



Comparison between headless compression screws and tension band wires for the fixation of medial malleolar fractures: a prospective randomized trial

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Abstract

Introduction To date, there has been no prospective randomized trial supporting the rationale of the use of headless compression screw (HCS) compared to conventional fixation methods for medial malleolar fractures. This study aimed to prospectively compare the outcomes of the HCS and tension band wire (TBW) for the fixation of medial malleolar fractures.

Material and methods Sixty patients were randomized to receive either an HCS or a TBW for the fixation of a medial malleolar fracture. Clinical outcomes were assessed using the Olerud–Molander ankle score (OMAS), EuroQoL five-dimensional instrument (EQ-5D) score, visual analog scale (VAS) score, patient satisfaction with implant-related symptoms, operative time, and incision length. Radiographic outcomes were assessed using the presence of nonunion, delayed union, and articular incongruity. Clinical and radiographic assessments were performed at 2 and 6 weeks and 3, 6, and 12 months postoperatively.

Results The OMAS, EQ-5D score, VAS score, and operative time did not differ between the HCS and TBW groups; however, the HCS group had greater satisfaction with implant-related symptoms and smaller incision than the TBW group. There was no difference in the presence of nonunion, delayed union, and articular incongruity.

Conclusion HCS fixation for medial malleolar fractures is not inferior to TBW fixation, while reducing implant-related symptoms. These findings suggest that HCS is a viable alternative for the fixation of medial malleolar fractures.

Keywords Ankle fractures · Fracture fixation · Internal fixators · Trauma

Introduction

Rotational ankle fractures are one of the most common skeletal injuries in the lower extremity, and one-third of them involve medial malleolar fractures [1, 2]. Well-reduced fractures can be treated nonoperatively; however, majority of medial malleolar fractures require open reduction and

internal fixation. Traditionally, medial malleolar fractures have been fixed through cortical screw fixation, tension band wire (TBW) fixation, or buttress plating [3–5]. Operative fixation of ankle fractures has generally shown good results; however, patient dissatisfaction can result from implant-related symptoms, such as persistent pain, local irritation, subcutaneous prominence, and psychological discomfort [6–8].

Recently, as an attempt to reduce the metal-related symptoms of conventional fixations, the use of headless compression screw (HCS) is gaining attention for the fixation of medial malleolar fractures [9]. Structurally, its use has the advantage of minimizing the implant protrusion because the screw head is flushed with the bone surface. Moreover, a previous biomechanical study found that HCS yields greater stiffness for fracture fixation than conventional screws [10]. Therefore, it can be a good viable option for the fixation of medial malleolar fractures. However, to date, there has been no prospective randomized trial supporting the rationale of

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the use of HCS compared to conventional fixation methods for medial malleolar fractures.

In this study, we investigated whether the use of HCS for the fixation of medial malleolar fractures in patients with rotational ankle fractures is comparable with that of TBW. The primary aim of this study was to compare the clinical and radiographic outcomes between patients who underwent HCS and TBW fixation of medial malleolar fractures. The secondary aim was to compare the patient satisfaction with implant-related symptoms between them.

Materials and methods

This study was designed as a prospective randomized clinical trial and was conducted at a single university hospital. After obtaining approval from the Institutional

Review Board, 60 consecutive patients with rotational ankle fractures who were willing to participate and meeting the inclusion criteria were recruited into the study from March 2018 to February 2020. The inclusion criteria were as follows: (1) skeletal maturity, male or female sex, and age between 18 and 65 years and (2) a rotational ankle fracture that contained displaced a medial malleolar fracture. The exclusion criteria were as follows: (1) a medial malleolar fracture that could not be fixed with screws due to avulsion from the tip of a malleolus or comminuted pattern; (2) open fracture, bilateral fracture, other notable ankle injuries, or history of ankle fracture; and (3) systemic diseases, including type 1 diabetes, multiple sclerosis, Parkinson's disease, and other disorders that might affect peripheral sensorimotor function. The other exclusions and flow diagram of the study are presented in Fig. 1.

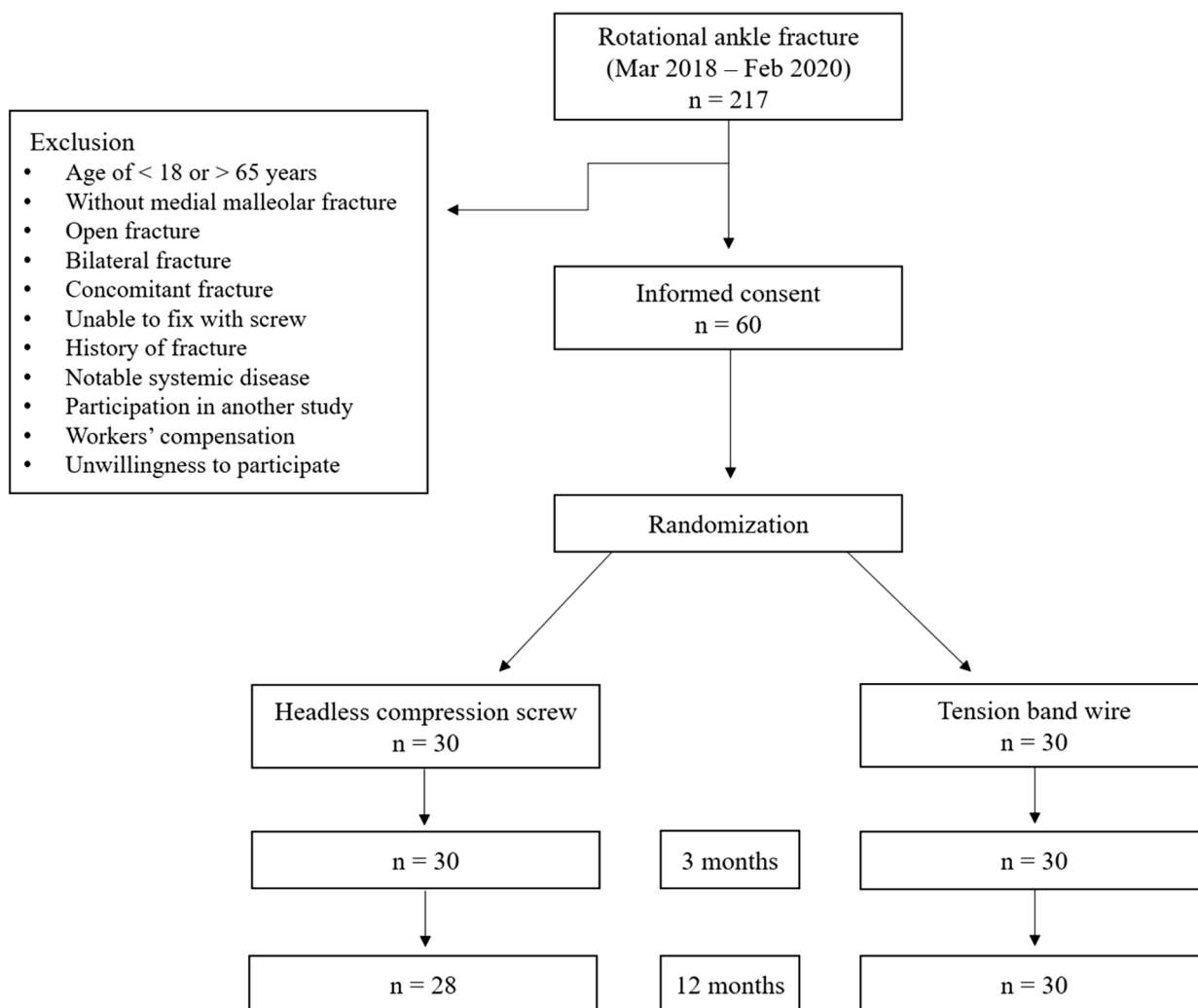


Fig. 1 Flow diagram of the study

Patient demographics

After obtaining informed consent from each patient eligible for inclusion in the study, data on patient demographics, including age, sex, body mass index (BMI), smoking status, injury mechanism, and fracture type, were collected prior to surgery. The fracture type was classified into three categories based on severity: isolated medial malleolar, bimalleolar, and trimalleolar fractures [11, 12].

Randomization

All patients were randomly assigned to one of the two groups using sequentially numbered opaque, sealed envelopes organized by the study coordinator. The randomization sequence was generated using a computer software (Excel 2016, Microsoft, Redmond, WA) [13]. Neither the patients nor the surgeons were aware of the results of the randomization process until the day of surgery. All patients had the option to withdraw from the study for any reason, without repercussion.

Operative procedures

The operative procedures were performed in accordance with standard AO principles [14]. Lateral and posterior malleolar fractures were treated with open reduction and internal fixation using a plate and screws. If syndesmosis instability was confirmed following the fixation of fractures, syndesmotic screw fixation was conducted. For medial malleolar fractures, a medial incision was created, and direct visualization and reduction of the fracture fragments were achieved. In the TBW group, a figure-of-eight wire loop was created on two 1.6 mm K-wires inserted as perpendicularly as possible to the fracture plane. To anchor the figure-of-eight wire proximally, a 3.5 mm cortical screw was used (Fig. 2A). In the HCS group, one bi-cortical 4.5 mm partially threaded HCS (DePuy Synthes Inc., West Chester, PA) was fixed and placed at the center of the fragment (Fig. 2B). In both groups, surgical wound was closed using absorbable braided sutures and topical skin adhesives.

Postoperative rehabilitation

All patients were followed up at 2 and 6 weeks and 3, 6, and 12 months after surgery. A short leg splint was maintained for 2 weeks. Thereafter, an air-stirrup ankle brace was applied, and forefoot-touch partial weight-bearing and active ankle-motion exercises were allowed. Full weight-bearing was allowed at 6 weeks after surgery, and patients were gradually weaned off the ankle brace. Personal physical therapy was not allowed, except for routine instructions for rehabilitation provided during the study period. Removal of



Fig. 2 Medial malleolar fracture treated with headless compression screw (A) and tension band wiring (B) fixation

the implant, including the syndesmotic screw, was not performed until 12 months after surgery regardless of whether the syndesmotic screw was broken.

Clinical outcome assessment

Clinical outcomes were assessed at 3 and 12 months after surgery, which included the following: Olerud–Molander ankle score (OMAS), EuroQoL five-dimensional instrument (EQ-5D) score, visual analog scale (VAS) score, and patient satisfaction with implant-related symptoms. The OMAS is a validated patient-reported outcome measure for ankle fractures, with higher scores indicating better outcomes and fewer symptoms (scale, 0–100 points) [15]. The OMAS was used as a primary outcome measure in this study. The EQ-5D is an instrument used to evaluate five generic items on quality of life. In the questionnaires on mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, patients selected one of the following three answers based on their severity level: score 1, no problems; score 2, some or moderate problems; and score 3, extreme problems [16, 17]. The VAS score for pain was determined by measuring the distance between the “no pain” anchor and pain in daily life marked by the patient on a 100 mm line, with the score ranging from 0 to 100 [18, 19]. A 5-point Likert scale was used to assess patient satisfaction with implant-related symptoms [20]. Patients were provided with information on the possible symptoms that could be caused by fracture fixation implants (persistent pain, local irritation, subcutaneous prominence, and psychological discomfort) in advance; in consideration of this, they reported their satisfaction with those symptoms with one of the following items: very unsatisfied, unsatisfied, neutral, satisfied, and very satisfied. In addition to patient-reported outcome measures, the operative time, incision length, and postoperative complications were assessed. The operative time was defined as the time from the start of skin medial incision to the end of medial

malleolar fracture fixation and skin closure, recorded in minutes by the assistant during surgery. The incision length was measured by the operator after closing the medial wound using a sterile surgical ruler in centimeters.

Radiographic outcome assessment

Radiographic outcomes were the presence of fracture union and articular incongruity, which were assessed using plain radiography and computed tomography (CT). Plain radiographs were obtained at each visit and CT scans were taken at 12 months after surgery. Nonunion was defined as a failure of achievement of union until 6 months, and delayed union was defined as no sign of healing at 3 months after surgery [12, 21]. Articular incongruity was determined if any of the following criteria were observed: (1) more than 2 mm of articular step-off, (2) intra-articular loose bodies, and (3) more than 2 mm of gap in the joint surface despite an anatomic reduction of the cortex [22]. Two orthopedic surgeons independently determined the radiographic outcomes, and when there was a discrepancy between them, the final decision was made via consensus.

Sample size calculation

The noninferiority trial method was used to determine the appropriate sample size [23]. Based on the OMAS at 12 months after surgery, which was defined as the primary outcome measure, the sample size was calculated to have a power of 80% and a significance level of 0.05. Twenty-seven patients per group were required to determine whether HCS fixation was inferior to TBW fixation, as the difference between the two treatment methods would be above the non-inferiority margin of negative 9 points (standard deviation, 11.6 points). As there is no universally established minimal clinically important difference for this score, we set this margin based on previously conducted prospective studies [24, 25]. With an assumption of a 10% dropout rate during follow-up, 30 patients were decided to be included in each group for the study.

Statistical analysis

Normality of the data was determined using the Kolmogorov–Smirnov test. An independent *t* test or the Mann–Whitney *U* test was used to compare the continuous variables, i.e., age, BMI, OMAS, VAS score, EQ-5D score, operative time, and incision length. The chi-square test or Fisher's exact test was used to compare the categorical variables, i.e., sex, injury mechanism, patient satisfaction, fracture type, fracture union, and articular incongruity. The Statistical Package for the Social Sciences version 23.0 software program (IBM Corp, Armonk, NY) was used for statistical

analysis, and a *P* value of <0.05 was considered to indicate statistical significance.

Results

Patient demographics

No difference was identified in terms of age, sex, BMI, smoking status, injury mechanism, or fracture type between the study groups (Table 1).

Clinical outcomes

There was no difference found in the OMAS, EQ-5D score, and VAS score between the groups at 3 and 12 months after surgery; however, patient satisfaction with implant-related symptoms was greater in the HCS group than in the TBW group (Table 2). The operative time in the HCS group (14.3 ± 7.3 min) was not different from that in the TBW group (16.9 ± 5.5 min) ($P=0.122$). The incision length in the HCS group (4.8 ± 0.8 cm) was shorter than that in the TBW group (5.6 ± 1.3 cm) ($P=0.008$). Except for one case

Table 1 Patient Demographics

	HCS (<i>n</i> =28)	TBW (<i>n</i> =30)	<i>P</i> value
Age, year	47.0 ± 14.8	46.4 ± 14.5	0.698
Sex			0.971
Female	12	13	
Male	16	17	
BMI, kg/m ²	25.5 ± 3.5	25.2 ± 3.0	0.268
Smoking status			0.622
Smoker	8	5	
Previous smoker	3	4	
Nonsmoker	17	21	
Diabetes			1.000
Type II	4	5	
None	24	25	
Injury mechanism			0.389
Fall	19	23	
Sports	1	1	
MVA	7	3	
Others	1	3	
Fracture type			0.666
Isolated medial malleolar	5	4	
Bimalleolar	9	7	
Trimalleolar	14	19	

Data are presented as means ± standard deviations or numbers of patients

HCS headless compression screw, TBW tension band wire, BMI body mass index, MVA motor vehicle accident

Table 2 Clinical outcomes

	3 months			12 months		<i>P</i> value
	HCS (<i>n</i> =30)	TBW (<i>n</i> =30)	<i>P</i> value	HCS (<i>n</i> =28)	TBW (<i>n</i> =30)	
OMAS	63.5 ± 21.8	65.2 ± 19.5	0.756	82.1 ± 14.5	84.0 ± 15.8	0.643
EQ-5D score						
Mobility	1.7 ± 0.5	1.9 ± 0.4	0.248	1.1 ± 0.4	1.3 ± 0.5	0.252
Self-care	1.4 ± 0.6	1.4 ± 0.6	0.827	1.0 ± 0.2	1.1 ± 0.3	0.336
Usual activities	1.7 ± 0.5	1.7 ± 0.5	0.630	1.1 ± 0.4	1.2 ± 0.4	0.386
Pain/discomfort	2.0 ± 0.6	2.0 ± 0.5	0.661	1.5 ± 0.6	1.8 ± 0.6	0.130
Anxiety/depression	1.5 ± 0.6	1.6 ± 0.6	0.682	1.1 ± 0.3	1.2 ± 0.4	0.206
VAS score for pain	34.8 ± 20.9	38.8 ± 23.9	0.493	13.3 ± 18.6	17.4 ± 16.0	0.370
Satisfaction with implant-related symptoms			< 0.001			< 0.001
Very unsatisfied	0	5		0	6	
Unsatisfied	6	21		3	16	
Neutral	22	3		3	6	
Satisfied	2	1		17	2	
Very satisfied	0	0		5	0	

Data are presented as means ± standard deviations or numbers of patients

Boldface indicates statistical significance ($P < 0.05$)

HCS headless compression screw, TBW tension band wire, OMAS Olerud–Molander ankle score, EQ-5D EuroQoL five-dimensional instrument, VAS visual analog scale

of superficial wound infection in the TBW group, no post-operative complications related to medial malleolar fracture fixation were noted. After debridement and intravenous antibiotics treatment, the lesion healed and implant removal was not needed.

Radiographic outcomes

In both groups, no nonunion or delayed union was identified. The incidence of articular incongruity in the medial malleolus at 12 months after surgery was 3.6% (1/28) in the HCS group and 3.3% (1/30) in the TBW group, with no significant difference noted ($P = 1.000$).

Costs

The implant cost was \$143.00 in the HCS group and \$85.23 in the TBW group. The costs can vary by region or country.

Discussion

The use of HCS for the fixation of medial malleolar fractures in terms of reducing the metal-related symptoms of conventional fixations is gaining attention; however, knowledge on the outcomes of HCS fixation is limited. To address this issue, we performed a prospective randomized trial of 60 patients to compare the outcomes between the use of HCS

and TBW for the fixation of medial malleolar fractures. The primary findings of this study were that the clinical and radiographic outcomes were not different between the HCS and TBW groups, except for patient satisfaction and incision length. The HCS group had greater satisfaction with implant-related symptoms and smaller surgical incision than the TBW group. As the outcomes of HCS fixation for medial malleolar fractures are not inferior to those of conventional TBW fixation while reducing implant-related symptoms, surgeons may perform HCS fixation as an alternative to conventional fixation methods for medial malleolar fractures.

The strengths of this study are its prospective design and sufficient sample size. Bulut and Gursoy [26] retrospectively compared the outcomes of HCS fixation for isolated medial malleolar fractures with those of TBW and cannulated lag screw fixation and found no difference in the fracture healing time and clinical outcome measures at the time of final follow-up; however, the VAS score associated with implant irritation of the medial malleolus was lower in the HCS group. In their study, the HCS was fixed in a uni-cortical manner; no anchor screw was used for TBW fixation; and the sample size was small. However, their results advocated the use of HCS for the fixation of medial malleolar fractures, similar to our study results.

The screw head of the HCS, which lies flush with the bone, is known to yield a benefit; HCS has fewer implant-related symptoms than TBW. However, in addition to this structural benefit of HCS, we deduced that the incision

length of HCS fixation also affected the implant-related symptoms. Medial pain or discomfort after surgical fixation of medial malleolar fractures is related not only to the fixation implant, but also to the scar tissue around the incision [27]. Owing to the wire configuration and the position of the proximal anchor suture, the incisions are inevitably longer in TBW fixation than in screw fixations. Therefore, shorter surgical incisions in HCS fixation than those in TBW fixation would have alleviated the symptoms, which can be another benefit of HCS fixation.

The main concern with HCS fixation for medial malleolar fractures is over-compression on the fracture site [5]. Over-compression results in closure of the medial clear space or malalignment, both of which can lead to inferior outcomes. In this study, one case of articular incongruity in the medial malleolus was observed in the HCS group due to medial shifting of the fracture during compression. However, at 12 months after surgery, the distal fragment united without further displacement, and the patient did not complain of any symptom related to over-compression; thus, additional intervention was not needed. Although we could not analyze the risk factors for over-compression due to the small number of cases, caution should be taken when performing HCS fixation for medial malleolar fractures.

This study has two limitations. First, the rates of implant removal were not compared between the two groups. As this study included patients with rotational ankle fractures rather than those with isolated medial malleolar fractures alone, it could not be clearly distinguished whether the patient discomfort that led to implant removal solely originated from the medial malleolar fracture fixation. Second, the postoperative complications were not compared. As the rates of complications after surgical treatment of ankle fractures are < 1.5% [11], a much larger sample size than what was aimed in this study was required to have an adequate power for detecting differences. Therefore, we decided not to compare the rates of implant removal and postoperative complications between the two groups.

Conclusion

The outcomes of the use of HCS for the fixation of medial malleolar fractures are not inferior to those of the use of conventional TBW while reducing implant-related symptoms. These findings suggest that HCS is a viable option for the fixation of medial malleolar fractures.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s00402-021-04003-x>.

Author contributions YHP: design of investigation, performed operation, data collection, data analysis, writing paper. HWC: design of investigation, data collection. JWC: data analysis and interpretation,

scientific discussion. HJK: design of investigation. Co-writer/editor of manuscript.

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Declarations

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval This study was approved by the local Ethics Committee (IRB No. 2018GR0086).

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