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Abstract

Title of Study	Development and validation of a synthetic model of the pancreatic anastomosis
Abstract and methodological description	A pancreaticoduodenectomy (PD) is an operation for the treatment of various disorders of the duodenum, distal common bile duct, and pancreatic head and periampullary region. Although PDs have been in existence for more than 80 years, it is still a challenging operation because the mortality rate is about 2–4% and the morbidity rate ranges from 40% to 58% in high-volume centres 3. Postoperative pancreatic fistula (POPF) and bile leakage remain the most important contributors to the high morbidity and mortality rates after PD surgery . Excellent and precise operating skills for a pancreaticoduodenectomy are key factors in reducing anastomotic leakage. POPF is major cause of morbidity and mortality after pancreaticoduodenectomy. Learning curve for pancreatic anastomosis is 50-60 cases suggesting that the execution of the anastomosis is important and requires experience. Most surgeons perform a maximum of 15-20 pancreaticoduodenectomy per year.

A surgical training model for pancreaticoduodenectomy would be advantageous for novices in the techniques. Practicing a specific procedure or operation should be required prior to an actual clinical situation.
Practical training models can be a viable and effective educational tool that allows surgeons to acquire specific surgical techniques or skills.
Various such training models are available but while developing these models none have taken into consideration the biomechanical properties of pancreas. Hence our aim is to develop a training module by measuring biomechanical properties of pancreas.
The study would help establish whether the learning curve of a complex procedure like pancreaticoduodenectomy could be shortened and hence reduce the chances of complications like POPF.

This study will be conducted in department of Hepato-pancreatico-billiary (HPB) and Liver Transplantation, Queen Elizabeth Hospital, Birmingham, UK in collaboration with biomedical engineers from University of Birmingham, UK.

Ethical committee clearance will be obtained. Review of literature will be done of existing studies on ex situ training (bio tissue or virtual reality) of pancreatic or other GI anastomosis and available models of pancreas/ pancreatic anastomosis.

Then a study of biomechanical properties of porcine and human pancreas will be done where in the dynamic mechanical analysis will be used to measure the viscoelastic properties of the pancreas. Based on these analyses a synthetic 3D printed model of pancreas will be developed.

For the development of this model, medical images of the pancreas will be used to generate 3D shapes (e.g. using 3D Slicer) from which CAD images (e.g. STL files) will be exported. These files are compatible with 3D printing technology. In the first instance, moulds will be 3D printed, with PDMS (Polydimethylsiloxane) which has comparable properties to other natural tissues. The possibility for industry to manufacture a construct which more closely matches the measured viscoelastic properties of the pancreas will also

be explored.

The model will then be compared with the biomechanical properties of the human pancreas to ensure that the engineered pancreatic anastomosis has properties which would comprise of the following:
• Similarity in structure and mechanical properties.
• Structural integrity (anastomotic leak).
• Mechanical properties before and after completion of the anastomosis
• Incidence of POPF for a novice surgeon as in comparison to an experienced pancreatic surgeon.

Appropriate statistical test of analyses will be applied and results will be formulated. The study would help establish whether the learning curve of a complex procedure like pancreaticoduodenectomy could be shortened and hence reduce the chances of complications like POPF.

Sample Size Synthetic model - 20 Porcine model-10 Human model- 10

After ethical approval, human pancreas - Post pancreatectomy specimens, a sample of tissue would be obtained from the histopathology lab and used for our study to measure biomechanics properties of the pancreas. After surgery, a portion of the resected tissue will be sent to pathology and to satisfy other clinical requirements. If enough tissue is left, the remaining portion would be prepared for indentation testing.
The tissue samples will excluded from study if patients have received chemo- or radiation therapy prior to surgery. ‘‘Normal” tissue with no histologic evidence of pancreatitis or malignancy will be included in the study. Conditions such as benign cystic lesions or duodenal adenomas will also be included.

The Young’s Modulus (E) is a measure of stiffness of an elastic material. This Elastic Modulus, can be defined as the ratio of the stress along an axis over the strain along that axis within the range of stress. This definition is limited to materials which obey Hooke’s law. Stress is the degree of compressive loading and strain is the amount of deformation, both of which are generated by external force imposed on a material. E can be derived experimentally from a

	stress-strain curve generated by conducting tensile testing of a material sample. The material may be hyper-elastic though, in which case it may not obey Hooke's law. In this case, stress-strain data will be characterised using a hyper-elastic material model (e.g. neo-Hookean, Mooney-Rivlin, Yeoh, or Ogden hyper-elastic models). Coefficients for hyper-elasticity will be obtained using material's characterisation packages within numerical modelling software (e.g. Abaqus). The testing protocol will include measurement of viscoelastic properties as obtained using Dynamic Mechanical Analysis. The storage and loss moduli (ability of the material to store and dissipate energy, respectively) which characterise its viscoelasticity can be measured as a function of strain, and frequency. All materials testing will be performed using a Bose 3200 material's testing machine. Before the start of this project, synthetic models with a tactile sensation similar to that of the human pancreas will used to calibrate the experimental apparatus with appropriate values, and 10 resected pancreatic specimens will be tested preliminarily to provide a learning curve for the measurement procedure. In every case, the measurement procedure and circumstances would be standardized, and all experiments will be performed by a single investigator. This study will help us device a model of pancreas and pancreatic anastomosis which could serve as a learning tool for bettering the skills of novice surgeon for a complex procedure like pancreaticodudenectomy. It would help in shortening the learning curve and hence reduce the high rate of morbidity associated with the complications occurring with pancreaticoduodenectomy such as postoperative pancreatic fistula (POPF). This would result in improved patient safety, less hospital stay and cost effective outcome.

Timetable

Name	Review of literature
Date	Completed

Name	Study of biomechanics properties of synthetic, porcine,human pancreas
Date	October 2021

Name	Development of synthetic 3D printed model of pancreatic anastomosis using moulds
Date	October 2022

Name	Development of prototype
Date	January 2023

Funding

Name	Synthetic material LifeLike Biotissue
Amount	1400.0

Name	Medical meat supplier/porcine samples
Amount	150.0

Name	Human Biomedical Resource Centre:Recruitment,Sample procurement,Transfer of samples, sample receipt, logging and retrieval
Amount	3568.0

Name	Consumables including gloves,virkon,disposable lab coats etc.
Amount	300.0

Name	Cost of material including testing machines eg:3D printing, powder,filaments etc.
Amount	2000.0

Name	Miscellaneous
Amount	500.0

Name	Development of prototype-industry made
Amount	2000.0

Details of ethical approval

Ethical approval will be obtained through Human Biomaterial Resource Centre- University of Birmingham, UK through proper channel.

Institutional approval information

This project is in collaboration with the mechanical engineers from the University of Birmingham.
The proposal has been approved by the committee and registered.

Declaration

Confirm Declaration: Yes

Head of Department

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