RESEARCH ON DEPLOYING TECHNICAL FUNCTIONAL ANALYSIS FOR ADDITIVE MANUFACTURING OF A SURGICAL DEVICE FOR INTRAVITREAL INTERVENTIONS

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În lucrare se prezintă o nouă metodologie de dezvoltare a produselor pentru aplicații ale tehnologiilor de fabricare aditivă. Metodologia are la baza tehnici ale analizei functionale tehnice, fiind aplicată la reproiectarea unui instrument chirurgical pentru intervenții oculare. Cercetările evidențiază îmbunătățiri semnificative în funcționalitatea produsului şi reducerea costurilor de producție. Designul unic şi inovant al produsului, a obținut recenzii excelente după testele în laborator şi in vivo. Simulări la oboseală s-au efectuat atât pentru materiale specifice prototipurilor, cât şi pentru cele biocompatibile în vederea comercializării pe piață în producție de serie. Rezultatele cercetărilor sunt folosite de sistemul național de sănătate din Marea Britanie pentru lansarea unui nou produs competitiv.

This paper presents a methodology on designing for additive manufacturing applications using technical functional analysis tools. The methodology is applied to the re-design of a device for intravitreal interventions. The present research leads to significant improvements in product functionality and reduction of manufacturing costs. The unique and innovative design of the product had encouraging reviews after laboratory and in vivo testing. Fatigue simulations were deployed for both prototyping materials and biocompatible materials, in the hopes of series production. Results of the current study are being used by a commercial company in the United Kingdom to support the launch of a new competitive product.

Keywords: life cycle analysis, design for multi-function, design for additive manufacturing

1. Introduction

Product development optimisation methods that give companies a head start have been the focal point of researchers for years. This paper proposes a

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study of functional analysis (FA) focused on the particularities of rapid manufactured (RM) custom products. The authors approach each stage of existence in the product life cycle with technical functional analysis in order to obtain a custom product that better satisfies the customer's needs and yet permits a sustainable manufacturing process. The FA study is targeted on the specific characteristics of rapid manufacturing for single part products and uses tools like FAST (Function Analysis System Technique) diagrams, product life cycle analysis, technical and economic matrices [1, 2, 3, 4]. The study focuses on the functionality of the product throughout its life cycle, starting with development, production, usage, maintenance and finishing with storage or disposal. The research also focuses on sustainability principles [5], like design for multi-functions (DF*x*), design for the reduction and reuse of waste and provide solutions that turn products into models to be followed.

Functional analysis provides a foundation for product management and marketing, being a systematic research method of the functions to be fulfilled by a high quality product or service [6]. This analysis proves essential, from the initial phases of development, as it defines and classifies the functions which a product must have, and at the same time, it sets a performance level to be reached.

The current research seeks to establish a new methodology for product development in additive manufacturing (AM) applications [7]. Functional analysis is used to redesign a surgical device for intravitreal interventions, and specifically in this research, an ocular speculum. The results gained validate the proposed methodology, and provide encouragement for applications in a large variety of sectors.

In the biomedical and healthcare sectors, AM is used in the fabrication of hearing aids, dental restorations, surgical drill guides, anatomical models, orthopaedic implants and the latest innovative application of bio-manufacturing and tissue engineering [8, 9, 10]. Merging of AM technologies with technical FA facilitates major changes, which will lead to product innovation and achievement of sustainable competitive advantage [11].

2. Background of the product

The ocular speculum (Fig. 1) is a surgical instrument used for intravitreal interventions (Fig. 3). The most common interventions are intravitreal injections used to treat a series of ophthalmologic conditions, such as: diabetic retinopathy, macular degeneration, macular inflammation, and occlusion of a retinal vein [12]. These conditions can lead to loss of vision and require immediate treatment, for improving the chances of recovery. Benefits of intravitreal injections depend on the ocular pathology being treated, but mainly include improvement of vision or prevention of worsening of the vision. In the case of an infection, the benefit is direct delivery of the antibiotic/antifungal into the eye close to the nidus of the infection.

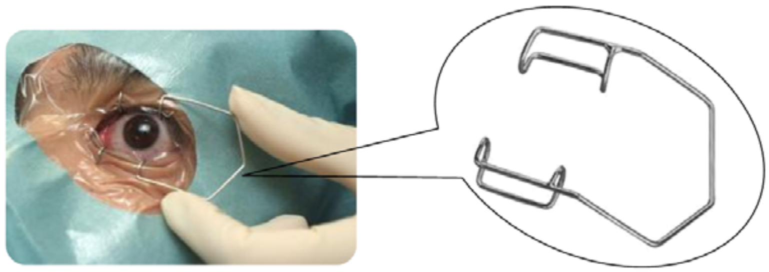

Fig. 1. Original ocular speculum used as the basis for the present research [20]

It is necessary to take into consideration the most common intravitreal medications [12], as it is a key element in the material selection stage, due to chemical interactions that will be studied in the test stage.

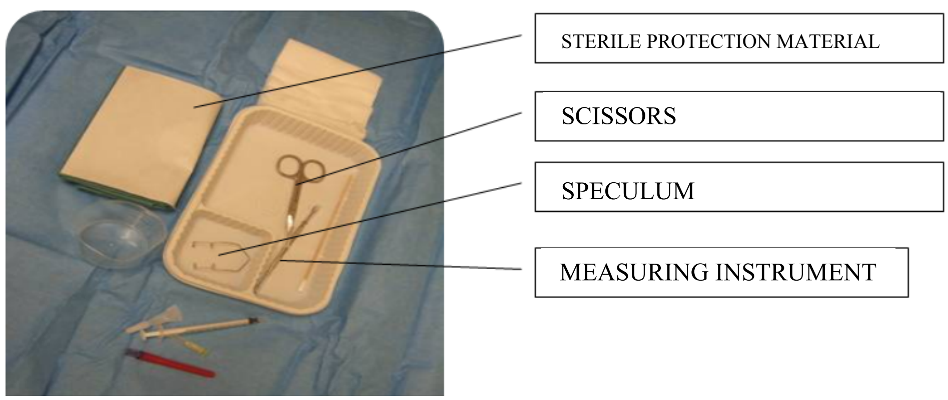

Fig. 2. Disposable eye surgery kit currently used by NHS (National Health System) in United Kingdom [20]

The current process for delivering intravitreal injections is described in the following stages: administering anaesthetic and antibacterial eye drops; utilisation of a disposable eye surgery kit (Fig. 2); injection and delivery of the active substance (Fig. 3).

The main disadvantages and complications of this procedure can be summarised, as follows [12, 20]: A high number of patients need this procedure, thus the demand for this product is high; A recent study conducted in the United Kingdom shows that there are currently 300,000 such procedures undertaken annually. The disposable kits have a relatively high purchase costs. The procedure is often painful for the patient, with lengthy recovery periods required; A high number of infections have been reported and complications can often lead to blindness and even the loss of the eye. Bleeding (subconjunctival, vitreous hemorrhage) and retinal tear / detachment can occur, even cataract (from inadvertently hitting the lens). The need for surgery (to address some of the complications above) and for multiple injections in future (according to specific pathology of the disease) has been observed.

Fig. 3. Intravitreal injection and delivery of the active substance [12]

3. Method

The FA approach consists of two successive assessments: external FA and internal FA [1, 2]. External FA, completed by Functional Specifications, expresses the client's point of view, which uses the product or service and highlights its external functions. Internal FA is used in the product design stage and helps the manufacturer to develop the optimal solution that best meets the concrete expression of need, at minimum cost. It expresses the manufacturer's point of view and highlights the technical functions (internal functions). When deployed, FA takes into consideration all life-cycle stages of the product, identifying the main stages of existence, thus highlighting the main functions that the product needs to perform in order to meet both customer expectations and producer specifications [3]. The FA method consists of the following steps: establishing the need, identifying the functions using FAST diagrams [3], function ranking and valuation matrices, and technical and economic dimensioning of functions. Economic analysis is undertaken considering different types of materials and their individual characteristics, costs, life span, recycling procedures, production volumes and other particular features of the parts and of the production process. The objective of FA, in this specific case, is to propose a new concept for the speculum that will further be subjected to FEA (Finite Element Analysis) studies and practical tests for validation.

3.1. Establishing the need

To correctly establish the need, the French Value Analysis Society [1, 2] proposes as an instrument "The insect with horns" – fr. Bête à Corne (Fig. 4) [3, 13]. The instrument is deployed by answering a series of questions as follows: 1. the body of the insect: "What product is being analysed?"; 2. the left horn of the insect: "To whom the product fulfils the need?"; 3. the right horn of the insect: "On what, or whom does it act?; 4. the support of the insect: "Why does it do what it does?" and "For what purpose does it exist?".

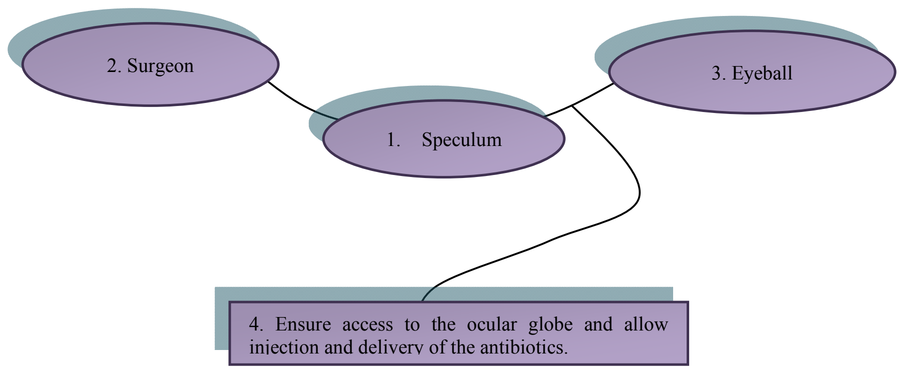

Fig. 4. Bête à Corne deployed for the eye speculum - Adapted from [2, 3]

According to Figure 4 above, the need can now be formulated accurately: "The eye speculum must allow the surgeon to perform intravitreal injections, ensuring proper access to the eyeball".

3.2. Function identification

In order to accurately identify the functions, FAST will be used. In this stage, FAST is applied for the "usage" state of existence of the product, as it was established that other states of existence do not have a significant influence in the product development process.

A FAST diagram is used to logically identify the product's functions, by hierarchically answering the question "How?", starting with the main function and then to other sub-functions, until the desired level of detail is reached (Fig. 5). To verify the accordance of the relations between the functions, the question "Why?" is answered from right to left.

A correct identification of the functions is vital, as it influences the entire process of FA. The areas for improvement must be accurately established, thus only the value of the most important functions will be increased.

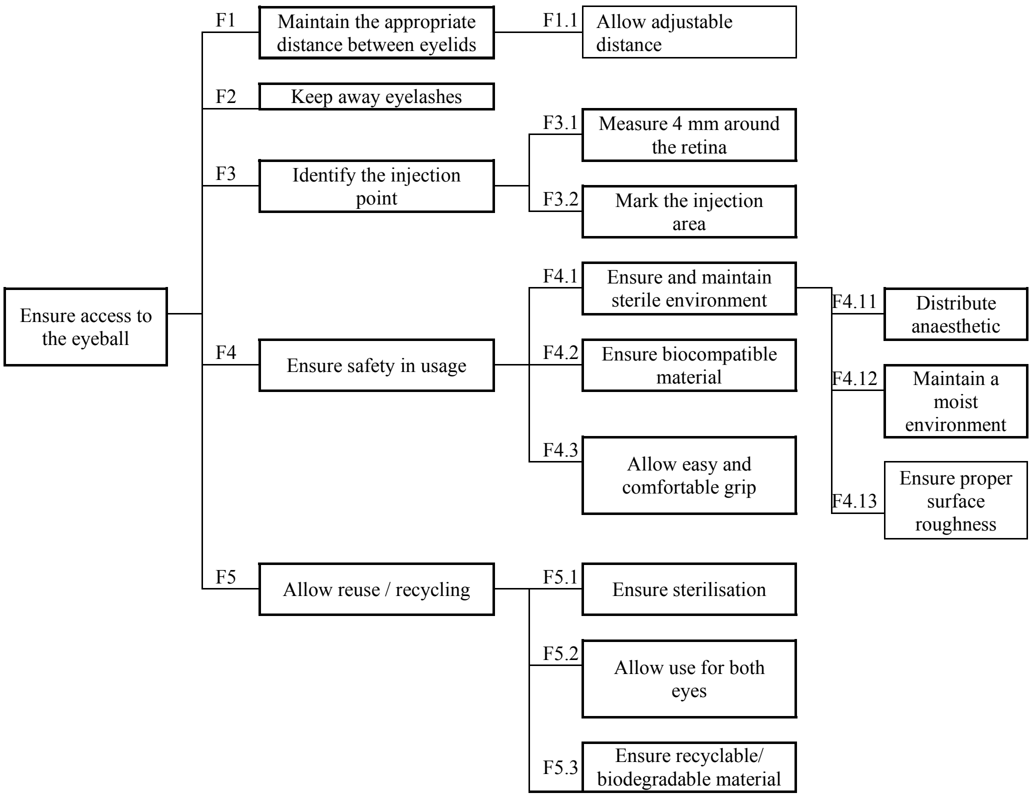

Fig. 5. FAST diagram for the ocular speculum.

3.3. Function ranking and the valuation matrix

Ordering the functions involves their classification in a logical manner, considering a redesign study. This step allows the identification of the interdependence relations between various functions. Ranking the functions allows evaluation of the importance of each function, independent of any constructive solution. To rank the functions and establish the global importance factor of each function, a ranking and valuation matrix must be put together [1, 2, 7, 13]. In order to do so, the FA team grades objectively, each function in relation with the other four. The FA team is comprised of AM specialists and surgeons with background knowledge in designing surgical devices.

To complete the valuation matrix, the following rules are applied [1, 2]:

- The functions are compared two by two, starting with the columns. If function F1 is more important than function F2, then at the intersection of

F1's column with F2's row, the number 1 is be written; therefore at the intersection of F2's column with F1's row, the number 0 is be written;

- On the diagonal of the matrix, the number 1 is be written (as the level of importance is equal).

The importance level of the function is calculated using the following formula:

$$I_i = \sum_{i,j=1}^{n} F_{ij} \quad (1)$$

The weight of the functions in the end use value of the product is analysed by calculating the following parameters:

- The coefficient of importance:

$$\mathrm{C_i} = \mathrm{F}_{ij} \Big/ \sum_{i,j=1}^{n} F_{ij} \quad . \quad (2)$$

- The weight of the function:

$$\mathrm{W_i} = \left(\mathrm{F}_{ij} \Big/ \sum_{i,j=1}^{n} F_{ij} \right) \cdot 100 \ , \quad (3)$$

where, $I_i = \sum_{i,j=1}^{n} F_{ij}$ is the sum of *j* elements from column *i* (Table 1).

After all FA team members and manufacturing practitioners complete the function valuation matrix, in order to establish the final ranking, the following had to be calculated:

- The calculated weighted value:

$$\bar{I} = (\sum_{k=1}^{N} I_k)/N \quad , \quad (4)$$

where, *N* is the number of team members;

I_k is the importance level for each function, given by *N* team members.

- The global importance factor:

$$\overline{C} = (\sum_{k=1}^{N} C_k)/N \ , \quad (5)$$

where, C_k is the coefficient of importance, given by *N* team members.

- Global weight:

$$\overline{W} = (\sum_{k=1}^{N} W_k)/N, \quad (6)$$

where, W_k is the weight of the function, given by *N* team members.

The final ranking matrix is displayed in Table 1 below. Values of the above estimators are shown in Table 1, for each individual function.

Table 1

Ranking Matrix for the ocular speculum

Function		F1	F2	F3	F4	F5
F1		1	0	0.33	0.67	0
F2		1	1	0	1	0
F3		0.67	1	1	1	0
F4		0.33	0	0	1	0
F5		1	1	1	1	1
Calculated Weighted Value	$\bar{I} = \left(\sum_{k=1}^{N} I_k\right) \Big/ N$	4.00	3.00	2.33	4.67	1.00
Global Importance Factor	$\overline{C} = \left(\sum_{k=1}^{N} C_k\right) \Big/ N$	0.267	0.200	0.155	0.311	0.067
Global Weight	$\overline{W} = \left(\sum_{k=1}^{N} W_k\right) \Big/ N$	26.7%	20%	15.5%	31.1%	6.7%

The importance of the function in the total value was noted with x_i, which will be used to analyse the disproportion of the functions for the ocular speculum (Fig. 5, Fig. 7 and Fig. 8).

The valuation matrix shows that the most important functions are F4 (31.1%), F1 (26.7%) and F2 (20.0%), corresponding to “Ensure safety in usage”, “Maintain the appropriate distance between eyelids” and “Identify the injection point” respectively. All the sub-functions that follow from these will have the same importance factor compared with the other groups. If it’s necessary, a more detailed ranking analysis can be conducted, to show the importance of the sub-functions amongst themselves within a single main function. This type of ranking is necessary so that the functions that need additional focus can be identified. In descending order, all the other functions will be dealt with.

3.4. Technical dimensioning of the functions

Technical dimensioning is necessary for establishing the characteristics and operating limits of the functions. For the ocular speculum, the final design must fulfil the technical requirements listed in Table 2 below. For an accurate technical dimensioning of the functions, the characteristics that best express the role of the functions within the assembly of the product must be identified. Thus each technical dimension is stated by a label, value and a measuring unit. Some functions can have multiple technical dimensions.

Table 2

Ranking Matrix for the eye speculum

<table>
<tr><th>No.</th><th>Function</th><th>Technical Characteristics</th><th>M.U.</th><th colspan="2">Limits</th></tr>
<tr><td>F1</td><td>Maintain the appropriate distance between eyelids</td><td>Distance</td><td>[mm]</td><td colspan="2">ϕ20 – ϕ25</td></tr>
<tr><td>F3.1</td><td>Measure 4 mm around the retina</td><td>Distance</td><td>[mm]</td><td colspan="2">3.5 – 4</td></tr>
<tr><td rowspan="2">F4.13</td><td rowspan="2">Ensure proper surface roughness</td><td rowspan="2">Roughness (Ra)</td><td rowspan="2">[μm]</td><td>X/Y</td><td>Z</td></tr>
<tr><td>16(±2)</td><td>38(±4)</td></tr>
<tr><td>F4.2</td><td>Ensure biocompatible material</td><td>ASTM</td><td>-</td><td colspan="2">According to the technology</td></tr>
<tr><td>F5.1</td><td>Ensure sterilisation</td><td>Autoclave</td><td>[^{0}C/min]</td><td colspan="2">120^{0}C for 20 min</td></tr>
<tr><td>F5.3</td><td>Ensure recyclable/ biodegradable material</td><td>British Material Standards</td><td>-</td><td colspan="2">-</td></tr>
</table>

3.5. Economic dimensioning of the functions

Economic dimensioning of the functions represents the manufacturing cost of a specific function, expressed by material costs, labour and overheads. Thus the cost of each product component is distributed on each function that contributes, in different proportions, to the physical realisation of that specific component. In the first step, a percentage distribution of the costs is recommended. In the second stage, the costs of each function are calculated. The ocular speculum is a single part product, thus the economic dimensioning is simplified by undertaking the second stage directly.

Table 3

Ocular speculum – cost/ value structure (Iteration 2)

<table>
<tr><th colspan="2" rowspan="2">Component Costs</th><th rowspan="2">Total Costs (£)</th><th colspan="5">Functions</th></tr>
<tr><th>F1</th><th>F2</th><th>F3</th><th>F4</th><th>F5</th></tr>
<tr><td rowspan="7">Speculum</td><td>Maintain eyelids position</td><td>1.80</td><td>1.80</td><td>-</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>Keep away eyelashes</td><td>1.40</td><td>-</td><td>1.40</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>Measuring element</td><td>1.10</td><td>-</td><td>-</td><td>1.10</td><td>-</td><td>-</td></tr>
<tr><td>Anaesthetic delivery system</td><td>0.50</td><td>-</td><td>-</td><td>-</td><td>0.50</td><td>-</td></tr>
<tr><td>Humidify system</td><td>0.50</td><td>-</td><td>-</td><td>-</td><td>0.50</td><td>-</td></tr>
<tr><td>Grip element</td><td>1.20</td><td>-</td><td>-</td><td>-</td><td>1.20</td><td>-</td></tr>
<tr><td>Use in both eyes elements</td><td>0.40</td><td>-</td><td>-</td><td>-</td><td>-</td><td>0.40</td></tr>
<tr><td colspan="2">Function Costs in Value (£)</td><td>6.90</td><td>1.80</td><td>1.40</td><td>1.10</td><td>2.20</td><td>0.40</td></tr>
<tr><td colspan="2">Function Costs in Percentage (%)</td><td></td><td>26.1%</td><td>20.2%</td><td>16%</td><td>31.9%</td><td>5.7%</td></tr>
</table>

The costs are represented in Sterling (£), considering the nature and area of the research conducted. Table 3 is put together in order to identify the cost structure in the value of the product, after the second iteration of the analysis.

The percentage values of the functions participation in the total costs are summarised as follows: y_1 = 26.1 %; y_2 = 20.2 %; y_3 = 16 %; y_4 = 31.9 %; y_5 = 5.7 %. Together with x_i values, these data will be used to evaluate the costs/value rapport of the functions. The most expensive functions will be identified and the individual contribution to value brought by each function to the product (Fig. 6, Fig. 7 and Fig. 8). If the costs are disproportionately higher than the contribution to value, then new technical solutions are proposed, in order to balance out the costs/value distribution.

4. Results and Discussions

The comparison of the functions value and cost weightings needs to identify: the functions that are very expensive in relation to the others; the functions that are too expensive in relation to their contribution to the value of the product; the functions that are too expensive in relation to the existing technical possibilities of production. In order to assess the relationship between costs and value, the diagrams in Figures 5, 6, 7 and 8 are plotted.

The computational elements for plotting the diagrams are calculated with the smallest squares method [14, 15, 16] and synthesised in Table 4 below.

Table 4

Computational elements for ocular speculum

No.	**Calculated Components**	**Function**					**Total value**
		F5	F3	F2	F1	F4	
1	x_i	6.70	15.50	20.00	26.70	31.10	100.00
2	y_i	5.80	16.00	20.20	26.10	31.90	100.00
3	x_i^2	44.89	240.25	400	712.89	967.21	2365.24
4	$x_i * y_i$	38.86	248	404	696.87	992.09	2379.82
6	$S=(y_i - a*x_i)^2$	0.886	0.164	0.006	0.585	0.370	2.010
7	S'	12.,61	-12.54	-3.07	40.83	-37.84	0

The following parameters have to be calculated [4] in order to apply the smallest squares method:

- The regression line:

$$y = a \cdot x \tag{7}$$

where, x_i represents the functions value weighting;

y_i – functions cost weighting;

a – regresion parameter:

$$a = \frac{\sum x_i y_i}{\sum x_i^2} \tag{8}$$

- The estimator S is determined with the smallest squares method:

$$S = \left(y_i - a \cdot x_i\right)^2 \rightarrow \min. \tag{9}$$

The solution is considered acceptable if the dispersion *S'* reaches towards zero. In other words, the faster *S'* reaches zero, the better the solution is:

$$S' = \frac{\partial S}{\partial a} \tag{10}$$

- Dispersion *S*' must be as close as possible to a zero value in order to validate the solution.

$$S' = \sum\left(2 \cdot a \cdot x_i^2 - 2x_i y_i\right) \rightarrow 0 \tag{11}$$

- Angle of regression line:

$$\alpha = arctg \frac{(a)180}{\pi} \tag{12}$$

After processing the information in Table 4, the following values have been obtained: a = 1.006, α = 45.18°, S = 2.01 and S' = 0.

The initial disproportions between the function costs and their contribution to the product value have been eliminated in the second iteration of the analysis. Nevertheless, some disproportions can still be observed for functions F1, F4 and F5 (Fig. 5, Fig. 6). If the designer decides that a third FA study must be undertaken, the functions mentioned above will be analysed.

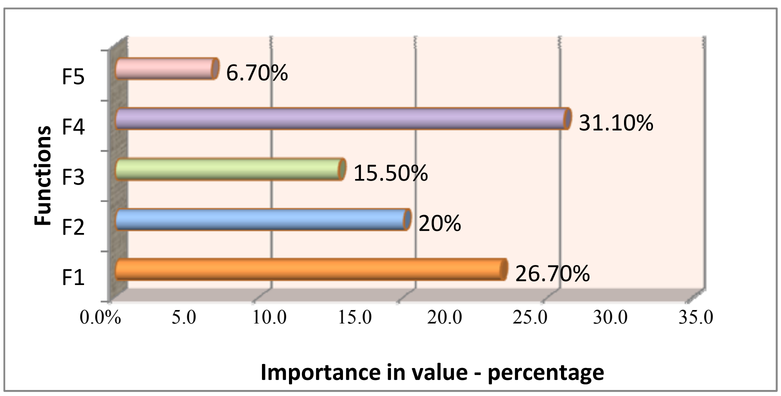

Fig. 5. The importance of functions in value (x_i) for the ocular speculum.

The research solution will be focused with priority on the components and materials that contribute to those specific deficient functions.

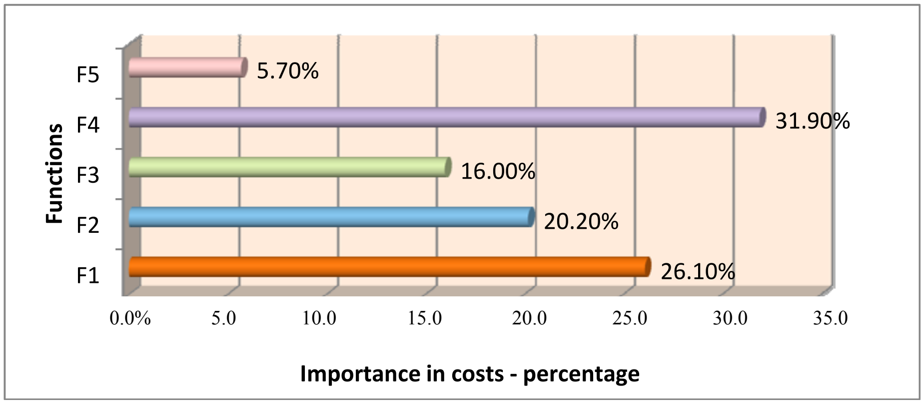

Fig. 6. The importance of functions in costs (y_i) for the ocular speculum.

The above diagrams are used for comparison of the functions costs in relation to their contribution to the value of the product. The most expensive functions and with the highest weighting in the total cost of the product can be identified. Secondary functions that are very expensive in relation to the objective functions, or even more expensive than these, can be highlighted for further improvement. The weighting of effort for a certain function must match its weighting in the total value of the product. To validate these aspects regression analysis is used. The real situation is represented in Figure 7 by plotting the regression line $y = 1.006*x$, with a tilt angle of $\alpha = 45.18°$, using the smallest squares method.

A base criterion for FA is obtaining a minimum value for estimator *S'* [4], which is in fact a dispersion that characterises the scattering degree of the system. In order to diminish estimator *S'* the points must be aligned as perfectly as possible along this straight line. Redesigning the functions placed above the regression line, entails either lowering the costs, or increasing the contribution in value. For the points below the line, the problem is more complicated, thus the objective is to redesign and diminish costs for the functions corresponding to the points above the line. By changing those specific points and re-plotting the diagram, the tilt of the regression line will change and the situation of the new values will be different. In this specific case the functions that need additional focus are F3 and F4.

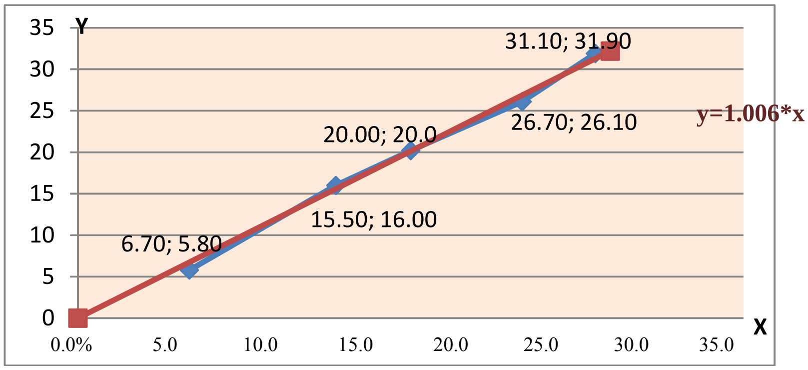

Fig. 7. The importance of functions in value (x_i) and costs (y_i) for the ocular speculum.

The minimisation of the dispersion *S'*, leads most of the times to cascading the FA studies, and thus optimisation of the constructive solution becomes an iterative process.

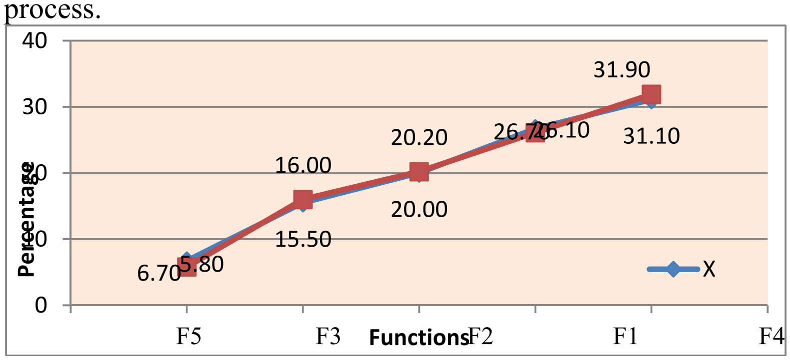

Fig. 8. Comparison of value weighting and functional costs.

Fig. 8 shows the value estimations of the experts compared to the cost weightings. In some cases, the cost is disproportionately higher for the value that the function provides. So during the FA process, the goal is to move all the cost points (y_i) such as to overlap the value points (x_i). This is done by either, decreasing the cost, or increasing the value of a specific function. In this case, functions F3 and F4 will be dealt with if the customer is not satisfied.

After analysing the above diagrams, the optimal design concept is proposed (Fig. 9). The model incorporates all the functions that the product needs to perform at the stated standards.

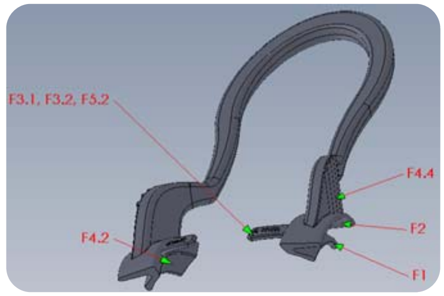

Fig. 9. Identification of the functions on the optimal concept of the ocular speculum.

The most important contributions brought to the ocular speculum after conducting the FA research, are as follows: Inclusion of a measuring element in the single part ocular speculum; Designing an internal channel for the distribution of the antibiotic solution or anaesthetic (Fig. 10); Replicating the surface of the eyeball for comfort improvement and reduction of lesions and lacerations caused by the original product; The possibility of utilisation of the same item for both eyes; Re-usage after sterilisation in an autoclave; Recycling of the product in accordance with European standards for medical waste (Clinical waste is EWC 18 01 03 and class 6.2 UN 3291, EWC – European Waste Classification).

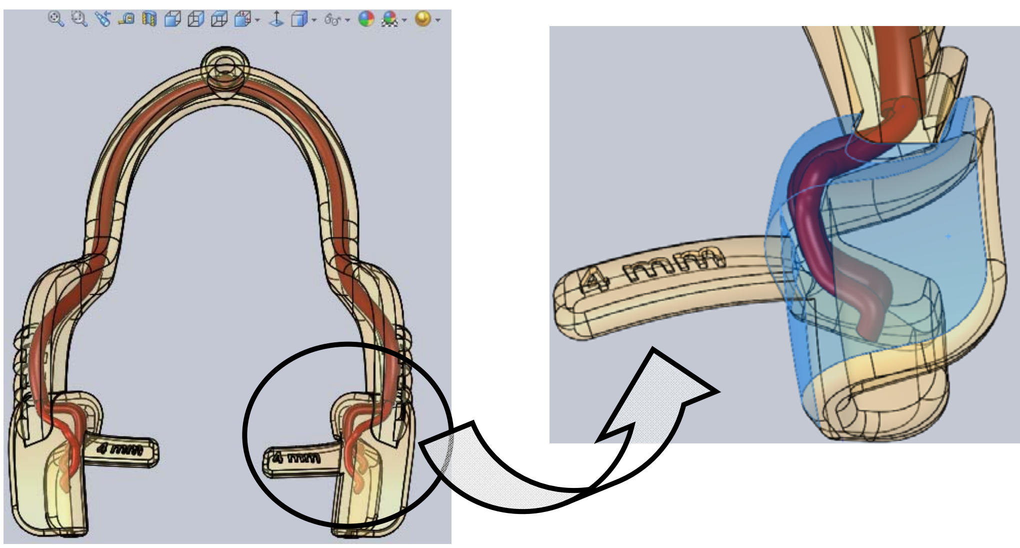

Fig. 10. Internal channel for distribution of antibiotic/ anesthetic.

Besides the theoretical research methods used for developing the product, the particularity of the application domain of the product imposes a series of tests in real working conditions. These tests aim to establish the conformity of the product with the existing regulations and the suitability with the patients' anatomy. For the ocular speculum, the feedback from the surgeon and patients led to minor changes in the shape of the product. An evolution of the product, starting from the first prototype, is subsequently presented.

The first prototypes were fabricated using AM and tested in situ by the surgeon. Figure 11 shows the first prototype that was manufactured using the Stratasys Dimension Fused Deposition Modelling AM process , from Acrylinitrile Butadiene Styrene (ABS).

Fig. 11. First ocular speculum prototype from white ABS

The feedback received led to the manufacturing of a second test prototype, presented in Figure 12. There are not many structural differences between the two prototypes, the majority of the observations were related to the shape of the handle.

Fig. 12. Second version of the ocular speculum prototype fabricated from black ABS (FDM printed products with support material - left picture)

The different changes to the prototypes, due to the feedback from in vivo testing, are illustrated in Figure 13 below. The first concept of the speculum was the initial prototype that was presented to the surgeons. The feedback led to changes in the shape of the gripping and measuring elements (Model 2, Fig. 13). Model 3 of speculum has a modified height and shape of the handle, an improved gripping surface with anti-slippage elements and different eye contact surface. Starting with model 4, the angle of the handle is changed to improve usage at both eyes. Model 5 has two measuring elements to provide guidance when used at both eyes and Model 6 has the internal channels for anaesthetic distribution.

Amongst the advantages of the new model of the eye speculum, obtained after deploying FA, the following are mentioned:

- Reduction of costs from £14 to £7 per part;
- Reduction of the number of surgical instruments used in the procedure of intravitreal injections, by multifunction design;
- Reduction of procedure time;
- Reduction of surgery steps and preparation steps;
- Increased number of patients treated per unit of time;
- Easier to use by the surgeon;
- Increased comfort for the patient by reproducing the eyeball surface;
- Reduced environmental impact;
- Helps reduction of the infection rate by distributing antibiotic during the procedure.

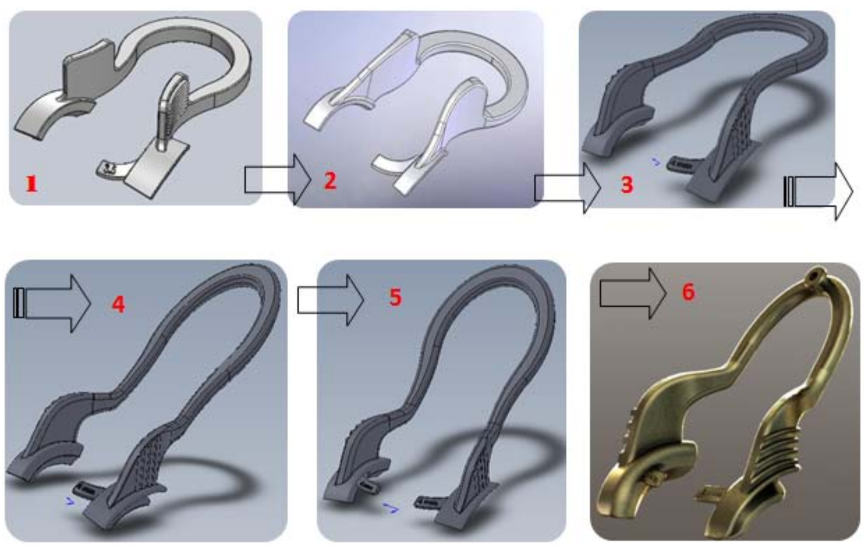

Fig. 13. Design evolution of ocular speculum prototypes; Prototype 6 is the optimal concept.

The inlet for the liquid antibiotic was designed to fit a standard syringe nozzle, thus it can be used without any additional tubing being required.

4.1. Material selection and stress analysis

After deciding on the final optimal concept of the speculum, stress analysis and fatigue test are undertaken with Solid Works Simulation Add-In. In order to run the simulations a build material must be selected.

The prototypes were fabricated from ABS plastic in white and black, and suitable biocompatible materials will be chosen for production. Choosing the appropriate material for mass production could turn out to be challenging, as it has to comply with the EU Medical Devices Directive 93/42/EEC and follow the safety assessments of ISO 1093/EN 3093 – Biological Evaluation of Medical Devices [17, 18]. Some examples of materials are listed in Table 4, along with the appropriate application.

Table 4

Proposed materials for prototyping and production

Material	Characteristics (and AM technology proposed)	Application
MED 60™	Biocompatible, Clear (Objet)	Production – ISO 10993 evaluated
FullCure®630 FullCure®655	Clear (Objet) Rose Clear (Objet)	Production – ISO 10993 evaluated
FullCure®680	Skin Tone (Objet)	Production – ISO 10993 evaluated
Full Cure 720TM	Simulate Standard Plastics – Transparent (Objet)	Prototyping & Functional Testing
DurusWhite™	Polypropylene-like (Objet) with secondary material for improved thermal resistance	Prototyping & Functional Testing

Static and fatigue analysis is undertaken for two of the above materials: MED 60™ and Durus White™. The biocompatible clear material from Objet is chosen for a possible production application due to its primary characteristics. MED610™ is a material featuring good dimensional stability and colourless transparency. The material is ideal for applications requiring prolonged skin contact of over 30 days and short term mucosal-membrane contact of up to 24 hours. Objet Bio-Compatible material has five medical approvals including Cytotoxicity, Genotoxicity, Delayed Type Hypersensitivity, Irritation and USP Plastic Class VI [17, 18]. Durus White™ is chosen for the simulation analysis considering it a proper material for the prototyping application. Objet DurusWhite™ is a polypropylene-like material, ideal for a broad range of applications that require the appearance, flexibility, strength and toughness of Polypropylene [17].

The mesh parameters used for both materials is identically defined, with a high mesh quality. The curvature based mesh has a maximum element size of 1.775mm, minimum element size of 0.355mm and an element size growth ratio of 1.6. The solid mesh with four Jacobian points was completed in 34 seconds. Figure 14 shows the complete mesh after defining all the above parameters and the static loads. A static fixture was defined around the inlet of the speculum and a force of 1 N per item was defined normal to the lateral surfaces, simulating the grip in usage. Material characteristics are defined from Objet data sheets provided on the company's web site [19].

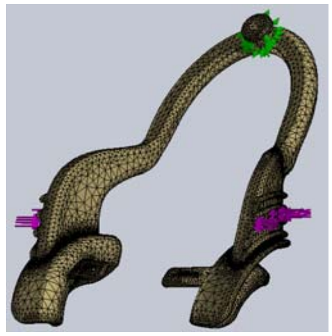

Fig. 14. Meshing and loads on the optimal concept of speculum.

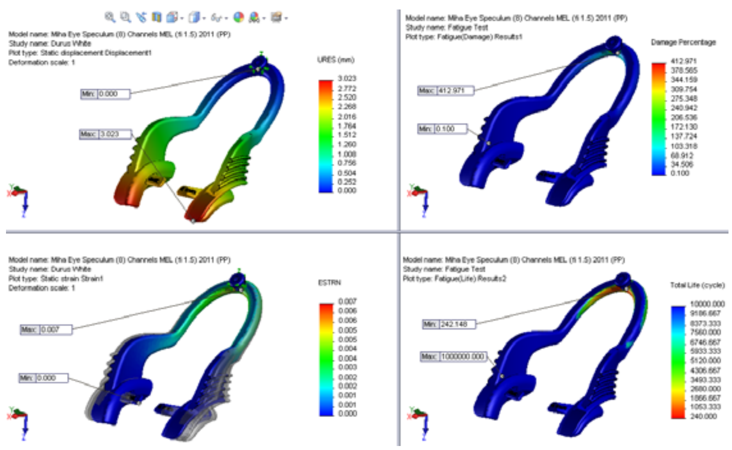

Fig. 15. Static simulations (left) and Fatigue Test (right) for Durus White™.

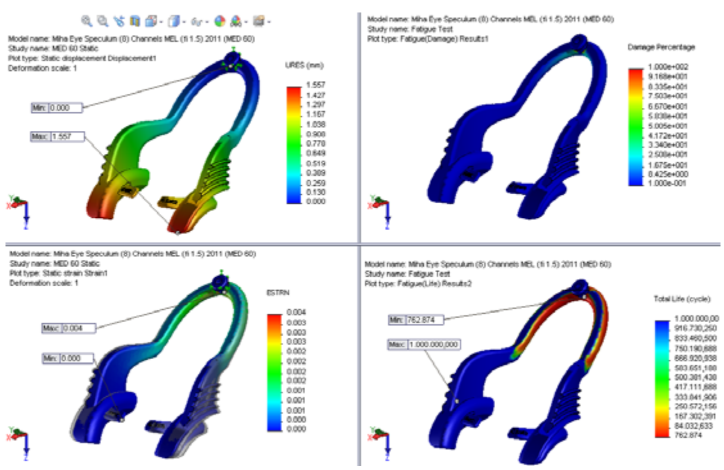

Fig. 16. Static simulations (left) and Fatigue Test (right) for MED 60™.

Simulations show that the product has a total life of minimum 242 cycles for Durus White™ (Fig. 15) and 762 cycles for MED 60™ (Fig. 16). Static displacement analysis reveals a maximum displacement of 3.02 mm for the polypropylene-like material (Fig. 15). For the biocompatible material, the maximum displacements are 1.557 mm on each side of the speculum (Fig. 16). Maximum equivalent strain was registered at 0.007 and 0.004 respectively (Fig. 15 and Fig. 16). After analysing the results, it can be stated that the new design of the speculum can be safely reused and tested, in both cases: prototype and final product.

5. Conclusions

In this case, the FA research facilitated the identification of the areas of possible cost and functional improvement for an ocular speculum used in intravitreal interventions. The fabrication of the intricate shapes of the proposed constructive solutions was possible only by employing AM technologies. This application was designed for rapid prototyping and rapid manufacturing. The shape and internal elements of the product can be obtained only with AM technologies, as more conventional manufacturing technology (e.g. machining, moulding, etc.) would be very expensive. The internal channel is an indispensable element, as it addresses one of the most important complications of the procedure, namely post-operatory infections. Therefore it can be stated that FA techniques and AM technologies are indispensable in developing the ocular speculum.

Future work involves designing a flexible element that will allow an adjustable diameter of the ocular speculum. Some concepts have already been presented to surgeons for validation. Fluid tests must be undertaken to assess the suitability of the internal channels. Three different versions are now being produced and will be tested. Variations in the diameter of the channels and the wall thickness are considered for testing.

Currently the ocular speculum is in its final in-vivo testing in actual eye procedures. The next step is to commercialise and manufacture this concept in a larger scale, starting with established markets in the United Kingdom.

R E F E R E N C E S

[1] *K.Ulrich., S.Eppinger*, Product Design and Development, 4th Edition McGraw Hill Ltd., 2009.

[2] *J.D.Bolton, D.J.Gerhardt*, Value Methodology: A Pocket Guide to Reduce Cost and Improve Value through Function Analysis, L.D. Miles Value Foundation, 2009.

[3] *AFNOR*, Management par la valeur et ses outils. Analyse fonctionnelle, analyse de la valeur, conception à objectif désigné, AFNOR Publishing, Standards Series, Paris, 2004.

[4] *F.Chichernea,* AnalizaValorii (Value Analysis), ISBN (10) 973 – 635 – 850 X, Transilvania University Publishers, Braşov, Romania, 2007.

[5] *** The Living Principles for Design, American Institute of Graphic Arts, Center for Sustainable Design, http://www.livingprinciples.org/ [Last Accessed 15.02.2012]

[6] *I.Ioniță*, Managementul calității şi ingineria valorii (Quality Management and Value Engineering): Manual universitar, Editura ASE, Bucureşti, ISBN 9786065050266, 2008.

[7] *M.E.Lupeanu, A.E.W.Rennie, C.Neagu, H.K.Celik,* Product optimisation by rapid manufacturing and targeted functional analysis: a case study for a pump impeller, The 16th European Forum on Rapid Prototyping & Manufacturing, Ecole Centrale Paris, France, 2011.

[8] *T.Wohlers*, Wohlers Report 2010: Additive Manufacturing State of the Industry Annual Worldwide Progress Report, Wohlers Associates, Inc., Colorado, USA, 2010.

[9] *B.Bidanda, P.Bartolo (Editors)*, Virtual Prototyping & Bio Manufacturing in Medical Applications, Springer, ISBN: 10: 0387334297; 2008.

[10] *I.Gibson (Editor), J.Wiley,* Advanced Manufacturing Technology for Medical Applications: Reverse Engineering, Software Conversion and Rapid Prototyping, ISBN: 13: 978-0470016886, 2006.

[11] *L.Hao, D.Raymond, G.Strano, S.Dadbakhsh*, Enhancing the sustainability of Additive Manufacturing, 5th International Conference on Responsive Manufacturing (ICRM 2010), Ningbo, China, 11-13 January 2010, pp. 390-395.

[12] *** http://eyewiki.aao.org/Intravitreal_Injections [Last Accessed 20.02.2012].

[13] *M.E.Lupeanu, A.E.W.Rennie, C.Neagu,* Additive Manufacturing Technologies and Functional Analysis used in Product Development, Proceedings of the 12th n Rapid Design, Prototyping & Manufacturing Conference, CRDM Ltd. Publishing, High Wycombe, Editors: Rennie A.E.W., Bocking C.E., Lancaster, United Kingdom, ISBN 978-0-9566643-1-0, 2011, pp. 105-112.

[14] *M.Iosifescu, O.Stănăşilă, D.Ştefănoiu*, Enciclopedie Matematică (Mathematical Encyclopaedia), Editura A.G.I.R, ISBN 978-973-720-288-8, 2010.

[15] *Gh.Cenuşă, C.Raischi, D.Baz, M.Toma, V.Burlacu, I.Săcuiu, I.Mircea*, Matematici pentru Economişti (Mathematics for Economists), Editura CISON, ISBN 973-99725-3-5, ISBN 973-594-138-4, 2002.

[16] *A.Filip*, Matematici aplicate în economie: Culegere de probleme (Applied Mathematics in Economy: Problems), Editura ASE, 2002, ISBN 973-594-138-4, 2002.

[17] *** Standard ISO 1093/EN 3093 – Biological Evaluation of Medical Devices http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=44908 [Last Accessed 23.02.2012]

[18] *S.S.Saliterman*, Biocompatibility, FDA and ISO 10993, Department of Biomedical Engineering, University of Minnesota, Biomedical Engineering Design Lecture, 2011, http://www.tc.umn.edu/~drsteve/lectures/Biocompatibility , [Last Accessed 23.02.2012]

[19] *** Objet Material Data Sheets, http://www.objet.com/Misc/_Pages/Materials_Data_Sheets/ [Last Accesed 25.02.2012]

[20] *T.Eke*, Consultant Ophthalmologist at Norfolk & Norwich University Hospital, A device for simpler, safer intra-vitreal (eye) injections, Health Enterprise East Innovation Competition, September 2010.