THE CASE FOR PRO-FLEX®

Less load, more dynamics™
The risk of developing osteoarthritis (OA) of the knee is 17 times higher for trans-tibial (below-knee) amputees than it is for non-disabled people\(^1\). This shocking statistic regarding the sound leg stems mainly from two key factors: asymmetrical gait and increased impact\(^2\). 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\(^11\).

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\(^3\), and are predicted to rise a further 50% in the next two decades. Responding to this challenge, Össur has developed Pro-Flex, the world’s first prosthetic foot to provide proven protection of the sound side. By enhancing loading symmetry and reducing peak impact forces and knee varus moment by 11% and 9% respectively\(^4\), it can help reduce the risk for amputees of knee OA and the costs associated with the condition.

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

Trans-tibial 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\(^2\).

The increased risk of hip and knee OA has prompted rising concern about the condition amongst amputees\(^1\). 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\(^8\).

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\(^13\).
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. OA in the sound-limb knee joint is 17 times higher than in age-matched non-amputees and knee pain is twice as common. Imaging studies have confirmed the increased prevalence of degenerative changes in the sound-limb knee. This is due to amputees typically spending more time on their sound limb than the prosthetic limb during walking. As a result, their gait is asymmetric and the loading on the sound limb is greater.

There has been a 66% increase in the costs associated with treating knee OA in the last 10 years, a figure that continues to rise.

Osteoarthritis (OA) is a leading cause of disability among older adults, and affects upwards of one in eight adults. OA is set to increase by about 50% over the next 20 years. 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. 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.

Comparative studies from 1993 and 2012 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 10.0% of DALYs due to musculoskeletal conditions. In the US, the rate of total knee replacement increased by 58% between 2000 and 2006, and that rate continues to rise. The cost of a total knee replacement in the USA is as significant as $46,000, and needs revision after 10 years. A patient suffering from knee OA can expect to require health care services at a cost of up to $5,500 per year. But society pays even more due to indirect costs (such as loss of productivity). During the years leading up to the procedure patients and society can expect a loss of up to $4,500 per year due to sick leave.
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 scrutinize prosthetic solutions. Technology that undertakes to reduce appreciably the wear and tear on a person’s body is worth considering, 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) on the sound side, unlike standard foot designs, which increase significantly both impact and knee instability.

The new Pro-Flex foot (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 mass is less elevated 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 – the two key factors that may be reducing the risk of OA.

Compared to Vari-Flex, the current ‘gold standard’ energy return foot, Pro-Flex has almost double the ankle motion when walking on level ground and ramps, and its ‘push-off’ power is about twice as high. The roll over progression of prosthetic feet typically slows down in mid-stance, while Pro-Flex allows the user to progress over the mid-stance, utilizing 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. Coronal plane moments, as well as vertical ground reaction forces, are significantly reduced. Both are important in counteracting the development of osteoarthritis.

CONCLUSION

Pro-Flex by Össur is the step in the right direction. It combines an incredible 27º 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 11% and 9% 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.

% INCREASE IN PEAK ANKLE POWER
% INCREASE IN ANKLE MOTION
% LOAD REDUCTION ON THE SOUND SIDE
% REDUCTION IN KNEE VARUS MOMENT
REFERENCES

4. Heitzmann DWW, et al; A novel prosthetic foot leads to increased ankle power and reduced sound side loads in transtibial amputees; Abstract, Oral Presentation at the AOPA National Assembly San Antonio, TX, USA, October 7-10, 2015.

* Costs in 2010 USD. Based on a technical report from the Swedish Institute for Health Economics. Model inputs localized to United States conditions