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A Retrospective Review of Psychosocial Outcomes After Microprocessor Knee Prescription

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1 A retrospective review of psychosocial outcomes following microprocessor knee

2 prescription

3 Abstract

4 **Study Design:** Retrospective Analysis

5 Introduction: Microprocessor knees have been shown to improve gait biomechanics and to
6 reduce the frequency of falls but evidence of their influence on psychosocial health is limited.

Objective: To evaluate the change in psychosocial outcome measures when prosthetic users
change from a Non-Microprocessor controlled Prosthetic Knee (NMPK) to a Microprocessorcontrolled Prosthetic Knee (MPK).

Methods: Using validated outcome measures, physical and psychological attributes of 26
 MPK users were analysed using data collected at routine appointments. Baseline data were
 collected using NMPK limbs first then compared to data collected four weeks and six months
 following initial MPK fitting.

- 14 **Results:** A significant improvement of 13.7% in Reintegration to Normal Living Index
- 15 (RNLI) scores was observed after six months (p=0.001). The PHQ-9 demonstrated a 64.6%
- 16 significant reduction in the presence of depression-like symptoms after six months of MPK
- use (p<0.001), including four participants who previously scored highly enough to be
- 18 diagnosed with major depressive disorder. Frequency of falls reduced significantly as well

19 (p<0.001). Increases in self-selected walking speed were seen in both the 2 Minute Walk and

- 20 6 Minute Walk Tests.
- 21 Conclusions: Significant improvements were seen in all psychosocial outcome measures,
- indicating participants' psychosocial health improved with the prescription of an MPK
- 23 despite a lack of clinically important improvements in parallel performance-based outcome
- 24 measures.
- 25 Clinical Relevance: MPKs are well documented to reduce trips and falls which is
- corroborated by this research. However, the psychosocial benefits of MPKs are not
- 27 documented extensively; this study provides evidence of an improvement in psychological
- 28 wellbeing in this cohort.

29 Abstract Word Count: 214

- 30 Keywords: Rehabilitation of prostheses users, prosthetic outcome measures, biomechanics of
- 31 prosthetic devices, rehabilitation of amputees, follow-up studies

32 Introduction

Psychological health is a major concern within the amputee population, with the prevalence 33 of depression and depressive symptoms reportedly as high as 28%.^{1,2} In the general 34 population, mental health is a major cause of disability in England³ with estimates of one in 35 six adults suffering with a mental health problem at any one time. Therefore, mental health 36 issues are much more common in amputees than in the general population, and there is a 37 paucity of research in this area. To date, MPK research has focused on gait biomechanics and 38 safety, but with mental health costing £6.5 billion to the UK Government in 2010/11 (most 39 recent figures)³ there is a need to understand the benefits that advanced technology may have 40 for patients psychologically. 41

Convincing evidence of improved kinetic and kinematic parameters when using a 42 43 Microprocessor-controlled Prosthetic Knee (MPK) compared to a Non-Microprocessorcontrolled Prosthetic Knee (NMPK) already exists.⁴⁻⁶ Reductions in the number of falls 44 experienced and increased symmetry of gait have been the most prominent findings in these 45 papers. Increased user satisfaction has also been reported in MPK users⁷⁻⁹ which follows 46 logically from reducing the frequency of adverse incidents. Novel research by Moller et al. 47 demonstrates that NMPK users typically exhibit greater cortical brain activity than MPK 48 users, suggesting that MPK users require less cognitive effort to walk.¹⁰ Outcome measures 49 specifically designed to study psychological health in the amputee population do exist in 50 published literature, such as the Prosthesis Evaluation Questionnaire (PEQ)¹¹ and have been 51 used to suggest preference for an MPK over NMPK limbs.⁸ 52

In order to prescribe an MPK limb to a patient in England a trial must be carried out in 53 54 accordance with guidelines set out in the Clinical Commissioning Policy from NHS England.¹² This policy has been in effect since December 2016. The policy requires 55 improvements in patient function and participation in daily life to be demonstrated using an 56 array of outcome measures before the new prosthesis can be prescribed. The authors were 57 granted access to the existing database of these outcome measures for MPK users at one limb 58 centre. Alongside the outcomes mandated by the policy. The Patient Health Questionnaire 59 (PHQ-9)¹³ was also included in this research as it was routinely recorded at the limb fitting 60 centre and deemed relevant to the aims of this study. 61

- 62 Two hypotheses were formed to guide analysis: 1) Improvements would be seen across all
- 63 outcome measures when comparing the NMPK measures to the MPK measures, and 2)
- 64 Psychosocial health improvements would come with improved physical ability.

65 Methods

Outcome measures were recorded for all potential MPK limb candidates at the limb fitting
centre in accordance with the prescription policy by the clinical team comprising of
prosthetists and specialist amputee physiotherapists. The authors of this paper analysed the
data separately from the clinical team and in retrospect. A short summary of the prescription
process is given:

71 The NHS England MPK prescription policy is a set of guidelines and procedures that are applicable nationally. Potential participants are screened by the clinical team to check they 72 meet the inclusion criteria outlined in the policy, namely: amputation involving destruction or 73 loss of the knee joint, ability to walk utilising a free mechanical prosthetic knee with the 74 potential or ability to vary cadence, ability to walk more than 50 yards on level ground, 75 76 presents with a history of falls or co-existing medical condition that has a very high risk of injury due to a fall, and demonstration of adequate commitment, strength and balance to 77 utilise the MPK unit. The limb fitting centre had added the criteria of wearing a prosthetic 78 socket rated 7 or higher on the Socket Comfort Score.¹⁴ A duplicate socket was then 79 produced, and all participants were assessed using their normal NMPK prescription as the 80 81 baseline measure before being fitted with the MPK. Each participant completed a 4-week 82 acclimation period before the first review and then were reviewed again at six months.

All outcome measures were completed at each review. This included all mandatory measures
from the prescription policy and any additional outcomes elected by preference of the
prosthetic service. During the four-week acclimation period each participant attended one
hour of physiotherapy per week. The data came from users who were provided with an Orion
3 MPK and Echelon prosthetic foot (Blatchford Ltd, Basingstoke UK): this was the preferred
MPK prescription of the centre.

To date, the majority of MPK research has focused on alternative manufacturers of MPKs.^{4,6} 90 ^{,15,16} For this reason, temporospatial outcome measures have been included in this study to 91 facilitate comparison with the populations in previously published literature. The Timed Up 92 and Go (TUG) Test was omitted from analysis since one specific function of an MPK is to slow down knee flexion when moving to sit down, and the TUG Test regards faster speeds as
more positive. The outcome measures analysed are provided below:

95 Psychosocial outcome measures

96I. The PHQ-9 questionnaire¹⁷ has 9 questions resulting in a total score between 0-2797and was used to assess the severity of depression at each point. A score ≥ 10 can98indicate major depressive disorder; therefore a lower score is considered more99positive. The PHQ-9 has been proven to be sensitive to change over time^{13,17,18} and100is valid for use in the general outpatient population.¹³

- II. The RNLI questionnaire measures how well-integrated to normal life the user feels
 and is validated for use with people with mobility limitations.^{19,20} A score of 100%
 represents the participant feeling fully reintegrated to community living, and 0%
 represents no reintegration to community living. This is an important aspect of
 amputee rehabilitation as the aim of treatment is to facilitate normal daily life.
- III. The PEQ investigates multiple aspects of perceived life and prosthesis quality and
 has been used extensively in the published literature. The PEQ was analysed in 9
 subsets as described by Legro et al.¹¹ Each subset relates to a different aspect of the
 prosthesis allowing for more specific comparison to be made between different
 users/time points.
- 111

112 Physical performance measures

I. Self-reported patient diaries of trips and falls experienced over the four-weekperiod leading up to each of the 3 appointments were completed.

115

II. The 2 Minute Walk Test (2MWT) as described by Brooks et al.²¹ (2006) was 116 conducted with verbal encouragement to ensure the participant achieved their best 117 result.²² For consistency for the participant, a version of the 6 Minute Walk Test 118 (6MWT) based on Brooks' 2MWT method was used. All tests were carried out 119 120 according to published protocol by a senior prosthetist or specialist amputee physiotherapist. These tests have previously been validated for use with amputees²³ 121 ^{,24} and can be easily converted to a walking speed, allowing comparison with the 122 existing literature. 123

- 124 One author accessed the database of MPK prosthesis users at the limb fitting centre and
- included patients who had completed the six-month review. Where individual data points
- were missing, the author manually searched the patient's paper records for the information.
- 127 Statistical analysis was performed using SPSS 2018 v. 26. Approval for this analysis of
- 128 patient information was provided by XXXX and XXXX. Patients had previously signed
- 129 informed consent for their data to be used in future research.

130 Statistics:

- 131 ANOVA Tukey tests for multiple comparisons were used to understand the mean differences
- between the three time-points for normally distributed data, whilst Kruskal-Wallis was used
- 133 for non-normally distributed data. Additionally, groups were split into two groups and t-tests
- 134 were used to determine statistical differences between NMPK and MPK at each timepoint.
- 135 When differences on the t-tests were observed, post-hoc Bonferroni adjustments were used to
- 136 control for Type 1 error using a new significance level of 0.017 (99.98% C.I.). Similarly,
- 137 Mann-Whitney (99.98% CI) were applied for non-normally distributed data. Clinical
- significance was measured against pre-existing published literature and expertise. For clarity,
- the measurement time points will be referred to as follows:
- NMPK Measurement taken when participant was using their NMPK prosthesis and
 used as a baseline for comparison.
- MPK 4 weeks Measurement taken 4 weeks after supply of the MPK prosthesis, at
 the end of the trial period.
- MPK 6 months Measurement taken 6 months after the MPK prosthesis was
 supplied; at this point the MPK was no longer being trialled and had been the
 participant's daily prosthesis for approximately 21 weeks.

147 **Results**

148 **TABLE 1 ABOUT HERE**

- Patient demographics are shown in Table 1. 26 patients had completed the six-month reviewat the time of data collection. There were 4 females and 22 males, 25 transfemoral amputees
- and 1 person with knee disarticulation, and the majority of amputations were due to trauma
- 152 (77%). On average, these prosthetic users had had their amputations for 29.5 years (range 8-
- 153 55 years). Results from the outcome measures are presented in Table 2.

154 **TABLE 2 ABOUT HERE**

- 155 The mean number of falls were: 1 (± 0.98) at NMPK baseline, 0 (± 0.19) at MPK 4 weeks, and
- 156 $0 (\pm 0.19)$ at MPK 6 months. The number of falls was statistically significantly different (K-
- 157 W, p<0.001; M-W, p<0.001) with the number of falls significantly greater for NMPK than at
- 158 both MPK timepoints (Figure 1).

159 FIGURE 1 ABOUT HERE

160 Walking speeds derived from both timed walk tests are presented in Table 3. This was

- 161 calculated by dividing the distance covered by the time of the test. No statistical difference
- 162 was found between groups (ANOVA, p=0.964), however statistical significance was found
- 163 when comparing between groups (NMPK and MPK) at the different timepoints (t-test,
- 164 p<0.001).

165 **TABLE 3 ABOUT HERE**

- 166
- 167 **PHQ-9:** The mean PHQ-9 score when using NMPK prostheses was 5.27(±6.40); at MPK 4
- 168 weeks the mean was 1.31 (\pm 2.67), and at MPK 6 months it was 1.89 (\pm 2.89). A significant

169 decrease was found in the depression scores when NMPK and MPK 4 weeks were tested

- 170 (W=838.00, p=0.003). A statistically significant decrease was also found when comparing
- 171 NMPK to MPK 6 months (W=800.00, p=0.022). There was no significant difference found
- between MPK 4 weeks and MPK 6 months (W-634.50, p=0.843).
- 173 As detailed in Figure. 2, of the 5 participants who could have been diagnosed with major
- depressive disorder when using their NMPK limb (PHQ-9 score ≥ 10), 4 scored below this
- 175 cut-off after 4 weeks of MPK use. Only one participant continued to score above this cut-off
- score and had improved by 18.75%.

177 FIGURE 2 ABOUT HERE

178 **RNLI**:

- 179 The average score in the RNLI questionnaire when using an NMPK was 80.17% (± 21.80).
- As shown in Fig. 3, after 4 weeks of MPK use this increased to 91.53% (± 13.25), and at 6
- 181 months it was 92.73% (±10.04). Significant differences were found between NMPK and
- 182 MPK 4 weeks (W=562.00, p=0.010, at 99.98% CI), and NMPK and MPK 6 months
- 183 (W=553.50, p=0.007). No statistically significant mean difference was found between MPK 4
- 184 weeks and MPK 6 months (W=685.00, p=0.474).

185 FIGURE 3 ABOUT HERE

- **PEQ:** For the purposes of this paper the authors focussed on 3 subsets of the PEQ:
- 187 "appearance"; "social burden"; and "utility". In the "appearance" subset, significant
- improvement was found between NMPK and MPK 4 weeks (W=509.50, p=0.001 at 99.98%
- 189 CI), and between NMPK and MPK 6 months (W=515.50, p=0.001), across all participants.
- 190 No significant difference was found between the MPK measures (W=687.50, p=0.493). In
- the "social burden" subset (shown in Figure 4), significant differences were found in the
- mean scores between NMPK and both MPK time-points (W=515.50, p=0.001, and
- 193 W=556.00, p=0.008, respectively). No significant mean difference was found between MPK
- 194 measures (W=732.50, p=0.790). In the "utility" subset, significant improvements were found
- between NMPK and both MPK timepoints (W=484.50, p<0.001, and W=503.00, p<0.001,
- 196 respectively). No significant difference was found between the two MPK measures
- 197 (W=686.00, p=0.482).

198 FIGURE 4 ABOUT HERE

- 199 While detailed results are presented from the analyses of only three subsets, statistically
- significant improvements were seen in all PEQ subsets between NMPK and MPK
- 201 measurements.

202 **Discussion**

This research sought to investigate if the introduction of an MPK influenced patient outcomes 203 with a specific focus on psychosocial health. It builds on the previous research predominantly 204 concerned with physical outcomes. Two hypotheses were tested. Firstly, if improvements 205 would be seen in all outcome measures by replacing the NMPK limb with an MPK. This 206 hypothesis holds true for this population as statistically significant improvements were seen 207 in both physical and psychosocial outcomes. Secondly, the hypothesis presuming physical 208 improvement would lead to psychosocial benefits needs to be examined further in subsequent 209 research as the mental health benefits found in this study were disproportionate to the 210 increases in physical performance. While statistical significance was seen, the clinical 211 relevance of walking 6 metres further over the course of two minutes is negligible. 212 The reduction in falls represents an important reason to advocate for the use of MPK 213

- prostheses and has been documented with multiple MPK prescriptions.^{6-8,25} As shown in
- Figure 1, only 1 of the 27 participants reported a fall when using the MPK, compared to 17

- who reported falling with their NMPK. The participant who reported one fall for each 4 week
- 217 period with the MPK had reported 3 falls in the 4 weeks of NMPK use. Average walking
- speeds found here are comparable to those reported by Orendurff ²⁶ and Kahle ²⁵. These
- results align the current study with the published literature for alternative MPKs.

220 Significant improvement was seen in the PHQ-9 between NMPK and both MPK time points,

suggesting a reduction in the presence of depression-like symptoms in these lower limb

amputees when changing to an MPK prosthesis. In all but one of the patients who scored 10

- or above using the NMPK prosthesis, scores at MPK 4 weeks were then below this threshold
- and importantly did not relapse at MPK 6 months. This cut-off score of 10 has been shown to
- be acceptably specific and sensitive to identifying major depression,²⁷ therefore this is
- considered a clinically meaningful improvement in this patient group.

227 The RNLI measures integration in domains including comfort in social situations, personal relationships and the ability to carry out daily activities. The introduction of a new prosthesis 228 229 demonstrated a significant increase in these users' perception of being able to integrate with society. The improvements in RNLI scores seen in this study when using an MPK are of 230 interest as these patients were established prosthetic users who lived in the community for an 231 average of 28.5 years. The improvements are above the 7% minimum clinically important 232 difference reported by Mayo et al.²⁸ and it is possible that a ceiling effect was present 233 particularly at the latter measurement time points. 234

The individual domain scores cannot be isolated for the RNLI but the PEQ subset "social 235 236 burden" provides more of an insight into this area. Significantly higher scores were reported after the introduction of the MPK prosthesis and maintained six months later, again 237 suggesting this type of prosthesis had a positive impact on the patients' lives. In the "utility" 238 subset comparable results were found, and similar findings were seen again in the 239 "appearance" subset. To date, the minimum detectable changes and clinically important 240 differences for PEQ subsets have not been reported, nor have these values been reported for 241 the PEQ as a whole. Research which was able to provide these values would potentially add 242 weight to the findings of this study. 243

It is important to note that no statistically significant improvements were found with ANOVA
in the timed-walk tests, however, when the data was treated as groups and t-tests were

- performed, statistically significance was found in between groups (Table 2), however, these
- do not necessarily imply clinically meaningful differences^{21,23,29}. One plausible explanation

for this is that since these participants are established prosthetic users and are already
ambulatory in a community setting; they have already achieved a desirable self-selected
walking speed. The lack of clinically important differences does however suggest that these
participants did not have any marked changes to their physical ability during the study period,

- thus increasing the likelihood of the new prosthesis being the cause of any differences in
- 253 outcome measures.

All users attended physiotherapy once per week for the first four weeks. The effect this had on outcomes should not be overlooked when interpreting these results. It is difficult to isolate the effect of each treatment component on overall results in this study and it would be interesting to see a similar study conducted with an intervention group receiving four weeks of physiotherapy and continuing to use an NMPK. Notably, the lack of change in outcome measures between MPK 4 weeks and MPK 6 months would suggest that the new prosthesis was an important factor in the differences between NMPK and MPK measurements.

Finally, albeit statistically significant, the differences in results between interventions were relatively low and deserve further exploration on a greater sample size. A prospective trial with a larger sample size that controls for the effect of physiotherapy input for example, would be useful in gaining a clearer picture of the whole population. Nonetheless, 26 participants is a relatively large cohort for research of this kind in an amputee population. The loss of a lower limb is a life-changing situation in which people are left to deal with a notable change in their quality of life and independence. This study adds to the existing

evidence base for the use of an MPK compared to non-MPK knees to positively affect quality
of life for above-knee amputees.

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271 Word Count: 2867

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- 300

356

			Time from	Cause of	Level of	K level	NMPK
nt	er		amputation	amputation	amputation		(used prior
utie	pua	Age	(years)	-	-		to baseline
P_{2}	Ğ	(Å ⁺					MPK
							measure)
1	F	64	55	Trauma	TF	3	Smart IP
2	F	62	36	Neoplasm	TF	3	Smart IP
3	Μ	65	48	Trauma	TF	3	ESK
4	Μ	53	12	Trauma	TF	3	Smart IP
5	М	55	37	Trauma	TF	3	Smart IP
6	М	61	45	Neoplasm	TF	3	IP+
7	F	33	17	Congenital	KD	3	Total Knee
8	Μ	61	43	Trauma	TF	3	ESK
9	М	31	15	Neoplasm	TF	3	Mercury
10	М	47	23	Trauma	TF	3	IP+
11	М	56	39	Trauma	TF	3	Smart IP
12	М	48	14	Trauma	TF	3	Mercury
13	М	45	8	Vascular	TF	3	ESK CaTech
14	М	60	43	Trauma	TF	2	Smart IP
15	М	65	48	Trauma	TF	3	ESK
16	М	41	12	Trauma	TF	2	ESK PSPC
17	М	36	14	Trauma	TF	3	Mercury
18	М	70	11	Trauma	TF	3	ESK PSPC
19	М	54	37	Trauma	TF	3	Smart IP
20	М	72	9	Trauma	TF	3	ESK PSPC
21	М	32	13	Congenital	TF	3	KX06
22	М	67	48	Trauma	TF	3	Smart IP
23	М	69	15	Trauma	TF	3	ESK PSPC
							HOKL
24	Μ	61	40	Trauma	TF	3	Smart IP
25	Μ	56	33	Trauma	TF	3	ESK PSPC
26	Μ	71	52	Trauma	TF	3	Smart IP
	3F,	55.19,	29.50, Range:	Trauma:20,	TF:25, KD:1	Level 2: 2;	
al	23M	Range:	[8,55]	Vascular: 1,		Level 3: 25.	
loti		[31,72]		Neoplasm:3,			
				Congenital:2			

Table 1 patient demographics

Ou	tcome measure	NMPK	MPK (4 weeks)	MPK (6 months)	
		$(mean \pm SD)$	$(\text{mean} \pm \text{SD})$	$(\text{mean} \pm \text{SD})$	
Falls		(1 ± 0.98)	$(0 \pm 0.19)^*$	$(0 \pm 0.19)^*$	
2MW	T [m]	(125 ± 25)	(133 ± 21)*	(131 ± 22)*	
6MWT [m]		(362 ± 74)	(391 ± 67)*	$(385 \pm 69)*$	
PHQ-9		(5 ± 6)	(1 ± 3)*	(2 ± 3)*	
RNLI		(80 ± 21)	(92 ± 13)*	(93 ± 10)*	
	Ambulation	(50 ± 21)	(86 ± 13)*	(85 ± 16)*	
	Appearance	(67 ± 24)	(86 ± 14)*	$(86 \pm 14)^*$	
	Frustration	(52 ± 34)	(87 ± 17)*	(83 ± 22)*	
PEQ	Perceived Response	(85 ± 18)	(95 ±7)*	(93 ± 8)*	
	Residual Limb Health	(71 ± 27)	(88 ± 11)*	(84 ± 12)*	
	Social Burden	(72 ± 25)	(93 ± 8)*	(88 ± 16)*	
	Sounds	(61 ± 31)	(82 ± 20)*	(86 ± 25)*	
	Utility	(66 ± 22)	(85 ± 11)*	(85 ± 12)*	
	Wellbeing	(63 ± 26)	(91 ± 10)*	(89 ± 11)*	



Table 3: Converted TWT distances to average walking speeds

	Average walking speed at each time point					
	NMPK	MPK 4 weeks	MPK 6 months			
2MWT	1.064 ms ⁻¹ (±0.174)	1.125 ms ⁻¹ (±0.154)	1.114 ms ⁻¹ (±0.164)			
6MWT	1.030ms ⁻¹ (±0.167)	$1.102 \text{ms}^{-1}(\pm 0.168)$	$1.022 \text{ms}^{-1}(\pm 0.169)$			

371 Table captions

- **Table 1.** Patients demographics (age, gender) and time (in years) from amputation; cause and level of
- amputation; K level; and type of NMPK used when recruited for the trial.
- **Table 2.** Mean and SD for all completed outcome measures by time point
- **Table 3.** Average walking speeds by time point

377 FIGURES

378 Figure 1



380 Figure 2





383 Figure 3



Figure 4



387 Figure Captions

388 Fig. 1 – Comparison of the total falls per patient between NMPK and MPK at 4weeks and NMPK and MPK at

389 6months. There was a 94% decrease in the number of people falling using MPKs (regardless of the timepoint)

390 when compared to NMPKs. Only 1 of the 26 patients reported to fall when using the new MPK prescription at

- both 4weeks and 6 months, compared to 17 patients who reported falling with their NMPK
- **Fig. 2** Comparison of PHQ9 scores per patient between the three interventions: NMPL, MPK at 4weeks and

393 MPK at 6months. From the 26 patients, 5 would have been diagnosed with a major depressive disorder when

- using their NMPK prescription (as shown by the Threshold for depression diagnosis dotted line ≥ 10). From
- those ones, four scored below this threshold after 4 weeks of MPK use whilst one patient continued to score
- above it, however, a score improvement of 18.75% can be appreciated.
- **Fig. 3** Comparison of the mean RNLI scores between interventions. When using an NMPK, the RNLI was
- $80.17\% (\pm 21.45)$, after 4 weeks of MPK use the average score was $91.53\% (\pm 13.25)$, and at 6 months it was
- 399 92.73% (±10.04). Significant mean differences were found between NMPK and MPK 4 weeks, and NMPK and
- 400 MPK 6 months (* denotes p=0.001). No statistically significant mean difference was found between MPK 4
- 401 weeks and MPK 6 months. Error bars denote standard error.
- **402** Fig. 4 Comparison of PEQ scores for the Social Burden subset between NMPK and MPK at 6months.
- 403 Statistically significant mean differences were found between these two interventions (W=245.5, p<0.001).