Bioresorbable implants vs. Kirschner-wires in the treatment of severely displaced distal paediatric radius and forearm fractures – a retrospective multicentre study

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Abstract

Background

Distal radius fractures are very common in paediatric patients. Severely displaced fractures may require surgical intervention. The gold standard surgical method is percutaneous K-wire osteosynthesis followed by immobilisation. Metal implants can be removed with a second intervention; however, these extra procedures can cause further complications. Several studies confirm the benefits of bioabsorbable implants for paediatric patients. The aim of this retrospective study was to compare the complication rates of displaced distal metaphyseal radius and forearm fractures in children operated on with K-wires versus a novel technique with bioresorbable implants.

Methods

We retrospectively reviewed 94 patients in three paediatric trauma centres who underwent operations due to severely displaced distal forearm or metaphyseal radial fractures between January 2019 and January 2020. The mean age was 8.23 (ranging from 5-12). 30 patients (bioresorbable group, BR-group) were treated with biodegradable PLGA implants (Bioretec®, ActivaPin®), 40 patients with one or two stainless steel Kirschner-wires (K-wires, Sanatmetal®) which were buried under the skin (KW I-group) and 30 children with K-wires left outside the skin. (KWII. Group). We examined the number of minor and major complications as well as the need for repeated interventions. Follow-up was at least one year.

Results

There was no significant difference between the complication rates at the two KW groups ($p = 0.241$; Cramer’s $V = 0.211$), while the complication rate of the BR group was significantly lower. ($p = 0.049$; Cramer’s $V = 0.293$ and $p = 0.002$; Cramer’s $V = 0.418$ respectively). No later than half a year after the injury, no difference was observed between the functional outcomes of the patients in each group. One and a half years after the injury, no signs of growth disturbance were found in any of the children. No second surgical intervention was required in the BR group.

Conclusions

Surgeries with bioresorbable intramedullary implants may have fewer complications than K- wire osteosynthesis in the treatment of severely displaced distal forearm fractures. The benefits are most pronounced in the first six weeks after surgery, reducing the number of outpatient visits and increasing the child's sense of comfort. As no second intervention is required, this can lead to significant cost savings. After half a year, there is no difference in the outcomes between the different surgical treatment strategies.

Background

Distal radius fractures are among the most common injuries of childhood. (1) Optimal treatment for distal radius fractures is still controversial. (2) Treatment of severely displaced and shortened fractures usually require narcosis and closed reduction. (1) Many surgeons recommend osteosynthesis if the fracture remains unstable after reduction. (3, 4, 5) The gold standard operative method is closed reduction and percutaneous pinning with Kirschner-wires. (1, 3, 4, 5) Although this technique is simple and inexpensive, due to relative instability, an additional 4-6 weeks of immobilisation in a long or short arm cast is also needed. Several studies reported alternative surgical techniques to percutaneous pinning. (6, 7, 8, 9, 10)

Favourable results with plate osteosynthesis or external fixation devices were reported, although these methods are more invasive or technically demanding. (6, 7) Modified elastic intramedullary nailing techniques adapted to distal fractures have also been reported. (8, 9, 10, 11, 12)

Plates and intramedullary implants buried under the skin can be removed with a second intervention. Although its absolute necessity is controversial, many surgeons routinely remove these implants after various paediatric osteosynthesis techniques. This may be a source of additional complications. (13, 14, 15) K-wires, on the other hand, must always be removed.

In recent years, there has been a growing interest in the orthopaedic application of resorbable implants. Their use in children may be particularly beneficial. (16)

Absorbable polymers have already been used as a surgical implant material for more than three decades. The first generations of biodegradable polymers, such as polyglycolic acid (PGA) and polylactic acid (PLA), showed disadvantages, which were related to excessively long degradation time and unfavourable tissue reactions. These disadvantages led to the development of the poly (l-lactide-co-glycolic acid) copolymer. (17, 18, 19, 20)

Poly(l-lactide)-co-glycolide acid (PLGA) is a biodegradable material that has been used in bone surgery for more than 20 years. (21, 22)

Several publications have already reported the successful use of intra-medullar PLGA implants in the treatment of paediatric diaphyseal forearm fractures. (22)

The aim of this retrospective study was to compare the complication rates of displaced distal metaphyseal radius and forearm fractures in children operated on with K-wires and bioresorbable implants.

Clinical application of the modified technique was accepted and permitted in 2017 by our medical review board, by the Hungarian Paediatric Trauma Committee, and by the Hungarian Paediatric Surgery Committee. This retrospective study was accepted and approved by the Local Ethical Committees. (License number:11/2021)

Methods

Data from patients of three different level I. paediatric trauma centres were examined between January 2019 and January 2020.

We retrospectively reviewed 94 patients, who underwent operations due to severely displaced distal forearm or metaphyseal radial fractures.

30 patients (bioresorbable group, BR-group) were treated with biodegradable PLGA implants (Bioretec®, ActivaPin®), 40 patients with one or two K-wires which were buried under the skin (KW I-group) and 24 children with K-wires left outside the skin. (KWII.-Group)

The inclusion criteria were as follows: open growth plates, severely displaced closed or grade I. open distal radial or complete forearm fractures with full bone width displacement and a shortening of more than 1 cm.

We excluded children with generalised bone disease, closed growth plates and for whom at least one-year follow-up was not possible. The function observed during the one-year follow-up was examined based on medical documentation or a telephone interview.

All procedures were performed under general anaesthesia and C-arm image intensifier control. A single-shot antibiotic prophylaxis was routinely used. All children were treated by orthopaedic or paediatric surgeons with an experience in paediatric trauma surgery.

Operative technique with biodegradable intramedullary implant

Patients are in supine position. The arm is extended and placed on a fluoroscopically translucent table. The first step is closed reduction under an image intensifier. After successful reduction, the insertion point of the nail is determined. This is the radial side of the wrist immediately proximal to the physeal plate in the midline of the radius. After skin incision the medullary canal is opened with an awl. A short, 10-12 cm long, curved 2.5 mm diameter titanium elastic nail is inserted into the distal medullary canal of the radius. The nail is gently moved forward along its curvature until its distal end enters the medullary canal of the proximal fragment.

The nail is guided until it is securely fixed. In this case, the greatest curvature is at the level of the fracture. In this position, the convex side of the nail faces the fracture line of the lateral cortex when observing from an anteroposterior view. By carefully controlled positioning of the nail, the final reduction can be set.

The titanium nail is then removed, and a biodegradable nail (ActivaPin™ of 2, 2.7 or 3.2 mm) is formed to a similar curvature. The biodegradable pin is inserted into the medullary canal in a similar way as the titanium nail. The bioresorbable implant should be oriented exactly in the same position as the titanium nail. During insertion, the implant is tensioned into the medullary canal in the same way as the titanium nail.

At the end of the operation, the protruding ends of the nails should be at the level of the bone. This can be achieved either with light hammer blows or by cutting off the end of the implant. Leaving the nail end too long can cause skin and soft tissue irritation. (Fig 1-2)

Statistical analysis

For the organisation, visualisation and statistical analysis of our data, we used Microsoft® Excel® and Jamovi 1.6.23 software. We defined statistical significance as $\alpha = 0.05$, with all data and significance values (p-values) approximated to the third decimal. We summarised the characteristics of the patients enrolled in our study, which can be seen in Table 1. For basic patient characteristics (e.g. sex, right/left hand ratio) and return hospital visits, we used ÷2 and Kruskal-Wallis (nonparametric equivalent of ANOVA) tests to compare data available. For the evaluation of the outcomes (complication rates, minor and major complications), we utilised ÷2 tests (with Yate's correction for continuity, when necessary). (table 2.) In case of complications, we also calculated Cramer's V to describe strength of association, with a minimum threshold of 0.1 (>0.5 = high association; 0.3 to 0.5 = moderate association; 0.1 to 0.3 = low association; 0 to 0.1= little if any association).

Table 1.
Characteristics of the patients enrolled in the study

Characteristics	K-wire group I. (n=40)	Bioresorbable group (n=30)	K-wire group II. (n=24)	Comments
Average age, years (mean ± standard deviation)	8.125 ± 2.334	8.067 ± 2.586	8.963 ± 2.638	No difference (Kruskal-Wallis test, p = 0.286; ε^2 = 0.026)
Sex ratio (Number of patients) (male: female)	3 (30:10)	1.7273 (19:11)	2.4286 (17:7)	No difference (Chi squared test, p = 0.571)
Injured upper limb side (No, %)				
Right	18 (45)	16 (53.3333)	N/D	No difference (Chi squared test, p = 0.49)
Left	22 (55)	14 (46.6667)	N/D	
Type of fracture (No)				
Isolated radius fractures (number of patients)	13	6	7	No difference (Chi squared test, p = 0.503)
Complete forearm fractures (number of patients)	27	24	17	
Follow-up history (mean ± standard deviation)				
Return hospital visits in the first six weeks	4.05 ± 1.3	3.067 ± 0.254	6.074 ± 1.269	Significant difference (Kruskal-Wallis test, p <0.001; ε^2 = 0.579)

Table 2.

Complications in the different groups

Complications (No, %)	**KWI Group**	**BR Group**	**KWII. Group**
Minor (total)	10 (25)	2 (6.6667)	10 (41.6667)
Skin irritation	5 (12.5)	0	1 (4.1667)
Dislocation (within limits of remodelling)	5 (12.5)	2 (6.6667)	9 (37.5)
Maior (total)	2 (5)	0	0
Dislocation (requiring intervention)	1 (2.5)	0	0
Extensor pollicis longus injury (related to primary intervention)	1 (2.5)	0	0
No complications (total)	28 (70)	28 (93.3333)	14 (58.3333)

Results

No statistically significant differences were found between the groups regarding age, sex, type of fracture and right- or left-hand injury (see Table 1, $p > 0.05$ in all cases).

Minor complication rates in the KW I. group, the BR group and KW II. group were 25%, 6,667% and 41.667% respectively. Regarding major complications, the rates were as follows: 5%, 0% and 0% (respectively). Testing for difference between those three groups, our statistical analysis showed a significant difference in complication rates ($p = 0.016$), which means that there is an association between the healthcare provider, where the patient was treated, and the outcome of the treatment. Our data showed no significant difference in the complication rates between the two KW groups ($p = 0.241$; Cramer's V = 0.211), while the complication rate of the BR-group was significantly lower than in any other K-wire group. ($p = 0.049$; Cramer's V = 0.293 and $p = 0.002$; Cramer's V = 0.418 respectively).

We also tested for outpatient visits within 6 weeks after surgical intervention. Our test showed that patients treated in the KW II. group returned the most often, followed by the patients treated in KW I. group. The least number of visits were observed amongst the patients treated in the BR group.

In the bioresorbable group no second surgical intervention was required. Of the 94 children, 16 developed a slight secondary displacement from the original synthesis, two of which were in the BR group and 14 in the KW groups. In the KW I. group, wires from four children could only be removed under general narcosis. Two children required repeated intervention due to a high degree of secondary displacement and extensor pollicis tendon injury. Wires were removed from the other children as a part of outpatient surgery. By half a year after the injury, no difference was observed between the functional outcomes of the patients in each group. Children who developed mild secondary dislocation showed complete radiological remodelling no later than half a year after surgery. One and a half years after the injury, no signs of growth disturbance were found in any of the children. (Fig. 3-4)

Discussion

Fractures of the distal forearm show good healing tendency in children. (1)

There are no clear indications for a surgical procedure. Most authors recommend surgery for either very unstable or secondary displaced fractures. The aim of the surgery is the restoration of an acceptable anatomical axis, the prevention of a secondary displacement and to accelerate rehabilitation. (1, 23, 24)

The most accepted and widespread surgical procedure is percutaneous pinning and casting. (25) Many authors reported various modifications and versions of the pinning techniques, but no evidence exists that confirms the superiority of either one. (25, 26, 27)

As the results of conservative treatment are also excellent, many surgeons recommend that surgery be performed only in the case of severe displacement. (1)

Kirschner-wire related minor complications are relatively frequent. According to some authors, the K- wire method can have a complication rate of up to 38%. (28)

Migration of the pins, superficial infections, and skin irritation are well manageable but significantly impair the child's sense of comfort. Deep infections, tendon or nerve injuries may occur less often. (28, 29, 30, 31) Removing the implants can also cause complications. (29, 30)

There is a controversy as to whether it is preferable to leave the wires outside the skin. (32) While wires left out of the skin increase the risk of infection, wires buried under the skin can only be removed with a second intervention. (32, 33) In the patients we studied, most of the complications were caused by wires buried under the skin. Four children in this group required general narcosis to remove the wires, which poses an additional health risk and a significant additional cost.

Constant monitoring of the position of the wires left outside the skin, wound care, and frequent replacement of cast require repeated outpatient visits, which is also uncomfortable for the child, as well as increased cost in time of parents and medical staff. We did not detect more superficial infections in the KW2 group where the ends of the wires were left outside the skin but the number of outpatient visits in the first six weeks and was the highest.

K-wires are not capable of providing sufficient stabilisation, so additional casting treatment is also required. (1, 34, 35).

The duration and the type of postoperative immobilisation varies greatly according to the practice of the surgeons. (34, 35)

There is no evidence to support any one singular optimal immobilisation procedure. 4-6 weeks of cast wearing is recommended by most authors. (35)

In the BR group, children received a cast for one week, after which they only wore a forearm brace for three weeks. The brace allowed full range of movement of the elbow and allowed minimal wrist mobility. The purpose of the brace was to improve the comfort of children and the protection of the wrist.

Some degree of mild secondary displacement was observed in all three groups.

All but one of these displacements remained below the expected remodelling limit, rather interpreted as a radiological phenomenon, The two KW groups had a higher rate of secondary displacement (5 children and 9 children, respectively) than the BR group (2 children), suggesting a greater instability of the K-wires. The intramedullary position of the PLGA implant and its ability to expand by 1-2 percent after insertion may all contribute to increased stability.

We have found two other benefits of treating distal radial fractures with PLGA implants.

The implant does not need to be removed with a second intervention. This reduces the risk of complications, it is more comfortable for the child, and it reduces the overall health burden on the patient as well as the entire healthcare system.

The absorbable implants can be submerged below the level of the bone cortex so that they do not cause soft tissue irritation at all in contrast to non-resorbable material.

Our surgical technique is a modified short elastic nailing technique. The concept of this method is to stabilize the dia-metaphyseal and distal radius fractures with short intramedullary nails.

Intramedullary fixation was performed with PLGA implants instead of titanium alloys. Some of the physical properties of PLGA pins resemble the titanium elastic nails: they are flexible, yet sufficiently resistant. We found pins of 2, 2.7 and 3.2mm in diameter to be excellent for replacing short intramedullary elastic nails.

PLGA does not show unfavourable soft tissue reactions, hydrolyses slowly, and is eliminated from bone tissue after several years. (21, 22) (Fig. 5)

To our knowledge, there is no evidence that PLGA implants, used clinically for 20 years, have any material-specific complication.

The biggest disadvantage of short PLGA pins is that they are hardly visible during fluoroscopy. Although targeting and fracture reduction are prepared with conventional titanium nails, the final implant placement is almost invisible. This requires a careful surgical technique.

Intramedullary PLGA nails with fluoroscopically bio-labelled ends are now available, and they may be a solution for this problem.

Another problem may be the development of an infectious complication.

Although no such complication has been observed in our patients, it is important to be prepared for such an event. The solution in this case can be complete removal of the nails and thorough cleaning of the medullar cavity. Since the nails may be difficult to remove due to swelling after insertion, they may also need to be drilled. However, the authors note that deep septic complications following intramedullary nailing in children are rare in the literature, and no such publication has been found for PLGA implants.

The greatest weakness of this study is that it is retrospective and presents only a small number of patients. The children in the BR-group were operated on by two experienced surgeons, which may have contributed to the good results. Given that this is one of the most common surgical indications in paediatric traumatology, it is questionable how long of a learning curve a resident with less experience needs.

There is no prospective comparative analysis which could confirm the superiority of this technique over other methods.

Notwithstanding the above, we believe that treating paediatric distal forearm fractures with biodegradable implants is a promising new technique.

Conclusions

Surgeries with bioresorbable intramedullary implants may have fewer complications than K- wire osteosynthesis in the treatment of severely displaced distal forearm fractures. The benefits are most pronounced in the first six weeks after surgery, reducing the number of outpatient visits and increasing the child's sense of comfort. As no second intervention is required, this can lead to significant cost savings.

Abbreviations

Kirschner- wires
K-wires
Poly(l-lactide)-co-glycolide acid
PLGA
Kirschner-wire group
KW group
Bioresorbable group
BR group

Declarations

Ethics approval and consent to participate

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Clinical application of the modified technique was accepted and permitted in 2017 by our medical review board, by the Hungarian Paediatric Trauma Committee, and by the Hungarian Paediatric Surgery Committee. This retrospective study was accepted and approved by the Local Ethical Committees. (Péterfy Hospital, Ethics Committee) (License number:11/2021)

A written informed consent was obtained from all individual participants included in the study.

Consent for publication

A written consent was obtained from all the individuals to all images or clinical details to publish it in this study.

Availability of data and material

The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

Competing interests

Authors declare that they have no financial or non financial competing interests.

Conflict of Interest:

Authors declare that they have no conflict of interest.

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No funding was obtained for this study.

Authors' contributions

MV: manuscript preparation, study design, performed measurements

GJ: performed measuerements

DH: statistics

MT: performed measuerements

BH: performed measuerements

ZsK: performed measuerements, manuscript preparation

TK: study design

All authors have read and approved the manuscript”, and ensure that this is the case.

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Figures

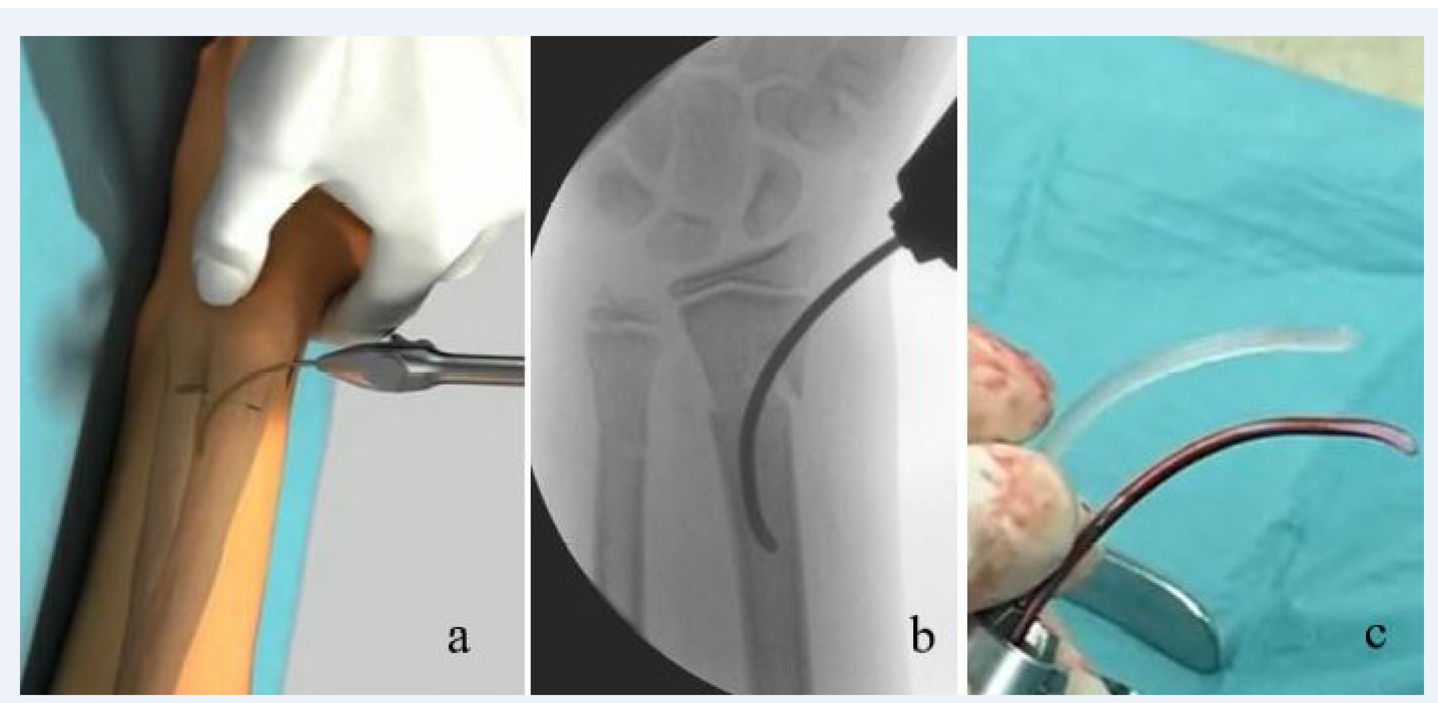

Figure 1

Temporary osteosynthesis with an elastic nail. a: schematic illustration b: intraoperative fluoroscopic picture c: short PLGA and titanium elastic nails

Figure 2

Insertion of the biodegradable Bioretec® Activa Pin™ as an intramedullary implant a: schematic drawing b: intraoperative picture, insertion of the implant c: fluoroscopic view– the PLGA implant is almost invisible

Figure 3

Distal forearm fracture of a 7-years old boy treated with Activa Pin™ a: shortened and displaced unstable distal metaphyseal fracture b: X-rays made in the postoperative first day c: X-rays made 24 months after surery

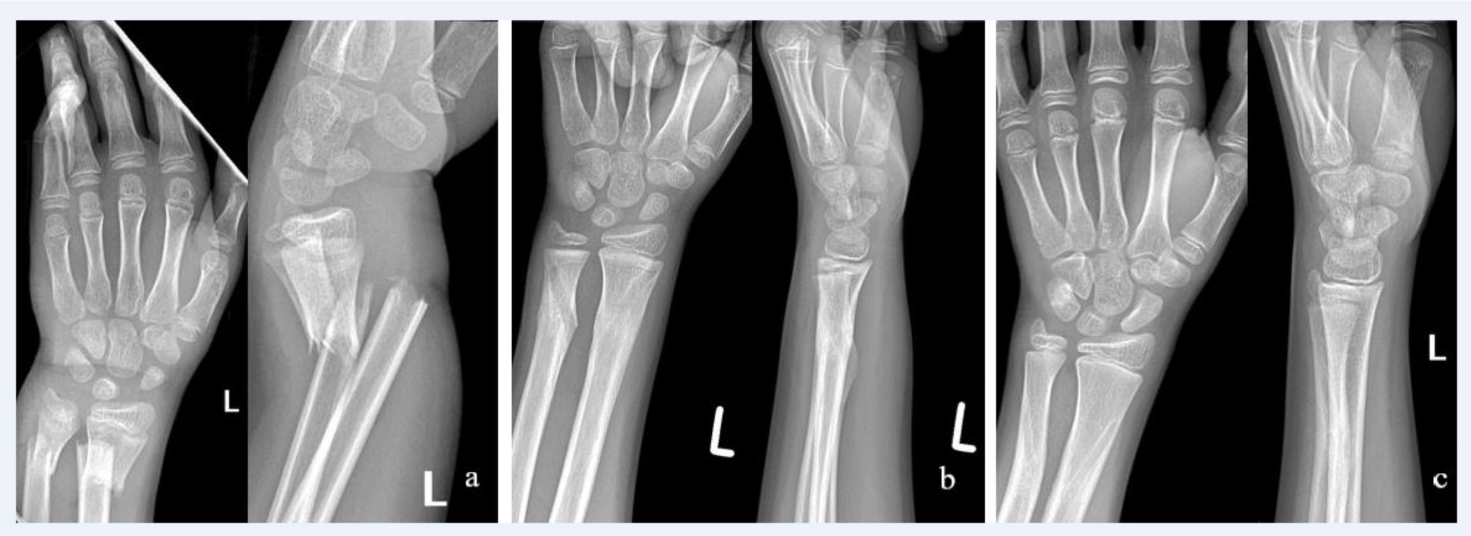

Figure 4

Distal forearm fracture of a 11-years old boy treated with Activa Pin a: shortened and displaced unstable distal meta-diaphyseal fracture b: X-rays made after 12 weeks of surgery c: X-rays made 24 months after surgery

Figure 5

MRI image after PLGA implant placement a: half a year after the surgery, the implant is clearly visible (arrow) b: two years later only minimal traces of the implant are visible (arrowhead)