

Development of a Novel Ankle-Foot Orthotic Using a User Centered Approach for Improved Satisfaction

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Abstract : Studies have shown that individuals who use Ankle-Foot-Orthoses (AFOs) have a high level of dissatisfaction regarding their current AFOs. Studies point to the focus on technical design with little attention given to the user perspective as a source of AFO designs that leave users dissatisfied. To design a new AFO that satisfies users and thereby improves their quality of life, the reasons for their dissatisfaction and their wants and needs for an improved AFO design must be identified. There has been little research into the user perspective on AFO use and desired improvements, so the relationship between AFO design and satisfaction in daily use must be assessed to develop appropriate metrics and constraints prior to designing a novel AFO. To assess the user perspective on AFO design, structured interviews were conducted with 7 individuals (average age of 64.29 ± 8.81 years) who use AFOs. All interviews were transcribed and coded to identify common themes using Grounded Theory Method in NVivo 12. Qualitative analysis of these results identified sources of user dissatisfaction such as heaviness, bulk, and uncomfortable material and overall needs and wants for an AFO. Beyond the user perspective, certain objective factors must be considered in the construction of metrics and constraints to ensure that the AFO fulfills its medical purpose. These more objective metrics are rooted in a common medical device market and technical standards. Given the large body of research concerning these standards, these objective metrics and constraints were derived through a literature review. Through these two methods, a comprehensive list of metrics and constraints accounting for both the user perspective on AFO design and the AFO's medical purpose was compiled. These metrics and constraints will establish the framework for designing a new AFO that carries out its medical purpose while also improving the user experience. The metrics can be categorized into several overarching areas for AFO improvement. Categories of user perspective related metrics include comfort, discreteness, aesthetics, ease of use, and compatibility with clothing. Categories of medical purpose related metrics include biomechanical functionality, durability, and affordability. These metrics were used to guide an iterative prototyping process. Six concepts were ideated and compared using system-level analysis. From these six concepts, two concepts - the piano wire model and the segmented model - were selected to move forward into prototyping. Evaluation of non-functional prototypes of the piano wire and segmented models determined that the piano wire model better fulfilled the metrics by offering increased stability, longer durability, fewer points for failure, and a strong enough core component to allow a sock to cover over the AFO while maintaining the overall structure. As such, the piano wire AFO has moved forward into the functional prototyping phase, and healthy subject testing is being designed and recruited to conduct design validation and verification.

Keywords : ankle-foot orthotic, assistive technology, human centered design, medical devices

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