

OTHER ANECDOTAL CASES

Subject 1

This case is the first true post-surgical pain treatment experience. The first treatment was 30 hours post ACL surgery on Saturday March 27th. A 1.25 inch diameter Pain Site Pad was placed laterally on her right knee. A 2" x 4" Feed Pad was placed in an opposing fashion on the medial side of the right knee. She reached an intensity level of 65% of max power. Pre-treatment, she rated her pain 6.5 out of 10 and really wanted to have a Percoset, however she did not take one. Following a 30 minute treatment, she rated her pain 3 out of 10, did not need to take the Percoset and was able to move about on her crutches much more comfortably. At 5 days post surgery, she started physical therapy, could not tolerate much resistance during the exercise portion of PT and had significant pain immediately post exercise. She used Biowave to successfully relieve the post exercise pain.

At 7 days post surgery, she used Biowave in the morning immediately before her physical therapy regimen. She also reported no post exercise pain for a full 24 hours following the PT regimen. All of the MDs and PTs familiar with her case thought she was progressing much faster than average. At 24 hours post physical therapy, she then had a significant amount of pain, not in the location of her ACL, but in and around her kneecap. She and the MDs believe this was from being a little too aggressive in the exercise regimen during her last session. She then used Biowave again that evening, had only moderate relief post treatment, but reported no pain when she woke up the following morning.

Subject 2

The subject has experienced radio frequency ablation, discectomies, injection therapies and finally resorted to back surgery to deal with his chronic pain, from which he still suffers. Six months ago, he received two total hip replacements simultaneously. He had two treatments, one on each side.

The pain site pad was placed on his rear where the top of the hamstring meets the gluteus maximus. The large Feed Pad was placed on the front of his thigh over his quadriceps as high up toward the groin as possible. The pad placements were switched to the other leg/hip for the second treatment. Each treatment lasted for 30 minutes and both occurred on a Monday mid-day between 12 noon and 1pm.

Following the treatment, his VAS pain score was reduced from 6/10 pretreatment to 1/10 post treatment. He was surprised that he had much less stiffness and a significant increase in mobility. He requested a second treatment on the following day (24 hours later) and found that he received similar results. He asked if he could continue using the device for

Subject 3

Patient 3 is a candidate to receive a Spinal Cord Stimulator (SCS) and would prefer not to receive an SCS if there was any type of pain treatment modality that could effectively reduce her pain. She has been through several failed surgeries. She read about Biowave in the current issue of CFO magazine. She has low back pain at L5 and radicular pain down her right leg. She has a lot of pain while in the sitting position and has difficulty sitting in and getting out of chairs. She also had a torn meniscus repaired on her right knee and has had chronic pain since the surgery in that location as well. She is on a Duragesic patch which needs to be replaced every 3 days and takes Neurontin and Elavil daily. Friday, the day of her Biowave treatment was her 3rd day on the patch so it is her worst day from a pain standpoint. She also did not take her Neurontin in the morning in anticipation of having the Biowave treatment. She rated her back and radicular pain at 6.5 out of 10 pre-treatment. She also rated her knee pain at about 4 out of 10 pre-treatment. We treated her lower back for 35 minutes - the pain site pad was placed directly over her scar at L5 on her spine on her lower back and we used a large feed pad on her abdomen. She got up to 56% of max power (about 17.4 volts rms).

Post treatment, about 1pm Friday, she rated her VAS pain score at zero out of ten. She had no pain in her lower back and no pain radiating down her leg. The painful "heat" that she described that she felt from the radicular pain pre-treatment had completely gone away. What was interesting was that her knee pain went to zero out of 10 as well, obviating the need for a separate treatment on her knee.

She commented directly for the remaining period through Saturday afternoon...

“Friday evening, "discomfort" was a "1" due to slight muscle twitching. "Pain" remains at "0". Possible contributors to discomfort: Drank 2 glasses of iced tea (ie: big caffeine dose) with dinner. In car on trip home (7:00 pm) began to feel heat discomfort on leg due to car heater. Leg recovered (cooled down) when heater adjusted. Normally, combination of iced tea + heat on leg would have brought muscle twitching to a "10" which would then bring on heavy, hot leg pain. Didn't sleep well Friday night due to caffeine in iced tea, but pain was "0". Took ibuprofen at bedtime for headache but took no neurontin or elavil.

Saturday am: Slow start due to joint stiffness. Sciatic nerve - quiet. Heavy pain - "0", heat pain - "0". No neurontin taken (for neuropathy). Navigated stairs between 1st & 2nd floor well (abnormal 1st thing in morning). From 11:00 - 11:45 am, tolerated 18 pound cat on lap well. Normally this would have started pain. Saturday noon: Localized pain at L5-S1 surgery site - "1.5", but not radiating elsewhere. Assessment: This is great! Will not resume neurontin or elavil till needed. I went back on my Neurontin medication at 1:30 pm on Saturday. So I did get 24 hours of relief. I was able to sleep without any pain or strange nerve feelings going up and down my back or leg. I just made the mistake of drinking tea (caffeine) at dinner. But even that didn't give me the strange nerve sensations I usually get. That's a very important point. It's also important to note that my energy level went a little higher. It usually does when the pain is gone. I am anxious to try Biowave for an extended period.”

Subject 4

Subject 4 has been diagnosed with Fibromyalgia by a rheumatologist. She has constant pain from knots in her muscles primarily in the cervical area of her upper back and in the lumbar area of her lower back. Subject 4 takes 800 mg of Ibuprofen and one dosage of Elavil (an antidepressant) every night before bedtime. We performed 2 separate treatments: one focused on the cervical area (middle to upper part of the back) and the other, the lumbar area (lower back). Each treatment lasted 20 minutes. For each location, the pain was uniform on each side of the spine. So for both treatments, we chose pad placements using two same sized pads, both 2 inches in diameter. For each treatment, each pad was placed directly over the center of the most painful area – one pad on the most painful area on the left side of the spine, the other over the most painful area on the right side of the spine. Her pretreatment VAS score was 8.0. She got up to an intensity level of 28% of maximum power for the low back treatment and 36% of max power for the cervical treatment. At the end of the treatment she recorded a VAS pain score of 4.0, a 50% reduction in pain. She did not take any of her medication following the treatments and before she went to bed. In the morning when she woke up she commented she had slept very well and that she still rated her pain 4.0 on the VAS scale. Normally she has a lot of discomfort in the morning when getting out of bed and was very surprised at how good she felt. She then followed up with a call 48 hours post treatment and reported that she had not taken any medication and that she still rated her pain at only 4.0 on the VAS scale.

Subject 5

Subject 5 injured her ankle in college and has developed and been diagnosed with osteoarthritis in her right ankle. She needs a cane to walk and has trouble walking more than one block in New York City. She has had this chronic pain problem for about 20 years and it has progressively gotten worse with time.

A 1.25” diameter pain site pad was placed on the top of the foot on the upper dorsum directly over the pain site. A 2” x 4” feed pad was placed in an opposing fashion on the bottom of the foot. She had a 20 minute treatment. Her pretreatment VAS score was 8.0 She got up to an intensity level of 40% of maximum power. At the end of the treatment she recorded a VAS pain score of 2.9, a 64% reduction in pain. She was able to walk much more comfortably without a cane. She continued to use Biowave for 3 months twice a day, once in the morning, once in the evening. Her VAS scores remained at similar pre and post treatment levels for about one month and then after 2 months her pretreatment VAS scores and gross assessment began to improve. She said that she is at an overall lower pain level, has more comfort, less stiffness and can get about more easily than she could 2 months earlier. Following a Biowave treatment, she can now comfortably walk about 8 blocks in New York City without her cane, which was not possible before. There were no other changes in her daily routine in terms of medication, exercise or otherwise that would have affected a change in her pain level.

Subject 6

Subject 6 has acute pain in his shoulder which is the result of a torn rotator cuff injury. His chronic shoulder pain has been constant over several weeks and in particular he has severe pain when he lifts objects and moves his arm in an upward motion towards the ceiling. A 1.25” diameter pain site pad was placed on the front of the shoulder over the pain site. A 2” x 4” feed pad was placed in a partially opposing fashion over the deltoid. He marked a VAS scale pre-treatment at 5.8 out of 10.0. He had a 20-minute treatment. He got up to an intensity level of 48% of maximum power. At the end of the treatment he marked a new clean VAS scale at 1.9 out of 10.0. As a result of the treatment, he obtained a 67% reduction in pain comparing his pre-treatment pain level to his post-treatment level. He was able to move his arm in all directions without any discomfort. When he moved his arm up toward the ceiling he was able to lift it much higher than before – a significant increase in range of motion and only when he got to the extreme end of the new range of motion did he experience any discomfort. He was very surprised and said “he had almost no pain following the treatment”. On following up with the subject, he stated that he estimated that his pain relief lasted for a full 24 hours following the treatment. In fact he was surprised that the following morning his shoulder felt much better than it had on previous mornings.

Subject 7

Subject 7 suffered an acute muscle strain and had been in constant pain for about 7 days without any signs of improvement. She had difficulty walking up stairs as a result of the strain. Pretreatment she could barely walk up steps (one at a time and very slowly) and had to hold the railing for support. We used one 2” diameter pain site pad placed just to the left of her spine over where she felt most tender. We used a large 5” x 8” feed pad on her abdomen (see diagram). She had a 30 minute treatment and got up to an intensity level of 46% of max power. She reported a 100% reduction in pain (7 VAS score pretreatment and 0 VAS score post treatment) and had a significant increase in range of motion and mobility. She then proceeded to walk up the stairs normally without any pain and without holding the handrail. She had no pain and the pain never returned.

Subject 8-New York Giants Employees

Subject 8, a coach for the NY Giants football team, has no cartilage remaining in his right knee according to one of the team’s head trainers. Subject 8 could not raise his knee upward (and his foot off the floor) more than a few inches without being in severe pain and is a candidate for a knee replacement, but refuses to have the surgery. His pre-treatment VAS score was 3 (out of 10). We placed a 1.25 inch diameter Pain Site Pad on the lateral side of his right knee directly over the location it hurt the most. We then placed a larger 2” x 4” Feed Pad opposite the pain site on the medial side of the knee. His pre-treatment VAS score was 3 (out of 10). He was treated for 20 minutes and maintained an intensity level of 67% of max power. Post treatment, he stood up and while standing was able to raise his treated knee all the way up to his chest with no pain, a very significant change in range of motion. He marked the VAS scale at 0 (no pain), a 100% reduction in pain. He reported continued

residual pain relief for about 8 hours following his treatment.

Subject 9-New York Giants Employees

The second treatment was on one of the coaching assistants that has elbow pain from a lifting injury. His pre-treatment VAS score was 7 (out of 10). We placed a 1.25 inch diameter Pain Site Pad on the lateral side of his left elbow directly over the location it hurt the most. We then placed a larger 2" x 4" Feed Pad opposite the pain site on the medial side (inside) part of the elbow. He was treated for 20 minutes and maintained an intensity level of 30% of max power. Post treatment, he did some push ups and said he had significantly less pain than pre-treatment. Post-treatment he marked the VAS scale at 3, a 57% reduction in pain. He reported continued residual pain relief for about 8 hours following his treatment. He said he was very impressed with the treatment and would use it again.

Subject 10- LONG TERM CASE STUDY

Subject 10 has severe TMJ pain that is consistently 8 or 9 out of 10 on a VAS scale on a daily basis. She has used Biowave to successfully treat TMJ pain for 2 months now. Following a 20 minute treatment with Biowave (one treatment per day) her pain level is consistently reduced by 30% - 50% daily (and as much as 87% for some treatments) and she has continued to have residual pain relief and an increase in range of motion for at least 12 hours following every treatment. A small 1.25 inch diameter Pain Site Pad was placed directly over the location of pain, below the ear near the temporomandibular joint. A 2" x 4" Feed Pad was placed on the opposing cheek. Previously, she had exhausted every non-surgical treatment without any success.

Subject 11 – Controlled Treatment

Subject 11 runs marathons and has chronic patella pain in both his knees. The pain is aggravated by running. We treated Subject 11's right knee and did not treat the left knee using it as a control. A 1.25" diameter Pain Site Pad was placed on top of the knee above the top edge of the kneecap. A 2" x 4" Feed Pad was placed in an opposing fashion on the lower portion of the hamstring on the back side of the leg. The treatment lasted for 30 minutes. Post treatment, subject 11 flexed his knees a little, looked up and said... "my right knee feels like a normal knee. It [Biowave] really works." He had no reduction in pain in his left knee – the control. He reported later on that he received about 24 hours of residual pain relief from this treatment in his right knee.

Subject 12

Subject 12 broke his right wrist in college and has had chronic pain since. Moving the wrist backwards and forwards is painful, as is squeezing an object like shaking hands. We treated his right hand. A 1.25" diameter pain site pad was placed on top of the back of the wrist. A 2" x 4" feed pad was placed in an opposing fashion on the front side of the wrist. The treatment lasted for 20 minutes. After we disconnected the device and removed the pads, he flexed his wrist forwards and backwards

and then he gave me a hard handshake. . He said... “I can’t believe it, there’s no pain.” He reported later on that he received about 24 hours of residual pain relief from this treatment.

Subject 13

Subject 13 has been diagnosed as having a herniated disk. He had severe localized chronic pain across his whole lower back (rating of about 9 out of 10. His range of motion was limited to about 30 degrees from the vertical. We used two same sized 2” diameter pads placed about 4 inches apart from each other, one on each side of his spine to treat the entire lower back with one pad placement. He received two treatments with Biowave and both times got up to an intensity level of 38% of max power. He reported a 70% reduction in pain. Additionally he could bend about 90 degrees from the vertical following the treatment – over a 100% improvement in range of motion. He also had increased mobility and found it was much easier for him to sit down and get up out of his office chair.

Subject 14

Subject 14 is a competition level amateur figure skater. She injured her lower back while skating 24 hours earlier. She had a lot of discomfort and limited range of motion bending over, twisting to the side and extending her arm in one direction and opposite leg in the other direction (as if doing a figure skating move on the ice). She had a treatment for 20 minutes. She got up to a maximum intensity level of 77% of maximum power – 23.1 Volts rms. Following the treatment, she rated her pain as a 99 percent improvement. She had complete range of motion and no pain bending over or twisting side to side. She also had complete range of motion and no pain when extending in the same position with her arms and legs as compared to prior to the treatment. She later reported back to us that she had continued relief for at least 24 hours.

Subject 15

Subject 15 has a herniated disk at the L4/L5 location. He has chronic pain radiating through his right hip and down the outside of his right leg down to his right knee.

Treatment 1: Pretreatment he could not lift his right knee up to his chest without the help of his hand. We used one 2” diameter pad placed just to the right of his spine where he felt most tender. We used a large 5” x 8” feed pad on his abdomen (see diagram). He had a 30 minute treatment and got up to an intensity level of 38% of max power. He reported a 71% reduction in pain (7 VAS score pretreatment and 2 VAS score post treatment) and had a significant increase in range of motion and mobility. He was able to raise his knee up to his chest without the help of his hand. The increase in ROM and mobility has lasted for 4 days since the treatment.

Treatment 2: Treatment 2 was 4 days after treatment 1. Pretreatment he could still lift his right knee

up to his chest without the help of his hand though not as easily as in the first 48 hours following treatment 1. We used the same placement as in treatment 1 – one 2” diameter pad placed just to the right of his spine where he felt most tender. We used a large 5” x 8” feed pad on his abdomen (see diagram). Mike had a 30 minute treatment and got up to an intensity level of 36% of max power. He reported again, approximately a 71% reduction in pain (7 VAS score pretreatment and 2 VAS score post treatment) and had a significant increase in range of motion and mobility. He was able to more easily raise his knee up to his chest without the help of his hand. He also felt more comfortable walking without any discomfort or twinges in his back or down the side of his leg toward his knee.

Subject 16

Subject 16 has a titanium cage that was implanted into his spinal column around C5 in his neck. Residents that finished the operation, had sewn up the surgical site and did not properly re-attach the muscle to the spinal cord in the area of the neck. The muscle tissue separated from the spinal cord and dropped into the shoulder area leaving Robert with little control to keep his head in an upright position. As a result of the condition, he has had severe constant chronic cervical pain 24 hours a day. We treated him for 30 minutes with a small set of pads on the posterior side of his neck with the pain site pad focused on the left side of his neck where the greatest pain resided (see diagram). He reached a maximum treatment intensity of 28% of max power. Following the treatment he said in amazement...*“I don’t have any pain, this is the first time I can remember since the surgery ever feeling pain free. I also can hold my head up straight without discomfort.”* He has since received 10 treatments over three weeks and said he has had no pain for 10 days now and he has even started playing golf again. He has averaged about 36% of max power over the last 9 treatments. There appears to be no accommodation to the intensity of the signal.

Subject 17

Subject 17 has severe muscle strain injury to the point where the gluteus maximus meets the top of the hamstring on the left leg. Two 2” diameter pads were placed at two major points of discomfort. Patient got up to 48% of max power over the course of a 30 minute treatment. Patient reported at least a 50% improvement in pain and 50% increase in ROM. Patient reported continued relief over the next several days and that his pain level and mobility stayed at the improved levels post treatment.

Subject 18

Subject 18 is 38 years old in fit condition and has chronic pain in his shoulder which is a result of brachitis that resulted from a high school football injury. His chronic shoulder pain has increased in intensity over the years and in particular he has severe pain when he works out and lifts weights. Moving his shoulder and arm above his head, in a throwing motion and/or in a circular motion causes severe discomfort. A 1.25” diameter pain site pad was placed on the front of the shoulder over

the pain site. A 2" x 4" feed pad was placed in an opposing fashion on the trapezius muscle at the top of the shoulder blade. He had a 20 minute treatment. He got up to an intensity level of 28% of maximum power. At the end of the treatment he was able to move his arm in all directions without any discomfort. He was very surprised and said "he had *no pain* following the treatment". On following up with the subject, he stated that he estimated that he received an 80% reduction in pain and that his pain relief lasted for a full 24 hours following the treatment. In fact he was surprised that the following morning his shoulder felt much better than usual, as he normally experiences stiffness and some discomfort in the morning.

Subject 19

Subject 19 had Hodgkin's disease and was treated with Prednisone for 3 years. The resulting side effects of the Prednisone caused him to have a severe deterioration of several joints. As a result, he ended up receiving three implanted operations - two total hip joints and one total replacement left knee joint. Subject 19 has had constant chronic knee pain in the left knee housing the replacement joint since his operation. He received a treatment on his left knee with chronic pain. A 1.25" diameter pain site pad was placed over the most painful area, which was on top of the knee above the top edge of the kneecap. A 2" x4" feed pad was placed in an opposing fashion on the lower portion of the hamstring on the back side of the leg. He received a treatment for 30 minutes. He stood up, flexed his knees a little, looked up and said... "this is the best my knee has felt in a year."

Subject 20

Subject 20 has been diagnosed as having a herniated disk. He has localized chronic pain across his whole lower back. We used two same sized 2" diameter pads placed 4 inches apart on either side of his spine to treat the entire lower back with one pad placement. He received two treatments with Biowave. Both times and got up to an intensity level of 36% of max power. He reported an 80% reduction in pain and had a 50% increase in range of motion. It was much easier for him to sit down and get up out of his office chair.

Subject 21-NISMAT (Nicholas Sports Medicine and Athletic Trauma Center)

Female patient had a severe knee injury and refused to perform physical therapy. Substantial scar tissue formed and prevented her from bending her knee. Her range of motion (ROM) was severely limited to only 20 degrees (measured with a goniometer) even with the Physical Therapists pushing and forcing her to bend her knee. She had a 20 minute treatment with a 1.25" diameter pain site pad placed over the pain site on the medial side of the knee and a 2" x4" Feed pad placed in an opposing fashion on the lateral side of the knee. She got up to an intensity of 55% of max power. Post treatment the patient stated that the pain was reduced by more than 50% and using a goniometer the Physical Therapists measured she was able to bend her knee 62 degrees from a straight position – over a 300% improvement in ROM.

Subject 22- Japan

Subject 22 had a snowboarding accident and was diagnosed with a severe pain syndrome called RSD in his wrist. He has had a constant level of chronic pain for 10 months since his accident. We gave him a total of 6 one-hour treatments. He was treated twice a day, once in the morning and once in the late afternoon for 3 consecutive days. With each treatment his pain level continued to diminish. The residual pain relief from each treatment lasted until the next treatment. There seemed to be a cumulative benefit over the three days. 2 months post treatment his pain condition remained at a significantly lower level, approximately 50% less than it had been for the prior 10 months.

Subject 23-Female/Age 28

Subject 23 had chronic foot pain as a result of a broken ankle that had been repaired with an internal plate and screws. She received one treatment for one hour and reported that she had significantly less pain (about a 75% reduction in pain) in her foot from walking for about 24 hours.

Biowave Corporation-Cases

Case 1

A 32 year-old female presented with a 2.5 cm long by 8 mm deep laceration on the palmar aspect of her right hand, proximal to the thumb. The injury was received at work when she placed her hand into a dish holder that contained a broken glass. I placed two 2” electrodes on opposite sides of her hand one very close to the wound. The wound was irrigated with sterile normal saline and padded dry. The Biowave device was engaged and ramped up to about 20% of maximum power. She noted that she felt a slight pressure and numbness in her hand. Additionally, her index finger abducted slightly. The wound was then cleaned with Betadine solution and the dried areas around the wound margins were removed. Additional Betadine was applied and the wound was closed with 10 interrupted 3-0 VICRYL sutures. A topical antibiotic was applied, the Biowave device was removed and the wound was dressed with a soft bulky bandage. She did not look at the procedure at all and remarked that she felt a slight “pushing” feeling as the sutures were applied but no sharp pain that is normally expected. After about 10 days the sutures were absorbed and the wound was clean and intact with very little scarring.

Case 2

A 44 year-old female complained of tightness and pain in her right knee. The diagnosis was made, by MRI, of a longitudinal tear of the posterior horn of the medial meniscus with moderate joint effusion. Non-steroidal anti-inflammatory therapy with ketoprofen supplied little or no relief. A large square pad was placed on the posterior surface of her right calf as proximal to the knee as possible. The second (1.25”) electrode was placed on top of the knee as close to the pain site (above the meniscus) as possible. Treatments lasted 20 minutes each and were repeated 3 times a day with an hour in between treatments. The average output level was around 35% of maximum available signal intensity. The treatment regime was performed for about 6 weeks (Monday-Friday, her working days). Within 2 days the pain was significantly diminished. After a week the pain was barely perceptible. Her load bearing and walking distance capacity increased as the treatments progressed. She was not using non-steroidal or steroidal anti-inflammatory drugs during the course of her treatment. She ceased the treatments when her knee felt normal. Subsequent examination showed that the effusion had receded and that the longitudinal tear had healed.

Case 3 -Severe Chronic Hand/Wrist Pain – LONG TERM CASE STUDY

Case 3 participated in the clinical trial at the Coren Clinic in Norwalk Connecticut for a severe pain condition in his right hand and wrist. He had had severe chronic pain from a hand/wrist injury, was not only unable to play tennis, but even with painkillers, was unable to perform physical therapy because the limited range of motion (ROM) and pain were too severe. After having heard about the Biowave clinical study in Norwalk, CT, he participated and received four successful treatments using a 1.25 inch pain site pad on the inside of his wrist and a larger 2" x 4" Feed pad on the back side of his wrist. He used the device every other day for 3 months. After the first week, he had enough of a reduction in pain and increase in ROM that he was able to begin physical therapy. He then continued using the device in conjunction with physical therapy and at the end of 3 months the pain was almost non-existent.