Rainer Trittler[1], J. Lüchtenborg[2], B. Altmann[2], M.J. Hug[1]

Leachable Analysis of Dental Materials

Medical Center - University of Freiburg, Germany
[1]Pharmacy
[2]Department of Prosthetic Dentistry

Background and Importance Knowledge about leachables gains importance, not only in the industrial drug and hospital pharmacy production, but also in the risk assessment of 3D printed medical devices. In the dental department of our hospital, the question arose, whether new 3D printed prostheses could release harmful monomers or additives, which may have an impact on the oral tissues in patients. The question was of particular interest as a result of the modification to the approval process for these materials, which now requires a more comprehensive understanding of their behaviour for the purposes of future procedures.

Aim and Objectives We aimed identifying and quantifying possible leachables, such as monomers or additives, released from resin-based 3D printing dental biomaterials. The data should be valid for a cooperation project assessing the risk of patient´s exposure with this leachables.

Results: We identified and quantified the monomer UDMA (Urethane dimethacrylate), one major component of the resin used for dentures, in all extracts. After 56 days the highest amount of UDMA was found in the ethanolic extracts up to 42,8µg/mL, whereas in all aequous extracts, independent of the pH, it was 3,4µg/mL [1]. Moreover, further peaks were detected indicating further leachables in our extracts.

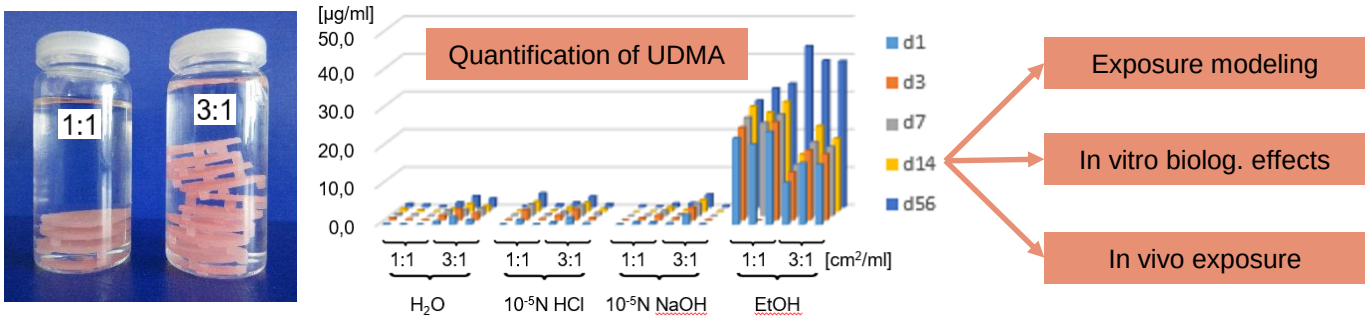

Fig.1: Extraction of 3D printed prosthesis material with different solvents, defined temperature, shaking, extraction time and surface area / volume ratio 1:1 cm^2/ml and 3:1 cm^2/ml and following steps.

Materials and Methods: Based on defined extraction methods of the USP665 and our own screening method for characterizing extractables in syringes for hospital pharmacy production, we prepared ethanolic and aequous extracts (neutral, pH9 and pH5) of CAD/CAM material denture base LP (Fromlabs Inc., Somerville, USA). UDMA analysis were performed by LC-MS (4000 qTrap, Sciex).

Conclusions The results of the extraction study revealed that residual monomer release from resin-based biomaterials intended for 3D printing of dental devices occurs and could be detected by the analytical methodology applied in our pharmacy lab. As our data could be used in a cooperation project for biological toxicity testing and to estimate patient exposure with monomers and leachables in general [1], it makes sense to open the analytical methods of the pharmacy for other purposes. At least there are analogies between dental laboratory and hospital pharmacy production concerning the approval process. Cooperation is therefore advantageous for both parties.

References:

[1] B. Altmann, A. Hauk, R. Trittler, J. Lüchtenborg, P. Tomakidi, R. Menzel, D. Heringlehner, B.C. Spies: Safety Assessment of 3D-Printed Oral Devices Integrating Exposure Modeling and Biocompatibility Testing: Bridging the Gap between Static Predictions and In Vivo Exposure, Biomaterials submitted

Poster 4CPS-163, EAHP Congress Copenhagen 20 - 22th March 2025
corresponding author: rainer.trittler@uniklinik-freiburg.de