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LETTER TO EDITOR

Flat magnetic stimulation treatment for urinary incontinence: Analysis and six months follow-up of 180 cases

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Dear Editor,

Urinary incontinence (UI) is defined as the involuntary loss of urine and divided into 3 subtypes: *stress urinary incontinence* (SUI), *urge urinary incontinence* (UUI) and *mixed urinary incontinence* (MUI). These conditions are often caused by dysfunction of the *pelvic floor muscles* (pFM). Lifestyle modifications, conservative therapies (Kegel exercises, biofeedback and electrical stimulation), pharmacotherapy (antimuscarinic and beta-agonist agents) are the available options for managing UI, depending on the subtype. Lastly, when conservative measures are ineffective or when severe UI is present, surgical methods may be useful (1). Due to the invasive nature of most of the therapies and the potential risks, the patients generally prefer less-invasive forms of treatment. As previously shown in the literature with qualitative and quantitative evaluations, Magnetic Stimulation is one of these non-invasive options (2, 3). Studies had been conducted on women with UI to investigate short- and medium-term data about magnetic stimulation, with good outcomes observed up to *3 months follow up* (3MFU) (4, 5). This observational and multicentre study analyses the effectiveness of PelviTouch treatment by Dr. Arnold device (*DEKA M.E.L.A. Calenzano, Italy*) after a prolonged period of observation on the 3 different types of UI. Using a chair applicator, PelviTouch produces stimulation through uniformly distributed electromagnetic fields (*TOP FMS–TOP Flat Magnetic Stimulation*) able to generate a large activation of PFM. All patients underwent the first 4 treatments with the protocol Hypotonus/Weakness 1 targeted to recover trophism and muscle tone, and the following 4 treatments with the protocol Hypotonus/ Weakness 2 targeted to increase volume and muscle strength. The *International Consultation on Incontinence Questionnaire-Short Form* (ICIQ-UI-SF) (6), the *Pelvic Floor Bother Questionnaire* (pFBQ) (7) and Potenziani-14 quality of life questionnaire (8) were used to assess the results from baseline up to *2 months of follow-up* (2MFU) and up to *6 months of follow-up* (6MFU) after the last treatment session. Every potential adverse effect was assessed.

A total of 180 women (mean parity number: 2.97 ± 1.07), 48% with SUI, 33% with UUI and 19% with MUI, were evaluated. Exclusion criteria were patients with genital infections, malignant tumors, severe neurological diseases, obesity and persons with pacemakers or metal implants. Every patient finished all her prescribed treatments and was followed up as scheduled. No patient experienced side effects during or after treatment. Our findings showed that any single questionnaire scores decreased from baseline to 2MFU and to 6MFU resulting in an improvement in the UI symptoms (see Figure 1). For patients with SUI, ICIQ-UI-SF score significantly decreased from 15.23 ± 3.60 at baseline, to 11.00 ± 3.91 ($p < 0.001$) at 2MFU, to 7.07 ± 4.62 ($p < 0.001$) at 6MFU; PFBQ score from 18.92 ± 6.83 at baseline, to 12.92 ± 7.54 ($p < 0.001$) at 2MFU, to 8.92 ± 5.67 ($p < 0.001$) at 6MFU; Potenziani-14 questionnaire score from 13.84 ± 1.90 at baseline, to 11.00 ± 1.91 ($p < 0.001$) at 2MFU, to 6.53 ± 2.06 ($p < 0.001$) at 6MFU. For patients with UUI, ICIQ-UI-SF score significantly decreased from 11.55 ± 4.66 at baseline, to 9.66 ± 2.73 ($p < 0.001$) at 2MFU, to 8.88 ± 4.28 ($p < 0.001$) at 6MFU; PFBQ score from 17.66 ± 7.43 at baseline, to 14.44 ± 9.36 ($p < 0.001$) at 2MFU, to 9.33 ± 5.63 ($p < 0.001$) at 6MFU; Potenziani-14 questionnaire score from 11.44 ± 2.12 at baseline, to 9.33 ± 1.58 ($p < 0.001$) at 2MFU, to 5.66 ± 1.32 ($p < 0.001$) at 6MFU. For patients with MUI, ICIQ-UI-SF score significantly decreased from 14.60 ± 3.20 at baseline, to 9.40 ± 4.82 ($p < 0.001$) at 2MFU, to 10.60 ± 4.44 ($p < 0.001$) at 6MFU; PFBQ score from 18.00 ± 11.22 at baseline, to 12.20 ± 6.20 at 2MFU, to 12.20 ± 7.08 at 6MFU; Potenziani-14 score decreased from 10.4 ± 1.34 at baseline, to 8.40 ± 1.34 at 2MFU ($p < 0.001$), to 5.00 ± 1.00 ($p < 0.001$) at 6MFU.

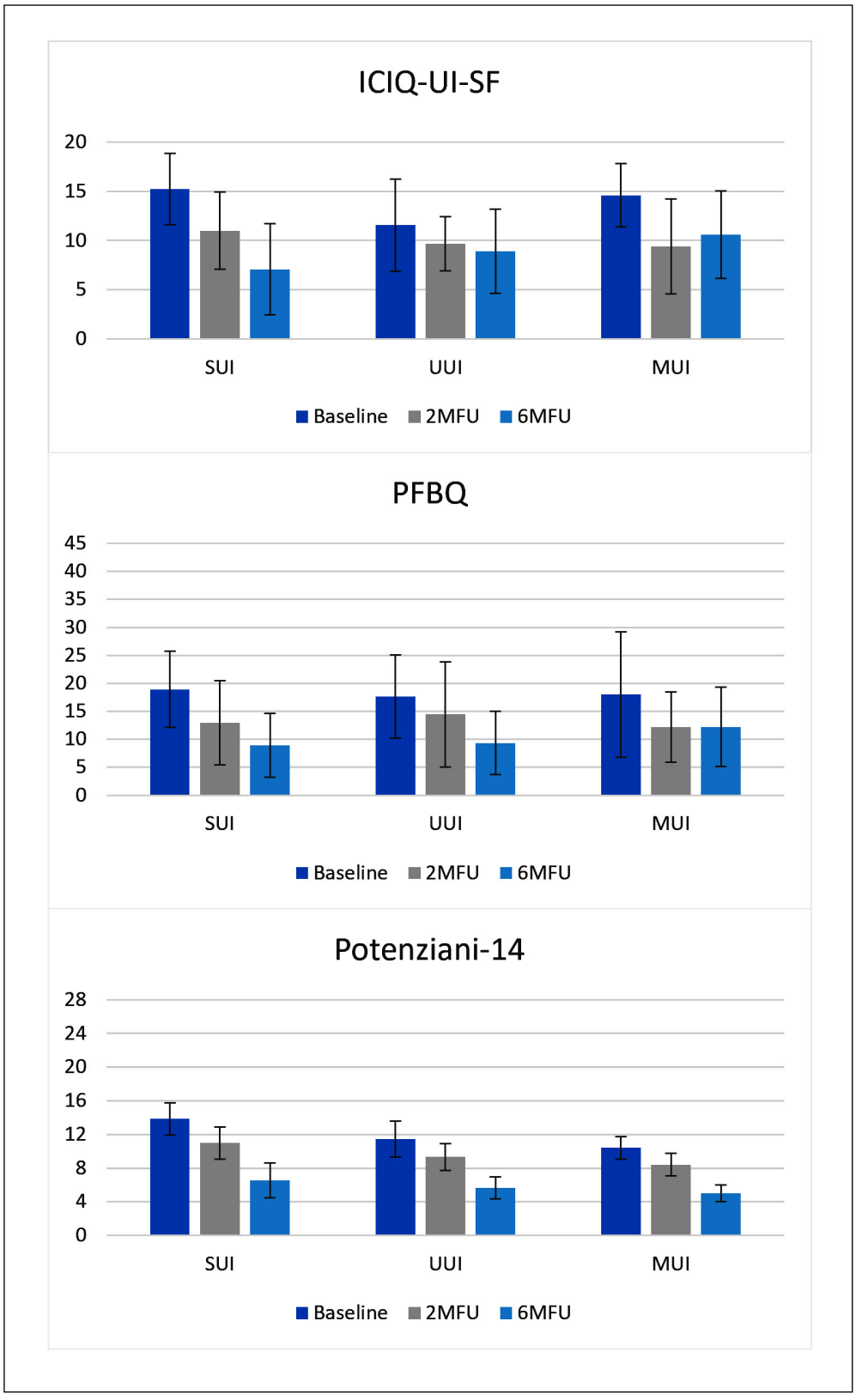

Figure 1.
Histogram representation of ICIQ-UI-SF (upper panel), PFBQ (middle panel) and Potenziani-14 (lower panel) mean score of patients suffering from SUI, UUI and MUI at baseline, 2MFU, 6MFU.

Study results revealed that PelviTouch reduced UI symptoms and these results concerning the severity, frequency, and impact of UI on quality of life, are sustained not only in the medium term but also up to 6MFU. PelviTouch helps the patient to understand how the PFM are used during the session, which gives him more awareness and control over how to manage his PFM. This, combined with muscle strengthening, helps to explain why the results last for up to 6MFU. In conclusion, our results suggest that this technology can be used as robust UI treatment tool with long-term results.

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Declarations

Ethical approval and consent for participate: *This study was conducted in accordance with the Good Practice Guideline and to the Declaration of Helsinki. No activity was carried out outside the scope of the device intended purpose or that no additional invasive or burdensome procedures were carried out compared to procedure performed under the normal condition of use of the device*

Consent for publication: *All eligible participants signed an informed consent form.*

Availability of data and material: *The datasets used and/or analysed during the current study were available from the corresponding author on reasonable request.*

Competing interests: *The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.*

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