Transactions on Additive Manufacturing Meets Medicine
Trans. AMMM, Vol 1, No 1, 2019, Article ID S03P24

Infinite Science | Publishing

Innovative revolving biopsy device design supported by additive manufacturing

M. AL-Maatoq[1*], A. Doshi[2], M. Kalmar[1] A. Boese[1] and M. Friebe[1]

[1] *Intelligente Katheter (INKA), Institute of Medical Technology, Otto-von-Guericke University Magdeburg, Germany*
[2] *Department of Biomedical Engineering, Martin Luther University, Halle (Saale), Germany*
[*] *Corresponding author, email: marwah.al@ovgu.de*

Abstract: Additive manufacturing is widely used in the meantime for medical device developments. Specially the BioDesign process with strong user integration and feedback loops benefits from fast prototyping. In this work, an innovative conceptual design of revolving biopsy needle is CAD modelled using SolidWorks software and subsequently 3D printed. The material properties of the resins were fit to use for fabrication of the different mechanisms that the prototype requires. 3D printing is a very good method of quickly checking different design ideas, to present functionalities to clinical partners, to optimize and define the ideal design. Even delicate structures are possible.

I. Introduction

Additive manufacturing known as three-dimensional (3D) printing technique is fast developing and has infiltrated into multiple industries including the healthcare industry. We employ 3D printing as part of the invention phase in the BioDesign process that starts with the identification of unmet clinical needs iteratively followed by ideation/invention and implementation [1]. 3D printing offers several advantages like facilitation to test the proposed medical devices concept-to-prototype development, faster design implementation, accurate tailoring of medical devices based on observed results of previous designs, cost-effective prototype solutions with that increased productivity and a democratization of design and manufacturing [2-5]. In addition, the variety of available material properties of 3D printing resin and the freedom of shapes can extend the design options of existing materials and manufacturing used in medical devices. But biocompatibility, inertness, mechanically durable, and easily moldable are still issues in 3D printing [6].

In this work, we propose an innovative design of a biopsy needle device that is capable of collecting multiple soft tissue samples from different locations using a single entry channel. This would allow a higher sensitivity of the diagnosis as multiple samples are collected from and around the suspected tumor zone. We had several design ideas that included different mechanisms to perform the required functionality. To verify functionality these ideas were conceptually implemented by additive manufacturing and subsequently tested and discussed with experts in medical application.

II. Material and methods

The biospy device parts were CAD modelled (SolidWorks 2018, Dassault Systèmes*)* and transferred to a 3D printer (Form 2, Formlabs Inc., USA*)*. The individual prototype parts were printed allowing the assembly of the device as shown in Fig 1 (a). In a first trial, we used Formlabs white resin to build up the prototype. But the different strain on the parts was not considered in this process. For this reason, parts break during the first tests. In a second design we considered the use of different materials according to the strain on the parts - white resin and durable resin. Material properties of both resins are shown in table 1 [7]. The tensile strength is a material's resistance to break under tension which is higher for white resin as compared to durable resin.

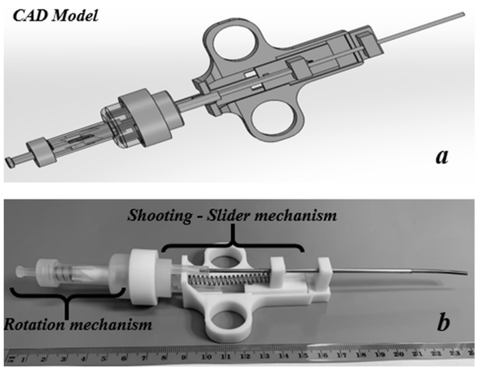

Figure 1: (a) SolidWorks design of the biopsy needle (b) 3D printed functional prototype of the biopsy needle.

Table 1: Material properties of the resins.

Material properties	White resin	Durable resin
Ultimate tensile stress	38 MPa	18.6 MPa
Tensile modulus	1.6 GPa	0.45 Gpa
Elongation at break	12%	67%
Flexural modulus	1.3 Mpa	0.16 Gpa
Notched IZOD	16 J/m	130.8 J/m

DOI: 10.18416/AMMM.2019.1909S03P24

The flexural modulus is the material's stiffness in the bending direction. As illustrated in table 1, white resin has a higher value of flexural modulus as compared to durable resin which makes white resin stiff and durable resin elastic. Therefore, each resin was used to build specific mechanismThe proposed biopsy design concept consists of two mechanisms: (1) rotational mechanism and (2) shooting-slider mechanism as shown in Fig. 1 (b). The main components of the rotational mechanism are the housing (a), plunger (b), cam (c) and revolving chamber (d) as shown in Fig. 2. Three out of these four components of the rotational mechanism, were 3D printed with durable resin (a, b, d) as the structure of the plunger, housing and

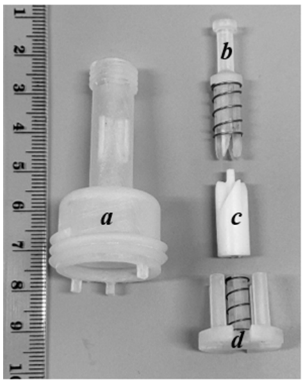

Figure 2: Components of rotational mechanism. (a) housing (b) plunger, (c) cam, (d) revolving chamber.

revolving chamber is delicate. The transparency of the durable resin allows visualization of the movement of the mechanism. The cam of the rotational mechanism must absorb the spring force from the plunger. Therefor white resin is suitable and was used for the 3D printing.

The shooting- slider mechanism composed of slider (e), grip (f), and trigger (g) is illustrated in Fig. 3. The shooting is actuated by a compressed spring force. The spring is placed between the grip and slider as shown in Fig.1 (b) and is compressed by pulling the slider back with the assistance of a trigger. The trigger and the slider are connected by an extruded part on the trigger. The grip and slider should be strong as their function is to compress the spring between them without deformation. To provide tensile strength to grip and slider, they were 3D printed with white resin. The trigger actuates the shooting mechanism. When the compressed spring is released, it shoots the slider to its original position. The extruded part on the trigger holds the slider in place after shooting by absorbing the energy released by the spring. Thus, the material of the trigger should be tough. As presented in table 1, durable resin has high impact strength, so the needle slider was printed with durable resin.

III. Results and discussion

For the initial evaluation of the rotational mechanism as well as the shooting-slider mechanism, all the components of the mechanism were 3D printed using white resin. The plunger, chambers, fixed tube, and trigger broke after few trials however. The trigger failed to absorb forces exerted by the spring (8.8 N) in shooting-slider mechanism. The white resin is brittle and has low impact strength. In the second design, these broken parts were reprinted with durable resin and trials for evaluation of the mechanism were performed. The components did not break as the

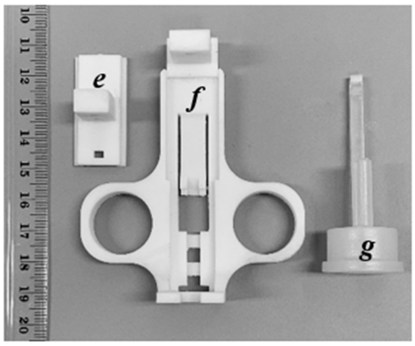

Figure 3: Structure of shooting- slider mechanism: (e) slider, (f) grip, and (g) trigger.

durable resin can resist higher impact energy and is less brittle than white resin. The quality and accuracy of the print for white and durable resin was remarkable. The mechanisms were evaluated by assembling the components. The rotational mechanism as well as shooting-slider mechanism actuated as per requirement which resulted in good quality test samples from the biopsy. The resulting prototype was used for discussion with expert in medical application.

IV. Conclusions

In this work, additive manufacturing was successfully used to develop a functional prototype of a novel biopsy device. The mechanisms involved were evaluated and tested using 3D printed prototypes. For future work, the holder of the shooting mechanism can also be 3D printed with a tougher material than the white resin and more elastic than the durable resin. The prototype is now can be used for further evaluation of the concept of a revolving biopsy gun. The adapted design offers the stability to "survive" a critical evaluation of clinical users. 3D printing again offered a fast concept to prototype cycle in the product development phase.

AUTHOR'S STATEMENT

This research was financially supported by the Federal Ministry of Education and Research (BMBF) in the context of the 'INKA' project (Grand Number 03IPT7100X). Authors state no conflict of interest

REFERENCES

[1] M. Friebe and J. Traub, "Image guided surgery innovation with graduate students-a new lecture format," Curr. Dir. Biomed. Eng., vol. 1, no. 1, pp. 475–479, 2015.

[2] L. E. Diment, M. S. Thompson, and J. H. M. Bergmann, "Clinical efficacy and effectiveness of 3D printing: a systematic review," BMJ Open, vol. 7, no. 12, p. e016891, 2017.

[3] C. L. Ventola, "Medical applications for 3D printing: current and projected uses," Pharm. Ther., vol. 39, no. 10, p. 704, 2014.

[4] Y. Wang et al., "Three-dimensional printing technique assisted cognitive fusion in targeted prostate biopsy," Asian J. Urol., vol. 2, no. 4, pp. 214–219, 2015.

[5] D. H. Ballard et al., "Clinical applications of 3D printing: primer for radiologists," Acad. Radiol., vol. 25, no. 1, pp. 52–65, 2018.

[6] K. Tappa and U. Jammalamadaka, "Novel biomaterials used in medical 3D printing techniques," J. Funct. Biomater., vol. 9, no. 1, p. 17, 2018.

[7] FormLabs, "Materials Data Sheet," pp. 76–77, 2014