

Use of resorbable magnesium screws in children: systematic review of the literature and short-term follow-up from our series

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We are proud that our publication raised such interest, and we thank the correspondent for the kind proposal of his personal point of view. Thus, we are pleased to respond to that *Letter to the Editor*.

The first point addressed by the correspondent is about the importance and interest toward the research, development, and production of resorbable fixation implants. In particular, based on a survey made in 2006 by Loder and Feinberg,¹ the correspondent claimed that implant removal is not necessary or rarely necessary. According to Loder and Feinberg, though, up to 77% of the 273 pediatric and 99 non-pediatric American orthopedic surgeons included in the survey, indicated that they remove implant “always,” “most of the time,” or at least “sometimes.” This results in only 22% of the participants not being at all concerned with implant removal. Thus, contrary to what is claimed by the correspondent, based on this study it is reasonable to suppose that resorbable implants would be at least of interest for most of the surgeons included in the survey.

Moreover, the decision to retain implants is of course highly biased by the concerns about eventual complications related to the removal procedure. In fact, it is well-accepted opinion that the potential consequences of implant retention should be weighted with the risk associated with a removal procedure.^{2,3}

Absorbable implants, such as magnesium (Mg) ones, completely avoid the potential complications of a surgical removal procedure thus making unnecessary this theoretical balance between risks and benefits. In conclusion, we do believe that this could at list be considered a relevant and worthy research field with potential future development, and the increasing interest in the scientific community during the latest years is a support to this opinion.

The systematic review is presented reporting the main characteristics, the type of procedure, number of patients, and the conclusions from the various authors. Most of the

included studies reported clinical outcome, but, given they were not comparable among them and a meta-analysis was not in the aim of our review, we did not consider the raw scores more relevant than authors' conclusions. In addition, all the studies reported have been included in the reference list for consult in case of interest.

Considering our series, we are of course aware of the low level of evidence, and this is reported as a limit. We clearly stated that this is a preliminary study aiming to assess the safety and efficacy of the only Mg-based implant approved for orthopedic procedures, in a skeletally immature population. We considered efficacy as the healing of the fracture, the absence of residual pain, and the patient-reported satisfaction. Safety was assessed by recording any suspect adverse local or systemic reaction. Implant failure was considered as loss of integrity of the implant associated with malunion, nonunion or delayed union of fractures, failure of the epiphysiodesis, or failure of the tenodesis.

Given the heterogeneity of the procedures performed, a thorough analysis of the functional score was not in the aim of our study and, in our opinion, would have been irrelevant both from a clinical and a statistical point of view. A similar structure was adopted by Stürznickel et al.,⁴ in a study accepted few months after our submission with similar results.

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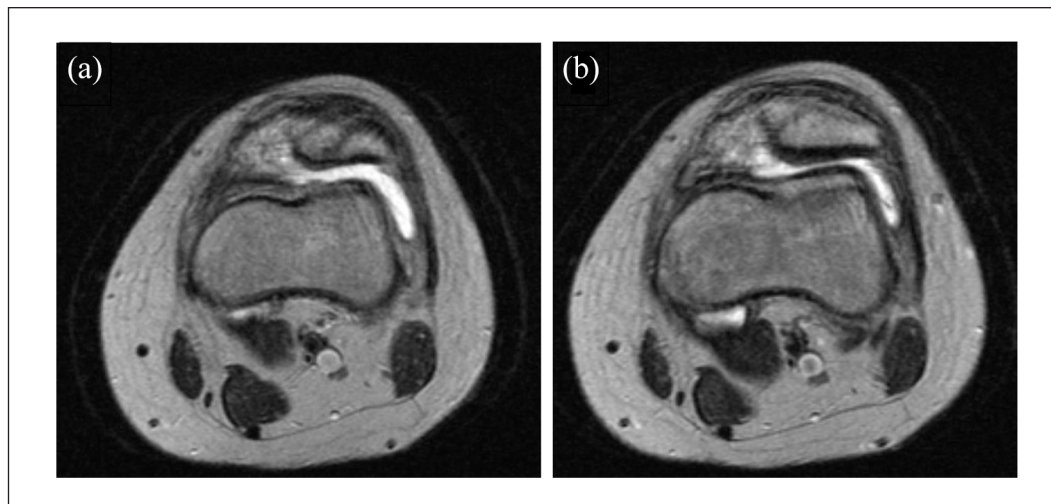


Figure 1. (a) and (b): Routine control knee magnetic resonance imaging of the index patient 20 months after surgery. Axial view shows advanced resorption of the three screws associated with bone regrowth around implants. No signs of chondrolysis or signs of osteolysis are identifiable. None of the three screws appear to protrude on the articular surface.

A positive debate on the usefulness of a new technology is always appreciated. Nevertheless, the correspondent stands against the results of our study apparently in a biased way, presenting his own personal point of view as it is solid evidence.

Due to the obvious impossibility to describe every single procedure, we reported as index case a patellar fracture dislocation treated with ORIF with 3 MAGNESIX® screws. At final follow-up (18 months), we reported excellent clinical results with complete range of motion (ROM) and function and complete absence of pain (visual analog scale=0). The patient was doing fitness training even if starting with a low preinjury level of activity. Moreover, even if it is a non-contact activity, fitness training can be extremely demanding in certain cases.

The correspondent stated that the index patient was “unable to do any other sport” and that “the inability to return to sport could be related to part of all 3 screws being outside the cortical bone potentially causing chondrolysis in addition to the extensive osteolysis.” The patient was assessed for pain and function and discharged with no sport limitation after 6 months, thus his decision to perform this activity was not at all associated with a *not-well-defined* increased risk of fracture groundlessly supposed by the correspondent. We do believe that patients are free to do whatever sport they prefer without considering “non-contact sports” as a treatment failure.

Finally, the correspondent raised concerns about osteolysis around Mg implants, claiming that this could “increase the risk to sustain a stress fracture around the implant, probably stopping children from participating with contact sport.”

Again, this is correspondent’s personal opinion that is largely countered by literature. Our review collected all orthopedic clinical studies reporting the use of Mg implants in human, and none of the authors reported a single case of

peri-implant fracture. Only one case from Wichelhaus et al. reported implant loosening requiring revision, after a peculiar surgical procedure. In all cases, prescription of activity or sport limitation was not described as different from rehabilitation protocols of other standard implants. Moreover, in our center, patients treated with Mg implants received the same rehabilitation protocol of patients treated with standard implants.

Osteolysis around implant is a historical potential concern described since the first uses of Mg-based materials in surgery. As deeply described in the discussion section of our study,⁵ refinement of composition and proportions of alloying materials is of utmost importance and has permitted to overcome this issue. Imaging from our casuistry clearly shows that peri-implant osteolysis is a benign, self-limiting phenomenon not at all affecting healing (Figures 1–3).

We look forward to strengthening the evidence and define indications with larger studies comparing Mg resorbable implants with standard of care implants for specific conditions. Nonetheless, our study further supports the increasing evidence that Mg screws are safe and effective in treatment of various conditions, both in orthopedic and traumatology also in skeletally immature patients. It allows the treatment of avulsion, small fragment fractures, meta-epiphyseal fractures, tenodesis and epiphysiodesis without any implant retention.

In conclusion, we are glad that our publication raised the interest of the correspondent pulling him to write a Letter to the Editor published in the present Issue. We strongly believe that path to increasing knowledge is grounded on healthy debates and discussions. Nevertheless, science is a place where opinions should be weighted against data and evidence. Doubts are welcomes, but personal skepticism should not allow unsubstantiated insinuations against evidence provided by colleagues.

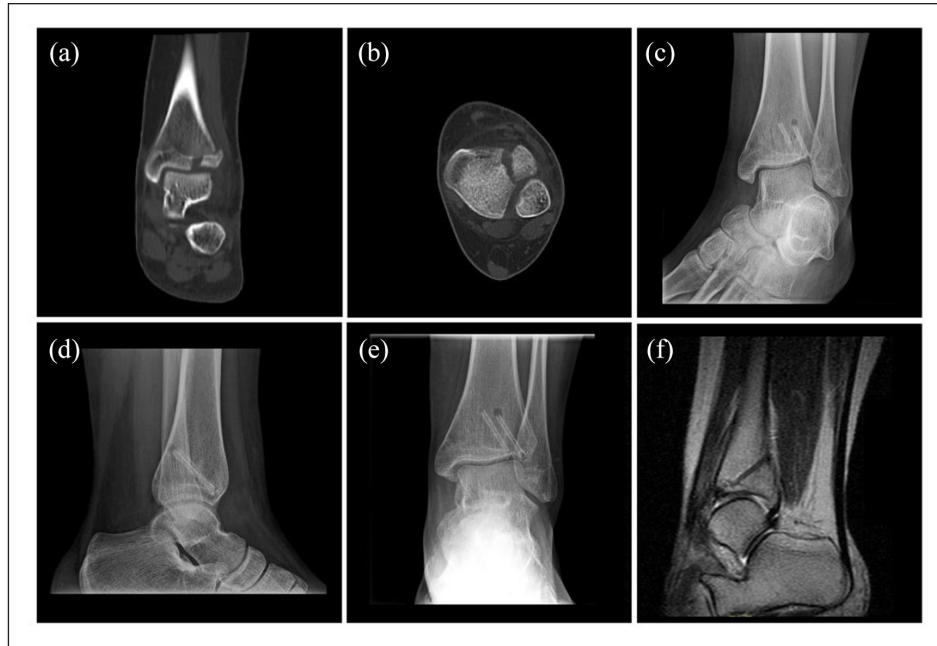


Figure 2. (a, b) Preoperative imaging of a Tillaux fracture sustained by a 13-year-old girl. (c–e) Routine X-ray 6 months after surgery. The fracture is healed without displacement or complications. Resorption of the implants is ongoing, with minimal evidence of peri-implant osteolysis. (f) Routine magnetic resonance imaging 12 months after surgery shows absence of peri-implant osteolysis and confirms complete healing of the fracture.



Figure 3. (a, b) Preoperative imaging of a symptomatic grade III osteochondritis dissecans of the medial femoral condyle. (c, d) Routine radiography taken 12 months after surgery shows radiographic healing of the fragment and absence of peri-implant osteolysis.

Declaration of conflicting interests

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