euspen's 25th International Conference & Exhibition, Zaragoza, ES, June 2025
www.euspen.eu

Design of a precision advancing needle for injection into the suprachoroidal space of the eye for the treatment of retinal detachment

Emma Rutherford[1], Rajeev Muni[2], Alexander Slocum[1]

[1]*Massachusetts Institute of Technology*
[2]*University of Toronto*

emmakr@mit.edu

Abstract

Rhegmatogenous retinal detachment (RRD) is a vision-threatening condition that affects ~ 1 in 10,000 people annually [1]. The most popular treatment is pars plana vitrectomy (PPV), an invasive and expensive surgical procedure that leaves patients unable to see well for four to six weeks. In addition, current methods tend to produce distorted vision upon recovery.

In-office Suprachoroidal Viscopexy™ (SCVEXY™) is a minimally invasive technique recently developed by Dr. Rajeev Muni for treating RRD which has been performed on a handful of people. SCVEXY works by using a small needle to inject viscous fluid into the suprachoroidal space (SCS), a "potential space" between the sclera and choroid, creating a "bleb" of viscoelastic underneath the tear that pushes the choroid towards the retina and allows it to reattach. This procedure has the potential to greatly reduce the cost and recovery time of RRD while also improving the quality of the repair.

However, difficulty with safely injecting into the SCS at the location of the tear currently limits widespread utilization of this technique. The needle tip must be precisely positioned in the SCS in order to inject the viscous fluid, but the thickness of the sclera varies from patient to patient and between locations on the eye. Additionally, the scleral and choroidal tissues are very thin, leaving little room for positional error. Bad outcomes may occur if the needle punctures through the choroid and into the subretinal space. It is also challenging to access posterior locations of the eye with current instruments.

This work presents a device developed to minimally invasively deploy an injection needle at posterior eye locations in-situ with high resolution in an ergonomic mechanical device.

Keywords: injection, retinal detachment treatment, needle, biomedical, precision, mechanism, accuracy, product, design

1. Background

The retina is the part of the eye that receives light and converts it to electric signals which can be interpreted by the brain. Rhegmatogenous retinal detachment (RRD) occurs when vitreous fluid in the eye enters a hole in the retina and separates it from the choroid, similar to water behind wallpaper. A hole in the retina is usually caused by liquification of the vitreous associated with aging, leading to increased tractional forces on the retina during movement. The lifetime risk of retinal detachment is about 0.1%, with higher risks for patients who are older or have high myopia [1].

While modern methods allow for successful final reattachment of the retina in over 90% of cases, there are still difficulties. Recovery time ranges from two to six weeks, and in this time, patients must minimize activity and hold their heads in a specific position to help the retina reattach. Visual acuity may not substantially improve until up to several months after the surgery, and often, quality of vision is significantly worse than prior to the detachment. About 40% of patients may not regain reading ability, 10% to 40% may need more than one procedure, and abut 5% of eyes will have permanent functional failure [2].

Evidence showing that current methods of retinal reattachement may be harmful in some cases has pushed surgeons to explore new techniques which not only can achieve high single-operation reattachment rates but also maximize the quality of the reattachment [3], [4], [5]. Suprachoroidal viscopexy™ (SCVEXY™) is a new minimally invasive procedure developed by Muni et al. which has the potential to improve outcomes, cost, and recovery time associated with retinal detachment repair. SCVEXY involves the injection of viscous fluid in the usually collapsed space between the sclera and choroid, known as the suprachoroidal space (SCS), to create a suprachoroidal buckle, as shown in Figure 1. The procedure can be performed in an office rather than operating room, significantly reducing costs. Additionally, due to the stability of the viscoelastic in the SCS, positioning is not required, and patients can resume normal activities immediately afterwards. Since the retina is allowed to naturally reattach to the retinal pigment epithelium, without the use of large gas tamponades and forced rapid reattachment, the quality of vision post recovery is expected to be higher.

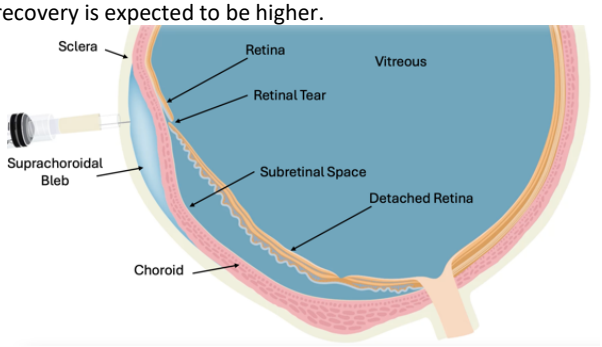


Figure 1. Suprachoroidal viscopexy (SCVEXY) procedure.

SCVEXY has currently been performed only on a handful of patients because a device does not yet exist which

can safely and reliably locate the suprachoroidal space and reach all necessary regions of the eye in a minimally invasive manner. However, in procedures performed with a makeshift guard placed over a standard hypodermic needle to only expose ~ 1 mm of the needle, pateints have had short recovery times and secure reattachments of the retina [6], [7].

A device must minimize multiple risks in order for it to be widely adopted. The suprachoroidal space is normally closed (~0.05-0.09 mm thick), with the sclera and choroid pressed together [8]. Both layers are very thin, approximately 0.5-1.3 mm and 0.15-0.3 mm respectively [9], [10]. Scleral thickness varies greatly from patient to patient and between locations on the eye. This narrow margin for error makes it difficult to position the needle in the potential suprachoroidal space without puncturing through the choroid. In the posterior regions of the eye, the choroid is highly vascular. If the needle only partially punctures, this likely won't cause problems since blood will remain in the suprachoroidal space. However, if the needle punctures all the way through the RPE and into the subretinal space, a subretinal hemorrhage may occur, increasing risk of recurrent detachment and poor outcomes. Therefore, a microneedle device for SCVEXY must be able to adjust the length of needle and reliably find the suprachoroidal space without overshooting.

An additional problem exists in accessing posterior regions of the eye where many retinal tears are located. The orbital bones make it difficult to perform this procedure with a straight microneedle in many cases. Suprachoroidal catheters and cannulas have been used to access the posterior SCS, however, these tools require an operating room and are far more invasive and risky. In order for SCVEXY to be adopted, the device that administers the viscous fluid must be able to reach necessary regions of posterior segment of the eye in a minimally invasive manner.

This paper explores the design of a precision advancing microneedle device which can reach posterior segments of the eye and deploy a microneedle in-situ with high resolution. The device aims to remove the challenges and risks that currently exist with SCVEXY in order to make it an accessible and widely used procedure across the world. Additionally, the device may also be used to improve suprachoroidal drug delivery for the treatment of many conditions.

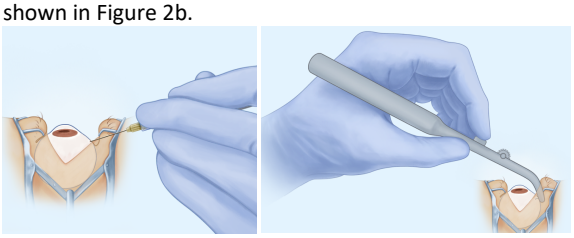
2. Device Design

2.1. Procedural Requirements of the Device

To reliably perform SCVEXY, the surgeon must be able to see from within the eye where the needle will come out relative to the retinal tear so that the bleb is placed directly beneath the tear. To do this, it is convenient for the surgeon to be able to probe the eye with the device tip while looking through an indirect opthalmoscope at the retina, meaning no needle should be exposed at this stage. Once the correct location is found, a 27 to 30-gauge microneedle should be advanced with fine resolution from 0 to ~1.5 mm to accommodate patients with varying scleral thicknesses. Additionally, risk of the needle advancing too far and damaging the choroid should be minimized. When complete, the needle should fully retract. A single physician should be able to comfortably actuate all of these operations with one hand. All necessary regions of the eye for treating RRD should be accessible, while keeping the device minimally invasive and able to be used in a non-sterile, office setting or operating room. The authors worked closely with Dr. Rajeev Muni to specify these requirements.

2.2. Device Body

The shape of the device must be intuitive for the physician to hold and control as well as conducive to reaching necessary regions of the eye and performing the procedure while minimizing potential complications. Most retinal tears occur in the region of the vitreous base or even further at the back of the eye. This makes them difficult to access with conventional microneedles where the needle bore is axially in line with the device due to the anatomy of the nose, eyelids, and ocular bones, as shown in Figure 2a. To reach the back of the eye without an invasive catheterization procedure, the form of this device took inspiration from the scleral depressor, which is a common tool in ophthalmology to indent the walls of the eye during retinal examinations. The tip safely can reach underneath patients' eyelids with ease. But rather than a simple metal depressor, in this SCVEXY injector device the needle extends from the face of a spoon-like tip at a right angle. This allows the needle to reach areas of the eye where a straight needle cannot, as shown in Figure 2b.



(a) (b)

Figure 2. (a) Illustration of how straight needles cannot access the posterior regins of the eye due to the bones around the eye. (b) Ergonomic concept of our device which slides under the eyelid and curves around the back of the eye.

The device tip curves to match the radius of curvature of the human eye (~12 mm) in all directions, creating a surface which conforms and promotes stability of the tip. The arc angle of the tip can also be adjusted to reach different areas of the eye comfortably, as shown in Figure 3. Ergonomic testing was performed to determine that the maximum thickness of the device tip to comfortably fit under a patient's eyelid is 4 mm and the ideal angle for doctors to reach areas where retinal detachment primarily occurs is ~20 degrees.

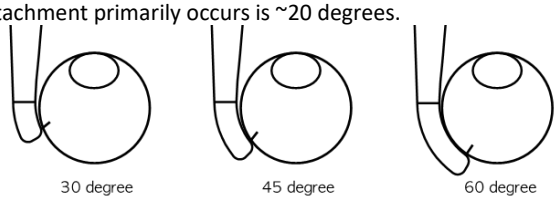


Figure 3. Illustration of how larger arc-angles of the device tip can reach further back in the eye.

2.3. Needle Actuation

The design of a length changing needle that actuates with fine resolution at a right angle within a very small space posed an interesting precison engineering challenge.

In all prior art, the injection needle is axially in line with the handle or proximal part of the device. If the needle is extendable, it is actuated by pushing the needle through concentric bodies. In some devices, a slight angle is achieved by having the concentric tubes curve. However, the radius of curvature must be large to accommodate the sliding of the needle. An approximately 90-degree turn of concentric, sliding metals tubes to allow perpendicular insertion into the eye cannot be made in a space small enough to fit under the eyelid comfortably.

Rather than concentric sliding, our strategy for needle actuation centered around the use of a beam which holds the needle perpendicularly at the tip. An actuation far from the tip of the device can cause bending or pivoting of the beam which leads to displacement at the end of the beam. By making the

length of the beam large compared to the needle displacement length, the angle of the needle caused by beam bending or pivoting is very small, as shown in Figure 4.

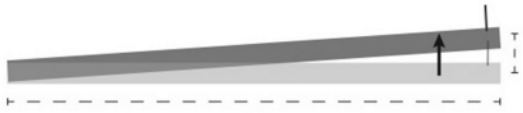


Figure 4. Strategy for actuating the needle at a right angle in a small space.

Stiffness of the needle holding structure was of high importance because the forces on the needle change throughout an injection process, which leads to small unintended changes in the position of the needle. According to literature, forces on a 27-30 gauge needle during insertion into the human sclera ranged from ~0.2-0.6 N but could be up to 1 N [11], [12], [13]. If the force drops suddenly when the needle enters the SCS, the needle may spring forward. Because a resolution of 0.1 mm was desired for the device, the maximum allowable deflection of the needle actuation system was defined as 0.05 mm. The stiffness of the needle actuating system must then be 1N / 0.05 mm which equals 20 N/mm.

Resolution is also an important ergonomic consideration to ensure the human user has fine enough control over the needle position. Motor-based needle actuation systems were considered to give surgeons finer control, but ruled out in order to keep the device inexpensive and disposable, as well as reduce the burden of regulatory clearance. Thus, a large mechanical transmission ratio of input to output motion is desired, where relatively large motions by the surgeon should result in small amounts of needle movement.

Multiple concepts included beams supported and actuated in a wide variety of ways to induce tip displacement. The one which we moved forward with was a beam with a pivot near the device tip and a pin at the the proximal end controlled by a spiral cam slot in a control wheel, shown in Figure 5. As the knob rotates, the proximal end of the pivoting beam is moved approximately horizontally to induce deflection of the needle at the tip, like a lever. The control wheel is split with the beam along its centerline to maintain symmetry. The two halves are connected by material in the middle which is shaped in a way to not interfere with the spiral slot or movement of the beam.

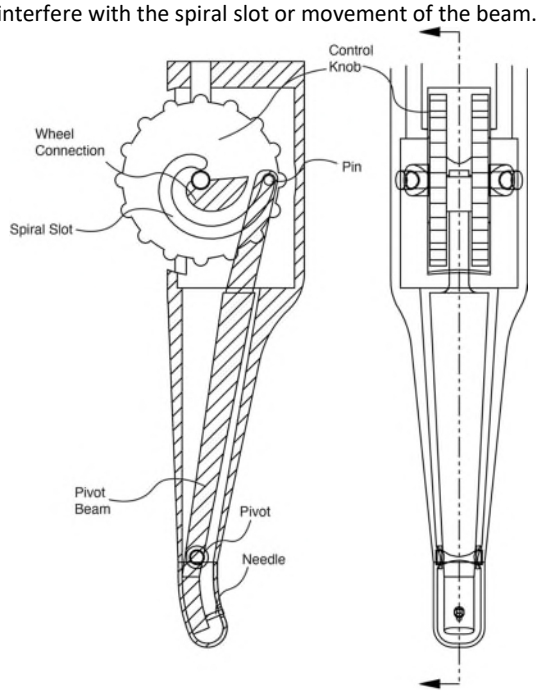


Figure 5. Pivoting needle holding beam and spiral cam slot wheel drawing.

Since this concept does not require bending of the beam, it can be made stiff without concurrently demanding high forces to actuate. The stiffness can be closely estimated by treating the pivoting beam as simply supported with overhang since the upper needle positioning pin is constrained from moving perpendicular to the spiral curvature but can move tangentially by small amounts. The gain and stiffness of the system can be adjusted by moving the pivot point and length of the lever arm. A diagram showing how this beam was modeled for first order calculations is shown in Figure 6. Deflection of the beam tip under needle insertion forces are estimated from this model in Equation 1.

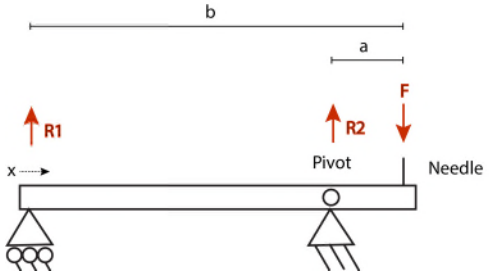


Figure 6. Stationary simply supported beam with overhang bending model.

$$y(b) = = -\frac{\boldsymbol{Fa^2b}}{\boldsymbol{3EI}} \rightarrow \frac{\boldsymbol{F}}{\boldsymbol{y}} = -\frac{\boldsymbol{3EI}}{\boldsymbol{a^2b}}$$

Equation 1. Singularity functions to calculate expression for stiffness of the pivoting needle holding beam concept.

Considering that the stiffness is inversely proportional to the square of the overhang distance, it is advantageous to maximize stiffness for the beam to have a short overhang. However, a shorter overhang in turn requires a larger angle of rotation of the pivot in order to meet the required fully actuated needle length. Given the ergonomic constraints of the device and maximum allowable angle the needle rotates through, the minimum stiffness requirement was able to be met.

The transmission ratio of the system, defined as the amount the needle extends per mm of circumferential rotation of the control wheel, is shown in Equation 2, given that the spiral cam slot has a contant pitch. This design was determined to have sufficient needle advancement resolution, as a person turning the control wheel can move it with their finger about 1 mm at a time and have a corresponding <0.05 mm of needle advancement.

$$P = spiral\ slot\ pitch$$
$$x_n = needle\ exposed\ length\ (in\ x-direction)$$
$$x_p = x\ position\ of\ proximal\ pin\ in\ spiral\ slot$$
$$\theta_{wheel} = angle\ of\ control\ knob$$
$$dl = Linear\ Distance\ Finger\ Moves\ on\ Wheel$$

$$dx_p = P\frac{d\theta_{wheel}}{2\pi}$$
$$dx_n = \frac{a}{b}dx_p = \frac{a}{b}\frac{Pd\theta_{wheel}}{2\pi}$$
$$dl = \frac{\pi D_{wheel} d\theta_{wheel}}{2\pi} \rightarrow d\theta_{wheel} = \frac{2\ dl}{D_{wheel}}$$
$$dx_n = \frac{a}{b}\frac{Pdl}{\pi D_{wheel}}$$
$$\frac{dx_n}{dl} = \frac{a}{b}\frac{P}{\pi D_{wheel}}$$

Equation 2. Calculation of transmission ratio between user input to control wheel and needle length increase.

Following the structural loop, notice that insertion forces applied to the needle will be felt at the control wheel. The design keeps these forces in line with the axis of rotation. This ensures that forces applied to the needle are not translated into torques on the wheel which would back-drive the system.

3. Testing

Prototypes were built using 3D printed parts, and video tracking using allowed analysis of needle length as the control wheel rotates. Dots along the edge of the control wheel were marked so that it was possible to correlate their position to angular position of the wheel. A still photo taken from the video is displayed in Figure 7.

The trajectories of three dots on the diameter of the wheel were plotted with a best fit circle based on the known diameter of the wheel. Once the center coordinates of the wheel were known, each point's position was translated to an angle. When one dot went into the device and was no longer visible, angular displacement was picked up by the next dot. The plot of x and y position of each dot are shown in Figure 8a. The maximum angle of the wheel of 5.34 radians corresponded to 85% of full rotation, which is exactly what this prototype was designed to rotate through at maximum needle extension.

The positions of the needle tip and needle base were also tracked with the software, and needle length was defined as the distance between the two. This allowed for vibrations of the entire device to be excluded from the needle length measurement. In this prototype, the needle started partially protruding from the device so that the needle was always visible.

Theoretical needle length versus wheel angle was plotted over the measured scatter plot. While the exact theoretical length is nonlinear, at small angular displacements it looks linear. This is confirmed by experimental data, shown in Figure 8b. It appears from the graph that there is slight backlash in the system, since for the first ~0.3 radians the needle length does not change. This makes sense due to a tolerance gap in the cam slot to fit the pin. This can be reduced by decreasing the gap. However, there will always be a small amount to allow for smooth motion, unless there is preload on the system biasing the pin to always stay against one edge of the cam.

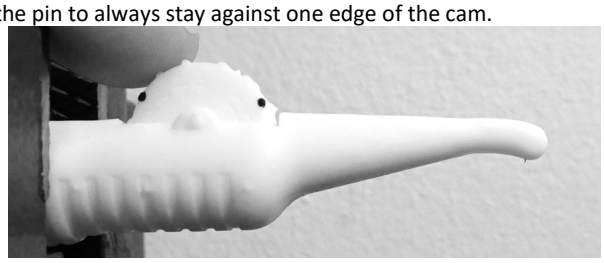
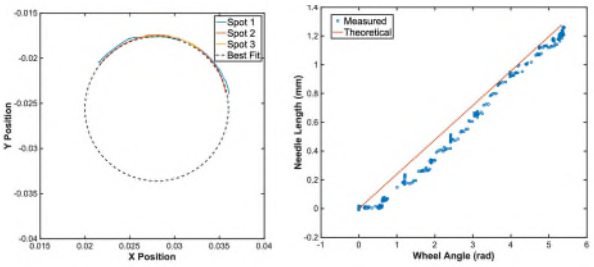


Figure 7. Still shot from video used to track needle vs wheel position.



(a) (b)

Figure 8. (a) Trajectories of dots on wheel (x positon and y position in meters). (b) Wheel angle versus time. (c) Needle length versus wheel angle.

5. Conclusion

In summary, this paper shows a possible design of a device for suprachoroidal drug and viscoelastic delivery, with the primary motivation of developing a precise and reliable way to perform a new surgical procedure for the treatment of retinal detachment. SCVEXY has the potential to fulfil an unmet need for minimally invasive and high-quality retinal detachment repair but requires a precise machine for administration of a highly viscous fluid into the suprachoroidal space. The prototypes shown indicate that this device could be highly effective at fulfilling this niche. In addition, small modifications to the device can be made to allow for suprachoroidal drug delivery targeted at the back of the eye, minimally invasive subretinal drug delivery, and subretinal drainage.

6. Acknowledgements

The authors thank Dr. Rajeev Muni who has pioneered suprachoroidal viscopexy in order to improve the lives of patients and was essential in defining the requirements of the device. I also want to acknowledge Radha Kohly and Aaron Weinroth who contributed greatly to design reviews of the device.

This work has been supported by DragonflEYE Therapeutics. A patent is pending on this device.

References

[1] J. M. Kwok, C. W. Yu, and P. G. Christakis, "Retinal detachment," *CMAJ Can. Med. Assoc. J.*, vol. **192**, no. 12, p. E312, Mar. 2020, doi: 10.1503/cmaj.191337.

[2] M. Haugstad, S. Moosmayer, and R. Bragadóttir, "Primary rhegmatogenous retinal detachment – surgical methods and anatomical outcome," *Acta Ophthalmol. (Copenh.)*, vol. **95**, no. 3, pp. 247–251, 2017, doi: 10.1111/aos.13295.

[3] K. Brosh *et al.*, "Retinal Displacement Following Pneumatic Retinopexy vs Pars Plana Vitrectomy for Rhegmatogenous Retinal Detachment," *JAMA Ophthalmol.*, vol. **138**, no. 6, p. 652, Jun. 2020, doi: 10.1001/jamaophthalmol.2020.1046.

[4] A. Bansal *et al.*, "Retinal Displacement after Scleral Buckle versus Combined Buckle and Vitrectomy for Rhegmatogenous Retinal Detachment," *Ophthalmol. Retina*, vol. **7**, no. 9, pp. 788–793, Sep. 2023, doi: 10.1016/j.oret.2023.05.012.

[5] C. L. M. Francisconi *et al.*, "Retinal Displacement after Pneumatic Retinopexy versus Vitrectomy for Rhegmatogenous Retinal Detachment (ALIGN)," *Ophthalmology*, vol. **129**, no. 4, pp. 458–461, Apr. 2022, doi: 10.1016/j.ophtha.2021.12.007.

[6] R. H. Muni, I. M. Melo, A. Pecaku, A. Mannina, H. Batawi, and A. Bansal, "In-Office Suprachoroidal Viscopexy for Rhegmatogenous Retinal Detachment Repair," *JAMA Ophthalmol.*, Aug. 2023, doi: 10.1001/jamaophthalmol.2023.3785.

[7] R. H. Muni *et al.*, "In-Office Suprachoroidal Viscopexy for Acute Rhegmatogenous Retinal Detachment," *JAMA Ophthalmol.*, Dec. 2024, doi: 10.1001/jamaophthalmol.2024.5202.

[8] K. Jung, A. Pecaku, I. Melo, S. Demian, M. Pimentel, and R. H. Muni, "The suprachoroidal space in rhegmatogenous retinal detachment assessed with swept-source optical coherence tomography," presented at the Vit-Buckle Society Annual Meeting, Miami, FL, United States.

[9] C. Boote, I. A. Sigal, R. Grytz, Y. Hua, T. D. Nguyen, and M. J. A. Girard, "Scleral structure and biomechanics," *Prog. Retin. Eye Res.*, vol. **74**, p. 100773, Jan. 2020, doi: 10.1016/j.preteyeres.2019.100773.

[10] V. Manjunath, M. Taha, J. G. Fujimoto, and J. S. Duker, "Choroidal Thickness in Normal Eyes Measured Using Cirrus-HD Optical Coherence Tomography," *Am. J. Ophthalmol.*, vol. **150**, no. 3, pp. 325-329.e1, Sep. 2010, doi: 10.1016/j.ajo.2010.04.018.

[11] J. S. Pulido, M. E. Zobitz, and K.-N. An, "Scleral penetration force requirements for commonly used intravitreal needles," *Eye*, vol. **21**, no. 9, Art. no. 9, Sep. 2007, doi: 10.1038/sj.eye.6702577.

[12] A. Matthews, C. Hutnik, K. Hill, T. Newson, T. Chan, and G. Campbell, "Indentation and needle insertion properties of the human eye," *Eye*, vol. **28**, no. 7, Art. no. 7, Jul. 2014, doi: 10.1038/eye.2014.99.

[13] I. Park, M. J. Kim, and W. K. Chung, "The development of system for measurement of needle insertion force into eye," in *2016 13th International Conference on Ubiquitous Robots and Ambient Intelligence (URAI)*, Aug. 2016, pp. 899–900. doi: 10.1109/URAI.2016.7734004.