Osteochondral lesions of the femoral condyle continue to pose a treatment problem to orthopaedic surgeons. Small lesions can be treated by marrow stimulation, osteochondral autografts, or autologous cartilage transplantation.31,42,52 Adult patients with stable lesions can be treated by drilling and fixation.34,47 In patients with open physes, stable chondral lesions can be treated by observation.3 Unstable lesions should be stabilized.58 Anderson and Pagnani demonstrated that treatment by excision alone may result in pain and degenerative changes.2 Ideally, fixation should provide compression and not require subsequent hardware removal surgery after healing has occurred. Traditional osteochondritis dissecans (OCD) lesion fixation has used metal implants, including Herbert and other screws10,13,20,28,40,48; various types of pins25,27,35; and metal staples.32 Depending on the implant configuration and method of application, compression may be achievable, but such implants generally require removal after healing because of the potential for joint damage from prominent hardware, which may result in complications.20,35,40 Furthermore, the presence of metal implants causes MRI interference.24,53 Autologous bone sticks or pegs have also been used,41,81 but their preparation requires valuable surgical time, their configurations are limited, and compression may not be possible.

Alternatively, devices made of synthetic absorbable polymers that obviate a removal surgery have been used for internal fixation since the early 1990s82 and have recently been applied toward the stabilization of OCD.
lesions. Most such devices are made from poly-\(\alpha\)-hydroxy acids that include poly(glycolic acid), or PGA, and poly(D or L-lactic acid), ie PLLA or PDLLA. Although it has been reported that the degradation products that form from absorbable polymers can elicit an inflammatory reaction, it is now known that there may be both implant material and implant-site predictors that can be applied to minimize this occurrence. Thus, when applying a bioabsorbable fixation device to a new clinical application, the clinician should be aware of the ability of the device to affect healing as well as be alert to any untoward biological response to the material.

LactoSorb (Biomet Inc, Warsaw, Ind), a PGA/PLLA copolymer, currently has a variety of extra-articular indications in orthopaedic and maxillofacial surgery and appears to be well tolerated. These screws, which have a low-profile head, are potentially well suited to the fixation of OCD lesions in the knee. The goals of this study were (1) to characterize the mechanical and in vitro absorption properties of a 2.5-mm-diameter LactoSorb copolymer screw and (2) to determine the clinical efficacy of using this screw to fix OCD lesions in a small patient cohort with clinical and radiographic healing taken as the endpoint.

**MATERIALS AND METHODS**

Biomechanical Testing of LactoSorb Screws

LactoSorb copolymer is a random copolymer of PGA and PLLA in an 18:82 molar ratio. It has a molecular weight of approximately 60 kDa and an inherent viscosity of approximately 1.6 dL/g at 30°C in chloroform. The polymer is oriented before machining the screw geometry. Orientation increases the strength in the longitudinal direction, yielding better performance in shear, bending, and tension. The LactoSorb copolymer screws tested in vitro were 2.5 mm in diameter x 7 mm in length (see Figure 1). The screw contains an auxiliary hex head that mates with the driver. When introduced into the pretapped hole, the screw is advanced until the primary head reaches the bone surface. The continued application of torque then shears off the hex head. The synthetic bone block used was composed of a dense, 3-mm-thick glass, mesh-filled epoxy cortical layer bonded to a 29-mm-thick, closed-pore (0.5-1.5 mm) foam polyurethane cancellous region (part 3002-1, Pacific Research, Vashon Island, Wash). The properties of this substrate are compared with those of human bone in Table 1. The substrate was cut into blocks that were 152 mm x 25 mm x 32 mm thick. Multiple 2.2-mm-diameter holes, 17 mm apart, were drilled perpendicular to the cortex, completely through the substrate. The holes were tapped the entire length with a 2.5-mm-diameter tap having a thread form identical to that of the screws. Screws were engaged in the hole as described earlier, with the exception that sufficient space was left beneath the primary screw head to permit placement of the appropriate steel loading fixture (see later). In this fashion, the hex head was left in place on the screws and had no influence on the test.

Pull-out testing was performed by placing a steel fixture with a 2.7-mm-diameter slot (smaller than the primary head diameter) around the screw shaft, in the space between the primary screw head and the substrate surface. The upper portion of the fixture was gripped by the movable crosshead of a Sinetech 1/S mechanical test system (Sinetech Inc, Research Triangle Park, NC). With the substrate held stationary, the crosshead was engaged to move upward at the rate of 30 mm/min, imparting an extraction force parallel to the axis of screw insertion (see Figure 2). Failure load and failure mode were recorded. Shear testing was performed similarly to pull-out testing with the exception that the load was applied in a direction parallel to the substrate surface or perpendicular to the screw axis (see

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**TABLE 1**

Properties of the Synthetic Bone Substrate Compared to Human Bone

<table>
<thead>
<tr>
<th></th>
<th>Synthetic</th>
<th>Human</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cortex(\text{a})</td>
<td>Cancellous</td>
</tr>
<tr>
<td>Specific gravity</td>
<td>1.82</td>
<td>0.14</td>
</tr>
<tr>
<td>Modulus</td>
<td>16.9 GPa</td>
<td>18.8 MPa</td>
</tr>
<tr>
<td>Compressive strength</td>
<td>328 MPa</td>
<td>1.52 MPa</td>
</tr>
<tr>
<td>Tensile strength</td>
<td>259 MPa</td>
<td>N/A</td>
</tr>
</tbody>
</table>

\(\text{a}\)Data supplied by Pacific Research.
Substrate blocks, with the implanted screws, were incubated in pH 7.4 phosphate buffer at 37°C for up to 12 weeks. At intervals of 2 weeks, blocks were removed and the screws were tested. Five replicates were performed, for each test, per time point. The significance of the difference between means was determined by analysis of variance followed by the Student-Newman-Keuls test at $P < .05$.

**Clinical Protocol**

Between February 2000 and February 2001, 7 patients—6 male and 1 female—showed symptoms attributable to OCD in the knee. The age range was 17 to 46, averaging 25.6 years. In the youngest patient, the physis was closing. In all patients, the physes were closed. All experienced an acute onset of symptoms after a twisting injury and complained of pain. Locking or catching was noted in 6 patients. One patient noted only an audible click as the knee went into terminal extension. Four of the 7 patients complained of swelling. Focal tenderness to direct palpation of the lesion (Axhausen sign) was present in 4 patients. The injury was associated with an effusion in 6 of the 7 patients. After the injury, the patients were unable to return to normal activities. The OCD lesion was noted on routine radiographs in all 7 patients. In all cases, the lesion was located on the lateral aspect of the weightbearing surface of the medial femoral condyle. The sizes of the lesions ranged from $1.5 \times 3$ cm to $2.4 \times 4.0$ cm. An MRI was performed to further delineate the size and potential loosening of the fragment. The OCD lesions were defined as unstable if on the MRI there was an area of high signal intensity beneath the lesion. The articular cartilage overlying the lesion was violated in each case. In none of the patients, however, was the OCD body loose in the joint. In all patients, an articular cartilage hinge remained on 1 side of the lesion. Based on clinical evaluation, radiography, and MRI, the OCD lesion was determined to be unstable but still present in its bed in all 7 patients. Nonsurgical treatment was not attempted.

All patients underwent an arthroscopic evaluation. The OCD lesion was probed and confirmed to be unstable in all 7 patients. The lesions were then treated through an open median arthrotomy. The unstable fragment was elevated and its bed curetted to bleeding bone. There was significant subchondral bone present in all of the OCD fragments. The amount of bone was substantial enough to be secured with internal fixation. Patients treated in the same time period whose OCD fragments did not have significant bone were not included in the study. Drill holes were placed in the bed to stimulate vascular ingrowth; the lesion was then reduced. If the reduction was not congruent at the edges of the lesion (indicating bone loss), the lesion was bone grafted. A bone graft was used in 4 of the 7 patients.

The bone graft was obtained by curettage through a drill hole in the proximal medial tibia. The bone graft was packed into the base of the defect. The osteochondral lesion was then reduced and temporarily fixed with K-wires. LactoSorb screws of 2.5 mm diameter and 21 to 27 mm length were inserted to stabilize the lesion after drilling with a 2.2-mm drill bit and tapping. The bone in the fragment was not overdrilled in a lag fashion. Because the screw hole is pretapped, the screw heads in most cases countersink themselves beneath the cartilage surface before the hex head snaps off. In the approximately 10% of
cases in which the head remains prominent, the screw can be countersunk with a tool in the instrument set called a spanner. Alternatively, a prominent head can be leveled with a heated wire loop, which comes in the instrument tray or a rongeur. Two screws were used in 2 patients and 3 screws in 5 patients. After reduction and fixation with the bioabsorbable screws, the knee was carried through a range of motion to check for stability and congruency of the reduction. Postoperatively, patients were placed on a continuous passive motion machine and allowed full range of motion. The patients were kept nonweightbearing for 6 weeks; weightbearing was then initiated. Between 9 and 12 months, an MRI with intra-articular gadolinium was performed to evaluate healing of the OCD lesion. All 7 patients were seen at follow-up, and Tegner\textsuperscript{57} and Lysholm\textsuperscript{36} scores were obtained.

RESULTS

Figure 4 shows the results of the mechanical testing. The initial average peak pull-out and shear loads were 20.1 kg and 22.3 kg, respectively. The pull-out strength did not significantly differ from the initial value until the 4th week. By contrast, the shear strength did not significantly decrease from its initial value until the 10th week, demonstrating that the strength loss profile for an oriented absorbable polymer undergoing hydrolysis is dependent on the nature of the mechanical strength measurement. In both cases, there was more than a 90% strength reduction by the 12th week.

The failure mode for the shear test was complete separation of the screw into 2 components, with a shear plane perpendicular to the screw axis, as expected. For the pull-out test, the failure mode varied with the in vitro incubation time. Three failure modes were identified: for mode 1, the sides of the primary screw head were sheared off by the load-application fixture, with the rest of the screw remaining intact and implanted in the substrate; for mode 2, the entire primary screw head separated from the screw shaft, with the balance of the screw remaining implanted; and for mode 3, the entire screw pulled out of the substrate. All screws exhibited a mode 1 failure with the exception that at 2 weeks, 1 screw each exhibited a mode 2 and a mode 3 failure, whereas 1 screw at 4 weeks exhibited a mode 3 failure. Thus, with the exception of 2 screws, the screw thread/substrate interface strength was greater than the measured failure loads.

The average follow-up in the 7 patients was 2.6 years (range, 2.1-3.1 years). Six of the 7 patients healed clinically, denying pain, catching, giving way, or swelling. The lesion in the seventh patient, who was 1 of the 3 who did not receive a supplemental bone graft, failed to unite and became a loose body, requiring surgical excision. The patient whose OCD lesion dislodged had a final Lysholm score of 75. The Lysholm scores in the remaining patients ranged from 87 to 94, with an average of 91. These 6 patients returned to their preinjury level of activity; their activities involved impact-loading competitive sports including football, basketball, volleyball, soccer, and track. Three classified as Tegner level 7 and 3 as Tegner level 8. All 7 patients had full range of motion. Three patients developed a slight effusion during the first 4 weeks after surgery. These were routine postoperative effusions, and all resolved without intervention. There were no cases of recurrent effusion, warmth, or erythema that could indicate an inflammatory reaction to the bioabsorbable implant. None of the patients had an effusion 6 weeks after surgery. There was no radiographic evidence of arthritic change in any of the 7 knees at follow-up. However, the duration of follow-up is much too short to determine the incidence of degenerative joint disease.

Follow-up MRIs were available for 5 of the 7 patients. The MRIs were performed between 9 months and 1 year after surgery. No artifacts attributable to the presence of the absorbable screws were noted. In all patients who had an MRI, there was evidence of healing of the OCD lesion. The MRIs, all of which had intra-articular gadolinium, showed an absence of contrast between the lesion and the condylar bone. There was also an absence of bony edema and contiguous articular cartilage on the articular surface. The patient who developed the loose body did not receive a follow-up MRI. The radiographs and MRI images are included in Figures 5 through 10.

DISCUSSION

The natural course of OCD is progressive avascularization of the lesion and separation from the femoral condyle by a fibrous interface, allowing little potential for union. This underlies the difficulty in effective treatment.\textsuperscript{14} Nevertheless, in the current study, an excellent clinical outcome was obtained in 6 of 7 (86%) patients. In recently reported series using various forms of fixation, good and excellent results have ranged from 78% to 88%.\textsuperscript{14,28,48,60} Thus, the clinical results obtained in this study compare favorably to those obtained by other investigators using traditional means (Herbert screws) or alternative means (bioabsorbable fixation) to stabilize OCD lesions.
In vivo degradation of bioabsorbable polymers occurs in a 2-stage process.46 First, the polymer hydrolyzes, whereby water molecules act to depolymerize the material, reducing the molecular weight. Second, macrophages phagocytize the low molecular weight debris and metabolically convert it to water and carbon dioxide. The following temporal sequence of events occurs: (1) a reduction in molecular weight, (2) a reduction in mechanical strength, and (3) a reduction in mass to eventually complete mass loss in the ideal situation.46 Thus, the in vitro strength loss profiles of the 2.5-mm-diameter LactoSorb screw are only an approximation of the in vivo degradation rate. Whereas the physiological pH and temperature in the model system can be expected to reasonably reproduce the initial polymer hydrolysis that occurs clinically, a metabolic response cannot be evoked. In general, the primary types of forces that screws are designed to resist are pull-out, shear, and bending. Pull-out and shear tests were performed to broadly characterize the strength and strength loss properties of the 2.5-mm-diameter LactoSorb screws. As such, the mechanical test protocol was not specifically designed to mimic the loading pattern in the knee, which would be expected to be a cyclic combination of gliding, compressive shear across the screw head. It should also be noted that the reduction in mechanical strength occurs before the reduction in mass. Although screw material may remain for 15 to 17 months,1 the mechanical strength of the screws is greatly decreased after 8 weeks.

The use of synthetic substrates in the testing of internal fixation screws is an established method.45 This usage is due to the inherent variability of cadaveric bone and the high reproducibility with which synthetic substrates can be produced. Ideally, the mechanical properties of the synthetic substrate should reasonably match those of the bone that it is simulating. However, because of the widely varying viscoelastic and anisotropic properties of bone, at best the mechanical properties of the synthetic substrate should be in the expected range. Most of the properties of the synthetic substrate we chose are within or close to the ranges cited in the literature for human bone. For the purposes of the in vitro portion of the study, the synthetic substrate provided a uniform medium in which to monitor the deterioration of the mechanical properties of the bioabsorbable screws. Although it is difficult to state with confidence that screw performance would be quantitatively identical in both the synthetic substrate and normal human subchondral bone in the femoral condyle, it is likely that there would be qualitative agreement in the temporal profile of the 2 regimens.

The initial pull-out and shear strength of the screws was about 20 to 22 kg, with measurable, but little, strength remaining by the 12th week. It is difficult to state with
Figure 7. T2-weighted sequence of MR arthrogram before surgery. Marrow edema surrounding osteochondritis dissecans fragment and presence of high signal intensity between the fragment and medial femoral condyle indicate an unstable lesion.

Figure 8. T1-weighted sequence of MR arthrogram before surgery. Sclerotic fragment and lucent rim between the fragment and medial femoral condyle.

Figure 9. T1-weighted sequence of MR arthrogram 1 year after surgery. Absence of an interface between the medial femoral condyle and osteochondritis dissecans and improvement of sclerosis of fragment indicate bony healing.

Figure 10. T2-weighted sequence of MR arthrogram 1 year after surgery. No marrow edema and absence of interface again indicate bony healing.
confidence that these initial strength values are both nec-

essary and sufficient for the proper fixation of OCD

lesions. It is possible that, given the small primary head
diameter of the bioabsorbable screws, the screw itself
could remain fixed within the subchondral bone, and the

osteocondral fragment could migrate past the screw

head. In 1 patient, the osteochondral fragment did not heal

and became a loose body. Whether this was due to break-

age of the screw and loss of fixation or migration of the

fragment past the head of the intact screw is unknown.

We have not measured the amount of compression gen-

erated with these screws. Others have compared the com-

pression generated with absorbable screws and similarly

sized metal screws in a cortical bone substrate.26 Whereas

initially, the amount of compression generated was com-

parable between the 2 types of screws, within 1 week, the

residual compression remaining in the absorbable screw

constructs was reduced by 80% to 90%, with only a 10% re-

duction in compression from the metal-fixed systems. In

the case of cancellous bone, however, there was rapid loss

in compression over a 2- to 4-day period in both the

absorbable and metal screw methods. This finding sug-

gests that, in the current study, little or no long-term com-

pression was maintained in the fixed OCD lesions be-

cause of stress relaxation in the bone, in the screws, or

both. It is possible that significant long-term compression

is not an absolute requirement for fixation of OCD frag-

ments. Overcompression can compress the articular sur-

face of the fragment below that of the remaining condyle.

It is necessary to capture the fragment and hold it reduced

in its bed until healed. We feel that fixation with threaded

devices with heads will capture the fragment and prevent

backing out more effectively than K-wire fixation.

As has been observed in earlier clinical studies with

LactoSorb copolymer,15-18,30 there was no evidence of any

inflammatory reactions or long-term effusions in this

patient series. Screws made of this material have been

shown to completely degrade and be eliminated from a

canine femur, both metaphysis and diaphysis, by 15 to 17

months. Eppele and Reilly investigated absorption of

plates and screws made of this copolymer in rabbit crania.

Two months after implantation, the hardware was com-

pletely intact; at 6 months, there was a 66% decrease in

the polymer slowly degrades, these crystals can release after

several years, causing a late-stage inflammatory reaction.5

Bølstad and Philtajamaki reported inflammatory reac-

tions in 0.2% of patients with PLLA implants versus 5.3% with

PGA implants.9 They described 1 case of a late inflamma-

tory foreign body reaction to a polylactide screw

occurring 52 months after implantation. Bergsma et al

reported on the swelling that occurred in 4 of 8 patients

treated for zygomatic fractures with PLLA plates and

screws from 3.3 to 5.7 years after implantation.5

Copolymers, such as LactoSorb, that contain both PGA and

PLLA domains have an intermediate absorption rate.46 Also, the randomness of their PGA and PLLA

domains precludes the development of significant crys-

talline regions. Both of these considerations are thought to

play a role in the relatively benign manner in which such

copolymers degrade in vivo.46

In addition to material considerations that can potenti-

ate inflammation, the nature of the tissue site also plays a

critical role. It is known that in regions of poor vasculari-

ty (eg, the scaphoid), the ability to clear the region of polymer

degradation products may be poor and possibly potentiate

an inflammatory response.5,6 In contrast, well-vascular-

ized sites such as the craniofacial skeleton appear to gen-

erally tolerate absorbable fixation well.15-18 There are, to

however, case reports of synovitis and gonitis in the knee

in response to bioabsorbable implants, which suggest that

such intra-articular placement is not a privileged loca-

tion. Barford and Svendsen reported on 2 cases of severe

synovitis in response to the intra-articular placement of

PGA rods in the knee after 8 and 13 weeks, respectively.4

Friden and Rydholm had a similar experience in 1

patient.21 Takizawa et al encountered a patient who devel-

oped foreign body gonitis caused by PLLA screw break-

age.30 Dervin et al documented 1 inflammatory sterile

effusion, resolved by aspiration, that had developed 5

months after surgery in 1 of 9 patients treated with 2-mm-

diameter PLLA pins in the knee.14 Tuompo et al treated 24

cases of OCD lesions with PGA pins in 12 patients, PLLA

pins in 11 patients, and both types of pins in 1 patient.50

At a mean follow-up of 3.3 years, synovitis occurred in 1

patient who had received PGA fixation, with no occurrence

in the PLLA group. The lack of inflammatory response in

the patients treated in the current study suggests that the

specific chemistries of the various bioabsorbable mate-

rials that are clinically available may significantly influence the

postoperative course in terms of tissue compatibility.

The use of absorbable screws does not necessarily pre-

clude problems associated with prominent hardware. For

instance, it has been observed that polyactic acid screws

may back out, causing abrasion of the opposing articular

surface.50 Subsidence of the cartilage around the screw

head can also cause the head to become prominent.25 In

addition, the portion of the screw that resides in the drill

hole may absorb faster than the screw head. This, in com-
bination with the mechanical forces imparted on the screw head during gait, may cause separation of the screw head and formation of an intra-articular loose body. Friederichs et al described 2 cases in which self-reinforced (oriented) 2.7-mm-diameter and/or 3.5-mm-diameter PLLA screws were used to stabilize the osteochondritic fragment. At 5 to 8 months after surgery, complaints of locking, pain, and swelling brought forth a second arthroscopy with the finding of a loose screw head that had broken off of the screw shaft. The screw material was still hard, without evidence of absorption or softening. Scioscia et al also described 2 cases in which such lesions were treated with 2.7-mm-diameter PLLA screws. After 6 to 12 months, the patients complained of pain and effusion. Follow-up arthroscopy revealed intra-articular bodies suggestive of broken screw fragments. The slow degradation of PLLA implants and the extended period of time over which they remain hard increase the risk that prominent screw heads or loose bodies derived from these type of implants may result in sequelae. No patient complained of symptoms consistent with a fragmented head floating in the joint in this study. The postoperative MRIs revealed that the screws had resorbed, with no prominent or remaining heads noted.

There are both general and specific advantages of the LactoSorb copolymer screw for use in OCD procedures. The general advantages are common to all absorbable screws for this application: (1) a second procedure for hardware removal is obviated, (2) an artifact-free postoperative MRI of the knee is obtainable if the need arises, and (3) improved fixation of the OCD fragment in its bed is obtained when compared with K-wire fixation. The PLLA/PGA copolymer has a degradation time intermediate between both PGA and PLLA copolymers. It will thus hopefully avoid both the inflammatory complications related to the rapid degradation of PGA and decrease the incidence of complications related to prolonged retention of hardware associated with PLLA implants. The screw also has a unique drive design that allows a very low-profile primary screw head to minimize the potential for abrasion of the opposing cartilage.

There are several limitations to this study. The number of patients is too small to identify the correct incidence of both complications and successful treatment. Two-year follow-up should be adequate to evaluate for inflammatory reactions with this screw; it is much too short of a follow-up period to evaluate patients for posttraumatic arthritis. This study is also limited by absence of a control group. The in vitro study is limited in that it was performed in synthetic bone rather than living bone. The evaluation of any reaction on the bony side that could have influence on the pull-out strength was not possible.

CONCLUSIONS

In our series of 7 patients in which fixation of OCD lesions was provided by 2.5-mm-diameter LactoSorb copolymer screws, a successful clinical and radiographic outcome was obtained in 6 patients (86%). This was corroborated by MRI in 5 patients. In 1 patient who had not been treated with supplemental bone grafting, the OCD lesion failed to heal and was removed. No acute inflammatory reactions were seen. Three patients had a slight effusion after surgery, but all resolved without treatment by 4 weeks after surgery. This suggests that the PGA/PLLA copolymer had not resulted in failure of the screw head/shaft junction and that no loose body reaction occurred. This study demonstrates that the 2.5-mm-diameter LactoSorb screws can provide adequate stability for the healing of OCD lesions without producing breakdown products that have resulted in acute inflammatory reactions.

REFERENCES


