FUSED DEPOSITION MODELLING TECHNIQUE (FDM) FOR FABRICATION OF CUSTOM-MADE FOOT ORTHOSES: A COST AND BENEFIT ANALYSIS

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ABSTRACT. *Rapid manufacturing (RM) techniques in medical sector are gaining more importance for fabrication of custom-made implants, rehabilitation aids and devices. The main advantages of the techniques are ease in fabrication of individual complex geometrical parts with increased accuracy, conformity and overall improved quality. Having the advantages of rapid manufacturing further research is required to investigate the feasibility of commercial scale applications of these techniques. In this paper, commercial aspects of rapid manufacturing technique called fused deposition modelling technique for fabrication of custom-made foot orthoses is analysed and evaluated. Based on number of assumptions for the costs involved using fused deposition modelling (FDM) technique, a cost and benefit analysis has been carried out. The fabrication costs were analysed and evaluated. The purpose of this research was to create low-cost high quality custom-made foot orthoses at commercial scale using FDM rapid manufacturing technique. However; currently the cost of using FDM technique for fabrication of custom-foot orthoses is exceeding the fabrication cost through traditional fabrication techniques.*

Keywords: Rapid Manufacturing, Foot Orthoses, Fused Deposition Modelling, Cost Modelling.

1. INTRODUCTION

Rapid manufacturing (RM) is a family of techniques used for direct fabrication of parts from 3D computer aided design (CAD) information without the need of moulding, tooling and casting. In rapid manufacturing techniques the 3D parts are fabricated layer by layer based on additive fabrication process guided through (CAD) information using different techniques including selective laser sintering (SLS), stereolithography (SLA), fused deposition modelling (FDM) and 3D printing (3DP) [1]. These techniques are widely used in various manufacturing sectors such as automotive, aerospace, electronics, computers and medical. There are number of successful examples of applications of rapid manufacturing techniques in medical sector for fabrication of custom-made devices, aids and implants. The RM techniques have shown main advantages of fabricating the individualised geometrical parts, devices and products with increased part accuracy, improved fit and quality in the final product. Some of the examples are in-the-ear hearing aid, lower limb prosthesis, ear prosthesis, dental devices and dental implants [2, 3 and 4].

Having the above mentioned advantages and benefits of the techniques, the commercial scale applications of rapid manufacturing techniques in medical sector have recently appeared for the provision of custom-made medical devices and products. Currently there are two commercial examples successfully producing custom-made devices. One of which is Align Technologies Inc; USA offering custom-made dental braces [18]. Align Technologies are fabricating the series of dental braces used for alignment of teeth. The teeth alignment is achieved through using the series of sequenced dental braces until required alignment is achieved. The dental braces improve cosmetic dental appearance. Invisalign USA, use stereo lithography (SLA) in fabrication of custom-made dental braces. The second commercial example is fabrication of custom-made in-the-ear hearing aid devices by Siemens and Phonak [19, 20]. Siemens is using selective laser sintering (SLS) and stereolithography apparatus (SLA) and Phonak are using selective laser sintering technique for fabrication of custom-made in-the-ear hearing aids. Figure 1 shows (a) in-the-ear hearing aid and (b) dental prosthesis.

(a)

(b)

Fig: 1 (a) in-the-ear hearing aid and (b) dental prosthesis

1.1 Fabrication foot orthoses.

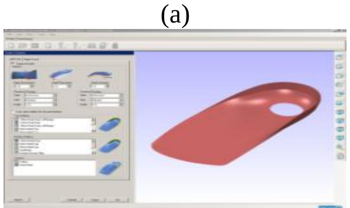
Foot orthoses are medical devices prescribed in clinical practice for treatment of foot problem, biomechanical disorder and foot diseases such as rheumatoid arthritis and diabetes. Figure 2 shows (a) foot orthosis and orthosis fitting in the shoe. Fabrication of custom foot orthoses has long history of handcraft art to fabricate supportive and comfortable orthoses for preventing disability, improving foot function and providing comfort [5 and 6]. The traditional fabrication process is based on trial and error involving manual labour and time consuming process. The traditional fabrication involves three main stages (i) foot impression capturing, (ii) correction/rectification of mould and (iii) final fabrication of orthoses. The process starts by taking physical measurements of the foot using plaster of Paris or foam impression box. After capturing the foot impression, a positive mould of the foot impression is developed and then necessary controls and orthoses design features such as wedging angles, heel cupping are incorporated. The orthosis is then created around the positive mould. Recent

(a)

(b)

Fig: 2 (a) foot orthosis and (b) orthosis fitting in shoe

(a)



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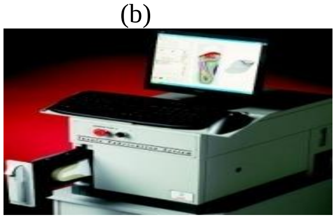

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Fig: 3 CAD/CAM orthoses fabrication process

developments in computer technologies such as computer-aided-design (CAD) and computer-aided-manufacturing (CAM) has replaced most of the traditional methods for foot orthoses manufacturing [7]. However, these techniques have limitations in fabrication of geometrical complex structures and orthoses design features which limits the product range. Figure 3 represents the CAD/CAM orthoses fabrication process which starts with (a) foot geometry capture through digital foot geometry capture device, (b) modification and correction through orthoses design software and (c) final fabrication of orthoses through CAD/CAM milling machine where a block of EVA is milled according to required design features in the final orthosis.

This paper presents an approach whereby the fused deposition modelling (FDM) technique is integrated in design and fabrication process to develop an automate design and manufacturing system for fabrication of custom-made foot orthoses. The purpose of this paper is to investigate the application of FDM techniques and evaluation of commercial scale feasibility of FDM technique for fabrication of custom foot orthoses.

2 Review of previous research work

Different research studies have shown the advantages of rapid manufacturing techniques, computer aided design (CAD) combined with medical scanning technologies for fabrication of custom-made medical products. The combination of these techniques has shortened the fabrication process and has reduced the labour work in various stages of manufacturing process. Freeman and Wontrocik [8] have conducted a cost and benefit analysis using stereolithography apparatus (SLA) for manufacture of custom-made prosthetic test sockets. The SLA technique has removed the traditional casting process for positive mould making in socket manufacturing and the sockets were designed through CAD system and fabricated directly from the designed information. The study demonstrated that the technique can built sockets with varying wall thickness with improved fitting and accuracy. In another study, Tan et al. [9] investigated viability of using fused deposition modelling (FDM) technique for manufacture of prosthetic socket. Herbert et al. [10] investigated the applications of 3D printing technique for fabrication of prosthetic socket. This technique also eliminates the casting process of mould making for socket and fabricates the socket directly from CAD design by using 3-D printing technique. Faustini et al. [11] at University of Austin Texas demonstrated the fabrication of prosthetic socket by using selective laser sintering (SLS) technique. In another study Colombo et al. [12] have used stereolithography technique in fabrication of custom-made below-knee prosthesis. There investigation have shown improved part accuracy and quality in the RM based fabricated below-knee prosthesis.

3. Fused deposition modelling (FDM) technique

Fused deposition modelling technique is a promising rapid manufacturing technique which fabricates the 3D parts from CAD data by deposition of material layer by layer. The technique uses variety of materials such as ABS plastics, elastomer and investment casting wax. ABS plastic offers good strength and has increased the capabilities of the FDM technique further in terms of part strength and quality. The main advantage of this technique is seamless integration with CAD techniques and less post production processing for fabricated parts. The technique was first commercialised by Stratasys Inc: [21] and patented in 1992. Figure 4 shows the schematic view of FDM technique. In this technique a computer controlled heated nozzle (B) deposits the thermoplastic polymer on the build platform supplied from plastic filament coil (A). The temperature controlled nozzle deposits the material in X, Y and Z orientation (C) in order to create three dimensional parts. The build platform (D) is maintained at lower temperature in order to make the molten thermoplastic quickly solidify. After the platform lowers, the extrusion nozzle deposits another layer upon the previous layer and this process is repeated until the completion of the final product.

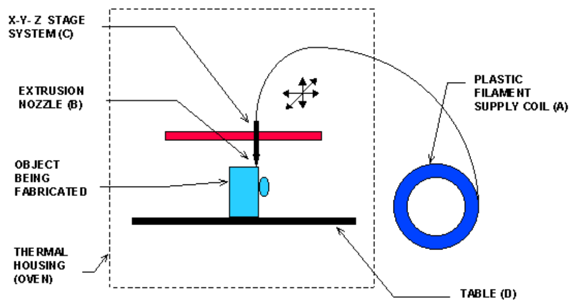
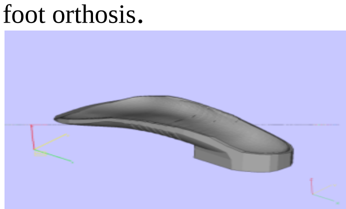


Fig: 4 schematic view of FDM technique

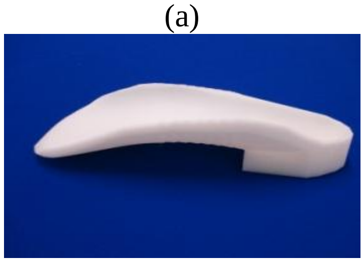
4. METHODOLOGY

4.1 Fabrication of orthosis model

Dimension BST 768 (FDM) system was used for fabrication of orthosis model on experimental basis. The system uses Catalyst®ex software that automatically imports the stl. file. Acrylonitrile butadiene styrene (ABS P400) material was used. The process starts with capturing the digital impression of the foot. In the next step, the captured digital foot information was transferred into CAD system for designing the 3D orthosis model. The designed orthosis model is then converted into stl. file and then sent to Dimension BST 768 FDM system for fabrication of orthosis model. Figure 5 shows the CAD based designed foot orthosis model (a) and (b) fabricated foot orthosis.



(a)



(b)

Fig: 5 shows the CAD based designed foot orthosis model

Table 1 Specifications of orthosis model and material consumed

Specifications of orthosis model and material consumed	
Orthosis specifications	Height 50.82, Width 179.52, Depth 79.81 mm
Build time	14 hours
Material	ABS P 400
Model material (ABS P 400)	90 grams
Support material	30grams

5 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 one machine one machine was assumed to work for one run of 14 hours of build time per day for 220 working days per year. Production volume was calculated by estimated annual production volume form the model. A Dimension SST 768 FDM system has a build volume of (length) 203, (width) 203 and (height) 305 mm in which two parts can be fitted per platform. A build time of 14 hours per run for fabrication of 2 parts was given by the catalyst® EX machine controlling software. The machine was assumed to work for 220 days per year. This gives a total of 3080 machine hours per year at the rate of 14 hours of build time per run per day approximately 35% of machine utilisation time per year.

Table 2 shows an estimated total cost of £101452 for fabrication of 220 pairs per year at the rate of £461.14 per pair. Machine cost per year was calculated by depreciation cost of the machine per year and 10% of the actual cost of the machine as the maintenance cost per year. The depreciation cost for machine was assumed for 5 years. This gives a total of £7000 as the machine cost per year. Material cost was calculated by weighing the material consumed in model part and material consumed in support structure. The weight of total material consumed was then multiplied by associated cost of the material. The material consumed in fabrication of orthoses model was 90 grams and material consumed in support structure was 30 grams. The total material consumed was 120 grams per part which gives an estimated material cost of £40.80 per part or cost of £81.60 per pair. Production overhead per year was calculated by floor space cost at the rate of £120/m^2 per year. This cost was added with energy consumption cost of the machine at the rate of £1.5 per hour. This gives an estimated total of £34200 per year as production overhead. A uniform cost of £2320 per year was included as administrative overhead.

Labour cost was calculated by required labour time for operation of machine. For operation of one run using Dimension SST 768 FDM system it was estimated that 2 hours of labour time of the technician was required. The labour time is based on 60 minutes of time for setting of machine and loading the cartridges of model and support material and 60 minutes of time for post processing of fabricated parts. However, in the initial model with one machine and one technician, the labour cost of £39980 per year is included as the annual salary of the technician for 1760 labour hours per year, based on 220 working days per year

5.1 Sensitivity analysis of the model

Scenario 1-Increasing the machine operation hours per year

The initial operating model based on 220 working days per year was assumed to work for 365 days per year. Table 3 shows the cost categories in assumed operating model working for 365 days per year. A part time technician working for 2 hours of time per day for 145 working days was included. The model has increased the annual production volume from 220 pairs to 365 pairs per year at the rate of £336.75 per pair. This has reduced approximately 18% in total cost per pair compared to initial operating model based on 220 working days per year.

Table 2 Calculation of cost per pair using SST 768 system in FDM technique

Cost calculations using Dimension SST 768 system in FDM technique		
Production volume per year		
Number of parts/build	N	2
Build time/run	T	14 hours
Production rate/hour	R = N/T	0.142
Operation hours/year	HY	3080
Production volume/year	V = R x HY	440 parts
Total pairs/year		220 pairs
Machine cost per year		
Machine & ancillary equipment	E	£20000*
Depreciation cost/year	D = E/5	£5000
Machine maintenance cost/year	M (10%/year)	£2000
Total machine cost per year	MC = D+M	£7000
Material cost per pair		
Material/part	90 grams @£0.34/grams	£30.60
Support material/part	30 grams @£0.34/grams	£10.20
Model material cost/kg	968.1 grams	£330*
Support material cost/kg	968.1 grams	£330*
Material cost/part		£40.80
Total cost/pair		£81.60
Production overhead per year		
Building area	246.5/m^2* @ £120/m^2 per annum**	£29580
Energy consumed by machine	@ £1.5/ hour x 3080 machine operation hours per year from operating model	£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	220 pairs per year	£101452
Cost/pair	£101452/220pairs	£461.14

*Cost quotation from system supplier (Laser Lines Limited UK, 2010), **UK trade and information enquiry services (www.ukti.gov.uk, 2010) and ***Ruffo et al, 2006

Table 3 shows the cost categories in assumed initial operating model working for 365 days per year

Total cost per pair using Dimension SST 768 system		
Machine cost per year		£7000
Material cost for 365 pairs	@ £81.60/pair	£29784
Production overhead per year		£37245
Administrative overhead per year		£2320
Labour cost per year	Full time + part time operator	£46566
Total cost	365 pairs per year	£122915
Cost per pair	£122915/365 pairs	£336.75

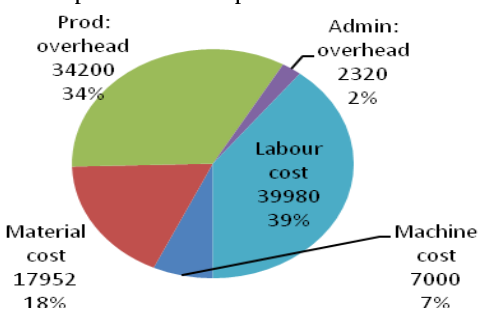
Figure 6 shows the detailed breakdown of the costs in the initial operating models based on (a) 220 and (b) 365 working days per year. The indirect cost accounts for 82%, 76% of the total cost respectively. This includes machine cost 7%, 6% production and administrative overheads 36%, 32% and labour cost 39%, 38% of the total cost in the model. Material cost accounts for 18%, 24% respectively of the total cost as the direct cost in the models.

Scenario 2-Development of "Best case" operating model

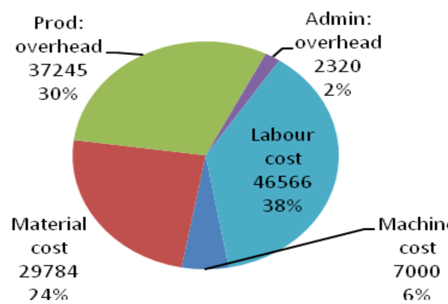
A "best case" operating model was developed based on one run of 14 hours of build time per day using Dimension SST 768 system. The developed model is based on 5 technicians working with 12 machines in order to obtain optimal productivity by balancing the machines working hours and labour hours. In the developed operating model one machine was assumed to work for one run of 14 hours of build time per day for 365 days year. This gives 5110 machine working hours per year and a total of 61320 machine working hours per year for 12 machines. For the labour hours in the model, one technician was assumed to work for 8 hours per day for 220 working days per year which gives a total of 8800 labour hours per year for 5 technicians.

Table 4 shows the operation hours of machines per year and labour hours per year for technicians in the "best case" operating model. The operation of one run on one machine requires 2 hours of labour time. The operation of 365 runs per year on one machine requires a total of 730 hours of labour hours per year. This gives a required estimated total of 8760 machine labour hours per year for operation of 12 machines. The labour hours per year for one technician are based on 1760 labour hours per year, which gives total of 8800 hours per year for 5 technicians. The operating model assumed to fabricate a total of 365 pairs per year based on one run of 14 hours build time per day on one machine. This gives an estimated annual production volume of 4380 pairs of orthoses per year using 12 machines.

Table 5 shows details of cost categories in "best case" model based on 5 technicians working with 12 machines. A floor space of 6 m^2 at the rate of £120/m^2 for each additional machine and ancillary equipment and energy consumption cost of £1.5 per hour for each additional machine is included. This is added with machine purchase and operation cost for 12 machines and material consumption cost per year. The labour cost for 5 technicians is estimated for £199900 per year at the rate of £22.71 per hour. The model gives an estimated total of £798628 for fabrication of 4380 pairs per year at the rate of £182.33 per pair; approximately 60% reduction in cost per pair compared to initial operating model based on 220 working days per year.



(a)



(b)

Fig: 6 Cost categories in initial operating models based on 220 and 365 working days per year

Table 4 Machine labour hours/year and technicians labour hour/year in "best case" cost model

No: of machines	Total required machine labour hours per year	No: of technicians	Total No: of technicians labour hours per year
1	730	1	1760
2	1460	2	3520
3	2190	3	5280
4	2920	4	7040
5	3650	5	8800
6	4380	6	10560
7	5110	7	12320
8	5840	8	14080
9	6570	9	15840
10	7300	10	17600
11	8030	11	19360
12	8760	12	21120

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

"Best case" model based on 5 technicians working 12 machines		
Machines cost per year		£84000
Material cost for 4380 pairs	@ £81.60/pair	£357408
Production overhead per year		£128480
Administrative overhead per year		£27840
Labour cost per year	Full time + part time operator	£199900
Total cost	4380 pairs per year	£798628
Cost per pair	£798628/4380 pairs	£182.33

Figure 7 shows breakdown of different costs in "best case" cost model. The indirect cost accounts for 55% of the total cost in the model. This includes machines cost 11%, production and administrative overheads 19% and labour cost 25% of the total cost in the model. Material cost accounts for 45% of the total cost as the direct cost in the model.

The developed cost model gives the cost of £182.33 per pair using fused deposition modelling technique in comparison to present per pair cost of approximately from £150 to £200 in the market (www.doctorsorthotics.com, www.londonorthtics.co.uk, doctorsfootlab.com). One of the most significant challenges in the market for custom foot orthoses is the lead-time; which normally ranges from 7 to 14 days depending on the manufacturer. The FDM technique has the advantages over the conventional manufacturing techniques in terms of cost competiveness and lead-time of 2 to 4 days as the application of technique removes the

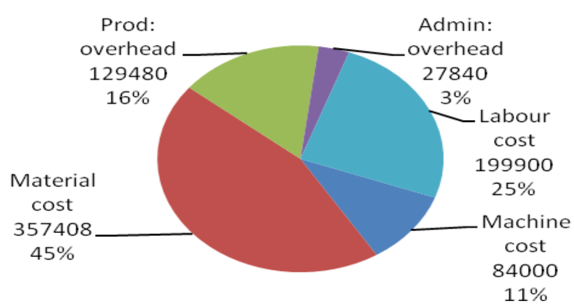


Fig: 7 Cost categories in "best case" cost model

traditional steps of making positive mould and manual designing of the foot orthoses. The orthoses fabricated through FDM technique results in more accurate, better fitting with improved quality final product

.6 CONCLUSION

Applications of rapid manufacturing techniques are progressing at rapid rate from which FDM is a well established and commonly used technique by many industries including automotive and other different manufacturing sectors. However, at present the cost of the material and machines are still higher. As the use of the FDM technique is increasing worldwide more efficient and faster machines could be introduced with introduction of new materials which will results in cost-effective method for fabrication of custom made devices and rehabilitation aids in the orthotics and prosthetic industry.

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