

<b>Case Study</b>		
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<b>CS-UD-LL</b>	CASE STUDY: THE ETHNOCARE UNDERLAY INTERFACE Target: TT and TF Applications	<b>1</b>

## **ABSTRACT**

Humidity, sweat, hyperhidrosis, and heat buildup inside prosthetic liners remain pervasive challenges for lower-limb prosthetic users. Excess moisture compromises comfort, skin integrity, suspension stability, and the overall daily prosthetic experience. This case study evaluates the Ethnocare Underlay, a specialized prosthetic textile interface designed to be worn directly on the residual limb underneath the prosthetic liner.

Feedback was collected from 15 lower-limb amputees (including both transtibial and transfemoral users) utilizing the Underlay under real-world conditions. Participants evaluated the interface during daily wear and high-exertion activities (e.g., long-distance walking, cycling, hockey, wheelchair rugby). Depending on their individual prosthetic setup, users tested either the open version, closed version, or both.

### **Key Findings**

- 51% Reduction in perceived humidity inside the liner.
- 38% Reduction in perceived heat buildup.
- 17% Reduction in objective relative humidity during clinical testing (see Annex 1), with moisture levels accumulating at a significantly slower rate during both resting and active phases.

Overall, the Underlay demonstrated clinically meaningful improvements at the limb-liner interface, helping users feel drier, cooler, and more comfortable.

## **INTRODUCTION**

Managing the microclimate inside a prosthetic liner is an ongoing challenge. Because traditional liners create an airtight, non-breathable seal around the residual limb, they inherently trap metabolic heat and moisture. This closed environment frequently results in skin maceration, blistering, compromised suspension control, and the inconvenient need for repetitive liner removal throughout the day to dry the limb.

Traditional management strategies, such as standard cotton or synthetic sweat socks, present significant drawbacks: they add bulk, cause tightly fitted sockets to bunch, lose shape when wet, and often exacerbate heat retention.

The Ethnocare Underlay was engineered to bridge this gap. Worn directly against the skin beneath the liner, it manages moisture and thermal dissipation while preserving the necessary skin-to-liner friction

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required for optimal suspension. This study pairs subjective patient-reported outcomes with objective clinical data to evaluate the Underlay's performance.

## METHOD

### Participant Profile

- **Cohort Size:** N = 15 lower-limb amputees (Transtibial and Transfemoral configurations).
- **Activity Levels:** Ranging from K2 (moderate community ambulation) to K4 (high-impact sports/demanding work environments).
- **Monitored Activities:** Daily wear, treadmill evaluation, long-distance cycling, hockey, wheelchair rugby, and physical labor.

### Data Collection & Metrics

1. **Perceived Humidity:** Rated on a 1–10 visual analog scale (1 = completely dry, 10 = saturated).
2. **Perceived Temperature:** Rated on a 1–10 visual analog scale (1 = fresh/cool, 10 = intensely hot).
3. **General Comfort:** Rated on a 1–10 scale (1 = uncomfortable, 10 = highly comfortable).
4. **Comparative Analysis:** Qualitative feedback contrasting the Underlay against traditional sweat socks.
5. **Clinical Evaluation:** Dynamic relative humidity (RH%) testing performed on a subgroup of 6 patients using embedded micro-sensors (methodology detailed in Annex 1).

## RESULTS

### 1. Reduced Moisture Inside the Liner

Most users reported that the Underlay helped reduce the feeling of moisture inside the liner, describing their residual limb as feeling drier with less sweat pooling throughout the day.

- Without Underlay: Rated at  $8.42 \pm 1.39$  (SD).
- With Underlay: Rated at  $4.08 \pm 2.24$  (SD).
- Net Improvement: A 51% reduction in perceived humidity inside the liner.

### Verbatim User Feedback:

- "Much less moisture in my prosthesis."

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- "There is substantially less moisture inside my liner."
- "Yes, much drier wearing it."
- "My legs are less sweaty."

These comments suggest that users experienced a noticeable improvement in dryness and moisture control while wearing the Underlay

## 2. Better Heat Management

Many users reported that their residual limb felt cooler while wearing the Underlay, especially during warm weather, longer wear times, and physical activity.

- **Without Underlay:** Rated at  $8.33 \pm 1.31$  (SD).
- **With Underlay:** Rated at  $5.17 \pm 2.02$  (SD).
- **Net Improvement:** A 38% reduction in perceived heat buildup inside the liner.

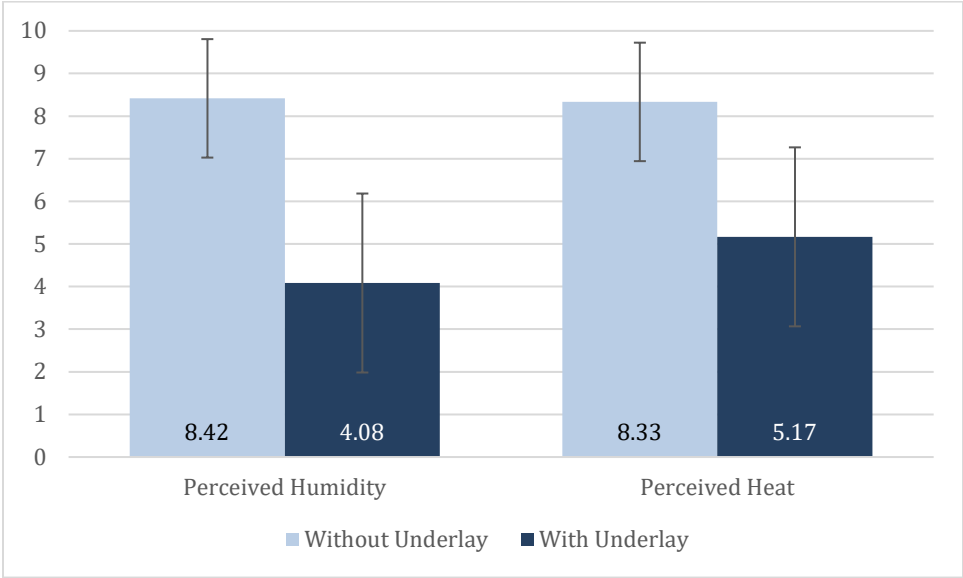
Participants described the experience as:

- Cooler
- More comfortable during activity
- Less affected by heat buildup inside the liner
- Easier to tolerate during longer wear periods

*(Note: One user reported that during a 100-mile bike ride, the temperature inside the liner felt significantly reduced while using the Underlay.)*

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Results from section 1 and 2 are shown below:



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### 3. Improved Comfort During Daily Wear

The Underlay received an average comfort score of 8/10, indicating that users generally found the product comfortable to wear. This result suggests that the Underlay can be integrated under the prosthetic liner without significantly compromising comfort during daily use.

Several users indicated that the Underlay enhanced the daily prosthetic experience by limiting the need to remove the liner and socket to dry the limb or liner, an interruption that is especially inconvenient for amputees. This was particularly important during long days of wear, public settings, or situations where removing the prosthesis was inconvenient.

#### Verbatim User Feedback:

- One transfemoral user reported that the Underlay reduced the number of times they needed to remove their full prosthetic setup to dry sweat from the liner.

This highlights that improved humidity management contributes not only to physical comfort, but also to convenience and confidence during daily activities.

### 4. Comparison With Traditional Sweat Socks

Not many users had even tried sweat socks in the past. For those who did, feedback suggested that the Underlay was often preferred because it felt lighter, stayed in place better, and reduced moisture more effectively.

Users described traditional sweat socks as:

- Hot
- Thick
- Loose-fitting
- More likely to bunch up or move
- Less effective at preventing moisture buildup

In comparison users described the Underlay as:

- Light and comfortable
- lower-profile option for managing sweat inside the liner
- better personal fit due to the extended size range.

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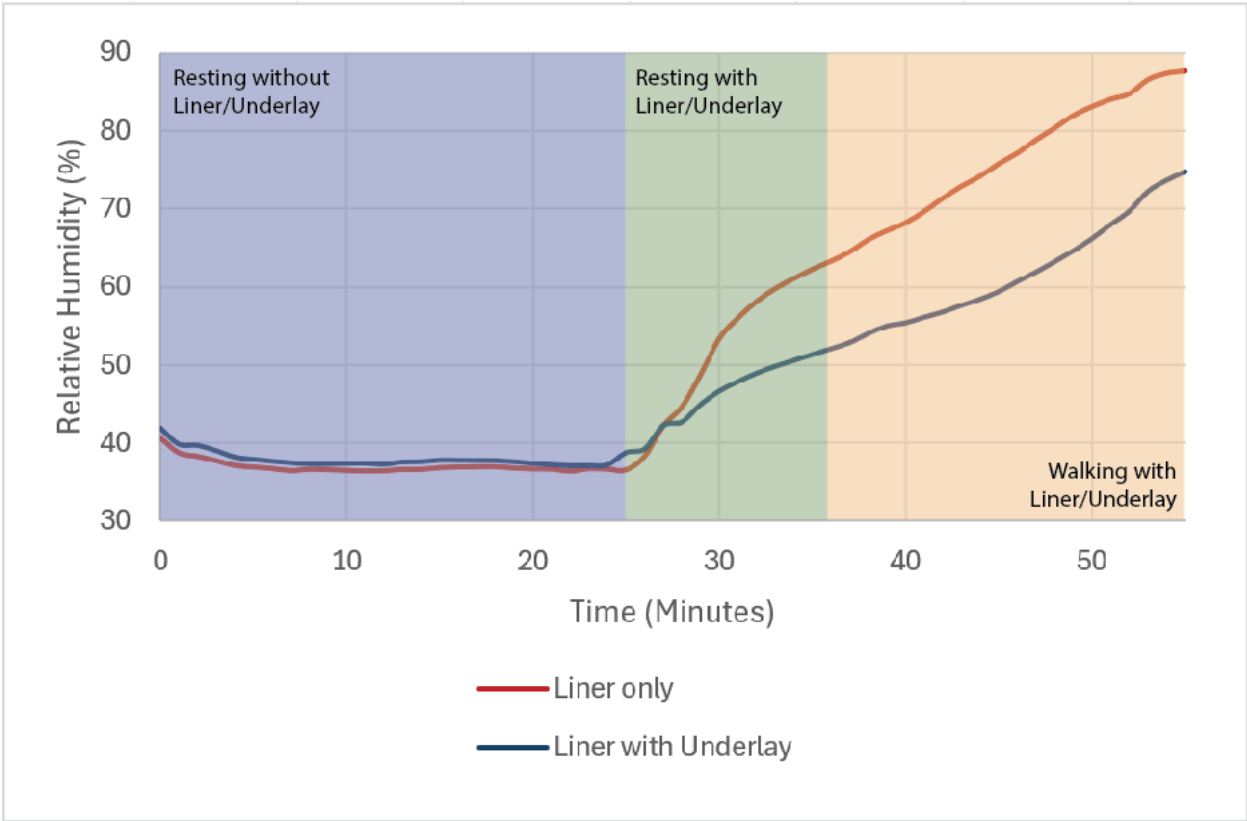
### Clinical Evaluation Results

During the Underlay testing phase, clinical trials were conducted to measure the actual impact of the Underlay on humidity levels inside the prosthetic liner. (See annex 1 for methodology)

The evaluation compared relative humidity between one limb wearing only a liner and another limb wearing a liner with the Underlay. The results showed that relative humidity increased more slowly inside the liner when the Underlay was used, both during the resting phase and the walking phase.

- Net Objective Improvement:** An overall 17% reduction in relative humidity inside the liner was observed when using the Underlay

These results correlate with user feedback collected during testing, where participants reported feeling less moisture, less sweat, and improved comfort while wearing the Underlay. The clinical results suggest that the Underlay has an immediate effect on humidity management, even before physical activity begins.



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## DISCUSSION

The results of this case study suggest that the Underlay may help address several common challenges associated with wearing a prosthetic liner, particularly humidity, sweat accumulation, and heat buildup. Some physicians even recommend using it alongside other perspiration-management tools to help reduce the effects of hyperhidrosis.

User feedback showed consistent improvements in perceived dryness and comfort. **The reported 51% reduction in perceived humidity** indicates that users felt a meaningful difference in moisture levels inside their liner. This is important because perceived moisture can directly affect user comfort, confidence, and willingness to wear the prosthesis for extended periods.

**The reported 38% reduction in perceived temperature** also suggests that the Underlay may help improve thermal comfort. Heat buildup inside the liner can be a major concern during warm weather or physical activity, and several participants specifically noted that the Underlay helped their limb feel cooler.

Physiological research indicates that in warm conditions or during physical activity, skin wettedness is a significant contributor to thermal discomfort and warm perception (Filingeri & Havenith, 2015; Filingeri et al., 2014). Relative humidity influences skin wettedness by modulating evaporative cooling capacity. **By reducing relative humidity by 17%** (as demonstrated in our Clinical Evaluation Results), the Underlay may **help mitigate this primary contributor to thermal discomfort.**

This **objective 17%** reduction in relative humidity inside the liner further supports these findings, showing that humidity increased more slowly during both resting and walking phases. This physical shift directly influences the user's neurophysiological perception of heat. Because the human body interprets thermal comfort largely through skin sweat saturation, flattening the humidity accumulation curve effectively lowers the subjective "hotness" of the socket environment. This mechanism explains why the Underlay provides immediate comfort benefits right from application, rather than only during periods of peak physical activity.

The Underlay also performed well during movement. Users tested the product in demanding situations such as cycling, hockey, long-distance walking, wheelchair rugby, and work activities. Feedback indicated that the product generally stayed in place and continued to manage sweat during activity.

Comparison with traditional sweat socks further highlighted the potential advantages of the Underlay. While sweat socks may absorb moisture, users often described them as hot, thick, loose-fitting, or prone to movement. In contrast, the Underlay was often perceived as lighter, more stable, and more effective at reducing moisture buildup.

Results varied depending on user anatomy, prosthetic setup, activity level, and fit. However, the overall pattern of feedback suggests that the Underlay may be especially beneficial for users who experience sweat accumulation, heat, or moisture-related discomfort during daily wear or physical activity.

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## **CONCLUSION**

The Ethnocare Underlay demonstrates strong potential for managing humidity, sweat, and heat inside lower-limb prosthetic liners. Across a diverse cohort of users, amputation levels, prosthetic configurations, and high-exertion activity states, participant feedback consistently validated its performance in reducing moisture, improving dryness, and mitigating heat buildup.

User-reported outcomes revealed an average 51% reduction in perceived humidity alongside a 38% reduction in perceived temperature inside the liner. These subjective evaluations are strongly supported by clinical testing, which demonstrated a 17% absolute reduction in relative humidity when the Underlay was implemented compared to a liner alone. By reducing relative humidity, the Underlay directly modulates evaporative cooling capacity and effectively limits skin wettedness—the primary physiological predictor of warm discomfort and thermal distress during physical activity.

While individual results naturally vary based on user anatomy, socket configuration, and fit, the Underlay appears to be particularly beneficial for lower-limb prosthetic users who experience chronic sweat accumulation, heat buildup, or moisture-driven socket instability.

In conclusion, by fundamentally improving the limb-liner microclimate and addressing the neurophysiological triggers of heat perception, the Underlay helps prosthetic users feel drier, cooler, and more comfortable during everyday life and active use.

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## **Annex 1**

### **Clinical Evaluation Methods**

To test the efficacy of the Underlay, miniature humidity sensors are affixed directly to the skin using medical tape. Two conditions are compared:

1. **Liner only** – baseline humidity levels under a conventional liner.
2. **Liner + Underlay** – humidity levels when the additional layer is present.

To prevent immediate sensor saturation from direct sweat droplets, the sensor window is oriented away from the skin surface. This setup enables measurement of the relative humidity in the microenvironment formed between the skin, liner, and Underlay.

The experimental design includes three distinct phases:

- **Initial rest period:** Establishes baseline humidity levels without the liner or underlay.
- **Rest with Underlay and liner:** Evaluates the effect of the Underlay on humidity buildup under static conditions.
- **Walking period with Underlay and liner:** Tests the Underlay's performance under increased activity, where perspiration and heat generation are elevated.

By comparing humidity measurements across these conditions, the study determines whether the Underlay effectively reduces and moderates humidity inside the liner environment.