

TRT- TISSUE REGENERATION TECHNOLOGY

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Acoustic wave therapy is over 30 years old and was first used in medicine for the treatment of kidney stones ([lithotripsy](#)). Sound waves are the standard of care worldwide for stones, pain pathologies, and bone healing. It is a thoroughly researched technology, and it is considered non-significant risk when used for the majority of indications. **TRT's** patented, unfocused acoustic waves, known as **SoftWaves**, produce both positive and negative (Tensile) forces on cells. Our probe generates waves that affect cells within a two inch diameter. Though all of the cells in this target area are exposed, only pathologic tissue reacts.

Cells are used to being exposed to many forces; however, the combination of simultaneous positive and negative forces puts shearing forces on the cell membrane. The shearing forces momentarily make the membranes permeable while still keeping the cell intact. During this duration of permeability, certain proteins and, more importantly, small pieces of RNA are ejected from the cell into the surrounding tissue.

Neighboring cells sense this RNA release via cellular receptors known as toll-like receptor 3 (TLR3). These receptors are activated by RNA pieces released when nearby cells are damaged or die. Softwave treatment, however, triggers TLR3 without damaging cells but rather by just making cells' membranes temporarily permeable. SoftWaves fool the body into thinking an injury has occurred, and we initiate the natural biologic process of repair.

Four to eight weeks after patients' first SoftWave treatment, we see up to a 400% increase in blood vessels (small, medium, and large). We also see a corresponding increase in permanent blood supply, which helps in fighting infections. Consequently, bacteria counts drop dramatically, and biofilms that protect bacteria colonies are destroyed. Immediately following treatment, there is a reduction in pain, swelling, and inflammation. Controlling the inflammatory response is critical in spine injury patients, as the swelling often destroys the remaining functional spinal cord post injury. In the battle against autism, controlling the inflammatory and immune response is also thought to be key factor.

A current 510K submission is under review with the FDA, number K182682, for pain, improved blood supply and connective tissue activation. Previously registered for pain and improved blood supply ISA Code. Several FDA filings in process, a 510K for wounds and for peripheral artery disease, and a 510K or PMA for non-healing bone fractures. OrthoGold 100 has been in

the FDA Q for over 10 years even though there is no debate on the safety and efficacy of the TRT device.

The device has been approved and marketed for over 10 years in nearly all markets outside the USA including Europe, China, Canada and South America. The German Workman's Comp utilizes the TRT technology for Chronic Pain, non union fractures and wound care and has found a 90% decrease in their cost to treat those patient types by utilizing the OrthoGold 100. MTS our manufacturing Partner from Austria Markets this technology.

Pain is the number one cause of addiction. Pain is treated with opioids, thus the addiction. What if the first line treatment of Pain was Softwave technology? Cure the pain first would be our plan. Back pain, lumbar pain is a big cause of Pain and opioid management. One treatment with Softwave cures the back pain just as one treatment with the softwave cures most pain. Cure the pain and decrease opioid management. It will be proven as a result of this initiative that the combination of a SoftWave treatment Pre surgery and one or two additional treatments post-surgery will reduce the number of pain medicine prescriptions by at least 50%. There are additional benefits as well: shorter recovery time, reduced scaring, fewer complications, and an improved appearance of the scar. Conservatively, the therapy could reduce the number of addicts created as a result of post-surgery pain medicines by at least 50%. If this therapy is available to surgeons and a reasonable reimbursement rate established, the number of new accidental addicts created post operatively each year are likely to be dramatically reduced. Even though many surgeons know this works, or even believe it may work, they will not offer this technology if they are not reimbursed to do so. The average cost of this therapy in the US is less than \$500 including the technician. This cost is often less than the cost of prescription medications, currently in use. It is also understood that a huge percentage of addicts become addicted as a result of an accident, trauma, or injury resulting in chronic pain such that they are prescribed pain medications and many of these patients progress to opioid addiction to manage the chronic pain. SoftWave therapy has a record of being a highly effective and widely adopted internationally technology to manage acute and chronic pain. The treatment has been used to successfully treat chronic pain experienced by more than 200 NBA and other professional athletes. Additionally, SoftWave is regularly flown to the Emirates to treat chronic pain experienced by dignitaries... There are 10,000 shock wave devices being used world-wide in the treatment of acute and chronic pain. SoftWaves are safe, relatively painless, non-pharmaceutical, and can be delivered quickly and inexpensively. SoftWaves can be added to the standard of care to support the recovering addict. Reason and experience tell us that if the pain is not addressed, the addiction will continue. Pain is treated with medication. The medication masks the pain; it does not cure the pain. Softwaves cure the pain thus medication is not needed or no longer needed to treat the pain. It is also understood that chronic and acute pain often presents during the detoxification and rehab process. This pain can also be managed by softwave technology to decrease detoxification time and pain. Additionally, a patent pending process of targeting a patient's reflexology points on the hands and feet during recovery may greatly reduce

the side effects felt by the patient during the withdraw period. Patients have stated and SoftWave operators have observed patients feeling calmer and more relaxed after these treatments. This is a very exciting discovery but the results are very preliminary. In the 20 plus cases that I have witnessed the outcomes most often produce amazing tearful response. Again, this can be quickly and safely proven or not. It is understood by doctors and therapist dealing with addiction that a huge percentage of males suffering from opioid addiction suffer from erectile dysfunction. This ED causes depression and prevents an obstacle to recovery. SoftWaves (electro hydraulic unfocused ESWT) therapy is the new patented standard of care for the treatment of ED with over 50,000 patients successfully treated last year. Finally, based on our related research, we believe that we will have a strong benefit when we treat the teeth and gums of meth addicts. We are supporting the first such trial and will apply for an IRB within 90 days to treat the first patient's.

Any improvement that we can make to the teeth, gums, and mouth of these patients is a positive. We proved in a periodontal disease at the University of Kentucky, that one treatment of the softwave technology would heal severe periodontal disease and that the treatment killed the pathogens that needed to be killed and left alone the good mouth flora. This was a stunning development in the study.

Many people abuse opioids initially prescribed to reduce pain resulting from surgery, trauma, injury or other pain related events. We call this the accidental addiction patient.

This device will prevent opioid abuse by drastically reducing pain post surgically such that prescribing opioids can be avoided in at least half of all surgical interventions in the USA. One 5 minute treatment post surgically in the OR and one at the first post office visit will reduce pain to a level that is tolerable without pharmaceuticals being required.

This device also we eliminate pain in 75% of all patients within 4 weeks with the application of two or three treatments.

Surgical Pain Patients, existing patients on opioids, existing patients addicted to opioids and experiencing pain, existing patients in treatment for opioid addiction but still experiencing pain. Patients in pain not taking any medications, just suffering in silence, nursing home patients, addiction patients, all pain patients including children can be treated with softwave technology.

- The patented "SoftWave" technology uses various lens configurations to produce pressure waves. These waves have a characteristic pressure profile of short rise-times reaching high amplitudes (comparable to a sonic boom). The pressure waves can be shaped through a reflector, which enables the transmission of either highly-focused SoftWave for use on urinary stones or non-union fractures, or soft-focused pressure waves (i.e., SoftWaves) for most soft tissue indications.

TRT's patented **SoftWave** technology is distinguished from competitors' shockwave technology in that TRT uses a patented parabolic (as opposed to an ellipsoid) reflector in the therapy head, which allows delivery of unfocused waves of acoustic energy over a broad target area. TRT's **SoftWave** technology generates less pain, has a higher efficacy rate, and has a lower re-treatment rate than competitors' high-energy, focused shockwave systems. TRT is the first company to discover that **SoftWaves** have the same or better clinical benefit as high energy focused shockwaves for most medical conditions. Following this discovery, TRT further developed the idea into a useful format, and secured patents protecting its inventions.

- All engineering and other data available to FDA in current 510K submittal K182682

The device is Novel in that it is recognized by the USPTO as the only technology in the world that can cause stem cell attractants to be produced in the targeted clinical area resulting in a biologic cascade that mirrors the body's natural healing process AND modulates inflammation immediately causing an immediate reduction in pain, redness, and swelling. It is the best technology in the world for chronic pain and is in use for this purpose today at Cleveland Clinic, UCSF, UPMC, HSS and over 50 professional sports teams.

Softwaves is proven to eliminate chronic pain and tens of thousands of patients each year eliminate their pain medicines or are prevented from requiring opioid management. This is not a question of if; it is a question of scalability and resources. No other therapies can prevent opioid addiction or help the recovering addict as we have already proven this device can do. Cure the Pain, than there is no need for opioids.

Reduce the number of addicts by 50% over the next 10 years as program launched throughout the USA. As part of our program, we want to treat all pain patients regardless if they are addicted or just simply need pain relief. In treating the patients that are addicted, the device will immediately relieve their pain. Once the patient is no longer addicted we want a program that will train and employ over 10,000 recovered addicts to operate and treat other addicts. We think curing the pain is the first part of the treatment and offering hope is the second part.

- Device is developed and available, and already in use at the finest hospitals and clinics in the world with more than 100 publications validating these claims. All we need is a reimbursement code of 700 dollars per treatment. This will enable us to treat all surgical patients immediately, treatment in an office setting immediately, and addiction center treatment immediately. This can prevent the addition of 2 million accidental addicts per year. We need the coding to include, hospitals, surgery center, clinics, addiction centers, nursing homes, and dental clinics. Dental pain is one of the fastest growing areas of pain addiction in the country. Three days of opioid utilization can cause a patient to be addicted.

We also require labeling from the FDA, CLASS I OR II ACKNOWLEDGING THAT WE REDUCE AND PREVENT CHRONIC PAIN ASSOCIATED WITH OPIOID ADDICTION.

- The endpoints are obvious, an actual measurable reduction of opioid addiction in the USA. We propose starting this program in Eastern Kentucky. Appalachia Kentucky is ground zero for the opioid epidemic and trt has the full support of Governor Bevin and his drug policy team.
- All of existing data is in our current application with the FDA. All engineering and other data available to FDA in current 510K submittal K182682
- Both the manufacturer MTS, and the distributor TRT have passed FDA inspection in the past as well as our leading clinical site and their database of our non union data, the Trauma Center, Meidlin, Vienna, Austria.
- Currently manufacture and sell 10 devices per month. We can double manufacturing capabilities every 4 months. Our Plan is to move our manufacturing from Germany to Eastern Kentucky. We believe we will create over 200 manufacturing jobs once we are at full scale.
- We are GMP compliant, in production with unlimited manufacturing capabilities as per above.
- We have had several applications over the last 12 years with the FDA. Our current FDA application number is K18268
- We request FDA Clearance for the following language. OrthoGold helps prevent or minimize chronic and acute pain both pre and post surgically. Softwaves minimize chronic and acute pain for all pain patients and could benefit recovering addicts by eliminating or reducing their chronic and acute pain such that they no longer require drugs, legal or illegal.

To prevent opioid addiction and to help addicts in their recovery.

SoftWaves are electro hydraulically generated acoustic waves delivered “unfocused” into a patient via a parabolic lens. The first shockwave patient was treated over 30 years ago for the first FDA approved indication, kidney stones. The technology has evolved considerably and is now used for a myriad of clinical conditions not requiring any analgesia, and it can be performed in any doctor’s office or health center. The risks are nearly nonexistent and the proven mechanisms of SoftWaves in medicine are well understood. The mechanisms of action that are of interests in our discussion regarding upload and other pharmaceutical addictions are as follows:

- SoftWaves immediately modulate inflammation, pain, and swelling and cause an immediate increase in the blood supply in the targeted area. This will immediately reduce pain and inflammation in most patients. The basic science is documented and includes certain cellular receptors (TLR3), an increased permeability of cellular surfaces, and the release of exosomes containing proteins and RNA that trigger a biologic cascade.
- A permanent increase in blood supply beginning as soon as 4 weeks after treatment and continuing to improve up to a period 12 weeks after treatment. It is proven in animal models that there is a 300% increase in small, medium, and large blood vessels in the targeted ischemic or pathologic tissue.
- It is estimated that 2 million opioid addicts are created annually as a result of elective surgeries alone. Plastic surgery is a large percentage of these cases. This number grows dramatically when you include all surgeries. In randomized controlled clinical trials, it was proven that when Softwaves are applied to a patient's surgical incision during surgery (after it is closed), the post surgery recovery time is reduced, there are fewer complications, and most importantly pain is reduced post-surgery requiring less medication and fewer prescription medications.
- Most plastic surgery (elective) patients return to their doctor's office shortly after surgery, in severe pain, demanding prescription pain medications. Historically, doctors prescribed these meds for an extended period of time. Studies have shown that even a few days of these prescription medicines can lead to long term addiction. In a recent small clinical trial, plastic surgery patients who returned to their doctor for their first examination demanding prescription pain medications were offered a SoftWave treatment at the surgical site before a prescription was written. Seventy Five percent (75%) of these patients obtained immediate pain relief such that they no longer required prescription pain meds.

- Team:

- **John Warlick – Co-founder, Manager and Chief Executive Officer**

- **Mark Gronowski – Co-founder and Manager**

- **Dr. Wolfgang Schaden – Manager and Director of Scientific Advisory Board**

- **Dr. Reiner Schultheiss – Chief technology advisor**

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- **Manager Senator Max Cleland, Chief policy advisor**
- **Cassie Rae Hammond - Manager**
- **John Finney VP of Legislative Affairs**
- **Dr. Bill Webb Pikeville KY Primary Care Specialist in Pain Management**
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- **All Team Members and their back grounds are listed on TRTLLC.com**
- **Team has 300 years experience in development of companies, healthcare technology, and success.**