3D Micro-Printing: A new Era for Med-Tech Applications

How three-dimensional thinking is turning a piece of material into smart medical devices

Alexander Steimle

Meet us at
Photonics West
North Hall
Booth 4320

In recent years, 3D printing has attracted increasing attention in many industries. From bioprinting of living organs to engine and airplane components, a variety of 3D printing techniques are already in use today, mainly differentiated by the additive or subtractive manufacturing approach. But what's the application potentiality in the med-tech industry with regards to 3D printing at micro-scale? And how innovative three-dimensional thinking can tackle human diseases such as the retinal vein occlusion (RVO) and create transformative products?

The prospect of machines that can print objects the same way an inkjet printer creates images on paper, or like ancient Greek sculptors used a chisel to create statues of mythological figures, has inspired enthusiasts to declare 3D printing a significant contributor of the 4th industrial revolution, also called the Digitization Era. Direct manufacturing out of 3D printing is considered a promising source of potential economic impact in industry for the upcoming years. According to a McKinsey report [1], 100 to 200 billion US dollars per year could be generated from direct manufacturing by 2025, especially in markets with complex, low-volume and highly customizable parts such as medical implants, with elimination of tooling costs, reduction in wasted material and handling costs.

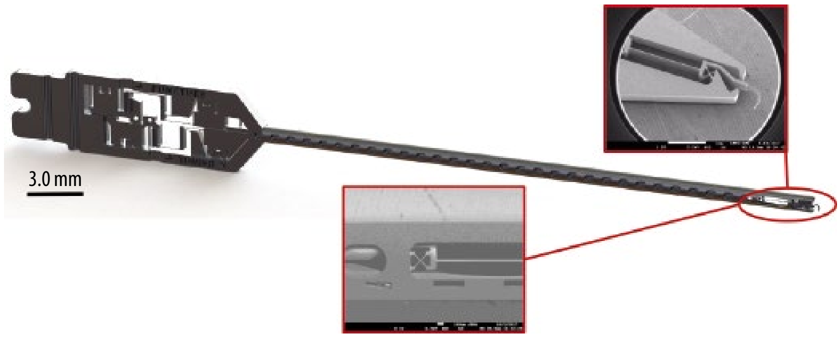

Fig. 1 Safe puncture tool made of a single glass substrate (Source: Instant Lab & Galatea Lab)

In the majority of the cases, additive manufacturing techniques such as selective laser sintering (SLS), stereolithography (SLA) or fused deposition modeling (FDM) are used, where one layer at a time is created, each layer on top of the previous until the final object is complete. The processes vary between material melting and subsequent deposition, or through solidifying material using lasers. Although the technologies are evolving rapidly, there are still limitations in building speed, limited object size, precision and resolution, limited material strength and homogeneity, incompatibility to high temperatures or living tissues such as the human body, and in some cases the need for mechanical support structures and a post-processing step for residual removing and smoothen surface.

At the micro scale, a more precise technique, namely the subtractive manufacturing, has gained significant success where high precision, complexity and resolution are critical factors for device functionalization. The FEMTOPRINT technology is a pioneering subtractive manufacturing technique, Prism Award finalist in 2015 among others. It is based on a two-step process of ultrashort-pulsed laser radiation in transparent materials, followed by chemical wet etching, to selectively remove the exposed material and form three-dimensional shapes (Fig. 2). The laser beam, focused inside glass, locally modifies the refractive index of the material and creates patterns that can be used to realize integrated optical components or to develop, by chemical etching, even three-dimensional structures, with high precision, aspect ratio and complexity. Today, this technology platform is a standardized process compliant to the ISO 13485:2016, and a micromachining reference in the industrial manufacturing of micro-devices. Further to optical patterns and 3D components, new complementary capabilities include glass-to-glass encapsulation at low temperature, hole drilling, glass cutting, and a self-developed thermal polishing process to reduce the surface roughness below 10 nm R_a.

The advantages of the technique consent the reduction of manufacturing steps, tools and costs. The direct writing process works in an out-of-cleanroom environment. It does not need masks, post-processing to remove residuals and

Company

FEMTOprint
Muzzano, Switzerland

FEMTOprint SA is a Swiss high-tech company manufacturing 3D printed microdevices out of glass and other transparent materials (e.g. fused silica and borosilicate) with sub-micron resolution, enabling the integration of fluidic, optical and mechanical functionalities in single monoliths at nano- and micro-scale. Through the innovative FEMTOPRINT tech-platform, Prism Award Finalist (2015) and ISO 13485:2016 certified, the company is transforming the way industrial, highly complex microsystems are conceived.

www.femtoprint.ch

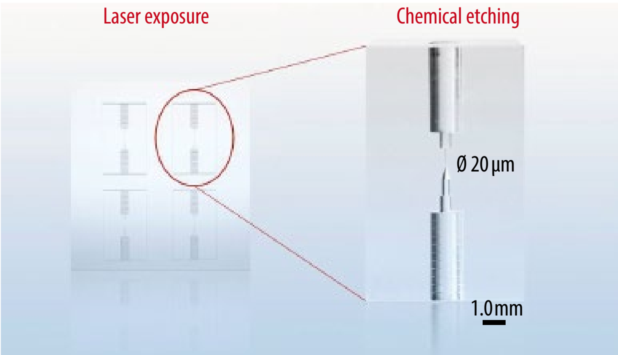

Fig. 2 Schematic view of the FEMTOPRINT process

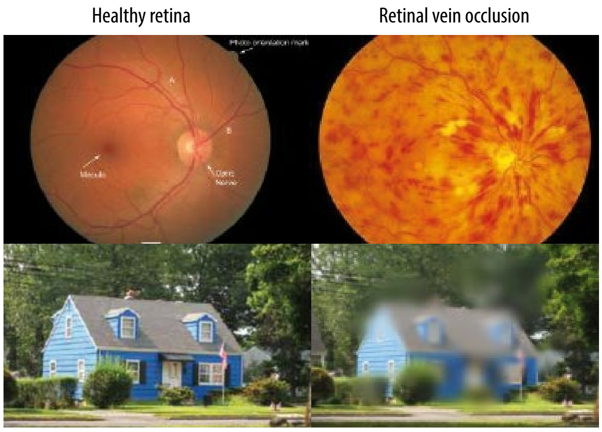

Fig. 3 Comparison of retinal veins and vision effect of healthy retina and RVO (Source: Instant Lab, Galatea Lab / Web)

is a versatile solution for rapid prototyping and serial productions, reducing new product development cycles. The novel technology is giving the opportunity to engineers to explore the third dimension at microscale with sub-micron resolution, adding feature-sized complexity and integrate optical, mechanical, fluidic and even electrical functionalities to the device, resulting in increased performances and reliability in a miniaturized space. The critical alignment of 2D microcomponents and the time-consuming assembly steps are now overtaken issues. Adding even more creativity and complexity, devices made with this technology can be coupled with complementary fabrications like metal evaporation to create embedded electrodes, several functionalization to form hydrophobic or hydrophilic surfaces, or coupling waveguides to structure opto-fluidic devices.

Glass has a widespread technological usage and is the main starting material of the process. At microscale, from an ordinary, amorphous material, it takes on surprising properties – including, but not limited to, optical transparency, thermal and chemical stability, low thermal expansion, high elasticity (as it is known from optical fibers), biocompatibility, homogeneity and unusual dielectric properties – that offers a powerful combination for new types of med-tech tools, biomedical chips with antibacterial surface treatments, micro-nozzles for nebulizers, integrated optical devices and interconnects, to end up in micromechanical watch components with embedded microfluidic channels and shock absorber.

In the med-tech industry, the capabilities of the technology significantly contribute to the improvement of medical engineering and, therefore, of life quality. Thanks to the unique 3D capabilities, innovative and cost-effective medical tools, implants and diagnostic chips can be easily fabricated.

FEMTOprint, in collaboration with Galatea Lab, Instant Lab (EPFL, Switzerland), and the Jules-Gonin ophthalmic hospital (Lausanne, Switzerland), recently joined their forces into a consortium to realize a challenging, glass-based compliant puncture tool for retinal vein occlusion (RVO), a common retinal vascular disorder causing severe loss of vision and affecting around 16 million patients worldwide over fifty years old (Fig. 3).

RVO can be treated by cannulation and injection of therapeutic agents in the affected vein to remove clots, which are limiting the oxygen transportation into the retina (Fig. 4). However, cannulation of small retinal veins is considered very risky and challenging, due to multiple reasons. The fragility of the puncturing tissues, the required puncture force (~20 mN) that is well below human sensing capability, surgeon hand tremor, eye motion during surgery and the dimensions of the tool that need to be compatible with the vein [2]. Current medical treatments do not address the underlying cause of vein occlusion

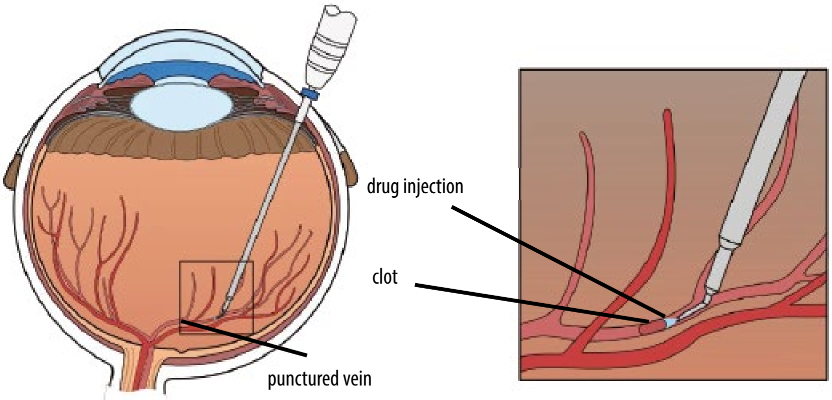

Fig. 4 Schematic view of a retinal vein cannulation (Source: A. Gijbels, KU Leuven)

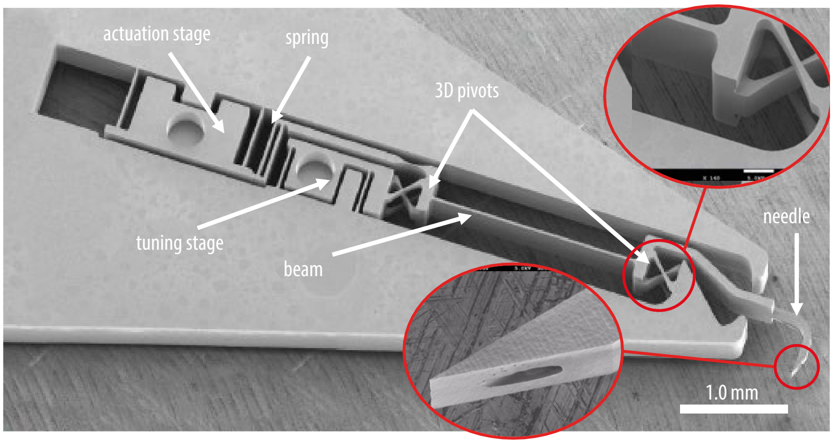

Fig. 5 SEM image of the puncture tool (Source: Instant Lab and Galatea Lab)

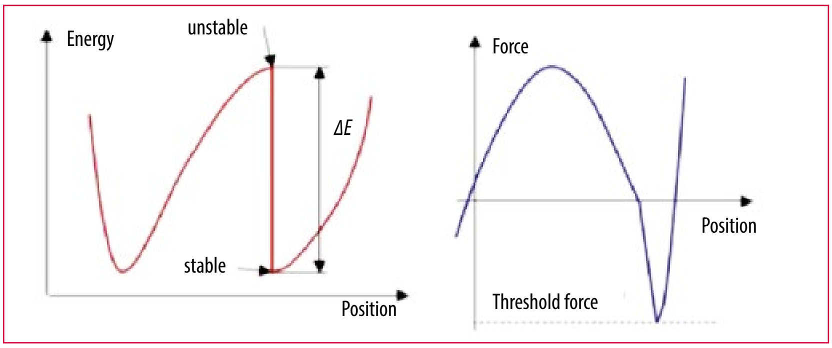

Fig. 6 Strain energy reaction force of a bistable mechanism (Source: Instant Lab and Galatea Lab)

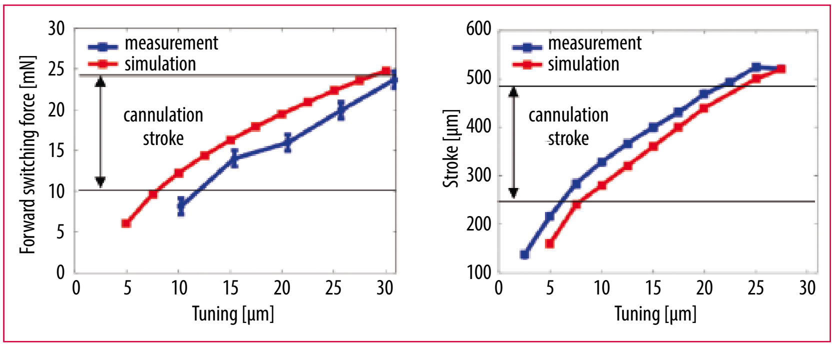

Fig. 7 Experimental and numerical values of puncturing force and stroke for different tuning displacements (Source: Instant Lab)

but only treat the complications such as macular edema.

The developing group conceived, manufactured and tested a passive compliant tool for retinal vein cannulation (RVC) that relies on a buckling mechanical principle to safely and precisely cannulate veins in eye surgery, independent of the actuation input. This has been possible by combining the advanced manufacturing capabilities of the FEMTOPRINT technology with the glass properties, like robustness and favorable elasticity, transparency and biocompatibility. The element was entirely fabricated out of a fused silica monolith that integrates three major features: mechanical 3D cross pivots acting as a bistable mechanisms (i.e., having two stable states and one unstable state), fluidic channels in the needle tip to vehiculate drugs and finally, optical elements to measure applied forces (Fig. 5).

The bistable mechanism releases a constant amount of energy when it passes from its unstable state to a stable state [3]. It follows that a threshold force can be obtained by limiting the stroke of the mechanism (Fig. 6). This ensures safe and precise cannulation of the retinal vein, assuming a very thin wall, with puncturing force lower than the threshold force, cannulation is guaranteed. The surgeon simply displaces the mechanism across its unstable state.

Experiments conducted to-date have been very promising. The stability programming of the double pinned bistable beam gives control over puncture force and stroke. The puncturing method has then been validated by FEM simulations and experimental measurements (Fig. 7), demonstrating several advantages for both the patient and the surgeon: Puncturing the force is independent of the surgeon force, actuation displacement is decoupled from puncturing position, it's insensitive to hand tremor and the tool is suitable also for long injection time. In an experimental trial, the tool successfully cannulated pig eye retinal veins (Fig. 8). In its final configuration, the surgical tool can be used in either stand-alone mode or mounted onto a robotic system.

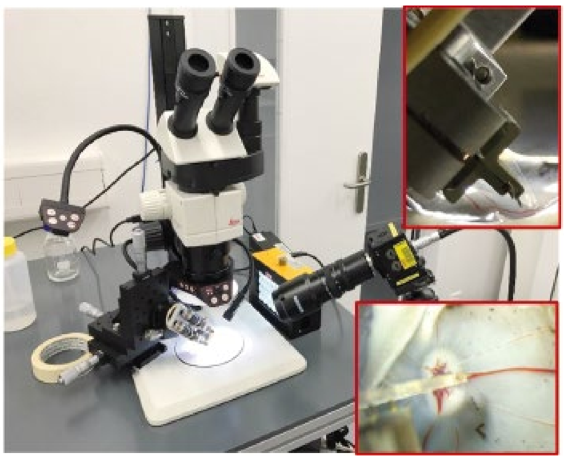

Fig. 8 Measurement setup of the experiment on a pig eye (Source: Instant Lab and Galatea Lab)

The results of this challenging project demonstrated once more the capability to boost engineering creativity and design real three dimensional free forms, taking advantage of material properties to obtain medical applications at sub-micron resolution, with high accuracy and complexity, according to the ISO 13485:2016 medical device certification and industrial standards for large volumes throughput.

Acknowledgements

This work is funded by the Swiss commission for technology and innovation, CTI. We thank all parties involved from the Jules-Gonin hospital, Galatea Lab and Instant Lab for the support, as well as Mr. Mohamed Zanaty and Mr. Thomas Fussinger for their contributions to this work.

DOI: 10.1002/latj.201800003

[1] *J. Manyika* et al.: Disruptive technologies: Advances that will transform life, business, and the global economy (2013) p. 111

[2] *M. Zanaty* et al.: Safe Puncture Tool for Retinal Vein Cannulation (2017)

[3] *S. Henein:* PhD thesis no 2194, EPFL (2000).

Author

Alexander Steimle holds a degree in business administration with a major in business development of the Haute École de Gestion in Lausanne, Switzerland. He has been working in technology and med-tech start-ups in Europe and Brazil, as an entrepreneur and from the VC perspective, where he led the advisory business (Criatec Fund and Venerdì Investments). Back in Switzerland in January 2016, he joined FEMTOprint as a Business Developer and is currently Head of Sales and responsible for Med-tech application developments.

Alexander Steimle, FEMTOprint SA, Via Industria 3, CH-6933 Muzzano, Switzerland, Email: alexander.steimle@femtoprint.ch