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Research Article

Total Knee Prosthesis after Knee Joint Distraction Treatment

Abstract

Background and purpose: During knee joint distraction (KJD) treatment, using an external fixation-frame, pin-tract infections frequently occur. These local skin infections, although treated successfully with oral antibiotics, might lead to latent infections. This raises concern about subsequent placement of a total knee prosthesis (TKP). This study evaluates the first five cases in which patients had to be treated with TKO after KJD failure.

Patients and methods: An overall survival analysis of the first 26 patients treated with KJD revealed five failures, because of declining efficacy over time. These patients were treated with TKP. Complications of these TKPs are described and all cases were compared with age and gender matched primary-TKP-controls. WOMAC and VAS pain scores were assessed before and after TKP treatment.

Results: The mean survival time of the five KJD before TKP was 61 ± 15 months (range 45-84 months). No peri-operative complications were registered and none of the patients suffered from an infection post-TKP. There were no differences between baseline characteristics of patients with primary TKP compared to those with TKP after KJD except for a higher VAS pain score ($p<0.02$) for primary TKP. Mean follow-up after TKP was 21 ± 12 months (range 9-39 months). Efficacy after TKP was similar for patients with primary TKP compared to those with TKP after KJD.

Conclusion: Based on the first five cases it appears safe to treat patients several years after KJD with a TKP. There is no indication these patients have a higher infection risk and post-operative outcome is comparable with primary TKP.

Introduction

Osteoarthritis (OA) is a degenerative joint disorder affecting all joint tissues [1]. Patients suffer from pain and impaired joint function. In most cases mechanically and metabolically induced 'wear-and-tear' of the articular cartilage results in loss of joint space width as measured on radiographs. Finally in end-stage disease placement of a total joint prosthesis is often the last remaining treatment option. In case of knee OA total replacement is not recommended in patients under 65 years of age, because of the limited life span of the prosthesis of approximately 15-20 years [2]. Nonetheless over 40% of the knee replacements are performed under the age of 65 years [3]. Furthermore, it is shown that patients treated <65 years of age need significantly earlier revision of the total knee prosthesis (TKP) expectedly because of their more active life-style [4], although literature is not consistent on this [5].

Because of the increased risk for revision surgery it is recommended to treat patients <65 years of age with (partial) joint preserving treatments like high tibial osteotomy (HTO) [6], unicompartmental knee prosthesis (UKP) [7], or knee joint distraction (KJD) [8,9]. These treatments decrease pain and improve function, and can postpone a first TKP when eventually necessary. For HTO the overall survival rate is about 90% after five years, and 70% after ten years before complaints return and subsequent treatment is necessary [10,11]. For UKP, being a more definitive treatment for unicompartmental OA [12,13], survival rate is 93% after four years and 87% after eight years, although data are still scarce [14].

In general outcome after a TKP is influenced by previous joint preservation knee surgery [15], however, results of a TKP after HTO in general appear to be good. In a systematic review published by van Raaij et al. [16], it was reported that there are no statistically significant differences between patient related outcome scores (PROMs) of primary placed TKP's and TKP's secondary placed after HTO treatment. Furthermore no differences with regard to aseptic loosening, deep infections or additional treatment necessities were found.

In case of conversion from the partial joint preserving option UKP into TKP (mostly in case of aseptic loosening) there is eventually a higher revision risk of the TKP in comparison with a primary TKP within the first five years [17]. The re-revision rate after conversion from UKP to TKP were reported to range from 4-14% [18]. Reason for re-revision were unfortunately not further specified. Six-month postoperative scores for patient's function after conversion from UKP to TKP were statistically significant poorer in comparison with conversion from HTO to TKP [19].

Besides HTO and UKP, other surgery prior to TKP has been described to increase the risk for infection and as a consequence the risk for revision surgery. These surgeries includes open and closed reduction and stabilization of a tibiaplateau fracture [20], previous operation around the knee joint, previous non-arthroscopic surgery, and previous open reduction and internal fixation (ORIF) around the knee joint [21].

KJD is a relatively new treatment in which the tibio-femoral joint is distracted about five millimeters with the use of an external fixation frame during six to eight weeks. KJD results in prolonged clinical benefit and cartilage tissue repair on radiographs and magnetic resonance images [9]. One major complication, as seen for external fixators in general [22], is pin-tract infections. In general, all clinical signs of infections end shortly after the external fixation frame is removed. Irrespectively, thus far, more than three quarter of the patients suffered from one or more pin-tract infections due to joint distraction in treatment of osteoarthritis [23]. In that respect, it is comprehensible that concerns rise about infection risks and overall outcome of TKP after KJD. However, to the best of our knowledge, no literature is available on the influence on surgery in the same area, after treatment with an external fixator, in terms of e.g. latent infection risks. As such, it is important to know if KJD affects subsequent TKP treatment.

In this study we evaluated peri-operative complications (infections) and clinical outcome of patients that underwent TKP after eventually failure of KJD, in comparison to age- and gender-matched patients receiving a primary TKP.

Methods

Patient selection

In this level III case-control study, twenty-six patients (average age 48,3±6,2 years, range 32-57 years) with end-stage knee OA and initially indicated for a TKP, because of persistent pain and loss of function and with clear radiographic joint damage, not adequately responding to conventional treatments, were treated with KJD between 2002 and 2008 (Department of Orthopedics, University Medical Center Utrecht (UMCU); six patients from a feasibility study and 20 patients from a prospective follow-up study [8,9]). From these 26 patients three patients refused to co-operate in further follow-up; one directly after KJD treatment, the other two patients after two years of follow-up. At inclusion all patients were under 60 years of age, had a VAS pain score of >60mm, and radiographic signs of primarily tibio-femoral OA joint damage (for inclusion details see 8).

During follow-up, five out of these 26 patients had to be treated with a TKP because of insufficient patient's satisfaction several years after the KJD treatment. For each of these five TKP after KJD cases, two age (at time of TKP) and gender matched-controls with primary TKP were selected from an ongoing randomized controlled clinical trial [24]. In this trial patients were randomized between TKP and KJD. This means that these primary TKP patients were on average comparable to those whom were treated with KJD as they fitted the inclusion criteria for randomization. Inclusion criteria have not been changed significantly over all KJD studies over the last years [8,24], and in principle comprises end stage knee osteoarthritis considered for TKP. Because the TKP after KJD group considered only five patients we matched them in a 1:2 ratio with primary TKP patients, for gender and as good as possible for age and follow-up time after TKP, blinded for clinical outcome at follow-up.

Both abovementioned studies were approved by the Medical Ethical Committee of the UMCU; (No. 01/046; No.04/086; and No.10/359), and all patients gave written informed consent. Patient characteristics of all cases (n=5) and matched-controls (n=10) are depicted in Table 1.

Joint distraction method

The distraction method was applied as previously described [8,9]. In short, an external fixation frame consisting of two monotubes with internal coil springs was placed, bridging the knee joint. Each monotube was fixed to two bone pins on each end and. In stages, the knee was distracted for five mm (confirmed by radiographs). After instructions about pin site care, daily exercise, and physical therapy, the patients were discharged from the hospital. Patients were allowed and encouraged to load the distracted joint with full weight-bearing, supported with crutches if needed. In case of superficial (skin) pin tract infections, treatment with oral antibiotics for 5-7 days was provided (Flucloxacillin). Every 2 weeks the patients returned to the hospital and the monotubes were temporarily removed. The knee was bent, for 3-4hrs, in a continuous passive motion device, with pain at the pin sites determining the maximum degree of flexion; on average, 25° (15°-80°) flexion and full extension was reached. The monotubes were replaced and sufficient distraction was confirmed by a radiograph and adjusted if needed. After 2-3 months (average duration 60±5 days, range 54-77 days), the tubes and pins were surgically removed and patients went home without imposed functional restrictions. After both surgeries, patients were treated with acetaminophen and NSAID when needed, according to a standard analgesia protocol. Upon discharge, pain medication and additional treatments along with daily exercise and physical therapy were regulated by the patient and its physician and not documented.

Total knee prosthesis

For the five cases, TKPs were placed in other hospitals, in regular care. No specific information about prosthesis type or rehabilitation

Table 1: Patient characteristics of cases (1-5) and controls (1a-5b). Cases are matched for age and gender.

Cases	Gender	Year of birth	Age at TKA	Controls	Gender	Year of birth	Age at TKA
1	M	nov 1952	59	**1a**	M	nov 1951	60
				1b	M	jul 1949	62
2	M	oct 1956	53	**2a**	M	nov 1951	60
				2b	M	oct 1954	57
3	M	nov 1955	56	**3a**	M	jan 1952	60
				3b	M	oct 1954	57
4	F	jul 1957	56	**4a**	F	jun 1957	55
				4b	F	jul 1957	54
5	F	mar 1962	51	**5a**	F	sept 1961	51
				5b	F	feb 1963	48

protocols was available. These five patients were interviewed in retrospect. During these interviews it appeared that rehabilitation was quite similar to the rehabilitation of the ten matched-controls.

All matched-controls were treated according to the RCT-protocol [24]. The whole joint was substituted with a posterior stabilized femur and tibia component of the Genesis II model (Smith and Nephew). After fixation with Genta Palacos® cement the definite insert was placed in between the components. After an average hospitalization of 6 days, with 2 days of CPM (continuous passive motion) exercise, patients were discharged and advised to regain gradually full weight bearing guided by a physiotherapist. After 6 weeks the stability of the knee was examined, clinically and radio graphically.

Peri-operative complications

All peri-operative complications (including wound healing problems and actual wound infections) were deduced in retrospect from patients' clinical charts until six weeks after TKP surgery, as they were not part of any protocol follow-up.

Patient related outcome scores (PROMs)

Except for the first three feasibility patients, patients were scored for clinical outcomes twice at baseline and post-operative at 3, 6, 9, 12, 18, 24 months follow-up. After two years the follow-up took place yearly until 10 years of follow-up was reached. The first three feasibility patients were followed prospectively for only one year. For the present study these patients were interviewed once again for a clinical *status praesens*. Clinical outcome parameters included pain, stiffness, and function, measured with the WOMAC questionnaire (version 3.0, normalized to a 100-point scale for total and subscales; 100 being the best score) and VAS pain (visual analogue score; 0 being the best score).

Statistical analysis

A Kaplan-Meier survival analysis was made, to evaluate the preservability of KJD treatment, until a TKP was placed.

Pooled baseline PROMs of the five KJD cases that underwent TKP were compared with the whole KJD cohort (n=23) and with baseline values of the matched-controls with primary TKP (n=10). Furthermore the last regular PROM measurements of the cases before receiving a TKP (defined: pre-TKP PROMs; n=5) were compared with baseline data of the matched-controls with primary TKP (n=10). These three analyses were done (non-parametrically, unpaired) with a Mann-Whitney-U test, using IBM SPSS Statistics version 20. Per follow-up time-point a comparison is graphically shown per case with the two matched-controls, without statistical evaluation, due to low n-values.

Results

Survival analysis

From the cohort a total of five patients received secondary a TKP, after first been treated with KJD. The mean survival time of KJD of these five patients was 61±15 months, range 45-84 months (survival curve shown in Figure 1).

Peri-operative complications

Two cases of the five with secondary TKP (#4 and #5, table 1) suffered from pin-tract infections during KJD treatment, which needed treatment with oral antibiotics (Flucloxacillin). After TKP case #4 had a delayed wound healing postoperative because of leakage, nevertheless the wound did not get infected. Case #2 (no pin-tract infection during KJD) had a superficial wound infection after discharge after TKP, which was treated with oral antibiotics for approximately one month. Case #1 and #3 did not report any problems for both KJD and TKP treatments. Of all matched controls peri-operative complications were limited to one case with delayed wound healing because of leakage, without actual wound infection.

None of the patients from neither cases nor controls needed additional intervention or revision surgery after placement of the TKP, with a follow-up of the TKP ranging from 9-39 months.

Baseline characteristics

Baseline clinical scores of the five KJD patients treated additionally with a TKP were not statistically significant different when compared to the whole cohort treated with KJD (Figure 2).

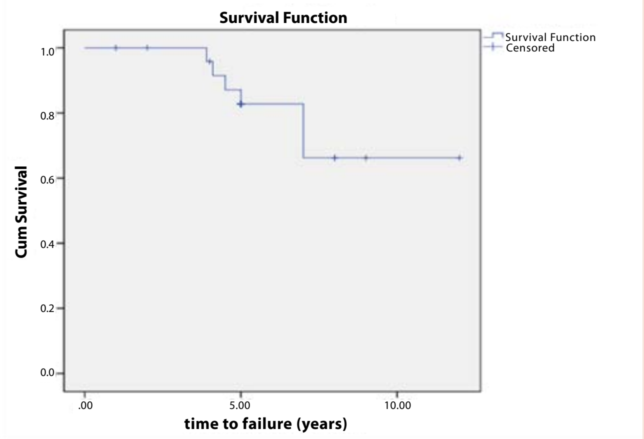

Figure 1: Kaplan-Meier survival curve.
From the 23 patients with follow-up data, three patients got a TKP before five years (45-58 months) and two after five years (64-84) of follow-up.

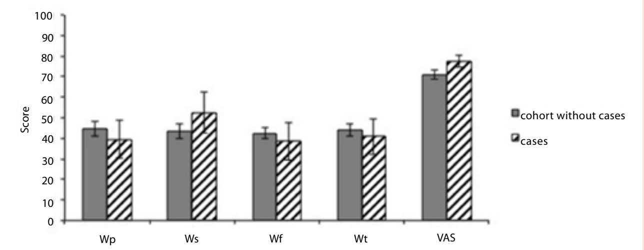

Figure 2: Baseline clinical characteristics of cases vs. total cohort.
Comparison of PROMs of KJD patients and KJD patients additionally treated with secondary TKP. No statistically significant differences were observed between both groups. Wp = WOMAC pain; Ws = WOMAC stiffness; Wf = WOMAC function; Wt = WOMAC total; VAS = VAS pain.

Baseline clinical scores prior to KJD (5 cases) and prior to primary TKP (10 matched-controls) were comparable between both groups for WOMAC scores, however VAS pain score was higher (more pain) in the primary TKP group at baseline (p=0.017; Figure 3). This was also the case when we compared pre-TKP clinical scores from the 5 KJD patients in comparison with the baseline clinical scores of the 10 matched-primary TKP-controls: WOMAC scores did not differ between the groups whereas the VAS pain score indicated more pain for primary TKP (p=0.008; Figure 4).

Follow-up

In Figure 5 WOMAC and VAS pain scores are depicted for cases (KJD-TKP) and controls (primary TKP). For each patient the latest time-point of follow-up is depicted. For case #2 at 24 months follow-up, pain was significantly worse for the TKP after KJD as compared to the matched-primary TKP-controls. The other cases had similar pain scores at 24 months follow-up compared to their matched-primary TKP-controls. Overall scores seem to be comparable between all TKPs; primary and secondary to KJD.

Discussion

TKP after KJD resulted in a similar function and pain reduction, not different from primary TKP treatment in the first five patients that received a TKP after joint distraction. Although pin tract infections are common in KJD treatments and were present in 2 of the 5 patients no complications were seen that could be related to potential latent (bone) infections.

KJD in treatment of end-stage knee osteoarthritis is developed to decrease pain and improve function, while postponing a TKP and potentially preventing revision surgery. The intrinsic joint tissue

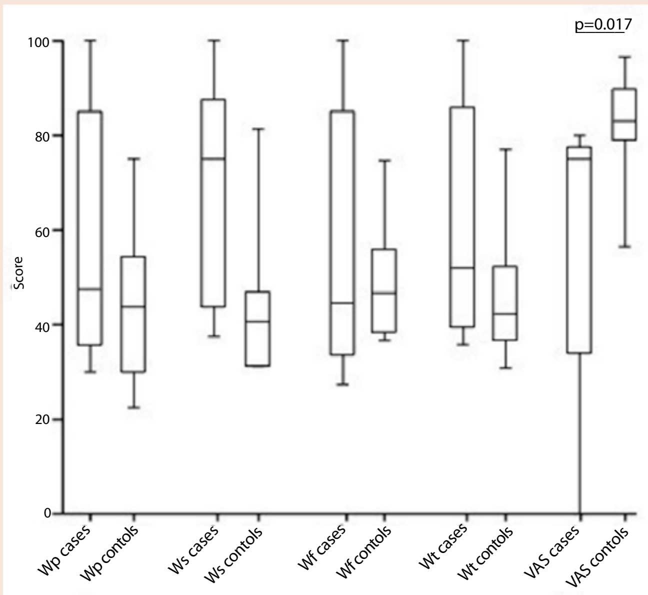

Figure 3: Baseline clinical scores of cases vs. matched-controls.
PROMs prior to KJD (cases; n=5) and primary TKP (controls; n=10) treatment. Wp = WOMAC pain; Ws = WOMAC stiffness; Wf = WOMAC function; Wt = WOMAC total; VAS = VAS pain.

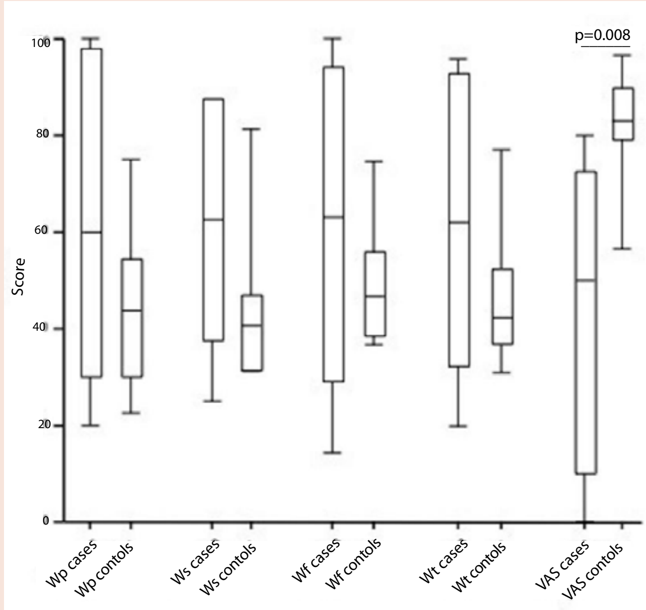

Figure 4: Clinical scores compared prior to TKP between cases vs. matched-controls.
Pre-TKP PROMs of cases (n=5) and baseline PROMs of matched-controls (n=10). For both groups measurements prior to TKP placement. Wp = WOMAC pain; Ws = WOMAC stiffness; Wf = WOMAC function; Wt = WOMAC total; VAS = VAS pain.

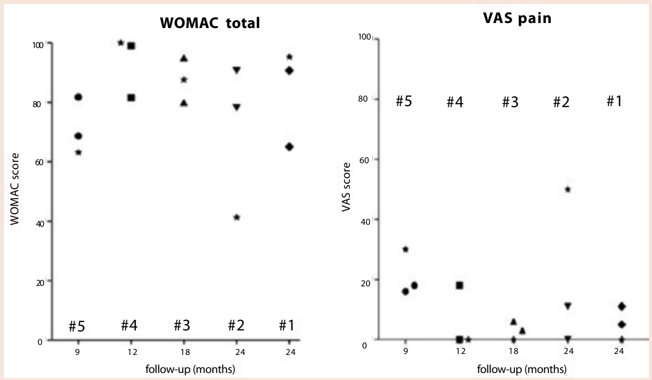

Figure 5: Individual scores of each of the five cases (*) with their two matched-controls (primary TKP), at the latest follow-up moment after TKP treatment. Patient number is depicted.

repair observed predicts prolonged clinical benefit [9], (five years follow-up manuscript under revision). Especially relatively young patients under the age of 65 years could benefit as ideally they should not to be treated with TKP yet, because of increased risk of revision surgery during lifetime.

KJD is a successful treatment, however concerns were raised about complications of subsequent TKP. The distracted joint might be compromised specifically because of the pin tract infections frequently observed during use of external fixation frames, despite adequate treatment with antibiotics when necessary. However, none of the five patients, receiving a TKP after KJD treatment, suffered from a peri-prosthetic joint infection. Furthermore, no deep wound infections were observed post-TKP treatment. All patients are still functioning well with their TKP, and at the time of follow-up none of the TKPs was revised.

Concerns about latent infection risks after treatment with an external fixation frame are conceivable, however reports about this in relationship with a total knee prosthesis are to the best of our knowledge not reported. It is known that increased duration of treatment with an external fixation frame, before conversion to internal nail or plate fixation increases the risk of infection [25-27]. Nonetheless, nothing is reported about the interval between external fixation treatment and internal fixation or prosthesiology. In case of KJD the interval between removal of the frame and placement of the TKP is rather long, at least 45 months, during which latent infection risks may have waned. The question is whether a shorter period after KJD failure is sufficient to safely perform TKP. Unfortunately, these cases are not present. It might be advised to wait a certain time after removal of the distraction frame before TKP is performed, although there is no evidence for this. In case of suspected infection an immunoglobulin scan could be made to diagnose areas of increased immunologic activity [28]. Furthermore the bone-pins are placed extra-articular; outside the area that is involved in TKP placement. Figure 6 shows the placement of the bone-pins for KJD and the position of the TKP. This is anticipated to be of importance to prevent potential infection because of previous KJD treatment, although in case of internal plate fixation there is no reported raised infection risk in case of overlap between pinholes and the plate [27].

Baseline and pre-TKP VAS pain scores were statistically significant higher for a primary TKP as compared to TKP after KJD, although not supported by WOMAC pain score. For baseline VAS pain this might be explained by variation as demonstrated by the extremely large range in VAS pain score, specifically in the context of a similar WOMAC pain score (Figure 3). For pre-TKP VAS pain levels this is rather surprising. It might be that a relative increase in pain level over time after KJD despite still relatively low absolute levels appealed these patients for a TKP, supported by still a young age (all <60 years) and active lifestyle. This fits with the WOMAC scores that all show a higher value (less pain and impairment) for the cases when compared to the controls. Patients may still be disappointed after KJD and then a step towards TKP is easily made, whereas a primary TKP is all at once a definitive option. This is however rather speculative and larger numbers in the future have to support the observation.

Figure 6: Position of the bone-pins from an anterior-posterior view compared with (later) placement of a TKP.

At last, no perioperative complications at the time of TKP are seen for patients previously treated with KJD. Regarding comparison with other joint preserving treatment modalities, local tissue fibrosis after HTO is known to cause difficulties with exposure of the proximal tibia and eversion of the patella in secondary TKP treatment. More lateral releases were reported necessary, which increased the operation-time. This was however not predictive for wound infections and did not affect the clinical outcome. Failure-rate observed with radio stereometry did not reveal differences between primary and secondary TKP's at ten years follow-up [29]. Radiolucent lines that are described in secondary TKP's, in general not leading to increased loosening in this group [30].

In comparison with HTO, which increases operation time in case of conversion, the overall operation time for TKP after UKP is comparable with a primary TKP [31]. However, when revising an UKP into a TKP, however, more often than with a former HTO or primary TKP revision components had to be used, i.e. larger stems in case of bone loss.

In conclusion, in relatively young patients (<65 years of age) with severe knee OA, joint-preserving surgery including KJD can safely be considered as there is no indication that subsequent TKP placement in case of failure of the KJD, will lead to worse results or higher complication rate than primary TKP. As such regarding clinical benefit there are no objective restrictions to perform a TKP after KJD or the other way around to perform KJD before TKP.

Author Contributions

KW collected, analyzed and interpreted the data, drafted the first version of the manuscript and performed the statistical analysis. PR, RH and SS provided patients and offered technical and logistical support. RC, NK and SM offered technical support and analyzed and interpreted the data. FL obtained the funding, designed the study, analyzed and interpreted the data and supported the statistical analysis. All authors contributed in the critical revision of the article for important intellectual content and all authors approved the final manuscript.

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