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# NOTES Suction Grasper for Tubular Viscera – Characterization of Gripping Force when Varying Hole Size, Diameter, and Number

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*Abstract*— **This paper details the design and characterization of a novel suction grasper for Natural Orifice Transesophageal Surgery (NOTES). Axial gripping force was optimized by changing hole size, number, and spacing. A 10 kg pig and a rabbit esophagus were used to simulate a neonatal esophagus. Maximum axial forces of up to 7.2 N were achieved. Hole pattern spacing had little to no impact on force while suction area was very significant. Additionally, there was a preference for a greater number of holes versus larger holes for relatively large hole sizes. Lastly, smaller holes resulted in smoother loss of gripping force when beyond maximum holding force was applied.**

## I. Introduction

Natural Orifice Transesophageal Surgery (NOTES) is a type of minimally invasive surgery where flexible surgical tools are inserted through the body's natural openings such as the mouth or nose, to gain access to more remote organs. This technique avoids the incisions normally required in standard laparoscopic or open surgery, and minimizes the risks of surgical site infection and scarring. There is also the potential for a reduction in the amount of sedation and analgesia required for the procedure as well as reduced post-operative pain and recovery times. This approach may also be beneficial for specific patient populations such as the morbidly obese where the traditional operative approach can be associated with significant morbidity [1].

While there is significant promise in NOTES, the technique is still in its infancy and new tools will be required before the field can achieve its full potential. One of these challenges is designing tools that can adequately grasp tissue without damaging it. A review of NOTES surgery found that "Most articles reported trial and error with different grasping techniques and equipment and the most optimal method is yet to be determined" and that "The development of new devices will speed the development of NOTES and improve outcomes" [1].

To address the need for more effective tissue grasping, a novel circumferential suction grasper has been developed for tubular organs. Similar suction gripping has already been successfully utilized to stabilize heart movement in cardiac surgery with the Medtronic EndoOctopus® [2] but this technology has not yet been translated to NOTES.

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This article will present the design and characterization of our novel suction grasping actuator for tubular organs. The focus will be on the neonatal esophagus, as a component of a system for the treatment of congenital esophageal atresia with tracheoesophageal fistula (TEF).

## II. Design Considerations

### A. Size and Material Constraints

The major constraints on the design of the tool are diameter, flexibility, smoothness, and biocompatibility. The neonatal esophagus is, on average, 5 mm in diameter and 8-10 cm in length [3]. Additionally, based on surgeon input, the tool should be as smooth as possible so that there is no abrasion on the esophagus lining and should have a bend radius of less than 2 cm. Generally, surgical tool material selection for biocompatibility applies and can be taken from existing surgical tools and standards.

### B. Force Considerations

Next, the amount of force required to cause tissue damage needs to be considered. Exact information is lacking in this area but tests on the small bowel of a porcine model showed that significant cell death did not occur at ~80 kPa of applied pressure but did occur at ~140 kPa [4]. The medical suction at the Hospital for Sick Children is ~85 kPa so significant cell death should not be encountered although we will be working on confirming this in the future.

## III. Experimental Design

### A. Tool

The tools for testing are shown in Fig. 1 below. The tips are Stereolithography (SLA) 3-D printed in SOMOS® 11122 material with +/- 0.005" tolerance which has low friction and is designed to be used in ISO 10993 approved devices [5]. The tubes are PTFE which is widely used in guide wires and catheters and well-known to be biocompatible and extremely low friction. The variables shown in Fig. 1 are varied according to Table I.

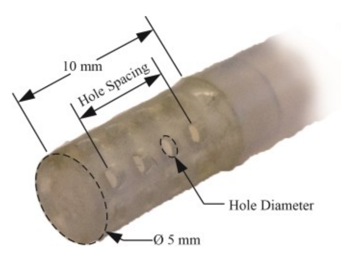


Figure 1. Tool Tip

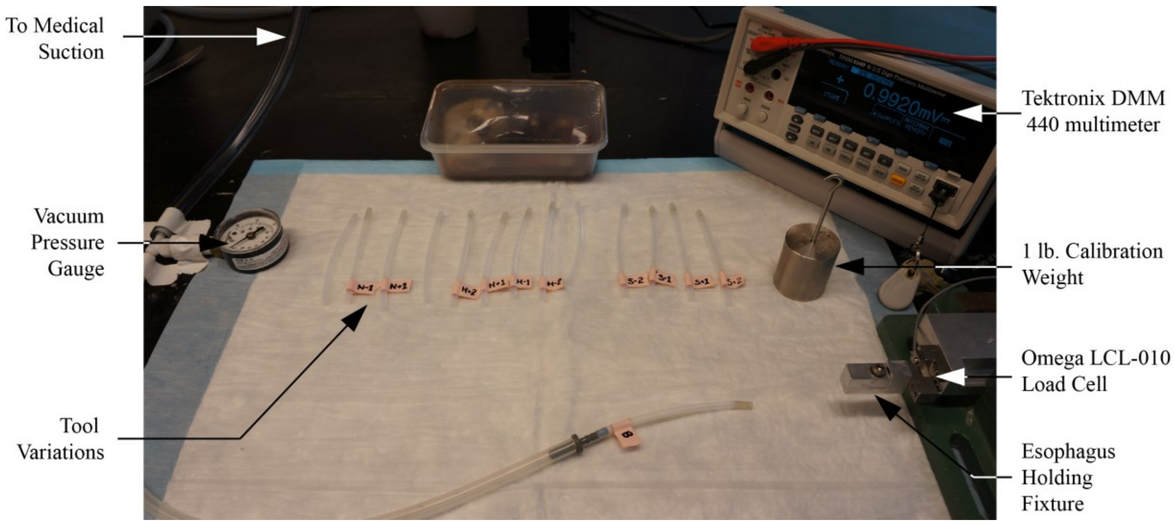


Figure 2. Experimental Setup

Table I. Tool Variations

| | |
|---|---|
| Length of Hole Pattern (mm) | 3, 4.5, 5.25, 6[a], 6.75, 7.5 |
| Number of Holes | 9, 16, 24[a], 32, 50 |
| Hole Diameter (mm) | 0.5, 0.75, 1[a], 1.25, 1.5 |

a. Base configuration.

These parameters were selected as they are obvious design variables; should you drill bigger or more holes and what effect does spacing of the holes have? Intuitively, if hole diameter or the number of holes is increased, the suction area should increase and, thereby, the axial gripping force. These are tested separately to answer the question as to which is best given the same surface area on a tool tip. Finally, spacing should have a slight effect on force because the esophagus is being held to a shorter section of tool

### *B. Setup*

The setup for testing the holding force on the esophagus consists of an Omega LCL-010 10 lb. load cell measured by a Tektronix DMM 440 multimeter. The load cell is held in-line with the esophagus by a custom-fabricated fixture and calibrated with a 1 lb. (~0.45 kg) test weight. The tools are attached directly to the hospital's medical suction and a pressure gauge is used to monitor the suction. The experimental setup is illustrated in Fig. 2.

### *C. Tissue Samples*

Esophagi were taken from a 10 kg pig and two rabbits and frozen to preserve them between harvesting and testing. In the future, the test will be repeated in vivo since it has been shown that in vivo and postmortem tissue sample mechanical properties vary significantly [6]. The rabbit and pig were selected because, based on surgeon feedback, the properties of human esophagus lie somewhere between the more fragile rabbit esophagus and the more robust pig esophagus. This allows testing of worst case damage on the weaker rabbit esophagus and worst case suction operation on the more rigid pig esophagus.

### *D. Testing Procedure*

The esophagus is held in the fixture and about 4 cm of esophagus is left out of the jaw. The tool is inserted into the esophagus until the entire tool tip is covered and then suction is engaged. The tool is manually removed by pulling axially. There are three runs for each tool tip on the same piece of esophagus. After the tool tip has completed its three runs, the used end of the esophagus is removed and the experiment is repeated with the next tool variation. The esophagus sample is kept wetted throughout the testing to simulate in-vivo conditions.

## IV. RESULTS

There was a significant difference in the structure of the rabbit esophagus and pig esophagus. The rabbit esophagus was much thinner and all the layers of the esophagus were joined, whereas the pig esophagus was much thicker and rigid and the mucosa and muscular layers were separate and could translate with respect to one another (see Fig. 3)

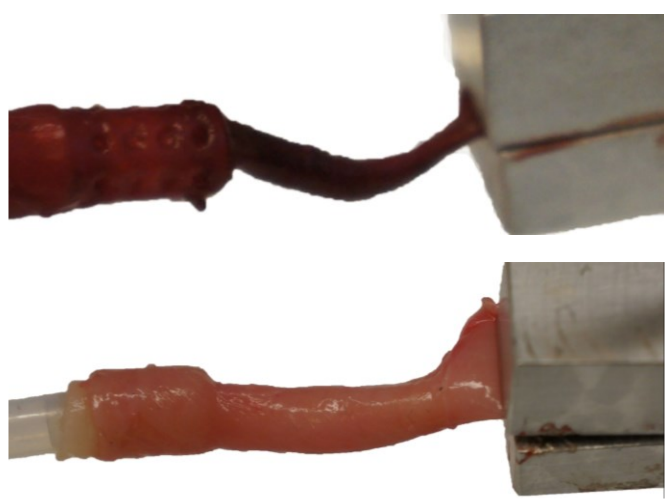

Figure 3. Rabbit esophagus (top) and pig esophagus (bottom) under suction with base tool.

The results for all of the experiments are given in Fig. 4, 5, and 6 where maximum axial gripping force is defined as the highest force achieved before the first loss of suction. To begin, the holding force on the rabbit esophagus is twice the pig esophagus for the base tool. During the experiment, two main effects were observed that will explain the results observed: the pull-in effect and suction sticking. The pull-in effect occurs when the suction pulls part of the esophagus into the tool, effectively grabbing onto it and establishing a normal force on the esophagus when being pulled in the axial direction. This effect was far more noticeable in the rabbit esophagus since it was much less rigid as demonstrated in Fig. 3. The other effect observed was suction sticking, which occurs when the vacuum pressure holds the esophagus to the side of the tool, causing increased friction when being pulled axially. This effect is not a strong as the pull-in effect and explains the overall lower force in the pig esophagus.

The pull-in effect is exacerbated by increasing the hole size in the rabbit esophagus. Conversely, when the hole size is reduced, the pull-in effect become less important and the rabbit esophagus behave similarly to the pig esophagus. The pig esophagus, on the other hand, does not benefit from the pull in effect as significantly and, while increasing the hole size increases the suction sticking effect up to 1 mm, increases in hole size thereafter doesn't seem to increase the effect. (see Fig. 4)

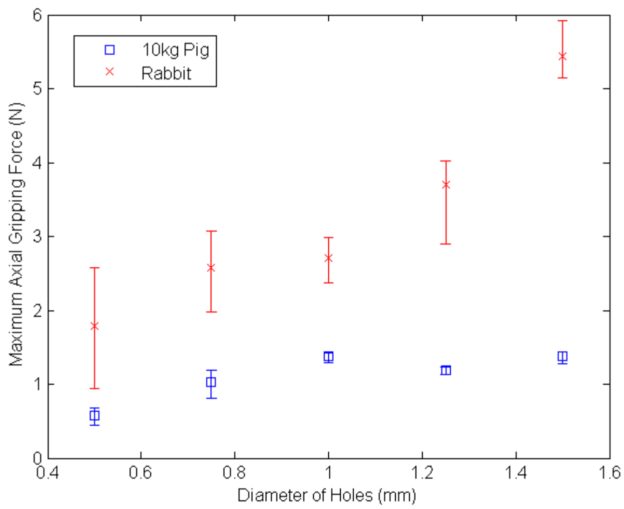


Figure 4. Effect of changing hole size on axial gripping force. Error bars denote maximum and minimum. n=3(pig), n=5(rabbit).

Both the pig and rabbit esophagi show a similar increase in gripping force when increasing the number of holes, likely due to the suction sticking increasing. Additionally, the rabbit esophagus shows its highest gripping force yet. It was observed that, when the holes are placed extremely close together, a ripple pattern is formed in the esophagus, which drastically increases holding force. The 'magic' of the hole pattern is likely that there is no slack in between holes which means the suction has to be broken all at once rather than sequentially. This same hole density occurs in the 3 mm hole spacing tool but with 3/5 of the number of holes and we see a marked jump from the pattern. (see Fig. 5)

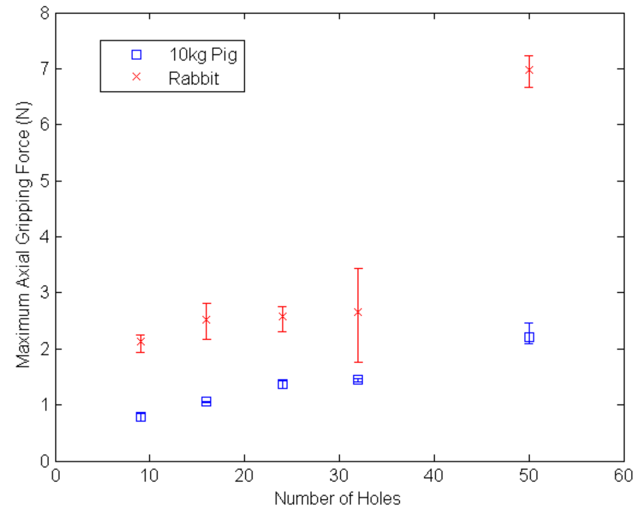


Figure 5. Effect of increasing the number of holes on axial gripping force. Error bars denote maximum and minimum. n=3.

Finally, the hole spacing has little effect on the rabbit esophagus except at the hole density mentioned earlier. The pig esophagus shows a dip in force as the spacing gets smaller; this is likely due to the suction sticking effect having less surface area to stick to. However, at the 3mm spacing the force jumps back up; this can attributed to the same cause as with the rabbit. (see Fig. 6)

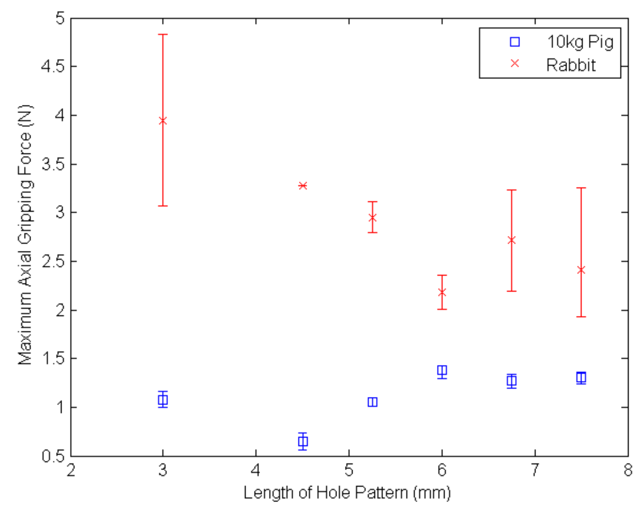


Figure 6. Effect of spacing of the hole pattern on axial gripping force. Error bars denote maximum and minimum. n=3.

By re-plotting hole diameter and number results with suction area as the independent variable, it can be determined whether it is better to drill a few large holes or many small holes given the same surface area on the tool tip. This is examined in Fig. 7. The results from the two esophagi are similar but vary, as one would expect from the previous observations; the hole size versus the number of holes is much closer for the rabbit esophagus due to the more dominant pull-in effect. Both show a preference for a greater number of holes versus large hole sizes.

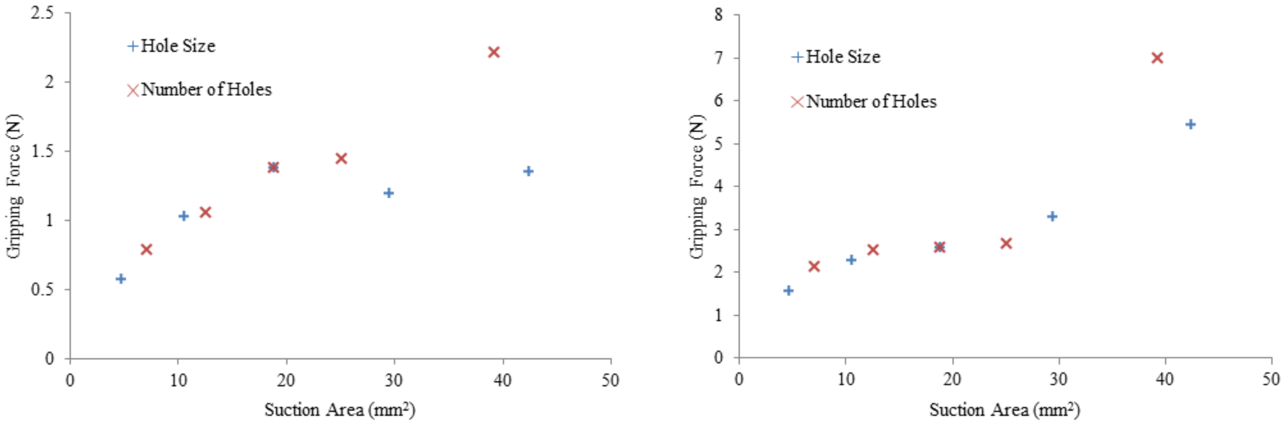


Figure 7. Effect of hole size versus number of holes for a specific suction area on axial gripping force exerted on a 10 kg pig esophagus (left) and a rabbit esophagus (right). n=3.

Additionally, tests were performed to see how the tool would fail if too much force is applied by placing the tool further into the esophagus before the application of force. It was found that, in the pig esophagus, the tool failed more smoothly and after suction was lost, a constant weaker force was observed. The rabbit esophagus reacted differently at larger hole sizes; once suction was lost, the esophagus would spring back and then the tool would pull the esophagus back into the suction holes, creating the jagged motion observed in Fig. 8.

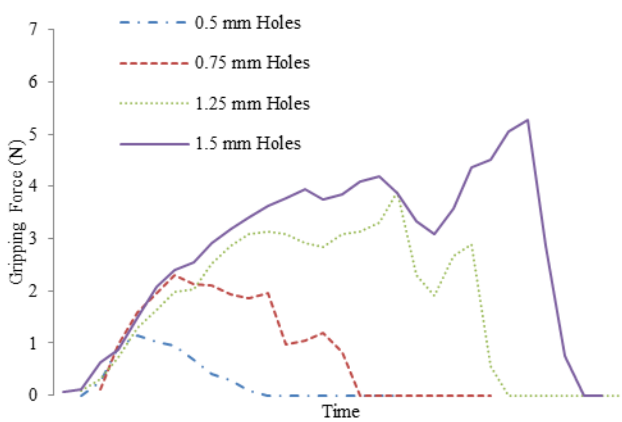


Figure 8. Force profile of tool being pulled out of rabbit esophagus for different hole sizes.

The human esophagus lies somewhere between the pig and rabbit esophagus and, therefore, it can be expect that some average of these relationships as well as use each set of data as tolerances to design for.

## V. Conclusions

For practical design parameters in the human esophagus, a maximum holding force between 2N and 7N is achievable with this actuator. Additionally, increasing suction area increases axial holding force, and the spacing of the hole pattern has little or no effect on force except when holes are very tightly packed together. Finally, smaller holes result in a smoother loss of gripping force.

In the future, the tests should be repeated immediately post-mortem with a larger sample size and cell damage analysis. Performing testing immediately post mortem will solve the issue of cell damage and death due to freezing. Additionally, the background used to determine the safety of the suction [4] only takes the vacuum forces into account and not the shear forces generated by the holes; this limitation will be addressed by cell damage analysis. A smaller pig esophagus should be used since the 10 kg pig was slightly oversized and may have skewed the results to the low side. Additionally, the scope of testing should be extended to adult patients and other tubular viscera such as the intestines. Finally, different patterns and shapes of holes should be evaluated to optimize the holding force and reduce or eliminate any damage.

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