

Designing a Novel Implant for Preventing the Risk of Postoperative Pancreatic Fistula in Whipple Surgery

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Abstract—The Whipple operation (pancreaticoduodenectomy) is a complex surgical procedure that involves the removal of the head of the pancreas, duodenum, gallbladder, and sometimes part of the stomach and bile duct. This procedure is performed to remove the tumorous structures surrounding the pancreas, leaving healthy tissue intact. To ensure the continuity of the digestive system, the remaining parts of the pancreas, bile duct, and stomach are reconnected to the intestines after the structures are removed. Due to the complexity of this operation, there are significant potential risks, one of which is pancreatic fistula, defined as the leakage of pancreatic fluid into the body cavities and surrounding tissues. Since pancreatic fluid contains potent digestive enzymes such as amylase, lipase, and trypsin, this can lead to severe tissue damage and infections. This situation typically occurs when the stitches placed by the physician in the anastomosis area, connecting the pancreatic duct to the duodenum, do not provide sufficient stability. The main reason for the formation of a fistula is that the suture line does not heal completely. To prevent serious complications in the patient, drug therapy, endoscopic stent applications, and revision surgeries may be required. This project aims to develop a new implant to prevent pancreatic fistulas. This new solution aims to connect the pancreatic duct directly to the duodenum without the use of sutures.

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

I. INTRODUCTION

A complicated surgical procedure called the Whipple procedure (pancreaticoduodenectomy) is frequently used to treat cancers of the duodenum, bile duct, or pancreatic head. The pancreatic head, duodenum, gallbladder, and a portion of the bile duct are removed, and several anastomoses are used to reassemble the organ. One of the most dangerous side effects after pancreatic surgery is pancreatic leakage [1]. The health of the patient may be seriously threatened by leakage from the pancreatojejunostomy anastomosis, especially following intricate procedures like the Whipple operation [2]. Severe inflammatory processes are triggered by the unchecked release of pancreatic enzymes into surrounding tissues, and this significantly raises the rates of postoperative morbidity and mortality [3]. Up to 33% of patients experience postoperative pancreatic fistula (POPF), which is still a widespread and difficult complication, even in specialized surgical centers [4,5,6].

The surgical procedure on the afflicted tissues is depicted in Figure 1. The anastomosis of healthy tissues occurs after the removal of the purple-colored areas, which represent the tumorous tissues.

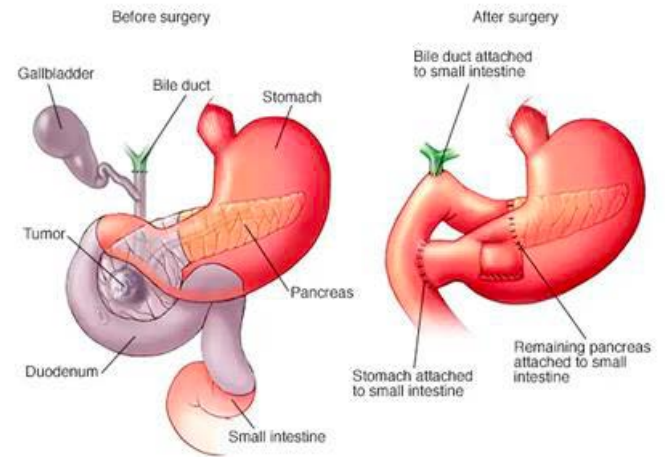


Figure 1: In Whipple surgery, the tumorous structure is removed and healthy tissues are anastomosed to ensure secretion.

An important anatomical feature that joins the common bile duct (ductus choledochus) with the Wirsung duct (pancreatic duct) before entering into the duodenum is the Ampulla of Vater. The constant passage of pancreatic and bile secretions through this region makes it extremely prone to problems. As a result, creating a biocompatible implant that stops pancreatic leakage without interfering with the Ampulla of Vater's ability to function should greatly enhance patient outcomes and lower the possibility of problems following surgery [6]. While avoiding leaking at the anastomosis site, such an implant must maintain the normal flow of pancreatic secretions.

When choosing materials for the implant, biocompatible and biomechanically stable materials must be evaluated. The materials chosen should be appropriate for long-term implantation and compatible with the surrounding tissues. Additionally, the implant needs to maintain the natural flow balance between the bile and pancreatic fluids without obstructing it and be physically compatible with the Ampulla of Vater [7].

There are currently very few implant-based methods for treating pancreatic fistula in the literature [8,9,10]. 3D-printed stents were used in one investigation; they demonstrated better recovery quality in animal models [9]. These stents' flow and leakage capabilities were not assessed, though. Despite the leak of the amount of design, the first thought design about this project has shown in Figure 2.

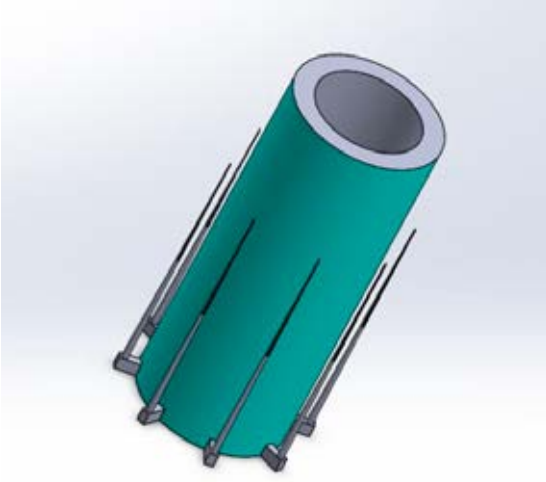


Figure 2: The CAD design of implant

It is anticipated that this effort will improve the quality of recovery for patients following Whipple surgery and lower the risk of postoperative pancreatic fistula.

II. MATERIALS AND METHODS

A. Mechanical Properties of Pancreas

The pancreas is a complex organ that has both exocrine and endocrine functions. It is placed retroperitoneal in the abdominal space and has three main anatomical parts: head, body, and tail [11]. The exocrine part includes the enzymes that are released from the pancreatic acini. These enzymes (amylase, lipase, and trypsin) play an essential role in digestion, and the transmission occurs in the Wirsung channel [12]. The endocrine part secretes insulin, glucagon, and somatostatin from the Langerhans cells. Mechanically, the pancreas has soft and easily damaged tissue.

There are no exact measurements available for the density of pancreatic tissue; however, in research, the density of all soft tissue has been standardized at 1000 kg/m^3 [13]. Due to its low elastic modulus of around $1.4 \pm 0.47 \text{ kPa}$, it exhibits high deformation ability [14]. It has a 0.495 Poisson's ratio, indicating that pancreas tissue is almost incompressible mechanically [15]. These mechanical properties make it challenging to maintain tissue stability after surgical procedures and increase the risk of leakage at the anastomosis site [3].

At the Whipple surgery, the head of the pancreas is removed, and a representation of the remaining part is designed using CAD software, as shown in Figure 3. The length of the remaining pancreas can be altered due to the operation and the

patient's condition. In this design, the total length of the body and tail has been determined to be 11 cm, and the thickness of the wall is 10.75 mm at the body and 6 mm at the end of the tail. Furthermore, the channel diameter is 3.5 mm at the body and 1.5 mm at the tail.



Figure 3: Pancreas design after Whipple surgery.

B. Mechanical Properties of Duodenum/Jejunum

The small intestine has three parts: the duodenum, jejunum, and ileum. The jejunum is the middle segment, which begins with the ligament of Treitz and continues into the ileum [11]. The duodenum is the first section of the small intestine, located between the stomach and the jejunum. It is approximately 25-30 cm long [16]. In this region, the bile duct and pancreatic duct open into the duodenum through the ampulla of Vater [7].

The wall of the duodenum consists of the mucosal layer, submucosa, muscle layer, and serosa. The average wall thickness is 2-3 mm [17].

The jejunum has an approximate length of 2.5 meters and plays a crucial role in the digestion and absorption of nutrients [18]. The jejunum has an elastic, flexible, and porous structure. In research, its density is reported as approximately 1120 kg/m^3 [19]. Its elasticity module ranges around 4 MPa, demonstrating its high elasticity and ability to change shape under tension [19]. The passion ratio is 0.45, indicating that the jejunum doesn't have significant volumetric changes when it is stretched [19].

During the surgery, most of the duodenum is removed and connected again to the pancreas. A representation of the duodenum is shown in Figure 4. The length of the duodenum is determined as 8 cm, the outer diameter is 5 cm, and the thickness of the wall is 3 mm. The duct diameter is 2.5 cm, which is determined by the width of the pancreatic duct.



Figure 4: CAD representation of duodenum.

C. Design of Implant and Organ Geometries

For this study, three-dimensional (3D) models of the implant and the surrounding anatomical elements were produced using SolidWorks 2024 CAD software. The implant was specifically designed to fit the pancreaticojejunostomy site smoothly following the Whipple procedure. For simple insertion during surgery, the implant was made with a snap-fit mechanism. The goal of this design was to establish a secure and leak-proof bond without harming the surrounding tissues. Figure 5 provides a graphic representation and placement of the finished implant.

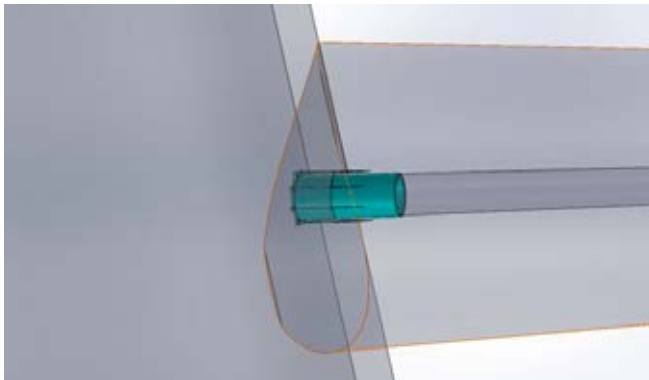


Figure 5: Placement of Implant: From the inside of the duodenum to the pancreatic duct.

D. Determination of Material Properties

The physical characteristics of the implant, pancreatic fluid, and surrounding tissues were carefully chosen during the modeling procedure. The biocompatibility and resistance to pancreatic enzymes of the materials used in the implant's manufacture were assessed. The goal was to prevent the structure from being damaged by digestive enzymes, such as trypsin, lipase, and amylase. The intestinal tissue's porous and flexible structure was noted; its flexibility is crucial for modeling dynamic motions in the regions that will come into contact with the implant following surgery. In contrast, a softer tissue with a low elastic modulus was used to simulate the pancreas. This delicate structure highlights the need for a sutureless solution. Despite having a low viscosity, pancreatic

fluid is quite biochemically active. For the sake of simplicity, it was treated as a Newtonian fluid in this study, even though it is typically described as a non-Newtonian fluid in the literature. The flow environment was also used to replicate a second fluid flow that came from the duodenum, in addition to pancreatic fluid. It was determined that this second fluid shared the same physical characteristics as water. Table 1 provides a summary of the mechanical and physical parameters.

Table 1. Mechanical properties of biological tissues

Mechanical Properties	Biological Part		
	Pancreatic Liquid	Pancreas	Duodenum
Density (ρ)	1010	1050 kg/m ³ [13]	1087 kg/m ³ [19]
Elasticity Module (E)	-	1.40 ± 0.47 KPa [14]	4 MPa [19]
Passion Ratio (ν)	-	0.495 [15]	0.495 [19]
Viscosity (μ)	1.17-1.72 mPa.s [17, 18]	-	-
Modelling	Not Newtonian	-	-
Substance	Amylase, Lipase, and Trypsin	-	-

III. RESULTS

The final implant model was designed to facilitate sutureless placement at the anastomosis site following the Whipple procedure. The implant, created using three-dimensional modeling, was optimized and placed based on the anatomical dimensions of the pancreatic duct and duodenum. Material properties and parameters were researched for future use and research. The implant's needle-based insertion mechanism was designed to allow for rapid placement and secure fixation during surgery. The goal was to minimize tissue damage caused by this structure. The model's surface geometry was adjusted for direct placement within the Wirsung duct. The implant was designed to ensure no gaps were left. Because duct widths can vary from patient to patient, future studies may aim to offer individual designs for each patient. The design prioritized both ease of placement and retention of the postoperative position. Due to the gap in the literature, reference sources were consulted, and the implant, designed to address the leakage problem, was mechanically enhanced to prevent removal from its original location, thereby prioritizing surgical time and ease of use.

IV. DISCUSSION

POPF, one of the most serious complications after the Whipple procedure, prolongs patient recovery time and increases the risk of mortality. Because traditional anastomosis techniques cannot always provide adequate protection against leakage due to the soft tissue of the pancreas and the small diameter of the pancreatic duct, an implant design that facilitates this situation is of significant importance in both the

literature and the clinic. The implant designed in this study aims to eliminate the need for surgical sutures and provide a seamless connection. This aims to reduce the risk of leakage from enzymatic fluids passing between the pancreatic duct and duodenum, as well as the risk of fistula problems resulting from the destructive effects of leakage. The snap-fit mechanism ensures implant retention and postoperative stability while potentially causing minimal tissue damage. While 3D-printed stent designs developed for similar purposes exist in the literature, the geometry of this implant has been optimized to adapt to the anastomotic anatomy specifically. While the design demonstrates the correct approach, analyses must be conducted to support its reliability. Further studies are particularly focused on leak tests and CFD analyses. Thanks to analyses and leakage tests, the clinical suitability of the implant will be checked, and the door can be opened for future studies.

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