without pain, a significant improvement at follow-up was seen in transfer/basic mobility ($P = 0.011$) and global functioning ($P = 0.020$), but there was a significant decrease in happiness ($P = 0.044$) (Fig. 2). However, all median values were again in the mid-90s to 100 pre-ROI and at follow-up.

Fig. 2



Median Pediatric Outcomes Data Collection Instrument (PODCI) scores pre-removal of implants (ROI) and at follow-up for the group without preoperative pain. *$P < 0.05$.

When comparing the PODCIs between the two groups with and without pain, pre-ROI scores were not significantly different for any of the scales. At follow-up, the group without pain had significantly higher median scores in the scales of pain ($P = 0.008$; 100 vs. 64) and global functioning ($P = 0.009$; 98.5 vs. 85) (Fig. 3).

A separate analysis was also performed for the group of patients with UE implants ($n = 11$) and those with LE implants ($n = 14$). The UE patients showed significant improvement at follow-up in UE ($P = 0.046$), sports ($P = 0.018$), and global functioning ($P = 0.012$) (Fig. 4). Pre-ROI and follow-up median scores for UE and global functioning scales were in the 90–100 range. Only sports had a pre-ROI median value in the 80s; it improved from 83 (range, 82–100) to 97 (range, 92–100). In the LE patients, no significant differences were found between pre-ROI and follow-up for any of the scales.

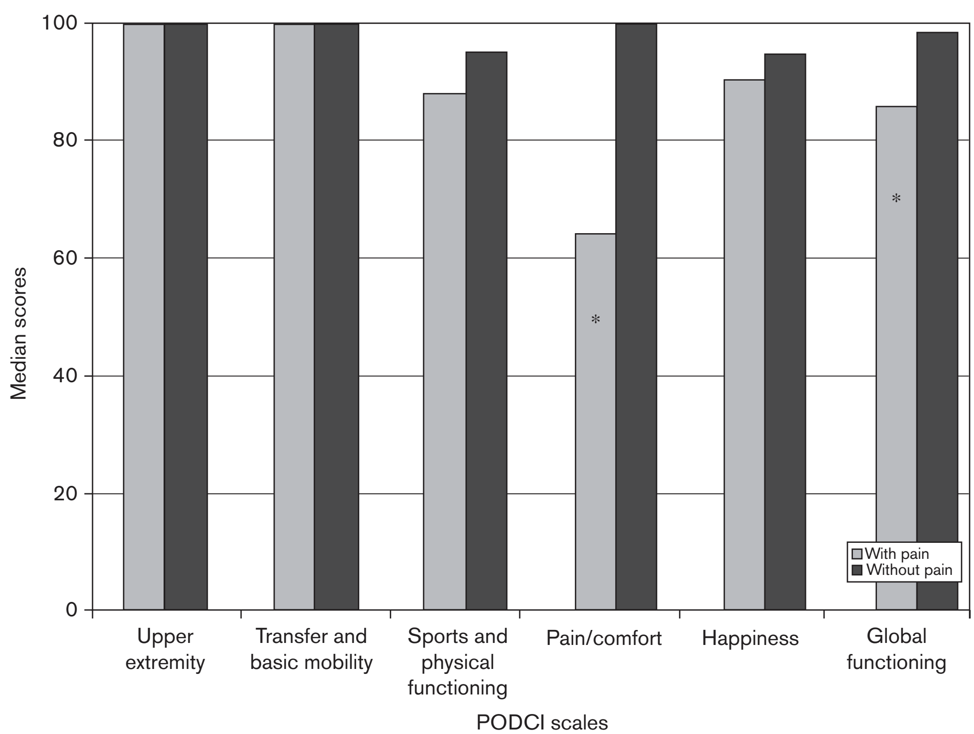
When comparing the pre-ROI PODCI scores for UE and LE groups, all scales were once again not significantly different. At follow-up, scores were significantly higher in the UE group in sports ($P = 0.029$), happiness ($P = 0.025$), and global functioning ($P = 0.021$) (Fig. 5). Again, all median scores were in the 90s to 100, except happiness, which was 85 for the LE.

In summary, our analysis shows a probable improvement in the sports scale of the PODCI questionnaire within patients undergoing implant removal. All other possible differences were obscured by very high, nearly normal pre-ROI PODCI scores. There was a trend towards improved post-ROI PODCI scores in patients without versus those with reported preoperative pain. There was also a trend towards improvement in post-ROI PODCI scores in patients with removal of UE implants versus those with LE implants.

Discussion

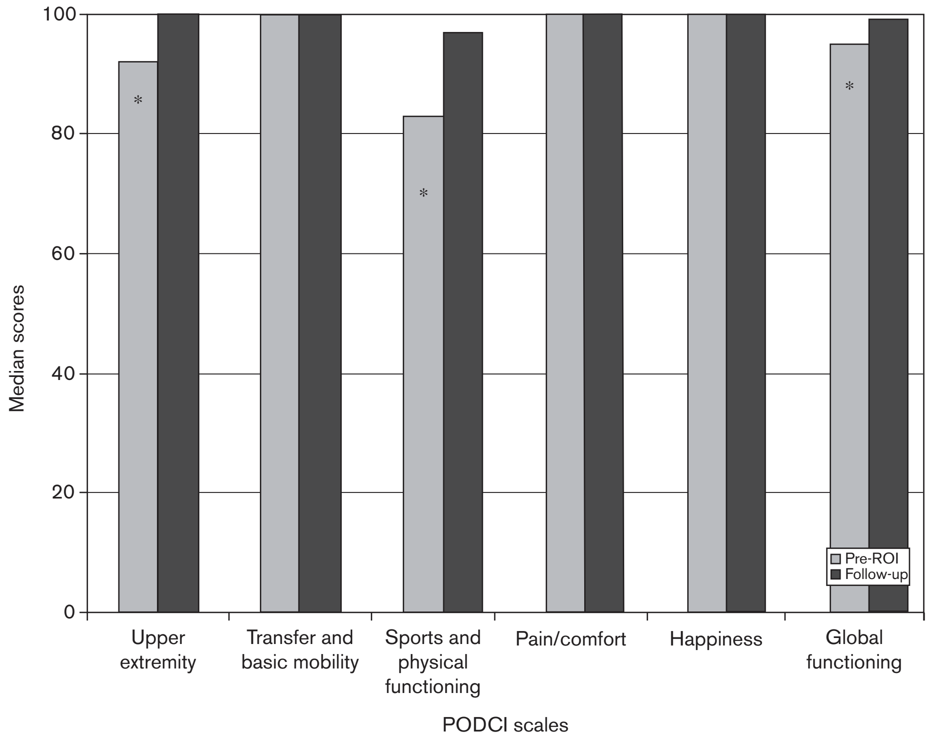
Routine removal of orthopedic implants in pediatric patients is carried out on a widely variable basis, with reported rates ranging from 13 to 69% depending on the particular surgeon or institution's customary protocol [2,8]. The associated costs of additional surgery to the patient may be unwarranted if clearly defined benefits are not achieved [10]. To that end, in adults, recommendations for ROI are generally made for selected indications such as pain, infection, or nonunion. In a group of adult patients undergoing removal of painful implants after successful fracture fixation, Minkowitz *et al.* [11] recently showed pain relief and improvement in function at 1-year follow-up. The average time of metal implantation before removal was greater than 3 years.

Fig. 3



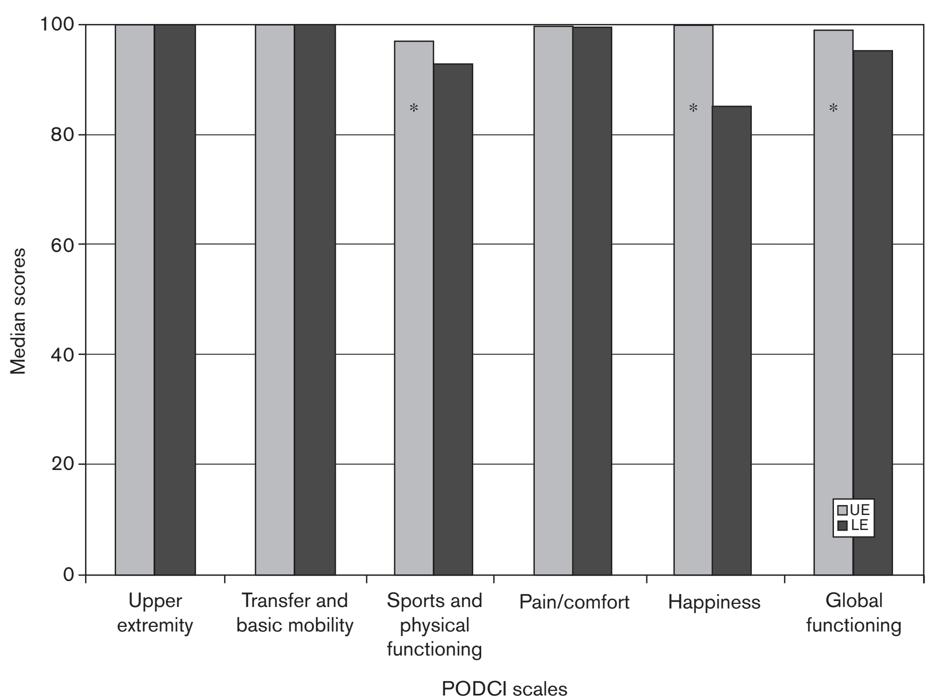
Median Pediatric Outcomes Data Collection Instrument (PODCI) scores at follow-up for the groups with and without preoperative pain. *$P < 0.05$.

Fig. 4



Median Pediatric Outcomes Data Collection Instrument (PODCI) scores pre-removal of implants (ROI) and at follow-up for the upper extremity (UE) group. *$P < 0.05$.

Fig. 5



Median Pediatric Outcomes Data Collection Instrument (PODCI) scores at follow-up for upper extremity (UE) and lower extremity (LE) groups. *$P < 0.05$.

Pediatric patients have a large capacity for bone remodeling, which can lead to difficulty with late cases of implant removal. Lovell *et al.* [6] noted that dynamic-compression plates retained for less than 12 months in patients with an average age of 8.0 years caused bone indentation of 36.3%, whereas dynamic-compression plates that remained for greater than 2 years led to indentation of 50%. In a group of 304 patients undergoing ROI at an average age of 11 years, Alzahrani *et al.* [7] found significantly higher blood loss and time of surgery for the subpopulation, which had ROI more than 3 years after the original procedure. Specific areas, such as the proximal femur, appear to have a window of opportunity lasting 1–2 years, beyond which ROI becomes substantially more challenging.

The argument for routine, rather than selected, implant removal in pediatric patients arises because the opportune time for removal is limited and symptoms may or may not develop within the ideal time frame. In one group of children having routine removal of flexible nails after an average implantation of 7 months, only 11% had any preoperative symptoms [12]. Morshed *et al.* [13] reported on a series of 24 patients, aged 5–13 years, in which femoral flexible intramedullary nails were recommended to be retained. At 3.6 years of follow-up, six patients had chosen elective removal of the nails at an average of 15 months postoperatively. In another study of hip blade plate removal from children, for which the indications were mostly painful implant or skin breakdown, the time from osteotomy to ROI covered a wide span of time, ranging from 2 to 74 months [8]. In addition, concerns about metal allergy and carcinogenicity, though not reliably substantiated, would take an average of 20 years to manifest [3].

At our institution, ROI for healthy pediatric patients is routinely scheduled 6–12 months following the index procedure. In certain cases where the implant clearly does not provide additional stability after fracture healing (e.g. individual screws), ROI can take place even earlier. We concur with most authors who support removal of pediatric hip implants, particularly those in the proximal femur [14]. One exception to that policy is screw removal for slipped capital femoral epiphysis, a procedure which is often more complicated, and yet, if retained, causes little morbidity at skeletal maturity [1,2,5]. In all cases of successful ROI, it is essential that preoperative indications for a well-healed osteotomy or fracture are met, and that post-ROI management such as protected weight-bearing or delay of return to sports is strictly enforced.

This prospective outcomes analysis of the effect of routine ROI found, in general, that patients scored highly on the PODCI pre-ROI as well as at follow-up. The majority of all median PODCI scores, in all analyses, were clustered at the very high end of each of the scales (range, 90–100), indicating an almost normal pre-ROI level of function [15]. Only the sports scale had a pre-ROI score in the 80s for the entire sample and the UE analysis, which significantly improved at follow-up to the mid-90s to upper-90s. Whether this was related to substantive physical improvement, increased patient or parental confidence, or the natural improving history after fracture or osteotomy is unknown.

Approximately, one-quarter of the patients had mild preoperative pain and at follow-up, 57% (four out of seven) no longer had pain. Two patients who continued to have pain had diagnoses reflecting chronic, as yet uncorrected conditions: patellofemoral instability and hip dysplasia. The third patient reported very mild residual pain 11 months after ROI from an ankle fracture. Although the number of patients with pre-ROI pain was small, the group as a whole showed general improvement at the post-ROI time point.

The limitations to the current investigation include a nonhomogenous population with respect to diagnoses and implants removed, a relatively small sample size, and the use of the PODCI rather than a more specific outcomes instrument. The purpose of the study was to compare pre-ROI and post-ROI pain and PODCI scores in all pediatric patients undergoing elective, routine ROI. As there was a mixed population, additional comparison could be made between different groups, for instance those with upper versus LE implant. All of the statistical analyses were specifically interpreted for smaller sample sizes. In addition, the PODCI is a widely accepted outcomes measure and one that we originally felt could show generalized improvement or worsening function in pediatric patients. In retrospect, given that so many patients had pre-ROI and post-ROI scores in the normal range, we believe that the PODCI could have been supplemented with other, more region-specific outcomes instruments.

In conclusion, routine, nonspinal implant removal in healthy pediatric patients was carried out without complications and with a few functional benefits. In the short-term, we found that retention of implants was not significantly impairing the function of the children and adolescents, and its removal did not change the patients' function, whereas it eliminated pain in some cases. Patients without pre-ROI pain and those with UE implants had a tendency for greater improvement on the follow-up analysis versus those reporting pre-ROI pain and those with LE implants.

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