



UK & Irish Consumers Report: ActiPatch Stops Pain

**First Results of
Try It and Tell Us Program**



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Introduction

Millions suffer from acute or chronic pain every year and the effects of pain exact a tremendous cost on each countries health care costs, rehabilitation and lost worker productivity, as well as the emotional and financial burden it places on patients and their families. The costs of unrelieved pain can result in longer hospital stays, increased rates of re-hospitalization, increased outpatient visits, and decreased ability to function fully leading to lost income.

The total cost of pain to the UK economy in terms of people removed from the workplace because of chronic pain is unknown, but is likely to be in the range of £10 - 20 billion. The assessment on the costs of treating chronic pain in the US was placed at \$635 billion annually. Statistics show for the UK that treating all types of back pain costs the NHS more than £1000 million per year. In 1998, the direct healthcare costs of all back pain in the UK were estimated at £1623 million - approximately 35% of these costs were related to services provided by the private sector. It is estimated that the costs of care for low back pain exceed £500 million per year in the private sector, with the NHS incurring costs of over £1000 million.

Lost production as a result of low back pain costs at least £3500 million per Year. Despite the relative pervasiveness of low back pain, and the enormous financial burden on the health care system, chronic low back pain remains a difficult condition to treat. Identification of efficacious noninvasive, non-pharmacological therapies could provide a valuable additional new mode of therapy and result in substantial population improvement in morbidity and associated healthcare costs.

Current conventional methods of pain management have a heavy reliance on analgesic drug therapy and often users show little knowledge or concern of the risks associated with their use, and pain medications are clearly an inadequate method of controlling pain.



ActiPatch® Survey

BioElectronics has set up a free sample program where interested parties sign up for a free 7 day (use time) ActiPatch Therapy device. The commercial ActiPatch Therapy device has a 30 day use time. After receiving the 7 day ActiPatch Therapy device the people who signed up for the 7 day samples are sent an email asking them to participate in a survey along with a link (Constant Connect). The survey contains both clinical questions and questions related to commercial purchase. In total 4400 emails were sent out and a total of 610 sent them back, resulting in a response rate of 14%.

Survey Questions

The questions are listed below;

1. Please rate your experience using the ActiPatch.

1 = Well Below Average, 2 = Below Average, 3 = Average, 4 = Above Average, 5 = Well Above Average

2. Where is your pain? Choices:

- Back Pain
- Knee Pain
- Neck Pain
- Shoulder Pain
- Hip Pain
- Other

3. Where did you use ActiPatch?

4. Do you know what causes your pain? Choices:

- Rheumatoid arthritis
- Osteoarthritis
- Fibromyalgia
- Sports injury
- Surgery
- Tendinitis
- Neuropathy
- Other

5. How long have you experienced this pain?

- Less than 3 months
- 3 - 6 months
- Greater than 6 months

6. On a scale from 0-10, please rate the amount of pain you experienced BEFORE you used ActiPatch. 0



being no pain and 10 being excruciating.

7. On a scale from 0-10, please rate the amount of pain you experienced AFTER you used ActiPatch. 0

being no pain and 10 being excruciating.

8. How long did it take for you to notice pain relief from using ActiPatch?

1-2 days

3 days

4 days

5 days

6 days

7 days

(note the free device has a 7 day use time)

9. How likely is it that you would recommend the ActiPatch to a friend or family member?

Very likely

Somewhat likely

Somewhat unlikely

Very unlikely

10. Which category describes your age?

18 - 24

25 - 34

35 - 44

45 - 54

55 - 64

65 or older

Note. The survey is on going, the data presented is the average of 5 surveys approximately 3500 sample users. During the course of the data collection the survey has been adapted and improved so that there is some discrepancy in the totals of responses to some of the questions.



Pain Data

A 7 day ActiPatch® Therapy device sent to people who sign up and request a sample e.g. via Facebook. The consumers are then sent a survey via email after they have completed the trial sample. Of the responses >90% reported chronic pain (pain > 6 months). Of the responses 77% reported a benefit on their pain levels with ActiPatch® Therapy use. The data is summarized in the tables below.

Table 1. The VAS (visual analogue scale) 0- 10 eleven point pain data and standard deviation for 351 survey responders asked this question, including baseline VAS, post ActiPatch use VAS and VAS difference. On the VAS pain scale, a score of 1-3 is considered mild pain, 4-6 moderate pain and 7-10 severe pain. Note that the VAS difference score controls for individual differences in how to score pain.

	VAS	VAS RANGE
BASELINE VAS	8.45 ±1.4	4 -10
POST ACTIPATCH VAS	5.06 ±2.7	0-10
VAS DIFFERENCE	3.49	
PERCENT DECREASE	41%	

Table 2. The VAS (visual analogue scale) 0- 10 eleven point pain data and standard deviation for the 77% who reported a VAS score reduction, including baseline VAS, post ActiPatch VAS and VAS difference.

	VAS	VAS RANGE
BASELINE VAS	8.58 ±1.4	4 -10
POST ACTIPATCH VAS	4.15 ±2.3	0-9
VAS DIFFERENCE	4.5	
PERCENT DECREASE	52%	



Cause and Location of Pain

Table 3. The cause of the Pain, - some patients noted multiple causes.

	Number	% reporting
Rheumatoid Arthritis	64	9.2%
Osteoarthritis	133	21.3%
Fibromyalgia	146	21.7%
Sports Injury	24	4.2%
Surgery	41	6.8%
Tendonitis	16	2.8%
Neuropathy	28	5.2%
Other	161	28.7%

Table 4. The location of the pain, - most patients noted multiple pain locations.

	Number	Percent with
Back Pain	281	64%
Knee Pain	132	38%
Neck Pain	94	28%
Shoulder Pain	136	38%
Hip Pain	97	31%
Other	77	22%

VAS Pain by Condition

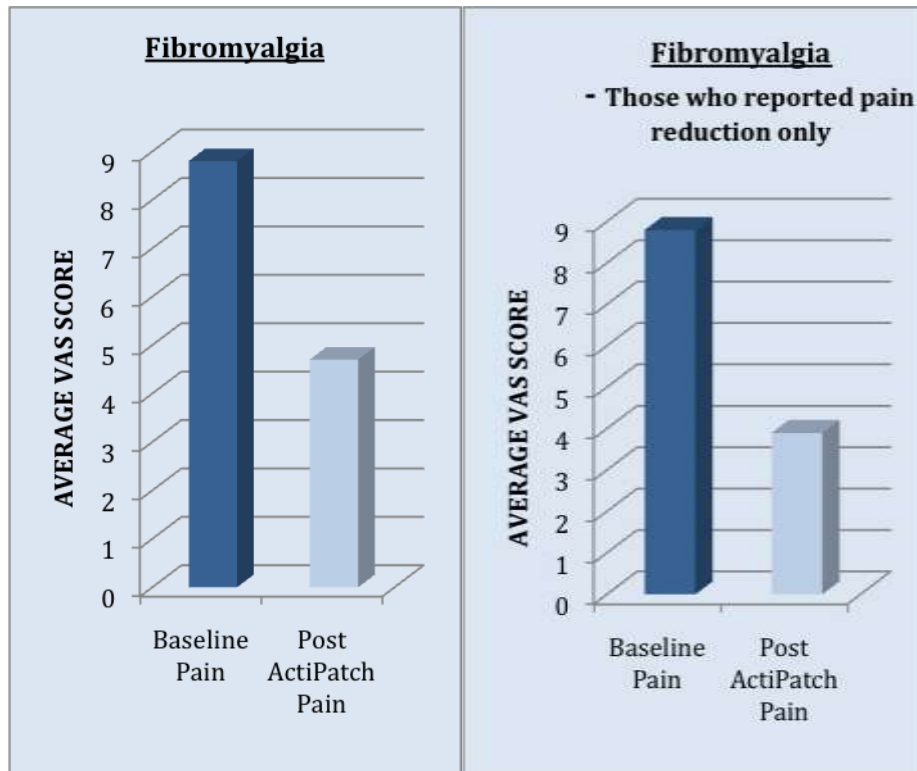
ActiPatch® - Fibromyalgia

Fibromyalgia is a disorder characterized by widespread musculoskeletal pain accompanied by fatigue, sleep, memory and mood issues. Researchers believe that fibromyalgia amplifies painful sensations by affecting the way your brain processes pain signals. The pain and lack of sleep associated with fibromyalgia can interfere with your ability to function at home or on the job. The frustration of dealing with an often-misunderstood condition also can result in depression and health-related anxiety. In general, treatments for fibromyalgia include both medication and self-care. Twenty one percent of the respondents reported suffering from this ailment.

A. Fibromyalgia - 108 of 145 (75%) reported a pain decrease

	VAS	VAS RANGE	VAS#	VAS RANGE#
BASELINE VAS	8.6 ±1.2	7 -10	8.8±1.2	7-10
POST ACTIPATCH VAS	5.4 ±2.4	0-10	4.5±2.0	0-9
VAS DIFFERENCE	3.2		4.3	
PERCENT DECREASE	37%		49%	

#those who reported pain reduction only



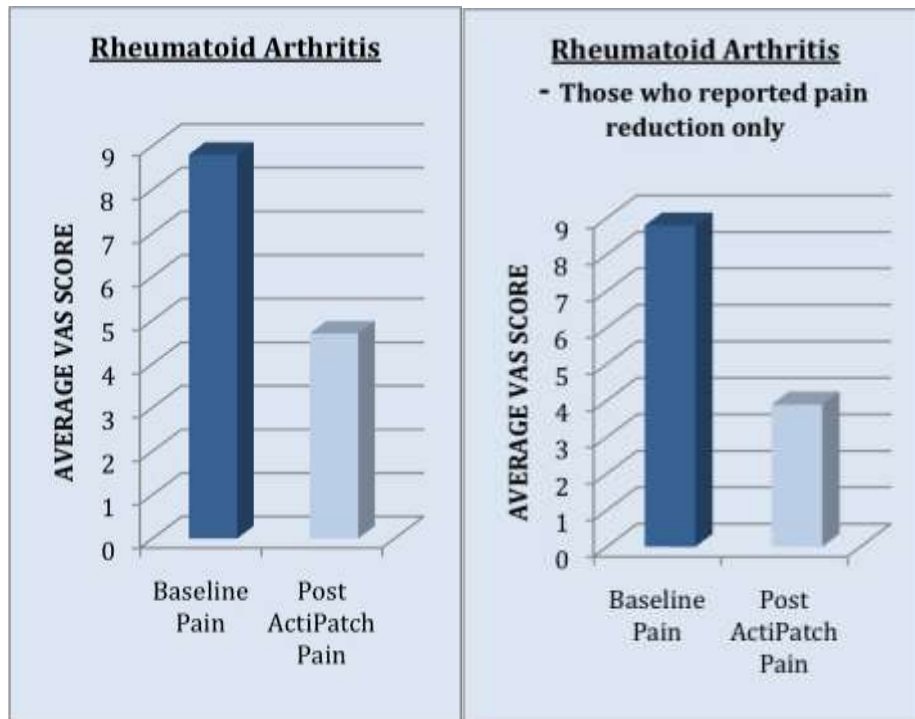
ActiPatch® - Rheumatoid Arthritis

Rheumatoid arthritis is a chronic inflammatory disorder that typically affects the small joints in your hands and feet. Unlike the wear-and-tear damage of osteoarthritis, rheumatoid arthritis affects the lining of your joints, causing a painful swelling that can eventually result in bone erosion and joint deformity. An autoimmune disorder, rheumatoid arthritis occurs when your immune system mistakenly attacks your own body's tissues. In addition to causing joint problems, rheumatoid arthritis sometimes can affect other organs of the body – such as the skin, eyes, lungs and blood vessels. Although rheumatoid arthritis can occur at any age, it usually begins after age 40. The disorder is much more common in women than in men. Treatment focuses on controlling symptoms and preventing joint damage. There is no cure for rheumatoid arthritis. Medications can reduce inflammation in your joints in order to relieve pain and prevent or slow joint damage. Nine percent reported this ailment.

B. Rheumatoid Arthritis - 36 of 43 (84%) reported a pain decrease of 50%

	VAS	VAS RANGE	VAS#	VAS RANGE#
BASELINE VAS	8.8 ±1.3	6 -10	9.0±1.2	6-10
POST ACTIPATCH VAS	5.0 ±2.3	4-10	4.3±2.0	0-8
VAS DIFFERENCE	3.8		4.7	
PERCENT DECREASE	43%		52%	

#those who reported pain reduction only





ActiPatch® - Osteoarthritis

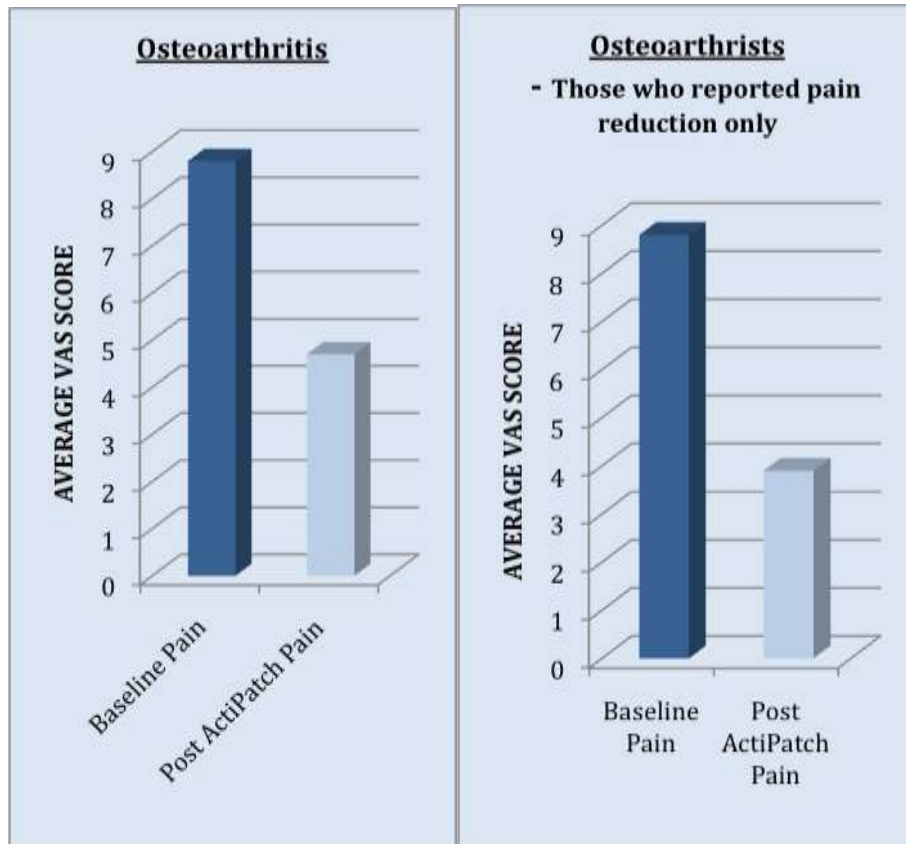
Osteoarthritis (OA) is a clinical syndrome of joint pain accompanied by varying degrees of functional limitation and reduced quality of life. It is the most common form of arthritis, and one of the leading causes of pain and disability worldwide. The most commonly affected peripheral joints are the knees, hips and small joints of the hands. OA is characterized by localized loss of cartilage, remodeling of adjacent bone and associated inflammation. A variety of traumas may trigger the need for a joint to repair itself. OA includes a slow but efficient repair process that often compensates for the initial trauma, resulting in a structurally altered but symptom-free joint. However, in some people, because of either overwhelming trauma or compromised repair, symptomatic OA eventually presents. There is a great deal of variation in clinical presentation and outcome seen between different people, and also at different joints in the same person. OA is one of the most common chronic diseases, with an estimated overall prevalence in the general adult population of 11% for hip OA and 24% for knee OA, respectively. Twenty one percent of our sample reported this ailment.

C. Osteoarthritis 107 of 126(85%) reported a pain decrease

	VAS	VAS RANGE	VAS#	VAS RANGE#
BASELINE VAS	8.7 ±1.3	4 -10	8.8±1.2	4-10
POST ACTIPATCH VAS	4.9 ±2.8	1-10	4.2±2.3	0-9
VAS DIFFERENCE	3.8		4.6	
PERCENT DECREASE	45%		52%	

those who reported pain reduction only





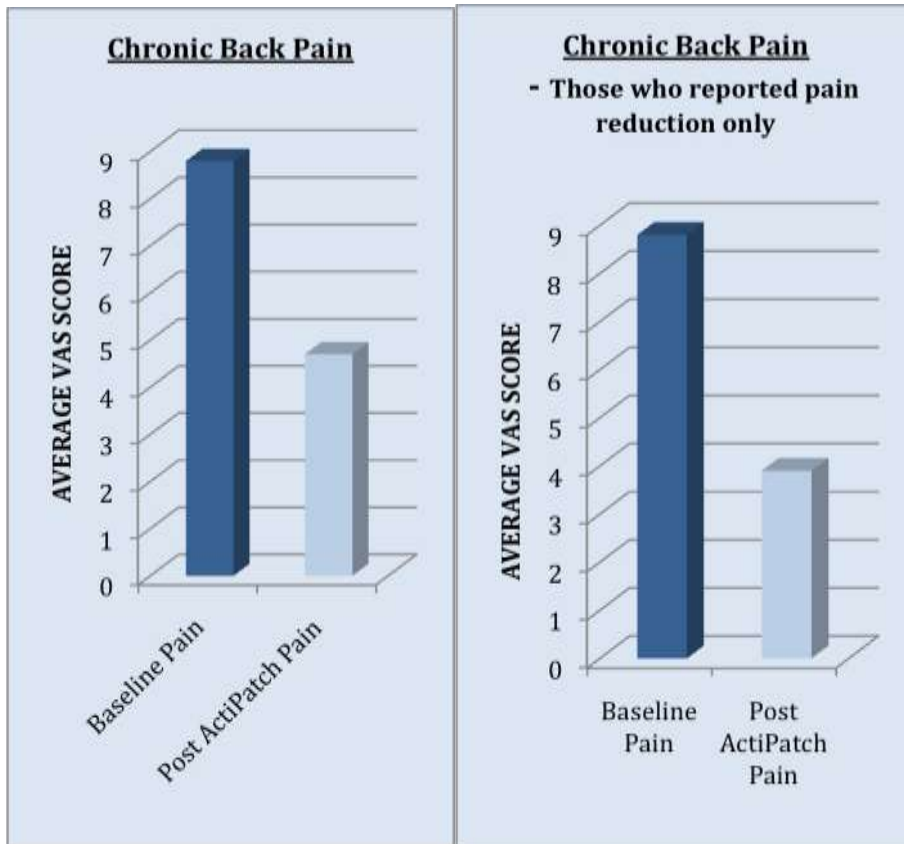
ActiPatch® - Chronic Back Pain

In the UK Up to 80% of the population will experience back pain at some stage in their life. During any one year, up to half of the adult population (15%-49%) will have back pain and the prevalence of chronic back pain is 23%. In only 15% of patients can a cause be identified. The general aims of treatment are to improve pain and to optimize physical, psychological and social functions. Physical therapies may improve pain and functional status but the vast majority of chronic back pain sufferers resort to drug treatment. Drug treatments are of limited effectiveness and have risks of serious adverse effects, particularly with consistent long term use. Sixty four of our sample reported this ailment. But only responders were included in this data who only marked back pain for the cause of their pain (28%).

D. Chronic Back Pain - (back noted as the only response for pain location) 136 of 179 (76%) reported a pain decrease, with a 50% reduction in reported pain.

	VAS	VAS RANGE	VAS#	VAS RANGE#
BASELINE VAS	8.4 ±1.4	7 -10	8.6±1.4	7-10
POST ACTIPATCH VAS	5.1 ±2.6	1-8	4.3±2.2	0-9
VAS DIFFERENCE	3.3		4.2	
PERCENT DECREASE	39%		50%	

those who reported pain reduction only



ActiPatch® - Knee Pain

The number of people affected by osteoarthritis of the knee has increased 2-4 fold over the past 50 years as the population ages and becomes more obese - two major risk factors for developing osteoarthritis. The condition accounts for more than a third of chronic moderate to severe pain in the UK. Painkillers, muscle-strengthening, exercise, and weight loss can all help to manage the condition, while joint replacement surgery can be extremely effective for people with severe, end-stage osteoarthritis. But there remains an acknowledged treatment gap, and more effective forms of pain relief are urgently needed.

E. Chronic Knee Pain - (new question added to clearly determine where ActiPatch was used) 11 of 15 reported knee pain as the treatment location.

	VAS	VAS RANGE	VAS#	VAS RANGE#
BASELINE VAS	8.3 ±1.1	7 -10	8.5±2.0	7-10
POST ACTIPATCH VAS	4.7 ±2.5	1-9	3.6±1.6	1-7
VAS DIFFERENCE	3.7		4.9	
PERCENT DECREASE	43%		58%	

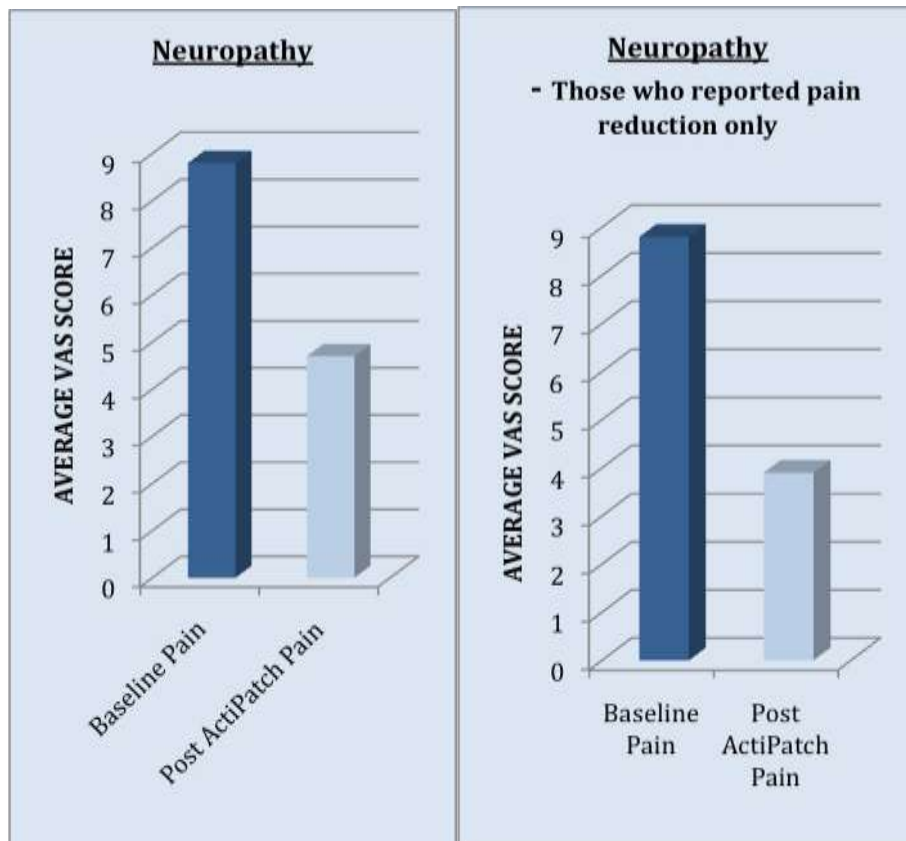
ActiPatch® - Neuropathy

Neuropathy - also known as peripheral neuropathy, polyneuropathy (to signify that it typically affects more than one nerve) and also simply as nerve pain - is a complication found in a number of different underlying conditions. When the underlying cause has not been diagnosed, doctors call it idiopathic neuropathy. Neuropathy means damage to nerves in the peripheral nervous system, and so affects nerves outside of the brain and spinal cord - it does not include nerve damage in the central nervous system. Five percent of our sample reported this ailment.

F. Neuropathy 14 of 22 (64%) reported a pain decrease.

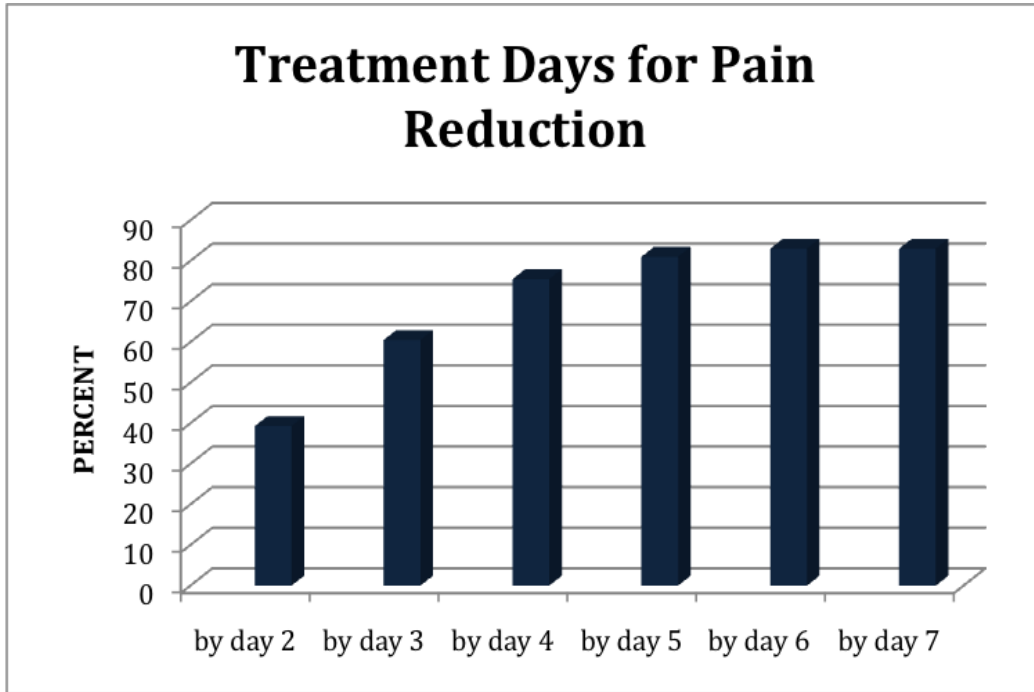
	VAS	VAS RANGE	VAS#	VAS RANGE#
BASELINE VAS	8.3 ±1.8	4 -10	8.4±1.6	4-10
POST ACTIPATCH VAS	5.5 ±3.2	0-10	4.1±2.8	0-9
VAS DIFFERENCE	2.8		4.3	
PERCENT DECREASE	34%		51%	

those who reported pain reduction only



Treatment Time

The time of treat from 165 respondents asked this question is shown below as a percent, as the time needed to obtain pain relief. (This data is currently from survey where the over 80% reported a reduction in pain with 40% reporting pain relief within two days, and 60% within 3 days.



Consumer Data

Table 5. When asked if they intended to purchase ActiPatch after using the trial sample. Close to 60% indicated they intent to purchase ActiPatch and another 22% indicated they might purchase. Only 20% indicated they were not planning to buy ActiPatch—a figure close to the percent that indicated they did not get pain relief from using the patch.

	Purchase Intent
YES	58%
MAYBE	22%
NO	20%

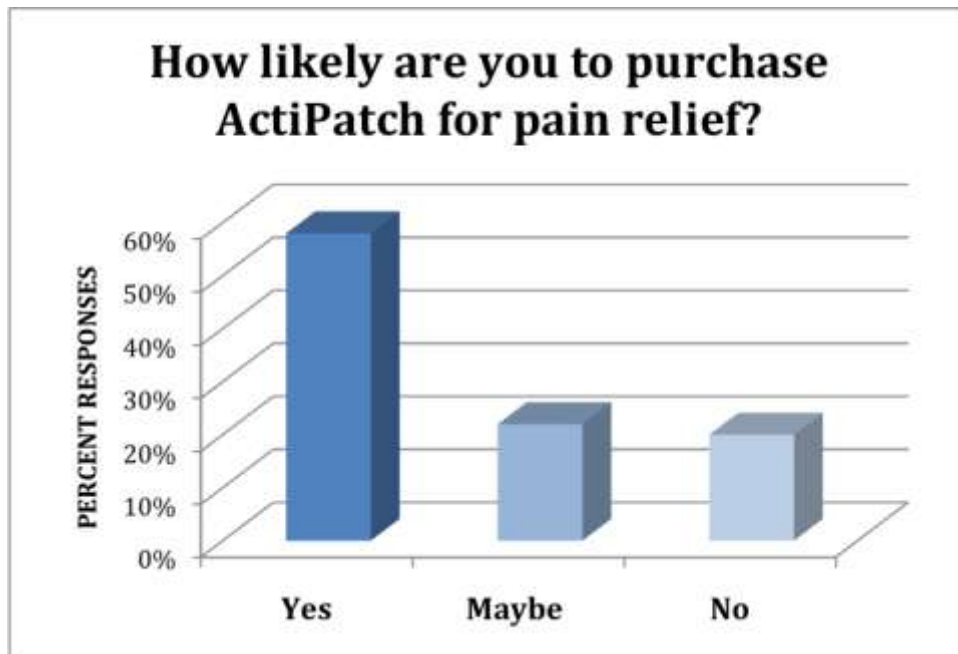
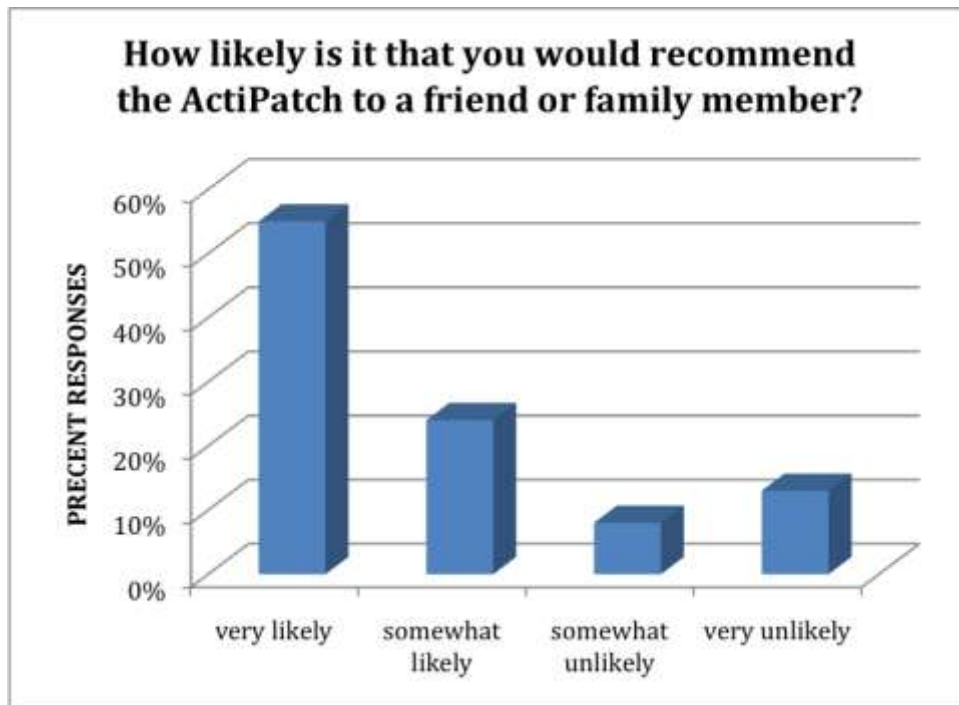


Table 6. The intent to purchase is closely matched to the degree of pain relief.

	YES	MAYBE	NO
BASELINE VAS	9.05	7.54	8.29
POST ACTIPATCH VAS	4.17	4.89	7.74
VAS DIFFERENCE	4.88	2.65	0.55
PERCENT DECREASE	54%	35%	6.6%

Table 7. When asked if they would recommend to a friend or family member. 79% indicated that they were likely to recommend ActiPatch to a friend or family member.

	Purchase Intent
VERY LIKELY	55%
SOMEWHAT LIKELY	24%
SOMEWHAT UNLIKELY	8%
VERY UNLIKELY	13%





Survey Data Non Response Bias

Non-response bias: One major issue with surveys is non-response bias, i.e., persons who respond are different from those who do not respond. If so, then using only the responses to estimate the views of the total population of sampled respondents can yield biased results. For example people who respond often feel more strongly on an issue or have some major reason for voicing their views with the researcher. One method of overcoming this non-response bias issue is to analyze the results over successive “waves” of responses under the assumption that persons who respond in later waves, e.g., after a second reminder are similar to the non-respondents. In a classic paper by Armstrong and Overton (Journal of Marketing, 1977), it was shown that by extrapolating any trends in the data over the two waves it was possible to predict the bias correctly in the third wave 89% of the time. They conclude that this method is the best method for determining non-response bias from just the obtained responses. We use this approach to look at the non-response bias (or lack thereof) in our survey.

Table 8. A total of 1550 ActiPatch sample uses emailed, data collected (first wave) and 5 days later sent a second email to elicit further responses (second wave). Total responses were 155, 113 in the first wave and 42 in the second wave.

	TOTAL 157 RESPONSES (BOTH WAVES)	FIRST WAVE 113 RESPONSES	SECOND WAVE 42 RESPONSES
BASELINE VAS	8.5±1.4	8.5 ±1.4	8.45±1.4
POST ACTIPATCH VAS	5.0±2.3	5.0 ±2.5	5.1±2.6
VAS DIFFERENCE	3.5	3.5	3.35
PERCENT DECREASE	41%	41%	40%
RRESPONSE RATE	81%	83%	75%

1. There was no statistical (or meaningful) difference in initial pain level across the two waves
2. There was no statistical difference in improvement across the two waves although there was a slight decrease in improvement from 41% to 40%
3. There was a slightly different number of people indicating no improvement across the two waves: 18% for the first wave and 25% for the second wave.



Summary:

There is no bias in terms of initial pain levels. There is a slight bias in terms of people responding in terms of getting improvement from the product. In fact we noted that some of the first wave respondents indicated that they got negative improvement—while this did not occur in the second wave. Instead some of the second wave were more likely to report no improvement. Thus a more conservative estimate of how many people get improvement would be somewhere between 82 and 75% (average obtained from 351 responses 77%).

Conclusion: The data from this two wave survey shows there is little concern with non response bias.

Survey Discussion

Musculoskeletal pain is wide spread in society, negatively impacts quality of life and is currently inadequately treated. The results from this study, of the use of a self-administered medical device ActiPatch® for musculoskeletal pain, indicate that it is an effective pain therapy for a wide range of causes of pain including osteoarthritis, rheumatoid arthritis, fibromyalgia and chronic back pain. Consumers showed a very high rate (77%) of indicating pain reduction and of these the average pain reduction was 52% and a 4.5 VAS that is clinically significant. By cause:

- Osteoarthritis efficacy rate was 85% with a 4.6 VAS (52%) pain reduction
- Rheumatoid arthritis efficacy rate was 83% with a 4.7 VAS (52%) pain reduction
- Fibromyalgia efficacy rate was 75% with a 4.3 VAS point (49%) reduction
- Chronic back pain efficacy rate was 76% with a 4.2 VAS point (50%) reduction

It has been previously shown that a decrease of 1.3 points is the minimal change needed to show clinical significance. Inadequately controlled pain has a detrimental effect on quality of life, and there is a proven association that decreasing pain will increase quality of life. It can therefore be concluded that ActiPatch® therapy for musculoskeletal pain will significantly improve quality of life.

Customer responses on intent to purchase and recommend ActiPatch® demonstrate it is a well-accepted therapy by the consumer.
