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Evaluation of reduced ('Lite') compression versus brief bandaging to manage post-operative pain after total knee arthroplasty surgery; a single-centre randomised controlled trial

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ABSTRACT

Purpose: Investigate efficacy of reduced compression bandage for the control of pain after total knee arthroplasty.
Patients & methods: Prospective, single-centre, randomised controlled trial involving data for 56 out of 94 consented patients; 29 standard care versus 27 Andoflex TLC Calamine Lite. Comparison of standard care (non-compression bandage applied for up to one day) versus Andoflex TLC Calamine Lite (25–30 mmHg) two-layer compression bandage worn for five days. Outcomes measured with validated pain (McGill, 10-cm visual scale) and functionality (KOOS) tools.
Results: At day 5 post-surgery, the median pain level was 3.0 cm vs 4.0 cm (p-value 0.47, Mann-Whitney *U* test) respectively. Generic pain levels, pain types, and knee functionality did not differ between the interventions at days 3/5/12 and week 6 post-surgery. An exception was the degree of 'tender' pain at day 12, which was significantly lower in the Andoflex TLC Calamine Lite arm (p-value 0.041, Mann-Whitney *U* test). Binary logistic regression analysis showed that application of Andoflex TLC Calamine Lite, administration of oxycodone, and male sex were all significantly associated with less 'tender' pain.
Conclusion: Reduced compression bandaging does not affect overall pain levels post knee arthroplasty surgery, but may alleviate pain experienced as 'tender', highlighting the different types of pain that may be experienced. Patients' need for, and the use of, opioid medication (oxycodone) is a significant confounding variable when assessing adjuvant therapy to control pain. The applicability of reduced compression bandaging may therefore be limited and is less efficient than medical pain control.

1. Introduction

Major knee surgery such as arthroplasty is associated with considerable post-surgery pain (Gaffney et al., 2017; Ramlall et al., 2019). For example, one study reported that 60% of patients experienced severe postoperative knee pain and 30% moderate pain (Seo et al., 2017). Pain may impact negatively on recovery time and active early rehabilitation due to physical impairment and evidence shows that more pain immediately after TKA is associated with poorer long-term functional and satisfaction outcomes for patients (Lo et al., 2021). These potential complications may increase hospital length of stay and poor patient reported-outcomes (Moretti et al., 2012; Williams et al., 2013). Various service improvement programmes, devices, and non-analgesic/anaesthetic medications have been introduced in knee surgery with the aim to reduce post-operative pain; these include the use of tranexamic acid, means to reduce intra-articular bleeding, tourniquets and medication (Martin et al., 2014; Li et al., 2019; Liu et al., 2020; Zhao et al., 2022). Non-medical interventions to alleviate pain may aid in reducing reliance on opioid medication use, which themselves may lead to undesirable side effects (Komann et al., 2019). Results for initiatives in post-surgical management of patients for pain management have been mixed, and have focused on use of cryotherapy (Aggarwal et al., 2023), and elastic bandaging (Hughes and Crosby, 1995).

Compression bandaging is another treatment mode that has been assessed for patients post knee surgery. The use of compression

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bandaging after total knee arthroplasty (TKA) was first introduced in the 1980s with the 'Robert Jones' bandage, and results for this device - that loses compression capacity over time - has again been mixed in terms of effects on pain and swelling Gibbons et al. (2001); Pinsornsak and Chumchuen (2013); Yu et al. (2018). The application of modern full compression bandages whose compression remains stable (at ~40–50 mmHg) for multiple days did not result in significant reduction in pain in knee replacement cases (Munk et al., 2013; Brock et al., 2017; Christensen et al., 2020), but may positively impact on the type of pain experienced by patients in a population of high tibial osteotomy patients (Jonker et al., 2020a). However, the potential efficacy of reduced (20–30 mmHg) compression bandages for pain control and types of pain experienced after total knee arthroplasty has not been explored before.

The aim of this trial was to assess the efficacy - pain levels after surgery - and safety of a five-day application of short stretch reduced ('Lite') compression bandaging, compared to standard wool & crepe bandaging, in patients who have undergone TKA.

2. Methods

2.1. Study design and subjects

Single-centre, prospective, open label, randomised controlled trial, which ran between October 2021 and July 2023. Full ethics and governance approval was received from the UK's National Research Ethics Service (reference 21/WA/0252), Health Research Authority (reference 288969) and local National Health Service Trust, and the trial was registered on a public database (https://doi.org/10.1186/ISRCTN10011099). Patients were identified and approached consecutively from orthopaedic clinic lists. At the patients' pre-assessment appointment consent and baseline parameters were recorded. Written informed consent was obtained from all participants in accordance with the Declaration of Helsinki (Good Clinical Practice), with more than 24 h' time given to patients to consider the study. Participant inclusion criteria were: patients aged 18 or over with mental capacity, listed to

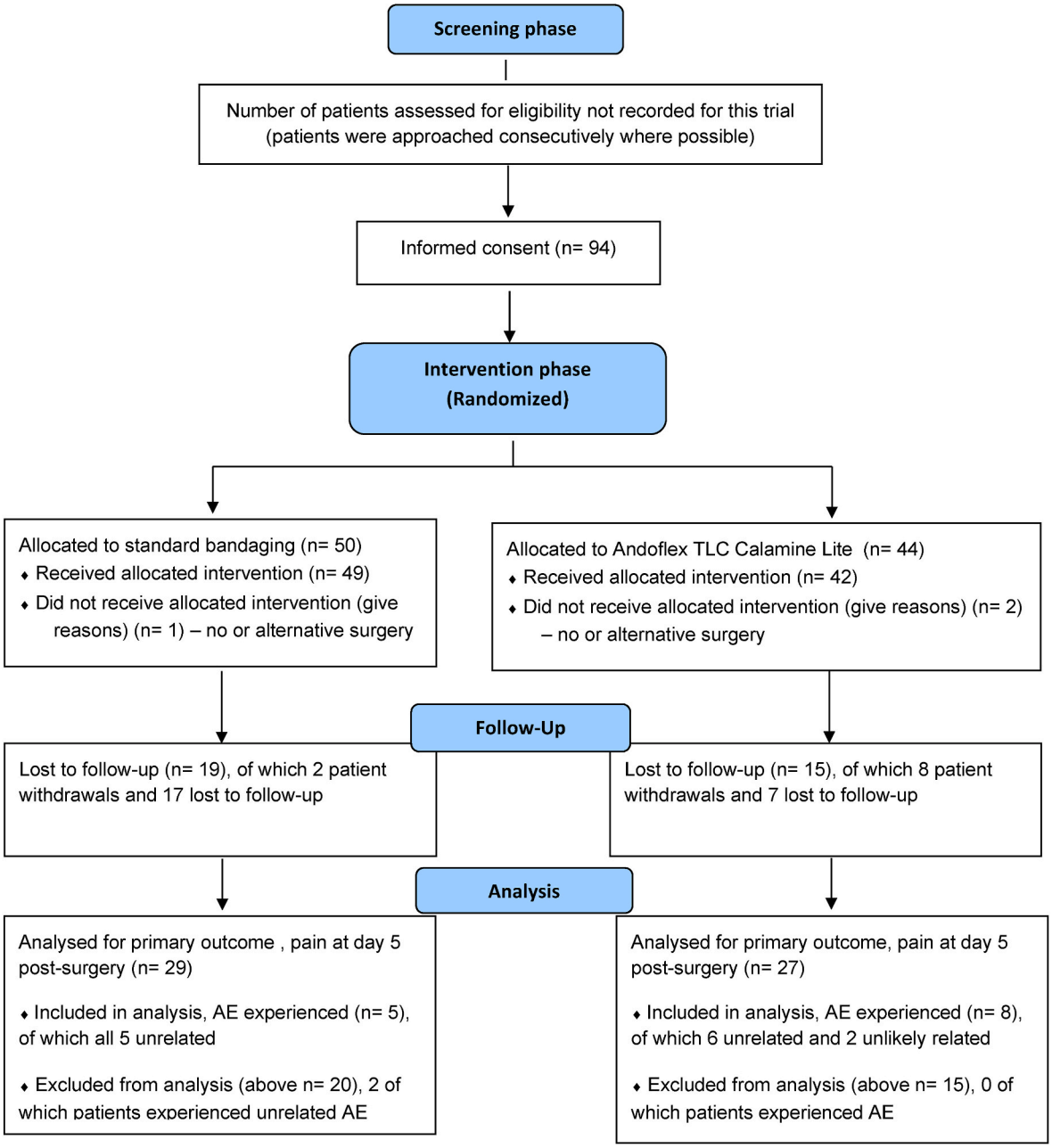

Fig. 1. CONSORT flowchart for CASK trial.

undergo total knee arthroplasty for primary osteoarthritis. Exclusion criteria were: revision surgery on previous index leg; any condition associated with excessive bleeding and/or use of coagulation disorder; cardiovascular, vascular or dermatological condition contraindicating the application of compression bandaging; severe mobility issues. A total of 94 patients consented to take part in the study (see Fig. 1). Patients were randomised 1:1 to either standard care or compression bandaging (Andoflex TLC Calamine Lite) using randomizer.org freeware. Due to availability of 120 randomisations for the study, ultimately 50 patient were randomised to standard care and 44 to compression bandaging. Blinding of participants and research staff could not be achieved due to visual difference between interventions in the two treatment arms.

2.2. Surgical procedures & rehabilitation

Apart from spinal anaesthetics for the surgery itself, levobupivicaine was infiltrated into the knee joint during surgery; gabapentin 300 mg bd is prescribed peri-operatively. Post-operatively, oxycodone 5 mg two-hourly was administered for breakthrough pain in addition to regular application of oxycodone 10 mg and Paracetamol 1 g IV within first day post-surgery and oral codeine and/or non-steroidal anti-inflammatory drugs. The intention of the surgical protocol was to achieve early mobilisation of the patient.

2.3. Study interventions and safety reporting

A standard bandage, consisting of one layer of soft synthetic bandage, stretching from proximal tibia to distal femur covered by a further layer of crepe bandage, was applied to participants in the standard care arm. It was removed in the recovery room or within 24 h on the ward. For participants in the intervention arm, Andoflex TLC Calamine Lite 25–30 mmHg two-layer compression system bandaging was applied by trained clinical staff, from the patient's toe to the groin on the affected leg. Staff competence in the application of the Andoflex TLC Calamine Lite system was achieved by internal training. Patients were asked to continue wearing the bandage for five consecutive days after surgery. In both trial arms, the bandages could be removed sooner, either due to patient preference or in the event of an adverse event that would necessitate removal. Early bandage removal was not deemed an adverse event, whereas any issue that required medical or surgical attention was reported as an adverse event requiring safety reporting. Apart from the difference in type of bandage, the protocol was otherwise identical for both Andoflex TLC Calamine Lite participants and standard care arm participants. This meant that an Aircast Knee Cryo/Cuff passive cooling system was applied to the knee region – over wound dressing - for up to 24 h once the patient had been moved to a ward post-surgery.

2.4. Outcome measures

The following were recorded for the index leg: visual display scale (VDS) for pain at rest and when standing/walking, and a short form McGill pain questionnaire (Melzack, 1987) at pre-surgery, day 3, day 5, day 12 and week 6 post-surgery. In a recent study involving compression bandage after osteotomy surgery for knee osteoarthritis, the authors identified that the application of the McGill short form pain scale - covering measurement of different types of pain - may enrich outcome measures (Jonker et al., 2020a). The McGill short form pain scale was applied at same time points as the VDS pain scale, and outcomes were none (0), mild (1), moderate (2), and severe (3) pain. Validated Knee injury and Osteoarthritis Outcome Score (KOOS) (Roos et al., 1998), patient-reported outcome measures related to knee function, was administered before surgery, week 6 post-surgery.

2.5. Data and statistical analyses

A-priori power calculation was performed using GPower 3.1 freeware, using visual analogue pain pain scale score at day 5 post-surgery as primary outcome with minimal clinically important difference (MCID) of 1.5 cm on a 10 cm scale as benchmark (Kelly 2001). Applying two-sided Mann-Whitney *U* test, at 80% power, 5% significance, and 20% attrition rate, a total of 48 participants (24 treatment arm) with available primary outcome data was therefore required for each of two surgery types. Any statistical difference in outcome measures between the two cohorts was assessed with two-sided Mann-Whitney test for ordinal and continuous data, and Chi-square test for binary data. An intention-to-treat approach was taken for data analysis where patients had surgery and reported on pain at least for the day 5 time-point. Data was collated in Microsoft Excel, and analyses conducted using SPSS v24.

3. Results

3.1. Participants and primary outcome measure

Fig. 1 shows an overview of the patient numbers as the trial progressed. An eventual 56 patients (29 standard care vs 27 Andoflex TLC Calamine Lite) had data available for the primary outcome measure, day 5 pain at rest post-surgery. The attrition rate was higher at 31% instead of the anticipated 20%, but the sample remained sufficiently powerful. Table 1 summarises the baseline anthropomorphic measurements and knee-specific pre-operative parameters for the participants in each treatment arm. Table 2 outlines that no significant difference can be detected for pain levels at the primary end-point of day 5 post-surgery, neither when patient at rest or 'walking' (which at this point may be merely standing out of bed). Likewise, at day 3 and day 12 post-surgery no significant difference in pain levels is seen between standard bandage and Andoflex TLC Calamine Lite arms. Binary logistic regression was conducted to determine if any other variables are associated with low or high level pain at rest at day 5 post-surgery; since the median score was 4.0 cm, a 0–3 cm and 4–10 cm score group were used for the dependent in the regression model. Table 3 shows that only the requirement for oxycodone prescription is associated with increased pain levels. The R^2 value indicates that 41% of the variation in low or high level of pain is explained by the model.

3.2. Secondary outcome measures

Table 4 shows the median pain levels for pain types, recorded using the McGill short form pain scale, where the median value was at any

Table 1
Demographics and baseline characteristics for Knee Replacement study subjects who completed day 5 post-surgery 'pain at rest' survey.

Parameter	Standard care (n = 29)	Andoflex TLC Calamine Lite (n = 27)
Age, mean in yrs (SD)	64 (14)	66 (8)
Sex, n (male/female)	15/14	15/12
BMI, mean in kg/m^2 (SD)	31 (6)	30 (5)
Pre-op pain at rest, 10-cm visual display scale, median (IQR)	4.0 (2.0)	4.0 (2.0)
Pre-op pain when walking, 10-cm visual display scale, median (IQR)	5.0 (4.0)	4.0 (2.0)
KOOS Symptom pre-op, median (IQR)[a]	46.0 (33.5)	57.0 (28.0)
KOOS Pain pre-op, median (IQR)[a]	44.0 (24.0)	47.0 (22.0)
KOOS Activities of Daily Living pre-op, median (IQR)[a,b]	47.0 (34.0)	54.0 (27.0)
KOOS Sport and Recreation pre-op, median (IQR)[a]	7.5 (25.0)	15.0 (15.0)
KOOS Quality of Life (knee) pre-op, median (IQR)[a]	18.8 (21.9)	31.3 (25.0)

[a] Transformed score, where 100 is optimal and 0 is worst possible knee function.
[b] Standard care n = 28, Andoflex TLC Calamine Lite n = 24.

Table 2
Pain level related to affected leg post-surgery, measured using 10-cm visual display scale.

Time point, post-surgery	Standard care arm (n = 29)	Andoflex TLC Calamine Lite arm (n = 27)	p-value[a]
3 days, pain at rest, median (IQR)	4.0 cm (3.0)	4.0 cm (4.0)	0.78
3 days, pain when walking, median (IQR)	4.0 cm (5.0)	5.0 cm (3.0)	0.95
5 days, pain at rest, median (IQR)	3.0 cm (3.0)	4.0 cm (4.0)	0.47
5 days, pain when walking, median (IQR)	4.0 cm (4.0)	4.0 cm (4.0)	0.83
12 days, pain at rest, median (IQR)	2.8 cm (2.0)[b]	3.0 cm (2.5)[c]	0.67
12 days, pain when walking, median (IQR)	3.0 cm (1.9)[b]	2.0 cm (2.5)[c]	0.18

[a] Mann-Whitney *U* test.
[b] n = 28.
[c] n = 25.

Table 3
Binary logistic regression analysis of variables and association with low (score 0–3) or high (score 4–10) level of pain at rest at day 5 post-surgery.

Variable	p-value	LR	95% CI	Interpretation
Trial treatment (bandage type)	0.30	2.07	0.52 to 8.32	
Age	0.36	0.96	0.87 to 1.05	
Sex	0.23	2.33	0.59 to 9.24	
BMI	0.37	1.07	0.92 to 1.25	
Gabapentin	0.41	3.22	0.20 to 52.73	
Oxycodone	0.038	6.56	1.11 to 38.78	More pain at rest when prescribed oxycodone
Codeine	0.36	1.98	0.46 to 8.53	
NSAID	0.95	0.95	0.21 to 4.33	
Paracetamol	0.52	2.14	0.21 to 21.60	
Length of stay (nights)	0.067	2.10	0.95 to 4.65	
Nagelkerke R2 value for regression model = 0.41				

LR, likelihood ratio; CI, confidence interval; NSAID, non-steroidal anti-inflammatory drug; BMI, body mass index; * statistically significant.

point at least 'mild'. The pain types throbbing, cramp, gnawing, splitting, sickening, fearful and punishing have been omitted from the table because median pain levels were always lower than mild. The two types of pain with the highest median score (moderate) are tender and aching. Only 'tender' pain at day 12 post-surgery differed significantly between standard bandage and Andoflex TLC Calamine Lite arms, even though the median score was 1.0 for both. Bearing in mind the putative confounding role that prescribed analgesics may have between different bandaging on pain outcomes, as seen for the primary outcome of pain at rest at day 5 post-surgery, binary logistic regression was conducted once more to determine if the statistically significant difference in tender pain levels held up. Table 5 shows that three variables significantly contribute to the regression model that differentiates the dependent into 'none'/'mild' or 'moderate'/'severe' tender-type pain as recorded by participants at day 12 post-surgery. This is based on the McGill short form pain survey completed by patients, and the median score being 'mild' for this study sample. The type of bandage influences the degree of tender pain experienced, as does prescription of oxyconde and patient sex. The R^2 value for this model explains 52.5% of variation in tender pain in this sample.

Knee functionality 6 weeks post-surgery was appraised with the KOOS survey, and scores calculated in accordance with the original paper where a score of 100 is optimal function and 0 is worst possible function (Roos et al., 1998). For the Symptoms element, the median scores were 61.0 (Inter-Quartile Range [IQR] 18.8) and 57.0 (IQR 27.0) for standard bandage and Andoflex TLC Calamine Lite respectively (p-value 0.79, Mann-Whitney *U* test). For the Pain element the median scores were 61.1 (IQR 13.9) and 63.9 (IQR 13.9), p-value 1.00; for the Activities of Daily Living element they were median score 72.1 (IQR 25.7) and 75.0 (IQR 28.7), p-value 0.92; finally, for the Knee-related Quality of Life element the median scores were 50.0 (IQR 18.8) and 50.0 (31.3), p-value 0.91. KOOS outcome data was available for up to 25 standard bandage and 21 Andoflex TLC Calamine Lite participants, whereas the Sport and Recreation element was not analysed due to insufficient number of completed surveys for that element.

3.3. Safety

A total of 13 adverse events were recorded, 5 in the standard care arm and 8 in the Andoflex TLC Calamine Lite arm. All five adverse events in the standard care arm were unrelated (clonic seizure, cellulitis, hypertension, gallstone and post-surgical site infection respectively), and six of the adverse events in the Andoflex TLC Calamine Lite arm were unrelated (encephalitis, hypertension, hypotension, respiratory infection, rash outside bandaged area, and post-surgical site infection respectively). The two adverse events unlikely related to the Andoflex TLC Calamine Lite intervention were a stitch-site abscess and haematoma and bruising on the thigh of the index leg post-surgery. The three categories of adverse event were therefore non-surgical infection or pathology, post-surgery issues related to anaesthetic medication, and surgery related infection of the wound site; the latter were deemed unrelated or unlikely related to application of a bandage by the chief investigator.

4. Discussion

Compression bandage therapy is established treatment of (the symptoms of) venous insufficiency (Jonker et al., 2020b; Patton et al., 2023). The current most common type of compression bandage is the short-stretch two layer design, which includes 3 M's Coban2 and Milliken Healthcare's Andoflex TLC family of bandages; they allow effective activation of the deep venous system and calf muscle pump with ambulation (Partsch, 2012; Patton et al., 2023). It has been postulated that compression bandaging can alleviate pain in total knee arthroplasty patients, but its putative efficacy is still unclear due to conflicting results in the literature and heterogeneous methodology (Munk et al., 2013; Pinsornsak P & Chumchuen, 2013; Matthews et al., 2019). Since full compression using current short-stretch bandaging is unlikely to result in a significant reduction in pain levels (Brock et al., 2017; Liu et al., 2020), a prospective trial using reduced compression bandaging was conducted to determine if this may aid in controlling post-operative pain. Reduced compression promotes venous flow but is less likely to have a negative impact on arterial flow compared to very strong compression (Partsch, 2012). Furthermore, full compression bandaging (40–50 mmHg) appeared too uncomfortable and therefore a reduced – or 'Lite' – compression bandage was applied in this present trial. Andoflex TLC Calamine Lite is impregnated with calamine to soothe the skin and is known to be more comfortable for patients than standard compression bandaging (Jonker et al., 2020b).

From data obtained in this present trial, no significant difference in overall pain and any specific pain-type could be detected when comparing standard brief (up to 24 h) bandaging and the Andoflex TLC Calamine TLC reduced compression bandaging (applied for up to five

Table 4
Types of pain experienced by participants post-surgery, measured with short form McGill questionnaire (types with minimum median score of 1 [mild pain] or higher at any time-point).

		3 days post-surgery[c]		5 days post-surgery[c]		12 days post-surgery[$]	
Type of pain	Treatment arm	Median (IQR)	p-value[a]	Median (IQR)	p-value[a]	Median (IQR)	p-value[a]
Shooting	Standard care	2.0 (2.0)	0.39	1.0 (2.0)	0.55	1.0 (2.0)	0.74
	Andoflex TLC Calamine Lite	1.0 (2.0)		1.0 (2.0)		1.0 (1.0)	
Stabbing	Standard care	1.0 (2.8)	0.26	1.0 (1.5)	0.49	1.0 (1.8)	0.96
	Andoflex TLC Calamine Lite	1.0 (2.0)		0.0 (1.0)		1.0 (1.0)	
Sharp	Standard care	1.0 (2.0)	0.85	1.0 (2.0)	0.66	1.0 (2.0)	0.34
	Andoflex TLC Calamine Lite	1.0 (2.0)		1.0 (2.0)		1.0 (1.0)	
Hot	Standard care	1.0 (2.0)	0.41	1.0 (2.0)	0.57	1.0 (2.0)	0.72
	Andoflex TLC Calamine Lite	1.0 (2.0)		1.0 (2.0)		1.0 (1.0)	
Aching	Standard care	2.0 (1.0)	0.68	2.0 (1.0)	0.86	2.0 (1.0)	0.43
	Andoflex TLC Calamine Lite	2.0 (1.0)		2.0 (1.0)		1.5 (1.0)	
Heavy	Standard care	2.0 (2.8)	0.43	2.0 (3.0)	0.15	1.0 (2.0)	0.20
	Andoflex TLC Calamine Lite	2.0 (1.5)		1.0 (2.0)		0.5 (2.0)	
Tender	Standard care	2.0 (2.0)	0.82	2.0 (1.0)	0.50	1.0 (1.0)	0.041[b]
	Andoflex TLC Calamine Lite	2.0 (1.0)		1.5 (1.0)		1.0 (1.0)	
Tiring	Standard care	2.0 (2.5)	0.74	1.0 (2.5)	0.73	1.0 (2.0)	0.99
	Andoflex TLC Calamine Lite	2.0 (2.0)		1.0 (1.0)		1.0 (2.0)	

[c] Standard care n = 29, Andoflex TLC Calamine Lite n = 26; $ Standard care n = 28, Andoflex TLC Calamine Lite n = 24.
[a] Mann-Whitney *U* test.
[b] Statistically significant difference.

Table 5
Binary logistic regression analysis of variables and association with low (none/mild) or high level (moderate/severe) of tender-type pain at day 12 post-surgery.

Variable	p-value	LR	95% CI	Interpretation
Trial treatment (bandage type)	0.024[a]	0.11	0.015 to 0.75	Less tender-type pain when Andoflex TLC Calamine Lite applied
Age	0.60	1.02	0.94 to 1.11	
Sex	0.038[a]	7.10	1.12 to 45.16	Less tender-type pain amongst males
BMI	0.14	1.15	0.96 to 1.39	
Gabapentin	0.84	0.67	0.014 to 31.35	
Oxycodone	0.049[a]	0.13	0.017 to 0.99	Less tender-type pain when prescribed oxycodone
Codeine	0.90	1.12	0.18 to 6.93	
NSAID	0.39	2.27	0.35 to 14.60	
Paracetamol	0.19	8.32	0.36 to 192.34	
Length of stay (nights)	0.31	0.47	0.11 to 2.00	
Nagelkerke R^2 value for regression model = 0.53				

LR, likelihood ratio; CI, confidence interval; NSAID, non-steroidal anti-inflammatory drug; BMI, body mass index.
[a] Statistically significant.

days). A comparison between baseline (pre-surgery) and 12-day follow-up (post-surgery) time point suggests that on average overall pain levels have improved across both treatment arms, see Tables 1 and 2 respectively. However, inferential statistical analysis is not indicated since the objective was not to assess the efficacy of the total knee arthroplasty procedure itself (Bland and Altman, 2011). A more specific pre-versus post-TKA pain appraisal has been reported previously (Ramlall et al., 2019). A few parameters should be considered when appraising the results of this study. These include the presence of confounder variables and types of pain experienced by patients. At day five post-surgery, the primary outcome measure, only prescription of oxycodone was observed to be associated with increased general pain levels as measured with a visual display scale. This shows the value of conducting multiple regression to take into account different – potentially confounding - variables that may influence pain levels. In other studies of compression bandaging after TKA this was not performed. Some studies reported that medication for break-through pain could be prescribed (Matthews et al., 2019; Munk et al., 2013), whereas others did not mention peri-operative pain relief medication at all (Pinsornsak and Chumchuen, 2013). In a previous study on osteotomy patients, the present authors did not take this detail into account either (Jonker et al., 2020a).

Previous studies assessing compression bandaging efficacy after TKA have used exclusively a visual analogue scale for measuring generic pain in the knee region (Liu et al., 2020). However, a previous study by the authors in a sample of osteotomy patients showed that measuring different types of pain can potentially differentiate better between different treatment arms (Jonker et al., 2020a). The use of the McGill pain survey as a secondary outcome measure has again allowed to differentiate in more detail how pain may differ between treatment arms, since at day 12 post-surgery the tender-type pain levels were lower in the compression bandage arm versus standard bandage. Multiple regression analysis highlighted that patient sex and oxycodone use also contributed to lower levels of tender-type pain, illustrating that pain levels can be affected by different variables. Earlier work has also shown that females are more likely to report higher levels of pain post-TKA surgery (Ramlall et al., 2010). Nonetheless, compression bandaging contributed to reduced tender-type pain despite other variables also being associated with it. By describing the type of pain experienced by TKA patients post-surgery, clinical staff can also describe better to patients what should be expected if they are to have this surgery: mainly pain with an aching, heavy, tender and tiring profile. In the recent osteotomy trial using the McGill pain survey, aching and tiring pain were also the most troublesome pain types post-surgery (Jonker et al., 2020a).

The results obtained with the KOOS knee functionality patient reported outcome measure mirror the pain outcome results. Since there was no difference in overall pain levels up to 12 days post-surgery, it is not surprising – in line with Lo et al. (2021) – that there was no difference in KOOS score at week 6 between control bandage and Andoflex TLC Calamine Lite bandage. A pre- and post-TKA intra-arm inferential statistical comparison of KOOS scores is not indicated, but particularly for the KOOS pain sub-score it is encouraging to see an improvement from median 44.0 to 61.1 (control bandage) and 47.0 to 63.9 (Andoflex TLC Calamine Lite bandage).

The choice of compression bandaging and duration of its application

complicates direct comparison of different studies. Since the first trials involving Robert Jones bandaging, companies are now supplying two-layered short-stretch bandaging (as mentioned, some with skin ointment incorporated). Additionally, the duration of bandage application can also differ per study. Unlike other TKA bandage trials, the compression two-layer compression bandage was applied to for five days rather than the more common period of 24 h (Liu et al., 2020). In a meta-analysis, significantly lower pain levels were not observed at 24 and 48 h post-surgery (Liu et al., 2020); a distinction was not made between different types of compression bandaging (elastic versus non-elastic, reduced versus full compression).

Similar to a previous trial conducted on osteotomy patients, which had a 24% attrition rate (Jonker et al., 2020a), loss to follow-up was again an issue in this present trial with 31% of participants not completing the primary outcome measure. Remote follow-up of patients, partially due to the COVID-19 pandemic, may have contributed to these figures. Unlike in the majority of other compression bandage trials (Liu et al., 2020), adverse events (AEs) were recorded in this trial. Patients in the Andoflex TLC Calamine Lite arm experienced more AEs but none were attributable to the intervention. The potential non-compliance regarding wearing the bandage is a recognised shortcoming of the trial, but since patients do not stay in hospital for the full five days post-TKA it was a decision made on pragmatic grounds. A further limitation is that due to the use of patient-reported outcome measures and with the two bandages looking distinctly different, blinding could not be applied. Despite these limitations, which also includes the high loss to follow-up rate, this study's strength is the prospective randomised trial approach and the follow-up at various time points both immediately and also some time after the TKA procedure. Recall bias was minimised by asking patients to report on outcome measures at the actual time point rather than retrospectively.

5. Conclusions

A minimal clinical important difference in overall pain post-surgery cannot be detected when standard care (brief application of non-compression bandage) and five-day application of reduced (25–30 mmHg) compression bandaging is compared in a sample of TKA patients. A significant reduction in tender-type pain is observed at a single time-point 12 days post-surgery but not at earlier time-points; along with aching pain, tender pain is the type of pain experienced the most by patients. Multivariable analysis aids to determine which variables, apart from the experimental intervention, may be associated with either increased or reduced pain levels. In this instance, the prescription of oxycodone was associated with both increased pain (five days post-surgery) and reduced pain (twelve days post-surgery). Andoflex TLC Calamine Lite was not causally associated with any adverse events and therefore from a risk perspective its application should not be an issue. Taken together, however, the evidence here suggests that there is only limited indication to apply reduced compression bandaging to total knee arthroplasty patients for the control of post-operative pain; this supports conclusions drawn from a meta-analysis by Liu et al. (2020) for full compression bandages. The core contributor to control of post-operative pain continues to be optimal medical management, though there may be scope for the identification of patients at high risk of significant post-operative pain to tailor patient management (Williams et al., 2013; Lavand'homme and Thienpont, 2015).

Ethics statement

Prior to commencing the research, ethics approval was obtained from the UK's National Research Ethics Service, through Wales REC7 Ethics Committee, reference 21/WA/0252; in addition, Health Research Authority (reference 288969) and local National Health Service Trust approvals were also obtained prior to commencing the trial. The project was registered on a public register, registration number ISRCTN10011099, date of registration November 17, 2021.

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CRediT authorship contribution statement

Matt Dawson: Supervision, Investigation, Funding acquisition, Conceptualization. **William Hage:** Supervision, Methodology, Investigation. **Cristian Nita:** Supervision, Methodology, Investigation. **Lucy Bell:** Methodology, Investigation, Funding acquisition, Data curation. **Janice Gorman:** Project administration, Methodology, Investigation, Data curation. **Leon Jonker:** Writing – original draft, Project administration, Methodology, Formal analysis, Conceptualization.

Declaration of competing interest

Leon Jonker has in past received a single honorarium for non-orthopaedic consultancy work for Milliken Healthcare. The other authors have no conflict of interest to declare.

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