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Fixation of Knee Osteochondral Lesions in Pediatric Patients with Magnesium-Based Implants

Fixace osteochondrálních fragmentů kolena biodegradabilními implantáty z hořčíkové slitiny u dětských pacientů

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ABSTRACT

PURPOSE OF THE STUDY

Fixation of osteochondral fragments are relatively common procedures in pediatric orthopaedic surgery. The use of biodegradable magnesium implants in these indications appears to be a promising alternative to polymer implants due to their favorable mechanical properties and biological behavior. The purpose of this study is to evaluate the short-term clinical and radiological outcomes of the fixation of unstable or displaced osteochondral fractures and osteochondritis dissecans lesions in the knee joint using MAGNEZIX® screws and pins in pediatric patients.

MATERIAL AND METHODS

In this study, 12 patients (5 girls, 7 boys) were included. The inclusion criteria were as follows (1) age below 18 years; (2) unstable or displaced osteochondral fragments secondary to trauma or as a result of osteochondritis dissecans, Grades III and IV in the ICRS (International Cartilage Repair Society) score, confirmed by imaging methods and indicated for surgical fixation; (3) fixation performed using screws or pins made of the magnesium-based MAGNEZIX® alloy; (4) minimum postoperative interval of 12 months. X-rays and clinical evaluation were assessed 1 day, 6 weeks, 3, 6, and 12 months after the operation. MRIs were performed 1-year postoperatively for evaluation of bone response and degradation behavior of implants.

RESULTS

The mean age at surgery was 13.3 ± 1.6 years. A total of 25 screws were used in 11 patients, a mean of 2.4 ± 1 per patient, 4 pins were used in 1 patient. In 2 patients, fixation with screws was complemented with fibrin glue. The mean follow-up was 14.2 ± 3.3 months. All patients exhibited complete functional recovery while showing no signs of pain at 6 months postoperatively. No adverse local reactions were observed. At 1-year follow-up, no implant failure has been reported. Complete radiographic healing occurred in 12 cases. Mild radiolucent zones were observed around the implants.

CONCLUSIONS

The use of screws and pins MAGNEZIX® has been found to provide satisfactory outcomes in terms of fracture healing and very good functional outcomes at 1 year postoperatively.

Key words: biodegradable implants, magnesium-based implants, osteochondral fracture, osteochondritis dissecans, MAGNEZIX®.

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INTRODUCTION

In the pediatric population, osteochondral lesions of the knee joint occur either as a result of osteochondritis dissecans or secondary to trauma, with one of the most frequent injuries leading to osteochondral fracture to the articular surface of the patella or the lateral condyle of the distal femur being patellar dislocation (6). Osteochondral fragments in the knee joint cause pain, swelling, or joint blockade.

The commonly used implants for the fixation of osteochondral fractures are made of biodegradable polymers (1, 15). However, relatively common complications are associated with these implants (7, 8, 21, 29).

Magnesium-based alloys have been extensively studied as potential biodegradable metals for bone temporary implants (31). In addition to biodegradability, magnesium alloys also have favorable mechanical properties. The low modulus of elasticity of Mg alloys reduces the possibility of stress shielding associated with the use of traditional metallic fixation hardware (25). Magnesium alloys also promote de novo bone formation (16) and seem to have anti-inflammatory properties (34).

The first magnesium-based implants certified for use in clinical practice are MAGNEZIX® implants, consisting of the magnesium-alloy MgYREZr (magnesium, yttrium, rare earth metal, and zirconium), commercially available since 2013. In an *in vivo* environment, mag-

nesium alloy MgYREZr has been reported to have good compatibility, osteoconductive (30), and favorable mechanical properties (9). Although the use of MAGNEZIX® implants has been widely described in adult patients in the field of orthopedics and traumatology, current literature includes only a limited number of clinical studies assessing the potential use of absorbable MAGNEZIX® implants in the management of osteochondral lesions in pediatric patients.

MATERIAL AND METHODS

This clinical study analyses data after osteochondral fragment fixation with MAGNEZIX® implants. The inclusion criteria were as follows: (1) age below 18 years; (2) unstable or displaced osteochondral fragments secondary to trauma or as a result of osteochondritis dissecans, Grades III and IV in the ICRS (International Cartilage Repair Society), confirmed by imaging methods and indicated for surgical fixation; (3) fixation performed using screws or pins made of the magnesium-based MAGNEZIX® alloy; (4) minimum postoperative interval of 12 months. Exclusion criteria were set as (1) history of previous surgery for an osteochondral cartilage defect on the knee; (2) the use of other than magnesium-based implants for fixation; (3) age over 18 years; (4) patients with severe metabolic bone disease.

The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Ethics Committee. Informed consent was obtained from all subjects involved in the study.

Cohort of patients

A total of 12 patients meeting the inclusion criteria were enrolled in the study (5 girls, 7 boys). 9 patients were excluded due to pre-specified exclusion criteria (see above). All surgical procedures were performed between February 2018 and February 2020 at the authors' center. The mean age of the patients at the time of surgery was 13.3 ± 1.6 years (10–16 years), with a mean follow-up period of 14.2 ± 3.3 months (12–24 months). Regarding the etiology of the osteochondral lesions, this included acute injury to the knee joint in 8 patients (6 patients with acute traumatic patellar dislocation, 2 patients with knee sprain). Development of an osteochondral lesion as a result of osteochondritis dissecans was observed in 4. 2 patients with osteochondritis dissecans lesion were indicated for fixation due to failure of the antegrade drilling technique, 2 patients were indicated for surgical fixation after 6–12 months of unsuccessful non operative treatment (temporary knee bracing, activity modification, *magnetic* stimulation and *laser therapy)*. Arthrocentesis for hemarthrosis at the time of emergency admission was undertaken in 4 patients, while 2 patients experienced hemarthrosis with the presence of lipid droplets. The mean time from injury to surgery in the subgroup of patients with osteochondral fracture secondary to trauma was 17 ± 17.76 days (range 0–55 days).

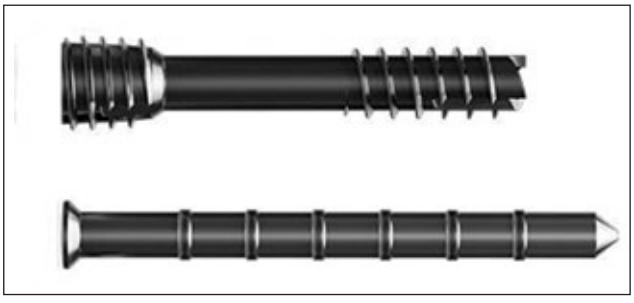

Fig. 1. Implants. Screw and pin made of the MAGNEZIX® magnesium-based alloy. (Source: Syntellix AG, http://syntellix.de).

Imaging and assessment

Standard radiological examination of the knee joint in anteroposterior and lateral projection was performed during on-admission evaluation, complemented by the axial projection of the patella in patients suffering a patellar injury. Radiological examination on admission to the hospital was complemented by MRI or CT scans, as indicated by the attending physician, with subsequent follow-up visits including a standard clinical examination of the knee performed at predefined intervals on Day 1, and at 6 weeks, 3 months, 6 months, and 12 months postoperatively. The pain intensity level was assessed using a Visual Analog Scale (VAS, 0 to 100 mm) and the range of motion (ROM) was measured preoperatively and at every follow-up interval. X-rays were routinely performed as part of the clinical follow-up (preoperatively, on day 1, and at 6 weeks, 3 months, 6 months, and 12 months postoperatively) to evaluate the position of the fragment and implants, describe the resorption process and radiolucent zones formation around the implants. MRI scans were obtained at 12 months postoperatively in all patients to evaluate implant degradation, bone healing, cartilage quality of the osteochondral defect, and potential new bone formation around the implant.

Implants used for fixation

Fragment fixation was undertaken using implants made of MAGNEZIX® (MAGNEZIX® CS; Syntellix AG, Hannover, Germany), consisting of magnesium-yttrium-rare earth-zirconium (MgYREZr alloy). The manufacturer's portfolio includes compression screws and pins. The procedure itself was performed using cannulated headless screws 2.0 and 2.7 mm in diameter and 16–28 mm in length, and pins 1.5 and 2 mm in diameter and 16–20 mm in length (Fig. 1).

Surgical technique and postoperative protocol

The procedures were performed in 12 knee joints. The mean operative time was 72.4 ± 24 minutes (range 45–130 minutes). Intraoperative findings included fragments of the lateral femoral condyle (8 patients), of the articular surface of the patella (3 patients), and the medial condyle (1 patient). Open reduction and internal fixation have been chosen in all 12 knee joints due to the extent of the lesions. In 11 knee joints, the open approach was preceded by arthroscopic evaluation. The lateral mini

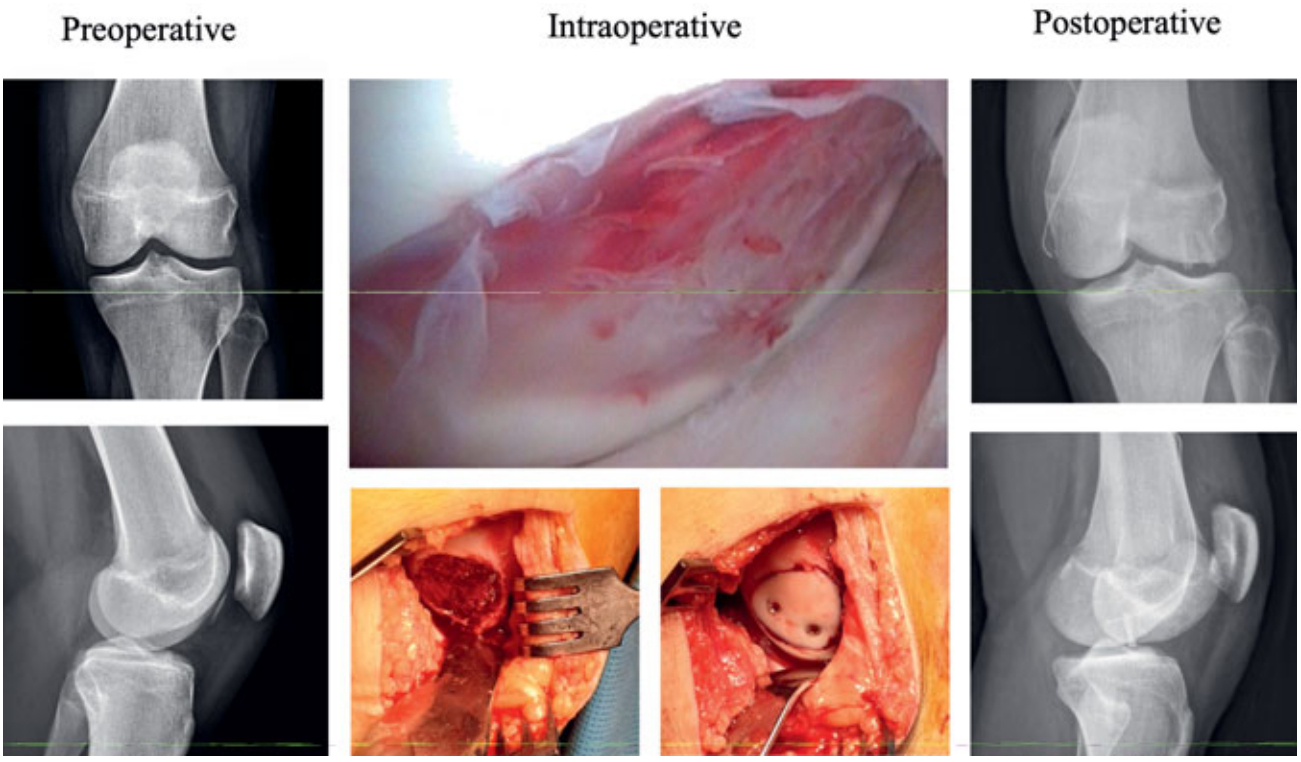

Fig. 2. Lateral condyle osteochondral fracture in a 13-year-old girl after an episode of patellar dislocation. Preoperative X-rays showing dislocated osteochondral lesion; intraoperative – arthroscopic evaluation of lesion, fixation with 2 MAGNEZIX screws Ø2.7 mm/16, 16 mm from lateral arthrotomy; postoperative X-rays confirm fracture reduction and show position of the implants. (Patient 1).

arthrotomy approach was used in 8 patients, the medial parapatellar approach in 3 patients, and medial mini arthrotomy in 1 patient. The mean size of the osteochondral fragment measured intraoperatively was 23.6 ± 8 mm in the sagittal plane and 16.3 ± 9.4 mm in the coronal plane. Fixation was preceded by temporary fragment extraction and, if appropriate, the rims were modeled to obtain an appropriate size and shape. After the notch had been cleaned and holes predrilled into the base of the defect with 1,5 mm K-wire, the fragment was fixed with MAGNEZIX® compression screws or pins. Both screws and pins were predrilled according to manufacturer instructions. Screws were inserted over a guidewire (Ø 1.2 mm), predrilling was performed using the hand-operated drill, a two-step pilot drill bit was used to make the countersunk hole in the head. Screws and pins were inserted perpendicular to the bone surface, beneath the surface of the cartilage to avoid intra-articular prominence (Fig. 2). A total of 25 MAGNEZIX® CS compression screws for fragment fixation were used in 11 patients, with a mean of 2.4 ± 1 screws per patient (range 1–4); the implants were 2.0 and 2.7 mm in diameter and 16–28 mm in length; 1 patient received MAGNEZIX® pins Ø1.5 mm and Ø2 mm in diameter (2 each) and 16–20 mm in length. In 2 patients, fixation with screws was complemented with Tissucol fibrin glue to enhance fragment adhesion. In 2 cases, the surgical procedure was complemented by the lateral release of the patella because of extensive tension of the lateral patellar retinaculum, while in 1 knee joint, fragment fixation was complemented by medial temporary hemiepiphysiodesis of the distal femur using a figure-of-eight plate for mild unilateral genu valgum deformity to correct the mechanical axis and gradually reduce the mechanical load from the area of the lateral compartment damaged by an osteochondral lesion. Acute osteotomy was not indicated due to mild valgus deformity and risk of growth plate injury in this particular patient. Medial patellofemoral reefing was performed in all patients after a patellar dislocation. The procedure was performed by placing 3-5 PDS stitches to the MPFL from a small mediopatellar incision. The MPFL was primarily repaired with the closure of the medial parapatellar arthrotomy in the group of patients treated from the medial parapatellar approach. The associated intraoperative findings included grade I lesion of the anterior cruciate ligament (2 knee joints) and medial patellar facet chondromalacia Outerbridge II (1 knee joint). A rigid knee brace in extension was used in 9 knee joints and a knee brace with limited range of motion in 3 cases. Fixation with a limited range brace was chosen for injuries of the dorsal aspect of the condyles in which there was no contact of the articular surfaces with the fracture area in the given range of motion. The range of motion was not increased during the 6-week follow-up. All patients were required to use walking sticks for 6 postoperative weeks to avoid weight-bearing, with intensive physiotherapy and full loading of the extremity after 6 weeks postoperatively. Detailed characteristics of the patient cohort are given in the table (Table 1).

Table 1. Demographic characteristics of the patients, fracture, and surgical procedure characteristics

Patient	Age	Sex	Fracture / fragment size (sagittal x coronal plane in millimeters)	ICRS	Assosiated intraoperative finding	Surgical technique/ approach	Implant diameter/length	Associated procedures	Immobilization	Follow-up (months)
1.	13	F	lat. condyle OCL 30x20	4	med. patellar facet chondromalacia	ASC / lat. arthrotomy	2 screws ∅2.7 mm/16, 16 mm	–	R	12
2.	12	M	lat. condyle OCL 20x10	4	–	ASC / lat. arthrotomy	1 screw ∅2.0 mm/16 mm, fibrin glue	–	R	16
3.	13	F	lat. condyle OCL 15x15	4	–	ASC / lat. arthrotomy	2 screws ∅2.7mm/16, 16 mm	–	R	12
4.	10	M	lat. condyle OCD 20x10 (2 fragments)	3	–	ASC / lat. arthrotomy	4 screws ∅2.7 mm/28, 22, 18, 18 mm	–	R	13
5.	14	F	med. patellar facet OCL 20x10	4	–	ASC / med. parapatellar approach	2 screws ∅2.7 mm/20, 20 mm	–	R	14
6.	16	M	med. patellar facet OCL 20x10	4	–	med. parapatellar approach	2 screws ∅2.7mm/ 16, 16 mm	–	R	12
7.	13	M	Central patellar facet OCL 20x10	4	–	ASC / med. parapatellar approach	4 pins ∅1.5 mm – 16, 20 mm ∅2 mm – 18, 18 mm	–	R	24
8.	12	F	lat. condyle OCL 18x10	4	–	ASC / lat. arthrotomy	2 screws ∅ 2.7 mm/18, 18 mm	lat. retinacular release	R	16
9.	13	M	lat. condyle OCL 20x10	4	grade I lesion of ACL	ASC / lat. arthrotomy	2 screws ∅2.7 mm/16, 16 mm	lat. retinacular release	R	13
10.	16	M	lat. condyle OCD 40x40	4	genu valgum, grade I lesion of ACL	ASC / lat. arthrotomy	4 screws ∅2.7 mm/16, 16, 16, 16 mm	distal femur med. temporary hemiepiphysiodesis	LR 0 – 40°	12
11.	14	M	med. condyle OCD 20x10	4	–	ASC / med. arthrotomy	2 screws ∅ 2.7 mm/28, 28 mm, fibrin glue	–	LR 0 – 30°	14
12.	13	F	lat. condyle OCD 20x20	3	–	ASC / lat.arthrotomy	2 screws ∅2.7 mm/16, 20 mm	–	LR 0 - 30°	12

Abbreviations
M – male, **F** – female, **OCL** – traumatic osteochondral lesion, **OCD** – osteochondritis dissecans, **ASC** – arthroscopy, **R** – rigid knee brace **LR** – limited motion knee brace

RESULTS

Course of healing and complications

VAS for pain demonstrated significant decrease (from 48 before to 12 at 6 weeks after surgery), only 2 patients reported persistent mild pain 6 weeks after surgery, which, however, gradually resolved once intensive physiotherapy had been initiated. One patient required multiple arthrocentesis postoperatively for recurrent hemarthrosis. At 6 months postoperatively, all patients exhibited complete functional recovery while showing no signs of pain. Over the 1-year follow-up, no signs of failure of fixation, implant migration or breakage, infection, or a foreign body response were observed. None of the patients developed pain on palpation, swelling, redness, palpable gas cavity, or other symptoms around the joint. One patient underwent recurrent patellar dislocation 1 year after MPFL reefing. This episode did not affect the already healed osteochondral fragment of the patella, the patient was treated conservatively by temporary fixation in a rigid knee brace. The complete union of osteochondral fragments was observed on X-ray and MRI at 12 months postoperatively using both pins and screws (Fig. 3). There was no need for a second surgery in any of the patients.

Assessment of radiolucent zones and resorption of implant material

Radiolucent zones were observed in all cases involving osteosynthesis with screws and pins, best visible at 6 weeks postoperatively; subsequent follow-up visits revealed gradual shrinking of the radiolucent zones to become almost invisible on X-rays at 12 months postoperatively. Progressive resorption of implants was characterized by a gradual decrease in the transparency of the material, occurring most rapidly in the zone of

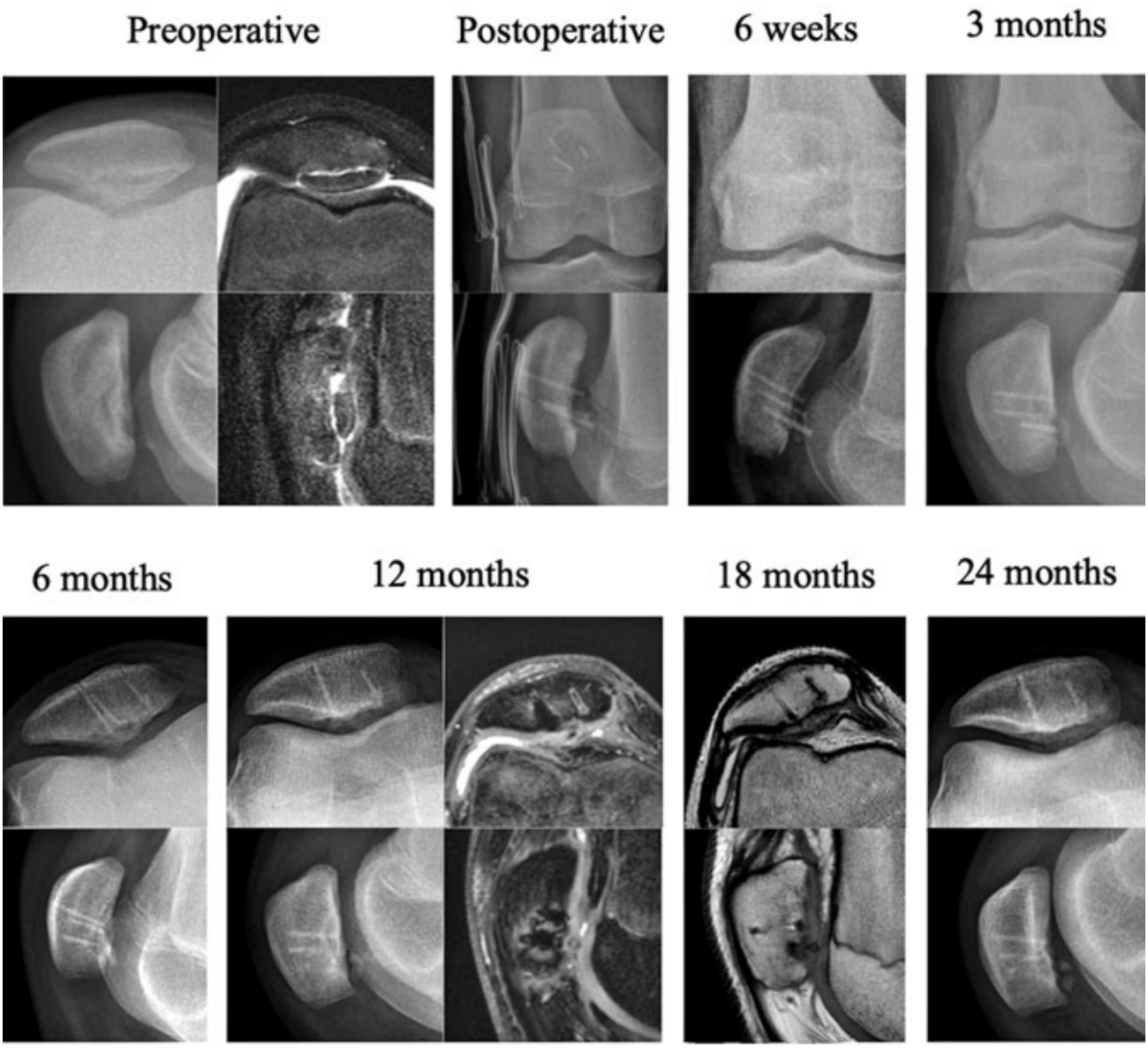

Fig. 3. Postoperative radiological and MRI follow-up of the osteochondral patellar fragment after an episode of patellar dislocation, fixed with 4 MAGNEZIX® pins in a 13-year-old boy. Radiolucent zones are best visible at 6 weeks postoperatively. Note the progressive resorption of the pins, most visible in the chondral zone at 3 months. MRI scans at 12 and 18 months show zones of hypointensity corresponding with the implant site suggestive of reactive cortical bone formation. The zone of cartilage at the site of the original fragment is viable. Implant remnants are still visible on MRI at 12 months after surgery. (Patient 7).

cartilage. More appreciable progression of resorption was noted on X-rays obtained at 3 months postoperatively. At 12 months, X-rays revealed only fine contours of the implants. The magnesium implants could still be detected but only as a weak silhouette (Fig. 4).

In all patients, the fracture lines were not visible on MRI at 12 months after surgery, chondral portions of the native osteochondral fragments were viable, with signal intensity comparable to surrounding intact cartilage, only small areas of cartilage thinning were observed, but no areas of full-thickness loss were observed. Areas of hypointensity corresponding to the former sites of the implants were observed in all cases. Remnants of the original implants were still visible in a central part of hypointensity in 5 cases at 12 months.

DISCUSSION

The first magnesium-based implants exhibited high corrosion rates that consequently generated subcutaneous gas cavities and reduced mechanical stability (19), recently developed magnesium-based implants demonstrate improved anticorrosive and mechanical properties (31). The first successful use of MAGNEZIX® implants was to fix metatarsal osteotomies for hallux valgus deformity in adult patients (33). The indications were later extended and several other studies were subsequently published addressing various topics in the fields of orthopedics and traumatology. With regards to management of intraarticular fractures using magnesium-based implants, the number of clinical studies published to

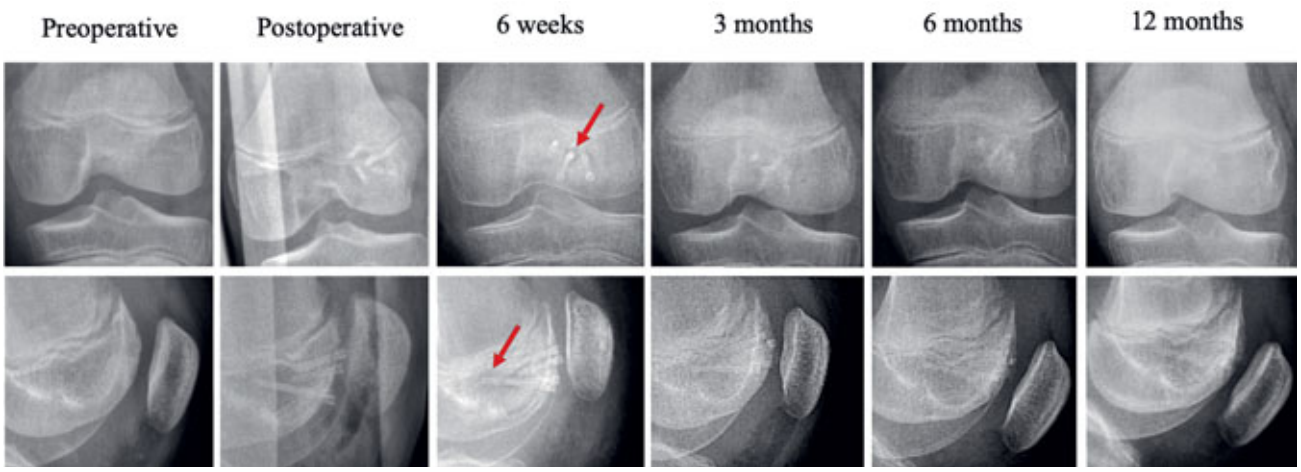

Fig. 4. Resorption of the implants and radiolucent zones. Progressive resorption of MAGNEZIX® screws is observed, most apparent in the zone of cartilage at 3 months postoperatively, only fine contours of the implants are visible at 12 months. Formation of radiolucent zones – most apparent at 6 weeks postoperatively (red arrows). Note the gradual reduction of the radiolucent zones around the screws at each subsequent follow-up examination up to 12 months. (Patient 4).

date is relatively small. In the pediatric population the literature resources on use of magnesium-based implants are even poorer. Jungesblut et al. present high stability and uncomplicated healing after fixation of pediatric knee OCDs and displaced osteochondral fragments with MAGNEZIX® pins in the short-term follow-up of 11 ± 4 months (12). Gigante et al. investigated the treatment of intercondylar eminence fractures with MAGNEZIX® screws in children with excellent functional results without complications related to fixation devices, which were completely resorbed after 6 months and replaced by newly formed bone after 12 months (10). Stürznickel et al. present good clinical outcomes of magnesium-based implants MAGNEZIX® in fracture stabilization, osteotomy, and osteochondral defect fixation in a group of 89 immature patients with a mean follow-up duration of 8.2 months (28). Baldini et al. concluded that resorbable Magnesium (Mg) implants MAGNEZIX® are safe and effective in orthopedic and traumatology procedures in skeletally immature patients (5). The first case report from our center describing a pediatric patient undergoing fixation of a trauma-related osteochondral patellar fragment with MAGNEZIX® pins over a 6-month follow-up also documented satisfactory clinical and radiological outcomes (11).

Treatment of osteochondral lesions depends on a variety of factors, such as the patient´s skeletal maturity, fragment stability, localization, size, and the time elapsed since the injury. Juvenile OCD typically responds to nonoperative treatment, such as immobilization, non–weight bearing, and activity modification. In patients with an unstable OCD fragment or loose body, or when nonoperative management has failed, surgical treatment should be an option (14), with the surgical techniques employed including drilling, debridement, microfracture, or other procedures involving cartilage restoration or replacement (6). Transarticular or retroarticular arthroscopic drilling of the stable juvenile OCD lesions leads to improved clinical outcomes and high healing rates after unsuccessful nonoperative treatment (3). Surgical fixation should be an option in juvenile patients with unstable lesions and can be performed by a variety of arthroscopic or open methods. For intact and congruous loose fragments, techniques typically involve curettage of the femoral defect, drilling, and internal fixation. The use of bioabsorbable screws, pins, and bone and osteochondral plugs in both pediatric and adult patients is reported in the literature (14).

The commonly used implants for fixation of osteochondral fragments are made of biodegradable polymers (most often polyglycolide, poly-L-lactic acid, or poly-p-dioxanone). They are associated with undesirable properties such as low mechanical strength (29), osteolysis around the implant (21), and adverse tissue reactions (7).

In terms of magnesium alloys, gaseous hydrogen (H2) accumulates in the surrounding tissues during the corrosion process. A formation of gaseous bubbles, resulting from the release of H2 into the soft tissues during the corrosion process has been described from 1 to 4 weeks after surgery with complete absorption from 2 weeks to 2 months in several studies (17, 24). Gaseous hydrogen can form gas pockets which may delay healing and can potentially lead to necrosis of the surrounding tissues, surgical wound dehiscence (25, 26), and formation of bone defects (13). We did not observe the appearance of gas bubbles in the soft tissues during the clinical and radiographic follow-up in our study.

Another well-described phenomenon, occurring in the surrounding bone during the degradation of the Mg alloys is the formation of radiolucent zones. While many studies show this phenomenon causes no complications (18, 33), some clinical studies do not recommend MgYREZr implants MAGNEZIX® due to the formation of extensive bone cysts around the implants (20, 32). Our results show the largest formation of radiolucent zones in the early period of 6 weeks to 3 months after surgery. The appearance seems to have no impact on

the healing process of the osteochondral fragments and had no association with undesirable clinical symptoms.

In terms of degradation, animal experiments showed that nearly 50% of the implant volume resorbs after 3 months and complete degradation of MgYREZr implants takes about one year (30). Other clinical studies have found that the screws completely degrade by 2 – 3 years after surgery (2, 23). In our study, the magnesium implants MAGNEZIX® could still be detected on radiographs at 12 months, but only as a weak silhouette. Clear remnants of implants with reduced density were seen on MRI in 5 cases at 12 months. According to our results, the rate of degradation was sufficient for the healing of fragments.

In our study, we observed areas of hypodensity corresponding with the former implant sites on MRI at 12 months, suggesting new bone deposition. This phenomenon has already been described in a clinical study assessing MRI findings of MAGNEZIX® implants in patients after distal metatarsal osteotomy (4), moderate bone formation around the MgYREZr implant remaining was observed in the histological analysis of bone samples, newly formed bone appeared to be grown into parts of the degraded material (30).

Moreover, preclinical studies have shown that Mg alloys are well tolerated both by osteoblasts and the growth plate chondrocytes, which is especially important when the implants are placed near the growth plates of the immature skeleton (22). In our study, all implants were placed extraphyseally therefore we did not observe any damage to the growth plate in the follow-up radiographs. In addition, Mg implants MAGNEZIX® generate fewer artefacts on imaging compared to standard metallic implants and therefore the postoperative healing progress can be better observed and documented (27).

The main limitations of this study are the small number of patients, short follow-up, and two relatively different pathologies (osteochondral fractures and osteochondritis dissecans lesions). The control group treated with polymer implants was not included due to a lack of relevant data, we are no more using the polymer implants for pediatric knee osteochondral fractures in our unit.

The relevant literature shows generally good results in the fixation of fractures in pediatric patients and adolescents with magnesium implants with a low rate of complications, but with a relatively short follow-up period. Future studies are needed to analyze the long-term performance of these implants.

In our study, the use of screws and pins MAGNEZIX® has been found to provide satisfactory outcomes in terms of fracture healing and very good functional outcomes at 1 year postoperatively.

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