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Partial meniscus substitution with a polyurethane scaffold does not improve outcome after an open-wedge high tibial osteotomy

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Abstract
Purpose The aim of the study was to determine whether medial meniscal substitution with a polyurethane scaffold (Actifit®) improves the outcome of medial meniscal-deficient varus knees undergoing open-wedge high tibial osteotomy.
Methods Sixty patients with symptomatic varus knees those who underwent open-wedge high tibial osteotomies were prospectively studied. In 30 patients, the medial meniscus was left with a defect larger than 25 mm (Group M). An Actifit® device was implanted (Group A) in the remaining 30 patients. Patients were functionally evaluated with WOMET, IKDC and VAS. Patient satisfaction was graded from 0 (not satisfied) to 4 (very satisfied).
Results Both groups were comparable preoperatively. They had similar follow-up periods (31.2 months; range 24–47.5; n.s.). WOMET improved a mean of 53.4 ± 8.4 and 42.4 ± 17.2 points in Groups M and A, respectively ($p = 0.002$). IKDC improved a mean of 56.7 ± 12 and 50.3 ± 15.6 points in Groups M and A, respectively (n.s.). VAS dropped 5.9 ± 2.1 and 4.7 ± 2.8 points in Groups M and A, respectively ($p = 0.006$). Patient satisfaction averaged 3.3 ± 0.8 and 3.3 ± 1 in Groups M and A, respectively (n.s.).
Conclusions Patients with symptomatic varus knees were treated with open-wedge high tibial osteotomies, and a meniscectomy was improved more at short-term follow-up in most of the evaluated functional scores than those patients with concomitant implantation of a medial Actifit® implant. However, there was no difference in terms of patient satisfaction with the procedure. Based on the short-term functional results of this study, no data were provided to support medial meniscal substitution with a polyurethane scaffold when an open-wedge high tibial osteotomy is being performed.
Level of evidence Prospective comparative study, Level II.

Keywords High tibial osteotomy · Actifit · Meniscal substitution · Polyurethane scaffold · Puddu plate · Varus knee

Introduction

In varus knees, tibiofemoral articular contact stresses are increased and there is evidence that this is related to the progression of osteoarthritis [3, 20]. Thus, limb realignment surgery is intended to disrupt that process. The aim of the procedure was to alter the mechanical axis so that the weight-bearing line is shifted into the lateral compartment of the knee, thereby reducing load through the affected medial compartment [3]. Previous studies have demonstrated good short- to midterm clinical outcomes for this group [8, 13, 19].

The loss of medial meniscal tissue is frequently observed in varus-aligned knees. In some cases, a previous

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meniscectomy may act as a trigger for the varus alignment [23], while in some others the degenerative varus knee may lead to large irreparable meniscal tears. It is well known that the menisci play an important mechanical role in the knee [2]. Numerous studies have documented the deleterious effects and degenerative changes that follow a decreasing amount of functionally working meniscal tissue [5, 11, 21]. The advent of tissue engineering has led to the use of scaffolding materials to fill defects so as to help regenerate host tissue. The Actifit® meniscal implant (Orteq Sports Medicine, London, UK) is a novel, biodegradable, acellular polyurethane scaffold designed to treat segmental meniscal defects in order to re-establish biomechanical function. In an experimental study, it has been shown to restore the contact pressures to those of the intact knee and improve peak contact pressures and the mean contact area relative to the partially meniscectomised knee [4].

The objective was to functionally compare patients those were operated on with an open-wedge high tibial osteotomy to a large meniscectomy or to a considerable deficit of viable meniscal tissue versus those with a concomitant medial meniscal substitution with the Actifit® polyurethane scaffold. It was hypothesised that medial meniscal substitution with a polyurethane scaffold might improve the outcome of open-wedge high tibial osteotomy in medial meniscal-deficient varus knees.

Materials and methods

A prospective study was performed on patients with a symptomatic varus knee who underwent an open-wedge high tibial osteotomy starting in September 2009. The study was conducted in two different institutions but with the same surgeons. The first 30 cases in which a medial meniscus defect larger than 25 mm was left in such a condition at the end of the arthroscopic procedure were considered as Group M. This group included patients with previous meniscectomies or with meniscal defects due to the degenerative process of the varus knee. The remaining 30 patients in whom an Actifit® (Orteq Sports Medicine) scaffold was concomitantly implanted in a defect larger than 25 mm were considered as Group A. The meniscal defects were located in the two posterior thirds of the menisci in all cases. The only meniscal remnants in those affected areas were the most peripheral third of the meniscal ring, which corresponded to zones 0 and 1 of Cooper's classification [7]. Assignment of the patients to each group was based on the institution where the procedure was performed. All the patients included in Group M were operated on in the same hospital while all the patients included in Group A were operated on in the other institution. The two main inclusion criteria were a knee with >5° of varus alignment and the above detailed loss of viable meniscal tissue due to a previous meniscectomy, to the degenerative process itself or to a meniscectomy performed during the index surgery. Meniscal loss had to be at least 25 mm in its length and 66 % of its width. Only patients below the age of 65 years and with a varus deviation at least 3° higher than on the contralateral side were included. Patients with lacking a meniscal rim or having a lateral compartment with either meniscal injuries or osteoarthritis, concomitant surgical procedures, patella baja, chondrocalcinosis, ICRS grade 4 chondral lesions, an allergy to metals or polyurethane as well as those with a BMI >4 were all excluded.

All the patients signed informed consent to participate in the study as well as for the evaluation and publication of the results. They were all informed that the device would eventually be implanted concomitantly with the tibial osteotomy.

Surgical technique

The same four surgeons, all experienced in limb realignment procedures and meniscal substitution, performed all the operations with the same technique and general conditions at the two institutions participating in the study. Any irreparable medial meniscal tear or any previous meniscal tissue loss was regularised until a healthy tissue bed was reached.

Actifit® implantation

Anterior and posterior healthy meniscal tissue as well as an intact meniscal peripheral rim on which to fix the Actifit® was a prerequisite. The location of the lesion was in the posterior and central zone of the medial meniscus in all cases. The polyurethane meniscus implant was trimmed with an extra of some 5–10 mm of the measured defect to compensate for the effect of the horizontal sutures, which partially shrinks the Actifit® device.

A release of the medial collateral ligament was systematically performed by piercing the ligament percutaneously with a spinal needle while applying valgus stress in order to have easier access to the medial femorotibial compartment. The Actifit® implant was then introduced and subsequently fixed to the host meniscus with the FasT-Fix all-inside device (Smith and Nephew, Andover, MA, USA). In those cases in which the zone chosen to place the suture was too anterior, it was fixed with an outside-in repair technique (Fig. 1).

Open-wedge high tibial osteotomy technique

The osteotomy was performed with a *free-hand* technique. The aim of the correction was around 3° of valgus relative

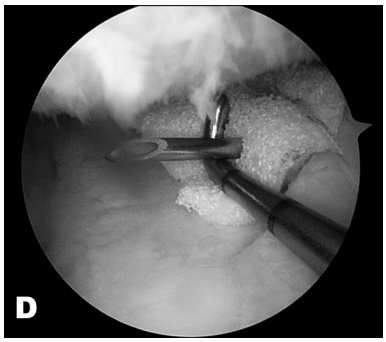

Fig. 1 Arthroscopic view of a medial Actifit® implantation in a right knee. In those cases in which the all-inside suture technique was not possible, the implant was fixed with an outside-in repair technique

to the mechanical axis unloading the medial compartment according to the preoperative planning [6]. Then, the appropriate steel Puddu plate (Arthrex, Naples, Florida, USA) along with the spacer tooth matching the obtained distraction was chosen and fixed to the tibia with two cancellous screws proximally and 2 cortical screws distally. Finally, the wedge gap was filled with an iliac crest bone allograft in all cases.

Post-operative protocol

Both group of patients followed the same post-operative protocol. Passive as well as active range of motion exercises were started immediately after surgery. Knee flexion was limited to 60° during the first 3 weeks and up to 90° between weeks 4 and 6. Then, unrestricted ROM was encouraged. Between the ROM exercises, a locked brace was worn until muscle control was reasonably restored. Weight-bearing was not allowed during the first 3 weeks. Between 3 and 6 weeks post-operatively, plantar contact and partial weight-bearing were allowed as tolerated on towards full weight-bearing not later than 8 weeks post-operatively. Patients returned to a normal workload by the fourth month after surgery. Running and unrestricted physical activity was allowed by the sixth month, depending on patient tolerance.

Functional and radiological evaluation

Patients underwent a physical examination in which they were evaluated, and the range of motion (side to side) was recorded. Functional evaluation included the Western Ontario Meniscal Evaluation Tool (WOMET) [16], the subjective IKDC [15] and the Kujala scores [18]. A 10-point visual analogue scale (VAS) for pain was also used. Patient satisfaction was evaluated with a subjective score and graded as very satisfied (4 point), satisfied (3 points), neutral (2 points), somewhat dissatisfied (1 point) and not satisfied at all (0 points). The scores were filled in at the consultation upon the instruction of a single sports medicine surgeon who was independent of the study.

Both preoperatively and post-operatively, weight-bearing long-standing AP radiographs and lateral radiographs were used to evaluate the mechanical axis and the lower limb length and the posterior tibial slope. The measurements were obtained placing a cursor, and distances and angles were computed automatically. The mechanical axis was measured by calculating the angle between a line transecting the centre of the femoral head and the centre of the tibial spine and a line transecting the centre of the ankle and the centre of the tibial spine. The posterior tibial slope was determined as the angle between the line perpendicular to the line passing tangentially to the posterior tibial cortex. The post-operative radiological evaluation was performed at the final follow-up. Measurements were taken with the ePACS viewer software (5.0; Real Time Image, San Bruno, CA). This software provides the values to one decimal place. Therefore, the measured and calculated data were reported to one decimal place as the results. The Ahlbäck classification [1] was used to determine the degree of knee osteoarthritis in the preoperative weight-bearing AP radiographs. An independent radiologist performed all the radiological measurements.

The clinical research ethics committee of ICATME-Institut Universitari Dexeus (Main investigation institution; ID 07/41/964) and of Hospital de la Santa Creu i Sant Pau, Universitat Autònoma de Barcelona (Secondary investigation institution; ID 07/41/964 002) approved the study.

Statistical analysis

In this comparative trial, an a priori sample size was determined based on the possible differences in the functional scores between both groups. It was calculated that, with an α set at 0.05 and with 80 % power and using a Student's t test for independent data, 30 patients on each study arm were necessary to detect a 0.8 SD difference between groups as statistically significant. A 15 % dropout rate was also considered. Statistical analyses were performed using SPSS 19 (SPSS, Chicago, IL). Categorical variables are expressed as percentages and frequencies. Mean and standard deviations as well as medians, minimums and maximums were calculated for each continuous variable. The results were statistically analysed and compared using a Student's t test for parametric data and contrasted using a Wilcoxon rank test. The level of significance was set at $p < 0.05$. The correlation between functional scores in both groups in terms of age, BMI and degree of varus malalignment was analysed with the Pearson's correlation coefficient (PCC). The results were contrasted with the

Table 1 Description of both groups

Variable	Group M	Group A	*p* value
Sex (male/female)	63/37 %	70/30 %	n.s.
Age (years)	51.2 ± 7.3	45.1 ± 8.3	n.s.
Knee (R/L)	53/47 %	47/53 %	n.s.
Body mass index	25.6 ± 5.9	26.2 ± 2.7	n.s.
Degree of varus malalignment	−9.2 ± 2.3	−8.5 ± 3.1	n.s.
Ahlbäck classification	II (1–3)	II (I–IV)	n.s.

Values are presented as percentages, mean ± SD or median (ranges). The degree of varus malalignment is expressed as negative values of the mechanical axis of the lower limb in contrast to positive values of the mechanical axis that correspond to valgus alignment

Spearman's rank correlation coefficient for nonparametric variables.

Results

Between 2009 and 2011, 60 patients who met the inclusion criteria were included in the study. There were 40 men and 20 women, with a median age of 51 years (range 27–62) and a mean body mass index of 25.9 ± 4 kg/m^2. In 30 patients, the lesion was located in the right knee and in the remaining 30 cases, in the left. The median follow-up time was 31.2 months (range 24–47) and was comparable in both groups ($p = 0.35$). Both groups were also preoperatively comparable in terms of age, body mass index, laterality, degree of varus malalignment, degree of knee osteoarthritis (Table 1) and functional scores (n.s.).

Surgical data

The surgical time was a mean 58 ± 7 min in Group M and 83 ± 11 min in Group A ($p = 0.002$). The mean length of the implant was 40.3 mm ± 6, and the mean length of the meniscal defect in Group M was 29 mm ± 7. The fixation of the Actifit® implant required mean 3.8 ± 1.1 FasT-fix devices and 0.7 ± 0.7 out-in sutures.

Complications occurred in only 3 patients. One patient from Group M developed a deep vein thrombosis in the post-operative period. Another 2 patients, one from each group, developed a local infection in the wound corresponding to the open-wedge high tibial osteotomy approach that required surgical debridement plus specific antibiotic therapy over a period of 6 weeks.

Functional and radiological results

All the patients restored their full knee extension and 140° of knee flexion. The mechanical axis was changed from a mean preoperative value from −9.2° ± 2.3 to 2.1° ± 0.7 ($p = 0.002$) in Group M and from −8.5° ± 3.1 to 1.8 ± 1.1 ($p = 0.003$) in Group A, respectively (negative values, varus alignment; positive values, valgus alignment). The differences between preoperative and post-operative values were comparable in both groups (n.s.). The posterior tibial slope showed a significant modification between preoperative and post-operative values ($p = 0.043$). A mean increase in the slope of 2.8° ± 1.3 and 2.1° ± 1.6 was observed in Groups M and A, respectively. This increase was comparable in both groups (n.s.). Lower limb lengthening was similar in the two groups (n.s.)

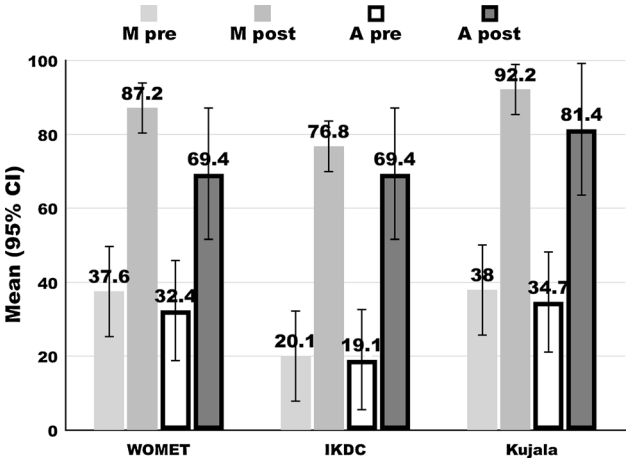

Fig. 2 Improvement in clinical outcomes from baseline to the last observation carried forward between Group M and Group A. WOMET, IKDC and Kujala scores (mean ± 95 % confidence interval; $N = 30$). *WOMET* Western Ontario Meniscal Evaluation Tool, *IKDC* International Knee Documentation Committee

An overall improvement was obtained in terms of the WOMET, IKDC, Kujala scores and VAS. However, from a comparable baseline of these functional scores, the improvement varied in each group. The WOMET score improved a mean of 53.4 ± 8.4 and 42.4 ± 17.2 points in Groups M and A, respectively ($p = 0.002$). The IKDC score improved a mean of 56.7 ± 12 and 50.3 ± 15.6 points in Groups M and A, respectively (n.s.). The Kujala score improved a mean of 50.4 ± 14.7 and 38.9 ± 21.6 points in Groups M and A, respectively ($p = 0.02$) (Fig. 2). It also showed a negative correlation between the age of the patients and the obtained improvement as younger patients showed greater improvements (PCC −0.41; $p = 0.001$). The VAS dropped 5.9 ± 2.1 and 4.7 ± 2.8 points in Groups M and A, respectively ($p = 0.006$). Patient satisfaction averaged 3.3 ± 0.8 and 3.3 ± 1 in Groups M and A, respectively (n.s.). The data for functional results are summarised in Table 2. A weak negative correlation was observed between the degree of preoperative varus alignment and the improvement in the WOMET (PCC −0.304; $p = 0.034$) and Kujala scores (PCC −0.32; $p = 0.017$). This means

Table 2 Comparison of functional outcomes

Variable	Group M	Group A	*p* value*
WOMET (pre–post)	33.8 ± 12.9 to 87.2 ± 10.7	27 ± 13.8 to 69.4 ± 22.6	0.002
IKDC (pre–post)	20.1 ± 4.4 to 76.8 ± 15	19.1 ± 5.9 to 19.1 ± 5.9	n.s.
Kujala (pre–post)	35.4 ± 11.2 to 67.8 ± 34.5	28.9 ± 14.1 to 67.8 ± 34.5	0.02
VAS (pre–post)	7.9 ± 1 to 2.1 ± 1.9	7.2 ± 1.1 to 2.5 ± 2.1	0.006
Satisfaction	3.3 ± 0.9	3.3 ± 1.1	n.s.

* The level of significance was set at $p < 0.05$

that higher corrections showed higher improvements in these two scores.

Discussion

The most important finding of the current study was that substituting the loss of medial meniscal tissue at the time that a varus knee is realigned with an open-wedge high tibial osteotomy did not provide any benefit when the patients were evaluated with different functional scores at a short-term follow-up. What is more, most of the evaluated scores showed a higher improvement when the loss of meniscal tissue was simply trimmed at the time of the tibial osteotomies undertaken. This was clearly in contrast to our hypothesis. However, these results did not lead to a difference in terms of patient satisfaction with the procedure.

With regard to the degree of mechanical axis correction, a correlation between higher corrected malalignments and higher improvements in the IKDC and Kujala scores was observed. However, both groups started from a comparable preoperative deformity and obtained a post-operative correction of around 2° of valgus. Similarly, although a non-intentional increase in the tibial slope was observed and had been previously correlated with lower clinical outcomes [14], this increment was minimum and it was comparable between groups.

The loss of medial meniscal tissue is frequently observed in varus-aligned knees. In some cases, a previous medial meniscectomy may act as a trigger for the degeneration of the medial compartment leading to a varus misaligned knee [23]. In some others, the degenerative varus knee may lead to large irreparable meniscal tears. The advent of tissue engineering has led to the use of scaffolding materials to fill defects so as to help regenerate host tissue. The Actifit® (Orteq Sports Medicine, London, UK) is one of the available meniscal scaffolds. In most series, similarly to the present study, no adverse reaction was attributed to with its use [9, 10, 17, 22].

As the alignment of the knee and the menisci both seem to play a crucial role in tibiofemoral load transmission and both of them are frequently encountered together, addressing both concomitant conditions seems a logical but rarely investigated scenario [14, 17]. Addressing this loss of meniscal tissue with this scaffold at the time of the high tibial osteotomy seems an attractive and logical scenario that could bring some benefit. Kon et al. [17] have reported lower functional scores at the 1-year evaluation and similar functional scores at the 2-year assessment when the Actifit® was implanted in patients undergoing combined surgery such as tibial osteotomies and others concomitant procedures. However, only 4 out of the 18 patients included in that study underwent concomitant tibial osteotomies. Surprisingly, when this was compared in this investigation, even lower functional results were observed when the open-wedge high tibial osteotomy was accompanied by a medial meniscus substitution. With the data available in this study, no evident cause for these poorer outcomes in the Actifit® group could be concluded. Both groups were statistically comparable in terms of demographic data, preoperative functional scores and degree of varus alignment. In addition, no complications related to the meniscal scaffold implantation were observed either. Perhaps, the fact that implantation of the scaffold was not blinded to the patient might have played a role in terms of higher expectations. Also, the additional morbidity of a considerable larger AM portal and the percutaneous release of the medial collateral ligament in the Group A might have also influenced the functional outcomes. This could have been avoided by creating at least a single-blinded situation. However, the patients were all informed post-operatively whether the device was implanted as the medical report had to include every surgical technique and device used in the surgery. Besides the limitation of this lack of patient randomisation, they were followed prospectively and longitudinally through all the clinical and radiological aspects.

Another important limitation is the short follow-up period. Considering that if one of the effects of high tibial valgus osteotomy is to act as a joint-preserving surgery that slows down the degenerative process of the medial compartment [6, 12, 13] and that this role might be synergistically enhanced by a meniscal substitution [4], evaluation at a much longer follow-up should be performed. Although the presence of the steel Puddu plate would interfere with an MRI evaluation, it could be assessed alternatively with a radiographic measurement of the joint space narrowing in the involved compartment (i.e. posteroanterior Rosenberg view at 45° of knee flexion). In addition, although

the patients who underwent open-wedge high tibial osteotomy with a meniscal substitution showed less improvement in some of the assessed functional scores in the studied period, assessing the outcome at a longer follow-up might well tell us whether the Actifit® implant represents an advantage in terms of joint preservation and a delay in the application of a total knee replacement in patients who had undergone open-wedge high tibial osteotomy.

The clinical relevance of the results observed in this investigation was that a large meniscal defect in a varus knee undergoing an open-wedge high tibial valgus osteotomy does not seem to need a meniscal substitution, at least at a short follow-up evaluation. In this scenario, mechanical correction of the varus malalignment is the only procedure that seems to be critical to improving the outcomes.

Conclusions

Patients with a symptomatic varus knee treated with an open-wedge high tibial osteotomy and meniscectomy improved more at a short-term follow-up in all but one of the evaluated functional scores than those patients with concomitant implantation of a medial Actifit® implant. However, there was no difference in terms of patient satisfaction with the procedure. Based on the short-term functional results of this study with limitations in patient selection, no data were provided to support medial meniscal substitution with a polyurethane scaffold when an open-wedge high tibial osteotomy is being performed.

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