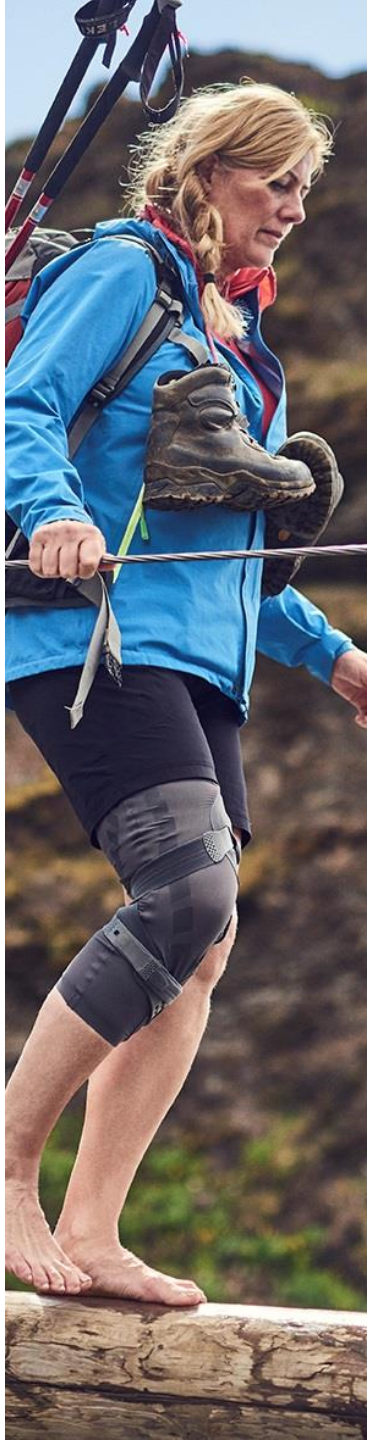


ÖSSUR®

ACADEMY

Introducing the New PROPRIO Foot

Sarah Mulroy-Lang (CPO) and Cathy Howells (Physiotherapist)

March 2019

Proprio Background

2006

Össur launches the world´s first microprocessor-controlled prosthetic ankle-foot system for lower limb amputees.

2016

Pro-Flex® is launched introducing carbon technology that provides significantly greater ankle power than conventional carbon feet.

2018

New PROPRIO FOOT® :

Innovative design of PROPRIO FOOT ®

+

Pro-Flex ® LP

Proprio – What's New

Weatherproof

Improved usability
- Simpler user interface
- Össur Logic connectivity

Faster terrain adaptation

Integrated battery

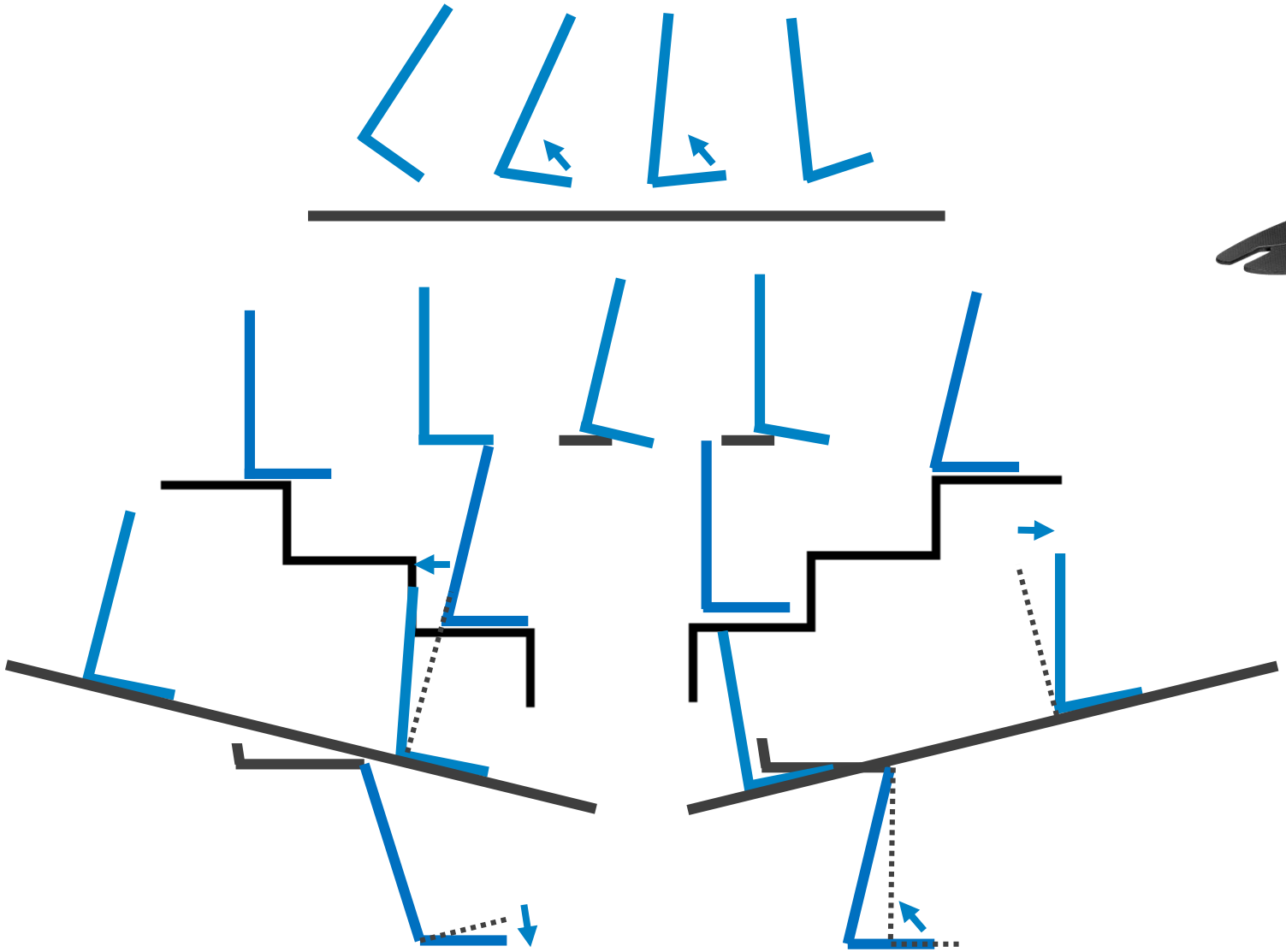
Increased ROM

Excellent stance dynamics

Proprio Foot Function Overview

Core functions:

- Swing dorsiflexion
- Ankle alignment
- Stair adaptation
- Ramp adaptation
- Relax/Chair exit



User Profile

ÖSSUR ACADEMY

- **Low to moderate active users**

- Unilateral transtibial amputation
- Bilateral transtibial amputation
- Unilateral transfemoral amputation

ÖSSUR DYNAMIC SOLUTIONS

User Information	
Amputation Level:	Transtibial and Transfemoral
Impact Level:	Low to Moderate
Maximum Patient Weight:	125kg (275lbs)

Case-by-case assessment:

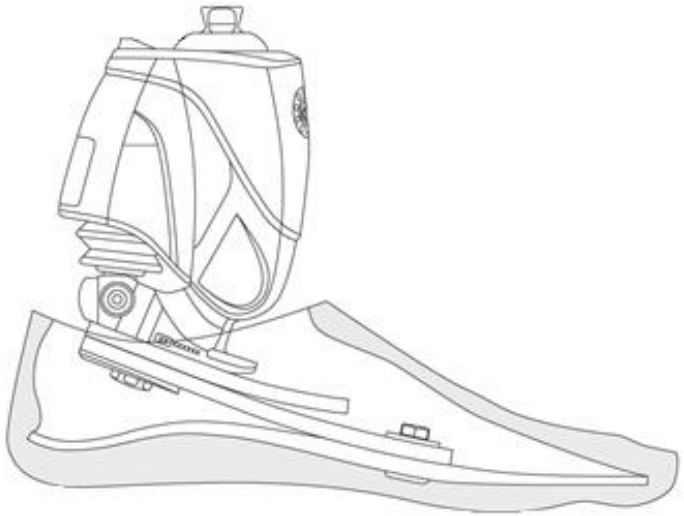
- Bilateral transfemoral amputation
- Limited residual limb control

Proprio Ankle ROM

- Total Ankle ROM: 33°
  - Size 27: **Movement range:** 19° Dorsiflexion to 14° Plantarflexion

    Ankle aligmment range: 2° Dorsiflexion to 14° Plantarflexion

    Heel Height Accommodation: up to 50mm
- Average ROM foot module: approx. 16°
- Unity available for sizes 25-30



CATEGORY SELECTION GUIDE

Weight kg	45-52	53-59	60-68	69-77	78-88	89-100	101-116	117-125
Weight lbs	99-115	116-130	131-150	151-170	171-194	195-220	221-256	257-275
Low Impact Level	1	1	2	3	4	5	6	7
Moderate Impact Level	1	2	3	4	5	6	7	8

Foot Cover

- Beige and brown foot covers
- FSF - narrow footcover
  - Used for small sizes, allows room for ankle module
  - No attachment plate
  - Lower opening
- FST - standard Pro-Flex family footcover
  - Attachment plate

FSF

FST

SELECTION CHART FOR PRODUCT VARIANTS

Category	1	2	3	4	5	6	7	8
Size 22	FSF Foot Cover No Unity available					N/A		
Size 23								
Size 24								
Size 25	FST Foot Cover Unity available							
Size 26								
Size 27								
Size 28	N/A			FST Foot Cover Unity available				
Size 29								
Size 30								

Warranty Information

- 2 year warranty included
- Extended warranty available for purchase
- Maximum total warranty is 5 years- must be purchase within 1 year of original purchase date

EXTENDED WARRANTY

PROPRIO FOOT KIT EXTENDED WARRANTY*

Part#	Description
PSXGE1Y	1 Year Extended Warranty
PSXGE3Y	3 Year Extended Warranty
PSX1SC40M	40 Months Service Check

* Initial PROPRIO FOOT limited warranty period: 24 months. Extended warranty is available for purchase, contact Össur Customer Service for options and prices. Maximum total warranty period is 5 years, must be purchased within one year of original purchase date.

Comparison of Old vs New Proprio

Specification	OLD	NEW
Ankle range of motion	29°	33°
Stair Adaptation	Ascent: After the second prosthetic step Descent: After the second prosthetic step	Ascent: After the first prosthetic step Descent: After the first prosthetic step
Ramp Adaptation	8 prosthetic steps to 85% of surface (15°)	3 prosthetic steps to 85% of surface (15°)
Relax	Yes	Yes
Chair Exit	Yes	Yes, faster detection
Auto-Adjustment	16 prosthetic steps	15 prosthetic steps
Minimum walking speed	2.3 km/h	1.4 km/h
Build Height (27 Cat 5)	169 mm	180mm
Weight (27 Cat 5)	1.4kg (incl. battery)	1.5kg (incl. battery)
App Connectivity	N/A	Össur Logic

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Swing Dorsiflexion

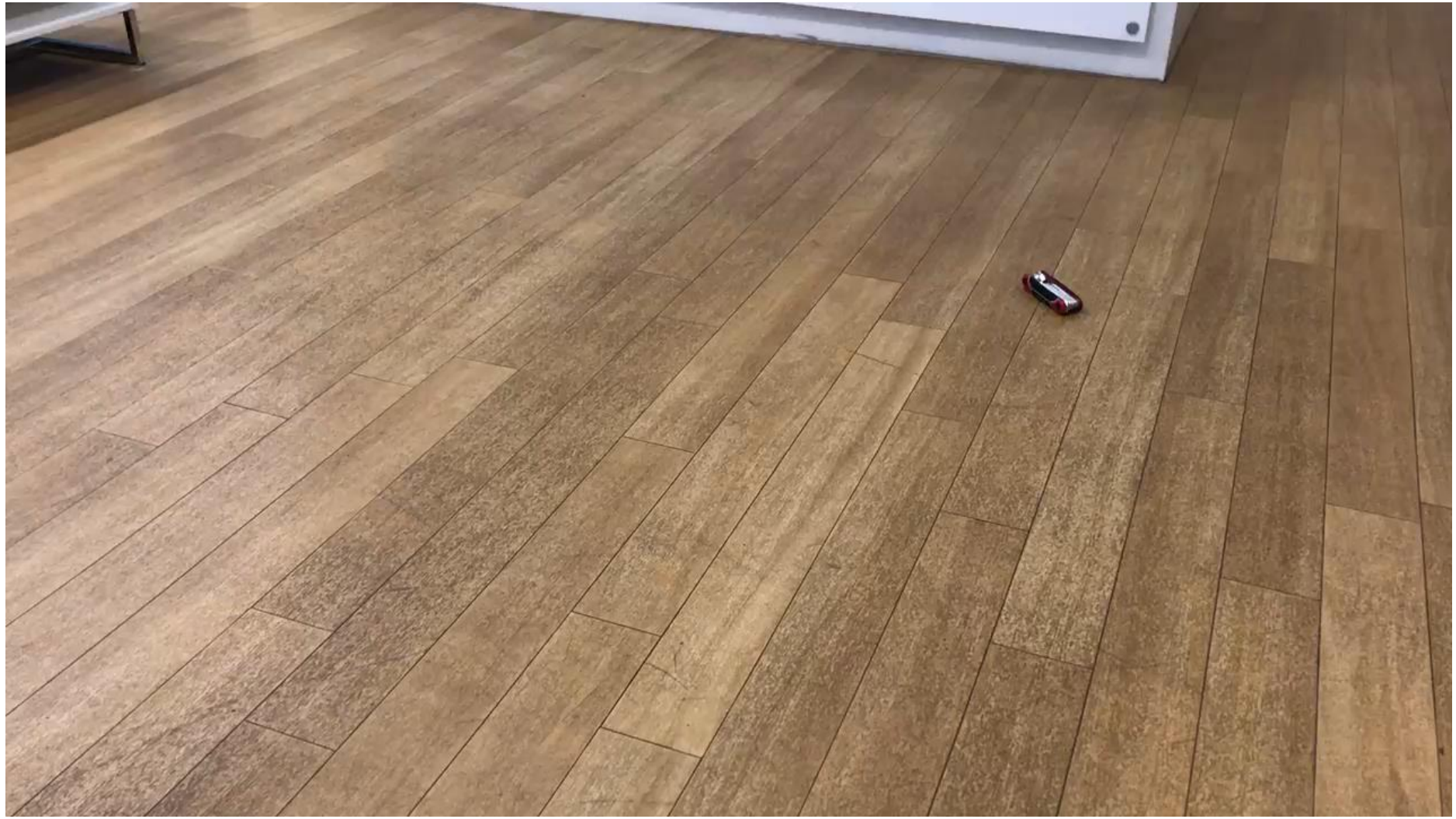
- After 2 prosthetic steps
- 4° toe-lift

- Stair descent
  - No toe-lift

	Minimum speed	Minimum swing phase duration
Level ground / ramps	1.4 km/h / 0.9 mph	0.4 seconds
Stair ascent	1.2 km/h / 0.8 mph	0.4 seconds

Swing Dorsiflexion

Mid-Swing Dorsiflexion- Clearing Objects



Features – Benefits: Swing Dorsiflexion

Technical Features	Functional Benefits	Medical Necessity	Benefits for the End User
Mid swing dorsal flexion	Improved ground clearance	Safety	Less risk of trips and falls

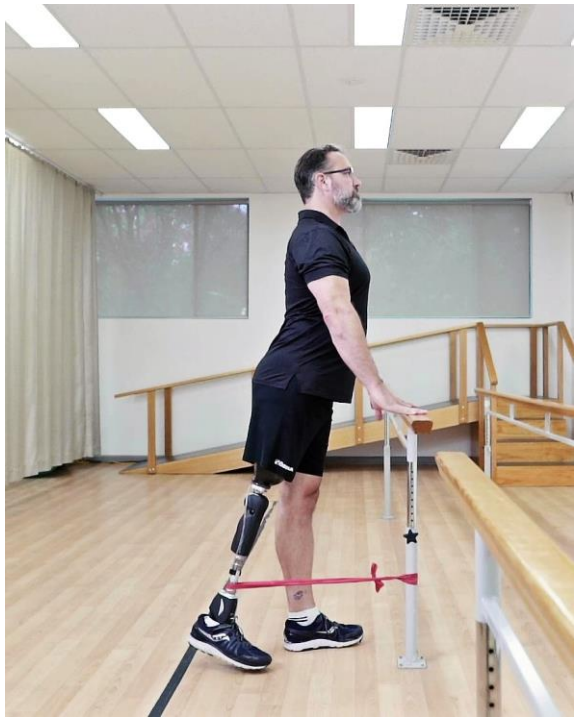
Improved Ground Clearance – Training Implications

- Reduces the propensity for hip hitching and premature prosthetic swing phase and so improving efficiency of gait.
- Increases the confidence of the amputee to reach a strong prosthetic toe off.

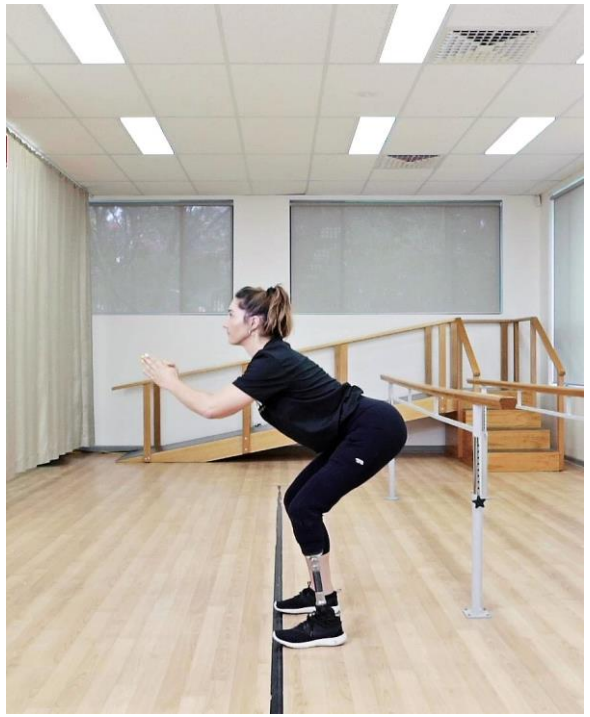
Training Implications: Using Prosthetic Toe Lever

- Allows energy return from the ProFlex LP component
- Allows Equal Step Length
- More Natural Gait
- Reduced walking effort on level ground, ramp ascent and descent
- Smoother progression onto the sound limb

Training Strategies for Achieving a Strong Toe Off:

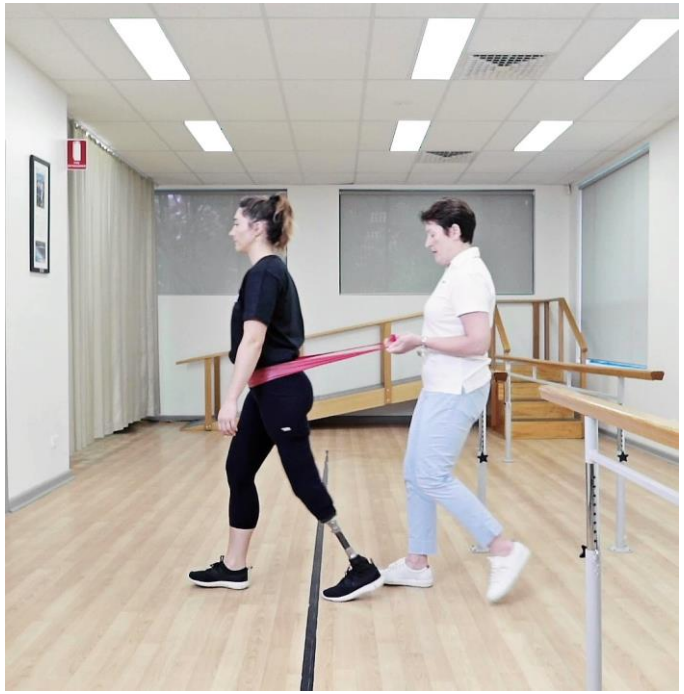


Full ROM hip E and E strength



Strengthen Extensor Mechanism for T/ts.

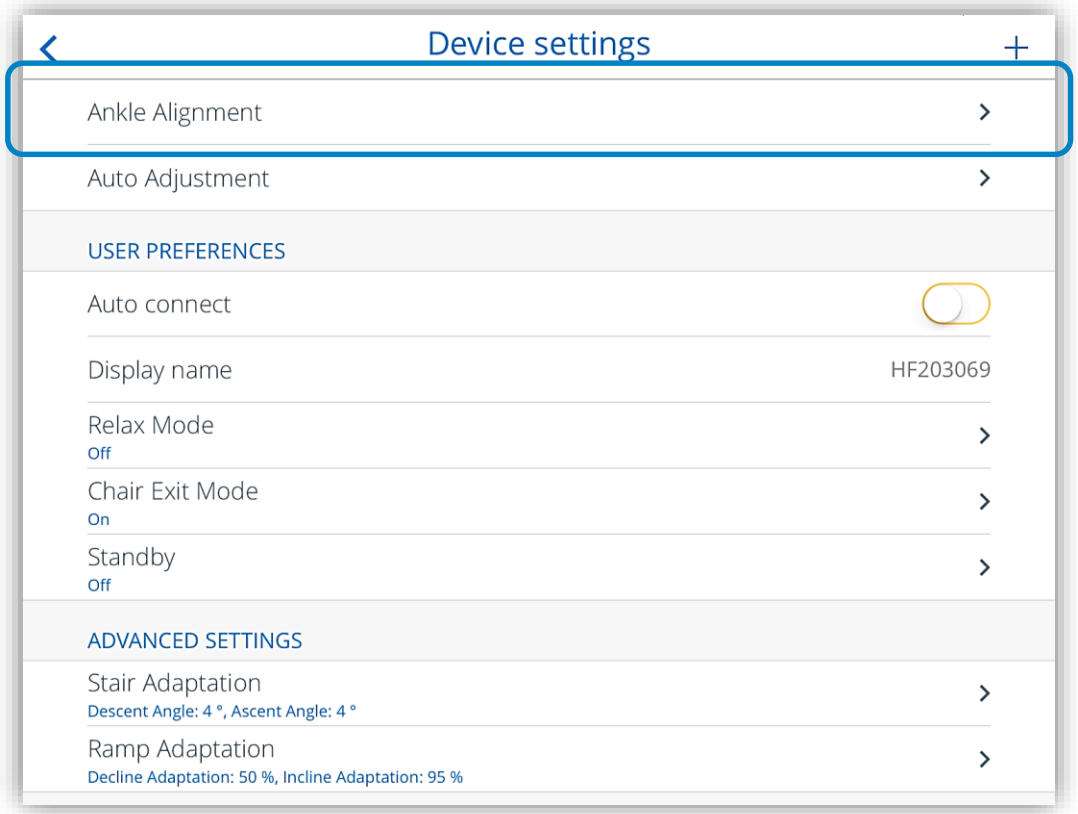
Eccentric and concentric control of the knee



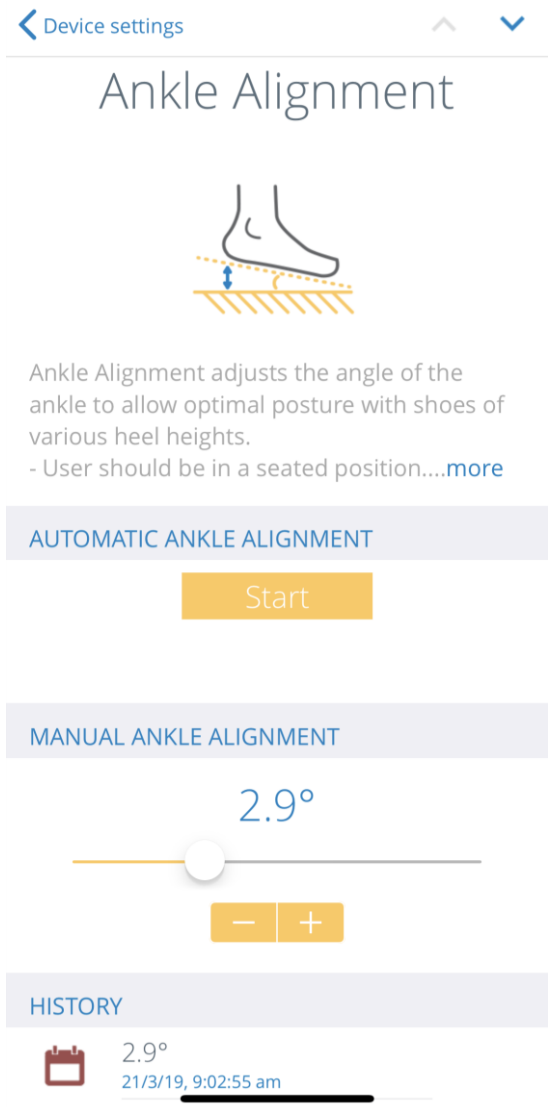
Resisted Gait Training

Alignment

- Ankle Alignment
  - User interface or Össur Logic app
  - Barefoot to 5 cm heel height
  - Performed by the user



Ankle Alignment- Using Össur Logic app

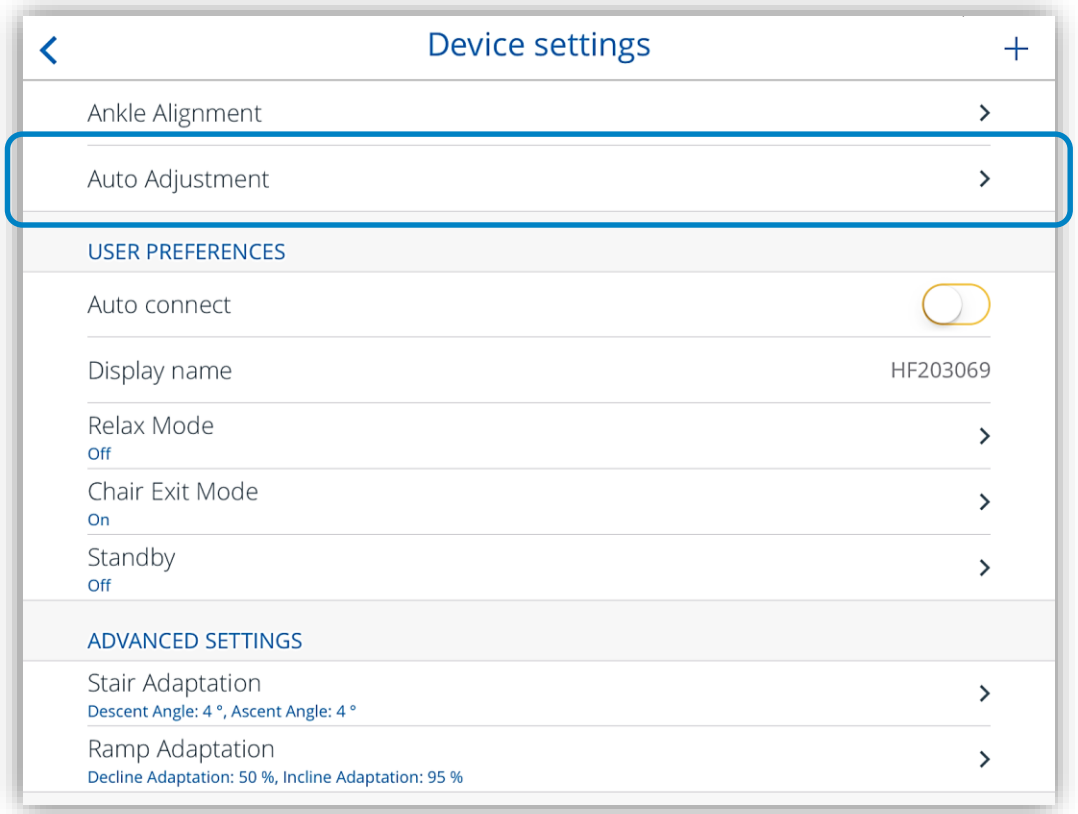


Ankle Alignment- User interface button

- Ankle Alignment
  - User interface or Össur Logic app
  - Barefoot to 5 cm heel height
  - Performed by the user

Adjustment

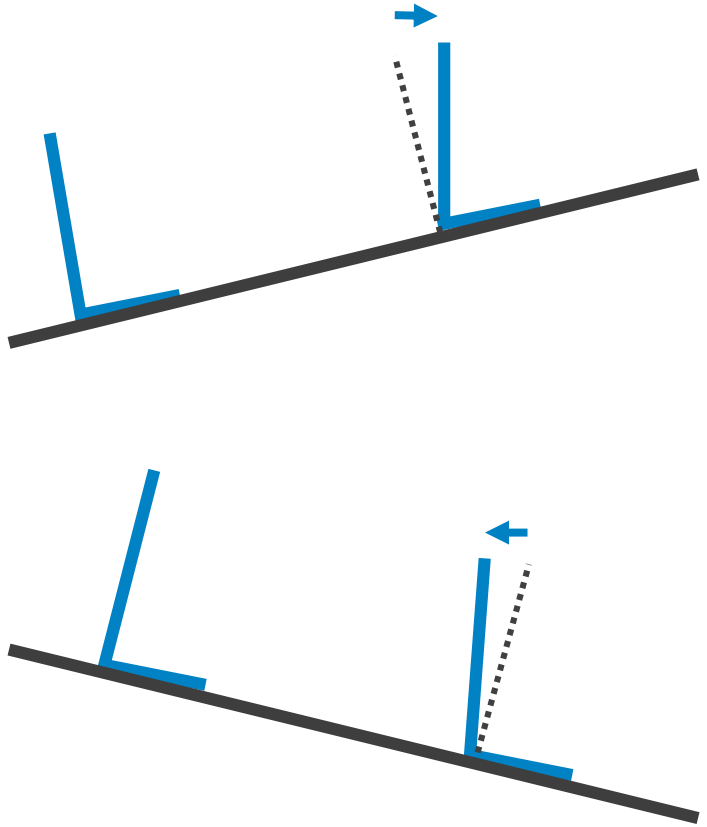
- Auto Adjustment
  - Recognition of user's specific gait parameters
  - Calibrates to user's gait parameters
  - Essential for accurate and consistent terrain detection



Ramp Adaptation

- Adjustable adaptation on ramps

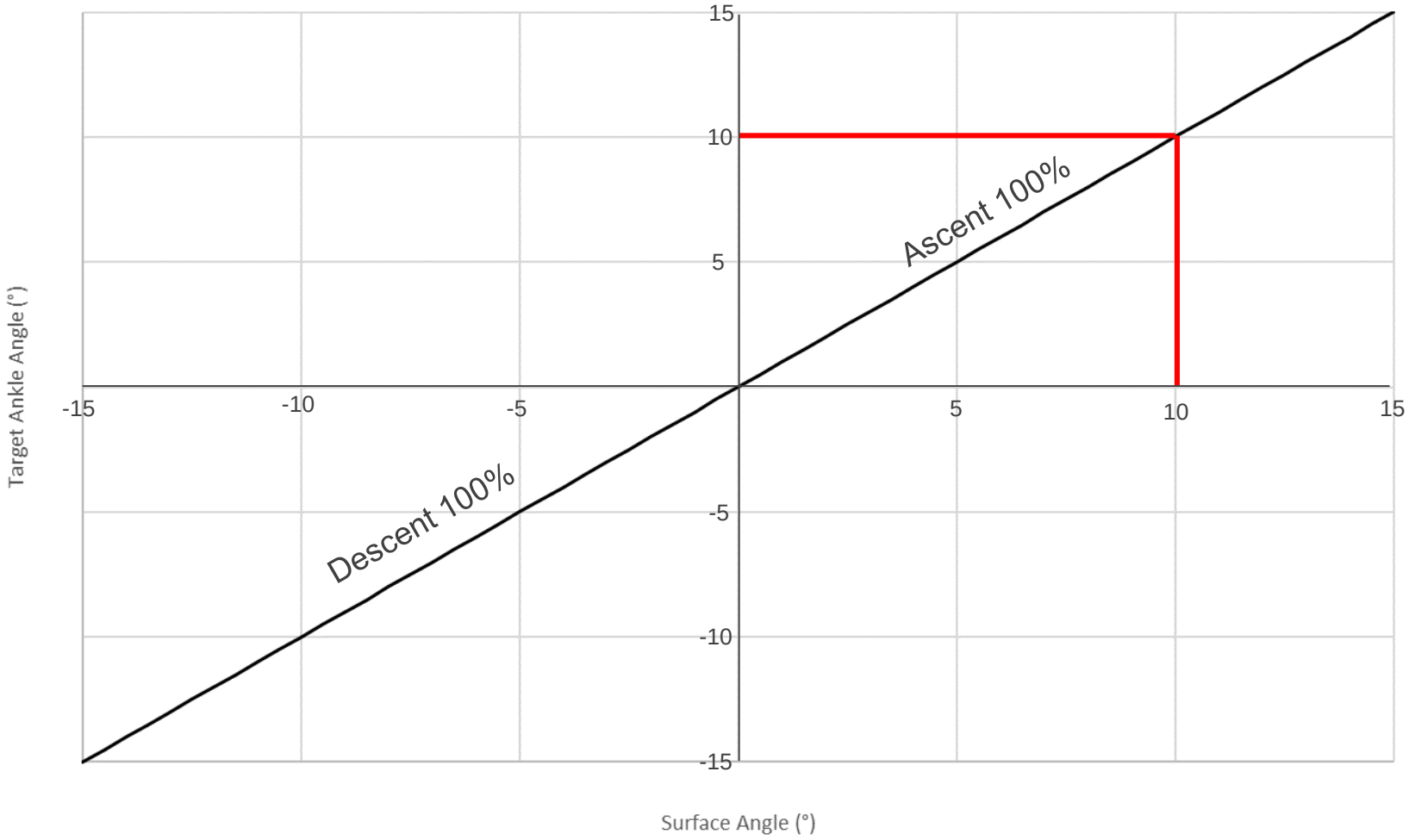
	Min	Default	Max
Ramp Ascent	0%	70%	150%
Ramp Descent	0%	65%	100%



- Near full adaptation - after three prosthetic steps
- Maximum ramp angle - approx. 15°
- Tips:
  - Very active users - consider lowering descent value (to about 30%)
  - Insecure users - consider increasing the descent value slightly

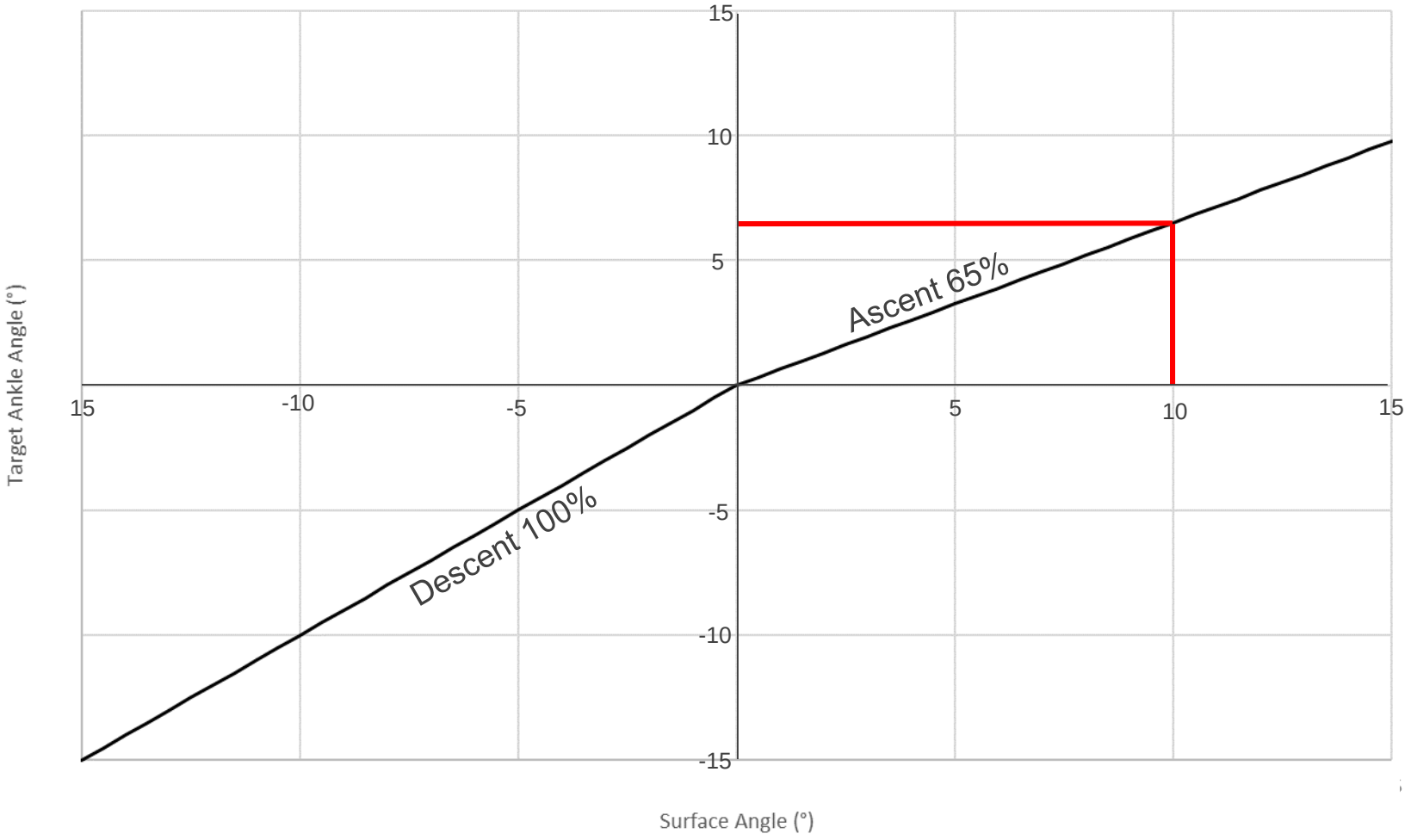
Ramp Adaptation

- Ramp Adaptation setting
  - Controls adaptation as percentage of surface angle
- Example:
  - Setting 100%
  - Surface angle 10°
  - → Ankle Angle 10°



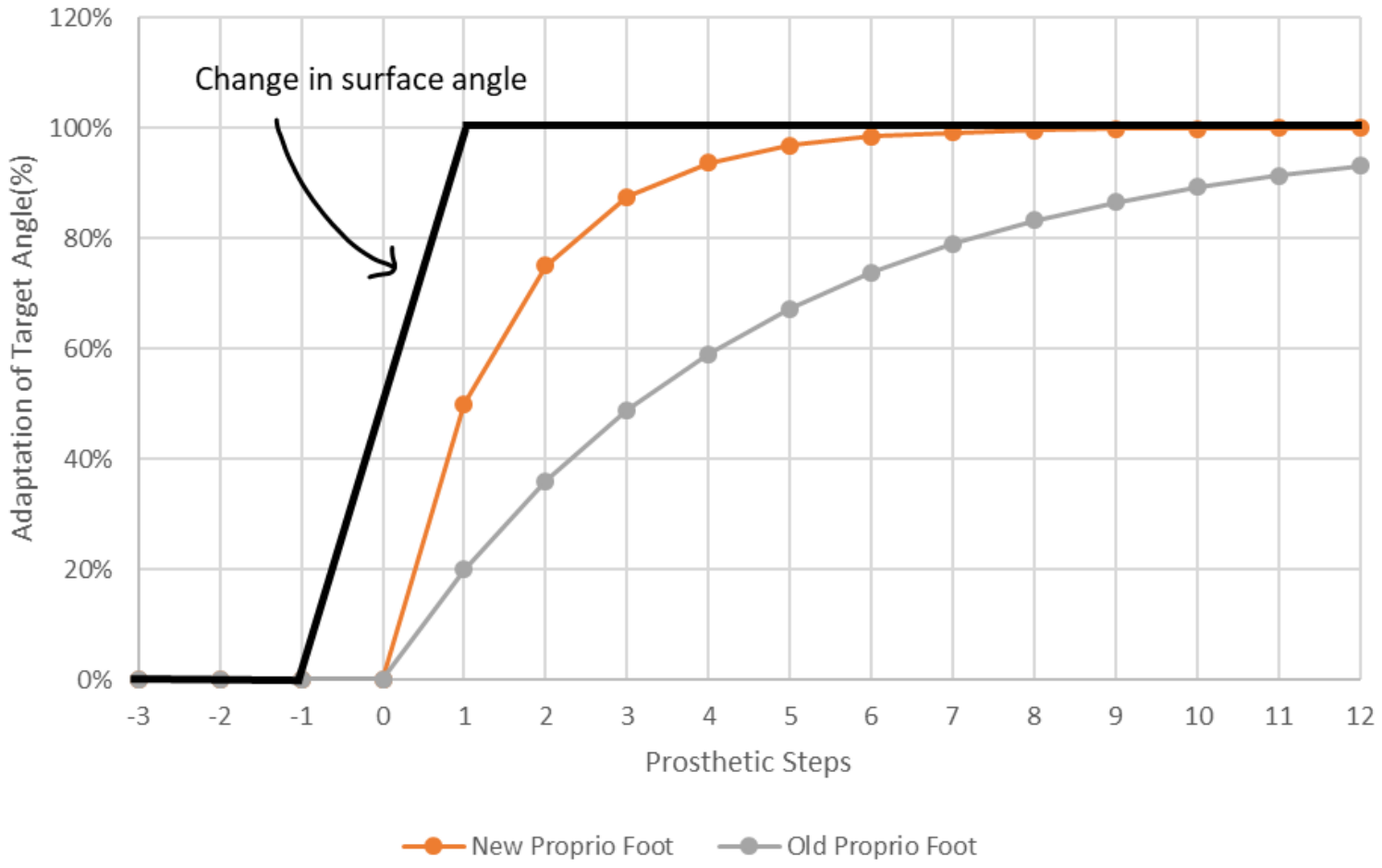
Ramp Adaptation

- Ramp Adaptation setting
  - Controls adaptation as percentage of surface angle
- Example:
  - Setting 65%
  - Surface angle 10°
  - → Ankle Angle 6.5°

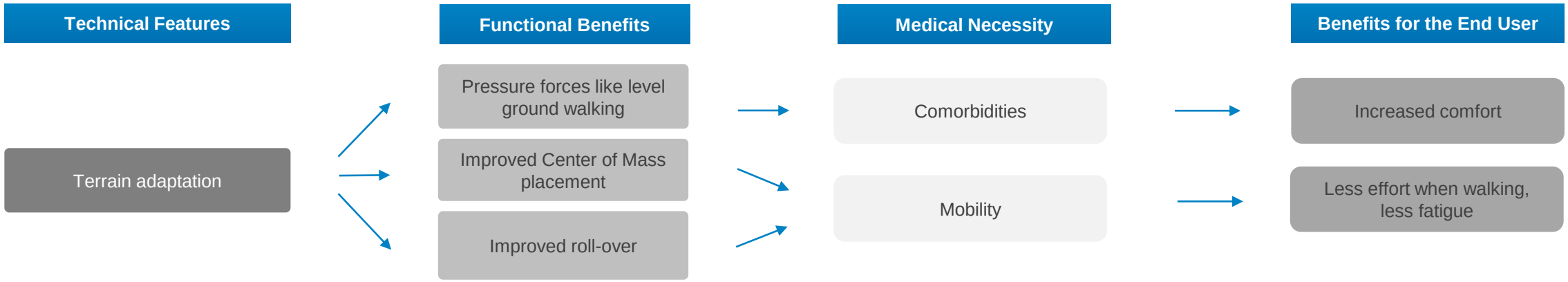


Ramp Adaptation

- Faster adaptation
  old (grey) vs new (orange)
- User's perception of adapted foot around 50% adaptation



Features – Benefits: Terrain Adaptation



Ramp Ascent

- Proprio increases ease of symmetrical ramp ascent due to improved foot clearance, progression over the foot and ability to increase sound stride length.

- The user will need to be trained to keep an upright posture and to strongly extend the affected side hip.

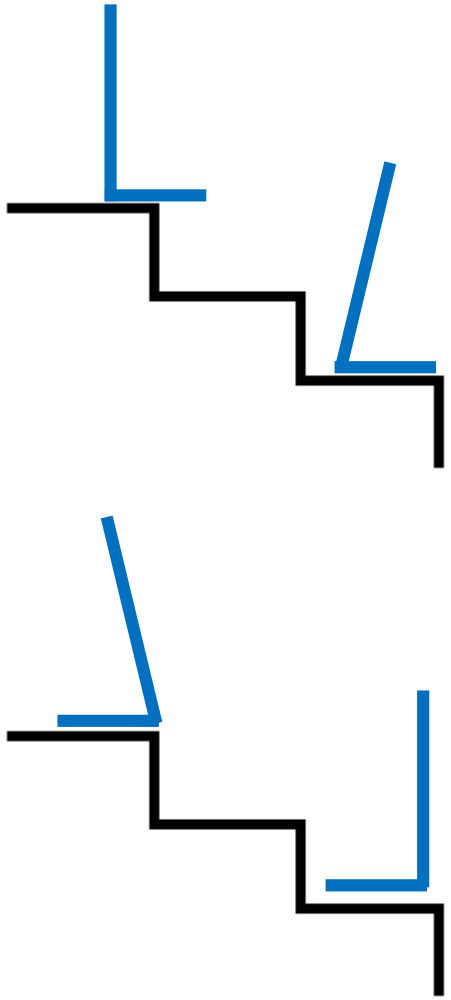
Ramp Descent- Training Considerations

- Maintenance of erect posture is essential for TT and TF users
- Transtibial amputees will need some eccentric/concentric quad control exercises to assist with control the knee as the body weight progresses over the foot.

Stair Adaptation

- Adjustable adaptation on stairs
  - Adaptation after the first full prosthetic step in stairs
  - Sound side first is the preferred way
  - Can adjust on the Össurlogic app

	Min	Max
Stair Ascent	0°	6°
Stair Descent	0°	6°



Stair Ascent Adaptation

Stair Adaptation – Ascent Training Considerations

- Stair adaptation enables activation of the quad/gluteal complex in a more ‘natural’ position so that less generation of force is required to move the body weight up over the prosthetic foot.
- When this is turned off, excessive knee hyperextension can occur
- Having this feature turned increases the potential for TT users to ascend stairs “leg over leg”.

OFF

ON

Stair Descent- Training Considerations

- More of the prosthetic foot length remains on the step.
- Improved user confidence.
- Enables a greater population of TT amputees to descend stairs with the “leg over leg” method.
- Inner range knee control exercises are of benefit here. In particular the eccentric component.

Features – Benefits: Stair Adaptation

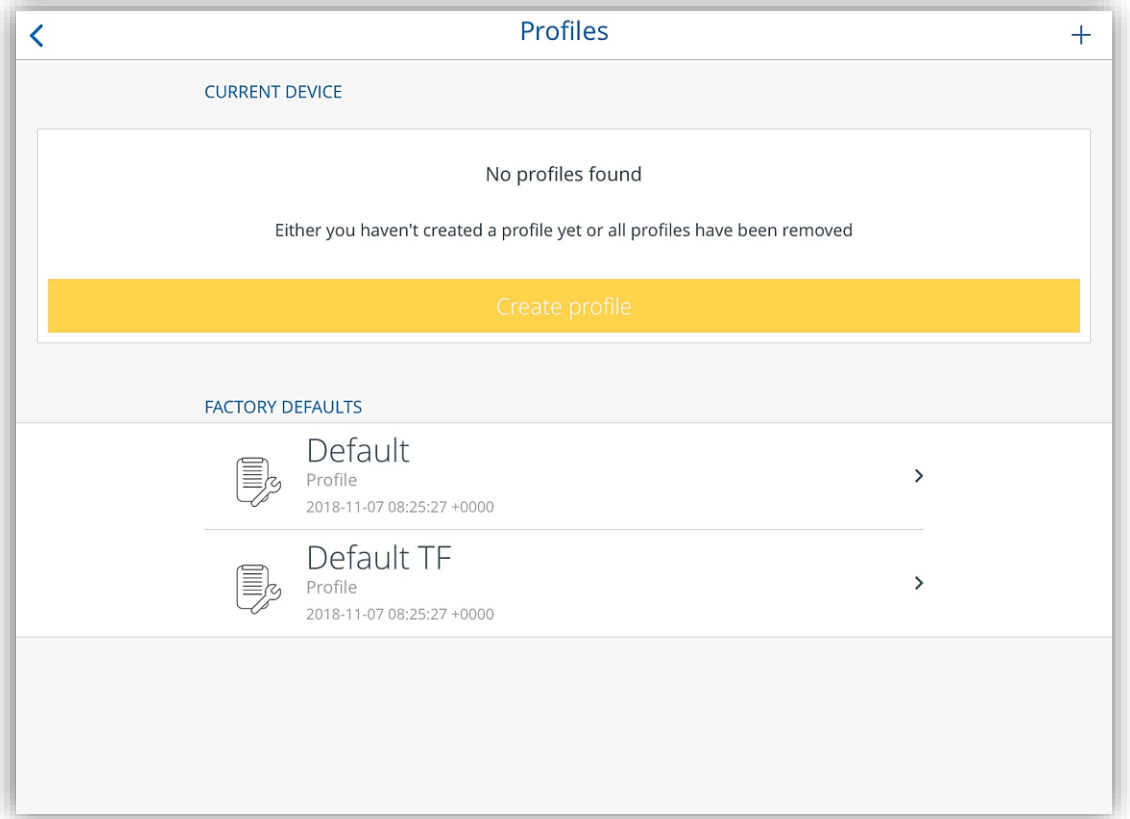
Technical Features	Functional Benefits	Medical Necessity	Benefits for the End User
Stair adaptation	Pressure forces like level ground walking	Comorbidities	Increased comfort
	Improved Center of Mass placement	Mobility	Less effort when walking, less fatigue
	Improved roll-over	Safety	Increased stability

Stair Adaptation OFF

Stair Adaptation ON

Profiles

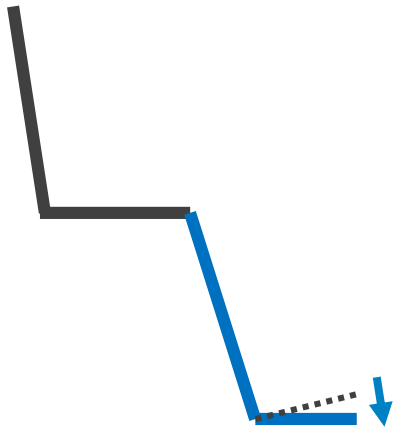
- Transfemoral (default profile)
  - Stair ascent: 0°
  - Stair descent: 0°
  - Safety:
    - Adaptation in stairs can cause instability for TF users
    - Depends on knee and walking style
- Transtibial
  - Stair ascent: 4°
  - Stair descent: 2°



Relax and Chair Exit Recognition

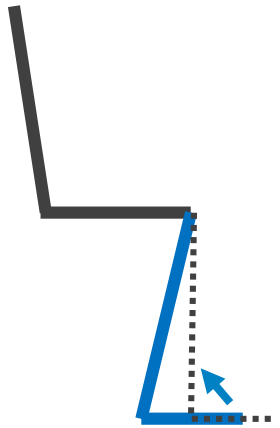
Relax:

- Detected when sitting and shank is tilted >30^{o}
- Foot still for two seconds
- Foot moves to full plantarflexion
- Also activated when kneeling (-60^{o})



Chair Exit:

- Detected while moving the foot backwards or sideways
- Foot moves to 5° dorsiflexion
- Back to neutral in next swing phase



Relax and Chair Exit Recognition

Ankle Appreciation Exercise

- Prepare to stand from your seated position.
- Place your feet under your knees with your ankles in plantargrade.
- Stand without allowing your knees to move forward. (ie **No DF** at your ankles)

Chair Exit Mode Training Considerations

- Increased DF of the Proprio increases ease of standing from the seated position.
- Enhancement of posture to assist the hip and knee extensors to propel the body weight to standing.

Pro-Flex Foot

vs

Proprio Foot

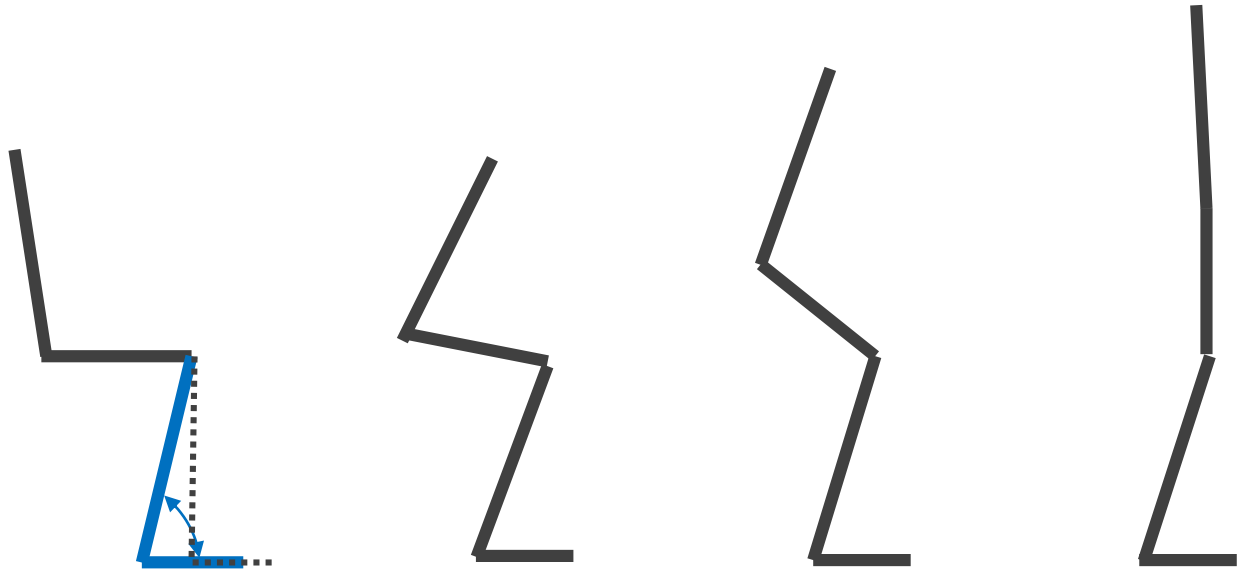
Resisted Training for Sit to Stand

- Resisted Training will increase the amount of weight taken through the prosthesis during this movement.

- Strain on the sound side is reduced.

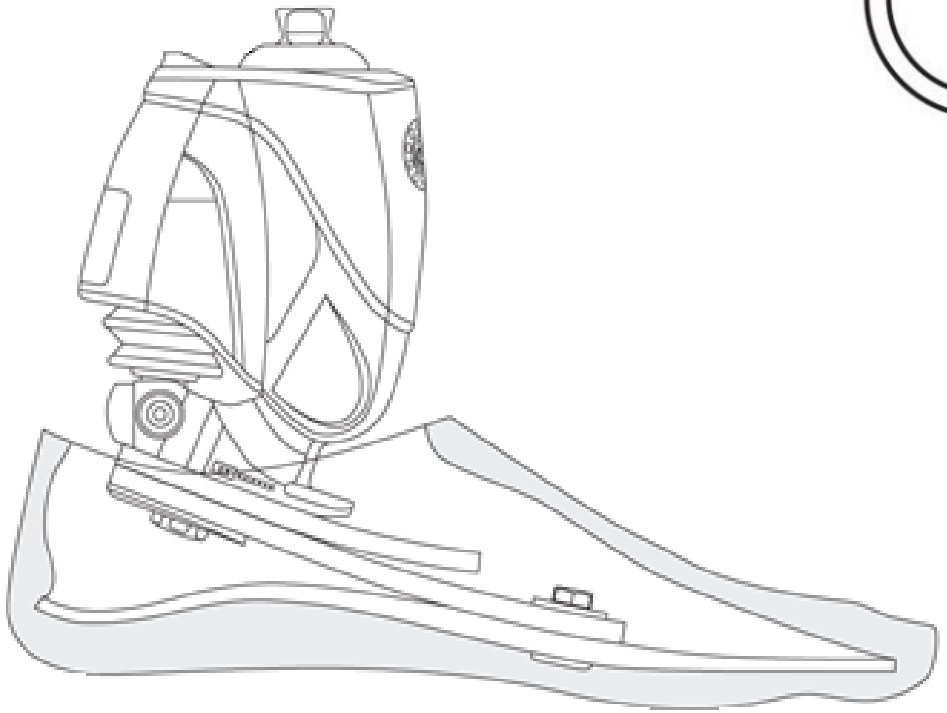
Features – Benefits: Chair Exit Adaptation

Technical Features	Functional Benefits	Medical Necessity	Benefits for the End User
Chair exit adaptation	Increased symmetry	Comorbidities	Less load on the sound side Easier standing up



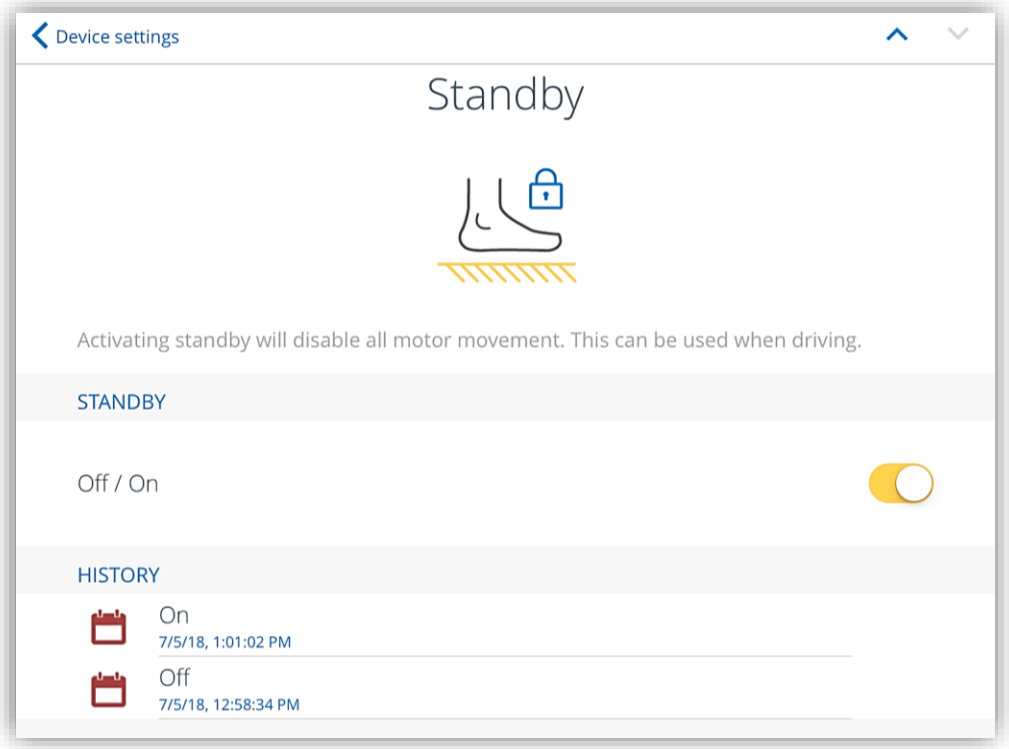
Automatic Cycling Recognition

- Cyclic movement detected when pedaling
- Motor movements disabled
- Holds neutral position



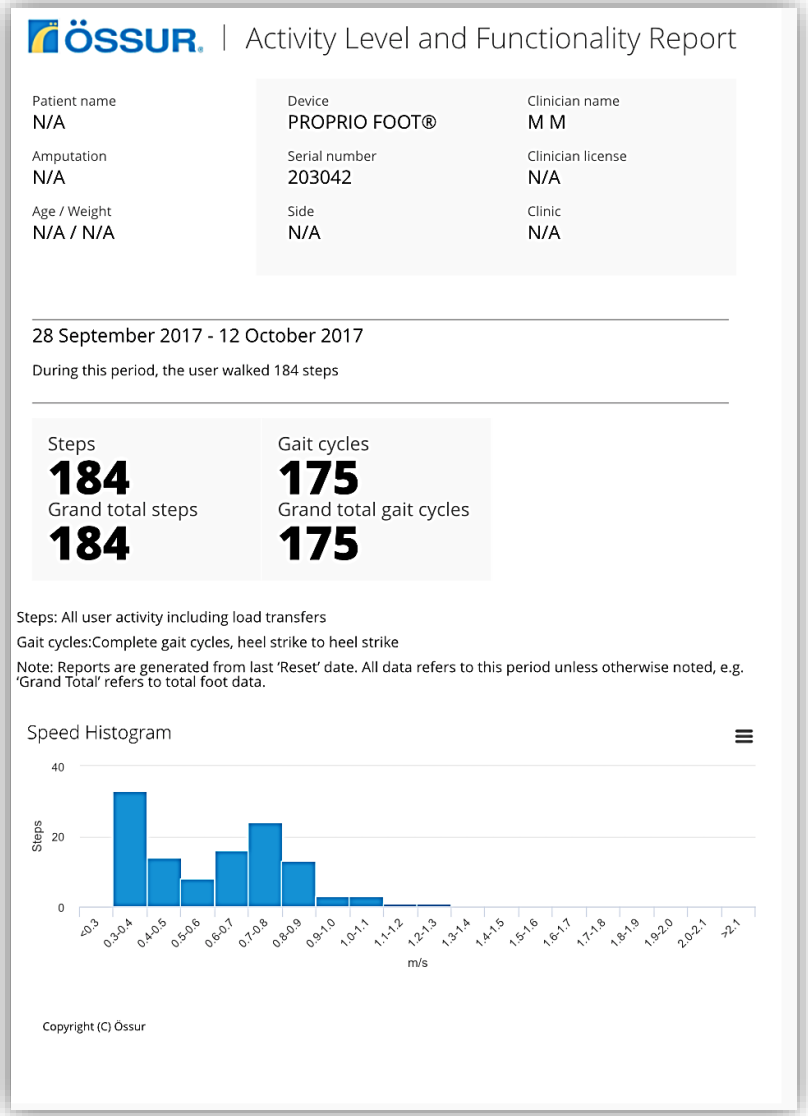
Standby

- Enable in Össur Logic App
- Disables all motor movements
- Example: used for driving



Activity Reports

- Four report options available:
  - Speed Histogram
  - Step Histogram
  - Distance Histogram
  - Surface Histogram



ÖSSUR | Activity Level and Functionality Report

Patient name N/A	Device PROPRIO FOOT®	Clinician name M M
Amputation N/A	Serial number 203042	Clinician license N/A
Age / Weight N/A / N/A	Side N/A	Clinic N/A

28 September 2017 - 12 October 2017

During this period, the user walked 184 steps

Steps	Gait cycles
184	175
Grand total steps	Grand total gait cycles
184	175

Steps: All user activity including load transfers

Gait cycles:Complete gait cycles, heel strike to heel strike

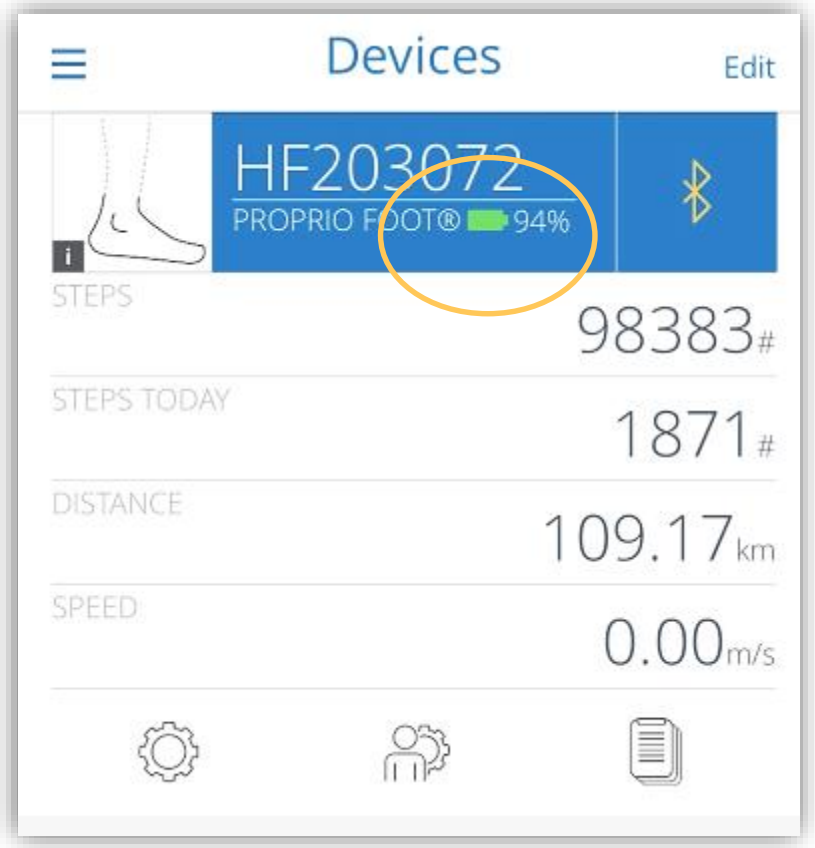
Note: Reports are generated from last 'Reset' date. All data refers to this period unless otherwise noted, e.g. 'Grand Total' refers to total foot data.

Speed Histogram

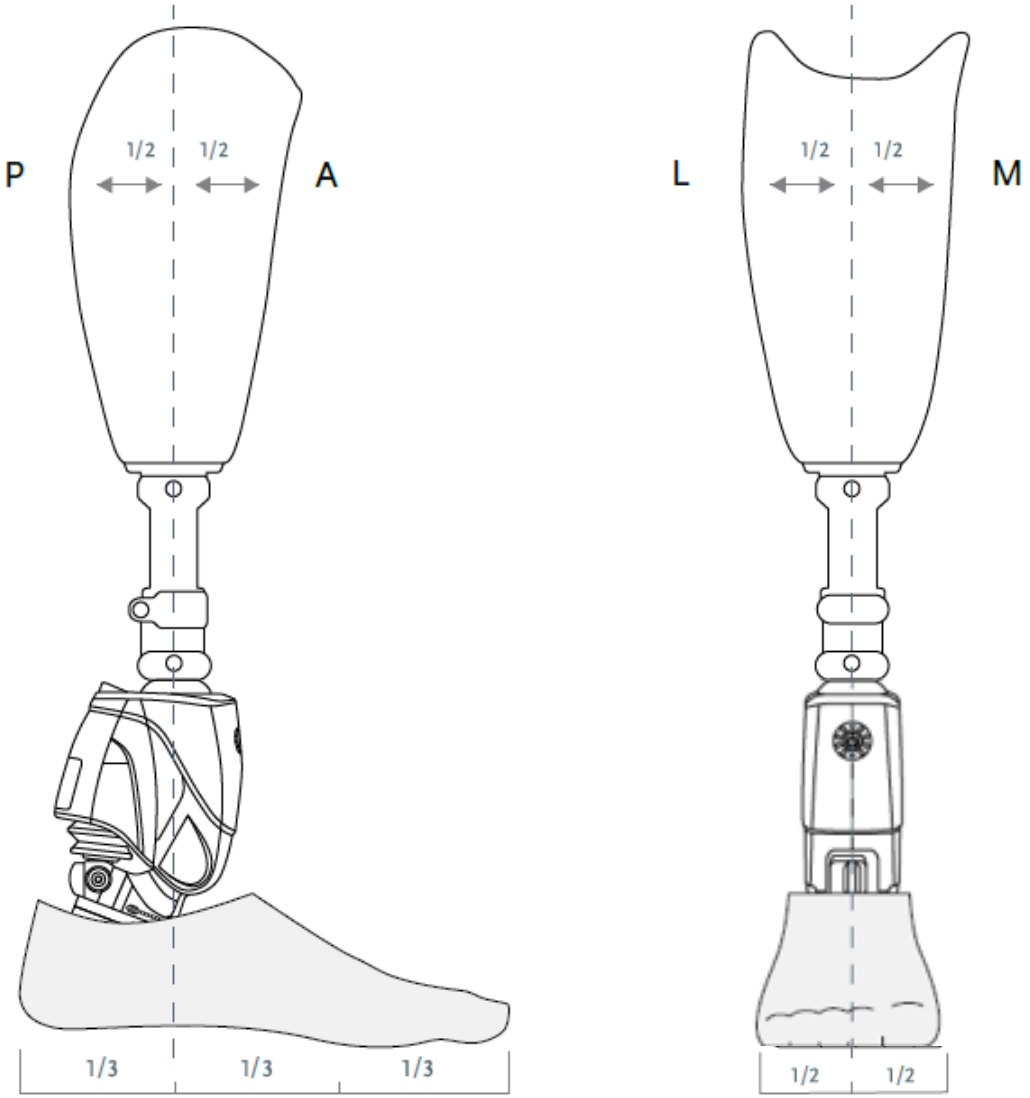
Battery status

- Battery level → solid green LEDs
- Charging in progress → flashing green LEDs

90% charge	~ 3.5 hours
Full charge	4 hours
Battery life	18-36 hours *depends on usage



Alignment



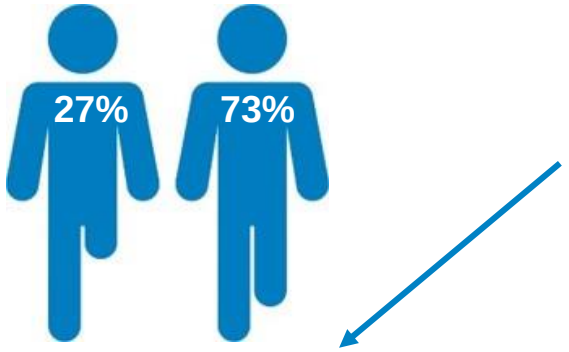
Össur Logic app

Proprio Fitting Sequence

- Turn ON
- Establish connection
- Ankle alignment (with shoe)
- Bench alignment
- Static alignment
- Dynamic alignment
- Auto-Adjustment
- Relax / Chair exit
- Stair adaptation
- Ramp adaptation
- Standby

Medical Necessity | Reported falls | Fear of falling

- n = 435
- Majority TT



52%
reported ≥1 fall in
the past 12 months

Miller, William C., Mark Speechley, and Barry Deathe. "The prevalence and risk factors of falling and fear of falling among lower extremity amputees." Archives of physical medicine and rehabilitation 82.8 (2001): 1031-1037.

- n = 435

52%
reported ≥1 fall in the past 12 months

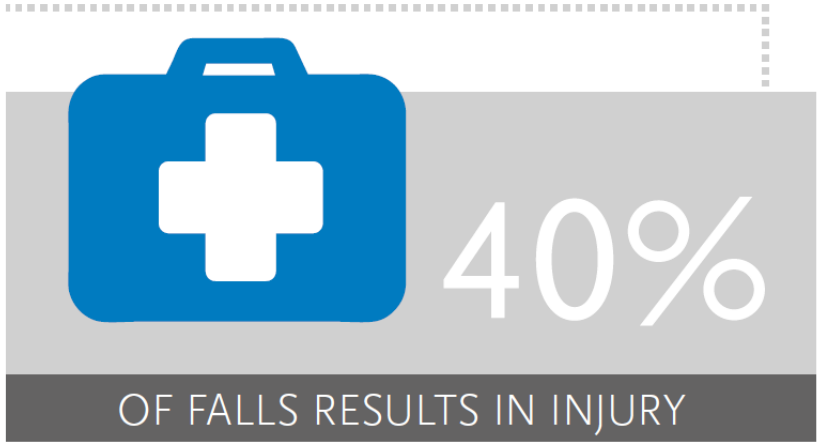
76%
afraid of falling again

49%
reported fear of falling

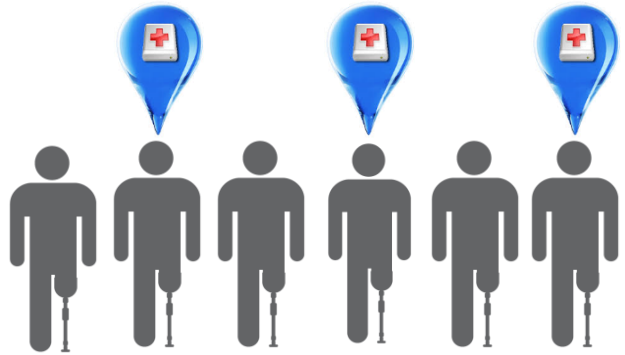
Miller, William C., Mark Speechley, and Barry Deathe. "The prevalence and risk factors of falling and fear of falling among lower extremity amputees." Archives of physical medicine and rehabilitation 82.8 (2001): 1031-1037.

Injuries because of falls

- High risk of TF amputees falling



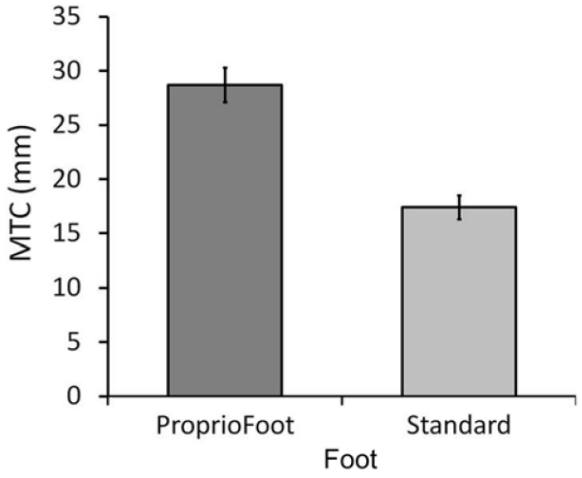
- “1 out of 2 amputees who fall require medical attention”



K. Kaufman, B. Mundell, S. Visscher, H. M. Kremers, D. Larson, and J. Ransom, “Risk factors and costs associated with accidental falls among adults with above-knee amputations: a population-based study,” Mayo Clinic, Rochester, MN, Apr. 2015.

- Changes to Minimum Toe Clearance (MTC) could increase the incidence of trips and fall risk

- MTC ~70% greater



Rosenblatt, Noah J., et al. "Active dorsiflexing prostheses may reduce trip-related fall risk in people with transtibial amputation." J Rehabil Res Dev 51.8 (2014): 1229-1242.

- Changes to Minimum Toe Clearance (MTC) could increase the incidence of trips and fall risk

- MTC ~70% greater

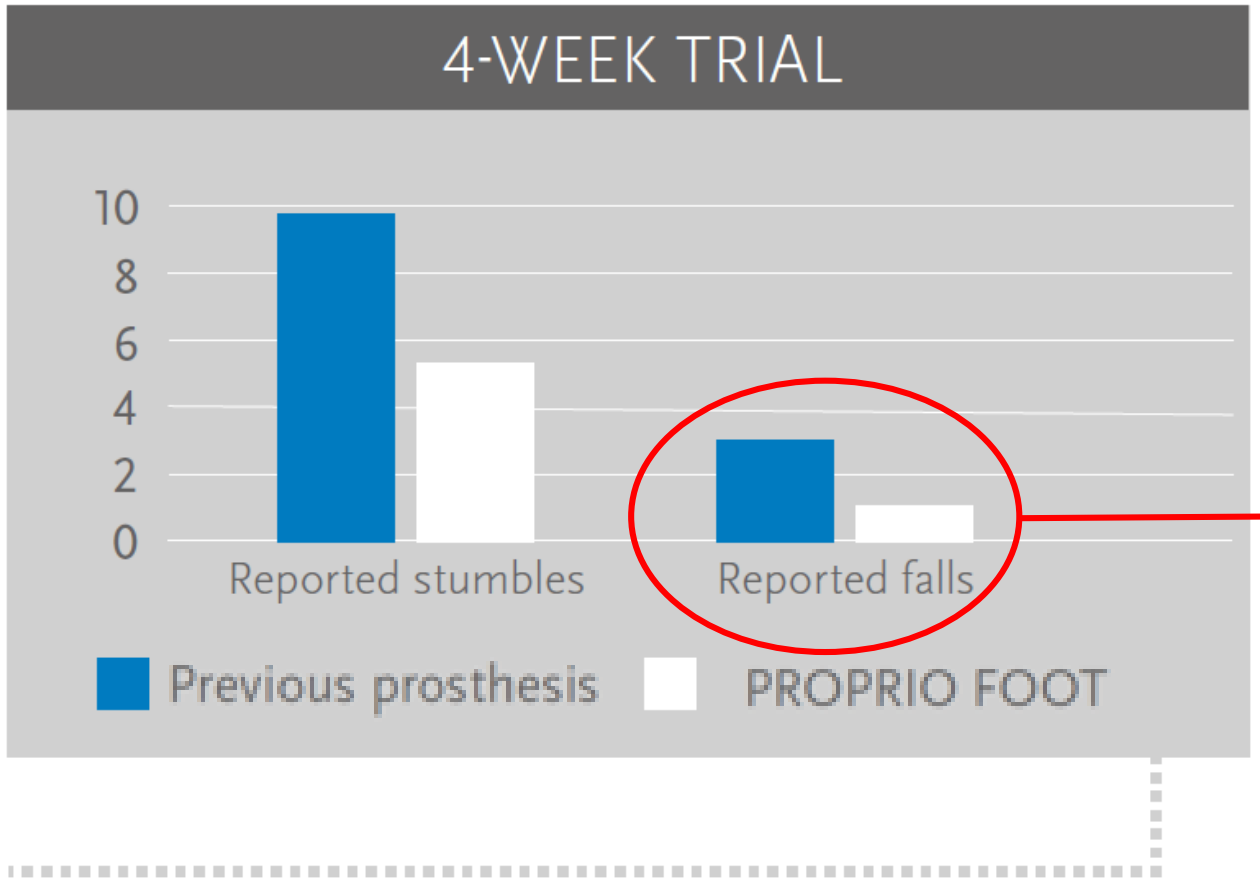
- Decreased likelihood of tripping (and thus the likelihood of a fall)

- Increased safety

Rosenblatt, Noah J., et al. "Active dorsiflexing prostheses may reduce trip-related fall risk in people with transtibial amputation." J Rehabil Res Dev 51.8 (2014): 1229-1242.

- Improved user mobility

- Fewer stumbles and falls



Ludviksdottir A, Gruben K, Gunnsteinsson K, Ingvarsson Th, Nicholls M. Effects on user mobility and safety when changing from a carbon fiber prosthetic foot to a bionic prosthetic foot. Presented at Orthopadie&Reha-Technik Congress, Leipzig, May 2012.

Medical Necessity

More natural stair ascent/descent

- 16 TTA + 16 non-amputees
- Neutral ankle angle vs. 4^{o} adaptation

Knee flexion is restricted because of limited (ankle) dorsal flexion

For both stair ascent and descent improvements of knee kinematics and kinetics

↓

Increased knee flexion and increased knee moment

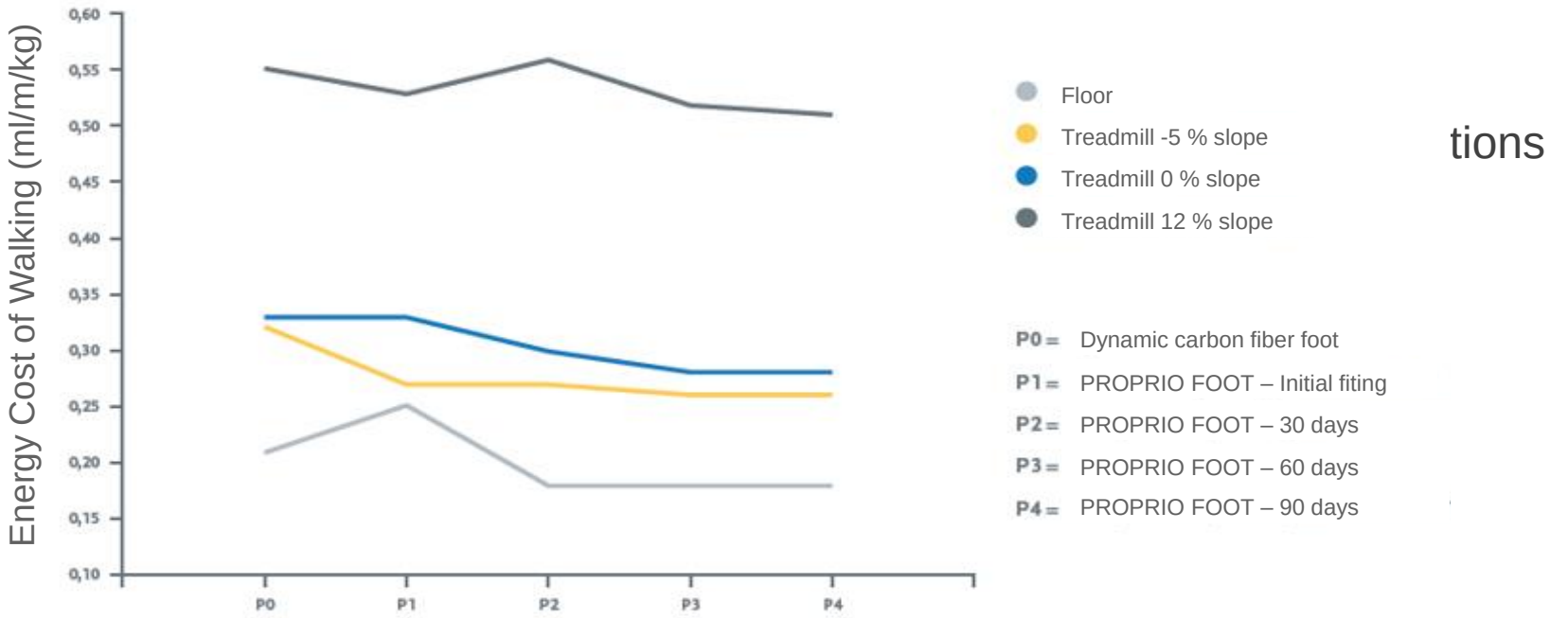
↓

More physiological knee flexion during stair ascent and descent

Alimusaj M, Fradet L, Braatz F, Gerner HJ, Wolf SI. Kinematics and kinetics with an adaptive ankle foot system during stair ambulation of trans-tibial amputees. Gait & Posture. 2009; 30:3:356-363.

Reduced energy consumption

- 10 TTA
- Dynamic carbon fiber foot vs. PROPRIO FOOT
- Suspension changed to Seal-In X5
- Final evaluation after 90 days of use



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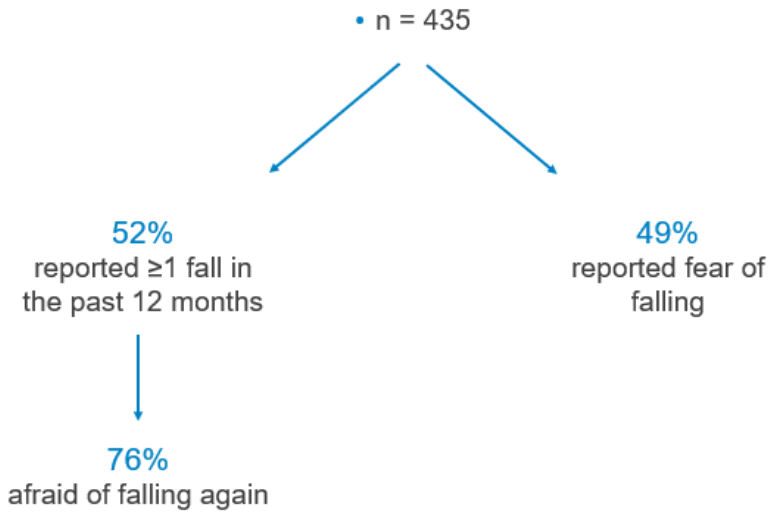
Delussu, Anna Sofia, et al. Assessment of the effects of carbon fiber and bionic foot during overground and treadmill walking in trans-tibial amputees. Gait & posture, 2013, 38. Jg., Nr. 4, S. 876-882.

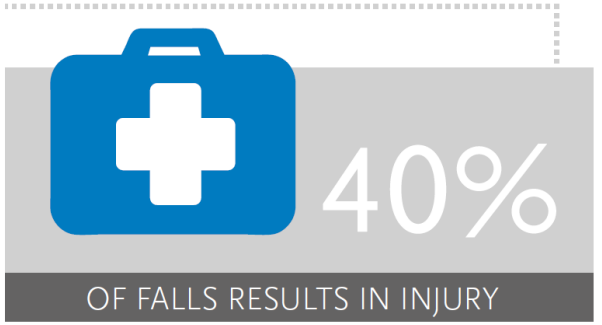
Medical Necessity – Conclusion

- Increase in reported falls
- Fear of falling
- Falls cause injuries



PROPRIO FOOT

- Increased ground clearance
- Decreased trips and falls
- More natural stair ascent/descent
- Reduced energy consumption



Medical Necessity – Whitepaper

PROPRIO FOOT®

Because the world is not flat

Amputees have reported to fall more often than the able-bodied population, contrib
of fear of falling within the amputee population. These challenges partially stem fro
not provide the same toe clearance during swing phase as the anatomical feet do, in
tripping and potentially a higher incidence of falls among amputees. Stability on a
phase can also be compromised when using a non-adaptive prosthetic foot on varia
and declined. Furthermore, the amputee's confidence and stability on stairs, in asc
negatively affected while using a prosthetic foot that does not adapt into a dorsiflexe
The impact of these challenges result in a reduction in amputee mobility, but are furt
and in terms of quality of life in the cost of care and pain and suffering following a fa

PROPRIO FOOT® is designed to address these challenges:

- Active swing phase dorsiflexion on PROPRIO FOOT has shown to increase ground clearance and reduce the likelihood of tripping, which could potentially reduce the risk of falls.
- PROPRIO FOOT stance phase and terrain adaptation technology is designed to improve stability on uneven terrains and thereby improve mobility.

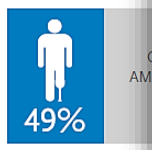
THE LINK BETWEEN LIMB-LOSS AND FALLS

Amputees fall more often than their able-bodied counter parts. According to a large study[1], half of the investigated amputee population, of which TT amputees represented the majority, reported to have fallen in the last year.

MORE THAN HALF
(...) REPORTED TO HAVE FALLEN IN THE LAST YEAR

Furthermore, a large study found that 1 out of 5 amputees has fallen during their rehabilitation time, while 18% of this population were injured seeking medical attention due to their fall.[2] Amputees with a history of falling show impaired mobility and significantly reduced outcome measures.[3]

While falls in the amputee popul
implications of the fear of fallin
fact, one out of every two amput
falling[3] which significantly reduc
life.[5]



COSTS ASSOCIATED W

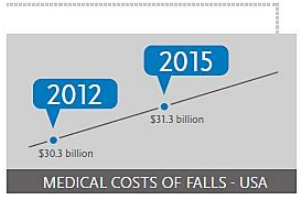
Although there is scarce publis
costs of falls within the amput
among older adults have bee
average one-year cost attribute
requiring subsequent medical a
$4,872. Furthermore, if the fall
cost may increase up to $35
population, it is estimated that
hospitalization.[4]

PROPRIO FOOT®

Because the world is not flat

A study on amputees' falls shows that up to 40% of their falls result in an injury and 1 out of 2 amputees who fall necessitates medical attention, which is higher than for the non-amputated elderly which has been estimated to be 30%.[7]

The only published study on transfemoral amputees indicated an estimated cost of $25,652 at 6 months for falls resulting in hospitalization, which is similar to the costs within the elderly population.[8] Direct medical costs related to all falls in the USA was $31.3 billion in 2015, up from $30.3 billion in 2012.[9]



PROPRIO FOOT: REDUCI

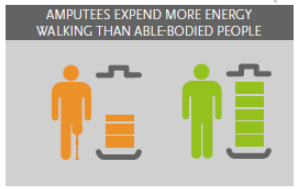
In light of the increased incidence
important to consider the overall e
solutions. Prosthetic technology
worth considering both from qua
healthcare cost perspective.

The choice of a prosthetic ankle
influence the user's perception of
tripping on unforeseen obstacles
ground clearance. Stumbles, which
falls, directly relate to ground clear
active dorsiflexion that provides 70
during swing phase, reducing the li

Users have reported fewer stumble
FOOT compared to their previous
4-week trial the number of reported
(previous prosthesis) to 5.3 (PROP
of reported falls decreased from 3.4

PROPRIO FOOT: PROVIDING ESSENTIAL BENEFITS TO AMPUTEES

Amputees expend more energy walking than able-bodied people.[12] This difference is intensified on uneven terrain: As the terrain gets more challenging, amputees are further taxed.[13] Amputees therefore tend to avoid obstacles which then limits their mobility to a higher degree. Some of these mobility limitations are related to the lack of ankle adaptation.



During stance, stability is affected by the ability of a prosthetic foot to adapt to the underlying terrain. PROPRIO FOOT adapts automatically to changes in terrain, providing an ankle position that matches the underlying slope angle, resulting in a larger base of support.[14]

Additionally, the energy cost of walking is reduced with PROPRIO FOOT on level ground, using a Seal-In® suspension system [15] and the knee and the hip move in a more physiological way on inclines, helping the user by walk more naturally[16], with more symmetry in loading[14], and with an increased perception of safety in ramp descent.[17] At the same time the users' interface, the socket, is affected by smoothed peak loads, in a more level ground like manner. The terrain compliant ankle compensates for increased peak loads from walking on uneven terrain.[18]

"My work environment involves walking
tunnels and up/down stairs. I usually t
day with my prescribed foot but I never
PROPRIO FOOT."

User comme
internal dat

Descending stairs presents another challen
user. When wearing a standard prosthetic fo
positions the prosthetic foot on the edge of t
prosthetic foot on this edge demands a hig
from the user while also reducing the surfa
step, allowing potential slippage. With the P
ankle is pre-positioned into an individu
dorsiflexion allowing for deeper positioning
results in more natural kinetics and kinemat
side[16]. Positioning the prosthetic foot furthe
also allow users with lower stair descent co
stairs with a more cyclical and natural patter

CONCLUSION

PROPRIO FOOT delivers value to both
the healthcare providers of the amputee
decreases the amputee's rate of falls thro
five degrees of swing phase dorsiflex
decreased likelihood of tripping. It
increased stability and socket comfor
inclines by adapting to the terrain slope a
stability and reducing the likelihood o
increase quality of life and reduce the e
of falls in the amputee population.
advantages over a lifetime of steps a
healthcare benefits become clear.

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"The literature cited in this brochure refers to previous versions of the Proprio Foot. The Proprio Foot version launching in 2018 includes updated performance features."

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