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Stability of the Physical Properties of Vascular Prostheses Made by Knitting Technique

Abstract
Straight and bifurcated vascular prostheses of differential diameters, as produced in 1992-1995 and 2002 in Poland by a domestic manufacturer, were evaluated regarding the stabilisation of resistance and elastic properties, namely the following: resistance and elongation at break, strength perforation and elongation at constant compression. All the evaluated vascular prostheses were subjected to radial sterilisation. This paper presents the evaluation of resistance and elastic properties in the contexts of analysis of their level and of these properties with respect to the requirements which the manufacturer must meet, and also describes the findings of the static evaluation conducted with respect to the repeatability of the research findings obtained.

Key words: *biomaterials, implants, wrap knitting materials, mechanical properties.*

Introduction

Vascular prostheses belong to the group of biomaterials for implants used in operative surgery. In Poland, these prostheses are made from polyester yarns, and they have a warranty for three years from the time of manufacture. Because these prostheses are used in the human body, their specific quality requirements are stringent: they should not provoke inflammations, should be proof against body fluids, demonstrate applicable resistance and elasticity properties, and have definite permeability.

Yarns made from polyester fibres on vascular prostheses have been the subject of testing for many research centres in Poland and around the world. The ageing process of the polyester fibres, as caused by many external factors, is a particularly important matter. The main factors in this process are chemical treatment conducted under different tensions, the influence of active agents such as water or solvents, and also radiation or chemical degradation.

The long-term exploitation of products made from polyester fibres results from their durability over a long period and lack of any perceptible modifications of their physical properties.

The current state of the art concerning the ageing of polyester yarns permits the conclusion that, upon the maintenance of specific manufacturing and storage conditions, this process is practically imperceptible over a few years, and the modification of the physical properties is minimal.

The foregoing problem has contributed to the IKTT 'Tricotextil's decision to undertake research work aimed at completing the current state of knowledge on determining the effect of the ageing process on the resistance and elasticity properties of vascular prostheses over a period of ten years, and also to definite the stability of these properties [1]. The positive test results obtained within the scope of this work could contribute to the eventual granting of a time of warranty longer than 3 years to biomaterials such as vascular prostheses.

Subject and Scope of Testing

The test specimens of straight and bifurcated Dallon vascular prostheses, manufactured in the years 1992-1995 and in 2002 and produced from textured polyester yarns, were tested after radial sterilisation. The prosthese had the diameters mentioned below:

- straight vascular prostheses of diameters ϕ in mm: 4, 8, 10, 16, 18, 20, 24,
- bifurcation vascular prostheses of diameters ϕ in mm: 14/8, 18/10, 20/11, 22/11, 22/12 (the first number defines the diameter of the root, and the second the diameter of bifurcation).

The usage durability of the physical features of the vascular prostheses was evaluated on the basis of the testing mentioned below:

- bursting strength (multi-directional strength),
- breaking force,
- breaking elongation,
- elongation by steady stress.

Additionally, for each prosthesis sample, the internal diameter in the state of relaxation was noted.

The testing were carried out on the basis of methods included in the Polish Standards compatible with the measurement techniques included in the International Standard ISO 7198:1998 and listed in the European Standard EN-12006-2:1998 in p. 7.4 [2-8]. The specification of the measurement techniques used is given in Table 1.

Table 1. *Specification of the measurement techniques used.*

Name of property	Testing method according to Polish Standard (PN)	Testing method according to ISO
Internal diameter	PN-83/P-04884.05	ISO 7198:1998 p. 8.5
Strength perforation	Testing Instruction IN-1/00, Edition B (elaborated on the basis of ISO 7198:1998 p.8.3.3.2)	ISO 7198:1998 p. 8.3.3.2
Breaking force	PN-87/P-04884.04	ISO 7198:1998 p. 8.3.2
Breaking elongation		
Elongation by steady stress	PN-83/P-04884.07	ISO 7198:1998 p. 8.4

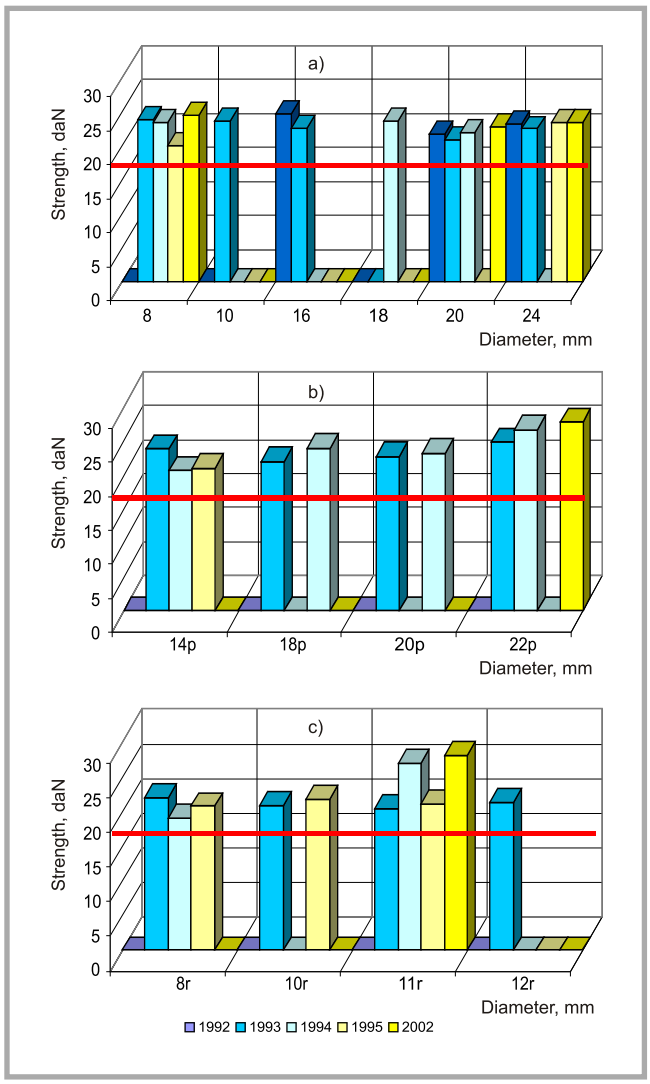

Figure 1. *Bursting strength of straight and bifurcated vascular prostheses; a - straight vascular prostheses, b - bifurcated vascular prostheses (bursting strength of root), c - bifurcated vascular prostheses (bursting strength of bifurcation).*

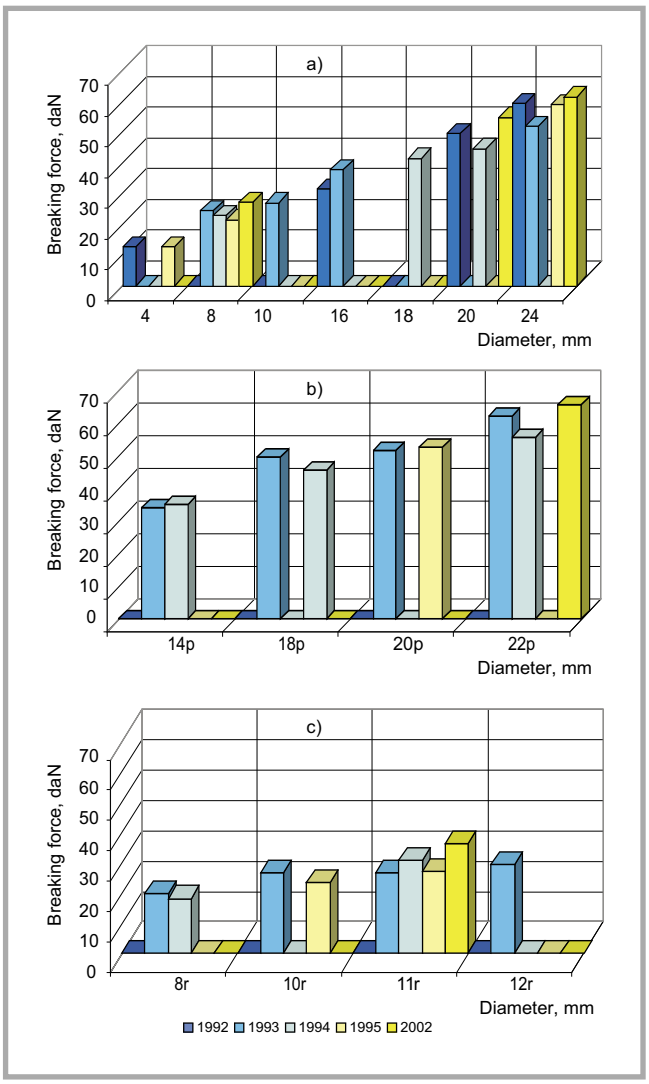

Figure 2. *Breaking force of straight and bifurcated vascular prostheses; a - straight vascular prostheses, b - bifurcated vascular prostheses (breaking force of root), c - bifurcated vascular prostheses (breaking force of bifurcation).*

Description of the Testing Methodology

- The measurement of the diameter of prosthesis (mm) consists of determining of its internal diameter in the state of relaxation with an accuracy of 0.1 mm, by use of a calibrated measuring cone.
- Testing the index of the prosthesis' bursting strength (in daN), thus determining its multidirectional strength, is performed on the tensile testing machine, working on the principle of elongation rate constant with time. The testing machine is equipped with devices for clamping, as well as a special holder fixing the sample of the prosthesis. The testing principle rests on punching the cut and straightened sample of the prosthesis by a cylindrical pin. The index of the bursting strength is definite for prostheses with a diameter greater than 4mm, taking into account the pin diameter size of 9.4 mm.
- Determining the breaking force (in daN) and breaking elongation of the prosthesis (in percent) is carried out by use of a tensile testing machine, working on the principle of elongation rate constant with time. The principle of testing rests on placing the ends of the sample (of a definite length) in the clamps of the tensile machine to be elongated in longitudinal direction to the break.
- The elongation by steady stress (in percent) of the prosthesis, as a property determining the elasticity of the vascular prosthesis, is measured by using the tensile testing machine, working on the basis of elongation rate constant with time, stretching the sample to the pre-determined steady stress. To define this property, a sample of a specified length is clamped in holders, and then elongated under the definite force which depends on the prosthesis perimeter. The tension value used only causes the alignment of prosthesis crimps without structure breakage, and is no higher than the tensile during surgery implantation. This length of prosthesis is called the use length, and compared to the initial length of the tested sample, determines the elongation by steady stress.

Estimation of Test Results

The estimation of the test results of strength and elasticity parameters of straight and bifurcated vascular prostheses was carried out in the following contexts:

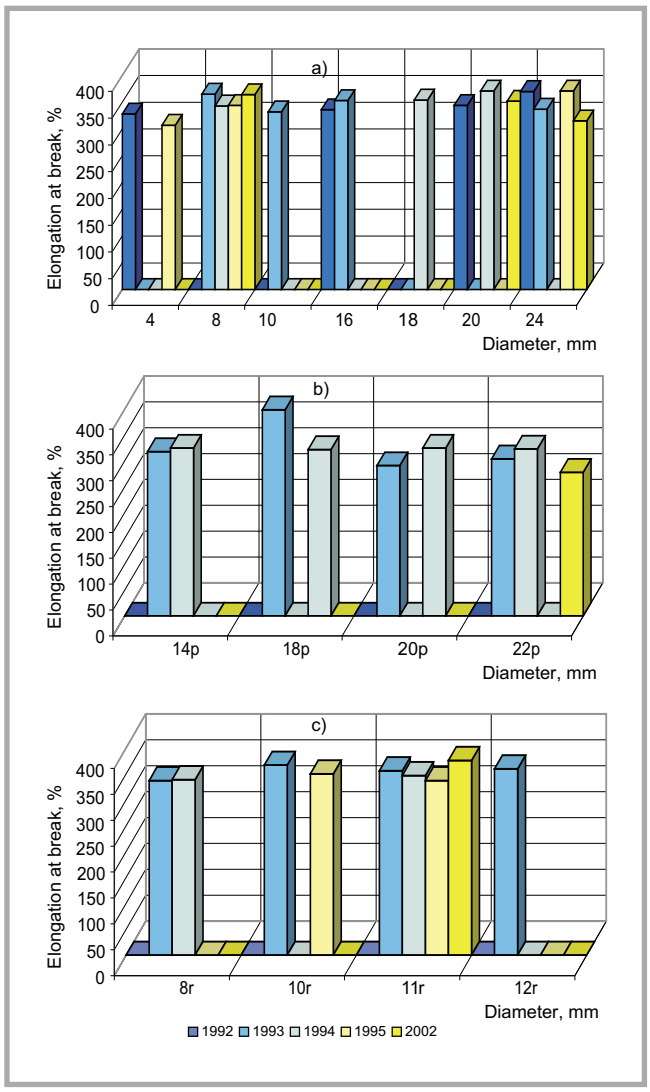

Figure 3. *Elongation at break of straight and bifurcated vascular prostheses; a - straight vascular prostheses, b - bifurcated vascular prostheses (elongation at break of root), c - bifurcated vascular prostheses (elongation at break of bifurcation).*

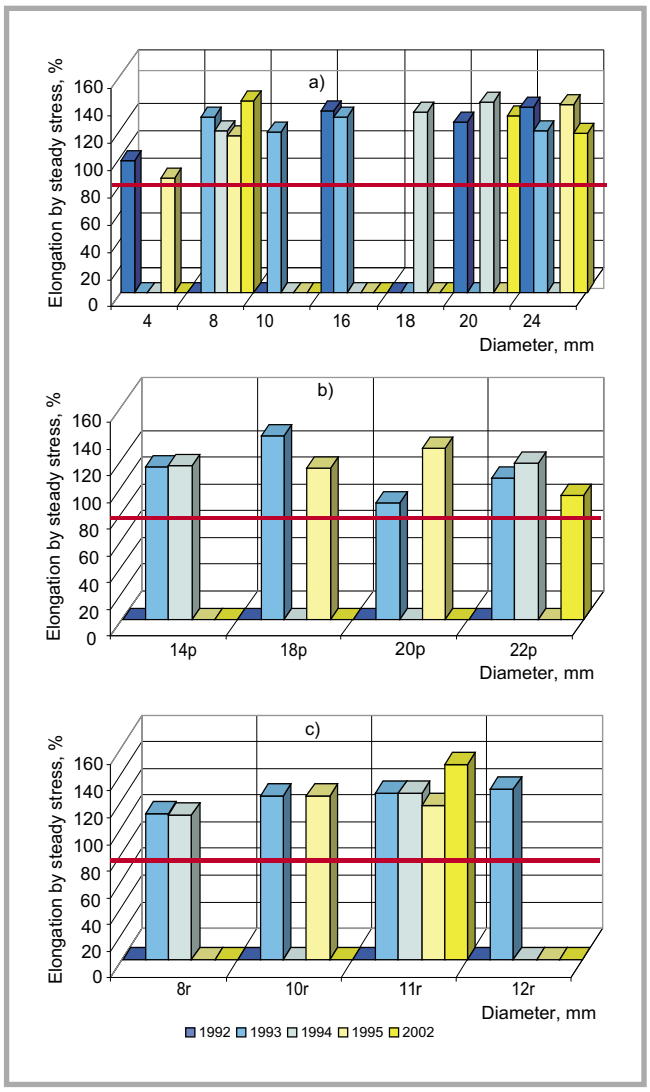

Figure 4. *Elongation by steady stress of straight and bifurcated vascular prostheses; a - straight vascular prostheses, b - bifurcated vascular prostheses (elongation by steady stress of root), c - bifurcated vascular prostheses (elongation by steady stress of bifurcation).*

- analysis of the level of testing characteristics,
- analysis of properties with the respect to the criteria established by the manufacturer,
- establishing the statistical significance of differences among the average values with the particular years of production.

Analysis of level of tested properties

On the basis of the test results obtained, as presented in graphic form on Figures 1-4, the following facts were ascertained:

- The level of bursting strength index (Figure 1) for tested specimens of bifurcated and straight vascular prostheses is higher than 20 daN, excluding one case concerning the bifurcation of prosthesis 14/8 (19.2 daN). The maximum values of this index amounted to:
  - 24.7 daN for a straight vascular prosthesis (diameter 16 mm, production year 1992), and
  - 28.3 daN for a bifurcated vascular prosthesis (diameter 22/11 mm, production year 2002).
- The level of breaking force (Figure 2) analysed for prostheses with the same diametersand produced in a given year is similar. It was noted that the higher level of breaking force for prostheses (both straight and bifurcated) of a greater diameter resulted from the testing method where the longitudinal strength direction was measured along the whole prosthesis sample. The lowest level of the breaking force, amounting to c. 12 daN, was found in prostheses with the diameters of 4 mm, and the highest level of c. 60 daN was found in prostheses with the diameters of 24 mm and 22 mm (at the roots of bifurcated prostheses).
- Unit elongation under break for almost all prosthesis samples (both straight and bifurcated) is at the level above 300% (Figure 3), at value limits from 307% to 399%. It was noted that the level of elongation of bifurcated prostheses was not less than 330% at their bifurcations.
- The elongation by steady stress (Figure 4) for almost all straight and bifurcated prostheses samples (excluding prostheses with diameters of 4 mm and roots with diameters of 20 mm and 22 mm) exceeded 100%, and was in the range from 108% to 145%.

Analysis of characteristics in relation to criteria established by the manufacturer

Considering that the manufacturer determined criteria only for bursting strength and elongation under steady stress, this analysis concerns only these characteristics.

- The bursting strength index (Figure 1) for all estimated samples of straight and bifurcated prostheses achieved the required minimum 18 daN, irrespective of the production date.
- Also, elongation by steady stress (Figure 4) for all estimated samples achieved the required minimum 85%, irrespective of the production date.

The level of the producer's requirements was shown in the figures mentioned above.

Establishing the statistical significance of differences among the means, in the particular years of production

In order to establish whether differences among the means of strength and elasticity parameters of the samples tested are significant from the statistical point of view, the obtained findings were statistically tested. The statistical interpretation of the testing results was carried out on the basis of Standard PN-ISO 2854:1994, with the assumption that the distribution of the testing characteristics of the vascular prostheses is normal.

The significance of differences among the means of the estimated parameters was analysed by statistically comparing these values for prostheses manufactured in the years listed. The statistical analysis did not cover the 10 mm and 18 mm straight prostheses, nor the bifurcation prosthesis 22/12 mm from one year of production.

The estimation of differences in the means for the two listed samples from the specified years of production was assumed for known variances. At first, the results were estimated by the F-Fisher-Snedecor test, where the significance of differences among variances of comparable prosthesis samples for each property was tested.

As an effect of the test, it was ascertained that if the probability amounts to 0.95, there are no significance differences among the calculated variances, and it is possible to use the test t. The obtained values of this variable, with the t-Student distribution and definite numbers of degrees of freedom, were compared with the values of the random variable t taken from the tables for the probabilities 0.95 and 0.99.

A discussion on the parameter t, for which the value was lower than the value $t_{0.95}$ taken from the tables, permits us to conclude that there are no significance differences among the means of estimated strength and elasticity properties of straight and bifurcated prostheses produced over the last ten years.

Conclusions

Thanks to the estimation of the stability of strength and elasticity parameters of Dallon vascular prostheses produced in 1992-1995 and 2002 in Poland by a domestic manufacturer, it was found that:

- The stability of physical characteristics in the range of strength and elasticity parameters is maintained. The positive test results form a basis for granting a period of warranty of more than three years to biomaterials such as vascular prosthesesa.
- The criteria determined by the manufacturer relating to strength and bursting strength by steady stress indices have been fulfilled.
- The differences among the means of the parameters tested are not significant from the statistical point of view.

References

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7. *Testing Instruction IN-1/00, Edition. B (elaborated on the basis of ISO 7198: 1998 p.8.3.3.2) Bursting strength of vascular prostheses.*
8. *Polish Standard PN-ISO 2854:1994 - Statistical interpretation of data. Techniques of estimation and tests relating to means and variances.*

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