Sterilization of 3D-Printed Devices: Microbiological and Structural Assessment

Rachel Zocratto da Silveira Cardoso MS RN[1], Alessandra de Fátima Bokor Manteiga RN[1], Daniele Aparecida Araújo Stuchi, RN[1], Wagner Aguiar PhD RN[2], Humberto Dellê PhD[3], Rachel de Carvalho PhD RN[3]
[1] Einstein Israelite Hospital, [2] University Hospital of the University of São Paulo, [3] Israelite College of Health Sciences Albert Einstein

Problem

Challenges in processing 3D-printed surgical molds/guides, ensuring microbiological safety and structural conformity for intraoperative use.

Objectives

1. Validate the sterilization process of 3D-printed surgical molds/guides using hydrogen peroxide plasma (HPP) autoclave;

2. Analyze structural conformity and microbial load of the pieces.

Literature Review

HPP sterilization is a low-temperature physical-chemical method, effective in eliminating microorganisms while maintaining the structural properties of materials.
3D-printed surgical molds/guides, used across various specialties, enhance procedural precision. Made from heat-sensitive materials such as polylactic acid (PLA), they require sterilization methods that preserve their characteristics, ensuring safety and functionality for intraoperative use.

Research Question

How can the processing of 3D-printed surgical molds/guides be validated to ensure microbiological safety and structural conformity?

Conceptual Framework

3D-printed surgical molds/guides are anatomical replicas of specific human body structures, increasingly applied in surgical practice. Since they are used directly in surgery, sterilization processes must guarantee absence of contamination and preservation of original dimensions, maintaining functionality and safety.

Methods

Quasi-experimental study conducted in a private hospital in São Paulo, Brazil, with a sample of 10 PLA (polylactic acid) molds/guides.
Measurements of height, width, and length were recorded, and pieces were subjected to HPP sterilization for 30 minutes. Chemical and biological indicators were used for monitoring. After sterilization, microbiological analyses were performed through sonication culture and new measurements were taken to verify structural conformity.

Data Analysis

Comparison of measurements throughout processing and analysis of indicator results.

Results

In the initial dimensional assessment, all pieces showed conformity. The mean preparation time was 1 minute and 10 seconds per piece, with a 30-minute sterilization cycle. Chemical integrators and biological indicators showed conforming and negative results, respectively.

For aerobic and anaerobic microorganisms, the solution was seeded on chocolate agar, blood agar, MacConkey agar, inoculated into thioglycolate broth, and 3 mL of concentrated solution were inoculated into a pediatric blood culture bottle. All results were 100% negative after 14 days.

For mycobacteria, seeding was performed on Lowenstein-Jensen solid medium and BD Bactec™ MGIT™ liquid tubes, with incubation for 42 and 60 days, and 100% negative results.
For fungi, Sabouraud and Mycosel tubes were incubated at 25°C–27°C and 35°C–37°C. After 21 days with daily screenings, results were 100% negative. The final structural measurement showed 100% conformity in all pieces' dimensions.

Conclusions

HPP sterilization is feasible and safe for 3D-printed surgical molds/guides in PLA, suitable for surgical use, and replicable in healthcare services.

Implications for Perioperative Nursing

The study contributes to standardizing the processing of 3D-printed materials and reinforces the active role of perioperative nursing in the use of these materials, an emerging and rapidly expanding global practice

References

1. Alexander AE, Wake N, Chepelev L, Brantner P, Ryan J, Wang KC. A guideline for 3D printing terminology in biomedical research utilizing ISO/ASTM standards. 3D Printing in medicine. 2022; 7:8. DOI: https://doi.org/10.1186/s41205-021-00098-5

2. Brasil. Ministério da Saúde. Agência Nacional de Vigilância Sanitária (ANVISA). Manual e tecnovigilância: uma abordagem sob a ótica da Vigilância Sanitária. [Internet]. 2021. Disponível em: https://www.gov.br/anvisa/pt-br/assuntos/

3. Associação Brasileira de Enfermeiros de Centro Cirúrgico, Recuperação Anestésica e Centro de Material e Esterilização (SOBECC). Diretrizes de práticas em enfermagem perioperatória e processamento de produtos para saúde. 8a ed. São Paulo: SOBECC/Andreoli; 2021. Parte I. Centro de Material e Esterilização.