Treatment of medial humeral epicondyle fractures in children using absorbable self-reinforced polylactide pins

Yuxi Su, MD, PhD, Guoxin Nan, MD, PhD

Abstract
The best treatment for medial humeral epicondyle fractures in children has been debated. In case of incarceration of the epicondylar fragment, particularly after elbow dislocation, several materials are used for fixation, including Kirschner wires (K-wires), metallic compression screws, tension band wire, and suture anchors. Herein, we introduce a new fixation material: the absorbable self-reinforced polylactide (SR-PLA) pin.

The aim of the study was to prove the feasibility of a new fixation material (absorbable SR-PLA pins) for the treatment of medial epicondyle fracture in children.

Thirty-two patients who underwent surgery in our hospital from August 2007 to January 2012 were retrospectively analyzed. The patients were divided into group A (K-wires) and group B (absorbable SR-PLA pin). Group A comprised 11 males and 4 females, aged 8 to 14 years (average, 12.6 years), with 12 patients with elbow dislocation. Group B comprised 13 males and 4 females, aged 7 to 15 years (average, 11.8 years), with 13 patients with elbow dislocation. The same approach was used for all patients by the same team of surgeons, and all the patients were followed up for over 12 months. In all patients, rehabilitation training was started after 3 weeks. The Broberg and Morrey elbow scale was used to evaluate elbow function at follow-up.

Four patients from group A developed pin-track infections that gradually resolved after removal of the K-wires, whereas no infections occurred in group B. One patient refractured her humerus after K-wire removal. Using the Broberg and Morrey elbow scale, outcomes in group A were classified as excellent in 5 patients (33.33%), good in 7 patients (46.67%), fair in 2 patients (13.33%), and poor in 1 (0.07%). Group B outcomes were scored as excellent in 12 patients (70.58%), good in 4 (23.53%), and fair in 1 (0.06%) and no patient (0.00%) had a poor outcome. The average Broberg and Morrey score for group A was significantly lower than that for group B (83.27 ± 7.02 vs 95.21 ± 5.04; P = .0238).

Absorbable SR-PLA pins can be safely used for medial epicondyle fractures in children. Our results indicate that SR-PLA pins are associated with better short-term functional outcome than K-wires.

Level of evidence: III

Abbreviations: K-wires = Kirschner wires, PDLLA = poly-DL-lactic acid, SR-PLA = self-reinforced polylactide, SR-PLLA = self-reinforced poly-L-lactic acid.

Keywords: absorbable self-reinforced polylactide pin, fracture, medial epicondyle humerus, pediatric

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1. Introduction
Fractures of the medial humeral epicondyle occur frequently in children, accounting for 12% of all elbow fractures in adolescents (9- to 14-year-old age group). The assessment and treatment of these fractures have remained controversial over the past decade. Historically, fractures with <5 mm of displacement have been treated with cast immobilization, although more recent studies have recommended surgical intervention. Of note, about half of all pediatric medial epicondyle fractures are associated with elbow dislocation, and ulnar nerve dysfunction may be seen in 10% to 15% of patients. Operative indications include open fractures, entrapped intra-articular fragment, and valgus instability. These patients are treated with open reduction and internal fixation with screws, pins, or sutures; with the most traditional and economical material being the K-wires. Although K-wires are cost-effective and most commonly used for fracture fixation, there is some debate on whether the wires used for fixation should protrude out of the skin or be buried subcutaneously.

Resorbable or biodegradable materials are polymers that have been used for more than 30 years in surgical applications. Initially used only for suture, and then in suture anchors, they are now commonly used for manufacturing devices for the field of maxillofacial surgery, such as resorbable plates and screws for osteotomy synthesis or mandibular fractures. The biomechanical stability of these materials has improved, and they have been shown to possess no hazardous biological properties. The main advantage is their usefulness to prevent the need for further surgery to remove devices composed of bioabsorbable material. We hypothesized that the use of absorbable pins for fracture fixation would allow us to overcome the shortcoming of metallic lag screws (i.e., the need for reoperation), while retaining their advantages. To test our hypothesis, we analyzed data from children with medial epicondyle fractures treated with either K-wires or absorbable SR-PLA pins in our hospital. Comparisons between the 2 groups were performed to determine whether internal fixation with absorbable pins might be feasible and safe for treating medial humeral epicondyle fractures in children.

2. Patients and methods
2.1. Patients
This is a retrospective review of 1 center’s experience with operative treatment of medial epicondyle fractures. All patients were evaluated and treated in the same hospital. The retrospective descriptive study was carried out between August 2007 and January 2012. The inclusion criteria for operation were open fractures and intra-articular entrapment of the epicondyle fragment. The exclusion criteria were as follows: displacement of the fracture of <10 mm, conservative therapy, disagreed with participation in our study, and a follow-up time of <12 months. The 32 patients who met the inclusion and exclusion criteria were divided into 2 groups: group A underwent K-wire fixation; and group B, fixation with absorbable SR-PLA pins. There were 11 males and 4 females in group A, aged 8 to 14 years (average, 12.6), with 12 patients having elbow dislocation. In group B, there were 13 males and 4 females, aged 7 to 15 years (average, 11.8), with 13 patients having elbow dislocation. Fractures were classified according to the classification by Papavasiliou, which is a 4-type classification system based on the Watson–Jones classification: type 1, small degree of avulsion of the epicondylar fragment; type 2, avulsed epicondylar fragment at the level of the joint but not trapped; type 3, avulsed fragment trapped in the joint; and type 4, avulsion of the fragment associated with an elbow dislocation and the fragment in the joint.

All methods were carried out in accordance with our hospital’s guidelines and with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. All experimental protocols were approved by our Medical University Ethical Committee (registration number 2017001216). The parents or guardians of the patients signed an informed consent form prior to their participation and authorized the publication of the study results and the use of photographs of their children.

2.2. Absorbable nails
The absorbable nails (diameter, 1.5 mm; length, 2.5 cm) were made of self-reinforced polylactide (SR-PLA) by Bionx Company, New York, USA (Finland, see http://www.conned.com/en/products/orthopedics/foot-and-ankle/fixation/smartnail-implant). SR-PLA is a self-reinforced composite material of poly-γ-lactic acid (SR-PLLA) and poly-ε-lactic acid plus SR-PLLA. In addition, a special drill, a depth scale, and a booster were used (Figs. 1 and 2).

2.3. Surgical technique
A pneumatic tourniquet was used during the surgery to minimize the blood loss. Under general and brachial plexus anesthesia, closed reduction was attempted in all patients and confirmed under C-arm fluoroscopy. A longitudinal incision was made overlying the medial epicondyle to expose the fracture. In patients with no symptoms of ulnar nerve injury before the operation, the ulnar nerve was not exposed and explored during the operation. In group A patients, the medial epicondyle was reduced and fixed with 2 K-wires (diameter, 1.8 mm) percutaneously. In group B patients, after anatomic reduction, two 1.5-mm K-wires were used for temporary fixation, and an electric drill was used to tunnel through the fracture for fixation. The nail length was determined, and 2 absorbable SR-PLA pins were used for fixation (Fig. 3). Finally, the incision was closed, and the elbow joint was immobilized at 70° to 90° of flexion and neutral forearm rotation with a plaster cast. Postoperative fluoroscopy examination showed that anatomical fracture reduction had been achieved.

2.4. Postoperative care and follow-up
The removable plaster cast was removed after 3 weeks for all the patients, and the patients were encouraged to start moving the elbow (Fig. 4). The K-wires of group B were removed according to the bone callus appearance 4 to 6 weeks after the operation. The longest removal time was 6 weeks even in patients without evident bone callus. The patients were encouraged to perform gentle motion at least 3 times per day. Active range of motion was initiated when palpation of the medial epicondyne was pain-free. About 2 to 3 weeks after the plaster was removed, the elbow function of all the patients was evaluated.

2.5. Outcome assessment
Twelve months after the operation, functional outcomes were assessed using the Broberg and Morrey elbow scale. This standard method assesses the elbow range of motion and evaluates clinical and X-ray results. The scores are classified as follows: 90 to 100 points, excellent; 80 to 89, good; 70 to 79, fair; and <70, poor.
Standard elbow anteroposterior and lateral projection radiographs were obtained to confirm union of fracture.

2.6. Statistical analysis

The SPSS 13.0 software package (SPSS Inc, Chicago, IL) was used for the statistical analysis. Chi-squared tests were performed, and $P < .05$ was considered statistically significant.

3. Results

Four patients of group A developed pin-track infections that recovered gradually after K-wire removal; however, no infections were seen in group B patients. One patient of group A experienced refracture after K-wire removal. Broberg and Morrey elbow scale scores are summarized in Table 1. The average score for group A ($83.27 \pm 7.02$) was significantly lower.
than that for group B (95.21 ± 5.04; \( P = .0238 \)). The X-ray healing evaluation was 8.3 ± 0.7 weeks for group A and 7.8 ± 0.9 weeks for group B; there was no significant difference between the 2 groups (\( P = .108 \)).

4. Discussion

Fractures of the medial epicondyle of the distal humerus are common pediatric elbow fractures.[1] Nevertheless, the management of displaced medial humeral epicondyle fractures in children remains controversial. Many surgeons advocate internal fixation for children who participate in gymnastics and throwing sports.[18] Thus far, most surgeons agree that open reduction and internal fixation are mandatory if the medial epicondylar fragment is entrapped in the elbow joint. In this study, all the surgical procedures were related to incarceration of the epicondylar fragment or associated with ulnar nerve symptoms. Fixation material options include metallic compression screw, K-wire with or without tension band wire. Metallic compression screw and K-wire were the most common materials used for fixation. Szymańska and Lee et al conducted retrospective studies on metallic compression screws and K-wires.[19,20] Szymańska proved that screw fixation is a better alternative than K-wires, but Lee et al reported that both of them can lead to good or excellent outcomes in all patients. Several authors suggest the use of K-wires in younger children and metallic compression screws in older children.[21,22] Sutures are only used for small fragments.[23] Since there is still controversy regarding the best option between metallic compression screws and K-wires, we preferred not to use metallic compression screws, and we selected the K-wires as control group.

Figure 3. Comparison of the 2 methods of fixation on the 1st day after surgery; two 1.8 mm diameter Kirschner wires are seen in (A); two 1.5 mm diameter self-reinforced polylactide pins are seen in (B).

Figure 4. Both X-rays were taken one month after operation; (A) the fracture after K-wire fixation, and (B) the fractured area after self-reinforced polylactide pins fixation of the fracture.
In this study, we used 2 bio-absorbable SR-PLA pins for fixation. SR-PLA is an absorbable polymer that causes no toxic reactions and has a good histocompatibility, as shown by animal studies. The SR-PLA pin expands vertically and shrinks horizontally after being immersed in water, thereby increasing the strength of fixation. The pin is completely absorbed within 2 to 4 years. There has been concern about possible immobility as a result of this method of fixation; however, none of our study patients in group B developed fracture displacement. To help avoid displacement, 2 SR-PLA pins were used to prevent subsequent rotation of the fragment. Secondly, the reverse barb design (Fig. 2) at the end of the pin prevents it from being easily pulled out after its fixation. Lastly, because the posterior-medial aspect of the medial epicondyle is an apophysis subject to traction forces, the SR-PLA pins opposed the forces in both directions.

In our study, the ulnar nerve was not routinely explored or transposed. Most authors agree that the ulnar nerve may be more susceptible after transposition in an elective nontraumatic procedure. However, none of our study patients in group B developed fracture displacement. To help avoid displacement, 2 SR-PLA pins were used to prevent subsequent rotation of the fragment. Secondly, the reverse barb design (Fig. 2) at the end of the pin prevents it from being easily pulled out after its fixation. Lastly, because the posterior-medial aspect of the medial epicondyle is an apophysis subject to traction forces, the SR-PLA pins opposed the forces in both directions.

Although absorbable SR-PLA pins are considerably expensive (about 500 USD) compared with K-wires, and some patients may not be able to afford the procedure, they offer the advantages over K-wires that there is no need to remove the K-wires. Moreover, with SR-PLA pins, the exercise starts earlier and there is less infection of pin sites. The above-mentioned advantages provided us with the needed information to select the absorbable SR-PLA pins.

A limitation of our study is its retrospective approach. The follow-up time in this study was only 1 year, hence studies with longer follow-up time are needed. Additionally, the number of the patients included in the study was relatively small.

### Table 1

| Patient | Age, yr | Sex | Injury side | Incarceration | Fracture kind | Fixation method | Results |
|---------|---------|-----|-------------|---------------|---------------|----------------|---------|
| 1       | 13      | F   | R           | Yes           | 3             | K-wires        | Fair    |
| 2       | 14      | F   | L           | Yes           | 4             | K-wires        | Poor    |
| 3       | 12      | M   | L           | Yes           | 3             | K-wires        | Fair    |
| 4       | 13      | M   | L           | No            | 4             | K-wires        | Excellent |
| 5       | 13      | F   | R           | Yes           | 4             | K-wires        | Good    |
| 6       | 14      | M   | L           | Yes           | 4             | K-wires        | Excellent |
| 7       | 14      | M   | L           | No            | 3             | K-wires        | Excellent |
| 8       | 14      | F   | R           | Yes           | 3             | K-wires        | Good    |
| 9       | 13      | M   | L           | Yes           | 4             | K-wires        | Good    |
| 10      | 14      | M   | R           | Yes           | 4             | K-wires        | Good    |
| 11      | 12      | M   | L           | Yes           | 4             | K-wires        | Good    |
| 12      | 12      | M   | L           | Yes           | 4             | K-wires        | Excellent |
| 13      | 14      | M   | R           | Yes           | 3             | K-wires        | Good    |
| 14      | 9       | M   | R           | No            | 4             | K-wires        | Excellent |
| 15      | 8       | M   | L           | Yes           | 3             | K-wires        | Good    |
| 16      | 11      | F   | L           | Yes           | 4             | SR-PLA pins    | Excellent |
| 17      | 14      | F   | R           | No            | 4             | SR-PLA pins    | Excellent |
| 18      | 13      | M   | R           | Yes           | 4             | SR-PLA pins    | Good    |
| 19      | 10      | M   | L           | Yes           | 4             | SR-PLA pins    | Excellent |
| 20      | 11      | F   | R           | Yes           | 3             | SR-PLA pins    | Fair    |
| 21      | 10      | M   | L           | No            | 4             | SR-PLA pins    | Excellent |
| 22      | 8       | M   | L           | Yes           | 3             | SR-PLA pins    | Good    |
| 23      | 14      | M   | R           | Yes           | 4             | SR-PLA pins    | Excellent |
| 24      | 9       | M   | L           | Yes           | 4             | SR-PLA pins    | Excellent |
| 25      | 11      | M   | L           | Yes           | 3             | SR-PLA pins    | Excellent |
| 26      | 15      | M   | R           | No            | 4             | SR-PLA pins    | Good    |
| 27      | 12      | M   | L           | Yes           | 4             | SR-PLA pins    | Excellent |
| 28      | 12      | F   | L           | Yes           | 3             | SR-PLA pins    | Excellent |
| 29      | 14      | M   | R           | Yes           | 3             | SR-PLA pins    | Excellent |
| 30      | 13      | M   | L           | No            | 4             | SR-PLA pins    | Good    |
| 31      | 12      | M   | R           | Yes           | 4             | SR-PLA pins    | Excellent |
| 32      | 12      | M   | R           | Yes           | 4             | SR-PLA pins    | Excellent |

F = female, K-wires = Kirschner wires, M = male, L = left, R = right, SR-PLA = self-reinforced polylactide.

According to Papavasiliou classification.

According to Brogerg and Morrey elbow scale.

Nonunion is another common complication after medial epicondyle fracture, especially in the nonoperatively treated group of children. Smith et al. reported that nonunion patients who underwent operation often had limited elbow motion or pain which were not observed in patients treated by conservative therapy. In our study, all of the patients healed after the operation, and we did not find differences in the healing time between the 2 groups.

A limitation of our study is its retrospective approach. The follow-up time in this study was only 1 year, hence studies with longer follow-up time are needed. Additionally, the number of the patients included in the study was relatively small.
patients was small, and studies with larger samples should be conducted. In this study, we only compared K-wires and absorbable pins. Metallic compression screws were not included in our study. Metallosis compression screws are strong enough and allow patients to start exercises soon after the surgery. Further study may be needed for comparing metallosis compression screws with absorbable SR-PLA pins.

5. Conclusion
Absorbable SR-PLA pins can be used in the surgical repair of medial epicondyle fractures of the humerus in children. In comparison with K-wires, our results indicate that SR-PLA pins are associated with better short-term recovery of elbow function.

Author contributions
Yuxi Su conceived the study, participated in its design and drafted the manuscript. Guoxin Nan conceived the study and helped in collecting the clinical data and drafted the manuscript. All authors read and approved the final manuscript. None of the authors have any conflict of interest to declare. No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article. Guoxin Nan orcid: 0000-0002-3374-7341.

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