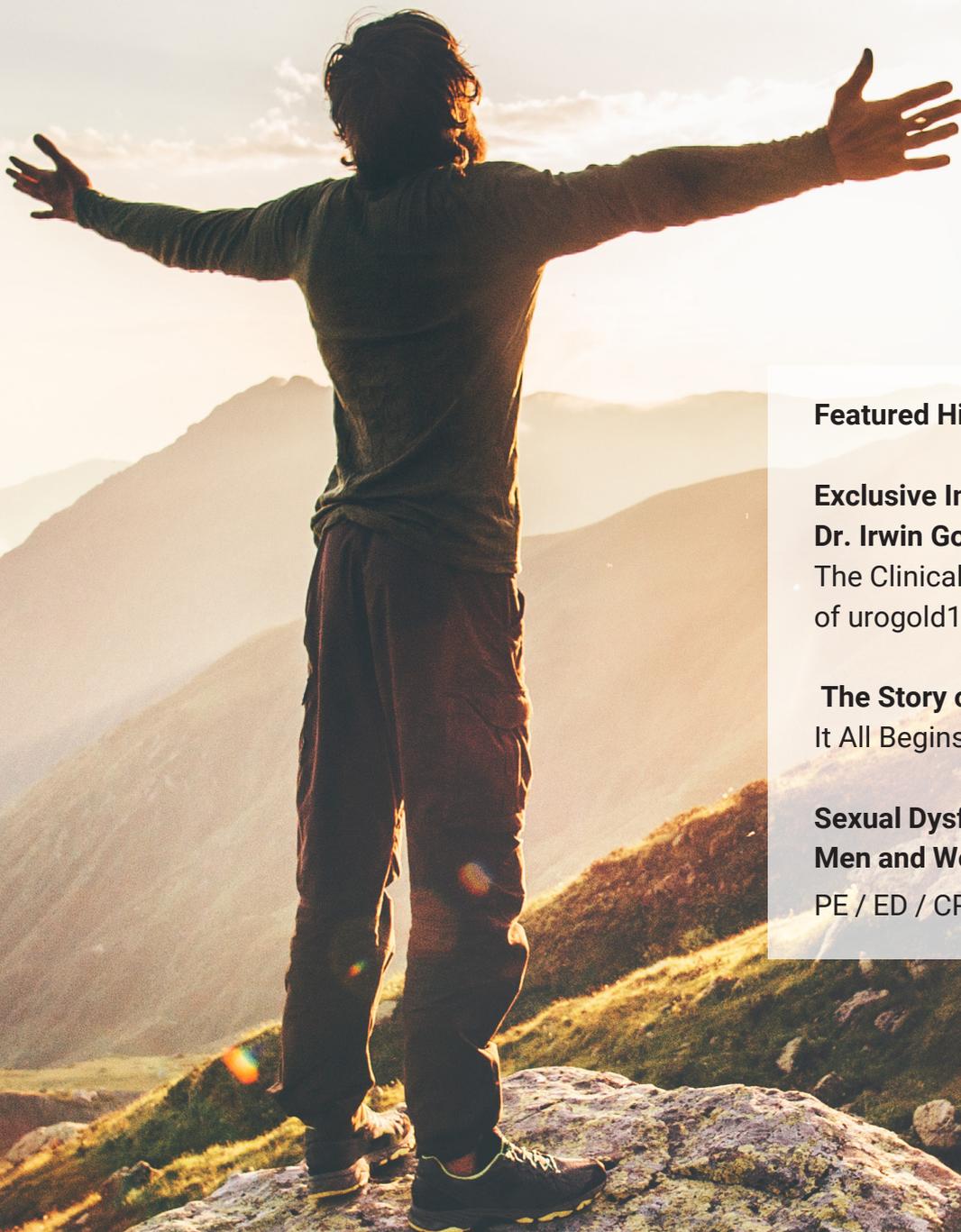




ED - Information

Medical Journal for Sexual Health

Edition 2023



Featured Highlights

Exclusive Interview with Dr. Irwin Goldstein:

The Clinical Application
of urogold100

The Story of Spark Wave:
It All Begins with a Spark

Sexual Dysfunction among Men and Women:

PE / ED / CPPS and more...

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Impressum

MTS Medical UG
(limited liability)
Robert-Bosch-Str. 18
D-78467 Konstanz
CEO: Nikolaus Hopfenzitz,
Ralph Reitmajer
Telefon: +49 (0)7531 36185-0
info@mts-medical.com
www.mts-medical.com
www.mts-science.com

SoftWave TRT, LLC
195 Chastain Meadows Ct, Suite 109
Kennesaw, GA 30144, USA
CEO: John Warlick
Tel.: (888) 862-6162
info@trtllc.com
www.softwavetr.com

Author: Liz Keener,
Christina Hauf
Layout by: Lea Engler
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Editorial

It is still a taboo subject, but nearly one in ten men over the age of 20 suffers from erectile dysfunction (ED), among those over 60, the figure is as high as one in three. However, only a few of those affected seek professional medical care. This journal provides information on various sexual dysfunctions such as ED, chronic pelvic pain, and Peyronie's disease.

Learn all about the different conditions and read about the therapeutic approach through shock wave technology! This technology offers a non-invasive treatment method that requires little financial and time investment and works completely without medication. Shock wave therapy stimulates the affected tissue and the body's own regeneration processes.

In addition, you will gain insights into the functionality as well as application areas of MTS Medical devices and applicators. We give a summary of the latest research results on the subject of sexual dysfunctions and shock wave therapy.

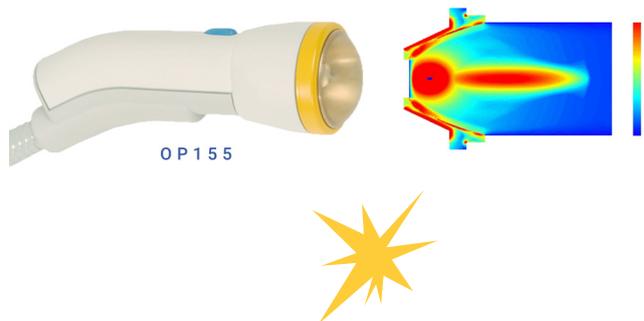
Talk to your urologist and get informed!



It All Begins with a Spark

The very first medical application using Extracorporeal Shock Wave Therapy (ESWT) was lithotripsy - a method for non-invasive removal of kidney stones. Today, ESWT is widely used as a solution for cell regeneration. This significant transition proves that there are many more possibilities for ESWT waiting to be discovered. MTS Medical was founded in 1996 by Nikolaus Hopfenzitz and Ralph Reitmajer continuing to develop the original technology. The innovation at MTS Medical brought quality to a new level and made it possible to expand the use of shock wave therapy from orthopaedics to other medical fields. Our U.S. partner company, SoftWave Tissue Regeneration Technologies, LLC, was founded in Woodstock, Georgia in 2004 by CEO John Warlick and business partner Mark Gronowski.

At the forefront of ESWT research and clinical trials in the United States and around the world, the partnership between SoftWaveTRT and MTS Medical has resulted in many breakthroughs that enable high-quality treatments in additional medical fields.



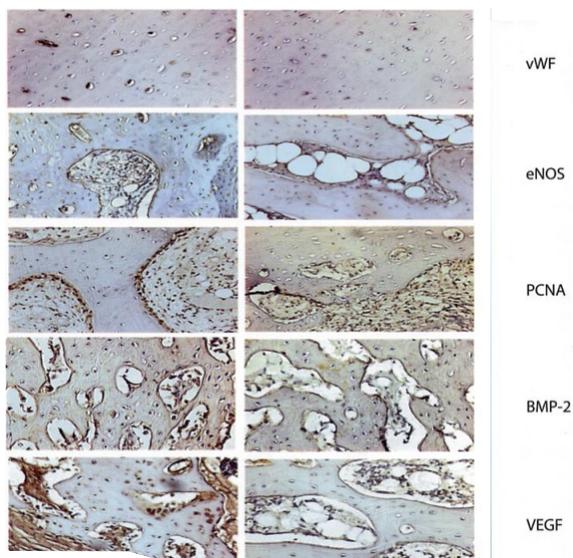
Mechanism of Shock Wave Therapy

MTS Medical Spark Waves are an effective and specific type of shock wave that play a unique role in tissue regeneration. Electrohydraulic shock waves are generated by discharges between high-voltage electrodes in the applicator of the urogold100. The pressure of the shock waves penetrates the body to a desired depth and with an adjustable Energy Flux Density (EFD), depending on the respective indication and pathophysiology. With its unique wide focus size and Pure Wave quality, shock wave technology delivers the highest possible amount of total biologically effective energy to the target area. This is recognised by receptors and converted into a chemical signal (mechanotransduction) that sets regenerative, cellular processes in motion. This includes the promotion of the body's own production of growth factors, the development of new blood vessels (angiogenesis), and the associated improvement of blood circulation, as well as the migration of stem cells. Moreover, shock wave therapy supports anti-inflammatory, as well as, antibacterial processes in the target tissue.

The shock wave thus makes an important contribution to regenerative medicine. With its unique broad focus size, this technology shows the best possible results in tissue regeneration. Conventional treatments can help with urogenital indications, however cannot correct the underlying pathophysiology and are therefore not fully satisfactory. Therefore, extracorporeal shock wave therapy is used in a broad clinical approach and has become a promising treatment for vasculogenic erectile dysfunction (ED), chronic pelvic pain, Peyronie's disease, and female sexual dysfunction.

Proven Effectiveness

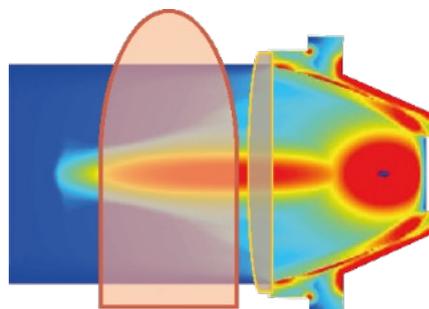
The effectiveness of shockwave therapy has been extensively proven in clinical trials. Research in recent years confirms its healing effects in dermatological, orthopaedic, and urogenital indications. On our Science website, you will find the latest scientific publications with Spark Wave Technology.



Numbers of neo-vessels and cells with positive eNOS, BMP-2, VEGF and PCNA expressions are significantly higher in high-energy shockwave group (left) than control group (right).

The Matching Applicator for the urogold100

The OP155 applicator has a particularly large focus, which enables the shockwave to be applied over a wide area. With this applicator, healing processes can be accelerated, pain reduced, and blood circulation improved. It allows a simple technical application of the shockwave and is therefore very well suited for the treatment of various urological indications.



Unfocused applicator OP155 especially effective for dermatologic and urogenital indications

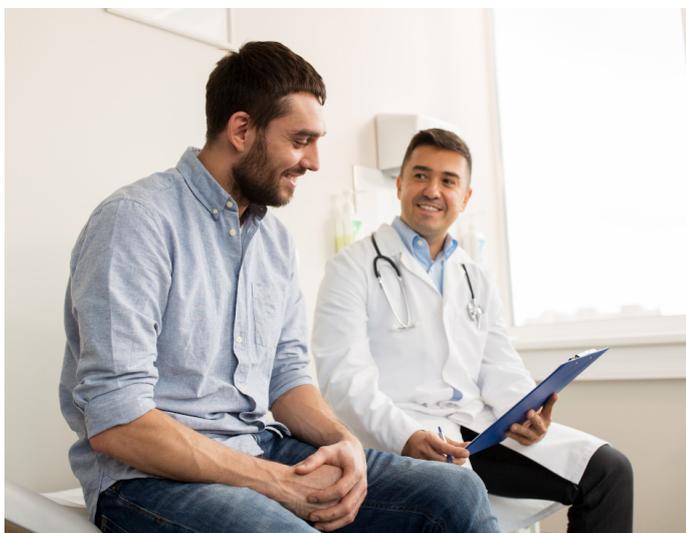
The Treatment Process: Insights into a Successful Therapy

Compared to all other therapies for sexual dysfunction, shockwave therapy is a non-invasive, drug free therapy in which the healing process is caused by stimulation of the tissue.

You may wonder how the therapy proceeds. In short, the treatment is done on an outpatient basis without the need for hospitalization. One therapy session lasts between 20 and 30 minutes. For good to excellent treatment results, the treatment protocol recommends several sessions over a period of about four to six weeks.

The first improvements can be noticed after about three weeks. Generally, no further therapy sessions are required after the treatment cycle has been completed. However, treatment can be resumed four weeks after the first treatment cycle.

Shockwave therapy is a simple and uncomplicated procedure and compared to surgical interventions, it is significantly less risky. If you suffer from sexual dysfunctions or other urological problems, do not hesitate to talk to your doctor.

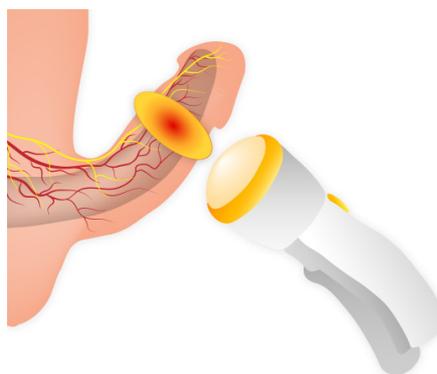


Premature Ejaculation (PE) - Dr. Irwin Goldstein

Dr. Goldstein and his team published a study in the *Journal for Sexual Medicine* in 2021¹ that addressed a novel use of the urogold100 shockwave device. In his study, he found that the sensitivity to shockwaves of patients with premature ejaculation (PE) was massively different from patients without PE, providing a new, objective indicator tool for dysesthesia/hypersensitivity of the penis. As a further effect, he showed that the use of the urogold100 with the SoftWave applicator OP155 leads to a reduction in sensitivity.

1. Uloko, M., et al. „041 Novel Use of a Shockwave Device for Energy Flux Density Threshold Testing of the Distal Ventral Erect Penile Shaft as a Marker of Penile Dysesthesia/Hypersensitivity Associated with Premature Ejaculation.“ *The Journal of Sexual Medicine* 18.3 (2021): S23.

Further clinical studies should show whether low-energy ESWT, which has very few side effects, can be developed as a treatment option for these patients. Existing therapies for PE are unfortunately very limited and many patients suffer from this problem for a lifetime.



Erectile Dysfunction

Erectile dysfunction (ED) is characterized by impaired or absent limb rigidity during sexual arousal.

There are many causes of erectile dysfunction. For example, it can be a side effect of medication, caused by circulatory problems, or hormonal problems. Unfortunately, ED occurs in more than 50% of all diabetic males. Other physiological causes include obesity, nicotine addiction, and excessive alcohol consumption. Nerve damage, such as a spinal cord injury or paraplegia, can also have a negative effect on erectile function. ED can also be an indication of serious cardiovascular disease, such as arteriosclerosis, and should therefore always be checked.

Regenerative Treatment Method - Shock Wave!

As mentioned before shockwave therapy is a gentle, non-invasive method that promotes new blood vessel formation and thus blood flow in the penis. This form of therapy is carried out without the addition of medication and leaves the intact tissue completely undamaged. Making it a very successful therapeutic approach for erectile dysfunction, caused by insufficient blood flow to the corpus cavernosum. Shockwave therapy provides a valuable contribution to successful treatment.

Are you concerned about having an erectile dysfunction problem?

Take a self-test at <https://ed-information.com/self-test/>.

This test can give hints whether a medical problem exists and if so estimates the severity of your ED.

Chronic Pelvic Floor Pain Syndrome (CPPS)

Men and women suffer from it equally: CPPS (Chronic Pelvic Pain Syndrome) has a major impact on quality of life. The symptoms are varied and often not very clear. They range from slight numbness in the pubic area to severe pain that radiates into the back and leg area. Women can also experience pain and cramps during sexual intercourse. The specialist often refer to vaginismus. Men on the other hand can experience pain in the perineum, scrotum, and testicles. Ejaculation is very unpleasant and those affected report about tensions. It feels „like sitting on a golf ball,“ patients often report. CPPS can also be caused by circulatory problems and tense muscles. The trigger points are pressure-sensitive and hardened. Tension and relaxation of the pelvic floor muscles tends to be impaired.



The Causes of CPPS

CPPS is diagnosed as myofascial pain syndrome. It is called „myofascial pelvic floor pain“: in a man, this would be so-called „chronic prostatitis“ and in a woman, so-called „vulvodynia“. Unfortunately, doctors and patients often assume psychological causes. Consequently, the Symptoms are often mistakenly treated with drugs.

Shockwave Treatment

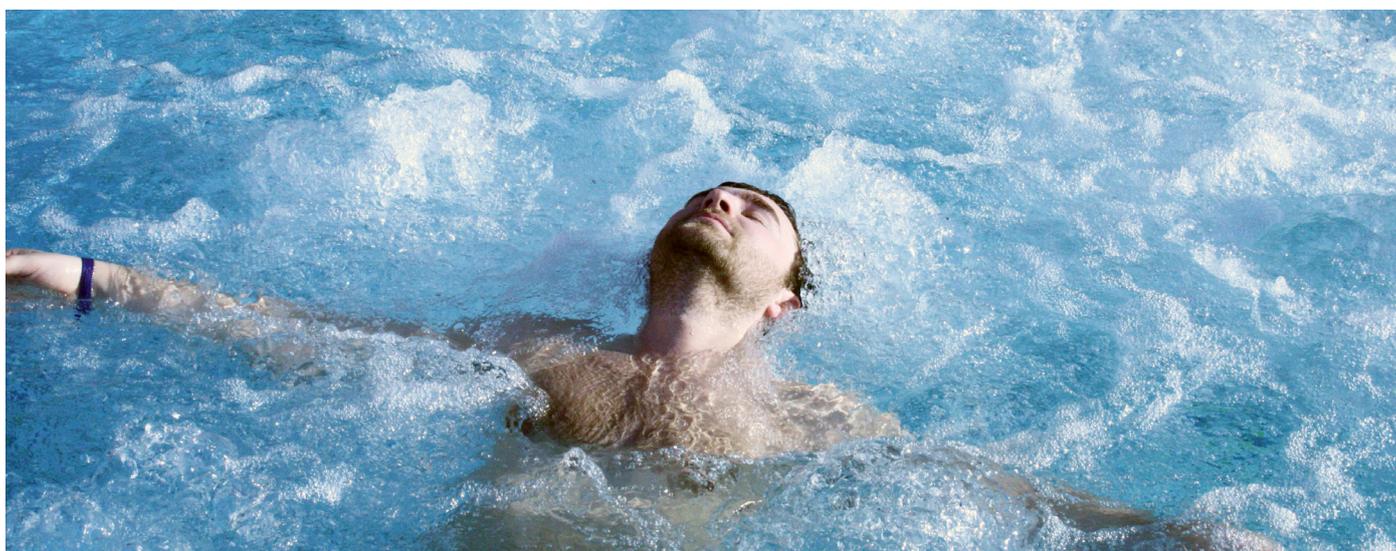
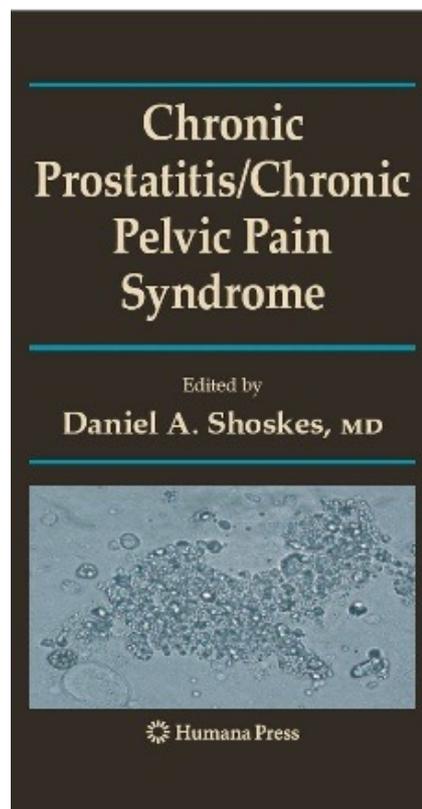
Patients with CPPS often have a long journey of suffering until they get the right diagnosis. False shame and the complex diagnosis make successful treatment difficult. Shockwave Therapy has been shown to loosen the tissue, relieve pain, and promote blood circulation. After 2-3 months of treatment, most patients experience fewer to no symptoms.



What is CPPS? - Book Presentation

A book on chronic prostatitis was published in 2008 by Dr. Daniel A. Shoskes, world-renowned urologist and expert on CPPS from Cleveland, Ohio. He has written a comprehensive work on the subject. In „Chronic Prostatitis / Chronic Pelvic Pain Syndrome“¹, Shoskes differentiates the four categories of prostatitis: acute, chronic, bacterial, CPPS, and asymptomatic inflammation. Physicians, psychologists, and pain specialists have contributed to the book, which gives the reader new approaches to help those affected by CPPS. There is no standardized therapy. However, Shoskes et al., 2018² shows that treatment with urogold100 can lead to symptom relief.

1. Shoskes, Daniel A., ed. *Chronic prostatitis/chronic pelvic pain syndrome*. Springer Science & Business Media, 2008.
2. Shoskes, D., and B. Mooney. „329 Case series of low intensity shockwave therapy for men with chronic prostatitis/chronic pelvic pain syndrome.“ *The Journal of Sexual Medicine* 15.7 (2018): S257-S258.



Interview with Dr. Irwin Goldstein

Meet Dr. Irwin Goldstein



In the Spotlight: Dr. Irwin Goldstein a pioneer in the diagnosis and treatment of sexual health concerns. He has an impressive career providing medical help to those with sexual problems and is involved in the field of sexual dysfunction since the late 1970's.

The World Association for Sexual Health awarded him the Gold Medal in 2009 in recognition of his lifelong contributions to the field. In 2012, he received the International Society for the Study of Women's Sexual Health Award for Distinguished Service in Women's Sexual Health. In 2013, the Sexual Medicine Society of North America awarded him their Lifetime Achievement Award, and in 2014, he received the ISSM Lifetime Achievement Award from the International Society for Sexual Medicine.

His interests include regenerative therapies for men and women, surgery for dyspareunia, physiologic investigation, diagnosis and treatment of sexual dysfunction. He has authored more than 350 publications in the field of sexual dysfunction, with 20 consecutive years of funding by the National Institutes of Health in this area.

Dr. Goldstein is the director of San Diego Sexual Medicine & Alvarado Hospital and a passionate user of urogold100 so we had the pleasure of interviewing him during the ISMST 2022 in Prague.

Interview with Dr. Irwin Goldstein

Q1: What is the latest state of your research? How did you come up with the ideas for numerous innovative research questions in the past? Where do you keep drawing the creative energy for your extraordinarily innovative research?

John came to our facility on April Fool's Day 2019 and left the device. Ever since we've been using the urogold100 as our prime treatment for the field of Sexual Medicine. We have identified many uses for shockwave therapy and started a double-blind sham-controlled active treatment clinical trial. As we think out of the box, to me, it was very logic to study shockwave therapy on the penis in an erect state, as you can't have sex with

a flaccid penis. During the treatment in a flaccid penis, there is limited blood flow and the applied shock waves flow through it. Whereas the shockwaves applied to an erect penis will actually impede and stay in the erectile tissue. We now added a reflector to see if the initial wave is reflected, which could increase the chances of improvement and reduce the number of treatment sessions per patient.

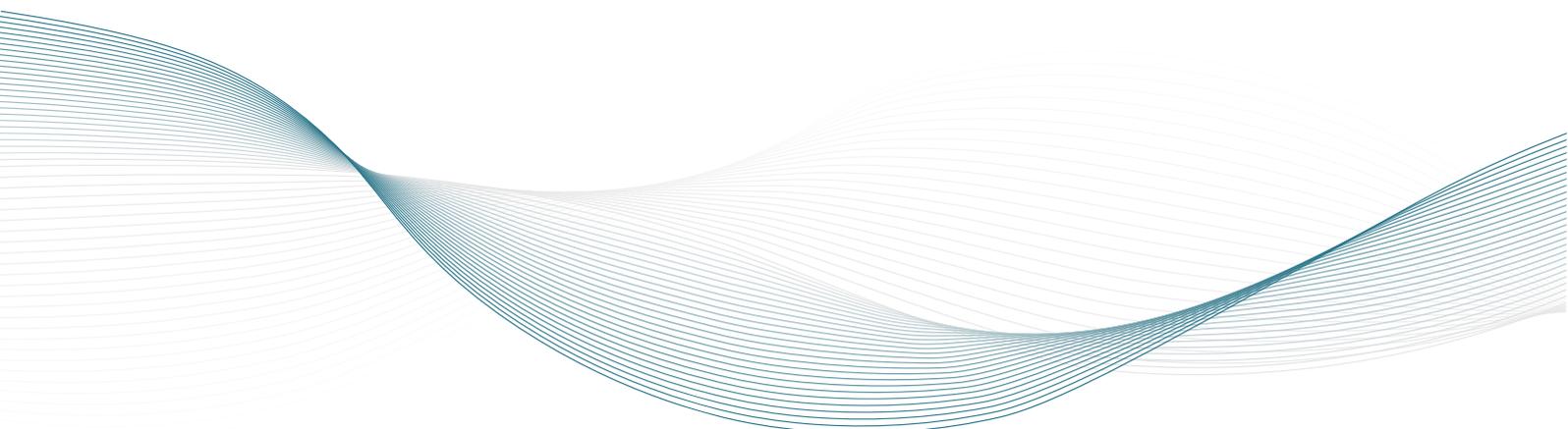
Q2: Ever since getting the device in 2019 how many patients have you successfully treated?

I have successfully treated over 3,000 patients. There are just so many uses for this device. From unwanted arousal to erectile dysfunction, Peyronie's disease, chronic pelvic pain and chronic wounds

Q3: Why is Shock Wave an ideal option for Erectile Dysfunction?

Mainly because it is successful, non-pharmacologic, and non-surgical. People interested in finding out what is wrong with them, if they have a condition or they find too much scar tissue in the penis can use the device. The scarred tissue prevents the trapping of blood, so

they get less hard erections or they disappear without their permission. Unlike Viagra, Shock Wave addresses the underlying pathology. We have evidence showing that the tissue scarring can be seen on an ultrasound and after shockwave you can see the improved tissue.



Q4: What has changed for you and your patients, in everyday life, since you started using shock wave therapy for sexual disorders?

It's black and white. Patients come in sad and leave with big smiles. I have testimonies galore on my website. We have people that don't like injecting themselves and many don't have to go back to taking medication. Men and women whose life quality changes, because of Sexual health issues, that in ge-

neral most health care providers are not interested in dealing with. Patients enjoy the treatment, because it's non-pharmacologic and non-surgical. We change people's lives and for a physician this is game changing strategy.



Innovation for Men's Sexual Health

We would like to present an innovative research study that focuses on penile rehabilitation after radical prostatectomy.

The sophisticated study by Karakose¹ et al. highlights the efficacy and safety of extracorporeal shock wave therapy in the treatment of erectile dysfunction, as well as, in the prevention of urinary incontinence after prostate cancer surgery.

Patients treated with shock waves and tadalafil, after surgery, showed significant improvements in the International Index of Erectile Function, as well as, a significant decrease in the rate of incontinence, compared to the group that did not receive shock wave therapy.

The underlying mechanism of action was investigated by Prof. Tom Lue and his research group at California University in 2016².

He was able to show that Spark Wave Therapy can improve the regeneration of nerves after trauma to the pelvic floor. He achieved this effect using the experimental device of MTS OW 180. The regeneration mechanism is also associated with stem cell migration and nerve cell repair.

ESWT induces recruitment of endogenous progenitor cells and leads to angiogenesis, as well as, tissue and nerve formation in a rat model of pelvic neurovascular injury.

The urogold100 device is particularly well suited for urogenital indications due to the unfocused SoftWave applicator OP155 and is also used for chronic pelvic pain. This study shows that in the future the application in the area of the pelvic floor will also be aimed at the rehabilitation after prostatectomy.

1. Karakose, Ayhan, and Yasin Yitgin. „Penile rehabilitation with low-intensity extracorporeal shock wave therapy in patients after prostate cancer surgery. Early physiological changes and postoperative follow-up outcomes.“ *International Journal of Clinical Practice* 75.12 (2021): e14804.
2. Li, Huixi, et al. „Low-energy shock wave therapy ameliorates erectile dysfunction in a pelvic neurovascular injuries rat model.“ *The journal of sexual medicine* 13.1 (2016):22-32



Reference Centers Worldwide

Shockwave therapy is used all over the world. We promote evidence-based medicine thanks to our extensive community and global research collaborations. All therapies are sourced based on current scientific evidence from systematic (pre-) clinical research. This now includes around 170 publications from 20 different countries and 75 institutions. MTS Medical's partners around the globe are professionally on hand to support you. You can find all our SparkWave centres and experts on the MTS Science website.



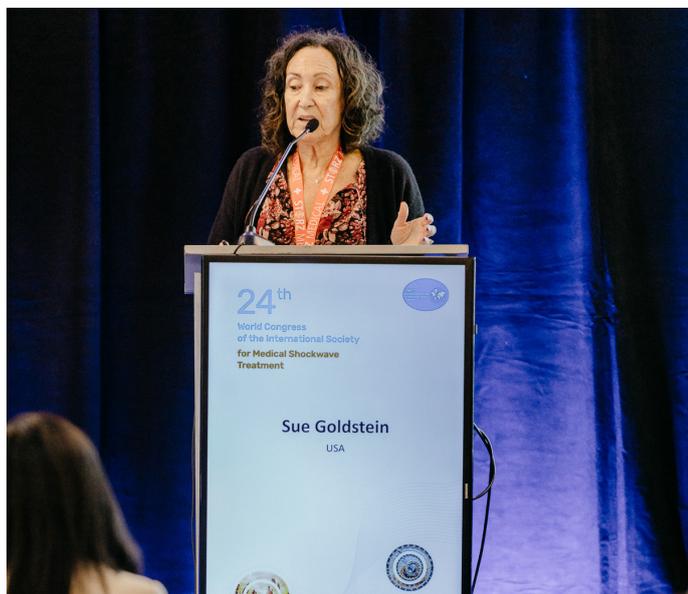
Award - Winning Presentation at the 2022 ISMST in Prague

Post-Finasteride Induced Erectile Dysfunction: Diagnosis by Grayscale/Doppler Ultrasound and Disease Modification Treatment with Erect Penile Extracorporeal Shock Wave Therapy

*Sue Goldstein, Marvin Carlisle, Alyssa Yee, Irwin Goldstein
San Diego Sexual Medicine, Sexual Medicine, San Diego, USA*

Introduction

Finasteride (1 mg), a 5-alpha reductase inhibitor that lowers dihydrotestosterone, is approved for treatment of male pattern hair loss, androgenic alopecia. Persistent sexual side effects have been reported following discontinuation of finasteride, including erectile dysfunction (ED). It has been postulated that post-finasteride induced ED is, in part, due to cavernosal smooth muscle cell apoptosis as a sequela of low serum dihydrotestosterone. Khera et al (2020) reported persistent penile vascular changes in 25 men after discontinuation of finasteride. The purpose of this study was to replicate Khera's findings in a larger population and examine treatment of those patients with post-finasteride induced ED using ESWT.



Material & Method

A chart review (2015-2020) was performed. Our patient population had **normal sexual function prior to finasteride use and experienced changes within 6 months of discontinuation of finasteride which persisted > 6 months.** Information collected included sexual function

history, current symptoms, validated instruments, hormone blood test values, data from grayscale/Doppler ultrasound during pharmacological erection (15.4 MHz probe; Aixplorer® Ultrasound) and data from erect penile ESWT treatment with UroGold 100 MTS.

Results

91 patients (median age 39) met inclusion criteria, 9.6% of men evaluated during this period. The most common symptom was ED in 95% (87/91). Mean IIEF-EF score was 14 ± 8.63 (n=81), consistent with severe (43%), mild-moderate (23%), moderate (12%), and mild (10%) ED. Of the 57 who underwent grayscale/Doppler ultrasound, 77% exhibited abnormal erectile tissue inhomogeneity. Mean cavernosal artery PSV/EDV values (n=61) were left $30.4 \pm 18.02 / 0.76 \pm 2.86$ cm/sec and right $29.63 \pm 14.97 / 0.60 \pm 1.89$ cm/sec, respectively. These data support that erectile tissue damage occurs in the corpora cavernosa after discontinuation of finaste-

ride. A total of 6 LiSWT were performed on the erect penis (erection hardness 3–4/4) in 18 (32%) of these men as a disease modification management option for their post-finasteride induced ED. A total of 3600 shocks per treatment, energy flux density 0.13 mJ/mm², 3 Hz, membrane pressure 1 using UroGold 100 MTS. After completion of the 6-treatment cycle of ESWT, grayscale/Doppler ultrasound was repeated. 58% exhibited improved erectile tissue homogeneity, (61%) patients had PSV increase, (32%) had EDV decrease and 65% reported improvement in Patient Global Impression of Improvement.

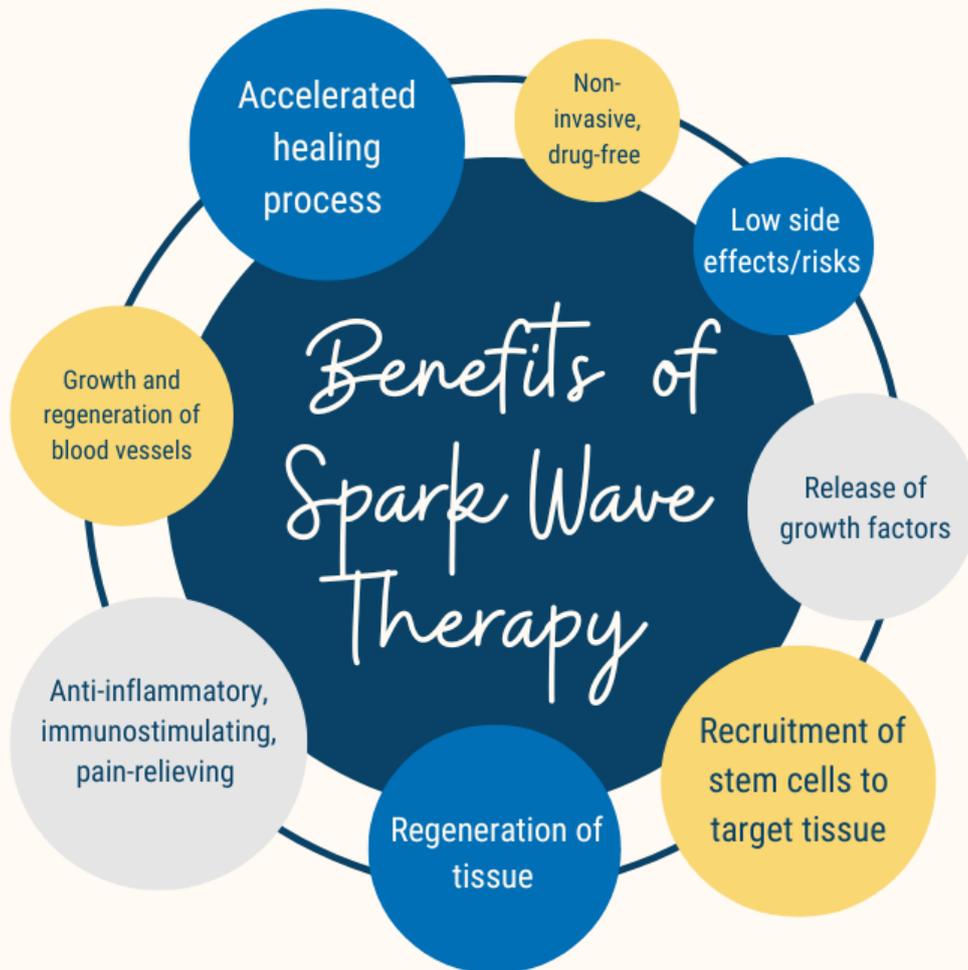
Discussion

In a large series of men with persistent ED, after discontinuation of finasteride, ESWT has been shown to provide improvement in erectile tissue homogeneity, PSV and EDV; therefore, improving the quality of erection in this otherwise difficult to treat population men.

Preliminary findings by Dr. Goldstein during his randomized controlled trial support significant erectile health improvement in as few as three treatments.



Summing up your Spark Wave Therapy BENEFITS in a Nutshell:



Witness. The Spark of Life.

Address SoftWave TRT:

SoftWave TRT, LLC
195 Chastain Meadows Ct, Suite 109
Kennesaw, GA 30144
Tel.: (888) 862-6162

Address MTS:

MTS Medical UG
Robert-Bosch-Str. 18
78467 Konstanz, Germany
Tel.: +49 7531 36185 023
Fax: +49 7531 36185 070