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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. (0.2018 Published by Elsevier B.V.

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 cm³ of demineralized bone matrix (NHS Blood and Transplant Tissue Services). No drain was used in any of the cases.

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