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A pilot study to assess the safety and radiological performance of a new low-profile locking plate for high tibial osteotomy

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ABSTRACT

Background: We report the first results of a new low-profile titanium locking plate for fixation of opening wedge high tibial osteotomy (OWHTO). Short spacer plates have been associated with a high hardware complication rate, whilst fixed angle locking plates have been associated with a high incidence of soft tissue irritation. This plate aims to achieve stable fixation whilst maintaining a low profile, allowing space for combined procedures.
Methods: All patients undergoing OWHTO with the Activmotion plate were retrospectively reviewed. Patients were allowed to progress to full weight bearing after two weeks. Radiographic assessment included the medial proximal tibial angle (MPTA) and posterior tibial slope at six weeks and then three monthly until union. All complications were recorded.
Results: Thirty-seven patients with 40 OWHTOs were included in the study. The mean MPTA increased from 85.2 preoperatively to 91.9 postop. Tibial slope changed from 5.2 to 4.2°. The correction was sustained until union with no loss of correction in the MPTA (median change 0.0, 95% CI for median (−0.25, 0.4)) or tibial slope (mean increase 0.32, 95% CI (−0.02, 0.67)).
Conclusions: In this pilot study the Activmotion plate raised no safety concerns with regard to implant related adverse events or loss of initial correction. Early rehabilitation with immediate partial weight bearing was possible and all cases proceeded to osteotomy union with the exception of one case that needed to undergo bone grafting with implant retention. Premature removal of the implant was necessary in four cases due to symptomatic hardware irritation.

1. Introduction

High tibial osteotomy (HTO) was popularised in the 1970s by Coventry, who reported good results when used as a treatment of osteoarthritis of the medial compartment and varus alignment [1]. More latterly, it has been shown to achieve similar clinical outcome scores to arthroplasty although high quality comparative evidence is lacking [2–4]. In addition to the improvement in pain levels, there is evidence of cartilage regeneration and a decrease in subchondral bone sclerosis in the medial compartment following realignment [5, 6].

More recently the importance of treating mal-alignment in patients with cartilage and meniscal deficiency has been recognized and consequently HTO is commonly performed with associated procedures such as ligament reconstruction and cartilage repair [7, 8].

The opening wedge high tibial osteotomy (OWHTO) has superseded the closing wedge technique as the preferred method of correction for the majority of surgeons [9]. It allows correction of the deformity whilst restoring bone stock, negating the need for a fibular osteotomy and avoiding the complications associated with the closing wedge technique such as nerve injury and tibial condylar offset [10, 11]. Traditionally, OWHTO was stabilized with external fixators until union and was associated with a high

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incidence of pin site infection. The introduction of the locking plate technology made OWHTO possible using internal fixation and without the need for bone grafting [12].

Complications associated with this technique can be divided into the following groups: progression of disease and persistence of pain leading to arthroplasty, complications relating to bone union, implant related complications and generalized complications of surgery [13]. Smaller spacer plates have been associated with high rates of complications largely relating to plate breakage [14,15] whilst larger rigid plates have been associated with soft tissue irritation in as high as 40.6% of patients [16]. Furthermore, the fixed angle nature of the screws and wide body of the locking plate interfere with positioning of tunnels and thus make combined ligament reconstruction or meniscal allograft transplantation technically more demanding [17].

The Activmotion plate (Newclip Technics, Haute Goulaine, France) is a titanium locking plate for fixation of OWHTO which attempts to provide stable fixation to allow early restoration of function and through its smaller, low profile design, less soft tissue irritation and improved access to perform associated procedures. The aim of this paper is to describe the early results of the use of this plate for OWHTO with a focus on the radiographic correction achieved, correction loss, complications and specifically implant related adverse events.

2. Materials and methods

All patients who underwent an opening wedge high tibial osteotomy using the Activmotion plate (Newclip Technics, Haute Goulaine, France) as an isolated or combined procedure between July 2013 and July 2017 were included in the study.

Indication for surgery was varus knee malalignment with clinical symptoms of medial compartment pain secondary to cartilage pathology or meniscal deficiency. OWHTO was offered to patients with no or minimal signs of osteoarthritis in the lateral compartment, a painless Patellofemoral joint (PFJ) and good range of motion. In the presence of concomitant patellofemoral joint degeneration, OWHTO was performed if the patient did not report anterior knee pain, clinical examination was negative for patellofemoral irritability and initial arthroscopy demonstrated that the degeneration was not significant. Patients with open physeal plates, a Body mass index (BMI) >35, a fixed flexion of >10° and flexion of less than 90° were deemed unsuitable for osteotomy.

2.1. Preoperative assessment and planning

Patients were investigated with short film, weight bearing x-rays on presentation to our clinic. Potential candidates for realignment were further investigated with long leg weight bearing radiographs. This was combined with an Magnetic Resonance Imaging (MRI) of the knee if the clinical picture suggested concomitant pathology such as cruciate instability or isolated chondral/osteochondral lesions. The Antero-posterior (AP) long-leg weight-bearing radiograph was used for preoperative planning.

The planned correction varied based on the pathology and its severity. In general, for individuals undergoing cartilage repair the mechanical axis was planned to be corrected to the up-slope of the lateral tibial spine and in osteoarthritis the correction was to the peak of the lateral tibial spine.

2.2. Surgical technique

All osteotomies were performed under combined general and spinal anaesthesia for postoperative analgesia. All patients received prophylactic antibiotics at induction. The patient was positioned in supine position over a radiolucent table with a proximal tourniquet applied to the operated limb. Using fluoroscopy, the centre of the hip and ankle joints was located and marked with palpable radiopaque markers in the form of disposable adhesive electrocardiogram (ECG) electrodes. Using the electrosurgery lead and fluoroscopy we confirmed the deformity (Mikulicz point) after correcting for rotation. Arthroscopy of the knee joint was performed in order to confirm integrity of the lateral compartment and to address any additional intraarticular lesions.

For exposure, a four to six centimetre medial oblique skin incision was performed just superior and parallel to the pes anserinus. The sartorius fascia was cut and retracted medially. The medial collateral ligament was exposed and released from its posteromedial insertion in order to reduce the risk of hinge fracture and unload the medial compartment during osteotomy [18]. Two two-millimetre K-wires were placed four centimetres distally to the medial joint line and advanced under fluoroscopic control, laterally just distal to the tip of the fibula. These wires guided the level of osteotomy at the coronal plane. The osteotomy was performed parallel to the tibia slope, on the undersurface of the K-wires and ended 10 mm from the lateral cortex of the tibia in order to preserve the lateral hinge. A second osteotomy located at the anterior third of the proximal tibia and at 45° to the first osteotomy was performed in order to preserve the patellar tendon insertion site. All osteotomies were performed with oscillating saws and completed with stacking osteotomes.

Following opening of the osteotomy the mechanical axis was adjusted as determined preoperatively using a laminar spreader placed posteriorly within the gap. With the help of fluoroscopy and the electrosurgery cable, correction of the axis was adjusted using the laminar spreader.

The sided anatomically contoured Activmotion plate was positioned and centred over the osteotomy site and inserted as per the manufacturer's instructions for use. In cases where the distal plate hole could not be reached through the incision, one additional stab incision was created directly over the screw hole. The osteotomy gap was then filled with 10 cm^3 of demineralized bone matrix (NHS Blood and Transplant Tissue Services). No drain was used in any of the cases.

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2.3. Post-operative period and follow-up

We used mechanical thromboprophylaxis in the form of intermittent calf compression (contralateral leg) and Thromboembolic Deterrent (TED) stockings until the patient was mobile. All patients were mobilized partial weight-bearing for two weeks with immediate active and passive Range of motion (ROM) at the knee joint encouraged unless associated procedures required further restriction. Full weight bearing was allowed following two weeks based on patient tolerance. Following an initial visit at six weeks, patients were followed with radiological assessment at three monthly intervals until union was achieved. Patients were discharged from the clinic following satisfactory clinical and radiological findings of osteotomy healing and/or removal of the osteotomy plate.

Radiological assessment at follow-up consisted of short film weight bearing x-rays of the knee. All radiographic measurements were carried out by two fellowship trained Orthopaedic surgeons (JP and FH) using our Picture Archiving and Communication System (Centricity, GE Medical Systems, UK). The medial proximal tibial angle (MPTA) was measured using the proximal tibial mechanical axis and the proximal tibial knee joint orientation line. The proximal tibial mechanical axis was defined as the axis connecting two midpoints of the proximal tibia, at least five centimetres apart. The proximal tibial joint orientation line was drawn by connecting two points on the concave aspect of the tibial plateau subchondral line [19] (Figure 2a). The posterior tibial slope was measured using the posterior tibial cortex (PTC) as previously described [20] (Figure 2b).

2.4. Data analysis

Data was analyzed using IBM SPSS Statistics for Macintosh, Version 24.0. Radiographic measurements were subtracted to generate the variables reflecting the change between time points. These were tested for normality using the Shapiro–Wilk test. For normally distributed data, the mean change and 95% confidence interval are presented. For non-normally distributed data the median and 95% confidence interval for the median are reported. Boxplots were generated to graphically represent the MPTA and tibial slope at the three measured points. An absolute agreement definition was used to calculate the Intraclass Correlation Coefficient (Figures 3 and 4).

3. Results

Between July 2013 and July 2017 a total of 40 opening wedge HTOs were performed on 37 patients fixed with the Activmotion plate. All operations were performed or directly supervised by the senior author. The mean patient age was 46 years (range 20 to 70 years old), of which 11 were women and 29 men. Mean follow-up period was 12 months (range two to 40 months).

Concurrent operations included: three patients with partial medial meniscectomy, one patient with a medial meniscal transplantation, three patients with chondroplasty, two patients with medial femoral condyle cartilage repair with bone marrow concentrate and synthetic scaffold and one with a combined distal femoral osteotomy. All patients were able to fully weight bear by six weeks.

No neurovascular complications were observed in the immediate post-operative period. There were no deep infections, loss of knee range of motion or deep venous thrombosis. There was one case of superficial wound infection which was treated successful with oral antibiotics for two weeks. In one case, there was delayed union at the osteotomy site which was confirmed with a Computed Tomography (CT) scan at 12 months postoperatively. The patient underwent debridement of the osteotomy gap and autologous iliac crest bone grafting with retention of the original plate at 14 months post-osteotomy. The patient subsequently went on to bony union by five months following revision surgery.

Plate removal is routinely performed by the senior author at 12 months post-operatively. In four patients plate irritation was the primary complaint following satisfactory osteotomy healing, and plate removal was subsequently performed with successful resolution of clinical symptoms (mean seven months, range six to eight months).

The mean MPTA correction was 6.73°. In the coronal plane, the achieved MPTA correction was maintained following the HTO. The median change from the immediate postop to the final x-ray (consolidation phase) was 0.0 (95% confidence interval (CI) for the median: −0.25, 0.4) (Table 1), Figure 2. In the sagittal plane the tibial slope mean change was a reduction by 0.83° (Standard deviation (SD) 3.06, 95% CI −1.9 to 2.2). In the consolidation phase, there was a mean increase of 0.32° (SD 1.02, 95% CI: −0.02 to 0.66) (Table 1), Figure 2.

Table 1
Medial proximal tibial angle (MPTA) and tibial slope (TS) measurements pre-operatively, postoperatively and at final follow-up.

Angle	Pre-op mean (SD)	Post-op mean (SD)	Final mean (SD)	Pre–postop change, 95% CI	Postop–final change, 95% CI
MPTA	85.2 (1.77)	91.9 (2.37)	92.1 (2.19)	6.73[a] (5.92, 7.54)[a]	−0.0[b], (−.25, 0.4)[b]
Tibial slope	5.16 (2.7)	4.23 (2.9)	4.66 (2.8)	−0.83[a], (−1.88, 0.22)[a]	0.32[a], (−0.02, 0.66)[a]

[a] Mean, 95% CI for mean.
[b] Median, 95% CI for median.

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3.1. Measurement variability

A subset of measurements was selected using systematic sampling to assess variability. Three observers performed the 12 measurements and the Intraclass Correlation Coefficient (ICC) was calculated. One of the authors (JP) repeated the measurements after a two-week interval. Interrater agreement was good for MPTA (ICC = 0.746) and tibial slope measurements (ICC = 0.734). Intrarater agreement was excellent for both MPTA and Slope (ICC 0.982 and 0.913 respectively).

4. Discussion

We identified no safety concerns during this pilot study using the new Activmotion plate for fixation in OWHTO. No structural graft or substitute was used and there were no cases of implant failure. In this limited sample, there was no loss of correction until osteotomy union.

The lateral closing wedge osteotomy as described by Coventry was a widely used surgical technique for medial unicompartmental osteoarthritis of the knee during the second half of the twentieth century. Currently the medial opening wedge technique is the preferred treatment in young active patients with medial compartment osteoarthritis with the aim of joint preservation [13, 21].

Short spacer plates have been associated with high complication rates. Spahn et al. reported 16.4% implant failure rate with the Puddu spacer plate (Arthrex, USA). They used hydroxyapatite granules to fill the osteotomy gap when the correction was under 12.5° and iliac crest autologous graft if the correction was over 12.5 [14]. Nelissen et al. reported their results with the Puddu I plate (Arthrex, USA) using a porous beta-tricalcium phosphate bone graft substitute in the osteotomy gap. They reported screw failure in 7.5%, plate failure in 6.1%, lateral cortical fracture in 18.4% and non-union in 22.4% of their cases. They reported no difference between the early weight bearing and delayed weight bearing groups. [22]. Using a new spacer plate (Position-HTO, Aesculap, Germany), Schroeter et al. reported an overall complication rate of 35%. This included two screw failures and malunion (six percent) and one loss of correction (three percent). They did not use bone substitutes or grafting within the osteotomy gap.

Plate fixators based on the locking compression plate (LCP) concept offer the advantage of a rigid fixation, obviate the need for rigid compression of the plate to the bone, whilst allowing early weight bearing and unrestricted knee range of motion by preserving posterior tibial slope [12, 16, 23]. By means of elasticity of the fixation device, bone growth inside the osteotomy gap is encouraged by mechanical stimulation via micromotion [24].

Staubli et al. reported two cases of non-union (two percent) in their report of 92 cases treated with the TomoFix plate [12]. Niemeyer et al. reported a single case of non-union (two percent) and one intraarticular plateau fracture also using the TomoFix plate [25]. The authors reported a small loss of correction in the femoro-tibial axis between the postoperative and subsequent x-rays, which was attributed to the slightly different positioning of the limb for the immediate postoperative radiograph [12]. We noted a similar trend of variation in the positioning of the limb for each set of radiographs that may affect the accuracy of the measurements. Another series of 40 OWHTOs stabilized with the TomoFix plate and tricalcium phosphate wedges reported no non-unions [26]. Its consistent results have made the TomoFix a very popular fixation device for OWHTO with a favourable complication profile [13]. It is however associated with a significant rate of soft tissue irritation which has been reported as high as 40.6% [16].

The fixation device which was used in this study (Activmotion, Newclip) (Figure 1), consists of a six-hole, T-shaped titanium (Ti–6Al–4V) plate with three locking holes in the proximal cross-bar section and three locking screws distally that engage at the distal segment of the osteotomized tibia. The middle proximal, locking slot allows for polyaxial, locking screw insertion up to 25°

Figure 1. The six hole LCP Activmotion plate, left and right sided plates depicted.

of range. The plate is anatomically contoured for left and right sides, and the headscrew–plate construct has a low profile in order to avoid hardware irritation. The plate is seated in the anterior-medial aspect of the proximal tibia and the direction of the screws should be anterior to posterior with an aim to distribute the screw trajectories in order to provide support for both the medial and lateral tibial plateaus. The goal is to protect the lateral compartment from increased loads during weight bearing and femoral rollback, following HTO.

This pilot study aimed to provide data that can inform a prospective, powered study to assess the outcomes using this new locking plate. The ideal fixation device for OWHTO would achieve a stable construct able to withstand compressive and torsional loads whilst protecting the lateral tibial cortex. Our postoperative program allowed immediate partial weight bearing and full ROM, with progression to full weight bearing at two weeks post-op. Comparing MPTA values in the early and late post-operative healing phases revealed no change in our series (median change 0, (95% CI for median −0.25, 0.4) (Table 1). Changes to the tibial slope following OWHTO are well documented in the literature [27]. The tendency for increased slope following OWHTO can be attributed to the strong mediodorsal ligaments which counteract osteotomy gap opening. We feel that a careful, soft tissue release should be carried out especially in cases of posteromedial soft tissue contractures, in order to avoid flexion malalignment in the sagittal plane [28]. In this study, the posterior tibial slope decreased immediately postoperatively by 0.83°, (95% CI −1.88, 0.22). During rehabilitation and osteotomy healing slope increased by a mean of 0.32° (95% CI −0.02, 0.66) (Table 1). The plate construct seems to offer adequate stability as demonstrated by no plate or screw failures and the lack of disruption of the lateral hinge, whilst maintaining appropriate elasticity to promote bone growth. There was one case of osteotomy delayed-union (>12 months) which had to be bone grafted with autologous bone graft whilst retaining the original implant. The case proceeded to uneventful bone union.

All osteotomy gaps where filled with demineralized bone matrix (DBM) in an effort to promote osteogenesis in the area [29, 30] and reduce bleeding. Whilst the plate provides satisfactory mechanical stability, we feel that a non-structural allograft may provide an additional osteoinductive, biologic stimulus for bone formation particularly in older patients and in cases where other comorbidities exist. However, there are studies that show satisfactory osteotomy healing with [31, 32] and without grafting [23]. Because of the donor-site problems encountered with autologous bone grafts, various substitute materials have also been used. However the efficacy of allograft and other bone substitutes for HTO has not been satisfactorily determined [33, 34].

There are a number of potential weaknesses in this study. We have not been able to comment on functional and patient reported outcome measures as our study is retrospective in nature with a heterogenous population with multiple indications for surgery. We aimed to report outcomes with regard to hardware complications and union using this implant. We have been able to demonstrate the progress to union in all patients with no loss to follow-up. Hardware removal was only required in

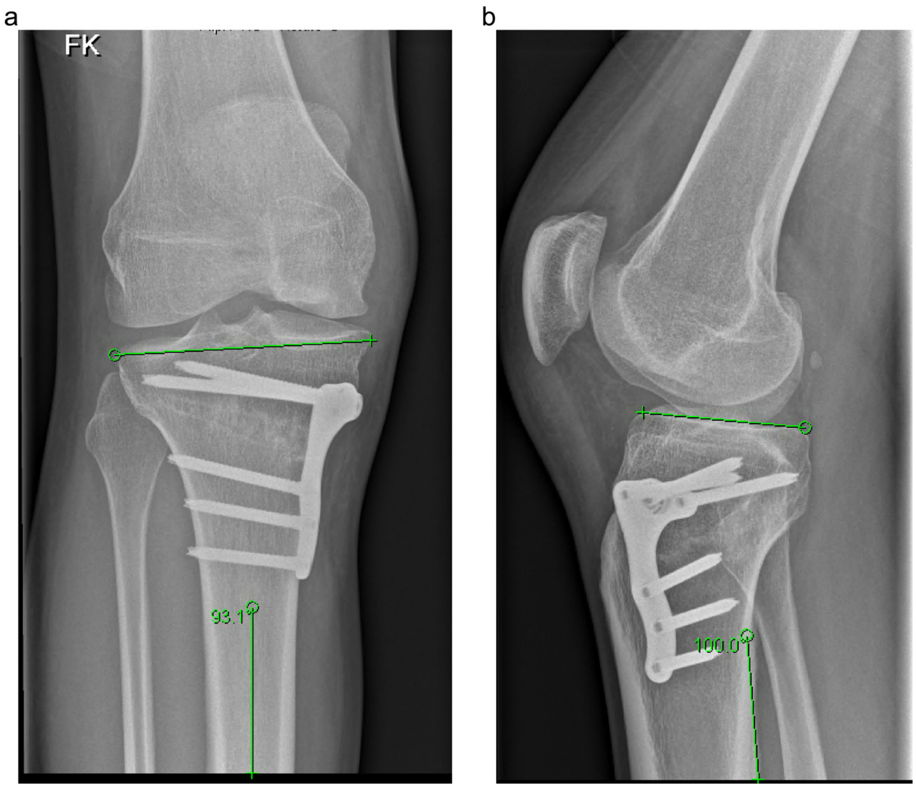

Figure 2. a. Medial proximal tibial angle measurement. Activmotion plate in situ at union. b. Measurement of the posterior tibial slope using the posterior tibial cortex technique. Activmotion plate in situ at union.

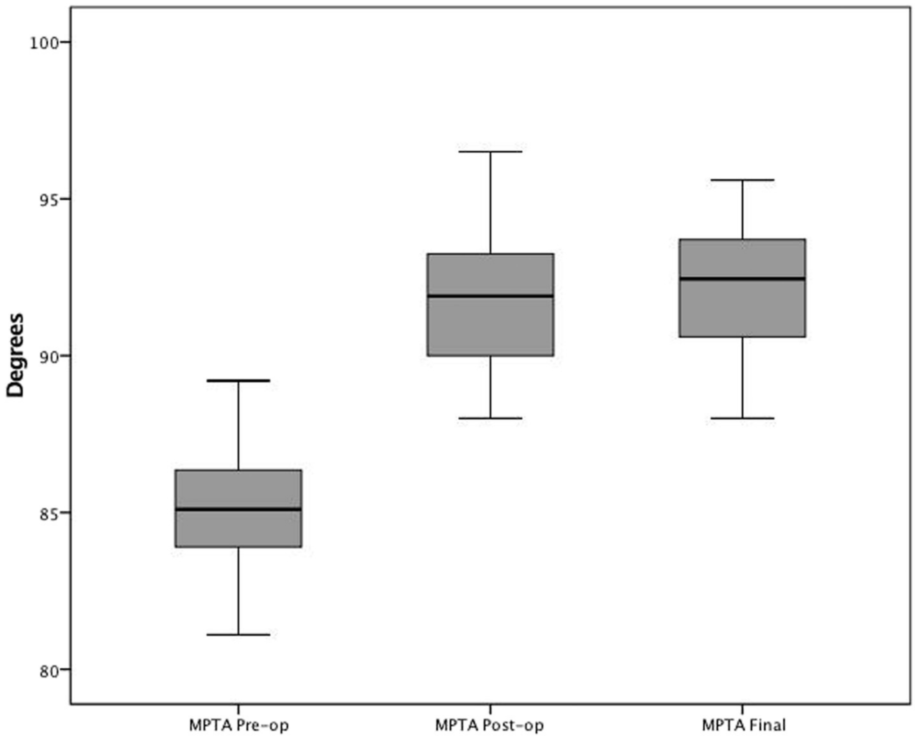

Figure 3. Boxplot of the medial proximal tibial angle (MPTA) in the pre-operative, post-operative and final follow-up stages.

four patients prior to the one year point. We used non-standardised short-film radiographs during post-operative follow-up. In the immediate postoperative period the x-rays are non-weight bearing and often the knee is kept in approximately 20° of flexion. This can lead to joint surfaces that meet the x-ray beam at inconsistent angles making identification of the subchondral bone

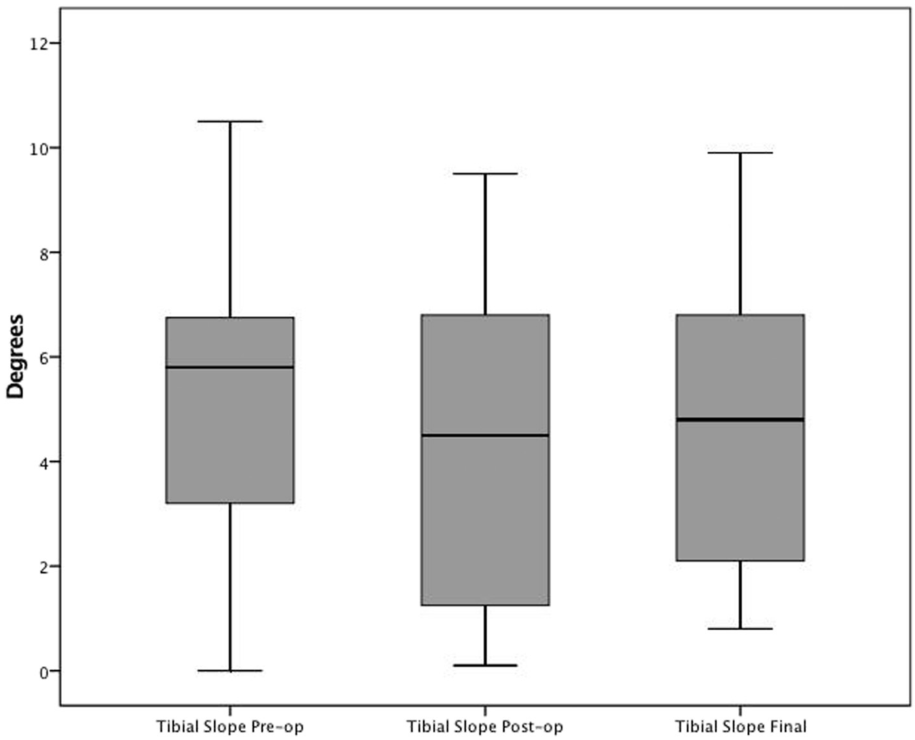

Figure 4. Boxplot of the tibial slope in the pre-operative, post-operative and final follow-up stages.

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challenging. This makes accurate measurement of the radiographic parameters more demanding however the intra- and inter-observer variability was good to excellent. The data presented in this study can facilitate sample size calculations for future comparisons between implants, ensuring adequate statistical power. In order to conclusively assess loss of correction to union, a study would need to be powered to identify a Minimal Clinically Important Difference (MCID) between the early postoperative phase and at union.

5. Conclusion

The fixation plate described in this study combined with biplanar open wedge osteotomy, raised no safety concerns with regard to implant related adverse events or loss of initial correction. Early rehabilitation with immediate partial weight bearing was possible and all cases proceeded to osteotomy union with the exception of one case that needed to undergo bone grafting with implant retention. Premature removal of the implant was necessary in four cases due to symptomatic hardware irritation.

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