Technoleg Iechyd Cymru
Health Technology Wales

Evidence Appraisal Report

Multi-grip myoelectric upper limb prosthetics for upper limb amputees

1. Purpose of the evidence appraisal report

This report aims to identify and summarise evidence that addresses the following question: What is the clinical and cost-effectiveness of multi-grip myoelectric upper limb prosthetics in people who have undergone upper limb amputation?

Evidence Appraisal Reports are based on rapid systematic literature searches, with the aim of published evidence identifying the best clinical and economic evidence on health technologies. Researchers critically evaluate this evidence. The draft Evidence Appraisal Report is reviewed by experts and by Health Technology Wales (HTW) multidisciplinary advisory groups before publication.

2. Health problem

Amputation is defined as the elimination of a body extremity and can be caused by trauma, peripheral vascular disease, tumour, infection and congenital anomalies (Das et al. 2018). Levels of upper extremity amputations include:

- fingers or partial hand (transcarpal);
- at the wrist (wrist disarticulation);
- below the elbow (transradial);
- at the elbow (elbow disarticulation);
- above the elbow (transhumeral);
- at the shoulder (shoulder disarticulation);
- above the shoulder (forequarter) (Cordella et al. 2016).

Approximately five to 6,000 major limb amputations are carried out each year in England, of which approximately a fifth are undertaken on the upper limb, most commonly at the transradial level. However, statistics relating to the prevalence of limb absence and provision of prostheses are poor (Chadwell et al. 2016). Based on limbless statistics from 2010/11, which report referral rates in England, it is estimated that approximately 10 people in Wales might benefit from a multi-articulating hand prosthesis, and three people might benefit from a multi-articulating partial hand prosthesis (for details refer to Section 7.2).

3. Health technology

Upper limb prostheses can be cosmetic, with the aim of providing aesthetic substitution for the missing body part, or functional, which aim to allow the facilitation of tasks that would normally be accomplished with the missing limb. Functional prostheses are either body-powered (via the use of a harness and cables), or electrically-powered (via rechargeable batteries)(Cordella et al. 2016).

Electrically-powered prostheses, commonly known as myoelectric prostheses, are the focus of this assessment. Myoelectric prostheses are controlled by biological signals created by the user and transmitted to the prosthesis. The mechanism for this is usually by measuring electromyographic signals created in the residual musculature, which are detected by electrodes housed within the prosthesis (Chadwell et al. 2016, Das et al. 2018).

Early myoelectric upper limb prosthetics were simple open and closed devices (single-grip). Modern prosthetics, however, aim to replicate more of the functions of a natural hand by providing separate or simultaneous control of each finger (multi-grip), with the addition of controllable joints of the fingers to improve dexterity in some cases (Geethanjali 2016, NHS England 2015).

The following section outlines the known manufacturers of multi-grip myoelectric upper limb prosthetics and the different devices they offer. Details of the specifications of each device are listed and compared in Appendix 2.

3.1. Össur Touch Solutions

Össur's Touch Solutions division produces myoelectric hands available in a range of four sizes. These all have five independently-powered digits and multiple grip positions controlled by either muscle signals or via a proprietary app. Individual devices produced by Touch Solutions include:

- i-Limb Access. This hand has individually motorised digits and a manually rotatable thumb that can be positioned between lateral and oppositional mode for creating different grip positions. The hand has 12 different grip positions; specific grips are accessed either via muscle signals or using a proprietary app, whereby touching an icon activates a specific grip position.
- i-Limb Ultra. In addition to the features of the i-Limb Access, this hand has powered thumb rotation, variable grip strength and an anti-drop safety feature. It offers 18 different grip positions.
- i-Limb Quantum. This hand has five independently articulating digits, including an electronically rotating thumb that automatically switches between lateral and oppositional grip patterns. In addition to the pre-programmed options, it offers up to 36 grip positions that can be customised. In addition to muscle signals or app control, grip positions can also be accessed by either the user making specific gestures (moving the hand in one of four directions accesses one of four chosen grips) or via proximity control using Grip Chips. These are small Bluetooth-enabled devices allowing users to enter any available grips by moving their prosthesis close to an object where a Grip Chip is placed.

All Touch Solutions hands have multiple cosmetic covering options available and are available with titanium-strengthened digits that increase the total carry load over the standard prosthetic hands. Touch Solutions also produce the i-Digits partial hand prosthesis, indicated for use in people with absence of one to five digits, distal to the wrist and proximal to the metacarpophalangeal joint. i-Digits is a fully customised partial hand prosthesis with individually-powered digits. The battery and microprocessor are worn as a wristband. i-Digits move independently and work in conjunction with the remaining fingers. As with i-Limb, i-Digits is available in Access, Ultra and Quantum specifications. i-Digits Quantum has 20 different grip options available and 12 customisable grips. All other i-Digits devices have 12 grip options available.

3.2. Ottobock

Ottobock produces the following upper limb prosthetics:

- Michelangelo prosthetic hand. This hand offers seven hand positions, a moveable thumb that can be electronically positioned, and a flexible wrist that has both passive and active wrist rotation. The hand is operated by two drives: the main drive is responsible for gripping movements and gripping force, while the thumb drive allows the thumb to be electronically positioned in an additional axis of movement. Actively driven elements are the thumb, index finger and middle finger, while the ring finger and little finger passively follow the other fingers. The Michelangelo hand is part of a modular system of prosthetic components suitable for transradial or transhumeral amputations, and can be combined with either prosthetic- or manually-powered elbow prostheses.
- Bebionic prosthetic hand. This hand is available in three sizes and three different wrist options to suit different type of amputations. The thumb can be set to two different positions (opposition and lateral), allowing for 14 different grips. Eight grips can be preconfigured using the adjustment software.

Ottobock have also developed the Myo Plus pattern recognition system, which is designed to offer more intuitive control of a prosthetic hand and is designed to be used with Ottobock prosthetic hands.

3.3. Open Bionics

Open Bionics Hero Arm is suitable for adults and children over eight years old with acquired or congenital below-elbow upper limb differences. The Hero Arm is available in three different hand sizes, two wrist sizes and two different arm layouts. The myoelectric hand offers six grips and a manually posable thumb and wrist. Each full prosthesis weighs less than one kilogram; bionic hands weigh 280 grams to 346 grams, depending on size.

4. Existing guidance

The British Society of Rehabilitation Medicine has issued standards and guidelines on amputee and prosthetic rehabilitation (British Society of Rehabilitation Medicine 2018). This includes 17 recommendations on the provision and use of prosthetics by upper limb amputees. These include the following:

- It should be recognised that the use of functional prostheses for more proximal amputations is difficult. In a study by Jones and Davidson, only 37% of upper limb amputees used their prosthesis regularly in the long term, with 19% being occasional users. There is a higher rate of rejection of prosthesis in proximal amputations. Many individuals may only need a cosmetic prosthesis. Cosmetic arms do have some function as they are used for back-up, steadying and supporting use, and may be better termed 'passive function prostheses' (Recommendation 6.25).
- There is a wide range of terminal devices available for use with artificial limbs, and these can be interchanged. It is usually recommended that the amputee start with an active functional terminal device to commence early prosthetic training. Provision of a passive cosmetic hand may also be appropriate at this stage. Future additions or changes depend upon the individual's lifestyle, occupation and leisure activities. The advantages and disadvantages of the different prostheses, especially the myoelectric prostheses, should be explained to the patient. Adequate and appropriate attention should be given to the appearance and cosmetic finish of the prosthesis (Recommendation 6.26).

The NHS England Clinical Commissioning Policy on multi-grip upper limb prosthetics (NHS England 2015) states that NHS England does not routinely commission multi-grip upper limb prosthetics. The conclusions of the policy state:

"Due to the lack of peer-reviewed publications evaluating the functional outcomes of individual digit control in amputees, myoelectric hand prostheses with individual control of digits are considered investigational. There is very little research comparing multi-function prosthetic hands with either body powered prosthetics or single grip prosthetics. However although the research is weak it strongly supports the clinical pathway treating all patients as individuals. The importance of the clinical pathway is ever more important for the patient to be provided with the prosthesis that enables and rehabilitates that individual to allow the highest level of independence possible."

5. Evidence search methods

The criteria used to select evidence for the appraisal are outlined in Appendix 1. These criteria were developed following comments from the HTW Assessment Group and UK experts.

Initial exploratory searches identified a systematic review, originally published in 2015 (Carey et al. 2015) and subsequently updated in 2017 (Carey et al. 2017), which summarises all evidence on the effectiveness of myoelectric and body-powered upper limb prosthetics published up to 2016. The findings of this review were used to inform this appraisal; HTW also conducted an update searches to identify any evidence published more recently (last date of search: 14 November 2019). The search strategy used is available on request.

Appendix 4 outlines the selection of articles identified from literature searches.

6. Clinical effectiveness

We identified one relevant systematic review (Carey et al. 2015) and an update to the same review (Carey et al. 2017). Design and characteristics of the review and update are summarised in Table 1. Appendix 3 summarises the trials included in the systematic review.

We identified a single study (Resnik et al. 2018) published subsequent to the systematic review by Carey et al. that met our inclusion criteria. The purpose of this study was to evaluate the measurement properties of a new measure of activity performance for adults with upper limb amputation, but it also includes some limited data comparing performance scores for users of different types of prostheses. Study design and results are summarised in Table 3.

6.1. Body-powered versus myoelectric prosthetics

We did not identify any sources of comparative evidence that focussed specifically on the intervention of interest (multi-grip myoelectric upper limb prosthetics). The systematic review by Carey et al. compared the effectiveness of any myoelectric prosthesis (type of grip not specified) to any body-powered prosthesis: the type of grip was not specified. The evidence included from this systematic review therefore does not allow separate conclusions to be drawn on the clinical effectiveness of single grip and multi-grip myoelectric upper limb prosthetics compared to body-powered alternatives.

The authors of the systematic review by Carey et al. developed a series of empirical evidence statements comparing body-powered and myoelectric upper limb prosthetics, based on the evidence they identified. Those of relevance to this appraisal are summarised in Table 2.

We identified one observational study (Resnik et al. 2018) published after the systematic review by Carey et al. that also provides some data on functional outcomes in upper limb amputees who used a body-powered or myoelectric prosthesis. Functional outcomes were assessed using the Brief Activity Measure for Upper Limb Amputees (BAM-ULA): scores from the linear regression revealed that myoelectric or hybrid device users completed an average of 2.5 more tasks in the BAM-ULA test than body-powered device users ($p = 0.017$) when controlling for amputation level.

6.2. Single-grip versus multi-grip prosthetics

We did not identify any studies that explicitly studied the comparative clinical effectiveness of single-grip and multi-grip myoelectric upper limb prosthetics. One observational study (Resnik, 2018) reported outcomes (BAM-ULA scores) in patients who used a prosthetic device with either single or multiple degrees of freedom. The descriptions given by the study authors suggest this classification is broadly equivalent to single-grip and multi-grip devices.

The only significant difference observed between users of single-degrees of freedom and multi-articulating terminal devices in crude analyses was in completion of the “tuck shirt” task ($p = 0.04$), with single degrees of freedom device-users having lower scores. There was no significant linear association between the BAM-ULA and degrees of freedom after controlling for amputation level.

Table 1. Systematic review of myoelectric and body-powered upper limb prostheses (Carey et al. 2015, Carey et al. 2017): characteristics and results

Included studies	Inclusion criteria	Quality	Observations/notes
Number of studies: 34 studies (27 experimental or observational studies with reported outcome data) **Total number of patients:** 1,859. Sample size ranged from one to 1,216; median sample size = 12. **Publication year:** 1993 to 2016. **Mean participant age**[1]: 43.3 years.	**Review period:** originally evidence reviewed up to July 2013; updated in 2016 (exact date limit not specified) **Review purpose:** to compare BP and MYO-controlled prostheses to help guide evidence-based clinical decisions. **Included study designs:** editorial, case study/series, observational research designs, experimental research designs, or literature reviews **Included outcome measures:** (1) surveys, (2) laboratory and clinical functional assessments, or (3) analysis of use and ability to perform ADLs	**Study design:** Systematic review Full inclusion and exclusion criteria were not specified Quality of individual studies was assessed using AAOP state-of-the-science evidence report guidelines (2008).	Review authors included a wide range of quantitative and qualitative study designs, and also included some articles that did not report any outcome data (such as narrative review articles). Studies reported outcomes with body-powered or MYO-controlled prostheses; not all studies included both interventions. Where studies did include both interventions, it is not always clear how outcomes were compared (e.g. whether intra- or inter-participant comparisons were undertaken).
Results			
Methods of assessment used: • Surveys (13 of 27 studies) • Functional or laboratory assessments (12 of 27 studies) • Ability to complete ADLs (three of 27 studies)			
AAOP = American Academy of Orthotists and Prosthetists; ADL = activities of daily living; BP = body-powered; MYO = myoelectric [1]Age data was only reported for 20 studies/1,754 patients.			

Table 2. Empirical evidence statements on the effectiveness of body-powered and myoelectric upper limb prosthetics developed by Carey (2015, 2017)

Empirical Evidence Statement	Supporting Studies and quality	Level of Confidence
Depending on functional needs, control scheme familiarity and user preference, either BP prostheses with conventional hook or MYO are advantageous compared with each other or other alternatives.	Five low-quality studies; five moderate-quality studies	Moderate
Compared with MYO prostheses, BP prostheses are more durable, require shorter training time, require less adjustments, are easier to clean, and function with less sensitivity to fit.	Three low-quality studies	Low
BP prostheses provide more sensory feedback than MYO prostheses.	Three low-quality studies	Low
Cosmesis is improved with MYO prosthesis over BP prostheses.	Three low-quality studies; one moderate-quality study	Low
Regular MYO prosthetic-use supports reduced cortical reorganisation and phantom-limb pain intensity.	Two moderate-quality studies	Low
Proportion of rejections are not different between BP or MYO prostheses.	Three moderate-quality studies	Insufficient

Quality of individual studies was assessed using AAOP state-of-the-science evidence report guidelines (2008).

Reviewers rated the level of confidence of each EES as “high,” “moderate,” “low,” or “insufficient” based on the number of publications contributing to the statement, the methodological quality of those studies, and whether the contributing findings were confirmatory or conflicting.

AAOP = American Academy of Orthotists and Prosthetists; BP = body-powered; EES; empirical evidence statement; MYO = myoelectric

Table 3. Characteristics and results of Resnik et al. (2018): a study of the effectiveness of body-powered, single-grip myoelectric and multi-grip myoelectric upper limb prosthetics

Study characteristics	Study design	Quality/reliability	Observations/notes
United States, three centres 35 subjects enrolled, 31 completed the study, mean age was 45 years (SD: 15 years), 89% male. Amputation level: • transradial 57.1% • transhumeral 37.1% • shoulder disarticulation/forequarter 5.7% Device type used in the study: • BP: 11 patients (31.4%) • MYO: 22 (62.9%) The remaining patients (n = 2) used a hybrid device Terminal device degrees of freedom: • Single: 23 patients (65.7%) • Multiple: 11 patients (31.4%) The remaining patient (n = 1) used a solely cosmetic device.	**Inclusion criteria:** Subjects who were at least 18 years old, with an upper limb amputation at the transradial, transhumeral, shoulder disarticulation, or scapulothoracic level. Subjects all completed the BAM-ULA at a screening visit and at a second visit within one week. The BAM-ULA is a 10-item observational measure of activity performance involving 10 standard test activities. Each item is rated as zero for unable to complete or one for did complete.	**Study design:** observational The study was not designed to compare the effectiveness of different limb prostheses, but to evaluate a new outcome measure in upper limb prosthesis users. Linear regression was used to compare BAM-ULA activity performance of users of BP and MYO devices, controlling for amputation level. However, other characteristics and demographics of the two groups, and whether these were similar, were not reported. Four patients were lost to follow-up.	Although functional outcome scores other than BAM-ULA were reported, outcomes with different types of prosthetic limb were not reported separately.

Results
Linear regression revealed that myoelectric or hybrid device users completed an average of 2.5 more tasks in the BAM-ULA test than BP device users (p = 0.017) when controlling for amputation level. The only significant difference observed between users of single-DOF and multi-articulating terminal devices in crude analyses was in completion of the “tuck shirt” task (p = 0.04) with single-DOF device users having lower scores. There was no significant linear association between the BAM-ULA and DOFs after controlling for amputation level. BAM-ULA = Brief Activity Measure for Upper Limb Amputees; BP = body-powered; DOF: degree of freedom; MYO = myoelectric; SD = standard deviation;

6.3. Ongoing trials

We identified one relevant ongoing trial comparing a multi-grip myoelectric prosthesis (Hero Arm, Open Bionics) with standard care (defined in the trial as a single-grip myoelectric prosthesis) in children and adolescents. This study is being conducted in the UK at two centres and runs until June 2020. The characteristics of the trial are summarised in Table 4.

Table 4. Ongoing trial of a multi-grip myoelectric prosthesis compared to standard care

Study name, ID	Design and setting	Eligibility criteria	Interventions	Outcomes	Expected completion
Delivering affordable, functional prostheses in the NHS: a trial across two clinical sites to compare existing care with an affordable, multi-grip prosthesis to increase function and choice for children and adolescents with upper limb difference ISRCTN11950127 https://doi.org/10.1186/ISRCTN11950127.	Randomised cross-over trial, two UK centres.	Patients aged eight to 18 who are trans-radial (forearm) upper limb amputees or with congenital (from birth) limb deficiencies.	Hero Arm™ multi-grip prosthesis Single-grip myoelectric prosthesis.	Upper limb function measured using Action Research Arm Test Health-related QoL measured using PedsQL™ Self-reported function and symptoms in the upper limb measured using DASH All outcomes will be measured at baseline, three and six months.	June 2020
DASH = Disabilities of the Arm, Shoulder and Hand; PedsQL = Paediatric Quality of Life Inventory™; QoL = quality of life					

7. Economic evaluation

7.1. Cost-effectiveness

No full studies evaluating the cost-effectiveness of myoelectric upper limb prosthetics were identified. One study was identified which was available as a conference abstract only (Baltzer et al. 2018). The study used a Markov model to estimate the cost-utility of composite tissue allotransplantation, myoelectric prosthetics, and body-powered prosthetics in bilateral amputees. The study took the perspective of the Canadian healthcare system and measured costs in Canadian dollars (CAD$). Cost-effectiveness was determined using a threshold of CAD$50,000 per quality-adjusted life year (QALY) (equivalent to £22,800 per QALY).

Body-powered prosthetics were found to be the most cost-effective strategy. Myoelectric prosthetics were more effective but not cost-effective, as the incremental cost-effectiveness ratio (ICER) of CAD$75,895 (£34,608) per QALY exceeded the threshold of CAD$50,000 (£22,800) per QALY. Myoelectric prosthetics were found to be cost-effective if the device cost was less than CAD$31,000 (£14,136). In probabilistic sensitivity analysis, myoelectric prosthetics had a 42.3% probability of being cost-effective at the threshold of CAD$50,000 (£22,800) per QALY, while body-powered prosthetics had a 57.5% probability of being cost-effective.

However, while these results were of some interest, it was not possible to critically appraise the study due to the lack of methodological details provided within the conference abstract. As such, the study does not meet the criteria for inclusion in the evidence review.

A de novo analysis on the cost-effectiveness of myoelectric upper limb prostheses was not undertaken because the evidence base was considered to be insufficient to base an analysis upon.

In particular, there is a lack of quality of life evidence available, meaning that it would not be feasible to provide a reliable estimate of QALYs with each prosthetic approach.

7.2. Resource impact analysis

The population that may benefit from myoelectric multi-grip upper limb prostheses was estimated using limbless statistics from 2010/11. The statistics show that there were 323 upper limb amputations in England in 2010/11: 187 had a wrist or above amputation and might have benefited from a multi-grip prosthesis, while 48 patients might have benefited from a multi-articulating partial hand prosthesis, and 88 might have benefited from finger prostheses.

Assuming that the prevalence would be equivalent in the Welsh population (estimated to be 3,138,631), it was estimated that approximately 10 people in Wales might benefit from a multi-articulating hand prosthesis, three might benefit from a multi-articulating partial hand prosthesis, and five might benefit from finger prostheses.

A costing analysis, undertaken as part of an NHS clinical commissioning policy report in 2015, estimated the cost of prostheses over five years, including the cost of equipment and warranty. In people with an amputation at the wrist or above, it was estimated that prostheses would cost £18,406 if an i-Limb device was used or £34,225 if the Michelangelo hand was used. The cost was estimated to be £18,406 (based on the cost of an i-Limb device) for partial hand prostheses and £10,350 for finger prostheses. The manufacturer of the Hero arm provided specific costs for their device. Based on the equipment and warranty cost provided, the Hero arm was estimated to cost £7,595 over a five year period.

The overall cost for the eligible population in Wales was estimated assuming that the myoelectric prostheses would be used in addition to conventional body-powered prosthetics and with a 100% uptake rate. The cost for multi-articulating hand prostheses varies depending upon the device used with a cost of £342,250 for the Michelangelo hand, £184,060 for the i-limb device and £75,950 for the Hero arm. The overall cost was estimated to be £55,218 for partial hand prostheses and £51,750 for finger prostheses. The overall cost impact for all eligible upper limb prostheses in Wales was therefore estimated to be between £182,918 and £449,218 (depending on device used for multi-articulating hand prostheses).

However, it should be noted that this cost estimate is likely to be an underestimate as it is based only on the cost of equipment and associated warranty. The true cost is likely to be much higher when considering the cost of fitting and training to use the device.

8. Organisational issues

People who have undergone upper limb amputation require long-term rehabilitation and, where they use a prosthesis, intensive training in using the device, initially followed by ongoing long-term support. This applies to all types of upper limb prostheses, but the complexity of multi-grip myoelectric upper limb prosthetics means that training and support needs are likely to be greater than for other types of upper limb prosthetics. In Wales, upper limb prosthetics care is delivered via three specialist centres in Swansea, Wrexham and Cardiff.

British Society of Rehabilitation Medicine guidelines recommend that initial rehabilitation and training of upper limb amputees is carried out within a prosthetic and amputee rehabilitation centre by a specialist team, which includes a consultant in rehabilitation medicine, prosthetists, physiotherapists, occupational therapists, clinical nurse specialists, a counsellor/practitioner psychologist and a rehabilitation engineer. Intense occupational therapy, where the patient has multiple appointments through the week for a week or more at the specialist rehabilitation centre, may sometimes be required.

9. Patient issues

We identified two relevant qualitative studies that described users' experiences of using multi-grip myoelectric upper limb prostheses.

Widehammar et al. (2018) investigated how environmental factors influence patients' use of a myoelectric arm prosthesis. The study interviewed patients who were recruited from three specialist centres in Sweden. Thirteen patients previously provided with a myoelectric prosthetic hand participated: six reported that they used their prosthesis daily, whilst seven were classified as 'non-daily' users (ranging from use at work only to never). Only a minority of participants in the study (n = 5) had an acquired amputation; the remainder (n = 8) used a prosthesis due to upper limb reduction deficiency.

The results identified four categories of environmental factors describing users' experience:

- *Prosthesis function*. Almost all participants commented on the fact that the prosthesis could not fully compensate for a real hand in terms of motor and sensory function, but they were satisfied with its functionality. Despite this satisfaction, hardly any of the participants trusted their prosthesis completely. All participants experienced limitations in the function of the prosthesis. Those who used the prosthesis the most, the daily users, found the most limitations. In contrast, non-daily users indicated that the limitations in functionality and appearance were the greatest barriers to use. Specific limitations mentioned included: lack of sufficient grip from the hand, the heavy weight of the prosthesis and the noise of the motor. Female participants noted that the prostheses for women were not made in suitably small sizes. For the non-daily users, this lack of trust was their reason for non-use, whereas for the daily users, the advantages of the prosthesis outweighed their mistrust and made it still worth using.
- *Other people's attitudes*. Other people's attitudes were perceived both as a barrier and a facilitator in terms of prosthesis use. The daily prosthesis users had no problem with other people's attitudes; they wore their prosthesis in social situations to draw attention away from their disability. Daily users felt uncomfortable when they were not wearing their prosthesis in public. For the non-daily users and those with only limited experience using the prosthesis, people's attitudes were a barrier. These participants had not integrated the prosthesis into their body language, and consequently, the prosthesis itself received unwanted attention. All groups stated that they did not want to stand out or to be considered less skilled because they only had one hand.
- *Support from family and healthcare*. All daily users described how they had been supported by their families or other social networks to use the prosthesis. Some non-daily users lacked social support for prosthesis use, while others stated that they neither wanted support for this nor missed it. Where there was insufficient support from healthcare professionals, people found it difficult to learn how to control their prosthesis, and they did not become daily users.
- *Individuals' attitude and strategies*. Individuals' attitudes toward the prosthesis itself and also their approach to life influenced their view on the usability of the prosthesis, with a positive attitude encouraging prosthesis use. Motivation for learning to use the prosthesis differed in different participants. The non-daily users found it difficult to learn how to wear and control their prosthesis. All of the participants said that they had to adapt to situations involving two-handed activities. The daily users adapted using the prosthesis, and the non-daily users adapted, for example, by using their residual limb, trunk, or teeth to compensate for the loss of a hand.

Franzke et al. (2019) describe the opinions of users (n = 15) and therapists (n = 7) with experience of multi-function myoelectric upper limb prostheses at two institutions in the Netherlands and one in Austria. Thirteen of the users were amputees: two had a congenital upper limb deficiency. All participants used one of the commercially available devices described in this report (bebionic: n = 3; i-Limb [various specifications]: n = 5; Michelango: n = 6). The article also described some users' experiences with an experimental pattern recognition control system: as this system appears to be not one that is commercially available, the data are not included in this evidence review. All prosthesis users had experience with a standard one-degree of freedom myoelectric prosthesis as well as a multi-grip prosthesis.

Seven of the 15 users said they were satisfied with conventional control, whereas five users clearly reported dissatisfaction, and three users made ambiguous statements about satisfaction. Nearly all of the participants described the process of switching between prosthesis functions as a major problem: users and therapists noted that switching functions could be time-consuming, unreliable, non-intuitive and mentally exhausting. Instead of adjusting the prosthesis to the given tasks by switching the prosthesis function, many users preferred using compensation strategies (e.g. trunk or shoulder motions) to appropriately position the prosthesis. Most of the users did not exploit more than two or three prosthesis functions because more functions and their corresponding "mode switching" muscle contractions were perceived as confusing and hard to remember.

Multi-function prostheses were perceived by users and therapists to be fragile: broken fingers and gloves were mentioned as recurring issues. When lifting heavy objects, the prosthetic hand was reported to open unintentionally. Many users tried to avoid using their prosthesis for tasks that they perceived as too difficult, due to the high chances of prosthesis damage or the device not functioning as intended.

The study authors concluded that one-handed behaviour is common in unilateral upper limb prosthesis users. Despite their multiple potential functions, multigrip prostheses are commonly used only as simple, stabilising and supporting tools for activities of daily living requiring two hands. The majority of the users stated that they used their multi-function prosthesis most often for tasks that cannot be executed in a unimanual way, which was strongly confirmed by the therapists.

10. Conclusions

The aim of this evidence review was to assess the clinical and cost-effectiveness of multi-grip myoelectric upper limb prosthetics, in comparison to standard care, for people that have undergone upper limb amputation. We identified very limited evidence to inform this comparison. Published evidence on the clinical effectiveness of multi-grip myoelectric upper limb prosthetics is only available from observational studies. These included some evidence on functional outcomes, cosmesis, and rejection rates in people who use different types of upper limb prosthetics. We did not identify any sources of evidence on complications or adverse events experienced by people using different types of upper limb prosthetics, or any quantitative evidence about quality of life in these individuals. To our knowledge, no published randomised trials comparing multi-grip myoelectric upper limb prosthetics to any other intervention have been published, although we did identify one ongoing trial in children and adolescents.

The studies included date back to 1993, and likely include technologies that are no longer relevant to current practice. Many of the studies did not include a control group. Where a control group was included, the direct applicability of the evidence to the review question is questionable, as nearly all comparative evidence studied myoelectric devices without specifying grip (i.e. it is not possible to separate evidence on single-grip and multi-grip devices).

Evidence suggests myoelectric and body-powered upper limb prosthetics offer a range of advantages and disadvantages, but based on current evidence, the clinical effectiveness of these interventions is difficult to compare quantitatively.

Based on the very limited evidence identified, it is not possible to draw any conclusions on the comparative effectiveness of single-grip and multi-grip upper limb prosthetics. Qualitative evidence and expert feedback emphasised that upper limb amputees require highly individualised care, depending on multiple factors, including their level of amputation and the range of activities/occupations that they undertake. Amputees' preferences for different devices may also be guided by a wide range of factors such as weight, customisation of fit, ease of use and type/number of grips provided. Amputees' preferences or needs may changes over time, due to aging or changes in personal circumstances/activity levels.

We did not identify any relevant sources of cost-effectiveness evidence to inform this review. De novo cost-effectiveness analysis was not undertaken because the evidence base was considered to be insufficient to base an analysis upon. Resource impact analysis showed that introducing myoelectric multi-grip prostheses for the eligible population in Wales would cost between £182,918 and £449,218. However, this is based only on the cost of equipment and associated warranty. The true cost is likely to be much higher when considering the cost of fitting and training to use the device.

11. Contributors

This topic was proposed by Dr Andrew Champion, Head of Evidence and Evaluation, Welsh Health Specialised Services Committee.

The HTW staff and contract researchers involved in writing this report were:

- J Washington: literature searching
- M Prettyjohns: project oversight and authored economics section
- D Jarrom: identified and appraised clinical effectiveness evidence, primary author of report
- S McAllister: expert review liaison, project management

The HTW Assessment Group advised on methodology throughout the scoping and development of the report.

A range of clinical experts from the UK provided material and commented on a draft of this report. Their views were documented and have been actioned accordingly. All contributions from reviewers were considered by HTW's Assessment Group. However, reviewers had no role in authorship or editorial control, and the views expressed are those of HTW.

Experts who contributed to this appraisal:

- Ian Massey, Clinical Lead Prosthetist, Artificial Limb & Appliance Service, Rookwood Hospital, Cardiff
- Katie Davis, Team Lead Prosthetist, Betsi Cadwaladar University Health Board
- Laurence Kenney, Professor in Rehabilitation Technologies, University of Salford
- Peter McCarthy, Artificial Limb & Appliance Service, Morriston Hospital, Swansea
- Sarah Cooper, Sales Manager UK and Ireland, Open Bionics Ltd

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Appendix 1. Evidence review inclusion and exclusion criteria

Research Question	What is the clinical and cost-effectiveness of multi-grip myoelectric upper-limb prosthetics in people that have undergone upper limb amputation?

	Inclusion criteria	Exclusion criteria
Population	People with upper limb amputation **Note**: May be subgroups for patients with amputations above or below the elbow	
Intervention	Myoelectric multi-grip upper-limb prosthetics with or without body powered prosthetics: • i-Limb products (i-Limb, i-Limb pulse, i-Limb Ultra, and i-Limb Ultra Revolution) • Ottobock Michelangelo Hand • Be-bionic **Note**: myoelectric prosthetics may be given as an addition to conventional prosthetics rather than an alternative. This may be the optimal approach as the different prosthetics have complementary strengths and weaknesses.	DEKA/LUKE arm Expert advice indicates that this arm is not currently available in the UK. It is a US based device that is still in the relatively early stages of development and so would only be used as part of a research project.
Comparison/ Comparators	Conventional upper limb prosthetics: • Body-powered prosthetics alone • Simpler forms of myoelectric prosthetics (e.g. single grip) No prosthetic	
Outcome measures	Functional assessment outcomes Cosmesis outcomes Rejection rates Complications Health-related quality of life	
Study design	We will include the following clinical evidence in order of priority: • Systematic reviews • Randomised or non-randomised trials. • Non-randomised trials. We will only include evidence for "lower priority" evidence where outcomes are not reported by a "higher priority" source. We will also search for economic evaluations or original research that can form the basis of an assessment of costs/cost comparison.	

Appendix 2. Design and specifications of different multi-grip myoelectric upper limb prosthetic devices

Device (manufacturer)	Intended use	Range of sizes/customisability	Device weight	Number of grips	Grip speed	Maximum carry load	Battery life	Expected service life	Reference
i-Digits (Touch Solutions)	Absence of one to five digits, distal to the wrist and proximal to the metacarpophalangeal joint.	Four digit sizes, two digit mounting options (straight and splayed)	Not known	Up to 20 plus 12 customisable	0.8 seconds from fully open to fully closed	20 kg total device or five kg per finger	Up to 16 hours	Five years	Ossur Touch Solutions (2019)
i-Limb (Touch Solutions)	Individuals with upper limb absence with the potential to use an upper limb prosthesis	Four hand sizes, hand is designed to be used with a socket customised to the individual user	392 g to 628 g, depending on size and specification	12 to 32 depending on specification	0.8 seconds from fully open to fully closed	40 kg total device or 20 kg per finger for extra small size, 90 kg total device or 32 kg per finger for all other sizes	Designed to last for a full day's use	Five years	Ossur Touch Solutions (2018)
Michelangelo prosthetic hand (Ottobock)	Upper limb absence, suitable for transradial or transhumeral amputations,	Single hand size, three wrist options, and can be combined with either prosthetic or manually powered elbow prostheses.	460 g to 510 g, depending on fitting	Seven hand positions with a moveable thumb that can be electronically positioned	325 mm per second	Not known	Not known	Two year standard warranty, intended lifespan not known	Ottobock (2019b)
Bebionic prosthetic hand (Ottobock)	Upper limb absence	Two hand sizes, three wrist options	433 g to 689 g, depending on size and fitting	14 grips, eight can be preconfigured	Not known	500 N on chassis, 32 N per finger	Not known	Five years	Ottobock (2019a)
Hero Arm (Open Bionics)	Acquired or congenital below-elbow upper limb differences	Three different hand sizes, two wrist sizes and two different arm layouts	280 g to 346 g, depending on size	Six grips and a manually posable thumb and wrist	0.5 to 1 second depending on type of grip	2 kg per finger, 35 kg using gripped hand	Up to 12 hours	Not known	Open Bionics (2019)
All devices known to be available to the UK NHS as of November 2019 are included.									

Appendix 3. Studies included in systematic review by Carey (2015, 2017)

Author	Year	Study design	Prosthesis types	Sample size	Mean participant age, years	Outcome measures
Sensinger	2015	Controlled Before and after trial	Body-powered	2	29	SHAP, survey
de Boer	2016	Cross-sectional study	Myoelectric	22	NR	Movement time, force control, box and blocks, hand opening duration
Major	2014	Cross-sectional study	Myoelectric	7	49	ROM, absolute kinematic variability (SD), kinematic repeatability (adjusted coefficient of multiple determination) quantified for triplanar trunk motion, shoulder flexion/extension, abduction/adduction, elbow flexion/extension
Carey	2009	Single-subject trial	Body-powered, myoelectric	1	32	Joint angles during ADLs
Hebert	2012	Single-subject trial	Body-powered, myoelectric	1	28	Modified Box and Blocks
Cupo and Sheredos	1996	Controlled before and after trial	Hybrid	7	55	Elbow control, terminal device control, elbow lock control, ease of use, reliability, appearance, battery charging procedure, cable control, noise level, weight, safety, comfort, training, durability
Cupo and Sheredos	1998	Controlled before and after trial	Body-powered	16	56	Custom survey
Kitayama	1999	Controlled before and after Trial	Body-powered	12	NR	Force to open TD at various elbow flexion angles. Hook opening force and angle. Cable operating efficiency
Atkins	1996	Cross-sectional study	All amputations	1216	45	Custom survey
Biddiss	2007	Cross-sectional study	Passive, body-powered, myoelectric	145	43	Prosthesis use and rejection rates
Bouwsema	2012	Cross-sectional study	Myoelectric	6	36	SHAP and kinematics
Dudkiewicz	2004	Cross-sectional study	Cosmetic, body-powered	33	41	Etiology
Gaine	1997	Cross-sectional study	Body-powered, myoelectric	55	NR	Custom survey: satisfaction, function, employment
Hafshejani	2012	Cross-sectional study	Body-powered, myoelectric	40	53	TAPES-Functional limitation
Hafshejani	2012	Cross-sectional study	Body-powered, myoelectric	40	53	TAPES-Psychosocial adaptation

Author	Year	Study design	Prosthesis types	Sample size	Mean participant age, years	Outcome measures
Hafshejani	2012	Cross-sectional study	Body-powered, myoelectric	40	53	TAPES-Prosthetic satisfaction
Kejlaa	1993	Cross-sectional study	Passive, body-powered, myoelectric	66	53	Custom survey: Potential disuse factors
Lotze	1999	Cross-sectional study	Cosmetic, myoelectric	14	47	fMRI, Multidimensional Pain Inventory, interviews
McFarland	2010	Cross-sectional study	All Combat Wounded Persons with Amputation	97	45	Custom survey
Bouffard	2012	Qualitative study	Body-powered, myoelectric	12	57	PLP, PLS. Used semi-structured interview on PLP and PLS as well as QUEST29 survey, Groningen Questionnaire
Carey	2008	Case series	Myoelectric	7	49	Joint angles during ADLs
Daly	2000	Case series	Myoelectric	13	NR	ROM, pull-off force
Meredith	1994	Case series	Body-powered, myoelectric	3	57	Nine hole peg test (timed coordination), JebsenTaylor Test (unilateral ADL hand function), Box and Blocks Test (timed manipulation and precision)
Berbrayer and Farraday	1994	Case study	Passive, myoelectric	1	31	Increased ADL capabilities
Highsmith	2009	Case study	Activity-specific: USF kayak hand	1	NR	Performance of activity
Hung and Wu	2005	Case study	Activity-specific: utensil	1	NR	ADL Independence
Kyberd	1993	Case study	Myoelectric	1	NR	Task completion times
Biddiss and Chau	2007	Systematic review	Body-powered, myoelectric	N/A	NR	N/A
Dougherty	2013	Expert opinion	Body-powered, myoelectric, hybrid	N/A	N/A	N/A
Huang	2001	Expert opinion	Body-powered, myoelectric, hybrid	N/A	N/A	N/A
Lim	1997	Expert opinion	Body-powered, myoelectric	N/A	N/A	N/A
Miguelez	2002	Expert opinion	Myoelectric	N/A	N/A	N/A
Uellendhahl	2000	Expert opinion	Myoelectric	N/A	N/A	N/A
Williams	2011	Expert opinion	Body-powered, myoelectric, hybrid	N/A	N/A	N/A

ADL = activity of daily living, fMRI = functional magnetic resonance imaging, N/A = not applicable, NR = not reported, PLP = phantom limb pain, PLS = phantom limb sensation, QUEST = Quebec User Evaluation of Satisfaction with Assistive Technology, ROM = range of motion, SD = standard deviation; SHAP = Southampton Hand Assessment Procedure, TAPES = Trinity Amputation and Prosthesis Experience Scales, TD = terminal device, USF = University of South Florida

Appendix 4 - PRISMA flow diagram outlining selection of papers for clinical and cost effectiveness