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# A Review of Medical Silicone 3D-Printing Technologies and Clinical Applications

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## Abstract

This paper discusses medical grade silicone use in the production of medical implants and devices and reviews the state-of-the-art silicone 3D printing technologies including stereolithography [1], moisture-cured extrusion [2], heat-cured extrusion, hybrid jetting and UV-extrusion [3] and freeform reversible embedding [4] including PICSIMA [5]. The advantages and disadvantages of each method are discussed in detail and the challenges unique to silicone 3D Printing are highlighted.

**Keywords:** Additive Manufacturing; Medical Devices; Medical Implants; Silicone 3D Printing; Silicone Resins

## Introduction

Silicone resins are thermoset materials which start out in liquid form and cures irreversibly into solid state with heat. The key attributes of liquid silicone resin (LSR) which make it the ideal material of choice include its hardness, tensile strength, compression strength and fluid resistance. Medical grade silicones, in addition, are selected for their biocompatibility and bio-implantability. The benefits of medical-grade LSR over other elastomeric materials include :1) its Bio-inertness in compliance with ISO 10993, USP Class VI and RoHS standards, 2) its ability to be sterilized by a variety of methods such as Autoclave, ETO, E-beam and Gamma-radiation processes, 3) its stability over a wide range of temperatures 150 F to 450 F and 4) its ability to maintain its resilience, flexibility and capability to transfer mechanical force at extreme temperatures. Using the standard ISO 10993 which evaluates the biosafety of materials in contact with the body, medical grade silicones can be grouped into 3 categories, namely: limited exposure, prolonged exposure and permanent contact. Limited exposure products have less than 24-hour contact with skin, mucosal membranes or breached surface. Prolonged exposure products have surface contact or are implanted more than 24 hours and up to 30 days and require tests protocols for haemolysis, genotoxicity, toxicity and intramuscular implantation with histopathology. Permanent contact silicone products are implanted for more than 30 days and require test protocols for carcinogenicity, chronic toxicity and developmental toxicity.

Silicone was first used for urethral implantation in 1950 and subsequently for shunts and interphalangeal joint silicone replacement prosthesis. It was not until 1962 that silicone breast implant made its debut and its development continued through the 1990s. Unfortunately, the use of silicones for meniscus replacement in knees have not been described in literature. Typical medical application of silicones is shown in (Table 1).

| Medical Applications | | Function of Silicone |
|---|---|---|
| Silicone implants | Electronic Cochlear implants | Encapsulate and insulate [6]. |
| | Cardiac Pacemaker | Encapsulate and insulate [7]. |
| | Elastomer intraocular lenses | Recover eyesight after retinal reattachment/cataract surgery [8]. |
| | Silicone tubing implant | Conduit repair of median and ulnar nerves injuries in the forearm [9]. |
| | Breast implant | Restoration of breast anatomy [10,11]. |
| | Hand/foot joint implant | Interphalangeal joints replacement [12]. |
| Extracorporeal equipment | Silicone tubing | Kidney dialysis, blood oxygenators, and heart bypass machines [13]. |
| | Silicone membranes | Extraction of oxygen [14]. |

**Table 1:** Medical applications of silicones.

Its use in silicone implants and extracorporeal equipment and devices are discussed below. Conventionally, silicone implants have been manufactured by direct or indirect molding techniques [15]. Since 2015, only a limited number of silicone 3D Printing, also known as additive manufacturing, technologies have been introduced such as stereolithography [1], moisture-cured extrusion [6], hybrid jetting and UV-extrusion [3] and freeform reversible embedding [4]. While these methods are only capable of printing industrial-grade silicones, only heat-cured extrusion technology is capable of printing medical grade silicones.

## Silicone Implants

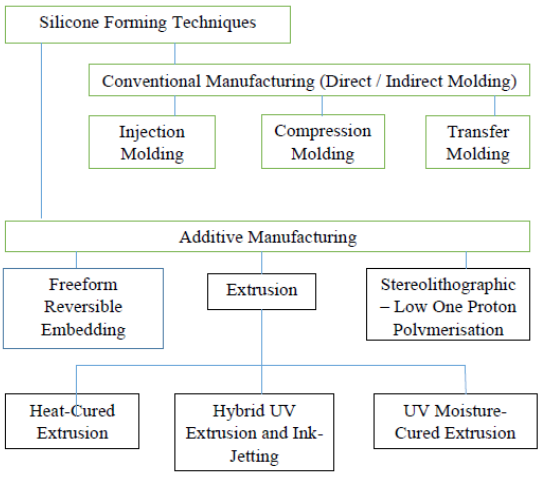
In 1946, F. Lahey first reported the use of silicone stents for bile duct repair [6]. Subsequently, silicone has been used to encapsulate and insulate electronic cochlear implants and cardiac pacemakers [7]. Recently, it has also been used for the production of intraocular lens, replacement of vitreous humor and restoration of the continuity of median and ulnar nerves in the forearm [8,9]. In 1962, Cronin. et al, [11] implanted the first pair of silicone gel-filled breast implants. Despite its approval for use by the U.S. Food and Drug Administration since 2006 [10], its long-term safety profile remained a major concern [16,17]. In contrast to Balk et al. which showed equivocal long-term health outcomes of silicone breast implants [18], Singh et al., in a 5 to 8-year follow-up, showed that these implants did not increase the risks of systemic diseases or suicidal rates when compared to saline implants [19]. In 1968, A. Swanson developed the first interphalangeal implants for the hands and feet. These implants were shown to be safe without provoking any immunological or systemic reactions [12,20]. Subsequently in 1973, F. Mazas, et al. developed a total knee silicone prosthesis with shock absorbing capabilities [20]. In reconstructive and plastic surgeries, silicone implants have also been used for nose and chin augmentation.

## Extracorporeal Equipment and Devices

Medical grade silicones are also used in the production of tubings and membranes of extracorporeal heart-lung bypass machines and blood oxygenators owing to its biocompatible, hemo-compatible and gas permeable properties [13]. In 1968, W. Robb also developed silicone membranes which can be used to extract oxygen from fresh water [14].

## Silicone Additive Manufacturing Technology

Conventionally, silicone parts or end-products have been manufactured by the molding process or indirect casting. Molding is, however, a major technical barrier since the molding process or mold fabrication is time consuming and expensive when only a few parts are needed. The molding process is also unable to manufacture hollow silicone parts with complex internal architectures or produce parts requiring multi-materials. The recent advent of various silicone AM technologies allow potential space for flexible applications such as components for soft robotics, wearable and custom assistive or rehabilitation devices. The current state-of-the-art technologies in silicone 3D printing are shown in the chart below. This section provides a review on the state-of-the-art AM technology for silicone printing. Current available techniques for silicone 3D printing described in literature are Freeform Reversible Embedding, Stereolithographic-ulltraviolet- (SLA-UV based vat photopolymerization), combined extrusion and ink-jetting, extrusion-based techniques in combination with UV-cured, moisture-cured and heat cured technologies. A comparison of the silicone printing features for available AM techniques is shown in (Table 2) below.




| AM Technology | Resolution um | Printing Speeds (mm/s) |
|---|---|---|
| Material Extrusion | 100 - 610 | 1 - 20 |
| Freeform Reversible Embedding | 30- 700 | 2 - 20 |
| Vat photopolymerization | 100- 400 | Not reported |
| Material Jetting | Not reported | 5 |
| Piezoelectric-Pneumatic Jetting | 500-600 | 104 |

**Table 2:** Comparison of the silicone printing features for available AM techniques.

## Freeform Reversible Embedding (FRE) using Carbapol [4]

**The Experimental Setup for Freeform Reversible Embedding:** Hinton et al. introduced this system in 2016, as shown in (Figure 1) [4].

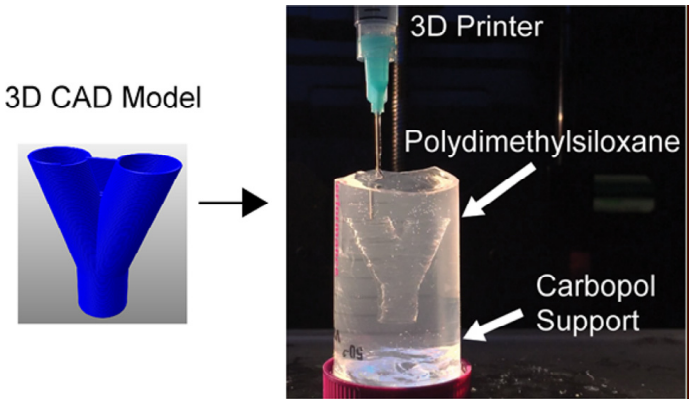



**Figure 1:** Experimental testbed of FRE using Carbapol (a) 3D Printing of hydrophobic PDMS prepolymer resins within a hydrophilic Carbopol gel support via Freeform reversible embedding. Carbopol confines the PDMS prepolymer within the support for up to 72 hours while maintaining dimensional stability (adopted from [4])

The PDMS ink Sylgard 184 was first prepared in a 10:1 base to curing agent ratio and degassed in a planetary centrifugal mixer. The FRE Printing Process was performed using MakerBot 3D Printer with a custom designed syringe pump extruder. The 3D models for printing were designed using SolidWorks CAD software. All STL files were processed by Slic3r software and sliced into 200 µm thick layers to generate G-code instruction, which was sent to the printer using Pronterface, an open source 3D printer host software suite. Before 3D printing, PDMS ink was drawn into a 10-mL plastic syringe and capped with a 400 µm-ID 0.75' stainless steel needle tip. This extruder needle nozzle was positioned at the bottom center of the Carbapol support bath.The typical print speed is set at 20mm/s. Post-curing of the PDMS is performed for 72 h at room temperature or for 4 h in an oven at 65˚C. The prints were then released from the support by immersing in PBS adopted from [4]).

**The Principles of Freeform Reversible Embedding:** The working principle of the system leverages on the immiscibility of the hydrophobic PDMS in the hydrophilic Carbopol support. The printing is freeform and is completed layer-by-layer. The Carbapol support fluidizes when the 3D printer needle moves through it and solidifies when PDMS is extruded within it. After printing and curing, the phosphate buffer solution is used to release the embedded PDMS prints.

**Proof of Concept of Freeform Reversible Embedding:** As a proof-of-concept, Sylgard 184 PDMS is used successfully to 3D print linear and helical filaments via continuous extrusion and cylindrical and helical tubes via layer-and-layer fabrication. These 3D printed tubes are manifold and perfusable, as shown in the (Figure 2) below.

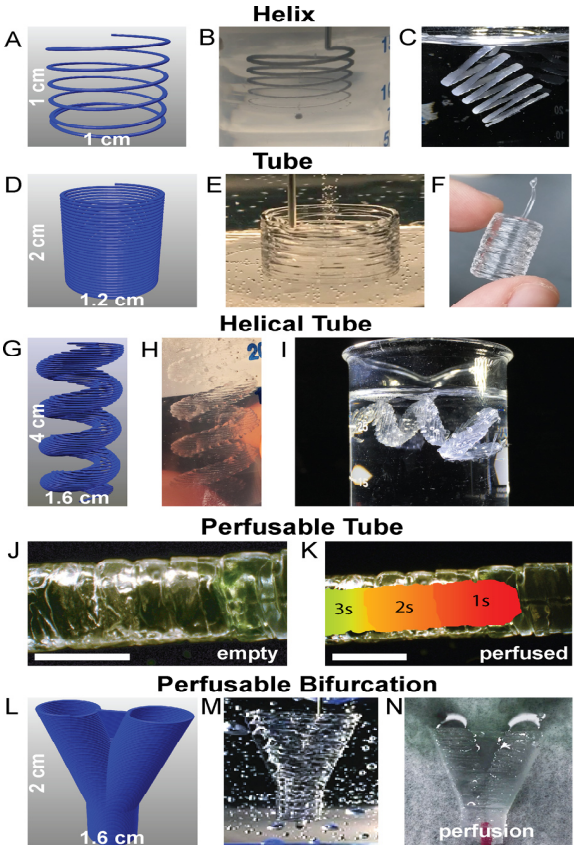



**Figure 2:** (adopted from [4]) Representative FRE printed PDMS structures using the Carbopol support. (adopted from [3]); **(A):** The Carbopol gel is capable of supporting freeform extrusion such as this helical path rendered in G-code; **(B):** The helical extrusion appears identical to the G-code when embedded in the Carbopol (dyed black for visualization); **(C):** After curing and release, the PDMS helix print retains its geometry when floating in water; **(D):** G-code for a cylindrical tube created using a helical extrusion; **(E):** The layers of PDMS filaments fuse into a monolithic surface; **(F):** After curing and release, the printed tube remains fused between layers and is stiff enough to maintain its geometry while being handled; **(G):** The G-code for more complex helical tube; **(H):** As with the tube, the layers of the helical tube are supported within the Carbopol; **(I):** Release of the helical tube from the Carbopol gel shows the maintenance of geometrical features, supported in water because it cannot support its own weight, even when cured; **(J):** A PDMS tube todemonstrate the manifold nature of the print's outer surfaces (scale baris 4 mm); **(K):** A time-lapse heat map of dye perfused through the tube (scale bar is 4 mm.); **(L):** G-code of a bifurcation with a webbed fork for stability; **(M):** The FRE printed PDMS bifurcation embedded inthe Carbopol; **(N):** Perfusion of dye through the bifurcation, splitting fluid flow.

**Pros and Cons of the Freeform Reversible Embedding:** The advantages of this FRE printing system are that: 1) it can print wide range of biomaterials which are hydrophobic in nature, using a hydrophilic support. Cycloaliphatic epoxies and fluoroelastomers may also be adaptable to FRE printing using Carbopol, 2) the Carbapol supports are highly stable over long periods of time, 3) it has a high degree of accuracy and precision of printouts and 4) it has a low cost of implementation of its open-source hardware and software tools. The disadvantages of this FRE printing system are that 1) it does not work well for lateral fusion, since no lateral pressure can be generated by the support. This is in contrast to the vertical fusion which can be generated by the printouts for the laying down of additional vertical layers to aid fusion of layers below, 2) Carbapol support may be trapped within the voids inside the print, 3) long curing times are necessary, 4) postcuring is required and 5) the low elastic modulus of pre-and post-cured PDMS restricts the 3D geometries that can be printed and 6) it cannot print medical grade silicone

## Hybrid UV-Extrusion and Ink-Jetting Technique [3]

**The Experimental Setup of the Hybrid UV-Extrusion and Ink-Jetting system:** The hybrid system, as shown in (Figure 3), consists of three piezoelectric-pneumatic material jetting printheads, one solenoid-actuated material extrusion printhead, one pneumatic material extrusion printhead and a UV lamp.

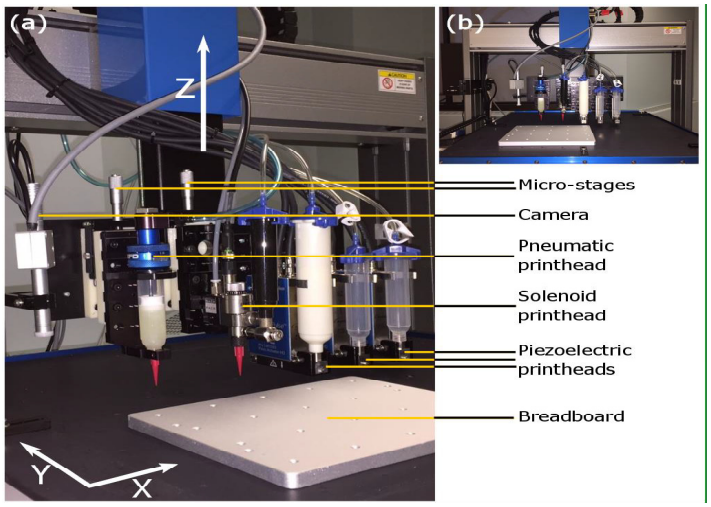



**Figure 3:** Experimental Setup of the Hybrid UV-Extrusion and Ink-Jetting system: (a) Main components; (b) Front view (adopted from [3])

Three controlling units actuate the piezoelectric stacks by sending out the voltage signals, and one controller coordinates the air-pressure in the extrusion-based printheads. The 3-axis motion stage has been used to make the printing of 3D structures possible.

The open source software Slic3r (slic3r.org) creates the toolpaths for the multiple nozzles while specifying the off-set between the nozzles in x- and y-directions. The resultant printing toolpath is extracted as a G-code. The UV-curable silicone used contains the photoinitiator, 2-Hydroxy-2-methyl propiophenone and has a dual UV/moisture curing mechanism. The polymerization process completes within a few seconds after the UV exposure with 365 nm wavelength. The full mechanical properties are achieved after exposure to the environmental moisture for 7 days.

**The Principles of the Piezoelectric-pneumatic material jetting AM in the Hybrid system:** The conventional material jetting system, formerly known as inkjet printing, is compatible with fluid shaving a maximum viscosity of 40 mPa.s. In these systems, fluids with an Ohnesorge number ($O$h) between 0.1 and 1 (or $1 < Z < 10$ where $Z = O$h−1) are considered jettable. Ohnesorge number is calculated according to Eq. (1): $Oh = \mu/(\gamma\rho a)1/2$ (1) where $\mu$ is the dynamic viscosity, $\gamma$ is the surface tension of the fluid, $\rho$ is the density, and $a$ is a characteristic of the length. Since medical-grade silicones with a minimum viscosity of approximately 25,000 mPa.s have an Ohnesorge value greater than one, this class of polymers are not printable via conventional material jetting.

The new generation of jetting printheads, however, is able to jet the droplets of fluids with a viscosity of up to 1,000,000 mPa.s at a high frequency. The dual piezoelectric-pneumatic jetting mechanism in these printheads can provide enough force to eject a droplet of the viscous paste with a volume in the order of pico-litre. The jetting mechanism in this system is illustrated in (Figure 4). In this printhead the valve is normally open. When an actuation voltage (e.g. 95 V) is applied, it moves the sealing ball downward and prevents fluid outflow as it sits on the ceramic nozzle seat (Figure 4b). A subsequent voltage drops results in the opening of the orifice, followed by the filling of the orifice with the fluid due to the air back-pressure (Figure 4c). Next, the voltage signal rises up to the closing voltage resulting in the downward movement of the sealing ball and jetting of one droplet (Figure 4d). The valve remains closed until the beginning of a new cycle.

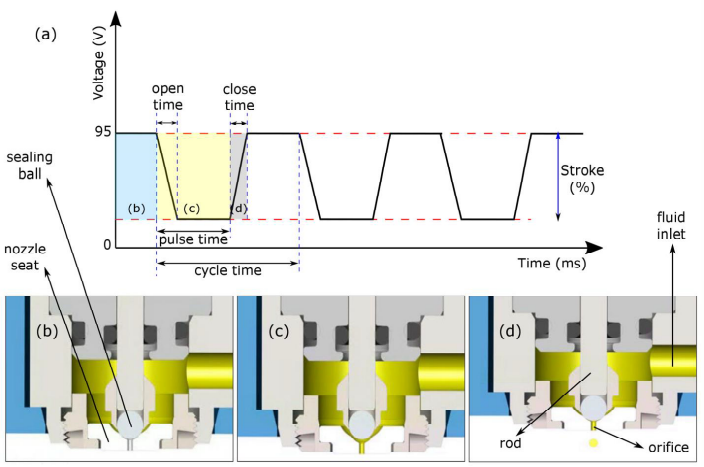



**Figure 4:** The working principle of the piezoelectric-based material jetting; **(a):** The plot shows the voltage signal sent to the piezoelectric stacks for three complete cycles, open time indicates how fast the valve is opened, close time indicates how fast the valve is closed, pulse time is the total time the valve is open, and the cycle time is the total duration of one open/close cycle; **(b):** Corresponds to the blue region of the plot showing the time duration that the valve is closed; **(c):** Corresponds to the yellow region of the plot when the orifice is open and filled with the material; **(d):** Corresponds to the grey region of the plot showing the closing ramp.

**The Principles of the Pneumatic Material Extrusion AM in the Hybrid system:** Material extrusion is a flow-based technology used to fabricate solid freeform structures by depositing a continuous stream of the material onto a surface or on top of the previous layers using a robotically controlled nozzle. The deposited fluid turns into solid after dispensing by cooling, photo-curing, or solvent evaporation. In this type of pressure-actuated print head, compressed air is used to activate the deposition process. The

nozzles are widely adopted for in-house developed 3D printers for their ease of operation and maintenance. The DOE analysis for the measured width averages shows that only four factors (pulse time, voltage, stroke, and close time) are significant at 95% confidence level. The results showed that when working with optimum parameter values, the XY resolution will be 500-600 µm for the jetting and 300-400 µm for the extrusion system.

**Pros and Cons of the hybrid UV-Extrusion and Material Jetting system:** The advantages of this hybrid system are as follows: 1) It can print 20 times faster than the current methods, 2) it encompasses the high printing quality of the extrusion system as well as the high printing velocity of the jetting system, 3) It can print highly viscous silicones directly at a high throughput rate and with high quality and 4) It can print a wide range of materials of different viscosities and complicated parts. The drawbacks of this system are: 1) its inability to print medical grade heat-curable silicones and 2) Post-curing of printouts are required.

## Combined Stereolithography-Low One-Photon Polymerization (SLA-LOPP) system [1]

**The experimental testbed of combined SLA-LOPP system:** Kim and Tai introduced this system in 2016, as shown in (Figure 5).

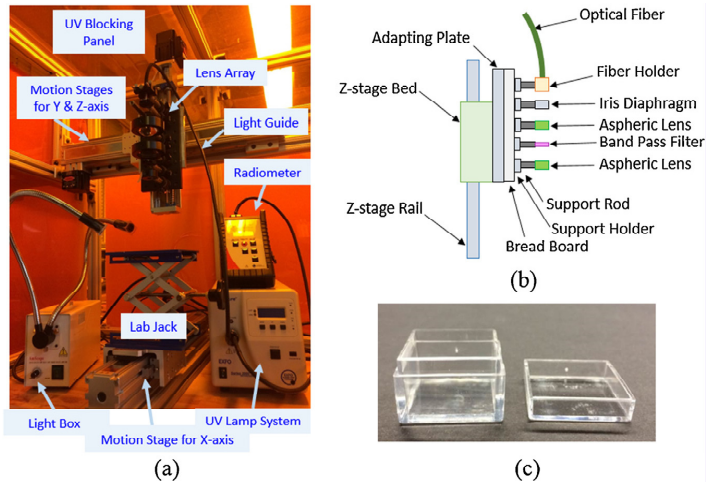



**Figure 5:** Experimental testbed of combined SLA-LOPP system: **(a):** The overall setup, **(b):** Schematic diagram of the lens array, and (c) acrylic boxes as a silicone resin container. (adopted from [1]).

A two-part UV curable silicone is used in order to achieve low one-photon polymerization (LOPP). The first part is the silicone resin and the second part is the UV activated photo-initiator. The optical system consists of a UV lamp system, the optical lens array and the 3-axis reconfigurable motion stage. The lamp system has a wide beam spectrum from 250 nm to 650 nm. The lens array is composed of the aspheric lenses, the band-pass filter set at 365nm and iris diaphragms to align the beam. The beam intensity is controlled by the electrical shutter of the lamp system. The entire system is built by 80/20 aluminum frames and linear sliders that have a resolution of 2.5 um and can be numerically controlled using G-codes. Small acrylic boxes are used as a silicone resin container. Using the dual light guide, the beam from the system can be connected simultaneously with the lens array and the radiometer.

**The principles of the combined SLA-LOPP system:** The key technology behind this method is the low one-photon polymerization (LOPP), which can initiate polymerization at the focusing spot under the resin surface, as opposed to the surface one-photon polymerization in Stereolithography (SLA). UV curable silicone photopolymers are formulated from photo-initiators and reactive liquid monomers. This process of curing photopolymers is known as photo-polymerization. This is an exothermic, energetically favorable reaction. The catalyst required is usually a free radical which is generated photo-chemically when a photo-initiator molecule reacts with an actinic photon from a UV source. These photo-initiator molecules, upon absorbing some photons, are converted into reactive initiator molecules which then react with a monomer molecule to form a polymerization initiating molecule. This initiation stage is followed by a chain propagation stage where the initiating molecules continue to elongate to form longer molecules until a chain termination process inhibits the polymerization reaction. During polymerization, it is important that the polymers are sufficiently cross-linked so that the polymerized molecules do not re-dissolve back into the liquid monomers. The key concept of the support-free fabrication is to create a hydrostatic condition for the solidified material. To achieve the hydrostatic support-free fabrication, the silicone resin must have a minimum difference in density before and after polymerization (i.e., cured and uncured silicone). This is because a large difference can cause the motion of the cured part as a result of gravity against buoyancy force.

**Proof of Concept of the combined SLA-LOPP system:** As shown in (Figure 6), H-shaped structure are printed as proof of LOPP concept.

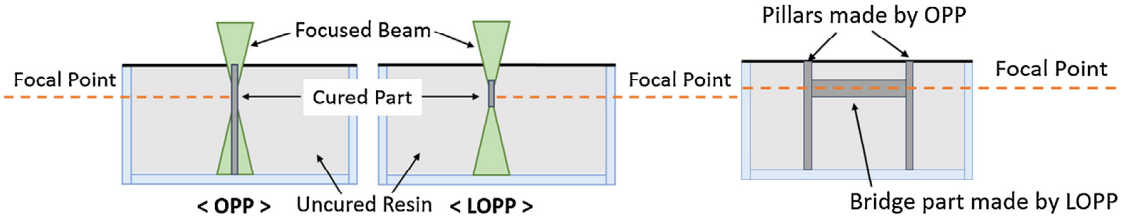



**Figure 6:** Schematic diagram of one-photon polymerization (OPP) and low one-photon polymerization (LOPP) showing printing of H-shape structure

for proof of LOPP concept. **(a):** Front view; **(b):** Side view. (Adopted from [1])

**Pros and Cons of the combined SLA-LOPP system:** The advantages of the system are that 1) it can operate round the clock, 2) build volumes can range from small to large, 3) it has one of the best surface finishes and 4) a wide range of materials can be used from general-purpose material to specialty material for specific applications. The disadvantages are that 1) Special room and complicated setup arrangements are required to carry out the experiments, 2) Support structures are required for overhangs, 3) requires post curing to cure the object completely and ensure integrity of the material, 4) post-processing procedures may not be suitable for all soft and fragile materials and 5) geometrical resolution and accuracy may be limited since LOPP can only cure the material in the middle of the silicone resin but the cured volume and shape are largely dependent on the UV beam gradient, intensity and exposure time and 6) medical grade silicones cannot be printed.

## Moisture-Cured Extrusion Based Silicone Technology [2]

**Experimental setup for moisture-cured extrusion-based technology:** The moisture-cured extrusion based setup, as shown in (Figure 7).

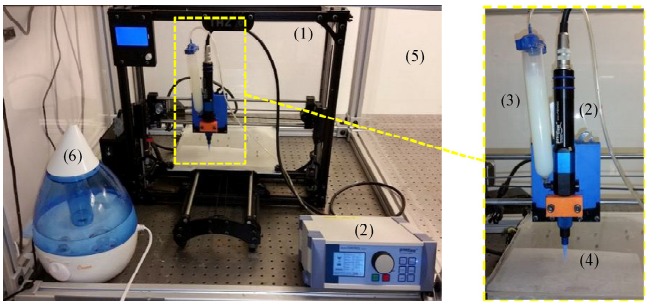



**Figure 7:** Experimental setup for moisture-cured extrusion-based silicone AM: legends: **(1):** Motion control platform; **(2):** Progressive cavity pump and controller; **(3):** Pressurized syringe barrel; **(4):** Tapered nozzle; **(5):** Enclosed build chamber; and **(6):** Humidifier. (Adopted from [2])

Consists of the following: 1) A motion control platform based on an open-source FDM machine, 2) A progressive cavity pump and controller, 3) A clear syringe barrel pressure set to 340kPa +/- which feeds the progressive cavity pump with silicone material while preventing the introduction of air bubbles into the silicone, 4)Tapered 22G nozzle (0.41 mm) and 18 G (0.84mm) tips, 5) Enclosed chamber to maintain humidity and 6) Humidifier to maintain at least 70% relative humidity environment for consistent cure rates. An open source 3D printing console, Pronterface, is used to perform the experiment and Simplify3D used for toolpath generation.

A one-part oxime cure silicone elastomer that cures upon exposure to atmospheric moisture. It features a durometer hardness of Shore 33A, time to develop a firm surface, of 3-6 min, a tack-free time of 14 min, a cure to handling time of 24 h, and a zero-shear rate viscosity of about 62.5 Pa s]. It has a viscosity high enough to resist wetting out, or self-leveling, before curing and low enough viscosity such that they can be extruded from the nozzle.

**The Principles of moisture-cured extrusion-based technology:** The silicone extrusion is based on 1) the material properties of the silicone, 2) the kinetic energy of the silicone as it leaves the nozzle, 3) the resultant edge profile of the overlapped extrusion lines and 4) the area of the part where material deposition is occurring. After layer-by-layer extrusion from the nozzle and exposure to atmospheric moisture, the silicone is cured and harden at a rate which is dependent on the silicone material and exposure time/ humidity in the environment**.** Extruded silicone will have sufficient viscosity to self-support and not free flowing. Subsequently, a compressive force is required to deform the surrounding silicone to fill the interstitial space for void-less printouts.

**Proof of Concept for the moisture-cured extrusion-based silicone technology:** As a proof-of-concept, sphere-like balloons and finger pneumatic actuators were printed, as shown in (Figures 8,9), respectively. The sphere-like balloons exhibited diametric expansion between 152 and 207% with burst stress between 1.46 and 2.55 MPa (which is comparable to the base material properties) while the pneumatic finger actuators were able to fully articulate over 30,000 cycles before failure. These pneumatic actuators exhibited high elongation and fatigue life due to their near void-less construction.

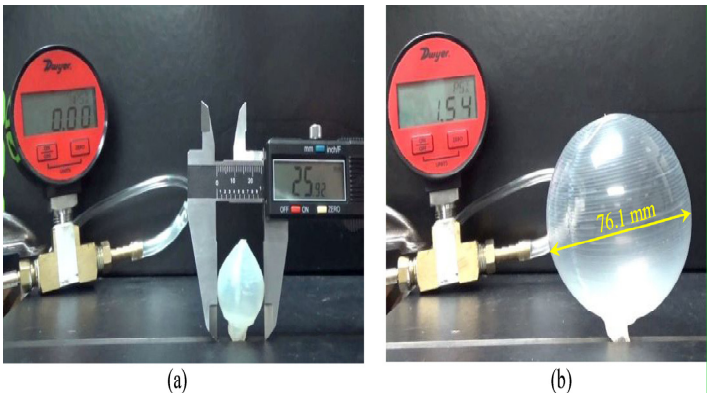
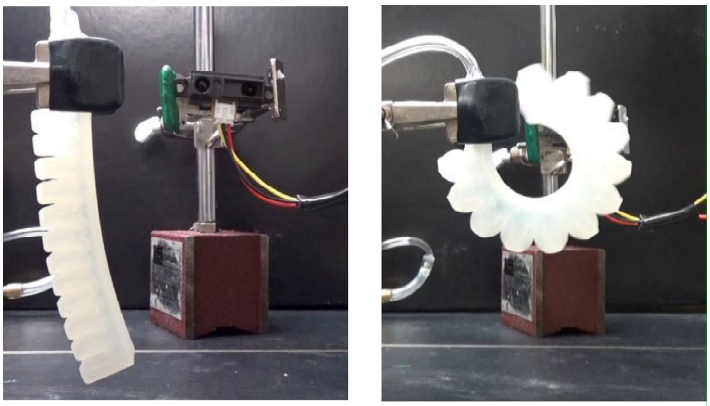



**Figure 8:** Burst pressure test of sphere-like balloon: **(a):** The 25.9 mm initial diameter measured with a caliper; and **(b):** The inflated close-to-rupture balloon with the diameter measured using the pixel-distance correlation of the image. (Adopted from [2])



(a) (b)

**Figure 9:** Finger pneumatic actuator in a **(a):** Non-articulated; and **(b):** Fully articulated configurations. (Adopted from [2]).

**Pros and Cons of the moisture-cured extrusion-based silicone technology:** The advantages of this moisture-cured system are that 1) the printouts are self-supporting, 2) the system has good fault tolerance and 3) it has unique part properties. The disadvantages are that 1) the system is unable to print heat-cured medical grade silicones, 2) long curing times with uneven degrees of curing since the curing commences from outermost layer to innermost layer, 3) Difficult to print parts with multi-material and 4) the system humidity sensitive

## Challenges in Medical Silicone 3D Printing

Unique challenges present in silicone 3d Printing are: 1) difficulty in the handling of silicone resins, 2) difficulty in printing multi-materials or different silicone resins, 3) finding suitable post-processing methods and 4) coming up with suitable standards in medical silicone 3d printing.

### Challenges in Silicone Resin Handling

Handling of silicone resins require meticulous even mixing to avoid trapping of air bubbles. Two-part resins are prone to disproportionate mixing and uneven curing. One-part resins are susceptible to moisture contamination and premature curing.

### Challenges in Printing Multi-grade Silicones and Multi-material Printing

Different grades of silicone resins or different materials require different printing parameters and printing processes for optimal output. Consequently, modifications and additions to the 3D printers are necessary to achieve multi-grade silicones or multi-material printing.

### Challenges in Post-Processing of 3D Printed Silicone Products

Unlike post-processing methods in the 3D printing of other solid, liquid or powder substrates, silicone rubber products are highly susceptible to cuts, fissures, abrasions and lacerations while undergoing post-processing. Conventional processing methods for the above substrates cannot be applied to silicone printing. Therefore, this is a unique case where post-processing should be avoided as much as possible.

### Challenges in prescribing ASTM / Similar Standards for Medical Silicone 3D Printing

Currently no ASTM or similar standards has been prescribed for medical silicone 3D printing. It is therefore imperative that one of the major areas of future works focus on the setting of standards in medical silicone 3D printing.

## Conclusion

A comprehensive discussion of the current state-of-the-art silicone 3D printing technologies, processes and challenges is presented in this paper.

## References

1. Kim DS, Tai BL (2016) Hydrostatic support-free fabrication of three-dimensional soft structures. Journal of Manufacturing Processes 24: 391-396.
2. Plott J, Shih A (2017) The extrusion-based additive manufacturing of moisture-cured silicone elastomer with minimal void for pneumatic actuators. Additive Manufacturing 17: 1-14.
3. Liravi F, Toyserkani E (2017) A hybrid Additive Manufacturing Method for the Fabrication of Silicone Bio-structures: 3D Printing Optimization and Surface Characterization. Materials and Design 2017.
4. Hinton TJ, Hudson A, Pusch K, Lee A, Feinberg AW (2016) 3D Printing PDMS Elastomer in a Hydrophilic Support Bath via Freeform Reversible Embedding. ACS Biomater Sci Eng 2: 1781-1786.
5. PICSIMA patent P751510GB-PCT/PF
6. Lahey FH (1946) Comments made following the speech "Results from using Vitallium tubes in biliary surgery," read by Pearse, HE before the American Surgical Association, Hot Springs, VA Ann Surg 124: 1027.
7. Clark G (2006) Cochlear implants: fundamentals and applications. Springer Science & Business Media 2016.
8. Dillehay SM (2007) Does the level of available oxygen impact comfort in contact lens wear?: A review of the literature. Eye & contact lens 33: 148-155.
9. Braga-Silva J (1999) The use of silicone tubing in the late repair of the median and ulnar nerves in the forearm. Journal of hand surgery 24: 703-706.
10. FDA update on the safety of silicone gel-filled breast implants. U.S. Food and Drug Administration 2018.
11. Cronin TD, Gerow FJ (1963) Augmentation mamma- plasty: A new "natural feel" prosthesis. Transactions of the Third International Congress of Plastic Surgery. Excerpta Medica. Int Congr Ser 41.
12. Swanson AB (1968) "Silicone rubber implants for replacement of arthritic or destroyed joints in the hand." Surgical Clinics of North America 48: 1113-1127.

13. Harmand MF, Briquet F (1999) *In vitro* comparative evaluation under static conditions of the hemocompatibility of four types of tubing for cardiopulmonary bypass. Biomaterials 20: 1561-1571.

14. Robb WL (1968) Thin silicone membranes-their permeation properties and some applications. Annals of the New York Academy of Sciences 146: 119-137.

15. Chugay NV, Chugay PN, Shiffman MA (2014) Body Sculpting with Silicone Implants. Springer Science & Business Media 2014.

16. Rohrich RJ, Wan D (2016) Working Toward a Solution: The Unanswered Questions About Silicone Gel Breast Implants. Annals of internal medicine 164: 201-202.

17. Jewell ML (2012) Silicone gel breast implants at 50: the state of the science 2012.

18. Balk EM, Earley A, Avendano EA, Gowri Raman G (2016) Long-Term Health Outcomes in Women with Silicone Gel Breast Implants: A Systematic Review. Annals of internal medicine 164: 164-175.

19. Singh N, Picha GJ, Hardas B, Andrew S, Diane KM (2017) Five-Year Safety Data for More than 55,000 Subjects following Breast Implantation: Comparison of Rare Adverse Event Rates with Silicone Implants versus National Norms and Saline Implants. Plastic and reconstructive surgery 140: 666-679.

20. Foliart DE (1995) Swanson silicone finger joint implants: a review of the literature regarding long-term complications. The Journal of hand surgery 20: 445-449.

21. Mazas FB (1973) Guepar total knee prosthesis. Clin Orthop Rel Res 94: 211-221.