VORTEX SURGICAL WHITE PAPER

# Realization of a next generation forceps platform

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## Realization of a next generation forceps platform

The following explores a new generation of retinal forceps looking from several points of view: an engineer's and multiple surgeons' evaluation of tissue grip and visualization. We will see how a holistic approach to instrument design can achieve an instrument that is easier to use with greater control.

### The Engineer:

A good user interface is fundamental to the design of any instrument. In the case of retinal forceps, the user interface is the handle. Even an excellent forceps tip can be handicapped by a sub-optimal handle. Handle features that define the ACTU8 handle are:

#### Actuation style
Squeeze action through a set of eight actuation links giving the ability to rotate the handle 360 degrees while actuating. The links have been optimized to reduce gaps and give broad fingertip support.

#### Handle length
The length supports varied grip styles. The ability to remove the tail accounts for less common circumstances that could cause interference with the microscope, the patient's brow, or nose. The handle length doesn't change with actuation i.e., the nosecone doesn't move. This allows the surgeon to use the entire length of the tip in longer eyes. It eliminates any push of the nosecone into the cannula caused by actuation.

#### Weight
11.5g the mass is centered in the handle to reduce manipulation effort.

#### Balance
10 percent distal of the handle midpoint

#### Handle diameter
Changes in the handle diameter, along its length, are minimized. This allows for a more secure grip, especially when the handle is grasped in a vertical orientation. The need for extra manipulation to compensate for large diameter changes is eliminated.

#### Actuator diameter
The actuator is big enough to reduce finger crowding with larger hands without overwhelming smaller hands. The nearly flat actuation surface allows for finger placement where it is comfortable.

#### Nosecone diameter
A smaller diameter avoids crowding around the cannula.

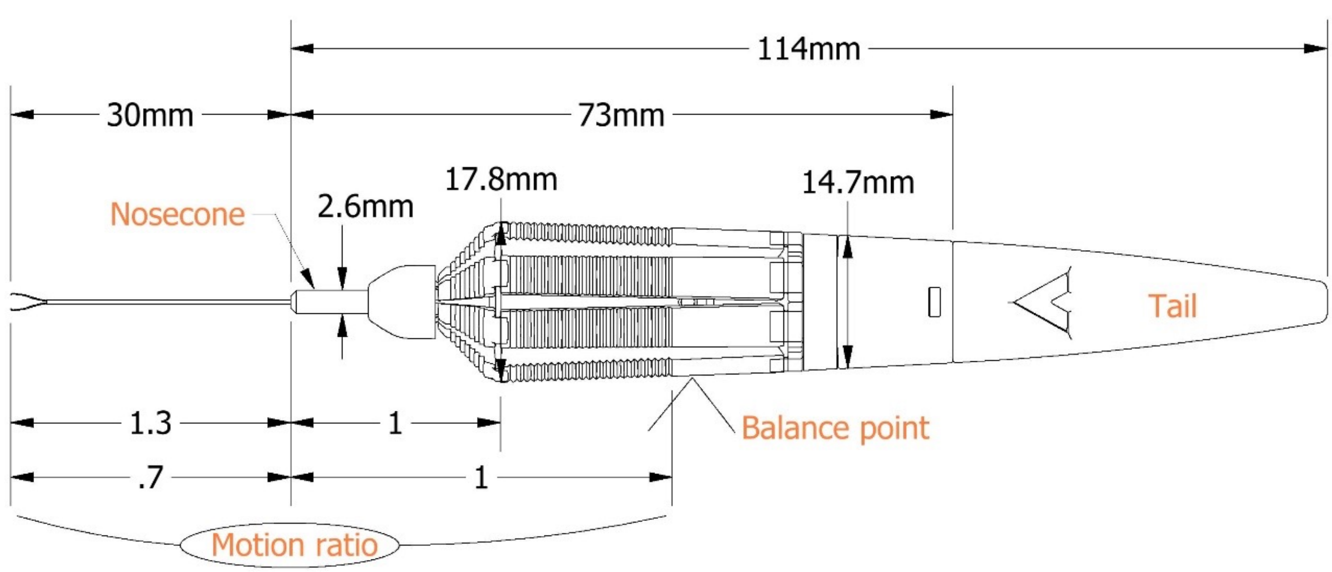
#### Motion ratio
The ratio of tip movement relative to control movement (see figure above). A ratio in the range of .7-1.4 gives good control over the position of the instrument tip. The long actuation surface allows the surgeon to adjust finger position for the desired ratio.

#### Actuation force
300g-260g linear force decline as the handle is actuated. Low predictable force aids in control and reduces the likelihood of fatigue and tremor.

#### Actuation stroke
2.5mm total (diameter change of actuator on full actuation) minimizes hand motion without compromising control of tip closure. Tip response to control inputs is immediate and predictable.

#### Tip retraction
8 microns nominal during the last half of handle closure. This avoids a requirement to adjust the tip's position during tip closure.

**Figure 1:** ACTU8 handle dimensions.



User preference has a big effect on the design of the forceps tip. Two criteria are common across users. First is an effective grip that doesn't cause membrane shredding. The second is maximized ability to see the site that the forceps will grab.

In the first round of consideration, grip (F) is determined by two factors. One is the amount of force applied normal to the gripping surface (N). Two is the coefficient of friction (μ) between the platforms and tissue. This is expressed $F=N\mu$. Note that the surface area of the contact between the two surfaces isn't a factor. A conclusion that can be reached is that to increase grip it's necessary to increase force (N) or coefficient of friction (μ) or both.

Changes to the coefficient of friction can be made through a material change of the forceps tip, a coating on the forceps tip, or a surface finish change on the forceps tip. These can be effective up to a point. The proprietary surface of the Vortex forceps increases the coefficient of friction for the tips.

An increase of the normal force (N) will also increase grip. However, the tissue will only tolerate so much force per square area (pressure) prior to failure. The failure manifests itself as shredding of the tissue. In the second round of consideration of grip, the amount of pressure applied must also be accounted for to avoid overloading the tissue. The entire process of applying pressure needs to be looked at because pressure distribution tends to change as the forceps close. A fair conclusion is that to maximize grip without increasing the risk of shredding, increased force should be spread over a bigger square area.

The figure below illustrates the relative position of the typical forceps platforms as they are closed. An evaluation of common forceps reveals that the platforms are stiff. At the forces they are normally exposed to, the platforms flex a negligible amount. Stiffness comes into play when evaluating pressure distribution as the forceps close. Note that the distal ends of the forceps' platforms come into contact first as the forceps close. This is required for the forceps to grasp all the way to the distal end. The platforms pivot around the contact point as the forceps continue to close until they reach full closure with the platforms approximated against each other. The force developed during the process of closing goes from zero prior to or just as the tips touch to the full force developed by the forceps at full closure.

**Figure 2:** Relative position of the typical forceps platforms as they are closed.

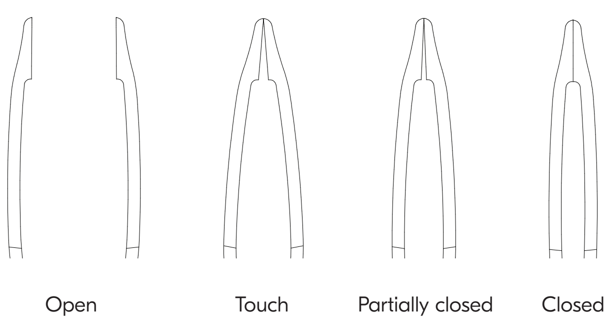
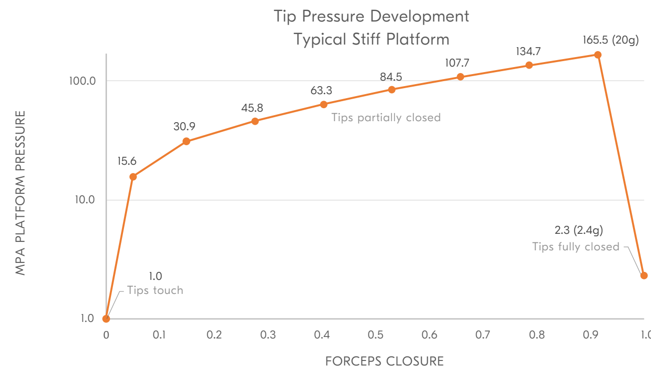



**Figure 3:** Pressure of typical forceps platforms as they are closed.

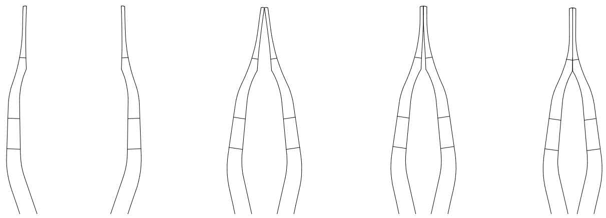



The chart above illustrates the pressure that is developed on the platform as the tip is closed. The pressure distribution is uneven prior to full approximation of the platforms. Because the distal ends of the platforms are all that are touching, the force generated is concentrated in a very small area. Just prior to full closure, the pressure is very high then falls drastically as the platforms come fully together and spread the force across the entire platform. If the pressure developed just prior to full closure is high enough, the tissue can fail which causes a site for shredding to occur from. This is a factor that limits the practical amount of force that the forceps can develop.

Rarely, is the entire platform engaged with tissue. In most instances only the distal portion of the platform is used. In the third round of consideration of grip, the effect of partial use of the platform is looked at. The tissue is often relatively thin and compliant. The pressure distribution across the forceps platforms tends to remain constant even with tissue engaged. This causes the tissue to only receive a portion of the available force. For example, using fully closed data from the chart above, if the tissue is engaged in one half of the platform, then the pressure across the whole platform would remain at 2.3MPa but the force on the tissue would only be 12g. The other 12g of available force will have been shielded by the unused portion of the platform. The amount of grip (F) proves to be much lower than expected based on the 24g of closing force available from the forceps. An evaluation of a forceps can be misleading if only the amount of force delivered is considered. The surface area of the platform and how much of the platform is engaged with tissue also needs to be considered. A large platform that delivers a large amount of force doesn't necessarily have more grip.

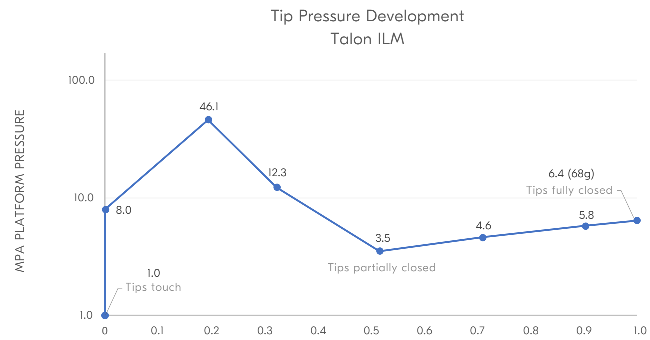
Many of the pressure distribution characteristics of the common forceps platform design are determined by how stiff it is. A flexible platform that is flat when relaxed helps relieve the high pressure buildup as it is closed because the platform flexes to increase the contact area earlier in the closing process. This allows for higher pressure delivery and ultimately, more grip. However, the force shielding experienced with the stiff and flat platform still occurs when only a portion of the platform is engaged with tissue. Adding a slight inward curve to the flexible platform is a further improvement. It helps reduce the high pressure buildup and force shielding effect because the curve tends to direct force towards the distal end.

**Figure 4:** Relative position of the ACTU8 Talon forceps platforms as they are closed.




The figure above illustrates the flexible curved platform used by the ACTU8 Talon forceps as the tip is closed. Note that the wedge shaped gap formed when the tips first touch is a feature that allows for better visualizing of tissue as it is engaged. This gap is noticeably larger than what is possible with stiff platforms. As the forceps is closed, the platforms flex giving **Dynamic Pressure Control (DPC)**™ to limit the high pressure buildup through an increase in surface area. When the forceps is fully closed, the platforms are approximated fully against each other. The pressure is spread across the surface area of the platform, but because of the curve in the platform, pressure is biased towards the distal end of the platform maintaining good grip at the distal end. See the chart top right.

**Figure 5:** Pressure of ACTU8 Talon forceps platforms as they are closed.




The maximum pressure buildup is 28% of what it was with the stiff platform (see Typical Stiff Platform chart). The pressure at full closure is 2.8 times what it was with the stiff platform. Because the surface is the same as other ACTU8 tips, the coefficient of friction is the same. With the added force delivered and the reduction in force shielding the amount of grip delivered relative to a stiff platform forceps is greatly increased.

Below is a table showing closed force and pressure of current Talon tips compared to the nearest ACTU8 tips. The Talon tips consistently deliver higher closed force and pressure with reduced maximum pressure.

**Table 1: Talon forceps versus ACTU8 standard forceps comparison of closing force and pressure.**

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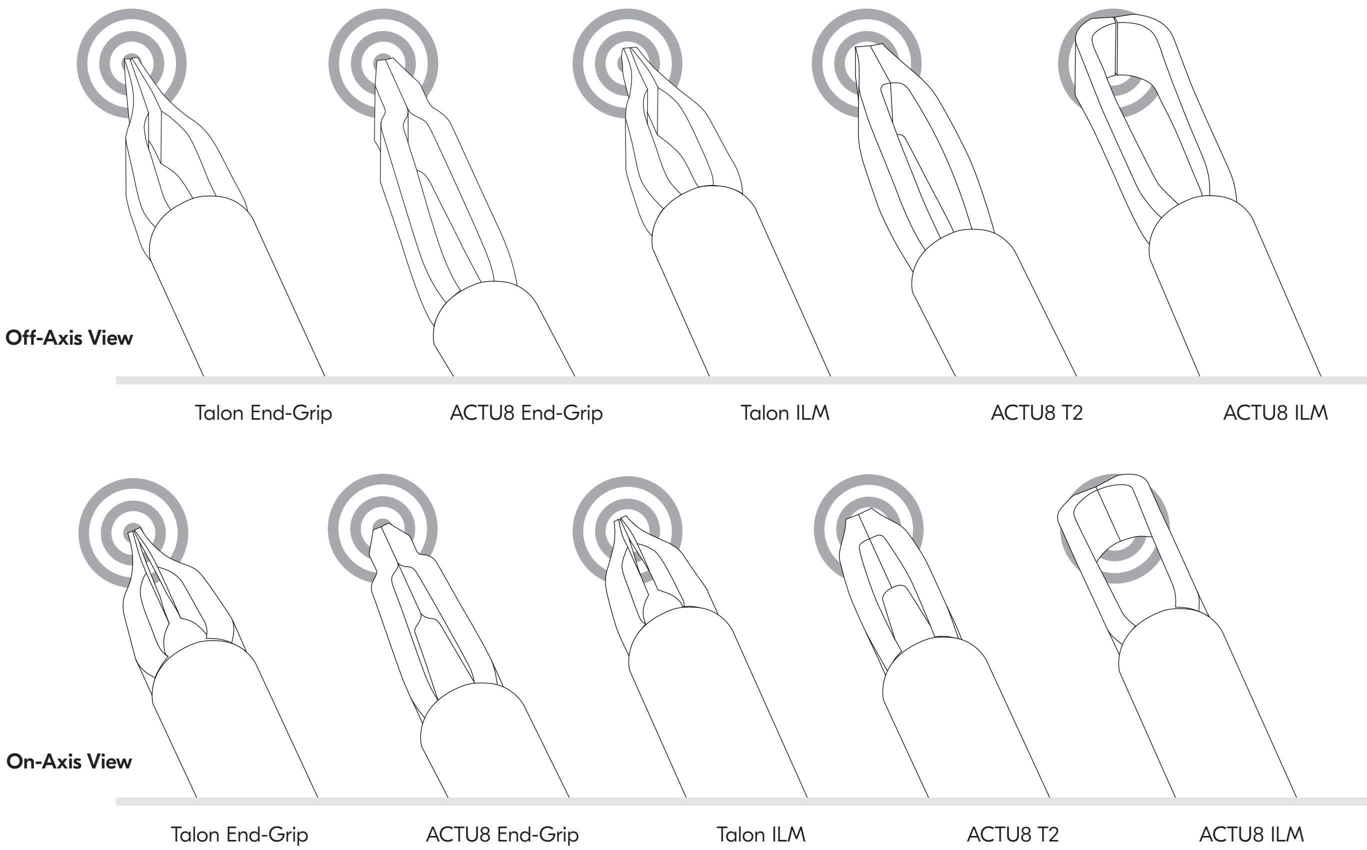
| Description | Closed force g | Platform area mm2 | Closed platform pressure MPa | Maximum pressure MPa |
|---|---|---|---|---|
| ACTU8 T2 23ga | 24 | 0.103 | 2.28 | 165.5 |
| ACTU8 T2 25ga | 24 | 0.103 | 2.28 | 165.5 |
| Talon ILM 23ga | 68 | 0.104 | 6.41 | 46.1 |
| Talon ILM 25ga | 68 | 0.104 | 6.41 | 46.1 |
| ACTU8 End-Grip 23ga | 20 | 0.145 | 1.38 | 89.2 |
| ACTU8 End-Grip 25ga | 19 | 0.109 | 1.71 | 83.0 |
| Talon End-Grip 23ga | 50 | 0.120 | 4.07 | 26.7 |
| Talon End-Grip 25ga | 50 | 0.120 | 4.07 | 26.7 |
| ACTU8 Pro-Grip 23ga | 40 | 0.256 | 1.52 | 160.4 |
| ACTU8 Pro-Grip 25ga | 40 | 0.256 | 1.52 | 160.4 |
| Talon Pro-Grip 23ga | 77 | 0.256 | 2.95 | 77.5 |
| Talon Pro-Grip 25ga | 77 | 0.256 | 2.95 | 77.5 |

Visualization of the point of interaction between the forceps tip and the tissue is challenging. The limited viewing angle generally causes the forceps to block the tissue that is being grasped.

**Figure 6:** Visualization of anatomy around the forceps tip.




The figures above Illustrate the ability to see anatomy around the tip of the instrument. The top figure shows the instruments off axis. The lower figure shows the instruments on axis. The targets have a 100 micron bullseye with a 500 micron outside diameter. The tips are adjusted to grasp the center of the target. Off axis viewing tends to reduce the effectiveness of large windows in between the forceps tips (see ACTU8 ILM). The sculpted platforms of the Talon forceps unshrouds the target to a large extent allowing for better visualization of the tissue in the center of the target. The improvement for visualization remains even when viewed off axis.

## The Surgeons:

### Eric Williams, M.D.

I have had the privilege of using the Talon forceps across a wide variety of cases requiring macular work, peeling of peripheral preretinal and subretinal proliferative vitreoretinopathy (PVR), and in handling lens haptics with scleral-sutured intraocular lenses (SSIOL). I have been very impressed with their adaptability.

The ACTU8 platform has always been an absolute dream to use. The eight broad actuation links provide a very sturdy base that allows easy rotation within your hand while never feeling like the forceps might slip or drop out of your grasp. The squeeze action is smooth with minimal closure force that allows you to focus on what's going on at the distal end of the forceps, as opposed to the platform in your hand.

I have been most impressed with the tip's ability to grip tissue. With very adherent epiretinal membranes (ERM), I typically expect to pick at the surface of the macula multiple times as the tissue shreds or slips out of my forceps. This has not been the case with the Talon forceps. The grip strength allows you to propagate the peel without worrying about losing the tissue from your forceps. The dynamic pressure control (DPC) allows you to do this all while avoiding the irritating shredding that we so often encounter. Their usefulness in dealing with PVR is very similar; a second-to-none grip strength that allows you to hang on to tissue while you delicately peel over detached retina in the periphery.

With great power comes great responsibility. There is some required care with this excellent grip strength and DPC. Whatever you grab, you will peel. However, with the platform design of the Talon forceps, the view is always clear, so you can be confident as you're working on the surface of the retina.

**Eric Williams, M.D.**
**The Retina Consultants of Carolina**

### Hong-Uyen Hua, M.D.

From the retina surgeon's perspective, the Talon retinal forceps provide superior visualization and tissue handling. Prior to the release of the Talon forceps, my retinal forceps of choice was the ACTU8 Adaptive Forceps. The large textured platforms provide excellent tissue grip and management for ILM and membrane peeling. However, when initially using these forceps, there is a steeper learning curve due to the broader platform and occluded view. With the Talon forceps, visualization is excellent, allowing for fine and precise manipulation of membranes that are friable, subtly elevated, or overlying boggy, edematous retina. This upgrade in visualization can obviate the need for re-staining of membranes with vital dyes and has made the Talon forceps my go-to forceps for peeling ILM, epiretinal membrane, tractional retinal detachments, and proliferative vitreoretinopathy.

In addition to the improved visualization, dynamic pressure control from the flexible platform tip allows for a greater grip at full closure with minimum shredding relative to traditional tip platforms. This translates to optimal performance in both visualization and tissue handling from the Talon Forceps, which have been excellently engineered for the retina surgeon.

**Hong-Uyen Hua, MD**
**Assistant Professor of Clinical Ophthalmology**
**Pediatric & Adult Retina**
**Bascom Palmer Eye Institute**
**University of Miami Miller School of Medicine**

### Brandon Busbee, M.D.

Over my 20 years in surgical retina, I have evaluated numerous forceps types and multiple gauges. I usually find a new forceps is a variation on an established theme with mild or modest improvement in functionality. I would submit the new Vortex Talon Forceps are the best forceps I have tried in 25 gauge for removing difficult membranes (PVR cases). The forceps appear to have some added length to the grasping portion that may improve its utility. The performance of the Talon forceps on mobile retina with membranes is best in class. The purchase is superior to any other forceps I have tried.

Once I moved exclusively to these forceps for my difficult cases, my natural progression was to use them for my ILM or pucker cases. It is an excellent forceps for a wide range of retina surgical cases. It is now my forceps for all my retina cases.

Congratulations to the engineering experts at Vortex for continuing to raise the bar to improve our surgical instrumentation. I would encourage any surgeon to try the Talon forceps, especially in difficult cases. Once you become facile with the extended tip and ergonomic handle, I suspect you will find yourself using this as your main forceps.

**Brandon Busbee, MD**
**Tennessee Retina**
**Retina Consultants of America**

**Leanne Clevenger, M.D.**

I have been using the Vortex ACTU8 Talon forceps for multiple applications and find the unique design useful for a variety of surgical cases. The forcep is designed to allow for a very precise touch at the distal end of the platform with initial gentle actuation, and with additional pressure on the handle, to engage a proportionately larger surface area of the forceps grasping platform. The fine, precise touch of initial actuation is appropriate for macular work such as initiating the "pinch-and-peel" technique for ILM peeling, while engagement of the larger surface area applies the strength needed to peel more dense tissues.

**Leanne Clevenger, M.D.**
**Cleveland Clinic**
**Cole Eye Institute**

**Sumit Sharma, M.D.**

I have had the opportunity to use the Talon forceps in a number of cases over the past few months including straightforward macular work, as well as in, complex PVR and TRD cases. I have found the forceps particularly helpful in the case of complex retinal detachments, where the Talon forceps is able to grip and peel PVR membranes yet is delicate enough to be useful for ILM peeling or more immature PVR in the same patient. The forceps are efficient in that they prevent the need to alternate between more heavy forceps, which lack the fine detail for ILM peels, and traditional ILM forceps. The fine early articulation with light pressure on the handle allows them to initiate ILM peels while more pressure on the handle allows them to grab larger membranes. The larger grasping platform allows for grabbing thicker, denser and more adherent membranes and peeling them without the membrane slipping out of the forceps or shearing as is often the case with ILM style forceps on PVR membranes. The same utility has been noted for tractional retinal detachments in patients with proliferative diabetic retinopathy, where both fine detail and intermittently increased grip strength are required.

The Talon forceps is also useful in traditional macular work with ERMs or macular holes with an ERM component, where a range of grip strength can be utilized in peeling the ILM or ERMs of varying tension. I have found the tip of the platform to be slightly smaller in width than other variations of ILM forceps, but this allows for improved visualization through the tips of the forcep. This is great when working with trainees as I have better visualization of what is happening at the tips of the forceps and can better guide them on pinch and peel technique. I have enjoyed working with the Talon forceps and find the learning curve towards its use to be a quick one and have quickly adapted it as my go to forceps for a variety of peeling needs. I particularly like that in complex cases I can open one forceps and do both fine ILM work and deal with the larger membranes without having to switch between two different style of forceps.

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