TREATMENT OF SYNDESMOTIC DISRUPTIONS OF THE ANKLE WITH BIOABSORBABLE SCREW FIXATION

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Background: Bioabsorbable implants have restricted indications because of their unique biochemical properties and their inferior biomechanical properties compared with those of conventional metallic implants. The purpose of this prospective study was to assess the efficacy of screws made of polylevolactic acid (PLLA) in the treatment of syndesmotic disruptions associated with ankle fractures and fracture-dislocations.

Methods: Thirty-three consecutive patients with a syndesmotic disruption were managed with standard metallic plate-and-screw fixation of the malleolar fracture and with 4.5-mm polylevolactic acid screws, with purchase in four cortices, for fixation of the syndesmosis. Intraoperative radiographs confirmed reduction of the syndesmosis, and all of the patients were managed with a non-weight-bearing plaster splint or brace for six weeks. Clinical and radiographic assessment and functional evaluation with use of the Olerud-Molander scoring system were performed at the time of follow-up.

Results: Ten patients were lost to follow-up prior to the twenty-four-month evaluation, leaving twenty-three patients with an average duration of follow-up of thirty-four months (range, twenty-four to forty-three months). All of the malleolar fractures healed in an anatomical position at an average of three months, and no postoperative displacement of the syndesmosis or widening of the medial clear space was detectable on radiographs. No episodes of osteolysis or late inflammation secondary to the hydrolyzed polylactide occurred. Nineteen patients (83%) had an excellent result, and four patients (17%) had a good result.

All twenty-three patients returned to their preinjury level of work and activities of daily living. No patient had malunion, nonunion, loss of reduction, or complications attributable to the biomechanical or biochemical properties of the implants.

Conclusions: Polylevolactic acid screws are effective in stabilizing disruption of the syndesmosis during healing of unstable ankle fractures. In this small series, the bioabsorbable screw was well tolerated, and there was no need for a second operation to remove it.

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Each of these polymers has a different rate of degradation related to its chemical composition. The compounds may be drawn or molded into rod or screw shapes.

Because their mechanical properties are inferior to those of conventional metal implants, bioabsorbable implants have been used predominantly in fracture patterns in which internal fixation is subjected to minimal stress. These implants are more expensive than the metal equivalents and are therefore best used in situations in which a second procedure for the removal of metallic hardware would otherwise be anticipated. Syndesmotic disruption of the ankle is such an indication because many surgeons believe that a second procedure for the removal of hardware is necessary when conventional metal screws are used. When absorbable implants are employed, the syndesmosis can be protected with the use of crutches during the healing process.

The purpose of this prospective study was to assess the
efficacy of polylevolactic acid screws in the stabilization of a syndesmotic disruption associated with an ankle fracture.

**Materials and Methods**

Between November 1995 and July 1997, thirty-three consecutive adult patients with a closed Weber type-C ankle fracture and intraoperative fluoroscopic confirmation of disruption of the syndesmosis were entered into this study. Operative indications included any unstable trimalleolar, bimalleolar, lateral malleolar, or Maisonneuve-type ankle fracture in which the fibular fracture was proximal to the syndesmosis. Fractures were judged to be unstable before the operation when there was widening of the tibiofibular clear space or evidence of a medial osseous or ligamentous injury associated with the fibular fracture. Polyethylene acid screws were approved for the internal fixation of fractures by the United States Food and Drug Administration, and this study protocol was approved by our Institutional Review Board. A signed informed-consent form for enrollment in this study was obtained from each patient before the operation. Patients who had sustained an open fracture, had a large soft-tissue injury, or had preexisting hardware within the ankle were excluded from the study at this point. Patients were also excluded from the study when the Weber type-C ankle fracture failed to demonstrate syndesmotic disruption during the operative procedure.

Open reduction and internal fixation of the ankle was performed as soon as the patient’s condition was stabilized as necessitated by associated injuries and as soon as soft-tissue edema was controlled. Lateral fractures were approached through a standard longitudinal incision, and internal fixation was performed with a metallic one-third tubular plate and 3.5-mm cortical and 4.0-mm cancellous screws inserted with standard AO technique. The only exceptions to this protocol were Maisonneuve-type fractures of the proximal third of the fibula, which were not internally fixed. Medial fractures were exposed through a straight medial incision, and all of the medial malleolar fragments were reduced and internally fixed with either one or two 3.5-mm poly lactide or 4.0-mm metallic cancellous screws, at the discretion of the surgeon.

The ankle mortise was then stressed with an external rotation load under intraoperative fluoroscopy to verify disruption of the syndesmotic ligaments. Patients were included in the study only when radiographs demonstrated >3 mm of widening of the tibiofibular clear space. Approximately fifteen patients were excluded at this point because the syndesmosis was deemed stable after internal fixation of the fracture. Thirty-three consecutive patients underwent fixation of a syndesmosis that had been identified as unstable in this manner.

Open reduction and internal fixation of the syndesmotic disruption was performed with bioabsorbable screws as has been previously described. The syndesmosis was held reduced with a pointed reduction clamp with the foot in the neutral position. One 4.5-mm polylevolactic acid screw was placed across the syndesmosis from the fibula to the tibia, with purchase obtained in four cortices approximately 1 to 2 cm proximal to the plafond. The screw was placed through a hole in the plate when possible. For patients with a Maisonneuve-type fracture pattern, one or two polylevolactic acid screws were placed percutaneously, parallel to the tibial plafond. Intraoperative radiographs confirmed reduction of the syndesmosis.

The screws (SmartScrew; Bironx Implants, Blue Bell, Pennsylvania) are made from polylevolactic acid, the levorotatory isomer of polylactic acid. The strength of the screw is increased by a self-reinforcing process known as orientraction. The implants, termed self-reinforcing polylevolactic acid (SR-PLLA) implants, manufactured with this process have been shown to be stronger in flexion and tension than their nonreinforced counterparts. Each screw is fully threaded and has an enlarged rectangular head over which a torque-limiting screwdriver fits for the purpose of insertion.

A 3.5-mm drill-bit was used to create the drill hole. The hole was tapped along its entire length with a 4.5-mm tap, and the screw was inserted. The most prominent portion of the screw head was then smoothed with an electrocautery loop, which removes polyester by melting it. Care was taken in each case to leave most of the screw head intact to maintain adequate purchase on the fibula.

The average age of the patients was thirty-three years (range, eighteen to fifty-three years). Nineteen left ankles and fourteen right ankles were fractured in twenty-three male and ten female patients. Six fractures involved disruption of the syndesmosis in a Maisonneuve pattern. Twelve other syndesmotic disruptions included tearing of the deltoid ligament and a midshaft fracture or a distal-third fracture of the lateral malleolus. Of the remaining fifteen fractures, five were trimalleolar and ten were bimalleolar. The average time from injury to surgery was 1.5 days (range, one to seven days).

Postoperatively, the patients were prohibited from bearing weight on the affected ankle for a period of six weeks, which is the standard protocol for unstable ankle fractures at our institution. Immobilization was achieved with either a plaster splint or a brace. Patients were instructed to gradually increase weight-bearing and ankle motion beginning at six weeks.

Clinical and radiographic follow-up was scheduled at two weeks, six weeks, three months, six months, one year, and yearly thereafter. At the one-year follow-up examination and at each subsequent yearly follow-up visit, patient outcome was assessed by means of the ankle fracture scoring scale as proposed by Olerud and Molander. This 100-point scale provides a subjective evaluation of pain, stiffness, swelling, use of supports, activities of daily living, and ability to climb stairs, run, jump, and squat. The scoring system was applied as a discontinuous variable in 5-point increments.

**Results**

Five patients were lost to follow-up before the fracture healed; the duration of follow-up of these patients ranged from no follow-up to 3.5 months. No known complications
occurred in these patients, but no functional ankle scores were available for them.

Five additional patients were lost to follow-up after the fracture had healed. The duration of follow-up of these five patients ranged from eleven to fifteen months (average, 12.3 months), and the one-year follow-up ankle scores were 65, 90, 95, 100, and 100 points. All five fractures healed with no known complications.

The remaining twenty-three patients were followed for an average of thirty-four months (range, twenty-four to forty-three months; Table I).

At the time of the most recent follow-up, the average dorsiflexion of the ankle was 17° (range, 5° to 40°) and the average plantar flexion was 40° (range, 20° to 60°). The difference relative to the contralateral side averaged a loss of 5° of dorsiflexion and 3° of plantar flexion.

The average ankle score for these patients was 94 points (range, 80 to 100 points). Ankles that lost points did so only because of mild swelling or stiffness, or both. All twenty-three patients returned to levels of work and activities of daily living similar to those before the injury.

Radiographs showed that all fractures had healed in an anatomical position, with complete obliteration of all fracture lines, at an average of three months (range, 2.5 to 4.0 months),

<table>
<thead>
<tr>
<th>Case</th>
<th>Gender, Side, Age (yr)</th>
<th>Mechanism of Injury</th>
<th>Fracture Pattern</th>
<th>Medial Injury</th>
<th>Lateral Plate Used</th>
<th>Duration of Follow-up (mo)</th>
<th>Range of Dorsiflexion-Plantar Flexion (deg) Involved</th>
<th>Contralat.</th>
<th>Olerud and Molander Score (points)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M, L, 32</td>
<td>Motor-veh. acc.</td>
<td>Trimalleolar</td>
<td>Med. malleolar fract.</td>
<td>Yes</td>
<td>29</td>
<td>5-40</td>
<td>10-50</td>
<td>80</td>
</tr>
<tr>
<td>4</td>
<td>M, L, 33</td>
<td>Motor-veh./ pedest. acc.</td>
<td>Bimalleolar</td>
<td>Med. malleolar fract.</td>
<td>Yes</td>
<td>40</td>
<td>30-40</td>
<td>45-50</td>
<td>100</td>
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<tr>
<td>5</td>
<td>M, R, 39</td>
<td>Misstep</td>
<td>Unimalleolar</td>
<td>Deltoid lig. rupt.</td>
<td>Yes</td>
<td>39</td>
<td>5-60</td>
<td>10-60</td>
<td>80</td>
</tr>
<tr>
<td>6</td>
<td>M, L, 43</td>
<td>Assault</td>
<td>Bimalleolar</td>
<td>Med. malleolar fract.</td>
<td>Yes</td>
<td>31</td>
<td>10-35</td>
<td>20-40</td>
<td>85</td>
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<tr>
<td>9</td>
<td>F, L, 24</td>
<td>Fall from height</td>
<td>Unimalleolar</td>
<td>Deltoid lig. rupt.</td>
<td>Yes</td>
<td>39</td>
<td>10-30</td>
<td>10-30</td>
<td>95</td>
</tr>
<tr>
<td>11</td>
<td>M, R, 43</td>
<td>Misstep</td>
<td>Unimalleolar</td>
<td>Deltoid lig. rupt.</td>
<td>Yes</td>
<td>28</td>
<td>20-30</td>
<td>20-30</td>
<td>100</td>
</tr>
<tr>
<td>13</td>
<td>M, L, 26</td>
<td>Work inj.</td>
<td>Trimalleolar</td>
<td>Med. malleolar fract.</td>
<td>Yes</td>
<td>37</td>
<td>40-60</td>
<td>40-60</td>
<td>85</td>
</tr>
<tr>
<td>15</td>
<td>F, L, 42</td>
<td>Fall off stair</td>
<td>Bimalleolar</td>
<td>Med. malleolar fract.</td>
<td>Yes</td>
<td>27</td>
<td>30-50</td>
<td>30-50</td>
<td>90</td>
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<tr>
<td>16</td>
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<td>Unimalleolar</td>
<td>Deltoid lig. rupt.</td>
<td>Yes</td>
<td>38</td>
<td>20-20</td>
<td>30-30</td>
<td>100</td>
</tr>
<tr>
<td>19</td>
<td>M, R, 42</td>
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<td>Deltoid lig. rupt.</td>
<td>Yes</td>
<td>36</td>
<td>20-30</td>
<td>25-30</td>
<td>95</td>
</tr>
<tr>
<td>21</td>
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<td>Bimalleolar</td>
<td>Med. malleolar fract.</td>
<td>Yes</td>
<td>39</td>
<td>20-50</td>
<td>20-50</td>
<td>100</td>
</tr>
<tr>
<td>22</td>
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<td>Maisonneuve</td>
<td>Med. malleolar fract.</td>
<td>No</td>
<td>24</td>
<td>10-30</td>
<td>10-30</td>
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<td>23</td>
<td>F, R, 49</td>
<td>Misstep</td>
<td>Trimalleolar</td>
<td>Med. malleolar fract.</td>
<td>Yes</td>
<td>37</td>
<td>30-45</td>
<td>30-45</td>
<td>90</td>
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</tbody>
</table>
and no postoperative displacement of the syndesmosis or widening of the medial clear space was detectable (Figs. 1-A, 1-B, and 1-C). Radiographs revealed no evidence of osteolysis around the implanted screws.

No episodes of drainage of the hydrolyzed polylactide occurred, and there were no infections or wound-healing problems.

Discussion

Bioabsorbable implants offer several advantages compared with conventional metallic implants for the internal fixation of fractures. Because the bioabsorbable implant is hydrolyzed and absorbed, there is less soft-tissue irritation from prominent hardware, thus eliminating the need for subsequent removal of the implant. The gradual resorption of the screw permits a gradual transfer of stress to the bone, which results in improved remodeling and healing without stress-shielding.

The material properties of the polylevolactic acid limit its potential uses, however. The viscoelasticity and reduced stiffness of these implants compared with stainless steel suggest that these screws are best suited for fracture patterns that do not require compression for healing. Polylevolactic acid has a lower ultimate tensile strength; therefore, it is best utilized in cases in which the surgical construct can be unloaded and subjected to minimal stress. Because polylevolactic acid screws are more expensive than stainless-steel screws, the ideal application is one in which a metal implant would have a high likelihood of requiring removal, thus necessitating a second surgical procedure.

Disruption of the ankle syndesmosis fulfills all of these qualifications. Internal fixation of the ankle syndesmosis is positional fixation in which strong compression between the tibia and fibula should be avoided. The ankle can easily be unloaded after the operation to protect the fixation. Finally, fixation of the syndesmosis is viewed by many authors as temporary, meaning that a metal implant would have to be subsequently removed.

In many fractured ankles, the syndesmosis is stable after reduction and internal fixation of the fibular fracture and any associated medial malleolar fracture. Yablon et al. stated that anatomical reduction of the fibula is the key factor in achieving a good outcome of treatment of ankle fractures that have accompanying syndesmotic disruption. Following these principles, we determined the necessity for syndesmotic stabilization by applying intraoperative stress to the syndesmosis under fluoroscopy after anatomic reduction and fixation of the lateral and medial malleolar fractures.

Some authors have recommended placing the screw across only three cortices so that some normal motion can occur at the syndesmosis. Compression can be generated when a metal cortical screw traverses all four cortices. Such compression across the syndesmosis is not desired and may be detrimental to the achievement of a full range of motion of the ankle. However, Tornetta et al. recently challenged this principle in a cadaveric study by demonstrating no loss of passive dorsiflexion with compression across the syndesmosis. Also, it is our belief that the viscoelastic properties of the polylevolactic acid polymer minimize any problem that may arise from this
Therefore likely that, with polylevolactic acid screw fixation, the implant fails at some point after the patient begins to bear weight. Although we cannot confirm it, we believe that the biochemical and biomechanical properties of the implant. Rapidly degradable polylevolactic acid degrades more slowly and retains more strength than do other polymers in clinical use, such as polyglycolic acid or the racemic form of polylactic acid. The highly crystalline polylevolactic acid isomer is less water-absorbent, so that it degrades more slowly than other, less crystalline polymers and thus is perhaps better suited for fracture fixation than other polymers that are available at the time of this writing.

Hydrolysis and degradation of the implant cause its strength to lessen with time. Rod implants made of self-reinforced polylevolactic acid lose 50% of their bending strength and 10% of their shear strength at twelve weeks in vivo. It is therefore likely that, with polylevolactic acid screw fixation, motion occurs at the syndesmosis when the patient begins to bear weight. Although we cannot confirm it, we believe that the implant fails at some point after the patient begins to bear weight, thus restoring normal motion at the syndesmosis.

Several investigations have shown that polylevolactic acid degrades more slowly and retains more strength than do other polymers in clinical use, such as polyglycolic acid or the racemic form of polylactic acid. The highly crystalline polylevolactic acid isomer is less water-absorbent, so that it degrades more slowly than other, less crystalline polymers and thus is perhaps better suited for fracture fixation than other polymers that are available at the time of this writing.

The Olerud and Molander scoring system is a subjective outcomes tool for grading results after the treatment of ankle fractures. In a large series of patients with ankle fractures, Olerud and Molander noted that the average score for the good results was 78 points and the average score for the excellent results was 92 points. Of our twenty-three patients with a minimum two-year follow-up, four (17%) had a good result (an ankle score of 80 to 89 points) and nineteen (83%) had an excellent result (a score of 90 to 100 points).

No patients were noted to have a complication due to the biochemical properties of the implant. Rapidly degradable polymers such as polyglycolic acid have produced cystic collections of the hydrolyzed polymer and have occasionally formed draining sinus tracts. To our knowledge, such tracts have not been documented with the more slowly degrading polylevolactic acid polymer. None of our patients had such a tract.

Additionally, areas of osteolysis have been seen adjacent to some of these devices. The rate of degradation of the polymer and the ability of the body to clear the degraded debris determine the local concentration of the breakdown products and the appearance of any cystic collection of degraded polymer. Osteolysis and a late foreign-body reaction have been documented with the use of polylevolactic acid screws. Böstman and Pihlajamäki described a case in which a foreign-body reaction to degraded polylactide occurred four years after implantation of the screw. We performed a careful periodic review of the radiographs to identify any evidence of osteolysis in our series, and none was seen. Although the average duration of follow-up in our series was more than 2.5 years, the case reported by Böstman and Pihlajamäki demonstrates that reactions may occur much later as a result of the highly crystalline, stable structure of polylevolactic acid. Consequently, the duration of follow-up represents a limitation of the current study.

Other weaknesses of this study include the lack of control for fixation of the medial malleolus and the percentage of patients lost to follow-up. Medial fractures were internally fixed with either metallic or polymeric screws at the discretion of the surgeon. All of the medial fractures healed, and no differences in healing could be identified according to the type of screw fixation. Although controlling for this variable would have produced a purer series, prior data from our institution demonstrated equal outcomes with the use of metallic and polylevolactic acid screws for fixation of medial malleolar fractures.

In this series of thirty-three patients, two-year follow-up data were available for twenty-three (70%) and one-year follow-up data were available for twenty-eight (85%). All efforts (including the use of Internet search engines and private investigators) were made to locate patients who were difficult to find or had been lost to follow-up. To encourage patients to return for scheduled follow-up appointments, a monetary incentive was given for the one-year and two-year visits. This incentive was offered solely and explicitly for the purpose of increasing accrual of patient follow-up. This study was performed at a level-I trauma center with a large, indigent population. We would have preferred a more complete follow-up, but we believe that these numbers are satisfactory given this population of patients.

The biochemical and biomechanical properties of resorbable polymers must be taken into account when selecting implants for fracture fixation. Disruption of the ankle syndesmosis appears to be a good indication for the use of self-reinforcing polylevolactic acid screws because the ankle can be easily unloaded and the syndesmosis does not require compression for healing. We recommend the avoidance of any weight-bearing on the limb for a minimum of six weeks after the operation to ensure that the screws do not fail before osseous and ligamentous healing takes place. Therefore, polylevolactic acid screw fixation of the syndesmosis may be contraindicated in a noncompliant patient.

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