Blood Flow Occlusion Device for Liver Resection

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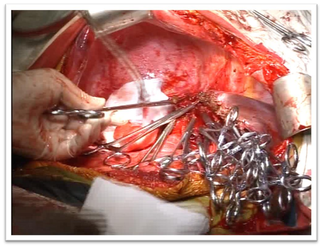
Abstract

Excessive bleeding is the most common complication of liver resection. Currently, no low-cost devices exist that reduce blood loss during resection while minimizing residual tissue damage, increasing speed of the procedure, and sealing bile ducts. We have designed such a device, the SutureTie, a purely mechanical apparatus that allows surgeons to insert resorbable zip-tie sutures into the liver parenchyma to obstruct local blood flow prior to manual transection. A proof-of-concept prototype has been tested successfully on a perfused, ex vivo porcine model.

Problem

- Excessive bleeding during liver resection increases perioperative and postoperative morbidity
- The Pringle maneuver, used to occlude blood inflow during resection, can only be applied in 15-20 intervals due to risk of hypoxia
- Current devices on the market have a number of drawbacks including
  - Excessive residual tissue damage
  - Slow transection speed
  - Inability to seal bile ducts
  - Excessive fluid influx
  - Prohibitively high cost



In the “clamp-and-crush” technique, Kelly clamps are inserted into the liver parenchyma to occlude blood flow prior to transection. Though manual and skill-intensive, this technique is the most widely used technique for liver resection due to its speed, low cost, and proven effectiveness.

Objectives

Design a device that

- Minimizes blood loss
- Minimizes residual tissue damage
- Occludes both blood vessels and bile ducts
- Does not increase surgical time
- Does not increase risk to patient
- Is low cost
- Can be widely adoptable, even internationally

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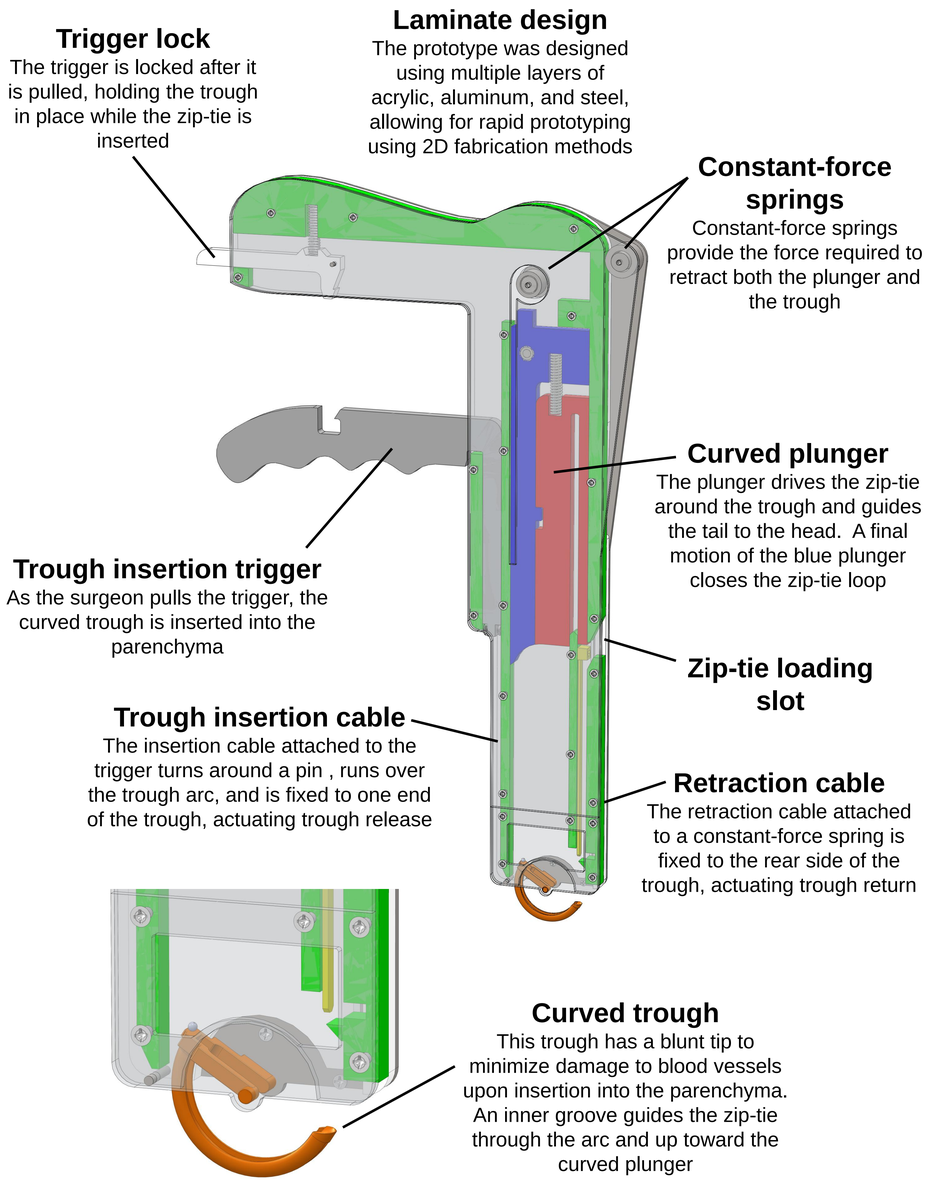
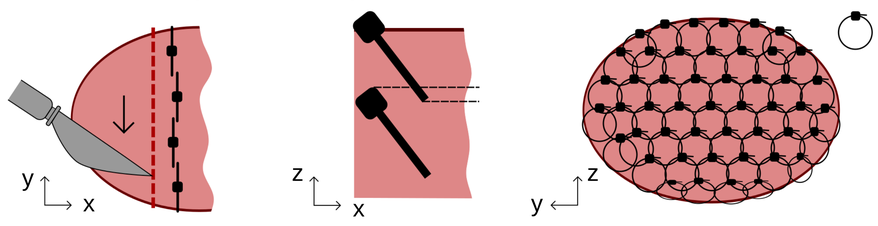


Time series showing trough release and zip-tie closure

Surgical technique for use of SutureTie



Sutures are applied slightly overlapping and along desired transection plane. Scalpel is then used to cut along plane

Process is repeated as another layer is occluded. In order to lay ties vertically on top of each other, a slanted insertion is necessary

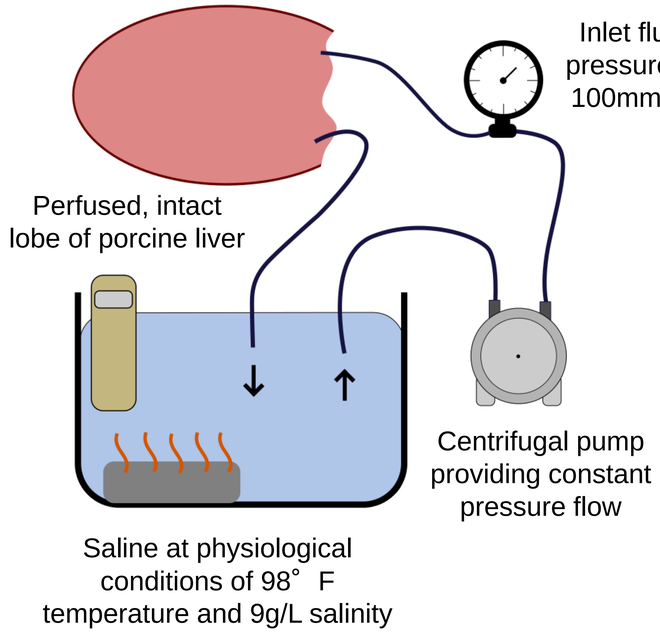
A cross-sectional view of a fully-occluded transection plane. Approximately 30 sutures are required for an average size plane

Evaluation

Several calculations were performed to ensure the feasibility of this design:

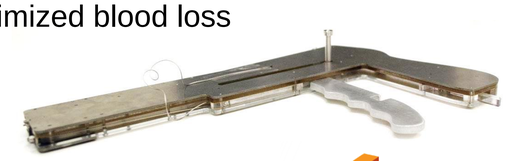
- Manual actuation forces are in ergonomic range
  - 13.2N to insert trough and puncture liver
  - 3.34 N to actuate plunger and close zip-tie
- Trough stress factor of safety of 4
  - FEA analysis shows maximum stress of 55 MPa
- Suture tensioning requires 43.5 N, easily provided by hand

Additionally, the proof-of-concept prototype was tested on an ex vivo porcine model:



Future Work

- One-handed operation
- Suture cartridge for rapid, automatic loading of subsequent zip-ties
- Suture tensioning mechanism to avoid manual tightening of zip-ties
- Added surgical blade to automatically make incision next to the occluded plane
- Testing on in-vivo porcine model to verify minimized blood loss



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