Appendix 1

Comparison of the first 5000 (A5000) assessments to the second set of 5000 (B5000) assessments.*

** Rawe IM, Kotak DC. (2015) A UK registry study of the effectiveness of a new over-the-counter chronic pain therapy. Pain Manag. Nov;5(6):413-23*

Demographics

Table 1. Gender Distribution (A5000 n= 4978, B5000 n = 5002)

Gender	A5000	B5000
Male	26%	31%
Female	74%	69%
Age		
18-24	0.9%	0.8%
25-34	2.9%	3%
35-44	15%	12%
45-54	25.4%	25%
55-64	29.5%	30%
65 or >	26.3%	27%

Table 2. Duration of Pain A5000 n= 1430, B5000 n = 5070

Pain Duration	A5000	B5000
0-6 months	13%	12%
6 m – 1 yr	11%	13%
1 – 2 yrs	14%	14%
2- 5 yrs	20%	22%
5 -10 yrs	21%	18%
10 – 20 yrs	12%	13%
20 yrs +	9%	9%

The baseline pain reported by the subjects in the study trended up in relation to its duration. Similar patterns were seen in both sets of 5000. Though the B5000 data had a slightly higher 0-6 month VAS scores.

Figure 1. Baseline Pain in Relation to Duration A5000 n= 1430, B5000 n = 5070

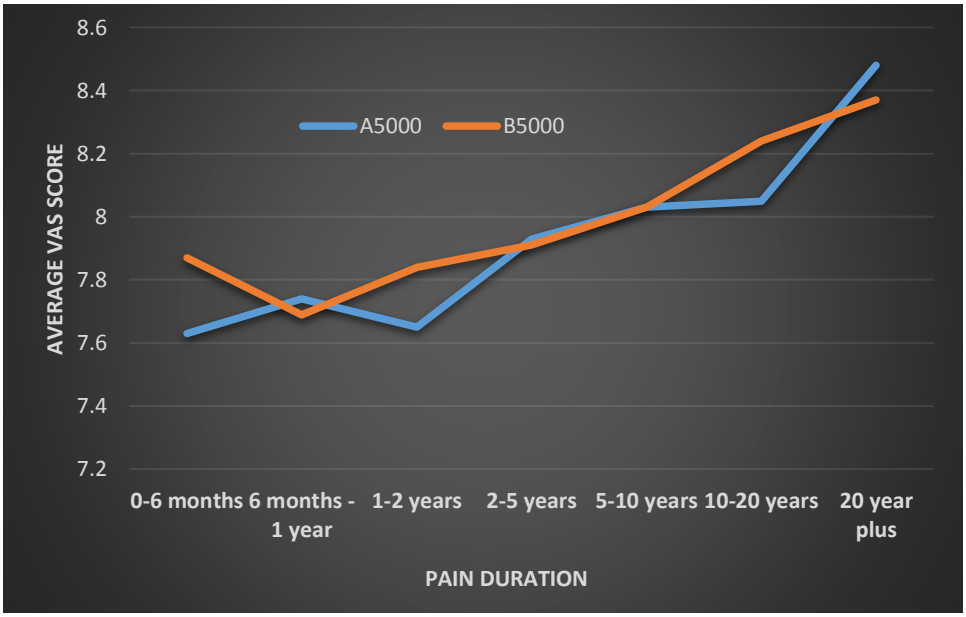

Table 3. Pain Etiology A5000 n= 5002, B5000 n = 5070

	A5000	B5000
Osteoarthritis	31%	28%
Rheumatoid Arthritis	15%	14%
Fibromyalgia	15%	11%
Sports Injury	8%	8%
Post-Surgery pain	6%	5%
Tendonitis	3%	3%
Neuropathy	5%	3%
Other	29%	39%

Table 4. Location of pain A5000 n 5002, B5000 n = 5070

	A5000 Location pain	B5000 Location pain

Back	58%	55%
Knee	34%	27%
Neck	17%	14%
Shoulder	26%	24%
Hip	20%	18%
Other	14%	13%

Table 5. Sample Use Location A5000 n= 5002, B5000 n = 5070

	Use location A5000	Use location B5000
Back	44%	46%
Knee	21%	18%
Neck	5%	5%
Shoulder	14%	16%
Hip	7%	8%
Other	8%	7%

Table 6. Medication Use A5000 n= 5002, B5000 n = 5070

Analgesic	A5000	B5000
Paracetamol (acetaminophen)	43%	50%
NSAID's	48%	48%
Cox-2 inhibitors	2%	3%
Weak Opioids	23%	27%
Strong Opioids	21%	21%
other	22%	23%

VAS Scores

This table shows the VAS scores from all the subjects in the two groups A5000 and B5000. Also the baseline score of who found the device effective defined by the two criteria, first as in the published Registry Study of ≥2 VAS reduction and then by the second criteria of ≥30% reduction (red text). The data is also shown in two figures, figure 2 gives the baseline and post device use VAS scores for all the subjects in both groups as well as the two benefit criteria. Figure 3 shows the percent in pain reduction by group criteria, either All, 2 or > VAS reduction or a ≥30 pain reduction.

A5000 n =5002, B5000 n=5088

	A5000	B5000
Baseline VAS (all)	8.02	7.98
ActiPatch VAS (all)	4.96	4.97
VAS Difference	3.06	3.01
Percent Reduction	38.1%	37.7%
Effective:		
Baseline >2 VAS	8.17	8.11
ActiPatch >2 VAS	3.49	3.43
VAS Difference	4.68	4.68
Percent Reduction	**57.3%**	**57.7%**
Subject No. Effective/Total	**3241/5002**	**3224/5088**
Percent Effective	**64.8%**	**63.4%**
Effective:		
≥30% pain reduction Baseline	**8.12**	**8.06**
≥30% pain reduction ActiPatch	**3.14**	**3.13**
VAS Difference	**4.98**	**4.93**
Percent Reduction	**61.3%**	**61.2%**
Subject No. Effective/Total	**2951/5002**	**2957/5088**
Percent Effective	**59%**	**58.1%**

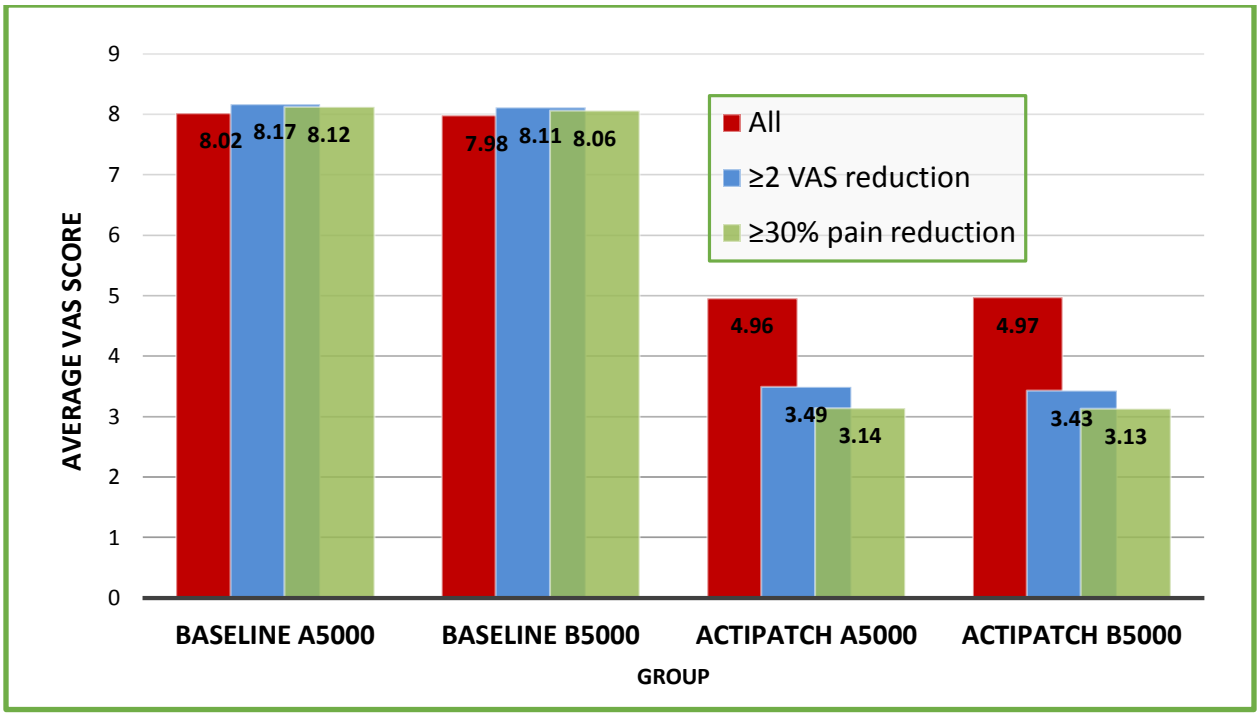

Figure 2. The baseline pain for and post treatment pain scores grouped by criteria. Either All the subjects, those reporting a 2 or > VAS reduction or a ≥30 pain reduction for both sets of 5000 responses.

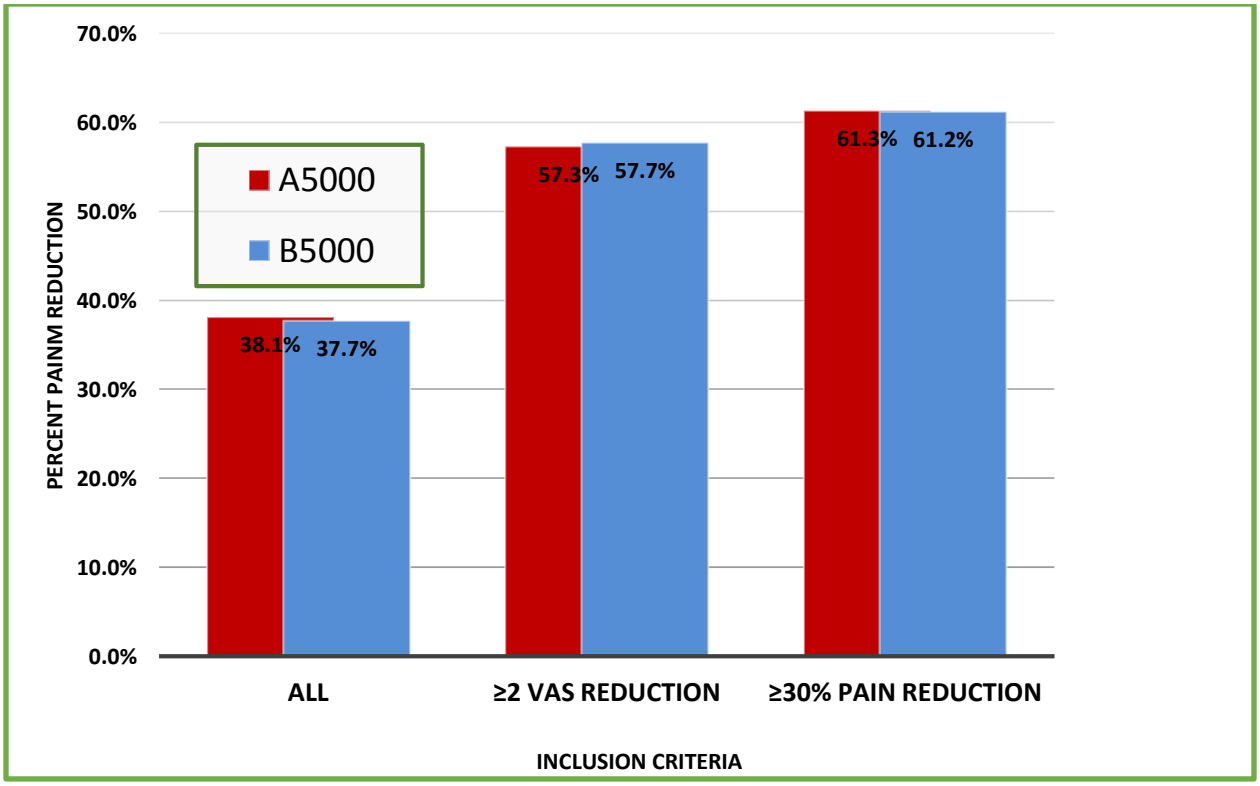

Figure 3. The percent pain reduction in the responses, grouped by criteria. Either all the subjects, those reporting a 2 or > VAS reduction or a ≥30 pain reduction for both sets of 5000 responses.

VAS Scores - Etiology of Pain ***A5000 n =4350, B5000 n=4525***

Note –

- *Benefit is the percentage reporting a 2 or > VAS reduction.*
- *The baseline scores are from the subjects reporting benefit.*
- *The ActiPatch VAS scores are from the subjects reporting benefit*

Cause of Pain	A5000 Benefit %	A5000 Baseline VAS	A5000 ActiPatch VAS	B5000 Benefit %	B5000 Baseline VAS	B5000 ActiPatch VAS
Osteoarthritis	66%	8.32	3.63	67%	8.23	3.56
Rheumatoid Arthritis	71%	8.54	3.62	65%	8.32	3.45
Fibromyalgia	68%	8.57	4.16	67%	8.45	3.95
Sports Injury	69%	7.68	3.23	64%	7.61	2.83
Post-surgery Pain	65%	8.26	3.72	66%	8.38	3.85
Tendonitis	67%	8.38	3.84	64%	8.19	3.53
Neuropathic	59%	8.39	3.82	60%	8.38	3.84
Other	63%	8.00	3.36	62%	8.04	3.51

VAS Scores - Location of Pain A5000 n=4350 B5000 n=4525

Note –

- *Benefit is the percentage reporting a 2 or > VAS reduction.*
- *The baseline scores are from the subjects reporting benefit.*
- *The ActiPatch VAS scores are from the subjects reporting benefit*

Location of Use	A5000 Benefit %	A5000 Baseline VAS	A5000 ActiPatch VAS	B5000 Benefit %	B5000 Baseline VAS	B5000 ActiPatch VAS
Back	65%	8.17	3.61	64%	8.10	3.52
Knee	69%	8.22	3.41	66%	8.17	3.40
Neck	61%	7.97	3.71	66%	7.92	3.38
Shoulder	68%	8.11	3.48	63%	8.19	3.56
Hip	70%	8.25	3.48	64%	8.10	3.36
Other	54%	8.24	3.31	61%	8.07	3.14

VAS Scores - Duration of Pain <u>A5000 n= 1430, B5000 n = 5070</u>

Note -

- *Benefit is the percentage reporting a 2 or > VAS reduction.*
- *The baseline scores are from the subjects reporting benefit.*
- *The ActiPatch VAS scores are from the subjects reporting benefit*

	A5000 Benefit %	A5000 Baseline VAS	A5000 ActiPatch VAS	B5000 Benefit %	B5000 Baseline VAS	B5000 ActiPatch VAS
0 – 6 months	65%	7.83	2.94	61%	7.99	3.08
6 months – 1 yr	62%	7.92	3.14	60%	7.86	3.26
1 – 2 yrs	61%	7.81	3.15	65%	8.09	3.37
2 – 5 yrs	69%	8.10	3.29	68%	7.93	3.28
5 -10 yrs	67%	8.16	3.41	64%	8.17	3.81
10 -20 yrs	66%	8.02	3.51	65%	8.30	3.61
20 yrs plus	70%	8.51	4.14	66%	8.43	3.80

Summary

The comparison with the first set of data comprising 5000 subjects responses to the second set of 5000 responses shows that the data is highly reproducible and show consistency of the benefit and effectiveness of the ActiPatch trial in the lay population with no healthcare practitioner involvement.

Supplemental Data

Data collected from 525 individual's trialing the 7 day sample. Responses show the same profile as from A5000 and B5000. Pain medication data was expanded with a more comprehensive list. A questions was added on adverse effects, a rating of pain medication effect on pain control and whether other changes had been made in the subjects pain management regime during the 7 day ActiPatch device trial period.

Table 1S. Gender and Age distribution between the three data sets

Gender	N=525	A5000	B5000
Male	25%	26%	31%
Female	74%	74%	69%
Age			
18-24	<1%	0.9%	0.8%
25-34	2.8%	2.9%	3%
35-44	16.9%	15%	12%
45-54	31.5%	25.4%	25%
55-64	27.2%	29.5%	30%
65 or >	19.8%	26.3%	27%

Table 2S. Pain duration compared in the three data sets

Pain Duration	N=525	A5000	B5000
0-6 months	11%	13%	12%
6 m – 1 yr	12.2%	11%	13%
1 – 2 yrs	13.8%	14%	14%
2- 5 yrs	20.8%	20%	22%
5 -10 yrs	17.4%	21%	18%
10 – 20 yrs	12.6%	12%	13%
20 yrs +	11.7%	9%	9%

Table 3S. The area of the body that the 7 day sample was used in the 3 data sets.

	N=525	Use location A5000	Use location B5000
Back	49%	44%	46%
Knee	13.6%	21%	18%
Neck	4.3%	5%	5%
Shoulder	16.2%	14%	16%
Hip	8.1%	7%	8%
Other	8.3%	8%	7%

Table 4S. Analgesics 510/525 used analgesics either systemic or topical

Analgesic	No. Responses	Percent
Non-steroidal anti-inflammatory drugs (NSAIDS e.g. ibuprofen)	252	48%
Paracetamol	271	51.6%
Weak opioids (Codiene)	198	37.8%
Strong opioids (Hydrocodone)	83	15.8%
Cyclo-oxygenase (COX)-2 inhibitors (Celebrex)	8	1.5%
Pregabalin (e.g. lyrica)	52	9.9%
Amitriptyline	130	24.8%
Topical opioid (e.g. morphine)	41	7.8%
Topical Non-steroidal anti-inflammatory drugs (e.g. Voltarol)	104	19.8%
Gabapentin	79	15.%
Other	15	2.9%

Table 5S. Quality of Pain Relief from Analgesics n=522

	No. Responses	Percent
Good pain relief	36	6.9%
Adequate pain relief	165	31.6%
Less than adequate pain relief	262	50.2%

No Real Pain Relief	59	11.3%

Adverse Side Effects From Analgesic Use

Were you experiencing any side effects from these pain medications? (select all that apply)

Of the 525 response 190 reported no side effects and of the 330 who reported side effects there were a total of 1444 side effects or average of 4.3 per individual (Figure 1S).

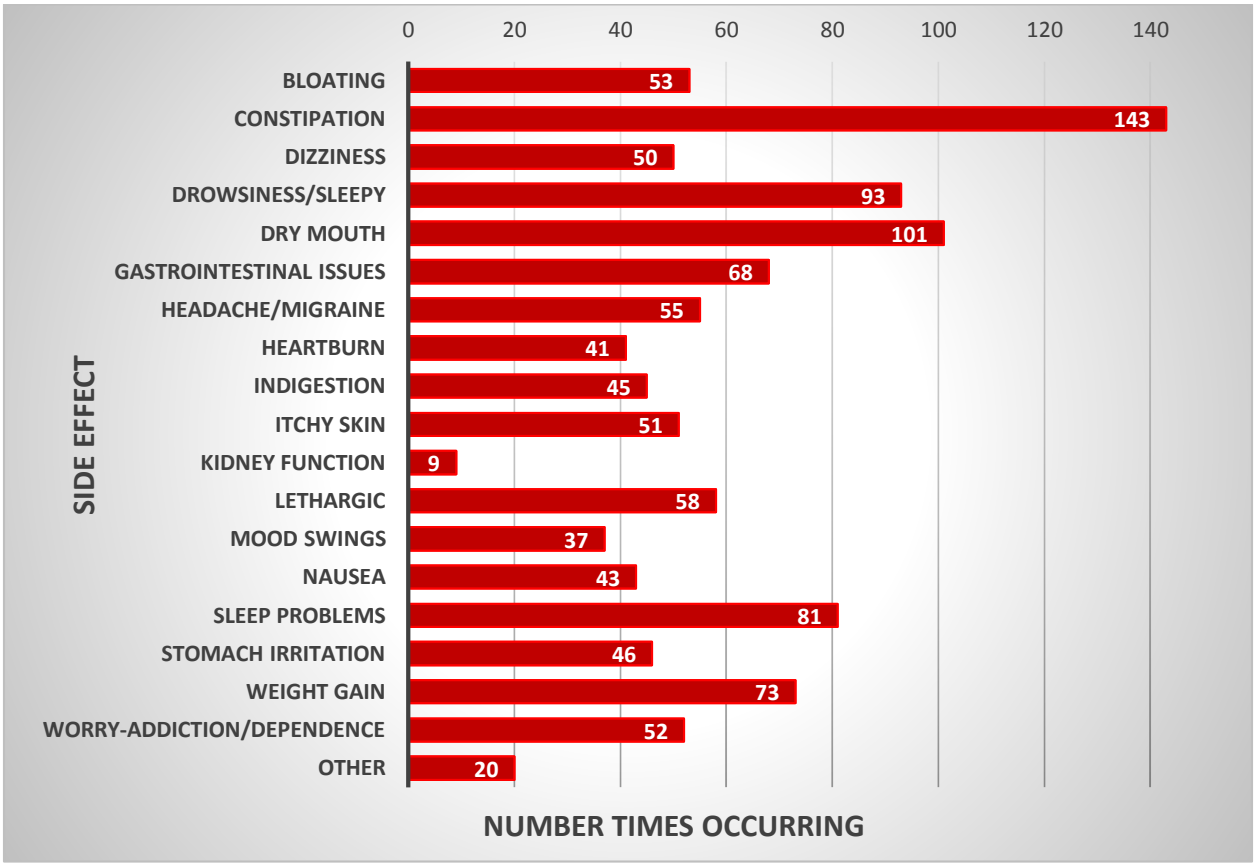

Figure 1S. A significant number, 65% of the subjects using analgesics reported adverse side effects with an average of 4.3 per subjects.

During use of the ActiPatch 7-Day Trial did you make any changes to your pain medication use?

Only 8 individuals increased or started a new pain medication during the 7 day trial. Whereas 281 decreased or eliminated pain medications. 233 reported making no changes.

Table 6S. During the 7 days of the ActiPatch trial 53.9% indicated that they either reduced or eliminated analgesic medication use. With 8 (1.6%) subjects indicating an increase or initiation of a new analgesic.

	No Responses	Percent
Increased current pain medications	4	<1%
Decreased current pain medications	181	34.7%
Eliminated current pain medications	100	19.2%
Started a new pain medication	4	<1%
Made no changes	233	44.6%
No Responses	3	1.6%

Comparison of the VAS scores and the percent receiving benefit in the Supplemental data (n=525) and A5000 and B5000.

Table 7S. A comparison of the VAS scores and the percent receiving benefit in the three data sets. The percent receiving benefit is consist between the subsets, all, ≥2 VAS reduction and ≥30% pain reduction

	N=525	A5000	B5000
Baseline VAS (all)	7.99	8.02	7.98
ActiPatch VAS (all)	5.06	4.96	4.97
VAS Difference	2.93	3.06	3.01
Percent Reduction	36.7%	38.1%	37.7%
Effective:			
Baseline >2 VAS	8.01	8.17	8.11
ActiPatch >2 VAS	3.49	3.49	3.43
VAS Difference	4.52	4.68	4.68
Percent Reduction	**56.4%**	**57.3%**	**57.7%**
Subject No. Effective/Total	**336/525**	**3241/5002**	**3224/5088**
Percent Effective	**64.0%**	**64.8%**	**63.4%**
Effective:			

≥30% pain reduction Baseline	**7.98**	**8.12**	**8.06**
≥30% pain reduction ActiPatch	**3.14**	**3.14**	**3.13**
VAS Difference	**4.84**	**4.98**	**4.93**
Percent Reduction	**60.7%**	**61.3%**	**61.2%**
Subject No. Effective/Total	**305/525**	**2951/5002**	**2957/5088**
Percent Effective	**58.1%**	**59%**	**58.1%**

Summary

Data sets are consistent adding weight to the finding in the published Registry Study. Data from 10500 individuals with approximately 58% reporting a 30% or greater pain reduction. Coupled to decreases in medication use demonstrate the effectiveness of ActiPatch by the lay user in the general population with no healthcare practitioner involvement.