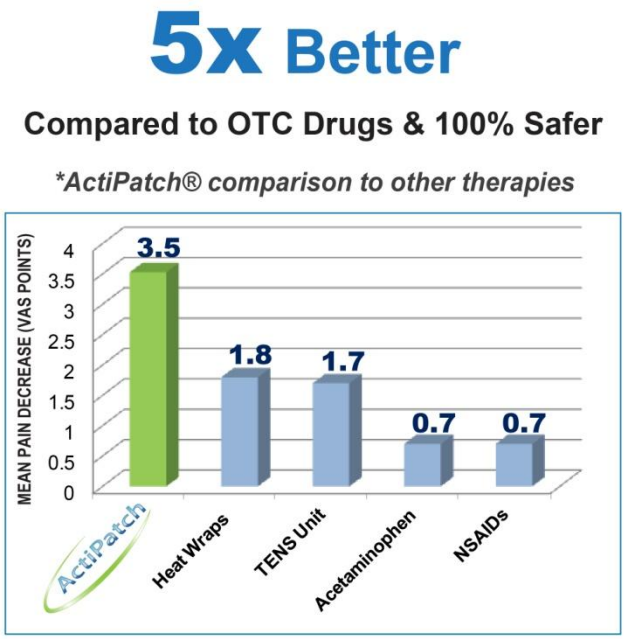
ActiPatch® Survey Results

Introduction

BioElectronics initiated an anonymous survey of customers who had bought and used the ActiPatch product for pain. The survey included questions on the condition that the ActiPatch therapy was used for, how much pain customers were experiencing prior to and post ActiPatch treatment, measured using a 10 point **V**isual **A**nalogue **S**cale (VAS). Measuring pain levels with a 10 point VAS, 0 being no pain and 10 being the worst pain, is an accepted method for measuring and assessing pain. A global assessment of the benefits of ActiPatch use, and the effect it had on quality of life, was determined through a standard and widely accepted **P**atient **G**lobal **I**mpressions of **C**hange (PGIC) scale. Also assessed was to what extent the use of ActiPatch therapy had on their pain medication consumption. Other general questions asked were, would they purchase another ActiPatch and would they recommend ActiPatch to a friend. A list of the complete survey questions is shown below.



*Analgesic effects of treatments for non-specific low back pain: a meta-analysis of placebo-controlled randomized trials. L. A. C. Machado, S. J. Kamper, R. D. Herbert, C. G. Maher and J. H. McAuley. Rheumatology 2009;48:520–527

Method

The survey was created by Qualtrics web based survey software (Qualtrics, Provo, UT), and was included as a link in an email to customers who had previously ordered the ActiPatch product. The link took responders to the survey

site where the questions were laid out with clear response fields. After completing the anonymous survey the data was submitted by clicking the final 'done' button. Data was compiled over 4 days and **totaled 223 responses**.

The survey questions were as follows:

1. *Please write below the main reason for why you used the ActiPatch (eg., back pain, wrist pain, etc.)*

2. *We would like you to describe the change (if any) in ACTIVITY LIMITATIONS, SYMPTOMS and OVERALL QUALITY OF LIFE related to your reason for using ActiPatch.*

*The responses for this question are for the **P**atient **G**lobal **I**mpressions of **C**hange (PGIC) scale*

No change or it got worse	☐	1
Almost the same, hardly any change at all	☐	2
A little better, but no noticeable change	☐	3
Somewhat, better, but the change has not made any real difference	☐	4
Moderately better, a slight but noticeable change	☐	5
Better, and definite improvement that has made a real and worthwhile difference	☐	6
A great deal better, and a considerable improvement that has made all the difference	☐	7

3. *Below we would like you to indicate by moving the slider, the pain level you were experiencing BEFORE and AFTER the ActiPatch treatment. A score of 0 means no pain and a score of 10 means the worst pain possible. (The VAS pain assessment)*

4. *Did you use any pain medication before trying ActiPatch?*

5. *How did the use of ActiPatch effect on your pain medication use?*

Had no effect	1
Reduced the use of pain medication a little	2
Reduced the use of pain medication a moderate amount	3
Reduced the use of pain medication a large amount	4
Eliminated the need for using pain medication	5

6. *Where did you first hear about ActiPatch?*

7. *Where did you purchase ActiPatch?*

8. *Would you purchase another ActiPatch if the need arises?*

9. *Would you recommend ActiPatch to a friend?*

10. *How many hours per day do you use the ActiPatch.*

11. *How many total days have you used the ActiPatch.*

12. *Why not? Check all that are applicable.*

13. *We are interested in how you might respond if a friend asked you to describe the ActiPatch and how it works. Below, briefly write out what you might say telling your friend about how the product works.*

14. *Is there anything else that you would like to tell us about the product? If so, use the space below.*

Results

Question 1: Please write below the main reason for why you used the ActiPatch (eg., back pain, wrist pain, etc.)

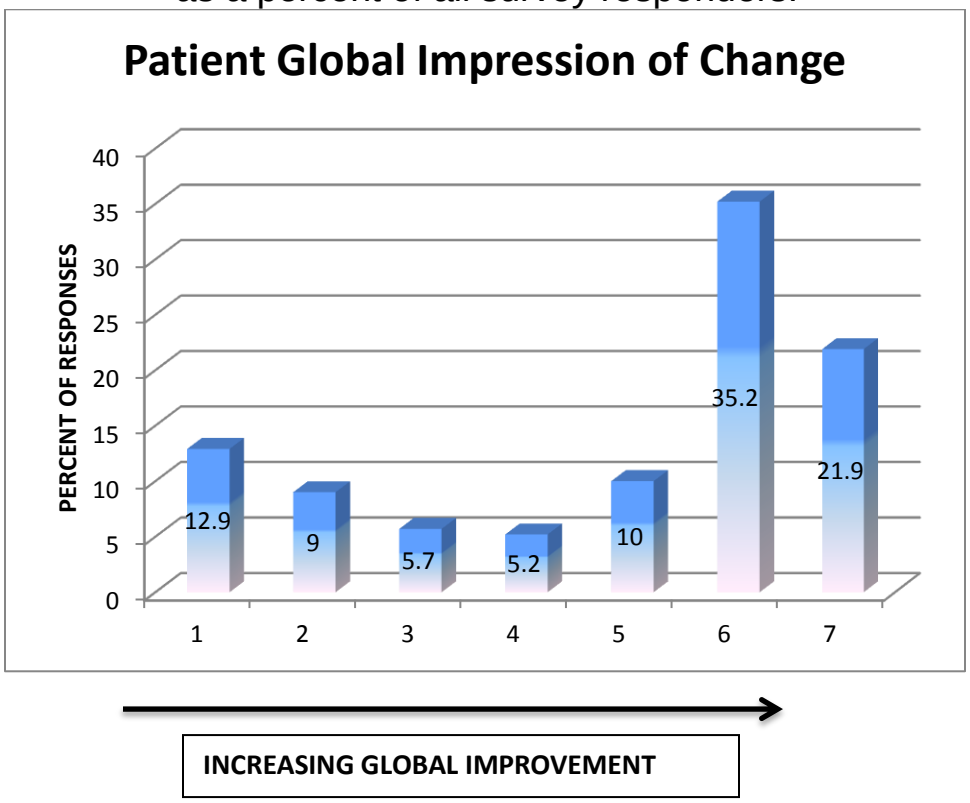
The list of conditions that ActiPatch was used to treat by responders in the survey were as follows:

Back pain (upper and lower) - Knee pain - Shoulder pain - Neck pain - Foot pain - Ankle pain - Toe pain - Wrist pain -Hand pain - Finger/thumb pain - Muscle pain - Leg pain – Fibromyalgia – Tendinitis -Menstrual pain - Multiple uses

Question 2: We would like you to describe the change (if any) in ACTIVITY LIMITATIONS, SYMPTOMS and OVERALL QUALITY OF LIFE related to your reason for using ActiPatch.

The results from the PGIC scale show that ActiPatch use had a significant effect on the improvement in global status rated by responders (figure 1.). 67.1% of survey responders reported a 5, 6 or 7 (moderate to considerable improvement) on the PGIC scale indicating that the ActiPatch has a marked improvement on their overall quality of life.

Figure 1: Patient global impression of change (PGIC) scores expressed as a percent of all survey responders.



1. no change, 2. hardly any change, 3. a little better, 4. somewhat better, 5. moderately better, 6. Definite worthwhile improvement, 7. considerable improvement.

Question 3: Below we would like you to indicate by moving the slider, the pain level you were experiencing BEFORE and AFTER the ActiPatch treatment. A score of **0 means no pain and a score of 10 means the worst pain** possible. (the **visual analogue scale (VAS**) for pain)

The results of the VAS pain question 3 are shown in table 2 and figure 2. Prior to beginning ActiPatch therapy survey responders had a mean reported pain of 7.28 VAS points. This reported pain had declined to 3.57 VAS points after ActiPatch use, a reported drop of 3.57 VAS points. This equates to a 51% decrease in the mean VAS pain. As can be seen from figure 3A there is a meaningful increased decline in VAS pain the longer the ActiPatch was used in hours per day. Comparing ActiPatch use of less than 3 hours per day to more than 16 hours per day there was a 1.18 VAS points or 40% greater decline in VAS pain in the 16 hour use group. As can be seen from figure 3B the average initial VAS pain was similar between the grouped time data. These results suggest that 16 hours of use or longer results in the most pronounced pain reduction.

Table 2: Minimum and maximum VAS pain values, as well as Mean VAS pain, and SD.

#	Answer	Min Value	Max Value	Average Value	Standard Deviation	Responses
1	Pain level BEFORE treatment	3.00	10.00	7.28	1.61	215
2	Pain level AFTER treatment	0.00	10.00	3.57	2.73	209

Figure 2: Survey reported VAS pain before and after ActiPatch use.

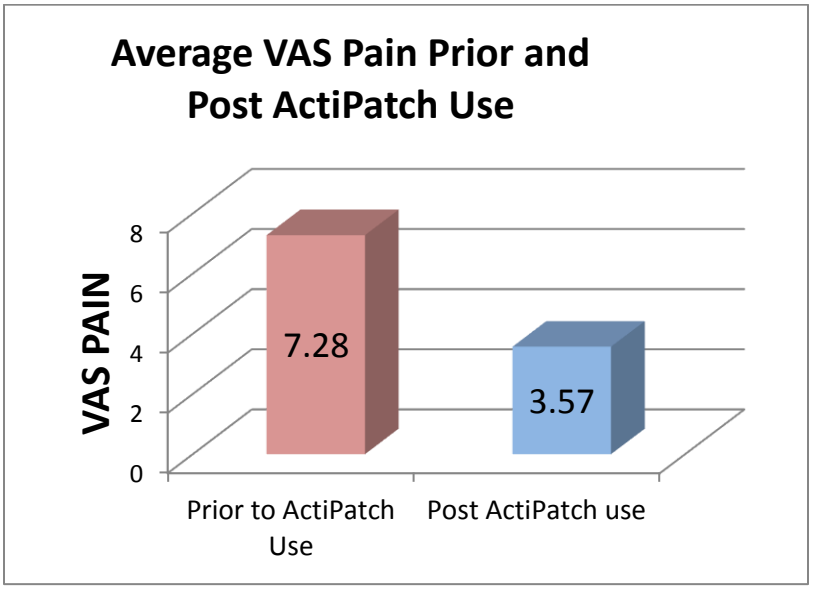


Figure 3A: VAS pain decreased in relation to daily hours of ActiPatch use

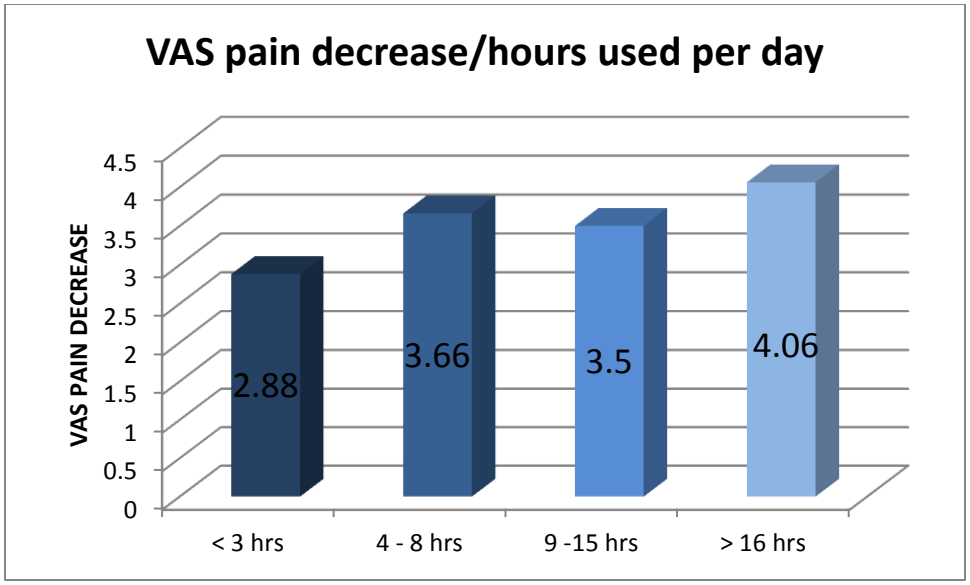
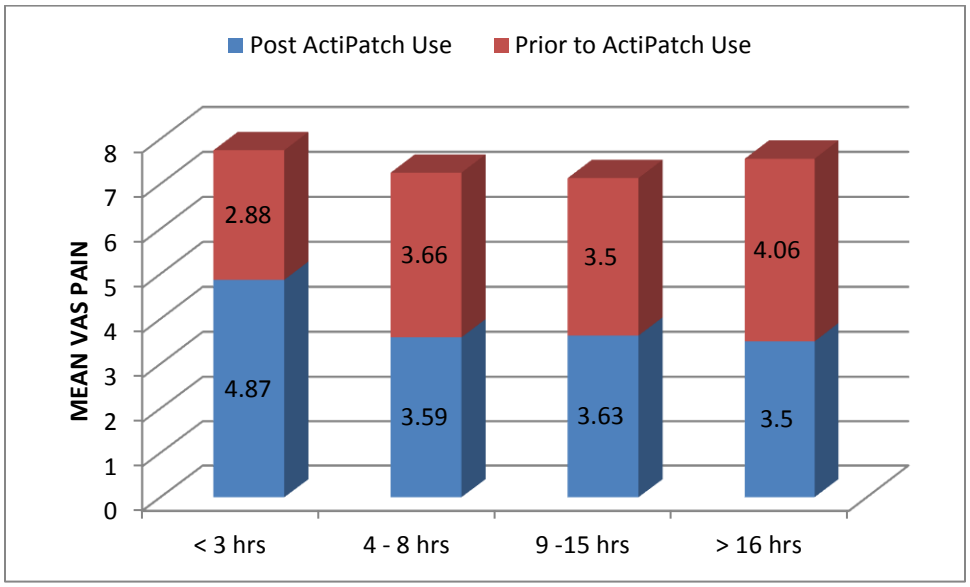


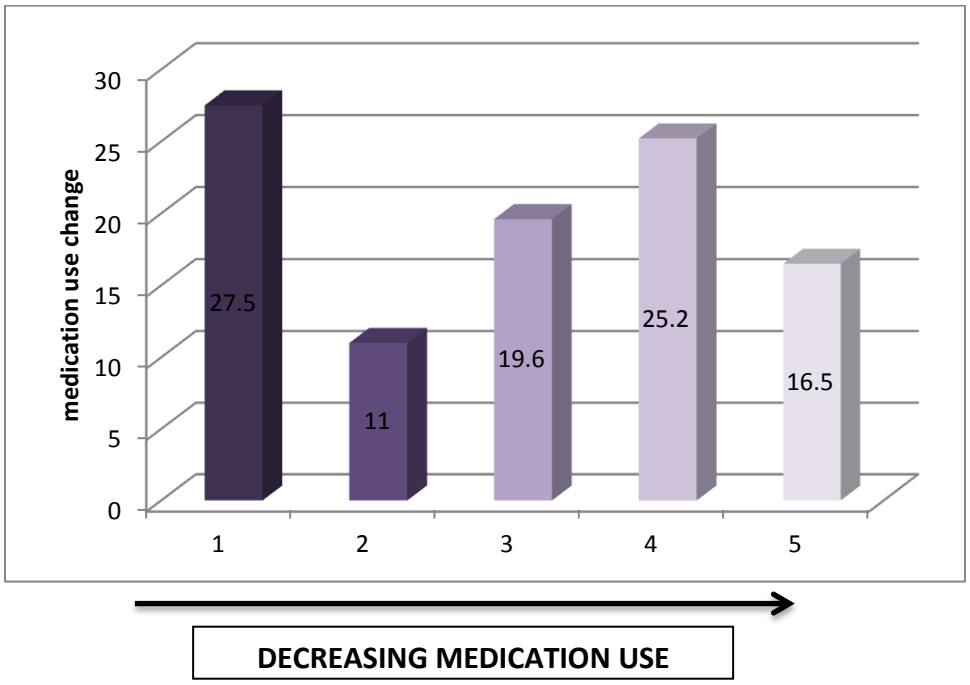
Figure 3B: VAS pain decrease in red and remaining pain (blue) in relation to daily hours used.



Questions 4 and 5: Did you use any pain medication before trying ActiPatch? How did the use of ActiPatch effect on your pain medication use?

Of the survey responders 70% indicated that they used pain medications. Figure 4 shows that of these survey responders, 72% reported a reduction in pain medication use, with 61.3% reporting a moderately or greater reduction.

Figure 4: Reduction in pain medication use



Medication use 1. no effect, 2.reduced a little, 3. moderate amount, 4. large amount, 5. eliminated.

Conclusion

The results from the survey indicate that the majority of ActiPatch users benefited from ActiPatch use, experiencing on average a 50% decrease in their pain, a global quality of life improvement and a decreased reliance on pain medications. Taking these three assessment tools together, it can be concluded that ActiPatch is an effective pain therapy for an array of musculoskeletal pain conditions.

Condition Specific VAS pain and PGIC Analysis: Back Pain

Back Pain: The survey responders who used the ActiPatch for back pain (68) were analyzed separately for VAS pain and PGIC scale. The mean average VAS pain score for responders was 7.04 before treatment and 3.51 post ActiPatch treatment and overall decrease in 3.53 VAS points or 50%. PIGC scale scores also showed a global improvement in the majority of responders with 63.7% recording a 5 or greater on the scale.

Conclusion: ActiPatch is an effective therapy for back pain.

Figure 4: VAS pain scores recorded for back pain before and after ActiPatch use

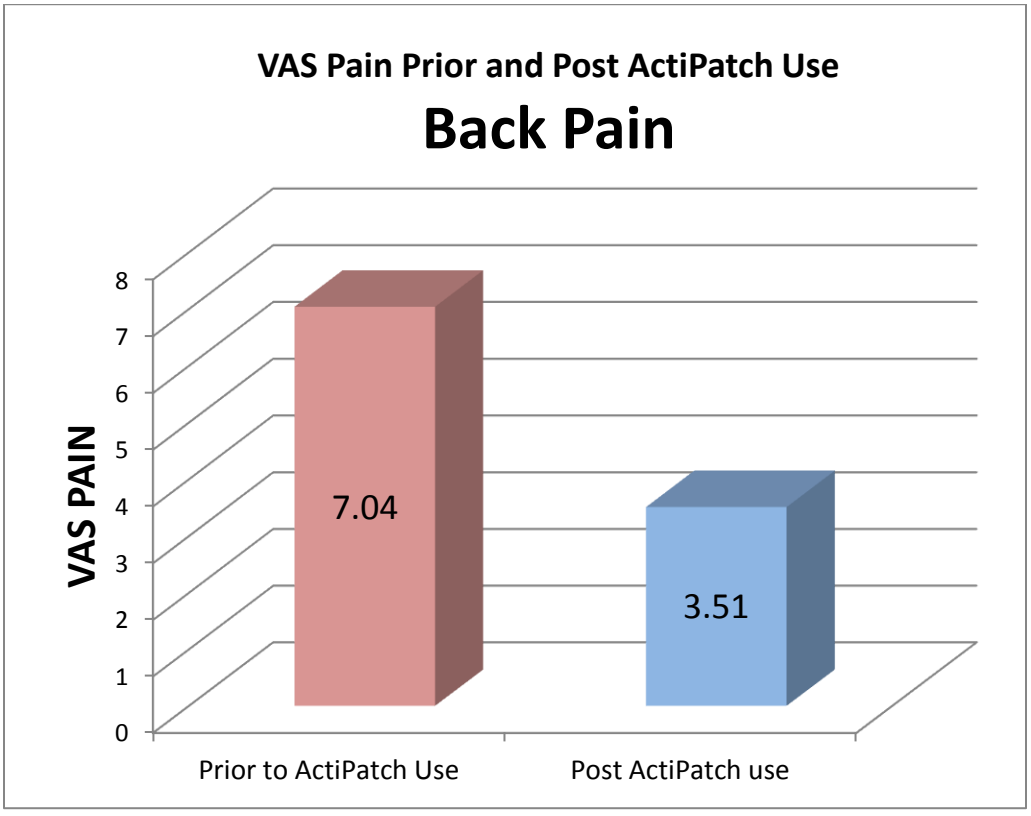
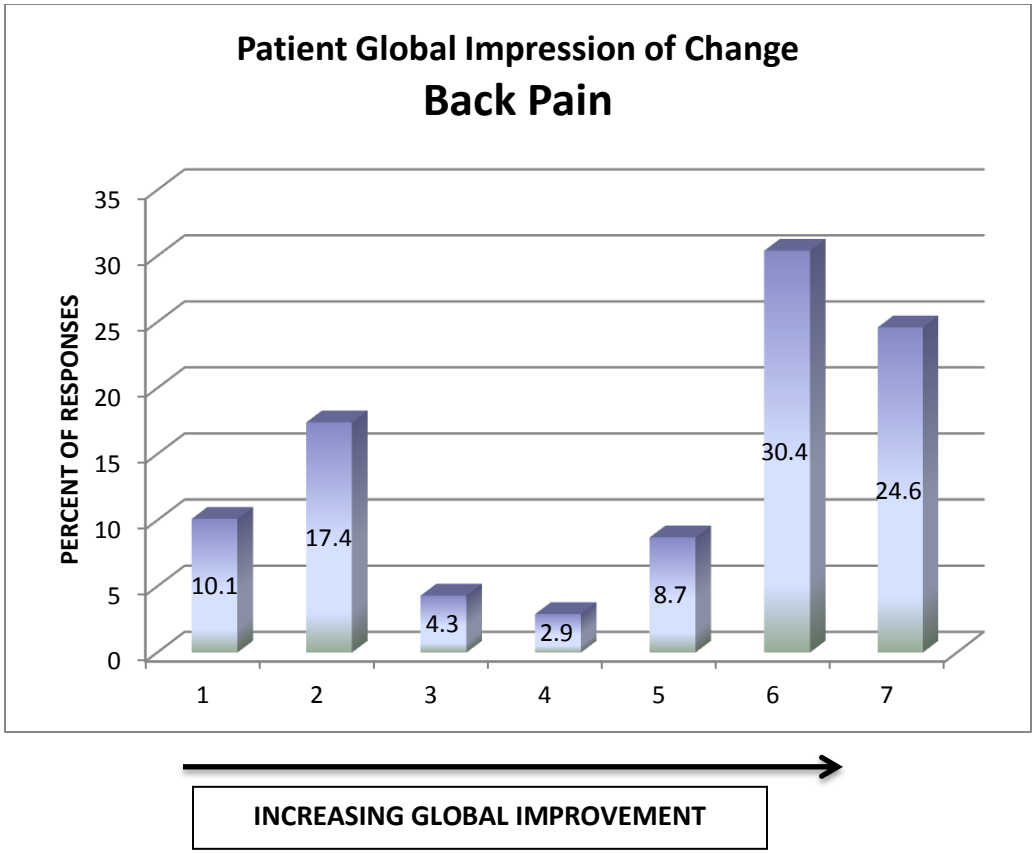


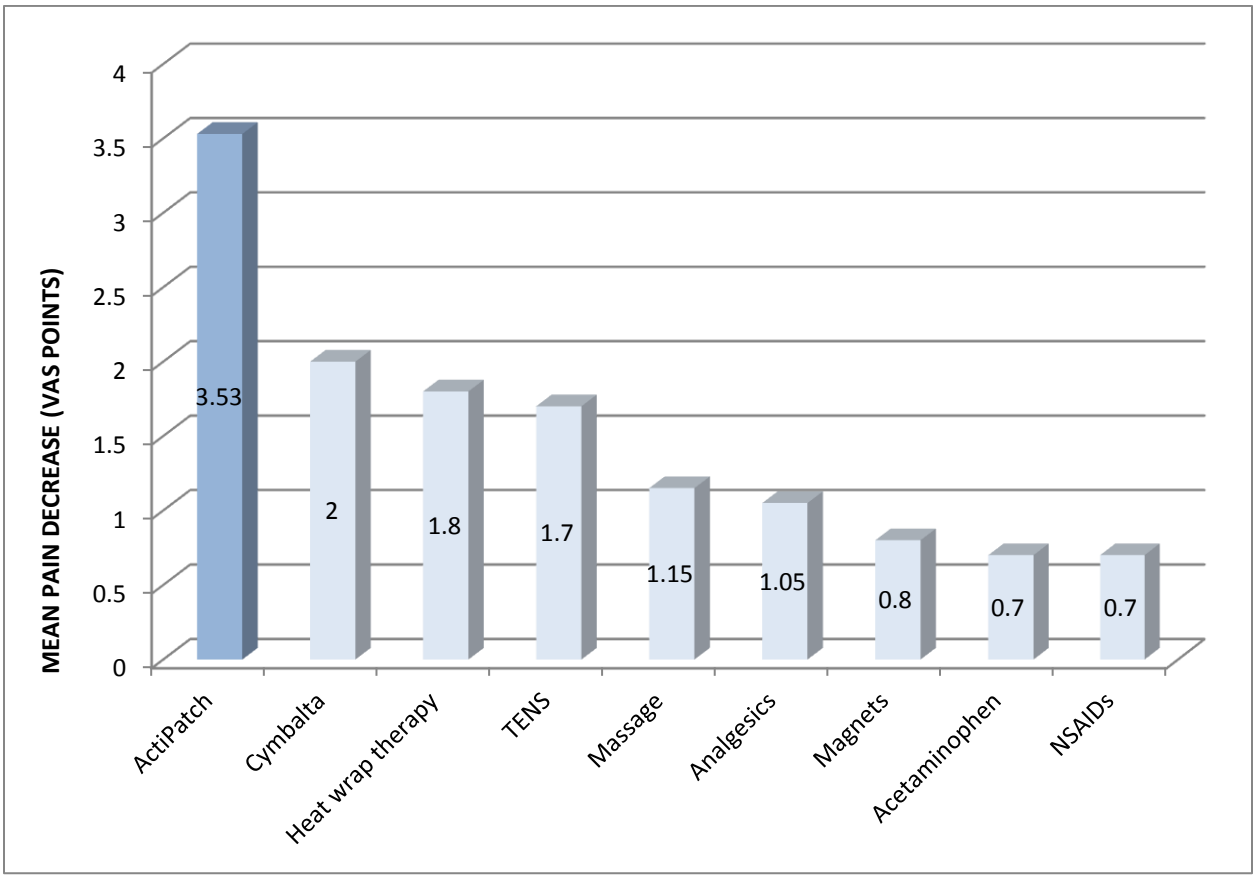
Figure 5: PGIC assessment after ActiPatch use.



ActiPatch - Comparison to therapies for undefined lower back Pain

Data was taken from the following review article - *Analgesic effects of treatments for non-specific low back pain: a meta-analysis of placebo-controlled randomized trials. L. A. C. Machado, S. J. Kamper, R. D. Herbert, C. G. Maher and J. H. McAuley. Rheumatology 2009;48:520–527* – which reported the VAS point decline, the measure of pain reduction, from published randomized controlled trials, or in some cases averaged data from a number of randomized controlled trials, from a diverse number of therapies. The data obtained from the ActiPatch survey from responders reporting the use of ActiPatch for back pain was used to compare to the published data. The decline in VAS pain from ActiPatch use was 3.53 VAS pain points which compares favorably to all the therapies documented in the review article.

Figure 6: A comparison between ActiPatch and published randomized control trial data on a number of therapies shows ActiPatch has the potential to be the therapy with the highest efficacy for back pain.



ActiPatch Compared to Non-Steroidal Anti-Inflammatory Drugs (eg. Ibuprofen) on Back Pain

The July 1998 issue of *The American Journal of Medicine* stated the following:

"Conservative calculations estimate that approximately 107,000 patients are hospitalized annually for nonsteroidal anti-inflammatory drug (NSAID)-related gastrointestinal (GI) complications and at least 16,500 NSAID-related deaths occur each year among arthritis patients alone. The figures of all NSAID users would be overwhelming, yet the scope of this problem is generally under-appreciated."

(June 1999) in the prestigious *New England Journal of Medicine*:

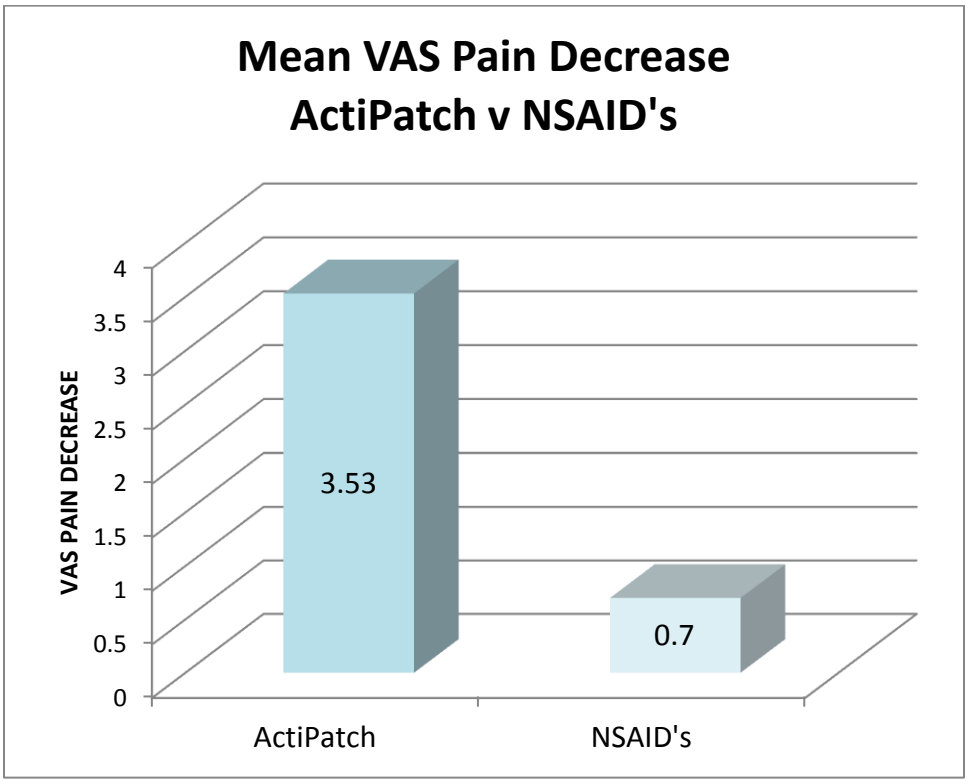
"It has been estimated conservatively that 16,500 NSAID-related deaths occur among patients with rheumatoid arthritis or osteoarthritis every year in the United States. This figure is similar to the number of deaths from the acquired immunodeficiency syndrome and considerably greater than the number of deaths from multiple myeloma, asthma, cervical cancer, or Hodgkin's disease. If deaths from gastrointestinal toxic effects from NSAIDs were tabulated separately in the National Vital Statistics reports, these effects would constitute the 15th most common cause of death in the United States. Yet these toxic effects remain mainly a "silent epidemic," with many physicians and most patients unaware of the magnitude of the problem. Furthermore the mortality statistics do not include deaths ascribed to the use of over-the-counter NSAIDS."

Annual cost of GI hospitalization due to NSAID use is estimated at $2 Billion

There have been many published studies documenting the effectiveness of non-steroidal anti-inflammatory drugs (NSAID's) on back pain. NSAID's drugs are often the first choice for people experiencing back pain, however clinical study has shown them to be minimally effectives, and have only short-term effects. Use of NSAID's also come with a relatively high risk of side effects, commonly with NSAID's these are gastrointestinal related, as NSAID's have an impact on the lining of the stomach. As document in this peer reviewed paper - *Analgesic effects of treatments for non-specific low back pain: a meta-analysis of placebo-controlled randomized trials. L. A. C. Machado, S. J. Kamper, R. D. Herbert, C. G. Maher and J. H. McAuley. Rheumatology 2009;48:520–527* – NSAID's have a minimal effect on back pain with an average VAS point reduction on back pain of 7mm on a 0 -100mm, or 0.7

points on a 0-10 scale. As shown from our survey results ActiPatch mean VAS point reduction was 3.53 points compared to the reported mean 0.7 point reduction with NSAID's (Figure 6). This comparison indicates that ActiPatch achieves a 5 fold greater pain reduction than commonly used NSAID's. ActiPatch has no side effects.

Figure 6: A direct comparison between ActiPatch and NSAID's on the effectiveness of reducing back pain VAS scores.



ActiPatch Compared to Over the Counter Pain Medication – Ibuprofen & Acetaminophen (Paracetamol) on Back Pain

Paracetamol hepatotoxicity is, by far, the most common cause of acute liver failure in both the United States and the United Kingdom

Paracetamol overdose results in more calls to poison control centers in the US than overdose of any other pharmacological substance.

In June 2009, a U.S. Food and Drug Administration (FDA) advisory committee recommended that new restrictions should be placed on paracetamol usage in the United States to help protect people from the potential toxic effects.

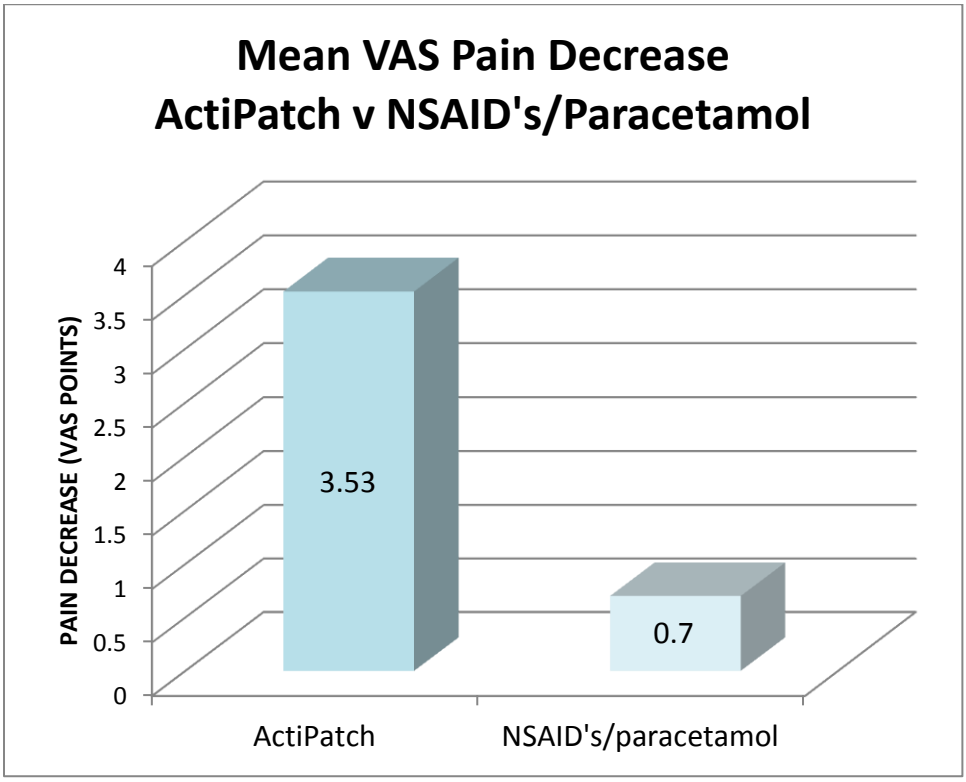
The FDA also is requiring manufacturers to update labels of all prescription combination paracetamol products to warn of the potential risk for severe liver injury.

Guidelines for the management of low-back pain in primary care have been published in various countries around the world. All these guidelines recommend the prescription of NSAIDs as one option for symptomatic relief in the management of low-back pain. In most guidelines, NSAIDs are recommended as a treatment option after paracetamol has been tried. Though clinical study indicates that ibuprofen and paracetamol has no differences as an analgesic for back pain.

There have been many published studies documenting the effectiveness of non-steroidal anti-inflammatory drugs (NSAID's) and paracetamol on back pain. NSAID's drugs are often the first choice for people experiencing back pain, however clinical study has shown them to be minimally effective, and have only short-term effects. This is also true for paracetamol. Use of NSAID's also come with a relatively high risk of side effects, commonly with NSAID's these are gastrointestinal related, as NSAID's have an impact on the lining of the stomach. As documented in this peer reviewed paper - *Analgesic effects of treatments for non-specific low back pain: a meta-analysis of placebo-controlled randomized trials. L. A. C. Machado, S. J. Kamper, R. D. Herbert, C. G. Maher and J. H. McAuley. Rheumatology 2009;48:520–527* – NSAID's and paracetamol have a minimal effect on back pain with an average VAS point reduction on back pain of 7mm on a 0 - 100mm, or 0.7 points on a 0-10 scale. As shown from our survey results ActiPatch mean VAS point reduction was 3.53 points compared to the reported mean 0.7 point reduction with NSAID's (Figure 7). This comparison indicates that ActiPatch achieves a 5 fold greater

pain reduction than commonly used over the counter pain medications - ibuprofen (Motrin, Advil,etc) and paracetamol (Tylenol). ActiPatch has no side effects.

Figure 7: A direct comparison between ActiPatch and NSAID's and paracetamol on the effectiveness of reducing back pain.



Condition Specific VAS pain and PGIC Analysis: Knee Pain

Knee Pain: The survey responders who used the ActiPatch for back pain (83) were analyzed separately for VAS pain and PGIC scale. The mean average VAS pain score for responders was 7.5 before treatment and 3.4 post ActiPatch treatment (figure 7) and overall decrease in 4.1 VAS points or 55%. PIGC scale scores also showed a global improvement in the majority of responders with 72.2% recording a 5 or greater on the scale (figure 8).

Conclusion: ActiPatch is an effective therapy for knee pain.

Figure 7: Reported VAS pain before and after ActiPatch use

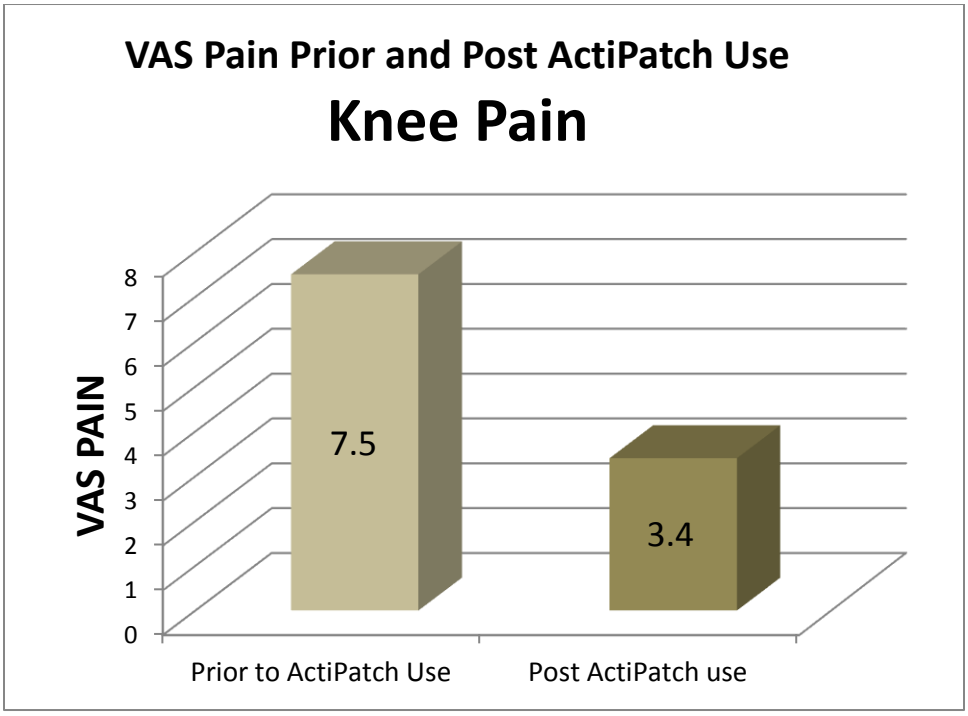
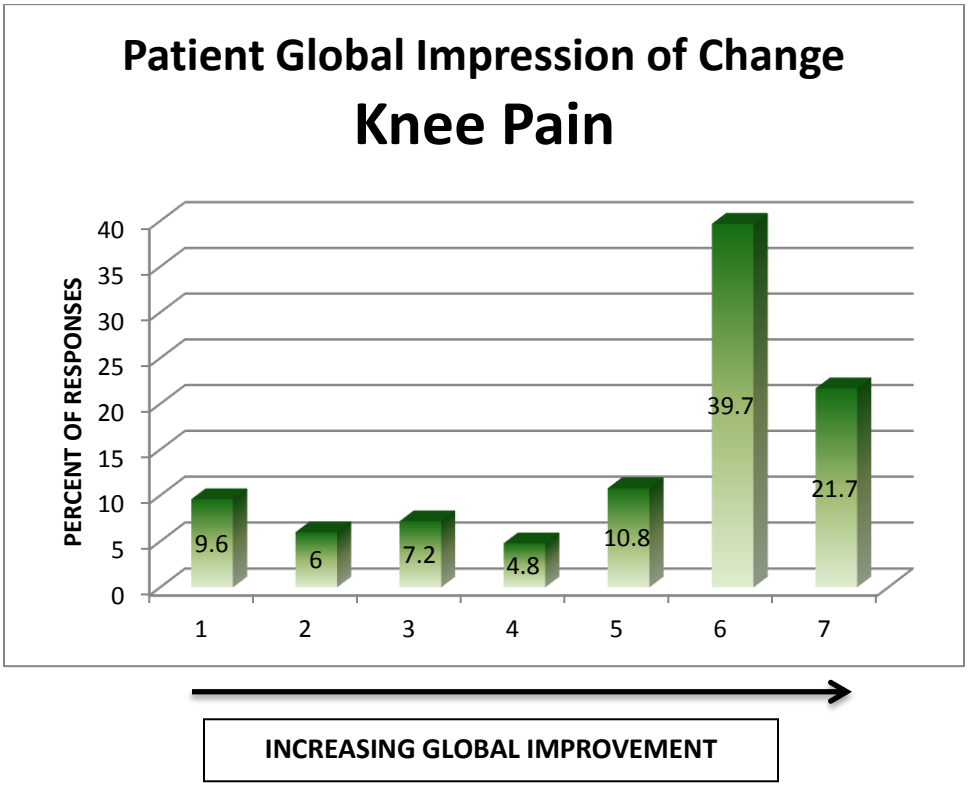


Figure 8: PGIC shows a marked improvement in survey responder quality of life.



ActiPatch Survey Q 8 & 9

Results of Question 8 and 9:

8. *Would you purchase another ActiPatch if the need arises?*

9. *Would you recommend ActiPatch to a friend?*

Of the survey responders 77% said they would recommend to a friend and 73% responded that they would repurchase another ActiPatch if the need arose.