

DEVELOPMENT AND CLINICAL TRIAL OF PROTOTYPE EXTERNAL DIGIT DEVICE FOR CORRECTION OF DIGIT FLEXION DEFORMITY

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Introduction: Finger flexion deformities are common sequelae of hand injuries. Current treatment modalities consist of invasive surgical interventions and rigorous physiotherapies. Our team attempts to treat the deformity using a non-invasive device providing continuous soft tissue traction which will gradually lengthen and release soft tissue contractures. We aim to provide a safe alternative treatment modality which can effectively correct finger fixed flexion deformities.

Methodology: The Digit Device Prototype Hinged (DDPH) was designed and developed with testing on machines in labs, to cadavers and then on normal volunteers. The device consisted of a series of hinged segments which fits onto the afflicted finger with Velcro straps. Continuous extension force was provided by a cable-tie traversing through the device from metacarpophalangeal to interphalangeal joints. Recruited patients were fitted with customized DDPH made from 3D printers. It was kept on for at least 23 hours a day for a period of 6 months, with regular tightening of the cable-tie to provide continuous extension force. Finger flexion deformity angles were measured during regular follow-ups using a finger goniometer. The progressive changes in deformity angles were then documented and analyzed.

Results: A total of 6 fingers from 5 patients with fixed flexion deformities were tested. There were noticeable improvements of finger flexion deformities with an overall mean improvement of 32 degrees and a significant p-value of 0.006940647, $p < 0.01$. No significant complications or side effects were noted. But there were complaints that the it was too cumbersome, and frequent breakages of the DDPH.

Conclusion: The DDPH could prove to be a viable alternative treatment option for fixed flexion deformity of the fingers that does not require invasive surgical procedures; and can provide more consistent physiotherapy-like extension with minimum supervision and follow-ups. A more comprehensive study with a larger sample size is needed, with a few design improvements made.