

Renova & MorenovaMen Clinical Synopsis

A Compendium of Research Articles and Conference Posters
on the Integration of LISWT into Men's Health

MORENOVA
Men



Table of Contents

Learn from Leading Practitioners	4
MorenovaMen at a Glance.....	5
Clinical Indications for Utilizing MorenovaMen	5
Scientific Evidence	7
Clinical Evaluation of Erectile Dysfunction Treatment Using Low-Intensity Shock Wave Therapy MORENOVA®	7
Effect of Low-Dose PDE5i and Low-Energy Shock Wave on Acute Phase of Peyronie's Disease	7
A Systematic Review of the Long-Term Efficacy of Low-Intensity Shockwave Therapy for Vasculogenic Erectile Dysfunction	8
Effect of Low-Dose PDE5i and Low-Energy Shock Wave on Acute Phase of Peyronie's Disease	9
A Phase 2 Randomized Trial To Evaluate Different Dose Regimens of Low-intensity Extracorporeal Shockwave Therapy for Erectile Dysfunction: Clinical Trial Update	9
Doppler Test in Penis Flaccid State to Asses Erectile Dysfunction Severity and Shockwave Treatment Outcomes	10
Twelve-Month Efficacy and Safety of Low-Intensity Shockwave Therapy for Erectile Dysfunction in Patients Who Do Not Respond to Phosphodiesterase Type 5 Inhibitors	10
Low-intensity Extracorporeal Shock Wave Treatment Improves Erectile Function: A Systematic Review and Meta-analys.....	11
Safety and Efficacy of Low Intensity Shockwave (LISW) Treatment in Patients with Erectile Dysfunction.....	11
Linear Shock Wave Therapy in the Treatment of Erectile Dysfunction.....	12
Long Term Efficacy of Low Intensity Linear Focused Shockwave Therapy for Vascular Erectile Dysfunction Patients: 20 months follow-up	12
Effectiveness of Low -Intensity Extracorporeal Shock Wave Therapy on Patients with Erectile Dysfunction (ED) Who Have Failed to Respond to PDE5i Therapy. A Pilot Study	13

Initial Experience with Linear Focused Shockwave Treatment for Erectile Dysfunction: a 6-Months Follow-Up Pilot Study	13
Safety and Efficient Duration of Linear Focused Shockwave Treatment for Erectile Dysfunction – a 12 months Follow-Up Pilot Study	14
Initial Clinical Experience of Linear Focused, Low Intensity Shockwave for Treatment of ED Patients with Different Severity	14
Low Intensity Linear Focused Shockwave Therapy: a New Treatment to Improve the Quality of Life of Vascular Erectile Dysfunction Patients	15
The Effect of Low Intensity Shockwave Therapy on the Erectile Function of Smokers and Non-Smokers – Initial Report with a Dedicated System.....	15
Linear Low Intensity Shockwaves Treatment of Vasculogenic ED – First Results.....	16
Low Intensity Shock Wave (LISW) Treatment (Renova) In Order to Improve Male Sexual Function: a Preliminary Data on 42 Patients	16
Efficacy and Safety of Linear Focused Shockwaves for Erectile Dysfunction (RENOVA) – A Second Generation Technology.....	17
Efficacy and Safety of Linear Focused Shockwaves for Erectile Dysfunction (RENOVA) – a Second Generation Technology	17
Line Focused Shock Wave for Erectile Dysfunction – a Different Technological Approach	18
Molecular Mechanism of Action	19

Learn from Leading Practitioners

This compendium lists selected publication references, synthesizing the knowledge and experiences from leading practitioners, and documenting a range of applications and models for implementing Renova and MorenovaMen in routine practice.

- ◆ We hold ourselves to a high standard when it comes to accumulating clinical evidence
- ◆ We are committed to extending research opportunities to medical professionals worldwide
- ◆ We strive to engage the professional community to explore existing guidelines in order to reach knowledge-based consensus recommendation for change, while recognizing the valued relationship between urologists and industry

To learn more about how MorenovaMen can benefit you and your patients, please contact us at:



<https://direxgroup.com>



info@direxgroup.com

MorenovaMen at a Glance

MorenovaFem is a new-generation shockwave-based non-surgical penile treatment aimed at restoring penile form and function for men of any age

Application made easy

Built on the success of Renova, an optimized version was introduced to clinical practice. MorenovaMen is the next step in shockwave evolution from linear to 'large-area' shockwaves, and a true upgrade in many ways. Displaying comparable excellent clinical outcomes to its predecessor, the reconfigured model has been enhanced in design, translating into significant procedural and operative improvements, including:

- ◆ New patented Large-Area Shockwave Technology (LAST) and dual-probe energy delivery, for efficient tissue coverage of a larger surface area in less time
- ◆ Modular arm-positioning mechanism – once locked in place, no manual holding required
- ◆ Soft-locking of penile shaft for accurate positioning and stable energy coupling
- ◆ Smaller and lighter table-top housing for easy man-portable deployment



Clinical Indications for Utilizing MorenovaMen

Indications in Urology

- ◆ Erectile Dysfunction (ED)
- ◆ Peyronie's Disease (PD)
- ◆ Chronic Pelvic Pain Syndrome (CPPS)

Future treatment indications

- ◆ Benign Prostatic Hyperplasia (BPH)
- ◆ Overactive bladder (OAB)

Clinical benefits

- ◆ Low- to zero-risk, no heating, no ablation, no side effects
- ◆ High safety and efficacy across various indications/ages
- ◆ Clinically validated regenerative effect
- ◆ Non-surgical, non-pharmacological
- ◆ Multiple men's health indications
- ◆ Improved patient compliance
- ◆ Low interoperator variability
- ◆ Durable results

Features and highlights

- ◆ Proprietary Large-Area Shockwave Technology (LAST) electromagnetic technology
- ◆ Optimal comfort: outpatient setting, anesthetic-free, quick and painless
- ◆ Time efficient: no preparations, no downtime, no recovery time
- ◆ Fits in standard workflow, requires no additional equipment
- ◆ Noticeable results directly after the first few sessions
- ◆ Exclusive hands-free application
- ◆ Straight-forward procedure

Scientific Evidence



22

The 111th Annual Meeting of the Japanese Urological Association

APRIL 2024

Clinical Evaluation of Erectile Dysfunction Treatment Using Low-Intensity Shock Wave Therapy MORENOVA®

Jun Kato, Hajime Nakano, Akira Tsujimura

Conclusions: MORENOVA® shows promise as a new option in the treatment of erectile dysfunction (ED). It may offer an alternative for patients who experience a reduction in efficacy with ED medications, as well as for those who cannot continue ED medication due to side effects or contraindications. Long-term clinical trials and comparative studies with other ED treatment methods are crucial and are expected to clarify MORENOVA®'s positioning in the treatment of ED.



21

Sex Med, 17(1):s118-s119

JAN 2020

The Journal of Sexual Medicine

Effect of Low-Dose PDE5i and Low-Energy Shock Wave on Acute Phase of Peyronie's Disease

Lu M

Conclusions: Both the low-dose PDE5i and low-energy shock waves can improve the symptoms of acute PD patients, mainly to relieve pain and improve erectile function in some patients. However, the above two methods did not significantly reduce PD plaque size and penile curvature. Both methods have good safety in the treatment of acute phase PD.

A Systematic Review of the Long-Term Efficacy of Low-Intensity Shockwave Therapy for Vasculogenic Erectile Dysfunction

Brunckhorst O, Wells L, Teeling F, Muir G, Muneer A, Ahmed K

Conclusions: LISWT may be a safe and acceptable potential ED treatment with demonstrated benefits at 6 months. There is some question regarding efficacy deterioration beyond this, but there is still a demonstrated benefit seen even at 12 months post treatment. However, quality of evidence remains low with larger multiinstitutional studies required, standardising confounders such as shockwave administration and oral medication use.

Effect of Low-Dose PDE5i and Low-Energy Shock Wave on Acute Phase of Peyronie's Disease

Lu M

Conclusions: Both the low-dose PDE5i and low-energy shock waves can improve the symptoms of acute PD patients, mainly to relieve pain and improve erectile function in some patients. However, the above two methods did not significantly reduce PD plaque size and penile curvature. Both methods have good safety in the treatment of acute phase PD.

A Phase 2 Randomized Trial To Evaluate Different Dose Regimens of Low-intensity Extracorporeal Shockwave Therapy for Erectile Dysfunction: Clinical Trial Update

Katz JE, Molina ML, Clavijo R, Prakash NS, Ramasamy R

Conclusions: Preliminary results from our study provide further evidence that low-intensity extracorporeal shockwave therapy is a safe and effective treatment modality for erectile dysfunction. Our treatment protocol with shockwaves given to men over 2 wk had the most robust effect.



17

World Meeting on Sexual Medicine

LISBON, MAR 2018

International Society of Sexual Medicine (ISSM) & European Society of Sexual Medicine (ESSM)

Doppler Test in Penis Flaccid State to Assess Erectile Dysfunction Severity and Shockwave Treatment Outcomes

Gatkin M, Sopotov A

Conclusions: Our experience shows the potential of using DPS and RI in flaccid penis for diagnosis and treatment assessment of results of LIST with Renova. This is an initial Pilot and additional studies have to be performed to assess the potential of this method.

THE JOURNAL OF
SEXUAL
MEDICINE

16

Sex Med, 4(4):e225-e232

DEC 2016

The Journal of Sexual Medicine

Twelve-Month Efficacy and Safety of Low-Intensity Shockwave Therapy for Erectile Dysfunction in Patients Who Do Not Respond to Phosphodiesterase Type 5 Inhibitors

Bechara A, Casabé A, De Bonis W, Cicilia PG

Conclusions: Extracorporeal LISWT in patients with ED unresponsive to PDE5i treatment was effective and safe in 60% of patients. The efficacy response was maintained for 12 months in most patients. Large-scale, multicentric, long-term, randomized, sham- controlled studies are needed to determine the benefits of this new line of treatment for ED.

Low-intensity Extracorporeal Shock Wave Treatment Improves Erectile Function: A Systematic Review and Meta-analysis

Lu Z, Lin G, Reed-Maldonado A, Wang C, Lee YC, Lue TF

Conclusions: In recent years, LI-ESWT as a therapy for ED has attracted extensive attention. Studies of this topic have increased sharply, and most of these studies reveal encouraging results, such as improved IIEF and EHS and an effect that lasts up to 3 mo. The setup parameters and the treatment protocols are important for the therapeutic effects of LI-ESWT for patients with ED. The mechanism of LI-ESWT is to improve or even reverse the pathologic damage of tissue that causes ED. Additional studies are needed to explore the influences of age and comorbidities on response to LI-ESWT and to define the effects of LI-ESWT in combination with PDE5-Is. From our review, it is clear that LI-ESWT may have the potential to be the first-choice noninvasive treatment for patients with ED.

Safety and Efficacy of Low Intensity Shockwave (LISW) Treatment in Patients with Erectile Dysfunction

Ruffo A, Capece M, Prezioso D, Romeo G, Illiano E, Romis L, Di Lauro G, Iacono F

Conclusions: LISW has a well- documented positive clinical and physiological effect on erectile function. The preliminary data at 1 and 3 months follow- up are very encouraging and indicate a therapeutic success of this second generation technology for treating ED with linear low- intensity shockwaves. We also noticed that this treatment is feasible and easy to administer and with no side effects reported. Clearly, we cannot assure the long- term efficacy of LISW, so further studies are needed in order to strengthen these results and to assess whether is possible to repeat cyclically the treatment.

Linear Shock Wave Therapy in the Treatment of Erectile Dysfunction

Pelayo-Nieto M, Linden-Castro E, Alias-Melgar A, Espinosa-Pérez Grovas D, Carreño-de la Rosa F, Bertrand-Noriega F, Cortez-Betancourt R

Conclusions: Our short term results are encouraging, but they demand a long-term evaluation. Based on our results, LSWT can be effective and safe for the treatment of vasculogenic ED. The feasibility and tolerability of this treatment make it an attractive new treatment option for patients with vasculogenic ED.

Long Term Efficacy of Low Intensity Linear Focused Shockwave Therapy for Vascular Erectile Dysfunction Patients: 20 months follow-up

Casarico A, Puppo P

Conclusions: A growing number of men develop vascular erectile dysfunction because of multiple comorbidities such as diabetes, hypertension, heart disease, dyslipidemia or smoke. PDE5i, alprostadil injections, vacuum constriction devices and surgical treatment are symptomatic therapies and do not help patients to achieve spontaneous erections. Moreover medications are contraindicated in some conditions and may have side effects. LISWT, is a promising, minimally invasive therapy without side-effects that induce the release of endothelial nitric oxide synthase, vascular endothelial growth factors and proliferating cell nuclear antigen and thus enhance neovascularization of the penis. The long-term follow up shows that the vast majority of patients who achieved a positive result from treatment with 20000 low intensity linear shock waves, delivered in 4 weekly sessions, continues to maintain the advantage gained after 19.8 months. The effect of treatment wanes gradually only in 21.4% of the patients. There is a need for further research to determine if modifications in the treatment protocol (number and intensity) of low-intensity linear focused shockwave could make the positive effect last longer and if an additional treatment could be useful for patients who did not have or lost a successful result from the treatment.

Effectiveness of Low -Intensity Extracorporeal Shock Wave Therapy on Patients with Erectile Dysfunction (ED) Who Have Failed to Respond to PDE5i Therapy. A Pilot Study

Bechara A, Casabé A, De Bonis W, Nazar J

Conclusions: According to our results, low-intensity extracorporeal shock wave therapy for patients with ED and vascular risk associated who are poor PDE5i responders, was safe and effective. This approach will thus enable the optimization and restoration of PDE5i response in more than 50% of patients. A large-scale multicentric study is required to determine the benefits of this new line of treatment for ED.

Initial Experience with Linear Focused Shockwave Treatment for Erectile Dysfunction: a 6-Months Follow-Up Pilot Study

Reisman Y, Hind A, Varaneckas A, Motil I

Conclusions: The initial results of this pilot study suggest positive outcome of this second generation technology for treating ED with linear low-intensity shockwaves. This study with 6 months follow-up from almost 60 patients is suggestive of a positive therapeutic efficiency in the majority of the patients. Pain is tolerated by 100% of the treated patients and no side effects have been recorded, demonstrating the potential of this technology, as a treatment option for men who are not satisfied by the currently available solutions.



9

16th World Meeting on Sexual Medicine

São Paulo, OCT 2014

International Society for Sexual Medicine (ISSM) & Latin American Society for Sexual Medicine (SLAMS)

Safety and Efficient Duration of Linear Focused Shockwave Treatment for Erectile Dysfunction – a 12 months Follow-Up Pilot Study

Reisman Y

Conclusions: With a success rate of 90% after 6 months, and an 83.3% sustainable positive effect after 1 year, the results of this pilot study suggest that this treatment is probably effective for at least 1 year. No anaesthesia or analgesia was needed, and no adverse effects were recorded, making it a potential good alternative for current available treatments.



8

16th World Meeting on Sexual Medicine

São Paulo, OCT 2014

International Society for Sexual Medicine (ISSM) & Latin American Society for Sexual Medicine (SLAMS)

Initial Clinical Experience of Linear Focused, Low Intensity Shockwave for Treatment of ED Patients with Different Severity Symptoms

Cruz N, Morales A

Conclusions: The results of both series at 3 months show a consistent and global improvement in IIEF-EF, SEP 2 and SEP 3 parameters. Since the baseline symptoms severity of patients in series B was much higher compared to series A, the end results obtained in series B are consistently lower compared to series A. This would imply that the outcome of the treatment is related to the baseline symptoms severity, meaning that in average, patients with more severe ED symptoms will improve, but will not reach the final level of improvement that can be obtained by mild to moderate patients. In our experience the Linear-Focused Low Intensity Shockwave treatment is a valid alternative or complement to current available treatments.



7

21st National Congress of the Italian Urological Association
Italian Urological Association (AURO.it)

ROME, JUN 2014

Low Intensity Linear Focused Shockwave Therapy: a New Treatment to Improve the Quality of Life of Vascular Erectile Dysfunction Patients

Puppo P, Casarico A

Conclusions: This pilot study was designed for assessing the efficacy of a novel device dedicated for the treatment of erectile dysfunction and based on an original technology that enables the delivery of low-intensity shockwaves onto a long focal area. The subjects in this study included also patients with multiple co-morbidities, different degrees of response to PDE5 inhibitors and wide range of ED severities. The results of this study demonstrate a possible alternative treatment for some of the patients who did not respond to first-line oral pharmacotherapy and thanks to this treatment may avoid turning to other therapy options which are less convenient to use. In parallel, these data imply on a potential mean to eliminate the need for PDE5 inhibitors which may significantly improve patients' quality of life. In order to establish the overall effect of this treatment on the quality of life of ED patients, a larger study with longer follow-up duration is required.



6

30th Italian Society of Andrology Congress
Italian Society of Andrology (SIA)

MARATEA, MAY 2014

The Effect of Low Intensity Shockwave Therapy on the Erectile Function of Smokers and Non-Smokers – Initial Report with a Dedicated System

Puppo P, Casarico A

Conclusions: This pilot study shows that eventually this new treatment for vascular ED could be suitable to smoking patients and patients with vascular risk factors. More research is required for confirming the efficacy of this treatment on different populations.



5

102nd Annual Meeting of the Japanese Urological Association
Japanese Urological Association (JUA)

KOBE, APR 2014

Linear Low Intensity Shockwaves Treatment of Vasculogenic ED – First Results

Motil I, Šramkova T

Conclusions: We have been able to prove that Linear SWT is an effective therapeutic option for men with erectile dysfunction of vasculogenic origin. Moreover the efficacy of linear application of low-intensity extracorporeal shock waves is superior to former non-linear methods.



16th CONGRESS OF THE EUROPEAN
SOCIETY FOR SEXUAL MEDICINE
joint by the 12th Congress of the
European Federation of Sexology
29 January – 1 February 2014 | Istanbul, Turkey

4

16th Congress of the European Society for Sexual Medicine
European Society for Sexual Medicine (ESSM) & European Federation of Sexology (EFS)

ISTANBUL, FEB 2014

Low Intensity Shock Wave (LISW) Treatment (Renova) In Order to Improve Male Sexual Function: a Preliminary Data on 42 Patients

Iacono F, Ruffo A, Prezioso D, Romeo G, Illiano E, Romis L, Di Lauro G

Conclusions: (LI) ESWT improves male sexual function inducing neovascularization in the treated tissues by stimulating the expression of angiogenesis-related growth factors, such as endothelial nitric oxide synthase, vascular endothelial growth factor, and endothelial cell proliferation factors, such as proliferating cell nuclear antigen. This therapy shows a statistically significant clinical improvement of erectile function without any side effect or contraindication. In our opinion further studies are needed even to assess the possibility to repeat the treatment cyclically or in association with PDE5-i or with nutraceutical composite.



2ND BIENNIAL MEETING OF THE
MIDDLE EAST SOCIETY FOR SEXUAL MEDICINE
31 October - 2 November 2013 - Park Hyatt Hotel - Dubai, UAE

3

2nd Biennial Meeting of the Middle East Society for Sexual Medicine

DUBAI, NOV 2013

Middle East Society for Sexual Medicine (MESSM)

Efficacy and Safety of Linear Focused Shockwaves for Erectile Dysfunction (RENOVA) – A Second Generation Technology

Reisman Y, Hind A, Varaneckas A, Motil I

Conclusions: The results of this study indicate success of the second generation technology for treating ED with linear low-intensity shockwaves. Initial follow up data from almost 60 patients demonstrate a clear therapeutic success in 82% of patients.



2

12th Congress of Latin American Society for Sexual Medicine

CANCUN, AUG 2013

Latin American Society for Sexual Medicine (SLAMS)

Efficacy and Safety of Linear Focused Shockwaves for Erectile Dysfunction (RENOVA) – a Second Generation Technology

Y. Reisman, A. Hind, A. Varaneckas, I. Motil

Conclusions: The results of this study indicate success of the second generation technology for treating ED with linear low-intensity shockwaves. Initial follow up data demonstrate a therapeutic success in almost 80% of patients. No side effects have been recorded, demonstrating the suitability of this treatment in an office setting.

Line Focused Shock Wave for Erectile Dysfunction – a Different Technological Approach

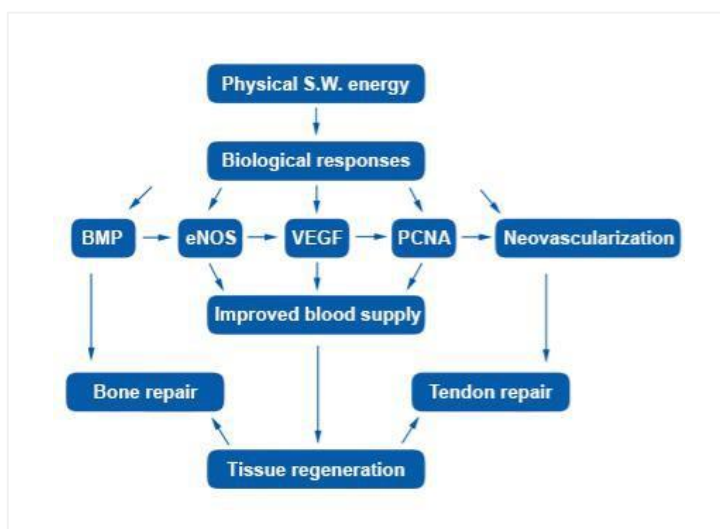
Hind A, Saleh O, Abu Asbeh Y

Conclusions: Initial results at 1 and 3 months show great progress in erectile function. Average IIEF-EF increased from 13.25 to 20.92 (57.86 % improvement). 84% Success according to success criteria. All mild to moderate cases have succeeded. One severe case has improved while 2 severe cases failed. SEP and GAQ results have improved. No pain and no complications were reported.

Molecular Mechanism of Action

Shockwaves are characterized by jump change in pressure, high energy peak, high amplitude and non-periodicity. The energy is transferred to the transmitter at the end of the applicator and further into the tissue.

Our bodies have a remarkable capacity to heal themselves. Low Intensity Shockwave Therapy (LISWT) augments the body's natural cellular repair mechanisms, using acoustic pressure waves which carry low-intensity energy to tissues. The cascade of biological actions that follows LISWT leads to accelerated tissue regeneration and cell growth, and is able to restore, improve, and even normalize tissue form and function.



Wang CJ, Wang FS, Yang KD,
Biological mechanism of musculoskeletal shockwaves
ISMST Newsletter 2006, 1 (I), 5-11

During and after treatment, LISWT delivers pulse waves to the vagina and pelvic region, stimulating the following regenerative and reparative processes simultaneously:

◆ Angiogenesis & Neovascularization

Nutrient blood supply and tissue oxygenation are vital to initiate and maintain the healing processes of damaged tissue structures. By causing capillary microruptures in the tissue, LISWT stimulates the recruitment of platelets and the subsequent increased expression of growth factors, which in turn activate the propagation and formation of new blood vessels.

◆ Decalcification of Plaques & Arterial Remodelling

Vascular and fibrocellular tissue calcification commonly result from repetitive stress, microtrauma and aging. Calcium build-up can lead to histologic and structural changes, reduce tissue elasticity and impact vessel hemodynamics. LISWT-induced shear stress breaks up fibrosis and existing calcifications, leading to fragmentation of calcium deposits into granular particles, which are then removed by the lymphatic system.

◆ Stimulation of Collagen Production & Restructuring

Collagen plays an important role in maintaining the integrity of myoskeletal and ligamentous structures. LISWT accelerates collagen synthesis and deposition, forming denser and stiffer fibers, and creating a firmer structure.

◆ Reversal of Chronic Inflammation

Mast cells are the foundation of inflammatory response, wound healing and defence against pathogens. LISWT increases Mast cell activation, followed by the production of chemokines and cytokines. Initially enhancing the inflammatory process, these pro-inflammatory compounds ultimately allow for halting of chronic inflammation conditions and associated pain.

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