ORIGINAL PAPER/PŮVODNÍ PRÁCE

Fixation of Osteochondral Lesions of the Knee Using MAGNEZIX Implants in Pediatric Patients: Midterm Clinical and MRI Results

Fixace osteochondrálních fragmentů kolena implantáty MAGNEZIX u dětských pacientů: střednědobé klinické a MRI výsledky

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Hanák F, Koukolská V, Krsková B, Kynčl M, Havlas V. Fixation of Osteochondral Lesions of the Knee Using MAGNEZIX Implants in Pediatric Patients: Midterm Clinical and MRI Results. Acta Chir Orthop Traumatol Cech. 2025;92:137–146.

ABSCTRACT

Purpose of the study
Fixation of osteochondral fragments is a relatively common procedure in pediatric orthopaedic surgery. This study analyzes clinical and MRI results of biodegradable MAGNEZIX® magnesium alloy implants used to fix osteochondral knee lesions in pediatric patients.

Material and methods
18 pediatric patients with unstable or displaced OCD lesions or osteochondral fractures were treated with MAGNEZIX® screws or pins. Clinical examinations were conducted at regular intervals, and the final clinical and MRI assessments were performed 24 months after surgery.

Results
The overall functional scores at 24 months were found to be good, with a VAS score of 1.22 points ± 1.83, Lysholm score of 87.61 points ± 11.31, and IKDC score of 76.94 points ± 10.85 for both groups. On MRI, 14 patients (77.78%) showed complete union, four patients (22.22%) showed incomplete union, and none of the patients experienced healing failure. Complete implant absorption was examined in eight patients (44.44%) on MRI. Most patients exhibited varying degrees of chondropathy, and one patient required reoperation due to screw breakage and migration.

Conclusions
The use of MAGNEZIX® implants in the treatment of pediatric osteochondral fractures and OCD lesions has shown good clinical outcomes and favorable healing of osteochondral lesions. However, varying degrees of chondropathy have been observed in most cases.

Key words: biodegradable implants, magnesium-based implants, osteochondral fractures, osteochondritis dissecans, pediatric orthopaedics, MAGNEZIX®.

INTRODUCTION

Osteochondral lesions of the pediatric knee joint, involving injuries to the cartilage and adjacent subchondral bone, can originate from either acute trauma or Osteochondritis Dissecans (OCD). Among them, trauma-based lesions are often caused by low-energy trauma, such as sports injuries, and frequently stem from an episode of patellar dislocation (1, 26). On the other hand, OCD is an idiopathic disorder characterized by focal alteration of the subchondral bone, leading to instability and disruption of the adjacent cartilage. In particular, it is

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manifested in active pediatric and young adult patients, often in the knee region (15). Surgical fixation of displaced osteochondral fractures and unstable OCD lesions is the preferred gold standard treatment, especially in younger patients (24).

The use of biodegradable implants in pediatric patients has been well-documented in the literature (2). For instance, magnesium alloys have been extensively considered as potential biodegradable bone implants (32). These materials offer favorable mechanical attributes like low modulus of elasticity, which minimize the risk of undesirable stress shielding (17). Furthermore, magnesium alloys have also been demonstrated to promote new bone formation (5, 21) and exhibit potential anti-inflammatory characteristics (34). According to the literature, the first magnesium alloy implants certified for clinical use were MAGNEZIX® MgYREZr (magnesium, yttrium, rare earth metals, and zirconium) alloy implants, which have been commercially available since 2013. Past experimental and clinical studies of the MgYREZr alloy have demonstrated favorable corrosion and mechanical properties (11, 33), remarkable biocompatibility, and osteogenic potential (25, 27, 31).

Several research studies have extensively discussed MAGNEZIX® implants in orthopaedic and trauma procedures for adult patients. However, the existing literature provides a scant number of studies that evaluate the clinical and radiological outcomes of osteochondral fracture fixation and OCD lesions in pediatric patients. This study aims to assess the clinical and radiological results of biodegradable MAGNEZIX® implants used for the fixation of osteochondral fractures and OCD knee lesions in pediatric patients at 24 months post-operatively.

MATERIAL AND METHODS

Study design

In this prospective cohort study, we have evaluated patients undergoing fixation of osteochondral lesions of the knee joint with MAGNEZIX® implants. The inclusion criteria of this study were:

I. age ≤ 18 years,
II. II. unstable or displaced osteochondral fragments resulting from acute osteochondral fracture (OCF) or OCD, Grade III–IV according to the International Cartilage Repair Society (ICRS),
III. III. fixation with screws or pins manufactured from MAGNEZIX® magnesium alloy, and
IV. IV. a minimum post-operative interval of 24 months.

Furthermore, exclusion criteria were:

I. age > 18 years,
II. II. complementary fixation of fragments with other types of materials,
III. III. severe metabolic or renal disease.

All procedures in this study involving human participants were performed in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study was approved by the Ethics Committee for Multi-Centric Clinical Trials of the University Hospital Motol and 2nd Faculty of Medicine Charles University in Prague (No. EK-532/18). Written informed consent was obtained from the parents participating in this study.

Clinical and radiological assessment

During this study, clinical and X-ray imaging assessments (anteroposterior, lateral projection, and skyline Laurin view in patients with patellar injury) were performed on admission. Subsequently, clinical examinations were conducted at predefined intervals of 1 day, 6 weeks, and 3, 6, 12, and 24 months post-operatively. Several local findings were recorded, including edema, joint effusion, inflammation signs, subcutaneous gas bubbles, tenderness to palpation, wound healing, range of motion, joint stability, cracking, and popping. Moreover, a Visual Analog Scale (VAS) in the range between 0 and 10 was used, with 10 being the worst. Similarly, modified *Lysholm* (30) and International Knee Documentation Committee (IKDC) (8) scores were employed to evaluate the functional status of both groups (OCF and OCD) 24 months after and before surgery in OCD.

Magnetic resonance imaging assessment

Magnetic Resonance Imaging (MRI) was performed 24 months after surgery, and three experienced radiologists evaluated the results. They analyzed the following aspects:

(i) healing of the osteochondral fragment, including total, partial, or no healing, and fragment displacement;
(ii) (ii) cartilage quality using the modified Outerbridge Classification System (10), grades 0–IV,
(iii) (iii) presence of bone marrow edema,
(iv) (iv) presence of joint effusion,
(v) (v) degree of implant resorption, indirectly assessed by metal-induced artifacts (signal pile-up, geometric distortion, failure of fat suppression) evaluation, rated using a custom 5-point Likert scale: ranging from extensive artifacts to no artifacts (1–5),
(vi) (vi) evaluation of new bone formation in the original implant site area, and
(vii) liquid collections around the implants.

Surgical technique and post-operative protocol

During this study, eighteen (18) patients underwent surgery (11 left knees and 7 right knees). Among these patients, surgery began with an arthroscopic examination, followed by an open

surgical approach. While performing the surgical procedure, temporary extraction of the fragment, debridement of the notch, and pre-drilling of holes into the defect base with a K-wire (Ø1.5 mm) were conducted. Moreover, the edges of the fragments were gently modeled to obtain an optimal shape suitable for fixation. Subsequently, the fixation was performed using MAGNEZIX® headless compression screws and pins (MAGNEZIX® CS; Syntellix AG). The screws were inserted along the guidewire (Ø 1.2 mm), and a hand-operated drill was leveraged to drill the hole. A two-step pilot drill bit was employed to create a countersunk hole in the head. The implants were inserted perpendicular to the fracture line and were embedded beneath the cartilage surface. It was ensured that all fragments were stable after fixation. Reefing of the Medial Patellofemoral Ligament (MPFL) using PDS sutures with lateral patellar release was conducted in all six patients after patellar dislocation. The MPFL was primarily sutured during wound closure using the medial parapatellar approach. In two patients, isolated lateral patellar release was performed due to excessive tension of the lateral patellar retinaculum. In one patient with unilateral genu valgum deformity, osteochondral fragment fixation of the lateral condyle was supplemented by medial temporary hemiepiphysiodesis of the distal femur using an eight-plate.

For all eighteen (18) patients, walking with a reduced load on sticks was recommended. Among them, a rigid hinged knee brace was suggested for 11 patients six weeks after surgery, and a range of motion knee brace ranging up to 45° flexion was used for injuries to the dorsal aspects of the condyles in 7 patients, with a set range of motion reducing the direct load on the lesion. The range of motion did not vary during fixation. Six weeks after the surgery, the patients started walking with gradual full weight bearing and underwent active exercises under the guidance of a physiotherapist.

Statistical analysis

Statistical analysis was performed using SPSS statistical software (IBM SPSS Statistics 20; Chicago, IL, USA). The results are presented as absolute values or the mean ± standard deviation (SD). The pre-and post-operative differences in VAS, Lysholm, and IKDC in the OCD group were evaluated using a paired t-test. An Independent Sample T-test in the final VAS, Lysholm, and IKDC between OCF and OCD groups was performed. A chi-square test was conducted to assess the difference in Cartilage Quality between OCD and OCL groups. A value of $p < 0.05$ was considered statistically significant.

RESULTS

Patient characteristics

Eighteen patients (10 boys and 8 girls) who met the inclusion criteria were enrolled in the study from June 2018 to May 2021. The mean age of these patients at the time of surgery was 14.55 ± 2.13 years (range 11–18 years). Twelve patients underwent surgery for an osteochondral lesion due to acute trauma, whereas six patients had unstable or displaced OCD lesions. An osteochondral fragment of the lateral condyle was observed after acute trauma in six cases (3 in OCD), the articular surface of the patella in six cases (one in OCD), and the medial condyle in zero cases (2 in OCD). Finally, the mean interval between acute injury and surgery was 12.50 ± 12.60 days (range 0–36 days).

Intra-operative findings

According to the ICRS, a grade IV lesion was described perioperatively in 14 patients (77.78%) and a grade III lesion in four patients (22.22%). The mean fragment size was 20.83 ± 6.31 mm (range 12–40 mm) in the wider part and 12.78 ± 7.85 mm (range 7–40 mm) in the narrower part. Fixation with screws was employed in 16 patients, and pins in two patients. The associated peri-operative findings were as follows: mediopatellar plica (2 patients), infrapatellar plica (2 patients), lateral patellar retinaculum hyperpressure (2 patients), chondropathy of the patella modified Outerbridge grade II (2 patients), and grade I anterior cruriate ligament (ACL) lesion (1 patient). The mean operative time was 66.88 ± 27.74 minutes (range 25–130 minutes). Table 1 describes the attributes associated with the surgical procedure (Table 1).

Clinical outcomes

No serious implant-related complications – *e.g.*, gas bubbles, reddening, wound dehiscence, or tenderness to palpation – were reported during the early post-operative period of up to three months. After six months, all patients exhibited remarkable functional recovery and muscle strength on examination, with no signs of effusion or swelling of the operated knee. Furthermore, they also showed a normal gait without limping. At the 24-month examination, a normal range of motion was witnessed in 15 patients, with three patients showing a 10° flexion deficit compared to the contralateral side. Moreover, six patients (33.33%) described transient swelling of the operated knee following major sports activity. Two patients (11.11%) reported occasional swelling even after regular activities like extended walking, whereas one patient (5.56%) reported occasional knee locking.

Two years after surgery, the overall functional scores for both groups were found as follows: VAS score of 1.22 points ±

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Table 1. **Attributes associated with the surgical procedure**

From injury to surgical treatment (days)	12.50 ± 12.60 (range 0–36)
SURGICAL APPROACH	
Lateral mini-arthrotomy	9 patients
Medial mini-arthrotomy	2 patients
Medial parapatellar approach	6 patients
Lateral parapatellar approach	1 patient
AVERAGE FRAGMENT SIZE	
Larger diameter (mm ± SD)	20.83 ± 6.31 (range 12–40)
Smaller diameter (mm ± SD)	12.78 ± 7.85 mm (range 7–40 mm)
Surgery length (minutes ± SD)	66.88 ± 27.74 (range 25–130)
IMPLANTS	
Screws used	35 screws in 16 patients (range 1–4 per patient)
Pins used	4 pins in 2 patients (range 1–3 per patient)
Screw sizes	Ø2.0 and Ø 2.7 mm, 16–28 mm lenght
Pin sizes	Ø1.5 a Ø2 mm, 16–20 mm lenght
FIXATION	
Rigid knee brace	11 patients
Limited ROM knee brace	7 patients
Complications	wound serous discharge (1)
	skin erythema (1)
	phlebotrombosis (1)
	recurrence of patellar dislocation (1)
	screw breakage and migration (1)

1.83 (range 0–6), modified *Lysholm* score of 87.61 points ± 11.31 (range 61–100), and IKDC score of 76.94 points ± 10.85 (range 53–87). In the OCD group, a significant decrease of VAS from 2.50 ± 1.05 pre-operatively to 0.67 ± 1.21 post-operatively ($p = 0.012$), increase in Lysholm score from 66.83 ± 17.07 to 94.83 ± 7.859 ($p = 0.009$) and increase in IKDC from 56.00 ± 14.41 to 82.67 ± 6.74 ($p = 0.006$) was noted. The results indicated a non-significant difference in final VAS scores between the OCD and OCF groups, $t(16) = 1.075$, with a 95% confidence interval (CI) ranging from -0.815 to 2.482 ($p = 0.29$). Conversely, there was a statistically significant distinction observed in final Lysholm scores between the two groups, $t(16) = -2.371$, with a 95% CI from –20.642 to –1.025 ($p = 0.033$). However, the difference in final IKDC scores between the two groups was not statistically significant, $t(16) = -1.981$, with a 95% CI from –17.799 to 0.633 ($p = 0.066$). There was no notable disparity in Cartilage Quality between the two groups, as determined by the chi-square test of independence, $\chi^2(df) = 9.225$ ($p = 0.05$).

Complications

Minimal serous discharge with spontaneous regression and complete healing was observed in one patient early after surgery. Another patient experienced mild erythema and warmth around the scar, atypically as late as five months after surgery, with spontaneous regression. Furthermore, one patient had an uncomplicated case of phlebothrombosis, while another had a recurrence of patellar dislocation twelve months after surgery. One patient necessitated a reoperation due to screw protrusion with screw head breakage four months following fixation of an osteochondral lesion of the patella (Fig. 1). One patient underwent routine follow-up arthroscopy related to the eight-plate extraction (Fig. 2).

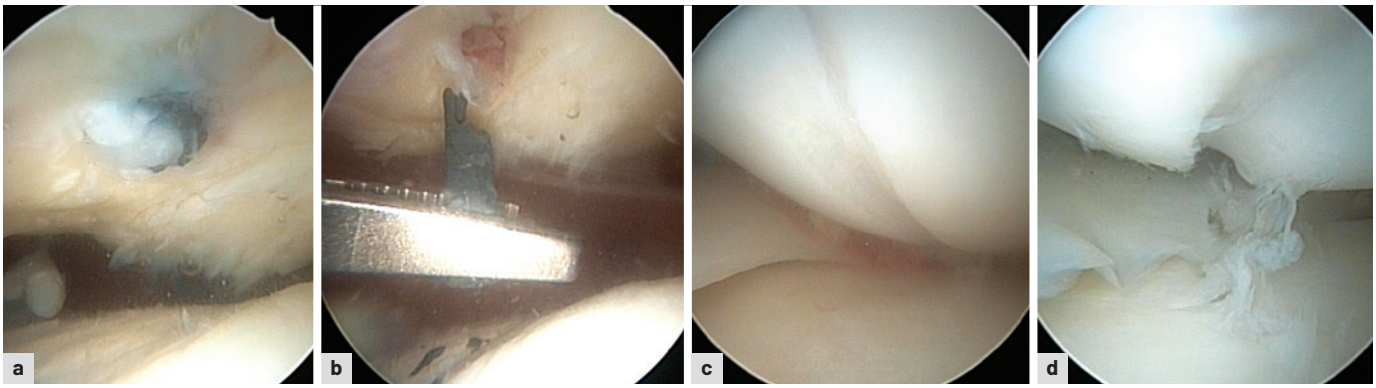

Fig. 1. **Screw protrusion with screw head breakage following fixation of an osteochondral lesion of the patella. Arthroscopic revision and screw extraction (a, b). Damage to the cartilage of the medial femoral condyle and tearing of the periphery of the medial meniscus due to entrapment of the broken part of the screw between articular surfaces (c, d).**

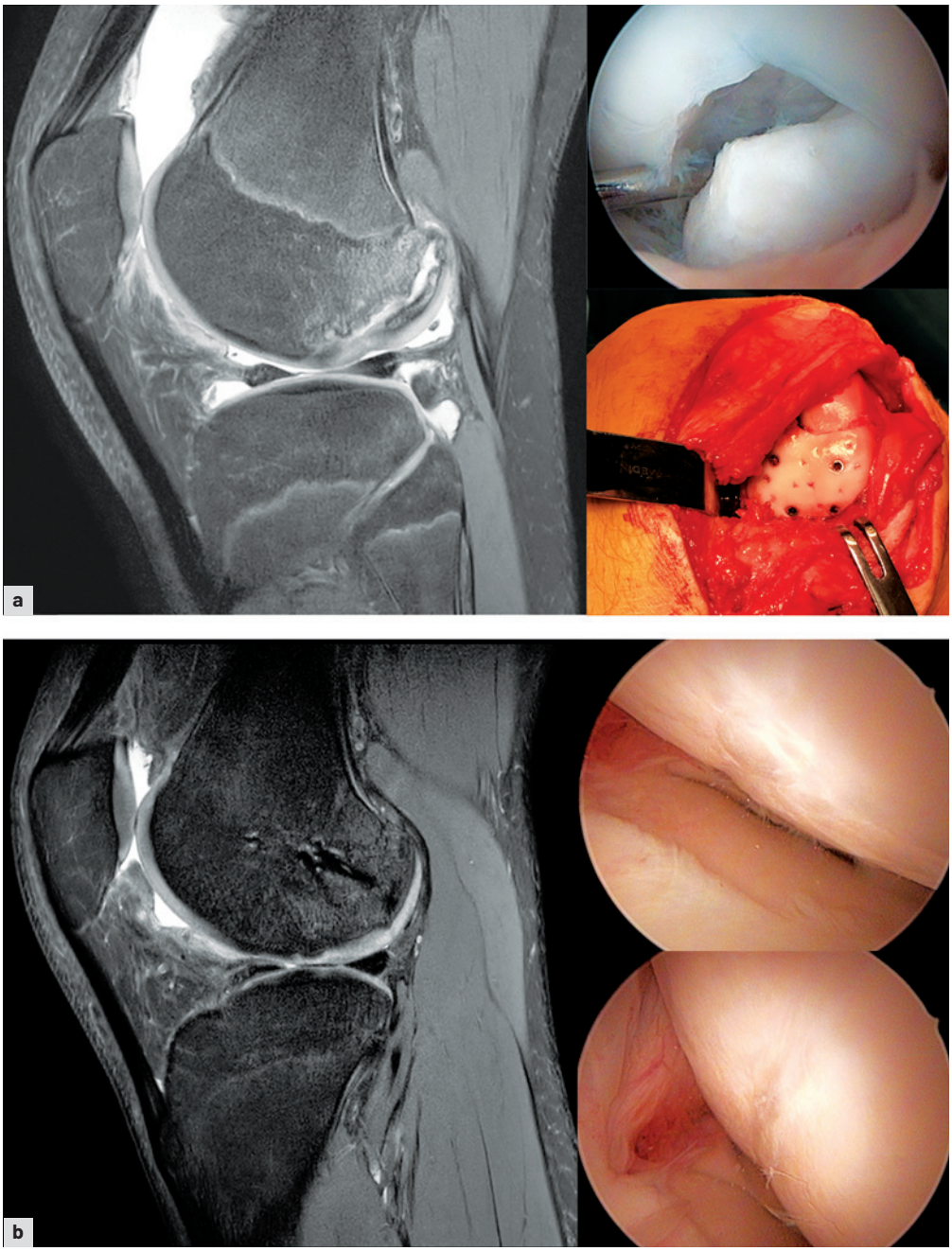

Fig. 2. **A rare case of massive OCD of the lateral femoral condyle. Preoperative MRI scan, peri-operative arthroscopic findings, and fixation with 4 MAGNEZIX screws (a), MRI and arthroscopic exploration 24 months after surgery show good integration with mild signs of chondropathy (b).**

Magnetic resonance imaging assessment

At a 24-month interval, fourteen patients (77.78%) exhibited a complete union of osteochondral fragments on MRI, while four patients (22.22%) had an incomplete union with high-intensity signals at the fragment-bone interface. However, no healing failure was observed. Normal cartilage morphology was found in four patients (22.22%), while chondromalacia according to the modified Outerbridge system grade I was observed in five patients (27.78%), grade II in one patient (5.56%), grade III in three patients (16.67%), and grade IV in five patients (27.78%). Furthermore, bone marrow edema and increased intra-articular fluid were observed in seven (38.89%) and three (16.67%) patients, respectively. Complete implant absorption was examined in eight patients (44.44%). Implant residues accompanied by apparent metal artifact formation were observed in ten patients (55.56%), with a rating of 4.05 ± 1.11 points on a custom Likert scale (Fig. 3). Distinct formation of hypointensities adjacent to the original implants was observed in eight cases (44.44%). Hyperintense linear signal

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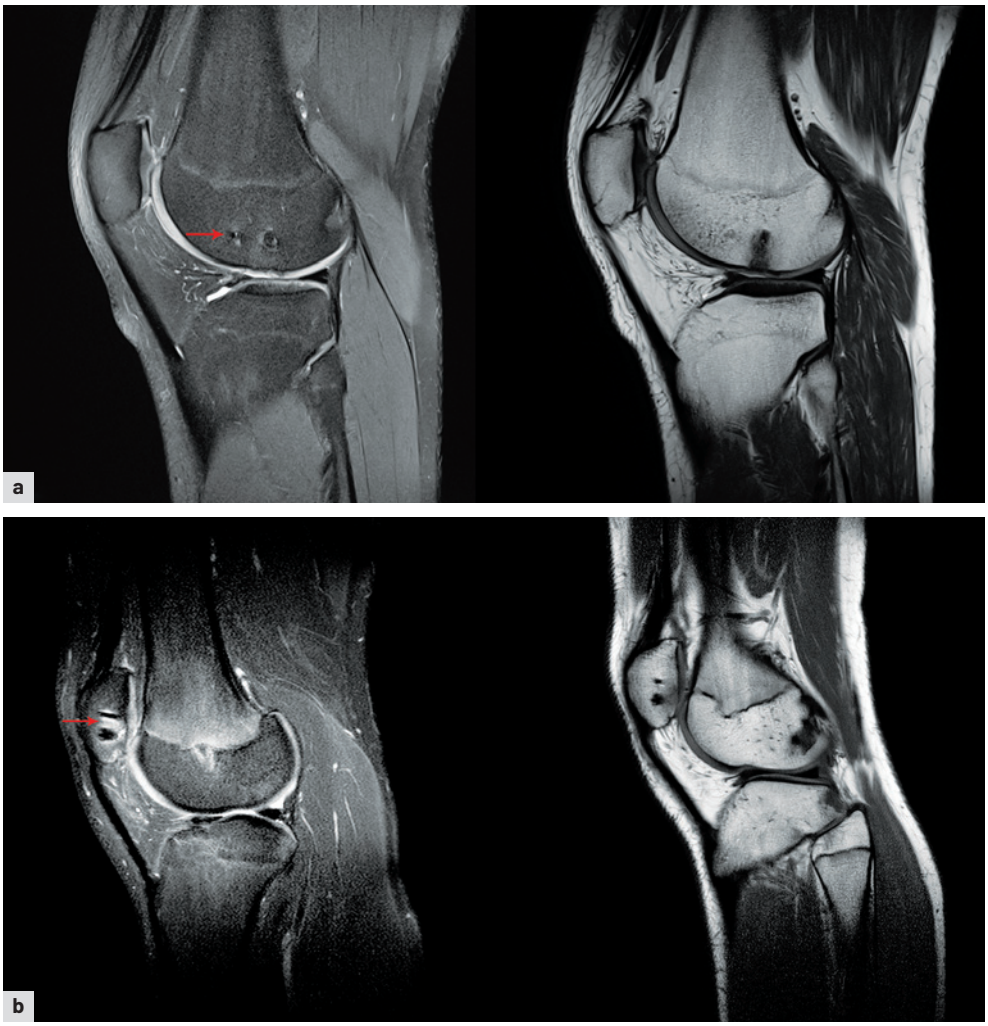

Fig. 3. **Differences in implant resorption on MRI in individual patients. Complete implant absorption with replacement of the original implant zone with a bone-like structure (a), evidence of non-absorbed implant with distinct original implant structure with metallic artifact formation (b).**

in fluid-sensitive sequences directly adjacent to the screw interpreted as the fluid collection was observed in five patients (27.78%), with a mean width of 1.2 mm (range 0.30–3.50 mm) (Fig. 4). Secondary MRI findings included chondromalacia of the patella (3), a small intra-articular loose body (2), intralesional osteophyte formation (1), ACL grade I lesion (1), patella lateralization or subluxation (1), post-thrombotic varicose enlargement of the femoral vein (1), medial meniscus lesions (1), and MPFL lesions (1).

DISCUSSION

Treatment of osteochondral lesions depends on various factors, such as the patient's skeletal maturity, fragment stability, location, size, and the time elapsed since the injury. In some cases, conservative treatment may be an option, while surgical techniques may include simple fragment extraction, fragment fixation, or more complex procedures involving cartilage restoration or replacement (29). Surgical fixation is the technique of choice with larger osteochondral fragments and preserved continuity of the cartilage of the loose fragment. Fixation of osteochondral fractures (or advanced OCD lesions) is routinely conducted with screws or pins manufactured from nonabsorbable metals or biodegradable implants (4). Although traditional metal implants offer stable fixation for healing (18), they produce complications such as breakage, loosening of the implant, or damage to the surrounding cartilage, as reported in the literature (13). In contrast, biodegradable implants eliminate the requirement for a second surgery for implant removal, which may be associated with surgical complications (14). In the past, Poly L-lactic Acid (PLA) and Polyglycolic Acid (PGA) polymer implants have been commonly utilized to fix osteochondral fragments. However, numerous complications of these implants have been reported in the literature. These complications include synovitis (19), osteolysis (6), and mechanical implant failures linked to destabilization, loosening, breakage, or failure to heal the osteochondral

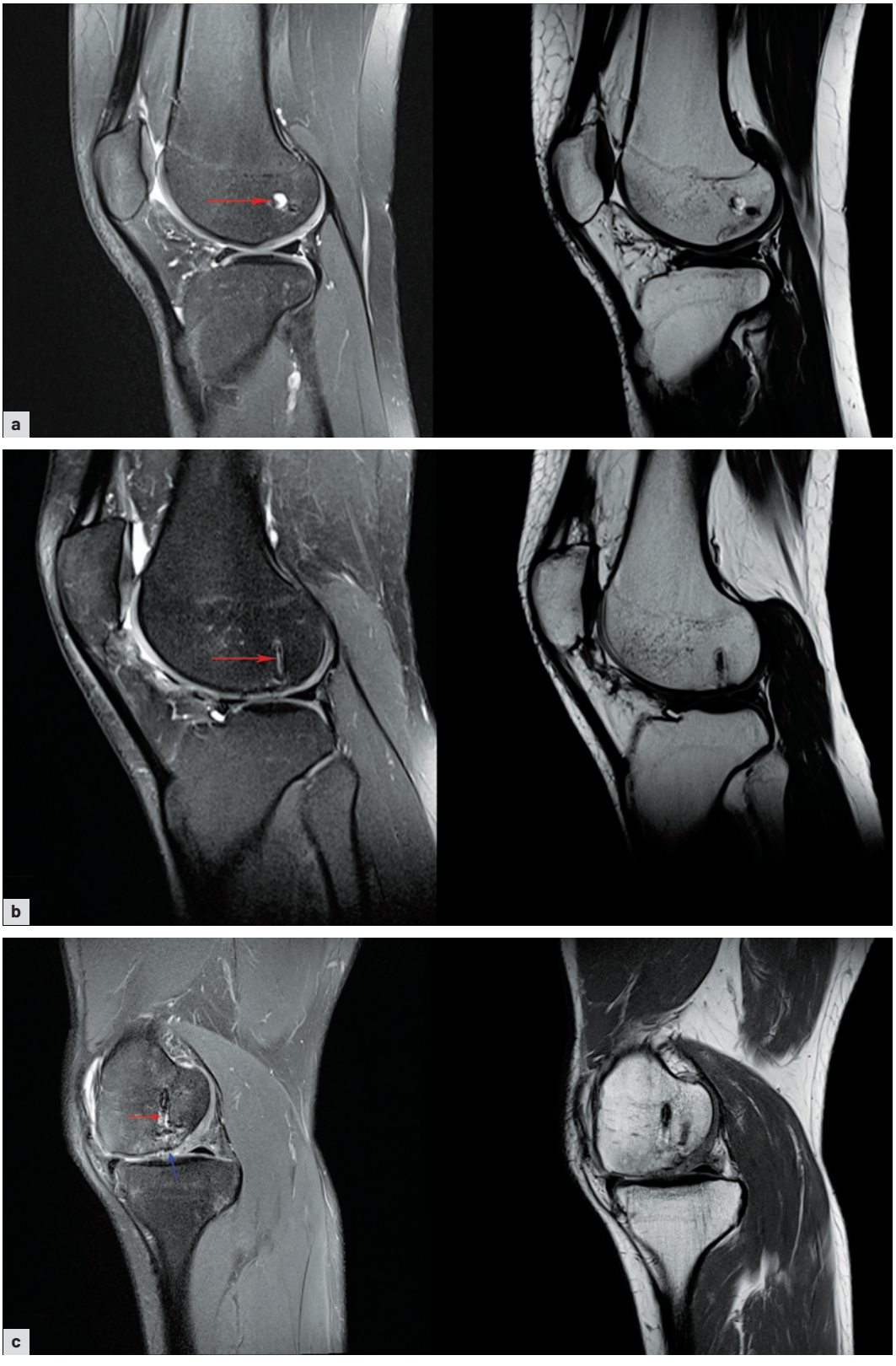

Fig. 4. **Fluid collection and formation of linear hyperintensities on MRI in individual patients. Localized fluid collection in the area of the original screw site (red arrow) (a). Linear hyperintensity in the area of the original screw site (red arrow) (b). Fluid collection is adjacent to the zone of the original screw (red arrow), and extensive chondropathy is noted (blue arrow) (c).**

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lesion (22). In pediatric patients, Camathias et al. reported a 23% failure rate of PLA implants in OCD of the knee joint (9). Similarly, Bradley et al. documented an 8.5% revision surgery rate due to polymer implant failure in 47 adolescents (7). Another study by Nguyen et al. Reported 104 children with 36.6% pin breakage, 38.5% joint effusion, 7.7% meniscal tears, and 13.5% cartilage irregularities after the fixation of osteochondral lesions with polymer pins (23).

On the other hand, magnesium alloys are potential substitutes for polymers due to their superior biomechanical properties, stronger bone-implant interface, and greater periimplant bone formation (11, 20). Attention towards the use of MAGNEZIX® implants in orthopaedics and traumatology was first drawn due to the successful clinical trial performed by Windhagen et al., which demonstrated comparable functional and radiological outcomes for a modified chevron osteotomy for hallux valgus as compared to a titanium control (33). In addition, a meta-analysis by Baldini et al., including 20 human studies, confirmed excellent clinical results for MAGNEZIX® implants (3). However, a relatively limited number of publications are available on the use of MAGNEZIX® implants in pediatric patients. For instance, Jungesblut et al. reported complete radiographic healing of osteochondral fractures and OCD lesions in 12 of 19 children treated with MAGNEZIX® pins, with early signs of healing in the remaining patients. Remarkably, all patients were pain-free and could perform a full range of motion after six months. Among them, one patient necessitated revision surgery due to pin breakage and migration (16). Stürznickel et al. presented good to very good clinical outcomes in 89 pediatric patients treated with MAGNEZIX® screws or pins for fractures, osteotomies, and osteochondral lesions, with one patient requiring revision surgery for pin breakage and migration (28). Another study by Baldini M et al. reported healing in all 14 pediatric patients with various pathologies (fractures, epiphysiodesis, OCD lesions, and tendon-to-bone fixation) treated with magnesium implants. All the patients showed no implant-related adverse complications (3). Similarly, Gigante et al. reported excellent functional results and no complications in three patients with intercondylar eminence fractures treated with MAGNEZIX® screws (12).

The main results of our study revealed that 14 of the 18 patients (77.78%) achieved good healing of osteochondral fragments with complete union on MRI. Besides, no loosening of the osteochondral lesion was observed. Moreover, the overall average scoring results (modified Lysholm, IKDC) of all participants were rated as good, with dramatic improvement in the OCD group when compared to pre-operative values and 16 of 18 patients (88.89%) were able to return to moderate- or high-intensity sports activities. In patients with traumatic injuries, a comparison of preoperative and postoperative conditions was not conducted due to the acute nature of the situation and the limited suitability of the scoring systems for this specific group. Among all the patients, only one required reoperation due to implant protrusion and breakage, which resulted in damage to the cartilage of the medial femoral condyle and tearing of the periphery of the medial meniscus due to entrapment of the broken part of the screw between articular surfaces. Despite good fragment healing, we must mention that advanced chondropathy grades III and IV were observed in eight patients on MRI scans. We observed weak statistical correlations between high levels of chondropathy (grades III and IV) and low functional scores (Lysholm, IKDC) but almost no correlation with VAS scores.

MRI artifacts near Mg implants arise from local magnetic field inhomogeneities due to considerable differences between the magnetic properties of the human tissue and those of the implanted metal. After 24 months, various artifact volume was detected in 10 patients (55.56%), which most likely correspond to implant residues. Signs of the presence of the implants were evident only in the bone zone, no remnants of the implants were observed in the chondral zone. Based on our observations, we cannot claim that complete implant resorption occurs within one year (27, 32).

In some cases, we observed persistent Bone Marrow Edema (BME) around the implants, characterized by an altered signal zone (intermediate or low signal intensity at T1 and high signal intensity at T2) compared with normal bone marrow. It can be assumed that BME is a nonspecific response to the degradation process of Mg implants, apparently unrelated to any clinical symptoms or signs of local infection. A frequently mentioned phenomenon in the literature is the formation of hydrogen gas and gas cavities, which are typically formed within the first weeks or months after implantation (25, 33). On our follow-up MRIs, gas formations were not detectable at 24 months. Besides, our MRI examinations also established that the implants were bioactive and replaced by materials with weaker magnetic properties characterized by hypointensity zones. These zones were observed in eight patients in our cohort and were probably created by residual magnesium and newly formed bone around the implants, as reported in past experimental and clinical studies (12, 25, 31). In addition to new bone formation, we have demonstrated the formation of fluid-filled lacunae in the immediate implant vicinity, described as focal or linear hyperintensity. In general, based on MRI assessment, it remains unclear exactly what happens at the implant-bone interface and how much Mg is replaced by bone tissue in clinical practice. Therefore, comprehensively understanding the corrosion process is vital.

A relative limitation of this study is the absence of a control group – in recent years, our department has used only MAGNEZIX implants in these indications, however, we believe this study delivers some important information about the biological behavior of magnesium implants in human medicine measured by clinical and MRI outcome evaluation.

CONCLUSIONS

The use of MAGNEZIX® implants in the treatment of pediatric osteochondral fractures and OCD lesions has shown good clinical outcomes and favorable healing of osteochondral lesions. However, varying degrees of chondropathy have been observed in most cases. ■

List of abbreviations

OCD	Osteochondritis Dissecans
ICRS	International Cartilage Repair Society
OCF	Osteochondral Fracture
VAS	Visual Analog Scale
IKDC	International Knee Documentation Committee
MRI	Magnetic Resonance Imaging
MPFL	Medial Patellofemoral Ligament
SD	Standard Deviation
ACL	Anterior Cruciate Ligament
PLA	Poly L-lactic Acid
PGA	Polyglycolic Acid
BME	Bone Marrow Edema

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