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Design of Plastic Medical Tray: A Case Study of Orthopaedic Implant Packaging

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Abstract

The plastic medical tray is commonly used for medical device packaging such as the implant or surgical instruments. The tray can be undergone gamma-ray exposure to sterilizing the medical devices inside. The tray keeps medical devices free from micro-living organisms and protects them from contaminated external environments. The plastic sheet is usually used for producing the tray which turns into a final tray shape using thermoforming. During the tray design process, factors such as the dimension of medical devices, ergonomics, and strength, have to be taken into consideration. Computer-Aided Design/Three-dimensional Printing (CAD/3DP) technologies were applied for verification of the tray geometry whereas finite element methods are applied for strength analysis. Three-dimensional (3D) models of the tray, which are referenced from the dimension of medical device, were 3D printed to test ergonomics for operating room (OR) nurses handling. After that, 3D models were evaluated the strength to ensure safety during delivery. From the analysis, the geometry of the tray was appropriate for handling with sufficient strength. The bottom corner of the tray is a critical point since it presents a high-stress magnitude. The load of 54.6 kg-f deforms the tray was less than 0.5-mm, confirming the vertical stack storage.

Keywords: Plastic medical tray, Medical device, Packaging design, Packaging analysis

1. Introduction

Medical devices, especially a long-term implanted in the body, requires sterile condition before serving to the surgery. Package for protecting medical devices away from contamination is considered as an essential requirement supplement to the implant design process. Desired characteristics of medical device packaging include sterilization compatibility, ease of forming, heat resistance during sealing, strength, and economic-scale (Bix & Fuente, 2009).

Generally, various sterilization methods are used to deactivate micro-living organisms which are autoclaves, stream, ethylene oxide gas, and gamma-ray radiation. For short-duration use invasive medical device or non-invasive medical device, the first four sterilization methods are used. However, the long term invasive implant or instrument in contact with blood such as a surgical glove, orthopaedic implant, and prosthesis, gamma-ray radiation is usually selected as a sterilization method. The gamma ray method presents the advantages in a high Sterility Assurance Level (SAL) and is simple to control. Compared to the other aforementioned techniques, they present complications in penetration in a narrow cavity, and a long period of time for the process.

Gamma-ray method uses Cobalt-60 (^{60}Co) or Caecium-137 (^{137}Ce) to generate the radiation. A-dose of 25 kGy is considered as a reference for sterilization (Silindir & Özer, 2009). In order to design the implant package which is good when undergoes gamma ray sterilization, a rigid plastic type is usually selected to make a package.

Suan Sunandha Science and Technology Journal

The shape of a package should depend on the shape of the implant. The optimal gap between package and the implant is required. The large gap may introduce the movement (momentum) of implant which could lead to damage of the package during transportation. The lower gap may be difficult to get the implant out of the package. In addition, the shape should be able to handle by operating room (OR) staff during the opening and transferring from unsterilized zone to sterilize zone.

The packages are kept in-stack to minimize the storage space in the hospital. The strength of the package is important to withstand the weight above it. Analysis of the strength can define the maximum storage package in a vertical direction. The deformation of the package could lead to a tear of plastic and eliminate the sterile conditions.

In this paper, it presents a case study of implant packaging design for humerus endoprosthesis. The endoprosthesis is intended to replace the tumor bone region, composing of four parts which are head, neck, body, and stem. The body and stem are available in three sizes in order to make it is selectable for various resection bone lengths. The requirements from the company are to design the single package which fits all parts for economic matters.

2. Materials and Methods

The design control process for the medical devices was applied to design the medical tray. The process contains six essential procedures as follows: (1) Getting user needs, (2) Identifying design input, (3) Performing design process, (4) Inspecting the design output, (5) Releasing the product, and (6) Design review. The (1) to (5) is a sequential procedure that needs to be done step-by-step. The design review in (6) is intended to be checkpoints during product development to ensure the product design is safe and effective. Thus, it has to be done in every procedure in (1) to (5). A comparison between design output in (4) and design input in (2) is “design verification”, and comparison between user needs in (1) and product performance in (5) is “design validation”. (Kinsel, 2012)

In this paper, the medical tray design process included step (1) to (5) and performed the design verification. The design validation in this case, which involves biological and clinical tests. It is beyond this scope of this paper.

The design process started by getting the user needs. The authors obtained the requirements from the medical practitioners. In addition, reviewing literature, industrial standard, product specification, drawing, and regulation relates to the design process was also performed in this step. The user needs and all related documents were summarized into design input.

In the design process, the 3D CAD models of endoprosthesis were reversely created using CAD software (VISI, Vero Software, UK). The external shape of the endoprosthesis is considered as an important shape in the design process. The unnecessary detail of the 3D model was neglected to simplify the CAD works. Endoprosthesis part has approximate bounding dimension 42 x 36 x 42 mm for head, 20 x 20 x 58 mm for neck, 18 x 18 x 76 for body, and 24 x 24 x 122 mm for stem.

After finishing the CAD design, the test for fitting was first evaluated in CAD software (VISI 21, Vero Software, UK). Then, the models of packaging and endoprosthesis were manufactured using fused deposition modeling (FDM) machine (M200, Zortrax, Poland) at Digital Industrial Design and Manufacturing Research Unit, Faculty of Engineering at Sriracha, Kasetsart University. The printed model was used to evaluate functions. Modification of the packaging model was once again revised if its functions are not met the requirements.

The following step after the 3D model was dimensionally and functionally reviewed, the 3D CAD model of packaging was evaluated the strength using the Finite Element (FE) method (ABAQUS, Dassault Systèmes, USA). In order to generate the FE model for analysis, four-node tetrahedral elements type were created based on the shape of the 3D CAD packaging model.

The evaluation was performed under various compression situations. The compression was simulated by placing the rigid plane over and under the packaging model. The upper rigid plane was controlled to displace downward. 0.5-mm, 1.0-mm, 2.0-mm, and 4.0-mm, as shown in Figure 1. Material assigned in the FE analysis was assumed to be linear elastic, in which elastic modulus and possion’s ratio has to be included. The values of material property was from tensile testing data according to ASTM D638-14 (American Society for Testing and Materials [ASTM], 2014). The

Suan Sunandha Science and Technology Journal

Equivalent Von Mises (EQV) stress of each case was compared to the yield strength of materials.

If there are no modification after reviewing the FE result, the final CAD drawing was deployed for manufacturing.

Figure 1. FE Boundary Condition**.**

3. Results and Discussion

The requirements for packaging design can be summarized as follows: (1) it has a shape which can be hold by a single hand, (2) it can be fit all components of the endoprosthesis, (3) it is feasible to manufacture with the thermoforming process, (4) it can undergo gamma ray sterilization, and (5) The package should have sufficient strength for vertical stacking.

According to the requirements, three of them were turned into design inputs which included (1) the width and length sizes of tray should be less than 180 mm (length of palm span from the tip of the thumb to the tip of the forefinger), (2) size of the tray should be covered the size of filled components, (3) the tray should be manufactured from the sheet with 0.7 mm or 1.0 mm (according to specification) and the shape must be able to release from the mold, and (4) the sheet should be in Polyethylene Terephthalate (PET) family (feasible to undergo gamma-ray sterilization).

In the design process, various engineering tools were used as tools to produce the design output as follow:

(1) For the dimension, the packaging was 150 mm length x 125 mm width x 47 mm height in dimension. With this size, the tray width was less than the size of a hand, this allows OR personal to carry on with a single hand.

(2) In addition, to dimension in (1), the tray was capable to fill components, as in Figure 2. During the development process, the 3D models of the tray and prosthesis were printed using a FDM machine to test the containing function. It was found that if the implant was filled inside, it created large movement during transportation. Therefore, the components were covered with a sterile pouch before putting into the tray to reduce the movement of the components inside the tray. The pouch pushes the cavity walls in all sides to balance the position of the components in place. In addition, the pouch also makes it is easy for OR personal to remove the pouch from the tray in sterile condition using scissor with low risk of touching the contaminated area.

(3) The tray has a taper angle of the degree to allow ejection from the mold during the thermoforming process.

(4) The edge of the tray was offset from the main portion by 8-mm, this is to stick the sterile barrier film covering on, and the choice for materials made of the tray was Polyethylene Terephthalate (PET) family. PET is suitable for making the tray and good for the radiation sterilization method (Bix & Fuente, 2009).

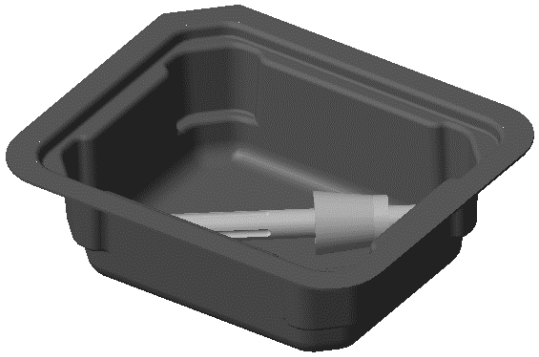

Figure 2. Tray and example of component filling test.

(5) The test for strength for vertical stacking was performed using FE analysis. The material of properties of PET (according to the selection in (4)) was tested according to ASTM D638-14 (ASTM, 2014) for gathering input for FE analysis. PET filaments were printed using a 3D printing machine (M200, Zortrax, Poland) to produce the specimen type I described in ASTM D638-14 (Tarathikhun, Chantarapanich, Valeeprakhon, & Wanchat, 2018). The specimens were used for tensile testing using Universal Testing Machine (Instron Model No. 9582, USA) at Geo-Informatics and Space Technology Development Agency (Public Organization). Three specimens were tested at a speed of 5 mm/min. The test was terminated when the specimen broke apart, as shown in Figure 3.

Suan Sunandha Science and Technology Journal

From the test, the average elastic modulus is 1,850 ± 28.5 MPa, and the average tensile strength is 39.8 ± 3.9 MPa. For possion's ratio, it was not possible to get the data from the tensile test. During the FE analysis, it was then assumed to be 0.30.

For the FE test, the thickness of PET sheet was 0.7 mm. The results showed that the high EQV stress portion of the tray was at the four bottom corners and the upper edge, as shown in Figure 3. Higher compression leads to higher stress and required more compression loads at 2.0 mm and 4.0 mm compression, the EQV stress at the upper edge is a critical level. High compression loads can cause breakage or tear at the upper edge. The stress level at 1.0 mm compression was still at risk since the high stress area is large. The safe use for tray was to allow maximum compression at 0.5 mm, which corresponds to 536.4 N (54.6 kg). This was sufficient to withstand the stack storage.

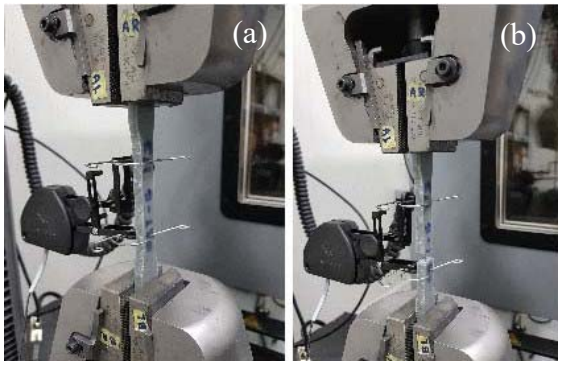

Figure 3. Material testing. (a) Test setting, and (b) Sample breakage.

As a result, the 3D model of the medical packaging tray was used for production. Figure 4 shows the finished shape of the PET tray used for the endoprosthesis.

For the design verification, design output was compared with design input. It was observed that all design output complied with the design input

There is still less work published which presents the whole design process specifically for the medical device package. Other works related to medical device package focused on cost analysis (Reymondon, Pellet, & Marcon, 2006), packaging analysis using imaging (Hindelang, Zurbach, & Roggo, 2015), and packaging materials (Wasikiewicz et al., 2008). Therefore, this current work is considered to be explained in detail paper which describing the method in medical packaging design, from design input consideration to final production.

The scope of this work focuses on the design process and its rationale in design which did not include the biological and clinical related tests of packaging i.e. bioburden, sterility test, and aging acceleration. These tests are required to determine the gamma dose used for sterilization prosthesis, the amount of microorganism exhibited on the prosthesis, and shelf life. This should be done by the manufacturer to conform ISO13485:2016 standard.

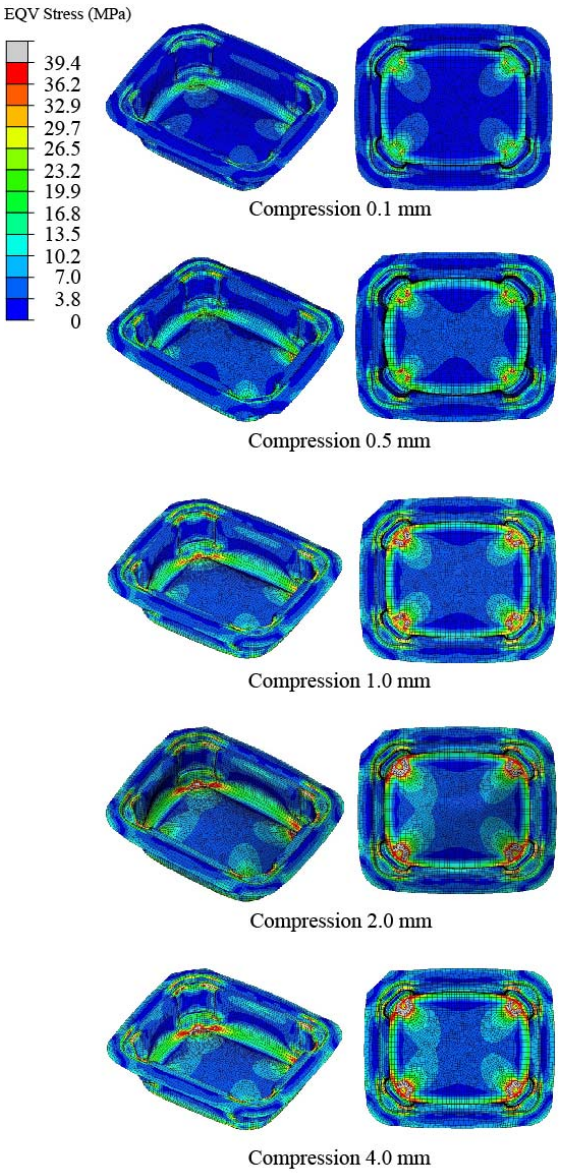

Figure 4. FE result.

4. Conclusion

This study presents the case study of

packaging design for the endoprosthesis. The characteristic required for design input includes: (1) it has a shape which can be held by a single hand, (2) it can be fit all components of the endoprosthesis, (3) it is feasible to manufacture with the thermoforming process, (4) it can undergo gamma-ray sterilization, and (5) The package should have sufficient strength for vertical stacking. The output for the design has the dimension of 150 x 125 x 47 mm with a taper shape. The materials made of the package were PET with a thickness of 0.7 mm. The package presents sufficient strength by withstanding 54.6 kg-f compression load. All design output complied with design input. In addition, the designed package has not yet included the biological and clinical related tests which should be performed in future work.

Conflict of Interest

None.

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