IMPACT OF A DYNAMIC ORTHOSIS ON MANUAL DEXTERITY IN PARKINSON'S DISEASE. A RANDOMISED TRAIL (Author's final version – Accepted Manuscript)

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19 Abstract

20 Importance: Dynamic elastomeric fabric orthosis (DEFO) could be a novel non-21 pharmacological treatment for motor symptoms in Parkinson's Disease. Objective: To 22 evaluate the efficacy of the orthoses in manual dexterity in Parkinson's Disease. 23 **Design:** A randomized trial with 20 participants in the control group and 40 in the 24 experimental group (N=60). Manual dexterity was assessed in ON/OFF states of the 25 disease with and without the orthosis. Setting: Burgos University Hospital. 26 Participants: Consecutive non-probabilistic sampling. Inclusion criteria: patients diagnosed with Parkinson's Disease, with motor symptoms in at least one upper limb, 27 28 and attending the neurology department of the Hospital. Age between 48 to 89, with an 29 average disease duration of 5.38 ± 4.23 years. Exclusion criteria: tremor due to another neurological disease and/or Montreal Cognitive Assessment score lower than 26. 30 31 Intervention: Implementation of the orthosis on the most affected upper limb for two 32 months, control group participants did not receive the orthosis. Outcomes and 33 Measures: Manual dexterity was measured with the Purdue Pegboard Test, Minnesota 34 Manual Dexterity Test, and Square Test. The paired t-test for related samples and 35 ANCOVA tests were used. Results: Improvements in some items of manual dexterity 36 were observed while wearing the orthosis. However, the improvement was not sustained 37 when the orthosis was removed after two months of use. Conclusions and Relevance: 38 This orthosis may improve certain aspects of manual dexterity in people with PD and the patient's functionality, but only while it is worn. What this article adds: A dynamic 39 40 orthosis can reduce the motor symptoms of Parkinson's Disease and improves upper 41 limb functionality.

42 Keywords: Parkinson's Disease; non-pharmacological treatment; dynamic elastomeric
43 fabric orthosis; motor symptoms; manual dexterity.

44 **1. Introduction**

Parkinson's Disease (PD) common motor symptoms such as muscle rigidity, tremors,
bradykinesia and impairments in manual dexterity, significantly impact the patient's
ability to perform activities of daily living (ADL) requiring fine motor skills and the
quality of life (QoL) (Bloem et al. 2021a).

A decline in manual dexterity, defined as the skill and precision in hands and fingers
fine and coordinated movements, impacts the functional use of the upper limb (UL) in
tasks like reaching, grabbing, and manipulating objects (Heffner & Masterton, 1983;
Poirier, 1988). Manual dexterity serves as a strong predictor of the levels of functional

53 independence for PD patients (Bloem et al., 2021b; Poewe et al., 2017).

54 The primary approach to motor symptoms in PD is pharmacological, primarily with

55 levodopa and dopamine agonists. Although medication temporarily improves

56 symptoms, there is currently no cure for PD (Connolly & Lang, 2014). Over time,

57 patients often develop motor complications such as dyskinesia and fluctuations in

58 medication response, limiting the long-term effectiveness (Choi et al., 2017).

59 In most cases, PD treatment is multifaceted, combining pharmacological treatment with

60 other non-pharmacological approaches to improve the patient's QoL. Various non-

61 pharmacological interventions such as exercise, acupuncture, and physiotherapy, among

62 others have been developed, with exercise especially showing improvements in QoL

63 (Ahn et al., 2017; Van de Weijer, Hommel et al., 2018).

64 Innovative non-pharmacological therapies, such as Motor Imagery, Action Observation,

65 Dual Therapy, Virtual Reality, and Robot-Assisted Therapy, are emerging in PD to

66 address functional issues, though there remains a lack of studies and uncertainty

67 regarding the optimal intervention dosage for effectiveness (Fusco et al., 2019; Righi et

68	al., 2022; Ryan et al., 2021; Strouwen et al., 2015; B. Wang et al., 2019). While some
69	orthoses have proven effective in reducing motor symptoms in the UL, existing devices
70	are often bulky and heavy, resulting in low treatment adherence (Fromme, Camenzind,
71	Riener, & Rossi, 2019).
72	Dynamic Elastomeric Fabric Orthoses (DEFO) are custom-made Lycra garments
73	individually designed that provide traction forces, aligning the limb biomechanically,
74	leading to reduced muscle tone and edema; and improved proprioception (Betts, 2015;
75	González-Bernal et al., 2017). They can be crafted as individual gloves or sleeves, full-
76	body suits, vests, or ankle-foot wraps (Betts, 2015; Powell et al., 2021). While DEFO
77	has proven effective in conditions like stroke, pediatric cerebral palsy, multiple
78	sclerosis, and complex regional pain syndrome, with positive results in motor function,
79	muscle strength, manual dexterity, and reach (Alexander et al., 2022; Giray et al., 2020;
80	Miller et al., 2016), its effectiveness in PD remains uncertain.
81	The main goal of Occupational Therapy (OT) is to promote and enable meaningful
82	contextual occupational performance. The impairment in fine motor skills in PD leads
83	to a decline in the patient's ADL performance and independence. Therefore, due to the
84	lack of devices or treatments and the promising research on DEFO in other neurological
85	conditions, the aim of this study is to assess the effectiveness of this device on manual
86	dexterity in the UL of PD patients.
87	
88	2. Method
89	2.1. Participants

90 A longitudinal study was undertaken involving a control group (CG) and an

91 experimental group (EG). Recruitment of patients diagnosed with PD at any stage and

92 experiencing motor symptoms in at least one UL took place between September and 93 October 2021 through consecutive non-probabilistic sampling at the neurology 94 department of the University Hospital of Burgos. Exclusion criteria comprised tremor 95 resulting from another neurological disease and/or a Montreal Cognitive Assessment 96 (MoCA) score equal to or lower than 26 (Postuma et al., 2015a). 97 PD diagnosis was based on criteria established by the International Parkinson and 98 Movement Disorder Society, requiring the presence of bradykinesia along with rigidity, 99 resting tremor, or both. Additionally, at least two out of four supportive criteria 100 (dramatic improvement from dopaminergic therapy, dyskinesias or loss of smell, resting 101 tremor, or cardiac sympathetic denervation on myocardial scintigraphy) needed to be 102 met (Armstrong & Okun, 2020; Postuma et al., 2015b).

103 The study adhered to ethical principles outlined in the Helsinki Declaration, and

104 participants provided informed consent. It was approved by the Clinical Research Ethics

105 Committee of the Health Area of Burgos and Soria (Spain) with reference CEIM-

106 2119/2019; and registered on ClinicalTrials.gov under the test number NCT04815382.

107 2.2. Procedure

N=60 (EG=40, CG=20).

115

The sample size calculation was based on the improvement in rigidity and tremor as the main variables. With an alpha risk of 0.05 and a beta risk of 0.20, using a two-tailed test, it was estimated that 40 participants (20 each group) would be needed to detect a minimum difference of 0.50 in rigidity and tremor of the most affected UL using Part III of the Motor Subscale of the Unified Parkinson's Disease Rating Scale (UPDRS) (Winter et al., 2022). Finally, due to the availability and interest of participants, the number of participants in the EG was increased to 40, leaving a total sample size of

In the first visit, participants who met the established criteria signed the informed consent. The sociodemographic and clinical data were collected by occupational therapists. One month prior to DEFO implementation, exact measurements of UL were taken by an occupational therapist (that was also a physical therapist) to be fitted for the personalized customization of the orthosis. The professionals who carry it out must be specifically trained to do so.

122 The orthosis used in this study is an UL limb DEFO that covers the entire arm and 123 therefore acts on the entire UL providing proprioceptive stimulation. Since tremor in 124 people with PD subsides with activity, muscle contraction and support; the orthosis aims 125 to activate the finger extensors, wrist extensors, radial deviators, supinators and external 126 rotators, thus, the UL limb is positioned with the musculature in contraction as when the 127 UL is placed in a support and load position. For its manufacturing, CADCAM 128 technology is used combined with traditional manufacturing techniques to guarantee 129 that each product matches the exact measurements of the patient. The power net 130 reinforcement panels are strategically placed to position the upper limb in better 131 postural alignment(Supplementary material 3).

132 Participants were randomly assigned to control group (CG) or experimental group (EG)

133 with Epidat 4.2 program. The treatment protocol involved implementing the DEFO on

the most affected UL along two months, while participants in the CG continued with

their usual daily activities. The EG participants had to wear the orthosis from the

136 moment they got up until they went back to bed. They only had to take it off to sleep

137 and shower. They were instructed to use it in all the activities they usually did and to try

to carry out those activities that they had stopped doing due to their motor symptoms,

- 139 such as fishing, sewing or planting. All patients continued with their usual
- 140 pharmacological treatment. The effects were evaluated both during the ON state (under

141 the effects of levodopa) and OFF state (1 hour before the next levodopa dose) as there 142 are significant fluctuations in PD's motor symptoms (Martin, Suchowersky, Kovacs 143 Burns, & Jonsson, 2010). The ON state refers to periods when medication is effective, 144 and patients experience significant improvement in their motor function. On the 145 contrary, the "off" state refers to periods when medication is not effective, and 146 Parkinson's motor symptoms reappear or worsen significantly, with patients 147 experiencing increased rigidity, bradykinesia, and tremors. In this research, it is 148 considered important to evaluate the effect of the DEFO in both states due to the 149 significant difference in motor symptomatology between them. 150 During the two months of treatment, scheduled calls were made to participants, one 151 after one week and one after one month of wearing the orthosis, to obtain information 152 about adherence to treatment; in the two-month evaluation, they were also asked about 153 this. All participants reported that they have worn the orthosis for the amount of time 154 indicated.

155 Motor assessments were conducted by occupational therapists at two time points (T1,

156 T2), immediately prior and following the 2-month intervention window. At both times,

157 two assessments were performed, one before and one after placing the DEFO, to check

158 for its immediate effects and its potential long-term benefits (Figure 1). The results were

159 analyzed by occupational therapists. Neither participants nor evaluators were blinded.

160 Figure 1. Study flow chart. DEFO: dynamic elastomeric fabric orthoses.





Firstly, the PPT consists of a wooden board with 50 holes in two parallel columns, a set 165 166 of pegs, washers, and collars placed in four cups at the top of the board. It has four subtests that evaluate the use of the right hand, left hand, alternating movements and the 167 168 combination of both. The score for each subtest is the result of the sum of the pieces 169 placed. All subtests were performed three times, and the total score was the average of 170 them. Higher scores indicate greater manual dexterity. It is a test with high test-retest reliability, with an intraclass correlation coefficient (ICC) of ≥ 0.90 (Lo et al., 2022; 171 172 Proud et al., 2019).

173 The MMDT consists of a rectangular board with 60 holes in 15 columns and 4 rows,

174 with 60 circular pieces with one side red and other black. It has got two subtests:

displacement and rotation (supplementary material 1 and 2), that are performed four

176 times, with the total score being the average of them. The less time taken in the tests, the

better the manual dexterity. It is a reliable and valid measure, with high test-retest
reliability, an intraclass correlation coefficient (ICC) of 0.88, and a 95% confidence
interval (Rane et al., 2017; Y. C. Wang et al., 2018).

The ST, which consists of a sheet of paper with four printed grids that consist of 20 squares. The patient is given 30 seconds to make a mark with a pen inside as many squares as possible. The score is the result of the sum of the marks made without touching the lines. A higher number indicates better manual dexterity. This is a reliable and valid test with excellent test-retest reliability for both hands (ICC \geq 0.93) (Soke et al., 2019).

186 2.3. Statistical Analysis

The data was analyzed using SPSS V28 program considering a p-value < 0.05 as 187 188 statistically significant. Mean and standard deviation (SD) were calculated for 189 quantitative variables, while frequency distribution and percentages for categorical 190 variables. To analyze the differences between not wearing and wearing the orthosis both 191 in T1 and T2 in the EG, the paired t-test for related samples was employed; adding in 192 this case a Bonferroni correction, in order to control for the family-wise error rate 193 (FWER); for which 4 tests were taken into account as adjustment (2 time points and 2 194 medication conditions) the corrected p-value obtained was 0.0125 (0.05/4). To analyze the differences between CG and EG after two months wearing the DAFO, means 195 196 between the two groups were compared using ANCOVA, with the group (CG or EG) as a fixed factor; differential scores of the analyzed variables as dependent variables, and 197 198 the pretest scores of each one as covariate. This ANCOVA was performed without 199 wearing the orthosis. Both t-student test and ANCOVA were performed in ON and OFF 200 states.

201

3. Results

- 203 3.1.Baseline Sociodemographic Characteristics of Participants
- 204 Sample was composed of 60 individuals with a mean age was 71 years old. 87.5% of
- 205 the participants lived with someone (N=53), 10% lived alone in their homes (N=6), and
- 206 one person in a religious community. Other sociodemographic data are shown in table 1.

207 Table 1. Baseline characteristics

Variables	Total (n= 60)	CG(n=20)	EP(n = 40)					
Age (years)	70.67 ± 10.37	69.94 ± 12.90	70.97 ± 9.32					
Gender								
Male	45	14	31					
Female	15	5	10					
Most affected UL								
Right	35	21	14					
Left	25	5	20					
Years of desease evolution	4.78 ± 3.83	3.75 ± 2.79	5.21 ± 4.14					
Current non-pharmacological								
treatment								
Physiotherapy	2	0	2					
Occupational therapy	0	0	0					
Spech therapy	1	1	0					
All	1	1	0					
None	55	25	30					
Others	1	1	0					
Abbreviational CC: Control Crown: ED: Even min antal Crown: LH - Llan on limb								

Abbreviations: CG: Control Group; EP: Experimental Group; UL: Upper limb

209 Table 2 shows the observed differences in the comparative analysis of motor dexterity

assessments (PPT, MMDT, and ST) at baseline (T1) with and without the orthosis in

both ON and OFF states.

212 Table 2. Comparative analysis of motor dexterity assessment at baseline (T1) with

and without the orthosis. Paired t-test for related samples (N=40)

²⁰⁸

Variables	State	Mean	SD	α	acorrected	p-value
DDT Subtest 1	OFF	.393	1.416	0.05	0.0125	.102
PPT Sublest 1 -	ON	.606	1.368	0.05	0.0125	.012
	OFF	007	1.404	0.05	0.0125	.975
PPT Subtest 2 -	ON	.073	1.872	0.05	0.0125	.814
	OFF	.024	.949	0.05	0.0125	.879
PPT Subtest 3 -	ON	.565	1.412	0.05	0.0125	.022
	OFF	.042	2.477	0.05	0.0125	.918
PP1 subtest 4 -	ON	.236	6.423	0.05	0.0125	.827
MMDT placing	OFF	-6.901	11.305	0.05	0.0125	.001
test	ON	-5.424	10.734	0.05	0.0125	.005
MMDT turning	OFF	1.583	42.367	0.05	0.0125	.826
test	ON	2.201	9.943	0.05	0.0125	.193
	OFF	971	7.278	0.05	0.0125	.435
ST Right hand -	ON	417	6.29	0.05	0.0125	.693
	OFF	828	7.422	0.05	0.0125	.513
SI Left hand –	ON	1.083	4.625	0.05	0.0125	.187

214 Mean: mean difference between the group with and without orthosis. ON: under levodopa

effects; OFF: 1 hour before next levodopa dose; SD: Standard Deviation; PPT: The Purdue

216 Pegboard Test; MMDT: Minnesota Manual Dexterity Test; ST: Square Test.

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Table 3 presents the observed differences in the comparative analysis of motor dexterity
assessments (PPT, MMDT, and ST) in the evaluation conducted 2 months after the
implementation of the DEFO (T2), both with and without the orthosis in both ON and
OFF states. **Table 3**. Comparative analysis of motor dexterity assessments after 2 months of

223 the implementation of the DEFO (T2), with and without the orthosis. Paired t-test

for related samples (N=40)

Variables	State	Mean	SD	α	acorrected	p-value
DDT Subtest 1	OFF	.341	1.31	0.05	0.0125	.064
PP1 Sublest 1	ON	.441	1.168	0.05	0.0125	.008
DDT Subtrat 2	OFF	05	1.053	0.05	0.0125	.733
PPT Sublest 2	ON	.661	3.323	0.05	0.0125	.154
	OFF	.066	1.455	0.05	0.0125	.740
PP1 Subtest 3	ON	.534	1.637	0.05	0.0125	.021
	OFF	-1.911	24.935	0.05	0.0125	.579
PP1 subtest 4	ON	.887	7.749	0.05	0.0125	.409
MMDT placing	OFF	-5.185	16.692	0.05	0.0125	.028
test	ON	-3.638	13.248	0.05	0.0125	.051
MMDT turning	OFF	-3.656	19.377	0.05	0.0125	.180
test	ON	3.453	11.116	0.05	0.0125	.028
ST Dicht hand	OFF	2.019	16.056	0.05	0.0125	.369
ST Right hand	ON	-2.642	8.204	0.05	0.0125	.023
ST Left here 1	OFF	-1.192	7.667	0.05	0.0125	.267
SI Left hand	ON	.170	6.100	0.05	0.0125	.064

225 Mean: mean difference between the group with and without orthosis. ON: under levodopa

effects; OFF: 1 hour before next levodopa dose; SD: Standard Deviation; PPT: The Purdue

227 Pegboard Test; MMDT: Minnesota Manual Dexterity Test; ST: Square Test

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229 No differences were observed between the CG and the EG in the PPT, in the MMDT or

230 in the ST without orthosis after the EG had worn the orthosis for two months

231 (Supplementary material 4).

232

4. Discussion

The main results of this study indicate that improvements in certain aspects of motor

235 dexterity occur when the patient wears the orthosis. However, after using the orthosis

regularly for two months, no differences were observed in manual dexterity of the ULwhen the orthosis was removed.

Among motor symptoms, bradykinesia, rigidity, resting tremor, and impaired motor

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239 dexterity are prominent and can manifest themselves in varying degrees as the disease 240 progresses, but they are highly bothersome and disabling, impacting performance in 241 ADL and QoL (Bloem et al., 2021b; Postuma et al., 2015a). 242 In recent years, the effectiveness of these devices has been tested in other conditions. 243 Jen et al. explored their implementation in stroke patients, observing an improvement in function and dexterity in the UL and promotion of participation in repetitive activities 244 245 (Alexander et al., 2021). Studies conducted in cases of cerebral palsy have demonstrated 246 their effectiveness in improving manual dexterity (Giray et al., 2020; Pavão et al., 247 2018), functionality and alignment of the affected UL (Yasukawa & Uronis, 2014). 248 These results partially align with those obtained in the present study as an immediate 249 effect of the orthosis was observed in some subtests both in T1 and T2. Therefore, 250 improvements in certain aspects of motor dexterity are observed when the orthosis is 251 being used. However, after using the orthosis for 2 months, no differences were 252 observed between CG and EG when the tests are performed without the orthosis, which 253 may be explained, in part, because while PD is a degenerative condition, stroke and 254 cerebral palsy are not. 255 Various orthoses tested have shown positive effects on reducing involuntary movement,

al., 2019; Mo & Priefer, 2021). Therefore, there is a need to design lighter and appealing

but they were also heavy and unattractive, leading to reluctance in their use (Fromme et

to the patient orthosis, while also providing an improvement in manual dexterity.

This research must be considered in the context of their strengths and limitations. DEFOs have proven to be easily implementable and adherent devices, resulting in improvements in some aspects of manual dexterity, both the ON and OFF states of the disease. Although no differences were found after removing the orthosis in manual dexterity, improvements were obtained in occupational performance with the orthosis on. Furthermore, they represent a non-pharmacological treatment without any contraindications for the patient.

266 In the results, there is a tendency for greater differences to appear between wearing or 267 not wearing the orthosis in the ON state; however, they lack statistical significance after 268 applying the Bonferroni correction. At first glance, there does not seem to be an obvious 269 reason for the medication state to interact with the use of the orthosis in this way; 270 however, the role of medication state and its interactions with findings should be 271 addressed more deeply in future research. Understanding the orthosis response in both 272 states allows for optimizing its use, adjusting the timing to maximize its benefits during 273 ON periods and minimize symptoms during OFF periods.

The observational nature of the study, and not having blinded evaluators or patients are limitations for this study. Additionally, due to the limited duration of the study, it was

276 not possible to ascertain whether longer-term treatment might lead to further

improvements or if it could slow down the progressive deterioration of the disease. Onthe other hand, although participants reported that they had worn the orthosis for the amount

of time indicated since they were able to perform their activities better, and they did not have as

280 much tremor; these devices do not include a sensor that allows obtaining objective data

281 on their adherence, and despite having obtained this information in the telephone calls

282 made during the intervention period as well as in the evaluation after two months, it

would be interesting to obtain objective data about both adherence and participation.

284 The use of the Bonferroni correction itself has some advantages and disadvantages to 285 consider. It is easy to apply and understand, and minimizes the risk of false positive 286 errors, as well as being a robust and conservative adjustment that does not depend on 287 the nature or distribution of the data or tests and works for any number of tests. On the 288 other hand, it may be too conservative, reducing the power of each test and increasing 289 the risk of false negative errors; it is also not flexible, as it does not take into account the 290 dependence or correlation between tests. All of this must be taken into account when 291 interpreting the results obtained in this research, since when applying the corrected α 292 value, some results that would be positive at a significance level of 0.05 are lost; this is 293 something that will have to be addressed in future research.

Furthermore, this orthosis was implemented during the winter months in a city with a cold climate, so it did not give heat to the participants, however it would be interesting to manufacture it with a breathable material so that heat would not be a problem and could maintain its adhesion in other warmer climates.

298 Currently, there is a lack of effective orthopedic devices that can be implemented as a non-pharmacological treatment in PD. The results obtained in the present study can be a 299 300 starting point to continue researching these devices in PD or encourage the development 301 of new ones that are easy to implement, lightweight, and with patient adherence, in 302 order to improve manual dexterity and thus allow greater participation in ADLs, 303 improving their functionality and quality of life. Given that no effects were found when 304 the device was removed, in a future, for a longer implementation of the orthosis for 305 months, it could be interesting to wear it only while performing those activities that are 306 relevant to the patient. Furthermore, given that the biggest problem with current orthoses is their lack of adherence because they are heavy, it would be interesting to 307

308 implement a sensor that allows checking the adherence in this orthosis and having309 objective data about it.

Although no differences were found in manual dexterity after removal of the orthosis, it
is possible that differences could occur in other variables not studied such as
occupational performance, daily use of the arm and hand, etc., which would be
interesting variables for future research.

314

5. Implications for Occupational Therapy Practice

Currently, PD's fundamental treatment is pharmacological; however, OT is of great relevance for the patient's occupational performance and QoL. Studies such as this one can encourage greater involvement of occupational therapy in this and other populations. This research shows an alternative non-pharmacological treatment that could reduce the motor symptoms, improve patients' functionality, and increase their QoL without adverse side effects.

In clinical practice, the implications of implementing DEFO could lead to a reduction inbothersome motor symptoms like tremors and rigidity, thereby enhancing functionality

324 fostering greater autonomy for patients in their daily lives. Moreover, such interventions

325 have the potential to substantially improve the quality of life (QoL) for patients,

326 fostering a positive self-image and reducing embarrassment and insecurity associated

327 with symptoms like tremors. By enabling individuals to participate more fully in social

328 activities and group outings without fear of functional limitations, these interventions

329 could enhance social integration and rekindle interest in activities that patients may have

330 previously abandoned. This, in turn, could bolster motivation to explore new activities

and experiences without the burden of apprehension or the fear of failure, ultimately

332 promoting a more fulfilling and enriching lifestyle for patients.

333

5. Conclusions

The DEFO is an easy-to-implement device that may improve manipulative dexterity when worn, and therefore may be a non-pharmacological adjunct to standard treatment to improve the motor aspects of the disease.

338 As few studies have been conducted with the DEFO in PD, further research is needed to

339 verify its efficacy in PD as well as to see if these possible improvements in

340 manipulative dexterity translate into improvements in occupational performance and

341 participation. Also, including treatment adherence variables in future research would342 also be of interest.

343

344 Author Contributions

- 345 Conceptualization, J.G.-S., E.C., M.J.-B. and J.M.T.G.-G.; methodology, J.G.-B. and
- 346 M.J.-B. ; software, J.G.-B. and J.M.T.G.-G.; validation, E.C. and J.M.T.G.-G.; formal
- analysis, M.J.-B., M.S.-P. and J.G.-B.; investigation, M.J.-B., C.C.-R. and M.S.-P.;
- 348 resources, M.J.A.M., C.C.-R. and M.S.-P.; data curation, J.G.-B., C.C.-R. and M.S.-P.;
- 349 writing—original draft preparation, M.J.-B.; writing—review and editing, J.G.-S., J.G.-
- 350 B., M.J.A.M. and C.C.-R.; visualization, M.J.-B., J.G.-B., M.S.-P., C.C.-R., E.C.,
- 351 J.M.T.G.-G, M.J.A.M. and J.G.-S.; supervision, E.C., M.J.A.M., J.G.-B. and J.G.-S.;
- 352 project administration, J.G.-B.; funding acquisition, J.G.-B. All authors have read and
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- 358 Regional Health Management of Castilla y León–Sacyl GRS/2010/A/19.

359 Institutional Review Board Statement

- 360 The study was conducted in accordance with the Declaration of Helsinki and approved
- 361 by Clinical Research Ethics Committee of the Health Area of Burgos and Soria (Spain),
- 362 with reference number CEIM-2119/2019 before participating in the present study on 25
- 363 March 2021 (ClinicalTrials.gov test number: NCT04815382).

364 Informed Consent Statement

- 365 Informed consent was obtained from all subjects involved in the study.
- 366

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499 Supplementary figure 1. Patient performing the displacement subtest with the500 DEFO. Own-made source

513 Supplementary material 2.



515 Supplementary figure 2. Patient performing the rotation subtest with the DEFO.516 Own-made source

530 Supplementary material 3. DEFO FABRICATION OVERVIEW

531

532 Dynamic elastomeric fabric orthoses (DEFO) are used to address the physical
533 symptoms associated with neurological, genetic, and musculoskeletal disorders. These
534 orthoses employ a soft, flexible, and durable compression fabric aimed at realigning the
535 affected body segment and influencing muscle tone and the proprioceptive system.
536 Custom-made for a precise fit, each orthosis applies pressure to the affected areas via

537 strategically positioned powernet reinforcement panels.

- 538 DEFO are garments that integrate an elastic material with biomechanical reinforcement539 panels, serving two main functions:
- 540 1- They enhance proprioception by stimulating the body's sensory systems.
- 541 542
- 2- The reinforcement panels realign the body and provide stability at a biomechanical level.

543 For movement control, appropriate stimuli are required (tremor in Parkinson's disease is 544 an example of involuntary movements in the extrapyramidal pathway). DEFO stimulate 545 the somatosensory system through the proprioceptors in the musculoskeletal system. 546 This sensory information is processed by the cerebellum to adjust movements and 547 posture, influence muscle tone, and provide proximal stability. Different regions of the 548 cerebral cortex then interpret these sensations in meaningful ways, leading to improved 549 movement. Consequently, DEFO can be utilized in both neurophysiological and 550 biomechanical therapies.

551 Measurements are taken using specific forms that therapists learn to use during 552 specialized training, ensuring the orthoses fit correctly without being too tight or too 553 Lease. These measurements are performed while the national is sected using a series of

loose. These measurements are performed while the patient is seated, using a series ofprecise reference points on the upper limb.

The DEFO are created after taking precise measurements to design the base garment, in this case, an orthosis for the upper limb, always aiming for a functional position. From this position, measurements are taken for the necessary reinforcements, based on the desired outcome. In the context of reducing tremor in individuals with Parkinson's disease, the objective was to activate the finger extensors, wrist extensors, radial deviators, supinators, and external rotators. This approach positions the upper limb with muscles contracting as they would when the limb is supported and bearing weight.

562 The reinforcements designed to achieve this effect include:

563 - External rotation reinforcement: panel to sleeve used to correct internal rotation564 of the shoulder/arm.

565 - Radial side reinforcement: from the base of the thumb to correct ulnar deviation

566 - Arm tremor proximal reinforcement: designed to reduce forearm tremor by567 applying pressure to the deep muscles of the upper forearm

- Thumb abduction reinforcement: from the proximal thumb joint on the palmar
 aspect, across the posterior of the wrist, to the ulnar aspect of wrist joint; to correct
 excessive thumb adduction.
- 571 Elbow flexion angle reinforcement: specifies the required degree of elbow
- 572 flexion with the arm in the patient's natural resting position.
- 573 Additional reinforcements can be applied to increase traction as needed. The prescribing
- 574 professional determines which reinforcements are necessary for each case based on their
- 575 training.



- **Imagen:** Dynamic elastomeric fabric orthose (DEFO).

Supplementary material 4. Inter-group comparison of PPT, MMDT and ST differential score evaluation T2 without orthoses in ON
 and OFF state. ANCOVA

	Variables	Group	Mean	SD	MS	F	p-value	η²
	ON – without orthoses	CG	.076	1.29	.489	.232	.632	.005
PPT Subtest 1		EG	175	1.50				
	OFF without orthogog	CG	.111	1.219	076	010	200	000
	OFF – without orthoses	EG	.189	1.803	.976	.019	.890	.000
	ON without orthogog	CG	.446	1.258	2 458	120	711	.003
DDT Cubtoct 2		EG	.934	5.317	2.400	.139	./11	
rri Sublest 2	OFF without orthogog	CG	.40	1.57	202	116	533	.008
	OFF – without of moses	EG	.116	1.425	.090	.410	.322	
	ON – without orthoses	CG	.177	1.323	1 597	507	480	010
DDT Cubboot 2		EG	.873	3.479	4.387	.507	.400	.010
FFT Sublest 5	OFF – without orthoses	CG	.001	1.194	10 100	1 1 2 7	201	022
		EG	1.069	3.790	12.132	1.137	.291	.022
	ON-without orthoses	CG	1000	5.280	28 460	410	E0E	008
DDT Cubboot 4		EG	1.793	11.674	36.400	.410	.325	.008
FFT Sublest 4	OFF-without orthoses	CG	222	1.250	40 201	2664	061	069
		EG	1.707	3.785	40.361	3.004	.061	.000
	ON – without orthoses	CG	.347	27.380	2.171	.005	042	.000
MIMD1 Placing tost		EG	1.392	17.442			.943	
r lacing test	OFF without orthogog	CG	3.256	24.600	365.771	.745	202	.015
	OFF – without orthoses	EG	-2.574	20.840			.392	
	ON without orthogog	CG	-6.967	17.023	424.270	1.721	.196	.033
Turning tost	On – without orthoses	EG	454	14.993				
running test	OFF – without orthoses	CG	.033	9.911	210.418	.313	.578	.006

		EG	-6.270	37.093				
	ON – without orthoses	CG	2.933	9.706	157.431	1.725	.195	.033
CT Dishthese d		EG	-1.132	9.416				
51 Kight hand	OFF – without orthoses	CG	333	9.693	588.302	2.089	.155	041
		EG	7.108	18.625				.041
	ON-without orthoses	CG	2.133	6.346	20.040	265	E 40	007
CT I of the and		EG	026	9.774	28.048	.305	.348	.007
51 Left hand	OFF-without orthoses	CG	6.949	6.949	210 549	0 417	071	065
		EG	10.534	10535	310.548	3.417	.071	.065

 PPT: Purdue Pegboard Test; MMDT: Minnesota Manual Dexterity Test; ST: Square Test; CG: Control group (n=20), EG: experimental group (n=40), SD: standard deviation, p value < .05