UDK 620.168:620.17:542.2:62-419:615.477.2
Original scientific article/Izvirni znanstveni članek

ISSN 1580-2949
MTAEC9, 55(5)655(2021)

MECHANICAL TESTING OF LAMINATED COMPOSITE MATERIALS FOR PROSTHETIC SOCKETS

MEHANIČNO TESTIRANJE LAMINIRANIH KOMPOZITNIH MATERIALOV ZA PROTETIČNO LEŽIŠČE

Matic Bombek[1], Uroš Vesenjak[1], Marko Pisek[1], Gaj Vidmar[1,2,3*], Sašo Knez[4], Sergej Medved[5]

[1]University Rehabilitation Institute, Republic of Slovenia, Ljubljana, Slovenia
[2]University of Ljubljana, Faculty of Medicine, Institute for Biostatistics and Medical Informatics, Ljubljana, Slovenia
[3]University of Primorska, Faculty of Mathematics, Natural Sciences and Information Technology, Koper, Slovenia
[4]Aereform Ltd., Trbovlje, Slovenia
[5]University of Ljubljana, Biotechnical Faculty, Department of Wood Science and Technology, Ljubljana, Slovenia

Prejem rokopisa – received: 2020-12-08; sprejem za objavo – accepted for publication: 2021-06-21

doi:10.17222/mit.2021.232

The mechanical properties of the composite materials for prosthetic sockets are a key determinant of the quality and usability of prostheses. Our aim was to compare the existing materials used in production at our institution with some modified, potentially improved materials. We conducted an industrial experiment. The existing material (A) was compared with three newly produced materials that introduced changes in the lamination process: B1, where an infusion spiral tube was added; B2, where the resin was degassed; and B3, where a mesh and peel ply were used. The specimens underwent laboratory strength testing. The strength measurements were statistically analysed using one-way analysis of covariance (ANCOVA) that was adjusted for specimen thickness because of the observed negative correlation of thickness with strength. Material A had the highest bending strength, on average, but there were no statistically significant differences in the bending strength between the materials after adjusting for the specimen thickness ($p = 0.941$). Materials B1 and B2 exhibited statistically significantly lower tensile strengths than material A ($p < 0.001$). Material B3 had the lowest average tensile strength, but it could not be statistically distinguished from the others, because of the significantly larger average specimen thickness. The compressive strength was tested only for materials B1, B2 and B3; their averages did not differ statistically significantly ($p = 0.291$). Laboratory strength testing provided important insights into the differences between the various laminated composite prosthetics materials. We did not reach our initial goal to produce a better material, but we will continue our research and development in this field with a more systematic, technological approach.

Keywords: composite materials, lamination, prosthetic socket, laboratory testing

Mehanske lastnosti kompozitnih materialov za ležišča protez pomembno določajo kakovost in uporabnost protez. Avtorji članka so želeli primerjati material, ki se v njihovi ustanovi uporablja v proizvodnji, s spremenjenimi materiali, ki bi lahko prinesli izboljšave. Izvedli so industrijske eksperimente. Obstoječi material (A) so primerjali s tremi materiali, pri katerih so vpeljali novosti v postopku laminacije: B1, kjer so dodali infuzijsko spiralno cev, B2, kjer so smolo degazirali, in B3, kjer so dodali mrežo in hrapalno tkanino. Vzorce so mehansko testirali v laboratoriju. Meritve trdnosti so statistično analizirali z enosmerno analizo kovariance (ANCOVA), z upoštevanjem debeline zaradi opažene negativne korelacije debeline s trdnostjo. Material A je imel v povprečju največjo upogibno trdnost, toda ob upoštevanju debeline vzorca, med materiali ni bilo statistično značilne razlike v upogibni trdnosti ($p = 0{,}941$). Materiala B1 in B2 sta imela statistično značilno manjšo natezno trdnost v primerjavi z materialom A ($p < 0{,}001$). Material B3 je imel najnižjo povprečno natezno trdnost, a ga ni bilo možno statistično značilno razlikovati od ostalih zaradi znatno večje debeline vzorcev. Kompresijsko trdnost so določili samo pri materialih B1, B2 in B3, njihova povprečja pa se niso statistično značilno razlikovala. Laboratorijska testiranja so omogočila objektivno oceno in primerjavo materiala za proteze, proizvedenega z različnimi postopki laminacije. Začetni namen, da bi se izdelal kakovostnejši material z večjo trdnostjo ni bil dosežen, vendar bodo avtorji nadaljevali raziskovanje in razvoj na tem področju z bolj sistematičnim tehnološkim pristopom.

Ključne besede: kompozitni materiali, laminacija, ležišče proteze, laboratorijsko testiranje

1 INTRODUCTION

The basic purpose of a prosthetic socket is the ability to transmit static and dynamic loads, control and suspension of the prosthesis. The material from which the socket is made must make it easy to produce various shapes, so it must allow a controlled and flexible socket-manufacturing process and guarantee that the socket's construction is consistent with the anatomy and biomechanics. In addition, the socket must have sufficient strength, be light weight and comfortable to use.[1]

The material-selection system used in most prosthetic laboratories is based primarily on past experience and the recommendations by the manufacturers of prosthetic components. The mechanical characteristics of the material from which the socket is built play a key role in the final quality of the socket. It is also important that new materials and manufacturing techniques that appear on the market are checked to see whether they actually benefit the function and safety of the prosthetic device.[2] Knowledge about the mechanical characteristics of cur-

*Corresponding author's e-mail:
gaj.vidmar@ir-rs.si (Gaj Vidmar)

rently widely accepted materials is necessary to objectively assess the advantages and disadvantages of new materials and manufacturing processes.

Laminated sockets are made of a polymer composite material; they are most often built from thermoset polymer (i.e., resin), reinforced with various layers of fabric or fibres. The most used are carbon fibres, glass fibres, a mixture of nylon and glass fibres, and nylon.[3] The strength of the composite material depends on the individual materials, the compatibility of the materials, the quality of the manufacturing process and the construction of the socket. The tensile and bending strength are the highest in the longitudinal direction of the fibres. Hence, the most common orientation of the fibres is such that the material can transfer as much as load as possible. Different types of weaving are employed, whereby the fibres are directed at a 45° angle (bi-directional) or at a 0°/90° angle (unidirectional).[4]

The most common techniques for producing plastic composite structures, reinforced with fibres, are wet manual application, vacuum infusion, filament winding and moulding the resin.[5] Vacuum infusion is mainly used in prosthetics and orthotics because of the ease of making composite structures for a medical device. Vacuum is applied to thrust and spread the resin over composite laminate and fabric. This procedure makes it easy to combine complex forms with high strength.[5]

In our daily practice of producing composite structures, we have often observed that a porous material or incomplete impregnation with the resin represents a defect that causes reduced strength of the material. Porosity is defined as the volume fraction of small gaps in the material. In the composite, the gap is a space that is not filled with resin or fibre. As voids become larger, they act as holes, and the negative effect of holes on composite materials is well studied.[6] However, the complete absence of porosity is very difficult to achieve. The basis for managing or reducing porosity is a knowledge of the sources of gaps and solutions or tools to reduce gaps. Porosity sources are trapped air, vapours and leakage of tools or vacuum bags. Gap-reducing tools or mechanisms are vacuum evacuation of the air, increased resin pressure and mobility of the bubbles in the resin.[7]

The aim of our study was to introduce a framework for systematic modifications of the lamination process that would hopefully lead to improving the quality of the composite material. We wanted to improve the impregnation with the resin and to reduce the formation of gaps between the layers of fibres and within the fibres. Our assumption was that a process that reduces porosity would lead to a composite structure of greater strength. The newly produced materials were qualitatively analysed by means of visual inspection and quantitatively analysed by means of laboratory strength testing in comparison with the existing material that we use routinely.

2 MATERIALS AND METHODS

The project was carried out at the University Rehabilitation Institute, Republic of Slovenia, within the Centre for Orthotics and Prosthetics in cooperation with two external partners: Aereform, a company that produces composite structures for the aerospace industry, who helped with producing the new materials (B1, B2 and B3, as described below), and the Department of Wood Science and Technology of the Biotechnical Faculty, University of Ljubljana, who carried out the mechanical testing.

2.1 Lamination procedure

We used the same standard material for prosthetic sockets that is used at our institute in all lamination procedures. The specimens were composed of the following layers and allocations:

- 2× nylon stockinette,
- 1× glass fibres (weaving twill, weight 280 g/m^2),
- 1× nyglass stockinette,
- 1× glass fibres (weaving twill, weight 280 g/m^2),
- 1× nyglass stockinette,
- 1× carbon fibres (weaving twill, weight 200 g/m^2),
- 1× nyglass stockinette,
- 1× carbon fibres (weaving twill, weight 200 g/m^2),
- 1× nyglass stockinette,
- 2× nylon stockinette,
- a Polymethyl methacrylate (PMMA) resin that was used for the matrix.

The specimens were produced from the same material, but with differences in the manufacturing process. The lamination-infusion technique was used in all the procedures. First, we prepared a plaster model, which was retained through all the lamination procedures. The model consisted of four flat surfaces. In the upper part, it had a curved surface that mimics the shape of the distal part of the stump and represents the curvature on which the resin flows towards the other end of the model. The model was smoothed and dried.

Before lamination, we fitted a thin nylon sock (for air extraction) and a polyvinyl alcohol (PVA) bag on the model. The bag was vacuumed to obtain a perfectly smooth surface of the model. The layers were put on the surface of the PVA bag in the order listed above. A second PVA bag was placed on the last layer and the whole object was vacuumed. When adding the resin, we followed four different procedures. Because the preparation of the model and the adding of the fibre layer were practically identical in all cases, the only differences between the lamination procedures were as follows:

- material A (control group) – the standard lamination procedure for a prosthetic lower-limb socket at our institute was used, as described above.
- material B1: unlike the standard manual mode of resin input, the resin was input using an infusion spiral tube (12 mm × 10 mm). The spiral was installed

on the edge of the upper side and across the entire surface of the model. Before the lamination procedure, the resin was degassed for 5 min under a vacuum of 10 mbar, thereby removing the air bubbles from the resin.

- material B2: lamination was carried out in a similar manner as in the standard procedure. The resin was applied manually, as is usual in the field of orthotics and prosthetics. The resin was poured into the upper part of the PVA bag and manually spread over the laminate. However, before casting the resin, the same resin degassing method as for material B1 was used.
- material B3: this was meant to be an improvement of the B1 procedure. A slightly modified method of adding the fibres for the last two layers of nylon was used. On the last layer of carbon fibres, a peel ply was fitted with an adhesive in a spray. A flow mesh, resin inlet with a spiral tube and a resin outlet were installed on the peel ply. A polyvinyl chloride (PVC) bag was used instead of a PVA bag for vacuuming.

2.2 Visual inspection

The specimens were visually inspected on all four sides. We tried to estimate the permeability and porosity based on external appearance.

2.3 Mechanical testing

Bending strength was determined by a three-point test on 100 mm × 15 mm (l = 100 mm) specimens. The distance between the supports (L) was 80 mm, the radius of the supports (R_2) was 5 mm, and the load speed was 10 mm/min (R_1 = 10 mm). The measurement was performed on six specimens of each material; for three specimens, the load was positioned to the outer side, and for three on the inner side. In addition to the strength measurement, modulus of elasticity was also determined.

Tensile strength was determined on specimens of size 200 mm × 20 mm ($L_3 \times b_2$), which were narrower in the middle. The load speed was 10 mm/min. Compressive strength was determined on specimens of size 100 mm × 15 mm; load speed was 5 mm/min. In addition, the modulus of elasticity during tension and during compression was also determined. The measurements were performed using the Zwick/Roell machine and the testXpert software.

The following equations were applied to obtain the measurements:

Tensile strength (σ_t, in N·mm^{-2})

$$\sigma_t = \frac{F_{max}}{t \cdot w} \tag{1}$$

F_{max} – maximum force, t – thickness, w – width;

Modulus of elasticity (E_t, in N·mm^{-2}) during tension

$$E_t = \frac{\sigma_2 - \sigma_1}{\varepsilon_2 - \varepsilon_1} \tag{2}$$

σ_2 – tensile strength at point 2 (at the end of the linear part of the curve, determined at ε_2 = 0.25 %), σ_1 – tensile strength at point 1 (at the beginning of the linear part of the curve, determined at ε_1 = 0.05 %), ε_2 – relative extension at point 2, ε_1 – relative extension at point;

Relative extension (ε)

$$\varepsilon = \frac{\Delta L_0}{L_0} \tag{3}$$

ΔL_0 – change (increase) in length within the extensometer range, L_0 – length within the extensometer range.

Bending strength (σ_f, in N·mm^{-2})

$$\varepsilon = \frac{\Delta L_0}{L_0} \tag{4}$$

F_{max} – maximum force, L_1 – distance between supports, t – thickness, w – width;

Modulus of elasticity during bending (E_m, in N·mm^{-2})

$$E_m = \frac{\sigma_{f2} - \sigma_{f1}}{\varepsilon_{f2} - \varepsilon_{f1}} \tag{5}$$

$$s_1 = \frac{\varepsilon_{fi} \cdot L_1^2}{6t} \tag{6}$$

σ_{f2} – bending strength at point 2 (at bending by s_2), σ_{f1} – bending strength at point 1 (at bending by s_1), ε_2 – relative extension at point 2, ε_1 – relative extension at point 1.

2.4 Statistical analysis

The association of the specimen thickness with the measured strength was assessed using the Pearson and Spearman correlation. The mean specimen thickness was compared between materials using a one-way analysis of variance (ANOVA). The strength was compared between the materials using a one-way analysis of covariance (ANCOVA, adjusting for specimen thickness) with post-hoc comparisons. Statistical analyses were performed using IBM SPSS Statistics 23 for Windows (IBM Corp., Armonk, NY, 2015).

3 RESULTS

3.1 Visual inspection

The material A specimens were impregnated. The outer and inner surfaces were smooth and flat. The lamination exhibited a small degree of porosity.

The material B1 specimens were soaked. The inner surface was smooth, but the outer surface was slightly rough. We could not detect the presence of air in the lamination.

The material B2 specimens were poorly soaked in some areas, so this material could not be used in prosthetic practice. There was an unintentional air leakage in the lamination process without a known cause. There

was also an unequal distribution of the resin. The inner surface was mostly smooth, but it was rough or porous in certain parts.

The material B3 specimens were well soaked, but polymerisation of the resin was poor due to the involuntary leakage of air into the lamination. The resin was well distributed. The inner surface was smooth, but the outside was rough due to the use of peel ply. The outer surface was soft and appeared to be non-polymerised. The last two layers (nylon stockinnete) could be peeled off manually (if applying sufficient force).

We observed that in all specimens the impregnation was better in the parts near the resin inlet.

3.2 Mechanical testing and statistical analysis

The number of specimens for individual measurements is summarised in **Table 1**. In all the comparisons of strength between the materials, we considered the thickness as a covariate because it was negatively associated with all three types of strength (**Table 2**). Average thickness was statistically significantly different between the materials (**Table 3**).

Table 1: Number of tested specimens for strength measurements

Strength type	Material	No. of specimens
Bending	A	6
	B1	6
	B2	6
	B3	6
Tensile	A	8
	B1	5
	B2	6
	B3	7
Compressive	B1	3
	B2	3
	B3	3

Table 2: Correlations of specimen thickness with measured strength

Correlation with specimen thickness	Bending strength (N/mm^2)	Tensile strength (N/mm^2)	Compressive strength (N/mm^2)
Pearson *r* (*p* - value)	–0.70 (<0.001)	–0.66 (<0.001)	–0.57 (0.109)
Spearman *rho* (*p* - value)	–0.63 (0.001)	–0.74 (<0.001)	–0.59 (0.097)

Table 3: Descriptive statistics and results of statistical tests for comparing the average thickness of specimens between groups for different strength measurements

Strength type	Material	Thickness (mm) Mean (SD)	*p* (ANOVA)	Summary of post-hoc comparisons
Bending	A	2.50 (0.14)	<0.001	A & B1 < B2 < B3
	B1	2.51 (0.15)		
	B2	2.82 (0.18)		
	B3	3.93 (0.26)		
Tensile	A	2.54 (0.11)	<0.001	A & B1 & B2 < B3
	B1	2.66 (0.22)		
	B2	2.67 (0.07)		
	B3	3.25 (0.06)		
Compressive	B1	2.77 (0.56)	0.010	B1 & B2 < B3
	B2	2.65 (0.06)		
	B3	3.35 (0.05)		

There were no statistically significant differences in the bending strength between the materials (material effect: $p = 0.941$, thickness effect: $p = 0.052$; **Figure 1**). The relationship between the modulus of elasticity during bending and the bending strength for various materials is shown in **Figure 3**. The materials A and B1, which were the thinnest, had the largest modulus of elasticity and bending strength; the values for material B2 were very scattered; material B3, which was the thickest, had the lowest modulus of elasticity and bending strength.

The differences between the materials in terms of tensile strength were statistically significant ($p < 0.001$; **Figure 2**; thickness effect: $p = 0.152$). Materials B1 and

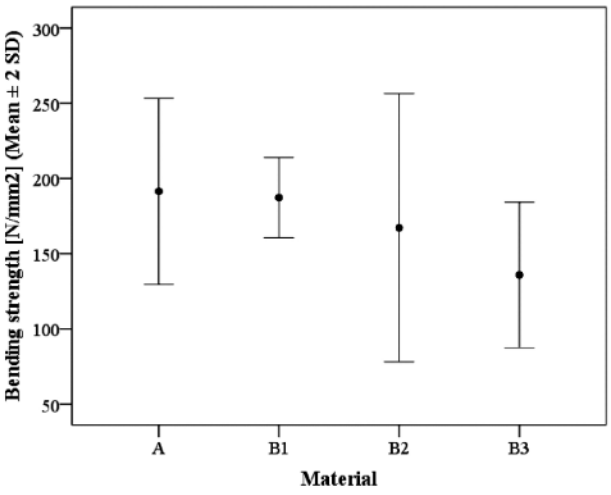

Figure 1: Observed means and variability of bending strength

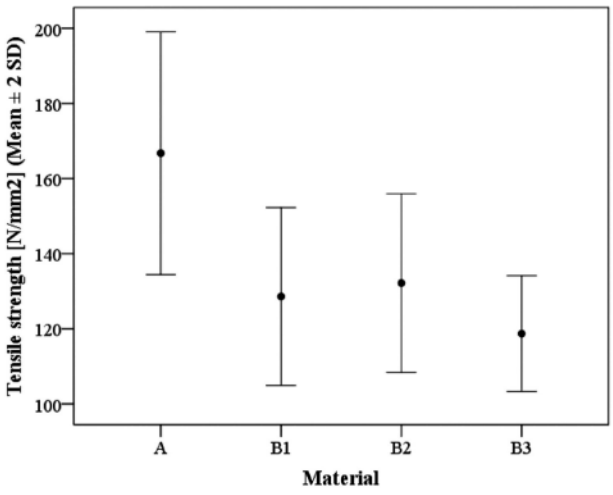

Figure 2: Observed means and variability of tensile strength

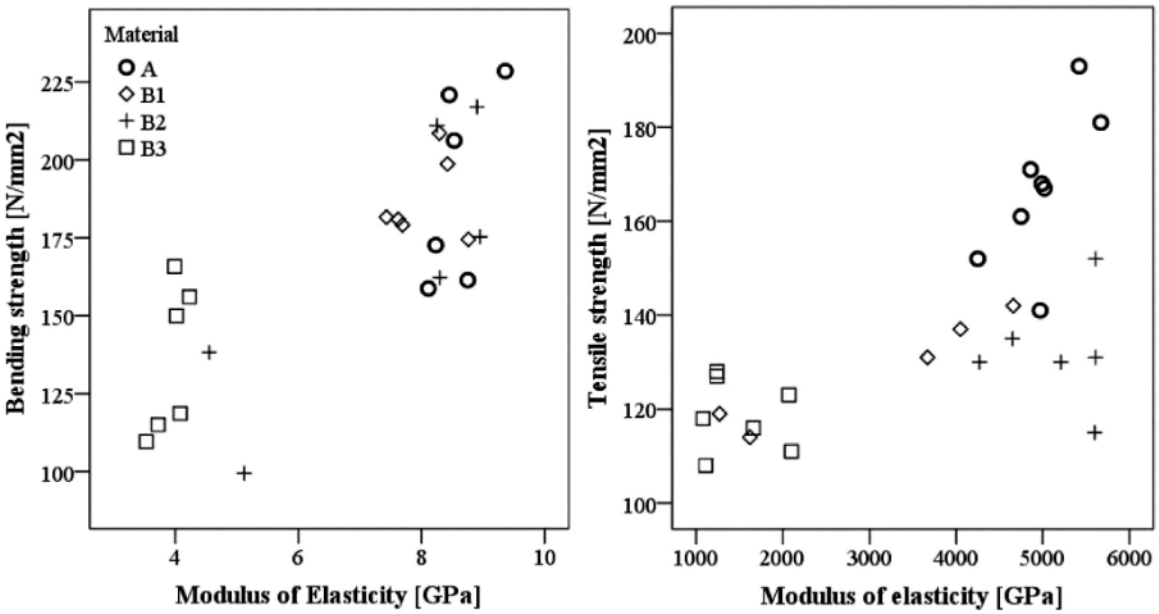

Figure 3: Measurements of modulus of elasticity and strength during bending (left) and tension (right)

B2 exhibited statistically significantly lower tensile strengths compared to material A (post-hoc comparison: $p < 0.001$). The relationship between the modulus of elasticity during tension and tensile strength for various materials is shown in **Figure 3**. Material B2 had the same modulus of elasticity as material A, but less tensile strength, while the values for material B1 were very dispersed. Material B3, which was the thickest, had the smallest modulus of elasticity and bending strength on average, but because of its greater thickness it was not possible to statistically distinguish it from the others.

There were no statistically significant differences in the compressive strength test between the materials (material effect: $p = 0.291$; thickness effect: $p = 0.234$; **Figure 4**). Like with the bending and tensile strengths, the B3 specimens were for the compressive strength testing the thickest on average.

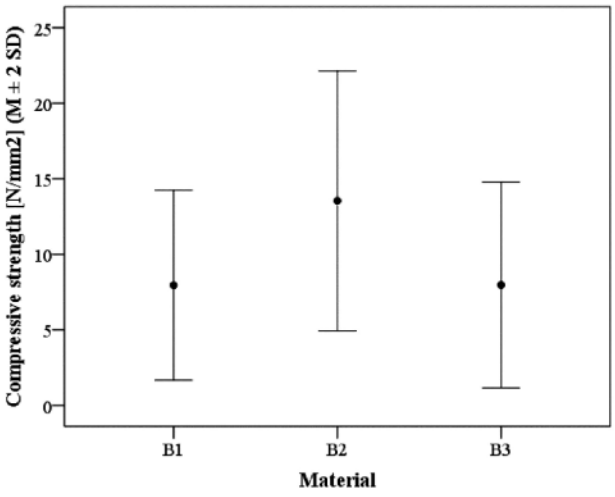

Figure 4: Observed means and variability of compressive strength

4 DISCUSSION

We conducted an industrial experiment to test whether some changes in the lamination process would improve the mechanical properties of the composite material for prosthetic sockets. The produced specimens were compared qualitatively based on visual inspection, and quantitatively based on laboratory strength testing.

Quantitative laboratory testing is useful for planning the construction of laminated prosthetic sockets because it provides objective feedback on the quality of the material. If an improved lamination technique yields a material with higher strength, we can plan the socket's construction more accurately in terms of the composition of the materials for lamination, and be more effective and economical in terms of the precise orientation and dosing of the fabric (which yields a better ratio between the matrix and the fabric).

Upon visual inspection, we observed that porosity was the most evident in material B2, while the standard material (A) and B1 and B3 modifications were comparable in terms of porosity. In the B3 specimens, the resin was incompletely polymerised, which represents a major defect, meaning that such material would not be usable in practice.

The lamination technique that we used is highly dependent on the human factor. The fabrication issues experienced in this experiment were mainly due to insufficiently skilled work and tools that were not specifically adapted for the process.

Thickness measurements showed that the material A specimens were the thinnest on average, while the B3 specimens were clearly the thickest. There was a strong negative correlation between the specimen thickness and all three types of strength.

The highest bending strength was observed with the material A, on average, followed by B1, B2 and B3. When adjusting for specimen thickness, there were no statistically significant differences between the materials. The measurements of the modulus of elasticity during bending were the highest and similar for materials A and B1, scattered for B2, and clearly the lowest in material B3 (as expected because of its thickness).

The highest tensile strength was measured in the standard material A. In the experimental materials B1 and B3, tensile strength was statistically significantly lower. Material B3 had the minimum measured tensile strength, but it could not be meaningfully compared with the others because of the excessive thickness. Modulus of elasticity during tension was the highest and similar in materials A and B2, scattered in B1, and clearly the lowest in material B3 (as expected because of its thickness).

When testing the compressive strength, the best values were shown by B2, but there were no statistically significant differences between the materials. This test we carried out without the control material A, because it was not available in a sufficient quantity.

Overall, we observed a positive association of the mechanical strength with the degree of impregnation of the composite material, i.e., a negative association with the degree of porosity. It is well known that porosity has a negative impact on the strength of the material.[6,8] We must therefore strive to design a technological process where the tools for reducing gaps will prevail and the causes of porosity in the material will be supressed. In addition, the material with greater thickness proved to be weaker. If we use the same material and increase the proportion of the matrix, it increases the ratio of the matrix compared to fibres, thus yielding a lower specific strength[9].

Previous studies in the field of prosthetics and orthotics that involved the mechanical testing of composite materials[3,4,10–13] mostly reported lower measurements of various types of strength of the materials compared to our study. This may be due to differences in the composition of the materials, different measurement devices and differences in the specimen geometry. Their aim was also different because they were interested only in the composition of the material or a combination of different reinforcements in the composite. Only two studies[1,3] tested a material that is used in practice for prosthetic sockets. We could not find a study that would compare the quality of materials manufactured by different techniques, so it was not possible to compare our results and findings with similar studies.

A limitation of our study is that no specimens of the standard material A were subject to compressive strength measurements. However, it is highly unlikely that the new materials would prove superior in this respect, and bending and tensile strength measurements clearly demonstrated that none of them were better than the standard material. Another limitation is that the specimen thickness varied between the materials, even though all the specimens were produced using the same plaster model. We controlled for this variation statistically when comparing strength between the materials, but future experiments should involve specimens of identical size. A further limitation is that we were not able to measure porosity, so it would be desirable to investigate porosity either by examining cross-sections with a microscope or using ultrasound (or thermography) in a future study. On a final note, we used specimens with flat surfaces and sharp corners, which are not typical for the shape of a prosthetic socket, so it would be desirable to use specimens with a more socket-resembling shape in the future.

5 CONCLUSIONS

Our experiment indicates that we are currently using a stable and mature technology for manufacturing the composite structures for prosthetic sockets, because with the potential improvements that we tried introducing into the manufacturing process and should have improved the strength of the material in theory, we observed no improvement. The introduction of a mesh and peel ply proved particularly unsuccessful. Nevertheless, we will continue to strive to improve the quality of the composite, whereby the experience gained from this study will be helpful. We also hope that our study contributes to a better understanding of the application of composite structures in the field of prosthetics and orthotics. We believe that such procedures need to be clearly documented and supported with systematic research, thus reducing the impact of a subjective heuristic approach to the manufacturing of composite structures in the field of prosthetics and orthotics.

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