



# Use of bioabsorbable staple reinforcement material in side-to-side anastomoses: Suture line reinforcement of the weak point of the anastomosis



Masahiro Kimura\*, Yukio Terashita

Gastroenterological Surgery, Nagoya City University Graduate School of Medical Sciences, 1 Kawasumi, Mizuho-cho, Mizuho-ku, Nagoya 467-8601, Japan

## HIGHLIGHTS

- The purpose of this study was to clarify the weak point of the side-to-side anastomosis and to evaluate the effect of Neoveil®.
- The use of Neoveil® is associated with reinforced staple lines and increased crotch burst pressures compared to non-buttressed staple lines.
- Neoveil® was found to perform comparably with clinically available buttress materials in this ex vivo model.

## ARTICLE INFO

### Article history:

Received 20 January 2016

Accepted 20 January 2016

### Keywords:

Side-to-side anastomosis

Crotch

Burst pressure

Reinforcement

Neoveil®

## ABSTRACT

**Background:** Few studies have been designed regarding optimal reinforcement of the crotch of a side-to-side anastomosis. The purpose of this study was to clarify the weak point of the side-to-side anastomosis and to evaluate the effect of bioabsorbable reinforcement material.

**Methods:** Fresh pig small bowel was used for all experiments. A side-to-side anastomosis was performed using a linear stapler, and the burst pressure of the anastomosis was measured. Three separate experiments were done.

In experiment 1, the weak point and the burst pressure of that point were defined. In experiment 2, the burst pressure of the side of the anastomosis was measured. In experiment 3, we evaluated the effect of Neoveil® to strengthen the weak point of the anastomosis.

**Results:** The weak point of the side-to-side anastomosis was the crotch and the burst pressure was  $39.8 \pm 5.7$  mmHg. The burst pressure of the side of the anastomosis was  $109.9 \pm 7.9$  mmHg. This was significantly higher than the burst pressure of the crotch ( $P = 0.008$ ). The burst pressure of the crotch in the group with Neoveil® was  $83.3 \pm 14.9$  mmHg. This pressure was significantly higher than the group with no Neoveil® reinforcement ( $P = 0.001$ ).

**Conclusion:** These findings suggest that the use of Neoveil® as a buttressing material is associated with reinforced staple lines and increased crotch burst pressures compared to non-buttressed staple lines. Neoveil® was found to perform comparably to clinically available buttress materials in this ex vivo model. Reinforcement of the weak point of the side-to-side anastomosis with Neoveil® may lead to fewer anastomotic leaks.

© 2016 The Authors. Published by Elsevier Ltd on behalf of IJS Publishing Group Limited. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

## 1. Introduction

There are many postoperative complications after gastrointestinal anastomosis, including leak, bleeding, and stenosis [1,2]. Of these, anastomotic leak is the most dreaded complication and can be life threatening.

Many techniques have been developed for use in the anastomosis of an intestinal tract aimed at minimizing postoperative complications [1]. With the development of stapling devices, the variation of anastomosis techniques between surgeons has decreased, as have postoperative complications.

The growth of laparoscopic surgery has further accelerated the frequency of the use of automatic suture instruments. The side-to-side anastomosis is widely used given the ease by which this is fashioned [2,3].

\* Corresponding author.

E-mail address: [mkimura@med.nagoya-cu.ac.jp](mailto:mkimura@med.nagoya-cu.ac.jp) (M. Kimura).

A side-to-side anastomosis is performed using linear staplers. The weak point of this anastomosis is the crotch area. The arrangement of the suture device leads to three rows of staples, making a robust anastomosis that is clinically sufficient to prevent leakage of intestinal contents, except for in the crotch area. Surgeons therefore typically reinforce the crotch with a hand thrown stitch [3]. However, laparoscopically, reinforcement is not easy. In thoracic surgery, there are reports that Neoveil<sup>®</sup> reduces air leak after wedge resections [4]. Therefore, we sought to examine whether Neoveil<sup>®</sup> reinforcement of the crotch of the side-to-side anastomosis strengthened this area and made it less prone to leak.

## 2. Material and methods

Fresh pig small bowel was used for all experiments. The specimens were obtained from an animal that had been sacrificed for use in approved non-gastrointestinal research studies. The specimens were used within 24 h after sacrifice. Each segment of the intestinal tract was 20 cm in length.

A side-to-side anastomosis was performed between two intestine specimens using a linear stapler. The stapler was inserted from the edge of each segment of intestinal tract. A 16-Fr catheter was then placed into the lumen through one intestinal wall. Each side of the anastomosis was clamped by forceps. The sphygmomanometer and tubing for instillation of air was connected, and the anastomosis was submerged in water. Air was then blown into the intestinal lumen with a syringe (Fig. 1).

The burst pressure of the anastomosis was indicated by the presence of bubbles. All procedures were performed by the same surgeon.

The stapling device used was the Endo GIA60AMT (Covidien, Tokyo, Japan). Suture length was 6 cm and the number of staplers fired was 90. These staplers consist of three rows of either 3/3.5/4 mm staples prior to firing. Post-fire heights are 1.25/1.5/1.75 mm.

### 2.1. Experiment 1: weak point identification and burst pressure of a side-to-side anastomosis

After creation of the anastomosis, the stump of each end of the small intestine and the side of the anastomosis were clamped by forceps. The burst pressure of the crotch was recorded. Five anastomoses were completed.

### 2.2. Experiment 2: burst pressure of the side of the anastomosis

Experiment 2 was done to assess the strength of the side of the side-to-side anastomosis. The crotch was clamped and the side burst pressure recorded. Five anastomoses were completed.

### 2.3. Experiment 3: effect of buttress on the crotch with Neoveil<sup>®</sup>

Experiment 3 was designed to evaluate the effect of Neoveil<sup>®</sup> (Gunze) on the crotch. For that purpose, tube type Neoveil<sup>®</sup> was attached to the stapling device. One side of tube type Neoveil<sup>®</sup> is PGA (polyglycolic acid) sheet, and another side is expandable nylon mesh sheet. These are fixed with 3-0 vucryl. To reinforce only the crotch of the anastomosis, the Neoveil<sup>®</sup> was cut to a length of 1.5 cm (Fig. 3a and b). As we could not deny that the reinforcement effect of Neoveil<sup>®</sup> may just be that it makes the anastomosis thicker, we added an experiment to sandwich Neoveil<sup>®</sup> between intestinal tracts and then perform an anastomoses (Figs. 2C and 3c,d). Five anastomoses in each group were completed.

### 2.4. Statistical analysis

Discrete variables were analyzed by the Mann–Whitney test and significance was indicated at  $p < 0.05$ .

## 3. Results

### 3.1. Experiment 1: weak point identification and burst pressure of a side-to-side anastomosis

All bursting points were at the crotch. Burst pressures were  $39.8 \pm 5.7$  mmHg (Table 1).

### 3.2. Experiment 2: burst pressure of the side of the anastomosis

The burst pressures of the side were  $109.9 \pm 7.9$  mmHg (Table 2). These were significantly higher than those of the crotch ( $P = 0.008$ ).

### 3.3. Experiment 3: effect of buttress on the crotch with Neoveil<sup>®</sup>

All burst points were in the crotch. The burst pressures in the buttress group with Neoveil<sup>®</sup> were  $83.3 \pm 14.9$  mmHg. The pressures were significantly higher than the group with no Neoveil<sup>®</sup> ( $P = 0.001$ ). On the other hand, in the group in which Neoveil<sup>®</sup> was sandwiched outside the intestinal tract, burst pressures were

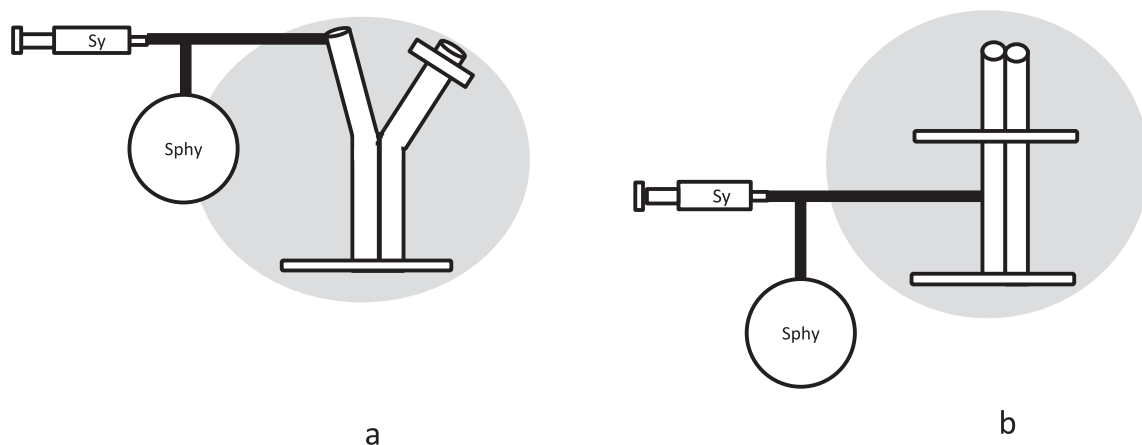
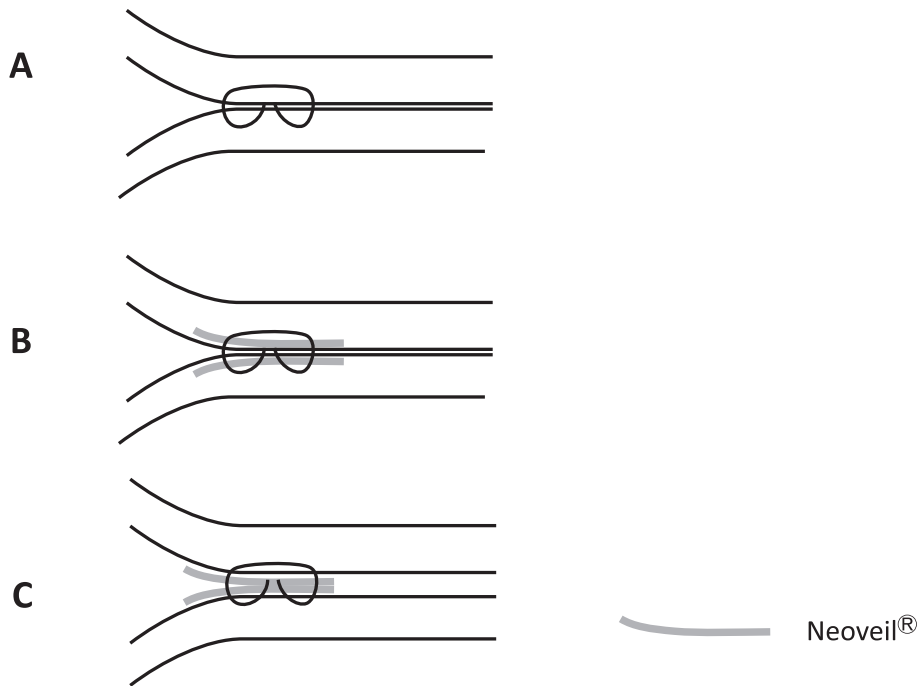
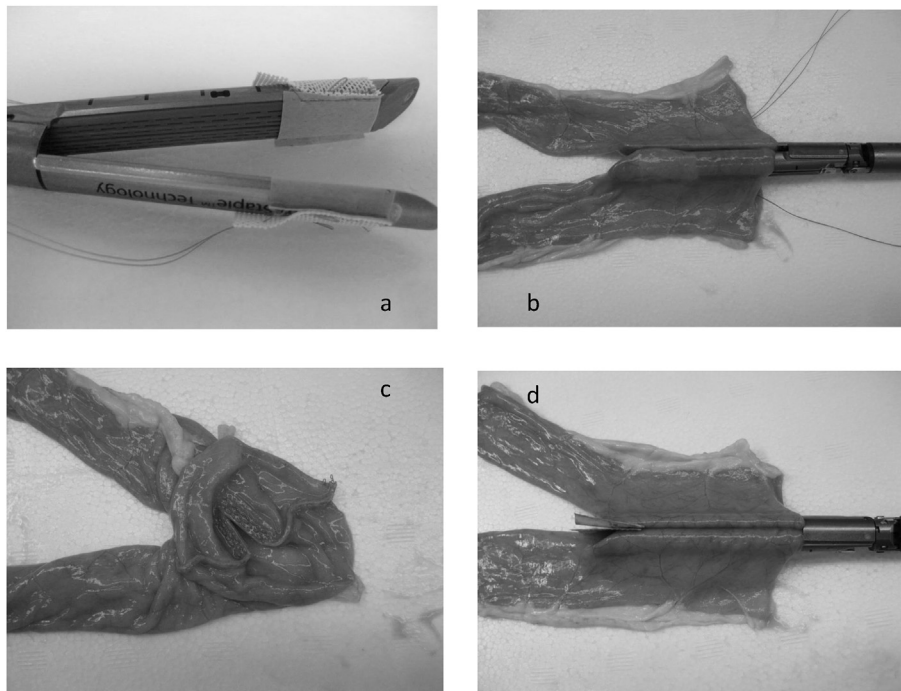


Fig. 1. System used to examine burst pressure. (a: Experiment 1, b: Experiment 2). Sphy: sphygmomanometer; Sy: syringe.



**Fig. 2.** Schema of experiment 3. (A: without Neoveil®, B: with Neoveil® attached to the stapling devices, C: Neoveil® sandwiched between intestinal tracts).



**Fig. 3.** a: tube-type Neoveil® was attached to the stapling devices, b: side-to-side anastomosis with stapler (with Neoveil®), c: intestinal lumen after the stapling with Neoveil®, d: sandwich Neoveil® between intestinal tracts.

$39 \pm 8.6$  mmHg, similar to the group without Neoveil crotch reinforcement (Table 3).

**Table 1**  
Burst pressure of side-to-side anastomosis.

Pressure (mmHg)	Leak point
$39.8 \pm 5.7$	Crotch

#### 4. Discussion

Creation of a gastrointestinal tract anastomosis is a fundamental and important surgical procedure. To reduce postoperative complications, such as bleeding and leak, surgical stapling instruments

**Table 2**

The burst pressure of side to side anastomosis (bursting pressure of the side).

Pressure (mmHg)
109.9 ± 7.9

**Table 3**

The bursting pressure of side to side anastomosis (with and without Neoveil®).

	Pressure (mmHg)	Leak point	P value
A: Neoveil (–)	39.8 ± 5.7	Crotch	A vs B 0.0012 A vs C 0.87
B: Neoveil® (+) inside	83.3 ± 14.9	Crotch	B vs C 0.0017
C: Neoveil® (+) outside	39 ± 8.6	Crotch	

are being increasingly used for gastrointestinal anastomoses not only in laparoscopic surgery but also in open surgery. In the 1960s, Steichen and Ravitch first introduced stapling instruments [5]. Improvements in stapling instruments have been ongoing for half a century [6–9]. For example, the suture device that included two suture lines on one side was improved to a suture device with three suture lines on one side, and suture strength has significantly increased. We performed a burst pressure experiment using the GIA™60-3.8 (2 line) and the Endo GIA™60-3.5 (three lines), and the burst pressure increased by approximately two-fold.

With the development of a variety of instruments, various anastomosis methods have also been developed. Mechanical side-to-side anastomoses are the basis of most methods. Even in open surgery, mechanical side-to-side anastomoses are easy, quick, and cost-effective because these can be performed using a single linear stapling device, while an end-to-side reconstruction requires both linear and circular staplers, thus incurring additional cost. Despite these advances, stapled anastomoses have inherent weak points. The present study was designed to investigate the mechanical strength of the side-to-side anastomosis by measuring the leak pressure detected on an ex vivo porcine small bowel model.

Experiment 1 identified the weak point of the side-to-side anastomosis to be the crotch, with a mean burst pressure of 93.8 mmHg.

We previously performed an experiment to measure the strength of a side-to-side anastomosis using the esophagus and the small intestine of a pig, and identified the weak point to be the crotch when using a three-row stapler device. Another study before that showed that, with a two-row suture device, leaks occurred with equal frequency between the crotch and the side of the anastomosis. Thus, with the more widespread use of three-row stapling devices, reinforcement of the crotch has become important. There were no experiments, however, quantifying the burst

strength difference between the side and the crotch. In experiment 2, we found that the mean burst pressure of the side was 109.9 mmHg, approximately 3 times that of the crotch.

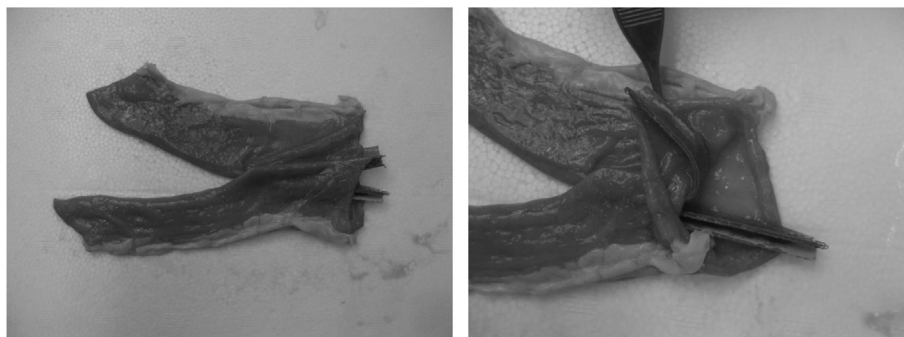
Clinically, the weakness of the crotch is widely recognized. As shown in Fig. 5, it is common to reinforce the crotch. Goto reported the effectiveness of buttressing of the crotch in a functional end-to-end anastomosis using pig intestine [3]. They reported that the burst pressure rose to 44 from 27.5 mmHg with a 3-0 silk suture to buttress. However, in laparoscopic surgery, crotch reinforcement with a suture is technically difficult. For example, the crotch of the side-to-side anastomosis after total gastrectomy, and the crotch of the functional end-to-end anastomosis after large intestine excision, are difficult to reinforce. Therefore we looked for a method to reinforce the crotch in a manner that did not require a suture.

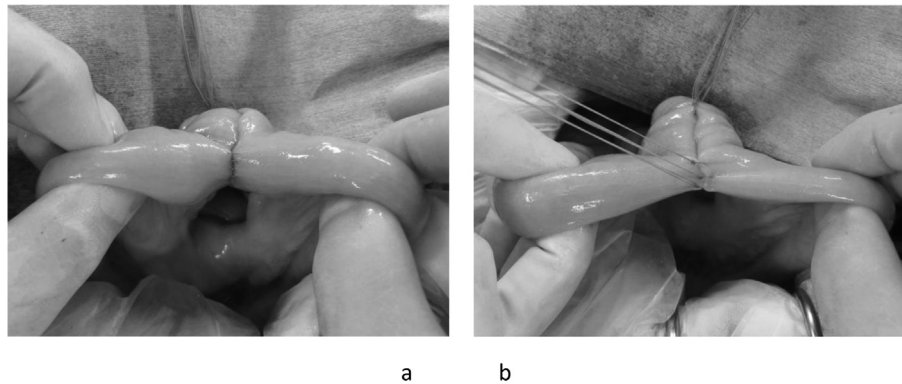
One such possibility is the use of buttress reinforcement materials. Buttress reinforcement materials are comprised of various synthetic polymers and biologically derived materials [10–17]. Examples of clinically available buttress reinforcement materials are bovine pericardium (Peri-strips), expanded-polytetrafluoroethylene carbonate (TMC), copolymer (Gore Seamguard), urinary bladder matrix (MatriStem), and small intestinal submucosa (Surgisis). These products have demonstrated some success in reducing leakage and bleeding complications associated with staple lines. Application of reinforcement material in the staple line is thought to moderate tension of the staple line because it acts as a neutralization plate. Further, the buttressing materials seal off the staple holes and narrow the spaces in between each staple. Thus, leakage, bleeding, and tearing at the staple line can be reduced, especially in diseased and fragile tissue. However, choice of material should be considered carefully. Although all types of staple line reinforcement seem equally adequate in reducing complications at the staple line, the material itself can cause problems. For example, bovine pericardium material is prone to erosion and migration due to inflammatory response and carries the risk of animal source contamination.

Neoveil® (polyglycolic acid felt: PGAF) has been described and tested in many clinical situations. Neoveil® is an absorbable reinforcement material, and its advantages have been widely recognized. PGAF is a soft and thin (0.15 mm depth) new absorbable material.

In thoracic surgery, Neoveil® reduces and prevents air leakage from the lung. In addition, Neoveil® has been used for reinforcement of a suture line on the trachea.

In digestive surgery, Neoveil® has been used for fragile organs such as liver and the gastrointestinal tract. Other than Neoveil®, there has been a report using BioGlue. Nandakumar reported the effectiveness of BioGlue® for the reinforcement of the gastrojejunostomy in obesity surgery [18]. They reported that the burst pressure significantly increased in the reinforced

**Fig. 4.** Neoveil® for the full length of the anastomosis (arrow: protruding Neoveil®).



**Fig. 5.** Operative findings. (a: crotch, b: reinforcement suture).

gastrojejunostomies from 27.4 to 59.1 mmHg. However, a more consistent method is needed as it is hard to apply BioGlue uniformly on an anastomosis.

There are some reports describing Neoveil<sup>®</sup> for gastrointestinal enterotomy closure of the small intestine and the stomach, but there are no reports that used Neoveil<sup>®</sup> for intestinal side-to-side anastomosis. Neoveil<sup>®</sup> is thin and soft, but has memory when applied to a stapling device. However, when we use Neoveil<sup>®</sup> for the full length of the anastomosis, closure of the enterotomy after staple firing becomes difficult (Fig. 4). As highlighted in our experiment, though, only the crotch needs be reinforced as opposed to the entire staple line.

While not part of its intended use, we inserted Neoveil<sup>®</sup> between intestinal tracts to be anastomosed and performed a burst pressure examination to show that the increase in tissue thickness did not affect pressure as an independent variable. There were no significant differences between the use or non-use of Neoveil<sup>®</sup>, and thus proved that the increase in burst strength of the crotch was not due to an increase in the tissue thickness.

Anastomotic failure depends on various parameters including tissue thickness, collagen content, blood flow, type of staple cartridge, ischemia, and tension [19]. It is not clear how burst pressure affects leak rate. However, clinically, many surgeons have experienced that the crotch in the anastomosis using a linear stapler is weak. We have shown that the burst pressure of the crotch can be nearly doubled with Neoveil<sup>®</sup> reinforcement.

Laparoscopic operations and anastomoses with stapler devices are increasing. Out findings suggest that the use of Neoveil<sup>®</sup> as a buttressing material reinforces the staple line and increases burst pressure of the crotch when compared to a non-buttressed staple line. Neoveil<sup>®</sup> was found to perform comparably with clinically available buttress materials in this ex vivo model.

#### Ethical approval

None.

#### Funding

None.

#### Author contribution

Masahiro Kimura: study design, data collection, data analysis, writing.

Yukio Terashita: data collection.

#### Conflicts of interest

None.

#### Guarantor

Masahiro Kimura.

#### References

- [1] L. Haverkamp, P.C. Sluis, R.J. Verhage, et al., Endo-to-endo cervical esophago-gastric anastomoses are associated with a higher number of strictures compared with end-to-side anastomoses, *J. Gastrointest. Surg.* 17 (2013) 872–876.
- [2] X. He, Z. Chen, J. Huang, et al., Stapled side-to-side anastomosis might be better than handsew end-to-end anastomosis in ileocolic resection for Crohn's disease: a meta-analysis, *Dig. Dis. Sci.* 59 (2014) 1544–1551.
- [3] T. Goto, K. Kawasaki, Y. Fujino, et al., Evaluation of the mechanical strength and patency of functional end-to-end anastomoses, *Surg. Endosc.* 21 (2007) 1508–1511.
- [4] Y. Saito, H. Omiya, Y. Shomura, et al., A new bioabsorbable sleeve for staple-line reinforcement: report of a clinical experience, *Surg. Today* 32 (2002) 297–299.
- [5] F.M. Stechen, The use of staplers in anatomical side-to-side and functional end-to-end enteroanastomoses, *Surgery* 64 (1968) 948–953.
- [6] S.C. Simper, J.M. Erzinger, S.C. Smith, Comparison of laparoscopic linear staplers in clinical practice, *Surg. Obes. Relat. Dis.* 3 (2007) 446–451.
- [7] R.S. Baker, J. Foote, P. Kemmeter, et al., The science of stapling and leaks, *Obes. Surg.* 14 (2004) 1290–1298.
- [8] K. Kawasaki, Y. Fujino, K. Kanemitsu, et al., Experimental evaluation of the mechanical strength of stapling techniques, *Surg. Endosc.* 21 (2007) 1796–1799.
- [9] C.M. Mery, B.M. Shafi, G. Binyamin, et al., Profiling surgical staplers: effect of staple height, buttress, and overlap on staple line failure, *Surg. Obes. Relat. Dis.* 4 (2008) 416–422.
- [10] C. Sakakura, Y. Ozamoto, T. Togawa, et al., A novel bioabsorbable sleeve for staple line reinforcement in laparoscopic sleeve gastrectomy (LSG) for morbid obesity: possible usefulness for the future application in operation for alimentary tract cancers, *JSM Clin. Oncol. Res.* 1 (2013) 1003–1005.
- [11] M. Ganger, J.N. Buchwald, Comparison of laparoscopic sleeve gastrectomy leak rate in four staple-line reinforcement options: a systematic review, *Surg. Obes. Relat. Dis.* 10 (2014) 713–724.
- [12] K.A. Miller, A. Pump, Use of bioabsorbable staple reinforcement material in gastric bypass: a prospective randomized clinical trial, *Surg. Obes. Relat. Dis.* 3 (2007) 417–422.
- [13] K. Burugapalli, J.C. Chan, J.L. Kelly, et al., Buttressing staples with Cholecyst-derived Extracellular Matrix (CEM) reinforces staple line in an ex vivo peristaltic inflation model, *Obes. Surg.* 18 (2008) 1418–1423.
- [14] L.S. Yo, E.C. Consten, H.M. Quarles van Ufford, et al., Buttressing of the staple line in gastrointestinal anastomoses: overview of new technology designed to reduce perioperative complications, *Dig. Surg.* 23 (2006) 283–291.
- [15] N.N. Basu, D. Leschinsky, D.L. Heath, The use of Seamguard<sup>®</sup> to buttress the suture repair of a staple line leak following laparoscopic gastric bypass for obesity, *Obes. Surg.* 18 (2008) 896–897.
- [16] K.C. Sasse, D. Warner, S.M. Ward, et al., Intestinal staple line reinforcement using MatriStem, *Surg. Sci.* 6 (2015) 65–70.
- [17] W. Arnold, S.A. Shikora, A comparison of burst pressure between buttressed versus non-buttressed staple-lines in an animal model, *Obes. Surg.* 15 (2005)

- 164–171.
- [18] G. Nandakumar, B.G. Richards, Trencheva, et al., Surgical adhesive increases burst pressure and seals leak in stapled gastrojejunostomy, *Surg. Obes. Relat. Dis.* 6 (2010) 498–502.
- [19] K. Perry, A. Banarjee, J. Liu, et al., Gastric ischemic conditioning increases neovascularization and reduce inflammation and fibrosis during gastroesophageal anastomosis healing, *Surg. Endosc.* 27 (2013) 753–760.