THE DROP FOOT SOCK

BRIDGING THE GAP IN DROP FOOT CARE

CLINICAL TESTING RESULTS

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I. Executive Summary

The S step sock is a pioneering solution in the treatment of drop foot, a condition characterized by difficulty lifting the foot during swing phase. This leads to mobility challenges and an increased risk of falls. Traditional treatments comprise of Ankle Foot Orthosis (AFOs) providing varying degrees of assistance, but they often come with limitations that result in discomfort, user noncompliance and dissatisfaction. Moreover, such solutions usually require the use of a shoe, limiting the use of such devices in many day-to-day activities where shoes are not typically worn.
This clinical white paper evaluates the efficacy of the S step sock in improving gait, mobility, and quality of life for individuals with drop foot. It compares such parameters while subjects use their AFO solution or while walking barefoot.

Key Findings from the clinical trial:

- Many subjects do not feel confident walking without a supportive device due to increased fear of falling or increased physical strain.

- For those confident to perform base-line tests without a supportive device, significant improvements in gait and mobility were achieved with the S step sock, as evidenced by increased distances in the 2-minute walk test and reduced times in the Timed Up and Go (TUG) test.

- For those relying on their preferred AFO solution for base-line tests, the S step provides comparable results as evidenced by distances in the 2-minute walk test and statistically significant reduced (improved) times in the Timed Up and Go (TUG) test.

- High user and practitioner satisfaction, with positive feedback on comfort, ease of use, and overall usability.

- Practical and versatile design suitable for both casual and formal settings, with continuous support whether wearing shoes or walking barefoot.

The study results support the integration of the S step sock into clinical practice for managing drop foot, highlighting its potential to improve patient outcomes and adherence to treatment regimens.

II. Background

Drop foot, also known as foot drop, is a condition characterized by the inability to lift the front part of the foot, leading to difficulty in walking and an increased risk of falls (1). It is commonly caused by neurological, muscular, or anatomical issues, such as stroke, multiple sclerosis, cerebral palsy, or peripheral nerve injuries (2).

Current solutions for drop foot include ankle-foot orthoses (AFOs), electrical stimulation devices, and physical therapy. (3)These solutions provide varying degrees of assistance especially with mobility. However, they often come with limitations such as bulkiness, discomfort, high cost, and a lack of adaptability to different footwear. Most notably, AFOs are effective only when worn with shoes, limiting functionality when subjects are at home and prefer to walk barefoot or in different types of footwear. Additionally, compliance and longterm use of these devices can be problematic for subjects. There is ongoing need for alternative remedy/tools that overcome the challenges associated with current available solutions to drop foot while providing versatility.

Individuals with drop foot face challenges that significantly impact their quality of life. They include pain, embarrassment, and difficulty navigating daily activities. Foot drop is highly distressing, making attention to the patient's psychological needs crucial.(4) For example, in the case of drop foot AFOs, subjects face several limitations, such as lack of support when walking barefoot at home, incompatibility with various types of footwear, and discomfort due to bulkiness. Many individuals reject their AFOs due to these issues, opting instead for a cane or no assistance at all, despite resulting in a less efficient gait. Additionally, Medicare typically covers only one device every 3-5 years, necessitating that this single device be as comfortable, durable, and versatile as possible to fit every scenario in a person's life. This often leads to dissatisfaction as no single device can meet all these needs. This understanding inspired the development of the “S step” sock.

III. Objectives and methodology

1. Research Objectives

2. To evaluate the efficacy of the S step sock in improving gait and overall mobility in individuals with drop foot.
3. To assess the reduction in the risk of falls and injuries when using the S step sock in comparison to when they are unable to use an AFO.
4. To determine the level of user satisfaction and comfort while wearing the S step sock.
5. To measure the impact of the S step sock on the quality of life, confidence, and independence of users.
6. To evaluate the durability and practicality of the S step sock in various daily activities and environments.

2. Hypothesis

1. The S step sock significantly improves gait and mobility in individuals with drop foot compared to baseline measurements without the sock or other assistive device.
2. The use of the S step sock reduces the incidence and fear of falls and injuries in individuals with drop foot.
3. Users of the S step sock report higher levels of satisfaction and comfort compared to their previous use of traditional AFOs.
4. The S step sock has a positive impact on the quality of life, enhancing users' confidence and independence.
5. The S step sock is durable and practical for use in various daily activities, including both indoor and outdoor environment.

3. Materials and Methods

Study Design

The study was designed as an observational study with a pre- post intervention approach. Subjects' mobility and stability were assessed before and after using the S step sock to evaluate its effectiveness.

Inclusion Criteria

- Subjects diagnosed with dorsiflexor impairment
- Subjects with mild to moderate spasticity
- Subjects without impairment of gastrocnemius and/or quadriceps muscles
- Subjects who can give informed consent and follow the study protocol

Exclusion Criteria

- Subjects with severe spasticity
- Subjects with significant cognitive impairments that would prevent them from following instructions
- Subjects with contraindications for wearing compression garments
- Subjects with severe cardiovascular or respiratory conditions that would prevent safe participation in physical tests

Patient participation

- 18 subjects
- Ages from 33 to 83 years of age
- Weight range from 115lbs to 285lbs
- Height from 5'0" and 6'1"
- Both male and female subjects participated
- Indications: CVA, MS, CIPD, TBI, MNN, Lumbar Injury

4. Control group(s) configuration

Subjects were given the option during the initial visit to choose whether they would prefer a comparison of the sock versus no device or versus their prior device. Six subjects chose no device versus sock, while ten subjects chose previous device versus sock, with both groups categorized under the user-preferred device. This led to the following control groups:

- Comparison of the S step outcome to Existing Devices (n=12)
- Comparison of the S step outcome to bare-foot (no-device) (n=6)
- Comparison to either user-preferred device or no-device (=18)

At the 2-week follow-up, 15 subjects returned with the sock, allowing for further analysis. This retention rate enabled continued evaluation of the sock's longterm effectiveness and comfort relative to initial impressions.

5. Key variables and outcome, measured vs previous assistive device

1. Baseline Measurements

- Distance walked during a 2-minute walking test with or without the current assistive device.
- Time taken to complete the Time Up and Go (TUG) test with or without the current assistive device.
- 15-second video recordings of gait with or without the current assistive device.

1. BASELINE MEASUREMENT ON USER-PREFERRED

2. Post-intervention Measurements

- Distance walked during a 2-minute walking test with the S step sock.
- Time taken to complete the TUG test with the S step sock.
- Video assessment (15s) of gait with the S step sock.

2. POST INTERVENTION MEASUREMENTS S step

3. Patient and Practitioner Questionnaires

- Satisfaction with the fit and comfort of the S step sock.
- Ease of applying and removing the S step sock after reading the IFU.

3. PATIENT AND PRACTITIONER QUESTIONNAIRES

4. Gait Efficiency and Mobility

- Confidence in stability and reduction in fear of falling.
- Overall usability and durability of the S step sock.
- Impact on daily activities and quality of life.

4. GAIT EFFICIENCY AND MOBILITY

5. Follow-Up Evaluation (2 weeks)

- Patients were required to wear the S step sock for 2 weeks, during which they kept notes.
- A follow-up evaluation was conducted after 2 weeks, repeating the initial measurements (2-4) and completing additional questionnaires to assess daily use.

5. 2-WEEK FOLLOW UP REPEAT OF STEPS 2-4

IV. Results

1. S step sock at initial fit and 2-week follow-up

The clinical testing of the S step sock demonstrated significant improvements in gait and overall patient satisfaction between initial fit and 2 week follow up.

A. Improved mobility, enhanced agility & balance

Improved Mobility: the results indicate that there was increased distance measured for the 2-minute walking test when comparing the user-performance at initial fit of the S step (210.1m) and during the 2-week follow-up re-test with the S step (229.7m). The TUG-test shows an improvement as well after 2 weeks of use of the S step, reflected in a reduction of time needed to perform the test. The reduction in the time needed to perform the TUG-test at initial fit (15.4s) and at 2 weeks of use (14.1s) indicates that subjects experienced improved agility and balance with the S step sock during the follow-up visit.

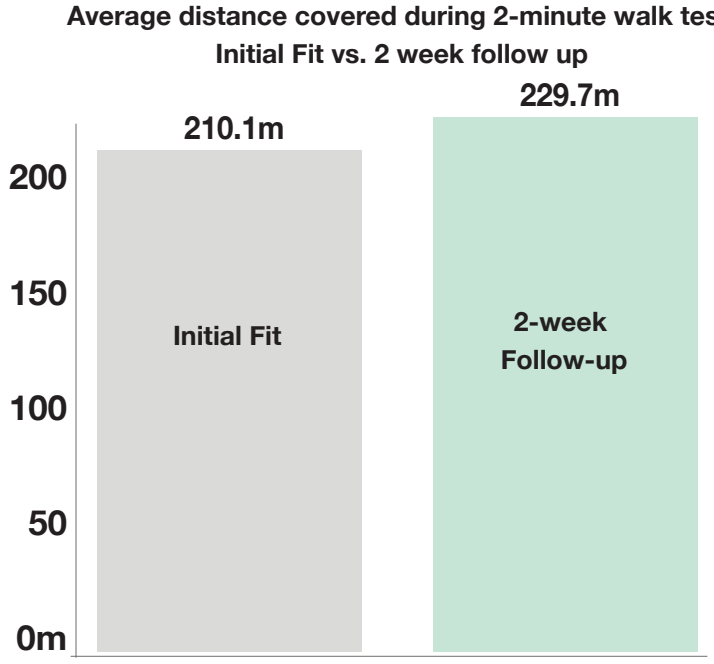


Fig 1. 2 minute walking test at initial fit and at 2 weeks

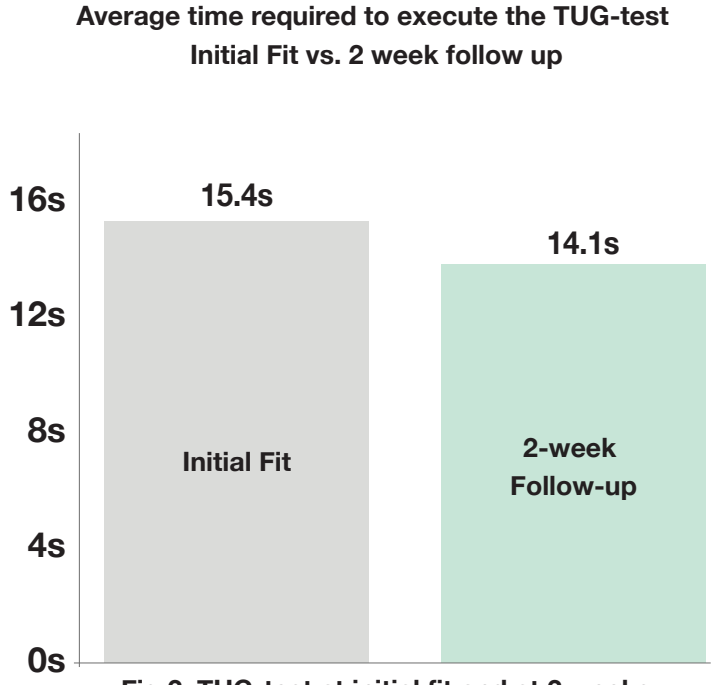


Fig 2. TUG-test at initial fit and at 2 weeks

B. High user and practitioner satisfaction

Overall Usability: The overall usability of the sock received high scores, with an average rating of 4.7 out of 5. These high ratings were consistent for both initial and follow-up visits, indicating immediate and sustained user and practitioner usability rating.

User and practitioner satisfaction: Patients and practitioners rated the fit, comfort, and usability of the S step sock highly. Most subjects found the sock comfortable (average rating of 4.3 out of 5) and easy to apply and remove (average rating of 4.2 out of 5).

Positive subjective feedback included: the sock was found to be discrete, soft, and slim, with subjects appreciating the stability and reduced fear of falling it provided.

Concerns or adverse effects: Some subjects reported minor concerns like discomfort from the strapping system and suggestions for improvements in suspension and padding behind the strap on the calf. None of these concerns were reason for drop-out.

C. Low fear of Falling:

The fear of falling is generally high amongst the drop foot population. This was reflected by the fact that only 6 out of 18 subjects felt comfortable performing the 2 minute walking test and TUG test without a supportive device (barefoot). Leaving 12 of them with lack of capability or too high of a fear of falling to execute the test without their assistive device. When wearing the sock, ALL users were able to perform and complete the 2 minute walking test. Sock users reported a score of only 9.4/100 in fear of falling, after performing the test at initial fit. A slightly increased fear of falling was noted at 2-week follow up, but the fear of falling remained below 15% as shown in Figure 3. None of the users reported a fall while walking with the sock during the 2-week trial, whereas several users had a history of frequent falls when walking without an assistive device.

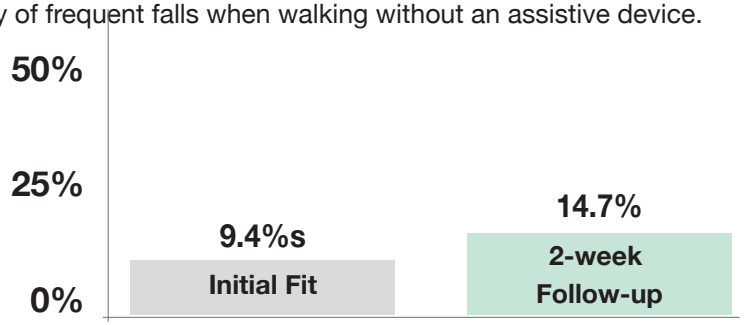


Fig 3. fear of Falling at initial fit and at 2 weeks

2. Comparison: S step vs. user-preferred device - 2-min walking and TUG at initial fit

A. Improved mobility enhanced agility & balance with S step sock

During the 2 minute walking test, subjects covered more distance on average with the S step sock (222.7m) compared to their previously preferred method (210.0m) (fig.4). The TUG-test showed a faster performance (14.11s) while using the S step, compared to their previously preferred method (15.69s) indicating better mobility and balance (Fig. 5).

Average distance covered during 2-minute walk test
Initial Fit vs. 2 week follow up

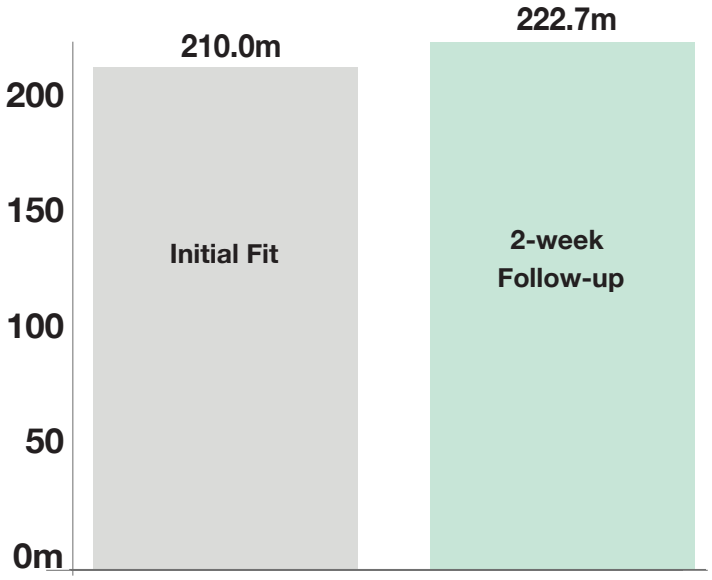


Fig 4. 2-minute walking test at initial fit and at 2 weeks

Average time required to execute the TUG-test
Initial Fit vs. 2 week follow up

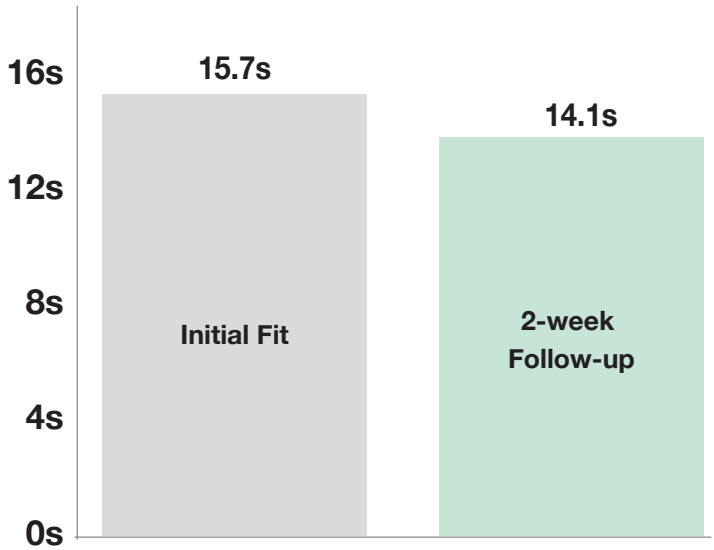


Fig 5. TUG-test at initial fit and at 2 weeks

IV. Statistical Analysis

1. Paired T-Test results

A. TUG-test

- T-statistic: 2.26
- P-value: 0.0381

Conclusion: The S step sock significantly improved TUG-test times compared to the preferred previous device used to perform the TUG-test at initial fitting ($p < 0.05$).

B. 2-minute walk-test

- T-statistic: -1.73
- P-value: 0.1026

Conclusion: No statistically significant difference was found in the 2-minute walk distances between the Drop Foot Sock and the Preferred Previous Device ($p > 0.05$).

2. Qualitative analysis based on open-ended responses

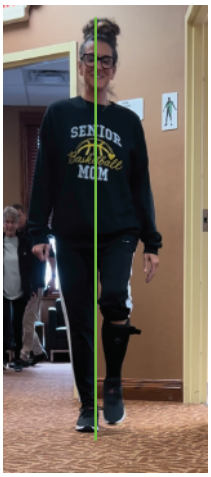
- Patients frequently mentioned the S step sock's comfort, ease of use, and the added confidence it provided in preventing falls.
- Common themes included the sock being discreet, lightweight, and beneficial for daily activities, especially when traditional braces were not practical.
- Practitioners highlighted the ease of adjusting and fitting the sock, and they noted improvements in subjects' gait and overall stability.

3. Main findings of the clinical testing

- Mobility improvement: the 2-minute walk test showed an increase in the distance covered using the S step sock
- Enhanced agility and balance: the TUG test time decreased significantly with the S step sock compared to the preferred method (with or without brace).
- Gait assessment by means of video footage supports visible improvement in ground clearance during swing, as well as improved stride-length. At the same time, gait deviations like steppage gait, lateral trunk bending and circumduction are visible reduced with the majority of the subjects.

Lateral bending & steppage gait

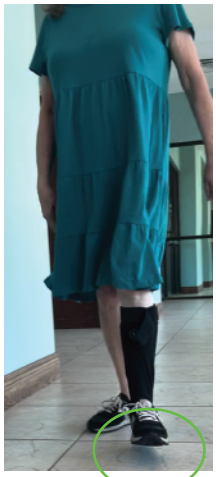
Without



With S step

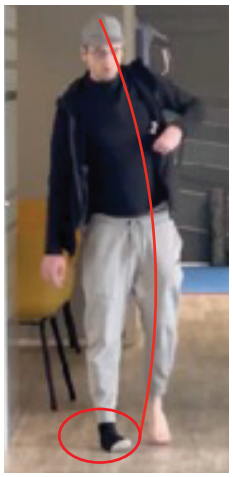
Ground clearance same as AFO

With AFO



With S step

Lateral bending, foot placement



Without

With S step

V. Discussion

The study results indicate a significant improvement in user mobility and stability with the use of the S step drop foot sock, particularly in tasks requiring short-duration, quick movements. The Time Up and Go (TUG) test demonstrated statistically significant enhancements measured in agility and balance when using the sock compared to previously preferred devices. While there were observational improvements in the 2-minute walk test with the sock, these changes were not statistically significant. Nonetheless, the findings suggest that the sock has potential benefits in enhancing longer-duration walking performance.

Many of the subjects felt uncomfortable performing the 2-minute walking test and TUG test without a supportive device. This was attributed to prior history of falls while not wearing their device or to limitation in physical ability to perform the requested tests. All subjects completed the 2-minute walking test and TUG test on the S step, and reported an average fear of falling ratings as low as 9.4/100 at initial fitting indicating a great immediate sense of security and confidence when ambulating with the S step.

Both subjects and practitioners reported high levels of comfort, ease of use, and overall satisfaction with the sock. These subjective assessments align with the objective improvements seen in the TUG test, underscoring the sock's effectiveness in boosting gait and confidence, especially in scenarios that demand quick mobility.

Strengths of the study

- **Diverse User Population**: The study included a wide range of subjects with varying ages, weights, heights, and medical backgrounds, ensuring that the findings are generalizable to a broad population of individuals with drop foot.
- **Multiple Testing Sites:** Conducting the study across several clinical sites, enhances the robustness of the findings.
- **Comprehensive Data Collection** :The use of both quantitative measures (e.g., walk test distances, TUG times) and qualitative feedback (e.g., patient and practitioner questionnaires) provided a well-rounded assessment of the sock's efficacy.
- **Comparative Analysis:** Comparing the S step sock to both no device and existing braces allowed for a thorough evaluation of its relative effectiveness.

Areas for improvement/continuation

- **Sample Size:** While diverse, the total number of participants (18 subjects) may be relatively small, potentially limiting the statistical power of some findings.
- **Short Follow-Up Duration:** The follow-up period of two weeks, while sufficient to demonstrate initial improvements, may not capture longterm efficacy and durability of the sock.
- **Technical Improvement Opportunities:** 3 subjects mentioned issues with the suspension of the sock with more intense use. Changes have been made to the design to increase suspension around the calf, and recent re-testing has confirmed the efficacy of the solution. Extreme atrophied calf muscles need to be treated with care, as they might not maintain suspension.
- **Self-Reported Data:** Some data, particularly related to user satisfaction and perceived improvements, were self-reported, which may introduce subjective bias.

VI. Conclusion

The findings from this study contribute significantly to the existing body of knowledge on drop foot treatment by demonstrating that the S step sock is a viable and effective complementary device for managing drop foot. While having similar efficacy to previous AFO devices, it offers greater comfort for subjects and improves versatility. Its key contributions include:

- **Enhanced Mobility Solutions:** The study provides evidence that the S step sock can improve gait and mobility compared to a non-braced condition, offering an alternative for subjects who may not tolerate or prefer not to use bulkier devices.

- **Practical Usability:** The high ratings for ease of application and comfort suggest that the sock can be easily integrated into daily life, potentially increasing patient adherence and overall quality of life.

- **Foundation for Future Research:** The study highlights areas for further investigation, such as longterm efficacy, design improvements to prevent sock migration, and broader testing with larger sample sizes.

Recommendations for Clinical Practice

1. Incorporate S step sock into Treatment Plans

Clinicians should consider integrating the S step sock into the treatment regimen for subjects with drop foot, particularly for those who may have difficulty using traditional braces or require additional support at home or in different footwear.

2. User Education and Training

Provide thorough education and training for subjects on the proper use, application, and adjustment of the S step sock. Ensuring subjects are comfortable and confident in using the sock can enhance adherence and outcomes.

3. Monitor and Address Adverse Effects

Teach the user to be vigilant about any adverse effects or complications, such as skin irritation or discomfort from strapping. Address these issues promptly to maintain user comfort and satisfaction.

4. Further Research

Conduct additional clinical trials with a larger user population and extend study duration, including comparisons with control groups, to obtain more objective and comprehensive results. These trials will help to further validate the efficacy and benefits of the S step sock.

VII. References

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APPENDIX 1.
DATA RESULTS

Measurement Initial Fit	
Metric	**Initial Fit**
Preferred Previous Method TUG-test	15.69 seconds
S step sock TUG Test	14.11 seconds
Preferred Previous Method 2-Minute Walking Test	210 meters
S step sock 2-Minute Walking Test	222.65 meters

Questionnaire Ratings Patient (Average)		
Metric	**Initial Fit**	**2-week follow-up**
Fit and Comfort (Patient)	4.4	4.2
Ease of Applying/Removing (Patient)	4.2	4.1
Overall Usability (Patient)	4.6	4.7

Questionnaire Ratings Practitioner (Average)		
Metric	**Initial Fit**	**2-week follow-up**
Fit	4.4	4.5
Ease in Adjusting	4.8	4.6
Ease of Application	4.4	4.4
Overall Usability	4.7	4.7
Quality IFU's	4.7	4.6
Ease of Application for Patient	4.2	4.3
Improvements in Gait	4.3	4.7
Overall Comfort	4.5	4.5
Ability to Meet Needs of Patient	4.5	4.7
Overall Durability	4.4	4.6