

Work in Progress

Do High Definition Silicone prostheses improve psycho-social and functional outcomes for patients with partial hand, feet or digital amputations?

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Background

What is High definition silicone (HDS)?

- The material currently used to create life-like cosmetic covers for digits, partial hand and foot prostheses, and prosthetic limb covers (see figures 1, 2 and 3).
- There are multiple colour options to optimise the match to a person's skin tone.
- Additional personalised features include matching hair, freckles, veins and tattoos [1].
- The National Health Service (NHS) does not routinely fund HDS prescriptions due to the insufficient evidence available to support a policy for routine commissioning [2].
- Therefore, further evidence is needed to evaluate its value.
- Thought to affect 550 patients per year [2].

What other options are available?

- Box mould silicone for partial foot prostheses / low definition silicone or polyvinylchloride (PVC) gloves for partial hand prostheses.
- Prescribed first and second-line ahead of HDS, as they are comparatively cheaper products which take less time to manufacture.

What evidence do we have?

- To date, little has been published on the potential value of prosthetic cosmesis.
- Feelings of poor body image are directly linked to depression and satisfaction with life in amputees [4,5].
- 49-59% people are neutral or dissatisfied with the colour, shape, and feel of their prosthesis [6].
- Donovan-Hall [3] explored the psychological and social effects of HDS compared to other options:
 - In a cohort of lower limb amputees, HDS improved engagement in activities involving revealing the body as well as confidence associated with partaking in day to day activities.
 - The major limitation was the comparison of the participants to themselves (as opposed to comparable participants), as receiving any new prosthesis may in itself improve psychosocial outcomes.
- Carroll and Fyfe [7]: patients with digital silicone prostheses (of any definition) had a better attitude towards their prosthesis and experienced less anxiety and depression.
- Wetterhahn et al [8]: found a significant positive relationship between the body image of individuals with lower limb amputations and physical activity levels.
- Providing function to an amputated limb may be key in altering central and/or peripheral pathways linked to pain: giving patients to move their phantom limb, for example using mirrors [9], visual avatars [10] or multi-modal sensory-motor training [11] has been shown to reduce phantom limb pain, above that which would be achieved by non-visual methods. A reduction in phantom limb pain has also been linked via the enhanced use of myoelectric prostheses [12].
- Studies have previously attributed cosmetic prosthetic devices as having significant functional value aside from their social functionality, being actively used in the performance of everyday activities [13,14,15]. However there has been no research examining specifically whether HDS influences function compared to other materials.

Figure 1



Aims

- To explore how and whether HDS affects psychological, social and functional outcomes when compared to conventionally prescribed products, for patients with partial hand/foot or digital amputations.
- To contribute to evidence available for NHS to decide on whether the routine commissioning of HDS is appropriate.

Design and Setting

The Prosthetics Rehabilitation Unit (PRU)

- The PRU in the Royal National Orthopaedic Hospital is an outpatient NHS department in London, United Kingdom.
- Over 1,600 patients of all ages with upper and/or lower limb amputations are registered to the department's database.
- The unit provides secondary and tertiary level services to patients across England.
- A retrospective cross-sectional study was undertaken at the unit between January 2019 and September 2019.

Table 2

Tool name	Summary
Trinity Amputation and Prosthesis Experience Scales-Revised (TAPES-R)	This is a multi-dimensional assessment of the psychological and social processes involved in adapting to amputation and wearing a prosthesis. At the time of its development, there was no psychometric assessment tool specific to limb loss that was theoretically and empirically derived. It has proven to have good reliability and validity for use in amputees. The 'revised' version exists for assessment of lower limb amputees. The TAPES-R is a self-reporting questionnaire comprising of 6 subscales in total. There are 3 for psychosocial adjustment (general adjustment, social adjustment, and adjustment to limitation), where higher scores indicate a favourable adjustment. There is 1 subscale for activity restriction, where a higher score indicates greater restriction. Lastly there are 2 for prosthesis satisfaction (aesthetic and functional satisfaction), where higher scores indicate greater satisfaction with the prosthesis. Current norms are being developed for the TAPES-R. At present, each score is compared against the group average.
Trinity Amputation and Prosthesis Experience Scales-Upper (TAPES-U)	The 'Upper' version exists for assessment of upper limb amputees. Desmond et al conducted a study of the TAPES used in a sample of veterans with acquired upper limb amputations. The original TAPES was modified to adjust for the location of the amputation. Internal reliability for each of the scales reached acceptable levels. In terms of how it differs, the TAPES-U includes the additional subscale optimal adjustment within the psychosocial subscale. It does not include the activity restriction subscale of the TAPES, as questions are based largely on lower limb functions such as walking. As such, it is recommended that a separate upper limb function assessment tool is used in conjunction with the TAPES-U. Lastly, the satisfaction with prosthesis subscale is not subdivided as in the TAPES-R. Scores for each subscale are interpreted as for the TAPES-R.
Disabilities of the Arm, Shoulder and Hand (QuickDASH)	The QuickDASH is a validated tool used to measure physical function of the upper limb. A study of veteran upper limb amputees provided evidence of reliability and validity in this cohort. It consists of 11 items to measure physical function and symptoms in persons with any or multiple musculoskeletal disorders of the upper limb. A higher score indicates greater disability.
The Hospital Anxiety and Depression Scale (HADS)	The HADS is a validated tool used to measure anxiety and depression in people with physical disorders. It has been validated in multiple languages, countries and settings. The HADS is scored between 0-21, scores of 0-7 being normal, 8-10 being borderline abnormal, and 11-21 being abnormal.

Figure 2



Methods

Selection process

- A database analysis identified the subjects. The inclusion and exclusion criteria are listed in Table 1.

Table 1

Inclusion Criteria
Any, two or all of: partial foot amputation, partial hand amputation, or amputated digit/toe
The person is currently using at least one prosthesis (HDS vs. other)
Over 18 years of age
Good understanding of the English language
Exclusion Criteria
Neurological and/or cognitive impairment to the extent that understanding is impaired

- Information pack sent to potential participants contained a covering letter, details of the project aims and processes, and consent form.
- Participants then contacted by telephone.
- Verbal consent documented in writing on the consent form by interviewer.
- A single telephone interview was conducted (30-60 minutes)
- Total 146 participants invited.

Data collected using structured questionnaire

- Demographical questions including age, sex, employment status, relationship status.
- Prosthetic questions including on the main prosthesis worn, when it was obtained, patterns of use, clinic attendance, and prosthesis overall satisfaction (Likert scale 0-10).
- Amputation-related questions included age at having an amputation and cause.
- Questions regarding whether the person experienced residual limb complications such as pain, phantom limb pain, or skin breakdown.
- Four validated tools included and/or substituted depending on the level of amputation: The Hospital Anxiety and Depression Scale (HADS), Trinity Amputation and Prosthesis Experience Scales-Revised (TAPES-R) for lower limb amputees, and Trinity Amputation and Prosthesis Experience Scales-Upper (TAPES-U) and Disabilities of the Arm, Shoulder and Hand (QuickDASH) for upper limb amputees. These tools have been summarised in Table 2.

Statistical analysis

- Non-parametric statistical analyses undertaken due to small number of participants.
- Participants split into 2 groups: those who used HDS as their primary prosthesis, and those who used other types.
- Results also give Z (standard) scores from which effect sizes can be calculated [16]. Cohen reports the value of effect sizes to be small at 0.2, medium at 0.5 and large at 0.8 [17].

Ethics

- Full ethical approval obtained via the NHS Health Research Authority.

Figure 3



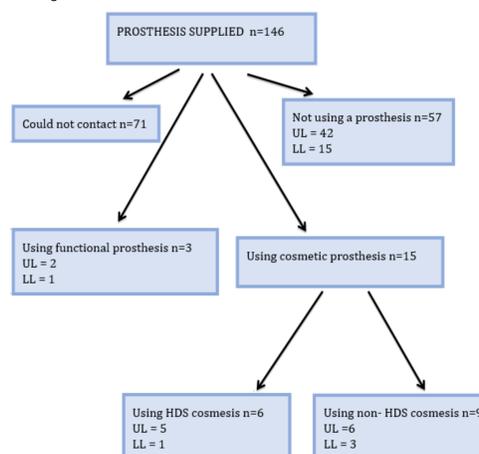
Preliminary Results

- A total of 15 participants were enrolled into the study: 6 wore HDS as their primary prosthesis, and 9 used other types of cosmetic prosthesis.
- See figure 4 for the process of participant selection.
- 39% population were no longer using a prosthesis following its provision and so were discluded from the study: 42 upper limb versus 15 lower limb.
- Reasons included;
 - Some found they were better able to function without a prosthesis than with one.
 - Others reported finding the prosthesis unacceptable in some way, for example its comfort or appearance.
 - This may be attributed to the Unit's policy to provide new amputees with low-definition prostheses first-line.
- HDS has a moderate effect on improving function in patients with upper limb partial hand or digit amputations.
- HDS has a moderate effect on improving phantom limb pain in patients with upper or lower limb amputations.
- Minimal effect demonstrated that HDS affects psycho-social function or mood.

Questions for You

- What is your unit's policy on prescribing HDS?
- What is your opinion of the effects of prescribing HDS over other products?
- Do you think HDS improves the psychological, social and functional statuses of your patients? If so, in which ways?
- Looking at our results so far: are they what you expected? If not, why not?
- Why do you think so many more upper limb amputees reject their prosthesis after its provision?
- Why do you think HDS has been shown to have a moderate effect on improving phantom limb pain?
- Any (constructive) feedback?

Figure 4



The experience of the participants

'(The HDS prosthesis) is an extension of my finger as far as I am concerned. It isn't a vanity thing; for typing it's invaluable. It's so useful for what is designed for, and perfect for it. I couldn't be more satisfied. You actually get some sense of a natural finger through the silicone, which I didn't get with the low definition silicone'.

'I switched to an HDS prosthesis as the others hardened too quickly and caused blisters. With the HDS it was a revelation: just like a second skin... It has been a constant comfort for me. I sleep with it on, I bathe with it on. You get so accustomed to wearing it, you couldn't wear the other one again. You can't even compare'.

When I read the paper, the prosthesis (PVC glove) goes black. It is hard to clean. The colour is not right on the prosthesis. The lip shows which I don't like. It is uncomfortable when I put my hand in.

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