Analysis of Plantar Contours and Derivation of Design Baseline for the Development of Functional Insoles to Prevent Diabetic Foot Ulcers

YoungYoon Bae[1], Hye Suk Kim[2], Hee Eun Choi[1,2,†]

[1]Department of Fashion and Textiles, Seoul National University, South Korea
[2]Research Institute of Human Ecology, Seoul National University, South Korea

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Introduction

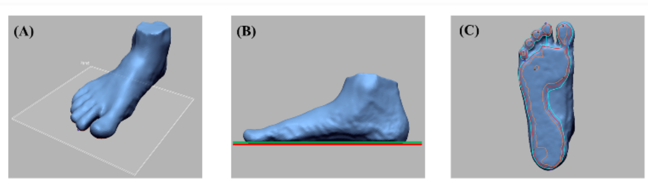
Prevention of diabetic foot ulcers requires active patient management, one strategy of which is the wearing of functional footwear. In particular, forefoot offloading and the reduction of peak plantar pressure are crucial (Bae et al., 2023). Non-removable offloading devices (e.g., Total Contact Cast) have demonstrated superior therapeutic benefits, but their daily use can be cumbersome, necessitating the need for easy-to-don devices for patients with mild symptoms or those at risk of ulceration. Consequently, the development of footwear that conforms to the wearer's foot anatomy and enhances user compliance is imperative.

The metatarsal head area (MHA) is where ulceration often begins, and structures that alleviate pressure in this area help prevent ulcers. While there have been proposals to insert a soft material pad into the MHA to offload the forefoot and reduce peak plantar pressure, there is no consensus on the geometrical contour basis line of the MHA pad that reflects the wearer's foot shape.

This study aims to present design standards for the MHA of functional insoles to prevent diabetic foot ulcers. To do this, we identify the features of the MHA's geometrical contour basis line through two-dimensional and three-dimensional analysis of the foot shape and utilize this as primary data for the detailed design of functional insoles.

Methods

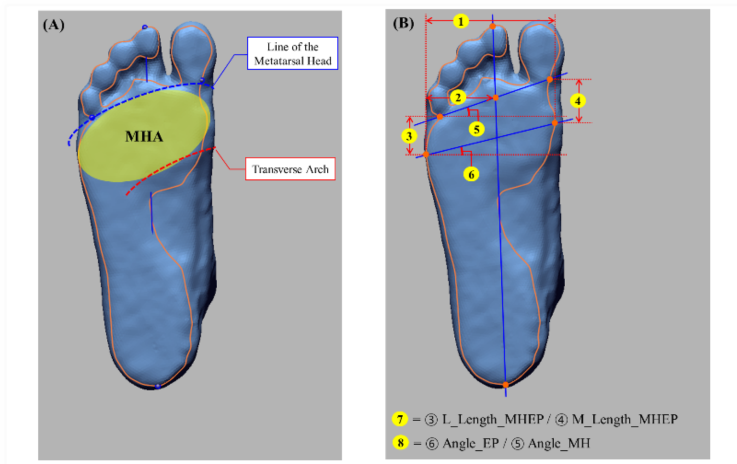
Acquisition and Analysis of 3D Foot Scan Data To establish the basis for the contour of the insole and the insert pad, we analyzed the 3D foot scan shape of adult men who have completed growth. We sorted through the 3D foot scan shapes of 2020 men aged between 20 and 69 from the 8th Size Korea (KATS, 2021), and selected foot shapes of 79 individuals whose foot straight length fell within the average



<Figure 1> Cross-Section Extraction for the Analysis of Plantar and MHA Contours
A: Creating the Extreme Bottom Plane of a 3D Foot scan data
B: A Plane (indicated in green) Formed by a 3mm Offset in the Z-Direction from the Bottom Plane (red)
C: Plantar Cross-Sections on Each 1mm (indicated in orange), 2mm (red), and 3mm (sky blue) Offset Planes

range (256.4±0.3mm). The collected shapes were processed using the 3D reverse engineering software Geomagic Design X (3D Systems, Rock Hill, SC, USA) for efficient shape analysis. We excluded low-quality data (n=4) deemed unsuitable for analysis, and used a total of 75 shape data for the final analysis.

Determining Key Dimensions from Horizontal Cross-Sections for Analysis of Plantar and MHA Contours We obtained horizontal cross-sections from an offset horizontal plane at 1mm intervals to understand the contours of the plantar and MHA in contact with the insole. Among them, we extracted the horizontal cross-section at the 3mm offset point where both the plantar contour and the MHA contour could be observed (Figure 1). Subsequently, we selected key dimension items that can identify the features of the MHA contour from the plantar horizontal cross-section (Figure 2), and measured each dimension using AutoCAD 2024 (Autodesk, San Rafael, CA, USA).



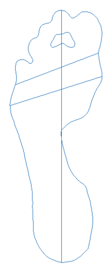
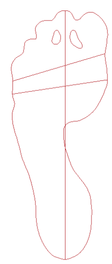
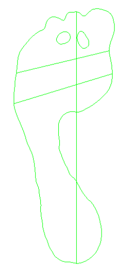
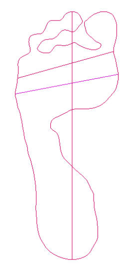
<Figure 2> Selection of Key Dimension for MHA Contour Analysis
A: Location of MHA (Metatarsal Head Area) in the Plantar Region. The forefoot area bounded by the line of the metatarsal head and the transverse arch (marked with yellow shading)
B: Key Dimension details. 1) plantar width (abbreviation: PW), 2) lateral width at the 2nd metatarsal head (L_Width_2ndMH), 3) lateral length between the metatarsal head and extrusion points (L_Length_MHEP), 4) medial length between the metatarsal head and extrusion points (M_Length_MHEP), 5) angle between the bilateral metatarsal head (Angle_MH), 6) angle between the bilateral extrusion points (Angle_EP), 7) the length ratio of L_Length_MHEP to M_Length_MHEP (L_ratio), 8) the angle ratio of A_EP to A_MH (A_ratio)

Statistical Analysis for Classification of Plantar and MHA Contours We conducted a statistical analysis using the key dimension items as variables to identify the features of each type of MHA contour. First, we confirmed the appropriate number of clusters through hierarchical cluster analysis, and identified the features of each cluster through K-means cluster analysis. We used 73 subject data for the analysis. Two subject data outliers in two index items were excluded from the final analysis. The statistical analysis was performed using SPSS Statistics 26 (IBM Corp., Armonk, NY, USA).

Results & Discussion

Characteristics of Four Types of Plantar and MHA Contour Hierarchical Cluster Analysis was conducted on six measured variables and two index variables, subsequently determining the number of clusters as four. Based on the results from the K-Means Cluster Analysis, the distribution and morphological characteristics of the four types of MHA plantar contours were identified (Table 1). Each type of MHA contour was differentiated according to tendencies in L_Length_MHEP, M_Length_MHEP, Angle_MH, Angle_EP, A_ratio and L_ratio. Type 1 (23.3%) exhibited a very narrow foot width overall, with the MHA shape tending to be short in length and steep in slope, hence labeled as the 'Narrow slope' type. Type 2 (26.0%) had a slightly narrower foot width than average, with the MHA shape tending to gradually widen from lateral to medial, hence named the 'crescendo' type. Type 3 (17.8%) had a slightly broader foot width than average, with the MHA shape tending to gradually narrow from lateral to medial, hence named the 'decrescendo' type. Type 4 (32.9%), which showed the highest distribution, had a wider foot width than average, particularly a wider lateral width around the second toe compared to the other types. As for the morphological characteristics of MHA, Angle_MH and Angle_EP were relatively parallel, with the slope tending to be gentler than average, hence named the 'Spacious Stable' type.

<Table 1> Results of Cluster Analysis on MHA Contour

MHA type (total n=73)	**Narrow Slope** (Type 1, n=17)	**Crescendo** (Type 2, n=19)	**Decrescendo** (Type 3, n=13)	**Spacious Stable** (Type 4, n=24)
Representative Contour Image				
Variable (Z-score)	**Final Cluster Centroid**			
PW	-1.00	-0.30	0.29	0.79
L_Width_2ndMH	-0.81	-0.45	0.65	0.57
Angle_MH	1.04	0.12	-0.82	-0.38
Angle_EP	1.12	-0.79	0.54	-0.46
L_Length_MHEP	-0.07	-0.93	1.08	0.20
M_Length_MHEP	-0.43	0.32	-0.67	0.42
A_ratio	0.28	-0.98	1.55	-0.26
L_ratio	0.17	-0.99	1.48	-0.14

Design Criteria of MHA Pad Outline for Developing Functional Insoles to Prevent Diabetic Foot Ulcers The features of the plantar contour and MHA differ even for the same foot length. Therefore, when designing the MHA insert pad to be applied to insoles, it is crucial to identify the wearer's MHA contour type and take into account the characteristics of each type. If insert pads fabricated according to these design criteria are assembled into insoles, we anticipate a decrease in the discomfort caused by the pad when the wearer is walking or standing, potentially improving user compliance. Based on the results of this study, we expect that subsequent research comparing and analyzing the MHA contour characteristics of healthy individuals and those experiencing diabetic foot issues will further refine the design requirements.

Conclusion

In this study, we identified various MHA contour types and determined the characteristics specific to each type. This led us to derive design criteria for the creation of functional footwear aimed at preventing diabetic foot ulcers. These findings can provide significant foundational information for the design of MHA insert pads, contributing to the overall offloading of the foot.

Acknowledgements

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References

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