Safety of a novel high tibial osteotomy locked plate fixation for immediate full weight-bearing: a case-control study

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Abstract

Purpose The safety and efficacy of the novel Limmed® system (locked plate fixation) for immediate full weight-bearing after medial opening wedge high tibial osteotomy (HTO) were evaluated in patients with symptomatic varus gonarthrosis.

Methods A case series of 85 consecutive osteotomies performed with Limmed® locked plate fixation for medial opening wedge HTO was compared to a historical matched case-control series of 85 HTOs (85 patients) performed using the same implant without locked screws. Subjects were observed at seven and 15 days and three, six and 12 months after surgery. Endpoints for evaluation included the reporting of adverse events, weight-bearing status without pain, radiographic evidence of bony union and changes in correction angle during healing.

Results Statistically significant differences were seen between groups in terms of safety (thrombophlebitis), time to weight-bearing, radiographic union and radiographic stability between the two groups. Patients of the Limmed® group reported less thrombophlebitis (one versus nine), outcome with shorter time for full weight-bearing (average 45 days difference, $p=0.01$) and a shorter time for union (average four weeks difference). At the one-year follow-up the post-operative hip-knee-ankle angle was 4.2° of valgus in the Limmed® group and 2° of valgus in the control group. The adjusted mean difference of 2.2° was significant ($p=0.02$) and related to loss of correction during healing in the control group with difference in implant stability. The severity of pain, knee score and walking ability improved in both groups with a significant difference before the third month (quicker for Limmed® group), while at the most recent follow-up only the difference for mobility in flexion was significant.

Conclusions The Limmed® 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 with immediate full weight-bearing.

Keywords High tibial osteotomy · Opening wedge · Locked plate fixation · Limmed® · Bone substitute · Kasios

Introduction

Osteotomy has long [9] been recognised as the treatment of knee osteoarthritis in young patients. The effect of the procedure is to redistribute body weight away from the diseased tibiofemoral compartment and onto the adjacent compartment. While osteotomy was for many years the surgical treatment of choice for unicompartmental tibiofemoral arthritis, it is increasingly giving way to unicompartmental and total knee arthroplasty as such techniques have become more widespread and surgeons more confident in their results following arthroplasty. Nevertheless, high tibial osteotomy (HTO) has undergone somewhat of a resurgence in popularity over the last ten years due to the greater number of sports injuries with an increase in the frequency of arthrosis in young people [1]. The improvement in surgical technique [2, 22], preservation of proximal tibial bone stock with medial opening wedge techniques [11] and advances in technology [3, 7, 16, 17, 24] allowing earlier range of motion and partial weight-bearing [4] have all played a significant part. However, in most series with locked plate and screws, the majority of authors allow only partial weight-bearing with crutches. In an attempt to make the medial opening wedge HTO procedure safer for full immediate weight-bearing without crutches after the osteotomy, a novel implant was designed. Its innovative design allows the implant to provide sufficient coronal plane, sagittal plane and rotational stability to allow the patient to walk without crutches immediately after surgery.

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The purpose of this study was to evaluate the safety and efficacy of this novel locked plate fixation for medial opening wedge HTO in patients with symptomatic varus osteoarthritis. The hypothesis was that no differences would exist when assessing non-union, loss of correction, healing of the osteotomy and pain relief when patients are allowed full weight-bearing without crutches with this novel implant (Limmed®) as compared with the previous technique where patients were not allowed weight-bearing before 45 days with the same device shape but without locked screws.

Materials and methods

This study involved different surgeons in the same orthopaedic centre in France. The surgeons were senior and junior in a university teaching hospital; the senior author (PH) has 35 years experience with opening wedge tibial osteotomy [11, 20]. Patients had clinically diagnosed medial gonarthrosis and varus malalignment.

Study design

A total of 85 consecutive patients were included in the Limmed® group (mean age 62.7, range 50–68, male to female ratio 38:47), paired with 85 control subjects (63.1, 50–69, 38:47). Eighty-five patients with unilateral surgery for osteoarthritis were recruited from 2009 to 2011 and treated with opening wedge HTO and fixed with the Limmed® plate fixation device (Fig. 1a) and locked screws (Fig. 1b) and therefore form the “Limmed® group”. All control patients had previously undergone proximal opening wedge HTO by the senior author with the similar plate according to the shape and number of screws but without locked fixation. This is a case-control study using historical matched control patients taken from the database held in the hospital. The size of the database (more than 1,000 HTO) 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. As such, a minimum of 85 patients in each group

was required to be followed up for a minimum of 12 months to satisfy outcome measures.

Matched controls were selected using demographic information in order to reduce possible selection bias. As control patients were selected, their gender, age, body mass index (BMI) and size of correction (expressed in millimetres of height on the medial face of the tibia) were used for selection of the matches.

Surgical technique

Osteotomy

The technique of the osteotomy was exactly the same for the two groups as described previously [11–13]. After longitudinal skin incision the insertions of the sartorius, gracilis and semitendinosus muscles are divided, and the tendons are separated from bone. The distal portion of the superficial medial collateral ligament is exposed and is separated from bone proximally as far as the level of the osteotomy. After the exposure of the proximal tibia, the osteotomy line, starting from three to four centimetres distal to the medial joint line, passes above the insertion of the patellar tendon to the tibial tubercle. The level and direction are checked under fluoroscopy (C-arm of the image intensifier) towards the lateral border of the tibia just at the level of the proximal tibiofibular joint. Maximum attention was given to keep the lateral cortex intact to benefit from its hinge feature. The cut is made with osteotomes, leaving the lateral part of the cortex of the lateral tibial condyle intact. The bone at the site of the osteotomy is forced open. The leg below the osteotomy is then pushed into valgus while the large osteotome maintains the upper end of the tibia in place. The surgeon puts his hand under the Achilles tendon to avoid flexion at the site of the osteotomy. The opening must be greater at the posterior part than at the anterior part of the osteotomy. As a wedge (Fig. 2a) we used the Duowedge® implant manufactured with reconstructive tridimensional ceramic stereolithography technology. Duowedge® is a tibial osteotomy wedge featuring two portions with different porosities: a solid highly resistant portion

Fig. 1 **a** The plate and **b** locked screw

Fig. 2 **a** Insertion of the wedge at the posterior part of the medial opening. **b** Duowedge® is a wedge featuring two portions with different porosities: a solid highly resistant portion, which fits into the cortical area, and a porous portion to be incorporated in the cancellous area

(+80 MPa), which fits into the cortical area, i.e. the maximum load-bearing zone and a porous portion to be incorporated in the cancellous area (Fig. 2b). A plate is then applied to the medial aspect of the tibia (Fig. 3). The wound is closed by repairing the divided tendons and superficial medial collateral ligament and then approximating the subcutaneous tissue and skin.

Plate and screws

For the Limmed® locked plate fixation the plates were manufactured according to the anatomical inclination of the proximal tibia, are made of steel and can be curved if necessary (Fig. 1a). The innovative locking sleeve, constricting ring and special screws in Block and Break® locking systems ensure an exceptional resistance to shear stress at the screw plate junction ensuring solid fixation regardless of bone quality. The Block and Break® screw plate withstands a maximum 1,200 kg shear stress at the junction and allows immediate full weight-bearing. In the matched controls, the plates had the same design as in the Limmed® group, but unlocked screws were used.

Post-operative rehabilitation

All patients received the same anticoagulation therapy over 45 days. The day after surgery, active and passive range of motion exercises using continuous passive motion and muscle strengthening were started. No plaster was used. Range of

motion training with continuous passive motion was continued until a maximum flexion angle of 130° or more was obtained within three weeks of surgery. Standing exercises were also initiated as soon as possible with the Limmed® device. Full weight-bearing was allowed immediately with or without crutches according to the pain of the patient. In the control group partial weight-bearing (20 kg) was allowed at two days and full weight-bearing was allowed at 45 days at a time when bone filling did not occur completely. A return to normal sports activities including jogging was not permitted before three months after surgery in either group.

Outcome measures

The safety endpoint of the study was a comparison of the frequency and severity of adverse events between the Limmed® study group and the matched controls. Serious adverse events were defined as those that required hospitalisation, surgery or medical treatment: for example thrombophlebitis with anticoagulation.

The efficacy endpoint for weight-bearing was to compare the patient's ability to stand and walk with full weight-bearing in two groups as measured clinically by the possibility of the patient to walk without crutches at a different period from the date of surgery.

The clinical outcome was measured with severity of pain [(visual analogue scale (VAS), range 0 (no pain) to 10], walking distance and the knee (International Knee Society Score, IKSS) function score [14].

Radiographic union was assessed on anteroposterior and lateral radiographs during follow-up visits and at the most recent follow-up examination (after ten years or more). Union at the osteotomy site follows the same process as normal bone healing [5]. Thus, on the lateral side of the osteotomy, the periosteal callus forms as a fibrous sleeve because the periosteum is continuous. The posterolateral callus was clearly visible on radiographs. On the medial side, healing occurs mainly through the medullary callus, due to the presence of an inter-fragment space created by the opening technique. Healing of the osteotomy was measured by the progression of bone filling the triangular surface of the

Fig. 3 Fixation of the osteotomy with a plate

osteotomy from the lateral cortex to the wedge. This triangle was divided into four zones on the post-operative radiographs (Fig. 4). The amount of filling (increase in density of the osteotomy) and its progression first in zone 1 (Fig. 5a) were assessed at each radiological session. Radiographic union was obtained when filling was observed in zone 4 (Fig. 5b). Radiographic evidence of non-union or delayed union included complications such as resorption within the osteotomy or collapse of the osteotomy. X-ray images from both the matched control patients and the Limmed® study patients were analysed at the same time from the osteotomy.

Radiographic stability during healing (changes in correction in the coronal and sagittal plane, and in patellar height) was measured on the coronal plane with the hip-knee-ankle (HKA) angle formed by lines drawn from the midpoint between the tibial spines to the centre of the femoral head proximally and to the centre of the talocrural joint distally. Therefore, this angle, which was called the HKA angle, was formed by the mechanical axis of the femur and the mechanical axis of the tibia. Normally these axes form a straight line (180°). To verify the correction that had been achieved, we measured the HKA angle ten days after the osteotomy on radiographs of the whole limb. Radiographs of the whole limb were made six months after the osteotomy to check an eventual loss of correction during bone healing. The difference between the valgus correction achieved at ten days and at six months was determined and considered as loss of correction. The tibial slope and its variations during healing were measured according to Brazier et al. [6] and patella height and its variations were assessed with the Caton index [8].

Statistical analysis

Medical history and adverse event data are displayed as descriptive statistics only (counts and frequencies). Means and standard deviations were calculated for the different measurements. All statistical hypothesis tests are two-sided tests, with $\alpha = 0.05$. Paired samples *t* tests were used to detect significant

Fig. 4 The opening wedge triangle was divided into four zones on the post-operative radiographs. Healing was observed in these four zones

alterations in measurements. The uncertainty in the angle measurements was determined to be within $\pm 1^\circ$. Transient changes of up to 2° were considered to be within measurement error. A change of 3° or more that persisted through the 12-month follow-up visit on at least two radiographs (six months and one year) was classified as a change of correction. Statistical tests were performed in Microsoft Excel (Microsoft, Redmond, WA, USA).

Results

Eighty-five patients underwent a medial opening wedge HTO with the Limmed® osteotomy system. Table 1 summarises the patient demographics of both groups. No differences existed between the Limmed® study group and the matched controls (n.s.).

Safety With regard to the serious events (Table 2), delayed wound healing was observed in two patients in each group and settled with the administration of oral antibiotics and did not require surgical intervention. Nine cases of clinical thrombophlebitis were diagnosed and treated in the control group as compared with one in the Limmed® group.

Efficacy (weight-bearing) At seven days, 20 % of the Limmed® subjects were fully weight-bearing without crutches, and the other 80 % of the Limmed® subjects were fully weight-bearing with crutches compared to none of the control subjects; At 15 days, 80 % of the Limmed® subjects were fully weight-bearing without crutches, and at one month 100 % were fully weight-bearing without crutches compared to none of the control subjects at the same date. Partial weight-bearing (20 Kg with two crutches) was authorised in the control group, but only 50 % could manage this during the first three weeks. By 45 days all of the patients in the control group were allowed full weight-bearing with crutches and at two months 50 % of the patients were capable of full weight-bearing without any crutches with no pain indicating healing of the osteotomy. By three months, all of the patients in both groups were able to bear weight without crutches.

Clinical outcome

The mean pain (VAS) score decreased quicker ($p = 0.04$) in the Limmed® group, from 6.5 to 2.1 points after one month compared to from 6.7 to 4.2 points for the control group, to arrive at 1.4 versus 1.5 after one year which was not significant ($p = 0.87$). The mean IKSS knee score (from 67 ± 8 to 89 ± 7 points for the Limmed® group versus 65 ± 7 to 87 ± 9 points for the control group) increased after surgery in both groups and the differences were not significant at the most recent

Fig. 5 **a** Healing of the osteotomy begins in zone 1. **b** Radiographic union was obtained when filling was observed in zone 4

follow-up ($p=0.78$, $p=0.65$, respectively); the only significant difference between the two groups was the range of motion in flexion that was significantly improved in the Limmed® group (135 versus 125°).

Radiographic union

The progression of bone filling was quicker in the Limmed® group. At the third month, 60 of the 85 knees were in zone 3 in the Limmed® group versus 40 in the control group. At the fourth month, 80 of the 85 knees were in zone 4 in the Limmed® group versus 60 in the control group. At a follow-up of six months, all of the knees except one of the control group were in zone 4.

Radiological union occurred on average after 4.5 months, with a minimum of two months and a maximum of six months. The time to union was longer for the control

group (4.3 ± 0.83 months) than for the Limmed® group (3.2 ± 0.51 months) and longer for osteotomies with more than 10° of opening (4.9 ± 0.75 months) as compared with opening of 10° or less (3.7 ± 1.5 months) ($p=0.03$). One non-union (nine months) was observed in the control group.

A greater number of patients in the control group (Table 2) showed fracture (Fig. 6) of the bone substitute (seven versus one in the Limmed® group) and persistent radiolucency with bone resorption (Fig. 7) at the osteotomy site at later time points (11 % at 12 months compared to 0 % in the Limmed® group).

Radiographic stability (changes in correction in the coronal and sagittal plane, and in patellar height)

- HKA angle (coronal plane): Before the surgery, the average varus was $171 \pm 3.18^\circ$ (168–176°); after the surgery (at ten days) the HKA angle was similar in both groups, $184.5 \pm 1.18^\circ$ (182–186°) for the Limmed® group and $184.7 \pm 1.19^\circ$ (183–187°) for the control group, respectively. This correction was maintained at follow-up in the Limmed® group ($184.2 \pm 1.19^\circ$, range 182–186°), while a loss of correction was observed in the control group with an average HKA angle of $182 \pm 1.60^\circ$ (range 175–186°) ($p=0.02$). At a follow-up of six months the target correction of 183–186° was not achieved in nine knees of the

Table 1 Patient demographics

Treatment			
	Limmed®	Control group	<i>p</i> values
Total subjects enrolled	85	85	
Gender			
Male	38	38	n.s.
Female	47	47	
Study knee			
Left	42	42	n.s.
Right	43	43	
Age (years)			
Mean (SD)	62.7 (8.2)	63.1 (6.7)	n.s.
Median	60.5	60.5	
Min., max.	50–68	50–69	
BMI (kg/m ²)			
Mean (SD)	24.3 (3.9)	23.4 (3.7)	n.s.
Median	24	24	
Min., max.	19–30	18–31	
Correction size (mm)			
Mean (SD)	10.1 (3.2)	10.2 (3.5)	n.s.
Median	11	11	
Min., max.	6–18	6–16	

Table 2 Post-operative complications reported within the 1-year follow-up period

Complication type	Implant/surgery	
	Limmed®	Control
Implant breakage	0	0
Bone non union	0	1
Fracture of bone substitute	1	7
Loss of correction	0	9
Soft tissue/wound		
Haematoma	2	2
General		
Thromboembolic complication	1	9

Fig. 6 Fracture of the bone substitute

control group that were under-corrected (less than 3°) with a loss of correction angle of 3° or more, which was deemed to be significant. It occurred between the two-week and three-month time points but went on to remain stable thereafter, with patients going on to union and full weight-bearing by five months. None of the Limmed® subjects had a significant loss of correction (over 3°) even in the four patients who had intraoperative lateral cortical hinge fractures and who were allowed full weight-bearing. Despite the absence of weight-bearing, loss of

Fig. 7 Persistent radiolucency with bone resorption at the osteotomy site

correction was observed in nine patients in the control group with four of them presenting intraoperative lateral cortical hinge fractures.

- The tibial slope did not significantly change: $6.5 \pm 2.87^\circ$ before the surgery and $6.3 \pm 2.45^\circ$ after the surgery and at the last follow-up ($p=0.62$) for patients with the Limmed® device. Some increase in the tibial slope was observed in the control group (from $6.1 \pm 3.41^\circ$ before the surgery to $10.3 \pm 5.25^\circ$ after the surgery). This increase in the tibial slope was observed in all nine patients who had loss of correction during healing in the coronal plane.
- The patella was significantly lower in the control group: the Caton index went from 0.84 ± 0.12 before the surgery in both groups to 0.77 ± 0.14 on average at the last follow-up in the control group as compared to 0.81 ± 0.09 on average ($p=0.02$) in the Limmed® group.

Discussion

From a historical point of view the difference between the first report in the English literature between the opening wedge osteotomy [11] and the closing wedge osteotomy [9] was the difference in weight-bearing, with earlier weight-bearing with the closing wedge osteotomy particularly when the closing wedge osteotomy is protected by a cast. Koshino et al. [15] were the first to propose a long leg cast and weight-bearing with the opening wedge technique, but this cast was applied to the patients three to four weeks after HTO, so weight-bearing was delayed and protected. Stoffel et al. [25] reported on a biomechanical investigation of the Puddu plate and of TomoFix®. They concluded that when the lateral cortex is injured, TomoFix® provides superior stability under both compressive and torsion stress when compared with the Puddu plate. They found that disruption of the lateral cortex results in increased micromotion at the osteotomy site and therefore recommended that weight-bearing be protected with two crutches for 45 days. This was confirmed by clinical studies: Spahn et al. [23] reported on a series of patients treated with the Puddu plate (Arthrex Inc., Naples, FL, USA); of the 55 patients who had a medial opening wedge HTO nine experienced a loss of correction. One of the perceived benefits of the TomoFix® plate is the possibility for early weight-bearing [26]. Takeuchi et al. proposed an early weight-bearing exercise programme with a T-cane at two weeks after surgery using TomoFix® [26]. However, most series report only on partial weight-bearing protected by crutches. The explanation for the delay in weight-bearing in these series is related to pain.

Our patients were allowed immediate full weight-bearing without crutches. Among our patient cohort with the Limmed® device, we did not observe any correction loss,

implant failure, collapse of the bone substitute or screw loosening with or without a lateral cortex fracture and with or without large corrections. An important factor in our procedure is the use of Limmed® in combination with the Kasios bone substitute. In this instance the stress applied to the osteotomy site is distributed across the artificial bone wedges and the device. The most important finding of this study was that superiority was found when comparing the Limmed® medial opening wedge HTO system to the same available osteotomy systems without locked screws used in the matched cohort, in terms of rate of osteotomy union, absence of loss of correction and pain. There were more adverse events (Table 2) reported in the control group than in the Limmed® study group, particularly thrombophlebitis (probably related to the absence of immediate weight-bearing), requiring medical treatment. The loss of corrections was more frequent in the control group despite the absence of weight-bearing, and a lower patella was more frequently observed in the control group (perhaps also related to the absence of immediate weight-bearing).

A number of other osteotomy systems are available for clinical use and it was not the purpose of this study to compare the Limmed® device with other locking plate devices. However, the rate of weight-bearing of the Limmed® group, in comparison with the TomoFix® studies, combined with the degree of osteotomy healing and lack of radiolucency around the Limmed® implant [10] is suggestive of a device 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 construction [21]; therefore, it is possible that stress shielding could account for the radiographic changes seen in these patients. However, the precise biomechanics of early weight-bearing remain unknown, and further studies are thus required. At present the most important issue of this study is that when appropriate, stable implants and a careful surgical technique are used, it is possible to minimise complications and optimise outcomes for patients, particularly when rupture of the lateral cortex or lateral plateau occurs [18, 19, 27].

There are a number of limitations of this study. It represented the first series of Limmed® cases; the rate of complications is low, but the senior author has a large and long experience with the opening wedge technique. It was designed as a safety study for the introduction of a new medical device allowing full weight-bearing. This explains the nature of the study design and comparison to matched controls. This is a short-term report and further analysis is required to ascertain as to whether long-term benefit is established. Time to weight-bearing without pain and without crutches was used as a surrogate measure of efficacy. Of course there is a part of subjectivity in pain report by the patient. Radiographs were used for bone healing. Computed tomography (CT) 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 and were not used in the matched control patients.

Conclusion

The Limmed® medial opening wedge HTO system has been shown to be a safe, novel implant using locking plate technology for use in proximal tibial osteotomy. The Limmed® 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 with immediate full weight-bearing.

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