

Analysis of The Control of Postoperative Pain with BioElectronics RecoveryRX after Breast Augmentation

Introduction

Postoperative Pain

Postoperative pain control following surgery is a major priority for both patients and doctors. Pain affects blood pressure, heart rate, appetite, and general mood. When pain is well controlled patients feel more:

- ❖ Comfortable which helps the body heal.
- ❖ Treating pain early usually brings quicker and better results.
- ❖ With less pain patients can become active sooner therefore allowing earlier recovery of strength.
- ❖ Patients with well controlled pain progress faster and may reduce the risk of developing certain complications after surgery such as pneumonia and blood clots.

Pain Medications

For moderate to severe postoperative pain, narcotic pain medications are used. These are often combined with ibuprofen and acetaminophen to enhance their effect. Side effects from narcotic medications use include nausea, vomiting, drowsiness, dry mouth, itching and difficulty urinating. Narcotic pain medications do not control inflammation.

Over the counter pain medications are also used to control postoperative pain, they include ibuprofen, acetaminophen and naproxen. However, care should be used, as in combination with narcotic drugs it can lead to overdose, as many narcotics contain acetaminophen or ibuprofen. Common side effects of these drugs are stomach upset and dizziness and liver damage. They should not be taken with patients who have kidney problems or a history of stomach ulcers, heart failure or are on blood thinner medications.

The use of Recovery Rx to control postoperative pain in a double blind, placebo controlled, randomized pilot study on postoperative pain after breast augmentation surgery

Study Design

Eighteen patients were recruited into a pilot study to assess the control of pain with BioElectronics RecoveryRx device. On completion of surgery baseline pain scores were taken using a 0-10 point visual analogue scale (VAS). Two devices were then placed, both either Active or Placebo, over each breast. VAS scores were recorded for the following 7 days and pain medication use, both narcotic and OTC, were logged. Randomization resulted in 10 patients receiving the Active devices and 8 patients receiving the Placebo devices.

Results

The mean baseline VAS was 6.29 for all patients in the study. Table 1 shows the mean daily VAS scores for the active and placebo groups on a daily basis. Starting at day 1 the mean VAS in the Active group was lower than the Placebo group, in fact the Active group had a 35% lower pain score. The difference in pain levels increased, with the Active group showing 53% less pain by day 3 and 80% less pain by

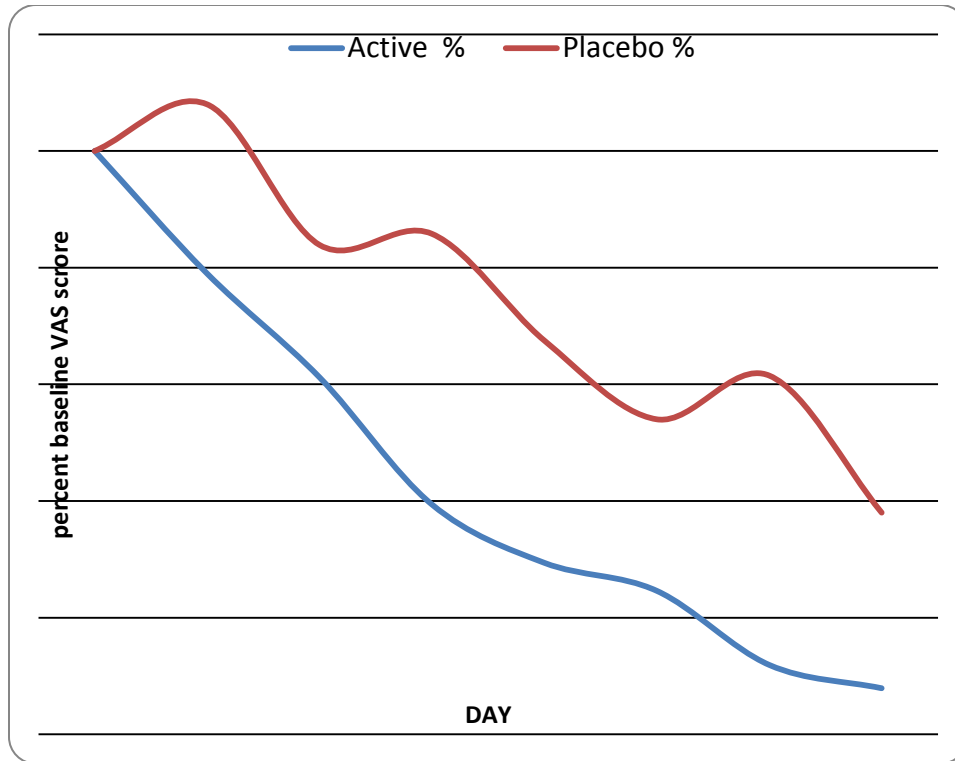
day 7. The VAS scores were significantly lower on each day, except day 2, as determined by a student t test.

Table 1.
The daily VAS scores and the Active group % lower along with p values.

DAY	P-VAS	A-VAS	A % lower	P value
(baseline)	6.29	6.29	-	-
1	6.80	4.40	35	0.017
2	5.20	3.85	26	0.21
3	5.40	2.57	53	0.008
4	4.25	2.00	53	0.02
5	3.40	1.55	55	0.027
6	3.80	0.75	80	0.0006
7	2.40	0.50	80	0.0006

Figure 1 shows the VAS scores plotted as a percent of the baseline VAS score. These results show that the rate of decline in pain is greater in the Active group compared to the Placebo group. Only 7.9% of the baseline score is remaining in the Active group at day 7, which compares to 38% in the Placebo group. The accumulated VAS point total for the Placebo group was 31.25 pts compared to 15.62 in active group. The Active group patient experience 50% less pain over the 7 day study period.

Figure 1.
The VAS scores are plotted as a percent of the baseline score.



Conclusion 1: The Active group had significantly lower pain.

Medication

The pain medication was logged for by each patient on a daily basis. Patients used both narcotic pain medication consisting of oxycodone/Percocet and hydrocodone/Vicodin. OTC medication use was acetaminophen and ibuprofen.

Narcotic Medication

In Table 2, the patient level use of narcotic medication is shown. It can be seen from this data that patient in the active group tended to use less narcotic pain medication than those in the Placebo group. One patient, shown as patient 10 in the Active group used 33 narcotic pain pills, this represents 30% of the total of the Active group narcotic medication use. Statistics are shown in Table 3. The means were 11.0 pills per patient in the Active group and 18.1 in the Placebo group, this represents a 64% more medication use in the Placebo group, though not significant ($p = 0.07$). However, with the outlier removed the mean pill use becomes 18.1 Placebo and 8.5 in the Active group. This then shows a significant difference ($p = 0.002$).

Table 2A and Table 2B show the patient level narcotic pain pills used.

Table 2A. Active Group

Table 2B Placebo Group

Patient A-g Pills

Patient P-g	Pills
1	6
2	13
3	18
4	19
5	21
6	22
7	23
8	23
1	2.5
2	4
3	5
4	6
5	7
6	10
7	14
8	14
9	14.5
10	*33*

** this patient used 30% of the Active group total.

Table 3

The total narcotic pills used by patient group, mean, median, standard deviation (SD) and p value, also the total, mean, median, SD and p value with the outlier ** removed.

	Total	mean	SD	median	P value	Total	mean	SD	median	P value
placebo	145	18.1	5.9	20	-	145	18.1	5.9	20	-
active	110	11.0	8.9	8.5	0.07	77	8.5	4.6	7	0.002

Table 4

The mean daily use of narcotic pain medication and P values.

DAY	1	2	3	4	5	6	7
P-MED	3.75	4.44	3.25	2.87	2.06	0.88	0.88
A-MED	2.95	4.05	2.3	1.1	0.5	0	0.1
P value	-	-	-	0.05	0.01	0.02	0.5

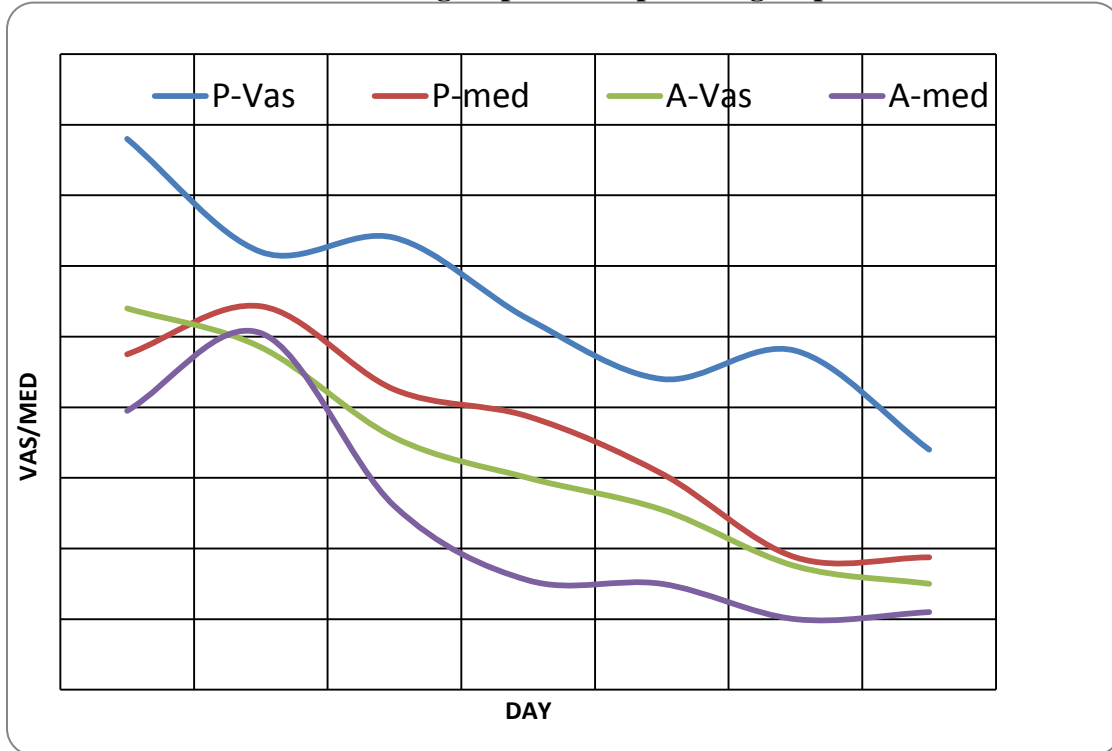
The prescription medication usage in the Active group was not significantly different from the placebo group until day 4 (Table 4). Days 4, 5, 6 and 7 were significantly different ($p < 0.05$). At day 3 the active group consumed 2.3 pills per patient compared to the placebo groups 3.25 pills; this represents a 29.2% decrease but was not significant. (These results contain the outlier).

Conclusion 2: The Active group used significantly less narcotic pain medication

In figure 2, the VAS scores and narcotic medication used on a daily basis are plotted together. There appears to be a close relationship between VAS and medication use which is what would be expected. As Vas scores decline so does the use of narcotic pain medication. Since the VAS scores in the Active group are significantly lower the narcotic medication use is also lower in the Active group.

Figures 2

The close relationship between the decline in mean VAS score and prescription medication use for the active group and the placebo group

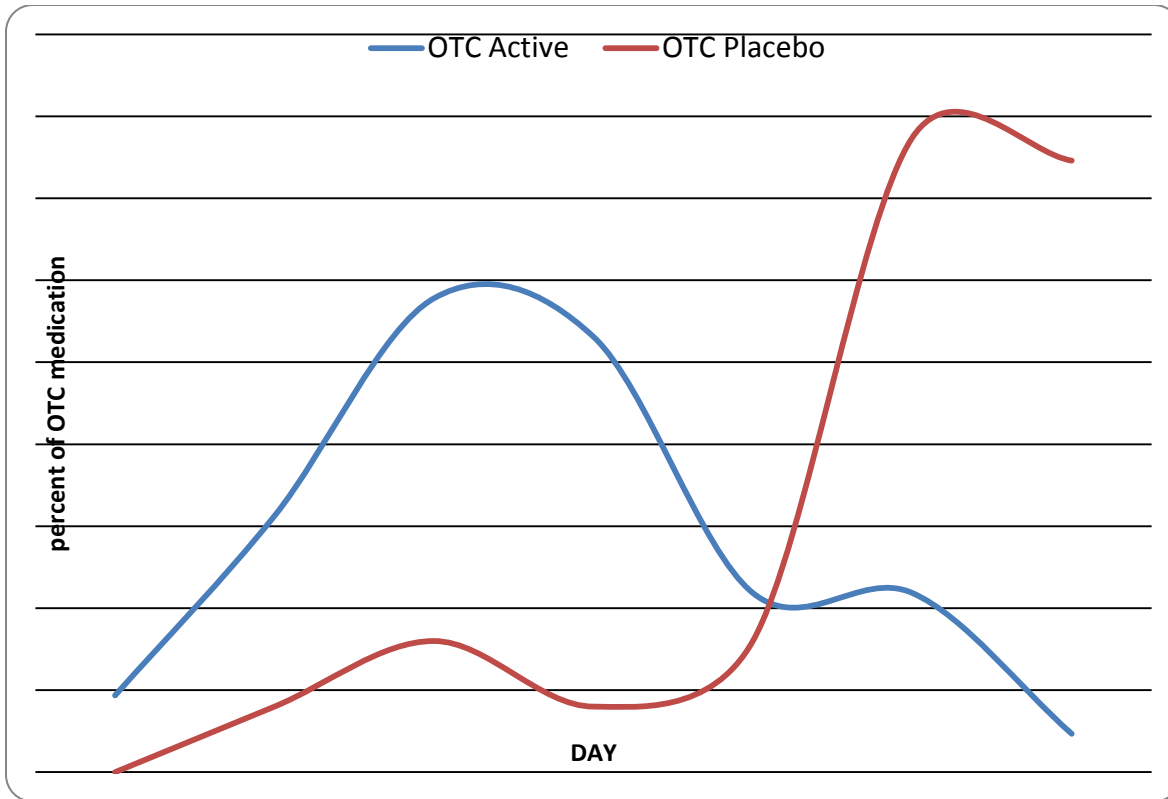


Over the Counter Pain Medication

Day	% OTC Active	% OTC Placebo
1	4.6	0
2	15.6	4
3	28.9	8
4	26.5	4
5	10.9	8
6	10.9	38.7
7	2.3	37.3

The total OTC medication use in the Active group was 127 pills, which was higher than the placebo group at 75 pills, and the average active group patient use was 12.7, compared to 9.3 pills in the placebo group. However, it can be clearly seen from the data as presented in Tables 5 and Figure 3 that the placebo group would have continued to use significant amounts of OTC pain medication beyond day 7, whereas in the active group this would not likely have been the case.

**Table 5. The daily use of OTC pain medication expressed as a percent of the total
Figure 3
Percent of the total OTC pain medication used in each group shown on a daily basis.**



Of the 18 patients in the study, 7 began using OTC pain medication by day 3, 6 in the active group and 1 in the placebo group. The OTC pain medication use was closely associated to lower VAS and lower prescription pain medication usage. The average VAS score and average prescription pain medication use for these 7 patients at day 3 was 2.0 and 1.0 respectively. This data demonstrates that as VAS scores decline there is switch to OTC pain medication and away from prescription pain medication. At day 4, 6 of 10 (60%) of the active patient group were using OTC pain medication compared to 1 of 8 (12.5%) in the placebo group, (VAS scores were 1.85 active and 4.25 placebo). At day 4 the use of prescription pain medication was significantly lower ($p < 0.05$) in the active group and the VAS score was 2.35 points lower in the active group. At day 7 the number of patients taking OTC pain medication in the active group was 1 of 10 (10%) and in the placebo group 5 of 8 (62.5%). The percent of the total OTC pill usage per day is shown in Figure 3. The OTC pain medication use in the active group peaked at days 3 and 4 compared to the placebo group which peaked at days 6 and 7.

Summary

Patients who used the Active Recovery Rx device had significantly lower postoperative pain scores than the patients with the placebo device. Active group patients experienced 50% less pain over the 7 day study. Along with these significantly lower pain scores, patients used significantly less narcotic pain medication. Patients using Recovery Rx would be expected to return to normal activity sooner and suffer fewer complications following surgery, and fewer complications from medication use.

Conclusion

*Recovery Rx significantly reduces postoperative pain and narcotic medication use.
Why operate without one?*

ACTIPATCH - A New way of treatment, Pilot investigation of 52 patients in general praxis.

Evaluated September – October 2008
Jørn Bennedbæk, MD

Hypothesis of treatment

In living healthy cells the potential of the membrane potential is stable equals rest potential. The inside of the membrane is negative in relation to the outside. Most of our cells have a rest potential in the membrane in the range about 70 millivolt. When it increases it is hyperpolarised, if it decreases the membrane will depolarise. If the 70 millivolt is valued as a field over the 7 nanometer thick membrane, the strength of the field equals 10.000 volt pr.mm. Changes in the environment/field has direct effect on conformation of proteins in the plasma membrane and due to this abilities of the composition of multi formations of

amino acid (ref. 1) The synthesis of proteins in fibroblasts in electromagnetic fields has been investigated earlier (ref.2)

Actipatch uses the modulated radio frequencies generated electromagnetic field to induce the low-frequency membrane stabilising pulse, with amplitude in the field of 1 kHz / 100 uV/cm the membrane will due to this, be forced to re-establish the rest potential.

The effect can be at more points. Stabilising the cell. Improvement of Cell-to-cell communication. Improvement of the neuron-transmission. The direct and indirect effect in inhibition of the inflammation process at all levels.

Duration of treatment

The patients received instructions in use with application from bedtime until morning every day for one week. The effect had to be noted on a visual scale from 0-5, where (vs5) is maximal (start) pain and (vs0) no-pain. Duration of the test was 7 days.

Diagnosis and results

3 patients with fasciitis pedis. 1 painfree after 5 days, 1 after 6 days No..3 was on stage (vs1) after 7. days

7 patients with epicondylitis lateralis. 1 was free of pain day 4. 4 on day 6. 1 had only slight pain (vs2) on day 7. 1 * had no effect.

2 patients with epicondylitis medialis had no pain, whatsoever on day 6.

4 patients with tibialis anterior syndrome. 2 were free of pain after 3 days and 2 on day 5.

2 patients with Mb.Osgood-Schlatter had no effect after 7 days.

2 patients with pes anserinus tendinitis had only slight problems on day 7 (vs1)

3 patients with polyarthrosis manuum verified also as arthritis rheumatoides . 2 had no pain after 6 days . 1 had only slight problems on day 7 (vs2)

2 patients with arthritis urica. On day 7 one had only slight pain (vs1) and the other had moderate pain (vs3)

8 patients with myosis lumbale et paravertebrale without referred pain or neurological deficits. 3 had no pain on day 4 ,2 on day 5 . 1 on day 6. and 2 had only slight problems on day 7 (vs2)

2 patients with pain one year after surgery for cervical prolaps of discus. No effect.

2 patients with pain one year after surgery for lumbal prolaps of discus .1 had moderate pain day 7 (vs2)
1 had no effect.

3 with distorsio pedis/laesio lig. talofibulare anterior. 2 had no pain day 6. 1 had day 7 only slight problems (vs1)

8 patients with various tendinites of wrist /forehand and antebrachium (flexors and brachioradialis). 4 had no pain day 3. 1 on day 4 1 on day 5 and 1 on day 6. 1 had no effect .

4 patients with tendinitis of Achilles. 3 had no pain day 5 .1 on day 6.

* Had earlier operation on pronator teres syndrome bilateralis.

Discussion

AP has proved convincing effect at many conditions. There were no side-effects reported nor complaints of any kind. The device is simple and easy to handle.

Spontaneous remission would appear at more of the patients in this investigation, but how fast in relation to these results ?

2 patients with rheumatoid arthritis concluded the relief of pain just as effective as the treatment of steroids in high-dose for short periods, but faster effect.

In this pilot project, application was only 8 hours per day. The device may and can be used 24 hours per day.

Could more of the patients had effect faster or some at least have had an effect if the device were used permanently. AP has power for 720 hours.

The primary impression in effect of the treatment of patients with the diagnosis, where positive response has been notified is effect at least as effective as usually treatment, but with far faster onset of relief.

AP has cell restitution effect and more test has been started in examination of wound healing and effect on post-operations conditions (healing proces, haematoma etc.) and latest in treatment of psoriasis.

Actipatch has been in use on more patients with ulcers of the lower limbs treated by nurses in the county.

Furthermore the joint pains of one psoriasis patient disappeared after 1 week of treatment. When stopped the joint paint went back after few days. Disappeared again with re-use of the AP for few days

More injuries from sport has been treated with AP and has proved excellent results. Many questions now and in the future will be asked in order to examine further possibilities and effects of the AP.

Further investigation on a scientific basis has to be done to find right indications of treatment and duration of the many diseases potentially involved.

References

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Human Experimental Wounds

Bentall, RHC 1981

A key parameter of wound healing is the migration of cells into the wounded area to repair the injured tissue. In this double-blind study, treatment with pulsed RF energy was found to affect the rate at which full-thickness skin wounds healed, and on the histological appearance of biopsies performed on the healed tissue.

First Series

a) Aim

The aim of this double-blind experiment was to determine the effect of treatment using pulsed RF energy on the histological appearance of human full-thickness skin wounds of the lower limbs.

b) Method

A full-thickness disc of skin (2cm diameter) was removed from each inner calf of a human volunteer. Each wound was allocated an identical treatment device, one active and the other placebo. The identity of the devices was revealed only when the wounds had completely healed. The devices were worn for 16 hours a day until that time. Biopsies of both wounds were performed nine months after healing. The tissue was sectioned and stained with either Haematoxylin & Eosin or Van Gieson. The sections were examined by a histopathologist who was not aware which wound had been actively treated.

c) Results

PLACEBO SIDE

This showed the features of normal secondary wound healing:

- i. thin epidermal layer
- ii. basal epidermal layer pleomorphism
- iii. lack of pallisading
- iv. endarteritis

The placebo treated wound took 54 days to heal.

ACTIVE SIDE

This showed some advantageous features not usually associated with secondary wound healing:

- i. almost normal depth of epidermal layer
- ii. no pleomorphism
- iii. basal cell pallisading
- iv. no endarteritis, but developed endothelium

The actively treated wound took 39 days to heal.

Second Series

a) Aim

The purpose of this second series of wounds was to establish when the thickened epithelium observed in the first study developed, and to obtain histological evidence confirming earlier cell migration into the defect.

b) Method

In this double-blind experiment, a series of twenty (3mm diameter) full thickness wounds were made on the upper aspect of the thighs of a human volunteer. Ten wounds received placebo treatment, the other ten received active treatment. The pulsed RF devices were similar to the lower power devices used in the rat tensile strength experiment and were worn continuously. Biopsies of the wounds were performed during the initial period of healing, at 1, 2, 3, 5, 7, and 14 days. The results shown below are a summary of all of time groups.

c) Device Specifications

Power Source. 3.5 Volt battery
Carrier Frequency. 44 MHz Pulse Width. 100 microsecs
Pulse Repetition Frequency. 1 KHz

d) Results

PLACEBO GROUP

As with the first series these wounds showed the typical features of secondary wound healing:

- i. thin epidermis
- ii. basal layer pleomorphism

TREATED GROUP

These wounds showed:




- i. earlier epidermal budding,
- ii. earlier migration into the wound,
- iii. earlier appearance of rete ridges, and
- iv. almost normal depth of final epidermis.

Conclusions (First and Second Series)

Treatment of skin wounds with pulsed radio frequency energy influenced the processes of acute secondary wound healing. The rate of healing was accelerated and the histological appearance of the actively treated wounds showed that the healed epidermis was more like normal skin than the scar tissue typical of secondary wound healing. The effect demonstrated in these studies indicates that low-level pulsed radio frequency energy has therapeutic potential.

Photographic Evidence of Clinical Effectiveness – Superficial Gangrene

Dr. Bentall effectively treated patients with superficial gangrene and decubitus ulcers using only the ActiPatch Therapy prototypes for treatment. The treatments provided dramatic turnarounds in situations where other therapy had failed to improve the patient’s condition.

<p>This sequence of photographs shows the progression of healing on a 76 year-old female's Decubitus ulcer. View one is before treatment with superficial gangrene.</p>	
<p>Second picture shows healing after 2 weeks.</p>	
<p>Last picture is a close up of the healed wound after 6 weeks. The only treatment was a prototype of the therapy.</p>	

Sacral Decubitus Ulcer

 <p>74 year old male, with 18 week old sacral decubitus ulcer that had been unsuccessfully treated by plastic surgery 4 weeks earlier.</p>	 <p>Six weeks after treatment started with only ActiPatch prototype</p>	 <p>Eleven weeks after treatment started the wound is almost healed</p>
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