

Comparative Analysis of Strap-Induced Pressure at the Toe Hold Area: Assessing the Impact of Rolled Inner Seam Flip Flops in Healthy Volunteers

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Abstract

Footwear-induced dorsal foot ulcers, particularly those caused by straps, can have devastating consequences, especially in individuals with diabetes and leprosy. However, there is limited literature specifically investigating strap-induced pressure on the dorsal foot. This study aimed to compare the pressure at the toe hold area between Rolled Inner Seam (RIS) and traditional strap designs in flip flops. Healthy female volunteers (n=5, for a total of 10 measures with 5 Right and 5 Left) participated in a 5-step walk trial wearing both types of flip flops. Pressure at the toe hold was measured using portable pressure sensors. Paired t-tests revealed a significant difference in pressure between RIS and traditional strap flip flops (p=0.0014). The RIS design exerted significantly lower pressure (-40.90) compared to the traditional strap. These findings have far-reaching implications, particularly in developing nations where flip flops are commonly worn and healthcare access is limited. RIS flip flops may offer a practical solution to reduce strap-induced pressure, potentially preventing dorsal foot ulcers. Further research is warranted to validate and extend these findings, particularly in populations with chronic conditions such as diabetes.

Keywords: Foot ulcers; Dorsal foot; Flip-flops; Strap design; Pressure distribution

Introduction

Footwear plays a critical role in the prevention and management of foot ulcers, particularly dorsal foot ulcers caused by straps, which can lead to discomfort, pain, and potentially serious complications [1]. Dorsal foot ulcers can occur as a result of excessive pressure and friction from straps, leading to tissue damage and breakdown. Individuals with diabetes and leprosy are particularly vulnerable to these ulcers due to factors such as sensory loss, peripheral neuropathy, and altered foot biomechanics [2]. While there is a considerable body of literature on pressure measurements for the plantar foot, there is a paucity of research specifically investigating strap-induced pressure on the dorsal aspect of the foot [3]. Most studies in the field of foot pressure analysis have focused on plantar pressure distribution, neglecting the potential impact of straps on dorsal foot regions. This research gap highlights the need to investigate the pressure characteristics specifically associated with strap design and their potential role in dorsal foot ulcer development.

Flip flops, a type of open-toe footwear characterized by a flat sole and a Y-shaped strap, are among the most commonly used footwear in the world [1,4]. Their popularity can be attributed to factors such as simplicity, convenience, and breathability, making them a popular choice in warm climates and for casual wear. However, the design of flip flops, particularly the straps, can contribute to increased pressure and friction on the dorsal foot, potentially leading to the development of ulcers [1]. Strap-related foot ulcers have been reported in individuals with diabetes and leprosy [1,5]. In a study by Ramaswamy et al. (2017) [1], it was found that 15.7% of individuals with diabetes-related foot ulcers had ulcers specifically caused by the straps of their footwear. Similarly, Kesav et al. (2013) [5] reported cases of non-trophic cutaneous ulcers in leprosy patients resulting from friction and pressure exerted by straps. These findings highlight the importance of examining the impact of strap design on the development of dorsal foot ulcers. Rolling the inner strap of the flip-flop is a simple solution that can reduce the pressure and friction on the top of the foot. The rolled inner strap

increases the surface area in contact with the skin, thus distributing the pressure evenly across the skin leading to less friction and reducing the risk of skin breakdown. We conducted a study on this design innovation, a rolled inner seam strap, compared to a traditional straight edge strap in healthy volunteers. By evaluating the pressure distribution and assessing the impact of different strap designs, this study seeks to identify footwear features that can reduce pressure and friction, thereby minimizing the risk of dorsal foot ulcers.

Methods

The study recruited 5 female volunteers for a total of 10 feet (5 left and 5 right) per arm of the study. All participants were healthy individuals without any known foot conditions or injuries. Two types of flip flops were compared in this study: Rolled Inner Seam flip flops (RIS) and traditional well-known brand flip flops (Control) Figure 1.

Both types of flip flops were made of standard materials, Rubber/PVC blends commonly used in flip flop manufacturing. Each participant performed a standardized 5-step walk trial wearing both types of flip flops. The order of flip flop conditions (RIS and Control) was counterbalanced across participants to minimize any potential order effects. For each trial, the participant walked the predefined distance on a hardwood floor. Pressure at the toe hold was measured using a Pressure Sensitive Switch (Cosikir3yb9dwz5q1976) equipped with portable, accurate, ultra-thin pressure sensors Figure 2.

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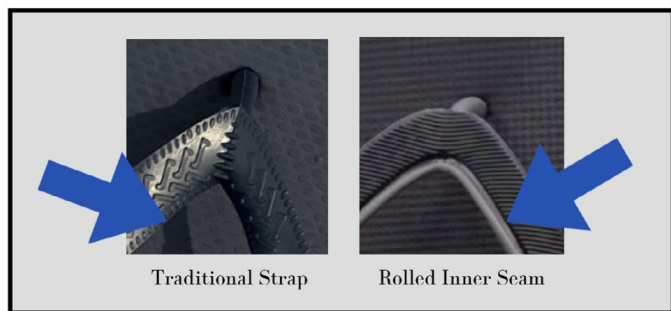


Figure 1: Comparison of traditional straight edge strap and Rolled inner seam strap.



Figure 2: Pressure sensor with switch, Comparison of traditional straight edge strap and Rolled inner seam strap.

The pressure sensors were positioned at the toe hold area of the flip flops and securely attached to ensure reliable data collection. During the walking trial, the pressure data from the sensors was continuously recorded. The maximum pressure recorded by the device during the walking trial was used as the primary outcome measure for comparing the RIS and Control flip flops. Each foot served as its own control, with pressure measurements obtained separately for each flip flop condition. Paired t-tests were performed to compare the maximum pressure at the toe hold between the RIS and Control flip flops. The mean difference, 95% confidence intervals, t-values, degrees of freedom, and standard error of the difference were calculated. The statistical significance level was set at $p < 0.05$.

Results

A paired t-test was performed to compare the pressure recorded at the toe hold between rolled inner seam flip flops (RIS) and traditional well-known brand flip flops (Control) in a sample of 10 feet (5 right and 5 left) Table 1.

The analysis using a paired t-test revealed a statistically significant difference in the pressure at the toe hold between RIS and Control flip flops. The two-tailed p-value was 0.0014, indicating strong evidence of a highly significant difference. The mean difference between RIS and Control was calculated to be -40.90 (all measures reported as grams), indicating that the pressure exerted at the toe hold was significantly lower in the RIS flip flops compared to the Control flip flops. The 95% confidence interval for this difference ranged from -61.22 to -20.58.

Table 1: Paired t-test.

Measure	Foot	RIS	Control
1	Left	32	102
2	Left	29	122
3	Left	37	42
4	Left	27	41
5	Left	12	71
6	Right	45	93
7	Right	46	63
8	Right	27	44
9	Right	16	50
10	Right	22	74

Intermediate values used in the calculations included a t-value of 4.5523 and a degrees of freedom (df) value of 9. The standard error of the difference was found to be 8.984. The mean pressure with RIS was 29.30, with a Standard Deviation (SD) of 11.22 and a Standard Error of the Mean (SEM) of 3.55. The RIS group and the control group each consisted of 10 observations in 5 right and 5 left feet ($N = 10$). The Control group had a mean pressure of 70.20, with an SD of 27.94 and an SEM of 8.83. These results demonstrate a significant difference in pressure at the toe hold between the RIS and Control flip flops. RIS flip flops result in significantly lower pressure compared to the traditional well-known brand flip flops. The results suggest the RIS design may offer benefits in terms of pressure redistribution and potentially reducing the risk of dorsal foot ulcers, particularly at the toe hold area.

Discussion

While numerous studies have investigated pressure measurements on the plantar foot, there is limited literature specifically addressing strap-induced pressure on the dorsal foot. This study examining the pressure at the toe hold area induced by straps in flip flops with Rolled Inner Seam (RIS) compared to a more traditional strap design fills an important gap in the existing knowledge by exploring the impact of strap design on pressure distribution at the dorsal foot/toe hold area. The results revealed a significant difference in pressure at the toe hold between the RIS and Control flip flops with a two-tailed p-value of 0.0014. The mean difference of -40.90 (95% CI: -61.22 to -20.58) suggests that the RIS exerted significantly lower pressure compared to the traditional strap design. This finding indicates that the rolled inner seam design effectively reduces pressure on the dorsal foot at the toe hold area. The study utilized a paired design, which allowed for direct comparisons between the RIS and Control conditions within the same 10 feet. This design choice strengthens the internal validity of the study, as individual foot characteristics and other potential confounding factors are accounted for by pairing the measurements. The implications of these findings are particularly relevant for individuals with neuropathic conditions such as diabetes and leprosy, as foot ulcers in these populations often result from increased pressure and shear forces, including those caused by footwear. In developing nations where flip flops are the preferred footwear and healthcare access is limited, the occurrence of foot ulcers can have devastating consequences. The reduction of blisters and abrasions resulting from strap-induced pressure can significantly mitigate the risk of foot ulcers and subsequent complications, especially in vulnerable populations. The use of RIS flip flops may offer a practical solution to address the issue of strap-induced pressure and its associated risks. By implementing the rolled inner seam design (patent pending), footwear manufacturers can potentially improve foot comfort and reduce the incidence of strap-related foot ulcers. This is particularly important in resource-limited settings where access to comprehensive foot care is often lacking. However, it is important to note the limitations of this

study. The relatively small sample size of healthy volunteers may limit the generalizability of the findings to larger populations. Additionally, the study focused solely on measuring pressure at the toe hold area, and other factors such as foot structure and gait patterns were not considered. Further research with larger sample sizes and diverse populations especially in populations with chronic conditions such as diabetes is needed to confirm and extend these findings. In conclusion, this study provides valuable insights into the impact of strap design on pressure distribution at the toe hold area of flip flops. The significant difference in pressure observed between the Rolled Inner Seam (RIS) and traditional strap designs highlights the potential benefits of RIS flip flops in reducing strap-induced pressure on the dorsal foot. This has significant implications, particularly in populations where flip flops are commonly worn and foot ulcers pose a major concern. Further research is warranted to explore the long-term effects of RIS flip flops and their efficacy in preventing foot ulcers and related complications.

Conclusion

This study provides valuable insights into the impact of strap design on pressure distribution at the toehold area of flip flops. The significant

difference in pressure observed between the Rolled Inner Seam (RIS) and traditional strap designs highlights the potential benefits of RIS flip-flops in reducing strap-induced pressure on the dorsal foot. This has significant implications, particularly in populations where flip-flops are primary footwear and foot ulcers pose a major concern. Further research is warranted to explore the long-term effects of RIS flip-flops and their efficacy in preventing foot ulcers and related complications.

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