SHORT COMMUNICATION

New concepts for a compression anastomosis: Superelastic clips and rings

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Abstract

Gastrointestinal anastomosis is a crucial step in many operative procedures, and responsible for a major portion of early and late post-operative complications. In order to improve on the results of current tools to perform an anastomosis, such as sutures and staplers, new concepts are being developed. One of these concepts is compression anastomosis. Compression anastomosis has been tried in the past but did not become popular mostly because of technical reasons. Recently, trials to accomplish compression anastomosis using Nitinol devices were conducted.

Two devices were made and tested in the past three years: A side-to-side device and an end-to-end device. The common principle in both devices is the compression of two bowel loops through the constant pressure of a Nitinol device, thus producing a dual process of necrosis and healing until the lumens of both bowels fuse, and the device falls into the lumen and is excreted. Both devices have been tested in animals and humans, with encouraging results. In animals, the anastomoses were shown to demonstrate minimal inflammation and no foreign body reaction, with perfect healing of the mucosa. The side-to-side device was tested in over 500 human patients, and the end-to-end device is currently used in a large, multi-centric human trial.

Key words: Gastrointestinal, anastomosis, Nitinol, compression

Gastrointestinal anastomosis is an important step in the majority of gastrointestinal surgical procedures, and it is directly related to several serious complications of these operations. It has been reported that half of the postoperative deaths following bowel surgery were caused by sepsis due to anastomotic leakage (1). Thus, improving the safety of the anastomosis and investigating alternative techniques to hand-sewn and stapled anastomoses still represents a challenge.

The idea of compression anastomosis was first reported in 1826 by Denan, who conceived a sutureless bowel anastomosis which encompassed the inverting technique proposed by Lembert. The idea was to compress two bowel walls together and cause a simultaneous necrosis and healing process that will lead to the joining of the two lumens. In 1892, Murphy introduced a mechanical device known as “Murphey’s button” that was used for years (2).

Additional compression devices, such as the Magnetic ring, the AKA-2 device and the biofragmentable anastomosis ring (Valtrac, Autosuture, Tyco Healthcare Group) were developed almost 100 years later (3–6). Although many animal experiments and clinical trials reported high efficacy and safety rates of these anastomotic devices, the awkwardness of use, narrow inner caliber and cost prevented them from becoming widely acceptable and they were substituted by staplers (7) which are in routine use today. Recently, the introduction of Nitinol with its unique properties has re-established the interest in such devices.

Nitinol (Nickel Titanium Naval Ordinance Laboratory) is an alloy containing an almost equal mixture of Nickel and Titanium that was invented in the late 1960’s and was considered for many years a “solution in search of a problem”. It has gained interest in the medical device world only in the past decade and become an important component in

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several revolutionary medical devices, such as stents, tools, and grafts. Nitinol belongs to a group of materials that are sometimes referred to as “smart materials”, mainly because of their unique physical properties and the fact that they behave surprisingly different from other metals.

The two physical properties that make Nitinol so appealing are shape memory and super-elasticity. These properties enable the design and production of new medical devices in different fields of medicine.

The atomic structure of Nitinol is a three-dimensional symmetric grid with each atom of Nickel surrounded by four atoms of Titanium. The atomic forces that bind these atoms create a unique three-dimensional structure that can exhibit a transition between two phases. The first, termed Austenite phase, is a high-temperature, stronger state. The second, Martensite phase, is a low temperature, unstable, weak phase. The transformation between the two phases gives Nitinol the ability to demonstrate its unique properties.

Two features can be memorized in a product made of Nitinol: Transformation temperature and memorized austenitic shape. When cooled below the transformation temperature, a product made of Nitinol transforms to its martensitic phase, in which it assumes lower mechanical properties, which would enable easy deformation of the product. As long as the deformation doesn’t exceed about 6% (very high for metals), when the product is reheated above the transformation temperature, it will fully resume its memorized austenitic shape and mechanical characteristics. This process is fully reversible. After being plastically manufactured in a certain form and at a given temperature, Nitinol will stay in that form as long as it is kept at or above this temperature. When cooled below the stable temperature it will transform into the weak, unstable phase and may be easily deformed into other shapes. Once warmed back to the stable temperature it will regain its original form exactly.

Nitinol demonstrates unique mechanical stress-strain behavior when it is loaded and unloaded. This unique behavior is characterized by typical loading and unloading plateaus which are usually not associated with metals, and resemble curves typical of live tissue, which makes Nitinol biocompatible when used as an implant either in bones or soft tissue. At room temperature Nitinol is typically in the stable, strong phase. When subjected to strain it goes into the unstable, weak phase that exhibits low stress forces and allows deformation with a resulting small change in stress or yield. In similar conditions, other metals will either resist the deformation or break. When the strain is no longer exerted the metal goes back to the more stable, strong phase and regains its original form with very little distortion.

When produced, the metallic surfaces of Nitinol may be finished in a way that leaves mostly titanium oxide atoms and a small proportion of Nickel atoms, strongly bound to the crystal structure. Thus, although Nitinol contains much higher concentrations of Nickel than stainless steel it releases much smaller amounts of free Nickel atoms into adjacent tissues and the blood stream than commonly used stainless steel medical devices. Nitinol is also completely MRI compatible and allows MRI scanning even with large implants, such as gastrointestinal and major vessel stents.

These properties of Nitinol make it a good candidate to create a new compression anastomosis device. A group of such devices was manufactured and tested recently, with promising results.

The devices are bowel anastomosis compression clips and rings, made by a NiTi Medical Technologies of Netanya, Israel. Currently, two concepts have been realized made and are being tested:

A double-loop clip (Figures 1 and 2) that after being cooled is deformed and inserted into two bowel loops.
through 2–3 mm incisions that are closed with a few sutures. After being warmed to body temperature the clip hardens and exerts a constant, low pressure on the bowel walls. During approximately seven days a simultaneous process of pressure necrosis and healing takes place, at the end of which the bowel loops are joined with a common lumen and the clip falls into the bowel and is excreted. The two versions of the device, for open and laparoscopic procedures, were FDA approved after safety and efficacy studies had been completed. In the past two years they have been used in over 400 human cases, with good results (8–10).

The side-to-side device was used in anastomoses along the entire gastrointestinal tract, including stomach, small bowel and colon and possible combinations of these anastomoses, including an animal study of consecutive anastomoses such as anticipated in gastric bypass procedures.

The most striking results were found when the anastomoses were studied microscopically: In contrast...
to the foreign body reaction and inflammatory process observed in stapled and hand-sutured anastomoses, in compression anastomosis there is minimal inflammation and no foreign body reaction, and as a result in the healed anastomosis there is very little scar tissue (Figures 3 and 4). Potentially this may reduce both the leak and the stricture rate in the short- and long-term follow up. Although the device showed good results in terms of healing, complications and leak rates, some problems were still noted that were unique to the device, and required to learn the pitfalls of using it. Problems such as the proper closure of the insertion incisions and the prevention of a twisted anastomosis were encountered and solved during the study. Another drawback to this specific device is the need for suture, rather than a stapled closure of the insertion incisions.

A second device that was designed and manufactured is an end-to-end compression anastomosis device. This device utilizes two separate synthetic rings that are mounted on an instrument very similar to a circular stapler. An anvil containing one ring is fixed to the proximal bowel end, and the instrument with the other ring is inserted trans-anally for a rectal anastomosis. When engaged, the rings are locked together by Nitinol springs that exert the desired constant pressure (Figure 5), and a circular knife resects the access tissue. Like in the side-to-side device, a simultaneous necrosis-healing process takes place, and at the completion of this process, after seven to ten days, the device is detached and expelled naturally.

The end-to-end device was extensively studied in animals (11–12) with excellent results (Figure 6), and currently has been used in over 50 human patients, with very good results. In microscopy it demonstrated similar features as the side-to-side device. It seems that in low rectal anastomoses the features of minimal inflammation and scar tissue formation have special benefits, as leak and stricture rates in this area are higher than in other sites in the gastrointestinal tract.

In conclusion, it seems that there are promising potential benefits of compression anastomosis, and that the re-institution of this concept using new materials has some future as an additional tool, or even as a replacement, for the currently available technologies for bowel anastomosis.

References