ottobock.

Adjust foot

Quality for life

Clinical Study Summary

This document summarizes clinical studies conducted with the Adjust foot. The included studies were identified by a literature search made on PubMed and within the journals Der Orthopäde, JPO Journal of Prosthetics and Orthotics, Orthopädie-Technik and Technology & Innovation.

Table of content:

1 Overview table

The summaries are organized in three levels depending on the detail of information. The overview table (Level 1) lists all the relevant publications dealing with a particular product (topic) as well as researched categories (e.g. level walking, safety, activities, etc). By clicking on underlined categories, a summary of all the literature dealing with that category will open (Level 2).

For those interested to learn more about individual studies, a summary of the study can be obtained by clicking on the relevant reference (Level 3).

Reference		Category									
		Functions and Activities								Participation	Environment
Author	Year	Level walking	Stairs	Ramps Hills	Uneven ground Obstacles	Cognitive demand	Metabolic Energy Consump-tion	Safety	Activity Mobility ADL	Preference Satisfaction QoL	Health economics
Paradisi	2015	x	x	x				x	x	x	
Total number		1	1	1				1	1	1	

2 Summaries of individual studies

On the following pages you find summaries of studies that researched Adjust foot. You find detailed information about the study design, methods applied, results and major findings of the study. At the end of each summary you also can read the original study authors' conclusions.

Reference

Paradisi F, Delussu AS, Brunelli S, Iosa M, Pellegrini R, Zenardi D, Traballesi M.

Santa Lucia Foundation, Scientific Institute for Research, Hospitalization and Health Care, Rome, Italy.

The Conventional Non-Articulated SACH or a Multiaxial Prosthetic Foot for Hypomobile Transtibial Amputees? A Clinical Comparison on Mobility, Balance, and Quality of Life.

The Scientific World Journal 2015: 261801.

Products

1M10 Adjust vs SACH

Major Findings

With 1M10 Adjust compared to SACH:

→ Self selected walking speed is higher

Level walking speed: 6% increase

Stairs walking time: up: 13% decrease, down: 15% increase

→ Ambulatory skills and balance improve significantly

LCI-5 score: +9%

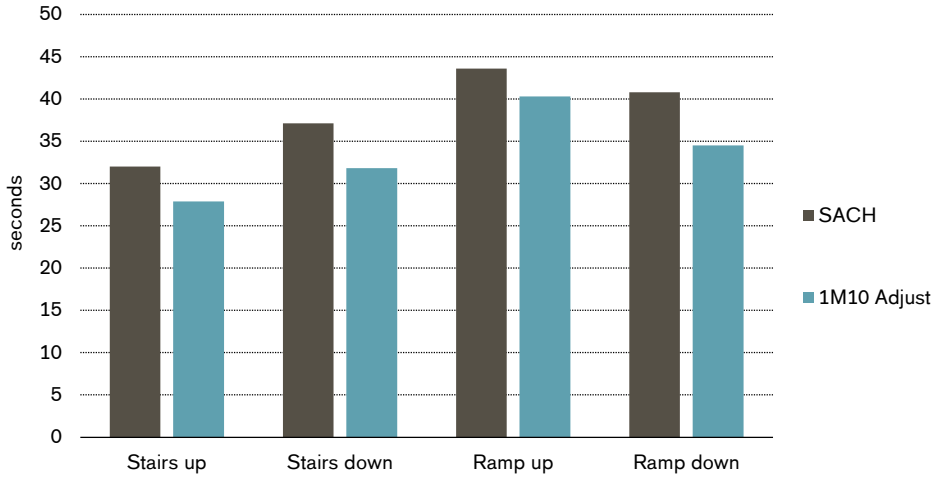
BBS score: +8%

→ Satisfaction with the prosthesis is significantly higher

Improvements in all domains

Statistical significant improvement: ambulation, residual limb health, utility, well-being

Reduced time to negotiate stairs and ramps



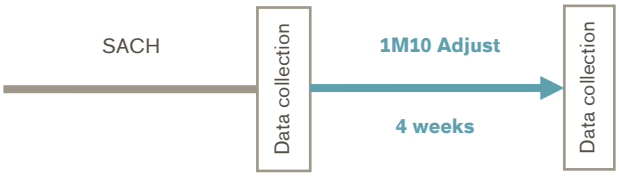
The time needed to traverse stairs or a ramp was measured. The stairs were 2 meters wide containing 12 steps. The ramp had a length of 28 meters with a slope of 10 degrees.

Population

Subjects:	20 transtibial amputees
Previous prosthesis:	SACH (solid ankle cushion heel) foot
Amputation causes:	vascular disease (65%), trauma (30%), neoplasia (5%)
Mean age:	66.7 ± 6.7 years
Mean time since amputation:	9.8 ± 13.5 years
MFCL:	K2 (95%), K1 (5%)

Study Design

Interventional, pre- to post-test design:



After fitting with 1M10 Adjust, subjects had an acclimatisation time of 4 weeks to get familiar with the new prosthesis.

Results

Activities								Participation	Environment
Level walking	**Stairs**	**Ramps, Hills**	**Uneven ground, Obstacles**	**Cognitive demand**	**Metabolic energy consumption**	**Safety**	**Activity, Mobility, ADLs**	**Preference, Satisfaction, QoL**	**Health economics**

Category	Outcomes	Results for 1M10 Adjust	Sig.*
Level walking	6 Minute Walking Test	**The self selected walking speed was significantly higher (+6%).**	++
	UGS (Upright Gait Stability)	Despite a higher walking speed the subjects gait was more stable.	+
Stairs	SAI (Stair Assessment Index)	**Going up and down stairs was performed significantly faster (up +13%, down +15%) and with an improved walking quality.**	<Sig.>
Ramps, Hills	HAI (Hill Assessment Index)	**Going up and down a ramp was performed with a significantly improved walking quality.** The performance time did improve, but did not reach a significant level.	++ +
Safety	BBS (Berg Balance Scale)	**The median BBS Score increased by 8%, indicating a signifantly improved balance.**	++
Activity, Mobility, Activities of Daily Living (ADLs)	LCI-5 (Locomotor Capability Index)	**The LCI-5 score increased significantly (+9%), indicating improved ambulatory skills.**	++
Preference, Satisfaction, Quality of Life (QoL)	PEQ (Prosthesis Evaluation Questionnaire)	**Significant improvements were found in the domains ambulation, residual limb health, utility and well-being.**	++

* no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)

Author's Conclusion

"To identify the most proper prosthesis and improve user efficiency and safety, it is important to study the effect of different feet on a specific category of amputees. This paper fills an important gap in the literature as, to the best of our knowledge,

there are no similar studies about the considered prosthetic feet for low-activity users with so wide a range of clinical evaluations. After the replacement of the SACH with a multiaxial foot, patients have maintained the same level of stability and perceived safety, while presenting a significant albeit slight improvement in some important clinical aspects of TTAs' daily living, as overall mobility, balance, general comfort, and the perceived satisfaction with their own prosthesis. Our findings demonstrate that a multiaxial foot represents an alternative solution with respect to the conventional SACH in the prescription of prosthetic feet for hypomobile TTAs. Thus, the range of prosthetic devices available to practitioners involved in amputee rehabilitation is increased, therefore allowing them to select themost appropriate solution for each specific subject based on their clinical experience." (Paradisi et al. 2015)

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