



Proprio Foot

Quality of Life





Proprio Foot®

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Amputees have reported to fall more often than the able-bodied population, contributing to a high incidence of fear of falling within the amputee population. These challenges partially stem from prosthetic feet that do not provide the same toe clearance during swing phase as the anatomical feet do, increasing the likelihood of tripping and potentially a higher incidence of falls among amputees. Stability on a prosthesis during stance phase can also be compromised when using a non-adaptive prosthetic foot on variable terrain, both inclined and declined. Furthermore, the amputee's confidence and stability on stairs, in ascent and descent, can be negatively affected while using a prosthetic foot that does not adapt into a dorsiflexed position when required. The impact of these challenges result in a reduction in amputee mobility, but are further realized economically and in terms of quality of life in the cost of care and pain and suffering following a fall.

Proprio Foot® is designed to address these challenges:

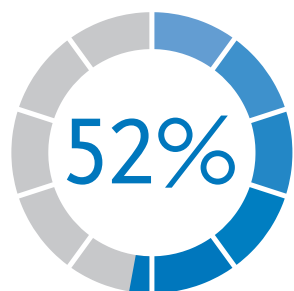
- Active swing phase dorsiflexion on Proprio Foot has shown to increase ground clearance and reduce the likelihood of tripping, which could potentially reduce the risk of falls.
- Proprio Foot stance phase and terrain adaptation technology is designed to improve stability on uneven terrains and thereby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

Amputees with a history of falling show impaired mobility and significantly reduced outcome measures.³

While falls in the amputee population are certainly a concern, the implications of the fear of falling should not be overlooked. In fact, one out of every two amputees (49%) reports to be afraid of falling¹ which significantly reduces their mobility⁴ and quality of life.⁵

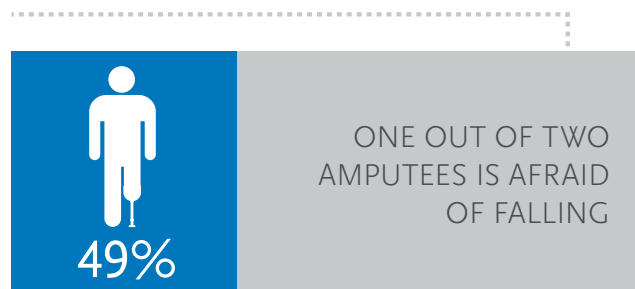
THE LINK BETWEEN LIMB-LOSS AND FALLS

Amputees fall more often than their able-bodied counterparts. According to a large study¹, 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

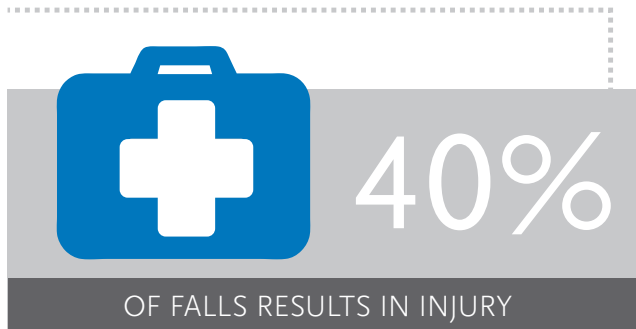


COSTS ASSOCIATED WITH FALLS

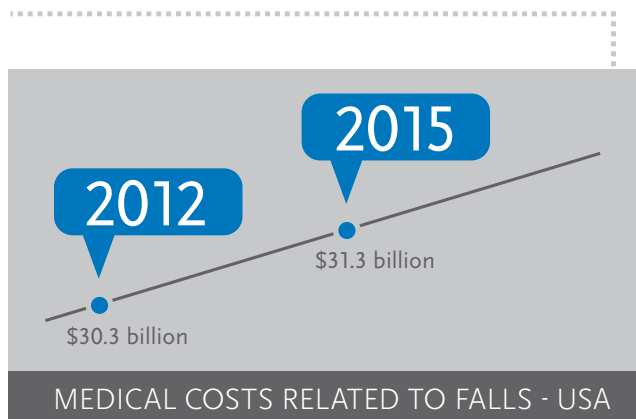
Although there is scarce published literature on the economic costs of falls within the amputee population, the costs of falls among older adults have been well studied. The estimated average one-year cost attributed to an elderly adult falling and requiring subsequent medical attention is between \$3,408 and \$4,872. Furthermore, if the fall results in a hospitalization, the cost may increase up to \$35,144 on average. Within this population, it is estimated that up to 1 in every 9 falls will lead to hospitalization.⁶



A study on individuals with lower limb extremity weakness 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 healthy 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

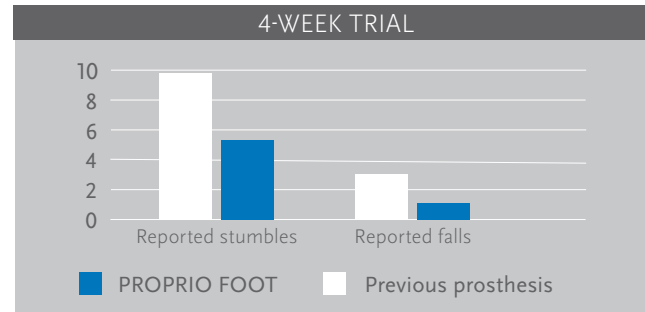


PROPRIO FOOT: REDUCING THE RISK

In light of the increased incidence of falls among amputees it is important to consider the overall efficacy of available prosthetic solutions. Prosthetic technology that can decrease fall rate is worth considering both from quality of life and the long-term healthcare cost perspective.

The choice of a prosthetic ankle and foot device is likely to influence the user's perception of stability. In swing, the risk of tripping on unforeseen obstacles may be reduced

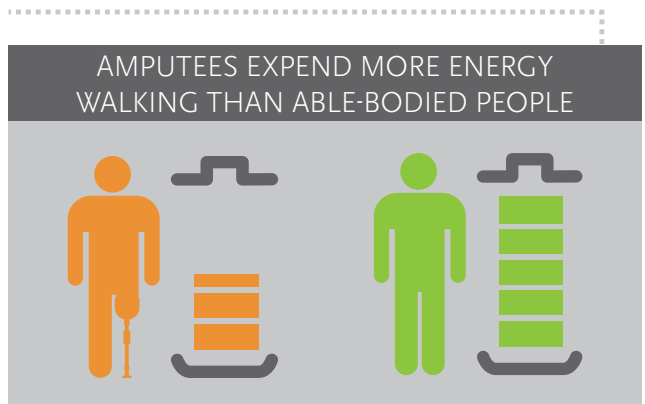
with increased ground clearance. Stumbles, which have the potential to cause falls, directly relate to ground clearance. Proprio Foot offers active dorsiflexion that provides 70% increased ground clearance during swing phase, reducing the likelihood of tripping.¹⁰



Users have reported fewer stumbles and falls with the Proprio Foot compared to their previous prosthesis. On average over a 4-week trial the number of reported stumbles decreased from 9.9 (previous prosthesis) to 5.3 (Proprio Foot) and the number of reported falls decreased from 3.4 to 1.0, a reduction of 70%.¹¹

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 system¹⁵ and the knee and the hip move in a more physiological way on inclines, helping the user to walk more naturally¹⁶, with more symmetry in loading¹⁴, 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

Quality of life (QOL) is defined by the World Health Organization as “an individual’s perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns”.¹⁹

Standard indicators of the quality of life include wealth, employment, the environment, physical and mental health, education, recreation and leisure time, social belonging, religious beliefs, safety, security and freedom²⁰ Improvement in the quality of life is evaluated by the SF-36 questionnaire with Proprio-Foot® and can be considered as the clinical outcome of the biomechanical properties of the foot. The quality of life appears improved using the Proprio Foot.²¹ The difference of 6.4 points on the physical component and 5.8 points on the mental component of the SF-36 are a little above the clinically relevant difference, which can be estimated at 5.



My work environment involves talking through sloped tunnels and up/down stairs. I usually trip 1-3 times per day with my prescribed foot but I never tripped with the Proprio Foot.

- User comment from Clinical Trial



CONCLUSION

PROPRIO FOOT delivers value to both the user and to the healthcare providers of the amputee population. It decreases the amputee’s rate of falls through its powered five degrees of swing phase dorsiflexion resulting in decreased likelihood of tripping. It also provides increased stability and socket comfort when walking inclines by adapting to the terrain slope angle. Increasing stability and reducing the likelihood of tripping could increase quality of life and reduce the economic burden of falls in the amputee population. Extend these advantages over a lifetime of steps and the potential healthcare benefits become clear.

Descending stairs presents another challenge to the prosthetic user. When wearing a standard prosthetic foot, the user typically positions the prosthetic foot on the edge of the step. Pivoting the prosthetic foot on this edge demands a high degree of balance from the user while also reducing the surface friction with the step, allowing potential slippage. With the Proprio Foot, the ankle is pre-positioned into an individually selected ankle dorsiflexion allowing for deeper positioning into the step, which results in more natural kinetics and kinematics on the prosthetic side¹⁶. Positioning the prosthetic foot further onto the step may also allow users with lower stair descent confidence to descent stairs with a more cyclical and natural pattern.





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“The literature cited in this brochure refers to previous versions of PROPRIO FOOT. The version launching in 2018 includes updated performance features.”

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