Sensor-based measures of knee brace adherence have low agreement with self-report methods: A multi-measure study among knee osteoarthritis patients.

CALLAGHAN, Michael J, FELSON, David T, HOLDEN, Melanie A, BORRELLI, Belinda, NICHOLLS, Elaine, BIRRELL, Fraser, FOSTER, Nadine E <http://orcid.org/0000-0003-4429-9756>, HALLIDAY, Nicola, INGRAM, Carol, JINKS, Clare, PEAT, George <http://orcid.org/0000-0002-9008-0184> and PROP OA TEAM (SEE TABLE S1)

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Michael J. Callaghan [a b 1 *], David T. Felson [b c 2], Melanie A. Holden [d 3], Belinda Borrelli [e f g 4], Elaine Nicholls [d h 5], Fraser Birrell [i j 6], Nadine E. Foster [k 7], Nicola Halliday [h 8], Carol Ingram [l], Clare Jinks [d 9], George M. Peat [d m 10], On behalf of the PROP OA team (see table S1)

[a] Department of Health Professions, Faculty of Health and Education, Manchester Metropolitan University, Manchester, UK
[b] NIHR Manchester Biomedical Research Centre, Manchester University Foundation NHS Trust, Manchester, UK
[c] School of Medicine, Boston University, Boston, MA, USA
[d] School of Medicine, Primary Care Centre Versus Arthritis, Keele University, Keele, UK
[e] Faculty of Biology, Medicine & Health, The University of Manchester, Manchester, UK
[f] Henry M. Goldman School of Dental Medicine, Boston University, Boston, Mass, USA
[g] School of Health Sciences, Division of Psychology and Mental Health, Manchester Centre for Health Psychology and Manchester Academic Health Science Centre, The University of Manchester, Manchester, UK
[h] Keele Clinical Trials Unit, Keele University, Keele, UK
[i] Medical Research Council Versus Arthritis Centre for Integrated Research into Musculoskeletal Ageing, Population & Health Sciences Institute, Newcastle University, Newcastle upon Tyne, Tyne and Wear, UK
[j] Northumbria Healthcare NHS Foundation Trust, North Shields, Tyne and Wear, UK
[k] STARS Education and Research Alliance, Surgical Treatment and Rehabilitation Service (STARS), The University of Queensland and Metro North Health, Brisbane, Queensland, Australia
[l] Patient representative and author, Keele, UK
[m] Centre for Applied Health & Social Care Research (CARe), School of Health and Social Care, Sheffield Hallam University, Sheffield, UK

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ABSTRACT

Objective: To explore agreement between self-report and objectively measured adherence to brace wearing by patients with knee osteoarthritis.
Method: A single-arm observational analysis nested within the PROP OA randomised controlled trial (ISRCTN28555470). Of 237 adults with symptomatic knee osteoarthritis randomised to brace treatment, 60 were included in this sub-study investigating three different methods of assessing knee brace wear time over 26 weeks: 1. Self-report questionnaires (SRQ) at 12 weeks and 26 weeks; 2. Short message service (SMS) questions (days worn in past week, typical hours per day when worn) administered from week 1 to week 24; 3. A skin temperature sensor embedded in the brace, sampling every 10 min for 26 weeks. The presence and reason for the sensor were concealed from participants. The estimated proportion of participants meeting "minimum brace use", defined a priori as ≥1 h on ≥2 days in past week, was described for each measurement method, overall and by brace type (unloader, neutral). For temperature sensor

* Correspondence to: Department of Health Professions, Manchester Metropolitan University, Manchester M15 6GX, UK.
E-mail address: Michael.callaghan@mmu.ac.uk (M.J. Callaghan).
[1] https://orcid.org/0000-0003-3540-2838
[2] https://orcid.org/0000-0002-2668-2447
[3] https://orcid.org/0000-0003-0374-2862
[4] https://orcid.org/0000-0002-0859-796X
[5] https://orcid.org/0000-0001-5643-616X
[6] https://orcid.org/0000-0002-6163-6155
[7] https://orcid.org/0000-0003-4429-9756
[8] https://orcid.org/0009-0003-8925-6124
[9] https://orcid.org/0000-0002-3407-2446
[10] https://orcid.org/0000-0002-9008-0184

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measurements, time spent above 24°C and time spent above 25°C were used. Agreement between the measures was summarised by percentage agreement and kappa (κ).
Results: The estimated proportions of participants meeting "minimum brace use" at 12 weeks were 83% (SRQ), 83% (SMS), 60% and 58% (temperature sensor, 24°C and 25°C thresholds, respectively). At 26 weeks, the corresponding estimates reduced to 72%, 71% (SMS at 24 weeks), 43% and 37%. Sensor data suggested the sharpest decline in brace use occurred within the first 12 weeks. Agreement between self-report measures was higher than between self-report measures and sensor (SRQ vs SMS at 12 weeks: 92% agreement, κ=0.67 (95%CI: 0.34, 1.00); SRQ vs Sensor at 12 weeks: 74%, 0.35 (0.10, 0.60); SMS vs Sens at 12 weeks: 76%, 0.36 (0.05, 0.66). Agreement between all measurement methods reduced at 26 weeks.
Conclusions: This novel use of a temperature sensor to monitor brace adherence in knee osteoarthritis indicates that self-report adherence substantially overestimates knee brace wearing time, with implications for clinical trials and practice.

Introduction

Monitoring treatment adherence is a vital element in evaluating an intervention's effectiveness in both clinical practice and research for osteoarthritis (OA) [1]. Adherence to treatment is defined by the World Health Organisation (WHO) as the extent to which a person's behaviour corresponds with agreed recommendations from a health care provider. Indeed, improving patient adherence is one of the WHO's major research priorities [2]. Treatments are unlikely to be effective if patients do not adhere to a treatment program. The accurate assessment of adherence is necessary for effective and efficient treatment planning [2].

International practice guidelines offer conflicting recommendations on the use of knee bracing for knee OA [3]. Several bodies and guidelines have strongly or conditionally recommended bracing for knee OA [4]. In contrast, the National Institute for Health and Care Excellence (NICE) concluded that the routine use of insoles, braces, tape, splints or supports was not supported by sufficient evidence and that further research was needed on devices, with consideration for a larger number of participants, sufficient blinding and allocation concealment [5].

A systematic review of adherence measures for orthotics identified two trials for knee bracing supplied after trauma or surgery and highlighted a lack of consistency in the methods, timing and frequency of adherence measurement [6]. Adherence to wearing external devices such as knee braces is known to be problematic due to wear discomfort, skin irritation, poor fitting, and their bulky appearance [7]. Additionally, many studies do not report adherence because of the difficulties in measuring treatment adherence accurately and reliably [8]. Reviews on adherence to OA treatments in joints outside the knee have noted that the majority of the measurement tools are self-report measures [6,9]. Although self-report adherence measures are inexpensive, practical and simple to use, patients may be unlikely to admit to non-adherence [10], and difficulty recalling adherence over time may lead to high levels of random error and systematic bias (typically overestimating adherence).

There has been little evidence on the role of adherence to brace wearing in achieving symptomatic relief from painful knee OA. A brace trial in patellofemoral OA provided data to indicate that for every hour the brace was worn daily, there was a 1 mm decrease in pain score on a 0–10 visual analogue scale [11]. However, these data were obtained through direct questioning which is known to affect participants' responses. Evaluating knee brace wear time objectively and independently would help to understand the link between treatment adherence and effectiveness.

In terms of objective measures of adherence, using temperature sensors to measure brace wearing time was highlighted in a recent review, which suggested they provide quantitative, objective data that are beneficial in both clinical and research settings [12]. Temperature sensors have been used in upper limb [13], hip [14], and lower limb braces [15] and foot orthoses [16]. However, none of these studies involved knee OA. Although Stetter et al. [17] used four different sensors (including temperature) to measure wear time in an OA knee brace over 6 weeks, there were no self-report measures of adherence, making our sub-group analysis the first to compare patient self-report and objective brace-wearing adheence measures for this common condition.

We used temperature as a surrogate measure of brace wearing adherence. We aimed to assess agreement between the amount of brace wearing between self-reported measures of adherence (short message service (SMS) and self-report questionnaire) and the brace-wearing time from a temperature sensor embedded within the brace. Based on previous studies comparing self-report and 'objective' adherence in other fields [18] (including medication adherence [19]) we hypothesised that self-report questionnaires would overestimate brace adherence up to 26 weeks follow-up. We also describe the patterns of adherence over time by brace type (unloader, neutral) based on estimates from each of the three measurement methods.

Method

This was a single-arm observational sub-analysis within the PROP OA randomised controlled trial ("parent trial" (ISRCTN28555470) [20,21]. The study was approved by Northwest Preston Research Ethics Committee, the Health Research Authority and Health and Care Research in Wales (REC Reference: 19/NW/0183; IRAS Reference: 247370). All participants gave their written, informed consent. We compared three measurement methods to explore patterns of brace use within the same subsample of trial participants over a 26 week period. Measurement methods were: two-way SMS text messages administered on a fixed, tapering schedule at 1,2,3,4,6,8,10,12,16,20, finishing at 24 weeks; a conventional self-report questionnaire administered by post or online at 12 and 26 weeks; a temperature sensor embedded in the brace and sampling local skin temperature every 10 min for 26 weeks. We sought to blind participants to the presence and purpose of the temperature sensor. The REC-approved protocol and Participant Information Sheet provided limited disclosure, stating only that some braces could be fitted with a device to monitor the brace. The sensors were attached to the unloader and neutral braces, concealed from participants, but who were informed of the presence of the temperature sensor after the 6 month primary endpoint. Analysis focused on comparing the estimated proportion of participants meeting a prespecified minimum criterion for brace wear adherence in a given week based on temperature threshold (see Data Analysis section below).

Overview of PROP OA trial

The parent trial - PROvision of braces for Patients with knee OsteoArthritis (PROP OA) - was a multi-centre, primary care, randomised (1:1), parallel-group, superiority trial of advice, written information, and exercise instruction plus knee brace (AIE+B) versus advice, written information, and exercise instruction alone (AIE) for adults with painful knee OA. Participants were recruited via general practices and the community around four regions in England and enrolled between November 2019 and September 2022. Trial interventions were delivered by trained physiotherapists. The primary endpoint for the clinical effectiveness analysis of the parent trial was at 26 weeks. Participants were instructed to wear the brace on painful weight-bearing activities, with a starting minimum usage of 1 h on at least 2 days/week. This was gradually increased based on tolerance to a maximum of 8–12 h/day. Patients were advised to wear the brace up to the primary end point at 26 weeks and continue to wear it beyond this time if they found it beneficial.

Participants

For this analysis of brace adherence, we focused on trial participants randomised to the brace intervention. Participants were adults aged 45 years and over with painful knee OA, fulfilling PROP OA trial eligibility criteria (Table S2) and randomised to AIE+B. Additional inclusion criteria for the current study were: a participant was issued a medial compartment unloading or a neutral brace (the temperature sensor could not be fitted to the patellofemoral brace used in PROP OA (Bioskin Q) as there was no obvious method of concealed attachment other than cutting into the brace material); a temperature sensor was returned after 26 weeks; a completed self-report questionnaire with items on brace wearing at the same time point. Participants were instructed to wear their brace under loose fitting clothes next to the skin.

Setting

Participants were recruited from NHS general practices and from self-referral within the community following an awareness raising campaign. The interventions were delivered within PROP OA community knee pain clinics held in NHS physiotherapy services within four regions in England: Staffordshire, Cheshire, Greater Manchester, and North Tyneside.

Data collection

Self-report questionnaires

Self-report questionnaires were sent to participants at 12 weeks and 26 weeks follow-up. They asked similar adherence questions to those we have used in previous trials of non-pharmacological care for OA [22] (**see** Table 1).

Two-way SMS text message

Two-way SMS text messages were sent by Keele Clinical Trials Unit (CTU) to all participants' mobile phones on a fixed, tapering schedule over the first 6 months of follow-up (1, 2, 3, 4, 6, 8, 10, 12, finishing at 24 weeks). Question phrasing and response options are in Table 1.

Temperature sensor

We identified a small and light temperature sensor (3.3 g; 17.3 mm x 5.9 mm; iButton DS1925L Thermochron Data Logger, Analog Devices, Wilmington, MA, USA) to objectively assess brace wearing adherence (Figure 1). The iButton is a wireless peripheral thermometry device. It is an inexpensive, practical method for obtaining valid human skin temperature accurately and continuously over long periods of time while allowing participants to continue normal daily activities [23]. When the brace is worn and the sensor is close to the skin, the temperature recorded by the sensor rises. It can detect temperature change even when fabric lies between the skin and the sensor [24]. It has been shown to be valid and accurate with an overall mean skin temperature difference between iButtons and calibrated thermocouples of ± 0.3°C [25]. It has been used in bracing studies for other conditions [14,15,24]. Healthy volunteer pretesting for this study confirmed the sensor was sensitive to detecting an increase in skin temperature after donning a neutral brace with a clear temperature difference between wearing and not wearing of typically 8°C. The temperature recordings were time stamped and accurate to ± 0.5°C. Sensors were fitted into the unloader (Össur Unloader One) and neutral (Össur Formfit) braces. The sensor on the Unloader one was in direct contact with the skin. The neutral brace's sensor was inserted in the material and not directly against the skin (Figures S1A, S1B).

Due to a limited supply of sensors, not all unloader and neutral braces had a sensor attached. Sensors were attached as available, creating a non-random sample of the PROP OA participants for this analysis. All PROP OA trial participants were informed that some knee braces would be fitted with a small, battery-operated sensor to check how the brace is working. Each sensor had a unique identification number in its memory. When the sensors were returned after 26 weeks, data were downloaded from the sensor to a PC or laptop via a USB interface and 1-wire iButton receptor cable.

SMS text message (1, 2, 3, 4, 6, 8, 10, 12, 16, 20, 24 weeks)	
Over the past 7 days, on how many days have you worn your knee brace for more than one hour per day? Please enter a number from 0 to 7On days that you wore the brace, for about how many hours per day did you wear it? Please enter a number from 1 to 24	
Self-reported questionnaires (12 weeks and 26 weeks)	
Over the past 7 days, on how many days have you worn a knee brace for more than one hour per day? (0–7 days)On the days that you wore the brace, for about how many hours per day did you wear it? (1–24 h)	

Table 1 Osteoarthritis and Cartilage

Self-reported questions used to determine if participants met the minimum criterion for brace use.

Fig. 1 Osteoarthritis and Cartilage

The iButton.

Data analysis

A review of studies in healthy volunteers and clinical populations noted a range of approaches to determine the optimal temperature threshold to define wearing and non-wearing of external devices [12]. These include absolute temperature thresholds (e.g. 24°C for a hip abduction brace, 25°C for an insole, and 35°C for a shoulder brace), group-specific or person-specific temperature thresholds (e.g. above sample mean), and more complex algorithms (e.g. based on speed and magnitude of change in temperature). This study opted for an absolute threshold approach. To determine a reasonable temperature threshold for this analysis four researchers (GP, MJC, MAH, DTF), independently inspected the temperature plots from six purposively selected participants. These six plots were selected based on the appearance of high, low or intermittent temperature changes between 0600 and 2400 h each day for up to 26 weeks each. We considered three absolute (24°C, 25°C, and 35°C) and three person-specific temperature thresholds (median, 95th percentile, 99th percentile of temperature readings obtained between 0000 and 0600 h when the brace would not be worn, calculating and comparing the total number of minutes above each threshold per day and the number of days with ≥60 min above threshold. The four researchers agreed on the absolute thresholds of 24°C and 25°C being optimal and consistent with healthy volunteer testing to decide if a patient was wearing a brace or not. The process of selecting an optimal threshold was conducted without knowledge of, or reference to, any other data on the participants, including the self-reported measures of brace adherence.

Anonymised temperature sensor data on all participants were initially displayed as a histogram using one-wire Viewer software (Maxim Integrated Products, Inc.), imported as.csv files into in R4.3.1/RStudio for cleaning, processing, and analysis. For each participant we summarised daily total minutes above 24°C and 25°C between 0600 and 2400 h (participants were advised to remove their braces at night time), dichotomised this at ≥60 min, and calculated the proportion of participants meeting the pre-specified minimum criterion of brace use for ≥1 h on at least 2 days in each week. We plotted the proportions and calculated agreement (percentage agreement, unweighted kappa coefficients) between each method focusing on 12 weeks timepoint for all three methods and 24 weeks (for SMS) and 26 weeks (for self-report questionnaire and sensor). In secondary analysis we compared the estimated proportion of 'adherent' participants by brace type (unloader brace versus neutral brace). Missing data from each of the three measurement methods were described, and available case analysis was conducted for all analyses.

Results

The parent trial had 237 participants randomised to the brace arm. Eighty six were assigned the Össur unloader brace, 25 of which had an sensor; 55 were assigned the Bioskin Q brace, none of which had a sensor; 94 were assigned the Össur Formfit brace, 35 of which had a sensor. Two participants were not given a brace at the initial treatment session due to broken skin/psoriasis on the knee and difficulties fitting the brace.

This analysis focused on 60 participants who were randomised to a brace, fitted with a sensor, and who returned the sensor, SMS text messages and the self-report questionnaire after 26 weeks. The sample comprised of 31 women (52%, mean age 64.6 (SD 8.9 years), with moderate to severe pain intensity (mean (SD) 6.1 (1.8) on a 0–10 numerical rating scale) and included participants from across all four clinical sites (Table 2).

Missing data were highest for SMS text message measures, ranging from 20% to 42% across all timepoints. Temperature sensor data could not be retrieved for the first two weeks from 14 (23%) participants (due either to non-fitting of iButton at initial visit, failed download or return of initial 2-week data, or lost data) but with little missing data thereafter (Table S3).

Agreement between SMS text messages and questionnaires was generally high. However, agreement between temperature sensor and both forms of self-report measure was considerably lower (Table 3, Table S4). Temperature sensor measurements produced systematically lower estimates of the proportion of participants meeting the minimum criterion for brace adherence, with the gap in estimates widening across follow-up time (Figure 2). The proportion of participants meeting the pre-specified criteria for minimum brace use at 12 weeks, estimated by each of the different methods was: 83% (self-report questionnaire), 83% (SMS), 60% (temperature sensor at the 24°C threshold), and 58% (temperature sensor at the 25°C threshold). At 26 weeks the estimates were 72% for self-report questionnaire, 43% for the sensor at 24 °C and 37% at 25 °C; at 24 weeks the estimate for SMS was 71%.

Secondary analysis suggested that brace use was slightly lower for the neutral (Össur Formfit) brace than the unloader (Össur Unloader One) brace (Figure S2), although differences were small and based on relatively small numbers (proportion of participants achieving minimum brace use at 26 weeks: neutral (13/35 (37%) vs unloader (13/25 (52%)) based on sensor 24°C threshold; 12/35 (34%) vs 10/25 (40%) based on sensor 25°C threshold).

To explore potential systematic under-estimation of brace use by the temperature sensor, we visually inspected the measurements for all participants who were classed as not meeting the minimum brace-use criterion at week 12 (according to temperature sensor measurements) but who met the minimum brace-use criterion on the self-report questionnaire and/or SMS text message. Of the 60 participants, there were 16 who were in this subgroup (8 men, 8 women, median age of 65 years (range 54–84)) and who were given the unloader (Össur Unloader One, n=7) and neutral (Össur Formfit, n=9) braces respectively. This suggests no obvious simple cause of systematic under-estimation based on patient demographic characteristics or brace type. Visual inspection revealed no single common pattern (temperature sensor plots available from Open Science Framework https://osf.io/bnw29/). In a small number of cases, it appeared plausible that either brace use was happening but just below the temperature threshold of 24 degrees (ID0702), that brace use was for only a single day in the past week (ID0014, ID0420, ID0464), or that minor misalignment of the time interval between patient recall and temperature sensor measurement might account for apparent under-recording of adherence (ID0677). However, in most other instances, sensor measurements appeared to be functioning as expected, typically showing plots consistent with initial short-term use but either declining, or with no use, by 12 weeks (e.g. ID0002, ID0278, ID0315, ID0769).

Discussion

This is the first analysis to use an objective measure of adherence to brace wearing in persons with knee OA and to compare this with two self-report measures of adherence. It is also the first paper to compare these measures over a long-term follow up of 24–26 weeks. It confirms the over-estimation of brace use by self-report methods, echoing similar findings from other fields, including exercise [26] and medication adherence [27]. Our results show poor agreement between the objective measure (a local skin temperature sensor) and self-report measures of brace wear adherence (questionnaire and SMS). Results also showed that the proportion of participants reaching minimum levels of adherence each week, as measured objectively by the sensor, decreased steadily from nearly 100% at baseline to less than 50% at 26 weeks. In contrast the two self-report

Age (years): mean (SD)	64.6 (8.9)
Female sex	31 (52%)
Lives in most deprived quintile of neighbourhoods	9 (15%)
Ethnicity:	
Asian	0 (0%)
Black	1 (2%)
Mixed/multiple	0 (0%)
Other	0 (0%)
White	58 (97%)
Prefer not to say	1 (2%)
Educational attainment: college/university	33 (55%)
Currently employed (full- or part-time)	24 (40%)
Has a long-term (> 12 months) physical or mental health condition, disability or illness	26 (44%)
Regularly takes 5 or more prescription medicines	17 (28%)
Body mass index (BMI) (kg/m^2): mean (SD)	29.2 (5.3)
Predominant compartmental distribution of index knee OA based on combination of clinical assessment and x-rays	
Medial tibiofemoral	21 (35%)
Lateral tibiofemoral	4 (7%)
Patellofemoral	1 (2%)
No clear predominant compartmental involvement)	34 (57%)
Kellgren-Lawrence (KL) highest grade for index knee (0–4)	
0	3 (5%)
1	0 (0%)
2	14 (23%)
3	30 (50%)
4	13 (22%)
Brace type	
Össur Unloader (medial or lateral)	25 (42%)
Össur Formfit Knee Hinged (neutral)	35 (58%)
Bioskin Q ♯	0 (0%)
KOOS-5 (primary outcome) (0–100): mean (SD)	44.7 (14.4)
KOOS subscale scores: mean (SD)	
Pain (0–100)	52.8 (14.7)
Symptoms (0–100)	47.3 (12.5)
Activities of daily living (0–100)	59.0 (19.1)
Sport/recreation (0–100)	32.9 (27.3)
Knee related quality of life (0–100)	33.0 (16.4)
Last 7 days, knee pain during activity in the knee (0–10NRS): mean (SD)	6.3 (1.8)
Physical activity (IPAQ-E) (MET minutes per week; 0–19278): mean (SD)	4462 (3538)

Numbers are N (%) unless otherwise stated.
BMI Body mass Index**; IPAQ-E** International Physical Activity Questionnaire – Elderly; **KOOS** Knee injury and Osteoarthritis Outcome Score; **MET** Metabolic Equivalent of Task; **NRS** Numerical Rating Scale; **SD** Standard Deviation.
‡Categories based on Office for National Statistics guidance on classification of ethnic groups (www.ons.gov.uk).
#The Bioskin Q brace was not suitable for the iButton.

Table 2

Osteoarthritis and Cartilage

Descriptive characteristics at baseline (N=60).

measures indicated much higher levels of adherence of nearly 100% at baseline reducing to 75% at 26 weeks. The results suggest that the proportion of participants deemed 'adherent' is significantly reduced when using the objective measure rather than the self-reports.

Adherence to wearing knee braces is known to be problematic and presents difficulties for clinicians when assessing treatment effectiveness. Self-report measures of adherence may be the most common and inexpensive method, but our analysis indicates this overestimates brace wearing time. An overestimation of actual brace wear time by self-report compared to a temperature sensor has also been noted in adolescent scoliosis [24].

These results show that a local skin temperature sensor, such as the iButton, can distinguish between the time wearing and not wearing a brace and show differences between objective and self-reported wear time. Direct comparisons of our results with other studies using temperature sensors is difficult, as the brace type, length of brace treatment time and medical conditions vary.

Rahman et al. [28] found a temperature sensor had similar recorded adherence to patient self-report diaries for adolescent patients wearing braces for scoliosis. The percentage error (i.e. the difference between sensor and diary times) over 4 weeks averaged only 2%, much lower than in the current study. A study on braces for scoliosis calculated patients' average compliance rate to be 67.5% (100% = 24 h wear; range 19.0–97.1%) but did not have self-report data for comparison [29]. It is possible that the difference between our results and these studies is that young patients might have had close parent or guardian supervision and encouragement to adhere to a brace wearing regime.

There are few prior trials of bracing for knee OA which have employed some form of wearable technology to assess adherence. A pilot study in knee OA compared data over 12 weeks from a 'brace plus sensor' group to a 'brace only' group [7]. The sensor used a smartphone application, visible to patients, to measure knee kinematics, range of motion, step count and the time spent doing daily activities. It aimed to assess if the brace plus sensor group had more improvement than the group without a sensor. Their results suggested that embedded sensors may have contributed to improved treatment engagement and provided patient feedback which improved adherence. The patients in that study were aware that their brace had a sensor. In contrast, patients in our study were blinded to

Timepoint	Method1		Method2	N					%agree	κ	(95%CI)
				Total	+/+	-/+	+/-	-/-			
12 weeks	SMS	vs	SRQ	36	29	1	2	4	92	0.67	(0.34, 1.00)
	TempSens24	vs	SRQ	54	33	12	2	7	74	0.35	(0.10, 0.60)
	TempSens25	vs	SRQ	54	33	12	2	7	74	0.35	(0.10, 0.60)
	TempSens24	vs	SMS	41	26	8	2	5	76	0.36	(0.05, 0.66)
	TempSens25	vs	SMS	41	26	8	2	5	76	0.36	(0.05, 0.66)
24–26 weeks	SMS	vs	SRQ	35	22	2	3	8	86	0.66	(0.39, 0.93)
	TempSens24	vs	SRQ	60	21	22	5	12	55	0.15	(-0.06, 0.36)
	TempSens25	vs	SRQ	60	20	23	2	15	58	0.25	(0.07, 0.43)
	TempSens24	vs	SMS	35	13	12	3	7	57	0.17	(-0.11, 0.45)
	TempSens25	vs	SMS	35	12	13	2	8	57	0.21	(-0.04, 0.46)

TempSens 24 Temperature sensor(24°C threshold).
TempSens 25 Temperature sensor (25°C threshold).
SMS 2-way short message service text message.
SRQ Short items in Self-Reported Questionnaire.

Table 3 Osteoarthritis and Cartilage

Agreement between three different methods of determining minimum brace use at 12 weeks and 24–26 weeks.

their objective monitoring as we felt that awareness of a sensor would likely influence adherence. As such, the suggestion by Darcy et al. [7] that patients' knowing they had wearable technology might improve their engagement and adherence to brace wearing was not assessed in our study. This reinforces the importance in our trial of blinding participants to the presence and rationale of a sensor.

Implications

Our results provide a clear rationale for using a temperature sensor or other forms of objective measure in any future clinical trials capturing adherence data of bracing. Furthermore, temperature sensors could be used explicitly in clinical practice to target objective monitoring for more expensive braces, encourage adherence and also to identify non-adherence earlier and potentially reduce wasteful or ineffective treatment.

Limitations

Skin temperature as a surrogate measure of adherence has some methodological issues. The first is the placement location of the sensor [23]. The parent trial was able to counter this by a consistent placement within the two knee braces which were able to have the sensor fitted.

The sensor data could have been influenced by the brace being worn over clothing. However, Haarman et al. [13] demonstrated that wearing the brace over clothing did not diminish accurate temperature readings. Nevertheless, patients in our study were instructed to wear the brace against skin, but this was not formally assessed.

The parent trial did not use daily measures of a patient's physical activity which might have affected local skin temperature. The trial was conducted in the midlands and north of England from November 2019 until September 2022. During this period, the monthly average daily outdoor temperature ranged from 3.3°C to 18.3°C. As suggested by others, it is possible that the accuracy of the results may vary in other climates and in other temperature ranges.

Our choice of absolute temperature thresholds was relatively simple to apply to the large quantities of data in our study but may be less optimal than an approach based on detecting rapid increase or decrease in temperature, which Menz and Bonanno [16] found to be optimal in their healthy volunteer study. While there may be no foolproof method for discriminating between brace wear and a brace placed in a hot environment, the peak detection algorithm approach may perform better than absolute thresholds in this regard.

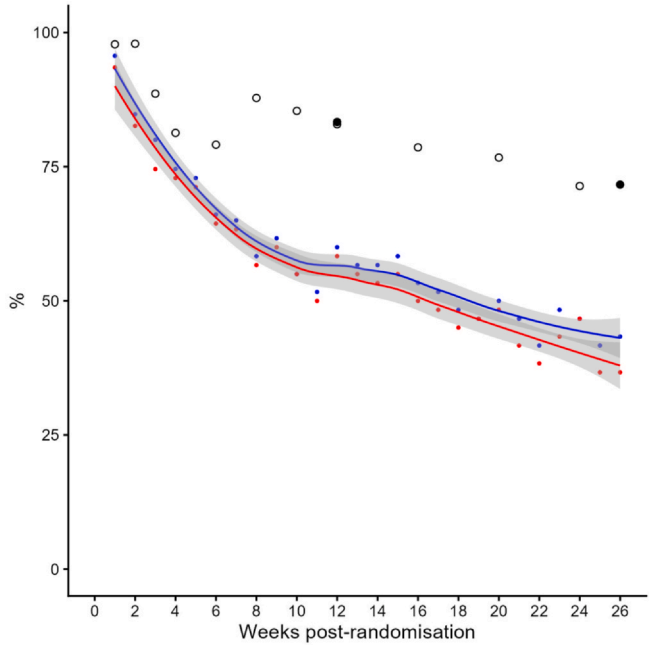

Fig. 2 Osteoarthritis and Cartilage

Proportion of participants meeting the minimum criterion for brace use in each week (n=60), assessed by multiple methods (open circles=SMS text message; filled circles=self-report questionnaire; blue line=temperature sensor (24°C threshold); red line=temperature sensor (25°C threshold); (lines fitted with Loess smoothing; shading represents 95%CI for Loess smoothed regression lines).

It was not possible to individually align all sensor and self-report data points exactly. This would introduce some non-systematic error that could bias our estimates of agreement, although the magnitude of this is likely to be small due to relatively stable weekly patterns of adherence/non-adherence within individuals.

Conclusion

Our novel study is the first to explore the methods of brace wearing adherence in knee OA by self-report and an embedded temperature sensor. The results suggest that self-report adherence is likely to substantially over-estimate the true extent to which patients with knee OA wear a brace. This has implications for both clinical trials and encouraging brace use in clinical practice.

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CRediT authorship contribution statement

We used CRediT (Contributor Roles Taxonomy) to detail individual author contributions to the PROP OA trial. Michael J. Callaghan: Conceptualisation and study design, funding acquisition, investigation, methodology, project administration, software, supervision, validation, original draft writing - review and editing. Melanie A. Holden: Conceptualisation and study design, resources, formal analysis, funding acquisition, methodology, project administration, data curation, supervision, validation, visualisation, writing - review and editing. Elaine Nicholls: Conceptualisation, resources, formal analysis, funding acquisition, methodology, data curation, software, validation, visualisation, writing - original draft, review and editing. Fraser Birrell: Conceptualisation, funding acquisition, investigation, methodology, project administration, software, supervision, validation, writing - original draft, review and editing. Belinda Borrelli: Conceptualisation, funding acquisition, methodology, supervision, writing - review and editing. David T. Felson: Conceptualisation, funding acquisition, methodology, supervision, writing - review and editing. Nadine E. Foster: Conceptualisation, funding acquisition, methodology, supervision, writing - review and editing. Nicola Halliday: Investigation, resources, project administration, data curation, supervision, writing - review and editing. Carol Ingram (PPI): Conceptualisation, resources, funding acquisition, methodology, writing - review and editing. Clare Jinks: Conceptualisation, resources, formal analysis, funding acquisition, methodology, project administration, data curation, software, supervision, validation, writing - review and editing. George M. Peat: Conceptualisation, resources, formal analysis, funding acquisition, methodology, project administration, data curation, software, supervision, validation, visualisation, writing - original draft, review and editing.

Authors' Conflicts of Interest

Michael J. Callaghan: None.
Melanie A Holden: None.
Elaine Nicholls: None.
Fraser Birrell: Received grants from the Jules Thorn Trust and MRC-Versus Arthritis- CIMA in the past 36 months. Editor-in-Chief, Lifestyle Medicine (Wiley). Received support for attending meetings and/or travel from Wiley for various Lifestyle Medicine meetings.
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Declaration of Competing Interest

The trial described in the manuscript has had no financial support from commercial sources, however, the braces supplied by Össur were donated and we received a discounted price on braces supplied by Bioskin, Beagle Orthopaedics, and Donjoy.

Declaration of Generative AI and AI-assisted technologies in the writing process

Not applicable.

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.joca.2026.06.005.

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