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LOW COST DIGITAL FABRICATION APPROACH FOR THUMB ORTHOSES

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Abstract

Purpose - The purpose of this paper is to describe a novel design workflow for the digital fabrication of custom-made orthoses (CMIO). It is intended to provide an easier process for clinical practitioners and orthotic technicians alike. It further functions to reduce the dependency of the operators' abilities and skills.

Originality - Although some research has been developed on digital fabrication of CMIO, few studies have investigated the use of desktop 3D Printing in any systematic way. This study provides a first step in the exploration of a new design workflow using low-cost digital fabrication tools combined with non-manual finishing.

Social implications - The feasibility of the process increases the impact of the study, as the great accessibility to this type of 3D printers makes the digital fabrication method be easier to be adopted by operators.

Methodology - The technical assessment covers low-cost 3D scanning, free CAD software, and desktop 3D Printing and acetone vapour finishing. To analyse its viability, a cost comparison was carried out between the proposed workflow and the traditional CMIO manufacture method.

Findings - The results show that the proposed workflow is a technically feasible and cost effective solution to improve upon the traditional process of design and manufacture of custom-made static TMC orthoses. Further studies are needed in order to become a clinically feasible approach and to estimate the efficacy of the method for the recovery process in patients.

Keywords:
FFF, 3D scanning, Meshmixer, lattice structures, surface treatment, costs analysis

1. Introduction

Orthoses are often classified as either static or dynamic. Static orthoses have no movable parts and are designed to support or limit joint activity. The principal objective of thumb TMC orthoses is to decrease inflammation by providing rest and immobilisation and to decrease pain as well as to prevent subluxation and deformity by stability of the thumb (Zhang et al., 2007). Thumb immobilisation orthoses can be prescribed for a range of conditions including rheumatoid arthritis, osteoarthritis, de Quervain tenosynovitis, and carpal tunnel syndrome (Barron et al., 2000; Coldham, 2006; Heath, 2010; Mardani-Kivi et al., 2014).

Currently, the manufacturing process of immobilisation orthoses is typically manual (Coppard and Lohman, 2008; Jacobs et al., 2003). There are available a great number of thumb orthotics designs, but mainly based on two types of designs: the short type that is based in the palm and immobilises the thumb only, and the long type that includes the wrist. When considering the manufacturing process, two types of orthoses can be observed namely custom-made and off-the-shelf, both in different types of material.

Custom-made static immobilisation orthoses (CMIO) commonly are manufactured by orthotic specialists out of thermoplastic sheets. There are mainly two approaches. The first approach uses low-temperature thermoplastic (LTT) that is adapted directly on the skin. If desired, the orthopaedic cast thermoplastic material can be heated before or after it is placed on the patient's extremity (Green, 1984). The second approach, Mould Casting Splinting (MCS), entails the creation of a mould from the patient's hand with alginate. It is then filled with plaster to make a hand model. When it rigidifies the model is used to adapt pre-heated thermoplastic sheets to the surface. For the this step a vacuuming system can be utilized to increase the adaptation precision and rigidity (Lusardi et al., 2013). The last steps entail the cut of extra material and finishing (Palousek et al., 2014). Then it is fitted with fasteners, to ensure a secure fit for the patient and to provide partial immobilisation of the radial wrist in the case of de Quervain tenosynovitis (Coldham, 2006; Mardani-Kivi et al., 2014), as can be seen in Figure 1. This type of orthoses should optimally support the thumb TMC joint while leaving other joints of the thumb and hand completely free so that thumb and hand function is maintained (Weiss et al., 2004).

The LTT conventional process, widely used among professionals, is unpleasant for the patient. Moreover, it often involves an iterative process if the product initially has a poor fit to the patient's anatomy (Paterson et al., 2015). By contrast, the MCS process allows better fitting and rigidity of the orthosis. This process is depicted in Figure 2 and can take up to 2 hours of fabrication time per part for an experienced practitioner. However, the orthosis finishing for this approach is more time consuming as it usually includes personalised designs or perforations. This results in a procedure with high material waste, and excessive time and effort, both for the specialists and the patients (Chandra et al., 2005). Furthermore, the fact that this work is manual makes it completely dependent upon the skills and abilities of the specialist (Cottalorda et al., 2005). It may also result in an inadequate or poorly fitting orthosis. This causes friction, directional misalignment, excessive pressure in some areas and pressure ulcers, amongst other problems (Coppard and Lohman, 2008). In addition, the limited skin ventilation of CMIO generates problems such as excessive perspiration, bacteria grow, and difficulty to keep clean

(Coppard and Lohman, 2008).

Consequently, several factors may adversely affect the patient's satisfaction, such as inconvenience and discomfort, along with dissatisfaction with aesthetics. This often results in less willingness to wear orthoses and follow the prescribed treatment. Aesthetics of orthoses may have implications on the implementation of the duration and suggested guidelines treatment (Veehof et al., 2008).

Figure 1. Long thumb CMIO made by MCS process

1.1 Anatomical data acquisition

3D scanning is becoming more prominent within medicine. Paterson et al. (2010) concluded that in terms of accuracy, resolution, patient safety, cost, speed and efficiency, laser scanning appears to be the most suitable to meet all needs, However, they identified that one significant problem is the inability to capture wanted internal structures and intricate surfaces due to line-of-sight limitations. Various sources suggest using reverse engineering software capable of post processing to produce a 'watertight' model by repairing and re-sculpturing void data (Gonzalez-Jorge et al., 2013; Surendran et al., 2009). Another solution is the use of sensors based on infrared structured light projection and computer vision techniques, such as the 3D Systems SENSE (3D Systems, Rock Hill, SC, USA), the Microsoft Kinect^{TM} sensor (Microsoft Corporation, Redmond, WA, USA) or Asus Xtion^{TM} (ASUSTeK COMPUTER INC., Taipei, Taiwan) (Gonzalez-Jorge et al., 2013). These sensors are able to scan the whole field of view at a maximum of 30 frames per second. This means that allow to perform the scanning process at a very fast speed reducing issues such as the noise and distortion due to involuntary movement of the patient (Paterson et al., 2010).

1.2 Additive Manufacturing of orthoses

To date, a number of studies tested the efficacy of Additive Manufacturing, or 3D Printing, for upper extremity immobilisation orthoses. The principal objective of using 3D Printing to manufacture orthoses is to achieve higher levels of compliance amongst patients. Kelly et al. (2015) summarised the reasons for non-adherence to wear a wrist orthosis and identified various examples of how AM has been implemented to produce CMIO.

In this regard, Laser Sintering (LS) is an extended technique to 3D print orthoses, the benefits of which include the relatively freedom of design compared to other AM processes due to the capacity of the powder to support any overhanging geometry, and the fabrication of part batches in the same print. Cortex (Evill, 2013) was one of the first orthoses to appear in the general media. The Hash Cast project (Studio Fathom, 2014), which creates the orthosis structure with the characters of messages sent by the patient's friends, and Splint+ (Carmichael, 2013) varied the density to increase the orthosis rigidity in fracture location. Paterson et al. (2015) also investigated the use of this AM process and compared it with other AM processes, such as Stereolithography (SLA), to improve fit, functionality and aesthetics.

SLA is one of the processes with better surface quality. The upper and side areas of the parts have a good finish. However, the lower areas and those that have been in contact with the support structure show imperfections. This is due to support removal. It can cause damage and discomfort in patients, requiring post-processing and later work to completely remove those supports (Paterson et al., 2015).

Another promising approach is material jetting, as proposed in the project Connex Carpal Skin (Oxman, 2011). In this project, an orthosis that integrates flexible rubber-like materials with rigid materials for custom motion in certain directions was created. Paterson et al. (Paterson et al., 2012a) proposed multi material jetting for wrist immobilisation orthoses in order to integrate different functions in the same part. They developed a range of orthosis prototypes using different processes and multiple materials and found that the heterogeneous orthosis was the most versatile and open to new possibilities.

On the other hand, Fused Filament Fabrication (FFF), also referred to as Fused Deposition Modelling (FDM) is one of the most widespread methods to fabricate 3D printed orthoses due to the rise of desktop 3D Printing (de Bruijn et al., 2010). These types of 3D printers have demonstrated their usefulness for concept generation in the first phases of design (Rodrigo Corbaton et al., 2016). Moreover, in the literature there can be found fully functional applications in fields such tissue engineering (Drescher et al., 2014; He et al., 2014), biomedical devices (Melgoza et al., 2012), scientific equipment (Pearce, 2012), education (Canessa et al., 2013; Fernández-Vicente and Conejero, 2016; Irwin et al., 2014), eyeglasses (Gwamuri et al., 2014), or electronic sensors (Leigh, 2012), to name a few.

The use of this type of systems for orthoses manufacture results in a dramatic reduction of the cost (Cazon et al., 2014). Palousek et al. (2014) tested the use of FDM for the production of wrist orthoses and confirmed its technical viability. To date, although several projects and designs have tested the use of this technology to CMIO manufacture, no controlled studies of its application in real patients have been reported. ActivArmor is a product line of 3D printed orthoses used on bone healing as a substitute of traditional casts (ActivArmor, 2014). Only as pilot prototypes, can be found examples as HealX, an orthosis composed by two parts glued to the patient (Kelly et al., 2015); Open Bionics, a dual-material flexible orthosis (Open Bionics, 2015); Novacast, which generates the orthosis shape without the need of a 3D Scan of the patient's limb (Mediprint, 2016); or Osteoid, which uses a low intensity pulsed ultrasound bone stimulator system to reduce healing time of fractures (Karasahin, 2013) while Exovite integrates an electro stimulator system to accomplish the same objective (Sher, 2015). Other designs by Bush (Royeen, 2015), WASP (2015), Zdravprint (Zdravprint, n.d.) or piuLab (2014) use the 3D printer to create a flat pattern that after heating it is adapted to the user, in a similar way as the traditional process.

1.3 Post-treatment of FFF parts

The FFF process has a higher surface roughness compared to other additive processes such as SLA. Consequently, it was not recommended for applications that require products with a reduced surface roughness (Paterson et al., 2015).

Tumbling and abrasive hand sanding are common finishing techniques, but have some drawbacks such as the impossibility of reaching the interior of small holes. Another possibility is chemical post-treatment, as it does not require excessive human intervention. Havenga et al. (2014) compared different part finishing techniques on ABS FFF parts to improve their appearance, performance, and quality. They suggested that stain and acetone vapour finishing methods provide a more adequate finish.

ABS is a copolymer with a low reticulation degree, including nitrile functionality having weak interaction with polar solvents such as acetone, ester and chloride solvents. This produces significant improvements in mechanical strength and surface quality (Percoco et al., 2012). In Galantucci et al. (2009), the authors presented a chemical treatment of ABS printed parts based on a bath of dimethyl ketone (acetone) for enhancing the surface finish. The chemical bath partly dissolved the surface layers that subsequently become joined. This reduces the roughness and increases the flexural strength of the treated ABS parts (Galantucci et al., 2010).

1.4 Open lattice structures in orthoses design

The use of AM in the fabrication of orthoses enables the easy incorporation of lattice structures into the orthoses design (Paterson, 2013). This includes the use of open lattice structures, such as voronoi patterns that provide lightweight comfort, maintaining its rigidity in order to immobilize the articulation (Gibson and Ashby, 1999). The open lattice structure in orthoses design also preserves a dry orthosis interior by increasing the ventilation and reducing, subsequently, the moisture trapped between skin and orthosis (Paterson, 2013). Moreover, in natural voronoi patterns the cell sizes vary across the surface, such as the ones in cork or leaf structures (Gibson et al., 2010). Its similarity to natural structures increases its aesthetic appeal (Clifford, 2011).

2. Aims and objectives

Although some research has been carried out on digital orthosis design and manufacture methods, few studies have investigated the use of desktop 3D Printing in any systematic way. This study aims to contribute to this growing area of research by exploring a new design workflow using low-cost design and manufacture tools combined with non-manual finishing. It will be applied for static long thumb immobilisation orthoses in particular, used in the treatment of de Quervain tendinitis (Coldham, 2006).

Regarding the surface design, including a voronoi pattern it is aimed to create a comfortable and aesthetically pleasing orthosis for the user without sacrificing any of its functionality. To analyse its viability, a cost comparison was carried out between the proposed workflow and the traditional CMIO manufacture method.

3. Method

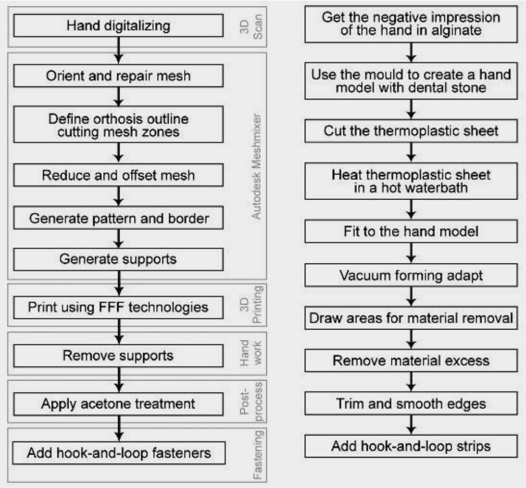

Figure 2. Comparison between CMIO fabrication workflows. Left: Proposed workflow. Right: MCS traditional method

The proposed workflow, as can be seen in Figure 2, may be divided into six main steps: (1) 3D Scan data acquisition; (2) CAD process; (3) 3D Printing; (4) Supports removing; (5) Chemical post-processing; and (6) Fastening. Each stage is described and discussed in the following sections. The person that performs the tasks will be referred as 'operator', as in real practice could be developed by clinical practitioners or orthotics technicians.

3.1 3D Scan data acquisition

In order to deliver a precise CMIO it is necessary to acquire and convert the limb geometry into a digital file. 3D scanning from a healthy volunteer was performed with a 3D Systems SENSE hand-held 3D scanner (3D Systems, Rock Hill, SC, USA). It is specially designed for ease of use and to capture 3D body surface with a spatial accuracy of 1mm and a depth resolution of 0.9mm (3D Systems, 2016). This sensor is based on infrared structured light projection as explained before. With a cost of around €430, the investment required for its acquisition is significantly lower than other 3D scanners, usually above €30,000.

The fingers, hand, and wrist position during digitization should be identical to the position inside the orthosis. Therefore, the hand was scanned in the picking position with contact between the thumb and the index finger without jigging the limb. This position allows palmar pinch without movement, stabilizing the thumb in slight adduction (Chaisson et al., 1997).

The 3D scanning was performed by moving the scanner around the hand and following the indications of the scanning software. The time required for the scan was close to 40 seconds, obtaining an accurately enough geometry for the following steps. However, a method of limb immobilisation would be necessary in the case of patients who suffer from medical conditions, such as Parkinson's disease (Paterson et al., 2010).

It is important to remark that even though holes in the scanned mesh can be repaired, this increases noticeably the time invested in the design process. This may result in a lower quality product, as the area covered will not be identical to the hand surface. Holes are therefore something to avoid. Approximately, 15 minutes were required for the whole process of setting up, scan, and file exportation.

3.2 CAD process

The design stage of the method was developed completely using

Autodesk Meshmixer free software (Autodesk Inc., San Rafael, CA, USA), as it is oriented to amateur users. Furthermore, in a recent software update it has included features to support the creation of custom-fit prosthetics and orthotics devices (Meshmixer, 2016). These characteristics will allow operators with minimal training to follow the sequence of steps.

The scan was imported into Meshmixer where firstly the arm was oriented vertically, and the holes were filled with the *Smooth Fill* mode of the *Inspector* tool. Then, the mesh was cut following the orthosis outline in order to obtain the shape according to clinical indications, in this case for long thumb CMIO (Jacobs et al., 2003). For this step the outline zones were selected using the *Brush select* tool, then the selection was smoothed using *Smooth Boundary* tool, and finally the selected triangles were deleted using the *Discard* tool. It should be noted that a narrow section in the wrist zone was also cut in order to allow the donning and doffing of the orthosis. Some screenshots of these steps can be seen in Figure 3.

Once it was obtained the orthosis shape, a reduction of the mesh density by the *Reduce* tool was necessary as it defines the final pattern design. This reduction was determined by allowing a maximum deviation of 0.1mm from the original mesh, but preserving the boundaries. A 1mm offset of the mesh was made to compensate the thickness of the final structure.

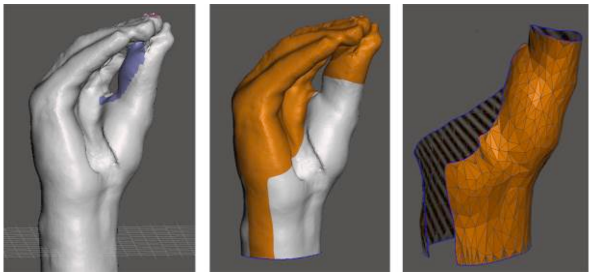

Figure 3. From left to right: Mesh filling / zones to cut / final shape with the reduced mesh

The open lattice structure was generated using the *Dual Edges* option of the *Make Pattern* tool, this generates a voronoi structure by connecting the centers of each triangle (Schmidt and Singh, 2010). Various thicknesses of the structure were printed and tested manually in order to find a suitable value between stiffness and printing time. The selected thickness of the structure was 2 mm.

This operation was repeated using the *Face Group Borders* option of the same tool in order to create the borders. This creates a rounded edge that provides rigidity to the orthosis and a smooth contact for the skin. It also avoids forearm pinching, in the same way as traditional orthoses (Paterson et al., 2012b). By increasing the cell size regularity could be generated a different structure design in order to attain a more isotropic mechanical behaviour (Chen et al., 1999; Gibson and Ashby, 1999). A different design could be obtained too by selecting the *Edges* option in the *Make Pattern* tool, as can be seen in Figure 4. However, it was decided to select the non-uniform voronoi structure design due to the reasons explained above.

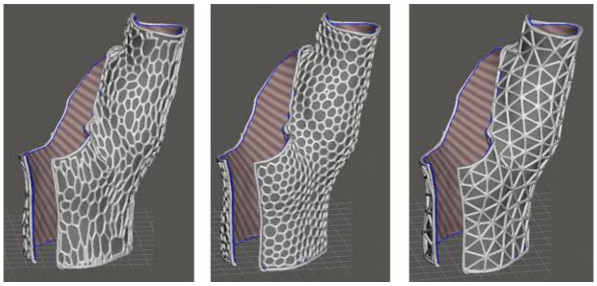

Figure 4. Different structures. From left to right: non-uniform voronoi, regular cell, mesh edges pattern.

In Figure 5 can be seen that *branching tree* supports were generated with the above-mentioned software, Autodesk Meshmixer (Schmidt and Umetani, 2014). As the walls of some cells from the final pattern surpass the 45º angle, the software automatically added supports inside the cells. However, the findings from previous studies about maximum bridge length were taken into account and those supports were removed digitally (Fernandez-Vicente et al., 2015). Then the geometry, orthosis and supports, was exported to the printing software.

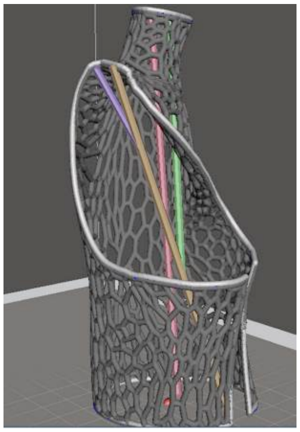

Figure 5. Final geometry ready for fabrication. Structure, border, and supports in different colours for better visualization.

3.3 3D Printing

To convert the CAD model into 3D printer G-code it was used the open-source software package Slic3r version 1.0 (Ranellucci, 2013). The predefined configuration was used as there are a large number of parameters that can be modified. The main slicing parameters used were: 0.2mm layer height, three perimeters, and 100% of infill density. This last parameter, infill density, was not crucial as the perimeters completely filled all of the orthosis structure, due to its narrow thickness. 3 mm black ABS copolymer thermoplastic filament was used due to its capability to be post-treated by acetone, as explained before.

The FFF 3D Printing system chosen was a RepRap-based low cost 3D Printer model, BCN3D+ (BCN3D Technologies, Castelldefels, Spain). The printing temperatures used were 230ºC for the extruder and 110ºC for the printing bed. It took six hours to fabricate the part.

3.4 Support removing

After removing the part from the build plate, it was necessary to remove the supports manually using long nose pliers (Figure 6). The contact surfaces between the part and the supports were filled to reduce its roughness. Due to the optimized supports design, this manual process took only 10 minutes to complete.

Figure 6. Manual removal of supports process.

3.5 Surface treatment

In this study acetone was chosen due to its low cost, very low toxicity and, added to this, very high diffusion. Currently, dipping in acetone, acetone hot vapours or cold vapours could be used for treatment. However, it was observed in preliminary tests that immersion in a bath of lukewarm acetone resulted in an infiltration and entrapment of liquid in the interior of the part. This was due to the small voids that the 3d Printing process leaves between filaments. On the other hand, it becomes difficult to control the chemical reaction using hot vapours because of the high speed of the treatment, as it leads to uneven smoothness (Garg et al., 2015). Therefore, the printed model was enclosed in an environment with a high concentration of acetone vapour at ambient temperature (22ºC), following the method described by Garg el al. (2015).

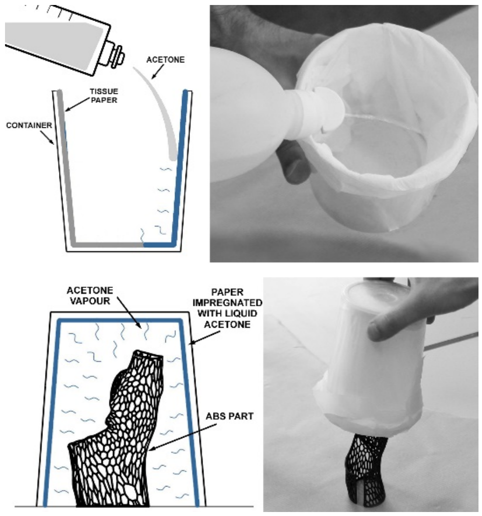

Figure 7. Illustration and images of the two steps of the acetone treatment.

To create the enclosed environment, a 100x150 mm cylindrical container with one open side was used. The container was lined with tissue paper and it was impregnated with 99.6% pure liquid acetone (MPL S.R.L, 2016). The container was then placed upside down above the part on a planar surface as can be seen in Figure 7. This, therefore, creates an airtight environment in which liquid acetone gets vaporized and fills the container due to its volatility at ambient temperature.

Different exposure times were tested, obtaining enough layer melting in a one-hour exposure period without any unwanted part deformation, but with edges and sharp corners rounded off, as observed by Garg et al. (2015).

After exposure, the container was removed in order to allow evaporation of the acetone from the part surface for two hours prior to the final fastening step.

3.6 Fastening

The hook-and-loop fastening method was selected in order to provide a way to easily don and doff the orthosis. Two circles were added to the orthosis on each side of the opened section of the structure. Then a short hook-and-loop strap was adhered to the circles to finalize the process, as can be seen in Figure 8. It should be noted that a longer strap could be used to encircle the wrist in order to increase the fastening strength.

Figure 8. Hook-and-loop fastening

4. Cost analysis

An initial cost analysis was performed in order to confirm the economic viability of the new method proposal. This analysis was based on a real scenario that would take place in a company. All the materials and equipment needed were taken into account, based on the cost calculation method reported by Jumani (2013).

Table 1 Cost calculations using the proposed workflow

Production volume per year	**Pv** = R x Hy	**660 parts**
Number of parts/build	N_p	3 parts
Build time/batch	T	21 hours
Production rate per hour	R = N_p/T	0.1428 parts
Working days/year	W_d	220 days
Operation hours/year	H_y = (W_d x T)	4620 hours
Machine cost per year	**Mc** = D + M	**€300**
Machine equipment cost	E	€1000
Depreciation cost/year	D = E/5	€200
Maintenance cost/year	M = E x 0.10	€100
Material cost per year	**Mat** = (M_f + M_m + M_s) x Pv	€3630
Material cost per kg	M_{cm}	€30[1]
Model material cost/part	M_m = 0.120 kg x M_{cm}	€4
Support material cost/part	M_s = 0.030 kg x M_{cm}	€1

Fastening/part	M_f	€1[2]
Production overheads per year	**Ovr** = E_{ph} x H_y	**€230**
3D printer energy consumption	E_{3d}	0.27 Kw/h [3]
Energy cost	E_c	0.184 €/Kwh [4]
Energy cost/hour	$E_{ph} = E_{3d}$ x E_c	€ 0.0497
Software and Hardware cost per year	**Spy** = Ta + Hd	**€327**
Hardware (Computer + 3D Scanner)	Hc = €700 + €435	€1135[1]
Software purchase	Sft	€0
Tools and ancillary	Ta	€100
Hardware depreciation	Hd = Hc/ 5 years	€227
Labour cost per year	**Lbr =** O_{cp} x Pv	**€6050**
3D scanning	S_t	15 minutes
Design time per part	D_{tp}	20 minutes
Post-processing time/part	M_{tp}	15 minutes
Operator total hours	$O_{th} = S_t + D_{tp} + M_{tp}$	50 minutes
Operator cost/hour	O_{ch}	€11
Operator cost/part	$O_{cp} = O_{ch}$ x O_{th}	€9.17
Total cost per year	Tc=Mc+Mat+Ovr+Spy+Lbr	€10536
COST PER PART	Tcpp = Tc / Pv	**€15.96**

[1] Cost quotation from 3D Printing Services S.L.U., Spain, 2015

[2] Cost quotation from EMO – especialidades médico ortopédicas, SL, Spain, 2015

[3] Wittbrodt, 2013

[4] Minetur Spain, 2016

The cost breakdown and total cost of the new proposed approach is shown in Table 1. It is calculated for a single printer and operator. The printing volume of the machine, a BCN3D+, can accommodate a maximum of three parts. A build time of 21 hours per batch was calculated by the software. Due to the characteristics of the process, it was assumed that the 3D printer could keep printing beyond the operator's working hours. Taking into consideration the values of Jumani (2013), the machine was assumed to work for 220 days per year, one run per day. This gives a total of 660 parts per year.

Machine cost was calculated using the depreciation cost of the machine per year and a 10% maintenance cost. The depreciation time for machine was assumed to be five years. Material cost was calculated by weighing the material consumed in the orthosis part and the support structure. The weight of total material consumed was then multiplied by associated cost per gram of the material. The material consumed for the orthosis fabrication was 120 grams and 30 grams for the support structure.

The energy cost of the fabrication was calculated using the average 3D printer consumption values from Wittbrodt (2013) and the estimated cost of energy for Spain (Minetur Spain, 2016). This gives an estimated €6930 per year for production overheads. A uniform cost of €327 per year was included as hardware and software expenses.

In regards to the labour cost, it was calculated by the time required of the operator per part. For one 3D printed part was estimated 15 minutes for limb scanning, 20 minutes of design and 3D printer setting up, and 15 minutes for post-processing of the part. These times could be reduced with the increase of operator experience, but it was decided to study the cost in the worst case.

It should be noted that this is a very time-dependent selection of processes and materials; access and affordability of equipment and materials are changing rapidly so it is anticipated that these costing will reduce with time.

Table 2 Cost calculations using traditional MCS fabrication process

Production volume per year	**Pv = R x Wy**	**880 parts**
Number of parts/build	N_p	1 part
Build time/part	T	2 hours
Production rate per hour	$R = N_p/T$	0.5 parts
Working hours/day	W_h	8 hours
Working days/year	W_d	220 days
Working hours/year	$W_y = (W_d$ x $W_h)$	1760 hours
Machine cost per year	**Mc** = D + M	**€450**
Vacuum forming machine	E	€ 1500[1]
Depreciation cost/year	D = E/5	€300
Maintenance cost/year	M = E x 0.10	€150
Material cost per year	**Mat** = $(M_{cm} + M_{cs})$ x Pv	**€ 5210**
Mould material cost/part (alginate, plaster)	M_{cm}	€2[1]
Orthosis material cost/part (Thermoplastic sheets, “hook-and-loop” fastener)	M_{cs}	€3.92[1]
Production overheads per year	**Ovr**	**€324**
Vacuum/heating consumption	Vcs	4 Kw/h
Vacuum time/part	Vt	30 minutes
Energy cost	Ec	0.184 €/Kwh [2]
Energy cost/part	Ecs = Vcs x Vt x Ec	€0.368
Labour cost per year	**Lbr =** O_{cp} x Pv	**€ 19,360**
Operator cost/hour	O_{ch}	€ 11
Operator cost/part	$O_{cp} = O_{ch}$ x T	€ 22
Total cost per year	Tc=Mc+Mat+Ovr +Lbr	€ 25343
COST PER PART	Tcpp = Tc / Pv	**€ 28.8**

[1] Cost quotation from EMO – especialidades médico ortopédicas, SL, Spain, 2015

[2] Minetur Spain, 2016

Taking into consideration the cost analysis performed for the new approach, a thorough cost benefit analysis against current splinting practices was then required. In Table 2 the analysis done for the proposed workflow was repeated for the MCS process, as illustrated in Figure 2, guided by an orthotic and prosthetic specialist.

5. Results and discussion

Comparing the proposed workflow of digital fabrication and the traditional MCS process in Figure 2, a great reduction of manual steps can be observed. This reduces the dependency on the operator skills and abilities. In the digital fabrication method, the clinical practitioner only needs to scan the patient's hand, while the rest of the process needs to be performed by an orthotics technician (Strömshed, 2016). However, under this workflow all of the processes can also be used in small clinics by the practitioner itself.

The results concerning the 3D scanning process show that low cost sensors could be accurate enough for this process, which enables a wider range of practitioners to embrace the digital fabrication method.

In regards to the design process, Autodesk Meshmixer has demonstrated its efficiency as all the design steps could be performed on the same free software platform. Furthermore, the open lattice structures of the free software provided aesthetic lightweight constructions and the possibility to be printed with only a few supports.

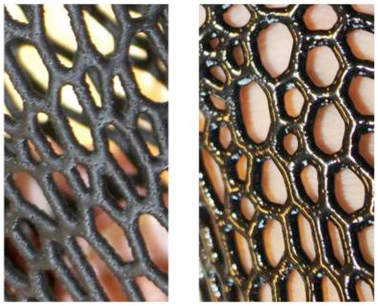

Figure 9. Orthosis surface before (left) and after (right) acetone post-treatment

In terms of the post-treatment process, an increase in the part ductility was observed for up to two hours after treatment. After the drying time, it was observed that the acetone post-treatment provided a surface with no visible layers and an enhancement of the part rigidity. The result was a shiny and smooth surface as can be observed in Figure 9.

For the fastening a standard solution was selected that simplifies this step. However, it has been observed that this feature could be included in the 3D printed part in order to reduce the fastening manual work.

The cost analysis of traditional MCS process shows an estimation of €15.95 for each part under the proposed workflow, and €28.8 for the traditional MCS process. This result suggests an approximated 55.4% cost reduction between the proposed workflow of the digital fabrication method and the traditional MCS process.

Figure 10. Final orthosis fitted to the user

6. Conclusions and further research

Several conclusions can be drawn from this study and must be highlighted. Despite its exploratory nature, this study offers some insight into the potential benefits of a digital design and manufacture process identified previously for other types of orthoses (Eggbeer et al., 2012; Palousek et al., 2014; Paterson et al., 2015; Strömshed, 2016). This study has presented a novel workflow using the digital fabrication methodology that validates an efficient and effective low cost approach using low-cost 3D scanning, free CAD software and desktop FFF 3D Printing. The use of FFF technology was the key to reduce the costs of 3D printed orthosis. The accessibility of this type of machines makes the digital fabrication method be easier to be adopted by operators.

Under the digital fabrication method, the operator needs to perform completely different tasks compared to the traditional method. These new tasks give rise to the need of specific 3D Printing education, as identified by Campbell et al. (2012). In the MCS process the result has a lot of dependency on the operator ability. A great reduction of this dependency can be observed when using the workflow proposed. Further development of the fastening method could improve the process.

This feasibility study did not capture the intent of the clinical practitioner design. The integration of this information in the workflow should be evaluated in further studies. Furthermore, it would be interesting to assess the new capabilities and education required to help the clinicians and operators to embrace these technologies and method.

The results of the cost analysis reveal a great reduction in cost per part and labour costs comparing with current practices, more than 50%, and corroborates the ideas of Paterson et al. (2012b). As they pointed out: '*The materials costs incurred in current practice are minimal and by far the greater proportion of cost is attributed to time and salary costs for the professionals involved*'. It opens the door to a scalability of the process, in which the clinical practitioner could scan the patient's limb, design the orthosis, and send the order to a queue for manufacture, using services such as Voodoo manufacturing (Voodoo Manufacturing, n.d.).

These data must be interpreted with caution because the costs have been calculated with quotations from Spain, and these would change significantly if the method is applied in other countries.

However, in order for this study to become a clinically feasible approach, a material suitability analysis must be performed and a perception and usability study on real patients should be conducted. Although that is not within the focus of this investigation, further investigation and experimentation into the mechanical behaviour and FEA is strongly recommended to address issues regarding structural integrity as evaluated in previous studies (Palousek et al., 2014). More research using controlled trials is required to determine the efficacy of the method for the recovery process.

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