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ORIGINAL ARTICLE • KNEE - OSTEOTOMY

Early results of medial opening wedge high tibial osteotomy using an intraosseous implant with accelerated rehabilitation

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Abstract

Background Accelerated rehabilitation protocols for medial opening wedge high tibial osteotomy (MOW HTO) using intraosseous implants have not previously been described. The present study provides early clinical and radiological outcomes of MOW HTO using a polyetheretherketone (PEEK) intraosseous system, in combination with an early weight-bearing protocol.

Methods Twenty consecutive knees (17 patients) underwent navigated MOW HTO using a PEEK implant with accelerated rehabilitation. Time to union and maintenance of correction were assessed radiographically for 12 months post-operative. Patient outcomes were monitored for a mean follow-up of 38 months (range 23–42) using standardised instruments (WOMAC, IKDC and Lysholm scores).

Results All knees were corrected to valgus. The mean time to unassisted weight-bearing was 55 days (SD 24, range 21–106). Bone union occurred in 95% of knees by 6 months, with correction maintained for 15 knees at 12 months post-operative. Knees for which correction was lost within 1 year of surgery had significantly greater preoperative varus alignment. Implant survivorship was 95% and 80% at 12 and 38 months post-operative, respectively. Significant improvements in patient-reported satisfaction, knee function and return to daily activities from preoperative to 38 months post-operative were reported (WOMAC 36 *v* 0; IKDC 35.6 *v* 96; Lysholm 44.5 *v* 100).

Conclusions Accelerated rehabilitation following MOW HTO with an intraosseous PEEK implant did not delay bone union, with significantly improved functional outcomes within 3 months post-operative. Early findings suggest that this approach may be suitable for a defined patient subset, with consideration for the extent of preoperative genu varum.

Keywords Medial opening wedge · High tibial osteotomy · Medial osteoarthritis · Navigation · PEEK · Accelerated rehabilitation

Abbreviations

HKA	Hip-knee-ankle angle
HTO	High tibial osteotomy
IKDC	International Knee Documentation Committee
MCL	Medial collateral ligament
MOW	Medial opening wedge
PCN	Precision computer navigation
PEEK	Polyetheretherketone
ROM	Range of motion
TKA	Total knee arthroplasty
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index

Introduction

Medial opening wedge (MOW) high tibial osteotomy (HTO), a technique used for the treatment of medial knee osteoarthritis (OA), is commonly performed with an extraosseous plate-fixation under tension [1]. Non-plate, intraosseous wedge implants constructed from polyetheretherketone (PEEK) and inserted under compression are also available [2]. In addition to the fixation hardware and surgical technique used, the long-term outcome of MOW HTO depends on the correction achieved after the osteotomy and the preservation of this alignment during bone healing [3, 4]. Factors such as appropriate patient selection and the post-operative

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rehabilitation protocol used also greatly influence the success of MOW HTO [3, 4].

Post-operative rehabilitation protocols for MOW HTO vary considerably depending on the type of fixation hardware and surgical technique used. Programmes typically encourage progressive weight-bearing, with limited weight-bearing in the first 6 weeks following surgery [5]. A perceived benefit of locking plate-fixators for MOW HTO has been the capacity for early weight-bearing [5]. Several studies have demonstrated that implementation of an accelerated rehabilitation protocol is not only practical, but can lead to superior clinical outcomes and improved patient satisfaction following MOW HTO [6–8]. Use of an intraosseous fixation system and changing the rehabilitation concept to early full weight-bearing is assumed to potentially increase the likelihood of loss of correction, delayed bone healing and implant failure [9, 10]. However, there is currently minimal literature describing the early weight-bearing capacity for intraosseous implants for MOW HTO.

Therefore, the purpose of the current study was to describe the early clinical and radiological results of a small case series of MOW HTO using a PEEK intraosseous implant, in combination with an early weight-bearing rehabilitation protocol, where the primary outcomes assessed were bone union and implant stability.

Materials and methods

Research design

This is a single surgeon cohort study of 20 consecutive MOW HTO cases using the iBalance HTO system (Arthrex, Naples, FL) between February 2014 and October 2015. Inclusion criteria included male and female patients over the age of 18 with preoperative varus malalignment and symptomatic medial knee osteoarthritis, and a BMI of < 35. Exclusion criteria included patients over the age of 70 years, with a BMI of > 35. Magnetic resonance imaging and long-leg radiographs were carried out preoperatively to assess limb alignment and to exclude lateral and patellofemoral OA, respectively. Patients with an Outerbridge grade 3 or higher score in the lateral or patellofemoral compartments (determined intraoperatively with arthroscopic evaluation) were deemed unsuitable for the procedure and therefore excluded from the study. Ethical approval for this study was provided by the local human research ethics committee.

Preoperative assessment and planning

Demographic data were collected and a thorough medical history and clinical examination performed for all patients preoperatively to eliminate confounding pathologies and anterior or lateral knee pain. The range of passive motion (ROM) was measured with a goniometer by a single surgeon, at each follow-up visit. Patient-reported outcome measures (PROM) of satisfaction and limb function were assessed preoperatively using WOMAC, IKDC and Lysholm questionnaires. Standing anteroposterior (A/P) long-leg weight-bearing radiographs were used for preoperative planning. The post-operative target correction for all patients was 2°–3°. The degree of correction required to achieve this was calculated using the formula: (weight-bearing hip-knee-ankle (HKA) angle—valgus stress HKA) + 2°.

Surgical technique

Surgeries were conducted under a combination of spinal, general and local anaesthesia with a thigh tourniquet. Intravenous antibiotic and thromboembolic prophylaxis were used. All patients underwent an arthroscopic examination of the knee at the commencement of surgery to confirm suitability for the procedure, prior to receiving MOW HTO. All HTO were stabilised using the iBalance implant, and the Stryker precision computer navigation (PCN) system was used for all surgeries to allow a minimally invasive approach and intraoperative measurement of the leg axis. Infrared active tracers were attached to two metal pins in the distal femur and proximal tibia (Fig. 1). Once registration of the tracers with the PCN system was performed, limb alignment values in neutral and valgus stress positions were recorded.

A medial transverse incision was made at the level of the pes anserinus. The sartorial fascia was exposed and incised immediately proximal to the tendon of Gracilis. The fascia, together with the tendon, was tagged with a suture to aid in retraction and to enable visualisation of the superficial fibres of the medial collateral ligament (MCL). To maintain the integrity of the superficial MCL, a step-cut osteotomy was performed. The longitudinal arm of the osteotomy was performed first, extending from deep to the insertion of the patella tendon to the level of the Gracilis insertion. Two kirschner wires were inserted parallel to the joint using an image intensifier to guide the transverse arm of the osteotomy. A Stryker precision saw (1.27 mm) was used to create the transverse arm of the osteotomy in combination with the image intensifier, so as to minimise risk of lateral cortex breach. Two lug holes were created using the free hand jig to accept the implant. Due to the step-cut formation of the osteotomy, requirement for an implant beyond the small size range is uncommon (range, SM 6°–13°; Table 1).

The osteotomy was teased open with two small lamina spreaders and the alignment checked with navigation. Once the desired alignment was achieved, a trial implant was inserted and the spreaders removed. Following confirmation that the desired limb alignment was maintained with the trial implant, the PEEK implant was inserted with

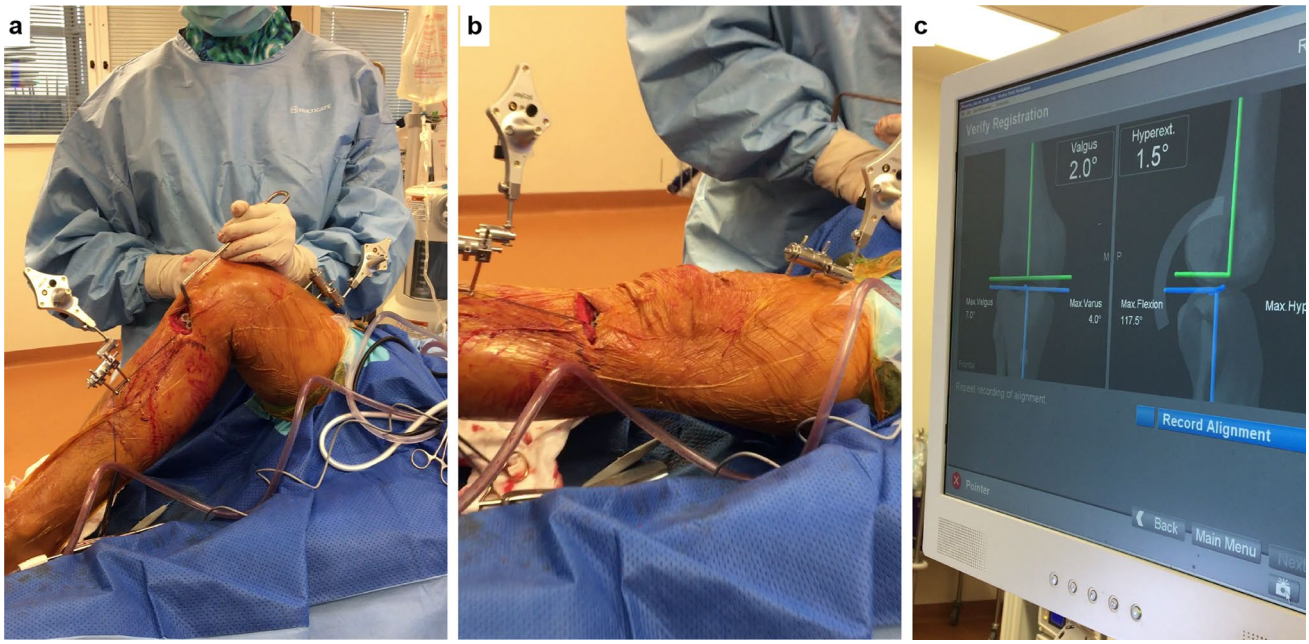

Fig. 1 Positioning of trackers for the precision computer navigation system

four anti-rotation screws. The sartorial fascia was closed and the wound subsequently closed in layers. Local anaesthetic (ropivacaine, 1%) was injected into the surgical site soft tissue for post-operative analgesia.

Intraoperative metrics

Pre- and post-procedure limb alignment parameters including weight-bearing HKA angle, valgus stress HKA angle and full knee extension and flexion angles were measured with navigation.

Post-operative rehabilitation

An accelerated rehabilitation protocol was implemented, with immediate active physiotherapy, from day 1 post-operative for all patients (Fig. 2). Weight-bearing was encouraged with the aid of crutches under the supervision of the physiotherapist from day 1 post-operative and prior to discharge. Patients were encouraged by the surgeon and physiotherapist to continue to mobilise with crutches after discharge, with progressive weight-bearing on the operated limb as the patient felt comfortable to do so. Exercises were introduced to improve range of movement, to strengthen the gluteal, quadriceps and hamstring muscles, and for active mobilisation of the knee. No braces or casts were used.

Post-operative assessments

The number of days to return to full weight-bearing without the aid of crutches was recorded. The mechanical HKA (mHKA) angle was measured on A/P long-leg standing radiographs at 2 and 6 weeks, 3, 6 and 12 months post-operative. Loss of correction over the first year following MOW HTO was assessed by comparison of mHKA angles at 2 weeks post-operative, to each subsequent follow-up visit. The accuracy of the navigated, valgus stress technique for intraoperative prediction of the corrected limb alignment angle following surgery was confirmed by comparing the mHKA on A/P long-leg standing radiographs at 2 weeks post-operative to intraoperative stress HKA captured immediately after implantation using methods described previously [11].

Bone union was assessed on A/P radiographs using a previously described radiological index for semi-quantitative measurement of osteotomy healing [12]. Briefly, a triangular region was demarcated along the borders and corner of the osteotomy. The region was divided into five zones, each corresponding to 20% of the osteotomy being filled, where filling was defined as increased radiographic density. Filling was assessed in post-operative radiographs to monitor progression of bone union. The osteotomy was considered stable if the patient reported no pain with weight-bearing on the operated leg and the osteotomy site was filled through zone 3 (40–60%).

Table 1 Summary of patient demographics

Patient no. (No. knees)	17 (20)
Age (years), mean ± SD (range)	52.1 ± 9.7 (32–69)
Gender, no. (%) male	15 (88)
BMI, no. (%)	
Normal	1 (6)
Overweight (25–30)	10 (59)
Obese (> 30)	6 (35)
Affected side, no. (%) right	12 (60)
Outerbridge grade, no. (%)	
PFJ	
Grade II	5 (25)
Grade III	7 (35)
Grade IV	1 (5)
MFC	
Grade II	1 (5)
Grade III	9 (45)
Grade IV	10 (50)
MTP	
Grade II	9 (45)
Grade III	4 (20)
Grade IV	5 (25)
Implant size	
SM 6°	8
SM 7°	5
SM 8°	2
SM 9°	1
SM 10°	3
SM 13°	1
Time to unassisted, full weight-bear (*d*), mean ± SD (range)	55.4 ± 24.0 (21–106)

Clinical outcomes were assessed using WOMAC, IKDC and Lysholm questionnaires at 6 weeks, 3, 6, and 12 months and a median follow-up time of 38 months (range, 23-42) after surgery to monitor changes in knee pain and stiffness, mental and physical health. PROM were completed at 38 months post-operative for 16 of 20 knees (follow-up, 80%).

Statistical analyses

SPSS 21 and GraphPad Prism (GraphPad Software, Version 7) were used for statistical analysis and graphical representation, respectively. Data are described as mean ± standard deviation or, where indicated, as median and range. Following assessment of skewness using Shapiro–Wilk test, a paired *t* test was used for comparison of changes in intraoperative parameters before and after surgery. Limits of agreement (LOA) were calculated between the navigated stress HKA values and 2 week post-operative mHKA angles, expressed using the Bland and Altman method and used to establish delimitations for assessing the accuracy of the navigated intraoperative alignment angles [11]. Kruskal–Wallis test was used to determine significance of changes in PROM scores following HTO, with Dunn's post hoc analysis to identify the location of differences between time points. Correlation between loss of correction and radiological and clinical parameters was not assessed in the current study due to the small sample size. For all tests, statistical significance was considered at $P < 0.05$.

Results

Patient demographics

Table 1 summarises the demographic and clinical data of the 20 knees (17 patients) that underwent navigated MOW HTO with the PEEK system. The patients included 15 men (18 knees) and 2 women (2 knees) with a mean age of 52.1 years

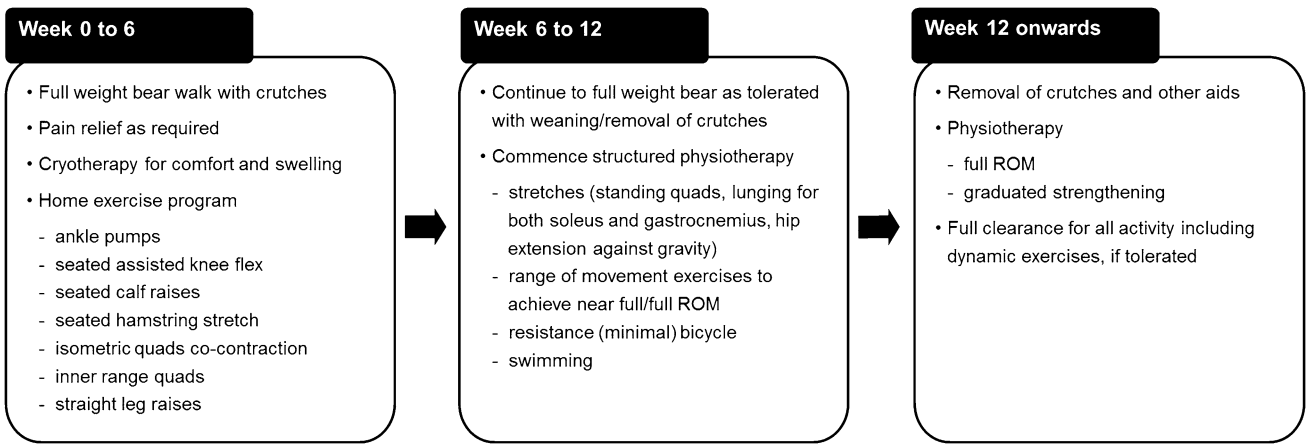

Fig. 2 Accelerated rehabilitation protocol

(range 32–69) and mean BMI of 30.2 (range 22.6–37.1). All patients had symptomatic OA changes localised to the medial compartment, with Outerbridge scores of ≤2 for the lateral femoral condyle and lateral tibial plateau for all knees. At the time of data collection for this interim report, 16 knees (14 patients) had reached a median follow-up time of 38 months (range 23–42). Implant survivorship and follow-up rate at 38 months post-surgery was 80%.

Surgical treatment

The mean surgery and tourniquet time was 77.1 ± 11.5 min (range 43–94) and 57.2 ± 14.8 min (range 33–98), respectively. No significant changes were observed for the mean ROM (125° ± 6° *v* 124° ± 6°) or mean posterior tibial slope (0.6° ± 4.5° *v* 0.8° ± 5.2°) following surgery. Intraoperatively, the mean neutral HKA (−4.9° ± 1.7° *v* 0.4° ± 1.7°; $P < 0.01$) and stressed HKA (−3.1° ± 1.6° *v* 2.7° ± 1.1°; $P < 0.01$) increased significantly from pre- to post-surgery. Based on navigated stress HKA values immediately following implantation, valgus correction was achieved for all patients (range 0.5°–5.5°), with the highly conservative target of 2°–3° valgus achieved in 12 of 20 knees (60%). Navigated stressed HKA angles measured intraoperatively were comparable to mHKA measured from 2 week post-operative long limb AP radiographs (Fig. 3a; $P = 0.12$) supporting accuracy of this intraoperative technique for predicting post-operative limb alignment (LOA −3.58°–5.16°).

Bone union and loss of correction after surgery

Full weight-bearing without crutches was possible within 4 weeks for 3 (15%) patients and 6 weeks for 11 (55%) patients after surgery. By 3 months post-operative, 19 patients (95%) were full weight-bearing, including the patient who went on to lateral cortical breach. All patients were off crutches within 6 months of surgery. Radiological union was evident in 9 patients (47%) at 3 months and 19 patients (95%) by 6 months following surgery (Fig. 3b).

No complications such as lysis or loosening, superficial or deep infections, peroneal nerve or vascular injury were observed for any patient. In the current study, loss of correction was regarded as change > ± 2° from the 2 week post-operative mHKA values determined radiologically. A catastrophic failure of the osteotomy occurred in one patient, a 56-year-old male smoker with a BMI of 29.4 within 5 months of surgery (Fig. 4a, b). The patient was weight-bearing without the aid of crutches at day 35 post-operative. Despite an acceptable loss of correction at 6 weeks post-operative (1.4°), the patient went on to open up through the lateral cortex hinge, medially, presenting to the 3 month visit with increasing varus deformity and pain. The patient was non-compliant with cessation of tobacco use and went on to an uneventful conversion to a TKA.

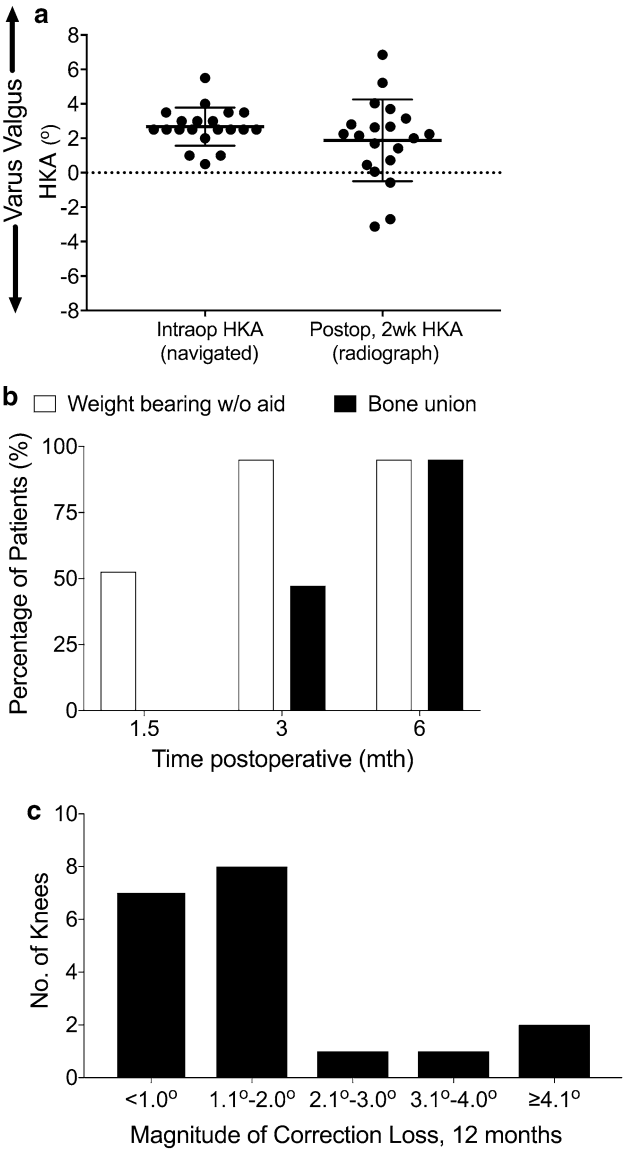

Fig. 3 **a** Navigated stressed HKA angles and mechanical HKA (mHKA) measured from 2 weeks post-operative radiographs were comparable, supporting accuracy of the navigated surgical technique. **b** Within 3 months of HTO surgery, 95% of patients were full weight-bearing without the aid of crutches, with bone union evident at the osteotomy site for all patients by 6 months post-operative. **c** Loss of correction, as assessed by the magnitude of change in mHKA between radiographs taken at 2 weeks and 12 months post-operative. Correction was maintained in 79% (15/19 knees) based on an acceptable range of ≤2° towards varus or more valgus

At 12 months post-operative, a mean absolute loss of correction of 1.4° ± 1.7° was observed in the remaining 19 knees with a mean mHKA of 0.7° ± 3.0° (range −5.62–7.31). Correction was maintained in 79% (15/19) of knees (Fig. 3c; Fig. 4c, d). Loss of correction of > 2° was

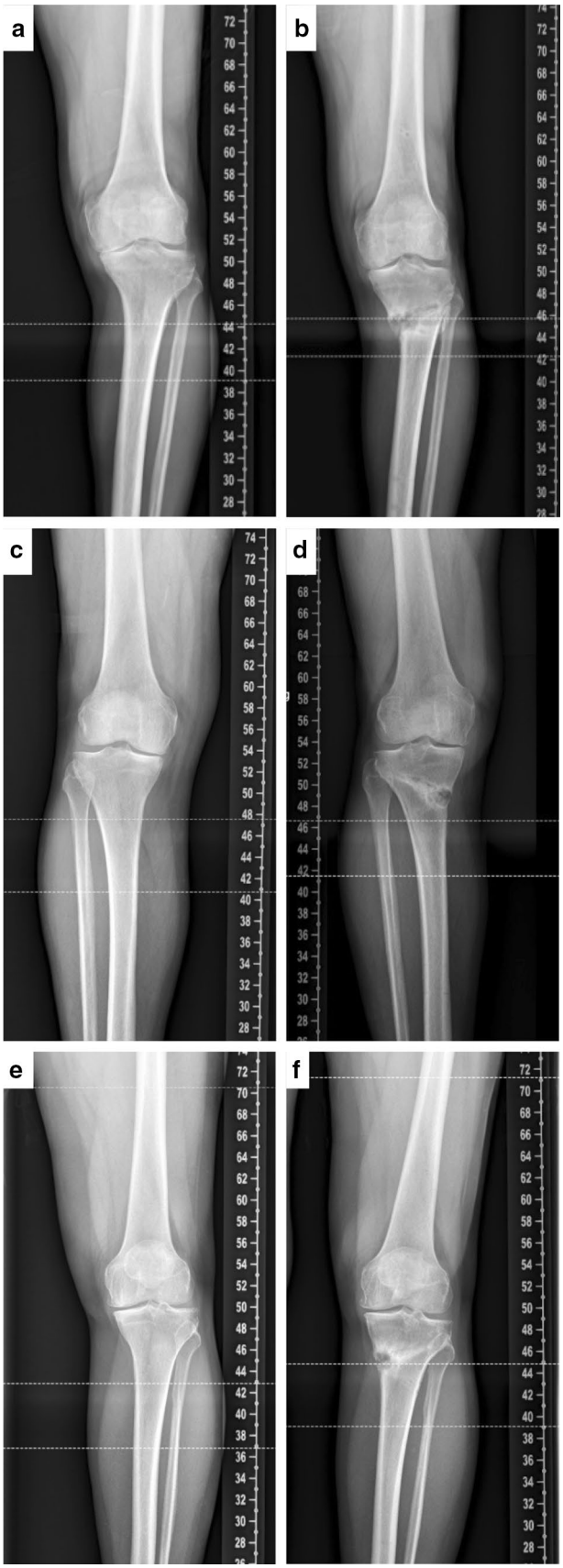

Fig. 4 Radiographic anteroposterior images at **a** preoperative and **b** 3 months post-operative of one patient for which a lateral cortical breach occurred. The patient underwent conversion to total knee arthroplasty within 6 months of the HTO procedure. Representative preoperative (**c**, **e**) and 12 months post-operative (**d**, **f**) A/P radiographs for knees where correction was maintained (**c**, **d**) or altered by > 2° (**e**, **f**)

observed for 21% (4/19 knees) at 12 months following surgery, with changes evident by 3 months post-operative. Bone union had occurred by 6 months post-operative for these 4 knees, with no further loss observed thereafter. The largest deviation in alignment at 12 months post-operative was 5.05° and occurred in a patient whose preoperative mHKA was − 10.7° varus and, who had been corrected to 3° valgus (Fig. 4e, f). Despite this deviation, at the most recent follow-up (41 months), this patient reported good functional outcomes and satisfaction with the implant (WOMAC, 3; IKDC, 90.8; Lysholm, 93).

One of the four knees had been under-corrected (preoperative mHKA, − 6.79° to stress HKA, 1°) with a loss of correction of 3.94° at 12 months post-operative. This patient had undergone MOW HTO with the PEEK implant on both left and right knees within 5 months of each other, with an acceptable loss of correction on the second knee at 12 months post-operative (Table 2). This patient subsequently went on to TKA conversion on both knees at 34 and 36 months post-operative, respectively. One additional knee (1 patient) underwent conversion to TKA at 35 months following MOW HTO due to progression of degenerative knee OA, despite maintenance of correction at 12 months post-operative (Table 2).

No significant differences were observed in age, BMI or tobacco use between knees for which correction was maintained and those knees for which loss of correction occurred (Table 3). The time to full weight-bearing without the aid of crutches and the pain experienced at this time was also comparable between groups. However, the preoperative mHKA of the knees that lost correction was significantly more varus than those for which the corrected limb alignment was maintained at 12 months post-HTO (Table 3; $P < 0.01$).

PROM

PROM indicated significant improvements in health and limb function after surgery (Table 4). The mean WOMAC summary score decreased from 36.1 (SD 15.0, range 1–62) preoperative to 1.7 (SD 2.3, range 0–7; $P < 0.001$) at final follow-up. Mean WOMAC functional scores improved significantly from 24.6 (SD 11.2, range 0–41) to 8.1 (SD 6.4, range 0–21) within 6 months post-operative ($P < 0.001$). Similarly, a significant improvement was observed for WOMAC pain scores by 6 months post-operative (Table 4;

Table 2 Clinical and radiological outcomes for knees that required conversion to TKA

	Pt_09 (right)	Pt_09 (left)	Pt_12
Time of TKA conversion post-HTO (months)	34	36	35
HKA (°)			
Preoperative	−6.79	−2.83	−3.5
Intraoperative, stress	1.0	4.0	2.5
Loss of correction to varus, 12 months (°)	3.94	2.0	−0.46
Time to unassisted, full weight-bearing (*d*)	68	55	76
WOMAC, summary			
Preoperative	37	37	23
post-operative, 12 months	14	15	43
IKDC			
Preoperative	41.4	41.4	44.8
post-operative, 12 months	70.1	64.4	29.9
Lysholm			
Preoperative	28	28	46
post-operative, 12 months	83	83	46

Table 3 Comparison of patient demographics and clinical parameters for knees that maintained correction and those that had lost correction by 12 months post-operative

	Correction maintained	Correction loss	*P* value
Age (y)	49.7 ± 9.0	57.8 ± 9.6	0.12
BMI	29.9 ± 4.4	30.8 ± 2.8	0.70
Tobacco use, *n* (%)	3 (20)	1 (20)	> 0.99
Preoperative mHKA (°)	−4.2 ± 1.4	−7.0 ± 2.6	0.01*
Time to unassisted, full weight-bearing (*d*)	59.4 ± 25	43.2 ± 18	0.20
Pain (WOMAC) at return to unassisted, full weight-bearing	4.7 ± 2.8	4.0 ± 2.0	0.60
Lysholm, 3 months	64 (31–87)	66 (55–88)	0.12

Data is mean ± SD or median (range)

*$P < 0.05$

Table 4 Changes in patient-reported outcome measures following MOW HTO

	Preoperative ($n = 20$)	Post-operative					*P*
		6 weeks ($n = 20$)	3 months ($n = 20$)	6 months ($n = 19$)	12 months ($n = 19$)	38 months ($n = 16$)	
WOMAC							
Pain	8.5 (1–15)	6 (0–13)	4.5 (0–10)	2 (0–6)	2 (0–11)	0 (0–2)	< 0.001*
Stiffness	3 (0–6)	3.5 (0–6)	3 (0–5)	2 (0–4)	2 (0–6)	0 (0–1)	< 0.001*
Physical Function	23.5 (0–41)	21 (0–37)	16 (2–35)	8 (0–21)	6 (0–27)	0 (0–4)	< 0.001*
Summary Score	36 (1–62)	29 (0–53)	24 (3–48)	13 (0–27)	12 (0–43)	0 (0–7)	< 0.001*
IKDC							
Subjective Score	35.6 (12.6–73.6)	37.4 (17.2–65.5)	52.9 (29.9–75.9)	64.4 (42.5–95.4)	65.5 (29.9–96.6)	96.0 (75.9–100)	< 0.001*
Lysholm							
Summary Score	44.5 (18–78)	62 (19–87)	64 (31–88)	80 (45–100)	83 (40–100)	100 (78–100)	< 0.001*

Data is expressed as median (range)

IKDC International Knee Documentation Committee, *WOMAC* Western Ontario and McMaster Universities Osteoarthritis Index

$P < 0.001$). From the preoperative assessment to final follow-up for this report, the mean total subjective IKDC score increased from 37.1 (SD 13.9, range 12.6–73.6) to 93.2 (SD 8.2, range 75.9–100; $P < 0.001$). Improved knee function was also supported by an increase in median Lysholm scores from preoperative (44.5, range 18–78) to 12 months post-operative (83, range 40–100; $P < 0.001$).

Discussion

We describe the early results of a case series of MOW HTO using a navigated technique for implantation of a PEEK intraosseous system, in combination with an accelerated rehabilitation protocol. Intraoperative use of navigation was able to achieve reliable prediction of post-operative mHKA, with all knees corrected to valgus and 85% corrected to > 2°. Bone union was evident in 95% of knees by 6 months of surgery with a cortical breach occurring in one patient prior to the 6-month follow-up. Loss of correction was documented at 12 months post-operative in 4 patients, with 2 patients requiring conversion to TKA at 3 years of post-surgery. The PEEK implant was well-tolerated with no soft tissue impingement occurring, nor complications such as lysis or loosening, superficial or deep infections, peroneal nerve or vascular injury.

Historically, the requirement for plate removal due to plate-related soft tissue impingement pain, pre-arthroplasty removal and plate failure due to non-union led to the development of an intraosseous fixation device [13, 14]. Comparable time to union and implant stability have been shown between intraosseous wedge and extraosseous plate systems for MOW HTO using unassisted surgical technique and traditional rehabilitation protocols [2, 9, 10]. Unassisted, full weight-bearing in the first 6 weeks post-HTO is discouraged in traditional rehabilitation protocols. A key advantage of implementing an early weight-bearing protocol following HTO is that the patient is able to regain knee function sooner and return to daily activities more quickly, thus improving patient satisfaction with the procedure. With HTO plate-fixation systems, patients are permitted to start partial weight-bearing immediately after surgery, dependent on pain scores, with progression to full weight-bearing after 2 weeks [5,7,12]. These studies demonstrated that, despite a reduced time to full weight-bearing, the long-term outcomes were similar to that of a traditional rehabilitation protocol with respect to PROM and radiological outcomes at 12 months post-operative. Since intraosseous HTO systems are historically considered less stable, traditional rehabilitation protocols are typically used. A previous study demonstrated that 81% of patients undergoing MOW HTO with a PEEK intraosseous implant and traditional rehabilitation protocol were able to fully weight-bear without crutches by 6 months post-operative, a significantly higher proportion than HTO cases performed with a plate-fixation system [2]. In the current study, 95% of patients were full weight-bearing by 3 months of surgery. Compared to preoperative scores, pain at the time of unassisted full weight-bearing was significantly reduced (8.3 *v* 4.6). In addition, inclusion of an accelerated rehabilitation protocol did not delay bone union following MOW HTO using the PEEK intraosseous implant, with time to union consistent with the 3 to 5 month times reported using plate-fixators with and without fillers [2, 12].

An overall loss of 1.4° was observed in the mean mHKA at 12 months post-operative in the current study. The largest change in mHKA occurred between 6 weeks and 3 months post-operative, with angles remaining consistent thereafter to 12 months post-operative. Correction was maintained in 79% of knees following MOW HTO with the PEEK implant and implementation of accelerated rehabilitation protocol. A loss of correction occurred for 4 patients within 12 months post-operative, though this did not adversely affect PROM with all patients reporting WOMAC summary scores of ≤ 14. One of the 4 patients went on to TKA conversion 34 months after HTO surgery. The remaining 3 patients reported good or excellent knee stability and the absence, or mild pain upon exertion at the final follow-up. The number of HTO patients for whom loss of correction occurred in the current study was higher than that reported by Getgood et al. [2] (2 of 32 patients), who used the same PEEK implant with a traditional rehabilitation protocol. Ghinelli et al. [16] observed no post-operative loss of correction following an average of 4.9° valgus correction in 15 patients who underwent MOW HTO with PEEK implant and traditional rehabilitation. These differences may be a reflection of small sample sizes, variability in target corrections and patient selection, rather than the rehabilitation protocol per se. Notably, a correlation between the preoperative mHKA and the loss of correction at 12 months post-operative ($P = 0.013$; $r = 0.558$) was observed in the current study, suggesting greater varus deformity may influence long-term outcomes following HTO and that stricter patient inclusion criteria based on preoperative mHKA may be necessary. Further investigation of the efficacy of accelerated rehabilitation following MOW HTO with the PEEK implant is warranted.

Complication rates following MOW HTO reportedly range from 8 to 55% [4, 17–19]. The PEEK implant used in the current study was well tolerated and was not associated intraoperative complications or delayed union, nor were there any incidences of post-operative implant pain that required further surgery for removal of the implant. This is consistent with the findings of Getgood et al. [2] and Ghinelli et al. [16]. A lateral breach that collapsed into varus and required conversion to TKA occurred in 1 knee in the current study. We note, however, that the continued high frequency of tobacco use in this patient following surgery

likely impacted on recovery and time to union and highlights the necessity for strict patient selection for this procedure. It is imperative that the lateral cortical hinge is maintained during MOW HTO and, if breached, we recommend conversion to a more rigid fixation system.

The mean 5-year implant survival rate for HTO plate-fixation systems is 87.8% [4]. To date, there have been two clinical studies reporting on the early and mid-term success of the PEEK intraosseous implant, in combination with traditional rehabilitation. Getgood et al. [2] reported clinical and radiological outcomes to 12 months only, with no conversions documented in this period. Ghinelli and colleagues [16] documented no conversions for 15 HTO patients over a 2-year period. In the current study, 3-year implant survivorship was 82%, with 2 of 3 patients converted to TKA at 3 years post-HTO. Moreover, the lateral breach requiring conversion within 6 months of surgery is likely a reflection of poor patient selection rather than failure of the implant itself.

Computer-assisted surgical navigation is reportedly superior to conventional techniques for reliably achieving pre-planned target alignment angles for MOW HTO [20–22], although a recent randomised controlled trial demonstrated a comparable level of surgical accuracy is achieved when using either gap balancing or navigation techniques for implantation of Tomofix plates [23]. While navigation has been previously described for implantation in MOW HTO using plate-fixation systems [20, 22, 23], the current study describes for the first time its application for implantation of the PEEK intraosseous system. A reported disadvantage of navigation in HTO is a slight extension of surgical time [24, 25]. However, this was not observed in the current study. The average operating time in the current study was 77 min, which is slightly lower than times reported by Ghinelli et al. [16] and Getgood et al. [2] using the same implant, without navigation. Similarly, these times are also lower than the surgical times reported recently for navigated and non-navigated HTO with arthroscopy using a plate-fixation system [20, 23]. Differences in the navigational systems used, surgeon experience with the navigation system and the surgical techniques used may partially account for the discrepancies observed between studies.

In the current study, navigation facilitated intraoperative prediction of the corrected mHKA, though wider variance was observed in alignment angles calculated from 2 week post-operative radiographs. This discrepancy in intraoperative values and post-operative radiographic angles is well described, with both Chang et al. [20] and Schroter et al. [23] highlighting the importance of intraoperative axial loading for simulation of weight-bearing radiographic measurements taken postoperatively. The consistency between the navigated stress HKA and 2 week post-operative radiographic mHKA in the current study supports the use of the navigated stress technique described for reliable prediction of post-operative limb alignment following MOW HTO with the PEEK implant.

Limitations

A strength of this study was that it was performed by a single surgeon with a standardised technique and protocol. However, a clear limitation was that this was a small cohort study, with no comparative group. Nevertheless, these data provide impetus for a randomised controlled trial to strengthen understanding of the relationship between the use of the intraosseous PEEK HTO implant in combination with an accelerated rehabilitation protocol and the implications on radiologic and functional outcomes. Cartilage regeneration in the affected compartment is a demonstrated benefit of limb realignment with HTO [26]. Whilst this aspect was not investigated in the current study, future trials investigating the effect of an accelerated rehabilitation protocol on post-MOW HTO cartilage recovery are warranted.

Conclusion

The PEEK intraosseous implant was well tolerated, with no requirements for hardware removal. Despite encouragement of early weight-bearing, post-operative pain levels decreased significantly within 3 months of MOW HTO with the PEEK implant and bone union was not adversely affected. While early functional outcomes were good and comparable to MOW HTO using alterative approaches, loss of correction occurred in a quarter of cases within the first year and was associated with greater preoperative varus alignment. While these data highlight the importance of strict inclusion criteria, use of an accelerated rehabilitation protocol in combination with a PEEK implant may offer an acceptable and alternate approach to MOW HTO in a defined patient subset, and warrants further research.

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Compliance with ethical standards

Conflict of interest The Orthopaedic Research Institute of Queensland receives annual funding from ARGO for offer of a Surgical Research Fellowship, as well as Stryker and Arthrex to support the salary of a Research Coordinator and an Orthopaedic PHO position. KH is a consultant for De Puy Synthes.

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