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Review Article

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Clearing Surgical Drains-There is Now a New Standard of Care

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Clearing surgical tubes is a common procedure in wound care, and it often comes as second-nature for clinicians. But it can still be time-consuming and complicated. So imagine how daunting and difficult it is for friends or family members who have never done such a thing, and are responsible for a loved one's after-surgery care. There is now a product available that makes the process of clearing tubes easier and faster. It's called TubeEvac.

A Big Idea

I was determined to make clearing drains easier and came up with an idea. It started with a pair of water pump pliers in the garage, some welded bolts, brass sleeves and a few pieces of aluminum. The final result was a crude invention that worked perfectly for draining tubes. And it was the beginning of what is now known as Tube-Evac, a device that makes it easier to care for patients.

The first TubeEvac device –– the Frankenstein Pliers very crude but they worked

How it Works

Since the initial prototype in January 2008, Tube-Evac has evolved into what it is today: a small device similar to a clam shell, with channels running lengthwise down the center. When shut, the two internal channels form a complete circle for the tubing to pass through. Two rollers are in place to squeeze or strip the drain, and the hinges on one side make it easy to open and close.

How does it work? The surgical tube is placed securely inside the clam shell, pulling the Tube-Evac device away from the body while the other hand holds the surgical tubing in place. As the tubing passes through the rollers in the clamshell, the fluid is forced in front of it. The fluid is then pushed into a collection bulb, to be measured and emptied on a regular basis.

We found clearing the drains to be one of the worst parts of the surgery - clearing those doggone drains constantly and stretching the tubing farther and farther. The more we stretched it the harder it became to clear the drain. Those 2 foot drains went to well over 3 ½ feet in length. This then made the process to clear harder and harder.

Tube-Evac device is invented and is now the new standard of care for surgical drains

In January 2008 my wife Linda had surgery to take out her breast implants. She had surgical drains and again we could not milk them. We had been told various ways to do it including using your fingers, running the drain across a pen or using alcohol swabs, using lotion on your fingers. We were very confused. However, out of her pain came a new device for clearing surgical drains.

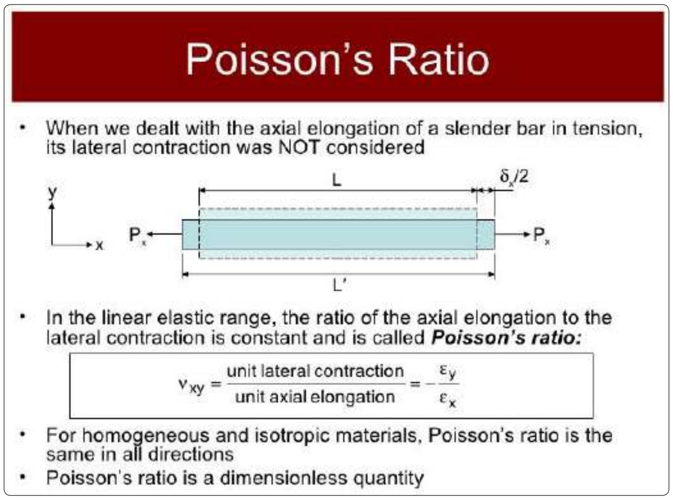
The real issue is constant pressure that is not too much to stretch the tube but enough to roll out the fibrinous tissue and clots. Mayo understood this right away and has been using the TubeEvac for 8 years.

Explanation: Milking surgical drains actually relates to Poisson's ratio. Poisson's ratio is the negative ratio of transverse to axial strain. This explains why the tubing was so difficult to clear as it got longer. When a material is compressed or stretched in one direction, it usually tends to expand or contract in the other two directions perpendicular to the direction of compression or stretching.

Conservation of volume

The volume in the drain must remain the same. So as the drain diameter gets even smaller, the drain gets longer and trying to get the blood clots and fibrinous tissue out is even more work because the drain is narrower. So the patient is trying harder and harder to clear the drain. What the patient is really doing is creating a scenario where it is more and more difficult to clear the drain as the drain gets thinner and thinner.

This is exactly what happened when Linda and I were trying to clear the drains. The harder we tried the more difficult it became because the drain was getting thinner and thus more difficult to push fluid and clots through.



Poisson's Ratio

- When we dealt with the axial elongation of a slender bar in tension, its lateral contraction was NOT considered

- In the linear elastic range, the ratio of the axial elongation to the lateral contraction is constant and is called ***Poisson's ratio:***

$$\nu_{xy} = \frac{\text{unit lateral contraction}}{\text{unit axial elongation}} = -\frac{\varepsilon_y}{\varepsilon_x}$$

- For homogeneous and isotropic materials, Poisson's ratio is the same in all directions
- Poisson's ratio is a dimensionless quantity

Poissons ratio is really important because this is the reason so many drains get clogged. As you try to clear the tube with your fingers or other mechanical friction device, the tube deforms more and more. Conservation of volume is always maintained in a container that has a non-compressible liquid. So as the patient or nurse pulls on the surgical tubing, the tubing gets longer and longer. Since the volume is maintained the diameter of the tubing must get less and less.

How it is done now vs how it will be done in the future

Since the initial invention of the TubeEvac device in January 2008 it has evolved to where it is about 1 1/2 inches long by 1 inch wide. The TubeEvac device is similar to a clam shell where you open the clam shell and it has a channel down the center of it in the center of the shell running lengthwise. One half of the channel is in one side of the clam shell while the other half of the channel is in the other side.

How it works

When the clamshell is shut the two ‘one half channels’ form a complete circle for the tubing to pass through the two rollers are used to squeeze, or strip, the drain.

The rollers are placed perpendicular to the channel and they have a predetermined distance between them. This distance between the rollers is changed depending on the diameter and wall thickness of the tubing being drained. This is accomplished by actually changing the diameter of the roller. This is what makes the TubeEvac device so efficient.

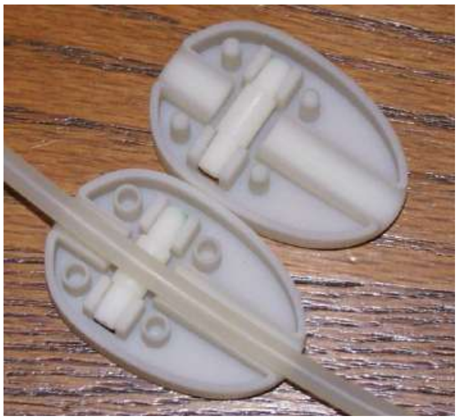
The current maximum size tubing that will fit in the TubeEvac channel is 19F.

The evolution and making of the TubeEvac device

The Tube-Evac device has hinges on the side so the clamshell can open and close easily. It also has 4 knobs that fit into a cavity on the opposite side of the clamshell to make sure the clamshell closes properly and does not twist or distort. Back pressure is built into the hinge so the TubeEvac device will open by itself when finger pressure is taken off of it.

There are imprints on the device where your thumb and finger should go so you are pressing directly on the rollers to get the maximum pressure transmitted directly onto the rollers.

The Tube-Evac device is manufactured in the USA. 70+ other patents existed for surgical drain clearing devices. The TubeEvac device is the only device on the market that will clear surgical drains. The original prototype halves with a 19F drain. There is no hinge on the prototype because the plastic is too brittle



Testing the efficiency of the TubeEvac device and how much the surgical drain stretched when TubeEvac is used on it

We tested it on a 19F drain full of water. When we were done the only water left in the drain was what started out behind the rollers at the bottom of the drain. As far as we could tell we had cleared the drain of 100% of the water that was in front of the rollers. We measured the length of the tubing again but the elongation was so minor that it looked like 2-3%. After the initial stretching they do not stretch a lot more. The Engineering College study by Professor Hector Medina has almost identical numbers that the tubing stretches. Compare that to almost 75% that my wife’s drains stretched when milked by hand.

We meet with the Director of Supply Chain Management at Mayo Clinic

We took some of these samples to Mayo Clinic in Rochester, Minnesota to test. We met with the director of Supply Chain Management, a surgeon, and a surgical nurse in a surgical suite. The director was stunned when he saw the efficiency of the TubeEvac device and told us “You just discovered a patient need we did not know existed “and asked to have 500 to test. 5 months later he said Mayo would buy it. Mayo Clinic has been using it since 2010 and other hospitals started using it when they accidentally found out about the TubeEvac device.

Survey says 78% of patients say they hate drains and managing them

A survey that was done in May 2017 said 78% of patients say surgical drains and managing them is the worst part of the surgery. It did not matter what the surgery was – the drains were always the worst part of it.

However with the Tube-Evac device patients tell us they are much happier. They have called and emailed us on various occasions to talk about their drains. Now they can take care of their own surgical drains and do not have to worry about the fluid backing up in their body. Also clots and other fibrinous tissue are blown right into the bulb with the Tube-Evac device.

Method for clearing drains that has been used for years and stretches drains a lot making it even harder to clear them

Put the Tube in the Groove

Close the TubeEvac device

Roll it down and you are done

Video of the TubeEvac device clearing a 19F drain
https://www.youtube.com/watch?v=ReN8fyVkKpo

The Tube-Evac device is so easy to use even a child can use it – and has. We have video showing a child using it. Put the tube in the groove, roll it down, and you are done! The Tube-Evac device makes it much easier for a person with arthritis because it is very simple to squeeze the Tube-Evac device closed around the drain.

In some hospitals, nurses normally no longer clear surgical drains because the patient or the caregiver does it. Nurses simply check to see if the drains are being cleared and the drain is not clogged. In some instances the nurses will clear the drains with the Tube-Evac device. However the patient very much appreciates knowing how to clear their own surgical drains when they go home and have a lot less anxiety because they know how to clear their drains.

Tube-Evac Advantages

Easy to use

Elderly patients – or those with arthritis – find it much easier to use since there is no squeezing involved. Also, it is designed to open automatically when pressure is taken away.

Saves time

Providers can go into a patient's room and have the surgical drain cleaned in a few seconds, saving valuable time for other patient needs.

No vacuum, no problem

If the patient forgets to put a vacuum on the suction bulb for the tubing, the Tube-Evac device will still push the fluid into the bulb and create a vacuum in the line to help evacuate more fluid from the surgical site.

Simple design

The Tube-Evac device can be used with either hand, so that the patient or caregiver can remove fluids on either side of the body using which ever hand is convenient. There is no front or back to the Tube-Evac device. Either end can face either direction.

No stretching

The Tube-Evac device is designed to keep a constant pressure on the tubing at all times, so it does not stretch or deform the tubing.

Peace of mind

Wound clinicians can show the patient how to use the Tube-Evac device, so when the patient goes home, both patient and caregivers have peace of mind knowing how to clear the surgical drains. To find out more about this device, visit the Tube-Evac.com website.

Mechanical Analysis of Tube-Evac System

Executive Summary

This document reports the experimental setup, the results and some analysis of the first study carried out in order to evaluate the mechanical behavior of the Tube-Evac System. By system, it is meant the device itself (with the roller) plus the draining tube. This report is composed of four sections. Each section describes a different experiment. The results and observations are included, as well as details about how the experiment was completed. Illustrations in the form of pictures and plots, as well as tables, are part of the document.

Among the main results observed:

- Tensile testing on the hinges after fatiguing it for 500 and 1000 cycles shows definitely and conclusively that hinges of both devices are more than strong enough to withstand any practical fatigue that could be experienced during their operation.
- As expected, the larger the draining tube, the larger the friction force; thus, the larger the elongation seen by the draining tube. Of course, there should be an optimal size.
- The Pink device on the 19fr produces 60% more rolling pressure than the Green device on the 15fr drain.
- The rollers were measured and found to be deformed beyond tolerances. This is a manufacturing problem. Recommendations were made to use new material for roller.
- Using the Green device on the 10fr has a similar effect (in terms of rolling pressure) as using the Pink device on the 15fr.
- Percent of elongation plateaus to certain values after a relative amount of rolling.
- Materials inhomogeneity causes draining tube to deform in more than one dimension.
- Computational simulations show that stresses seen by tube-evac are about 4 times less than the yield stress of the polymeric material. Also, strains observed are fractions of a millimeter.
- Future work will include experiments using new rollers

Section I: Fatigue and Tensile Fracture Test

This experiment explored the durability of the hinge of the device with respect to fatigue. For preliminary purpose, tests at 0, 500, and 1000 uses were conducted to determine the maximum load and tensile stress that were applied to the hinge before failure. The "loading cycles" are the number of times the device was folded, fatiguing the hinge before testing. This means that for the third test, the device was folded 1000 times; greatly fatiguing the device more than it would be used before being discarded.

The tensile tests can be illustrated in the following figures:

Figure 1: Tensile Fracture Setup

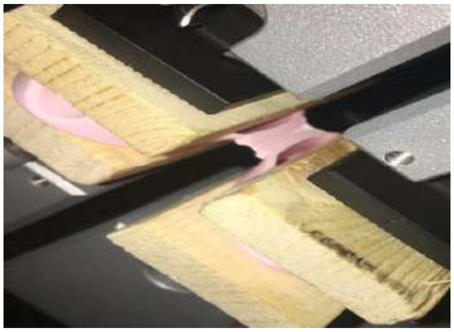


Figure 2: Device under tension. Notice deformation in the walls

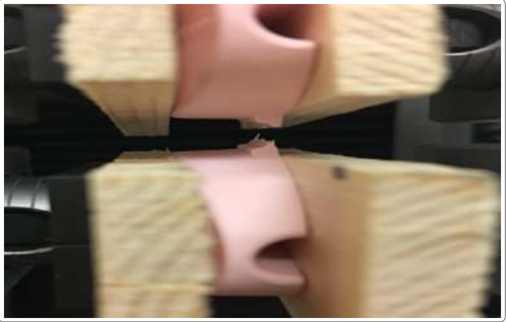


Figure 3: After Tensile Fracture

Results

Specimen	Specimen Label	Number of loading cycles	Maximum Load (N)	Maximum Elongation (mm)	Percent of Max Load Lost to Fatigue
1	Tube_Evac_	0	158.37	5.8	0.00%
2	Tube_Evac_	500	139.62	7.1	11.84%
3	Tube_Evac_	1000	108.49	8.25	31.50%

Table 1A: First set of Fatigue and Tensile tests

Specimen	Specimen Label	Number of loading cycles	Maximum Load (N)	Tensile Stress at Max Load (MPa)	Maximum Elongation (mm)
1	Tube_Evac_500_Pink	500	167.28	22.08	8.9
2	Tube_Evac_500_Green	500	97.64	12.93	6.1

Figure 1B: Second set of Fatigue and Tensile tests

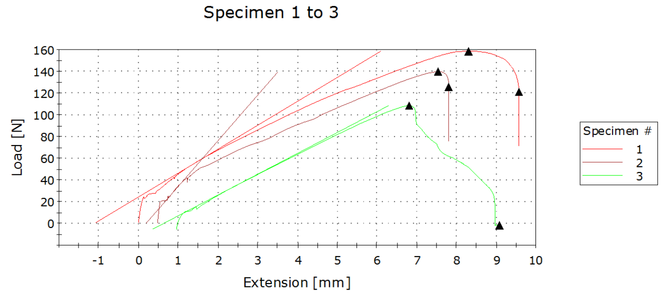


Figure 4: Tensile Fracture Extension vs Load Results Chart

Observations

This Experiment saw much success and can be used to show that after 1000 uses, the hinge of the device can still support about 108N in tension before failing, which is only about a 32% reduction. This is very good and shows that the device is durable and will have very little chance of failing under normal circumstances. Furthermore, during testing, the wall of the device began bowing outward, stretching in tension with the hinge as seen in figure 2, which is in contrast to its original position in Figure 3. This showed that the hinge was strong enough to cause an elastic deformation in a significant part of the wall of the device. Even though this will cause the overall results to be larger than if the hinge was truly isolated, because each experiment was completed with the same conditions, it is safe to say that after 1000 loading cycles, the hinge only lost 32% of its strength.

After the preliminary runs, a second set of tests were performed which corroborated the results. Although brought a little more variance to the found values. What is definitely conclusive is that hinges of both devices are definitely strong enough to withstand any practical fatigue that could be experienced during their operation.

Section II: Tube-Evac Force on Different Sized Tubes

This experiment is intended for finding the maximum force that the device exerts on two different draining tubes (19fr and 15fr). Two methods of measuring the pull force of the device on the tubes were carried out. One method consisted in the tube connected at both ends; for the other method, the tube was connected just at one end, with the other end being free to move or extend. This resulted in the force being generally larger for the tubes with a free end than those without, but the differences appear to be small. A larger number of experiments combined with statistical analysis will help decide whether the observed difference is statistically insignificant or not.

Because the machine used to calculate the force is not intended to be used in this particular way, the force values were manually recorded, as the device was drawn down the tube as seen in Figure 5. The results reported show the maximum force shown by the machine during the drawing, and therefore, are reflective of the maximum force the tubes used experience. (Figure 5)

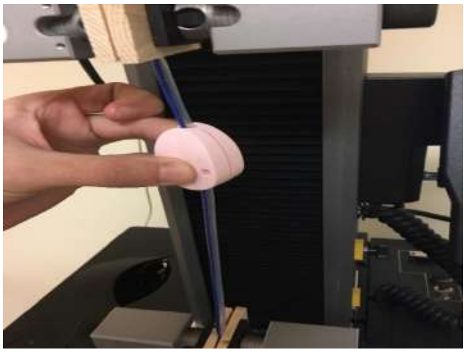


Figure 5: 15fr Tube with Secured Base Drawn by Device Downward

Each tube was also washed with a damp cloth to remove any dust and particulates and then dried to make the interaction between the device and tube as true as possible. This was important because dust and particles can make a surface have a smaller friction coefficient, thus skewing the data. The experimental setup for each tube can be seen in figures 6-9, and the results in tables 2 and 3.

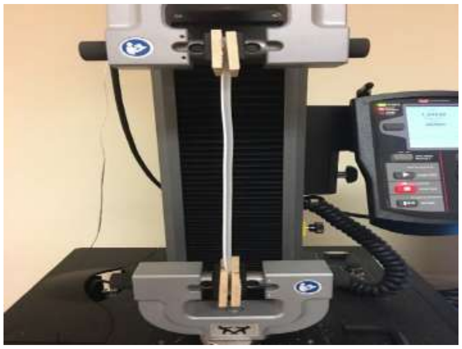


Figure 6: 19fr Tube with Secured Base

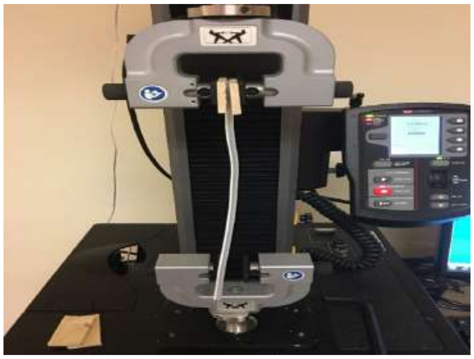


Figure 7: 19fr Tube with Free Base

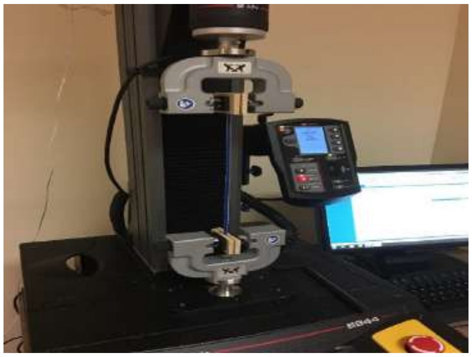


Figure 8: 15fr Tube with Secured base

Figure 9: 15fr Tube with Free Base

Result

19 fr	Force (N)	
Trial	With Base	Without Base
1	32.4	34.2
2	32.6	38.6
3	33.8	34.6
4	32.1	38.7
5	32.4	33.9
Average	32.66	36

Table 2: 19fr Force Analysis for pink device Set 1

15 fr	Force (N)	
Trial	With Base	Without Base
1	3.45	4.7
2	3.33	4.27
3	3.56	3.98
4	3.26	4.45
Average	3.4	4.35

Table 3: 15fr Force Analysis for Prink device

15 fr	Force (N)	
Trial	With Base	
1	21.6	
2	21.2	
3	19.7	
4	21.3	
5	19.7	
Average	20.7	

Table 4: 15fr Force Analysis for Green device

10 fr	Force (N)	
Trial	With Base	
1	2.8	
2	2.9	
3	2.94	
4	3.21	
5	3.42	
Average	3.054	

Table 5: 10fr Force Analysis for Green device

19 fr	Force (N)	
Trial	With Base	
6	34.4	
7	35.9	
8	31.7	
9	37.7	
10	34.6	
Average	34.86	

Table 6: 19fr Force Analysis for pink device Set 2

Observations

The results reported in tables 2 and 4 show the maximum forces exerted on the studied tubes as a slow draw rate. As can be seen in the aforementioned tables, besides maximum force at each trial, the average forces for the sets trial were calculated as well. One may notice the trend that when the base is free the force is greater. This trend might be counterintuitive since, even though the tube might behave elastically, there could be a resultant force on the secured base that may make the force less in the tube. These results show a great difference in the forces experienced by the 19fr tube and the 15 fr tube. This observation might have important implications on the next experiment as well.

The two larger forces in table 2 show that the device does not always roll freely. Sometimes, the roller does not roll in the device and causes a direct frictional rubbing, increasing the force for that portion of the tube, thus resulting in a larger maximum force.

More experiments were carried out using the aforementioned experimental method and new data was recorded using the green device and green rollers to provide a more substantial result and recommendation. The results are in tables 4-6. Based on the data collected, the Green device produced a rolling pressure on the 15fr drain that is about 4 times as high as that produced by the Pink device on the same drain (15fr). In addition, using the Green device on the 10fr has a similar effect (in terms of rolling pressure) as using the Pink device on the 15fr.

Section III: Tube-Evac Elongation Experiment

Series of 20 trials on either three or four specimens of the 15fr and 19fr tubes (since this is a preliminary study) were conducted on 20-cm sections of tubes. Figures 10 and 11 show the setup of the experiments. For the 19fr tubes, four specimens were tested. Two of which were done smoothly and controlled, giving up tension in the specimen gently when the device rolled down to the end, whereas the other two specimens were "snapped" by allowing the tension in the tube to be released all at once, causing a springing effect in the tubes. The results from this were quite interesting.

Figure 10: Initial Setup of Elongation Test

Figure 11: Elongation Test with Device

Observations

This experiment was quite interesting, especially in regards to the properties of the provided draining tubes, and how to use the device effectively.

In the case of the 19fr tubes, snapping them caused less permanent deformation, however, after the first trial, there was still a good amount of deformation regardless of the trial. This means that after one use of the device, depending on which method is used, snapping or not snapping, there could be in average either a 3.5% or a 6.5% elongation in the tube. The data also shows that after that initial spike, there was very little deformation with each subsequent trial; However, the snapping strategy did result is less overall deformation. In addition, the tube that underwent snapping appeared to deform in more than just an elongation sense as depicted in Figure 12. This shows that when snapped back, some of the material in the tube returned to its original state whereas other parts remained elongated. This is most likely due to inconsistencies in the material properties of the tube. It appears that some material has deformed permanently.

Figure 12: 19fr Tube after "snapping." Notice Deformation

In the case of the 15fr tubes, there was very little noticeable difference across each trial with a maximum percent elongation of 0.86%. This elongation was so small the values could be negligible since the tube is so elastic. The act of measuring against the ruler could have resulted in an accidental stretch of the material, meaning that the deformation measured could just simply come from human error. Because of the small forces found in the previous experiments of 3-5 N, it makes sense that there is very little permanent deformation, meaning that the device can be used on 15fr tubes without any noticeable deformation in the tube whatsoever.

Further experimentation confirmed the original data for the pink device and data for the green device mirror the results of the experiments for the pink device. In the green, the 15fr device experienced the same type of deformation that the 19fr tube experienced with the pink device, and very little deformation happened in regard to the 10fr device in the green device, similar to the 15fr in the pink device.

Section IV: Finite Element Analysis (Tube-Evac)

Computational model

A computational model for the Tube-Evac was developed using Solid Works. A mesh of the model is shown in figure 13. From the model, one can see multiple locations of potential stress concentration. Also, shown in figure 13 are the forces applied onto the model based on the operational conditions of the device. Note that these forces do not include the roller forces, as these will be studied separately. Although the arrows do not seem evenly distributed, the force. This force was 7.9kgf. This was the average force a male pinches with thumb and first three fingers [1]. Gravity was also not used in the analysis so the entirety of the right part of the device can be ignored, there is no fixed supports or external loads.

The material is Polypropylene with all of the material properties as given in the specification sheet.

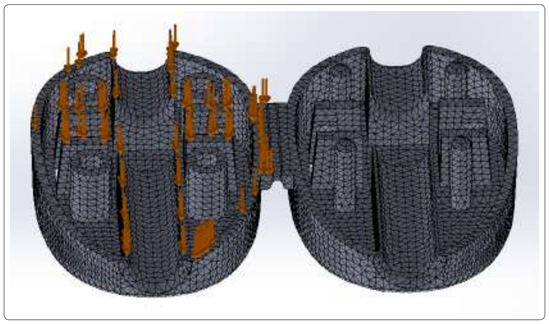


Figure 13: Mesh of tube-evac with forces being applied

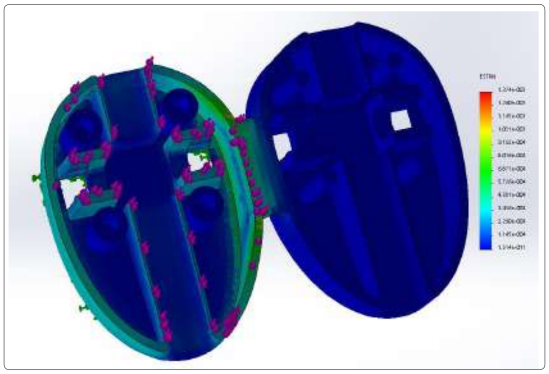


Figure 14: Strain distribution in Tube-Evac for the loading conditions and mesh shown in figure 13

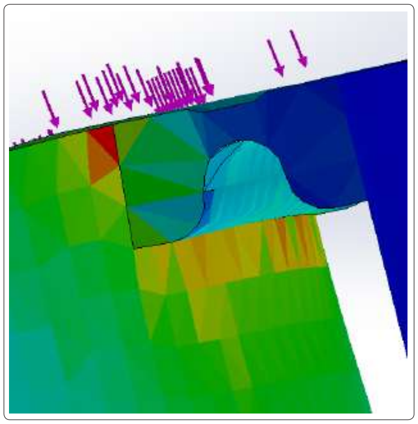


Figure 15: Close-up of strain distribution. Color scheme is similar to that shown in figure 14.

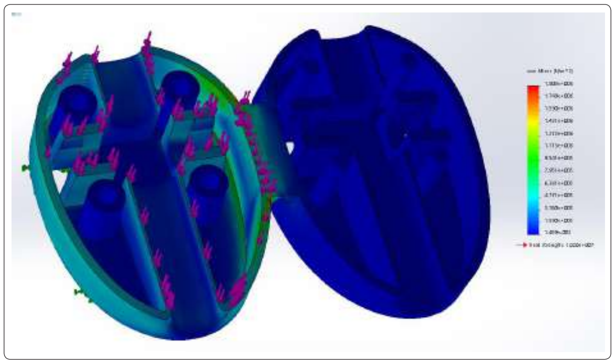


Figure 16: Von Mises stress distribution in Tube-Evac for the loading conditions and mesh shown in figure 13

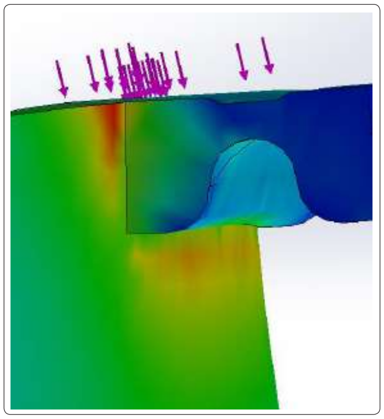


Figure 17: Close-up of stress distribution. Color scheme is similar to that shown in figure 14

Observations

There was a stress concentration near the hinge of the device; this resulted in the maximum stress being present at this point.
Maximum Stress = 1.908MPa
Yield = 10.204MPa
If we want a safety Factor of 2.5, then the cross sectional area experiencing the force can be reduced by half, provided all areas are reduced by the same percentage, causing an assumed maximum stress of 4MPa, which would result in savings on the material [2]. Consider figure 18. Since the deformation on the right is not "true deformation, as is it a result of the bend indicated by the red arrow, the deformation of importance is about .03353mm from its original position. As you can note, figure 18 has been exaggerated for illustration purposes. Note that "green arrows" on the bottom of the device for all figures denote a fixed geometry with the attempt to illustrate pinching; that is, one side is held while the other experiences a force.

Simulation for Tube-Evac Roller

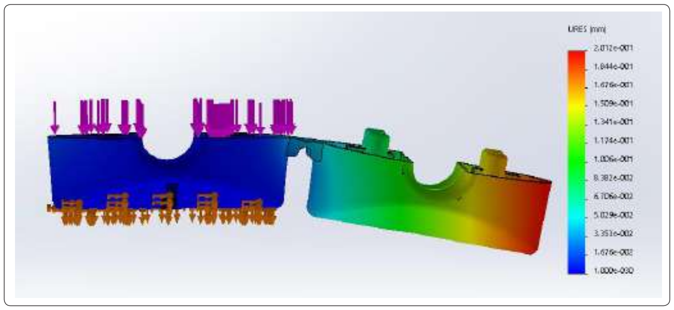


Figure 18: Front view of deformation (strain) distribution

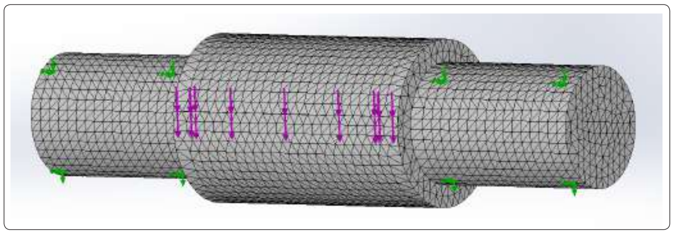


Figure 19: Mesh and loading conditions for roller of tube-evac.

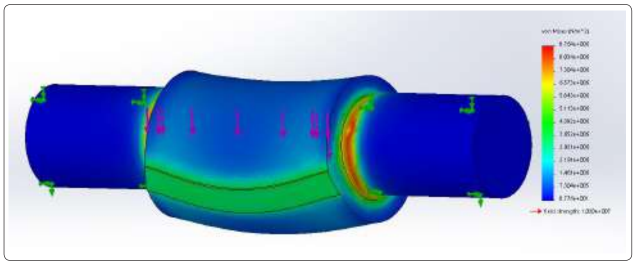


Figure 20: Von Mises stress distribution of roller for the mesh and loading conditions shown in figure 19

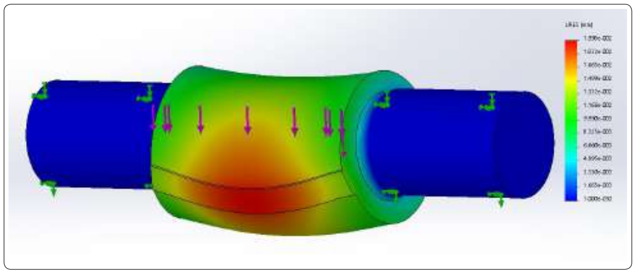


Figure 21: Strain distribution of roller for the mesh and loading conditions shown in figure 19

Observations

Because the roller is designed to rotate, the creation of a fixture was attempted that would allow for free rotation of the outer cylinders, but that option was not available in the software used. Instead, outer cylinders were fixed, at the location where they would be in contact with the supports from the device. Because of this, the stress concentration seen figure 20, at the shoulder of the roller (in red) is much higher than it should be if the system could rotate in the simulation. This means that the stress concentration would be at the point in which the force is applied to the roller, at about 3.5MPa. Compared to the assumed yield strength of 10.204MPa for polypropylene.

The deformation observed seems very realistic, considering the fixed cylinders cannot bend due to the supports. The maximum deformation obtained was only 0.02mm, which seems to be negligible

References

1. Polyhedron Laboratories. Polypropylene Testing. Houston, Texas: Polyhedron Laboratories, Inc.
2. Swanson AB, Matev IB, de Groot G (1967) The Strength of the Hand. Bull Prosthet Res 10: 145-153.

Based on Dr. Medina's observations and discussions with Plastic Concepts we changed the rollers to a much harder plastic. The new plastic is now being used in all production runs.