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Authors	Sandre, Cristian;De Bernardez, Leopoldo;Poggi, Luciano;Sanguinetti, Juan Manuel
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Application of Material Jetting technology for the development of incision and closure surgical devices

Cristian Sandre [a,*], Leopoldo Santiago De Bernardez [a], Luciano Poggi [b], Juan Manuel Sanguinetti [a]

[a] Instituto Tecnológico de Buenos Aires, Iguazú 341, C1437ETC Ciudad Autónoma de Buenos Aires, Argentina
[b] INCLODE SA, French 3085, C1425AWK, Ciudad Autónoma de Buenos Aires, Argentina

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ABSTRACT

Material Jetting technology has proven to be very useful in the manufacture of parts with a variety of shapes, consistencies, textures, transparencies and colours, and a great diversity of mechanical properties can be achieved, from low hardness elastomers to rigid materials.

Applications range from manufacturing parts in limited production runs with bright, colourful designs to be distributed as marketing items to functional prototypes that closely resemble final products.

The possibility of creating digital materials with a wide range of mechanical properties by combining resins that polymerize with UV light makes it possible to approach the final properties of a piece that will later be produced on a larger scale with commercial polymers, both thermoplastic and elastomers, through traditional manufacturing processes such as injection moulding, compression moulding or thermoforming.

Keeping in mind these advantages, we have used Polyjet technology for the development of incision and closure surgical devices. The prototypes were manufactured using a combination of resins that allow the properties of commercial elastomers, potentially used for the final product, to be approached. The characteristics of the device, the requirements of the prototypes, and the mechanical properties of the combinations of resins that were considered suitable for this application are described. The differences found between the experimental results and the values reported in the data sheets of the digital materials that were used are discussed.

1. Introduction

Material Jetting 3D printing was patented by the Objet Ltd. company in 1999, which merged with Stratasys in 2012, thus giving rise to the name PolyJet or Photopolymer Jetting, also for this technology, it combines Inkjet technology and the use of photopolymers, is a 3D printing technology in which a head moves in an XY coordinate system and injects droplets of photo polymeric resin onto a platform that descends along the Z axis, building the part layer after layer [1]. The resin deposited through the head is polymerized almost immediately by ultraviolet light (UV) light while the thickness of each layer is rectified by means of a roller (see Fig. 1). These three processes (i.e. resin injection, photo polymerization and rectification) are solved by the head in a single process almost simultaneously.

The printing process includes the printing of support material as requires. This support material is unique and the software defines where it should be placed for the printing process to proceed normally. At the end of the printing process it must be manually removed with appropriate tools or by means of pressurized water.

After curing with UV light, the photopolymers that were used to materialize the pieces achieve characteristics that can resemble those of the polymers used in the industry to manufacture different products. The aim is to get characteristics of the part produced via MJ technology as close as possible to those of a part manufactured with traditional industrial processes such as injection and thermoforming, which will eventually be used to manufacture the final part after the development and prototyping stage. This technology has some interesting peculiarities. In addition to

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* Corresponding author.
E-mail address: scristian@itba.edu.ar (C. Sandre).

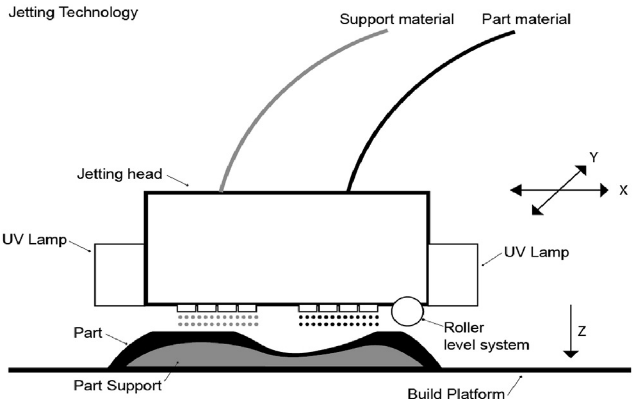

Fig. 1. Schematics of Material Jetting equipment.

achieving an excellent surface finish, it is possible to combine a variety of resins with different properties to achieve what are known as digital materials [2]. Thus, different mechanical properties can be obtained by combining flexible and rigid materials in different proportions.

The combination is produced in the piece when micro drops of each of the resins are injected in the correct proportion to obtain the desired final properties. This allows rigid and flexible areas to be printed on the same piece by varying the relative proportion of the resins used.

The assortment of digital materials that can be obtained is wide and varied, from both opaque and transparent rigid materials to other flexible ones and also with a color palette of your choice. At the present time this technology is frequently used for the printing of prototypes as part of the product development process, being able not only to materialize a piece but also to present the final graphic design associated to the product in the same process, generating hyper-realistic models.

An important area of interest is medicine, where it is used for different applications such as model creation, not only for planning but also for surgical practices when dealing with complex morphologies, allowing the simulation of tissues, cartilage and bone, which bring the doctor closer to a more realistic situation [3,4].

Also in the case of dentistry, there are applications with biocompatible materials that allow contact with the mucosa for a short time to, for example, make surgical guides for dental posts [5].

However, unlike other technologies such as Fused Filament Fabrication (FFF) or Selective Laser Melting (SLM) that can be used for serial part manufacturing, MJ is frequently applied to the development of high-quality prototypes.

In the present case Polyjet technology was used to develop a surgical device speeding up the process with considerable cost savings.

2. Experimental

The purpose of the aforementioned device is to facilitate incision and closure in surgical procedures. It includes a guide for the cutting instrument and a mechanism for a posterior sutureless incision closure. The device is adhered to the skin by means of an adhesive tape and has a central slit whose edges are reinforced by two strips that delimit a central incision groove. It has a removable central partition that maintains a constant separation between the elastomeric strips before making the incision.

At the end of surgery, a removable snap or magnetic closure approximates the elastomeric strips and brings the underlying wound edges together.

While a rigid material must be used for the closure mechanism to ensure its correct anchorage, the strips adhered to the skin and used to easily access the area after making the incision must have elastomeric properties. Fig. 2 shows one of the final designs of the device as described in the granted US patent [6].

Polyjet was the chosen technology because it allows to achieve different properties of the deposited materials depending on the requirements. Based on the available technical information, variants of digital materials were identified as potential candidates to carry out different tests during the development process. It was decided to use a combination of available resins, namely TangoPlus, Agilus30, VeroClear and VeroWhite, which made it possible to get a material allowing to perform functionality tests.

From the data presented in Table 1 it is possible to see the differences in Tensile Strength and Elongation at break between TangoPlus and VeroClear resins. The mechanical properties of the digital material defined by Stratasys as FLX9070/FLX9970 resulting from a particular combination of both resins is also presented in Table 1. TangoPlus gives elastomeric characteristics to the resulting material [7] while VeroClear increases its mechanical resistance [8].

Fig. 3 shows the values of Tensile Strength vs Shore A hardness for different combinations of TangoPlus and VeroClear resins showing that, depending on the relative proportions of both, the mechanical properties can be varied over a wide range.

If the hardness of the digital material needs to be increased, a higher proportion of VeroClear has to be used [9]. It can be seen in Fig. 3 a) and b) that an increase of hardness is associated with an increase of Tensile Strength and a decrease of Elongation at break, both resulting from the increment of VeroClear resin proportion in the final material.

Taking advantage of the possibility to get different digital materials to print a piece with characteristics resembling those that will finally be used in surgical applications, the physical properties of two commercial materials were compared with one of the possible combinations of Polyjet resins that offer potential advantages for

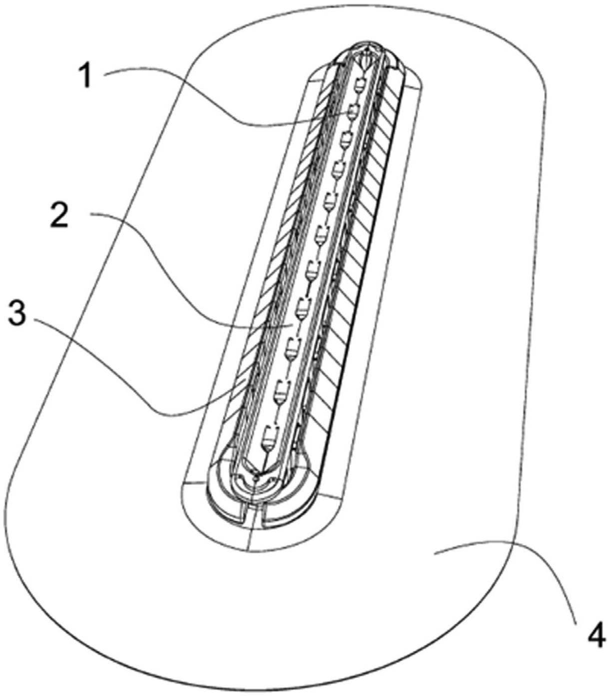

Fig. 2. Perspective view of an incision and closure device as described in the US patent [5]. 1) Snap-fit, 2) Upper face of the strips, 3) Bilateral and parallel strips, 4) Stick-to-skin adhesive tape.

Table 1
Physical properties of Polyjet resins, a digital material of interest and two different commercial elastomers. (a) Polyjet resin, (b) Polyjet digital material [ref 9], (c) Commercial silicone from www.dongjuesilicone.com, (d) Commercial polyurethane from www.huafontpu.com.

Mechanical properties	VeroClear (a)	TangoPlus (a)	FLX9070/FLX9970 (b)	Silicone NE-8171 (c)	TPU HF-1070AP (d)
Tensile Strength [Mpa]	62,5 +/−2,5	1,2 +/−0,4	4,3 +/−0,7	≥7,5	25
Elongation at break [%]	17 +/−7	195 +/−25	73 +/−7	≥260	950
Tensile Tear Resistance [kg/cm]	–	3 +/−1	16,5 +/−1	≥22	107
Shore A Hardness	–	27 +/-1	70 +/-2	70 +/-2	72
Shore D Hardness	84 +/−2	–	–	–	–
(a) Polyjet Digital Material	(b) from https://www.dongjuesilicone.com			(c) from https://www.huafontpu.com	

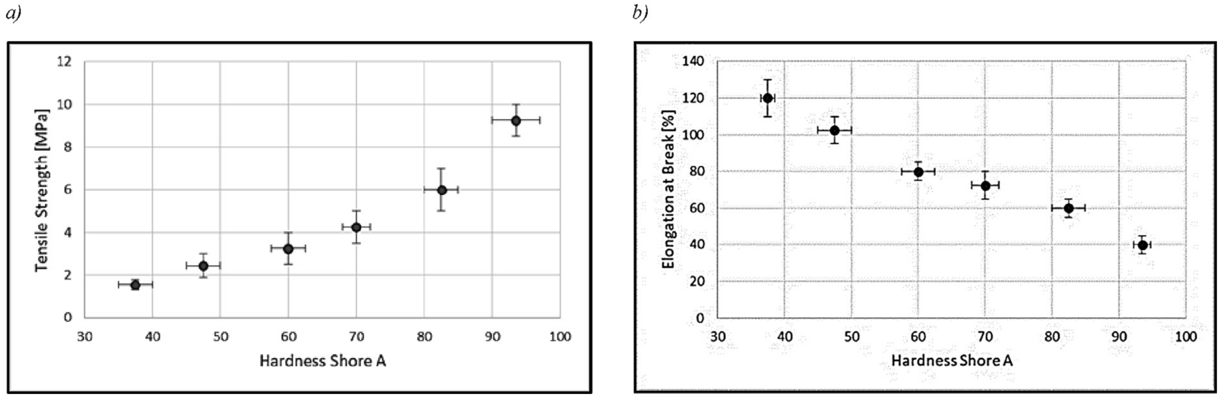

Fig. 3. Mechanical properties vs. Shore A hardness of digital materials resulting from a combination of TangoPlus and VeroClear resins according to Polyjet technical specifications (Ref 3): a) Tensile Strength, b) Elongation at break.

the first trials (see Table 1). However, as it can be seen in the table, the mechanical properties of the digital material significantly differ from those of commercial use.

In order to verify the possible differences between the mechanical properties obtained in a printed piece and those reported in the Stratasys Technical Data Sheets (TDS) [10], test pieces were printed according to the ASTM D412 standard with different combinations of Agilus30 and VeroClear resins. ASTM D412 standard was used to get comparable results with those reported in the TDS. The specimens were tested with a universal testing machine Instron 3382 equipped with a long travel 2603-080 extensometer. Fig. 4 shows a photograph of the set of specimens that was simultaneously printed in Polyjet with different proportions of resins and Fig. 5 shows a specimen mounted for testing in the Instron testing machine.

Fig 6a compares the experimental results of Tensile Strength vs Shore A hardness with those reported in the TDS [10] for combinations of Agilus30 and VeroClear resins. Fig 6b shows the same kind of comparison for Elongation at break vs Shore A hardness.

It can be seen in Figs. 6a and 6b that there are some differences between the experimental results and the data reported in the TDS probably due to variations in the printing conditions, resin conservation and sample conditioning.

The aforementioned differences between TDS and experimental results highlight the importance of carrying out local tests with the equipment and the resins to be used in order to know with greater certainty the mechanical properties of the digital material that is sought to be obtained in order to ensure the adequate performance of the final product in the event that specific mechanical properties are required.

A particular combination of Agilus30 and VeroClear resins, defined by Stratasys as FLX9770 FLX9870, was used to get a digital material with adequate characteristics for the printing of the prototype. Fig. 7 shows the prototype near the end of the printing process and Fig. 8 shows the bilateral flexible strips and the elastomeric part of the devise after removal of support material.

Fig. 4. Picture of the set of the 18 specimens after finishing the printing process.

Fig. 5. Instron 3382 performing the tensile tests on a printed sample.

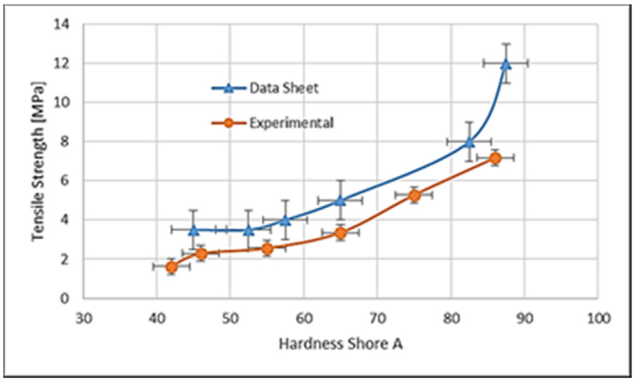

Fig. 6a. Experimental results of Tensile Strength vs. Shore A hardness compared with TDS data for combinations of Agilus30 and VeroClear resins.

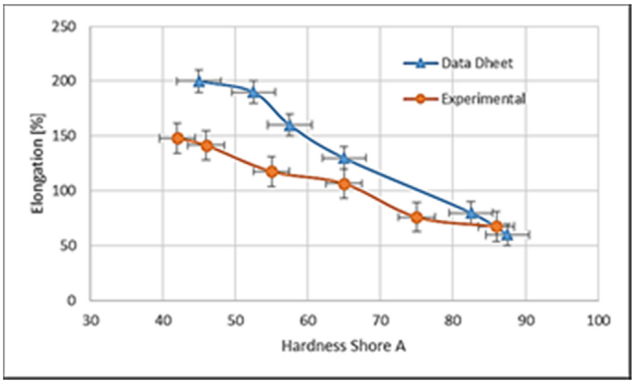

Fig. 6b. Experimental results of Elongation at break vs. Shore A hardness compared with TDS data for combinations of Agilus30 and VeroClear resins.

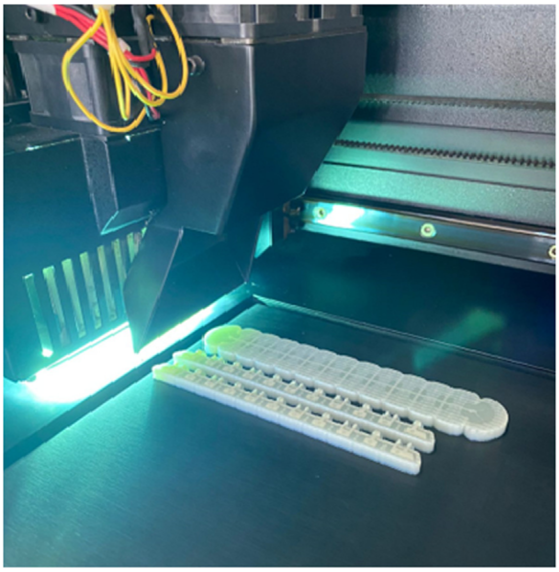

Fig. 7. Picture of the prototype during printing in the Stratasys J750 machine.

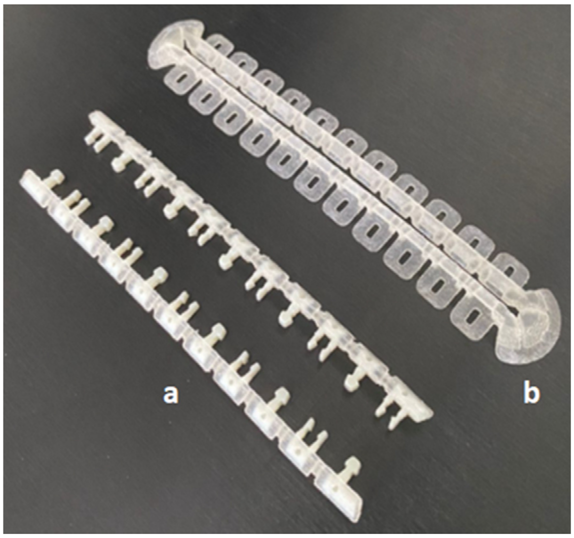

Fig. 8. Picture of different parts of a prototype printed with Polyjet technology a) Bilateral flexible strips that can be hooked together. Note the displacement of the pins that allow the hitch to be secured b) Elastomeric part of the devise. Note the central groove.

According to the TDS, Shore A hardness would be about 65, in agreement with the experimental results shown in Fig. 6. Shore A hardness measured on the device was also around 65. Tensile strength and elongation at break were adequate to perform the initial device functionality tests.

The prototypes printed with Polyjet technology made it possible to analyse the shapes, dimensions and characteristics of the device. Among the advantages obtained with the use of this technology during the product development stages, it can be mentioned that they were significantly accelerated when compared to the use of traditional commercial elastomer casting processes where it would have been necessary to manufacture a mould for each design alternative.

The strategy used was to simultaneously print several designs, with different dimensions and anchoring systems, and then select the most suitable one to continue advancing in the development process.

Using the printed prototypes it was possible to verify the degree of anchorage of the septum and the plugs to the elastomeric band.

Tests could be performed to assess how well the device fit the skin, but surgery in vivo was not performed because the final device was not made of suitable materials to ensure the necessary biocompatibility. It was also possible to evaluate the behaviour of the closure in its coupling with the elastic band as well as the adjustment of the band at the closing point, which allowed an adjustment to be made in the geometry of the end of the band. It was possible to evaluate the form of use and the access to the surgery area, which is related to the opening of the elastomeric band in the area of the surgical intervention as can be seen in Figs. 9a and 9b. On the contrary, it was not possible to evaluate the resistance of the clamp because final dimensions comparable to those of a piece injected in polycarbonate were not obtained.

3. Conclusions

Material jetting technology allowed for a faster iteration process in the design of the device, as well as the functional verification and validation of different closure mechanisms without the need to make casting moulds or machine the clamps during the first steps of development.

Although, due to the limitations of the Polyjet technology, other methods had to be used to check the closing behaviour of the device with greater precision, the MJ technology allowed a significant step forward in the development process.

Nevertheless, the gap between the properties of digital materials and those commonly used for large-scale production must always be taken into account if successful results are to be achieved. Moreover, it would be necessary to test the mechanical properties of the digital materials to be produced because they can differ from the values reported in the data sheets. Also, as it was the case of the developed surgical device, it could be necessary to make the latest prototypes with the material finally used in order to get more reliable results.

In conclusion, Material Jetting technology speeds up the development process and lowers its costs, although care must be taken in extrapolating the results obtained to commercial materials.

CRediT Author Contribution Statement

Cristian Sandre: Conceptualization, Investigation. **Leopoldo Santiago De Bernardez:** Formal Analysis, Methodology, Supervision, Writing. **Luciano Poggi:** Validation. **Juan Manuel Sanguinetti:** Formal Analysis.

Fig. 9a. Picture of one of the first devise test in pig skin.

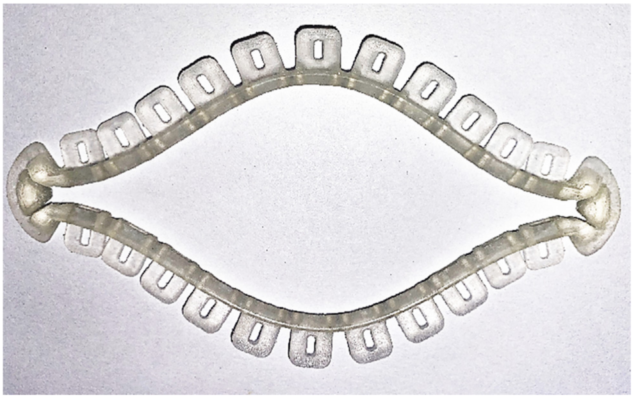

Fig. 9b. Image of the aperture on a printed prototype using Agilus30 + VeroClear digital material.

Data availability

Data will be made available on request.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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