

## TECHNICAL NOTE

# The use of superelastic suture clips in laparoscopic gastric banding

MARCO MARIA LIRICI, FLORA SALERNO & ANDREA CALIFANO

Department of General and Thoracic Surgery, BMM Hospital, Reggio Calabria, Italy

### Abstract

Nickel-Titanium suture clips have been developed to enhance suturing in cardiovascular surgery (U-CLIP™, Medtronic, Minneapolis, MN, USA). The first applications of superelastic suture clips in bariatric surgery were reported by Barba and Kane in 2004. No other experiences in this field have been reported or published. Our experience with this newly developed suture clip, used for suturing the anterior wrap in laparoscopic gastric banding, started in 2007. The U-Clip™ technology and the surgical technique are described and discussed in this article.

**Key words:** Nitinol suture clips, superelastic alloys, shape memory alloys, tissue approximation, laparoscopic gastric banding

### Introduction

Laparoscopic suturing is often a challenging task, above all if the tissue to be approximated or the anastomosis to be accomplished are in a position within the body cavities which is difficult to be reached. Intracorporeal knot-tying of interrupted sutures is often time-consuming. Superelastic suture clips have been developed to enhance and speed up laparoscopic and open suturing.

Nickel-Titanium sutures have first been designed for cardiac and vascular surgery (1–4). Superelastic suture clips eliminate the need of knot-tying to secure interrupted sutures. The use of superelastic clips in bariatric surgery was first reported by Barba and Kane in 2004 (5–6). No other experiences have been reported in more recent years. Our early experience with the U-CLIP™ anastomotic and approximation device (Medtronic, Minneapolis, MN, USA) for fashioning a wrap around the adjustable gastric band in obese patients started in 2007. To date, four cases have been performed with such a technique. We here describe the technology and technique of laparoscopic gastric banding with the use of superelastic suture clips.

### U-Clip anastomotic and approximation device features and function

The U-CLIP™ is a 510K FDA cleared device developed in the early 2000s, and intended for

endoscopic and non-endoscopic general soft tissue and prosthetic material approximation/attachment and/or ligation and the creation of anastomoses in blood vessels, grafts and other tubular structures. Besides its application in cardiovascular surgery, only few indications in general surgery have been reported: Esophago-gastric end-to-end anastomosis (inner and outer layers), closure of jejunostomy, oversew and reinforcement of gastro-jejunostomy, closure of mesenteric defects, fixation of jejunum and oversew of the lap band placement (5–7).

The clip is fabricated from a superelastic alloy (50% nickel–50% titanium) with a ring-shaped pre-deployment form. The nitinol wire is both highly elastic and magnetic resonance compatible. Nitinol is a memory shape alloy which responds to thermal exposure. Thus, the U-CLIP™ wire transforms to the predetermined shape when applied and exposed to body temperature.

The components of the suture clips are shown in Figure 1. The system consists of a standard curved needle connected to a nitinol flexible member, which works as a standard suture thread, at the end of which there is the clip release mechanism and the superelastic clip. The structure of the flexible member consists of three braided nitinol threads. Between the flexible member and the release trigger there is a transition zone of plastic material with a conical shape. The transition zone eases U-CLIP™

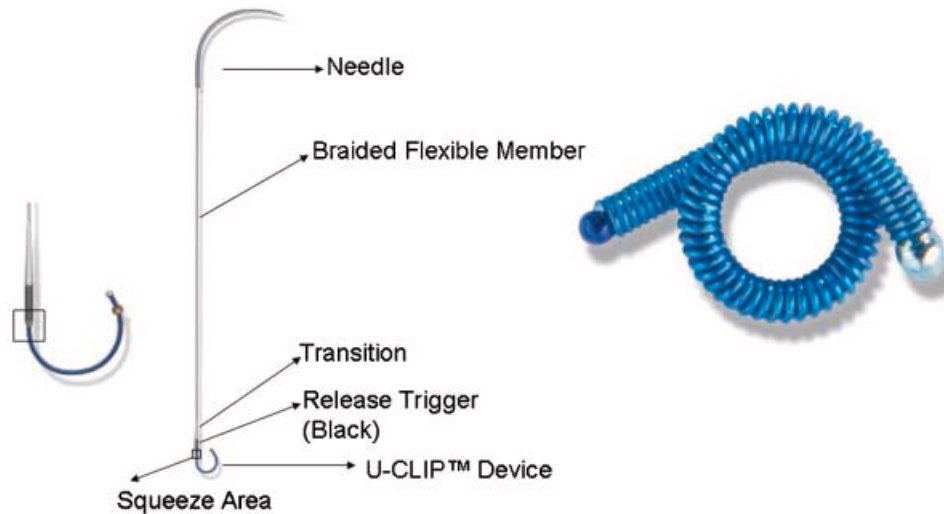


Figure 1. U-CLIP™: Components and structure.

passage through tissue. Between the transition zone and the suture clip there is the release trigger. The trigger is black, has a cylindrical cross section and seven internal cones with circular alignment. Its function is to allow the deployment of the U-CLIP™. The suture clip is connected to the release trigger. Its structure – an internal nickel-titanium alloy coated by an external nickel-titanium wire – is designed to approximate and hold tissues together, when detached, comparable to an interrupted suture.

U-CLIPs are placed by means of a standard needle-holder (laparoscopic or for open surgery) and do not require specially designed clip applicators. Once the needle is passed through the tissue to be approximated, further traction on the needle or the flexible member makes the superelastic clip pass through the tissue, too (Figure 2). At this point the U-CLIP™ is deployed from the remnant suture by applying a pressure with the needle-holder jaws onto the release trigger. Suture clip separation from the release mechanism allows the clip itself to return to the predetermined closed-loop configuration. Thus, the superelastic properties of nitinol enable precise suture clip delivery and placement and thus to accomplish strong and atraumatic tissue approximation. There is no need for further suture management: The self-closing property of the memory shape alloy makes knot-tying unnecessary while fashioning interrupted sutures.

### Technique

Laparoscopic adjustable gastric banding is the best known and most performed restrictive procedure in

bariatric surgery. In the standard technique, a small opening is created in the lesser omentum and right above the first short gastric vessel and a retrogastric tunnel connecting the two openings is created mostly by blunt dissection. The adjustable gastric band is then passed from the left to the right through the tunnel and closed around the stomach, creating a very small pouch of  $\leq 30$  ml, right below the oesophago-gastric junction. The anterior wall of the stomach body is approximated to the gastric pouch by passing three polypropylene 3-0 interrupted sutures secured by either intracorporeal knots or extracorporeal sliding knots. In this way, an anterior wrap is fashioned around the band, thus minimising the risk of band displacement. The gastric band is connected via a small tube to a subcutaneous reservoir, allowing to adjust the gastric pouch outlet according to the patient's needs during the postoperative course.

Our technique of laparoscopic adjustable gastric banding with superelastic clip band oversew is similar to the procedure described above. A large bore gastric tube is inserted into the esophagus down to the stomach, to enable better recognition of anatomical structures and dissection manoeuvres. A silicon adjustable gastric band with a soft cuff (Swedish Adjustable Gastric Band, SAGB – Obtech Medical (Johnson&Johnson), Zug, Switzerland) is positioned around the stomach according to the technique described above (Figure 3). The band is closed and the volume of the pouch checked. Three suture clips are placed to fix the anterior gastric wall, used to make a wrap which covers the band and keeps it in place, to the small gastric pouch. U-CLIP™ is available off the shelf in different needle and clip sizes and flex

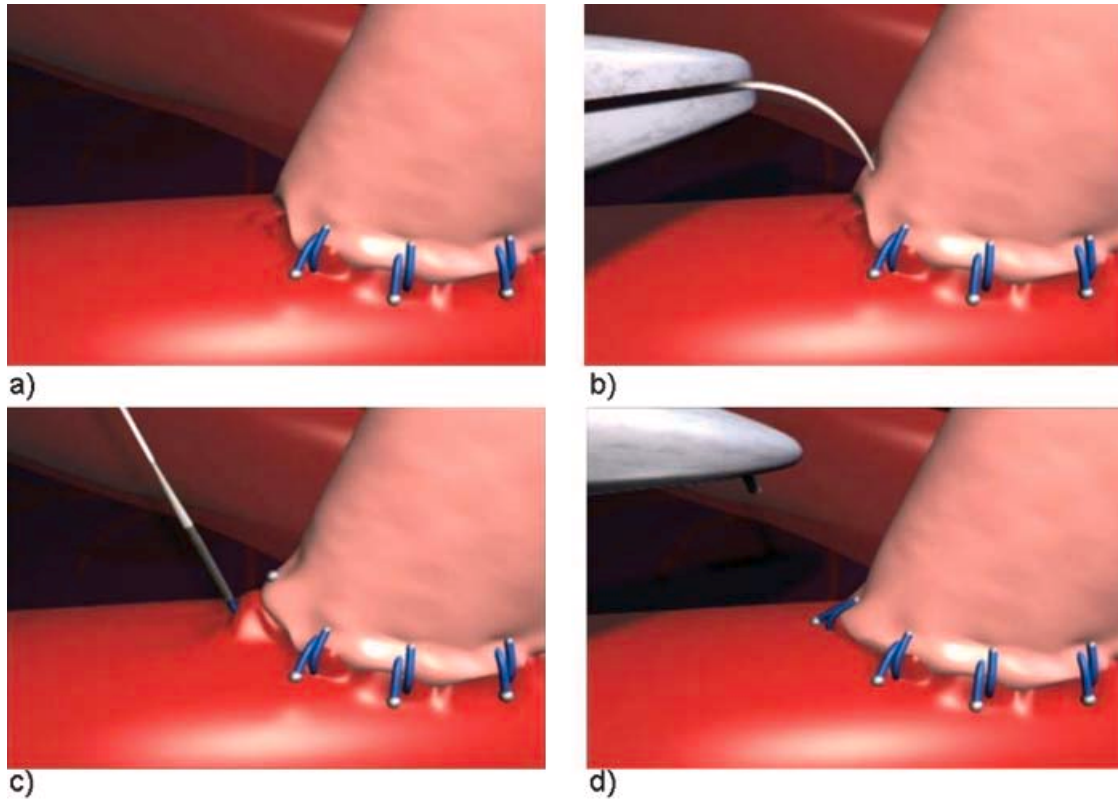


Figure 2. Sketches showing the correct placement and deployment of superelastic suture clips for vascular anastomosis.

member lengths. To approximate the gastric wall either S105 or S120 U-CLIP<sup>TM</sup> are suitable, with  $\frac{1}{2}$  circle 26 mm needle and regular flex member length. Figure 3 shows the correct procedure to place the U-CLIPs. Once the superelastic clip is passed through the tissue, its deployment is achieved by squeezing the release trigger, easily recognized for its black colour, between the jaws of the laparoscopic needle-holder. Once detached, the U-CLIP<sup>TM</sup> self-closes in a ring-shaped fashion. The final view of the gastric band oversew is shown in Figure 4. The final step of the gastric banding procedure is the subcutaneous positioning of the reservoir, connected via a silicon tube to the adjustable band.

## Discussion

The clinical application of superelastic alloys seems promising even in the field of suturing.

Overall, we performed four LAGBs with the use of superelastic suture clips. Patients' BMI ranged from 42 to 48. Outcomes at this early stage (follow-up ranging 3–9 months) were satisfying: Weight loss ranged between 18 and 40 Kg and the U-CLIP's ability to keep the band in place seemed good, with no displacement seen at short and medium term follow-up.

The time required for suturing the wrap was shortened in all cases but the difference was not significant. In our standard technique, the gastric tissue of the wrap is approximated with three interrupted sutures secured with extracorporeal sliding knots and usually this is a very fast procedure. Greater benefits in term of time saving should be achieved when superelastic suture-clips are used for fashioning anastomoses in the digestive tract, as has been shown in cardiovascular surgery. No experimental data to show the safety of the device are yet available in this field.

Distal and proximal U-CLIP<sup>TM</sup> burst and tensile strengths have been assessed *in-vitro* and *in-situ* (test report 04VA0659.00, dated March 28, 2001), comparing the performance of most common sized proximal (S60) and distal (S18) U-CLIP<sup>TM</sup> cardiovascular anastomoses to size 6-0 and 8-0 polypropylene sutures in the same applications. Table I summarizes the results of tests performing vascular anastomosis with S-60 U-CLIP<sup>TM</sup> vs. 6-0 standard sutures. The test data show evidence that proximal and distal anastomoses constructed using S60 U-Clips<sup>TM</sup> (similar data were obtained with S18 U-CLIPs<sup>TM</sup>), display higher burst strengths than anastomoses created conventionally using polypropylene suture. Pull strengths between the two methods were shown not to be statistically different.

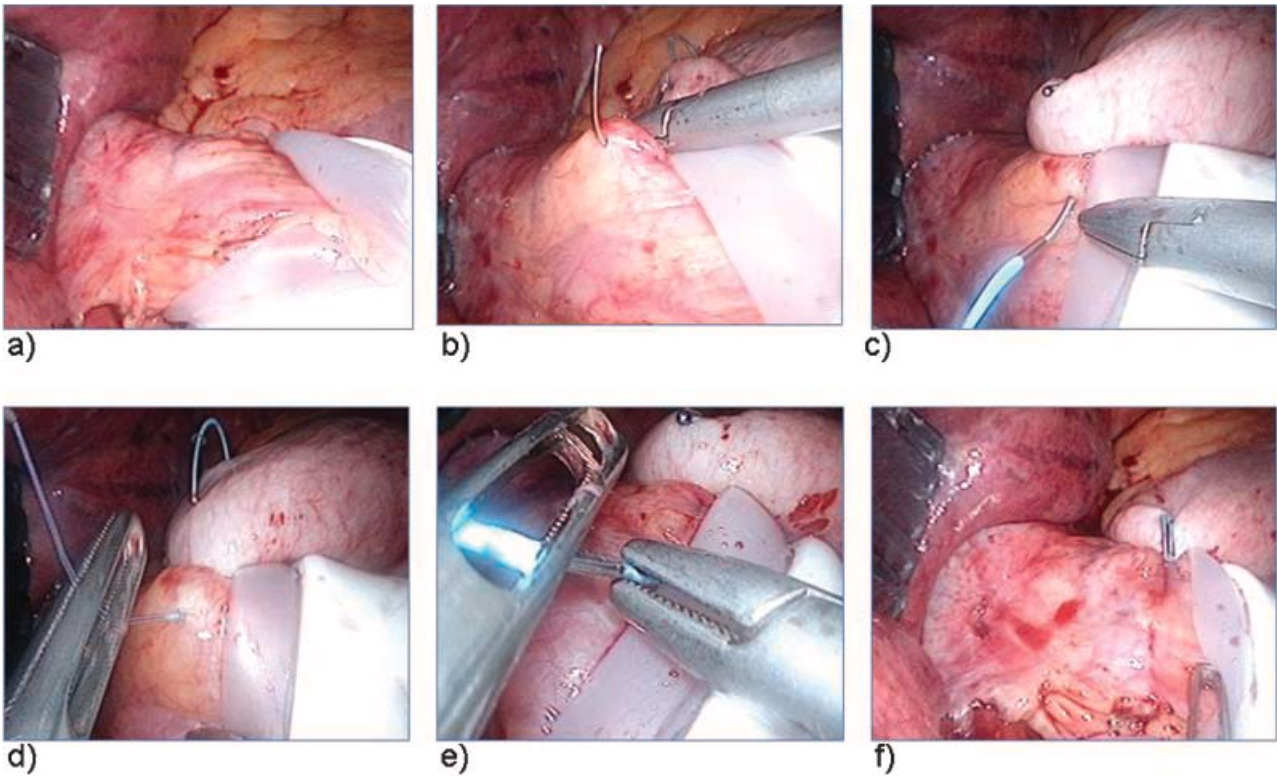


Figure 3. Gastro-gastric wrap for tunnelization of the gastric band at the end of laparoscopic gastric band placement: a) The band has been placed creating  $\leq 30$  ml gastric pouch right below the o.g. junction; b) the needle is passed through the gastric walls to be approximated; c) traction is applied on the flexible member (the thread) to enable the passage of the U-CLIP<sup>TM</sup> through the tissue, the transition zone eases a smooth clip passage; d) the U-CLIP<sup>TM</sup> passage is completed; e) the clip release trigger is squeezed between the needle-holder jaws to deploy the U-CLIP<sup>TM</sup>; f) after deployment the U-CLIP<sup>TM</sup> self-closes around the tissue.

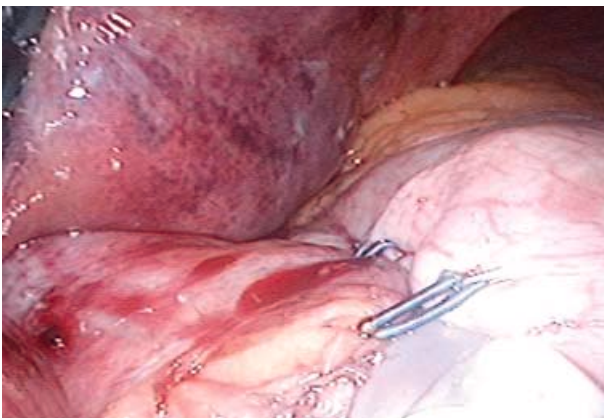


Figure 4. Final view of the lap - gastric band oversew.

No data are yet available on the assessment of greater size U-CLIPs, as those used for oversewing a gastric banding, comparing the performance of tissue approximation or anastomosis in digestive surgery.

Our early experience shows that Nitinol clips are a safe device that facilitates approximation of tissue in laparoscopic surgery. They may be indicated any time an interrupted suture is requested to

Table I. Burst and tensile strengths: comparative study of proximal vascular anastomosis with S-60 U-CLIP<sup>TM</sup> vs. 6-0 standard sutures

(10) Samples	Burst (psi)		Tensile (lbs)	
	6-0 Suture	S60 U-Clip	6-0 Suture	S60 U-Clip
Mean	18.48	22.92	1.40	1.18
Std. Deviation	2.14	3.35	0.31	0.21
T-Test	0.003		0.076	

approximate tissue of the digestive tract. Nevertheless, data available are not sufficient to evaluate the safety of superelastic suture-clips to perform a complete anastomosis in the digestive tract and further reports and comparative studies are needed.

**References**

1. Hill AC, Maroney TP, Virmani R. Facilitated coronary anastomosis using a nitinol U-clip device: bovine model. J Thorac Cardiovasc Surg. 2001;121:859-70.

Minim Invasive Ther Allied Technol Downloaded from informahealthcare.com by Dr Marco Maria Lirici on 07/22/12 For personal use only.

2. Demaria RG, et al. Interrupted coalescent nitinol clip versus continuous suture coronary anastomosis: a comparative endothelial function study. *The Heart Surgery Forum*. 2003;6:72–6.
3. Hamman BL, White CH. A novel device for clipless proximal anastomosis in OPCAB surgery: the IPAD. *The Heart Surgery Forum*. 2004;7:374–5.
4. Lin PH, et al. A prospective evaluation of interrupted nitinol surgical clips in arteriovenous fistula for hemodialysis. *Am J Surg*. 2003;186:625–30.
5. Barba C, et al. The use of U-Clip device in LapBand. Poster session presentation at ASBS; 2004.
6. Kane J, et al. A retrospective study comparing stomal stenosis rates of the gastrojejunostomy in laparoscopic Roux-en-Y gastric bypass with and without the use of nitinol sutures (U-Clip<sup>TM</sup>). Plenary Session Presentation at ASBS; 2004.
7. Tirabassi M, et al. Feasibility of thoracoscopic U-Clip esophageal anastomosis: an alternative for esophageal atresia reconstruction. *J Pediatr Surg*. 2004;39:851–4.