Open Reduction and Internal Fixation Compared with Circular Fixator Application for Bicondylar Tibial Plateau Fractures. Results of a Multicenter, Prospective, Randomized Clinical Trial

The Canadian Orthopaedic Trauma Society


This information is current as of April 5, 2011

Supplementary Material
http://www.ejbjs.org/cgi/content/full/88/12/2613/DC1

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Publisher Information
The Journal of Bone and Joint Surgery
20 Pickering Street, Needham, MA 02492-3157
www.jbjs.org
Open Reduction and Internal Fixation Compared with Circular Fixator Application for Bicondylar Tibial Plateau Fractures

Results of a Multicenter, Prospective, Randomized Clinical Trial

By the Canadian Orthopaedic Trauma Society

Background: Standard open reduction and internal fixation techniques have been successful in restoring osseous alignment for bicondylar tibial plateau fractures; however, surgical morbidity, especially soft-tissue infection and wound necrosis, has been reported frequently. For this reason, several investigators have proposed minimally invasive methods of fracture reduction followed by circular external fixation as an alternative approach. To our knowledge, there has been no direct comparison of the two operative approaches.

Methods: We performed a multicenter, prospective, randomized clinical trial in which standard open reduction and internal fixation with medial and lateral plates was compared with percutaneous and/or limited open fixation and application of a circular fixator for displaced bicondylar tibial plateau fractures (Schatzker types V and VI and Orthopaedic Trauma Association types C1, C2, and C3). Eighty-three fractures in eighty-two patients were randomized to operative treatment (forty-three fractures were randomized to circular external fixation and forty to open reduction and internal fixation). Follow-up consisted of obtaining a history, physical examination, and radiographs; completion of the Hospital for Special Surgery (HSS) knee score, the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and the Short Form-36 (SF-36) General Health Survey; and recording of complication and reoperation rates.

Results: There were no significant differences between the groups in terms of demographic variables, mechanism of injury, or fracture severity and/or displacement. However, patients in the circular fixator group had less intraoperative blood loss than those in the open reduction and internal fixation group (213 mL and 544 mL, respectively; \( p = 0.006 \)) and spent less time in the hospital (9.9 days and 23.4 days, respectively; \( p = 0.024 \)). The quality of osseous reduction was similar in the groups. There was a trend for patients in the circular fixator group to have superior early outcome in terms of HSS scores at six months (\( p = 0.064 \)) and the ability to return to preinjury activities at six months (\( p = 0.031 \)) and twelve months (\( p = 0.024 \)). These outcomes were not significantly different at two years. There was no difference in total arc of knee motion, and the WOMAC scores at two years after the injury were not significantly different between the groups with regard to the pain (\( p = 0.923 \)), stiffness (\( p = 0.604 \)), or function (\( p = 0.827 \)) categories. The SF-36 scores at two years after the injury were significantly decreased compared with the controls for both groups (\( p = 0.001 \) for the circular fixator group and \( p = 0.014 \) for the open reduction and internal fixation group), although there was less impairment in the circular fixator group in the bodily pain category (a score of 46) compared with the open reduction and internal fixation group (a score of 35) (\( p = 0.041 \)). Seven (18%) of the forty patients in the open reduction and internal fixation group had a deep infection. The number of unplanned repeat surgical interventions, and their severity, was greater in the open reduction and internal fixation group (thirty-seven procedures) compared with the circular fixator group (sixteen procedures) (\( p = 0.001 \)).

Conclusions: Both techniques provide a satisfactory quality of fracture reduction. Because percutaneous reduction and application of a circular fixator results in a shorter hospital stay, a marginally faster return of function, and similar clinical outcomes and because the number and severity of complications is much higher with open reduction and internal fixation, we believe that circular external fixation is an attractive option for these difficult-to-treat fractures. Regardless of treatment method, patients with this injury have substantial residual limb-specific and general health deficits at two years of follow-up.

Level of Evidence: Therapeutic Level I. See Instructions to Authors for a complete description of levels of evidence.

A commentary is available with the electronic versions of this article, on our website (www.jbjs.org) and on our quarterly CD-ROM (call our subscription department, at 781-449-9780, to order the CD-ROM).
fractures was open reduction and internal fixation with plates and screws through an extensile anterior incision. However, while this technique was optimal for fracture visualization, reduction, and fixation, it required extensive soft-tissue dissection over the predominantly subcutaneous proximal end of the tibia. The combination of damage from the energy dissipated through the soft tissues from the original injury and the extensive surgical dissection led to a high rate of complications including skin necrosis and infection. Young and Barrack reported infection in seven of eight patients with bicondylar tibial plateau fractures treated with medial and lateral buttress plates through an anterior incision, with two patients requiring amputation. In studies of bicondylar fractures treated similarly, Moore et al. reported deep infection or dehiscence in eight of eleven patients and Mallik et al. found infection complicated four of five such injuries.

As the detrimental effects of excessive dissection of the tenuous soft-tissue envelope and devascularization of the osseous fragments became apparent, a number of alternative methods of treatment have been popularized, including percutaneous reduction and circular frame stabilization, minimally invasive techniques and implants, and temporary external fixation followed by delayed definitive surgery. The advantages of circular frame fixation (with or without percutaneous lag-screw fixation) include minimal soft-tissue disruption, the ability to correct deformity in multiple planes, early knee motion, and the option of spanning the knee in patients with concomitant ligament injury. Early reports by Stamer et al. (who reported good or excellent results in sixteen of twenty-three knees, with three infections) and Watson (who described good or excellent results in twenty-seven of thirty-one bicondylar fractures, with one infection) confirmed the clinical utility of this method. However, there remains doubt as to the quality of articular reduction with circular fixation, and a direct comparison with standard reduction techniques has not, to our knowledge, been performed.

The purpose of our study was to compare the outcome after standard open reduction and internal fixation with use of medial and lateral plates and that after circular fixation with percutaneous reduction techniques for patients with displaced bicondylar tibial plateau fractures.

**Materials and Methods**

We conducted a multicenter, randomized, prospective clinical trial in which standard open reduction and internal fixation with medial and lateral plates was compared with circular fixator application with percutaneous and/or limited open reduction techniques for patients with displaced bicondylar tibial plateau fractures (types V and VI, according to the system of Schatzker, and types C1, C2, and C3, according to the system of the Orthopaedic Trauma Association [OTA]). Five university-affiliated level-I trauma centers participated. Sixteen surgeons

**Figs. 1-A through 1-D** A thirty-three-year-old man with a displaced bicondylar tibial plateau fracture that was managed with a circular fixator. **Fig. 1-A** Preoperative radiograph. Note the intra-articular displacement of the lateral plateau fracture and the varus deformity. **Fig. 1-B** A preoperative computed tomographic scan clarifies the main fracture lines. This step is essential if a percutaneous or limited open reduction and fixation technique is planned.
performed the procedures in this series (mean, 5.2 procedures per surgeon). This study was approved by the Research Ethics Board at each participating institution.

The primary outcome measure was the Hospital for Special Surgery Knee score (HSS score) at two years postoperatively. A prestudy power analysis suggested that, to have an 80% chance of detecting a 25% difference between the scores in the groups (with an alpha value of 0.05), approximately forty patients would be required in each group. Secondary outcome measures included the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), complications, reoperation, the quality of radiographic reduction, the presence of degenerative osteoarthritis, and scores on the Short-Form 36 (SF-36) health status questionnaire.

Patients with a fracture who presented to a participating center were identified by the attending orthopaedic surgeon or resident as being eligible for the study. The patients were then screened for suitability, and, if they met study criteria, they were approached by the research study nurse and informed consent was obtained for study participation. The patients were randomized by sequentially numbered, opaque, sealed envelopes to either standard open reduction and internal fixation with medial and lateral plates (the control group) or percutaneous reduction and application of a circular fixator (the experimental group) in a 1:1 ratio. Patients with a bilateral fracture were randomized once, and the same treatment was used on both fractures. Although randomization in this type of trial would ideally be performed intraoperatively, it was thought that this would necessitate an unacceptable delay in the logistics of equipment assembly and the construction of the circular frame (which most surgeons preferred to do preoperatively). Therefore, randomization was performed on the morning of the planned operative intervention.

Inclusion Criteria
All patients had a displaced bicondylar tibial plateau fracture (Schatzker type V and VI and OTA types C1, C2, and C3) with at least one of the following features: an intra-articular step or gap of >2 mm, extra-articular translation of >1.0 cm or angulation of >10°, an open fracture, compartment syndrome requiring fasciotomy, or an associated ligament injury requiring repair.
Exclusion Criteria
Patients were excluded if they had any of the following features: a pathologic fracture, definitive surgery more than fourteen days after the injury, a preexisting joint disease (osteoarthritis, inflammatory arthritis, or a prior fracture), a severe systemic illness (active cancer, chemotherapy, insulin-dependent diabetes, renal failure, hemophilia, or a medical contraindication for surgery), open growth plates, a vascular injury requiring repair (a Gustilo Grade-IIIC fracture\textsuperscript{3}), an age of more than sixty-five years, or a severe head injury (initial Glasgow coma scale score of <8) or other neurological condition that would interfere with rehabilitation.

Surgical Technique
All procedures in both groups were performed with the patient under general anesthesia, with prophylactic antibiotic coverage administered and image-intensifier assistance. Arthroscopic visualization of the reduction was not performed. The timing of surgical intervention was left to the discretion of the treating surgeon. All procedures were performed by the attending staff surgeon with resident and/or fellow assistance. In the circular fixator group, the patients were managed with a closed, percutaneous or limited open reduction of the articular surface followed by the insertion of percutaneous lag screws to stabilize the articular fragment(s); no plates were used. To accomplish this, a variety of techniques, including fracture table traction, ligamentotaxis, use of a femoral distractor, and fragment manipulation with percutaneously inserted elevators or reduction forceps, were used. No bone grafts were used in the circular fixator group. An anterior miniarthrotomy to repair an obvious anterior cruciate ligament injury was performed four times in the circular fixator group. No ligament reconstruction with a graft was performed. Next, a standard Ilizarov circular fixator was applied, according to the method of Watson, with a minimum of four points of purchase proximally (i.e., three olive wires and a half-pin)\textsuperscript{1,30,31}. Attempts were made to keep the proximal wires at least 1 cm from the joint surface to avoid the capsular reflection if this was possible\textsuperscript{32}. Then, the shaft was reduced and fixation was applied through the distal rings of the frame. The circular fixator was composed of three (if the metaphyseal-diaphyseal fracture was very proximal) or four rings in every case\textsuperscript{1,30,31}. Compression was applied or angulation was corrected at this point (Figs. 1-A through 1-D). The knee was examined following the completion of fixation. If proximal purchase and/or stability was poor, or a substantial knee ligament injury was present, a hinged frame that spanned the knee was then applied (four knees). It was removed at the discretion of the surgeon (at a mean of 4.5 weeks).

In the open reduction and internal fixation group, standard AO principles of exposure and fixation were used\textsuperscript{3}. A single anterior incision or combined medial and lateral incisions (at the discretion of the treating surgeon) with arthroscopy were used to perform an open reduction and lag-screw fixation of the articular surface. The menisci and cruciate ligaments were examined and identified, and soft-tissue injuries were repaired if possible. Typically, this involved screw and/or wire and/or suture fixation of avulsed cruciate ligaments with fragments of bone and repair of detached menisci with use of drill-holes in bone or suture anchors. Next, plates were applied in every knee medially and laterally to reestablish tibial alignment and buttress the articular repair. No locking plates were used in this series. Iliac crest bone-grafting was performed to support any impacted articular fragments after they were elevated and secured according to the preference of the surgeon. Standard wound closure over drains was performed (Figs. 2-A, 2-B, and 2-C).

Open fractures were treated with immediate irrigation and débridement followed by immediate repair or temporary external fixation or splitting until the definitive procedure could be performed (see below).

Postoperative Management
In the open reduction and internal fixation group, knees without a ligamentous or meniscal abnormality were placed in a removable knee immobilizer and allowed early motion. Weight-bearing was restricted for six weeks, and then partial weight-bearing was allowed for an additional six weeks. Partial to full weight-bearing was allowed in the circular fixator group (according to the preference of the surgeon) immediately postoperatively. At twelve weeks postoperatively, full weight-bearing and strengthening were allowed in both groups for patients without complications. Postoperative care was individualized in patients with concomitant knee ligament injury or complications.

Follow-up
Patients were assessed by the study nurse at the time of inclusion in the trial, and they completed outcome forms to document their preinjury status. In addition to routine clinical follow-up, patients were assessed by the study nurse, completed outcome questionnaires, and had radiographs performed at six, twelve, and twenty-four months after the injury.

Radiographic Assessment
Radiographic parameters were measured by the study nurse coordinators in each center using a standard measurement technique and were recorded on a trial-specific radiographic data sheet. In difficult knees or when parameters were unclear, assistance was obtained from the principal investigator for the site or the treating surgeon. Initial measurements and joint parameters at the time of follow-up were made from standard “trauma series” radiographs. Final alignment was calculated on full-length standing radiographs.

Statistical Analysis
Statistical analysis was performed with use of the SPSS software package (version 13; SPSS, Chicago, Illinois). A chi-square test was used for categorical variables between the two groups, such as gender, sex, etc. A traditional Pearson chi-square test was used when statistical conditions were met. A Student t test was used for continuous variables, such as age and range of motion. The Fisher exact test was used in cases
when one or more of the expected variables were less than five, and the linear-by-linear association was used when three or more categorical variables were under consideration (i.e., mechanism of injury). A p value of <0.05 was considered to be significant.

**Results**

From November 1998 through May 2003, 116 fractures in 114 patients were identified. Twenty-four patients refused to participate or, after being introduced to the study, insisted on one form of surgical intervention; such patients were followed as a separate “nonrandomized” group (see below). Eight patients (two who had preexisting knee osteoarthritis, two who had an ineligible age, one who had vascular injury, and three who had no fixed address) were excluded. Thus, eighty-two patients with eighty-three fractures were randomized into the study: forty-two patients (forty-three knees) in the circular fixator group and forty patients (forty knees) in the open reduction and internal fixation group. Two patients who were randomized to the circular fixator group underwent an open reduction and internal fixation because of an inability to reduce the intra-articular portion of the fracture (both were

**TABLE 1 Demographic Data on the Patients**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Standard Open Reduction and Internal Fixation (N = 40)</th>
<th>Circular Fixator (N = 42)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male gender</td>
<td>23</td>
<td>29</td>
<td>0.278</td>
</tr>
<tr>
<td>Workers’ Compensation claims</td>
<td>4</td>
<td>6</td>
<td>0.738</td>
</tr>
<tr>
<td>Mechanism of injury*</td>
<td>0.974</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean age (yr)</td>
<td>43.3</td>
<td>46.2</td>
<td>0.250</td>
</tr>
<tr>
<td>Associated systemic injuries</td>
<td>9</td>
<td>12</td>
<td>0.529</td>
</tr>
<tr>
<td>Injury Severity Score</td>
<td>9.9</td>
<td>6.6</td>
<td>0.087</td>
</tr>
</tbody>
</table>

*See text for data on mechanisms of injury.

Figs. 2-A, 2-B, and 2-C A thirty-two-year-old man with a displaced bicondylar tibial plateau fracture that was managed with conventional open reduction and internal fixation with medial and lateral plates, performed through two incisions. **Fig. 2-A** Preoperative radiograph. **Fig. 2-B** Postoperative radiograph. **Fig. 2-C** Final radiograph made two years postoperatively. There is mild residual deformity of the lateral plateau, but the leg is clinically straight, the knee is stable and pain-free, and the patient had returned to preinjury activities.
OTA type-C3 fractures). Both of these patients were followed with use of the intention-to-treat principle (i.e., they remained in the circular fixator group). One patient had bilateral injury and was randomized to the circular fixator group.

**Follow-up**

Seventy-six patients completed the six-month assessment (two patients, including one who had a bilateral fracture, in the circular fixator group and four in the open reduction and internal fixation group were lost to follow-up). One patient in the open reduction and internal fixation group died of unrelated causes at nine months postoperatively. Seventy-two patients completed the twelve-month assessment (five in the circular fixator group and four in the open reduction and internal fixation group were lost to follow-up), and sixty-six patients completed the two-year assessment (nine patients in the circular fixator group and six in the open reduction and internal fixation group were lost to follow-up). No significant differences were detected between the groups with respect to the number of patients who were lost to follow-up (p = 0.781).

**Demographic Data on the Patients**

No significant differences were detected between the groups with regard to demographic variables (Table I). There was no difference between the groups (as measured by the linear-by-linear association test) with respect to the mechanism of injury, which included a fall (fifteen patients in the circular fixator group and eight in the open reduction and internal fixation group), a motor vehicle collision (eleven and seventeen, respectively), a motor vehicle-pedestrian collision (six in each group), a sports-related injury (two and five, respectively), a work-related injury (two and one, respectively), a bicycle accident

---

**TABLE II Injury Characteristics and Associated Injuries**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Standard Open Reduction and Internal Fixation (N = 40)</th>
<th>Circular Fixator (N = 43)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schatzker type-V fracture</td>
<td>9</td>
<td>9</td>
<td>0.907</td>
</tr>
<tr>
<td>Schatzker type-VI fracture</td>
<td>31</td>
<td>34</td>
<td>0.907</td>
</tr>
<tr>
<td>OTA fracture type*</td>
<td></td>
<td></td>
<td>0.702</td>
</tr>
<tr>
<td>C1</td>
<td>8</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>C2</td>
<td>18</td>
<td>21</td>
<td></td>
</tr>
<tr>
<td>C3</td>
<td>14</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Diaphyseal-metaphyseal translation† (mm)</td>
<td>9 ± 14</td>
<td>9 ± 9</td>
<td>0.849</td>
</tr>
<tr>
<td>Diaphyseal-metaphyseal angulation† (deg)</td>
<td>7 ± 8</td>
<td>8 ± 7</td>
<td>0.886</td>
</tr>
<tr>
<td>Intra-articular step-gap† (mm)</td>
<td>10 ± 8</td>
<td>9 ± 9</td>
<td>0.817</td>
</tr>
<tr>
<td>Fasciotomy (no. of knees)</td>
<td>4</td>
<td>3</td>
<td>0.712</td>
</tr>
<tr>
<td>Open injury (no. of knees)</td>
<td>9</td>
<td>5</td>
<td>0.134</td>
</tr>
<tr>
<td>Associated injuries (no. of knees)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neurologic injury</td>
<td>4</td>
<td>2</td>
<td>0.374</td>
</tr>
<tr>
<td>Cruciate ligament injury</td>
<td>12</td>
<td>8</td>
<td>0.233</td>
</tr>
<tr>
<td>Collateral ligament injury</td>
<td>8</td>
<td>4</td>
<td>0.120</td>
</tr>
<tr>
<td>Meniscal injury identified</td>
<td>13</td>
<td>3</td>
<td>0.001</td>
</tr>
</tbody>
</table>

*OTA = Orthopaedic Trauma Association. †The values are given as the mean and the standard deviation.

**TABLE III Intraoperative Parameters**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Standard Open Reduction and Internal Fixation (N = 40)</th>
<th>Circular Fixator (N = 43)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean total operative time (min)</td>
<td>183</td>
<td>170</td>
<td>0.229</td>
</tr>
<tr>
<td>Mean tourniquet time (min)</td>
<td>96</td>
<td>48</td>
<td>0.001</td>
</tr>
<tr>
<td>Mean blood loss (mL)</td>
<td>544</td>
<td>213</td>
<td>0.006</td>
</tr>
<tr>
<td>Meniscal repair (no. of knees)</td>
<td>12</td>
<td>2</td>
<td>0.008</td>
</tr>
<tr>
<td>Cruciate ligament surgery (no. of knees)</td>
<td>10</td>
<td>4</td>
<td>0.436</td>
</tr>
<tr>
<td>Hospital stay* (days)</td>
<td>23.4 ± 3.8</td>
<td>9.9 ± 1.6</td>
<td>0.024</td>
</tr>
</tbody>
</table>

*The values are given as the mean and the standard deviation.
Injury Characteristics and/or Associated Injuries

There were no significant differences in fracture or injury pattern between the groups (Table II). There were nine Schatzker type-V and thirty-four Schatzker type-VI fractures in the circular fixator group and nine Schatzker type-V and thirty-one Schatzker type-VI fractures in the open reduction and internal fixation group. According to the OTA classification, there were eight type-C1 fractures, eighteen type-C2, and fourteen type-C3 fractures in the group managed with open reduction and internal fixation and twelve type-C1, twenty-one type-C2, and ten type-C3 fractures in the circular fixator group. Fracture displacement was measured after closed reduction and splinting and demonstrated no significant differences between the groups in terms of fracture displacement or angulation, Injury Severity Score, or associated injuries.

Intraoperative Parameters

The mean total operative time was 170 minutes for the circular fixator group and 183 minutes for the group managed with open reduction and internal fixation (p = 0.229) (Table III). The mean tourniquet time was significantly less in the circular fixator group (forty-eight minutes) than that in the open reduction and internal fixation group (ninety-six minutes) (p = 0.001). Also, the mean intraoperative blood loss was significantly less in the circular fixator group (213 mL) than in the

### TABLE IV Outcome Data

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Standard Open Reduction and Internal Fixation* (N = 40)</th>
<th>Circular Fixator (N = 43)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range of motion* (deg)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flexion</td>
<td>113 ± 32</td>
<td>123 ± 15</td>
<td>0.114</td>
</tr>
<tr>
<td>Extension</td>
<td>4 ± 6</td>
<td>3 ± 6</td>
<td>0.499</td>
</tr>
<tr>
<td>Total arc of motion</td>
<td>109 ± 33</td>
<td>120 ± 19</td>
<td>0.091</td>
</tr>
<tr>
<td>Return to preinjury activity (no. who returned/total no. in group)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 mo</td>
<td>1/36</td>
<td>8/40</td>
<td>0.031</td>
</tr>
<tr>
<td>1 yr</td>
<td>2/35</td>
<td>10/37</td>
<td>0.024</td>
</tr>
<tr>
<td>2 yr</td>
<td>4/33</td>
<td>10/33</td>
<td>0.128</td>
</tr>
<tr>
<td>Mean HSS knee score†</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 mo</td>
<td>61</td>
<td>72</td>
<td>0.064</td>
</tr>
<tr>
<td>1 yr</td>
<td>67</td>
<td>72</td>
<td>0.406</td>
</tr>
<tr>
<td>2 yr</td>
<td>68</td>
<td>75</td>
<td>0.307</td>
</tr>
</tbody>
</table>

*The values are given as the mean and the standard deviation. † HSS = Hospital for Special Surgery.

### TABLE V Complications and Reoperations

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Standard Open Reduction and Internal Fixation* (N = 40)</th>
<th>Circular Fixator* (N = 43)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incision and drainage</td>
<td>8</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Split-thickness skin graft</td>
<td>5</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Screw removal</td>
<td>0</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Knee manipulation</td>
<td>3</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Plate removal</td>
<td>8</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Total knee arthroplasty</td>
<td>2</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Above-the-knee amputation</td>
<td>1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Soft-tissue flap</td>
<td>4</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Revision open reduction and internal fixation</td>
<td>4</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>37</td>
<td>16</td>
<td>0.001</td>
</tr>
</tbody>
</table>

*The values are given as the number of reoperations.
open reduction and internal fixation group (544 mL) \( (p = 0.006) \). There was no difference in the number of patients in each group who underwent contralateral lower-extremity surgery \( (p = 0.626) \).

**HSS and WOMAC Scores**

There were no differences between the groups with regard to the mean preinjury HSS knee score \( (94 \text{ for the group managed with a circular fixator and } 95 \text{ for the group managed with open reduction and internal fixation}) \ (p = 0.724) \). At six months after the injury, the group managed with a circular fixator demonstrated a trend for a higher HSS score \( (72 \pm 18 \text{ than those in the group managed with open reduction and internal fixation (mean, } 61 \pm 23) \ (p = 0.064) \) (Table IV). At one year, no difference in the mean score was detected between the two groups \( (72 \pm 17 \text{ for the circular fixator group and } 67 \pm 18 \text{ for the open reduction and internal fixation group (p = 0.406)). At the two-year follow-up examination, the mean HSS score was } 75 \pm 19 \text{ in the circular fixator group compared with } 68 \pm 20 \text{ in the open reduction and internal fixation group; the difference was not significant (p = 0.307) (Table IV). There were no differences between the groups with regard to the mean pain, stiffness, or function scores on the WOMAC at six months, one year, or two years (see Appendix). However, there were significantly decreased mean scores at two years after the injury in both groups relative to the preinjury score \( (p < 0.05 \text{ for all categories in both groups), confirming significant residual lower-extremity disability.} \)

**General Health Status (SF-36) Outcome**

There were no significant differences between the groups with respect to the general health at baseline. Significant decreases were detected in all domains in both groups when the mean preinjury and two-year follow-up scores were compared \( (p = 0.001 \text{ for the circular fixator group and } p = 0.014 \text{ for the open reduction and internal fixation group). There were no differences between the groups at the two-year follow-up evaluation with respect to any SF-36 domain except for bodily pain, which demonstrated significant improvement in the circular fixator group \( (mean, 46) \text{ compared with that in the open reduction and internal fixation group (mean, 35) } (p = 0.041) \) (see Appendix). \)

**Return to Preinjury Activity Level**

Relatively few patients in either group were able to return to normal preinjury activities. Patients in the circular fixator group were more likely to have returned to the preinjury level of activity than were those in the open reduction and internal fixation group at the six-month evaluation \( (eight \text{ of forty compared with one of thirty-six patients, respectively; } p = 0.031) \) and at the one-year evaluation \( (ten \text{ of thirty-seven compared with two of thirty-five patients, respectively; } p = 0.025) \). However, this difference was not significant at two years \( (ten \text{ of thirty-three patients compared with four of thirty-three patients, respectively; } p = 0.128) \).

**Range of Motion**

The group managed with the circular fixator demonstrated a trend toward a superior range of motion of the knee in a number of parameters at the two-year follow-up examination compared with the group that had open reduction and internal fixation, but the differences were not significant \( (i.e., \text{ the mean total arc of motion was } 120^\circ \text{ in the circular fixator group compared with } 109^\circ \text{ in the open reduction and internal fixation group, } p = 0.091) \) (Table IV).

**Radiographic Parameters**

There were no differences in the amounts of initial fracture articular displacement, diaphyseal-metaphyseal translation, or diaphyseal-metaphyseal angulation between the groups \( (see Table II). Postoperatively, there was no difference between the groups with respect to the quality of the reduction \( (p = 0.122 \text{ for the proportion with anatomic reduction, } p = 0.963 \text{ for proportion with a step deformity, } p = 0.866 \text{ for proportion with a gap deformity, and } p = 0.236 \text{ for proportion with an abnormal mechanical axis) (see Appendix). At one year postoperatively, there were radiographic signs of osteoarthritis (narrowing of the joint space compared with that in the contralateral knee, osteophyte formation, and sharpening of the tibial spines) in ten of the thirty-five knees managed with open reduction and internal fixation and in fourteen of thirty-seven knees managed with a circular fixator \( (p = 0.461) \). At two years postoperatively, there were radiographic signs of osteoarthritis in eleven of thirty-four knees that had open reduction and internal fixation and in thirteen of thirty-two that had a circular fixator \( (p = 0.372) \). \)

**Hospital Stay**

The groups were not significantly different with respect to the mean number of days between the fracture and the time of surgery \( (3.7 \pm 4.4 \text{ days for the circular fixator group and } 4.2 \pm 4.6 \text{ days for the open reduction and internal fixation group; } p = 0.645) \). However, the mean total length of stay in the hospital was significantly shorter for the group that had the circular fixation \( (9.9 \pm 1.6 \text{ days) compared with that for the group managed with open reduction and internal fixation (23.4 \pm 3.8 \text{ days) } (p = 0.024). This was primarily due to the increased hospital stay for patients managed with open reduction and internal fixation who had complications develop and required multiple procedures. \)

**Reoperation and Complications**

Procedures done prior to the definitive intervention \( (i.e., \text{ irrigation, debridement, and temporary external fixation for an open fracture}) \) were not considered a reoperation or a complication. Twenty-seven of the forty-one circular fixators were removed in the operating room with use of a brief general or neuroleptic anesthetic; the other fourteen were removed in the clinic and these were considered “planned” procedures—not complications or unplanned reoperations \( (the \text{ mean time to removal of the circular fixator was sixteen weeks). Eighteen patients managed with open reduction and internal fixation} \)
required thirty-seven unplanned additional surgeries, whereas fifteen patients who had a circular fixator required sixteen unplanned surgeries \(p = 0.001\). Although it is a subjective finding, the procedures in the circular fixator group (pin-track débridement, screw removal, and knee manipulation) tended to be of a lesser magnitude than those done in the open reduction and internal fixation group (above-the-knee amputation, rotational and/or free flaps, incision and drainage with plate removal, and osteotomy) (Table V).

Nonrandomized Patients
Since the exclusion of a large number of eligible patients can introduce substantial bias into a clinical trial (through the “selection” of ideal patients and the exclusion of “difficult” ones), we recorded and followed potentially eligible patients who were not randomized (twenty-four who refused to participate and eight who were excluded). No differences were detected between this group (eighteen managed with a circular fixator and fourteen managed with open reduction and internal fixation) and the randomized group with regard to demographic data, mechanism of injury, fracture pattern or type, associated injuries, Injury Severity Score, or treatment method chosen \(p > 0.05\) for all parameters).

Discussion
Although standard techniques of open reduction and internal fixation have proven to be routinely successful in restoring osseous anatomy\(^7,9\), the tenuous soft-tissue coverage and predilection for high-energy trauma of the proximal end of the tibia has led to a substantial rate of severe complications. Reports by Young and Barrack, Moore et al., and Mallik et al. highlighted the risks of conventional plate fixation\(^1\). While it could be argued that these series were reported before our degree of understanding with regard to the importance of the soft-tissue envelope (and the surgical techniques to preserve it) in the proximal end of the tibia had improved to its current level, complications still occur. In an article from a leading level-I trauma center in 2004, Barei et al. described complications associated with plate fixation of high-energy bicondylar tibial plateau fractures in eighty-three patients\(^7\). While their results were an improvement from those in previous studies, there were still seven patients (8.4%) who had a deep infection that required an average of 3.3 additional procedures for resolution. This was despite the use of “modern” techniques including delayed definitive surgery (mean, nine days after the injury), small, widely spaced incisions with minimal soft-tissue dissection, and the use of low-profile implants.

These complications have prompted the introduction of alternative techniques for the treatment of these injuries, including the use of percutaneous reduction techniques and stabilization with circular fixator frames. The promising initial results described by Watson, Buckle et al., and Stamer et al. revealed reasonable outcomes with dramatically reduced infection rates (i.e., one deep infection in thirty-one patients)\(^1,10-11\). However, the quality of fracture reduction with the circular fixator technique for bicondylar tibial plateau fractures has been questioned\(^1\). In the present study, we found that there was no difference in our restoration of the osseous anatomy, either of the articular surface or of the metaphyseal-diaphyseal junction, between the circular fixator group and the open reduction and internal fixation group. However, it is important to note that in two of forty-three fractures randomized to treatment with a circular fixator, we were unable to effectively reduce the joint surface percutaneously or through a limited open incision and were forced to resort to a formal open technique. This does not necessarily mean that the reductions were perfect in all patients (in either group); there was a considerable rate of nonanatomical intra-articular reduction, but the outcome did not appear to be compromised in these individuals. We were generally successful in restoring overall limb alignment, with only four patients in the open reduction and internal fixation group and six in the circular fixator group who had >5° of metaphyseal-diaphyseal angulation at the time of the final follow-up. This lends additional support to current evidence that articular reduction is of less importance and that a straight leg, a stable knee, and the absence of complications are primarily responsible for optimizing outcome in these severe bicondylar plateau injuries\(^1,16-24\).

Another concern that has been raised with regard to the circular fixator technique is the inability to clearly identify (and potentially repair) intra-articular soft-tissue abnormalities. Obviously, these injuries are easier to identify (and repair) with open reduction and internal fixation. In our study, meniscal injuries were identified and repaired in twelve (30%) of forty patients managed with open reduction and internal fixation; presumably the rate was similar in the circular fixator group, in which only two repairs were performed through limited open incisions. Despite this, no patient in the circular fixator group required secondary surgery for meniscal or cruciate abnormalities during the follow-up period of two years, and the clinical outcome scores were similar or superior to those in the group managed with open reduction and internal fixation. This finding, which is similar to the results from other series describing the circular fixator technique, brings into question the necessity of aggressive identification or repair of intra-articular soft-tissue pathological conditions, including cruciate ligament reconstruction with grafts\(^1,16-24\). We have found that stiffness, rather than instability, tends to be the clinically more relevant problem. Also, while prior studies have pointed out that the rate of associated soft-tissue injuries is as high as 56%, no study has, to our knowledge, confirmed that aggressive investigation and treatment (apart from repairing obvious soft-tissue lesions evident in the course of fracture fixation) improves clinical outcome\(^5,16-24\).

Our study confirmed the significant rate of complications seen following open reduction and internal fixation of these difficult fractures, despite the use of “modern” fracture fixation and soft-tissue handling techniques. The rate of deep infection in the open reduction and internal fixation group in the present study was 17%. This is higher than the rate of 8.4% recently reported by Barei et al., but it is much improved compared with earlier series\(^5,15,15\). Reoperations in the open reduction and internal fixa-
tion group tended to be of greater severity and included numerous soft-tissue procedures for bone and hardware coverage and revision of fixation. There was a lower reoperation rate in the circular fixator group, and the unplanned procedures that were required were of lesser magnitude (i.e., screw removal).

There were significant residual deficits in both groups, as measured by both limb-specific and general patient-oriented outcome measures. For example, two years following the injury, only 12% of the patients managed with open reduction and internal fixation and 30% of the patients managed with the circular fixator felt that they had returned to all of their preinjury activities. There are a number of possible reasons for this. In general, patient-oriented outcomes are more sensitive to residual disability following a fracture than are surgeon-based or radiographic outcomes, which have been the focus of many previous studies. The return to “normal” activities may be compromised by concomitant injuries, which affected some of the patients in this series. Also, Gaston et al. recently reported on the return of objectively measured muscle strength in the leg following (mostly unicondylar) tibial plateau fractures. They found that only 14% of the patients achieved normal (defined as that of the uninjured, contralateral leg) quadriceps strength, while 30% had normal hamstring strength one year following the injury. It is reasonable to assume that the more severe bicondylar fractures seen in our trial would exhibit even greater strength deficits with an obvious negative effect on function. This may be the explanation for the higher disability measured by the WOMAC function subscale (range, 41 to 56) compared with the stiffness (range, 7 to 10) or pain (range, 11 to 15) subscales.

There was some evidence (an earlier discharge from the hospital, improved HSS scores at six months, and less bodily pain as measured with the SF-36) that the circular fixator group had a faster recovery from the injury than the group managed with open reduction and internal fixation. This could be due to a number of factors, including the more aggressive rehabilitation program in the circular fixator group with earlier weight bearing, the lower postoperative complication rate, and the decreased soft-tissue dissection with decreased pain and swelling. Given the current societal emphasis on rapid recovery and return to function, this must be considered an important advantage of the circular fixator technique over conventional surgery. In addition, patients managed with the circular fixator lost significantly less blood, had a shorter hospital stay, and did not require as much operative time compared with those who had open reduction and internal fixation. While it was not the focus of this study, the circular fixator technique with decreased soft-tissue dissection allows earlier definitive intervention in patients with a compromised soft-tissue envelope compared with current standards of provisional external fixation followed by delayed (often by two or three weeks) definitive surgery. However, an acceptable reduction may not always be achievable by limited open procedures, and a formal open approach may be required.

It is important to emphasize that this study was conducted before the advent of locking plates, and it is not a comparison of the circular fixator and open reduction and internal fixation with locking plates. Although there are no comparative trials that we are aware of, there is some preliminary evidence that the use of locking plates for fractures of the proximal end of the tibia may provide superior results compared with conventional plate fixation.

Despite its randomized and prospective nature, our study has several weaknesses. There are a number of results in our trial that show trends that approach the accepted level of significance (p < 0.05); for example, the mean 11° increase in the arc of flexion-extension in the circular fixator group at two years (a mean of 120° for the circular fixator group compared with 109° for the group managed with open reduction and internal fixation; p = 0.091). It is possible that this represents a “true” (and clinically relevant) improvement in motion that does not reach significance because of a sample size that is too small or a standard deviation that is too large or both. This is defined as a potential beta error (a failure to confirm a true difference between experimental groups) that could be eliminated by a larger study with more patients. Although we used the best available measurement tools at the time of the study, a more precise outcome measurement tool might also be able to detect a clinically significant difference in the two techniques. In addition, the final follow-up evaluation was only twenty-four months after the injury. It is possible that, with time, many of these patients may have postraumatic arthritic change develop in the knee, especially since the articular reduction was imperfect in some of them. It is possible, even probable, that the prevalence of degenerative change may increase with time. However, one would anticipate that, since the prevalence and severity of such change was equal in the groups at two years, the rate of subsequent degeneration would be similar. Also, late reconstructive surgery following postraumatic arthritic change after tibial plateau fractures usually requires total knee arthroplasty. In general, arthroplasty in this setting is technically simpler with a lower complication rate if prior incisions, soft-tissue scarring, and implanted hardware are minimized. This would typically favor the circular fixator group. However, the presence of indolent infection from old pin tracks in the proximal end of the tibia is also a concern for future arthroplasty.

In conclusion, both techniques provided a reasonable quality of fracture reduction. Closed reduction and application of a circular fixator resulted in a shorter hospital stay; fewer and less severe complications, marginally faster return of function, and similar or superior clinical outcomes compared with conventional open reduction and internal fixation with plates. These benefits are obtained (in the majority of patients) without compromising the quality of fracture reduction. Regardless of treatment method, patients with this injury have significant residual limb-specific and general-health deficits at two years of follow-up.

Appendix

A table showing the WOMAC outcome values and the radiographic reduction parameters at one year and a histogram presenting the SF-36 scores at two years are available with the electronic versions of this article, on our web site at...
FIXATOR FOR TIBIAL PLATEAU FRACTURES
OPEN REDUCTION AND INTERNAL FIXATION VS. A CIRCULAR FIXATOR FOR Tibial Plateau Fractures

The Journal of Bone & Joint Surgery - JBJS.org
Volume 88-A - Number 12 - December 2006

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References


