MV.Health

Clinical Evidence

Evidence-based outcomes, backed by science, shaped by data & grounded in clinical rigor. Over the past decade, our devices have been at the forefront of **independent clinical research** across the US, UK & Europe. All studies are designed, conducted & published by **leading urologists, Ob-Gyns, pelvic floor therapists & sexual health researchers,** completely independently to ensure objectivity & deliver the highest scientific standards.

With over **20 studies** completed & dozens more underway, we are continually deepening our understanding of where vibratory stimulation can be most effective, how they can be improved, and what innovations are needed next. This ongoing research spans a wide spectrum of sexual health challenges, from **erectile dysfunction, prostatitis, and pelvic pain to arousal, dryness** and **orgasmic disorders.**

This growing body of clinical evidence, led by experts, published in peer-reviewed journals, is crucial in delivering trusted sexual healthcare.

Women's Health Studies

Numerous clinical trials have demonstrated the **strong efficacy of Crescendo 2, Poco, Legato & Molto** in treating conditions like **genito-pelvic pain, arousal & lubrication disorders, anorgasmia and vaginismus.**

Led by clinicians, these studies have shown **2X to 5X improvements in FSFI domains of pain, lubrication & orgasm,** with no adverse effects, establishing these devices as **safe, effective & clinically significant interventions** in modern sexual medicine.

Studies with CRESCENDO / CRESCENDO 2

Multicenter Study with Crescendo for the Treatment of Genito Pelvic Pain

Genito-Pelvic Pain Penetration Disorders (GPPPD), a common but challenging sexual pain condition in women. Over 12 weeks, patients experienced a **5X improvement in sexual pain scores** (FSFI domain increased significantly from 0.40 to 2.32). The treatment demonstrated effectiveness and safety, with no adverse effects reported, suggesting Crescendo as an important therapeutic option for managing GPPPD. (**LINK**)

A Cognitive Behavioral Intervention for Female Sexual Arousal Disorders using Crescendo

Researchers assessed the effectiveness of combining Cognitive Behavioral Therapy (CBT) with the Crescendo device for treating Female Sexual Arousal Disorders (FSAD), aiming to boost sexual arousal and lubrication. After 12 weeks, patients showed a **73% improvement in FSFI Arousal scores and a remarkable 93% improvement in Lubrication scores.** The combination therapy significantly improved both domains with no adverse effects, highlighting Crescendo and CBT as a powerful therapeutic duo. (**LINK**)

Use of Crescendo in the Management of Female Situational Anorgasmia

This prospective case series assessed Crescendo 2's effectiveness for women experiencing situational anorgasmia, characterized by difficulty achieving orgasm during sexual intercourse. Within 6 weeks, participants reported a **2X improvement in orgasmic function (FSFI orgasm scores from 1.62 to 3.47)** and a 90.47% success rate achieving orgasm during intercourse. Crescendo 2 was effective, safe, and also reduced the overall duration and cost of treatment. (**LINK**)

Effects of Focused Mechanical Vibration with Different Frequencies & Intervals on Female Sexual Dysfunctions using Crescendo 2

This study assessed Crescendo II, a flexible vibrating device, for improving sexual function, specifically orgasm, lubrication, and arousal - in women experiencing sexual dysfunction, including difficulties achieving orgasm during intercourse. Patients showed significant improvement in FSFI orgasmic domain scores (**scores increased from 1.62 to**

approximately 3.47 after 6 and 12 weeks) and achieved an impressive coital orgasm success rate of **90.47%.** Additionally, lubrication and arousal significantly improved, emphasizing Crescendo II's safety and effectiveness. (**LINK**)

Studies with LEGATO

Treatment of FSAD using A Pattern of Focused Mechanical Vibration using Legato

Researchers investigated Legato, a device employing focused mechanical vibration (FMV), for women experiencing sexual arousal and lubrication issues. After 8 weeks, women achieved an **83% improvement in FSFI Arousal scores** and a **remarkable 4X improvement in Lubrication**. Legato effectively enhanced arousal and lubrication when used during intercourse, demonstrating substantial clinical promise for managing female sexual dysfunction. (**LINK**)

Studies with MOLTO

Novel Therapeutic Approach for Vaginismus using Molto

This case report explored an innovative therapeutic approach using Molto, a flexible vibratory device, to treat vaginismus, a condition causing severe genital pain during penetration. Over an 8-week protocol, the patient experienced a significant **5X improvement in FSFI pain scores (from 0 to 4.8 on a 0-6 scale),** and comfortably achieved intercourse. This individualized therapeutic approach using Molto provides a promising, accessible alternative to traditional vaginismus treatments. (**LINK**)

Studies with POCO

Focused Mechanical Vibration to Enhance Sexual Arousal in a Female Cancer Survivor using Poco

This study evaluated the effect of a 6-week focused mechanical vibration (FMV) protocol on a 46-year-old breast cancer survivor with FSIAD. The patient used a vibrating device (50 Hz) for 10-15 minutes, 3-5 times per week. The intervention resulted in a significant improvement in overall sexual function, with the **total FSFI score increasing from 12.2 to 22.4**. The most notable gains were seen in the **FSFI domains for Desire (1.2 to 3.6), Arousal (1.5 to 3.6), and Lubrication (1.5 to 3.6)**. The patient reported high satisfaction, no adverse events, and rated her condition as "Much Improved," supporting FMV as a potential non-hormonal therapy for this population. (**LINK**)

Intervention for Female Sexual Interest/Arousal Disorder (FSIAD) using Poco

This study assessed the impact of a combined sexual education program and the Poco wearable stimulation device on 18 premenopausal women with FSIAD. Participants used the Poco device, which delivers focal mechanical vibration (FMV), during intercourse. The intervention resulted in a **significant improvement in the FSFI Lubrication domain and positive trends in the Arousal domain**. No significant changes were noted in the Desire domain, suggesting the intervention effectively addresses arousal-related symptoms, particularly lubrication, but may not impact desire. (**LINK**)

Exploring Intimacy & Empowerment: Impact Of Vibrator Use In Urogynecology

This qualitative study explored the impact of scheduled vibrator use for women with Pelvic Floor Disorders (PFDs) and sexual dysfunction (FSFI < 26.5). Over an 8-week period, 15 participants (mean age 60.3) used Poco at least 3 times per week. Participants reported significant positive experiences, including improved self-confidence, elevated mood, better sleep, and increased relaxation. The study also found **improvements in sexual function, such as improved desire and orgasms , as well as pelvic floor health, including decreased urinary urgency and leakage, and improvement in vaginal dryness and pelvic pain**. The findings suggest that vibrators are a beneficial therapeutic intervention that should be part of patient care options. (**LINK**)

Vibrational Interventions for Sexual and Pelvic Health: A Randomized Controlled Trial

This 8-week randomized controlled trial (RCT) included 81 women with pelvic floor disorders (PFDs) and sexual dysfunction (FSFI < 26.5). Participants were randomized to receive either an educational handout alone or the handout plus a vibrator for scheduled use (3x/week). The **vibrator group showed significantly greater improvement in total**

FSFI scores (22.2 vs. 16.3). Significantly more participants in the **vibrator group achieved normal FSFI scores (>26.5)** compared to the handout-only group **(35% vs. 12.2%)**. The vibrator group also saw significant improvements in FSFI domains for Arousal, Lubrication, Orgasm, Satisfaction, Pain and experienced a reduction in urinary distress. (**LINK**)

Urogynecology Patient Perspectives On Vibrator Use For Sexual Health

This mixed-methods qualitative study explored the beliefs and opinions of urogynecology patients (median age 69) regarding discussions about vibrator use with their healthcare providers. The study identified significant barriers that prevent patients from broaching the topic, including shame, embarrassment, fear of judgment, and perceived provider discomfort. **Patients expressed a strong desire for providers to initiate the conversation and suggested facilitators like pre-appointment screening questions, informational brochures, and framing vibrator use within a health context**. The findings provide key strategies to help normalize and facilitate these crucial conversations in a clinical setting. (**LINK**)

Using Poco as an Adjunct to Vaginal Dilator Therapy in Women with Vaginismus

This was the first study to formally assess the acceptability and feasibility of using vibrators as an adjunct to standard vaginal dilator therapy for women with vaginismus. After the treatment period (a minimum of 6 months), the intervention group showed a **2.4X improvement in FSFI pain scores (1.40 to 3.36)** compared to 1.3X in the control group (1.96 to 2.62). Poco was rated as highly acceptable (90% found them 'mostly' or 'completely' acceptable). The study concluded that patient-controlled vibrator therapy is an acceptable and beneficial addition to the current multi-modal approach for managing vaginismus. (**LINK**)

Men's Health Studies

Numerous clinical trials with **Tenuto 2, Tenuto Mini & Molto** have shown significant improvements in erectile function, ejaculation & prostate health.

Across diverse patient populations such as those with psychogenic ED, post-prostatectomy dysfunction & chronic prostatitis, patients experienced **2X to 2.7X improvements in IIEF-5 scores**, along with notable gains in **sexual satisfaction and partner intimacy.**

Studies with TENUTO 2

Improved erectile function after focal muscle vibrations therapy in a patient with neurogenic erectile dysfunction

This clinical case explored using focal muscle vibrations (FMV) via Tenuto to manage neurogenic Erectile Dysfunction (ED) following colorectal cancer surgery, focusing on reducing muscular spasticity to enhance erectile function. Within just 5 weeks, the patient experienced a **2X improvement in erectile function (IIEF-5 score from 7 to 15).** Results indicated FMV through Tenuto effectively improved erectile function by managing spasticity and improving muscle synergy, suggesting strong therapeutic potential. (**LINK**)

Potential Effectiveness of Focused Vibration Treatment for Psychogenic Erectile Dysfunction

The study examined Tenuto 2, an on-demand focused vibration device, for men with psychogenic Erectile Dysfunction (pED), a condition often challenging to treat with traditional methods. Participants saw an impressive **81% improvement in erectile function over 8 weeks,** demonstrating Tenuto 2's potential as a safe and effective therapeutic alternative for treating psychogenic ED, especially when medications or counseling alone fall short. (**LINK**)

Improvement in Erectile Dysfunction After Radiotherapy for Prostate Cancer Using Focused Muscle Vibration (FMV)

This clinical case evaluated Tenuto 2's effectiveness using focused muscle vibration (FMV) therapy in managing erectile dysfunction following radiotherapy for prostate cancer, particularly for patients who had not responded to standard ED

treatments. Within just 5 weeks, erectile function improved by **2.3X (IIEF-5 score from 6 to 14),** highlighting FMV via Tenuto 2 as an effective second-line therapy for post-radiotherapy ED, offering meaningful clinical improvement where other treatments had failed. (**LINK**)

Penile Rehabilitation using the Tenuto 2 device after Prostatectomy

This research explored the use of Tenuto 2, a wearable vibrating device, for improving erectile function during rehabilitation following radical prostatectomy - a surgical treatment for prostate cancer often resulting in significant erectile dysfunction. After 6 months, participants showed notable recovery, with erectile function scores (IIEF) significantly improving (**from an average of 11 pre-treatment to 19 post-treatment**). Patients preferred Tenuto 2 to traditional rehabilitation methods, reporting enhanced intimacy, ease of use, and partner communication during their recovery period. (**LINK**)

Studies with TENUTO MINI

Clinical Case Demonstrating the Use of Tenuto Mini For Non-Organic Erectile Dysfunction

This case demonstrated the clinical utility of Tenuto Mini, a constriction vibration ring using focused mechanical vibration (FMV), for situational, non-organic erectile dysfunction - especially valuable when traditional couple-based therapies were not applicable. Within 2 months, the patient's erectile function improved by **2.7X (IIEF-5 scores from 6 to 16)**, showcasing Tenuto Mini's ability to effectively manage ED independently, providing a viable therapeutic solution without medications or extensive therapies. (**LINK**)

Safety and Preliminary Outcomes of Tenuto Mini for Psychogenic Erectile Dysfunction

The safety and preliminary effectiveness of Tenuto Mini, a vibrating constriction ring, were evaluated in men with psychogenic Erectile Dysfunction (pED). Patients experienced a substantial **79% improvement in erectile function (IIEF-5 scores increased from 10.95 to 19.56)** after 8 weeks. The device's unique combination of constriction and FMV proved highly effective, especially for patients unable or unwilling to pursue medications or therapy involving a partner. (**LINK**)

Efficacy of Tenuto Mini Device for Psychogenic Erectile Dysfunction

This study evaluated the effectiveness of **Tenuto Mini**, for men diagnosed with **psychogenic erectile dysfunction (pED)**. The study enrolled 30 men (mean age ~39) over an 8-week period. Patients experienced a **significant improvement in erectile function**, with IIEF-5 scores increasing from **14.44 to 22.31** ($p < 0.001$), and reported high treatment satisfaction (mean EDITS score: **78.57%)** with no adverse effects were reported. (**LINK**)

Studies with MOLTO

An IDEAL Stage 1 Study Of Vibration using the Molto Device In Chronic Non-bacterial Prostatitis

This study investigated Molto, a malleable vibrating device designed to manage refractory chronic non-bacterial prostatitis - a condition notoriously challenging to treat due to persistent pain and sexual dysfunction. After 3 months of device use, participants showed substantial pain relief (**pain scores decreased significantly from 7/10 to 3/10**) along with notable improvements in erectile function and sexual satisfaction. Patients found Molto easy to apply, reporting no adverse events, highlighting its promising therapeutic potential. (**LINK**)

Evaluation of Molto for the Management of Delayed Ejaculation and Anejaculation

Researchers evaluated the effectiveness and tolerability of Molto, an anal insert device, in managing delayed ejaculation or anejaculation, conditions with limited and inconsistent treatment options. Nearly half **(45.5%)** of the patients who completed the study successfully resolved their ejaculation issues within an average of 4 weeks of treatment. The device demonstrated good safety, comfort, and tolerability, representing a meaningful advancement in managing these challenging ejaculatory disorders. (**LINK**)

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Prostatic Vibratory Stimulation as a Novel Intervention for Delayed Ejaculation using Molto

This study evaluated the effectiveness of the Molto device, used for prostatic vibratory stimulation (PVS) during intercourse, in 13 men with Delayed Ejaculation (DE). After an 8-week intervention, **ejaculatory success rose from 46.2% (at baseline) to 100%**, and the mean **Intravaginal Ejaculatory Latency Time (IELT) was significantly reduced from 32.3 minutes to 23.2 minutes**. 69% of patients reported their condition as "very much improved" or "much improved". The findings suggest PVS with Molto is a promising intervention for DE, though a partial relapse after device discontinuation indicates a need for maintenance strategies. (**LINK**)

Prostatic Vibratory Stimulation for Refractory Chronic Prostatitis: A Case Report

This study evaluated the effectiveness of the Molto device, used for targeted mechanical prostatic stimulation during sexual activity, in a 44-year-old man with refractory chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS). After a 12-week intervention, the **patient's NIH-CPSI total score improved from 26 (at baseline) to 14, and the pain domain score was significantly reduced from 13 to 7**. The patient reported his condition improved on the Patient Global Impression of Improvement (PGI-I) scale. The findings suggest prostatic vibratory stimulation with the Molto device is a promising, well-tolerated non-pharmacological intervention for CP/CPPS, with no adverse events reported during the treatment period. (**LINK**)

Studies with All Devices

Overview of Sexual Enhancement Tools in Clinical Practice

This comprehensive overview discussed various sexual enhancement devices and their emerging **evidence-based roles in clinical sexual medicine**, aiming to bridge the gap between therapeutic utility and traditional perceptions of such devices. **MV devices including Molto, Tenuto, Crescendo, and Legato**, were highlighted as clinically relevant devices that not only **enhance sexual pleasure** but also provide **measurable medical benefits**. This acknowledgment reinforces the expanding role of such tools within **evidence-based sexual health interventions**. (**LINK**)