Comparing 3D Printed and Off-the-Shelf AFOs for Stroke Inpatients: A Pilot Study

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Summary

This paper reports results from an ongoing study aimed to evaluate use of 3D printed (3DP) AFOs for inpatient gait training. Though demonstrating feasibility, it has underscored the challenges of conducting inpatient research. Our results have overall been promising but mixed on metrics of skin integrity, pain, therapist burden and patient preference.

Introduction

Ankle foot orthoses (AFOs) are commonly used to manage walking impairments and correlate with improved walking outcomes. AFO use often begins during the inpatient stay with a primary focus of improving gait stability and efficiency, however this requires use of off-the-shelf (OTS) devices due to the short nature of inpatient stays and insurance limitations. This can lead to sub-optimally fitting and functioning braces as well as increased therapist (PT) time dedicated to correcting these factors rather than in gait training. This study aimed to quantify these effects and whether using a non-custom brace led to greater incidence of skin related issues and pain. In addition, we aimed to assess whether 3D printed (3DP) AFOs could ameliorate these issues.

Methods

Patients were recruited to participate from an inpatient rehabilitation facility. All provided informed consent for this IRB approved study protocol. Physical therapists administered the gait training during therapy sessions with use of either the 3DP or OTS AFO, performed skin integrity, general and limb pain evaluations, monitored for adverse events, and communicated to the research team required brace modifications. Some modifications were made directly by therapists. All were logged. Therapists performed a brief survey regarding their satisfaction and perceived efficiency of orthotic use for each patient. Data analysis was done by the study team medical residents and an undergraduate student.

Results and Discussion

The OTS arm of the study satisfied enrollment target (30) with 26 providing usable data. The 3DP arm of the study is still enrolling subjects with a current N of 13. Length of stays were similar (16 for OTS vs. 15.1 for 3DP). To date, the 3DP braces have been printed by a commercial outfit and it has taken 8.4 days (N = 13) for the 3DP brace to arrive leaving just under 5 days of use before discharge. Therapist used OTS braces until 3DP study braces were available. Five of the subjects preferred the OTS over the 3DP braces due to preferring the initial fit and not wanting to change what they were used to during gait training. Two of the subjects never wore their study brace as they were discharged or received their definitive custom AFOs by the time the study brace arrived. Two subjects had medical complications necessitating return to acute care and were not able to complete the study course. The average satisfaction rating of PTs with using the 3DP AFO was 7.29 out of 10, and 7.0 out of 10 for orthosis optimization efficiency. Common modifications needed were reducing the length of the footplate post-production. Of the subgroup that used the 3DP AFO for three or more sessions, 50% (n=6) never developed pain or skin changes; the other 50% developed skin changes after 1 session, all of which were superficial and temporary. The 3DP AFOs were durable and did not cause any severe injury. Of the 26 patients using *only* OTS AFOs, 46% developed orthosis related limb pain, 62% developed general pain and 42% had orthosis related skin changes.

3D printing is rapidly a developing technology that has gained widespread use in many technical sectors. Despite this and its increasingly affordable and rapid capabilities to create custom devices, it remains infrequently used in the inpatient rehabilitation clinical setting. There is a need for large-scale research to standardize 3D-printing into practice.

Conclusions

OTS skin and pain rates initially seemed high, suggesting reduction may be possible with better fitting AFOs for post-stroke inpatient gait training. Due to use of OTS braces until 3DP braces were ready, comparisons of skin and pain issues are not straightforward. Delivery time for 3DP braces has been high so far and has somewhat clouded our understanding of the benefits of 3DP AFOs. In addition, the 3DP braces tended to be very stiff likely affecting both comfort and performance. Going forward, we will print study AFOs in-house and anticipate a reduction in delivery time. Equally important, it will be interesting to assess if custom 3DP AFOs can improve *functional* outcomes and the overall care for inpatients.