

CONFIDENTIAL REPORT

INDEPENDENT RESEARCH ON HAYMAX™ POLLEN BARRIER BALM

From

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INTRODUCTION

This organic product is sold without prescription and is described as safe to be used by all age groups. The HayMax™ balm is sold as a remedy for hay fever and is thought to work by trapping pollen grains as they enter the nostrils thus reducing the amount of allergen breathed into the nose. However no independent scientific research has been done on Haymax balm as a remedy for hay fever.

The study aimed to assess the number of pollen grains that are trapped by the HayMax™ balm when applied in a standard manner to the rim and the inside of nostrils compared with the amount deposited on uncoated nostrils. The study did not aim to assess the impact of this on symptoms of hay fever.

METHOD

A pilot study was conducted to develop the study protocol. This was mainly to establish a uniform method for application of the balm and an efficient method of sampling the pollen from the nostrils. Once these processes were in place the variance in the results of the pilot study helped to determine the sample size required for the study.

The study used adult volunteers (over 18 years). Inclusion and exclusion criteria were applied. The volunteers did not have a history of asthma or hay fever. They did not have any obstructions to breathing (e.g. polyps) or any nasal deformities. They had no symptoms of cold, flu or rhinitis at the time of the experiment, and were in good health generally. Informed consent was obtained.

Grass pollen is the most important allergenic pollen type in the UK as research indicates that 95% of hay fever sufferers are allergic to this, whereas as about 25 % are allergic to tree pollen and 20% are allergic to allergic to weed pollen. For this reason the experiment was done on high grass pollen count days (50 grains per cubic meter or more daily average). The daily average pollen counts and the short term actual counts during the experiment periods were determined from the NPARU national pollen sampling site which is on the roof of a building at the same location as the experiment site.

For each person the procedures were explained in detail. Both nostrils are cleansed with sterile swabs (clean one for each) and allowed to dry while the person sat in laboratory with filtered air.

A standard amount of neutral (unscented) HayMax™ balm was applied evenly to the lower part and rim of one nostril (right) and the other nostril was left clear.

The person then walked around outdoors on a set route through an area with flowering grass for 60 mins. The people were told to breathe through their noses and not to blow their noses. Any sneezing was noted. They were instructed to keep their mouths shut.

The person returned to the lab where the nostrils were sampled separately by a specifically developed standard method using low tack tape. From the pilot study it was known that any pollen on the nostrils would adhere to the low tack tape. The tape was mounted onto a microscope slide, then stained with basic fuchsin. The pollen in the sample was counted under a high power microscope using x100 and x 400 magnification. The number of grass pollen grains was counted separately from other grains and a total count was taken. In every case the whole slide was scanned.

The experiment had 18 repeats (person sets of data). This sample size was determined by a power calculation based on the results of the pilot study.

The study was not placebo controlled as it would have been obvious which nostril has the HayMax™. In any case this is not an issue because for each subject the nostrils will be exposed to the same amount of pollen, the subject cannot influence the amounts of pollen adhering to individual nostrils and symptoms are not being considered.

RESULTS

Pollen counts on the days of the experiments

The experiment was conducted on 6 days during the peak grass pollen season in 2009. Grass pollen counts on all of the days had daily averages at 50 grains per cubic metre or above which is taken as the threshold for “high”

in the UK. Similarly the grass pollen counts for the 2 hour period in which the experiments took place during the day were at 50 grains per cubic metre or above apart from one day (Table 1). The main pollen types in the “other pollen “ category were summer flowering trees such as lime, and weeds, such as nettles.

Table 1. Daily average pollen counts on the days of the experiment and the two hourly averages over the times of the trials. Figures are as grains per cubic metre air.

Date	Two hour period		Daily average	
	Grass	Other	Grass	Other
18/06/2009	73	115	61	52
23/06/2009	303	424	202	200
24/06/2009	170	236	153	131
25/06/2009	145	182	117	131
30/06/2009	30	36	53	120
02/07/2009	164	181	179	116

No sneezing or nose blowing was reported.

The individual results for the pollen on the nostrils of the 18 cases are given in Table 2 and are shown on Figs 1 to 3. In all cases the total number of pollen grains present on the nostril with the HayMax™ were greater than with the uncoated nostril. This was also the case for grass pollen and in all but one case with “other pollen types”.

There was considerable variance between people in the amounts of pollen collected on the nostrils. This ranged for the “total pollen “ on uncoated nostrils from 6 to 604 on different days, and from 20 to 604 on one day. Similarly for the nostrils with HayMax™, results ranged from 19 to 3,490 on different days and 55 to 3,490 on one day.

For “total pollen” individual percentage differences between uncoated nostrils and those with HayMax™ ranged from 25 to 91%. For grass pollen individual differences ranged from 22 to 95%, and for “other “ pollen from 0 to 100%.

Table 2. Individual results per subject

2009	subject	Grass Pollen			Other Pollen			Total Pollen		
		uncoated	HayMax™	% more with HayMax™	uncoated	HayMax™	% more with HayMax™	uncoated	HayMax™	% more with HayMax™
June										
18	1	6	122	95	5	3	0	11	125	91
23	2	16	21	24	3	6	50	19	27	30
	3	20	36	44	3	14	79	23	50	54
	4	224	328	32	5	22	77	229	350	35
	5	225	586	62	8	41	80	233	627	63
	6	165	513	68	14	68	79	179	581	69
24	7	20	43	54	0	12	100	20	55	64
	8	588	3419	83	16	71	78	604	3490	83
	9	196	340	42	20	44	55	216	384	44
25	10	56	446	87	2	17	88	58	463	87
30	11	6	31	81	2	8	75	8	39	79
	12	22	206	89	4	9	56	26	215	88
	13	124	183	32	6	9	33	130	192	32
	14	8	51	84	3	11	73	11	62	82
July										
2	15	47	62	24	2	3	33	49	65	25
	16	4	10	60	2	11	82	6	21	71
	17	7	9	22	5	10	50	12	19	37
	18	6	14	57	4	6	33	10	20	50

The average number of pollen grains trapped are shown by category on Table 3.

Table 3. Average number of pollen grains on the nostrils. (N=18)

	Uncoated nostril	Nostril with HayMax™	% more on nostril with HayMax™
Grass pollen	67.3	185.7	64
Other pollen	5.7	20.3	72
Total pollen	102.4	376.9	73

There was a significant difference at the $p \leq 0.05$ level by the t test between the results for grass pollen grains between uncoated nostrils and those with HayMax™. Similarly there was a significant difference at the $p \leq 0.01$ level by the t test for “other “ pollen grains between uncoated nostrils and those with HayMax™. There was also a significant difference at the $p \leq 0.05$ level by the t test for total pollen grains between uncoated nostrils and those with HayMax™.

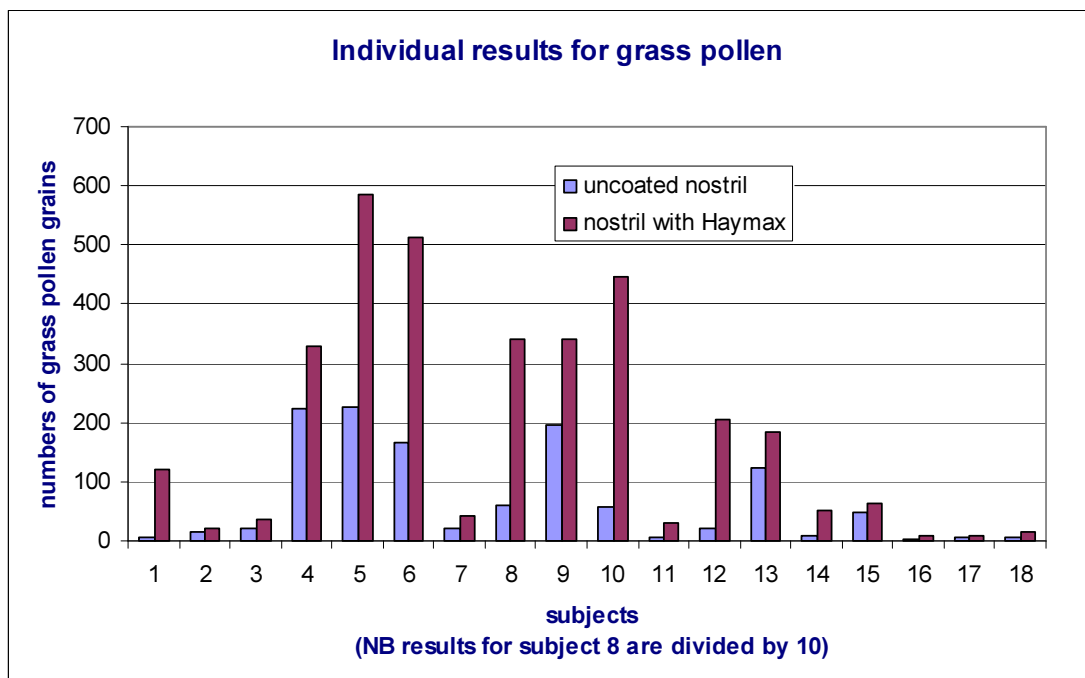


Fig 1.

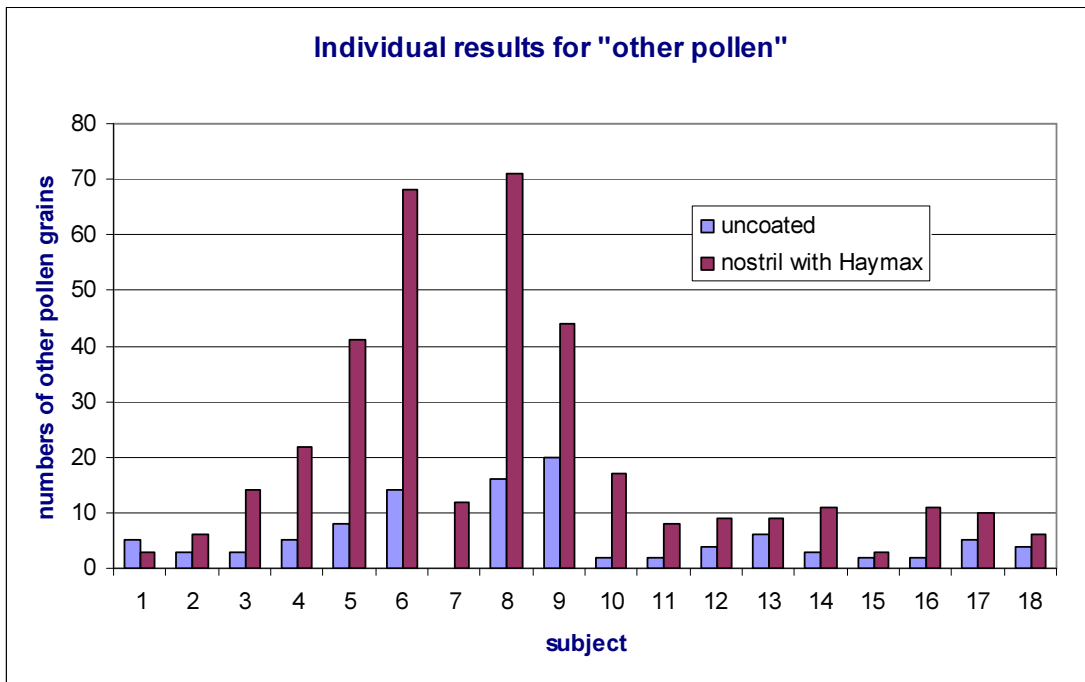


Fig 2

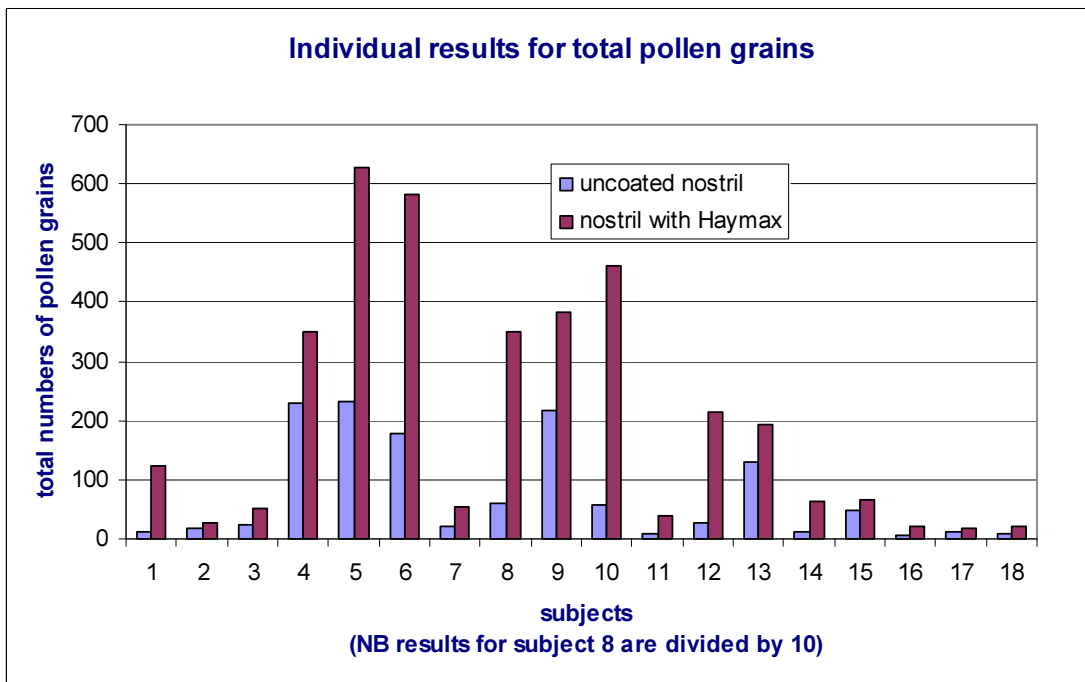


Fig 3

DISCUSSION AND CONCLUSIONS

The variance in amounts of pollen collected on the nostrils between individual subjects could be due to several reasons, including differences in anatomy between people as some had smaller nostrils than others. There may also have been some non compliance, for example talking, so that breathing was partly or wholly through the mouth during the test time. The subjects started walking round at slightly different times within the 2 hour period. Pollen amounts may have differed within this time due to wind etc.

In all cases the numbers of grass pollen grains and the numbers of total pollen grains collected on the nostrils with HayMax™ were larger than the numbers collected on the uncoated nostrils. This was also the case in all but one subject for the “other “ pollen types. In all three categories i.e. grass, “other” and total pollen the results were significantly different between uncoated nostrils than those with the HayMax™.

The results show that the application of HayMax™ to the lower part and rim of the nostrils does trap significantly more pollen than an uncoated nostril. This would result in some reduction to the amount of allergen entering the nose.

However the results do not give any indication of the amount of reduction of pollen entering the nose as many particles including pollen would go into the nose without being near to the surface of the nostrils.

The study has not investigated the impact of HayMax™ on symptoms of hay fever.

Study design, analysis and report by Prof Jean Emberlin

The practical work for the study was done by Angie Warren BSc (Hons) and Noel Egginton BSc (Hons).