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Surgical treatment of 22 pediatric forearm fractures with biodegradable Activa IM-Nail™ - a personal surgical experience

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Introduction

Activa IM-Nail™ is a new surgical method of treating displaced pediatric diaphyseal forearm fractures. We have used this CE marked biodegradable intramedullary nail with 22 children in our clinic, Péterfy Hospital, National Trauma Center, Department of Pediatric Trauma Surgery, Budapest, Hungary. The following summarizes our surgical experience so far. More accurate conclusions can only be drawn after operating on more children.

Patients and methods

We have operated on 22 children with Activa IM-Nails™. The average age of children was 9.125 years (range 6-14 years). The boy : girl ratio was 14:8, with the left and right forearms operation ratio being 50/50 per cent.

Three children already had a previous fracture on the same limb within a year, so these fractures were considered refractures. One child had a forearm fracture three years earlier, so this injury was not considered a refracture. One child with titanium nails from a previous injury had developed a fracture due to repeated trauma. Another child had a concomitant supracondylar humeral fracture with a displaced forearm fracture. The other 16 children suffered an acute fracture without any previous injury or comorbidity. 19 children had closed, completely displaced both-bones forearm fracture, and three children had an isolated radial diaphyseal fracture, with complete displacement.

The surgical time and the radiation exposure time were also recorded for all surgeries. The surgeries were performed by three surgeons familiar with the ESIN technique and had been performing pediatric traumatology interventions for more than 20 years. All children underwent surgery within 24 hours. Single-shot antibiotic prophylaxis was used routinely.

Fractures operated with Activa IM-Nail™					
Complete forearm diaphyseal fracture	Isolated radial diaphyseal fracture	Refractures operated with	Fracture with supracondylar humeral fracture	Boys /girls ratio	Left/right hand ratio
14	3	4	1	14:8	11:11

Results

Closed fracture reduction was feasible in 19 patients, open reduction was required in 3 children. In a child who had an isolated radius fracture, closed reduction could not be performed due to severe soft tissue interposition. For a child who had a refracture, the medullary cavity was closed, a medullary cavity had to be drilled with an open reduction. One child whose radial diaphyseal fracture had been treated conservatively showed secondary displacement after three weeks. His fracture required an open technique because mild callus formation had made closed reduction impossible.

We have not observed any deep or superficial infection or skin irritation. All fractures showed callus formation no later than 4-12 weeks after surgery. One mild malalignment within the range of remodelling has been observed without the need for reoperation. We have not detected any refractures after the insertion of Activa IM-Nail™. The children who underwent surgery at least six months ago have now regained their full range of motion.

Discussion

The nails are made of PLGA material, and at the distal end, there is an absorbable β-tricalcium phosphate (TCP) marker. This marker allows the end of the nail to be visualized during surgery.

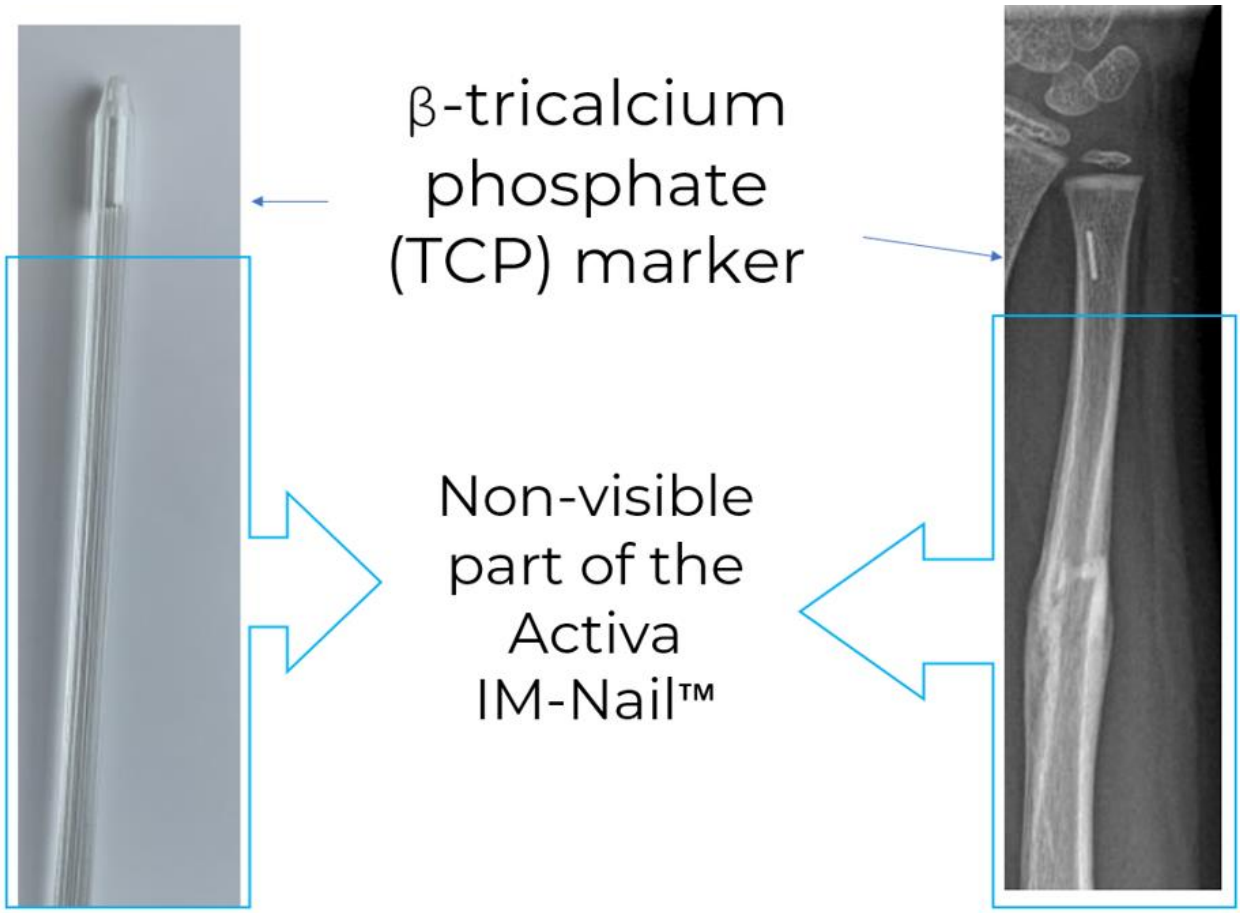


Figure 1. β-tricalcium phosphate (TCP) marker of the Activa IM-Nail™

The nails are available in several sizes and lengths. Currently, the surgeon can choose from nail thicknesses of 2.0, 2.7 and 3.2 mm in diameter. Except for the TCP marker, the material is the same as the material of the ActivaPin™ implant. ActivaPin™ has been on the market since 2006. At first glance, the nail appears flexible, especially compared to a titanium implant of similar thickness. The flexibility is essential during nail insertion as the insertion technique differs from the conventional ESIN technique.

Before introducing the nail, the fracture is reduced and stabilized temporarily with metal alloy implants, so-called dilators, similar to the elastic titanium nails. The difference is that the dilators are less flexible. The dilators are also available in three thicknesses

according to the size of the Activa IM-Nail™. There is also a special insertion tool for the Activa IM-Nail™. This is slightly different from the usual T-handle inserters. When it appears high force may be required for the dilation (as with narrow medullary canals), the traditional T-handle may seem better at first because it may be difficult to tighten the nail in the device. However, I suggest using the official inserter for the Activa IM-Nail™ itself because its design allows the nail to be pushed in without applying much force.

Figure 2. The inserter of the Activa IM-Nail™

Surgical technique

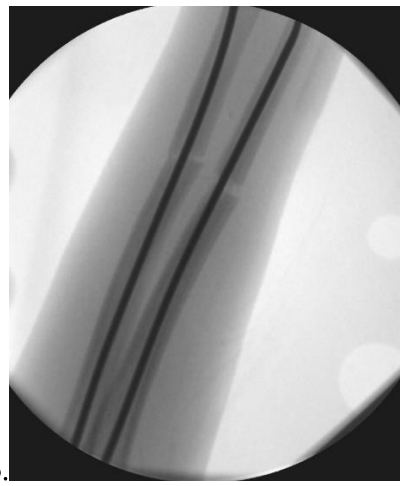
Position

The patient's positioning and preparation are no different from the traditional elastic nailing procedure protocol. Of course, this is not uniform around the world. We always use a single antibiotic prophylaxis shot in our practice and do not routinely use an esmarch. The child lies in a supine position, and the arm is on a fluorescent table. It is essential to use an image intensifier during surgery in a position where the surgeon can view the entire forearm.

Dilation

The surgery's first steps are essentially the same as those used with the traditional elastic nailing technique. The fracture is first reduced, and then the radius and ulna are stabilized with dilators. The dilators' insertion points are the same: the radial side of the radial distal end, proximal to the growth plate, and the radial area of the proximal end of the ulna, distal to the physis. A significant difference is that the dilators are stiffer, making it harder to push them through the medullary space.

If the dilators cannot achieve a satisfactory result due to their increased rigidity (e.g. the dilator exits the bone at the fracture gap site and cannot be positioned), then the dilation can be safely performed with conventional titanium elastic nails. In this case, the titanium nails' diameter must be at least equal to or thicker than the planned Activa IM-Nail™ thickness.

a.  b. 

Figures 3a and 3b. Temporary osteosynthesis with the dilators

Replacing the nails

The next step in the surgery is to replace the inserted alloys with resorbable implants. This is the most challenging point. Replacement can only be started once both bones are stabilized with the dilators. The dilators are removed from only one bone at a time. It can only be removed from the second bone once the first resorbable implant is in its place. This reduces the chance of a secondary displacement after the dilators are removed. If despite this, a secondary displacement still occurs after the removal of the dilator (e.g., the fracture is very unstable), a repeated reduction must be performed. It is advisable to perform this part of the surgery with an assistant who can manually maintain the reduction.

Insertion of the Activa IM-Nails™

The next step is to insert the bioabsorbable Activa IM-Nail™ into the medullary canal. The nail does not have to be guided like a conventional metal implant, i.e. rotating. High-force movements are not allowed. Ideally, the nail can be pushed in easily (if it goes too easily, maybe the nail is too thin), or it can be pushed in with a bit of resistance, even with slight pressure.

Figure 4. Insertion of the Activa IM-Nail™

If the nail gets stuck in the medullary canal, it is forbidden to force it. In this case, it must be removed, and the cause of the problem should be determined. It is common that the medullary canal is still not wide enough yet. If so, repeated dilation is required. It is advisable to guide a thicker dilator or titanium nail through the fracture. A medullary space of adequate width can be formed by moving the nail back and forth several times. Complete dilation is an essential condition for surgery. Always try to insert the thickest possible nail. The β-tricalcium phosphate marker confirms the correct position of the nail. The nail should be guided to the physis, but we do not pass through it, similarly to elastic nails.

Cutting off the ends of the Activa IM-Nail

After both bones have been positioned with the Activa IM-Nail™, the protruding proximal end of the nails are cut off. Cutting can be done with several tools. Perhaps the most suitable is a particular instrument that resembles a soldering iron, a high-temperature cautery. This allows the end of the nail to remain smooth. (Conventional surgical wire cutters can also be used.)

Figure 5. Cutting off the nail´s proximal end

A significant advantage is that the end of the nail does not have to protrude out of the bone at all. The Activa IM-Nail™'s protruding proximal end needs to be pushed a little further past the incision to ensure that no skin irritation develops later. To date, no skin irritation or superficial infection has been observed in any of the surgeries.

Operation time

With this implant we can avoid the removal operation and additional operating room time and expenses. However, I wanted to eximine the time in the OR in the learning phase. Although this paper is not comparative, the surgical times are longer than the time of an average elastic nailing technique. There are two reasons for this. Surgery will certainly always be longer, as the fracture will need to be nailed twice - once with the dilators and once with the resorbable implants. On the other hand, the technique also has a learning curve - the time of our more recent surgeries has already been significantly reduced.

The average operation time was 63 minutes (range of 30-105 minutes). The average radiation exposure time (seconds when fluoroscopy was used) was 147 sec., range 69-323 sec. In two children, we had surgery times of more than 90 minutes - on one occasion, the child also had a simultaneous elbow fracture that needed to be stabilized. In another child, we had to drill the medullary canal with an open technique due to the closed medullary cavity. These surgical times were thus not delayed because of the new nail, but because of the unique nature of the fractures. Similarly, the beam exposure time can be longer than with the conventional technique - however, this can certainly be reduced by accurately and carefully positioning the image intensifier.

Immobilization

After surgery, the limb must be immobilized in an above-the-elbow cast. This is also a difference from the traditional technique. The current recommendation suggests an immobilization period of 4-6 weeks. In practice, the immobilization time may be shorter, and the above-the-elbow cast even may be changed to a short cast or brace later. However, the synthesis must be protected in the first few weeks because the resorbable implants are not as strong as titanium nails. In fact, after surgery, the surgeon who is not used to this technique may have a “bad feeling” that the implants are not holding correctly, but in the first 24 hours, the nails swell a bit and tighten even more into the medullary space.

In my opinion, the postoperative immobilization time and method (long cast, short cast, brace) are not yet precise. It is advisable to be more cautious for the time being and it is preferred to maintain the cast for longer (3-6 weeks). Starting mobilization should always be decided on by the surgeon, considering the quality of the synthesis, the child’s age, and the cooperation.

Visualization of the nails

Image intensifiers and X-rays:

The TCP marker is usually clearly visible during surgery on the image intensifier. Because image intensifiers and their settings are different, the image of the TCP marker may be fainter in some cases. It is also worth noting that despite its visibility, a TCP marker never gives as strong an image as a metal alloy. Eight months after the surgeries, TCP markers are still evident on X-rays.

MRI:

MRI is not part of the routine checking procedure of the Activa IM-Nail™ technique. However, it can be used safely with the implant. An MRI scan can visualize the entire nail in the medullary space. One child underwent MRI immediately after surgery and did not experience any discomfort.

Figure 6. Postoperative MRI scan and X-ray of a forearm fracture. Only the TCP end of the Activa IM-Nail™ is visible in the X-ray, while its entire length can be visualized with an MRI.

Summary

Our initial experience with Activa IM-Nail™ is excellent. So far, parents have always preferred the surgical technique with an absorbable implant, even though it is a new method. We hope that in the future, we will be able to report further positive experiences.

Patients

Patient case 1 - fall from a trampoline, 8-year-old child

7a. 7b.

Figure 7a. X-rays of the fracture. 7b. X-rays on the first postoperative day

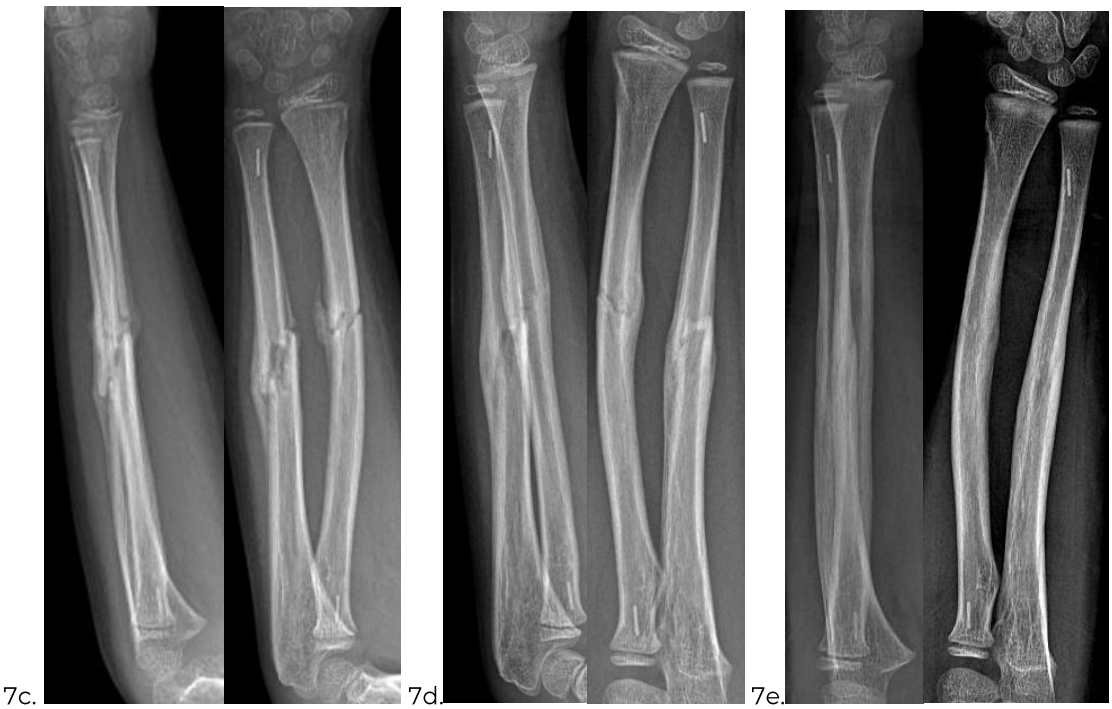


Figure 7c. X-rays 4 weeks postoperatively. 7d. X-rays 8 weeks postoperatively.
7e. X-rays 5 months postoperatively.

Patient case 2 – 8-year-old boy, refracture after three months of conservative treatment

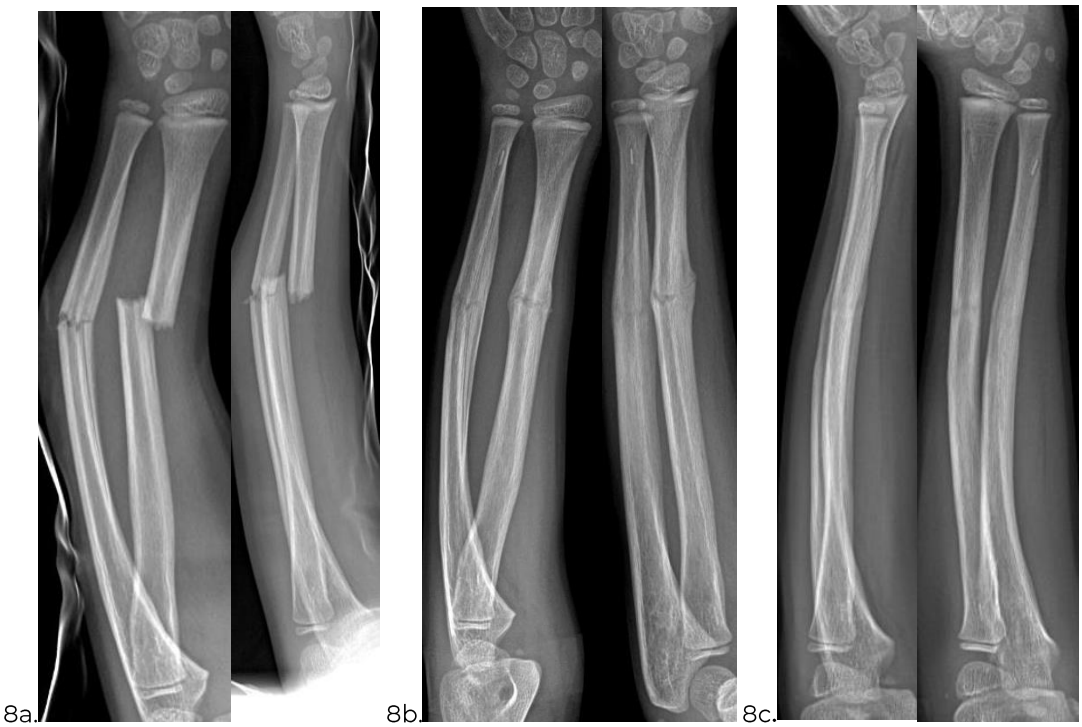


Figure 8a. X-rays of the fracture. 8b. X-rays 8 weeks postoperatively.
8c. X-rays 4 months postoperatively.

Patient case 3 - Refracture with a titanium elastic nail inside

9a.  9b.  9c. 

Figure 9a. Refracture with titanium elastic nail. 9b. Titanium nail replaced with Activa IM-Nail™ 9c. X-rays 3 months postoperatively.

Contact Information Concerning the Case

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