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Tissue-Disruptive Forces during Median Sternotomy

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ABSTRACT

Background. Acute and chronic pain after median sternotomy is common and often underestimated. The mechanical retractors used for median sternotomy exert significant forces on the skeletal cage. We hypothesized that instrumented retractors could be developed to enable real-time monitoring and control of retraction forces, functions that may provide equivalent exposure with significantly reduced forces and tissue damage, and thus, less postoperative pain.

Methods. We developed a novel instrumented retractor designed to enable real-time force monitoring during surgical retraction and then tested it by performing median sternotomies on 16 mature sheep. For 8 of these median sternotomies, retraction was performed to 7.5 cm at a standard "clinical pace" of 7.25 ± 0.97 minutes without real-time monitoring of retraction forces. For the other 8 median sternotomies, we performed retraction to the same exposure using real-time visual force feedback and, consequently, a more deliberate pace of 12.05 ± 1.73 minutes ($P < .001$). Retraction forces, blood pressure, and heart rate were monitored throughout the procedure.

Results. Full retraction resulted in an average force of 102.99 ± 40.68 N at the standard clinical pace, compared to 64.68 ± 17.60 N with force feedback (a 37.2% reduction, $P = .021$). Standard retraction produced peak forces of 368.79 ± 133.61 N, whereas force feedback yielded peak forces of 254.84 ± 75.77 N (a 30.9% reduction, $P = .1152$). Heart rate was significantly higher during standard clinical retraction ($P = .025$).

Conclusions. Use of the novel instrumented retractor resulted in lower average and peak retraction forces during median sternotomy. Moreover, these reduced retraction forces correlated to a reduction in animal stress, as documented by heart rate.

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INTRODUCTION

Most surgical procedures involve retraction of patient 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 cause reversible and sometimes irreversible damage to the patient tissue. This damage probably contributes to postoperative acute and chronic pain after various surgical interventions [Eisenberg 2001; Gotoda 2001; Hazelrigg 2002]. Currently the literature contains no data regarding retraction-force amplitudes during median sternotomy and no reports of attempts to monitor these forces in real time.

In a previous study we performed surgical evaluation of an instrumented retractor for lateral thoracotomy using an animal model [Bolotin 2007]. The use of that retractor enabled us to reduce the retraction forces, tissue damage, and animal stress during lateral thoracotomy [Bolotin 2007]. We hypothesize that the use of real-time monitoring and control could similarly reduce retraction forces and minimize tissue damage while providing equivalent exposure in median sternotomy.

MATERIALS AND METHODS

Animal Model

We used a novel instrumented retractor to perform median sternotomies on 16 mature sheep (age 17-18 months, weight 37-47 kg). Animals were divided into 2 groups. The sheep in group 1 (the control group, n = 8) underwent median sternotomy at a standard "clinical pace" without real-time force feedback. The sheep in group 2 (n = 8) underwent median sternotomy using force-controlled retraction. In both groups the median sternotomies 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* [NAS 1985].

Anesthesia

Before surgery animals were paralyzed with an initial loading dose of atrocurium (0.2 mg/kg). A 16-gauge 3.5-inch indwelling catheter was placed in the jugular vein. All sheep were anesthetized with intravenous midazolam (5 mg) plus ketamine 4 (6 mg/kg), intubated, and maintained with

1.5% to 2.5% isoflurane delivered by a positive-pressure ventilator and 100% O_2. Paralysis was maintained with a constant rate of infusion of atrocurium (5.8 µg/kg per minute). Throughout the surgery lactated ringers was given via jugular catheter at 10 mL/kg to 15 mL/kg per hour. Noninvasive blood pressure, electrocardiogram, end-tidal CO_2, oxygen saturation, and temperature were monitored throughout the experiment. Body temperature was kept constant by use of a water-circulating heating pad. Animals were killed at the end of the experiments.

Instrumented Retractor System

A novel instrumented retractor (Figure 1) was developed to enable real-time force monitoring during surgical retraction. This device features 6 stainless-steel blades to facilitate lateral-thoracotomy and median-sternotomy procedures performed on human cadavers and sheep. Strain gauges mounted on each arm are calibrated to measure applied forces during retraction.

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, Austin, TX, USA) 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 multicolored strip chart. This chart is color-coded to the retractor blades, enabling the surgeon to readily monitor and control retraction forces.

Surgical Technique

One surgeon performed all 16 procedures using the instrumented retractor and standard surgical instrumentation.

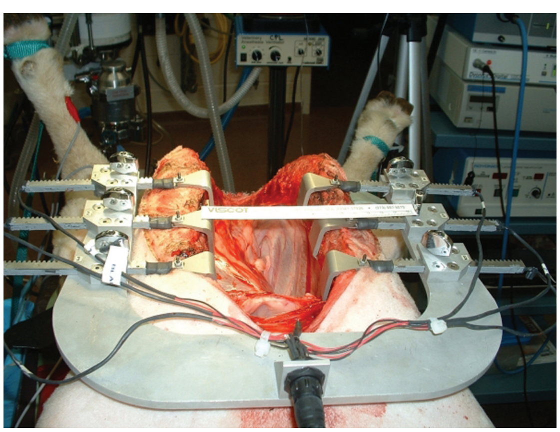

Figure 1. A novel instrumented retractor to enable real-time force monitoring during surgical retraction was used in the performance of standard median sternotomies in sheep placed in a supine position.

Animals were in a supine position and underwent standard median sternotomy (Figure 1).

The initial skin incision was placed from the suprasternal notch to the xiphoid process. The sternum was divided using an oscillating sternal saw (Stryker 810, Kalamazoo, MI, USA), and the instrumented retractor was then inserted. For the standard retraction procedures (group 1), the retractor was opened gradually to achieve a 5.0 cm opening within the first minute, followed by a 2-minute rest period, followed by another 4 minutes of retraction to 7.5 cm, resulting in approximately 7 minutes for each retraction. Although the forces induced by the retractor were acquired, the surgeon did not receive force-feedback information during these procedures. For the force-controlled procedures, the acquired 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 the retraction reached 5 cm, the force was relaxed for 2 minutes and then retraction was continued up to 7.5 cm. To conclude this portion of the experiment, we performed further soft-tissue dissection under the skin (both in the upper and lower margins of the incision) on all animals and documented the force reduction in all 16 median-sternotomy procedures.

Statistical Analysis

The 2 procedures were compared using a 1-sided Wilcoxon signed-rank test, the nonparametric equivalent of the unpaired *t*-test. The changes in pulse and in systolic, diastolic, and mean blood pressure were examined using repeated-measures ANOVA models, and were restricted to the measurements obtained during the first 10 minutes. Fixed effects included in the initial model were the relevant baseline measurement (obtained prior to the beginning of the procedure), linear and quadratic time effects (t and $t2$), procedure type, and the procedure by time interactions terms (procedure × t and procedure × $t2$). Correlation between multiple measurements across time for each procedure was modeled with the spatial power correlation structure, which allows the time points to be unequally spaced. The models were fitted using the "PROC MIXED" function in the SAS/STAT® software (SAS Institute Inc., Cary, NC, USA), and the final models were chosen using backward selection. The data are presented as mean ± SD, with a $P < .05$ considered significant.

RESULTS

Operative Force Data

Successful median sternotomy completion, defined as full retraction (7.5 cm), was achieved for all 16 procedures. Weight and sex did not differ between the 2 retraction-technique groups. Force-controlled retraction required more time (12.05 ± 1.73 minutes) than standard retraction (7.25 ± 0.97 minutes, $P < .001$). The average force applied during force-controlled retraction (64.68 ± 17.60 N) was significantly less (37.2% reduction) than the force exerted during standard retraction (102.99 ± 40.68 N, $P = .021$).

Retraction Forces during Median Sternotomy*

Standard Retraction					Force-Controlled Retraction				
Sheep No.	Mean Force, N	Peak Force, N	Weight, kg	Sex	Sheep No.	Mean Force, N	Peak Force, N	Weight, kg	Sex
1	149.47	597.23	49	M	2	94.26	306	44	M
3	81.26	237.65	34	M	4	70.96	251.95	47	M
5	79.86	336.83	42	M	6	52.45	172.87	42	M
7	71.29	298.15	37	M	8	72.03	210.53	45	M
9	116.23	466.58	73	F	10	47.79	239.56	58	F
11	171.94	467.1	72	F	12	62.11	352.47	57	F
13	53.24	195.47	52	F	14	77.5	350.38	65	F
15	100.64	351.27	70	F	16	40.32	154.91	68	F
Average	102.99	368.79	53.63		Average	64.68	254.84	53.25	
SD	40.68	133.61	16.04		SD	17.60	75.77	10.08	

*P values for force-controlled compared to standard retraction: mean force, .021; peak force, .1152; weight, not significant.

A 30.9% reduction of the maximum force during force-controlled retraction (254.84 ± 75.77 N) was documented, compared to the peak force exhibited during standard retraction (368.79 ± 133.61 N). However, this reduction did not reach statistical significance ($P = .1152$). The peak and average force data are presented in Table. Figure 2 shows a graphical comparison of retraction forces for a force-controlled sternotomy and a standard sternotomy on 2 animals with similar weights. No correlation between sheep weight and average or peak retraction force was documented.

At the end of the experiment, a further significant reduction in forces was documented as a result of soft-tissue dissection (Figure 3). On average, forces were reduced from 123.38 ± 56 to 72.38 ± 27 N (41.3% reduction, $P < .001$) and from 100.63 ± 51.53 to 52.25 ± 34.49 N (48.0% reduction, $P < .001$) for the clinical-pace and force-controlled retractions, respectively. The differences between the 2 groups were statistically significant ($P = .046$).

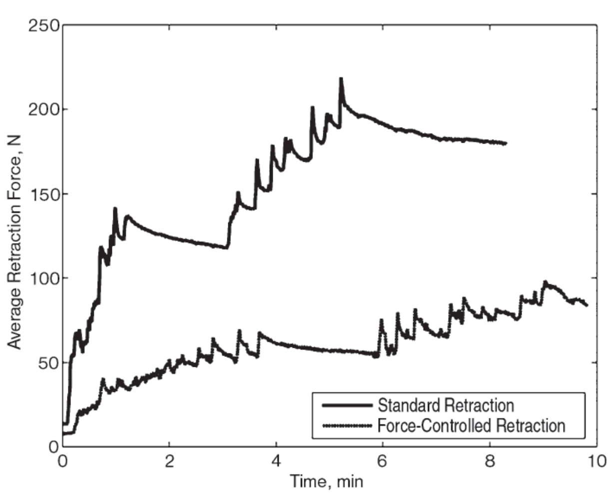

Figure 2. Comparison of retraction forces for a force-controlled sternotomy and a standard sternotomy, performed on 2 animals with similar weights.

Operative Biological Data

Comparison of systolic, diastolic, and mean blood pressures between the 2 groups of animals revealed no significant differences. Weight and sex did not have a significant effect on any of these measures. Comparison of systolic, diastolic, and mean blood pressure changes over time between the 2 treatments groups did not reveal any significant differences, but repeated-measures ANOVA models showed significantly different patterns of pulse change over time during the 2 procedures ($P = .0254$). After an initial drop, the pulse rate increased in animals undergoing standard retraction, whereas it did not change in the force-controlled group (Figure 4). As the figure further suggests, the pulse rate leveled off in both groups 4 to 5 minutes after the beginning of the procedure, and remained the same for the remainder of the procedure.

DISCUSSION

Our results demonstrate that when force-controlled retraction was used, average tissue-disruptive forces during median sternotomy were significantly less than for median sternotomy without force-controlled retraction. The same level of exposure was achieved with both surgical groups, although the chest-opening procedure was 5 minutes longer with force-controlled retraction. The differences in heart-rate patterns between the 2 groups during the retraction phase indicate that animal pain and stress were decreased when force-controlled retraction was used during the procedure. The primary benefit of force-controlled retraction is the reduction of tissue damage, which could result in reduced postoperative acute and chronic pain.

In principle, force-controlled retraction could be applied to any surgical procedure involving retraction. In addition to this study involving median sternotomies, we previously tested our hypothesis on animals undergoing lateral thoracotomy [Bolotin 2007]. Before discussing current results, however, we address the question of whether pain after median sternotomy is a significant clinical problem. Although the prevalence of chronic postoperative pain is poorly documented, a recent study reported post–cardiac-surgery pain (PCP) in 56% of

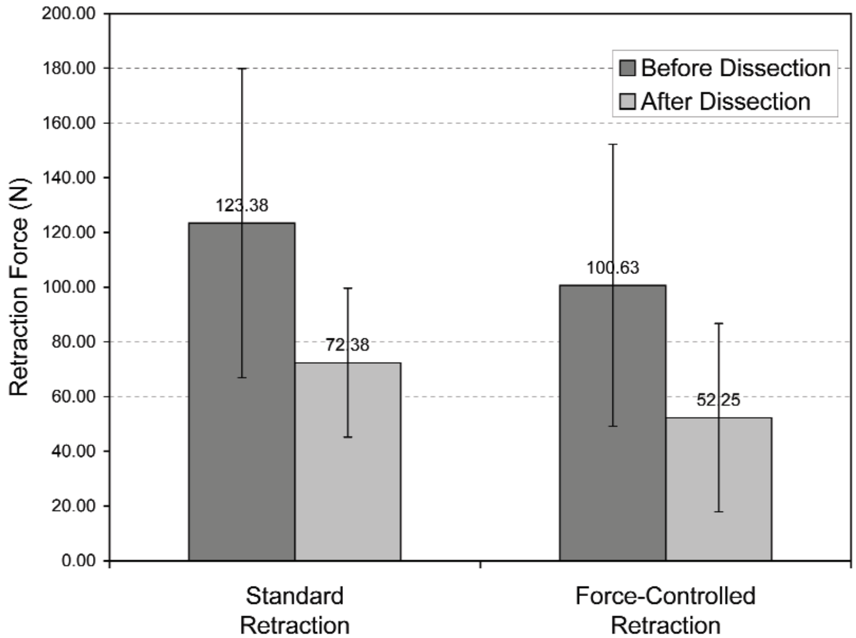

Figure 3. Reduction in retraction forces as a result of soft-tissue dissection. Soft-tissue dissection at the end of the procedure resulted in 32% to 39% reduction in forces. RT indicates real time.

patients [Eisenberg 2001]. Pain was "moderate to severe" in 65% of patients, and 72% of the patients reported that the pain interfered with their daily activities [Eisenberg 2001]. Other studies reported PCP in 80% of patients at 3 months postoperatively and in 28% to 61% at 1 to 3 years postoperatively [Perttunen 1999; Meyerson 2001]. The variations in results from different studies may be related to variations in surgical technique, definitions of pain, and degree of analgesia use [Rogers 2000]. Nevertheless, in contrast to common belief, the prevalence and severity of PCP is clearly significant [Eisenberg 2001; Kalso 2001; Bruce 2003].

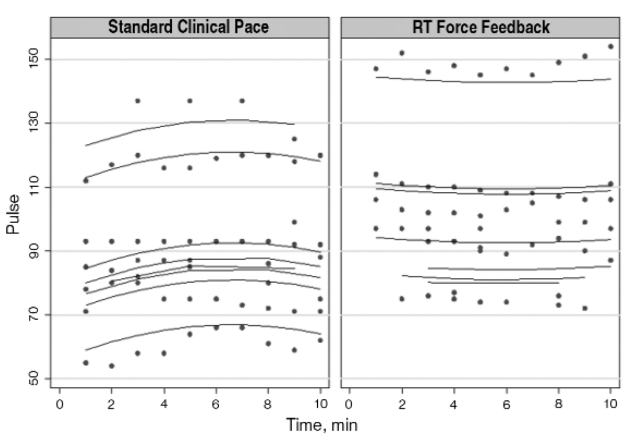

Figure 4. ANOVA models showing significantly different patterns of pulse change over time during the 2 procedures (P = .0254). After an initial drop, the pulse rate increased in animals undergoing standard retraction, whereas it did not change in the force-controlled group.

Several mechanisms have been reported to be responsible for pain after median sternotomy procedures. The most frequently cited are rib fractures (usually occult), brachial plexus injuries, and sternal fractures [Baisden 1984; Moore 1994; Meyerson 2001]. Rib fracture after median sternotomy was already reported in 1975 [Curtis], while a more recent study using bone scans in 24 patients detected 44 occult rib fractures (first rib through the sixth rib) that were not detected during routine chest x-rays [Baisden 1984]. Other groups that used routine postoperative chest x-rays reported rib fractures in 13% of patients, and most of the fractures were in the left side of the first rib [Gumbs 1991]. There was no statistical correlation to total operating time, bypass time, or global ischemic time, but a higher prevalence was found in heavier patients or those with a large body surface [Gumbs 1991]. These findings suggest that the amount of retraction force applied, combined with mechanical characteristics of the thorax, are risk factors for PCP. Brachial plexus neuropathies were detected by electromyography and nerve-conduction tests in 37.7% of patients after coronary artery bypass grafting [Seyfer 1985]. Other studies found that patients with an injured brachial plexus were older and had undergone surgeries of longer duration [Canbaz 2005] and that the nerve plexus was most at risk for pathologic injury during retraction of the sternum for internal mammary artery harvest [Jellish 1994]. Sternal fracture was associated with the use of sternal-retraction devices for internal mammary artery harvesting in coronary bypass procedures [Moore 1994]. Although most sternal fractures were well tolerated, some patients suffered major respiratory compromise due to postoperative pain [Moore 1994]. Moreover, some studies demonstrated a relation between postoperative infection such as pneumonia and the treatment for postoperative pain [El Solh 2006].

Methods suggested to reduce rib fractures and brachial plexus injuries associated with coronary artery bypass graft surgery include the use of less traction on the manubrium, variations in patient positioning, and reduced retraction of the sternum [Baisden 1984; Seyfer 1985; Woodring 1985; Jellish 1997]. No data are available in the literature to quantify the forces exerted by retractor blades on the sternum and skeletal anatomy during retraction. Existing data, however, suggest a correlation between the magnitude of retraction force required to achieve adequate exposure during cardiac surgical procedures and the incidence of postoperative pain [Seyfer 1985; Gumbs 1991; Bruce 2003].

This study is the first to quantify the forces applied to the tissue during median sternotomy on an animal model. Because peak (368 N) and average retraction forces (102 N) measured in the animal model were high, future studies should compare these results to those of clinical median sternotomies to confirm their clinical relevance. The use of the force-controlled retractor resulted in reduced forces and more gradual rates of increase in force. Both effects should be important for clinical reduction of postoperative pain given all 3 possible mechanisms: occult rib fracture, brachial plexus injuries, and direct tissue trauma [Baisden 1984, Seyfer 1985, Gumbs 1991]. Moreover, future knowledge from clinical trials regarding the levels of force that cause tissue damage will allow us to prevent damage by further reducing the speed of chest opening or by doing more soft-tissue dissection when needed. In the current study, a soft-tissue dissection at the end of the procedure resulted in 41% to 48% reduction in forces (Figure 3). Future use of the retractor in the clinical setting will allow surgeons to know when additional dissection of this nature is needed. The benefit of this additional dissection in some instances is of more importance than slow retraction. Indeed, our results suggest that the non–evidence-based, well-known benefits of slower retraction rates have a scientific basis; but they also suggest that reduction in retraction forces and tissue damage cannot be achieved simply by retracting "slowly." Additional tissue dissections may be required in some cases, and the rate of retraction must be increased or decreased throughout the surgery based on real-time force feedback.

In our animal model, force-controlled retraction required a mean of 5 minutes longer to achieve the same exposure goal. Given that the actual surgical procedure, such as coronary artery bypass graft or valve surgery, may take 120 minutes to 440 minutes, the extra 5 minutes is not clinically significant.

In a previous study involving lateral thoracotomies, reductions in average force were also significant but smaller (24% compared to 37% in the current study), and reductions in peak force were similar (28% compared to 30% in the current study). In the current median-sternotomy study, the maximal force reduction of 30% did not reach statistical significance, probably because of the need to use a nonpaired *t*-test rather than a paired *t*-test, which was used in the previous study.

The limitations of the current study are attributable to the use of an animal model. The skeletal cage of a sheep differs from that of a human and thus significantly different forces may be required during median sternotomy. Moreover, we did not investigate the correlation between reduced forces and animal stress during the operation and reduction of postoperative acute and chronic pain in humans. Methodologically and ethically, a randomized clinical trial should provide that answer.

In conclusion, the use of the novel instrumented retractor during median sternotomy resulted in lower average retraction forces in an animal model. Moreover, these reduced retraction forces correlated to a reduction in animal stress, as documented by heart rate.

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