

# Summary of Biowave Clinical Case Studies at HealthSouth

## Jacksonville Rehabilitation Center

November 8, 2001

We met with the Director of Physical Therapy at HealthSouth, Matt Serlo, who evaluates new medical devices and technologies for all of their Physical Therapy & Rehabilitation ("PT") Clinics. HealthSouth owns the largest number of PT clinics in the U.S. (over 1,500 clinics). We treated three patients with chronic low back pain in the clinic with Biowave's Homewave device. Each of the cases is described in detail below. All had either herniated or bulging discs that were the source of their pain. All had very positive responses to Biowave treatments. We also treated 3 physical therapists (including Matt Serlo) with Biowave's Homewave device and noted their responses and impressions of the treatments.

### Treatments on Patients

For the patient treatments, each person controlled the intensity level themselves.

#### *Patient #1*

The first patient treated in the clinic was a 32-year-old Caucasian man, about 190 pounds, with a herniated and bulging disc who was a truck driver for beverage company. Prior to the treatment, he came into the clinic in a lot of pain and had limited range of motion as he could only bend about 50 degrees from the vertical. One large 5 inch x 8 inch Feed Electrode was placed on his abdomen. One 2-inch diameter Pain Site electrode was placed directly over the source of his pain on his lower back. During the course of the treatment, he got up to 16.7 V rms which is about 56% of max power. He said the sensation from the device was "very comforting" and that it "felt like someone was pressing on his lower back directly over the pain site, which felt good." Following the treatment his first comment was, "how much does this cost and how soon can I buy one for home" and "can I use this next time I come to the clinic?" Additionally, his range of motion significantly improved to about 95 degrees from the vertical (upon bending forward, he could touch the top of his feet). His second comment after bending over and back up and twisting side to side was "I don't feel any pain at all, this is great."

#### *Patient #2*

The second patient was a 37-year-old African American female, about 140 pounds, with a bulging disk. She also had come into the clinic in a lot of pain. She got up to 6.0 V rms, 22% of max power and was treated for 30 minutes. Following the treatment she felt much less stiff and had less pain. She then continued with her physical therapy exercise. When she finished her exercise regimen she said, "every time I come for physical therapy, whenever I finish this exercise, my back is very stiff and sore. Since the Homewave treatment, I have no soreness and no stiffness." She said she wanted to continue treatments with Homewave when she comes for future physical therapy visits.

This is a prime example of why Homewave should be used first, prior to physical therapy. The patient has less pain, more range of motion, and as a result can handle more resistance through a greater range of motion and as a result, get more benefit out of the physical therapy exercise and heal faster. Currently, the HealthSouth standard operating procedure is for patients to receive an interferential treatment along with ice at the end of the physical therapy session. The HealthSouth Director of Physical Therapy said “that one of the reasons interferential therapy is provided only at the end of the physical therapy session in conjunction with ice is because the ice numbs the skin and area slightly beneath the skin so that the patient can better tolerate the uncomfortable twitching or pulsing sensation caused by the interferential device.”

### ***Patient #3***

The third patient was a 54-year-old Caucasian woman, about 130 pounds and had a laminectomy about one year ago to repair a herniated disc. The disc then reherniated, and additionally, disc material was left behind following the operation which continues to push on a nerve giving her pain in her lower back and left buttock and occasionally numbness in her left calf and foot. We performed two treatments on her. We first treated her lower left buttock because that was the location where she had the most pain. We then subsequently treated her lower back directly over the incision where the laminectomy took place, as that was the probable source of pain. She also had some stiffness and soreness in this location (beneath the incision) as well. Each treatment lasted about 20 minutes. Following the first treatment, she said that her buttock felt much better - in fact had almost no pain, but that her lower back was still stiff and sore. We then decided to treat over the incision. We used one large 5 inch x 8 inch Feed Electrode placed on her abdomen, and one 2-inch diameter Pain Site electrode placed directly over the incision on her lower back. After about 20 minutes on the second treatment she said her left leg, particularly her calf and foot was starting to feel more "numb" than before and that she didn't want to have more numbness there. At this point we stopped the treatment. When she stood up though, she was surprised and said, "it feels like my back's been lubricated with silicone." She said that her back felt much looser and less stiff. The numbness in her leg also lessened over the next 30 minutes. She said, and the therapist verified, that she has had interferential therapy (at this clinic) and that the interferential therapy was uncomfortable during the treatment as compared to the sensation from the Homewave device during this treatment, which she liked. She also said the interferential device aggravated her pain condition following a 20-minute treatment and that she had no beneficial outcome from using it. She said the interferential device, unlike the Homewave device, did not make her feel looser, less stiff and did not reduce her pain. She said she would definitely use the Homewave device again in the clinic if it was available (even with the additional numbness). She said following the treatment she had with the interferential device, she had never used it again.

As a side note, we found it interesting that the Homewave device appeared to induce additional numbness along a nerve running down to her foot. This is similar to patient responses to spinal cord stimulator treatments. It appears that the Homewave electrode placement location properly captured the nerve in question resulting in a beneficial outcome.

## **Treatments on Therapists**

### ***Subject #1***

For Matt Serlo, we used a wrist placement as if he were a patient with carpal tunnel syndrome or a broken wrist. Matt said that the sensation is very comforting and that he not only felt the electric field deep in his wrist but down through his entire hand and fingers both on the front and back sides. He also said, "this is very different from other electric stim devices that I've tried and I could see how this could be much more beneficial." He also liked that the Biowave device was very simple to use because there is only one control - the intensity level. All of the other electrotherapy devices have to be programmed. He said the therapist literally has to have an electrical engineering degree to try and understand the meaning and hypothetical benefits that can result from different pulse widths, frequencies and pulse patterns. He said with the Biowave device, the therapist doesn't have to worry about the device settings or what the device is doing because it's fixed. The therapist can use their knowledge of the body and make a determination regarding pad size and placement. He thought because the Biowave device is so much more user friendly, it would be much easier to market it for use in a professional setting (pain clinics, physical therapy clinics, chiropractic and physiatrist offices, etc.)

### ***Subject #2***

The next therapist that we used Homewave on was a woman who actually had a significant pain condition located on the upper back side of her left shoulder about 3 inches away from her spine. She is very familiar with electrotherapy devices including TENS and interferential therapy. Her own experience with these devices both on her self and on patients that she treats is that with interferential devices she gets a mediocre response on about half of the patients on which she uses it. She does not use TENS therapy at all because she rarely ever has positive results with it. When we treated her with Homewave, she said, "The Homewave treatment was more comfortable, seemed to have a deeper, more focused penetration and provided more pain relief during and following the treatment than interferential therapy."

### ***Subject #3***

The last therapist we tried Homewave on was a woman whose specialty was treating wrist and hand injuries. Like Matt, she liked the sensation, depth of penetration and the fact that the signal spread throughout the entire hand.

**Birmingham Rehabilitation & Sports Medicine Center**  
**HealthSouth Corporate Headquarters, Birmingham, AL**  
**January 15, 2002**

We met with the Director (Head Administrator), Steve Brobst and two physical therapists (PTs), Todd Howatt and Jeff Douglass at HealthSouth's largest Rehabilitation and Sports Medicine Center that is based in Birmingham. This was the second clinical evaluation by HealthSouth PTs.

We treated two patients with chronic low back pain in the clinic. Each case is described in detail below. For the patient treatments, each person controlled the intensity level themselves. Both had very positive responses to Homewave treatments.

***Patient #1***

The first patient treated in the clinic was a 20-year-old Caucasian girl, about 135 pounds, with chronic low back pain that has persisted for over one year. Prior to the treatment, she had discomfort in her lower back just to the right side of her spine and significant pain and limited range of motion when arching backwards and when bending from side to side. One large 5 inch x 8 inch Feed Electrode was placed on her abdomen. One 2-inch diameter Pain Site electrode was placed directly over the source of her pain on the right side of her lower back. During the course of the treatment, she got up to 12 V rms at 32% of max power and received a treatment for about 20 minutes. Following the treatment she said she had significantly less pain and her range of motion improved by about 50% arching backwards as well as when she extended to each side. She said the sensation from the device was "very comforting" and that it "felt like someone was pressing on my lower back directly over the pain site, which felt good." She said she has received electrotherapy treatments on interferential (IFC) devices at HealthSouth in the past which she found "very uncomfortable and which produced an annoying electrical twitchy feeling in the skin." She said the Homewave treatment felt much deeper and more concentrated than the IFC treatment and that she would definitely use Homewave again.

***Patient #2***

The second patient was a 61-year-old Caucasian male, about 220 pounds. This patient had stenosis and as a result had surgery – a fused disk between L4 and L5 to relieve his pain. Eight months later the pain returned now because of stenosis between L3 and L4. Prior to the treatment, the patient was in a lot of pain and could only bend forwards about 50 degrees from the vertical and was about 12 inches from touching his toes. One large 5 inch x 8 inch Feed Electrode was placed on his abdomen. One 2-inch diameter Pain Site electrode was placed directly over the source of his pain directly over his spine between L3 and L4 on his lower back. During the treatment the patient increased the intensity to 21.8 V rms or 72% of maximum power during the course of a 20 minute treatment. Following the treatment he felt much less pain and stiffness and his range of motion improved dramatically to about 90 degrees from the vertical and he was only about 2 inches away from touching his toes. He described the treatment as "soothing" that it felt like "a little bit of a tingle and a pressure sensation that felt deep through his lower back." This patient asked if he could have another treatment with Homewave next time he comes into the HealthSouth clinic and asked if and when a wearable home use device would be available because he would definitely purchase one.

### ***Discussion with Head Administrator***

Subsequently, I had a discussion with Steve Brobst, the Head Administrator, regarding the use of Biowave in a PT setting. I explained that Biowave should be used first in place of heat, prior to the exercise regimen during physical therapy because the patient has less pain, more range of motion, and as a result can handle more resistance through a greater range of motion, get more benefit out of the physical therapy exercise and as a result heal faster. Additionally the patient has no post-exercise pain and soreness because Biowave provides a very significant residual period of reduced pain. Also, Biowave is a much more comfortable treatment for the patient as compared to current electrotherapy treatments like TENS and interferential which are currently provided in conjunction with ice at the end of the physical therapy session. Current electrotherapy treatments are provided only at the end of the physical therapy session in conjunction with ice is because the ice "numbs" the skin so that the patient can much better tolerate the uncomfortable twitching or pulsing sensation caused by these devices.

I also discussed that the Biowave devices are very user friendly and are purposely not programmable like prior generation electrotherapy devices. I explained that we have determined an optimal frequency setting for blocking pain transmission in the body. As a result the only control on the Biowave device is intensity level. With other devices PT's need an electrical engineering degree to make sense of all of the different wave patterns, pulse widths and frequency settings from which they can choose. With Biowave, the PT only needs to be concerned about the anatomy of the patient and the pad placement location. Pad placement is also very simple – one smaller electrode over the pain site, one larger Feed electrode opposite the pain site. Our device also has a built in count down timer that shuts the device off automatically at the end of a treatment. Steve as well as both PT's really liked the simplicity and ease of use of the design.