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MICROSTRUCTURED ADHESIVES FOR SKIN ADHESION: TECHNICAL REALIZATION AND IMPLEMENTATION OF A REGULATORY STRATEGY

ABSTRACT

Microstructured elements integrated into polymeric skin adhesives are a new and promising concept in the design of wound dressings and skin adhesion systems. Focusing especially on adhesive performance, theses bio-inspired dressings possess clear advantages, enabling novel design concepts. For a comprehensive overview, the main mechanical principles and design features will be discussed in detail. One of the envisioned applications is the treatment of tympanic membrane perforations. This medical affliction, affecting several million patients worldwide each year can result in hearing loss and represents a significant healthcare burden.

The design and development of a polymeric wound dressing for the treatment of tympanic membrane perforations will be presented, focusing on pre-clinical analytical verification and validation studies in an animal model. Compliance with selected standards and medical device specific regulations is an elemental process already at early developmental stages. Therefore, the implementation and key elements of a regulatory strategy according to the MDD and MDR 2017/745 will be presented in the second part, focusing especially on the challenging, but exciting environment of research organizations during the development phase of prototypes.