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## Abstract

**Background:** Knee osteoarthritis (OA) is a chronic, debilitating, musculoskeletal condition that affects millions. The increase in prevalence and its economic impact on healthcare and society raise the need for additional non-surgical interventions.

Utilising a non-surgical intervention in the

knee osteoarthritis care pathway: a 6-year

retrospective audit on NHS patients

**Objective:** To assess the referral rates to secondary care consultation and clinical outcomes in patients with severe knee OA treated with a home-based, non-surgical intervention. **Design:** This was a retrospective audit on 571 patients with knee OA who met the clinical criteria for total knee replacement (TKR) and received the service between October 2015 and March 2020.

**Methods:** Patients were treated with a non-surgical, home-based, biomechanical intervention that aims to reduce pain and improve function, involving a foot-worn device for gait rehabilitation. The device is adjusted to the patient based on their gait patterns and clinical symptoms. Patients are advised to use the device at home or work and continue their routine. Patients are also advised to return to follow-up appointments to readjust the device and treatment plan. The primary outcome measure was the referral rates to secondary care consultation. Secondary outcomes included patient-reported outcome measures to assess pain and function and a computerised gait test. Follow-up time was between 1 and 6 years post-treatment initiation with a mean follow-up time of 1308.1 (SD=473.4) days (i.e. 3.5 years.). **Results:** There were 65 (11.4%) referrals for secondary consultation with an average follow-up of 3.5 years. The mean days to referral was 480.9 (SD=399.2) days. Of all referrals, 48% (n=31) occurred during the first year of treatment, and 32% (n=21) occurred during the second year. The rest were after more than 2 years of treatment.

Significant improvements were seen in all clinical outcomes, including a reduction in pain and an improvement in function and gait patterns (p < 0.05 for all).

**Conclusion:** Utilising this intervention as a non-surgical option for patients with knee OA who met the clinical criteria for TKR led to a significant reduction in pain and improvement in function after 3 months that was maintained for up to 3 years. Most patients (89%) did not proceed to secondary care consultation during their time in treatment for up to 6 years.

## Plain language summary

# Utilisation of a non-invasive biomechanical intervention improves pain and function and helps postpone total knee replacement

Knee osteoarthritis is a degenerative disease that causes pain and functional limitations. Currently, most of the treatments aim to address symptoms (reducing pain and improving function). Those include traditional physical therapy, exercise, body mass loss if appropriate. Other treatments include pain relief medications and intra-articular corticosteroid knee injections. Knee surgery is considered the end-stage solution if the patient has tried all Correspondence to: **Robyn Benn** Circle Integrated Care, 30 Cannon Street, London, EC4M 6XH, UK **Robyn.Benn**(a circlehealthgroup.co.uk

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non-surgical interventions and is still in pain. The constant increase in the prevalence of knee osteoarthritis together with limited and short-term effect of the current treatment options, leads to an increase in the burden of knee osteoarthritis on healthcare and society. The purpose of this study was to assess the rates of referral to secondary care consultation and clinical outcomes after using a non-surgical, biomechanical, home-based intervention that focuses on gait rehabilitation amongst NHS patients diagnosed with knee osteoarthritis who meet surgical criteria. The results of the study suggest that 11% of the patients who meet the clinical criteria for a total knee replacement progressed to secondary care consultation. Utilising this intervention as a non-surgical option for patients with knee OA who meet the clinical criteria for TKR led a significant reduction in pain and improvement in function after three months that maintained for up to three years. Most patients (89%) did not proceed to secondary care consultation during their time in treatment. This intervention can potentially help reduce the likelihood of TKR and help manage the surgical waiting lists and the ongoing increase in demand for TKR due to the increase in prevalence and lack of effective non-surgical interventions.

*Keywords:* knee osteoarthritis, pain, function, gait, biomechanical treatment, TKR

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## Background

The global prevalence of knee osteoarthritis (OA) in individuals aged 40 years and older is almost 23%, equaling roughly 654 million people worldwide.<sup>1</sup> As of 2020, about 87 million people aged 20 years and older are diagnosed annually with knee OA.<sup>1</sup> The rates are expected to rise with the ageing of the population and obesity.<sup>2</sup> A recent report on the prevalence and incidence of knee OA in the United Kingdom suggests a prevalence rate of almost 11% and an incidence rate of 6.8 per 1000 person-years in those above 20 years of age.<sup>3</sup> About 20% of those over 45 years of age have knee OA.<sup>4</sup> Currently, the overall annual costs of OA to the UK healthcare system are estimated to be £10.2 billion and are expected to increase.<sup>5</sup>

National Institute of Clinical Excellence (NICE) guidelines for knee OA management were recently updated. They suggest core interventions to include exercise, education and body mass reduction when appropriate and topical Non-Steroidal anti-inflammatory drugs (NSAIDs). If symptoms are not resolved, additional interventions should be considered, including assistive devices, braces, and Transcutaneous electrical nerve simulation (TENS). Pharmacological treatment options include medications and corticosteroid injections to relieve pain and inflammation.6 The effectiveness of non-surgical interventions varies and all of them are short-termed. There is a need for innovative non-surgical interventions that will significantly

help reduce pain and improve function.<sup>7</sup> Moreover, interventions should focus on personalisation and optimisation of care management.<sup>8</sup>

The coronavirus disease 2019 (COVID-19) pandemic negatively affected patients with OA who experienced a disruption in access to the healthcare system, resulting in delays in treatment such as physiotherapy, intra-articular knee injection and joint replacement surgeries, leaving many patients untreated.9 Moreover, during the COVID lockdown period, the number of total knee replacement (TKR) surgeries performed annually fell to around a third of previous levels.9 Data by the Hospital Episode Statistics on admitted patient care indicate that the mean waiting time for TKR is substantially longer and has almost doubled during the COVID period (211 days in 2020-2021 compared with 120 days in 2018–2019).<sup>10</sup> This reality creates an urgent need to increase healthcare resources to accommodate the new incoming cases without adding to the backlog, addressing the existing backlog and preparing for the future increase in the prevalence of patients with sever knee OA.11

Recently, a study by Greene *et al.* reported their experience with a new non-surgical, home-based, biomechanical intervention for patients with knee OA. Their audit included 365 National Health Service (NHS) patients who met the criteria for orthopaedic referral as set out in the Clinical Commissioning Group Value-Based Commissioning Policy<sup>12</sup> and suggested that 84% of patients avoid a TKR at 2 years. In addition, this intervention was recently recommended by the NICE as a safe, clinically effective and cost-saving non-invasive treatment for patients with severe knee OA who cannot or do not want to have a surgery.<sup>13</sup> The NICE highlighted the need for longer-term data on surgery avoidance and their impact on the quality of life.<sup>13</sup>

Circle Health Group is the leading independent provider of hospital services in the United Kingdom. Part of this group, Circle Integrated Care, offers innovative musculoskeletal rehabilitation services and pathway management. Circle has been implementing this biomechanical intervention since 2015 and positioned it in the knee OA care pathway for patients who met the clinical criteria for TKR. Currently, the service is provided in clinical practices in Bedfordshire and Greenwich, covering a population of over 780,000. The aim of the current study was to assess the referral rates to secondary care consultation and clinical outcomes in patients with severe knee OA who were treated with a homebased, non-surgical intervention. It was hypothesised that the referral rates to secondary care consultations (i.e. primary outcome measure) would be low. Secondly, it was hypothesised that the low rate to secondary care consultations would be supported by reduced pain and improved function.

## Methods

#### Participants, design and setting

This was a retrospective analysis of 955 patients who were evaluated between October 2015 and March 2020. Patients received a routine referral to secondary care for knee OA and had a telephone appointment with MSK practitioner clinicians. As part of the shared decision-making (SDM) NHS framework, patients discuss the options for treatment, both surgical and non-surgical, including risks and benefits personalised to them. If they are suitable for this intervention they will be offered this within those options. Inclusion criteria were patients who met the surgical threshold for orthopaedic referral: Oxford Knee Score (OKS) < 20, radiological evidence of moderateto-severe knee OA, and whose symptoms have failed to improve from conservative management, as reported to their GP or another MSK clinician and discussed during a SDM telephone appointment (physiotherapy, activity modification, body mass management and non-steroid

were patients suffering from uncontrolled inflammatory conditions (e.g. rheumatoid arthritis); patients suffering from avascular necrosis of the knee; patients suffering from neuropathic arthropathy (Charcot's joint); patients exhibiting a lack of physical or mental ability to perform or comply with the treatment; patients with a history of pathological osteoporotic fracture; patients whose main complaint is another lower limb joint other than the knee and patients who are unsafe to participate in the treatment and fail to pass the balance protocol at the initial consultation (balance screening tool). Once referred into the service, specially trained physiotherapists assessed the patients, and the suitable ones were enrolled in the programme. All patients who started treatment signed a consent acknowledging that their data might be used for research while maintaining their privacy. Of the 955 patients who were referred to treatment and evaluated in clinic, 100 were found to be unsuitable (for safety reasons such as poor balance) during the initial consultation, and 55 were treated outside of Bedfordshire and were not included in this analysis because they started treatment years later than the rest of the group. Of the 800 patients, 157 had primary hip OA and were not included in the analysis. Seventy-two patients were missing information about their primary pain area and were also not included in the analysis. Finally, 571 (N=571) patients with knee OA participated in this study. NHS Research Ethics Committee's approval was not required under the UK Policy Framework for Health and Social Care Research as this data are unidentifiable. Furthermore, Health Research Authority's approval is also not required for this research database. This study complies with the Strengthening the reporting of observational studies in epidemiology (STROBE) statement.14

anti-inflammatory medication). Exclusion criteria

#### Intervention

All patients received a personalised, non-invasive, home-based, biomechanical treatment that aims to alleviate knee pain and improve function (AposHealth<sup>®</sup>). The device uses a shoe as an interface to attach two convex pods to the plantar surface of the sole using screws (Figure 1). A specially trained physiotherapist calibrates the device based on a treatment methodology that includes an assessment of gait patterns, symptoms and physical examination. The clinician calibrates the device individually to the patient and positions the convex pods to reduce pain in the knee while walking. Adjusting the location of the pods

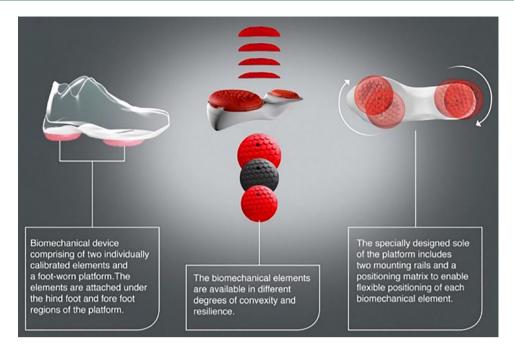


Figure 1. Apos system.

changes the center of pressure and the ground reaction force vector and reduces pressure on the area immediately.<sup>15-17</sup> The convex nature of the elements induces a level of controlled perturbation for neuromuscular training.18,19 Once the initial consultation and device calibration is completed, patients receive a home-based treatment plan. This includes wearing the device for approximately 20 min daily while doing regular tasks at home or work. Typically, patients gradually increase the device wear time for up to 2-3h per day indoors. Depending on their progress, some patients will be encouraged to add outdoor walking. In addition, patients are advised to return to follow-up appointments to recalibrate the device and adjust the treatment plan as needed.

## Outcomes

A clinical audit (i.e. a review of all patients who were treated with this intervention from the inception of the programme to the date of audit) was performed to identify and retrieve outcomes. The primary outcome measure was the referral rates to secondary care consultation, including the service type and sub-service classification, between the commencement of treatment and the audit date (January 2022). Secondary outcome measures included two patient-reported outcome measures and a computerised gait test. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)<sup>20</sup> questionnaire and the OKS<sup>21</sup> were used to assess changes in pain and function. The WOMAC questionnaire contains 24 visual analogue scale (VAS) questions that can be divided into three subcategories (Pain: 5Q, Functional Limitation: 17Q, and Stiffness: 2Q). Results range between 0 and 100 mm, in which 0 mm indicates no pain or limitation in function and 100 mm indicates the most severe pain or limitation in function. The OKS was developed and validated for use with individuals undergoing knee arthroplasty and measured outcomes following rehabilitation of patients with knee OA. It contains 12 Likert Scale questions. Results range from 0 to 48, where 0 reflects the worst condition and 48 is the best.<sup>16,17</sup>

A computerised spatiotemporal gait assessment, OptoGait system (Microgate Corporation, Version 1.11), was used to assess the gait velocity (cm/s).<sup>22</sup> Patients walked barefoot at a self-selected speed over a 4m measurement area, with 2m before and after to allow for sufficient acceleration and deceleration time outside the measurement area.

## Statistical analysis

Data were analysed with IBM SPSS statistics software version 28.0. (SPSS Inc. Headquarters, 233 S. Wacker Drive, 11th floor Chicago, Illinois 60606, USA). The significance levels were set at 0.05.

Parameter	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Ν	571	520	320	228	102	15
Age	65.6 (8.4)	65.2 (9.3)	64.9 (9.7)	66.7 (8.0)	66.3 (7.9)	60.7 (9.0)
Gender (F/M)	360/221	333/187	202/118	130/98	56/46	5/10
Pain	55.5 (19.6)	56.8 (20.5)	55.9 (19.9)	57.3 (18.2)	53.9 (19.1)	61.7 (17.6)
OKS	23.4 (7.1)	22.1 (6.6)	22.6 (8.0)	20.9 (6.6)	22.5 (6.3)	21.8 (6.3)
There were no significant differences between groups in baseline characteristics.						

Table 1. Subgroup characteristics. Results are presented as frequencies for gender and mean (SD) for age and pain.

OKS, Oxford Knee Score.

Data were presented as mean, standard deviation and 95% confidence interval (CI) for continuous variables and as frequency and percentage for categorical variables. Repeated measures model was used for the four continuous outcomes with up to five time periods: baseline, 3 months, years 1, 2 and 3. The general linear mixed model provides a valuable approach to analyse the unbalanced repeated measures data. It was used to assess the changes over time while accounting for missing data. In addition, a sub-cohort of patients with complete data set was analysed and used for sensitivity analysis to support the general linear model results. Therefore, changes over time are based on the available data points and their *p*-values, assuming they reflect the entire cohort. Two subgroup analyses were performed to provide more information to help interpret the results, including their long-term outcomes and potential contributors to referral rate and clinical response. First, a subgroup analysis of the referral rates to secondary consultation in patients with different amounts of time spent in treatment was conducted (i.e. at least 1 year, 2 years, 3 years, 4 years, 5 years and 6 years). Second, a comparison of the baseline characteristics and clinical outcomes between those who received a referral to secondary care consultation and those who did not was done.

## Results

A total of 571 patients with knee OA (365, 65% females) with a mean age of 65.6 (SD = 8.8) years were included in this analysis. All patients completed at least 1 year of follow-up. The number of patients thereafter were 520 (91%) at 2 years, 320 (56%) at 3 years, 228 (40%) at 4 years, 102 (18%) at 5 years and 15 (3%) at 6 years. The average days from treatment initiation to audit date was 1308.1 (SD=473.4) days per patient.

Overall, there were 73 referrals for secondary care. Of them, 68 referrals were for orthopaedic services, 2 were issued before treatment initiation and 1 was missing a referral date, leaving a total of 65 (11.4%) valid referrals for secondary consultation. The mean days to referral was 480.9 (SD=399.2) days. Of all referrals, 48% (n=31)occurred during the first year of treatment, 32% (n=21) occurred during the second year, 12% (n=8) occurred during the third year and the rest were after more than 3 years into treatment.

A subgroup analysis of the referral rates to secondary consultation in patients with different time spent in treatment was conducted. Six subcohorts were identified, comprising of patients who have been in treatment for at least 1 year, 2 years, 3 years, 4 years, 5 years and 6 years. There were no significant differences between groups (i.e. sub-cohorts based on time since inception) in baseline characteristics, including age, gender and pain levels (Table 1). The progression to secondary care was similar across all sub-cohorts, most occurring during the first 2 years (Table 2).

The attendance follow-up rates at 3 months, 6 months, 1 year and 2 years follow-up appointments were 80, 75, 62, 44 and 21%, respectively. Significant improvement was seen in all clinical outcomes after 3 months and maintained for up to 3 years. Pain decreased by 43.2% from an average (SD) [95% CI] of 56.4 (19.5) [54.8-58.0] to 32.0 (23.5) [27.6–91.4] at 3 years, p < 0.001, F=4.661. Functional disability improved by 41.2% from an average (SD) [95% CI] of 55.1 (20.3) [53.4-56.8] to 32.4 (23.9) [30.4-34.4] at

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Year	6-year FU ( <i>n</i> = 15) (%)	5-year FU ( <i>n</i> = 102) (%)	4-year FU ( <i>n</i> =228) (%)	3-year FU ( <i>n</i> = 320) (%)	2-year FU ( <i>n</i> =520) (%)	1-year FU ( <i>n</i> = 571) (%)
Year 1	100	94	95	94	94	95
Year 2	100	89	92	91	92	-
Year 3	100	89	91	90	-	-
Year 4	100	89	90	-	-	-
Year 5	100	88	-	-	-	-
Year 6	100	_	-	-	-	
FU, follow-up.						

Table 3. Clinical outcomes following 3 years of treatment are presented as mean (SD) [95% CI].

Parameter B	Baseline	3 months	Year 1	Year 2	Year 3
Pain 56	6.4 (19.5) [54.8–58.0]	40.1 (23.5) [38.1–42.1]	37.6 (25.1) [35.1–40.2]	35.3 (23.7) [32.5–38.1]	32.0 (23.5) [27.6–36.5]
Function 55	5.1 (20.3) [53.4–56.8]	40.2 (24.2) [38.2–42.3]	37.6 (24.9) [35.1–40.1]	36.3 (24.4) [33.4–39.2]	32.4 (23.9) [27.9–36.9]
Velocity 86	6.0 (17.0) [84.5–87.5]	97.4 (17.6) [95.9–98.9]	100.5 (18.4) [98.5–102.5]	103.1 (18.8) [100.7–105.5]	107.3 (20.6) [103.0–111.6]

Pain and function are measured using the WOMAC VAS scale. Results are measured on a scale between 0 and 100, where lower scores indicate less pain and better function. Gait velocity is expressed in cm/s.

VAS, visual analogue scale; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

3 years, p < 0.001, F = 4.851. OKS increased by 29.2% from an average (SD) [95% CI] of 21.9 (6.9) [21.1–22.7] to 28.3 (9.3) [27.3–29.3] at 12 months, p < 0.001, F = 15.477. Gait velocity has increased by 24.8% from an average (SD) [95% CI] of 86.0 (17.0) [84.5–87.5] to 107.3 (20.6) [103.0–111.6] at 3 years, p = 0.013, F = 3.267. Table 3 summarises the clinical outcomes over time.

There were significant differences in the clinical response between patients who received a referral to secondary care consultation and those who have not. Patients who received a referral for secondary care consultation demonstrated less improvement compared to those who avoided it (p < 0.001, F=30.147 for pain; p < 0.001, F=23.686 for disability; p < 0.001, F=15.477 for OKS and p=0.009, F=6.957 for gait velocity). Figure 2 illustrates group differences in clinical response over time.

#### Discussion

This study aimed to report the referral rates to a secondary care consultation and clinical outcomes

in patients with severe knee OA who met the surgical threshold for orthopaedic referral while treated with a non-surgical, home-based, foot-worn device. Results suggest that 11.4% of patients required a referral for secondary care consultation at an average follow-up rate of 3.5 years. Knee OA is a debilitating chronic condition that affects the patient's ability to perform daily activities and significantly compromises their quality of life. Current guidelines suggest a limited number of non-surgical options to manage symptoms, most of them with limited and short-term effects.7,23,24 New nonsurgical interventions are urgently needed to help manage the growing number of knee OA incidences as well as optimising and personalising care management.<sup>8</sup> More specifically, introducing new treatment options will help address the surgical waiting lists, which have doubled since COVID-19, and are constantly increasing, posing an immense burden on healthcare and society. Recently, NICE recommended new adapted shoes for patients with knee OA who met the clinical criteria for TKR but cannot or do not want to have a surgery.<sup>13</sup> The treatment has been utilised as part of the musculoskeletal pathway management and

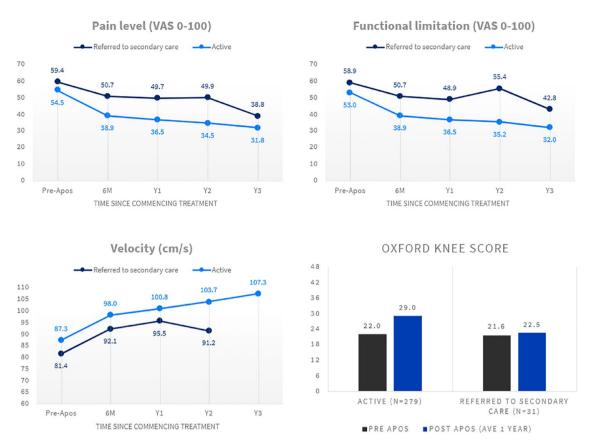


Figure 2. Clinical outcomes in patients who received a referral for secondary consultation and those who have not.

Post-Apos OKS shows the most recent record, reflecting median, (inter-quartile range) of 374.5 (210.5–616.5) days from treatment initiation to questionnaire completion.

The number of active patients with questionnaire data was 479, 348, 257 and 105 at 6 months (6M), 1 year (Y1), 2 years (Y2) and 3 years (Y3), respectively.

The number of active patients with gait data was 459, 309, 219 and 84 at 6M, Y1, Y2 and Y3, respectively.

The number of patients who received a referral to secondary care consultation and have questionnaire data was 56, 32, 14 and 4 at 6M, Y1, Y2 and Y3, respectively.

The number of patients who received a referral to secondary care consultation and have gait data was 55, 24 and 11 at 6M, Y1, and Y2, respectively.

service since 2015 and have treated over 1000 patients to date. The results of the study are slightly better than previous publications that reported the rates of TKR among patients with severe knee OA. Drew *et al.* looked at surgery avoidance among 237 patients with knee OA who were surgical candidates, suggesting that 86% avoided TKR at 2 years.<sup>25</sup> Greene *et al.* reported the outcomes of an audit that was done on 365 NHS patients with knee OA who met the clinical criteria for TKR and received this intervention after exhausting all other non-surgical interventions. Their results suggest an 84% surgery avoidance at 2 years.<sup>12</sup> For comparison, McHugh *et al.* looked at the surgical rates of patients with severe knee OA who had a GP

referral for TKR consideration.<sup>26</sup> Their study showed that 33% of patients who receive a referral for TKR would have it within 12 months.<sup>26</sup> It may be assumed that most patients will have it within 3 years. In this trial, all patients have met the clinical criteria for TKR and have exhausted all other non-surgical interventions. In theory, their next option was to go on to secondary care consultation, but instead, they were offered a dedicated SDM appointment and chose this intervention as their last non-surgical option. The results demonstrate that most patients did not receive a referral for secondary care consultation, suggesting that the surgical option is currently on hold or even aborted. One explanation for the low referral rates is the clinical improvement reported by patients. Previous studies found that pain is a primary contributor to the decision to progress with TKR.27 A recent study used data from the OA Initiative and evaluated the relationship between pain reduction and the prevention of TKR. They found that the risk for TKR decreased when pain decreased.<sup>28</sup> Moreover, there is a greater reduction in TKR when pain decreases more and when interventions are introduced at lower pain levels.28 Therefore, any improvement in symptoms is likely to reduce the risk of having TKR. One way to quantify the clinical relevance of the improvement is to use the minimum clinically important difference (MCID), which represents the smallest improvement considered worthwhile by a patient.<sup>29</sup> In the current study, patients reported a significant reduction in pain and improvement in function and objective gait velocity, meeting the recommended MCID.30,31 The symptomatic improvement following the use of the device is attributed to two biomechanical mechanisms. First, positioning the pods changes the centre of pressure to alleviate loads from the affected joint.<sup>16</sup> Second, neuromuscular training is applied via controlled perturbation,18,32 both leading to gait rehabilitation and acquiring healthier gait patterns.33

Some limitations should be acknowledged. First, this study lacked confirmation on actual TKRs. Having actual rates of surgery avoidance could support an economic calculation of cost savings. However, even when using the referral rates to secondary consultation as a worst-case scenario, the potential cost savings are significant and support previous findings.<sup>12,25,34</sup> Secondly, this was a retrospective registry analysis with no control group. Without a control group it is difficult to determine the effectiveness of the intervention and its ability to reduce referral rates to secondary care consultations. However, the musculoskeletal rehabilitation services triage centre determined eligibility and referred patients to the programme. Thirdly, patients were allowed to have other treatments in parallel to the examined one which might have a potential bias in interpreting the results. The examined intervention is already a part of the NHS pathway, and we cannot control for primary care or private practice interventions that may have occurred simultaneously. This is rare as most patients have tried all other options and if they are not working they are not likely to continue them. Currently, this intervention is

positioned as a last non-surgical intervention and an alternative to surgery. It is reasonable to assume that patients have already tried all other treatment modalities, and that the outcomes of this study can be primarily attributed to the intervention.

Some strengths should also be acknowledged. This intervention was utilised in clinical practice settings and demonstrated an ability to integrate this intervention within musculoskeletal rehabilitation services and pathway management, which should help with adoption across other clinics. Secondly, utilising this intervention in clinical practices as part of the care pathway allows broader accessibility, including more flexible inclusion criteria (i.e. secondary complaints and comorbidities) and lenient monitoring protocol. The significant reduction in pain and improvement in function that were reported by patients indicate that the examined intervention is sustainable and effective when generalised to the population outside of research settings. Lastly, clinicians were unaware that the data would be used for research purposes. Therefore, reducing bias and strengthening the credibility of outcomes.

## Conclusion

The results of the current study provide additional evidence of the long-term outcomes of a non-surgical biomechanical intervention that NICE recently recommended. The results suggest that the majority of patients with severe knee OA who met the clinical criteria for TKR and were treated with the device did not proceed for secondary consultation, most likely due to relief in pain and improvement in function. This intervention can potentially help reduce the likelihood of TKR and help manage the surgical waiting lists and the ongoing increase in demand for TKR due to the increase in prevalence and lack of effective non-surgical interventions.

## Declarations

#### Ethics approval and consent to participate

NHS Research Ethics Committee's (REC) approval was not required under the UK Policy Framework for Health and Social Care Research as this data are unidentifiable. Furthermore, Health Research Authority's approval is also not required for this research database.

## Consent for publication

All patients who started treatment signed a consent that acknowledges that their data might be used for research purposes while maintaining their privacy

#### Author contributions

**Robyn Benn:** Conceptualization; Data curation; Formal analysis; Project administration; Writing – original draft.

**Lewis Rawson:** Data curation; Project administration; Writing – review & editing.

**Amanda Phillips:** Conceptualization; Formal analysis; Supervision; Writing – review & editing.

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#### Competing interests

The authors declare that there is no conflict of interest.

## Availability of data and materials

The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

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