

**AVVISO PUBBLICO, PER TITOLI E COLLOQUIO, PER L'ASSUNZIONE A TEMPO DETERMINATO DI N. 1 RISORSA NEL PROFILO DI COLLABORATORE PROFESSIONALE DI RICERCA SANITARIA – CATEGORIA D, DA ASSEGNARE ALLA UOC UROLOGIA DELL'ISTITUTO REGINA ELENA NELL'AMBITO DEL PROGETTO DAL TITOLO “*LOW-INTENSITY EXTRACORPOREAL SHOCKWAVE THERAPY ON PENILE REHABILITATION AFTER ROBOT-ASSISTED SURGICAL TREATMENT OF GENITOURINARY CANCERS*”, AFFERENTE AL SECONDO AVVISO PUBBLICO PNRR, CUP MASTER H53C24000260001, P.I. DR. GIUSEPPE SIMONE**

**Prova Colloquio**

**24 ottobre 2024 alle ore 12:30**

**Prova tecnica**

1. Cosa si intende per disfunzione erettile post-operatoria e a quali interventi è correlata;
2. Cosa sono le onde d'urto extracorporee e quali sono le loro potenziali applicazioni nella disfunzione erettile;



The bottom of the page contains several handwritten signatures and a circular official stamp. The stamp is from the "Ospedali - Istituti Fisioterapici Roma" and is surrounded by multiple handwritten signatures in black ink.

Domanda estratta n. 2

**AVVISO PUBBLICO, PER TITOLI E COLLOQUIO, PER L'ASSUNZIONE A TEMPO DETERMINATO DI N. 1 RISORSA NEL PROFILO DI COLLABORATORE PROFESSIONALE DI RICERCA SANITARIA – CATEGORIA D, DA ASSEGNARE ALLA UOC UROLOGIA DELL'ISTITUTO REGINA ELENA NELL'AMBITO DEL PROGETTO DAL TITOLO “*LOW-INTENSITY EXTRACORPOREAL SHOCKWAVE THERAPY ON PENILE REHABILITATION AFTER ROBOT-ASSISTED SURGICAL TREATMENT OF GENITOURINARY CANCERS*”, AFFERENTE AL SECONDO AVVISO PUBBLICO PNRR, CUP MASTER H53C24000260001, P.I. DR. GIUSEPPE SIMONE**

**Prova Colloquio**

**24 ottobre 2024 alle ore 12:30**

**Prova di informatica**

1. Cos'è Excel
2. Cos'è un database?



The bottom of the page features several handwritten signatures and a circular official stamp. The stamp is from the "Istituti Riuniti Ospedali - ROMA" and contains the text "Fisioterapia". There are five distinct signatures: one at the top right, one to the left of the stamp, one overlapping the stamp, one to the right of the stamp, and one at the bottom right.



# Linear Low-Intensity Extracorporeal Shockwave Therapy as a Method for Penile Rehabilitation in Erectile Dysfunction Patients after Radical Prostatectomy: A Randomized, Single-Blinded, Sham-Controlled Clinical Trial

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## Keywords

Shockwave therapy · Penile rehabilitation · Erectile dysfunction · Radical prostatectomy

## Abstract

**Introduction:** The objective of this study was to investigate the effect and feasibility of linear low-intensity extracorporeal shockwave therapy (LI-LiESWT) as a penile rehabilitation method for erectile dysfunction (ED) after bilateral nerve-sparing (NS) radical prostatectomy (RP). **Methods:** Patients who had undergone bilateral NS RP (either radical retropubic prostatectomy or robot-assisted laparoscopic RP), 3 or more months prior to the study, and who had no ED preoperatively and were suffering from mild to severe postoperative ED were included in the study. Four treatments were given over a 4-week period, using the PiezoWave2 device with a linear shockwave applicator and the linear shockwave

tissue coverage (LSTC-ED<sup>®</sup>) technique. If the improvement in erectile function was still considered insufficient (less than an IIEF-5 score of 22–25) at 2 months after the start of LI-LiESWT, penile rehabilitation was supplemented by pharmacological penile rehabilitation. The final effect of treatment was evaluated after 12 months. The main outcome measure was changes in the five-item International Index of Erectile Function (IIEF-5) score. **Results:** Between September 2019 and September 2020, a total of 40 patients were included in the study and randomly divided into 2 groups: treatment group and sham group. Eight patients were excluded from the study and were not evaluated due to other conditions which required additional treatment (COVID-19 disease, postoperative incontinence, urethral stricture, and ischemic stroke). Thirty-two patients were included in the final analysis: 16 in the control group and 16 in the intervention group. At 6 months from the end of treatment, patients in both the treatment and the sham group achieved physiological IIEF-5



values, and the beneficial effect persisted for 12 months after the end of treatment. **Conclusions:** LI-LIESWT using the LSTC-ED® technique is a suitable and safe method for penile rehabilitation in patients with ED after bilateral NS RP, not only because of the vasculogenic effect of LI-LIESWT but also because of its neuroprotective and/or regenerative effects.

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## Introduction

A number of randomized controlled trials have shown that low-intensity extracorporeal shockwave therapy (LiESWT) can improve erectile function. Nevertheless, the efficacy of LiESWT in patients who develop erectile dysfunction (ED) after radical prostatectomy (RP) remains unclear due to the exclusion of these patients from almost all clinical trials. To date, only a few clinical trials have been carried out which investigate the effect of treatment with LiESWT after radical pelvic surgery. Frey's study stated that LiESWT may improve erectile function after bilateral nerve-sparing (NS) RP, and Zewin's study which included 152 patients after bilateral NS-RCP comes to a conclusion that 16% more patients in the LiESWT group had recovery of potency as compared to the control group [1–3]. Based on the conclusions of these studies, further clinical trials in patients with ED after NS RP are recommended. The standard primary research target in clinical trials of LiESWT focuses on the vasculogenic effect. It has been suggested that, in addition to its vasculogenic effect, LiESWT may also have neuroprotective and/or regenerative effects related to the expression of neuro-pathic factors and the reduction of free radicals. Both of these factors could be beneficial for patients who have had radical pelvic surgery with varying levels of injury to neurovascular bundles (NVBs), which can occur even with NS surgery [4, 5]. Currently, the widespread use of prostate-specific antigen checks has led to younger men being diagnosed with prostate cancer at an earlier stage. These patients are more likely to have longer life expectancies after RP and may suffer more from the loss of their sexual function. Although some of these patients may improve, 20–80% will never recover their preoperative sexual function status. The aim of this study was to investigate the effect of linear low-intensity extracorporeal shockwave therapy (LI-LIESWT) as a method for penile rehabilitation and to evaluate the effect of phosphodiesterase-5 inhibitors (PDE5is) or prostaglandin E1 combined with LI-LIESWT as an additional (or supportive) treatment option.

## Methods

Between September 2019 and September 2020, 40 patients were enrolled in the study and randomly divided into 2 groups: treatment group and sham group. There was no difference in age, surgical techniques used, Gleason score, frequency of vascular comorbidities, testosterone levels, or incontinence between groups ( $6.2 \pm 1.9$  vs.  $5.8 \pm 1.7$ ,  $p = 0.590$ ). Initial IIEF-5 scores for the two groups were  $5.4 \pm 2.1$  versus  $5.9 \pm 2.4$  ( $p = 0.515$ ), which equates to severe ED. Over the course of the study, 8 patients had to be excluded and were not evaluated due to other conditions requiring additional treatment (COVID-19 disease, postoperative incontinence, urethral stricture, and stroke). Thirty-two patients were included in the final analysis: 16 in the control group and 16 in the intervention group.

Inclusion criteria for the study were

- Three to eighteen months post-NS RP (median 7 months)
- Rigidity score  $\leq 2$  during PDE5i therapy
- In a stable heterosexual relationship for more than 6 months
- Patients were informed that the study protocol does not permit any PDE5i treatment until week 12 and consented to this
- No evidence of hypogonadism or other endocrinological diseases such as hyperprolactinemia or hypothyroidism

Exclusion criteria were

- Previous surgery or radiotherapy of the pelvic region
- Penile anatomical abnormalities
- Clinically significant chronic hematological disease
- Anti-androgens, oral or injectable androgens
- Cardiovascular conditions that prevent sexual activity

This was our first experience of administering LI-LIESWT treatment to patients with oncological pelvic disease (prostate cancer). We therefore took the decision to use lower doses (4,000 shocks in one session) when treating patients. In healthy individuals, we usually apply an average of 8,000 shocks during one session. LI-LIESWT was performed using a PiezoWave2 device (RichardWolf/ELvation GmbH). The penis is placed in a dedicated penile holder, stretched, and shockwaves are administered with a linear therapy source (applicator) using the linear shockwave tissue coverage (LSTC-ED®) technique which makes it possible to administer shockwaves homogeneously to all of the erectile tissue. We applied 2,000 shocks with an energy flux density of  $0.16 \text{ mJ/mm}^2$  and a focal shockwave depth of 10 mm at a frequency of 8 Hz to the penile shaft and 2,000 shocks with the same parameters over the crura of the penis. In the placebo group, a special therapy source was used with a gel head that blocked shockwaves. The device produced shockwaves and their accompanying noises; thus, patients could not know whether their treatment was a placebo. Four treatments were given over a 4-week period. Two months after the end of the treatment, selected patients were additionally allowed to take the PDE5i tadalafil 5 mg daily, and after 6 months, they were permitted topical or intracavernous prostaglandin E1. The final treatment outcomes were evaluated after 12 months. The main outcome measure was changes in the five-item International Index of Erectile Function (IIEF-5) scores. Any increase in the IIEF-5 score has been classified as a success as we consider the treatment of severe ED in patients after RP very difficult.

*[Handwritten signatures and a circular stamp reading "Istituto Fisioterapico Ospedale - ROMA - Italia"]*