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- 1 **Title**: Application of compression bandaging post-osteotomy results in altered pain profile;
- 2 results of a single-centre randomised controlled trial.
- 3 **Running title:** Outcomes for bandaging after osteotomy
- 4 Leon Jonker PhD, Lucy Bell, RGN, Kirsty Robinson, RGN, Katherine Davidson, Matt Dawson FRCS.

5 Author details

- 6 Dr Leon Jonker, Science & Innovation Manager, North Cumbria Integrated Care NHS Foundation
- 7 Trust, Carlisle, CA2 7HY, UK, <u>leon.jonker@ncic.nhs.uk</u>, ORCID 0000-0001-5867-4663.
- 8 Lucy Bell, Specialist Orthopaedic Nurse, North Cumbria Integrated Care NHS Foundation Trust,
- 9 Carlisle, CA2 7HY, UK, <u>lucy.bell@ncic.nhs.uk</u>
- 10 Kirsty Robinson, Specialist Orthopaedic Nurse, North Cumbria Integrated Care NHS Foundation
- 11 Trust, Carlisle, CA2 7HY, UK, <u>kirsty.robinson@ncic.nhs.uk</u>
- 12 Katherine Davidson, Research Practitioner, North Cumbria Integrated Care NHS Foundation
- 13 Trust, Carlisle, CA2 7HY, UK, <u>katherine.davidson@ncic.nhs.uk</u>
- 14 Mr Matt Dawson, Consultant Orthopaedic Surgeon, North Cumbria Integrated Care NHS
- 15 Foundation Trust, Carlisle, CA2 7HY, UK, <u>matt.dawson@ncic.nhs.uk</u>
- 16 **Corresponding author:**
- 17 Ms Lucy Bell, Specialist Orthopaedic Nurse, North Cumbria Integrated Care NHS Foundation
- 18 Trust, Cumberland Infirmary, Newtown Road, Carlisle, Cumbria, CA2 7HY, UK. *Phone number:*
- 19 +44 (0) 1228 811 4279, Email: <u>lucy.bell@ncic.nhs.uk</u>

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

27

28 Abstract

- 29 Purpose
- 30 To assess if application of dual-layer compression bandage to osteotomy patients post-surgery
- 31 can positively influence levels of post-operative pain and swelling.
- 32 Patients & Methods
- 33 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
- 35 of osteotomy patients.

36 Results

- 37 Primary outcome data was available for 36 out of 49 study subjects (18 standard care versus 18
- 38 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:
- 40 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
- 42 patients. Changes in limb swelling measures, comparing before and after the surgical procedure,
- 43 did not differ between treatment arms. Compression led to more patients reporting bandage-
- 44 related discomfort (6% standard care versus 63% Coban[™] 2 patients).

45 Conclusion

- 46 Compression bandaging changes the post-surgery pain profile in osteotomy patients, but does
- 47 not reduce leg swelling. Any subsequent leg compression trials must take into account patient
- 48 comfort and titrate intervention length and compression rates.
- 49 **Keywords**: osteoarthritis, osteotomy, compression bandaging, pain, swelling, patient recovery.

50

51

52 Introduction

53

Medial osteoarthritis of the knee can be treated with open-wedge high tibial osteotomy (HTO). 54 55 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 56 57 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 & 58 Margheritini, 2014). There are two features associated with post-knee surgery recovery that 59 60 seem to very frequently occur in patients: pain and swelling (Garrett & Walters, 2010). Postsurgery leg swelling occur due to bleeding and particularly inflammation-related fluid build-up in 61 the intraarticular tissues; one contributing factor to patients experiencing pain is the increased 62 circumference of the limb causing increased tension of the soft tissue (Holm et al, 2010; Gao et 63 64 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 65 (Yu et al, 2002; Mizner & Snyder-Mackler, 2005). Many service improvement programmes and 66 techniques have been introduced in knee surgery over the years, including means to reduce 67 intra-articular bleeding, tourniquets and medication (Martin et al , 2014). Some initiatives in 68 69 post-surgical management of patients have been less successful, such as the use of a cold 70 compress and cryotherapy (Morsi, 2002; Adie et al, 2012). More recent efforts have focussed on 71 the putative role that the application of compression can have on pain and swelling post knee 72 surgery.

73 Background

Compression bandage therapy is the established treatment for venous ulcers and lymphoedema 74 75 (Franks et al, 2004), aiding venous return and reducing hydrostatic pressure in the leg by (i) 76 improving the efficacy of the calf muscle pump and (ii) moving blood from the superficial to deep 77 venous system, subsequently allowing movement of fluid from the interstitial space. This mode of 78 action may therefore be of benefit to patients who undergo knee surgery. Efficacy trials of 79 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 80 81 amongst orthopaedic surgeons in South Africa suggests that increased post-operative swelling is 82 associated with higher pain levels (Garrett & Walters, 2010).

The use of compression bandaging after TKA was first introduced in the 1980s with the 'Robert 83 84 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 85 10 mm Hg within 48 hours; some observed reduced pain and swelling (Gibbons et al, 2001) 86 whereas others failed to see a difference (Pinsornsak & Chumchuen, 2013; Yu et al, 2018). More 87 recently, work by Christensen and colleagues demonstrated that 23 mmHg stockings applied 88 straight after surgery and worn for two weeks do not significantly alter swelling or pain levels 89 90 experienced by TKA patients (Christensen et al, 2020). When Munk and colleagues first treated 91 patients with 3M[™] Coban[™] 2 Two-Layer Compression bandaging for 24 hours, achieving 35-40 92 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 93 94 the first week and two to three weeks after surgery. As the above examples illustrate, despite its 95 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 96 97 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, 98 99 Christensen et al, 2020). Direct evidence on the role that extended use of full compression 100 bandaging may play in terms of post-operative outcomes after osteotomy surgery is lacking. The 101 aim of this trial was to assess the efficacy (pain and swelling levels after surgery) and safety of a 7day application of short stretch compression bandaging, compared to standard wool & crepe 102 103 bandaging, in an osteotomy patient population as opposed to TKA cohorts studied to date.

104 Methods

105 Study design and subjects

106 The study concerns a single centre, prospective, open label, randomised controlled trial, 107 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. 108 Subsequently, at the surgery pre-assessment visit written informed consent and baseline 109 parameters were obtained; therefore, patients had a minimum of 24 hours to consider 110 participation in the study. Two different surgeons performed all the operations. For the osteotomy 111 112 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 113 114 prospectively and consecutively from surgical lists. Ethics approval was obtained from the UK's 115 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 116

117 obtained prior to commencing the trial. Participant inclusion criteria were: adult patients 118 undergoing unilateral high tibial osteotomy (HTO), distal femoral osteotomy (DFO) or a double 119 osteotomy (HTO and DFO); ankle brachial index measured within 12 weeks and with value ≥ 0.8 ; 120 mental capacity to give written informed consent. Exclusion criteria were: revision of previous 121 osteotomy; diabetes; any condition associated with excessive bleeding, coagulation abnormalities 122 or any other significant haematological condition; cardiovascular, vascular or dermatological condition contraindicating the use of compression bandaging. Written informed consent was 123 124 obtained from all participants in accordance with the Declaration of Helsinki (Good Clinical Practice), 125 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 126 127 visual difference between interventions in the two treatment arms, blinding of patient and research staff was not applied. 128

129 Surgical procedures & Rehabilitation

The opening or closing wedge HTO and/or DFO was conducted according to the method outlined 130 131 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 132 anaesthesia was applied to all patients - between 60-120 mls (depending on the size of the 133 operative field and patient weight) of Chirocaine[®] 1.25 mg/ml before closure of the wound. All 134 patients were administered a calf pump and prescribed enoxaparin sodium (Clexane®) whilst 135 136 hospitalised, and prescribed rivaroxaban for two weeks once discharged home. Patients were 137 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 ofsingle crutch), and full weight bearing without aids from 6 weeks onwards.

140 *Study interventions*

For participants in the standard care arm, after surgery a standard wound dressing and bandaging 141 142 was applied. This consisted of one layer of soft synthetic bandage, stretching from proximal tibia 143 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 144 applied directly onto the limb with the wound dressing left in situ. Sometimes standard bandaging 145 was maintained for up to 48 hours if wound leakage mandated some pressure application to 146 147 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 148 149 surgical wound dressing stretching from the patient's toe to the groin on the affected leg to 150 achieve 35–40 mmHg compression. Competence in the application of the Coban[™] 2 system was 151 achieved by initial demonstration of its application by a company representative and the 152 consultation of a subsequent instruction video that could also be used as an aide memoir. The 153 application of bandage from thigh to groin required removal of the tourniquet first and so the leg 154 was kept elevated until the bandaging is complete. A cryocuff was applied in the recovery room 155 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 156 proven period for Coban[™] 2 efficacy. In both trial arms, the bandages could be removed sooner in 157 the event of any adverse events that would require their removal. Apart from the difference in 158

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

161 *Outcome measures*

162 Either pain or swelling could have been chosen as the primary outcome measure for this trial. In 163 this case, for sample size calculation purposes we opted for operation site-related pain 164 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 165 166 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 6 167 168 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 169 170 using standard clinical measuring tape were taken pre-surgery, and at day 12 and week 3 post-171 surgery at three anatomical locations with leg in stretched position: thigh (10 cm above top of 172 patella), top of patella, and calf (widest part, approximately 10-15 cm from bottom of patella) 173 (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 174 Knee Score (OKS) (Dawson et al, 1998; Roos & Lohmander, 2003). Finally, patient satisfaction levels 175 in relation to the bandage intervention were measured by means of a short survey at day 12 post-176 177 surgery.

178 Statistical analysis

Study data was populated in Microsoft Excel and analyses were performed with SPSS v20, whereas 179 180 an a-priori power calculation was performed using GPower 3.1 freeware. The participants' median 181 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 182 183 2001). Applying two-sided Mann-Whitney U-test, at 80% power, 5% significance, and 10% attrition 184 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 185 186 assessed with two-sided Mann-Whitney test for ordinal and continuous data, and Chi-square test 187 for binary data. An intention-to-treat approach was taken for data analysis where patients had 188 surgery and reported on pain at least for day 5 and day 12.

189 Results

A total of 49 patients provided written informed consent to participate in the trial, one short 190 191 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 192 193 4 trial participants, the planned surgery did not take place; one of the patients underwent a 194 total knee arthroplasty instead. Twenty-six patients underwent HTO, 13 had DFO, and on 6 195 patients a double osteotomy was performed. Figure 1 shows a diagram of the patient 196 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 197 198 thrombosis (DVT) 4 days after surgery, one was a pulmonary embolism 4 weeks after surgery, 199 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 200 201 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 202 203 suture abscess 6 weeks post-surgery (requiring non-operative anti-bacterial dressing 204 intervention). A total of 36 patients (18 in each group) had data available for day 12 postsurgery. Three of the Coban[™] 2 group did not complete the week long application of their 205 206 bandaging but with intention-to-treat approach they were included in the analysis. The 207 remaining patients who were not included in the analysis either had no surgery or withdrew 208 and did not report on pain at day 5 and day 12 post-surgery. Table 1 summarises the baseline 209 anthropomorphic measurements and clinical parameters for the participants in each of these 210 treatment arms.

The level and type of pain experienced by patients was measured at various intervals post-211 212 surgery. Table 2 shows the results for the level of pain recorded by patients on a standard 10-213 cm visual descriptor scale, which is a scale accompanied by faces to illustrate the degree of 214 pain. At day 5 and day 12 (primary outcome measure) the difference in median pain level did 215 not differ significantly. There appears to be a disparity in the type of pain experienced by 216 patients in the two treatment arms, as shown in Table 3. Overall pain levels (based on adding 217 scores for the different types of pain) and the degree of tiring pain were higher at day 5 in 218 usual care patients, though statistical significance was not reached for either. At day 12 post-219 surgery, no difference was observed any more in terms of total pain score and tiring pain, but 220 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 221

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 222 223 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 224 225 1.0 [0.5-2.0], p-value 0.027. None of the other types of pain scored high, with no median score 226 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 227 228 different post-operative limb girth measurements for each location at and around the knee 229 joint. No significant differences between standard and compression bandaging are observed. 230 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 231 232 12 post-surgery.

233

234 Discussion

Orthopaedic teams are continuously looking to optimize patient outcomes, through 235 236 innovation in pre-, intra-, and post-surgical techniques. The application of compression 237 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, 238 239 1986; Charalambides et al, 2005; Andersen et al, 2008; Munk et al, 2013; Pinsornsak P & 240 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 241 bandage was applied to osteotomy patients and for a longer intended period of 7 days rather 242

than the more common period 24 hours. The current published evidence does not indicate 243 244 that a reduction in swelling and pain is achieved in TKA patients when the intervention is 245 brief. One rationale for not applying compression bandaging for longer than 24 hours in TKA 246 patients is to allow commencement of knee joint flexion (Munk et al, 2013); for osteotomy 247 patients this is less of an issue since the knee joint itself is not operated on. In a meta-analysis, 248 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 249 250 or when ambulatory (Liu et al, 2020). A MCID of at least 1.5 cm on the 10 cm visual display 251 scale was observed between the standard bandage and Coban[™] 2 treatment arms at both 5 252 and 12 days after surgery. Despite observing this clinically relevant difference, the variation 253 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 254 255 pain was the most troublesome for all patients at day 5, patients allocated a standard bandage 256 also seem to experience a more tiring pain. At day 12 post-surgery, and even at week 6, any 257 difference in tiring pain had subsided but now Coban[™] 2 patients experienced significantly 258 more throbbing pain than standard care patients; the median level of throbbing pain for the 259 Coban[™] was at the 'discomforting' level. We cannot associate the throbbing pain with limb 260 girth, although it can potentially be a sign of venous congestion (Leung & Kik, 1979; Khan et 261 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 265 patient's skin was not prepared in prior to applying the compression bandaging; this contrasts 266 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 267 levels perceived by patients who wear them (Jonker et al, 2020). If compression bandaging is 268 269 continued to be used despite building evidence that its therapeutic effect may be very limited, 270 then input from vascular clinicians would be indicated to at a minimum optimise patient 271 comfort levels associated with wearing the devices. There are a number of study limitations 272 to note. The attrition rate, at 24%, was higher than the anticipated 10%; this has impacted on 273 the power achieved for the trial. Withdrawal rates and loss to follow-up numbers were higher 274 than expected, leading to less data being available for day 5 and da 12 post-surgery time 275 points; the issue of incomplete outcome data was worse still at week 6 and week 12 post-276 surgery. Unlike the majority of other compression bandage trials, adverse events and 277 complications are reported for this trial (Liu et al, 2020). Although patients were randomly 278 assigned to a treatment arm, neither patients nor clinical staff were blinded to the allocated 279 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. 280 281 Blinded metrologist staff were not deployed for taking measurements, and limb girth was 282 measured to record swelling - rather than using a water displacement tool - to measure limb 283 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 287 288 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 289 290 swell after osteotomy and therefore the degree of swelling was measured at day 5 in 291 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, 292 293 2013) after 24 hours of compression, we did not observe any significant differences in swelling 294 between control and compression interventions at 5 days or 12 days after surgery despite 295 applying compression for longer. Despite early evidence of the physiological benefit of 296 compression of the leg for 24 hours (Charalambides et al, 2005), more recent studies have 297 been unable to confirm that this translates into reduced pain at day 1 and day 2 post-surgery 298 or swelling up to a month post-surgery as summarized in a recent meta-analysis (Liu et al, 299 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 300 301 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 302 303 KREBS, in which Coban[™] 2 is applied for up to 48 hours to TKA patients' legs (Cook et al, 2019). 304 A similar approach is indicated specifically for osteotomy cases to elucidate if there is an 305 optimum application period for compression bandaging post-surgery or if other means need to be considered to control symptoms. 306

307 Conclusions

308 This trial describes the type of pain that patients experience after osteotomy surgery and the 309 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 310 patients a degree of pain relief whilst the bandaging is worn. However, a drawback is an 311 312 increase in specific throbbing pain and a lack of swelling reduction, once compression 313 bandaging is removed. In summary, our results do not support the use of full compression 314 bandaging for a week in osteotomy patients for the control of post-operative pain and 315 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 316 317 degree of compression affects outcome measures, and c) 'titration' of the intervention period to determine whether compression can be effective. 318

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436		Analysis	
43 438	Analysed for primary outcome , pain at day 12 post-surgery (n= 18)		Analysed for primary outcome, pain at day 12 post-surgery (n= 18)
439	 Included in analysis, AE experienced (n= 2) 		 Included in analysis, AE experienced (n= 3)
440	 Excluded from analysis (give reasons) (n= 2) patients' decision to withdraw from study (of 		 Excluded from analysis (n= 4) – patients' decision to withdraw from study (of those, 3
441	those, 1 patient experienced AE)		patients experienced AE)
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Table 1, demographics and baseline characteristics for study subjects included in analysis of

444 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)

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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)

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

455 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	2.0 (1.5-2.5)#	2.8 (1.0-5.8)*	0.21
	value (IQR)			
456	[#] n = 16; * n=17			
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- Table 3, Pain at rest, measured with short form McGill questionnaire at 5 and 12 days post-
- 469 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	
Неаvy	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	

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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	Standard care	12.5	10.0-17.8	0.051	10.0	5.0-15.3	0.79
pain score	Coban™ 2	10.0	2.8-14.3		11.5	4.0-18.5	

470 #Mann-Whitney U-test; ¹Statistically 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

479 #Mann-Whitney U-test

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483 Table 5, patient satisfaction 12 days after surgery

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

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

485 #Mann-Whitney U-test; *Fisher exact test; ^a response options were: very poor, poor, average, good,

486 excellent; ^b response options were: intolerable (i.e. needed to be taken off), very uncomfortable, slightly

487 uncomfortable, comfortable, very comfortable.

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