Treatment of Lateral Tibial Condylar Fractures Using Bioactive, Bioresorbable Forged Composites of Raw Particulate Unsintered Hydroxyapatite/Poly-L-Lactide Screws

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abstract

Forged composites of raw particulate unsintered hydroxyapatite/poly-L-lactide (F-u-HA/PLLA) devices possess high mechanical strength, bioactivity, and radio-opacity. The aim of this study was to assess the efficacy of F-u-HA/PLLA screws in the treatment of lateral tibial condylar fractures. From January 2005 to December 2010, a total of 7 patients with displaced closed lateral tibial condylar fractures (Schatzker type II) were treated using F-u-HA/PLLA screws. Open reduction and internal fixation was performed using 2 or 3 F-u-HA/PLLA screws. After surgery, weight bearing was not allowed for 6 weeks. Range of motion exercise was initiated after removal of the plaster splint. Radiographs were evaluated for fracture healing, joint depression, and the radio-opacity of F-u-HA/PLLA screws. Clinical outcomes and postoperative complications were also assessed. Average follow-up was 44 months. All fractures were successfully healed. Average values for joint depression were 4.7 mm (range, 2-9 mm) preoperatively, 0.4 mm (range, 0-1 mm) postoperatively, and 0.4 mm (range, 0-1 mm) at final follow-up. Whole shadows of F-u-HA/PLLA screws were observed during the follow-up period. Breakage of screws, osteolysis, and a radiolucent zone around the screws were not observed at final follow-up. Average knee flexion and extension were 134° (range, 110° to 150°) and -1° (range, -10° to 0°), respectively. No patient had wound infection, late aseptic tissue response, or foreign body reaction postoperatively. None of the patients reported pain at final follow-up. These results suggest that F-u-HA/PLLA screws could be an alternative option for the treatment of lateral tibial condylar fractures. [Orthopedics. 201x; xx(x):xx-xx.]

Tibial condylar fractures involve a major weight-bearing joint and are serious injuries that result in functional impairment.1 Tibial condylar fractures compose 1% of all fractures and 5% to 8% of lower limb fractures.2,3 These fractures are most commonly the result of falls, motor vehicle accidents, and sports trauma.3 The Schatzker classification system is one method of classifying tibial plateau fractures. Schatzker type II fractures are intra-articular and are recognized as split depressed fractures of the lateral tibial plateau.4 To achieve and maintain the joint surface, the most common method of treating Schatzker type II fractures involves metallic screw fixation.4,5

Forged composites of raw particulate unsintered hydroxyapatite/poly-L-lactide (F-u-HA/PLLA) screws are highly suited
for use in bone fixation owing to their bioactivity, bioresorbability, and retention of high mechanical strength. They also possess excellent biocompatibility and osteoconductivity, which promote direct bone bonding and new bone formation. Furthermore, F-u-HA/PLLA devices are radio-opaque. Thus, these implants have many potential applications in various clinical fields, including orthopedic, oral maxillary/mandibular facial, and traumatic surgeries.

The clinical application and efficacy of F-u-HA/PLLA screws have been reported for the treatment of pediatric lateral condyle humerus fractures and adult ankle fractures. However, the efficacy of F-u-HA/PLLA screws in the treatment of tibial plateau fractures, which disrupt the major weight-bearing surface, has not been verified. The purpose of this study was to investigate the efficacy of F-u-HA/PLLA screws for the treatment of Schatzker type II fractures in adult patients.

**Materials and Methods**

From January 2005 to December 2010, closed displaced lateral tibial condylar fractures (Schatzker type II) in 7 patients were treated using F-u-HA/PLLA screws (OSTEOTRANS; Zimmer, Warsaw, Indiana). During this period, all patients with Schatzker type II fractures and intra-articular displacement of more than 2 mm were treated using F-u-HA/PLLA screws. The average age of the patients was 51.1 years (range, 17-79 years) (Table). Clinical and radiographic follow-up were scheduled postoperatively. Radiographs were evaluated for joint depression, fracture healing, breakage of screws, and radio-opacity of screws. Clinical assessments included pain, range of motion, delayed inflammatory reaction, and foreign body reactions.

Surgery was performed under spinal anesthesia. Following exposure, the lateral displaced fragment was reduced anatomically and temporarily fixed using K-wires. Joint reconstruction was confirmed using an image intensifier. Hydroxyapatite or β-tricalcium phosphate granules were grafted in 4 of 7 patients. Two F-u-HA/PLLA screws (6.5 mm) with F-u-HA/PLLA washers were inserted from the lateral side of the tibial plateau into the medial side in 6 of 7 patients (Figure 1). Two 6.5-mm and one 4.5-mm F-u-HA/PLLA screws were used in 1 of the 7 patients. Postoperatively, patients were prohibited from bearing weight for 6 weeks. Patients were instructed to gradually increase knee motion starting 2 weeks postoperatively.

**Results**

Average follow-up was 44 months (range, 15-78 months). All fractures were successfully healed. Average joint depression improved from 4.7 mm (range, 2-9 mm) preoperatively to 0.4 mm (range, 0-1 mm) postoperatively and was maintained at 0.4 mm (range, 0-1 mm) at final follow-up (Figures 2-3). Whole shadows of F-u-HA/PLLA screws were observed during the follow-up period. Breakage of screws, osteolysis, and a radiolucent zone around the screws were not observed at final follow-up. Average knee flexion and extension were 134° (range, 110° to 150°) and -1° (range, -10° to 0°), respectively. No patient had wound infection, late aseptic tissue response, or foreign body reaction postoperatively. No patient reported pain at final follow-up, and all had returned to

<table>
<thead>
<tr>
<th>Patient Age, y/Sex</th>
<th>Side</th>
<th>Implant</th>
<th>Joint Depression, mm</th>
<th>Flexion</th>
<th>Extension</th>
<th>Follow-up, mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>68/Female</td>
<td>Left</td>
<td>Two 6.5-mm cannulated screws</td>
<td>5</td>
<td>0</td>
<td>130°</td>
<td>75</td>
</tr>
<tr>
<td>58/Female</td>
<td>Left</td>
<td>Two 6.5-mm cannulated screws</td>
<td>2</td>
<td>0</td>
<td>140°</td>
<td>30</td>
</tr>
<tr>
<td>55/Female</td>
<td>Left</td>
<td>Two 6.5-mm cannulated screws</td>
<td>7</td>
<td>0</td>
<td>120°</td>
<td>15</td>
</tr>
<tr>
<td>49/Female</td>
<td>Left</td>
<td>Two 6.5-mm cannulated screws</td>
<td>2</td>
<td>1</td>
<td>145°</td>
<td>67</td>
</tr>
<tr>
<td>32/Male</td>
<td>Right</td>
<td>Two 6.5-mm cannulated screws</td>
<td>2</td>
<td>0</td>
<td>150°</td>
<td>28</td>
</tr>
<tr>
<td>17/Male</td>
<td>Right</td>
<td>Two 6.5-mm cannulated screws</td>
<td>6</td>
<td>1</td>
<td>145°</td>
<td>15</td>
</tr>
<tr>
<td>79/Female</td>
<td>Right</td>
<td>Two 6.5-mm and one 4.5-mm cannulated screws</td>
<td>9</td>
<td>1</td>
<td>110°</td>
<td>78</td>
</tr>
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</table>
their preinjury level of work and activities of daily living.

**DISCUSSION**

This study showed that F-u-HA/PLLA screws are useful for the treatment of lateral tibial condylar fractures. It is well-known that joint depression and incongruity lead to pain and functional impairment in tibial condylar fractures and that metallic screw fixation is the most common method of treating tibial plateau fractures. Generally, bone fixation devices used to treat fractures require much higher initial mechanical strength than natural cortical bone, which has a bending strength of 200 MPa. The F-u-HA/PLLA material has an initial bending strength of 270 MPa; however, the endurance of F-u-HA/PLLA screws on full weight bearing has not been verified. In the current study, no breakage of F-u-HA/PLLA screws was observed, and the joint surface was maintained at final follow-up in all patients, leading to no reports of pain. Therefore, although this case series was performed for the lateral tibial condyle, where the main loading force does not pass through, F-u-HA/PLLA screws seem to be strong enough for full weight bearing and this area.

 Earlier bioresorbable implants used to treat fractures were made of PLLA and polyglycolic acid. The F-u-HA/PLLA devices are made of a composite of uncalcined and unsintered HA and PLLA and have several advantages compared with PLLA and polyglycolic acid devices. First, F-u-HA/PLLA devices promote direct bone bonding. An in vivo study reported that direct bony contact was observed on the F-u-HA/PLLA device after implantation in the bone defect, whereas a fibrous tissue layer was seen on the PLLA device. In addition, new bone formation was observed on the PLLA device within 2 weeks of implantation, and the bone gradually grew along the surface of the device. These osteological bioactivities of the F-u-HA/PLLA device may contribute to the early positional stability of the implant in bone. Second, unlike polyglycolic acid and PLLA devices, F-
u-HA/PLLA devices have radio-opacity and therefore can be observed on postoperative radiographs. If the F-u-HA/PLLA screw is broken after surgery, this can be detected on follow-up radiographs.

Such bioresorbable devices also possess biodegradable features. The earlier biodegradable implants such as polyglycolic acid or PLLA caused issues. Polyglycolic acid implants degrade rapidly and cause tissue reactions, such as skin ulcers or aseptic tissue responses.16,17 Implants of PLLA only degrade after many years, and foreign body reactions and late aseptic swelling have occurred owing to a long degradation period and uneven PLLA fragments, which are the result of irregular heterogeneous hydrolysis.18,19 Akagi et al20 reported severe infiltration of histiocytic cells in the implantation site on histology at 5 years after PLLA screw insertion. On the other hand, the F-u-HA/PLLA composite structure is designed to allow homogeneous hydrolysis and steady degradation of the PLLA throughout the degradation process. This uniform hydrolysis brings steady release of small amounts of fragments as the materials degrade, resulting in the decreased adverse tissue response.6 In the current study, there were no tissue reactions, late aseptic swelling, or foreign body reactions at final follow-up; however, whole shadows of F-u-HA/PLLA screws were still observed during the follow-up period. Further follow-up is necessary to confirm the reaction until the follow-up period. Further follow-up is essential for the treatment of lateral tibial condylar fractures.

**CONCLUSION**

Lateral tibial condylar fractures were successfully treated using F-u-HA/PLLA screws. These screws could be an alternative option for the treatment of lateral tibial condylar fractures.

**REFERENCES**