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Biodegradable Implants in Orthopaedics and Traumatology

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Abstract: Biodegradable implants are an alternative to metallic implants and have the advantage of not being necessary to remove once the fracture has healed. Twenty-two patients with fractures were treated with biodegradable implants. There were osteolysis in eleven patients; however, no serious complication was encountered. Although biodegradable implants are expensive, a second surgical procedure to remove the implants is not necessary, relieving the patient of the related costs and risks.

Key Words: Biodegradable, bioresorbable, bioabsorbable, fracture fixation.

Introduction

Biodegradable implants are derived by transforming compounds that are present in nature to structural plastics. Organic molecules are polymerized to form strong fibers and solid compounds. When these polymers are implanted in patients, they degrade and are eliminated from the body in a period of time.

The first biodegradable material was made from animal intestines and used as a suture material by Galen in 175 BC (1). The first usage of these materials in ortopaedic surgery was in 1984 by Rokkanen for the treatment of internal fixation of ankle fractures (2). Since then, various forms of implants have been designed in the form of screws, rods, interference screws, etc.

Widely used biodegradable materials include polyglycolic acid (PGA), poly-L- lactic acid (PLLA), poly-DL-lactic acid (PDLLA), PGA/trimethylenecarbonate compolymers (PGA/TMC), poly-p-dioxanone (PDS) and poly-beta-hydroxybutyric acid (PBHBA). Biodegradable materials need to be hydrolytically labile and sturdy, at least for a period of time. To meet these requirements, they are produced by the "self-reinforcing" (SR) technique (1).

The biodegradation process takes from one to six months. This period depends on contact with body fluids, temperature, motion, molecular weight, crystal form and geometry of material, and the tissue that is implanted. Biodegraded metabolites are excreted from the body in urine and feces and by respiration in the forms of H_2O and CO_2. The in-vivo degradation process can be visualized with magnetic resonance imaging (1).

PGA sterilized with ethylene oxide and PLA with gamma irradiation (1).

Biodegradable materials are used in orthopaedic surgery mostly for the fixation of fractures. The mechanical properties of the materials permit them to be used with metaphyseal and peri-articular fractures where the loading is relatively low. Therefore, they have mainly been used for treating small-bone fractures such as ankle fractures (3). Vasenius has reported 1202 cases of ankle fractures that have been treated with these implants (4). Vasenius has reported 1202 cases of ankle fractures that have been treated with these implants (4). The author has reported that they are safe for the majority of ankle fractures, but not suitable for comminuted and unstable fractures.

Another suitable anatomic area for application is the elbow joint. They may be used for fixing fractures of the radial head, olecranon, capitellum and distal humerus. Nonetheless, comminuted fractures in these locations are not good candidates (5, 6).

Other conditions for which these implants can be used are fractures of the distal radial styloid, patella, glenoid fossa and acetabulum; osteochondral fractures in the knee, tibial plateaux, phalanx, calcaneus and talus; and also hallux valgus surgery (3, 5, 6, 7, 8). Biodegradable

screws or rods may also be used for treating epiphyseal fractures (9, 10).

Materials and Methods

From March 1991 to February 1997, biodegradable implants were used in the treatment of (22) patients at Gazi University Medical School, Department of Orthopaedics and Traumatology (Table 1). The mean age of the patients was 26 (range: 11 to 61). Thirteen patients were male and nine were female. The patients were followed up for a mean period of 36.3 months (range: 12 to 69 months).

Seven patients were treated for fracture of the medial malleolus, five for medial epicondylar fracture (Figure-1a, 1b), four for bimalleolar ankle fracture, four for fracture of the phalanx, one for radial head fracture and one for fracture of the tibial eminence. SR-PGA or SR-PLLA (Biofix-Bioscience LTD., Tampera, Finland) screws or rods were used for fixing these fractures. The diameters of the rods were 1.1 to 3.2 mm and their lengths were from 25 to 75 mm. The screws had a diameter of 3.5-4.5 mm and a length of 20 to 70 mm.

Results

all fractures healed within the normal, expected periods. There were no post-operative wound complications or loss of fracture fixation. All patients had excellent or good results.

Twelve patients (90%) demonstrated radiographically visible osteolysis at the implant canals that lasted for a mean period of 16 months.

Table 1. The characteristics of 22 patients treated with biodegradable implants.

Case No.	Age	Sex	Type of the fracture	Follow-up	Type of the material
1	15	F	Medial malleolus	69 months	1.1mm rod
2	13	M	Eminentia tibialis	58 months	3.2mm rod
3	36	M	Prox Phalanx of index finger	53 months	3.2mm and 2mm rod
4	43	F	Medial-lateral malleolus	53 months	3.2mm rod and 3.5mm screw
5	42	F	Medial-lateral malleolus	52 months	3.2mm rod and 3.5mm screw
6	18	M	Medial epicondyl	52 months	3.2mm and 2mm rod
7	21	F	Medial malleolus	49 months	4.5mmscrew
8	20	F	Medial malleolus	47 months	4.5mm screw
9	61	M	Medial malleolus	42 months	3.2mm rod and 4.5mm screw
10	21	F	Medial malleolus	40 months	4.5mm screw
11	15	M	Medial epicondyl	33 months	2mm rod
12	11	M	Medial epicondyl	33 months	2mm rod
13	39	F	Medial malleolus	33 months	4.5mm screw
14	19	M	Medial epicondyl	32 months	3.2mm and 2mm rod
15	23	M	Medial-lateral malleolus	27 months	4.5mm screw
16	30	F	Medial malleolus	23 months	3.2mm rod
17	19	F	Medial malleolus	23 months	3.2mm rod
18	25	M	Medial-lateral malleolus	22 months	4.5mm screw and 2mm rod
19	35	F	Prox. phalanx of thumb	22 months	1.1mmrod
20	60	M	Radial head	12 months	2mm rod
21	25	F	Prox. Phal. of 2nd finger of foot	12 months	1.1mm rod
22	23	M	Prox.Phalanx of index finger	12 months	1.1mm rod

Figure 1a. Preoperative x-ray of a medial epicondylar fracture (Case No. 14). Open reduction and internal fixation with two parallel Biofix® rods were accomplished.

Discussion

The main advantage of biodegradable implants is that a secondary operation for removal is not necessary, in constrast to metallic implants, which need to removed because of osteopenia, corrosion and irritation of adjacent tissues. As biodegradable implants degrade, they lose strength and this puts pressure bone, strengthening it and therefore preventing bone resorption.

However, the have the disadvantage of being expensive, having less strength than metals, causing tissue reactions, causing osteolysis around the implant and sterile draining sinuses. They may also cause synovitis when implanted intra-articularly (11, 12). The only complication we have encountered has been peri-implant osteolysis. Böstman has reported this complication to occur in half of the patients, beginning three months after the operation and the bone tissue dissolving at the end of the first year (13). This condition lasted for a mean period of sixteen months in our patients, but caused no significant problem.

These implants have been reported to cause serious synovitis in intra-articular applications (11). Our only intra-articular application was for the fixation of a tibial eminence fracture, and we observed no such complication.

Other uses of these implants in orthopaedic surgery are as interference screws in knee ligament surgery; for the promotion of osteogenesis in bone defects; for the slow release of antibiotics and growth factors; as an anti-adhesive membrane for preventing adhesions in flexor tendon surgery; as a matrix for cells in cartilage, bone or connective tissue engineering (14, 15).

The orthopaedic surgeon thoroughly evaluates the fracture before using these implants. In suitable cases, the perform well and save the patient from the costs and morbidity of a secondary operation that is necessary for removing metallic implants.

Figure 1b. Six months after the operation.

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