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REVIRE

Is the Use of Bioabsorbable Materials in Orthopaedic Surgery Associated with Infections? Review of the Literature

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ABSTRACT

Bioabsorbable materials have been extensively used in medicine. Many have suggested the use of these implants for treating fractures as well as other orthopaedic conditions since they may lead to less implant morbidity, and they have additional advantages: they are radiolucent, they eliminate hardware removal procedures, they limit stress-shielding and they gradually transfer load to healing fractures. Despite the popularity of these implants, reports of complications continue to appear in the literature. Although these complications have rarely adverse effect on the long term outcome they are quite frequent and have been reported with most of the commercially available implants with varying incidence rates and reactions to them. The purpose of this review is to summarize the infections reported in clinical trials of bioabsorbable materials.

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Key words: Infection; Bioabsorbable materials; Orthopaedic surgery

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INTRODUCTION

The use of bioabsorbable materials in surgery is not new as cutgut suture is described in the Galen writings in the second century AC. Nowadays these implants are becoming more popular not only in orthopaedic surgery but in other surgical specialties also such as maxillofacial surgery or plastic surgery as well. A reliable and stable fracture fixation can be achieved by metal implants, which are still the "gold standard" in such cases.

However, they become unnecessary or even harmful after consolidation.

Long-term follow-up and implant-related complications become frequent, even worse for the lower limb where the weight bearing makes the removal of the metal implants necessary in most of the cases.

The main advantage of bioabsorbable implants is that there is initial stability adequate for healing and then gradual resorption after biologic fixation has been established. In addition these implants have other advantages over the traditional metallic implants such as reduced stress shielding of bone as they gradually apply load as they degrade, obviate hardware removal procedures and facilitate postoperative radiologic imaging. Although there have been reported cases where biodegradable implants have to be removed[1-3], the incidence of a required second surgery to remove the implants is much lower than with metallic implants[4].

In the late 1960s and early 1970s animal studies reporting the use of biodegradable implants begun to appear in the literature. In 1966 Kulkarni[5] published a report on the biocompatibility of LPLA(poly-L-Lactide) in animals. Both the histological response and the degradation of the polymer were studied over the course of two months. It was found that the polymer was non-toxic, non-tissue reactive and degraded slowly. In 1971 the same author[6] presented the results of using LPLA plates and screws to fix mandibular fractures.

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The study demonstrated that the material did not cause detrimental inflammatory or foreign body reactions, although the material had not completely degraded by the end of the study.

Bioabsorbable implants have three main disadvantages: lower mechanical strength, higher cost and in some cases undesired biological response[7]. Many studies have shown that the strength reduction during degradation is slow enough to allow tissue healing[8,9]. Many studies also have shown that these implants can provide the necessary initial strength for orthopaedic application[9-11]. Bostman[4] estimated that if the removal rate for metallic implants is above 19-54% (depending on the fracture type) resorbable implants would be cost effective. So the main disadvantage for these implants is foreign body reaction.

This foreign body reaction to bioabsorbable implants vary from mild fluid accumulation to discharging sinus formation to irreversible tissue damage[7]. In most of the reported clinical trials these reactions themselves have no effect on the long term outcome. However in a few studies there have been moderate to severe complications and have necessitated second surgeries. This review is limited to the studies that have reported complications and particularly infections.

BIOABSORBABLE MATERIALS

The modern bioabsorbable materials have been primarily polymers of poly-alpha-hydroxy acids in the polyester family[12]. These polymer chains have properties which are specific to the independent monomers which comprise them and to the bonds that exist between the monomers. The nature and arrangement of these bonds determines the structure and properties of the polymer. The polymerization process is controlled by temperature, pressure, chemical composition and timing of the chemical reaction involved. Different monomers may be combined to obtain a material with a fusion of the characteristics of the individual components.

The materials mainly used in orthopaedic surgery are polyglycolic acid(PGA) and polylactic acid (PLA). PGA was introduced in 1970 as the suture material Dexon. It is more susceptible to hydrolysis and early breakdown than PLA, usually being absorbed in several months. PGA is also more susceptible to gamma radiation and ethylene gas oxide sterilization.

Many variables control final implant mechanical properties. The polymerization reaction can be modified to create cross links that increase fiber rigidity. The chemical reaction can be controlled by altering the temperature and the rate of heating and cooling. The glass transition temperature is the temperature above which the substance is brittle and below which it is more ductile. For PGA is near 40°C whereas for PLA is well above 60°C. It is a useful property because heating the material allows it to be contoured easily.

The L-isomer of PLA (PLLA) is the enantiomer found in large amounts in orthopaedic implants[12-14]. This isomer has a high degree of crystallinity and is more resistant to hydrolysis. A pure PLLA remains detectable for between 18 months and four years *in vivo*. The D isomer (PDLLA) is amorphous and provides less tensile strength. It promotes resorption of the implants over time.

Biodegradation occurs in two phases. In the first phase, hydrolysis of the bonds linking the monomers occurs. The second phase of the degradation is the enzymatic breakdown of the monomers themselves into lactic and glycolic acids. The rapid breakdown of these implants is thought to be the underlying cause of the clinical scenario of sterile sinus formation, synovitis, and other foreign body reactions. This is supported by the observation of a higher incidence of these reactions with the more rapidly absorbed PGA than PLA. The rates of degradation are controlled by copolymer ratio (the ratios of PLLA, PDLLA and PGA) and by configuration structure, crystallinity, molecular weight, morphology, stresses, residual monomer, porosity and site of implantation[15].

CLINICAL APPLICATIONS

The use of bioabsorbable fixation for the attachment of soft tissue to bone is being increasingly utilized by orthopaedic surgeons, particularly in the treatment of soft tissue lesions in the shoulder. These implants have facilitated the repair of labral and rotator cuff lesions. The development of bioabsorbable tacks, pins, anchors, screws, washers has given to the surgeons more treatment alternatives[16].

The complications observed with the use of bioabsorbable suture anchors are similar to those seen with metallic. According to Warris[17] the risk of implant associated infection, stress shielding, peri-implant osteoporosis is reduced. Bostman[18] reported 4.3% of clinically significant local inflammatory reaction in 2,528 patients treated with absorbable pins, screws, rods, bolts made of PGA(Polyglycolide) or PLLA. The incidence was 5.3% and 0.2% respectively. The mild reactions consisted of a painful erythematous papule of a few weeks' duration. Those of medium severity had a sinus that discharged remnants of the implant for up to 6 months. In the patients affected by severe reactions, extensive osteolytic lesions developed at the implant tracks. The histopathologic picture was that of a nonspecific foreign body reaction with no evidence of infection. Rokanen *et al*[19] reported complication rate included bacterial wound infection of 3.6% in 2,500 patients managed with absorbable fixation devices. In 20% of these patients however reoperation was not necessary. The occurrence of non-infectious foreign body reaction 2-3 months post-op has been observed in 2.3% of patients with PGA implants but none in patients with PLLA implants. The inflammatory tissue response often required either aspiration with a needle or a small incision, did not influence the final clinical or radiological outcome. According to the author the bioabsorbable implants can be also used for open fractures or infection operations. In another review article by Sinisaari[20] totally absorbable devices have been used for a total of 2,114 operations for the treatment of fractures, osteotomies and fusions. The overall infection rate was 3.5%, for PGA implants was 4% whereas for pure PLLA implants was 0.7%. When the infection rate with absorbable implants was compared to that with metallic implants in another series the rates was 4% and 9% respectively. The difference was due to technical reasons. Sinus formation due to foreign body reaction was observed in 2.5% of the 2114 cases and was subsequently infected in 20%. The clinical course was uneventful in over 90% of the total series. The authors concluded that the overall infection rate with absorbable implants is lower to that with metallic ones. Rokkanen *et al* four years later reported[21] complication rate with bacterial wound infection included of 4%, in total of 3,200 patients who were managed using bone or ligament fixation devices made of self-reinforced (matrix and fibres of the same polymer) bioabsorbable alpha-hydroxy polyesters. The occurrence of non-infectious foreign-body reactions two to three months postoperatively has been observed in 2% of the patients operated in the last few years with polyglycolide implants but none of the patients managed with polylactide implants. This inflammatory tissue response often required aspiration with a needle but did not influence the functional or radiologic result of the treatment. The authors again concluded that bioabsorbable implants can be used in open fractures or infection surgery.

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REPAIR OF SHOULDER LESIONS

The bioabsorbable anchors have been widely used in labral lesions, in Bankart repairs as well as in rotator cuff lesions. The first absorbable tack used for such cases, was constructed of PGA and has been implicated in several cases of aseptic synovitis secondary to histiocytic or phagocytic reaction to the rapidly degrading polymer[22].

MENISCAL REPAIR AND ACL RECONSTRUCTION

Complications with the Bionx arrow for meniscal repairs have been published in several case reports[23-25]. No infections reported.

McGuire *et al*[26] in his prospective randomized controlled trial compared the linvatec Bioscrew with metal interference screws in 204 patients. There were no reported complications related to loss of fixation, toxicity, allerginicity, osteolysis or infection. Inflammatory reaction and sterile abscess formation have been reported in several case reports[27,28], but no bacterial infection reported. In a recent meta analysis of randomized controlled trials Shen *et al*[25] found no difference in infection rate between the metallic and the bioabsorbable screws.

TRAUMA SURGERY

In a review of more than 2,500 cases of fracture fixation in which bioabsorbable implants were used Rokanen[19] reported that the incidence of bacterial wound infection was 3.6%. Compared with metallic fixation, absorbable fixation has shown a lower incidence of infection[20]. Bucholz *et al*[30] performed a prospective randomized controlled trial comparing PLA screws with stainless steel screws for fixation of medial malleolar fractures. He found no statistically significant difference in operative or postoperative complications including infections.

In a recent multicenter retrospective review from two level one trauma centers Bausuener[31] reported 6% infection rate in 78 patients with 80 periarticular comminuted fractures treated with bioabsorbable pins. The authors concluded that bioabsorbable pins are an intriguing alternative to traditional fixation methods. They afford similar effectiveness in maintaining stability without evidence of pin migration or other concerns of buried metallic implants.

In another recent prospective randomized trial Zhang[32] compared the absorbable screws and metallic plates in treating calcaneal fractures. In group A (metallic implants), there were six cases of poor wound healing, one case of deep infection, and four cases of peroneal tendon irritation. In group B (bioabsorbable implants), there was one case of superficial infection and no deep infection or tendon irritation. The same author in another paper regarding surgical treatment of calcaneal fractures treated with bioabsorbable screws[33] reported one patient who had a superficial wound infection which healed after irrigation and debridement without removal of the implant. Two patients had consistent effusion from the wound for two weeks which healed after drainage and elastic dressing. They identified no evidence of soft tissue irritation or other complications directly attributed to the bioabsorbable screws.

Bioabsorbable implants have also been used for the treatment of open fractures. Ye[34] reported no cases of deep infection in 16 open dislocated ankles treated with a combination of bioabsorbable screws/rods and external fixation.

HAND SURGERY

Complication rates can be high especially in complex hand trauma. Pin infection rates between 7% and 15% have been associated with pin loosening, migration, osteomyelitis, tendon rupture and nerve injury[35]. The use of bioabsorbable implants have been proposed to reduce many of these problems. Pins do not need to be removed. Plates that slowly resorb transfer stress to the bone prevent bone weakness over time[15]. However these implants do not come without a price of their own. They have been associated with synovial reactions, sterile fluid and sinus formation and fibrous encapsulation[19,21]. Nevertheless there have not been reported cases of established bacterial infection in hand surgery attributed directly to the use of biodegradable implants. Givissis *et al*[36] in 12 metacarpal fractures in 10 patients who had ORIF with bioabsorbable plates and screws reported 4 cases of foreign body reaction during the second post-op. year required surgical debridement. Histological examination confirmed the diagnosis of foreign body reaction but no infection. The same author in 2006[37] in 21 patients with radial head fractures reported no material tissue adverse effects during and beyond the degradation period. The author concluded that concerns about soft tissue or bony reactions are not justified.

BIOABSORBABLE IMPLANTS IN OTHER SURGICAL SPECIALTIES

Bioabsorbable implants have been widely used in oral and maxillofacial surgery as well as plastic and reconstructive Surgery. Fereti[38] in 2008 reported in his prospective trial 9 patients in a total of 31, who had PLLA/PGA implant fixation for mandibular fractures and developed complications ranging from minor dehiscence (4 patients) to frank sepsis requiring plate removal (5 patients), resulting in a total of 22.5% complication rate. The reported complication rate following titanium internal fixation of mandibular fractures is 13.7%-43%. PLLA/PGA co-polymer plate and screw fixation although technically more challenging and costly, represents a viable alternative to traditional metal devices.

In another prospective study in 2006[39] in which biodegradable implants were used for fixation of displaced zygoma fractures and compared with traditional titanium fixation, there was no significant difference between the groups with respect to fracture healing and postoperative complications including infection. In a comparative study published in 2006[40] which compares the results of autogenous bone graft with bioabsorbable poly-L/DL-lactide plates to fix inferior orbital wall bony defects, again it seems that there is no significant deference I post operative complication rate.

DISCUSSION

The available literature which deals with the issue of infection associated with the use of bioabsorbable implants is very poor since all the available literature mostly deals with the issue of foreign body reaction rather than true infection. Actually there are only two papers[19-20] which clearly report infection rate of 3.5% in 2114 operations[19] and 3.6% in a total of 2,500 operations[20] respectively, which is lower comparing with fixation with the traditional metallic implants[41,42]. The implants were either PGA, PLLA or a combination and the main indications was displaced malleolar fractures, chevron osteotomies for hallux valgus, radial head fractures and ruptures of ulnar collateral ligament of the thumb.

The type of implant, method of manufacture, method of sterilization, and site of implantation all affect the degradation of the implant and the resulting biological response, making it difficult to make generalizations on the cause and possible solution to the

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foreign body response and also infections associated with the use of these implants. Most of the clinical trials presented in this paper are unable to clearly identify risk factors for this reaction. Nonetheless one study[18] presented a large enough number of patients to establish risk factors for the inflammatory response. The presence of quinone dye, an implant with large surface area, and implant sites with low vascularity such as the scaphoid were all found to be related to higher incidence of adverse tissue reactions.

Bioabsorbable fixation implants offer potential advantages over the metal implants. When bioabsorbable fixation implants are used, no removal operation is necessitated and still no long-term interference with tendons and the growing skeleton remains. In intra- and periarticular fractures, bioabsorbable pins are of advantage, since pins can be cut flush or beneath the bone surface, minimally violating the articular surface. Bioabsorbable implants do not interfere with clinical imaging. Additionally, the risk of implant-associated stress shielding and peri-implant osteoporosis is reduced.

The use of bioabsorbable implants in orthopaedic surgery as well as other musculoskeletal procedures is gaining acceptance. Complications associated with the use of these materials have diminished with the development of newer self-reinforced polymers. It is important to note that although the incidence of undesirable responses is high, most of the reactions were not accompanied by adverse clinical symptoms and did not affect the final outcome[43]. The overall infection rate with the use of biodegradable implants is not higher comparing to the traditional metallic devices. Clearly, future work in the field of orthopaedic biomaterials can be focused on the area of foreign body reaction which is the most common complication and thus reduce even more the incidence of any adverse reactions including infection.

CONFLICT OF INTERESTS

There are no conflicts of interest with regard to the present study.

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