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## SoftWaves™ Training Guide

### Pre-Treatment:

For pain indications, it is important to explain several items to the patient in advance and for the technician to understand:

The average number of treatments for pain pathologies is between 3 and 5 treatments. The additional treatments usually target an expanded or additional injury site not recognized during the first treatment. A patient can only sense pain from the most painful spot for any single chronic injury. During the first treatment this primary area is identified with exploratory pulses and the vast majority of pulses are directed at this level. Additional treatments are typically scheduled at weekly intervals; however, earlier or later treatments are also beneficial. During second, and additional treatments, the primary injury site is usually much less painful. This site should be treated again with at least 500 pulses, but newer, adjoining, or related areas should be sought out and identified with exploratory pulses. There are almost always secondary injury sites for any given chronic injury.

Exploratory pulses are intended to identify the injury sites. You cannot move over the potential injury sites too quickly. Oddly enough, sometimes it takes 10 plus pulses in a location to initiate a pain response. A single pulse will not typically cause a patient to respond with pain. Take your time and be thorough with these exploratory pulses to get a clear picture of the painful sites. Mark these sites down on an anatomical drawing to help locate the painful sites for additional treatments if required.

**SoftWaves™** offer a huge advantage as they cover a very broad area helping you to easily locate and treat the pathologies. When you understand and accept that the technology's mechanism of action is a true biologic response, it is not hard to accept that ultimately each location may only require one treatment if it is thoroughly covered with adequate pulses. Additional treatments may be limited to treating secondary and tertiary locations. Radial devices often require up to 12 treatments as they do not generate a biologic response as they do not create sheering (negative) forces on the cell walls.

The historical trend for treating pain pathologies with electrohydraulic waves (true shockwaves) is with fewer treatments, lower energy, and fewer shocks for better outcomes. Do not over treat the patients, as it is theoretically possible to disrupt the initial biologic response with additional treatments. The vast majority of treatments are not required for healing, but only to moderate pain in the interim. Remember, the initial healing response (stem cells) last up to 12 weeks. The inflammatory (pain reduction) response is nearly immediate and this is what most patients recognize and appreciate in the short term. The inflammatory response should not be confused with long term healing and remodeling.

Healthy tissue is not painful to treat. Only inflamed tissue is painful to treat. A patient will give excellent feedback when you have located the actual injury site. The operator should pulse (at a low frequency so as not to waste pulses) the suspected injury site each treatment with exploratory pulses to identify all painful areas. These areas should be marked on the patient or on a treatment form so fewer pulses are wasted. The pulses should only be directed at the painful areas.

Any pulse that is not uncomfortable is a wasted pulse with the exception of exploratory pulses to identify the injury sites. There is a huge correlation between the level of pain during a treatment and outcomes. If the treatment is painless there usually will be no benefit. The more painful the treatment the better the outcome

It must be explained that there are two mechanisms of action for **SoftWaves™**. First, **SoftWaves™** reduce inflammation and swelling, oftentimes immediately which leads to the immediate or near-term reduction of pain and swelling. The effects of the first treatment can best be explained via a comparison to a deep tissue massage. These massages are painful at times but result in an immediate improvement. This first reduction in pain is not permanent healing. This reduction in pain is due to managing the inflammatory system in the short term. The second, more important mechanism of **SoftWaves™** is that the pulses fool the body into thinking that it has been injured. The waves cause the localized cell walls to become permeable and pass proteins through the walls via exosomes that mimic cellular injury. This stimulates the body to initiate a biologic cascade, including the production of stem cell attractants, the recruitment of stem cells, and the activation and differentiation of stem cells that leads to new and healthy tissue. This “healing” takes place over 12 weeks from the last treatment. Additional treatments can be utilized to reduce pain and make a patient comfortable over this 12-week healing cycle. Treatments in excess of 3 only help manage short term pain and inflammation. These additional treatments do not lead to statistically significantly higher success rates. Patients can return to normal lifestyle immediately after treatment including light athletic workouts. Gyms such as CrossFit should be avoided until the patient returns to health. Whatever a doctor has prescribed in the past, such as stretching, and PT should be continued.

The longer a patient has been injured, the more likely that there is a secondary or tertiary injury site. Imagine favoring one heel (plantar fasciitis) for months. This often requires a patient to change gait and not place weight on the affected heel. This often leads to additional injuries in the achilles, midfoot and even the mid-calf. Ask the patients about these sites and briefly explore and mark these sites with exploratory **SoftWaves™**. A patient will react with pain when you have identified another injury site.

Think Biomechanics. For every muscle or pathology that is constricted over time, another muscle has been over extended over the same timeframe and probably has suffered some injury. Use common sense when evaluating a patient. During the first treatment, a patient oftentimes does not even realize there are other painful areas. Explore these obvious

biomechanical links at the beginning of each therapy session with exploratory, low frequency **SoftWaves™**.

**If a patient does not get better after 12 weeks and after multiple treatments it is because you did not treat the correct area/areas or undertreated the area.**

Although there are very few contraindications, explain them in detail to the patient. Some important reminders: the lungs and esophagus should be avoided as they contain air.

**SoftWaves™** release their remaining energy when they enter air from tissue, and this could cause bruising. Bruising could be harmful in the esophagus and lungs. When treating the shoulders or back, be aware if a patient starts coughing, or has a tickling feeling in their throat, change the location and direction of the SoftWave probe.

It is best that treatments only be directed to the extremities.

Make certain a patient is seated or laying down during the treatment. There have been a few reported incidences of a patient fainting during a treatment from anxiety, increased pain, or even low blood pressure.

Very rarely, a patient will complain of increased pain after a treatment (sometimes even severe pain). These rare cases have been explained in the past by the patient having had recent multiple steroidal injections in the injury site. We have only witnessed a handful of these cases over our ten-year history. Patients should be questioned about steroidal injections prior to the first treatment and warned of the potential response. These injections fool the smart response initiated by the **SoftWaves™**. Wait at least 4 to 6 weeks after steroid injections before applying ESWT (wash out). These injections mask the inflammatory levels at the injury site and cause the **SoftWaves™** to actually increase the inflammation in the short term. This increased pain can be managed with OTC pain meds for less than 24 hours and ultimately the site heals as normal.

Make certain a patient is not on pain medication during therapy as this may prevent a correct diagnosis of the injury. Pain medications to avoid prior to treatment include Advil, Motrin (Ibuprofen), Aleve (Naproxen Sodium), and Ascriptin, Bayer, Ecotrin (Aspirin). Please avoid prescription NSAIDs including Anaprox (Naproxen Sodium), Cambia, Cataflam (diclofenac potassium), Celebrex (celecoxib), Clinoril (sulindac), Daypro (oxaprozin), Feldene (piroxicam), Indocin, Tivorbex (indomethacin), Mobic, Vivlodex (meloxicam), Nalfon (fenoprofen), Narprelan, Naprosyn (naproxen), Vimovo, Voltaren, Zorvolex (diclofenac, diflunisal, etodolac, ketorolac tromethamine, meclofenamate, nabumetone, salsalate

The treatment varies in pain level. The entire treatment lasts only a few minutes. The pain is highest in the beginning and should moderate as the patient becomes less inflamed and gets used to the treatment. Less than 1 in 1000 patients have refused treatment after the initial pulse. Never start the treatment directly in the most painful region. Always start delivering the

first pulses before touching the skin to get the patient used to the noise. The pain can be managed by starting therapy at lower energy levels and starting on the margins of the injury and working inward, slowly raising the energy levels to the therapeutic levels required to initiate the biologic cascade (levels 10 or 11).

Most patients have some immediate improvement although not everyone does. Immediate improvement is a very good indicator of the ultimate success of the therapy. It is very important to tell the patient to be careful to avoid overuse shortly after ESWT because the immediate reduction of pain after ESWT does not mean that the tissue has completely healed!!It is expected that at least 80% of the patients to be 100% pain free at 12 weeks. This varies by indication.

See the complete list of contraindications in the operator's manual. This Training Guide does not replace the operator's manual. The manual should be read and understood in full prior to treating any patients.

## **Treatment**

Before the first treatment, it is important to pulse a patient's hand so they can get used to the sensation, including the light flashes and the noise. Many patients are nervous at first and this helps to acclimate them.

Always clean the membrane with alcohol prior to and immediately after each treatment. Follow all additional standards of care for disinfection at your facility. Infections, open wounds, or abrasions must be covered with either a sterile drape or disposable ultrasound probe cover, and sterile ultrasound gel.

You can never use too much ultrasound gel. Do not skimp. Constantly add gel or move into place with the therapy head during treatment. Air is your enemy as **SoftWaves™** cannot propagate through air and release their energy in the presence of air. If you overwork gel by movement, you add micro air bubbles in path of the **SoftWaves™**. Air dramatically reduces the effect of **SoftWaves™**. Even excess amounts of hair increase air and reduce effectiveness. Excessive hair can be shaved in the target areas. Even thick calluses can reduce the effectiveness (frequent on heel and midfoot). A pedicure in advance may be required to remove calluses or excess dry skin.

Dirty water and filters increase the air levels in the pathway. Always exchange water cartridges with each probe exchange to minimize both.

Look for air bubbles in the membrane prior to the treatment. Work them out with gravity and your hand. A SoftWave sounds different as it passes through air and you will quickly learn to identify this sound and to make adjustments.

Try to limit the number of treatment sites during any one therapeutic session. A typical session, especially the first session, consist of identifying the most painful area and focusing on it with at least 1500 pulses per area/joint. Only in rare cases should more than 4000 pulses be delivered during any session.

The minimum therapeutic energy level is .08 mj/mm squared. This corresponds to levels 10 and 11. Lower levels can be used initially to limit the pain of the patient. Get to the therapeutic level as quickly as possible to get the best outcome.... yes, no pain, no gain. If a patient does not recognize pain at level 11, increase the energy level until you locate the painful areas. Excessive tissue in the path requires higher levels (hips or muscular arms for example).

You may be able to identify secondary injury sites during the second and third treatments. Also use about a third of the pulses on the initial primary site during these sessions while treating the newly found sites.

Never trust a patients or physicians previous diagnosis. The patients are visiting us for a reason. The previous treatments DID NOT WORK. The probe is an incredible diagnostic tool as it identifies inflammation/injuries via a painful patient response. The vast majority of patients do not realize they have alternative/additional injuries until we locate them with the probe. It is very common for a patient to present insisting that they have had plantar fasciitis for years only to discover the Achilles and calf are actually more inflamed. These areas have never been treated before, and when treated the patients recover quickly.

Over time as a patient continues to use an injured limb, inflammation builds up and spreads. A tennis elbow after 6 months may affect nearly the entire arm. The initial treatments reduce this broad inflammation, and only after several treatments can you recognize the actual injury site.

In extremely rare cases an analgesic may be required or requested. NEVER use a local anesthetic as this is proven to reduce successful outcomes. If necessary use a block only. Some people use freezing spray to reduce pain.

A maximum frequency of 4 pulses per second are recommended, 3 is suggested.

The pressure setting should be at the lowest level as this maximizes the amount of energy that enters the body. To minimize pain for sensitive patients, you can fill to higher levels to minimize pain (at the expense of outcomes however).

If a patient has not shown improvement after several sessions, try to identify alternative injury sites and change parameters, increase or decrease energy or change the frequency. It is rare that we cannot have a positive outcome.

Experienced patients can be trusted to hold the probe and to treat themselves. This is quite beneficial as they can immediately identify the pain and they trust themselves not to hurt

themselves allowing for higher energy levels to be used. Patients who are scared can also be encouraged to hold the probes as this minimizes anxiety.

Constantly monitor the treatment as it can be quite boring and you may have moved off the painful area, or not be making good contact. **Any painless pulse is a wasted pulse.**

Ask patient frequently if you are on the most painful location. This changes over the course of a treatment.

### **After Treatment**

Note all of the patient treatment protocols including treated areas, number of pulses, frequency, and range of energy levels. If possible maintain the database to be provided by TRT. These databases can be used to learn ideal protocols over time.

Remind patient to avoid extreme exercise.

Remind patient that just like after a massage, they need to drink lots of water.

Remind patients that oftentimes patients are tired after **SoftWave™** treatment. Avoid a long drive (as a driver) for instance after your treatment.

Remind patients that many report a tingling sensation in the treatment area for several days after therapy. This is good.

Avoid anti-inflammatory medicine (as described above) for several days after therapy as this may reduce outcomes.

Wait a full 12 weeks after your last treatment to evaluate outcomes as the biologic response is active during this entire 12 weeks.

If an operator notices several consecutive patients do not have successful outcomes, consult service as the device may be malfunctioning. You will learn to differentiate good from bad pulses with your ears and with your hands.

### **Erectile Dysfunction/Peyronie's Protocol differences**

Unlike pain pathology patients, the treatment should not be painful. Each patient should be told to tell the SoftWave Operator of any pain. The energy level can be turned down, and any painful area avoided. If pain persist, the treatment should be discontinued as the device has located a condition other than ED. It is best to space out the treatments over a 9-12 week time period as the patients can see more results, and extend their healing process.

Also, unlike any pain pathology, the patient and probe needs to be protected from any potential cross contamination. There are several disposable ultrasound probe covers, or large condoms, or other disposable covers that can be utilized.

First, apply a large amount of gel to the membrane of the probe after checking for any air bubbles in the probe. Next, apply disposable cover, check for any substantial air bubbles in gel, remove if necessary, and lock in place with a multiple rubber bands around the colored ring on the probe. Finally, apply more gel to shaft of penis, perineum, and to the probe as well. Never skimp on the Gel. Air is your enemy.

The typical treatment is 2000-3000 pulses. Make sure the patient is lying flat on the table and stirrups are highly recommended. I usually apply more shocks during the first treatment. An equal number of pulses should be applied to the left and right hilum, shaft, and perineum. The hilum and shaft should be targeted laterally (from the side), all along the shaft, including targeting the base of the penis and below as well. The tip of the penis, and pubic bone should be avoided as this is sometimes painful.

The perineum should also be targeted using adequate pressure, perpendicular to the patient's perineum, and parallel to the treatment table. Always ask for patient feedback to make sure the probe is not angled too far up towards their pubic bone, or down towards the anus. The pubic bone is typically painful to treat, especially for women, and the patient can feel the SoftWaves radiating inside their pelvic region.

After the treatment, the disposable probe cover should be removed, disposed of properly, and the probe disinfected with alcohol or other disinfectant.

A total of 6 treatments is recommended and improvement continues for up to 12 weeks after the last treatment. Early symptom improvement can be seen as early as a few weeks from the first treatment. Patients with frequent urination, typically due to enlarged prostate, will notice improvement within 1-2 weeks, if not a few days, after first application. One of the first signs of improvement for the typically ED patient is morning erections. A minimum of 12 weeks from first treatment should be reserved prior to final outcome evaluation.

The Peyronies patient's protocol should be adjusted such that 80% of the pulses should be applied to the plaque/scar tissue associated with the condition from several different angles. The best way to target the area is bending the penis in the opposite direction of the curvature, focusing in that area. The balance of pulses should be applied to the shaft and perineum if patient also suffers from poor blood supply or ED.

Improvements are thought to last from 12 to 24 months based on early analysis of publications.

