Development of Implants to Prevent Pancreatic Fistula and Evaluation of the Effects of Computational Fluid Dynamics

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***Abstract*— The Whipple procedure is a complex surgery in which the head of the pancreas, a part of the duodenum, the gallbladder, and a portion of the stomach are removed. This procedure is performed to remove the tumor and preserve the healthy structure. One of the potential risks and the most common one is the postoperative pancreatic fistula (POPF), which is caused by the pancreatic fluid leakage from the anastomotic sutures. This study aims to develop an implant for reducing the leakage and the suture needs. Furthermore, the design is supported with computational fluid dynamics (CFD) analysis to evaluate the pancreatic fluid flow behavior.**

***Keywords*— Pancreatic leakage, implant, pancreaticoduodenectomy, pancreatic fistula.**

I.INTRODUCTION

According to data published by the American Cancer Society, pancreatic cancer accounts for 3% of all cancer diagnoses. However, because the disease grows and spreads rapidly without symptoms, it also accounts for 7% of cancer-related deaths [1].

Due to the removal of cancer from the pancreas, there is a very difficult and complex surgery called the Whipple operation. In this operation, the pancreas head, some part of the duodenum, a part of the stomach, and potentially the bile duct can be removed. The risk of this operation is that, after combining all these remaining parts, pancreatic fluid, which contains very powerful digestive enzymes (amylase, lipase, and trypsin), can leak through the sutures and damage the surrounding organs by causing the POPF [2,3]. A representative image of the Whipple procedure is shown in Figure 1.

Sutures are used to reattach the remaining parts removed during surgery. The placement of these sutures varies depending on the technique. First, the outer wall of the pancreas is attached to the intestine and sutured in one direction. Then, a hole approximately the same diameter as the Wirsung duct, which opens into the duodenum for the anastomosis site, is sutured to the duct. After the internal suture is completed, the outer wall is completely sutured to ensure stability [2]. This double suture provides strong stability to the region. Figure 2 shows a schematic of the Heidelberg technique, one of the suture techniques.

Suturing is a good approach for stabilization, but it is not always sufficient. It involves a long surgical time and technical difficulties. One of the risks is the possibility of tearing the soft tissue of the pancreas. As a result, destructive digestive enzymes (amylase, lipase, and trypsin) leak out and damage surrounding tissue. This damage results in POPF, which can increase patients' mortality risk by 5-10 times, prolong hospital stays, and even require repeat surgery. The rate of postoperative pancreatic fistula varies between 11.4% and 40% [3].

The limited number of engineering-based approaches to prevent POPF in the literature is one of the most challenging aspects of such research. This limited number of resources makes it difficult to accurately predict research results. In a study conducted in this field, they demonstrated the ability to create patient-specific stents using 3D printing and tested this clinically in animal studies [6]. While the study observed a reduction in leakage, there was a problem with the mechanical stabilization of the stent at its placement point, and over time, the stent began to migrate from its location into the small intestine.

This research aims to design an implant that will be placed between the pancreas and duodenum at the anastomosis site, and reduce the leakage and suture need. Also, testing the design in computational fluid dynamics (CFD) analysis of pancreatic fluid, to see the fluid flow after the implantation. Even though lack of this subject in current literature, there are a few implant-based methods for preventing the leakage [6,7,8], but none of those studies have a simulation analysis for flow control.

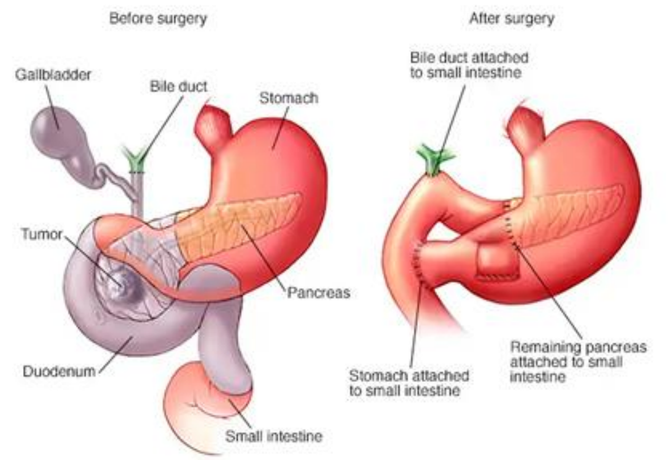

Figure 1: In Whipple surgery, the tumorous structure is removed, and healthy tissues are anastomosed to ensure secretion.

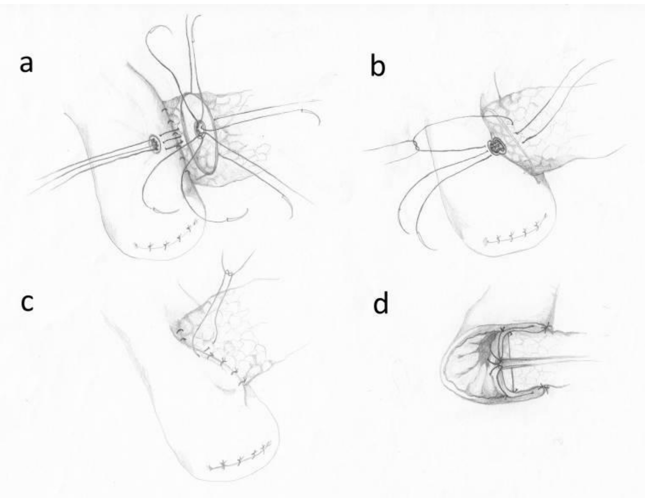

Figure 2: The modified Heidelberg technique. a The posterior external wall and four of the MPD stitches (8, 10, 12, and 2 o'clock). The 4 and 6 o'clock stitches were omitted for the clarity of the figure. b The posterior internal wall of the anastomosis is tied. c The anterior external wall of the anastomosis is tied. d The frontal section of the anastomosis [2].

II.*MATERIALS and METHODS*

A. CAD Design of Organs and Implant

In this study, the ECG-ID dataset from the PhysioNet database was used [14]. This dataset contains ECG signals from 90 individuals (44 males and 46 females), each consisting of 20-second recordings. The signals have a frequency of 500 Hz, and for some individuals, multiple recordings were collected at different times.

All the designs made by the SolidWorks 2024 software and it also used for CFD analysis for pancreatic fluid. Designs made as a sample representative for organs. During the Whipple procedure, the pancreatic head is removed. Therefore, while doing the CAD design, the pancreas head was not included. For the pancreas, the body and tail are included, and the total length is accepted as 11 cm. The width of the pancreatic wall and diameter of the wirsung channel narrow through the tail. At the start of the body area, the width is accepted as 10,75 mm and 3.5 mm for the wirsung channel diameter. Following through the tail, the diameter reduced to 1.5 mm, and the width got thinner, but not specified due to it wouldn't affect the result.
The duodenum is designed as a cylindrical pipe with a realistic size for the anastomosis area. The length of the duodenum is set to 8 cm, and the outer diameter to 5 cm. The wall thickness of the duodenum is specified as 3 mm, and that is considered for the needle design of the implant. The anastomosis site has been drilled in design for the implant placement, and the diameter of the area is set to 3.5 mm (same as the wirsung channel and the desired outer diameter of the implant).
The implant is designed to join the wirsung channel to the drilled area of the duodenum. The outer diameter is set as 3.5 mm to fit in the wirsung channel. The needles are designed to pierce through (> 3 mm) the duodenum and hold the pancreas in place. The length is designed as 8 mm. The desired outcome of this design is to hold the pancreas and duodenum together and reduce the leakage and damage caused by pancreatic fluid. The CAD designs are given in Figure 2.

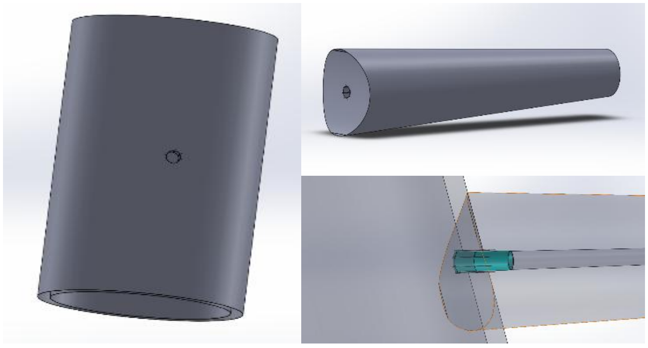

Figure 2: The CAD design of the duodenum, pancreas after the Whipple operation, and the placement of the implant on the anastomosis area.

Table 1. CAD Size Parameters of Organs and Implant

Size Parameters	Biological Part		
	Pancreas	***Duodenum***	***Implant***
Outer Diameter	10.75 mm	5 cm	3.5 mm
Inner Diameter	3.5 mm	4.4 cm	3 mm
Length	11 cm (body and tail)	8 cm	2 cm

B. Determination of Material Properties

For CFD analysis of pancreatic fluid inside the implant, the parameters of pancreatic fluid should be known. Also, the mechanical properties of the duodenum and pancreas have been found by analysing other research for future studies. There weren't enough resources for pancreatic tissue density, and it was assumed as 1000 kg/m³ for all soft tissues [9], and the duodenum and jejunum have been reported as 1087 kg/m³ [10].

The elastic modules are 1.40 ± 0.47 KPa [11] for the pancreas and 4 MPa [10] for the duodenum. The mechanical properties of the duodenum and pancreas are one of the critical factors determining how an implant will respond during insertion. An elastic modulus of approximately 4 MPa indicates that the wall is neither too stiff nor too soft, creating an ideal environment for implant needles to pass through and secure themselves within. If the tissue were weaker, tearing could occur during puncture; if it were stiffer, adequate implant penetration would be difficult. Therefore, wall thickness, deflection capacity, and expected loads were considered together in implant design, aiming to ensure a secure attachment without damaging the tissue.

The pancreas is one of the softest tissues in the human body and has very low mechanical strength. Its elastic modulus of approximately 1–2 kPa [11] means the tissue can tear easily. Therefore, the designed implant was intended not only to provide flow control but also to reduce mechanical load by supporting this delicate tissue. This aimed to both reduce the need for sutures and control the risk of tissue-related leaks.

Passion ratio found as 0.495 for both pancreas and duodenum [12,13]. The pancreatic fluid contains three different main enzymes: amylase, lipase, and trypsin. The parameters of this fluid count as one whole liquid. The density is 1010 kg/m³, viscosity 1.17-1.72 mPas [13,14], and it is modelled as not Newtonian. The parameters are given in Table 2.

Table 2. Mechanical properties of the pancreatic fluid, pancreas, and duodenum.

Mechanical Properties	Biological Part		
	Pancreatic Liquid	***Pancreas***	***Duodenum***
Density (ρ)	1010	1050 kg/m3 [9]	1087 kg/m3 [10]
Elasticity Module (E)	-	1.40 ± 0.47 KPa [11]	4 MPa [10]
Passion Ratio (v)	-	0.495 [12]	0.495 [10]
Viscosity (u)	1.17-1.72 mPa.s [13, 14]	-	-
Modelling	Not Newtonian	-	-
Substance	Amylase, Lipase, and Trypsin	-	-

C. Meshing

To conduct CFD analyses, SolidWorks Flow Simulation was used. The software's automatic mesh generation tool was used to convert the prepared 3D models into the solution space. Level 4 was chosen in this procedure from a user-configurable resolution range of 1 to 7. In order to balance calculation time and solution accuracy, this option was selected. SolidWorks divides the volume into blocks using cut-cell structures and a Cartesian grid system. In particular, the technology adaptively produced a denser mesh at the channel inlet-outlet areas and implant-tissue junctions. Near-wall flows were more accurately modeled with the default wall resolution. Solution stability was evaluated experimentally, even though a mesh independence analysis was not carried out in the conventional sense.

D. Definition Of Boundary Conditions

Boundary conditions were established based on the behavior of the biological system to make the model more realistic. The duodenal intake and the proximal end of the pancreatic duct were chosen as the locations for the flow beginning. For these surfaces, a constant pressure and a constant velocity of 0.002 m/s were established, respectively [15]. Free outlet conditions were used to illustrate the surfaces where the flow escapes. Every internal surface where the fluid comes into contact with the walls was given a slide wall condition. This presumption makes the assumption that there is little to no friction between the tissue and the fluid, which has no bearing on the flow. Periodic boundary conditions were also included in the model to account for the periodic flow assumption.

The main reason we used laminar flow in the model is the natural behavior of pancreatic fluid and the low flow velocities within the duct. Since the average velocity measured in the pancreatic duct is around 0.002 m/s, the calculated Reynolds number of the system is well below 2300. This clearly demonstrates that the flow is laminar in nature. Furthermore, the higher viscous nature of pancreatic fluid compared to water naturally suppresses turbulence. Therefore, using a laminar model not only aligns with biological reality but also yields more stable and meaningful simulation results.

D. CFD Analysis

CFD studies were carried out to determine the implant's fluid handling capacity and potential leakage risks. Simulations were conducted in the steady-state phase under the assumption of laminar flow. The solution algorithm was a pressure-based coupled solver. At each solution cycle, iterations were carried out until the error stayed below 10^{-6}. The analysis specifically looked at the following parameters: pressure distribution, wall shear stress, microleakage trends at the implant-tissue interface, the flow profile of pancreatic fluid within the device, and the possibility of fluid mixing between the two. The evaluation of the implant's postoperative safety was informed by these results. The combined design of organs and implant has shown that the flow in the pancreas is shown in Figure 3.

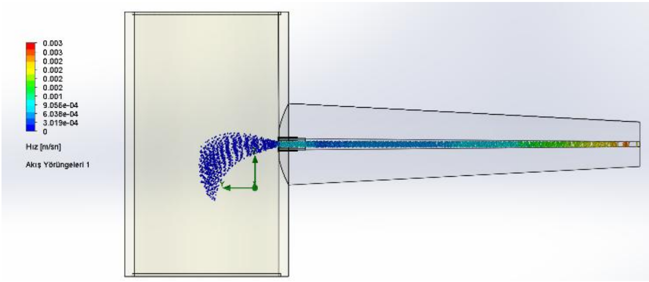

Figure 3: Velocity analysis of pancreatic liquid.

III.RESULTS AND DISCUSSION

The CFD analysis was performed in the SolidWorks Flow Simulation software. The analysis demonstrated a balanced and laminar flow of pancreatic fluid in the implant. As shown in Figure 3, the direction of flow changed as soon as it flowed out from the implant, which occurred due to the gravity parameter in the software. The velocity gained a constant speed while the fluid goes through the middle area of the implant.

The average velocity of pancreatic fluid has been determined as 0.002 m/s. A gradual reduction of the velocity has been seen at the transition zone to the duodenum, due to the expansion of the channel diameter. This reduction provided the even distribution of the flow by preventing the sudden pressure buildup at the duodenum. Analysis showed that the pressure decreases steadily from the narrow entry region within the implant to the large internal volume of the duodenum. This transition is consistent with the natural decrease in fluid velocity and is actually desirable. This prevents sudden pressure buildup at the anastomosis line. Such a buildup could create additional stress on the tissue and increase the risk of leakage. The resulting uniform pressure profile ensures a homogeneous distribution of the forces transmitted by the implant to the tissue, creating a mechanically safer environment.

The back flow hasn’t occurred in the analysis, and it supports the idea of the sealing ability of the implant, and the flow passage is controlled. So, in a simple analysis, this design showed that it has the hydrodynamic ability to prevent or reduce the risk of POPF.

At the implant surface and tissue interfaces, wall shear stresses were measured at low levels; they did not rise to critical values that would have supported the damaging effects of pancreatic fluid. This demonstrates that the fluid does not exert enough force to cause tissue irritation or microdamage. The risk of microleakage was taken into consideration because of the high enzyme content of pancreatic fluid (trypsin, lipase, and amylase); however, analyses showed no discernible tendency for backflow or leakage at the implant-tissue junctions. Low shear stress values are crucial for the healthy progression of healing at the anastomosis site. High shear stress can cause inflammation or tissue separation in the healing tissues. Therefore, the low stress values obtained demonstrate that the implant creates a biologically compatible flow environment and can support the healing process. These findings demonstrate a competitive and stable structure in terms of flow regulation, which contrasts with the 3D printing-based solutions proposed by Xiang et al. (2024) [6].

Because pancreatic duct diameters vary from patient to patient, future studies aim to develop patient-specific designs. Both ease of surgical placement and the ability of the implant to maintain its position postoperatively were prioritized during the design process. The analysis results demonstrate that the implant not only facilitates fluid management but also can be a practical surgical stabilization tool. Surgical experience is crucial in Whipple anastomoses because the tissue is very soft and sutures must be applied with care. The use of implants can reduce surgeon burden, reduce the need for sutures, and shorten operating time. Furthermore, the implant's stability in place reduces the likelihood of postoperative migration or new leaks. These aspects of the design offer real potential for clinical application. Due to the limited literature on this topic, existing resources were utilized during the design process, and the implant, designed to address the leakage problem, was also mechanically reinforced to prevent dislodgement. Thus, it is aimed to provide improvements in terms of surgical time, ease of application, and reliability.

IV.CONCLUSION

POPF, one of the most serious complications of the Whipple procedure, prolongs patient recovery time and increases the risk of mortality. The implant designed in this study aims to provide a snap-fit connection by eliminating the need for surgical sutures.

While 3D-printed stent designs developed for similar purposes exist in the literature, the geometry of this implant has been specifically optimized for the anastomotic anatomy. Further work will focus specifically on leak testing and Computational Fluid Dynamics (CFD) analyses. These analyses and leak testing will verify the clinical suitability of the implant and pave the way for future studies.

REFERENCES

[1] National Cancer Institute. (2025). Cancer stat facts: Pancreatic cancer. Surveillance, Epidemiology, and End Results Program (SEER).

[2] Mayo Clinic. (n.d.). Whipple procedure (pancreaticoduodenectomy). Mayo Clinic. Retrieved February 13, 2025

[3] Unegbu, F. C., & Anjum, F. (2023). Pancreatic Fistula. In StatPearls [Internet]. StatPearls Publishing.

[4] Olakowski, M., Grudzińska, E., & Mrowiec, S. (2020). Pancreaticojejunostomy—a review of modern techniques. Langenbeck's Archives of Surgery, 405(1), 13-22.

[5] Hassan, R. A., Zidan, A., Jabir, M. A., Abdelshafy, M., Abdallah, M., & Taha, A. M. (2022). Risk factors

predicting the development of a pancreatic fistula following pancreaticoduodenectomy: a retrospective cohort study. International Journal of Surgery Open, 45, 100509.

[6] Hackert, T., Werner, J., Weitz, J., Schmidt, J., & Büchler, M. W. (2018). Postoperative pancreatic fistula. Surgeon, 16(1), 5-12.

[7] Xiang, F., Yao, C., Guan, G., & Luo, F. (2024). Application of 3D Printing to Design and Manufacture Pancreatic Duct Stent and Animal Experiments. Bioengineering, 11(10), 1004.

[8] David, J., & Susan, S. (2008). Gray's anatomy: the anatomical basis of clinical practice.

[9] Nabavizadeh, A., Payen, T., Iuga, A. C., Sagalovskiy, I. R., Desrouilleres, D., Saharkhiz, N., ... & Konofagou, E. E. (2020). Noninvasive Young's modulus visualization of fibrosis progression and delineation of pancreatic ductal adenocarcinoma (PDAC) tumors using Harmonic Motion Elastography (HME) in vivo. Theranostics, 10(10), 4614.

[10] Liu, C., & Ma, J. (2023). Simulation Analysis of Small Intestinal Peristalsis Based on Finite Element. Advances in Engineering Technology Research, 4(1), 480-480.

[11] Pagnanelli, M., De Gaetano, F., Callera, A., Nappo, G., Capretti, G., Carrara, S., ... & Zerbi, A. (2024). Analysis of the Mechanical Characteristics of Human Pancreas through Indentation: Preliminary In Vitro Results on Surgical Samples. Biomedicines, 12(1), 91.

[12] Rubiano, A., Delitto, D., Han, S., Gerber, M., Galitz, C., Trevino, J., ... & Simmons, C. S. (2018). Viscoelastic properties of human pancreatic tumors and in vitro constructs to mimic mechanical properties. Acta biomaterialia, 67, 331-340.

[13] Tympner, F., & Rösch, W. (1978). Viscosity of pure pancreatic juice in chronic pancreatitis. Klinische Wochenschrift, 56, 421 –422.

[14] Tajikawa, T., Aoki, K., & Fukuzawa, H. (2023). Investigation of pancreatic juice reflux mechanism in high confluence of pancreaticobiliary ducts and pancreaticobiliary maljunction (Development and validation of a mathematical model for pancreatic and bile juice flow based on fluid mechanics). Journal of Biorheology, 37(2), 44-55.

[15] Hoshi, H., Sugita, R., & Machida, Y. (2023). Using spin-labeled MR imaging to depict slow pancreatic juice flow. *Magnetic Resonance in Medical Sciences*, *22*(3), 361-371.