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Original Research

User-friendliness of a dedicated orthopedic device for knee joint distraction: Experiences from clinical practice

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ABSTRACT

Introduction: Knee joint distraction (KJD) is a surgical technique for treatment of severe knee osteoarthritis at a relatively young age. In the absence of devices intended for KJD, this procedure has only been performed with devices with another intended use. In collaboration with patients, clinicians and medical device experts, a dedicated distraction (DD) device intended for KJD was developed.

Objectives: To compare user-friendliness between the new DD device and a previously used concept distraction (CD) device.

Methods: Patients were treated with either of the devices ($n = 22$ versus $n = 22$). The intervention duration and treatment complications were registered. After treatment, patients filled out a questionnaire about user-friendliness of the device during treatment, containing questions on difficulties performing activities regarding clothing, sleeping, pin care, daily activities, mobility, and complications. Results were compared between the 2 groups.

Results: Intervention duration was on average 56 versus 44 minutes ($P < .001$) for CD and DD device, respectively. Pin tract infections were the most prevalent complication (73% of CD patients vs 55% of DD patients; $P = .210$). 34 patients filled out the questionnaire (16 CD device vs 18 DD device). User-friendliness was better for the DD device for 6/25 questions (all $P < .05$) and not different between devices for remaining questions (all $P > .1$).

Conclusions: The DD device intended for KJD reduces surgery time and improves user-friendliness compared to the CD device. As such, the DD device contributes to implementation of KJD treatment in regular care.

Introduction

Knee joint distraction (KJD) is a joint-preserving surgical technique for treatment of severe tibiofemoral osteoarthritis (OA) in younger patients who are indicated for total knee arthroplasty (TKA).[1] Performing a TKA in this relatively young population

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Table 1
Overview of principles used in the development of the dedicated KJD device.

Device characteristics of the dedicated knee distraction device
○ *Device weight is below 1500 g.*
○ *Surgery can be performed within 45 min.*
○ Bone pins are positioned extra-articular, not compromising the area for primary TKA.
○ Bone pins are positioned perpendicularly to longitudinal axis of tibia.
○ System can be adjusted in case of complications (soft tissue swelling/infection).*
○ *No protruding parts are present above the most proximal and below the most distal bone pins.*
○ *Protruding bone pins are shielded for minimal interference during treatment.*
○ The pin tracts are accessible for pin tract care.*
○ The distraction direction and method is visually indicated.
○ 5 mm distraction is applied in the longitudinal axis of the tibia.
○ Within the distraction, 3 mm deflection is present at full weight-bearing.

TKA, total knee arthroplasty.
Italics indicate characteristics that are new with respect to the concept distraction device.
*indicate characteristics that have been improved with respect to the concept device.

(<65 years) brings an increased risk of a complex and costly revision surgery later in life.[2-4] This is specifically the case for male patients, who encounter an almost doubled risk for revision compared to female patients.[2] Joint-preserving therapies, such as KJD, aim to delay TKA in this population and possibly prevent a revision surgery.[5,6] Data from multiple clinical trials showed clinical improvement and cartilage regeneration of the affected joint in patients treated with KJD.[7-11] Also, it was shown that a primary TKA could be postponed for a clinically relevant period of 5 years in over 70% of the patients up to even 9 years in around half of the patients.[12,13] The best results have been described in males (72% survival after 9 years), who also show the highest risk for revision of a primary TKA, making KJD worth considering in treatment of severe knee OA.[2,13]

During KJD, the affected joint is temporarily and fully mechanically unloaded by increasing the joint space with a distraction device, which is rigidly connected with half pins to the femur and tibia. The most common fixation and distraction technique is performed bilaterally with 8 extra-articular half pins and 5 mm distraction for a period of 6 to 7 weeks.[14-16]

In the absence of a dedicated device intended for KJD, this procedure has been performed in clinical trials with external fixation devices that are applied for various indications including stabilization of fractures and limb lengthening.[1] This broad range of applications comes with unrequired features when these devices are used for KJD, and limitations in terms of complexity of surgery, procedure time, alignment of the device and ease of use for all users including surgeons and patients. The treatment burden might be reduced when a dedicated device for KJD with optimized specifications for its intended use, for example, the size, weight, and application method, is used. The continued use of existing external devices in daily care outside intended use, is not allowed under EU Medical Device Regulations, motivating the development of a specific device for KJD, This KJD device might also reduce the risk of misuse, ultimately leading to a safer and more efficient procedure.[17]

The clinical demand for a dedicated KJD device originated from the clinical benefits that were achieved with KJD treatment in clinical trials.[10,12] In a multi-disciplinary setting with clinicians, patients, and medical device experts, a device intended for KJD was developed and made available for clinical application. Device characteristics that were defined and incorporated in the dedicated device are given in Table 1. In this study, user-friendliness is compared between the newly developed dedicated distraction (DD) device and the previously used device that served as a proof-of-concept distraction (CD) device for KJD (Fig. 1); clinical efficacy and tissue structure repair are beyond the scope of this study.

Materials & methods

Groups and patient selection

44 Patients were treated for severe knee OA with KJD either with the CD device ($n = 22$) (Monotube Triax, Stryker GmbH, Selzach, Switzerland; the most often used KJD device reported on in previous studies) or with the DD device ($n = 22$) (KneeReviver, BAAT Medical BV, Hengelo, The Netherlands). The criteria for study participation were equal for the 2 groups (Table 2).

The 2 device types generally require the same anatomical sites and method of fixation as described previously, except for device specific differences.[1] In short, the external fixation device was surgically fixated to the femur and tibia using 8 self-drilling, 5 mm half pins. The CD device consisted of 2 rigid distraction tubes (Monotubes, see above), while the DD device (KneeReviver) was non-rigid to allow more user-friendly positioning around the joint (Fig. 1). Both devices contain internal springs. After positioning of the pins and frame, 2 mm distraction distance was provided intra-operatively and extended with 1 mm per day to reach 5 mm distraction, confirmed radiographically. Afterwards, patients were discharged from the hospital and allowed full weight-bearing, supported with crutches if needed, and after 6 weeks of distraction the frame and pins were removed.

All patients were treated within the University Medical Center Utrecht, Utrecht, The Netherlands (UMC Utrecht), where ethical approval was obtained from the ethical committee for a prospective study design (protocol number 17–293). No randomization of patients between the 2 devices was allowed, since the DD device for KJD was available for standard care at the start of the study. It was anticipated in advance that the DD device was of added value, therefore, the ethical committee considered that randomization

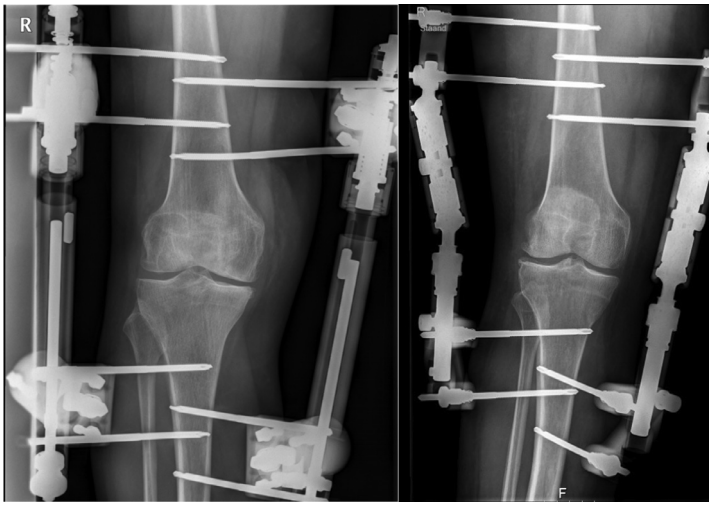

Fig. 1. Radiographs of the concept (CD) device (left) and dedicated distraction (DD) device (right) in use.
The surgical procedure for fixation of both devices is equal and performed with similar half pins.

Table 2
Inclusion and exclusion criteria for knee joint distraction treatment in this study.

Inclusion criteria	Exclusion criteria
Age < 65 years	Varus/valgus malalignment > 10°
BMI < 35 kg/m^2	History of inflammatory or septic arthritis
VAS pain > 40 mm	Primary patellofemoral OA
Kellgren & Lawrence grade ≥ 2	Surgical intervention within past 6 months prior to KJD
Persistent medication and conservative treatment resistant tibiofemoral pain	Osteopenia hampering proper pin fixation
	Physiological inabilities to cope with the treatment
	Arthroplasty of other joints, or expected need within 6 months
	Flexion contracture
	Vascular and/or soft-tissue abnormalities
	Body mass > 130 kg

BMI, body mass index; VAS, visual analogue scale; KJD, knee joint distraction.

to an inferior device (viz. the CD device) would be non-ethical. As such, patients that had been treated with the CD device previously with written permission for future use of their data in retrospect, were included for analysis. The study was performed in accordance with the ethical principles from the Declaration of Helsinki and all patients gave written informed consent.

Data collection

As a measure for user-friendliness of the devices for the orthopedic surgeons, the duration of the intervention was collected from the surgery reports in the electronic medical records, defined as the time between the first incision and the end of the procedure as registered in clinical practice. Complications as a result of KJD treatment were assessed from medical records as well. After treatment, patients filled out a customized questionnaire, composed with a patient panel, on the user-friendliness of the distraction device as experienced during treatment. Device characteristics relevant for analysis of user-friendliness and therewith for improvement of KJD treatment were incorporated in the questionnaires. The questionnaire consisted of 25 questions on difficulties performing activities regarding clothing, sleeping, wound care, general daily activities, and complications and were equal for the 2 devices (supplementary file I & Table 4). The effect of complications on the experienced user-friendliness was part of the analysis.

Within the cohort available for analysis, 3 patients were treated with both the CD device and the DD device. These patients received a questionnaire for a direct comparison of experiences during treatment between the CD and the DD device (supplementary file II).

Statistical analysis

Baseline characteristics were compared between groups using independent *t* tests or, in case of categorical variables, chi-square tests. Statistical testing for significance of all outcome parameters was performed with independent *t* tests and results are displayed using mean and standard deviations. In case of non-normal distribution, Mann-Whitney U tests were used instead of independent *t* tests and results are displayed using median and interquartile range (IQR). For categorical variables with only 2 categories (questions

Table 3
Baseline characteristics of patients treated with knee joint distraction in this study.

	Concept distraction (CD) device (n = 22)	Dedicated distraction (DD) device (n = 22)	P value
Age, mean ± SD	54.8 ± 4.8	52.0 ± 6.7	0.123
Male sex, n (%)*	14 (64)	11 (50)	0.361
BMI, mean ± SD	58.3 ± 3.9	27.5 ± 2.9	0.501
Left index knee, n (%)*	12 (55)	9 (41)	0.365

BMI, body mass index.; SD, standard deviation.
P values of continuous variables are calculated with independent t tests and for categorical variables with chi-square tests (indicated with *).

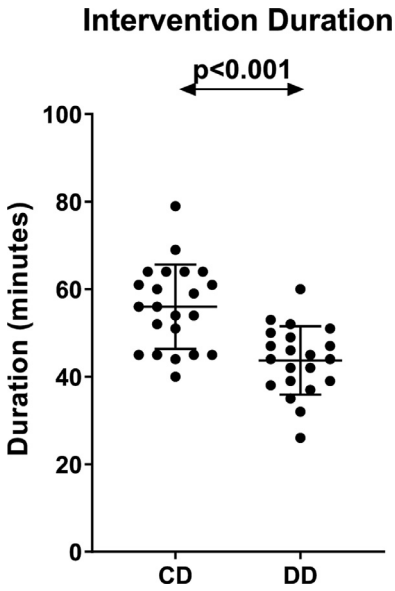

Fig. 2. The registered intervention duration for the concept (CD) device versus the dedicated distraction (DD) device.
Intervention duration is defined as the time between the first incision and the end of the procedure. Each dot represents a patient/procedure. Lines indicate mean ± standard deviation. The *P*value indicates statistical significance of the differences between groups (bold indicating statistical significance, $P < .05$).

21 and 22; Table 4), chi-square test were used and the number of occurrences (and% of the total amount of patients) are given . P values <0.05 were considered statistically significant. IBM SPSS Statistics version 25 (IBM Corp; Armonk, NY) was used for all statistical analyses.

Results

Patients

The patients' baseline characteristics are presented in Table 3. There were no statistically significant differences between the 2 groups regarding these baseline characteristics. Patient age ranged from 46 to 63 years in the CD group and 38 to 63 years in the DD group.

Intervention duration

The intervention duration was on average 56 (±10) minutes for the CD device and 44 (±8) minutes for the DD device ($P < .001$), showing a statistically significant reduction of 12 minutes (21% reduction) for the DD device (Fig. 2).

Complications

The most frequently seen complications were pin tract skin infections, occurring somewhat more often in the CD patients (16/22; 73%) than the DD patients (13/22; 59%) but showing no statistically significant difference between devices ($P = .210$). In the CD group, 3 patients required hospitalization and intravenous antibiotics for their pin tract infections, as did 1 patient who experienced osteomyelitis and 1 patient who experienced osteomyelitis and septic arthritis along with their pin tract infections. Also, 1 patient in the CD group had a broken bone pin (which was replaced) and 1 patient experienced a flexion limitation that required knee

Table 4
User-friendliness questionnaire results per question for the concept distraction device and dedicated distraction device.

#	Aspect	Concept distraction (CD) device	Dedicated distraction (DD) device	*P* value
Clothing and dressing (treated leg)				
1	Changing clothes, median (IQR)	7.0 (4.5)	8.5 (5.3)	0.281
2	Clothes catching on device, median (IQR)	6.0 (3.8)	8.5 (4.3)	0.070
3	Finding suitable/fitting clothes, median (IQR)	5.0 (4.5)	10.0 (3.0)	**0.003**
Sleeping and night rest				
4	Sleeping in desired position, median (IQR)	3.0 (3.0)	2.0 (4.0)	1.000
5	Disturbance of night rest, median (IQR)	4.5 (2.0)	6.0 (8.0)	0.463
6	Damage to bedding, median (IRQ)	6.0 (6.0)	10.0 (0.0)	**0.002**
Pin care and device handling				
7	Performing pin care, median (IQR)	4.0 (4.0)	9.0 (6.0)	**<0.001**
8	Understanding pin care instructions, median (IQR)	8.0 (3.0)	10.0 (3.3)	0.274
9	Extending the device, median (IQR)	8.0 (5.0)	10.0 (5.0)	0.791
10	Understanding extension instructions, median (IQR)	9.0 (5.0)	9.0 (6.0)	1.000
Daily activities				
11	Getting caught / bumping during daily activities, median (IQR)	6.0 (5.0)	5.5 (3.3)	0.484
12	Getting in and out of chair, median (IQR)	5.0 (7.0)	6.0 (9.0)	0.135
13	Performing daily activities, median (IQR)	4.0 (2.0)	4.0 (4.0)	0.198
14	Harm to the other leg, median (IQR)	7.5 (3.5)	10.0 (6.0)	**0.003**
15	Loosening/losing shielding caps from bone pins, median (IQR)	7.0 (7.0)	8.5 (7.0)	0.735
Mobility				
16	Walking without crutches, median (IQR)	4.0 (3.0)	5.5 (6.3)	0.403
17	Resume daily domestic activities, median (IQR)	3.0 (5.0)	4.0 (2.0)	**0.042**
18	Resume paid activities (job), median (IQR)	1.0 (0.0)	1.0 (4.0)	0.116
19	Daily travelled distance (0 to 2500 [meter/day]), median (IQR)	3.0 (7.0)	4.0 (2.3)	0.175
Complications				
20	Antibiotic courses started, n (n per patient)	29 (1.8)^	29 (1.6)^	0.463
21	Patients with pin tract infection, n (%)	14 (88)^	10 (56)^	**0.041***
	Total pin tract infections, n (n per patient)[$]	77 (4.8)^	66 (3.7)^	0.237
22	Doctor visits related to the device, n (%)	10 (63)^	7 (39)^	0.169*
Other aspects				
23	Need for new clothing, median (IQR)	8.0 (3.0)	7.0 (2.8)	0.325
24	Importance of signs of previous use (scratches), median (IQR)	1.0 (5.3)^	4.5 (5.3)^	0.102
25	Importance of device color, median (IQR)	1.0 (0.0)^	1.0 (2.0)^	0.597

In all cases a higher value represents the best (most desirable) answer, except for values marked with ^.
P values were calculated using Mann-Whitney U Tests; for categorical parameters (indicated with *) chi-square tests were used instead. Statistically significant differences between devices ($P < 0.05$) are indicated in bold. The original questionnaire is provided in the supplementary data file I.
[$]Defined as the total number of pin tract infections infected over the course of the treatment for all patients with every infected pin tract counting separately; a pin tract be infected multiple times during a treatment period.
IQR, interquartile range.

manipulation under anesthesia. In the DD group none of the patients required intravenous antibiotics and apart from the pin tract infections, 1 person experienced thrombosis and was treated with anticoagulation.

Questionnaires

Out of the 44 included patients, 34 filled out the questionnaire (16/22 patients with the CD device versus 18/22 patients with the DD device). Baseline characteristics did not differ significantly between patients who did or did not fill out the questionnaire in each group. Results per question are provided in Table 4. As most of the answers were not normally distributed, Mann-Whitney U tests and mean with IQR were used for all parameters. For 6/25 (24%) of the questions a statistically significant difference in favor of the DD device is seen. For all other questions, scores were all in the direction of benefit for the DD device, but not statistically different between both devices (all $P > .05$).

Based on responses of patients included in this study and on pre-determined DD device characteristics (Table 1), 3 questionnaire aspects were identified as most relevant in experiencing user-friendliness: the incidence of clothes catching the device (question 2), the pin care (question 7), and the harm to the contralateral leg (question 14). These were aspects that patients specifically indicated as important with respect to user-friendliness during treatment when they completed their questionnaire. Moreover, these items were also considered as points that were likely important in reducing treatment burden during the development of the device. Detailed results on these aspects are provided in Fig. 3 demonstrating favor for the DD with the latter 2 aspects statistically significant (both $P < .004$).

A statistically significant difference was found for the ease of performing pin care between patients with (median 5.0, IQR 2.3) and without (median 9.5, IQR 2.3) developed pin tract infections ($P.= .001$).

Data for direct comparison of the CD device and the DD device based on the response of 3 patients who were treated over time with both devices is given in Fig. 4. The overall performance of the DD device appears to be somewhat better compared to the CD

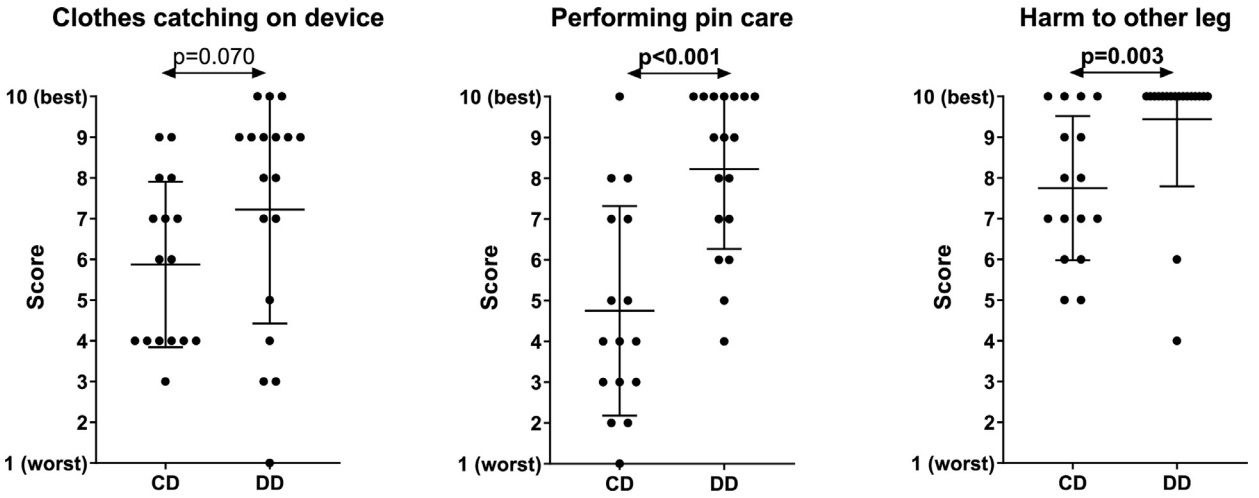

Fig. 3. Individual patients' user-friendliness scores for the 3 aspects considered the most relevant by included patients.
Each dot represents a patient's given score, with 10 the best score with respect to user-friendliness, while the lines indicate mean ± standard deviation. The *P* values indicate statistical significance of the differences between groups (bold values indicate statistical significance, $P < .05$).

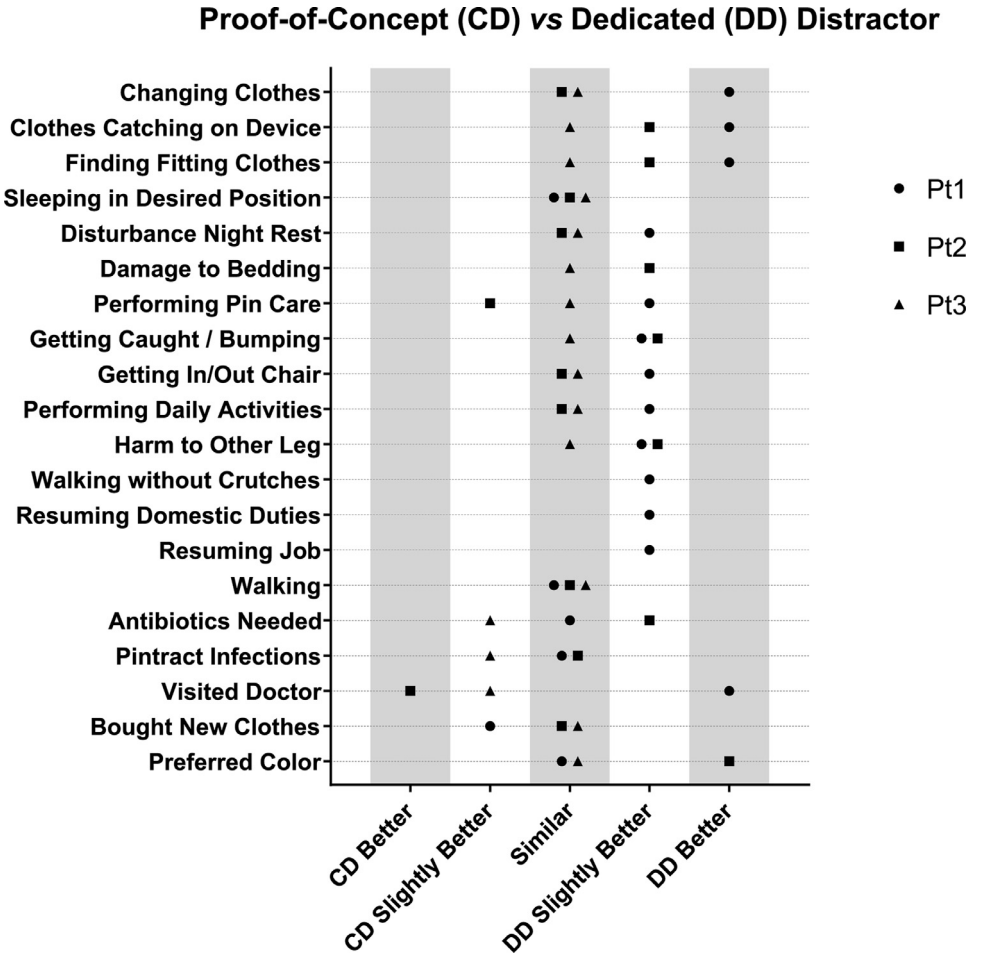

Fig. 4. Questionnaire results from patients that received treatment with both the CD and DD device.
CD, concept device; DD, dedicated device. Statistical testing was not opportune for this small number of responders ($n = 3$).

device for questions regarding device characteristics, as the 3 patients more often indicated that the DD was better or slightly better than the CD than the other way around, but no statistical testing was performed because of the small size of this group ($n = 3$).

Discussion

The performance of a DD device for KJD, in terms of user-friendliness, was evaluated against a CD device in clinical practice amongst the primary intended users, viz. surgeons and patients. The development of the DD device focused on optimization of use-related aspects that had no direct effect on the safety of the device, with essential characteristics kept equal to the CD device. As such, the DD device was introduced according to the applicable regulations without a study on clinical efficacy. It was found that the DD device for KJD provides improved user-friendliness for both clinicians (reduced surgery time) and patients as compared to the CD device. Independently of the user-friendliness of the device, it remains to be evaluated whether the DD device has similar clinical efficacy as the CD device.

The shortened surgical procedure (21% time reduction) is considered not only beneficial for the surgeon, but also for the patient (shorter sedation, reducing risks for complications, for example, surgical wound infection) and reduces healthcare costs by shortening the operating room occupation. The time difference is not considered attributable to a learning curve from the CD device as the surgeon performing the surgeries with the DD device already had extensive experience with the CD device following a similar surgical procedure. As such, the time difference is considered to result from improved user-friendliness for the DD device.

It was noticeable that the incidence of pin tract infections was lower in the DD device group, although the difference was statistically significant only in patients who filled out the user-friendliness questionnaire and not in the whole group. The total number of complications seemed somewhat less in the DD group as well, although because of the low occurrence of complications other than pin tract infections and limited sample size this outcome could be influenced by coincidence. Pin tract infections are considered a significant and well-known burden of treatment with external fixator devices, as is the case in KJD.[18] The reduced number of patients with pin tract infections in the DD group fits with the patients' experience that pin tract care is easier in the DD device compared to the CD device, which means the DD device seems to be successful in making pin tracts are accessible for pin tract care. This might indicate that difficulties in performing pin care increase the risk of pin tract infection development. On the other hand, the effect is could be related to differences in patient instructions for performing pin tract care as well. However, despite the reduction, the incidence is still high and extra attention in future developments towards improvement of treatment is demanded.

In general, all parameters related to patient user-friendliness were in favor of the DD device, some reaching statistically significance. For the 3 aspects that patients reported as most relevant for user-friendliness, the questions concerning harm to the contralateral leg and the pin tract care showed statistically significant improvement for the DD device, while the 22% improvement regarding the aspect of catching clothes was not statistically significant on group level. The latter aspect is likely inherent to the use of any externally fixated distraction device, regardless of minimization of protruding parts. Still, like the question concerning harm to the other leg, the significantly improved scores of finding suitable/fitting clothes and damage to bedding seen for the DD device are likely the result of the fact that no protruding parts are present above the most proximal and below the most distal bone pin and protruding bone pins are shielded. The fact that patients using the DD device indicated they could better resume daily activities seems to be the result of a combination of improvements in device characteristics as described in Table 1. Further improvement of the system should involve critical analysis of the defined device characteristics including clinical experiences from this study. Specifically, characteristics that may have high impact on patients during treatment should be carefully considered for evolvement of the device. In this respect, especially the items 'providing pin care' and 'harm to other leg' appear to be relevant for increasing user-friendliness for patients.

The 3 patients who were treated with both the CD and DD device generally rated user-friendliness higher for the DD device, but there was clearly a lot of variation between their answers. Comparison of these outcomes should be interpreted with care, and only considered suggestive. Besides the fact that the group of patients that were treated with both devices is limited in size, data is likely to be influenced as a result of the period between the treatments.

This study had several limitations. First, this evaluation of user-friendliness would ideally have been performed in a randomized study. However, this was considered unethical by the responsible ethical committee due to the fact that the DD device was already available in clinical practice at the start of the study, which is why the current study setup was chosen. Second, the number of patients evaluated in this study was limited. Once further introduction of the DD device is established and more data becomes available, further evaluation is recommended to see if the current findings hold. Although longitudinal clinical and structural results with the DD device are expected to be similar to results seen in patients who received treatment with the CD device, this should be evaluated as well. Lastly, the patient questionnaire that was used to evaluate user-friendliness was not a validated questionnaire. Due to a lack of validated outcome measures relevant for evaluating the CD against the DD device, the current questionnaire was made based on demands and wishes as judged by the multidisciplinary team of patients, clinicians and medical device experts before development of the DD device. As such, the current questionnaire does incorporate aspects that are considered important by key users, but using a validated patient questionnaire would have been preferable.

In conclusion, the DD device provides a surgical instrument intended for KJD which reduces surgery time and improves user-friendliness compared to the CD device. Furthermore, it was demonstrated that incorporating patients as end-users in the development process of the DD device increases insights in user-friendliness, which potentially may further reduce treatment burden and facilitate implementation in regular care. Taken together, the DD device contributes to implementation of KJD for severe knee OA at a relatively young age.

Patient consent

Ethical approval was obtained from the ethical committee of the UMC Utrecht for a prospective study design (protocol number 17–293). The study was performed in accordance with the ethical principles from the Declaration of Helsinki and all patients gave written informed consent.

Authors' contributions

MJ acquired, analyzed and interpreted the data, and drafted the work. TS contributed to the design of the work, interpreted the data and drafted the work. JJ contributed to the design of the work, interpreted the data and revised the work. SM and RC contributed to the design of the work, interpreted the data and substantively revised the work. All authors approved the submitted version. All authors have agreed to both be personally accountable for their own contributions and ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature.

Declaration of competing interest

TS received personal fees from ArthroSave BV, outside the submitted work, and has 2 patents pending to ArthroSave BV, a medical device company involved in marketing a user-friendly knee joint distraction device. SCM has 1 patent pending to ArthroSave BV. MJ, JJ and RC have no potential conflict of interest to disclose.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jcjp.2021.100007.

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