

APPLICATION OF A COMBINED ELECTRICAL STIMULATION TREATMENT IN OSTEOARTHRITIS

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Arthritis, formally called degenerative joint disease affects 1 in 5 people, mostly striking after the age of 50. In the UK, arthritis results in 15% of all complaints to physicians and causes 40% of all severe physical disabilities. In the United States, according to the Arthritis Foundation, arthritis accounts for 70 million lost work days and 500 million restricted days per annum.

Arthritis is not one singular entity, but is actually a group of 100+ diseases that affect the joints. By far, the most common type is osteoarthritis (OA), commonly known as the wear and tear disease since the damage done to the joint is progressive and related to loss of cartilage. In effect, the normal breakdown and replacement of cartilage is weighted toward breakdown. Ultimately, the cartilage that covers the end of bones degenerates, allowing the bones to rub against each other. This usually first causes pain, then decreased ROM and inflammation.

The majority of OA treatments are strictly palliative. These include drug therapy, special exercises, splinting and ultimately joint replacement surgery. There has been little done to address the true causes of the disease or to attempt to treat the progressive loss of cartilage.

Since the early 1960's much research has been done concerning the use of electrical impulses to stimulate both soft and hard tissue regeneration. These studies reveal that the proper use of electrical stimulation may locally stimulate blood circulation, relieve pain and reduce swelling. Cellular effects include increased ATP production, increased protein synthesis including DNA and increased mitotic activity. Specifically, it has been shown that several chondrocyte and osteoblast functions are controlled by electrical fields. It appears in these studies that chondrocytes can be stimulated by externally applied current. The types and waveforms of the electrical stimulation used have been variable from low voltage direct current to high voltage pulsed stimulation.

Recently research has been published about the effects of low voltage pulsed electrical stimulation treatments of osteoarthritis of the knee.' In this double blind, randomised controlled study done at several major medical universities in the United States, 77 osteoarthritis patients were treated with a battery powered low voltage pulsed stimulator. Currents were adjusted by the patient to their tolerance level (currents were set to just below where the patient feels a tingling sensation). Each person used the portable stimulator daily, passing the current through two surface electrodes placed on the joint and thigh. The conclusions reached in this study showed that there was a statistically significant reduction in knee pain, knee flexion, function and morning stiffness. There were no consequential side effects reported.

In numerous other studies, it has been shown that electrical stimulation applied to the arthritic joint will increase the rate of repair of the bone and cartilage as well as the soft tissue surrounding. However, the stimulation used in each study was variable and set to patient's tolerance.

The specific combination of stimulation parameters incorporated into the device developed for this trial were created as a result of the authors' 20 years of experience with electrical stimulators in the treatment of arthritis.

MATERIALS AND METHODS

Subjects

For these trials we selected 16 subjects who had a previous diagnosis of osteoarthritis of the knee and showed active involvement of the affected joint. The average age of the subjects was 66 (range 37-77); there were 6 males and 10 females.

Each subject agreed to use the stimulator once per day as per instructions. Each agreed to keep an accurate log of treatments including date, time of day and general health condition. Each subject was instructed to continue with any current treatments including NSAID therapy and to remain under the care of their physician.

The device automatically timed the treatment and shut itself off at the end of the 30 minute treatment time. Each subject treated the affected knee once per day. Each subject was instructed to place the electrodes on the medial and lateral side of the knee to pass current completely through the joint.

Trial Period

The subjects treated themselves daily for 12 weeks. Baseline measurements were obtained prior to the first treatment. Final measurements were obtained at 12 weeks on the day following the last treatment.

Three criteria were used to measure efficacy of the treatments:

- 1 . Subject evaluation of joint pain - measured by 10cm visual analogue scales (VAS) with 0 as no pain and 10 as maximum pain.
2. Goniometric measurement of the knee ROM-measured in degrees by the investigator bi-weekly. Total ROM was measured from full flexion to full extension.
3. Knee circumference measured in cm by the investigator bi-weekly. Measurements were made at the same anatomical point each time using a Gulick anthropometric tape.

Summary

Overall 6 out of 16 patients (38%) showed improvement in all 3 categories. 8 out of 16 (50%) showed improvement in 2 out of 3 categories. 2 out of 16 (12%) had improvement in 1 out of 3 categories.

Side Effects

No side effects were reported with the exception of tingling at the electrode site reported by 6 out of 10 subjects during the treatment period. Mild erythema under the electrodes was reported in all subjects but disappeared within 30 minutes.

DISCUSSION

Medical management of osteoarthritis has generally failed a large number of people. This is either due to patient intolerance, lack of appropriate response or patient noncompliance with the protocols. Most of the treatments make no attempt to treat the underlying loss of cartilage. There are now many reports showing the healing and regeneration effects of externally applied current. Unfortunately a great range of currents, frequencies and waveforms were used in these studies, the great majority of which used patient tolerance as the setpoint of the current intensity. Many animal studies, however, have shown that there is a specific current intensity at which the cells show maximal response.

Much like there are specific dosages of medications offered, there should theoretically be specific current levels that are the most efficacious for treating damaged joints. There must also be specific treatment durations which are the most efficient and the most convenient for patients to use on a daily basis.

The stimulation mode and timing used in this trial, with its short duration and automatic settings were certainly well accepted by the subjects in this study. With no reported side effects, the subjects were willing to continue the treatments indefinitely beyond the study period.

CONCLUSIONS

The clinical data presented here seems to show that the device parameters used in a specific duplicates the treatment successes of past research. The advantage of the protocol used in these trials is that a specific dose of current was delivered to each subject for a much shorter time period than previously thought necessary. This will enable many more subjects to use such a stimulator every day as their symptoms warrant.

Certainly, based on these trials and other published studies, this form of treatment should be considered by all with osteoarthritis, especially those for whom conventional treatments are failing.

Additional research needs to be done with these parameters utilising a larger subject base in a double blind controlled trial. The long term effects of electrical stimulation of osteoarthritis needs further research, including the specific effects on human cartilage and surrounding soft tissue.

Subject	Initial Knee ROM	Final Knee ROM	Actual Change	% Change
1	60	65	5	8%
2	80	80	0	0%
3	80	85	5	6%
4	95	105	10	10%
5	90	96	5	6%
6	75	75	0	0%
7	60	55	-5	-8%
8	75	85	10	13%
9	85	85	0	0%
10	90	100	10	11%
11	95	95	0	0%
12	85	90	5	6%
13	80	90	10	12%
14	70	75	5	7%
15	85	85	0	0%
16	80	95	15	19%
Average	80	85	5	6%

Table 3 - Knee Range of Motion Measurements

Subject	3 out of 3	2 out of 3	1 out of 3	0 out of 3
1	X			
2		X		
3		X		
4	X			
5		X		
6		X		
7			X	
8	X			
9		X	X	

10	X			
11		X		
12	X			
13		X		
14	X			
15		X		
16		X		

Table 4 - Subject Improvement for Each of the Three Measured Outcomes

Pain. 14 out of 16 subjects reported less pain in the treated joint following the 12 weeks of active treatment. The average reduction of pain was 50% or 3 units. 2 subjects reported no change.

Knee Circumference. Measured knee circumference for the 16 subjects showed an average 2% or 1 cm decrease in size. 11 out of 16 subjects showed a decrease in circumference. 2 subjects had an increase in knee circumference and 3 subjects showed no change in the 12 week period.

Knee Range of Motion. Measured knee ROM showed an average increase of 5 degrees. 10 out of 16 showed an increase of 5 degrees or more, 5 out of 16 showed no change over the 12 weeks and 2 showed a 5% decrease in ROM.

The data was analysed to include both actual change in measured criteria and percentage change from the initial measurement to the final measurement.

Any side effects either observed by the investigator or reported by the subjects were recorded

RESULTS

Each of the 16 subjects completed daily treatments for the full 12 week cycle. The results of the initial v final measurements for each of the 3 outcome criteria are in tables 1, 2 & 3. A summary of outcomes is listed in table 4.

Subject	Initial Pain Evaluation	Final Pain Evaluation	Actual Change	% Change
1	8	6	-2	-25%
2	5	2	-3	-60%
3	5	4	-1	-20%
4	3	0	-3	-100%
5	5	3	-2	-40%

6	7	3	-4	-57%
7	7	7	0	-0%
8	6	3	-3	-50%
9	5	3	-2	-0%
10	6	3	-3	-50%
11	9	4	-5	-55%
12	7	4	-3	-43%
13	4	4	0	-0%
14	3	1	-2	-67%
15	6	1	-5	-83%
16	7	2	-5	-71%
Average	6	3	3	-50%

Table 1 - Subject's Evaluation of Pain

Subject	Initial Knee Circumference	Final Knee Circumference	Actual Change	% Change
1	8	6	-2	-25%
2	5	2	-3	-60%
3	5	4	-1	-20%
4	3	0	-3	-100%
5	5	3	-2	-40%
6	7	3	-4	-57%
7	7	7	0	-0%
8	6	3	-3	-50%
9	5	3	-2	-0%
10	6	3	-3	-50%
11	9	4	-5	-55%
12	7	4	-3	-43%
13	4	4	0	-0%
14	3	1	-2	-67%
15	6	1	-5	-83%
16	7	2	-5	-71%
Average	6	3	3	-50%

Table 2, Knee Circumference Measurements