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Full weight bearing and dynamisation with Limmed® locked plate fixation accelerates bone regeneration in the volume of opening wedge high tibial osteotomy

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Abstract

Purpose The efficacy of immediate full weight bearing in accelerating bone regeneration after medial opening wedge high tibial osteotomy (HTO) was evaluated in patients operated with the Limmed system (locked plate fixation) that allows dynamisation of the site of the osteotomy.

Methods A case series of 50 consecutive osteotomies performed with Limmed locked plate fixation for medial opening wedge HTO had full weight bearing immediately after the HTO; they were compared to a case-matched control series of 50 HTOs (50 patients) performed using the same implant without locked screws. Radiographs were observed at 30 days and two, three, four, five and six months after surgery. The osteotomy gap was only partially filled by a medial bone substitute leaving the lateral part unfilled. Bone surface areas of osteotomy planes were quantified and opening volumes were determined applying wedge heights. End points for evaluation included radiographic evidence of bone regeneration in the volume created by the opening of the osteotomy.

Results Statistically significant differences were seen between the groups in terms of radiographic union and radiographic stability between the two groups. Patients of the Limmed group reported a shorter time for union (average four weeks difference) without loss of correction during healing. At the radiographic evaluation, there was a significant increase in osseointegration in the group with weight bearing compared to the control group without weight bearing with increased rate of speed to fill the void volume of the osteotomy. The computed tomography scan of the grafted area at four months after surgery showed no significant difference in the quality of the newly formed bone between the two groups.

Conclusions The Limmed medial opening wedge HTO system with immediate full weight bearing accelerates bone graft substitute osseointegration and bone healing as compared with controls without full weight bearing.

Keywords High tibial osteotomy · Locked plate · Dynamisation · Bone healing · Opening volume

Introduction

Radiological long-term studies of bone healing after an opening wedge high tibial osteotomy (HTO) have shown that the healing response starts from lateral to medial [21, 22] and usually takes six weeks. These radiological observations are supported by histological findings [21]. However, the capacity for bone healing may vary among individuals and depends on various biological factors which cannot be fully assessed prior to an osteotomy. Bone healing is improved in fractures with weight bearing [14]. The improvement in surgical technique [1, 2, 5, 14, 15, 17, 20] allows preservation of proximal tibial bone stock with medial opening wedge techniques and in some circumstances immediate full weight bearing [2, 10, 24]. However, no investigation has been performed to determine the efficacy of full weight bearing in accelerating bone regeneration in patients undergoing opening wedge high tibial valgus osteotomy. Proximal tibial geometry is quantifiable and reproducible; the volume created by the opening wedge HTO (Fig. 1) was chosen as an ideal setting to verify the possible effects of weight bearing and dynamisation in bone regeneration and osseointegration after HTO. The term 'dynamisation' has been associated in the literature with both

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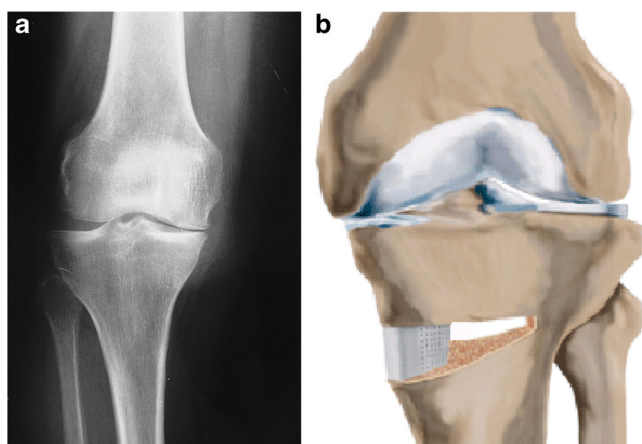
Fig. 1 **a** Pre-operative radiograph of a patient with varus deformity. **b** The osteotomy gap is only partially filled by a medial bone substitute leaving the lateral part unfilled. The volume created by the opening of the osteotomy was chosen to evaluate the possible effects of weight bearing in bone regeneration and osseointegration after HTO

cyclic movements [14] and with progressive, irrecoverable displacement [12, 13] and gap closure. Due to the technique of opening wedge HTO that creates a gap in relation to the correction, in this study the term dynamisation was related to cyclic movements allowed by the system.

The purpose of this study was to evaluate the efficacy of immediate full weight bearing in accelerating bone regeneration after medial opening wedge HTO. Healing of the osteotomy was assessed by measurement of the progression of bone filling the prismatic volume of the osteotomy from the lateral cortex to the wedge.

Materials and methods

Study design

Fifty consecutive patients were included in the weight bearing group (mean age 62.7, range 50–68, male to female ratio 28:22) that had osteosynthesis with the Limmed locked plate previously described [9]. This group was paired with 50 control subjects (63.1, 50–69, 26:24). All control patients had previously undergone proximal opening wedge HTO with a similar plate according to the shape and number of screws but without locked fixation. Case-matched controls were selected using demographic information in order to reduce possible selection bias. 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 control patients were selected, their gender, age, body mass index (BMI), size of correction (expressed in millimetres of height on the medial face of the tibia) and surface (width of the tibia) of the osteotomy were used for selection of the matches.

Surgical technique

The technique of the osteotomy was exactly the same for the two groups as described previously [8–10]. The osteotomy gap was only partially filled by a medial bone substitute leaving the lateral part unfilled. A plate was then applied to the medial aspect of the tibia. The wound was closed by repairing the divided tendons and superficial medial collateral ligament and then approximating the subcutaneous tissue and skin. For the patients with full weight bearing, the Limmed locked plate fixation was used (Fig. 2). In the case-matched controls, the plates had the same design as in the Limmed group, but unlocked screws were used. With the Limmed device, full weight bearing was immediately allowed with or without crutches according to the patient's pain. In the control group full weight bearing was allowed at 45 days.

Outcome measures

#### Mathematical modelling of the volume gap of the opening osteotomy

A ruler was attached to each specimen at the level of the osteotomy. With the aid of a navigation system used for total knee arthroplasty allowing simulating bone cuts, images of all osteotomy planes were acquired (Fig. 3). After successful calibration of each ruler, bone surface square centimetres of all osteotomy planes were quantified and estimated as an ellipse (Fig. 4). To estimate the approximate opening volume, the formula for an elliptic cylinder was used. It is a cylinder with an elliptical cross section.

The elliptic cylinder is a quadratic ruled surface. The volume (V) of an elliptic cylinder of height (h), semimajor axis a, and semiminor axis b is $V = \pi abh$. The volume of opening was calculated as half of the elliptic cylinder (Fig. 5).

For calculation of accuracy, ten tibial bone substitute models were used. After opening, the volume of the opening was filled with acrylic cement and the volume of the cement piece was measure by displacement of fluid; the two methods were compared; the one-sample t test was applied. The p value


Fig. 2 Fixation of the osteotomy with the Limmed locked plate fixation
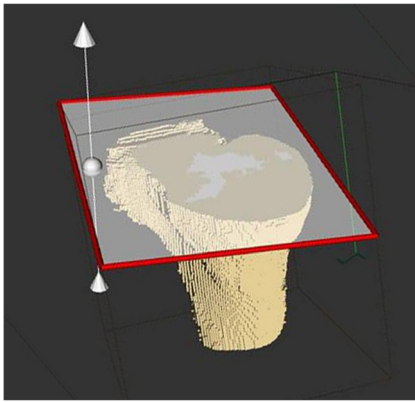
Fig. 3 Osteotomy cut

for accuracy was 0.24, demonstrating no difference between the sample mean and the specific value.

Radiographic union was assessed on anteroposterior (AP) and lateral radiographs during follow-up visits. Union at the osteotomy site follows the same process as normal bone healing. Thus, on the lateral side of the osteotomy, the periosteal callus forms as a fibrous sleeve forms 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 osteotomy from the lateral cortex to the wedge. This triangle (Fig. 6) was divided into four zones on the postoperative radiographs. The amount of filling (increase in density of the osteotomy) and its progression first in zone 1 were assessed at each radiological session. Radiographic union was obtained when filling was observed in zone 3. Because the wedge is in zone 4, this zone was not used to count the amount of filling. Using this method a semi-quantitative technique of measurement of volume filling was obtained, the total volume filling corresponding to the filling of the three zones (Fig. 7). Radiographic stability during healing (changes in correction in the coronal and
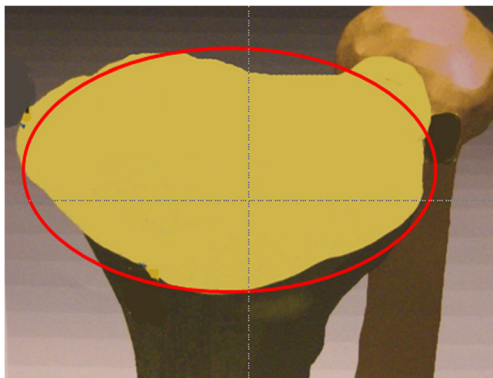
Fig. 4 Surface of osteotomy evaluated as an ellipse
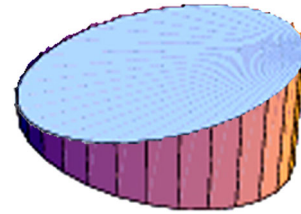
Fig. 5 The volume of opening was calculated as half of the elliptic cylinder

sagittal planes [4] and in patellar height [6] was measured as previously reported [10].

A computed tomography (CT) evaluation of the opened area was performed at 4 months following surgery in patients in order to assess the osseointegration in the opening volume. The osseointegration was estimated through a quantitative measure, by Hounsfield unit (HU) scale, of the density of the newly formed bone in the opening volume.

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 $a=0.05$. Paired sample t tests were used to detect significant alterations in measurements. Statistical tests were performed in Microsoft Excel (Microsoft, Redmond, WA, USA).

Results

Surfaces and wedge volumes resulting from osteotomy

The bone surface created by the osteotomy was on average 14 ± 3 cm^2. Comparable amounts of bone surfaces were found between the two groups (patients with and without weight
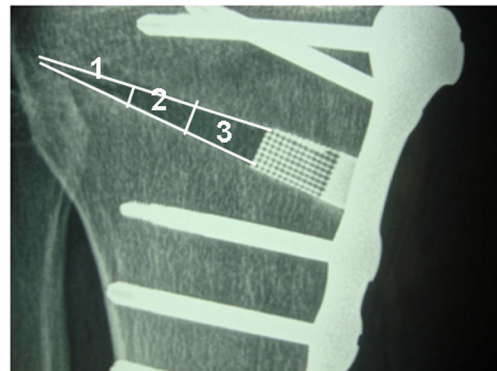
Fig. 6 The opening wedge triangle was divided into three zones on the postoperative radiographs. Healing was observed in these three zones. This radiograph at 2 months postoperatively demonstrates healing in zone 1
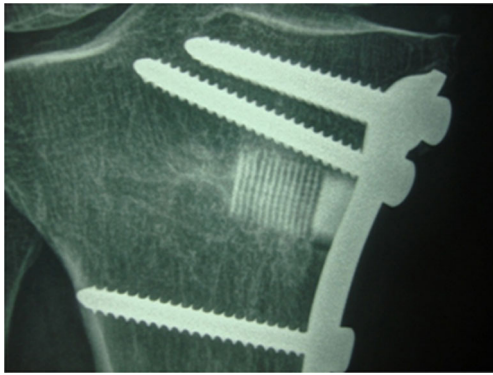
Fig. 7 Total filling of the three zones at 5 months postoperatively

bearing) with no significant difference (15 ± 2 cm^2 and 13 ± 4 cm^2, respectively, $p=0.6$). According to our mathematical model, Table 1 gives the volume of opening according to the width of the tibia and the height of the opening.

The wedge volumes resulted from the different heights of opening that were chosen for the correction. In Table 1 the volume in cubic centimetres of the opening is in boldface; for example if the width of the osteotomy line is 5.5 cm and the height of opening 1 cm the volume of opening is 7.9 cm^3. No significant differences of wedge volumes were found between the two groups, according to the fact that patients were matched for the size of height of the wedge.

The volume of each zone was estimated with a mathematical formula with:

– Zone 1=V/16
– Zone 2=3 V/16
– Zone 3=6 V/16

This means that for a volume of 16 cm^3 obtained in the table the volume of each zone can be estimated as:

– Zone 1=1 cm^3
– Zone 2=3 cm^3
– Zone 3=6 cm^3

Radiographic bone regeneration

The progression of bone filling was estimated in each zone at each month. For example with the values described previously, if at 3 months zones 1 and 2 were filled the volume was 4 cm^3, and when zone 3 was filled at five months the volume was 10 cm^3. This means that for such an example, at three months 40 % of filling was obtained and at five months 100 % of filling was obtained. The results are reported for each group of patients (with and without weight bearing in Fig. 8. Using this semi-quantitative radiographic volume evaluation of each zone, osseointegration was significantly increased in the group of patients with full weight bearing in comparison with the group without weight bearing.
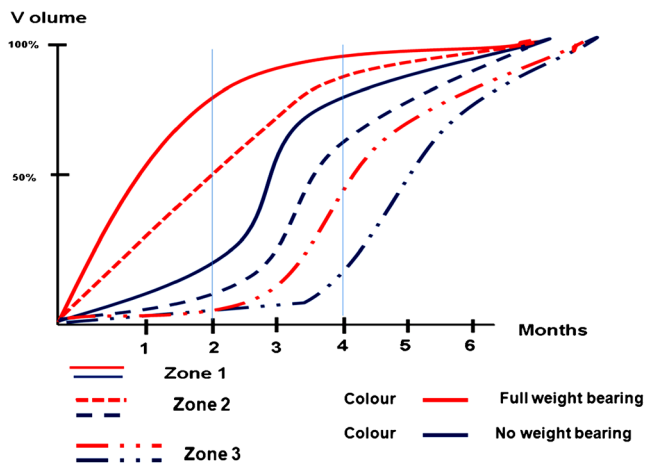
Quantitative CT evaluation of bone mineral density

The newly formed bone in the different zones showed no significant differences ($p>0.4$) at four months in the HU scale between the two study groups.

– Zone 1=520 ± 34 HU with weight bearing (WB) versus 515 ± 31 HU for non-WB
– Zone 2=410 ± 28 HU with WB versus 423 ± 30 HU for non-WB
– Zone 3=350 ± 23 HU with WB versus 347 ± 26 HU for non-WB
– Zone 4=310 ± 25 HU with WB versus 304 ± 21 HU for non-WB

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

Hip-knee-ankle (HKA) angle (coronal plane): Before the surgery, the average varus was $173\pm3.12°$ (169–178°); after the surgery (at ten days), the HKA angle was similar in both groups: $184.5\pm1.18°$ (182–186°) for the Limmed group and

Table 1 The volume in cubic metres of the opening is in boldface; for example if the width of the osteotomy line is 5.5 cm and the height of opening 1 cm the volume of opening is 7.9 cm^3

Width	AP distance	Surface	Height of opening																
			0.4	0.5	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0
4.0	2.7	8.4	**1.7**	**2.1**	**2.5**	**2.9**	**3.3**	**3.8**	**4.2**	**4.6**	**5.0**	**5.4**	**5.9**	**6.3**	**6.7**	**7.1**	**7.5**	**8.0**	**8.4**
4.5	3.0	10.6	**2.1**	**2.6**	**3.2**	**3.7**	**4.2**	**4.8**	**5.3**	**5.8**	**6.4**	**6.9**	**7.4**	**7.9**	**8.5**	**9.0**	**9.5**	**10.1**	**10.6**
5.0	3.3	13.1	**2.6**	**3.3**	**3.9**	**4.6**	**5.2**	**5.9**	**6.5**	**7.2**	**7.9**	**8.5**	**9.2**	**9.8**	**10.5**	**11.1**	**11.8**	**12.4**	**13.1**
5.5	3.7	15.8	**3.2**	**4.0**	**4.7**	**5.5**	**6.3**	**7.1**	**7.9**	**8.7**	**9.5**	**10.3**	**11.1**	**11.9**	**12.7**	**13.5**	**14.2**	**15.0**	**15.8**
6.0	4.0	18.8	**3.8**	**4.7**	**5.7**	**6.6**	**7.5**	**8.5**	**9.4**	**10.4**	**11.3**	**12.2**	**13.2**	**14.1**	**15.1**	**16.0**	**17.0**	**17.9**	**18.8**
6.5	4.3	22.1	**4.4**	**5.5**	**6.6**	**7.7**	**8.8**	**9.9**	**11.1**	**12.2**	**13.3**	**14.4**	**15.5**	**16.6**	**17.7**	**18.8**	**19.9**	**21.0**	**22.1**
7.0	4.7	25.6	**5.1**	**6.4**	**7.7**	**9.0**	**10.3**	**11.5**	**12.8**	**14.1**	**15.4**	**16.7**	**18.0**	**19.2**	**20.5**	**21.8**	**23.1**	**24.4**	**25.6**

Fig. 8 The volume that was filled in each zone for each group of patients at different periods; for example at two months zone 1 was filled for 75 % of the patients with weight bearing but for only 20 % of the patients without weight bearing

184.7±1.19° (183–187°) for the control group. The tibial slope did not significantly change: 6.5±2.87° before the surgery and 6.3±2.45° after the surgery and at the last follow-up (p=0.42) for patients with weight bearing or without weight bearing. The Caton index [5] 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

In this series of opening wedge HTO patients, full weight bearing was allowed as soon as wound healing and pain permitted it in the study group, and no loss of correction and no adverse effects occurred. In HTO, the implant used for fixation should be able to retain the correction achieved at the time of surgery. Rehabilitation protocols and time to full weight bearing after HTO vary. The amount of initial weight bearing that is allowed postoperatively depends strongly on the type of fixation used. Hernigou et al., with autologous grafts in the absence of osteosynthesis [7], differed weight bearing at two months, allowed weight bearing at 45 days with unlocked osteosynthesis [8] and allowed immediate full weight bearing with the locked plate Limmed [10]. Staubli et al. [22–24], using TomoFix for fixation in opening wedge HTO without filling the gap and without using a brace or cast, found that full weight bearing was possible at eight and ten weeks, respectively. More recently, a shorter time to full weight bearing after opening wedge HTO has also been reported by Takeuchi et al. [25] or Brinkman et al. [3] who allowed full weight bearing after two weeks. As with our findings, they did not observe any loss of correction or implant failure.

Gap filling in opening wedge HTO may be used to increase initial stability and facilitate or promote bone healing [11, 18, 19]. The porous β-tricalcium phosphate (TCP) bone substitute inserted into the gaps created in our patients is not shaped to fill the gap, but rather to add initial stability. We had no non-union. It can be concluded that bone healing occurs with or without filling of the gap. Furthermore, bone healing times do not vary. It can therefore be debated whether the gap should be filled at all. In the absence of filling all the gap, we used the volume of opening to analyse osseointegration.

These results of the radiographic evaluation demonstrate that osseointegration appeared to be significantly accelerated by weight bearing and dynamisation. The term dynamisation has become associated with both cyclic movements [16, 17]. Previous studies have indicated that cyclic movements applied soon after fracture correlate with faster healing rates as shown by measurements of fracture stiffness [7]. We tested the dynamisation of the Limmed locked plate on a mechanical test system: synthetic tibia were cut at the site of the osteotomy and fixed with plate and locking screws. Cyclic testing was performed with monotonically increasing load. Relative movements at the plate–screws interface were registered by motion tracking. Cyclic movements of 0.5 mm were obtained with load corresponding to weight bearing. Cyclic movements act as a stimulus to the growth of callus in the early weeks, while increased stability and compression of callus may be more appropriate stimuli in the later phase of callus maturation. The cyclical movement at the medial cortex is larger than that at the lateral cortex, as a result of bending in the plane of the bone screws and preservation of a hinge at the lateral cortex. This finding may explain the observation of greater amounts of progression of the callus from the lateral side to the medial side in patients with dynamisation by weight bearing. The locked plate and bone screws act as a spring and reopen the osteotomy gap after it has been closed by the application of load by weight bearing.

No significant difference in the bone density of the newly formed bone was observed between the groups with weight bearing and without weight bearing, as shown by the quantitative CT measure. Taken together, all these observations suggest that weight bearing may be safely recommended and accelerates osseointegration and bone growth without reducing the bone density of the newly formed tissue.

Criticisms that can be levelled at this study include the small sample size of the cohorts. They were from the same patient population, however, and patients in both groups were recruited based on the same criteria. Inclusion criteria were stringent to minimise the influence of factors other than the amount of weight bearing on the primary outcome measurement. Demographics were similar. Furthermore, all patients in both groups were operated on by the same surgeons using a standardised technique. Another limitation of this study is the technique of calculating the wedge volumes based on a

geometrical idealisation with computer navigation rather than measuring it, e.g, according to the method of Archimedes using bone cement to fill the osteotomy gap. Although a systematic error is inherent to the formula for prism volume calculation, the comparison of wedge height and wedge volume ratios was felt to be adequate to show differences between techniques.

In conclusion, the findings of this study suggest the possible use of weight bearing to enhance osteogenesis in patients undergoing opening wedge high tibial valgus osteotomy. These observations are in agreement with results of other studies, both in animals and in humans, suggesting a possible positive effect of weight bearing in enhancing tissue repair and regeneration when dynamisation of the site of a fracture or an osteotomy is obtained.

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