

Executive Summary



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1. Title of the Project: Design and commercialization of an indigenous lever-operated orthotic knee.
2. Date of Start of the Project: Feb 01, 2020.
3. Aims and Objectives: To develop a functional and affordable alternative to the orthotic drop-lock knee joint used in a Knee-Ankle-Foot Orthosis (KAFO) incorporating user-centric design. The device should be functionally superior to the existing drop-lock knee, while being more suitable and affordable than imported alternatives to the drop-lock.
4. Significant achievements (not more than 500 words to include List of patents, publications, prototype, deployment etc):

Individuals with weak quadriceps and low residual muscular strength (for instance, with post-polio syndrome) need to be given a KAFO to enable them to walk without falling. A gravity-operated drop-lock type knee joint is used in the majority of the KAFOs prescribed for such individuals. To sit down, the user needs to slide the drop lock on either side upwards. The lock is awkward to operate, may get stuck in clothing causing unreliable locking, and is extremely difficult to use for bilateral KAFO users, but is widely used as it is the only indigenous low-cost option [1].

A new design with a lever-operated system was developed and garnered a lot of interest from potential users. In the course of this project, multiple iterations of the design were explored with feedback from short-term user testing to ensure a finalized user-centric design (shown in Figure 1). Improvements from the first version include reduced

mediolateral play and anteroposterior play, as well as prevention of accidental unlocking while walking. The latest version uses a different cabling system for actuation instead of the cable-lever combination originally used.

In the last one year, user trial protocols were prepared and Institute Ethics Committee approval was obtained. Test methods were customised for effective user study.

About 50 prototypes were manufactured for user trials with 20 users. Trials were initiated for 15 users but had to be halted to sort out manufacturing issues

Version 1 is covered by two Indian Design Registrations - **No. 290751 and 290752**. Subsequently, design applications **No. 394448-001 and 394449-001** for “Easy operable orthotic knee joint using a cable” were filed on 7th Sep 2023.

After a few months of successful long-term user testing, the design will be licensed for commercialization.



Figure 1: Finalized version to be deployed for long-term user testing

[Video link of the user trying the device](#)

5. Concluding remarks: While the new design has shown promise in addressing the drawbacks of the drop-lock design while ensuring affordability in comparison with imported designs, the manufacturing challenge needs to be resolved. Once resolved, long term user trials have to be resumed to ensure quality and user comfort.

The co-development involving the user-testing partner with commercialization capabilities (Mobility India) has the potential to impact the lives of millions of users in India who use knee-ankle-foot-orthoses.

References:

- [1] G. Bapat and S. Sujatha (2019). Identification and analysis of Knee-Ankle-Foot orthosis design requirements based on a feedback survey of orthosis users in India. Disability and Rehabilitation - Assistive Technology 14(1), 82-90.