EVALUATION OF THE STRENGTH PROPERTIES OF MATERIALS INTENDED FOR TRACHEOBRONCHIAL TUBES

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Abstract

The desire to increase the comfort of patients and to continue production despite the decreasing amount of available materials on the market has led to the constant search for novel materials that could be used to obtain tracheobronchial tubes. The aim of this study is to determine the mechanical properties of a new thermoplastic elastomer. Two materials - the thermoplastic elastomer and the natural rubber were subjected to three tests: static tensile test, static compression test and static three-point bending test. During the static tensile test, samples of the tested materials were examined, and during the next two examinations, the final products. The materials underwent the processes of sterilization, hydrolytic degradation and degradation by oxidation. The treated samples were also tested in order to compare the obtained results.

The mechanical properties of the tested materials improved both after the hydrolytic degradation and oxidative degradation, as well as after the sterilization process. Yet the thermoplastic elastomer revealed a more noticeable increase. The elastomer hardening is a positive phenomenon potentially leading to fewer accidental closures of the tubes cross-section. Both the sterilization process and various degradation methods improved the mechanical properties by strengthening the tested materials. This phenomenon seems to be desirable to avoid the closure of the implemented tube during its application.

Keywords: *thermoplastic elastomer, tracheobronchial tubes, oxidative degradation, hydrolytic degradation*

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Introduction

Both T-type endotracheal tubes and Y-type tracheobronchial tubes are used to allow patients to breathe freely in cases of stenosis or obstruction of the airway lumen as a consequence of e.g. cancer or trauma. Endotracheal tubes additionally support the larynx and trachea tissues during the reconstruction of these organs, not only providing natural airway through the upper respiratory tract but also bypassing breathing through the tracheostomy. The main function of tracheobronchial tubes is to restore the trachea and main bronchi patency [1-3].

As any medical device inserted inside the human body, both types of tubes may cause side effects, such as infection and bleeding in the respiratory organs, shortness of breath and inflammation. There is also a possibility of stent displacement. In order to minimize the likelihood of such adverse effects, the tubes must be properly implanted by qualified medical personnel. At the same time, these devices should be made of a suitable material that does not cause severe or chronic reactions and is characterized by high bio-tolerance and appropriate strength properties [3-6].

So far, endotracheal and tracheobronchial tubes have been made of natural rubber but its availability on the market is constantly decreasing. The need to maintain tubes production and help patients made scientists search for innovative, more cost-effective and convenient solutions. Thermoplastic elastomers are widely used for medical applications and can be processed using a variety of manufacturing technologies. The use of this material has the potential to increase the production of tracheobronchial tubes and to reduce the cost per part, compared to the currently used material [7-9].

Thermoplastic elastomers are composite elastomeric materials showing the features typical for elastomers at normal use temperatures and thermoplastic resins at elevated temperatures, and their production is based on methods for generating thermo-reversible nodes of a spatial network. Such a network is made up of soft elastomeric phases separated at the nanoscale level and crystalline or amorphous phases [10-12].

Considering the described problems, the aim of this study is to determine the mechanical properties of new material - a thermoplastic elastomer used in the production of tracheobronchial tubes.

Materials and Methods

The research was carried out in two stages at the Faculty of Biomedical Engineering of the Silesian University of Technology. The first stage was to test the samples cut from tracheostomy tubes made of two materials: the thermoplastic elastomer and natural rubber. In order to perform the cutting procedure correctly, a special handle was prepared, using the 3D printing technology. The dimensions of the resulting samples are shown in FIG. 1.

The obtained samples were divided into five groups:

- sterilized samples,
- samples sterilized and subjected to the process of hydrolytic degradation lasting 60 days,
- samples sterilized and subjected to the process of hydrolytic degradation lasting 2 days,
- samples sterilized and subjected to the process of oxidative degradation lasting 60 days,
- samples sterilized and subjected to the process of oxidative degradation lasting 2 days.

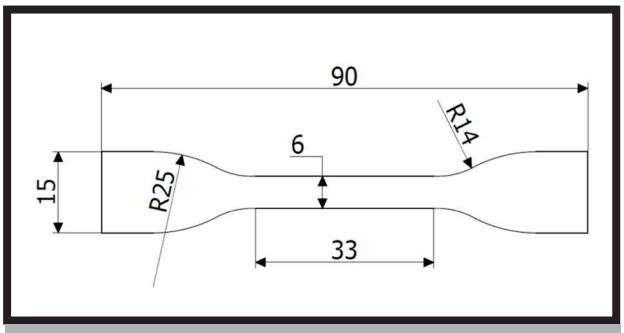

FIG. 1. Dimensions of tested samples.

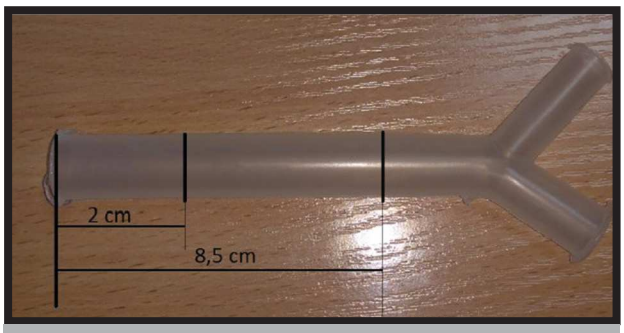

FIG. 2. Measuring distances for static compression test.

Hydrolytic degradation and oxidative degradation were performed in accordance to the standard PN-EN ISO:10993-13:2010 („Biological evaluation of medical devices – Part 13: Identification and quantification of degradation products from polymeric medical devices"). The factor of hydrolytic degradation was distilled water and for oxidative degradation – 3% hydrogen peroxide of pharmacological pureness (replaced daily). The specimens were stored in glass. A heat chamber Venticell 111 was used. The test was performed using the accelerated method at the temperature of 70°C +/- 2°C for two periods of time: 2 days and 60 days.

The sterilization process was carried out under the same conditions as for all medical products and accessories. The samples were sterilized with ethylene oxide (10% of C_2H_4O and 90% of CO_2) for minimum 3 hours. The sterilization temperature was 53°C +/- 5°C, the pressure 2.5 bar +/- 5%.

Each group contained 10 samples: 5 made of thermoplastic elastomer and 5 made of natural rubber. The total was 50 samples. The samples were subjected to the static tensile test at a speed of 20 mm/min, using the static testing machine MTS Criterion Model 43. The following properties were determined on the basis of the performed measurements:

- maximum force F [N],
- Young's modulus [MPa],
- ultimate tensile strength R_m [MPa],
- maximum deformation [mm/mm],
- dimension of sample at the measuring site [mm].

Each tested sample was fixed in the holder so that the measuring distances had the same length for every sample. The results were obtained with accuracy to 1 N. The samples after the hydrolytic and oxidative degradation processes were prepared according to the standard PN-EN ISO:10993-12:2010 *(„Biological evaluation of medical devices – Part 12: Sample preparation and reference materials"*). In the second stage, two tests were carried out on the final products made of natural rubber and the thermoplastic elastomer. Each examination was performed twice, the second time 30 days after the oxidative degradation. The results revealed how the following properties of the tested material changed:

- maximum bending force [N],
- maximum tension [MPa],
- Young's modulus [MPa].

A total of 78 laboratory tests were performed.

The static compression test was performed at a speed of 5 mm/min with the cross-section of the tracheobronchial tube closed at a distance of 20 mm and 85 mm from the tube edge. The measuring distances are shown in FIG. 2.

The static three-point bending test consisted in placing the tube on two supports spaced 50 mm apart and applying the load perpendicular to the longitudinal axis of the product. The supports and the loading element were three cylinders with a diameter of 3 mm. The load was applied at a speed of 5 mm/min.

Results and Discussion

The results of the static tensile tests for the analyzed non-degraded samples are presented in TABLE 1.

The conducted tests revealed that the samples of natural rubber had lower stiffness than those of the thermoplastic elastomer, which was evidenced by the maximum deformation values. Natural rubber had an average value of 4.41 [mm/mm], while the average deformation for the thermoplastic elastomer was 1.6 [mm/mm]. Moreover, a significant difference in Young's modulus was noticed. For the natural rubber samples, the average value was 2 MPa, while for the thermoplastic elastomer samples it was 15 MPa.

The second static tensile tests were performed after the hydrolytic degradation processes lasting for 2 and 60 days. The results concerning the 2-day process are presented in TABLE 2, while those obtained after 60 days are shown in TABLE 3.

Subsequent static tensile tests were performed on the samples subjected to the oxidative degradation process lasting respectively 2 and 60 days. The obtained results are presented in TABLES 4 and 5.

The graphs presented below show how the values of the three most important criteria - Young's modulus, maximum strength and maximum deformation changed for the samples made of natural rubber and the thermoplastic elastomer subjected to various degradation processes (FIGs. 3-5).

The tests on the final products were carried out on the sterilized and unsterilized samples after the 30-day degradation by oxidation process (30 days is the maximum implant placement time in the body). In each case, the samples of two lengths were observed: 85 mm and 20 mm. The obtained results are presented in TABLES 6-7.

The last static three-point bending test was carried out on the samples prepared in the same way as for the static compression test. The results of that study are presented in TABLES 8-9.

The conducted static tensile tests proved that both the hydrolytic and oxidative degradation processes altered the strength properties of the tested materials. For natural rubber, as a result of hydrolytic degradation, the value of maximum breaking strength increased by 17.5% after 2 days and by 20% after 60 days, when compared to the samples subjected to sterilization only. As a result of degradation by oxidation, the value of maximum breaking strength increased by 23% after 2 days and by 17.7% after 60 days. The same tendency was noticed when determining the ultimate tensile strength. In the case of hydrolytic degradation, the maximum tension increased by 4% after 2 days and by 11.9% after 60 days. In the case of degradation by oxidation, it increased respectively by 11.1% and 8.1%.

TABLE 1. Static tensile test results for samples made of natural rubber (marked as K) and thermoplastic elastomer (marked as E).

Number of sample	Young modulus [MPa]	Ultimate tensile strength R_m [MPa]	Maximum force F [N]	Maximum deformation [mm/mm]	Thickness [mm]	Width [mm]
K1	2	6.4	65	4.101	1.7	6
K2	2	7.9	81	4.498	1.7	6
K3	2	8.4	74	4.532	1.6	5.5
K4	2	8.8	84	5.525	1.6	6
K5	2	5.3	51	3.404	1.6	6
Average	**2**	**7.36**	**71**	**4.41**	**1.64**	**5.9**
SD	**0**	**1.47**	**13.36**	**0.77**	**0.05**	**0.22**
E1	17	2.9	26	1.544	6	1.5
E2	13	2.2	21	1.229	6	1.6
E3	15	2.5	24	1.679	6.2	1.55
E4	15	2.7	26	1.557	6	1.65
E5	15	2.9	28	1.989	6	1.6
Average	**15**	**2.64**	**25**	**1.5996**	**6.04**	**1.58**
SD	**1.41**	**0.30**	**2.65**	**0.27**	**0.09**	**0.06**

TABLE 2. Static tensile test results for samples made of natural rubber (K) and thermoplastic elastomer (E) after the 2-day hydrolytic degradation.

Number of sample	Young modulus [MPa]	Ultimate tensile strength R_m [MPa]	Maximum force F [N]	Maximum deformation [mm/mm]	Thickness [mm]	Width [mm]
K11	2	7.3	88	4.842	2	6
K12	2	6.7	71	4.435	1.7	6.2
K13	2	7.6	86	4.597	1.9	6
K14	2	6.8	74	4.235	1.8	6
K15	2	9.9	98	5.043	1.7	5.8
Average	**2**	**7.66**	**83.4**	**4.6304**	**1.82**	**6**
SD	**0.0**	**1.30**	**11.0**	**0.32**	**0.13**	**0.14**
E11	16	2.6	29	1.636	1.8	6.1
E12	17	2.9	27	1.554	1.6	5.9
E13	15	2.7	31	1.326	1.7	6.88
E14	14	2.9	29	1.745	1.7	6
E15	18	2.6	26	1.135	1.6	6.2
Average	**16**	**2.74**	**28.4**	**1.4792**	**1.68**	**6.2**
SD	**1.6**	**0.15**	**1.9**	**0.25**	**0.08**	**0.39**

TABLE 3. Static tensile test results for samples of natural rubber (K) and thermoplastic elastomer (E) after the 60-day hydrolytic degradation.

Number of sample	Young modulus [MPa]	Ultimate tensile strength R_m [MPa]	Maximum force F [N]	Maximum deformation [mm/mm]	Thickness [mm]	Width [mm]
K6	2	6.9	73	5.042	1.8	5.9
K7	2	8.5	92	5.251	1.7	6.4
K8	2	7.7	73	4.536	1.6	5.9
K9	2	8.4	91	5.433	1.9	5.7
K10	2	9.7	97	5.52	1.7	5.9
Average	**2**	**8.24**	**85.2**	**5.154**	**1.74**	**5.96**
SD	**0.0**	**1.04**	**11.4**	**0.39**	**0.11**	**0.26**
E6	13	3.1	0.032	1.647	6.45	1.6
E7	18	2.8	0.026	1.643	5.7	1.6
E8	14	2.6	0.028	1.555	6.5	1.6
E9	17	2.7	0.024	1.506	5.7	1.55
E10	16	2.9	0.03	1.48	6.1	1.7
Average	**15.6**	**2.82**	**0.028**	**1.5662**	**6.09**	**1.61**
SD	**2.1**	**0.19**	**0.0**	**0.08**	**0.39**	**0.05**

TABLE 4. Static tensile test results for samples of natural rubber (K) and thermoplastic elastomer E after the 2-day oxidative degradation.

Number of sample	Young modulus [MPa]	Ultimate tensile strength R_m [MPa]	Maximum force F [N]	Maximum deformation [mm/mm]	Thickness [mm]	Width [mm]
K21	2	9	90	5.482	1.7	5.9
K22	2	8.9	97	5.12	1.8	6.1
K23	2	8.1	83	4.685	1.7	6
K24	2	6.7	73	4.077	1.8	6
K25	2	8.2	94	5.039	1.9	6
Average	**2**	**8.18**	**87.4**	**4.8806**	**1.78**	**6**
SD	**0.0**	**0.92**	**9.6**	**0.53**	**0.08**	**0.07**
E21	16	3	29	1.683	1.6	6
E22	19	3.4	34	1.906	1.6	6.2
E23	16	2.8	25	1.575	1.5	6
E24	18	2.8	27	1.26	1.6	6.2
E25	16	2.5	31	1.196	1.9	6.5
Average	**17**	**2.9**	**29.2**	**1.524**	**1.64**	**6.18**
SD	**1.4**	**0.33**	**3.5**	**0.30**	**0.15**	**0.20**

TABLE 5. Static tensile test results for samples of natural rubber (K) and thermoplastic elastomer (E) after the 60-day oxidative degradation.

Number of sample	Young modulus [MPa]	Ultimate tensile strength R_m [MPa]	Maximum force F [N]	Maximum deformation [mm/mm]	Thickness [mm]	Width [mm]
K16	2	6.3	64	4.192	1.8	5.7
K17	2	8.5	10	5.748	1.8	6.5
K18	2	9.8	99	5.477	1.6	6.3
K19	2	8	89	5.585	1.8	6.2
K20	2	7.2	66	4.397	1.6	5.7
Average	**2**	**7.96**	**83.6**	**5.0798**	**1.72**	**6.08**
SD	**0.0**	**1.32**	**34.5**	**0.73**	**0.11**	**0.36**
E16	19	1.8	18	0.343	1.7	5.9
E17	15	1.5	15	0.29	1.6	6.1
E18	17	1.4	15	0.288	1.7	6
E19	16	1.4	16	0.379	1.7	6.5
E20	17	1.2	11	0.253	1.5	6.4
Average	**16.8**	**1.46**	**15**	**0.3106**	**1.64**	**6.18**
SD	**1.5**	**0.22**	**2.5**	**0.05**	**0.09**	**0.26**

TABLE 6. Results of static compression test obtained for thermoplastic elastomer samples.

Type of sample	8.5 cm			2 cm		
	Maximum force F [N]	Maximum tension [MPa]	Young modulus [MPa]	Maximum force F [N]	Maximum tension [MPa]	Young modulus [MPa]
Samples unsterilized	6.66	0.128	1.53	5.96	0.118	1.31
Samples unsterilized, after 30 days of degradation	7.42	0.138	1.86	6.43	0.120	1.47
Samples sterilized	7.33	0.137	1.61	6.35	0.118	1.34
Samples sterilized, after 30 days of degradation	7.66	0.142	1.96	6.75	0.126	1.59

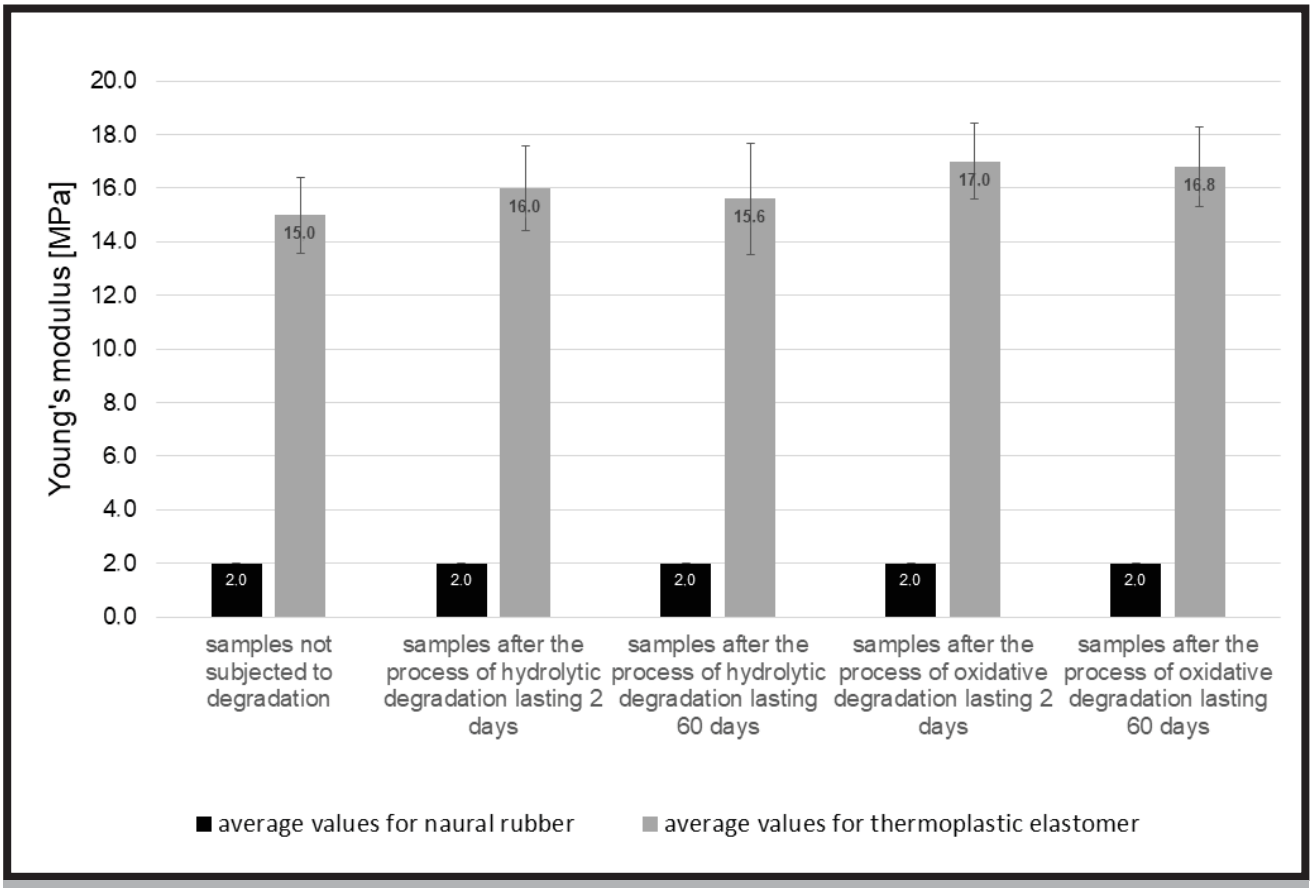

FIG. 3. Values of Young's modulus obtained for the samples subjected to various degradation processes.

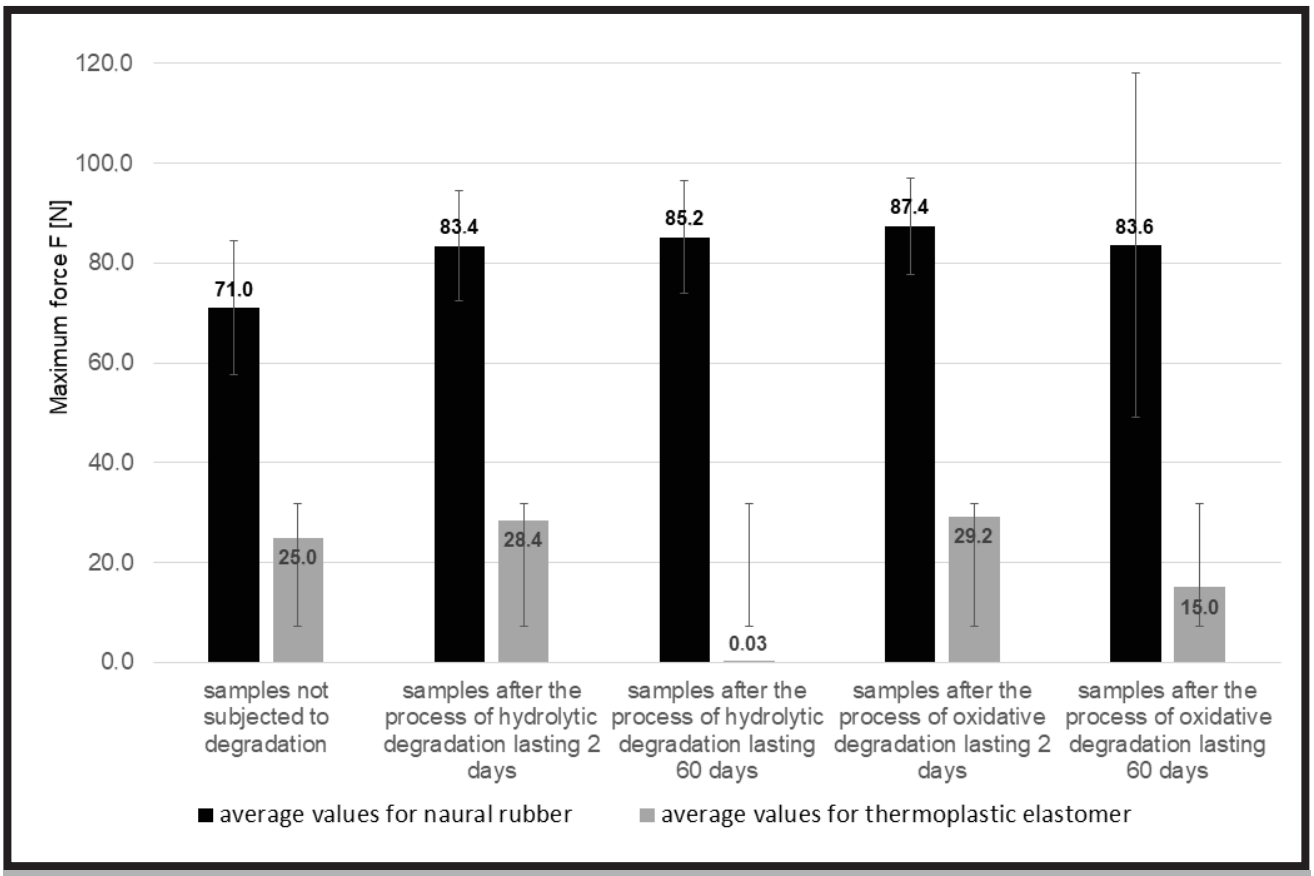

FIG. 4. Values of maximum strength F obtained for the samples subjected to various degradation processes.

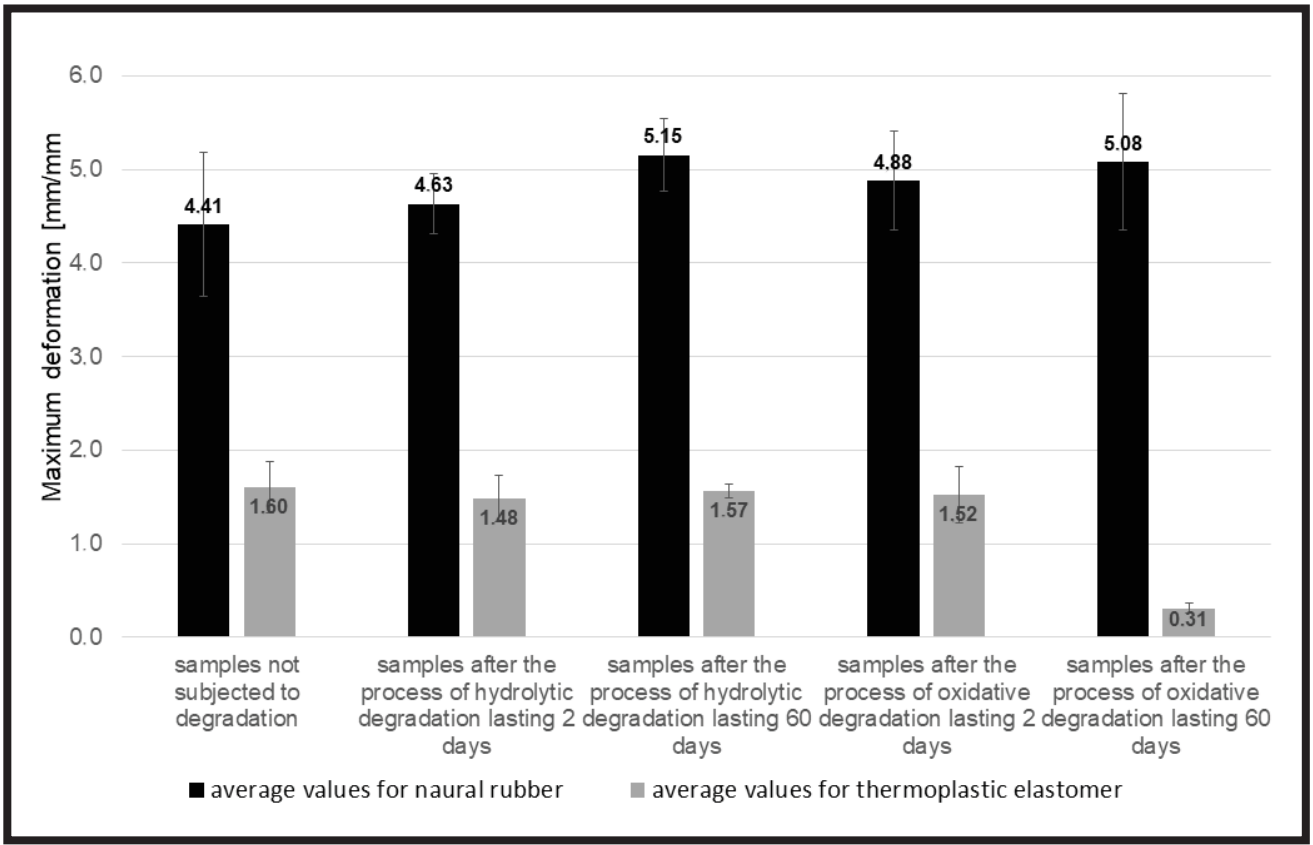

FIG. 5. Values of maximum deformation obtained for the samples subjected to various degradation processes.

TABLE 7. Results of static compression test obtained for natural rubber samples.

Type of sample	8.5 cm			2 cm		
	Maximum force F [N]	Maximum tension [MPa]	Young modulus [MPa]	Maximum force F [N]	Maximum tension [MPa]	Young modulus [MPa]
After sterilization	4.95	0.094	0.86	5.20	0.099	0.96
30 days after sterilization	4.86	0.073	0.76	4.76	0.072	0.73

TABLE 8. Results of three-point bending test obtained for thermoplastic elastomer samples.

Type of sample	Maximum force F [N]	Maximum tension [MPa]	Young modulus [MPa]
Before sterilization	4.2	0.081	1.4
30 days before sterilization	6.96	0.134	1.62
After sterilization	4.5	0.083	1.3
30 days after sterilization	7.08	0.131	1.60

TABLE 9. Results of three-point bending test obtained for natural rubber samples.

Type of sample	Maximum force F [N]	Maximum tension [MPa]	Young modulus [MPa]
After sterilization	3.3	0.063	0.7
30 days after sterilization	5.41	0.102	0.99

The Young's modulus value for all the variants remained unchanged at 2 MPa. For the thermoplastic elastomer it was observed that, as a result of the hydrolytic degradation, the maximum breaking strength value increased by 13.6% after 2 days and by 12% after 60 days. As a result of oxidative degradation, the strength increased by 16.8% after 2 days and decreased by 40% after 60 days. The ultimate tensile strength after the hydrolytic degradation increased by 3.7% after 2 days and by 6.8% after 60 days. The 2-day degradation by oxidation increased the ultimate tensile strength by 9.8%, while the 60-day degradation caused its decrease by 44.6%. Unlike the natural rubber case, the modulus of elasticity of the tested elastomer samples also changed - as a result of the hydrolytic degradation after 2 days its value increased by 6.6% and by 4% after 60 days, while the degradation by oxidation caused the increase by 13.3% and 12%, respectively.

The static compression tests showed that after the oxidative degradation process the strength properties and stiffness of the thermoplastic elastomer tubes improved. The maximum strength the cross-section was closed with, increased after 30 days of degradation for both types of tubes, before (11.4% increase) and after sterilization (4.5% increase), and the maximum tension increased by 7.8% for the tubes before sterilization and by 3.6% after that process.

However, the biggest difference was observed for the longitudinal elasticity modulus. The non-sterilized tube value increased by 21.5%, and the sterilized one by 12.2%. On the other hand, the natural rubber tubes revealed the lowered mechanical properties over time. After 30 days the maximum closing strength decreased by 1.8%, the maximum tension value by 22.3% and Young's modulus by 11.6%.

During the three-point bending test, an increase in the values was observed over time for the tubes made of thermoplastic elastomer and of natural rubber as well.

On the basis of the conducted research, it can be concluded that both the sterilization and the degradation processes improved the mechanical properties of natural rubber and the thermoplastic elastomer. A similar tendency was noticed for polyethylene intended for injection processing whose mechanical properties improved after the processes of hydrolytic and oxidative degradation [4]. Our tests proved that the tested thermoplastic elastomer was characterized by higher strength than natural rubber, which was observed in both stages of the study. Since the main function of tracheobronchial tubes is to restore the patency of the trachea and main bronchi, the material strengthening will reduce the likelihood of accidental cross-section closure of the implanted tubes. Therefore, taking into account the strength properties, the tested thermoplastic elastomer meets the requirements set for materials used to produce tracheobronchial tubes. It seems that the elastomer properties are advantageous to even a greater extent than the previously used natural rubber, however, further biological evaluation of the tested material is necessary. The authors are also planning to carry out studies on a larger number of samples to perform statistical analysis.

Conclusions

Both the technological aspect and the desire to increase the comfort of patients led to the search for new better solutions in the production of tracheobronchial tubes. The aim of this study was to determine and compare the mechanical properties of the thermoplastic elastomer and the currently used natural rubber. Based on the research, it can be concluded that the desired mechanical properties of both the tested materials improved after the processes of hydrolytic degradation and degradation by oxidation. The properties were also upgraded via the sterilization process, and in the case of the thermoplastic elastomer the increase was more noticeable. The strengthening phenomenon seems to be desirable for endotracheal tube designs, mainly to avoid the accidental closure of the tube cross-section during its application in the body. In order to determine whether the tested material can be used for tracheobronchial tubes, it is necessary to perform biological evaluation of the medical devices.

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