

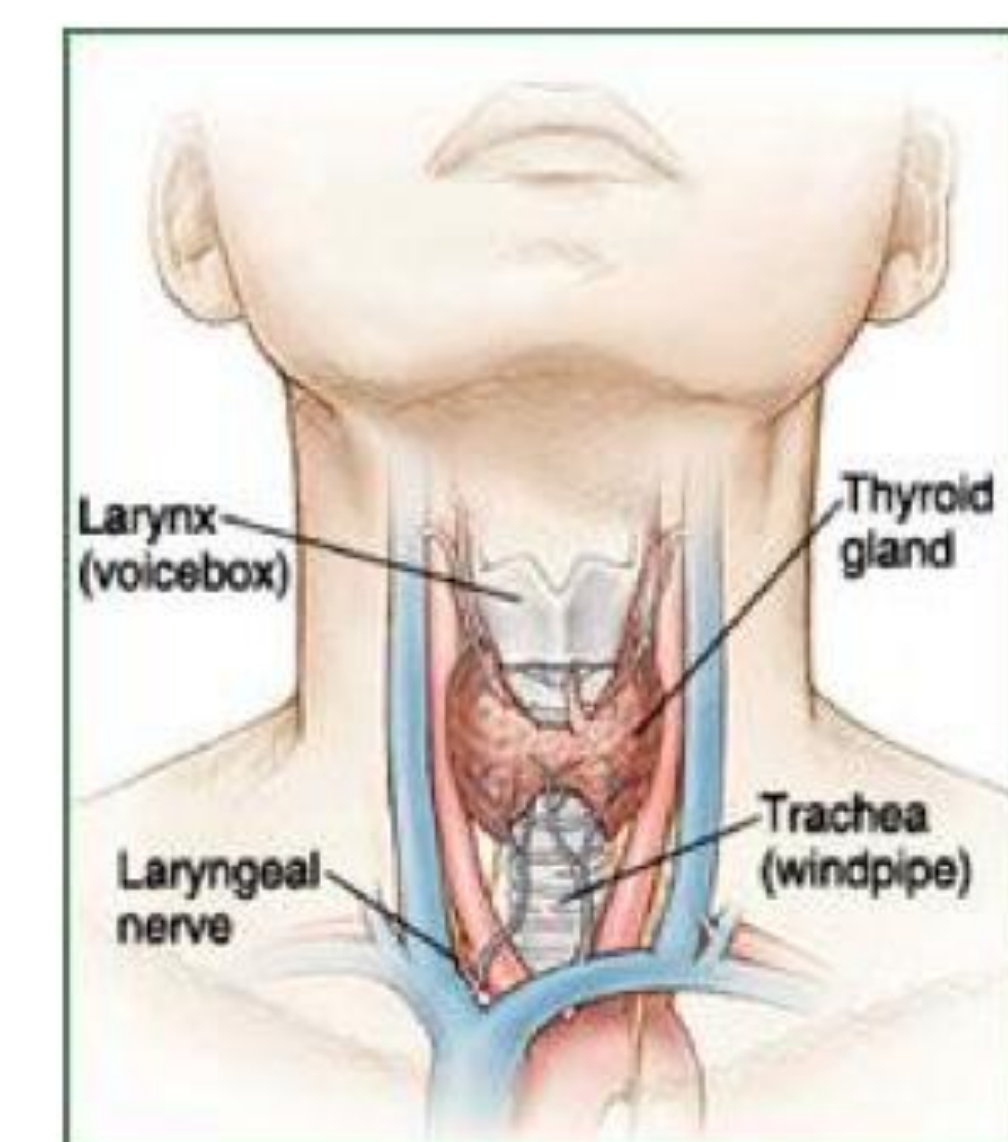
## 1. Abstract

Metal retractors used in thyroid surgery cause ischemic tissue damage and scarring as a result of uneven pressure distribution. A modification was requested of a device currently used in abdominal surgery: the Alexis® Wound Device (Applied Medical). Modification of the device would provide even force distribution to fit the anatomy of the neck.

The final prototype consists of two top oval rings (4 by 6 cm), one bottom round ring (6 cm diameter) and a shorter polypropylene tube (5 cm). Floral foam was used to analyze pressure distribution and chicken breast was used to mimic human tissue. This confirmed that the revised Alexis® device distributes force evenly.

A survey sent to the American Association of Endocrine Surgeons found that eighty-five percent would be interested in an improved device. Also, the revised Alexis® device is not limited to thyroid surgery; application to other surgeries in the neck and head, tumor or lymph node removal and even abdominal pediatric surgery is possible. The potential sale of the revised Alexis® device in thyroid surgery is \$4.33 million in 2020, but can increase greatly when applied to other surgeries.

## 2. Background Information



### Thyroid Anatomy

- Located at the front of the neck
- 2 lobes
- Positioned around trachea<sup>1</sup>
- Produces hormones that regulate metabolism<sup>1</sup>

### Surgical Removal of Thyroid

- 3-4 cm incision across the neck, above the collar bone<sup>1</sup>
- Retractors used to expose thyroid<sup>1</sup>
- Thyroid separated for the trachea and removed<sup>1</sup>
- Duration: 60-90 minutes<sup>1</sup>

Fig 1: Diagram of thyroid<sup>2</sup>

### Thyroid Surgery Data

	2006	2020	Increase
Complete Thyroidectomy	22,943	24,743	7.27%
Unilateral Thyroid Lobectomy	26,931	30,139	10.64%
Partial Thyroidectomy	16,477	20,226	18.54%
Excision of Thyroid Lesion	9,485	11,550	17.88%
<b>Total</b>	<b>75,836</b>	<b>86,658</b>	<b>12.49%</b>

Table 1: According to the National Hospital Discharge Summary and the National Survey of Ambulatory Surgery<sup>3</sup>, 75,836 thyroid surgeries were performed in the United States in 2006. There is a projected increase of 12.49 percent to 86,658 total thyroid surgeries in 2020.

### Metal Retractors Currently In Use

- Hold the skin in desired position during surgery
- Combination of sharp, small edges with a large amount of force cause tissue damage
- Ischemic trauma results from the uneven pressure distribution

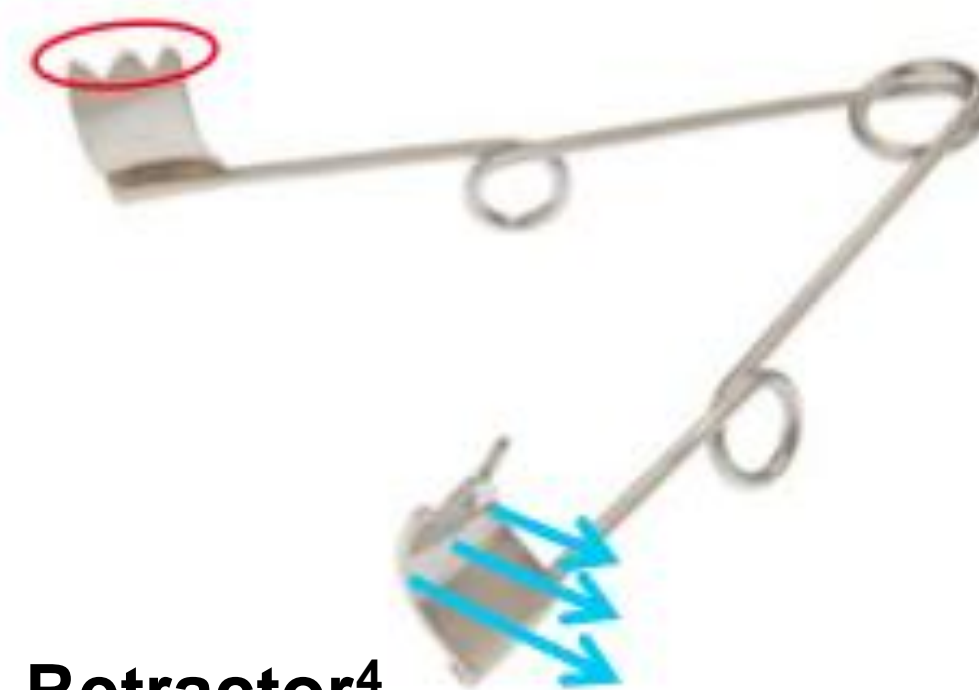


Fig 2 : Spring Retractor<sup>4</sup>

Red circle shows sharp edges. Blue arrows illustrate relative force distribution.

## 3. Design Specifications

A modified Alexis® Device that meets the following requirements:

- **Delocalizes pressure** over a large contact area
- **Compatible** with varying anatomies
- **Opens the wound** in an "eye" shape (ellipse with pointed edges)
- **Minimizes damage** to tissue
- Is compatible with electrocautery (i.e. **insulating**)

## 4. Testing

The metal retractors and the three different revised Alexis® devices were analyzed for  
1) Pressure Distribution 2) Performance Ability in Tissue Model (chicken breast).

### Devices Tested:

- Large metal spring retractor and small metal spring retractor
- Three modifications of the Alexis® device
  1. Silicone top oval rings, polyurethane tube with bottom circular ring
  2. Silicone top oval rings, polyurethane tube with bottom circular ring from Alexis® device
  3. Silicone top oval rings, synthetic nitrile and bottom circular ring

### Qualitative Data: Chicken Breast to Mimic Tissue

- Tissue slit of 3.5 cm in length was cut through chicken breast
- Change in slit length was measured after device was removed
- Observed the effect of the device on the chicken breast qualitatively
- Represents model of human tissue



Fig. 3: Tissue Testing

Large metal retractor (right), revised Alexis® with nitrile tubing (middle), and revised Alexis® with polyurethane tubing.

### Assembly of devices:

- Silicone tubing cut to length of 17 cm
- Wire inserted in ring
- Two of these rings constructed and glued together
- Tubing glued to bottom and top rings

### Quantitative Data: Floral Foam to Analyze Pressure

- Incisions of 3x4 cm were cut into the floral foam with the "eye" shape
- Initial displacement was measured by inserting the device and then removing immediately
- Final displacement was measured after two hours in floral foam



Fig. 4: Floral Foam Testing

Large retractor (back to front), small retractor, Alexis revised with polyurethane tubing and Alexis® revised device with nitrile tubing and bottom circular ring.

## 5. Results

**Final Design: A modified Alexis® device consisting of two top oval rings (4 by 6 cm), one bottom round ring (6 cm diameter) and a shorter polypropylene tube (5 cm) to fit the varying anatomy of the neck.**

### Avg. Displacement vs. Pressure in Floral Foam

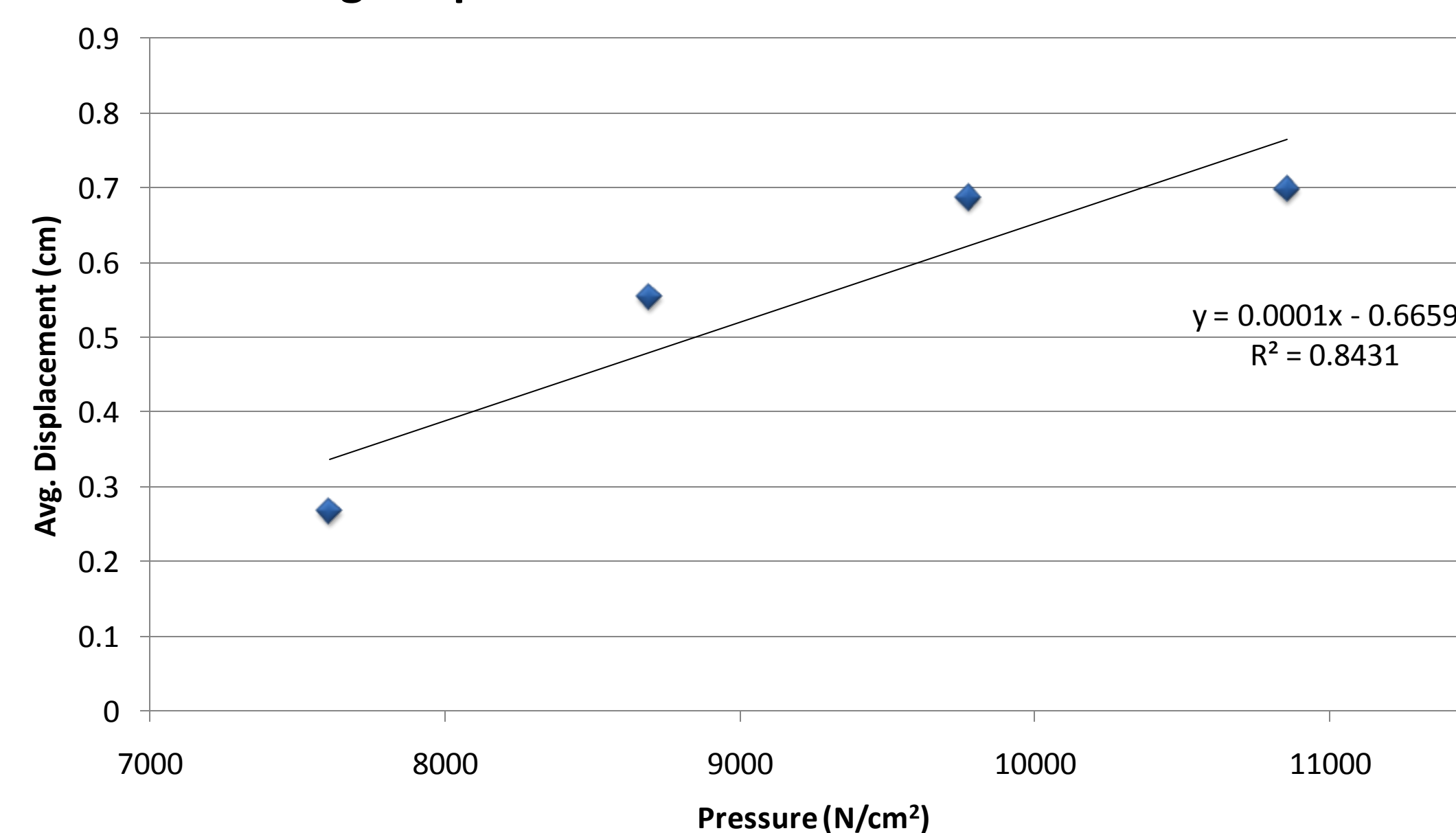


Figure 5: A linear relationship between pressure and average displacement was determined for weights of 700, 800, 900 and 1,000 grams (n=10).

### Pressure Exerted by Retractors at 0 Hours and 2 Hours

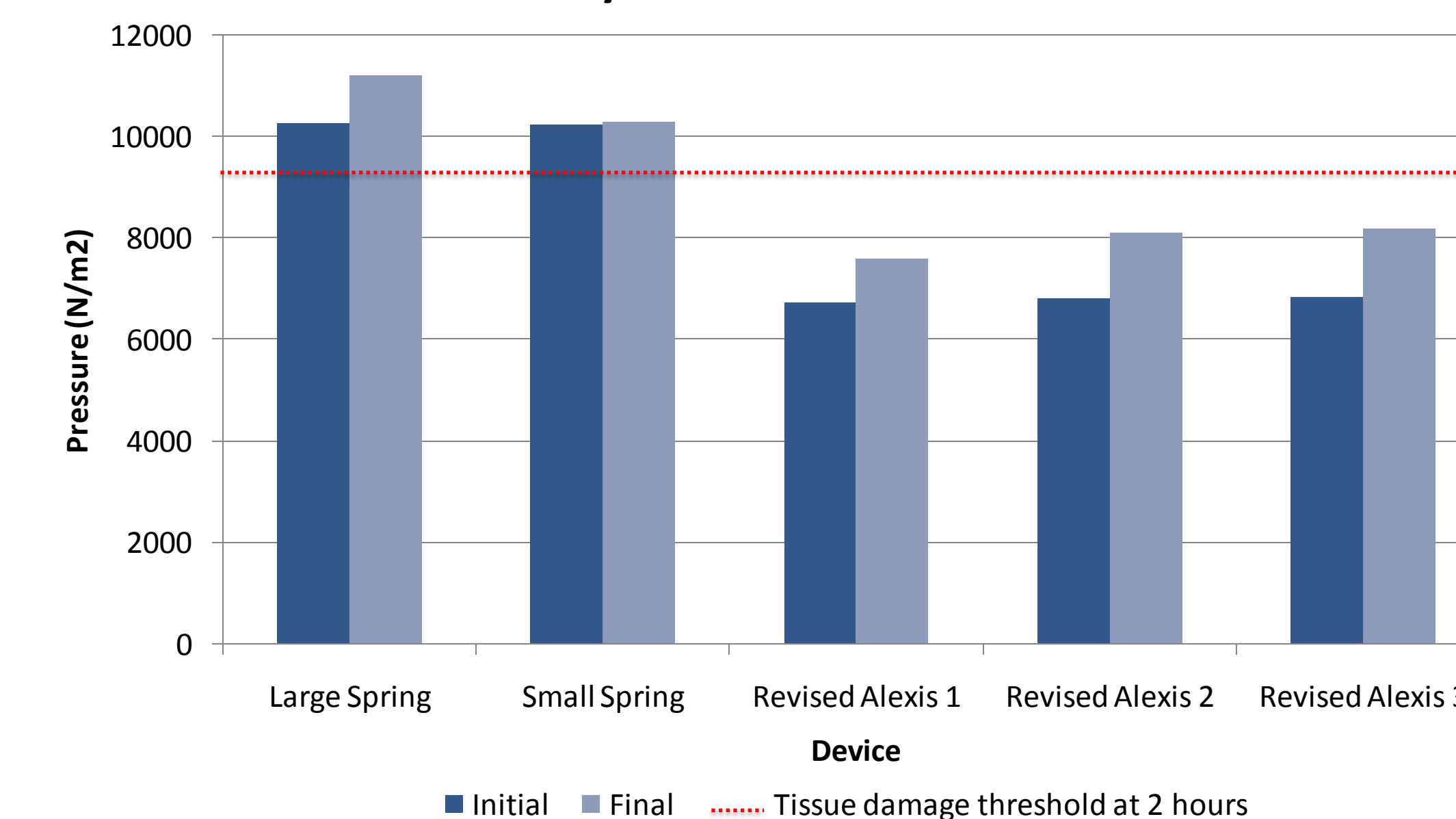


Figure 6: The large spring retractor and the small spring retractor exert a pressure greater than the threshold of tissue damage (n=10). Revised Alexis® devices distribute less pressures and do not reach threshold for tissue damage.

## 6. Marketability

A survey was sent members of the American Society of Endocrine Surgeons. Twenty percent responded (75/383) and eighty-five percent desired a modified device.

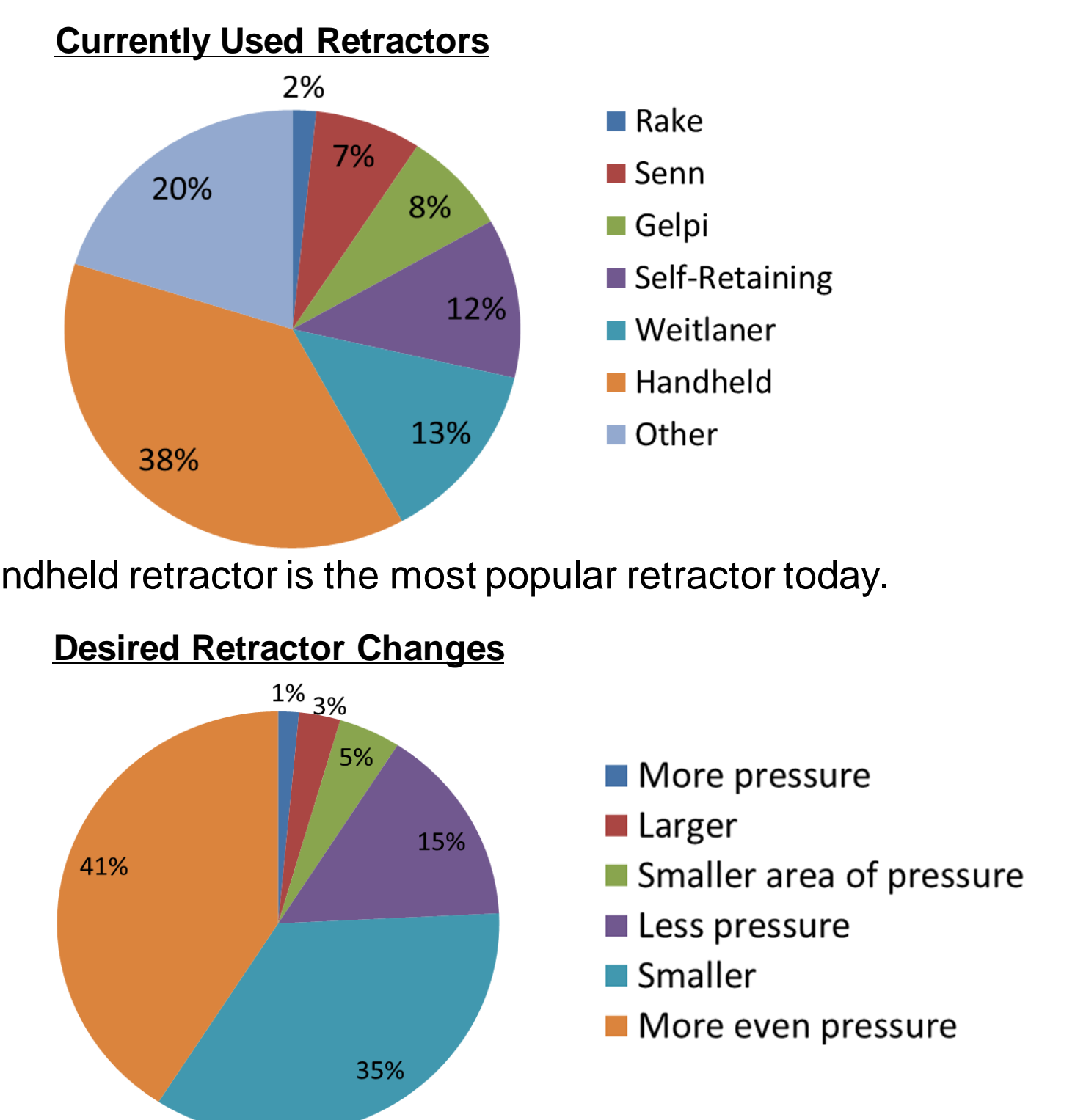


Figure 7: The handheld retractor is the most popular retractor today.

Figure 8: Forty-one percent of the surveyed population requested more even pressure. This is a key benefit of the revised Alexis® Device.

## 7. Conclusion

- Final design: revised Alexis® device: two top oval rings (4 by 6 cm), one bottom round ring (6 cm diameter) and a shorter polypropylene tube (5 cm)
- Pressure analysis of floral foam provided quantitative data of force distribution
- Chicken breast mimicking animal/human tissue ensured that it can retract
- Forty-one percent of surveyed population of surgeons requested even pressure
- Potential sales could reach \$4.33 million and beyond by 2020 when applied only to thyroid surgeries
- Sales increase greatly when applied to other surgeries

## 8. Future works

- Manufacture durable, efficient final designs (preferably from material in original Alexis® devices)
- Ensure biocompatibility of final design
- Perform extensive pressure/force testing, possibly in animal models
- Apply final design to other types of surgeries in the neck and pediatric abdominal surgery
- Develop plan to sell the revised Alexis® device back to Applied Medical®

## 9. Acknowledgement

- Dr. Rebecca Sippel and Dr. David Yu Greenblatt (Clients)
- Mitch Tyler (Advisor)

## 10. References

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