ABSORBABLE FIXATION DEVICES

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INTRODUCTION

After John Lister introduced aseptic surgical techniques between 1860 and 1870, many studies were made in the advancement of surgery, especially in orthopaedics. Before this time only a select number of bold surgeons attempted the repair of broken bones with an internal device. With this introduction of sterile technique, the likelihood of postoperative infection was decreased, therefore surgeons began using different devices such as plates and screws made of various types of metals. "Toward the end of the 19th century, operative fracture treatment emerged from a position as a supplementary form of treatment to a primary role for certain fractures."[1] Many materials were used ranging from various metals to ivory pegs and bone inserts. In 1909 Lambotte[1] reported the use of brass plates as well as aluminum, silver, and copper. He later recommended steel plates plated with gold or nickel. During this early period of internal fixation many surgeons showed the potential for the satisfactory application of implants to facilitate the union of fractures, but the materials at that time were not suitably inert and were lacking in sound mechanical properties as well.

In 1958 the A.O. group was assembled with the purpose of developing an ideal material and technique for fixation.[2] With much research, the proper principles of internal fixation, proper instrumentation and implants were developed. The implants must meet many criteria, such as being tissue-compatible, workable, corrosion resistant as well as stable.

The ideas and principles of the A.O. group are solid, but variable situations exist, and therefore, the rigid non-absorbable devices are not always ideal. There are some disadvantages to A.O. principles, such as continued stress protection to the affected bone, as well as the possible requirement of a second surgery for removal of the fixation device.

Kirschner wires and other metal pins are often used for fixation and stabilization of osteotomies and fractures today. These materials are beneficial and practical in many circumstances, but they also have disadvantages. Pin tract infections may occur or the pin may be inadvertently removed with potential loss of stability at the surgical site. Also, protruding wires are certainly not attractive to the patient and may cause increased anxiety. The ideal fixation material is not available at this time. Therefore different materials for various situations are being studied and utilized.

Absorbable devices have been considered for different types of fixation for many years. Originally, natural absorbable material such as an autogenous onlay bone graft was used. This is a means of absorbable fixation, but is not the focus of our current discussion. Presently, there are various biodegradable synthetic polymers being used for internal fixation. These polymers will be reviewed with reference to past and present research and current availability. The purpose of this presentation is not to promote or disrepute absorbable synthetic devices, but instead to review what is available and evaluate usage.

MATERIALS

"Polymers are macromolecules composed of many repeating units (monomers) that have carbon atom backbones, although oxygen, nitrogen, silicon, and sulfur also can be present."[3] A chain of identical monomers is a homopolymer, whereas a combination of two different monomers is a copolymer. There are several polymers that are used for absorbable fixation devices. Polyglycolic acid (Dexon), polylactic acid and polyparadioxanone(PDS) are synthetic homopolymers. Polyglactic acid is a copolymer composed of polylactic acid and polyglycolic acid. These were originally marketed as sutures, but have also been used for fixation of fractures.[3]

Until synthetic polymers were produced, natural materials such as collagen and gut were the only available absorbable materials. Around 1965 polylactic acid (PLA) was produced as the first synthetic absorbable suture. It had good handling characteristics but it took two years to absorb, and therefore was not marketed. In 1970 polyglycolic acid (Dexon) was introduced and approximately three years later, the copolymer of polyglycolic and polylactic acid (Vicryl) was produced.[4] Dexon and Vicryl are almost identical when considering tissue reaction and absorption of the sutures. In the early 1980's a fourth absorbable suture, polyparadroxanone (PDS), was marketed. PDS has superior properties when considering tensile strength and absorption time.[3,5]

The absorbable synthetic polymers are far superior to and more dependable than the natural materials such as collagen, gut and even bone.

Each of these synthetic polymers biodegrade by hydrolysis. PLA is degraded into monomers of lactic acid which become incorporated into the tricarboxylic acid cycle and is excreted by the lungs as carbon dioxide and water. PGA is broken down to glycolic acid monomers and excreted in the urine or used by the body.[3]

With Vicryl and Dexon, studies have shown that at two weeks post-implantation, approximately 55% of the original tensile strength remains. At three weeks, approximately 20% of its original strength is retained. PDS which has prolonged retention of tensile strength, retains approximately 70% of its strength at two weeks, and 50% at 4 weeks. Even at six weeks post-implantation this suture has 25% of its original strength, therefore its potential use in osseous fixation is better.[6, 7, 8]

EXPERIMENTAL STUDIES

Original use of absorbable devices for osseous fixation began in the early 1970's. At this time PLA, PGA and their copolymer were studied. "An ideal implant material for use in bone fracture fixation should be rigid, non-inflammatory, non-allergenic and remain until sufficient healing as occurred to withstand functional stress."[9] Through multiple experimental studies[10,11,12,13,14] with monkeys, dogs, and sheep, it was shown that PLA and PGA are slowly absorbed and well tolerated when used for osseous fixation. Fixation was achieved with absorbable pins, sutures, plates and screws. Adequate healing was noted in each instance. There were no detrimental defects observed, and the degradation process did not interfere with osseous union and healing.

In these early experiments, the time of absorption was considered important. Cutright, et.al.,[15] realized that the absorption rates could be altered with various mixtures of copolymers or the use of different homopolymers. He used different proportions of PLA and PGA in the copolymer to develop an ideal material which would sufficiently fixate bone fragments for four to ten weeks and yet dissipate rapidly. Homopolymers require a longer period to resorb, with PGA being absorbed slower than PLA.

In the early studies, little emphasis was placed on the tensile strength of these absorbable devices. Even though it was shown that absorbable devices were adequate for mandibular fractures, no studies indicated the possible usage in long bones. There was little progress in absorbable implant usage for many years in that area. More recently clinical success has been achieved at Helsinki University Central Hospital using biodegradable fixation devices. A study[16,17,18] beginning in 1984 was done utilizing a self-reinforced PGA/PLA copolymer and then self-reinforced PGA rods to compare the results with AO fixation in displaced malleolar fractures. All malleolar fractures displaced greater than two millimeters were managed by open reduction with internal fixation using either the biodegradable implants or AO metal screws and plates. The fixation device was randomly selected.

Properties of these materials had been previously studied experimentally both as sutures and as possible fixation devices. The original PLA/PGA copolymer was shown to have adequate mechanical properties, but after further *in vitro* studies it was found that the self-reinforced PGA rods had better initial strength and strength retention after four weeks than did the PLA/PGA copolymer rods.[19,20] Therefore, the material was changed to the superior material (self-reinforced PGA rods) midway in the study.

The implants used were constructed into cylindrical rods with a diameter of 3.2 or 4.5 mm and between 50 to 70 mm in length. The 3.2 x 70 mm rod has an initial flexural strength of 370 mmPa, a value higher than the yield strength of comparable metallic implants. At two weeks, one half of the flexural strength is lost, but the shear strength of the rod at five weeks is still higher than that of cancellous bone.

After use of the biodegradable implant in 102 patients with displaced malleolar fractures, it was concluded that both anatomical and functional results of biodegradable fixation and conventional osteosynthesis with metal were equal. When compared with results that have been achieved with non-rigid metallic fixation such as cerclage wire and staples and pins, biodegradable fixation was superior. The disadvantages of biodegradable materials in comparison to rigid metal is that early mobilization of the ankle joint cannot be performed with absorbable devices.

The favorable results of biodegradable implants in ankle fractures have led to their routine use at Helsinki University Central Hospital. This approach decreases the need for a second surgery, and therefore, reduces overall expenses. These rods are now marketed in Europe as Biofix.[20] They are not presently available in the United States.

CLINICAL USE

PDS has become a popular choice for material used as an absorbable device because of its mechanical properties. Today, the sole absorbable device marketed, Orthosorb absorbable pins, is made of PDS.[21] There have been attempts to produce screws or dowels with PGA and polyglactin in order to attain fracture stabilization, but most reports have only been experimental. Clinical efforts were thwarted with

these other polymers due to rapid absorption.

Orthosorb absorbable pins which are now marketed in the United States were originally marketed in 1985 in Europe by Ethicon of Germany under the trade name Ethipin. Many experimental studies were done at that time to determine its efficacy as a fixation device. In 1985 Greve and Holste[22] evaluated the PDS splints as an option to K-wires, mini surgical screws, and fibrin adhesives for fixation of small bone or osteochondral fragments. In 18 osteochondral fragments produced in rabbits, it was shown that PDS rods maintained stability and allowed for healing. They also showed that the fixation of the rods in the bone was strengthened by the surrounding bone after a short time. In 1986 Claes, et. al.[23] agreed with Greve and Holste that sufficient mechanical stabilization is achieved with PDS rods for fixating osteochondral fragments. Their experiments were done using sheep.

In 1985, the "Berufsgenossenschaftliche Unfallklinik" in Frankfurt, Germany used PDS splints for fixation of hand fractures.[24] Thirteen fractures including phalangeal fractures and metacarpal head fractures were successfully fixated. No defective healing, infection of bone, or dislocation was seen.

The material of Orthosorb, PDS, is the same material that has been successfully used for several years as suture material. The pin will be completely absorbed in approximately six months. It maintains approximately 85% of its tensile strength at two weeks post-op and approximately 60% of its tensile strength at four weeks post-op.[21] With these properties the pin gradually loses its tensile strength as the bone gains its strength. The idea of stress protection with secondary osteoporosis is lost.[25]

The Orthosorb absorbable pin is well accepted by the body as is the PDS suture. There has been no reported adverse tissue reaction including rejection, irritation, encapsulation, and inflammation. The FDA has approved the use of these devices for fixation of small bony or chondral fragments in the knee and hand. It is also approved for fractures of the base or head of phalanges and metacarpal fractures.[21] Even though approval has not been granted for more extensive use, this device could be ideal for other locations in the body and presently its use is being studied and submitted for approval. A fracture or osteotomy of any location that is moderately stable could benefit from this device. The Orthosorb pin will add stability and assure adequate healing.

In podiatry there is great interest in using the Orthosorb pins for stabilizing various osteotomies, and for interphalangeal joint fusion in hammertoes. At this time no literature is available, but studies are in the process of being submitted for publication. Michael Trepal, D.P.M. and Grant Braly, M.D.[21] are investigating the use with Austin osteotomies for submission to the FDA with the hope of gaining FDA approval. Encouraging results have already been achieved using Orthosorb pins for fixation of Austin osteotomies. Blackwell and Francis[26] have performed over fifty Austin osteotomies with Orthosorb fixation without complication. The osteotomy is fixated with two Orthosorb pins in a crossed fashion. This gives adequate stabilization, and primary bone healing occurs. The patient is allowed to ambulate weight bearing immediately post-operatively.

The Orthosorb pin has also been used for fixation of Reverdin - Laird osteotomies, Akin osteotomies, and tailor's bunionectomies. Blackwell and Francis[26] have only performed a limited number of these procedures, but again results have been encouraging with the exception of one Akin procedure. The patient experienced a secondary trauma to the toe after the procedure and the osteotomy did not heal. A second procedure with cross K-wire fixation was warranted. Digital fusion is another possible option of Orthosorb pin use, but there is no available data on results of this procedure.

The use of Orthosorb pins is advantageous in many ways. Compared with percutaneous K-wire fixation, the pin has no external exposure, therefore pin tract infections will be eliminated and the risk of pain and displacement from accidental movement is decreased. The patient will not experience anxiety from pin removal and may have a better acceptance of an internal device. Compared with buried K-wires and screws, the Orthosorb pin does not necessitate a second surgery for removal. In addition, the Orthosorb pin will not give continued stress protection as do rigid fixation devices.

Disadvantages to the Orthosorb pin are also known and should be considered before performing the surgery. The pins are very expensive. They are non-radiopaque, and therefore placement of the pin cannot be evaluated post-operatively. The Orthosorb pin has less flexural strength than do K-wires and screws, therefore if the surgical area were subjected to a significant disruptive force, there could be an easier displacement of the fracture. When used for digital fusion the option of removing the pin post operatively in a vascular compromised digit is lost. Finally, the pin cannot be used in osteoporotic bone or for fractures in which the anticipated healing period is protracted. Currently there is no data available with regard to the performance of these devices in the face of bone infection.

CONCLUSION

In summary, the idea of absorbable devices has been considered for many years. With the advancement of polymer technology many materials have been used. Even though initial studies for many materials were encouraging, there was little subsequent documentation of results and surgeons are reluctant to change from previously acceptable methods. The newly manufactured Orthosorb absorbable pin does have potential and may gradually become of use with various situations. At present it is not approved for use in the foot, but approval is likely in the near future.

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