

## A novel instrumented retractor to monitor tissue-disruptive forces during lateral thoracotomy

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Gil Bolotin and Gregory Buckner report pending patents on the instrument described in this study.

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**Objective:** Acute and chronic pain after thoracotomy, post-thoracotomy pain syndrome, is well documented. The mechanical retractors used for the thoracotomy exert significant forces on the skeletal cage. Our hypothesis was that instrumented retractors could be developed to enable real-time monitoring and control of retraction forces. This would provide equivalent exposure with significantly reduced forces and tissue damage and thus less post-thoracotomy pain.

**Methods:** A novel instrumented retractor was designed and fabricated to enable real-time force monitoring during surgical retraction. Eight mature sheep underwent bilateral thoracotomy. One lateral thoracotomy was retracted at a standard clinical pace of  $5.93 \pm 0.80$  minutes to 7.5 cm without real-time monitoring of retraction forces. The other lateral thoracotomy was retracted to the same exposure with real-time visual force feedback and a consequently more deliberate pace of  $9.87 \pm 1.89$  minutes ( $P = .006$ ). Retraction forces, blood pressure, and heart rate were monitored throughout the procedure.

**Results:** Full lateral retraction resulted in an average force of  $102.88 \pm 50.36$  N at the standard clinical pace, versus  $77.88 \pm 38.85$  N with force feedback (a 24.3% reduction,  $P = .006$ ). Standard retraction produced peak forces of  $450.01 \pm 129.58$  N, whereas force feedback yielded peak forces of  $323.99 \pm 127.79$  N (a 28.0% reduction,  $P = .009$ ). Systolic blood pressure was significantly higher during standard clinical retraction ( $P = .0097$ ), and rib fracture occurrences were reduced from 5 to 1 with force feedback ( $P = .04$ ).

**Conclusions:** Use of the novel instrumented retractor resulted in significantly lower average and peak retraction forces during lateral thoracotomy. Moreover, these reduced retraction forces were correlated with reductions in animal stress and tissue damage, as documented by lower systolic blood pressures and fewer rib fractures.

Most surgical procedures involve retraction of the patient's tissue to achieve sufficient exposure to perform the operation. The mechanical retractors used to facilitate the retraction exert significant forces on these tissues. These forces, in direct correlation to their magnitude, cause reversible and sometimes irreversible damage to the patient's tissues. This damage is one of the reasons for postoperative acute and chronic pain.<sup>1-3</sup> Currently, the literature contains no data regarding retraction force amplitudes and no attempt to monitor these forces in real time. Our goal was therefore to design, fabricate, and use an instrumented retractor to provide the surgeon with real-time data regarding surgical retraction forces.

We hypothesized that real-time monitoring and control could reduce retraction forces while providing equivalent exposure and minimizing tissue damage. We opted to test this novel technology and surgical concept on an animal model of lateral thoracotomy.

## Materials and Methods

### Animal Model

Eight mature sheep (17-18 months old) weighing 37 to 47 kg underwent bilateral thoracotomy procedures with a novel instrumented retractor. Animals were divided into two groups, with each animal serving as its own control. In group 1, the sheep underwent lateral thoracotomy on one side at a standard clinical pace without force feedback, followed by lateral thoracotomy with force feedback (at a more deliberate pace) on the other side. In group 2, force-controlled retraction on one side was followed by clinically paced retraction on the other side. Both sides were retracted to the same exposure of 7.5 cm. All animals received humane care in compliance with the "Guide for the Care and Use of Laboratory Animals" (<http://www.nap.edu/catalog/5140.html>).

### Anesthesia

Animals were paralyzed with an initial loading dose of atrocurium (0.2 mg/kg) before the start of the procedure. A 16-gauge, 3.5-inch indwelling catheter was placed in the jugular vein. All sheep were anesthetized with 5 mg intravenous midazolam plus ketamine (4-6 mg/kg), intubated, and maintained with 1.5% to 2.5% isoflurane delivered with a positive-pressure ventilator and 100% oxygen. Paralysis was maintained with a constant rate of infusion of atrocurium at 5.8  $\mu\text{g}/(\text{kg} \cdot \text{min})$ . Lactated Ringer's solution was given by jugular catheter at 10 to 15 mL/(kg  $\cdot$  h) throughout the surgery. Blood pressure (noninvasive), electrocardiography, end-tidal carbon dioxide, oxygen saturation, and temperature were monitored throughout the experiment. Body temperature was kept constant with a water-circulating heating pad. Animals were killed after a resting period of 15 minutes after removal of the retractor.

### Instrumented Retractor System

A novel instrumented retractor (Figure 1) was developed to enable real-time force monitoring during surgical retraction. This device features six stainless steel blades to facilitate lateral thoracotomy and median sternotomy procedures on cadavers and sheep. Strain gauges mounted on each arm are calibrated to measure applied forces during retraction.

Each pivoting retractor blade has a curved profile and narrow lip for optimal deployment and stress distribution. Fine-pitch rack and pinion gears enable precise actuation. Reversible pawl mechanisms ensure that each retractor blade can be locked to withstand forces up to 500 N. Strain gauges mounted on each blade are strategically positioned and sealed to maximize force resolution. Signal wires are routed through a sealed slot in the rack to eliminate surgical obstructions.

Watertight locking cable receptacles are used for electrical connection to the signal processing hardware. A customized signal conditioning circuit was designed to amplify and balance the measurements, and a LabVIEW "virtual instrument" (National Instruments Corporation, Austin, Tex) was created to display and record these forces for the duration of each surgical procedure. This program samples data at 10.0 Hz and displays forces on a multicolor strip chart. This chart is color coded to the retractor blades, enabling the surgeon to readily monitor and control retraction forces.

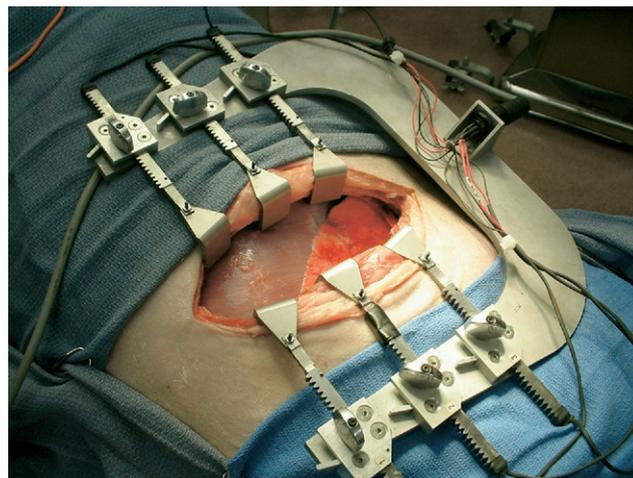


Figure 1. Instrumented retractor prototype.

### Operative Technique

One surgeon (G.B.) performed all 16 procedures with the instrumented retractor and standard surgical instrumentation. Animals were positioned on the side and underwent standard lateral thoracotomy (Figure 1). Two lateral thoracotomies were performed on each animal, one with standard retraction and one with force-controlled retraction. To avoid side or order bias, half of the animals began with left thoracotomy and half of the animals (group 1) underwent standard clinical procedures first (without monitoring of retraction forces). The order in which the procedures were performed is given in Table 1.

The initial skin incision was placed from the tip of the scapula along the ribs toward the sternum, with a length of 20 to 22 cm. The sixth intercostal space was entered, and the instrumented retractor was then inserted. For standard retraction, the retractor was opened to achieve a 5-cm intercostal opening within the first minute, followed by a 2-minute rest period, followed by another 3 minutes of retraction to 7.5 cm, resulting in approximately 6 minutes for each procedure (a standard clinical pace). The forces exerted by the retractor were recorded; however, the surgeon did not receive force feedback from the computer monitor. For force-controlled retraction, the measured forces were displayed on the computer monitor in real time, and the surgeon opened the retractor under force control to achieve equivalent exposure with less force and in reasonable clinical time. As in the clinical pace group, after 5 cm was reached, 2 minutes of force relaxation were followed by continuing retraction to 7.5 cm. To conclude this portion of the experiment, all animals underwent further soft tissue dissection under the skin to document the reduction in forces in all 16 thoracotomy procedures as a result of soft tissue release.

### Statistical Analysis

The maximum forces, average forces, and average time to complete retraction were summarized as mean  $\pm$  SD. Comparisons of these measurements between the two procedure types were made with the 1-sided Wilcoxon signed rank test, the nonparametric equivalent of the paired *t* test. Rib fracture rates were compared between the two procedure types with the McNemar test. Changes

**TABLE 1. Retraction forces during lateral thoracotomy**

Sheep	Standard retraction			Force-controlled retraction		
	Procedure	Peak force (N)	Average force (N)	Procedure	Peak force (N)	Average force (N)
1	Left, initial	726.95	210.52	Right, secondary	549.72	165.20
2	Right, secondary	465.70	136.92	Left, initial	474.66	103.72
3	Right, initial	427.16	105.33	Left, secondary	333.78	52.15
4	Left, secondary	342.71	61.28	Right, initial	222.09	55.86
5	Right, initial	291.22	64.26	Left, secondary	210.07	62.31
6	Left, secondary	490.12	69.75	Right, initial	208.40	55.79
7	Left, initial	447.69	97.62	Right, secondary	262.40	66.50
8	Right, secondary	408.50	77.33	Left, initial	330.78	61.50
Average		450.01	102.88		323.99	77.88
SD		129.58	50.36		127.79	38.85

SD, standard deviation.

in heart rate and in systolic, diastolic, and mean blood pressures were examined with repeated measures analysis of variance models and were restricted to measurements obtained during the first 10 minutes. Fixed effects included in the initial model were the relevant baseline measurement (obtained before the beginning of the procedure), linear and quadratic time effects ( $t$  and  $t^2$ ), procedure type, and the procedure by time interactions terms (procedure  $\times t$  and procedure  $\times t^2$ ). The animal random effect was included in the model to account for the within-animal correlation between the two thoracotomies performed on each animal. Correlations between multiple measurements across time for each procedure were modeled with the spatial power correlation structure, which allows the time points to be unequally spaced. The models were fitted with PROC MIXED in the SAS/STAT software (SAS Institute, Inc, Cary, NC), and the final models were chosen with backward selection.

## Results

### Operative Force Data

All 16 lateral thoracotomy procedures were completed successfully, which in this study was defined as achievement of full retraction (7.5 cm). Force-controlled retraction required more time ( $9.87 \pm 1.89$  minutes) than did standard retraction ( $5.93 \pm 0.80$  minutes,  $P = .006$ ). The average force applied during force-controlled retraction ( $77.88 \pm 38.85$  N) was significantly less (a 24.3% reduction) than the force exerted during standard retraction ( $102.88 \pm 50.36$  N,  $P = .006$ ). The maximum force displayed during force-controlled retraction ( $323.99 \pm 127.79$  N) was also significantly lower than the peak force exhibited during standard retraction (a 28% reduction,  $450.01 \pm 129.58$  N,  $P = .009$ ). The order in which the thoracotomies were performed is given in Table 1, along with peak and average force data. One animal's average force profiles with the two methods are presented in Figure 2.

A reduction in average forces in both groups during the first four procedures was observed, probably representing the surgeon's learning curve from the real-time data (Figure 3); however, standard retraction consistently yielded higher average and peak forces with larger vari-

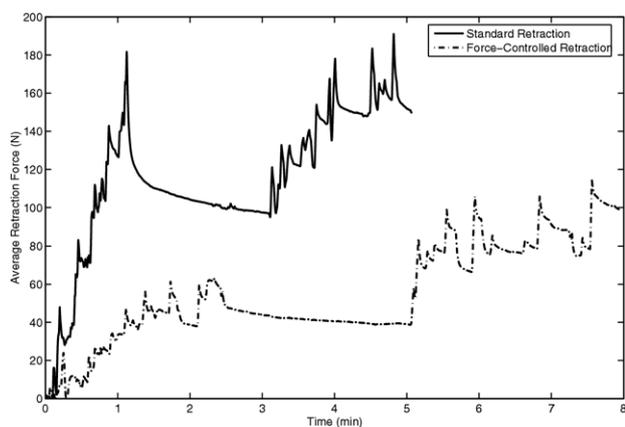
ances than did force-controlled retraction. At the end of the experiment, a further significant reduction in forces was documented as a result of soft tissue dissection. On average, forces were reduced by  $38.13\% \pm 15.6\%$  and  $48.76\% \pm 11.6\%$  for the clinical pace and force-controlled retractions, respectively, but the differences between the two groups were not statistically significant ( $P = .20$ , Wilcoxon signed rank test).

### Operative Biologic Data

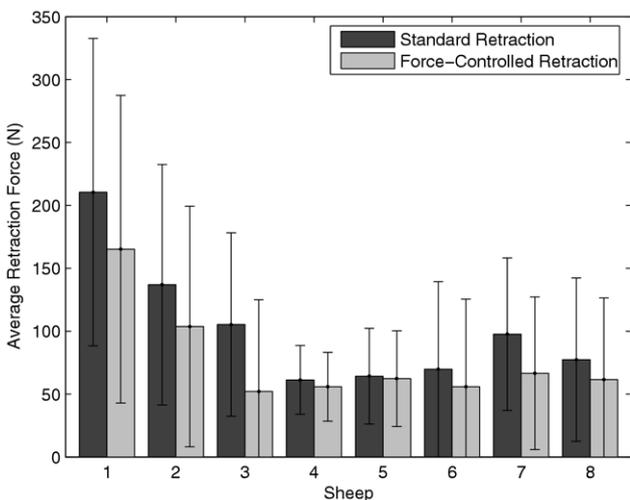
Rib fracture occurrences were reduced from 5 in the clinical group to 1 in the force-feedback lateral thoracotomy group. These differences were found to be significant even though the sample size was small ( $P = .04$ , McNemar test).

Comparison of heart rate changes during the retraction period revealed no significant differences between the two groups. Standard retraction, however, induced significant increases in systolic, diastolic, and mean blood pressures (Figure 4). Systolic blood pressures in the clinical retraction group were  $120 \pm 11.8$  mm Hg at 5 minutes and  $120 \pm 8.0$  mm Hg at 10 minutes, versus  $110 \pm 8.9$  mm Hg and  $112 \pm 14$  mm Hg, respectively, in the force-controlled retraction group. The increase in systolic blood pressure with time was also nonlinear but significantly different between the two procedures ( $P = .035$ , procedure  $\times t^2$  interaction). The generalized F test of the three hypotheses of no differences (in procedure, procedure  $\times t$ , and procedure  $\times t^2$ ) showed that the patterns of systolic blood pressure change with time were significantly different between clinical pace and force-controlled retraction groups ( $P = .0097$ ). The systolic blood pressure measurements, along with the model-based fitted values, are presented in Figure 4.

Both diastolic and mean blood pressures increased during the first 10 minutes, and the differences between the procedures were highly significant according to the generalized F test of procedure and procedure  $\times t$  ( $P = .0007$  and  $P < .0001$  for diastolic and mean blood pressures, respectively). The rates at which the diastolic and mean blood



**Figure 2. Average retraction forces during lateral thoracotomy: standard versus force-controlled retraction.**



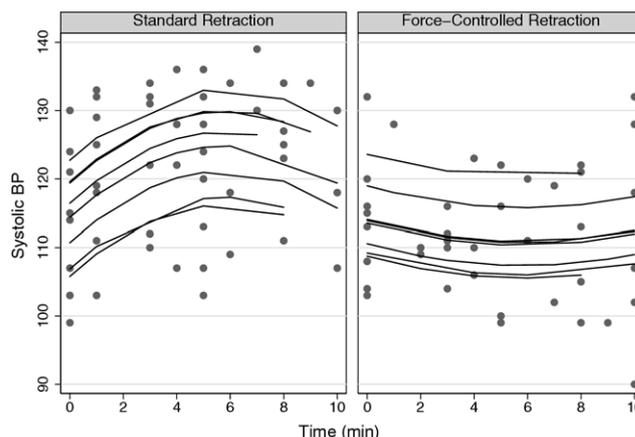
**Figure 3. Average force comparison and surgeon's learning curve.**

pressures increased were higher during standard retraction, but the procedures were not significantly different at the 5%  $\alpha$  level ( $P = .056$  and  $P = .095$  for diastolic and mean blood pressures, respectively).

**Discussion**

Our report represents the first known attempt to use an instrumented retractor to monitor forces during cardiothoracic surgery. The instrumented retractor delivers knowledge of retraction forces to surgeons in real time, allowing the chest cavity to be carefully opened with the least amount of tissue damage.

Force-controlled retraction with the novel instrumented retractor effected reductions in the average and peak forces exerted on the skeletal cavity, along with reductions in



**Figure 4. Systolic blood pressure (BP) measurements (black dots) with time, with predicted values (solid lines) based on repeated measurements analysis of variance model. Fixed effects included in the final model were baseline systolic blood pressure, procedure, linear and quadratic time effects, and linear and quadratic time interaction terms.**

systolic blood pressures and rib fractures. Lateral thoracotomy (including posterolateral and anterolateral) is the most common approach to the chest cavity for noncardiac surgical procedures. The lateral thoracotomy consists of incising one side of the chest and spreading the ribs with a mechanical retractor to expose the thoracic cavity. Persistent pain after thoracotomy, postthoracotomy pain, is a well-documented syndrome.<sup>2,3</sup> There are significant incidences of acute immediate and chronic long-term pain after thoracotomy.<sup>4</sup> Between 39% and 50% of patients reported persistent pain at 1 to 2 postoperative years, with a higher prevalence among women.<sup>2,3,5</sup> Unfortunately, though common, post-thoracotomy pain is rarely mentioned in the medical literature and is dismissed by many thoracic surgeons as a banal, transient postoperative sequela.<sup>6</sup> Although the precise mechanisms responsible for post-thoracotomy pain are not known, the most likely causes are healing rib fractures and damage to the intercostal nerves with or without rib fracture.<sup>3,7</sup> The personal experiences of many thoracic surgeons suggest that a gradual opening of the chest retractor reduces the incidence of rib fractures and possibly reduces postoperative pain. The higher prevalence of chronic post-thoracotomy pain among female patients suggests that the relatively wide retraction relative to smaller patient size may contribute to the syndrome.<sup>2</sup>

The amount of tissue damage and postoperative pain should be influenced by the subject's tissue factors and the force amplitudes exerted on the tissues by the mechanical retractor. We therefore found it extremely peculiar that there are no data in the surgical literature regarding measurement and documentation of the forces applied by mechanical

retractors for thoracotomy or any other tissue retraction. In this study, we have demonstrated for the first time that it is possible to measure the forces applied by the retractor and to present them in real time on a computer monitor. Moreover, we have demonstrated that by monitoring these forces the surgeon is able to reduce the peak and average forces significantly.

Occult rib fracture has been identified as one of the causes of pain after cardiac surgery.<sup>8</sup> Rib fractures are most probably in correlation with peak retraction forces during the opening of the retractor, combined with the physical qualities of the patient's tissue. The average retraction forces exerted with time may be responsible for intercostal nerve damage and other local ischemic damages. We demonstrated significant reductions in force for both standard and force-controlled retraction. This may represent a learning curve of the surgeon equipped with the real-time information regarding retraction forces and rates, which in turn may represent another important advantage of using the system in a clinical setting to train surgeons to reduce tissue retraction forces and thus tissue damage during any kind of surgical retraction.

In our animal model, force-controlled retraction required a mean of 4 minutes longer to achieve the same exposure goal. An actual surgical procedure, such as lobectomy or pneumonectomy, may take 30 to 90 minutes, so this extra 4 minutes is not clinically significant. The major reduction in forces produced at the end of the experiment by adding tissue dissection may add another clinical advantage. With existing mechanical retractors, surgeons have minimal information about the actual forces exerted by the retractor blades during surgical procedures. High forces monitored by the new system may alert the surgeon to perform directed dissection and thus significantly reduce the forces for the remainder of the procedure.

In this study, two biologic variables were found to be reduced with force-controlled retraction. The first was a reduction in rib fractures, from 5 of 8 in the standard thoracotomy group to 1 of 8 in the force-controlled thoracotomy group ( $P = .04$ ). Rib fracture is a well-known cause of acute and chronic pain after trauma and after chest operations,<sup>8,9</sup> and thus this trend represents a major potential advantage of force-controlled retraction, supplying the surgeon with a real-time tool to reduce the unwanted rib fractures during the retraction. The other biologic difference was a reduction in blood pressure (systolic, diastolic, and mean) during the first 10 minutes of the retraction and postretraction phase. Taken together, the hemodynamic analyses suggest that there are significantly different effects on blood pressure from the two retraction methods. Overall, the blood pressure measurements—systolic, diastolic, and mean—were higher during standard retraction, whereas pulse increased with time regardless of procedure type.

Additionally, the patterns of systolic blood pressure increase were different between the two retraction techniques.

The animals were well anesthetized with intravenous midazolam (5 mg) plus ketamine (4-6 mg/kg) induction and maintained with 1.5 to 2.5% isoflurane. Patient awareness and pain during procedures under general anesthesia are well-documented phenomena, and systolic blood pressure has been reported as one of the indicators.<sup>10</sup> Moreover, systolic blood pressure has been documented to be one of the sympathetic signs of pain and therefore higher during acute and chronic pain in human beings.<sup>11,12</sup>

The clinical application of force-controlled retraction should be easy from a technologic point of view; however, it may be more challenging to persuade the surgeon to accept the new concept and its possible advantages. Obviously, a randomized clinical trial is needed to confirm our preclinical findings. Our prototype was developed to test the force-controlled concept in an animal model. For clinical trials, a commercially available retractor with upgraded force-measurement capabilities should be used. This new technology and concept can be applied to other surgical fields that involve retraction for exposure during procedures. Even minimally invasive procedures may be performed more safely and with less postoperative pain, because in some cases small incisions may involve high retraction forces and significant postoperative pain.<sup>13</sup>

In conclusion, our attempt to design, fabricate, and use an instrumented retractor to monitor forces during cardiothoracic surgery was successful. The use of force-controlled retraction results in significantly reduced retraction forces and in indications of reduced tissue damage and animal stress. This novel technology and concept should be evaluated clinically and could become a standard of care for many surgical procedures.

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