Abstract

Dysfunctions of the stomatognathic system (US) are among the leading health ailments requiring specialised treatment regarding the doctor's extended skills, including access to diagnostics and using specialised devices manufactured personally in the dental technology laboratory. At the same time, clinical success and the possibility of recouping the incurred costs are lower than endodontics or prosthetics, which contributes to limited access to treating US dysfunctions. Developing innovative medical devices and bringing them to market is demanding and highly regulated.

As indicated in the literature review, most devices for the treatment of occlusion disorders work on the principle of an occlusal obstruction or jaw positioner. Still, the influence of material elasticity and structure stiffness on the treatment effects has yet to be considered. There are few solutions activating the action of muscles opposite to the adductor muscles, and the influence of the elastic properties of materials and the ability to elastic deflection of the elements of these devices on the biomechanical effects are not recognised, which limits the effectiveness of rehabilitation. The second deficiency of current devices operating on the occlusal obstruction principle is their colonisation by pathogenic microorganisms, which progresses with the extension of time of use.

Due to the above, there is a need to develop a trainer intended for treating bruxism, which will be designed based on biomechanical working conditions and whose aim will be to activate the muscles antagonistic to the adductor muscles thanks to its design. At the same time, achieving appropriate functional features will be possible thanks to the indication of material solutions selected according to the criteria of the biomechanics of the system and the reduction of problems occurring in clinical practice related to microbial colonisation. Research in the indicated direction requires considering legal regulations about medical device design, production and marketing. The presented products must be classified into appropriate categories of medical devices that affect the manufacturer's obligations at all regulated stages of the device's life cycle and are an essential element of the planned implementation process.

Due to the above, the following work objectives were formulated:

- the first aim of the work was research aimed at developing the design of a trainer intended for the treatment of bruxism based on the results of biomechanical diagnosis of its functioning conditions along with the selection/development of materials to ensure its proper functioning,

- the second goal was to research the possibility of developing a material dedicated to the implemented structure, which, in addition to functional mechanical properties, will ensure the improvement of the microbiological properties of the solution.

Achieving the assumed goals required the verification of thesis 1, stating that it is possible, based on the biomechanical recognition of the functioning of the stomatognathic system, to develop the material and structure of the elastic element in such a way that it will function during the action of the tongue muscles, assuming that this solution can be mass-produced in a prefabricated form intended for individualisation in the patient's mouth.

Thesis 2 was based on the possibility of developing a material dedicated to the solution in question and guaranteeing the fulfilment of biomechanical requirements and the form of a prefabricated structure while achieving improved microbiological resistance.

First, a numerical mandible model was developed based on identifying the functional and morphological features. FEM simulation studies of the effect of controlled changes in muscle activity on joint and occlusion reactions were performed to confirm the action pattern of activation of muscles opposite to the adductors and the beneficial effect in the treatment of bruxism.

Secondly, prototyping of a range of design features of the tongue trainer was performed. Two basic types of trainers were made and assessed in terms of empirical testing of the shape and location of the elastic (compliant) element by the team involved in the project. Then, based on the prototypes and the obtained survey results, two digital models of the trainer were made. Simulation tests and FEM evaluation of the influence of the elastic properties of the trainer material on the deflection and strength of a flexible obstacle were performed on them.

Based on the results obtained, materials for the trainer were selected and blends and a method of obtaining them were developed. Based on the results of material tests, their functional properties were assessed. For the optimal variants, technological tests were carried out to determine the possibility of producing prefabricated trainer elements based on the production of injection molds. Injection tests were performed in the technology of a small series of prefabricated trainer elements.

Then, innovative composites with antimicrobial properties were developed. This was achieved by developing a method of introducing fillers using the solvent and mechanical method, performing material tests, and testing the adherence of *Candida albicans* and *Streptococcus mutans* and cytotoxicity for microbiological assessment.

For the optimal blends and composites from the previous points, trainers' prototypes were made per the assumed technology, and the biofunctional features of the devices were tested.

Based on the results obtained, the following conclusions were formulated:

- simulation studies using the finite element method have shown that the use of a trainer in the form of a medical device, by our own patent application, equipped with an elastic element made of an appropriately selected material and with specific geometric features and loaded with tongue forces, will favour the rehabilitation process of patients with occlusion disorders biomechanical changes,
- simulation tests using the finite element method allowed for the identification of the desired material properties, enabling the construction of a trainer with a planned structure and geometric features of the elastic element,
- a series of materials with the desired mechanical properties and related to the processing of the obtained blends has been developed, allowing the production of trainers with varying compliance depending on the individual patient's ability to load the elastic element with different values of tongue forces,
- composite materials modified with silver-hydrogen zirconium phosphate particles were developed, which allowed for a significant reduction in the number of colonies of pathogenic yeast-like fungi and cariogenic bacteria in the surrounding environment while maintaining no cytotoxic effect and maintaining the remaining analysed beneficial biofunctional features related to mechanical, physicochemical and processing properties,
- demonstrators were made and tested, which allowed for confirmation of its biofunctional features related to the behaviour of the elastic element in conditions close to real ones, thus achieving implementation readiness for clinical tests and verification of the trainer's effectiveness,
- a technology for small-batch production was developed, and a methodology for self-adjusting the product by the patient to individual anatomical conditions was developed,
- proposed a number of design solutions supported by FEM tests allowing for the improvement of some aspects of the trainer's functioning compared to the original assumptions, which in particular include making an appropriately located hole to reduce the accumulation of saliva without a significant change in the load-bearing capacity of

the obstacle and examining the possibility of making trainers with zones characterised by diversified stiffness for patients with asymmetrical ability to load the obstacle.