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Bistable Puncturing Tool for Retinal Vein Cannulation

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Abstract
An innovative surgical tool prototype dedicated to safe puncturing has been developed for the treatment of retinal vein occlusions (RVOs). The tool is manufactured monolithically by femtolaser printing in fused silica. It consists of a programmable bistable mechanism equipped with a puncturing needle and a fluidic channel to transport and inject drugs into retinal veins. The outer diameter of the segment of the tool entering the eye is below 1mm. The innovative approach used for the manufacturing of the long flexible fluidic channel is based on a series of chimneys reducing the etching time, which are then sealed by CO2 laser melting. First tests made by a medical surgeon with tool prototypes show that the puncturing function is successful: the rapid and repeatable puncturing motion of the tool tip provided by the bistable mechanism allows safe vein puncturing, while the programming allows the tuning of the puncturing stroke.

Bistable Mechanism, Compliant Mechanism, Needles, Surgery, Femtolaser printing, Glass, Retina

1. Introduction

Retinal Vein Occlusion (RVO) occurs when the retina blood flow is slowed down or blocked by a clot. The pressure increase can then lead to bleeding and oedema, resulting in a sudden decrease in visual acuity. In 2010, a study showed an age- and sex-standardised prevalence for the pathology of 3.77 per 1000, which corresponds to about 16 million people affected worldwide [1].

Common treatments for the disease, like intravitreal injections, focus on the consequences without trying to eliminate the causes. This is due to the difficulty of intervention on the retinal veins (vein diameter of about 100µm, vein mobility, risk of over-puncture, etc.). Tremor and excessive stroke at the tool tip could be responsible for surgery failure on the retinal veins and should be eliminated. For this reason, current research for RVO treatment techniques [2]-[4] generally aims to develop robotically assisted methods. A tool producing physical stimuli near the vein [5] has also been recently developed. The energy released by the collision of electrically-induced bubbles at the occlusion area allows the clot to be expelled.

The tool presented in this article aims to provide a purely mechanical single-solution that simplifies the process while suppressing the risks involved in this approach. The device, originally called SPOT (Safe Puncture Optimised Tool), allows a vein to be cannulated using a mechanism whose stroke and force are independent of those exerted by the surgeon. An integrated long fluidic channel connected to the puncturing hook allows to safely inject therapeutic substances in order to remove the clot.

The designed fused silica glass monolithic mechanism exploits the capabilities of multistable systems [6]. This makes it possible to offer a solution with rapid puncturing motion and controlled stroke and force.

In the following sections, we will discuss the mechanism working principle, its dimensionning and the main design choices that allowed us to obtain the current working solution.

2. Programmable multistable mechanism

Multistable mechanisms can be defined as systems with several stable states in their operating range [6]. The deformation of a flexible element allows storing and releasing strain energy. Controlling the input displacement determine the number and position(s) of stable state(s). For a system with N stable equilibrium states $s_1,...,s_n$, the energy curve will have N-1 unstable equilibrium state $u_1,...,u_n$. Figure **1** illustrates the energy curve of a bistable system.

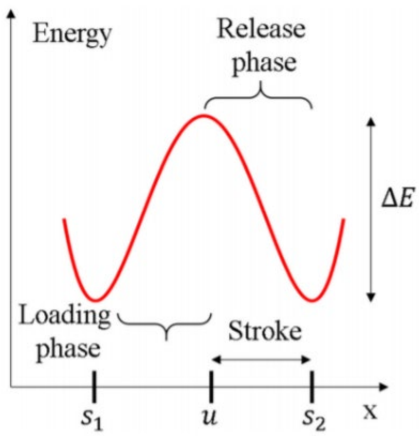

Figure 1. Strain energy of a bistable mechanism as a function of its position x [6]

Programmable multistable mechanisms are based on controlling the displacement of parts of the mechanism serving as programming inputs, in order to modifying the energy profile.

Their properties in terms of stability (position and number of stable equilibrium states) are then impacted. This solution is used in our tool to minimise the impact of the triggering action made by the surgeon on the mechanism output, while making a fast puncturing motion to enter the vein without displacing it.

3. Multistable Snaping Puncturiung Tool

The tool implements a programmable multistable mechanism based on a pinned-pinned buckled blade mounted on two cross-spring pivots. The mechanism is made either monostable or bistable by displacing the mechanism inputs. It makes it possible to decouple the displacement imposed by the surgeon from the hook dynamic motion, while offering a high puncturing speed [7]. The two inputs, for tuning and actuation, are located at the tool base. The motion is then transmitted throughout the tip to allow the multistable mechanism to be actuated at the tool end.

Figure **2** illustrates the considered steps in case of treatment on retinal veins: the system in its initial state (**2**a) is loaded by the surgeon using the tuning input (**2**b). Once located close enough to the retinal vein to be treated, the second actuation input is activated. The hook state remains unchanged during the actuation (**2**c) until it reaches a critical value that allows it to snap at high speed into an other stable state (**2**d). Fluid can then be sent to the punctured vein through a channel connected to the puncturing hook. The tool tip can be withdrawn from the vein by operating the actuation trigger in the opposite direction: the first stable state is then reached again.

The tool is designed as a single piece. All the transmission elements, the channel for fluid supply and the multistable mechanism are implemented with flexure joints, making this tool a high-precision system that is free of friction and assembly steps.

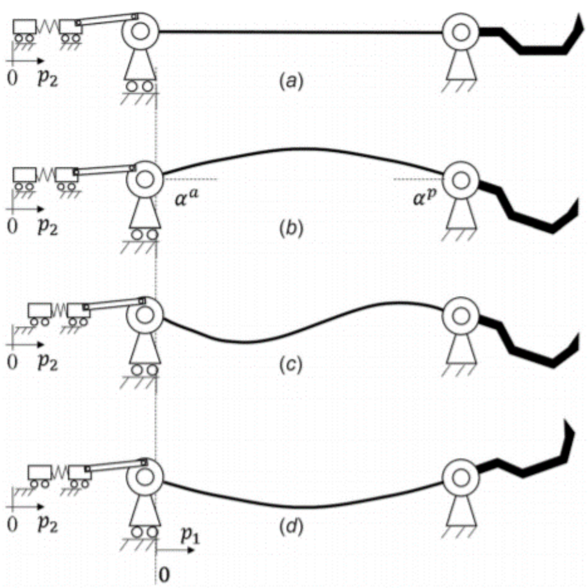

Figure 2. Main mechanism states [6]

3.1. Motion transmission

As mentioned above, the system is equipped with two inputs p_1 and p_2, respectively to ajust hook stroke and to trigger the tool tip once the mechanism is loaded.

A first mechanism located at the tool base, shown in figure **3**a, makes it possible to convert the input motion imposed by the operator into smaller micrometric displacements, p_{1o} and p_{2o}, required to operate the multistable system. The flexure implementation used in our tool is presented in figure **3**b. As part of the programmable multistable system, the spring added after p_{2o} is used to decouple the manual actuation from the output state.

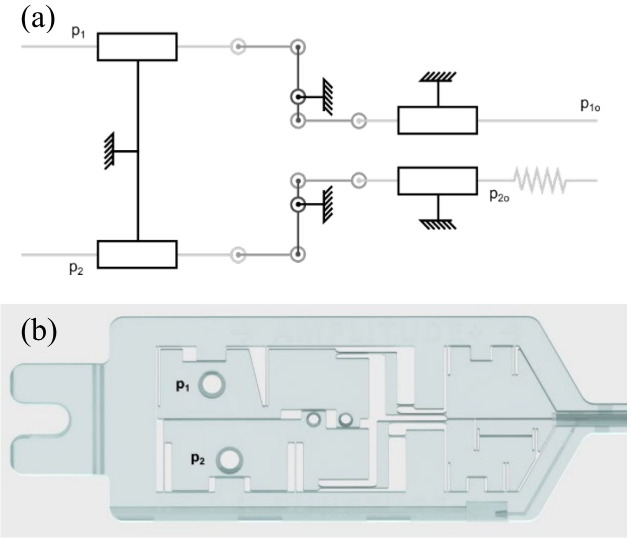

Figure 3. Kinematic chain of tool base transmission (a), flexible implementation (b)

The constraints imposed by retinal surgery require a reduced volume for the tool to be introduced into ther eye trough a cannula. For the same reasons, the tool tip must be long enough to reach the veins lining the back of the eye. The converted p_{1o} and p_{2o} motions must be transmitted along a thin and long section. It is then necessary to optimise compactness and high stiffness.

In response to those limitations, the converted motion obtained after the tool base mechanism is directly transmitted to the tip using mechanical tendons whose interlocking T- and U-shaped profiles prevent bending. Figure **4** shows a 3D-drawing cross-section of the tool tip.

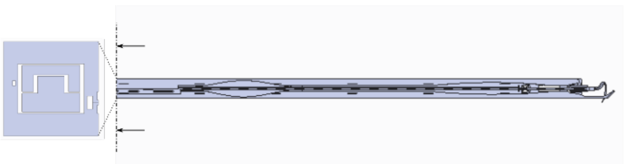

Figure 4. U- and T-shaped mechanical tendons for motion transmission

3.2. Suspended fluidic channel

Unlike conventional treatments that rely on the dispensing of a drug in the vicinity the retinal veins, this tool was designed to bring a fluid into the defective vein itself. The monolithic system is equipped with a long channel to transport the substance from the outer actuating handle to the tool tip.

The integration of the fluidic channel into the tool had to meet all of the following requirements:

- Fluid transport from the tool base to its tip.
- Monolithic integration into the tool.
- Compatibility with femtoprinting manufacturing.
- No mechanical interference with the multistable mechanism.

The fused silica glass buckled blade integrated in the tool has a thickness of 35µm. Today's femtoprinting manufacturing technology does not allow for manufacturing a fluidic channel into this flexible element.

The chosen solution was to integrate a separate flexible suspended channel running parallel to buckled blade. As shown in figure **5**, the motion imposed by input p_1 buckles one part of the channel. The remaining bended part follows the hook motion.

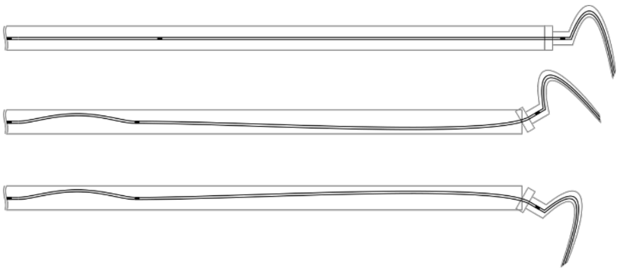

Figure 5. Suspended channel behaviour: initial state; pre-puncture state; postpuncture state.

The channel has been dimensioned by finite element modelling (COMSOL solid mechanics). It is 21mm long and has an inner cross-section of 30x40µm and an outside cross-section of 80x90µm. Figure **6** shows two microscope views (pre- and post-puncture states) of the tool where the buckled suspended channel is visible.

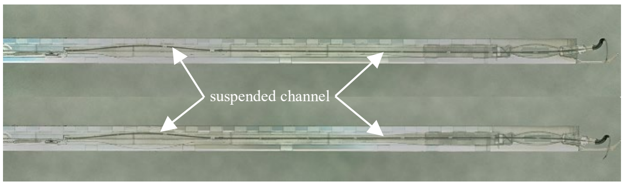

Figure 6. Buckled suspended channel under microscope in pre-puncture state and post-puncture states.

4. Manufacturing

Manufacturing by femtolaser printing is carried out in several stages. Starting from a fused silica glass blank, the laser beam is focused at the points where the material is to be removed. This results in a local change of the glass properties depending the etching time. The workpiece can then be immersed in an acid bath in order to eliminate the material that has been exposed to the laser.

Femtolaser printing constraints must be considered at the design stage for long channels. As shown in figure **7**, the manufacturing process requires a homogeneous etching time in order to avoid the risk of degredation of functional surfaces. The length of a channel made by femtoprinting is also limited by the depletion of acid, which loses its concentration while etching the material. For this purpose, temporary openings along the entire length of the channel are provided at regular intervals to allow better penetration of the etchant and to reduce etching time [8]. Theses chimneys are then closed in a second step in order to seal the channel.

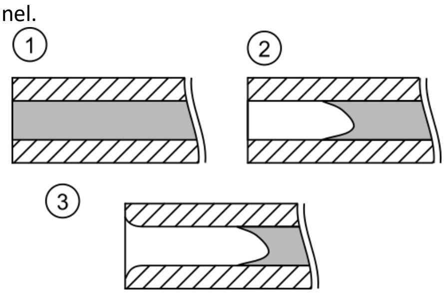

Figure 7. Steps showing the problem of long channel etching: ① initial state; ② after short etching time only undesired material is attacked; ③ after long etching time functional surfaces are degraded.

A surplus of material at each opening is provided for this purpose. Illustrated in figure **8**, the channel notches are designed in the form of chimneys. After the manufacturing process by femtolaser is completed, the chimneys are closed using a CO2-laser. The beam is focused on the upper edge of the chimneys. By adjusting the power, the material can locally be melted, controlling the collapse of the material resulting in sealing. The excess material melted by the heating allows the channel openings to be plugged.

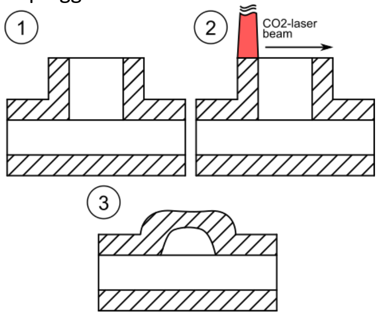

Figure 8. Closing of the suspended channel chimneys in three steps :① initial state; ② CO2-laser beam is focused on the chimney edge; ③ sealed chimney.

Figure **9** shows two microscope views of the suspended channel of our tool before and after CO2-laser closing operations.

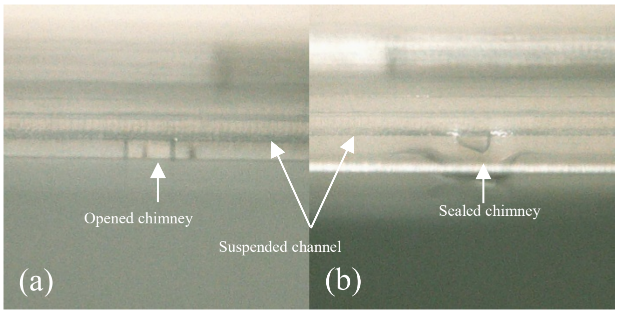

Figure 9. Suspended channel chimneys: (a) Opened Chimney: (b) Sealed chimney after CO2-laser closing operation.

5. Results

In vivo tests were performed at the Jules Gonin Hospital by a medical surgeon on 12-day-old chicken embryos. Veins were selected to match the size of the veins lining the retina of the human eye. A handle was designed to allow manual actuation of the SPOT. Mechanical puncturing tests were successfully performed.

6. Conclusion

This tool demonstrates the advanced design possibilities of high-precision monolithic programmable multistable flexible mechanisms manufactured by femtolaser printing. This approach allows to achieve sub-millimetric dimensions with tight tolerances, which is essential for the proper functioning of flexures exploiting buckling. The realised tool is a kinematically complex mechanism integrated in a submillimeter shaft diameter.

The monolithic structure of the tool eliminates assembly steps and guarantees high precision. The tool is suited for sterilisation in medical environment since it is purely mechanical and made of fused silica glass.

The implementation of a programmable multistable mechanism coupled with a motion conversion system has demonstrated the feasibility of high-speed perforation of retinal veins in a safe and repeatable manner without robotic assistance.

We were able to demonstrate the possibility of integrating a long channel in fused silica glass into the tool without assembly. The chosen flexible design makes it possible to follow the motion of the hook and maintain the desired dynamics.

Further development of this prototype is required in order to validate its fluidic delivery function on the human eye. The promising results obtained so far indicate that this novel bistable micro-mechanism could potentially lead to the treatment of retinal vein occlusion by delivering treating substances directly into the occluded vein retinal vein of patients.

7. Acknowledgments

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References

[1] Rogers, S. et al. The Prevalence of Retinal Vein Occlusion: Pooled Data from Population Studies from the United States, Europe, Asia, and Australia. Ophthalmology 117, 313-319.e1 (2010).

[2] Gijbels, A., Vander Poorten, E. B., Stalmans, P. & Reynaerts, D. Development and experimental validation of a force sensing needle for robotically assisted retinal vein cannulations. in 2015 IEEE International Conference on Robotics and Automation (ICRA) 2270–2276 (IEEE, 2015). doi:10.1109/ICRA.2015.7139500.

[3] Gonenc, B., Tran, N., Gehlbach, P., Taylor, R. H. & Iordachita, I. Robot-assisted retinal vein cannulation with force-based puncture detection: Micron vs. the steady-hand eye robot. in 2016 38th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC) 5107–5111 (IEEE, 2016). doi:10.1109/EMBC.2016.7591876.

[4] Yu, H., Shen, J.-H., Joos, K. M. & Simaan, N. Design, calibration and preliminary testing of a robotic telemanipulator for OCT guided retinal surgery. in 2013 IEEE International Conference on Robotics and Automation 225–231 (IEEE, 2013). doi:10.1109/ICRA.2013.6630580.

[5] Sumimoto, M. et al. Establishment of Treatment of Retinal Vein Occlusion by Physical Stimuli of Electrically-Induced Bubbles. in 2019 20th International Conference on Solid-State Sensors, Actuators and Microsystems & Eurosensors XXXIII (TRANSDUCERS & EUROSENSORS XXXIII) 809–812 (IEEE, 2019). doi:10.1109/TRANSDUCERS.2019.8808464.

[6] Zanaty, M. et al. Programmable Multistable Mechanisms for Safe Surgical Puncturing. Journal of Medical Devices 13, 021002 (2019).

[7] M. Zanaty, C. Baur, S. Henein, “Device for controlled puncturing of an object”, EP3487460A1, Assignee: EPFL, 2017

[8] C. Baur, Y. Bellouard, D. Braga, T. Fussinger, D. Lambelet, A. Lovera, S. Pollonghini, R. Arno “Machining process for microfluidic and micromechanical devices”, WO2019106407A1, Assignee: Femtoprint SA, 2017