# AN APPROACH TO REPLICATING CLINICAL PROSTHETIC SOCKETS TO SUPPORT RESEARCH

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## ABSTRACT

Research into upper-limb prostheses is often limited by access to prosthetic sockets, each custom-fitted by a prosthetist. Many technological advances in upper-limb prostheses come from engineering focussed labs. Unfortunately, with a global shortage of prosthetists, often, these labs cannot rely on access to a prosthetist to support experimental work, making it hard to undertake quality research reflective of clinical realities. We propose a process to replicate the internal shape of a clinical standard prosthetic socket and facilitate broader access to more representative research. Our proposed method uses a combination of silicone, alginate, and plaster. This proof-of-concept study demonstrates that the proposed new approach is feasible and accurate. This technique will facilitate improvements in the assessment of prosthetic technologies. The process is non-destructive, thus also opening opportunities for socket design and electrode placement research with the removal of confounding factors relating to socket shape. Improving access to prosthetic sockets for research purposes will undoubtedly have international impact.

## INTRODUCTION

Studies requiring socket manufacture are often small, recruiting only people local to the research team/clinic. Manufacture of bespoke sockets on a larger scale is costly and puts excessive strain on an already stretched clinical service. Without a feasible and accurate approach to socket creation, many technical initiatives such as take-home training, real-world monitoring, and large-scale pattern recognition studies remain extremely challenging to deliver. We present a proof-of-concept for a socket replication process, which can be undertaken without a prosthetist present.

This research was in part inspired by the drive to upscale upper-limb prosthetics research to increase its impact [1]; one approach being to move research out of the lab and take it directly to participants. In cases where a bespoke research prosthesis is needed, this will require a mobile socket fitting process. Even where labs are fortunate enough to have access to in-house or local prosthetists, it is unlikely they will have capacity to spend significant time travelling to participants' homes; consequently, an alternative approach to socket manufacture is required.

One option is to replicate a participant's existing socket shape. Physical replication techniques are sometimes used clinically [2]; however, in all cases we could identify, the replication process is poorly documented, sometimes destructive, and mould removal can be difficult with narrow or long upper-limb sockets. The authors were also unable to identify any validation studies of such approaches. Photogrammetry, to digitally replicate internal socket surfaces, has been shown to have some success for lower-limb sockets [3], however, as an upper-limb socket is smaller and usually bent at the elbow, line-of-sight can be obstructed.

A reliable and accurate socket replication process would have wider impacts beyond simply enabling research studies to reflect clinical realities. Socket design and manufacture is rarely documented [4]. In the absence of a validated socket replication method, controlled studies of the impact of socket shape and local physical attributes, such as mechanical compliance, on fit and comfort are difficult to deliver. This is because the nature of casting means that no two sockets manufactured for a person will be the same.

Here we demonstrate the feasibility of accurately replicating a prosthetic socket's shape without damaging the original. A case-study is provided, using a myoelectric socket to demonstrate accurate capture of both socket shape and precise electrode position. This is key to the performance of the resulting prosthesis.

## METHODOLOGY

Limbtex Limbcopy Silicone, Platsil Gel Silicone, and alginate were evaluated as materials to capture the negative mould from the socket. Our proposed approach uses the Platsil Gel Silicone which was easiest to work with and kept its shape well for a prolonged period. We also trialled both full-fill and layer coating techniques; our proposed approach combines the compressibility and ease of extraction associated with the layer coating with the structural benefits of the full-fill.

Initial preparation of the socket involved covering the electrodes and any holes/rivets with Tegaderm film bandage to avoid damage or leakage of the moulding agent into the void between the inner- and outer- socket. A tape collar was built up above the socket trim lines. We added a tube into the mould ensuring it filled as much of the void as possible without touching the edges of the socket: Note that, to make it easier to remove later, the tube can be wrapped in a layer of clingfilm. The mould was then filled with silicone and left to cure. Once cured the tube was removed allowing the mould to be compressed and displaced from the socket walls. The tube was then re-inserted into the mould after extraction to ensure the shape was maintained. We recommend using Platsil Gel00 (a softer silicone) for ease of mould extraction although we have tested this method with different Shore hardnesses (A25-0030).

We converted the silicone negative (Figure 1a) into plaster (Figure 1b) via an alginate positive. As there is a risk of compound error, it is important to carefully avoid changes in the shape of the mould between steps. The plaster negative was carefully smoothed down to remove any bumps from bubbles in the alginate whilst avoiding any change in the shape or volume. The area above the trim lines was tidied so as not to tear the bag during lamination.

As can be seen in Figure 1, the electrodes leave an impression in the mould. When traditionally manufacturing a myoelectric prosthetic socket, electrode dummies are used. These are thinner than an electrode and designed to sit flat against the mould. To manufacture the clone socket these same electrode dummies are used, therefore the electrode indent must be infilled, restoring the shape in this area to match the mould for the original socket. The position of the electrodes needs to be identical for the replica sockets and original, so a plaster replica of the electrode was created via a silicone mould (Figure 1c). The depth of the plaster electrode was matched to the difference between the electrode and the dummy. The quality of the moulding process means that the plaster electrode could be easily aligned with the original electrode position by lining up the imprints of the metal contacts (Figure 1d). The web created by the protective Tegaderm must also be backfilled. To ensure the infill accurately reflected the original shape, the wet plaster was smoothed to the line of the plaster electrode and existing socket negative using a tongue depressor (Figure 1e). The plaster electrode was also coloured to help locate the dummy.

Once complete, the plaster mould was provided to prosthetics technicians to manufacture a prosthetic socket using their traditional approach to manufacturing a laminated socket.

To assess whether the clone socket accurately replicated the original, 3D scanning was used (Einscan-Pro 3D scanner). As it is difficult to accurately capture the internal shape of an upper-limb socket due to the small size and likelihood of occlusions, a silicone negative mould from the original socket was compared to another negative silicone mould from the clone socket. The alignment between the scans was assessed using CloudCompare software (v2.12.2). The meshes were aligned and the distance between the meshes computed using the ‘cloud-to-mesh’ function.

## RESULTS

When comparing the silicone negative of the clone socket to the silicone negative of the original socket, the mean distance between points was 0.16mm (standard deviation 0.38mm). A positive difference suggests the clone is outside of the original reference scan (volumetrically larger), whilst a negative difference suggests the clone is inside (volumetrically smaller). Figure 2 shows a histogram of the distances between the sockets and highlights top right the areas where the difference was greater than 1mm. There are small areas on the posterior aspect of the socket and at the edge of the electrodes where the clone is 1-2mm larger than the original. Around the edge of the electrodes this will be caused by a new web being created by the Tegaderm which will not align perfectly with the original web. What is important to note is that the metal contacts of the electrode show very little error between the two moulds (<0.5mm) as shown in the close-up bottom right.

## DISCUSSION

This study shows the recommended socket replication technique to be highly accurate. Although it has not been assessed quantitatively, we anticipate this technique will generate a significantly more accurate replica than a new socket manufactured from scratch using traditional casting or scanning techniques.

By removing the requirement for several socket iterations, this technique offers significant time, cost, and labour saving to researchers, technicians, and participants themselves. The process of taking the silicone mould may not be quicker than casting due to curing time, however, only the prosthesis is required, thus freeing the participant up to continue with their activities. Most importantly, this process can easily be taken to the participant, without the requirement for a prosthetist. With the confidence that the final socket will fit, it also becomes more feasible to post sockets and moulds between labs [5].

This socket replication process can facilitate take-home trials of instrumented prostheses, thus opening a new opportunity to understand the impact of various factors relating specifically to socket fit. Additionally, by manufacturing sockets matching those prescribed clinically we can assess a range of socket types, originally manufactured by a broad pool of clinicians, rather than by one or two clinicians affiliated with the research, thereby reducing the risk of unconscious bias. These factors should all increase confidence in the validity of results. As the recommended process does not destroy or damage the original negative mould, this technique also opens new opportunities for us to evaluate socket design. We can manufacture several matching sockets with subtle changes, such as adjusting electrode positions or changing wall thickness. Additional electrodes may be added to form arrays, facilitating more applied pattern recognition research. Further, we can explore the impact of manufacturing the socket using emerging materials. By producing these sockets from identical plaster moulds, we can reduce the confounding factors in research.

## CONCLUSION

This case study, focussing on an upper-limb myoelectric prosthesis, has demonstrated that the proposed new approach to replicating a clinical prosthetic socket is feasible and accurate (mean difference 0.16 mm). The non-destructive method involves shape capture using silicone and conversion into a plaster mould via alginate. This new method will facilitate the development of research prostheses without the requirement for an on-site prosthetist, opening up more opportunities for prosthetics research representative of the clinical realities. In addition, with an increased interest in real-world prosthetics research, this technique will enable engineering focussed labs to develop take-home versions of new technologies allowing exploration of the real-world practicalities of developments in prosthesis control. With the cost of novel prosthetic technologies increasing, funders require increased evidence of clinical and cost effectiveness. To generate this evidence base, research must represent the clinical population and their real-world use of their prostheses. This socket replication technique brings these studies a step closer to feasibility. Although the example socket presented here includes electrodes, this method would be similarly suitable for a non-myoelectric socket.

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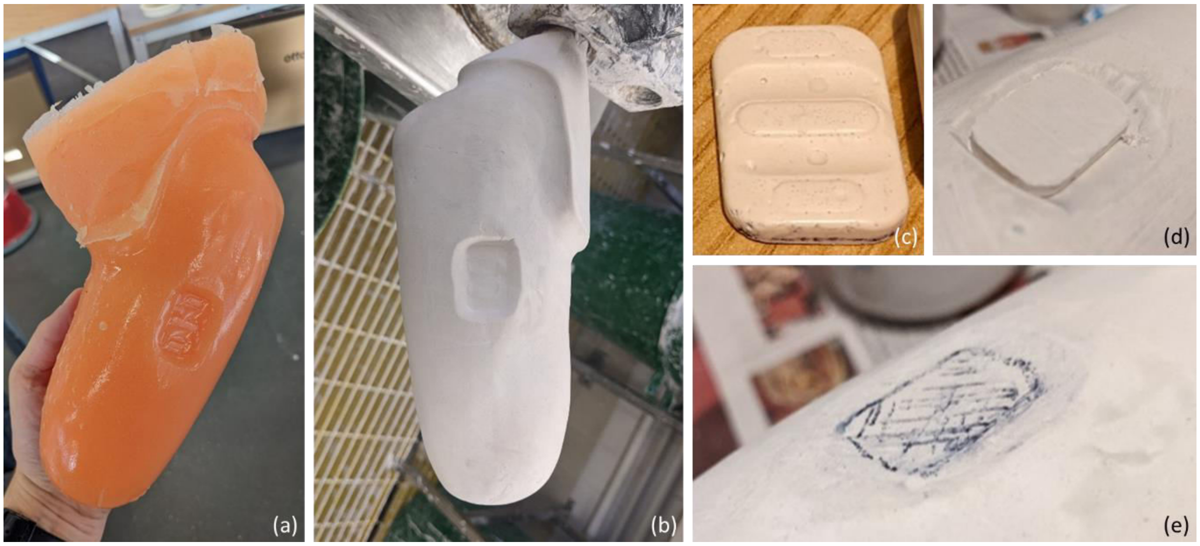


Figure 1: Examples of mould making process. (a)  Silicone negative mould produced from original socket. (b) Smoothed plaster negative mould produced from silicone negative via an alginate positive. (c)  A plaster electrode infill, shaped to match the front of the electrode, and at a thickness which when combined with the thickness of the dummy, matches the electrode. This is placed into the recess in the socket (d), seated in the correct location by the shaping from the metal electrode contacts, and coloured in to mark its position. The void around the edge is filled with wet plaster and flattened so as not to adjust the shape of the socket itself (e).

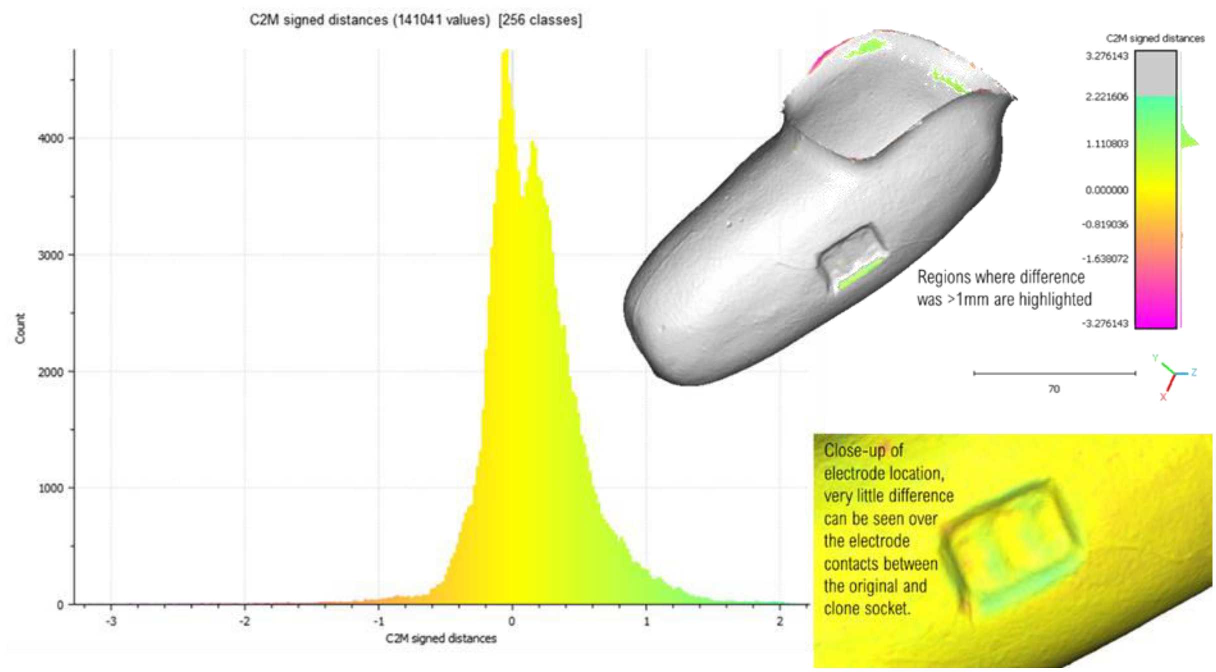


Figure 2:  Histogram showing the distribution of Cloud to Mesh (C2M) distances (in mm) between the mesh of the silicone mould taken from the original socket and the mesh of the silicone mould taken from the replica socket. A positive difference indicates that the surface of the replica lies outside of the original reference scan, whilst a negative difference indicates the opposite. Top right any distances greater than 1mm can be seen highlighted on the socket. The discrepancy around the electrodes can be attributed to the Tegaderm web, but as can be seen bottom right, there is almost no discrepancy in the positioning of the electrode contacts.