

A Novel Mattress with Inboard Heating Fabric prevents the Build-up of the Dust Mite Allergen Der p1 in a 2-year In-home Field Trial

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Abstract

To reduce the build-up of house dust mites (HDM) allergens in beds, a heatable mattress was developed and its effectiveness investigated in a two year field trial. Circular knitted heatable fabrics were integrated in polyurethane mattresses and heated three times a week for 2 hours. Hygrothermal measurements and survivability tests with living HDM were performed in vitro. Living HDM placed inside a prototype mattress was completely killed after two hours of heating due to the climatic conditions. In vitro measurements revealed that the hygrothermal death points for HDM (51°C, 30 % relative humidity) were rapidly reached within the heated full-sized mattresses. To validate the effectiveness of this intervention in practise, a field trial was run with 20 HDM-patients and The accumulation of the mite allergen Der p1 in dust samples taken from mattresses was measured 12, 18 and 24 months. Mattresses of the intervention group showed significant lower mean HDM allergen contents during the field trial. The heatable anti-dust mite mattress helps to prevent the build-up of HDM allergens in new mattresses in the long-term use and may thus help to reduce the allergy symptomatology. As an avoidance strategy, the novel mattress supports other textile-based HDM allergy interventions, e.g. encasings.

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1 Introduction

House dust mites (HDM, *Dermatophagoides pteronyssinus*, of the Pyroglyphidae family) are amongst the most important sources of indoor allergens [1, 2]. Early exposure to HDM allergens has been established as an important risk factor for mite allergen sensitization and the development of asthma in most parts of the world [3, 4]. The rate of sensitization to mite allergens is directly related to their exposure and commonly based on current exposure in the home [5, 6, 7]. According to Arbes et al. approximately 27 % of individuals in the United States already show increased IgE antibodies towards HDM allergens and are thus classified as sensitive [8]. Internationally, 24 % - 58 % of the households in European countries are at risk to mite allergen sensitization in their homes [9, 10].

An effective way to improve the condition of asthma patients is the residence in mite allergen free environments such as hospitals [11] or high alpine sanatoria [12, 13], where sufferers improve symptomatically and in terms of their bronchial symptoms. These results suggest that avoidance of mite allergens leads to decreased hyperresponsiveness. But it is obvious that most patients are unable to live durably under such optimised conditions and even after a sanatory stay at higher altitudes people suffer from rapid relapses and their symptoms quickly reoccur after re-exposure in their homes [14].

HDM are found in almost all dwellings and in much larger concentrations in mattresses than on floors [15]. Avoidance of HDM in their beds is therefore crucial for HDM allergic patients. Beside residence in allergen-free environments, there are other methods of allergen avoidance at home, many of them textile-based. Reduction of allergen exposure in the bedroom is the primary target of avoidance measures, since mattresses are the most important habitat and source of mite allergens to which we are exposed for many hours during nocturnal sleep [16]. The most effective and probably most important avoidance measure up to now is to cover the mattress, pillows and duvets with mite-allergen impermeable barrier covers, so-called encasings [14, 17, 18]. However, it has not yet been shown that encasement of bedding is associated with clinical benefits [19]. Clinical benefits of this intervention are likely to be confined to the subgroup of atopic asthmatics whose asthma is precipitated by HDM allergen exposure [20]. Beside the interventions with barrier fabrics, other physical approaches so far used hygrothermal techniques, but only on the lab level. Kinnaird for example found, that higher temperatures and low ambient relative humidity is detrimental to the survival of HDM and that the thermal death point of HDM can be reached at 60 % relative humidity [%rH] and exposure to 51°C for several hours [21]. Such conditions may be achieved e.g. by heating the mattress from the outside with electric blankets, which are placed on top of the mattress cover at times that they are not being slept on [22]. However, this concept is quite inconvenient for patients and requires a high voltage source. A more practical way to use the efficient hygrothermal intervention for HDM sufferers would be the total integration of a flexible and heatable source inside the mattress.

In order to reach this more practical objective, our study investigated the development of a circular knitted heating fabric based on electric conductive alloy yarns and its integration into polyurethane mattresses. We thought to design the heatable double knit wear in such a way, that it could be supplied with low voltage, in order to reach hygrothermal conditions at any points of space in full-sized mattresses, so as to exceed the thermal death point of HDM. We also investigated the lethality of this intervention in vitro with living dust mites placed inside of the foam block of a prototype mattress.

Finally, we conducted a two-year field trial with 20 HDM allergy patients, separated in intervention (heatable mattresses) and control (non-heatable mattresses) group and measured the accumulation of the mite allergen Der p1 within the mattresses after one year and then every six months.

2 Methods

2.1 Circular Knitted Heatable Fabric

A planar electrical heatable fabric was manufactured by a circularly knitted base element that comprised synthetic conductive PES Poly(oxy-1,4-phenylsulfonyl-1,4-phenyl) fibres. The synthetic PES fibres, surrounded by a conductive alloy yarn, were integrated into the knitwear rectilinearly by means of a double knitting technique. The heating conductors run substantially parallel to each other within the base element with a distance of at least 8 mm. At its free ends the heating conductors were connected to an electric terminal made of a woven metal band by ultrasound welding. The heating element was manufactured to fabric of 0.9 x 2 m² and to 0.4 x 0.5 m² for the prototype and connected with alligator clips to the positive and negative terminals of a low voltage power supply (18 V direct current generator) that could be switched in stages. The heat up phase of the fabric was recorded with an infrared thermographic camera (FLIR Systems GmbH, Frankfurt, Germany). The stiffness of the textile was determined by measuring the bending angle of a fabric strip placed on a thin bar using a laser beam.

2.2 Construction of Anti-dust Mite Mattresses

A conventional polyurethane foam block of 16 cm thickness was cut horizontally leaving a lower 7 cm layer. A high density (HD) polyfoam (RG 55) with a density of 28.8 g/dm³ was used since it is utilized in almost all mattresses made by the major manufacturers. The circular knitted heating element was then placed onto the lower 7 cm thick polyurethane layer, covered by the 9 cm thick top layer, connected to the power supply and then re-packed in the mattress cover. 20 full-sized mattresses of (0.9 x 2 m²) were equally structured and used for the hyothermal experiments and the field trial. In addition a prototype of 0.4 x 0.5 m² was manufactured for the in vitro survivability tests.

2.3 In Vitro Experiments

All in vitro experiments were repeated 10 times. The relative humidity within the prototype and full-sized mattresses was measured in a climate chamber with a relative humidity measuring device (Data Logger DK812 LCD-12, Driesen und Kern GmbH, Bad Bramstedt, Germany). A temperature data logger was used for the temperature kinetics. Both probes were placed at five measuring points (MP), thus covering the whole profile of the mattress: Control measuring point MP 1 above the mattress cover, level of the mattress cover MP 2, upper third of the mattress MP 3, centre of the mattress MP 4 and below the heating element in the lower third of the mattress MP 5 (figure 3).

To prove the lethality of the heating device towards HDM, small cores were drilled at the six measuring points of the prototype. Afterwards, 3.5 ml sample vials (Sarstedt AG & Co, Nümbrecht, Germany) were each filled with selected 20 healthy adult HDM, separated

from a long-term HDM culture in the lab by stereomicroscopy. The cups were then sealed with air-permeable but dust-impermeable meshes (pore size 50 µm, Sefar AG, Heiden, Switzerland) to prevent mite escape. Finally, cups were placed in the drilling holes. After heating the prototype, the cups were retrieved and HDM survivability / lethality was evaluated using a stereomicroscope (Olympus SZX12, Hamburg, Germany). Mites were counted as dead, when they did not recover over the next 6 hours.

2.4 Field Trial-design and Population

A parallel group controlled trial with heating mattresses in the intervention group and identical but non-heatable mattresses in the control group was conducted. Participants were not blinded for their status, since programming was switched off in the control group. The trial comprised 20 adults and children with allergy to Der p1 recruited by physicians. All patients were administered the leukotriene receptor antagonist montelukast orally to relieve symptoms of seasonal allergies, but no further desensitisation was run. All participants were positive in skin prick test to Der p1, which, in contrast to Der f1, is the prevailing allergen in Europe. The symptom scores of all participants comprised disturbed sleep, breathlessness, wheeze, running nose, watering red eyes and overall symptoms, but there was no diagnosis for asthma. Patients were provided with clear information regarding the trial and, since any burden for the participants could be excluded, all gave their informed consent. Patients of different age (9-43 years) and gender were therefore randomly allocated to the intervention (n = 10) and control group (n = 10).

2.5 Interventions in the two year field trial

Encasements of the bedding with impermeable covers (encasings) were not allowed during the field trial. Instead all participants used cotton covers for pillows and duvets. Participants were also instructed to place conventionally washed cotton bed linen on the bed outside. Both groups were requested to follow their routine cleaning and washing procedures for the bedding. No specific washing instructions or any other information on avoidance of mites was given to the patients. Sleeping habits were normal and comparable (~7-9 hours).

2.6 Assessment of Allergen Levels

Dust samples of the full-sized mattresses were taken after 1 year and then every six months by blinded samplers. At each visit, dust samples were collected from the mattresses using a vacuum cleaner (type Dirt Devil-Skuppy M7011-1) equipped with a sterile PES-Satin fabric. Dust was hoovered from the whole area of the mattress in a meandering pattern at constant pressure over 5 min. Dust samples were frozen over night, the amount of dust was weighed and an extract was obtained by 200 rpm rotation for 2 hours at room temperature in 3 ml of PBS-Tween 20 (0.05 %) buffer. Extracts were stored at 4°C +/- 2°C over night until measurement of Der p1 levels of the fine dust by a standard immunoassay (Indoor Biotechnologies, Warmister, UK) [23]. Lab workers were also blinded regarding the dust samples of the intervention/control group.

2.7 Statistics

T-Tests were performed to analyse the effectiveness of the heatable mattress with regard to the Der p1 accumulation. The mean Der p1 content of the intervention group was compared to the mean Der p1 content of the control group after 12, 18 and 24 months of the field trial. $p < 0.05$ was considered as significant ($\alpha = 0.05$). Statistical analysis was performed using MS Excel (Microsoft Corporation, USA).

3 Main Results

3.1 Fabric and Prototype Construction plus Performance

The heating fabric elements displayed the typical bending stiffness and flexibility of circular knitwear ($s = 58.9^\circ$), a prerequisite feature for the mechanical stress of mattresses in use. Details of the construction are shown in Figure 1-I. Starting heating at 20 °C room temperature at low voltage (24 V, 17 A), the fabric exceeded after 3 minutes the published thermal death point of HDM of 51 °C at its surface (Figure 1-II). After 25 minutes the surface of the fabric reached its top temperature of 97 °C, which is still way below the melting point of HD polyfoams (~ 180 °C), used within customary mattresses.

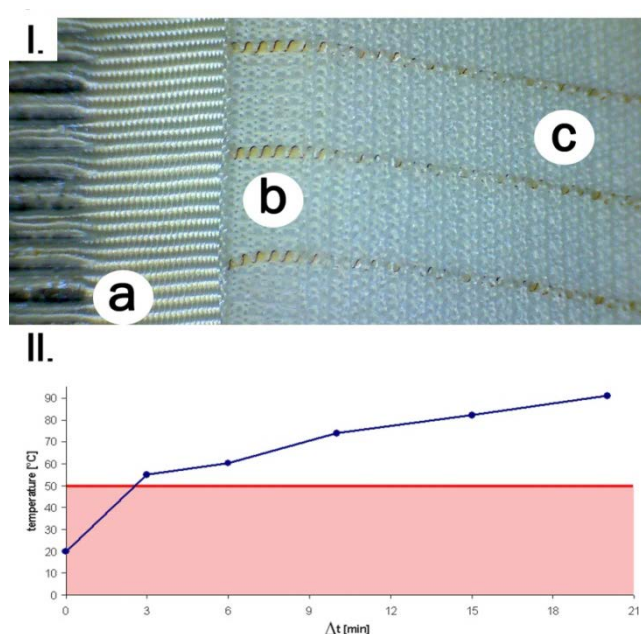


Figure 1: I. Stereoscopic view of the circular knitted heatable fabric. (a) Connectivity of the heating element to an electric terminal, (b) conductive fibres made of PES surrounded by a conductive alloy yarn, (c) circular knitted base element made of PES fibres. II. Surface temperature curve of the heatable fabric recorded by thermography. Note that the thermal death point of 51 °C is already reached after less than 3 minutes (bold line).

In order to evenly distribute heat and humidity in a 3D object across a conventional full-sized mattress with only one heating element, a polyurethane foam block (0.9 x 2 m²)

was cut in a ratio of 9/7. The knitted heating technical fabric was then placed asymmetrically onto the lower part inside of the full sized mattress. In laboratory experiments the profiles for relative humidity (Figure 2-I) and temperature (Figure 2-II) within the mattress were recorded over 5 hours at five measuring points (MP). A schematic drawing of the construction is shown in figure 3 (Control measuring point MP 1 above the mattress cover, level of the mattress cover MP 2, upper third of the mattress MP 3, centre of the mattress MP 4 and below the heating element in the lower third of the mattress MP 5). The heating fabric was operated at low voltage for 2 hours. Starting at 16°C room temperature and a relative humidity of 35 % rH (most common ambient conditions), there was a slight rise in all replicates in the relative humidity followed by a steep drop for the next 50 min. When the power was switched off after 2 hours, the relative humidity within the mattress remained between 0 - 15% rH (Figure 2-I). Within the first hour, the temperature within the mattress quickly exceeded 51 °C (MP 2) and reached 95 °C (MP 3 - 5), values clearly above the hygrothermal death points for HDM (Figure 2-II). As heat always ascends, the chosen construction resulted in a close and uniform distribution of relative humidity and heat inside the mattress prototype. Even when the mattress was operated at 12 °C RT and 65 % rH, the hygrothermal death point was exceeded in less than 90 min (data not shown). Thus, the asymmetrical position of the heating fabric turned out to be ideal for the conditions of the field trial.

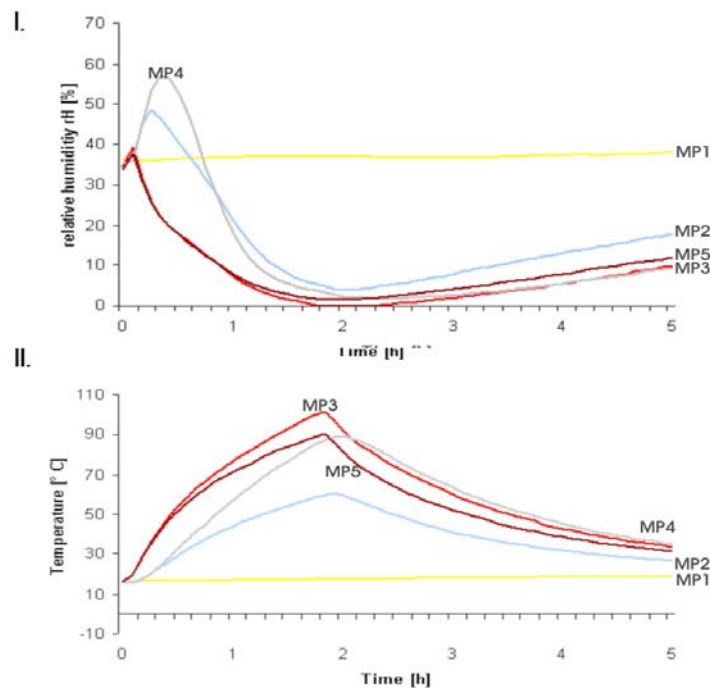


Figure 2: Representative diagram of relative humidity (I.) and temperature (II.) curves of the anti-dust mite mattress at 5 measuring points (MP) over 5 hours. Heating the mattress caused a dehydration of the mattress foam. A reduced humidity could be maintained for more than 5 hours after heating. Within the first 2 hours, a steep rise in the temperature of the MP in space occurred, which slowly decreased after the power supply was switched off. Note that after one hour the hygrothermal death points for HDM were already reached throughout the mattress.

In another set of laboratory experiments, we ran survivability tests using living HDM. For this purpose, a representative population of living HDM was taken from the HDM stock breeding and placed within sample cups at the five different measuring points of the prototype mattress (Figure 3), which covered the whole profile of the foam block, respectively. Then again the demonstrator was operated for 2 hours. The hygrothermal values were identical to the values observed within the full-sized mattresses. As the cups were covered by air-permeable, but dust-impermeable meshes, HDM were not allowed to escape. Subsequently, cups were removed and HDM survivability / lethality was evaluated. Heating of the prototype showed that all HDM cohorts at MP 2-5 looked dehydrated and were effectively killed, except for HDM placed at the control measuring point outside of the mattress (MP 1).

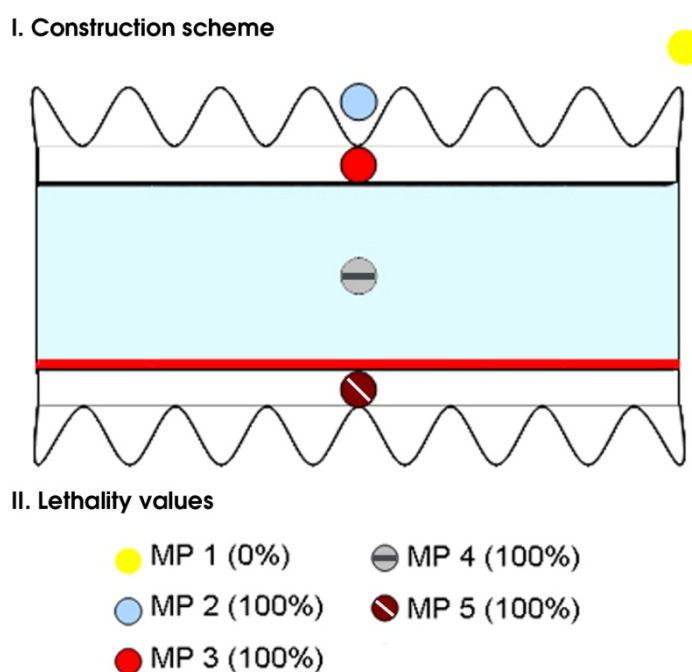


Figure 3: I. Construction scheme of the anti-dust mite mattress II. Lethality values after heating the mattress prototype. Values in brackets indicate the HDM lethality within sample cups after 2 hours of heating at the five measuring points (MP). Above the mattress cover (MP 1, control), level of the mattress cover (MP 2), upper third of the mattress (MP 3), centre of the mattress (MP 4) and below the heating element in the lower third of the mattress (MP 5). Bold line = position of heating fabric.

3.1 Two Year Field Trial

To prove the efficacy of the heatable anti-dust mite mattress in practise, a two year field trial with parallel groups (intervention group, control group) was run. Since all mattresses were new, the HDM allergen content was not detectable at the start of the study. Ambient allergen contents were not recorded. The power supply was programmed, so that

mattresses in the intervention group automatically heated up 3 times a week for 2 hours in the afternoon, i.e. at times, when participants did not use their sleeping room. Dust samples of the mattresses were collected after 12, 18 and 24 months and Der p1 allergen was quantified (Figure 4). A notable contamination of the new mattresses with dust mite allergen was already observed after 12 months in the control group. Up to 7 µg Der p1 per g of dust were found after 18 months. In contrast to that, heatable mattresses showed a significant lower Der p1 build-up (< 0,28 µg/g house dust, 18 months) over the whole test period. The allergen level within mattresses of the intervention group did not exceed a basic contamination value. A comparison of the intervention group to control showed a significant ($p < 0.05$) reduction of the mean allergen load within 2 years.

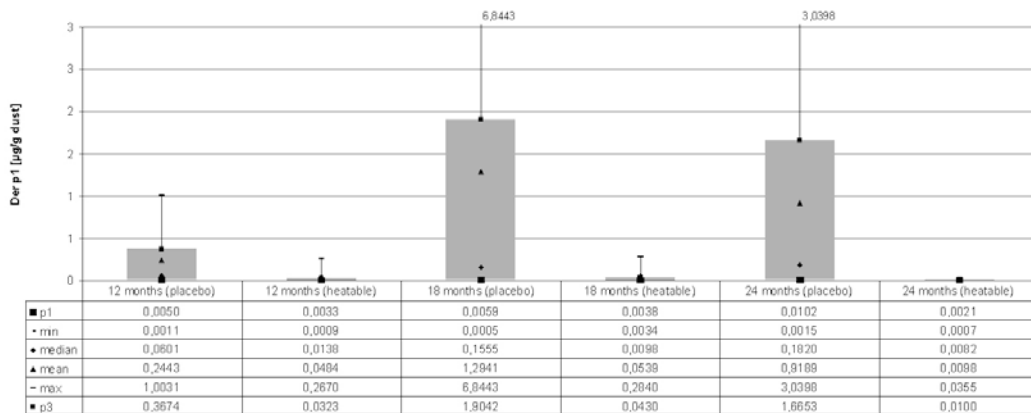


Figure 4: Content of the dust mite allergen Der p1 within bed dust taken from test mattresses over two years. A notable contamination of the control mattresses was already observed after 12 month, whereas a significant lower mean contamination within all dust samples of the heatable (intervention) mattresses was observed during the whole trial (24 months).

The inquiry of patients in the intervention group showed that 57.1 % stated, that the applicability of the heatable mattress was excellent, 26.6% declared it was fine, whereas 14.3.% stated it is worth of improvement. However, when this group was asked for their satisfaction, all patients recommended the mattress. With respect to the influence of the allergy symptoms, 30% of the test persons in the intervention group stated a considerably lower and 50% a slightly lower symptomology. 20% declared an unchanged condition. In the control group the ratio of unchanged to slightly lower symptomology was 50% to 50%. No one in the control group declared a considerably lower symptomology. A deterioration was not stated in both groups.

4 Discussion

In this study we followed a novel strategy to prevent the long-term build-up of the HDM allergen Der p1 using mattresses with inboard heating fabrics. The concept of heating mattresses to oust HDM is not new, since it is known that HDM are susceptible to changes in humidity and especially temperature [21, 22] and thus desiccate from dehydration when the ambient relative humidity drops below 60% or temperature rises

above 51°C (i.e. their hygrothermal death points) [24]. De Boer for example, found evidence that HDM are present deeper inside mattresses, and therefore they tried to eliminate HDM by heating the mattress from the outside with electric blankets, which were placed on top of the mattress cover at times that they were not being slept on [22]. However, this approach is quite inconvenient for patients and requires a high voltage source. To avoid these drawbacks, in our study the mattresses with the inboard-positioned, circular knitted and flexible fabrics were operated with a low-voltage source. In addition, it allowed all participants to operate their sleeping place consumer-friendly via a build-in automatic timer option three times a week, e.g. in the afternoon, when they did not sleep. Approximately 2 hours after heating, people were able to use their beds as usual. From this perspective, mattresses with inboard heating fabrics are a practicable approach for the long-term use.

The *in vitro* hygrothermal measurements in a full-sized mattress showed, that a single heating fabric is able to manipulate the inner humidity levels and temperature of the foam block regardless of the ambient temperature and relative humidity levels. Even at outer space points, i.e. the upper or lower edge of the foam block facing the mattress cover, the hygrothermal death points were reached and exceeded. Since in beds the critical temperatures for HDM survival lie between 15-35°C, are thus independent of the climatic ambient bed room conditions and the HDM allergen content in mattresses is quite variable [25], it is important that the inboard heating reached the crucial hygrothermal values under various climatic conditions within only 2 hours. Even at the same geographic area, where houses have nearly the same indoor humidity level and temperature, there is still a marked difference in the mite allergen levels between houses [26]. However, although the heated mattress reached levels above the hygrothermal death point, it is noteworthy, that heating might still leave safe havens in foam blocks, for HDM can rapidly run away from heating [24]. We therefore ran another *in vitro* experiment to look, whether the fast heating period of the mattress (reaching 51°C within a few minutes) was efficient to kill living HDMs from a stock breeding, that were placed in sealed cups at different space points within a prototype mattress. In this setup, the swift heating dehydrated and killed all caged HDM rapidly regardless of their position inside of the mattress prototype. Since the cups were sealed by meshes, it is obvious that in this setup, the HDM were unable to escape into the foam or out of the mattress. In a home situation, where HDM are not caged in the mattress, one can assume that a slower heating phase might only banish HDM out of the foam. Once outside of the heating device they might survive within carpets, pillows or toys. As we observed in the field trial a basic but discrete Der p1 contamination in mattresses of the intervention group, this might be the result of droppings of HDM moving back and forth between the foam and toys, fabrics or pillows, etc.. For this reason, the heatable mattress cannot prevent the transfer of HDM from other areas of home

It is reasonable to conclude from the *in vitro* tests, that heating also killed HDM within the prototype due to a hygrothermal effect. Therefore we also assume that in the field trial the same effect kept HDM population and Der p1 allergen levels low in the full sized mattresses and thus prevented the build-up of the HDM allergen Der p1 within new mattresses of the intervention group. Over 2-years, Der p1 was basically not measurable by immunoassay in heated mattresses, whereas mattresses in the control group showed a significant increased accumulation of the mean HDM allergen. Unfortunately, for technical reasons HDM cannot be isolated from mattresses which are in use in order to count their number and measure the viability/lethality ratio. For this reason, we observed

the build-up of the allergen load in dust from new mattresses over 2 years instead. Dust samples were taken by hovering the mattresses in a meandering pattern and at constant pressure using a vacuum cleaner and a tightly woven PES/satin fabric with an exclusion limit of $>30\ \mu\text{m}$. Since HDM droppings in average have larger diameters (around $40\ \mu\text{m}$), we thus assume to have collected dust samples with comparable particle sizes. Since HDM are found in much larger concentrations in mattresses than on floors in almost all dwellings, no further ambient measurements were made [15].

Custovic et al. [16] were able to show that new mattresses can become a significant source of exposure to mite allergens after less than 4 months (0.1 to $4\ \mu\text{g Der p1/g dust}$). Our field trial results clearly confirm these findings: After 12 months we found up to $1\ \mu\text{g Der p1/g house dust}$ within dust samples of the control group. The pre-values determined for bed dust were $< 0.1\ \mu\text{g Der p1/g dust}$ and thus approximately 100 times lower than in dust samples after 12 months. After 18 months we found up to $6.8\ \mu\text{g Der p1/g house dust}$, which clearly ranged within the range of a high allergen load and therefore a higher sensitization risk (2 - $10\ \mu\text{g Der p1/g house dust}$) [27-31]. HDM allergen concentrations above $0.4\ \mu\text{g/g house dust}$ are known as significant allergen load [27]. In contrast to that, dust samples from the heatable mattresses of the intervention group showed a maximum of $0.035\ \mu\text{g Der p1/g dust}$ during the whole two year field trial. As there was no increase of the allergen load after 24 month, it can be assumed that the heating mattress can reduce the propagation of the HDM in bed. Although there is presently no consensus on the threshold levels for mite sensitization, a mite allergen level of $2\ \mu\text{g Der p1 per g dust}$ is considered a risk level for sensitization and symptoms of asthma [5]. This means that there are also no standard values for the acceptable allergen load in bed dust. But taken into account that according to Weber [31] an allergen load between 0.4 and $<2\ \mu\text{g/g dust}$ may elicit medical condition in people with a distinct, pre-existing sensitization, our results imply that the novel heatable mattresses might be an additional effective avoidance strategy for HDM sufferers.

The study was not designed to assess the clinical benefit of the intervention. Due to the small sample of the test subjects, no valid statement can be deduced with regard to the allergy symptomology. In fact, we thought to prove the reduced build-up of the allergen load in the mattress. However, since we enrolled not only test persons but patients with similar symptomology, we dare to interpret our inquiry as a trend. The field trial showed a positive correlation between the reduced HDM load, indicated by the reduction of the Der p1 allergen, and the subjective allergy status of the test persons with sustainable effect, as 80 % of the test persons stated a decrease of symptoms and medical condition, especially in the last two month of the study. Moreover, all subjects were satisfied with the technical features and the applicability of the heatable mattress. To give a better answer to whether preventing the development of HDM allergen symptoms is possible, clinical trials with a longer follow-up period are necessary.

To our knowledge, heatable mattresses have been investigated on the lab level so far, but did not appear in the market [22]. Therefore our study is the first to observe a HDM allergen prevention measure by a heating approach in a small field trial. Another measure to reduce the HDM allergen loads in beds are barrier fabrics, i.e. encasings. However, a couple of much larger studies have shown that in their long-term effectiveness, encasings turned out to be ineffective and their presence may thus lead to a false sense of security. Although these studies observed a reduction in exposure towards Der p1 (by other interventions like e.g. encasings), they did not find an effect on symptomology. For example, Rijssenbeck showed that albeit encasement of bedding was able to reduce the

Der p1 levels in carpet-bedrooms, in patients with moderate to severe asthma, airway hyperresponsiveness and clinical parameters were not affected by this allergen avoidance [20]. This finding was then reproduced by Terreehorst et al., who found, that despite a reduction of mite allergen levels, encasings did not lead to a significant improvement of clinical symptoms in patients with allergic rhinitis [32]. Finally, the ineffectiveness of encasings was confirmed in a Cochrane meta-analysis study by Gotzsche and Johansen [33]. It is reasonable to conclude that maybe a single intervention (encasing) is insufficient to affect allergic symptoms and a double intervention strategy (e.g. encasings plus heating) might achieve better clinical benefits. A synergistic usage of encasings and heatable mattresses might not only be beneficial for patients suffering from HDM induced asthma or allergy. Recent studies by Kim et al. or Fuiano showed evidence, that even atopic dermatitis (AD) in children is associated with HDM allergy [30, 34, 35]. These groups found that the severity of skin symptoms is associated with the indoor concentrations of HDM in children with AD and that Der p1 likely acts as a nonspecific irritant. Our group of test subjects included only one child with AD, therefore it is not possible yet to speculate that the heatable mattress might also have positive effects on the skin lesions of AD children.

5 Conclusion

This project has developed a mattress which, through the use of heatable knitted material, creates a permanently anti-HDM climate within new mattresses, and thus virtually prevents the build-up of HDM allergens. Heating three times a week for 2 hours by inboard heating fabrics can significantly keep the mean HDM allergen load low. The heatable mattresses proved their practicability and reduced the HDM load compared to non-heated mattresses in a 2 year long-term use. This intervention could be an effective measure for reducing HDM allergen levels below the accepted threshold level for the induction of allergic asthma and might support other textile-based HDM allergy measures, e.g. encasings.

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