Spring 2023

Side Cutting Biopsy Needle for Endoscopes

Cade Smarr
cps47@uakron.edu

Ella B. Brinkman
ebb18@uakron.edu

Christine Skakun
cjs236@uakron.edu

Vincent Grosso
vg55@uakron.edu

Intracranial Biopsy Needle compatible with Neuroendoscopes

Ella Brinkman, Vince Grosso, Cade Smarr, Christine Skakun

Dr. Tsulee Chen at Akron Children's Hospital and Dr. Ge Zhang from the University of Akron

The University of Akron

April 28, 2023

Abstract

The intracranial biopsy needle for an endoscope was completed during Fall 2022 and Spring 2023. This needle is used to take biopsies of tumors in the fluid space of the brain. The products that are currently on the market do not take adequate tissue samples the first time and usually need a few more passes to fulfill tissue requirements; however, taking multiple tissue samples can be very difficult. Once the first tissue sample is taken, the fluid space becomes clouded with blood, which results in poor vision for the operator. This design aims to reduce the effects of bleeding by having an outer sheath which holds the position and an inner needle that takes the tissue samples. If the surgeon decides more tissue is needed, they simply insert the inner needle back into the outer sheath, which holds the position so that the operator does not have to find the tumor again. The needle takes more tissue on the first pass, but also allow for lack of sight to not hinder the surgery.

Introduction

This project focuses on a need for a larger biopsy sample from tumors in the fluid space of the brain with an endoscopic biopsy needle while taking into consideration the instrument size limitations. The tissue samples need to be 2mm X 10mm, the device should be long enough to completely go through the endoscope plus more, there needs to be a safety mechanism in place for needle depth, syringe suction to be strong enough to give adequate sample, and the syringe suction to be weak enough that the tissue sample is not unusable. This device needs to reduce the amount of bleeding during the procedure or take an adequate sample the first time before blood becomes a factor causing visual impairment of the camera of the endoscope. Also, this device needs to minimize the number of "bites" to obtain a sufficient sample, improve the locking and suction power, fit through the working channel of an endoscope, and deliver larger tissue samples.

Currently, the endoscope used with the client is the Lotta (*The LOTTA System for Intraventricular Neuroendoscopy* 2021) with the Nico Myriad. The Nico Myriad is used alongside a syringe to suction the tissue samples; however, the suction and locking power are very loose (*Myriad* ® 2019). The other option used is a vacuum, but this vacuum is often too strong, and the tissue sample gets contaminated. In the current procedure with the Nico Myriad, only one or two small tissue samples can be taken due to bleeding of the patient which leads to loss of sight (*Myriad* ® 2019). Due to the bleeding, it would be optimal to be able to retrieve one tissue sample that is large enough to test versus trying to take multiple smaller tissue samples. The client also preferred a sharp tipped needle to take samples from firmer tumors. The client suggested the addition of a cauterizer on the tip of the needle to help the bleeding. To take a sample of a tumor in the brain, surgeons use the neruroendoscope along with the side cutting needle to access the tumor. The neuroendoscope allows the surgeon to access additional areas within the brain that would not be able to be reached with traditional surgery procedures. To use the neuroendoscope, the surgeon drills a hole in the patient's skull which allows insertion of the endoscope and needle. The endoscope then is lowered down into the fluid space of the brain, and then penetrates the tumor to retrieve the sample.

User Needs

The user needs of the side cutting needle were established during the first gate of the design process. Gate one started with research regarding endoscopes and how they worked. The project description for this project was vague, so research was done on a variety of endoscopes. The group concluded that samples would come from the gastrointestinal tract but after speaking with the clinical advisor, it was brought to the attention of the group members that the instrument in mind was an endoscope and needle used for neuroendoscopes. Currently, this procedure is performed in two ways. The first way requires an endoscope and biopsy forceps. The forceps produce small tissue samples and the vision on the endoscope rapidly declines due to bleeding. If there were to be a need for an additional sample, this would be difficult due to the reduction in sight. The second way is by using a side cutting needle with stereotactic equipment. There is an extreme loss of vision during this procedure. Ultimately, the physician wanted a larger tissue sample in one go. This would reduce bleeding and increase the chances of a successful biopsy. Another goal was regarding suction and the system. The suction power used was either not enough or too much. A goal for the team was to be able to control the suction. Different endoscopy systems and needles were researched to completely understand the problem. The user needs were developed based on research and advice from the clinical advisor. These user needs were having the device be able to fit through the working channel of the endoscope, obtain larger tissue samples the first time, a longer device, a side cutting needle, stronger and more efficient locking and suction power, sharp tip of the needle, a cauterizer, and a 2mm by 10mm tissue sample.

Design Inputs

Design inputs involve physical and performance characteristics of the device you are planning to design. These inputs must be reviewed and verified in accordance with the user needs. Additionally, the requirements should be appropriate by addressing the user needs and intended use in terms that are measurable. Once the design inputs are gathered, they need to be addressed to determine if there are any conflicting or incomplete requirements. For this project, the first quality function deployment (QFD) was developed to transform customer requirements into design, production, and manufacturing process characteristics. From our QFD 1, the customer requirements were established and compared to the competitive products. A 0-5 scale where (0 = worst) and (5 = best) was used and it was found that the Sedan Side Cutting Needle scored the highest on the competitive analysis. This result allowed more research and development toward a product that scores higher than the sedan side cutting needle.

The engineering requirements included the following: tissue sample is at least 2mm x 1 cm, reduce bleeding to little or no visual impairments, an attachment that is reasonably longer than the endoscope, and syringe suction. Acquiring a large enough tissue sample with less bites will reduce the bleeding with impairs the surgeon's vision. Once blood enters the fluid space in the brain, total visibility is lost. Additionally, the attachment must be easy to use with the endoscope to reduce complications between the surgeon and patient. Having a syringe suction will provide stronger locking and suction power as well as larger tissue samples. From these engineering requirements, a competitive analysis was developed to determine how well each competitive product scored according to the engineering requirements.

A failure mode and effect analysis (FMEA) was developed to determine each item/function risk priority number (RPN). The FMEA helped distinguish which function of the

product was the most significant. As seen in table 1, the nine item/functions of the product were evaluated to calculate the function with the highest RPN. After doing this, the core needle jamming was the highest scoring function. The risk assessment and the FMEA allows us to focus on the crucial aspects of the device to ensure proper safety for the patient. The leur lock in the design has a relevant industry standard ISO594-2 which is found on the FDA website.

Design Process

Figure (1) shows a brainstorming idea of a side cutting needle with an extra metal sheath to cut the tumor sample instead of the twisting motion to cut the biopsy. Figure 2 shows a brainstorming idea that twists with a needle to retrieve a spiraling biopsy sample rather than taking a side cutting sample. Figures 3 and 4 are examples of including a cauterizer onto the side cutting needle. After considering all the user needs and the criteria and suggestions from Dr. Chen, it was decided to base our model on Figure 2. Since the brainstorming, the initial design has changed and improved after talking to professionals and testing.

One engineering requirement to the design was a tissue sample at lease 2mm by 10mm. Figure 2 allows for a larger spiral biopsy sample than 2mm by 10mm. Another engineering requirement was to reduce the bleeding to a little or reduce visual impairments. Due to the spiral mechanism, only one sample is required. The next requirement was to ensure the length of the design was longer than the endoscope. The design allows for the length to be as long as necessary. Another engineering requirement was to provide syringe suction to ensure a sufficient sample. The addition to a luer lock and a syringe to the design will allow for suction. Lastly, another engineering requirement to ensure the pressure of the syringe does not damage the tissue sample. Since the physician controls the pressure, they will be able to determine the need for increasing or decreasing pressure to ensure an adequate sample.

Design Outputs

After the final design was selected, six 3-D prints were developed in order to fine tune the device. In the first 3-D print, the device exceeded the proper length of a biopsy needle which caused a slight bend. From this, the length was shortened, and thicker walls were created to reduce the bend in the needle as seen in the second 3-D print. Following this change, a shorter inner stylet with a change in diameter for a looser fit was printed to allow the needle to easily enter the stylet, but conflict arose from a slight bend due to warping of the part. In the fourth 3-D print, the size of the needle walls and diameter were increased to allow a better fit in the inner stylet. After discussing with the clinical advisor, it was determined that replacing the inner stylet with the needle itself would allow better cutting of the tissue sample. The fifth print resulted in a dull tip, which restricts puncturing ability, so a sixth print was necessary. In this final print, a double helix, which created the cutting channel, provided a sharp tip to allow easier puncture of the tumor.

Design Verification

The medical device was verified with the user needs. This was obtained with “proof of concept” testing to determine if the device was able to satisfy the user needs. To perform this verification, a mold was made with Jell-O representing the brain matter and grapes that

represented the tumors. The device was then inserted into the Jell-O to obtain "tissue" samples. After this testing, it was determined that a different type of gelatin would perform better than the Jell-O. This other gelatin was used along with larger "tumors" made of melon pieces to adjust for the enlarged device. Once this testing was finished, the results showed that the device was able to enter the Jell-O, puncture the grape, and retrieve a sample from the inside of the grape. The desired tissue sample was at least 2mm x 10mm, acquired from our engineering requirements. After reviewing the results from testing, our device fell short and did not retrieve the desired sample size, but this could be due to the "tumor" samples not being the same size ratio as a real-life situation. Additionally, the device was easy to use and provided sufficient suction power to retrieve the sample.

Medical Device

Our final medical device was a larger version of a current endoscopy needle because of our limitations in creating a to-scale device. The device was scaled up 3.5x to allow proper testing. The scaled-up medical device provided the capability to test and validate the medical device with reference to the engineering and user needs.

Validation

The medical device must be validated with the engineering requirements to ensure that all the requirements are met. The inner and outer diameters were all measured to determine if they fell within the tolerances that were set. The parts have tight tolerances due to the small scale of working in endoscope, most are only ±0.05mm. The spiral of the inner needle should be inspected for any material blocking the cutting paths into the hollow portion. Parts should be assembled for packing to ensure the parts meet tolerances and determine defects such as a bend. Lastly, a visual inspection was performed to determine if the part needed sanding or needed supports broken off.

Risk Mitigation Process

The risk assessment process used through the design was to identify the potential hazards of the design. Some critical risks that were identified in the design were the addition of a cauterizer to the needle, the inner and outer stylet mechanism and the sharp tip. However, due to the hazards of the cauterizer, the team designed a needle that did not need the addition of the cauterizer. The inner and outer stylet mechanism may cause a need for surgical removal if the device malfunctions, an inadequate tissue sample may have been taken or cause excessive bleeding in the brain. The sharp tip, if used incorrectly, could cause damage to the tissue or damage to the user. The outer stylet is a placement vessel for the inner stylet; therefore, if one were to malfunction, surgical removal would not be necessary. Also, the sharp tip would be maneuvered with the camera on the endoscope, which would limit the possibilities of allowing unnecessary damage on the tissue. Both risks would account for and be included for any device entering the brain through the endoscope. Since this is such a critical and necessary procedure, the device would outweigh the residual risk.

Summary Feasibility Discussion

The final design satisfies the need identified at the beginning of the effort. As mentioned previously, the main objective of the side cutting needle is to retrieve a larger biopsy sample for more accurate readings and minimize the chance of repeating the invasive surgery. Through testing, the design has proved that it retrieves a long spiral-like sample. The problem statement originally advised to create a side cutting needle, but through research and experimentation, the screw like method seems to retrieve a larger sample. Our final product is a prototype of the needle. The prototype is sized up and made from a polymer, while the actual needle would have to be smaller and made from metal. Due to three-dimensional printing restrictions, our needle prototype could not be scaled to actual size. Additionally, the needle was not printed using a metal alloy three-dimensional printer because it would create an unnecessary costly prototype. Since the product is a prototype, creating an additional prototype from metal is redundant.

Discussion, Lessons Learned, Conclusion

The device obtained after this process was adequate. The device obtains tissue samples, but more testing is required to determine if the tissue samples obtained relate to the size of the device. The device will also need to be created using a metal 3D printer to create a version that could be used by the clinician. Overall, the device needs a few modifications for it to be optimal. The tissue size could be larger, and the ease of use could be improved upon. It was hard to verify the device due to limitations in creating it. The plastic 3D printer did not make a reliable to scale version, but a metal 3D printer was not obtainable.

Future Work

Future work includes the creation of a beta prototype. The inner needle will be created using 316 stainless steel direct metal laser sintering. The plastic components which attach the needles and facilitate the attachment of a syringe for suction, will be resin printed to scale. The outer needle will be made using 316 stainless steel capillary/needle pipe from McMaster. This will allow beta prototype one to be assembled and tested to compare tissue size in proportion with the scaled alpha prototype. Overall, the quoted beta prototype should cost between $275-350. Data could be obtained using the current brain and tumor phantoms, but the data/sample size could be inaccurate due to imperfect properties. To prevent this, the creation of more accurate brain and tumor phantoms using agarose hydrogels will also be included in future work. The improved phantoms should match the stiffness and shearing behavior better due to the tunable amount of agarose. With both the new prototypes and phantoms we can obtain data to decide if there is need for further development and research. One final part of the future work will include the sterilization of the parts to analyze the feasibility of DMLS parts included in the medical device.

Individual Roles and Responsibilities

Many components of this process were done together as a team. The team would meet weekly and decide who would perform each task. Ella Brinkman would delegate tasks and lead the team meetings, Cade Smarr performed the role of the designer and worked on all the

Solidworks drawings, and Christy Skakun and Vince Grosso did not have defined roles, but completed much of the written components of the project.

Professional and Ethical Responsibilities

As the final design was developed, the professional and ethical responsibilities that related to the product were considered. Since the product is designated for brain surgery, the group aimed to develop aspects of this device to allow the user, the medical clinician, to easily perform the surgery without harm to the patient. Developing a device that reduces risk during procedure will allow the clinician to uphold the ethical responsibilities which include loyalty, respect for others, and doing good and avoiding harm to others. During development, the safety of the patient was our major concern, and we strategically designed the device to reduce the amount of risk during surgery.

Acknowledgements

Dr. Tsulee Chen: Clinician

Stephen Paterson: Lab Tech

Elijah Wreh: Professor

Dr. Ge Zhang: Faculty Advisor

References

"2022 GI Endoscopy Coding and Reimbursement Guide," *Cook Medical*, 2021. [Online]. Available: https://www.cookmedical.com/wp-content/uploads/2021/12/RG_ESC_50099_RE_202201-1.pdf. [Accessed: 22-Apr-2023].

C. W. Chow, S. A. Haider, K. Ragunath, G. P. Aithal, M. W. James, J. Ortiz-Fernandez-Sordo, A. D. Aravinthan, and S. V. Venkatachalapathy, "Comparison of the reverse bevel versus franseen type endoscopic ultrasound needle," *World journal of gastrointestinal endoscopy*, 16-Sep-2020. [Online]. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7503614/. [Accessed: 22-Apr-2023].

"Carr," *McMaster*. [Online]. Available: https://www.mcmaster.com/stainless-steel-tubing/od~0-115/. [Accessed: 22-Apr-2023].

"Community here. breakthroughs ahead.," *National Brain Tumor Society*, 20-Apr-2023. [Online]. Available: https://braintumor.org/. [Accessed: 22-Apr-2023].

D. C. Stewart, A. Rubiano, K. Dyson, and C. S. Simmons, "Mechanical characterization of human brain tumors from patients and comparison to potential surgical phantoms," *PloS one*, 05-Jun-2017. [Online]. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5459328/. [Accessed: 22-Apr-2023].

D. Lauritzen, “Cancer diagnostics & surgery products,” *Mammotome*, 22-Feb-2023. [Online]. Available: https://www.mammotome.com/products-overview/. [Accessed: 22-Apr-2023].

“Endoscopy - 2023 Procedural Payment Guide,” *GI Procedural Reimbursement*, 2023. [Online]. Available: https://www.bostonscientific.com/content/dam/bostonscientific/Reimbursement/Gastroenterology/pdf/GI_Procedural_Reimbursement_Guide.pdf. [Accessed: 22-Apr-2023].

“The LOTTA System for Intraventricular Neuroendoscopy,” *EndoWorld*, 2021. [Online]. Available: https://www.karlstorz.com/cps/rde/xbcr/karlstorz_assets/ASSETS/3656724.pdf. [Accessed: 22-Apr-2023].

“Myriad ®,” *NICO Corporation*, 31-Oct-2019. [Online]. Available: https://niconeuro.com/myriad/. [Accessed: 22-Apr-2023].

“Revolve™ Stereotactic Biopsy device,” *Mammotome*. [Online]. Available: https://www.mammotome.com/products/mammotome-revolve/mammotome-revolve-sterotactic/. [Accessed: 22-Apr-2023].

S. Budday, R. Nay, R. de Rooij, P. Steinmann, T. Wyrobek, T. C. Ovaert, and E. Kuhl, “Mechanical properties of gray and white matter brain tissue by indentation,” *Journal of the mechanical behavior of biomedical materials*, Jun-2015. [Online]. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4395547/. [Accessed: 22-Apr-2023].

“Welcome to CAB direct,” *CAB Direct*. [Online]. Available: https://www.cabdirect.org/cabdirect. [Accessed: 22-Apr-2023].

Y. Choi, H. S. Choi, W. K. Jeon, B. I. Kim, D. I. Park, Y. K. Cho, H. J. Kim, J. H. Park, and C. I. Sohn, “Optimal number of endoscopic biopsies in diagnosis of Advanced Gastric and colorectal cancer,” *Journal of Korean medical science*, Jan-2012. [Online]. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3247772/. [Accessed: 22-Apr-2023].

Appendix

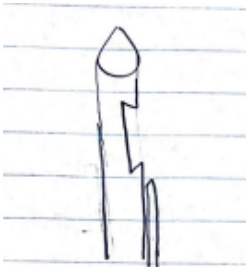

Figure 1: Brainstorm 1

Figure 2: Brainstorm 2

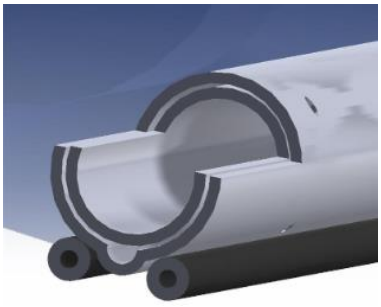

Figure 3: Brainstorm 3

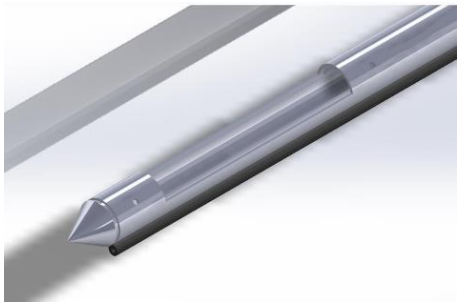

Figure 4: Brainstorm 4

Table 1: Design FMEA

System _____

Subsystem _____

Component _____

Design Lead _____

Core Team _____

Potential Failure Mode and Effects Analysis (Design FMEA)

Key Date _____

Item / Function	Potential Failure Mode(s)	Potential Effect(s) of Failure	Sev	Potential Cause(s)/ Mechanism(s) of Failure	Prob	Current Design Controls	Det	RPN	Recommended Action(s)
vaccuum	excessive suction	loss of sight	1	user error of vacuum pressure	2	N/a	1	**2**	
syringe length set lock	lock shifting or sliding along the syringe	Overextension /length of device	5	screw not set with a tight	2	user controled and set	1	**10**	
syringe lock and seal	incomplete seal	Insufficient suction	1	inner stylet not pushed in far enough	2	user controled and set	1	**2**	
Cauterizer	excessive current	Brain or tissue damage	5	circuit failure	1	N/a	3	**15**	
stylet rotation take sample	incomplete cut	Inadequate cut/sample	1	incomplete rotation	1	rotational ridge on stylet connection	1	**1**	
outer stylet/puncture tumor guide inner stylet	Weakness/ fracture	surgical removal may be needed	5	material defects	1	Quality Assurance	2	**10**	