EXPERIMENTAL AND COMPUTATIONAL APPROACH TO STUDY STAPLED COLORECTAL ANASTOMOSIS

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SUMMARY
This paper presents a methodology to study and understand the mechanics of stapled anastomotic behaviors by combining empirical experimentation and finite element analysis. Performance of stapled anastomosis is studied in terms of leakage and numerical results which are compared to *in vitro* experiments performed on fresh porcine tissue. Results suggest that leaks occur between the tissue and staple legs penetrating through the tissue.

INTRODUCTION
Continuity of the gastrointestinal tract after surgery is usually re-established with a sutured or stapled anastomosis. The stapled anastomoses technique is highly standardized with many benefits such as excellent blood control and reduced tissue manipulation. Conversely, major issues such as post-op bleeding, leakage and/or stenosis remain with stapled anastomoses [1,2,3]. Anastomotic dehiscence with successive peritonitis may have detrimental consequences and possibly result in death. This paper presents a methodology that has been developed to study mechanics of tissue stapling. We have developed a simplified finite element model for simulating the circular stapling process in order to study and evaluate mechanical performance. Numerical simulation is compared to experiments done on fresh porcine tissue.

METHODS
Six rectangular samples of fresh porcine transverse colon are tested in both circumferential and longitudinal tensile directions. Intermediate fit by exponential function is used to identify a mean tensile curve. The mean tensile curve is fitted with 3rd order Ogden incompressible hyperelastic model in order to identify specific material coefficients of the tissue (Table 1). Material stability and convexity of the stored strain energy function are checked to ensure good physical behavior of the material. Moreover, three cylindrical samples of fresh porcine transverse colon are tested in compression. The fitted curve is compared to the experimental curves to ensure compatibility of material model in both tensile and compressive modes (Figure 1).

Table 1: Material coefficients identified for tissue.

μ_1 (Pa)	α_1 (–)	μ_2 (Pa)	α_2 (–)	μ_3 (Pa)	α_3 (–)
8300	7.625	200	13.875	6200	7.625

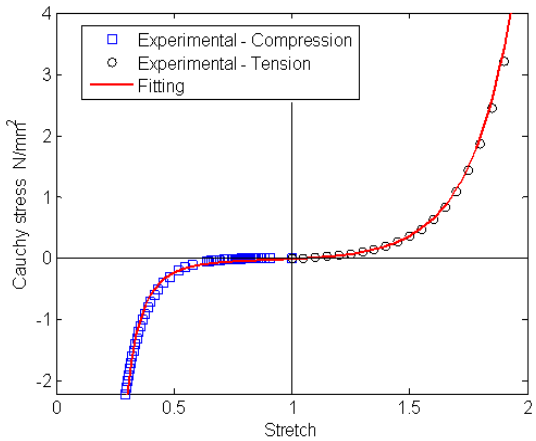

Figure 1: Curve fitting for the tissue with Ogden model.

An *in vitro* burst test is done on the tissue from the same animal to evaluate strength and leak pressure of the colorectal end-to-end anastomosis (EEA). This data is also used to compare the finite element simulation with experimental results. The tissue specimen with a circular anastomosis is emerged in water with the bottom end closed by a plug and top end attached to a fluid circuit containing colored liquid (Fluorescein sodium salt, Sigma-Aldrich). Pressure in the circuit is detected by pressure transducer (Heise® DXD). A computer controlled syringe pump (Harvard Apparatus PHD 2000) fills the tissue with colored liquid until leak and/or burst occurs. Leak is when first colored water appears on the outside. In case of burst, there are so many leaks that the pressure cannot be increased. The tissue sample is observed by penetrating dye (Figure 2) by three cameras (Stingray F146C IRF 1394) and the whole experiment is recorded. Leaks are detected visually by the operator observing the computer screen showing real-time images of the three cameras. These videos are recorded for review.

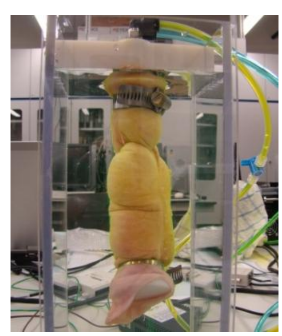

Figure 2: Burst test of stapled colorectal anastomosis.

The DST™ Series EEA™ Circular Stapler 25 mm with 2 mm closed height of the staples is evaluated in this study. The finite element model consists of two tissue layers, two compressive platens and two rows of staples. Simulation of stapling procedure consists in several phases: 1) both tissue layers are compressed by platens to fit in the staples' islets; 2) contact between back-spans of staples and surfaces of tissues is activated and stabilized; 3) platens are released while tissue layers are being held together only by the staples; 4) pressure is applied on the interior faces of the tissue layers to simulate the burst test. To reduce computational cost and since there are 11 staples per row, only a portion of 360°/11 is modeled. Thus, there is one complete staple in the inner row and two half-staples in the outer row. Symmetry boundary conditions are prescribed on symmetry faces of the tissue and half-staples. The initial thickness of tissue wall is 1.5 mm giving the total thickness of 3 mm. This is in good correspondence with the thickness of the tissue used for burst test that was approximately 3.12 mm. Compression is applied by prescribing displacements on both platens. The tissue is compressed by 32.6% from 3 mm to 2.02 mm to fit the islets of the staples. The tissue is modeled as an incompressible hyperelastic material while the platens and the staples are considered linearly elastic. Platens are made of steel with Young's modulus 200 GPa and Poisson's coefficient 0.3. Staples are made of titanium with Young's modulus 96 GPa and Poisson's coefficient 0.36. Frictional contact with a friction coefficient equal to 0.1 is defined between tissue and platens and between both tissue layers. Tight (bonded) contact is defined between surfaces of tissues and interior surfaces of staples' back-spans. A general-purpose FE implicit code Ansys® Structural™ Release 13.01 was employed in the analysis.

RESULTS AND DISCUSSION

As the tissue is compressed, it is partly squeezed out of the stapler while the anastomotic lip (inner part of the tissue) remains inside. There exists a neutral surface with zero radial displacement in the tissue. The contact between the two tissue layers opens slightly at the area of the anastomotic lip. During the release phase, the neutral surface moves towards center of the stapler and disappears at approximately 13% of the release. Thus, the anastomotic lip has a tendency to slip outside the stapler. The opening of the anastomotic lip is growing wider. When the internal pressure is applied, this opening is closed. Leak pressure of 1586 Pa and burst pressure of 3820 Pa were recorded for the burst test. The leakage mode is not clear even though it seems that leakage occurs mainly at the interface of tissue with staple legs. Our model does not take into account the penetration of staple legs through the tissue. On the other hand, the contact between the two tissue layers is closed and sticky around the staples all along the simulation suggesting that no leakage can appear due to dehiscence of the tissue layers. Thus, one may accept a hypothesis that leaks occur mainly around staple legs by cutting the surrounding tissues. Maximum principle stress within the tissue does not exceed 0.2 MPa except for the concentrations up to 1.5 MPa occurring around corners of staples and mainly caused by sharp edges of the tissue-staple contact. Such stress seems to be high enough to induce closure of blood vessels within the tissue in order to prevent bleeding. The model features various kinds of non-linearities: non-linear material, large deformations and frictional contacts. The model also allows for relative movement of the staples. However, compared to the real stapling procedure, several simplifying hypotheses are accepted: there is no interaction between the staple legs and the tissue and the knife cutting through the tissue to assure appropriate lumen is not considered at all. Neglecting these phenomena is related directly to model limitations and convergence difficulties. At the end of the release phase, the only fixed nodes are those of the internal radius of the bottom and top faces of the tissue cylinder. Thus, majority of the structure can experience rigid body motion leading to serious convergence issues. This could be a consequence of neglecting the knife cutting the tissue. Internal pressure is not applied on open contact faces of the anastomotic lip. One might suppose that considering this phenomenon could lead to even wider opening and, by consequence, to leakage between the tissue layers. However, uniform pressure as loading condition is only a model situation that does not entirely reflect the reality.

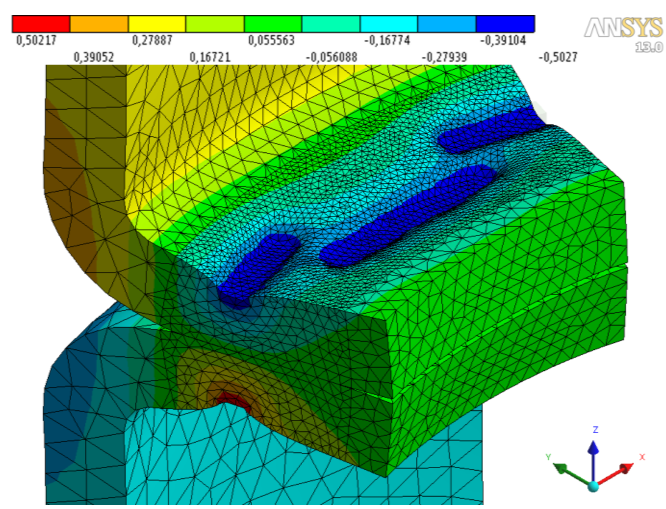

Figure 3: Detailed view of the field of displacement (in mm) in longitudinal axis (Z) after application of leak pressure. Only tissue is displayed.

CONCLUSIONS

Developed tools allow studying mechanics of tissue stapling. Computed stress distribution could be related to blood supply within the tissue. The model is limited to study only leakage between the tissue layers. Further improvements and validation should lead to a model able to investigate leak modes in more details.

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