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AMT Bridle Clip Re-design

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AMT Bridle Clip Re-design

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Department of Biomedical Engineering

Honors Research Project

Submitted to

The Honors College

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Introduction

Applied Medical Technology (AMT) is a rapidly growing medical device company located in Brecksville, Ohio. AMT designs and manufactures enteral feeding devices and feed sets, as well as many different types of feeding accessories. In October of 2014, AMT came to The University of Akron's Biomedical Engineering department for help with a project regarding one of their top selling products, The AMT Bridle. This project was assigned to a group of senior Biomedical Engineering students consisting of Alexandra Bruck, Frandy Cador, Boubacar Ide, and Andrew Lang. After being assigned the project from AMT, the team would go on to appropriately call themselves "Ameri-Clip Medical," and would spend the next several months focusing on improving the AMT Bridle as requested.

Based on the needs statement provided by AMT (Appendix I), Ameri-Clip Medical was able to generate the following problem statement to help focus their efforts for the project:

- The AMT Bridle Nasal Tube Retaining System features a small clip used to hold a nasal tube in place. The clip must be small in size in order to minimize obstruction around the patient's nose. The small size makes the clip difficult for the nurse or physician to handle. Therefore, a need exists for a clip redesign. The design should maintain the same size and shape as the current clip and should be manufactured using the same mold tooling. The design should be easier to handle and attach to the nasal tube while still providing adequate nasal tube retention.

The team was to work independently for the most part, but if any questions arose, they were to consult Derek Williams, the Engineering Manager at AMT. Mr. Williams would be the main contact for the project and would have the final say in any design changes that Ameri-Clip Medical proposed to implement.

Background Information

The AMT Bridle Nasal Tube Retaining System is a product used in healthcare facilities worldwide to reduce the risk of inadvertent nasal feeding tube pullouts. The Bridle system consists of a piece of umbilical tape that is passed through the nasopharynx and around the vomer bone. The umbilical tape is then anchored to the feeding tube using a specially designed Bridle clip. Figure 1 illustrates how the Bridle system looks and how it is placed.

The Bridle system comes in a variety of packages which depend on the size of the nasal tube that the patient has. The umbilical tape component of the Bridle remains the same regardless of the size of the feeding tube. The clip however, will change based on the size of the feeding tube that it is retaining (referred to as French Size). The clips all have the same outside dimensions, but the inner slot that holds the feeding tube changes to accommodate the different tube French sizes. The current AMT clips are color coded based on French size, but there is no labeling to indicate which French size each color clip is compatible with. The team felt that this lack of labeling could lead to confusion and misuse if the wrong size clip was used for a patient's feeding tube.

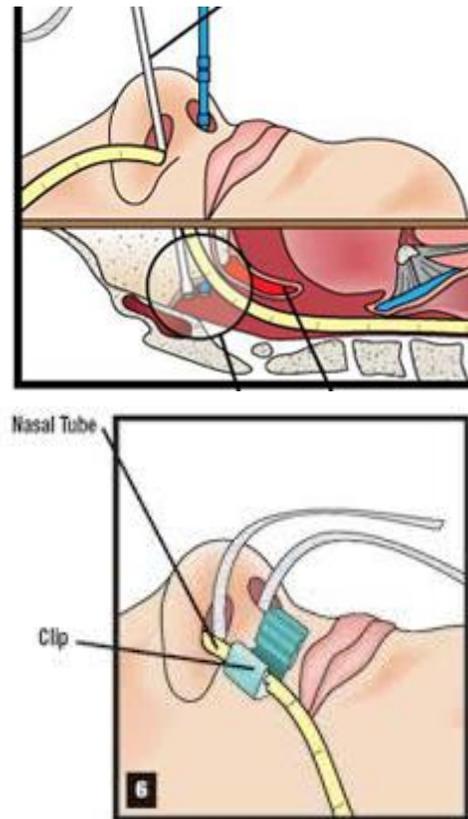


Figure 1: AMT Bridle System

The current Bridle clip is very small in size. Therefore, it is sometimes difficult for the nurse or physician to handle while applying to the patient. For this reason, AMT recruited a

BME design team for help in re-designing the clip to make it more user-friendly. It is imperative that clip maintains roughly the same overall size to minimize obstruction around the patient's mouth and nose. Also, the existing mold tooling should still be used to save cost. Overall, the clip should be more user friendly, while still serving its purpose in the Bridle system.

The fundamental problems with the current AMT clip are its small size, slippery texture,



Figure 2: AMT Bridle Clip

and high level of difficulty for opening. Since the clip is a separate component of the Bridle system, it must be picked up and connected to the feeding tube and umbilical tape after the Bridle system is placed. Therefore, the small size of the clip could potentially cause the practitioner to drop it, causing inconvenience and sanitation problems. The difficulties only increase when the practitioner must

handle the clip in the close quarters near the patients face. Figure 2 shows the current AMT Bridle clip in the open position as it appears after molding and how it would appear to the practitioner.

After thorough evaluation of AMT's current bridle clip, the team was able to compile the following list of problems regarding the clip that they would like to solve:

1. Clip is slippery/difficult to handle
2. Clip is difficult for the physician to open (important for removal and replacement)
3. No French size labeled on clip

Team Ameri-Clip Medical was confident that if the above issues could be remedied, then the new clip design would be more user-friendly and effective while still serving its purpose in the Bridle system.

Project Objectives and Goals

The team's primary goal for this project assignment was to improve the quality and ease of use of the AMT Bridle clip. The team also wanted to be sure to follow the accepted design process to ensure thorough attention to detail. The goal was to re-design the Bridle clip by methodically going through the design process and adequately resolving the issues discovered with current Bridle clip that were previously outlined. The team wanted to solve these problems while still abiding by the constraints and limitations (Appendix III) that were both spelled out by AMT's needs statement (Appendix I) and deduced by the team members. Overall, Ameri-Clip Medical's goal was to work hard and satisfy all the needs of their customer, AMT, while professionally and cooperatively adhering to a design process that would help ensure quality results.

Methods

The team began meeting to discuss the project shortly after it was assigned to them, and would continue meeting weekly for the next several months to accomplish the task. At the very first meeting, the team began by signing AMT's non-disclosure policy per the company's request. For this reason, the team was not at liberty to discuss some of the finer details of the project with outsiders. The first meeting was also when the needs statement was introduced to the team, and everyone became acquainted with the problem at hand. The team agreed to name themselves "Ameri-Clip Medical" and would be referred to as such for the duration of the project.

Early meetings also covered items such as determining the team's mission statement, team member expectations and goals, and problem statement (see Introduction section) so that Ameri-Clip Medical could properly focus their efforts in the right direction. After the problem

was fully defined, the team began brainstorming on the functional requirements (Appendix II) for the new Bridle clip that was to be designed. Functional requirements were deduced in two fashions: by simply listing out the requirements as well as putting together an objective tree. By conducting these exercises, Ameri-Clip Medical fully understood all the necessary components that must be included in the new design.

The team's next step was to spell out any constraints or limitations that could be encountered during the design process (Appendix III). The project constraints could be broken up into three categories: patient constraints, nurse/practitioner constraints, and engineering constraints. The patient constraints included items such as the cost, availability, comfort, and aesthetics of the device. The nurse/practitioner constraints included ease of use requirements. The engineering constraints were spelled out for the team by AMT in the needs statement. These included requirements for the clip to maintain relatively the same size and shape, and for the device to be made using the same mold tooling as the current Bridle clip. As far as limitations, the team recognized that since three of the team members had either previously worked or currently work at AMT, that they may be biased as far as design ideas, a problem that must be dealt with properly.

Once the design requirements, constraints, and limitations were spelled out, Ameri-Clip Medical became comfortable with the project and the true underlying problems and was ready to begin researching new ideas. The team began by looking at AMT's current and past Bridle clip designs. The team members who work at AMT were able to acquire several of the clips that the team could examine and use however they felt necessary throughout the project. Ameri-Clip Medical also researched what other nasal tube retention systems were available on the market. The intention was to gather some design ideas from other styles of clips that the team could

modify and incorporate into a new design. Unfortunately, the team quickly realized that there are only a few devices that are used in similar ways to the Bridle clip, but they made the most of what they were able to find. After thoroughly evaluating each alternative design and comparing these to the current design, a short list of general problems was developed (see Background Information section). The overall goal was to use some ideas from their research meshed together with some original ideas to remedy the issues that were discovered. After the problem was adequately defined and research was complete, the team was ready to begin the design phase of formulating solutions. To start brainstorming on how to fix the issues with the clip, the team thought it best to tackle the issues one by one.

Problem #1 - The Clip is Difficult to Handle

The current AMT clip is made out of polypropylene. This material is beneficial because its pliability allows the living hinge of the clip to function effectively. Also, polypropylene is cost efficient, aesthetically pleasing, and is compatible with the injection molding process. However, the downside is that the clip has a slippery texture once it is completed. The team's first idea was to explore different materials to mold the clip with. However, after researching different materials and talking with AMT, the team decided polypropylene was still the best option due to mold-ability, cost savings, and aesthetics. There is really no other material that stands its equal in those categories.

Since the material would not be changed, Ameri-Clip Medical had to come up with another way of making the clip easier to handle. After a little brainstorming, the team decided that if they could add some treads to some portion of the clip, it would make it much easier for the practitioner to get a good grip on the clip. The team members began making sketches of different tread types and different locations on the clip (see Figure 3 for example). After much

debate and experimentation, the team decided that best type of tread pattern would consist of a few small “speed bumps” raised off the surface of the clip to make it easier to hold on to. The optimum location of these treads was discussed and debated as well,

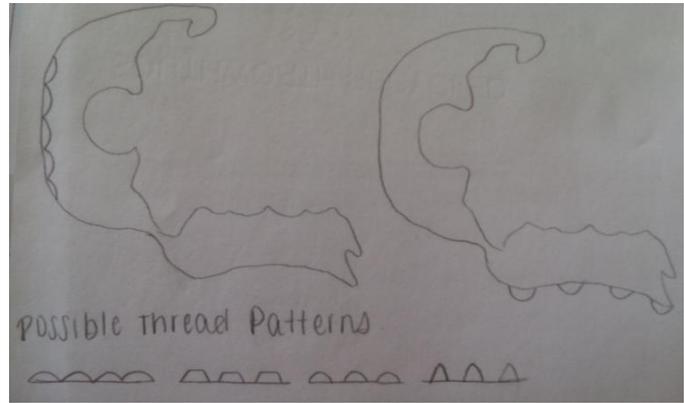


Figure 3: Tread Brainstorming

but after some critical thinking and some feedback from AMT, the team decided that the treads would be best suited on the “thumb” area of the clip (see Figure 4). AMT provided the team with the information that most practitioners handle the clip with their thumb on the bottom of the clip and index finger on the “lid” of the clip.



Figure 4: Clip Regions

For this reason, the team thought that the treads would be best suited in the thumb area so that hand-to-clip contact area could be maximized, thus allowing for better grip.

As the team continued brainstorming, they concluded that if the clip was unable to be dropped at all, the practitioners would have a much easier time with placement. This sparked the idea of incorporating the clip into Bridle system itself. In doing so, the steps of picking up the clip, opening it, and having to place it separately would be eliminated. Ideally, the clip would already be stationed in a close proximity to its final position after the umbilical tape was placed around the patient’s vomer bone. In order to make this happen, the team thought of a creative solution. The idea was to put a hole in the Bridle clip that would allow the umbilical tape to be threaded through it. This way, AMT could sell the Bridle system with the clip already attached to the umbilical tape. With a system like this, all the practitioner would have to do was pass the

umbilical tape through the patient's nose, then slide the clip up to the appropriate position and snap it shut against the feeding tube. This method would completely eliminate any possibility of the clip being dropped. As an added bonus, the time required for application of the device should actually decrease as well.

The team still needed to determine where the through-hole would be located on the clip, as well as its shape and size. Again, the team brainstormed by sketching out various ideas for the through-hole as shown in Figure 5.

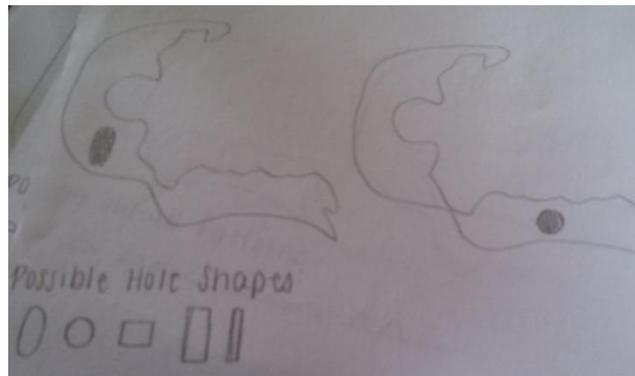


Figure 5: Through-hole Brainstorming

Initially, Ameri-Clip Medical wanted to have the hole in the body of the clip as shown in the left side of Figure 5. However, it was brought to the team's attention by AMT that the hole could not be placed in that location because that is one of the areas in the mold tooling that is used to eject the clip after it is molded. If the hole was placed in this location, the clip would not eject from its mold properly after production. As a backup plan, the team decided to place the hole in the "lid" portion of the clip as shown on the right side of Figure 5, and utilize an oval shaped through-hole slot. This location would fall right in between two ejector pin sites and should not cause any molding complications. The hole needed to be small enough such that the clip could be secured with a simple knot in the umbilical tape, but large enough to allow the clip to slide freely up the tape. The team thought that incorporating this through-hole along with the gripping treads would definitely solve the problem of the clip being difficult to handle and apply.

Problem #2 - The Clip is Difficult to Open

The second problem with the Bridle clip that Ameri-Clip Medical wanted to fix was the opening method. The current opening method includes using a custom AMT guitar pick to pry the clip open as shown in Figure 6. The space provided for inserting the pick is extremely small and substantial force is



Figure 6: Clip Opening Method

required to get the pick in between the lid and the body of the clip for prying. Some early ideas for improving the opening method included incorporating some sort of tab onto the lid of the clip

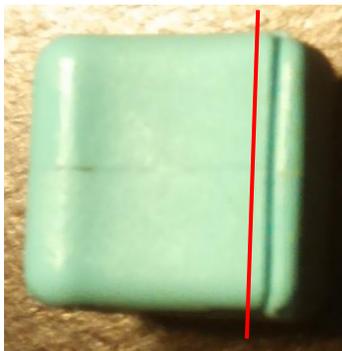


Figure 7: Lid Modification

that could be pulled to open the clip. After further deliberation however, the team decided that this sort of modification might be too intricate to successfully add to the mold tooling, and the result might make the clip a bit bulkier than desired. Instead, the team decided that they should simply widen the gap between the lid and the base for opening. This way, the practitioner could continue using the same opening method with the guitar pick, but a lot less force would be required to successfully open the clip due to the increased space for insertion. This change could easily be implemented by cutting back the top surface of the lid of clip as shown by the red line in Figure 7. Modifying the clip in this way would make it much easier to open using the existing guitar pick method.

Problem #3 - No French Size Labeling on Clip

The third and final problem that the team aimed to solve was the lack of labeling on the clips. As mentioned earlier, the clips were color coded based on size but the team thought it would be a good idea to actually incorporate the French size labeling into the mold so that it showed up on each clip. With each clip's size being readily visible, the likelihood of a practitioner attempting to use the wrong size Bridle clip for a given feeding tube would be decreased. The team determined that the lid of the clip would be an ideal location for the French size labeling so that it could be easily seen when the clip is in the closed position. Ideally, the text would be slightly raised off the surface of the clip.

Prototyping

After the team had formulated all of the solutions discussed above, the next step was to begin prototyping. For preliminary prototypes, the team used some of AMT's current Bridle clips and



Figure 8: Preliminary Prototype

modified them using equipment in the machine shop at AMT. Figure 8 shows the finalized “rough” prototype which displays all of the changes that were discussed above. The treads were made in the thumb area of the clip using a razor blade. On the finished product however, the treads would be raised off the surface instead of cut into it. The through-hole and the guitar pick opening were cut using an end mill with a very small bit. As a finishing touch, the French size was written on the clip in pen. Although this was just a rough prototype, it was enough to give Ameri-Clip Medical and AMT the confidence to move forward with the design changes.

After AMT approved the design changes, the next step was to produce a 3D model and drawing using SolidWorks CAD software. Figure 9 shows a screenshot of the SolidWorks part file which includes all of the design changes that the team wanted to implement. It depicts an image of the finished part once the mold modifications are complete.

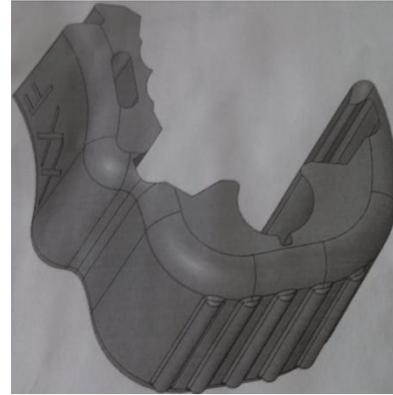


Figure 9. SolidWorks File

After the SolidWorks file was created, the team was ready to create a final working prototype. The team discussed stereolithography (SLA) as well as 3D printing for prototyping methods. To save cost, the team decided to use 3D printing because AMT

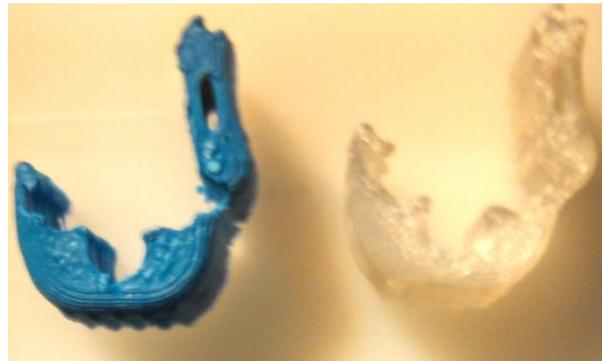


Figure 10: 3D Prints

had recently bought a desktop 3D printer for in-house prototyping purposes. The team uploaded the SolidWorks file into the 3D printing software and completed two separate prints using two different materials. The results can be seen in Figure 10.

Implementing Design Changes

Ameri-Clip Medical and AMT were very pleased with the results from the 3D printed prototypes and confidently sent the mold out to be modified. The mold tooling was sent to a local company called Diemaster Tool and Mold, Inc. When the modified mold returns to the factory, AMT plans to begin molding the new clips immediately and start selling the Bridle system with the new clip design already attached to the umbilical tape as Ameri-Clip Medical suggested.

Umbilical Tape Threading

Unfortunately, threading the umbilical tape through the through-hole in the new Bridle clip is difficult without a specialized fixture or method. Since the team completed the clip modification before the deadline, time was utilized to determine a method for threading the umbilical tape through the new clip. The method needed to be quick and effective and should not substantially slow down production of the Bridle kits. Ameri-Clip Medical had several ideas for how the threading could be done. One of the first ideas was to laminate the tip of the umbilical tape and stiffen it, which would aid in guiding it through the hole in the clip. After further evaluation however, the team decided that laminating just the tip of each piece of umbilical tape would drastically elongate the manufacturing process. Instead, the team thought that they could incorporate a needle-and-thread method. The umbilical tape could be run through the eye of a needle or small piece of looped wire. Then the wire could be passed into the through-hole of the clip causing the umbilical tape to be forced through the hole as well. More time is required to refine this idea but the idea is promising. A threading method like this would not take very long to complete, and it would be easy to accomplish in mass production.

Performance Testing

The new design was tested informally throughout the entire design process. The team performed testing of the through-hole dimensions using the 3D printed prototype. Again, the goal was to verify that the hole was small enough to allow a simple knot to secure the clip to the tape, but large enough to allow the clip to slide freely along the tape. This was done by simply threading a piece of umbilical tape through the prototype to make sure the hole was sized properly. This preliminary testing was done to ensure that mold modification would result in an

appropriately sized through-hole in the final molded part. The 3D prints were also used to verify the tread dimensions and appearance before the final mold was sent out to be modified.

Dimensional verification and functional testing of the new design is yet to be completed. Feeding tube retention force of the new clip design must be tested using a specialized setup at AMT. The average retention force of the new clip must not be less than that of the current AMT Bridle clip. AMT possesses data regarding the current retention forces.

Future Directions

As mentioned above, if Ameri-Clip Medical were to continue working on this project, the next steps would be to conduct dimensional analysis and functional testing. Pending the results, the new Bridle clip design would be ready for market. However, more work still needs to be done to refine the umbilical tape threading method. Fixtures should be created to aid operators in completing this new assembly step and should be simple and easy to use. Ideally, adding this assembly step to the Bridle kit will not substantially increase production time. In the event that production time is noticeably increased, work should be done to attempt to automate the umbilical tape threading step. If the threading goes smoothly, the new AMT Bridle Kit will be a great success.

APPENDIX I

AMT Bridle Nasal Tube Retaining System – Clip Redesign

The AMT Bridle Nasal Tube Retaining System was designed to reduce the likelihood of a nasal feeding tube inadvertently dislodging. The Bridle is easily placed by passing magnets through the nasopharynx to position a loop of umbilical tape around the vomer bone. This umbilical tape loop is then anchored to the feeding tube with a clip.

Reference AMT Bridle Instructional Video: <http://youtu.be/O0QCkUj56Uw>

The clip used to anchor the bridle system to the feeding tube consists of a simple molded piece (diameter size specific to correspond to the tube size) with a living hinge and snap engagement. It is attached manually by a nurse or physician to the feeding tube and umbilical tape loop. The clip is relatively small (roughly the same outer profile as a dime) to provide minimal obstruction in and around the nose area and allow for use in smaller patients. The small size, however, often makes it challenging for the nurse or physician to handle. Therefore, there is a need for a revised clip design to make the part more user friendly, yet still serve its purpose in the Bridle system.

Design constraints include:

- (1) Maintaining roughly the same overall clip size/shape
- (2) Reusing the current mold tooling and raw material to make it

Critical specifications for the revised clip design are:

- (1) Internal tube channel diameters within the clip cannot change, as these already interact well with current feeding tubes available on the market.
- (2) Snap retention edges cannot change, as retention of the tube must remain constant.

A SolidWorks file of the current clip design will be provided, along with a number of parts to use for evaluation, prototyping and/or various testing. Applied Medical Technology, Inc. (AMT) will also provide additional assistance where needed, including purchase of SLA models or fixturing components if required. Approval for any purchases must first be obtained through AMT's Engineering Manager, Derek Williams – who will be the supervisor and main contact for the project.

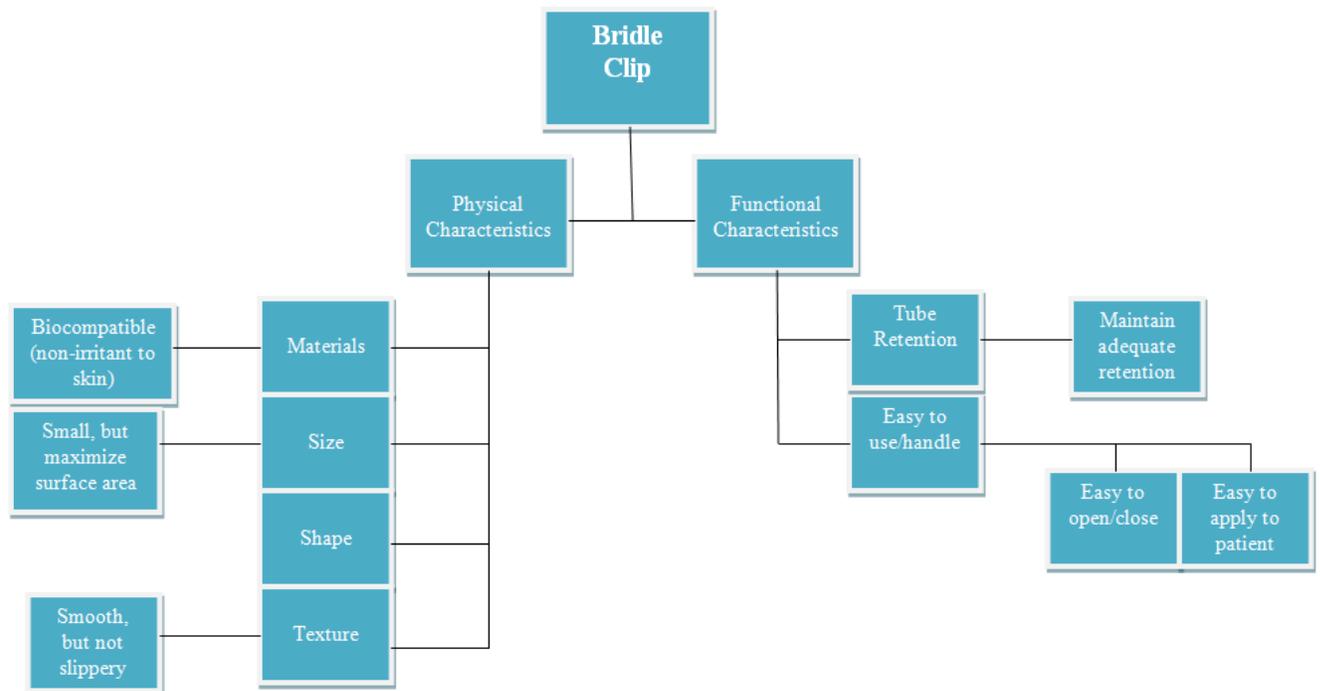
Derek Williams, Engineering Manager
Applied Medical Technology, Inc. (AMT)
Direct Line: 440-717-4230
dwilliams@appliedmedical.net

APPENDIX II

Functional Requirements

1. Small size (must minimize obstruction around patient's face)
2. Easy to open and easy to close (makes application much easier)
3. The device should be easy to apply to the patient for the nurse or practitioner (application should not take longer than a few seconds, and a first time user should be able to do it easily)
4. The diameter of the hole that surrounds the nasal feeding tube itself should not restrict the tube in any way or block flow (the clip shouldn't alter functionality of the feeding tube)
5. The material of the device should not irritate the patient and should be biocompatible (if clip caused irritation, it couldn't be used on some patients)
6. The material of the device should not be too slippery (for ease of handling)
7. The material should be lightweight and not noticeable to the patient (for patient comfort)
8. The device should have a sufficient retention force (new design must maintain retention forces of AMT's current clip)
9. The device should be aesthetically appealing because it is in close proximity to the patient's face (for patient comfort and peace of mind)
10. The device should have maximum possible surface area that would make it easier for handling (maximum surface area for a given volume will allow the practitioner to handle the clip better and make it easier to snap to the feeding tube)
11. The material of the device should not have any odor because it is in close proximity of the patient's nose (for patient comfort)
12. The clip should be labeled to indicate the size of tube that it is intended to go with (this will prevent size mix ups and misuse)

Objective Tree



APPENDIX III

Constraints and Limitations

Customers/Clients:

1. Patients
2. Nurses/Practitioners
3. AMT

Patient Constraints:

1. The cost of the device should be within the patient's financial limits.
2. The size of the device should be small.
3. The device should be comfortable to wear and should not cause irritation if it contacts the skin.
4. The device should be unnoticeable to the patient when worn.

Nurse/Practitioner Constraints:

1. The device should be quick and easy to apply.
2. The device should feel comfortable in the practitioner's hand when applying (no sharp edges).
3. The device should be easy to open if necessary.

Engineering Constraints:

1. The device is required to have a similar shape and size as the previous design.
 2. The snap retention edges of the device must not change because they already interact well with the current feeding tubes on the market.
 3. The device is required to be made using the same mold tooling that AMT currently uses to mold the part.
- **Engineering Constraint #3 is the largest constraint in this project. Since the team must use the same mold tooling as the previous Bridle clip, it really limits the directions that could be taken with the project. The team can't really start from scratch to completely reshape the clip. Instead, the team will brainstorm to make modifications to the current mold tooling to produce a Bridle clip similar to the existing one, but that is easier to use.**

Engineering/Team Limitations

1. The project has a deadline and the team must ensure to balance this project with other obligations.
2. Funds will be provided for research, prototyping, and other related items by the Biomedical Engineering Department at the University of Akron (up to \$500) and any other funds will be provided by AMT. Funding should not be an issue.
3. Any and all biases that may come from the team members previously working at AMT must be recognized.
4. Team members all have busy personal schedules. Finding meeting times that work for everyone is challenging.

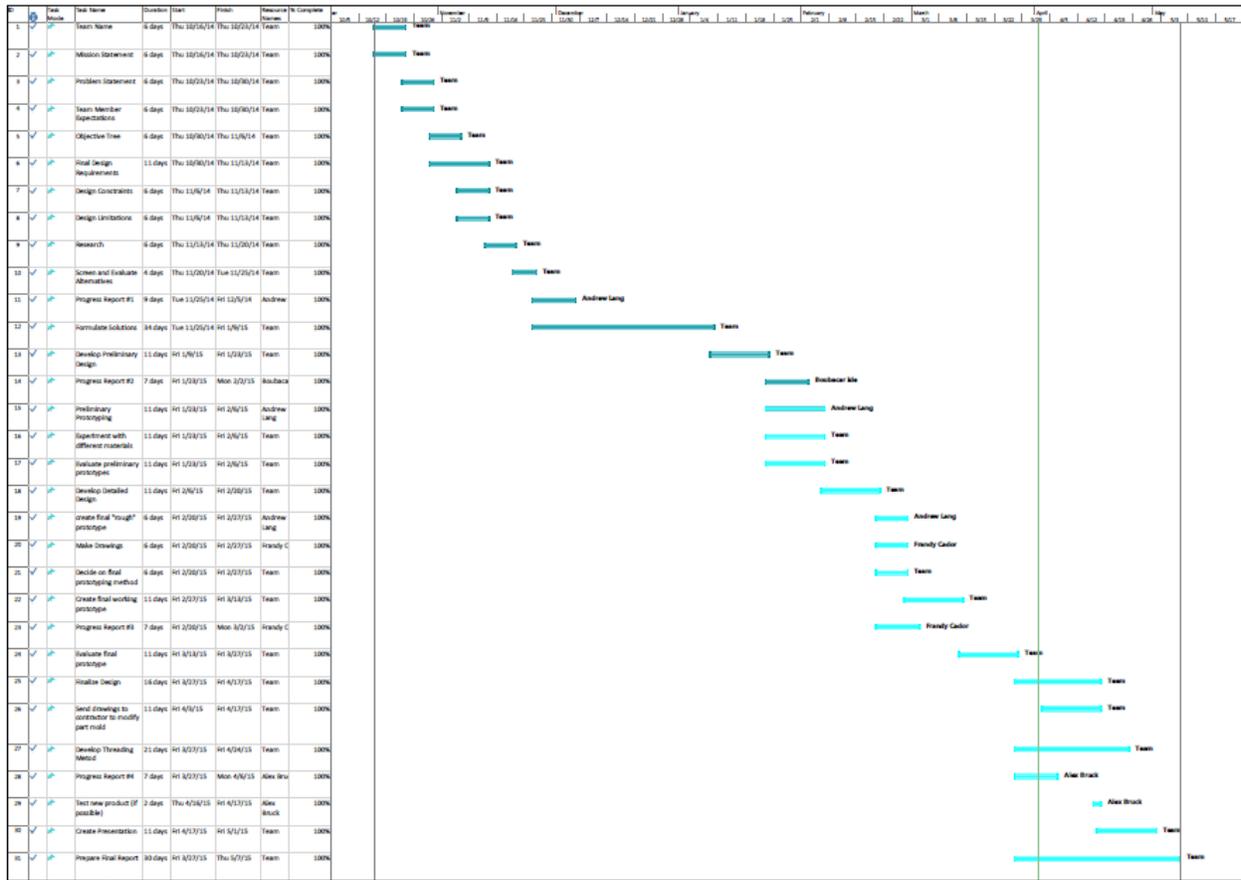
APPENDIX IV

Timelines – Original Gantt Chart

Ameri-Clip Medical

	Task Name	Start	Finish	Duration
1	Team Name	10/16/14	10/23/14	6
2	Mission Statement	10/16/14	10/23/14	6
3	Problem Statement	10/23/14	10/30/14	6
4	Expectations	10/23/14	10/30/14	6
5	Objective Tree	10/30/14	11/06/14	6
6	Final Requirements	10/30/14	11/13/14	11
7	Constraints	11/06/14	11/13/14	6
8	Limitations	11/06/14	11/13/14	6
9	Research	11/13/14	11/20/14	6
10	Screen and Evaluate alternatives	11/20/14	11/25/14	4
11	Progress Report #1	11/25/14	12/05/14	9
12	Formulate Solutions	11/25/14	01/02/15	29
13	Develop Preliminary Design	01/02/15	02/06/15	26
14	Proposal (Prepare), Revise and Submit	02/06/15	02/27/15	16
15	Develop detailed Design	02/27/15	04/03/15	26
16	Make Drawings	02/27/15	03/20/15	16
17	Create Prototypes	03/06/15	04/03/15	21
18	Evaluate Prototypes	04/03/15	04/10/15	6
19	Finalize Design	04/10/15	04/17/15	6
20	Create Presentation	04/17/15	05/01/15	11
21	Prepare Final Report	04/24/15	05/07/15	10

Timelines – Final Gantt Chart



APPENDIX V

Budget

This project was completed with very little expense. However, any expense that did occur was taken care of by AMT. Rough prototyping was completed for free using equipment at AMT. Final working prototypes were completed for free as well using AMT's 3D printer. The only expense was the actual modification of the Bridle clip mold tooling, which was done by a company called Diemaster Mold and Tool, Inc. AMT paid for the mold modification since they have an open PO with the company, and chose not to discuss the cost with Ameri-Clip Medical.

If this project was done by an individual without access to additional funding from a company like AMT, there would have been much more out of pocket expense. The 3D prints can be estimated at approximately \$100 each. Modifying the mold tooling for the injection molding machine would cost roughly \$5000 - \$7000.