ASSESSMENT OF THE CLINICAL TOLERANCE OF THE ACTIVMOTION® PLATE FOR MEDIAL OPENING WEDGE HIGH TIBIAL OSTEOTOMY

Preliminary study on a consecutive series of 54 osteotomies evaluated after a maximum review period of 42 months.

S.TOMES, G.DESCHAMPS
(Centre Orthopédique Médico Chirurgical in Dracy le Fort.
71640 Dracy le Fort)

Introduction

The high tibial valgus osteotomy is a surgical procedure with good track records over the mid- and long-term, in the treatment of medial femoro-tibial osteoarthritis in patients with varus deformity, and more particularly active patients.

This type of surgery requires the fitting of a plate for the fixation of the osteotomy so that the angular correction achieved does not decrease during bone regrowth.

The device should be as hardwearing as possible to avoid any loss of correction after realignment. It should also be as minimally invasive as possible since the antero-medial surface of the tibia where the osteotomy has been performed is rather thin and the implant could cause pain and discomfort if it is too big.

The ideal solution would be a hardwearing but minimally invasive device that could prevent the necessity for revision surgery to remove the plate, as is too often the case. This could result in significant money savings, while patients would avoid additional surgery.

Purpose

The purpose of our study is to assess the clinical tolerance and mechanical strength of the Newclip® Activmotion® osteotomy plate.
Implants and methods
Our study focuses on a consecutive series of 54 knee operations performed on 48 patients between March 2011 and December 2012 by one single surgeon (GD). All the cases have been reviewed by an independent observer (ST).
The average review period was 19.6 months (9-42 months / SD 7.1), and the average age of patients was 53.6 (30-67 years).

Unfortunately we lost contact with 5 patients (10%), meaning that these patients had no clinical follow-up after the maximum review period of 42 months. We consider that when studying the tolerance of implanted material, a mere phone interview is not good enough to determine if the device is actually the real cause of potential residual pains.

All patients had a comprehensive radiographic evaluation: knee X-ray including frontal, lateral and flexion views, radiograph of the patello-femoral joint with the knee in slight flexion (30°) and a long-leg standing X-ray done preoperatively in a weight-bearing position. At the latest follow-up examination, the evaluation was similar except for the flexion view, which we judged to be unnecessary.

We graded the femorotibial arthrosis stage using the Ahlback classification, and the patello-femoral arthrosis using the Iwano classification. The femorotibial mechanical angle and tibial mechanical axis were measured on the long-leg view.
Concerning arthrosis stages:
- 20 knees (37%) had reached stage 1
- 30 knees (55%) had reached stage 2
- 4 knees (8%) had reached stage 3.

Consequently, we selected patients in the early stages of the wearing process of the cartilage since we consider that the purpose of valgus-producing osteotomy is to hold back damage and obtain the best functional outcome possible with the least disruptive angular correction to the body schema. Waiting for more advanced wear is counter-productive as we think that if the joint wear is well advanced, the level of pain will be higher and the osteotomy will not sufficiently
prolong the time before a knee replacement becomes necessary. Additionally, to be pain-relieving, the operative correction should be larger with the possible result of preventing patients practicing sports while some women may consider it unsightly.

Clinical assessment was carried out using the scoring system of the International Knee Society (IKS). During a follow-up examination, painful areas or discomfort caused by the implanted device were identified, whether they were spontaneously felt by patients and/or occurred with palpation.

**Surgery and post-operative care**

All osteotomies were carried out using the Newclip® Activmotion® plate. Bone graft substitutes were made of lyophilized bone from a bone bank (Biobank®).

The rehabilitation protocol was standard, with no weight bearing for 6 weeks. All osteotomies had consolidated at the latest date of follow-up.

**Results**

Among the 54 operated knees, a feeling of discomfort on palpation of the device was noted for three knees (two patients). Spontaneous pain caused by the device was observed in one knee and the removal of the plate was necessary for two knees.

We noted no device breakage or loss of correction.

No case of non-union was observed.

The mechanical femorotibial axis was 175° (166-177°) before surgery. The correction angle was 181.3° (175-186 / SD 1,9) on average after surgery, with a target value of 182°.

**Discussion**

Out of the 54 operated knees, discomfort due to the device was noted in four cases (7%). The assessment was carried out exclusively on patients who underwent clinical follow-up, to the exclusion of those who were contacted by telephone. Indeed some patients may have residual pains due to arthritis that should not be mistaken for pains due to the implanted device (this is known as a false positive). The patients we lost contact with are those patients who could not physically attend the scheduled follow-up examination.
We did not want merely to assess the rate of implant removal because that does not in itself reflect the level of discomfort due to the implanted device. As a matter of fact some patients still feel localized pains after the device has been removed.

When examining painful knees more carefully, we noted that those patients in our study who had physical discomfort due to the device mainly reported it very early after the operation. Among those four patients, two underwent bilateral HTO and suffered strong pains in both knees. In those two cases, we can speak of a actual intolerance to the device rather than mechanical discomfort.

We also noted that the device had excellent mechanical strength since there has been no breakage of the device or loss of angular correction. Additionally no case of non-union was recorded, unlike another series of 175 opening wedge HTO previously reported that had been fixed with a rigid plate (Surfix®) (1). These observations support the concept of a locked plate with an internal “external fixation” principle (screws are locked onto the plate rather than the bone). This construct avoids fracture of the lateral hinge of the osteotomy, which may occur with rigid plates.

**Conclusion**
Our preliminary study allowed us to confirm good tolerance of the device, and the absence of mechanical problems thanks to the minimally invasive features of the construct. The Activmotion® plate has a locking system that eliminates risks of cold welding between the screw thread and the plate. Its principle (internal “external fixation”) enhances consolidation and seemed to meet the mechanical requirements we had set perfectly. It is now necessary to assess it on a larger number of patients over a longer period of time, to further our study.
(1) Tomes S, Deschamp G, Baulot E. Does the posterior positioning of the bone wedge in medial valgus opening wedge tibial osteotomy have an impact on patellar height and tibial slope? Survey on a consecutive series of 175 cases. “Communications particulières”, 88th SOFCOT yearly meeting, 2013.