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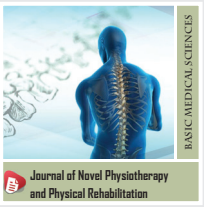

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Research Article

Pilot Study on the Clinical Applicability of Non-invasive Joint Distraction using the JD Device for Knee and Hip Osteoarthritis: A Retrospective Observational Study

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Abstract

Background: Knee and hip osteoarthritis are among the most common degenerative joint diseases and are associated with significant limitations in quality of life. Mechanical joint distraction is considered a promising approach to pain relief and joint function improvement. The aim of this retrospective observational study, designed as a pilot study to serve as a starting point for subsequent controlled studies, was to evaluate the effectiveness of a non-invasive home therapy device for joint distraction (JD device) in patients with knee or hip osteoarthritis.

Methods: 39 users of the JD device (average age: 62.7 years) took part in an anonymous online survey. Pain levels before and after use were recorded using a numerical rating scale (NRS), along with subjective perceptions of effectiveness and information on duration of use. In addition, user-related experience data was collected using closed questions and evaluated as percentage distributions. The Wilcoxon test, effect size calculation, and Spearman correlation were used for statistical analysis.

Results: The average pain intensity (total knee and hip osteoarthritis) decreased significantly from 6.82 to 3.28 ($p < .001$, $r = 0.75$), which corresponds to an average pain reduction of 3.54 points through the use of the JD device. 71.8% of participants achieved a pain reduction of at least 30%. A positive correlation between duration of use and pain improvement was demonstrated ($\rho = 0.53$; $p = .003$). 81.3% of respondents used the JD device daily at home. 82% reported that therapy with the JD device had reduced their symptoms. With regard to surgical procedures, 47.8% of those who had already been recommended artificial joint replacement stated that they were able to avoid or postpone it by using the device. For another 43.5%, this was still unclear at the time of the survey. 8.7% were unable to avoid surgery despite using the device. In addition, 92.3% of participants would recommend the JD device they used to others.

Conclusion: The results of this pilot study suggest that regular self-administered home therapy with a non-invasive JD device may be an effective option for pain relief in knee and hip osteoarthritis, potentially delaying or avoiding upcoming surgery. A planned clinical RCT study will verify this statement in the future.

Introduction

Knee osteoarthritis is one of the most common degenerative joint diseases worldwide. A recent meta-analysis shows a radiologically detectable prevalence of 24.3% in men and 32.6% in women, with a significant increase in older age Spahn, et al. 2011. The disease is characterized by progressive cartilage degradation, joint pain, restricted movement, and a significant reduction in quality of life. Clinical practice guidelines consistently recommend active exercises, education, and weight management as core elements of treatment [1]. Passive measures, such as manual therapy, can be used in combination with these interventions [2,3]. Patients (especially younger ones) prefer joint-preserving conservative alternatives or

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surgical joint-preserving measures that do not require bone cutting or bone removal, as opposed to endoprosthetics [4].

Joint distraction is a promising therapeutic approach for slowing the progression of knee osteoarthritis [5]. Animal studies have shown that joint distraction leads to inhibition of cartilage degradation, normalization of the subchondral bone structure, and a reduction in inflammatory processes [6]. Clinical studies on invasive knee joint distraction (KJD) using an external fixator have shown that this procedure achieves significant structural and clinical improvements, including significant cartilage regeneration, particularly in younger patients with terminal gonarthrosis. Jansen, et al. [7,8] reported a survival rate of the native knee joint of 48% nine years after KJD, accompanied by clinical improvement even in patients who subsequently underwent TKA. Struik, et al. [9] also confirmed sustained pain reduction, improved quality of life (SF-36), and an increase in joint space width over a period of two years, despite frequent local complications such as pin track infections. Joint distractions can also be used as part of manual therapy [10] or as a form of self-treatment in the sense of autotraction. These non-invasive forms of joint distraction are often applied in conjunction with other physiotherapeutic measures and have been studied by various authors in the past. A case series by Albano [11] showed that manual flexion distraction therapy led to a significant reduction in pain (VAS) after an average of five sessions. Similarly, Khademi-Kalantari, et al. 2014 reported significant improvements in pain, function, and quality of life through the use of mechanical distraction in addition to standard physical therapy in a randomized controlled study. Abdel-Aal, et al. [12] also showed that mechanical traction from 90° and 20° knee flexion achieved significantly better results in terms of pain and function compared to physiotherapy alone. Further studies also confirm the effectiveness of intermittent and continuous traction in knee osteoarthritis [13,14]. While the evidence base for joint distraction in knee osteoarthritis has steadily improved in recent years, very few studies have been conducted on the use of this method in coxarthrosis. The potential effects of distraction on the hip joint—particularly about cartilage regeneration, pain reduction, and functional improvement—remain largely unexplored. Against this background, the present pilot study was initiated to assess the subjectively perceived effectiveness of non-invasive, mechanical joint distraction in the home environment using the JD device in people with knee and hip osteoarthritis. To this end, an online survey was conducted among previous users of the device to gain insights into their experiences with regard to pain reduction, functional improvement, and general benefits. The study also aims to investigate whether the JD device used can apply the principle of joint-friendly distraction in a manner comparable to or even more effective than classic distraction methods for gonarthrosis and coxarthrosis, thus offering a potential opportunity to delay or even avoid upcoming surgeries.

Methods

Sample

To determine the required sample size for the planned hypothesis test, an a priori power analysis was performed in advance using the G*Power software (version 3.1.9.7). A two-tailed t-test for paired samples ("Means: Difference between two dependent means (matched pairs)") was chosen as the statistical procedure, following common conventions for pilot studies. A medium effect of dz = 0.5 Cohen, 1988, a significance level of $\alpha = .05$, and a target test power of 0.80 were assumed. The calculation showed that a sample size of at least 34 people was required to statistically prove an effect of this magnitude with sufficient statistical power. This choice was justified because the paired t-test is the standard approach for power calculations in dependent pre–post designs. However, as the distribution of the pre–post differences violated the assumption of normality (visual inspection, Shapiro–Wilk test), we analysed the data using the nonparametric Wilcoxon signed-rank test. To verify that this change of test did not compromise statistical power, we additionally conducted an a priori power analysis for the Wilcoxon signed-rank test in G*Power. This analysis yielded a required total sample size of N = 35 for the same assumptions (dz = 0.50, $\alpha = .05$, power = 0.80). A total of 39 individuals (female = 13, male = 26) who had been using the JD device for at least four weeks at the time of the survey were included in the evaluation. The majority of respondents used the JD device due to knee osteoarthritis or knee problems (56.4%), followed by hip osteoarthritis or hip problems (30.8%). A further 12.8% of participants stated that they used the JD device to treat both joints. About the affected side of the joint, 33.3% of participants stated that only the left joint was affected. In 35.9% of cases, the right joint was affected, and 30.8% reported symptoms on both sides. The average age of the participants was 62.74 years (median = 62.5). The age range was from 42 to 80 years. One person did not provide any information about their age. Inclusion criteria were the use of the JD device for a minimum period of four weeks and willingness to participate voluntarily in the online survey.

Measuring instruments

Data was collected online using Google Forms. The survey was conducted in German and took an average of 4 to 6 minutes to complete. Two standardized numerical rating scales (NRS), ranging from 0 ("no pain") to 10 ("worst pain imaginable"), were used to record pain intensity. The first scale measured pain intensity before the JD device was used, while the second scale measured current pain at the time of the survey. According to reviews, the numerical rating scale (NRS) is considered valid, reliable, and objective and is well-suited for measuring clinically relevant changes in pain [15]. The difference between the two values was used to calculate pain reduction (difference = before - after). An open-ended single item was used to determine the time of subjectively perceived improvement: "How long did you use the Flextrainer before the symptoms in the affected joint improved?" The answer was given in weeks. This question was developed specifically for the present study and enabled an individual classification of the perceived effectiveness in relation to the duration of use. The conversion of free text entries into numerical values was performed manually based on defined criteria. Additional information on possible

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supplementary therapies was also collected. Participants were able to indicate whether they were currently using other measures such as physiotherapy, medication, dietary supplements, or other methods by selecting multiple options. They also had the option of selecting "none" or specifying an individual measure in a free-text field. The answers were converted into dichotomous variables for evaluation. Other items related to sociodemographic information (age, gender) and usage patterns, such as frequency of use and product satisfaction. These questions were used for exploratory context analysis and were formulated specifically for the project. After the survey was completed, all data were exported as an Excel file and then statistically evaluated in R.

Description of the device used for noninvasive joint distraction

The JD device used is called Flextrainer and is a non-invasive Class I medical device that has been approved for the conservative treatment of knee and hip osteoarthritis since May 2, 2024 (UDI-DI basis: 42700042986480H5). It follows the principle of mechanical joint distraction for the gentle decompression of the hip and/or knee joint.

Technical description: The Flextrainer Single is a CE-marked Class I medical device made of birch plywood (body and feet) with rubberized non-slip feet. The frame dimensions are approx. 70×33×60 cm, and the device weighs 9–14 kg (depending on the weights applied). The maximum pulling force is 11.25 kg. The traction mechanism includes a rope and pulley system: standard weight plates can be attached to the rope, which runs over a pulley, as pulling weights (30 mm hole, total weight up to 11.25 kg, for example). This allows the pull weight to be adjusted to the body weight (recommended approx. 1/7 of body weight) (Figure 1).

Instructions for use: The Flextrainer is designed as a home therapy device. The patient sits on a chair, sofa, or couch and places the leg to be treated in a relaxed position on a stool. For use in cases of knee osteoarthritis, the knee is bent at an angle of approximately 20°, and for hip osteoarthritis, it is stretched. The Flextrainer must be positioned in line with the leg axis. Traction is achieved by placing weight plates on a cuff on the foot. Treatment usually takes place for 30–60 minutes per day, recommended daily, with the weight being increased slowly. Every 5 minutes, a slight tension should be applied 5 times (slightly pull the knee, slightly bend the hip).

Figure 1: JD device Flextrainer single and application.

Contraindications and safety: Contraindications include acute infections (e.g., flu, fever) or inflammatory joint processes. In cases of severe osteoporosis, active tumors, or similar serious illnesses, as well as during pregnancy, the device should only be used after consulting a physician. After recent knee or hip surgery (joint replacement), use is only advisable after approximately three months and once pain has completely subsided. Only minor pain should occur during use; if more severe discomfort occurs, traction should be discontinued and medical advice sought. The instructions for use contain detailed safety information and instructions for proper use.

Procedure

The data collection period ran from June 11, 2025, to June 23, 2025. Recruitment was carried out via a targeted email distribution list (Brevo) to 137 existing users of the GD device who had been using it for at least 4 weeks and had explicitly agreed to be contacted by email. A total of three email campaigns were sent out between June 11 and June 19 (two of which were follow-ups). The recipients had the opportunity to participate in the survey by clicking on the button in the email. A total of 39 people took part in the survey. The survey was conducted anonymously via an online form (Google Forms) and could be completed using any internet-enabled device, regardless of location or time. At the end of the survey, respondents had the option of leaving their email address in a separate form to participate in a competition for shopping vouchers from an online department store. Participation in the competition was independent of the answers given and served solely to increase the response rate. The present study involved an anonymous, voluntary online survey without the collection of identifiable or sensitive health information. According to national and institutional regulations, such studies do not require formal approval by an ethics committee. All invitations were sent exclusively to individuals who had previously provided explicit consent to be contacted by e-mail. Before starting the survey, participants were informed about the study's purpose and the anonymity of their data, and they were required to confirm their consent to participate. By completing the questionnaire, participants agreed that their anonymized responses could be used for scientific evaluation within this pilot study. The study was conducted in accordance with the principles of the Declaration of Helsinki adopted in October 2024 [16].

Statistical analyses

All calculations were performed using R (version 2024.04.2+764). Since the pain values were not normally distributed (visual inspection & Shapiro-Wilk test), nonparametric methods were used. The raw data were first cleaned (removal of test runs), and relevant variables were renamed. To assess the therapeutic effect, the difference between the reported pain level before and after using the JD device was calculated. Since no normal distribution could be determined when checking the distribution assumptions, the Wilcoxon signed-rank test was used to compare the

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paired measurements. To assess the practical relevance of the change in pain, Rosenthal's effect size was also calculated ($r = z/\sqrt{n}$). Participants who showed a pain reduction of at least 30% compared to the baseline value were defined as "responders" [17]. The proportion of responders was calculated and supplemented by an exact binomial test with a two-sided confidence interval (95%). In addition, a Spearman rank correlation test was performed for exploratory analysis to investigate the relationship between the reported time to improvement and pain reduction. The statistical tests were performed with a significance level of $\alpha = 0.05$.

Results

Descriptive analysis (Tables 1-7)

Table 1: Shows the descriptive statistics of the variables (*N* = 39).

Variable	n	Mean	Median	SD	Min	Max
pain_before	39	6.82	7	1.7	2	10
pain_after	39	3.28	3	2.16	0	8
Difference	39	3.54	4	2.77	-2	8

Table 2: Participants' responses to the question "The Flextrainer helped me with my symptoms" (*N* = 39).

Variable	*n*	%
Yes, clearly	21	53,8
Yes, a little	11	28,2
No, unchanged	6	15,4
No, the symptoms got worse	1	2,6

Table 3: Participants' responses to the question "Did you use the Flextrainer daily during the application period?" (*N* = 32).

Variable	n	%
Yes, (almost) daily	26	81,3
No	6	18,8

Table 4: Participants' responses to the question "Would you recommend the Flextrainer to someone?" (*N* = 39).

Variable	n	%
Yes	36	92,3
No	3	7,7

Table 5: Participants' responses to the question "Did you receive support from a treating physician or therapist during the application?" (*N* = 39).

Variable	*n*	%
Yes, from a physician	2	5,1
Yes, from a therapist	6	15,4
No	31	79,5

Table 6: Participants' responses to the question "Has a doctor ever recommended surgery (artificial joint replacement) for your joint problems, or have you considered such an operation yourself?" (*N* = 39).

Variable	*n*	%
Yes	23	59
No	16	41

Table 7: Participants' responses to the question "Were you able to avoid or postpone the planned surgery by using the Flextrainer?" (*N* = 23).

Variable	*n*	%
Yes	11	47,8
No	2	8,7
Still unclear	10	43,5

Statistical inference

The statistical analysis was performed using R (version 2024.04.2+764). To examine the change in subjective pain perception before and after using the JD device, a Wilcoxon signed-rank test for dependent samples was performed, as the difference values did not show a normal distribution. In addition, the effect size r was calculated, with a value of r = 0.75 indicating a large effect according to Cohen, 1988. The proportion of so-called responders was calculated to assess clinical relevance. Responders were defined as participants whose pain scores after use were at least 30% lower than at baseline. The responder rate was 71.8% (n = 28 of 39). For more precise classification, a 95% confidence interval was calculated using an exact binomial test. In addition, we investigated whether there was a correlation between the duration until subjectively reported improvement (in weeks) and the extent of pain reduction. A Spearman rank correlation was calculated for this purpose. This revealed a moderate positive correlation ($r_s = 0.53$, $p = 0.003$), suggesting that longer duration of use tended to be associated with greater pain improvement.

Test	Value
Wilcoxon-test	V = 461, $p < .001$
Effect size (r)	r = 0.75
Responder-rate	71.8 %
95%-CI Responder-rate	[55.1 %, 85.0 %]
Spearman-correlation	$\rho = 0.53$
p-value (Spearman)	$p = .003$

Discussion

Summary and interpretation of the results

The results of this pilot study indicate a significant reduction in subjectively perceived pain after using the JD device for home therapy. The observed difference in pain levels before and after the intervention was statistically significant, with a large effect size (r = 0.75) being found. In addition, more than two-thirds of participants experienced a pain reduction of at least 30%, which, according to IMMPACT recommendations, can be considered a moderate clinically relevant improvement and thus a therapeutic success [17]. The correlation between the duration of application and the extent of pain reduction was positive, suggesting a possible dose-response effect. These results support initial assumptions about the effectiveness of the JD device used as a non-invasive method for joint distraction in knee and hip osteoarthritis. The high responder rate in particular speaks for the practical relevance of the intervention. The observed effect is consistent with previous studies that have shown that mechanical joint distraction

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(both invasive and non-invasive) contributes to pain reduction and functional improvement [9,11-13]. It is noteworthy that the effect observed in this study was achieved despite the short duration of use and the low-threshold, home-based application, which emphasizes the flexibility and suitability of the method for everyday use. The results of the survey show that the JD device was used regularly to a high degree: 81.3% of participants reported daily use in a home environment. The subjective perception of effectiveness is supported by the fact that 82% of respondents reported relief from their symptoms through use of the device. With regard to the assessment of planned surgical procedures, 47.8% of participants stated that they were able to avoid or postpone knee or hip surgery through the use of the JD device. A further 43.5% were still undecided in this regard, while 8.7% had to undergo surgery despite using the device. In addition, 92.3% of participants stated that they would recommend the JD device they used, indicating an overall high level of satisfaction with the intervention. These results suggest that the use of the JD device studied was rated as helpful by the majority of users, particularly about pain reduction and subjective benefits in everyday life. With regard to the finding that almost half of the respondents reported being able to postpone or avoid surgery, these statements must be interpreted with caution. The retrospective survey design does not allow for establishing causal relationships between the use of the JD device and the decision against surgery. Other factors such as disease course, concurrent therapies, or individual patient preferences may also have contributed. The present results therefore only indicate a possible association, which needs to be verified under controlled conditions in future studies.

Mechanisms

Due to the selected outcome parameters (pain measured using the NRS, recourse to surgical intervention), we can only speculate about the underlying mechanism of symptom relief. If we transfer the current state of research from manual therapy to the autotraction performed, we find, among other things, biomechanical-structural (e.g., joint space widening), neurological (activation of the body's own pain inhibition), neuroimmunological (e.g., reduction of proinflammatory cytokines), neurovascular (e.g., altered blood flow), or neuromuscular (e.g., reduced muscle tone) factors [10]. The neurological mechanism in particular is currently considered to be the most important [10,18]. Permanent joint space widening and/or cartilage hypertrophy, as evidenced by invasive distraction therapy, cannot be ruled out. However, this is rather unlikely due to the significantly shorter duration of the intervention. However, since complete relief is not achieved even during invasive distraction [5], a structural effect could also be achieved with a much shorter intervention time in autotraction. This needs to be investigated in future studies.

Practical implications

The results of this pilot study indicate that non-invasive joint distraction using an approved JD device may be a promising, non-invasive method for reducing osteoarthritis pain. Especially for patients with knee or hip osteoarthritis who have exhausted conservative measures or wish to avoid or delay surgery, such as endoprosthetics, the JD device offers a low-threshold option with very few side effects compared to other therapies within a multimodal treatment concept. Regular use at home without the need for therapeutic supervision expands the possibilities for self-administered treatment of chronic joint pain, with significantly lower risk and effort compared to invasive distraction, as well as very low treatment costs. The high application rate (81.3%) and willingness to recommend (92.3%) indicate good acceptance and suitability for everyday use, especially among older or less mobile patients. There are also potential health economic benefits: almost half of those surveyed stated that the application had enabled them to avoid or postpone surgery. In the long term, this could lead to a reduction in healthcare costs due to a lower need for surgical interventions, pain medication, or rehabilitative measures. Joint distraction using the JD device used here could therefore not only be a valuable addition to existing conservative therapies, but also be relevant from a health economics perspective. If these initial therapy results are confirmed in a prospective randomized study, it would make sense from both an economic and preventive perspective to include this therapy in the catalog of therapeutic products in the future.

Outlook for the future

Due to the pilot nature of this study, the results should be considered preliminary. Future studies should include a larger, more representative sample and incorporate control groups to draw causal conclusions. Longer observation periods would also be useful to better assess the long-term effects of the treatment. Measuring additional parameters such as joint function, quality of life, or radiological changes could contribute to a more comprehensive assessment of the therapeutic potential. In addition, a direct comparison with established distraction methods in a randomized setting would be desirable in order to assess the effectiveness of noninvasive joint distraction with an approved JD device relative to existing procedures.

Strengths and weaknesses

A particular strength of this study lies in the fact that it was conducted under real-life conditions: the survey took place in the users' natural home environment, which ensures a high degree of ecological validity. In addition, the results show a statistically significant reduction in pain with a large effect size ($r = 0.75$), indicating that the intervention is substantially effective. Nevertheless, several limitations must be taken into account. The study design was not controlled, so there was no direct comparison group. There was also no randomised allocation of participants, which limits the significance of the findings with regard to causal relationships. Furthermore, all data is based on subjective self-assessments by the participants, which does not rule out potential bias due to memory effects or social desirability. The exclusive reliance on self-reported outcomes can be viewed as both a limitation and a strength of this pilot study. While no additional objective measures (e.g., imaging,

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functional tests) were available within the retrospective survey design, patient-reported outcomes (PROMs) such as pain relief and subjective benefit are considered highly relevant indicators in osteoarthritis research, as they directly reflect what matters most to patients and society. PROMs are frequently used as primary endpoints in registry and effectiveness studies and therefore provide an appropriate starting point for a pilot evaluation. Importantly, the observed effect size and responder rate from this survey offer valuable input for the design of the planned randomized controlled trial (RCT): they inform realistic sample size assumptions and support the choice of PROMs as primary outcomes, complemented by objective parameters as secondary endpoints. In this way, the current findings not only highlight the feasibility and patient relevance of non-invasive joint distraction but also pave the way for rigorous confirmation under controlled conditions. A further limitation concerns the retrospective design and the recruitment procedure. Data were obtained via an online survey among 39 existing users who voluntarily agreed to participate. This convenience sample entails the risk of selection bias (e.g., inclusion of more motivated or satisfied users) and therefore limits the generalisability of the findings. As this is an initial pilot study, the main objective was to gather initial evidence on the applicability and effectiveness of non-invasive joint distraction using an approved JD device in a home environment. A comprehensive, controlled clinical study is already planned. This study will specifically address the methodological weaknesses mentioned above, in particular by including a control group, more objective measurement methods, and a randomized study design.

Conclusion

This pilot study provides initial convincing evidence of the effectiveness of a device approved for non-invasive joint distraction in reducing osteoarthritis-related pain in the knee and hip joints. A significant proportion of users showed a marked improvement in symptoms under real-life conditions in their home environment, without direct therapeutic support. These results underscore the potential of non-invasive joint distraction both as a complementary measure to existing conservative treatments and as a standalone therapy option. Given its ease of use, high acceptance among users, and potential cost savings by avoiding surgery, its integration into existing standard therapy procedures for the treatment of gonarthrosis and coxarthrosis appears objectively reasonable. In addition, this study provides a robust basis for future controlled studies to further validate the observed effects and verify them under clinical conditions.

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