Upper Limb Prosthetic Outcome Measures (ULPOM) Group

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Background
In recent years there has been a sea change in the field of hand prosthetics, an increasing number of clinicians and researchers have a desire to be able to objectively measure the functional effectiveness of a prosthesis, or the ability of a user with their device. The problem has been that there are many tools to measure the function of hands and arms, but few seem appropriate to prosthetics. Also the tools that do exist seem to have conflicting aims and methods, so it is hard to choose the appropriate test. If practitioners have no meaningful way to test if a device is better for one user (compared with another device), they have no easy way to demonstrate to funders or providers that one solution is more effective than any other. Similarly, they lack a common language to simply pass on their professional judgement to their colleagues.

What does exist is an array of different tools for measuring different aspects of prosthetic design, function and use. There is little standardisation between centres in the same country, let alone across borders and seas. Worse, there is evidence that existing techniques are being invalidated (conceivably through ignorance, and definitely due to pressures of time to conduct a truly systematic study). To save time, or effort, fully validated tests are being shortened, or favoured sub tests are being selected from the greater whole, so that the results obtained are incomplete, invalid, or simply wrong.

Evolution of an approach
From the above, it became apparent to many in the field that there was a need to attempt to achieve greater knowledge and understanding by practitioners and engineers who are connected to this field.

The first stage in meeting this need was a workshop hosted by the Institute of Biomedical Engineering and chaired by Wendy Hill, (OT at the IBME limb centre), as part of the MEC Symposia in 2005. It aimed to advance the knowledge of outcome measures and allow sharing of some of the latest ideas and work in the field. This workshop was summarised by Virginia Wright in the Journal of Prosthetics and Orthotics [1]. The information contained in this paper fed directly, and indirectly, into subsequent moves to create a standard approach.

Following MEC, a small working group was set up to progress the ideas further. A workshop was hosted by Øyvind Stavdahl and the Norwegian University of Science and Technology (NTNU) with Wendy Hill and Peter Kyberd from the IBME as the organising committee.
It brought together an international group of researchers, therapists and users in the field of upper limb prosthetic research, to illuminate the technical outcomes measures from many perspectives. They attempted to identify key issues in the deployment of assessment techniques and tried to identify a more consistent means of making assessment of outcomes from prosthetics research and fitting.

It was stated that an ambitious long term goal sought by this work would be to:

*Establish a terminology and methodology for the pre-clinical assessment and comparison of alternative prosthesis designs that allow for clinically relevant results to be reported and compared across different studies and countries.*

Following the two-day workshop the results were brought back to a wider audience at the World Congress of the International Society of Prosthetics and Orthotics in Vancouver in August 2007. From this a broader working group, known as the Upper Limb Prosthetic Outcome Measures (ULPOM) Group was formed, organised by Shawn Swanson. The group’s aim was to produce recommendations to help standardise the practice within the profession.

One of the implicit aims of the group was not to invent yet another test to add to the tests that already existed, so the process they have adopted has been to proceed through all the existing tests and identify those tests which are most appropriate to prosthetic use, to judge which of these are already validated for use with prostheses, or to identify what would need to be undertaken to validate them, and, in the long term, assist in the process of validating them. From this it is hoped that a toolbox of techniques and measures with a standardised approach to assessment will be evolved. This paper describes the methods by which this approach is being developed.

### Assessment

The lifecycle of any healthcare product or device proceeds from the Research arena to Development and on through the Clinic to the Home. At each stage it is important to be able to measure the design against preceding designs, in order to gauge whether the changes are worthwhile and are what the designer intended. Each player in each area has a different perspective on what information they need or can use and a different way of seeing the problem. Often they have been unable to communicate unambiguously. This had lead to confusion about what a particular test has to offer and how it might perform the assessment. In 2002 the World Health Organization produced an International Classification on Functioning, Disability and Health (WHO-ICF) [2]. One consequence of this process was to express clearly the different information domains that exist in the development of a healthcare product or service.

The three domains are:

1/ Body structures and functions

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2/ Activities
3/ Participation

They reflect the aspects of the provision and the mode of treatment/care required. Once expressed this way it becomes easier to see that each has its own set of particular requirements and so the process of assessing progress or function within each domain has to be different. It also becomes more apparent that previous attempts to measure function without such insight were less likely to prove effective, as the measurement might not be focused on the right domain, or using the right means to measure it.

The three domains map easily on to the three broad areas of assessment:

**Functional**
Device performance - measures are related to the way the device works, such as speed of grip, strength, range of motion.

**Activity**
Assessment of function within a clinical setting - Integrating grasp and hold, but using the device in abstraction.

**Participation**
The user’s experience with the prosthesis in everyday life; how the prosthesis is actually used.

Each area can then be measured using a different technique, shown table 1:

<table>
<thead>
<tr>
<th>Domain</th>
<th>Assessment technique</th>
<th>Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Function</td>
<td>Technical tasks</td>
<td>Picking up objects, measuring grip strength, grasp types</td>
</tr>
<tr>
<td>Activity</td>
<td>Clinical assessment</td>
<td>Observations within the clinic or centre</td>
</tr>
<tr>
<td>Participation</td>
<td>Self rating</td>
<td>User’s own opinion, questionnaires</td>
</tr>
</tbody>
</table>

**Table 1** Assessment techniques and their relation to WHO-ICF domains

Naturally, each of these methods has their own biases and shortcomings. However, the most important conclusion to draw from this is that for a complete analysis, knowledge of each domain is necessary. One method can only serve some of the range. What is needed to unify them is not one test to cover all domains, but a single approach, with different tests to elucidate the information, hence the aim of the ULPOM.

A second insight is that through the lifecycle, different stakeholders have different levels of importance to the process as the different techniques dominate/operate. One way to express the relative importance is in figure 1.
Figure 1 The relationship between the level of importance each stakeholder group has to the process of development of a prosthesis and the sorts of techniques needed to assess these domains

Thus, following the development of a prosthesis, initially: Initially the engineer wishes to know a prosthetic hand design can open wide enough to admit objects or close fast enough to be practical. S/he would then use basic Functional/technical tests, such as simple measurements based on motion tracking. Once the device is more complete, the assessment moves on to Activity based measures which are generally conducted in the clinic or lab. Can the device pick up household objects? Can it hold on to them and move them about? This information is important to the engineer, but now the input from the clinical team becomes important as their insight into its long-term use becomes relevant. Early fittings in the clinic also need activity-based measures as the clinicians need to compare the device to others, and to monitor progress in using a specific device.

Finally, the device moves out into the home and the activities may revolve around tasks specific to the needs of that user. This may tell the clinician about the functional capabilities of the device or of the person and something of their motivations, but when the therapist wants to know more about how the user feels about their device and how it integrates into their daily lives, then the information will more likely to be obtained through a questionnaire. Hence it can be seen that at each stage a different tool is used to obtain the information. Each is important and provides a different insight. Some techniques overlap into different domains, but only with multiple assessments will the full picture be clear.
important and provides a different insight. Some techniques overlap into different domains, but only with multiple assessments will the full picture be clear.

From this, it can be seen that different existing tools cover different areas of the continuum, for example Figure 2 shows three tests straddling the four domains

![Diagram](image)

**Figure 2** Possible range of applicability of three different tests. SHAP is a technical test. ACMC is Activity based and COPMPUFI is a questionnaire.

An additional factor is the design of such tools. It tends to control how well it is received by practitioners, and if it is to be used generally. It must therefore be user friendly, easy to administer, inexpensive and the results must be easily understandable and interpretable. It must also have validity and reliability. This ensures that the measures are repeatable and do not depend on who conducts the test or when or where.

**Future directions**
The ULPOM group is making progress towards the identification of the tests and tools that are appropriate and usable in the prosthetics arena. The process of dissemination of information has been conducted at MEC. Potential roadblocks that may hinder the progress towards effective outcome assessment have been identified and the group is addressing them over the next few years.

**References**