The use of shape memory NiTi alloy clips in small bowel anastomosis in pigs

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ABSTRACT: The usefulness of compression anastomotic clips (CAC) for small bowel anastomosis in animals was evaluated. Implants made of nickel-titanium alloy (NiTi) in the form of elliptical double-coil springs with one-way and two-way shape memory were applied. The studied animals were subjected to jejunal resection and side-to-side bowel anastomosis with the use of CACs. The experiment was conducted on 10 pigs divided into three groups. The speed and ease of the surgical procedure, implant excretion time and leak tightness were evaluated by macroscopic observations and X-ray examinations. Tissue samples from the anastomotic site were subjected to histopathological analysis. The applied method was characterised by tight connections between fused tissue, the absence of complications and ease of use. The results of the study indicate that shape memory NiTi clips are a promising tool in veterinary gastrointestinal surgery.

Keywords: CAC; shape memory implants; intestinal anastomosis

List of abbreviations
BAR = biofragmentable anastomosis ring, CAC = compression anastomotic clips, CAR = compression anastomotic ring, NiTi = nickel-titanium

Bowel compression anastomosis has been used in abdominal surgery for nearly 200 years. In 1826, Felix Nicholas Denans presented the results of experimental side-to-side bowel anastomosis in dogs with the involvement of zinc and silver rings (Kaidar-Person et al. 2008). The advancements made in gastrointestinal surgery brought new methods for effective bowel anastomosis. In 1892, Murphy proposed a new surgical device, known as "Murphy's button" The device was comprised of two connected metal rings adapted to intestinal diameter. According to the initial concept, the force of clip compression would promote fusion of intestinal walls, causing anastomosed tissues to necrotise. After release, the ring would be naturally expelled from the body. Murphy's button was believed to cause compression that was too tight, leading to a restricted intestinal lumen (Nudelman et al. 2002). The 20th century witnessed the introduction of new stapler and mechanical suture techniques as well as novel tools for bowel compression anastomosis. In 1984, Kanschin developed the AKA-2 device for colorectal surgery which was made of two plastic rings with metal pins and metal springs. AKA-2 was inserted transanally with the use of an applicator. After four to six days, the rings made of non-absorbable material and compressed bowel margins would be disconnected and removed transanally (Kaidar-Person et al. 2008). Another anastomosis device was the Valtrac biofragmentable anastomosis ring (BAR) which was invented by Hardy et al. (1985). Valtrac-BAR rings are made of absorbable materials: polyglycolic acid and barium sulphate as a radiographic marker (Nowicki et al.

2008). The size of the rings is accommodated to the intestinal lumen and a 1.5–to 2.5 mm gap is left between the rings to prevent tissue ischaemia. After 14–21 days, BAR rings are expelled with faeces. Recent surgical practice witnessed the advance of shape memory NiTi alloy clips with near-equiatomic chemical composition (Nudelman et.al. 2002). Shape memory of these alloys is associated with thermoelastic reversible martensitic transformation. At low temperature, the clip is easy to open in the martensitic B19 phase, and it is automatically locked under the influence of body heat produced during reverse transformation to the parent B2 phase. The above mechanism supports bowel anastomosis (Morawiec et al. 2008). Two types of bowel anastomosis implants have been developed: the compression anastomotic clip (CAC) (side-to-side) and the compression anastomotic ring (CAR) (end-to-end) (Kopelman et. al. 2007). Both tools are expelled naturally with faeces. The use of NiTi alloy clips in veterinary medicine is not widely described in the literature, which prompted us to perform experimental side-to-side small bowel anastomosis in a porcine model with the use of CACs.

MATERIAL AND METHODS

The experiment was performed at the Department of Surgery and Radiology of the Faculty of Veterinary Medicine at the University of Warmia and Mazury in Olsztyn in collaboration with the Department of Materials Science at the University of Silesia in Katowice. It was approved under Resolution No. 12/2011 of the Local Ethics Committee for Animal Experimentation.

The experiment was carried out on 10 age-matched pigs of both sexes, with body weights of 25–30 kg. The animals were divided into three groups. In group I, side-to-side jejunal anastomosis was performed in six subjects with the use of one-way and two-way shape memory NiTi clips. In group II, side-to-side anastomosis was created by manual suture in two pigs. Group III comprised two animals which were not operated on and served as controls. Body weight gains in groups I and II were compared against the control. Implants made of $Ni_{50.8}Ti_{49.2}$ and $Ti_{50}Ni_{48.7}Co_{1.3}$ alloys in the form of elliptical double-coil springs, measuring 25 mm × 7 mm, were used (Figure 1). The shape of the implant changes under the influence of temperature. At low temperature, the rings are pulled back and inserted into anastomosed bowel sections. The implants become locked under the influence of body heat, and intestinal walls become fused. Prior to anastomosis, the clips were immersed in liquid nitrogen. After cooling in liquid nitrogen, one-way shape memory clips had to be manually opened with forceps to an angle of approximately 30 °C. The two-way memory shape clips opened automatically after cooling in liquid nitrogen. An open clip was inserted through an incision in the intestinal walls where a side-to-side anastomosis was created. The clip was locked automatically under exposure to body heat. Clip cooling time was 15 seconds. The force of clip compression was determined at 7–10 N in a laboratory test.

Before the surgery, the animals were fasted for 12 h and were premedicated and anaesthetised

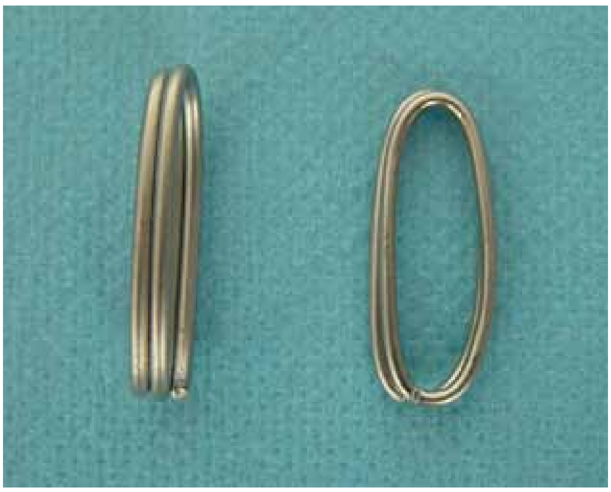

Figure 1.Compression anastomotic clip used in the experiment

Figure 2. Closure of jejunal lumen with a purse-string suture device

Figure 3. Cooled clip - opening of a two-way shape memory clip

Figure 4. Insertion of a compression anastomotic clip into the lumina of two jejunum sections

in accordance with standard procedures for the species. Antibiotic prophylaxis was administered for five days after surgery. The surgical field was prepared in accordance with the aseptic surgical technique. Abdominal integuments were incised along the midline in the umbilical region. In group I animals, jejunal loops were removed from the abdominal cavity and dissected. The lumen of both dissected jejunum fragments was closed with a purse-string suture device (Figure 2). Free jejunum sections were anastomosed side-to-side with two interrupted sutures, and 7 mm-wide incisions were made on the antimesometrial border of both jejunum fragments. A cooled clip was inserted into the incision (Figure 3), and it was locked under the influence of body heat (Figure 4). Both intestinal walls in the lumina of clipped bowels were cut to guarantee patency. The wounds were closed with two layers of 3-0 absorbable sutures. One-way shape memory clips were used in three group I animals, and two-way memory shape clips were applied in the remaining three pigs. Abdominal incisions were closed with three layers of sutures. In group II, side-to-side bowel anastomosis was performed with two layers of manual sutures. Abdominal integuments were closed with three layers of sutures.

The animals were administered feed and water 12 h after surgery. On the first and fifth day after the procedure, all pigs were subjected to X-ray examinations of the abdominal cavity with barium sulphate as the contrast medium. Antibiotic prophylaxis was administered for five days after surgery. Group I and group II animals were euthanised 14 days after the procedure, and the site of jejunal anastomosis was macroscopically examined. Intestinal samples were collected for histopathological examination. The samples were fixed in 10% buffered formalin, processed using a routine paraffin technique, and histological sections were stained with haematoxylin and eosin (HE). The obtained slides were scanned using a slide scanner (Panoramic Scanner Midi, 3Dhistech, Hungary).

RESULTS

Postoperative complications were not reported in any of the experimental groups. Fourteen days after surgery, identical body weight gains were reported in operated pigs and in pigs which did not undergo operation. Radiological examinations did not reveal leaks or bowel constrictions in group I animals. The results of a contrast X-ray examina-

Figure 5. Site of side-to-side anastomosis 14 days after surgery

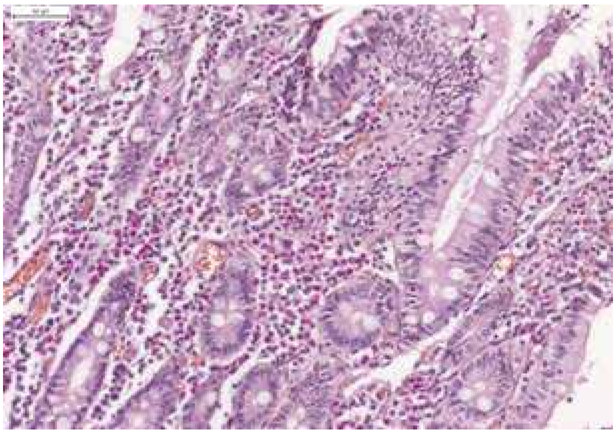

Figure 6. Histopathological image of the anastomotic site – inflammatory infiltration by a large number of acidophilic granulocytes and smaller numbers of lymphocytes, plasma cells and macrophages. HE staining, barium = 200 μm

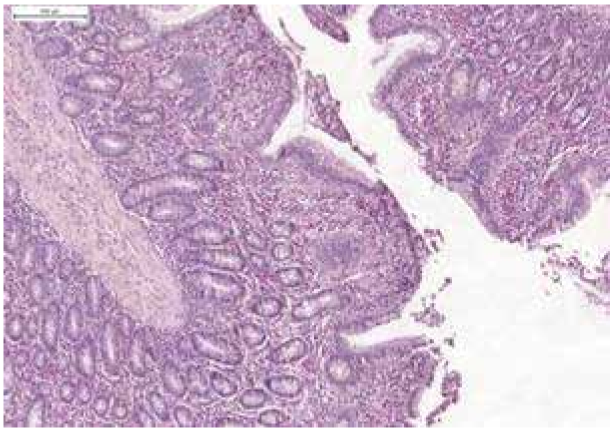

Figure 7. Intestinal villi at the anastomotic site: flat, club shaped. Inflammatory cell infiltration of intestinal mucosa. Proliferation of villus epithelial cells and intestinal glands. HE staining, barium = 200 μm

tion revealed a visibly constricted intestinal lumen in one pig from group II.

The clips were expelled by all animals seven to nine days after the procedure. Anastomosis was examined macroscopically in euthanised animals from group I (Figure 5). The luminal diameter at the anastomotic site was determined at approximately 20 mm. In one animal, the omentum was fused with the anastomotic site along a 20 mm section. In group II, a constricted intestinal lumen was observed in one animal and wound fusion with the jejunal loop was noted. The average time of surgical procedure was 30 min in group I and 50 min in group II.

A histopathological analysis of the intestinal mucosa in the anastomotic site revealed inflammatory infiltration by a large number of acidophilic granulocytes and smaller numbers of lymphocytes, plasma cells and macrophages (Figure 6). Inflamed mucosal vessels, thin intestinal villi of varied height, club shaped or flat, were observed (Figure 7). An abundance of intraepithelial lymphocytes, exfoliation of surface mucosal cells, proliferation of villus epithelial cells, intestinal crypts and glands was also noted. Small amounts of inflammatory exudate composed of exfoliated surface mucosal cells, lymphocytes, macrophages, fibrin and protein substance were found on the surface of intestinal mucosa. Inflammatory granulation tissue with infiltration by foreign-body giant cells, macrophages and lymphocytes, proliferating connective tissue, small vessels and adipocyte accumulation were observed at the anastomotic site. Granulation results from the presence of foreign bodies, such as suture material and CACs, and is characteristic of tissue regeneration in surgical wounds. The noted changes in intestinal mucosa and intestinal walls at the anastomotic site are normal processes that accompany tissue regeneration and cellular responses to foreign bodies.

DISCUSSION

Compression anastomotic clips made of nickel-titanium shape memory alloy are not used in standard gastrointestinal surgery in animals. One-way and two-way shape memory clips were applied in this experiment. In the authors' opinion, two-way shape memory clips offer a more practical solution because they open automatically, and do not require a device that will open the clip after it has been cooled in liquid nitrogen (Morawiec et al. 2009). The clips were easily inserted, and additional finger pressure was applied to speed up locking. Published studies describe anastomosis procedures where intestinal walls between clips were not incised, and digesta passage took place only after tissue necrosis and clip excretion. The above technique was not used in this study due to parenteral nutrition problems in pigs. An absence of differences in body weight gains between group I and group III animals points to normal functioning of the gastrointestinal tract in patients operated with the involvement of CACs. The applied method requires smaller quantities of suture material than the manual suturing technique. This is a significant advantage because double-layer suture anastomosis leaves more material at the surgical site, and increases the risk of leakage. Manual suturing often leads to uneven closure of joined tissue due to human error (Nudelman et al. 2000). This problem is eliminated with the use of clips which exert equal pressure along the entire tissue surface.

Staplers represent an alternative for manual suturing and compression anastomosis. The use of staplers requires much larger incisions on intestinal walls. Staplers have to be inserted into the lumen which significantly increases the risk of infection. Unlike clips which come into direct contact only with the intestinal mucosa and are expelled from the digestive system in their entirety, a broad mechanical suture remains in direct contact with abdominal organs. Patients with mechanical sutures cannot be subjected to MRI exams (Lampe et al. 2008). Mechanical and manual suturing can constrict the intestinal lumen, whereas in surgical procedures involving CACs, the lumen of an anastomosed bowel has the size of the applied clip.

The cost of the CAC procedure is several dozen times lower in comparison with the stapler technique (Nudelman et al. 2002), which is a very important consideration in veterinary medicine. Clips significantly shorten surgical time, and in group I animals, operating time was 20 min shorter on average in comparison with group II. Shorter surgical and anaesthesia times considerably increase patient safety.

In veterinary medicine, shape memory NiTi clips offer a promising alternative to conventional surgical techniques that rely on manual suturing and expensive mechanical suturing. The results of the described experiment are highly promising, and pave the way for future research into the use of CACs in other animal species, in particular cats and dogs. The use of compression clips in small bowel anastomosis, gastroenterostomy and cholecystenterostomy in conventional and laparoscopic surgery (Nudelman et al. 2004) will open new avenues of research in veterinary medicine.

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