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Low-intensity pulsed ultrasound does not promote bone healing and functional recovery after open wedge high tibial osteotomy

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Aims

To evaluate whether low-intensity pulsed ultrasound (LIPUS) accelerates bone healing at osteotomy sites and promotes functional recovery after open-wedge high tibial osteotomy (OWHTO).

Methods

Overall, 90 patients who underwent OWHTO without bone grafting were enrolled in this nonrandomized retrospective study, and 45 patients treated with LIPUS were compared with 45 patients without LIPUS treatment in terms of bone healing and functional recovery postoperatively. Clinical evaluations, including the pain visual analogue scale (VAS) and Japanese Orthopaedic Association (JOA) score, were performed preoperatively as well as six weeks and three, six, and 12 months postoperatively. The progression rate of gap filling was evaluated using anteroposterior radiographs at six weeks and three, six, and 12 months postoperatively.

Results

The pain VAS and JOA scores significantly improved after OWHTO in both groups. Although the LIPUS group had better pain scores at six weeks and three months postoperatively, there were no significant differences in JOA score between the groups. The lateral hinge united at six weeks postoperatively in 34 (75.6%) knees in the control group and in 33 (73.3%) knees in the LIPUS group. The progression rates of gap filling in the LIPUS group were 8.0%, 15.0%, 27.2%, and 46.0% at six weeks and three, six, and 12 months postoperatively, respectively, whereas in the control group at the same time points they were 7.7%, 15.2%, 26.3%, and 44.0%, respectively. There were no significant differences in the progression rate of gap filling between the groups.

Conclusion

The present study demonstrated that LIPUS did not promote bone healing and functional recovery after OWHTO with a locking plate. The routine use of LIPUS after OWHTO was not recommended from the results of our study.

Introduction

Good clinical results have been reported with open-wedge high tibial osteotomy (OWHTO) with locking plates that act as internal fixators.[1-7] Rigid long plates provide high initial stability without bone grafting for early weight-bearing and can maintain optimal postoperative lower leg alignment.[8-11] However, despite these newer implants, most authors have recommended a period of protected weight-bearing after OWHTO.[12-15] This ranges from six to eight weeks until bony consolidation as seen on radiographs. Potential reasons for avoiding early full weight-bearing are loss of correction and delayed union or nonunion of the osteotomy site. This slow rehabilitation prevents early return to work, sports, and activities of daily

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┌─────────────────────────────────────────────┐
│  136 knees undergoing OWHTO without           │
│  bone grafting between January 2012           │
│  and December 2017                            │
└─────────────────────────────────────────────┘

┌─────────────────────────────────────────────┐
│  Exclusion: 46 knees                          │
│  Receiving osteoporosis treatment: 34         │
│  HTO combined ACL reconstruction: 1           │
│  Delayed infection after surgery: 3           │
│  No adequate data: 8                          │
└─────────────────────────────────────────────┘

                  ┌──────────────┐
                  │  90 knees    │
                  └──────────────┘

   ┌──────────────────┐      ┌──────────────────┐
   │  Control group   │      │  LIPUS group     │
   │  45 knees        │      │  45 knees        │
   └──────────────────┘      └──────────────────┘
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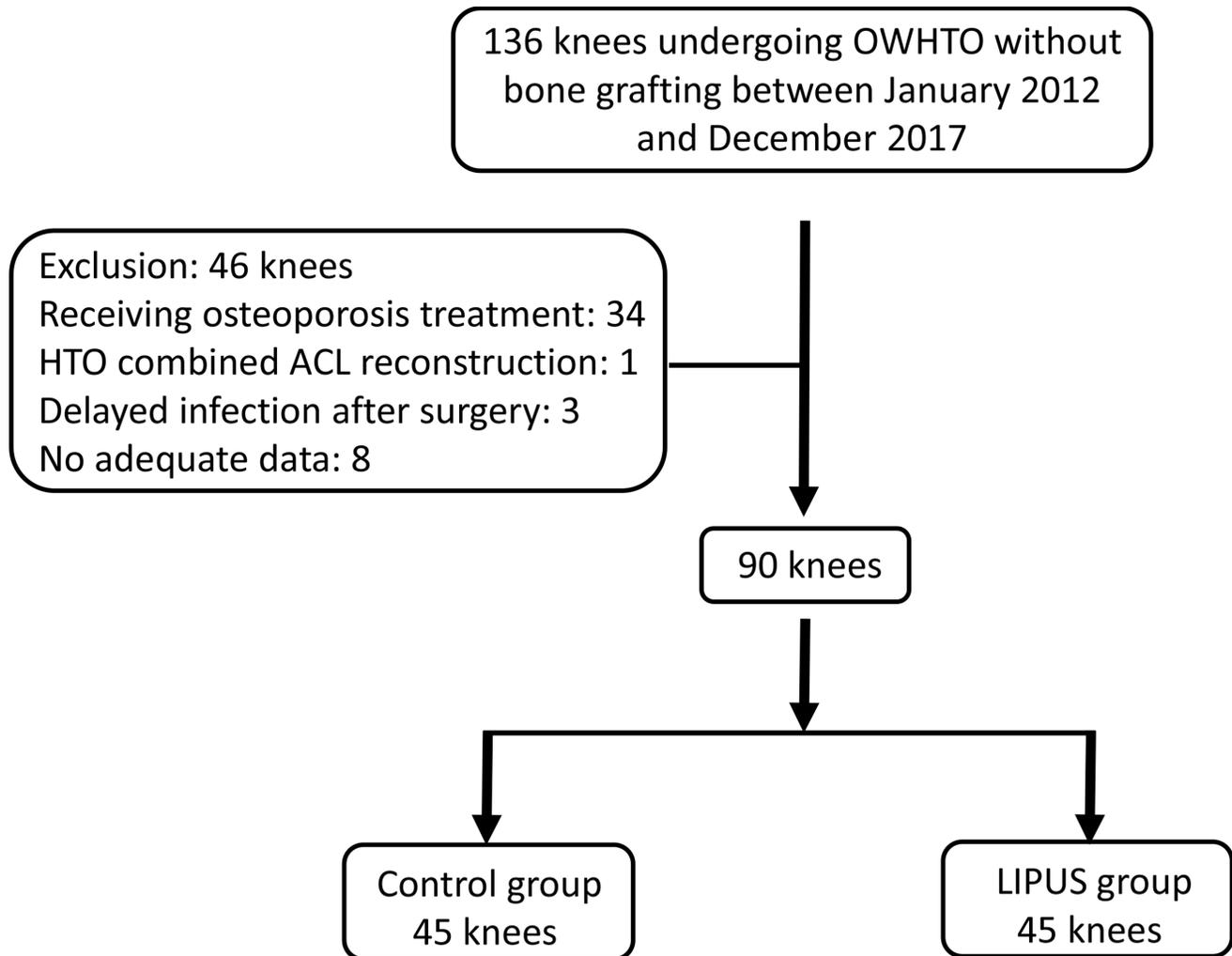
Fig. 1

Flowchart showing reasons for exclusion. ACL, anterior cruciate ligament; HTO, high tibial osteotomy; LIPUS, low-intensity pulsed ultrasound; OWHTO, open-wedge high tibial osteotomy.

Table I. Comparison of preoperative patient demographic data between the groups.

Demographic	Control group (n = 45 knees)	LIPUS group (n = 45 knees)	p-value
Mean age, yrs (SD; range)	62.2 (8.7; 43 to 82)	65.2 (11.9; 42 to 79)	0.102*
Sex, male/female, n	16/29	23/22	0.136†
Mean height, cm (SD; range)	159.4 (9.9; 141 to 182.3)	161.9 (9.5; 142 to 181)	0.216‡
Mean body weight, kg (SD; range)	63.6 (11.8; 39 to 92.4)	65.5 (11.5; 43 to 88.2)	0.442*
Mean BMI, kg/m^2 (SD; range)	24.9 (2.9; 19.6 to 31.3)	24.9 (3.2; 18.9 to 32.5)	0.963*
Mean opening width, mm (SD; range)	11.8 (2.6; 7 to 19)	12.0 (2.6; 7 to 17)	0.762*
Mean preoperative WBLR, % (SD; range)	23.0 (9.6; 0.6 to 44.2)	21.8 (12.7; -12 to 42.2)	0.607*

Patient demographic data (age, sex, height, body weight, and BMI) were collected at the time of inclusion.
*Independent-samples *t*-test.
†Chi-squared.
‡Mann-Whitney U test.
LIPUS, low-intensity pulsed ultrasound; WBLR, weight-bearing line ratio.

living. The length of time taken for the osteotomy site to unite is an important factor in a patient's recovery. Therefore, the acceleration of bone healing at the osteotomy site can provide social and financial benefits for patients undergoing OWHTO.
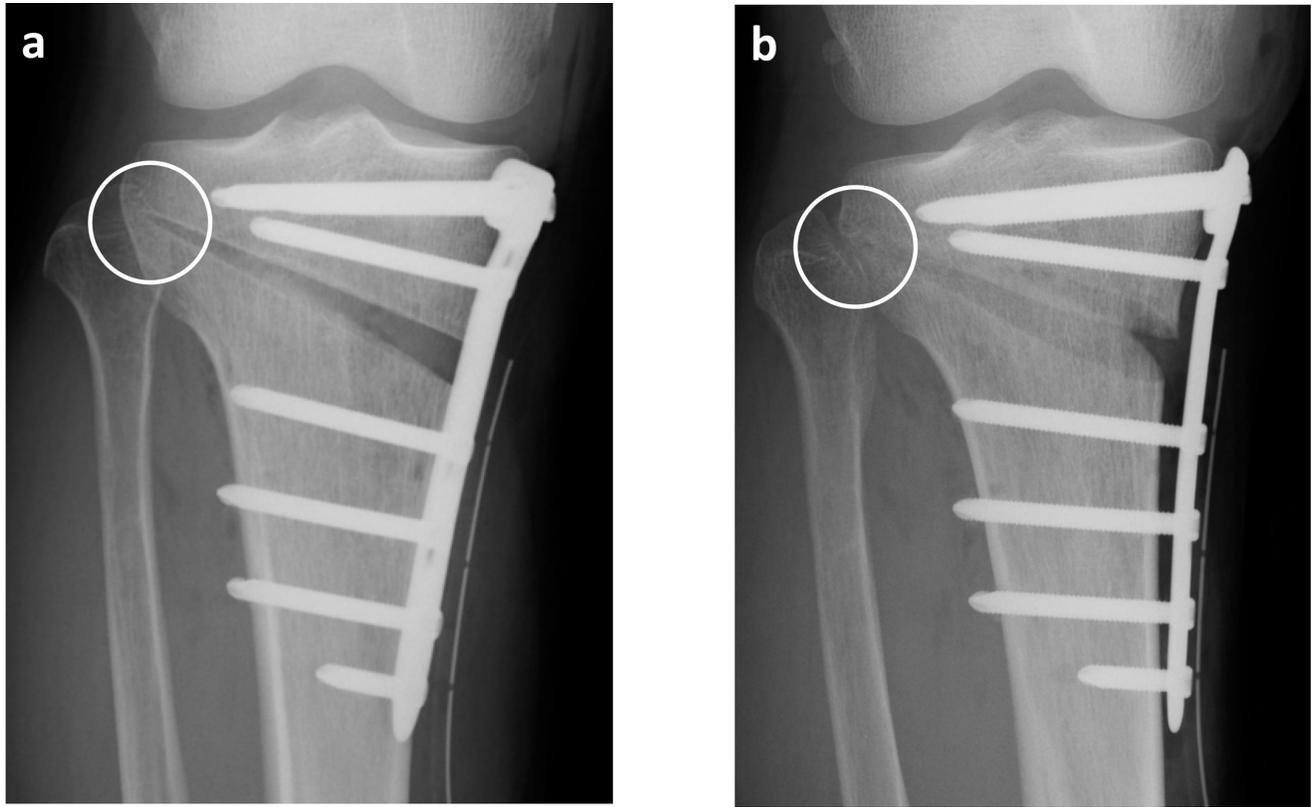
Fig. 2

For this 52-year-old female patient, the target site was marked on the lateral hinge using a) anteroposterior radiograph and b) internal rotation view. These radiographs were taken immediately after the operation.
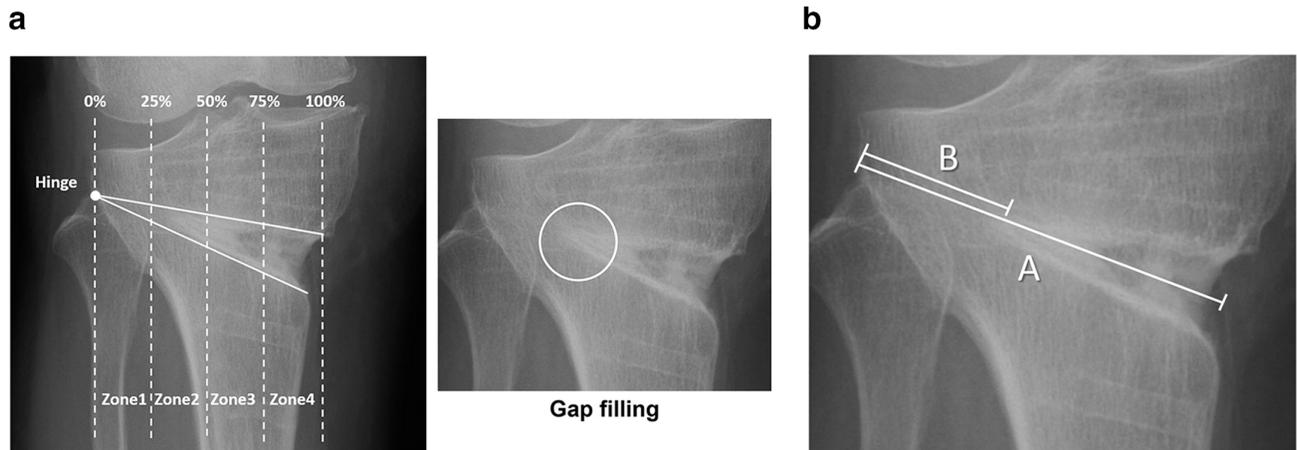
Fig. 3

Radiographs taken from a 56-year-old female patient at one-year follow-up post-surgery. a) The osteotomy gap was divided into the lateral hinge and four zones on anteroposterior radiographs, and the zone in which trabecular bone continuity could be observed was defined as gap filling. b) Result of (Distance B/Distance A) × 100 was the progression rate of gap filling.

Low-intensity pulsed ultrasound (LIPUS) is frequently used to enhance or to accelerate fracture healing. Early double-blind, randomized controlled trials (RCTs) reported accelerated healing in patients with an acute fracture of the tibia and distal radius, respectively.[16,17]

Moreover, several studies demonstrated that LIPUS enhanced bone healing after osteotomy surgeries.[18-21] Urita et al[20] reported that LIPUS shortened the time to cortical union by 27%, and to endosteal union by 18% after forearm bone shortening osteotomies. Furthermore,

Table II. Comparison of clinical outcomes between the groups.

Score	Control group (n = 45 knees)	LIPUS group (n = 45 knees)	p-value
Mean VAS (SD)			
Preoperative	61.8 (16.0)	61.4 (22.9)	0.919*
6 weeks	38.7 (16.7)	32.2 (15.8)	0.031†
3 months	36.4 (22.3)	27.5 (21.1)	0.027†
6 months	19.4 (15.1)	19.6 (18.1)	0.939*
12 months	9.8 (9.2)	10.9 (13.7)	0.678*
Mean JOA score (SD)			
Preoperative	65.4 (12.5)	68.3 (9.5)	0.219*
6 weeks	72.6 (7.7)	72.9 (8.4)	0.845*
3 months	79.8 (10.0)	82.0 (8.8)	0.267*
6 months	87.7 (7.5)	89.3 (7.5)	0.295*
12 months	95.2 (7.2)	92.8 (7.0)	0.106*

*Mann-Whitney U test.
†Independent-samples *t*-test.
JOA, Japanese Orthopaedic Association; LIPUS, low-intensity pulsed ultrasound; SD, standard deviation; VAS, visual analogue scale.

Table III. Comparison of postoperative alignment and lateral hinge fractures between the groups.

Variable	Control group (n = 45 knees)	LIPUS group (n = 45 knees)	p-value
Mean postoperative WBLR, % (SD)	65.6 (9.6)	64.8 (10.5)	0.409*
Lateral hinge fracture, n (%)			
Type I	11 (24.4)	14 (31.1)	0.479†
Type II	3 (6.7)	2 (4.4)	0.644†
Type III	0	0	N/A

*Independent-samples *t*-test.
†Chi-squared test.
LIPUS, low-intensity pulsed ultrasound; N/A, not applicable; SD, standard deviation; WBLR, weight-bearing line ratio.

Tsumaki et al[19] suggested that LIPUS accelerated callus maturation during the consolidation phase after OWHTO by hemicallotasis. However, few reports evaluated whether LIPUS promoted bone healing after modern OWHTO with a locking plate.[22,23] Moreover, previous reports had small sample sizes and evaluated only radiological bone healing by LIPUS and not functional recovery. Its clinical effectiveness as a treatment modality for OWHTO remains uncertain. Therefore, the purpose of this study was to evaluate whether LIPUS promotes bone healing and functional recovery after OWHTO. We hypothesized that LIPUS could accelerate bone healing at the osteotomy site and improve postoperative recovery after OWHTO.

Methods

This retrospective case series was approved by the Institutional Review Board of Toyama Municipal Hospital (IRB No.2014-17), and informed consent was obtained from each patient for their participation in the study. We included 121 patients (136 knees) with osteoarthritis (OA) or osteonecrosis (ON) who underwent OWHTO without bone grafting between January 2012 and December 2017. From 2015, LIPUS was routinely used after OWHTO with the consent of patients. Exclusion criteria were as follows: receiving medications for osteoporosis, such as bisphosphonate, vitamin D, and parathyroid hormone (n = 34); simultaneous anterior cruciate ligament reconstruction (n = 1); delayed infection after surgery (n = 3); and missing or inadequate data (n = 8). Therefore, we analyzed the remaining 90 knees in this nonrandomized retrospective study, which comprised two groups: LIPUS group (n = 45) and control group without LIPUS (n = 45) (Figure 1). Patients with complete postoperative follow-up records for at least one year were included, and the mean follow-up period was 51.3 months (standard deviation (SD) 21.5). The baseline patient characteristics of both groups are shown in Table I. There were no significant differences in preoperative patient characteristics between the groups.

Our inclusion criteria for the OWHTO procedure were as follows: symptomatic medial OA or ON of the medial femoral condyle; varus malalignment – femorotibial angle (FTA) > 176°; and active patients with good postoperative rehabilitation programme compliance. There were no age restrictions. The contraindications for OWHTO were: history of joint infection; symptomatic OA of the lateral compartment or patellofemoral joint; joint instability; FTA > 185°; and flexion contracture > 15°.

Surgical procedure and postoperative rehabilitation. The surgical technique and preoperative planning used in the present study were as previously described.[24] The
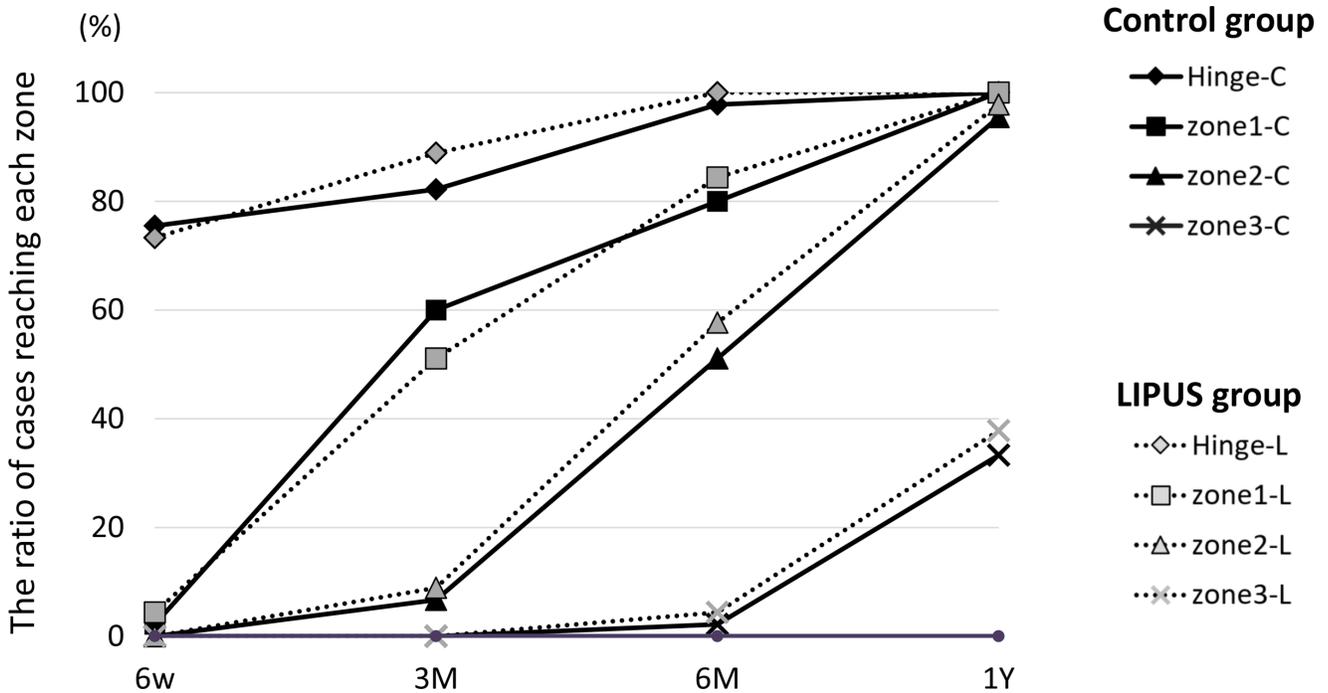
Fig. 4

Comparison of the gap filling progression between the groups. LIPUS, low-intensity pulsed ultrasound.

weight-bearing line was aimed at a point 65% to 70% lateral on the transverse diameter of the tibial plateau. Arthroscopy was routinely performed prior to HTO to evaluate the medial, lateral, and patellofemoral cartilage. The biplanar OWHTO was internally fixed with a TomoFix plate (DePuy Synthes, Switzerland). No bone graft or bone substitute was placed in the osteotomy site. Isometric quadriceps, active ankle exercises, and straight leg raises were started on the first postoperative day. Partial weight-bearing started one week postoperatively. Full weightbearing was permitted after four weeks.

Application of low-intensity pulsed ultrasound. Ultrasound energy was provided by a Sonic Accelerated Fracture Healing System 2000 (Smith & Nephew, USA). LIPUS used in this study had a frequency of 1.5 MHz, a signal burst width of 200 µs, a signal repetition frequency of 1 kHz, and an intensity of 30 mW/cm². The target site was marked at two locations on the lateral hinge using an anteroposterior (AP) radiograph and internal rotation view postoperatively (Figure 2). Two weeks after surgery, we began applying daily 20-minute ultrasound treatments for each marked point and continued the application for three months postoperatively or until the investigator (TS) judged there to be sufficient bone healing at the lateral hinge site. The head module was located on the lateral hinge site, where bone healing begins in OWHTO and was firmly fixed with a strap. Compliance with the device was assessed as a percentage of compliance with

daily use and percentage of treatment time out of the prescribed 20-minute period.

Clinical evaluation. The pain visual analogue scale (VAS) and the Japanese Orthopaedic Association (JOA) score[25] were measured preoperatively and at six weeks and three, six, and 12 months postoperatively to evaluate the clinical outcomes. Pain was assessed using a 100 mm VAS; the best score corresponded to 0, and the worst score corresponded to 100. Further, we evaluated postoperative complications that required additional surgery.

Radiological evaluation. Radiological evaluations were performed preoperatively and at six weeks and three, six, and 12 months. The weight-bearing line ratio (WBLR) and FTA were evaluated to assess the alignment. WBLR was measured from standing AP whole-leg radiographs. To calculate the WBLR, a line was drawn from the centre of the femoral head to the midpoint of the proximal talar joint surface. The WBLR was defined as the horizontal distance from the weight-bearing line (WBL) to the medial edge of the tibial plateau divided by the width of the tibial plateau. A standing AP view, with an extended knee joint, was used to assess FTA, and FTA was defined as the lateral angle between the axis of the femoral and tibial shafts. Moreover, lateral hinge fracture was evaluated according to Takeuchi's classification: type I, the fracture reaches just proximal to or within the tibiofibular joint; type II, the fracture reaches the distal portion of the proximal tibiofibular joint; and type III, lateral plateau fracture.[26]
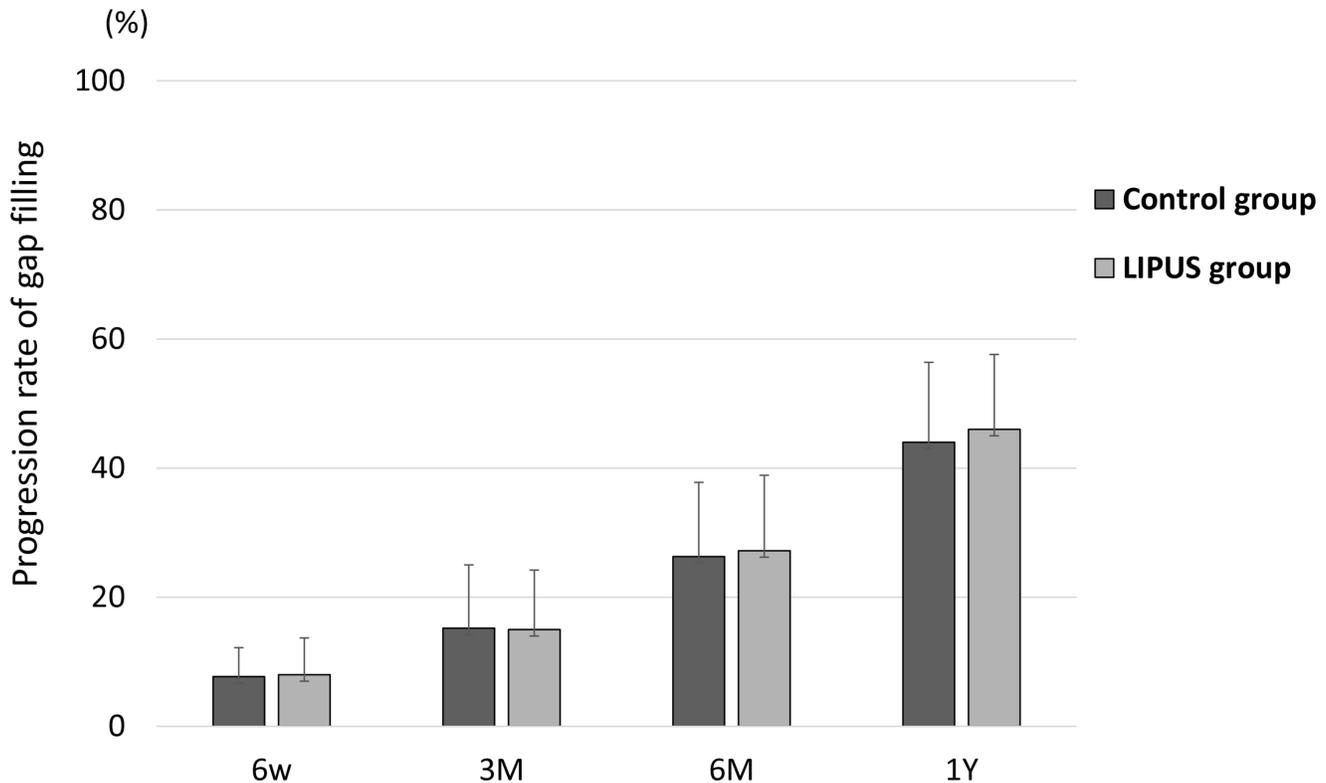
Fig. 5

Comparison of the progression rate of gap filling between the groups. LIPUS, low-intensity pulsed ultrasound.

Radiological evaluation of bone formation in the osteotomy gap. Bone formation in the osteotomy gap was assessed as previously reported.[24] The osteotomy gap was divided into the lateral hinge and four zones on the AP radiographs, and the zone in which trabecular bone continuity could be observed was defined as gap filling (Figure 3a). According to this definition, we evaluated bone formation in the osteotomy gap at six weeks and three, six, and 12 months postoperatively. Further, the progression rate of gap filling was calculated to compare the two groups (Figure 3b). All radiological parameters were measured twice by two observers (KG and SI), with a more than four-week interval between each measurement. The observers were blinded to the previous observations.

Statistical analysis. JMP version 11 (SAS Institute, USA) was used to analyze and manage the data. The data are presented as means and SDs. Differences in continuous variables were analyzed using independent-samples t-test or Mann–Whitney U test according to the test for normality, and the chi-squared test was used to analyze qualitative data. Paired t-test was used to analyze the pre- and postoperative WBLR. The reliability of measurements was assessed by examining the intra-rater and inter-rater reliabilities by using the intraclass correlation coefficient. The intra- and inter-observer reliabilities for the measurement of radiological parameters were satisfactory, and

the mean values were 0.98 (0.93 to 0.99) and 0.94 (0.87 to 0.98), respectively. Power analysis was performed using G*power (version 3.1.9.7; Heinrich-Heine-Universität Düsseldorf, Germany). Based on prior literature,[27] to detect a 10% difference in means, with a common SD of 12% in bone formation in the osteotomy gap, with the two-sided t-test and 80% power ($\alpha = 0.05$), the required total sample size is 48 (24 patients per group). Therefore, 90 patients are a sufficient sample size to assess significant difference in bone formation.

Results

Clinical outcomes. The pain VAS and JOA scores significantly improved after OWHTO in both groups. Although VAS in the LIPUS group was better than in the control group at six weeks and three months postoperatively, there were no significant differences in JOA score between the groups (Table II). Regarding the postoperative complications, there were no adverse events such as nonunion and loss of correction requiring additional surgery.

Radiological outcomes. The mean WBLR significantly changed from 22.3% (SD 11.1%) preoperatively to 65.2% (SD 10.0%) at the final follow-up (p < 0.001, paired t-test). There were no significant differences regarding postoperative knee alignment between the groups (Table III). Intraoperative and postoperative lateral hinge fractures
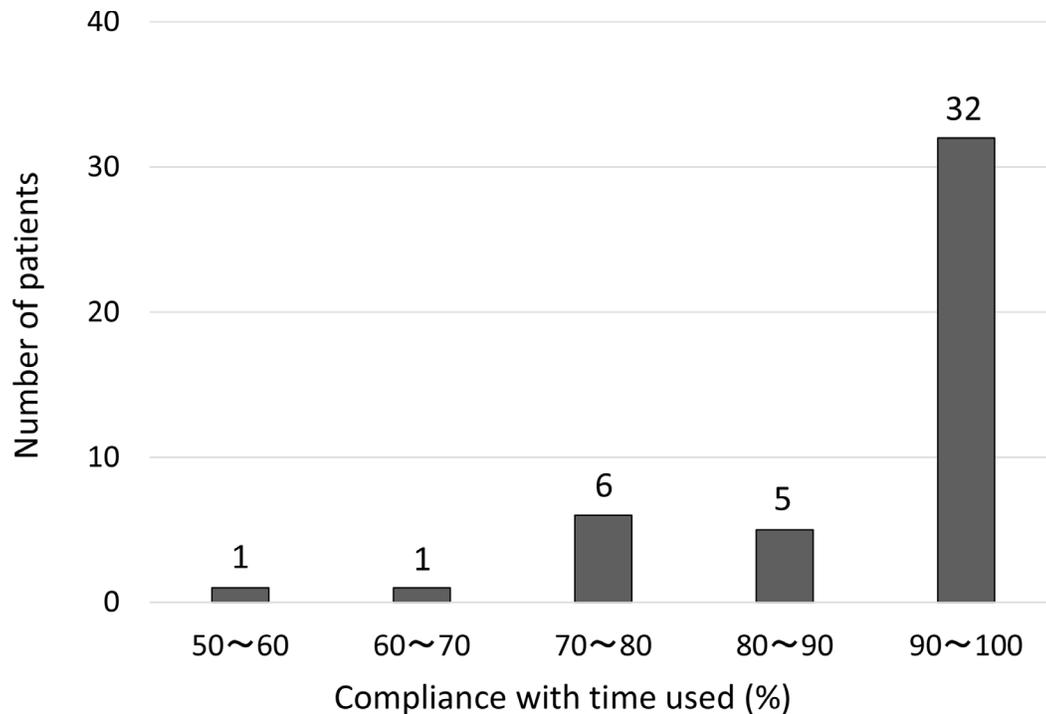
Fig. 6

Compliance with low-intensity pulsed ultrasound (LIPUS) in 45 cases.

were observed in 14 knees in the control groups and 16 knees in the LIPUS group. There were no significant differences in the rates of the lateral hinge fractures between the groups (Table III).

Comparison of bone formation in the osteotomy gap between the groups. The results for bone formation in the osteotomy gap are shown in Figure 4. Bone formation progressed from the lateral hinge to the medial direction after OWHTO. The lateral hinge union was confirmed at six weeks postoperatively in 34 (75.6%) knees in the control group and 33 (73.3%) knees in the LIPUS group. There were no significant differences in bone formation in the osteotomy gap between the groups. Furthermore, the progression rate of gap filling did not show any significant differences between the groups (Figure 5).

Compliance with LIPUS. Patient compliance in this study is shown in Figure 6, and the mean rate of patient compliance was 92.3% (SD 11.4%).

Discussion

The most important finding of this study was that LIPUS did not accelerate bone formation at the osteotomy site after OWHTO. Although the LIPUS group had better pain score at six weeks and three months postoperatively, there were no significant differences in JOA score between the groups.

LIPUS is frequently used to enhance or to accelerate fracture healing in the clinical setting. Accelerated fracture healing was proven by RCTs of acute fractures of the tibia and distal radius in humans and in animal studies on fractured and osteotomized long bones.[16,17,28,29] However, more recent RCTs showed no statistically significant differences in healing when LIPUS was used for acute fractures of the clavicle or ankle.[30,31] Simpson at al[32] reported that LIPUS did not influence bone healing by distraction osteogenesis in a multicentre double-blind RCT. Given the conflicting data, recent systematic reviews concluded that there was insufficient evidence to support the routine use of LIPUS for acute fractures.[33-35]

Although the same cellular processes are present in bone healing after osteotomies and fracture healing, a few studies demonstrated that LIPUS enhanced bone healing at the osteotomy site after osteotomy surgeries.[18-21] Regarding HTO, Tsumaki et al[19] suggested that LIPUS accelerated callus maturation during the consolidation phase after open-wedge HTO by hemicallotasis. They reported that the external fixators were removed at a mean time of one week earlier from the ultrasound treated limbs than from the control limbs. Nolte et al[18] reported that LIPUS enhances bone healing in closed wedge HTO and reduces the occurrence of delayed union or nonunion. However, there are few reports that evaluated whether LIPUS promotes bone healing after modern OWHTO with a locking plate.[22,23] Furthermore, the previous reports had small sample sizes and evaluated only radiological bone healing by LIPUS and not functional recovery. Thus, its clinical effectiveness as a treatment modality for OWHTO remains uncertain. In the present study, we did not find

evidence of accelerated bone healing at the osteotomy site after OWHTO with the use of LIPUS. Regarding the clinical effectiveness of LIPUS, there were no significant differences in JOA score between the groups. Although there were statistically significant differences in VAS at six weeks and three months postoperatively, the differences were small. Thus, these differences were considered to have a little clinical impact regarding functional recovery after OWHTO.

Various factors, including smoking, obesity, advanced age, poor bone quality, infection, and metabolic disease affecting bone healing after fracture have been described.[36] Regarding bone healing after OWHTO, previous studies have identified obesity, smoking, the size of osteotomy gap, and the lateral hinge fracture as risk factors that negatively influence bone healing after OWHTO, which potentially leads to delayed union or nonunion.[24,37,38] In our study, there were no significant differences in age, BMI, the opening gap size, and the rate of lateral hinge fractures. Therefore, we believe that the present study demonstrates the substantial effects of LIPUS on bone healing at the osteotomy site after OWHTO.

There were several reasons why LIPUS did not accelerate bone healing after OWHTO in this study. First, the target site of LIPUS might have influenced the results. Although LIPUS was applied from the anterior to the lateral hinge in this study, the rigid bone cortex of the anterolateral tibia may have reduced the effect of LIPUS. Previous studies demonstrated that bone formation progressed from the lateral hinge to the medial direction after OWHTO.[24,39] Kobayashi et al[40] reported that bone union was initiated at the flange and the lateral hinge of the osteotomy after OWHTO using CT evaluation. Therefore, LIPUS should be applied to the flange in addition to the lateral hinge in future studies. Second, TomoFix plate provides superior stability in both compression and torsion compared with a short spacer plate. Hence, in most cases, bone union was achieved six weeks after surgery without LIPUS, and it is possible that there was no difference between the control and LIPUS groups in the present study. Third, patient compliance could have also affected the results. A literature review on the LIPUS device shows a correlation between clinical effectiveness and patient compliance.[41] The mean patient compliance in our study was 92.3% (SD 11.4%), which was comparable with that reported in the previous studies.[32,41] However, some patients had low compliance in this study, and patient education is needed to improve the radiological and clinical effects of LIPUS.

This study had several limitations. First, there may have been patient selection bias because this was a nonrandomized retrospective study. Second, bone healing was assessed only in an AP radiograph. Although CT is the most suitable method for assessing bone healing after OWHTO, it is impractical to perform CT repeatedly. Moreover, Kobayashi et al[40] examined the effectiveness of radiography and CT to evaluate bone union in OWHTO, and they concluded that plain radiographs are useful for evaluating bone union of the lateral hinge and provide similar results as a CT analysis. Third, we started to apply LIPUS from two weeks after surgery in the present study. If LIPUS had been initiated earlier than two weeks postoperatively, the results might have been different. However, during the early postoperative period, there are some concerns about using LIPUS, such as local swelling, pain, and wounds near the target site, which could be a risk of infection. Lastly, we did not use a sham device in the control group. Ideally, we should have applied a sham device to patients in the control group.

In conclusion, LIPUS does not promote bone healing and functional recovery after OWHTO with a locking plate. The routine use of LIPUS after OWHTO is not recommended based on the results of our study.

Take home message
- Low-intensity pulsed ultrasound (LIPUS) does not promote bone healing and functional recovery after open-wedge high tibial osteotomy (OWHTO) with a locking plate.
- The routine use of LIPUS after OWHTO is not recommended based on the results of our study.

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