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*ORIGINAL STUDY*

# Clinical study of the novel FlexitSystem implant for high tibial open wedge osteotomy

Nienke Van Egmond, Sebastiaan A.W. Van De Groes, Albert Van Kampen

*From the Gelderse Vallei Ede, The Netherlands*

**The FlexitSystem implant is a novel implant used in open wedge high tibial osteotomy.**
**A clinical safety study was performed. Retrospectively 50 patients were analyzed who were treated with an open wedge high tibial osteotomy and the new FlexitSystem implant, with a minimal follow-up of one year. Complication rate, radiographic outcomes and implant removal were investigated. One patient underwent a revision surgery because of loss of correction and non-union. The complication rate was 10.0%. No other radiographic complications (screw breakage, implant failure) were found. In 24 patients (48%) the FlexitSystem implant was removed at a mean follow-up of 12.6 months (range 2.6 till 24.0 months). The mean reason was irritation of the implant. The FlexitSystem implant is a clinical safe and stable implant for an open wedge high tibial osteotomy, with a low complication rate. The rate of implant irritation requiring removal remained high.**

**Keywords** : Open wedge high tibial osteotomy ; FlexitSystem implant.

## INTRODUCTION

Patients with knee osteoarthritis (OA) of the medial compartment often present with varus leg alignment which causes an overload of the medial compartment. Malalignment increases the risk for progression of knee OA and is associated with a decline in physical function and progression of pain *(2,29)*. In order to unload the medial compartment, a valgus high tibial osteotomy is the treatment of choice for the young and active patient *(5,14,16,24)*.

The most commonly used techniques include closed-wedge osteotomy (CWO) and open-wedge osteotomy (OWO) *(4,19,36)*. The disadvantages of a CWO are the need for a fibular osteotomy, the high rate of tibial neuropathies, bone stock loss, and a potentially more demanding subsequent total knee arthroplasty *(4,19,21)*. On the other hand, OWO has been associated with high non-union rates and loss of correction due to unstable fixation *(19,21)*. Therefore, fixation strength and maintenance of stability until osseous consolidation is obtained are a prerequisite of the implants used in OWO (*20*). Several implants have been designed for OWO *(1,17,20,34)*. The TomoFix implant (DePuy Synthes Trauma, West Chester, USA) is widely used because of a well-reported clinical *(4,9,15)* and biomechanical *(1,27,33)* track record. The TomoFix

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■ Nienke van Egmond, MD
■ Sebastiaan A.W. van de Groes, BSc, PhD, MD
■ Albert van Kampen Prof, MD, PhD
*Department of Orthopaedics, Radboud University Medical Center, Nijmegen, the Netherlands*
Correspondence : N Van Egmond, Department of Orthopaedics, Radboud University Medical Center, P.O. box 9101, 6500 HB Nijmegen,The Netherlands. Tel : +3124-3611111. Fax: +3124-3540230.
E-mail : nienkevanegmond@hotmail.com


***Fig. 1.*** — FlexitSystem implant
A : FlexitSystem implant, B : 3 plate sizes ; 4-, 6,- and 7-holes plate.

implant is a long and rigid titanium plate with locking screws, functioning as an internal fixator *(20)*. Due to its size, the disadvantages of this implant have been reported to be local irritation and wound healing issues *(24,25,35,39)*. Therefore, implant removal after surgery is often needed *(39)*. The FlexitSystem implant (Neosteo, Nantes, France (Fig. 1)) is a novel implant to be used in case of an OWO. The FlexitSystem implant is shorter and thinner compared to the TomoFix implant. To compensate for the smaller dimensions, a different grade titanium alloy (stiffer and stronger) is used for the FlexitSystem. The potential benefit of the implant is that, due to its smaller dimensions, patients may experience less discomfort from the plate, which may eliminate the necessity of implant removal after surgery. A potential concern is that the smaller dimensions of the implant may affect the primary stability of the reconstruction.

Recently an experimental test was performed to evaluate the initial stability of the FlexitSystem implant. The tests were performed in cadaveric tibiae, with the TomoFix implant serving as a base for comparison *(37)*. The current results in this experimental study showed that there were no differences between the two implants and from a biomechanical point of view, the FlexitSystem implant is a suitable alternative to the TomoFix implant for OWO. In this study the clinical outcomes of this new implant, the FlexitSystem implant, were analyzed.

Our primary objective was to investigate the complication rate, union outcomes and incidence of implant removal with a minimal one year follow-up in 50 patients who were treated with an OWO and the new FlexitSystem implant. Our hypothesis was that this is a safe and stable implant to be used in patients who underwent an OWO.

## MATERIALS AND METHODS

This retrospective follow-up study was performed between June 2016 and October 2016. Fifty patients with medial knee OA and a varus leg alignment, who were treated between March 2013 and October 2015 with an OWO and FlexitSystem implant in Hospital Gelderse Vallei Ede, the Netherlands were included in this study. Informed consent was obtained. There were no exclusion criteria. Approval of the Medical Ethics Committee (Hospital Gelderse Vallei Ede, the Netherlands, ID-number BC/1603-157) was obtained.

All operations were performed in a standardized manner. There are three different sizes of the standard FlexitSystem implant (4,- 6,- and 7-holes) (Fig. 1B). In most of the patients a 6-holes plate (80.0%) was used. A 4-holes plate was used in 4 patients (8.0%) and a 7-holes plate in 5 patients (10.0%). A 10-holes plate (5 screws proximal and 5 screws distal) was used in one patient (2.0%), because of stock problems (standard plate was not available). In 48 (96.0%) patients a wedge (Tricalcium phosphate or hydroxy apatite) was used and in 2 (4.0%) patients no wedge was used. A wedge was standard used in this hospital and independent of the amount of correction. The mean degrees of correction was 7.9 (range 5.0-12.0) All patients received antibiotic prophylaxis preoperatively (Cefazoline 2 gram intravenous), except for three patients. Postoperative antithrombotic therapy for 6 weeks (Nadropin 0.3 milliliters) was given. All patients received physiotherapy. Mobilization started on the first postoperative day with partial weight bearing (touch toe weight bearing) with crutches and full range of motion exercises for six weeks..

Baseline patient parameters (age, gender, height, length, BMI, side of the operation, smoking, general prehistory, previous operations at the same leg) were obtained. Clinical outcomes were evaluated by analyzing medical files. The complications registered were wound complications, infection, non-union, loss of obtained correction and other complications. Hardware removal and reason

Table I. — Baseline Parameters

| Parameters | Total group (50 patients) |
|---|---|
| Gender (m/v)[1] | 28/22 (56.0/44.0) |
| Age (yr)[2] | 57.4 (37.2-73.7) |
| Height (cm)[2] | 175 (155.0-196.0) |
| Weight (kg)[2] | 91.3 (58.0-159.0) |
| BMI (kg/m²)[2] | 29.7 (21.8-41.8) |
| Side (L/R)[1,a] | 26/24 (52.0/48.0) |
| Prehistory (N):<br>- Hypertension<br>- Diabetes Mellitus<br>- Cardial history<br>- DVT<br>- Astma/COPD<br>- THA<br>- HTO (controlateral)<br>- Spine problems<br>- Proximal Tibial Fracture (ipsilateral)<br>- Other | <br>22<br>5<br>6<br>1<br>2<br>2<br>2<br>11<br>2<br><br>2 |
| Previos surgery ipsilateral leg (N):<br>- Arthroscopy ± partial lateral or medial meniscectomy<br>- Arthroscopy + ACL repair<br>- Open (partial) meniscectomy<br>- Other | <br>30<br><br>1<br>1<br>1 |
| Smoking (N) | 8 |

*Yr* years, *cm* centimeter, *kg* kilograms, *L/R* Left/Right, *N* Number, *DVT* Deep venous thrombosis, *COPD* Chronic Obstructive Pulmonary Disease, *THA* Total Hip Arthroplasty, *HTO* High Tibial Osteotomy, *ACL* Anterior Cruciate Ligament. [1] Number (%). [2] Mean (range). [a] 5 bilateral.

for removal were also analyzed. Radiographic evaluation parameters were implant failure and loss of correction.

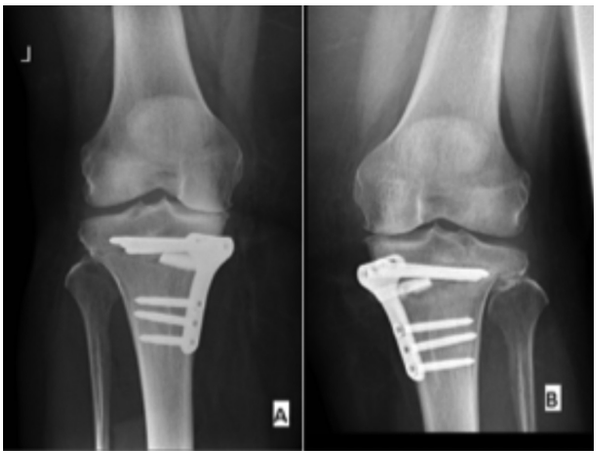


***Fig. 2.*** — Revision case
A : Direct postoperative Xray. Notice the position of the screws and the lateral cortex fracture, B : 2.6 months postoperative Xray. Loss of correction.

Table III. — Osteosynthesis removal

| Reason of osteosynthesis removal | Number of patients (%) |
|---|---|
| Irritation | 19 (38.0) |
| Deep late posttraumatic infection | 1 (2.0) |
| Revision | 1 (2.0) |
| No reason known | 3 (6.0) |

## RESULTS

Baseline patient parameters are shown in Table I.

Mean follow-up was 28.4 months (range 12.3 till 39.8 months). Mean correction angle was 8.0° (range 5° till 12°). There was one revision (2.0%), due to loss of correction and non-union. This was treated with a bone graft and a new FlexitSystem implant after 2.6 months (Fig. 2).

Table II — Complications and treatment

| Complications | Treatment | Outcomes (Number of patients (%)) |
|---|---|---|
| - Infection<br>- uperficial | Removal FlexitSystem implant, debridement and oral antibiotics<br>Oral antibiotics | 1 (2.0)<br>2 (4.0) |
| Lateral Cortex Fracture | Expectative<br>Revision[1] | 1 (2.0)<br>1 (2.0) |
| Loss of correction | Revision[1] | 1 (2.0) |
| Woundhealing disorder | Expectative | 1 (2.0) |
| Haematoma | Operative debridement | 1 (2.0) |

[1] Same patient

No other radiographic complications (screw breakage, implant failure) were found. All complications are shown in Table II.

In 24 patients (48.0%) the FlexitSystem implant was removed at a mean follow-up of 12.6 months (range 2.6 till 24.0 months) (Table III). No patient needed conversion to a total knee arthroplasty.

## DISCUSSION

The most important finding of our study is that the novel FlexitSystem implant is a safe implant to be used in an open wedge osteotomy.

In our study, only one revision (2.0%) was needed due to loss of correction and non-union. This is comparable to the TomoFix Implant (3.6 to 5.4%) *(22,39)*. Non-union rates requiring revision for other implants are between 0.0 to 4.3% *(3,10,13)*. In a previous experimental study the initial stability of the FlexitSystem implant was investigated, compared to the TomoFix implant *(37)*. In that study it was concluded, that from a biomechanical point of view, the FlexitSystem implant is a suitable alternative to the TomoFix implant for OWO *(37)*. The clinical results found in the current study confirmed this conclusion. Also, no screw breakage and plate breakage were found. This is comparable to the TomoFix implant (0.0-0.5%) *(22,39)* and superior to other implants (2.2 to 22.9%) *(6,18,32)*. If this revision case was looked in further detail, a peroperative unnoticed lateral cortex fracture was noticed. Also the location of the screws was partial in the osteotomy gap. This suboptimal surgical technique contributed to the failure mechanism.

Two (4.0%) lateral cortex fractures were found postoperative. In the literature lateral cortex fractures were reported with frequencies between 0.3 to 34.0% *(3,7,12,26,31,34,38)*. In lateral cortex fractures, sufficient fixation is needed to maintain alignment and union of the osteotomy. The TomoFix Implant creates immediate stability in case of a lateral cortex fracture *(7,33)*. Although one revision was needed in a patient with a lateral cortex fracture, the position of the screws was suboptimal, which is more likely to contribute to the failure mechanism. In the other patient with a lateral cortex fracture no non-union was found, nor was a revision required.

A postoperative complication rate of only 10.0% (excluding revision and osteosynthesis removal) was noted. The complications registered, were two superficial infections (4.0%), one woundhealing disorder (2.0%) and one large haematoma (2.0%). The infection rate is comparable to the TomoFix implant (0.5 to 10.8%) *(22,34,39)* and other implants (0.0-10%) *(3,6,8,10,11,13,18,31,32)*. The superficial infections were successfully treated with oral antibiotics, and did not require in-hospital treatment.

No deep venous thrombosis, deep postoperative infection or other more severe complications (e.g. compartment syndrome, vascular injury) were found in our study. Severe complications after an OWO are rare, being less than 2% in the literature *(39)*

In our study, the FlexitSystem implant was removed in 48% of the patients, mostly due to irritation (79%). In the literature percentages between 0 to 23% implant irritation requiring plate removal are reported *(3,8,10,23,28,30,34,38,39)*. These outcomes are superior compared to ours. Implant removal due to irritation in 38% of the patients was found. No clear explanation for the high percentage could be found. This study was a single centre study and in this hospital the indication for implant removal was knocking pain over the plate. It could be that the indication for implant removal was more surgeon driven then patient driven. Another option could be that the FlexitSystem implant caused more irritation compared to other implants. This is however not obvious, as the FlexitSystem implant is thinner (2.8 mm plate thickness) compared to the TomoFix implant.

Some limitations of this study should be discussed. First, this study is a single centre retrospective study. A randomized clinical trial comparing the TomoFix implant with the FlexitSystem implant would be ideal. Second, 6 different surgeons performed the operations. This could contribute to heterogeneity of the results, although the different surgeons performed the OWO in a standardized manner. Third, the patient related outcomes measurements (PROMS) were not investigated. This study focused on the clinical outcomes of the implant and not on the outcomes of a OWO, which is already proven in the literature *(4,14,16,19,21,36)*.

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