

Abstract

Biocompatibility and bio-efficacy of 3D printed dexamethasone loaded implants after autoclaving: Comparison of three different silicone brands

M. Knabel^{1*}, T. Lenarz¹, and V. Scheper^{1*}

¹ Clinic for Oto-Rhino-Laryngology and Cluster of Excellence "Hearing4all", Hannover Medical School, Germany

* Corresponding author, email: knabel.martina@mh-hannover.de, scheper.verena@mh-hannover.de

© 2024 M. Knabel, V. Scheper; licensee Infinite Science Publishing

This is an Open Access abstract distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited (<http://creativecommons.org/licenses/by/4.0>).

For the treatment of sudden sensorineural hearing loss (SSNHL), dexamethasone (DEX) delivery via silicone implants, customized to individual patient anatomy through 3D printing, may be used. To ensure safety, the sterility of these implants must be verified. Autoclaving was employed as a potential sterilization method, and the biocompatibility and bio-efficacy of 3D-printed, DEX-loaded implants, using three different medical-grade silicones, were assessed post-autoclaving.

UV-Silicone 60A MG (Momentive, Niskayuna, USA), Nusil Med-4960 (Avantor, Radnor, USA), and Amsil Silbione 24503-50 A (Elkem, Oslo, Norway) loaded with 0, 1, 10, or 20 (w/w) % DEX (caelo, Hilden, Germany) were 3D printed as 6x6x6 mm cubes using an EnvisionTEC Bioplotter (Desktop Metal, Burlington, USA). Afterwards, samples were autoclaved with Lisa Remote Plus Sterilizer (W&H, Bad Reichenhall, Germany) at a maximum temperature of 134°C for the duration of 350s. The whole autoclaving process took 23 minutes. Subsequently, the samples were incubated for 72h at 37°C in artificial perilymph to obtain eluates. 60 µl of those eluates were used per well each for the biocompatibility (water soluble tetrazolium (WST) assay) and bio-efficacy test (TNFα (tumor necrose factor-α) reduction assay).

All samples made of Momentive silicone were biocompatible and all samples containing DEX reduced the TNFα expression, the extent correlating with the DEX amount within the sample. The results of the Nusil samples were more heterogeneous with few samples reducing cell survival compared to the respective control. The bio-efficacy tended to be slightly better than that of the Momentive samples. The Elkem samples were biocompatible, performing slightly worse in comparison to Momentive and Nusil silicone.

All three tested silicones can be sterilized via autoclaving. The biocompatibility was good. The contained DEX showed a slightly lowered potency in TNFα reduction test after autoclaving, which could be countered by increasing the DEX amount in the silicone.

AUTHOR'S STATEMENT

Conflict of interest: Authors state no conflict of interest. Animal models: Not applicable. Informed consent has been obtained from all individuals included in this study. Ethical approval: Not applicable. Acknowledgments: We thank Michaela Kreienmeyer for her help as well as Samuel John and Hörsys for the access to their autoklave. Research funding: This work was funded by the Deutsche Forschungsgemeinschaft (DFG, German Research Foundation) under Germany's Excellence Strategy – EXC 2177/1 - Project ID 390895286

REFERENCES

- [1] V. Scheper, C. Wei, Z. Gao, F. Matin-Mann, T. Lenarz: Development of an Individualized Round Window Niche Implant for Inner Ear Drug-Delivery. *Laryngo-Rhino-Otologie* 2022; 101(S02): 243 - 244. doi: 10.1055/s-0042-1746865