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REVIEW ARTICLE

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Erectile dysfunction is defined as the inability to achieve and maintain an erection to satisfactorily complete intercourse. Treatment depends on the cause and includes phosphodiesterase 5 inhibitor medications, penile pumps, implants, and surgery. Low-intensity shockwave therapy has been shown to be effective and safe for the treatment of erectile dysfunction.

We explored the role of low-intensity radial shockwave therapy for erectile dysfunction treatment in a dermatology and/or medical aesthetic practice setting.

A literature review was conducted on radial low-intensity shockwave technology in use for erectile rejuvenation to explore its positioning, safety, efficacy, tolerability, subject satisfaction, and usability in a dermatology and/or medical aesthetic setting.

Low-intensity shockwave therapy was shown to be effective in subjects with organic erectile dysfunction, and the treatment effect was maintained for up to 2 years post-treatment. The treatment is reported to be safe and well-tolerated and have little downtime. Many dermatologists use low-intensity shockwave therapy for the treatment of cellulite and other conditions. This type of treatment is now available for erectile dysfunction and seems an attractive and safe option for subjects with organic vascular erectile dysfunction.

Studies and clinical experience suggest that male erectile rejuvenation using low-intensity radial shockwave therapy seems an attractive option. The treatment can be safely, and effectively, delivered by trained staff as part of the total package that is available to men in a dermatology and/or medical aesthetic practice.

erectile dysfunction, low-intensity shock wave therapy, medical aesthetic practice

Erectile dysfunction (ED) comprises the persistent inability to attain or maintain an erection that is sufficient for satisfactory sexual intercourse.[1-3] The condition affects men mainly over 40 years of age but may also occur in younger men.[1-3] Initial ED treatment recommendations include education, counseling, and lifestyle changes, such as minimizing risk factors, healthy diet, and cardiovascular exercise. For symptomatic treatment of ED, pharmacological therapies have been recommended such as phosphodiesterase 5 inhibitors (PDE5Is); intracavernous, topical, or intraurethral vasodilators; and nonpharmacological treatments such as the use of vacuum pumps.[1]

Low-intensity shockwave therapy (LI-SWT) has been recommended for ED treatment as it has been shown to be a safe and effective alternative

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for those that do not benefit from pharmacological therapies, do not want to take them, or have contraindications to these medications.[1,4] LI-SWT has been included in guidelines for ED treatment as a first-line option that can be applied on its own or in combination with other treatments.[1,4] The objective of this review was to examine the role of LI-SWT for ED treatment in a dermatology and/or medical aesthetic practice.

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The target group included healthcare professionals and physicians involved in dermatology, aesthetic medicine, and male erectile rejuvenation treatment. To explore the role of LI-SWT for ED treatment in a dermatology and/or medical aesthetic practice, a literature review was conducted exploring the current status on male erectile rejuvenation using these energy-based devices. The review addressed the following clinical questions on the application of LI-SWT use in a dermatology and/or medical aesthetic practice:

- Clinical positioning of the treatment, what is the ideal subject profile?
- Clinical efficacy, optimal dose, frequency of application, and need for maintenance treatment.
- Safety of the procedure, contraindications to implementation, risks/benefits, and adverse events when applying these treatments.
- Subject comfort and postprocedure impact, such as downtime, when applying LI-SWT.
- Subject satisfaction, and tools to manage subject expectations when implementing LI-SWT in a dermatology and/or medical aesthetic practice.
- Combination therapy, combining LI-SWT with other methods such as vacuum, injectable and oral medications.

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Explorative literature searches took place on PubMed, MEDLINE, EMBASE, CINAHL, and the Cochrane Library databases. The literature searches included in vitro, in vivo, animal studies and clinical studies as well as review articles and were prospectively limited to publications in English. Publication dates were between January 2010 and September 2018. Medical subject headings terms used in various combinations were as follows: erectile dysfunction, diagnosis, treatment, and classification; extracorporeal shock wave therapy; radial low-intensity shockwave therapy; low-intensity shockwave therapy; and low-intensity shockwave therapy in a dermatology and/or medical aesthetic practice.

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Erectile dysfunction is defined as the persistent inability to attain and maintain an erection sufficient for satisfactory sexual performance.[1] The risk of sexual dysfunction increases with diabetes, cardiovascular disease, dyslipidemia, hypertension, aging and smoking.[1] The condition is estimated to affect one in every five men with 57% reported to be 40-60 years old; however, young men are also affected.[2] ED prevalence is on the increase due to the aging male population and an increase in comorbid conditions.[1] Those suffering from ED may have concerns about body composition, cognition, and lack of sexual energy significantly impacting quality of life and that of partners.[3] Men frequently underreport their signs and symptoms, hesitant to discuss sexual health with their physician. [1]

Most cases of ED are of mixed etiology. Organic etiologies of ED include vasculogenic, neurogenic, psychogenic (such as performance anxiety and depression), endocrine (for instance low testosterone levels), anatomic (such as birth defect, trauma, and Peyronie's disease), or Iatrogenic (such as the use of beta blockers and selective serotonin reuptake inhibitors). Diagnostic evaluation should include a comprehensive medical and sexual history, preferably using a validated questionnaire on ED, physical examination, and laboratory tests (including glucose-lipid profile and total testosterone).[1]

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Treatment of ED includes the identification of curable causes, education and counseling to sufferers and partners, Lifestyle changes, and risk factor modification.[1] Conservative treatments such as phosphodiesterase type 5 inhibitors (PDE5is) continue to be the mainstay treatment but are associated with some side effects. In addition, a significant proportion of men do not respond to therapy.[4] Other treatment options are medicated urethral suppositories for erection, intracorporal injections, and penile prostheses.[1] Long-term usage rates of therapy are hindered as these treatments attempt to improve erectile function without treating the underlying pathophysiology.

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The use of low-intensity shockwave therapy (LI-SWT) may offer benefits for the treatment of ED, such as improving cavernous penile blood flow.[5-12] Although the mechanism of action of LI-SWT is not fully understood, animal studies using LI-SWT have shown that the shear stress exerted during treatment induced the release of angiogenic factors resulting in revascularization.[12,13] Further mechanisms of action of LI-SWT shown in animal studies are regeneration of microvasculature and improvement of penile hemodynamics.[12,13]

There are now reports of LI-SWT using various types of energy (electrohydraulic, electromagnetic, or piezoelectric), several protocols and devices have been described, and encouraging results have been reported.[4-11]

A meta-analysis[11] including seven randomized controlled trials[1,4,9,14-17] using LI-SWT compared with sham for the treatment of 602 subjects with vasculogenic ED showed a statistically significant improvement in erectile function for the LI-SWT-treated subjects

compared with sham at 6-week follow-up, maintained up to 1 year. The included subjects received identical treatments with LI-SWT (twice weekly for 3 weeks; once weekly for 3 weeks; and three more weeks of twice-weekly treatments; Table 1). Kitrey and colleagues[18] conducted a 2-year study to evaluate long-term efficacy of LI-SWT using the International Index of Erectile Function-Erectile Function (IIEF-EF) questionnaire.[19] The 15-question scoring tool examined four domains (erectile function, orgasmic function, sexual desire, and intercourse satisfaction) which are scored on a 6-point scale (0 = no, 6 = almost always or always).[19] The authors concluded that treatment efficacy was maintained after 2 years in 50% of the subjects and that LI-SWT seems to be more beneficial for the less severe forms of ED.[18]

A specific type of treatment of radial low-intensity shockwave therapy (RSWT) has generated recent interest. The device creates radial pulses by using a projectile 5× heavier than standard air compressor systems and a reduced final velocity upon contact with the applicator (Figure 1). Though the force of the accelerator and the mass of the projectile are efficient down to the required depth, they may be more comfortable during treatment than comparable systems, while maintaining a longer pulse rise time. The lower peak and longer rise time minimize the stinging and painful sensation that is normally associated with this type of therapy.

The clinical questions and result of the literature review on the application of LI-SWT in a dermatology and/or medical aesthetic practice are summarized in Table 2.

For symptomatic management of ED, the use of pharmacological therapies has been recommended, such as PDE5Is; intracavernous, topical, or intraurethral vasodilators; and nonpharmacological treatments such as the use of vacuum pumps.[1] These treatments have been proven to be safe and effective, but do not alter the pathophysiology of ED.[1,20] LI-SWT is used for its angiogenetic properties in various types of conditions including chronic wounds, peripheral neuropathy, cardiac neovascularization, reduction in edema, and cellulite.[21] Clinicians working in a dermatology and/or medical aesthetic practice may already be familiar with LI-SWT for strengthening of connective tissue, improving elasticity and firmness of the skin.[21] LI-SWT applied for ED is aimed to modify the underlying pathological process that causes ED and may include regenerative elements, for example, neovascularization of cavernous tissue and improved endothelial function.[10-13]

Currently, subjects with ED may consult their general practitioner, urologist, or specialized male sexual health clinic. For those subjects with ED seeking LI-SWT treatment, a dermatology and/or

TABLE 1 Effects of LI-SWT from seven randomized controlled trials

Hatzichristou and Kalyvianakis, 2015[1]	6	56	30	16	13.8	14.6	5.3	1.4
Yee et al, 2014[4]	6	13	30	28	10.2	10.2	7.6	5.6
Vardi et al, 2012[9]	6	13	40	20	12.6	11.5	6.7	3.0
Kitrey et al, 2016[14]	6	13	37	16	7.0	8.0	6.0	0.5
Feldman et al, 2015[15]	6	13	84	40	–	–	6.1	2.5
Fojecki and Osther, 2015[16]	10	18	63	63	10.9	11.5	0.6	1.5
Sirini et al, 2015[17]	6	13	95	40	9.5	9.2	12.5	1.4

Note: Adapted from Clavijo RI, et al[11] All seven studies used an energy flux density of 0.09 mJ/mm^2. The 15-question scoring tool examines four domains (erectile function, orgasmic function, sexual desire, and intercourse satisfaction) which are scored on a 6-point scale (0 = no, 6 = almost always or always).[19]

Abbreviation: IIEF-EF, International Index of Erectile Function-Erectile Function; Tx, treatment with LI-SWT.



FIGURE 1 Radial low-intensity shockwave therapy device. A, applicator. B, cut across of the applicator. C, the device generates radial pulses by using a projectile 5× heavier than standard air compressor systems and a reduced final velocity upon contact with the applicator

TABLE 2 Clinical questions and results of the literature review on the application of LI-SWT in a dermatology and/or medical aesthetic practice

Clinical positioning of the treatment, what is the ideal subject profile.	LI-SWT seems to be more beneficial for the less severe forms of ED.[18]
Clinical efficacy, optimal dose, frequency of application, and need for maintenance treatment.	LI-SWT twice weekly for 3 wk; once weekly for 3 wk; and three more weeks of twice-weekly treatments.[1,4,9,14-17] Efficacy of LI-SWT was maintained after 2 y.[18]
Safety of the procedure, contraindications to implementation, risks/benefits, and adverse events when applying these treatments.	Randomized controlled trials have shown LI-SWT to be safe and effective compared with sham at 6-weeks follow-up, maintained up to 1 y.[1,4,9,14-18]
Subject comfort and postprocedure impact, such as downtime, when applying LI-SWT.	LI-SWT seems to cause little discomfort, however RSWT may be more comfortable during treatment than comparable systems, while maintaining a longer pulse rise time.
Subject satisfaction, and tools to manage subject expectations when implementing LI-SWT in a dermatology and/or medical aesthetic practice.	Education of staff on pathology, diagnosis, and treatment using LI-SWT is mandatory. No data available yet of LI-SWT use in a dermatology and/or medical aesthetic practice.
Combination therapy, combining LI-SWT with other methods such as vacuum, injectable and oral medications.	No data available yet.

Abbreviations: LI-SWT, Low-intensity shockwave therapy; RSWT, Radial low-intensity shockwave Therapy.

medical aesthetic practice setting may offer a low threshold access to therapy. LI-SWT for male erectile rejuvenation can be safely and effectively delivered by trained staff as part of the total package that is available to men in a dermatology and/or medical aesthetic practice.

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As this is an evolving field, studies conducted on LI-SWT delivering treatment in a dermatology and/or medical aesthetic practice have not yet been performed. The studies discussed in this manuscript were conducted by urologists or physicians practicing in specialized male sexual health clinics. Education of staff on pathology, diagnosis, and treatment using LI-SWT for male erectile rejuvenation is necessary to ensure optimal outcomes.

The use of LI-SWT has been shown to offer benefits for the treatment of male erectile rejuvenation, particularly for the less severe forms of ED.

The device is suggested to improve cavernous penile blood flow by stimulating the release of angiogenic factors resulting in revascularization.

Low-intensity shockwave therapy for male erectile rejuvenation can be safely and effectively delivered by trained staff in a dermatology and/or medical aesthetic practice, thereby reducing hurdles men may experience for access to the treatment.

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