The aim of the study was to present the first long-term results on the clinical use of compression anastomosis clips (CAC) in upper and lower gastrointestinal tract anastomoses.

Material and methods. The study included 50 patients who underwent anastomosis of the upper (n = 32) or lower GI tract (n = 18) with the use of CAC. In the period of 6-7 months after the surgery, patients underwent endoscopic examination and computed tomography evaluation of the anastomosis. Each anastomosis was evaluated macro and microscopically. The width of anastomoses was evaluated using a 4-point-scale for grading stenosis.

Results. Of the 50 patients who underwent anastomosis with compression anastomosis clip, 28 (56%) patients reported to the follow-up examination within 190-209 days of the execution of the anastomosis. Among the 22 patients who did not report to the study, 18 (36%) patients died within 91-154 days from the execution of the anastomosis (mean 122 days), 4 (8%) patients were impossible to contact after discharge from hospital. Two mild stenoses (I0) were diagnosed; 1 of them was found in the gastroenterostomy and 1 in Braun enteroenterostomy. Microscopic changes were diagnosed in 4 anastomoses (3 gastroenterostomies, 1 Braun enteroenterostomy). Anastomoses were well-formed and wide, scars in the line of anastomoses were thin.

Conclusions. During the period of 6 months after the anastomoses performed using CAC have been formed, they were evaluated as unobstructed and functioning properly; therefore, they can be safely performed within the upper and lower gastrointestinal tract.

Key words: compression anastomosis clip, gastrointestinal anastomoses, long term results, stenosis

Anastomotic leakage and dehiscence constitute an important problem in surgery of the gastrointestinal tract as they cause an increase in the number of complications and mortality, thus reducing the total survival time. In the late postoperative period the surgeon’s efforts can be blighted by the anastomotic stenosis. When performing anastomoses, surgeons apply different types of sutures, staplers, and other devices (such as, for example, Valtrac). Mechanical sutures are considered an accepted and most commonly used technique in anastomoses of the digestive tract.

The purpose of the present study was to present the first long term results regarding clinical application of compression anastomosis clips (CAC) in anastomoses of upper and lower gastrointestinal tract. The compression clips were made of a superelastic Nickel and Titanium shape memory alloy. The method of using CAC consists in compressing two anastomosed walls in order to simultaneously induce necrosis and initiate the healing process, which results in forming an intestinal wall connection (1, 2, 3).

MATERIAL AND METHODS

Fifty-two anastomoses were performed using compression anastomosis clips (fig. 1). The principle and method of applying the CACs have been described in previous publications (4, 5). Figure 2 shows a side-to-side anastomo-
sis between two loops of the small intestine. Due to complications in the early postoperative period, two patients were excluded from the study. The study included 50 patients who had anastomoses performed in the upper (n = 32) or lower (n = 18) gastrointestinal tract with the application of CACs. The patients were 23 women and 27 men, aged 38-77 years, while the average age in the group was 64.28 years.

In 37 (74%) patients the anastomoses were performed as they had malignant changes diagnosed (adenocarcinoma), in 13 (26%) of them due to benign changes (12 cases of chronic pancreatitis, 1 patient with pancreatic serous cystadenoma). In 32 (64%) of the cases, the anastomosis was a palliative procedure, while in 18 (36%) patients underwent a resective surgery procedure with anastomosis (tab. 1).

The following anastomoses were performed: the small intestine with the large intestine (5 anastomoses), the small intestine with the small intestine (13 anastomoses), and the stomach with the small intestine (32 anastomoses) (4, 5). Types of treatments and anastomoses are presented in tab. 1. During the period of 6-7 months after the surgery, patients who reported for check-ups were interviewed on the symptoms from the gastrointestinal tract and underwent endoscopy.

![Fig. 1. Compression anastomosis clip](image1)

![Fig. 2. A side-to-side anastomosis between two loops of the small intestine – compression anastomosis clip visible](image2)

### Table 1. Operative procedures and the distribution of anastomotic sites performed with CAC

<table>
<thead>
<tr>
<th>Operative procedures</th>
<th>The distribution of anastomotic sites performed with CAC</th>
<th>n</th>
<th>Patients included</th>
<th>Patients excluded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total gastrectomy</td>
<td>Roux enteroenterostomy</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Whipple pancreatoduodenectomy</td>
<td>Braun enteroenterostomy</td>
<td>2</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Clagett pancreatoduodenectomy</td>
<td>Braun enteroenterostomy</td>
<td>1</td>
<td>-</td>
<td>1 N</td>
</tr>
<tr>
<td>Flautner pancreatoduodenectomy</td>
<td>Braun enteroenterostomy</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>By-pass anastomosis (gastroenterostomy and hepaticojejunostomy)</td>
<td>Braun enteroenterostomy</td>
<td>3</td>
<td>1</td>
<td>2 D</td>
</tr>
<tr>
<td>Middle pancreatectomy</td>
<td>Roux enteroenterostomy/</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Total pancreatectomy</td>
<td>Braun enteroenterostomy</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Small bowel resection</td>
<td>ileoileostomy</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Right hemicolecctomy</td>
<td>ileotransversostomy</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>By-pass anastomosis</td>
<td>ileotransversostomy</td>
<td>1</td>
<td>-</td>
<td>1 N</td>
</tr>
<tr>
<td>Oesophagus and stomach resection, the right half of the colon was used to create a substitute</td>
<td>duodenotransversostomy</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Gastroenterostomy with Roux-Y hepaticoenterostomy</td>
<td>gastroenterostomy</td>
<td>16</td>
<td>7</td>
<td>1 N</td>
</tr>
<tr>
<td>Gastroenterostomy with Braun enteroenterostomy</td>
<td>gastroenterostomy</td>
<td>16</td>
<td>9</td>
<td>7 D</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>50</td>
<td>28</td>
<td>22</td>
</tr>
</tbody>
</table>

N – not in evidence, D – dead
to evaluate anastomoses. The examinations were performed by two doctors, who were not informed about the anastomosis execution technique. Depending on the location of anastomosis, either a gastroscopy or colonoscopy was performed. In every case, also computed tomography with contrast (CT) was performed, as it was one of control examinations for monitoring the course of the disease (neoplastic or inflammatory changes). In the event of difficulties in assessing the anastomosis the given patient additionally underwent radiographic examination of the gastrointestinal tract with water soluble contrast (passage). In the case of macroscopic changes recognized thanks to the endoscopic procedure, samples were taken for histopathological examination.

The width of the anastomoses performed was evaluated according to the four-point stenosis scale (6). I° stenosis—mild, allowing for the passage of a 10.5 mm endoscope through the anastomosis; II° stenosis—moderate, allowing for the passage of an 8.5 mm pediatric endoscope; III° stenosis—severe, allowing for the passage of a guide; and IV° stenosis—full, impenetrable to an endoscope (6). The performed CT scans and radiographic examination of the upper gastrointestinal tract with contrast were used to evaluate the passage of contrast through the earlier performed anastomoses.

**RESULTS**

Out of the 50 patients who underwent anastomosis with the application of compression anastomosis clips, 28 (56%) patients reported for check-up during the 190-209 days after the anastomoses had been performed (tab. 1). Among the 22 patients who failed to report for check-up, 18 (36%) patients died during the 91-154 days after the anastomoses had been performed (an average of 122 days), and 4 (8%) patients did not seek contact after discharge from the hospital.

All 28 patients included in the study underwent a CT scan of the abdomen with contrast administered orally and intravenously. In each patient an attempt was made to execute an endoscopy of the upper or lower gastrointestinal tract. During the endoscopic procedure no anastomosis was visible (a long and winding intestinal loop) in any of the three cases where enteroenterostomy had been performed with the application of Roux method. In these cases, and in the case of 1 anastomosis of the small intestine with the small intestine, the evaluation was based on CT scan examination. Additionally, two of these patients underwent upper gastrointestinal X-ray examinations with contrast administered orally to enable a precise evaluation of anastomoses which had not been visible sufficiently in CT examination (2 enteroenterostomies with the application of Roux method). While the endoscopic procedure was applied in the examination of all the gastroenterostomies (16 anastomoses), Braun enteroenterostomies (5 anastomoses), and anastomoses of the small intestine with the large intestine (3 anastomoses) (tab. 2).

Table 2 shows the macroscopic and microscopic changes identified during the performed endoscopic procedures and radiographic examinations. Anastomoses were well-formed and wide, scars in the line of anastomoses were thin (fig. 3). Two mild stenoses (I°) were diagnosed, 1 of them was found in the gastroenterostomy (confirmed both with an endoscopic examination and CT scan), and in 1 Braun enteroenterostomy (identified via endoscopy, while in CT scan the passage through the anastomosis was assessed as appropriate). Macro- and microscopic changes were diagnosed in 4 anastomoses (3 gastroenterostomies and 1 Braun enteroenterostomy) (tab. 2).
There are few publications concerning the application of compression anastomosis clips in the clinical conditions. A series of researches published by Nudelman et al. refers to early postoperative period (7, 8, 9). Nudelman has presented the results of applying compression anastomosis clips in patients undergoing the left half of the colon resection (4 patients), the right half of the colon resection (3), sigmoid colon resection (2), and transverse colon resection (1 patient). No early postoperative complications associated with the use of clips were reported. As regards the remote results, the authors only limit themselves to state that during the period of 6 months of observations no symptoms of anastomotic stenosis and patients returned to active life (7). In the next work, Nudelman et al. anastomoses within the small intestine and colon with the use of CAC were performed in 30 patients (8). In addition to the analysis of the early postoperative complications, the results indicated that the colonoscopies the patients underwent during the 6 months of observations confirmed the good functioning of anastomoses. Our results are consistent with the ones reported by Nudelman, i.e. no stenoses were reported or any other pathology in the smooth functioning of anastomoses between the small and the large intestines. Similar conclusions are drawn from reports presenting the first laparoscopic application of CAC in large intestine surgery (5 patients) (9).

A prospective randomized multicenter clinical study on the application of the CAC in enteroenterostomy performed with the Roux method after a total resection of the stomach was published by Hur et al. (10). In two patients, out of a group of anastomoses performed using CAC, a postoperative leakage was diagnosed (10%). While Jiang et al. did not describe any complications after 20 total resections of the stomach with the application of CACs in Roux enteroenterostomy (11). Both studies include only the early postoperative period. In our study we have evaluated three enteroenterostomies performed with the application of Roux method and

**DISCUSSION**

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CACs. All anastomoses showed valid patency after 6 months of observation. Due to the difficulty with endoscopic assessment (technical difficulties in reaching the anastomoses), in two cases apart from the evaluation of CT scans gastrointestinal X-ray with contrast was additionally performed. Encouraging results were presented by Lee et al. in the work concerning the application of the CACs in 63 anastomoses of the small intestine with the small intestine, and the small intestine with the large intestine (12). In the postoperative period the leakage occurred in 1 patient (1.5%) and the colonoscopies performed after 6 months revealed that the anastomoses were patent.

Experimental study on the anastomoses between the stomach and the small intestine with the application of the CAC was carried out by Tucker et al. (13). Two months after performing anastomoses in pigs, by means of endoscopic sampling procedure it was determined that the result was the complete adhesion of mucous membrane and full patency of all anastomoses. Liu performed 18 anastomoses between the stomach and the small intestine with the application of compression clip in the clinical conditions (14). After 6 months of observation, endoscopic examinations confirmed that no significant stenoses were found there, the line of anastomosis was covered with a smooth mucous membrane, without scars, and completely healed. The current study presents similar results. Out of the 16 anastomoses performed between the stomach and the small intestine, in one case there was a mild degree of stenosis accompanied by acute inflammation of the mucous membrane, erosion and lots of jejuno biliary reflux to the stomach. In one case macroscopic examination revealed some redness of the mucous membrane in the stomach along the lining around the anastomoses, and in 1 case a polyp was removed and diagnosed as a hyperplastic one. Because the surgical treatments were performed as palliative in the non-resectable pancreatic tumors, difficulties with the passage of contrast through anastomosis cannot be excluded in the case of gastroenterostomy, due to the loop modeling on the tumor confirmed in the CT scan or neoplastic infiltration in the superior mesenteric vessels.

The creation of scars and stenoses in anastomoses is due to many factors. Ischemia, the presence of ulcers in the anastomosis, the jejuno biliary reflux to the stomach, scar retraction, and an inappropriate surgical technique – to name some of them (6). Among the factors related to surgical technique having an impact on stenosis occurrence in gastroenterostomy one may enumerate the diameter of a circular staple used in the procedure, retrocolic or antecolic positioning of the Roux loop and the original dimension of the anastomosis (6). Anastomoses performed using the CAC was characterised by a smooth, well-healed line of anastomosis in the form of very thin circular tissue layer (15, 16). Kopelman et al. suggest that this is related to the lack of foreign body, suture material in the line of anastomosis and gradual pressure of the CAC on the tissues intestinal walls being anastomosed (16). Thanks to the expulsion from the body, the compression anastomosis clips allow to avoid the lasting presence of a foreign material in anastomosis, resulting in less inflammatory reaction (17). The first experiments with the CAC carried out on animals showed – by means of a microscopic examination – adequate mucosal healing, small formation of fibrous tissue, and a poorly visible scar tissue in the anastomosis line (1, 17, 18). The range of scar tissue is proportional to the quantity of the granulation tissue, which creates it (16, 19). Because in most patients the stenosis of anastomosis occurs in period of 3 months from the date of its formation, the evaluation of anastomosis carried out by us after 6 months allows to conclude that the compression clips form anastomoses which maintain a valid patency in the postoperative period (6).

When evaluating the anastomoses performed with the application of the CAC during the period of 6 months from their formation, it was determined that they function properly and can be safely performed within the upper and lower gastrointestinal tract. The encouraging results, however, should be backed up by further research on a larger group of patients.
REFERENCES