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Prospective evaluation of the connected biofeedback EMY Kegel trainer in the management of stress urinary incontinence

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- O GARBIN : Project development, Data collection
- J GODET: Data analysis
- M RAGUENEAU : Data collection
- C MEYER : Data collection
- S BILLECOCQ : Protocol writing

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1 **ABSTRACT**

2

3 **Introduction**

4 The aim of this study was to evaluate changes in the quality of life with the connected biofeedback EMY Kegel
5 trainer in patients suffering from stress urinary incontinence.

6

7 **Material and methods**

8 This was a prospective, single-center, non-comparative study, which took place between September 2019 and
9 October 2020, in the University Hospitals of Strasbourg. Eligible patients were instructed to use the EMY probe
10 for a minimum of 10 minutes per day for five days per week. To assess quality of life and urinary symptoms, the
11 Contilife and ICIQ-SF scores were completed each month until the final visit (M3). The PGI-I was also completed
12 at 3 months to assess the benefit of the EMY Kegel Trainer.

13

14 **Results**

15 A total of 55 patients were included. At the inclusion visit (M0), the mean Contilife and ICIQ-SF scores were
16 respectively at 6.6 ± 1.5 and 10.5 ± 3.0 points. At the final visit (M3), the mean Contilife score increased to $9.2 \pm$
17 1.0 , indicating an improvement in quality of life. The mean ICIQ-SF score decreased to 4.2 ± 4.0 , indicating an
18 improvement in urinary symptoms. The PGI-I questionnaire identified a positive assessment of the EMY Kegel
19 trainer. On the 55 patients included, 35 (64%) reported completing at least 36 sessions during the study, i.e. an
20 average of 3 sessions per week.

21

22 **Conclusions**

23 This study suggests that perineal rehabilitation by biofeedback using the EMY Kegel trainer might be beneficial.

24

25 **Keywords**

26 Stress urinary incontinence – Perineal rehabilitation – Biofeedback

27

28

29 INTRODUCTION

30

31 Urinary incontinence is a common condition leading to a significant decrease in quality of life. All expert panels
32 agree that pelvic floor muscle training with hygiene and dietary rules are the first step in the management of
33 stress urinary incontinence [1–3]. Functional electrostimulation seems less effective than voluntary contraction
34 exercises, and is not currently recommended [2]. A Cochrane review published in 2011 investigated the role of
35 biofeedback [4]. It included 24 trials comparing pelvic floor muscle training and pelvic floor muscle training with
36 biofeedback. The rate of improvement of urinary incontinence symptoms was greater in patients undergoing
37 biofeedback therapy. The authors point out, however, that this outcome could be skewed by a confounding factor
38 such as amount of contact time with health professionals. Given these circumstances, current guidelines do not
39 currently recommend biofeedback as a first-line treatment.

40 Recently, the French society Fizimed developed a medical device to improve the management of
41 women suffering from stress urinary incontinence: the EMY Kegel trainer. This device is a biofeedback vaginal
42 probe that connects to the patient's smartphone. The product was developed following strict safety and
43 performance criteria for medical devices and has received CE conformity marking.

44 The aim of our study was to evaluate changes in the quality of life with the connected EMY Kegel trainer
45 in patients suffering from stress urinary incontinence. Secondary objectives were to assess patient compliance
46 with pelvic floor muscle training the EMY Kegel trainer, to observe changes in urinary scores over the duration of
47 the trial, and to evaluate the benefit of using the EMY connected perineal probe for stress urinary incontinence.
48 Patient feedback and impressions will be used to improve this device prior to setting up a comparative study.

49

50 MATERIAL AND METHODS

51

52 Study participants and design

53 This was a prospective, single-center, non-comparative study. It took place between September 2019 and
54 October 2020, in the University Hospitals of Strasbourg, France. In order to be eligible for the study, patients had
55 to 1) report at least one episode of urine leakage per week in the last 3 months; 2) be 18 years of age or older
56 with no upper age limit; 3) have given birth at least 6 months beforehand; 4) be able to perform an effective

57 voluntary contraction and avoid abdominal synergy and apnea during the contraction (attested by the partner
58 health professional referring the patient to the study); 5) have responded favorably to perineal re-education for
59 stress urinary incontinence or mixed stress incontinence in at least two sessions (attested by the partner health
60 professional referring the patient to the clinical trial); 6) have signed an informed consent form; 7) be using
61 effective contraception throughout the study (declarative); 8) have a functioning smartphone with at least Android
62 5 and iOS 8; and 9) be able to read and write in French.

63 Non-inclusion criteria were patients who 1) were undergoing other forms of perineal rehabilitation during
64 the study period; 2) had a neurological disease, congenital malformation, urinary incontinence or prolapse treated
65 surgically or medically, perineal hypoesthesia or local conditions prohibiting the use of an intravaginal probe; 3)
66 presented urge incontinence or mixed urinary incontinence with predominance of urgency; 4) presented a
67 contraindication to the use of the medical device; 5) with genitourinary cancer (within the previous five years); 6)
68 had extra-urethral "incontinence" (fistula, ectopic ureter); 7) had severe urinary retention; 8) were fitted with a
69 sacral neuromodulation box; 9) were in a period of exclusion (determined by a previous or current study); 10)
70 could not give fully informed consent (subject in an emergency situation, difficulties in understanding the subject,
71 etc.); 11) were under legal protection, guardianship or trusteeship; 12) were pregnant (positive urine test) or 13)
72 breastfeeding.

73 This study was approved by the institutional review board and by the Patient Protection Committee in
74 February 2019 (CPP Ouest 1 No. 2019-A00059-48).

75

76 **Medical device: the EMY Kegel trainer**

77 The EMY Kegel trainer is a biofeedback device measuring 105mm x 32mm and weighing less than 55g (Figure
78 1). Its design was developed to fit the natural anatomy of women and based on the perineal rehabilitation probes
79 used in perineal rehabilitation. It is entirely manufactured, assembled and stocked in France. EMY is composed
80 of 1) an internal (intra-vaginal) part equipped with sensors based on an innovative and patented technology
81 measuring perineal contractions (biofeedback technology); 2) an external part which sends recorded data to the
82 smartphone via a Bluetooth antenna. The sensors are based on an innovative and patented technology, and
83 allow a sensitive and reproducible measurement of perineal muscle contractions. The device is a class 1 medical
84 device, and the entire product was designed and produced to medical standards. All its constituent materials are

85 medical-grade and biocompatible, in line with the CE Medical standard. The Bluetooth emitter used is Bluetooth
86 Low Energy, which is of very low intensity (emits around 1000 times fewer waves than a smartphone) and meets
87 the ISO 60 601 standard.

88 The EMY Kegel trainer comes with a case for storage, transport and recharging. The user can connect
89 this box using a USB cable and recharge the probe by induction. The probe does not have a recharging port so
90 that it can be thoroughly cleaned, thus avoiding the risk of bacterial contamination.

91 A smartphone application comes with the EMY Kegel trainer. It contains several sections. The first is a
92 “play” sequence where the patient practices rehabilitation exercises which are piloted by the EMY Kegel trainer.
93 All exercises are based on clinical protocols. The second allows follow-up of the patient's objectives, which she
94 can define in terms of session duration and number of sessions per week. She can then simply see where she
95 stands in relation to the objectives initially set. Other sections include a reminder function, instructions for use and
96 FAQs, and an encyclopedia where the patient can learn more about the perineum, rehabilitation, and
97 incontinence. Exercises are adapted to each patient and based on recognized therapeutic protocols. These
98 protocols are derived from the PERFECT Scheme: Power, Endurance, Repetitions, Fast contractions, Every
99 Contraction Timed[5]. The application's built-in program can analyze the results obtained and automatically set
100 the difficulty level of the next workout.

101

102 **Outcome definition**

103 The main outcome is the Contilife questionnaire to evaluate changes in the quality of life. Contilife is a quality-of-
104 life questionnaire that includes 28 questions exploring which daily activities are disrupted by urinary incontinence
105 symptoms, types of stress causing urinary incontinence, as well as emotional impact, self-image and sexuality[6].
106 The higher the score, the better the quality of life. While this questionnaire has the disadvantage of being long, it
107 has the major advantage over other more restricted questionnaires of exploring a wider field.

108 Secondary evaluation criteria are the logbook for assessing compliance, the ICIQ-SF (International
109 Consultation on Incontinence Questionnaire-Short Form) for changes in urinary symptoms, as well as the PGI-I
110 (Patient Global Impression and Improvement) for assessing benefits accrued from using the probe. The logbook
111 records the frequency of the exercises performed, their duration and any additional comments. The ICIQ-SF is a
112 validated and standardized questionnaire for assessing the severity of urinary incontinence symptoms [7]. The

113 overall score is from 0 to 21 points, with 0 corresponding to mild urinary symptoms and 21 to very severe
114 symptoms. A minimal clinically important difference for the ICIQ-SF is an improvement of 2 points. The PGI-I
115 questionnaire was originally modelled after psycho-pharmacological scales first described in 1976 (Clinical Global
116 Impression)[8], and has been validated for stress urinary incontinence[9].

117

118 **Practical conduct of the study**

119 During a routine consultation at the University Hospitals of Strasbourg (in the urology and gynecology
120 departments) or in a partner practice (doctors, physical therapists, midwives), eligible patients were informed
121 about the study and given the opportunity to participate. When patients showed interest in the study, they were
122 given a written briefing document.

123 After a minimum period of 7 days' reflection, patients were invited to attend an inclusion visit (M0) and
124 sign the informed consent. A pregnancy test (urinary) was performed for each eligible patient. If the test was
125 positive, the patient could not be included. During this inclusion visit, the following data were collected by the
126 investigator: age, weight, height, socio-professional profile, number of births, type of delivery, menopausal or not,
127 and hormonal treatments. The Contilife, ICIQ-SF and PGI-I questionnaires were presented by the investigator.
128 Only the first two were completed by participating patients at this time. The investigator also handed over the first
129 logbook. An introduction to the EMY biofeedback probe was provided by a Fizimed representative. If needed, the
130 representative also helped the patients to download the application on their smartphone. Patients could perform
131 an on-site trial if desired.

132 Patients included in the study were instructed to use the EMY probe for a minimum of 10 minutes per
133 day for five days per week. Exercises had to be performed in a semi-seated position, with the back, head and
134 shoulders resting on a cushion. The EMY application offers numerous exercises which can be classified into four
135 categories: 1) Strength, requiring a powerful contraction to increase the strength of the perineum; 2) Endurance,
136 requiring a long contraction to increase the duration of perineal contraction; 3) Repetition, requiring repeated
137 contractions to simulate perineal contractions when walking or running; and 4) Fast, requiring rapid contractions
138 to simulate the activity of the pelvic floor during reflex contractions (coughing, sneezing). In each category,
139 patients could opt for analytical exercises with simple graphics (sphere, scales, etc.) or exercises with a more
140 playful universe (rocket, birds, hot-air balloon, etc.).

141 Two follow-up visits at 1 month (M1) and 2 months (M2) were conducted, the first at the University
142 Hospitals of Strasbourg and the second by telephone. These visits served to assess difficulties encountered and
143 patient compliance. During the M1 follow-up visit, physical therapists ensured that abdominal synergy and apnea
144 were absent during the contraction. The first logbook was retrieved at this visit. Both the Contilife and ICIQ-SF
145 questionnaires were completed at each follow-up visit.

146 At the end-of-protocol visit at 3 months (M3), PGI-I was completed in addition to the Contilife and ICIQ-
147 SF scores. The last two logbooks were retrieved at this visit.

148

149 **Statistical analysis**

150 A descriptive analysis of all the variables was performed. Qualitative data were reported as frequency
151 (percentage) and quantitative data were described using mean and standard deviation or median and inter-
152 quartile range. Linear mixed model with subjects used as random effect were used to estimate change over time.

153 All statistical analyses were performed using software R version 4.0.3.

154 As the study had only one treatment arm, it was not necessary to calculate a sample size. The number of
155 patients participating in the study was set at 55. With this sample size, and assuming a standard deviation of 1.5
156 points on the Contilife score, the width of 95% confidence interval of the mean score would then be less than 1
157 points (0.8).

158

159 **RESULTS**

160

161 **Patient characteristics**

162 A total of 55 patients were included in our study. Initial characteristics of these patients can be found in Table 1.

163

164 **Quality of life**

165 At the beginning of the study, the mean Contilife score was 6.6 ± 1.5 points (mean \pm SD). At 1 month and 2
166 months it was 8.2 ± 1.5 and 8.9 ± 1.0 respectively. At the final visit, the mean score had increased to 9.2 ± 1.0 .

167 Overall changes in the Contilife score can be visualized in Figure 2, and for each sub-setion in Figure 3. Changes

168 in the score over time were significant ($p < 0.001$ - mixed model) with a mean increase of 0.8 ± 0.1 points on each
169 measurement.

170

171 **Urinary symptoms**

172 At the inclusion visit, the mean ICIQ-SF score was 10.5 ± 3.0 (mean \pm SD). At 1 month and 2 months it was 8.2
173 ± 3.4 and 5.5 ± 4.2 respectively. At the final visit (three months), a mean score of 4.2 ± 4.0 was observed. Figure
174 4 shows changes in this score over time. Again, changes in the ICIQ-SF score over time were significantly
175 different ($p < 0.001$ - mixed model), with a mean decrease of 2.2 ± 0.3 points on each measurement.

176

177 **Utility**

178 Of the 55 patients included, 26 (55%) described their post-operative condition as “very much better”, 12 (26%) as
179 “much better” and 5 (11%) as “a little better”. A total of 43 (91%) patients thus experienced a benefit from using
180 the EMY Kegel trainer. Two patients (4%) found no improvement after using the EMY Kegel trainer, and two (4%)
181 described it as “a little worse” and as “very much worse”. A total of 4 (9%) patients thus experienced no benefit
182 from using the EMY Kegel trainer. Eight patients did not complete the PGI-I questionnaire, i.e. 15% of data were
183 lost to follow-up. Overall, the utility of the probe was positively rated at 4.5 ± 0.8 out of 5. Thirteen patients (26%)
184 reported experiencing a side-effect or adverse event (mainly discomfort, dryness or irritation). No major side-
185 effect or adverse event was reported.

186

187 **Compliance**

188 On the 55 patients included, 35 (64%) reported completing at least 36 sessions during the study, i.e. an average
189 of 3 sessions per week. The median number of sessions performed per week by the patients in this study was 3.8
190 [1.7 – 4.4] (median [IQR]).

191

192 **DISCUSSION**

193 **Summary of Main Results**

194 In this prospective study, we evaluated the value of biofeedback therapy using the EMY Kegel trainer in patients
195 with stress urinary incontinence. A significant improvement in quality of life over time was observed, as well as an

196 improvement in urinary symptoms. Patients included in this study confirmed the utility of the EMY Kegel trainer,
197 both in terms of treatment outcome and compliance. The advantage and novelty of this perineal rehabilitation
198 device is that remedial exercises can be carried out at home. This makes it possible to adapt the number of
199 sessions per week according to the time available, thus boosting compliance.

200

201 **Results in the Context of Published Literature**

202 Biofeedback has been used for many years to assist patients and clinicians in rehabilitation in many different
203 areas of medicine[10]. Previous studies have sought to evaluate the impact of biofeedback in perineal
204 rehabilitation[11–13], but their results have been inconstant. The goal of this technique is to provide patients with
205 real-time biological information that would otherwise be unknown. Providing patients and clinicians with
206 biofeedback during rehabilitation may potentially improve the accuracy of functional tasks, increase compliance
207 with treatment, and reduce the need for ongoing contact with healthcare professionals to monitor its
208 implementation. It is important to emphasize, however, that biofeedback is not a stand-alone therapy, but a
209 complementary technique for pelvic floor muscle training in all cases. Several studies have recently investigated
210 the value of a home rehabilitation probe, with biofeedback or electrostimulation[14–17]. Due to the highly variable
211 primary endpoint in these studies, a comparison of the results between the different devices is currently not
212 feasible. However, the study of the benefit of home rehabilitation remains interesting. Legendre et al. conducted a
213 prospective longitudinal study of ten patients with de novo urinary incontinence evaluating a home electro-
214 stimulation named Keat pro system[14]. They concluded that self-rehabilitation in addition to conventional pelvic
215 floor muscle training objectively improves the perineal muscle building achieved after conventional rehabilitation.
216 Their primary endpoint was the biometric of the levator ani and was assessed by three-dimensional perineal
217 ultrasound. Another study on the evaluation of a biofeedback rehabilitation probe named Elvie was partially
218 published in 2007[17]. From a self-reported questionnaire sent electronically to patients in the United States and
219 the United Kingdom, an increase in compliance was observed suggesting a potential benefit of self-rehabilitation.
220 Home rehabilitation thus seems promising. It is important to note, however, that this technique mainly aimed at
221 young women able to use a smartphone and presenting moderate but still disabling incontinence. Our study
222 included a young population with a median age of 41.0 [34.5, 46.5] years and a mean baseline ICIQ-SF score of

223 10.5 ± 3.0. The same characteristics were found in the previously mentioned studies, confirming the target
224 population of these self-rehabilitation probes.

225

226

227 **Strengths and Weaknesses**

228 The main strength of this study is its strict methodology with prospective recruitment. The inclusion of a
229 multidisciplinary team (gynecologist, urologist and physiotherapist) for the elaboration of this study is also one of
230 its qualities. The main shortcomings of this study are the absence of a comparative group and the small sample
231 size. It was however planned as a preliminary study in order to evaluate the possibility of carrying out a controlled
232 prospective intervention study at a later date.

233

234 **Implications for Practice and Future Research**

235 This study seems to open new therapeutic perspectives for stress urinary incontinence in women and provides
236 additional data on a still controversial technique. Given the potential impact of this technique on the quality of life
237 of many women suffering from urinary incontinence, further research in this area is to be encouraged, particularly
238 on its effectiveness and the medico-economic aspect. The Emy Kegel trainer currently costs 199 euros and is not
239 yet covered by French social security. It can however be partially or totally covered by the patient's private health
240 insurance. Moreover, after the initial therapeutic education and acquisition of autonomy by the patient, its use
241 may allow to avoid appointments related to the rehabilitation. In the medium term, it could reduce the cost of
242 managing stress urinary incontinence.

243

244 **Conclusion**

245 In conclusion, this study suggests that perineal rehabilitation by biofeedback using the EMY Kegel trainer might
246 be beneficial. A comparative study with pelvic floor muscle training should be conducted in the future to confirm
247 the benefit suggested by this study.

248

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252

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FIGURES LEGEND

Figure 1. Picture of EMY Kegel Trainer

Figure 2. Overall changes in the mean Contilife score (the higher the score the better the quality of life)

Figure 3. Changes in the Contilife score in each sub-section (DA: Daily activities, EA: Effort activities, SI: Self-image, EI: Emotional consequences, SE: Sexuality, WB: General Well-being)

Figure 4. Changes in the ICIQ-SF score (the lower the score the better the urinary symptoms)

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TABLE

Table 1. Characteristics of the patients included

	Total
Total number	55
Age, years	41.0 [34.5, 46.5]
Weight, kg	66.0 [59.0, 75.5]
Height, cm	165.0 [163.0, 170.0]
BMI, kg/m ²	23.9 [20.7, 26.3]
Socio-professional profile	
Farmer	0
Craftsman, shopkeeper and company director	2 (3.7%)
Executive and senior intellectual profession	23 (42.6%)
Intermediate profession	0
Employee	25 (46.3%)
Worker	0
Retired	1 (1.9%)
No professional activity	3 (5.6%)
Gestity	2.0 [2.0, 3.0]
Parity	2.0 [1.0, 2.0]
Years since last birth	6.4 [3.0, 13.3]
Menopause	
With hormonal treatment	1 (2%)
Without hormonal treatment	6 (11%)

emy







