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Staged medial opening wedge high tibial osteotomy for bilateral varus gonarthrosis: biomechanical and clinical outcomes

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Abstract

Purpose (1) To evaluate the effect of staged bilateral medial opening wedge high tibial osteotomy (HTO) on established biomechanical risk factors for disease progression and on validated measures of pain and function and (2) To compare outcomes in patients having the second surgery staged within or beyond 12 months of the first surgery.

Methods Thirty-seven patients with bilateral varus alignment and medial compartment osteoarthritis underwent staged bilateral medial opening wedge HTO (21 within and 16 beyond 12 months). Patients underwent full-limb standing anteroposterior radiographs to determine frontal plane alignment (mechanical axis angle) and three-dimensional gait analysis to estimate the distribution of load across the tibiofemoral compartments (external knee adduction moment). Patients also completed the Knee Injury and Osteoarthritis Outcomes Scores (KOOS), the Lower Extremity Functional Scale, the Short Form Health Survey and the six-minute walk test (6MWT). Patients (both limbs) were evaluated before and approximately 6, 12 and 24 months after each surgery.

Results There were statistically and clinically significant changes in both limbs that were of similar magnitudes and that remained relatively stable over time postoperatively. Mean (95 % CI) improvements in outcomes were as follows. Mechanical axis angle: 9.4° (8.4°, 10.4°) (i.e. average change of both limbs), peak knee adduction moment: −1.7 %BW*Ht (−2.1, −1.4 %BW*Ht) (i.e. average change of both limbs), 6MWT: 36.7 m (19.4, 54.0 m), SF-12 Physical Component Summary: 12.0 (8.5, 15.5) and KOOS Pain: 25.4 (19.6, 31.2). Other than the shorter time period to reach maximum benefit of both surgeries, there were no remarkable differences at final assessment between patients having surgeries staged within or beyond 12 months.

Conclusions The present findings demonstrate that patients with bilateral varus gonarthrosis experience marked improvements in established biomechanical risk

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factors for disease progression bilaterally (mechanical axis angles and external knee adduction moments), as well as clinically important improvements in patient-important outcomes, after staged medial opening wedge HTO. Current findings suggest no difference in outcomes for patients who have the second surgery staged within or beyond 12 months of the first surgery.

Level of evidence IV.

Keywords Medial compartment knee osteoarthritis · Alignment · Knee adduction moment · Staged knee surgery

Introduction

Varus alignment of the lower limb and associated higher loads on the medial compartment of the tibiofemoral joint during walking are strong, potentially modifiable biomechanical risk factors for osteoarthritis (OA) [2, 24, 31, 32]. Medial opening wedge high tibial osteotomy (HTO) aims to correct varus alignment, lessen medial compartment loading and ultimately improve pain and function in patients with varus alignment and medial compartment OA (varus gonarthrosis) [5, 12, 23, 25]. When evaluated using radiographs and three-dimensional gait analysis, recent studies suggest that unilateral medial opening wedge HTO can indeed lessen these important risk factors for disease progression. Most importantly, these studies suggest that HTO can correct varus malalignment and result in substantial reductions in the frontal plane knee moment during the stance phase of gait [5, 9, 12, 21], a measure indicative of the distribution of load across the tibiofemoral compartments and a strong risk factor for disease progression in patients with varus gonarthrosis [2, 24].

As varus gonarthrosis is often bilateral [20, 22], it may be appealing to perform HTO on both limbs. Bilateral medial opening wedge HTO can be performed in a staged manner to enable healing and rehabilitation of each limb separately after each surgery. However, the effects of staged bilateral HTO on risk factors for disease progression have not been previously investigated. The pattern of recovery and changes over time for each limb, and the comparative effects of the first versus second surgery, are therefore unknown. Additionally, the optimal timing for staged lower extremity surgeries is also presently unclear [15, 27]. For example, patient-reported outcomes continue to improve beyond the first 12 months after unilateral medial opening wedge HTO [5]. As a result, it may be beneficial to wait 12 months before performing the second HTO. Alternatively, most of the improvement is observed within the first 12 months, and dynamic loading of the medial compartment of the non-operative limb may actually increase after the first surgery in patients with bilateral varus [6, 21]. Therefore, performing the HTO surgeries within 12 months may enable the patient to achieve greater overall outcomes from the two surgeries and achieve them within a shorter time period.

The primary objective of this study was to evaluate radiographic alignment, dynamic knee joint loading and patient-reported and performance-based outcomes after staged bilateral medial opening wedge HTO. The secondary objective was to compare outcomes in patients having the second surgery staged either within or beyond 12 months of the first surgery. It was hypothesized that patients would experience statistically and clinically significant improvements in all outcomes by 24 months after the second surgery and that the limb-specific improvements in the MAA and knee adduction moment would be approximately equal. It was also hypothesized that patients undergoing the second surgery within 12 months of the first surgery will report greater improvements (at 24 months after the second surgery) than those undergoing the second surgery beyond 12 months of the first surgery.

Materials and methods

This prospective study was conducted from April 2003 through June 2011 and followed suggestions for performing descriptive observational studies in orthopaedics [19]. Outcome measures were assessed preoperatively and postoperatively for both the first (L1) and second (L2) limb. Specifically, baseline assessments occurred before the first surgery, and follow-ups for that limb alone occurred at 6 and perhaps 12 months postoperatively, depending on when the second surgery was performed. The second limb preoperative assessments coincided with a postoperative assessment of the first limb. Follow-ups then occurred 6, 12 and 24 months after the second surgery and continued on an annual basis.

Participants

Patients were included if they had bilateral varus alignment, pain located primarily at the medial aspect of the tibiofemoral joint(s), evidence of OA (radiographic or confirmed with arthroscopy) primarily affecting the medial compartment of the tibiofemoral joint (i.e. greater than lateral compartment disease) in both knees and were considering bilateral medial opening wedge procedures within 24 months. Exclusion criteria included advanced symptomatic patellofemoral disease, inflammatory or infectious arthritis of the knee, multi-ligamentous instability, major neurological deficit that would affect gait, pregnancy, inability to speak or read English, or a psychiatric condition that could limit informed consent.

Forty-five patients were screened, 40 were deemed eligible and were entered into the study, and three were lost to follow-up. Baseline demographics and clinical characteristics for the 37 participants are provided in Tables 1 and 2, respectively. Patients were primarily male, relatively young, had a BMI classifying them as overweight, had substantial bilateral varus alignment and advanced bilateral arthritic degeneration isolated mainly to the medial tibiofemoral compartments. One patient had a small area of advanced arthritic degeneration in one lateral tibiofemoral compartment, but the surgeon deemed it to still be in the best interest of the patient to proceed with the HTO. Twenty-one patients had their surgeries staged within 12 months (9.9 ± 2.2 months), whereas 16 had surgeries staged beyond 12 months (21.2 ± 8.9 months). Patient demographics and clinical characteristics were similar between these subgroups ($p > 0.05$) (Tables 1, 2). All patients attended baseline (preoperative L1), follow-up 2 (preoperative L2) and the last follow-up (most recent assessment). Of the 259 potential assessment time points, 241 were attended (93 %). Six patients had missing data at follow-up 5 (L2 24 month postoperative) which required imputation using the next annual assessment data.

Intervention

Operative procedure

The HTO was performed using a medial opening wedge technique similar to the method previously described by Fowler et al. [11]. The desired correction for the osteotomy was calculated using a method similar to that described by Dugdale et al. [10]. Using preoperative long leg alignment views, the goal was to shift the weight-bearing line laterally to a point ≤62.5 % of the width of the tibial plateau from medial to lateral cortex. Additionally, preoperative templating included the size of correction required to shift the weight-bearing line to 50 % of the width of tibial plateau to facilitate adjustments to the surgical plan depending on the status of the articular cartilage in the lateral tibiofemoral compartment viewed during arthroscopy prior to completing the HTO. Fixation was achieved with a 4-hole non-locking plate (Arthrex Opening Wedge Osteotomy System; Arthrex, Naples, FL, USA) fixed proximally and distally with cancellous and cortical bone screws. Cancellous allograft bone was used in osteotomies greater than 7.5 mm.

No major intraoperative complications were observed. Six limbs had evidence of lateral cortex violations at the time of surgery. Fifteen patients did not achieve bony union of the osteotomy by 6 weeks after surgery and were successfully managed conservatively with an extended period of non-weight bearing. Eleven patients elected to have their hardware removed (total of 16 limbs).

Postoperative management

Patients were placed in a hinged knee brace and crutch use was mandated for at least 6 weeks with only feather-touch weight bearing. With radiographic and clinical evidence of surgical site healing, partial weight bearing was permitted at 6 weeks and full weight bearing at 10–12 weeks. Patients started exercising in the brace immediately postoperatively until healing of the osteotomy site had occurred. Active and passive range of motion and isometric strengthening were completed for both the knee and hip. Non-weight-bearing concentric exercises started at approximately 8 weeks postoperatively and progressed until full weight-bearing was permitted. Weight-bearing exercises focusing on balance and proprioception were

Table 1 Baseline demographic characteristics

Characteristic	All participants ($N = 37$) Mean (SD)	Participant subgroup	
		Within 12 months ($n = 21$) Mean (SD)	Beyond 12 months ($n = 16$) Mean (SD)
Sex, no. (%)			
Male	29 (78.4)	18 (85.7)	11 (68.8)
Female	8 (21.6)	3 (14.3)	5 (31.2)
Age (years)	49.3 (7.7)	49.0 (9.4)	49.8 (4.8)
Height (m)	1.77 (0.09)	1.78 (0.09)	1.77 (0.10)
Weight (kg)	93.6 (17.2)	93.4 (14.8)	93.8 (20.4)
BMI (kg/m^2)	29.7 (4.4)	29.6 (3.9)	29.7 (5.0)
Time between surgeries (months)	14.7 (8.2)	9.9 (2.2)	21.2 (8.9)

BMI body mass index

Table 2 Baseline clinical characteristics

Clinical characteristic	All participants ($N = 37$)		Participant subgroup			
			Within 12 months ($n = 21$)		Beyond 12 months ($n = 16$)	
	Limb 1	Limb 2	Limb 1	Limb 2	Limb 1	Limb 2
Mechanical axis angle[a] (°), mean (SD)	−8.9 (3.6)	−7.8 (3.0)	−8.8 (3.9)	−8.4 (3.5)	−9.2 (3.2)	−7.1 (1.9)
Medial compartment OA grade[b], no. (%)						
0	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
1	2 (5.4)	2 (5.4)	1 (4.8)	1 (4.8)	1 (6.3)	1 (6.3)
2	2 (5.4)	3 (8.1)	1 (4.8)	1 (4.8)	1 (6.3)	2 (12.5)
3	5 (13.5)	23 (62.2)	4 (19.0)	14 (66.6)	1 (6.3)	9 (56.3)
4	28 (75.7)	9 (24.3)	15 (71.4)	5 (23.8)	13 (81.3)	4 (25.0)
Lateral compartment OA grade[b], no. (%)						
0	13 (35.1)	2 (5.4)	8 (38.1)	0 (0)	5 (31.3)	2 (12.5)
1	14 (37.8)	22 (59.5)	7 (33.3)	13 (61.9)	7 (43.8)	9 (56.3)
2	9 (24.3)	13 (35.1)	5 (23.8)	8 (38.1)	4 (25.0)	5 (31.3)
3	1 (2.7)	0 (0)	1 (4.8)	0 (0)	0 (0)	0 (0)
4	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Limb 1 is the first limb to receive HTO

Limb 2 is the second limb to receive HTO

[a] Negative values indicate varus alignment

[b] Kellgren–Lawrence scale grade of OA severity

implemented approximately 12 weeks after surgery and progressed until patients' demonstrated normal gait patterns determined at a physiotherapist's discretion.

Outcome measures

Radiographic measurements

Bilateral, standing hip-to-ankle digital radiographs were assessed using custom software and techniques shown to have excellent reliability [34]. Radiographs were taken in an anteroposterior direction with the patient's feet straight ahead to control for foot rotation and to facilitate accurate measurement of frontal plane alignment. The mechanical axis angle [33, 34] and severity of tibiofemoral OA (Kellgren-Lawrence grade) [18] of both limbs were assessed by a single trained examiner.

Gait analysis

An eight-camera 3-dimensional optical motion capture system (Motion Analysis Corporation, Santa Rosa, USA) was synchronized with a floor-mounted force plate (Advanced Mechanical Technology Inc., Watertown, USA). Twenty-two passive reflective markers were attached to the patient using a modified Helen Hayes configuration [17]. Four additional markers were placed bilaterally over the medial knee joint line and medial malleolus for an initial standing trial with the patient stationary on the force plate with all markers visible. This static trial was used to determine the patient's body mass and joint centres for the hips, knees and ankles. The four extra markers were removed prior to gait testing.

Patients were instructed to walk over an 8-m runway at their usual self-selected pace. Patients walked barefoot to negate the potential confounding effects of different types of footwear. Five walking trials with clean force plate strikes were collected for each limb. Kinematic data (sampled at 60 Hz) and kinetic data (sampled at 1,200 Hz) were collected during the middle of several strides to avoid the acceleration and deceleration phases at the start and end, respectively, of each trial. Kinematic and kinetic data from each trial were used to calculate moments about the knee using inverse dynamics and were expressed as external moments relative to the tibial anatomical frame of reference (Orthotrak 6.0; Motion Analysis Corporation). Gait data were processed using commercial software (Motion Analysis Corporation, Santa Rosa, USA) and custom postprocessing programs previously described [4, 13, 16, 28].

Gait characteristics commonly suggested to affect knee joint loading in patients with knee OA were averaged across the five trials for each lower limb. For each trial, the external knee adduction moment waveform was normalized to body weight and height, plotted over stance phase and inspected visually. The knee adduction moment waveform was then represented in the following ways: first peak (peak within first half of stance), second peak (peak within second half of stance), absolute peak (higher of the first or second peak) and the angular impulse (integral of the positive portion of the stance phase waveform) [35] (Fig. 1). Gait speed was defined as the average speed of the tested limb between successive footsteps. Toe-out angle was defined as the angle created between the midline of the foot (a line from the centre of the ankle to the head of the second metatarsal) and the straight-forward movement of the body. Lateral trunk lean over the stance limb was defined as the angle created from the vertical by a line drawn between the midpoints of the acromion processes and the midpoints of the anterior superior iliac spines [14]. These measures have been shown to have excellent test–retest reliability [4, 13].

Patient-reported and performance-based measures

Patients completed the Knee Injury and Osteoarthritis Outcome Score (KOOS), Lower Extremity Functional Scale (LEFS), 12-item Short Form Health Survey (SF-12) and six-minute walk test (6MWT). The KOOS was used to evaluate patient symptoms (7 items), pain (9 items), function during activities of daily living (17 items), function during sports and recreational activities (5 items) and quality of life in relation to the knee (4 items). Each item was scored on a 5-point Likert scale. A normalized score out of 100 was calculated for each subscale, with higher scores indicating greater knee function and health. A change of ten points on a KOOS subscale was suggested to be clinically meaningful [29]. The KOOS has been shown to be valid and reliable for individuals with knee OA and ligamentous injuries and is responsive to changes after

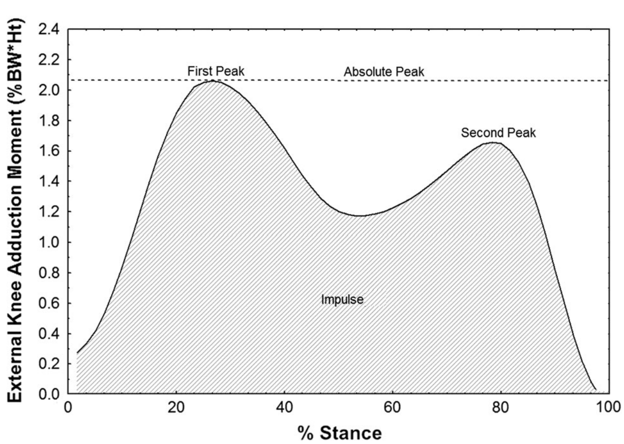

Fig. 1 Illustration of the external knee adduction moment during the stance phase of gait. *First*, *second* and *overall peaks* were identified. The knee adduction moment curve was also integrated with respect to time (i.e. positive portion of the frontal plane moment waveform) to calculate the angular impulse

knee surgery [30], including HTO [5, 36]. The LEFS was used to assess overall function of the lower extremity. The 20-item questionnaire was scored on a 5-point Likert scale. A total score for the questionnaire out of 80 was calculated, with higher scores indicating higher function. A change of nine points on the LEFS was suggested to be clinically meaningful [3]. The SF-12 health survey was used to assess the patient's overall physical function, mental health and wellbeing. SF-12 scores were calculated for both the physical function component summary score (PCS) and the mental health component summary score (MCS). A normalized score out of 100 was calculated for each summary score, with higher scores indicating greater health [37]. The 6MWT was also used to measure physical function [26]. Distance walked in 6 min on a 24.4 m (80 foot) track inside the laboratory was recorded to the nearest 0.3 metres. The study was approved by the institution's Research Ethics Board for Health Sciences Research Involving Human Subjects. All participants provided informed consent prior to inclusion in the study.

Statistical analysis

For the primary objective, means and standard deviations were first calculated for all variables that were measured at baseline and the final assessment for both limbs. If patients missed the 24-months follow-up, data were imputed from the subsequent follow-up. Mean changes with 95 % confidence intervals (95 % CI) were also calculated between baseline and final assessments and Student's *t*-tests were completed for dependent samples. For the outcomes of most interest, data were plotted at all assessments (seven time points in total). These outcomes were determined a priori and included mechanical axis angle, first peak knee adduction moment and KOOS scores. Any missing data for interim points were imputed using the linear trend at each point (IBM SPSS Statistics 19.0, Chicago, IL, USA). For the secondary objective, the above analyses were completed for each subgroup. Mean differences in the improvements between subgroups with 95 % CIs were calculated and then compared using Student's *t*-tests for independent samples.

Results

There were statistically significant changes in the mechanical axis angle and all gait parameters investigated, with the magnitudes of change being similar for the first and second limb (Table 3), and remained relatively stable postoperatively (Fig. 2). There were statistically significant improvements for all of the patient-reported and performance-based outcomes, with the exception of the SF-12

MCS (Table 4). The 95 % CIs around mean changes for all outcomes were quite narrow and even their lower ends were greater than reported suggestions of clinically important improvements for the KOOS and the LEFS (Table 4).

All mean domain scores of the KOOS increased by values greater than the suggested minimum clinically important change of ten points by the first follow-up (Fig. 3a). Smaller improvements continued before plateauing at follow-up 4, with the notable, temporary decrease in the Sport and Recreation and Symptoms domains from follow-up 2 to follow-up 3 (described below). The patterns exhibited by the two component summary scores of the SF-12 differed. The PCS increased steadily from baseline to the final follow-up assessment, while the MCS remained relatively stable (Fig. 3b). Distance walked for the 6MWT increased substantially from baseline to follow-up 4, then plateaued.

With the exception of small differences in lateral trunk lean angle, there were no clinically or statistically significant differences between subgroups for any of the baseline patient demographics and clinical characteristics. Although the improvements in both subgroups were also generally very similar, and are therefore not reported, there were some notable differences. Potentially of most interest were the patterns exhibited by the KOOS domain scores during the interim assessments (Fig. 4). The patients with surgeries staged beyond 12 months (Fig. 4b) experienced decreases in most KOOS domains that were larger in magnitude and later in the recovery process than those experienced by patients with surgeries staged within

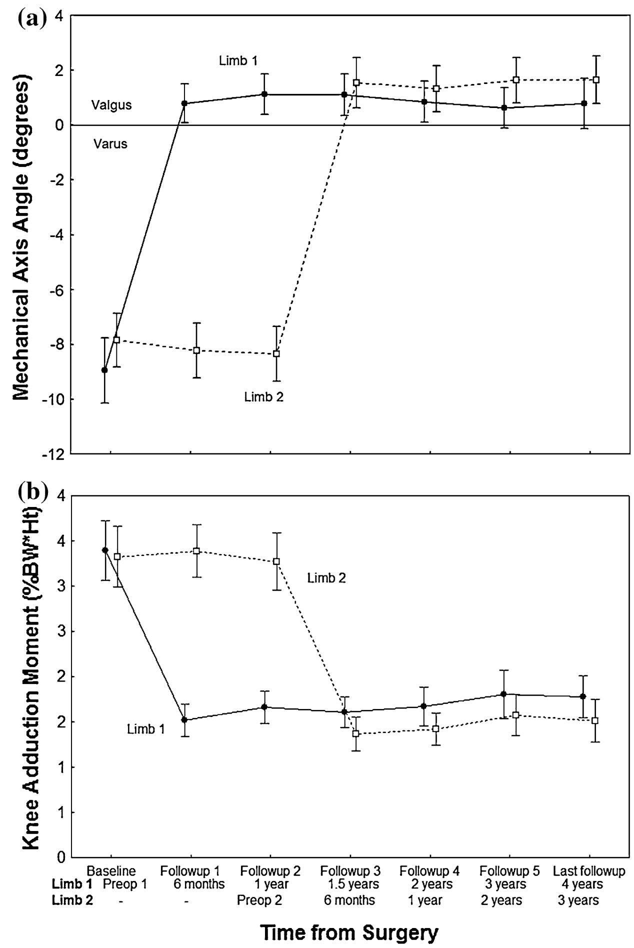

Fig. 2 Means ± 95 % CIs for mechanical axis angle (**a**) and peak knee adduction moment (**b**) over all assessments ($N = 37$)

Table 3 Radiographic alignment and gait biomechanics ($N = 37$)

Outcome measure	BaselineMean (SD)		Final assessmentMean (SD)		Mean change(95 % CI)	
	Limb 1	Limb 2	Limb 1	Limb 2	Limb 1	Limb 2
Radiographic alignment						
Mechanical axis angle[a] (°)	−8.9 (3.6)	−7.8 (3.0)	0.8 (2.7)	1.7 (2.6)	9.7 (8.3, 11.1)[b]	9.5 (8.3, 10.6)[b]
Gait						
Knee adduction moment						
First peak (%BW*Ht)	3.24 (0.91)	3.19 (1.15)	1.70 (0.74)	1.41 (0.67)	−1.54 (−1.90, −1.18)[b]	−1.78 (−2.18, −1.37)[b]
Second peak (%BW*Ht)	3.12 (0.96)	2.87 (0.93)	1.54 (0.77)	1.33 (0.84)	−1.58 (−1.98, −1.19)[b]	−1.54 (−1.91, −1.17)[b]
Absolute peak (%BW*Ht)	3.40 (0.99)	3.33 (1.02)	1.78 (0.69)	1.51 (0.72)	−1.62 (−1.99, −1.25)[b]	−1.81 (−2.21, −1.42)[b]
Angular impulse (%BW*Ht*s)	1.63 (0.50)	1.59 (0.55)	0.79 (0.36)	0.68 (0.46)	−0.84 (−1.02, −0.67)[b]	−0.91 (−1.09, −0.73)[b]
Speed (m/s)	1.08 (0.20)	1.08 (0.20)	1.17 (0.17)	1.17 (0.17)	0.09 (0.05, 0.12)[b]	0.09 (0.05, 0.12)[b]
Toe-out angle (°)	11.3 (5.6)	12.7 (5.0)	12.5 (5.6)	14.1 (5.0)	1.2 (0.1, 2.4)[c]	1.4 (0.1, 2.7)[c]
Lateral trunk lean (°)	3.3 (2.9)	3.4 (2.8)	1.5 (2.0)	1.6 (1.7)	−1.8 (−2.9, −0.7)[b]	−1.8 (−2.8, −0.8)[b]

[a] Negative values indicate varus alignment; positive values indicate valgus alignment

[b] $p < 0.001$

[c] $p < 0.05$

Table 4 Patient-reported and performance-based outcome measures ($N = 37$)

Outcome measure	Baseline Mean (SD)	Final assessment Mean (SD)	Mean change (95 % CI)
SF-12 (range 0–100)			
PCS	33.4 (7.8)	45.2 (9.7)	11.8 (8.5, 15.5)[a]
MCS	52.9 (11.2)	49.9 (8.0)	–3.0 (–6.6, 0.6)
KOOS (range 0–100)			
Pain	43.6 (16.2)	69.0 (22.1)	25.4 (19.6, 31.2)[a]
Other symptoms	38.9 (11.4)	59.1 (17.3)	20.2 (13.8, 26.6)[a]
Function in activities of daily living	50.3 (17.0)	78.1 (18.3)	27.8 (21.6, 33.8)[a]
Function in sport and recreation	19.5 (20.9)	51.6 (26.8)	32.1 (23.1, 41.2)[a]
Quality of life	19.1 (19.9)	49.7 (27.9)	30.6 (21.2, 40.1)[a]
LEFS (range 0–80)	36.3 (12.5)	55.0 (17.8)	18.7 (13.0, 24.7)[a]
6MWT, metres	419.5 (96.1)	436.5 (79.7)	40.4 (4.6, 62.8)[b]

[a] $p < 0.001$

[b] Data were not normally distributed and therefore reported as median (interquartile range) and median (25th, 75th percentile)

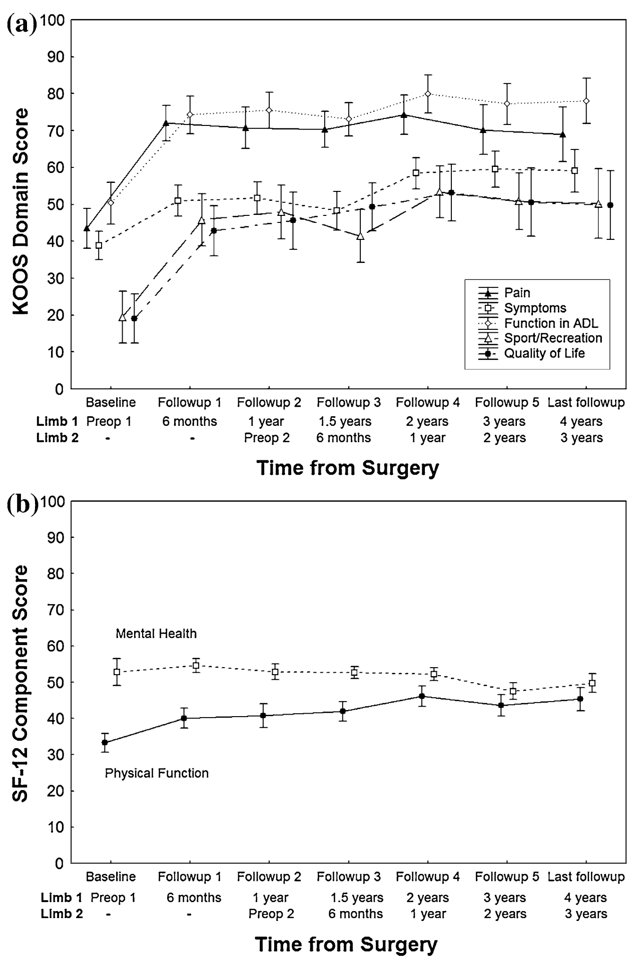

Fig. 3 Means ± 95 % CIs for Knee Injury and Osteoarthritis Outcome Score (KOOS) domain scores (**a**) and Short Form-12 (SF-12) physical function component summary score (PCS) and mental health component summary score (MCS) (**b**) over all assessments ($N = 37$)

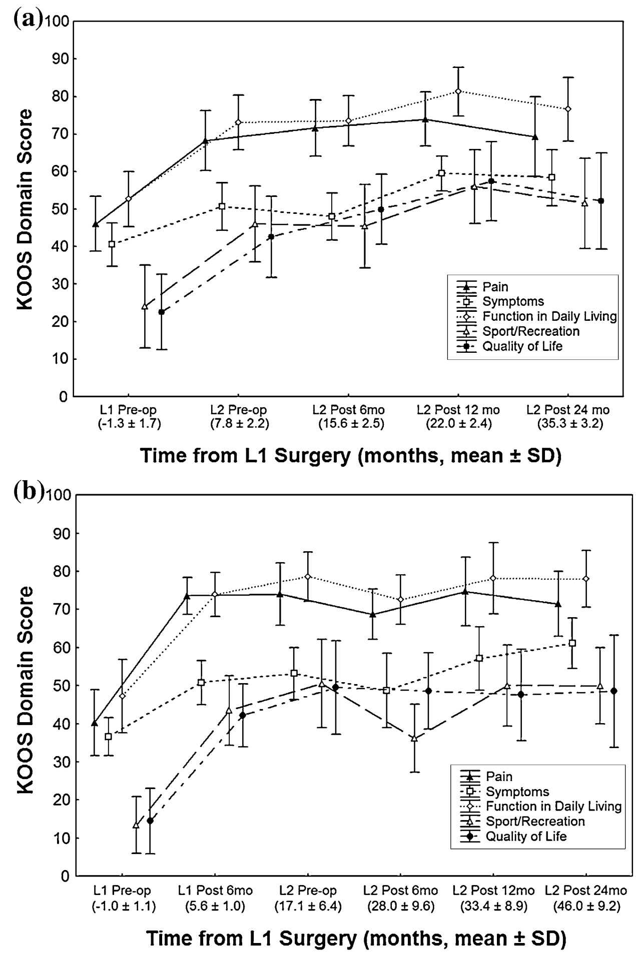

Fig. 4 Means ± 95 % CIs for Knee Injury and Osteoarthritis Outcome Score (KOOS) domain scores over all assessments for patients having surgeries staged within 12 months (**a**, $n = 21$) and patients having surgeries staged beyond 12 months (**b**, $n = 16$)

Table 5 Mean differences at the final assessment between subgroups for radiographic and gait biomechanics

Outcome measure	Mean difference (95 % CI) Limb 1	Mean difference (95 % CI) Limb 2
Radiographic		
Mechanical axis angle[a] (°)	−1.4 (−4.2, 1.4)	2.1 (−0.1, 4.3)
Gait		
Knee adduction moment		
First peak (%BW*Ht)	−0.28 (−1.02, 0.45)	−0.58 (−1.36, 0.21)
Second peak (%BW*Ht)	0.14 (−0.69, 0.98)	−0.11 (−0.87, 0.65)
Absolute peak (%BW*Ht)	−0.22 (−0.69, 0.98)	−0.11 (−0.87, 0.65)
Angular impulse (%BW*Ht*s)	−0.04 (−0.39, 0.31)	0.02 (−0.35, 0.40)
Speed (m/s)	−0.04 (−0.11, 0.04)	−0.04 (−0.11, 0.03)
Toe-out angle (°)	−1.6 (−4.1, 0.8)	−0.6 (−3.3, 2.2)
Lateral trunk lean (°)	1.8 (−0.4, 4.0)	−2.2 (−4.2, −0.2)[b]

[a] Negative values indicate varus alignment; positive values indicate valgus alignment

[b] $p = 0.03$

12 months (Fig. 4a). Also, although both groups reached approximately the same magnitude of improvement, it is worth emphasizing that the patients with surgeries staged within 12 months reached that magnitude of improvement in nearly one year less time than the patients with surgeries staged beyond 12 months.

Discussion

The present findings support the primary hypothesis and suggest that patients who undergo staged bilateral medial opening wedge HTO exhibit substantial improvements in established risk factors for disease progression (i.e. excessive varus alignment and large knee adduction moments). Improvements in these measures were of approximately equal magnitude in both limbs (Table 3), and both remained relatively stable postoperatively (Fig. 2). The findings also suggest that patients experience clinically significant improvements in measures of pain and function. Specifically, the effect sizes for changes in mechanical axis angle (L1 2.7; L2 3.2), first peak knee adduction moment (L1 1.6; L2 1.8), all KOOS domains (1.4–1.8), LEFS (1.5) and SF-12 physical function component score (1.5) are well above the suggested threshold for a large effect (0.8) [8]. Even the lower ends of the 95 % CIs for the mean improvements for all KOOS domains and LEFS score exceed the suggested minimum clinically important differences. Overall, the biomechanical and patient-reported gains observed nearly 4 years after the first surgery, and nearly 3 years after the second surgery, strengthen the suggestion that surgical correction of both lower limbs to approximately neutral alignment has the potential to substantially benefit this patient population.

Several changes in gait were observed that support the underlying biomechanical principles for HTO [1]. After surgery, both limbs experienced large decreases in the knee adduction moment postoperatively, suggesting concomitant large decreases in medial compartment loading. These decreases occurred despite increases in gait speed and decreases in lateral trunk lean towards the stance limb, both of which would normally act to increase loading on the medial compartment of the knee. Interestingly, a small increase in toe-out angle, a characteristic that would typically act to decrease the second peak knee adduction moment and protect against disease progression [7], was also observed bilaterally. It is not clear whether this occurred due to a modification in gait pattern by the patient, or because of an anatomical change in external rotation of the tibia itself brought about by the osteotomy. After surgery, the mean mechanical axis angle was quite stable over all follow-ups. Although not statistically significant, the mean knee adduction moment of both limbs appeared to very slightly increase beyond 6 months, despite no change in the mechanical axis angle. Whether or not the knee adduction moment continues to increase requires further investigation. These findings are consistent with observations previously made when evaluating unilateral medial opening wedge HTO [5].

It was also hypothesized that patients staged within 12 months would report better final outcomes than those staged beyond 12 months. This hypothesis was not supported (Table 5). There were, however, some findings during the interim assessments that highlight potential benefits of staging the surgeries within a shorter time span. Specifically, patients with surgeries staged within 12 months appear to experience a more subtle set back in improvement of KOOS domain scores after the second surgery (Fig. 4). For example, for patients with surgeries staged within 12 months, the Sport and Recreation domain score decreased from a mean of 46 points at 8 months to 45 points at 16 months. Conversely, the Sport and Recreation domain score decreased from a mean of 53 points at 17 months to 40 points at 28 months for patients with surgeries staged beyond 12 months. As the patients in this subgroup had a longer period between surgeries, they made further gains in their rehabilitation after the first surgery. Therefore, the imposed activity restrictions after the second surgery likely impacted these patients to a greater degree.

It is unclear what led the patients and surgeons in the present study to decide upon timing of the second surgery. At baseline, there were no clinical or statistical differences between subgroup means for all measures reported in Tables 1 and 2 including gender distribution, age, height, weight, BMI, mechanical axis angle of each limb and the severity of OA in both the medial and lateral compartments of each limb. This may suggest personal preference, convenience, or surgical wait times impacted on the timing of the second surgery more so than any patient characteristic. Regardless, the present findings suggest that while both patient groups ultimately reach very similar improvements by the last assessment, patients staged within 12 months reach the maximum improvements in a shorter overall amount of time and with smaller set-backs after the second surgery (Fig. 4).

Limitations of this study included those typical of prospective case series. This study was conducted without a control group or randomization. The study also had a relatively a small sample size to investigate its secondary objective and that subgroup analysis was complicated by the fact that it was unclear what influenced the patients and/or surgeons to select the time between surgeries. However, Kooistra et al. [19] remind us of the important role that case series study designs have in research, as they most accurately reflect clinical practice. Strengths of this study included its prospective design and the range of validated outcome measures relevant to HTO.

Conclusion

The present study demonstrates that patients with bilateral symptomatic varus gonarthrosis who undergo staged bilateral medial opening wedge HTO experience substantial improvements in radiographic alignment, gait, patient-reported and performance-based outcome measures. Current findings suggest no difference in outcomes for patients who have the second surgery staged within or beyond 12 months of the first surgery. Maximum benefits are achieved after the second surgery, and outcome measures continue to improve up to 24 months after the second surgery. Although longer term follow-up continues, the present results suggest substantial improvements in the studied established risk factors for OA progression, and in patient-reported outcomes, that remain at 4 years after the first surgery and 3 years after the second surgery.

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