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# Six weeks of continuous joint distraction appears sufficient for clinical benefit and cartilaginous tissue repair in the treatment of knee osteoarthritis

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ABSTRACT

*Background:* Knee joint distraction (KJD) is a surgical joint-preserving treatment in which the knee joint is temporarily distracted by an external frame. It is associated with joint tissue repair and clinical improvement. Initially, patients were submitted to an eight-week distraction period, and currently patients are submitted to a six-week distraction period. This study evaluates whether a shorter distraction period influences the outcome.
*Methods:* Both groups consisted of 20 patients. Clinical outcome was assessed by WOMAC questionnaires and VAS-pain. Cartilaginous tissue repair was assessed by radiographic joint space width (JSW) and MRI-observed cartilage thickness.
*Results:* Baseline data between both groups were comparable. Both groups showed an increase in total WOMAC score; $24 \pm 4$ in the six-week group and $32 \pm 5$ in the eight-week group (both $p < 0.001$). Mean JSW increased $0.9 \pm 0.3$ mm in the six-week group and $1.1 \pm 0.3$ mm in the eight-week group ($p = 0.729$ between groups). The increase in mean cartilage thickness on MRI was $0.6 \pm 0.2$ mm in the eight-week group and $0.4 \pm 0.1$ mm in the six-week group ($p = 0.277$).
*Conclusions:* A shorter distraction period does not influence short-term clinical and structural outcomes statistically significantly, although effect sizes tend to be smaller in six week KJD as compared to eight week KJD.


## 1. Introduction

In generalized knee osteoarthritis (OA) with persistent severe pain, a total knee arthroplasty (TKA) is often indicated [1]. Nevertheless, joint replacement has its drawbacks. Especially in young and active patients results of TKA are less satisfactory with higher revision rates due to mechanical, aseptic loosening [2,3]. Therefore, in these patients alternative joint-preserving treatment strategies are required. Among these alternatives, knee joint distraction (KJD) is increasingly investigated. In KJD, an external fixation frame of two bilaterally placed monotubes is put in place and gradually separates the femur and tibia for several weeks. Goals of the distraction are reducing mechanical stress on the cartilage, preventing further wear and tear, and stimulating chondrocytes to initiate cartilaginous tissue repair [4]. Moreover, springs in the distraction frame increase synovial fluid pressure changes in the knee during walking. This might improve nutrition of the cartilage and further stimulate chondrocytes [5].

KJD was associated with both joint tissue repair and clinical benefit (pain and function) in several clinical studies in knee OA patients [6–11]. Benefits were maximum between the first and second year post-operatively [6,7] and resulted in the planned TKA being postponed for at least five years in the vast majority of patients [8]. In these studies, distraction was performed for eight weeks and combined with returning visits to the hospital every two weeks. During these visits, distraction tubes were temporarily removed from the frame and the knee was passively exercised on a continuous passive motion (CPM) device in order to prevent contractures. Since patients experienced these returning visits as a significant burden, KJD is nowadays performed for six weeks and without frame removal and CPM. However, it remains

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to be studied whether this shorter distraction period influences outcome. Therefore, in the present study we compared one-year structural and functional outcomes between eight-week intermittent distraction and six-week continuous distraction.

## 2. Materials and methods

### 2.1. Patients

The eight-week intermittent (eight-week) group consisted of twenty end-stage knee OA patients with an indication for a TKA. These subjects are part of an observational cohort study and were included between 2006 and 2008 at the University Medical Center Utrecht. Inclusion criteria were: age <60 years, Visual Analogue Scale (VAS) ≥60 mm and primarily tibiofemoral OA at radiographs. Exclusion criteria were: contralateral knee OA requiring treatment, primarily patellofemoral OA, severe knee malalignment (>10° varus or valgus), a history of inflammatory or septic arthritis, and inability to cope with an external fixator.

The six-week continuous (six-week) group consisted of twenty patients that were part of two ongoing randomized controlled trials and were included at the Maartenskliniek Woerden [12]. In these trials, KJD is compared with TKA and high tibial osteotomy (HTO). In the KJD–TKA trial patients in clinical practice considered for TKA were included and in the KJD–HTO trial patients considered in general clinical practice for HTO (with an axis deviation < 10° varus) were included. Inclusion and exclusion criteria were comparable to the eight-week intermittent group: age <65 years, intact knee ligaments, normal range-of-motion (ROM; minimum of 120° flexion) and a Body Mass Index (BMI) <35. The medical ethical review committee of the University Medical Center Utrecht approved all studies (Nos. 04/086, 10/359/E, and 11/072) and all patients gave their written informed consent.

### 2.2. Distraction method

KJD was performed as previously described by Intema et al. [6]. In short, a commercially available proof-of-concept distraction device was used, consisting of two bilaterally placed dynamic monotubes (Triax/Stryker), fixed on two bone pins at each end, bridging the knee joint at the lateral and medial side. Distraction was gradually increased to five millimeters and confirmed radiographically (see Figure 1). Instructions about pin-site care and physical therapy (on demand) were given. Patients were instructed to fully load the distracted joint, supported with crutches.

For subjects in the eight-week group, return visits to the hospital were planned every two weeks. During these visits, the monotubes were temporarily removed from the bone pins and they received CPM exercise for three to four hours. The maximum degree of knee flexion averaged 25° (15 to 80°) and full extension was reached. The monotubes were re-installed after exercising and distraction was confirmed radiographically. At the end of the eight-week period (average duration 59 days, range 54 to 64 days), frame and pins were removed at day care. Patients returned home without any functional restrictions, and with physiotherapy and pain medication on demand (the latter two were not registered).

In the six-week group, frame and pins were surgically removed after six weeks (average duration 42 days, range 39 to 47 days). As the ROM of the knee joints was limited due to adhesions in the surrounding soft tissues, the knee joints were flexed gradually by hand under anesthesia. At the first post-operative day, partial weight-bearing (maximum 20 kg) was allowed. After discharge, patients gradually regained normal full loading in approximately six weeks (expansion of 15 kg every week). Physiotherapy and pain medication were used on demand (not registered). For details see Wiegant et al. [12]. The skin surrounding bone pins was treated to minimize pin tract infection [13]. Prophylactic low-molecular-weight heparin was prescribed for nine weeks (six-week distraction period and three weeks after). At three to four weeks, patients visited the outpatient department for radiographic evaluation of the distraction and pin tract.

### 2.3. Clinical outcome

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) was used to score clinical improvement, normalized to a 100-point scale; 100 being the best condition. A visual analogue scale for pain (VAS-pain; 0 to 100 mm, 0 meaning no pain) was the secondary clinical outcome parameter. At baseline, three, six, and twelve months the WOMAC questionnaire, and the VAS-pain were assessed.

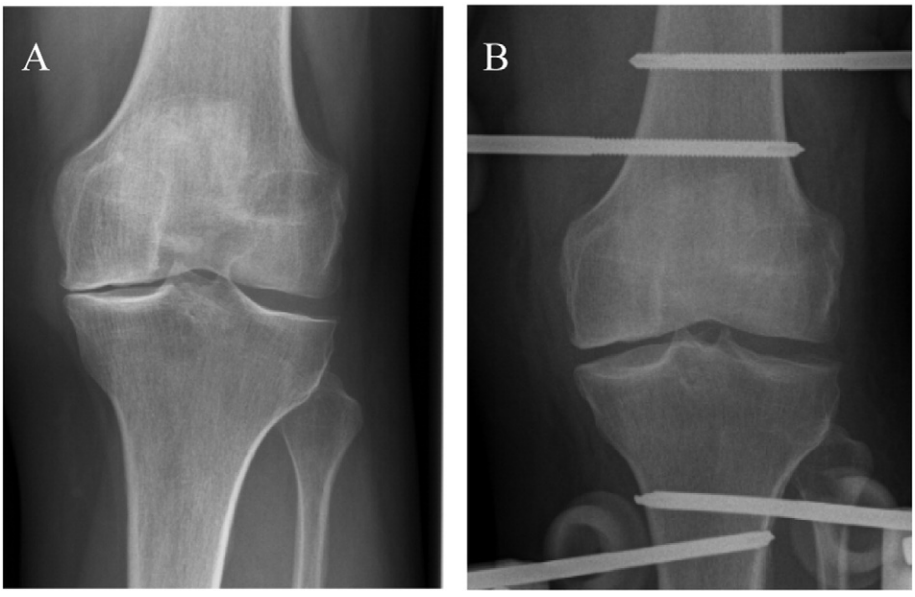


**Figure 1.** (A) Example of a pre-operative radiograph of a patient treated with knee joint distraction. (B) Radiograph of the same patient during distraction treatment with five millimeters of distraction.