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Bioabsorbable versus metallic screw fixation in pediatric traumatology

Zastosowanie śrub biowchłanialnych w porównaniu ze śrubami metalowymi w truamatologii dziecięcej

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ABSTRACT

Introduction: Metal stabilizing implants used in pediatric fractures have to be removed to not inhibit the growth of bones. Bioabsorbable implants can save children from surgical removal of the fixating material. As there have been only a few reports regarding children, we decided to evaluate the clinical advantages of bioabsorbable screws in the treatment of selected bone fractures in pediatric traumatology.

Materials and methods: The study group included 35 patients with bone fractures aged 5–17 years (mean 13.2 years) fixed with LactoSorb® bioabsorbable screws made of polymeric lactic acid and polyglycolic acid. The follow-up was compared with a matched control group of 35 children that underwent operative fixation of the same type of fractures with metal screws.

Results: Clinical and radiological follow-up showed that bone unions were obtained in all cases, with no signs of osteolysis. The time of immobilization was slightly shorter in the study group (5.5 weeks) than among controls (6.2 weeks; p = 0.038). There were no differences in complications, wound infections, pain management and time of hospitalization between both groups.

Conclusions: The use of bioabsorbable material in the treatment of fractures in pediatric traumatology is a safe alternative to metal stabilizing devices, with clinical benefits for young patients including no necessity of a second surgery and anesthesia.

Keywords: bioabsorbable implant; bone screws; bone fractures; traumatology.

ABSTRAKT

Wstęp: Stosowanie metalowych zespoleń w leczeniu złamań u dzieci wymaga ich późniejszego usunięcia z powodu trwającego wzrostu kości. Natomiast biowchłanialne materiały nie wymagają ponownego zabiegu operacyjnego. Ze względu na małą liczbę publikacji dotyczących tego zagadnienia w odniesieniu do dzieci podjęto próbę oceny korzyści klinicznych wynikających z zastosowania biowchłanialnych śrub w leczeniu wybranych załamań z zakresu traumatologii dziecięcej.

Materiały i metody: Badaną grupę stanowiło 35 pacjentów w wieku 5–17 lat (średnia 13,2 lat) z rozpoznanym złamaniem kości długich. Zespolenie odłamów kostnych wykonano przy użyciu biowchłanialnych śrub LactoSorb® wykonanych z polimerowego kwasu mlekowego i kwasu poliglikolowego. Wyniki leczenia grupy badanej porównano z wynikami 35 pacjentów grupy kontrolnej, u których zespolenie kości w tym samym typie złamań wykonano śrubami metalowymi.

Wyniki: Badanie kliniczne i radiologiczne wykazało całkowity zrost odłamów u wszystkich dzieci w obu grupach, bez cech osteolizy. Okres unieruchomienia był nieznacznie krótszy w grupie badanej (5,5 tyg.) w porównaniu z grupą kontrolną (6,2 tyg.; p = 0,038). W obu grupach nie obserwowano różnic w obecności komplikacji, zakażeń rany, leczenia bólu pooperacyjnego oraz długości okresu hospitalizacji.

Wnioski: Stosowanie materiału biowchłanialnego w leczeniu złamań kości w traumatologii dziecięcej jest bezpieczną alternatywą dla stabilizacji materiałami metalowymi i wyklucza konieczność powtórnej operacji i znieczulenia.

Słowa kluczowe: biowchłanialne implanty; śruby kostne; złamania kości; traumatologia.

INTRODUCTION

Skeletal system trauma ranks among the most frequent injuries in children, with a 1.2–5% incidence rate of fractures according to various studies [1, 2, 3, 4]. Especially concerning are injuries of epiphyseal plates which are responsible for bone growth. Damage to this area may lead to growth disturbances and in the long term to limb dysfunction. High frequency of aforementioned injuries in children requires early management, with optimal treatment choice based on the location and the type of fracture.

Most surgeons use metal implants such as Kirschner wires, intraosseous wires, plates, screws and intramedullary devices for fixation of unstable fractures. Usually these metal devices

require removal in a growing skeleton. Therefore, the use of bioabsorbable materials for fracture fixation may be an alternative that saves from the second surgery.

The first study, concerning biodegradable materials used for fracture fixation, was presented in 1966 by Kulkarni et al., in which biocompatibility of poly-L-lactic acid (PLLA) was studied on animals [5]. A few years later, the authors reported the use of PLLA plates and screws for mandibular fracture fixation in dogs [6]. Mollaoglu et al. compared early tissue response following treatment of maxillofacial fractures using both titanium and LactoSorb® screws in a mature animal model. The authors concluded, that the in vivo biodegradation of the bioabsorbable material was sufficiently long to fully support proper fracture healing. At the same time due to its eventual absorption the implant did not require a second operation for removal [7]. These encouraging results on animal models prompted studies on fracture fixation with bioabsorbable materials in humans, mostly adults. Publications showing results of fracture fixation with the use of bioabsorbable implants in children have been published. Authors present either large series of craniofacial surgery or small series of selected traumatological cases [8, 9, 10].

The aim of this study is to evaluate clinical advantages of the use of bioabsorbable screws in the treatment of bone fractures in pediatric traumatology.

MATERIALS AND METHODS

The study group included 35 patients (15 girls and 20 boys) between 5 and 17 years of age (mean 13,2 years), who underwent surgical fracture stabilization of long and flat bones between 2008 and 2010. The bioabsorbable materials used for fracture fixation in this group were LactoSorb® screws made of 82% PLLA and 18% of polyglycolic acid, manufactured by BIOMET® (Toermalijnring 600; 3316 LC Dordrecht, Netherlands). The control group consisted of 35 children (10 females and 25 males) aged 5–17 years (mean 13,4 years) matched for localization and type of fracture, who underwent surgical fracture fixation with metal stabilizing screws during the time period from 2000 to 2008.

Retrospective analysis of the study group included patient history, physical and radiological examinations (Fig. 1a). After the surgery standard X-ray in 2 projections (AP and lateral) was taken 24 hours post-op and a follow-up physical examination and control X-ray obtained 4–6 weeks following the surgery. Additionally, a final X-ray was taken 6 months postoperatively. For the control group, the same parameters were evaluated using a retrospective analysis of medical documentation.

In 9 cases in the study group and 5 among controls, a computed tomography was performed to precisely visualize the fracture.

All surgical procedures were performed under general anesthesia. Intraoperative radiographic imaging was used to aid in proper screw placement. All used screws were cannulated ranging in length (11–58 mm) and diameter (2.0–4.0 mm) depending on patient's age and fracture type. Screw position was controlled with a k-wire. Preoperative antibiotics were implemented in all cases with anticoagulant prophylaxis administered only in lower extremity fractures.

Statistical analysis was performed using the χ^2 independence test, the Fisher test, the Shapiro-Wilk test and the sum of rang Wilcoxon test.

RESULTS

Patients in the study group presented the wide range of fractures localization including fractures of both upper and lower limb (Table 1). Furthermore, the majority of patients in the study group suffered from fractures of distal tibial epiphysis (24 cases). In the control group patients presented exactly the same type of fractures managed with surgical fixation with metal screws.

In X-rays taken 24 hours post-op bioabsorbable screws were either weakly visible or not visible at all. In the control group all the metal fixation devices were readily visible (Fig. 1b). The follow-up X-rays taken 4–6 weeks post-op confirmed correct

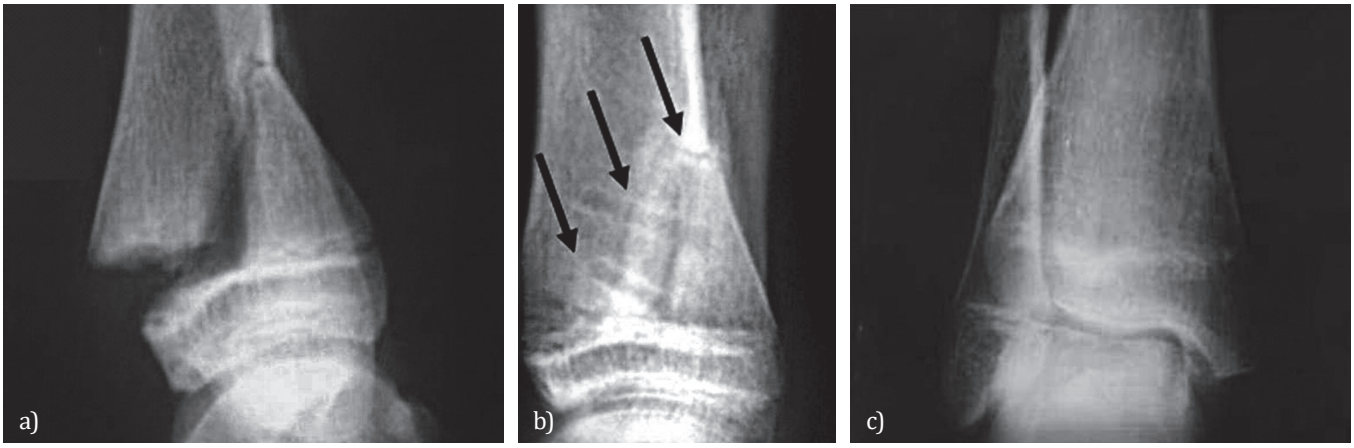

FIGURE 1. Radiological examinations of a 14-year-old patient with a fracture of the right tibia: a) lateral projection showing a fracture of the distal tibial epiphysis; b) post-operative X-ray 1 day after fixation with bioabsorbable screws (arrows); c) 6 months follow-up with no signs of the bioabsorbable material

TABLE 1. Localization of fractures

Fracture localization	Study group	Control group
Distal tibial epiphysis	24	24
Tibial tuberosity	1	1
Patella	1	1
Pelvis	1	1
Humeral medial epicondyle	5	5
Humeral lateral epicondyle	1	1
Olecranon	1	1
Proximal phalanx of thumb	1	1
Total	35	35

bone realignment and complete fractures' unions in all patients in both groups (Fig. 1c). Ten patients from the study group had further radiographic imaging taken 6 months postoperatively. Good bone healing with no signs of osteolysis was noted. In both groups, post-operative wound healing was uncomplicated with no wound infection or allergic reaction observed. There were no differences in pharmacological pain management between both groups. Mean hospitalization period was 6.00 days and 6.77 days in the study and the control groups respectively. The mean post-op immobilization period was slightly shorter in the study group (5.5 weeks) compared to 6.23 weeks in the control group ($p = 0{,}038$). All children from the control group were qualified for surgical removal of their metal devices.

DISCUSSION

Skeletal system in children varies from that of an adult in several aspects including bone structure anatomy, types and location of injuries and the progression of the healing process. A characteristic feature of an immature skeleton is a presence of growth plates. These areas of bone are age and gender dependent and express variable activity until skeletal maturation. Fracture close to or across the growth plate can result in alteration of limb growth. Therefore proper fracture reduction and stabilization is crucial in minimizing complications. Surgical treatment approach is based on, among other factors, X-ray examination and in some cases on CT scans [11]. In 9 study group patients and in 5 controls a CT scan revealed fracture features unrecognized on a standard X-ray, thus aiding in preoperative planning.

Metal implants are frequently used for fixation of unstable fractures. One of their disadvantages is rigidity, which causes accumulation of stress forces in affected bone close to the implant, the so-called „stress-shielding". According to Wolff's law, a healthy bone will develop a structure most suited to resist the force acting upon it. Therefore, areas of bone experiencing high load or stress will respond by increasing solid bone mass while areas under lower load or stress will respond by decreasing bone mass [12].

Studies on animal models were indispensible in testing bioabsorbable implant use, bone reaction to material and operative techniques development. In 1985, Rokkanen et al. first used bioabsorbable self-reinforced polyglycolide implants in the fixation of ankle fractures [13]. Since 1988 they have also been using a biodegradable self-reinforced poly-L-lactide screw to fixate of cancellous bone fractures [14]. Waris et al. reported preliminary results using self-reinforced bioabsorbable implants for stabilization of open metacarpal and phalangeal fractures. The authors compared the stability of bioabsorbable fixation devices with various metal counterparts concluding that ultra-high strength self-reinforced implants provided sufficient fixation stability for treatment of hand fractures [15, 16, 17, 18]. Many studies have shown that bioabsorbable implants are non-toxic or tissue reactive, degrade slowly, are biocompatible and are effective in the fixation of osteochondral fragments. Furthermore, they can also be effective in stabilizing phalangeal fractures during replantation procedures [11, 19, 20, 21, 22, 23]. Although some authors observed the low rate of complications with these implants, Rokkanen et al. reported a 10% complication rate with the use of absorbable materials. These included bacterial wound infections in 47% of cases, failure of fixation in 4% of cases and nonspecific foreign body reaction in 2% of cases [14]. The absorbable implants used in our study did not cause local foreign body reaction or an allergic reaction.

We have used cannulated bioabsorbable screws to fix displaced or unstable fractures in selected children. Using cannulated screws made the surgical procedure easier, and more importantly, allowed the use of an image intensifier intraoperatively for more accurate screw and wire placement. Non-cannulated screws make the fixation procedure more difficult because screws cannot be visualized in radiographs during or after insertion [24]. Similarly to other investigations we attribute this to the amorphous structure of the co-polymer (82% L-lactic acid – LactoSorb® and 18% glycolic acid) and to the prolonged release of the polymer fragments [22].

Lactic acid polymers are absorbed in a defined time period and do not cause stress between the implant and the healing bone. In vitro studies have shown that the implants maintained 70% of their strength for 6 to 8 weeks following implantation and were completely degraded within approximately 12 months [25, 26]. In their long-term in vivo study in sheep, Jukkala-Partio et al. reported results of biodegradation and strength retention of poly-L-lactide screws. They observed a controlled strength and gradual degradation process making the use of biodegradable screws safe, also in demanding fixation procedures [27]. According to many authors, biomaterials for bone regeneration, bioactive composites and tissue engineering applications will also provide new possibilities for the reconstruction of tendons, ligaments, vessels, nerves and bone [28]. The advantages of using such materials include avoidance of metal implant-related long-term complications and secondary removal operation and as such can be viewed as an optional procedure in selected patients [15, 16, 17, 18, 22].

In our study majority of cases concerned fractures of distal tibia epiphysis. Podeszwa et al. retrospectively compared use of bioabsorbable and metallic screws in the same amount of pediatric cases with no significant differences between both

groups [29]. Our converging results emphasize the need of prospective randomized studies. Objectively in children this kind of trials would be difficult from ethical point, as the group with metal stabilizing devices would have to undergo a second surgery. Nevertheless in adults, in a recent study from 2015 Gaiarsa et al. have confirmed similar clinical and functional results of use of bioabsorbable and metallic plates in the ankle fractures [30]. A recent meta-analysis of 4 studies regarding use of bioabsorbable and metallic screws in fixation of malleolar fractures with tibiofibular syndesmotic raptures in 280 adult patients showed no statistically significant difference in number of complications and range of motion [31].

Our study group included the wide range of fractures including tibial, humeral, pelvis and phalanx fractures. It is one of the biggest series of pediatric cases so far published and its variety shows a big potential in use of bioabsorbable materials. Despite different functional impairment in such various fractures, if metal materials were used in any growing child they would have to be removed under general anesthesia later with its risks.

CONCLUSIONS

The following conclusions were made based on our study results: in the treatment selected of fractures in pediatric patients, the use of bioabsorbable screws is warranted as an alternative to metal stabilizing devices with clinical advantages such as no need of surgical removal of the fixating material in the future.

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