ADVANCED POLYMERIC MATERIALS FOR RECONSTRUCTIVE TREATMENT AFTER THE INTRA-ORAL TUMOR RESECTIONS

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Abstract: Obturators/blocking devices are used to reconstruct physiological functions of the oral cavity after extensive resections in the facial part of the skull. The article shows the study of mechanical properties of foamed polyurethanes, potentially used as a flexible obturatos filling. Recently, hard silicone-coated plastics have been used in the construction industry. In the course of study, static tensile test, wear test of the surface and microscopic examination of the obtained porous structure together with statistical evaluation of the obtained results were performed. The obtained foamed polyurethanes (PUF) showed adequate deformation and strength. The results obtained during the study allowed to determine the presence of a non-porous shell, which may constitute a barrier for the penetration of saliva, liquids and food into the porous structure. The resistance to abrasion was about one month of exploitation, which is sufficient for the expected exploitation period taking into account hygienic considerations.
Key words: obturator, polyurethane foams, oral biomedical application, cancer defects

1. INTRODUCTION

Abnormal embryogenesis, genetic conditions or cancer appear to be the main causes of a congenital or acquired condition in which the space of the maxillary sinuses or nasal cavity joins the space of the oral cavity. Head or neck cancer is the diagnosis that 5% of cancer patients will have to face each year, according to WHO data from 2012. A densely vascularized and well-bloodied location makes even early detection of cancer relatively bad prognosis. Surgical treatment involving extensive facial resections is usually supported by chemo and/or radiotherapy [18,49,56]. Prosthetic rehabilitation of patients with massive cavities resulting from extensive facial surgeries is one of the most difficult problems faced by modern prosthetics. Oncological therapy leads to very unfavorable conditions within the prosthetic field and makes the tissue reconstruction difficult. They result from large soft and hard tissue loss and deformation of surrounding tissues, xerostomia (dry mouth), inflammatory changes in the mucous membrane, changes in saliva pH, as well as circular caries and pathological tooth clash [24]. Intraoral resections which result in a connection between the oral cavity and the nasal cavity or the maxillary sinus space are common. The connection causes in swallowing, difficulty in speaking and chewing impairment [26,32,43,60].

The condition of patients creates difficulties at every stage of denture design, and required individual and unconventional solutions. The traditional approach to prosthetic rehabilitation of patients with oral communication with the maxillary sinus is to create an obturator to close the acquired resection cavity primarily within the hard palate, but also on the adjacent structures of the alveolar cavity and soft tissues. Once the face looks as natural as possible, swallowing, speech and chewing conditions are restored, the patient also improves his/her mental condition, which has beneficial effects on the systemic effects of treatment. The obturator is a part of the postoperative maxilliary prosthesis, which is an additional element closing the junction created after resection [4,32,33]. The retention force of the obturator is important factor, which decreases significantly with its mass, which leads to impaired speech function and food consumption [2,3,10,14,16,19,46,38,44,50,54].

The materials commonly used for obturators include acrylates (methyl polymethacrylate), silicones and also titanium [32,39] and postoperative dentures [4,6,30,33,60] are made from thermoformed polymers, including polyurethane[5]. However possibility of using foamed polyurethanes was not investigated.

Polyurethane is a polymer often used for medical purposes. High biocompatibility and its relative chemical stability in the tissue environment have been identified as potentially useful for prosthetic purposes [64].

Additional use of foaming agents could reduce weight and increse flexability, which improves retention and equalizes pressure. In the work polyurethane foams were examined, which were made using the one-shot process with the use of the natural blowing agent in the form of acetone [24,30,53].

The development of the one-shot process for obtaining foams as the most common, simplest and most frequently used technology for manufacturing polyurethanes [53,57]. Technologic simplicity is important factor in dental technique.

2. EXPERIMENTAL

2.1 Materials characteristics

Samples of material were made of flexible polyurethane foam (PUF) available commercially under the name Flex 140. The PUF is a two-component polyurethane system designed for mold production with increased density and mechanical strength. The foam consists of two components which are chemically different and have different physical properties as shown in the Table 1.

Table 1. Physical characteristics of the flex 140 components

Feature	component A	component B
Appearance	Prescription polyol mixture in the form of an oily liquid without Suspensions.	Liquid without suspensions
Colour	White	Honey - brown
Density at temp. 20^0	1.05 ± 0.02 g/cm^3	2.33 ± 0.03 g/cm^3
Viscosity at temp. 20^0	300 – 700 mPa·s	250 – 450 mPa·s
Smell	Characteristic, not intrusive	Characteristic, not intrusive

To make the samples with a possibly homogeneous structure and repeatable production method, a 50 cm^3 polypropylene form was prepared. Additionally, to obtain a more porous structure it was decided to add blowing agent in the form of acetone by C% ≥99.6%. The foam was obtained by the one-shot process with set process parameters presented in the Table 2 below:

Table 2. Foam production parameters

Parameter	Value
Form volume	50cm^3
Apparent sample density	0.425g/cm^3
Mixing time	15s
Component A to B ratio	17ml / 8ml
Mixer speed	1100 rpm (6 vane agitator)
Added porophor (aceton)	0.35ml; C% ≥99,6%
Process temperature	40 , 50 , 60 ºC

The temperature of the process has been selected to correlate the crosslinking time of the polymer with the appropriate boiling intensity of the blowing agent. The qualitative evaluation was based on the homogeneity of the obtained structure and the average size of the pores. During the polymer crosslinking reaction, specific stages occur one after another, the occurrence of which determines the final properties. According to the manufacturer's data, their duration is presented in the Table 3 below:

Table 3. The occurrence and duration of the different reaction steps

Parameter	time [s]
Starting time[1]	18-22 s
Gelation time[1]	65-85 s
End of growth	90-115 s
Apparent density[2]	0.14±0.02 g/cm^3

[1] Response time measured from the start of mixing; start time until the mixture starts to grow.

[2] Apparent density determined as the quotient of the weight of the foam in the casting mold to the volume of the casting mold.

2.2 Samples preparation for microscopic observatio

The samples for microscopic examination were cut with a sharp tool lengthwise to the direction of foam growth so as not to damage the non-porous layer intended to protect the material from absorbing the liquid. After taking pictures showing the non-porous layer, the samples were turned by 90 degrees so that the cross-sectional area across the entire porous surface becomes visible.

2.3 Microscopic observation

Using the ZEISS Axio Vert A1 light microscope with the AxioCam ERc 5s microscope module, the microstructure on the cross-section and the surface of the samples were taken for each polymerization temperatures (40, 50 and 60ºC) at magnifications of 100x, 200x, 500x. The photos were taken by coupling with a PC microscope with AxioVision software installed.

2.4 Static tensile test

The static tensile test was carried out with a Zwick Roell Z. Samples were cast in polypropylene molds, which allows obtaining uniform thickness and repeatable conditions for the formation of a non-porous coating. To obtain reliable statistics, 5 correct static tensile tests were carried out for each polymerization temperature. Sample dimensions are showed at Figure 1. Samples were stretched to its destruction and tensile strength and elongation were obtained [24]. The test was carried out following the standard PN-EN ISO 6892-1.

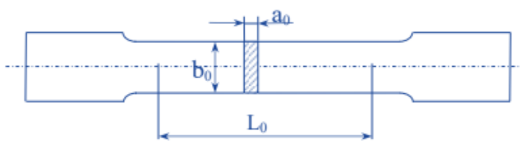

Fig. 1. Tensile test standard sample a_0 - sample thickness, b_0 - width at the point of narrowing, L_0 - measurement length

2.5 Tribological tests

The tribological pin–on-disc tests were performed with the CSM Instruments Tribometer. Samples differing in polymerization temperature were testing in a demineralized water environment and under the same test conditions. The preparation of the samples consisted of cutting out a circle with a diameter of 30mm in the longitudinal direction to the direction of foam growth (perpendicular to the non-porous layer). The measurements were recorded on diagrams according to the distance traveled between a tool steel sample and the friction force recorded by the device during the measurement. Tests were carried out following ASTM G99 & DIN 50324 standard. The Table 4 presents the test parameters [8].

Table 4. Tribological test parameters

Parameter	Value
Circle Radius	4.98 [mm]
Linear speed	2.00 [cm/s]
Load	4 [N]
Distance	20.00 [m]
Sampling rate	10.0 Hz
Temp. of the environment	25°C
Environment	demineralized water

3. RESULTS AND DISCUSSION

3.1 Microscopic observation

As a result of microscopic observations made using light microscopy, a strongly porous structure was found on the cross-section. Irregular pores were created as a result of rapid evaporation of the blowing agent during the exothermic polymerization reaction. It was observed that as the polymerization temperature increases, the pores increase and initially at 50°C they are heterogeneous. However, as the polymerization temperature increases to 60°C the obtained pores are much more homogeneous, but their size decreases slightly. This shows a better correlation between the time of blowing off the blowing agent and the curing time of the polymer. During the examination of the surface of the samples, a thin "membrane" was found.
Results of microscopic observations are presented in Figures 2-4.

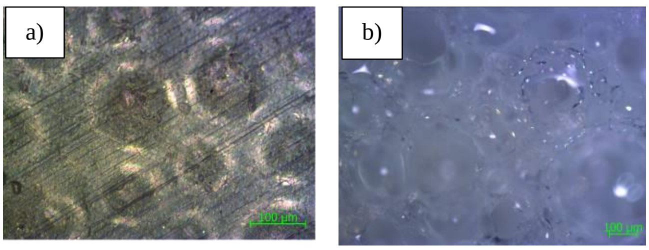

Fig. 2. Microscopic image of the polyurethane sample polymerised at 40° C, a) surface, b) section

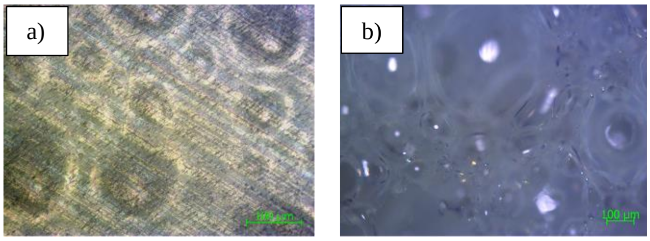

Fig. 3. Microscopic image of the polyurethane sample polymerised at 50° C, a) surface, b) section

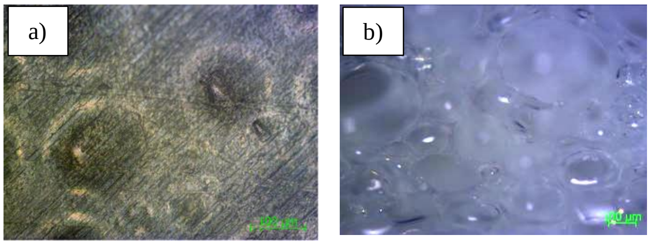

Fig. 4. Microscopic image of the polyurethane sample polymerised at 60° C, a) surface, b) section

The obtained microscopic images allowed for the analysis of material porosity using Image J software are presented at Figure 5 and Table 5.

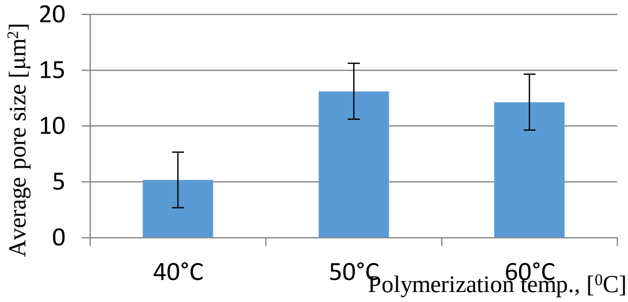

Fig. 5. Average pore size due to polymerization temperature

Table 5. Average pore size due to polimerization temperature

Polymerization temperature, [°C]	40	50	60
Average size [μm²]	5.2	13.1	12.1
Standard deviation	3.2	9.6	6.8

3.2 Static tensile test

The shape of the recorded tensile curves showed in the Figures 6-8 are typical of hyperelastic foam materials without a specific yield point suggesting the pores of the porous material slowly closing. As the temperature of the polymerization reaction increases, the tensile strength of the materials reduces, this is due to the presence of a more porous form correlated with the evaporation of the blowing agent during the crosslinking of the polymer resulting in a lower proportion of the polymer compared to the substrate thickness. Mechanical characteristics showed low deviations at a level of 0.06MPa for the stress and 7.53% for elongation (Tables 6–8), which were satisfying despite the laboratory scale of obtainment. This is due to the introduction of an electric stirrer and the correctly measured ambient temperature in which the reaction occurred.

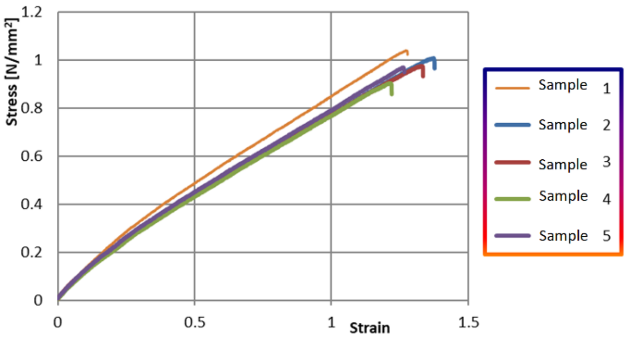

Fig. 6. Tensile test result for the PUF cross linked at 40ºC

Table. 6. Statistical averaged results for samples with polymerization temperature 40ºC

Serie	σM, [MPa]	εM, [%]
x	0.97	115.31
s	0.05	5.47
ν	5.20	4.74

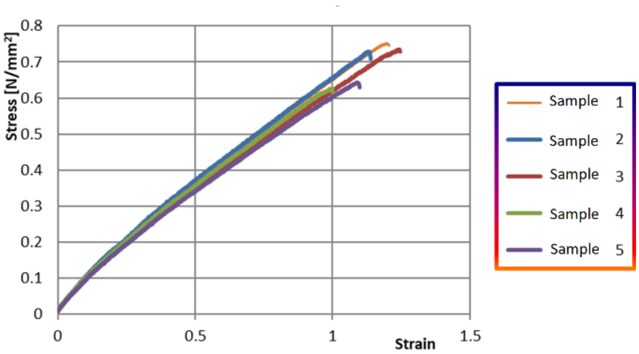

Fig. 7. Tensile test result for the PUF cross-linked at 50ºC

Table 7. Statistical averaged results for samples with polimerization temp 50ºC

Serie	σM, [MPa]	εM, [%]
x	0.70	101.14
s	0.06	8.48
ν	8.29	8.39

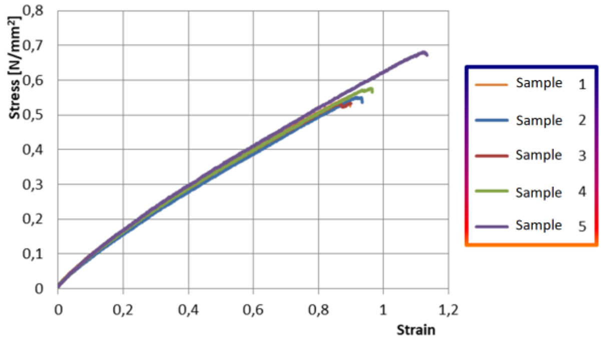

Fig. 8. Tensile test result for the PUF cross-linked at 60ºC

Table 8. Statistical averaged results for samples with polimerization temp 60ºC

Serie	σM, [MPa]	εM, [%]
x	0.58	85.44
s	0.07	8.64
ν	12.09	10.11

3.3 Tribological test

The shape of the recorded wear curves are showed in Figures 9-11. During the surface samples analysis it was noticed that some of the samples were completely degraded - while others were damaged unnoticed by the naked eye. To observe the extent of surface degradation, the samples were again microscopically checked after the tribological test using the Zeiss SteREO Discovery Stereo light microscope – Figures 12-14. Samples from every tested polymerization temperature exhibit rapid wear under the specified test conditions, but the average distance to degradation of the non-porous coating was not less than 500 cm.

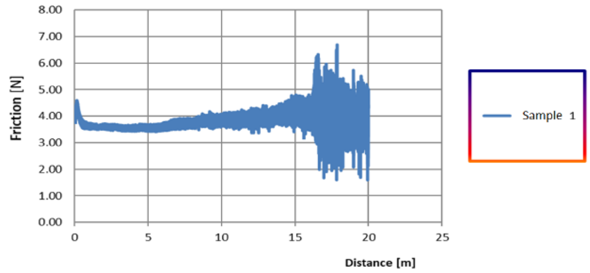

Fig. 9. Tribological test of the sample polimerized at temperature 40ºC

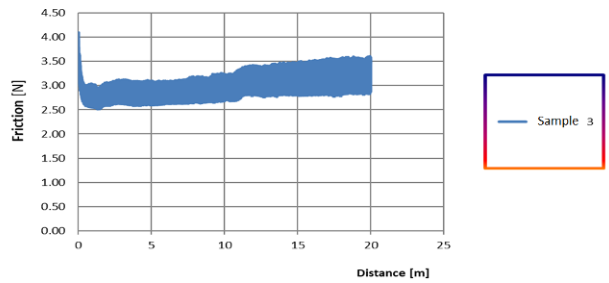

Fig. 10. Tribological test of the sample polimerized at temperature 50ºC

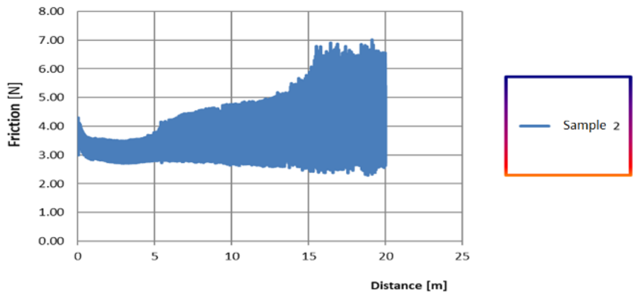

Fig. 11. Tribological test of the sample polimerized at temperature 60ºC

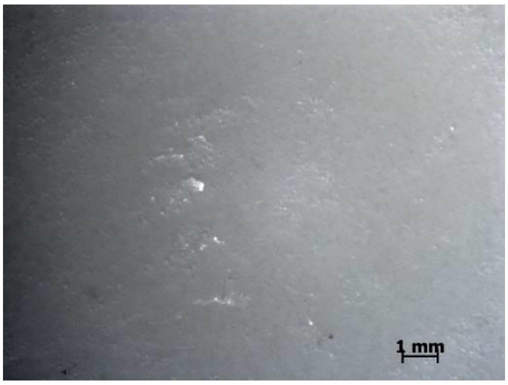

Fig. 12. Almost imperceptible damage of the surface of the sample polymerized at 40°C, magnification 10x

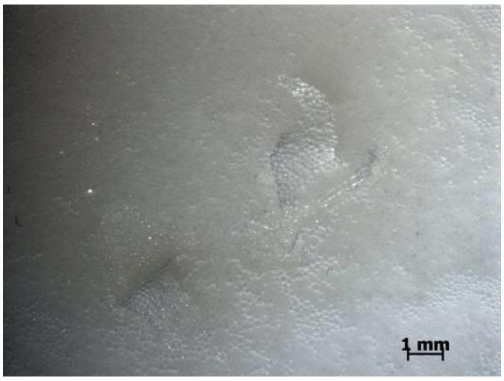

Fig. 13. Minor damage to the the surface of the polymerised sample at 50°C, magnification 10x

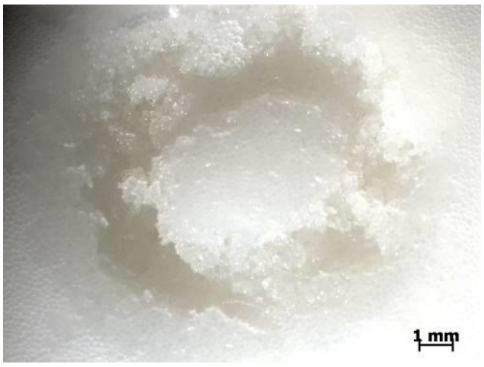

Fig. 14. Heavy degradation of the surface of the sample polymerized at 60°C, magnification 10x

PUFs shows favorable thermal insulation properties [12,34,61,] which are important due to heating of the obturator while drinking and eating. Favorable mechanical properties in the case of obturators differ from other bone reconstructions. In the case of bone implants desired foam stiffness is similar to bone [51]. In the case of obturators, the characteristics more closely match the breast implants [28,47] and articial skin [35]. However, in the case of both bone and breast implants, tissue ingrowth into open pores is expected [17,25,27]. In the case of obturator tigth and wear-resistant cover is desired. Foams generally works under compression [13,20,23,36,51]. The obturator can be not only compressed, but also stretched while being removed from the mouth or by the cycling mastication forces generating a lever. The pilot mechanical study was performed in the work and use of biotolerant polyurethane was assumed in the future from economic reason. It was possible to state that the course of the registered tensile curve is typical for hyperelastic foam materials, without a clear yield point, which indicates gradually closing pores of the porous material [6,8,24,33]. The scattering of the results of a static tensile test despite the laboratory scale of obtaining can be considered to be satisfactorily low. This is due to the introduction of an electric stirrer and a precisely adjusted temperature of process. As the temperature of the polymerization reaction temperature increases, the tensile strength of the samples decreases. In the work [45] tensile strength of the PU foam decreases with increasing foaming pre-heat temperature from 20-70°C. It is related to the occurrence of an increasingly porous structure associated with the evaporation of blowing agents during the polymer crosslinking, which results in a lower proportion of polymer with the material volume [24, 30]. However, with increasing pre-heat temperature, there is a tendency to increase compliance [57] which is important factor related to soft tissue pressure [45]. Excessive values of permanent load can induced pressure ulcer, but too little interference can result in impairment of retention even during the action of tongue that can affect the retention of prostheses [65]. In cancer patients, this is particularly important because the state of soft tissues and salivation is usually worse, and these factors affect the load bearing ability [29, 66].

The tests of polyurethane foam samples showed that the material exhibit relatively rapid wear under the given conditions. Chemical environment of the oral cavity, body temperature and foods and drinks, as well as hygienic procedures [10, 42, 59] are other factors accelerating changes in chemical composition and foam structure [62, 48].

Microscopic examination revealed the presence of a thin layer of non-porous material 'membrane', which potentially can protect the foam from uptake fluid into the structure. The microscopic examination performed after the tribological test revealed complete degradation of the surface layer for some samples. Elastomer foams based on PU characterized relatively low abrasion resistance which decrease with blowing agent content [7,63]. Taking into account six insertions and removings of obturator per day and of about 1cm for each movement an average wear distance of 3.6m per month can be estimated.

However, the duration of use in oral cavity should also be considered in the hygienic criteria [21,22,41,52]. The colonisation of micro-organisms (bacteria, fungi) inside the material is significant after about a month [9]. Work on improving bacterial resistance of soft denture lining materials has been going on for years. Although the beneficial effects of some biocides have been demonstrated [11,31,55,58], such materials have not yet been implemented in clinical practice. It seems reasonable to limit the time of use to one month when consider the disadvantages of bacterial colonization of obturators [1,15,37,40]. The worst sample significantly exceeds the assumed lifetime.

4. CONCLUSIONS

The pilot study, including stress-strain behaviour and wear resistance allowed to conclude that foamed polyurethane with non-porous surface showed wear resistance sufficient to be used for about a month as obturator.

The higher polymerization temperature resulted in an increase of pore size, which reduced strength and slightly affected foam deformability.

5. ACKNOWLEDGMENTS

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