

# MEDTRONIC SUMMARY: CLINICAL PAPER

Medtronic provides the following review of a publication comparing the use of absorbable ligation clip to metal and absorbable latch-closure clips in laparoscopic surgery.

**TITLE:** "Initial experience with an absorbable laparoscopic ligation clip"

**AUTHORS:** A. Darzi, B. Soin, J. Coleman, N.M. Lirici and L. Angelini

**JOURNAL:** British Journal of Surgery, 1997, 84: 974-976

## PURPOSE OF THE STUDY

To evaluate and compare the performance of the absorbable ligation clip to the metal clip and currently available absorbable ligation clips.

## METHODS

Four-hundred and fifty one patients were entered into the study. Two-hundred and 30 patients underwent laparoscopic cholecystectomy using Lapro-Clip™ ligating clips, 146 patients went under the same procedure using metal or latch-closure absorbable clips (Absolok™ ligation system), the remaining 21 patients had laparoscopic procedures other than cholecystectomy using the Lapro-Clip™ ligating clips and these were matched against 18 patients undergoing the same procedures using metal or latch-closure absorbable clips. Forty of 164 patients had laparoscopic procedures performed with absorbable latch-closure ligation clips.

Data collected included: intraoperative complications, postoperative complications during hospitalization and postoperative outcome at 1 and 3 months. Also, a questionnaire asking surgeons to assess the handling characteristics and subjective security of the Lapro-Clip™ ligating clips in comparison to the controls was completed.

## RESULTS

Operations other than laparoscopic cholecystectomy are included in Table 1.

- Minor bleeding occurred due to partial cystic artery occlusion by the Lapro-Clip™ ligating clips.
- No postoperative complications such as bile leakage or bleeding in either group.
- Total postoperative complication rates were similar for both groups (Lapro-Clip™ ligating clips group 6.7% vs. control group 5.5%).
- Two patients (0.8%) of 233 patients (92.9%) of test group had unsatisfactory results at 1 month post-op.
- Two patients (1.2%) of 150 patients (91.5%) of control group had unsatisfactory results.
- There was a high degree of operator satisfaction with the Lapro-Clip™ ligating clips loading mechanism, security and clip closure.

**TABLE 1:** Operations other than laparoscopic cholecystectomy

PROCEDURE	LAPRO-CLIP™ CLIP APPLIER	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
Oophorectomy	0	1
Polypectomy	1	1
Sigmoid Colectomy	2	0
Thoracoscopic lung resection	1	1
Vagotomy and seromyotomy	1	0
TOTAL	21	18

- Operators found the large size of the Lapro-Clip™ ligating clips made full visualization of the distal ends difficult.
- However, it was advantageous when a large or bulky cystic duct was encountered.
- Satisfactory results recorded by assessors were in favor if the Lapro-Clip™ ligating clips over controls in areas of clip loading, security and haemostatic effect (Table 2).
- The mean Lapro-Clip™ ligating clips used was 6.6 per patient compared to 7.7 in control clips procedures

**TABLE2:** Handling characteristics reported by surgeons in 415 cases\*

CHARACTERISTIC	LAPRO-CLIP™ CLIP APPLIER (N = 251)		CONTROL (N = 164)	
	SATISFACTORY N (%)	UNSATISFACTORY N (%)	SATISFACTORY N (%)	UNSATISFACTORY N (%)
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)

\*some assessors failed to provide data for all categories in all cases

## CONCLUSION:

The use of Lapro-Clip™ ligating clips was not associated with any increase in complications up to 3 months after surgery. Therefore, the results suggest that the Lapro-Clip™ ligating clips is as safe and effective as the standard metal clip or latch-closure clips for vessel and duct ligation.

**\*\*This concludes the clinical synopsis of this publication\*\***

