THE CASE FOR PRO-FLEX® PIVOT

The risk of developing osteoarthritis (OA) of the knee is 17 times higher for transtibial (below-knee) 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.

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 has developed Pro-Flex Pivot, the world's first prosthetic foot to provide proven protection of the sound side. By enhancing gait symmetry and reducing peak impact forces and knee varus moment by 19% and 13% respectively[41], it can help reduce the risk for amputees of knee OA and the costs associated with the condition.

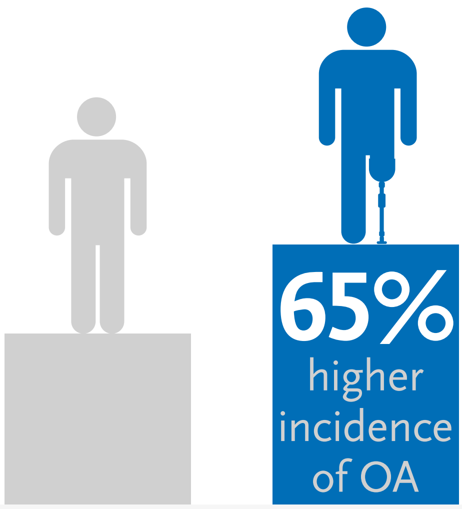
THE LINK BETWEEN LIMB-LOSS AND OA

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[8,9,10].

Asymmetrical gait and **greater impact** are the two key factors behind this increased risk.

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[12].

The increased risk of hip and knee OA has prompted rising concern about the condition amongst amputees[13]. This type of comorbidity often goes hand-in-hand with limb loss, as does pain[14], with both being capable of diminishing people's mobility further still[7].



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].

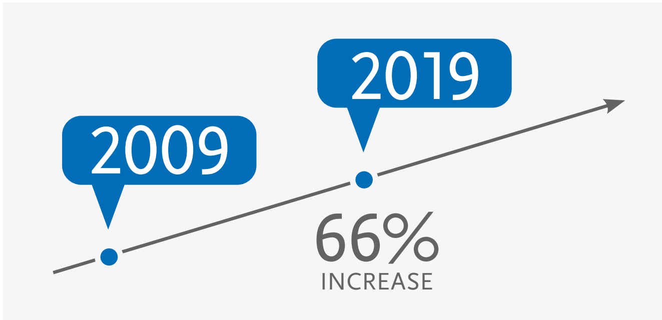
Perhaps unsurprisingly, people with unilateral limb-loss experience a higher incidence of OA in the joints on their sound side, compared both with joints in their prosthetic side and the joints of non-disabled people[20,14,21]. OA in the sound-limb knee joint is 17 times higher than in age-matched non-amputees[10] and knee pain is twice as common[10].

Imaging studies have confirmed the increased prevalence of degenerative changes in the sound-limb knee[23,24]. This is due to amputees typically spending more time on their sound limb than the prosthetic limb during walking[25,26,27]. As a result, their gait is asymmetric[28,29,30] and the loading on the sound limb is greater[31,32].

COSTS ASSOCIATED WITH KNEE OA

Osteoarthritis (OA) is a leading cause of disability among older adults, and affects upwards of one in eight adults[15,16]. OA is set to increase by about 50% over the next 20 years[17,18,19]. The associated financial cost to healthcare systems is soaring as a result of increasing numbers of joint replacements, the assistance necessary for daily living and loss of productivity[1,2]. OA is a degenerative disease, typically accompanied by chronic pain. That pain is part of the human cost of OA, along with diminishing mobility and a markedly reduced quality of life.

There is a need to **change healthcare policies** in order to reduce the progression of this costly disease[36].

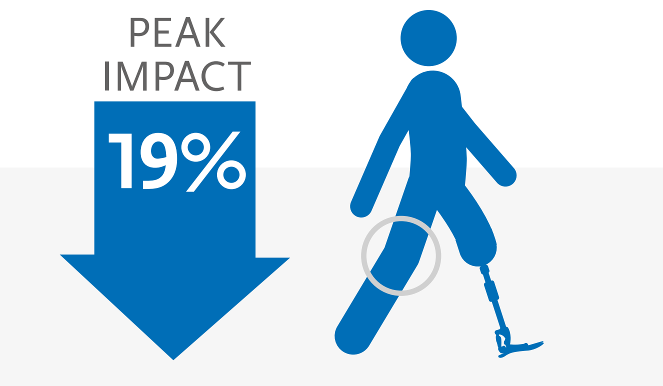


COST ASSOCIATED WITH TREATING KNEE OA[36]

Comparative studies from 1993[33] and 2012[34] show that the prevalence of OA in France, for example, had risen by 54%, and the direct medical costs by 156%. In the UK, the cost associated with joint replacement has increased to GBP 514 million in 2010, a rise of 66% over the preceding decade. OA accounted for 10% of DALYs due to musculoskeletal conditions[35]. In the US, the rate of total knee replacement increased by 58%[(34a)] between 2000 and 2006, and that rate continues to rise. The direct costs in the United States associated with total knee replacements are as significant as $51,000. When indirect costs (such as loss of productivity) of some $21,000 are included, the total expenditure for the first five years after replacement surgery goes up to a staggering $72,000, or $14,500 per year[46].

PRO-FLEX: REDUCING THE RISK

Against a backdrop of rising levels of knee OA among the general population, and higher risks for those with limb loss in particular, it is important to scrutinise prosthetic solutions. Technology that undertakes to reduce appreciably the wear and tear on a person's body is worth considering,



PRO-FLEX PIVOT ENHANCES GAIT SYMMETRY & REDUCES PEAK IMPACT BY 19%[41]

both from a quality-of-life perspective and that of long-term healthcare costs.

The choice of prosthetic foot can influence impact levels on the sound side. More specifically, the Flex-Foot® design has been shown to reduce ground reaction forces (GRF)[37] on the sound side, unlike standard foot designs, which increase significantly both impact and knee instability[38].

The new Pro-Flex Pivot (from the makers of Flex-Foot) exhibits exceptional behavior in terms of roll over. Its smooth and consistent progression towards terminal stance terminates with a powerful push-off. This unprecedented push-off power means the body's center of pressure is less elevated[42] on the prosthetic side[37] at the time of stepping forward onto the sound side. The result is a smoother, more symmetrical gait and reduced impact or load on the sound side[43,44,45] – the two key factors in reducing the risk of OA.

Compared to Vari-Flex®, the current 'gold standard' energy return foot, Pro-Flex Pivot has almost double the ankle motion when walking on level ground and ramps, and its 'push-off' power is about twice as high[39]. The roll over progression of prosthetic feet typically slows down in mid-stance, while Pro-Flex Pivot allows the user to progress over the mid-stance, utilising the momentum to generate push-off power that carries the user's weight more effectively, reducing the drop-off effect and loading on the sound side[40]. Coronal plane forces, as well as vertical ground reaction forces, are significantly reduced. Both are important in counteracting the development of osteoarthritis[42].

Both legs matter. By decreasing impact and enhancing dynamics, Pro-Flex Pivot helps to protect the body and reduce the risk of OA.

CONCLUSION

The Pro-Flex Pivot by Össur is the step in the right direction. It combines an incredible 27° ankle motion; significantly greater energy return than a conventional carbon fiber foot; and a powerful push-off that reduces peak impact forces and knee varus moment on the sound limb by 19% and 13% respectively. Multiply those advantages over a lifetime of steps and the potential health benefits become clear: by decreasing the impact or load and enhancing dynamics, the impact on the financial and human cost of osteoarthritis can be reduced.

REFERENCES

1. Hunter, David J., Deborah Schofield, and Emily Callander. "The individual and socioeconomic impact of osteoarthritis." Nature Reviews Rheumatology 10.7 (2014): 437-441.
2. Nho, Shane J., Steven M. Kymes, John J. Callaghan, and David T. Felson 2013, The Burden of Hip Osteoarthritis in the United States: Epidemiologic and Economic Considerations. The Journal of the American Academy of Orthopaedic Surgeons 21 Suppl 1: S1–6.
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. 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.
11. 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.
12. 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.
13. 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.
14. 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
15. Centers for Disease Control and Prevention (CDC). Prevalence and impact of chronic joint symptoms—seven states, 1996. MMWR Morb. Mortal. Wkly Rep. 47, 345–351 (1998).
16. Dunlop, D. D., Manheim, L. M., Song, J. & Chang, R. W. Arthritis prevalence and activity limitations in older adults. Arthritis Rheum. 44, 212–221 (2001).
17. Hunter, D. J. Lower extremity osteoarthritis management needs a paradigm shift. Br. J. Sports Med. 45, 283–288 (2011).
18. Hootman, J. M. & Helmick, C. G. Projections of US prevalence of arthritis and associated activity limitations. Arthritis Rheum. 54, 226–229 (2006).
19. Perruccio, A. V., Power, J. D. & Badley, E. M. Revisiting arthritis prevalence projections—it's more than just the aging of the population. J. Rheumatol. 33, 1856–1862 (2006).
20. 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.
21. Hungerford D, Cockin J. Fate of the retained lower limb joints in World War II amputees. J. Bone Jt. Surg., 57 (1975), p. 111
22. 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
23. 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.
24. Lemaire ED, Fisher FR. Osteoarthritis elderly amputee gait. Arch Phys Med Rehabil 1994;75(10):1094–9.
25. Breakey J. Gait of unilateral trans-tibial amputees. Orthot Prosthet. 1976;30:17–24.
26. 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.
27. Engsberg JR, Lee AG, Tedford KG, Harder JA. Normative ground reaction force data for able-bodied and below knee amputee children during walking. J Pediatr Orthop. 1993;13(2):169–73.
28. Zernicke RF, Hoy MG, Whiting WC. Ground reaction forces and center of pressure patterns in the gait of children with amputation: Preliminary report. Arch Phys Med Rehabil. 1985;66(11):736–41.
29. Menard MR, McBride ME, Sanderson DJ, Murray D. Comparative biomechanical analysis of energy-storing prosthetic feet. Arch Phys Med Rehabil. 1992;73(5):451–58.
30. Schneider K, Hart T, Zernicke RF, Setoguchi Y, Oppenheim W. Dynamics of below-knee amputee child gait: SACH foot versus Flex foot. J Biomech. 1993;26(10): 1191–1204.
31. Suzuki K. Force plate study on the artificial limb gait. J Jpn Orthop Assoc. 1972;46:503–16.
32. Engsberg JR, Lee AG, Patterson JL, Harder JA. External loading comparisons between able-bodied and below knee amputee children during walking. Arch Phys Med Rehabil. 1991;72(9):657–61
33. E. Levy, A. Ferme, D. Perocheau, and I. Bono, "Socioeconomic costs of osteoarthritis in France," Revue du Rhumatisme, vol. 60, no. 6, pp. 63S–67S, 1993.
34. Chen, A., et al. "The global economic cost of osteoarthritis: how the UK compares." Arthritis 2012 (2012).
34a. Centers for Disease Control and Prevention (CDC). Racial disparities in total knee replacement among Medicare enrollees— United States, 2000-2006. MMWR Morb Mortal Wkly Rep 2009;58(6):1338.
35. Murray, C. J. et al. Disability-adjusted life years (DALYs) for 291 diseases and injuries in 21 regions, 1990–2010: a systematic analysis for the Global Burden of Disease Study 2010. Lancet 380, 2197–2223 (2013).
36. Hunter, David J., Deborah Schofield, and Emily Callander. "The individual and socioeconomic impact of osteoarthritis." Nature Reviews Rheumatology 10.7 (2014): 437-441.
37. 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.
38. Lehmann JF, Price R, Boswell-Bessette S, Dralle A, Questad K. Comprehensive analysis of dynamic elastic response feet: Seattle Ankle/Lite Foot versus SACH foot. Archives of Physical Medicine & Rehabilitation 1993;74(8):853-61.
39. Heitzmann DWW. et al; Evaluation of a novel prosthetic foot while walking on level ground, ascending and descending a ramp; Gait & Posture 42 (2015): S94-S95. Abstract, Oral Presentation at the ESMAC 24th annual Meeting Heidelberg, Germany, September 10-12, 2015; E-mail: daniel.heitzmann@med.uni-heidelberg.de
40. Morgenroth, David C., et al. "The effect of prosthetic foot push-off on mechanical loading associated with knee osteoarthritis in lower extremity amputees." Gait & posture 34.4 (2011): 502-507.
41. 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.
42. Powers, Christopher M., et al. "Influence of prosthetic foot design on sound limb loading in adults with unilateral below-knee amputations." Archives of physical medicine and rehabilitation 75.7 (1994): 825-829.
43. 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.
44. Kuo, Arthur D. "The six determinants of gait and the inverted pendulum analogy: A dynamic walking perspective." Human movement science 26.4 (2007): 617-656.
45. Kuo, Arthur D., J. Maxwell Donelan, and Andy Ruina. "Energetic consequences of walking like an inverted pendulum: step-to-step transitions." Exercise and sport sciences reviews 33.2 (2005): 88-97.
46. Ostheoarthritis kneebracing – A health economic evaluation – USA, 2012. On file at Össur

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