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1	A KNEE BRACE ALTERS PATELLA POSITION IN PATELLOFEMORAL
2	OSTEOARTHRITIS: A STUDY USING WEIGHT BEARING MAGNETIC
3	RESONANCE IMAGING.
4	
5	ABSTRACT
6	Objective: To assess using weight bearing MRIs, whether a patellar brace altered
7	patellar position and alignment in patellofemoral joint (PFJ) osteoarthritis (OA).
8	
9	Design: Subjects age 40-70 years old with symptomatic and a radiographic K-L
10	evidence of PFJOA. Weight bearing knee MRIs with and without a patellar brace
11	were obtained using an upright open 0.25 Tesla scanner (G-Scan, Easote Biomedica,
12	Italy).
13	Five aspects of patellar position were measured: mediolateral alignment by the bisect
14	offset index, angulation by patellar tilt, patellar height by patellar height ratio (patellar
15	length / patellar tendon length), lateral patellofemoral contact area and finally a
16	measurement of patellofemoral bony separation of the lateral patellar facet and the

adjacent surface on the femoral trochlea (Figure 1).

18

Results: Thirty participants were recruited (mean age 57 SD 27.8; BMI 27.8 SD 4.2);
17 were females. Four patients had non-usable data. Main analysis used paired t tests
comparing within subject patellar position with and without brace.

For bisect offset index, patellar tilt and patellar height ratio there were no significant differences between the brace and no brace conditions. However, the brace increased lateral facet contact area (p = .04) and decreased lateral patellofemoral separation (p = .03).

Conclusion: A patellar brace alters patellar position and increases contact area
between the patella and femoral trochlea. These changes would lower contact stress
at the PFJ. Such changes in patella position in weight bearing provide a possible
biomechanical explanation for the success of the PFJ brace in clinical trials on
PFJOA.

31

32 INTRODUCTION.

Patellofemoral (PF) osteoarthritis (OA), a common subtype of knee OA, is a major 33 34 cause of pain with stair climbing, arising from a chair and activities involving kneeling or squatting. It is associated with pain, stiffness and functional limitation^{3, 5}. 35 Guidelines for the non-surgical management of generalised knee OA found 'fair' 36 quality of evidence for the use of knee braces and knee sleeves ²¹⁹. Treatment of 37 PFOA is similarly limited but one potential treatment is a patellar sleeve device. 38 Evidence for its clinical efficacy is provided by two clinical trials in PFOA^{1,8}. These 39 40 trials had positive effects on pain and structure from wearing a patellar sleeve brace compared to no brace¹ and on pain with or without the patellar retaining strap.⁸ 41 One of the proposed reasons for this clinical success is that the patellar brace may, 42 during weight bearing activities, change patellar alignment and alter patellar tracking 43 relative to the trochlear groove both of which are considered major contributions to 44 the pathomechanics of PF pain. Whilst a brace's effects on the biomechanics of the 45 PF joint are still not well understood, there is evidence from studies in non-arthritic 46 PF pain that it may correct malalignment¹⁷ and increase contact area of the PF joint¹⁸. 47 This distribution of forces over a greater area could decrease the contact stresses. 48 Several authors agree that magnetic resonance imaging (MRI), with its capability of 49 viewing the patellar position in various planes, is more useful and informative than 50

plain radiography^{6, 10, 12}. MRIs also have the advantage of using non-ionising radiation 51 enabling repeated imaging, as in the present study, with and without a brace. Weight 52 bearing MRIs may give a more valid view of PF congruence and position under 53 54 natural loads exerted by body mass. Patellofemoral position is usually assessed clinically through palpation of the patella through a range of motion or by observing 55 the motion of the skin over the patella. This assessment is commonly performed in a 56 seated, unloaded posture that does not reflect joint movement during functional, 57 weight bearing tasks. 58

To date, one study has used weight bearing MRIs to assess braces on non-arthritic, symptomatic PF pain⁴. To our knowledge there have been none assessing PFOA, although McWalter et al ¹¹ assessed a knee sleeve in PFOA with *simulated* weight bearing MRIs by applying 15% of body weight of axial load through the patient's foot.

Since PFOA is likely to affect either medial or lateral patellar compartments⁷, the effects of braces on patellar position might have a bearing on treatment choices and brace design. Consequently, the weight bearing MRI may give a more realistic view of PF congruence and be a more appropriate technique when assessing patella position.

69

70 Purpose

The purpose of this study on PFOA was to use weight bearing MRIs to assess whether a sleeve brace altered patellar position. The hypothesis was that there would be differences in measures of PF position after the application of a patellar brace compared to no brace.

74

75

76 METHODS

The study was approved by the XXX Local Research Ethics Committee (Ethics number
09/H1012/35). It was performed at the XXXX and at the University XXXX

79

80 Subjects

We recruited a subset of subjects age 40-70 years who had been enrolled in a previous 81 randomized trial of patellar brace treatment for people with PFOA². They had a K-L 82 score grade 2 or 3 in the PF compartment which was greater than K-L score for the 83 84 tibiofemoral compartments (this score required at least probable narrowing of the PF joint on X-ray and definite osteophytes in the PF compartment). Those who did not 85 have plain radiographs were assessed for PFOA by either MRIs or arthroscopy, for 86 87 which we required typical changes of OA with at least cartilage loss present in the PF joint. Subjects were also assessed by an experience clinician for PF joint symptoms 88 such as pain reproduced with stair climbing, kneeling, prolonged sitting or squatting 89 90 or if they had lateral or medial patellar facet tenderness on palpation or a positive patellar compression test. Pain must have been present daily for the previous 3 months 91 92 and the pain had to be sufficiently severe for a nominated aggravating activity to score of 40 or above on a 0-100mm visual analogue scale (VAS_{NA}). The VAS_{NA} has been 93 found to be at least as sensitive, and in some cases more sensitive to change than the 94 KOOS or WOMAC questionnaires^{13, 14}. Typically, subjects' nominated aggravating 95 activities were stair climbing, kneeling, prolonged sitting or squatting. 96

97

98 Exclusion criteria

99 Participants were excluded if they had a previous patellar fracture or patellar100 realignment surgery, if the predominant symptoms emanated clinically from the

tibiofemoral joint, from meniscal or ligament injury, if they had rheumatoid arthritis or other forms of inflammatory arthritis or if they had an intra-articular steroid injection into the painful knee in the previous month. For the purposes of the MRI, patients were excluded if they had a cochlear implant, metal objects in the body including a joint prosthesis, a cardiac or neural pacemaker, a hydrocephalus shunt, an intrauterine contraceptive device or coil, if they had kidney dysfunction or were undergoing renal dialysis.

108

109 MRI procedures

Participants had MRIs of their knee joint using an upright open 0.25 Tesla scanner 110 (G-Scan, Easote Biomedica, Italy). Participants first remained supine for 111 112 approximately 5 mins to enable the recovery of viscoelastic structures in the knee, as the participant had been weight-bearing prior to entering the scanner. Following this 113 114 rest period, an initial positioning scan (scout) was performed followed by axial and 115 sagittal plane scans. Scans had a TR range of 690 - 830ms and TE range of 14-28ms with a slice thickness of around 4mm and a gap between slices of 0.4mm. The bed of 116 the MR scanner was then be tilted into the upright position 4 degrees inclined from 117 the vertical to allow weight-bearing. Foot position was controlled by aligning the 118 great toe with a piece of tape on the platform. The scan time for each sequence was 119 120 2:43 mins, with 1 acquisition. Subjects were randomised to the order of brace or no brace by sealed opaque envelopes under the supervision of the study statistician. 121 Images were viewed off line. 122

123

124 Study Intervention

The brace intervention consisted of a Bioskin Patellar Tracking Q Brace (Ossur UK,Stockport, England) (figure 1).

127

128 Patellar Alignment Measurements

Medical imaging software Clear Canvas Workstation (Version 7.0.0.) was used. All images were anonymised so that examiners were blinded to the patient identification and group conditions (brace or no brace).

132 Five measurements of patellofemoral alignment and congruence were taken.

133 Bisect offset index assessed medio-lateral patellar displacement relative to the femur The technique was initially described by Stanford et al^{20} and used by Powers et al^{16} . 134 A line was drawn connecting the posterior femoral condyles on the slice in which the 135 136 posterior condyles were most obvious and a perpendicular line was projected up through the deepest point (apex) of the trochlea. Then another slice was found on 137 which the patellar width was clearest and on which a line could be drawn to measure 138 139 the width. Finally, these two slices were superimposed allowing us to project the line anteriorly from the bisection of the posterior condylar line through the second line on 140 the patella ¹⁶. To determine the patellar displacement by the bisect offset, the extent of 141 the patella lateral or medial to the perpendicular midline was expressed as a 142 percentage of the total patellar width. (Figure 2). 143

Medio-lateral patellar tilt angle was measured as the angle formed by the lines joining the maximum width of the patella and the line joining the posterior femoral condyles 146 ^{15, 16} (Figure 3).

Lateral patellofemoral joint contact area was defined as areas of patella and femur approximation in which no distinct separation could be found between the cartilage borders of the two lateral joint surfaces (Figure 4). A line of contact was drawn

between the patella and the femur¹⁷. The contact area for each slice was measured and 150 151 multiplied by the length of the contact line with the slice thickness (0.4mm). Each sequential image was summed to obtain the total lateral contact area Σ ($\Box \Box \times$ 152 153 $(\Box \Box \times \Box \Box)$ (CL = contact length; SL = slice length; SG = slice gap) x (slice length + slice gap). Because cartilage was relatively bright on fat suppressed fast spoiled 154 155 gradient echo images, we used the operation definition of contact area as white on white ¹⁷. The determination of non-contact was made when a line of separation could 156 be observed between the articular surfaces of the patella and trochlear groove. 157 The level of agreement between the MRI and pressure sensitive film techniques in 158 159 cadaver specimens was for ICC 0.91 and for CV 13%. When averaged across all specimens, the contact area obtained through MRI was 2.94 (SD 1.01 cm²) while 160 the contact area obtained using the pressure sensitive film technique was 3.05 161 162 (0.95 cm^2) . The average individual specimen difference between the two methods was 10.9%. 163 The Insall-Salvati ratio was measured on the sagittal views by a ratio between patella 164 tendon length relative to the superior-inferior length of the patella (patellar length / 165

166 patellar tendon length)¹⁹.(Figure 5).

Patellofemoral distance (the distance between the patella and the femur) was 167 168 measured to assess if the brace reduced the distance between the opposing surfaces of 169 the patella and the femur, specifically the lateral patellar facet and the adjacent surface on the lateral femoral trochlea. First, the area between patella and femur was 170 171 determined by drawing a trapezoid on an axial slice where patellofemoral distance 172 was greatest. The average distance between the patella and femur was measured by 173 dividing the area (automatically calculated by the Clear Canvas program) by the longest side of the trapezoid (Figure 6). 174

175 Reliability

176	Inter rater reliability for the MRI measurements was assessed between two assessors
177	using a 2 way random model for absolute agreement inter-class correlation coefficient
178	(ICC _{2,1}). The results were for bisect offset index ICC _{2,1} 0.97 (95%CI 0.96, 0.98) SEM
179	2.6, for patellar tilt angle $ICC_{2,1}$ 0.96 (95%CI 0.94, 0.97) SEM 1.43 ⁰ , for lateral
180	patellofemoral joint contact area ICC _{2,1} 0.73 (95%CI 0.53, 0.85), SEM 3.1cm ² , for the
181	Insall-Salvati ratio $ICC_{2,1}$ 0.95, (95% CI 0.80, 0.98) SEM 0.031, and for
182	patellofemoral distance ICC _{2,1} 0.84, (95% CI 0.48,0.97), SEM 0.32cm.
183	
184	Analysis
185	Data were visually analysed with histograms, Q-Q plots and Kolmogarov-Smirnov
186	tests which confirmed normality of distribution. The main within subjects analysis
187	used paired t tests comparing patellofemoral alignment and congruence with and
188	without a brace. Statistical significance was set at $p \le 0.05$.
189	
190	PESLILTS
	NESOE15

191 Thirty subjects with PFOA were recruited (mean age 57, SD 7.8years, BMI mean

192 27.8, SD 4.2); 17 were females (56%). Five subjects had their PFOA assessed by

193 MRIs or arthroscopy. Four patients had non-usable MRI data because of missing data

194 on some parameters or because of technical problems such as movement artefact.

195 Therefore 26 patients' data were analysed. There were no adverse events.

196 For bisect offset index, patellar tilt and patellar height ratio there were no significant

197 differences between the brace and no brace conditions. However, the brace significantly

increased lateral facet contact area $(0.94 \text{cm}^2, 95\% \text{ CI} 0.07, 1.8, \text{p} = .04)$ and decreased lateral

199 patellofemoral distance (-0.06cm 95% CI -0.12, -0.01, p = .03) (Table 1).

200 DISCUSSION

This is the first study using weight bearing MRIs on subjects with symptomatic PFOA 201 to evaluate the effects of bracing on the PF joint. It found that the brace significantly 202 increased the lateral contact area of the PF joint and decreased PF joint lateral 203 distance. The other measures of PF joint position (bisect offset index, patellar tilt and 204 patellar height ratio) were not altered significantly. MRIs are more useful and 205 informative than plain radiography by viewing the patellar position in various planes 206 ^{6,10,12}. MRIs also have the advantage of using non-ionising radiation enabling 207 repeated imaging, as in the present study, with and without a brace. Using a scanner 208 with the capability of providing standing weight bearing images adds to its usefulness. 209 Comparison with previous research is compromised by the few weight bearing studies 210 available, all of which were only done on non-arthritic PF pain. Draper et al.⁴ found a 211 patellar sleeve brace in females with non-arthritic PF pain produced non-significant 212 reductions in weight bearing patellar tilt (0^0) and bisect offset (4%) at full knee 213 214 extension. Similarly, we did not find any significant differences in full knee extension between our patellar brace and no brace in bisect offset (1.39%, 95% CI -2.3, 5.1) and 215 patellar tilt (-0.25⁰, 95% CI -1.61, 1.1). The reasons for different values recorded are 216 likely due to us assessing subjects with symptomatic PFOA and differences in the PF 217 brace design suggesting that commercially available braces may have different 218 biomechanical effects. McWalter et al¹¹ is the only comparable study looking at the 219 same patellofemoral brace in the same knee condition, but differed from ours by using 220 knee flexion up to 50° and lying subjects in supine with a simulated body weight load 221 222 of 15%. They found the brace significantly altered patellar rotations and translations compared to no brace but questioned its clinical significance because no reduction in 223 pain was observed in their parent trial⁸, which compared the brace with a modified 224

225 brace without a T-strap. The clinical significance of our findings for the parameters of 226 lateral contact area and lateral patellofemoral distance may also be questioned, even though a clinically significant reduction in pain was observed in our parent trial which 227 compared the brace to no a brace control². As a result of our findings, we join with 228 Draper et al.⁴ in asking whether the small changes observed with a brace are 229 sufficient to alter PF lateral contact area and lateral patellofemoral distance by a 230 clinically meaningful amount. The small increases we recorded in these parameters 231 concur with the work by Powers et al. ¹⁷ to explain the possible mechanism for the 232 233 decrease in PF pain. They found, albeit in non-arthritic PF pain, that compared to no brace at full knee extension a PF brace had its greatest effect on lateral patellar facet 234 contact area, had clinically small but statistically significant effects on the bisect 235 236 offset index, but no effect on patellar tilt. They proposed the concept that the increased contact area would result in a decrease in joint area stress. Our PFOA 237 subjects might have also benefitted from decreased joint area stress. Additionally, 238 239 they may have benefitted from a sense of stability and confidence created wearing the brace. Although this was not objectively assessed in this study, patients in the parent 240 trial² reported that their knee felt more stable and secure from brace wearing. 241 All our subjects had an improvement in their VAS for a nominated activity and their 242 KOOS after wearing the patellar brace as part of a randomised trial². This trial, in 243 244 conjunction with the present study shows that a PF brace has both symptomatic and biomechanical benefits for those with symptomatic PFOA. 245

246

247 LIMITATIONS

The limitations of this study are that the MRIs were taken only in a single WB position, with no variability of knee flexion. The 0.2T field strength for the weight

bearing MRI scanner used in this study has implications for the contrast resolution obtainable in an acceptable time. Participants were not blinded to the brace wearing condition. Additionally, as this was a subgroup from a previous trial, there was no further subgroup analysis of patients based on the severity or location of the PFOA.

255 CONCLUSION

A patellar brace significantly increases PFJ lateral contact area and decreases PFJ lateral distance. This likely lowers contact stress at the PFJ. Such changes in PFJ position in weight bearing provide a possible biomechanical explanation for the success of the PF brace in clinical trials on PFOA.

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- 268 Conception and design: Callaghan, Felson, Reeves, Maganaris.
- 269 Analysis and interpretation of the data: Callaghan, Felson, Guney, Bailey, Hodgson.
- 270 Drafting of the article: Callaghan, Felson, Guney, Bailey, Hodgson.
- 271 Final Approval: Callaghan, Felson, Hodgson, Guney, Reeves.

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288 Competing interests

289 None of the authors have competing interests related to this work.

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Figure 1 The Bioskin Patellar Tracking Q brace.



Figure 2 Mediolateral displacement (Bisect Offset index) Figure 2 a: ideal image to measure patellar width. Figure 2 b: ideal image to view posterior condyles and trochlea





Figure 3 Patellar Tilt Angle



Figure 4 Lateral Patellofemoral Contact Area



Figure 5 Insall-Salvati Ratio Patellar bone length / Patella tendon length



Figure 6 Patellofemoral Distance Area of Trapezoid $a+b/2 \ge h / length$ of lateral PF contact



Table 1. Patients' Demographics

	Mean \pm SD
Age (year)	57.17 ± 8.1
BMI (kg/m ²)	27.76 ± 4.39
Gender (female/male)	15/13
K-L PFJ Score 3/2/1	12/6/1
K-L TFJ Score 3/2/1	12/5/2

Legend:

BMI = Body Mass Index K-L = Kellgren Lawrence PFJ = Patellofemoral Joint

	Patellar tilt	Bisect offset Index	Patellar length/	Patellofemoral	Patellofemoral
	Mean (SD) deg	Mean (SD)%	tendon length ratio	Lateral Contact area cm ²	Distance cm
	N = 27	N = 27	Mean SD	Mean SD	Mean SD
			N = 27	N = 26	N =26
Brace	8.63 (6.6)	72.4 (19.1)	1.0 (0.17)	2.73 (2.4)	0.27 (0.12)
No Brace	8.39 (4.9)	73.8 (18.4)	0.96 (0.13)	1.79 (2.2)	0.33 (0.13)
Mean	-0.25	1.39	0.05	0.94	-0.06
difference	(95% CI -1.61, 1.1)	(95% CI -2.3, 5.1	(95% CI -0.01, 0.11	(95% CI 0.07, 1.81)	(95% CI -0.12, -0.01
P value	0.71	0.44	0.09	0.04	0.03