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FEM simulation of a novel medical device for TMJ therapy

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ABSTRACT

Purpose: Temporomandibular disorders (TMD) are one of the leading health problems in dentistry. The work aimed to evaluate, using FEM, the influence of the material elastic properties of the flexible obstacle of the tongue trainer on the range of deflection and strength.

Design/methodology/approach: In prototyping the trainer tongue, the starting point was real models with different extents of the tongue obstacle. moulded from dental wax on a dental stone model. Then versions were tested intraorally for the perception of the space occupied by the tongue. The models were scanned on a 3D scanner, and then a parametric CAD model (NX Siemens) was made on their basis. Finally, in order to take into account, the anatomical aspects, the two extreme ranges of the tongue obstacle, named "Long " and " Short ", were developed. Simulation deflection and material strength tests were made using FEM in the linear range (NX Siemens). Calculations were made for materials with Young's modulus equal to 8 MPa, 80 MPa and 800 MPa. The interaction of the tongue with the force of 5N was assumed. The support was provided by the retention surface on the teeth, with the support of the posterior edge of the obstacle on the palate (palatal variant) or lack of support, i.e., the obstacle freely bending in this area (free variant), was additionally tested. In order to assess the drop or retention of the trainer on the teeth, the second type of simulation was performed with the assumption of horizontal (anteriorly directed) tongue pressure with the force of 10N for the condition of rigid support in the area of the teeth and the periodontal zone from the lingual side. In this variant, a simulation was adopted for a material with a modulus of elasticity E=80 MPa.

Findings: The stress values of the flexible obstacle of the trainer were obtained, allowing for the selection of potentially valuable materials for the trainer's construction. The results obtained in the simulations indicate the possibility of using ethylene vinyl acetate (EVA) and its blends.

The accumulation of saliva inside the sealed obstacle was found, which indicated the need to look for an area to perforate without losing the load capacity of the obstacle. The structural feasibility of solving the problem of saliva accumulation without a significant change in the load capacity and stiffness of the obstacle was confirmed by simulation.

Research limitations/implications: Simplifying the model to a linear range does not allow buckling analysis. In addition, the assumption of a linear material further limits the possibility of analysing materials with softening and plateau characteristics, where the compliance of the structure leads to elastic buckling.

Practical implications: The range of deflections and stresses for different stiffness of the elastic element of the trainer was determined in order to select the appropriate material for the medical device (MD). Polyurethanes or silicones provide the range of deflection and strength, but in the case of manufacturing prefabricated trainers thermoformed in the patient's mouth (maximum temperature 75°C), the material that can be used is ethylene vinyl acetate (EVA).

Originality/value: Simulation tests made it possible to determine the range of deflections and stress for different stiffness of the flexible obstacle of the trainer in order to select the appropriate material for the medical device.

Keywords: FEM, Disorder, Stomatognathic system, Bite splint, Dental material, Thermoforming, Moulding

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BIOMEDICAL AND DENTAL MATERIALS AND ENGINEERING

1. Introduction

Dysfunctions of the stomatognathic system (SS) are one of the leading health ailments requiring treatment by dentists [1]. The progress of civilisation and the related stress affect the number of people concerned by these TMD dysfunctions [1, 2-6]. There are no unequivocal data on the occurrence of TMD dysfunction. However, clinical studies indicate the severity of symptoms in 50-88% of the population [7]. The main TMD disorders are irregular mandibular movements and temporomandibular joint (TMJ) symptoms, e.g. in the form of clicks and bruxism [6, 8-11].

Most devices for treating occlusal disorders work on the principle of an occlusal obstruction or mandibular positioner [12]. Solutions to activate the muscles opposing the adductor muscles are few. Clinical studies have shown beneficial therapeutic effects of flat sublingual plates [13] and palatal plates [14]. The effects of therapy using a static rigid tongue positioner are presented [15]. Among such devices, only one works on the principle of a bending flexible obstacle (tongue trainer) under the pressure of the tongue [16,17]. It should be noted that in devices activating the action of muscles opposing to the muscles inducing the influence of the elastic properties of materials and the ability to elastic deflection of the elements of these trainers on the biomechanical effects are unknown. Indicating the material and technological solution for the construction of a flexible obstacle and its range of deflection in the context of individual treatment needs requires the selection of material for the trainer. Individualisation and the use of advanced technologies in the design of medical devices are part of the idea of Industry 4.0 [18]. In the first stage, it is helpful to prototype the trainer's biomechanics using numerical simulations, e.g., FEM [19].

The work aimed to evaluate, using FEM, the influence of the elastic properties of the material of the flexible obstacle of the tongue trainer on the range of deflection and strength. The work hypothesised that it is possible to obtain the deflection of the obstacle under the force of the tongue until the obstacle is supported on the palate without exceeding the strength of the material.

2. Material and methods

In the prototyping of the tongue trainer, the starting point was real models formed of dental wax on a plaster model with different tongue obstruction ranges and tested intraorally in terms of the feeling of the space occupied by the tongue. The models were scanned on a 3D scanner, and then a parametric CAD model (NX Siemens) was made on their basis. Finally, in order to take into account the anatomical aspects, the two extreme ranges of tongue obstruction, named "Long" and "Short", were developed.

During this stage, the accumulation of saliva inside the sealed obstacle was found, which indicated the need to search for an area to perforate without losing the load capacity of the obstacle.

Designed two models of the trainer with a shorter and a longer range of flexible obstacles for the tongue. Figure 1a shows the model of the tongue trainer with a flexible obstacle in the "Short" version, while Figure 1b shows the view of the spring element. A thickness of 1mm of a flexible obstacle was assumed.

Simulation deflection and material strength tests were made using FEM in the linear range (NX Siemens). Calculations were made for materials with Young's modulus equal to 8 MPa, 80 MPa and 800 MPa. The interaction of the tongue with the strength of 5N was assumed. The support was provided by the retention surface on the teeth, with the support of the posterior edge of the obstacle on the palate (palatal variant – Fig. 2a) or lack of support, i.e., the obstacle freely deflected in this area (free variant – Fig. 2b), was additionally tested.

3. Description of achieved results

The usefulness of FEM simulation in dentistry, prosthetics and maxillofacial surgery has been repeatedly confirmed in tests of the strength of materials and both hard and soft tissues [20-22]. The results of the tested trainer are difficult to relate directly to other works because the device is innovative. However, FEA simulations concerning the assessment of the impact of the tongue on the stability of dentures presented in [23-26] show that it is possible to test the state of stress in devices operating in the oral cavity and caused by the load of the tongue force.

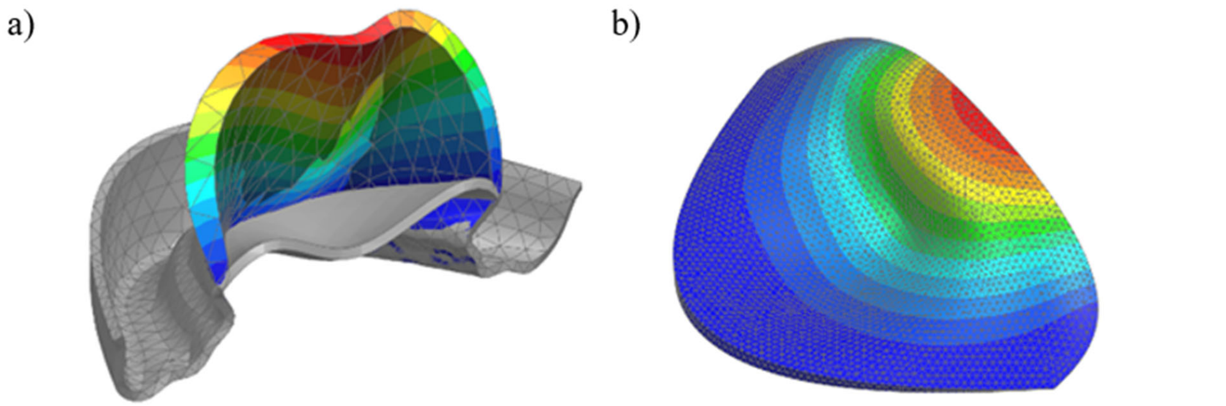

Fig. 1. a) View of the tongue trainer model with a flexible obstacle for the tongue in the shorter version ("Short"); b) view of the flexible obstacle

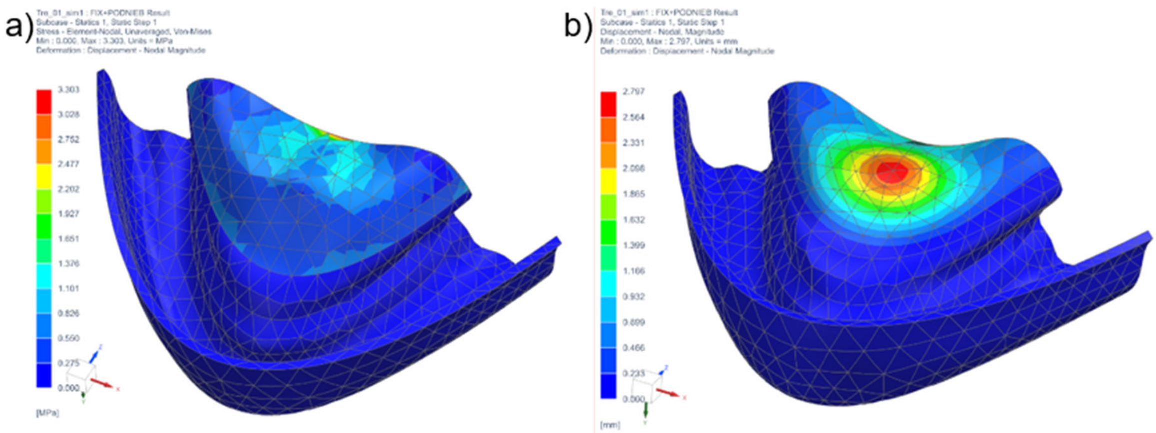

Fig. 2. Long trainer with support for the posterior margin of the obstacle on the palate

Figure 3a shows the deflection in the shorter model, which for E=8 MPa reached a maximum value of 21.7 mm. The Huber- Mises reduced stress in Figure 3b reached a less than 5 MPa value. However, the stresses in the nodes at the edge of the support on the teeth are a FEM artefact. Based on the values in the elements along the edge of the support but in the nodes not lying on the edge, the values were estimated at about 3 MPa. In fact, deflection of the palatal tissues should be encountered within the calculated range; the resilient element would rest on the palate. Thus, the stresses in the model have been overestimated, and the material, whose strength reaches 3-5 MPa, will provide the load capacity of the susceptible obstacle with a margin.

A longer trainer with support on the back edge of the obstacle on the palate for material E=8 MPa is shown in Figure 4, and without support in Figure 5. The deflection for the first case reached 6.7 mm (Fig. 4a). On the lingual bulge, the stress value (Fig. 4b) was approx. 3.35 MPa on the palatal side (extension) and slightly less than 2 MPa on the lingual side (compression). For the case shown in Figure 5, the stress outside the artefact is approx. 3 MPa and the deflection exceeds 32 mm.

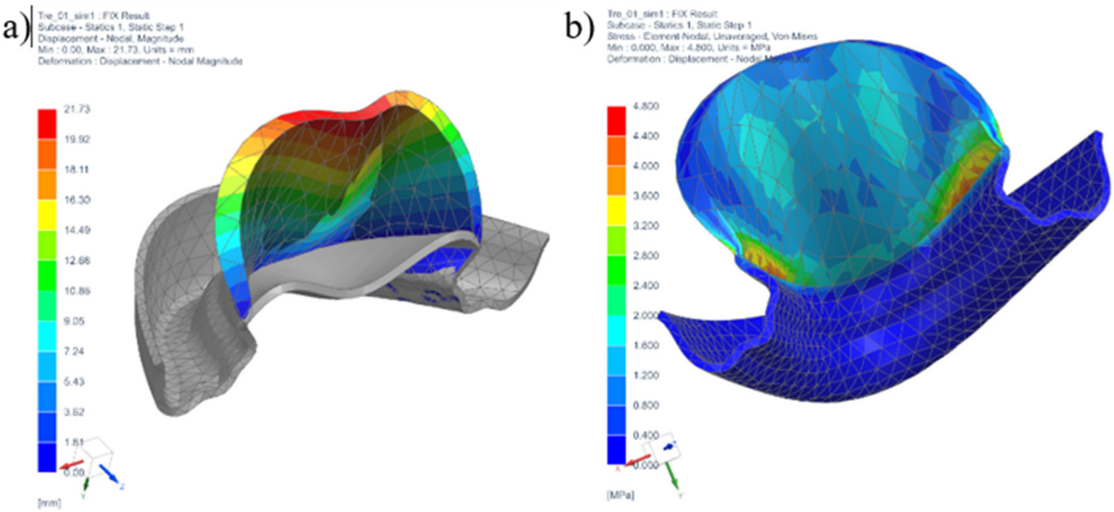

Fig. 3. a) Distribution of displacement (deflection) of the obstacle in the "short" model and (b) Huber- Mises equivalent stress for material E=8 MPa

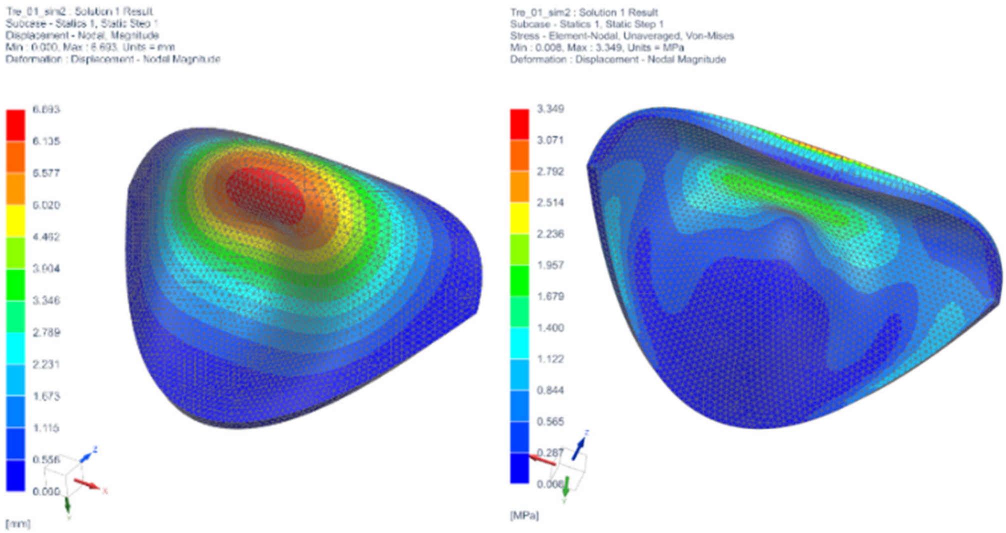

Fig. 4. Distribution of obstacle deflection, a long trainer with support for the posterior margin of the obstacle on the palate, material E=8 MPa

The following figures show the long model without support on the palate for the material E=80 MPa – Figure 6 and E=800 MPa – Figure 7, respectively. Because the short model has a higher stiffness, the long model was initially selected for further research to show the effect of increasing E on the stiffness of the obstacle. The deflection was approximately 3 mm and 0.3 mm for the tested materials. In the linear model, the stresses did not change.

The second step was a simulation study of dropping the trainer. The deflections and stresses did not change significantly. Despite the increase in force, the value of the stress outside the artefact remained at the level of about 4 MPa – Figure 8. The reaction force was distributed at the upper edge of the support in a strip not exceedingly approx. 3 mm wide – Figure 9a. The simulation provided valuable information regarding the criterion area of influence of the trainer's adhesion on its stability. Bending the obstacle to the sides transfers the force to the lateral areas and uses the support on the undercuts of the lateral molars. Resigning from the range of the obstacle to the front area will introduce an increase in the reaction in the front part, which creates better resistance conditions for the force directed in front, but worse for the force pulling the trainer vertically down from the teeth. At the same time, it is visible that the forward

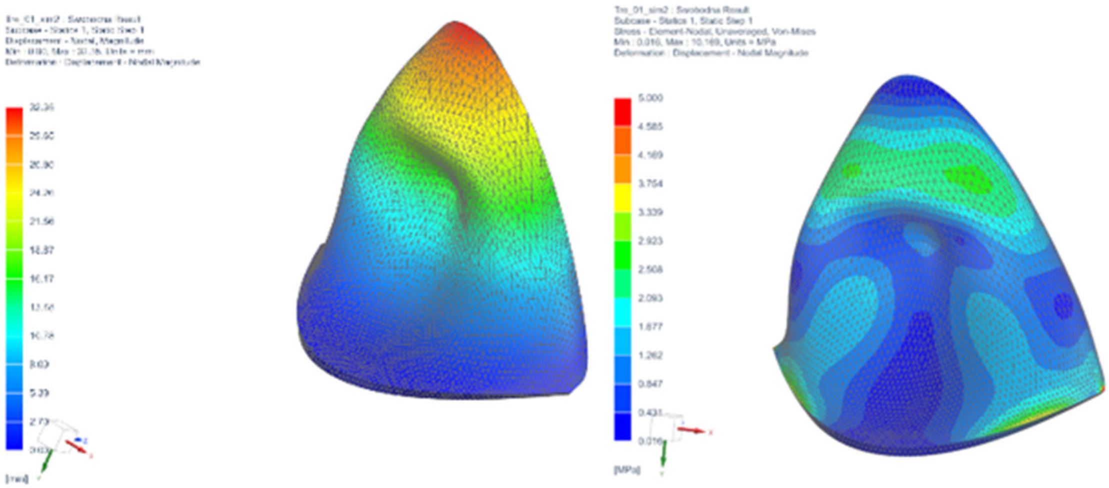

Fig. 5. Distribution of deflection of the obstacle and Huber- Mises stress of the long trainer with no support of the posterior margin of the obstacle on the palate, material E=8 MPa

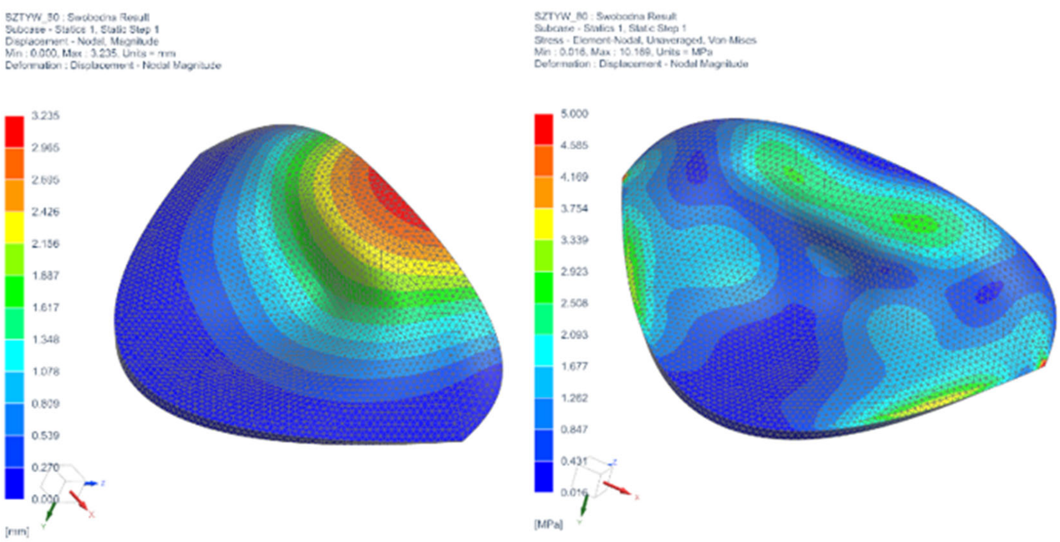

Fig. 6. Obstacle deflection tests, the long trainer without support on the palate, E=80 MPa

force was balanced by lateral reactions, least of all in the anterior section, which results from the deformation of the obstacle, in which the bend towards the palate dominates.

In the area of the depression - marked in Figure 9b in red, in which saliva is collected, low-stress values were found through simulation tests. The test results allowed to conclude that cutting holes in this lightly loaded area will solve the problem of saliva accumulation without significantly changing the load capacity and stiffness of the obstacle.
Stresses for different stiffness of the flexible obstacle of the trainer were determined in order to select the appropriate material for the medical device. Polyurethanes or silicones provide the range of deflection and strength, but in the case of manufacturing prefabricated trainers thermoformed in the patient's mouth (maximum temperature 75°C), the material that can be used is EVA (Ateva ® EVA). EVA with 28% vinyl acetate (EVA28) for medical applications has flexural modulus at 23°C – 15 MPa and Tensile stress at break 11 MPa, and EVA with 40% vinyl acetate (EVA40) accordingly flexural modulus at 23°C – 1.9 MPa and tensile stress at break 5 MPa [27]. The results obtained in the simulations indicate the possibility of using EVA28 or a blend. Implementing the trainer requires further research to determine the mechanical properties of the EVA28 and EVA40 blend that could meet the parameters assumed in the work.

Attention should be paid to the limitations in applying the results to the real system. Simplifying the model to a linear range does not allow buckling analysis. In addition, the assumption of a linear material further limits the possibility

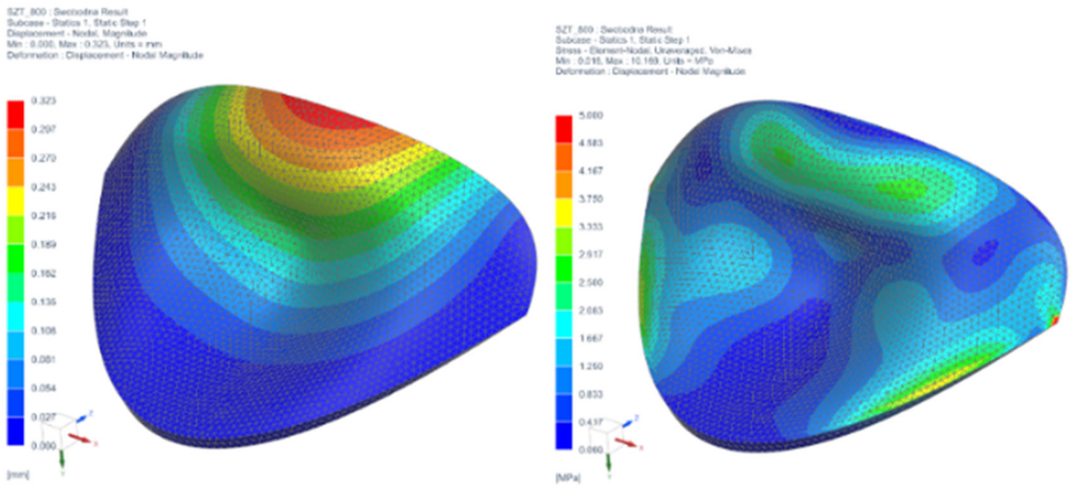

Fig. 7. Obstacle deflection tests, the long trainer without palate support, E=800 MPa

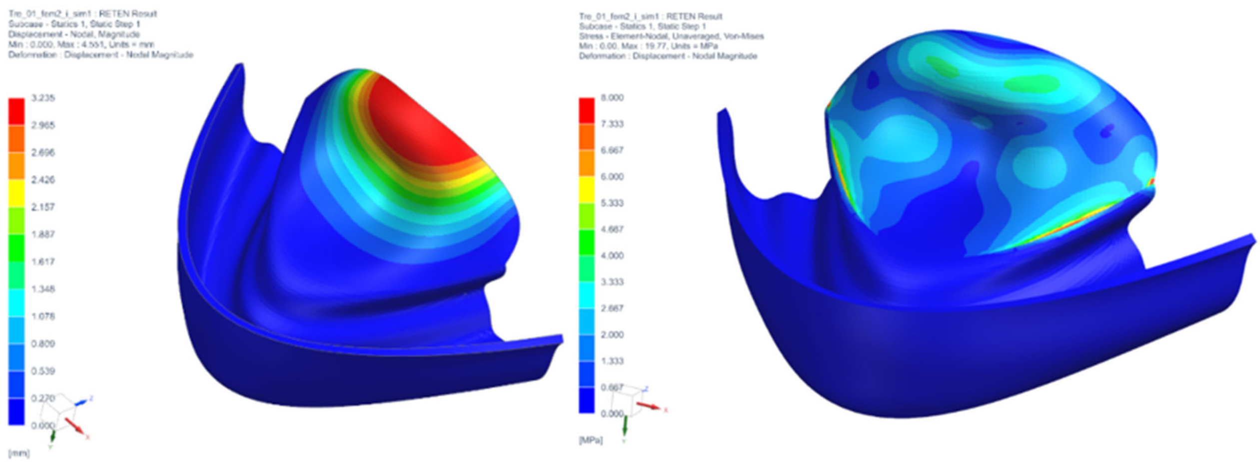

Fig. 8. Testing the dropping of the trainer. Deflections and distribution of Huber Mises stresses

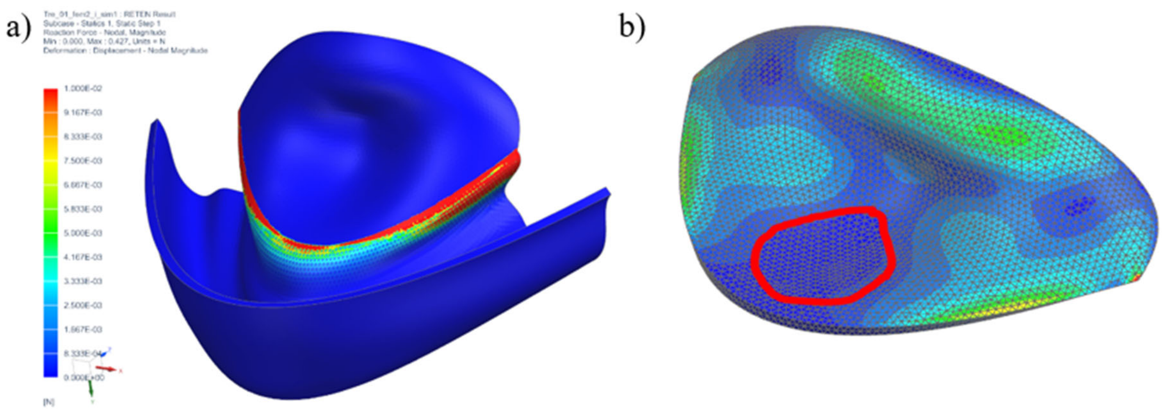

Fig. 9. a) Trainer dropping test. b) Saliva accumulation area

of analysing materials with softening and plateau characteristics, where the compliance of the structure leads to elastic buckling. However, these phenomena are desirable due to the biomechanics of the trainer, where it is assumed based on physiology that it is not the force value but any level of activation of the tongue muscles that prevents activation of the mandibular adductor muscles.

The cost of the analysis dictated the assumptions. Still, the simplifications allowed to obtain results sufficient to determine the effect of material elasticity on deflections and stresses, which were crucial for the selection of the material.

4. Conclusions

1. Simulation showed that under the force of the tongue, the deflection of the obstacle can be in sufficient range without exceeding the strength of the material.
2. Stress values obtained in the flexible obstacle of the tongue trainer allowed for the selection of EVA as a material useful for the trainer's construction.
3. The structural feasibility of solving the problem of saliva accumulation without a significant change in the load capacity and stiffness of the obstacle was confirmed by simulation.
4. In further research, determining the mechanical properties of EVA blends and modelling the buckling of the obstacle are needed.

Additional information

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