

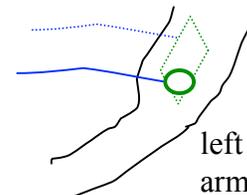
**Three Case Clinical Study at NISMAT**  
**(Nicholas Sports Medicine and Athletic Trauma Center)**  
**Lennox Hill Hospital, New York, NY**

Testing was performed to evaluate pain relief using the Biowave Deepwave device on the Biceps for induced muscle damage. Using a standard model called DOMS, muscle damage was induced to both biceps using an isokinetic machine and the resulting pain was tracked over a 4 day period. The normal course for induced pain according to the DOMS model is that maximum pain typically peaks at 2 days post use of the isokinetic machine exercise and returns to baseline over the next 2 - 3 days. The Biowave Deepwave treatment was applied at 48 hours following each patient's use of the isokinetic machine which was the point in time of maximum induced muscle pain in the biceps. Three (3) Cases were enrolled in July 2002 at NISMAT at Lennox Hill Hospital as follows:

Case 1: Male/Age 37/171 lbs- Bicep treatment for induced muscle damage

Muscle damage to both biceps was induced using an isokinetic machine to induce pain. The RIGHT bicep was used as a control. The first treatment was performed on the LEFT bicep with a 1.25 inch Pain Site Pad placed slightly to the inside of the bicep, not over the belly of the bicep, rather over the tendon. The 2" x 4" Feed pad was placed on the tricep in an opposing manner (see diagram to the right). The percent of maximum power attained was 40% during a 20 minute treatment. VAS scores were as follows:

Left Arm (treatment lateral to distal tendon)  
Pre treatment ("tx") Pain - 4 out of 10  
5 min post tx - 1 out of 10  
1 hr post tx - 2 out of 10  
22 hr post tx - 2 out of 10



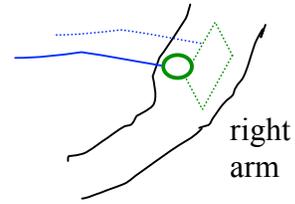
The resulting improvement was 75% (i.e. a 75% reduction in pain).

There was a clear difference and noticeable improvement between the LEFT arm and the RIGHT arm, which was used as a control. On a subjective note, the subject thought the treatment was much more comfortable than both TENS and interferential electric stimulation treatments that are regularly used at the NISMAT clinic.

The subject then tried a different pad placement on his RIGHT arm. A 1.25 " pain site pad placed directly over the belly of the bicep. The 2" x 4" Feed pad was again placed on the tricep in an opposing manner (see diagram). Percent of maximum power attained was 36% during a 20 minute treatment. This pad placement was less comfortable than in the first treatment. VAS scores were as follows:

Right Arm (treatment over muscle belly)

Pre tx Pain - 3 out of 10  
5 min post tx - 2 out of 10  
1 hr post tx - 2 out of 10  
22 hr post tx - 2 out of 10



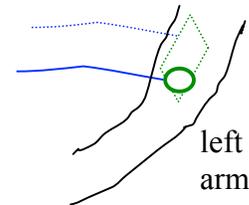
Post treatment the VAS score was 2, resulting in a 33% improvement (i.e. a 33% reduction in pain). In this case the first pad placement provided a significantly better benefit.

Case 2: Female/Age 21/125 lbs- Bicep treatment for induced muscle damage

Muscle damage to both biceps was induced using an isokinetic machine to induce pain. Pretreatment VAS score for the LEFT bicep was 3 and for the RIGHT bicep, 3. The RIGHT bicep was used as the control. One treatment was performed on the LEFT bicep with a 1.25 inch pain site pad placed slightly to the inside of the bicep, not over the belly of the bicep, rather over the tendon. The 2" x 4" Feed pad was placed on the tricep in an opposing manner (see diagram). Percent of Maximum power attained was 30% during a 20 minute treatment. VAS scores were as follows:

Left Arm (treatment medial to distal tendon)

Pre tx Pain - 3 out of 10  
5 min post tx - 1 out of 10  
1 hr post tx - 0.5 out of 10  
22 hr post tx - 1 out of 10



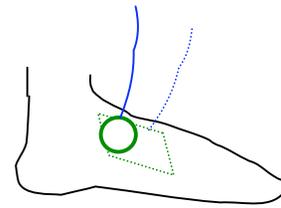
Right Arm Untreated (control)

Pre tx Pain - 2 out of 10  
5 min post tx - 2 out of 10  
1 hr post tx - 2 out of 10  
22 hr post tx - 1 out of 10

Post treatment, the resulting improvement was 66% (i.e. a 66% reduction in pain). The patient reported a distinct difference between the treated and control arms and liked the sensation better than TENS.

Case 3: Female/Age 35/156 lbs - Ankle treatment for chronic arthritic ankle pain

Patient has articular cartilage defects in the talus – an arthritic ankle and as a result chronic ankle pain next to her left ankle. Patient regularly has pain at 3 – 5 on a VAS scale as a result of walking/jogging. One 20 minute treatment was performed just below the left ankle with a 1.25 inch pain site pad placed on the side of the ankle directly over the pain site (see diagram). The 2” x 4” Feed pad was placed on the left ankle in an opposing manner. Percent of Maximum power attained was 84% during a 20 minute treatment. VAS scores were as follows:



Baseline Pain: 3 out of 10 with walking,  
5 out of 10 with jogging

5 min post tx - 0 out of 10 walking and jogging  
1 hr post tx - 0 out of 10 walking  
6 hr post tx - 0 out of 10 jogging  
22 hr post tx - 0 out of 10 walking

left  
ankle

The post treatment VAS score was 0 while the patient walked on the ankle. She commented she had no pain at all. The resulting improvement was 100% (i.e. a 100% reduction in pain). The patient reported that the post treatment VAS score under heavy exercise conditions was also 0 out of 10 still resulting in a 100% reduction in pain. This patient is also a regular user of TENS on her ankle and was amazed at the difference between the result achieved from the Biowave Deepwave treatment and her regular TENS treatment. Each of the above three subjects expressed an interest in purchasing the Biowave Deepwave device when it is cleared through FDA.