SUMMARY - PROCESSING AND AGING ASSOCIATED CHANGES OF POLYMERIC BIOMATERIALS RELATED TO LEACHABLES AND EXTRACTABLES

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The analysis of leachables and extractables from polymeric biomaterials is of particular importance as they are in direct contact with the human biological system. It is therefore essential to qualify and quantify soluble substances from polymers in order to estimate the burden on the human body. Or also to determine the intentional release of active substances. In addition, conclusions about the structure-property relationships of polymeric materials with regards to processing and aging related changes can be drawn on the base of this analysis.

In this context, the doctoral thesis deals with processing and aging associated changes of polymeric biomaterials, with a focus on dental materials, related to leachables and extractables. A total of six scientific articles can be found: four of these have been published in peer-reviewed journals, one has been published as a peer-reviewed short paper and one is currently in preparation.

Main topics are:

- Processing- and composition-related changes of dental composites
- Aging-related changes of dental composites
- Drug-incorporation in dental composites
- Sterilization-related changes on lubricant additivated polypropylene

On the one hand, the consideration of leachables and extractables offers the possibility to draw conclusions about the structure-property relationships of polymers, especially in consideration of the influences of processing and aging. On the other hand, research in this area offers fundamental insights into the number and extent of substances that can leak from polymers and are absorbed into the human organism. By considering various fields of research in the scientific articles presented here, a contribution to knowledge could be achieved. Among other things, it was found that the processing of dental composites with the same basic composition has an influence on the release of residual monomers. Self-curing materials released significantly more residual monomers than those produced by additive manufacturing or CAD/CAM. The same applies to the susceptibility to hydrolysis and enzymatically catalyzed hydrolysis of these materials. Again, increased degradation and thus release of monomers and degradation products occurs in the self-curing materials. On the other hand, if different material compositions are considered, which are based on a uniform curing mechanism, it can be seen that the hydrophilicity of the monomer composition as well as the filler type and amount have an influence on the release of residual monomers. In addition to this unintentional release of

substances, the phenomenon can also be exploited by incorporating medically active substances into a dental composite matrix to prevent secondary caries, for example. In the investigations carried out, it was found that there are strong differences in the performance of matrix-active substance combinations. The incorporation and the subsequent release of active substances are effective against the bacterium *Streptococcus mutans*, but the mechanical properties of the matrix are weakened. When an additive is added to a polymer, the resulting property changes should be closely examined. This also applies to the influence of processing on the added additives. The example of lubricant in polypropylene can be used to illustrate how different types of sterilization influence the content and thus the effectiveness of the lubricant on the sample surface. Sterilization by ethylene oxide increased the lubricant content to some extent, γ-sterilization and autoclaving reduced it. It was possible to show that the coefficient of frictions was dependent on the measured lubricant content at the surface.

The conducted studies of this dissertation indicate that although these are different materials with different fields of application, the release of substances must be considered as an essential property. Changes in the manufacturing process are directly reflected in the type, number and amount of substances released. Likewise, material aging can have an influence, although this appears to be greater in the simulated application of the materials than in storage alone. In summary, in any production, the entire process chain up to storage, simulated use and aging must be investigated in order to obtain medical devices that are safe for humans.