First approach for the optimization and fabrication of a customizable esophageal stent prototype by 3D printing technologies

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Abstract: The design of an esophageal stent is optimised using finite element analysis (FEM). The proposed design has been optimized in order to be manufactured by Fused Deposition Modelling (FDM) so that it can be easily customised to the patient. TPU is an elastomer that sometimes proposes some difficulties to be printed especially in relation to retraction, to avoid this kind of movements the stent has been specially designed to be printed in vase mode.

Keywords: Stent, 3D print, Optimization, Radial force, Plastic deformation.

1. Introduction

During the recent years stents have been employed as an efficient treatment for patients with gastrointestinal diseases. Self-expandable metallic stents (SEMSs) have become a one of the most notable innovation in therapeutic endoscopy since in 1990s were introduced [1]. Most of the patients who need this kind of treatment suffer from a tumor in the esophagus area, which often results in dysphagia affecting the health-related quality of life (HRQL). Some of the problems when suffering from dysphagia can be difficulties in swallowing solids and liquids due to a narrowing of the duct [2].

Metallic stents are used in patients with malignant pathologies due to their better mechanical properties. The main problems are the associated side effects such as inflammation, perforations, anastomotic strictures, and peptic strictures. In order to avoid such complications in patients with benign pathologies, stents made of thermoplastics are used despite their inferior mechanical properties [3-5]. Due to the low stiffness of the polymers, the radial force provided by this kind of stets is low [6, 7]. For solving this problem, many studies have been performed to optimize the geometry of them. To this effect, Finite Element Modeling (FEM) has been employed to explore the effect of different geometries [8-10].

The introduction of thermoplastics offers the opportunity to introduce new manufacturing process like additive manufacturing (3D printing). With this kind of technique, personalized stents can be obtained in a short period of time [11]. The customization of the treatment ensures the device to fit in the correct place while offers the adequate properties for its kind of pathology [12-14].

The main objective of this study was to develop a prototype of stent made from TPU (Thermoplastic Polyurethane) an elastomer that can be printed by Fused Deposited Modeling (FDM), the proposed models have been simulated with Finite Element Modelling to improve the radial force of the stent. Frequently, it is recommended to disable retraction movements for the TPU in order to avoid the...
clogging of the hotend. For this reason, the geometry of the stent should be designed to be printed without retractions.

2. Experimental

2.1. Fabrication of the samples

The equipment employed for the fabrication of the stent was the Sigma x R19 from BCN3D (Barcelona, Spain). The material employed for this propose was TPU from BCN3D (Barcelona, Spain), it is a flexible material with a Shore-A hardness of 98. In this case, due to it is a prototype to analyze stent viability, the used material is a commercial TPU of which the biocompatibility was unknown. Nevertheless, several studies have demonstrated the biocompatibility of TPU [15, 16].

The TPU was printed with a 0.4 mm nozzle at 235ºC, a printing speed of 45 mm/s and 0.2 mm layer height. The provider proposed a range of temperatures between 225-240 ºC, single wall cubes were printer at different temperatures to obtain the best layer adhesion at 235 ºC. Dogbone specimens (ISO 527-2:2012) with 100% infill were printed with a linear pattern in the longitudinal direction and in the transverse direction as proposed in figure 1 (taking into account the direction of application of the forces in the tensile test). In this sense, the properties of the TPU manufactured by 3D printing could be obtained. For the stent fabrication, the above conditions were used and the trajectories were generated by using the vase mode.

![Figure 1. Dogbone samples obtained by 3D printing; the print pattern of each kind of sample, follows the direction of the arrows.](image)

2.2. Simulation

For the simulation, Ansys 2020 R2 was employed, to find out the model that offers the best radial force, the stets were submitted to a vertical deformation of 10 mm. The results considered for the discussion were the force applied to achieve the deformation and the final deformation after the unload. A bilinear hardening model was established and in order to assess the mechanical properties of the considered material. To this effect, six 3D printed dogbone tensile test specimens were tested in a universal test machine from Ibertest (Madrid, Spain) with a 5kN gauge and a cross-head speed of 40 mm/s. Figure 2 shows the modulus for the definition of the material, as can be seen, the properties of TPU in both directions were very similar, for this reason, intermediate properties in both directions were used for the simulation model. These results are similar to those obtained by Tawk et al [17].
2.3. Geometry
As proposed, in this case the stent geometry should be printed using vase mode. This means that the printer would do a continuous movement in all the axes avoiding the travel movements so that the retraction movement is not necessary. The designed stents have an empty cylindrical shape without any holes in the walls, for all the proposals, the walls have 0.4 mm and the inner dimensions are the same. Different configurations of the wall reinforcements (figure 3) were considered to assess the best design to improve the radial force.

![Different wall geometry reinforcement for the stent](image)

**Figure 3.** (a) Different wall geometry reinforcement for the stent, (b) Graphical representation of the parameters considered for the optimization.

The width of the reinforcement elements (w) and the separation of them (h) have been tested. To assess the effect of each parameter, different combinations have been tested as proposed in table 1.
### Table 1. Dimensions considered for the optimization.

| w (mm) | h (mm) |
|--------|--------|
| 2      | 10     |
|        | 20     |
|        | 30     |
| 4      | 10     |
|        | 20     |
|        | 30     |
| 6      | 20     |
|        | 30     |

2.4. Experimental validation

To validate the stent performance, 3 samples of each of the types of stents made were tested with an Ibertest universal test machine equipped with a 100N gauge and a cross-head speed of 20 mm/min. A compression test was performed in which the force was measured as a function of stroke. The result was compared with the counterpart obtained by finite element simulation as proposed in figure 4.

![Compression test of stent prototype](image)

**Figure 4.** Compression test of stent prototype.

3. Results and discussion

For the analysis of the results, different FEM models were made following the geometries proposed in the experimental section. The material properties assigned to the FEM model were those obtained for the dog bone samples described above. Figure 5 and figure 6 show the results obtained after the simulation of all the proposed stents. One of the clearest trends arises when it is changed the w
parameter. When larger values of \( w \) are used, the radial force increases. This is because the size of the reinforcement elements is larger and therefore the desired effect of increased stent stiffness is achieved. However, this is not always a positive modification. A clear example of this is the variation of radial force for the circular reinforcement with \( h_{10} \), the difference that arises between \( w_{4} \) and \( w_{6} \) is very small, this is mainly since this modification results in an increase of the plastic deformation as can be seen in figure 5.

**Figure 5.** Radial force: C (circular shape), E (Ellipse shape) and T (triangular shape).

Another phenomenon that can be observed in this case is the improvement in radial strength that arises when \( h \) it is reduced. In all cases, a smaller separation of the reinforcement elements allows a greater number of turns to be added and thus achieve the desired effect. In this case, the relation obtained is linear in all cases, the different models show a linear improvement between the different models. This modification has a minor negative effect on the plastic deformation of the stent, resulting in a linear increase of the residual deformation when \( h \) decreases.

**Figure 6.** Final deformation after the vertical deformation: C (circular shape), E (ellipse shape) and T (triangular shape).
Modifying the shape of the reinforcement especially has an effect on the final deformation of the stent. It can be seen from figure 6 that the ellipse and triangle shapes have a very positive effect in reducing the plastic deformation of the stent. This modification does not have a significant effect on the maximum radial force that can be generated.

After the design process, the stents were printed as can be seen in figure 7, the geometries can be printed with TPU. The processing time for each stent was 13 minutes, so it is a fast method to obtain a customized stent. Moreover, in figure 8, one of the stents was crimped manually and after the unload it was able to recover its initial shape.

![Figure 7. 3D printed models of the stent.](image)

![Figure 8. 3D printed models of the stent.](image)

Additionally, to corroborate the results obtained in Ansys, these results were compared with those obtained experimentally in the compression test. In general terms, the differences that arise between the different curves are mainly due to the fact that during testing with the manufactured stents, a smaller plastic deformation was obtained. Due to this phenomenon, the final zone of the curve has a greater slope and therefore the force obtained was higher.

4. Conclusions

As can be seen, the optimisation process has resulted in a very significant improvement in the radial force generated by the stent. The best radial force values are associated with those designs in which the spacing between the reinforcement elements (h) is smaller and the width (w) of the reinforcement...
elements is larger. Among the different reinforcement shapes, it can be noted that the most interesting are those with elliptical and triangular shapes because they generate a lower plastic deformation. The verification of the behavior showed a high correlation between the information obtained by simulation and the result obtained experimentally. In the future, 3D print could be an alternative for the fabrication of customized devices in a quick and easy way, in this case each stent took only 13 minutes.

![Figure 9 Radial force for the Ansys and experimental test: C (circular shape), E (ellipse shape) and T (triangular shape).](image)

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