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Technical note

# A pin-array method for capturing tissue deformation under defined pressure distributions and its application to prosthetic socket design

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ABSTRACT

The Fit4Purpose project aims to develop upper limb prosthetic devices which are suitable for deployment in lower- and middle-income countries (LMIC's). Open-frame trans-radial socket designs are being considered, formed of several, linked components, including pads which interface directly with the skin surface. A mechanical tool has been developed to aid the design of pad shapes, using an array of square brass bars of varying lengths (i.e. a pin-array) to apply a chosen normal pressure distribution to an area of tissue. The shape to which the tissue is displaced can then be captured by clamping the bars together to fix their relative positions. The device is described, then three short studies are used to demonstrate its use on the forearm of a single, anatomically intact subject. The first investigates the effect of array size on the measured surface stiffness, finding an inverse relationship with a similar characteristic to previous published results. The second tests the hypothesis that a pad with a shape which duplicates that captured by the device will generate a similar overall load to the original pins if applied to the same region of tissue. The results support the hypothesis, but also highlight the sensitivity of the interface loading to the underlying muscle activation. Finally, the tool is used to demonstrate that different tissue displacements are observed when the same pressure distribution is applied to different areas of the forearm. Whilst the tool itself is a simple device, and the techniques used are not sophisticated, the studies suggest that the approach could be useful in pad design. Although it is clearly not appropriate for clinical application in its current form, there may be potential to develop the concept into a more practical device. Other applications could include the design of other devices which interface with the skin, the generation of data for validation of finite element models, including the application of known pressure distributions and tissue deformations during Magnetic Resonance Imaging, and the assessment of matrix pressure sensing devices on compliant materials with complex geometries.



## 1. Introduction

Although data on the prevalence of limb absence are poor, the World Health Organisation (WHO) estimates that there are 40 million amputees worldwide, with likely higher prevalence in countries experiencing conflict, and/or with poor road safety [1]. Another WHO report finds that approximately 8% of cases (3.2 million) are at the trans-radial level [2].

Conventionally, sockets for a trans-radial prosthesis are manufactured as bespoke, endoskeletal units. The manufacturing process begins with residuum geometry acquisition, using plaster- or 3D-scanning-based techniques; the resulting shape is then adjusted in a process called rectification. Finally, the socket is manufactured by drape-forming of polymers, or lamination of resins and fibres. These designs are usually 'self-suspending', with the socket extending around the olecranon and humeral epicondyles. The final shape is determined by the 'trim-lines' at which the proximal end is cut away.

A well-fitting, comfortable socket is recognised as an important factor in the acceptance and use of upper-limb prostheses [3,4], and achieving a good fit with the above process often requires multiple visits to a clinic. This, together with the reliance on skilled prosthetists and technicians, using specialised (often imported) materials and tools, makes it difficult to implement in low income settings. In such situations, well-resourced and properly staffed centres may be scarce, making it difficult for patients to access these services [5].

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If this design approach may be described, in engineering terms, as 'monocoque', an alternative is the 'open-frame' approach. Here the socket is built up from several components, some extending along the residuum, and some around it, with either fixed or adjustable connections between them. An example is the 'socket-less socket' from Martin Bionics [6]. An adjustable, open-frame design such as this, but made from locally sourced materials, offers the potential for increased access through a quicker fitting process, with fewer (ideally single) clinic visits required; the user could make some adjustments themselves, on a daily basis if necessary; the socket could be more easily repaired; and the open frame design may lead to better heat dissipation, a widely reported problem for users of monocoque sockets [7].

The open-frame approach is being considered as part of the 'Fit4Purpose' project [8], which links universities in the UK, Uganda and Jordan to perform research into upper limb prosthetics for LMICs. One design would use longitudinal pads to transmit loads to the underlying tissue. These loads may be categorised as constant, 'Intrinsic' loading, generated only by donning the socket with relaxed muscles, and additional but intermittent (task-related) 'Activity' loading. Anatomical and physiological factors will control how the resulting stress and strain at the pad-skin interface distributes into deeper tissues [9]. Similarly, whilst there is an inverse relationship between the duration and magnitude of tissue stress and strain which can be safely tolerated [10], the precise relationship will be governed by a dynamic set of subject-specific factors [11]. It is thus not possible to define a 'safe' level of intrinsic loading. However, studies on the interface pressures in existing, well tolerated upper limb sockets report peak figures, under intrinsic loading only, from 6.9kPa to 11.7kPa [12], and $>$12.5kPa [13].

Clearly, the shape and size of the longitudinal pads will influence the loading experienced by the tissue local to the pad. For a rigid pad with a given external load, the area interfacing with tissue will determine the average pressure; however, the distribution of tissue strain and pressure will be governed by the cross-sectional profile of the pad. Avoidance of a high normal pressure gradient is important, particularly at the boundaries of the loaded area, as this generates radial shear stress in the underlying tissue, often referred to as 'edge effects' [14]. Therefore, it would be useful to know how different areas of tissue deform under a desired pressure distribution, thereby obtaining the shape of a pad that would produce that pressure distribution. To address this, a simple mechanical tool, which uses an array of metal bars (i.e. a pin-array), contained within a clamping frame, has been used to capture the gross deformation caused when a chosen interface pressure distribution is applied over an area where such a pad might be placed. It is hypothesised that a bespoke pad, generated using the captured shape of the loaded tissue, will produce a similar pressure distribution when it engages to the same tissue depth in the same anatomical location. This approach could be useful to guide the design of pads and adjustment elements of an open frame socket, such that the intrinsic loading remains at an acceptable level; the socket adjustment elements could be designed so that it is easy to ensure that the pads are pushed into the soft tissue to the correct depth.

The paper describes the pin-array tool and demonstrates its application in a single subject. In Study 1, we compare previously published tissue stiffness characteristics from discrete indenter measurements, taken over the area of soft tissue where a pad is to be placed, with those derived from the displacement of a single central pin from within the array. In Study 2, we investigate the validity of the approach for pad design by first capturing the shape of deformed tissue under a known pressure distribution, then replicating this shape in a plaster pad and measuring the force required to engage the pad to the same tissue depth. Finally, in Study 3, we compare pad shapes generated at different locations around the forearm to explore whether bespoke pad shapes, derived using the pin-array tool, may be required in all cases, or whether there is a generic pad shape independent of the anatomical location.

## 2. Methods and results

### 2.1. The pin-array tool

The tool (Fig. 1) uses an array of 3.13mm square-section brass bars ('pins'), contained within a frame made of two aluminium side rails and two 3d-printed polylactic acid (PLA) adjustable end stops. The side rails can be clamped against the pins using a lockable device. Each pin is a 'dead weight', with the pressure generated at the base being a function of density and length. For example, a vertical brass pin of length 61mm generates an average pressure at its base of 5kPa. Adjusting the length or density of each pin in the array allows control of the overall pressure distribution.

The array is first set in its default starting position by placing the tool on a level, horizontal surface, then unlocking the clamp to allow the pins to also rest freely on this surface. The pins are then clamped together, such that their bases lie on the base plane of the tool. The array is then placed over the skin surface in the area of interest, with the pins approximately vertical (guided by a bubble sight). The clamping mechanism is released, allowing the pins to rest on the skin, and the resulting shape of the deformed tissue, under the known pressure distribution, captured by re-clamping the pins.

A single, anatomically intact subject (the lead author) was used to demonstrate the use of the tool in three studies. For studies 1 and 2, a test rig was constructed consisting of: A base-plate, to which a back-slab plaster cast of the arm was attached, providing underside support and axial positioning by location of the olecranon; additional fixed arm guides for the axilla and hand to further constrain rotation or translation of the arm in the back-slab; and a removable support frame, located by guides on the base-plate, to support the pin-array tool's side rails. Together these ensured a repeatable arm pose relative to the support frame, which itself had guides for the pin array tool to control relative positioning of the tool and the forearm. The upper surface of the support frame, on which the base surface of the pin-array rests, also acts as a datum level for the starting position of the pins. To perform a measurement, the arm was first placed in position, which made the upper (ventral) surface approximately horizontal. The support frame and pin-array were then placed over it. The cycle of unclamping and re-clamping was then performed to load the tissue with the pins and capture the resulting shape. The subject removed their arm for a rest between each change of array size in Study 1, and between each force measurement in Study 2.

### 2.1. Study 1: Comparison of various pin-array-derived, pressure-displacement data with previously published results

As a first demonstration of the validity of the approach, we investigate if the tool can be used to generate soft tissue pressure-displacement curves similar to previously published studies using single rigid indenters. Different sized square arrays of equal length brass pins (thereby generating a constant pressure across the array) were used to capture representative pressure-displacement curves and thereby investigate the effect of array size on tissue deformation. A wide range of sizes of rigid indenter have been used in the existing literature, with cross-sectional areas from $3mm^2$ to over $2000mm^2$ [15-20]. Three array sizes were chosen to apply pressure over areas which lay within the range of the indenter areas used by two of these studies [17,19] (Table 1). The range of pin lengths and hence mean pressures were chosen to apply loads

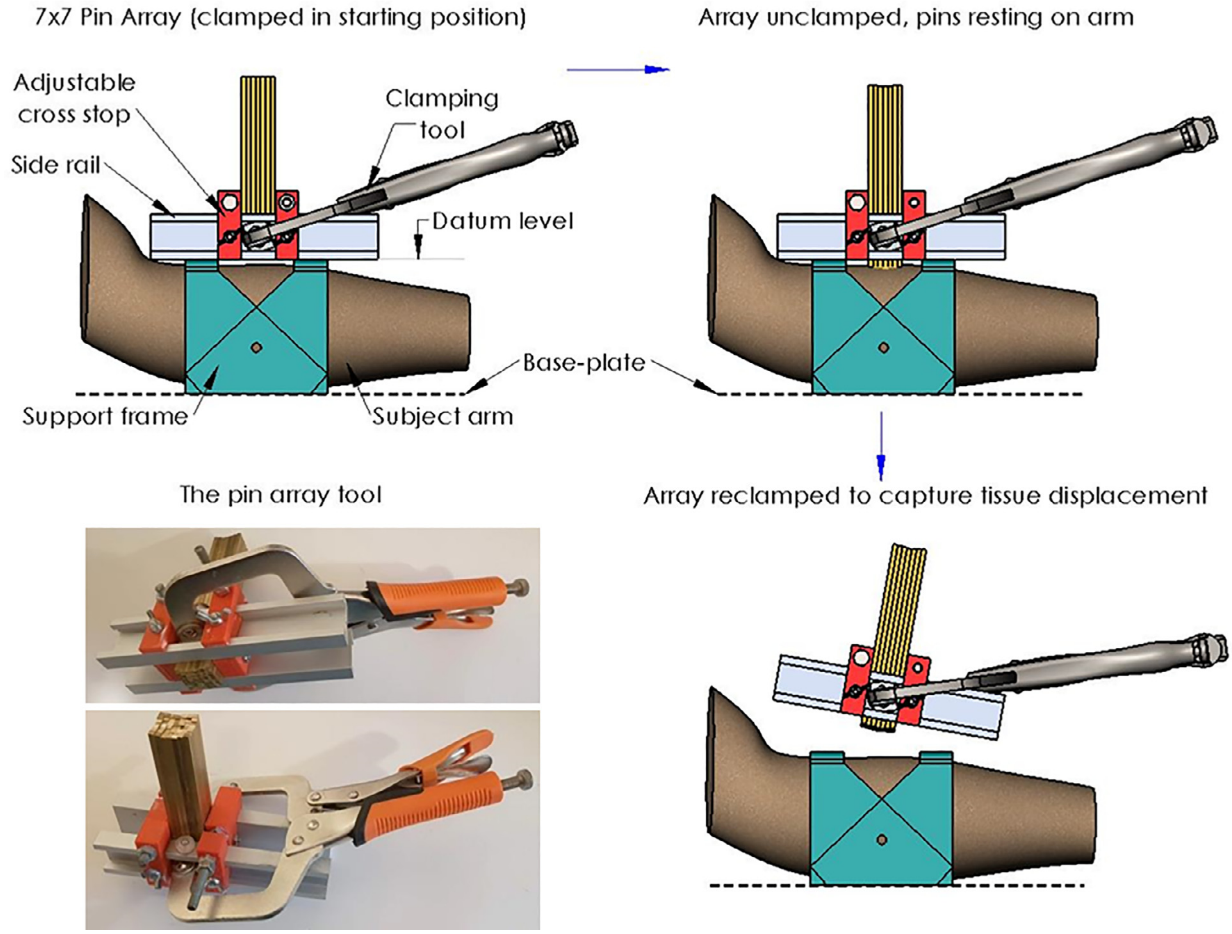


**Fig. 1.** The pin-array tool and the process of capturing the shape of the loaded forearm tissue (back-slab support and arm guides not shown).

**Table 1**
Indenter details from two previous studies compared with the pin-arrays used in Study 1. Pressure values for previous studies are average figures obtained by dividing the force values by the indenter areas given in the papers.

| Previous studies<br>Study | Indenter details | Indenter Area ($mm^2$) | Pressure ranges reported (kPa) |
|---|---|---|---|
| Zheng et al, 1999 [17] | 9mm diameter, flat ended (US probe tip) | 63.6 | 0-79 |
| Sang et al, 2016 [19] | 26mm x 100mm rectangular, flat based | 2600 | 0-38 |
| **Arrays of 3.13mm square brass pins** | | | |
| Array size (number of pins) | Total Area ($mm^2$) | Pin Lengths (mm) | Mean Pressures (kPa) |
| 3 × 3 | 88.2 | 35 | 2.8 |
| 5 × 5 | 244.9 | 61 | 5.0 |
| | | 90 | 7.4 |
| 7 × 7 | 480.0 | 119 | 9.8 |
| | | 240 | 19.8 |

that were acceptable to the participant, produced easily measurable deflections, and allowed for comparison with the previously published data.

The tool was initially configured for the 7 × 7 array, then spacers were used to reduce the array size to 5 × 5 or 3 × 3, whilst retaining the same position for the central pin relative to the tool. The control of the relative positions of the arm and tool provided by the rig thus placed the central pin of the array over the same arm location irrespective of the array size. The position of this central pin on the arm was marked, and the vertical offset from the unloaded skin surface to the datum level of the support frame was measured with a digital caliper. The displacement of the tissue under the central pin, for each size of array and pressure value, was then calculated by measuring the pin's displacement and subtracting the offset value. Each measurement was performed 10 times, with the pins resting on the arm for approximately 3 seconds, at 90 second intervals, and the average value taken. The results are shown in Fig. 2, with 1 SD error bars and cubic trendlines added. For comparison, stiffness values obtained from a similar region of the anterior forearm to that reported by Sang et al. [19] have been added, with a cubic trendline again used for visualisation, whilst the quadratic expression developed by Zheng and co-workers [17] for a region of the posterior mid-forearm over the radius is also plotted. In both cases, the pressure values were obtained by dividing the force values given in the respective papers by the indenter areas noted above. A trend of reducing surface stiffness with increasing indenter size, whether single indenter or the central indenter of an array, can be seen.

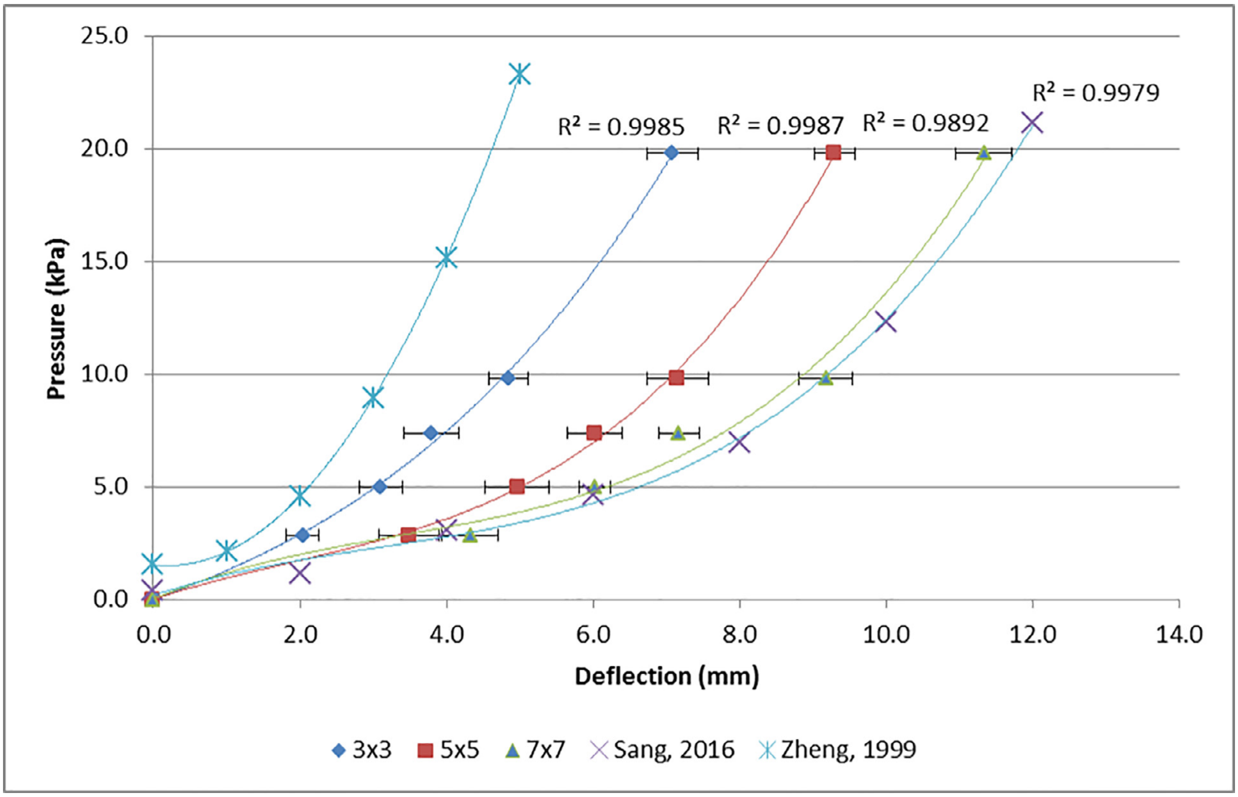


**Fig. 2.** Pressure against maximum tissue displacement (under the central pin) for three different array sizes, together with data from previous studies (Zheng et al, 1999 [17] and Sang et al, 2016 [19]).

### 2.2. Study 2: Total force generated by a captured shape

We demonstrate the validity of the pin-array method for pad shape design by first capturing the shape of deformed tissue under a known pressure distribution, and then investigating whether a pad of the deformed tissue shape, when loaded until it engages to the same tissue depth, produces the same pressure distribution as the pin-array. Specifically, the hypothesis is that the pad will generate approximately the same pressure distribution as that of the unlocked pins, if applied to the same area of tissue, in the same state of muscle contraction. Therefore, the total force required to push the pad into the tissue will be approximately equal to the total weight of the pins. A key concept here is that the pad is pushed into the tissue to the correct datum level, or 'waterline' depth, in order to duplicate the gross tissue deformation originally generated by the pins.

This second study used a larger, 19 × 13 array, which was more representative of the size of pad which might be used in an open-frame socket. For the purposes of initial evaluation, a peak normal pressure of 9.8kPa was chosen. This corresponded to an existing pin length, used previously, and was lower than that measured in well tolerated sockets [12,13]. To reduce edge effects, the pressure dropped in steps from 9.8kPa over the central 13 × 7 pins, to 2.8kPa at the edge of the pad, with a gradient of approximately 0.75kPa/mm. The total weight of the pins was 1635gf.

The tool was placed on the support, as before, and the pins were released (Fig. 3). After one minute the pins were re-clamped, to capture the tissue deformation. Before removing the tool, the four corners of the array perimeter were marked on the skin using a pen. Using plaster bandage, a cast was taken of the pins protruding below the lower surface of the aluminium side rails (datum level), with the surrounding bandage flattened against the rails to form a datum frame. Filling the cast with plaster to the level of this frame then created a plaster pad which replicated the shape of the pins, with the top surface corresponding to the pin-array datum (base surface). A bespoke, load-cell device was then used to measure the force required to depress this pad into the arm tissue. The device used a YZC-133, 2kg load cell with a HX711 amplifier (Zhuhai Guang Ce Electronic Technology Co. Ltd), connected through an Arduino Uno, sampling at 10Hz. It incorporated a central loading plate, with stops on either side at the same level as the plate.

The pen marks were used to position the plaster pad on the arm in the same location as the pin-array. The loading device was then used to push the pad down until the stops rested on the support frame, such that the top of the pad was level with the datum (top surface of the support), theoretically producing the same tissue deformation as the pin-array. Hence, the force registered by the load cell should be approximately equal to the integral of the required pressure distribution over the area of the pad (the total weight of the pins).

A single plaster pad was made and used to load the arm in a series of tests, of one-minute duration, at ten-minute intervals. The effect of muscle activity was investigated by varying the routine between tests: Isometric finger flexion (gripping a cylinder) was carried out for approximately two minutes prior to each of the first ten tests (tests 1-10), then there was minimal activity (subject sitting still) throughout the next ten tests (tests 11-20), before finger flexion was again performed prior to three final tests (tests 21-23). Whilst stress relaxation was seen in all tests, with the pad force falling gradually over time (Fig. 4a), the initial and final values varied. The final value after muscle exercise (average of tests 1-10, 21-3) was 1590gf (SD 54gf), whilst without exercise (tests 11-20) the average was 1359gf (SD 110gf).

An individual may contract their residual forearm muscles whilst the socket is being worn. To investigate the effect of this on

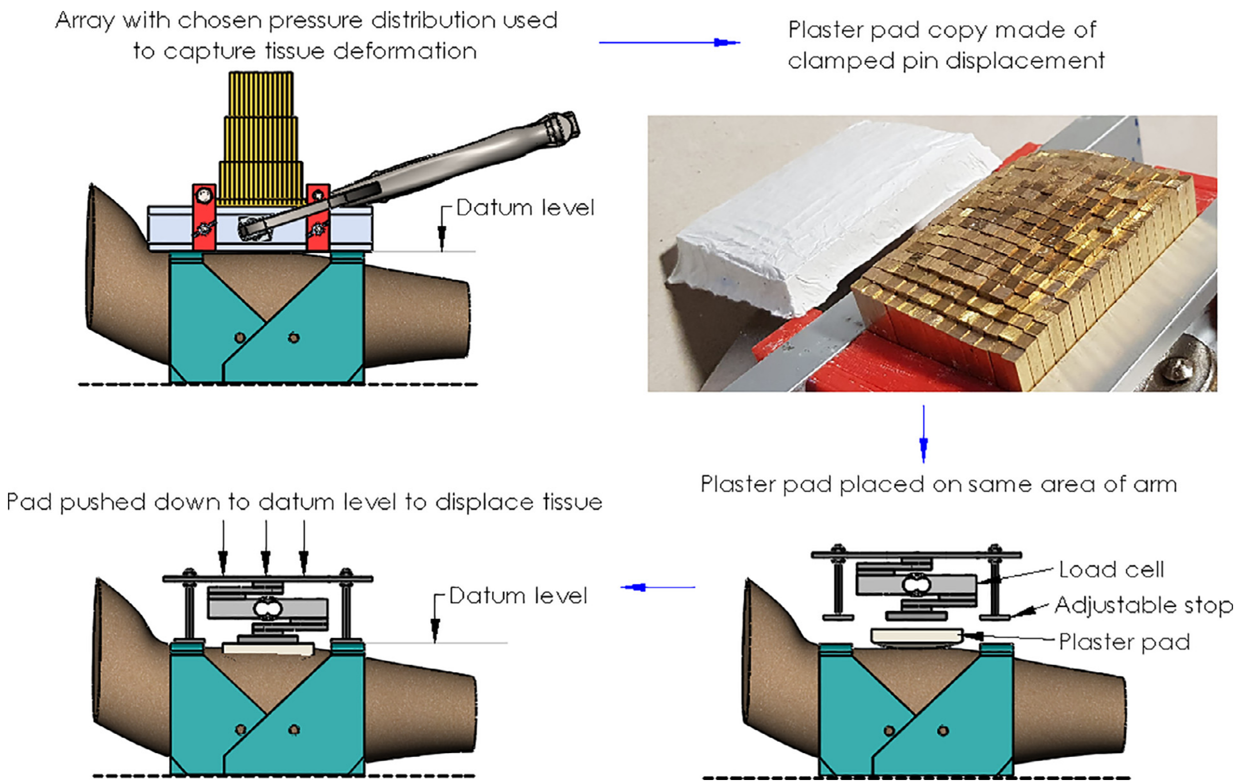


**Fig. 3.** The process to capture tissue displacement relative to a datum level, replicate the shape in plaster, and then measure the force required to re-load the same area of tissue to the same depth.

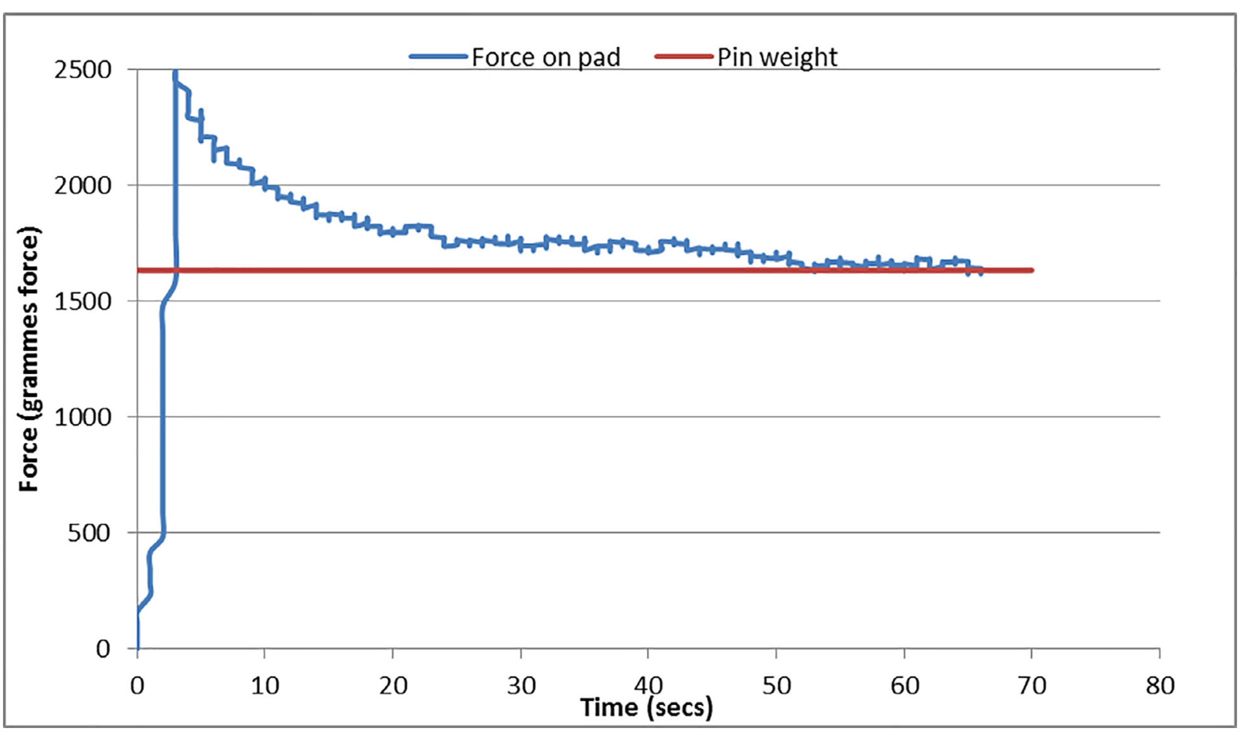


**Fig. 4.** a: An example plot of the force required to push the pad down to the datum level. Stress relaxation was seen in all tests, with the average final value varying from 1590 gf if flexion exercises were used for pre-conditioning, to 1359 gf without exercise. b: Effect of variations in isometric forearm muscle contraction on the force required to push the pad down to the datum level. A 7 × 7 array was used, with a constant pressure distribution of 9.8kPa.

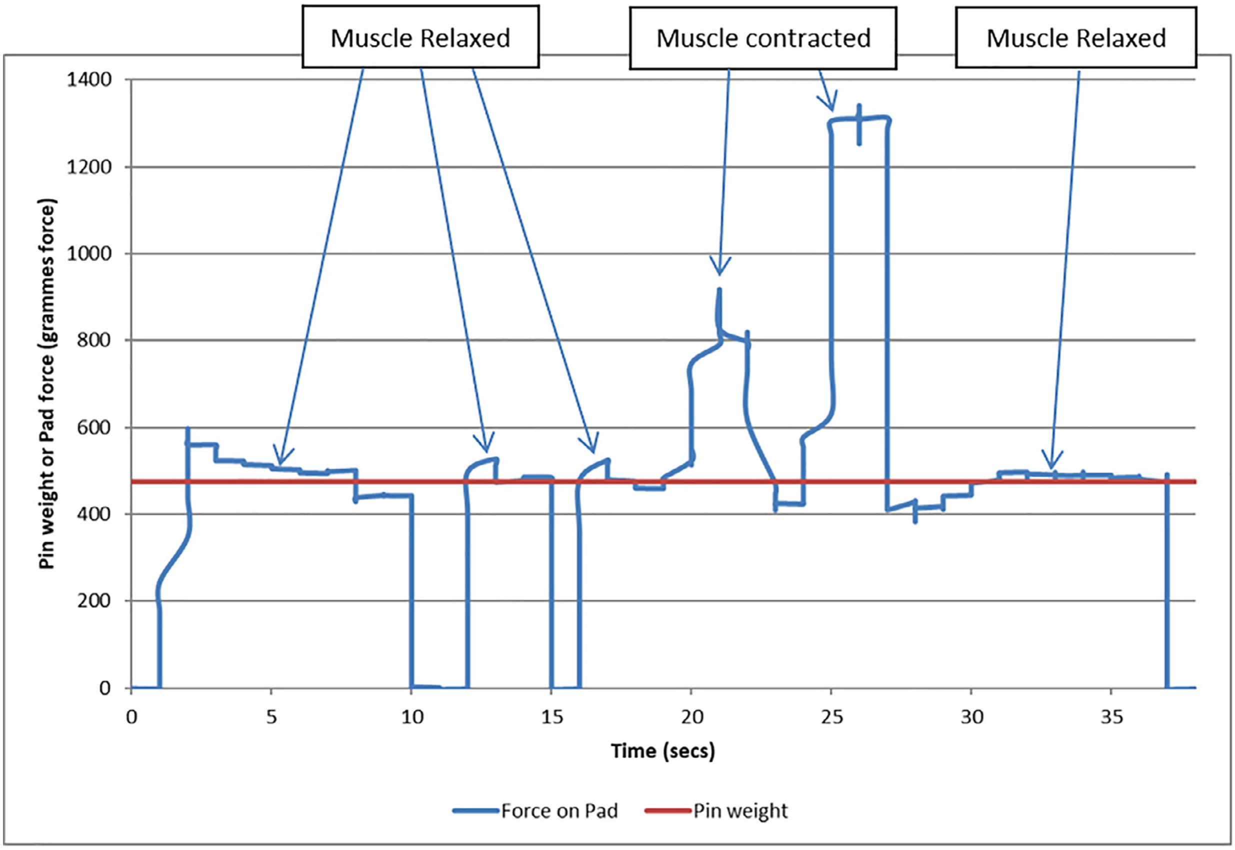


**Fig. 4.** Continued

the displacement of tissue under load, the subject in Study 2 intermittently clenched their fist during a measurement, whilst the pad was held down at the datum level (Fig. 4b). This muscle contraction caused a large increase in the force required to hold the pad in place, so a smaller plaster pad, created using a 7 × 7 constant pressure (9.8kPa) array, was used. This avoided the force increasing beyond the range of the load cell.

### *2.3. Study 3: Captured deformation from different areas of the arm*

Using the 19 × 13 array we compared pad shapes generated at different locations around the forearm to explore whether bespoke pad shapes, derived using the pin-array tool, may be required in all cases, or whether there is a generic pad shape independent of the anatomical location (Fig. 5). In each case, the arm was positioned so that the target area was uppermost and approximately horizontal. No guide rig was used for this, with the tool simply being held by the investigator so that the side struts were approximately on a horizontal plane and gently touching the skin surface, without the weight of the tool actually resting on the tissue. The pins were then unlocked and allowed to rest on the tissue for 10 seconds, before the tool was re-clamped to capture the resulting shape of the pin displacements. This shape was then captured digitally with a 3D scanner (Einscan Pro).

## 3. Discussion

A simple pin-array device may assist with the design of pads for an open-frame prosthetic socket. Three studies have been presented using equally simple measurement methods. The three studies aimed to establish whether further work towards a more clinically usable device was merited, and to demonstrate the potential for our approach to be used in other applications. The repeatability of arm pose, muscle activation, and placement of the device, whilst controlled, were not quantified. Other potentially relevant factors such as indenter temperature and room temperature were not measured [20], though for each study all measurements took place on the same day, in the same room with thermostatically controlled heating. Lubrication between pins was not used as this would increase the required clamping force, leading to a need for stiffer side rails. However, it was assumed that the frictional forces between un-clamped pins were negligible, with any stick-slip behaviour being minimised by giving the array a gentle shake before clamping. Results will also be inherently subject-specific, and only a single subject was used. Overall, it was not felt that these limitations compromised the goal of demonstrating the new technique, but they should be considered in future work. Furthermore, a potential risk in using the current design of the device has been identified: Skin could become trapped or pinched between pins, or between pins and side-rails, when the device is clamped. This was not a problem in the tests, but we would not recommend that the device is replicated and used in its current format, and we are considering alternative designs which restrain the pin movement with a different mechanism.

The first study generated surface stiffness characteristics of the forearm which clearly demonstrate the effect of indenter size, whilst falling within the range found in other work using more sophisticated equipment (Fig. 2). The displacement of the central pin increases, leading to the observed stiffness reducing, as pin-array area increases. This is perhaps unsurprising as, moving inwards from the outer pins, the displacement of each successive pin tends to be additive, building on the surrounding tissue deformation and leading to a curved pin-array profile. This means that increasing the number of pins leads to a greater displacement in the

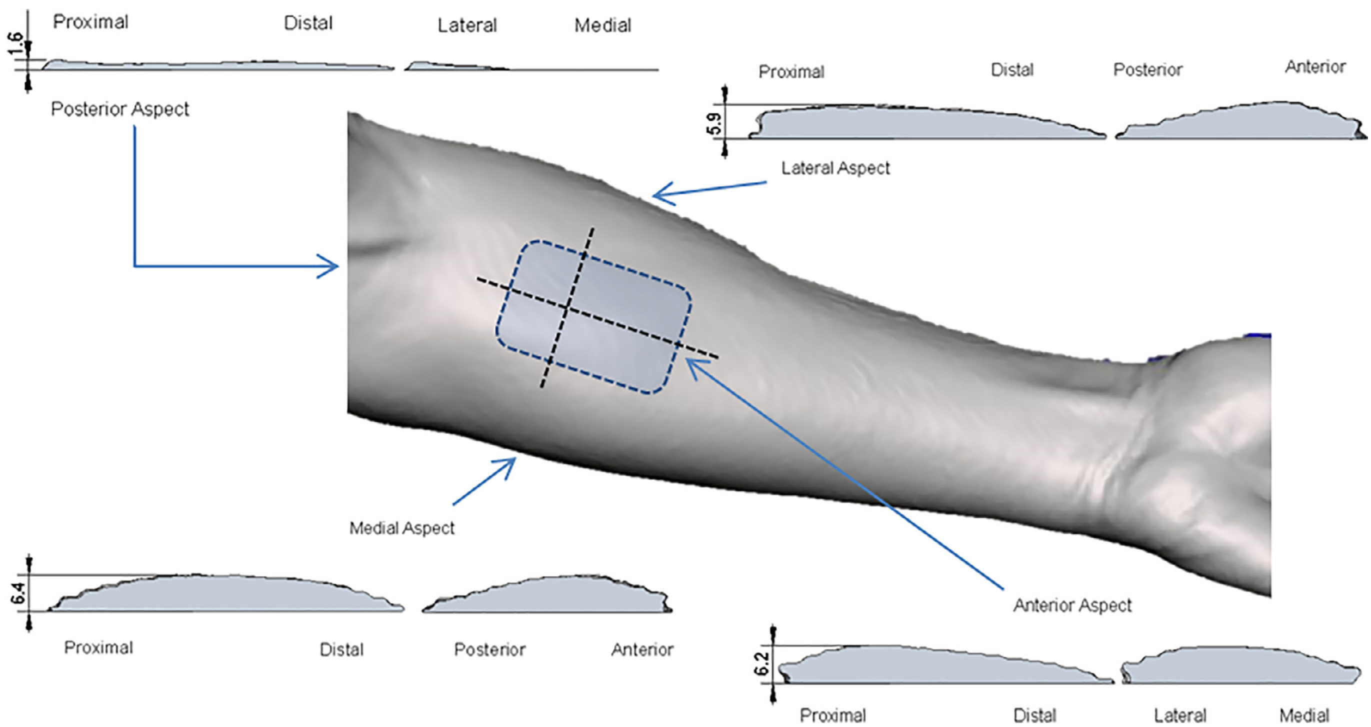


**Fig. 5.** The 19 × 13 array from Study 2 was applied to different areas around the forearm, with the location and orientation of the anterior placement illustrated by the blue box. Scans of the locked, displaced pins were taken, converted to solid bodies in solid modelling software (Alibre Design), and then sectioned (as shown by the two black dotted lines for the anterior position) to create the views shown for each location.

centre of the array. In contrast, the displacement is common across the whole of a rigid flat-bottomed indenter. Indeed, the soft tissue in the middle of the contact area may be pulled down by the surrounding tissue, off-loading the rigid indenter centrally. This means a flat bottomed indenter may produce a non-uniform pressure distribution, with lower pressures in the middle and higher pressures around the edges where the tissue displacement gradient occurs: This pressure distribution is not known, and calculated average interface pressures were used to generate the rigid indenter curves in Fig. 2. We have not attempted a complex analysis, and there are issues with the application of established models of contact mechanics to large strains [21]. However, parallels may be drawn with standard Hertzian solutions, which give similar predictions for the stress distribution under a rigid indenter [22]. As a result, the maximum tissue displacement for a single rigid indenter is less, and the observed stiffness higher, than that seen with the central pin of an array applying the same average pressure over the same total area. This is illustrated by the curve for the large rigid indenter [19], which is further to the left in Fig. 2 than one would expect given its area (see Table 1). The same is true of the curve from Zheng et al. [17], though here the effect may be amplified by the indenter being applied to the posterior, rather than anterior, forearm.

The first study thus demonstrates that a pin-array covering the whole of the interface area of a pad, whilst providing control over the applied pressure distribution, could inform pad design more appropriately than a single rigid indenter. The second study goes on to consider whether this information can lead to pad designs which generate loads commensurate with a safe and comfortable socket. The use of a one minute loading duration before capture of the deformed tissue shape, and then the monitoring of the pad force values for the same length of time, was an attempt to reduce variation caused by the effects of initial loading rate, creep and stress relaxation [23]. When muscle contraction was used between readings, the average of the measured force values at 1 minute was 97% of the original pin weight. This supported the hypothesis that a pad of the deformed tissue shape captured by the pin-array, when loaded until it engages to the same tissue depth, produces approximately the same pressure distribution as the pin-array. When muscle contraction was not used between readings, the average dropped to 83% of the original pin weight, which is considered close enough to justify further work on this approach to pad design. The observed differences between the two measured force values may have been due to exercise 're-setting' any longer-term stress relaxation. However, as there was no specific control of arm activity prior to the tests with repeated muscle contractions, further work under more controlled conditions is also merited to fully understand this.

A limitation of Study 2 is that only a single pad was used, with the arm fully supported by the backslab cast on the opposing side, whilst in a socket there would be several pads around the circumference of the arm. This will be investigated in other ongoing work using multiple pads. In practice, the pin array information is envisioned to be a guide to the shape of a pad for a particular region, rather than an exact profile to replicate. Indeed, slight modifications will always be required, such as smoothing the captured surface to avoid small edge effects at the perimeter of each pin. The flexibility of the system could also allow bespoke modifications to the loading profile generated by the pins, to reduce interface pressure in sensitive areas.

When the forearm muscles were contracted whilst the pad was held in place, force values of almost three times the original pin weight were observed, demonstrating one source of additional intermittent 'Activity' loading, due to performing tasks. This highlights the dynamic nature of the gross tissue stiffness, and suggests that muscle contraction may be a strategy that users can adopt to increase the coupling between socket and residuum while performing tasks.

The results of the final study demonstrate how the deformed tissue shape, which can be used to design a pad shape, can vary with anatomical position around the forearm of a single subject. This suggests that there may be benefits from using bespoke, rather than generic, pad shapes for an open-frame socket. A limitation with this part of the study is the short settling time prior to capturing the pin array displacements (10 seconds). Although this decision is unlikely to have impacted on the conclusions, future studies capturing pad shape should consider longer durations. At this stage, the tool is clearly not suitable for clinical use, but with modifications to the method of pin restraint, it could be used as a research tool in the development of such designs. It may then be possible to use it to validate another, more practical device, which could be used clinically to supplement manual palpation. If this device offers less detailed information than the current tool, but does allow rapid quantitative comparisons between different areas of tissue, the information could be used to choose an appropriate pad from a set of shapes generated using the approach described here. Such pads could then be fabricated using materials and techniques appropriate to the available resources, from 3D printing to woodworking.

In addition to the potential use in socket design described here, the tool could be useful in other applications involving devices which interface with the skin. It could be used to provide validation data on gross tissue deformation for Finite Element (FE) models which investigate how local tissue strain varies under different pressure distributions. Non-metallic, bespoke pads might be used to apply a known interface pressure distribution to a subject's arm during Magnetic Resonance Imaging, with the resulting data again being useful in validating FE models. The tool might also be used to assess the accuracy of matrix pressure sensors when used on the complex geometry of soft tissue.

## 4. Conclusion

Three studies are presented to demonstrate the use of a simple, novel mechanical tool, which can be used to apply a known pressure distribution to a relatively large area of tissue, before capturing the shape of the resultant tissue displacement. The tool could be used to inform the design of the pads of an open-frame socket such that the tissue loads generated, without additional external forces, are safe and comfortable. These pads might then be suitable for manufacture using materials and methods appropriate to a low resource setting. Other potential applications include the design of other components which apply loads at the skin surface, validation of FE models and the assessment of other devices for measuring the interface pressure distribution on soft tissue and compliant materials.

## Declaration of Competing Interest

None declared

## Ethical approval

Not required

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