ACP Solutions Ltd

Results of Analysis of the Astex "Active" Diary Cards

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Introduction

ACP Solutions Limited arranged an assessment of the potential influence of its Astex anti-allergy bed covers on patients suffering from either asthma, eczema, rhinitis or a combination of these allergies. The assessment was conducted by Practice Nurses who provided one or more of their patients with Astex covers and an Astex Patient Diary Card recording the patients' allergic condition, as perceived or measured, over 16 weeks. Following the initial assessment by the Practice Nurse, the Diary cards were filled in either by the patient or by a parent if the patient was a child. The card was then checked by the Practice Nurse before being returned to ACP.

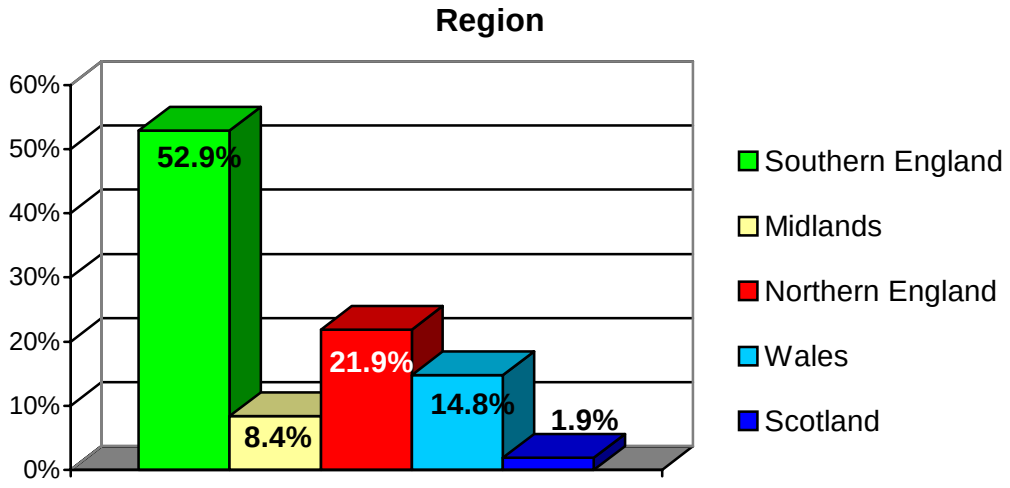
Some 500 practice nurses were recruited to take part in this study, and by the middle of October, 155 Diary Cards had been completed and returned. ACP Solutions approached Kember Associates to provide an independent analysis of these cards and to interview a sample of 'non-returns' to find whether results among this group were similar to those Diary Cards already received by ACP.

This study focuses on patients' perceived benefits of the Astex covers and although not a fully controlled clinical trial, was carried out under the guidance of practice nurses.

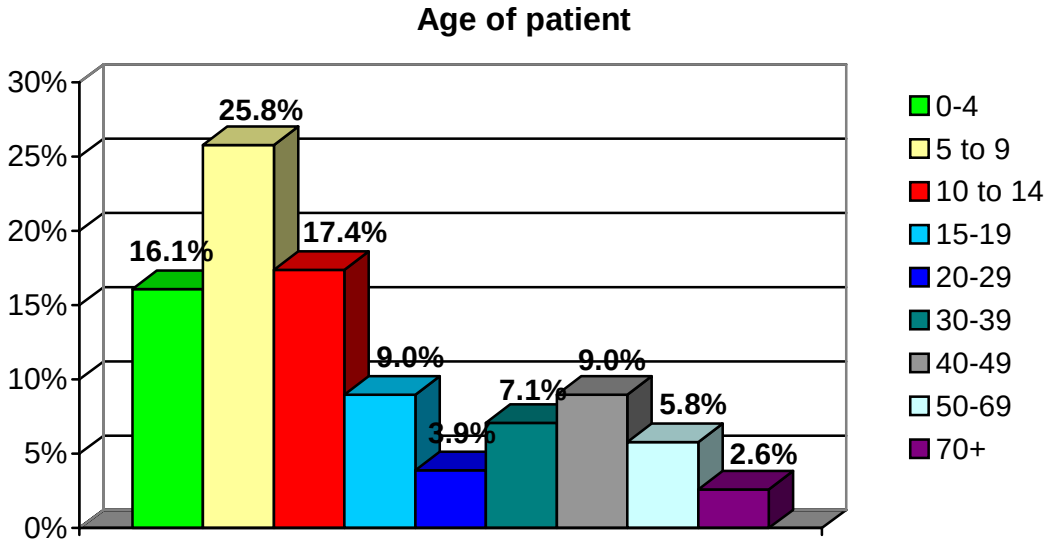
This report presents the results of this analysis, with tabulations available in a separately bound report.

Research Sample

Responses were from throughout the country, but with a bias towards Southern England. This was due to the distribution of the Diary Cards.



The average age of the patients was 18.8 years, with the youngest being just one year old and the oldest 73 years. Over half of the patients were aged under 15 years of age. 51% of patients were male.



In addition to the analysis of the returned Diary Cards, Kember Associates interviewed 10% of those who had not yet returned their Diary Cards to determine the reasons for this. In total 35 interviews were obtained with Practice Nurses who had originally agreed to take part in the study. Of these 26 had received both the Diary Cards and the Astex covers and had started a patient on the trial. The most common reason for not returning the Diary Card was that the nurse had been unable to get it back from the patient. In addition some nurses said they had returned the card, but it had apparently not been received by ACP in time to be included in this analysis.

Of those who had a patient taking part in the study 62% said there had been an improvement in their patient's condition, with some 15% saying there had been no change and just two respondents saying that the patients condition had worsened as they proved to be allergic to the covers.
However, one of the patients had major health and allergy problems and the nurse felt that the itching may not have been due to the covers but an allergy to something else. The remainder did not know whether there had been any change. It is accepted that the reaction of the two patients could be to the polyester rather than the active ingredient permethrin, which is understood to have virtually nil irritability at low dosage in contact with humans. The two respondents should therefore be seen in context of the total survey, as none of the other nurses interviewed by telephone or returning diary cards (a total of 179) noted any adverse reactions.

The nurses comments regarding their patients' conditions echoed those made by nurses and patients in the main study.

This part of the study strongly suggests that the Diary Cards which were returned before the deadline for analysis were representative, and that the reason why some cards were not returned was not related to a lack of success in using the Astex covers.

Research Results

Allergies

The most commonly reported allergy was asthma, a problem for 80.6% of patients, while 43.9% suffered from rhinitis and 36.1% had eczema. Those suffering from rhinitis were more likely to report an allergy to house dust mite, while those with asthma or eczema were more likely to not know whether they were allergic to house dust mite.

In total 42.6% of the patients taking part in the study said they were allergic to house dust mite, and 51% said they did not know whether they were. The remainder did not give an answer suggesting that they did not know. Only 1.3% said they were not allergic to house dust mite (two respondents both aged under 5 years old). Nearly three quarters of those with such an allergy said they had been diagnosed by their doctor, the remainder saying or implying they had been tested by the nurse or other medical professional.

Whether a patient is allergic to house dust mite or not is highly relevant to the outcome of this study because only those who had such an allergy could be expected to benefit from the use of the Astex covers. Those falling into the 'don't know' group may or may not have a house dust mite allergy, and so one would expect a smaller percentage of these seeing an improvement in their symptoms.

The study is further complicated by the multi-symptom/multi-causal nature of allergies, which is clearly demonstrated by the number of patients who had two or more allergic symptoms, and by those who mentioned that they were allergic to grass, pollen or other substances in addition to house dust mites.

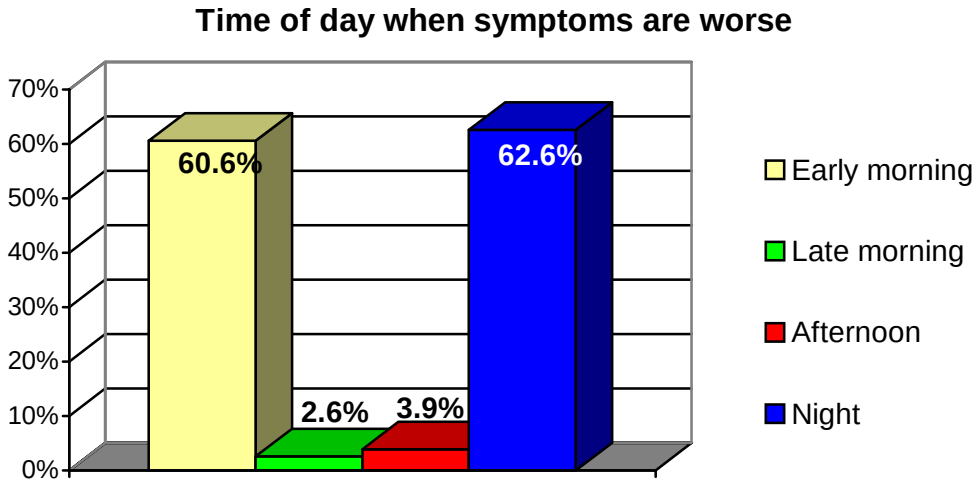
37.6% of those suffering from asthma also had eczema, rhinitis or both. 69% of those with rhinitis and 83.9% of those with eczema also had asthma, while one third of those with eczema had rhinitis as well.

Multiple Allergies
(numbers and percentages)

	Base	Asthma	Eczema	Rhinitis	Other
Base	155	125 80.6%	56 36.1%	68 43.9%	9 5.8%
Asthma	125	125 100.0%	47 37.6%	47 37.6%	8 6.4%
Eczema	56	47 83.9%	56 100.0%	19 33.9%	3 5.4%
Rhinitis	68	47 69.1%	19 27.9%	68 100.0%	1 1.5%
Other	9	8 88.9%	3 33.3%	1 11.1%	9 100.0%

Time of day when symptoms are worse

The night time and early morning were the times of day when symptoms seem to be worse, with nearly one third of patients having problems both at night and in the early morning, about 28% suffering at night only and 26% having symptoms in the early morning only. Just a few patients had more severe symptoms at other times of day. The following chart shows the percentage reporting severe symptoms at certain times of day and includes multiple answers.

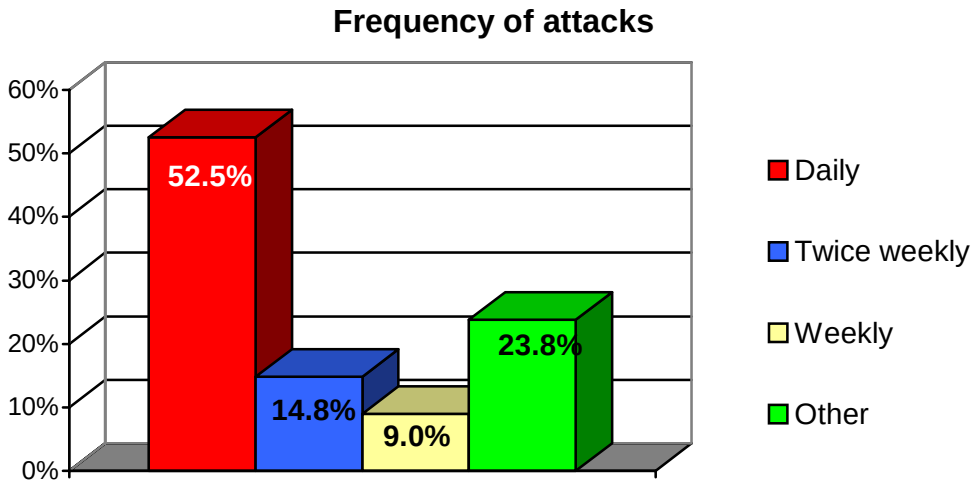


Patients with rhinitis were considerably more likely to have severe symptoms in the early morning, while those with eczema tended to suffer more at night. Patients with asthma also tended to have worse symptoms at night, but the early morning was also a bad time for them.

Probably due to the link with rhinitis, those who were allergic to house dust mite tended to find their symptoms were worse in the early morning.

Frequency of attacks

Just over half of those answering the question on frequency of allergy attacks said that they had daily problems. Around a quarter had attacks once or twice a week, while the remaining quarter had symptoms at other times, usually less frequently for example seasonally or in response to certain substances or infections. In some cases symptoms were either well controlled or constant and therefore this question was not always answered.



Severity of condition

The severity of patients conditions was investigated on a four point scale, from ‘Clear’ through ‘Mild’ to ‘Moderate’ and then ‘Chronic’. In addition peak flow readings, where available and relevant to the patients’ condition were recorded.

At the start of the study the nurse in charge assessed the patients usual condition and his/her condition on the starting day on these criteria, in order to give a base point. Across all patients the following results on severity of condition were obtained

	Normal severity of condition	Severity of condition on starting day
Base	155	155
Clear	3.9%	4.5%
Mild	32.3%	31.6%
Moderate	45.8%	43.2%
Chronic	8.4%	7.7%
No reply	9.7%	12.9%

Peak flow readings were available and relevant for just over half of patients. The normal average (mean) peak flow reading among these was 339.4, with a range from 60 to 610. The peak flow reading on the starting day of the assessment averaged 315.8, and ranged from a low of 50 to a maximum of 610. This lower than average figure on the starting day of assessment is probably due to some patients being recruited to take part in the trial when they visit the surgery with allergy symptoms.

	Peak flow reading - Normal	Peak flow reading - Starting day
Base	155	155
No reply	73	79
Mean	339.39	315.79
Minimum	60	50
Maximum	610	610
Standard Deviation	126.0357	127.3
Standard Error of the Mean	13.91831	14.60231

Changes in symptoms during the trial period

Patients recorded their symptoms for each week of the 16 week trial, classifying symptoms on the same four point scale used at the initial assessment. Peak flow readings were also recorded where possible and relevant.

The following table shows the percentage of patients assessing their symptoms as clear, mild, moderate or chronic in each week of the trial. Those who did not reply in any one week are not tabulated for that week, hence percentages do not amount to 100%.

	Clear	Mild	Moderate	Chronic	% of total survey responding
	%	%	%	%	
Starting day	4.5	31.6	43.2	7.7	87.0
Week 1	8.4	29.7	41.3	7.1	86.5
Week 2	11.0	32.3	38.7	3.2	85.2
Week 3	16.8	38.1	27.7	3.9	86.5
Week 4	18.7	36.8	25.8	4.5	85.8
Week 5	20.6	38.7	23.2	2.6	85.1
Week 6	28.4	31.0	23.2	3.9	86.5
Week 7	32.3	35.5	12.9	3.9	84.6
Week 8	29.0	38.1	13.5	3.9	84.5
Week 9	31.0	34.2	15.5	3.9	84.6
Week 10	33.5	28.4	17.4	3.2	82.5
Week 11	35.5	34.2	11.0	2.6	83.3
Week 12	36.1	30.3	11.6	3.2	81.2
Week 13	29.0	32.3	12.9	2.6	76.8
Week 14	33.5	25.8	12.9	1.3	73.5
Week 15	35.5	22.6	11.6	0.6	70.3
Week 16	34.2	29.0	6.5	2.6	72.3

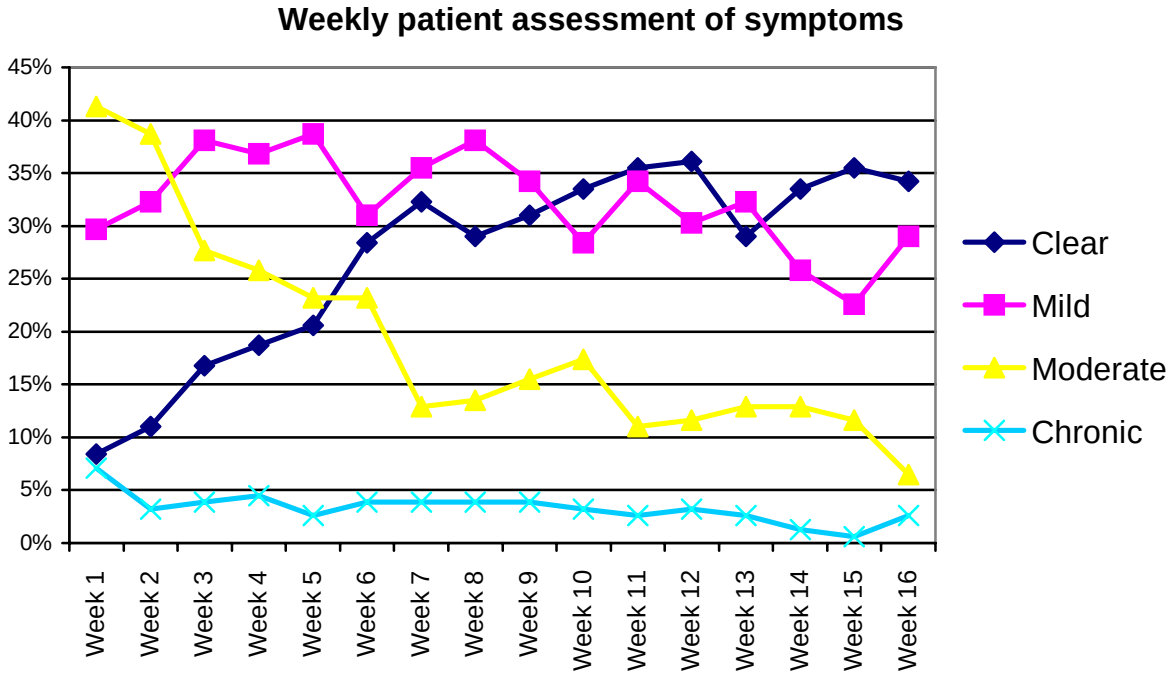
The percentage of those reporting ‘chronic’ symptoms dropped between week 1 and week 2 and apart from a slight rise in week 4 then remains at a lower level until the end of the trial period.

The percentage reporting ‘moderate’ symptoms falls quite steeply between weeks 2 and 3, and drops again in week 7. A slight rise in week 10 is then followed by further falls to a low point at the end of the sixteen weeks.

Meanwhile those reporting ‘mild’ symptoms rises in week 3, as those who previously had chronic or moderate symptoms improve. After 8 weeks the percentage in the ‘mild’ category declines somewhat as there is a rise in the proportion of those reporting their symptoms as ‘clear’.

The percentage of those who say they are ‘clear’ of their allergy symptoms rise from 8.4% in week 1 to 34.2% in week 16, a considerable increase which occurs steadily over the trial period.

The following chart graphically illustrates these changes over the sixteen week trial period.



In order to quantify changes in patients conditions, a score was applied using the following scale:

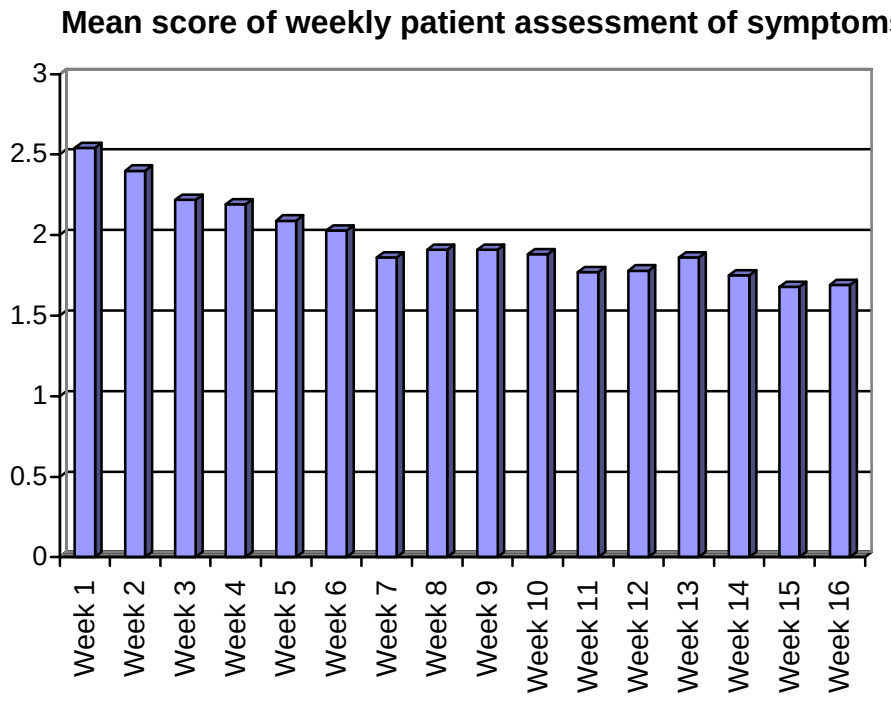
Clear	= 1
Mild	= 2
Moderate	= 3
Chronic	= 4

The mean score for each week of the trial was then calculated, giving the following results:

	Mean	Standard Error
Week 1	2.54	0.07
Week 2	2.40	0.07
Week 3	2.22	0.07
Week 4	2.19	0.07
Week 5	2.09	0.07
Week 6	2.03	0.08
Week 7	1.86	0.07
Week 8	1.91	0.07

	Mean	Standard Error
Week 9	1.91	0.07
Week 10	1.88	0.08
Week 11	1.77	0.07
Week 12	1.78	0.07
Week 13	1.86	0.07
Week 14	1.75	0.08
Week 15	1.68	0.07
Week 16	1.69	0.07

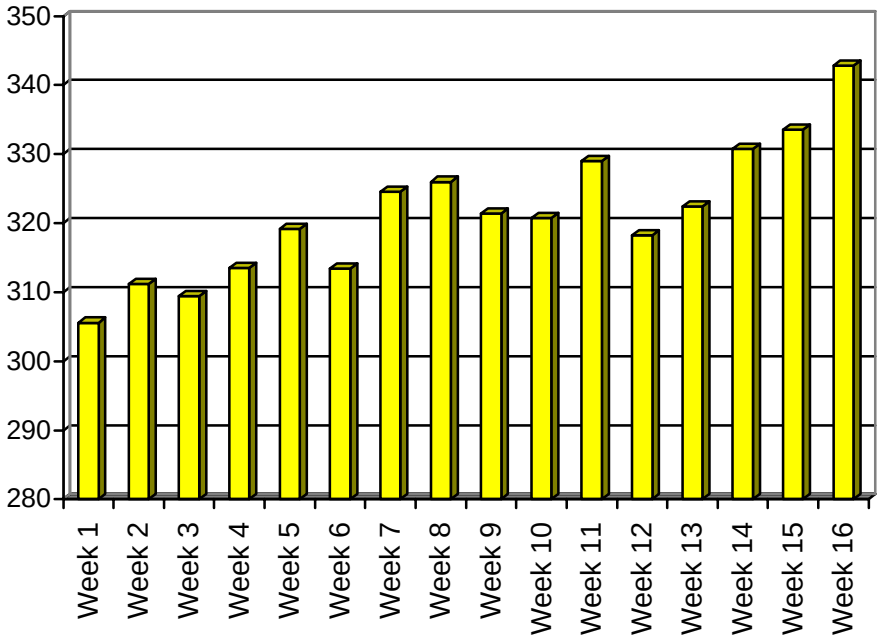
This shows a steady improvement in symptoms week on week, which is statistically significant. The following chart gives a graphic illustration of the trend.



In addition, weekly peak flow reading were noted by some respondents, and the improvements in the average (mean) reading across the sixteen weeks confirms respondents assessments. Data on peak flow readings is shown in the following table and chart

	Number of patients	Mean peak flow	Minimum peak flow	Maximum peak flow	Standard Error of the Mean
Week 1	99	305.59	33	610	13.03
Week 2	94	311.22	60	610	13.36
Week 3	95	309.47	60	620	13.19
Week 4	95	313.53	60	650	13.41
Week 5	94	319.15	50	650	13.36
Week 6	94	313.46	60	650	13.35
Week 7	94	324.57	60	660	13.26
Week 8	91	325.99	50	650	13.38
Week 9	88	321.42	70	660	13.23
Week 10	89	320.79	60	620	13.14
Week 11	94	328.99	60	680	13.29
Week 12	84	318.21	50	650	14.31
Week 13	84	322.44	60	650	13.75
Week 14	79	330.76	60	640	14.08
Week 15	79	333.54	55	650	13.85
Week 16	81	342.83	60	650	14.18

Mean weekly peak flow readings



Respondents were invited to comment on their symptoms each week, and many took the opportunity to explain changes in their condition, or to record relevant factors such as holidays or changes in medication. Coughs and colds and other allergies were frequently recorded, as were general comments on how the patient felt. A selection of comments follow:

Patient A

Week 1	*Easy breathing*
Week 2	*Apart from one day feeling well*
Week 3	*Disaster - sprung a spring in the mattress and tore the cover*
Week 4	*Had bad cold - not very well.*
Week 5	*Getting over cold but easing*
Week 6	*Much better this week*
Week 7	*No night attacks*
Week 8	*Brilliant*
Week 10	*Weather changed again but no night attacks*
Week 11	*Apart from the 1/2 attacks per week feeling well*
Week 12	*Only have day time attacks*

Patient B

Week 1	*On Flixotide 1000mcgs daily*
Week 2	*S/B chest paediatrician oral steroids started*
Week 3	*S/B chest Paediatrician oral steroids continued and Erythromycin*
Week 7	*Improved - no cough*
Week 8	*Improved - no cough*
Week 9	*Improved - no cough*
Week 10	*Review by chest Paediatrician. Chest now clear. Flixotide 200 mcgs.*
Week 14	*Has a cold*
Week 16	*On Flixotide 200 mcgs*

Patient C

Week 2	*Symptoms worse*
Week 6	*Improving*
Week 7	*Less chesty and congested in the morning*
Week 10	*Cold may be starting*
Week 11	*Blocked sinus*
Week 13	*Still acute blocked sinus - no cough*

Patient D

Week 1	*Night sneezing*
Week 2	*Sneezing / rhinitis*
Week 3	*Still waking 3/4 times in the night – sneezing and runny nose*
Week 4	*Late evening / early morning wheeze*
Week 6	*No night sneezes noticeable difference*
Week 8	*Vacuumed bed*
Week 11	*Hay fever starting*

Week 12	*All symptoms returned but due to hayfever*
Week 13	*Taking oral steroids*
Week 14	*Becotide and Ventolin*
Week 15	*Becotide and Ventolin*
Week 16	*Even though hayfever worse the nocturnal sneezing/rhinitis is better*

Patient E

Week 1	*Wheezy and coughing at night*
Week 2	*Wheezy and coughing at night - some slight improvement*
Week 4	*Improving - using Ventolin working*
Week 5	*Much improved*
Week 6	*Not waking up. No night time coughing*
Week 7	*Wheezing.*
Week 8	*Settled sleep - no coughing*
Week 9	*No problem*
Week 10	*Symptom free – sleeping well*

Patient F

Week 3	*Had quite a bad cough*
Week 4	*Chest infection. Flixotide inhaler increased to 4 puffs*
Week 9	*Severe chest infection*
Week 10	*Antibiotics – inhalers increased to 4 puffs twice a day*

Patient G

Week 1	*Worse at night when in bed and central heating is on*
Week 5	*Feeling much better first thing in the morning*
Week 8	*Bed vacuumed*
Week 9	*Suffering from a cold*
Week 10	*Just recovering from cold*

Patient H

Week 1	*Eyes sore*
Week 2	*Quite a bit coughing during night*
Week 3	*Coughs a little throughout night - eyes sore*
Week 5	*Coughs a little during night*
Week 6	*No coughing day or night at all - not even when running around*
Week 7	*No coughing during the night*
Week 11	*Had a cold*
Week 12	*No coughing during the night*
Week 14	*Cough once in night*
Week 15	*Nicole came off Loratadine medicine*
Week 16	*No coughing - still off medication*

Patient I

Week 1	*Still waking at night for his medicine*
Week 2	*Very bad week due to hayfever. On steroids and up all night*
Week 3	*Better this week not waking at night*
Week 4	*Getting very tired due to hot weather*

Week 5	*Has no energy*
Week 6	*Had best week for a very long time*
Week 7	*Good in start of week*
Week 8	*Getting bad at end of week. Waking at night again*
Week 9	*Had bad attack and went into hospital. Put on Becotide.*
Week 10	*Getting better as new medicine starts to work*
Week 11	*Better still. Eating better than ever*
Week 12	*Back to the healthy boy that he was before asthma*
Week 13	*Doesn't need Ventolin. New medicine has stopped his asthma*
Week 14	*Perfectly well*
Week 15	*Perfectly well*
Week 16	*Perfectly well*

Patient J

Week 1	*No real difference*
Week 5	*Eczema very bad*
Week 6	*Eczema still bad – cortisone cream used*
Week 7	*Fucibet cream from doctor*
Week 8	*Eczema improving*
Week 9	*Eczema better*
Week 10	*Asthma attack. Hospital attended*
Week 14	*On holiday. Skin clear for first time in years*
Week 15	*On holiday*
Week 16	*Skin still really clear*

Patient K

Week 1	*Sneezing at least 10 times each morning and throughout the day*
Week 2	*Improved no end. Less sneezing*
Week 5	*Hayfever season. Not too bad*
Week 9	*Take cover off hoover and put back. Sneezing much better*
Week 13	*Hayfever quite bad during the day*
Week 14	*Not as many sneezes*

Patient L

Week 1	*Start of a cold*
Week 2	*Have a cold at the moment*
Week 3	*Cold still lingering*
Week 4	*Cold has gone. Rhinitis- although never diagnosed feel that my sinuses are clear*
Week 5	*Not a lot of change with asthma*
Week 6	*Sinuses were blocked this morning*
Week 7	*Vacuumed bed*
Week 8	*Sinuses not blocked*
Week 9	*On holiday*
Week 10	*On holiday*
Week 11	*Sinuses clear in the morning*
Week 12	*Sinuses not blocked*

Patient M

Week 1	*Eyes very sore*
Week 3	*Eyes improving considerably*
Week 9	*Eczema bad seen doctor given antibiotics for one month*
Week 13	*Eczema worse referred to consultant*
Week 1	*Hard to tell because of cold - not sneezing so much*
Week 2	*Not sneezing so much*
Week 4	*Not a continuous sneeze when waking up*
Week 6	*Bad cold*
Week 7	*Bad cold*
Week 16	*The cover definitely seems to work*

Patient N

Week 1	*Serevent and Ventolin via nebuliser*
Week 2	*Improving*
Week 4	*Coughing less*
Week 5	*Brighter*
Week 6	*Active*
Week 8	*Serevent reduced*
Week 11	*Cold made chest worse*
Week 12	*Antibiotics*
Week 15	*Antibiotics stopped*
Week 16	*Ventolin at night*

Personal assessment of condition

At the end of the trial period patients were asked whether they had felt an improvement in their condition. In total, two thirds said that they had improved, while just 12% said they had not, and 19% were unsure. This improvement was most apparent among those who had a proven allergy to house dust mite: over three quarters of them (77.3%) said that their condition had improved.

			Allergic to House Dust Mite?		
		Base	Yes	No	Don't know
	Base	155	66	2	79
Have you felt an improvement in your condition?	Yes	66.5%	77.3%	50.0%	59.5%
	No	12.3%	7.6%	-	17.7%
	Not sure	18.7%	13.6%	50.0%	19.0%

Further analysis shows that those who had symptoms of rhinitis were particularly likely to see an improvement in their symptoms, as were those whose asthma symptoms were linked to house dust mite allergy. In addition 71% of patients who suffered from their allergies at night also saw an improvement in their condition by the end of the sixteen week trial period.

Patients who had reported chronic symptoms at their initial assessment at the start of the trial were also particularly likely to see an improvement in their condition.

Perceived improvements in their condition varied between the various age groups, but does not indicate a trend and is probably due to individuals specific allergies rather than their age.

Use of allergy medication

Patients in the trial were using a variety of medication to control and treat their allergy symptoms with some of the more commonly used drugs shown in the following table:

Flixotide / Flixonase	28.7%
Ventolin	21.7%
Becloforte / Beconase	13.9%
Salbutamol	13.9%
Serevent	11.3%
Clarityn	10.4%
Pulmicort	10.4%
Bricanyl	5.2%
Piriton	3.5%
Other	18.3%
None	3.5%

They were asked whether they had been able to reduce their allergy medication. Some 85% of respondents answered this question and of these 51.5% said that they had. One third of respondents gave details, recording a decrease either in the frequency of taking medication or the dosage used. In some cases patients had been able to reduce their medication to virtually none. However, the variation in drug regimes and types of medication used makes it impossible to quantify the decrease. Some typical comments are given below:

Start of assessment *Becotide, Ventolin, 4 puffs per day*
End of assessment *Ventolin occasionally, Becotide,2 puffs per day*

Start of assessment *Pulmicort 2 puffs, Bricanyl 5/6 times a day*
End of assessment *Pulmicort Twice a day, Bricanyl Twice a day some days*

Start of assessment *4 puffs, Twice daily*
End of assessment *As and when required, Only when cold or cough*

Start of assessment *Creams, Twice daily*
End of assessment *Still twice daily but not as much required*

General comments

At the end of the trial respondents were asked for further comments. Many of these focused on the improvements in patients' conditions, with both patients and nurses saying they were pleased with the results. Some mentioned other conditions or infections which may have influenced the results. In addition a number of letters were received which gave further information, usually on the successful outcome of the trial. A small selection of comments follow:

Mr R has noticed a marked improvement in his condition since using the Astex cover.

Overall I have felt there was an improvement - his cough especially at night is under control and his runny nose is not as persistent. It is very possible that this improvement is due to Astex covers however when Daniel's improvement started to be noted his inhaler had also been changed from Becotide to Flixotide.

Jessica was a persistent cougher. She is now able to enjoy a good nights rest. Jessica has also had no GP consultations since using this product. Usually coughing at night - now resolved. Peak flow much improved.

We are very grateful to have had a chance to use this product and are sorry it has not worked for our daughter,

I have recommended the cover to parents attending the asthma clinic,

Mum very happy with product - child unable to reduce medication due to infections

We went away for a few days and when he woke up all he did was sneeze - different beds. Now peaks flow is 250-300 whereas before it was 200-270.

Noticed an improvement in my daughters skin plus she doesn't have restless night sleep anymore. I will buy another set, it is brilliant. Patient happier and more relaxed. Her asthma is well controlled on low doses of prophylactic therapy and her eczema is calmer and controlled on weaker strength creams. Sleep and appetite have also improved.

My son had a bad asthma attack at the end of June, since then he has been on a high dose of Pulmicort and Flixonase nasal spray. Thank you for the opportunity of trying the mattress cover. Although it was not the answer for patient the family bought one themselves and Dad's asthma has improved.

Chest so much less wheezy, more active little boy.

Asthma does seem much better to this time last year. His rhinitis and eyes are beginning to get worse now in the mornings but I feel this is seasonal. Miles feels his mattress has helped him,

I chose this patient not only because of her asthma but also because of her moderate eczema which I was quite concerned about. I am pleased to say that this appears to have improved since using the Astex products

Conclusions

Although not a controlled clinical trial, this study demonstrates that the majority of patients with allergic symptoms benefited from the use of the Astex covers, while those who had a known allergy to house dust mite were very likely to benefit. In a number of cases this had a marked improvement on the patient's quality of life and some were able to substantially reduce their dependence on medication.

The multi-facetted nature of many allergies had an impact on the results of this study. In a number of cases improvement was seen, but this was confused by the presence of other allergic reactions, for example a patient with rhinitis might see improvement in their symptoms in the morning as a result of their house dust mite allergy being controlled, but a worsening of symptoms during the day due to hayfever.

Infections, weather conditions and types of activity undertaken also have a major effect on symptoms and these could not be fully controlled or eliminated from the study. The effect of these factors is usually negative and their existence may have served to conceal any improvement due to the control of house dust mite. Despite this just over two thirds of patients reported an improvement in their condition, and this was confirmed by the Practice Nurses. Initial improvement was often seen within weeks of starting the trial, with further improvements continuing or maintained for most patients.

This study strongly suggests that the Astex covers are perceived by patients and Practice Nurses as being very effective against allergic symptoms such as asthma, eczema and rhinitis.