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Gastrointestinal Anastomosis with the Nickel-Titanium Double Ring

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Abstract. We used a dog model to test the safety and effectiveness of sutureless gastrointestinal anastomoses ($n = 23$) (end-to-end, end-to-side, or side-to-side) with the nickel-titanium double ring with temperature-dependent shape memory. Results were compared to conventional hand-sutured anastomoses ($n = 5$). Examination performed after 2 weeks' follow-up showed no leaks and no difference in return of bowel function between the experimental groups and the control group. Microscopic studies showed a complete epithelial lining and perfectly functioning anastomoses. We conclude that the nickel-titanium double-ring device may have an important place in the armamentarium of the gastrointestinal surgeon.

Gastrointestinal tract anastomosis is a basic technical component of almost all gastrointestinal procedures. It was performed manually for the first time by Billroth and colleagues [1] at the end of the nineteenth century in Vienna. In 1892 Murphy introduced a mechanical device for bowel anastomosis [2] consisting of two metal rings that held circular segments of the intestine under continuous pressure, leading to tissue necrosis. The rings were expelled after a few days along with the stool. It was almost 100 years later that permanent staples for securing the two edges of the resected bowel were developed. In 1985 Hardy et al. [3] developed their biofragmentable anastomotic ring (BAR; Valtrac, Danbury, CT, USA); although clinical trials indicate that BAR anastomosis is safe [4, 5], it has not been universally accepted [5, 6].

The aim of the present experimental work was to test the safety and effectiveness of a new surgical device, the nickel-titanium double ring with temperature-dependent shape memory, for gastrointestinal anastomosis (end-to-end, end-to-side, side-to-side) (Fig. 1).

Materials and Methods

The idea was to create a sutureless, perfectly functioning anastomosis by compression of both intestinal lumens to be anastomosed with this new device. The double rings were made from an alloy of nickel-titanium, which were tested at high temperature in metallurgic ovens.

This new device possesses the unique biomechanical property of becoming flexible when cooled in ice water at −2°C for 2

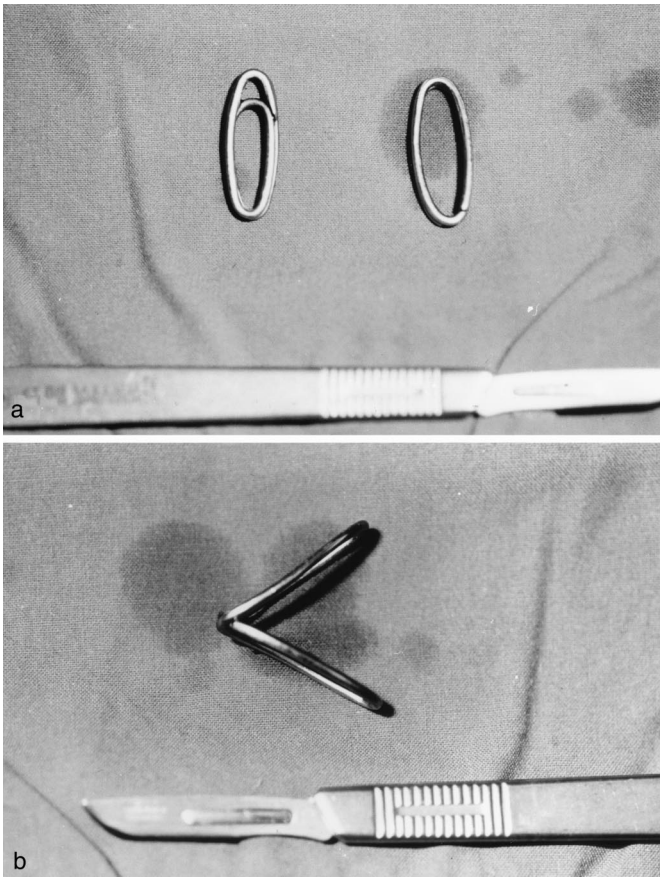

Fig. 1. Nickel-titanium double ring with temperature-dependent shape memory. **a.** Closed position. **b.** Open position, before insertion in the bowel lumen.

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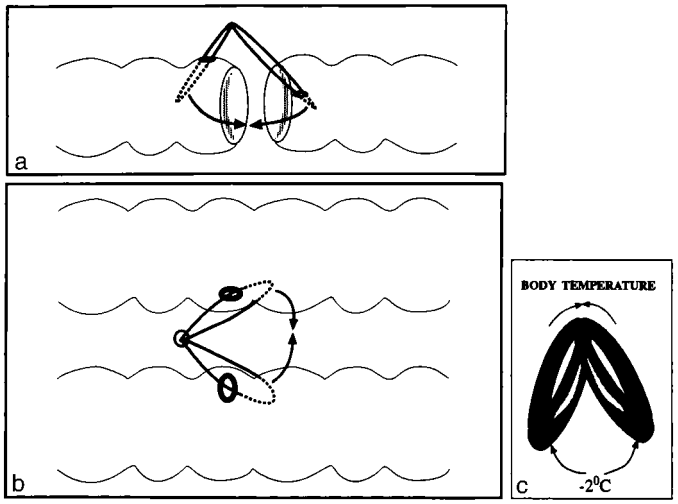

Fig. 2. Surgical technique for placing the ring for anastomosis. **a.** End to end. **b.** Side to side. **c.** The ring closes at body temperature.

minutes while retaining its original shape (Figs. 2b, 3b). In this open and flexible state, the ice-cooled (−2°C) nickel-titanium ring, with a diameter of 2.5 to 3.0 cm, is inserted into both bowel lumens (bowel diameter 2.0–2.5 cm) through a 5 mm opening in each of the bowel segments to be anatomized. Owing to body temperature, the double nickel-titanium ring contracts to its original closed shape and configuration, which by continued compression of the entrapped bowel wall leads to tissue necrosis, creating an ideal anastomosis. The rings are expelled after a few days (up to a week) with stool. The double rings, 2 cm diameter, have a compression power of 400 g/cm^2. During this period a perfectly uniform, symmetric anastomosis is formed, without leaks or other complications, such as bowel obstruction.

Twenty-six anastomoses were performed in 21 mongrel dogs of various ages under sterile conditions with general anesthesia by intravenous pentitol and halothane inhalation and intratracheal intubation. Surgery was performed through a midline abdominal incision.

The animals were divided into three study groups and one control group. The first (n = 8) underwent a side-to-side and end-to-end entero/enterostomy using a small bowel loop 40 cm distal to the Trintz ligament. The loop was disconnected by cautery. A nickel-titanium double-ring device (diameter 2.5 cm) was water-cooled (0°–2°C for 2 minutes) to achieve the desired shape of the planned anastomosis (Fig. 2) and was inserted in both lumens. The anastomosis was established with the contraction of the device (due to body temperature) to its original shape and diameter (Fig. 3). The small 5 mm openings in the bowel were closed with one layer of 3-0 Dexon.

The second group of dogs (n = 6) underwent a colocolostomy by the same technique as the first group (end-to-end, side-to-side anastomoses). The third group (n = 7) underwent a side-to-side gastroenterostomy. A 0.5 cm hole was made in the stomach and a small-bowel loop; and the double ring, with a diameter of 3.0 cm, was inserted through the hole and placed on both organs. The small opening was closed by one layer of Dexon sutures. Two of the dogs with a gastrointestinal anastomosis also underwent side-to-side cholecystojejunostomy, performed in the same manner as the gastroenterostomy.

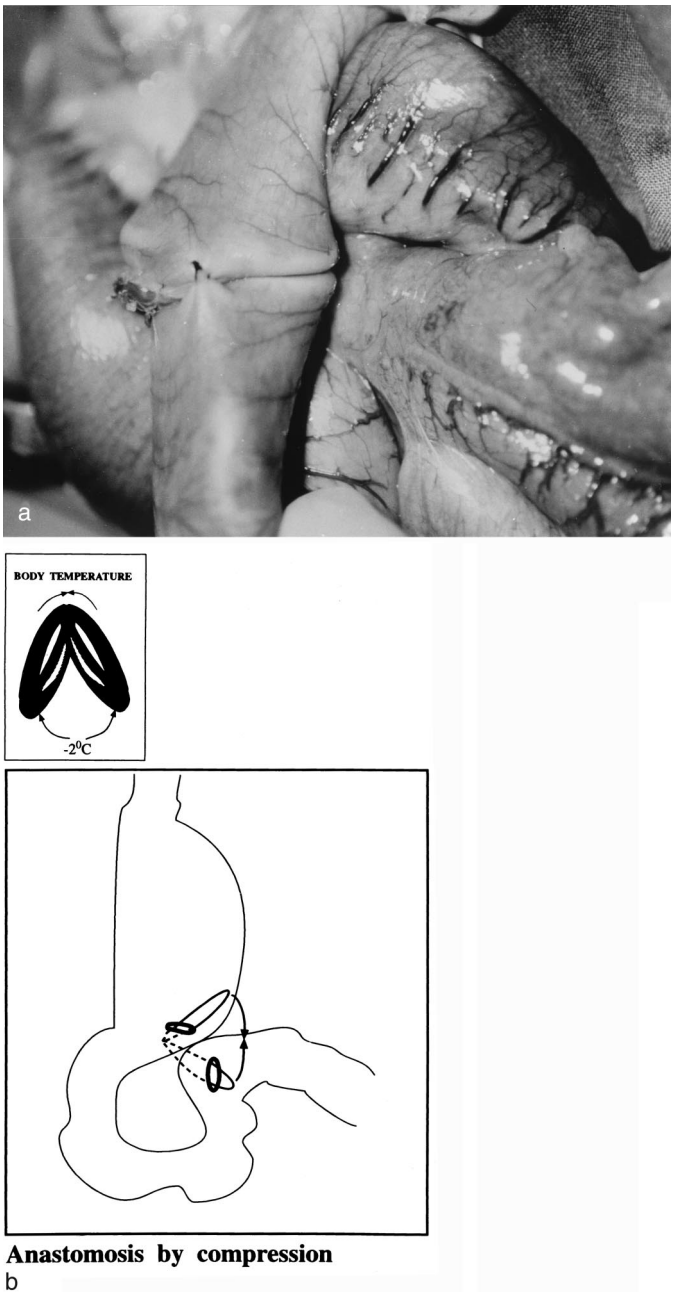

Fig. 3. a. Established anastomosis by closure of the ring device. **b.** Surgical technique for placing the nickel-titanium double-ring with memory shape-temperature dependent for gastroenterostomy compression anastomosis.

All dogs were followed for 2 weeks and then anesthetized and sacrificed. The anastomoses were resected for histologic examination.

Results

All the dogs recovered uneventfully from the operation. The rings were expelled about 7 days after surgery. On examination after 14 days there were no signs of intraabdominal sepsis or leakage and no intestinal obstruction; the anastomotic diameter was similar in

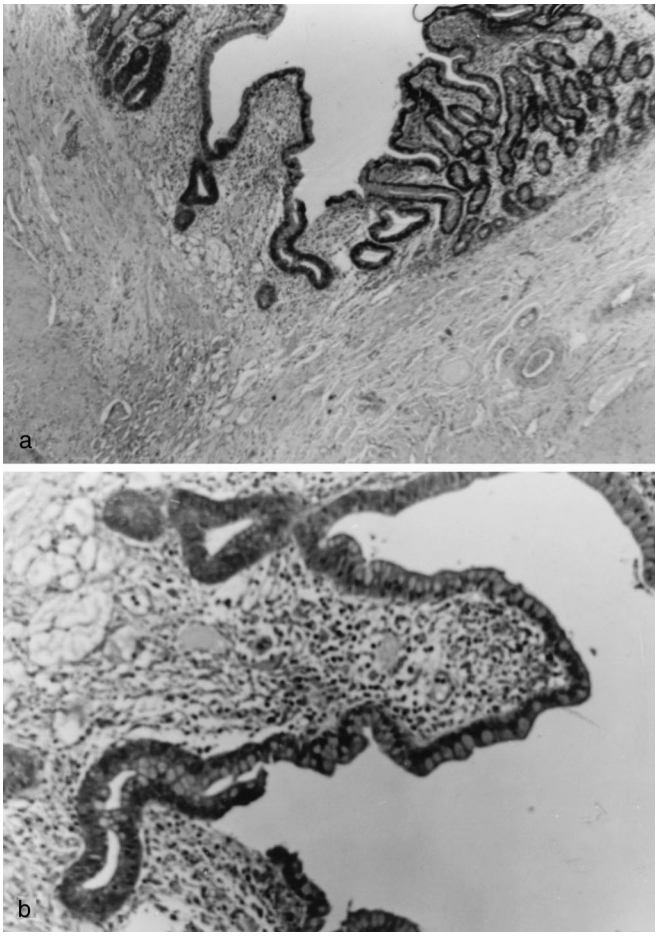

Fig. 4. a. Hematoxylin-eosin stained section shows complete reepithelialization of the mucosa at the anastomotic site. The newly formed epithelium is columnar in type and shows mild anisocytosis. **b.** Magnified view of the same section, showing the newly formed epithelium.

the experimental and control groups. Macroscopic and microscopic studies showed a complete mucosal epithelial lining (Fig. 4) with reepithelialization of the mucosa at the anastomotic site and an intact, functioning anastomosis. All the experimental studies were performed on normal bowel, without pathologic conditions such as ischemia, sepsis, or inflammation.

Discussion

This work examined the safety and effectiveness of a double ring device with temperature-dependent shape memory for gastrointestinal tract anastomoses. In none of our experimental groups were there operative complications or anastomotic leakage. On microscopic examination, the resected segments showed a complete epithelial lining throughout the anastomosis, indicating a perfectly intact, functioning anastomosis with no narrowing or signs of bowel obstruction.

Many clinical studies have shown that mechanical instruments are superior to manual anastomoses in terms of the length of procedure, rate of postoperative complications, and time of return of bowel function. However, all the instruments introduced to date have the major disadvantage of high cost, which is especially important in Third World countries.

The device tested here, the double ring, which is placed directly on the tissue, exerts strong local pressure, inducing local necrosis, similar to the mechanism of Murphy's button or the BAR device. When necrosis occurs, the rings detach from the tissue and are expelled with the stool, and a uniform anastomosis is created. Our device is more versatile than the BAR [7] because it can be applied not only for end-to-end anastomoses but also for side-to-side and side-to-end procedures owing to the flexibility of the temperature-dependent metal ring. In addition, it is easier to use and is available at a much lower cost than other devices on the market today. We developed this original device to create a perfectly uniform sutureless intestinal anastomosis. The idea of creating such an anastomosis by compression with this nickel-titanium ring, which has temperature-dependent shape memory, is promising. The compressive anastomosis has advantages over the conventional suture anastomosis, including shorter duration of surgery, shorter hospitalization due to absence of complications (e.g., anastomotic leaks, sepsis, intestinal obstruction, bursting of stitches), and the benefit of elasticity of the anastomosis and a fully dynamic valve, plus of course the benefit of low cost. The ring device costs approximately $1, the suture anastomosis (two-layer anastomosis using Vicryl stitches) costs approximately $5–$8, and the GIA stapler costs about $100.

We believe the nickel-titanium double-ring device with temperature-dependent shape memory can enrich the armamentarium of the gastrointestinal surgeon. Further clinical studies with longer follow-up are needed to establish its role for human use.

Résumé

Nous avons testé, chez 23 chiens, la sûreté et l'efficacité d'une anastomose gastrointestinale (termino-terminale, termino-latérale ou latéro-latérale) sans suture, en utilisant un anneau double en nickel-titanium dont la mémoire est dépendante de la température. Les résultats ont été comparés à ceux des anastomoses conventionnelles manuelles (n = 5). L'examen réalisé après deux semaines n'a montré aucune fuite anastomotique, ni aucune différence en ce qui concerne le retour à l'activité intestinale entre les deux groupes. Les études microscopiques ont montré une ré-épithélialisation complète et l'anastomose fonctionnait parfaitement bien. Nous concluons que l'appareil d'anneau double en nickel-titanium devrait avoir une place importante dans l'arsenal du chirurgien digestif.

Resumen

Se investiga en un modelo canino (n = 23) la seguridad y efectividad de la sutura gastrointestinal aninotica (sin hilos) termino-terminal, termino-lateral y latero-lateral, mediante el empleo de un anillo doble de niquel-titanio configurado con memoria temperatura-dependiente. Los resultados se comparan con anastomosis realizadas mediante sutura manual convencional (n = 5). Los hallazgos obtenidos, tras un seguimiento de dos semanas, demostraron la ausencia de fugas anastomóticas y la inexistencia de diferencias significativas, en el restablecimiento de

la función intestinal, entre ambos grupos. Los estudios microscópicos mostraron una completa reepitelización y un perfecto funcionamiento de las anastomosis. Concluimos señalando, que el anillo doble de niquel-titanio ha de conseguir un importante lugar en el armamentario del cirujano gastrointestinal.

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