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Stereolithography Technique for Fabrication of Custom Foot Orthoses: A Cost Benefit Analysis

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Abstract: In medical field applications of rapid manufacturing techniques for production of personalised medical aids, prosthesis and orthoses are increasing at fast rate. Stereolithography (SLA) is a rapid manufacturing technique that directly fabricates three dimensional (3D) parts from computer aided design (CAD) based information. This includes the advantages of technique to fabricate the complex geometrical parts with increased accuracy and consistency. This paper presents a new approach whereby a stereolithography technique is used for production of personalised foot orthoses. A CAD based 3D foot orthosis model was used to fabricate the orthosis using stereolithography technique. Furthermore, a cost and benefit analysis was undertaken to evaluate the feasibility of the technique for the production of custom foot orthoses on a commercial scale. The estimated fabrication cost of foot orthoses per pair through stereolithography technique is lower than the fabrication cost per pair through traditional techniques. However, at present the initial capital cost of machines and materials is still higher when compared to traditional materials and manufacturing techniques.

Keywords: Rapid manufacturing, stereolithography technique, foot orthoses, cost modelling.

1. INTRODUCTION

Foot orthoses are shoe inserts used for correcting abnormal and irregular biomechanics of the foot (Hunter *et al.,* 1995; Redford *et al.,* 1995). The purpose of personalised foot orthosis is to improve the foot function by redistributing the forces from the body in a controlled manner to protect and give relief to patients. The need for foot orthoses arises due to biomechanical foot disorders, congenital defects, sports injuries, diabetes, and rheumatoid arthritis diseases (Obrovac *et al*., 2005). The primary function of the foot orthoses is to reduce and redistribute the weight bearing stress, control alignment and functions of the foot in order to treat and prevent injury causing forces on foot bones, joints, tendons and ligaments. Foot orthoses are applied to improve the joint functions of the foot and redistribute the body pressure to give relief in the pain and prevent further deformation in foot shape and to promote corrective gait. **Figure 1** shows the foot orthoses.

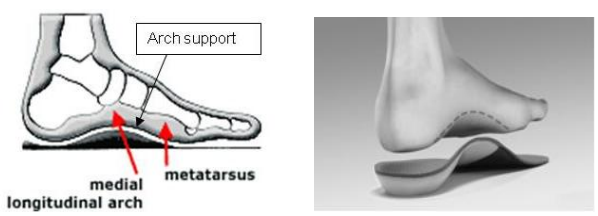

Fig. 1: Schematic of foot orthosis and fabricated orthosis

1.1 Fabrication of Foot Orthoses

Fabrication of custom foot orthoses involves three main steps (i) Foot geometry capture, (ii) orthoses design, and (iii) orthoses fabrication. The traditional fabrication process begins with capturing the foot geometry and measurements of foot using plaster of Paris. After foot impression captured; a positive mould of the foot is developed. The positive mould is then modified manually by adding and dressing with additional materials in order to incorporate the required design features such as filling gaps, adding wedging angles and other orthoses design features (Pratt, 1995). The orthosis is then created around the corrected and developed mould by draping a heated plastic sheet over it or using a vacuum pressing process (Doxey, 1985). Finally the fabricated orthosis is fitted with the patient (Lusardi *et al.,* 2000).

In 1960s computer based orthoses fabrication was introduced with the applications of stereophotography and numerically controlled (NC) milling machines. Currently in custom orthoses production process the computer aided design and computer aided manufacturing (CAD/CAM) techniques are applied (Lusardi, *et al.,* 2000). The CAD/CAM techniques for production process of custom foot orthoses are based on digital foot geometry capturing process (Davis, 1993; Smith *et, al.,* 2001; Grumbine, 1993; Staats, *et al.,* 1989), CAD orthoses design and automated numerically controlled (CNC) machine for milling the orthoses (Davis, 1993). However, the personalised foot orthoses require individualised anatomical design features in the prescribed orthoses which have shown difficulties in using CAD/CAM

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techniques; resulting in product variety restrictions to specific design features only. Besides, experts in the field have shown the problems of lake of training in using CAD/CAM techniques in orthoses manufacturing industries (Otto, 2008).

Rapid manufacturing techniques offer advantages in comparison with conventional manufacturing techniques in production of personalised products. The techniques can build the custom made products with greater design freedom, ability of creating undercuts in products with accuracy and consistency. Some of the successful examples of production of personalised products including in-the-ear hearing aids and dental braces are well established in the literature (Tognola *et al*., 2003; Gibson *et al*, 2010; Jumani *et al*., 2013). The fabrication of personalised in-the-ear hearing aids by Phonak and Siemens, production of personalised dental braces by Align Technology, USA and personalised dental bridges and crowns by Sirona Dental Systems GMBH, Germany (Strub *et al*., 2006) have shown key benefit in terms of improved fit product and increased reliability. Having the advantages and benefits of rapid manufacturing techniques, stereolithography technique is used in the fabrication process for fabrication of personalised foot orthoses.

2. STEREOLITHOGRAPHY TECHNIQUE

Stereolithography (SLA) is considered as the founding process in rapid prototyping patented in 1984. The first commercial implementation of system was introduced by 3D systems Inc, USA in 1986 (Pham and Dimov, 2001; Chua *et al*., 2003; Hopkinson *et al*, 2006; Wohlers, 2010). **Figure 2** represents the schematic process of SLA technique. The technique gradually builds up a three-dimensional part from liquid photosensitive monomer (C) contained in vat (B); layer by layer (Noorani, 2006). Computer aided design (CAD) is used to drive the laser beam (D) to strike at the selected spots of surface of liquid polymer that turns it into solid state forming a solid layer (Kruth *et al.*, 1998). The part is built on a platform and once the first layer is adhered, the platform is then lowered and a fresh layer of liquid monomer is swept over the previous layer. The CAD data guided laser beam again strikes on newly deposited liquid polymer forming another solid layer over the previous layer. The process of adding the material is continued until the final product is fabricated (Yan *et al*, 1996; Rosochowski, and Matuszak, 2000).

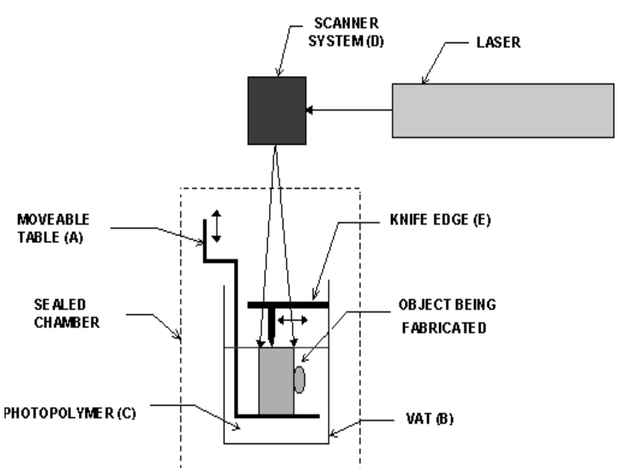


Fig. 2: Schematic of Stereolithography technique

3. METHODOLOGY

3.1 Orthosis model measurements and material

The orthosis model was designed through CAD technique the designed model was used to build the foot orthosis on stereolithography system. The orthosis designed model was used from the work of Pallari (Pallari, 2008; Jumani et al., 2013) for mass customisation of foot orthoses for rheumatoid arthritis. Table 1 presents measurements of fabricated orthosis, fabrication time and material consumed.

Table 1: Measurements of the orthosis model

Dimension (mm)	Height 50.82, Width 179.52, Depth 79.81
Build time	6 hours
Material	Accura 55 resin
Model material	60 grams
Support material	30 grams

3.2 Production of the orthosis model

An *ipro* 8000 stereolithography (SLA) system by 3D systems Inc, USA was utilized for production of orthosis model. The system uses 3DPrint^{TM} machine control software which converted the CAD design into an .stl file format which is defecto file for rapid manufacturing systems. The system has build size of 650 (length), 350 (width) and 300 mm (height) (25.6 × 13.7 × 11.8 inch). The system has layer thickness of 0.002 inch (.05 mm) and 0.006 inch (1.5 mm).

4. RESULTS AND DISCUSSIONS

4.1 Cost modelling in rapid manufacturing

Fabrication costs in rapid manufacturing techniques broadly fall into four main categories; production and administrative overheads, machine purchase and operation, labour and material costs (Hopkinson and Dickens, 2003; Ruffo *et al.*, 2006, Gibson *et al*., 2010; Eleonora *et al*., 2010). In this work for cost modelling an important assumption was made regarding the productivity of the machine which was calculated on the basis of (i) build time per run and (ii) estimated total runs per year operated on the machine. The useful life span of the machine was assumed to be for five years as both the worst case and most realistic.

4.2 Cost and lead-time modelling

An initial model was developed for a facility with one machine and one technician for modelling the cost and lead-time. In the model it was assumed that one machine will be operated for 2 runs of 7 hours of fabrication time per run for 220 working days per year. The total volume of production per year was calculated from the model based on total runs operated per year. In an *ipro* 8000 SLA system 10 parts can be fitted per build. A build time of 7 hours for fabrication of 10 parts was given by 3DPrint™ software used for operation of machine. The machine was estimated to operate for 14 hours of time for 220 days per year that makes a total of 3080 hours per year for machine operation time.

The estimated total cost of £439560 for fabrication of 2200 pairs per year at the rate of £199.8 per pair is shown in Table 2. The cost of machine per year was calculated by depreciation cost of machine. The depreciation cost was calculated by 10% of the total cost of machine as maintenance cost. This makes an estimated total of £210000 as the machine cost per year. The cost calculation for one pair of orthoses was calculated by weighing the material consumed in model part and material consumed in support structure. The weight of total material consumed is then multiplied with associated cost of material. The material consumed in orthosis model was 60 grams and material consumed in support structure was 30 grams. The total material consumed including support material was 90 grams per part which gives an estimated material cost of £25.2 per part or £50.4 per pair.

For calculation of production overhead per year; a floor space cost at the rate of £120 per meter^2 was included. For the operation of facility an energy cost of £1.5 per hour was added with production overhead (Ruffo *et al*., 2006; Jumani *et al*., 2013). The total production overhead per year is estimated for £34200 per year. The cost of £2320 was also added as administrative cost per year. For labour time per run was calculated by required machine operation time per run. The operation of one run on ipro SLA 8000 involve two hours of labour of operator comprised of one hour for starting and feeding of the material and one hour for removing the fabricated product and finishing of the product. However, in the initial model with one machine and one technician, the cost of £39980 is estimated as per annum salary of the operator (Jumani *et al*, 2013).

Table 2: Cost calculations of orthoses per pair using *ipro* 8000 SLA system

Cost calculations for *ipro* system in SLA technique		
Production volume per year		
Number of parts/build	N	10
Build time/run	T	7 hours
Production rate/hour	R = N/T	1.42
Operation hours/year	HY	3080
Production volume/year	V = R x HY	4400 parts
Total pairs/year		2200 pairs
Machine cost per year		
Machine & ancillary equipment	E	£700000*
Depreciation cost/year	D = E/5	£140000
Machine maintenance/year	M	£70000
Total machine cost/year	MC = D+M	£210000
Material cost per pair		
Model material/part	60 grams @£0.28/grams	£16.8
Support material/part	30 grams @£0.28/grams	£8.4
Material cost/kg		£285*
Material cost/part		£25.2
Cost/pair		£50.4
Production overhead per year		
Building area	246.5/m^2* @ £120/m^2 per annum**	£29580
Energy consumption by machine	@£1.5/hour*** x 3080machine operation hours/year	£4620
Total cost/year		£34200
Administrative overhead per year		
Hardware		£2175*
Software purchase		£2175*
Consumables cost/year		£1450
Hardware depreciation cost/year		£435**
Software depreciation cost/year		£435**
Total cost/year		£2320
Labour cost per year (annual salary of operator)		£39980
Total cost	2200 pairs/year	£439560
Cost/pair	£439560/2200 pairs	£199.8

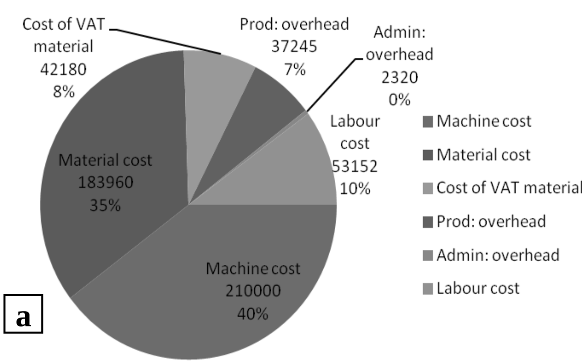
***Cost quotation from system supplier, 3D Systems Europe Ltd, UK, 2010, **UK trade and information enquiry services (www.ukti.gov.uk, 2010) and ***Ruffo *et al*, 2006.**

4.3 Sensitivity analysis of the cost model Scenario 1-Increase in machine working hours per year

The machine working hours per year were assumed to increase from 220 days per year to 365 working days per year. The assumed model based on 356 days per year gives the estimated production of 3650 pairs per year at the rate of £144.89 per pair. In the enhanced model of 356 days per year an operator was included who works for 4 hours of time per day for 145 working days per year. The different cost categories in the assumed 365 days per year are shown in the Table 3. The enhanced model of 365 working days per year shows the substantial decrease of 28% in per pair cost; as compared to initial model of 220 days working hours per year. The detailed cost categories in the both models are shown in the Figure 3. The cost of material is comprised of 48% and 40%, as the direct cost in the models. Machine cost accounts for 48% and 40%, production and administrative overheads 8% and 7% and labour cost accounts for 9% and 10% of the total cost which makes 65% and 57% respectively of total cost as indirect cost in the models

Table 3: Total cost per pair in the initial operating model based on 365 working days per year

Total cost per pair using *ipro* 8000 SLA system		
Machine cost/year		£210000
Cost of full VAT of material	@£285/litre for 148 litres	£42180
Material cost for 3650 pairs	@ £50.4/pair	£183960
Production overhead/year		£37245
Administrative overhead/year		£2320
Labour cost/year	Full time + part time operator	£53152
Total cost	3650 pairs per year	£528857
Cost/ pair	£528857/3650 pairs	£144.89



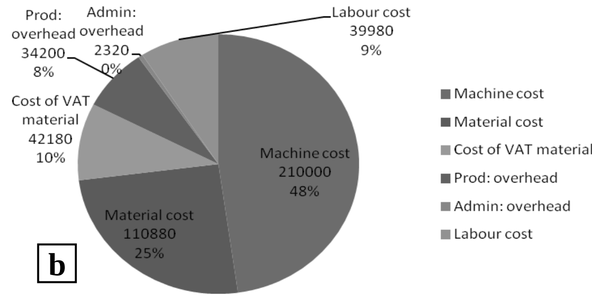


Fig. 3: Cost categories in operating model based on (a) 220 and (b) 365 working days per year.

Scenario 2-Development of "low cost" operating model

For the optimum results a low cost working model was developed. The model was estimated to work for 2 runs of 7 hours of fabrication time per day for 365 days per year. In the low cost developed model 5 operators were included working with 6 machines for getting optimum balance between machines operation hours and labour hours of operators per year. As in the low cost developed model one machine was assumed to work for 2 runs of 7 hours of build time per day for 365 days per year; the model gives a total of 5110 working hours per year for each machine and a total of 30660 machine hours per year for 6 machines; approximately 41% operation of machine time per year. The total estimated working hours of machines and total estimated working hours of operators in low cost operating model are shown in Table 4.

Table 4: Machine labour hours/year and operators labour hour/year in "low cost" model

No: of machines	Required machine operation hrs/year	No: of technicians	No: of labour hrs/year
1	1460	1	1760
2	2920	2	3520
3	4380	3	5280
4	5840	4	7040
5	7300	5	8800
6	8760	6	10560
7	10220	7	12320
8	11680	8	14080
9	13140	9	15840
10	14600	10	17600

As the ipro SLA 800 system requires 2 hours of labour time of the operator for operation of one run on the system. This requires a total of 1460 labour hours of the operator per year for running of 730 runs on each machine per year. The operation of six machines requires an estimated total of 8760 labour hours per year. The different cost elements are shown in the **Table 5** for low cost operating model based on 5 operators running with 6 machines per year. In the low cost developed model an additional floor space of 20 m^2 at the rate of £120/m^{2} is estimated for each machine and the necessary equipment. The energy cost is also added of £1.5 per hour for each additional machine. In the low cost developed model the cost of purchase of six machines and operational cost are also included. The cost of labour of operators was estimated for £199900 per year at the rate of £22.71 per hour. The total cost calculations from the model and estimated production of total volume of orthoses; the model gives estimated total of £2918230 for production of 21900 pairs per year at the rate of £133.25 per pair. This has reduced approximately 33% in the total cost per pair in comparison to initial developed cost model.

Table 5: Total estimated fabrication cost per pair in "best case" cost model

"Low cost" operating model for 5 technicians working with 6 machines	
Machine cost/year for 6 machines	£1260000
Material cost for 21900 pairs @£50.4/pair	£1103760
Production overhead /year for 6 machines	£87570
Admin: overhead/year for 6 machines	£13920
Labour cost for 5 technicians	£199900
Total cost for 21900 pairs	£2918230
Cost/pair £2918230/21900 pairs/year	£133.25

The different costs categories in the "low cost" cost model are shown in **Figure 4**. Material cost accounts for 47% of the total cost as the direct cost in the model. Machine cost accounts for 43%, production and administrative overheads 3% and labour cost accounts for 7%, which makes 53% of the total cost as the indirect cost in the model (Jumani *et al*, 2013).

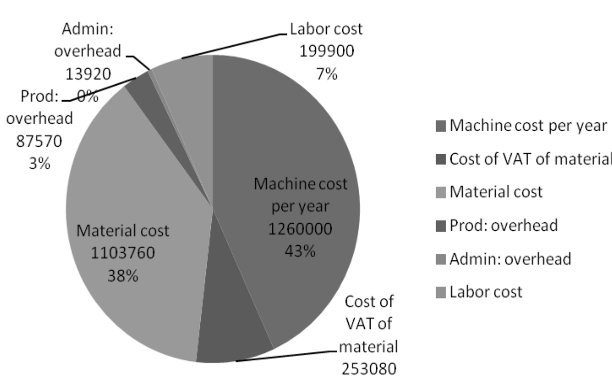


Fig. 4: Cost categories in "best case" cost model.

Custom foot orthoses can be fabricated through stereolithography technique. Figure 6 shows that material and machine cost constitute approximately 90% of the total cost in the best case developed model. The model gives the cost of £133.25 per pair using stereolithography technique in comparison to present cost of custom foot orthoses in the market, where one pair of orthoses costs approximately from £150 to £200 (Doctorsorthotics, 2013). The lead-time in procurement of orthoses is another important challenge for the orthoses manufacturers and suppliers. The lead-time ranges from one week to two weeks depending on the supplier. The stereolithography technique using ipro 800 SLA system have shown advantages in comparison to traditional production techniques in terms of lower production cost and minimum lead-time. The technique removes the need of traditional steps of making positive mould and manual designing of the foot orthoses. The orthoses fabricated through stereolithography technique are resulting in more accurate, better fitting with improved quality final product.

5 CONCLUSION

Rapid manufacturing techniques are progressing at rapid rate from which stereolithography is well established and commonly used technique by many industries. However, in rapid manufacturing techniques the cost of the material and machines are still higher at present times. The applications of rapid manufacturing techniques specifically stereolithography is growing quickly in different manufacturing sectors worldwide. This will results in introduction of faster systems and low cost material will contribute in low cost methods for production of personalised devices and aids in the orthotics and prosthetic industry

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