# Made to Measure: The Future of Personalised Prostheses

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## Abstract:

Current prostheses are expensive, slow to manufacture and come in a limited range of sizes. According to the World Health Organisation, approximately 30 million people in developing countries need prosthetic limbs, braces and other assistive devices [1]. Furthermore, the fitting and measuring process is time-consuming, as a system of moulds need to be used and a good fit requires trial and error. Traditional prostheses are 'off-the-shelf', i.e. they come in a limited range of sizes and shapes. Thus, these limbs are not able to move as freely, which results in 'compensatory movements'. Compensatory movements can cause pain and injury to muscles and joints in the long-run, due to strain injuries and overuse syndromes.

Thus, future prostheses need to be inexpensive, quick to manufacture and fit, and highly customised to a patient's unique anatomy. 3D-printing, combined with 3D-scanning and motion capture technology, are viable ways of measuring, manufacturing and fine-tuning a customised prosthesis. By examining current 3D-printed patient-specific medical devices and an experiment to determine the extent of 'compensatory movements' through wearing a traditional hand prosthesis, it is concluded that 3D printing and scanning, combined with motion capture technology, are viable and necessary technologies for producing future prostheses.

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## 1. Introduction

A prosthesis is an artificial device which helps to replace a missing body part both visually and biomechanically. This section will explore why many people cannot access prostheses - this is mainly due to prohibitive costs and a lack of skilled technicians and resources (especially in developing countries). Furthermore, traditional 'off-the-shelf' prostheses have a restricted number of degrees of freedom (DOF). The effects of having too few DOF results in more 'compensatory movements' because limbs are not able to move freely. Thus, this makes customisation in future prosthesis a necessity. In order to tailor a bespoke prosthesis to a patient, suitable methods of measurement, manufacture and fine-tuning are needed - these will be examined later in the section. Finally, to test whether customisation is a necessary feature of future prostheses, an experiment was carried out in this project – the aim and objectives will be outlined at the end of this section.

*Figure 1 Two medical prostheses: A traditional 2 DOF hand gripper (left) and an inexpensive 3D-printed prosthetic hand (right)*

## 1.1 Overview of current prostheses

Every year, roughly 185,000 amputations occur in the United States alone, with many more in developing countries [2]. For example, there is an amputation rate of around 20% in both Egypt and Yemen [3]. Yet, there are considerably fewer prosthesis users than those with amputations. This is due to the fact that traditional prostheses are expensive, ranging from £4,000 to £40,000 due to complex materials (usually carbon fibre, aluminium and titanium) and high design costs. Combined with the short lifespan of these prostheses (3 to 5 years), these are inaccessible for many [4,5]. Prostheses are especially cost-prohibitive for children, as the anatomy is constantly changing. In developing countries, there are few technicians capable of fitting more complex prosthesis to patients and shortages in necessary componentry. For example, in Uganda, despite having only 200 trained prosthetists, there are an estimated 5000 patients for each prosthetist waiting for a new prosthetic limb [6].

In order for more people to access these medical devices, there is a necessity for future prostheses to be highly customised. This is because traditional prostheses can greatly affect the motion of the limbs – extra 'compensatory' movements can be damaging towards a patient's anatomy.

## 1.2 Why is customisation necessary?

Traditional prostheses are generally restricted in their DOF. For example, the human hand has 27 DOF [7]. Yet, myoelectric[1] and body-powered[2] hand prostheses often have only 2 DOF (refer to *Figure* 1 [4,8]). As a result, individuals must compensate for the lack of DOF by changing the movements of their limbs. However, these extra movements can result in secondary injuries to limbs and the musculoskeletal system - amputees with more significant injuries have a greater chance of sustaining further injury.

Like prostheses, other medical devices such as implants require customisation (discussed in section 4.3). For both hip and knee implants, there are roughly 8 different sizes, with each option having 4 finer adjustments [9]. The size and shape of these 'off-the-shelf' implants are dictated by X-Ray scans which can have issues with magnification – errors in measurement can range from 5 to 20%. Although moulds, rather than X-Rays, are used to measure and fit prostheses, similar to traditional prostheses, there is a degree of trial and error – common problems encountered by amputees include osteoarthritis[3] and poor socket fit.

Future prostheses need to be manufactured with not just cost and time considerations, but for the necessity for customisation. 3D-printing is a viable way of achieving this.

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[1] Externally powered artificial limb that is controlled with electrical signals generated by muscles
[2] Artificial limb which uses cables to control movement
[3] Medical condition which breaks down joint cartilage and bone, causing joint pain and stiffness

## 1.3 Manufacture using 3D-printing

3D-printing is the process whereby a physical device is fabricated from a digital file by placing layers of material in succession (*Figure 2* [10]). Thus, the ability to create customised designs is a key part of this technology. Most traditional production processes use patterns and moulds to shape materials, such as molten plastic and metal into different shapes – traditional methods scale well only for many identical copies [11]. In addition, 3D-printing has the capability of fabricating complex designs quickly, whilst using less raw material than traditional manufacturing methods. A greater detail in - depth discussion of 3D-printing in general, its applications and the 3D-printing process will be explored in Section 2.

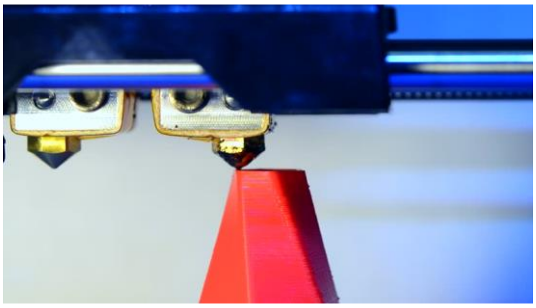

*Figure 2 Molten plastic fed from a nozzle is solidified as it is placed down in layers. This is a fused deposition modelling printing technique and will be explored in Section 2.2*

One current method of creating prostheses, currently being trialled in Uganda, involves taking scans from a 3D scanner which are then used to build up a 3D computer aided-design (CAD) model of the patient's limb [6]. Based on this model, a prosthesis can be created - a range of 3D-printed prosthetic designs can be printed simultaneously.

The application of motion capture technology helps to make further, fine adjustments to the prosthesis – these can be made quickly by tweaking aspects of the 3D file. Unlike with traditional prostheses, where multiple visits to a clinic/ hospital are needed to fit a prosthesis, this method minimises the need for trial and error.

## 1.4 Fine-tuning through motion capture technology

Motion capture technology can measure changes in the kinematics of limbs, due to compensatory movements (Figure 3 [12]). This technology is used for gait analysis, which concentrates specifically on locomotion achieved through the movement of limbs. In addition, motion capture is often used for rehabilitation – this is a dynamic process. After an operation, the progress of recovery of a patient can be continuously monitored quantitively, not just qualitatively. This technology offers a degree of objectivity, i.e. changes in limb kinematics can be accurately measured which based on previous readings, can be used to judge a patient's progress and if necessary, alter the recovery procedure.

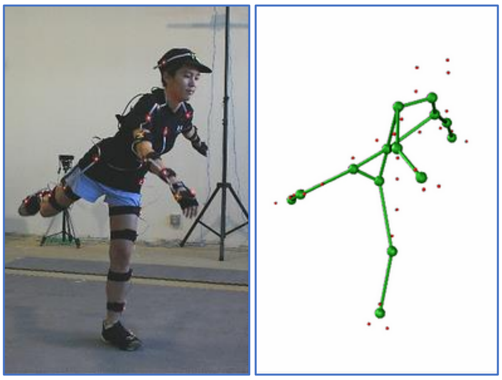

*Figure 3 A subject poses, whilst wearing a body suit with active markers with cameras tracking the movement (left). The diagram on the right shows a stick-figure representation.*

With respect to prostheses, the change in kinematics and joint angles from wearing different prostheses can be measured precisely - this data was collected in the experiment of this project. Motion capture will be further explored in Section 3.

### 1.5 Experiment

The aim of this experiment is to test whether customisation is required for prosthesis. In other words, whether changes in joint angles for a person wearing with/without a prosthesis were significant. In order to test this, the change in upper-body kinematics whilst wearing a wrist orthosis (wrist brace) was observed (*Figure 4*) whilst performing 3 activities. The wrist brace was used to mimic the effect of a 2 DOF myoelectric hand prosthesis, which lack a controllable distal joint (such as a controllable wrist and/or forearm rotation). To determine the changes in the kinematics of the limbs with and without the brace, joint angles were measured. These angles correspond to the angle between the segments on either side of a joint and are generally reported as Euler angles. The corresponding X, Y and Z angles have been standardised by the International Society of Biomechanics [13]. Additionally, the time taken to complete the tasks was recorded, and the variability of movements between the braced and unbraced trials.

*Figure 4 A subject preparing for experimentation.*

# 2. 3D-printing

## 2.1 Broad and medical uses of 3D-printing

3D-printing, also known as additive manufacturing, is a rapidly growing industry. According to the Wohlers Report, the industry surpassed £3.8 billion in 2017 and is expected to grow by £9.3 billion in 2018 [14]. Although 3D-printing is a relatively new technology (the idea was first proposed in the 1980s), it is already being used in a variety of fields [15]. For example, in product design, this technology speeds up the prototyping stage of development, which is followed by the rapid production of a physical representation of the design on a 3D printer. 3D-printing also allows for the quick fine-tuning of designs which is done by tweaking a CAD (computer-aided design) file. Whereas it would take weeks to receive a traditionally-manufactured prototype, 3D-printing can achieve this in a few hours - additional changes can be made quickly and inexpensively (*Figure 5* [16,17])

Furthermore, 3D-printing is helping to streamline the production process. For instance, producing a traditional steel bracket via traditional methods will involve many distinct processes, such as cutting, welding, grinding, drilling, sanding and coating – each of which requires a separate machine (or tool) and for the part under manufacture to be passed from station to station – this is time consuming and expensive [18]. In the aerospace industry, Boeing has saved roughly £2 million in construction costs for each 787 Dreamliner since 3D-printing titanium parts [19].

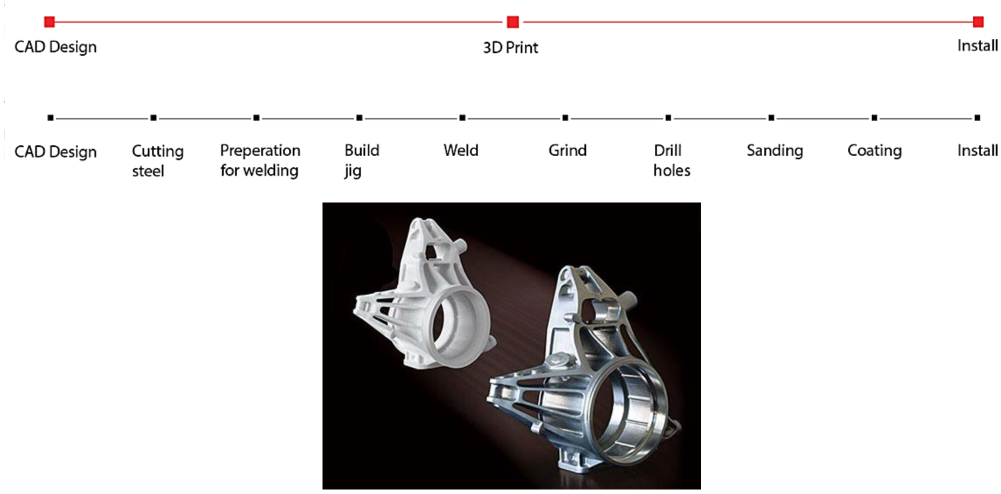


*Figure 5 3D-printing stages compared to traditional manufacturing to fabricate a custom steel bracket (Above). A 3D-printed prototype and the final product (Below)*

Although 3D-printing has only recently been introduced in medicine, due to advancements in materials, improvements in speed and a reduction in cost, 3D-printing is paving the way for more personalisation, reduced surgical time and thus and improved medical outcomes [20]. In the medical sector, 3D-printing has been growing quickly: as of 2017, 13.1% of the industry was associated with the medical sector [21].

*Figure 6 (From left to right) Customised hip implant, patient specific guide, hand prosthesis*

Currently, in addition to prostheses, 3D-printing has been used to create patient-specific anatomical models, surgical guides and implants (*Figure 6* [22–24]). Anatomical models, of internal body structures, such as organs, have been tailored specifically to a patient. These are made from different materials, with the unique tactile qualities of these models helping surgeons become more prepared for surgery. Moreover, bespoke surgical-guides help reduce risks associated with more complicated surgery and patient-specific implants reduce the likelihood of further muscle and joint pain. The widespread use of these medical devices has been limited – most of the cases thus far are one-offs. However, bottom-up approaches towards enabling patients to access 3D-printed medical devices are promising. For example, 'Project Daniel' is using 3D-printing to help treat child victims of war in South Sudan [25].

## 2.2 The 3D-printing process

3D-printing is part of a group of techniques called rapid prototyping, which involves creating a model of an object from a computer - aided design (CAD) file [26]. There are a range of 3D-printers, printing methods and materials currently available, making it accessible for both hobbyists and firms alike. Although plastic is currently the most popular material, other materials, such as metal and ceramic are not as accessible for the average hobbyist. This section will discuss the 3D-printing process, from initial design using CAD, to printing and post-processing the model.

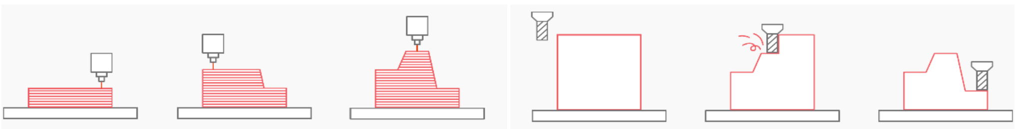

*Figure 7 3D-printing (left) and CNC Machining (right). Wasted material from CNC Machining contributes to roughly half of the total material used to create this object*

Rapid prototyping incorporates both additive (3D-printing) and subtractive (computer numerical control) technologies. Whilst subtractive manufacturing involves removing material, additive manufacturing adds layers of materials (*Figure 7* [16]). Thus, in addition to saving time and cutting costs, it is possible to design complex geometries with intricate external and internal geometries, which would otherwise be difficult/impossible using traditional manufacturing techniques [27,28].

The 3D-printing process encompasses 3 main stages: modelling, printing and finishing [29]. The modelling stage of the process normally involves the use of computer-aided design software (CAD) or 3D-scanners. This 3D-representation of this surface is triangulated: the outer surface of the model is converted into triangles, or facets to store information about the object [30]. The 3D mesh is then converted into a *.stl file format[4] (*Figure 8* [16]). The final part of the modelling stage involves 'slicing' the model, a process where a model is divided into thousands of horizontal layers. During this process, the *.stl file is converted into G-Code, a numerical control language[5].

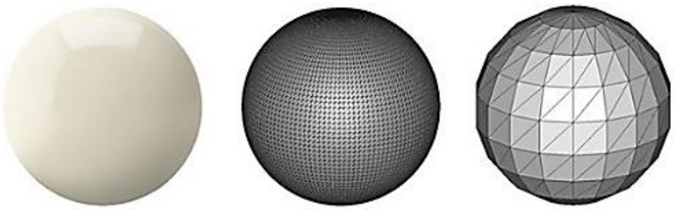

*Figure 8 The left figure shows the 'original' object, the middle a high-resolution mesh representation and the right figure a low-resolution representation. The low-resolution representation differs significantly from the original object away from the sampling points.*

The printing process can be achieved using a variety of different methods. The three main methods are fused deposition modelling (FDM), stereolithography (SLA) and selective laser sintering (SLS).

Fused deposition modelling is an extrusion technique and is the most inexpensive and user-friendly (Figure 9 [16]). Although a variety of materials can be used, plastic (often Polylactic acid (PLA) and Acrylonitrile butadiene styrene (ABS)) is most widely used. Plastic filament from a spool is fed into the printer, where it is heated into a semi-liquid state in the printer nozzle. A printer head extrudes this semi-melted plastic along a pre-defined path. As this material is extruded, it cools and hardens, forming layers [31].

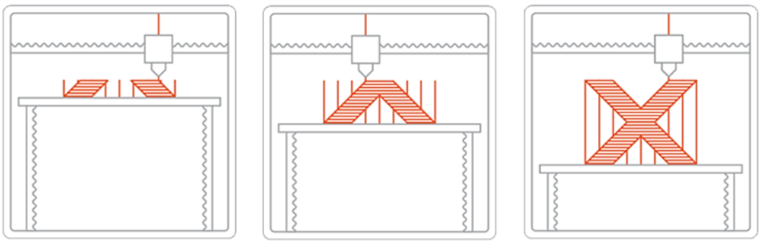

*Figure 9 Fused deposition modelling: Lines of extruded, hardened filament are laid in layers which build up successively to form the printed object.*

Stereolithography was the first additive manufacturing method developed and is an example of a photopolymerisation[6] printing technique [15]. This involves shining a laser into a vat of photopolymer resin (*Figure 10* [16]). The laser is pre-programmed to move along the vat, shining on certain areas of the photopolymer resin - this causes parts of the resin to solidify. The build platform, which sticks to the solid

[4] A widely used file format which only describes the surface geometry of a 3D model, i.e. the size, dimensions, colour etc. are irrelevant

[5] A language used to pre-programme machines: G-code is the most widely used numerical control language.

[6] Light causes molecules to link, forming polymers.

resin, moves progressively upwards away from the laser, as further layers of the object are solidified.

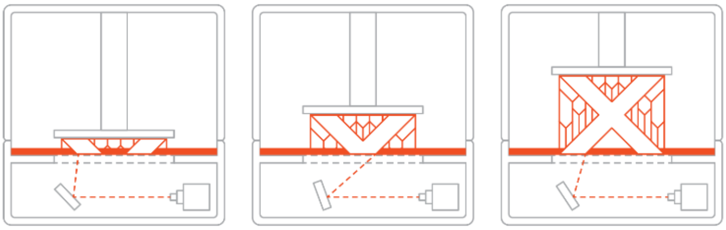

*Figure 10 Stereolithography: A focussed laser beam induces the hardening of successive printed layers.*

The third 3D-printing method, SLS, is a powder bed technology (Figure 11 [16]). This involves spreading a powdered polymer (e.g. plastic, ceramic, glass-filled nylon) across a surface. A laser moves across this powdered-surface, 'selectively' sintering[7] the powder, which helps to bind together the grains. Although most 3D-printing is done with plastic, a subset of SLS, Direct Metal Laser Sintering (DMLS) uses a metallic powder. Although costly, the greatest advantage of this method is its ability to create objects with low residual stress, a problem which plagues traditionally-manufactured parts. For example, this is ideal for creating components which are subject to high stress, such as aerospace parts [32].

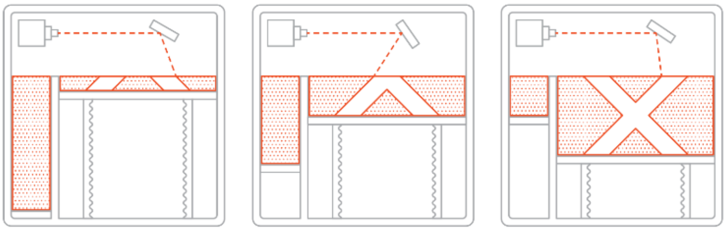

*Figure 11 Selective laser sintering: A thin layer of powder is spread across the build surface. A laser moves, selectively 'sintering' sections of the layer, solidifying powder in the process. The platform moves down, and the process is repeated.*

Finally, the models can be 'finished' or post-processed depending on the method of manufacture. Models printed by FDM generally show many lines, which can be removed by sanding. For SLA, excess resin needs to be cleaned off the model using a solvent, and in SLS, excess powder can be washed away and to an extent, be reused. Sometimes, 3D-printed parts uses support material (applies to overhangs which exceed 45 degrees to the normal) (*Figure 12* [16]). This can be removed by both physical and chemical means, depending on the printing method used.

[7] The metallic powder is heated into a semi-solid state, i.e. the metal does not become liquid. This helps binds the metallic cations together.

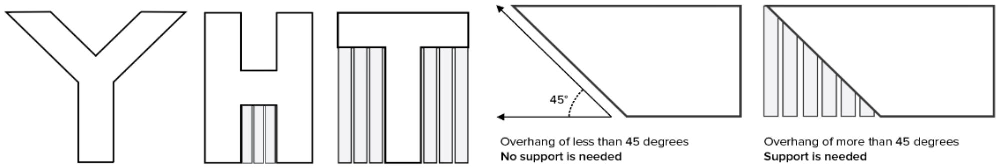


*Figure 12 Use of support-material when printing the letters 'Y', 'H', and 'T'. Note Y does not need support material*

# 3. Motion Capture Technology

## 3.1 Brief history of motion tracking

Human motion has been studied and analysed for thousands of years (*Figure 13* [33,34]). Starting with Aristotle, his treatise 'De Motu Animalium' (On the Movement of Animals) helped to set out the general principles of animal locomotion [35]. Since Aristotle, Leonardo da Vinci's intricate anatomical drawings helped to represent the mechanics of standing, walking, sitting and jumping of humans [36]. Since these early attempts to visualise the effects of motion on the human anatomy, scientists such as Borelli and Newton began to quantitatively measure the effects of human motion. In the late 19$^{th}$ century, Étienne-Jules Marey, by correlating ground reaction forces with movement helped to pioneer modern motion analysis. Combined with contributions from 20$^{th}$ century researchers and engineers, human motion is now fairly well understood.

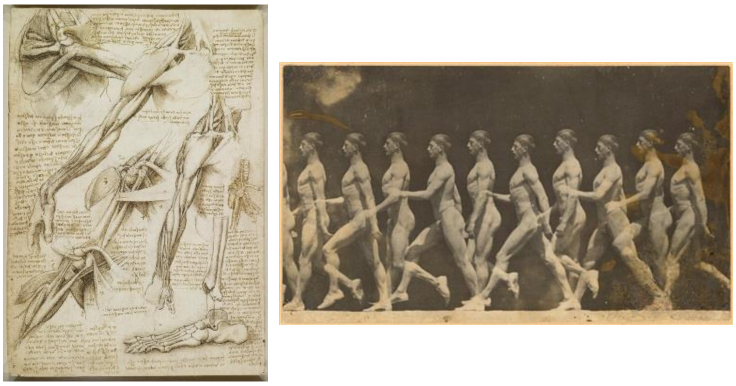

*Figure 13 Da Vinci's anatomical drawing to show the pronation and supination of the arm (left) and Marey's 'Motion Study - Man Walking' (right)*

## 3.2 Variations between the upper and lower extremities

However, the nature of human motion varies with the lower and upper limbs. Lower limb movements are directly linked to gait. According to Rau et al [37], 'Gait is a cyclic sequence of movements occurring from heelstrike to heelstrike of the same foot'. This is well defined, being symmetrical to a high degree with each cycle is highly reproducible, which improves the reliability of the data. Thus, the analysis of lower limb movements is well established [37]. However, the upper extremities are less well understood – the nature of free arm movements is completely different from being restricted to one plane of movement, repeatable or cyclic in motion. Thus, the analysis of experimental evidence in this project was limited to changes in joint angle.

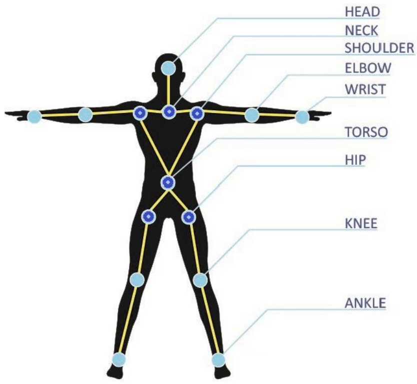


*Figure 14 A 15-joint structure showing rigid-body parts and limbs.*

### 3.3 Human body as a rigid structure

In motion and gait analysis, the human body is considered to be a system consisting of rigid links, connected via joints [38]. Thus, stick figures can be created, which reflect the positions of limbs during movement (*Figure 14* [39]). However, this can be seen visually, so the real advantage of motion analysis is the capability of calculating joint angles - joint angles can be differentiated, to give joint moments and jerks. Finally, according to Rau et al [37], if the masses of different limb segments, centres of gravity and moments of inertia are known, the work power and energy transfer between different body segments can be calculated.

*Figure 15 Marker-based, visual motion capture (left), vs. Inertial, non-visual motion capture (right)*

### 3.4 Types of motion capture technology

Tracking systems are categorised into both visual and non-visual tracking systems (Figure 15 [40]). Visual tracking technology, which encompasses a wide range of technologies, uses a system of cameras record movement. Markers are often used, these being passive (reflective) or active (light-emitting). Markers are often preferred over marker-free visual systems. For example, in places with cluttered scenes and varied lighting, markers are preferred. In general, the key advantage of visual motion capture technology over non-visual tracking systems is accuracy. For example, Zhou et al [41] consider VICON and Optotrak tracking systems to be the 'gold standard' in human motion analysis - position data is accurate up to 1mm.

On the other hand, non-visual tracking systems use sensors (mechanical, inertial, acoustic, radio, microwave, magnetic) placed around the body to record movement data. These systems are often cheap, physically compact and lightweight. Furthermore, data, such as accelerations, can be exported without complicated computation [42]. Disadvantages of non-visual tracking systems depends on the type of sensor used. Accelerometers can suffer from the 'drift problems' – sensors can, over time, move relative to a joint which leads to inaccurate readings. Magnetic systems can also be affected by electromagnetic interference [43].

### 3.5 Applications

Motion capture technology, as well as being used for gait analysis, is primarily used for both video games and computer-generated effects [44]. For example, 'The Lord of the Rings: The Two Towers' was the first feature film to utilise a real-time motion capture system [45]. Other applications include virtual reality and in sport [46].

## 4. Customised Medical Devices

Although most 3D-printed devices in medicine are still in the R&D stage, there have been notable advancements in the areas of maxillofacial, cardiac and spinal surgery. Within these surgical domains, a majority of studies have shown 3D-printing to be clinically effective [21]. Advantages include more effective surgical preparation, reduced time during surgery and an increased chance of a successful surgery, especially for less proficient surgeons.

This section focuses on three medical devices currently being trialled, where the ability to be customised towards a patient is a key advantage - anatomical models, surgical guides and implants. The advantages and disadvantages specific to each device will be discussed. Overall issues facing 3D-printed medical devices will be discussed at the end of this section.

### 4.1 Anatomical models

Anatomical models (Figure 16 [20]) represent a patient's internal body structure in model form. Usually printed by fused deposition modelling, these models help to streamline surgical planning, which in turn reduces surgical time - this is likely to improve surgical outcomes [20].

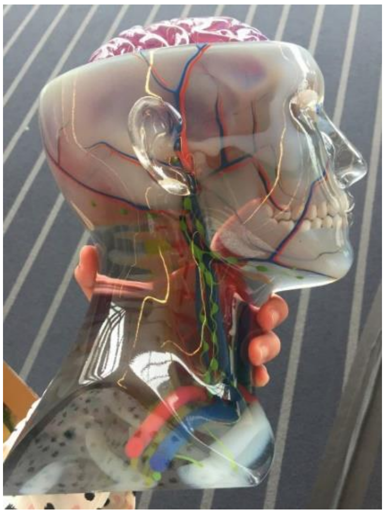

*Figure 16 Plastic anatomical model showing a person's head and neck, with blood-vessels and significant bones shown.*

Firstly, anatomical models give better visual and more importantly, tactile information to the surgeon. During conventional surgical planning, doctors must work with 2D images obtained from X-Ray and CT scans to understand the pathologies involved [47]. This requires excellent visualisation skills by the surgeon, especially when dealing with complex scenarios.

In addition, the tactile qualities of the models make it possible for surgeons to feel how different parts of an organ will physically react during surgery. For example, an anatomical model of the heart would help a surgeon to better differentiate between different tissue thicknesses, thus gaining muscle memory of the procedure. This is important as this would affect how much force the surgeon would need to use during surgery [48]. Although virtual reality technology, which is currently being trialled, provides more visual information than regular 2D images from scans, it does not give tactile information. Thus, with anatomical models, surgeons can design a patient-specific surgical plan, based on additional visual and tactile information.

However, there are problems specific to anatomical models, namely cost of production and issues with materials. Anatomical models must be geometrically accurate, uniquely responsive based on the material and have different surface textures. Combined with the need for colour, to differentiate different elements of the anatomical model, it would be necessary to use high-end 3D printers. This considerably increase costs. Currently, anatomical models are made of plastic. Surgeons practise on these with medical tools. However, these tools will generate heat due to friction, which can cause the surgical models to warp or deform. This results in an unrealistic experience that would not prepare the surgeon adequately for surgery [48].

## 4.2 Surgical Guides

3D-printed surgical guides (*Figure 17* [20,49]) help guide surgical instruments along bones, based on a patient-specific surgical plan. These guides are designed to sit on bones and muscles to guide cutting and drilling. Made of plastic and sometimes titanium, these are well incorporated in orthopedic, spinal, maxillofacial and dental surgery, with benefits including greater accuracy and consistency of surgical procedures. In general, studies reported that patient-specific guides were best utilised when dealing with procedures of high complexity and with less-experienced surgeons [50,51].

*Figure 17 Surgical guides showing positions for cutting angles and locations (left); drilling angles and locations (right). Note, right figure shows a 3D-printed bone for demonstration purposes.*

Surgical guides have been particularly effective in spinal surgery which can be inherently dangerous, due to the delicate nature of the surrounding anatomy [50]. For example, asymmetry between the left and right cervical spine, differences in bone structure and the sensitive nature of surrounding tissues which makes procedural success more difficult to achieve. Thus, it is possible that surgical guides can reduce the chance of complications.

Current method of reducing complications include computer-assisted surgery (CAS) (Figure 18 [52]). This involves using scans to create a real-time moving picture of a patient's anatomy. Using this information, the surgeon can instruct robots to make the necessary cuts/ incisions. However, Lanfranco et al [53] report that cost is a major drawback, as CAS machines cost millions of dollars. Furthermore, CAS systems have 'relatively cumbersome robotic arms', making it difficult to use in small operating theatres. Furthermore, the benefits of computer assisted surgery are debatable, with Jeong et al [54] suggesting that Humans are still faster and more precise than robots, especially for smaller operations. Thus, 3D-printed surgical guides, whilst being cheaper than CAS, can still retain the benefits of superior human dexterity, whilst improving procedural accuracy during surgery.

*Figure 18 A typical CAS system*

Despite reductions in surgical time and greater accuracy of these guides there are currently issues with soft tissue, which limit the utilisation of these surgical guides. Wilcox et al [50] reported the most commonly reported issue was the necessity to remove soft tissue from bones. Soft tissue (fat, ligaments, tendon etc.) must be completely removed for the template to fix into the correct location, which increases operation time and blood loss.

### 4.3 Implants

Customised implants, similar to prostheses, can be manufactured using 3D-printing (*Figure 19*). Most patient-specific implants use the titanium alloy $TiV_6Al_4$, due to its biocompatibility (non-toxic and does not get rejected by the body), strength and good osseointegration (connection between the implant and the bone). These patient-specific implants have significant advancements over traditional ‘off the shelf’ implants, which are sized based on averages and compromises – this required the patient to adapt to the implant, not vice-versa [55]. Thus, patients being subjected to complex surgery with difficult anatomy and deformity have an increased risk of implant failure [50]. Furthermore, 3D-printed implants are more stable, as they match the contours of the patient’s anatomy – this helps to reduce stress shielding, a reduction in the density of bones due to the removal of normal stress from a bone by an implant [56].

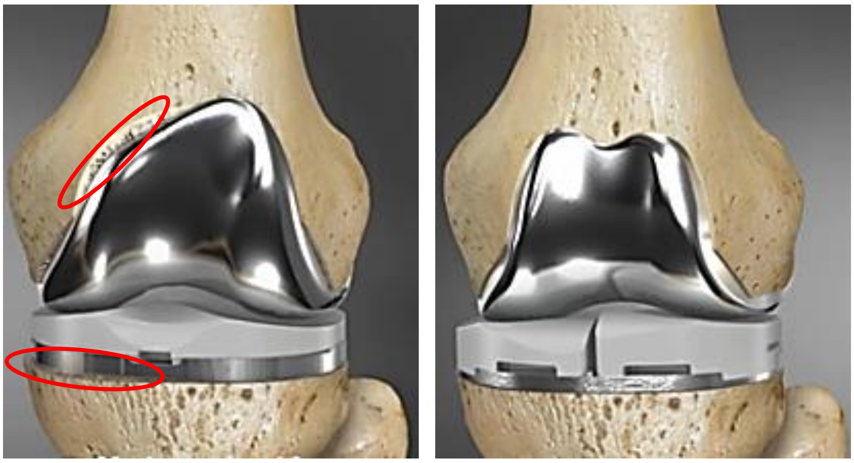

*Figure 19 ‘Off-the-shelf’ implant (above) vs. a bespoke implant (below). Areas marked in red shows a lack of osseointegration – this can cause further issues with movement*

In general, few studies assessed the efficacy and efficiency of 3D-printed medical devices, with even fewer studies assessing patient-specific implants – most devices assessed were anatomical models and surgical guides. Efficacy refers to the effectiveness of the medical device, i.e. the performance under ideal conditions. Efficiency refers to the performance under typical clinical conditions. This may be due to the fact that clinical outcomes from using anatomical guides and surgical guides are more easily quantifiable. For example, reductions in operating time and volume of blood loss can be easily measured after using anatomical models and surgical guides.

## 4.4 Overall issues

Overall, 3D-printed medical devices encountered issues with long times to design the medical device, a lack of standardisation and a lack of long-term. Despite surgical time being reduced, studies in the literature did not factor in the time taken to design and produce them [48]. It would therefore be unlikely for 3D-printed guides to be used in an emergency. The accuracy of 3D-printed medical devices depends heavily on the manufacture process - this is highly dependent on the quality of scans [51]. Poor quality scans can result in medical devices which do not fit a patient. Thus, even if 3D-printed devices are more accurate, this could increase the intensity of any radiation exposure the patient undergoes. Quality control is also an issue, not just for 3D-printed medical devices, but for 3D-printed devices in general. Although having a range of 3D-printers and materials allows this technology to be affordable, it may be difficult to gauge the quality and strength of 3D-printed parts [57]. This is particularly important in medicine, where instrument failure is risky. There is also a lack of long-term data on the performance of these medical devices – this is necessary to evaluate the potential risks and benefits of these devices to patients. Finally, it is important to emphasise that as 3D-printing is a new field, so conclusions from data are likely to be subject to bias. In addition, advantages in one area of surgery, e.g. spinal, cannot necessary be extrapolated to other surgical domains.

# 5. Experiment

## 5.1 Experimental design

An experiment was designed to test whether changes in joint angles for a person wearing with and without a prosthesis were significant. Most hand prostheses have few degrees of freedom. The human hand alone has 27 DOF (degrees of freedom): 4 in each finger, 3 for flexion and extension (bending/unbending around a joint) and one for abduction and adduction (movement away and towards the midline of the hand). The thumb is more complicated, having 5 DOF. This leaves 6 DOF (includes pronation/supination) for the rotation and translation of the wrist [6]. Designing prosthetic hands which closely match limb movements is challenging as the hand has numerous feedback mechanisms and acts as one of the main external sensing apparatus. This includes feedback, pressure, thermal sensing, and proprioception[8]. Current prostheses have a lack of DOF as it is difficult for multiple DOF to be controlled simultaneously [58].

A wrist orthosis (wrist brace) was used to mimic the effect of a 2 DOF traditional myoelectric hand prosthesis. Three activities were designed in order to replicate activities of daily living (ADLs). These activities were:

- Activity 1: Turning over a page.
- Activity 2: Moving a bottle in front of the body.
- Activity 3: Moving a bottle across the body.

These activities were designed to observe the effects of motion on the upper extremities. Thus, all three activities involved sitting in a chair, to reduce any limb motion from the lower extremities. Furthermore, different types of grip were chosen, to replicate common daily tasks. These include the pinch grip (Activity 1) and a cylindrical grip (Activities 2 and 3). Each activity was repeated three times for each subject and was done at a self-selected pace. The subject familiarised themselves with the procedures before experimentation. For each activity, the subject sat at a comfortable height, with the forearm perpendicular to the upper arm. The palm of their right hand was facing down at the start of each activity – this setup was used for Activity 1.

In this experiment, each subject wore a Lycra upper-body suit, with Velcro fittings at pre-defined locations. Additional Velcro straps were used to attach sensors for the inertial tracking system (*Figure 20)*. A sensor for the head was attached to a headband and a hand sensor was placed in each glove for each hand. For each subject, a calibration process was necessary. After standing still, in a neutral pose for 10 seconds (*Figure 18*), the subject walked up and down for a total distance of 3m and stood in a star-pose for the remainder of the calibration.

[8] The ability to sense stimuli arising within the body regarding position, motion, and equilibrium.

*Figure 20 Subject in the starting position for Activity 2 (left). Subject standing in neutral pose for calibration (right). Note, the two sensors for the left and right shoulders were attached to the back of the subject (not visible)*

To mimic the effect of the 2 DOF, a metal splint, supported in a wrist brace, was sellotaped to the subject's hand. A further two 3D-printed PLA slats were used to restrict the degrees of freedom of the fingers and thumb. Thus, the hand was restricted to pronation/supination in the wrist, and flexion/extension of the hand. This could be achieved in a Myoelectric hand either through a powered wrist or through the forearm muscles in the residual limb. The apparatus is shown in (*Figure 21*)

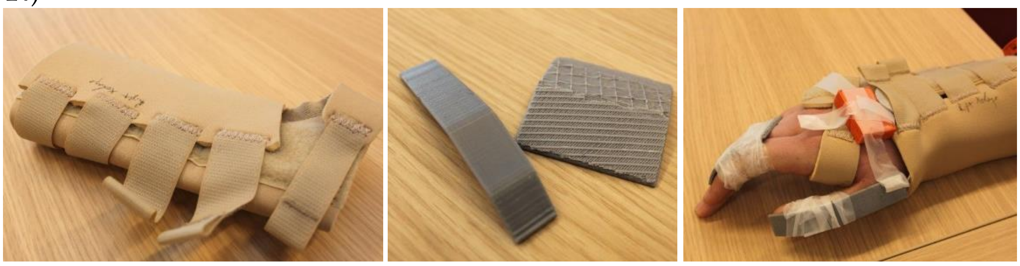

*Figure 21 Wrist brace (left), PLA slats (centre) and final arrangement (right)*

It was hypothesised that wearing the wrist brace would increase the time taken to complete the task, the range of joint angles needed and the jerkiness of the movement. The joint angles of interest were the shoulder, elbow and wrist.

### 5.2 Experimental procedure (Next page)

## Activity 1 (Turning over a page):

### Setup:

- Subject will sit at a comfortable height
- The right forearm will be perpendicular to the right upper arm.
- The palm of the right hand will face down, on the table

### Procedure:

- From the top of the right edge of the paper, turn the piece of paper right to left by placing the fingers underneath the paper and using the thumb as a support.

- Whilst still holding the paper, flip the paper position

- Return the hand to the original position

## Activity 2 (Moving a bottle in front of the body):

### Setup:

- In additional to setup in Activity 1:
- Initial position of the bottle is determined by the length of the subject’s forearm
- Final position of the bottle is determined by how far the subject can extend their right arm whilst still maintaining the perpendicular angle between their forearm and upper arm - these positions are marked with a cross

### Procedure:

- Move the hand and grasp the bottle in the middle

- Lift bottle and transfer to the marked position


- Whilst still grasping the bottle, return the bottle to its initial position


- Return the hand to the original position

## Activity 3 (Moving a bottle across the body):

### Setup:

- In additional to standard setup in Activity 1
- Position of markers will be the same as in Activity 2, except the final maker will be positioned 45 degrees anticlockwise relative to the final marker in Activity 2 - these positions are marked using a cross

### Procedure:

- Move the hand and grasp the bottle in the middle

- Lift bottle and transfer to the marked position


- Whilst still grasping the bottle, return the bottle to its initial position


- Return the hand to the original position

## 5.3 Experimental Results

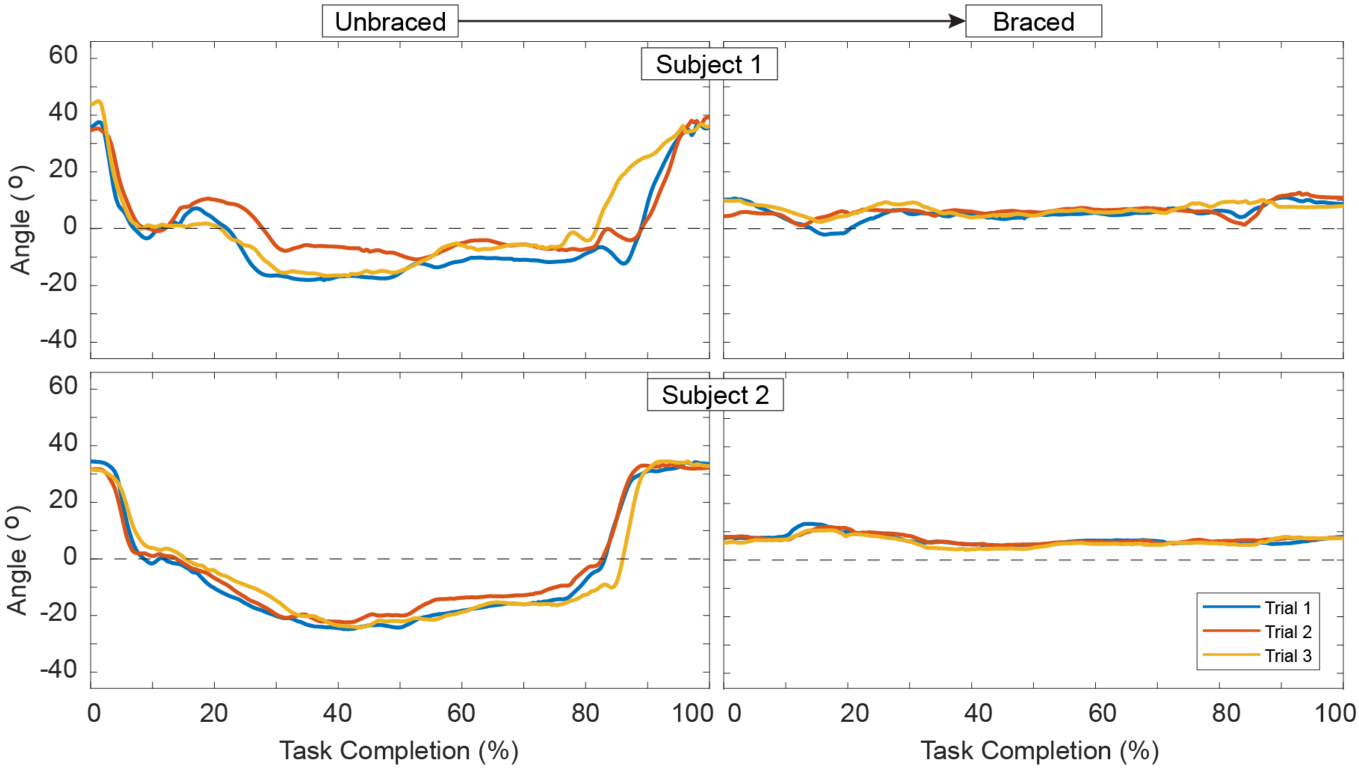


*Figure A Internal/external rotation of the wrist for Activity 3 (moving bottle across the body). Considering all of the degrees of freedom of the wrist were restricted, this confirms the brace was functioning as intended.*

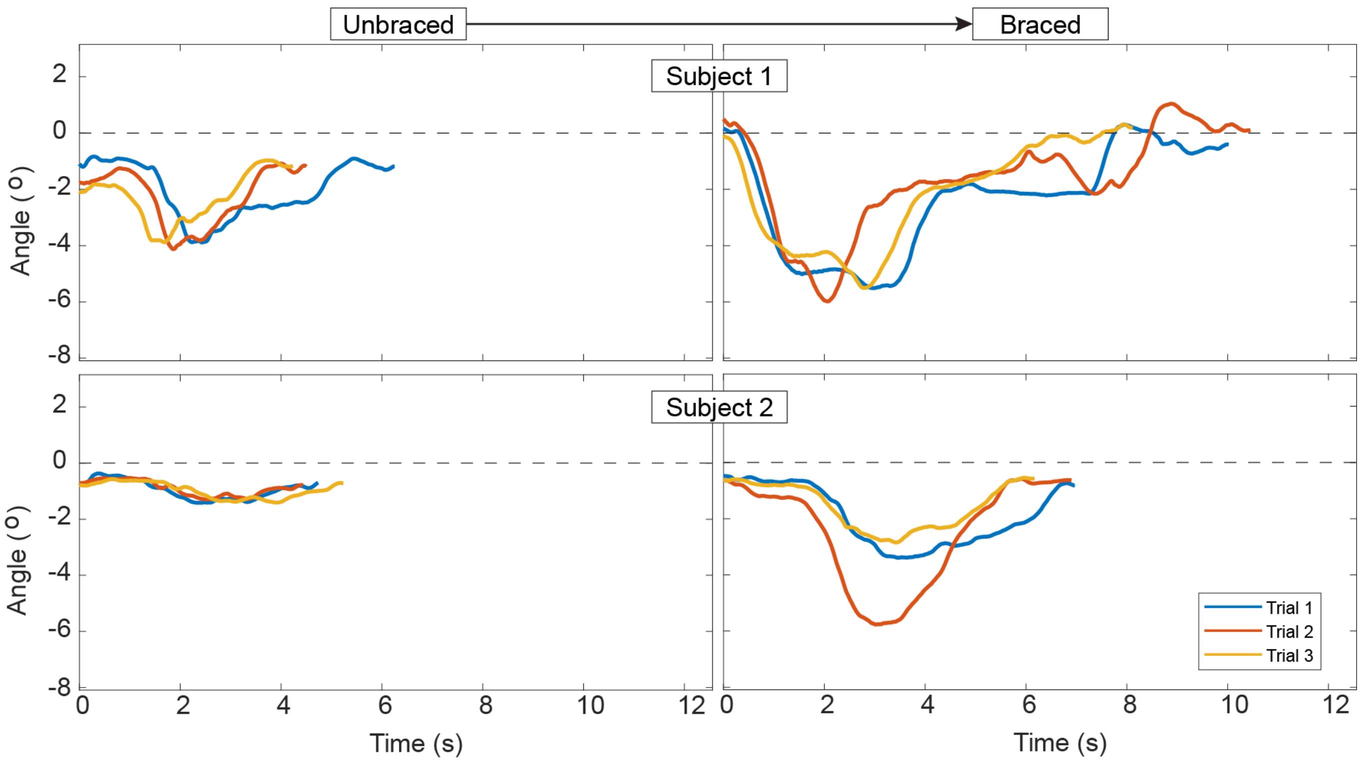


*Figure B Lumbar flexion and extension for Activity 1 (turning page). These graphs show that the wrist brace has greatly increased the range of joint angles. Time taken to complete the task has also roughly doubled.*

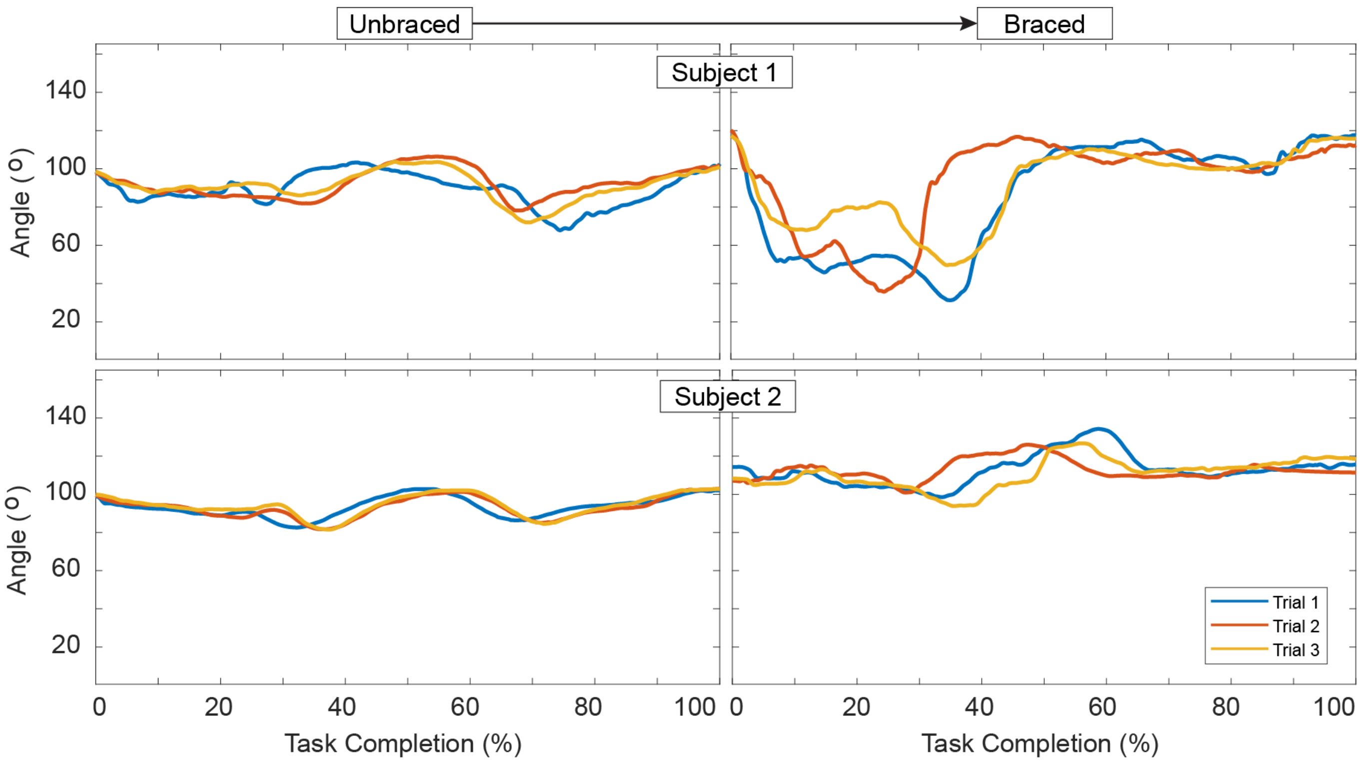


*Figure C Pronation/supination for the forearm for Activity 1 (turning page). Joint angles, especially for Subject 1, increased up to 40 degrees. Moreover, the jerkiness, and variability of trials increased significantly.*

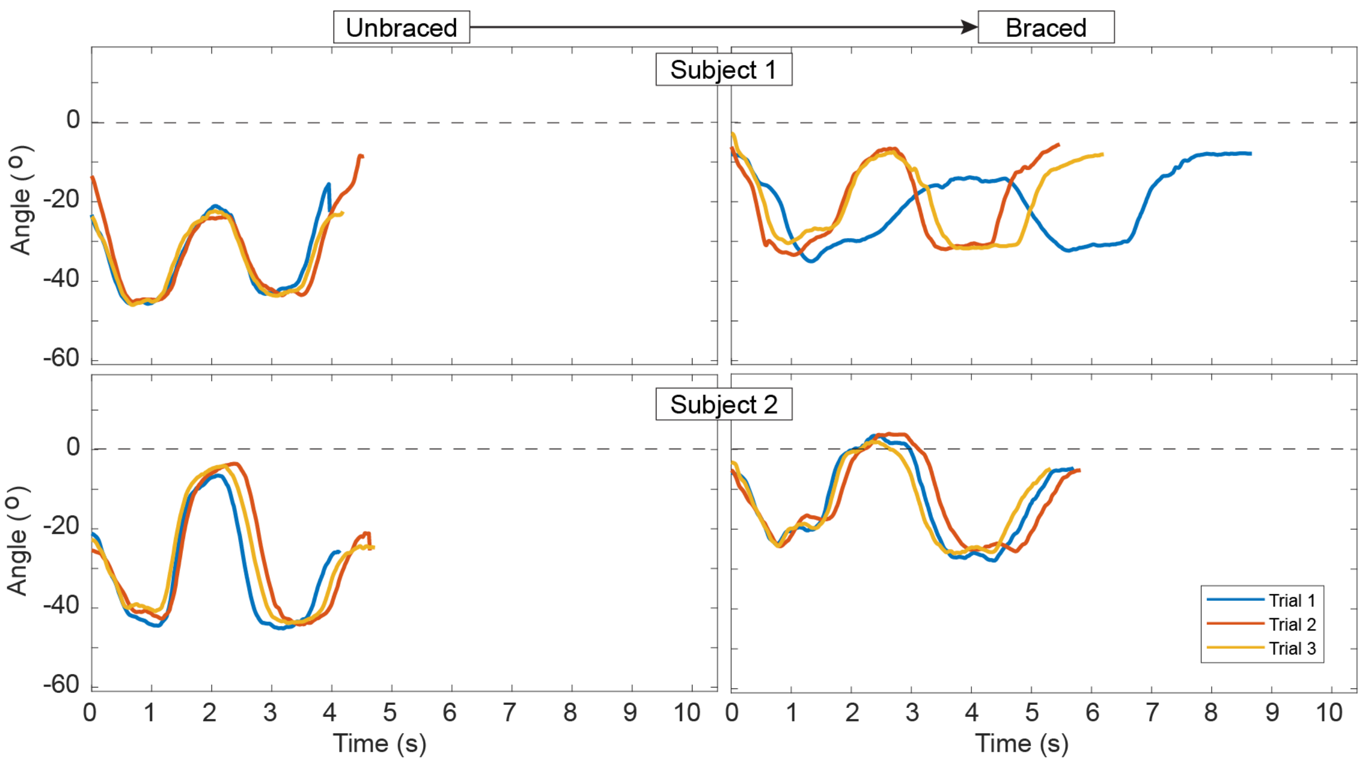


*Figure D Abduction/ adduction of the wrist for Activity 2 (moving bottle in front of body). Both joint angles and jerkiness have partially increased. Note, for the braced trial for Subject 1, the 1st trial is clearly anomalous. Overall, for braced trials, the 1st trial takes the longest.*

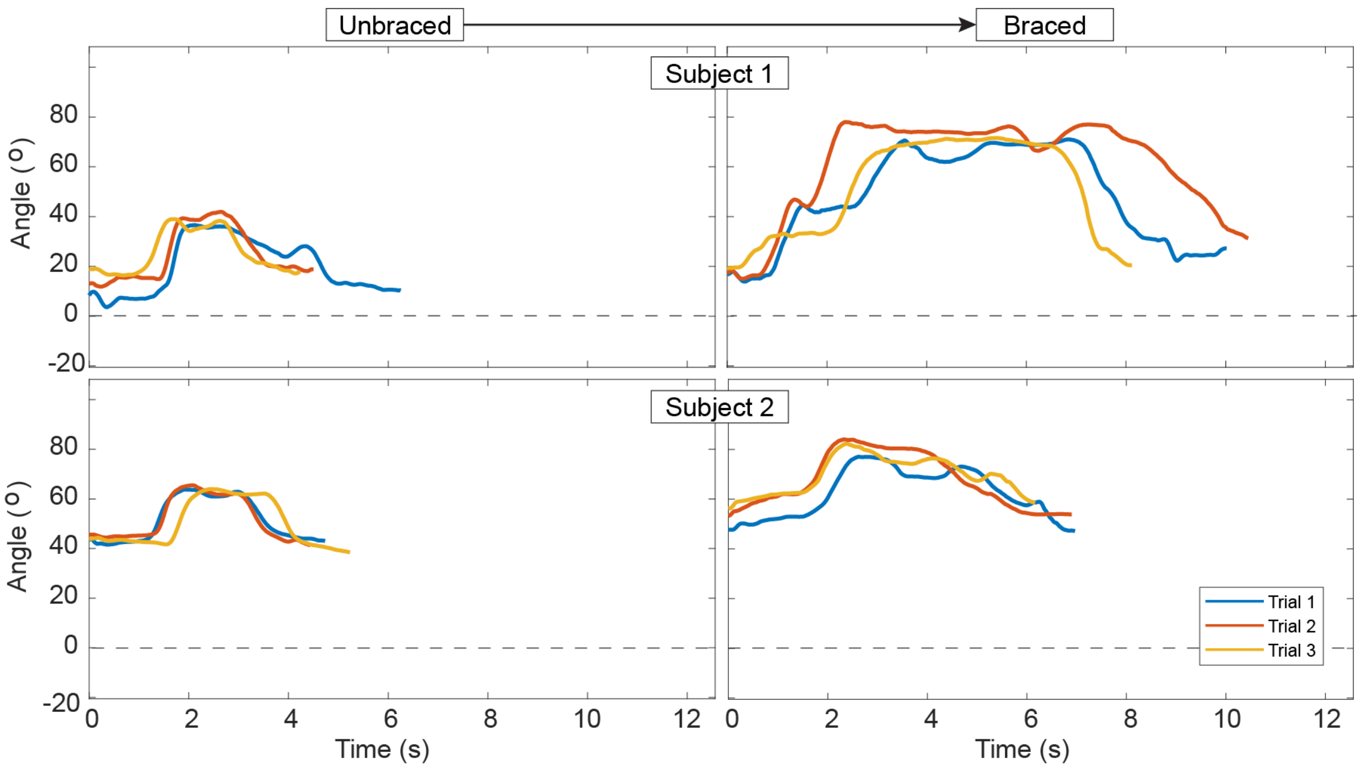


*Figure E Flexion/extension of the right shoulder for Activity 1 (Turning page). There are a greater range of joint angles, especially for Subject 1.*

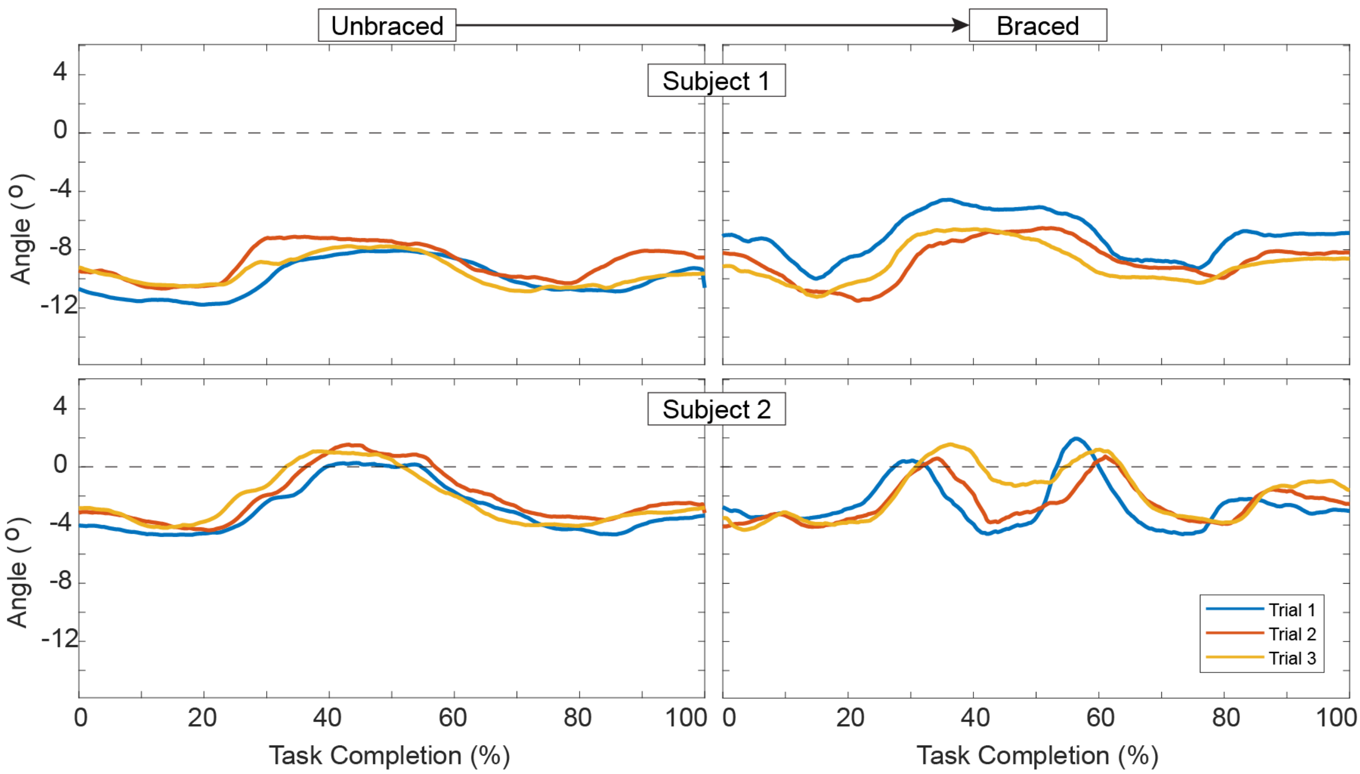


*Figure F shows abduction/adduction of the right shoulder for Activity 2 (Moving bottle in front of body). Although the range of movements has not increased, the braced measurements show jerkier movements, especially for subject 2, where there are two distinct 'humps'.*

## 5.4 Analysis

For this experiment, a total of 2 male, right-dominant subjects were used. The mean height was 189.4 cm and mean age was 17.1 years old. A total of 10 sensors were used and 30 joint angles in the X, Y and Z planes were recorded for each subject, activity and trial, so there were 540 joint angles measurements in total. 5 sensors, including 4 on the left-hand side of the subject and one of the head, were discarded, as plotted data was shown to be significant. For each activity, joint angles from each sensor were plotted, for braced and unbraced activities, for the two different subjects. These graphs were plotted in MATLAB. 6 larger graphs, comprised of 24 smaller graphs, were especially of interest – Figures A to F are shown above.

## 5.5 Discussion of results

Firstly, there was a significant increase in the range of joint angles. For example, (*Figure A*) shows the pronation/supination of the wrist. Without a brace, the joint angle ranges from -20 degrees and 40 degrees for the flexion/ extension of the hand. With a brace, the range of joint angles was significantly decreased. Similarly, for the radial and ulnar deviation of the wrist, a decrease in joint angles whilst wearing the brace was observed, although less pronounced. These results are expected since the brace restricts all of DOF for the wrist. It is thus likely that there were increased compensatory movements for the forearm. This may be suggested in (*Figure* C), which shows considerably increased pronation in the forearm.

Secondly, the wearing of the brace increased the time taken to complete the task, roughly by a factor of two (*Figures B, E*). Although this increase in time could be attributed to a necessity for increased compensatory muscle movements, it is also possible that the subjects were at first, unfamiliar with the tasks undertaken. For example, in (*Figure* D), the 1$^{st}$ braced trial for Subject 1 took significantly longer than other trials for the same task – this is clearly an anomalous result - in general, the 1$^{st}$ braced trial was longest. The long-term effects of wearing this brace was not investigated, so it is possible that the subject could decrease the amount of time needed to perform these activities – further testing would need to be done to test this claim.

Finally, an increase in the jerkiness and variability of the movement was observed (*Figures C, D, F).* For example, in (*Figure F*) Subject 2 shows two distinct peaks for the when braced. Although there was increased flexion/extension of the shoulder, as the number of trials within an activity increased, the jerkiness of the movements increased, which suggests that the procedure was uncomfortable, which again suggests that the long-term use of a traditional prosthetic cause secondary muscular issues. Further analysis of data includes differentiating joint angles to give joint moments and jerk. The braced trials for Subject 1 in (*Figure C*) show lots of variability between trials. This may suggest a lack of control in the forearm – as well as increased compensatory movements, it is also possible to suggest that the control of movements are reduced.

Although it was hypothesised that wearing the brace would only significantly increase the joint angles only for the shoulder, elbow and wrist, a sizeable increase in lumbar abduction was observed (*Figure B*). This is despite the fact that the backrest of the chair may have restricted any backward bending of the trunk during the task.

In addition to the significant increases in time for Subject 1, this suggests that whole body compensatory motions are required when wearing a prosthesis.

Thus, to conclude, the results from this experiment suggest that a traditional prosthesis can significantly increase the range of joint angles, which increases the amount of compensatory muscle movements needed – this is damaging to a patient's anatomy in the long-run. It is also important to note that for both subjects, different results were measured for the same task. Despite the small sample size, this variability of data is another argument to argue for the need for customisation. Additional increases in time taken and variability between trials suggests that prostheses additionally hinder the free movements of limbs. Overall, this suggests that customisation is required in order to allow limbs to move freely whilst wearing a prosthetic device.

# 6. Conclusion

Based on a survey of current, 3D-printed medical devices and an experiment to determine the necessity for customisation in prostheses, this project proposes that future prostheses need to be inexpensive, quick to manufacturable and customisable. Prostheses need to be inexpensive, in order to help more people, especially children and those on low-incomes to improve their quality of life. In order to reduce costs, future prostheses can be 3D-printed. 3D-printing can fabricate a range of designs for prosthesis, which are based on 3D-scans of a patient's anatomy, in a few hours. In order for prostheses to fit properly, customisation is a requirement for future prostheses – this is suggested by experimental data in this project. Motion capture technology can be used to quantitively detect and measure the extent to which the movement of limbs are restricted. From this data, adjustments can be made to a 3D CAD-file, which helps to create a better-fitting prosthesis quickly. This saves time, reduces costs and prevents any long-term damage to the body by improving the fit of the prosthesis.

From a review of current 3D-printed medical devices (including prostheses), which are in early stages of use, evidence suggests that 3D-printing is a viable way of improving patient outcomes. This is through improving surgical planning, saving surgical time and reducing costs by providing alternative methods of surgery, such as computer-aided surgery. However, more importantly, it must be stressed that 3D-printing is helping to introduce a more customised and personalised healthcare delivery.

Current issues faced by 3D-printed medical devices include time to design devices, high costs associated with printers, a lack of standardisation and the extent to which these devices can be manufactured on a large scale. However, as 3D-printing becomes more integrated with existing medical practice, more medical professionals will be proficient at scanning and designing 3D-printed medical devices. Currently, Stryker Corporation has invested £9 billion in 'Just-in-time' 3D implants. Through scanning, an implant can be printed simultaneously with a surgery, which improves the fit of the implant [59]. Similarly, although high-end printers are only accessible for firms, due to high costs, the cost of 3D-printers in general have decreased significantly, since the technology was conceived in the 1980s. For example, an FDM printer would have cost in excess of £100,000, whereas now, these printers can be bought for less than £1,000 [60]. Similarly, 3D-printed medical devices are becoming more standardised. For example, the U.S. Food & Drug (FDA) have recently announced frameworks for 3D-printed devices [61]. Although in early stages, quality control measures will help to standardise 3D-printed medical devices in the future. It is suggested that customised prostheses can be mass-produced in the future. Three factors: costs and time need to be considered. 3D-printing intrinsically offers reductions in costs and time during the manufacturing process. Motion capture technology was setup within 30 mins during the experiment in this project. Data from motion capture is helpful in quickly making changes to designs in prosthesis – this certainly offers time reductions over traditional prostheses, where multiple visits to hospitals/clinic are needed.

In summary, despite the fact 3D-printed customised prostheses are in early stages of development, significant investments in 3D-printing in the medical sector, combined with constant improvements in 3D-printing technology are helping to make less expensive, easily manufacturable and highly customisable prostheses to become viable in the future.

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