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SCIENTIFIC NOTE

Development and validation of a measurement system for continuously monitoring postoperative reservoir levels

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Abstract

Following cardiac surgical procedures, multiple drainage systems remain in place inside the patient's chest to prevent the development of pericardial effusion or pneumothorax. Therefore, postoperative bleeding must be diligently observed. Currently, observation of the exudate rate is performed through periodical visual inspection of the reservoir. To improve postoperative monitoring, a measurement system based on load cells was developed to automatically detect bleeding rates. A reservoir retaining bracket was instrumented with a load cell. The signal was digitized by a microcontroller and then processed and displayed on customized software written in LabView. In cases where bleeding rates reach critical levels, the device will automatically sound an alarm. Additionally, the bleeding rate is displayed on the screen with the status of the alarm, as well as the fluid level of the reservoir. These data are all logged to a file. The measurement system has been validated for gain stability and drift, as well as for sensor accuracy, with different in vitro examinations. Additionally, performance of the measurement device was tested in a clinical pilot study on patients recovering from cardiac surgical procedures. The in vitro investigation showed that the monitoring device had excellent gain and drift stability, as well as sensor accuracy, with a resolution of 2.6 mL/h for the bleeding rate. During the clinical examination, bleeding rates of all patients were correctly measured. Continuously recording drainage volume using the developed system was comparable to manual measurements performed every 30 min by a nurse. Implementation of continuous digital measurements could improve patient safety and reduce the workload of medical professionals working in intensive care units.

Keywords Postoperative monitoring · Surgical reservoir · Measurement system

Introduction

After cardiac surgical procedures, patients are transferred to an intensive care unit (ICU). Multiple drainage systems stay connected to a reservoir during the first postoperative period to prevent a pericardial effusion, pneumothorax, or pleural effusion, and to facilitate the draining of lymphatic exudates and blood. Despite the advancements made in technology and care found in modern ICUs, the occurrence of postoperative hemorrhaging is still one of the main factors leading to an adverse outcome [1–4].

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It is important to consider the rate of and the total amount of postoperative bleeding when deciding postoperative treatment options [5, 6]. Based on the blood volume inside the reservoir and the rate of bleeding, this can determine decisions made regarding blood transfusions, the administration of coagulation activating agents, or reoperation [7, 8]. If critical hemorrhaging of a patient is detected early with the fast consideration of treatment options, the postoperative complication rates, 30-day mortality rates, and hours under a mechanical ventilation system can still remain low [9].

Currently, the amount of bleeding into a reservoir is only detected periodically via visual inspection of the reservoir scale. The value is subsequently documented in the patient's record, and in cases where it reaches a certain level during the visual inspection, a decision is made regarding further treatment options.

However, this practice has several disadvantages. Information concerning the reservoir's height level is limited to the time interval in which the visual inspection occurs. Depending on the standard of care, this may vary from 30 min, in the best scenario, to even longer intervals. Additionally, as the reservoir is not always locked in an absolute horizontal position, this can lead to certain deviations or errors that may occur during the visual assessment of exudate inside the reservoir [10].

Additionally, there is a lack of direct continuous visualization of the bleeding curve, as well as no automated documentation process of the patient`s file. To overcome these problems, a system to continuously monitor surgical reservoir volume has been developed and validated both in vitro and under clinical conditions.

Materials and methods

Hardware measurement equipment

A 5 kg load cell (166-H; Conrad Electronic, Hirschau, Germany) is integrated into a cardiotomy reservoir retaining bracket (Stöckert, Munich, Germany). The bracket is fixed to a pillar with rolls. To stabilize the tubes that are attached to the drainage catheter running between the patient and the reservoir, a board with different hose clamps is attached to the top of the pillar. The board is mounted to limit interference signals on the load cell due to the patient's movements.

The load cell is connected to a precision 24-bit analog-to-digital converter for weight scales (HX711; Avia Semiconductor, Xiamen, China). The data from the converter are then processed by a microcontroller (Atmega328P; Atmel, San José, CA, USA). When the microcontroller is powered on, the load cell is set to zero and independent from the load that is applied to the reservoir retaining bracket. Measurement values are delivered via a USB cable to a personal computer (PC) with a sample frequency of 5 Hz. The density of the exudate is calibrated to 1 g/mL. Details of the retaining bracket setup are shown in Fig. 1.

A custom-made software based on Labview (Labview 2011; National Instruments Germany GmbH, Munich, Germany) was installed on a PC to document and visualize the bleeding curve, as well as to signal an alarm when necessary.

When starting the program, the user is able to predefine the volume that is already inside the reservoir before measurements are taken for documentation purposes. Additionally, the patient's name and identification number can be written into the documentation file.

The mean value of accumulated secretion is determined every minute and displayed over time. The monitoring system creates a system alarm in two cases. In Case 1, an alarm is signaled with a red light on the graphical user interface if the bleeding rate is > 100 mL/h, or a total volume of 700 mL is reached. In Case 2, an alarm for the bleeding rate is set. This records a measurement taken every 10 min and compares it continuously to detect the slope of the bleeding rate. Data measuring the average total bleeding amount over 1 min, as well as the status of the alarm, are logged with a timestamp every minute and recorded in the documentation file. A detailed flow chart of the algorithm is shown in Fig. 2.

Validation of the measurement equipment and sensor accuracy

The gain stability of the setup was measured over a 210-min period. The sensor was calibrated to zero, and after 30 min with no load, the weight was increased every 30 min by adding a 560 g calibrated load (500 mL filled sterile medical water bottle, Spüllösung; B Braun, Melsungen, Germany). After reaching a total load of 1710 g, the load was decreased every 30 min by removing 570 g. This was done to detect if any hysteresis effect of the sensor system occurred. Data were analyzed using linear regression.

Accuracy of the measurement equipment during continuous volume addition was tested using a calibrated 50 mL-syringe pump (Orchestra; Fresenius Kabi, Bad Homburg, Germany) with a delivery rate between 6.2 and 200 mL/h. The syringe pump was connected to a standard cardiotomy reservoir (Livanova Germany, Munich, Germany) placed inside the bracket. The pump was then started at a defined velocity and data were logged for each case at a frequency of 0.1 Hz. Details of the chosen pump speed rate and an illustration of the measurements are shown in Fig. 3.

Clinical examination using the measurement equipment

This study was approved by the Medical Ethics Committee of the medical faculty at the Technische Universität

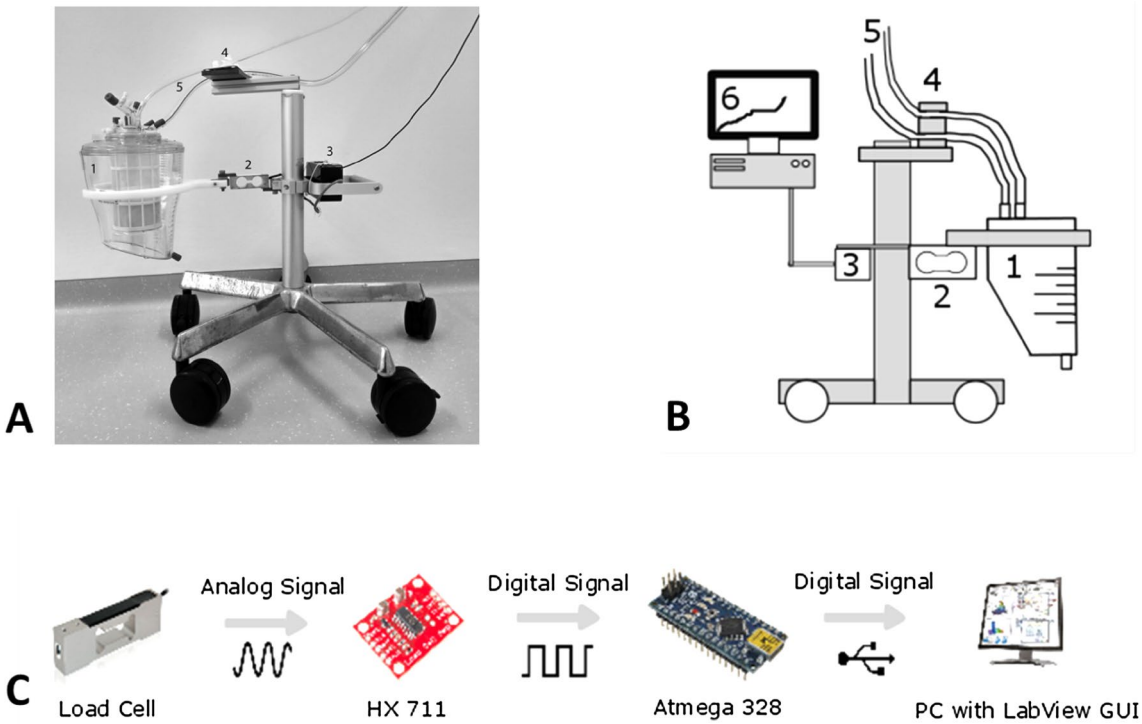

Fig. 1 **a, b** Illustration of the measurement setup. 1: Cardiotomy reservoir; 2: load cell; 3: microcontroller; 4: clamps to stabilize the tubing; 5: tubing going to the patient; 6: personal computer. **c** Electrical signal sequence from the load cell to the personal computer. *PC* personal computer, *GUI* graphical user interface

München (No. 517/16K). All participants gave informed patient consent.

In 20 patients who underwent different cardiac surgical procedures (e.g., isolated valve replacement, valve replacement and coronary artery bypass grafting [CABG], isolated CABG, etc.), postoperative bleeding was measured over 15 h, or until the surgical reservoir was changed for the first time. Measurements were immediately taken after a patient was transferred from the operating room to the ICU. Additionally, bleeding amount was determined through visual inspection of the surgical reservoir and documented in the patient file by the ICU nurse every 30 min.

Quality of the bleeding curve, especially regarding noise, drift, or unrealistic values, from the generated measurement files was then analyzed. The file data were then compared with the manually written data from the patient's record. Additionally, the nurse was asked about any problems that may have occurred during the measurements.

Results

Measurement accuracy and gain stability were both verified during the in vitro experiments. No drift or hysteresis effects occurred during the testing for accuracy. Signal drift was detected to be less than 1 mL/24-h. Signal accuracy was validated down to a resolution of 2.6 mL/h bleeding velocity. Linear regression analyses indicated a very strong correlation between the measured data and the applied load ($R^2 = 1$). Examples of recorded patient data on the measurement device and results of the linear regression analysis are shown in Fig. 3.

No measurement errors occurred due to air bubbles in the drainage, or in conjunction with bleeding velocity. There were no complaints on the handling of the device during the clinical setup. The algorithm successfully accounted for artefacts, which may have resulted from the movements of the tubing or the patient, by generating an average value of all measurements over 1 min. This was also aided by the additional hose clamps mounted on the pillar. Figure 2 illustrates an example of the average filtering algorithm; a bleeding curve was recorded with and without filtering. Artefacts due to movements or jerking were seen without the applied filtering algorithm. During the clinical trial, bleeding was successfully detected and recorded in all 20 patients.

In cases that fell within the criteria of Case 1 for an alarm (bleeding rate > 100 mL/h, or a total volume of 700 mL), the alarm was correctly signaled in every case. Data logging the average values and alarm status were also recorded correctly.

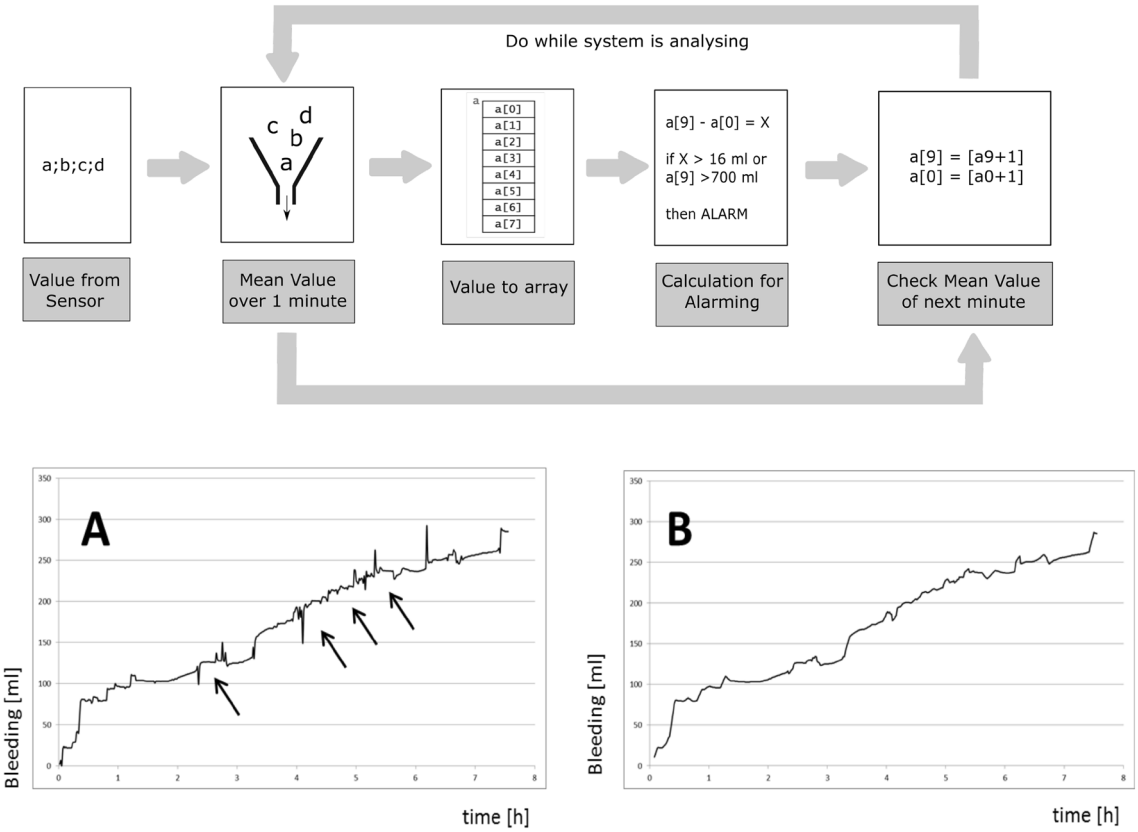

Fig. 2 Upper panel: Flow chart of the algorithm for documentation, average filtering, and generating an alarm. An average of the measured values is generated every minute and stored in an indexed array. Then, values taken 10 min apart are compared and a decision is made based on the rules illustrated. Bottom panels: Recorded patient data. **a** Without average filter and artefacts (arrows); **b** with average filter

Additionally, forcing the efflux of exudates by moving the patient or increasing the suction, as is required during the postoperative period, was accurately detected in the bleeding curve. A typical stepwise vertical increase in the bleeding rate could be identified every time an efflux of exudates occurred. Typical bleeding records are shown in Fig. 4.

Discussion

Multiple techniques that measure the volume of exudates or urine have been evaluated. For monitoring urine output, different apparatuses based on optical or capacitive sensors have been previously described [10, 11]. Load cells are widely used in both technical applications and medical research [12–15]. A load cell for measuring the cardiotomy reservoir level during an extracorporeal perfusion was first used roughly two decades ago [16]. However, compared to the current study, the volume flow was higher with a shorter measurement time.

The technical solution that allows the detection of the volume inside the reservoir via a load cell that is integrated into a retaining bracket offers distinct advantages. In contrast to other measurement techniques, such as ultrasound-based or capacitive techniques, the load cell can detect changes in volume that are independent from the reservoir's shape or tubing diameter. Other measurement devices based on physical features other than a load cell require reservoirs with a special shape that need to be exclusively manufactured [10, 11, 17]. By using a load cell inside the bracket, the shape and size of the reservoir do not influence the measurement in any way. Therefore, any clinically-available reservoir can be used without limitations, with no special customizations needed for taking measurements.

Another advantage of this study is that the measurements taken are independent from bleeding velocity. Sensors that are based on the ultrasound Doppler-effect, or conductive techniques, require high-flow velocity with no air bubbles present inside the drain. During the clinical evaluation, air could be seen in the tubing near the reservoir in every case, with a low bleeding velocity also observed. This would be an issue for the previously mentioned techniques. Load cells, as well as amplifiers for weight scales, are widely commercially available and cheap; there is also excellent gain stability and no hysteresis effects that occurred during the whole

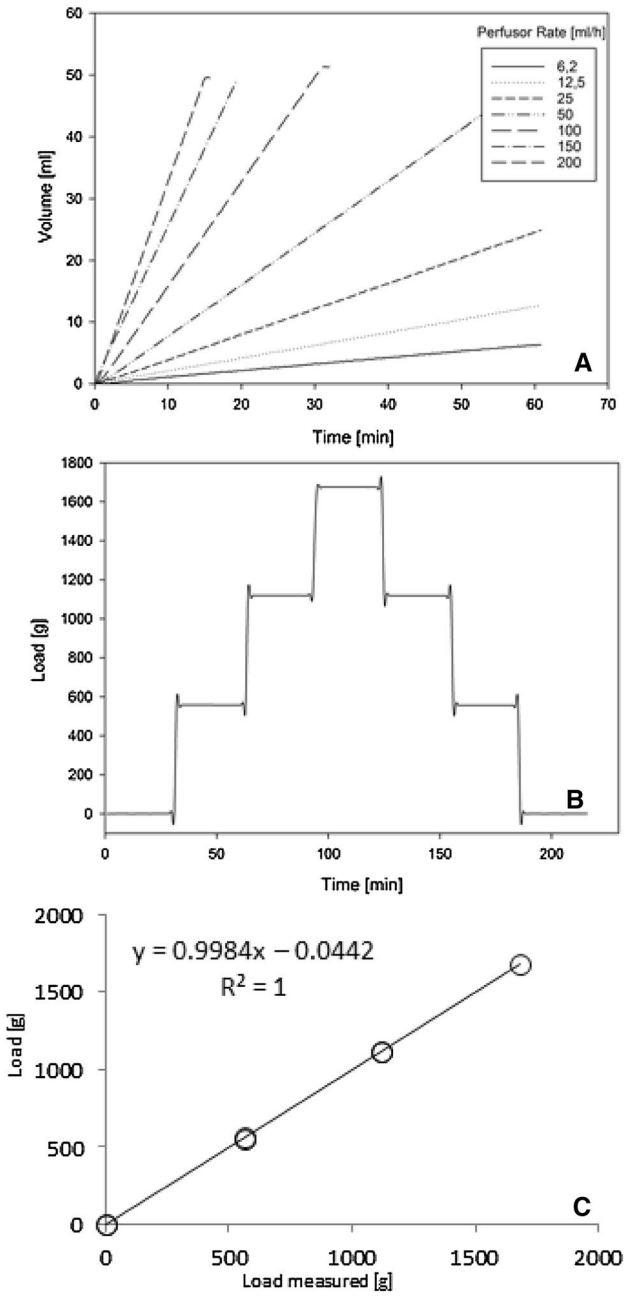

Fig. 3 **a** Log file validating the measurement accuracy of different syringe pump rates from 6.2 to 200 mL/h. **b** Log file of the experiment on drifting and hysteresis effects. The load was either increased or decreased every 30 min by a defined step of 570 g. **c** Linear regression analysis of load vs. measured load data for the drifting and hysteresis experiments. A strong correlation of the measured values with the applied load ($R^2 = 1$) is shown

measurement chain, which is important during periods that require prolonged measurements.

Using a load cell requires an initial zeroing, or taring, process when the reservoir is first attached to the retaining bracket. During our application, the zeroing process was implemented when the microcontroller (that is integrated into the bracket) was turned on. Additionally, a tare function was implemented in the software, with the possibility of adding a starting value that was equal to what was already inside the reservoir when the measurement began. No problems occurred during the clinical study due to the zeroing process. Patients were transferred to the ICU with the successful connection of all other medical devices, including respirators, invasive blood pressure measurements, and ECG monitors. The reservoir was then placed inside a bracket with tubing attached to additional hose clamps. Finally, the microcontroller was then turned on.

However, using a load cell to detect fluid volume inside reservoirs does come with some risks that should be addressed. If the reservoir touches the ground, or the tubing is not properly attached in the clamp of the bracket, a high risk of system failure due to the unloading of the load cell can occur. Normally, the reservoir is connected to the bed of the patient at an adjustable height. If the bed is adjusted to the lowest position, the reservoir may touch the ground. To avoid this, the bracket holding the reservoir can be mounted on a separate frame; however, this requires more space than a device that is directly connected to the bed. Additionally, the tubing that is connected to the reservoir should also be slightly longer. In the clinical setting, these were the only differences that needed to be considered by the caregivers, and caused no complaints.

Furthermore, the sensor system itself is sensitive to mechanical impulses that are caused by the patient`s movements (e.g., walking or jerking) or other causes. However, these artefacts are nearly entirely compensated by the algorithm that processes the data delivered from the load cell. The algorithm, which efficiently filters artefacts due to certain motions, creates an average value of all measurements taken over 1 min. This time interval was found to be sufficient with a flawless measurement curve, as illustrated in Fig. 2.

Calibrating the exudate to a density of 1 g/mL also needs to be discussed. Normal healthy blood densities range from 1.04 to 1.06 g/mL [18]. A 1% change in hematocrit values causes a change in density by 0.008 g/mL; and a 1% change in plasma protein levels causes a 0.002 g/mL deviation in blood density [19]. Immediately following a cardiac surgical procedure with extracorporeal circulation, hematocrit values, as well as plasma protein levels, can reduce up to 10–15%, which may lead to lower blood density. In a study measuring intraoperative blood loss by Vitello et al., they conclude that the density of blood is nearly equal to that of water [20]. Therefore, potential measurement deviations due to density calibrations may be negligible.

Different algorithms that rate patient hazard due to bleeding velocity and total volume have been previously described. For example, Ranucci et al. [5] used several criteria for reoperation; drainage greater than 500 mL during the

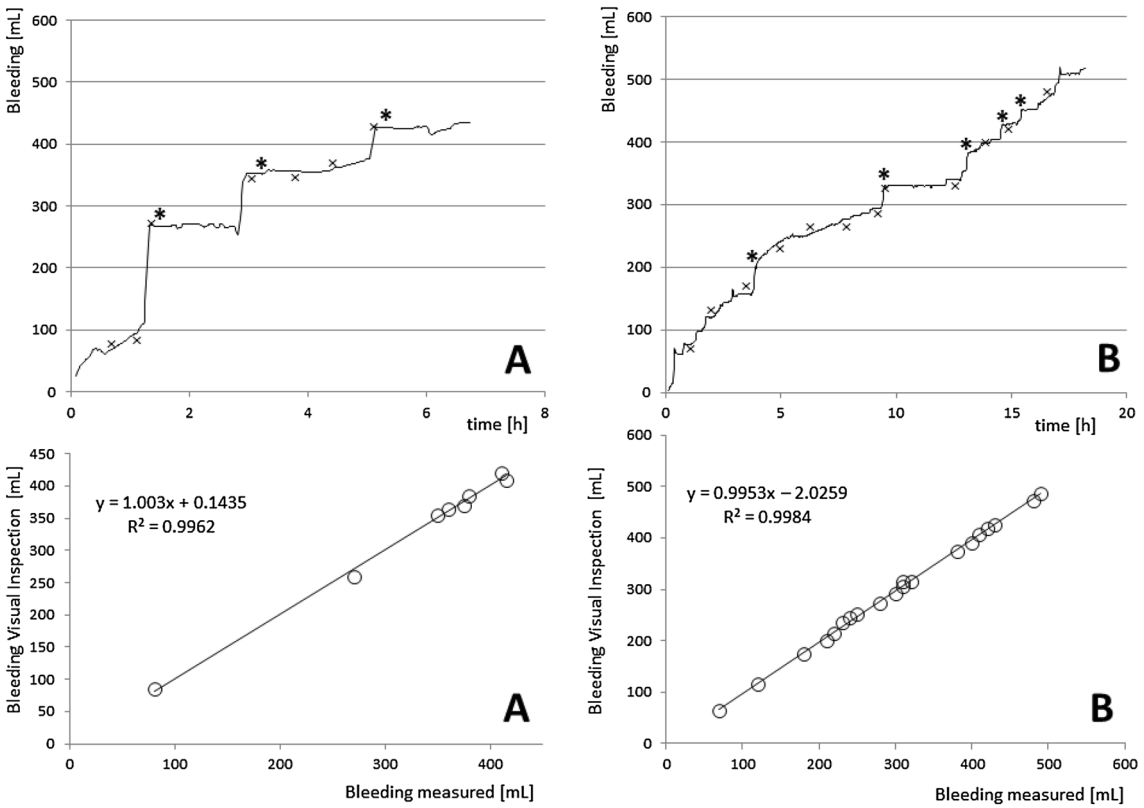

Fig. 4 **a** Measurement data taken over 7 h from a patient with a high bleeding rate after a surgical procedure. ×Measurements performed by visual inspection of the reservoir. *Forced efflux of exudates; a typical immediate stepwise increase could be observed and documented. Linear regression analysis indicates a very strong correlation between visual inspection and measured data ($R^2 = 0.9962$). **b** Measurement data taken over 18 h from a patient with minor bleeding and lymphatic exudates after surgical procedures. ×Measurements performed by visual inspection of the reservoir. *Forced efflux of exudates performed by a caregiver. Linear regression analysis indicates a very strong correlation between visual inspection and measured data ($R^2 = 0.9984$)

first hour, or more than 400 mL in each of the first 2 h, are both indicators for reoperation. Additionally, a total bleeding rate faster than 100 mL/h leads to treatment considerations. In a multicenter trial by Fergusen et al. [21], massive postoperative bleeding was defined as a composite outcome of bleeding from chest tubes that exceeded 1.5 L during any 8-h period. Diprose et al. [22] defined massive bleeding as greater than either 4 mL/kg/h for 1 h, 2 mL/kg/h for 2 h, or 5 mL/kg/h for the first 4 h after an operation.

In our algorithm for detecting critical situations, we chose a more conservative hemorrhagic level compared to other studies. Our intention was to let the caregiver know that the patient required intense observation due to bleeding, and to not only alert them during severe bleeding episodes that definitively required reoperation.

In the clinical trial an additional effect occurred, that has to be noted. During the postoperative period, by manipulating the patient, and increasing the suction at the reservoir for a short time, the efflux of exudates at the drainage is forced in an interval of about 120 min. This intervention was clearly displayed in the measurement file. This could be useful for studies focusing on small drainage diameters or clotting problems, or in determining the most efficient drainage positions.

Nonetheless, there are still some possibilities to improve the current monitoring setup. For example, substituting the cable from the load cell and the amplifier to the PC with a wireless module via Zigbee or Bluetooth to transmit data in the near future could help eliminate the obstacles formed due to the cables. Automatic data integration by the device into the patient data management system should also be incorporated.

Introducing a measurement setup which avoids unexpected unloading/loading of the load cell due to movement of the reservoir or ground contact could be another major improvement. Currently, a special kind of “cage” that protects the tubing and the reservoir itself from mechanical influences during measurements is under development. Finally, more extensive and detailed clinical examinations need to be performed to gather more data that will help improve the current algorithm.

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Compliance with ethical standards

Conflict of interest All authors declare no conflict of interest.

Ethical approval All procedures involving human participants were performed in accordance with the ethical standards of the institutional and/or national research committee (the Committee for Medical Ethics of the medical faculty at the Technische Universität München / No. 517/16K) and with the Declaration of Helsinki and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individuals participating in this study.

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