Macedonian Pharmaceutical Bulletin, 72 (Suppl 1) 143 - 144 (2026)
Online ISSN: 1857-8969
DOI: 10.33320/maced.pharm.bull.2026.72.03.069
Short communication

Design and fabrication of 3D-printed molds for suppositories for pediatric applications

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Introduction

A major challenge in pediatric therapy is the lack of age-appropriate dosage forms and strengths tailored to children of different ages and body weights. As a result, manipulation of conventional dosage forms, such as tablet splitting or crushing, capsule opening, and suppository division, is often required in clinical practice. However, these procedures may compromise dosing accuracy, stability, and dose uniformity, emphasizing the need for more flexible and individualized pharmaceutical approaches (Andersson et al., 2023). Pediatric suppositories are commonly designed as torpedo-shaped dosage forms with a typical weight of approximately 1 g to facilitate rectal administration. Nevertheless, dose adjustment for younger children remains challenging, since pediatric doses are frequently extrapolated from adult doses based on body weight, while physiological differences may additionally influence drug absorption and therapeutic response (Jannin et al., 2014).

To address these limitations, 3D-printed molds were developed using fused deposition modelling (FDM) technology to produce suppositories suitable for pediatric population. Due to their low production cost and design flexibility, such molds could represent a practical approach for individualized pediatric therapy in hospital and community pharmacies.

Materials and methods

Materials

TPU 95A filaments composed of thermoplastic polyurethane (Ultimaker, Netherlands) were used for the fabrication of suppository molds, while Witepsol® H15 (IOI Oleo GmbH, Germany) was used for suppository preparation. Liquid paraffin was used as a lubricant for the inner surfaces of the molds.

Design of 3D printed molds for suppositories

The design of 3D-printed suppository molds was performed using SolidWorks software integrated with Ultimaker Cura. After defining the required dimensions, digital models of suppository molds were created and prepared for the printing process.

Printing process

The printing process was carried out using an Ultimaker S5 3D printer (Ultimaker, Netherlands) at the Faculty of Mechanical Engineering. TPU 95A

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was selected as the printing material, with infill density of 10%. The nozzle diameter was set to 0.4 mm, while the layer height was adjusted to 0.15 mm. The printing speed was maintained at 25 mm/s, and the fan speed was set to 20%. During printing, the extruder temperature was maintained at 225 °C, whereas the build plate temperature was set to 0 °C.

Suppository fabrication from 3D printed molds

Suppositories were prepared using Witepsol® H15 without an active pharmaceutical ingredient. The base was melted at 70 °C, poured into lubricated molds, and cooled for 1 hour under ambient conditions. After solidification, suppositories were demolded and visually inspected. Uniformity of mass of the prepared suppositories was determined using an analytical balance BTA-210 (AXIS, Poland).

Results and discussion

The dimensions and volume of the rectum change during development, with adult dimensions reached at approximately 10 years of age. Since dose adjustments in pediatric patients are commonly based on body weight, height, or body surface area, the availability of age-appropriate dosage forms remains an important challenge (Batchelor & Marriott, 2013). Although the European Medicines Agency (EMA) recommends that manipulation of adult dosage forms for pediatric use should be avoided whenever possible, splitting or modifying medicines is still frequently required due to the limited availability of suitable pediatric formulations (Andersson et al., 2023). In rectal drug delivery, dose adjustment is particularly challenging because suppositories do not allow simple and accurate modification of the administered dose. In clinical practice, portions of adult suppositories are often used in children under the assumption of uniform drug distribution within the matrix. However, such practices may lead to inaccurate dosing and unsuitable suppository geometry for rectal administration (Batchelor & Marriott, 2013).

To address these limitations, 3D-printed molds were designed for the preparation of suppositories of approximately 1 g intended for pediatric patients. The developed molds manufactured from TPU 95A material demonstrated good dimensional accuracy and flexibility. However, due to the elastic nature of the material, slight leakage of the molten suppository mass was observed during filling, requiring manual compression of the mold halves to ensure proper sealing. Despite this limitation, the obtained suppositories showed smooth surfaces, uniform appearance, and no visible defects, cracking, or deformation. Application of liquid paraffin as a lubricant facilitated demolding and prevented adhesion of the lipid base to the mold surface.

Suppositories prepared using Witepsol® H15 showed satisfactory macroscopic properties and good compatibility with the 3D-printed molds. The average mass of produced suppositories was 0.854 ± 0.058 g, indicating acceptable reproducibility of the preparation process despite the flexibility of the mold material.

Conclusion

3D-printed molds may enable flexible dose adjustment and reduce the need for manipulation of adult suppositories in pediatric patients. Although TPU 95A molds showed slight leakage during filling due to their flexibility, the produced suppositories demonstrated satisfactory uniformity and macroscopic quality. Further optimization of the mold design or use of more rigid materials could improve handling and sealing properties.

Acknowledgements

This work was supported by the Federal Ministry of Education and Science of Bosnia and Herzegovina.

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