RAPID MANUFACTURING TECHNIQUE FOR FABRICATION OF CUSTOM-MADE FOOT ORTHOSES

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ABSTRACT: *Rapid manufacturing (RM) refers to fabrication of parts directly from CAD information through layer by layer addition of material until completion of final parts. The techniques include different fabrication processes from extrusion, binding, fusing, sintering and other methods of material deposition. Recently, application of these techniques for direct fabrication of parts has increased in different manufacturing sectors. However, there is a significant gap in literature for economic analysis of rapid manufacturing techniques versus conventional fabrication techniques when it comes to production of final product. In medical sector foot orthosis is medical device prescribed for improving foot function and gait in foot related diseases and problems. This paper introduces application of rapid manufacturing technique using polyjet technique for fabrication of foot orthoses. The cost and lead-time models developed gave the cost of £187.44 per pair using polyjet technique in comparison to present market cost of £150 to £200 per pair. The cost benefit analysis showed that total per pair cost of orthoses produced through polyjet technique is competitive with per pair cost of foot orthoses produced through traditional fabrication techniques.*

Keywords: Rapid manufacturing, Polyjet technique, Foot orthoses, cost modelling and lead-time

1. INTRODUCTION

Rapid manufacturing (RM) is new group of techniques that fabricate the parts directly from CAD information using different processes including extrusion, binding, fusing and sintering for deposition of material layer upon layer [1]. The techniques were initially used for prototyping of products for concept and product verification. The application of these techniques for direct part manufacturing has increased from 4% in 2003 to nearly 20% in 2011 [2]. The techniques have the advantages of increased design freedom for fabrication of complex geometrical parts without tooling and fixtures. The techniques have shown successful examples in production of small volume products or batch of one especially in medical sector for production of individualized geometrical parts, devices and rehabilitation aids to suit individual anatomy [3]. In-the-ear hearing aids and dental prosthesis are the well discussed successful examples of these techniques at commercial scale [4 and 5]. In medical sector prosthesis and orthotics is concerned with provision of individualized products to patients in order to facilitate and fulfil the individual needs of the patients. In orthotics and prosthetics foot orthoses is a medical device prescribed to the patients suffering from congenital defects, sports injuries, arthritis, diabetes and other biomechanical disorders and problems in the foot [6, 7]. A proper and well designed and fabricated foot orthosis prevents the patients from the progressing disability and provides comfort and improves the overall gait of patients.

2. Foot orthoses and production methods

Orthoses are externally applied devices prescribed for modification of functional characteristics of the neuro-muscular and skeletal system. Foot orthoses (FO) are commonly prescribed device for pain relief in foot and improve the gait of patients suffering from foot related problems occurred through diseases including arthritis and diabetes [8]. Figure 1 shows the custom-made foot orthoses. The Custom-made foot orthoses have been reported to provide more effective outcome in terms increased fit, improved comfort and aesthetics [9 and 10]. However, traditional fabrication process of custom-made orthosis is more costly and involves time consuming process. Custom-made orthotics have traditionally been fabricated through vacuum forming of thin shell plastics [8], however the state-of-the-art is moving towards the digital manufacturing; mainly through Numerically Controlled (NC) milling machines and with some initial attempts for RM-based production processes [11].

Fig: 1 Foot orthoses

2.1 Traditional orthoses fabrication

Custom-made foot orthoses are traditionally fabricated through vacuum forming which is one of the most rooted method for orthoses fabrication [12]. The process involves heating of mouldable thermoplastic sheet with thickness ranging from 2mm to 4mm [13, 14]. The heated sheet is then draped over the developed mould whilst vacuum is applied. The fabrication process is shown in Figure 2. The quality and functions of the orthoses fabricated through vacuum forming greatly depends upon the individual skills and craftsmanship of designer.

Fig: 2 Orthosis fabrication process through vacuum forming

2.2 Numerically Controlled (NC) milling

With the advancements in technologies and applications of computers in manufacturing processes Numerically Controlled machines (NC) were introduced in the fabrication process of custom foot orthoses [15, 16 and 17]. The process involves capture of 3D information of the foot geometry then modifying and correcting the captured foot geometry through specific orthoses designing software. Once the orthoses is designed the data is sent to milling machine where EVA block is milled by NC machine until the final shape of the designed orthoses. EVA blocks are ranging from different thickness and hardnesses according to required stiffness in the prescribed orthoses. In NC milling machines material is removed from the original block across 3 axes until the desired shape is achieved. However, the NC milling machines have limitation in incorporation of required complex orthoses design features and under cuts which restricts the product range [10].

3. Rapid manufacturing for fabrication of custom foot orthoses

Rapid manufacturing is emerging group of automated fabrication techniques having the advantages of greater design freedom, tool less fabrication process, involving less labour content, increased accuracy and improved consistency in the final product [18]. The techniques are reported as better solution in customisation of products and in low volume production [19 and 20]. Various researches have used rapid manufacturing in the production of custom made products and parts. Fastuni et al. [21] used selective laser sintering (SLS) in fabrication of passive-dynamic ankle foot orthoses (AFO). Atzeni and colleagues [22] fabricated the prosthetic feet with tuneable stiffness through the same process. Pallari and colleagues [10] developed a mass customisation framework for custom-made foot orthoses for rheumatoid arthritis patients. There are some successful commercial scale applications of rapid manufacturing techniques in the fabrication of in-the-ear hearing aids and dental prosthesis using the selective laser sintering (SLS) and stereolithography (SLA) technique in the fabrication process. In this work a well established rapid manufacturing technique named polyjet technique is used in the fabrication of custom foot orthoses.

3.1. Polyjet rapid manufacturing technique

In polyjet technique the parts are created using CAD design f the parts by selective deposition of photopolymer resin through a jetting head on to a build tray. Once the material is jetted on the build platform it is cured by ultra violet lights that turn the resin into solid layer. This process is one of the 3D printing techniques introduced by an Israel based company named Objet Geometries [23 and 24].

4. METHODOLOGY

A CAD based orthosis model shown in Figure 3 was used to fabricate the orthosis model using polyjet technique. The designed orthosis model was adopted from the work of Pallari [25] for mass customisation of foot orthoses for rheumatoid arthritis. Table 1 presents specifications of the orthosis model, build time and material consumed in the fabrication of orthosis model.

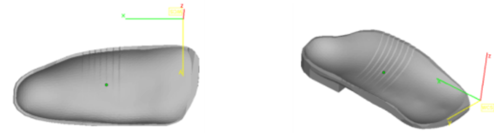

Fig: 3 CAD based orthosis model

Table 1 Specifications of orthosis model and material consumed

Specifications of orthosis model and material consumed	
Orthosis specifications	Height 50.82, Width 179.52 and Depth 79.81 mm
Build time	30 hours
Material	Verowhite fullcure
Material per part	180.9 grams
Support material/part	194.7 grams

4.1. Fabrication of orthosis model

Connex 500 system has a build volume of 500 (length), 400 (width) and 200 mm (height) in which 10 parts can be fitted per build. A build time of 30 hours per run for fabrication of 10 parts was given by Objet Studio™ machine controlling software.

5. RESULTS AND DISCUSSIONS

5.1 Cost and lead-time modelling

In polyjet technique using Connex 500 system one machine was assumed to work for one run of 30 hours of build time for 220 working days per year. Production volume per year was calculated from the developed model. A build time of 30 hours per run for fabrication of 10 parts was given by Objet Studio™ machine controlling software. The machine was assumed to work for 220 days per year in which a total of 110 runs can be operated. This gives a total of 3300 hours per year at the rate of 30 hours of build time per run; utilisation of 37% machine utilisation time per year.

Table 2 shows an estimated total cost of £190755 for fabrication of 550 pairs per year at the rate of £346.82 per pair. Machine cost per year was calculated by depreciation cost of machine and 10% of actual cost of machine as the maintenance cost per year. The depreciation time for machine was set for 5 years. This gives an estimated total of £57000 as the machine cost per year. Material was cost calculated by weighing the material consumed in the model part and material consumed in support structure. The weight of total material consumed is then multiplied by the associated cost of the material. The material consumed in orthosis model was 180.9 grams and material consumed in support structure was 194.7 grams. The total material consumed including support material was 375.6 grams per part which gives an estimated material cost of £51.75 per part or £103.50 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 the energy consumption cost of the machine at the rate of £1.5 per hour which gives an estimated total of £34530 per year as production overhead. A uniform cost of £2320 per year was included as administrative overhead [26].

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Table 2 Cost calculation per pair using Connex 500 system in polyjet technique

Production volume per year		
Number of parts/build	N	10
Build time/run	T	30 hours
Production rate/hour	R = N/T	0.33
Operation hours/year	HY	3300
Production volume/year	V = R x HY	1100 parts
Total pairs/year		550 pairs
Machine cost per year		
Machine & ancillary equipment	E	£190000*
Depreciation cost/year	D = E/5	£38000
Machine maintenance cost/year	M	£19000
Total machine cost /year	MC = D+M	£57000
Material cost per pair		
Material/part	180.9 grams @£0.2/grams	£36.18
Support material/part	194.7 grams @£0.08/grams	£15.57
Model material cost/kg		£200*
Support material cost/kg		£85*
Material cost/part		£51.75
Total cost/pair		£103.50
Production overhead per year		
Building area	246.5/m^2 @ £120/m^2 per annum**	£29580
Energy consumption by machine	@£1.5/hour x 3300 machine operation hrs	£4950
Total cost/year		£34530
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/year
Total cost	550 pairs per year	£190755
Cost/pair	£190755/550 pairs	£346.82

Labour cost was calculated by labour time of the operator per run. For operation of one run on Connex 500 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 the fabricated parts. However, in the initial model with one machine and one technician, the labour cost of £39980 is included as the annual salary of the technician

5.2 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 model working for 365 days per year. A part time technician working for 2 hours of time per run was included in order for operation of 72 runs in 145 days. This has increased the production volume from 550 pairs to 910 pairs per year at the rate of £257.71 per pair. This has reduced approximately 26% in total cost per pair compared to initial operating cost model based on 220 working days per year.

Table 3 Total cost/pair in operating model based on 365 days per year.

Cost modelling in Connex 500 system		
Machine cost/year		£57000
Material cost 910 pairs/year	@£103.5/pair	£94185
Production overhead/year		£37770
Admin: overheads/year		£2320
Labour cost/year		£43250
Total cost	910 pairs/year	£234525
Cost/pair	£234525/910 pairs	£257.82

Figure 4 and 5 shows the detailed breakdown of different cost elements in initial operating models based on 220 and 365 working days per year. The indirect costs account for

70%, 60% of the total cost respectively in the models. This includes machine costs 30%, 24% production and administrative overheads 19%, 17% and labour costs 21%, 19% of the total cost. Material costs accounts for 30% and 40% respectively of the total cost as the direct cost in the models.

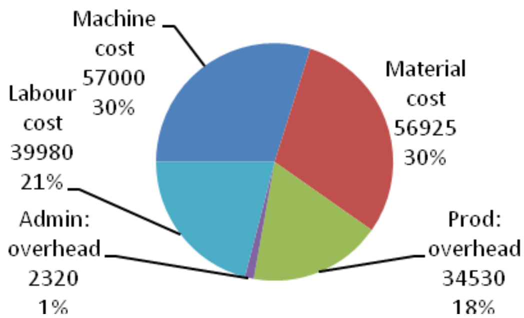

Figure 4 Cost categories in initial operating model based on 220 working days per year

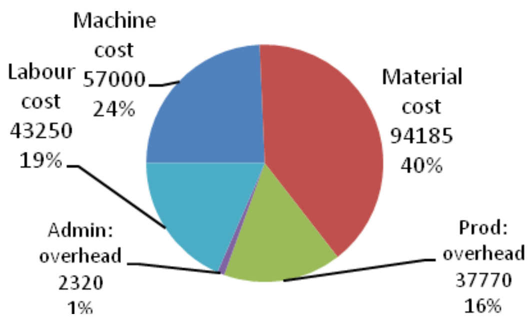

Figure 5 Cost categories in initial operating model based on 365 working days per year

Scenario 2-Development of "Best case" operating model

A "best case" operating model was developed based on 30 hours of build time per run operating for 182 runs per year. The developed model is based on 2 technicians working with 10 machines in order to obtain optimal productivity by balancing the machines working hours and labour hours. In the model one machine was assumed to work for 30 hours of build time per run operating for 182 runs per year. This gives a total of 5460 working hours per year for each machine; approximately 62 % machine utilisation time per year.

Table 4 shows the operation hours of machines per year and labour hours per year for technicians in the "best case" model. The operation of one run on one machine requires 2 hours of labour time. The operation of 182 runs per year on one machine requires a total of 364 hours of labour hours per year. This gives a required estimated total of 3640 machine labour hours per year for operation of 10 machines. The labour hours per year for one technician based on 1760 labour hours per year gives a total of 3520 labour hours per year for 2 technicians. The operating model based on one run of 30 hours of build time on one machine was assumed to fabricate a total of 910 pairs per year which gives an estimated annual production volume of 9100 pairs of orthoses per year using 10 machines.

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

No: of machines	Total required machine labour hours/year	No: of technicians	Total No: of technicians labour hours/ year
1	364	1	1760
2	728	2	3520
3	1092	3	5280
4	1456	4	7040
5	1820	5	8800
6	2184	6	10560
7	2548	7	12320
8	2912	8	14080
9	3276	9	15840
10	3640	10	17600

Table 5 shows details of cost categories in "best case" cost model based on 2 technicians working with 10 machines. A floor space of $6m^2$ 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 the machine purchase and operation cost of 10 machines and material consumption cost per year. The labour cost for 2 technicians is estimated for £79960 per year at the rate £22.71 per hour. The model gives an estimated total of £1705760 for fabrication of 9100 pairs per year at the rate of £187.44 per pair approximately 46% reduction in cost per pair compared to initial operating model based on 220 working days per year.

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

"Best case" operating model for 2 technicians working with 10 machines	
Machine cost/year for 10 machines	£570000
Material cost for 9100 pairs @£103.5 per pair	£941850
Production overheads/year for 10 machines	£90750
Administrative overheads /year for 10 machines	£23200
Labour cost for 2 technicians	£79960
Total cost for 9100 pairs	£1705760
Cost per pair £1705760/21900 pairs/year	£187.44

Figure 6 shows breakdown of different costs in "best case" cost model. The indirect cost accounts for 45% of the total cost. This includes machine cost 34%, production and administrative overheads 6% and labour cost 5% of the total cost. Material cost accounts for 55% of the total cost as the direct cost in the model.

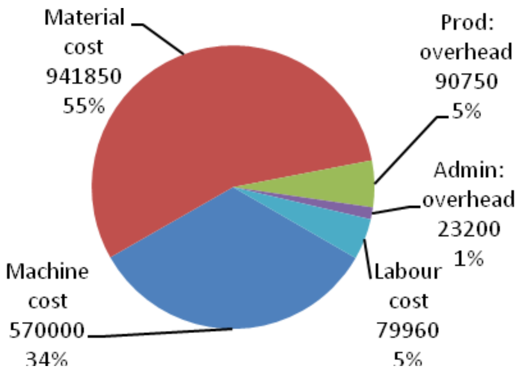

Fig: 6 Cost categories in "best case" cost model

Custom-made foot orthoses can be fabricated using polyjet technique. Figure 6 shows that material and machine cost constitutes approximately 89% of the total cost in the "best case" developed model. The model gives the cost of £187.44 per pair using polyjet technique in comparison to present cost of custom foot orthoses in the market, where one pair of orthoses costs approximately from £150 to £200 [27 and 28]. 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 polyjet technique has the advantages over the conventional manufacturing techniques in terms of cost competiveness and lead-time of 2 to 4 days delivery time; as the application of technique removes the traditional steps of making positive mould and manual designing of the foot orthoses. The orthoses fabricated through polyjet technique results in more accurate, better fitting with improved quality final product.

6. CONCLUSION

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

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