

Antoni Niekraszewicz,
Magdalena Kucharska,
Iwona Kardas,
Marek Szadkowski

Institute of Biopolymers and Chemical Fibres
ul. M. Skłodowskiej-Curie 19/27, 90-570 Łódź, Poland
E-mail: ibwch@ibwch.lodz.pl

Resorbable Tightening of Blood Vessel Protheses Prepared from Synthetic Polymers

Abstract

A method was prepared for the sealing of artificial blood vessels by combined soaking and spraying. Biocompatible and resorbable copolymers of poly(DL-lactide-co-glycolide) with varying contents of two co-monomers were used in the investigations. The materials were provided by Boehringer Ingelheim Co, Germany under the trade name Resomer. The polyester double-sided veloured knitted fabric vessel prosthesis DALLON H, by TRICOMED Co, constituted the matrix. Application trials resulted in the selection of Resomer RG 755S, containing 75% mol. residues of D,L-lactide and 25% mol. residues of glycolide. A modified polyester blood vessel prosthesis was prepared bearing the surgery tightness (water permeability below 30 ml/cm²/min) and physical-mechanical properties required, including elasticity adequate for such a medical device. Conditions for the sealing were elaborated at large laboratory scale with a notable composition of the coating bath and application of the coating. Results of the investigations can be considered as a basis for a technology layout for the sealing of artificial blood vessels with biocompatible and resorbable synthetic copolymer poly(DL-lactide-co-glycolide).

Key words: polyester vessel prosthesis, tightening, poly(DL-lactide-co-glycolide).

Introduction

Since the 50's, the defects of blood vessels have been repaired with synthetic textile materials. In the very beginning, polyamide fibres like Vinyon-N or acrylic fibres like Orlon [1, 2] were used for this purpose; both materials had the disadvantage of decreasing elasticity after the implantation. Textile prostheses prepared from Dacron and Teflon appeared to be a solution to the problem of providing tenacity that last many years unchanged. Prostheses are manufactured by knitting or weaving texturised multifilament yarns; the fabrics prepared are single- or double-sided veloured. Several commercial artificial blood vessels made of PET or PFET are offered by various companies, such as Protegraf, Vascutek, Polythese, GORE PROPATEN® Vascular Graft, and Dallon. The double-sided veloured polyester vessel prostheses commonly used are distinguished by good elasticity, handiness, and adequate biological permeability, providing facility for the penetration of fresh tissue and capillary vessels. On the other hand, the considerable porosity of knitted prostheses, usually within the range of between 1200 and 1900 ml/cm²/min at a hydrostatic pressure of 164 hPa (120 ml Hg) [3], does not provide the surgery tightness required, resulting in internal bleeding straight after implantation. The upper limit of permeation through the prosthesis wall allowable was determined in clinical investigations as 50 ml water/cm²/min [4]. To meet the requirement, the prosthesis is, prior to implantation, subjected to so-called preclotting [5] in the patient's blood. The treatment is uncomfortable

both for the patient and surgeon, prolongs the operation and, in some cases, may be the cause of embolism [6]. For many years investigations have been on the way to preparing prostheses which could be implanted without preclotting. Undesired treatment could be eliminated by a temporary tightening of the prostheses by means of polymeric materials prone to absorption by the patient's organism [7, 9]. On the medical market various prostheses of blood vessels tightened with protein biopolymers like collagen [10], gelatin [11-13], and albumin [14] are available under such trade names as Hemashield Gold, InterGard® Heparin, Artegraft – Collagen Vascular Graft, and Tricogel. The proteins, however, pose the danger of zoonoses like BSE, viruses of African and classical pig fever and other pathologic retro-viruses. Such biological material may overcome the immune system, causing fever, an allergenic reaction and chronic inflammation. Moreover, the proteins used for the temporary sealing of prostheses are chemically cross-linked with potentially toxic compounds like formaldehyde and glutaric aldehyde. The alleged danger of inter-species transmission of diseases and the requirements of Standard PN-EN 12442-1/2/3:2002 (Animal tissues and their derivatives used in the manufacture of medical materials) inspire researchers to investigate the possibility of using biocompatible and resorbable synthetic polymers in the sealing of blood vessel prostheses [15 - 19]. Up to now, the commercial use of synthetics as temporary tightening materials for prostheses is unknown.

The aim of the present investigation was to elaborate a sealing method for artificial blood vessels by means of a biocompatible synthetic copolymer based on DL-lactic acid (lactide) and glycolide. The usefulness of the Resomer polymers offered by Boehringer Ingelheim was assessed for this purpose. The polymers have already found wide use as construction material in a number of biomaterials like implants, resorbable sutures and carriers for the slow release of medication [20 - 24]. Another reason why the Resomers were selected was their availability and preferential prices. A blood vessel prosthesis produced by TRICOMED S.A. under the trade name DALLON H was used as the matrix onto which the polymeric coating was applied by combined soaking and spraying.

Materials and raw materials

- Polyester warp knit, double-sided veloured prosthesis DALLON H made by TRICOMED S.A. The letter H in the trade name informs that the prosthesis surface was modified with the purpose of conferring permanent hydrophilic properties upon the material. [25]. A non-tightened prosthesis, 8 mm in diameter, constituted the half product in the investigation. The structure of the knitwear of the prosthesis and kind of yarn used in its manufacture are the know-how of the producer.
- Resorbable polymers of the Resomer type (Boehringer Ingelheim). **Table 1** shows the basic properties of the Re-

Table 1. Characteristics of the Resomers.

Symbol of the Resomer	Composition	Inherent viscosity, dl/g
	DL-Laktide/glikolide, mol%/mol%	
Resomer R 203H	Poli-DL-Laktyd	0.33
Resomer RG 503	51/49	0.42
Resomer RG 504H	51/49	0.52
Resomer RG 755S	75/25	0.68
Resomer RG 858S	85/15	1.70

somers used (given by the manufacturer).

- Solvents: chloroform, analytically pure. 1,4-dioxane, analytically pure. (POCH), petroleum benzene, analytically pure – (Chempur).
- Plasticisers: glycerol, analytically pure (Fluka), polyethylene glycol 400 and 600 – (Merck).

Methodology

Examination of the structure

The surface and cross-section of the vessel prostheses were examined by means of an SEM Quanta 200 scanning electron microscope (FEI Co., USA)

Examination of the water permeability of the vessel prostheses

The water permeability of the modified prostheses was tested according to a suitable standard [26]. Measurements were performed on a device in which the amount (in ml) of water passing through the vessel walls in 1 minute at a pressure of 164 hPa was measured.

Analytical methods

Estimation of the average molecular weight by gel chromatography

Samples (ca. 15 mg) of the test material and 7 ml of chloroform HPLC (or 1.4 dioxane) were placed in a 10 ml measuring flask. On dissolving the sample, the flask was filled up to 10 ml with the solvent used, and the solution was filtered and injected into a chromatography column to carry out the analysis. Parameters of the chromatography analysis were as follows:

- solvent (mobile phase): chloroform
- column: Plgel Mixed C, 300 mm, 5 µm (Polymer Laboratories Ltd.)
- temperature of the column: 35 °C,
- flow speed: 0.7 ml/min,
- injection volume: 100 µl,
- calibration standards: polystyrenes with a molecular weight in the range of 580 to 3040000 and polydispersity from 1.04 to 1.14 (Polymer Laboratories).

Estimation of inherent viscosity

Measurements were made at 25 °C with a Ubbelohde' viscometer with a capillary Nr 0a and constant K = 0.00498, using a polymer solution in chloroform of concentration $c = 0.1$ g/dl. From the flow time of the solvent (t_0) and solution (t_r), parameter η_{inh} [dl/g] was calculated from the equation:

$$\eta_{inh} = \frac{\ln\left(\frac{t_r}{t_0}\right)}{c}$$

Estimation of the residual solvent in the polyester prostheses modified

Dried, modified prostheses were kept in water at 20 °C for 24 h, with a module of 100:1 without stirring. The presence of the solvent in the supernatant was estimated by UV spectrometry at a wavelength of $\lambda = 195$ nm.

Testing of mechanical properties

Mechanical properties of the film and modified prostheses were estimated according to Standards:

- Film:
 - Thickness: PN-ISO 4593:1999
 - Max extension strength: PN-EN ISO 527-3:1998
 - Tenacity: PN-EN ISO 527-3:1998
 - Elongation at max. stress: PN-EN ISO 527-3:1998
- Vessel prostheses
 - Internal diameter: ISO 7198:1998
 - Suture retention strength: ISO 7198:1998
 - Bursting strength: ISO 7198:1998
 - Displacement at burst: ISO 7198:1998

Estimation of the coating rate

The percentage of the polymer coating on the vessel prosthesis was estimated gravimetrically from the weight difference between the dried modified prosthesis and the unmodified prosthesis.

Technological and analytical equipment

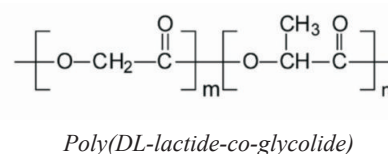
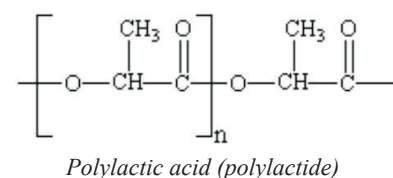
1. Roller coating machine by Benz Co
2. Aerograph by Paasche Co

3. Homogeniser IKA-WERKE T50
4. Laminar chamber
6. Inherent viscosity measuring set
7. Scanning electron microscope SEM Quanta 200 firmy (FEI Co., USA)
8. Vertical steriliser ASVE, semi-automatic
9. Miscellaneous laboratory equipment (magnetic mixer, air flow and vacuum dryer, pH-meter, scales).

Results of the research and discussion

Selection of biodegradable copolymers suitable for the surface modification of vessel prostheses

Commercially available polymers of the Resomer group (see **Table 1**) were harnessed for the sealing of knitted prostheses. Save Resomer R203H, which is a homopolymer [poly(D,L-lactide)], the remaining are copolymers of D,L-lactide and glycolide – poly(DL-lactide-co-glycolide), with different portions of the two co-monomers. The co-polymers reveal an amorphous morphology which makes the compounds degrade faster than crystalline polymers of L-lactide and glycolide. The structural formulae of polylactide and co-polymers from D,L lactide and glycolide are presented below.



High chemical purity and the ability of resorption by the human organism were decisive factors for the selection of these co-polymers. [19]. The manufacturer of the Resomers selected recommends the materials for medical application; the materials have suitable certificates and are used in implants as construction materials. In the human organism their degradation proceeds toward carbon dioxide and water, which means complete resorption [19].

The following properties were adopted as criteria for the selection of a specific material to be used in the tightening of polyester prostheses:

1. estimation of the molecular weight distribution
2. ability to form stable solutions
3. film- and coating-forming properties from the solutions of co-polymers.

At an advanced phase of the investigations, the susceptibility of the selected co-polymers to enzymatic degradation in the presence of lysozyme was also considered

Estimation of the molecular weight distribution

Estimation of the molecular weight distribution was performed by the GPC method. Five Resomer polymers with different contents of the co-monomers were tested. **Table 2.** contains the test results.

Conceptually, the polymers applied are only to provide a short sealing time of the vessel prostheses; the resorption time should be no longer than 2 - 3 months. It was found that the average molecular weight increases with an increase in DL-lactide content. From earlier works at the IBChF and literature announcements, it is known that an increase in the DL-lactide component and average molecular weight results in a slowing of the biodegradation rate of co polymers [20]. It was, therefore, in further steps of the investigation, decided to exclude homo-polymer R 203H and Resomer RG 503, which contains a similar amount of DL-lactide residue (about 50%) to Resomer RG504H. Consequently, the three remaining Resomers were used in the actual research. The materials can be differentiated by the DL-lactide content (51 - 95% mol) and average molecular weight but show similar polydispersity coefficients.

Dissolvability of the co-polymers

The Resomers selected were used in the form of solutions in chloroform or 1.4 dioxane. It was found that the co-polymers dissolve readily at ambient temperature in both solvents without the need of turbulent stirring (a magnetic stirrer was used). A homogeniser had to be employed only for solutions with 5% or more content of the polymer. The impact of the solvent upon the change in average molecular weight was estimated by GPC measurements. Also examined were film samples prepared by casting of the copolymer solutions in chloroform or dioxane on a Teflon plate. Results are shown in **Table 3.**

Table 2. Distribution of the molecular weight of the Resomer co-polymers.

Symbol of the sample	\bar{M}_n , g/mol	\bar{M}_w , g/mol	M_w/M_n	Distribution of the molecular weight, %	
				M < 10000	M > 10000
R 203 H	15592	29436	1.9	10	90
RG 503	14849	41263	2.8	10	90
RG 504 H	14009	50363	3.6	10	90
RG 755 S	21085	81040	3.8	6	94
RG 858 S	76738	270892	3.5	2	98

Table 3. Influence of the solvent on the average molecular weight of the Resomer polymers.

Symbol of the sample	Kind of solvent	\bar{M}_n , g/mol	\bar{M}_w , g/mol	M_w/M_n	Distribution of the molecular weight, %	
					M<10000	M>10000
RG 755 S	-	21085	81040	3.8	6	94
	chloroform	19051	80916	4.2	6	94
	1,4 Dioksane	20454	79931	3.9	6	94
RG 858S	-	14849	41263	2.8	10	90
	chloroform	13650	39899	3,1	9	91
	1,4 Dioksane	14230	40256	3,0	10	90
RG 504H	-	14009	50363	3.6	10	90
	chloroform	13870	49050	3,8	10	90
	1,4 Dioksane	13933	49566	3.7	10	90

Table 4. Impact of the kind of solvent upon the physical-mechanical properties of the film prepared from Resomers.

Kind of Resomer	Solvent	Thickness, mm	Max. drawing force, N	Tenacity, MPa	Elongation at max. stress, %
RG 755 S	chloroform	0.049	18.5	24.5	3.7
	1,4 Dioksane	0.046	20.1	28.9	4.5
RG 504 H	chloroform	0.051	18.0	21.9	3.2
	1,4 Dioksane	0.048	19.1	23.4	3.9
RG 858S	chloroform	0.046	18.0	22.5	3.4
	1,4 Dioksane	0.047	19.3	24.1	4.0

It can be seen that the use of 1.4 dioxane does not substantially change the average molecular weight (decrease of M_w by 1.5 - 2.5%) nor the polydispersity coefficient (increase of 2.5% to 7.1%) of the Resomer film samples tested. More pronounced were changes in films prepared from chloroform solutions. Of the copolymers tested, rather smaller changes could be observed for RG 504H and RG 755S, pointing at better suitability for the purpose. It must also be mentioned that all solutions of the co-polymers tested, both in chloroform and 4-dioxane, were stable and did not show any opacity nor sedimentation during storage for 1 month at 5 °C

Estimation of the film- and coating properties of the co-polymers

The ability of the polymers to form a film is crucial for the method by which the materials are placed on the prostheses (coating). The film-forming properties were tested for the Resomers selected: RG 504 H, RG 755 S, and RG 858S.

From 1.0% solutions of the co-polymers in chloroform or dioxane, a film was cast on Teflon plates. Dried at 40 - 50 °C, the film samples were tested for mechanical properties, and their surface structure was inspected. Results of the physical-mechanical testing are presented in **Table 4.**

The film samples prepared are characterised by a similar thickness as well as good tenacity and elasticity, while those made of the solutions in 1.4-dioxane reveal somewhat better parameters, mainly elasticity. The film of Resomer RG 755 S solution in dioxane manifests the best properties (tenacity of 28.9 MPa and elongation at max. stress of 4.5%). Scanning electron microscopy was employed to assess the surface structure of the film samples. The films prepared showed a smooth and uniform surface, proving the good film-forming properties of the Resomers selected.

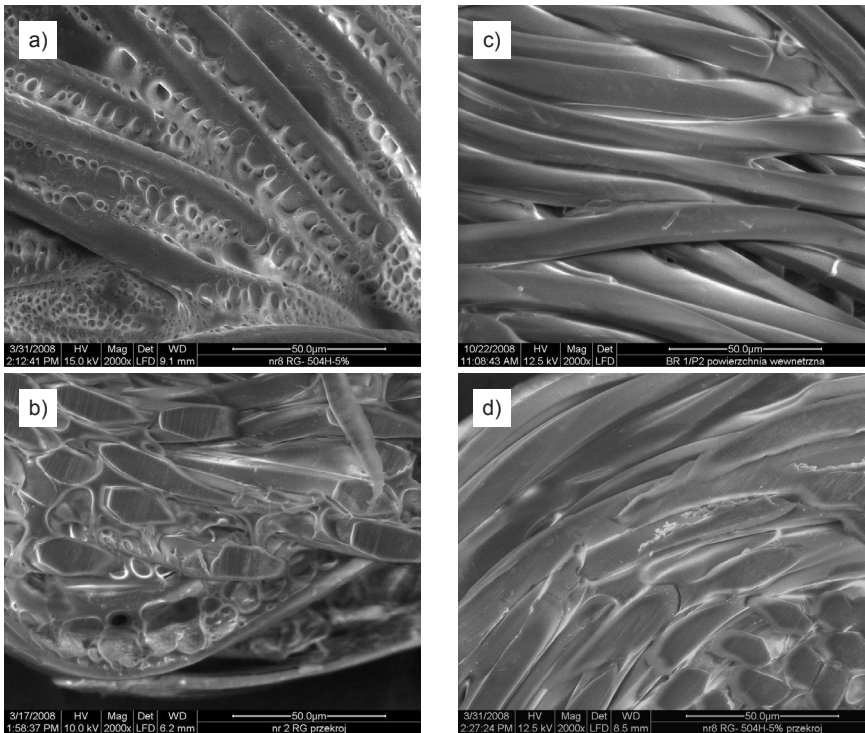


Figure 1. Microphoto of the outer surface and cross-section of polyester prostheses coated with Resomer 5% RG 504H in various solvents; chloroform, coating – 1×, surface (a) and cross-section (b), 1,4-dioxane, coating – 1×, surface (c) and cross-section (d).

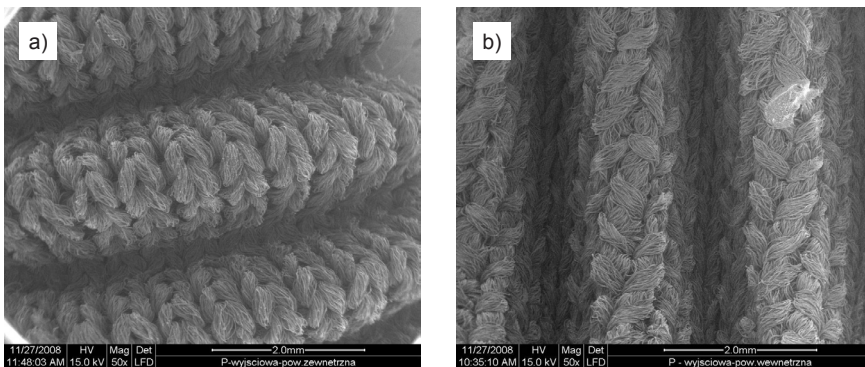


Figure 2. SEM micro-photo of the surface of DALLON H polyester prosthesis; a) Outer surface of the prosthesis, b) Inner surface.

Trials were also performed to settle the solutions on the surface of polyester prostheses. Double sided soaking on a roller coating machine was employed in initial attempts. Prostheses with deposited co-polymer were dried at 50%. The film-forming ability of the Resomers and the adhesion of the coating to the knitwear surface were assessed. The structure of the coating was inspected by scanning electron microscopy. Prostheses with coatings prepared from solutions in chloroform and 1,4-dioxane were observed. Examples of the surfaces and cross sections of the prostheses modified are shown in the images below RG 504H (Figure 1).

The trials revealed that the quality of coating obtained depends upon the sol-

vent used. A uniform and smooth coating could not be prepared with chloroform, the reason being the quick evaporation of the solvent and insufficient adhesion of the coating formed to the prosthesis surface. With dioxane a coating was obtained which uniformly covered the polyester yarn, and the polymer solution better penetrated the prosthesis, filling the voids between filaments. The polymer coatings prepared with solutions of Resomers RG 504H, RG 755S and RG 858S in dioxane revealed good adhesion to the knitwear surface; the extension and bending of the prosthesis did not cause the crumbling of the coating material. The results allowed to select 1,4-dioxane as a suitable solvent for the consecutive steps.

Preparation of conditions for the sealing of vessel prostheses

In this part of the project, investigations were concerned with the technique of applying a sealing coating to fibrous prosthesis material. Based on earlier results, Resomers RG 504H, RG 755S and RG 858S were selected for application to Dallon H prostheses. (see Figure 2)

The soaking technique was first employed in the sealing of the prostheses. Prostheses 8 mm in diameter, characterised by a water permeability of about 3500 ml/cm²/min, were applied. Prior to the coating operation, the prostheses were immersed in petroleum benzene for 12 hours at 20 °C to remove the spin finish of the polyester fibres, thus improving the adhesion of the Resomers to the surface of the prostheses and providing conditions for a more uniform coating. 1 to 6% solutions of the co-polymers in 1,4-dioxane were used as the coating substance. Single- or multi-soaking was carried out on a roller coating machine followed by the drying of the coated material under a slight tension. The effectiveness of the method was assessed in terms of the amount of polymer deposited (weight), the elasticity of the prosthesis (organoleptic) and water permeability. Wetting with physiological salt solution did not provide sufficient elasticity to the modified vessel prostheses assessed. Regardless of the concentration of the solution used, the coating largely deteriorated the prostheses elasticity, save at the lowest coating rates. The highest coating rate at which the prostheses retained sufficient elasticity was at about 20%, with the use of a plasticiser. Such coating did not, however, provide the necessary tightness: the water permeability measured was 2500 ml/cm²/min.

At higher coating rates, the prostheses were too stiff, worsening surgery handiness and, hence, usefulness. The defect could not be much improved by an addition of the plasticiser.

The trials showed that all the Resomers selected for the purpose revealed good coating ability. The highest coating rate, 31.2%, was attained after fivefold soaking with a 1% solution of Resomer RG 504H containing 4% (on the polymer) of polyethylene glycol as a plasticiser; the water permeability was still too high - about 1620 ml/cm²/min. A lower coating rate (about 20%) and a higher water permeability of 2400 - 2500 ml/cm²/min. was achieved using Resomer RG 504H under the same conditions.

With Resomer RG 858S having the lowest affinity to the prosthesis surface, the highest coating rate achievable did not exceed 8%, which only slightly improved water permeability (2870 ml/cm²/min) compared to the unmodified prosthesis.

Since the soaking method had produced unsatisfactory elasticity in the prostheses and excessive water permeability, the spraying technique was retained for further trials. The polymer solution was sprayed under pressure onto a rotating prosthesis, which also moved longitudinally. The technique provided a much better penetration of the textile material by the solution, the coating applied being thinner, retaining elasticity.

An aerograph with a slot die was used in the spraying, which at an air pressure of 3000 hPa generates an aerosol giving a "spot" of 1.5 mm diameter. Resomer RG 755S was applied, with which the highest coating grades and best tightness of the prostheses could be achieved in the proceeding trials Polyethylene glycol 400 and 600 in the amount of 5% of the Resomer was used as a plasticiser. Spraying was carried out in three ways:

1. Spraying onto a dry surface (the prosthesis was dried after each spraying)
2. First spraying on the dry prosthesis. After drying, all consecutive sprayings on the water-wetted prosthesis (accelerated coagulation).
3. First spraying on the wetted surface; consecutive ones are on a dry surface

In **Table 5** parameters of the trials are shown.

Elevenfold spraying with 1% and 3% RG 755 S solutions with 5% of polyethylene glycol (on polymer) produced the highest coating rate, 55%, at which good elasticity could be maintained (Trial No 37).

Solutions with a polymer concentration of 1% were used in the first three sprayings to provide better penetration of the polyester textile, arising from the low viscosity of the solutions. The 3% solutions sealed the inter-fibre voids of the knitwear. The highest coating rates were achieved without wetting the prosthesis surface (Trial P30). In the remaining variants, 2 and 3, the coating rate was about 2 and 4 % lower (Trials P31 and P32). The vessel prostheses sealed by spraying with Resomer RG 755 and a plasticiser produced the best elasticity of the prosthesis, meaning better surgery handiness. Wetting improves the adhesion of the polymer prosthesis surface which, in consequence, leads to a nearly

Table 5. Trials to tighten vessel prostheses with Resomer RG 755S solutions in 1,4-dioxane by spraying; all prostheses were elastic, without that obtained by the trial P40 which was low elastic.

Symbol of trial	Composition of spraying solution	Spraying variant and number	Coating rate, %	Water permeability, ml/cm ² /min
P30	1% RG755S+ Polyethylene glycol.400	Spray /18× (variant 1)	38.3	1762
P31	1% RG755S + Polyethylene glycol.400	Spray/18× (variant 2) 1 st layer on wetted prosthesis, consecutive layers on dry prosthesis	36.6	1576
P32	1% RG755S Polyethylene glycol.400	Spray/18× (variant 3) 1 st layer on dry prostheses, consecutive on wetted ones	34.0	366
P36	1 - 3% RG755S + Polyethylene glycol.400	Spray/14× (Variant 3) 1 st layer on dry prostheses, consecutive on wetted ones: layers 1 - 10 – spray 1% 755S, layers 11 - 14 – spray 3% 755S	45.9	44
P37	1 - 3% RG755S + Polyethylene glycol.400	Spray/11× (variant 3) 1 st layer on dry prostheses, consecutive on wetted ones: layers 1 - 3 – spray 1% 755S, layers 4 - 11– spray 3% 755S	54.8	29
P40	1% RG755S + Polyethylene glycol.400 1% RG755S + Polyethylene glycol 600	Spray/8× (variant 3) 1 st layer on dry prostheses, consecutive on wetted ones: layer 1 - spray 3% 755S, layers 2 - 8 – spray 5% 755S	50.8	96
P41	1% RG755S + glikol polietyl.600 3% RG755S + glikol polietyl.600	Spray/10× (variant 3) 1 st layer on dry prostheses, consecutive on wetted ones: layers 1 - 3 – spray 1% 755S, layers 4 - 14 – spray 3% 755S	43.0	25

Table 6. Comparison of the main physical-mechanical parameters of unmodified vessel prostheses of the Dallon H type with a prosthesis spray-sealed with poly(DL-lactide-co-glycolide) of the RG 755S type.

Parameter	Prosthesis	
	unmodified	modified
Internal dia, mm	7.97	7.97
Coating rate, %	0	43
Bursting strength, N	294	260
Displacement at burst, mm	5.4	7.1
Suture retention strength, N	22.3	16.6
Water permeability, ml/cm ² /min	3500	25

complete tightness; water permeability being below 30 ml/cm²/min. Much attention was given to the removal of the residual solvent from the polymer coating. 1,4- dioxane may cause irritation, as well as an allergic or even cytotoxic reaction. Modifications of biomaterials like vessel prostheses causing reactions with blood or tissue are unacceptable. The 1,4- dioxane used, with its 102 °C boiling point, is not a volatile liquid, therefore two-step drying was employed:

- 1st step blow drying -5 h., temperature 50 °C,
- 2nd step vacuum drying – 12 h., temperature 50 °C, pressure 0.07 MPa.

UV spectrophotometric analysis of aqueous extracts of the dried prostheses did not reveal traces of 1,4-dioxane.

Mechanical and structural properties of the vessel prostheses modified

Mechanical properties were tested, and the surface structure of the prostheses modified by both soaking and spraying was inspected.

The surface structure was inspected by scanning electron microscopy; the mechanical properties were tested according to the methodology given above on page 94.

SEM inspection confirmed the insufficient filling of the internal prosthesis structure with the polymer coating (**Figure 3**) by soaking.

Inspection of the surface structure of the vessel prostheses sprayed revealed good penetration of the knitwear by the polymer, which can be easily seen in the outer

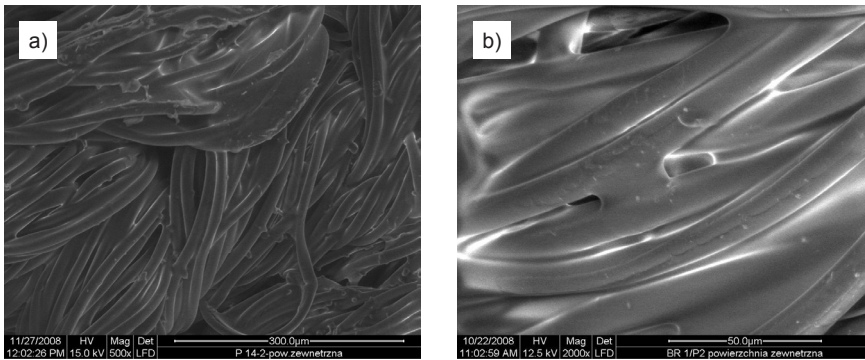


Figure 3. Exemplary SEM microphotos of a prosthesis surface modified by soaking; a) outer surface, 1× soaking, b) outer surface, 5× soaking.

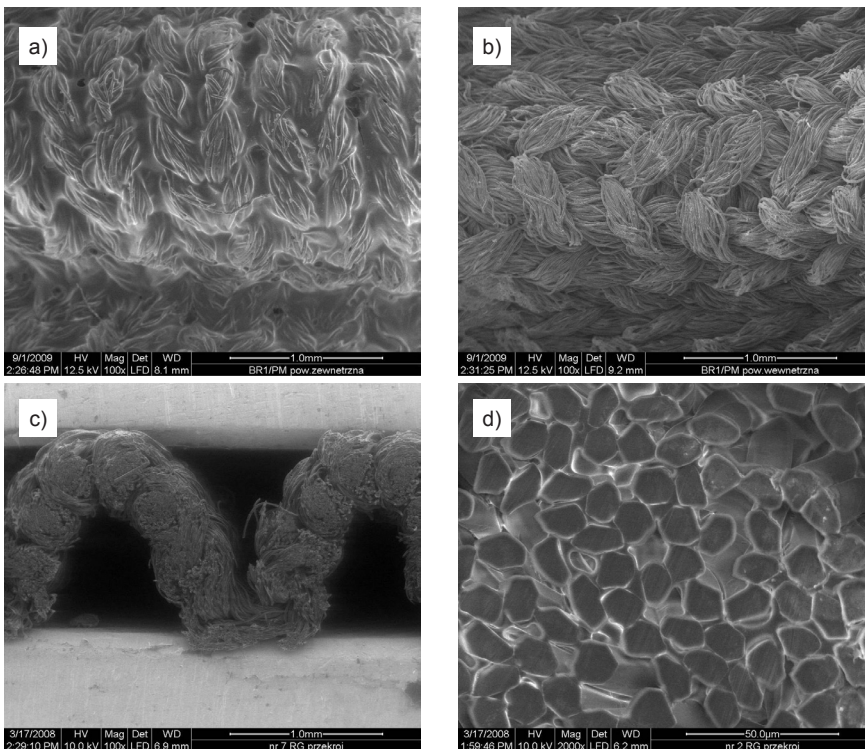


Figure 4. SEM microphotos of the surface and cross-sections of prostheses modified by spraying (10-fold spraying); a. outer surface, b. inner surface, c. cross-section of the wall, d. cross-section.

surface, showing a uniform polymer coating that also fills the inter-fibre voids (**Figure 4.a**).

Testing of the mechanical properties showed that the modification has some influence on the strength of prostheses (**Table 6**) The bursting strength and suture retention strength were 11% and 26% lower for the sealed prostheses, respectively.

Conclusions

Vessel prostheses of polyester fibres do not provide sufficient surgical tightness, the reason being the specific structure of the textile material (knitwear). The tightness desired can be attained by the

surface coating of the prosthesis with a polymer.

For the sealing of the polyester prosthesis (Dallon H) selected, biocompatible copolymers of poly (DL-lactide-co-glycolide) can be used. Such polymeric materials are offered by Boehringer Ingelheim under the trade name Resomer.

The best sealing of a Dallon H prosthesis can be achieved by coating it with solutions of Resomer RG 755S in 1,4-dioxane (1 - 5%) containing polyethylene glycol 600 as a plasticiser. In big laboratory trials aerograph apparatus can be used for this purpose.

A multi-step application of the polymer solution on the prosthesis surface

by spraying at a coating rate of 50% wt of Resomer RG 755S allows for the preparation of modified Dallon H prostheses with water permeability below 30 ml/cm²/min.

Acknowledgment

This investigation was carried out within the research project No 3 T08E 03727 sponsored by the Ministry of Science and Higher Education in cooperation with TRICOMED S.A.

References

1. Teng P., Feigin I.; *J. Neurosurg* 12, 1955 pp. 591–600.
2. Harrison J. H.; *AMA Arch Surg.* 74(4), 1957 pp. 557–561.
3. Taner D. Durmuş, *Blood Vessel Substitutes* http://www.biomed.metu.edu.tr/courses/term_papers/Blood-Vessel-Substitutes_durmus.htm.
4. Wesolowski S. A., Fries C. C., Karlson K. E., Bakey M., Sawyer P. N.; *Surgery* 50 (1961), pp. 91–96.
5. Głowiński S., et al.; *Hematologia*, 14, 1981 pp. 393–398.
6. Głowiński S.; *Polimery w medycynie*, 18, (4), 1988 pp. 221–235.
7. M. Kucharska, Ph. D. Thesis "Investigation in the use of chitosan for the modification of vessel prostheses made of polyester knitwear (in Polish)", 1992 Technical University of Łódź.
8. Kethamathan V., Christie B. A.; *Arch Surg* 115 (1980) pp. 967–969.
9. Woodhouse K.A., Klement P., Chen V., Gorbet M.B., Keeley F.W., et al.; *Biomaterials*, 25 (2004) pp. 4543–53.
10. Patent USA 5, 108,424; 1996
11. Patent USA 4, 747,848; 1988
12. Patent USA 4, 902,29; 1990
13. Patent WO 0117571; 2001
14. Patent USA 5, 584,875; 1996
15. Greisler H.P., et al.; *Surgery* 110(4), 1991 pp. 645–64.
16. Yu T.J., et al.; *J. Invest. Surg.*, 7(3), 1994 pp. 195–211.
17. Perewgo G., et al.; *J. of Biomaterials Science*, 14(10), 2003 pp. 1057–1075.
18. Lian Xue, Greisler H. P.; *J. Vasc. Surg.*, 37 (2003) pp. 472–480.
19. Greisler H.P., et al.; *J. of Biomed. Materials Research*, 27(7), 2004 pp. 955–961.
20. Middleton J. C., Tipton A. J.; *Biomaterials* 21 (2000), pp. 2335–2346.
21. Lakshmi S. Nair, Cato T. Laurencin, *Prog. Polym. Sci.* 32 (2007) pp. 762–798.
22. Williams D.F., *Biomaterials Vol.: 30, Issue: 30, October, 2009*, pp. 5897–5909.
23. Conference proceedings 8th School of X-Ray Sterilization and Hygiene Promotion, Institute of Radiation Chemistry and Technique, 20–21.10.2005, Warsaw.
24. Kroeze R. J., Helder M. N., Govaert L. E., Smit T. H.; *Materials* 2, (2009) pp. 833–856.
25. Polish patent appl. 358157
26. PN-79/P-04884.03 – Polish standard Methods of textile testing Knitted medical devices-prosthese of blood vessels Estimation of water permeability (in Polish).

Received 11.10.2008 Reviewed 13.05.2009



Institute of Biopolymers and Chemical Fibres Instytut Biopolimerów i Włókien Chemicznych IBWCh

According to earlier consolidation processes, the **Institute of Pulp and Paper Manufacture (ICP)** was on July 1st 2007 included into the **Institute of Biopolymers and Chemical Fibres (IBWCh)** by the order of the Polish Ministry of Economy of June 5th 2007.

Director of the Institute: Danuta Ciechańska Ph.D., Eng.

The research subject of IBWCh is conducting scientific and development research, as well as implementing their results into praxis in the following fields:

- processing, modifying, and application of biopolymers,
- techniques and technologies of manufacturing, processing, and application of chemical fibres and other polymer materials and related products,
- techniques and technologies connected with manufacturing, processing and application of products of the pulp and paper industry and related branches

R&D activity includes the following positions, among others:

- biopolymers – modifying and processing,
- functional, thermoplastic polymers,
- biodegradable polymers and products from recovered wastes,
- industrial biotechnology, e.g. bioprocesses for modifying and processing polymers and fibres, and biosyntheses of nano-biomaterial polymers,
- biomaterials for medicine, agriculture, and technique,
- nano-technologies, e.g. nano-fibres, polymer nano-coatings, nano-additives for fibres.
- processing of polymer materials into fibres, films, micro-, and nano- fibrous forms, and nonwovens,
- paper techniques, new raw material sources for manufacturing paper pulps,
- environmental protection,

The Institute is active in implementing its works in the textile industry, medicine, agriculture, plastic processing, filter and packing materials manufacturing, as well as in the cellulose and paper industries.

The Institute is equipped with unique technological apparatuses and equipment. An outstanding example is the technological line for fibre spinning by the wet method which enables cellulose, chitosan, alginate, starch, and composite fibres to be spun.

The Institute is member of domestic and international scientific organisations, the following, among others: EPNOE - European Network of Excellence, Polish Technological Platform of the Textile Industry, European Technological Platform of the Textile & Clothing Industries, 'Pro Humano Tex' Consortium, Centre of Advanced Textile Technologies Friendly for Human Beings, EN-VITECH-Net - 'Technologies of Environmental Protection' Int. Scientific Network, 'Biodegradable Polymers from Renewable Resources' - Int. Scientific Network. Polish Scientific Network for 'Nano-technologies in Textile Science and Praxis.

The Institute organises educational courses and workshops in fields related to its activity.

The Institute's offer of specific services is wide and differentiated, and includes:

- physical, chemical and biochemical investigations of biopolymers and synthetic polymers,
- physical, including mechanical investigation of fibres, threads, textiles, and medical products,
- tests of antibacterial and antifungal activity of fibres and textiles,
- investigation in biodegradation,
- investigation of morphological structures by SEM and ESEM
- investigation and quality estimation of fibrous pulps, card boards, and paper products, including paper dedicated to contact with food, UE 94/62/EC tests, among others.
- Certification of paper products.

The Institute is active in international cooperation with a number of corporation, associations, universities, research & development institutes and centres, and companies.

The Institute is publisher of the scientific journal '**Fibres and Textiles in Eastern Europe**'; the journal is since 1999 on the 'Philadelphia List' of the Institute for Scientific Information.

Instytut Biopolimerów i Włókien Chemicznych (IBWCh) Institute of Biopolymers and Chemical Fibres
ul. Skłodowskiej-Curie 19/27; 90-570 Łódź, Poland; Phone: (48-42) 638-03-02, Fax: (48-42) 637-65-01
E-mail: ibwch@ibwch.lodz.pl <http://www.ibwch.lodz.pl>