In-vitro Force Assessments of an Autoclavable Instrumented Sternal Retractor

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Abstract: It is well known that median sternotomy might lead to rib and/or sternum micro/macro-fractures and/or brachial plexus injuries, eventually resulting in chronic pain with significant impact on patient's quality life.Postoperative chronic pain is recognized as a multifactorial complex issue, it has been assessed that excessive sternum retraction forces can be considered one of these factors. On this basis, the Authors developed a reliable and sterilizable system potentially able to real-time monitor and control the retraction forces along the hemisternums. A Finochietto sternal retractor was instrumented by means of ultra-thin force sensors interfaced with *ad hoc* electronic circuitry. Two different sets of sensors were adopted, one of which able to support autoclave operating conditions. *In vitro* tests were performed by means of a made on purpose dummy. The instrumented retractor allows monitoring of the force exerted on both the arms during the opening procedure. Force *versus* time patterns were real-time acquired and stored, distribution of forces was determined along with the values of mean, maximum and plateau force. Results demonstrate the reliability of the instrumented retractor in measuring forces, up to 400N. Cost-effectiveness and feasibility can be considered further additional values of the proposed instrumented retractor.

1 INTRODUCTION

Persistent postoperative pain following sternotomy is the Achilles' heel of surgical procedures because it can lead to patients' discomfort, increased morbidity, prolonged hospital stay, and increasing costs **(**Wildgaard, 2001 and Hazelrigg, 2002**).** Chronic pain has been defined as pain in the location of surgery, different from that suffered pre-operatively, arising post-operatively and persisting beyond three months. Recently, in a prospective study, Van Gulik et al. (Van Gulik, 2011) identified a number of independent predictors for the development of persistent thoracic pain following sternotomy including non-elective surgery, re-sternotomy shortly after the original surgery and severe pain on the third postoperative day. In this study, at one year, 42 (35%) patients reported chronic thoracic pain. Similarly, another study reported the prevalence of post-operative pain as high as 39.3% at the mean time of 28 months after surgery (Bruce, 2003). Meyerson et al. in 2001 **(**Meyerson, 2001**)** estimated a 28% overall incidence of non-cardiac pain one year after surgery. Several studies assessed that women are substantially more likely to suffer early and chronic postoperative pain than men (Van Gulik, 2011 and Ochroch, 2006) and that the prevalence of post-sternotomy chronic pain decreases with age (Van Gulik, 2011 and Meyerson, 2001). Chronic post-sternotomy pain can be related to secondary sternal osteomyelitis, incomplete bone healing, sternocostal chondritis, and surgical technique of internal mammary(Bolotin, 2007 and Aigner, 2013).

Indeed, Aigner et al. 2013 **(**Aigner, 2013) pointed artery harvesting (required for myocardial revascularization) and, particularly, mechanical trauma associated to improperly applied sternal retractors that might lead to rib and sternum fractures (Van Gulik, 2011; Woodring, 1985; Unlu, 2007).Of course the relevance of this issue is expected to be different for each individual patient in terms of a number of variables such as weight, age, osteoporosis and cartilage calcification.

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To access to the mediastinum, retractors are used to allow adequate surgical field (Steele, 2013). Hemisternums separation might lead to rib fracture, eventually associated to brachial plexus injury (BPI) (Baisden, 1984; Greenwald, 1983; Gumbs, 1991; Healey, 2013; Suzuki, 1991).

Median sternotomy provides a wide access to the thoracic cavity. It is considered the standard approach for open heart surgical procedures, but it is also a useful incision for a number of other operations. It is well known that a certain risk of chronic pain is associated to the extent of the force impressed during sternum opening due to rib fractured and/or BPI. Thus, there is an actual clinical need to provide to the surgeons suitable instrumented retractors able to monitor in real time the forces exerted on the two halves during the sternum opening procedure. Furthermore, with the increasing interest of shifting the cardiac surgery procedures from full to partial sternotomy, including the “J” and “T” incisions, the proposed study might be useful to evaluate and compare the forces applied on the sternum in the various surgical approaches to determine the best access to that supposed to be the optimal sternum separation allowing at the same time the optimal surgical view.

Only few data are available for the actual value of the forces exerted by a retractor on the skeletal cage and all reported studies have been conducted on corpses or animal models. Data obtained from human patients are not presently available in the literature probably due to the lack of an instrumented sternal retractor readily suitable for the translation to surgery.

For this purpose, we designed and realized a sterilizable system based on a commonly adopted straight sternal retractor (*Finochietto*) equipped with ultrathin force sensors and conditioning electronic circuitry. The forces experienced during the retraction were monitored in real-time by means of a home-made dummy.

The idea is to acquire data on the intensity and distribution of exerted retraction forces during hemisternums separation, in view of future challenging clinical studies aimed at reducing the risk of chronic post-sternotomy pain.

2 MATERIALS

A commonly adopted straight sternal retractor,Finochietto type (Figure 1a) was equipped with ultra-thin force sensors and conditioning electronic circuitry. This instrument was tested by means of a home-made dummy.

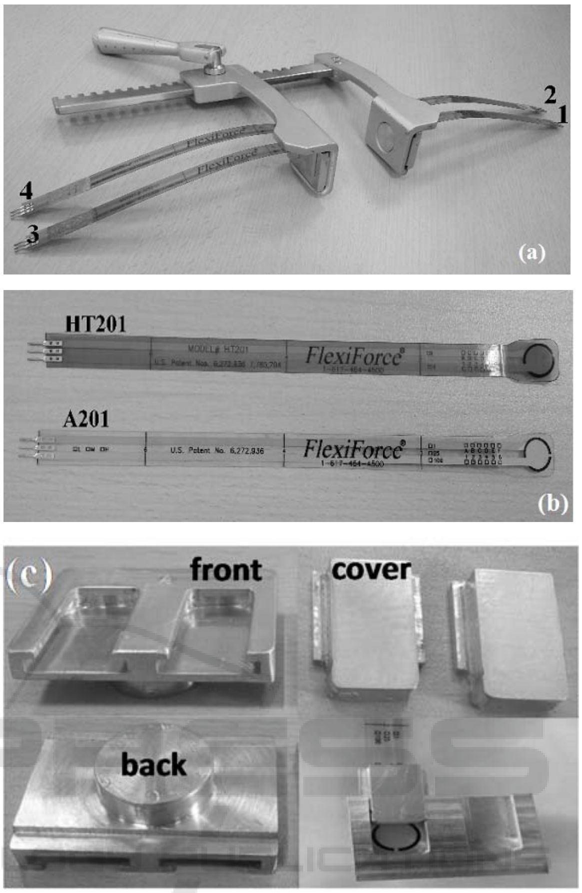

Figure 1: (a) The Finochietto retractor equipped with the four sensors placed in positions designed from 1 to 4 according to the figure. (b) The ultra-thin force sensors, HT201 (top) and A201 (bottom) types. (c) Aluminum sensors’ housings: front, back and cover.

2.1 Force Sensors

We considered two different types of commercial piezo-resistive flexible ultra-thin (0.203mm, 0.008in.) off-the-shelf force sensors, the FlexiForce® A201 (these according to Aigner et al., 2013) and the FlexiForce® HT201 (both types by Tekscan, Boston, USA), having a circular sensing area of 9.53mm (0.375in.) in diameter (Figure 1b). The A201 type, with a polyester substrate, can measure forces up to 440N, within a temperature operating range of -9°C to +60°C (15°F to 140°F). The HT201 type, with a polyimide substrate, can measure forces up to 445N, within -9°C to +204°C (15°F to 400°F).

2.2 Electronic Circuitry

The electronic circuitry was developed on the basis of a previous one, which was made to interface flex and electromyography sensors (Saggio,2016). In particular, the electrical resistance values (outputs of the sensors) were converted into voltages by means of voltage dividers. Those voltage signals fed an electronic circuitry, based on Luigino328 (an Arduino-compatible microcontroller board based on an ATMega328 MCU), which operated 10bit digital conversions and sent data to a personal computer via USB port at a sampling rate of 175Hz. The following data process was handled by ad-hoc home-made LabVIEW routines (National Instruments, Austin, TX, USA).

2.3 Sternal Retractor

An aluminum straight Finochietto retractor (by Tekno-Medical Optik-Chirurgie GmbH Tuttlingen, Germany) was equipped with an array of four force sensors. Two sensors were placed on the blade of the mobile arm and two on the blade of the fixed arm (Figure 1a), the size of the blade being 44.4mm (1.75in.) in length and 30.9mm (1.22in.) in width. The sum of the single detected forces on each blade yielded the total force for both the fixed and the mobile arm. The ultra-thin force sensors were placed in *ad-hoc* smooth aluminum housings (Figure 1c).

2.4 *In Vitro* Test

In vitro tests of the instrumented retractor were performed by means of a made on purposedummy built up with four gas pistons (manufactured by Team Pro), two for each side, laterally anchored to a wooden shell (Figure 2a). Different set of gas pistons were evaluated, *i.e.*150N, 100N and 80N.On the basis of several opening/closing cycles performed by three different surgeons, the dummy equipped with the 80N pistons offered the most realistic feeling with respect to the clinical practice. The Authors are aware that the mechanics of the proposed dummy is very simple with respect to the complex biomechanics of the rib cage. Anyway, the idea was to realize a dummy able to support the test of the device and not meant to be taken as a biomechanical model of the rib cage.

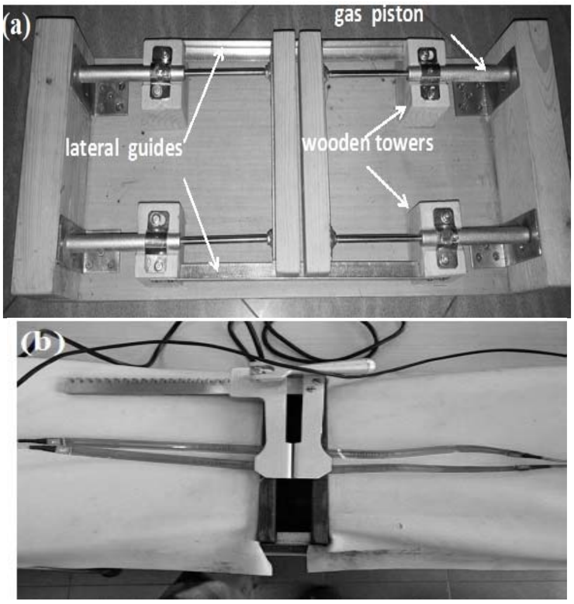

Figure 2: (a) The home made dummy built up using four gas pistons fixed to a wooden skeleton, the compressible parts positioned outward in a face-to-face configuration. In vitro tests: (b) the instrumented Finochietto retractor positioned into the dummy.

3 METHODS

Beforehand, eight sensors of each type were characterized in terms of electrical resistance versus applied force (R *vs* F), by means of an universal tensile test machine (LRX, by Lloyd Instruments, Berwyn, PA, US). In order to investigate if HT201 sensors can effectively support autoclaving conditions, these sensors were also characterized following the same procedure after five cycles of autoclave treatment (VaporMatic 770, AsalSrl, Milan, Italy).

Test procedure consisted in four opening/closing cycles of the dummy by means of the instrumented retractor up to two different fixed widths, *i.e.*5cm (1.97in.) and 10cm (3.94in.). On the basis of the feeling/practice of the surgeons, each opening/closing cycle was performed at a roughly constant rate of 2s/cm, that is 10s for 5cm (1.97in.) and 20s for 10cm (3.94in.). The two final positions (5cm, 1.97in. and 10cm, 3.94in.) were held for 60s so to evidence response decay, if any. The response of all the sensors in term of force (F) versus time (t) was real-time acquired. Then, mean force (F_{mean}), maximum force (F_{max}) and plateau force ($F_{plateau}$) were evaluated, the latter as the mean value of the force recorded during 60s in the final rest position.

The distribution of the forces exerted along the two halves of the dummy was also determined.

4 RESULTS AND DISCUSSION

Ultrathin flexible force sensors HT201 and A201 both showed exponential resistance decay with the impressed force (Figure 3a-b).

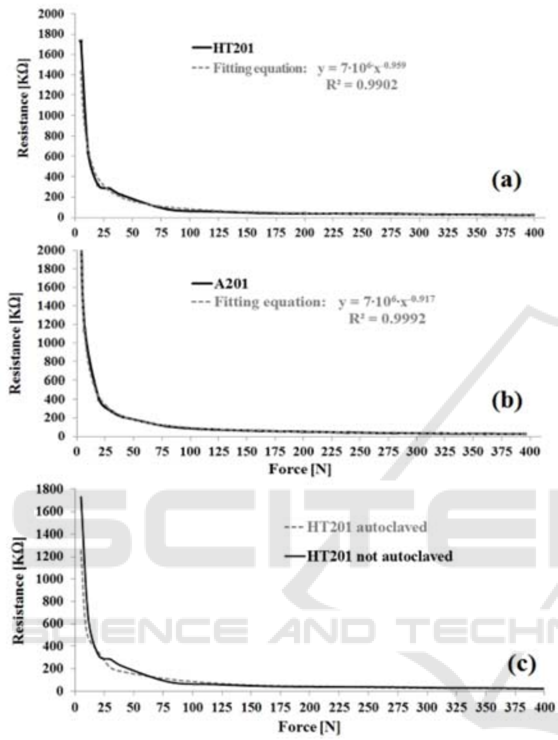

Figure 3: Measured resistance versus force (R vs. F) for different sensor (a) HT201 type, (b) A201 type and (c) H201 type in comparison before and after autoclave treatments.

Moreover, HT201 sensors did not show a significantly different behaviour after five cycles of autoclave conditioning (Figure 3c), which is reasonable result since these sensors have been specifically designed for high temperature applications (up to 400°F, approximately 200°C). In any case, in the occurrence of degradation in performances, those sensors can be easily and conveniently replaced.

The investigated range of force (*i.e.* 5-400N) includes the values reported by Bolotin et al. (Bolotin, 2007) and by Aigner et al. (Aigner, 2013). In more details, Bolotin et al. in 2007 reported the first known successfully attempt to employ an instrumented retractor to monitor forces during cardiothoracic surgery. They equipped stainless steel curved profile retractor blades with strain gauges to measure applied forces during retraction, and reported results for lateral thoracotomy and median sternotomy on cadavers and sheep. The average force applied during force-controlled retraction was (77.88±38.85N) and the maximum force displayed during force-controlled retraction (323.99±127.79N).

Aigner et al. equipped a straight (SSR) (MTEZ 424 735; Heintel GmbH, Vienna, Austria) and a curved retractor (CSR) (Dubost Thoracic Retractor DC30000-00; Delacroix-Chevalier, Paris, France), with FlexiForce sensors, A201 type (Tekscan Inc). The blade of the mobile arm of the SSR (length 6.5 cm and width 4.5cm) was equipped with two arrays of 4 sensors, and the mobile arm of the CSR (length 9.7cm, width 4.8cm, curvature radius 21cm) was equipped with two arrays of 5 sensors. The sum of the single sensor forces yielded the total force. Force distribution, total force and displacement were recorded to a spread width of 10cm in 18 corpses (11 males and 7 females). For every corpse, 4 measurement iterations were performed for both retractors; each retraction was performed in 14.3±6.2s to reach 10cm widespread. The Authors concluded that the shape of sternal retractors considerably influences the force distribution on the sternal incision. On the other side, it is reported that the total mean retraction force was not significant different between SSR and CSR (222.8±52.9N *versus* 226.4±71.9N). Nevertheless, the recorded mean total force was remarkably dependent on the gender. For the first retraction, it was 256.2±43.3N for males and only 174.9±52.9N for females. Moreover, in the case of SSR the forces on the cranial and caudal sternum are significantly higher than in the median section. For SSR the maximum total force for full retraction was 349.4±77.9N, while force distribution during the first retraction for the cranial/median/caudal part of the sternum was 101.5±43.9/29.1 ±33.9/63.0 ±31.4N.

Aigner et al assessed that the force distribution did not change significantly for the other 3 retractions, for the different investigated spread widths (i.e. 5, 7.5, and 10cm) and not gender-dependent. The maximum force for full retraction was 493.6N, whereas the smallest maximum force was 159.0 N.

Results obtained for HT201 sensors are resumed in Table I and the typical force (N) *versus* time (s) patterns are presented in Figure 4-5.

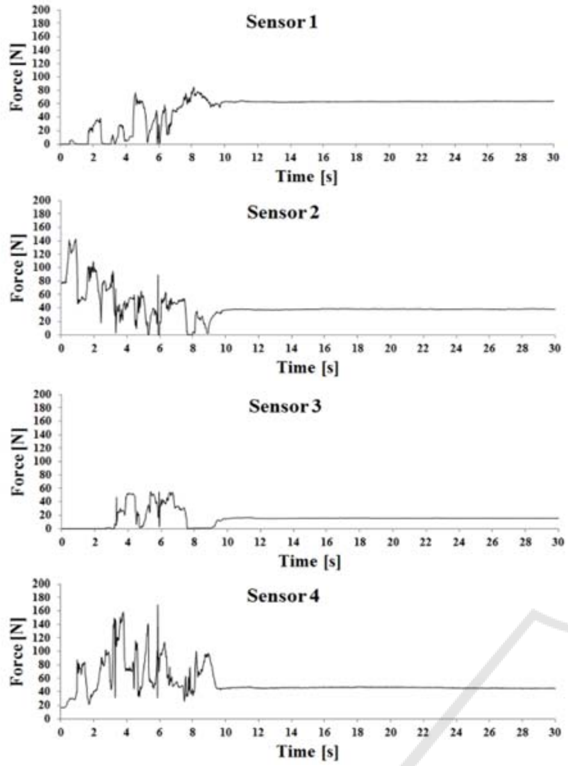

Figure 4: Response of the four sensors (housed as shown in Figure 1a) in terms of force [N] versus time [s] during the 5cm opening procedure.

In all cases, a high stability of the response to a fixed exerted force was evidenced. In fact, the value of $F_{plateau}$ showed a mean standard deviation as low as 0.33±0.16N. Some valuable information can be obtained from the acquired data. For example, the total average force for the mobile blade ranged between 60.1±6.0N for 5cm spread and 98.0±36.5N for 10cm spread, as expected for a dummy built-up with 80N gas pistons. The deviation with respect to this value is also expected and has to be attributed to the uneven pressure distribution onto the circular sensors due to the rough surface finishing of the contact area *i.e.* wood in the dummy.

It is interesting to observe during the retraction, the *Finochietto* experienced along the mobile arm a total F_{max} (sensor#4 + sensor#3) that exceeded 200N, ranging from 219.1±9.7N for 5cm spread and 266.6±25.4N for 10cm spread.

The force distribution along the retractor blade is also particularly interesting. In fact, in all cases, the highest maximum force (F_{max}) was detected by sensor #4 positioned on the mobile arm in proximal (cranial) position (Figure 4-5), the value ranged between 156.4±12.5N for 5cm spread and 199.7±21.2N for 10cm spread. The lowest F_{max}

Table 1: Values of the mean, maximum and plateau forces (expressed in N) measured by HT201sensors positioned according to Figure 1a (i.e. S1, S2, S3, S4). The related standard deviation values are reported in parentheses.

spread	*Force [N]*	***S1***	***S2***	***S3***	***S4***	***S1+S2 fixedblade***	***S3+S4 mobile blade***
5cm	*mean*	**60.8 (5.7)**	**39.2 (4.4)**	**18.3 (2.1)**	**41.8 (7.7)**	**100.1 (8.5)**	**60.1 (6.1)**
	max	**97.3 (10.6)**	**115.0 (19.5)**	**62.7 (5.4)**	**156.4 (12.5)**	**212.2 (14.8)**	**219.1 (9.7)**
	plateau	**63.9 (5.8)**	**39.4 (4.9)**	**17.9 (1.8)**	**38.3 (8.3)**	**103.3 (9.0)**	**56.3 (7.2)**
	max-mean	**36.5 (8.7)**	**75.7 (21.1)**	**44.4 (4.0)**	**114.6 (12.9)**	**112.2 (12.5)**	**159.0 (12.6)**
10cm	*mean*	**37.6 (8.8)**	**82.5 (5.60)**	**15.2 (10.4)**	**82.8 (26.8)**	**120.1 (12.8)**	**98.0 (36.5)**
	max	**79.6 (17.5)**	**126.3 (6.62)**	**66.9 (4.3)**	**199.7 (21.3)**	**205.9 (20.8)**	**266.6 (25.4)**
	plateau	**41.2 (6.7)**	**89.1 (7.02)**	**13.1 (12.9)**	**84.7 (32.0)**	**130.2 (11.7)**	**97.8 (44.4)**
	max-mean	**42.0 (14.1)**	**43.8 (6.98)**	**54.7 (9.4)**	**116.9 (16.9)**	**85.8 (13.6)**	**168.6 (26.3)**

values were 62.7±5.4N for 5cm and 66.9±4.3N for 10cm, registered in correspondence of sensor #3 of the mobile arm in distal (caudal) position. Interestingly, median sternotomy in corpses performed by means of a straight sternal retractor gave a comparable force distribution **(**Aigner, 2013).

This result suggests that the made-on-purpose dummy enable to perform reliable test and thus it might also be employed by surgeons in order to assess their own learning curve for each specific instrumented retractor.

Furthermore, sensor #4 detected also the highest value of (F_{max}-F_{mean}), *i.e.* 114.6±12.9N and 116.9±16.9N, respectively for 10cm and 5cm opening. For all the other sensors, this value does not exceed 75.7±21.1N, independently from the position on the retractor.

On the basis of these results, the presented implementation system can be considered a valuable tool to evaluate intensity and distribution of retraction forces in human patients for conventional sternotomy procedures. On the basis of our knowledge, these data are not yet available in the Literature. As already previously suggested by Bolotin (Bolotin, 2007), the final goal is to develop clinical studies aimed at coherently correlating the biomechanical information obtained for a specific surgical procedure with the incidence of post-sternotomy chronic pain. In this respect, for example, the actual outcomes of cranial *versus* caudal positioning of the sternal retractor could be assessed. On the basis of our knowledge, in the past decade such kinds of studies have not yet been performed probably due to the lack of an implemented user-friendly retractor suitable for conventional clinical sterilization process.

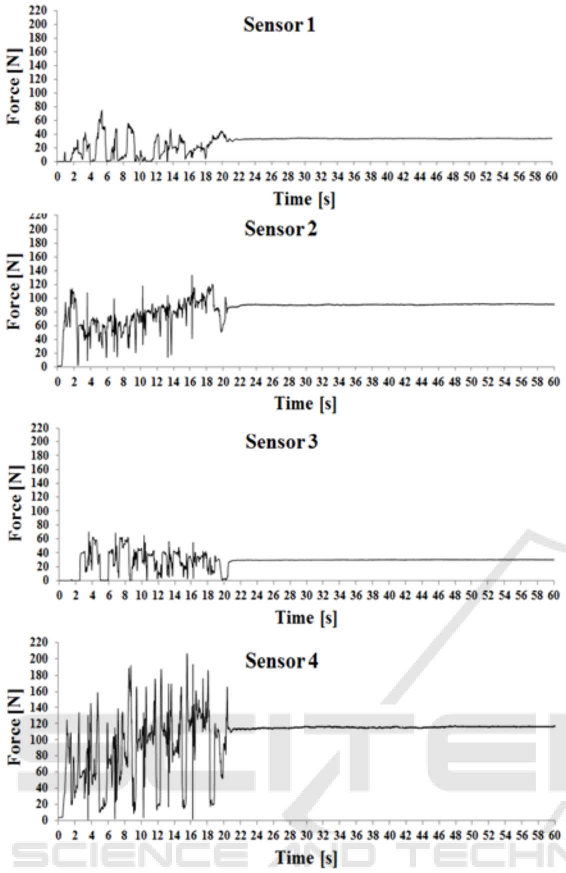

Figure 5: Response of the four sensors (housed as showed in Figure 1a) in terms of force [N] versus time [s] during the 10cm opening procedure.

Moreover, the performance of this versatile design might also contribute to estimate the actual impact of minimally invasive cardiac surgery techniques. In fact, since the 1990s, these procedures are receiving an increasing interest due to a number of potential advantages with respect to traditional sternotomy, including reduced operative trauma, less perioperative morbidity along with improved aesthetic outcomes, shorter hospital stay and accelerated rehabilitation (Ward, 2013). According to recent studies, the overall outcomes and costs are believed to be comparable with those of conventional sternotomy (Reser, 2015; Alturi, 2015). It has to be considered that partial sternotomy, in minimally invasive cardiac surgery procedures, allows the displacement of only a part of the hemithorax, the latter might be subject to increased exerted forces eventually leading to excessive stress on the "dynamic" chest wall. The proposed study might be useful in the clinical setting to determine the optimal balance between surgical field and sternum separation.

The system can be considered cost-effective and potentially adaptable to different surgical retractors simply providing the appropriate housings.

5 CONCLUSIONS

This study demonstrates that the proposed system allows performing measurements of retraction forces in the range 5-400N using different models of flexible force sensors; in particular *Flexiforce* A201 and HT201, the latter being suitable to operate in a temperature range compatible with conventional autoclave procedures. The implemented system was thus demonstrated to be able to support autoclave sterilization either removing or keeping in place the force sensors, thus eventually allowing the reuse of the HT201 sensors, which is more cost-effective than a disposable use. In this perspective, we plan in future work to investigate the maximum number of autoclaving cycles that preserve the performances of HT201 and other ultrathin force sensors available on the market.

The user-friendly and low cost developed system allowed at instantaneously measuring, displaying and storing the force *versus* time pattern for each sensor, during and after the opening phase. Accurate and reliable data were obtained, in terms of maximum force, mean force, total force and force distribution. Measurements were acquired in real time and readily available on a computer monitor.

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