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Short-term safety and efficacy of a novel high tibial osteotomy system: a case controlled study

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Abstract
Purpose To evaluate the safety and efficacy of the novel iBalance Medial Opening Wedge High Tibial Osteotomy (HTO) system in executing lower limb realignment in patients with symptomatic varus gonarthrosis.
Methods A multicentre case series of iBalance medial opening wedge HTO was compared to an historic case-matched control series of HTO's performed using another implant. Subjects were prospectively observed at 3, 6 and 12 months after surgery. Primary endpoints included the reporting of adverse events, weight-bearing status without pain and radiographic evidence of bony union. Secondary endpoints included maintenance of osteotomy correction angle, patient reported outcome (KOOS and SF-36) and gait analysis.
Results Thirty-two consecutive patients were included in the iBalance group (mean age 49.7, 30–67; M:F, 20:12), paired with 32 control subjects (49.8, 35–66; 21:11). Three patients (9.4%) in the iBalance group experienced a complication requiring intervention versus one patient (3.1%) in the control group. No statistically significant differences were seen between groups in terms of time to weight bearing, radiographic union, implant stability or patient reported outcome. Gait analysis revealed a statistically significant reduction in knee external adduction moment ($P < 0.001$).
Conclusions The iBalance medial opening wedge HTO system has been shown to be a safe, novel implant for use in proximal tibial osteotomy. This study shows that the iBalance medial opening wedge HTO system has an equivalent short-term safety and efficacy profile to the 2nd generation Puddu system.

Keywords iBalance · High tibial osteotomy · Open wedge

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Introduction

Among the few treatments available for symptomatic medial gonarthrosis of the knee, high tibial osteotomy (HTO) remains a popular surgical option where symptomatic relief can be achieved whilst preserving the native knee joint and maintaining patient function [1]. Popularised by Coventry in the 1970s [9], HTO has undergone somewhat of a resurgence in popularity over the last 10 years. This may be in part due to the expansion of indications, including the concomitant treatment of ligamentous instability and arthrosis [17]. The improvement in surgical technique, preservation of proximal tibial bone stock with medial opening wedge techniques, and with advances in plating technology allowing earlier range of motion and weight bearing, have all had a significant part to play [14].

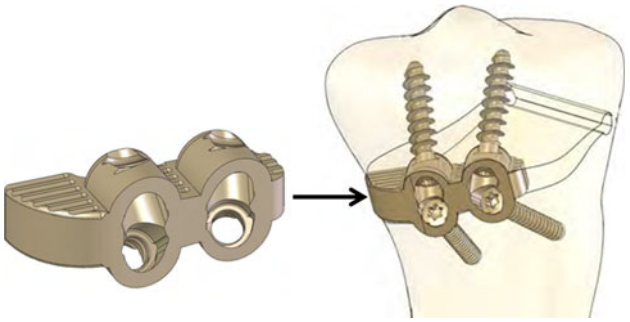

Fig. 1 The iBalance medial opening wedge HTO system

Although, good long-term results have been reported [1], medial opening wedge HTO remains a challenging procedure. Intra-operative risks include neurovascular injury, fracture of the lateral cortical hinge or fracture into the lateral tibial plateau and resultant osteotomy instability, loss of correction and delayed/non-union. In a series of 65 cases reported by Asik et al. [3], the risk of a complication requiring treatment was documented to be approximately 9%.

In an attempt to make the medial opening wedge HTO procedure more reproducible with less risk of intra-operative complications, the iBalance HTO system (Arthrex, Naples, FL) was developed (Fig. 1). Employing an innovative jigging system to make the proximal tibial bone cuts, an accurate correction angle can be achieved while potentially limiting fracture risk by hinging on a predrilled hole to allow dissipation of forces laterally. The novel implant is made of polyetheretherketone (PEEK), a radiolucent bio-inert material which, is used in many other orthopaedic implants [4, 8]. Its innovative design allows the implant to sit within the opening wedge, in combination with two proximal and two distal PEEK screws providing coronal plane and rotational stability. The low profile nature of the implant also potentially negates the need for implant removal due to soft tissue irritation, as seen with a number of other implant designs [7, 16].

The purpose of this study was to evaluate the safety and performance of this novel medial opening wedge HTO system in executing knee realignment in patients with symptomatic medial compartment osteoarthritis with varus malalignment. The hypothesis was that no differences would exist when assessing adverse events and healing of the osteotomy over the course of 12 months, in comparison with primarily one established osteotomy system in widespread clinical usage.

Materials and methods

This multicentre pilot study involved five different surgeons in five different orthopaedic centres in Canada, Poland, Norway and Australia. The study was carried out under an ethics committee approved protocol compliant with the jurisdiction of the respective country.

Patients were invited to partake in the study if they were experiencing chronic medial knee pain with clinically diagnosed medial gonarthrosis and varus malalignment. Full inclusion and exclusion criteria are detailed in Table 1. Full informed consent was given prior to the enrolment. The treatment group (iBalance) consisted of patients who met the inclusion and exclusion criteria agreed to enter the study and who were then treated with a proximal tibial opening wedge HTO using the iBalance medial opening wedge HTO system (Arthrex Inc, Naples, FL).

Study design

This is a case controlled pilot study using historical case-matched control patients taken from a database held at the Fowler Kennedy Sport Medicine Clinic in London Ontario, Canada. This study formed the basis of an application to the Food and Drug Administration (FDA) for approval of the iBalance medial opening wedge HTO system for use as a medical device. As such, a minimum of 25 patients was required to be followed up for a minimum of 12 months to satisfy primary and secondary outcome measures.

Patients in the iBalance treatment group were recruited from one of the five international centres. All control patients had previously undergone proximal opening wedge HTO by the senior author (RL or other FKSMC surgeons) using a different fixation device. The patients in the database provided valid study controls for the following reasons:

1. The surgical procedures, devices used and follow-up practices are representative of current practices in other major medical institutions in the United States, Canada, Australia and Europe.
2. The follow-up regimen for the case-matched control patients selected from the database is similar to the follow-up regimen for the study patients following the iBalance clinical protocol.
3. The size of the database enabled case matching on the basis of demographic criteria, in order to ensure comparability of the patients in the control group to patients in the study group.

Case-matched controls were selected using only demographic information in order to reduce possible selection bias. As study patients were enrolled, their gender, age, body mass index (BMI) and size of correction (expressed in millimetres of height on the medial face of the tibia) were sent to the Fowler Kennedy Sports Medicine clinic

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Age between 18 and 70	Diabetes (any type or status) or any metabolic disorder or other condition that may impair bone formation (e.g. osteoporosis)
Patients require 3–12 degrees of correction	Inflammatory joint disease
	Patients who, in the opinion of the investigator, have a medical condition that would preclude this patient from completing the study (e.g. concurrent chronic illness such as neuropathy, HIV, cancer or other terminal illness)
Localised pain in postero-medial quadrant of the knee	Previous reconstructive surgery that would prohibit use of the iBalance system or compromise the iBalance surgical technique
Medial compartment arthritis graded at II, III or IV on the Kellgren Lawrence scale	Previous lateral meniscectomy >30%
	Previous knee osteotomies in the study knee
	Previous patellectomy
	Gross tibial tubercle deformity
	Cruciate ligament instability with Lachman test, grade 2 or higher
	Posterior draw test, grade 2 or higher
	Evidence of grade 3 or higher lateral compartment osteoarthritis (Kellgren Lawrence scale)
	Evidence of grade 3 or higher patella osteoarthritis (Kellgren Lawrence Scale)
	Proximal tibial width <64 or >88 mm
	Current smoker or quit smoking <1 year prior to enrolment
	BMI over 35
	Female is pregnant or breast feeding
	Patient of childbearing age who is unwilling to use effective contraception for the period of the study
	Enrolment in an investigational study evaluating another device or drug

Table 2 Priorities in case matching for control group patients

Variable	Unit
Gender	
Age*	±10 years
BMI*	±3 units
Correction size	± 2 mm

* When these priorities could not be achieved, a match was selected that had little overall bias in the combination of age and BMI. For example, if the available case matches are somewhat older than the desired age range, selecting a match that also had a higher BMI was avoided

where the study coordinator had final responsibility for selection of the matches. The study coordinator was blinded to outcome data of the potential case matches and the outcome data of the iBalance cases. Table 2 details the priorities in case matching. Statistical analyses could be carried out on paired data due to the linkage of the individual records.

Patient assessment occurred pre-operatively, 2 and 6 weeks, and 3, 6 and 12 months. All patients included in the iBalance study group were analysed on an intention to treat principal.

Surgical technique

A standardised surgical technique was used for all patients across all centres who received an iBalance medial opening wedge HTO. Pre-operative planning includes full hip-knee-ankle long leg alignment anteroposterior radiographs to allow calculation of the tibiofemoral angle and degree of correction required to move the mechanical axis to the so called Fugisawa point, 62.5% of the way across to the lateral tibial plateau as described by Dugdale et al. [10]. An anteromedial approach is used to allow the sartorious fascia to be incised and superficial medial collateral ligament (MCL) to be elevated and reflected. Thereafter, a posterior elevator is placed across the posterior aspect of the tibial metaphysis in the direction of the osteotomy to protect the neurovascular structures. Using fluoroscopic guidance, a proprietary jigging system is attached to the proximal tibia. The position is checked on AP and lateral views and the position of the osteotomy hinge point confirmed as being at least 1.5 times greater the distance from the lateral plateau than the distance to the lateral cortex. A drill hole is then placed in this position and pins placed to secure the jig. The osteotomy can then be completed in a reproducible manner with the soft tissues protected. The hinge point being drilled allows for stress to be dissipated potentially

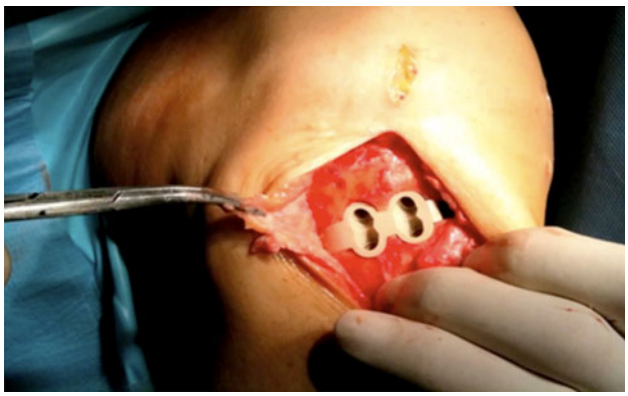

Fig. 2 The iBalance medial opening wedge HTO implant in situ

reducing the risk of intra-operative fracture. Once completed, the osteotomy is opened to the desired correction as calculated pre-operatively using the jig, bone allograft chips impacted into the defect and the implants inserted and fixed in situ (Fig. 2). Postoperative care included touch weight bearing for 4–6 weeks in a tracker brace set at full range of motion. Full weight bearing was allowed once radiological evidence of union was noted.

In the case-matched controls, an HTO was performed as per the technique described by Amendola et al. [2] (Puddu system). All patients were treated with either a 2nd generation Puddu plate (Arthrex Inc., Naples, FL) or a Tomofix plate (Synthes, Westchester, PA), with bone allograft chips also filling the defect. All followed a similar postoperative protocol as was used in the iBalance study group.

Primary outcome measures

The primary outcome measures for the study focussed on safety and efficacy. The primary *safety* endpoint of the study was a comparison of the frequency and severity of adverse events between the iBalance study group and the case-matched controls. Serious adverse events were defined as those that required medical intervention. Those that did not require intervention were classed as non-serious. The primary *efficacy* endpoint was to compare bone healing in two groups as measured clinically by the patient's ability to withstand full weight bearing without crutches and to show no clinical signs of non-union or delayed union. Radiographic evidence of non-union or delayed union including complications such as radiolucency around the implant, resorption within the osteotomy or collapse of the osteotomy was also reported. X-ray images from both the case-matched control patients and the iBalance study patients were sent to an independent musculoskeletal radiologist for review (Fig. 3). All images were output in DICOM format, 8-bit depth and 150 dpi or greater resolution. The radiology reports included

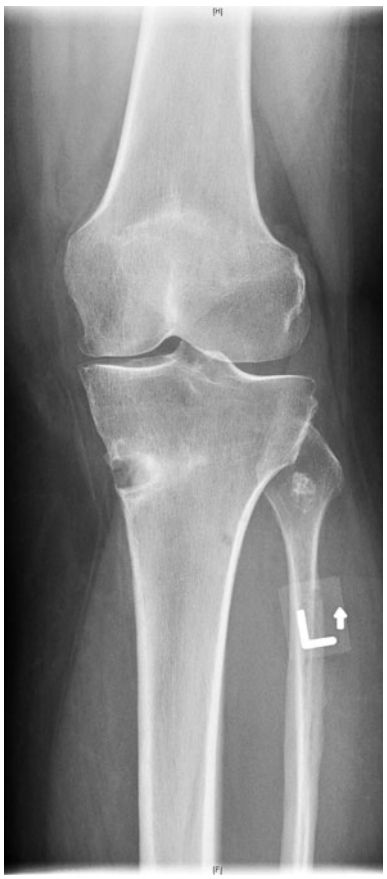

Fig. 3 Anteroposterior radiograph of iBalance medial opening wedge HTO at 12 months postoperative

assessment of changes in bone-healing patterns: ingrowth in the osteotomy void, presence or absence of radiolucency or signs of bone resorption in postoperative images. These assessments were made using routine visual review techniques and criteria.

Secondary outcome measures

Secondary outcome measures included the following:

1. Assessment of stability of the osteotomy construct by measuring the osteotomy angle in standardised weight-bearing A/P X-rays with neutral foot position at specified time points as previously described [11, 20]. The osteotomy angle was also measured in the postoperative images for both the case-matched control patient and the iBalance study patients by measuring the angle formed by lines drawn along the osteotomy lines. The angle measurements were made using the built-in tools included in E-Film, a commercially available image analysis software package (eFilm Medical, Inc., Toronto, Ontario). The uncertainty in the angle measurements was determined to be

within ±1° and expressed to one decimal place. Transient changes of up to 2° were considered to be within measurement error. A change of 2° or more that persisted through the 12-month follow-up visit was classified as a loss of correction.

2. Assessment of changes in symptoms and quality of life as measured by the SF-36 survey and Knee Osteoarthritis and Outcome Survey (KOOS).
3. Assessment of reduction in external knee adductor moment as measured by gait analysis. Gait analysis was performed on those patients who were recruited into the study in the Fowler Kennedy Sport Medicine Clinic. The methods used are those reported by Birmingham et al. [5] using the external knee adductor moment as a surrogate measure of loading of the medial compartment. Gait was evaluated using an 8-camera motion capture system (Eagle EvaRT; Motion Analysis Corporation, Santa Rosa, CA) synchronised with a floor mounted force platform (Advanced Medical Technology, Watertown, MA). A modified Helen Hayes 22 passive-reflective marker set was used [12]. All values were normalised to % body weight × height.

Statistical analysis

Data analysis was completed in SAS version 9.1.3 (SAS Institute). All confidence intervals are two-sided 95% CI. All statistical hypothesis tests are two-sided tests, with $\alpha = 0.05$. McNemar's test was used to test for differences in paired categorical data with binary categories. The Cochrane Mantel–Haenzel test with modified rid its rank was used to test for differences in paired ordinal data (e.g. weight-bearing status). The signed rank test was used to test for differences in paired continuous data. The exact χ^2 test was used to test the null hypothesis that categorical data are homogenous across study sites.

Medical history and adverse event data are displayed as descriptive statistics only (counts and frequencies). There are too few counts in most categories to enable meaningful statistics to be generated. Change in external knee adduction moment was tested using a paired Student's *t* test.

Results

Thirty-three patients underwent a medial opening wedge HTO with the iBalance osteotomy system. One patient did not fulfil all inclusion/exclusion criteria therefore were excluded from the study. Table 3 summaries the patient demographics of both groups. No differences existed between the iBalance study group and the case-matched controls (n.s.). A number of concomitant procedures were performed in each treatment group, mostly addressing cartilage injury (Table 4).

Table 3 Summary of patient demographics

	Treatment group		*P* values*
	iBalance	Control	
Total subjects enrolled	32	32	
Gender			
Male (%)	20 (62.5)	21 (65.6)	n.s.
Female (%)	12 (37.5)	11 (34.4)	
Study knee			
Left (%)	16 (50.0)	19 (59.4)	n.s.
Right (%)	16 (50.0)	13 (40.6)	
Age (years)			
Mean (SD)	49.7 (9.2)	49.8 (7.7)	n.s.
Median	50.5	50.5	
Min, max	30, 67	35, 66	
BMI (kg/m^2)			
Mean (SD)	29.3 (4.0)	29.4 (3.7)	n.s.
Median	30.1	29.8	
Min, max	20.8, 35.8	22.5, 36.5	
Correction size (mm)			
Mean (SD)	11.1 (2.2)	11.6 (2.5)	n.s.
Median	11.1	12.5	
Min, max	7, 14	8, 17	

* McNemars test to test homogeneity between groups

Table 4 Intra-operative details

Summary	Patient group	
	iBalance	Control
Total subjects enrolled	32	32
Duration of procedure (min)		
Mean (SD)	94.3 (22.2)	89.5 (19.2)
Median	90.9	88.5
Min, max	62,155	57,135
Concomitant procedure (s) performed		
Diagnostic arthroscopy (%)	2 (6.3)	11 (34.4)
Debridement (%)	4 (12.5)	10 (31.3)
Microfracture (%)	1 (3.1)	0
Osteochondral grafting (%)	1 (3.1)	0
Other (%)	2 (6.3)	7 (21.9)
Device manufacturer		
iBalance (%)	32 (100.0)	0
Puddu (%)	0	28 (87.5)
TomoFix (%)	0	4 (12.5)

Primary outcome: safety

Table 5 summaries the serious and non-serious device-related and patient-related adverse events during the study. With regard to the serious events, both the postoperative infection and the fasciitis settled with the administration of intravenous antibiotics and did not require surgical intervention. The two fractures in the iBalance group occurred during the opening of the wedge, propagating into the lateral tibial plateau. Both required cannulated screw fixation from the lateral side. These represented two of the very early cases in the cohort, representing the early part of the learning curve. As a result, the surgical technique was modified, with the fulcrum of the osteotomy moved more distally from the joint line. Subsequently, no further fractures requiring fixation were encountered in the study.

The two non-serious fractures (one in each group) occurred during the opening of the wedge. These were seen to propagate to the lateral cortex on fluoroscopy but did not result in instability of the osteotomy. This is a well-recognised phenomenon that does not require further fixation.

A greater number of patients were noted to have joint pain and swelling in the iBalance group which persisted throughout the study period. None of these were deemed to be device related and were residual effects of the underlying degenerative change.

None of the implants in either group were removed by the end of the study period and none had been planned for removal at the time of data analysis.

Primary outcome—efficacy: clinical bone healing

By 3 months, a small but equal proportion of patients in both groups were able to weight bear without crutches with no pain indicating healing of the osteotomy. At 6 months, 81% of the iBalance subjects were fully weight-bearing compared to 54.5% of the control subjects (n.s. odds ratio 3.6). All patients were able to bear full weight by 12 months.

Primary outcome—efficacy: radiographic union

Serial radiographs showed a similar progression in bone formation in both groups at all time points. A greater number of patients in the control groups showed persistent radiolucency and bone resorption at the osteotomy site at later time points (20% at 12 months compared to 0% in the

Table 5 Adverse events

Summary	Patient group			
	iBalance		Control	
	Number of events	Number of subjects	Number of events	Number of subjects
Total subjects enrolled	32		32	
Total number of non-serious device-related adverse events	**4**		**7**	
Fracture	2	2	2	2
Impaired osteotomy healing	2	2	4	4
Medical device complication	0	0	1	1
Total number of non-serious patient-related adverse events	43		24	
Persistent joint line pain	18	16	10	10
Persistent joint swelling	9	9	2	2
Joint stiffness	1	1	1	1
Ligament laxity	1	1	0	0
Impaired wound healing	9	9	8	8
Altered sensation around wound	4	4	3	3
Deep vein thrombosis	1	1	0	0
Total number of serious device-related adverse events	**2**		0	
Fracture	2	2	0	0
Total number of serious patient-related adverse events	**1**		**1**	
Infection	1	1	0	0
Fasciitis	0	0	1	1

iBalance group). The clinical significance of these findings is unclear as all subjects were deemed to have clinically and radiographically united their osteotomy by the 12-month time point.

Secondary outcome—stability

All patients in both groups were noted to have achieved the desired angle of correction, as calculated pre-operatively. At follow-up, 2 patients in the iBalance group were noted to have a loss of correction angle of 2° or more, which was deemed to be significant. Both occurred between the 6 week and 3 month time points but went on to remain stable, with both patients going on to union and full weight bearing by 12 months. None of the control subjects had a loss of correction (n.s.).

Secondary outcome: patient reported outcome

A significant improvement in all domains of the KOOS score was observed in both treatment groups following surgery (Fig. 4). The extent of improvement was similar, with the mean improvement from baseline at 12 months exceeding the recommended threshold of 10 points for a clinically significant difference. No statistical difference was observed between the groups. Of note, the clinical outcome of the two patients who experienced loss of correction angle was not significantly affected.

At 12 months, a statistically significant improvement in the physical domain of the SF-36 score was observed in both groups, with each group exceeding the Minimum Important Difference of 2–3 points indicating a clinical improvement (Fig. 5). A minimal difference was seen in the mental health domain. Again, no statistical differences existed between the groups.

Secondary outcome: gait analysis

Eight iBalance patients underwent gait analysis. The mean pre-operative external knee adduction moment in the iBalance group was 3.1 (SD 0.5) reducing to 1.7 (SD 0.5) at 12 months ($P < 0.001$). The mean reduction was 1.4 (95% CI 1.0, 1.8). These results are similar to the larger cohort published by Birmingham et al. [5] who showed a mean reduction of 1.4 (95% CI 1.5, 1.2).

Discussion

The most important finding of this study was that non-inferiority was found when comparing the iBalance medial opening wedge HTO system to the other commercially available osteotomy systems used in the case-matched cohort, in terms of rate of osteotomy union, time to full weight bearing without pain, patient reported outcome at 12 months after surgery and reduction in external knee adduction moment on gait analysis. There were more adverse events reported in the iBalance study group than in the controls. The vast majority of these were classified as non-serious patient-related complications, which did not

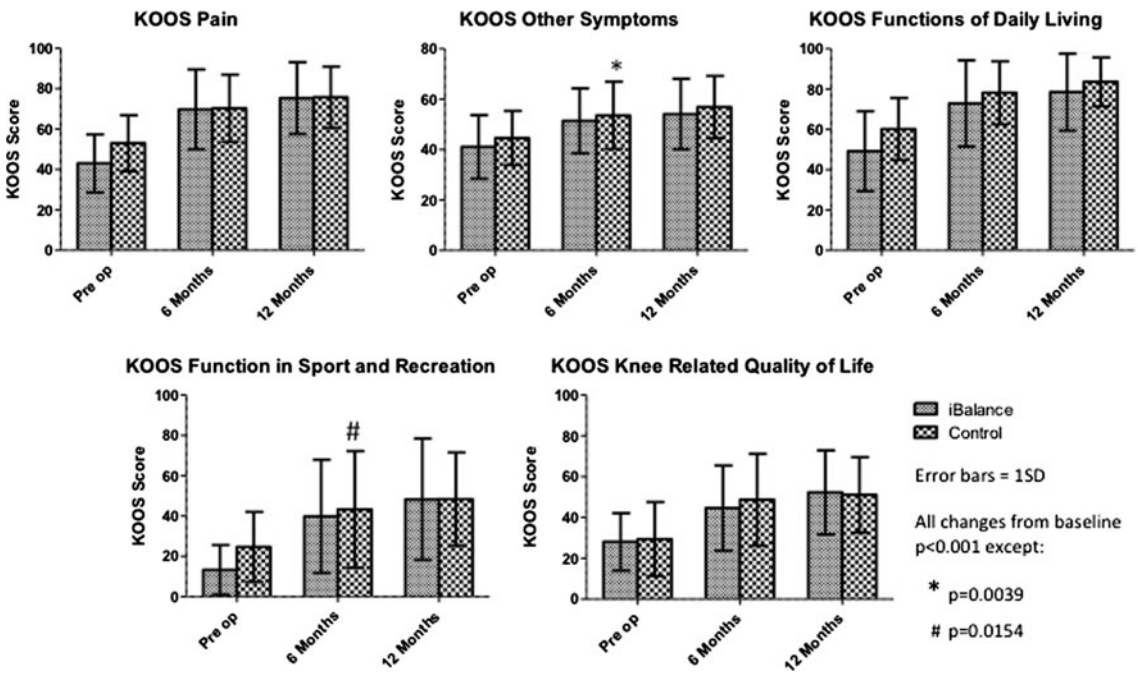

Fig. 4 Knee injury and osteoarthritis outcome score (KOOS)

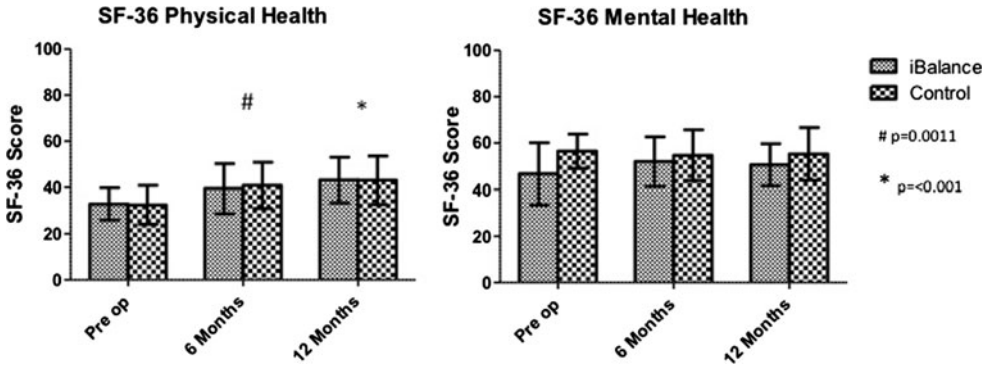

Fig. 5 SF-36 score

require medical intervention. There were no particular problems that were particularly associated with the iBalance device, apart from the two early fractures, which were addressed by the change in surgical technique. Those patients, who reported persistent joint line pain and joint swelling in the iBalance group, also had significant improvements in KOOS scores indicating that the device was still able to provide the desired outcome. PEEK is used extensively in medical devices and is known to be a safe and bio-inert material. Local soft tissue reactions around the implant were not noted, and no patients had planned removal of hardware throughout the duration of the study. The difference in the groups may be explained by the way in which the data were collected. The iBalance study group formed the basis of an FDA application for the iBalance medial opening wedge HTO system to be licensed as a medical device in North America. As a result, the reporting of adverse events is much more rigorous, and often not so clinically relevant, as would have been the case for reporting of complications in the case-matched controls. As a result of the differences in the way data were collected between the groups, we did not feel it was valid to calculate the odds ratio. It is more important to focus attention to the serious adverse events that required medical intervention. The numbers reported were low in both groups, similar to that reported in other studies [16, 21, 23]. Two fractures occurred in the iBalance group early in the series, representing 6.3% of the patient cohort. This is still within the limits of other series, where lateral plateau fracture has been described to occur between 11 and 12.1% [19, 24]. As previously discussed, no further fractures occurred following modification in the surgical technique. It is important to note that the early cases represented a learning curve for the investigating surgeons.

A number of other osteotomy systems are available for clinical use, as shown in our case-matched controls. Spahn et al. [19] reported a series of patients treated with the Puddu plate (Arthrex Inc, Naples, FL). Of the 55 patients who had a medial opening wedge HTO 43.6% had a complication. Of these patients, 9 experienced a loss of correction. This is in direct contrast to no episodes of loss of correction in our control group. Although, two patients in the iBalance group had a loss of correction of >2°, this was not found to be statistically significant nor did it seem to affect the resultant clinical outcome as measured by KOOS.

Brouwer et al. [7] published results of a randomised study comparing the closing wedge technique to medial opening wedge HTO fixed with the Puddu plate. Although, they did not see a loss of correction similar to the series above, 60% of patients with the Puddu plate required the metalwork to be removed due to persistent discomfort and soft tissue irritation. This is in significant contrast to the iBalance series in which none of the patients complained of pain that was directly relating to prominence of the implant.

Birmingham et al. [5] have shown that good to excellent results can be achieved with the Puddu plate in medial opening wedge HTO. At 2 years, clinically important improvements in malalignment, medial compartment load during gait, as assed by measurement of external knee adduction moment, and patient reported outcomes were maintained in a series of 126 patients. The iBalance study group achieved equivalence to the case-matched controls, many of which were also included in this larger prospective patient cohort.

In a study by Niemeyer et al., patients who had a medial opening wedge HTO fixed with the TomoFix plate (Synthes, Westchester, PA) were evaluated at a minimum of 36 months after surgery [16]. Although, good clinical outcome and stability was achieved, 40.6% of patients complained of soft tissue irritation from the prominent metalwork at some stage during their postoperative recovery. In many cases, this was resolved by implant removal.

One of the perceived benefits of the TomoFix plate is the ability for early weight bearing [6]. Interestingly, the weight-bearing status of all of the patients in both groups in this study was prolonged. However, a greater number of iBalance patients were able to fully weight bear at 6 months than control cases, but this was not statistically significant. The numbers of TomoFix patients (4) were too

small to analyse whether this type of fixation device would have been superior, although the literature does suggest that this is a particularly stable implant allowing early weight bearing [6, 13]. The explanation for the delay in weight bearing in both groups is likely to be due to the way in which data were recorded. The definition of full weight bearing included 'without pain'. Other series have also shown a prolonged recovery from medial opening wedge HTO that can similarly last from 6 to 12 months [15]. However, the rate of weight bearing of the iBalance group, in comparison with the control group, combined with the degree of osteotomy healing and lack of radiolucency around the implant is suggestive of a biomaterial with more favourable biomechanical properties. A number of the TomoFix implants in the control group were found to exhibit radiolucency and bone resorption. The TomoFix plate has been shown biomechanically to be an extremely rigid construct [22], therefore it is possible that stress shielding could account for the radiographic changes seen in these patients.

Due to the rigidity of the Tomofix implant, and the recommended biplanar surgical technique [18], larger corrections >15 mm can be performed with the knowledge that stability should be maintained. The patients in this study treated with the iBalance medial opening wedge HTO system included those up to 12°. Caution should therefore be used when addressing larger corrections.

There are a number of weaknesses within this study. It was primarily designed as a safety study for the introduction and licensing of a new medical device. The nature of the study design and comparison to case-matched controls introduced an element of measurement bias as was seen in the reporting of adverse events. Time to weight bearing without pain was used as a surrogate measure of bony union and primary efficacy endpoint. Computed tomography may have been a more accurate measure of bone healing, but serial CT scans were not deemed appropriate due to the associated significant radiation exposure, or accurate enough to be included in the study protocol. The secondary endpoints included patient reported outcomes. These are short-term reports and further analysis is required to ascertain as to whether long-term benefit is established; however, this was not a primary objective of this study. The study was underpowered to show a significant difference between in the primary outcome measures between the two groups. This was by design a pilot study. It represented the first series of iBalance cases therefore the rate of complications which would be encountered was not clear. Based upon the study by Spahn et al. in which a complication rate of medial opening wedge HTO with the Puddu system was 43%, >300 subjects would be required to reduce the complication rate by 10%. It therefore was not deemed possible to design a study to show superiority for complication rate. However, a post hoc power analysis performed using the standard deviation of the matched control data for KOOS pain showed that 29 patients were required in each group to show non-inferiority of the iBalance group, based on a minimum clinical difference of 10 points, with a power of 80% and alpha value of 0.05.

The iBalance medial opening wedge HTO system represents a novel method of achieving a reliable correction while producing a stable fixation allowing satisfactory stability and bone healing, comparable to the 2nd generation Puddu plate. It has a number of advantages over other plating systems including:

1. The novel instrumentation that allows protection of the posterior and lateral neurovascular structures and preservation of tibial slope.
2. The low profile nature of the implant reduces the prevalence of soft tissue irritation and pain requiring implant removal.
3. Non-metallic material allows postoperative magnetic resonance imaging permitting non-invasive examination of the articular surfaces without significant metal artefact. This is particularly helpful when performed alongside articular cartilage restoration procedures.
4. The potential in the future for the implant to be made from biologically active composite materials which may have the ability to bear weight and produce bone.

These features combined with the results of this study have shown that this novel plating system can be used safely to address medial gonarthrosis of the knee. However, future comparative studies are required to fully assess its clinical potential.

Conclusion

The iBalance medial opening wedge HTO system has been shown to be a safe, novel implant for use in proximal tibial osteotomy. Longer term studies are required to establish whether clinical improvement can be maintained and whether similar results can be achieved to those systems utilising locking plate technology.

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