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Lower limb prosthetics in England: From national prescription policies to patient satisfaction

Natalie Vanicek
Professor of Clinical Biomechanics
University of Hull

n.vanicek@hull.ac.uk
@NatalieVanicek

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Lower limb amputations in England

- Hospital data from 1 April 2003 from 31 March 2009 reported:
  - 25,312 major lower limb amputations
  - Mean age 70.6 years
  - 68.5% were men
  - 28.6% were from the most deprived areas
- Disease risk factors were diabetes (44%), hypertension (39%) and coronary heart disease (23%)

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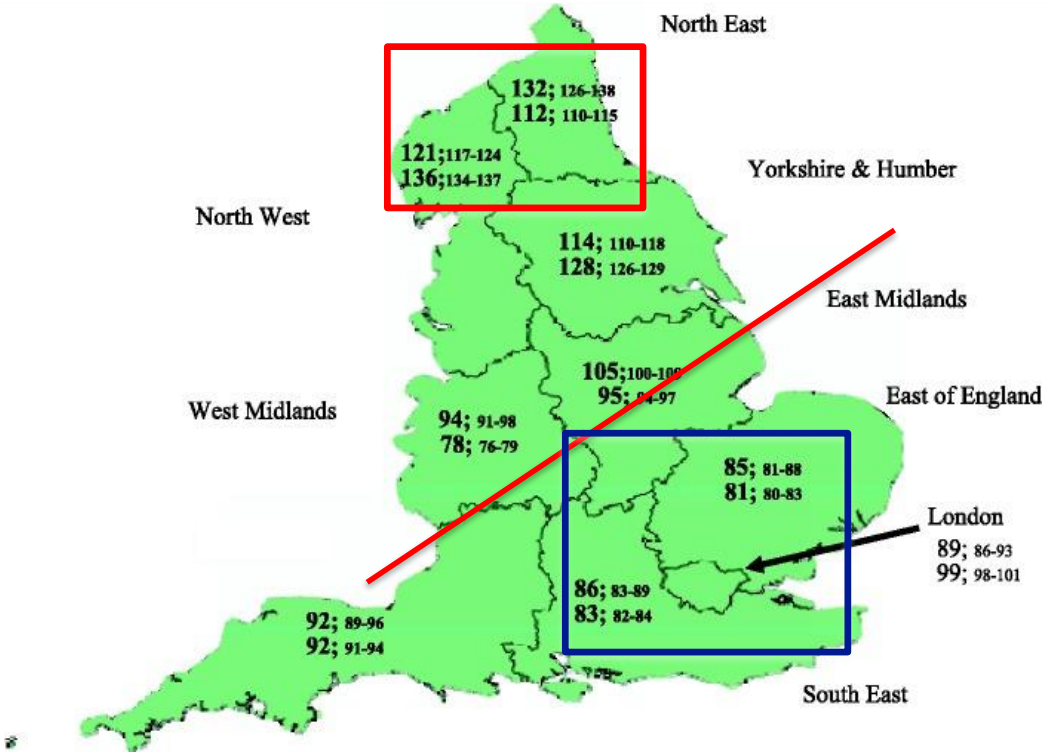
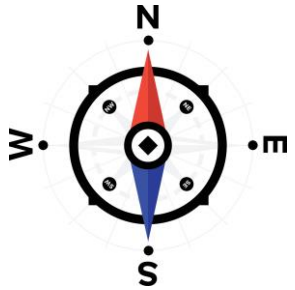
Lower limb amputations in England





Proportional rate of amputation (upper value) and revascularisation (lower value) (95% confidence intervals) by English region (England rate = 100).

Ahmad et al. *J R Soc Med* 2014; 107; 483-489.

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Early gait retraining

Prosthetics and Orthotics International
June 2009; 33(2): 135–147

informa
healthcare

ORIGINAL ARTICLE

Kinematic gait adaptations in unilateral transtibial amputees during rehabilitation

CLEVELAND BARNETT[1], NATALIE VANICEK[1], REMCO POLMAN[2], AMANDA HANCOCK[3], BARBARA BROWN[3], LYNNE SMITH[3], & IAN CHETTER[4]

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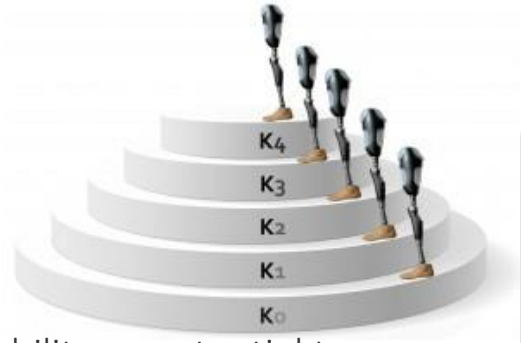
Mobility grades



The amputee K-levels ranking system

•K0 – No Mobility. This base level is assigned to amputees who do not have the ability or potential to ambulate or transfer safely with or without assistance. A prosthesis does not enhance the quality of life or mobility of the amputee.

•K1 – Very Limited Mobility. The amputee has the ability or potential to use a prosthesis for transfers or ambulation in level surfaces at a fixed walking pace. Walking at various speeds, bypassing obstacles of any kind are out of the K1 class.

•K2 – Limited Mobility – The amputee has the ability or potential to use a prosthesis for ambulation and the ability to adjust for low-level environmental barriers such as curbs, stairs, or uneven surfaces. K2 level amputees may walk for limited periods of time however, without significantly varying their speed.

•K3 - Basic to Normal Mobility. The amputee has the ability or potential to use a prosthesis for basic ambulation and the ability to adjust for most environmental barriers. The amputee has the ability to walk at varying speeds.

•K4 – High Activity. The amputee exceeds basic mobility and applies high impact and stress to the prosthetic leg. Typical of the prosthetic demands of the child, active adult, or athlete.

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Mobility grades

DISABILITY AND REHABILITATION, 2003; VOL. 25, NO. 15, 833–844

Taylor & Francis healthsciences

The SIGAM mobility grades: a new population-specific measure for lower limb amputees

N. H. RYALL†*, S. B. EYRES‡, V. C. NEUMANN†, B. B. BHAKTA‡ and A. TENNANT‡

† Prosthetics Department, Chapel Allerton Hospital, Chapeltown Road, Leeds, UK
‡ Rheumatology and Rehabilitation Research Unit, Clarendon Road, Leeds, UK

A Limb wearing abandoned or use of cosmetic limb only.

B Therapeutic wearer wears prosthesis only for transfers, to assist nursing, walking with the physical aid of another or during therapy.

C Walks on level ground only, ⩽50 metres, with or without use of walking aids: a = frame, b = crutches/sticks, c = 1 crutch/stick, d = no stick.

D Walks outdoors on level ground only and in good weather, more than 50 metres, with or without use of walking aids: a = frame, b = crutches/sticks, c = 1 crutch/stick.

E Walks more than 50 metres. Independent of walking aids except occasionally for confidence or to improve confidence in adverse terrain or weather.

F Normal or near normal gait.

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Professional organisations

British Association of Prosthetists and Orthotists

Empowering the Professional to Enable the User

British Society of Physical & Rehabilitation Medicine

British Association of Chartered Physiotherapists in limb Absence Rehabilitation

The Vascular Society for Great Britain and Ireland

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Patient organisations

Limbless Association
Providing support to amputees and the limb-loss community

30 years of inspiration
DBF
DOUGLAS BADER FOUNDATION

Blesma
THE LIMBLESS VETERANS

Limb POWER
Living life without limbs

STEEL BONES
FOR CIVILIAN AMPUTEES
www.steelbonesuk.co.uk

AF
Amputation Foundation

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Prosthetics provision by NHS England

- The number of patients with an amputation or congenital limb deficiency attending specialist rehabilitation service centres in the UK is estimated at 55,000 – 60,000
- NHS England spends approximately £60 million per year on these services (NHS England, 2020)
- There are 35 centres in England that provide specialised prosthetic services (NHS England, 2018)

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Prosthetic ankle-feet

- Insufficient evidence to support the ‘overall superiority of any individual type of prosthetic ankle-foot mechanism’ [1]
- No RCTs involving prosthetic componentry (only socket systems) [2]
- No standardised criteria for the prescription of ankle-foot prostheses

Solid Ankle Cushioned Heel (SACH foot)

Avalon K2 self-aligning foot, hydraulic ankle (Blatchford, UK)

1 Hofstad et al. *Cochrane Database Syst Rev* 2004;1:CD003978
2 Healy et al. *Plos One*. 2018;13(3):42.

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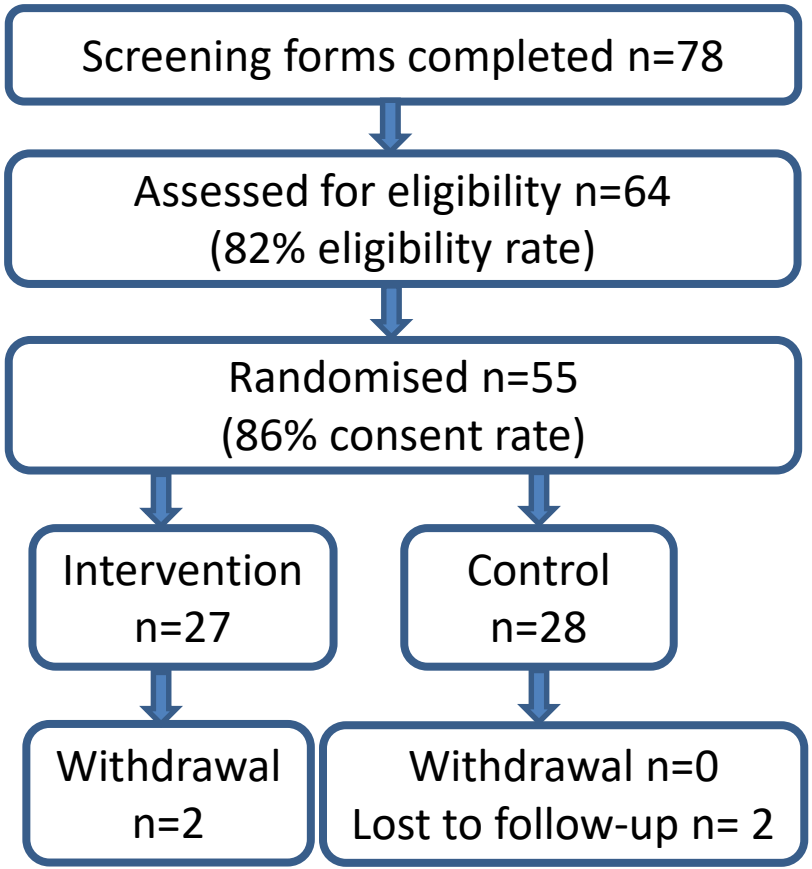
STEPFORWARD



Open access Original research

BMJ Open

STEPFORWARD study: a randomised controlled feasibility trial of a self-aligning prosthetic ankle-foot for older patients with vascular-related amputations

Natalie Vanicek ,[1] Elizabeth Coleman,[2] Judith Watson ,[2] Kerry Bell,[2] Catriona McDaid ,[2] Cleveland Barnett,[3] Martin Twiste,[4] Fergus Jepson,[5] Abayomi Salawu ,[6] Dennis Harrison,[7] Natasha Mitchell[2]

http://dx.doi.org/10.1136/bmjopen-2020-045195

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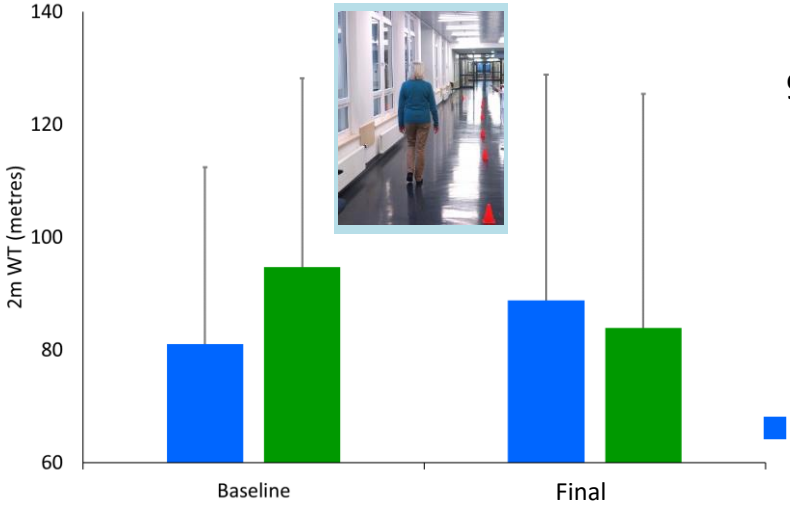
STEPFORWARD outcomes



95% completion rate for all measures

EQ-5D-5L utility scores and unadjusted mean difference

Follow-up	Intervention Mean (SD)	Control Mean (SD)	Difference (Int-TAU) (95% CI)
Baseline	0.62 (0.30)	0.63 (0.35)	-0.009 (-0.188, 0.169)
Interim	0.64 (0.18)	0.57 (0.24)	0.067 (-0.055, 0.189)
Final	0.75 (0.16)	0.63 (0.32)	0.120 (-0.021, 0.262)

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STEPFORWARD take-home message

- STEPFORWARD is one of few clinical trials involving prosthetics intervention

- Full-scale trial will be powered appropriately to detect a difference in the primary outcome between the two trial arms
  - Broadening inclusion criteria
  - Longer follow-up period (final follow-up at 1 year)

- Full-scale trial is required to inform clinical commissioning policies, which would impact the majority of patients with a major lower limb amputation

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Prosthetic knee components

Clinical Commissioning Policy: Microprocessor controlled prosthetic knees

NHS England

December 2016

Reference: NHS England: 16061/P

	Domain 1	Domain 2	Domain 3	
	Preventing people from dying prematurely	Enhancing quality of life for people with long-term conditions	Helping people to recover from episodes of ill health or following injury	Effectiveness
Domain 4	Ensuring people have a positive experience of care			Experience
Domain 5	Treating and caring for people in a safe environment and protecting them from avoidable harm			Safety

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MPK policy

In order to qualify for consideration for an MPK, the patient needs to:

- Meet at least one criteria in each of: 'Amputation level', 'Activity Level' and 'Mobility level'
- Meet all criteria in 'Patient must demonstrate'
- Have at least one of the indications in 'Indications'
- Have none of the contra-indications in 'Contra-indications'.

Amputation level

- Unilateral Trans-femoral
- Hip disarticulation
- Knee disarticulation
- Bilateral lower limb amputee with at least one trans-femoral amputation

Activity level

- K3, patient is able to walk with a free mechanical knee and has the ability or potential for ambulation with variable cadence and traverse environmental barriers as a community ambulator.

Mobility level

- SIGAM D or above. Able to walk more than 50 yards on level ground

Patient must demonstrate

- Commitment to prosthetic rehabilitation through active participation with the therapy team
- Adequate strength and balance to be able to activate the knee unit
- Requirement of MPK as the main day to day prosthesis
- Cognitive reasoning to master control, operation and care of the device
- Sufficient cardiovascular abilities to meet the fitness demands of ambulating outdoors with free knee

To be considered for an MPK prescription, the user should have a comfortable, well-fitting socket and be able to walk out doors with a free knee. In this case an MPK would be indicated:

- With a clinical presentation of unstable gait evidenced as history of frequent falls, stumbles or near misses (e.g. due to contra-lateral limb impairment or amputation). A trial is required to prove reduced risk of falls .
- When the risk of injury from a fall is very high due to a co-existing medical condition (e.g. upper limb joint replacements, inability to protect head in case of a fall due to upper limb impairment, increased risk of fracture). A trial is required to prove reduced risk of injury.
- When the reduced energy requirements for walking would allow the user to improve mobility and environmental obstacle negotiation.

Contra-indications

- Limited cognitive ability to understand operating and care requirements
- K4 activities (mainly activities that include running as most MPK manufacturers recommend against that), except when the manufacturer specifically states suitability for K4 activities as most manufacturers of MPKs would not recommend use for K4 activities
- Low activity level – amputee with no or limited ability or potential to ambulate on level ground at fixed cadence
- Patient's weight or height falls out of manufacturer's recommendations
- Water related activities, unless the MPK manufacturer specifically states the MPK is water proof
- Not enough space to fit the MPK (built on length available) or where cosmetic appearance will be an issue for the user
- Failure to achieve good socket fit or comfort
- Low mobility level (SIGAM A-C), which can't be improved through an MPK trial
- Patient not able to tolerate weight of unit
- Significant hip flexion contracture preventing correct knee alignment and MPKs activation as per manufacturer's recommendations. A hip fixed flexion of 30 or above is unlikely to be suitable for MPK prescription

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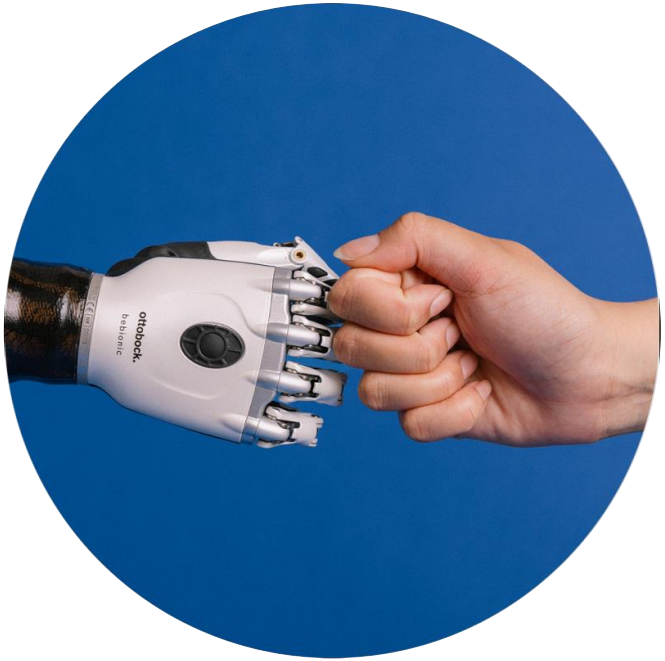
Multi-grip prosthetic hands

NHS England



Clinical Commissioning Policy
Multi-grip prosthetic hand (all ages) (2009) [220801P]

Publication date: August 2022 Version number: 1.0

Commissioning position

Summary

The policy is that the multi-grip myoelectric control prosthetic hand is recommended to be available as a routine commissioning treatment option for congenital upper limb deficiency or upper limb amputation within the criteria set out in this document.

A multi-grip prosthetic allows more than one grip pattern. It can be controlled in two ways, body-powered (using the remaining joint, finger or the muscles on the other side) or myoelectric (powered by a battery source and controlled by learnt specific muscle movements in the remaining arm, hand or finger). It can facilitate a greater range of movements making completing tasks easier for the user.

Patient satisfaction

- Specialised Commissioning: Prosthetics Patient Survey Report 2018
- 855 responses:
  - 88% from adult patients, mostly from patients aged 50-70 years
  - only 6% identified as non-white
  - ~2/3 had lower limb loss; 1/3 had upper limb loss
- Half of respondents travel >30 km
- >2/3 were satisfied with services; 16% were dissatisfied (mostly related to socket fit issues; unnecessary appointments and delays)
- Dissatisfaction with prosthetics, esp. difficulty accessing MPKs and joints that are not moveable, heavy and ‘ugly’

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Patient responses

NHS England

70 YEARS OF THE NHS 1948 - 2018

"There should be a clear catalogue of available options/limbs/sockets under the NHS, which is the same for all providers in England".

"Money should follow the patient with options to easily go to another centre".

"There's significant scope to improve rehabilitation and proactively support patients in having an active life. Provide a more person-centred approach to rehabilitation, not just the prosthesis. Some centres have gyms and group sessions but many do not have anything of that sort".


HOME GUESTS
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HAKA

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THANK YOU

Prof Natalie Vanicek n.vanicek@hull.ac.uk @NatalieVanicek