# Should osteosynthesis hardware be systematically removed in children?

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## I. Defining the subject

When faced with such a vast subject, we would first start by defining the subject matter more precisely.

**"Osteosynthesis hardware":** We have decided to concentrate on orthopedic and peripheral trauma osteosynthesis hardware, thereby excluding the spine.

**"Should it be removed":** Two different concepts are opposed: Systematic removal and optional removal.

**"In children":** The age of the child should be considered, and the decision based simultaneously on the effect of skeletal growth on the orthopedic hardware, and the hardware on growth, as well as to determine the influence of the underlying condition.

## II. Problem, discussion, and literature

Osteosynthesis hardware is used for numerous indications in children, both in orthopedic and traumatology. Once the bone has healed, their function has ceased (1) and they represent a foreign body which can be the source of potential complications. Similarly, additional surgery for the removal of the hardware may in itself lead to complications. As a result, the benefits of hardware removal are controversial and should be weighed against the risks, whether it is to remove the hardware or leave it in place indefinitely. Faced with this dilemma, there is a lack of evidence and recommendations for best practice. As a result, the fate of osteosynthesis hardware in children lies on expert opinions, the preferences of different departments, and the personal experience of each surgeon.

Practically, there is diversity in the literature as to the frequency of routine removal of hardware in children and may be as high as 60% (2). These are most often motivated by the willingness to avoid hardware-realted complications.

***Systematic hardware removal***

When a child presents hardware-related symptoms, its removal is justified (1,3,4). However, according to Henson et al., 58% of surgeons would not endorse the systematic removal of

hardware in asymptomatic children and argue that a second surgery might be riskier than leaving it in place (5).

As a result, Raney et al. reported a complication rate of 10% after removal of hardware (this rate is variable and ranges from 7 to 40% according to the different studies (1)) with a non-negligible proportion of major complications (6).

Among the primary risks, we cite:

- Risks related to the anesthesia
- Risks related to the surgical morbidity:
    - Extension of the surgical wound
    - Blood loss
    - Hematoma
    - Vascular, nervous, and tendinous injuries

In addition to the above would also be added possible intraoperative exposure to ionizing radiation if image intensification were to be used.

It should also be noted that some authors have reported that an initial complicated surgery increased the risk of complication during hardware removal by a factor of 2.48 (1,7).

The economic consequences of the cost of a new hospitalization and postoperative care should also be considered, as well as scheduling constraints placed on surgeons for the programming of a high volume of interventions to the operating room, sometimes to the detriment of cold cases (3).

Finally, specifically in the case of pediatric surgery, the decision to undergo a second surgery would lead to more parental worries and schooling and socio-familial consequences due to the patient's absence and necessary parental availability.

***Is the metal toxic?***

The metals used in osteosynthesis hardware represents an inert foreign body that interacts with the human body. In fact, this metal reacts with the saline environment in the human body by releasing certain particles (3). The materials used are meant to resist corrosion, although this phenomenon is found in 75% of cases. These particles may, along with certain other toxic salts, accumulate locally, as well as in other distant tissues, although this fact should be taken relative to the low doses and concentrations that are released.

In this sense, the human body may react to the metal in different ways:

- Inflammation: Similar to any foreign body, an inflammatory reaction takes place when human tissues is in contact with the hardware, and a granulation tissue, that could be

responsible for swelling and pain that could take place with some latency, is formed. This reaction is less intense with Titanium.

- Allergy: A histologic study on soft tissues that remained adherent to the implants after their removal showed that, at least part of the discomfort reported by the patients was due to an allergic reaction (8).
- Carcinogenesis: While the carcinogenic nature of hardware has been reported in numerous animal studies, it is more controversial in humans, and especially in children; only 2 cases have ever been reported in the literature. These cancers appeared with an average delay of 10 years, either in tissues that were in contact with the hardware or at a distance (3). Until this day, this risk remains hypothetical since the causality remains to be proven. Furthermore, we would ask ourselves if this risk would be due to the hardware itself or rather local changes secondary to the fracture or the surgery.

Nevertheless, even though no studies have directly proven the local toxic effects of these implants (9), certain hardware companies, through the Agence Nationale de Sécurité du Médicament, actually impose the systematic removal of their hardware after a certain period of time. Such is the case of the Precice NuVasive® magnetic growing nail.

***Growth***

Since the child is not a small adult, the prolonged presence of hardware in the immature skeleton may be questioned. Most surgeons agree that the presence of orthopedic hardware may be deleterious for skeletal growth, especially in younger children, but the presumed impact that they might have has not been clearly described in the literature.

As such, multiple hypotheses may be considered:

- The risk of epiphysiodesis in the case of hardware traversing the physis, increased by certain types of trauma, such as epiphyseal fracture-separations.
- Risk of bony overgrowth with plates due to periosteal stripping.
- The discomfort of the hardware that is at a progressively increased distance from the physis (Figure 1)
- Hardware migration, especially with the use of K-wires.

*Anteroposterior radiographs of the pelvis – example of migration of a proximal femoral plate.*

Nevertheless, the deleterious effects of a second surgery, especially if the hardware removal proves difficult, remains an interesting question (1).

As such, the presence of the hardware and its removal should be discussed on a case-by-case basis relative to its possible risks on potential growth.

***Medical condition***

When the underlying bone is pathological, such as in osteogenesis imperfecta, or fibrous dysplasia, the use of osteosynthesis hardware is most often definitive due to the high risk of bony deformity or pathological fracture after its removal (9).

In patients presenting with a neuromuscular pathology, since the bone is of a lower quality and the patient more fragile, it is often recommended that the hardware be removed within the year due to the higher risk of infection and mechanical complications (10). However, inversely, it has been described that hardware removal in patients with neuromuscular pathologies have a relative complication risk of 1.5. This risk is doubled if the patient is non-ambulatory (7). Truong et al. compared the complications due to hardware removal and, relative to the indication (Systematic vs. in case of symptoms), reported a significantly higher proportion of refractures and infection in the group presenting symptoms, even though 80% of the patients in this group could have avoided hardware removal (11).

Therefore, although hardware removal in patients with neuromuscular diseases might seem indicated based on certain surgical conclusions, these indications should take into consideration the risks involved with the anesthesia, which are non-negligeable.

***Location***

Many authors have highlighted the fact that certain anatomical regions have a higher risk of complication during the implantation of hardware, such as the long bones of the lower limbs and the metaphysis (3,7), while for others, the risk of complication seems independent of the anatomical region (12,13).

Chu et al. evaluated the functional impact of hardware removal in children (14). In the upper limb, a significant improvement in terms of global function and sports participation, as well as in terms of pain, was reported. No such improvements have been found for the lower limb.

As a result, it might seem more pertinent to recommend hardware removal at the level of the upper limb than the lower limb.

***Pain and discomfort***

Pain and discomfort are some of the primary complaints.

Certain implants and anatomical regions are more susceptible to discomfort, or even pain, such as Elastic Stable Intramedullary Nailing (ESIN) or Kirschner wires if they are not cut at the level of the bone, ulnar plates, or wiring of the olecranon or the patella, subcutaneously irritating the tissues and menacing the skin. As a result, their removal seems justified. However, these symptoms may be also found in other situations where the pain is more difficult to explain, and where the results are more heterogeneous, ranging from completely subsiding after hardware removal (2) to an absence of improvement in 5 to 50% of cases, even though the surgery had undergone without complications (7,15). As such, a second intervention should be thoroughly contemplated when its benefit is uncertain. Furthermore, Vopat et al. found that most patients who had not undergone hardware removal regained their functional capacity and previous levels of activity and are satisfied with the results (16).

Therefore, it is difficult to arrive to a conclusion on the functional impact of the hardware, at least in the long term.

***Infection***

The osteosynthesis hardware represents a foreign body where pockets of deep infection may develop, either due to local or hematogenous spread. This may be found either in the acute or chronic setting, independently from the surgical technique and despite the use of prophylactic antibiotics, as is recommended by the French Society of Anesthesia and Reanimation and the per- and perioperative precautions undertaken.

In case of such infections, in addition to the antibiotics, removal of hardware is recommended for more efficient treatment. In fact, according to the literature, hardware infections heal in 100% of cases when the hardware is removed, compared to a 25% risk of recurrence if the hardware is left in place (17,18).

As such, healing from an osteitis related to an implant seems more difficult if said implant is left in place.

***Hardware migration***

Some authors recommend the systematic removal of certain types of hardware at high risk of migration, in order to avoid a more complex and dangerous future intervention (3). Among the situations known for being at high risk of migration, the use of K-wires for the synthesis of the clavicle should be noted. The indications for the initial surgery with such hardware should therefore be pertinent, and if surgery is undertaken, to anticipate an early removal of hardware (19). Fortunately, other situations are extremely rare and are listed in table 1 and highlight the fact that no situation is void of risk (20).

| From | To |
|---|---|
| Finger | Mediastinum |
| Distal radius | Pericardial cavity |
| Humerus | Right ventricle |
| Shoulder | Jugular foramen |
| Clavicle | Ascending aorta |
| Hip | Abdominal aorta |
| Spine | Pulmonary artery |
| Mandible | Lung |
| | Abdomen |
| | Spleen |
| | Ureter |
| | Trachea |
| | Spinal cord |
| | Orbit |

*Table 1: cases of K-wire migration found in the literature. From Seipel RC, Schmeling GJ and Daley R, in "Migration of a K-wire from the distal radius to the heart. Am J Orthop. 2001;30:147-151."*

***Fracture***

Osteosynthesis may be complicated by a fracture by varied mechanisms:

- If the hardware is removed prior to sufficient bone consolidation or remodeling: Schaaf et al. found in a study on osteotomies for osteochondritis, that the risk of an iatrogenic fracture after hardware removal is decreased if it is delayed: Every month reduces the risk of fracture threefold. The predictive duration for 95% of children to avoid a fracture is 5 to 6 months (21).

  In a study of diaphyseal fractures of both bones of the forearm in children, Makki et al. found a refracture rate of 14% after removal of the ESIN (which corroborates other studies (23)), and of 10% after removal of a plate. Refracture always took place at the site of the initial fracture. The risk of refracture was significantly higher if removal of the plate or ESIN was realized before 12 months or 6 months, respectively. Furthermore, a significantly higher risk of refracture risk was found after 12 years in plates and 9 years in ESIN.

It is therefore convenient to respect the timeframe of minimal consolidation based on the anatomical region of the fracture. In practical terms, for example, ESIN in fractures of both bones of the forearm should be removed systematically after 6 months and radiographic verification of perfect consolidation should be obtained.

- If the hardware is removed after consolidation is obtained, the bone may be temporarily more fragile due to the removal of hardware, especially at the level of the previous screws.
  Furthermore, due to bone remodeling in children, the bony callous may cover the hardware completely or partially (Figure 2), which would require osteotomies at the level of the hardware site leading to lengthier operative times and increased blood loss, which could lead, in certain extreme cases, to iatrogenic fractures, either perioperative or postoperatively due to cortical weakening (24).

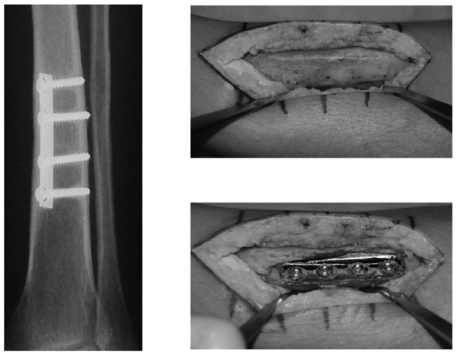


*Figure 2: An example where the entire plate is covered by the bony callous. From Davis JR et al. in "Removal of deep extremity implants in children. J Bone Joint Surg Br. juill 2010;92(7):1006 12."*

- If the hardware is left in place, there are two risks: Firstly, the presence of the osteosynthesis hardware leads to modifications in the constraints applied to the bone, as per Wolff's law, and leads to a decrease in bone density and a phenomenon of endosteal resorption (25) may take place at the junction between healthy bone and hardware. This risk is further increased in more rigid constructs. This relative osteopenia constitutes a weak zone that could refracture. Certain locations, such as the load-bearing areas, are at higher risk of stress shielding, as is highlighted in the study by Jain et al. who describe a 15.2 times higher risk of fracture around the hardware at the level of the femur (26). This is classically a reason cited by some authors who champion the systematic removal of hardware from load-bearing areas (3). Clement et al. found, in one of the only prospective studies tackling this subject, that 7.3% of children with a forearm plate presented with a fracture within 3 years (2). Nevertheless, these values are not higher than the reported risk of refracture after hardware removal. Rousset et al. also found a refracture rate of 10.5% in children with an ESIN of the forearm with a significantly increased risk in children younger than 7 years of age (23).

Additionally, fractures on hardware render the surgical management more complex (removal of previous hardware and osteosynthesis options).

Concerning the risk of fracture, it is all about timing and the anatomical region.

***Surgeon's experience***

Hardware removal is generally considered as a minor surgery, and this errand is often delegated to less experienced surgeons. However, "you can never look good with hardware removal" (27). Sanderson et al. conducted a study concluding that complication rates were not significantly altered based on the surgeon's experience (28), and complication rates were found to be around 20% regardless. However, more severe complications (such as nerve injury) were found when a junior surgeon was operating while unsupervised.

Inversely, Kim et al. conducted a study where all hardware removals were undertaken by a junior surgeon, but less than one third were not directly supervised by a senior surgeon (29). Complication rates were lower than 10% and no nerve injuries were reported.

It would appear that these surgeries should not be underestimated and the proper supervision by an experienced surgeon seems indispensable in order to steer clear of avoidable complications.

***For future interventions***

Children are growing beings and the natural histories of different pediatric pathologies should be kept in mind since they may require further surgeries in during adulthood. The persistence of the hardware may complicate further surgeries and increase their morbidity. As such, some authors recommend, especially in children with hip dysplasia of all etiologies, to remove the hardware as soon as possible to facilitate an eventual arthroplasty (3,21,30) (Figure 3). Loder and Feiberg highlighted that the difference in point of view as well as the mutual ignorance between pediatric and adult surgeons explains the absence of clear and mutual recommendations (31).

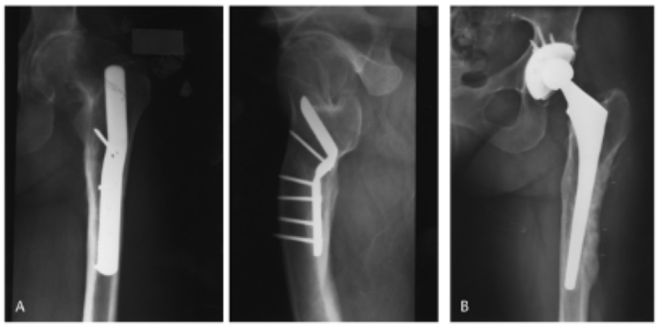



*Figure 3: An example of a proximal femoral pathology initially managed by an osteotomy (A) with interval migration of the hardware (A), and final requirement of a hip arthroplasty (B). From Peterson HA in "Metallic Implant Removal in Children. J Pediatr Orthop. 2005;25(1):9."*

### *The special case of Slipped Capital Femoral Epiphysis (SCFE) screws*

The removal of screws placed for preventing the progression of SCFE is reputed as being complicated. In a 2008 literature review conducted by Raney et al., the complication rate was as high as 34% in these cases, a rate three times higher than the global rate. Although the initial surgery is undertaken percutaneously, hardware removal often requires a larger and more invasive approach with greatly increased operative times. This is due to the difficulty in removing the hardware from a very deep area, with these children often being overweight (32,33). There is often fracture of the hardware leading to osteotomies, often in vain, thus weakening a bone that is otherwise healthy (34). It should be noted that the removal of hardware in such cases in undertaken only once the physis has closed, which imposes a delay of many years. This delay has been shown to significantly increase the risk of complications (33).

### *What about failure?*

Failure of hardware removal is the primary complication of removal surgeries, with a rate of 7% in the literature. Some anatomical locations are known to be at higher risk, such as the hip. The complications of incomplete hardware removal might be pondered. According to Schmalzried et al., complications are rare if the remaining portion is intra-osseous (35) (Figure 4).

*Figure 4: An example of Perthes disease having previously been treated by a triple osteotomy of the pelvis and osteosynthesis with screws (A). Fracture of the screws at the level of the screw head while attempting hardware removal three years later (B).*

### *Sports and professional activity*

Sports is contraindicated in the acute phase after hardware removal. However, once there is enough bony healing and there has been sufficient time has passed, one of the first questions asked is on the return to sports. Contact sports are the main worrisome activities owing to the high risk of fracture. Many pediatric surgeons agree on a prophylactic removal of the hardware before returning to sports, which would further increase the postoperative timeframe of precaution and reluctant return to sports. However, a study by Evans showed that, in professional rugby players aged between 18 and 32 years, return to sports with the hardware intact may be possible for the majority within 6 months, with a return to their previous level and with only a 1% complication rate (36). This should reduce some reluctance, especially in adolescents.

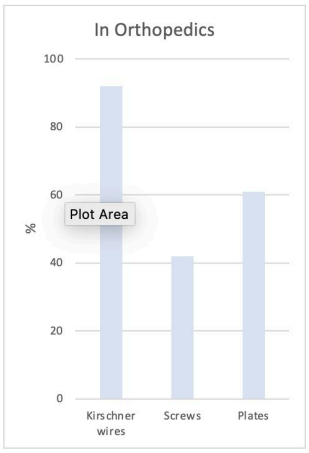
Finally, we are occasionally faced with young patients who have the ambition of pursuing a career in the military, demanding a removal of their hardware which is compulsory for their recruitment in the army (this information could not be verified by the authors).

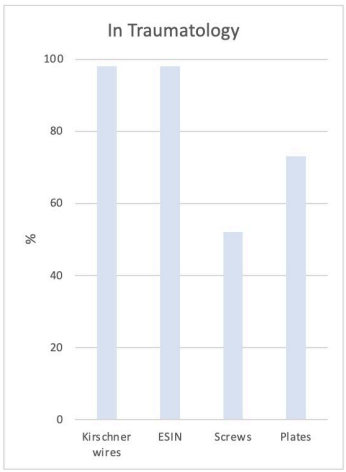
## III. Survey of practice 2021

A survey was conducted in 2021 on the practices and habits of French pediatric orthopedic surgeons in terms of osteosynthesis hardware in orthopedics and peripheral traumatology. A survey containing 6 questions was sent by mail to all members of the French Society of Pediatric Orthopedics (SoFOP). 118 responses were collected in total, with the following results:

In France, removal of hardware is routinely undertaken by 65% of pediatric orthopedic surgeons.

In traumatology and in orthopedics, the removal of K-wires and ESIN is almost systematically undertaken (>96% of cases), whereas screws and plates are often left in place in almost half and a third cases, respectively. It should be noted that, among the surgeons in whom hardware removal is not done systematically, the majority (94.3%) would remove K-wires and ESIN in trauma patients.




*Figures 5 and 6*

The main reasons for hardware removal are when further local interventions are considered in the future, for fear of migration, of local conflict, and the risk of fracture.

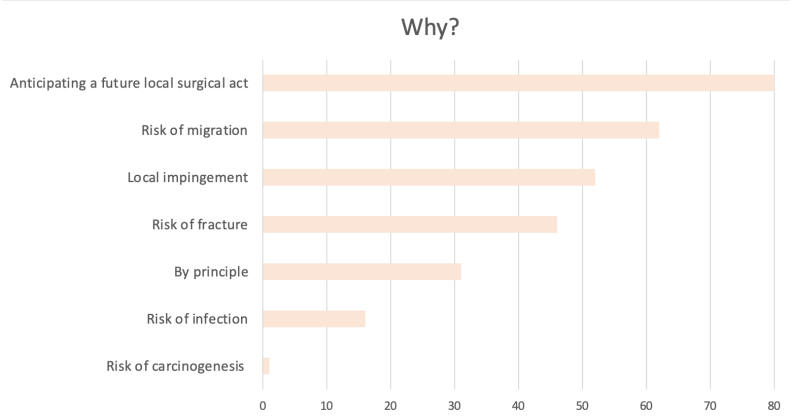



*Figure 7*

Around 80% of surgeons reported having already faced one or more complications if the hardware is left in place. Inversely, over 90% of surgeons reported having already faced one or more complications during hardware removal.

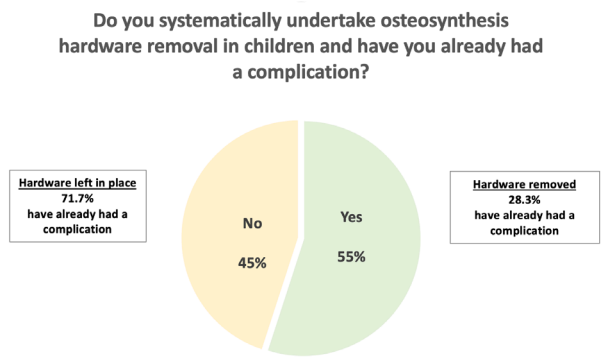



*Figure 8*

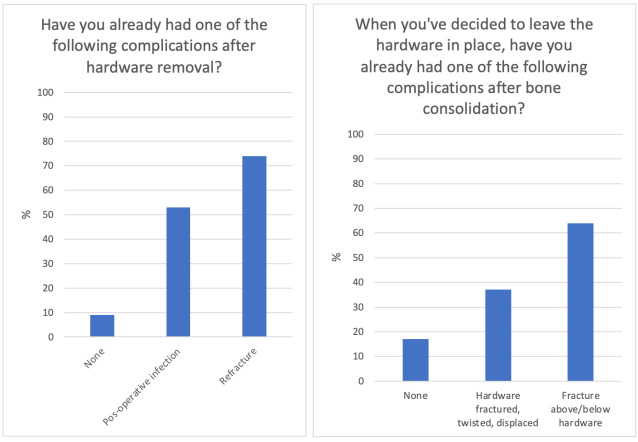



*Figure 9*

## IV. Conclusion

In conclusion, there is no consensus on the removal of hardware, even though the principle of prophylaxis prevails with pediatric orthopedic surgeons since the majority remove the hardware systematically.

Reviews of the literature are often little or unenlightening on whether the hardware should be removed, but rather invite us to consider certain situations in which the evidence may guide our practices.

As such, the younger the child, the more convincing the indication for hardware removal. Patients with pathological fragile bones, such as in cerebral palsy, should be considered in much the same way.

Certain anatomical locations may be more compelling for hardware removal, such as the pelvis and the lower limbs. Other situations, including when there is significant risk of hardware migration such as in pinning of the clavicle, impose an earlier removal of hardware and strict surveillance for sufficient bony consolidation.

Removal of hardware is an intervention that could be complicated and should not be trivialized.

Based on the indications for osteosynthesis and the anatomical region of the fracture, hardware removal is delay until there is sufficient consolidation, such as in fractures of both bones of the forearm. Inversely, removal of hardware should not be uselessly delayed once the bone has sufficiently healed, due to higher risks of complication.

If the site of fixation is infected, removal of hardware would facilitate healing and should be the norm.

Finally, no matter the preference, whether it is to remove the hardware or to leave it intact, the decision should be made during the primary surgery, in order to foresee the facilitation of its removal, or in the contrary, the discomfort it may cause.

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