THESIS ABSTRACT (PhD)

DEVELOPMENT, ANALYSIS AND CLINICAL EVALUATION OF KNEE-ANKLE-FOOT ORTHOSIS WITH ALTERNATIVE KNEE JOINT DESIGNS

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ABSTRACT

A Knee-Ankle-Foot Orthosis (KAFO) is commonly prescribed to individuals with severe lower limb muscle weakness due to poliomyelitis, trauma, incomplete spinal cord injury, ageing, etc. The knee joint in a KAFO is a key component that decides the functional performance of the orthosis. Different classes of users need different types of orthotic knees (single-axis, free, offset, locked, etc.) for enabling walking. However, a KAFO with a single-axis locked knee is the most common and low-cost solution to provide stability during walking. Literature shows that walking with a locked knee results in an abnormal and tiring gait. Additionally, there are unmet needs and problems in terms of usability, functionality and biomechanical aspects faced by KAFO users in India, as identified from a feedback survey conducted by the author. Advanced imported orthotic devices are expensive and not designed to perform activities of daily living (ADLs) such as squatting, cross-legged sitting, kneeling and walking on uneven terrain, which are integral parts of life in India. There is a critical need to solve these problems to improve the quality of life of KAFO users in India. In this work, a user-centric design approach has been developed and tested using a structured framework.

Stance flexion may offer biomechanical benefits to some users who use a stiff, locked knee. For such users, a joint with a drop-lock that provides 12° stance flexion (called the Semi-flexion knee) was designed. The knee joint was tested to meet safety standards. Gait analysis was conducted on eight KAFO users to study the effect of stance flexion on the gait and energy efficiency. The results show statistically significant improvement in the physiological cost index (p=0.016), which implies improved energy efficiency with the Semi-flexion knee when compared to the locked knee. Changes in spatiotemporal parameters, symmetry indices, and joint forces, though not statistically significant for the group, show improvements for individual users walking with the Semi-flexion knee. The results imply that a spring resisted stance flexion need to be incorporated in future designs.

CITATION


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KEYWORDS

KAFO; Orthosis; Knee joint; Gait; Four-bar; Pistoning; Assistive knee; Biomimetic knee; User-centric design.
For certain users, a KAFO is used for post-operative knee immobilization to allow knee flexion-extension while maintaining mediolateral stability. In such cases, to reduce the pistoning motion and improve the comfort of the user, a biomimetic four-bar design was proposed. An optimally synthesized biomimetic four-bar mechanism (4BM) that traces the anatomical knee motion precisely was designed. A method for alignment of the new design with respect to the anatomical knee is presented. Clinical evaluation of the proposed design will be conducted in the future. Further, to solve biomechanical problems such as abnormal gait, absence of swing flexion and stability on uneven terrain, and to meet the user requirements of greater knee flexion to perform various ADLs, use of a non-biomimetic 4BM was explored. An assistive 4BM was optimally synthesized to provide stable stance and reduced effort during the swing. This new design provides improved stance stability compared to an offset single-axis knee joint and the absence of a physical locking system allows for swing flexion. A KAFO with an assistive 4BM can serve as an affordable alternative to expensive Stance Control Orthoses available in the market. Further exploration of 4BM orthotic knee joints is required with regard to the testing, alignment, and fabrication before conducting clinical studies.

Participants in the feedback survey mentioned skin problems, pressure points and comfort related issues due to orthosis, which are attributed to misalignment and resulting pistoning motion. A biomechanical model to predict the relative motion between the limb and the orthosis due to orthotic knee axis misalignment was presented. Stand-to-sit transitions for a KAFO user were simulated using the proposed model. The model predicts probable pressure points on the thigh and the thigh strap sliding due to sagittal plane linear misalignments in the orthotic knee axis. The proposed model can be applied in a software simulation tool to help orthotists in accurate alignment and fitting of orthoses.

A lever-operated knee joint that solves the majority of the functional problems faced by KAFO users as identified in the feedback survey was designed. The design was tested for safety using finite element analysis and mechanical testing. The new design is functionally superior because it solves the problem of tearing of clothes, provides 122° of maximum knee flexion and allows comfortable and reliable locking and unlocking during stand-to-sit transitions. Future designs will focus on improving the knee flexion range and make other modifications based on feedback from the clinical trials that are underway.

In summary, this work addresses biomechanical and functional needs of different classes of KAFO users and proposes alternative orthotic knee joint designs to meet their needs. A structured user-centric framework involving prototype development through computer-aided design, mechanical analysis, load testing of prototypes, and clinical evaluation using participants of the relevant user groups is proposed and applied to varying extents to the novel and practical solutions developed. The structured approach presents a model for research and innovation that has the ability to make a great impact on a neglected research area. The various orthotic knee joint designs presented in this dissertation have the potential to empower and improve the lives of millions of people with lower limb disability in India and other developing countries.

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LAY ABSTRACT

A Knee-Ankle-Foot Orthosis (KAFO) is commonly prescribed to individuals with severe lower limb muscle weakness due to poliomyelitis, trauma, incomplete spinal cord injury, aging, etc. The knee joint in a KAFO is a key component that decides the functional performance of the orthosis. Different classes of users need different types of orthotic knees for enabling walking. A KAFO with a single-axis locked knee is the most common and low-cost solution to provide stability during walking, but it results in an abnormal and tiring gait. In this work, various knee joint designs for a KAFO are proposed, namely, the semi-flexion, biomimetic four-bar, assistive four-bar, and easy lever-operated (EZ-LOK) knee. These designs address problems of various classes of KAFO users in developing countries and the work attempts to improve the baseline performance of existing orthotic knee joints as well. A structured user-centric design framework involving prototype development through user feedback survey, computer-aided design, mechanical analysis, load testing of prototypes, mathematical modeling, and clinical evaluation using participants of the relevant user groups is proposed and applied to varying extents to the novel and practical solutions developed. The various designs developed in this work have the potential to empower and improve the lives of millions of people with lower limb disability in India and other developing countries.

SHORT SCIENTIFIC BIOGRAPHY

Dr. Ganesh graduated with his Bachelors in Mechanical Engineering from Walchand College of Engineering, Sangli, India after which he worked in engineering industry for a few years. Currently, he is a Postdoctoral Research Fellow in the TTK Center for Rehabilitation Research and Device Development at Indian Institute of Technology Madras. His research interests include: design and optimization of mechanisms, gait analysis and design for Prosthetics and Orthotics. His doctoral research work has resulted in innovations (2 design patents granted, 1 other patent pending) related to orthotic knee joint designs.

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