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CS-OV-TT	**CASE STUDY OF THE OVERLAY FOR TRANSTIBIAL AMPUTEE**	***3***

Abstract

The pursuit of optimal comfort and fit in prosthetic devices remains a central challenge in prosthetic care. This study evaluates "The Overlay," a novel prosthetic accessory designed with an integrated pneumatic system integrated to a fabric sleeve to allow fine volumetric adjustments within the prosthetic socket. We conducted a comparative analysis of The Overlay versus traditional prosthetic ply socks, focusing on key factors such as comfort, ease of use, socket fit, cushioning effect, and pain levels. Twenty-seven participants, all transtibial amputees, completed a crossover trial using both The Overlay and ply socks over multiple weeks, followed by a self-reported survey on their experiences. After excluding data from three participants due to study-related challenges, results from 23 completed surveys demonstrated that The Overlay significantly outperformed ply socks across all parameters, offering higher comfort (8.61 ± 0.52 vs. 6.43 ± 1.06), better fit in the socket (8.29 ± 0.62 vs. 6.71 ± 1.31), superior cushioning (8.93 ± 0.53 vs. 6.14 ± 1.41), reduced pain (2.65 ± 0.82 vs. 4.26 ± 1.12), and increased ease of use (8.74 ± 0.57 vs. 5.78 ± 1.29). The Overlay not only provided more consistent performance across users but also offered significant enhancements in user experience, suggesting its potential to improve quality of life for prosthetic users. These findings support The Overlay as a preferable alternative to ply socks, with implications for improved prosthetic comfort and usability. Future research may expand on these results by examining long-term effects and refining design for broader adaptability in prosthetic care.

INTRODUCTION

In the dynamic field of prosthetics, achieving optimal comfort and fit for users remains a critical challenge. The Overlay, an innovative prosthetic device, addresses this issue with a creative solution. Designed to be worn over a prosthetic liner, The Overlay features a pneumatic system integrated into a fabric sleeve, allowing for precise volumetric adjustments within the prosthetic socket. This case study compares The Overlay to traditional prosthetic ply socks, evaluating key factors such as comfort, ease of use, socket fit, cushioning effect, and pain levels. Through this comparative analysis, we aim to demonstrate how The Overlay can significantly improve the overall prosthetic experience for users, enhancing their comfort, fit, and quality of life.

METHOD

To evaluate the effectiveness of the Overlay compared to traditional prosthetic ply socks, we conducted a comprehensive study involving a diverse group of prosthetic users. The methodology for this case study is outlined as follows:

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Participants: Individuals with transtibial limb loss were included in the study if their amputation occurred at least 18 months prior and they regularly used a definitive prosthesis with prosthetic ply socks. Overall, a total of 27 participants participated in the study. A total of 4 participants data was discarded for the following reasons: one person dropped out of the study, two participants had cognitive issues and were not able to understand the questions and a fourth participant had compatibility issues with his socket and the Overlay.

Study Procedure: The study employed a crossover design, where each participant used both The Overlay and traditional prosthetic ply socks over an extended period of time ranging from four weeks to a few months. The order of usage was randomized to mitigate bias. Participants were instructed to use each device in their daily activities for a minimum of two weeks each.

Data Collection: Data was collected using a self-reported questionnaire. Participants were asked to respond to a survey that included questions and rating scales.

The key parameters evaluated were:

- **Comfort**: Participants rated their level of comfort on a scale from 1 (very uncomfortable) to 10 (very comfortable).
- **Ease of Use**: Participants rated the simplicity and convenience of using both The Overlay and ply socks on a scale from 1 (very difficult) to 10 (very easy).
- **Fit in the Socket**: Participants assessed the fit of the device in the socket, considering stability and alignment, rated on a scale from 1 (poor fit) to 10 (perfect fit).
- **Cushioning Effect**: Participants rated the perceived cushioning effect and shock absorption during movement on a scale from 1 (no cushioning) to 10 (excellent cushioning).
- **Pain Levels**: Participants recorded their pain levels while using each device, rating them on a scale from 1 (no pain) to 10 (extreme pain).

Data Analysis: Quantitative data from the rating scales were analyzed using statistical methods to compare the performance of The Overlay and traditional prosthetic ply socks.

Through this methodology, we aimed to provide a comprehensive comparison of The Overlay and traditional prosthetic ply socks, highlighting the potential benefits and areas for improvement in prosthetic device design.

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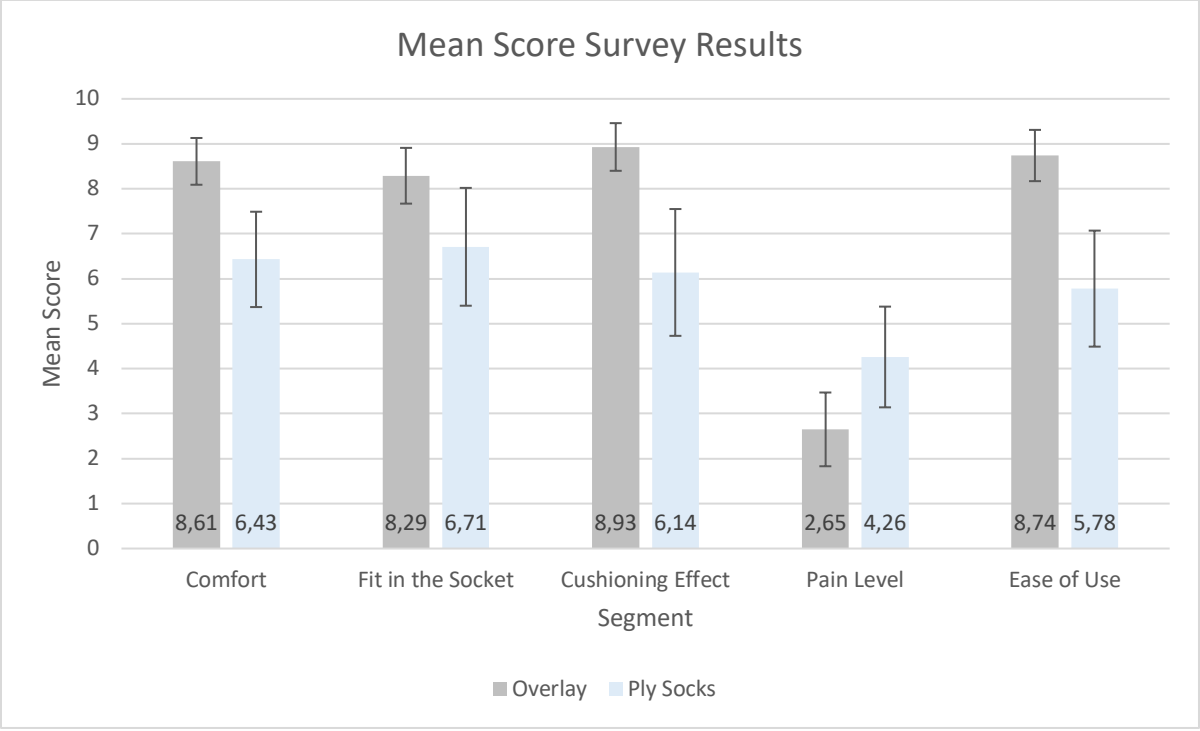
RESULTS

Data from 27 participants, consisting of 21 males and 6 females with amputation causes ranging from trauma to medical complications, were collected and analyzed. While most participants fully completed the survey, responses to questions on socket fit and cushioning effect were provided by 14 of the 27 participants, with all other questions receiving responses from the entire group. For data integrity, four surveys were excluded: two due to cognitive difficulties that affected the participant's ability to understand questions and formulate answers, a third due to compatibility issues with the participant's suspension method, and a fourth related to challenges in using the device during the adaptation phase that led to having him drop out of the study.

This refinement resulted in a final sample of 23 completed surveys for comprehensive analysis of results.

A score was attributed to each possible scale rating by multiplying the number of responses choosing that rating by the corresponding level of the scale. For example, if 3 participants chose a scale rating of 4 on the Comfort Level scale, a score of 12 would be attributed. The scores for each scale were then summed to create a total score for the related question. This total score was divided by the number of responses received for that question to create a weighted mean score. Here are the results for the questions related to Comfort, Ease of Use, Fit in the Socket, Cushioning Effect, Pain Levels for both prosthetic ply socks and the Overlay:



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Comfort Segment

- **Overlay**: 8.61 ± 0.52
- **Ply Socks**: 6.43 ± 1.06

The Overlay scores significantly higher in comfort compared to ply socks. The smaller margin of error (0.52) for the Overlay suggests more consistent comfort ratings among users, whereas the larger margin of error (1.06) for ply socks indicates more variability in user experience.

Fit in the Socket Segment

- **Overlay**: 8.29 ± 0.62
- **Ply Socks**: 6.71 ± 1.31

The Overlay also outperforms ply socks in terms of fit within the socket. The margins of error indicate that while there is variability in both ratings, the Overlay has a more consistent fit experience among users compared to ply socks.

Cushioning Effect

- **Overlay**: 8.93 ± 0.53
- **Ply Socks**: 6.14 ± 1.41

This segment shows the most significant difference between the Overlay and ply socks. The Overlay provides a much better cushioning effect, as indicated by the higher mean score and the smaller margin of error (0.53) compared to ply socks (1.41). This suggests that users consistently perceive the Overlay as providing superior cushioning.

Pain Level Segment

- **Overlay**: 2.65 ± 0.82
- **Ply Socks**: 4.26 ± 1.12

In terms of pain levels, the Overlay significantly outperforms ply socks, with a lower mean score indicating less pain experienced by users. The margins of error (0.82 for Overlay and 1.12 for ply socks) show that the pain reduction is not only significant but also relatively consistent among users of the Overlay.

Ease of Use Segment

- **Overlay**: 8.74 ± 0.57
- **Ply Socks**: 5.78 ± 1.29

The Overlay is also rated higher in ease of use compared to ply socks. The smaller margin of error for the Overlay (0.57) indicates that users find it consistently easier to use, while the larger margin of error for ply socks (1.29) suggests more variability in user experience.

DISCUSSION

The findings demonstrate a strong preference for the Overlay over ply socks across key prosthetic use domains, including comfort, fit, cushioning, pain reduction, and ease of use. Additionally, the Overlay provides a more consistent experience, evidenced by lower variability in scores across categories, which enhances user satisfaction and functional outcomes.

Future studies could further investigate the specific use of suction systems and assess long-term outcomes to substantiate the Overlay's advantages.

In examining the comparative data on the comfort, fit, cushioning, pain, and ease of use between the Overlay and ply socks, the results reveal notable advantages in user experience associated with the Overlay across all categories.

Comfort

The comfort scores reveal that participants consistently rated the Overlay as more comfortable (8.61 ± 0.52) than the ply socks (6.43 ± 1.06). The smaller margin of error for the Overlay implies greater consistency in comfort perceptions, which may suggest that its design more effectively meets the range of needs for users, potentially due to materials or adaptability of the product. The larger variability in comfort ratings for ply socks might indicate that the fit and feel of ply socks are more susceptible to individual differences, such as residual limb shape or skin sensitivity.

Fit in the Socket

Regarding the fit within the socket, the Overlay again shows higher mean scores (8.29 ± 0.62) compared to ply socks (6.71 ± 1.31). The consistency in fit scores for the Overlay is indicated by the narrower margin of error, pointing to a more universally stable fit across participants. This stability may be attributable to the Overlay's ability to conform better to the socket, which could be a crucial factor for user satisfaction and overall comfort in prosthetic wear.

Cushioning Effect

The Overlay demonstrates a significant advantage in cushioning effect, with a mean score of 8.93 ± 0.53 compared to 6.14 ± 1.41 for ply socks. The high score for the Overlay indicates a strong, consistent perception of enhanced cushioning, which likely contributes to user comfort and pain reduction. The high variability for ply socks suggests that cushioning may depend heavily on factors like sock thickness, layering, or material, potentially causing inconsistent experiences among users. This segment emphasizes the Overlay's potential as a preferred option for individuals requiring enhanced shock absorption.

Pain Levels

The Overlay achieves a notably lower mean pain score (2.65 ± 0.82) compared to ply socks (4.26 ± 1.12), indicating that users experience significantly less pain with the Overlay. The lower variability in pain ratings for the Overlay further emphasizes its consistency in reducing pain across users. This may be tied to the Overlay's superior cushioning and fit, as poorly fitting or less cushioned solutions can exacerbate pressure points and lead to discomfort or pain. This result strongly supports the Overlay's advantage in improving daily comfort by reducing pain associated with prosthetic wear.

Ease of Use

The Overlay is also rated higher for ease of use (8.74 ± 0.57) compared to ply socks (5.78 ± 1.29), suggesting it is generally easier for users to handle and apply. The smaller margin of error for the Overlay underscores a uniform user experience in this regard, while the larger margin for ply socks points to more varied experiences. This could reflect potential challenges with ply sock layering or adjusting for a proper fit, which can be more complex and less intuitive than using the Overlay.

Summary and Implications

These findings illustrate a consistent pattern favoring the Overlay over ply socks in all evaluated dimensions, with participants perceiving it as more comfortable, better fitting, more cushioned, less painful, and easier to use. Given these results, the Overlay could represent a more effective prosthetic solution, particularly for users who prioritize comfort and convenience. Future research could expand upon these findings by examining long-term user experiences or evaluating other user demographics, as well as potential design refinements to address any remaining areas of variability, such as those observed with ply socks.

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CONCLUSION

The comparative analysis of the Overlay and traditional prosthetic ply socks reveals a clear preference for the Overlay across all evaluated segments. The Overlay demonstrated superior performance in comfort, fit in the socket, cushioning effect, pain level, and ease of use. The higher mean scores and smaller margins of error for the Overlay indicate not only better overall performance but also a more consistent and reliable user experience.

In the Comfort segment, the Overlay's significantly higher score (8.61 ± 0.52) compared to ply socks (6.43 ± 1.06) highlights its ability to provide a more comfortable prosthetic experience. Similarly, the Fit in the Socket scores show that the Overlay offers a better and more consistent fit (8.29 ± 0.62) than ply socks (6.71 ± 1.31).

The most notable difference was observed in the Cushioning Effect segment, where the Overlay scored substantially higher (8.93 ± 0.53) compared to ply socks (6.14 ± 1.41). This suggests that the Overlay provides superior shock absorption and comfort during movement.

The Pain Level segment further emphasizes the benefits of the Overlay, with users reporting significantly lower pain levels (2.65 ± 0.82) compared to ply socks (4.26 ± 1.12). This indicates that the Overlay not only enhances comfort but also reduces the discomfort associated with prosthetic use.

Finally, the Ease-of-Use scores reflect the Overlay's user-friendly design, scoring higher (8.74 ± 0.57) compared to ply socks (5.78 ± 1.29). This ease of use is crucial for users who rely on their prosthetics for daily activities.

In conclusion, the Overlay represents a significant improvement in prosthetic volume management, offering enhanced comfort, fit, cushioning, pain reduction, and ease of use compared to traditional prosthetic ply socks. These findings suggest that adopting the Overlay could substantially improve the quality of life for prosthetic users, making it a preferred choice in the field of prosthetics.

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