WHITE PAPER

THERAPEUTIC BEDDING: A NIGHTTIME INTERVENTION FOR HOT FLASHES & NIGHT SWEATS ASSOCIATED WITH MENOPAUSE

Running title: *Bedding for Hot Flashes and Night Sweats*

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ABSTRACT

Objective:

The purpose of this study was to demonstrate the efficacy of state-of-the-art fabrics in overcoming the deficiencies which exist in today's cotton bedding, with regard to its ability to provide a drier, smoother, and more comfortable sleep surface and thereby minimize the impact of hot flashes and night sweats on the quality of life of menopausal women.

Design:

Twenty-eight women, experiencing hot flashes and night sweats as a result of menopause, were assigned to sleep on experimental bedding. Sleep quality was measured by using the *Pittsburgh Sleep Quality Index* at Baseline, and Weeks 2, 4, and 8. An assessment of the *quality of life* was also made in terms of the bedding's effects on the study participants' ability to keep cool, their amount of sweating, and the level of perceived comfort while using the experimental bedding.

Results:

Global PSQI scores, the measure of overall sleep quality, indicated that poor sleepers regained more normal sleep habits with the use of the experimental bedding.

Specific components of sleep quality, including subjective sleep quality, sleep latency, sleep duration, sleep disturbances, and daytime dysfunction were all significantly improved.

Improvements in amount of uninterrupted sleep, ability to keep cool, ability to keep dry, amount of sweating, comfort, and overall perception were demonstrated after only two weeks of using the experimental bedding.

Conclusions:

This study has shown that state-of-the-art synthetic fibers and fabrics can be used to dramatically enhance the therapeutic properties of bed linens, particularly as they relate to hot flashes and night sweats.

Keywords:

Bedding menopause hot flashes night sweats

INTRODUCTION

Hot flashes and night sweats are well known symptoms of menopause, presenting significant challenges to millions of women in achieving a good night's sleep.(1; 2) Hot flashes and night sweats are thought to result from a disorder of the body's thermoregulatory set point as fluctuations in estrogen levels confuse the hypothalamus.(3) Menopausal women experiencing hot flashes and night sweats tend to awaken throughout the night, which increases sleep latency and reduces sleep efficiency, leading to poor quality sleep and daytime dysfunction.(4; 5; 6; 3; 7) Nearly 75 percent of American women experience hot flashes during menopause. In a recent survey of 485 women, 42 percent of menopausal women reported sleep disturbances every night, and more than a quarter of them reported experiencing sleep disturbances several times each night.(8)

As a result of the risks noted in the Women's Health Initiative trials, published in July 2006, there has been a decline in the use of hormone therapy in treating menopause-related symptoms like nocturnal hot flashes and night sweats. Consequently, the development and use of alternative treatments, both medical and natural, have grown.(9; 10; 11) In attempting to better manage menopause-related symptoms, women continue to search for non-hormonal interventions which are safe and effective.

Extensive research has been done on the moisture management and comfort levels provided by modern synthetic textile materials as used in active outerwear and sportswear, i.e., "daytime" textiles. However surprisingly, almost no research exists related to the impact which "nighttime" textiles, such as bed linens, might play on the quality of sleep for women experiencing night sweats and hot flashes. Indeed, we spend 6-8 hours each night in intimate contact with a cotton fabric of ancient origins, without giving substantive consideration to its therapeutic properties. For women suffering from hot flashes and night sweats, an engineered textile for bedding should be a priority. The research described herein is intended to explore this proposition.

THE BEDDING FABRIC TECHNOLOGY

The pervasive use of 100% cotton and cotton fiber blends in today's bedding overlooks the aesthetic and performance advantages offered by modern synthetic fibers. Throughout the daytime, we wear sophisticated textile fabrics designed to enhance comfort and manage moisture. However, we sleep each night on bedding made of cotton fabrics, woven in fabric constructions which have remained essentially unchanged for decades, and which have no therapeutic properties.

The bedding evaluated in this research utilizes a new fabric technology developed by Precision Fabrics Group, and marketed as DermaTherapy®. The new bedding fabric (referred to herein as "experimental fabric") can generally be described as plain-weave constructions of 100% continuous-filament yarns. The preferred embodiment of the technology involves 100% nylon yarns in one direction of the fabric, with 100% polyester yarns in the other direction. Non-round fiber cross-sections are used to create micro-channels to facilitate moisture wicking and rapid drying. Such combinations of synthetic fibers and constructions are much different than cotton fabrics. Modern materials provide the opportunity to achieve specific material properties, such as moisture management and a smoother sleep surface, leading to greater comfort.

Rapid drying of liquid moisture and transport of moisture vapor along the fabric's planar surface are very important with regard to the skin's ability to remain dry and comfortable. Past studies have shown that moisture markedly increases the frictional forces of bed sheets, which can cause skin irritation and a reduction

in comfort.(12; 13; 14) Damp sheets increase the potential for friction and therefore the potential for sleep disturbances. Over-hydration accelerates the abrading action on the skin by increasing the frictional force and decreasing the shear resistance of the skin.(12) In order to provide a quick-drying sleep surface, the experimental fabric is woven of fibers that have a clover or cross-shaped cross section creating micro-channels which draw moisture away and dry the skin more quickly. A durable hydrophilic finish is also applied to the fabric which encourages liquid moisture to wick through the porous fiber network. The fabric's capillary network of microfibers quickly disperses liquid moisture so that it quickly evaporates from the fabric. In Figure 1, a photomicrograph of the experimental fabric shows the continuous-filament fibers with non-round cross sections in the horizontal direction.

Such a fabric construction significantly improves the rate of drying over that of cotton-blend fabrics. To evaluate the comparative drying rates of the experimental fabric with standard cotton-blend bedding fabric, test fabrics were completely wet out with water and allowed to air dry under standard laboratory conditions of 70 degrees F and 65% relative humidity. Fabric weights were taken at 5-minute intervals to calculate a percent-dryness over time. In Figure 2, the drying rate of the experimental fabric is compared with a standard 55% / 45% polyester/cotton bedding fabric. The experimental fabric is completely dry after 25 minutes, while the cotton fabric takes up to one and one-half hours to dry.

The experimental fabric was also designed to provide high moisture vapor transport. From a physiological view point, a bedding fabric is judged to provide greater comfort as permeability to sweat increases, creating a higher potential for moisture to evaporate away from a sleeper's body. Using the Hohenstein Skin Model (15), the moisture vapor transport of the experimental fabric was compared with standard cotton-blend bedding fabrics. Both the experimental fabric and the cotton-blend bedding had water vapor resistance of 2.03 – 2.08 m^2Pa/W, and were rated as having "very good" permeability to moisture vapor. At this level of water vapor resistance, the body is effectively able to evaporate moisture vapor away from a sleeper's skin to maximize comfort.

Cotton-blend fabrics used in conventional bed linens are woven of millions of discontinuous short-staple fibers. Studies have suggested that such fabrics may present a roughness that irritates sensitive skin and diminishes comfort. (16; 17) To counter this potential for abrasion, the experimental fabric is woven of continuous-filament yarns with no fiber ends protruding from the fabric's surface. This comparison can be seen in Figure 3. The sleep surface of the experimental fabric minimizes friction with the skin and enhances comfort. Plain-weave fabric constructions used in the experimental fabric have an average surface roughness of 1.46 microns, while 100% cotton and 55/45 polyester/cotton bedding fabrics have been measured at 2.30 and 3.65 microns, respectively, or 37% rougher than the experimental fabric.(18)

The smooth surface of experimental fabric also brings laws of thermodynamics into play in creating a cooling sensation for the user. When temperature differences exist between two solids, heat tends to move from a higher-temperature system to a lower-temperature system, until they both are at thermal equilibrium.(19) The smooth surfaces of the fabric and skin accentuate the heat transfer, given that the rate of thermal conductivity is directly related to the surface area of the contact points. That is, the very smooth fibers bring more of the surface area of the bed sheet in contact with skin which serves to draw heat from the skin into the fibers of the fabric, as heat flows from the higher temperature surface (the skin) to the lower temperature surface (the fabric). As such, the fabrics feel cooler to the skin – an important attribute in reducing the sensations of hot flashes.

OBJECTIVES OF THE RESEARCH

A review of scientific literature did not identify substantive research which addresses the impact of bedding or bedding fabrics as tools to manage perspiration, perceived skin temperature, or comfort levels related to hot flashes and night sweats. The authors believe that the research reported herein is the first to focus on this important area. A key objective of this study has been to demonstrate the efficacy of state-of-the-art synthetic fibers and fabrics in overcoming the deficiencies which exist in today's cotton bedding with regard to its ability to provide a drier, smoother, and more comfortable sleep surface and thereby minimize the impact of hot flashes and night sweats on the quality of life of menopausal women. To test the hypothesis, women experiencing hot flashes and night sweats were recruited to sleep on the experimental bedding over an eight-week period, during which the women made specific assessments of the quality of their sleep and the overall quality of their lives. The efficacy of the bedding was determined by tracking the changes in these assessments.

METHODS

To evaluate the ability of the experimental bedding to improve sleep quality of menopausal women, a short-term longitudinal study was carried out by Northeast Surgical Associates of Ohio, Ltd., led by the principal investigator, S. Kwon Lee M.D. The study period lasted from November 2006 through May 2007. Women, experiencing hot flashes and night sweats as a result of menopause, were assigned to sleep on bedding manufactured of the experimental fabric. The study protocol was reviewed and approved by the Western Institutional Review Board of Olympia, WA.

SUBJECTS

Participants in the study were recruited from two Obstetrician/Gynecology Clinics in the Northeast Ohio area. Inclusion criteria included the following parameters:

- Menopausal women
- Must be experiencing hot flashes and night sweats
- No menstrual periods for at least 6 months
- Non-smoker
- Ages between 45 and 65 years
- English speaking
- Access to a telephone
- Availability for the entire study period
- Agree to maintain usual diet
- Agree to maintain usual exercise habits

Participants were excluded from this study if they were currently enrolled in another investigational device or drug trial.

EXPERIMENTAL DESIGN

Twenty-eight postmenopausal women, experiencing hot flashes and night sweats, were assigned to sleep on bedding (in the form of a bed sheet set, including a pillow case, a flat top sheet and a fitted bottom sheet) fabricated from the experimental fabric. The study period consisted of an 8-week treatment phase. Subjects were instructed to place the provided bed sheets on the bed in which they sleep for the eight-week period. Subjects were instructed to dress in underwear for the night in order to leave as much of the skin in contact with

the bed sheets as possible. If the wearing of underwear were not possible, subjects were asked to wear bed clothes with short sleeves and short pants or a sleeveless short nightgown.

Two evaluation tools were used in the study.

The primary outcome was an investigator assessment of the *quality of sleep* from baseline to Week 8. Sleep quality was measured by using the *Pittsburgh Sleep Quality Index* (PSQI) at Baseline, and Weeks 2, 4, and 8. The PSQI is a self-rated questionnaire specifically designed to assess sleep quality. Through an assessment of qualitative and quantitative data, PSQI determines patterns of sleep dysfunction. The PSQI consists of seven components, including sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbance, use of sleep medications, and daytime dysfunction. The sum of scores from all seven components yields a global PSQI score. For the PSQI global and component scores, higher scores reflect poorer sleep quality, Individuals with PSQI global scores of 5 and higher indicate "poor" sleepers, while individuals with PSQI scores less than 5 are considered "good" sleepers.(20)

The secondary outcome was an assessment of the *quality of life* (QOL) in terms of the bedding's effects on the study participants' ability to keep cool, their amount of sweating, and the level of perceived comfort while using the experimental bedding. Satisfaction with the bedding was measured by a QOL Questionnaire administered at Baseline, Weeks 2, 4, and 8.

Participants were also instructed to report any adverse events which they experienced during the study.

DATA ANALYSIS

The study participants were asked a series of questions, comprising the PSQI and QOL surveys, about their experiences with the experimental bedding over an eight-week period. Data was collected at the beginning of the study (Week 0), and at the end of the second, fourth, and eight weeks. Data analysis looked for significant trends from the beginning of the study through Week 8. The objective of the data analysis was to determine whether the experimental bedding improved the quality of sleep and general quality of life for the menopausal women during the eight-week period. There was no control group or an attempt to randomly compare the experimental bedding with other types of bedding. The t-test, a statistical tool suitable for small samples, was used to compare the mean of one variable to the mean of another. In Table 1, the means and t-test results are reported for the PSQI global score and components during the study.

In addition to the PSQI instrument, data was also collected from additional questions more directly related to the effects of the experimental bedding on the participants' quality of life, such as their ability to keep cool, dry and comfortable while using the bedding. Again, the participants' were asked to compare their impressions of their previous bedding with the experimental bedding used during the study.

In Table 2, the means and t-test results are reported for the factors associated with the study participants' quality of life during the study. In completing the QOL surveys, participants were asked to rate these attributes as "Made Worse" = -1, "No Change" = 0, "Some Improvement" = 1, and "Significant Improvement" = 2. The numbers shown in Table 2 represent the average ratings of all study participants. Data is coded with asterisks (**) where Week 2 is significantly different ($p < 0.01$) from "initial" scores at Week 0.

RESULTS

At the beginning of the study, participants had a mean global PSQI score of almost 9 (Table 1), which characterizes the participants as "poor sleepers". After sleeping on the experimental bedding for 4 and 8 weeks, the global PSQI scores were reduced by 32% and 52%, respectively. As shown in Figure 4, the average global scores were 6.00 and 4.24, which means that the study participants had moved into the category of "good sleepers" by Week 8.

As shown in Figure 5, use of the experimental bedding also reduced scores in five of the seven PSQI components: *subjective sleep quality*, *sleep latency*, *sleep duration*, *sleep disturbances*, and *daytime dysfunction*. (Again, *reductions* in PSQI components scores indicate *improvements* in the participants' responses in these areas.) By Weeks 4 and 8, use of the experimental bedding reduced the *subjective sleep quality* scores by 36% and 60% respectively, while scores for *sleep latency*, the time necessary to fall asleep, were reduced by 33% and 53%, respectively. PSQI scores for *sleep duration*, the number of hours asleep, dropped 38% and 49%, respectively. Scores for *sleep disturbances* record problems such as waking in the middle of the night to use the bathroom, disturbances in sleep due to noises or snoring, or feeling hot, cold, sweating, or pain. Use of the experimental bedding significantly reduced scores for *sleep disturbances* by 22% and 31%, respectively. *Daytime dysfunction* scores record trouble staying awake during daytime hours or problems maintaining enthusiasm. At the end of Weeks 4 and 8, use of the experimental bedding reduced *daytime dysfunction* scores by 30% and 45%, respectively.

No statistically significant differences were found for two PSQI components: *habitual sleep efficiency* and *use of sleep medication*. As such, changes in these measures cannot be attributed to the experimental bedding.

In addition to the PSQI instrument, data was also collected from additional questions more directly related to the effects of the experimental bedding on the participants' quality of life (QOL), such as their ability to keep cool, dry and comfortable while using the bedding. Again, the participants' were asked to compare their initial impressions of their previous bedding to the experimental bedding used during the study.

As seen in Figure 6, improvements in participant's QOL perceptions of the experimental bedding were present almost immediately. Statistically significant improvements were measured between Week 0 and Week 2 for all parameters except *skin irritation* and *ability to keep you warm*. All parameters, *amount of uninterrupted sleep*, *skin dryness*, *ability to keep cool*, *ability to keep you dry*, *amount of sweating*, *comfort*, and *overall perception*, saw improvements from Week 0 through Week 2, with these improvements persisting from Week 0 through Week 8 ($p < 0.05$).

During the study, no serious adverse effects were noted.

DISCUSSION

QUALITY OF SLEEP

Results from this study suggest that the experimental bedding was effective in improving the quality of sleep for menopausal women, as evidenced by improvements in *subjective sleep quality*, where scores improved 60% from a *Neutral* initial rating to an average rating of *Very Good* at Week 8 ($p<0.01$). Scores for *time to get to sleep* improved 53%, from a *Neutral* initial rating to a *Very Good* rating by Week 8 ($p<0.05$). *Time asleep* improved 49% from a *Fairly Good* initial rating to a *Very Good* rating by Week 8 ($p<0.05$). *Frequency of sleep interrupted by disturbances* also improved, with an initial rating of *Fairly Bad* climbing 31% to a *Fairly Good* rating by Week 8 ($p<0.01$). The *level of dysfunction on the day following sleep* improved 45%, from a *Fairly Good* initial rating to a *Very Good* rating by Week 8 ($p<0.05$). As characterized by the PSQI global score, the *overall quality of sleep* improved 52%, with participants exhibiting *Poor Sleep Quality* initially and then improving to *Good Quality Sleep* by Week 8 ($p<0.01$).

QUALITY OF LIFE

The experimental bedding was also effective in relieving menopausal symptoms closely associated with hot flashes and night sweats and thereby improving their quality of life. Participants reported statistically significant improvements in the *amount of uninterrupted sleep*, *ability to keep cool*, *ability to keep you dry*, *amount of sweating*, *comfort*, and *overall perception*. These improvements quickly manifested themselves with the participants, in that significant changes occurred by Week 2 of the study. These improvements persisted from Week 0 through Week 8 ($p<0.05$).

INTERPRETATION OF THE DATA

The experimental bedding was effective in managing moisture and providing a more comfortable sleep surface for the study participants. The strongest changes occurred in physiological factors associated with participants' ability to stay cool and dry during the night. The amount of sweating perceived by the participants was markedly diminished. As such, participants fell asleep more quickly and slept more comfortably, with fewer disturbances throughout the night. This study did not address improvements in cognitive skills, however participants did appear to be more rested in the daytime following sleeping on the experimental bedding as evidenced by the PSQI daytime dysfunction scores.

The small sample size precludes the use of more sophisticated statistical analyses. As such, we were not able to predict and compare multivariable relationships and their relative contribution to overall satisfaction. A certain amount of bias is always inherent in such a small sample size. The assumption here is that the sample was not biased. This study also made no attempt to evaluate multiple fabrics to determine the impact of differing material properties on particular aspects of sleep quality. The general objective to determine if moisture management and enhanced comfort of the experimental bedding fabric could positively impact sleep quality was achieved.

IMPLICATIONS OF THE STUDY

Cotton is ubiquitous in our lives. It is commonly used in the bed linens that we all come in contact with for extended periods of time each day. However, very little research has been done on conventional bedding

fabrics and their potential to improve our quality of life. Purchase decisions for bedding are generally made based on *thread count* (number of yarns per square inch) and *price point*. Neither of these factors have an impact on the physiological quality of life. With the trend towards higher thread counts for bedding, associated with higher quality, cotton bedding fabrics have become even more restricted in providing a comfortable sleep surface. Extremely tight constructions significantly reduce air and moisture vapor transport and, therefore, the rate of drying. Dense fabric constructions also increase fabric stiffness, making them more uncomfortable, particularly when wet. Cotton fabrics also have an inherent layer of discontinuous fibers on the fabric surface. This fiber nap creates a thermally insulating microclimate next to the skin which has little or no impact on the skin's cooling sensation. Synthetic fabrics woven of continuous-filament yarns have no such napped surface and are able to bring more surface area into direct skin contact. As such, the experimental fabric causes a cooling sensation, which was confirmed in this study.

This study has shown that state-of-the-art synthetic fibers and fabrics can be used to dramatically enhance the therapeutic properties of bed linens that we all have come to depend on each day, particularly as it relates to hot flashes and night sweats associated with menopause.

CONCLUSIONS

- Global PSQI scores, the measure of overall sleep quality, indicated that poor sleepers could regain more normal sleep habits with the use of the experimental bedding made of state-of-the-art synthetic fibers and fabrics.
- Specific components of sleep quality, including subjective sleep quality, sleep latency, sleep duration, sleep disturbances, and daytime dysfunction, were also significantly improved.
- Enhancements in the overall quality of life in terms of the amount of uninterrupted sleep, ability to keep cool, ability to keep dry, amount of sweating, and comfort were seen after only two weeks of using the experimental bedding.

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TABLES

Table 1

The Pittsburgh Sleep Quality Index Scores

Means and t-test Results

Components	Survey Category Change (from Week 0 to Week 8)	Week 0	Week 2	Week 4	Week 8	p value (Wk 0-8)
Subjective Sleep Quality	From *Neutral* to *Very Good*	1.48	1.23	0.95	0.59	$p < 0.01$
Sleep Latency	From *Neutral* to *Very Good*	1.50	1.31	1.00	0.71	$p < 0.05$
Sleep Duration	From *Fairly Good* to *Very Good*	1.15	1.23	0.71	0.59	$p < 0.05$
Habitual Sleep Efficiency	No change	0.73	0.88	0.43	0.24	$p < 0.05$
Sleep Disturbances	From *Fairly Bad* to *Fairly Good*	1.96	1.73	1.52	1.35	$p < 0.01$
Use of Sleep Medication	No change	0.92	0.65	0.86	0.71	$p < 0.05$
Daytime Dysfunction	From *Fairly Good* to *Very Good*	1.08	1.08	0.76	0.59	$p < 0.05$
PSQI Score (overall)	From *Poor Sleep Quality* to *Good Sleep Quality*	8.77	8.25	6.00	4.24	$p < 0.01$

Table 2

Quality of Life Scores

Means and t-test Results

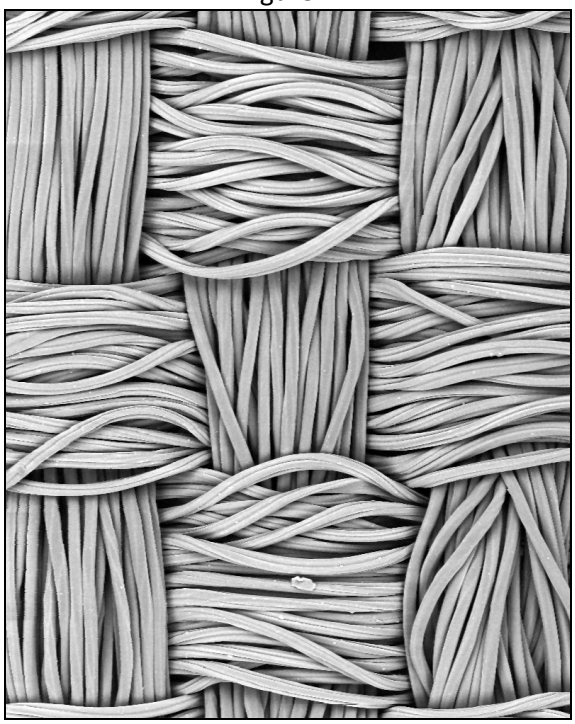
QOL Factors	Survey Category Change (from Week 0 to Week 8)	Week 0	Week 2	Week 4	Week 8	p value (wk 0-8)
Uninterrupted sleep	From *No change* to *Some improvement*	0.22	0.85**	0.71	1.12	$p < 0.01$
Ability to keep cool	From *No change* to *Some improvement*	0.30	1.27**	1.14	1.24	$p < 0.01$
Skin dryness		0.33	0.85*	0.95	0.82	
Skin irritation		0.37	0.25	0.50	0.75	
Ability to keep dry	From *No change* to *Some improvement*	0.15	1.12**	1.00	0.94	$p < 0.01$
Amt of sweating	From *No change* to *Some improvement*	0.11	0.92**	0.95	1.18	$p < 0.01$
Ability to keep warm		0.37	0.54	0.67	0.82	

Comfort	From *No change* to *Some improvement*	*0.50*	1.38**	1.38	1.18	$p < 0.05$
Overall assessment	From *No change* to *Some improvement*	*0.26*	1.29**	1.35	1.29	$p < 0.01$

** signifies $p<0.01$.

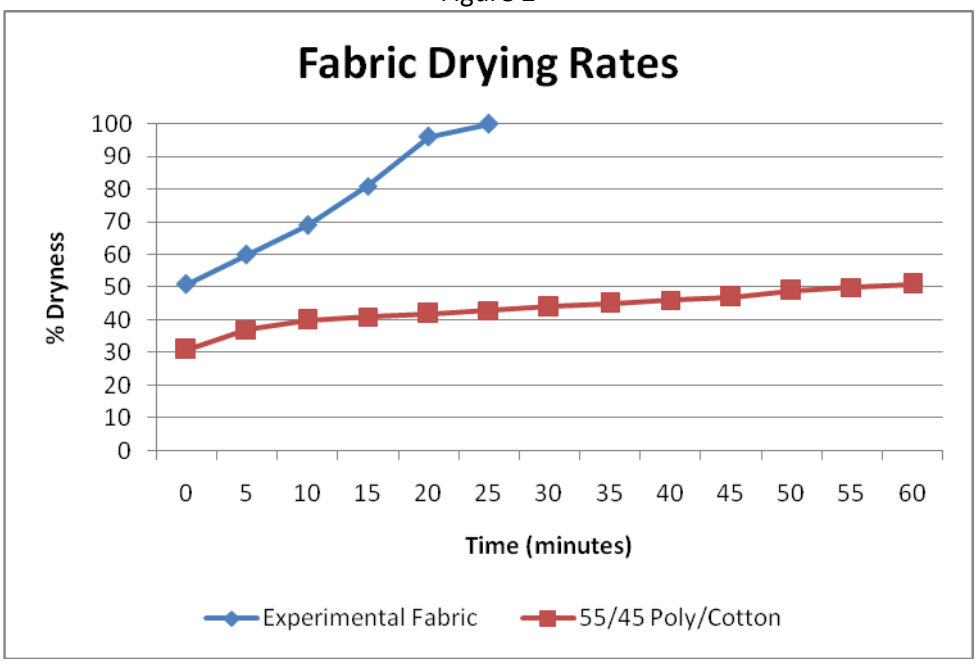
FIGURES

Figure 1



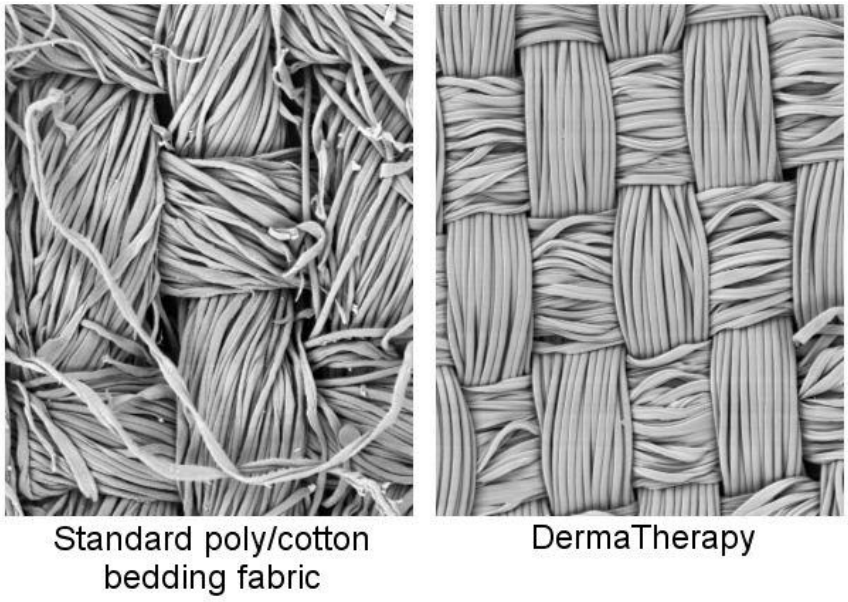
Photomicrograph of experimental fabric showing continuous-filament fibers with non-round cross sections in the horizontal direction

Figure 2



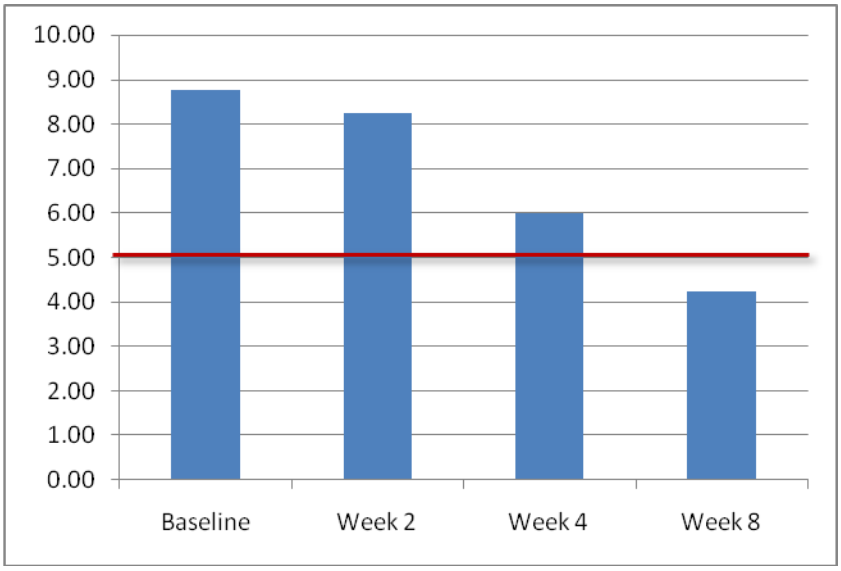
Comparison of drying rates for experimental fabric and cotton-blend fabric

Figure 3



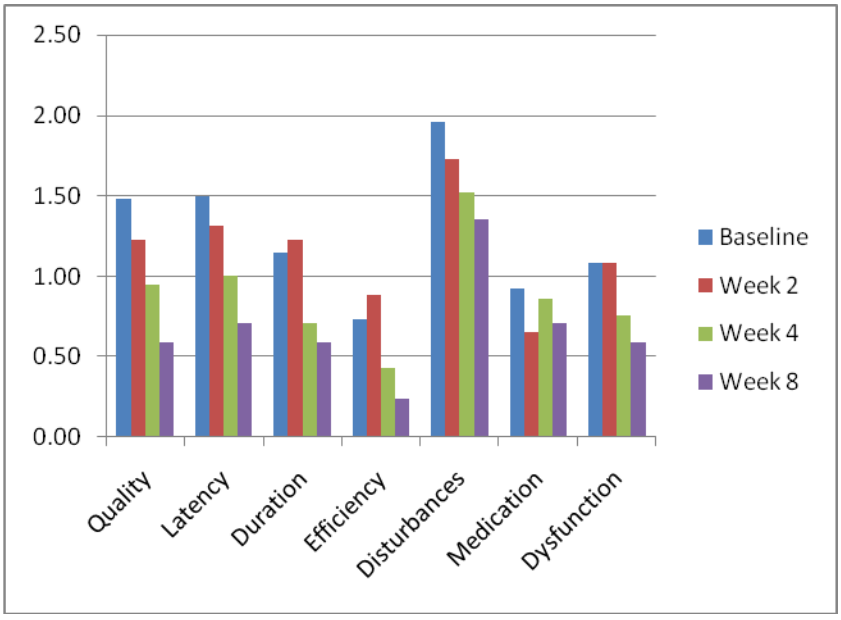
Comparison of cotton-blend and experimental fabric surfaces

Figure 4



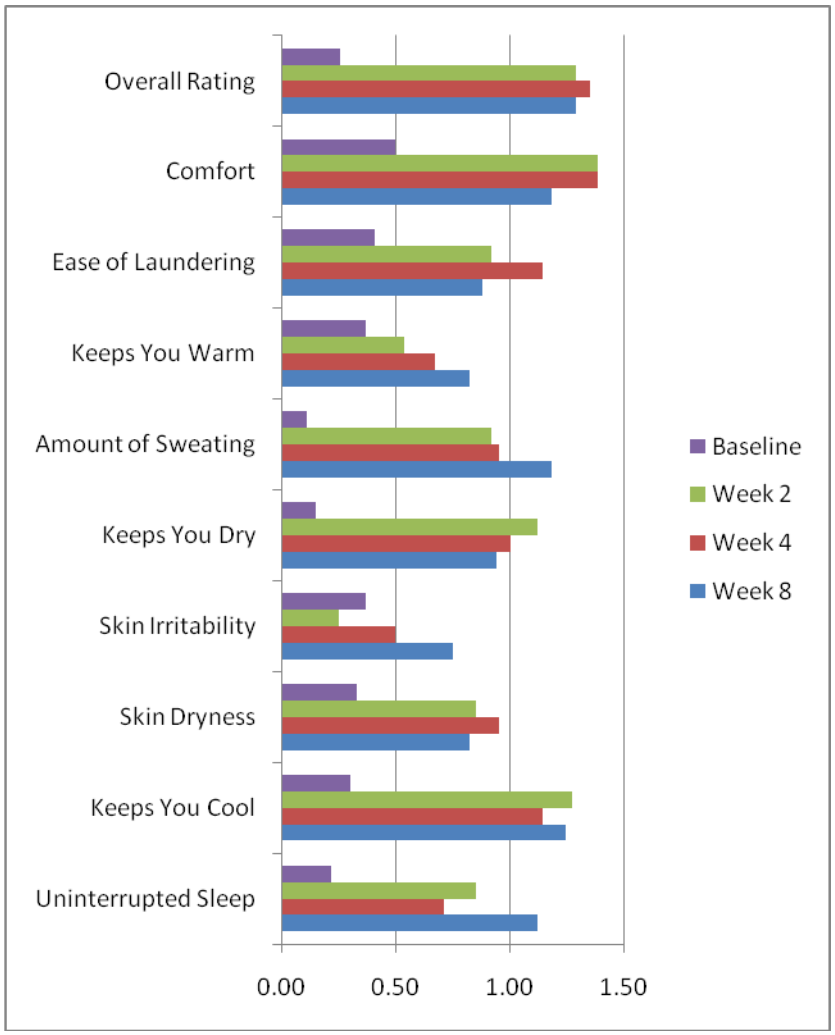
Global PSQI scores over study period

Figure 5



PSQI sleep-quality components scores over the study period

Figure 6



Participants' "quality of life" scores over the study period