Applications of a resorbable interbody spacer in posterior lumbar interbody fusion

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Polyhydroxy acids are a promising class of resorbable materials with potential applications in spinal surgery. One such polymer, MacroPore (MacroPore Biosurgery, Inc.), offers a balance of strength, predictable degradation, lack of stimulus of foreign body reaction, and biocompatibility with neural tissue. MacroPore can be formed into an array of shapes and can be manufactured, sterilized, and stored using conventional techniques. Limited clinical experience has been gained with resorbable implants used as load-sharing devices in a posterior lumbar interbody fusion construct.

Key Words • bioabsorbable implant • spinal fusion • lumbar spine

Implants placed during spinal fusion have several functions. Pedicle screw rod or plate systems utilized in conjunction with a posterior intertransverse bone graft maintain spinal alignment and provide immediate structural stability, thereby allowing early mobilization of the patient while promoting arthrodesis. The bone graft is not under compression, and significant stress is placed on the hardware, particularly in the presence of deficient anterior column support. Both of these factors may contribute to some of the failures seen after spinal fusion. On the other hand, a bone graft or spacer device placed in the anterior column can function both in a direct load-sharing manner and in providing temporary segmental stability through distraction of a disc space with the resulting tensioning of the anulus fibrosus. Such an interbody spacer can be placed through anterior, lateral, posterior, or transforaminal approaches, utilizing both open and endoscopic techniques. Although stand-alone procedures are still performed, interbody constructs are generally supplemented by posterior instrumentation, a 360° procedure, and high rates of fusion have been reported with these techniques. Regardless of the manner of insertion, the spacer must function until the formation of a solid bone bridge through the former disc space is complete.

A variety of materials have been explored for use in filling the defect that results after preparation of the disc space for interbody grafting. The gold standard has been autologous iliac crest graft, which has osteoconductive and osteoinductive properties in addition to its structural function. In many cases, there may be inadequate bone remaining because of previous graft harvest. Iliac crest may not be strong enough for the planned construct (especially in the elderly or osteoporotic case) and the harvest of an adequate-sized graft may not be possible. In addition, there has been appreciable morbidity and long-term pain associated with iliac crest harvesting. Allograft bone has been used for this purpose, but concerns of infection and graft strength remain (depending on the methods of harvest and processing). Also, problems of inadequate supply in some countries and cultural prohibitions against allograft in other countries make this option less desirable.

Both titanium alloy and stainless steel have been shaped into a variety of spinal implants. Although both of these metals have performed well in primary function, there are drawbacks such as stress shielding due to the excessive rigidity and permanence of the constructs that can in turn lead to bone resorption and osteopenia. Corrosion, wear debris, and rare allergic reactions have been seen, more so with stainless-steel implants. Imaging studies on metallic artifact can obscure anatomical detail and cause diagnostic dilemmas such as in the assessment of fusion. When necessary, explantation of metallic hardware in the interbody location can be challenging. Carbon fiber constructs are radiolucent and may be better matched to bone in terms of the modulus of elasticity, but they are nonresorbable and have not gained widespread acceptance in spinal applications.

Bioresorbable polymers have been explored as replacements for metal, bone, and nonresorbable synthetic materials in recent years. Biodegradable implants eliminate the need for explantation. In addition, these implants can reduce stress shielding by having a better match of strength and elasticity to bone, as well as by gradually reducing the
Resorbable interbody spacer in lumbar fusion degree of load sharing as the structural integrity of the device is lost.4,14,24 Biodegradable polymers minimize complications of metal corrosion, debris, and imaging artifact. This article reviews the properties and potential uses of spacers fashioned from one class of such polymers, the polyhydroxy acids, in PLIF procedures.

**General Characteristics of Polyhydroxy Acids**

Biodegradable materials are man made and degrade to byproducts that are found in the body such as metabolites or tissue constituents. These materials have been used to manufacture sutures10 but have been increasingly used in orthopedic trauma surgery, craniofacial reconstruction, and drug delivery systems.1,28 Biodegradable materials must not induce significant inflammatory reactions, must not be carcinogenic, mutagenic, or teratogenic, and must not cause allergic or toxic responses.14,28 Fashioned into an implant, the material must maintain adequate biomechanical properties for a length of time suitable to its function in the construct.1 The material should degrade at a rate that allows for the metabolism and clearance of the byproducts. Ideally, the material should be able to be shaped, stored, and sterilized using common techniques.14 Polyhydroxy acids are polymers that are the best known and most studied resorbable materials for implantation. Their mechanical and physical properties depend on the constituents of the polymer.14 The primary degradation is caused by the mechanism of random, bulk hydrolysis of the ester bonds between the molecules of the chain. The monomeric acids that result from this process are subsequently metabolized via the Krebs cycle to carbon dioxide and water (Fig. 1).14 As degradation proceeds, the implant will begin to fragment, with the expected loss of strength. Once the polymer has been reduced to fragments of low molecular weight, there can also be a variable contribution of phagocytosis and enzymatic activity in the final degradation of the material.15

The most common polyhydroxyacids are composed of PLA, PGA, or a mixture of both, although there are many other closely related compounds that have similar characteristics.14 No significant toxicity, carcinogenicity, teratogenicity, or mutagenesis has been associated with either PLA or PGA.4,28

The implant resorption time is most affected by the chemical composition of the polymer, but there are many additional variables in this process.1,28 Gogolewski et al.14 have identified the physical structure and mass, polymeric molecular weight, chain orientation, and presence of additives of the implant as factors influencing the rate of degradation, along with the stress on the implant and the characteristics of the implantation site. For example, an implant placed under significant load in a highly vascularized site will likely degrade at an accelerated rate.5 Generally, PGA polymers degrade more rapidly than PLA polymers, with copolymers being intermediate.28 The specific requirements of the implant depends on which polymer is preferable.14 The mechanical properties of the implant are determined by the conditions of the synthesis and processing of the polymer, along with the other factors that have already been discussed.1,14 Implants with better mechanical prop-

![Fig. 1. Schematic illustration of the degradation of a prototypical resorbable polymer. Certain intermediate products of degradation can also be excreted in urine.](image-url)
Hydrosorb can be formed into a variety of shapes, and it can be stored and sterilized using conventional techniques. It can be heated and shaped to conform to the actual site of implantation, and it will hold the desired shape once cooled without loss of structural integrity.

Hydrosorb devices cannot be readily visualized on routine radiography, although the devices can be seen distinctly on computerized tomography scans prior to significant degradation. Polyactic acid implants do not degrade the quality of MR images, and MR imaging has been used to evaluate the tissue response of PLA implants. Polyactic acid implants are visible on MR images as areas of homogeneous low signal intensity, which can be distinguished from the high signal intensity of the adjacent bone.

Early Clinical Experience With Resorbable Implants

Hydrosorb sheets have been used to reconstruct iliac crest donor site defects. Iliac crest reconstruction may diminish pain, prevent bowel herniation through large defects, improve cosmesis, and improve donor site regeneration. The benefits of a protected healing space have been recognized in promoting optimal bone healing. Specifically, if soft tissue is prevented from prolapsing into a bone defect, the regrowth of bone may be better than that with graft materials alone. In terms of the iliac crest, once the bone is harvested, the donor site is back-filled with allograft or bone matrix material if desired. A MacroPore sheet is then heated to 70°C, contoured to the defect site, and allowed to cool. It is then secured using screws or tacks. This is an example of the potential use of MacroPore as a barrier-type implant.

Limited experience has been gained in the use of Hydrosorb as a load-sharing device in spinal fusion constructs. We have previously reported the off-label use of Hydrosorb cement limiters in an instrument-assisted PLIF in 15 patients. All patients suffered symptomatic, one-level lumbar spondylosis or Grade I spondylolisthesis, had failed conservative treatment, and were considered candidates for a fusion procedure. Cement limiters are plugs that are placed in the medullary cavity of a bone adjacent to an arthroplasty to block unwanted spread and allow pressurization of polymethylmethacrylate cement, and improve the performance of the implantation of the intramedullary device. Cement limiters have been manufactured in a variety of materials and are available in a range of shapes and sizes. Recently, experience has been obtained with the use of bioresorbable cement limiters in the femur during hip arthroplasty; they seem to perform as well as those made of nonresorbable materials.

In this PLIF application, the devices are placed bilaterally in a manner similar to impacted allograft bone, following appropriate osteous decompression, complete discectomy, and disc space distraction. Morselized autograft bone is packed both within and around the devices. Preliminary results show equivalent clinical outcomes at 6 months to those obtained in a historical cohort of patients with allograft bone spacers, and ongoing follow-up has now reached 1 year with the same conclusion (unpublished data). The devices produce no artifact on postoperative imaging, allowing better visualization of the maturing bone fusion. Serial radiographs demonstrate maintenance of the disc space height during the early phase of bone healing, consistent with the known rate of degradation of this material.

Discussion

Ralph Cloward, M.D., was one of the first surgeons to recognize the advantages of and to apply interbody fusion in the treatment of lumbar degenerative disease, beginning in the 1940s. He was able to achieve successful fusion rates using either autograft or allograft placed via a PLIF technique. Although his results have been confirmed by other surgeons, the "carpentry" involved in his technique was demanding and it was never widely adopted within the spine surgery community. With the introduction of posterior instrumentation systems, this technique was abandoned. In the 1990s, better understanding of the biomechanics of the spine, growing dissatisfaction with both clinical and radiological outcomes of posterior intertransverse fusions in the treatment of degenerative spondylolisthesis and the regulatory status of the pedicle screw led to a renewed interest in the interbody fusion.

A search for more reproducible alternatives was prompted by difficulties with obtaining adequate autograft or allograft, because the procedure was time consuming, and because obtaining the precise shape and the insertion process of the grafts was also difficult. Successful outcomes obtained in preclinical studies with the use of stand-alone, titanium cylindrical cages placed via a PLIF led to rapid Food and Drug Administration clearance and widespread adoption of this procedure. In some cases, strict patient selection criteria and careful adherence to recommended insertion protocols were not followed, which led to an unexpectedly high construct failure and revision rate. The titanium nature of these devices made revision and removal challenging, as well as hampered the assessment of the progress of fusion.

In response to these complications, the traditional technique of allograft PLIF has been modified. Preformed cortical allograft bone grafts have been developed, as have specialized instrumentation systems that facilitate safe and precise insertion. Similar to the allograft anterior lumbar interbody fusion, these grafts are supplemented with autograft and segmental fixation devices, and high rates of fusion have been reported. Fusion assessment is easier without the metallic artifact in the disc space. A critical shortage of suitable allograft bone continues to hamper the spread of this technique in the United States. Worldwide, cultural and supply-related problems exist with the use of

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**TABLE 1**

*Values are based on results obtained at MacroPore Biosurgery, Inc.*

<table>
<thead>
<tr>
<th>Degradation Time</th>
<th>Strength (%)</th>
</tr>
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<tbody>
<tr>
<td>implantation</td>
<td>100</td>
</tr>
<tr>
<td>6 mos</td>
<td>100</td>
</tr>
<tr>
<td>9 mos</td>
<td>100</td>
</tr>
<tr>
<td>12 mos</td>
<td>97</td>
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Resorbable interbody spacer in lumbar fusion

allograft. For these reasons, a search continues for synthetic materials with the necessary characteristics.

Extensive experience has been gained with polyhydroxy acid implants in Europe, particularly in orthopedic trauma applications. In spinal applications, bioresorbable materials can serve as interbody spacers and fixation devices. In both applications, once the support or tension-band functions have been fulfilled and the fusion has matured, the “hardware” has no further function and hinders imaging studies by the creation of artifact. The biomechanical demands on an interbody spacer are considerably less than those of a fixation screw/plate construct. The gradual degradation of an interbody graft may promote arthrodesis by exposing the maturing interbody bone to increased load sharing. This is opposed to the stress riser at a screw–rod junction, which may significantly alter the expected local degradation rate of the biopolymer and lead to sudden catastrophic failure of this type of implant.

Summary

The versatile nature of bioresorbable material allows it to be formed into cages, dowels, and interbody spacer shapes. In addition, its desirable strength and degradation characteristics, lack of artifact on imaging, low potential for foreign body reaction, and the biocompatibility with the dura and nervous tissue make it a promising material for this application. Although the challenges are greater, it is likely that resorbable polymers can be developed into other spine fixation systems. Because such implants may have to be bulky to meet biomechanical needs, there may be problems with foreign body–type reactions in the terminal degradation phase. Early potential applications in the spine might be screws for C1–2 transarticular, lumbar transfacet, or odontoid fixation, as well as interference screws for anterior interbody grafts. Small, nonconstrained plating systems intended to provide a cervical tension-band effect can also be envisioned.

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