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## Non-Opioid Pain Relief Technology



# TrueRelief: FDA-Cleared Pain Relief

- Non-opioid, non-invasive medical device cleared by the FDA for the relief of:
  - Chronic intractable pain.
  - Post-surgical pain.
  - Post-traumatic acute pain.



TrueRelief is a doctor prescribed treatment that can be used as frequently as needed. The treatment itself is painless.

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# TrueRelief: A New and Different Therapy

- TrueRelief is very different compared to other electrical therapies both because of the proprietary electrical recipe, as well as the probe delivery system:
  - Combination of high frequency (20,000 Hz vs 50-400 Hz).
  - Pulsed direct current (vs alternating current).
  - Dynamically operated probes (vs static electrodes) administered by trained technicians.
- TrueRelief is protected by nine U.S. patents.



# United Health Group/Orthology

**TrueRelief just completed a pilot study with United Health Group's Orthology Physical Wellness division (a chain of physical therapy clinics) and has now been clinically approved for system-wide utilization.**

- Orthology's experience to date is that 97% of treatments have resulted in pain reduction and the average pain reduction has been 64%.



UnitedHealth Group®



ORTHOLGY

physical wellness

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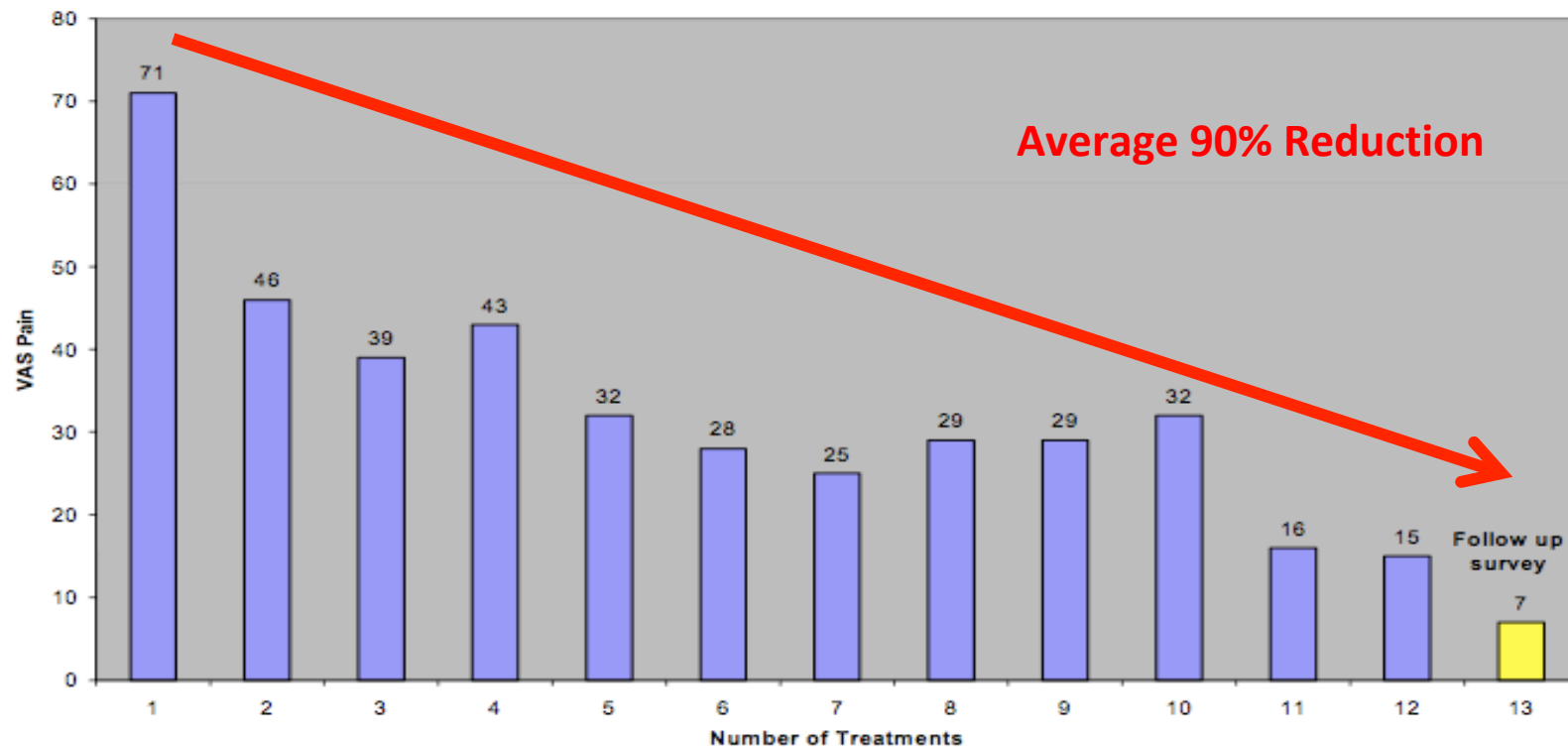
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# Clinical Trial Data

## Louisiana State University Medical School study of 58 subject/ pain conditions treated up to 12 times over four weeks

- 41% of subjects experienced 90% average reduction in pain.
- 62% of subjects experienced 50%+ reduction in pain.



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# Clinical Trial Results Have Been Surpassed by Customers' Patient Outcomes

## Katie Cusack operates a physical therapy practice in Charlotte, NC. In her first two months using TrueRelief:

- Gave 90 TrueRelief™ treatments to 25 patients (an average of 3.6 treatments per patient).
  - ❖ Treated conditions included: Achilles tendinitis, shin splint, sciatica, OA knee, frozen shoulder, lumbar radiculopathy, cervical radiculopathy, acute hip flexor strain, headache, and piriformis syndrome among others.
- 99% of all treatments generated some level of pain relief, with an average of 72.4% relief for each treatment.
- 100% of patients experienced 78% or better total reduction of their pain after the full course of their treatments (which ranged from one treatment to eleven, varying by patient and condition).
- 84% of the patients treated achieved TOTAL (100%) elimination of their pain after the full course of their treatments (which ranged from one treatment to eleven, varying by patient and condition).

# Clinician Testimonial

## Louis Zuniga, PT and owner, Fyzical (4 locations):

*"I am a skeptic by nature. Too much junk in our industry. But TrueRelief really works. I had a patient with post op fusion of her neck with chronic pain for several years. She went from pain of 8 out of 10, to zero in six treatments. I had a physician as a patient with a shoulder issue and in one treatment we increased his range of motion at least 30 degrees. But perhaps my best success to date was lady with significant history of lower back pain who was unable to climb stairs. We literally did the treatment and then she climbed and descended stairs and laughed about it. After just one treatment. It was pretty unbelievable."*

All testimonials are produced with the permission of the patient or medial provider. The outcome stated is the personal opinion of the patient or medical provider only and is not necessarily representative of all users of TrueRelief.

# Clinician Testimonial

## Rudy Byron, MD:



*“Before I was exposed to TrueRelief five years ago there were not many options to address a chief complaint of pain other than pharmaceutical management (pain pills) such as anti-inflammatories. Having TrueRelief as a tool to treat pain has been a game changer in my practice. The speed with which it works is nothing short of astounding.”*

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# Clinician Testimonial

## No one has used TrueRelief more than Harry Glassman, MD:

In response to your inquiry about my use of TrueRelief, I have used it to my benefit and more importantly to the benefit of my patients in over 4,500 cases.

I began using it immediately after surgeries. We treated the operative area before awakening the patient from anesthesia, and then again for the first two days postop. Many of the surgeries that are done by plastic surgeons are not painful, but others such as breast augmentation and abdominoplasties are. Early on I was amazed that the patients having what would usually require narcotics needed no medication at all. As far as reimbursement I did not add any additional charge to the surgery fee for those patients.

The pain management aspect really grew from the surgery patients' amazement that they had no postop pain and some inquired about other conditions they might have had like back pain, plantar fasciitis, TMJ, etc. Consequently we began treating those individuals with clearance from a specialist in their area of pain that I was not missing any serious underlying pathology.

Soon word got out in the community and people started to coming to see me and my staff for issues unrelated to plastic surgery. We got so busy that we had to dedicate a portion of the office specifically for TrueRelief.

We did not bill insurance for the pain management but rather charged them on a cash basis. Originally we were charging around \$450 per treatment and then decided to package 5 treatments for \$1500. Keep in mind that some treatments took 20-30 minutes (sprained ankle) while others took 90 minutes (fibromyalgia). Since this was not my specialty and since it was new and revolutionary and combined with considerable skepticism on the part of many patients, I made the offer to reimburse all \$1500 regardless of how many of the five treatments they had if they did not achieve meaningful relief. In the 12-14 years we had to reimburse less than 10 patients.

In full disclosure we had two patients whose conditions were made more painful after one treatment. We were of the opinion that if they had additional treatments they would improve but it was a hard sell to convince those two individuals, one of whom was my associate in plastic surgery, to continue.

I hope this adequately summarizes my experience. I might add that I have been on the receiving end of the device. Following back surgery 12 years ago I required no medications because the orthopedic surgeon who did my surgery was open minded and allowed my staff to come into the O.R. and treat me before I was awakened from anesthesia.

Harry A. Glassman, M.D.

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# Patient Testimonials

*“My experience with True Relief is unbelievable. I had Achilles tendinitis for 6 months. I got to the point where I could barely walk. I was scheduled for surgery since all other treatment measures had failed. After 1 treatment of True Relief my pain went from a 10/10 to a 2/10. After 4 sessions, I could walk without pain and I cancelled my surgery. I highly recommend True Relief. It saved me from the cost and inconvenience of surgery.” -- Larry*

*“Bottom line, I can play sports again, pain free, thanks to you and TrueRelief! I was truly amazed that after just one short session on my feet that I immediately stepped on the floor without pain. In addition, I played softball that night without pain in my knees for the first time in years. I had so much fun, I felt like a kid...running around just to run around. Even after only two sessions, the pain and swelling of both my feet and knees are virtually gone. I was in the Army for over 22 years resulting in arthritis in both my knees, plantar fasciitis in both my feet, and several other injuries that kept me from fully enjoying life after military retirement. Now I play softball four nights a week, and baseball one day a week, with little to no pain thanks to you and that lovely little TrueRelief machine. Thank you for changing my life!!” -- Stephanie*

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# TrueRelief Innovation Recognized by H&HS + NIH

**The TrueRelief technology was awarded a \$244,000 federal grant from the Health & Human Services Department, in conjunction with the Treasury Department and the National Institutes of Health**

- This Therapeutic Discovery Project Program was initiated by the government to improve healthcare by supporting biotech firms with the largest potential.
- The selection criteria was centered on identifying new technologies that offered significant likelihood to produce new therapies, address unmet medical needs, and reduce the long-term growth of healthcare costs.

# Additional Clinical Trials Planned

## Multiple Clinical Trials and Research Planned

- **Cleveland Clinic:** clinical study of post-surgical pain relief.
- **MD Anderson:** clinical study of post surgical pain relief and wound healing (following Mohs surgery).
- **Duke:** clinical study of post surgical pain relief (following spine surgery).
- **Duke:** clinical study of relief from back pain (non-surgical).
- **UNC Chapel Hill:** clinical study of pain relief and inflammation reduction for lateral ankle sprain.
- **NC State College of Veterinary Medicine:** clinical study of pain relief on dogs.
- **Feinstein Institute for Medical Research/Northwell Health:** basic research on the mechanism of action (pain relief/ inflammation/wound healing) behind TrueRelief.

# Watch Our Short Video Using the Link Below



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# Advisors

## **Clarence L. Shields, M.D.**

Clarence Shields, MD is an orthopedic surgeon specializing in sports medicine, shoulder, elbow and knees; and Senior Partner at Kerlan-Jobe Institute. While in practice, he initiated the Kerlan-Jobe Sports Medicine Fellowship Program, which has produced over 300 alumni. Dr. Shields is the former Los Angeles Rams team physician (22 years) and currently a neutral physician for the National Football League.

Dr. Shields is board certified by the American Board of Orthopedic Surgeons and the National Board of Medical Examiners. He is an active and significant contributor in the medical professional community and is a past-president of the American Orthopedic Society for Sports Medicine and was named "Mr. Sportsmedicine" by the AOSSM in 2006. He is a member of a number of other medical professional societies including the Herodicus Society, American Academy of Orthopedic Surgeons, Los Angeles County Medical Association, California Orthopedic Association, Pan Pacific Surgical Association, American College of Sports Medicine, International Society of the Knee, International Arthroscopy Association and Arthroscopy Association of North America. Dr. Shields has authored a book and numerous publications, editorials and book chapters, and has facilitated over 200 lectures. He is the founder of Team HEAL Foundation, which provides certified athletic trainers and related services to athletes at participating high schools.

## Indication for Use

- TrueRelief has been cleared by the FDA for temporary symptomatic relief of chronic intractable pain, and as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain.

## Contraindications

- Never place electrodes in a manner that applies current to the carotid sinus (neck) region.
- Never use the TrueRelief on patients who have a demand-type cardiac pacemaker.
- Never place the electrodes in a manner that causes the current to flow trans-cerebrally (through the brain).
- Never use the device when pain syndromes are undiagnosed until the etiology is established.

## Warnings

- The safety of TrueRelief for use during pregnancy or birth has not been established.
- TrueRelief is not proven effective for pain of central origin. This includes headache.
- TrueRelief should be used only under the continued direct supervision of a physician.
- TrueRelief has no proven curative value.
- TrueRelief is not proven to be more than a symptomatic treatment and, as such, may suppress the sensation of pain, which would otherwise serve as a protective mechanism.
- Keep this device out of the reach of children.
- Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when TrueRelief is in use.
- Simultaneous connection of a patient to high frequency surgical equipment may result in burns at the site of the TrueRelief electrodes and possible damage to the TrueRelief device.
- Operation in close proximity (e.g. 1m) to a short wave or microwave therapy equipment may produce instability in the TrueRelief output.

## Warnings (Cont.)

- TrueRelief uses dense electrodes and the user should use special attention in their placement and the patient's response.
- The equipment generates, uses and can radiate frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
  - ❖ Reorient or relocate the device.
  - ❖ Increase the separation between the equipment.
  - ❖ Connect the equipment into an outlet on a circuit different from that which the other device(s) is connected.
  - ❖ Consult the manufacturer or field service technician for help.
- Applications of electrodes (probes) near the thorax may increase the risk of cardiac fibrillation. Use of TrueRelief in such a manner should only be done after consultation with a qualified medical professional.
- Current should not be applied directly on the eyes, covering the mouth, on the front of the neck, or across the heart with electrodes (probes) placed on either side of the heart or one (electrode) probe on the chest near the heart and the other (electrode) probe on the upper back (so that current flows through the heart) without consulting a qualified medical professional.



## Precautions

- Isolated cases of skin irritation may occur at the site of electrode placement following long-term application.
- Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain patients.
- The TrueRelief device has IP20 Ingress Protection: protected against solid foreign objects of 12.5 mm diameter and greater; not protected against water ingress.
- TrueRelief is not suitable for use in an oxygen rich environment.

## Adverse Reactions

- Skin irritation is a potential adverse reaction to electrical stimulation. Skin reddening may also result from increased blood flow.