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O1 Introduction



Knee osteoarthritis (KOA) is a chronic degenerative joint disease and a leading cause of disability over the worldwide.Laterally Wedged Insoles (LWI) are a non-surgical treatment that aims at reestablishing correct knee biomechanics in patients with medial KOA. The putative mechanism behind the effectiveness of LWIs is creating an external moment aiming at unloading the medial

compartment.

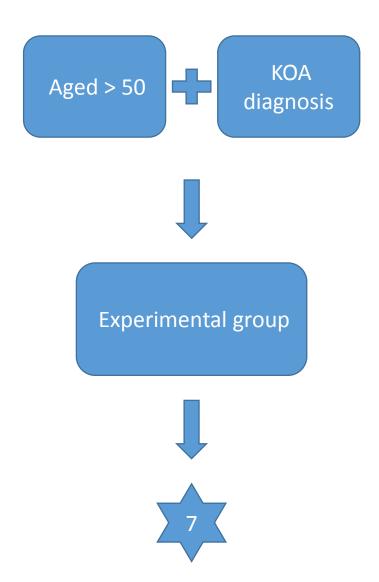
However, there is limited evidence regarding the biomechanical effectiveness of this intervention. Small reduction of first and second peaks and of impulse of the knee adduction moment have been summarised in a meta-analysis. The large variation in orthotic design and disease severity contribute to the variability of treatment response.

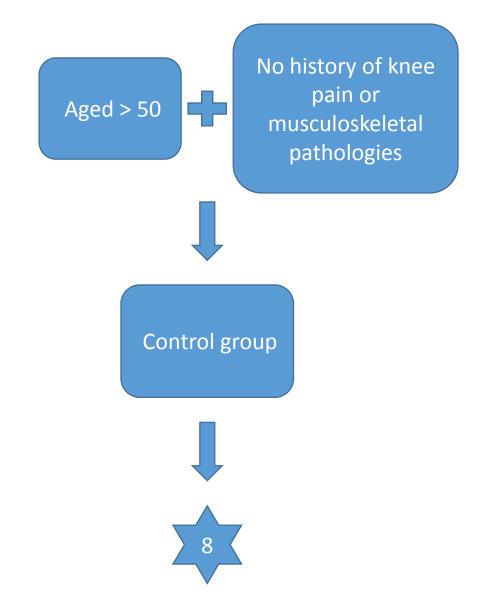


O2
Methodology

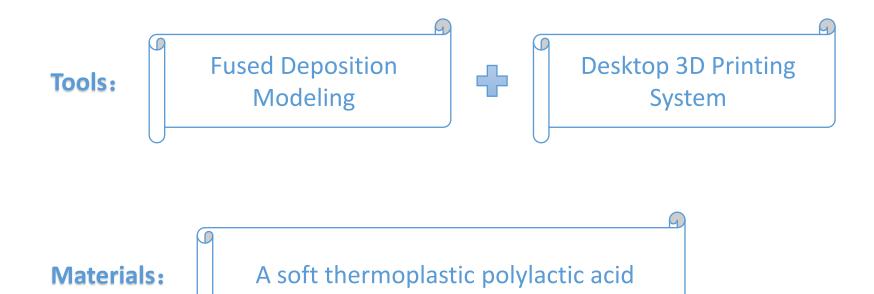


① Population

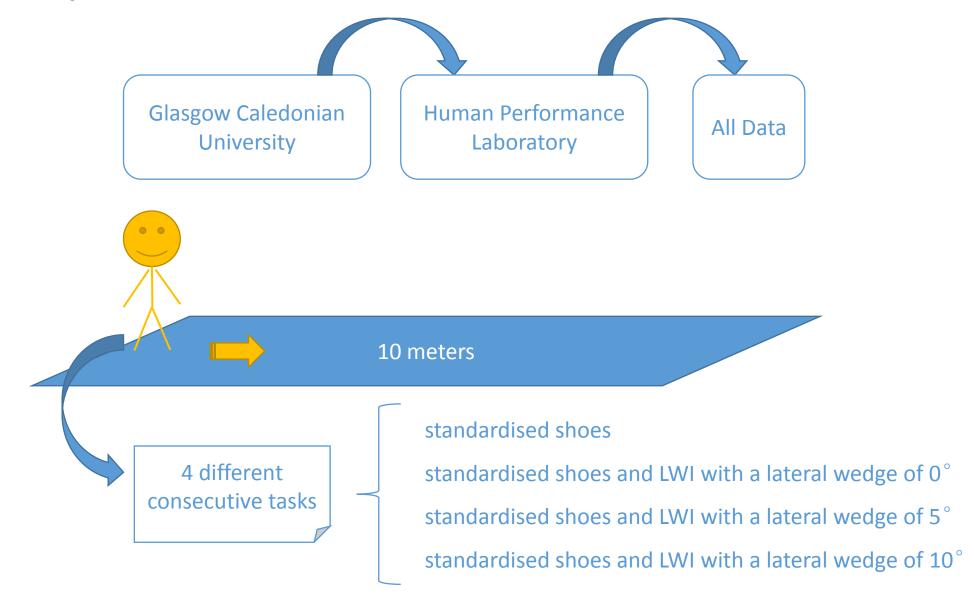




② LWI manufacturing



3 Gait analysis



4 Musculoskeletal model



These studies reported a moderate to high correlation coefficient when internal forces were compared to a dataset acquired with an instrumented knee prosthesis. The standing reference acquisition was used to generate a stick figure based on the anatomical landmarks. An inverse kinematics approach was used to estimate the joint kinematics during the dynamic trials.

⑤ Data analysis

The peak value and the impulse over the entire stance phase of the CF were selected as the biomechanical variables of interest. The peak value and the impulse were calculated as the average of three trials for each gait condition. Medial to lateral ratio, defined as the ratio between the medial and the lateral CFs, was used to quantitatively assess the different distribution of load between the two-analysed groups.



O3
Results



Table 1Demographic data.

	Controls $(n = 8)$	KOA (n = 7)
Age (years)	56 (3.4)	62 (6.6)*
Gender (M:F)	3:5	5:2
BMI (Kg/m^2)	25.22 (2.18)	31.7 (3.89)*
Knee angle ^y (°)	-1.3(2.25)	6.3 (1.97)*
Walking speed at baseline (m/s)	1.32 (0.21)	1.14 (0.19)

^{*}statistically significant (p < 0.05) $^{\gamma}$ varus angles are presented as positive value, valgus angles are presented as negative.

Table 2
Individual relative difference [%] of the peak of the CF with respect to the SO condition for controls and KOA participants during the stairs ascending. Group results are presented as [median (25th/75th interquartile)]. Negative values indicate a reduction with respect to the SO condition.

	LWI 0°			LWI 5°			LWI 10°		
	Medial	Lateral	Total	Medial	Lateral	Total	Medial	Lateral	Total
CNTRL_1	1.41	-5.14	-1.46	-1.88	-9.69	-5.18	-1.28	-7.2	-3.82
CNTRL_2	-0.11	-3.29	-0.51	8.72	-0.17	4.35	5.24	-4.32	0.53
CNTRL_3	1.13	-2.01	-2.17	0.82	-0.17	-1.08	-1.55	-6.52	-3.52
CNTRL_4	-0.04	-4.41	-1.92	-0.36	-4.98	-2.27	3.65	1.52	2.7
CNTRL_5	-5.03	0.2	-3.07	-6.78	-3.36	-5.74	- 9.45	-8.93	-9.5
CNTRL_6	-3.08	-6.01	-4.27	-6.24	-6.89	-6.37	1.46	-5.63	-1.71
CNTRL_7	-6.07	-8.3	-7.14	-2.8	-5.17	-3.96	-7.34	-9.63	-8.59
CNTRL_8	5.44	-6.02	-3.24	2.98	-5.07	-4.42	2.66	-9.34	-7.63
Controls Mdn	-0.07 (1.34/-	-4.77 (-2.33/-	-2.62 (-1.57/-	-1.12 (2.44/-	-5.02 (-0.97/-	-4.19 (-1.38/-	0.09 (3.41/-	-6.86 (-4.65/-	-3.67 (-0.03/-
(IQR)	4.54)	6.02)	4.01)	5.38)	6.46)	5.60)	5.89)	9.23)	8.35)
KOA_1	1.11	-6.41	0.14	-0.3	-7.23	-2.91	-4.45	-5.34	-2.21
KOA_2	3.63	8.69	5.29	5.24	9.79	6.99	7.57	10.32	8.85
KOA_3	-2.94	-1.37	-2.74	1.57	2.11	1.59	-0.01	-2.19	-1.31
KOA_4	-1.31	3.24	0.39	0.87	-10.8	-3.05	1.6	-5.67	-0.79
KOA_5	-3.22	-5.75	-4.12	-5.38	-5.32	-5.43	-4.12	-3.25	-3.79
KOA_6	-2.48	-5.04	-3.25	-1.75	-9.03	-3.54	-0.69	4.06	0.33
KOA_7	-4.81	-2.52	-3.96	-0.27	-2.41	-0.99	-3.1	-5.52	-3.96
KOA Mdn (IQR)	-2.48 (1.11/-	-2.52 (3.24/-	-2.74 (0.39/-	-0.27 (1.57/-	-5.32 (2.11/-	-2.91 (1.59/-	-0.69 (1.60/-	-3.25 (4.06/-	-1.31 (0.33/-
	3.22)	5.75)	3.96)	1.75)	9.03)	3.54)	4.12)	5.52)	3.79)
Total Mdn (IQR)	-1.31 (1.13/-	-4.41 (-1.37/-	-2.74 (-0.51/-	-0.30 (1.57/-	-5.07 (-0.17/-	-3.05 (-0.99/-	-0.70 (2.66/-	-5.52 (-2.20/-	-2.21 (0.33/-
	3.22)	6.01)	3.40)	2.80)	7.23)	5.18)	4.12)	7.20)	3.96)

a high variability was found in the relative difference between the three LWI condition with respect to the SO condition

Table 3
Individual relative difference [%] of the impulse of the CF with respect to the SO condition for controls and KOA participants during the stairs ascending. Group results are presented as [median (25th/75th interquartile)]. Negative values indicate a reduction with respect to the SO condition.

	LWI 0°			LWI 5°			LWI 10°		
	Medial	Lateral	Total	Medial	Lateral	Total	Medial	Lateral	Total
CNTRL_1	8.59	-1.81	4.63	6.53	-1.58	3.44	1.57	-4.58	-0.78
CNTRL_2	0.2	-1.25	-0.26	-0.6	-0.12	-0.45	0.03	5.67	1.81
CNTRL_3	0.93	0.54	0.79	0.55	2.84	1.36	2.41	1.57	2.11
CNTRL_4	3.42	-5.54	-0.03	2.11	-3.76	-0.15	1.1	-3.56	-0.69
CNTRL_5	-0.35	0.52	-0.02	-3.55	2.43	-1.28	-1.4	1.23	-0.4
CNTRL_6	0.56	-3.25	-1.15	-0.99	-2.25	-1.56	3.22	3.53	3.36
CNTRL_7	-0.59	-8.89	-4.16	-4.55	-7.77	-5.94	-7.67	-10.58	-8.92
CNTRL_8	-5.58	-5.91	-5.72	-7	-4.31	-5.9	-7.37	-3.55	-5.8
Controls Mdn	0.38 (2.80/-	-2.53 (0.08/-	-0.14 (0.59/-	-0.80 (1.72/-	-1.9 (1.79/-	-0.86 (0.99/-	0.57 (2.20/-	-1.16 (3.04/-	-0.55 (2.03/-
(IQR)	0.53)	5.82)	3.41)	4.30)	4.17)	4.81)	5.88)	4.33)	4.54)
KOA_1	-4.6	-6.67	-5.36	-4.68	-7.85	-5.83	-6.17	-4.5 3	-5.57
KOA_2	4.8	9.46	6.01	4.16	4.69	4.3	4.42	6.29	4.9
KOA_3	-1.8	-6.9	-3.26	-1.52	-2	-1.66	2.56	-4.84	0.44
KOA_4	3.35	3.91	3.51	0.6	-1.81	-0.1	2.6	-0.57	1.68
KOA_5	-11.65	-12.85	-12.02	-11.12	-8.33	-10.25	-5.2	3.3	-2.55
KOA_6	10.22	-17.23	5.67	5.36	-8.51	3.06	5.93	-2.01	4.61
KOA_7	-2.19	-1.11	-1.83	-0.86	-1.24	-0.98	-0.2	-2.83	-1.08
KOA Mdn (IQR)	-1.80 (4.80/-	-6.67 (3.91/-	-1.83 (5.67/-	-0.86 (4.16/-	-1.20	-0.98 (3.06/-	2.56 (4.42/-	-2.01 (3.30/-	0.44 (4.61/-
	4.60)	12.85)	5.36)	4.68)	(-1.24/-8.33)	5.83)	5.20)	4.53)	2.55)
Total Mdn (IQR)	0.2 (3.42/-2.2)	-	-0.26 (3.51/-		-1.20	-0.98 (1.36/-	-	-2.01 (3.30/-	•
	, ,,	6.90)	4.16)		(-0.12/-7.77)	5.83)	, ,,	4.53)	2.55)

Table 4
Walking speed [m/s].

	Shod	LWI 0°	LWI 5°	LWI 10°
CNTRL_1	1.66	1.50	1.54	1.58
CNTRL_2	1.03	1.12	1.16	1.16
CNTRL_3	1.33	1.37	1.35	1.33
CNTRL_4	1.18	1.24	1.20	1.28
CNTRL_5	1.44	1.41	1.37	1.41
CNTRL_6	1.23	1.15	1.12	1.14
CNTRL_7	1.15	1.09	1.13	1.16
CNTRL_8	1.55	1.55	1.52	1.51
Controls mean (SD)	1.32 (0.21)	1.30 (0.18)	1.30 (0.17)	1.32 (0.17)
KOA_1	1.32	1.38	1.40	1.38
KOA_2	1.26	1.28	1.31	1.32
KOA_3	0.99	0.97	1.01	0.95
KOA_4	1.32	1.29	1.36	1.35
KOA_5	0.82	0.90	0.87	0.85
KOA_6	1.14	1.12	1.22	1.19
KOA_7	1.17	1.12	1.12	1.13
KOA mean (SD)	1.15 (0.19)	1.15 (0.18)	1.18 (0.19)	1.17 (0.2)



O4
Discussion



In this study, the effect of 3D printed subject-specific LWI insoles on the MCF in a population characterised by varus alignment and medial compartment KOA was investigated and compared with a control group of healthy volunteers. Despite the KOA group showing a higher load on the medial compartment at baseline (SO), the use of LWI with different level of posting did not result in a consistent response in terms of MCF. The results showed a statistically significant difference between KOA and controls for the impulse only. It suggests that research evaluating the biomechanical effect of non-surgical interventions should take into consideration the impulse rather than focusing solely on the reduction of the peaks of the force.

This study has several key limitations.

- (1) The complexity and length of the protocol required for such investigation led to a small sample size potentially leading to inconclusive or non-significant results.
- ②The potential heterogeneity of our KOA population which was not stratified as suggested in previous studies.
- ③Because of the cross-sectional nature of the study, it was not possible to draw conclusion regarding the long-term effect of LWI.



OS Conclusion



In the present study, the researchers investigated the immediate effect of different LWI on the MCF in a population characterised by medial KOA and varus malalignment. The results showed an overall inconsistency with high variability across participants with reduction and increase of both the impulse and the peak of the MCF. Moreover, no overall dose-response trend, according to the degree of lateral wedging, was observed. The high variability observed suggests that the optimising LWI treatment to each participant remains challenging. Further work is required to understand more fully the mechanical efficacy of LWIs for personalised non-surgical management of KOA.



THANKS

