Day-Case Opening Wedge High Tibial Osteotomy With Intraosseous PEEK Implant

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**Purpose:** To evaluate the short-term clinical outcomes, complications, hospitalization time, and readmission rate related to day-case opening wedge high tibial osteotomy (OWHTO) with intraosseous PEEK (polyether ether ketone) implant, in the treatment of knee osteoarthritis. **Methods:** An observational study on patients treated with OWHTO using intraosseous PEEK implant was performed with a period of 12 months follow-up. Grade of Knee Injury and Osteoarthritis Outcome Score (KOOS) was assessed preoperatively, at 6 months, and at 12 months postoperatively. A simple t test was used to analyze the outcomes. P values <.05 were considered significant. Complications and revision surgeries were registered. **Results:** In the period from 2016 to 2017, a consecutive group of 40 patients (13 female, 27 male) with symptomatic medial knee osteoarthritis and varus malalignment were included in the study. The average age of the patients was 54.9 (± 7.6) years. In total, 30 (77%) patients met the criterion for minimal clinically important difference in KOOS scores. The KOOS symptoms improved from 58.1 ± 20 to 78.5 ± 16.5 (P < .0001), pain from 48.1 ± 18.2 to 78.6 ± 18.5 (P < .0001), activities of daily living from 59.0 ± 19.5 to 84.1 ± 15.2 (P < .0001), sport from 23.2 ± 17.6 to 55.6 ± 26.3 (P < .0001), and quality of life from 28.4 ± 12.8 to 61.5 ± 22.5 (P < .0001) at 1-year follow-up. The average hospitalization time at the Day Surgery Unit was 5.6 ± 0.7 hours, and 4 (10%) patients had to be readmitted to the hospital within 2 weeks postoperatively. The overall complication rate was 18%. Complications that required revision surgery were registered in 4 patients (10%), including 2 non-unions and 2 progressions of osteoarthritis. **Conclusions:** The day-case OWHTO with intraosseous PEEK implant was a success in 77% of the cases. The results and complications were comparable with other published studies. Despite a short hospitalization time, the readmission rate was low. **Level of Evidence:** IV, therapeutic case series.

High tibial osteotomy (HTO) is a well-established joint-preservation surgery for the treatment of medial knee osteoarthritis (OA) with varus malalignment. The procedure unload the affected part of the joint and moves the mechanical axis laterally to the unaffected part of the knee joint. Earlier studies showed a survival rate of up to 82% at 10 years follow-up, meaning that 82% of the patients postponed the implantation of TKA for at least 10 years. The surgical techniques most frequently used have been opening wedge high tibial osteotomy (OWHTO) and closing wedge HTO. There have not been reported significant differences between these surgical techniques regarding clinical outcomes, complications, or survival rate. The surgical procedure is less technically demanding, preserves the bone stock, and leads to lower leg length discrepancy, better predictability, and adjustability of the correction angle. One also avoids the complications related to fibular osteotomy, disruption of the proximal tibiofibular joint, and possible fibular nerve injury. Despite an 82% survival rate of OWHTO at 10 years’ follow-up, there are still some challenges. Intraoperative and postoperative complications such as fractures of the lateral cortex, fractures of the metal plate, and delayed union with loss of correction are reported in up to 9% of the cases. Hardware...
irritation and hardware removal rates have been reported to be up to 41% and 60% to 99%, respectively.1,8,14 Moreover, unintended correction of slope and axis in the sagittal plan might lead to an alteration of knee biomechanics and hence affect joint stability and joint contact pressure.14,15 It has been reported that the exact correction of the varus angle is a predictor of success after OWHTO.1 However, to achieve the exact correction angle using a standard HTO plate system can be technically challenging.16

To address some of these issues, a new low-profile PEEK (polyether ether ketone) implant has been developed.16 The advantages of the PEEK implant are radiolucency, mechanical properties similar to cortical bone, and implant placement flush to the tibial cortex. In addition, a unique fluoroscopy-based guidance system has been introduced to the surgical technique.1,16–18 It includes cutting guides, a hinge pin providing a stop to the saw cut laterally (not to create a fracture in the lateral cortex), and a shield protecting the posterior neurovascular structures during the osteotomy cutting. The guidance system facilitates an exact correction of the varus deformity while preserving the slope. Moreover, because the implant is placed flush to the cortical bone, it is easy to perform soft-tissue closure over the implant and it makes removal of the implant unnecessary. Because the implant is made of PEEK and do not usually interfere with the component placement, it is not needed to remove it when converting HTO to total knee arthroplasty (TKA).16–18

HTO is usually conducted as an inpatient procedure in the majority of institutions and the reported hospitalization time varies from 4.5 to 5.5 days,19,20 thus imposing a substantial cost of hospital admission.21 The purpose of this study was to evaluate the short-term clinical outcomes, complications, hospitalization time, and readmission rate related to day-case OWHTO with intraosseous PEEK implant, in the treatment of knee OA.

Our first hypothesis was that the OWHTOs performed as a day-case procedure would have similar clinical outcomes and complication rates compared with other similar studies. The second hypothesis was that day-case OWHTOs would have a short hospitalization time and low readmission rate the first 2 weeks after the procedure.

Methods

Study Design

In the period from January 2016 to September 2017, an observational study on patients treated with OWHTO using intraosseous PEEK implant was performed. The inclusion criteria were based on the clinical and radiologic findings. Inclusion criteria based on the clinical findings were symptomatic medial knee OA with activity dependent pain and morning stiffness. The patients with flexion or extension contractures were not included in the study (accepted range of motion—full extension to minimum 100° of flexion). All of the patients had a duration of symptoms for at least 12 months and had tried nonoperative treatment with a focus on strengthening exercises of the muscles around the knee joint for at least 6 months before surgery. Bilateral standing long leg radiographs, together with front, lateral, and Rosenberg view, were used to assess the grade of OA.

Inclusion criteria based on the radiologic findings were medial OA Kellgren–Lawrence grade 3 to 4 with varus malalignment of at least 5°, Ahlbach grade 1 to 2 medially, normal joint height laterally, and patellofemoral arthritis Kellgren–Lawrence grade 1 to 3. The exclusion criteria included patients with a serious cardiovascular condition (American Society of Anesthesiologists score 3-5), patients with an acute systemic infection, patients with known systemic rheumatoid disease, and patients with known alcohol or drug abuse. Patients with flexion or extension contractures (unable to fully extend the knee or a knee flexion <100°) also were excluded from the study. Previous knee surgery was not an exclusion criterion. The hospital’s local ethical board approved the study. The patients were referred to our hospital by other surgeons, general practitioners, or physiotherapists based on a tentative diagnosis of medial knee OA. They were then assessed by the treating surgeons at the hospital’s outpatient clinic. Suitable patients were informed about the procedure, its potential risks, and the postoperative rehabilitation. At the same time, the patients were invited to participate in our study.

Surgical Technique

The surgery was performed at the Day Surgery Unit at our clinic by 3 different surgeons and executed as previously described.16 Preoperatively, the correction angle was planned using the Fujisawa point on long leg radiographs. The size of the implant (small, medium, large, extra-large) was measured based on the width of the tibia metaphysis. The patient was in supine position with a tourniquet placed around the thigh. A standard proximal anteromedial tibia incision was made, the tissue dissected, and the periosteum released with an inverted L-shaped incision. A periosteal elevator was used to carefully detach the periosteum from the posterior tibia in the direction of the osteotome until the fibular head was reached. The guide block (iBalance; Arthrex, Naples, FL) was then assembled. First, the lateral alignment was controlled under fluoroscopic guidance and the guide block was secured with a pin. Next, the guide block was aligned to the tibia plateau in anteroposterior view and secured with another pin. The lateral keyhole was drilled through the guide block and
the lateral hinge pin was placed. Then, 2 large keyholes were drilled medially through the guide. The cutting block was assembled and attached to the main guide block. The posterior protector shield was positioned on the posterior part of the tibia and secured to the guide block. The tibia cutting was then performed with a saw through the cutting guide. The guide block was removed and the osteotomy was opened up to the desired correction angle, using a distractor jig. The PEEK implant (iBalance; Arthrex) of planned size was positioned in situ. Four locking PEEK screws (iBalance; Arthrex), 2 proximal cancellous and 2 cortical distal ones, were placed through the implant to anchor it to the bone (Fig 1). The osteotomy was then filled with bone cement (Quickset; Arthrex). The periosteum and fascia were closed over the implant if possible and a standard wound closure was performed.

A standardized multimodal perioperative pain management was applied: preoperative, orally administered dexamethasone (12 mg) and paracetamol (1 g), ultrasound-guided peripheral nerve blocks of the popliteal sciatic, saphenous, and obturator nerves with 20 mL, 10 mL, and 10 mL, respectively, using a solution of ropivacaine 5 mg/mL. Dexamethasone (4 mg) was added to the local anesthetic solution in the popliteal sciatic nerve block. Peripheral nerve blocks were applied postoperatively before the patient woke up from the general anesthesia. The pain management after the discharge from the Day-Surgery Unit included orally administered paracetamol 1 g ×4, oxycodone controlled-release (Oxycontin) 5 mg ×2, and oxycodone immediate-release 5 mg up to 4 times daily.

Postoperative plain radiographs were used to assess the correction angle, possible hardware-based complications, or unintended intraoperative fractures. A removable knee cast was applied in all patients for the first 6 weeks postoperatively. The cast was locked from 0° of extension to 20° of flexion and the patients were allowed partial weight bearing (10 kg). If signs of union were present at the 6-week plain radiographs, the cast was removed, and increasing weight bearing was allowed. Full weight bearing and range of motion were permitted a few weeks after removal of the cast. The rehabilitation program focused on range of motion and strengthening exercises.

Data Collection

The treating surgeons assessed the patients preoperatively, at 6 months postoperatively, and at 1 year postoperatively. The Knee Injury and Osteoarthritis Outcome Score (KOOS) questionnaire was administered preoperatively by a nurse at the Day Surgery Unit and postoperatively by the treating physiotherapist. Any complications or revision surgeries were also recorded. Based on earlier studies, the minimal clinically important difference (MCID) in KOOS score was 14.5.22,23 The complications not requiring revision surgery were regarded as minor. The complications requiring revision surgery were regarded as major. The patients who were in need of revision surgery were categorized as a failure in the study.

Statistical Analysis

Continuous variables were described by means and standard deviations. A simple t test was used to analyze the preoperative and postoperative outcomes. P values <.05 were considered significant.

Results

A consecutive group of 40 patients (13 female, 27 male) with symptomatic medial knee OA and varus malalignment were included in the study and treated with OWHTO using intraosseous PEEK implant. The average age was 54.9 ± 7.6 years (range, 42-65 years) (Table 1). The follow-up data were obtained from 39 patients and 1 patient was lost to follow-up. All of the surgeries were performed as day-case procedures. The average hospitalization time was 5.6 ± 0.7 hours (range from 4.0 to 7.5 hours). Three of the patients had to be readmitted to the hospital for more intensive pain management within the first 2 weeks after the surgery.
and one patient was readmitted because of social reasons.

The average correction angle was 9.7° ± 1.7° (range, 6.0°-12.0°). In total, 30 (77%) patients met the criterion for MCID in KOOS (>14.5). In average, the KOOS symptoms improved from 58.1 ± 20 to 78.5 ± 16.5 (P < .0001), pain from 48.1 ± 18.2 to 78.6 ± 18.5 (P < .0001), activities of daily living from 59.0 ± 19.5 to 84.1 ± 15.2 (P < .0001), sport from 23.2 ± 17.6 to 55.6 ± 26.3 (P < .0001), and quality of life from 28.4 ± 12.8 to 61.5 ± 22.5 (P < .0001) at 1-year follow-up. Table 2 and Figure 2 show the gradual improvement in KOOS scores at 6 and 12 months postoperatively.

None of the patients experienced severe intraoperative complications, such as popliteal artery injury, or intraoperative implant failures. The overall complication rate was 18%. Complications that required revision surgery (major complications) were registered in 4 patients (10%). Two of these patients experienced non-union with lateral hinge fracture and the loss of correction. Both presented with increasing pain. Furthermore, there were no signs of union on the plain radiographs 6 weeks postsurgery. The removable cast was therefore continued. When signs of union were not present on the 3-month radiographs, but a lateral hinge fracture was discovered, a computed tomography scan was conducted. It confirmed both the fracture and the lack of union. The revision surgeries in these 2 cases included removal of the implant, debridement, bone grafting with structural iliac crest autograft, lateral fixation with stepped metal staples (High Tibial Osteotomy Staples; Stryker, Kalamazoo, MI), and medial fixation with an HTO plate (Activemotion size two; Newclip, Haute-Goulaine, France). Two additional patients were converted to TKA because of the progression of OA and worsening of the clinical symptoms approximately 1 year after the surgery. None of the PEEK implants interfered with the component placement during the TKA surgery. Three other minor complications not requiring revision were registered. One of these patients was diagnosed with an undislocated intraarticular lateral tibia-plateau fracture at 6 weeks follow-up with plain radiographs. The fracture was not discovered on postoperative plain radiographs. The patient was treated for 2 additional weeks with a removable knee cast and the fracture healed without impairing the clinical outcomes. The second patient was diagnosed with a regional pain syndrome after the surgery. The third patient experienced a superficial skin infection that was successfully treated with orally administered cloxacillin 1 g ×4 for 10 days.

### Discussion

The results of our study show that 77% of the patients met the criterion for MCID in KOOS. At 1-year follow-up, the average KOOS symptoms improved from 58.1 to 78.5, pain from 48.1 to 78.6, activities of daily living from 59.0 to 84.1, sport from 23.2 to 55.6, and quality of life from 28.4 to 61.5. Other studies have reported similar clinical improvement after OWHTO with intraosseous PEEK implant. Getgood et al.16 reported the outcomes of 32 patients treated with PEEK OWHTO compared with a control group of 32 patients treated with metal plate. The patients in the PEEK group reported significant improvement in KOOS scores and SF-36 at 12 months’ follow-up. No statistically significant differences were seen between the groups in terms of time to weight bearing, radiographic union, implant stability, or patient-reported outcomes. Three patients in the PEEK group and one patient in the control group experienced complications requiring revision surgery.16

Ghinelli et al.1 reported the outcomes of 15 patients treated with OWHTO with intraosseous PEEK implant. The patients reported clinically significant improvement

### Table 1. Demographic Data of the 40 Included Cases

<table>
<thead>
<tr>
<th>Age, y</th>
<th>54.9 ± 7.6 (42-75)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>27 (67.5)</td>
</tr>
<tr>
<td>Female</td>
<td>13 (32.5)</td>
</tr>
<tr>
<td>Side</td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td>24 (60)</td>
</tr>
<tr>
<td>Right</td>
<td>16 (40)</td>
</tr>
</tbody>
</table>

Data are presented as n (%) or mean ± SD (range).

### Table 2. Functional Outcomes Following Opening Wedge High Tibial Osteotomy Using Intraosseous PEEK Implants

<table>
<thead>
<tr>
<th>KOOS</th>
<th>Symptoms</th>
<th>Pain</th>
<th>ADL</th>
<th>Sport</th>
<th>QoL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative</td>
<td>58.1 ± 20</td>
<td>48.1 ± 18.2</td>
<td>59.0 ± 19.5</td>
<td>23.2 ± 17.6</td>
<td>28.4 ± 12.8</td>
</tr>
<tr>
<td>6 months’</td>
<td>73.8 ± 12.7</td>
<td>74.0 ± 17.7</td>
<td>77.5 ± 17.7</td>
<td>43.5 ± 23.8</td>
<td>52.1 ± 21.6</td>
</tr>
<tr>
<td>follow-up</td>
<td>P &lt; .0005</td>
<td>P &lt; .0001</td>
<td>P &lt; .0002</td>
<td>P &lt; .0002</td>
<td>P &lt; .0001</td>
</tr>
<tr>
<td>12 months’</td>
<td>78.5 ± 16.5</td>
<td>78.6 ± 18.5</td>
<td>84.1 ± 15.2</td>
<td>55.6 ± 26.4</td>
<td>61.5 ± 22.5</td>
</tr>
<tr>
<td>follow-up</td>
<td>P &lt; .0001</td>
<td>P &lt; .0001</td>
<td>P &lt; .0001</td>
<td>P &lt; .0001</td>
<td>P &lt; .0001</td>
</tr>
<tr>
<td>Difference vs 20.4</td>
<td>30.5</td>
<td>25.1</td>
<td>32.4</td>
<td>33.2</td>
<td></td>
</tr>
</tbody>
</table>

Data are presented as means ± standard deviation.

ADL, activities of daily living; KOOS, Knee Injury and Osteoarthritis Outcome Score; QoL, quality of life.
in clinical scores at the final follow-up. The International Knee Documentation Committee (IKCD) scores improved from 66.8 to 73.6, KOOS from 61.3 to 88.1, visual analog scale from 8.6 to 2.9, and Tegner score from 4.1 to 3.1. No severe intraoperative or postoperative complications were reported. Only one superficial wound infection was registered and was resolved by per oral antibiotics. No hardware removal procedures were reported. 

Roberson et al. reported the outcomes of 21 patients treated with PEEK implant compared with a control group of 20 patients treated with a metal plate. The IKCD score in the PEEK group improved from 15.0 to 94.0, Western Ontario and McMaster Universities Osteoarthritis Index score from 0-69.0, Tegner score from 0 to 10.0, and Single Assessment Numeric Evaluation score from 37.0 to 98.0 76.5 at final follow-up. There were no significant differences in the clinical outcomes compared with the control group. The complications in the PEEK group included 1 pain syndrome, one deep vein thrombosis, 1 non-union requiring revision, 1 hardware loosening, and 1 infection. There was no significant difference in the complication rates between the PEEK and control group, but the control group had a greater rate of hardware removal (four patients) compared with the PEEK group (none).

Morris et al. reported the results of PEEK OWHTOs in 20 cases (17 patients). The patients reported improvement in IKCD from 35.6 to 90.0, Lysholm from 44.5 to 100.0, and Western Ontario and McMaster Universities Osteoarthritis Index from 36.0 to 0 at 38 months final follow-up). Regarding the complications, one non-union with consequent revision to TKA was reported. Two additional patients were also revised to TKA. No hardware removal was reported.

Hevesi et al. reported the outcomes of 95 OWHTOs in 90 patients with a mean 4.2 years of follow-up. In total, 50 cases were treated with plates and 45 with PEEK implants. Two patients with metal and 2 patients with PEEK HTO experienced non-unions, resulting in revision HTO at a mean of 1.0 years postoperatively. Twelve patients (24%) in the metal group and 5 patients (11%) in the PEEK group experienced intraoperative lateral cortex fractures. Three patients in the metal group experienced a superficial infection and 1 patient had a deep venous thrombosis with concurrent pulmonary embolus. One patient in the PEEK group developed an acute deep infection requiring revision surgery and hardware removal. The hardware removal rate was 46% in the plate group and 7% in the PEEK group. Six percent of the patients in the plate group and 22% in the PEEK group were converted to TKA within 5 years after the HTO surgery.

Although OWHTO was a day-case procedure in our study, we did not experience more or different types of complications compared with the mentioned studies. Our overall complication rate was 18% and the revision rate 10%. The major complications requiring revisions...
included 2 cases of non-union with a lateral hinge fracture and 2 progressions of OA. Minor complications not requiring revisions included 1 intraarticular lateral tibia-plateau fracture, 1 superficial infection, and 1 regional pain syndrome. In comparison, Getgood et al.\textsuperscript{16} reported around 10% major complications requiring revision, Ghinelli et al.\textsuperscript{1} around 6% minor complications and no revisions, Roberson et al.\textsuperscript{18} 10% minor complications and 14% revisions, Morris et al.\textsuperscript{24} 15% revisions, and Hevesi et al.\textsuperscript{17} 28% revisions. As in our material, the revisions mostly included surgeries for non-unions and implantation of TKAs.

The average hospitalization time for OWHTOs at the Day Surgery Unit was 5.6 hours. Despite a short hospitalization time, our readmission rate was low (10%). To our knowledge, OWHTO is still conducted as an inpatient procedure in the majority of institutions and the reported hospitalization time varies from 4.5 to 5.5 days.\textsuperscript{19,20} Hence, the publications reporting OWHTOs performed as day-case procedures are limited. Hart et al.\textsuperscript{21} reported the results of 33 patients including 23 inpatient admissions and 10 day-cases. They showed comparable clinical outcomes and high patient satisfaction when the OWHTO was conducted as a day-case procedure compared with patients treated as inpatients. Average KOOS score improvement for the inpatient pathway was 24.68 and for the outpatient one 31.8. The outpatient group unanimously agreed that if to undergo OWHTO once more, they would desire to be treated in an outpatient setting again.\textsuperscript{21}

**Limitations**

We recognize that our study has limitations. First, we present an initial experience in terms of a consecutive case series without any control group. Second, the results are only short term and we do not know the surgical outcomes in the long term.

**Conclusions**

The day-case OWHTO with intraosseous PEEK implant has been a success in 77% of the cases. The results and complications were comparable with other published studies. Despite a short hospitalization time, the readmission rate was low.

**References**

17. Hevesi M, Macalena JA, Wu IT, et al. High tibial osteotomy with modern PEEK implants is safe and leads to...


