



Contents lists available at ScienceDirect

Respiratory Medicine Case Reports

journal homepage: www.elsevier.com/locate/rmcr

Case Report

A numerical analysis of ventilation motion after chest surgery with a RESPIRholter device

Marco Ceccarelli^{a,*}, Manuel D'Onofrio^b, Vincenzo Ambrogi^b, Matteo Russo^a^a Department of Industrial Engineering, University of Rome Tor Vergata, Via del Politecnico 1, 00133, Rome, Italy^b Department of Surgical Sciences, University of Rome Tor Vergata, 00133, Rome, Italy

ARTICLE INFO

Handling Editor: DR AC Amit Chopra

Keywords:

Biomechanics
 Medical devices
 Wearable devices
 Respiration
 Rib cage
 Chest surgery

ABSTRACT

This case report presents a numerical evaluation of respiration in terms of biomechanical parameters of chest motion. This experimental evaluation is performed with RESPIRholter, a wearable device specifically developed to monitor the movement in the ribcage through the motion of the sixth rib whose characteristic motion is considered as representative of the motion of the thorax. Here we present test results acquired with a RESPIRholter device in a 6-h acquisition. These results characterize respiration biomechanics for diagnostic purposes in a chest surgery patient, highlighting the diagnostic utility of RESPIRholter in the identification of post-operation respiratory problem.

1. Introduction

This report presents the results of an experimental investigation for analyzing rib motion during respiration with RESPIRholter, a wearable device that is based on an IMU sensor. The aim of this report is to broaden knowledge of how thoracic surgery affects rib cage movements through an experimental evaluation of rib motion.

There are three different categories of methods that are currently used to measure only respiratory rate, namely: estimation from other physiological parameters such as ECG or peripheral blood oxygen saturation, measures of the movements of the rib cage, measures the inhaled or exhaled air flow. The most accurate method can be considered to use a combination of accelerometer and gyroscope data achieving an error of 0.7 respiratory acts [1]. Other methods can give results with a minor efficacy like optical fibers (1 respiratory act of error) [1,2] or piezoelectric-piezoresistive sensor (1.79 respiratory acts of error) [1,3]. Few researchers have tried to develop new techniques [4–8] to monitor respiratory rate measuring rib cage movements. Limitations of these methodologies are high cost, difficulty in setting up or continuous presence of an operator during the sampling. Likewise, SENSIRIB device [9–11], precursor from which RESPIRholter is derived [12], requires the presence of an operator during the sampling. RESPIRholter as new Holter device for respiration evaluation provides a continuous monitoring of the respiratory rate without any operator assistance since it can be used by a patient on her/his own, being cost effective, lightweight, and comfortable. Both the RESPIRholter and SensiRib devices collect more data than other devices, such as the angular motion around the X and Y axes and the linear acceleration along the X, Y, and Z axes. This enables an extremely accurate visualization of the morphology of ventilation.

Spirometry, as the standard in clinical practice to analyze the respiratory system status, requires a contribution from the subjects under testing. Conversely, the proposed RESPIRholter device [12] is a passive diagnostic device that does not require an active contribution from the subject under testing and can be used in non-compliant patients as patient with dementia or children too.

* Corresponding author.

E-mail addresses: marco.ceccarelli@uniroma2.it (M. Ceccarelli), manuel.donofrio@students.uniroma2.eu (M. D'Onofrio), ambrogi@uniroma2.it (V. Ambrogi), matteo.russo@uniroma2.it (M. Russo).<https://doi.org/10.1016/j.rmcr.2024.102005>

Received 2 August 2023; Received in revised form 9 December 2023; Accepted 6 March 2024

Available online 13 March 2024

2213-0071/© 2024 Published by Elsevier Ltd.

This is an open access article under the CC BY-NC-ND license

<http://creativecommons.org/licenses/by-nc-nd/4.0/>.

In this paper, results of implementing RESPIRholter as a device for ventilation monitoring are discussed coming from a first campaign of tests with a patient at the Thoracic Surgery Unit of the University Hospital Policlinico Tor Vergata in Rome. The outcomes of the reported experimental investigation will have future interesting implications in preventing early postoperative complications in patients with major thoracic surgery as well as have a diagnostic device useful during preoperative assessment and in checking the respiratory health status.

2. Materials and methods

2.1. Issues in patients after thoracic surgery

Patients with thoracic surgery are sensitive to several postoperative complications such as air leak due to an Alveolar-Pleural Fistula (APF), atrial fibrillation, pneumonia, pulmonary edema, atelectasis, pulmonary insufficiency, as reported in Refs. [13,14]. Preoperative ventilatory functional tests can be performed to prevent complications during and after surgery and to define the patient's fit. The incidence of postoperative complications in major thoracic surgery occurs in approximately 25% of the patients [13] and pulmonary function analysis can play a key role in predicting it. In general, initial screening consists of anamneses, spirometry, diffusion capacity, if necessary 6-min walking test, and assessment of the cardiovascular status.

The incidence of postoperative pneumonia is in 2.2–20% of the patients according to diagnosis criteria. When it occurs, it can be related to a significant morbidity and mortality (7.5%) [14]. Atelectasis is a common complication after thoracic surgery; and when it involves a lung segment or more, there is a relevant risk for the onset of pneumonia. Poor cough, im-paired pulmonary function, diaphragmatic dysfunction, and chest wall instability are risk factors for segmental atelectasis. The best treatment option is a prevention by performing chest physiotherapy, walking at least three to four time daily, controlling secretions, and coughing.

Pulmonary insufficiency remains a postoperative complication. The difficulty usually occurs on day 2 or 3 of postoperative care, due to pneumonia, poor coughing, or pulmonary edema. Clinical signs precede the evidence from the radiograph, and treatment is aimed to maximize the pulmonary mechanism through intense chest physiotherapy, intravenous fluid, bronchodilators, incentive spirometry, ambulation, and control of secretions. All the above can be more conveniently addressed using a regular check also of the respiration looking at the rib cage motion and functionality. A practical evaluation with numerical values can be worked out by analyzing the motion parameters of the ribcage during respiration such as the displacement of the ribcage reference points and motion quality such as acceleration ribcage response during respiration.

Four basic movements can be identified from the rib cage motion during respiration as listed in Fig. 1. The pump-handle movement in Fig. 1a) is characterized by sternum swinging upward and outward. The bucket-handle movement in Fig. 1b) involves the lower ribs that moves laterally and upward as the handle of a bucket. The caliper movement in Fig. 1c), as most used by lowest ribs, consists of ribs swinging laterally. The torsion movement in Fig. 1d) is characterized by ribs twisting around costovertebral joints.

Identification and monitoring of these movements in Fig. 1 can be worked out by considering motion characteristics of a representative rib of the rib cage with data referring to the frequency of motion, angular excursions and angular accelerations as significant kinematic parameters of the quality and quantity of respiration motion. Fig. 2 shows an approach aimed at a diagnostic evaluation of the respiratory act by considering those kinematic characteristics with an analysis of quality and quantity with reference to the tem-



Fig. 1. A scheme of the basic rib motions: a) pump-handle, b) bucket-handle, c) caliper, d) torsion.

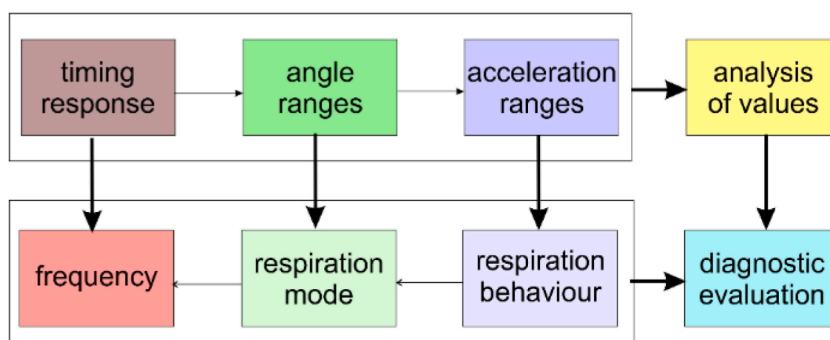


Fig. 2. A scheme of main parameters for respiration evaluation via ribcage biomechanics.

poral response, to the angles of movement, and to the acceleration excursions of the movement monitored of a representative rib. A scheme is reported for which the acquisition of the time data can be evaluated as a characteristic of the respiratory frequency, the angular excursions can be indicative of the breathing modality and the acceleration ranges can be useful in evaluating the efficacy of the respiratory act.

2.2. Design and operation of RESPIRholter device

In order to detect those motion parameters a suitable device was designed as RESPIRholter [12,15–18], to detect specifically acceleration and angle ranges of the VI cost as the most representative of the ribcage motion during respiration. The measured angle ranges reflect the expansion of the rib cage, the more the rib rotates, the more the volume of the rib cage increase. The acceleration of a reference point on the rib can give indication about the smoothness and regularity of respiratory acts. Then, an IMU is used to acquire the acceleration components along the three axes of the reference frame and the roll and pitch angles of the VI rib according to the scheme in Fig. 3.

The main mechanical element of the used RESPIRholter prototype is the box that contains an Arduino NANO 33 IoT board that is equipped with a 6-axis LSM6DSL IMU sensor. A MicroSD module supports the placement of the storage unit microSD; such module works on the same 5V power input of the Arduino microcontroller. The board communicates the starting in-operation of the device to an operator through blink sequences of a LED (low power led, 1W of power consumption) varying their frequency and period, if problems arise. The sensitivity of the acquisition procedure is adjusted conveniently to the slow motion of respiration by using a data acquisition frequency of 35 Hz with resolution of the IMU sensor of 0.1 deg and 0.001 m/s² for angle and acceleration, respectively. The data are reported as unfiltered by default, even if a mobile average can be applied to the most recent 10 or 20 acquisition for a smoother representation by using data elaboration code integrated in the Arduino Nano microcontroller. The power supply is provided by a power bank using a micro-USB connector cable. The device is lightweight, being of only 33g, and its size is 55mm × 30mm × 16mm, as shown in Fig. 4. The WiFi and Bluetooth data transmission has not used in order to avoid possible interference with other medical equipment near the patient since still it is not investigated if such a transmission can be of interference with other necessary medical instrumentation near the patient bed. However, since the purpose of the work is to present the procedure for acquiring data in a near future creation of a database, it is not necessary WiFi and Bluetooth data transmission for immediate visualization and elaboration of the data.

RESPIRholter is set up to perform a 6-h long acquisition sampling 1 minute each 20 minutes for each motion parameter [10], as summarized in the scheme of Fig. 5a). Data analysis is performed through a customized user-friendly RESPIRholter code in MATLAB with data post-processing that can be operated by a physician during the process. Clicking on preview, the physician can take a quick look at the acquisitions and eventually delete acquisitions that are not considered valid, whereas, clicking on execute, autonomous operation is enabled.

In the post-sampling data elaboration, the first step is to divide each acquisition into five segments with same time duration and all the initial and final intervals with no data can be eliminated. Then, the designed RESPIRholter code automatically computes the averages of the five acquisitions for each parameter P according to the scheme in Fig. 5b). the acquired data are stored and then are visualized in the form of plots. The average of all the acquisitions is computed as the algebraic average of the averages according to the scheme in Fig. 5 b) yet. In addition, RESPIRholter code allows the physician to select a representative plot and a selected plot as per diagnosis purposes in a synthetic representation of the results.

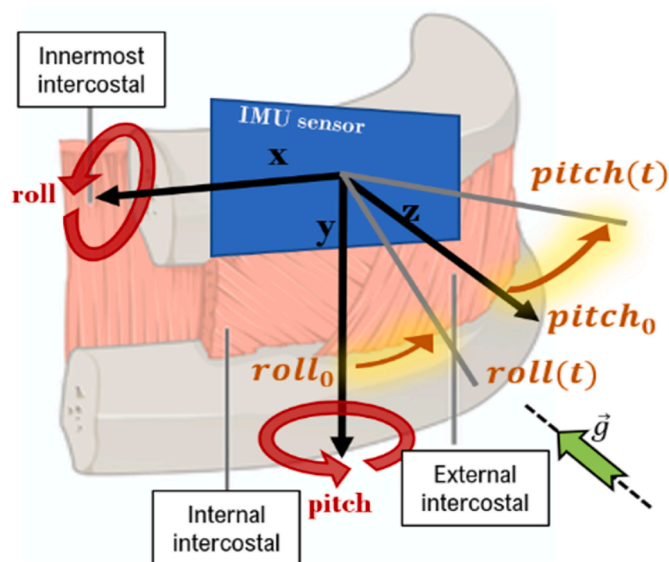


Fig. 3. A scheme of the proposed monitoring of the rib motion using an IMU.

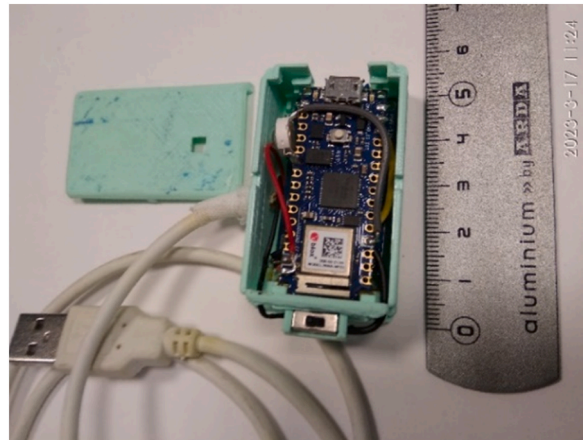


Fig. 4. Prototype of the RESPIRholter device.

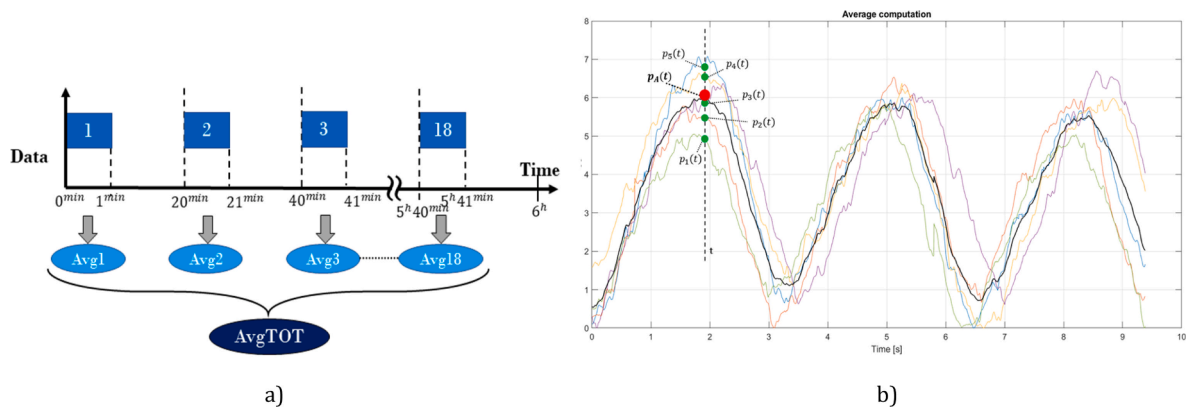


Fig. 5. Scheme for data elaboration: a) timeline of sampling; b) average computation.

2.3. Test design and modes of testing

The testing is designed as a specific protocol to standardize the experimental conditions as reported in Fig. 6.

- The first step is the collection of the informed consent from a patient. The purpose of the research, the processing of personal data, and how the experiment will be carried out are explained so that, the patient decides whether to join the trial and then signs the informed consent. A brief medical anamnesis interview is carried out, which includes anthropometric data such as height and weight, biographical data such as age and date of birth, and relevant information about behaviors, diseases, and previous surgeries.
- The second step consists of the application of the RESPIRholter device. The intersection between the anterior axillary line and the sixth rib is identified as the point of application, so that the zone of application and the device are disinfected with chlorhexidine 2%. Thus, the device is fixed with silk patch as shown in the example in Fig. 7 and it is connected to a power bank and turned on.
- The third step coincides with the acquisition session and lasts 6 h. The patient wears the RESPIRholter device lying on the bed during the night.
- The last step consists in removing the device and re-disinfecting the surrounding skin where the device was placed as well as the device itself.

3. Case presentation

The reported case study refers to a 62-year-old man with a BMI of 34.21. He had undergone pulmonary lobectomy surgery, and on the night between the first and second postoperative day he was tested with RESPIRholter. Monitoring has been performed with Respirholter device that was positioned at the intersection angle between the sixth rib and the anterior axillary line on the left hemithorax, Fig. 7. A pleural drainage has been placed during surgery at the fourth intercostal space. The patient on the first postoperative day was clinically eupnoic with good peripheral oxygen saturation. On the second postoperative day, peripheral oxygen saturation was SpO₂ 92% (target > 94%) and oxygen therapy delivered in nasal cannulae 2 L/min became necessary.

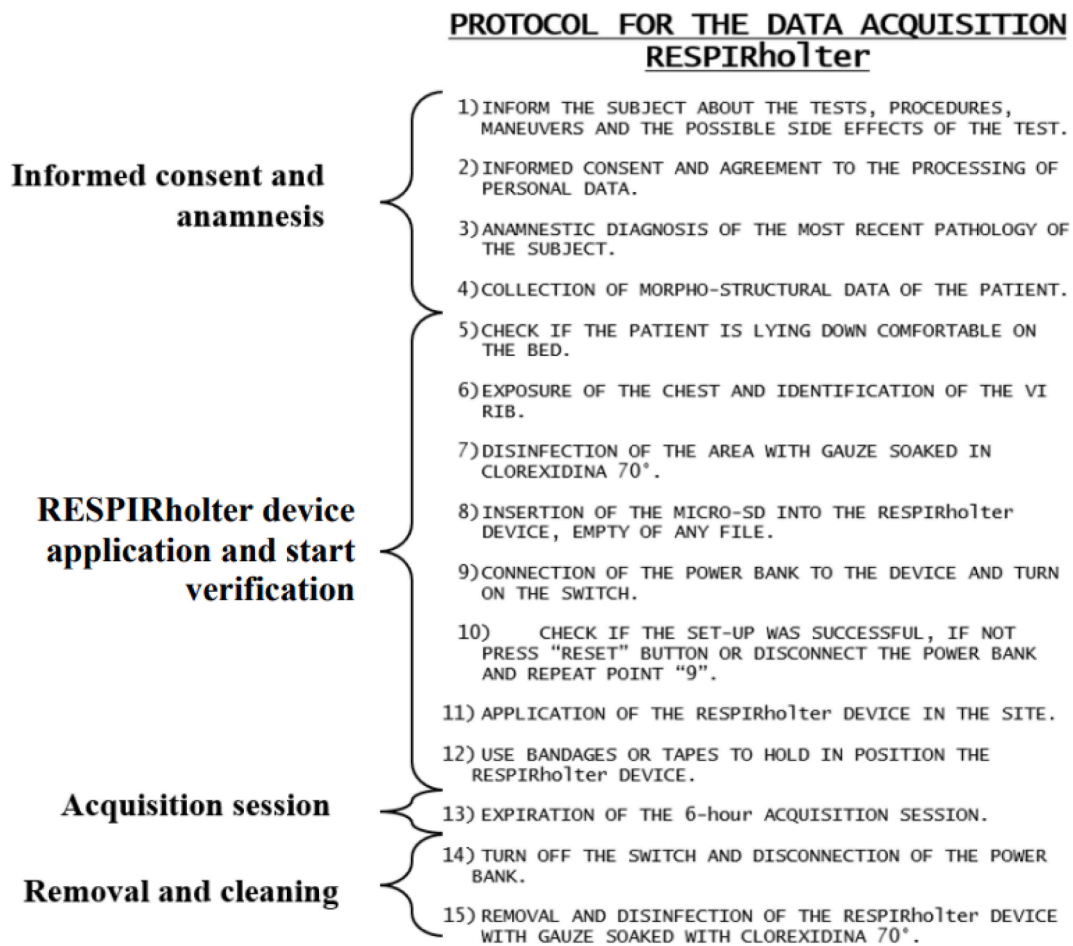


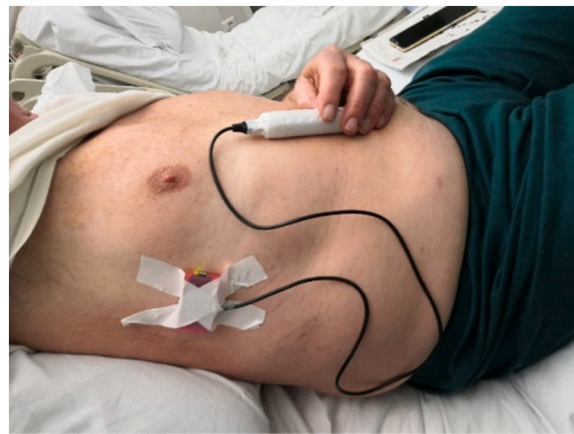
Fig. 6. The protocol workflow of RESPIRholter operation in the reported campaign of tests.

A data acquisition session has been performed in the night after the operation collecting results in the behavior and values of the respiration for 6 h while sleeping. Analysis of the results collected with the RESPIRholter has revealed a constant pattern throughout the 6 h of sampling that was characterized by breathing followed by a stage of apnea. The results are reported with the plots of the main outcomes for a clinical diagnosis in Figs. 8 and 9. In each plot curves are reported for comparison purposes between the results from the case of study with healthy patient data (obtained in acquisitions on 10 other patients) to emphasize the detected anomalies in a respiration characterization. All the results are reported for a representative respiration cycle as an average of the whole data collection.

Fig. 8a shows the typical kinematics of respiration in the red curve referring to a healthy patient where the local noise can be ascribed both to the real functionality of respiration and, mostly, to the compliance of the skin and adipose layer tissue on which it is installed the sensor in correspondence with the rib being measured. Of significant importance is the roll angular variation of the movement which can be estimated at about 5 deg between the peak and the stationary phase of respiration. In the blue curve referring to the patient of the case study, it can be clearly noted how the breathing kinematics is considerably different, showing only initially a more or less regular first cyclical phase, followed by a stationary phase whose prolongation can be interpreted as a state of the patient's apnea. The angular variation, while remaining approximately 5 deg, refers only to that at the initial stage.

In Fig. 8b, representing the angular motion of pitch, the anomaly can be noted even more between the normal respiration represented in the red curve and the respiration of the case study patient in the blue curve. Also, in this case the angular variation is the significant parameter in addition to the temporal trend resulting in the first case a variation of about 6 deg while in the patient case study the variation is even larger with almost 8 deg. The temporal trend is still characterized by the fact that the cyclicity in the healthy patient is not found in the patient the case of the study whereas a long almost stationary phase can be identified as indicative of the absence of significant angular motion and therefore of respiratory apnea.

The analysis of the data acquired in terms of acceleration components, Fig. 3, further confirms the anomalous state of respiration in the case study, reporting numerical values that indicate a serious impairment of respiratory regularity. In particular, from the curve in the data acquired with respect to X axis it can be noted not only a reduction in accelerations in the stationary phases but even their variations that are characterized respectively by a variation of 0.08 g and 0.02 g to indicate an excessive stationarity of the respiratory movement along the X axis. Similarly, the Y component shows a similar reduction of the acceleration variation in the stationary phase

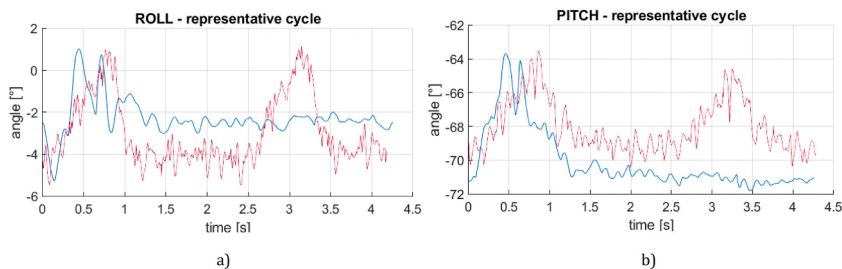


a)



b)

Fig. 7. An example of application of RESPIRholter in a patient for thorax surgery: a) before the operation; b) after the operation.



a)

b)

Fig. 8. Comparison of acquired results during test between a patient with a good outcome (red line) and the case study patient (blue line): a) rib roll angle; b) rib pitch angle. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

with values from 0.05 g to 0.02 g with an indication, however, of a variation of the initial peak increased from 0.13 g to 0.15 g. Even more significant is the result of the acquisitions of acceleration along the Z axis as it can be noted how the well-defined cyclic behavior in the respiration of the case in good health is considerably modified both in the time trend and in numerical values. In fact, the cyclicity in the Z component of the acceleration is completely non-existent and with completely different values both in absolute and in variation being the acceleration peak of 0.45 g increased up to about 0.5 g with a variation from 0.07 g to of almost 0.2 g, while the stationary phase shows values translated downwards from about 0.4 g to little more than 0.3 g with variations still of 0.02 g. [Table 1](#) summarizes the main numerical values whereas the time evolution of the elaborated data is equally important to interpret the acquired data which shows that the holter functioning is an efficient procedure for a complete respiration characterization.

The results obtained in the experimental campaign were highlighted by a comparative analysis between cases in good health and operated cases, allowing to identify the kinematics and functionality of respiration in terms of time trend with typical cyclicity and

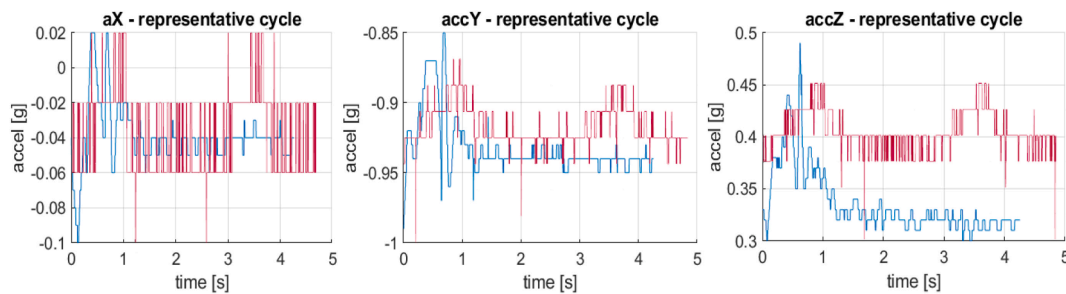


Fig. 9. Comparison of acquired results of rib acceleration during test between a patient with a good outcome (red line) and the case study patient (blue line). (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

Table 1

Main numerical data from plots in Figs. 8 and 9.

	Δ Roll (deg)	Δ Pitch (deg)	ax-min (g)	ax-max (g)	ay-min (g)	ay-max (g)	az-min (g)	az-max (g)
Healthy subject	5.17	8.10	-0.11	0.02	-1.0	-0.87	0.31	0.45
Patient	5.12	6.02	-0.10	0.02	-0.98	-0.85	0.30	0.49

significant numerical values which, as for the reported case study, they can be used in clinical monitoring of the respiratory status of an operated patient. The results of the tests make possible to highlight the temporal trends typical of normal breathing and consequently any anomaly with respect to it with a numerical evaluation which highlights even more the severity of the anomaly and therefore can give an indication of a diagnosis which may require adequate therapy still under monitoring.

4. Discussion

As previously indicated, functionality in respiration can be assessed in terms of motion in the ribcage and in particular by reference to a representative rib which has been identified in the sixth rib. Monitoring the movement of the sixth rib through an holter breathing device, such as RESPIRholter, in six-hour acquisition sessions allows for a sufficiently objective assessment of the quality and quantity of respiration given the long examination interval without neglecting the possibility of highlighting specific situations in brief moments of analysis. The results that can be obtained with RESPIRholter as reported in the case study can be useful for an interpretation of the respiratory state of a patient and can help surgeons in analyzing the evolution of the recovery of normal respiratory functions. In the case study in particular the anomaly that was detected not only in specific moments of short durations but even at the average level in the obtained acquisition allowed the surgeon to intervene to resolve this criticality before it became a source of further more serious problems. In particular, the interpretation of the results reported for the case study in Figs. 8 to 10 can be summarized in the quality of breathing in terms of time trends and the cyclicity lost or at least very reduced and in the quantity in terms of angular variations of the movements in roll and pitch relative to the movements in the ribcage in breathing of suitable volume while the data acquired in terms of acceleration were useful for quantifying the entity of the motion deficiency of the respiratory act. This above all quantitative analysis made it possible to identify the respiratory criticality characterized by anomalous cyclicity with excessive periods of apnea and irregular movements in the ribcage, and therefore it was possible to predict a respiratory crisis with a diagnosis 12 hours earlier than possible with the usual postoperative diagnostic techniques.

Furthermore, quantitative analysis especially with accelerations could identify unexpected patient behavior. Looking at the acceleration plots, it can be noted that the Z component was the most different from the pattern of the patient with good outcome, as referring to a different mode of respiration from the expect one the abdominal mode against the usual upper chest mode for males. Given the patient's condition of obesity, it would be expected that the component that most differs is the one along the Y-axis, which starting from the thorax heads toward the abdomen as chest respiration mode. The fact that instead it was detected the Z component as the most affected by respiratory failure, let to think that the respiration problem was not primarily caused by the patient's obesity.

Therefore, the experience reported with an efficient clinical result could demonstrate not only the effectiveness of monitoring using RESPIRholter but also the diagnostic utility of the numerical evaluation of the acquired data. This positive result is encouraging future more in-depth statistical investigation work to have a database of normal respiratory behaviors and cases of diagnostic states with criticalities according to age, gender, and physical constitution in order to then facilitate the analysis of results and efficient diagnostics not only in the thoracic surgical field.

5. Conclusions

The main contributions in the reported work can be summarized in two aspects, namely in the successful usage of RESPIRholter device and significant numerical evaluation of respiration biomechanics in thorax operated patients. In particular, the RESPIRholter device, specifically designed to be applied on patients with a comfortable installation and an acquisition procedure for a duration of 6 h, is proved effective with results in experimental tests of which the discussed example emphasizes the practical diagnostic utility in having identified breathing problems in an operated patient well in advance of traditional medical diagnostics. Since the campaign is

carried out with 10 volunteers for each group only, it cannot be significant for a statistical significance of the campaign results, but however it can be considered convenient to report one case of study to show the practical significance of the procedure and the possibilities that its results can give also for diagnosis purposes.

Funding

This research received no external funding.

Institutional review board statement

The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Ethics Committee of Policlinico di Tor Vergata, Rome, with protocol code RS. 197.22 on November 15, 2022.

Informed consent statement

Informed consent was obtained from all subjects involved in the study. Written informed consent has been obtained from the patients to publish this paper.

CRedit authorship contribution statement

Marco Ceccarelli: Conceptualization, Investigation, Methodology, Project administration, Resources, Supervision, Writing – original draft, Writing – review & editing. **Manuel D'Onofrio:** Data curation, Formal analysis, Visualization, Writing – original draft. **Vincenzo Ambrogi:** Conceptualization, Formal analysis, Investigation, Methodology, Supervision. **Matteo Russo:** Data curation, Formal analysis, Methodology, Writing – review & editing.

Declaration of competing interest

The authors declare no conflict of interest.

References

- [1] H. Liu, J. Allen, D. Zheng, F. Chen, Recent development of respiratory rate measurement technologies, *Physiol. Meas.* 40 (7) (2019 Jul 1) 07TR01.
- [2] M. Krehel, M. Schmid, R. Rossi, L. Boesel, G.L. Bona, L. Scherer, An optical fibre-based sensor for respiratory monitoring, *Sensors* 14 (7) (2014 Jul 21) 13088–13101.
- [3] J. Yang, B. Chen, J. Zhou, Z. Lv, A low-power and portable biomedical device for respiratory monitoring with a stable power source, *Sensors* 15 (8) (2015 Aug 11) 19618–19632.
- [4] A. Alfvèrti, A. Cesareo, A Wearable Device for the Continuous Monitoring of the Respiratory Rate, Patent Nr. WO 2019/012384, Italy, 2019.
- [5] M. Ciochetti, et al., Smart textile based on fiber bragg grating sensors for respiratory monitoring: design and preliminary trials, *Biosensors* 5 (3) (2015) 602–615.
- [6] J.F. Freeman, et al., Devices and Methods for Respiratory Variation Monitoring by Measurement of Respiratory Volumes, Motion and Variability, Patent WO2012021900A1, 2012.
- [7] A. Aliverti, A. Cesareo, A Wearable Device for the Continuous Monitoring of the Respiratory Rate, WO2019012384A1, 2019.
- [8] G. Gentili Biffi, Device for Monitoring of Respiration Functions, Patent IT1222263B, Italy, 1990.
- [9] M. Ceccarelli, Portable Device for Measuring the Movement of Human Ribs, Patent N. 102021000005726, Italy, 2021.
- [10] M. Ceccarelli, L. Puglisi, F. Mesiti, M. Aquilini, V. Ambrogi, A device for experimental characterization of biomechanics of breathing and coughing, in: 26th ABCM International Congress of Mechanical Engineering, Florianópolis, Paper COB-2021-0273, 2021.
- [11] M. Ceccarelli, P.E. Papuc, R. Taje, M. Aquilini, V. Ambrogi, A biomechanics analysis of ventilation in thorax operated patients, *International Journal of Clinical Studies & Medical Case Reports* 15 (1) (2021) 1–3.
- [12] M. Ceccarelli, M. Ambrogi, L. Puglisi, M. Aquilini, Ventilatory Holter Device, Patent No. IT102021000008585, Italy, 7/4/2021.
- [13] G.A. Patterson, J.D. Cooper, J. Deslauriers, A.E.M.R. Lerut, J.D. Luketich, T.W. Rice, *Pearson's Thoracic and Esophageal Surgery*, third ed., Churchill Livingstone Elsevier, Philadelphia, 2008.
- [14] J. LoCicero III, R.H. Feins, Y.L. Colson, G. Rocco, Shields' General Thoracic Surgery, eighth ed., Wolters Kluwer, Philadelphia, 2019.
- [15] M. Aquilini, RESPIRholter a Device for Breathing Monitoring, Master Thesis in Mechatronic Engineering, University of Tor Vergata, Roma, 2022.
- [16] M. Aquilini, M. Ceccarelli, Design and testing of RESPIRholter device for respiratory monitoring, in: V. Niola, A. Gasparetto, G. Quaglia, G. Carbone (Eds.), *Advances in Italian Mechanism Science-IFToMM Italy*, Springer, Cham, 2022, pp. 480–488, https://doi.org/10.1007/978-3-031-10776-4_55.
- [17] Aquilini, M., Ceccarelli, M., D'onofrio, M., Ambrogi, V.:An experimental characterization of respiration biomechanics by a holter device. In: *Proceedings of 5th Jc-IFToMM International*.
- [18] M. Ceccarelli, M. Ambrogi, L. Puglisi, M. Aquilini, Ventilatory Holter Device, Patent No. IT102021000008585, Italy, 7/4/2021.