A Study of the Efficacy of the Biowave Deepwave Device

A study was performed to determine the efficacy of the Biowave Deepwave Device at the Meiji University School of Oriental Medicine in Japan. The Biowave Deepwave device was used for the treatment of the chronic pain in the low back, knee, and shoulder. The evaluation method was the Visual Analog Scale (VAS) and treatment took place at the University of Oriental Medicine Nursing Home Hospital (GP). The purpose of the study was to evaluate Biowave Deepwave's efficacy in reducing low back, osteoarthritic knee, and shoulder pain. Additionally, patients with hip, elbow and wrist pain were also enrolled in the study. A total of 94 patients enrolled and were treated in the study. Patients received a 20 minute treatment with Biowave Deepwave. Visual Analog Scales (VAS) were used to measure pain scores before the treatment as well as immediately post treatment, at one hour post treatment and at 24 hours post treatment. There was no control used in this study. Patients were recruited by the Investigator, Dr. Nishikawa at the Hospital. The results are shown in Table 1 below.

Study Site: **Meiji University School of Oriental Medicine**
Investigator: **Professor Nishikawa**
Sponsor: **OMRON Corporation**
Date: **April – May 2003**

		1 HOUR POST TREATMENT			24 HOURS POST TREATMENT		
Treatment	Total Patients	# Patients with >50% Pain Reduction @ 1 hr post treatment	% Patients with >50% Pain Reduction @ 1 hour post treatment	AVG % **REDUCTION in VAS Pain** Score @ 1 hr post treatment	# Patients with >50% Pain Reduction @ 24 hrs post treatment	% Patients with >50% Pain Reduction @ 24 hrs post treatment	AVG % **REDUCTION in VAS Pain** Score @ 24 hrs post treatment
Low Back	34	25	74%	77%	19	56%	72%
Osteoarthritic Knees	33	26	79%	78%	21	64%	77%
Shoulder	14	11	79%	73%	12	86%	85%
Other *	13	9	69%	71%	9	69%	71%
TOTAL/AVERAGE	94	71	76%	75%	61	65%	76%

* Other includes elbow, hip, wrist, finger, thigh, and calf

Table 1. Percentage and Number of Responders to the Deepwave Device

As shown in the table above, the data was analyzed to determine the percentage of patients that received more than a 50% reduction in pain at one hour and at 24 hours post treatment. The average percentage reduction in VAS pain scores for these

patients was also analyzed at one hour and at 24 hours post treatment. Pain reduction was measured for each patient comparing their pre-treatment to post-treatment VAS scores.

Column 1 lists the total number of patients enrolled for each type of treatment. Columns 2, 3 and 4 analyze data at one hour post treatment. Column 2 displays the *number* of patients for each type of treatment that had more than a 50% reduction in pain at one hour post treatment. Column 3 shows the *percentage* of patients for each type of treatment that had more than a 50% reduction in pain at one hour post treatment. Column 4 shows the average percentage reduction in VAS Pain scores for the patients that had more than a 50% reduction in pain at one hour post treatment.

Columns 5, 6 and 7 analyze data at 24 hours post treatment. Column 5 displays the *number* of patients for each type of treatment that had more than a 50% reduction in pain at 24 hours post treatment. Column 6 shows the *percentage* of patients for each type of treatment that had more than a 50% reduction in pain at 24 hours post treatment. Column 7 shows the average percentage reduction in VAS Pain scores for the patients that had more than a 50% reduction in pain at 24 hours post treatment.

Overall, at one hour post treatment, 71 out of 94 patients or 76% of the patients had more than a 50% reduction in pain. These 71 patients averaged a 75% reduction in pain comparing their average baseline pre-treatment VAS score to their average VAS score at one hour post treatment. At 24 hours post treatment, 61 out of 94 patients or 65% of the patients had more than a 50% reduction in pain. These 61 patients averaged a 76% reduction in pain comparing their average baseline pre-treatment VAS score to their average VAS score at 24 hours post treatment.

Figure 1 below shows a plot of average percent reduction in VAS pain scores at 0 hours, 1 hour and 24 hours post treatment for each group of patients within each treatment group (shoulders, arthritic knees, low back and other).

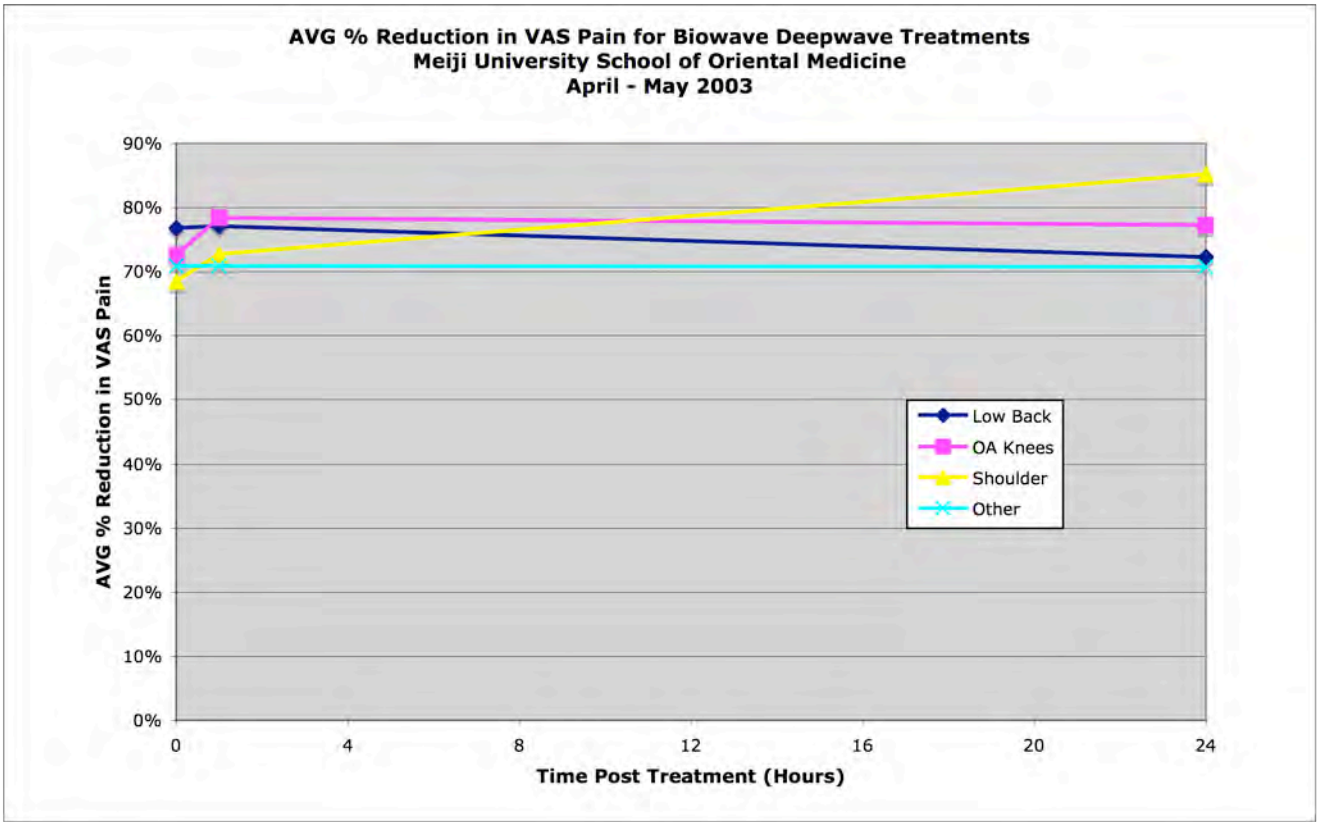

Figure 1. Average % Reduction in VAS Pain
Meiji University School of Oriental Medicine

Two patients received a blister and two developed an ulcer while using the Biowave Deepwave device. Some patients complained of slight pain when they removed the pad (especially the pads on abdomen) at the end of the treatment, however, they did not have inflammation or itchiness at the pain site.

The results from this independent study in Japan replicate the results obtained at Weill Medical College at Cornell University in both the dosage study (Phase 1 & 2) and the double blinded randomized crossover study (phase 3) in that the reduction in pain post treatment lasted for 24 hours for the majority of the patients demonstrating that the Biowave Deepwave device provides pain relief for 24 hours.