Detachable Parallel Action Clamp for Endoscopic Surgery

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The existing occlusive clamps used in endoscopic surgery are modifications of the basic conventional "scissors clamp" design used in open surgery. All the current clamps, including "atraumatic" ones, cause tissue damage. The scissors design is intrinsically unsound because the occlusive force is not uniformly distributed and is much greater near the pivot end than between the free ends of the jaws. The ideal occlusive clamp should be based on "parallel occluding jaws," as this mechanism ensures a uniform occlusion without undue crushing of the bowel. During the last two years we have been involved in the development of a detachable endoscopic atraumatic clamp.[1,2] This has necessitated considerable biological experimentation, mechanical engineering design work, and clinical evaluation. The biological studies were concerned with the measurement of the forces (compression and friction) necessary to occlude and seal bowel at different intraluminal pressures without causing surface damage. The mechanical engineering and design development of the parallel jaw action clamp incorporating pseudoelastic nickel-titanium (Ni-Ti) spring was based on the data obtained from the biological studies. Once the basic design was established, miniaturization allowed the production and clinical evaluation of an endoscopic detachable parallel action clamp (DPAC) that can be introduced through 5.0-mm ports.

EXPERIMENTAL BOWEL OCCLUSION AND FRICTION FORCES

Occlusive Forces

The force required to occlude bowel and prevent seepage of bowel contents after the application of the clamp was investigated using a customized test rig which applied parallel occlusion to segments of porcine bowel (jejunum and ileum) by the application of varying loads. The freshly harvested bowel segments were perfused with water at known pressures (2kPa - 5kPa) to simulate varying intraluminal pressures within the small intestine. The effect of incremental loads applied in a parallel fashion to the bowel on the outflow from the intestinal loop was observed. In these experiments, reduction of flow was found to occur in two distinct stages. The first stage consisted of apposition of the two bowel walls when the bowel distal to the site of compression collapsed while the bowel proximal to compression site (inflow side) became distended. At this stage some seepage continued and the bowel slipped between the parallel occluding jaws until the tension in the bowel wall on the outflow side equalled the hydrostatic force. This *first sealing load* had to be increased further to obtain complete continence at the occlusive site–*continent occlusive force*. The results of these experiments at various predetermined intraluminal pressures and differing widths of jaws (5 mm and 10 mm) have been reported elsewhere.[1] With a bowel perfused such that its intraluminal content is at a pressure of 2.5kPa, a continent occlusive force of 5 N is needed for thick wall bowel (10 mm), but allowing for the variation in the data, a value of 7 N would give an additional safety margin. Since real bowel contents are considerably more viscous than water (used in our experiments), complete safe occlusion in human bowel without leakage is likely to occur at smaller forces than those obtained in these experiments.

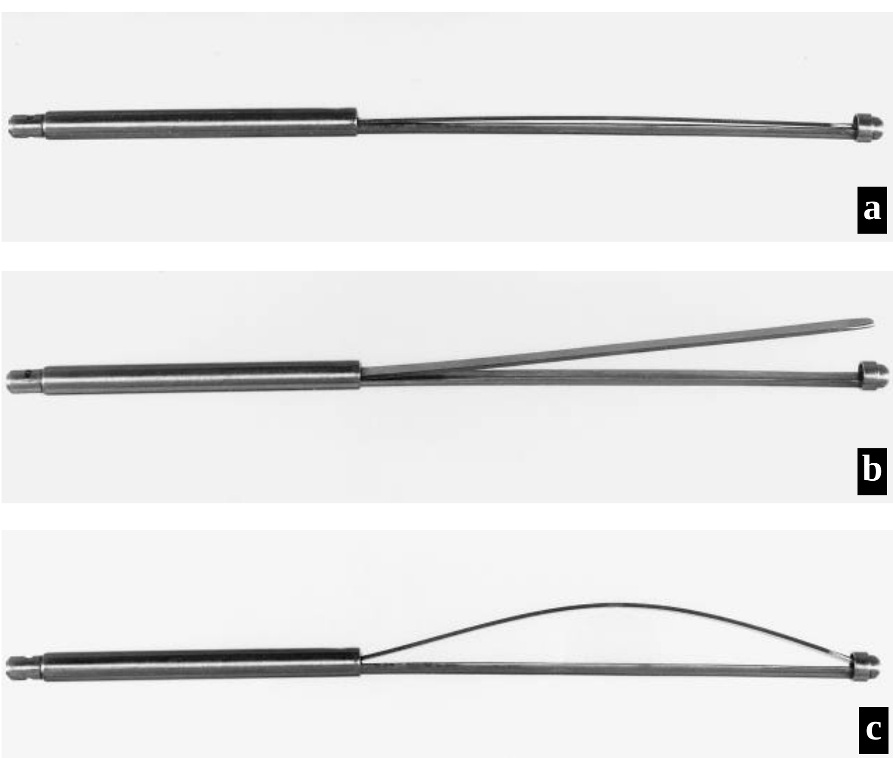
Friction between Bowel and Various Surfaces

Friction is necessary to prevent slipping of the engaged clamp when relatively low parallel forces are applied. To measure the force required to pull the isolated small bowel segments between the parallel jaws, these specimens were attached to a load cell which was pulled by hand and its output recorded in real time on a computer data recording system. This procedure was carried out with various loads (100 N to 500 N) and varying surface texture of the clamp jaws.[1]

Three different grades of waterproof emery paper were selected for this (P80 =197 μm, P320=46 μm, P500=30 μm), and strips of each were glued to dummy jaws. The raw data were transferred to a data analysis software package which enabled the calculation of the average force values. The best fit straight line (method of least squares) to the equation $F_z=2\mu F$ (where F is the applied force) was obtained and the coefficient of friction read from the slope.

Acceptable friction without bowel damage was achieved by jaws covered with P500 (friction coefficient of 1.0 ± 0.01). P80 and P320 resulted in a higher friction coefficient (1.4 ± 0.2), but these surfaces caused trauma to the serosal layer of the bowel.[1] A jaw surface reproducing the surface texture of P500 waterproof emery paper is ideal for the design of atraumatic bowel clamps.

Figure 1. Ni-Ti "sling bar" parallel action" clamp: (a) clamp closed, (b) opened before deployment, (c) engaged.



These biological studies indicated that the ideal atraumatic bowel clamp should have a parallel jaw mechanism applying an occlusion force of around 7.0 to 10 N and with a friction coefficient of around 1.0.

CLAMP DESIGN

Two parallel closing clamp designs were developed. In the first, the clamp had jaws that could be closed at the distal end (Figs. 1a-c). These prototypes, based on an active Ni-Ti "sling bar," exerted the right closing force in a 5-mm device. However, the endoscopic deployment, particularly the opening and closing of the distal catch, proved difficult.

The second design was based on a four-bar-link (parallelogram) mechanism. The jaws of this clamp remain open at the proximal end and allow a simple attachment mechanism to be incorporated for endoscopic deployment. This design was chosen for further development as an intestinal detachable parallel action clamp.[2]

DETACHABLE PARALLEL ACTION CLAMP

To achieve size reduction and maintain a sufficient occlusive force, one of the bars of the four-bar-link system was replaced with a spring strip constructed from pseudoelastic Ni-Ti alloy. This material which has shape memory properties in its martensite state, is notable for its large recoverable strain and is resistant to corrosion. The spring in the final clamp design consists of a specially treated Ni-Ti strip of 0.7-mm by 2.0-mm cross-section.

The final design of the DPAC consisted of five parts (Figs. 2a-d): (1) the main body (half-round bar of the lower jaw and short end-tube), (2) upper jaw (half-round bar), (3) pseudoelastic spring strip, (4) rear arm, and (5) connecting link. The clamp applicator consists of a rod (with a hook at the end) within a tube and a two-pan handle (Fig. 2d).

Mechanism of Action of DPAC

The upper jaw, lower jaw, rear arm, and spring strip make up the four-bar link with parallel sides. In this arrangement, the spring strip functions as a rigid bar with a pivot at each end, but since its unstressed form is straight, it also acts to force the jaws together. The spring strip thickness, which determines its strength, was chosen to give a mean force of about 10 N. The jaw surfaces were machined with a pattern of grooves to provide the necessary friction.

Deployment of DPAC

The clamp jaws are opened by the connecting link which pulls the rear arm at a pivot point. This link has an eye at the proximal end. To engage the clamp, the applicator hook is first passed through the eye of the connecting link. As the two components of the handle are squeezed together, the hook and the eye are pulled inside the outer tube of the applicator until this docks on to the end-tube of the clamp body. To open the clamp jaws, the handles are squeezed closer together. This system of deployment was found to be easy to use in preliminary trials using laparoscopic trainers and video equipment.

For clinical use, the clamp is hooked on to the applicator and introduced in the relaxed (closed) configuration through a 5.5-mm port. The closed clamp is brought to the viscus under visual control and then opened. The bowel is grasped and brought between the clamp jaws which are then released to occlude it. The applicator is then detached from the clamp and removed via the access port. The process is repeated using another clamp for the occlusion of the other viscus to be included in the anastomosis. On completion, the applicator is reintroduced and hooked to the clamp. The inner rod is retracted to open the clamp and thus releases the bowel when traction on the rod is eased to effect closure of the clamp prior to its removal through the port.

Clinical Evaluation

The 5-mm DPAC clamps have been evaluated in patients undergoing thoracoscopic esophagectomy with right intrathoracic anastomosis and during laparoscopic surgery, where the clamps were applied to the gallbladder and jejunum (palliative cholecystojejunostomy), stomach and jejunum (gastrojejunostomy), and the right colon and ileum (right hemicolectomy). Good atraumatic occlusion with no leakage after transection or enterotomy was observed when esophagus, stomach, gallbladder, jejunum, ileum, and colon were clamped. The clamps are easy to deploy and all aspects of their use posed no technical problems–introduction, visceral application and occlusion, release of the engaged clamp from the applicator, re-engagement of the clamp by the applicator, and release from bowel on completion of the anastomosis with closure and withdrawal of the clamp.

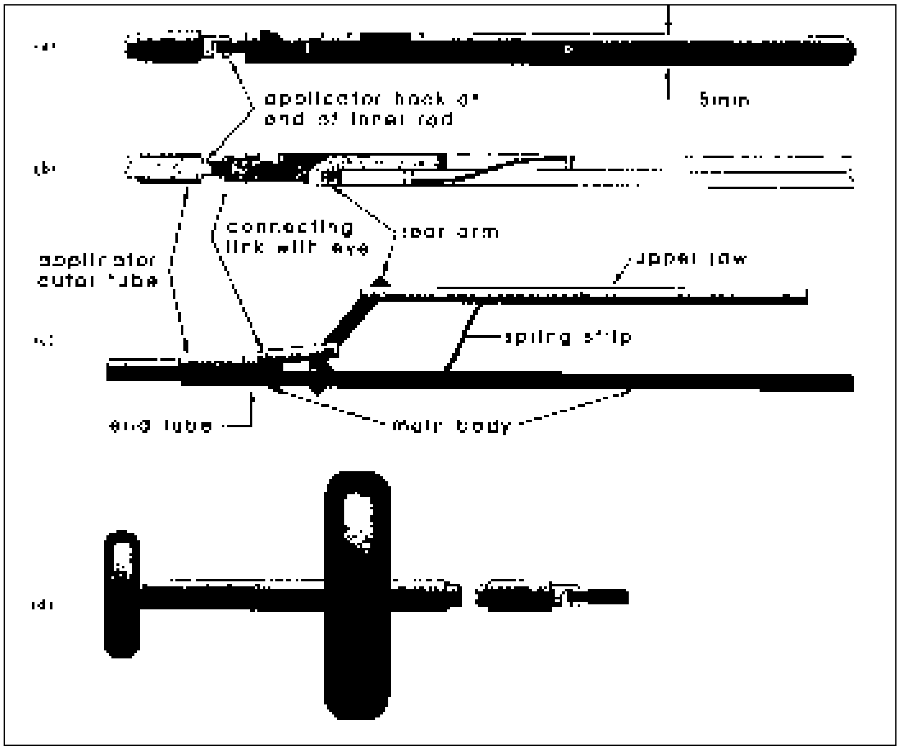


Figure 2. Diagrammatic representation of DPAC based on the four-bar-link principle: (a) top view of clamp, (b) side view of clamp, (c) clamp engaged and opened by applicator, (d) applicator mechanism.

DISCUSSION

A new endoscopic clamp based on the four-bar-link principle has been developed and tested experimentally and clinically. It achieves effective closure and sealing of the bowel during anastomosis and applies a uniformly distributed force of about 10 N. The detachable nature of the clamp frees up ports for use for other purposes during the operation. The work, involved in the development of this clamp, exemplifies the need for close cooperation between surgeons, biologists, and engineers in the design of equipment for endoscopic surgery. Technological advances in the instrumentation for endoscopic surgery will emanate from exploring novel mechanisms involving shape memory alloys rather than the production of endoscopic variants of the conventional surgical instruments traditionally used in open surgery. STI

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