Foot and Ankle Surgery 22 (2016) 103–108

Contents lists available at ScienceDirect

Foot and Ankle Surgery

journal homepage: www.elsevier.com/locate/fas

A new "tension side" locking plate for Hallux Valgus: A prospective multicentre case series

Daniel Goldbloom FRACS(Orth)[a,*], Nilesh Makwana FRCS(Orth)[b], Patrick Laing FRCS[b], Eric Toullec[c], Wilfrid Graff[d], Antoine Charbel[e]

[a] Robert Jones Agnes Hunt Orthopaedic Hospital (Foot and Ankle Department), Oswestry SY10 7AG, United Kingdom
[b] Wrexham Maelor Hospital, Croesnewydd Road, Wrexham LL13 7TD, United Kingdom
[c] Polyclinique de Bordeaux-Tondu, Service de chirurgie du pied et de la cheville, 143 rue du Tondu, 33082 Bordeaux Cedex, France
[d] Groupe Hospitalier Diaconesses Croix saint Simon, 18, rue du Sergent Bauchat, 75018 Paris, France
[e] Centre Hospitalier universitaire Notre Dame de secours, Boite Postale 3 – Jbeil, Byblos, Lebanon

ARTICLE INFO

Article history:
Received 17 December 2014
Received in revised form 20 May 2015
Accepted 20 May 2015

Keywords:
Hallux Valgus
Locking plate
Opening wedge
Basal Osteotomy

ABSTRACT

Background: Proximal osteotomy of the first metatarsal is often indicated for Hallux Valgus correction. Previously recognised complications however, include transfer metatarsalgia, first metatarsophalangeal joint stiffness, problems with fixation and prominence of metalware.
Methods: We report on one year follow up of an international prospective series between June 2009 and October 2012 involving three centres, including 91 feet (58 patients) that underwent proximal osteotomy, using a new locking plate applied to the plantar surface of the metatarsal.
Results: Mean Hallux Valgus angle improved from 27.9 (±13.1)° to 12.4 (±8.2)° while mean Intermetatarsal angle improved from 12.5 (±8.4) to 7.1 (±3.4) and there was a statistically significant improvement in both mean AOFAS-HMI score 54.2 (±13.9) to 94.0 (±9.5) and Visual Analogue Pain Scale 4.7 (±1.5) to 0.6 (±1.3). 70% of patients were back at their preoperative employment at five weeks. Mean surgical time was 56 min and the plate was generally well tolerated. There were five implant related complications.
Conclusions: Locked fixation from the tension side of the construct encourages early weight bearing with a low risk of implant prominence. Our radiological, functional and clinical parameters are comparable with similar series and we therefore recommend this technique.

1. Introduction and rationale

Hallux Valgus is normally associated with a high 1–2 intermetatarsal angle (IMA), i.e. >15° [1]. Proximal osteotomies such as basal crescentic [2–5], proximal chevron [6–9] and medial opening wedge [10–15] provide a powerful correction for the deformity and have been reported on over many years. Recognised complications include first metatarsophalangeal (MTP) joint stiffness [13], non union [12], transfer metatarsalgia [5], recurrence of deformity [4], hallux varus [7], and hardware issues such as irritation [14] and failure [15]. This study describes a prospective case series of a basal osteotomy internally fixed with a locking plate applied to the plantar surface of the metatarsal. The concept of plantar fixation has more commonly been studied for first metatarsocuneiform fusion [16–18]. The technique theoretically confers biomechanical superiority in that the fixation is from the tension side of the construct [19]. Plantar aspect fixation also theoretically lowers the risk of wound problems and irritation related to prominent metalware.

2. Aims

The aim of this study was to assess a new plate applied to the plantar surface of the first metatarsal for fixation of a basal osteotomy in terms of functional improvement, decrease in pain and overall complications.

3. Methods

This was a multicentre international prospective post marketing clinical trial with one year follow up. Four investigators, from two centres across Europe, (Wrexham Maelor Hospital,

* Corresponding author at: Alfred Hospital, Orthopaedic Department, PO Box 315, Prahran, Victoria 3181, Australia. Tel.: +61 3 9076 2025.
E-mail addresses: goldbloom.daniel@gmail.com (D. Goldbloom), nilesh@bhanu.freeserve.co.uk (N. Makwana).

http://dx.doi.org/10.1016/j.fas.2015.05.010
1268-7731/

Croesnewydd Road, Wrexham LL13 7TD, United Kingdom), (Groupe Hospitalier Diaconesses Croix saint Simon, 18, rue du Sergent Bauchat, 75018 Paris, France) and one from the Middle East (Centre Hospitalier universitaire Notre Dame de secours, Boite Postale 3 – Jbeil, Byblos, Lebanon) were involved. For each centre, ethics committee approval was obtained as required by local regulation and the study was performed in compliance with good clinical practises.

We used an alpha risk of 5% and a power of 90% to evaluate the number of patients to be included in the study. This was based on a hypothesised 5% implant related complication rate and a mean 30-point improvement in the AOFAS-HMI score with 10% loss to follow up at one year. The result was a requirement to include 80 cases in the study. The Signed-rank Wilcoxon two-sided test was used and significance was declared at a 0.05 threshold with 95% confidence intervals.

There was no specific indication for inclusion in the study and each investigator was encouraged to include cases where they felt that a proximal osteotomy was clinically indicated. Hallux varus was also an acceptable indication. Exclusion criteria included suspected or documented metal allergy, active infection, local or systemic acute or chronic inflammation and mental illness preventing accurate follow up.

An initial questionnaire was used to obtain basic demographic information. It also included questions about level of employment and whether the patient considered themselves "Very active", "Active" or "Sedentary" in their daily occupation.

There were two primary outcomes for which data was collected up to one year. The first was efficacy of the implant as measured by the improvement in the American Orthopedic Foot and Ankle Society Hallux Metatarsophalangeal-Interphalangeal Scale (AOFAS HMI) [20], and the second was overall complication rate and analysis of complications.

We also recorded data for a number of secondary outcomes. Radiological data included, Hallux Valgus angle (HVA), IMA, distal metatarsal articular angle (DMAA), 1st MTP joint congruency (reported as "yes" or "no" on X-ray), medial sesamoid position (classified as stage 1–4 where 1 was no subluxation, 2 was subluxation less than 50% of the width of the medial sesamoid, 3 was greater than 50% and 4 was 100%), dorsal malalignment (measured on weight bearing lateral X-ray as "none", "minor" (less than 10° deviation between the axis of the distal part of the first metatarsal and the axis of the second metatarsal) or "major" (greater than 10°), metatarsal length (measured according to each centre's protocol) and union of osteotomy (at the discretion of the investigator based on X-rays where the choices were "no union", "in progress" and "united").

Functional and clinical outcomes were recorded by pain assessment via a visual analogue scale, 1st MTP range of motion measured by goniometer, presence of oedema, time to return to original level of employment and overall satisfaction. This last category included a "yes or no" type response as to whether they felt their activity was "limited due to their foot", whether they were satisfied with the appearance of their foot and whether they would undergo surgery again.

Lastly an overall assessment of correction involving both clinical and radiological assessment was graded as overcorrection, good correction or undercorrection. HVA >15 on X-ray was considered as undercorrection and the clinical appearance of Hallux varus as overcorrection.

The study schedule review was adhered to as closely as possible. It involved a pre operative visit followed by clinical review at 8–15 days, five weeks, three months and one year. X-rays were performed at the five week, three month and one year reviews. Clinical reviews and the recording of data and interpretation of X-rays were undertaken by the surgeon who performed the operation. Data collection was performed via anonymous electronic case report forms.

Fig. 1. photograph of the plate with locking screws in situ.

3.1. Surgical technique

The technique for the indication of Hallux Valgus was as follows: a medial approach was performed that allowed exposure of both the 1st metatarsophalangeal (MTP) and 1st tarsometatarsal (TMT) joints. After MTP capsulotomy the medial eminence was resected and preserved. The precise location of the TMT joint was then identified and the proximal metatarsal was exposed by subperiosteal dissection.

The plate (B-BOP Integra lifesciences, Saint Priest, France) is 30 mm long and made from a titanium alloy, Fig. 1. It has four 3 mm screw holes in series with either a left or right sided 5° valgus bend. It is precontoured to the shape of the plantar surface of the metatarsal with the option of further bending intraoperatively. The plate has a 15° variable angle locking screw facility to all screw holes using a threaded lock cap.

The plate was applied to the plantar surface via the most proximal screw only, to ensure clearance of the TMT joint. An osteotomy was then performed 2 cm distal to the TMT joint and perpendicular to the axis of the axis of the metatarsal. The lateral cortex was left intact unless a plantarflexion element was planned in which case only the plantarlateral corner was left intact. The width of the opening wedge was determined clinically with the aid of both intraoperative X-rays and a selection of wedges between 10° and 20° as seen in Fig. 2. The standard wedge size, although not formally recorded, was between 3–4 mm at its base. Fixation was completed with two screws both proximal and distal to the osteotomy. The medial eminence was fashioned as bone graft to fill the defect.

If the indication was Hallux varus then a lateral closing wedge osteotomy was performed instead.

Further procedures to the first ray were performed when it was deemed necessary by the surgeon. These were recorded along with any procedures undertaken to the lesser rays.

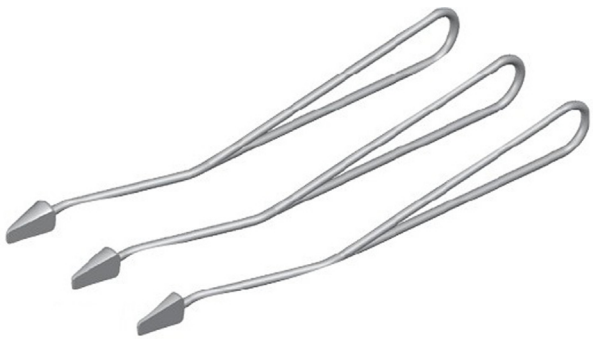

Fig. 2. 10°, 15°, 20° wedges to assist with sizing of opening wedge osteotomy.