Title: Application of compression bandaging post-osteotomy results in altered pain profile; results of a single-centre randomised controlled trial.

Running title: Outcomes for bandaging after osteotomy

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Title: Application of compression bandaging post-osteotomy results in altered pain profile; results of a single-centre randomised controlled trial.

Abstract

Purpose

To assess if application of dual-layer compression bandage to osteotomy patients post-surgery can positively influence levels of post-operative pain and swelling.

Patients & Methods

Prospective, single-centre, randomised controlled trial comparing standard care, non-compression bandaging, versus Coban™ 2 (3M). Seven day application of the latter to index leg of osteotomy patients.

Results

Primary outcome data was available for 36 out of 49 study subjects (18 standard care versus 18 Coban™ 2 subjects). Median 10-cm scale pain levels showed a statistically non-significant difference at day 5 and day 12 post-surgery between standard care and Coban™ 2 respectively: 5.5 cm vs 2.5 cm (p-value 0.068) and 4.0 cm vs 2.3 cm (p-value 0.39). However, on day 12 (p-value 0.029) and week 6 (p-value 0.027), 'throbbing pain' was significantly higher for Coban™ 2 patients. Changes in limb swelling measures, comparing before and after the surgical procedure, did not differ between treatment arms. Compression led to more patients reporting bandage-related discomfort (6% standard care versus 63% Coban™ 2 patients).

Conclusion

Compression bandaging changes the post-surgery pain profile in osteotomy patients, but does not reduce leg swelling. Any subsequent leg compression trials must take into account patient comfort and titrate intervention length and compression rates.

Keywords: osteoarthritis, osteotomy, compression bandaging, pain, swelling, patient recovery.

Introduction

Medial osteoarthritis of the knee can be treated with open-wedge high tibial osteotomy (HTO). The current most common way of performing HTO is to use fixation plates with locking screws implanted in the patient's tibia (Brinkman et al, 2008). The same medial to lateral translation of the mechanical axis as it crosses the knee joint can also be achieved through distal femoral osteotomy (DFO) or an operation in which both HTO and DFO are performed (Rosso & Margheritini, 2014). There are two features associated with post-knee surgery recovery that seem to very frequently occur in patients: pain and swelling (Garrett & Walters, 2010). Post-surgery leg swelling occur due to bleeding and particularly inflammation-related fluid build-up in the intraarticular tissues; one contributing factor to patients experiencing pain is the increased circumference of the limb causing increased tension of the soft tissue (Holm et al, 2010; Gao et al, 2011). Swelling and pain may impact negatively on recovery time and active early rehabilitation due to physical impairment, impinging on clinical and patient reported outcomes (Yu et al, 2002; Mizner & Snyder-Mackler, 2005). Many service improvement programmes and techniques have been introduced in knee surgery over the years, including means to reduce intra-articular bleeding, tourniquets and medication (Martin et al , 2014). Some initiatives in post-surgical management of patients have been less successful, such as the use of a cold compress and cryotherapy (Morsi, 2002; Adie et al, 2012). More recent efforts have focussed on the putative role that the application of compression can have on pain and swelling post knee surgery.

Background

Compression bandage therapy is the established treatment for venous ulcers and lymphoedema (Franks et al, 2004), aiding venous return and reducing hydrostatic pressure in the leg by (i) improving the efficacy of the calf muscle pump and (ii) moving blood from the superficial to deep venous system, subsequently allowing movement of fluid from the interstitial space. This mode of action may therefore be of benefit to patients who undergo knee surgery. Efficacy trials of compression bandaging after orthopaedic surgery have thus far focused on knee arthroplasty. The main outcome measures reported on are often both swelling and pain; results from a survey amongst orthopaedic surgeons in South Africa suggests that increased post-operative swelling is associated with higher pain levels (Garrett & Walters, 2010).

The use of compression bandaging after TKA was first introduced in the 1980s with the 'Robert Jones' bandage (Brodell et al, 1986). Others have trialled the application of this compression bandage, which achieves compression of 40 to 50 mm Hg pressure at application, reducing to 2 to 10 mm Hg within 48 hours; some observed reduced pain and swelling (Gibbons et al, 2001) whereas others failed to see a difference (Pinsornsak & Chumchuen, 2013; Yu et al, 2018). More recently, work by Christensen and colleagues demonstrated that 23 mmHg stockings applied straight after surgery and worn for two weeks do not significantly alter swelling or pain levels experienced by TKA patients (Christensen et al, 2020). When Munk and colleagues first treated patients with 3M™ Coban™ 2 Two-Layer Compression bandaging for 24 hours, achieving 35-40 mmHg, before switching to 23 mmHg stockings, again no effect on swelling or pain could be observed (Munk et al, 2013). For most trials, outcome measures were typically obtained within the first week and two to three weeks after surgery. As the above examples illustrate, despite its introduction, mostly non-supporting results have been reported on the efficacy of leg compression

on pain and swelling. However, to date mainly modest rather than full compression, often for 24 to 48 hrs, has been applied (Charalambides et al, 2005; Andersen et al, 2008; Munk et al, 2013; Pinsornsak P & Chumchuen, 2013; Cheung, Lykostratis, Holloway, 2014; Brock et al, 2017, Christensen et al, 2020). Direct evidence on the role that extended use of full compression bandaging may play in terms of post-operative outcomes after osteotomy surgery is lacking. The aim of this trial was to assess the efficacy (pain and swelling levels after surgery) and safety of a 7-day application of short stretch compression bandaging, compared to standard wool & crepe bandaging, in an osteotomy patient population as opposed to TKA cohorts studied to date.

Methods

Study design and subjects

The study concerns a single centre, prospective, open label, randomised controlled trial, conducted between June 2018 and May 2020. Patients were identified and approached at one hospital Trust by the orthopaedic clinical team when the patients first presented at consultation. Subsequently, at the surgery pre-assessment visit written informed consent and baseline parameters were obtained; therefore, patients had a minimum of 24 hours to consider participation in the study. Two different surgeons performed all the operations. For the osteotomy either the Tomofix plate (DePuy Systhes, West Chester, USA) or Newclip plate (Newclip Technics, Haute-Goulaine, France) was applied to achieve the knee joint correction. Patients were identified prospectively and consecutively from surgical lists. Ethics approval was obtained from the UK's National Research Ethics Service, through Wales REC7 Ethics Committee, reference 18/WA/0027; in addition, Health Research Authority and local National Health Service Trust approvals were

obtained prior to commencing the trial. Participant inclusion criteria were: adult patients undergoing unilateral high tibial osteotomy (HTO), distal femoral osteotomy (DFO) or a double osteotomy (HTO and DFO); ankle brachial index measured within 12 weeks and with value ≥ 0.8; mental capacity to give written informed consent. Exclusion criteria were: revision of previous osteotomy; diabetes ; any condition associated with excessive bleeding, coagulation abnormalities or any other significant haematological condition; cardiovascular, vascular or dermatological condition contraindicating the use of compression bandaging. Written informed consent was obtained from all participants in accordance with the Declaration of Helsinki (Good Clinical Practice), as part of the trial protocol. Patients were randomised 1:1 to either standard care (crepe bandaging) or compression bandaging, with randomizer.org freeware used to achieve randomisation. Due to visual difference between interventions in the two treatment arms, blinding of patient and research staff was not applied.

Surgical procedures & Rehabilitation

The opening or closing wedge HTO and/or DFO was conducted according to the method outlined by Lobenhoffer and colleagues, and by Elson and colleagues (Lobenhoffer, van Heerwaarden, Staubli, 2009; Elson, Petheram, Dawson, 2015). At the end of the surgery, field block local anaesthesia was applied to all patients - between 60-120 mls (depending on the size of the operative field and patient weight) of Chirocaine® 1.25 mg/ml before closure of the wound. All patients were administered a calf pump and prescribed enoxaparin sodium (Clexane®) whilst hospitalised, and prescribed rivaroxaban for two weeks once discharged home. Patients were encouraged to achieve full mobility by advising the following activities: toe touch in first two

weeks, partial weight bearing after 2 to 4 weeks, full weight bearing after 4 to 6 weeks (use of single crutch), and full weight bearing without aids from 6 weeks onwards.

Study interventions

For participants in the standard care arm, after surgery a standard wound dressing and bandaging was applied. This consisted of one layer of soft synthetic bandage, stretching from proximal tibia to distal femur covered by a further layer of crepe bandage with 50% overlap of each layer. The bandaging was removed in the recovery room or within 48 hours on the ward and a cryocuff was applied directly onto the limb with the wound dressing left in situ. Sometimes standard bandaging was maintained for up to 48 hours if wound leakage mandated some pressure application to prevent bleeding. For participants in the compression bandaging (intervention) arm, trained clinical staff applied 3M™ Coban™ 2 Two-Layer Compression System bandaging over the routine surgical wound dressing stretching from the patient's toe to the groin on the affected leg to achieve 35–40 mmHg compression. Competence in the application of the Coban™ 2 system was achieved by initial demonstration of its application by a company representative and the consultation of a subsequent instruction video that could also be used as an aide memoir. The application of bandage from thigh to groin required removal of the tourniquet first and so the leg was kept elevated until the bandaging is complete. A cryocuff was applied in the recovery room or upon return to the ward without removal of the 3M™ Coban™ 2 bandage. Patients were asked to continue wearing the bandage for 7 consecutive days after surgery, which is the maximum proven period for Coban™ 2 efficacy. In both trial arms, the bandages could be removed sooner in the event of any adverse events that would require their removal. Apart from the difference in

type of bandage, the protocol was identical for both Coban™ 2 arm participants and standard care arm participants.

Outcome measures

Either pain or swelling could have been chosen as the primary outcome measure for this trial. In this case, for sample size calculation purposes we opted for operation site-related pain experienced at day 12 post-surgery using a 10-cm visual descriptor scale for pain. The time-point was chosen since all osteotomy patients return to the clinic for a follow-up appointment anyway and therefore it avoided placing extra burden on patients and clinical staff alike. This was also measured, along with the short form McGill pain questionnaire (Melzack, 1987) at day 5, week 6 and week 12 post-surgery. The scores for individual elements of the questionnaire: 0 = no pain; 1 = mild; 2 = discomforting; 3 = distressing; 4 = horrible; 5 = excruciating. Limb girth measurements using standard clinical measuring tape were taken pre-surgery, and at day 12 and week 3 post-surgery at three anatomical locations with leg in stretched position: thigh (10 cm above top of patella), top of patella, and calf (widest part, approximately 10-15 cm from bottom of patella) (Ishida et al, 2011). Validated patient-reported outcome measures related to knee function were administered before surgery: Knee injury and Osteoarthritis Outcome Score (KOOS) and Oxford Knee Score (OKS) (Dawson et al, 1998; Roos & Lohmander, 2003). Finally, patient satisfaction levels in relation to the bandage intervention were measured by means of a short survey at day 12 post-surgery.

Statistical analysis

Study data was populated in Microsoft Excel and analyses were performed with SPSS v20, whereas an a-priori power calculation was performed using GPower 3.1 freeware. The participants' median pain level at day 12 was used as primary outcome, and the trial was powered to detect the established minimal clinically important difference (MCID) of 1.5 cm on a 10 cm VDS pain (Kelly 2001). Applying two-sided Mann-Whitney U-test, at 80% power, 5% significance, and 10% attrition rate, the result is an effect size of 0.88; a total of 50 participants was therefore required, 25 per treatment arm. 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 day 5 and day 12.

Results

A total of 49 patients provided written informed consent to participate in the trial, one short of the target sample size. Due to cancellation of all elective surgery in early 2020, for an unknown period, the decision was made to conclude recruitment into the trial. For a further 4 trial participants, the planned surgery did not take place; one of the patients underwent a total knee arthroplasty instead. Twenty-six patients underwent HTO, 13 had DFO, and on 6 patients a double osteotomy was performed. Figure 1 shows a diagram of the patient numbers at various stages of the trial. Nine adverse events were recorded, 3 in the standard care arm and 6 in the Coban™ 2 arm. For the control arm cases, one was a deep vein thrombosis (DVT) 4 days after surgery, one was a pulmonary embolism 4 weeks after surgery, and one involved increased inflammation 2 days after surgery. In case of the Coban™ 2 arm

participants, reported issues included: 2 patients reported significant leg numbness (DVT subsequently diagnosed in one of these cases), 2 patients experienced skin blistering, 1 patient needed to have bandaging removed due to general discomfort and 1 experienced a suture abscess 6 weeks post-surgery (requiring non-operative anti-bacterial dressing intervention). A total of 36 patients (18 in each group) had data available for day 12 post-surgery. Three of the Coban™ 2 group did not complete the week long application of their bandaging but with intention-to-treat approach they were included in the analysis. The remaining patients who were not included in the analysis either had no surgery or withdrew and did not report on pain at day 5 and day 12 post-surgery. Table 1 summarises the baseline anthropomorphic measurements and clinical parameters for the participants in each of these treatment arms.

The level and type of pain experienced by patients was measured at various intervals post-surgery. Table 2 shows the results for the level of pain recorded by patients on a standard 10-cm visual descriptor scale, which is a scale accompanied by faces to illustrate the degree of pain. At day 5 and day 12 (primary outcome measure) the difference in median pain level did not differ significantly. There appears to be a disparity in the type of pain experienced by patients in the two treatment arms, as shown in Table 3. Overall pain levels (based on adding scores for the different types of pain) and the degree of tiring pain were higher at day 5 in usual care patients, though statistical significance was not reached for either. At day 12 post-surgery, no difference was observed any more in terms of total pain score and tiring pain, but the median throbbing pain level was significantly higher in the Coban™ 2 arm (p-value 0.029). At 6 weeks post-surgery, the total McGill pain score had subsided to a lower level with the

median scores now 5.0 (IQR 2.0-8.5, n = 17) and 9.0 (IQR 3.5-12.0, n= 17) for standard care arm and Coban™ 2 arm respectively (p-value 0.18). Throbbing pain remained higher in the Coban™ 2 arm compared to standard care, median 0.0 [IQR 0.0-1.0], Coban™ 2 arm, median 1.0 [0.5-2.0], p-value 0.027. None of the other types of pain scored high, with no median score higher than 1.0 (meaning mild pain) reported for any of the sub-categories of pain type. Table 4 shows the outcomes of limb girth measurements, comparing pre-operation girth with two different post-operative limb girth measurements for each location at and around the knee joint. No significant differences between standard and compression bandaging are observed. Patient satisfaction levels concerning the application of bandaging are summarized in Table 5, with patients who were applied Coban™ 2 reporting considerably more discomfort at day 12 post-surgery.

Discussion

Orthopaedic teams are continuously looking to optimize patient outcomes, through innovation in pre-, intra-, and post-surgical techniques. The application of compression bandaging after knee surgery has been utilized and trialled for over 20 years with the aim to reduce swelling and pain, and subsequent serious post-surgical complications (Brodell et al, 1986; Charalambides et al, 2005; Andersen et al, 2008; Munk et al, 2013; Pinsornsak P & Chumchuen, 2013; Cheung, Lykostratis, Holloway, 2014; Brock et al, 2017). Unlike other trials of bandaging after TKA surgery, in this present trial a full compression two-layer compression bandage was applied to osteotomy patients and for a longer intended period of 7 days rather

than the more common period 24 hours. The current published evidence does not indicate that a reduction in swelling and pain is achieved in TKA patients when the intervention is brief. One rationale for not applying compression bandaging for longer than 24 hours in TKA patients is to allow commencement of knee joint flexion (Munk et al, 2013); for osteotomy patients this is less of an issue since the knee joint itself is not operated on. In a meta-analysis, Liu and colleagues reviewed the effect of compression bandaging on pain levels at 24 and 48 hours post-surgery, and concluded that compression did not improve pain levels either at rest or when ambulatory (Liu et al, 2020). A MCID of at least 1.5 cm on the 10 cm visual display scale was observed between the standard bandage and Coban™ 2 treatment arms at both 5 and 12 days after surgery. Despite observing this clinically relevant difference, the variation was not statistically significant. Apart from a potential change in the level of overall pain, there may also be a shift in the type of pain experienced by patients over time. Whereas an aching pain was the most troublesome for all patients at day 5, patients allocated a standard bandage also seem to experience a more tiring pain. At day 12 post-surgery, and even at week 6, any difference in tiring pain had subsided but now Coban™ 2 patients experienced significantly more throbbing pain than standard care patients; the median level of throbbing pain for the Coban™ was at the 'discomforting' level. We cannot associate the throbbing pain with limb girth, although it can potentially be a sign of venous congestion (Leung & Kik, 1979; Khan et al 2003).

More patients who were allocated Coban™ 2 experienced adverse events compared to standard crepe bandage patients, and the patient satisfaction survey at day 12 post-surgery confirmed that Coban™ 2 caused more discomfort than standard crepe bandaging. The

patient's skin was not prepared in prior to applying the compression bandaging; this contrasts to clinical practice in vascular surgery, where emollient is first applied to moisturise the skin (Jonker et al 2020). Various compression bandages are available and they differ in the comfort levels perceived by patients who wear them (Jonker et al, 2020). If compression bandaging is continued to be used despite building evidence that its therapeutic effect may be very limited, then input from vascular clinicians would be indicated to at a minimum optimise patient comfort levels associated with wearing the devices. There are a number of study limitations to note. The attrition rate, at 24%, was higher than the anticipated 10%; this has impacted on the power achieved for the trial. Withdrawal rates and loss to follow-up numbers were higher than expected, leading to less data being available for day 5 and da 12 post-surgery time points; the issue of incomplete outcome data was worse still at week 6 and week 12 post-surgery. Unlike the majority of other compression bandage trials, adverse events and complications are reported for this trial (Liu et al, 2020). Although patients were randomly assigned to a treatment arm, neither patients nor clinical staff were blinded to the allocated treatment because the two bandages look and feel different and this may lead to performance bias. A balance was struck between logistic feasibility and method optimization. Blinded metrologist staff were not deployed for taking measurements, and limb girth was measured to record swelling - rather than using a water displacement tool - to measure limb volume.

Different types of compression bandaging have been used in trials, from Modified Robert Jones (Yu, Schubert, Khoury, 2002; Pinsornsak & Chumchuen, 2013) to 3M Coban (Munk et al, 2013), the compression intervention was intended to achieve approximately 40 mmHg.

The present study is no different in that respect. A key surgical difference between osteotomy and TKA is that the proximal tibial or distal femoral metaphyseal bone is cut but there is no violation of the knee joint cavity as with arthroplasty. Nonetheless, the operated leg does swell after osteotomy and therefore the degree of swelling was measured at day 5 in particular, which is the peak day of swelling after TKA (Gao et al, 2011). Similar to results from other trials where swelling was measured at 3 days (Yu et al, 2002) or 7 days (Munk et al, 2013) after 24 hours of compression, we did not observe any significant differences in swelling between control and compression interventions at 5 days or 12 days after surgery despite applying compression for longer. Despite early evidence of the physiological benefit of compression of the leg for 24 hours (Charalambides et al, 2005), more recent studies have been unable to confirm that this translates into reduced pain at day 1 and day 2 post-surgery or swelling up to a month post-surgery as summarized in a recent meta-analysis (Liu et al, 2020). In addition, our data indicates that a 7-day application of compression bandage may potentially be too long: it may suppress pain early on after an operation, but may then introduce issues related to extended compression of the leg. A next step would therefore be to apply compression bandaging for > 1 day and < 7 days. There is one trial ongoing, called KREBS, in which Coban™ 2 is applied for up to 48 hours to TKA patients' legs (Cook et al, 2019). A similar approach is indicated specifically for osteotomy cases to elucidate if there is an optimum application period for compression bandaging post-surgery or if other means need to be considered to control symptoms.

Conclusions

This trial describes the type of pain that patients experience after osteotomy surgery and the impact that different bandaging may have on the pain experienced by patients. The application of compression bandaging for an extended period of a week may give osteotomy patients a degree of pain relief whilst the bandaging is worn. However, a drawback is an increase in specific throbbing pain and a lack of swelling reduction, once compression bandaging is removed. In summary, our results do not support the use of full compression bandaging for a week in osteotomy patients for the control of post-operative pain and swelling. Any future work, involving larger sample sizes, should focus on a) optimising the comfort level of the applied compression bandaging, b) determining if a difference in the degree of compression affects outcome measures, and c) 'titration' of the intervention period to determine whether compression can be effective.

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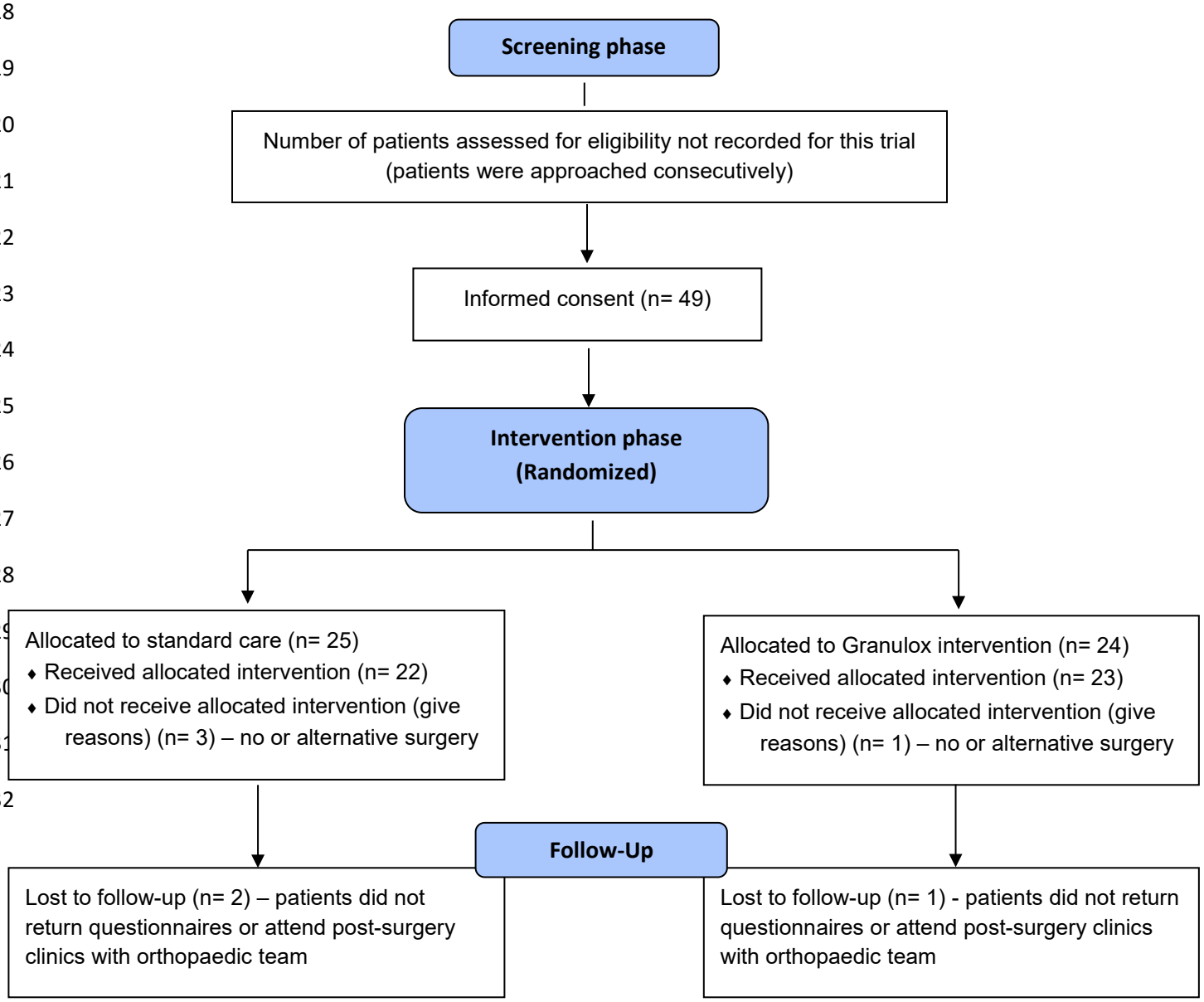
Figure 1, CONSORT flowchart for ROBOT trial



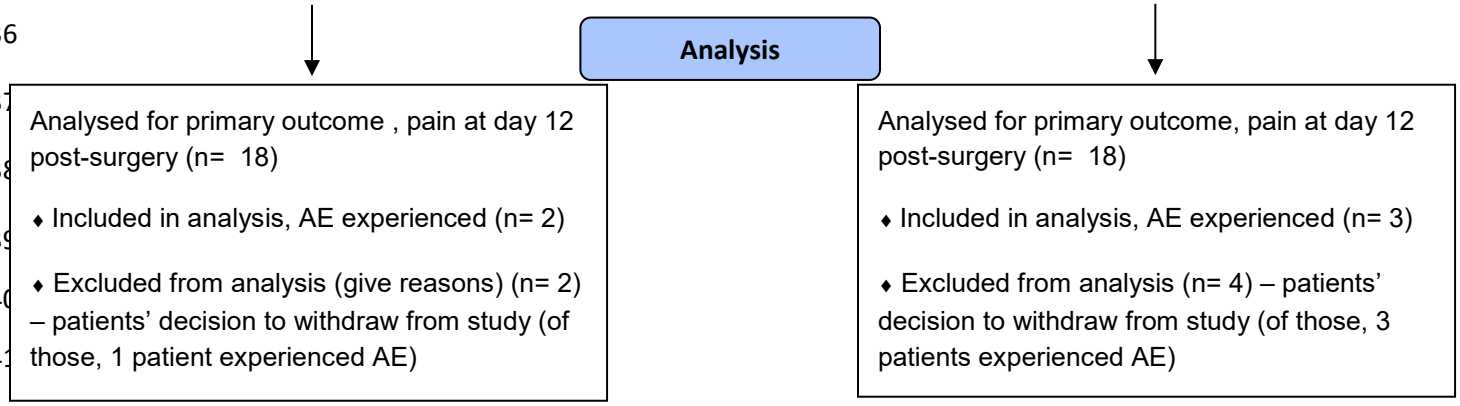


Table 1, demographics and baseline characteristics for study subjects included in analysis of primary outcome measure (pain at 12 days post-surgery)

Parameter	**Standard care (n = 18)**	**Coban™ 2 (n = 18)**
Age, mean in yrs (SD)	52 (11)	56 (10)
Sex, n (male / female)	17 / 7	14 / 4
Weight, mean in kg (SD)	83 (26)	89 (16)
Height, mean in cm (SD)	171 (6)	174 (9)
BMI, mean in kg/m^2 (SD)	30 (5)	29 (4)
Leg affected, left/right, n	10 / 8	9 / 9
Device used, Tomofix/Newclip, n	13 / 5	13 / 5
OKS pre-op, median (IQR)	26.5 (13.5)	25.0 (11)
KOOS S pre-op, median (IQR)	50.0 (37.5)	50.0 (37.5)
KOOS P pre-op, median (IQR)	37.5 (25)	37.5 (25)

KOOS A pre-op, median (IQR)	61.0 (24.5)	59.0 (23)
KOOS SP pre-op, median (IQR)	25 (40.5)	37.5 (37.5)
KOOS Q pre-op, median (IQR)	25 (19)	25 (25)

Table 2, At rest pain level related to affected leg post-surgery, measured using 10-cm visual display scale

Time point	**Standard care arm (n = 18)**	**Coban™ 2 arm (n = 18)**	**p-value**
5 days post-surgery, median value (IQR)	5.5 (2.5-7.0)	2.5 (1.5-6.5)	0.068
12 days post-surgery, median value (IQR)	4.0 (3.0-5.3)	2.3 (1.4-5.6)	0.39

6 weeks post-surgery, median value (IQR)	2.0 (1.5-2.5)[#]	2.8 (1.0-5.8)*	0.21

[#] n = 16; * n=17

Table 3, Pain at rest, measured with short form McGill questionnaire at 5 and 12 days post-surgery

		5 days post-surgery			12 days post-surgery		
Type of pain	**Treatment arm**	**Median**	**IQR**	**p-value[#]**	**Median**	**IQR**	**p-value[#]**
Throbbing	Standard care	1.5	1.0-2.0	0.54	1.0	1.0-1.0	0.029[1]
	Coban™ 2	1.0	0.0-2.0		2.0	1.0-2.0	
Shooting	Standard care	1.0	0.0-1.3	0.24	1.0	0.0-1.3	0.84
	Coban™ 2	0.0	0.0-1.0		1.0	0.0-1.3	
Stabbing	Standard care	0.5	0.0-2.0	0.36	0.0	0.0-1.3	0.36

	Coban™ 2	0.0	0.0-1.3		1.0	0.0-1.3	
Sharp	Standard care	1.0	1.0-2.0	0.24	1.0	0.0-2.0	0.66
	Coban™ 2	1.0	0.0-2.0		1.0	0.0-1.0	
Cramp	Standard care	0.0	0.0-1.3	0.67	0.0	0.0-0.3	0.99
	Coban™ 2	0.0	0.0-0.3		0.0	0.0-0.3	
Gnawing	Standard care	0.0	0.0-1.0	0.24	0.0	0.0-1.0	0.56
	Coban™ 2	0.0	0.0-0.3		0.0	0.0-1.3	
Hot	Standard care	1.0	0.0-2.0	0.18	0.5	0.5-1.3	0.61
	Coban™ 2	0.5	0.0-2.0		1.0	0.0-2.0	
Aching	Standard care	2.0	1.0-2.0	0.25	1.5	1.0-2.0	0.52
	Coban™ 2	1.0	0.8-2.0		1.0	1.0-2.0	
Heavy	Standard care	1.0	0.0-2.3	0.34	1.0	0.0-2.0	0.61
	Coban™ 2	1.0	0.0-2.0		1.0	0.0-2.0	
Tender	Standard care	1.5	1.0-2.3	0.46	1.0	0.0-2.0	0.72
	Coban™ 2	1.0	0.0-2.3		1.5	0.8-2.0	
Splitting	Standard care	0.0	0.0-0.3	0.56	0.0	0.0-0.3	0.99
	Coban™ 2	0.0	0.0-0.0		0.0	0.0-0.3	
Tiring	Standard care	1.5	0.8-2.3	0.055	1.0	1.0-2.0	0.32
	Coban™ 2	0.5	0.0-2.0		1.0	0.0-2.0	
Sickening	Standard care	0.0	0.0-1.0	0.20	0.0	0.0-1.0	0.91
	Coban™ 2	0.0	0.0-0.0		0.0	0.0-0.3	

Fearful	Standard care	0.0	0.0-1.0	0.41	0.0	0.0-0.3	0.61
	Coban™ 2	0.0	0.0-0.0		0.0	0.0-0.0	
Punish	Standard care	0.0	0.0-0.3	0.41	0.0	0.0-0.0	0.82
	Coban™ 2	0.0	0.0-0.0		0.0	0.0-0.0	
Total McGill pain score	Standard care	12.5	10.0-17.8	0.051	10.0	5.0-15.3	0.79
	Coban™ 2	10.0	2.8-14.3		11.5	4.0-18.5	

#Mann-Whitney U-test; [1]Statistically significant difference

Table 4, Measurement of limb girth changes after high tibial osteotomy

	Standard care arm	**Coban™2 arm**	**p-value[#]**
12 days post-surgery vs pre-surgery, Δ cm, median (IQR)	n = 18	n = 17	
Thigh	0.5 (7.1)	1.0 (3.8)	0.66

Suprapatellar	1.5 (3.5)	2.5 (4.0)	0.77
Calf	0.0 (2.1)	0.0 (3.8)	0.29
3 weeks post-surgery vs pre-surgery, Δ cm, median (IQR)	n= 18	n= 16	
Thigh	-1.0 (5.4)	1 (3.1)	0.21
Suprapatellar	1.0 (2.1)	2.3 (2.8)	0.081
Calf	-0.5 (1.1)	-0.5 (3.9)	0.83

#Mann-Whitney U-test

Table 5, patient satisfaction 12 days after surgery

Question	**Standard care**	**Coban™ 2**	**p-value**
At this moment in time, how do rate the dressing that you were allocated after surgery?[a], response (n)	Excellent (8) / Good (6) / Average (1)	Excellent (8) / Good (6) / Poor (1)	0.57[#]

Has the dressing given you any discomfort?	15 no / 1 yes	6 no / 10 yes	0.002*
How comfortable did you think the bandaging was?, response (n)[b]	Very comfortable (8) / comfortable (5) / slightly uncomfortable (1)	Very comfortable (3) / comfortable (6) / slightly uncomfortable (6) / very uncomfortable (1) / intolerable (2)	0.056#

#Mann-Whitney U-test; *Fisher exact test; [a] response options were: very poor, poor, average, good, excellent; [b] response options were: intolerable (i.e. needed to be taken off), very uncomfortable, slightly uncomfortable, comfortable, very comfortable.