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Non-compressive sleeves versus compression stockings after total knee arthroplasty: A prospective pilot study

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ABSTRACT

Background: Compression stockings are routinely prescribed after total knee arthroplasty (TKA). Non-compressive sleeves embedded with semiconductor elements (Incrediwear) are designed to enhance blood flow. The objective of this investigation is to compare compression stockings and Incrediwear on post-TKA measures.

Methods: In this single-center prospective clinical pilot study, patients undergoing TKA were assigned to either the compression stocking (control) or Incrediwear (experimental) group. Subjects were evaluated preoperatively and postoperative at 3 weeks for pain, knee effusion, knee range of motion (ROM), thigh and calf circumferences.

Results: Incrediwear subjects had slightly higher preoperative effusion than controls (mean effusion 1.38 vs. 1.16, $p = .28$); however, by week 3, Incrediwear subjects had lower levels of effusion than controls (1.12 vs. 1.56, $p = .015$). At week 3, when compared to pre-op, Incrediwear subjects experienced a 19% decrease in effusion while controls experienced a 35% increase in effusion ($p = .003$). Preoperatively, there were no differences observed between Incrediwear subjects and controls flexion ROM (mean ROM 117 vs. 116, $p = .67$); however, by week 3, Incrediwear subjects had greater flexion ROM than controls (113 vs. 108, $p = .02$). Incrediwear subjects experienced only a 3% decrease in flexion ROM while controls experienced a 7% decrease in ROM ($p = .07$). Incrediwear subjects reported higher preoperative pain than controls (mean pain 4.2 vs. 3.2, $p = .051$); however, by week 3, there was no difference observed between these groups (2.9 vs. 3.0, $p = .440$).

Discussion: Non-compressive sleeves embedded with semiconductor elements (Incrediwear) appeared to reduce effusion and improve knee flexion better than traditional compression stockings 3 weeks after total knee arthroplasty.

1. Introduction

Compression stockings or Thrombo-Embolism Deterrent (TED) hose are commonly prescribed after total knee arthroplasty (TKA) primarily to reduce the risk of deep vein thromboses[1–3] and leg swelling.[4,5] Early postoperative interventions have been shown to improve functional outcomes and associated measures; however, there is a paucity of data on compression stockings' impact on such measures.[6–14] Non-compressive sleeves embedded with semiconductor elements (Incrediwear) are designed to enhance blood flow and functional outcomes.[15] Compared to compression stockings, it is hypothesized that subjects utilizing Incrediwear will demonstrate better post-TKA outcomes.

2. Methods

2.1. Design and sample

This was a single-center prospective pilot study with one experienced, board-certified, fellowship-trained orthopedic surgeon. Patients undergoing TKA between August 2021 and March 2022 were approached for preoperative consent. The primary total knee arthroplasty procedure was done using a 3D CT-based minimally invasive robotics system. Female and male patients ages 40–90 were included. Consenting participants were enrolled in the study. Standard care protocol after TKA included patients wear compression stockings (TED hose) on both legs for 23 h per day for 3 weeks (control). Post-TKA subjects in the Incrediwear (experimental) group were discharged from the hospital with the Leg Sleeve (Fig. 1) on the operative extremity

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Fig. 1. Incrediwear (incrediwear holdings, inc., chico, CA) leg sleeve.

and a traditional TED hose worn on the non-operative extremity, both to be worn for the first three weeks 23 h per day. The non-compressive semiconductor-embedded Leg Sleeves emit mid and far infrared waves when exposed to heat from the wearer's body. Subjects were assigned to either the control or experimental group. Balanced subject assignment was achieved by patients selecting their group. Exclusion criteria were subjects with rheumatoid arthritis, poorly controlled diabetes (HbA1c > 7.5), history of blood clots, BMI >35, and varicosities. The study was approved by the WCG institutional review board.

2.2. Outcome measures

The following measures were assessed preoperatively and post-operative at 3 weeks: pain (0-10), knee effusion (0–3; measured using the Stoke Test), knee range of motion (ROM; measured using a goniometer)—both flexion and extension, thigh and calf circumferences, and patient-reported Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR) questionnaires. The Stoke Test for knee effusion is graded as follows: 0 – no wave produced with the lateral downward stroke, 1+ - large wave returns with lateral downward stroke, 2+ - effusion spontaneously returns to medial side after upstroke (without lateral downward stroke), and 3+ - so much fluid that it is impossible to move any of the effusion out of the medial aspect. Using a tape measure, extremity circumferences were measured 10 cm above the superior pole of the patella for the thigh and 10 cm below the mid-patella for the calf.

2.3. Statistical methods

All analyses were conducted using R (R Core Team and the R Foundation for Statistical Computing, Vienna, Austria) with the following packages[16–20]: lme4, lsmeans, pbkrtest, emmeans, and mer-Tools. Outcomes include pain (0-10), effusion, thigh circumference, calf circumference, range of motion flex, random of motion Extend, and KOOS questions 1–7. As this is a pilot study, no effect size or variance estimates were available to perform a power analysis. Outcomes were modeled over time by treatment group using generalized linear modeling with maximum likelihood estimation, where observations were nested within patients. Tests for superiority include interactions and contrasts between groups between baseline and week 3 follow up with Kenward-Roger degrees of freedom; exploratory analyses were conducted for all timepoints. Bilateral TKA subjects were adjusted for being in both conditions using generalized linear mixed modeling—since all bilateral subjects received both conditions, there should be no systematic confound between the conditions. Alpha was defined a priori at the 0.05 level and all interval estimates were calculated for 95% confidence.

3. Results

3.1. Subjects

A total of 55 subjects were enrolled in the study with 25 in the control group, 25 in the Incrediwear group, and 5 bilateral TKA subjects with one leg assigned to the control stocking and the other leg assigned to Incrediwear. The groups' demographics were not dissimilar (Table 1).

3.2. Pain

Incrediwear subjects reported higher preoperative pain than controls (mean pain 4.2 vs. 3.2, $p = .051$); however, by week 3, there was no difference observed between these groups (2.9 vs. 3.0, $p = .440$) (Table 2 and Figure Panel 2).

3.3. Effusion

Incrediwear subjects had slightly higher preoperative effusion than controls (mean effusion 1.38 vs. 1.16, $p = .28$); however, by week 3, Incrediwear subjects had lower levels of effusion than controls (1.12 vs. 1.56, $p = .015$). At week 3, when compared to pre-op, Incrediwear subjects experienced a 19% *decrease* in effusion while controls experienced a 35% *increase* in effusion. This change was statistically significant ($p = .003$).

3.4. Range of motion

Preoperatively, there were no differences observed between Incrediwear subjects and controls (mean ROM 117 vs. 116, $p = .67$); however, by week 3, Incrediwear subjects had greater flexion ROM than controls (113 vs. 108, $p = .02$). Incrediwear subjects experienced only a 3% decrease in flexion ROM while controls experienced a 7% decrease in ROM. This change approached statistical significance ($p = .07$). No statistical differences were observed for extension ROM (Table 2).

3.5. Calf and thigh circumferences

As the results are in Fig. 2 and Table 2, calf circumference for all timepoints approached statistical significance ($p = .08$), where Incrediwear subjects had lower (and sustained) circumference compared with controls.

Table 1
Demographics by group.

Group	BI			CTL			EXP		
	N	Est		N	Est		N	Est	
Race (White)	5	100%		25	100%		24	96%	
None-Hispanic	5	100%		25	100%		25	100%	
Current tobacco (yes)	1	20%		1	4%		2	8%	
History of tobacco (yes)	2	40%		5	20%		9	36%	
History Brace Use (yes)	8	80%		19	76%		15	60%	
Prior Surgery (yes)	8	80%		19	76%		14	56%	
Female	2	40%		12	48%		11	44%	
Height	5	67.4	(3.6)	25	68.08	(4.3)	25	67.52	(4.2)
Weight	5	175.4	(46.1)	25	194.975	(34.0)	25	195.56	(38.0)
BMI	5	26.854	(5.2)	25	29.424	(3.3)	25	30.033	(3.9)
Laterality	10			25			25		
BILAT	10	100%		0	0%		0	0%	
Left	5	50%		14	56%		11	44%	
Right	5	50%		11	44%		14	56%	
ROM EXT Pre	10	1.3	(2.5)	25	5.68	(6.0)	25	4.08	(5.3)
ROM FLEX Pre	10	127.2	(5.0)	25	125.52	(14.6)	25	126.68	(10.1)
TRNQT.TIME.IN.MINS	10	66.9	(10.7)	25	57.96	(7.5)	25	61.88	(12.7)
LEG.CIRC.10CM.ABOVE.PATELLA	10	48.15	(1.9)	25	46.144	(5.4)	25	47.208	(8.4)
LEG.CIRC.MID.PATELLA	10	40.28	(3.5)	25	40.712	(4.0)	25	41.028	(5.3)
LEG.CIRC.10CM.BELOW.PATELLA	10	37.85	(3.1)	25	37.06	(2.7)	25	38.124	(6.4)
ROM_EXT_END	10	−1.1	(3.5)	25	0.32	(0.9)	25	0.44	(1.2)
ROM_FLEX_END	10	135.8	(7.5)	25	132.68	(10.7)	25	134.32	(7.3)

Est = estimate (Mean or Percentage, when appropriate); N = count; SD = standard deviation.

Table 2
Estimates between pre-Operation and week 3.

	TX	Time	Mean	LCL	UCL	Delta	SE	P-Value	TX*TIME
Pain	*CTL*	*0*	3.15	2.4	3.9	−1.038	0.527	0.051	0.074
	EXP	*0*	4.19	3.44	4.94				
	CTL	*3*	2.88	2.14	3.63	−0.071	0.527	0.999	
	EXP	*3*	2.96	2.21	3.7				
Effusion	*CTL*	*0*	1.16	0.868	1.45	−0.2205	0.204	0.281	0.003
	EXP	*0*	1.38	1.089	1.68				
	CTL	*3*	1.56	1.268	1.85	0.4461	0.204	0.015	
	EXP	*3*	1.12	0.822	1.41				
Thigh	*CTL*	*0*	49	47.3	50.7	1.122	1.007	0.2673	0.2426
	EXP	*0*	47.8	46.2	49.5				
	CTL	*3*	49.7	48	51.4	0.103	0.98	0.4581	
	EXP	*3*	49.6	47.9	51.3				
Calf	*CTL*	*0*	37.7	36.6	38.8	−0.3816	0.694	0.5837	0.1682
	EXP	*0*	38.1	37	39.2				
	CTL	*3*	38.2	37.1	39.3	0.4892	0.676	0.2355	
	EXP	*3*	37.7	36.6	38.8				
ROM Flex	*CTL*	*0*	116	112	120	−1.05	2.46	0.671	0.073
	EXP	*0*	117	114	121				
	CTL	*3*	108	105	112	−4.98	2.46	0.022	
	EXP	*3*	113	110	117				
ROM EXT	*CTL*	*0*	2.4	1.225	3.57	−0.655	0.828	0.4306	0.999
	EXP	*0*	3.05	1.879	4.22				
	CTL	*3*	1.76	0.591	2.94	0.345	0.828	0.999	
	EXP	*3*	1.42	0.246	2.59				

Note: CTL = controls, EXP=Incrediwear, TX = treatment group, SE = standard error, TX*Time = interaction effect, LCL = lower confidence level, UCL = upper confidence level, both of 95% confidence, delta = difference between a given timepoint.

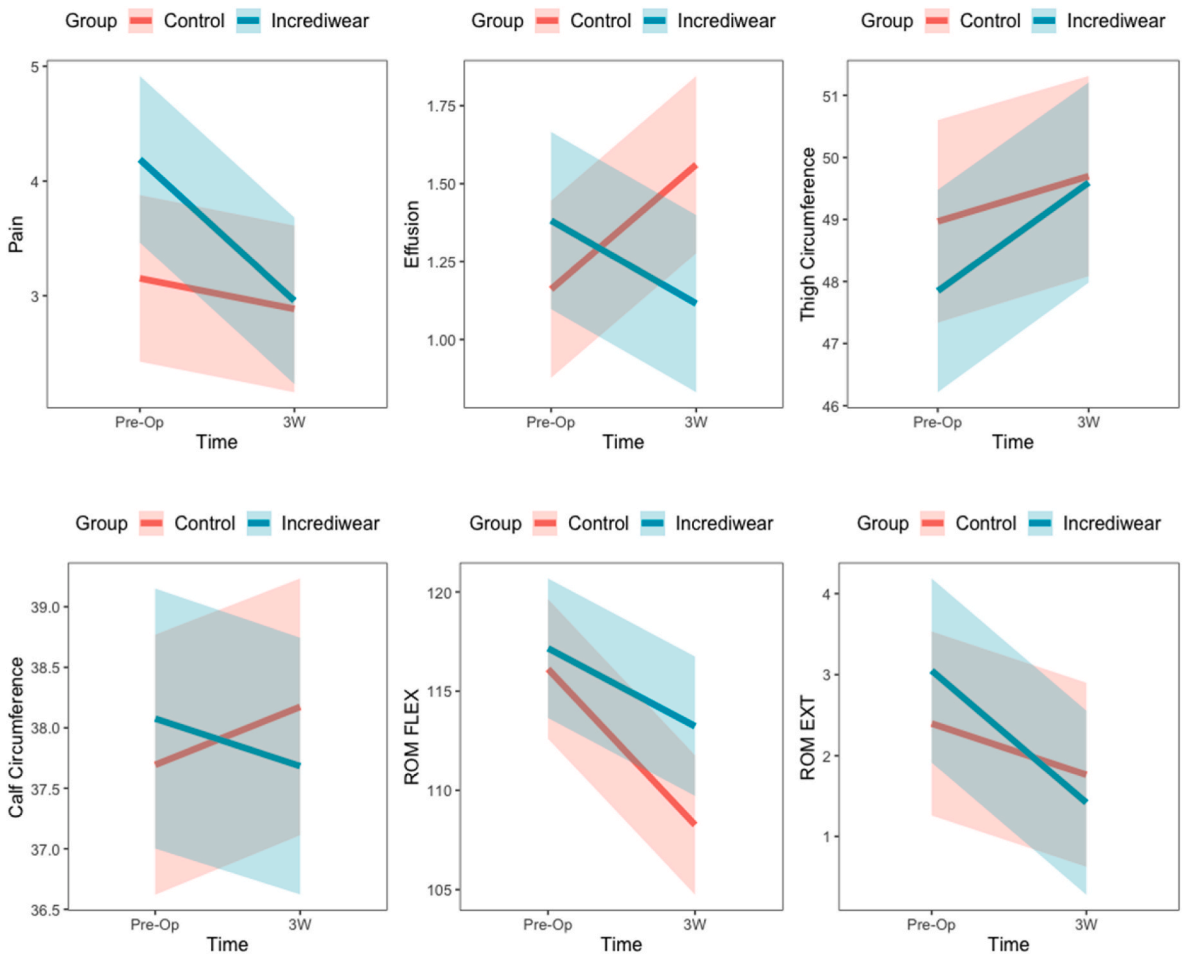
3.6. KOOS, JR questionnaire

No statistically significant differences were observed with patient reported KOOS, JR questions.

4. Discussion

A prospective superiority clinical pilot study was completed to compare the postoperative effects of non-compressive sleeves embedded with semiconductor elements (Incrediwear) to traditional compression stockings in patients undergoing total knee arthroplasty. As was hypothesized, subjects utilizing Incrediwear demonstrated improvement in several important post-TKA outcomes compared to compression stocking controls. Incrediwear appears to reduce effusion and improve knee flexion better than traditional TED hose after TKA.

A core objective of joint arthroplasty is to improve function. Increased flexion ROM has been repeatedly shown to be a critical component related to function outcomes and patient satisfaction after TKA.[21–27] Oka et al.[27] demonstrated improvement in early post-TKA knee flexion predicted ROM goals at 12 months. In a study with minimum 2-year follow up, Ha et al.[26] demonstrated that postoperative ROM was associated with functional outcomes after TKA. Although some degree of effusion is expected after surgery, effusions can be seen with different post-TKA complications[28,29] and the associated swelling may contribute to patient satisfaction after TKA.[30,31] Low- or non-compliance rates are commonly seen with compression stockings[32]—commonly due



Panel 1. Pre-op and Week 3 (3W) change between Incrediwear and controls.

related to discomfort.[33] Fundamentally, if patients do not reliably tolerate compression stockings, affecting their utilization, the value of such an intervention merits reassessment.

This study has several limitations. As this was only a single-center investigation with one surgeon, this commonality may reduce generalizability of the results and may artificially reduce variability between groups. Although some interesting results observed did not reach statistical significance (i.e., $p < .05$), this pilot study likely was not adequately powered to detect said differences; however, these possible findings can be further investigated now that the effect size estimates observed in the present study can be used to adequately power confirmatory randomized clinical trials. Although adherence could not be measured, there is no indication that a systematic difference in adherence existed between conditions. However, if adherence were systematically different between groups, this becomes an important factor of a device's effectiveness (e.g., if patients fail to wear a device because it is uncomfortable, then the device's efficacy is no longer relevant). Therefore, future studies should monitor and quantify device compliance, such as with wearable sensors and use-tracking technology. As TED hose lose compression and stretch out, their efficacy will likely diminish over time; therefore, a study examining both replacement time to maintain efficacy and a cost-effectiveness comparison between the two devices should be conducted. To assess the impact of Incrediwear's therapeutic semiconductor technology, sham sleeves without semiconductor elements could serve as a control.

After TKA, Incrediwear's non-compressive sleeves embedded with semiconductor elements appear to have reduced effusion and improved knee flexion better than traditional compression stockings. Such findings highlight the need for additional studies to further optimize postoperative care.

Ethical statement

Western Institutional Review Board, (IRB) approval obtained prior to our clinical work. IRB approved patient informed consent was use to consent patient for this pilot. Pilot protocol approved by the IRB and performed in accordance with The Collaborative Institutional Training Initiative, (CITI Program).

Guardian/Patient's consent

IRB approved consent document used to obtain written informed consent from all pilot participants.

Conflict of interest

Dr. Jacob reports the following relationships:
Aesculap/B.Braun: Paid consultant; Research support
EnMovi: Paid consultant; Research support
Flexion Therapeutics: Paid consultant.
Johnson & Johnson: Stock or stock Options.
Link Orthopaedics: Paid consultant.
OrthoSensor: Paid consultant; Research support.
Stryker: Paid consultant; Paid presenter or speaker; Research support; Stock or stock Options.
Zimmer: Stock or stock Options.

CRediT authorship contribution statement

T. Elaine Justice: Funding acquisition, Writing, Investigation, Data curation, Validation, Formal analysis. **Paul B. Jacob:** Conceptualization, Methodology, Project administration, Investigation, Supervision, Visualization.

Declaration of competing interest

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