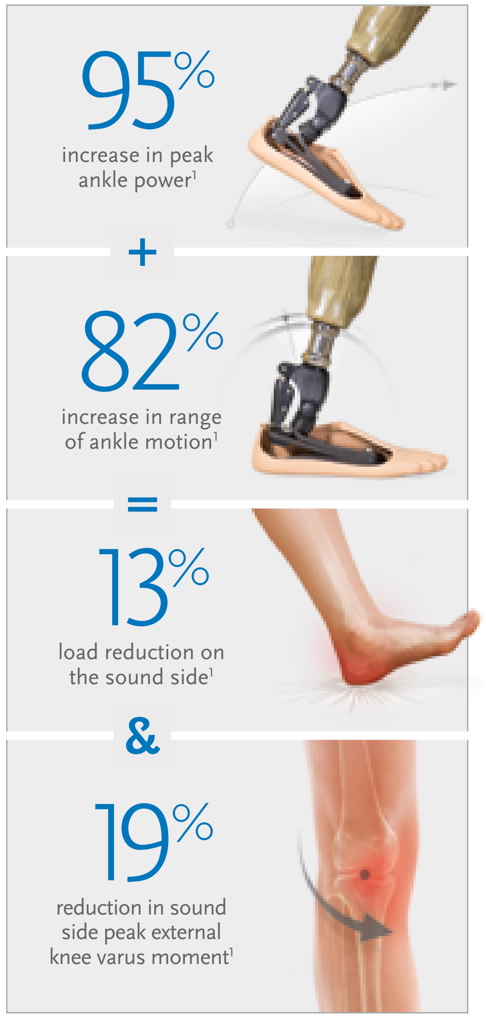
LIFE WITHOUT LIMITATIONS

PRO-FLEX® PIVOT

Reimbursement Support

PRO-FLEX® PIVOT - PRODUCT FEATURES

The Pro-Flex Pivot features Pivot Technology delivering 27° ankle motion without comprising ankle joint moment and progressive stiffness for a more physiological gait[1]. Immediate adaptation to ramps, stairs and uneven surfaces increases walking ease, comfort, and stability for daily activities.



THE CASE FOR PRO-FLEX PIVOT

The risk of developing osteoarthritis (OA) of the knee is 17 times higher for transtibial amputees than it is for non-disabled people. This shocking statistic regarding the sound leg stems mainly from two key factors: asymmetrical gait and increased impact. The latter is partly a consequence of asymmetrical walking movements, which result in an increased amount of time being spent on the sound side, in comparison with the prosthetic side[2].

Knee OA is 17 times more likely to develop in below-knee amputees than in non-disabled people.

In addition to increased pain and diminishing mobility for the individual, the financial costs associated with knee OA have risen by 66% over the last 10 years, and are predicted to rise a further 50% in the next two decades.

Responding to this challenge, Össur developed Pro-Flex Pivot. By enhancing gait symmetry and reducing vertical ground reaction forces by 13% and knee varus moment by 19%[1], it has features that may be beneficial to lower the risk of developing OA.

THE LINK BETWEEN LIMB-LOSS AND OA

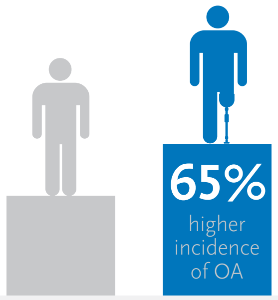
Osteoarthritis (OA) of the hip and knee joints is one of the world's leading causes of chronic disability. At present, there are more than 700,000 people with lower-limb loss living in the US, and that number is growing by some 50-60,000 each year[3] potentially doubling by the year 2050[4]. As well as suffering with reduced levels of mobility[5,6,7] lower-limb amputees have been shown to experience increased loading, and therefore impact on the sound limb. This contributes to a high incidence of joint pain and degeneration, and the eventual development of osteoarthritis[8,9,2].

Transtibial amputees are known to load their sound limb to a greater extent than their prosthetic limb during gait[11], and the difference between their two limbs in terms of knee pain and degeneration suggests that mechanical loading is a contributory factor. Minor compensatory movements, as well as asymmetrical gait, can increase stress on the sound limb and potentially predispose the long-term prosthetic user to premature degenerative arthritis[11].

The increased risk of hip and knee OA has prompted rising concern about the condition amongst amputees[2]. This type of comorbidity often goes hand-in-hand with limb loss, as does pain[12], with both being capable of diminishing people's mobility further still.[7]

THE LINK BETWEEN LIMB-LOSS AND OA

Perhaps unsurprisingly, people with unilateral limb-loss experience a higher incidence of OA in the joints on their sound side, compared both with joints in their prosthetic side and the joints of non-disabled people[8,12,14]. OA in the sound-limb knee joint is 17 times higher than in age-matched non-amputees[2] and knee pain is twice as common[2]. Imaging studies have confirmed the increased prevalence of degenerative changes in the sound-limb knee[15,16]. This is due to amputees typically spending more time on their sound limb than the prosthetic limb during walking[17,18]. As a result, their gait is asymmetric[19,20] and the loading on the sound limb is greater[19,12].



For a sample group of active and inactive lower-limb amputees, the combined increase in the incidence of OA was 65.6% higher than for non-disabled people[22].

MOBILITY BENEFITS

Product Features	27˚ Ankle Range of Motion
Mobility Benefit	Increased function and satisfaction: Subjects felt that the Pro-Flex Pivot provided sufficient support while offering a perceived smooth roll over[23].
Reference	23. Heitzmann, D. W. W. et al. Benefits of an increased prosthetic ankle range of motion for individuals with a trans-tibial amputation walking with a new prosthetic foot. Gait Posture 64, 174–180 (2018).

Product Features	Increased Ankle Range of Motion on Slopes
Mobility Benefit	'Better conformity to different slopes in comparison to traditional ESR feet'
Reference	24. Childers, W. L. & Takahashi, K. Z. Increasing prosthetic foot energy return affects whole-body mechanics during walking on level ground and slopes. Sci Rep 8, 5354 (2018).

Product Features	3 Blade Carbon Design with Pivot Technology
Mobility Benefit	The Pro-Flex pivot design provides an increased peak ankle power of 95% (in comparison to Vari-Flex). This contributes to normalised whole body mechanics: No significant differences were found between the prosthetic and anatomical ankle joints[23]. The increased energy return provided was used to increase whole body propulsion[24].
Reference	23. Heitzmann, D. W. W. et al. Benefits of an increased prosthetic ankle range of motion for individuals with a trans-tibial amputation walking with a new prosthetic foot. Gait Posture 64, 174–180 (2018). 24. Childers, W. L. & Takahashi, K. Z. Increasing prosthetic foot energy return affects whole-body mechanics during walking on level ground and slopes. Sci Rep 8, 5354 (2018).

MOBILITY BENEFITS

Product Feature	3 Blade Carbon Design with Pivot Technology
Functional benefit	Smoother more symmetrical gait: The Pro-Flex Pivot provides smooth roll over. Its consistent progression towards terminal stance terminates with a powerful push-off. The increased ankle range of motion has been shown to minimise the elevation of the body centre of gravity which showed to contribute to a reduction of sound limb loading, as patients do not need to raise the heel to maintain tibial progression[19]. The result is a **more symmetrical gait.**
Reference	19. Snyder, R.D., et al., The effect of five prosthetic feet on the gait and loading of the sound limb in dysvascular below-knee amputees. J Rehabil Res Dev, 1995. 32(4): p. 309-15.

HEALTH BENEFITS

Product Feature	3 Blade Carbon Design with Pivot Technology
Health benefit	Reduces impact on sound side by 13% The Pro-Flex Pivot provides smooth roll over. Its consistent progression towards terminal stance terminates with a powerful push-off. The increased ankle range of motion has been shown to minimise the elevation of the body centre of gravity which showed to contribute to a reduction of sound limb loading, as patients do not need to raise the heel to maintain tibial progression[19]. The result is a **more symmetrical gait** and reduced impact or load on the sound side[25] – the two key factors in reducing the **risk of OA.**
Reference	19. Snyder, R.D., et al., The effect of five prosthetic feet on the gait and loading of the sound limb in dysvascular below-knee amputees. J Rehabil Res Dev, 1995. 32(4): p. 309-15. 25. Segal, Ava D., et al. "The effects of a controlled energy storage and return prototype prosthetic foot on transtibial amputee ambulation." Human movement science 31.4 (2012): 918-931.

HEALTH BENEFITS

Product Feature	3 blade carbon design with pivot technology
Health benefit	Pro-Flex Pivot provided a 52% increase in ankle range of motion during downhill walking and 54% increase during uphill. The full length toe lever and powerful push off provides support in late stance whilst on slopes, contributing to a reduction in sound side loading.
Reference	23. Heitzmann, D. W. W. et al. Benefits of an increased prosthetic ankle range of motion for individuals with a trans-tibial amputation walking with a new prosthetic foot. Gait Posture 64, 174–180 (2018). 24. Childers, W. L. & Takahashi, K. Z. Increasing prosthetic foot energy return affects whole-body mechanics during walking on level ground and slopes. Sci Rep 8, 5354 (2018).

Product Feature	27˚ Ankle Range of Motion – Improved ROM on inclines/declines
Health benefit	Pro-Flex Pivot provided a 52% increase in ankle range of motion during downhill walking and 54% increase during uphill. The full length toe lever and powerful push off provides support in late stance whilst on slopes, contributing to a reduction in sound side loading.
Reference	23. Heitzmann, D. W. W. et al. Benefits of an increased prosthetic ankle range of motion for individuals with a trans-tibial amputation walking with a new prosthetic foot. Gait Posture 64, 174–180 (2018). 24. Childers, W. L. & Takahashi, K. Z. Increasing prosthetic foot energy return affects whole-body mechanics during walking on level ground and slopes. Sci Rep 8, 5354 (2018).

Product Feature	3 Blade Carbon Design with Pivot Technology
Health benefit	Reduced varus moment on sound side knee by 19% 'Significantly greater energy return than a conventional carbon fibre foot; and a powerful push-off that reduces peak impact forces and knee varus moment on the sound limb by 19%' The result is a **more symmetrical gait** and reduced impact or load on the sound side[25] – the two key factors in reducing the **risk of OA.**
Reference	23. Heitzmann, D. W. W. et al. Benefits of an increased prosthetic ankle range of motion for individuals with a trans-tibial amputation walking with a new prosthetic foot. Gait Posture 64, 174–180 (2018). 25. Segal, Ava D., et al. "The effects of a controlled energy storage and return prototype prosthetic foot on transtibial amputee ambulation." Human movement science 31.4 (2012): 918-931.

LIFESTYLE BENEFITS

Product feature	Weatherproof
Lifestyle benefit	Patient works/lives in a wet environment: Pro-Flex Pivot can withstand splashing of fresh water from all angles, permitting the user to utilise it in a wider range of conditions/weather/humidity.
Reference	IFU

Product feature	27˚ Ankle Range of Motion – Improved ROM on Inclines/Declines
Lifestyle benefit	Pro-Flex Pivot provided a 52% increase in ankle range of motion during downhill walking and 54% increase during uphill. User can traverse comfortably on slopes and stairs.
Reference	23. Heitzmann, D. W. W. et al. Benefits of an increased prosthetic ankle range of motion for individuals with a trans-tibial amputation walking with a new prosthetic foot. Gait Posture 64, 174–180 (2018). 24. Childers, W. L. & Takahashi, K. Z. Increasing prosthetic foot energy return affects whole-body mechanics during walking on level ground and slopes. Sci Rep 8, 5354 (2018).

Product feature	Multi-Articulating Technology
Lifestyle benefit	Dorsiflexion range enables the user to transfer load through the foot when exiting a chair, easing the process of standing up, increasing symmetry and reducing the load on the sound side.

PRODUCT INFORMATION

Pro-Flex Pivot White Paper:
https://media.ossur.com/image/upload/v1605834819/documents/AU/white-paper/Ossur-Pro-flex-White-Paper.pdf

Pro-Flex Family Brochure: https://media.ossur.com/image/upload/v1616546263/documents/AU/Brochures/P-800271_Pro-Flex_Family_Brochure.pdf

Instructions for Use:
https://media.ossur.com/image/upload/v1587727458/product-documents/global/PN20158/IFUS/PN20158_Pro-Flex_Pivot.pdf

TESTIMONIALS

Eliza Ault-Connell's Pro-Flex Pivot story:
https://ossur.com/en-au/prosthetics/client-experiences/eliza-ault-connells-story

Gordon Richard's PASO Knee and Pro-Flex Pivot story:
https://ossur.com/en-au/prosthetics/client-experiences/gordon-richards-story

Steve Stoyko's RHEO KNEE and Pro-Flex Pivot story:
https://ossur.com/en-au/prosthetics/client-experiences/steve-stoykos-story

FURTHER INFORMATION

Microlearning Content:
https://ossur.com/en-au/professionals/ossur-academy/microlearning-library

Workday Courses:
https://wd3.myworkday.com/ossur/learning/course/1bf5e7ccac9701b3f8a95f48a0019602?type=9882927d138b100019b928e75843018d

Please see the AOPA accredited course for the Pro-Flex Pivot and Pro-Flex Family:
https://aopa.org.au/events/event/ossur-pro-flex-introduction-course

WARRANTY

Össur provides a warranty of 36 months for this foot module and 6 months for the foot cover.

REFERENCES

1. Heitzmann, D. W. W., et al. "Evaluation of a novel prosthetic foot while walking on level ground, ascending and descending a ramp." Gait & Posture 42 (2015): S94-S95.
2. Struyf, Pieter A., et al. "The prevalence of osteoarthritis of the intact hip and knee among traumatic leg amputees." Archives of physical medicine and rehabilitation 90.3 (2009): 440-446.
3. HCUP: Healthcare Cost and Utilization Project, June 2015. Agency for Healthcare Research and Quality, Rockville, MD, U.S. Department of Health and Human Services. http://hcupnet.ahrq.gov/HCUPnet.jsp Agency for Healthcare Research and Quality
4. Ziegler-Graham, Kathryn, et al. "Estimating the prevalence of limb loss in the United States: 2005 to 2050." Archives of physical medicine and rehabilitation 89.3 (2008): 422-429.
5. Miller, William C., et al. "The influence of falling, fear of falling, and balance confidence on prosthetic mobility and social activity among individuals with a lower extremity amputation." Archives of physical medicine and rehabilitation 82.9 (2001): 1238-1244.
6. Burger, Helena, C. R. T. Marincek, and Eli Isakov. "Mobility of persons after traumatic lower limb amputation." Disability & Rehabilitation 19.7 (1997): 272-277.
7. Geertzen JH, Bosmans JC, Van der Schans CP. Claimed walking distance of lower limb amputees. Disabil Rehabil 2005;27:101-4.
8. Nolan L, Wit A, Dudzinski K, Lees A, Lake M, Wychowanksi M. Adjustments in gait symmetry with walking speed in trans-femoral and trans-tibial amputees. Gait Posture.2003;17(2):142–51 prosthetic knee. Arch Phys Med Rehabil 2007;88:207-17.
9. Burke MJ, Roman V, Wright V. Bone and joint changes in lower limb amputees. Ann Rheum Dis. 1978;37(3): 252–54.
10. Gailey R, Allen K, Castles J, Kucharik J, Roeder M. Review of secondary physical conditions associated with lower-limb amputation and long-term prosthesis use. J Rehabil Res Dev 2008;45(1):15–29.
11. Hurley GR, McKenney R, Robinson M, Zadravec M, Pierrynowski, MR. The role of the contralateral limb in below knee amputee gait. Prosthet Orthot Int. 1990;14(1):33–42
12. Kulkarni J, Adams J, Thomas E, Silman A. Association between amputation, arthritis and osteopenia in British male war veterans with major lower limb amputations. Clin. Rehabil., 12 (4) (1998), pp. 348–353
13. Nolan L, Wit A, Dudzinski K, Lees A, Lake M, Wychowanksi M. Adjustments in gait symmetry with walking speed in trans-femoral and trans-tibial amputees. Gait Posture.2003;17(2):142–51 prosthetic knee. Arch Phys Med Rehabil 2007;88:207-17.
14. Hungerford D, Cockin J. Fate of the retained lower limb joints in World War II amputees. J. Bone Jt. Surg., 57 (1975), p. 111
15. Norvell DC, Czerniecki JM, Reiber GE, Maynard C, Pecoraro JA, Weiss NS. The prevalence of knee pain and symptomatic knee osteoarthritis among veteran traumatic amputees and nonamputees. Arch Phys Med Rehabil 2005;86(3):487–93.
16. Lemaire ED, Fisher FR. Osteoarthritis elderly amputee gait. Arch Phys Med Rehabil 1994;75(10):1094–9.
17. Breakey J. Gait of unilateral trans-tibial amputees. Orthot Prosthet. 1976;30:17–24.
18. Murray MP, Mollinger LA, Sepic SB, Gardner GM, Linder MT. Gait patterns in above-knee amputee patients: Hydraulic swing control vs constant-friction knee components. Arch Phys Med Rehabil. 1983;64(8):339–45.
19. Snyder, R.D., et al., The effect of five prosthetic feet on the gait and loading of the sound limb in dysvascular below-knee amputees. J Rehabil Res Dev, 1995. 32(4): p. 309-15.
20. Levine D, Whittle M, Richards J. Whittle's gait analysis. 5th ed. Edinburgh: Churchill Livingston; 2012
21. Melzer I, Yekutiel M, Sukenik S. Comparative study of osteoarthritis of the contralateral knee joint of male amputees who do and do not play volleyball.J. Rheumatol., 28 (1) (2001), pp. 169–172
22. Morgenroth DC, Segal AD, Zelik KE, Czerniecki JM, Klute GK, Adamczyk PG et al. The effect of prosthetic foot push-off on mechanical loading associated with knee osteoarthritis in lower extremity amputees. Gait & Posture 2011;34(4):502–7.
23. Heitzmann, D. W. W. et al. Benefits of an increased prosthetic ankle range of motion for individuals with a trans-tibial amputation walking with a new prosthetic foot. Gait Posture 64, 174–180 (2018).
24. Childers, W. L. & Takahashi, K. Z. Increasing prosthetic foot energy return affects whole-body mechanics during walking on level ground and slopes. Sci Rep 8, 5354 (2018).
25. Segal, Ava D., et al. "The effects of a controlled energy storage and return prototype prosthetic foot on transtibial amputee ambulation." Human movement science 31.4 (2012): 918-931.

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