Pediatric medial humeral epicondyle fracture in children
Are biodegradable pins with tension band absorbable sutures efficient?

Tamás Kassai, MD\textsuperscript{a}, Marcell Varga, MD, PhD\textsuperscript{a}, Gergő Józsa, MD, PhD\textsuperscript{b,*}

Abstract
Medial humeral epicondyle fractures account for 10% to 20% of elbow injuries in children. We hypothesized that in the fixation of medial humeral epicondyle fractures, safety and efficiency of bioabsorbable poly(l-lactide-co-glycolic acid) implant are comparable to traditional metallic and other novel approaches.

A retrospective cohort study was performed between 2016 and 2019, analyzing 24 children who had medial humeral epicondyle fractures. Every fracture was stabilized with biodegradable poly(l-lactide-co-glycolic acid) implants (Biotoretc\textsuperscript{c} ActivaPin\textsuperscript{d}) and tension band polydioxanone sutures. Indications for surgery included closed fractures with >1 cm dislocation and incarcerated fractures. Postoperatively, the degree of anatomic reduction and the presence or absence of nonunion or fragmentation were confirmed with X-rays. In this clinical study, we evaluated the operation time, age, and gender distribution.

The mean age at the time of injury was 12.3 (8–16 years). In the fourth week, every patient’s X-ray showed callus formation, and the range of motion of the elbow after 6 months of the operation was almost complete in all children. Transient ulnar nerve palsy was developed in 1 patient, which was spontaneously resolved in the fourth postoperative month. No other complications were observed during the average follow-up period of 34 months (16–60 months).

Bioabsorbable pins with absorbable sutures are a good alternative treatment of medial epicondyle humeral fracture. No permanent complications were noted while using this technique. We suggest this method because it does not require a secondary (metal removal) operation.

Abbreviations: K-wire = Kirschner wire, PLGA = poly(l-lactide-co-glycolic acid).
Keywords: absorbable implants, children, elbow, fractures, PLGA

1. Introduction
Medial humeral epicondyle fractures account for 10% to 20% of bony elbow injuries in children.\textsuperscript{1,2} While nondisplaced fractures do not require surgery, the optimal treatment of fractures with varying degrees of displacement is still controversial.\textsuperscript{1,3,4} Fractures of >1 to 2 cm displacement or incarcerated fractures are usually candidates for operative fixation.\textsuperscript{4,6}

Surgical treatment is usually performed under general anesthesia with open reduction and internal fixation with Kirschner wires (K-wires) or screws.\textsuperscript{7–9} K-wires are indicated for smaller fragments or in younger children. Prevent injury to isolate and prevent the ulnar nerve and fix the medial humeral epicondyle as stable as possible. Although the results are generally good regardless of the type of surgical technique, usually, the implants can be removed with a second operation. Implant removal is generally required in the young population and about 20% to 30% of the older patients, due to protruding devices, or other complications, and optional in others.\textsuperscript{9–11} Absorbable polymers have been used as a surgical implant material already for >3 decades. Polyglycolic acid and polylactic acid showed some disadvantages related to too long degradation and unfavorable tissue reactions.\textsuperscript{12–14}

The goal of this study was to assess the efficiency of 2 novel biodegradable implants, poly(l-lactide-co-glycolic acid) (PLGA) copolymer (Bioretetc ActivaPins\textsuperscript{d}) and polydioxanone sutures, in the treatment of medial epicondyle fractures in children. We hypothesized that our results are comparable to treatments using metallic and other resorbable implants in terms of postoperative function, bone union, and complications.
2. Materials and methods

2.1. Patients

In this cohort study, we retrospectively reviewed 24 consecutive patients who underwent operations due to medial epicondyle fractures between January 2016 and January 2019. Inclusion criteria were children aged 5 to 16 years with a closed medial humeral epicondyle fracture (>1 cm or incarcerated fracture) needing open reduction and osteosynthesis. The surgery was done a maximum of 72 hours after the injury. Exclusion criteria were open fractures and associated fractures and bone diseases. The data were retrieved from the patient charts, and critical descriptive analysis was performed.

Clinical application of the technique has been accepted and permitted in 2010 by our medical review board, by the Hungarian Pediatric Trauma Committee, and by the Hungarian Pediatric Surgery Committee. Possible benefits, risks, and complications, along with other methods, were explained to the parents of each child, and informed consent was obtained by them. This retrospective study was approved by our Ethics Committee.

2.2. Methods

All procedures were performed under general anesthesia and C-arm image intensifier control. Single-shot antibiotic prophylaxis was routinely used. All children were treated by 1 of 3 surgeons experienced in pediatric elbow surgery. The parents were informed about other treatment options as well. The arm is extended and placed on a fluoroscopically translucent table. A tourniquet is used for better visualization. The ulnar nerve is prepared after a slightly curved 5- to 6-cm long medial incision and gentle soft tissue dissection. The hematoma is evacuated, and the fracture is manually reduced. The ulnar nerve is always brought into view and carefully pulled away with a fine rubber loop. After anatomical reduction is achieved, the fracture is temporarily stabilized with 2 K-wires as described in the literature.\(^9\) The starting point of the wires is at the center of the avulsed fragment. The K-wires are placed at an angle of 40° to 60° in the proximal direction and are just drilled through the lateral humeral cortex. After checking the position of the wires, their exact length is measured, then they are replaced with biodegradable pins. The ends of the pins are cut off so that a few millimeters remain outside the bone. A hole is drilled proximally to the wire insertion site through the medial humeral condyle. A 2-mm diameter polydioxanone suture is led through the hole. The free ends of the suture are then crossed, and 1 thread is looped around the cut ends of the pins. The 2 ends of the suture are knotted together to form a tension band system (Figs. 1–3).

Postoperatively, a long-arm cast or removable brace was used for 3 weeks. After brace or splint removal, physiotherapy is applied until the full range of motion returns. Routinely X-ray was performed postoperatively and at the fourth week and the sixth month after the surgery. Final functional result was measured 1 year after the primary reconstruction. Magnetic resonance imaging (MRI) was performed in only 3 patients to confirm the absorption and changes of the absorbable implants during the healing time (Fig. 4).

2.3. Methods of assessment

In this retrospective clinical study, we observed the duration of surgery, and gender distribution. The degree of anatomic reduction based on postoperative X-ray, presence, or absence of non-union or fragmentation were confirmed on plain radiographs obtained at the first and fourth week, sixth month, and 1 to 4 years postoperatively. Not routinely, but 3 patients underwent MR, to monitor the absorption and changing of the implants.

Full function was considered when no additional physiotherapy was required, and the child was able to continue his sports activities without restrictions. We focused on the rate of complications such as ulnar nerve palsy, tissue reaction, delayed bone union, infections, and growth disturbances of this method.

2.4. Statistical analysis

The assessment of the endpoints was done using Microsoft Excel 2021 (Microsoft Corporation, USA). Means and ranges were calculated for the evaluated demographic and interventional outcomes. No patient was lost to follow-up; thus, no analyzed values were missing.

3. Results

Twenty-four children underwent surgery due to an acute injury. In the case of 9 children, there was an absolute indication as a
result of elbow dislocation and incarceration of the medial epicondyle. The remaining 15 children had a displacement of the medial epicondyle with at least 1 cm.

All fractures with joint dislocation and incarcerated epicondyles were operated on within 24 hours. For other fractures, a maximum of 72 hours elapsed between injury and surgery.

Mean age at the time of injury was 12.3 years (range: 8–16 years). The average operation lasted 46 minutes (range: 30–75 minutes), and the mean follow-up time was 34 months (range: 16–60 months). One child had a transient ulnar nerve palsy which spontaneously resolved by the fourth postoperative month. Another patient developed irritation of the skin a few weeks after the surgery, which required the removal of the polydioxanone suture. Due to the implant, neither tissue reaction nor septic complications were observed in the 24 operated children.

At 4 weeks, the whole cohort showed callus formation on the X-ray. By the third postoperative month, the range of motion of the elbow was complete in 22 patients, and the other 2 children regained their full range of movement by the sixth month.

Growth disturbance, necrosis, or axial malalignment were not observed during the follow-up period, neither any nonunion nor delayed union (Table 1).

Three patients underwent an MRI scan 4 months, 1.5 years, and 5 years after surgery. The 18-month MRI showed that the implant diameter was significantly reduced in the bone canal with no excessive bone resorption. Later MRI scans showed the complete disappearance of the implants (Fig. 4).

4. Discussion

Displaced medial epicondyle fractures can be treated with a variety of implants, such as different techniques of K-wires, screws, and tension band wires.[10-14] Excision of the fragment and soft tissue reattachment have poor outcomes.[11]

Figure 3. Incarcerated medial epicondyle avulsion: pre-and postoperative X-rays of an 11-yr-old girl.

Figure 4. MRI scans after fixation with PLGA pins: 4 mo after surgery. The 2 black dots showing the location of the pins, absorption has not yet begun (A). Eighteen months after surgery. Two white areas show the bone canal. The diameters of the implants have significantly reduced, they are represented by smaller black dots. The absorption is almost complete (B). Five years after surgery: No sign of the bone canal or the implants (C). MRI = magnetic resonance imaging, PLGA = poly-1-lactide-co-glycolic acid.
Most surgeons prefer open reduction because the ulnar nerve is close to the fracture and closed techniques may cause iatrogenic injuries.[14] Incarcerated fractures with joint dislocations cannot be reduced with closed manipulations. Based on the literature, the open procedure is absolutely indicated if the indication of operation is standing.

The sources of the most frequent complications of surgical management are the implants themselves. Protruding metal implants can cause skin irritation, soft tissue scarring, and ulnar nerve irritation. These complications are usually resolved with a second surgery when the implants are completely removed. The need to remove implants in noncomplicated patients after pediatric orthopedic surgery is highly controversial.[3–5] Many surgeons routinely remove implants because they do not want to leave them in the growing bone and their long-term effects are unknown.[11] The second surgery and associated general anesthesia may be a source of additional potential complications.[4]

Absorbable polymers have been used as a surgical implant material already for >3 decades. The first-generation biodegradable polymers like polyglycolic acid and polylactic acid showed disadvantages, which were related to too long degradation and adverse tissue reactions. These disadvantages led to the development of the PLGA copolymer. PLGA does not show unfavorable soft tissue reactions, it hydrolyzes slowly, and is eliminated from the bone tissue after several years. Several publications have already reported the successful use of PLGA implants in pediatric bone surgery.

Demand for polymer-based biodegradable implants has increased recently. Older polymer-based products have caused adverse reactions such as osteolysis and inflammatory processes. Screws and pins made from new-generation polymer-based implants no longer show similar complications.[12] The biggest advantage of resorbable implants is that they do not require a second surgery. Because implants can be sunk below the level of the bone, the expected soft tissue irritation complications may also be reduced.[12,14] Several publications report techniques that do not require hardware removal after medial humeral epicondylo fracture reconstruction. Thelen et al used bony anchor sutures for fixation, while Poiriciute[12] also employed PLGA pins for stable internal stabilization.[13] Su and Nan[14] reported that self-reinforced polylactide pins showed better short-term functional outcomes than K-wires.

We used PLGA-based bioabsorbable pins in our patients. PLGA has been known for decades as a safe substance in bone surgery.[11] PLGA implants do not cause toxic side effects. They hydrolyze slowly and are gradually replaced by bone tissue.[16] PLGA pins have been successfully used in pediatric fractures around the elbow and knee and reconstructive foot surgery.[16–19] Another favorable property of the pins is that after insertion, they increase their volume by 1% to 3%; thus, they will have a particularly strong hold in the bone canal.[18–20]

This may be particularly advantageous in medial epicondylo fractures where stable osteosynthesis is required, as the distraction forces of the flexor muscles may cause displacement. Conventional wires may not resist these forces sufficiently. True compression can be achieved with screws, but due to the small size of the avulsion fragment, screw insertion can be difficult in certain cases.

Recovering the full range of motion of the elbow can be a difficult part of its management. It is desirable to start physiotherapy as soon as possible, but 3 to 6 weeks of immobilization is also recommended for most surgical techniques. Prolonged immobilization causes increased joint stiffness and delayed functional recovery. We increased the stability of the biodegradable pins with a polydioxanone tension band loop. Thus, we have found the osteosynthesis so stable that physiotherapy could be started within 2 to 3 weeks. Furthermore, we discovered that children who started physiotherapy early and wore a dynamic brace regained function faster. In the introduction period of the surgical technique, we recommended a stiff long-arm cast for at least 3 weeks, and physiotherapy was not started in the first postoperative month. In no case was secondary displacement observed. One child required secondary intervention because of persistent skin irritation. In his case, complaints were caused by the polydioxanone suture, which was placed just under the skin. This was considered a technical error. The polydioxanone suture was removed in local anesthesia, so these complaints disappeared.

Despite the positive results, the authors have several important remarks. Positioning the bioabsorbable pins in the place of the previously drilled wires requires careful technique, which can increase the time of the procedure.[20] Because the pins are almost invisible under fluoroscopy, they should be inserted after an accurate measurement. If the ends of the pins go far beyond the opposite cortical bone and protrude laterally, soft tissue or the radial nerve may be irritated. In our patients, we have not experienced this type of complication.

A further weakness of our study is that it was retrospective in nature with a relatively small number of patients.

5. Conclusions
Despite the weaknesses mentioned above, the authors think that the use of bioabsorbable pins with tension band absorbable sutures is a promising way of treating medial humeral epicondylo fractures. This technique is an effective and safe procedure for the treatment of medial humeral epicondylo fracture in children. In the cases of the 24 patients, we could achieve good functional and radiological results without any major complications. If so, the advantage of using resorbable implants would be to avoid any discussion about implant removal and complications, such as tissue reactions.

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Author contributions
T.K. participated in the data curation, formal analysis, interpretation and visualization of the data as well as writing the original draft and reviewing and editing the article. M.V. took part in the investigation, project administration, supervision, and reviewed and edited the article. G.J. was involved in the conceptualization, methodology, investigation, project administration, and supervision processes in addition to reviewing and editing the article. All authors approved the final manuscript to be published.

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Table 1
Complications and examined data are shown in this table.

| Indicator                              | Fracture with joint dislocation and incarceration | Avulsion fracture with displacement >1 cm |
|----------------------------------------|--------------------------------------------------|------------------------------------------|
| N = 24                                 | n = 9                                            | n = 15                                   |
| Septic complication                    | 0                                                | 0                                        |
| Transient ulnar nerve palsy            | 1                                                | 0                                        |
| Slow (>3 mo) functional recovery       | 2                                                | 0                                        |
| Growth disturbance                     | 0                                                | 0                                        |
| Soft tissue irritation                  | 0                                                | 1                                        |
| Operation time (min)                   | 38–70                                            | 30–75                                    |

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