

Development of Mechanism to Improve Neonatal Rat Gastrostomy

Final Report

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Abstract

Our client is currently in need of an improvement to the surgical procedure of inserting a feeding tube into neonatal rats. Due to previous research, the procedure cannot be changed significantly for comparison. The rat pups are being used to test the effects of iron deficiency on physiological development. The present procedure involves a polyethylene tube (PE-20) being inserted through a catheter into the stomach. It is secured to the stomach with three phalanges that are cut and molded at the tip of the PE-20 tube. The current procedure has less than a 50% survival rate.

In order to improve this survival rate, our team has designed a new tip for the gastrostomy tube which combines a curlicue and phalange. The design focused on increasing the mechanical strength of the tip instead of reducing the .56 mm diameter difference between the PE-20 tube and the catheter being inserted in order to preserve the procedure. The new curlicue-phalange combination tip showed to hold significantly more weight ($p=0.051$). The tip was tested in four different rats. Three out of the four died within the first two days. Autopsies showed that the cause of death was due primarily to the size of the curls. The team is confident that a smaller version of the design would prove more successful. Mechanical testing shows that smaller tighter curls do not lose any strength and is approximately 1/2 the size of the original curlicue-phalange design.

Motivation and Problem Statement

Every year 30,000 premature babies are born and affected by anemia in the United States [3]. The current, common treatment for anemia in adults is erythropoietin. Erythropoietin is an endocrine hormone that stimulates the production of red blood cells. However, this treatment is ineffective for the premature babies. In the Kling laboratory at Meriter Hospital they are trying to figure out why this treatment is unsuccessful on the premature babies.

One of the ways Dr. Pamela Kling and her staff are studying the red blood cell production is by altering the levels of iron present in neonatal rats since iron directly

affects the efficiency of erythropoietin. Rats are a good subject to study because there are a large number of rats in each litter at a small cost. Since the rats can only consume the artificial milk, they must be separated from their mother when they are two days old. Since they are small in size, a living space can be easily made to house the rats during the artificial rearing. These characteristics make rats the most studied species by means of the artificial rearing method [2].

Individually hand rearing the rats is a very time consuming process and has too many variables for an experimental situation such as teaching the rat pups how to feed orally at a young age [4]. In order to control the amount of iron that the neonatal rats are consuming, a procedure involving gastrostomy is used. Gastrostomy is an opening in the stomach so that a tube can be inserted [1], [5]. Iron deficient milk can be fed directly to the rat through the tube. However, if the tubing is not properly anchored into the rat's stomach, it will slip out into the abdominal cavity and the rat will die. The goal of this project is to increase the survival rate of these rat pups being tested. Our task is to design a mechanism and/or procedure to secure feeding tube inserted through the abdominal wall in a neonatal rat's stomach.

Current Procedure

Once the rats are two days old, they are ready for the gastrostomy surgery. The tubing that is inserted into the stomach is made of polyethylene-20 (PE-20) and is 10 cm long. The diameter of the inside of the tubing is .388mm, and the diameter of the outside is 1.09mm. First, our client uses surgical tools to cut three small phalanges on the tip of the tubing. Each slit is folded backward with a small coil of copper wire. It is placed in 80° C water for 3 minutes and then in an ice bath for 3 minutes to set the phalanges. Our client uses ethanol and distilled water to rinse the tubing. The ice bath is repeated, and the phalanges retain their structure. Right before the surgery the tubing with the phalanges is inserted into a guiding catheter, which temporary straightens the phalanges for easier insertion into the stomach.

On the day of the surgery, the rat is anesthetized using chloroform. The rat's white stomach can be best seen if the pup is on its back bent back slightly. The stomach is forced to the edge of the abdominal wall so the needle can be inserted. The needle, with a sheath over it, is injected directly into the pup's stomach. It must be inserted without going too deep into the rat's body injuring the surrounding organs. The needle is then pulled out leaving only the plastic sheath. The guide catheter with the tubing and



Fig. 1: PE-20 tube being inserted through sheath into stomach

phalanges created in the first portion is now guided into the rat's stomach as seen in Figure 1. The tubing goes through the catheter, into the sheath of the needle, and then finally into the stomach of the rat. The two sheaths are removed leaving only the phalange tubing in the rat's stomach as seen in Figure 2.

Next, the tubing has to be secured in the stomach. Our client pulls on the tubing to make sure it is in the stomach. She then secures the tubing with a washer. The tension created by the washer pulls the phalanges against the stomach wall. Since the rat pups move around a lot when they are young, extra reinforcement is required. A guitar string pierces the rat's neck, and the tubing is fastened to the neck skin by two washers as seen in Figure 3.



Fig. 2: PE-20 tube inserted into stomach after procedure



Fig. 3: Molded tube wrapped around rat pup through the back of the neck

Finally, the rat's normal rearing environment is imitated. The rats are individually placed inside a deli cup that has been padded with 1/4" cob bedding so that it is 1/4 to 1/3 full of bedding. This cup is placed inside a separate cup with a washer attached to the bottom. Holes are drilled on the top of the cups to circulate air inside of the cup. The cups are placed inside a distilled water bath kept at a constant temperature of 40.0 degrees Celsius. Styrofoam is added to the bath to keep the individual floating cups separated [6].

Problems with the Existing Procedure

The current procedure involves using a catheter to insert a small tube made from PE-20 into the stomach of a neonatal rat. This procedure has a less than 50% survival rate of the rats. Our ultimate goal is to increase the survival rate of the rats in order to decrease the number of rats that are needed for the research. This survival rate is low due to problems with the existing procedure.

One of the main problems is that the needle creates a larger hole than the tubing. Our client uses a 16-gauge needle with a 1.651 mm outer diameter, whereas the tubing has an outside diameter of 1.09 mm. This 0.56 mm gap between the stomach lining and the tubing allows milk to be able to leak out of the stomach and into the abdominal cavity. Also, the hole created by the needle does not always heal properly around the tube. The larger this gap between the tubing and the stomach lining is, the longer the hole is going to take to heal and close up.

The phalanges cause the next problem associated with the technique. The phalanges are small and difficult to make. Our client needs a magnifying glass, very small medical scissors, and a lot of patience in order to make sufficient phalanges. Each phalange has to be the same length and width, which makes this process to be very tedious and time consuming.

Securing the phalanges against the stomach wall also involves a lot of practice. The phalanges do not always open up correctly after being threaded through the catheter. Since the phalanges pull the stomach up against the abdominal wall and the

skin, there is a lot of tension on the phalanges. This is the main source of two major problems. The first problem is that the tips of the phalanges can be sharp, thus, ripping or tearing the stomach lining. These tears allow milk and stomach acid to leak out. The next problem deals with the phalanges not functioning properly. Since the phalanges naturally want to bend back to their original shape, they have the tendency to bend back together, and the whole tubing system can slip out of the stomach and rat completely.

The baby rats do not move very much at the beginning of the 10 days, but towards the end of the experiment, they start to become active. This movement can cause a lot of tension on the tubing and can also cause the tubing to slip out of the stomach. Our client currently connects the tubing to the neck using plastic discs and wraps the tubing around the rat's body, which helps alleviate some of the tension on the tubing but it does not solve the problem completely.

This procedure is very time consuming and has a lot of room for error. In order to help improve the system, we need to design a catheter system that will alleviate tension, have secure phalanges, and have a smaller opening between the hole that the needle makes and the tubing. The team chose to focus primarily on solving the securement issue of the phalanges by improving the strength of the tip because we could not change the procedure significantly.

Specifications

The tubing needs to be secured inside the stomach of the rat for 8 to 10 days. During these ten days the tubing needs to be secure enough so that no milk leaks out of the stomach. Since we are improving a research technique, we need to keep the technique as close to the original one as possible in order to be able to compare the results from future studies to past studies. Our design needs to be reliable, repeatable, and have consistent results.

Ethical Considerations

Our project included several different ethical considerations. The first ethical issue deals with the handling and experimenting on neonatal rats. To handle any of the rats we would be required to acquire a rat handling certification, by attending a class. However, our client did not think that this would be necessary for the semester; we were not allowed to perform any of the surgeries on the rats or handle them in any way.

The current procedure that our client and her neonatal research center uses has been approved by and complies with the Institutional Animal Care and Use Committee guidelines. Any improvements to the surgical technique could be seen as improving the humane treatment of the tested rats.

All data presented in this report is based on the un-skewed raw data acquired through testing. The mechanical testing methods were consistent for all tips, testing the tips the same amount of times and in the same manner. No outliers were removed. In the future, to assure the future designs are humane, a model of a neonatal rat stomach should be created based on accurate measurements in order to assure that the curlicues fit comfortably in the rat stomach and allows the stomach to empty the milk.

Design Alternatives Tips (Solving for Stomach Securement)

To improve the method of securing the tube to the inside of the stomach wall, we first look at what minor adjustments could be made to make the phalanges a more viable technique. As previously mentioned, the tube often comes out of the hole. The client has looked at several of the rats that died, and found there to be a correlation between the size and consistency in each phalange to the rats dying. The rats seemed to survive most often when each phalange is the same size, and is longer (compared to the unsuccessful phalanges). If the team could solve this issue of inconsistent phalange length, the current use of phalanges could still be a good option.

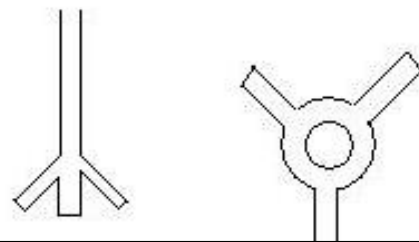


Fig. 4: Phalanges tip, side view and frontal view.

To make these phalanges, the process would remain the same as described above, where the phalanges are cut and then molded. The only difference is the phalanges would be cut using some sort of cutting tool that the team would fabricate. This cutting tool may consist of a system involving razorblades where the user puts the tube into the tool and then pulls a trigger, producing three identical phalanges at the tip.

The phalanges design, however, has several problems. The most critical is the fact that the method has a proven high failure percentage, and not all of the deaths can be attributed to an inconsistent phalange length. The cuts made can produce cracks that radiate down the tube, outside the stomach, so even when the phalanges hold the tube in the stomach, milk can leak out into the peritoneal cavity.

Another alternative to the phalanges is the “Disc tip”. This design is similar to the current phalange method, except instead of phalanges at the end of the tube there would be a circular disc. This method would solve the issue of possible cracks in the tube leaking milk outside the stomach because no cuts would be made. It would also create fewer pressure points on the inside of the stomach wall thus limiting the potential of the tip ripping out of the stomach.

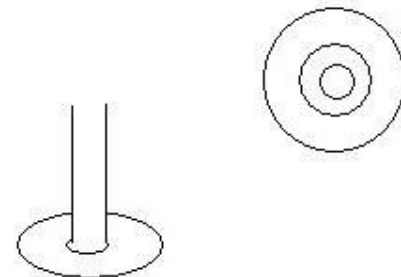


Fig. 5: Disc Tip (side view and frontal view)

The disc would be made is by melting the tip through use of an item like a hot plate or soldering gun. When the tip of the tube begins to melt, the tube is pressed against a flat surface to create the disc shape. This is immediately flattened in order to make the disc thin enough to fit inside the catheter. Early attempts have shown this method to be difficult because once the plastic melts, the disc it creates is too thick to be able to bend and fit inside the catheter.

Our third design, the “Curlicue Tip” incorporates a series of tight coils that would fit inside the stomach. The basis of this design originates from

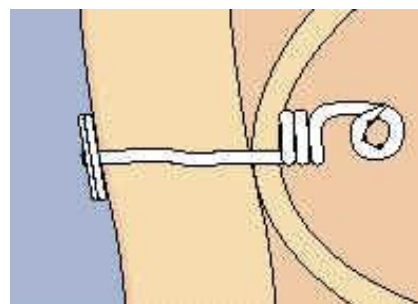


Fig. 6: Curlicue tip [7]

the pigtail catheter, which is widely used in humans. The curlicue method would also prevent the possibility of ripping out of the stomach, as it does not involve 3 specific pressure points but rather fairly well balanced circle of pressure.

The “Curlicue Tip” is made through use of a molding process similar to that described earlier in the current procedure to make coils that provide an ergonomic curve around the outside of the rat’s body. The end of the tube would be grasped by a pair of exceptionally thin surgical pliers and then wrapped repeatedly around the end of the pliers. Once this is done, the coiled tubing is emerged in hot water followed by an ice bath. It alternates between the two baths two to three times. The main problem with this method is that there is currently nothing in the design to prevent the tube from sliding completely out of the stomach slowly as the rat moves around.

Our last design is the “Balloon tip”. It would operate in an identical method to that of the balloon catheter commonly used in humans. A sheath would surround the tube, which would be able to inflate at the tip. Once the tube has been inserted into the stomach, the sheath is then filled with water that inflates the tube.



Fig. 7: Balloon tip [8]

If the balloon tip is not ordered as its own part, the tip would prove to be difficult to make as it would most likely involve several different parts being welded together. Additionally, the rat’s stomach is only 1-2 mL at this stage, and the balloon would fill a lot of this space up.

Design Matrix – Type of Tip

The design matrix for the tip designs is shown in table 1. The categories chosen to evaluate the designs are: function, ease of fabrication, consistency, size in stomach, and size for insertion. We define the function category as the ability of the design to hold the tubing in the stomach or anchor the tubing in place. Next, the ease of

fabrication category looks at how simple it would be for our client to make this design for each tube for each rat. The consistency category determines how easily the design can be identically replicated. The size in the stomach category is to make sure the design does not take up too much room, block holes, or hinder the rat from digesting. Finally, the size for insertion category analyses if the design will be able to fit easily into the guiding sheath. Each category is given a rank from 1-4 with 1 being the worst and 4 being the best. The categories function and consistency are given double weight (x2) to emphasize their importance. All the scores are added for a total value out of 28.

Tip Designs						
	Function (x2)	Ease of fabrication	Consistency (x2)	Size in stomach	Size for insertion	Total
Disk	4	3	2	4	1	20
Curlicue	3	4	3	3	3	22
Phalanges	2	3	2	4	4	19
Balloon	3	2	4	1	3	20

Table 1. Design matrix summarizing criteria and results for tip designs. The curlicue design won due to its high scores in each category, especially ease of fabrication.

Even though the disk design has the highest score in function, it did not win due to problems with inserting the disk. The end winner is the curlicue design with high scores in each category and the highest in ease of fabrications.

Curl tip

After deciding that the curlicue was the best tip, we began looking into different methods of making the curlicue. We explored several shapes and sized curls. Most notably we looked into a simple straight curlicue, a flat curl, an inverse curlicue and a curlicue with phalange combination. The straight curlicue was made by simply wrapping the tubing around tweezers putting it in a pipette tip to hold in place. It

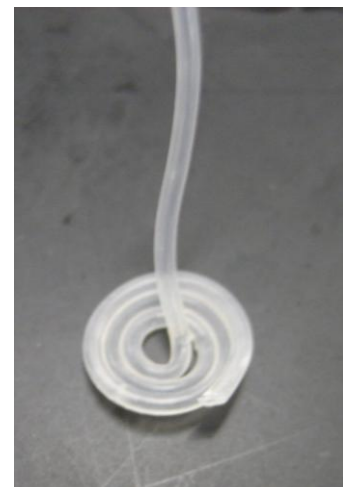


Fig. 8: Flat curl

was molded into place by alternating hot and cold water. The flat curl was more or less a disc tip made by curling the tube around itself. It can be seen in Figure 8. It was held in place while molding by surrounding it with duct tape. Wrapping the tip around itself proved to be a difficult task, as it was hard to hold in place while winding the tubing around itself. The inverse curlicue looked like a cone at the end of the tube. The base of the tip would be resting against the inside of the stomach, and the point extending into the middle of the stomach. It was created by making a flat curlicue and then extending the curl downwards. The curlicue-phalange tip was made using the same method as making the curlicue but two phalanges were cut at the end.

The flat curl, and inverse curlicue were the most difficult designs to produce, because the shapes were difficult to hold in place while molding. Additionally, the two designs were excessively large.

Mechanical Testing

In order to obtain quantitative data on the ability of the tip design to hold in the stomach, mechanical testing was performed to see how much weight each type of tip can hold. Multiple of each tip type were created and set up as shown in figure 9. The tubing was held, by its tip, in a flat piece of zip-lock bag. To insert the tip into the bag, the rat surgery procedure was performed in order to have an accurate hole size, and stretch out the tip just as if it had to be inserted through the sheath into a rat's stomach. At the bottom end of the tube, a whole zip-lock bag was attached to hold increasing amounts of weight. Larger weights (5.36 g) and smaller weights (2.34 g) were added until the tip was pulled through the piece of plastic zip-lock bag that the tube was held in. The final weight of the bag was measured and recorded for data analysis. The average weight held for each tip type is summarized in figure 10.

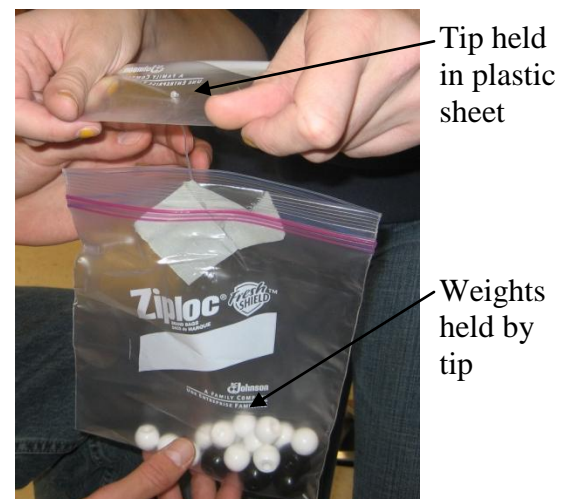


Fig. 9: Example of testing set-up

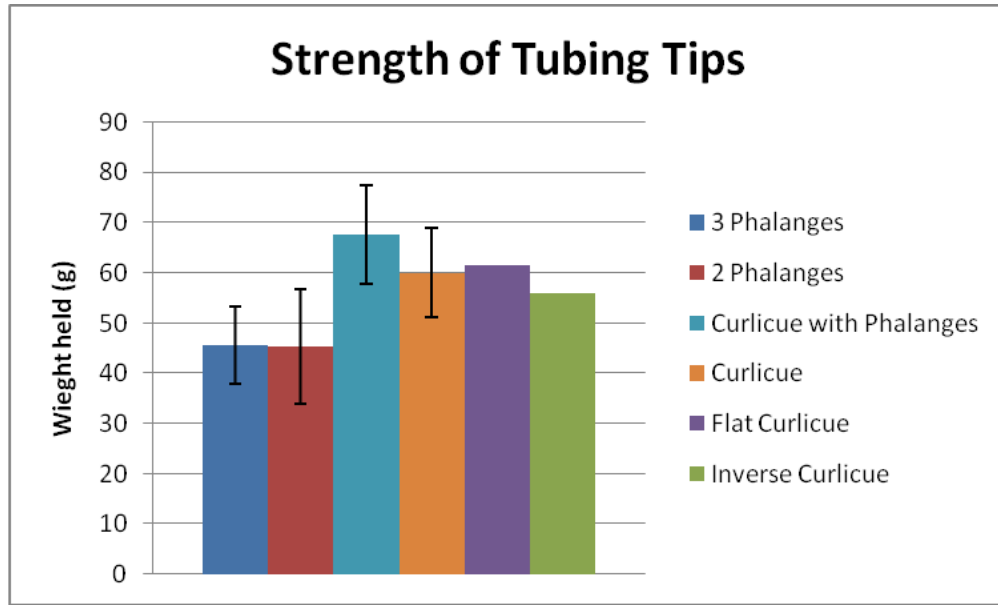


Fig. 10: Graph of weight held for each type of tip. Error bars shown are standard deviation.

The first tip tested was the original 3 phalange design that our client made. The average weight held for the 3 phalange tips was 45 ± 7.7 g (n=4). Next a 2 phalange tip was tested. This design was tested in order to see the affect of the phalanges. Since 2 phalanges are much easier to make (simply cut the tip in half), it would be beneficial if it could hold the same weight than 3 phalanges can hold. The average weight held of the 2 phalanges was 44 ± 11 g (n=3). Using a two sample t-test assuming equal variance, a p-value of 0.5 was obtained. Since this value is much greater than 0.05, it is concluded that there is no statistical difference in the amount of weight a 3 phalange tip can hold compared to a 2 phalange tip.

A straight curlicue was found to hold 60 ± 8 g (n=7). Using another two sample t-test assuming equal variance in comparison to the original 3 phalange design, a p-value of 0.07 was obtained. This means that the amount of weight held was statistically significant at the 0.1 significance level, or we are 90% confident that the curlicue holds more weight than the 3 phalange tip.

The inverse curlicue and flat curlicue were tested and found to hold about as much weight as a straight curlicue. These designs were not pursued, since the two designs are much more difficult to make and too large.

Finally, a curlicue with 2 phalanges at the tip was tested. This design was found to hold 68 ± 8 g (n=7). Using a two sample t-test assuming equal variance to compare to the original 3 phalange design, a p-value of 0.05 was obtained. Since this is at the 5% significance level, we can conclude with 95% confidence that the curlicue with 2 phalanges at the end holds more weight than the 3 phalange tip design.

Design Matrix – Types of Curlicue

Based on the mechanical testing, how easy it was to make each tip, and the size of the tip, we created a design matrix to choose our final design (see table 2). The criteria looked at are the strength, as determined by the amount of weight each tip held in the mechanical testing, ease of fabrication, and size. Size was considered to make sure the tip can fit into the insertion sheath and into the rat’s stomach. Each category was given a score from 1-4, with the strength category score multiplied by two for importance, for a total possible score of 16.

Type of Curlicue Designs				
	Strength (x2)	Ease of fabrication	Size	Total
3 phalange	2	2	4	10
2 phalange	2	4	4	12
Straight curlicue	3	4	3	13
Curlicue with 2 phalange	4	4	3	15
Inverse curlicue	3	2	1	9
Flat curlicue	3	2	1	9

Table 2: Design matrix summarizing criteria and results for specific tip designs. The curlicue with 2 phalanges design won due to its high scores in each category, especially strength.

Clearly, the best design considered is the curlicue with 2 phalanges on the end. It is able to hold the most amount of weight, as determined by our mechanical testing, is still simple to make, and small enough to fit into the insertion sheath and rat stomach.

Final Design

The final design that we chose was the curlicue with two phalanges (figure 11). We chose this because it was mechanically the strongest tip that we designed. The curlicue with two phalanges both retained its shape the best after going through the catheter, and held statistically more weight than its competitors.



Figure 11: Final design- two phalanges with curlicue

Procedure for Making Final Design

To begin making a curlicue with two phalanges, first start with an 18 cm long and 1.09 mm diameter PE-20 tubing. Next, using a razor blade make a $\frac{1}{2}$ cm slit into the middle of the PE-20 tubing (see figure 12). After you have cut the phalanges, insert a small copper wire into the tubing to prevent the tube from being crimped during the heating and cooling process.

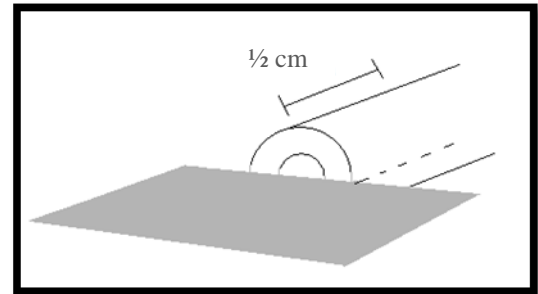


Figure 12: Razor blade slicing tubing

Using the needle nose pliers grab the tubing just after the phalanges and tightly wrap the tubing around the pliers three times to create the three curls.

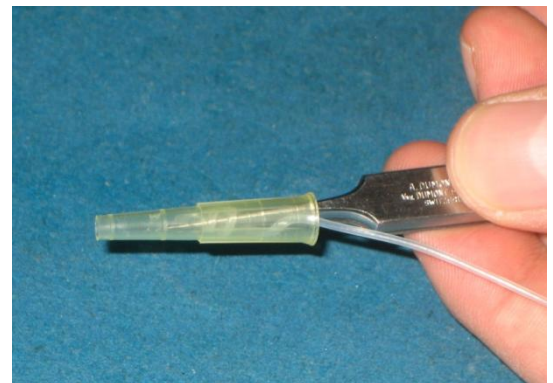


Figure 13: Pipette tip over tubing

After the curls have been made and the tubing is correctly positioned on the pliers, place the pipette tip over the tubing to secure the tubing against the pliers (see figure 13). Also, when placing the pipette tip on make sure that the phalanges are spread apart from one another to ensure that they

are heated in an open position. Next, place the pliers in 100° C (boiling) water for 3 min, and then in an ice bath for 3 more minutes. Then repeat the heating and cooling process so that the tubing goes through a total of 12 minutes of heating and cooling.

Once the tubing is done heating and cooling, take the pipette tip off and remove the tubing, the two phalanges and three curlicues are ready to be inserted into the rat. The tips will look like figure 11.

In Vivo Testing

Our client let us test our final curlicue/double phalange design on 4 out of her 16 neonatal rats. The other 12 rats were used the original 3 phalange method. Our rats were numbered 8, 12, 15, and 16. Rat number 8 was the first to get our new design inserted into it. At first, our client was having trouble sliding the tubing through the guiding catheter and the sheath. We brought silicon spray to spray the outside of the tubing so that it would reduce the friction between the tube and catheter. With the help of an assistant holding the guiding catheter and sheath steady, the tube was easy to insert. The double phalange and all of the curlicues were inserted into rats 8, 15, and 16. As for rat 12, the curlicues remained on the outside of the body leaving only double phalange in the stomach.

Unfortunately, 3 out of the 4 rats died within two days. Rat number 8 lived for 6 days. We were able to figure out the problems with our design by dissecting the rats and observing the effects of the tubing tip. Rat 12 had an evidently bloated abdomen. Either the phalanges never made it into the stomach or they came out of the stomach sometime during the first day. The peritoneal cavity was filled with milk but the stomach was still in good shape. Rat 15 did not have a bloated abdomen; however, the stomach was about twice as big as rat number 12 as seen in figure 16. All of the curls stayed in the stomach which, acting like a rib cage,



Figure 14: Size difference in the two stomachs. Rat 16 on bottom, normal size on top.

prevented the stomach from churning and emptying the milk out of the stomach. Rat 16 was a little different in the fact that the curls stayed in between the outside stomach lining and the abdominal wall rather than in the stomach. The stomach had somehow been twisted about itself. We hypothesize that the rat's stomach twisted when the tube curls recoiled after insertion resulting in the rat's death.

As for the other 12 rats that our client tested, 8 of them survived the experiment trial period of 8 days. This significant improvement suggests that the survivability depends more on the actual procedure, such as the insertion into the stomach, than the method of securing the tubing in the stomach.

Future work

With the results of the *in vivo* testing, it is clear that our final design needs some changes. The team still believes that curlicues with phalanges would be the best design, so we propose a smaller version of the design. This size reduction can be achieved by reducing the number of curls from 3 to just 2, in addition to making the curls tighter by using smaller tweezers or by wrapping the tube tighter around the tweezers. We have already attempted making these curlicues, with success. The smaller curlicue-phalange tip has already been tested and it was determined that the reduction in size of the curls did not affect the mechanical strength of the tip. It was able to hold 68 ± 8 g (n=7), which is exactly the same result for the larger curlicue, and using a two sample independent t-test compared to the 3 phalange, a p-value of 0.003 was obtained. Since this p-value is well below the 0.05 significance level, we can conclude that the smaller curlicue holds statistically more weight than the 3 phalange. After testing, the smaller tip was approximately 1/2 as large as the original curlicue-phalange tip. With a little more work, this smaller curlicue-phalange tip could prove to be very successful with the *in vivo* studies.

As the *in vivo* studies suggest, however, improving the tip alone will not "save the rats." With such a drastic increase in success rate that our client had over the course of the *in vivo* testing of her original 3-phalange design, the overall surgical procedure

and placement of the tube has a lot to do with the whether the rat will live or not. The team noted the difficulty the client had with getting the needle into the stomach. Occasionally the needle looks like it is in the stomach, but is not; meaning the tube never makes it into the stomach. Other instances, the needle nicks other organs such as the spleen, causing additional problems such as internal bleeding. We would like to explore various imaging techniques that may be able to assist the client in the initial insertion of the gastrostomy tube; maybe an ultra-sound device allowing her to view the organs and internal location of the needle. If the client does continue to see a consistent increase in success with the 3 phalange-tip, without any imaging device, the team could at the very least make the phalange cutting procedure more expedient and consistent by creating a special cutting tool. Early attempts at creating such a tool have proved unsuccessful due to the size of the tube, but with more time and resources it would be a feasible task.

Conclusion

Throughout the semester, much time and energy was put into making and testing various designs of tips. Because the team was unable to change the needle size, or insertion method, many tip designs were ruled out because they could not fit in the insertion catheter. The curlicue design allowed us to form the tip into many shapes, while allowing it to be inserted through the catheter. After many mechanical tests were run, the team was confident that the curlicue-phalange tip would work best due to its strength and ease of fabrication. Unfortunately design flaws became evident through the *in vivo* testing: the curls were too large. The team still has confidence however, and with a smaller version of the tip, and possibly an accompanying imaging device, feels that the design will prove successful. As a design team, we would like to thank our client Sharon Blohowiak for this opportunity to save the rats, and for her enthusiasm about our work. We would also like to thank our advisor Prof. Paul Thompson for his assistance and helpful ideas through the semester, as well as Amit, who helped get the team on the right path early on in the semester.

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Appendix A: PDS

Neonatal Rat Gastrostomy Procedure (PDS)

12/9/09

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Function: The purpose of this project is to increase the survival rate of rat pups being tested for the effect of iron deficiency on their physiological development. Our task is to adapt the current gastrostomy procedure by designing a mechanism and/or technique to secure a feeding tube inserted through the abdominal wall into the rat's stomach.

Client requirements:

- Repeatable and simple
- Noninvasive procedure (as humane as possible)
- Stable/secure (Won't move out of Stomach)
- Improve survival rate (80%)

Design requirements:

1. Physical and Operational Characteristics

- a. *Performance requirements:*
 - i. 8-10 days continuous use (to fruition)
 - ii. 20 minutes per hour milk is pumped to Rat
 - iii. Needs to be secured in stomach for entire time
- b. *Safety:*
 - i. Can't puncture through opposite side of stomach wall
 - ii. Shouldn't expand insertion hole
- c. *Accuracy and Reliability*
 - i. Repeatable fabrication
 - ii. Repeatable surgical procedure
 - iii. Consistent initial securement for each rat
- d. *Life in Service:*
 - i. 8-10 days for each procedure
- e. *Shelf Life:*
 - i. Sterile before use
- f. *Operating Environment:*
 - i. Inside Rats Stomach: volume 1-2 mL
 - ii. Temperature (38-39° C)
 - iii. Acidity (pH = 3-4)
 - iv. Minimal friction and tension on stomach wall
- g. *Ergonomics:*
 - i. Form to Rats body
- h. *Size:*
 - i. Fit in Stomach (1-2)mL without impeding digestive tract
 - ii. *Current PE-20 tubing dimensions:*

1. .38 mm inner diameter
2. 1.09 mm outer diameter
- iii. Catheter Dimensions: 16 Gauge (1.68 mm)
- i. *Weight:*
 - i. Light weight (does not harm rat pup)
- j. *Materials:*
 - i. Metal catheter
 - ii. Razor blade
 - iii. 18 cm Polyethylene tubing (PE 20)
 - iv. Small copper wire
 - v. Needle nose pliers
 - vi. Pipette tip
 - vii. 100 degree boiling water bath
 - viii. ice bath
- k. *Aesthetics, appearance, and finish:*
 - i. Function over aesthetics

2. Production Characteristics

- a. *Quantity:*
 - i. Surgical Procedure with prototype
- b. *Target Product Cost:*
 - i. Saving a Rats life: Priceless (\$250)

3. Miscellaneous

- a. *Standards and Specifications:*
 - i. Do not handle rats without rat handling class
- b. *Client:*
 - i. Client must be able to perform procedure
- c. *Patient-related concerns:*
 - i. Survival Rate
 - ii. Milk Leaking from Stomach
 - iii. Procedure
 - iv. Control of the research
- d. *Competition:*
 - i. Feeding Tube through mouth procedure
 - ii. Modifying current procedure