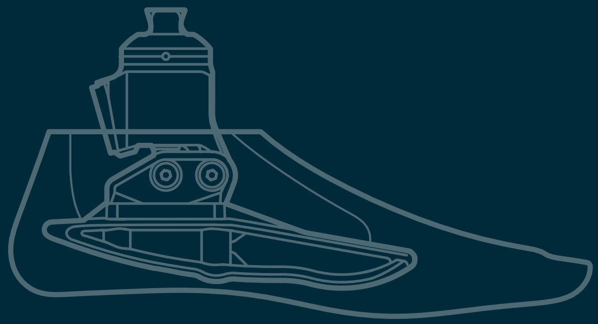


A Study of Avalon^{K2}

Blatchford

Avalon^{K2}

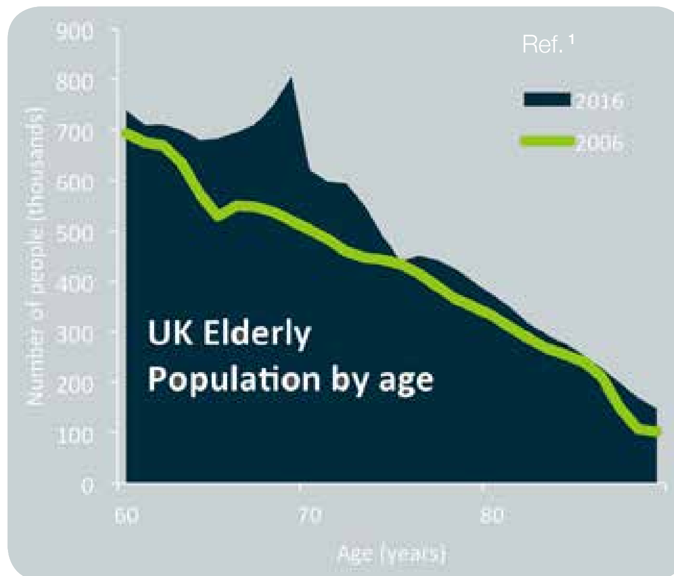
Hydraulic prosthetic feet can improve mobility and independence for limited community ambulators.

The main driving force behind advancing lower limb prosthetic technology in the 21st century is biomimetic design; reproducing the biomechanical performance of natural limbs. Inherent in this is recognising that different demographics of the amputee population have different biomechanical requirements, and that the engineering principles behind different devices must accommodate for this.

Amputee Demographics

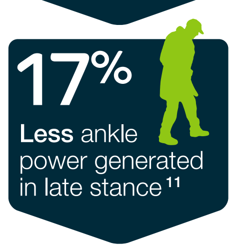
The global trends of increasing ageing population and incidence of chronic disease in developed countries are well known. Over 60s make up approximately 23% of the UK population – approximately 14.7 million people[1]. The Office for National Statistics reports that this proportion has grown by 21% in the last 10 years[1]. This trend is consistent with that in the United States where over 60s make up approximately 20.3% of the population – 65.5 million people[2]. Globally, almost 1 in 10 people are over 60 and by 2050, this is estimated to become 1 in 5 people[3].

The prevalence of diabetes and cardiovascular disease increases with age[4], with vascular disease being the cause of over 80% of lower limb amputations[5,6]. There are 5200 lower limb amputations per year in the UK[5] and 185,000 in the US[7], of which 75% occur in over 60s[5,6].



The Biomechanics of Elderly Gait

It is well documented that there are a number of biomechanical differences between the gait of elderly people and that of young people[8]. Older people tend to walk more slowly[9,10], contributing to a shorter step and stride length[9-11]. These differences affect the ranges of motion of the joints, predominantly through plantarflexion of the ankle and extension of the hip[9–12]. Lower limb muscle weakness is common amongst elderly people and therefore the power generated by the ankle in late stance is significantly reduced[11,13].

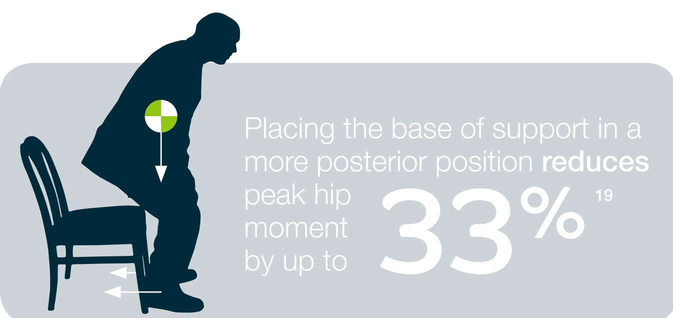


All of these differences influence the motion of the body's centre-of-mass in relation to its base of support at the ground, and must be considered during prosthetic foot design. Elderly amputees are often described as being 'Activity Level 2' which refers to someone who has the "ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces". Older people also have a much greater variability in their gait[10,14–16] meaning a prosthesis that can provide consistency and predictability of function is of even greater importance in order to ensure safety.

Domestic Independence

Older people tend to spend less time outside and more time around the home. This means for those with lower mobility capabilities, functional domestic tasks, such as rising from a chair, become imperative to maintaining independence and quality of life. In fact, the transition from a seated position to standing has been described as "the most mechanically demanding functional task routinely undertaken during daily activities"[17].

Older people can adapt their movement strategy to account for their abilities. When rising from a chair, if they bring their feet to a more posterior position they reduce the distance between their body's centre-of-mass and their base of support[18]. Consequently, there is less demand on the lower limb muscles and joints, allowing them to generate enough force to stand more easily[19–21]. Scientific studies have identified foot placement as a critical factor in the sit-to-stand movement[22]. Consideration of foot placement and the ankle range of motion in prosthetic design enables a more optimised body posture and movement that requires less effort.



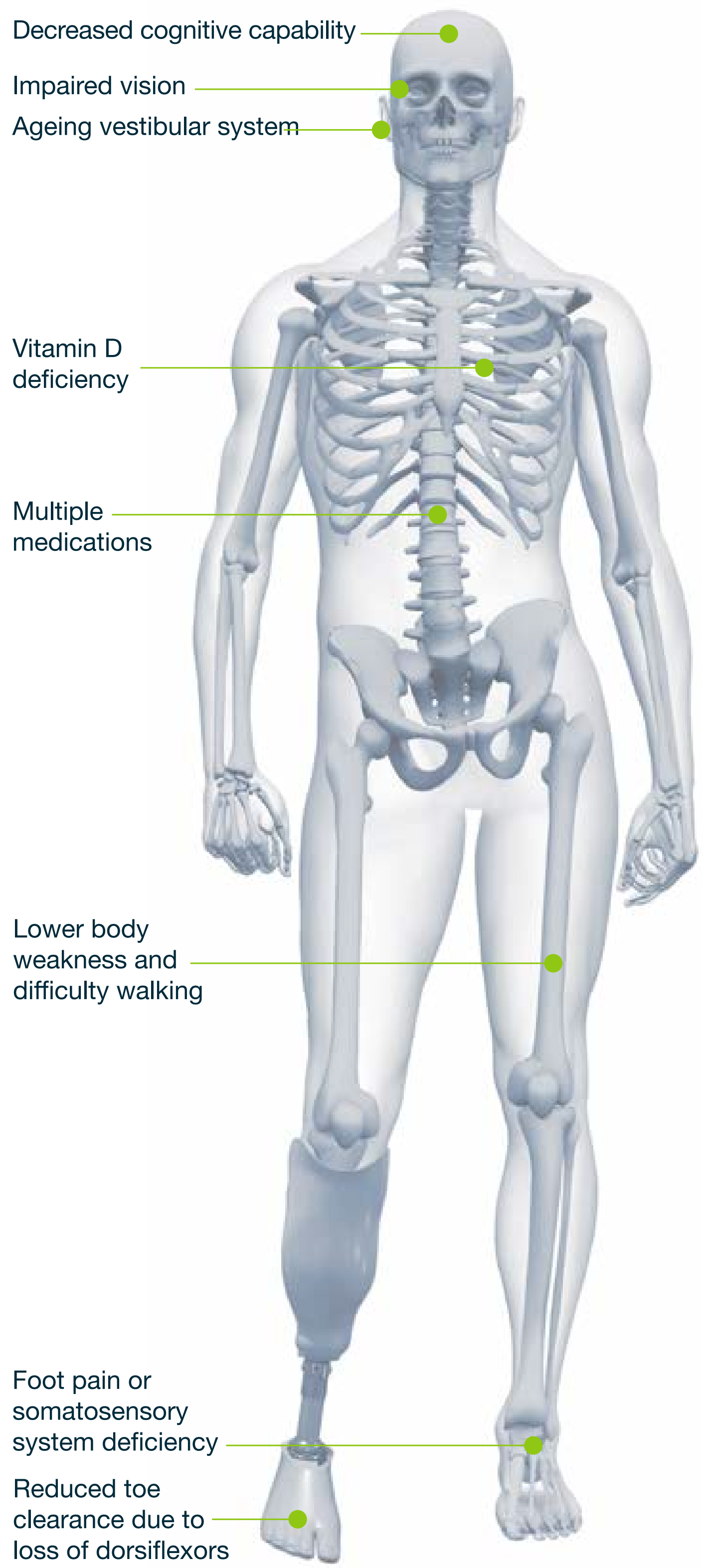
The Risk of Falling

Gait patterns are a significant contributor to the risk of falling in the elderly[23,24]. Their increased variability from one step to the next has been linked to the frequency of falling[10,25–28], as has shorter stride length, reduced plantarflexion and reduced hip extension[27].

Other common characteristics of advanced age make elderly people more susceptible to the risk of falls[29]. As vision deteriorates, there is a greater reliance on other sensory inputs to detect potential trip hazards, and as the central nervous system ages, a decline in cognitive ability can occur. The vestibular system, which provides sensory information regarding motion, spatial awareness and balance, begins to weaken and becomes less reliable. Poor circulation leads to peripheral neuropathy, reducing sensation at the extremities, slowing reactions to external stimuli, such as changes in slope or uneven terrain.

Beyond physical characteristics, certain medications, such as those for high blood pressure or painkillers, have shown a correlation with the likelihood of falling. Particularly at risk are those who are taking multiple medications at once[30,31].

Studies looking at amputee falls indicate 58% of unilateral amputees fall at least once a year[32]. Of those who fell, 50% sustained a tissue injury, while 7% required hospital treatment[32]. Other effects of falls include broken bones, head injuries[33,34] and a loss of independence[31,35,36], that can severely affect the quality of life of the amputee.



The Cost of Falls

As well as physical consequences, falls can impact other areas of life. 60% of amputees who fall say it affects their daily life and 36% report a loss of confidence[32].

Falls can also cause a financial burden, both on the amputee and their family if extra social care is required, and to the economy as a whole. In 2000, in the United States, medical costs for falls totalled $19.2 billion[37]. Reducing the risk of falls and the need for institutional care has the potential for a positive health-economic effect due to reduced care cost over time.

60%

of amputees say that their daily lives are affected by falls[32]

Vascular Health

The majority of elderly amputees have an amputation aetiology relating to vascular disease or diabetes[5]. The resulting poor circulation and impaired sensation mean the skin and soft tissue of the residuum are vulnerable to irritation and damage. Any resulting wounds heal more slowly and are vulnerable to infection. An infected wound may potentially necessitate further amputation surgery.

Musculoskeletal Concerns

Amputees walk with more reliance on the unaffected leg and asymmetry of gait and standing has been linked to the increased likelihood of developing osteoarthritis[38–40] which is two to three times higher among amputees[38], and an increased chance of developing back pain[41]. In fact, 60% of amputees report moderate to extreme back pain within two years of amputation[42].

Advanced Technology Can Advance Functional Ability

It is common for health services to prescribe inexpensive devices with restricted function to limited community walkers. Prosthetic interventions that are specifically designed for the biomechanical requirements of the older user could help reduce the risk of falls, maintain greater mobility and independence, improve quality of life and help reduce the long term burden on health care services.

Hydraulic Ankle Technology

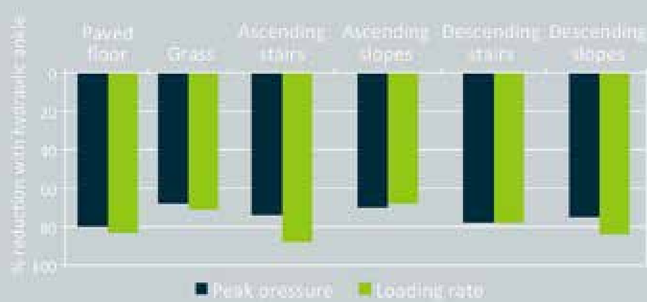
Conventional prostheses are usually firmly attached to the shin or 'pylon' and rely on the deflection or deformation of polymeric foot components to replicate the dorsiflexion and plantarflexion behaviour of the natural ankle. Models of the biological foot have shown that this elastic behaviour is present at normal walking speeds[43]. However, at slow speeds, the ankle becomes a net absorber of energy and the elastic model no longer fits[43]. The viscoelastic behaviour of hydraulic ankles better replicates natural ankle biomechanics.

Hydraulic ankle technology has been proven to provide a number of benefits to elderly amputees. During walking, the deformable components of a prosthesis are deflected when loaded and return to their original position when unloaded. With a hydraulic ankle, when unloaded, the ankle joint remains in a dorsiflexed position, meaning that the toe clearance during swing phase is increased by 18%[44] so there is less chance of catching the foot on the ground or another object and a trip occurring.

The damped motion of the ankle joint also absorbs energy and reduces the loading on the residual limb within the socket. One study measured reductions in peak pressures by up to 81% and in the rate of loading by up to 87%, during a number of different everyday activities[45]. Hydraulic prosthetic ankles seek to mimic biological ankle action with a hydraulically-damped, articulating joint in combination with the deformable foot.

81% reduction in peak pressure when using hydraulic feet on a hard floor[45]

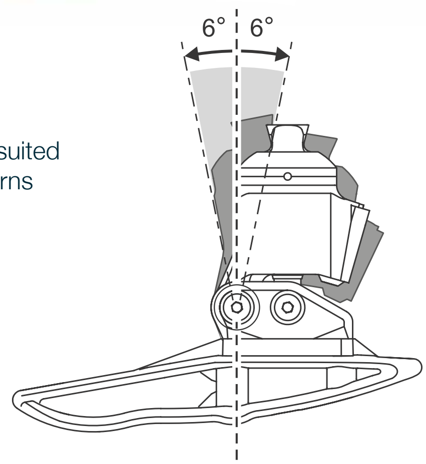
Peak pressure and **loading rate** on residuum compared to previous foot[50]



When using hydraulic feet to climb stairs[45] loading rate reduces by 87%

The Avalon^{K2} Effect

Avalon^{K2} was designed specifically to cater for the biomechanical requirements of older or less active, Activity Level 2 users. It enhances walking confidence because it hydraulically adjusts to inclines and steps. The hydraulic dorsiflexion movement also enhances comfort and balance when sitting down, standing up from a chair or crouching down. Avalon^{K2} self-aligns to secure the knee joint and encourage good posture and joint position, this enhances transfemoral knee stability to help prevent falls and it reduces unwanted moments on the knee joint of transtibial users. The ankle dorsiflexes after mid stance and 'toes' remain elevated during swing phase leading to increased ground clearance for safety and efficiency, providing the best performance for Activity Level 2 biomechanics.



Ankle range of motion suited to elderly walking patterns

Features:

- Waterproof K2 hydraulic ankle foot
- Optimised keel for ease of rollover
- Single valve adjustment for simultaneous plantarflexion and dorsiflexion
- Plantarflexion compliance when descending slopes
- Sandal toe allows different footwear styles

The most energy efficient "rollover" shape has been identified as 30% of the walker's leg length[46,47]. Evidence suggests that when walking at different speeds and on changing inclines, people will adapt other gait kinematics in order to maintain this consistent rollover shape[48]. For a person of a typical adult height between 1.5m and 1.8m, this equates to approximately 245-290mm. The geometry for the Avalon^{K2} keel has been measured to produce a rollover shape of ~250mm[49] of which this rollover is consistent, regardless of footwear[49] .

Another design consideration of Avalon^{K2} was the action of standing from a chair. The keel and shape, along with the 6° of dorsiflexion permitted by the hydraulic ankle, help move the base of support closer to the body's centre-of-mass. Having the feet in a more posterior position reduces joint moments[18–21], making it easier for the user to perform the movement.

Clinical Evidence for Avalon^{K2}

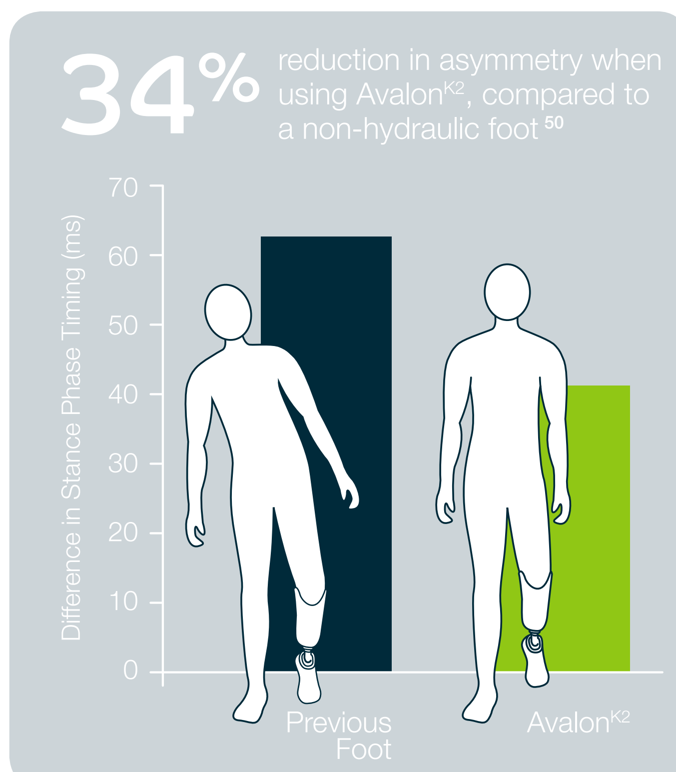
Improved Symmetry

One study sought to measure the impact of Avalon^{K2} compared to non-hydraulic designs, with regards to Activity Level 2 amputees[50].

A mixed group comprising unilateral and bilateral, above and below knee amputees participated in the study. Their gait was assessed with their habitual foot whilst walking at a self-selected speed. Afterwards, these same amputees were provided with Avalon^{K2} hydraulic feet and given four weeks to acclimatise. After the acclimatisation period, their gait was assessed again.

The result of this study was measured by the time for which weight was borne on each leg, with a particular focus on asymmetry between their limbs. Typically, amongst amputees, stance phase duration is longer on the sound side because their residuum may be painful to load, they may have a lack of prosthesis control or there may be a lack of stability provided by the prosthesis. This asymmetry has detrimental consequences for stability and long term health.

Three quarters of the amputees saw a reduction in asymmetry between the two limbs giving a mean reduction of 34%. The greatest improvement observed was for a unilateral below knee amputee, who saw an 86% reduction in asymmetry. When weight bearing is more evenly distributed, there are improvements in gait stability and postural sway. These factors act to reduce the risk of falling, as well as the risk of developing back pain. When there is less reliance on the sound limb for weight bearing, the chances of long term health problems such as osteoarthritis in the joints or lower back pain are reduced.



User Satisfaction

21.9% increase in gait satisfaction with Avalon^{K2} [51]

Patient feedback ratings when using **previous foot** and **Avalon^{K2}** [51]

In another investigation[51], 14 Activity Level 2 users, originally Multiflex wearers were surveyed using the Seattle Prosthesis Evaluation Questionnaire (PEQ) for both Multiflex and Avalon^{K2}. The group consisted of 12 below knee amputees including one bilateral, and two above knee amputees. The group evaluated their Multiflex feet at the start of the research programme, they then wore Avalon^{K2} for a period of four weeks, before completing the same Questionnaire. This scientifically validated instrument asks the amputee about all aspects of their prosthesis through six distinct subsets of questions from mobility capabilities and utility to hygiene and well being.

When evaluating the results, the mean scores throughout the six question categories were consistently higher for Avalon^{K2}. The mean improvement across all categories was 14.7% and included a 17.3% improvement in ambulation, a 17.2% improvement in prosthesis satisfaction and a 21.9% increase in gait satisfaction. When broken down by amputation level, transtibial amputees had a mean improvement across all categories of 16.6%. For transfemoral amputees the cross-category mean improvement was 6.2%.

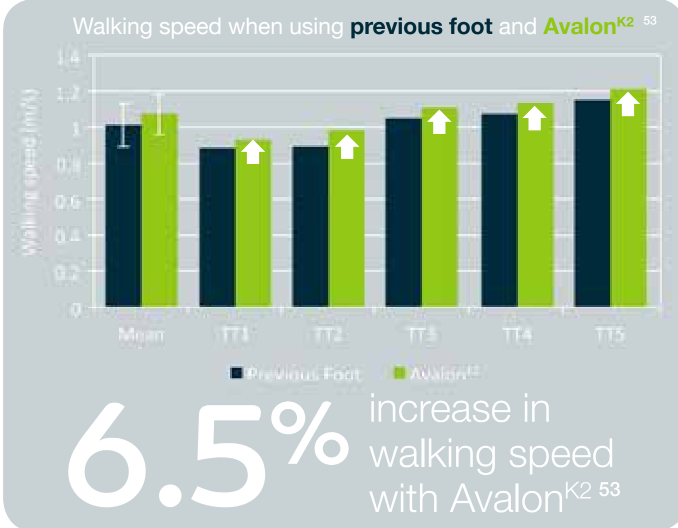
Amputees' perceptions of their own abilities are an important element in prosthetic design. In a published survey[52], a mixture of Activity Level 2 and 3 amputees rated their self-assessed

abilities with hydraulic feet, compared to their prescribed feet. They were asked to rate their ability sitting and standing from chairs of different heights, getting in and out of cars and using the bathroom. Bilateral amputees particularly benefitted from the hydraulic feet, with the average score out of 100 increasing by approximately 12 points. This emphasises the suitability of the Avalon^{K2} design for Activity Level 2 amputees, providing the necessary performance for activities of daily life and maintaining independence.

Increased Walking Speed

For lower mobility amputees, the distance they are able to walk in two minutes is a simple clinical test to indicate the outcome of a prosthetic intervention. One group of researchers performed such tests with five unilateral below knee amputees[53]. Each performed the tests wearing a Navigator foot and an Avalon^{K2}. Navigator uses the same keel design and shape as Avalon^{K2}, but doesn't have an articulating, hydraulic ankle component, so observed differences could be attributed to this additional component. As part of the same study, biomechanical measures were investigated using 3D gait analysis.

All amputees taking part walked further with Avalon^{K2} with a mean walking speed increase of 6.5%. From the gait analysis, it was discovered that participants displayed more symmetrical inter-limb loading – which is related to reducing the risk of back and joint pain development – and a smoother progression of the centre-of-pressure during gait.



Conclusion

The clinical needs of patients must drive prosthetic design. The engineering principles of the design and the technical specifications of its performance must cater to the targeted demographic of amputees.

For limited community ambulators, a change in practice for the prescription of prosthetic feet could provide improved long term outcomes. More advanced technology such as Avalon^{K2}, a hydraulic foot specifically designed to cater for the older user's requirements, could not only be beneficial for the safety and health of the user, but could also be a more sound investment in terms of healthcare economics, helping to reduce the costs associated with fall related injuries and tissue health complaints.

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