MAGDALENA BARTKOWIAK-JOWSA[1)*], ROMUALD BĘDZIŃSKI[1)], JAN CHŁOPEK[2)], JAROSŁAW FILIPIAK[1)], BARBARA SZARANIEC[2)]

Comparative analysis of the deformation characteristics of biodegradable polymers considered as a material for vascular stents

Summary — The research represents an attempt to find a polymer alternative to intravascular metallic implants. Materials were selected considering mechanical properties and deformation behavior of blood vessels, assuming that convergence regions of vessel and polymeric material strain characteristics ensure the uniformity of deformations at the implant/tissue interface and may reduce postimplantation side-effects. The findings of the research facilitated review the potential use of biodegradable polymers and their composites for the development of vessel stents; a successful attempt to create stent prototype using selected material has been made.
Keywords: bioresorbable stent, biodegradable polymer, polymer composite.

ANALIZA PORÓWNAWCZA CHARAKTERYSTYKI ODKSZTAŁCENIOWYCH POLIMERÓW BIODEGRADOWALNYCH ROZWAŻANYCH JAKO MATERIAŁ NA STENTY NACZYNIOWE
Streszczenie — Przeprowadzono badania właściwości mechanicznych biodegradowalnych polimerów bazowych oraz ich kompozytów z dodatkiem włókien lub proszków (tabela 1). Materiały selekcjonowano biorąc pod uwagę charakterystyki naprężeniowo-odkształceniowe naczyń krwionośnych (rys. 5), poszukując pokrywających się obszarów sprzyjających zachowaniu ciągłości odkształceń na granicy implant-tkanka (rys. 6, tabela 5). Materiałem wykazującym największą zbieżność pod względem charakterystyki naprężeniowo-odkształceniowej z tkanką naczyniową, w obszarze liniowym, jest poli(laktyd-ko-glikolid) (rys. 6b). Spośród materiałów o charakterystyce naprężeniowo-odkształceniowej typowej dla materiału ulegającego umocnieniu, największy stopień zbieżności uzyskano w przypadku kompozytów z dodatkiem włókien poliakrylonitrylowych (PAN) (rys. 6c) oraz alginianu sodu (NaAlg) (rys. 6d). Na podstawie przeprowadzonej analizy materiałowej wykonano prototyp stentu naczyniowego z polilaktydu PL(DL)A z długim włóknem alginianowym (rys. 7). Udało się uzyskać implant o zamierzonych wymiarach i założonej charakterystyce geometrycznej.
Słowa kluczowe: stent bioresorbowalny, polimer biodegradowalny, kompozyty polimerowe.

Angioplasty with stent placement remains one of the main methods to treat atherosclerosis, although no type or model of metallic implant used so far ensures full efficiency, neither in the short nor long term. Some side effects (the so-called restenosis) associated with excessive proliferation of the vessel wall's structural components and thrombosis can be observed [1] as a result of the stent's interacting with the vessel, both in biological and mechanical terms. They include post-implantation inflammation [2, 3] or electrostatic interaction of metal with blood components [4]. Restenosis risk factors are also associated with the mechanical function of the implant [5] and involve changes in flow hemodynamics [6, 7], or, above all, a high stiffness depending on the material employed and the design of the implant [8—11]. The latter can cause local stress concentrations in the artery, stimulating cellular processes that disturb the appropriate regeneration of the vascular endothelium. The consequence can be damage to the arterial wall, restenosis, or remodeling of the tissue's structural components. The effect is particularly visible on the implant's ends; the area of abrupt changes in stiffness along the vessel is a frequent focus of restenosis [12].

Due to a high percentage of failures in coronary angioplasty with stent placement, it can be concluded that none of the materials and designs that are presently in use ensures optimal biomechanical compatibility with the vessel's tissue, there is therefore a need to evaluate new solutions. A growing interest can be seen in the pos-

[1)] Wroclaw University of Technology, Institute of Machine Design and Operation, Division of Biomedical Engineering and Experimental Mechanics, ul. Łukasiewicza 7/9, 50-371 Wrocław, Poland.
[2)] AGH-UST University of Science and Technology, Faculty of Materials Science and Ceramics, Department of Biomaterials, Al. Mickiewicza 30, 30-059 Kraków, Poland.
[*)] Author for correspondence; e-mail: magdalena.bartkowiak@pwr.wroc.pl

sibility of using biodegradable materials that would help develop an implant capable of degrading after a specific period close to the regeneration time of the tissue [13]. In such a stent, restenosis could be eliminated through temporariness, but it remains essential to obtain an implant which, apart from being biologically and mechanically neutral to the vessel's wall, would help to create conditions conductive to the proper regeneration of the arterial wall until the stent degrades and the vessel resumes its mechanical function.

Optimization of the vascular implant's geometrical structure involves, therefore, seeking new materials with desired stress-strain characteristics and modifying the implant's geometry to reduce the discontinuity of strains at the tissue/stent interface. In the study, mechanical properties of a wide array of biodegradable polymer materials and derived composites with addition of fibers and powders were researched. The aim was to correlate stress-strain characteristics obtained for coronary artery tissue and tested polymers and composites to preselect materials that could be used as the basis for a structural solution of the vascular prosthesis.

EXPERIMENTAL

Analysis of literature on polymer materials used in vascular tissue implants [15—22] indicates that there are still problems with optimizing the selection of their parameters to obtain a structure with adequate strength, elasticity, expandability, and safety of use.

Research was undertaken on the mechanical properties of unfilled biodegradable materials, mostly based on lactic (polylactide) and glycolic (polyglycolide) acids and their blends. Materials were chosen based upon their safety of use in the vascular system, as described in literature [17, 21—23].

Materials

Test material included:

— poly(D,L-lactide-*co*-glycolide) (PDLGA; Lactel, USA) with D,L-lactide to glycolide ratios of 75/25 (M_n = 97 · 10^3) and 51/49 (M_n = 63 · 10^3),

— poly(L-lactide) (PLLA, M_n = 93 · 10^3; Boehringer Ingelheim, Germany),

— poly(D,L-lactide/L-lactide) [PL(DL)A]: L-lactide 70 %, DL-lactide 30 % (M_n = 93 · 10^3; Polish Academy of Sciences Center of Polymer and Carbon Material Chemistry, Zabrze),

— poly(lactide-*co*-glycolide) (PGLA): glycolide 17 %, L-lactide 83 % (M_n = 75 · 10^3; Polish Academy of Sciences Center of Polymer and Carbon Material Chemistry, Zabrze),

— poly(ε-caprolactone) (PCL, M_n = 37 · 10^3; Perstop, China),

— poly(β-hydroxybutyrate) (PHB, M_n = 60 · 10^3; Biocycle, Brazil),

— poly(β-hydroxybutyrate/hydroxyvalerate) (PHB/PHV): HV 13 %, HB 77 % (P209; Biomer, Germany).

The unfilled polymers PGLA and PL(DL)A were modified with:

— polyacrylonitrile (PAN; Polish Academy of Sciences, University of Łódź; E = 5.7 GPa, σ = 330 MPa, ε = 17 %) and carbon fibers (CF) (T-300, Torayca; diameter d = 7 μm, density ρ = 1.76 g/cm^3, E = 235 GPa, σ = 3.2 GPa, ε = 1.4 %) and with the particles:

— hydroxyapatite (HAP; Cracow University of Science and Technology; ρ = 3.16 g/cm^3, total surface area S_w = 79.7 m^2/g), polyaspartic acid (ASP; Cracow University of Technology; M_n = 184 · 10^3, polydispersion P_d = 1.18), tricalcium phosphate (TCP; Sigma-Aldrich, USA; M_n = 310.18) and sodium alginate (NaAlg; NovaMatrix-Biopolimer, Norway; M_n = 198 · 10^3) (Table 1).

T a b l e 1. Tested materials, method of manufacture*)

Unifilled polymer	Method of manufacture	n	Composite	Method of manufacture	n
PDLGA 75/25	F	5	PGLA + 15 % CF	IM	2
PDLGA 51/49	F	5	PGLA + 15 % HAP	IM	2
PLLA	IM	7	PGLA + PAN	HP	2
PL(DL)A	IM	4	PGLA + CF	HP	2
PGLA	IM	2	PGLA + TCP	HP	2
PGLA	HP	2	PGLA + ASP	HP	2
PCL	IM	8	PL(DL)A + PAN	HP	4
PHB	IM	8	PL(DL)A + NaAlg	HP	4
PHB/PHV	IM	8	PL(DL)A + CF	HP	4

*) F — films, IM — injection molding, HP — hot press molding, n — number of samples.

Substances were selected based on literature reports [24] demonstrating their impact on the improvement of mechanical properties and changes in the stress-strain characteristics of materials. Biostable fibers and powders we used since there is a possibility of not causing significant biological reaction due of their small dimensions, although further investigation is required.

Methods of manufacture of samples

Tests were conducted on the three types of specimens: film prepared by solution casting method using dichloromethane as a solvent (dimensions: 35 × 3 × 0.1 mm); oar-shaped [according to EN ISO 527-1:1996 (Fig. A1—1BA)] prepared by injection molding and multi-layer hot press molding (see Table 1).

Methods of testing

Due to the possible effect of the solvent on the filling materials employed, tests were conducted on

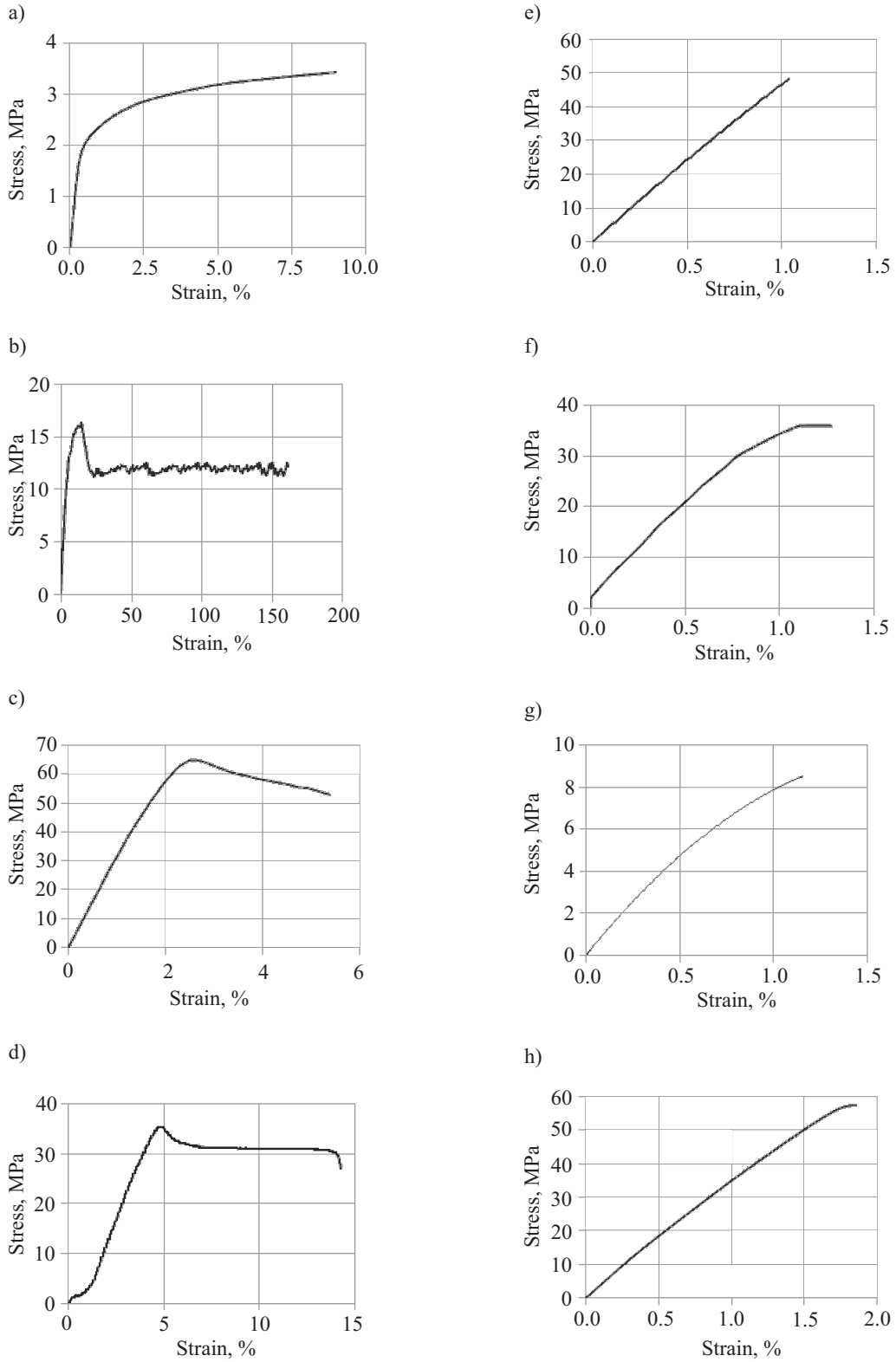

Fig. 1. Stress-strain characteristics of tested materials: a) poly(D,L-lactide-co-glycolide) (PDLGA), b) polycaprolactone (PCL), c) poly(L-lactide) (PLLA), d) poly(lactide-co-glycolide) (PGLA/HP), e) poly(D,L-lactide/L-lactide) [PL(DL)A], f) poly(β-hydroxybutyrate) (PHB), g) poly(β-hydroxybutyrate/hydroxyvalerate) (PHB/PHV), h) poly(lactide-co-glycolide) (PGLA/IM); IM — injection molding, HP — hot press molding

oar-shaped specimens prepared by injection or multi-layer hot press molding. Uniaxial tensile tests were carried out on MTS Mini Bionix 858, MTS Synergie 100 and Zwick 1435 testing machines using a transversal strain measurement extensometer (MTS 630.12-50). Due to small number of samples made of PGLA and its composites, for those materials standard deviation was not reported.

RESULTS AND DISCUSSION

The pure polymers can be divided into the three groups: ductile materials with low strength, elasto-plastic materials, and rigid and brittle materials. The first group of polymers with distinct viscoelastic properties is represented by poly(DL-lactide-*co*-glycolide) (PDLGA) (Fig. 1a) and poly(ε-caprolactone) (PCL) (Fig. 1b). PDLGA shows low tensile strength σ_M, which does not exceed 4 MPa and is close to that of the vascular tissue [13, 25], strains (ε_M) corresponding to σ_M reach over 800 %, whilst yield strains ε_γ over 45 % (Table 2). Composition was observed to affect Young's modulus *E*, which is 19 % lower for PDLGA 51/49 with a higher glycolide content. Stress σ_M for PCL can reach 16 MPa, with its corresponding strain ε_M up to 10.7 %. Young's modulus *E* of the material is the lowest across all polymers tested, and it amounts to 234.9 MPa.

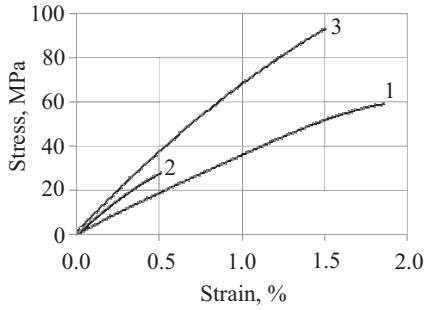

Fig. 2. Stress-strain characteristics of PGLA — 1 and composites: PGLA + HAP — 2, PGLA + CF — 3. Method of manufacture: IM — injection molding

Materials with strain characteristics typical of brittle material are poly(D,L-lactide/L-lactide) [PL(DL)A] (Fig. 1e), poly(β-hydroxybutyrate) (PHB) (Fig. 1f), poly(β-hydroxybutyrate/hydroxyvalerate) (PHB/PHV) (Fig. 1g), and PGLA (samples prepared by injection molding) (Fig. 1h). They are featured with small ε_M, ranging within 0.2—1.8 %, and high stiffness; highest Young's modulus amounting to 3884 MPa was noted for PHB.

T a b l e 2. Tensile strength (σ_M), corresponding strain (ε_M) and Young modulus (*E*) of tested materials*)

Material	Method of manufacture	*E*, MPa	σ_M, MPa	ε_M, %
PDLGA 75/25	F	324 ± 27	2.7 ± 0.4	780 ± 55
PDLGA 51/49	F	262 ± 25	2.6 ± 0.6	896 ± 62
PLLA	IM	3215 ± 207	63.8 ± 2.2	2.43 ± 0.1
PL(DL)A	IM	2192 ± 153	48.6 ± 4.1	1.2 ± 0.3
PGLA	IM	3453	51.2	1.8
PGLA	HP	1604	23.3	2.9
PCL	IM	235 ± 37	15.8 ± 0.9	10.7 ± 2.2
PHB	IM	3884 ± 108	28.3 ± 5.3	0.9 ± 0.2
PHB/PHV	IM	947 ± 121	9.5 ± 1.6	1.6 ± 0.1

*) F — films, IM — injection molding, HP — hot press molding.

Elasto-plastic polymers include poly(L-lactide) (PLLA) (Fig. 1c) and poly(lactide-*co*-glycolide) (PGLA, samples prepared by multi-layer hot press molding) (Fig. 1d), for those polymers a slow drop in stresses in the area of plastic strains can be observed. PLLA is the material with highest σ_M amounting to 63.8 MPa, whereas ε_M of both PLLA and PGLA does not exceed 3 %.

T a b l e 3. Tensile strength (σ_M), corresponding strain (ε_M) and Young modulus (*E*) of tested materials*)

Material	Method of manufacture	*E*, MPa	σ_M, MPa	ε_M, %
PGLA	IM	3453.0	51.0	1.8
PGLA +15 % CF	IM	6762.0	87.0	1.5
PGLA +15 % HAP	IM	4565.0	28.0	0.7

*) IM — injection molding.

The tests conducted showed that after adding hydroxyapatite (HAP) or carbon fibers (CF) as a filler to injection-molded specimens of PGLA the latter retains strain features typical of brittle material (Fig. 2). A 10 % addition of HAP causes decrease in σ_M and its corresponding strain ε_M by 40—60 % (Table 3). For PGLA + CF composite, σ_M increases by 70 % and ε_M decreases by about 15 %. By comparing Young's modulus, it can be concluded that value obtained for PGLA with a 10 % addition of HAP increases by 30 %, whereas Young's modulus of a composite of PGLA + CF is over 95 % higher than that of unfilled PGLA.

Enriching multi-layer hot press molded PGLA specimens with tricalcium phosphate (TCP) does not affect the stress-strain curve typical of elasto-plastic material with a distinct yield point (Fig. 3a). Composites reinforced with CF and ASP (curve 3, 5) demonstrate the typical features of brittle material. For PGLA + ASP composite σ_M is higher by over 60 %, and for PGLA + TCP composite, by over 50 % than for unfilled PGLA (Table 4). Substantially

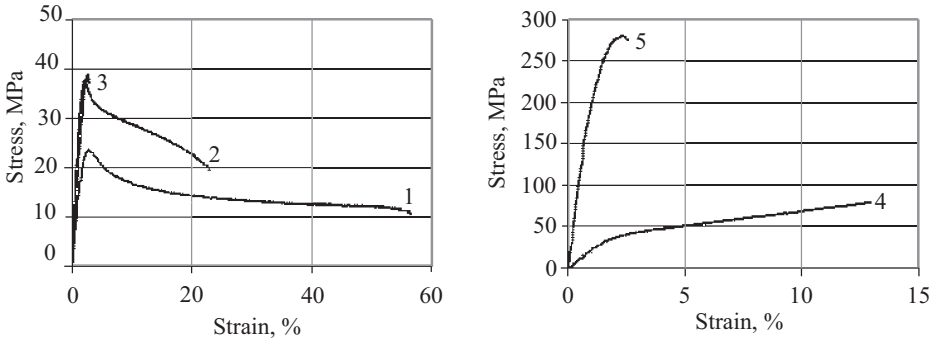

Fig. 3. Stress-strain characteristics of PGLA — 1 and composites: PGLA + TCP — 2, PGLA + ASP — 3, PGLA + PAN — 4, PGLA + CF — 5. Method of manufacture: HP — hot press molding

higher levels of σ_M were obtained for PGLA composites reinforced with CF and PAN fibers. For PGLA + CF (Fig. 1b) composite the σ_M value is over ten times and that for PGLA + PAN (Fig. 3b) four times as high as for unfilled PGLA. Young's modules of the tested composites are quantitatively similar, and they do not exceed 2500 MPa; only the value recorded for PGLA + CF composite amounts to over 21 000 MPa. Strains ε_M amount to 1.6—2.5 % for the tested composites, and are the highest for PGLA + ASP composite (Table 4).

Addition of polyacrylonitrile (PAN), sodium alginate (NaAlg) and carbon fibers (CF) to poly(D,L-lactide/L-lactide) [PL(DL)A] increases tensile strength by 304 %, 149 % and 520 %, respectively, although unfilled and filled specimens can be manufactured using various methods (Table 5). For PL(DL)A composites with PAN (Fig. 4b) and NaAlg (Fig. 4c) ε_M increases almost 8 times, whilst it remains unchanged for composite with addition of CF (Fig. 4d). Young's module of composites with addition of NaAlg and PAN falls within a range of 5495—6178 MPa, whereas ε_M within 8—10 %. Highest σ_M, amounting to 253.1 MPa, was obtained for PL(DL)A + CF composite, but its deformability ε_M is lowest, and

T a b l e 4. Tensile strength (σ_M), corresponding strain (ε_M) and Young modulus (*E*) of tested materials*)

Material	Method of manufacture	*E*, MPa	σ_M, MPa	ε_M, %
PGLA	HP	1604	23.3	2.9
PGLA+PAN	HP	2481	87.9	1.6
PGLA+CF	HP	21 744	276.4	2.1
PGLA+TCP	HP	2420	35.8	2.2
PGLA+ASP	HP	1841	38.6	2.5

*) HP — hot press molding.

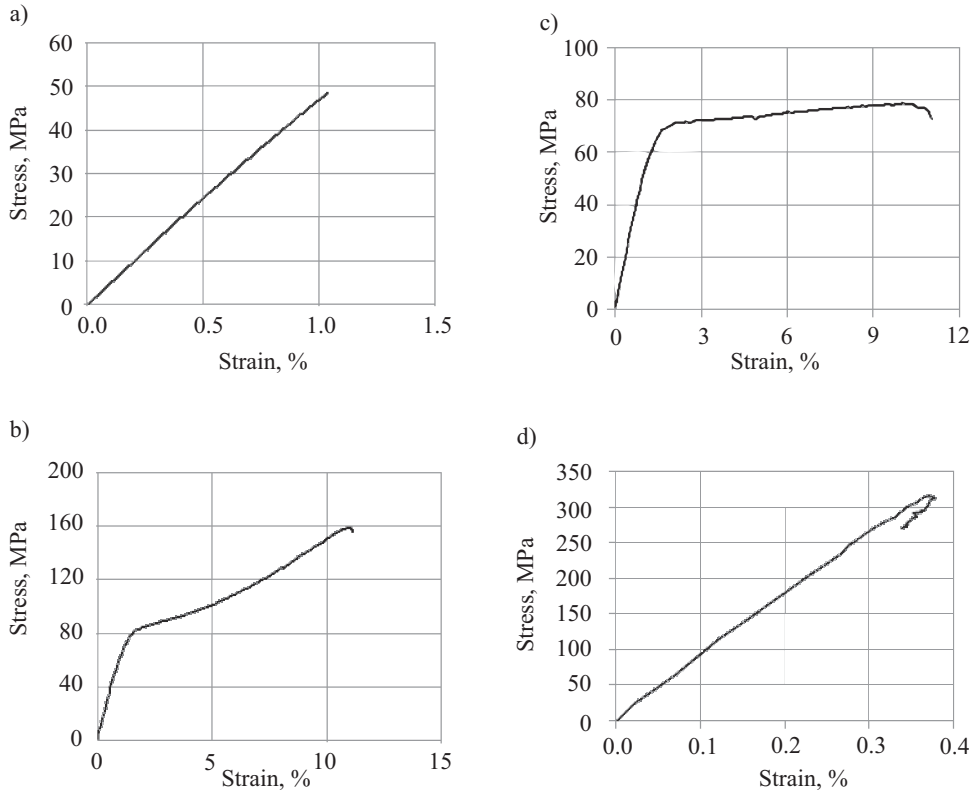

Fig. 4. Stress-strain characteristics of a — PL(DL)A, b — PL(DL)A + PAN, c — PL(DL)A + NaAlg, d — PL(DL)A + CF. Method of manufacture: HP — hot press molding

T a b l e 5. Tensile strength (σ_M), corresponding strain (ε_M) and Young modulus (E) of tested materials*)

Material	Method of manufacture	E, MPa	σ_M, MPa	ε_M, %
PL(DL)A	IM	2192 ± 153	48.6 ± 4.1	1.2 ± 0.3
PL(DL)A + PAN	HP	6178 ± 420	146.3 ± 10.0	9.5 ± 2.9
PL(DL)A + NaAlg	HP	5496 ± 173	72.5 ± 10.0	8.4 ±3.7
PL(DL)A + CF	HP	89 637 ± 2617	253.1 ± 66.4	0.3 ± 0.1

*) IM — injection molding, HP — hot press molding.

amounts to 0.3 % (see Table 4). For composites with addition of PAN and NaAlg, stress and strain curves change and resemble those typical for strain hardening materials, whereas those for CF composite remains unchanged.

Based on the test results, materials representing various types of stress and strain characteristics, with highest tensile stresses and corresponding strains were selected. Materials showing the characteristics of brittle materials and the lowest deformability were excluded from further analysis. Stress-strain curves of selected materials were divided into the two areas of elastic (A1) and plastic (A2) strain, and corresponding strain percentages were determined (Table 6). An analogous division was performed based on the stress-strain curve obtained for the coronary artery. For further considerations stress-strain curve of the artery's wall being deformed in the transverse direction (Fig. 5) was used, although in the *in vivo* (real life) environment the artery tends to be deforming in the three directions simultaneously: longitudinal, circumferential, and radial, with radial strains being compressive in nature and accounting for only 5—10 % of the strains occurring in the remaining directions [26]. The analyzed curve was selected because it is circumferential strains that assume maximum values during stent placement, and the vessel can increase its diameter even by up to 150 % of the initial value.

T a b l e 6. Elastic (A1) and plastic (A2) strain range of coronary artery and tested materials

Material	A1 elastic strain, %	A2 plastic strain, %
Coronary artery	10	—
PLLA	2.4	5.7
PGLA	3.9	8.9
PGLA + PAN	1.6	10.9
PGLA + TCP	2.2	17.8
PGLA + ASP	2.5	—
PL(DL)A + PAN	1.8	7.7
PL(DL)A + NaAlg	1.9	6.5

It should be noted that despite high deformability of the arterial vessel, the physiological working area is the nonlinear region of lower strains within the elastic range [27]. Due to the tension of collagen, muscular, and elastin structures, this range is changing during the expansion of the stent, with a higher tension of the collagen fiber being capable of causing irreversible changes in the structure of the tissue and leading to loss of mechanical strength [4, 25]. To prevent this and maintain biomechanical conditions similar to the physiological ones while ensuring the appropriate apposition of the stent in the vessel, the area of interaction between the tissue and the biodegradable implant was determined to be that corresponding to the linear fragment of the stress-strain curve of vessel A1 (see Fig. 5). Structural components of the vessel's wall become stretched in this area, without their continuity being compromised, nor their structure being irreversibly damaged.

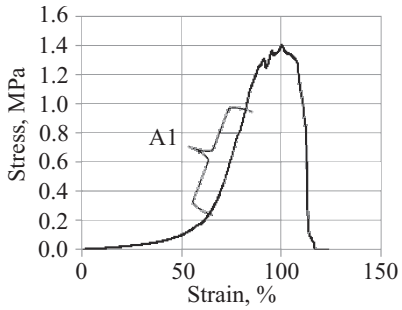

Fig. 5. Stress-strain characteristics of human coronary artery — transverse direction [13]

Depending on the method of placement, the implant-tissue interaction region is distributed across various ranges of stress-strain characteristic. The development of a biodegradable polymer stent is mainly oriented toward designing self-expandable stents that will expand due to the energy accumulated during compression. The operating ranges of such implants fall within the elastic area of the stress-strain characteristics of polymers. For the materials tested, this linear range A1 (Fig. 6) encompasses strains from 1.5 to 4 %, and matches, to a small degree, the curve obtained for the arterial tissues tested in the transverse direction (see Fig. 5). The strongest convergence was obtained for poly(lactide-*co*-glycolide), for which the range of elastic strains reaches 4 %, whereas for the vessel this values amounts to approx. 10 %. PGLA is also featured by lowest Young's modulus E and tensile strength σ_M, and when the yield point is exceeded

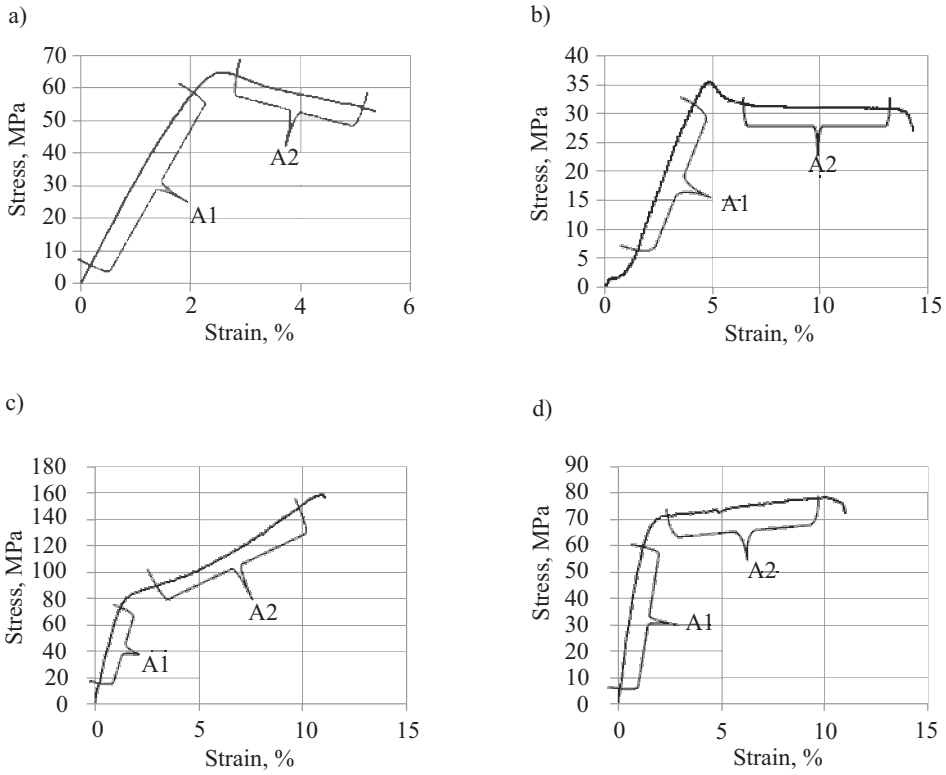

Fig. 6. Stress-strain characteristics of selected materials, elastic (A1) and plastic (A2) strain range: a) poly(L-lactide) (PLLA), b) poly(lactide-co-glycolide) (PGLA), c) poly(D,L-lactide/L-lactide) [PL(DL)A] + PAN, d) poly(D,L-lactide/L-lactide) [PL(DL)A] + NaAlg

stresses decrease dramatically. Similar characteristics are exhibited by PLLA, with the lowest range of elastic strains across all tested materials, which amounts to 1.8 %.

For balloon-expandable stents, the material needs to be introduced into the range of plastic strains. For the materials tested, this range exists for poly(L-lactide), poly(lactide-*co*-glycolide) with addition of PAN and TCP fibers, and poly(D,L-lactide/L-lactide) with PAN and NaAlg addition, and encompasses strains from 5.7 to 17.8 %. The highest range of elastic strains amounts to 17.8 %, and was noted for PGLA + TCP composite, which indicates the lowest value of σ_M. The range of plastic strains of PL(DL)A + PAN and PL(DL)A + NaAlg composites with the highest values of σ_M across all materials with elasto-plastic characteristics amounts to 7.7 % and 6.5 %, respectively.

CONCLUSIONS

The stress and strain characteristics obtained for the tested polymers and composites are non-linear. The pure materials are rigid and brittle, or elasto-plastic, with an area of decrease in stresses when the yield point is exceeded. The use of additions such as HAP and CF improves the strength of the tested composites, reducing their deformability. Although they enhance their mechanical properties, long time of residence in the body and reactivity cause that they are used above all in long-term implants such as bone or tendon implants [24]. It is reported [28], however, that carbon fiber composites can be used in treatment of blood vessels, but still further research on the behavior of degradable vessel implants made from them is needed. The stress and strain curves of composites with addition of CF and HAP show no district range of plastic strains, which makes the replication of the shape and placement method of metal structures impossible. A range of plastic strains is existent for composites with addition of tricalcium phosphate (TCP) and polyaspartic acid (ASP), but their strength is low, or lower than that of the vessel tissue [13], which excludes them as a construction material.

A correlation of the basic mechanical properties and the characteristics of the tested polymers and arterial tissues helped to identify areas of their compatibility. The materials were selected based on the stress-strain curves with overlapping areas, which gives hope for reducing the discontinuity of strains across the implant-tissue interface, as well as those showing mechanical properties that are essential to ensure radial stability. Poly(lactide-*co*-glycolide) is a material indicating the strongest convergence with the stress-strain characteristics of the vessel tissue within the linear area. Out of polymers and composites with stress-strain characteristics typical for strain hardening materials, the strongest convergence was obtained for composites with addition of polyacrylonitrile fibers (PAN) and sodium alginate (NaAlg). This raises hopes of using such a type of polymers as materials

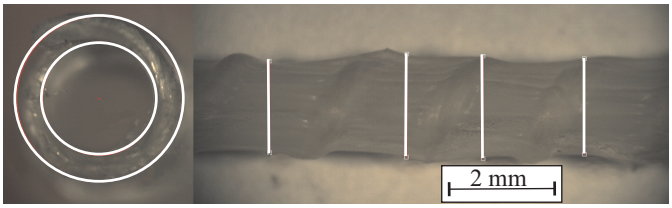

Fig. 7. Biodegradable stent made of PL(DL)A and NaAlg

to build vessel stents because they have good mechanical properties and a wide area of plastic strains that can accommodates the operating range of the implant.

Based on the analysis performed, a prototype of vessel stent was made of polylactide PL(DL)A with long alginate fiber (Fig. 7). The assumed geometry and dimensions of the implant — external diameter: approx. 2 mm, and internal diameter: 1.4 mm, could be obtained.

The results of the research conducted make clear that the use of biodegradable polymers and their composites in the design of vessel implants provides wide opportunities for modifying degradation time and a wide range of physicochemical and mechanical properties through the incorporation of additions. Thus, it is possible to develop a material with characteristics similar to the stress-strain characteristics of the vessel tissue, and optimize the biomechanical conditions that remain in the vessel after stent placement. Further research will be used to determine the reactivity of materials in the biological environment and find an optimal composition of material and implant geometry.

Based on the stress and strain characteristics obtained, a structural solution for vessel prosthesis can be optimally found depending on the severity of condition and the place of implantation.

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