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Mitigation of Design Issues in Development of Anatomical Models Using Rapid Prototyping

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Abstract: *Literature indicates rapid prototyping (RP) application has become more widespread in design and development of human anatomy models. Practitioners are facing challenges in deployment of RP tools for development of cost-effective medical models, because there are no proven decision support systems in the selection of parameters such as speed, accuracy, materials, and customisation of commercial software. This study aims at alleviating some of these issues by exploring the use of a Genetic Algorithm (GA) approach combined with computer-aided design (CAD) and fused deposition modeling (FDM) techniques. Experiments were conducted using response surface methodology (RSM) to facilitate the optimisation process with build time and model material volume as responses. The validation of the study has been performed with a patella model and the results verified the effectiveness of the proposed RSM-GA approach in the design and development of the anatomical model. The results showed a 27% savings on model material compared to a non-refined model and was deemed satisfactory for practical use as there was a reduction in irregularities from CT data. The study also reveals that the parameter hollow has the largest effect on the responses, followed by the smooth parameter and then the wrap parameter.*

Keywords: *Anatomical model, computer aided design approach, design optimisation, genetic algorithm, RSM, rapid prototyping, fused deposition modeling*

1. Introduction

Anatomical modelling is the process of using medical scanned data to fabricate accurate solid models of a patient's anatomy (Mallepree and Bergers, 2009). In the past, reverse engineering (RE) and medical image-based modeling technologies were applied successfully for construction of three-dimensional (3D) anatomical models of human body from scanned data such as computerised tomography (CT) and magnetic resonance imaging (MRI). Further, the 3D printed anatomical models have several downstream applications such as surgical training, preoperative planning, surgical simulation, diagnosis and treatments (Yap et al., 2017).

Sun and Liu (2018)'s review shows that 3D printed kidney models can replicate renal anatomical structures and renal tumors with high precision. The authors concluded that there is a need for further investigations of more cases and with an emphasis on production of cost-effective 3D printed models as well as the ways to reduce the 3D model production time. Computer Aided Design (CAD) and Rapid Prototyping (RP) tools are proven beneficial in the contemporary medical profession. Further, these technologies can produce complex-shaped anatomical parts directly from scanned data (Negi et al., 2014). RP models also serve as customised implants (Dhakshyani et al., 2011). This concurs with study of Sun and Liu (2018) on the usefulness of 3D printed models for improved patient's understanding of renal anatomy and pathology, medical students' understanding of renal malignant tumors, and surgical planning and procedures.

On the other hand, the key issues surrounding the use of 3D printed models in the medical field are speed, cost, accuracy, materials, and ease of use (Gibson et al., 2006; Sun and Liu, 2018). The first critical limitation of RP technology is the investment of time and training required for data preparation. As such, anatomical models cannot be generated as surgical aids in emergency situations. Another limitation of RP technology specific to anatomical modelling is the accuracy of the medical imaging data used for model segmentation, as most methods of medical imaging introduce inaccuracies due to noise and other sources of error that will prolong the model design as well as the fabrication process.

The literature indicates that the model design and development time are the key performance measures which affect the selection of AM technology for development of anatomical models. In particular, the slow building times of the 3D printing machines severely

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increase the waiting time for fabrication of prototypes (Wu et al., 2018; Sun and Liu, 2018).

Literature has been reviewed from the context of GA applications in the field of RP where user discretion is needed for parameter selection. Pandey et al. (2004) and Byun et al. (2005) obtained optimal part orientation while minimising build time in FDM process by considering two objective functions simultaneously using a non-dominated sorting genetic algorithm-II (NSGA-II). Panda et al. (2009) deployed a central composite design (CCD) approach to optimise FDM process parameters. Additionally, empirical models were developed using analysis of variance (ANOVA) technique and optimisation was accomplished using a bacterial foraging tool.

The purpose of this study is to develop an improved methodology for design development of anatomical models to reduce costs and material usage, improve accuracy and build time whilst reducing the need for frequent user inputs. The proposed methodology includes the use of GA technique for optimisation of build time (BT) and model volume, as well as to develop a relationship between the selected medical CAD operations and performance measures. The proposed methodology is expected to provide fast, repeatable results. The effectiveness of the technique was verified by evaluating the process of modelling and prototyping a patella, also known as kneecap, located at the front of the knee joint, within the patellofemoral groove of the femur.

2. Research Methodology

Figure 1 shows the research methodology. The methodology consists of anatomical model design, optimisation and development stages. The associated operational details of each stage are explained in the following sections.

2.1 Phase 1: Anatomical Model Design

i) Data Acquisition

The selected data was derived from a computer tomography (CT) imagery of a patient-specific human knee. Importation of the CT image files was performed by means of Mimics base software in DICOM V3.0 format to an appropriate number of image slices.

ii) Windowing

Windowing is a tool available in Mimics software to

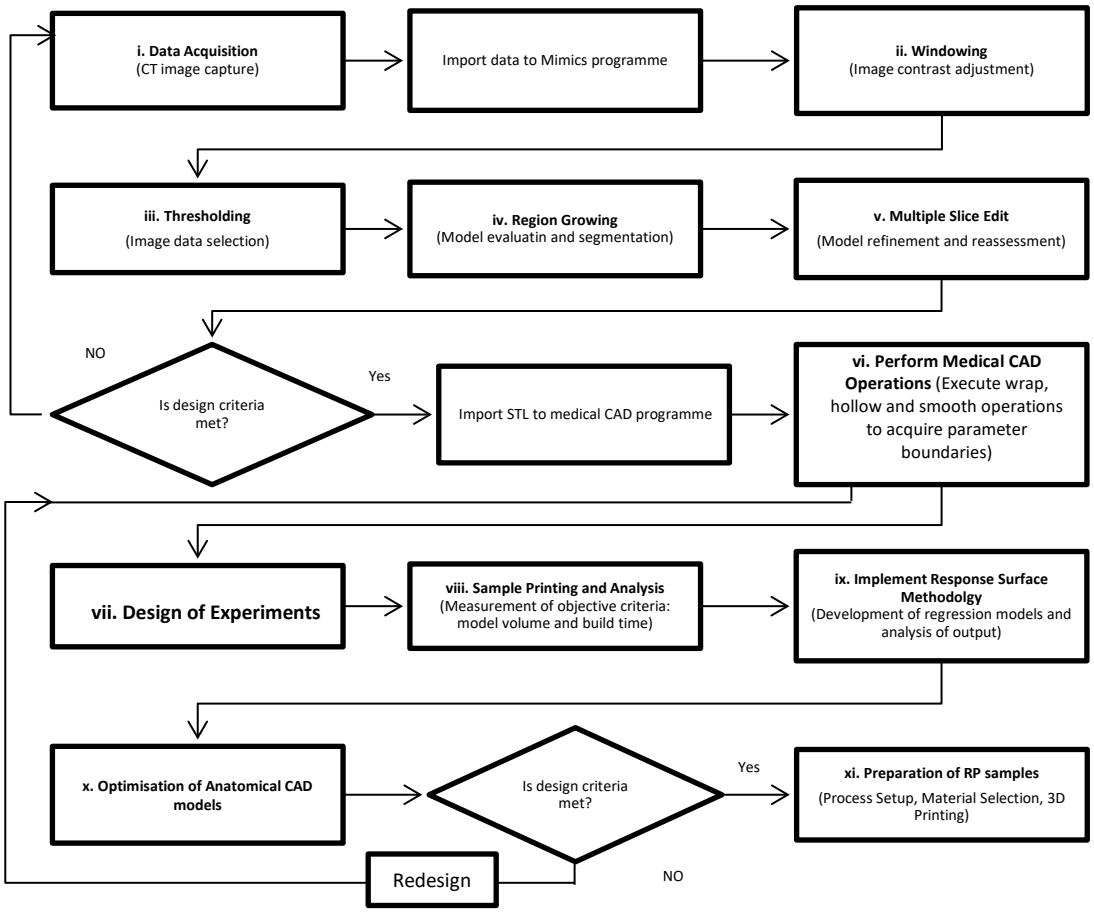

Figure 1. Proposed Research Methodology for Design, Optimisation and Development of Anatomical Models

adjust the image contrast. Windowing of the imported model was performed to increase visibility by adjusting the contrast of the selected CT image to the user requirements. Figure 2 shows the raw CT imagery. The right image was chosen due to its high quality.

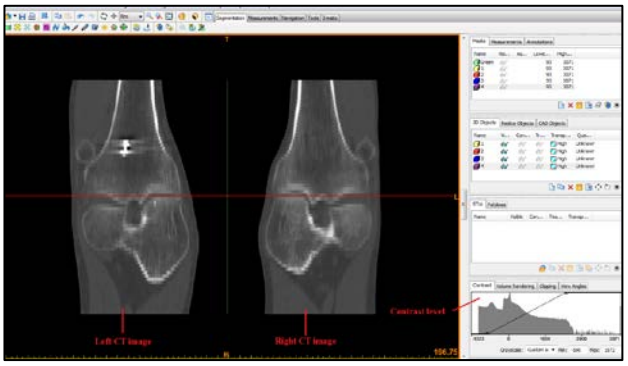

Figure 2. Windowed Knee CT Scan

iii) Thresholding

The medical images coming from CT scanners normally include some noisy information. However, designers need to create models in terms of industry's accepted gray values within these images (Materialise, 2010). Gray values are nothing but Hounsfield units in CT images and each gray value is a number associated with an image pixel defining the shade (white, gray, or black) of the pixel.

In general, there is a relationship between material density of the scanned object and the gray value assigned to each pixel in the image data. By grouping together similar gray values, the CT image data can be segmented, and models created. This type of segmentation is called thresholding and yields accurate models. A lower threshold allows segmentation of soft tissue, whereas a higher threshold of +700 to +3000 is recommended for segmentation of bone (Bibb et al., 2014).

iv) Region Growing

Region Growing is a model calculation tool used in this research to produce an improved patella structure by removing floating pixels. However, the structures may still contain noise, in the form of residual pixels, at points where different structures connect. Therefore, this noise must be cleaned manually before completing the model segmentation process. Further, for enhancement of the segmentation process, various tools such as 'Edit Mask' and 'Crop Mask' were used to threshold the selected case mask.

v) Multiple Slice Edit

The Multiple Slice Edit tool of Mimics was used to reduce noise in experimental data. In addition, the Boolean operation tool was also utilised for visualisation of the selected combination of masks.

vi) and vii) Design of Experiments

The patella model obtained from the previous stage, was generated and exported as binary STL to the Materialise software to acquire parameter boundaries. As per Gibson et al. (2006), this activity was completed by executing various medical CAD operations such as wrap, smooth and hollow. Then it was noted that there were no gaps in the revisited exported model. Moreover, the lower limit for the wrap parameter was taken as the minimum wall thickness of 0.5 mm and the upper limit was set at the suggested maximum of 5 mm. The smooth parameter was set as 0 to 1mm. The hollow parameter was set from 10 mm maximum wall thickness to the minimum wall thickness of 0.3 mm. From the acquired boundaries, using CCD approach, five parameter levels were generated (See Table 1). Figure 3 shows the solid patella model, highlighting the issues requiring CAD operations and it was chosen as a reference model for optimisation purposes.

Table 1. Experimental Parameters and Levels as per CCD Approach

Parameter	Level				
	-2	-1	0	1	2
Wrap	0.5	1.25	2.5	3.75	5.0
Smooth	0	0.25	0.5	0.75	1.0
Hollow	0.3	2.5	5.0	7.5	10.0

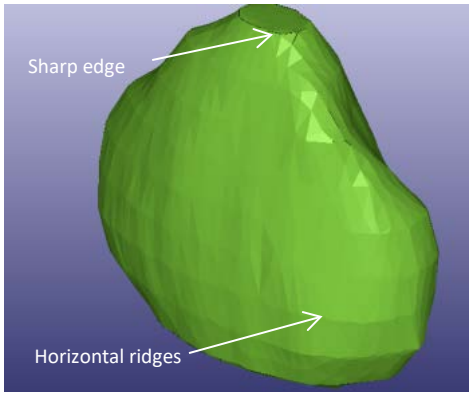

Figure 3. Patella STL Model Chosen as Reference for Optimisation

2.2 Phase 2: Optimisation and Rapid Prototyping of Anatomical Models

viii) Samples Printing and Analysis

Twenty experimental models were derived from the patella reference STL model (see Figure 3) by means of the acquired parameter combinations as presented in Table 1. The selected objective criteria, model volume and build time (BT) were measured using Insight software.

ix) Development of Response Surface Models

The Response Surface Methodology (RSM) technique was used to establish the mathematical relation between input parameters and the selected objective criteria. The acceptability of the two generated regression models in terms of BT and model volume was verified by means of ANOVA technique. The results show that all experimental values are well fitted in the two regression models. The results along with the associated regression model for BT and model volume are presented in Table 2 and Table 3, respectively.

x) Optimisation of Anatomical CAD Models

The Multi-Objective Non-Sorting Genetic Algorithm (M-NSGA) module available in MATLAB has been used to optimise the objective criteria (MathWorks, 2012). Using the decoded regression Equations (1) and (2), the fitness function was written in MATLAB software. Further, the GA settings for population size, crossover probability, mutation probability and number of generations were adapted from Panda et al. (2009).

xi) Preparation of RP Samples

The optimised STL model was printed using the Fortus 400mc FDM machine. Polycarbonate (PC) was selected as model material and PC-10 as the support material. PC has high strength and gives sufficient representation of the actual color of bone. The preparation of samples for printing involved specification of the RP parameters including the layer height, infill, build orientation, support material and tool paths, in the machine control center. As

Table 2. The Regression Equation for Build Time

Predictor Term	**Coded Coefficient**			**P Value**	
Constant	167			0.000	
A	-0.7			0.956	
B	-16.7			0.237	
C	-79.2			0.000	
A*A	-11.9			0.553	
B*B	-70.2			0.006	
C*C	-59.9			0.014	
A*B	0.0			1.000	
A*C	0.0			1.000	
B*C	1.0			0.978	
Model Summary: S =25.4706 R-Sq = 85.27%					
Analysis of Variance					
Source	DF	Adj SS	Adj MS	F	P
Regression	9	37546.5	4171.8	6.43	0.004
Linear	3	25008.3	8336.1	12.85	0.001
Square	3	11483.4	3827.8	5.90	0.014
Interaction	3	0.5	0.2	0.00	1.000
Residual Error	10	6487.5	648.8	-	-
Total	19	44034.0	-	-	-
Regression Equation for BT in terms of Wrap (A), Smooth (B), Hollow (C)	BT = 114.0 + 12.7 A + 245 B + 9.7 C - 2.36 A*A - 280.8 B*B - 2.547 C*C + 0.4 B*C …Eq. (1)				

Table 3. The Regression Equation for Model Volume

Predictor Term	**Coded Coefficient**			**P Value**	
Constant	28.797			0.000	
A	-0.039			0.946	
B	-0.835			0.207	
C	10.524			0.000	
A*A	-0.571			0.544	
B*B	-3.500			0.004	
C*C	-7.197			0.000	
A*B	-0.01			0.993	
A*C	-0.01			0.993	
B*C	0.03			0.985	
Model Summary: S =1.1822 R-Sq = 97.57%					
Analysis of Variance					
Source	DF	Adj SS	Adj MS	F	P
Regression	9	566.001	62.889	44.54	0.000
Linear	3	426.587	142.196	100.71	0.000
Square	3	92.245	30.748	21.78	0.000
Interaction	3	0.001	0.000	0.00	1.000
Residual Error	10	14.119	1.1412	167.08	-
Total	19	580.12	-	-	-
Regression Equation for model volume in terms of Wrap (A), Smooth (B), Hollow (C)	Model volume = 6.04 + 0.61 A + 12.30 B + 5.318 C - 0.113 A*A - 14.00 B*B - 0.3060 C*C - 0.01 A*B - 0.001 A*C + 0.013 B*C …Eq. (2)				

Table 4. Objective Performance of the Experiments

Model No.	CCD Parameter combinations			Model Volume (cm^3)	Support Volume (cm^3)	Build Time (BT) (minutes)
	Wrap (A)	Smooth (B)	Hollow (C)			
1	0	0	0	28.487	8.996	173
2	0	0	0	28.487	8.996	173
3	-1	1	1	29.951	2.163	67
4	-1	-1	-1	19.653	9.739	172
5	-2	0	0	28.776	8.762	173
6	1	-1	1	29.974	2.152	67
7	-1	-1	1	29.974	2.152	67
8	1	1	1	29.920	2.119	67
9	2	0	0	28.740	8.71	173
10	0	2	0	24.059	2.909	79
11	0	0	0	28.738	8.711	173
12	0	0	2	33.800	2.15	67
13	0	0	0	28.738	8.711	173
14	1	1	-1	19.583	9.913	171
15	0	0	0	28.738	8.711	173
16	-1	1	-1	19.583	9.913	171
17	0	0	0	28.738	8.711	173
18	0	0	-2	10.786	10.786	171
19	0	-2	0	27.289	6.589	145
20	1	-1	-1	19.653	9.731	172
Reference model				35.10	2.157	65

the influence of these RP parameters were not being investigated, they were kept constant for all experiments.

3. Experimental Data and Analysis

As per the previous section, three CAD parameters were selected for the optimisation of the developed anatomical CAD model. These parameters are wrap (A), smooth (B) and hollow (C), for which factor levels can be seen in Table 1. The factor levels have been determined by considering the capability of the Materialise 3-matic software (Materialise, 2010), and the experience of the authors in this domain. The experimental results for the twenty STL models, as well as the reference, are given in Table 4. The reference model possessed the lowest BT of 65 minutes despite having the greatest model volume. This is due to the reduced supporting material and linearity of the tool path. By comparison, experiments 6, 7, 8 and 12 obtained a BT of 67 minutes despite having a reduced model volume. This was expected due to the non-linearity of generated tool path. It was noted that experiments with higher supporting material obtained much higher BTs. A sample screenshot of the simulated RP models is shown in Figure 4.

4. Data Analysis

For second-order experimental models such as FDM process optimisation, RSM is a commonly selected experimental design (Mohamed et al., 2015). For this study, the main effects and interaction plots provided sufficient evidence to identify the critical parameters. In this regard, the impact of each CAD operation (wrap, smooth and hollow) on the objectives was compared in the following sections.

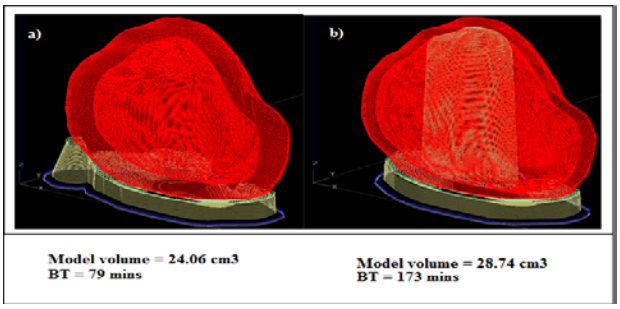

Figure 4. Simulated RP Models for (a) Experiment 10 and (b) Experiment 9

i) Main Effects Plots

Using the 3-matic design software, the wrap, smooth and hollow operations were performed on the extracted CT model. Figure 5(a) shows the main effects plots for model volume. The observed effects are, as follows:

1) *Wrap*: Applying wrap parameter of 2.5 produces a maximum model volume of $29cm^3$, whereas at the upper and lower boundaries was slightly reduced by approximately $1cm^3$.
2) *Smooth*: With a smooth parameter of 0, the model volume was $26cm^3$. As the smooth parameter increased to 0.5, the model volume increased to its maximum value of $29cm^3$.The lowest model volume of $24cm^3$ can be seen at a smooth parameter of 1. High smoothing thus provided reduced model volume.
3) *Hollow*: Applying a hollow parameter of 0.3mm, the model volume was at its lowest value of $11cm^3$. As the hollow parameter increased to 10mm, model volume also increased to its maximum value of $32.5cm^3$.

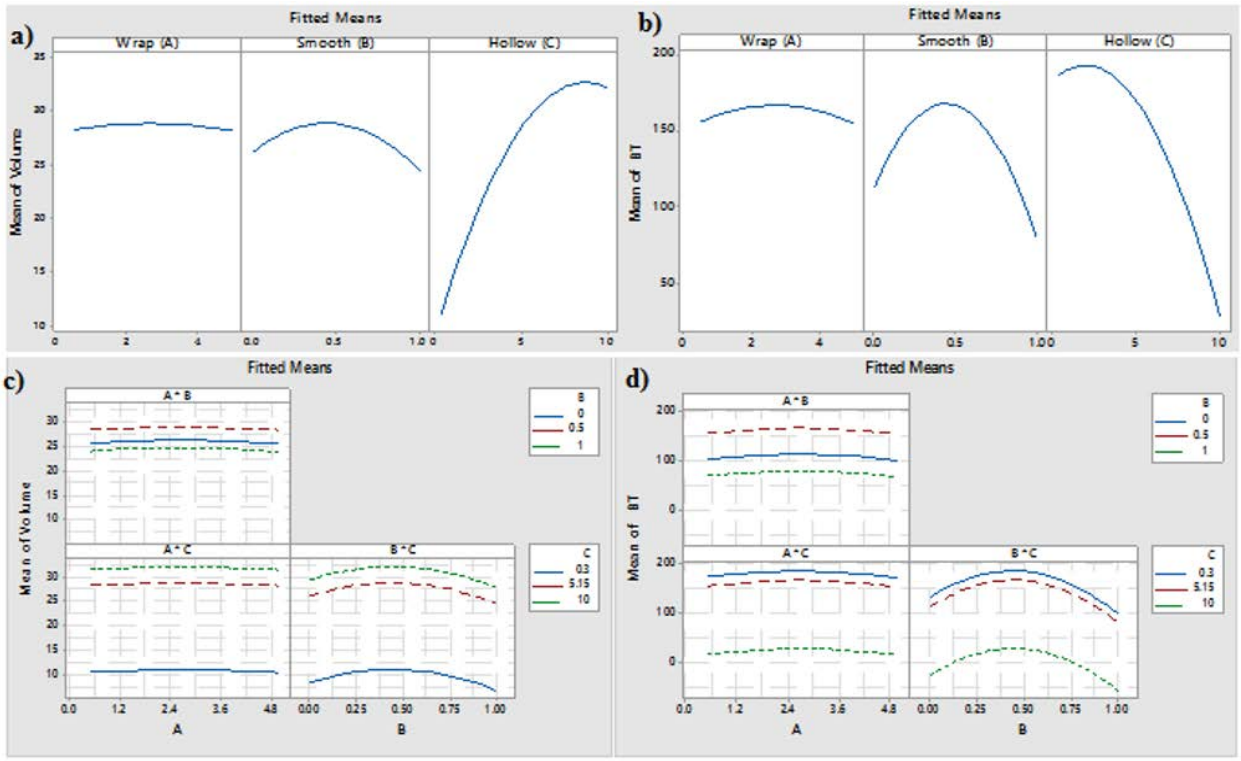

Figure 5. Main Effects Plot for (a) Model Volume and (b) Build Time; Interaction Plot for (c) Model Volume and (d) Build Time

Figure 5(b) shows the main effects plots for BT, and several observations can be deduced. These are:

1) *Wrap*: At wrap = 0.5, the BT was found as 155 minutes and it increased to 170 minutes at wrap = 2.5. Both high and low wrap suggest better performance in terms of BT.
2) *Smooth*: With no smooth parameter, the sample requires a BT of 112 minutes. As the smooth parameter increases to 0.5, BT was increased to its maximum value of approximately 170 minutes. High smoothing provided the lowest BT of approximately 80 minutes.
3) *Hollow*: With a hollow parameter of 0.3mm, BT was approximately 190 minutes. When the sample hollowness increased to 10mm, the model volume was decreased to its minimum value of approximately 12.5 minutes.

ii) Analysis of Interaction Plots

The interaction plots for model volume can be seen in Figure 5(c). The moderate interaction for the parameters smooth and hollow (B*C term) can be seen in the regression model (refer Eq. 2). This interaction supports the earlier observation of a significant decrease in model volume at the lower boundary of 0.3 and a rapid increase at a hollowing value of 5.15. The interaction plots for BT can be seen in Figure 5(d). The significant interaction for the parameters smooth and hollow (B*C) can be noted in the regression model for BT (refer Eq. 1).

iii) Optimisation Using GA

The regression models (Eq. 1 and Eq. 2) were used to optimise the three parameters (A, B and C) to improve the two selected performance measures. A summary of model parameters and performance criteria is shown in Table 5.

5. Analysis of Pareto Front

The GA optimised model parameters were used to generate final specifications of the anatomical models under consideration. The optimised models revealed a wide distribution of results which allow to take appropriate decisions. However, the results of the Pareto front showed two occurrences of negative BT values of -69.50 minutes for solutions 2 and 9. These anomalous results (as shown in Figure 6) were due to insufficient constraints to the BT regression model, particularly with respect to a large hollow value.

The distribution of the Pareto front shown in Figure 6 suggested that all optimised samples showed a decrease in model volume from the reference model volume of 35.10cm³. However, majority of the generated samples had BT values between 60 and 80 minutes. The selection criterion for deciding BT may be between 50 to 70 minutes, providing a feasible solution set of four (4) optimised samples.

For further analysis, these optimised samples (6, 7, 14 and 15) were modelled using the parameter values as shown in Table 5. Performance criteria were verified by means of a commercial RP software.

Table 5. Optimal Solution Set from GA Optimisation

GA Solution	BT (minutes)	Model Volume(cm³)	Wrap (A)	Smooth (B)	Hollow (C)
1	93.29	16.02	0.500	1	2.500
2	-69.50	27.32	0.501	0.999	9.994
3	18.56	27.32	0.501	0.999	7.424
4	74.37	23.04	0.501	0.999	4.757
5	29.63	26.94	0.501	0.999	7.009
6	64.92	24.39	0.501	0.999	5.360
7	69.61	23.78	0.500	1	5.075
8	78.64	22.23	0.500	1	4.435
9	-69.50	27.32	0.501	0.999	9.994
10	41.90	26.33	0.501	1	6.504
11	93.29	16.02	0.500	1	2.500
12	87.32	19.85	0.504	0.999	3.603
13	34.14	26.76	0.525	0.999	6.840
14	51.72	25.79	0.527	0.997	6.102
15	59.27	25.02	0.513	0.999	5.682
16	91.75	17.55	0.501	1	2.917

Table 6. Summary of Sample Parameters and Performance Criteria

Design Features	Original Reference Model	Optimised Solution 6	Optimised Solution 7	Optimised Solution 14	Optimised Solution 15
Wrap	0	0.501	0.500	0.527	0.513
Smooth	0	0.999	1	0.997	0.999
Hollow	0	5.360	5.075	6.102	5.682
Actual BT (minutes)	65	80	75	80	80
Model Volume (cm³)	35.10	25.18	24.29	27.29	26.12

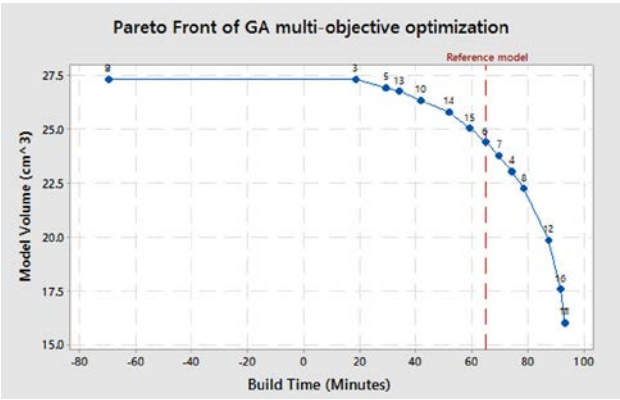

Figure 6. GA Optimisation Pareto Front

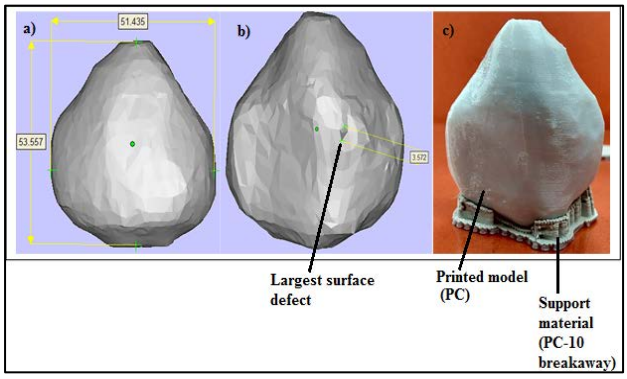

Figure 7. Optimised STL Model; (a) Anterior View (b) Posterior View (c) RP Model

From Table 6, sample 7 showed the most desirable performance criteria. For the sample 7 an STL file was created using the optimised parameter values and this was used to manufacture the patella model by means of Fortus FDM 400mc. A sample of screenshots that represents the fabricated RP model can be seen in Figure 7(a-c).

6. Discussion

This study recommends a methodology for mitigating the design issues faced in fabrication of RP models which is especially suited for medical applications: The methodology involves aa fair degree of automation. An important feature of this methodology was the use of the GA technique in optimisation of model parameters to overcome the resource constraints such as material, cost, and time.

The parameters of the study were wrap, smooth and hollow. The wrapping operation creates a layer of pixels on the selected geometry for filtering minute inclusions and removing holes and surface deformities. The smoothing operation reduces noise in the STL model by resisting the mesh elements, thus increasing model accuracy and quality. The hollowing of medical samples is one design strategy used to decrease cost, material consumption and manufacturing speed. This observation concurred with a previous study suggesting that building efficiency can be enhanced by hollowing thin-shell prototypes (Zhengyu et al., 2004).

The proposed research methodology will be applicable for design and development of an anatomical model that has surface irregularities. Further, for fabrication of RP samples, the model material was selected as PC and the support material as PC-10 break-away. PC is very strong and commonly used in medical RP applications.

Geometric errors in RP models can be attributed to the scanning process, pre-processing stages, and the actual process itself. Here a key design challenge is manipulation of the raw imaging data. This imaging data may possess errors including inaccuracies in artifacts. The application of Mimics 3-matic module operations and automated segmentation techniques may be an effective way for reduction of such errors. It was proven that the wrap and smooth operations of this module will reduce the imaging errors. Additionally, except two instances, it was observed from the RSM analysis that the BT and model volume regression equations have capability to predict model accuracies of 85.27% and 97.57%, respectively.

Further, the CAD operations on the optimised model removed all visible indication of the horizontal ridges or sharp edges which were the major issues of the reference model. The 3-matic hollowing operation is a simple economic tool for reduction in material consumption and build time. However, the operation has some risk of degraded model strength. In this study, the savings in material cost was found as 27% of the reference model.

RP models could be custom-built and could be produced in a shorter time compared to conventional methods. BT was one of the responses investigated in the study and it was found that the BT of the optimised model was 15% greater than that of the reference model. However, this increase in BT is permissible to overcome the degradation in model strength.

The individual effect of the parameters is analyzed in the main effects plots as illustrated in Figure 5(a) and 5(b). The analysis reveals that hollowing is the highest contributor to the performance objectives, with smoothening being second and the lowest contributor being the wrap parameter. The interactive effect of the parameters were analysed in the interaction plots as illustrated in Figures 5(c) and 5(d). The RSM suggests that the interaction of terms does not contribute significantly to the regression model. Moreover, the analysis of these plots reveals that the interaction of smooth and hollow parameters results in the highest contributing interaction.

6.1 Process Optimisation by Genetic Algorithm Technique

A multi-objective GA approach was chosen from the literature due to its robustness, suitability and capability to produce a Pareto front, which is the necessary tool for establishing a solution set. As observed from the obtained solution set (refer to Table 5) the two parameters; smooth and hollow, gave optimal values of approximately 0.5 and 1, respectively. The hollow parameter, however, was the populating variable for the Pareto front. In selecting the optimal model, a compromise of BT had to be made as none of the optimal solutions had an actual BT lower than the original model. This may be due to the limited capabilities of the regression model as well as characteristics of STL file increased triangles which would result in a less linear tool path being generated and increase machine movement. This observation coincided with the study of Pandey et al. (2004).

6.2 Validation of the Proposed Approach

Validation of the proposed design methodology was conducted using a questionnaire. The survey sample consisted of 30 medical students. The participants were given images of the CT imagery and optimised model. The responses were measured on a Likert scale of 1-10, where 1 represented ‘not at all’, 5 represented ‘partially’ and 10 represented ‘completely’. The high responses indicate general end-user satisfaction. Table 7 gives a summary of the feedback.

Table 7. Consolidated Responses of the End Users

No.	Question	Mean
1	To what extent do you believe that the design method is feasible for model production?	8.5
2	To what extent do you believe that the optimised model can be utilised during instruction or practice at your organization?	8.0
3	To what extent do you believe that the optimised model satisfies the end-user needs?	8.0
4	To what extent do you believe that the optimised model is an accurate representation of the intended anatomy?	7.5
5	To what extent do you believe that the models generated using this design method will save on resources and expenses at your organization?	8.0

7. Conclusion

The study indicates that the application of RSM and RP principles to anatomical design has potential usefulness in the medical field. The high-fidelity anatomical models created using this method can be effective tools for training medical students, bringing awareness to patients and improving the overall surgeon-patient communication. To minimise the technological barrier, a design methodology for mitigating the design challenges in fabrication of RP anatomical models was investigated. Moreover, for development of anatomical models, the current study focuses on alleviating the issues of cost and model build time by exploring the use of GA approach combined with CAD and FDM techniques.

Experiments were conducted using RSM approach to facilitate a multi-objective optimisation for the selected objective criteria BT and model volume. The multi-objective optimisation was successful in producing a RP patella model which meets the objectives of the study. Due to deployment of RSM-GA based statistical tools, efficiency of the RP process was increased whilst maintaining anatomical model integrity. The results

showed a 27% savings on model material compared to a non-refined model, minimizing tedious user inputs and manipulation of complex RP machine parameters.

Moreover, this study is an attempt at technical improvements in generating inherently sustainable 3D anatomical models, requiring less post-processing, and lowering 3D printing cost in terms of reducing model and support materials. Thus, these accurately replicated anatomical RP models will be incorporated into routine clinical diagnosis, pre-surgical planning and analysis of complex surgical procedures in the near future.

Furthermore, the customised patient-specific RP models can be used as a decision support tool to develop acceptable CT scanning standards. Future research studies can incorporate more clinical cases to assess the impact of RP models on medical education, surgical planning and patients' outcomes.

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