MEDTRONIC REVIEW
CLINICAL SUMMARY

Medtronic provides the following synopsis of a clinical publication around anvil technology in thoracic surgery.

TITLE "Anvil Extension Technology in Thoracic Surgery"

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PURPOSE OF THE STUDY

Although complex thoracoscopic operations like pulmonary lobectomy have been well established with the endoscopic linear staplers, concern regarding the ability to pass the straight anvil through tubular structures has lead to an improved design. This study evaluates the time needed to pass surgical staplers around dissected structures during complex thoracoscopic pulmonary resections using the traditional and curved tip designed linear staplers.

METHODS

- Two independent concepts for anvil extensions (the attachable Anvil Leader Extension and the Integrated Curved Extension for the stapler anvil), were combined to modify the design of the traditional linear stapler in order to mimic the design of preferred dissecting instruments and improve efficiency.

- A retrospective, systematic review of 45 de-identified, unedited video of medium to high-complexity thoracoscopic lung resection cases was conducted for the period of 2004 through 2011.

- The amount of time taken to dissect specific anatomical structures (artery, vein, fissure, and bronchus) during procedures with both traditional and curved-tip designs was measured in seconds and defined as the point from which the device is introduced with intention to divide, through successful division and removal of device.

- Intervention times for dissections, adjuvant maneuvers, and failed attempts to pass the device were included as well. In addition to basic procedural information, adjunctive measures like the use of latex catheter leaders and silicone "vessel loop" slings for each pass were documented as also.

RIGHT SIDE RESECTIONS	LEFT SIDE RESECTIONS
Lobectomies	Lobectomies
Upper (13)	Upper (10)
Middle (2)	Middle (0)
Lower (4)	Lower (6)
Bilobectomy (1)	Bilobectomy (0)
Pneumonectomy (3)	Pneumonectomy (6)

Table 1. Medium - High Complexity Cases

RESULTS

- From the 45 archived videos, 220 structure division times were measured and included all major anatomic resections (36 lobectomy and 9 pneumonectomy). No complications with passing the stapler were noted.
- Overall the curved tip anvil was associated with better time savings (median 61s vs. 115s, p =0.003)
- In two (2) instances stapling was abandoned to use an energy sealing device on a small vessel
- Curved tip use reduced the > 120s group from 51% to 24% (p=0.001); and > 300s group from 20% to 6% (p = 0.02).
- Most time passed after dissecting adhesions, using different passage ports, or placing adjuvant devices like silicone slings.

STRUCTURE	N	Times (s)	Median (s)	Range	% > 120s (2 min)	% > 300s (5 min)	Sling Use	Leader Catheter Use
Arterial branch	54	226 ± 361	104	22-2,304	43%	22%	17%	17%
Curved	19	148 ± 221	68	20-986	32%	11%	37%	5%
Main PA*	3	2,308 ± 1,327	2151[b]	1,066-3,707	100%	100%	0%	100%
Curved	4	136 ± 83	117[b]	61-249	50%	0%	0%	100%
Vein	32	193 ± 250	78	23-1,323	53%	16%	48%	3%
Curved	20	73 ± 84	38	24-325	15%	5%	15%	0%
Fissure	45	168 ± 153	117	10-611	49%	13%	42%	47%
Curved	8	76.1 ± 54.6	70	17-193	13%	0%	50%	38%
Curved not used								
Bronchus	33	263 ± 251	167	44-1,025	61%	0%	0%	0%
Other	2	78 ±78	78	23-133	50%	0%	0%	50%

Table 2. Characteristics of Stapler Structure Division

*PA = pulmonary artery

[a] Systemic sequestration artery and accessory bronchus. For the individual subset comparisons, p > 0.1 was observed, except as noted: b p = 0.03 Kruskall-Wallis; c p = 0.01 x2; d p = 0.02 t test; e p = 0.01 Kruskall-Wallis; f p = 0.004 t test; g p = 0.07 Kruskall-Wallis; h p = 0.05 x2.

- Median times for stapler passage included 121 no adjunct (63 s); 56 sling (112 s) and 43 red rubber passes (243 s) p <0.001.
- Regression analysis showed no trend in improvement passage time by year (p = 0.5)
- In 798 cases in general clinical use 606 vascular (tan) and 192 general (purple) curved tip reloads were used by six thoracic faculty members at one institution, with only one complication of low-volume bleeding requiring conversion. The cause was unclear but possibly due to injured vessel from previous firing.

****THIS CONCLUDES THE CLINICAL SYNOPSIS OF THIS PUBLICATION****

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