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Initial experience with an absorbable laparoscopic ligation clip

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Background Laparoscopic surgery requires secure and safe methods of ligation and haemostasis. This study evaluated the efficacy of an absorbable ligation clip with a novel compression closure mechanism.

Methods A new compression-closure absorbable clip was compared with currently available absorbable and non-absorbable clips used in a variety of laparoscopic procedures in 12 centres worldwide.

Results At follow-up to 3 months after the procedure, no complications specific to the use of the compression-closure clip were detected. Operator satisfaction with the clip was high, with criticism directed at its relatively large size.

Conclusion This new clip is as safe and effective as presently available metal and absorbable clips in providing haemostasis and securing tubular structures.

The technique of laparoscopic surgery requires adequate methods for securing haemostasis and closure of tubular structures such as the cystic duct stump during cholecystectomy. The currently available metal ligation clips, while satisfactory in the majority of cases, suffer certain drawbacks. These include electrical current conduction, ease of dislodgement, interference with imaging techniques such as computed tomography and magnetic resonance imaging, and acting as a nidus for common bile duct stone formation[1–4]. The currently available absorbable clips rely on a latch mechanism, which may be impeded if tissue becomes interposed between the jaws, causing incomplete closure[5,6].

This study was designed to evaluate the performance of a new absorbable ligation clip, with a novel compression closure mechanism, for use in laparoscopic surgery in comparison with metal and currently available absorbable ligation clips.

Patients and methods

The Lapro-Clip (Davis and Geck, Danbury, Connecticut, USA), which is made from a bioabsorbable polymer, is radiolucent and has a novel two-part compression closure mechanism (*Figs 1* and *2*). The inner flexible polyglyconate track piece closes around the vessel or duct, and a rigid outer polyglycolic body then slides over the track piece to occlude the vessel or duct. This closure mechanism reduces the risk of excess tissue interposition causing clip failure. The clip degrades by hydrolysis in 180 days. It is applied with a reusable applicator introduced through a 10-mm port.

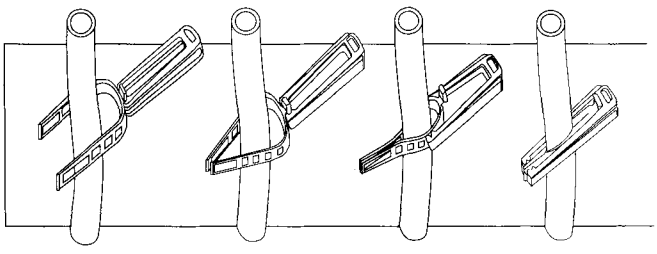
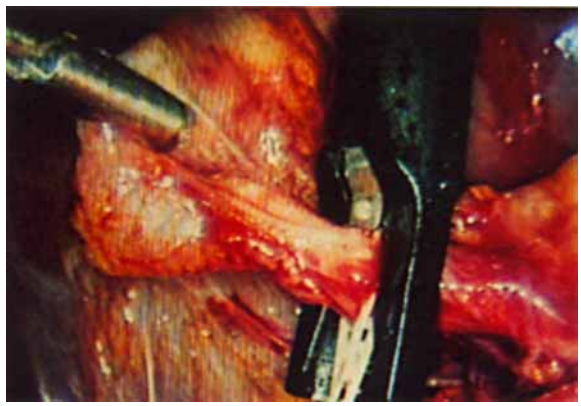


Fig. 1 Closure sequence of the Lapro-Clip

A total of 415 patients were entered into the study. In the test group 230 underwent laparoscopic cholecystectomy using Lapro-Clips, and these were compared with 146 unselected prospective



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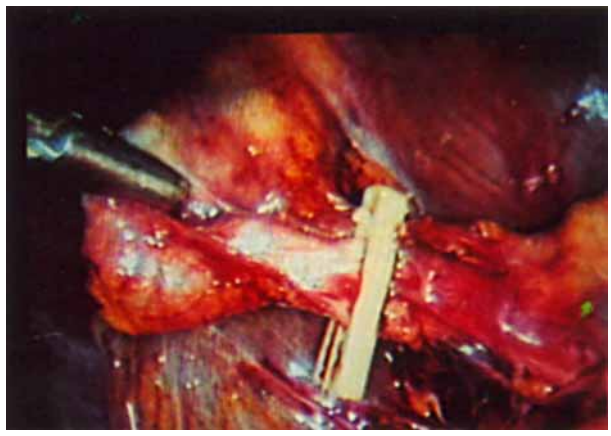

b

Fig. 2 **a** Application of the Lapro-Clip to the cystic duct; **b** the Lapro-Clip in place

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control patients having laparoscopic cholecystectomy with metal or latch-closure (Absolok; Ethicon, Somerville, New Jersey, USA) absorbable clips. Twenty-one patients had laparoscopic procedures other than cholecystectomy using the Lapro-Clip; these were matched against 18 controls undergoing laparoscopic procedures other than cholecystectomy with metal or latch-closure (Absolok) absorbable clips (*Table 1*). Forty (24·4 per cent) of 164 control patients had laparoscopic procedures performed with absorbable latch-closure (Absolok) ligation clips. Metal clips applied with either single- or multi-fire applicators were used in the remaining 124 control patients (75·6 per cent).

Patients were enrolled from 12 surgical centres worldwide. The disparity in group size occurred because two centres worked only with Lapro-Clips and provided only historical control data, which were not included in the trial.

Assessments were made of: (1) intraoperative complications; (2) postoperative complications during hospitalization; and (3) postoperative outcome at 1 and 3 months. An unsatisfactory result was recorded when the patient complained of any of the following: persistence of preoperative symptoms, persistent postoperative pain or other postoperative complication such as deep venous thrombosis or wound infection.

The surgeons involved were also asked to assess the handling characteristics and subjective security of the Lapro-Clip in comparison with controls for each case by completion of a standardized questionnaire.

Table 1 Operations other than laparoscopic cholecystectomy included in the study

Procedure	Lapro-Clip	Control clip
Adrenalectomy	1	0
Anterior resection	1	1
Appendicectomy	1	4
Colectomy (total or partial)	4	4
Oesophagectomy	1	0
Herniorrhaphy	1	1
Hysterectomy	1	2
Liver biopsy	1	0
Nissen fundoplication	5	3
Oöphorectomy	0	1
Polypectomy	1	1
Sigmoid colectomy	2	0
Thoracoscopic lung resection	1	1
Vagotomy and seromyotomy	1	0
Total	21	18

Table 2 Characteristics of the study subjects

	Lapro-Clip group ($n = 251$)	Control group ($n = 164$)
Mean(s.d.) (range) age (years)	50·7(15·3) (14–90)	50·5(15·6) (18–83)
Sex ratio (M:F)	82:169	49:115
Mean(s.d.) weight (kg)	73·0(14·6)	74·6(26·3)

Results

The demographic features of the groups were similar (*Table 2*).

The only clip-related complication was one minor bleeding episode during operation due to partial cystic artery occlusion by the Lapro-Clip; this was readily controlled by further clip application. There were no postoperative complications, such as bile leakage or bleeding, related to clip application or use in either group. Total postoperative complication rates were similar for both groups (Lapro-Clip 17 (6·7 per cent) *versus* control nine (5·5 per cent)).

One month after operation 233 patients (92·9 per cent) in the test group were reviewed and two (0·8 per cent) had an unsatisfactory result; in the control group 150 patients (91·5 per cent) were seen and two (1·2 per cent) had unsatisfactory results. These findings were the same at the 3-month review. None of the persisting unsatisfactory results could be attributed to clip-related complications.

There was a high degree of operator satisfaction with the Lapro-Clip loading mechanism, security and clip closure (*Table 3*). However, one criticism was the large size of the Lapro-Clip, which sometimes made full visualization of the distal ends of the clip difficult. The larger size of the clip was advantageous when a large or bulky cystic duct was encountered. A greater proportion of satisfactory results was recorded by assessors in favour of the Lapro-Clip over controls in the areas of clip loading, security and haemostatic effect.

The mean(s.d.) number of Lapro-Clips used was 6·6(1·5) (range 1–30) per patient compared with 7·7(1·8) (range 2–30) control clips per procedure.

Discussion

The results of this study suggest that the Lapro-Clip is as safe and effective as standard metal clips for vessel and

Table 3 Handling characteristics reported by surgeons in 415 cases*

	Lapro-Clip ($n = 251$)		Control ($n = 164$)	
Characteristic	Satisfactory	Unsatisfactory	Satisfactory	Unsatisfactory
Visibility of ligation site	176 (70·1)	70 (27·9)	148 (90·2)	3 (1·8)
Clip size	203 (80·9)	43 (17·1)	149 (90·9)	2 (1·2)
Clip closure	241 (96·0)	6 (2·4)	151 (92·1)	0 (0)
Clip security	241 (96·0)	6 (2·4)	148 (90·2)	3 (1·8)
Clip loading	247 (98·4)	0 (0)	151 (92·1)	0 (0)
Trigger pressure	185 (73·7)	62 (24·7)	151 (92·1)	0 (0)
Visibility of clip	197 (78·5)	50 (19·9)	150 (91·5)	1 (0·6)
Applicator function	223 (88·8)	24 (9·6)	149 (90·9)	2 (1·2)
Haemostasis	241 (96·0)	1 (0·4)	143 (87·2)	0 (0)

Values in parentheses are percentages. *Some assessors failed to provide data for all categories in all cases

duct ligation. Its use was not associated with any increase in local or general complications up to 3 months after operation, when compared with metal or currently available latch-closure absorbable clips.

Animal work has suggested that the design of absorbable clips may make them more secure than metal clips that close by simple compression[6]. However, currently available latch-closure clips may fail if tissue becomes interposed between the jaws. The new compression closure mechanism of the Lapro-Clip may provide a more secure closure than latch closure mechanisms by reducing the risk of tissue interposition.

Most of the criticisms of the Lapro-Clip by the operators related to its large size, making visualization of the distal ends of the clip difficult. A smaller 8-mm clip is being developed.

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