

## WHY DOCTORS ARE USING SOFTWAVE TO TREAT HARD-TO-HEAL WOUNDS

## SOFTWAVE BRINGS INNOVATION THAT WORKS





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# HARD-TO-HEAL WOUNDS ARE A GLOBAL DILEMMA

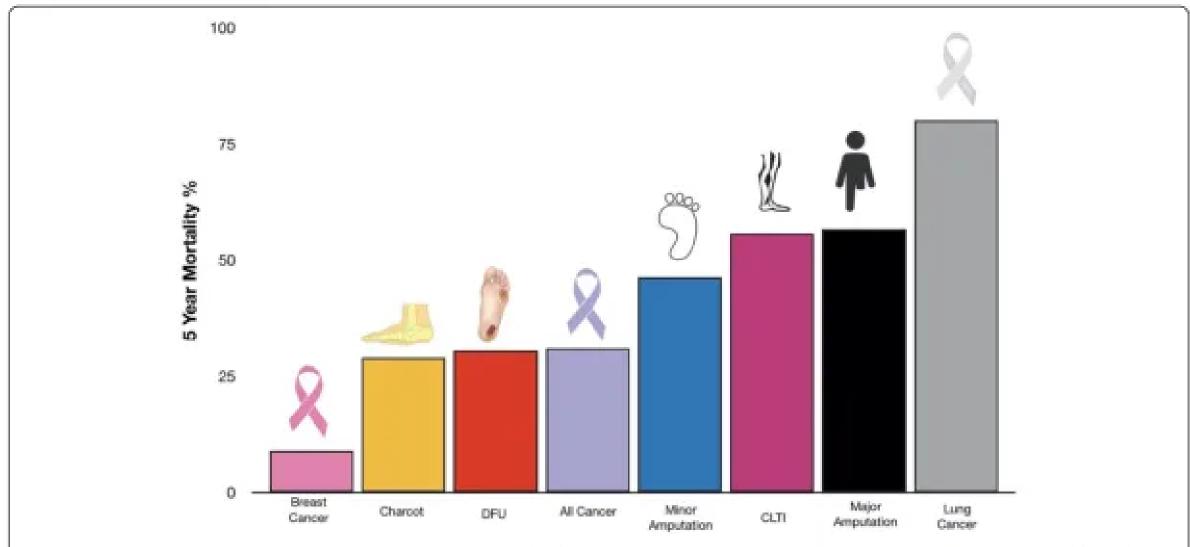


Fig. 1 Five Year Mortality of Diabetic Foot Complications and Cancer. Diabetic foot complications compared to cancer. DFU = diabetic foot ulcers [11] = 30.5%. Charcot = Charcot neuroarthropathy of the foot [14]. All Cancer = pooled 5 year survival of all cancers [11]. CLTI = chronic limb threatening ischemia [28, 29]. Major Amputation = above foot amputation [20–22, 26, 27]. Minor Amputation = foot level amputation [17, 27]

Chronic wounds are associated with high health care costs, poor quality of life and significant morbidity and mortality.(1) They are those wounds that fail to proceed through the normal phases of wound healing in an orderly and timely manner, often stalling in the inflammation phase of healing and showing no progress in 30 days or more.(2)

Wounds that have become chronic are associated with significant morbidity and mortality, and they impose a major medical and financial burden. For example, the mortality rate for an individual developing a diabetic foot ulcer (DFU) is approximately 40%, thus making accurate diagnosis and implementation of appropriate interventions imperative.(3)

HARD-TO-HEAL WOUNDS LACK AN EFFECTIVE, CONVENIENT TREATMENT OPTION UNTIL NOW



## SOFTWAVE IS A COST-EFFECTIVE AND CONVENIENT THERAPY FOR **WOUND HEALING**

Shockwave therapy is typically a 10-minute treatment performed once a week for 6-8 weeks. SoftWave produces an unfocused shock wave which has the patented advantage of distributing maximum energy to a wide and deep area. This makes for reduced treatments and better outcomes.



Accelerated healing Non-invasive Well-tolerated Fast and easy to use Convenient for provider and patient Reimbusement pathway Less costly than HBOT, skin substitutes and NPWT



# WOUND MANAGEMENT EXPENSES CONTINUE TO ESCALATE

Wound management, including acute and trauma wounds, is a clinical challenge across all care settings and one with high associated costs.

In the United States, approximately 5% of hospital budgets are devoted to wound care.

The total national cost is between \$28.1 billion and \$96.8 billion dollars a year.(4)

Complex and chronic wounds often take longer to heal, and this delay significantly increases the cost of treatment.



IN THE U.S., CHRONIC
WOUNDS AFFECT
APPROXIMATELY
6.7 MILLION INDIVIDUALS
AND AN EXCESS OF
\$50 BILLION IS SPENT
ANNUALLY ON TREATMENT. (5)





## DIABETIC FOOT ULCERS COMPLEX WOUND MANAGEMENT

DFUs are among the most common complications of diabetes mellitus. These wounds are caused by peripheral neuropathy, small vessel occlusion, and secondary infection or trauma.(6) Because DFUs have a complex etiology and have various interactions between local and systemic factors, treatment established in current guidelines is not always successful.(7) Patients with DFUs often experience pain and are likely to have a recurrence when the DFU does heal. Approximately 40% of patients will experience recurrence within three years and 65% within five years.(8) Severe ulcers may lead to amputation of part of the lower extremity (LE).

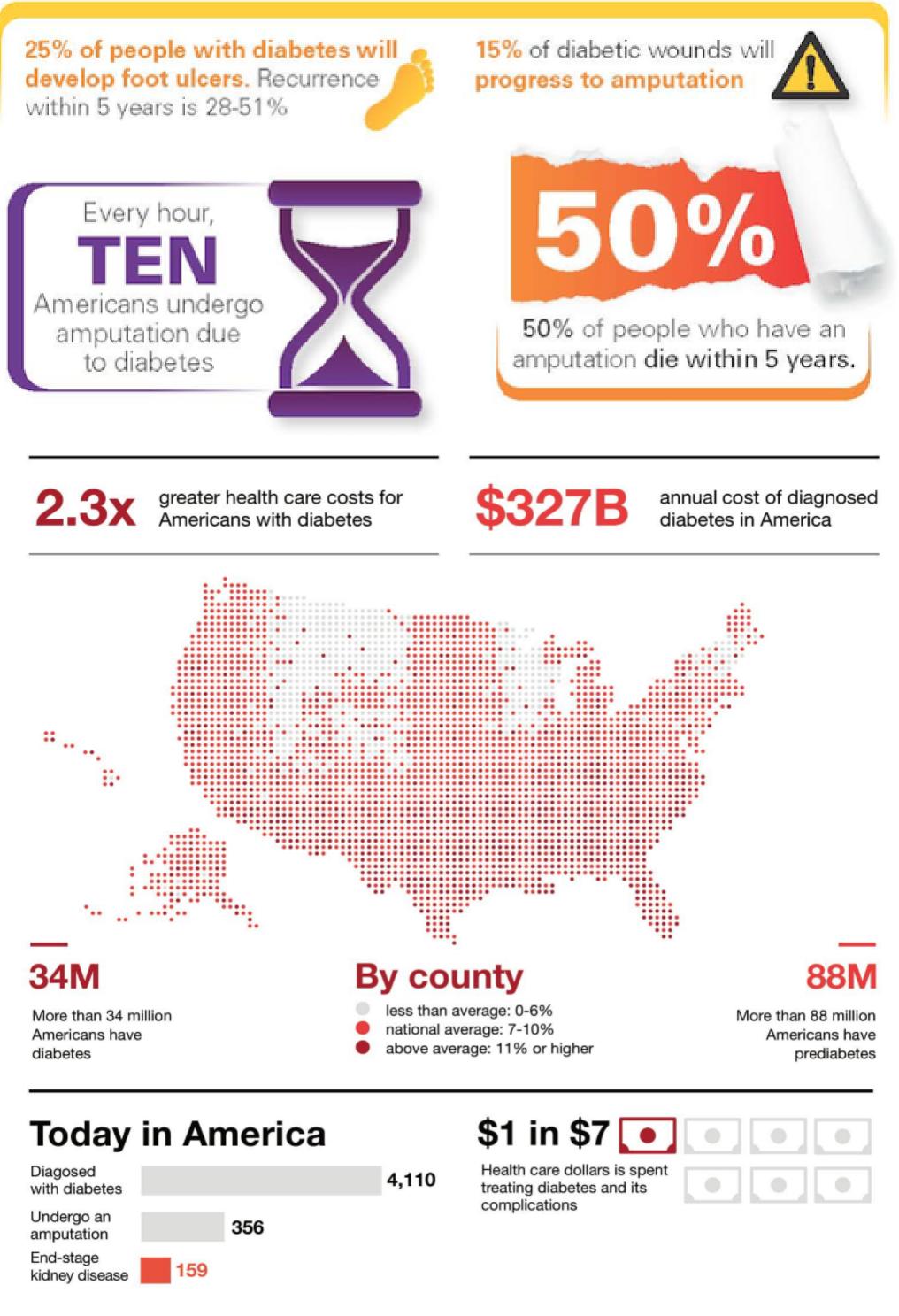
DFUs have an extreme effect on patients with these wounds. These patients often feel socially isolated and may have limited mobility, sometimes to the extent that simple, daily tasks are impossible to perform. They also commonly have pain and discomfort. The widespread effects of DFUs often worsen patients' quality of life and can even lead to depression.



Diabetic foot ulcer after surgical intervention 71 years old, female, diabetic; 5 SoftWave treatments in total, 2.500 impulses



# COSTS ARE TREATING DIABETIC FOOT ULCERS ARE RISING



2017 Stats according to the American Diabetes Association



#### SECOND DEGREE BURNS

Burns are among the most complex forms of injury. Unlike first-degree burn injuries, second-degree burns damage the outer layer of skin and the layer underneath. There are two types of second-degree burns, superficial partial-thickness burns, and deep partial-thickness burns. Superficial partial-thickness burns affect the epidermis and papillary dermis. Deep partial-thickness burns also extend to the reticular dermis. The burn will appear red and white, with a slow capillary refill. Thick-walled blisters are commonly present.(9)

Burns can have various etiologies depending on the source of the injury, and they are among the most complex injuries to treat. Patients who have been burned often face physiological and psychological trauma, and the pain resulting from burns is often described as the most severe pain felt by patients.(10) Controlling the patient's pain level and managing the threat of infection are two of the greatest challenges for clinicians treating these types of wounds. ESWT can aid in the treatment of burn wounds by increasing perfusion and assisting epithelialization.(11)





Burn injury
Before and after 7 weeks / 4 SoftWave sessions applied in total



### SECOND DEGREE BURNS

**EACH YEAR NEARLY** 

## 500,000 AMERICANS

RECEIVE TREATMENT FOR BURNS

40,000
HOSPITALIZATIONS

**3,400**DEATHS

BURN RELATED U.S. MEDICAL COSTS EXCEED

# \$1.5 BILLION PER YEAR

INDIRECT U.S. COSTS
ASSOCIATED WITH BURNS
EXCEED

# \$5 BILLION PER YEAR

The average cost of a burn-related hospital stay is \$24,000, more than double the cost of non-burn-related stays.(12)



## SURGICAL SITE INFECTIONS (SSIs)

SSIs occur in 2% to 4% of all patients undergoing inpatient surgical procedures. Although most infections are treatable with antibiotics, SSIs remain a significant cause of morbidity and mortality after surgery.

They are the leading cause of readmissions to the hospital following surgery, and approximately 3% of patients who contract an SSI will die as a consequence.

According to data from AHRQ, more than 10 million patients undergo surgical procedures as inpatients each year, accounting for over one-fourth of all hospital stays.

Surgical site infection (SSI)—defined by the Centers for Disease Control and Prevention (CDC) as infection related to an operative procedure that occurs at or near the surgical incision within 30 days of the procedure, or within 90 days if prosthetic material is implanted at surgery—is among the most common preventable complication after surgery.





71y, female, diabetic, polyneuropathy after two surgical revisions

5 treatments (2500 pulses total - 8 mins/



### PRESSURE RELATED WOUNDS

A Pressure Ulcer is a localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear.(13) Nowadays, pressure ulcers are the third most costly disease after cancers and cardiovascular diseases. The mortality rates from this disease are 2 to 6 times as much as from other diseases, with 60,000 deaths annually due to this complication.(14)

# \$11 BILLION PER YEAR

U.S. SPENDS FOR THE PREVENTION AND TREATMENT OF PRESSURE ULCERS





#### **CLICK HERE**

to access the Infected Decubitus Ulcer Treated with SoftWave DermaGold Case Study by Dr. Richard Thiele, MD

#### The long-term consequences of a pressure ulcer

If the wound becomes infected, the infection can spread to other parts of the body.

Several conditions that may occur if an infection spreads include:

Cellulitis: An infection of the skin.

Osteomyelitis: An infection of the bone.

Bacteremia: An infection of the blood.

Meningitis: An infection of the brain and spinal cord.

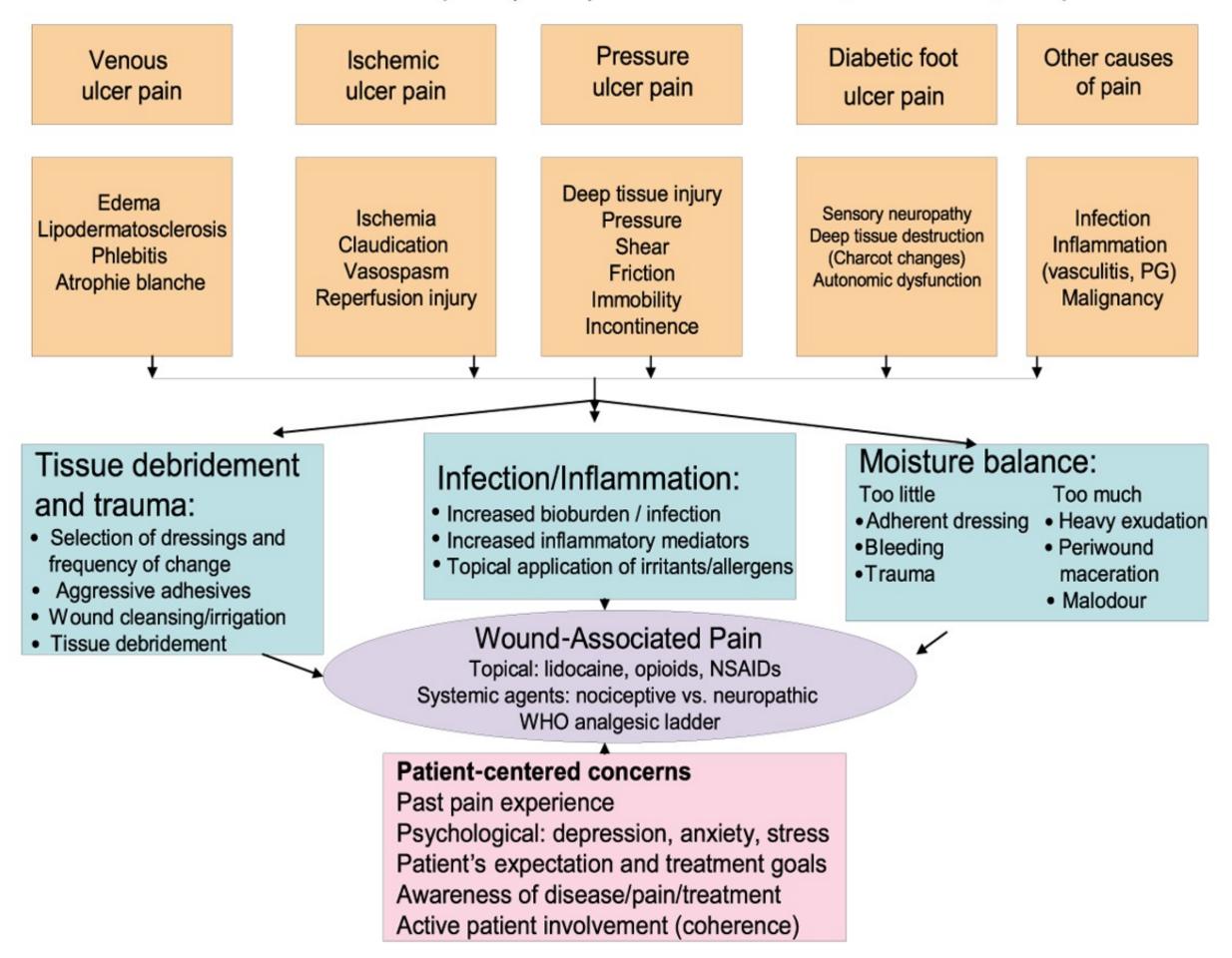
Endocarditis: An infection of the heart.

# IS WOUND PAIN A COMMON PROBLEM?

Wound pain can be due to four causes: the presence of the wound, the disease process (neuropathy, inflammation, ischemia, and infection), treatment procedures (including debridement, dressing changes, and cleansing) or very low pain tolerance.(15) The source of the pain can be described as nociceptive(16) or neuropathic and its occurrence as noncyclic, cyclic, or chronic.(17) Nociceptive pain involves pain receptors in the area of injury. In contrast, neuropathic pain is processed by the central nervous system, as in for instance phantom limb pain, or in the peripheral nervous system as in peripheral neuropathy.

Studies of patients with venous leg ulcers indicated that more than 80% of patients reported acute or chronic wound pain, with half of them rating pain as moderate to the worst possible pain.

Chronic wound-associated pain (WAP) model: the wound, the cause, the patient

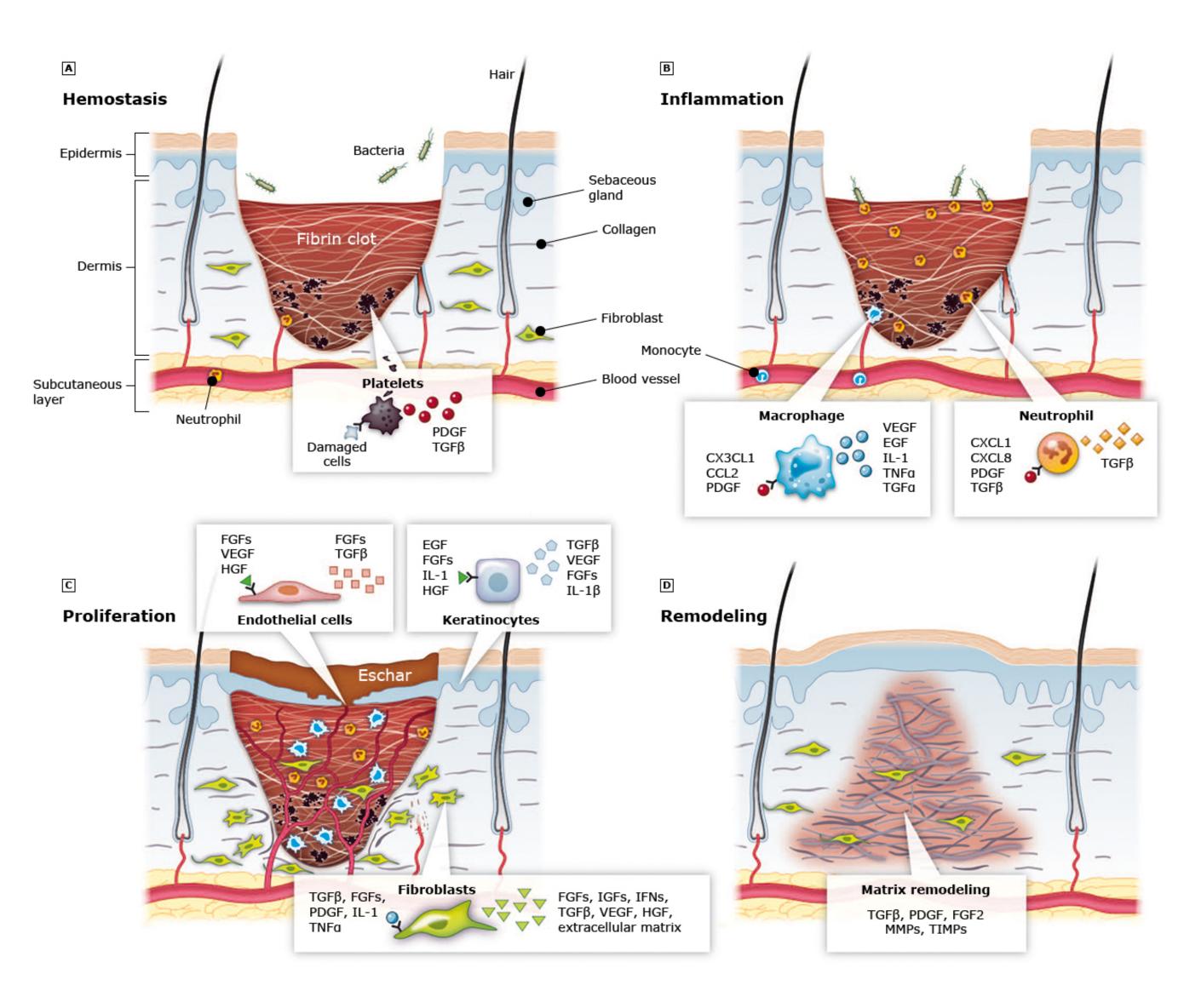


PG = Pyoderma gangrenosum; NSAID = nonsteroidal anti-inflammatory drugs; WHO = World Health Organization

Woo and Sibbald 2007

# SOFTWAVE ACCELERATES THE STAGES OF WOUND HEALING

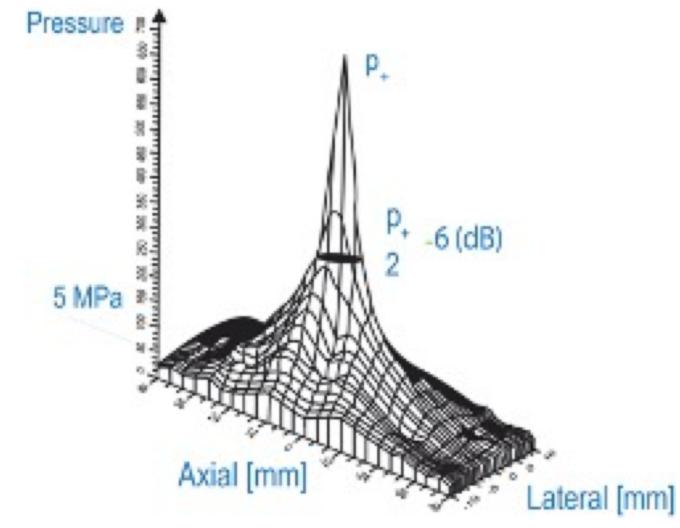




Increasing leukocyte activation assists in the inflammatory phase of wound healing by triggering the release of pro-angiogenic factors. After shockwave treatment, wounds move much faster through the inflammatory phase6 when compared to the normal inflammatory process.(18)



# SOFTWAVE EXTRACORPOREAL SHOCKWAVE THERAPY (ESWT) PRODUCES A TRUE ACOUSTIC SHOCKWAVE



# MECHANOTRANSDUCTION MECHANISM WITH 3 PHASES

#### 1. PHYSICAL -

Generates a large positive pressure wave followed by a negative pressure wave.

#### 2. CHEMICAL -

Mechanical stimulus leads to biochemical reactions. Biomolecules are released and cell signaling is activated.

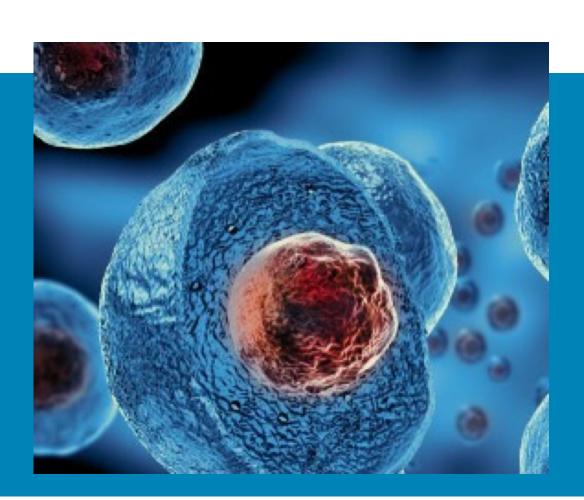
#### 3. BIOLOGIC -

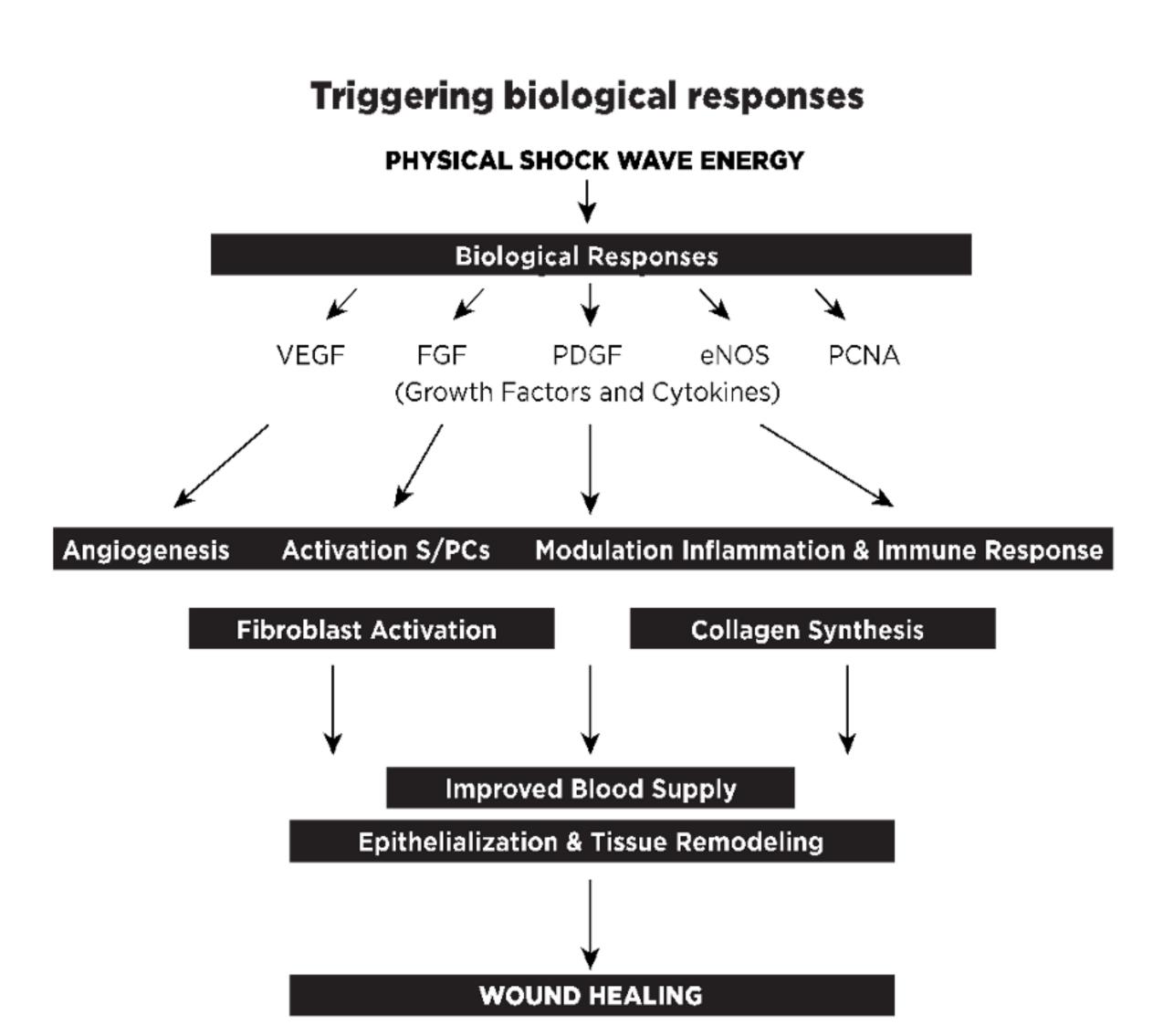
Angiogenesis, inflammatory modulation, stimulation of tissue regeneration.



### THE SCIENCE

SoftWave produces a cellular biological response that accelerates angiogenesis and revascularization which promotes faster wound healing.





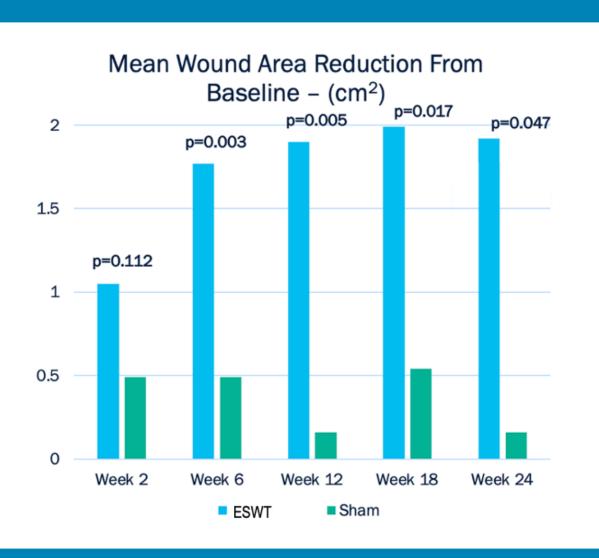


### **RESULTS**

SoftWave TRT uses patented parallel acoustic shockwaves to accelerate wound healing and reduce pain.

- Promotes angiogenesis
- Increases blood supply
- Modulates inflammation
- Stimulates cytokines and growth factors
- Repairs, remodels and regenerates tissue
- Induces antibacterial effect
- Faster wound epithelialization



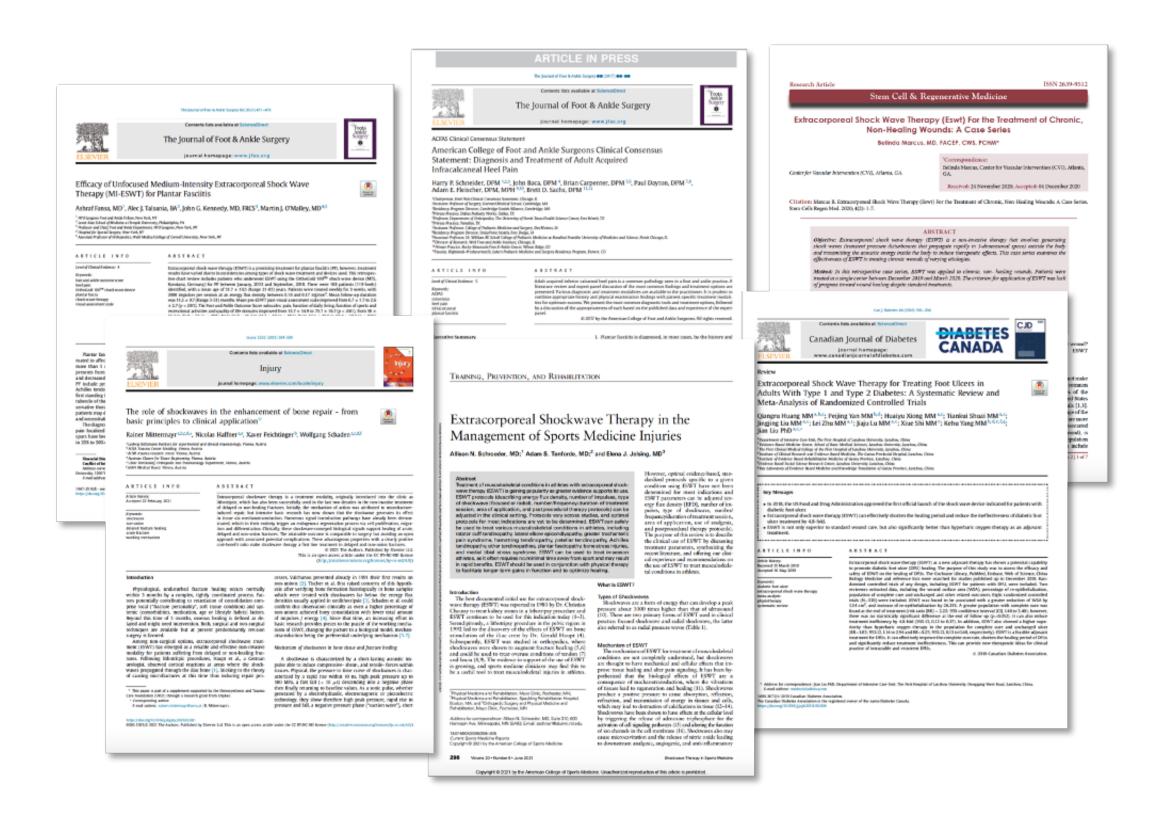


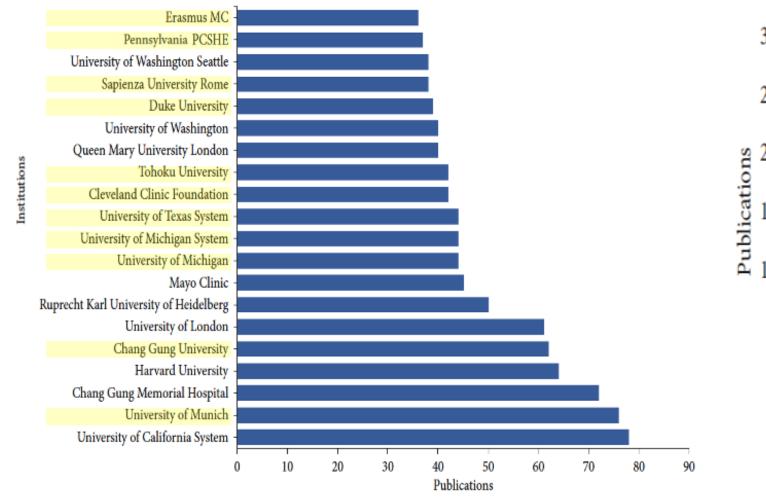
Data on File by SoftWave TRT

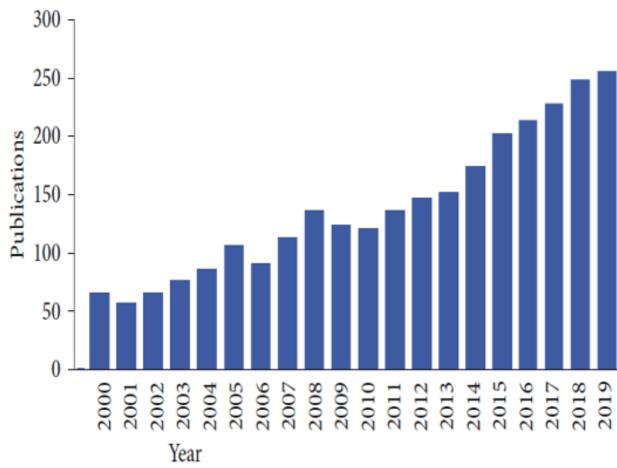


# EXTRACORPOREAL SHOCKWAVE THERAPY IS EVIDENCE-BASED

Studied over 1,000 times in the past 5 years Studied in major U.S. academic institutions









# ORIGIN OF USING UNFOCUSED PARALLEL SHOCKWAVES

My first study of applying SoftWave for non-healing bone fractures was done to prove that this 'new technology' does not work. The results converted not only me but also the AUVA Board, not just because SoftWave therapy is as efficient as surgery and has practically no complications, but also because almost 85% of the costs could be saved. The AUVA Board not only equipped all of its trauma centers with this technology, but SoftWave technology became the standard of care in Austria for the treatment of non-healing fractures. I chose to dedicate my professional career to SoftWave research and applications."



Dr. Wolfgang Schaden

Dr. Wolfgang Schaden is the renowned and premier researcher and clinician of shockwave technology. He has nearly 30 years as a senior physician at Trauma Center Meidling, one of the largest trauma centers in Europe. In 1993, he conducted the first clinical studies on the application of shockwave therapy.

Dr. Schaden helped found the European Society for Musculoskeletal Shockwave Therapy (ESMST) in 1997, which was renamed in 2000 to International Society for Medical Shockwave Treatment (ISMST). He has written 100 published articles and book chapters and given more than 500 presentations on extracorporeal shockwave therapy. As president of the ISMST he is on the forefront of the research and its early results.

#### **CLICK to WATCH**

A video by Dr. Shaden

explaining shockwave

technology and his

decades of experience

using the SoftWave device

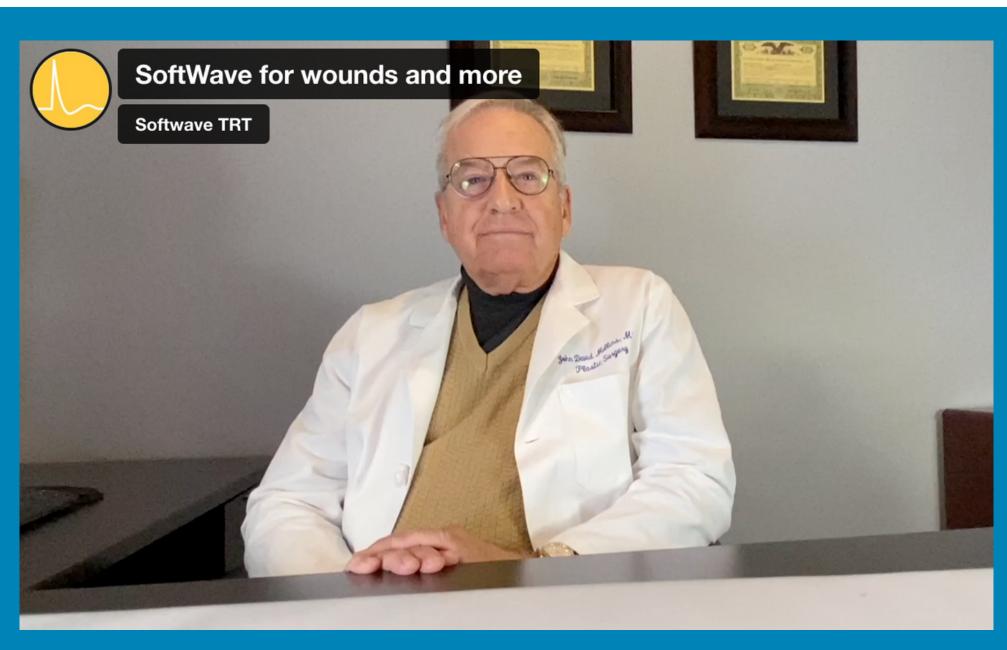


# "UNEXPECTED POSITIVE RESULTS THAT I HAVE NOT SEEN IN 30 YEARS OF PRACTICE"

#### Dr. John David Mullins MD, FACS

Dr. Mullins serves as the Chairman of the Department of Surgery at Piedmont Atlanta Hospital and is a practicing reconstructing plastic surgeon

# CLICK HERE to watch Dr. Mullins share his experience using SoftWave technology



"As the use of acoustic shockwave has changed my approach to many things from wound care to limb salvage to prosthetic salvage to complex wound and hardware preservation including joints and circulatory assist devices."

—Dr. John Mullins



## VENOUS LEG ULCERS A MAJOR CLINICAL CHALLENGE



"SoftWave's ESWT enhances cell migration and angiogenic signaling on chronic wounds through mechanotransduction resulting in significant proliferation and healing."

Dr. Matthew Regulski, DPM, FFPM, RCPS

VLUs are among the most common chronic wounds presenting on the lower extremities and feet. Between 1.5 and 3.0 in 1000 people have active leg ulcers. Prevalence increases with age to about 20 in 1000 people aged over 80 years.

Dr. Matthew Regulski DPM, FFPM RCPS (Glasgow), ABMSP states: 93% of Venous leg ulcers (VLUs) are open longer than one year because of comorbidities, lifestyle, and work demands. These wounds are challenging to treat because of chronic inflammation, robust biofilms, hypoxia, and inflammatory exudate that contribute to continued tissue breakdown and chronicity. The longer the wound is chronic the greater the risk of infection, hospitalization, and lost work days.

Dr. Regulski: a case series of patients with chronic venous leg ulcers demonstrated that ESWT was associated with timely wound closure.

ESWT, applied every 7 days for 6 sessions in conjunction with good standard wound care treatments, was a convenient, outpatient (10-to-15-minute sessions) treatment without adverse effects. Complete healing suggests that incorporating ESWT into the wound care regimen for chronic non-healing wounds may be beneficial.

SoftWave ESWT was applied to chronic venous leg ulcers. Patients were treated at a single center between 2/2022 and 5/2022. The criteria for application of ESWT was a lack of progress toward wound healing despite evidence-based medicine protocols. Wounds were considered healed after 6 shockwave treatments.



## **VENOUS LEG ULCERS CLINICAL CASE STUDY SUCCESS**



Dr. Matthew Regulski DPM, FFPM RCPS

#### **BEFORE** One year old wound



### **AFTER** 6 SoftWave treatments



#### Extracorporeal Shockwave Therapy (ESWT) For the Treatment of Non-Healing Venous Leg Ulcers: A Case Series

#### Introduction

Extracorporeal shock wave therapy (ESWT\*) is a non-invasive therapy that involves generating shock waves (transient pressure disturbances that propagate rapidly in 3-dimensional space) outside the body and transmitting the acoustic energy inside the body to induce thempeutic effects. This case series examines the effectiveness of ESWT in treating non-healing venous leg ulcers.

#### SoftWave

#### Methods

These patients had venous ulcerations verified by venous reflux study and adequate arterial flow verified by arterial dopplers with toe pressures. They had evidenced based procedures applied to their wounds including sharp debridement, moist wound balance, multi-layer compression bandaging, biofilm management and skin substitutes. Shockwave was applied seekly: 2,000 shocks at 3.5MHz. Total of 4200mJ.

#### Results

This retrospective case series. ESWT was applied. to chronic venous leg ulcers. Patients were treated at a single center between 2/2022 and 5/2022. The criteria for application of ESWT was a lack of progress toward wound healing despite evidence based medicine protocols. Wounds considered healed after 6 shockwave treatments.

#### Discussion

93% of Venous log ulcers (VLUs) are open longer than one year because of comorbidities, lifestyle, and work demands. These wounds are challenging to treat because of chronic inflammation, robust biofilms, hypoxia and inflammatory exodate that contribute to continued tissue breakdown and chronicity. The longer the wound is chronic the greater the risk of infection, hospitalization and lost work days.

This case series of patients with chronic venous leg ulcers demonstrated that ESWT was associated with timely wound closure. ESWT, applied every 7 days for 6 sessions in conjunction with good standard wound care treatments, was a convenient, out-patient (10-to-15-minute sessions) treatment without adverse effects. Complete healing suggests that incorporating ESWT into the wound care regimen for chronic non-healing wounds may be beneficial.

#### Patient A

53 yo Male referred for chronic wound over one year duration. Patient had pelvic compression syndrome treated with stents in the common femoral vein. Patient had robust arterial flow per doppler. 10 applications of neonatal foreskin applied prior. Wound biopsied from various areas was negative for skin cancer. I initiated biofilm management with anti-biofilm wound gel, collagen and an absorptive hydrofiber dressing with multi-compression bundaging. Weekly shockwave therapy commenced.

#### Patient B

63 yo Male, long-time smoker, referred for chronic ulceration for over one year. Arterial doppler showed adequate arterial flow, venous reflux study showed significant GSV reflux which required endovenous ablation. Sharp debridement was then performed with biofilm management with anti-biofilm wound gel, collagen and absorptive hydrofiber dressing with multi-compression bandaging. Weekly shockwave therapy commenced.

























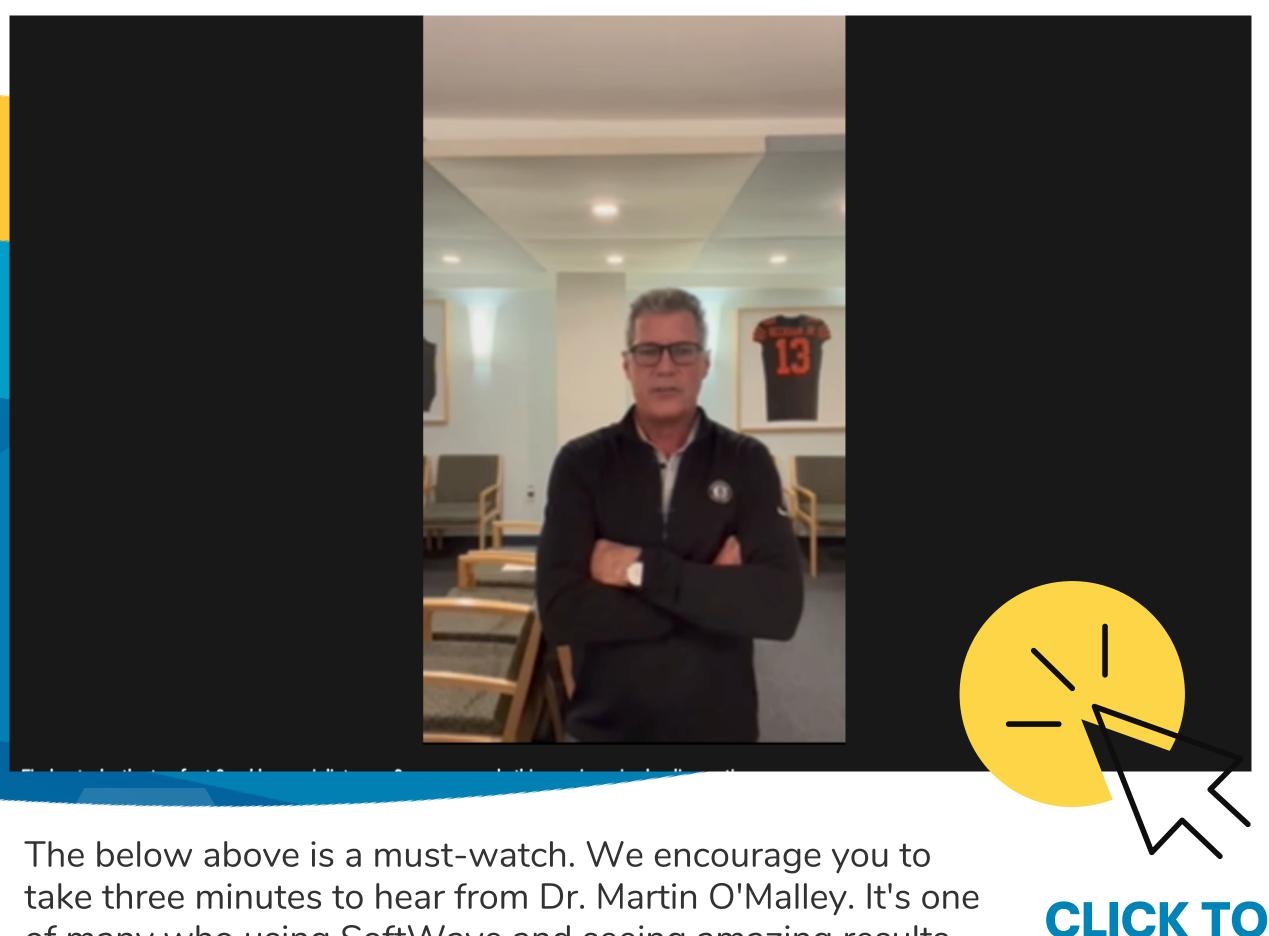


Dr. Matthew Rogaldo DVM, FFFM HCPS (Glasgow), ABMSP NEST device used in the Decrea Gold 100 by Soft New Tissue Regenceation Technologies



## **Dr. Martin O'Malley**

Practicing Orthopedic Physician at the Hospital for Special Surgery in New York, Team Physician for the New York Giants and USA Basket Ball.



of many who using SoftWave and seeing amazing results.

#### Highlights from Dr. O'Malley:

- His experience with the machine
- How he uses it in his practice
- How SoftWave works
- Why he thinks every practice should have one

**WATCH** 



#### **INCREASED REVENUE**

"Our investment in SoftWave TRT has helped not only our patients but also our clinic as a way to increase revenue potential and position our practice as a leader in innovation."



Dr. Duane Cumberbatch, DPM



(There is a reimbursement pathway.) Personally, incorporating SoftWave has been gratifying knowing I'm able to offer patients an innovative way to heal, even those with neuropathy who can still feel pain.

Dr. Duane Cumberbatch, DPM is fellowship trained in limb salvage and completed the Ilizarov fellowship in Kurgan, Russia. Dr. Cumberbatch's area of specialty includes reconstructive surgery of the foot and ankle, limb preservation, and wound care. Dr. Duane Cumberbatch is currently a practicing podiatrist in Fort Myers, FL.



#### REIMBURSEMENT PATHWAY

"Two codes define SoftWave's (OrthoGold) ESWT treatment of a wound, 0512T and 0513T. These codes may be billed by the physician noting the place of service on the claim.

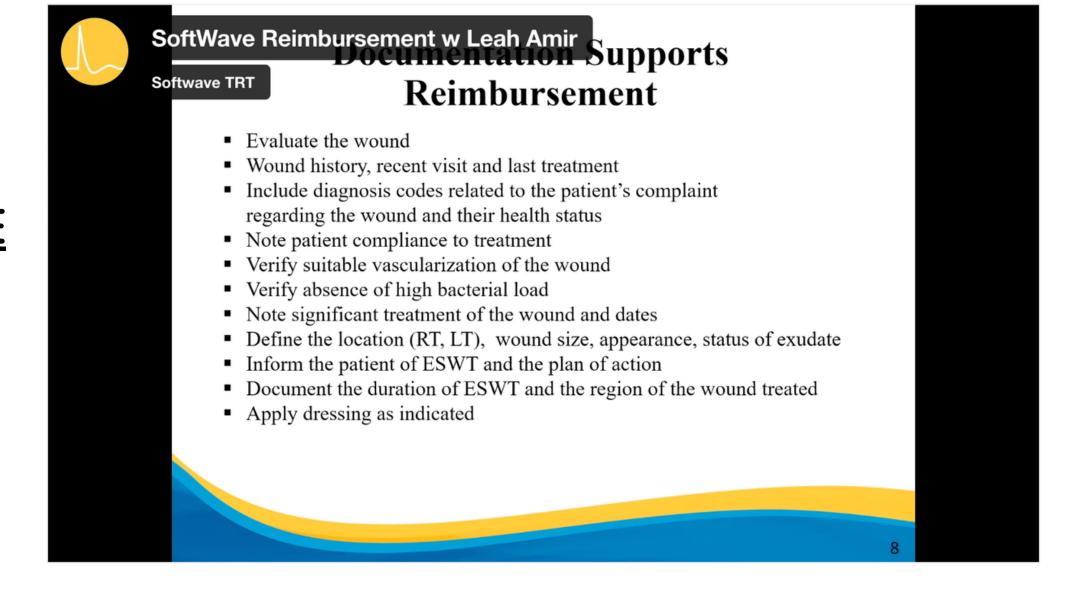
There is facility payment available for hospital outpatient and ambulatory surgical centers. 7 out of 8 of the Medicare Administrative Contractors.

Payment requires appropriate documentation as evidence of the patient's medical condition that is intended to be treated by OrthoGold ESWT. With appropriate billing and documentation physicians and their facility are receiving expected payment."



Leah Amir, MS, MHA

# to access the presentation





## **ACCESSIBLE AND AFFORDABLE ADVANCED WOUND CARE**

## A more practical and overall cost-reducing treatment for the patient



VS

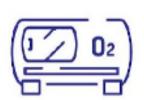


- Extracorporeal shock wave therapy (ESWT) can effectively shorten the healing period and reduce the ineffectiveness of diabetic foot ulcer treatment by 4.8-fold.
- •ESWT is not only superior to standard wound care, but also significantly better than hyperbaric oxygen therapy as an adjuvant treatment.
- Q. Huang et al (2019). Extracorporeal Shock Wave Therapy for Treating Foot Ulcers in Adults With Type 1 and Type 2 Diabetes: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Canadian Journal of Diabetes, 44 (2020) 196-204

#### FASTER HEALING TIME



**SOFTWAVE** 1x/wk; 6-8wks; No side effects 28-42 days healing time



HYPERBARIC Daily treatment Up to 80 days healing time



#### NEGATIVE PRESSURE

Daily treatment, 2-3 dressings changes 96 days healing time



SKIN SUBSTITUTE inventory management

#### **COST-EFFECTIVE**



**SOFTWAVE** \$320/wk - \$1960 total





**NEGATIVE PRESSURE** \$500/wk - \$4,650 total

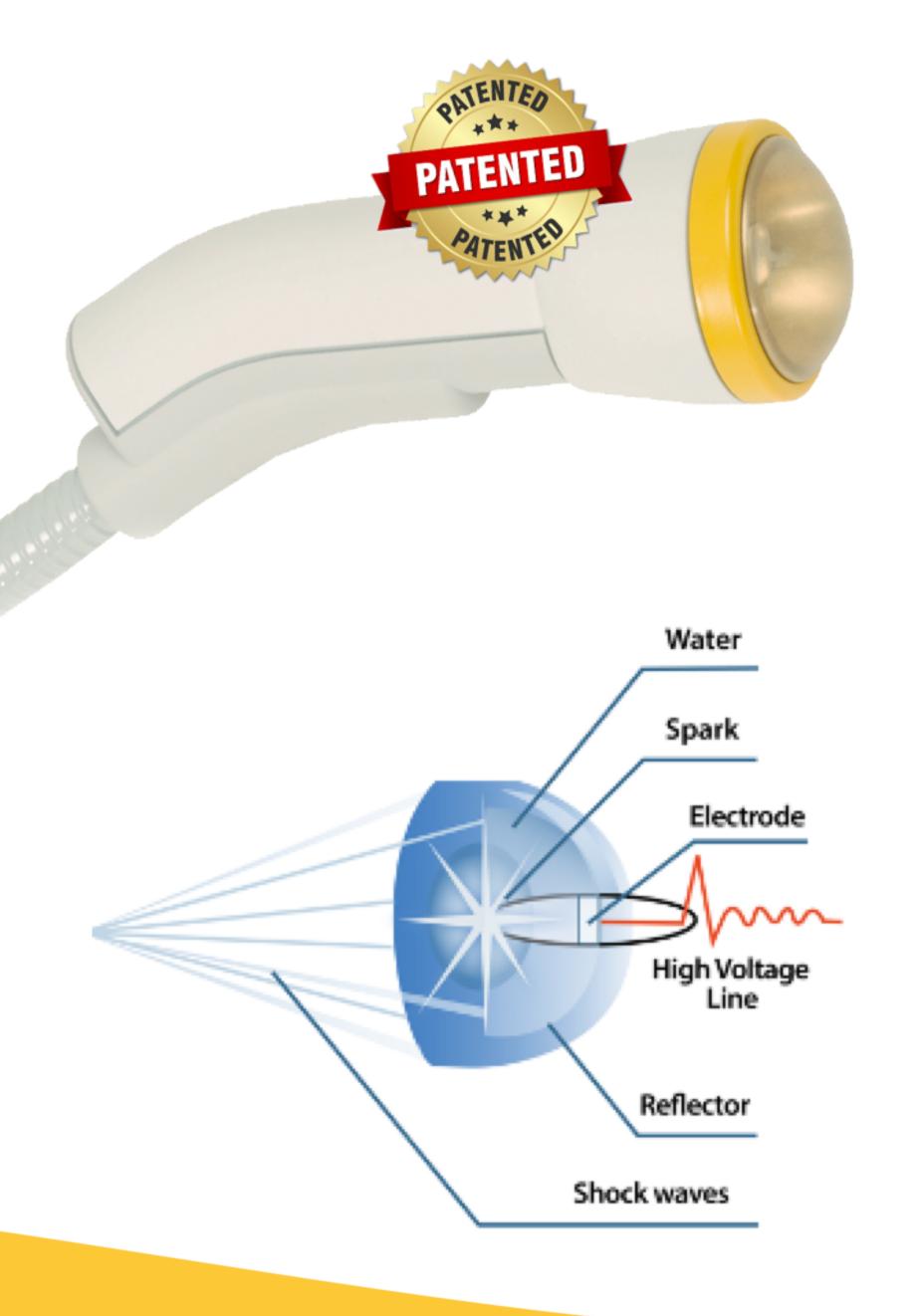


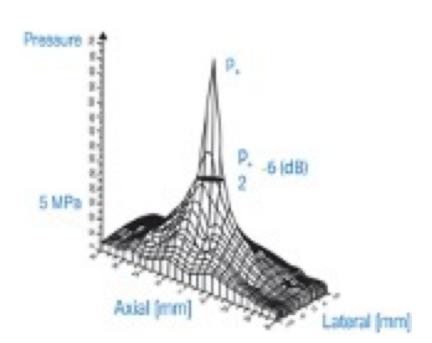


### WHY SOFTWAVE TRT IS DIFFERENT

#### PATENTED APPLICATOR

The SoftWave TRT patented, unfocused applicator design makes it possible to spread energy to a large treatment area to stimulate the body's natural healing process and without microtrauma.



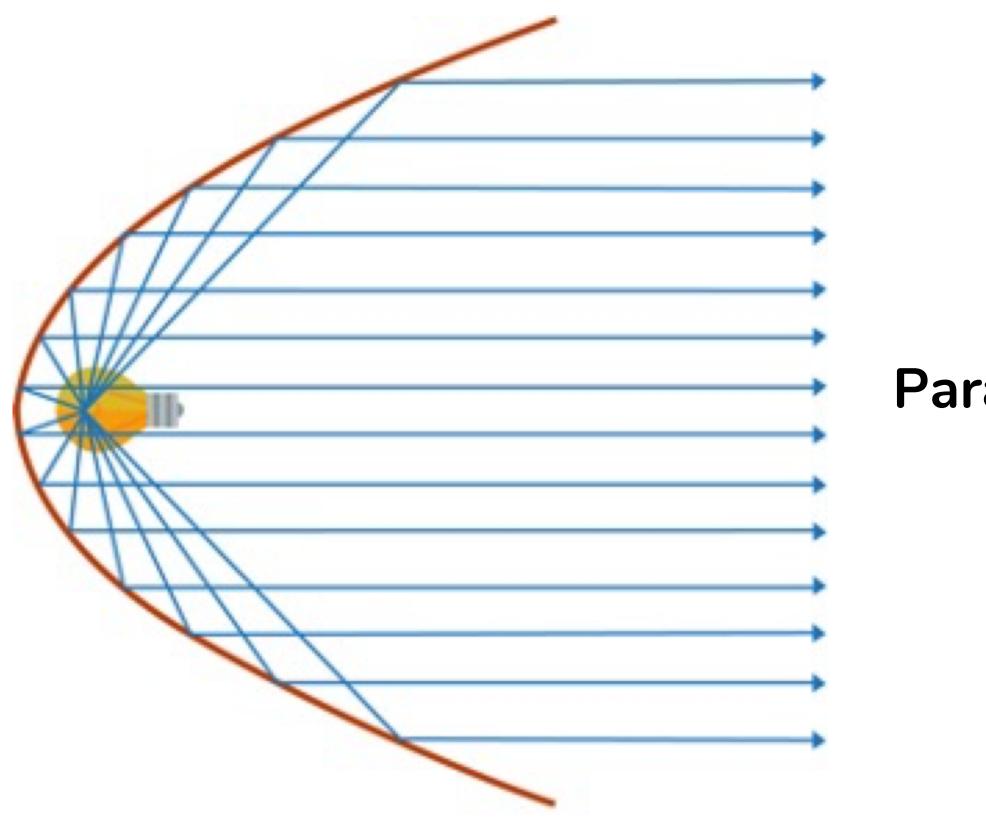


A true shock wave that accelerates wound healing



# DIFFERENTIATING SOFTWAVE FROM OTHER TECHNOLOGIES

SoftWave® technology offers the ONLY Parallel acoustic Shock Wave



Parallel waves



FDA 510(k) cleared for:

- Activation of connective tissue
- Treatment of chronic diabetic foot ulcers
- Treatment of acute second-degree burns
- Improved blood supply
- Temporary pain relief



## LOW INTENSITY PATENTED SHOCK WAVE TECHNOLOGY THAT HEALS



62 yr old DFU patient after 4 SoftWave sessions

Modulates inflammation
Increases blood supply
Promotes angiogenesis
Stimulates cytokines & growth factors
Wound epithelialization
Tissue regeneration

## RESEARCHED | EFFECTIVE | TRUSTED



Fast healing Non-invasive Well tolerated & safe Fast treatment times

Less costly than HBOT, NPWT & CPT

True shock wave that reaches an area wide and deep

- Fast and easy to use
- Convenient for patient and provider
- Position your practice as a leader in innovation
- Reimbursement pathway available CPT codes 0512T and 0513T
- Increase your revenue potential





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www.SoftWaveTRT.com





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