Clinical Improvements with SYNSYS Microprocessor Total Leg System After 4 Weeks of At-Home Use

Introduction

Uneven ground, slopes, stairs, sidewalks are walking situations requiring increased ankle mobility compared to level ground walking. These walking situations can be difficult to overcome for persons with transfemoral amputation (TFA) if they are wearing an energy storage and return (ESAR) foot without ankle articulation. ESAR feet are suitable on level ground but do not allow adaptation to daily walking situations like slopes (ascent and descent) or up and down stairs. Increased fall risk could be partly attributed to this lack of terrain adaptation. This risk is increased by the muscle atrophy seen with amputation and the absence of mobility of the prosthetic ankle during the swing phase[1] when using a ESAR foot.

PROTEOR developed the SYNSYS microprocessor-controlled knee/ankle system to address these concerns featuring a kinematic coupling that allows controlled triple flexion of the hip, knee, and ankle. SYNSYS total leg system has a microprocessor knee range of motion (ROM) of 125° and a microprocessor ankle ROM of 42° total (22° dorsiflexion, 20° plantarflexion).

A study, *Biomechanical Evaluation of a Knee-Ankle Synergetic Device for Individuals with Transfemoral Limb Loss* (Pillet et al) was completed on the SYNSYS to perform a biomechanical analysis of persons with transfemoral amputation wearing a microprocessor-controlled knee-ankle system (SYNSYS) specifically designed to address these issues. This paper summarizes the results of that study.

Methods

Twelve low to moderate impact Medicare level K3 (above International Classification of Functioning, Disability, and Health (ICF) d4602) adults (46 ± 15 years old, 178 ± 9 cm and 75 ± 9 kg,) gave their informed consent in participate in this prospective, multicenter, and randomized cross-over study approved by a national ethics committee (CPP Sud Est III n° 2018-045B). Participants were randomly placed into two groups, with one group wearing their typically worn (over 3 months) MPK/foot (MPK_HAB) and one group switched to the SYNSYS. Participants were then instructed to return in 4 weeks.

After 4 weeks of at-home use, participants returned to the clinic. Each participant completed gait analysis on level ground, 12% slope ascent and descent, stair descent, and the 6 Minute Walk Test (6MWT) followed by the Borg Rating of Perceived Exertion (RPE). They also completed the 36-Item Short Form Health Survey (SF-36) questionnaire and the modified Prothesis Evaluation Questionnaire (m-PEQ). Once data was collected, the participants were either swapped from the SYNSYS back to their MPK_HAB, or to the SYNSYS from their MPK_HAB, depending on which group they were in. Participants were then instructed to return in 4 weeks.

At the final visit, after 4 weeks of at-home use, each participant returned to the clinic and completed the same gait analysis and questionnaires.

Quantified gait analysis was conducted with a VICON® optoelectronic system (Vicon Motion Systems, Oxford Metrics, UK, sampling at 100Hz). Time in Foot Flat (TFF, period of the gait cycle where the foot angle in the sagittal plane was within ± 1.25° of its orientation at 20% of the gait cycle) and Minimum Toe Clearance (MTC, minimum distance in cm between the foot and the ground during the swing phase) were calculated for both prostheses and averaged over trials and compared through student or Wilcoxon test ($p=0.05$). Statistical significance is at $p<0.05$.

Results

For gait analysis results, Figure 1 shows a statistically significant increase (92%) in TFF with SYNSYS, coming closer to able bodies (AB) values. Figure 2 shows a different view of the statistically significant difference during gait activities. Figure 3 shows a statistically significant difference in the percentage of the gait cycle with the prosthetic foot on the ground with SYNSYS. Figure 4 shows statistically significant increase of the MTC during swing with SYNSYS on level ground and slopes. Table 1 shows a statistically significant increase in MTC when walking in level ground and slope ascent with the SYNSYS.

Analysis of the SF-36 showed statically significant increases in both the Physical (PCS) and Mental (MCS) components with SYNSYS. For the m-PEQ, there was a statistically significant increase in the appearance score, 12 of the 8 questions had increased scores, >80% rated their residual limb health better, and 100% reported better utility when using SYNSYS. The Borg RPE completed after the 6MWT showed a lower perceived effort when SYNSYS was being used (from 11.2/20 to 9.75/20 with SYNSYS).

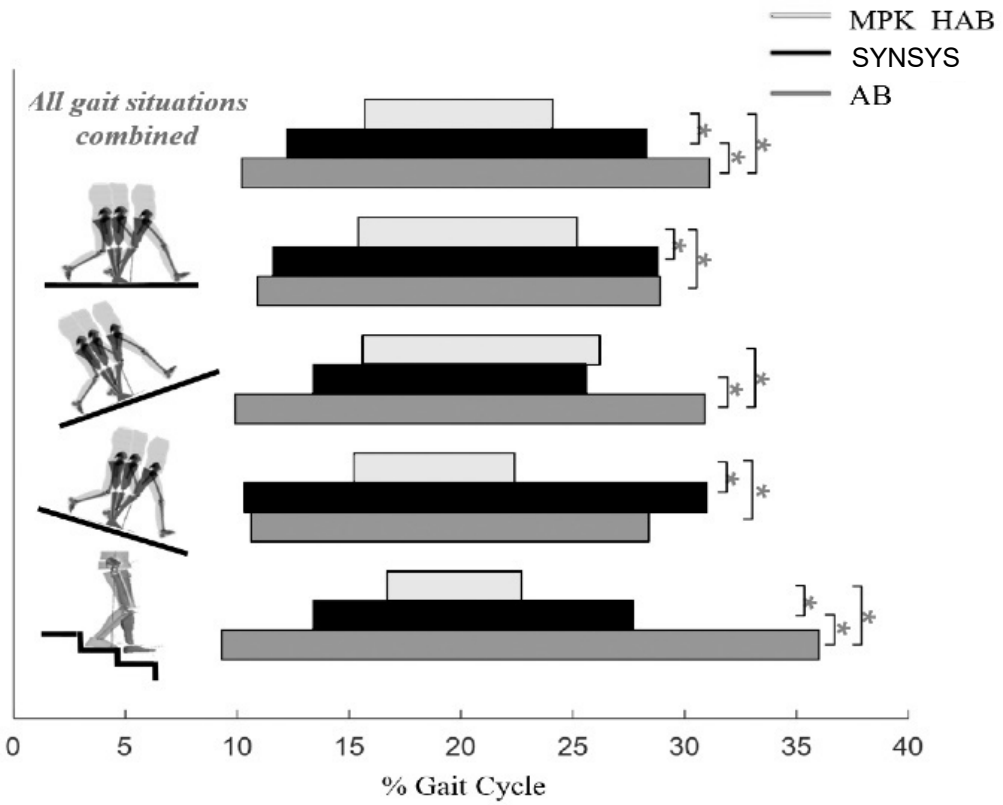

Figure 1 Time in Foot Flat During Different Activities

* marks a statistically significant difference (AB data taken from literature[2])

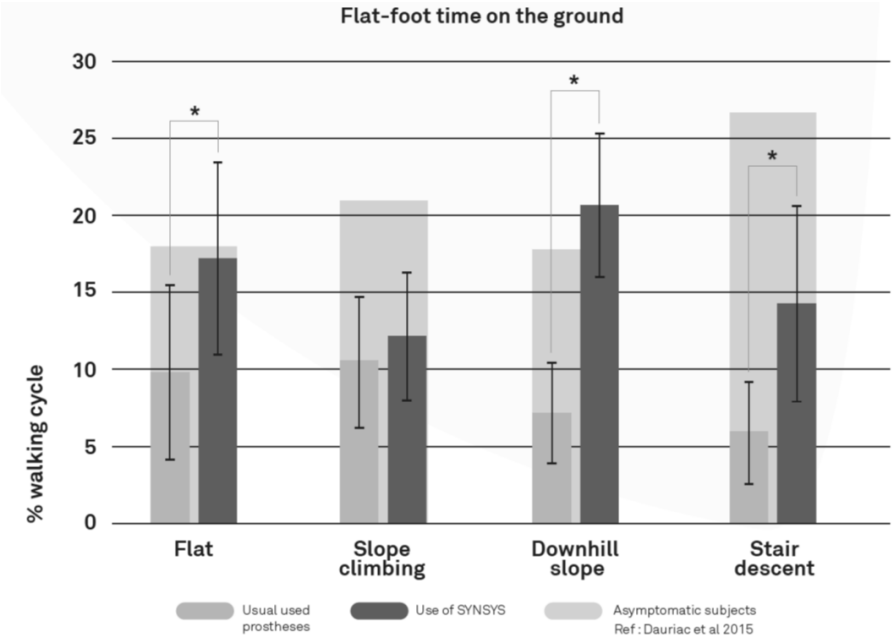

Figure 2 Time in Foot Flat During Activities View 2

* marks a statistically significant difference (AB data taken from literature[2])

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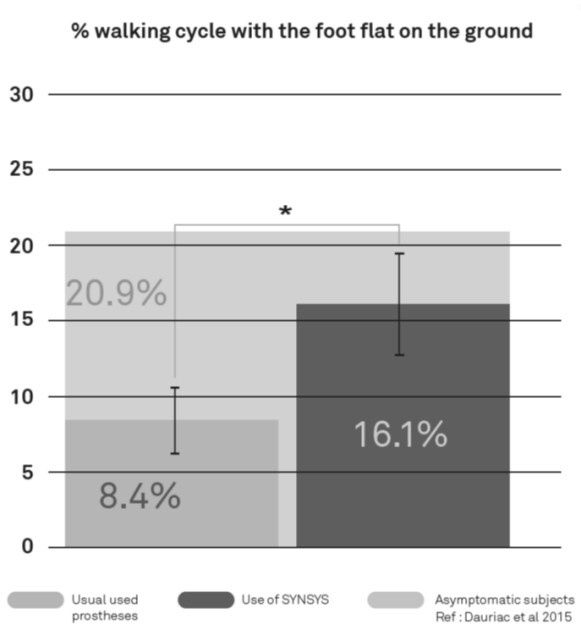

Figure 3 Percentage of the Gait Cycle with Foot Flat

* marks a statistically significant difference (AB data taken from literature[2])

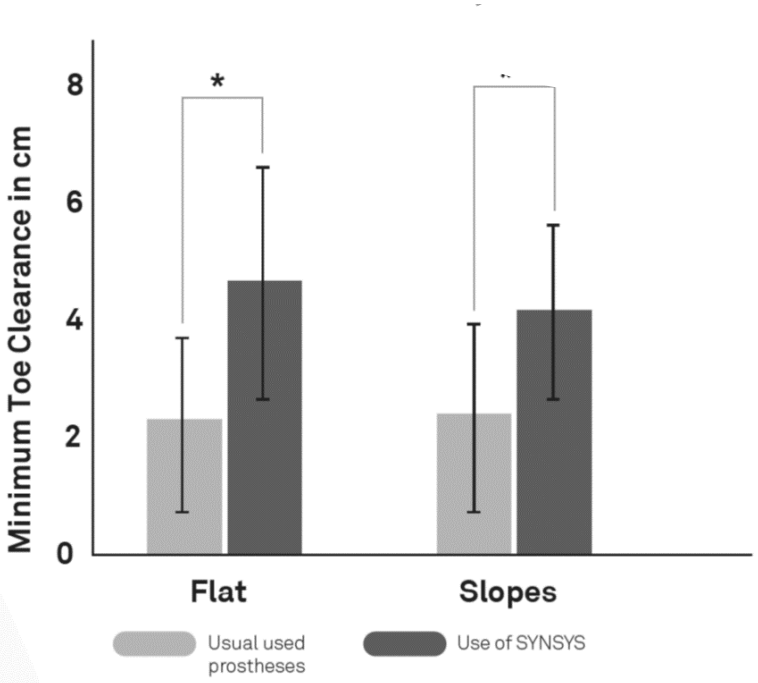

Figure 4 Minimum Toe Clearance During Swing- Level Ground and Slopes

* marks a statistically significant difference (AB data taken from literature[2])

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	Level Ground		Slope Ascent	
	MPK_HAB	SYNSYS	MPK_HAB	SYNSYS
MTC (cm)	2 ± 1	5 ± 2*	2 ± 1	4 ± 2*

Table 1. Minimum Toe Clearance (MTC) with each prosthesis

* marks a statistically significant difference

Discussion

When persons with amputations are fit with a prosthesis, it is always the goal to restore natural gait and motion as closely as possible, allowing users to participate in their activities of daily living with the least amount of disruption to their usual routine. Multiple studies have shown multiple benefits of MPKs with feet that have ankles that provide ROM to adapt to different terrains. SYNSYS takes these benefits to the next level, providing a controlled kinematic coupling between the knee and the ankle. These increased benefits are shown during swing and stance, ascending and descending slopes, and descending stairs.

During stance phase, the longer the user is in foot flat, the more stable the user feels. This study shows with SYNSYS the foot stays flat on the ground 92% longer than other MPKs with ESAR feet, and closer to natural gait, during level ground walking, walking down a slope, and walking down the stairs. There was a statistically significant increase in all these activities using SYNSYS. The 42° of ankle ROM allows the user to traverse varying terrain with more confidence, place their full foot on the stair when descending, and decreases the need to alter their everyday life to feel safe. This also decreases the mental load of daily ambulation.

During swing phase, increased toe clearance is desirable to decrease the risk of the toe catching on obstacles during level ground walking and adapt to the terrain during slope ascent. SYNSYS was shown in this study to provide statistically significantly increased minimum toe clearance during swing on level ground and slopes when compared the other MPKs with ESAR feet. The minimum toe clearance during swing was twice as much as users typically used prostheses allowing users to have more confidence to traverse differing terrains with less mental effort.

There can be a concern with fitting microprocessor total leg systems like the SYNSYS due to added weight or possible cosmesis concerns. This study showed statistically significant increases in the physical and mental wellbeing, residual limb health, and utility, and decreased perceived effort when they were using SYNSYS. These results should decrease cosmesis and weight concerns.

Conclusion

Ankle plantarflexion during stance and active dorsiflexion during swing with SYNSYS increases stance stability and swing phase toe clearance, bringing prosthesis users closer to natural gait dynamics and decreasing their mental load during ambulation. The total leg system also increased physical and mental wellbeing and decreased perceived effort during ambulation.

References

[1] Rosenblatt NJ.,Prosth Orth Int. 41:387–392. 2017.
[2] Dauriac B. Phd Thesis. 2018.

Summary of: BIOMECHANICAL EVALUATION OF A KNEE-ANKLE SYNERGETIC DEVICE FOR INDIVIDUALS WITH TRANSFEMORAL LIMB LOSS
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