SoftWave

Tissue Regeneration Technologies

INNOVATIVE TECHNOLOGY THAT'S VERSATILE & EFFECTIVE FOR FOOT & ANKLE SPECIALISTS

SoftWave
Tissue Regeneration Technologies

FDA
510(k)
CLEARED

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SOFTWAVE –
THE DREAM MACHINE FOR FOOT & ANKLE SPECIALISTS

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TODAY

Foot and Ankle Specialists have limited options to help patients heal without surgery. Some patients are living with chronic pain affecting everyday life. There should be a way to treat these patients and run a healthy clinic that's profitable while offering value-based care.

NOW THERE IS...

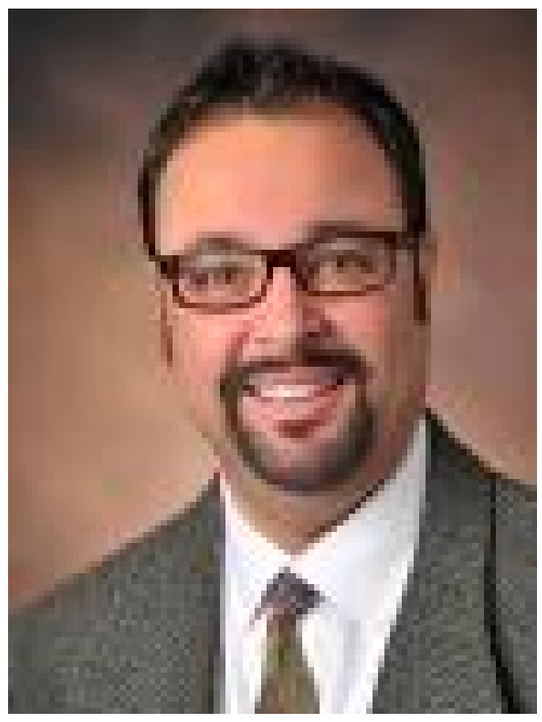
SoftWave
Tissue Regeneration Technologies

A TRUSTED SOLUTION

"We have been using SoftWave Technology in the office for the past 12 months. Our experience has been overwhelmingly positive from both clinical staff and patient satisfaction. We have been able to treat very difficult and chronic conditions while also adding a new tool to treat ulcers.

We have been very satisfied and continue to find new conditions to address with SoftWave.

From a reimbursement standpoint, Wound Care applications are well covered by Medicare and the self-pay model for musculoskeletal applications has been well received by patients."



Zahid Ladha, DPM FACFAS
New Albany, IN

Dr. Ladha founded Foot First Podiatry in New Albany, Indiana in 1998.

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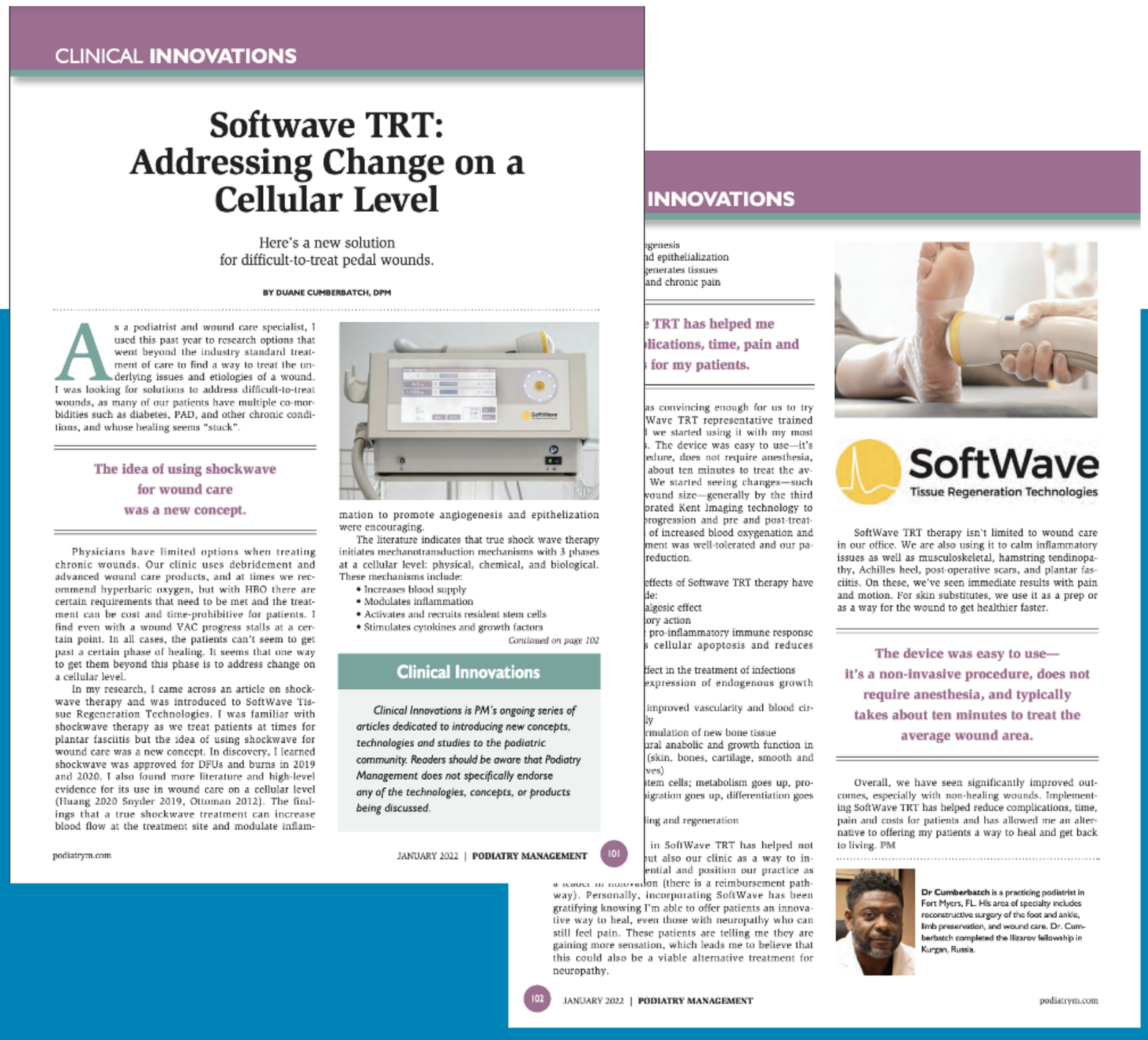
INCREASED REVENUE

"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



CLINICAL **INNOVATIONS**

Softwave TRT: Addressing Change on a Cellular Level

Here's a new solution
for difficult-to-treat pedal wounds.

BY DUANE CUMBERBATCH, DPM

As a podiatrist and wound care specialist, I used this past year to research options that went beyond the industry standard treatment of care to find a way to treat the underlying issues and etiologies of a wound. I was looking for solutions to address difficult-to-treat wounds, as many of our patients have multiple co-morbidities such as diabetes, PAD, and other chronic conditions, and whose healing seems "stuck".

The idea of using shockwave for wound care was a new concept.

Physicians have limited options when treating chronic wounds. Our clinic uses debridement and advanced wound care products, and at times we recommend hyperbaric oxygen, but with HBO there are certain requirements that need to be met and the treatment can be cost and time-prohibitive for patients. I find even with a wound VAC progress stalls at a certain point. In all cases, the patients can't seem to get past a certain phase of healing. It seems that one way to get them beyond this phase is to address change on a cellular level.

In my research, I came across an article on shockwave therapy and was introduced to SoftWave Tissue Regeneration Technologies. I was familiar with shockwave therapy as we treat patients at times for plantar fasciitis but the idea of using shockwave for wound care was a new concept. In discovery, I learned shockwave was approved for DFUs and burns in 2019 and 2020. I also found more literature and high-level evidence for its use in wound care on a cellular level (Huang 2020 Snyder 2019, Ottoman 2012). The findings that a true shockwave treatment can increase blood flow at the treatment site and modulate inflammation to promote angiogenesis and epithelization were encouraging.

The literature indicates that true shock wave therapy initiates mechanotransduction mechanisms with 3 phases at a cellular level: physical, chemical, and biological. These mechanisms include:

- Increases blood supply
- Modulates inflammation
- Activates and recruits resident stem cells
- Stimulates cytokines and growth factors

Continued on page 102

Clinical Innovations

Clinical Innovations is PM's ongoing series of articles dedicated to introducing new concepts, technologies and studies to the podiatric community. Readers should be aware that Podiatry Management does not specifically endorse any of the technologies, concepts, or products being discussed.

…genesis
…d epithelialization
…enerates tissues
…and chronic pain

…e TRT has helped me …lications, time, pain and … for my patients.

…as convincing enough for us to try …Wave TRT representative trained …l we started using it with my most …. The device was easy to use—it's …edure, does not require anesthesia, …about ten minutes to treat the av… We started seeing changes—such …wound size—generally by the third …orated Kent Imaging technology to …progression and pre and post-treat… of increased blood oxygenation and …ment was well-tolerated and our pa… reduction.

…effects of Softwave TRT therapy have …de:
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…rmulation of new bone tissue
…ural anabolic and growth function in …(skin, bones, cartilage, smooth and …ves)
…stem cells; metabolism goes up, pro…igration goes up, differentiation goes

…ling and regeneration

… in SoftWave TRT has helped not …ut also our clinic as a way to in…ential and position our practice as …a leader in innovation (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. These patients are telling me they are gaining more sensation, which leads me to believe that this could also be a viable alternative treatment for neuropathy.

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SoftWave TRT therapy isn't limited to wound care in our office. We are also using it to calm inflammatory issues as well as musculoskeletal, hamstring tendinopathy, Achilles heel, post-operative scars, and plantar fasciitis. On these, we've seen immediate results with pain and motion. For skin substitutes, we use it as a prep or as a way for the wound to get healthier faster.

The device was easy to use—it's a non-invasive procedure, does not require anesthesia, and typically takes about ten minutes to treat the average wound area.

Overall, we have seen significantly improved outcomes, especially with non-healing wounds. Implementing SoftWave TRT has helped reduce complications, time, pain and costs for patients and has allowed me an alternative to offering my patients a way to heal and get back to living. PM

Dr Cumberbatch is a practicing podiatrist in Fort Myers, FL. His area of specialty includes reconstructive surgery of the foot and ankle, limb preservation, and wound care. Dr. Cumberbatch completed the Ilizarov fellowship in Kurgan, Russia.

"(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.

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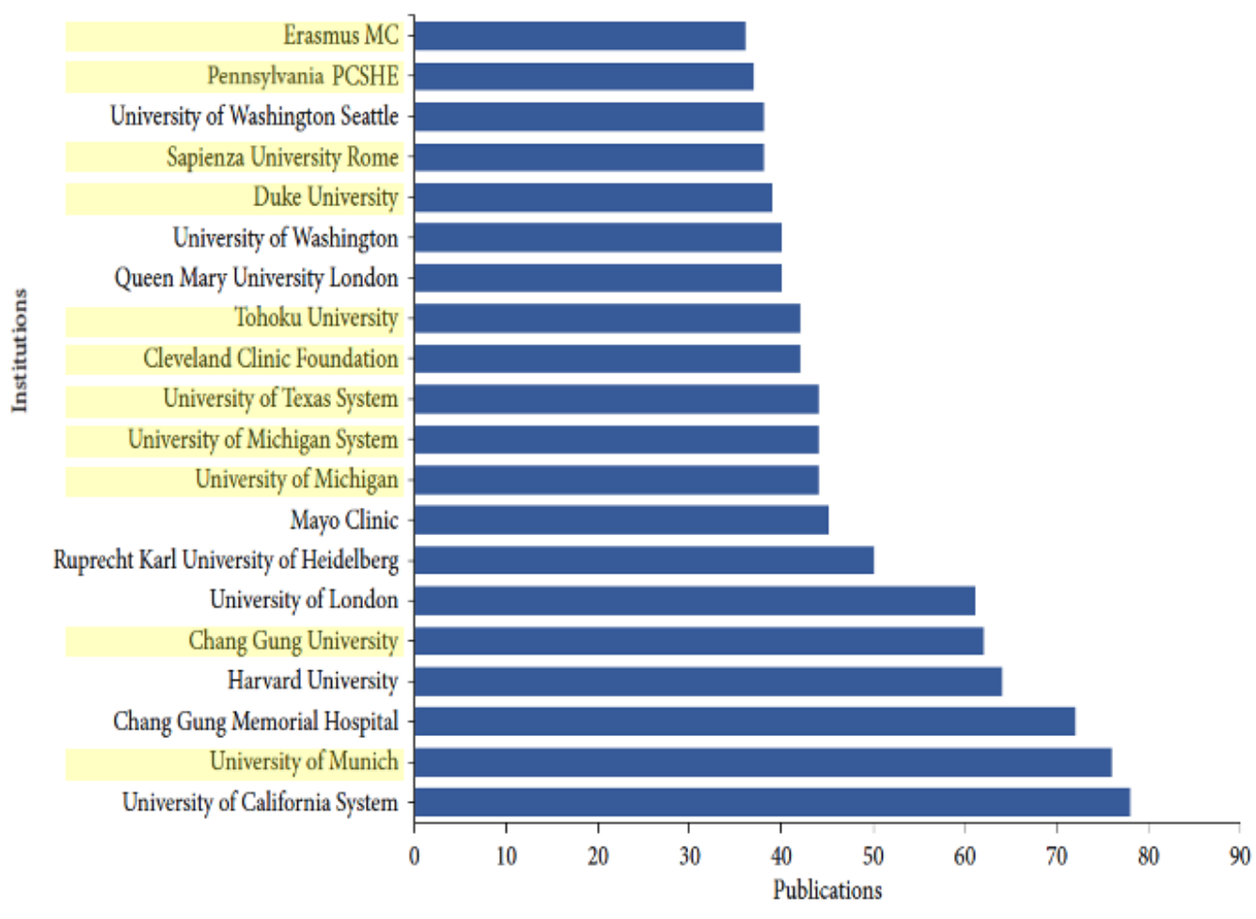
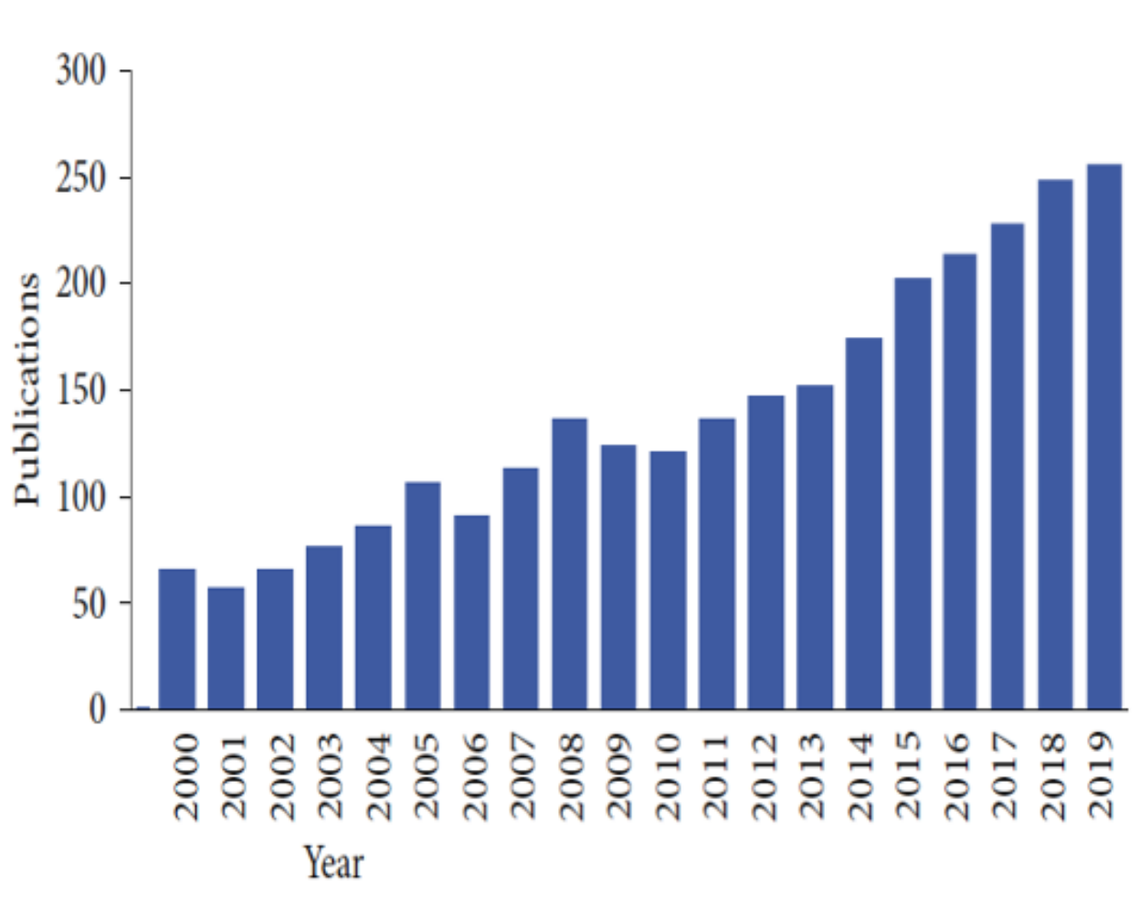
EXTRACORPOREAL SHOCKWAVE THERAPY IS EVIDENCE-BASED

Studied over 1,000 times in the past 5 years

Studied in major U.S. academic institutions





THE AMERICAN COLLEGE OF FOOT AND ANKLE SURGEONS STATE

"Extracorporeal shockwave therapy (ESWT) is safe and effective in the treatment of plantar fasciitis."

The Journal of Foot & Ankle Surgery ■■ (2017) ■■–■■

Contents lists available at ScienceDirect

The Journal of Foot & Ankle Surgery

journal homepage: www.jfas.org

ACFAS Clinical Consensus Statement

American College of Foot and Ankle Surgeons Clinical Consensus Statement: Diagnosis and Treatment of Adult Acquired Infracalcaneal Heel Pain

Harry P. Schneider, DPM [1,2,3], John Baca, DPM [4], Brian Carpenter, [5,6], Paul Dayton, DPM [7,8], DPM Adam E. Fleischer, DPM, MPH [9,10], Brett D. Sachs, DPM [11,12]

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2 *Assistant Professor of Surgery, Harvard Medical School, Cambridge, MA*
3 *Residency Program Director, Cambridge Health Alliance, Cambridge, MA*
4 *Private Practice, Dallas Podiatry Works, Dallas, TX*
5 *Professor, Department of Orthopedics, The University of North Texas Health Science Center, Fort Worth, TX*
6 *Private Practice, Paradise, TX*
7 *Assistant Professor, College of Podiatric Medicine and Surgery, Des Moines, IA*
8 *Residency Program Director, UnityPoint Health, Fort Dodge, IA*
9 *Associate Professor, Dr. William M. Scholl College of Podiatric Medicine at Rosalind Franklin University of Medicine and Science, North Chicago, IL*
10 *Director of Research, Weil Foot and Ankle Institute, Chicago, IL*
11 *Private Practice, Rocky Mountain Foot & Ankle Center, Wheat Ridge, CO*
12 *Faculty, Highlands Presbyterian/St. Luke's Podiatric Medicine and Surgery Residency Program, Denver, CO*

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consensus
heel pain
infracalcaneal
plantar fasciitis

ABSTRACT

Adult acquired inferior calcaneal heel pain is a common pathology seen in a foot and ankle practice. A literature review and expert panel discussion of the most common findings and treatment options are presented. Various diagnostic and treatment modalities are available to the practitioner. It is prudent to combine appropriate history and physical examination findings with patient-specific treatment modali- ties for optimum success. We present the most common diagnostic tools and treatment options, followed by a discussion of the appropriateness of each based on the published data and experience of the expert panel.

Executive Summary

The following document represents the findings of the adult acquired infracalcaneal heel pain consensus panel sponsored by the American College of Foot and Ankle Surgeons. The 6-member panel used a modified Delphi method to reach a clinical consensus regarding the diagnostic and treatment methods based on the best available evidence in the literature, combined with clinical experience and best patient practice.

The panel determined that the following statements are appropriate:

1. Plantarfasciitisisdiagnosed,inmostcases,bythehistoryand physical examination findings alone.
2. Routine use of radiographs is not necessary for the diagnosis of nontraumatic plantar fasciitis.
3. Thepresenceofacalcanealspurwillnotgenerallyalterthetreatment course.
4. Advancedimaging,suchasmagneticresonanceimagingandultrasonography, is not necessary for the diagnosis or guidance of treatment of nontraumatic plantar fasciitis.
5. Inmostcases,infracalcanealheelpainisasofttissue-baseddisorder and calcaneal spurring is most likely not a causative factor.
6. Appropriate treatment of plantar fasciitis requires sufficient understanding of the patient's chronicity of symptoms.
7. Biomechanicalsupportissafeandeffectiveinthetreatmentof plantar fasciitis.
8. Stretching is safe and effective in the treatment of plantar fasciitis.
9. Corticosteroid injections are safe and effective in the treatment of plantar fasciitis.

Financial Disclosure: The development of this consensus statement was funded by The American College of Foot and Ankle Surgeons, Chicago, IL.
Conflict of Interest: Revance Therapeutics sponsored A. Fleischer's research on botulinum toxin injection for plantar fasciitis.
Address correspondence to: Harry P. Schneider, DPM, Clinical Consensus Statements, American College of Foot and Ankle Surgeons, 8725 West Higgins Road, Suite 555, Chicago, IL 60631-2724.
E-mail address: hschneider@cha.harvard.edu (H. Schneider).

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https://doi.org/10.1053/j.jfas.2017.10.018

10. Extracorporeal shockwave therapy (ESWT) is safe and effective in the treatment of plantar fasciitis.
11. Plantar fasciotomy (opened and endoscopic) is a safe and effective option for chronic, refractory plantar fasciitis.
12. Gastrocnemiusrelease is a safe and effective option for chronic, refractory plantar fasciitis when clinically significant equinus is present.

The panel determined that the following statements were uncertain—neither appropriate nor inappropriate.

1. Nonsteroidalantiinflammatorydrugs(NSAIDs)aresafeandeffec- tive in the treatment of the pain associated with acute plantar fasciitis.
2. Diagnostic ultrasonography is an important adjuvant tool in the diagnosis and treatment of nontraumatic plantar fasciitis.
3. Other injection techniques (e.g., amniotic tissue, platelet-rich plasma, botulinum toxin, needling, and prolotherapy) are safe and effective in the treatment of plantar fasciitis.
4. Other surgical techniques (e.g., ultrasonic debridement using a microtip device, cryosurgery, and bipolar radiofrequency ablation) are safe and effective options for chronic, refractory plantar fasciitis.

This document was created to serve as a clinical consensus statement (CCS) from the American College of Foot and Ankle Surgeons (ACFAS) and serves as an update to the ACFAS's 2010 Heel Pain Clinical Practice Guideline (1). It is important to appreciate that consensus statements do not represent "clinical practice guidelines," "formal ev- idence reviews," "recommendations," or "evidence-based guidelines." Rather, a CCS reflects information synthesized by an organized group of content experts from the best available evidence. It can also contain opinions, uncertainties, and minority viewpoints. In contrast to clin- ical practice guidelines, which are based primarily on high-level evidence, clinical consensus statements are more applicable to situ- ations where evidence is limited or lacking, yet there are still opportunities to reduce uncertainty and improve quality of care. A CCS should open the door to discussion on a topic, in contrast to attempt- ing to provide definitive answers. Adherence to consensus statements will not ensure successful treatment in every clinical situation, and the physician should make the ultimate decision using all available clinical information and circumstances with respect to the appropriate treatment of an individual patient. Given the inevitable changes in the state of scientific information and technology, periodic review and revision will be necessary.

Anatomy of the Plantar Fascia

The plantar fascia is synonymous with the plantar aponeurosis of the foot and provides a mechanical linkage between the calcaneus and the toes. It is composed of densely compacted collagen fibers that are mainly oriented in a longitudinal direction, although some fibers run in a transverse and oblique direction (2). The plantar fascia arises mainly from the medial calcaneal tuberosity and attaches distally, through several slips, to the plantar forefoot and the medial and lateral inter- muscular septa. Anatomically, it can be divided into the medial, lateral, and central components (3).

The medial band is anatomically thin and virtually nonexistent at its proximal level. Similarly, the lateral band varies in its structure from relatively thick to nonexistent in 12% of individuals (4,5). When present, the lateral band provides a partial origin for the abductor

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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 Basketball.

"SoftWave is the most user-friendly and effective."

— Dr. O'Malley

The below above is a must-watch. We encourage you to take three minutes to hear from Dr. Martin O'Malley. It's one of many who using SoftWave and seeing amazing results.

CLICK TO WATCH

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

Click Here:
To Schedule a call today

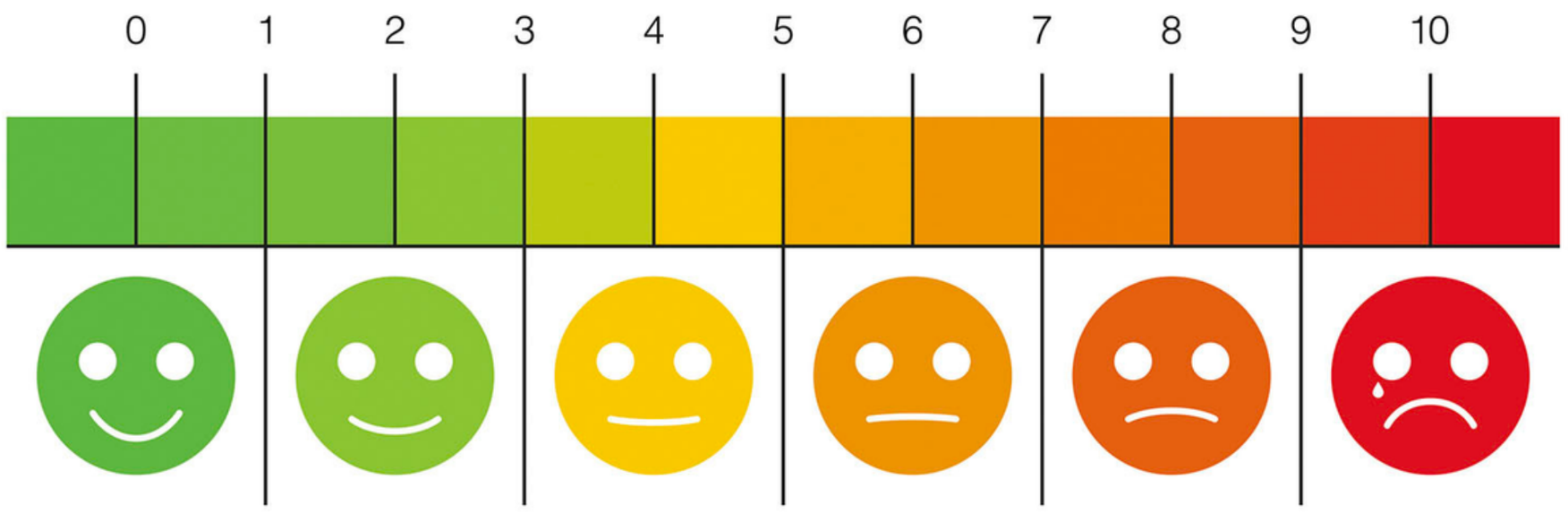
Dr. O'Malley findings

AFTER
SoftWave
2.6

BEFORE
SoftWave
6.7

81%
Patient satisfaction

PAIN SCALE



Foot and Ankle Outcomes Score

53.7 to 75.7

The Journal of Foot & Ankle Surgery 60 (2021) 471–476

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The Journal of Foot & Ankle Surgery

journal homepage: www.jfas.org

ELSEVIER

Efficacy of Unfocused Medium-Intensity Extracorporeal Shock Wave Therapy (MI-ESWT) for Plantar Fasciitis

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ARTICLE INFO

Level of Clinical Evidence: 4

Keywords:
foot and ankle outcome score
heel pain
OrthoGold 100™ shock wave device
plantar fascia
shock wave therapy
visual assessment scale

ABSTRACT

Extracorporeal shock wave therapy (ESWT) is a promising treatment for plantar fasciitis (PF), however, treatment results have varied due to inconsistencies among types of shock wave treatment and devices used. This retrospective chart review includes patients who underwent ESWT using the OrthoGold 100™ shock wave device (MTS, Konstanz, Germany) for PF between January, 2013 and September, 2018. There were 108 patients (119 heels) identified, with a mean age of 51.7 ± 16.5 (Range 21-83) years. Patients were treated weekly for 3 weeks, with 2000 impulses per session at an energy flux density between 0.10 and 0.17 mJ/mm². Mean follow-up duration was 11.5 ± 9.7 (Range 3-51) months. Mean pre-ESWT pain visual assessment scale improved from 6.7 ± 1.7 to 2.6 ± 2.7 ($p < .001$). The Foot and Ankle Outcome Score subscales: pain, function of daily living, function of sports and recreational activities and quality of life domains improved from 53.7 ± 14.9 to 75.7 ± 16.7 ($p < .001$), from 38 ± 15.2 to 71.8 ± 23 ($p < .001$), from 55.8 ± 16.4 to 71.4 ± 18 ($p < .001$), from 42.4 ± 21.5 to 59.4 ± 20.3 ($p < .001$) and from 44.9 ± 16.4 to 69 ± 23.9 ($p < .001$), respectively. Eighty-eight (81.5%) patients were satisfied with the procedure at final follow-up. Treatment of PF with unfocused shock waves was well tolerated and led to significant pain reduction, functional improvement, and patient satisfaction.

Plantar fasciitis (PF) is the most common cause of heel pain, estimated to affect 10% of people during their lifetime and accounting for more than 1 million office visits per year (1-5). PF most commonly presents from age 40 to 60, and risk factors include obesity, running, and decreased ankle dorsiflexion (4,6,7). Other factors associated with PF include pes planus, pes cavus, spondyloarthropathies, and a tight Achilles tendon (8). Patients with PF typically complain of pain upon first standing in the morning and are tender to palpation at the medial tubercle of the calcaneus (5,8). The majority of cases resolve with conservative therapy alone within 6 to 18 months (4,9). However, 10% of patients may develop chronic pain, significantly affecting quality of life and necessitating further intervention (10).

The diagnosis of PF is mostly clinical, supported by the characteristic pain localized at the medial tubercle of the calcaneus (9). Calcaneal spurs have been associated with PF and may be present on radiograph in 35% to 50% of patients, however their presence is not diagnostic and is often regarded as an incidental finding (8,11,12). Ultrasound may be used to rule out other causes of foot pain and may show plantar fascia thickening (>4 mm), which has been reported in 47.3% of feet with PF (11). Magnetic resonance imaging (MRI) may also be obtained to confirm a diagnosis of PF or to rule out other pathology, however it may be normal in 20% of patients (13).

Available treatments for PF can be broadly divided into nonsurgical and surgical treatments. Nonsurgical modalities include rest, activity modification, ice massage, oral analgesics, strengthening and stretching exercises, orthotics, and splints (1,2). More invasive nonsurgical options include corticosteroid injections, Platelet-rich plasma (PRP) injections, dry needling, and botulinum toxin injections (2,14-16). About 5% to 10% of patients may fail nonsurgical treatment and go on to require surgical management, which includes plantar fasciotomy, neurotomy, neurolysis, calcaneal spur resection, and calcaneal decompression (9). Currently, endoscopic plantar fasciotomy is the authors' preferred surgical approach.

Extracorporeal shock wave therapy (ESWT) is an innovative modality that has been shown to be a promising technique in treating PF (17-22). Since its introduction to orthopedics, it has since been used to manage multiple orthopedic conditions, including lateral epicondylitis, calcifying tendinitis of the shoulder, and fracture nonunions (23-28). The

Financial Disclosure: None reported.
Conflict of Interest: None reported.
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PLANTAR FASCIITIS

Plantar fasciitis has emerged as a persistent kind of repetitive strain injury that afflicts runners, hikers, and walkers, and also nearly everyone who stands for a living, especially on hard surfaces. The multi-factorial etiology of plantar fasciitis has led to a significant surge in the number of sufferers while laying a firm base for the growth of companies that provide treatment for this condition.

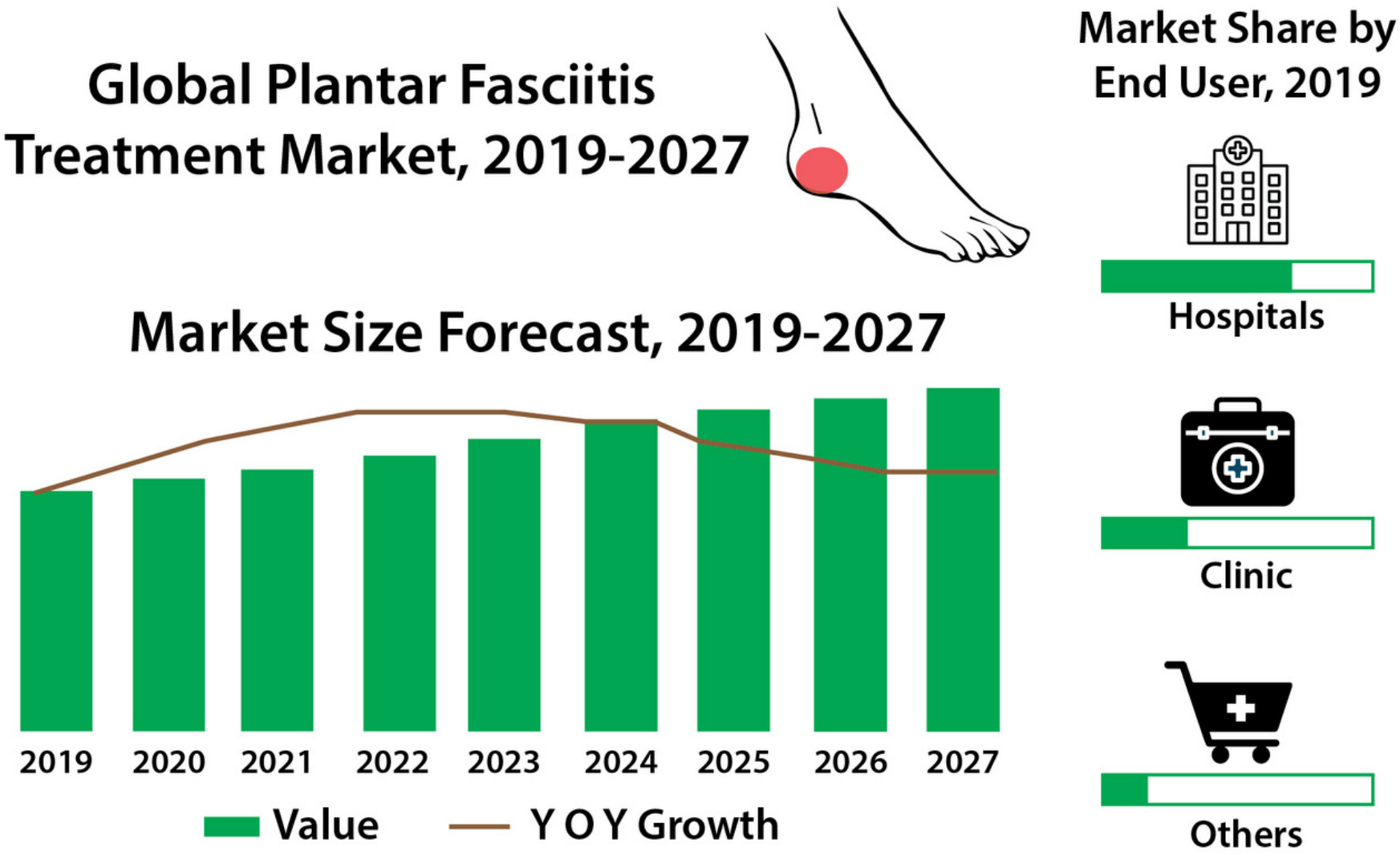
The steadily growing patient population has opened a window of opportunities for stakeholders who are widely adopting technologically-advanced products to alleviate heel pain in less period of time and provide better relief even in worse cases.

No surgery
No injections
No downtime
No medication
Effective treatment

The global Plantar Fasciitis Treatment market size is projected to reach USD 728.1 million by 2028, from USD 596.8 million in 2021,

Plantar fasciitis is a common problem that one in 10 people will experience in their lifetime.

Studies on a cortisone injection reveal short-term pain relief of a few months. This relief can last for a few months and perhaps longer.



ACHILLES TENDINOPATHY

Shockwave therapy to treat Achilles tendonitis is an excellent treatment option for patients who have failed other forms of treatment. It can also be an excellent tool for treating an acute injury since it can help act as a pain reliever and kickstart the healing process.

Did you know?

Approximately

1/5 of Adults

report issues with chronic pain.

This can lead to almost

$300 Billion

lost in productivity each year.

Shockwave therapy for Achilles tendonitis can help reduce inflammation, promote blood flow, and reduce calcifications. Ultimately, combining the effects of shockwave therapy can improve the body's natural healing process.

ADVANTAGES OF SOFTWAVE THERAPY FOR MORTON'S NEUROMA

Safe
Effective pain relief
Non-invasive
Proven
No downtime

1. Safe
Minimal side effects
2. Efficacy
SoftWave therapy has been studied in clinical settings with effective results. It is often used to increase the available space for the neuroma to sit. By releasing the space around the large nerve, the pain decreases and may be acceptable to the patient. It may also be used as a bridge to other more definitive treatments.
3. Non- invasive
The safety profile of this treatment is very high because it is a non-invasive treatment. Eliminating surgery eliminates risks such as complications of infections and anesthesia.
4. Unique Mechanism
No other treatment for Morton’s neuroma works quite in the same way. Other treatments are surgical that involve breaking the skin barrier to remove or excise the neuroma. Cryotherapy and radiofrequency ablation have been used but these methods involve the death of certain cells, despite being noninvasive.
5. Proven Track Record
SoftWave therapy has been studied in clinical trials with a good track record of success.
6. Efficient
SoftWave therapy is fast for patients and providers. Since there is no postoperative recovery time, patients have no downtime.

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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/)

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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.(1) Because DFUs have a complex etiology and have various interactions between local and systemic factors, treatment established in current guidelines is not always successful.(2) 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.(3) 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

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COSTS OF TREATING DIABETIC FOOT ULCERS ARE RISING

25% of people with diabetes will develop foot ulcers. Recurrence within 5 years is 28-51%

15% of diabetic wounds will **progress to amputation**

Every hour,
TEN
Americans undergo amputation due to diabetes

50%

50% of people who have an amputation **die within 5 years.**

2.3x greater health care costs for Americans with diabetes

$327B annual cost of diagnosed diabetes in America

34M
More than 34 million Americans have diabetes

By county
less than average: 0-6%
national average: 7-10%
above average: 11% or higher

88M
More than 88 million Americans have prediabetes

Today in America

Diagosed with diabetes	4,110
Undergo an amputation	356
End-stage kidney disease	159

$1 in $7
Health care dollars is spent treating diabetes and its complications

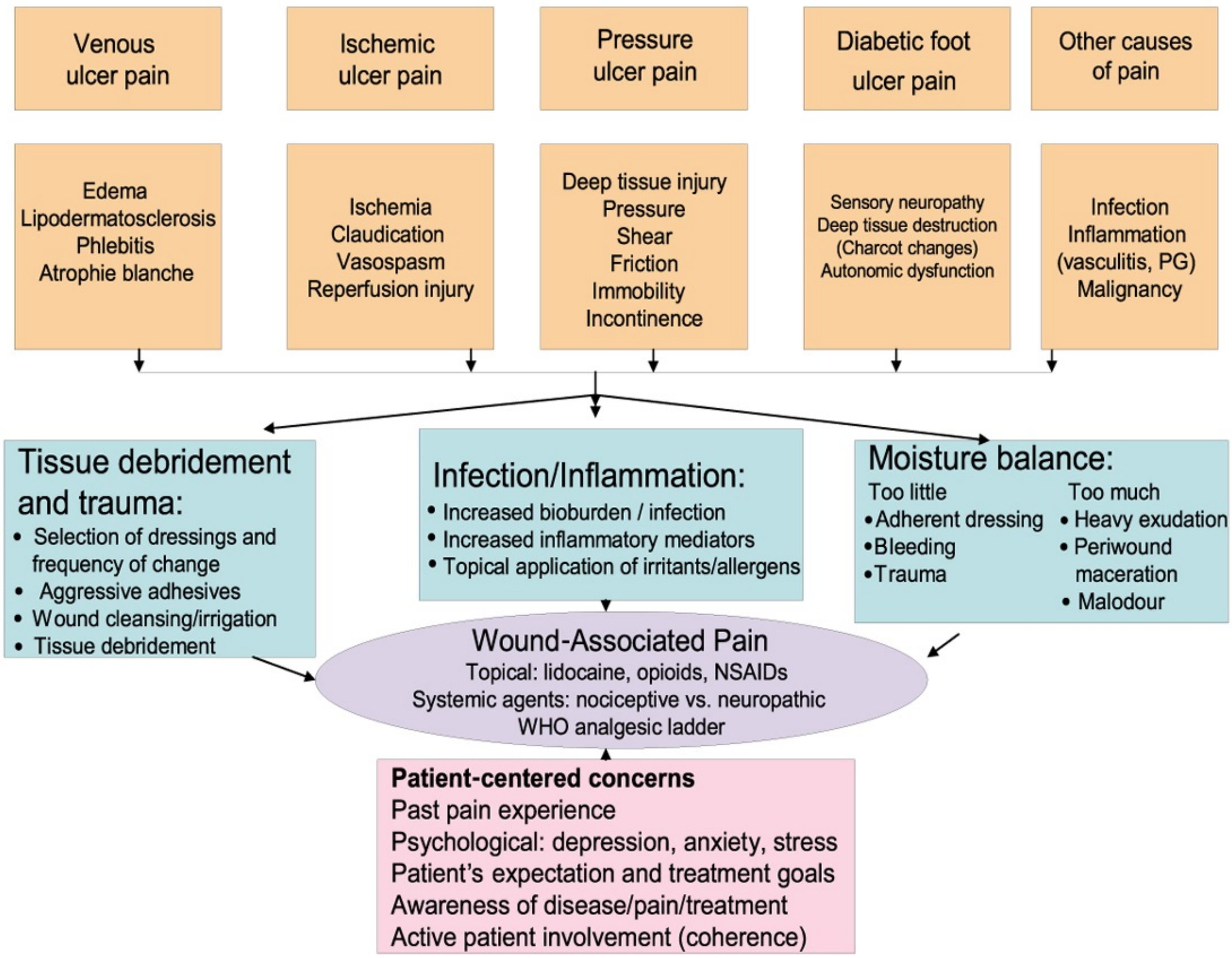
2017 Stats according to the American Diabetes Association

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.(4) The source of the pain can be described as nociceptive(5) or neuropathic and its occurrence as noncyclic, cyclic, or chronic.(6) Nociceptive pain involves pain receptors in the area of injury. In contrast, neuropathic pain is processed by the central nervous system, as in 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

SoftWave
Tissue Regeneration Technologies

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 compared to other non-invasive therapies.

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

FDA 510(k) CLEARED

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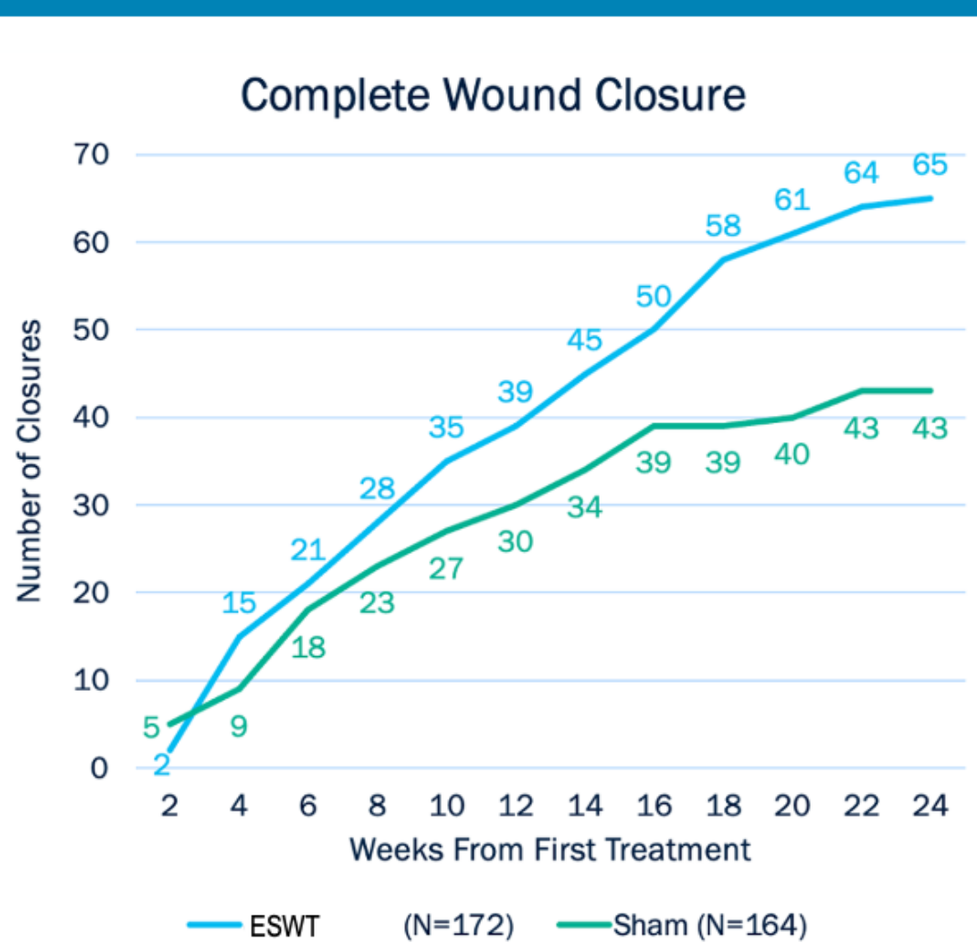
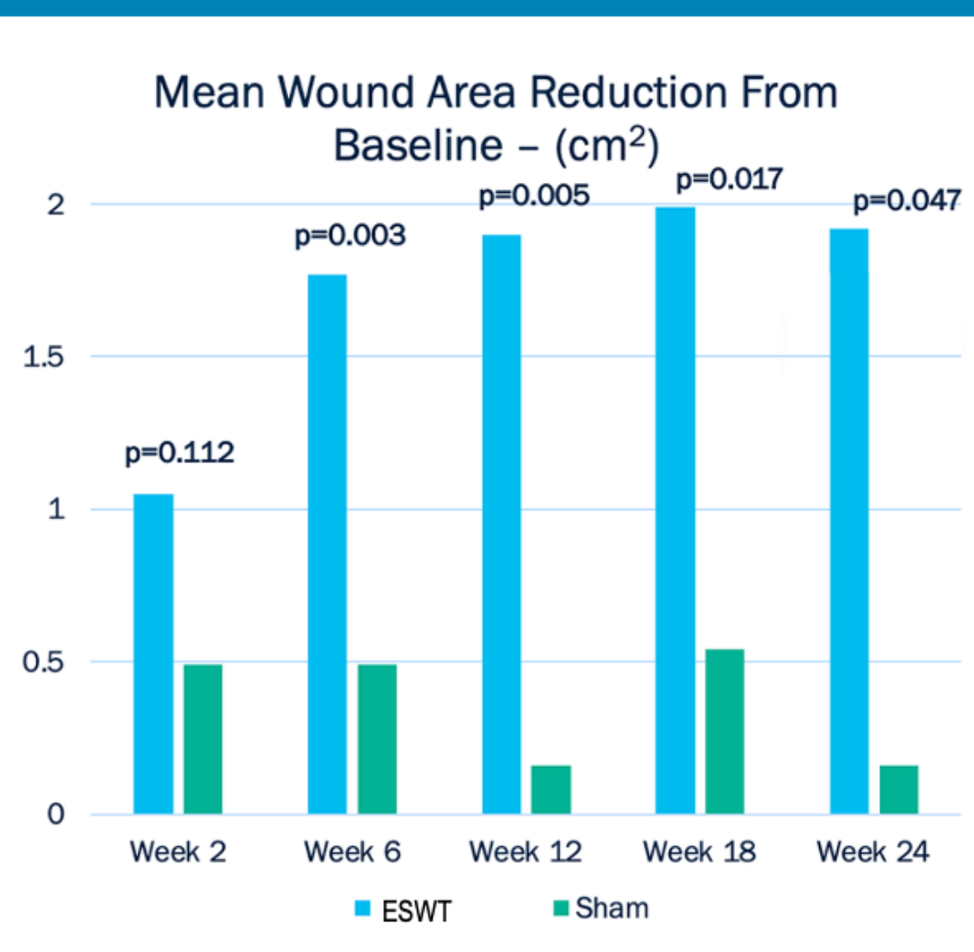
RESULTS

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

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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.

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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 therapeutic effects. This case series examines the effectiveness of ESWT in treating non-healing venous leg ulcers.

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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 weekly: 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.

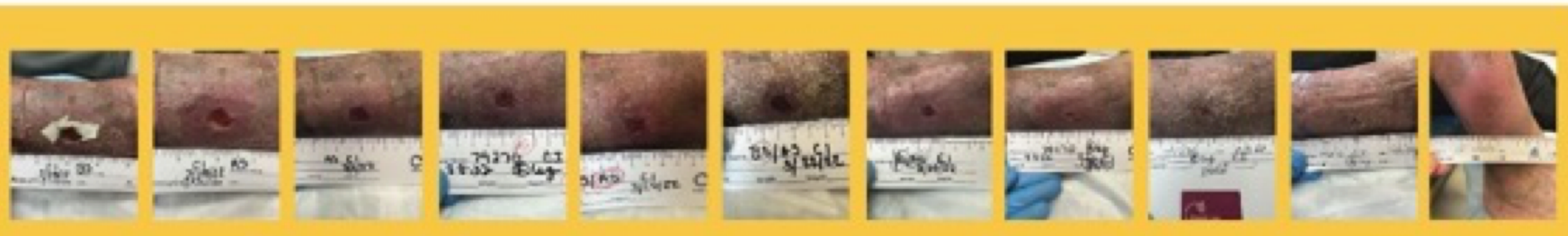
Discussion

93% of Venous 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.

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 bandaging. 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 Regulski DPM, FFPM RCPS (Glasgow), ABAHP

*ESWT device used is the DermaGold 100 by SoftWave Tissue Regeneration Technologies

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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

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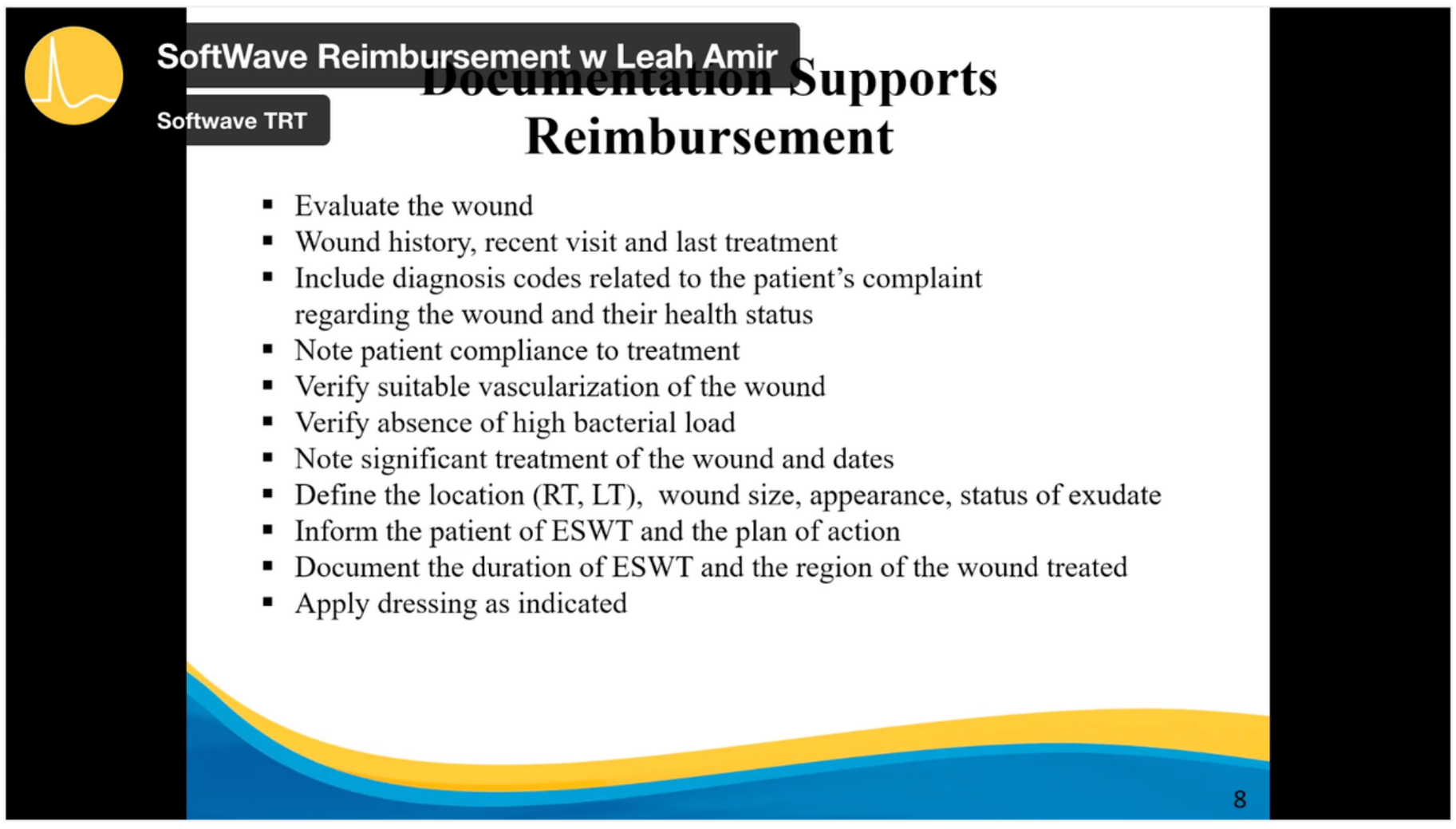
to access the presentation



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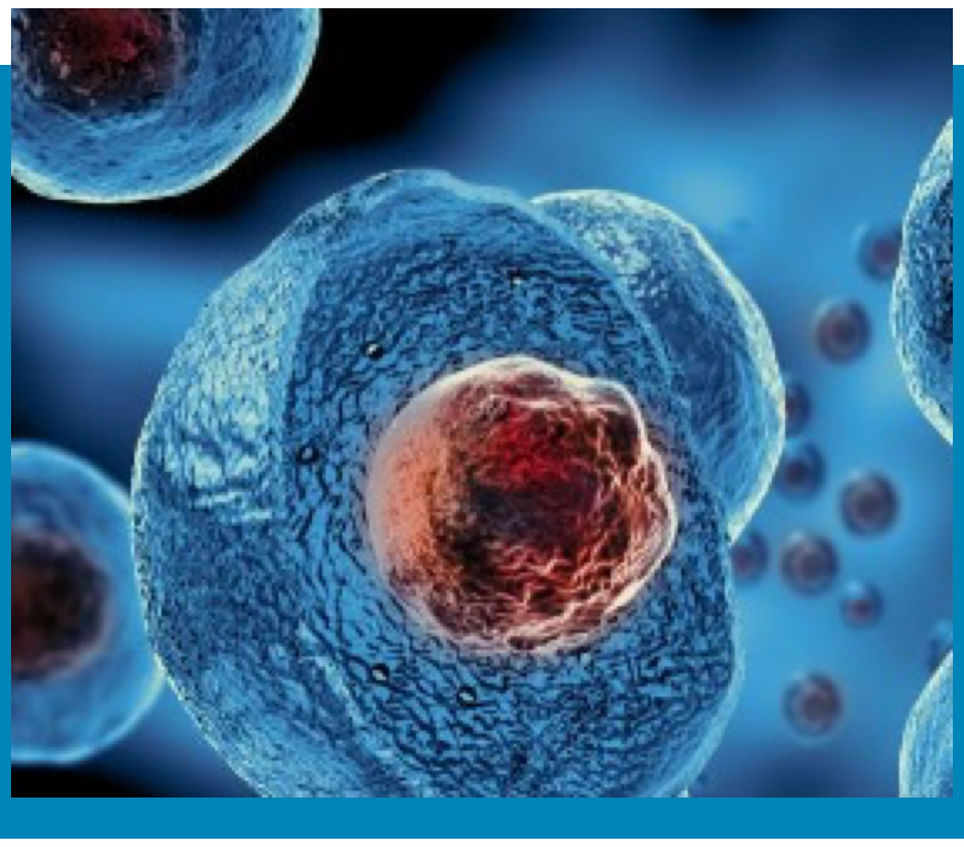
THE SCIENCE

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



Triggering biological responses

PHYSICAL SHOCK WAVE ENERGY

↓

Biological Responses

VEGF FGF PDGF eNOS PCNA

(Growth Factors and Cytokines)

Angiogenesis **Activation S/PCs** **Modulation Inflammation & Immune Response**

Fibroblast Activation **Collagen Synthesis**

Improved Blood Supply

Epithelialization & Tissue Remodeling

WOUND HEALING

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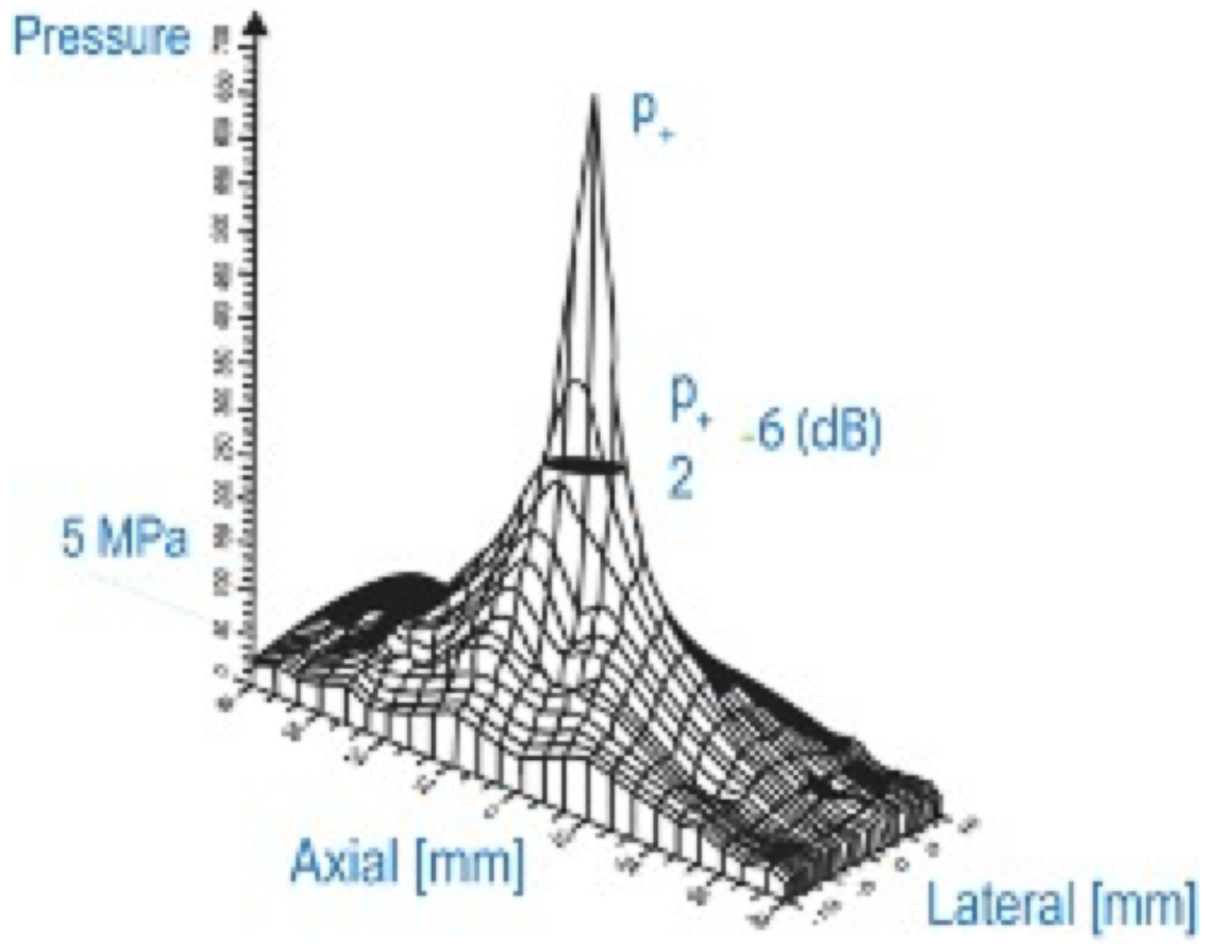
SOFTWAVE EXTRACORPOREAL SHOCKWAVE THERAPY (ESWT) PRODUCES A TRUE ACOUSTIC SHOCKWAVE



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.

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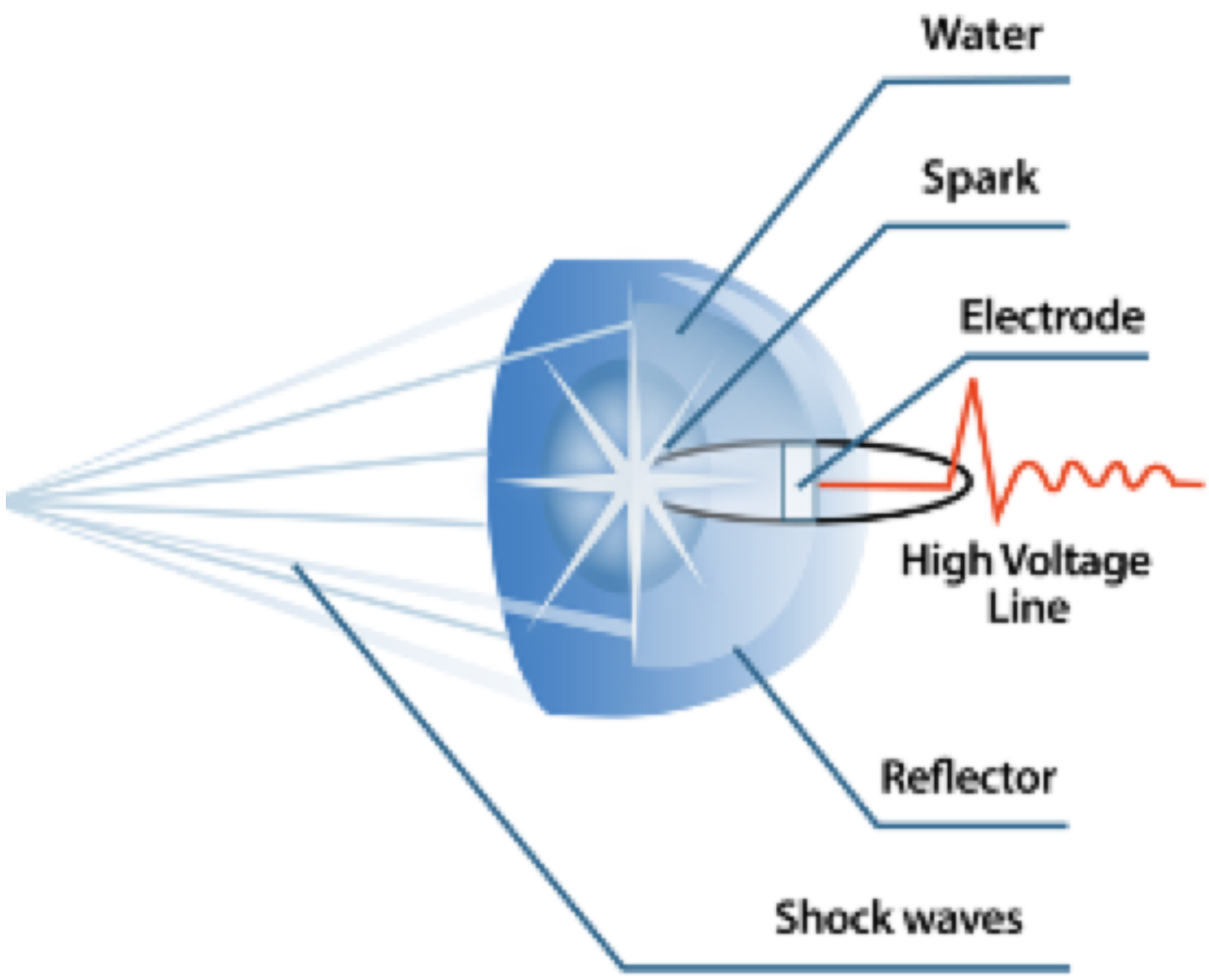
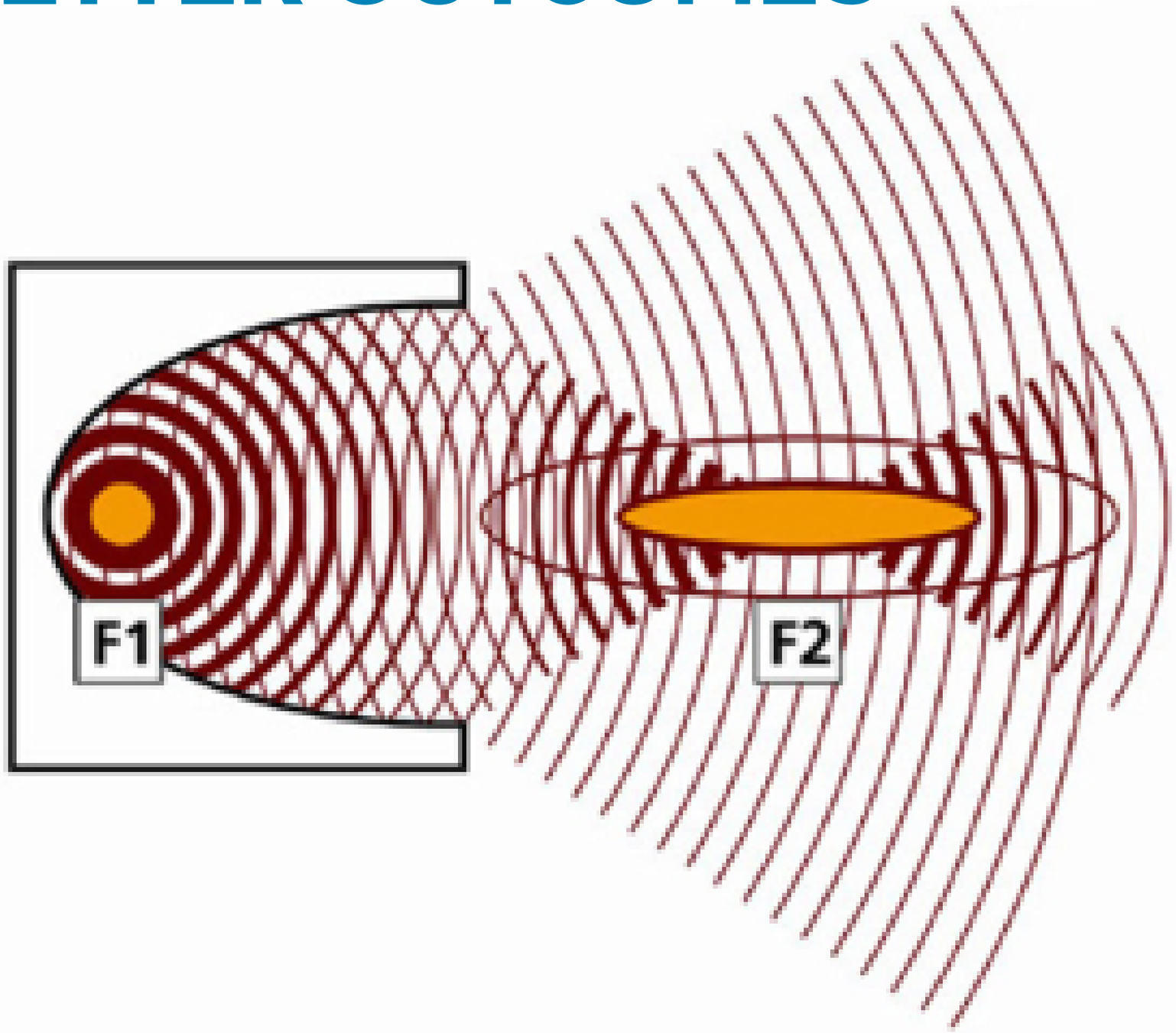
WHY SOFTWAVE TRT IS DIFFERENT

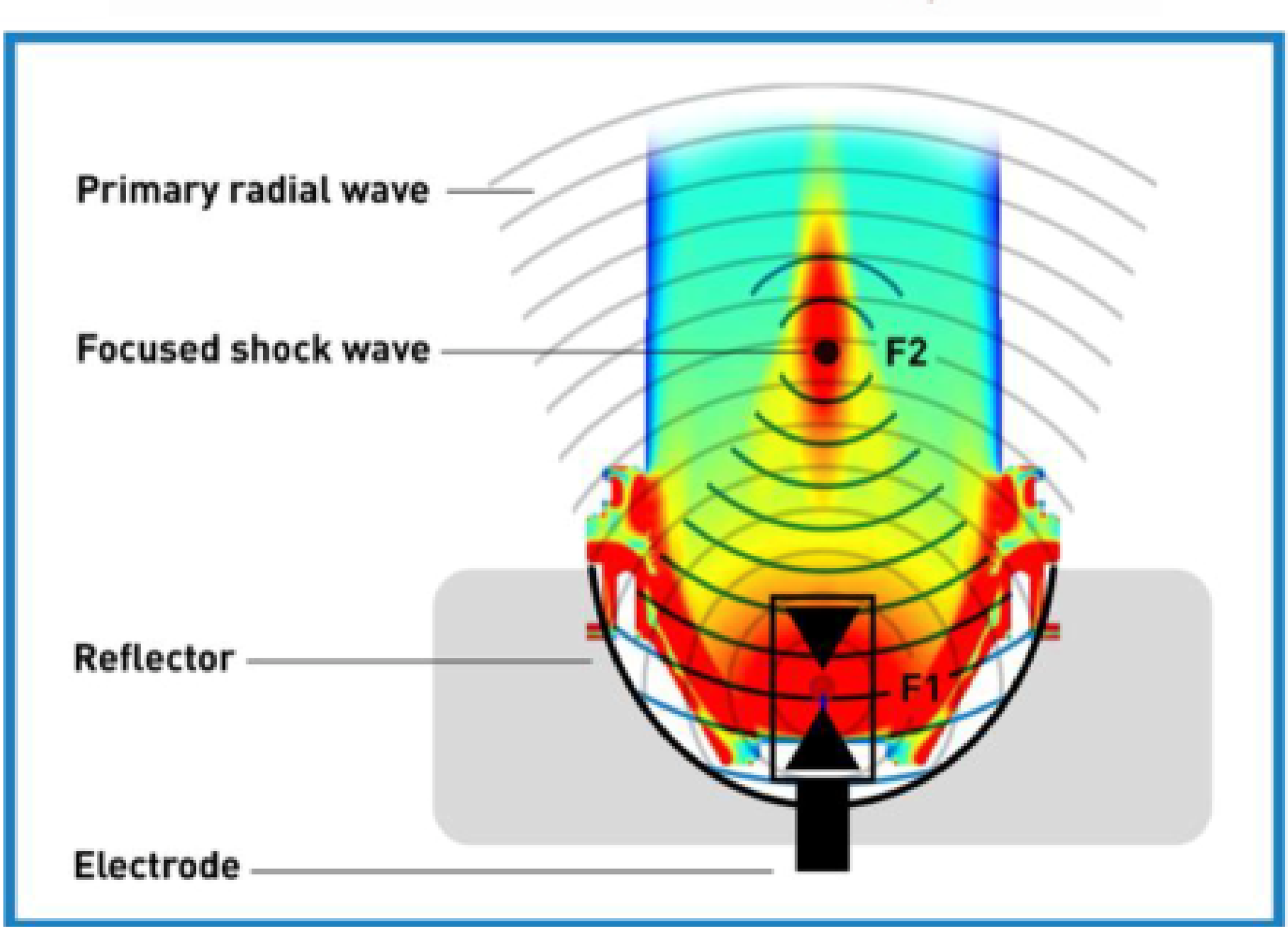
PATENTED APPLICATOR

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 without microtrauma.



SOFTWAVE'S PATENTED PARABOLIC RELECTOR APPLICATOR GENERATES A PRIMARY AND SECONDARY WAVE FOR BETTER OUTCOMES





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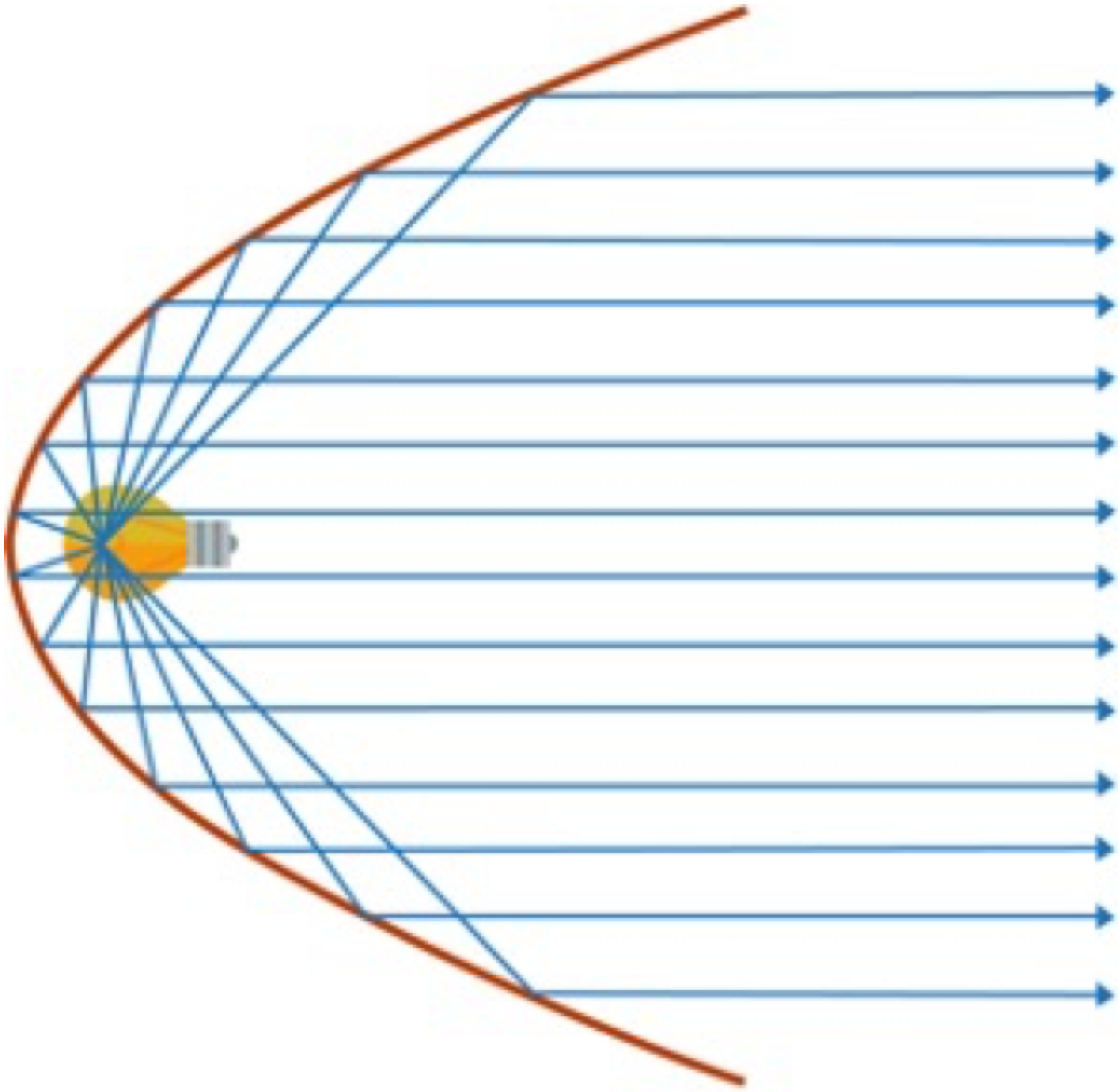
DIFFERENTIATING SOFTWAVE FROM OTHER TECHNOLOGIES

SoftWave technology offers the ONLY parallel acoustic shockwave



Parallel waves

FDA
510(k)
CLEARED

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

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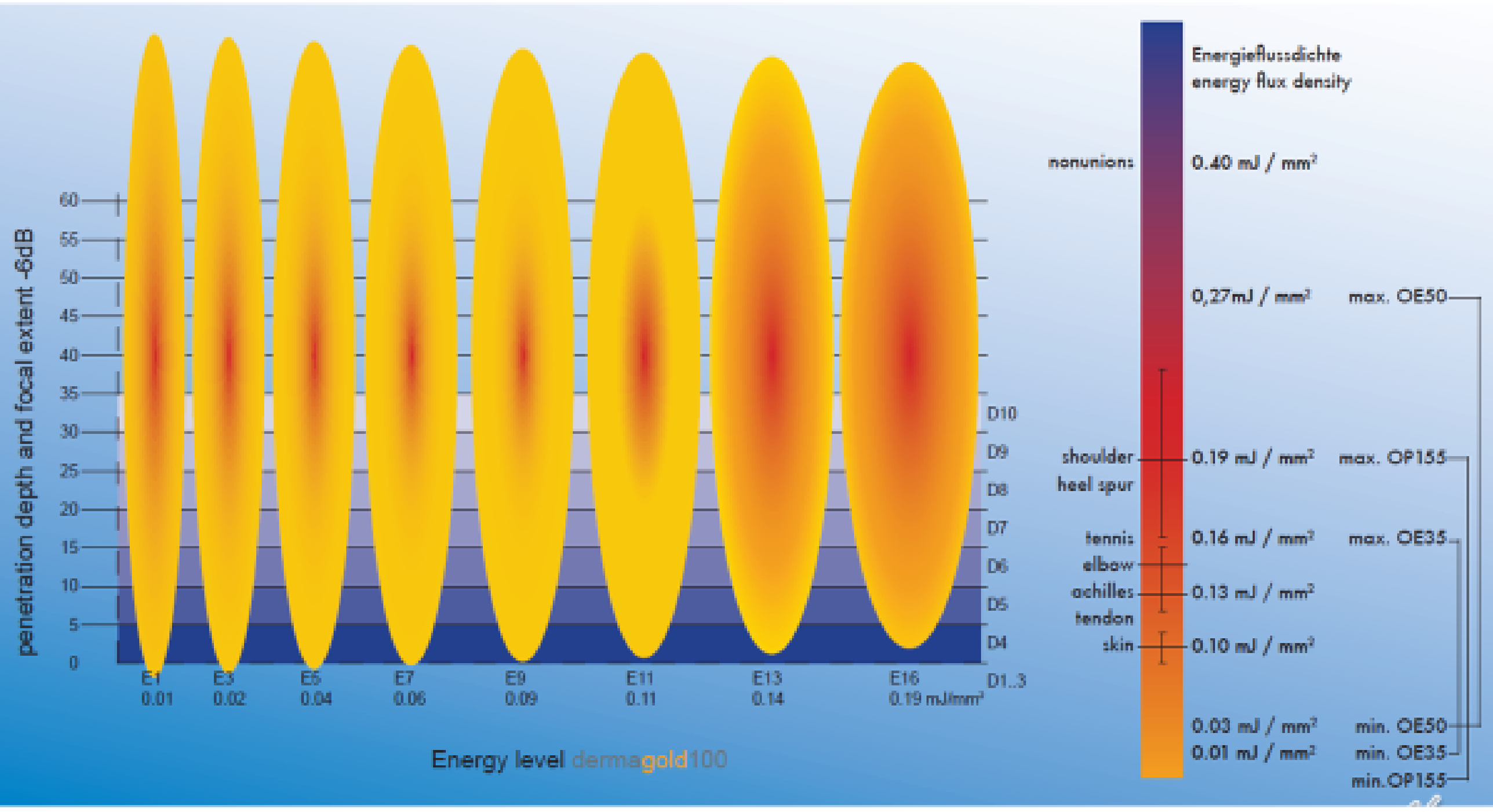
OP155 UNFOCUSED APPLICATOR PENETRATES WIDE AND DEEP



SOFTWAVE

Wider and deeper and is a true shockwave vs a pulse wave

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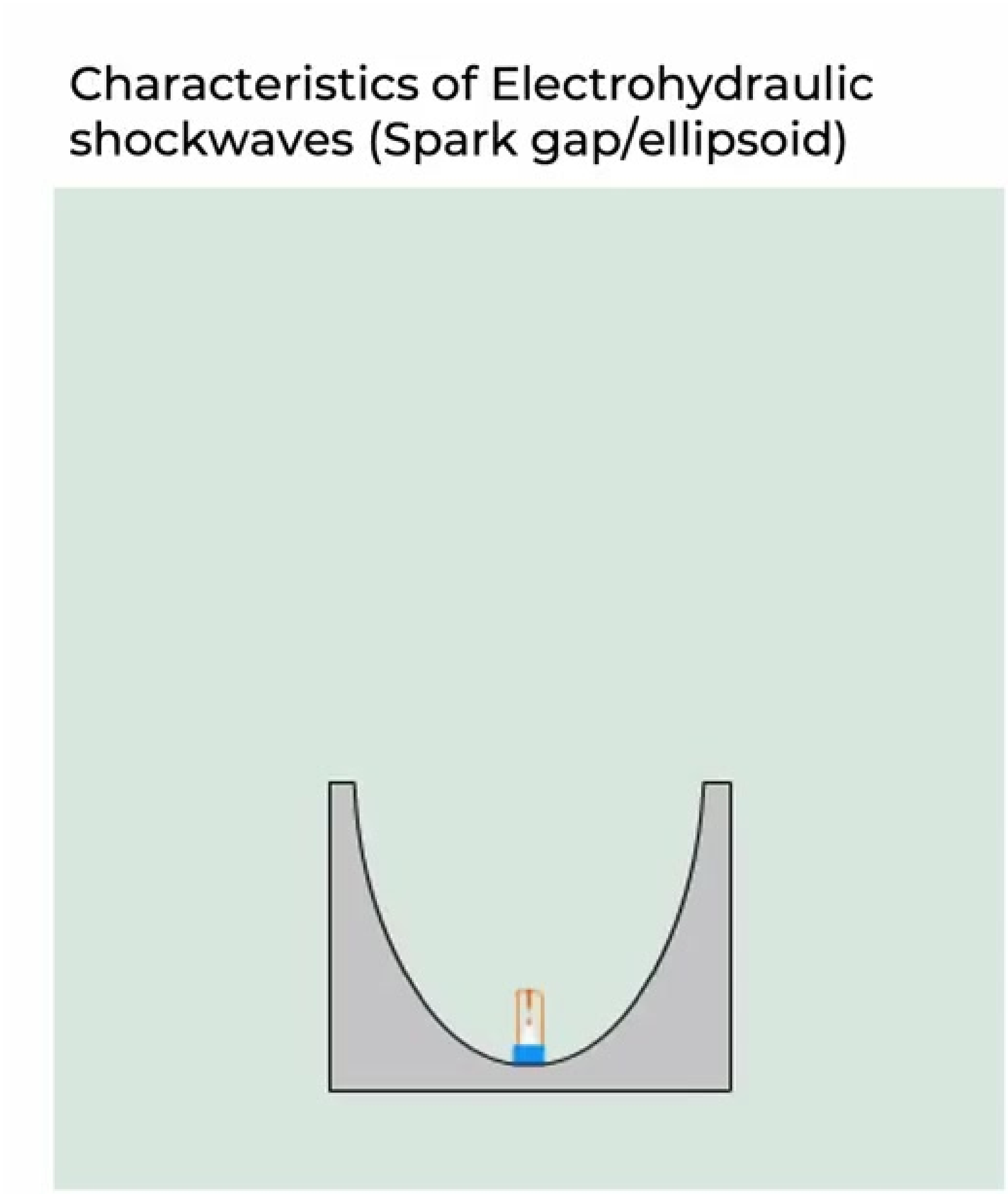
SOFTWAVE DELIVERS

A TRUE ELECTROHYDRAULIC SHOCKWAVE WITH SPARK GAP TECHNOLOGY ensuring optimum energy composition and distribution.

THE ONLY PARALLEL UNFOCUSED SHOCKWAVE DELIVERED FROM A PARABOLIC REFLECTOR



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VERSATILE EFFECTIVE PROFITABLE

"From a Practice Administrator and clinical staff perspective, incorporating Softwave has been very easy. The treatment process is quick, efficient, and very effective. Patients are responding very well and clinical outcomes have been excellent. Also, the increase in revenue has been significant."

Tressea Harvey, PMAC
Foot First Podiatry

Fast and easy to use

Can be applied by SoftWave-trained staff

Convenient for patient and provider

Position your practice as an innovatior

Increase your revenue potential

Expand your business model

SoftWave

Tissue Regeneration Technologies

Get better results with the physics and design of SoftWave's true shockwave technology and get your patients healing faster

Non-invasive

Well tolerated & safe

Fast healing

Fast treatment times

Less costly than HBPT, NPWT & CPT

Modulates inflammation

Increases blood supply

Promotes Angiogenesis

Stimulate cytokines & growth factors

Wound epithialization

Tissue regeneration

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VISIT OUR WEBSITE ON:

www.joinSoftWave.com

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