Acta Scientific Orthopaedics (ISSN: 2581-8635)

Volume 6 Issue 12 December 2023

Research Article

Analysis of Using Bioabsorbable Implants in Orthopedic and Trauma Surgery in a Chilean Children's Hospital

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Received: October 30, 2023

Published: November 24, 2023

Abstract

The use of osteosynthesis in children, for traumatic and orthopedic pathologies, presents a progressive increase, determined by the materials accessibility for the different treatments needed for the children [1].

Fractures in children usually require orthopedic treatment, but in the last decade the use of osteosynthesis became more common, as in those fractures with joint involvement or unstable fractures that the orthopedic treatment fail, in those the osteosynthesis allows us to maintain the congruence and stability of the fragments. This is how currently mainly the orthopedic surgeon chose using several materials as screws or Kirschner pins (if it is necessary to go through the physis). However, this kind of material usually requires a second intervention with general anesthesia for their removal, a situation that can be avoided with the use of resorbable implants.

Keywords: Bioabsorbable; Implants; Osteosynthesis

Introduction

Historically, osteosynthesis elements have long durability for being of titanium. Permanent or non-resorbable implants remain in the body after healing and bone reshaping. However, in most cases the implant serves a temporary function, and it is not necessary to keep itwithin the bone structure after healing. Resorbable implants are made of moleculesthat exist in the human body and are reabsorbedafter the tissue has healed.

Osteosynthesis materials based on resorbable polymers have begun to be used gradually,considering the speed of bone healing in children which allows mechanical demands notto be prolonged as in adult patients [1,2].

Other advantages are to avoid their extraction after getting their objective, and it in the futurebeing eliminated from the organism promotingthe restoration of the original tissues, reducing the risk of subsequent migration and long-termcomplications related to the presence of external materials, etc. [3,4].

The present work aims to show the experience of orthopedic surgeons using the resorbableimplants in children, in the treatment of fractures or in orthopedic pathologies. Before using those materials, it was considered that inchildren surgeons already have used biodegradable resorbable sutures to fix small chondral fragments in fractures without presenting adverse reactions, those materials were polyglycolic and polylactic acid. After anextensive review in the literature of the use of resorbable implants in animals, adult and pediatric patients; we analyzed the work of Mäkelä., *et al.*, who studied the effects of transphyseal perforation of the distal femur in rabbits using polydioxanone and polyglactinpins, observing the regeneration of the physis in the area of perforation and later these

same authors described the use of resorbable pins in supracondylar fractures of humerus in childrenaged 7.7 to 9 years [5-7].

However, Gil Albarova., *et al*. observed in rabbits that self-tapping screws of polyglycolicacid are unable to achieve an epiphysiodesis ofthe greater trochanter, behaving as aninterposition material that prevents the formation of a physiary bridge [8].

Another study that caught our attention is the one of P. Hope., *et al*, who in 24 children compared the outcome of using regular pins and biodegradable pins in elbow fractures, 14 fractures of the lateral condyle, 8 of the medialand 2 of olecranon. Eleven fractures were fixedwith regular pins and thirteen with polyglycolicacid pin. Surprisingly, no complications were described with biodegradable materials [9].

At the university Orthopedic and Children'sSurgery Center in Zurich, Switzerland, some surgeons share their experience with resorbableimplants that we found amazing and will describe at the following.

Dr. Theddy and F. Slongo have shown that theuse of bioabsorbibles implants in children is anemerging field based on the experience of eachauthor and creates the necessity to researchmore about the topic and their develop becauseof their healing potential and the benign biological reactions with the children's bones. At the same time, O. Illi., *et al*, from the same orthopedic center, in five years of experience using biodegradable implants in orthopedic surgery concludes that the bioabsorbable material meet all expectations and he plans to increase the use of this material in pediatric trauma surgery [10].

However, implant resorption has rarely been associated with adverse clinical effects from foreign body reaction such as skin flushing on the implantation site, pain, edema, drainage of implant fragments through skin holes. These reactions are related to the local accumulation of degradation products of the implant and the ability of the surrounding tissues to eliminate such waste. In children the size of the implantsis smaller than those required in the adult patients so they have a less chance to have a adverse reaction to external material, and by the other side; the children's bones have a largeamount of cartilage and physis, which are often compromised by trauma or in the correction of an orthopedic pathology that sometimes makesit necessary to cross the physis with elements ofosteosynthesis that in sometimes the extractioncan be difficult as trying not to damage the physis [11].

Once again demonstrating the advantages of bioabsorbable implants, Otsuka., *et al*. studied the effects of the degradation of polydioxanoneimplants which were installed through the physis, however they verified that this degradation did not alter the normal physisgrowth [11].

In another study, Nordström., *et al*. haveinvestigated the tissue and sponge bone in the distal third of rat´s femurs with the self tappingimplants of polyglycolic acid and polylactic acid. They verified the presence of an bone stimulation response between the implant and the recipient tissue of different presentation in both implants. With polylactic acid implants, the bone response was maximal in the first postoperative week, decreasing progressively after that time. However, with polyglycolic acid implants, the response was significantly higher than that observed with the polylactic acid implants at 6, 12 and 24 weeks postoperatively, coinciding with the greater local accumulation of macrophages [12].

As conclusion Polyglycolic acid implants havea high rate of adverse tissue response, this risk decreases with lactic acid polymers, however, its long degradation in years can be a disadvantage in several situations behaving asa metal implant [13].

As we can see in the literature, the ideal bone substitute should be osteogenic (bone producer), biocompatible (local biological tolerance), bioresorbable (degrade into components of lower molecular weightnormally included in human body), capable of providing structural support, capable of transporting other substances, easily usable inclinic and with an adequate cost-benefit ratio.

Objectives

- Assess the competence of biorreabsorbible implants.
- Determining the efficiency and efficacy of bioresorbable material in fracture and orthopedic surgeries for children.
- Analyze the cost benefit of surgery with bioabsorbable implats versus regular nonabsorbable osteosynthesis.
- Determining the biocompatibility of bioabsorbable implants in pediatric patients.

Material and Methods

- **Population:** During the period April 2005 to July 2010, fractures and orthopedic surgeries that required osteosynthesis and did not involvehigh mechanical demand during the time of bone consolidation were included (Table 1).
- **Excessive mechanical demand:** consolidationtime greater than the resistance presented by thebioresorbable material.

Inclusion criteria

- Children under 15 years of age with fractures and orthopedic surgeries requiringinternal osteosynthesis with screw and/or needles, without high mechanical demand.

Cases					
	PIN	Screw	Anchor	Screwand pin	Total
Fractures	15	5		2	22
Orthopedia Surgeries	6	3	2	1	12
total	21	8	2	3	34

Table 1

Exclusion criteria

- Children with exposed fracture with highmechanical demand.
- Children with comminute fracture.
- Fractures with orthopedic treatment optionwithout fixation needed.

Material pre analysis

Bioresorbable polymer implants are made of the same molecular building blocks of lactic acid which is naturally produced in the human body by different systems, such as the muscularsystem during intense activity. Long polymericmolecular chains are created by combining lactic acid derivatives called lactids. Theresulting polymers are usually calledpolylactides or PLLA. The implants used are formed of a copolymer in proportion of 82% (PLLA) and 18% (PGA), comparable with the strength of a titanium plate but which is reabsorbed within 9 to 15 months. However, itsresistance is maintained for 8 weeks.

The copolymer maintains its strength during the healing process, and by hydrolysis slowly breaks down into lactic acid molecules. The resorption process occurs in two phases, the first H2O (water) penetrates the implant, reactswith the polymer, and breaks the polymer chains by hydrolysis; and the second hydrolysisconverts long chains into shorter chains until the polymer fragments into simple molecules oflactic acid. The lactic acid molecules are then metabolized by the liver into CO2 and H2O, and finally expelled by the lungs. Bioresorbablepolymers provide relatively high strength and predictable resorption rates for hard or softtissue applications. Different resorption rates are beneficial for different surgical applications. For example, the fast bone healingof the pediatric tissue may require an implant with a faster resorption rate than an implant designated for adult tissue that may experience slower or incomplete healing. Resorption ratesare controlled by material selection and manufacturing methods.

The advantage of the bioresorbable polymer implant are many which are describe by Jainandunsing JS., *et al*.; who conducted a review of bioresorbable implants for musculoskeletal injuries involving bone andligaments in adults concluding that they may have significant advantages compared to non- resorbable metal implants such as bone fracturehealing, maintaining the articular fracturecongruence during the healing after the surgery, bone support after orthopedic surgery and a avoiding a second surgery for taking out the nonabsorbable implant in case that were used [14].

Results

The average age at the time of surgery was 9.5years for fractures and 9.6 years for orthopedicsurgeries.

There were 9 surgical reductions of Milch II humeral condyle fractures, just one presented adeformity due hypertrophic ossification at the lateral condyle, which we did not attribute to the use of resorbable pin because this event is not uncommon in both surgical treatment with metal osteosynthesis and orthopedic treatments.

Another 3 epitrochlear fractures were treated with biorreabsorbible pins, two of them passedthrough an open reduction and pin fixation, andone more with close reduction andpercutaneous fixation.

In ankle fractures, there were no complicationsin a case of Tillaux fracture treated with close reduction and percutaneous fixation, with at least 6 months of follow-up. Another patient with triplane fracture who received an open reduction plus fragments fixation with screw 2.5 and a pin of 1.5, pitifully the patient did not attend to controls (Figure 1).

Figure 1: Triplane ankle fracture open reduction and osteosynthesis with screw and pin

All these surgery technics where previouslydone and published as case reports or cohorts ofcases with successfully achievement [15-19].

Fractures of knee, tibial spine and patella, havenot either complication after being treated withreabsorbable material, and surprisingly those with intra articular reabsorbable screws. Besideit was easy to see all the structures at the MRNcontrol, without artefacts [20-22]. (Figure 2).

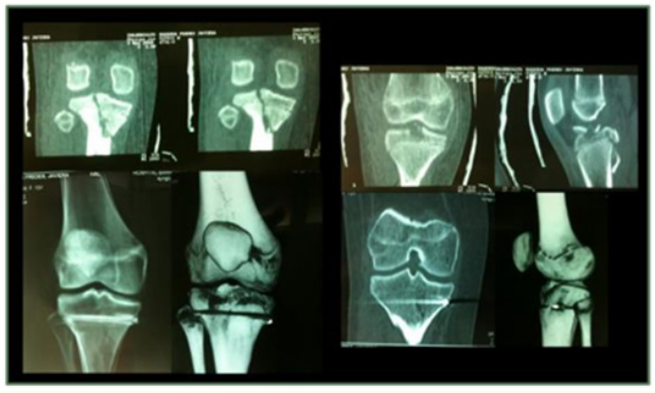

Figure 2: On the left box, Salter IV fracture of proximal tibia treated with regular screws, and in the right box a tibial spine fracture M&M III treated with reabsorbable screws. The proximal tibia fracture shows artefacts at the control imagens while the tibial spine shows no artefacts.

A 15-year-old patient consulted in ER for an angled fracture of the diaphysis of the 5th metacarpal with two previous reduction failed attempts, after that the following action was orthopedic reduction and intra medullary fixation with a reabsorbable pin 1.5 mm was performed. There were no further complications and have had an adequateconsolidation.

However, we describe the case of a 12-year-oldpatient who was admitted to the emergency department with a fracture of olecranon and displaced radial fracture. We perform a reduction and direct fixation of olecranon with2 reabsorbable pins # 2mm and PDS suture with Obenque technique. In the radial fracture,the reduction was performed with TEN with theMetezeau technique. At the 5th week of evolution with a complete consolidation, the patient presented an external body reaction,being necessary to take out the operative scar granulomatous area. However, it evolved well in subsequent controls. It is thought that, afterthe Obenque technique, the resorbable pins hada long time in the subcutaneous space, close tothe skin, condition that can be a risk factor for inflammatory reaction of an external material. The patient presented a small area of physisbridge in the olecranon, but it has not beenrelated with the reabsorbable pin site.

As the Hospital is also a children orthopedic surgery center, we also performed a lot of surgeries like Dega technique in developmentaldysplasia of the hip, surgeries for Hallux Valgus and osteotomies for fractures with residual torsion or angulation, all those procedures have some complications and can be treated with different techniques, in thisinvestigation we also look after for complications related with using reabsorbable material that will be discus in bellow.

A patient who was diagnosed for Hallux valgus, haven been get into an Akin osteotomyin which the reabsorbable pin transfixed from proximal to distal the phalanx bone by about 5 mm out of the skin, required second surgery forremoval of detritus.

A Chevron surgery that was performed in a Hallux Valgus in a child foot with resorbable screws of 2.0 mm diameter, the patient did not present second and were adequately tolerated conventional treatment with metal needles, alsodescribed in other studies [23,24].

Another case to show the good evolution of reabsorbable is a child who has had an unicondylar fracture of the first phalanx index,treated with a percutaneous pin, presented a reaction of an external body in the prominent area but it was not necessary to perform asecond surgery for removal, and the fracture evolved correctly.

A patient with interphalangeal pseudoarthrosis of the thumb secondary to severe trauma with loss of proximal phalanx was treated with a screw 2.0 mm in diameter plus and inguinal flap, evolved adequately without complicationswith an interphalangeal fusion in functionalposition, such as Pietrzak., *et al*, described in his review [25].

Two patients with club foot with relative insufficiency of peroneal muscles, transposition of the anterior tibial muscle was performed to the second wedge bone, where it was fixed with a bioresorbable anchor.

The average evolution time to the last control was 1.9 years for fractures and none describe any complications.

And for the end we like to describe the evolution of 4 patients who had hip dysplasia development, the original Dega osteotomy treatment was combined with the bioresorbableosteosynthesis material.

The procedure was with 2 resorbable pins crossed from proximal to distal iliac fragment through open osteotomy, to give greater

support with tricortical graft wedges,decreasing the possibility of resorption and at the same time suspending the use of pelvic plaster post-surgery, finally the hip surgery gotgreater stability with excellent outcomes such as the original technic described in the paper ofJan S., *et al*. [26] (Figure 3).

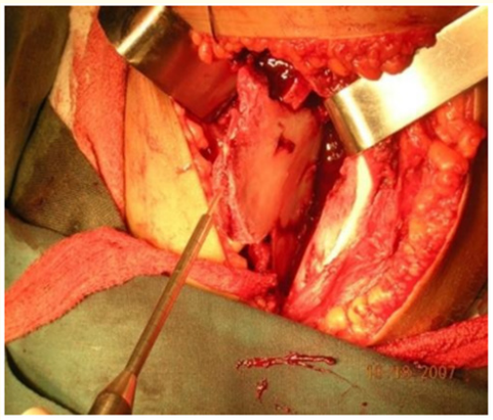

Figure 3: Pin as bicortical graft support in Dega osteotomy.

Complications

The patients who have participated at the study,none had physis edge, considering the use of implants with a diameter of less than 3mmacross the physis.

Only the 10% of patients of our study who documented adverse reaction to the reabsorbable material, we think that it can maybe caused by the size of the implant, its positionoutside the bone and its proximity to the skin, a similar effect in adult patients in whom the amount of resorbable material to be used is bigger. . In the literature we found evidence thatimplants which are made of polylactic acidpolymers in greater proportion have lessinflammatory reaction to foreign body [28].

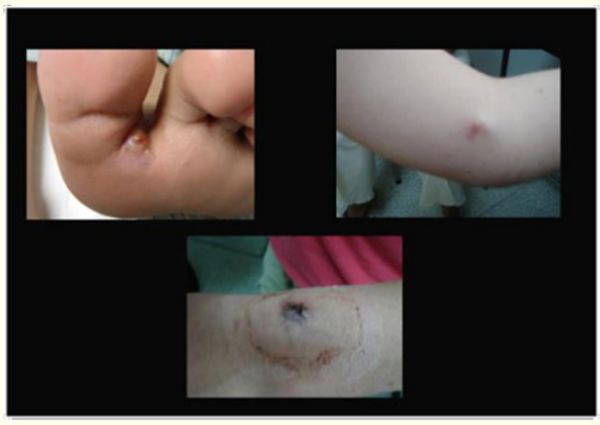

Figure 4: Skin adverse effect of bioabsorbable pinning.

And finally, in addition of analyzing the clinical and radiological outcome of patients operated with bioabsorbable osteosynthesis, thecost and benefit of using this kind of material was analyzed. As being a Chilean public hospital where the study was done, without having access to commercial houses or post- purchase benefits of surgical material, it is the guaranteed that the researchers haven't benefitscommenting the results of this research. Therefore, a financial analysis was requested from the hospital's finance service, to comparethe cost of surgery in one of the patients studiedwith triplane fracture, and analyze the cost of two choses, one if he would been treated with aregular non-absorbable screw versus the cost of surgery with an absorbable screw.

Initially, the cost of the first intervention was quite similar between the two options, taking into surgery price time, materials, and health personal, the difference highlights only in the osteosynthesis material, the difference betweentwo screws bioabsorbable vs non-absorbable was 200 USD. However, the cost for the removal of non-absorbable screws is 1100 USD, while bioabsorbable screws do not need a second intervention, decreasing the cost for the public service, furthermore, to significantlyreducing the patient's risks whether anesthesia effects, as immediate or subsequent clinicalpost-surgical complications, besides knowing that the patients are children with high psychological susceptibility. Data obtained from the SIGCOM MINSAL system for the month of May 2023 and tenders for clinical supplies carried out by the hospital, through the Public Market.

Conclusions

The use of bioresorbable implants in trauma ororthopedic treatment in children should be evaluated case by case basis with careful consideration of the benefits and risks involved.

Factors to consider include the patient itself, thenature of the injury, technical considerations, and the experience of the surgeon.

According to the experience obtained, we can describe the following benefits in pediatric patients

- It is useful in every patient avoiding second surgery for osteosynthesis removal after achieving consolidation, in addition to avoiding possible complications of a second intervention, whether physical or psychologicaldamages.
- It is useful in any fracture or orthopedic correction that does not have an excessive mechanical demand.
- Only the cost of surgery for removal theosteosynthesis material in our center cost almost twice than the use of bioresorbable implants in the first intervention, not counting the cost of further medical appointment forstiches, or possible complications.

- Allows imaging examinations such as CT andMRI without artefacts in the images that affectthe study or visualization.

We must not forget that the use of bioresorbableimplants are not exempt from complications, however, these complications according to ourresearch and experience are apparently related to the improper use or little experience of surgery, but not with the same implant materialwithin the bone structure.

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