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# Development of a Modified Cervical Collar to Eliminate Overheating and Dysphagia Side Effects

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**Development of a Modified Cervical Collar to Eliminate Overheating and  
Dysphagia Side Effects**

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**Department of Biomedical Engineering**

**Honors Research Project**

**Submitted to**

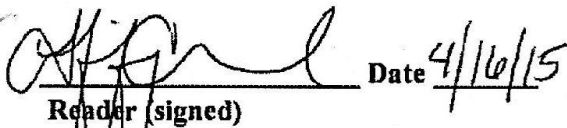
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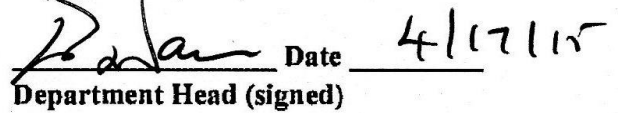
  
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**I. Abstract**

Currently, thousands of people each year require the use of a rigid cervical collar. The collars are used in situations of emergency, as well as in situations of precaution, when spinal injury is or may be present. There are many different styles and sizes of cervical collars available on the market today; however, common side effects are noticed when wearing the collars that may reduce the effectiveness to the patient. Often patients complain of general discomfort issues or may suffer from more serious side effects such as pressure sores, increased intracranial pressure, dysphagia, and abnormal distraction within the upper spine. A need exists for the modification of current cervical collars to reduce the painful or uncomfortable side effects associated with wearing them which would, in turn, increase the effectiveness of the therapy that the collar provides to the spine.

There are two main components of most cervical collar designs: the rigid outer shell and the inner padding. Both of these components have been considered by our design team in the modification design to improve the efficacy of the cervical collar and to reduce side effects from wearing them. The main goals of this project were to reduce the overall discomfort patients experience that is associated with overheating and dysphagia side effects. As a team, we have researched and tested many materials to determine the best fit for our modified cervical collar. The tests included an end user survey that determined the overall comfortability between the available collars, a cold temperature retention test that showed how long the prospective cooling materials would maintain lower temperatures, and an in-collar temperature test that looked at the temperatures of the materials within the lining of a collar

As a team, we have designed a rigid cervical collar that utilizes a slightly flexible, but durable 1/16th inch polyethylene outer shell with padded gel inserts. The outer shell is a two piece design that incorporates the favorable concepts of currently manufactured collars. The two pieces were cut using a scroll saw and molded using an application of heat to the desired positions. There are multiple cut outs in the plastic of both pieces that give flexibility when fitting the collar and the pieces can be connected using velcro straps. The inner “cooling system” is composed of two hydrogels: TheraPearl Technology freezable beads and a pressure activated cooling pad marketed by The Green Pet Shop. The cooling materials will then be wrapped together in polyolefin shrink wrap and placed within specified cutout positions in the antimicrobial padding. Finally the components will be covered in a heat resistant cloth material to ensure direct contact with the skin is compatible and comfortable for the patient. The modifications focus on reducing the hot spots on the cheeks, chin, and neck that are commonly associated with discomfort in patients, will address the discomfort of the chin and neck associated with dysphagia, and will also maintain the rigidity and restriction of motion necessary of the collar. Testing on the efficacy of the design concepts brought forth is still in progress, but we believe the modified cervical collar can increase patient comfort levels and reduce overheating.

## **II. Introduction**

In October 2014, Jessica Augustynovich, Samantha Ballash, Katharine Hodgson, and Elizabeth Rondinelli comprised a biomedical engineering team for a research and design project. The modified cervical project, presented by Dr. Mary Verstraete, was chosen as the desired work for the project from October 2014 to May 2015.

## **III. Problem Statement**

As an essential tool in trauma, rigid cervical collars are placed on every patient with potential cervical spinal injuries. If cervical spine injury is diagnosed, the collar remains on the patient until surgery and is often utilized in the recovery process for extended time periods. Although the purpose of the standard rigid collar is to stabilize the cervical spine, side effects such as pressure sores, increased intracranial pressure, dysphagia, and abnormal distraction within the upper spine result from improper fitting. Because of spinal degeneration and age-related decrease in muscle mass and vascularity, these side effects occur more prominently among elderly patients. A need exists, particularly for the elderly, to create a personalized cervical collar that prevents unwanted side effects, conforms to the patient's body, and limits movement of the spine to 30 degrees in order for proper healing to occur.

## **IV. AK Design Solutions**

Jessica Augustynovich, Samantha Ballash, Katharine Hodgson, and Elizabeth Rondinelli formed AK Design Solutions to meet the customer request provided by Dr. Tiffany Marchand of Summa Health Systems. The design team was tasked to develop a modified cervical collar that prevented unwanted side effects, such as overheating and dysphagia, while maintaining the efficiency of limiting cervical spine movement to less than 30 degrees in all directions.

### **Mission Statement**

We strive to inspire new ideas that improve upon the existing biomedical field. The unique engineering solutions we create are built upon a foundation of strong team compatibility, an unbiased perspective on the current industry, and a thorough understanding of quality patient care. Our designs allow for caregivers, loved ones, and patients to receive the best in efficiency, ease of mind, comfort and quality of life, making even the toughest situations easier every step of the way.

## **V. Background**

To obtain the proper knowledge prior to beginning this project, a substantial amount of research was performed in order to assess the current cervical collars and the current problems with them. In addition to gaining a thorough understanding of the device, the research helped AK Design Solutions to refine its problem statement to focus on a select number of important issues and assess how the current designs may help to solve them.

### **Currently Available Cervical Collars**

To accommodate the size of each patient and the circumstances of the injury, cervical collars are manufactured in several forms. The patient may either be fitted with a soft or a rigid collar. The soft collar is most often used short term for patients who are suffering from minor neck pain. Though it provides a more comfortable brace than a rigid collar, it is less restrictive of cervical spine movement (1). For serious accidents involving the cervical spine, a rigid collar is required in order to restrict movement to the required 30 degrees of motion.

The sizing of today's collars is also commonly seen in two forms. The first is a universal design that may be adjusted to the size of any user and the second is a less adjustable collar that is manufactured in a line of several sizes. There are many advantages to both types. Most notably, the universal collars require less storage space before use, particularly for EMTs and requires no risk in applying the wrong size collar in an emergency. However, with its many added parts, the universal collars are heavier, more expensive, take a longer time to adjust once applied, and are found to be less comfortable to patients.

Two of the most dominating manufacturers in the cervical collar market were studied for this project: Ossur (the Miami J collar) and Aspen. The Miami J is recognized for its comfortable Sorbatex foam padding designed to be antibacterial, antimicrobial, and moisture wicking. The classic Miami J is available in 6 sizes, each based on a phenotype designed for a specific size patient. Also available from Ossur is a universal model, the Miami J Advanced and the Philadelphia models which provide rigid support with less cushion (2). The Aspen model has similar features to the Ossur models but is also recognized for its unique inner padding material. The foam liner is designed to be hypoallergenic and customizable to any neck shape. The Aspen Universal also has a unique trachea opening that is adjustable by use of a crank rather than straps, which allows for a more comfortable fit along the chin (3). Both Aspen and Ossur manufacture the outer shell portion of the cervical collars using polyethylene plastic. This material allows the collars to provide the needed support, yet it is flexible enough to bend if necessary (2, 3).

As stated above, Aspen and Ossur are the dominating manufacturers in the cervical collar market today, resulting in AK Design solutions focusing on devices made by those two companies in the testing and design phases of the project. For further information regarding the research done on each of the collars, refer to *Appendix A*.

### **Current Commonly Seen Issues/Current Design Flaws**

Because the singular purpose of a cervical collar is to restrict the patients' movements to less than 30 degrees, the main complaint with the device is patient comfort. Based on the

valuable input from Dr. Tiffany Marchand, patient discomfort was narrowed down to “feeling overheated” and “too much pressure” underneath the chin and on the jaw. Though comfort is certainly not a priority over a patient’s health, it can lead to many other serious problems such as pressure ulcers or causing patients to remove their collars prematurely in the prescribed duration of use. Also, Dr. Marchand emphasized that many of the problems with current cervical collars are seen with elderly patients. Research was conducted on the degenerative issues among the elderly that can increase patient risk for secondary side effects from cervical collar use (4).

## **VI. Design Method**

The team maintained the standard design process throughout the modified cervical collar design. By creating an objective tree, constraints and limitations list, and functional requirements, the AK Design Solutions team members were able to formulate a clear vision of the design methods necessary to execute the modified cervical collar.

### **Constraints and Limitations**

Several constraints exist when designing a modified cervical collar. Although each cervical collar is initially sized and fit for each patient by medically trained personnel, the patient is often asked to manage the use of the collar while outside of medical facilities. In many cases, this can be for many weeks of recovery. Without medical training, many patients struggle complying with the guidelines of cervical collar use. It is necessary for the team to consider the limitations that occur with patients without medical backgrounds. Many patients remove the collars because of discomfort, overheating, and the inability to perform daily functions. While designing the modified cervical collar, the team must modify and/or eliminate the patient’s ability to remove the collar in order to secure patient safety and their ability to heal properly. Limitations also include those which exist within a medical facility. Many professionals are limited by an inability to communicate with patients about their comfort needs. While some complaints from patients are due to inexperience with the collars, many patients have severe discomfort problems that can lead to pressure sores and/or dysphagia. The constraint of limited design time greatly affected the team. Although six months is sufficient to design a modification to a cervical collar, it is difficult to research, design, test and produce a final and successful project in the short time. The team worked vigorously to maintain this time constraint.

### **Functional Requirements**

Please refer to *Appendix B* to view the functional requirements for the project organized into an objective tree prior to the manufacture stage.

## **VII. Procedures and Manufacturing**

After defining the design methods, constraints, and requirements, the team divided into sub-teams to design the two main portions of the modified cervical collar design. Samantha Ballash and Elizabeth Rondinelli created the prototype for the Outer Shell Design. Katharine Hodgson and Jessica Augustynovich created the inner padding design for the modified cervical collar.

### **Justification of Outer Shell Design**

The process of developing a new design for the outer frame began by interpreting results of an end-user survey generated by AK Design Solutions. Similar to the comfort evaluation utilized by Sigurbergur et al., “Evaluation of Clinical Efficacy and Safety of Cervical Trauma Collars: Differences in Immobilization, Effect on Jugular Venous Pressure and Patient Comfort” (5), the end-user survey included simple questions evaluating a patient’s overall comfort, ability to perform daily tasks, and comfort in specific regions including the neck, chin, etc. Each person surveyed rated their level of comfort on a scale from 1 to 5, 1 being strongly disagree and 5 being strongly agree. Team members administered this survey to friends and associates by asking them to wear a popular cervical collar for a minimum of twenty minutes and then recorded the answers regarding the experience. A total of fifteen end user survey results were documented. From the results, the average comfort score of each individual was summarized. The higher average score resulted in a more comfortable cervical collar as determined by the individuals tested. The interpretation of the results, in addition to the engineering perspective of the design team, led to the decision that the prototype cervical collar would include the most beneficial aspects of both the Aspen and the Miami J outer frame designs, two of the most widely used cervical collars currently on the market. Although the Philadelphia adjustable collar received the highest score from the survey, it is a soft collar; thus, it should have resulted in a more comfortable experience for the surveyed individuals. Please see *Appendix C* for the end-user survey utilized and the results of this survey.

### **Outer Shell Prototype Design**

The sub-team met and drafted the final collar design soon after selecting the frame material, 1/16th inch thick polyethylene. The material was chosen based off the material used in the Aspen and Miami J collars and with advice from Baker Plastics in Youngstown, Ohio. It was decided that the team would create a non-universal, phenotypically sized collar relatively close to the “regular” size that is utilized by both Aspen and Miami J. The “regular” size collar is the proper size for most mature females; thus, allowing the team to perform testing utilizing the team members. The modified cervical collar design utilizes a two-piece design with velcro straps to connect the collar from front to back. The back piece of the new shell design is 10.20 inches by 6.65 inches with small cutouts and a large opening in the center for flexibility. This design was chosen because it lends enough support to the occipital region without applying excess pressure from the plastic. The inner padding design for the back portion is much larger



that than outer shell, providing the extra support where necessary. The front piece of the collar is 14.30 inches by 6.20 inches. It extends beneath the ears on both sides and onto the chest area. A hole was cut in the center for a tracheal opening in case of emergencies. Several designs for the chin support have been discussed by the sub-team. The team has eliminated small portions of the polyethylene below the jaw line while maintaining the same shape as the original design. The modified front piece includes a chin support that rests on the patient's jaw line. Using heat, the polyethylene was curved to support the chin area. A small 2 inch section of polyethylene was removed from below the chin as compared to current collars. This modification should reduce dysphagia in patients; however, the team must evaluate the modification during testing in order to prove that the modified collar reduces patient discomfort, yet maintains the restraint of 30 degrees or less range of motion of the cervical spine.

The sub-team sketched the front and back pieces with various chin modifications on large polyethylene sheets and utilized the scroll saw in the biomedical engineering design lab to construct the outer shell prototype. Sandpaper was used to smooth all of the edges of the collar. The team used heat to mold the collar to the appropriate shape and to thin the edges of the back piece to better support the occipital region and provide less pressure in that area.

### **Inner padding/ Gel material**

For the second design change, AK Design Solutions has designed a cooling system to be integrated into the current inner foam padding of the collar. The purpose of this system is to cool the patient while also relieving pressure at commonly irritated areas. Through testing and validation, the team hopes to create a collar that remains ten degrees (° F) cooler than the patient for at least an hour after wearing.

### **Testing and Justification of Cooling System**

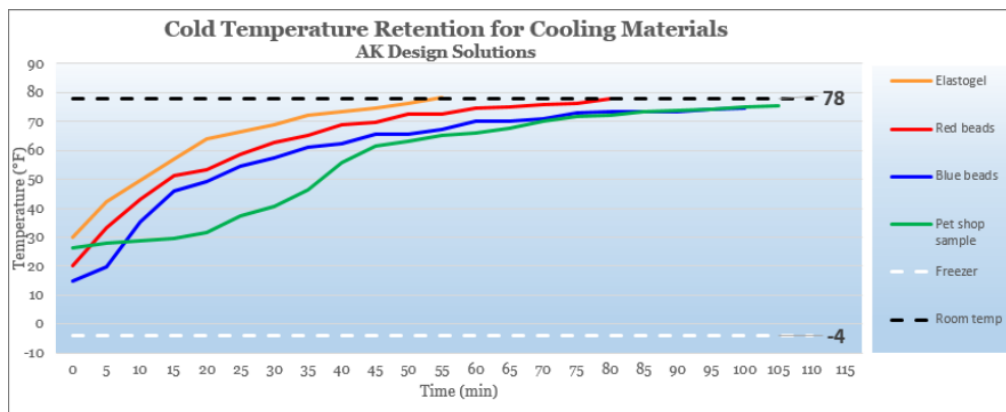
The design and manufacture of the inner portion of the collar depended on several layers of material acting together to help cool the patient. Therefore, testing was performed in order to select optimal materials for each material requirement of the cooling system: the active cooling material, padding, and outer fabric. Much of the testing performed is largely due to the aid and expertise provided by L. Terry Clausing, P.E., CEA of Drysdale & Associates, Inc. AK Design Solutions made two separate visits to his laboratory facility located in Cincinnati, OH. During the first visit, thermal images were taken with an IR camera for visualization purposes of determining heat mapping. *See Appendix D.*

As there are many existing products that are designed for cooling purposes, it was necessary to perform testing on several options in order to determine which would have the greatest effect on body temperature.

Three materials were selected as potential cooling materials:

1. small freezable beads (ThearPearl Technologies)
2. a pressure activated cooling pad (The Green Pet Shop)
3. Elastogel freezable therapy pads (Southwest Technologies)

The cooling gel pack material was chosen based on the results of two tests conducted by the sub-team: a cold temperature retention test and an in-collar test involving temperature monitoring via a quad-thermocouple. The cold retention test was performed by taking all potential cooling materials chosen from researching options, placing them in a freezer at -4° F for three hours and then monitoring the temperature in five minute intervals until room temperature was once again recorded. Reference *Appendix E*. The results of this test were favorable to the pressure activated cooling pad as well as the small freezable beads (see *Figure 1*). The second test performed to aid in the selection of a cooling gel material was an in-collar temperature test, in which four thermocouples were placed in strategic locations inside a cervical collar and temperature was monitored for a subject first wearing the collar only, and again with the subject wearing the collar with a test material inside it.



**Figure 1. Cold Temperature Retention Test: Selecting Cooling Material**

Results from both tests were consistent with the sub-team hypothesis, and the final cooling material for the prototype was selected to be a combination of the dog cooling pad and the free-moving freezable beads. The gel pad proved to sustain the lowest temperature for the longest period of time and the beads are a simple addition that will provide some pliability and cushion to the stiffer gel pad.

The final padding material was selected based on criteria for functionality developed by the team. The padding needed to be antimicrobial, waterproof, puncture resistant, and have fair airflow to reduce heat and pressure accumulation. Based on the design requirements and budget restrictions, the padding selected for use was a reticulated foam sheet from Fabric Empire.

The fabric selection for the prototype is currently in process. Similar to the gel, several fabrics were chosen in order to test the sustainability of the cooling system through a fabric. Assuming similar results, the same testing as was done on the gels was repeated with each fabric on the chosen gel combination. All potential fabric test materials have been collected and the final selection will be chosen based on the results of two tests. The first test will be a repeat of the in-collar quad-thermocouple temperature monitoring test with the variable material being the fabric selection in place of the cooling gel pack material selection. This is significant because the fabric must not insulate the cooling gel pack material inside in the lining, which would eliminate its entire purpose of keeping the patient cool. The second test will be a very basic skin-compatibility test in which members of the sub-team will place patches of potential materials in direct contact with their skin for approximately twelve hours and observe adverse effects, (if any).

The final components chosen for the “cooling system” based on the tests above are as follows:

- 1 part pressure activated cooling gel (The Green Pet Shop)
- 1 bag freezer beads (TheraPearl Technologies)
- 1 puncture resistant, polyolefin film shrink wrap bag (various sizes) (National Shrinkwrap)
- Antimicrobial foam padding (various sizes) (Fabric Empire)
- A fabric covering (examples seen in *Appendix E* are still to be tested)

Manufacturing of the inner lining containing all components of the cooling system will be assembled with by use of a heat gun/hair dryer and a sewing machine.

## VIII. Performance Testing

The performance and effectiveness of the final prototype will be evaluated by means of three tests. See *Appendix E* for all associated figures and tables.

1. Comparison to baseline temperature test results for the Aspen, Miami J collars
2. Validation of the benchmark design goal: Collar effectively keeps the body at least ten degrees cooler than body temperature for a minimum of one hour
3. Patient Comfort Evaluation
4. Validation that the collar successfully restricts the patient to a maximum 30 degrees range of motion during use.

Baseline data for the inner padding material was established during the first visit with L. Terry Clausing, monitoring temperatures on the neck for subjects wearing the Aspen and Miami J cervical collars. The performance of the final inner padding of the prototype will

be evaluated by executing the same testing protocol on a subject wearing the prototype device and comparing the data to the baseline test results. The design goal will be considered complete if the system successfully remains at least ten degrees cooler than body temperature for at least one hour following application.

Testing for the outer shell modifications will be determined utilizing the same end-user survey to evaluate patient comfort. Preferably, the same individuals will be surveyed comparing the comfort of the modified design to the Aspen and Miami J collars. Also, the prototype and various chin support designs must be evaluated for movement limitation under 30 degrees. A universal goniometer will be used to obtain general range of motion values for the modified cervical collar prototype as a whole. If possible, the team would like to perform testing similar to the testing provided by Sigurbergur et al. The outer shell sub-team is interested in utilizing a Cervical Range of Motion instrument, CROM, if possible. The performance testing is necessary to provide data that demonstrates the team's overall design modifications as successful.

## **IX. Future Direction of Project**

Testing of the modified cervical collar prototype must be completed in order to provide results of the substantial changes as stated above. Upon completing the goals outlined above, AK Design Solutions will maintain contact with Dr. Tiffany Marchand to obtain any further suggestions that she may have to refine the collars design. AK Design Solutions also hopes to implement some of the design changes that were cut due to time constraints most notably, the idea to create perforated edges for easy sizing adjustments. Finally, the team plans to manufacture the collar in several sizes so that testing may be done on a wider range of patients.

## **X. Project Timeline**

Please refer to the original and final GANTT charts in *Appendix F*.

## **XI. Budget**

As a team, we were allocated a budget of \$500 to complete our design project including the research phase, prototype construction, and performance testing. A request for increased funds could have been made if needed; however, the team was able to keep our project under budget while maintaining a high standard of quality in our chosen device materials. Donations of various cervical collars and cooling materials were made to AK Design Solutions from the following companies: Ossur, Aspen Medical Products, Steris, DeRoyal, Southwest Technologies, Inc., and Green Pet Shop. This enabled the team to remain comfortably under budget while conducting preliminary research on the current collars and available gel materials in determining our material selections. At the near completion of our design, the vast majority of our expenses was designated to prototype design and production.

## **XII. Acknowledgements**

AK Design Solutions would like to thank the following persons and businesses for their contributions to this project:

- I. **Terry Clausing** for consultation with his expertise in thermal properties and free access to his laboratory facilities and equipment.
- II. **Dr. Mary C. Verstraete** for her dedication to the team's success, and continuous support and availability during each phase of the design process.
- III. **Dr. Tiffany Marchand** for her valuable input on current design flaws in cervical collars, her field experience, and her evaluation of proposed design concepts.
- IV. **Michelle Evancho-Chapman** for her project guidance and expertise in patents.
- V. **Dan Daubner** from **Steris** for donating two aquagel pressure relieving pads and spending time responding to team inquiries.
- VI. **Brian Frazier Wright** from **The Green Pet Shop** for donating a sample of their pressure activated cooling pads to the team, for allowing AK Design Solutions to implement it into their final design, and for taking the time to answer many questions regarding its material and mechanical properties.
- VII. **Maxy D'Llachieza** from **Southwest Technologies Inc.** for a generous donation of several hot/cold therapy packs and informative associated marketing materials.
- VIII. **Rebecca Harnon** from **DeRoyal** for a generous donation of three cervical collars.
- IX. **Danielle Woodburn** from **Ossur** for her dedication in locating the data requested by the team and generous donation of several top of the line cervical collars.
- X. **Steve Burke** from **Aspen Medical Products** for donating his time and attention to the design teams efforts. The 10 collars, including the Aspen Vista, that Steve was able to contribute to the project were invaluable during the research, testing, and final design process.
- XI. **Mrs. Karen Augustynovich** for her time and effort in aiding assembly of sewed materials for both testing purposes and final prototype production.

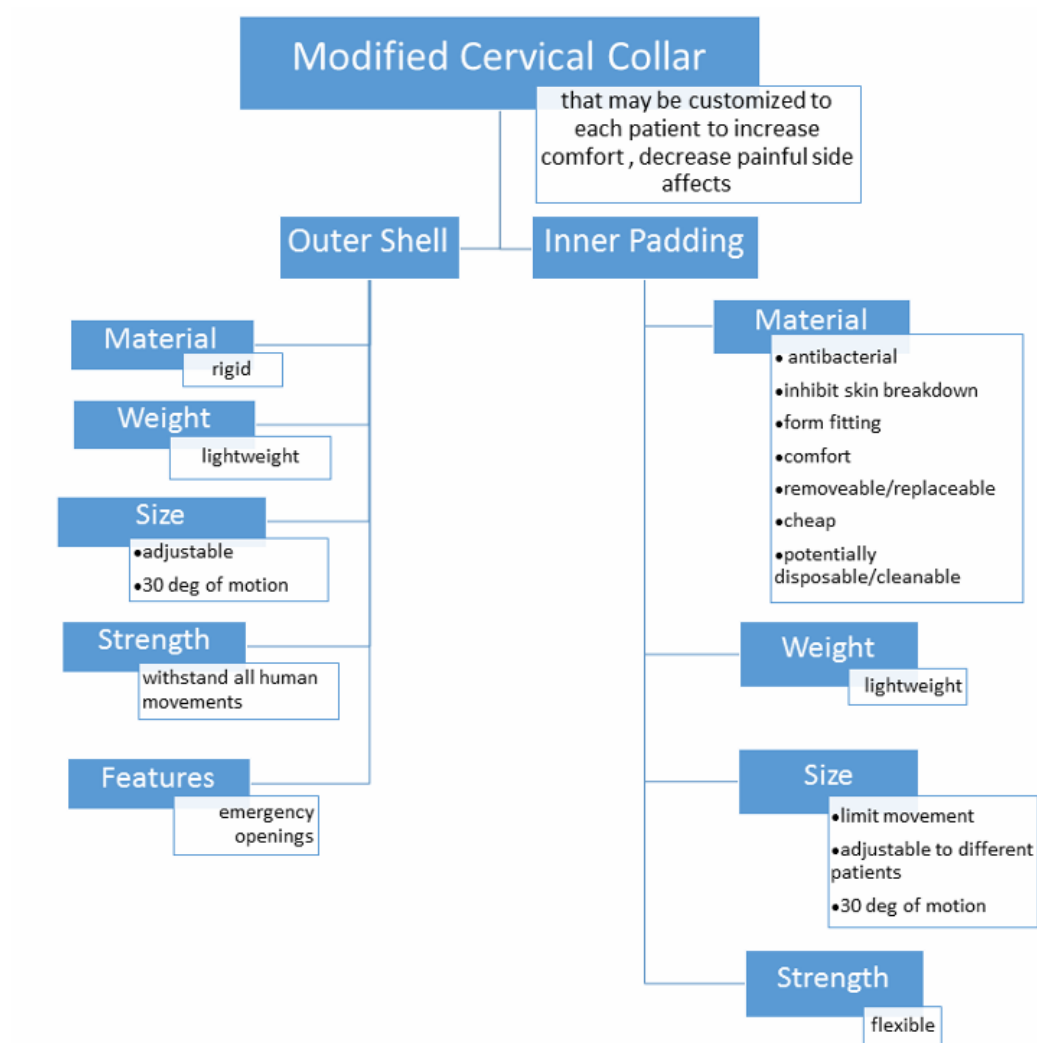
### XIII. References

- (1) "Soft and Rigid Cervical Collars". South Beach Orthotics & Prosthetics. Web. 8 Apr. 2015  
[http://www.southbeachop.com/orthotic\\_services/soft-and-rigid-cervical-collars/](http://www.southbeachop.com/orthotic_services/soft-and-rigid-cervical-collars/)
- (2) "Miami J." *Miami J.* Össur Americas, 2014. Web. 29 Oct. 2014.  
<http://www.ossur.com/injury-solutions/products/spine/hospital-and-rehabilitation-collars/miami-j>
- (3) "Aspen Cervical Collar." Aspen® Collar. Aspen Medical Products, n.d. Web. 29 Oct. 2014.  
<http://www.aspenmp.com/index.php/products/upper-spine/aspen-collar/>
- (4) Haid, Regis W., Jr. "How Aging Affects Your Cervical Spine." SpineUniverse. Vertical Health, LLC, 28 Jan. 2014. Web. 24 Nov. 2014.
- (5) Karason, Sigurbergur, Kristbjorn Reynisson, Kristinn Sigvaldason, and Gisli H. Sigurdsson. "Evaluation of Clinical Efficacy and Safety of Cervical Trauma Collars: Differences in Immobilization, Effect on Jugular Venous Pressure and Patient Comfort." *Scandinavian Journal of Trauma, Resuscitation, and Emergency Medicine* 22.37 (2014). SJTREM. BioMed Central, Ltd., 6 June 2014. Web. 24 Nov. 2014.

XIV. Appendices

**Appendix A: Current Cervical Collar Summary**

	Aspen	Miami J	Miami J Advanced	Philadelphia Tracheotomy	Philadelphia Adjustable	Malibu
<b>Website</b>	<a href="http://www.aspenm.com/index.php?option=com_content&amp;view=article&amp;id=12:aspen-cervical-collars">http://www.aspenm.com/index.php?option=com_content&amp;view=article&amp;id=12:aspen-cervical-collars</a>	<a href="http://www.ossur.com/factory-solutions">http://www.ossur.com/factory-solutions</a>	<a href="http://www.ossur.com/factory-solutions">http://www.ossur.com/factory-solutions</a>	<a href="http://www.ossur.com/factory-solutions/product">http://www.ossur.com/factory-solutions/product</a>	<a href="http://www.ossur.com/factory-solutions/product">http://www.ossur.com/factory-solutions/product</a>	<a href="http://trulife.com/all-products/ortho/">http://trulife.com/all-products/ortho/</a>
<b>Information Available Online</b>	Sizing Charts, Product Information, Instruction Book, Patient Handbook, several really useful related studies	Catalog, Patient Care Handbook, Sizing and Application Instructions, useful related studies on cervical collars	Catalog sheet, Instructions for Use, Technical Manual	Instructions for use, catalog page, related studies	Instructions for use, related studies,	Product brochure, ordering information
<b>Manufacturer</b>	Aspen Medical Products	Ossur	Ossur	Ossur	Ossur	Trulife
<b>Cost</b>	~ \$40	~ \$60- \$130	Ossur	~ \$10 - \$30	?	~ 130
<b>Advertising Points</b>	*Effective Motion Restriction *Minimal Skin Breakdown *Custom Support	*Sorbatex padding enhances comfort and helps assure patient compliance *Minimize pressure points *Sizing based on 6 phenotypes to assure proper fit and immobilization *Comfort adjustment buttons and removable sternal pad for swallowing	*Sorbatex padding and soft, overmolded edges minimizes skin breakdown and prevents pressure sores *Adjustable sizing allows you to reduce inventory, without compromising fit *Two distinctly shaped frontback pads male use intuitive	*Limits movement, maintains neutral alignment of c-spine *Water resistant *Easily customizable *Plastazote foam (trademarked) reduces skin irritation *X-ray lucent *Hospital safe *Washable with soap and water	*Limits movement, maintains neutral alignment of c-spine *Water resistant *Easily customizable *Plastazote foam (trademarked) reduces skin irritation *X-ray lucent *Hospital safe *Washable with soap and water *Adjustable bilateral fasteners *Ventilation openings *Tear off tabs in foam to provide better fit	*Heat Mouldable *Lightweight, washable Kydex *Trachea Opening *Optional Liner available *Anterior/Posterior independently height adjustable *Made of non-ferrous materials *Rigid support controls flexion, extension, and rotation
<b>Unique Features</b>	CushionFlex tabs Occipital Support Strap	Sorbatex foam padding Assist Strap Angulation Buttons	*Flex Edge™ (TM) overmolding Removable sternal extension Sorbatex foam padding Self Adjustment slide (for 6 phenotypes)	Plastazote hook and loop fastener	Tear off tabs in foam to provide better fit, adjustable bilateral fasteners	Thoracic Extension, heat moldable
<b>Shell Material</b>	?	?	?	"rigid plastic,"	same as Philadelphia Tracheotomy	Kydex
<b>Shell Features</b>	Trachea opening, Occipital support Strap allows customization for a better fit, CushionFlex tabs	Angulation Buttons, Trachea opening, removable sternal extension	Angulation Buttons, Ventilation holes, security hooks, Trachea opening, removable sternal extension,	waterproof, trachea opening for pulse monitoring and emergency tracheotomy	Waterproof, trachea opening for pulse monitoring and emergency tracheotomy, adjustable bilateral fasteners for better fit, ventilation openings to reduce heat and moisture, waterproof, trachea opening for pulse monitoring and emergency tracheotomy.	trachea opening, Thoracic extension, mouldable composite uprings.
<b>Foam Material</b>	cotton-lined ??	Sorbatex (trademarked)	Sorbatex (trademarked)	Plastazote (trademarked)	Plastazote (trademarked)	?
<b>Foam Features</b>	Hypoallergenic, "clickable" foam (means that when it is cut, it will not have a pinched edge, but will regain its original shape), cotton-lined	antibacterial, antimicrobial, moisture wicking, high thermal conductivity (keeps patient cool)	antibacterial, antimicrobial, moisture wicking, high thermal conductivity (keeps patient cool)	antibacterial, antimicrobial, moisture wicking, high thermal conductivity (keeps patient cool)	Latex-free, non-toxic, hypoallergenic, waterproof, tear-off tabs to provide for a better fit	Replaceable
<b>Replacement Pads</b>	Yes, changed/cleaned daily	Yes, changed 1x/shift for admitted patients changed 1x/24 or 48 hrs for discharged patients	Yes, changed 1x/shift for admitted patients changed 1x/24 or 48 hrs for discharged patients	No, There are optional washable and reusable liners to wear overtop of collar, sold separately.	No, There are optional washable and reusable liners to wear overtop of collar, sold separately.	Yes.
<b>Sizes Available</b>	Infant/Pediatric (sizes 1 - 5) Adult Short Adult Regular Adult Tail Extra Tail	Super Short Short XS Regular Tail Short Bariatric	Short Tail Regular Short Bariatric	Infant Pediatric X-Small Small Medium Large X-Large	one adjustable size ("fits 95% of patients")	Pediatric Small Pediatric Large Adult
<b>Strengths</b>	Occipital support strap for customization					
<b>Weaknesses</b>						
<b>Add'l notes</b>	See "Education" > "Research" > "Upper Spine" for very useful publications to add to our research	also has useful studies that would be useful to our team's information gathering	Improved model of Miami J, more adjustable so less sizes available	*They also sell Coolmax(TM) liners to put over the collars and padding, they are washable and reusable. <a href="http://assets.ossur.com/issalibgetfile.aspx?itemid=7157">http://assets.ossur.com/issalibgetfile.aspx?itemid=7157</a>	Improved and very new model of the Philadelphia	There are 4 different models: Side snap buckles, hook and loop fastener, MRI compatible, and Pediatric.



**Appendix B: Functional Requirements/Objective Tree**



AK Design Solutions  
End User Survey

Name: \_\_\_\_\_

Date: \_\_\_\_\_

After wearing the collar for a minimum of 20 minutes, please answer the following questions as honestly as possible. The collar may be removed after completion of this survey.

1                      2                      3                      4                      5  
Strongly Disagree.....Strongly Agree

Collar: (circle one)

Aspen (Small/Reg/Tall)      Aspen Vista      Miami J      Miami J Adv.      Other: \_\_\_\_\_

1. I feel that the collar is fitted properly. <i>No gaps between the neck and the collar, collar fits snugly under the chin. Left-Right and Up-Down movement should not comfortably exceed 30° of motion.</i>	
2. I am able to swallow water well.	
3. I am able to chew food well.	
4. My collarbones feel fine and are not in pain.	
5. My jaw/chin feels fine and is not in pain.	
6. While sitting straight and in good posture, my back is not in pain.	
7. I feel I am able to complete normal everyday tasks (i.e. brush my teeth).	
8. I feel no skin irritation or itchiness because of the collar.	
9. I am able to look to the left and right without twisting my neck. <i>You should be inclined to turn your torso Left/Right instead of sharply tweaking your neck while wearing the collar.</i>	
10. I could wear this collar for an entire day.	
11. On a scale of 1-5, how warm does your neck feel? <i>1 = Comfortable, not warm at all..... 5 = Very Uncomfortably warm</i>	
12. On a scale of 1-5, how warm do your chin/cheeks feel? <i>1 = Comfortable, not warm at all..... 5 = Very Uncomfortably warm</i>	
13. On a scale of 1-5, how warm does your jaw feel? <i>1 = Comfortable, not warm at all..... 5 = Very Uncomfortably warm</i>	
14. On a scale of 1-5, how warm does the back of your head feel? <i>1 = Comfortable, not warm at all..... 5 = Very Uncomfortably warm</i>	

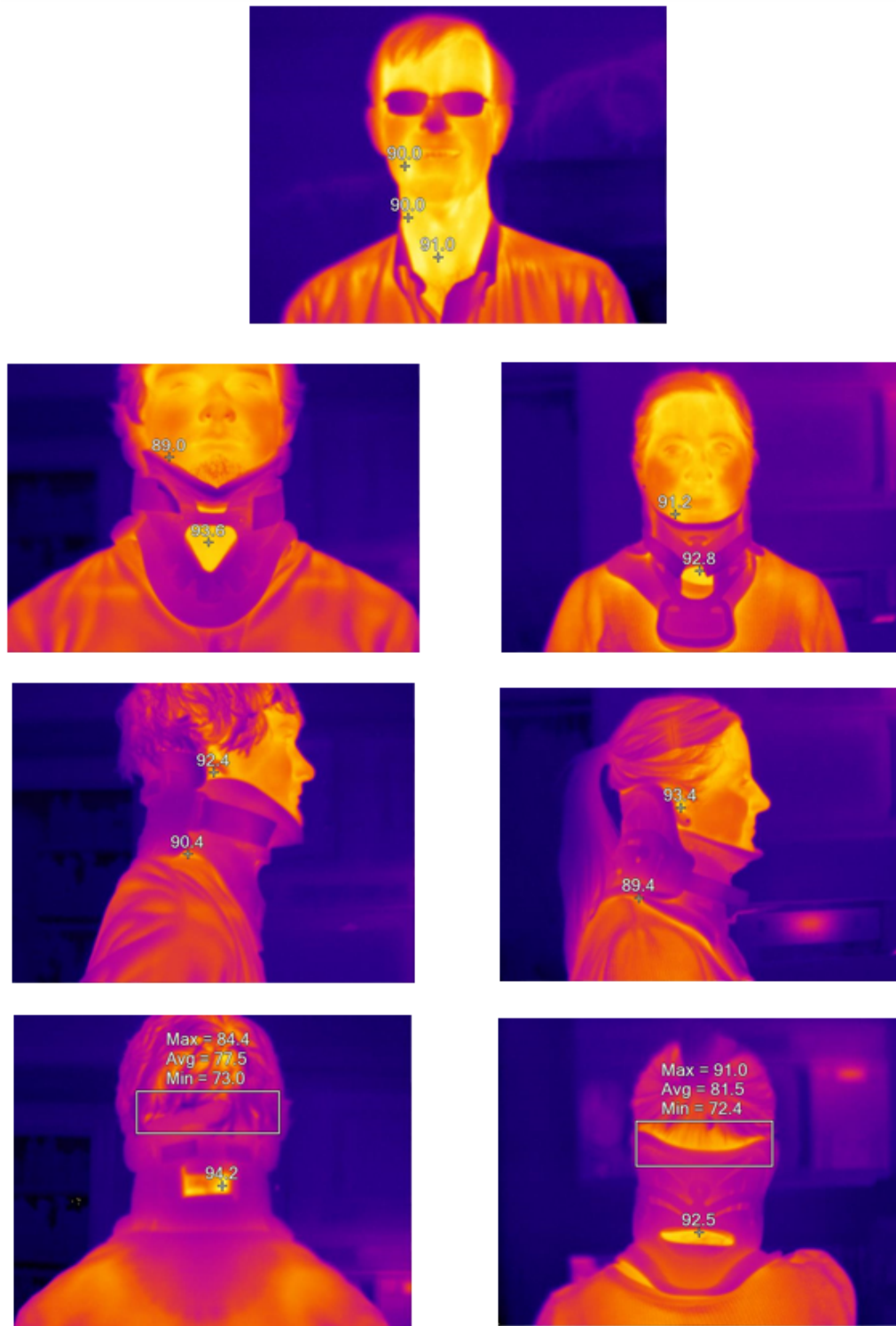
If you have tried on several collars, which do you prefer and why?

**Appendix C: End User Survey**

**Survey Results**

<b>Collar Type</b>	<b>Average Score</b>
Aspen (Small/ Regular/Tall)	45.67
Aspen Vista (Universal)	43.67
Miami J Advanced (Universal)	40.50
Miami J (Regular)	45.67
Philadelphia Adjustable (Universal)	47.33
DeRoyal Capital	40.33

**Appendix D: Thermal Images of Collars in Use**



**Figure D1. Aspen (pictured Left) and Miami J (pictured right)**

**Appendix E: Testing; Associated Figures and Tables**

Cooling Gel Material: Cold Temperature Retention Test



**Figure E1. Potential cooling gel materials**

Freezer Temperature: -4 °F				
Avg Room Temperature: 78 °F				
Time (min)	Elastogel (4"x4")	Freezable beads, air insulated (4"x4")	Freezable beads, open air (4"x4")	Pressure activated cooling pad (4"x4")
0	10.7	12	8.1	21.4
5	30	20.1	14.9	26.3
10	42.2	33.4	19.9	27.8
15	49.5	43.2	35.2	28.6
20	56.8	51.4	46	29.4
25	64.1	53.2	49.2	31.5
30	66.5	58.8	54.5	37.5
35	69	62.6	57.4	40.6
40	72.2	65.1	61	46.4
45	73.3	68.8	62.3	55.8
50	74.8	69.6	65.5	61.3
55	76.2	72.5	65.7	63.3
60	78.4	72.5	67.3	65
65		74.5	69.9	66.2
70		74.9	70.2	67.8
75		75.9	71.1	70.2
80		76.3	73	71.6
85		77.8	73.3	72.2
90			73.5	73.2
95			73.5	73.8
100			74.1	74.3
105			74.8	74.9
110				75.3
115				
120				

**Table E1. Cold Retention Test Results**

Cooling Gel Material: In-Collar Test



Figure E2. Quad-Thermocouple placement in Aspen and Miami J collars

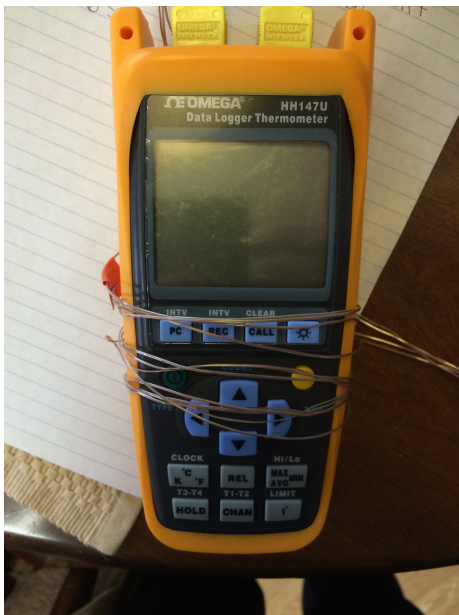


Figure E3. Omega Data Logger Thermometer



Fabric Material: Cold Temperature Retention Test (To Be Completed)

Fabric Material: Skin Compatibility Test (To Be Completed)



**Figure E4. Potential fabric materials**

Outer Shell: Cervical Range of Motion Test (To Be Completed)

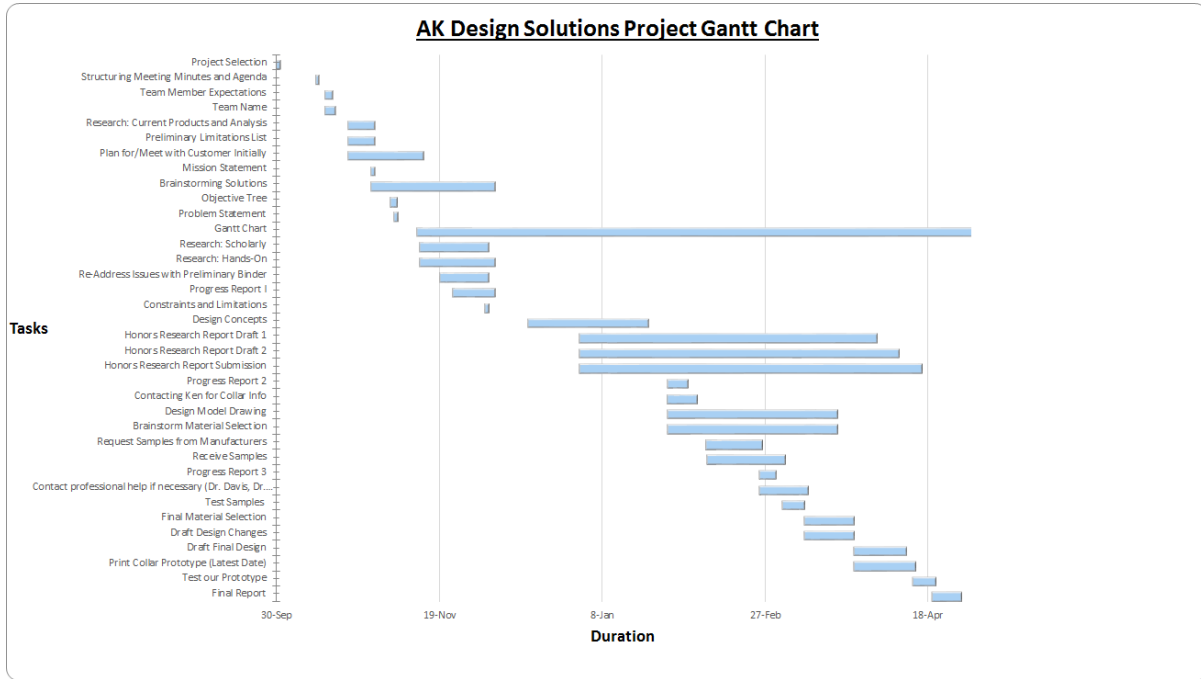
Final Prototype: In-Collar Test (To Be Completed)

Final Prototype: Validation of Effective Cooling (To Be Completed)

Final Prototype: Patient Comfort Evaluation (To Be Completed)

**Appendix F: Project Timeline**

Original GANTT Chart. Date of creation: 30 September 2014



Finalized GANTT Chart. Date of final revision: 09 April 2015

