Polymer materials to produce wrist-hand orthoses using the additive method*)

Paweł Szczygieł[1), **)] (ORCID ID: 0000-0002-3113-3557)

DOI: https://doi.org/10.14314/polimery.2024.2.4

Abstract: Wrist-hand orthosis was developed using PolyJet Matrix (PJM) and Fused Filament Fabrication (FFF) additive technologies. MED610 and PLACTIVE were used as the biocompatible materials. The orthosis was divided into parts A and B. The accuracy of both parts was checked using an optical scanner. The PJM method was more accurate. The compressive strength and stress relaxation of the orthosis were also tested. Greater strength was achieved for part A made using PJM technology, and for part B made using FFF technology.

Keywords: orthosis, additive manufacturing, PJM, FFF.

Materiały polimerowe do produkcji ortez nadgarstkowo-dłoniowych metodą addytywną

Streszczenie: Ortezy nadgarstkowo-dłoniowe otrzymano przy użyciu technologii przyrostowych PolyJet Matrix (PJM) i Fused Filament Fabrication (FFF). Jako biokompatybilny materiał zastosowano MED610 oraz PLACTIVE. Ortezę podzielono na część A i B. Sprawdzono dokładność wykonania obu części za pomocą skanera optycznego. Większą dokładnością charakteryzowała się metoda PJM. Zbadano także wytrzymałość ortezy na ściskanie i relaksację naprężeń. Większą wytrzymałość uzyskano dla części A wykonanej w technologii PJM, a dla części B wykonanej w technologii FFF.

Słowa kluczowe: orteza, wytwarzanie przyrostowe, PJM, FFF.

Additive technologies have been developing at a rapid pace since the 1970s and have applications in industries such as electronics, automotive, architecture, industry, aeronautics, medicine, culture, and art. Recently, additive manufacturing has become increasingly important in medicine and pharmacy [1]. In pharmacy it enables the creation of new drug delivery systems [2–4], and in medicine is being used in tissue engineering [5, 6], cardiology [7], dentistry [8], prosthetics [9], neurology [10], orthopaedics [11], to produce precision surgical instruments [12], implants [13], medical devices [14] and anatomical structure models [15].

The development of additive technology is associated with the production of new materials. Polymer-based biomaterials for orthopaedic applications are known and can be classified into four groups: natural polymers (collagen, alginate, chitosan, fibrin), synthetic polymers (polylactic acid, polyethylene glycol, polycaprolactone, polyetheretherketone), hydrogels (structures held together as water-swollen gels) and composites [11]. Since the early days of polymer production, scientists have tried to optimize the chemical composition of polymers to achieve desired properties. In the case of polyamide (PA) modification, the addition of glass microbeads improved temperature resistance and thermal insulation but reduced flexural strength. In contrast, the addition of carbon fibres resulted in reduced hygroscopic properties and shrinkage of the material during the extrusion process, increasing flexural strength but negatively affecting the overall ductility of the material [16]. In the case of polylactic acid (PLA), a filler in the form of bamboo, cork and wood dust was used, due to the modification an increase in impact strength and hardness was observed, as well as an improvement in the fluidity of the material [17]. PLA-based composites with colloidal silica, hydroxyapatite, bentonite, polyethylene grafted with maleic anhydride additives have also been obtained, these modifiers significantly improved mechanical properties but caused a decrease in PLA elasticity [18]. In numerous medical applications, including tissue engineering or regenerative medicine, cardiovascular implants, dental niches, drug carriers, orthopaedic treatments, cancer therapy,

[1)] Kielce University of Technology, Faculty of Mechatronics and Mechanical Engineering, Tysiaclecia Państwa Polskiego 7 Ave., 25-314 Kielce, Poland.

*) The material contained in the article was presented at the VI Scientific Conference on „Szybkie Prototypowanie, Druk 3D&4D w zastosowaniach inżynierskich", September 14–15, 2023, Warsaw, Poland.

**) Author for correspondence: pszczygiel@tu.kielce.pl

Table 1. Chemical composition of materials [24-26]

MED610						
Isobornyl acrylate	Acrylic monomer	Urethane acrylate	Acrylic monomer	Epoxy acrylate	Acrylate oligomer	Photo initiator
wt%						
15–30	15–30	10–30	5–10 10–15	5–10 10–15	5–10 10–15	0.1–1 1–2

SUP705					
Acrylic oligomer	1,2-Propylene glycol	Polyethylene glycol	Glycerine	Photo initiator	Acrylic acid ester
wt%					
<50	<35	<30	<25	<0.5	<0.3

PLACTIVE	
Polylactide resin	Nano Cu Zeolite 4A: 75% Copper hydroxyacetate: 25%
wt%	
>99	<1

Table 2. Materials properties [22, 27]

Property	ASTM	MED610	PLACTIVE
Tensile strength, MPa	D638	50–65	–
Elongation at break, %		10–25	–
Yield, MPa	D882	–	60
Elongation at yield, %		–	6
Flexural strength, MPa	D790	75–110	83
Notched Izod impact strength, J/m	D256	20–30	16

skin and tendon healing, and medical tools, PLA has demonstrated potential as a biomaterial. In addition, modifiers are used to improve mechanical properties as well as biocompatibility [19].

Limb injuries often require the use of orthotic prostheses, and the use of additive manufacturing technologies provides a quick and personalized way to manufacture them. In studies [20, 21] wrist-hand orthoses (WHO) were made using the layered material extrusion additive manufacturing method and satisfactory results were obtained in terms of strength. It is worth noting that orthoses made by additive manufacturing can replace the popular plaster cast, the disadvantages of which are difficult hygiene, air impermeability, weight, and lack of adjustment.

The use of additive manufacturing in orthopaedics is a solution with many of the benefits. The expanding market for polymeric materials, especially biocompatible ones, increases the possibilities for additive manufacturing in medicine. The search for these applications is forward-looking and reasonable. In this study, the accuracy of fabrication of a wrist-hand orthosis (WHO) by additive PolyJet Matrix (PJM) and Fused Filament Fabrication (FFF) methods from biocompatible materials was evaluated. A static compression test and a compressive stress relaxation test were also performed on the models made.

EXPERIMENTAL PART

Materials

Orthosis model was obtained using MED610 (Stratasys Corp., Minneapolis, United States) with SUP705 (Stratasys Corp., Minneapolis, United States) as support material and PLACTIVE (Copper3D Co., Santiago, Chile). Table 1 shows the chemical composition of the presented materials while Table 2 states the selected material properties in accordance with the relevant standards. MED610 and PLACTIVE materials are biocompatible, according to the ISO 10993 standard [22, 23].

Methods

The study adopted the procedure shown in Figure 1. Digital imaging and communications in medicine (DICOM) data was available from the Harvard Dataverse [28]. The DICOM file was imported using the open-source software InVesalius version 3.0 (Technology Information Centre, Campinas, Brazil) to reconstruct the CT images. The software's tools made it possible to recreate a model of the hand's surface including the skeletal system (Figure 2a). The 3D model of the hand was saved in STL format.

The modelling process initially required the removal of redundant elements from the 3D model (Figure 2b) – remnants of CT scanner elements. SelfCAD software (SelfCAD Co., New York, United States) was used for this purpose. The finished 3D model of the hand was imported into MediACE3D software (Real Dimension Inc., Daegu, Republic of Korea). MediACE3D is a unique 3D CAD software for custom 3D printed orthosis design. The mesh quality of the STL model was improved and then by preserving the skeletal system, reference anatomical points were set to accurately design the orthosis model (Figure 2c). It is worth noting that the software

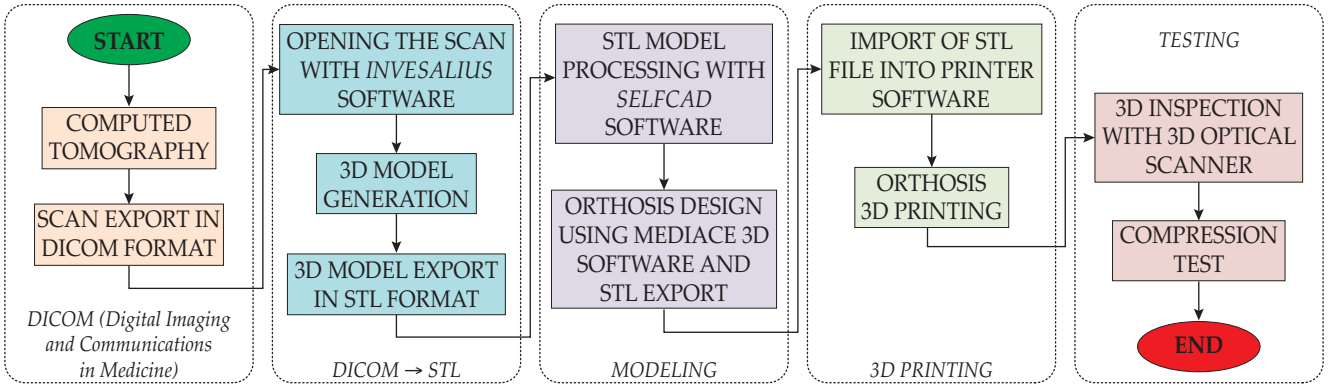


Fig. 1. Scheme of the conducted research

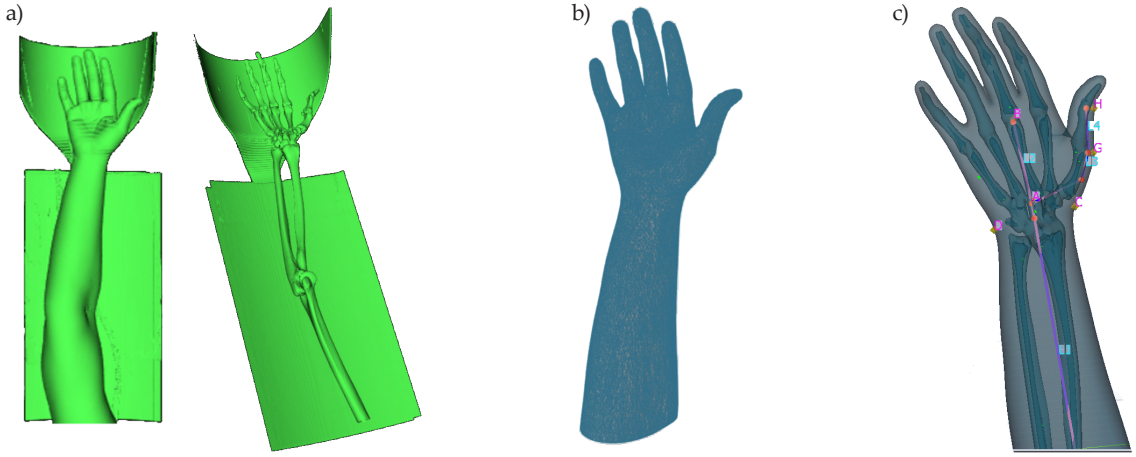


Fig. 2. 3D model of the hand: a) based on DICOM file in InVesalius software, b) after removing unnecessary elements in SelfCAD software with visible mesh, c) with preset anatomical reference points in MediACE3D software

also has an option to place the hand in the correct position.

When designing an orthosis, it is worth paying attention to the anatomical layout of the affected limb (Figure 3). In the case of the present study, the orthosis was designed to stabilize the wrist in a functionally favourable position, allowing full range of motion in the metacarpophalangeal (MCP) and interphalangeal joints (DIP and PIP) except for the metacarpophalangeal joint of the thumb. This orthosis does not prevent rotation in the distal radioulnar joint (DRUJ), so it is not used to treat injuries to this joint.

The finished design of the orthosis is shown in Figure 4. The orthosis was divided into two parts in such

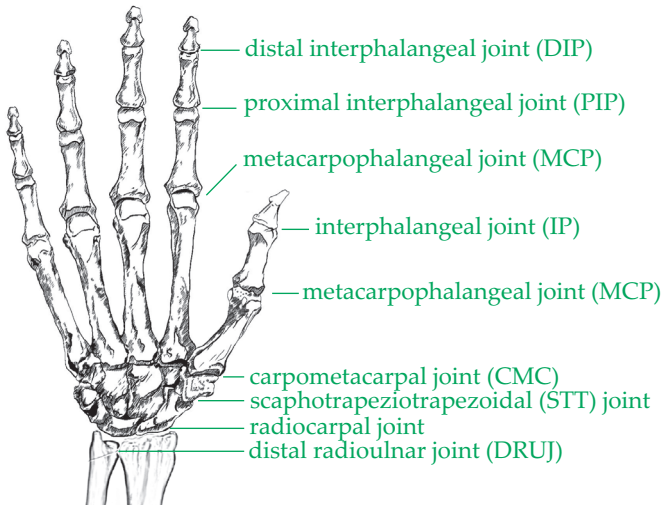


Fig. 3. Anatomy of the human hand joints

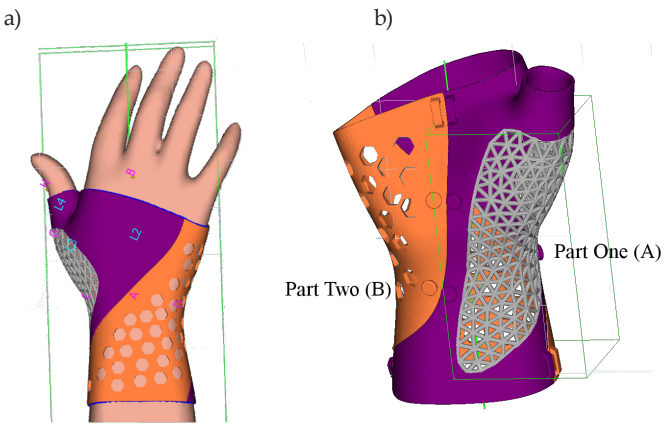


Fig. 4. 3D model of the orthosis: a) view on virtual hand model, b) along with the possible use of fasteners

a way as to be wearable. MediACE3D software has an option to add fasteners, but as they were not the subject of the study, physical models were made without them. To reduce the weight of the orthosis and increase the air permeability of parts of the orthosis, hexagonal and triangular pattern cutouts were made. The wall thickness of the orthosis model was 2 mm.

Currently, in the field of additive manufacturing, many processes have been standardized. The normative document ASTM 52900 details seven basic additive manufacturing processes: VAT Photopolymerization, Material Extrusion, Powder Bed Fusion, Directed Energy Deposition, Material Jetting Additive, Binder Jetting and Sheet Lamination. Two technologies: PolyJet Matrix (PJM) which belongs to the Material Jetting group of additive manufacturing processes, and Fused Filament Fabrication (FFF) which belongs to the material extrusion group, were used during 3D printing. PJM technology involves printing liquid material in the form of small droplets to the printer's worktable at the location of the model cross-section currently under construction, layer by layer. As a result of UV irradiation of the object, a process of polymerization takes place, i.e. the transition from the liquid to the solid state. Model resin and support resin are supplied to the print head via wires. Depending on the type of support material, it is removed after the printing process in aqueous solutions or using a water pressure washer [29]. Fused Filament Fabrication technology uses a filament wire with an approximate thickness of 1.75 mm, which is heated and extruded through a nozzle and deposited on a heating bed. The nozzle moves in the X- and Y-planes, and the bed moves in the Z-direction, allowing the semi-liquid filament to be deposited on the bed, forming a single layer of sample. When one layer is extruded, it forms a bond with the other layer and solidifies [30]. The printing process with PJM technology was carried out using Object Studio software and a Connex 350 (Stratasys Corp., Rehovot, Israel) printer and for FFF technology using MakerBot Print software and a MakerBot Sketch (MakerBot Industries, New York, United States) printer. Table 3 shows the printing parameters of one orthosis (parts A and B). Printing time using FFF technology was much longer, however, the process itself required less material consumption. The models were made with the smallest layer height possible for the setup for both technologies. The parts were printed flat with respect to the worktable (Figure 5b).

Table 3. Printing parameters

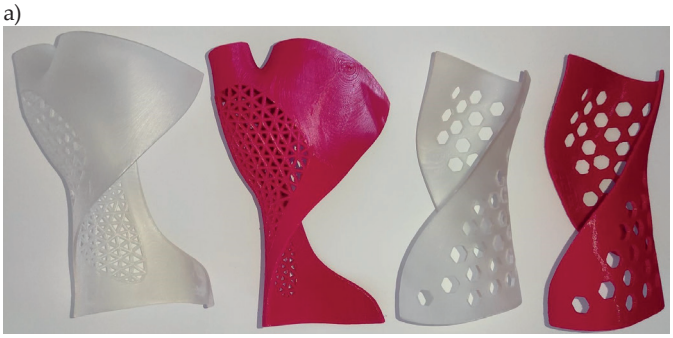
Parameter	Value	
	PJM	FFF
Printing time	11 h 30 min	37 h 20 min
Material consumption, g	Model: 265 Support: 580	185
Layer thickness, mm	0.016	0.1
Infill density, %	100	95
Infill pattern	N/A	Linear
Nozzle diameter, mm		0.4
Platform/extruder temperature, °C		50/210
Printing speed, mm/s		50
Number of shells		2

Printed parts of the orthosis needed to be cleaned of support structures. PJM printing was carried out using model and support material. Removal of the support structures was done according to the manufacturer's recommendations [31] using waterjet, a freshly prepared 1-percent solution of sodium hydroxide and water. FFF printing was carried out using a printer with a single print head, so the support structure was also made from model material. Removal of these structures was done using hand tools and therefore by mechanical means. Printed orthosis components after the process of cleaning from support structures are shown in Figure 5a). These components were weighed using a calibrated electronic balance.

Accuracy of the 3D model

According to the adopted procedure (Figure 1), a 3D inspection was performed using an ATOS II Triple Scan optical scanner with the GOM Inspect Pro software (GOM Co., Brunswick, Germany). The scanner head was positioned automatically. After measurement, the scanner head

a)



MED610 Part One (A) weight: 34 g | PLACTIVE Part One (A) weight: 33 g | MED610 Part Two (B) weight: 22 g | PLACTIVE Part Two (B) weight: 20 g

b)

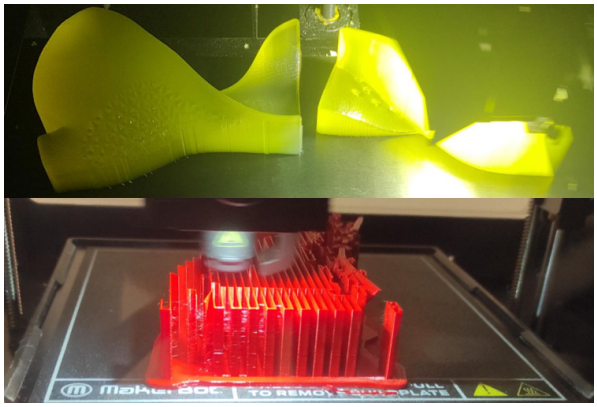


Fig. 5. Orthosis parts: a) after printing and cleaning, b) during printing

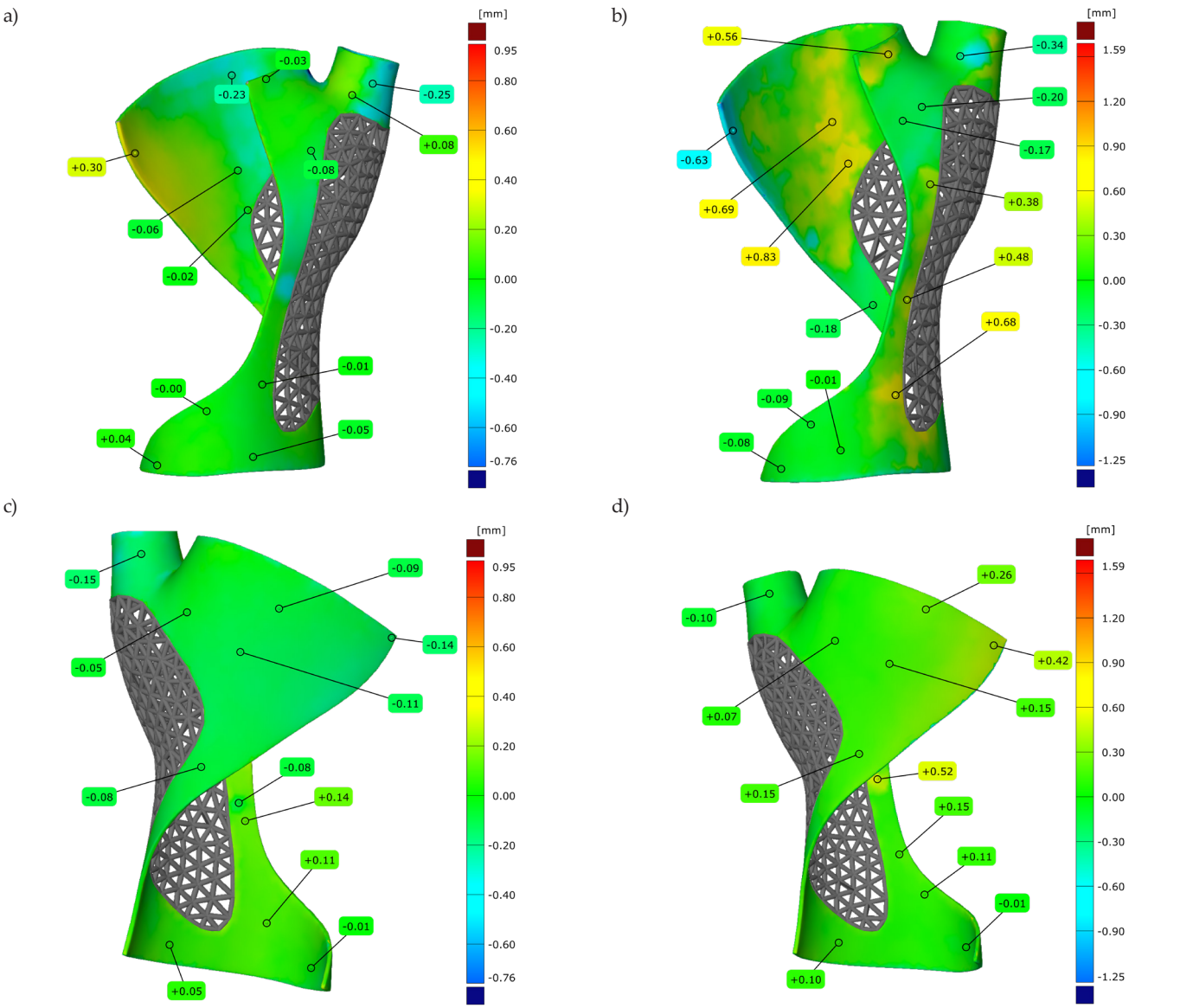


Fig. 6. 3D inspection of part one: a) PJM/MED610 first view, b) FFF/PLACTIVE first view, c) PJM/MED610 second view, d) FFF/PLACTIVE second view

or the scanned item was moved to measure areas that were not scanned in the previous positioning. The entire measurement was automatically transformed to a common coordinate system and generated a cloud of 3D points.

Mechanical properties

Compression tests were performed using an Inspect Mini strength testing machine with the LabMaster software (Hegewald and Peschke, Nossen, Germany) in accordance with ISO 604 and ISO 3384 standards.

RESULTS AND DISCUSSION

3D inspection

The 3D inspection was performed using a 3D optical scanner along with a rotary table. It is worth noting that the fabricated parts were difficult to scan due to the complex shape, the transparent MED610 material and the glossy printing surface of the PLACTIVE material. Due to the mentioned difficulties, a good-quality scan of the fine structure of the triangular pattern located in part 1 (A) was not obtained, so the analysis of this area was omitted. Nevertheless, the area was evaluated by visual inspection with the naked eye, the workmanship was judged to be particularly good with no visible cracks, losses, or deformations. The results of the 3D inspection of part one (A) and part two (B) are shown in Figure 6 and Figure 7, respectively.

The 3D inspection was performed at the same points for parts produced with both technologies. Analysing the results for the first part (Figure 6), it is possible to notice larger deviations of the print made with FFF technology reaching up to +0.83 mm (Figure 6b), these values are due to trace residues of support structures that were mechanically removed with hand tools. Printing made with PJM technology is characterized by negative deviations

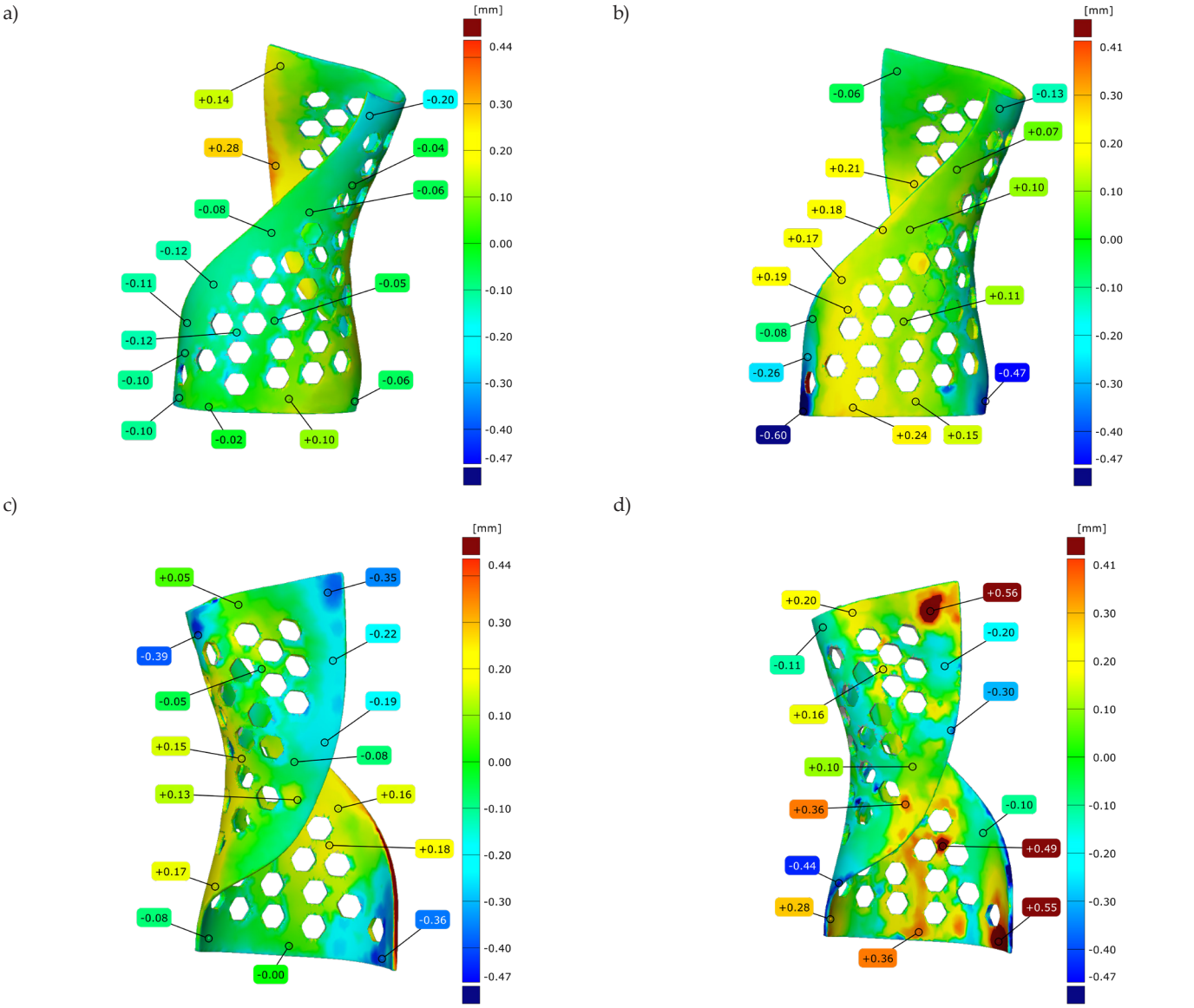


Fig. 7. 3D inspection of part two: a) PJM/MED610 first view, b) FFF/PLACTIVE first view, c) PJM/MED610 second view, d) FFF/PLACTIVE second view

(Figure 6a, 6c), while FFF technology has positive deviations (Figure 6b, 6d). In the case of the second part of the orthosis (B), this predisposition also appears (Figure 7). However, the deviations are much larger, occur locally and take the maximum of positive and negative values: +0.56 mm, –0.60 mm for the part made with FFF technology (Figure 7b, 7d) and for PJM technology: +0.28 mm, –0.39 mm (Figure 7a, 7c). Tsiokou *et al*. also performed an inspection using a 3D scanner for an orthosis made with FFF technology from custom tritan copolyester (CPE) TX1501 with chopped carbon fibres (CFs) and thermoplastic polyurethane (TPU) [21]. Inspection showed mostly negative deviations, as reported by the authors "possibly related to material shrinkage during solidification". The largest positive deviation was +1.599 mm, and the largest negative deviation was –0.822 mm. Moreover, dimensional accuracy in FFF technology is affected by the established print path. In this technology, a manufactured part with simple shapes where the printing

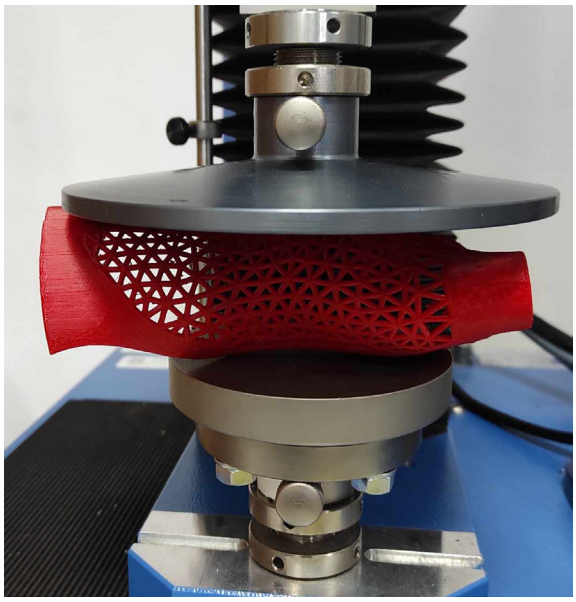


Fig. 8. Compression test of orthosis

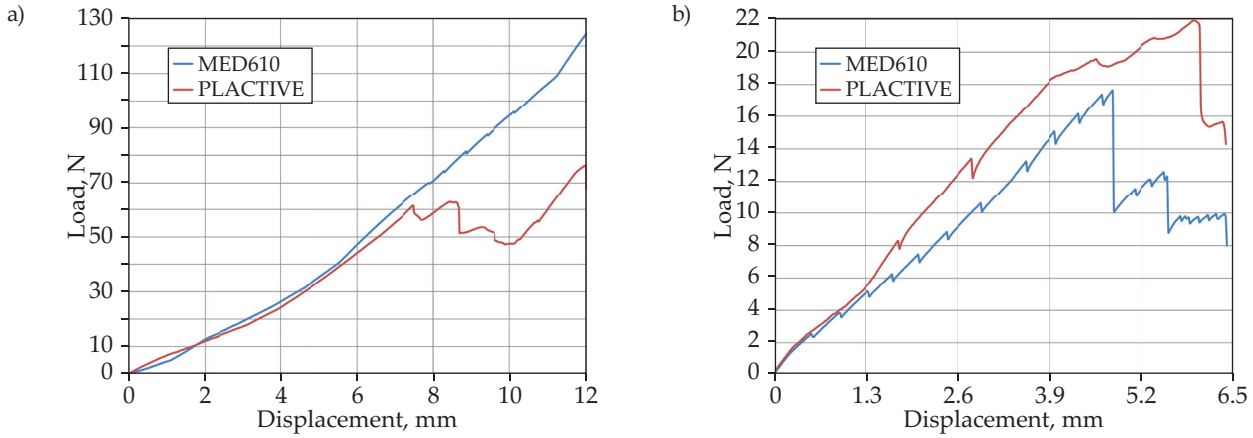


Fig. 9. Load – displacement curves of orthosis: a) part A, b) part B

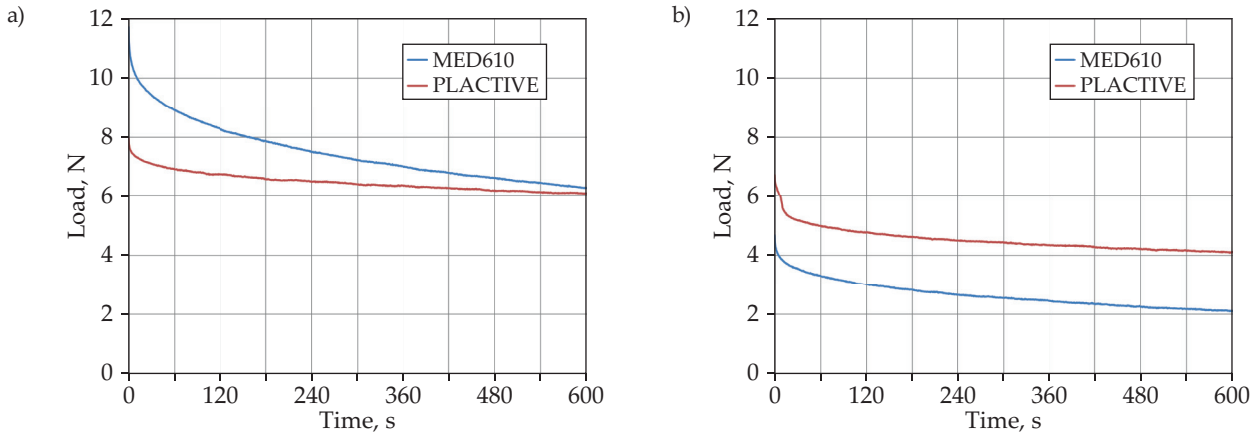


Fig. 10. Compression stress relaxation curves for orthosis: a) part A, b) part B

path follows a straight line has insignificant deviations, but in the case of parts with complicated shapes such as an orthosis (which additionally has many rounds), these deviations are much larger [32].

Compression resistance

The study was completed by performing a static compression test and a compression stress relaxation test (Figure 8). The results in graphical form are shown in Figure 9 and Figure 10.

The static compression test showed for first part (A) that the MED610 material did not fail when the displacement reached 12 mm, while the part made of PLACTIVE material failed at this value. The part made of MED610 material achieved a 93% higher maximum load. For the second part (B), both components made of MED610 and PLACTIVE failed at a displacement of about 6.5 mm. Nevertheless, a higher load was obtained for the part made of PLACTIVE material by 24% compared to that made of MED610. The curves have acquired non-linear characteristics, this is due to the gradual breaking of the structures during the compression test.

The stress relaxation test was carried out at a constant strain of 1 mm. The load decrease over time for the MED610 material is much higher, amounting to 46% for part one (Fig. 10a) and 55% for part two (Fig. 10b). For the PLACTIVE material, the load drop was 23% for part 1 (Fig. 10a) and 39% for part 2 (Fig. 10b). Similarly to the static compression test, higher load values were obtained for the first part for the one made of MED610 material, while the second part for the one made of PLACTIVE material.

CONCLUSIONS

The accuracy of making wrist-hand orthoses from biocompatible materials using additive methods (PJM, FFF) was assessed. Orthosis parts made of MED610 were characterized by greater accuracy compared to parts made of PLACTIVE. In the case of the PJM method, part A of the orthosis had a higher compressive strength, and in the case of the FFF method, part B. Moreover, part A made of MED610 showed a greater load drop over time, indicating a greater risk of deformation or damage. FFF technology required longer printing times (over 200%) than PJM. Despite this difference, FFF is economically preferred because the material used (PLACTIVE) is 84% cheaper than that used in PJM technology (MED610). Unfortunately, in post-processing, parts made using FFF technology required mechanical removal of supports, which in turn is associated with the likelihood of damaging the model, and the surface finish depends on the operator's skills. When

making a critical choice which technology is more suitable for the manufacture of orthosis, PJM should be indicated, taking into account the accuracy of obtaining, ease of removal of supporting structures and durability, but in terms of economy and the prospect of using the orthosis for a longer period of time (stress relaxation test showed a smaller decrease in load in time for the PLACTIVE) FFF technology is also promising. Due to their complex shape, the manufactured orthosis elements required the use of supporting structures, which increased the material consumption and, therefore, the production cost. Future research will focus on manufacturing orthoses using low-impact technologies such as selective laser sintering (SLS), which is part of the Powder Bed Fusion group of additive manufacturing processes. The lack of supporting structures in this technology allows for significant material savings, especially in the case of elements such as orthoses.

Author contribution

P.S. – conceptualization, methodology, software, validation, formal analysis, investigation, resources, data curation, writing, visualization, supervision, project administration. Author have read and agreed to the published version of the manuscript.

Funding

This research received no external funding.

Conflict of interest

The authors declare no conflict of interest.

REFERENCES

[1] Oleksy M., Dynarowicz K., Aebisher D.: *Pharmaceutics* **2023**, *15(8)*, 2169. https://doi.org/10.3390/pharmaceutics15082169
[2] Wei H., Luo Y., Ma R. *et al*.: *Pharmaceutics* **2023**, *15(9)*, 2336. https://doi.org/10.3390/pharmaceutics15092336
[3] Al-Nimry S.S., Daghmash R.M.: *Pharmaceutics* **2023**, *15(6)*, 1597. https://doi.org/10.3390/pharmaceutics15061597
[4] López-González I., Hernández-Heredia A.B., Rodríguez-López M.I. *et al*.: *Pharmaceutics* **2023**, *15(6)*, 1763. https://doi.org/10.3390/pharmaceutics15061763
[5] Pantermehl S., Emmert S., Foth A. *et al*.: *Biomedicines* **2021**, *9(4)*, 336. https://doi.org/10.3390/biomedicines9040336
[6] Kantaros A.: *International Journal of Molecular Sciences* **2022**, *23*, 14621. https://doi.org/10.3390/ijms232314621
[7] Sun Z., Wee C.: *Micromachines* **2022**, *13(10)*, 1575. https://doi.org/10.3390/mi13101575
[8] Kharmanda G.: *Journal of Functional Biomaterials* **2023**, *14(7)*, 334. https://doi.org/10.3390/jfb14070334
[9] Wendo K., Barbier O., Bollen X. *et al*.: *Machines* **2022**, *10(6)*, 413. https://doi.org/10.3390/machines10060413
[10] Gander C., Shi K., Nokhodchi A. *et al*.: *Pharmaceutics* **2023**, *15(3)*, 892. https://doi.org/10.3390/pharmaceutics15030892
[11] Gide K.M., Islam S., Bagheri Z.S.: *Journal of Composites Science* **2022**, *6(9)*, 262. https://doi.org/10.3390/jcs6090262
[12] Wu S., Zeng J., Li H. *et al*.: *Processes* **2023**, *11(6)*, 1736. https://doi.org/10.3390/pr11061736
[13] Alontseva D., Azamatov B., Safarova Y. *et al*.: *Coatings* **2023**, *13(7)*, 1175. https://doi.org/10.3390/coatings13071175
[14] Kozior T., Bochnia J., Gogolewski D. *et al*.: *Polymers* **2022**, *14(3)*, 408. https://doi.org/10.3390/POLYM14030408
[15] Turek P.: *Polimery* **2022**, *67(4)*, 162. https://doi.org/10.14314/polimery.2022.4.4
[16] Mazurkiewicz M., Kluczyński J., Jasik K. *et al*.: *Materials* **2022**, *15(14)*, 5079. https://doi.org/10.3390/ma15145079
[17] Bulanda K., Oleksy M., Oliwa R. *et al*.: *Polimery* **2020**, *65(7-8)*, 557. https://doi.org/10.14314/polimery.2020.7.8
[18] Oleksy M., Dynarowicz K., Aebisher D.: *Polimery* **2023**, *68(6)*, 323. https://doi.org/10.14314/polimery.2023.6.3
[19] DeStefano V., Khan S., Tabada A.: *Engineered Regeneration* **2020**, *1*, 76. https://doi.org/10.1016/j.engreg.2020.08.002
[20] Łukaszewski K., Raj R., Karwasz A.: *Materials* **2023**, *16(18)*, 6132. https://doi.org/10.3390/ma16186132
[21] Tsiokou V., Papatheodorou A., Ntenekou D., *et al*.: *Processes* **2023**, *11*, 2204, https://doi.org/10.3390/pr11072204
[22] https://www.stratasys.com/siteassets/materials/materials-catalog/biocompatible/mds_pj_med610_0720a.pdf (access date 20.09.2023)
[23] https://www.3dmprint.it/Download/pdf/booklet__plactive2.pdf (access date 20.09.2023)
[24] https://www.sys-uk.com/wp-content/uploads/2016/01/MSDS-Clear-Bio-Compatible-MED610-English-US-1.pdf (access date 20.09.2023)
[25] https://www.sys-uk.com/wp-content/uploads/2016/01/MSDS-Objet-Support-Material-SUP705-English.pdf (access date 20.09.2023)

[26] https://formfutura.com/datasheets/copper3d-sds-plactive.pdf (access date 20.09.2023)
[27] https://www.mediace3d.com/plactive.html (access date 20.09.2023)
[28] Cabibihan J. J., Abinahed J.: *Harvard Dataverse, V1* **2018**. https://doi.org/10.7910/DVN/TJTSCM
[29] Patpatiya P., Chaudhary K., Shastri A. *et al*.: *Journal of Mechanical Engineering Science* **2022**, *236*, 7899, https://doi.org/10.1177/09544062221079506
[30] Yadav A., Rohru P., Babbar A. *et al*.: *International Journal on Interactive Design and Manufacturing* **2022**, *17*, 2867. https://doi.org/10.1007/s12008-022-01026-5
[31] https://support.stratasys.com/en/Materials/PolyJet/Biocompatible (access date 20.09.2023)
[32] Sherugar S., Birkett M., Blacklock M.: *Progress in Additive Manufacturing* **2023**. https://doi.org/10.1007/s40964-023-00502-y

Received 13 XI 2023.
Accepted 11 XII 2023.