



An Experimental Study of Intraluminal Hyperpressure Reproducing a Gastric Leak Following a Sleeve Gastrectomy

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Abstract

Introduction A gastric leak (GL) represents the main post-operative complication following a sleeve gastrectomy (SG) and occurs most commonly at the top of the stapling, without any clear explanation.

Objective This experimental study evaluates the biomechanical behavior of post-SG gastric specimens using both insufflation and tensile tests.

Materials and Methods A total gastrectomy followed by an ex vivo SG was performed in 15 pigs. The “sleeved” stomachs were subjected to intraluminal hyperpressure until failure. Uniaxial circumferential and longitudinal tensile tests were performed using gastric strips obtained from the “resected” stomachs. All the deformations and burst pressures were recorded and analyzed.

Results A GL appeared in the upper third of the stapling in 73% of cases. The mean burst pressure was 26.3 ± 5.3 mmHg and was significantly correlated with the volume of the “sleeved” stomachs ($p = 0.02$). The overall deformation of the “sleeved” stomachs was comparable in the frontal (38.3%) and profile (40.5%) planes. The greatest displacement was observed at the failure zone (11 mm on average). The biomechanical behavior of the stomach wall differed according to the strip orientation. The circumferential strips presented a higher strain-to-failure rate (97%) and a lower Young’s modulus (0.99 MPa) when compared to the longitudinal strips (45% and 2.58 MPa, respectively).

Conclusion This preliminary study reproduced a GL in the same location as observed during clinical practice. The volume of the SG influenced the burst pressure. Further experimental studies and numerical simulations should evaluate the impact of shape modifications on an SG.

Keywords Obesity · Sleeve gastrectomy · Gastric leak · Hyperpressure · Biomechanical behavior

Introduction

According to the World Health Organization, obesity affected 600 million people worldwide in 2014 and it has become a global health problem [1]. The effectiveness of the surgical management of obesity has been shown to be

superior in terms of the associated weight loss [2, 3], complications [4, 5], and mortality rate [6, 7] when compared to medical care alone [8]. A sleeve gastrectomy (SG) is currently the most commonly performed type of bariatric surgery [9]. However, although SGs are practiced routinely, certain risks remain. The mortality rate following an SG is approximately 0.1%, with the major morbidity rate ranging from 5 to 7%, notably because a post-operative gastric leak (GL) has been found to occur in about 2–3% of cases [10–12]. Although the risk of a GL following an SG is relatively low, given the increasing frequency of SG (the number is increasing by approximately 5000 year-over-year in France), a growing number of patients will likely be treated for this complication. The most common location for a GL following an SG is the upper third of the stapling, which is the case for 70% of patients [13], suggesting a preponderant mechanism. At least three pathophysiological explanations have been proposed for GLs,

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although none of them have been found to be reliable. Some authors have suggested GLs to stem from an inappropriate choice of staples based on the gastric wall thickness. Indeed, the thickness of the gastric wall varies depending on the location (with the fundus being the least thick area), although it can also be influenced by external factors, such as male gender or a body mass index (BMI) > 50 kg/m², both of which are associated with a thicker gastric wall [14]. A vascular explanation has also been proposed, since some anatomical studies have shown that the staple line may pass through an area of vascular weakness secondary to both the greater curvature dissection and the section of splenic short vessels [15, 16]. Finally, a mechanical theory has recently emerged concerning hyperpressure in the “sleeved” stomach, which is related to both gastric volume reduction and pylorus preservation. One clinical consequence of hyperpressure is the onset or worsening of gastroesophageal reflux disease (GERD) following an SG, which is only rarely seen following gastric bypass. Mion et al. [17] confirmed the presence of post-SG hyperpressure using high-resolution impedance manometry (HRIM). Their study noted increasing pressure at the lower esophageal sphincter level in 77% of cases, which was associated with the significantly smaller volume and diameter of the “sleeved” stomachs in patients with manometry reflux.

However, even if hyperpressure is a likely explanation for the presence of a fistula following a SG, no prior experimental studies have sought to reproduce a GL by means of exerting hyperpressure on a “sleeved” stomach. Indeed, previous experimental studies intended to evaluate the pressure and the failure zone at the level of the staple line have mostly been performed on “resected” stomachs. The originality of our study, therefore, lies in the decision to test “sleeved” stomachs when reproducing the consequences of a GL, as observed during clinical practice. In this study, we describe the damage caused by hyperpressure, as well as the failure of the “sleeved” stomach. In addition, we evaluate the biomechanical properties of the gastric tissue.

Materials and Methods

Model Choice and Operative Technique

Sus scrofa domesticus (5 months old, 30–34 kg) were chosen due to their anatomical and functional similarity to humans. Porcine stomachs were collected at the end of surgical teaching sessions conducted at the Centre d’Enseignement et de Recherche Chirurgical (CERC) at Aix-Marseille University-France, with the agreement of the animal ethics committee. Under general anesthesia, a total gastrectomy (removal of the

distal esophagus and the proximal duodenum) was performed via a laparotomy. After the surgery was completed, the animals were euthanized without interrupting the anesthesia or awakening. The stomachs were cleaned and emptied of their contents, and the lengths of the smaller and greater curvature (cm) were measured (Fig. 1a). The volume of each whole stomach (ml) was determined after filling with water and quantification of the introduced volume. Following these measurements, an SG was performed ex vivo using a calibration probe of 36Fr and a linear cutting stapling device (Ethicon®, 60 mm). The antrum was preserved with a resection beginning 4 cm from the pylorus. Four reloads were used per procedure: one green (4.1 mm) for the first inferior firing, followed by three golds (3.8 mm). After the SG was completed, the length of the staple line, the SG’s circumference at three different levels (upper third, middle, and lower third), and the SG’s volume were measured (Fig. 1b). Each specimen was preserved in a phosphate-buffered saline (PBS) solution (ThermoFisher Scientific®) and kept cool. All the tests took place less than 24 h after excision.

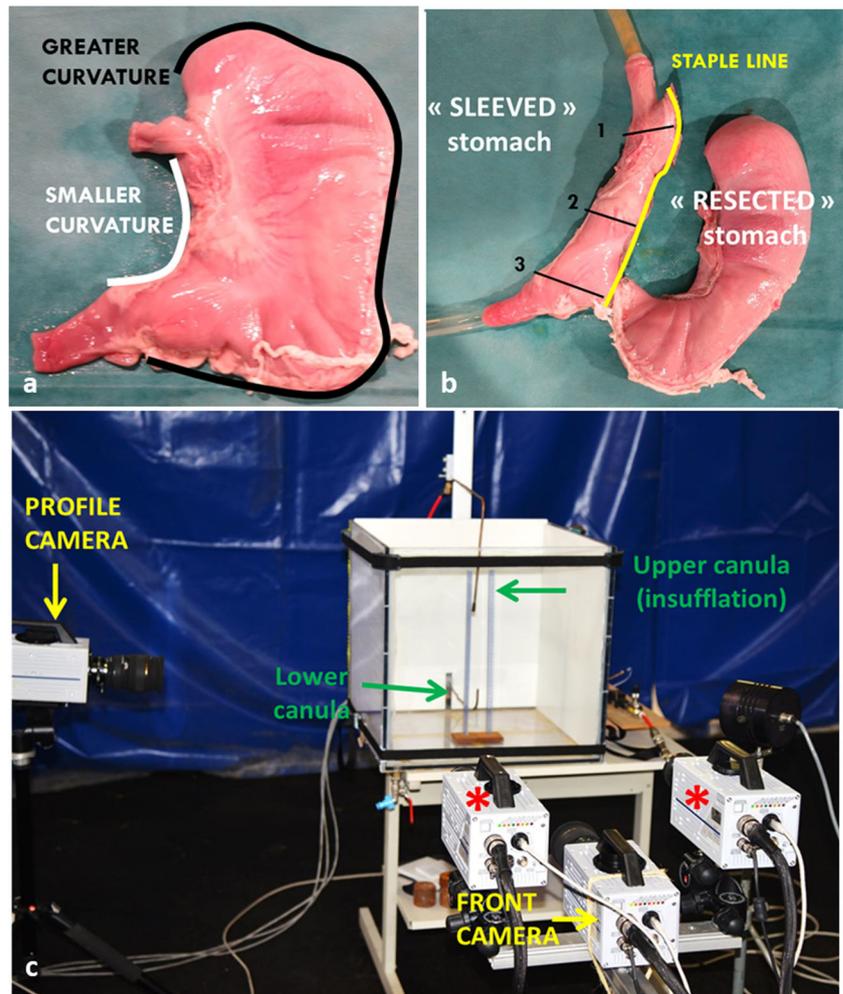
Insufflation Tests

An air insufflation test bench was specially designed for the present study. The “sleeved” stomachs were placed in a 0.5-m³ capacity tank, which was positioned on two 5 mm in diameter copper cannulas: the esophagus on the upper and the duodenum on the lower cannula. Following fixation with plastic clamps (Serflex®), the specimens were immersed in a PBS solution at 37 °C. The upper cannula was connected to an air compressor (Condor 8 bar) generating intraluminal hyperpressure, which was determined to have a flow rate of 1 l/min using an airflow sensor (AWM 5000, Airflow Sensor). The pressure was recorded using two pressure sensors (MEAS France SO, model EPX-N011) inserted into each side of the stomach. The gastric insufflation ceased when bubbles appeared in the tank, which indicated that a GL had occurred. The deformation of the “sleeved” stomachs was recorded at two angles of view (front and profile) using high-speed cameras (Photron SA3 120k) at 100 Hz. Two other cameras were used to film the staple line, as required for the digital image stereo-correlation, using Vic3D software (Kilonewton®) (Fig. 1c).

Uniaxial Tensile Tests

Four strips of gastric tissue (65 × 25 mm) were retrieved from the “resected” stomach: two circumferential and two longitudinal strips (Fig. 2a). Each strip was inserted into a hydraulic test system (MTS 370.10 Landmark, USA), with both ends of the strip being fixed using a clamp (Fig. 2b). Each test was performed at 1 cm/s. As the stomach is comprised of

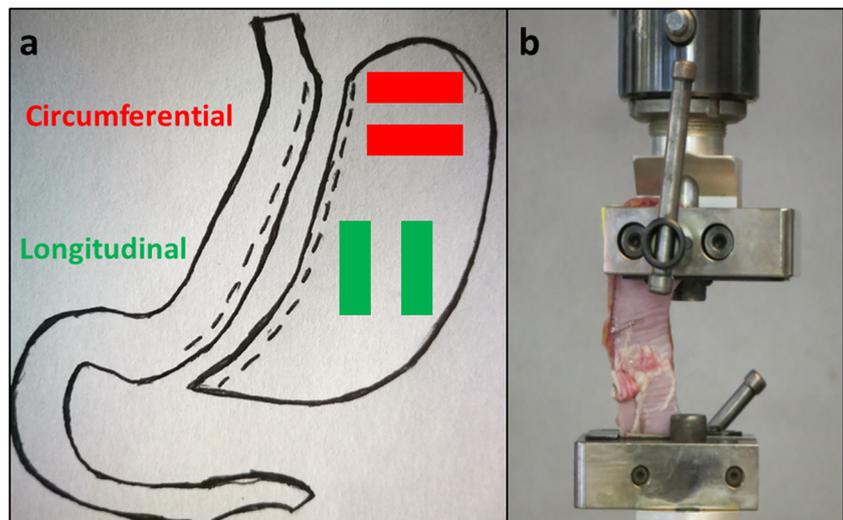
Fig. 1 Sleeve gastrectomy (SG) and insufflation device. **a** Whole stomach following total gastrectomy. **b** “Sleeved” and “resected” stomachs at the end of the SG. The “sleeved” stomach is divided into three parts (1 upper third, 2 middle third, 3 lower third). **c** Insufflation test bench with the upper and lower cannulas (green arrows) and the recording system: frontal and profile cameras (yellow arrows); Vic-3D cameras (red asterisks)



viscoelastic tissue, a pre-conditioning test phase (10 sinusoidal cycles, amplitude 6 mm) was performed prior to the

traction (as described in a previous study involving the colon) [18]. The tensile tests were started immediately after the pre-

Fig. 2 Uniaxial tensile tests. **a** Representation of the four gastric strips on the “resected” stomach (two circumferential in red, two longitudinal in green). **b** A gastric strip instrumented on the hydraulic test system



conditioning. The strip deformation until failure was filmed using a high-speed camera, and the load was recorded using a sensor (Kistler 9327A 0-500N).

Data Post-Processing

For the insufflation tests, data were collected using an acquisition system (KiDAU Advanced, Kistler) at a sampling rate of 100 Hz. The frontal and profile surfaces of the “sleeved” stomachs were calculated using snapshots obtained from a video recording. Two-dimensional (2D) contouring and surface measurements were performed using Matlab software (MathWorks®) to determine the initial surface (*S_{initial}*) and the failure surface (*S_{failure}*) (Fig. 3). The specimen surface deformation was defined as the difference between the two surfaces, as related to the initial surface: deformation (%) = $[(S_{failure} - S_{initial}) / S_{initial}] \times 100$. The use of Vic-3D stereo-correlation software (Kilonewton®) allowed the local deformations to be studied (radial displacement and major principal strain). The stress–strain curves obtained following the uniaxial tensile tests were used to compare the mechanical behavior of the strips according to their orientation

(Young’s modulus, strain and stress at yield, and failure points).

Statistical Analysis

Each specimen’s characteristics were presented using the mean and the standard deviation (SD). To assess the correlation between the volume of the “sleeved” stomach and the burst pressure, Pearson’s correlation coefficient (*R*) was used, and a result was considered to be significant if the *p* value was <0.05.

Results

Characteristics of the “Sleeved” Stomachs and Mean Burst Pressure (Fig. 4)

Fifteen SGs were performed. The average volume of the “sleeved” stomachs was 150 ± 38 ml (approximately 10% of the initial average volume). The mean burst pressure was 26.3 ± 5.3 mmHg, with a significant positive linear correlation

Fig. 3 Contouring of initial and failure surfaces in two planes (frontal and profile) using Matlab Software

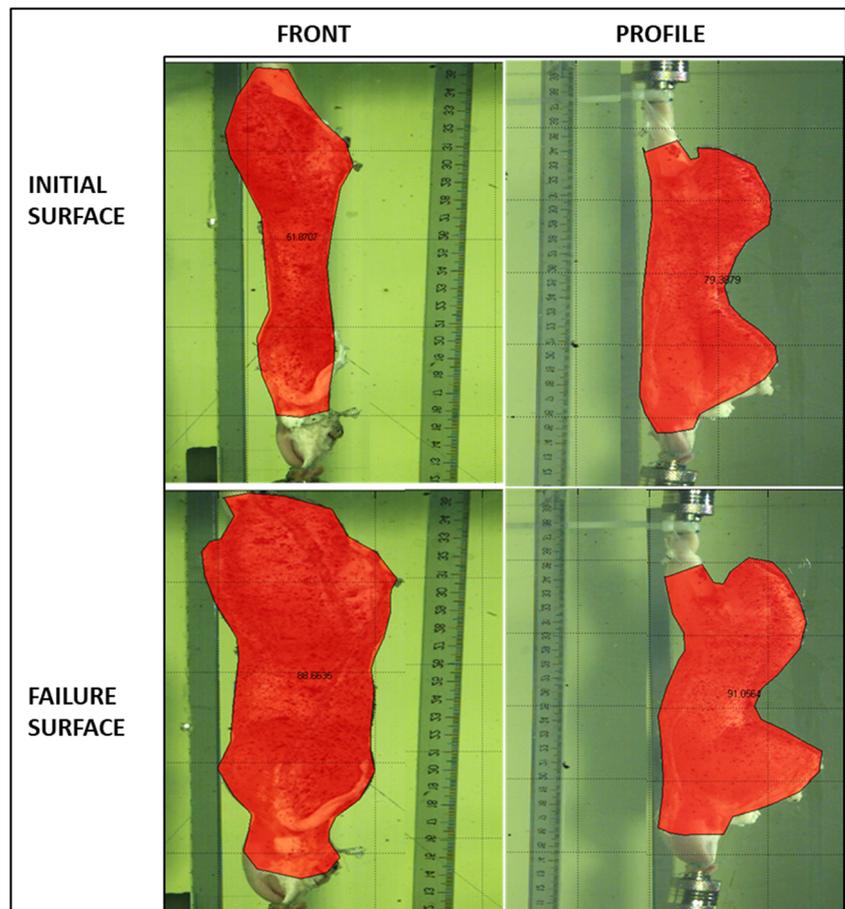


Fig. 4 Specimens (whole and “sleeved” stomachs), global deformation, and gastric leak (GL) characteristics

	WHOLE STOMACHS		« SLEEVED » STOMACHS	
	Mean	SD	Mean	SD
Staple line length (cm)	40.1	3.7	18.8	1.5
Smaller curvature length (cm)	12.5	2.3	12.5	2.3
Circumference (cm)				
- upper 1/3	18.8	0.98	9.7	1.4
- middle 1/3	22.2	1.5	8.7	0.98
- lower 1/3	22.3	5.2	11.9	1.6
Volume (ml)	1273	281	150	38
Burst rupture (mmHg)			26,3	5,3
Front surface deformation (%)			40,5	13,6
-Front initial surface (cm ²)			47,7	8,5
-Front failure surface (cm ²)			67,3	13,3
Profile surface deformation (%)			38,3	14,3
-Profile initial surface (cm ²)			73,2	12,5
-Profile failure surface (cm ²)			53,1	14,3
Rupture zone distance/top of stapling (cm)			4,3	1,7
Gastric leak (GL) localization (n)				
-Upper 1/3			11 (73%)	
-Middle 1/3			4 (27%)	
-Lower 1/3			0	

($R = 0.58$, $p = 0.02$) being identified between the mean burst pressure and the volume of the “sleeved” stomachs.

Analysis of the Global Deformation and Failure Localization (Fig. 4)

The mean deformation of the “sleeved” stomachs was determined to be 40.5% in the frontal plane and 38.3% in the profile plane. The GL was always initiated on the staple line, with 73% (11/15) of GLs being located in the upper third and 27% (4/15) in the middle third of the stapling. No fistula was observed in the lower third of the stapling. On average, a GL was observed 4.3 ± 1.7 cm from the top of the stapling.

Analysis of the Localized Deformation at the Failure Zone

Figure 5 shows the resulting strain field in the three planes using three-dimensional (3D) stereo-correlation. The burst zone (white arrow) underwent the maximum radial deformation, with a local deformation of 11 mm on average. Focusing on the major principal strain showed that the main principal direction in the radial plane was coupled with a vertical direction.

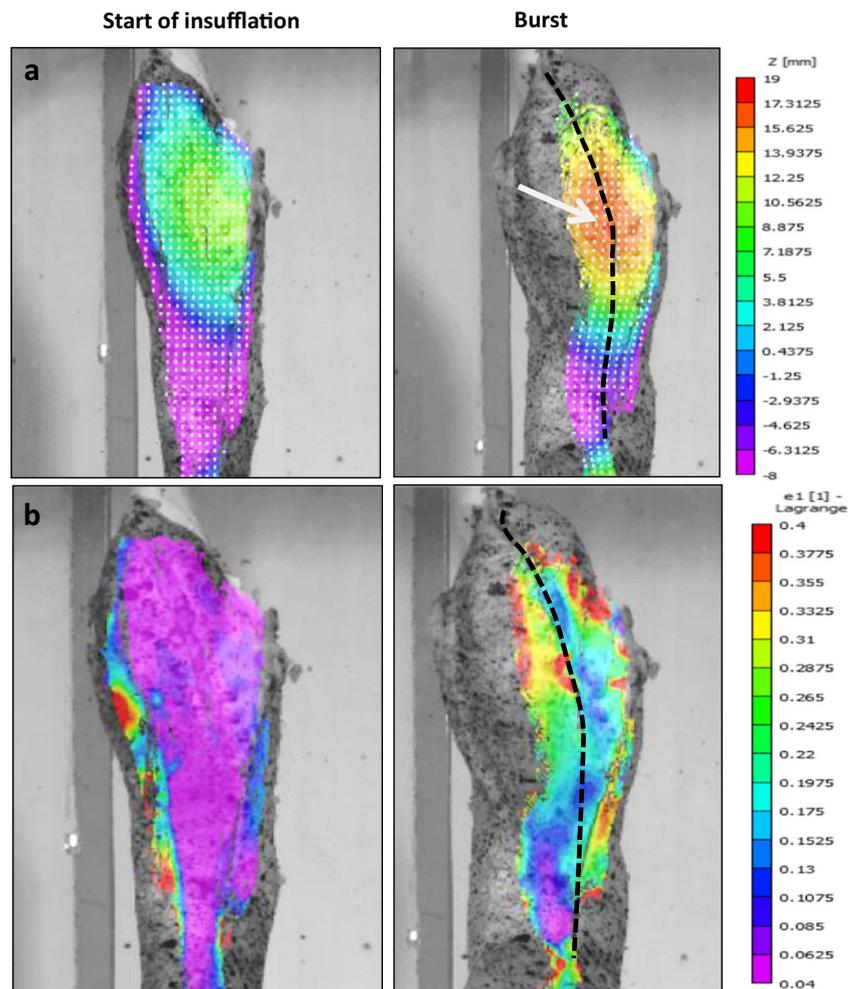
Mechanical Behavior of the Stomach According to the Orientation of the Strips

Figure 6 shows the stress–strain curves for (a) the circumferential and (b) the longitudinal strips with (c) a comparison of the mechanical parameters. The overall shape of the stress–strain curves for both the circumferential and longitudinal orientations shows an initial linear part (elastic phase), followed by a second nonlinear part (damage phase) until failure. Some differences were observed between the two types of strips. Indeed, the longitudinal strips were stiffer, and they had a higher Young’s modulus. Their yield strength was hence lower, as was their failure stress, which resulted in less deformation than that seen in the case of the circumferential strips.

Discussion

This experimental study is the first to analyze the gastric deformation seen following an SG in intraluminal hyperpressure conditions. Most fistulas observed in this study occurred in the upper third of the stapling at an average burst pressure of 26.3 mmHg, which was significantly correlated with the volume of the “sleeved” stomachs. Indeed, the smaller “sleeved” stomachs exhibited a leakage at lower pressures. The experimental set-up of this study allowed for the reproduction of the

Fig. 5 Resulting deformations at the start of insufflation and at the moment of burst according to Z displacement (**a**) and major principal strain (e_1 -Lagrange) (**b**) (Vic 3D images). The white arrow represents the burst location on the staple line shown by the dotted black line



conditions necessary to obtain similar GLs to those seen during clinical practice. The GL rate at the top of the stapling in this study (73%) is comparable to the rate of 70% observed in humans [19], which supports the idea that intraluminal hyperpressure is a serious hypothesis in the GL process, although this study does not support the conclusion that hyperpressure is the main mechanism involved.

Even without any complications, a SG is associated with intraluminal hyperpressure, which is caused by the gastric volume reduction. In a study involving 20 patients, Yeoshua et al. [20] demonstrated positive linear correlation between the SG volumes and the post-operative intraluminal pressures. Greater pressure in the “sleeved” stomachs was recorded when compared to the maximum pressure measured prior to the resection (43 mmHg [32–58] versus 34 mmHg [21–45]). The impact of the SG volume on the occurrence and severity of post-operative complications has previously been demonstrated in studies investigating the fistula rate according to the size of the utilized calibration probe. SGs calibrated with larger tubes had less fistulas [21], which is why recommendations as to the appropriate calibration size now exist (32–36F) [22].

This experimental study can be compared to previous biomechanical studies. Similar burst pressures have been observed in two prior studies: 25 mmHg (3–75 mmHg) in the study of Natoudi et al. [23], which was conducted on pigs, and 19 ± 8 mmHg in the study of Causey et al. [24], which was conducted on humans. However, the latter study used “resected” stomachs rather than the “sleeved” stomachs used in our study, and both prior studies are only descriptive of the Vmax and Pmax necessary to reach failure. They do not involve the continuous follow-up of the deformation. The main objective of these prior studies was to assist with the appropriate selection of staple loaders as a function of the gastric thickness [25]. Other fully biomechanical studies have evaluated the physiological behavior and the viscoelastic nature of digestive tissues, for example, in the colon [26]. In terms of bariatric surgery, a recent study of Carniel et al. involving insufflation tests into pig stomachs evaluated the changes seen in the mechanical behavior following the insertion of an adjustable gastric band (AGB) [27]. In their study, the AGB changed the gastric conformation and affected its structural rigidity by increasing its stiffness and thereby decreasing its storage capacity. Unlike our study, the pressure was insufflated in

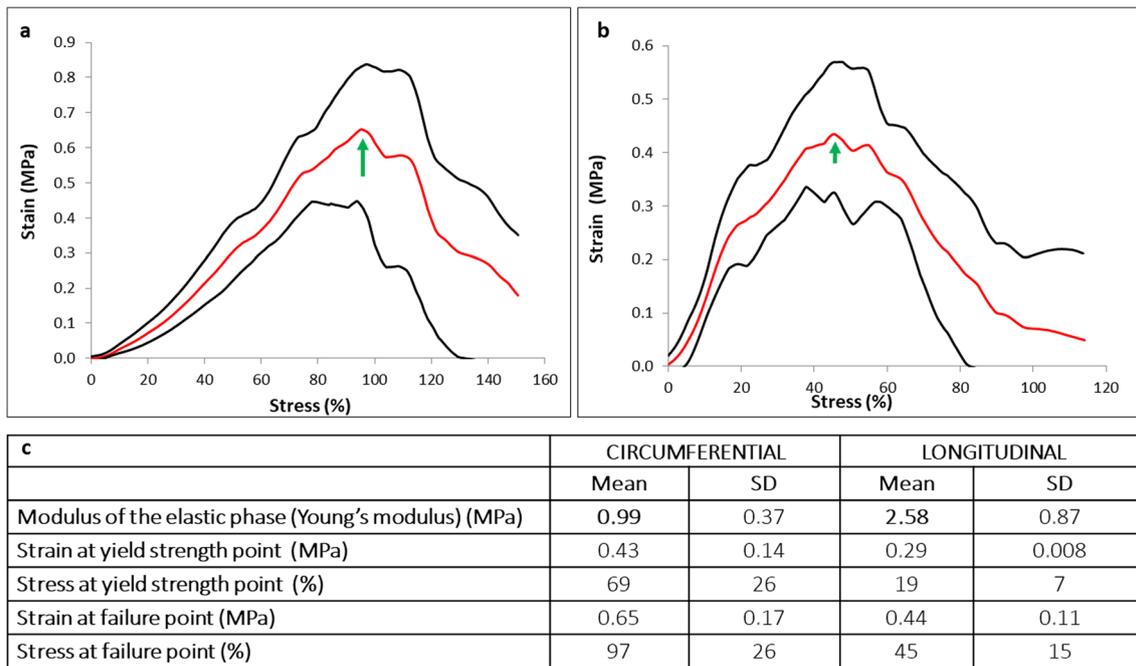


Fig. 6 Stress–strain curves and mechanical parameters comparison. Typical stress–strain curves for circumferential (a) and longitudinal (b) strips. The x-axis corresponds to the strain (%) and the y-axis corresponds to the stress (MPa). The red line represents the average of all trials; the

two curves formed by black lines represent a corridor created by the mean plus or minus the standard deviation. The comparison of the mechanical parameters is shown in panel c

stages (interspersed with phases of rest that allowed for recovery), and it remained lower than the burst pressure.

In addition to our insufflation study (where the radial deformation also had a vertical component) and our desire to create a personalized numerical model of an SG, uniaxial tensile tests were performed on the “resected” stomachs using circumferential and longitudinal strips so as to study the gastric biomechanical properties. These properties were inhomogeneous, as well as to be dependent on the anatomical regions (fundus, antrum, or body) and different gastric wall layers studied [28]. The mechanical behavior of the stomach was also anisotropic and variable along the axis of mechanical stress (in relation to the orientation of the muscle fibers). Our tensile tests confirmed the anisotropic and heterogeneous nature of the gastric behavior, as described in the literature. Here, the circumferential strips were less rigid than the longitudinal ones, and they exhibited greater tensile strain. In 2015, Jia et al. [29] proved that the tensile stress and stiffness (for the same stretch) were higher with longitudinal strips than with circumferential specimens. The mechanical behavior of the three gastric regions has also previously been studied using biaxial tensile tests [30], which again confirmed the occurrence of the maximum deformation in the circumferential plane, especially at the fundus, leading to greater deformations under moderate pressures (lowest coefficient of rigidity), which is consistent with its physiological storage role.

Our study did have a number of limitations. The first limitation concerns the choice of a porcine model. Although porcine anatomy and physiology are very close to those of humans, pigs

do have their own histological characteristics. However, fresh porcine tissue seemed closer to human tissue than either cadaveric or frozen tissues. The second limitation was the realization of an ex vivo SG, which was justified to first measure the whole stomach volume. We could not reproduce the in vivo post-surgical environment, although our SG surgical technique was similar to that typically performed. The mechanical behavior can change ex vivo when compared to in vivo conditions, which is related to the disappearance of vascularization and the lack of environmental constraints. The ischemia time was minimized by performing the tests immediately after collection, and the samples were immersed so as to apply a stress simulating in vivo conditions to their walls.

Despite the relatively small size of our series, the creation of a numerical 3D model of an SG to track the deformation over time would be the next step in accurately understanding the geometry and mechanism of fistula onset. Numerical models are interesting tools for reproducing the conditions of experimental tests while allowing for the variation of many parameters. Moreover, they may help to facilitate the study of kinetic deformations, especially in relation to the gastric wall [31].

Conclusion

Precise knowledge of the deformations and biomechanical consequences stemming from intraluminal hyperpressure on a post-SG stomach is essential considering the surge in this

surgery. Our preliminary study provides a precise description of the mechanical behavior of a stomach following an ex vivo SG that is subjected to air insufflation. It shows the link between the volume of the SG and the burst pressure. Further investigations are needed, particularly in vivo studies, to evaluate potential modifications to the surgical technique and their influence on reducing the intraluminal pressure.

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Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

Statements Regarding Ethics and Consent The study has been performed in accordance with the ethical standards.

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