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Article

Research and Development of Zero-Point Detector of Catheter and Its Clinical Application Effects

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Abstract: Patients in intensive care units often need to use various catheters to monitor their physiological conditions. The caregiver connected the invasive catheter and pressure transmission line to the physiological monitor. For the intensive and continuous monitoring of hemodynamic changes, the measured physiological data is used for medical judgment and treatment. However, in the current clinical situation, nurses do not have consistent horizontal calibration tools or equipment, and the reliability and accuracy of the data obtained by physiological monitors need to be confirmed. Different conduits need to be matched with the fixing seats provided by the original factory. When catheters of different specifications and types are used together, nurses need to use the fine movements of the hand knob to fix the seat to adjust or replace the fixed seat, which caused potential injuries to the hands. Based on creative ideas from clinical needs, an innovative device was developed. Its fixed base template combined the three major features of "adjustable fixed frame", "laser light source calibrator" and "electric track". The fixed base was suitable for catheters of different specifications. The laser light source was used to accurately align the pressure converter vent with the zero point marked outside the patient's body. The electric track was used to move the fixed base up and down during horizontal calibration. Therefore, it was named "Comprehensive Catheter Zero Point Detector". The product was tested in clinical trials and information on the relevant application effectiveness was collected. The innovatively developed product was used in three intensive care units. Nearly 90% of nurses believed that the "all-around catheter zero-point detector" achieved accurate measurement and reduced operating errors. Not only did it provide patients with better and more precise care, but the satisfaction of nurses operating the equipment was also greatly improved.: This developed device allowed for the convenience of using measurement tools and precise horizontal positioning. Visual errors between operators were reduced and the accuracy of measurement values was effectively improved.

Keywords: catheter zero point measurement, precise horizontal positioning, innovative medical material invention

1. Introduction

The contraction of the human heart and the flow of blood-generated energy and pressure are controlled using invasive catheters placed within blood vessels (arteries, central veins, and pulmonary arteries). With the assistance of high-tech medical equipment, the status of pressure, vascular resistance, cardiac contraction, and blood flow of the cardiovascular system is monitored [1,2]. In hemodynamic monitoring, intravascular pressure and volume parameters were continuously transmitted. The calculated relevant physiological parameters were detected for the patient's cardiopulmonary function and perfusion volume, distinguishing specific cardiovascular problems or identifying types of shock. The data serves for medical care, different treatment strategies, and the evaluation of the effectiveness of treatment, which reduces the occurrence of organ failure and mortality [1,3−5]. Nursing staff are connected to the invasive catheter, pressure tube set, transmission line, and physiological monitor. In addition to measuring hemodynamic values, pressure monitoring equipment is connected to an external ventricular drain (EVD) to measure intracranial pressure [6-9].

To ensure the accuracy of pressure measurement, the pressure transducer must be calibrated (transducer leveling) and zeroed [1,8,10]. The function of the metal surface on the pressure transducer is to detect changes in pressure and send the signal to the monitor. The pressure transducer needs to be aligned with the zero point outside the body. The zero point outside the body for hemodynamic monitoring is the imaginary line between the fourth intercostal space and the midpoint of the anteroposterior diameter of the chest [1,7]. The purpose of adjusting the pressure converter to align the external zero point is to reduce the hydrostatic pressure generated by the weight of the blood. The height of the body's posture affects the hydrostatic pressure. When the converter is aligned with the zero point outside the body, the impact of hydrostatic pressure does not exceed 1 mmHg [1]. The improper pressure

transducer level causes errors in measured values. When the pressure converter is higher than the zero point outside the body, the measured value of blood pressure becomes lower than the patient's actual blood pressure, resulting in an overdamped arterial waveform. On the contrary, if the pressure transducer is lower than the zero point outside the body, the measured value becomes higher than the patient's actual blood pressure value and the arterial waveform is underdamped. Therefore, the zero point outside the body needs to be adjusted as the body posture changes [1,8] which impacts blood pressure values [10]. Only if the arterial blood pressure waveforms are correctly recorded and analyzed, blood pressure and advanced hemodynamic variables can be reliably measured.

The calibration and zeroing of the operating pressure transducer are supplemented at an instrument level [6-8] or a laser level [11]. However, it is not mandated to be a necessary instrument. However, clinical practice is limited by the lack of consistent calibration tools or the lack of related instruments to assist in positioning the horizontal height. Therefore, when nurses perform level calibration, they usually pull the drip line from the bedside to align it or make a visual judgment of the level. After the pressure converter is horizontally calibrated, it is reset to zero. By closing the three-way piston toward the patient end, the metal surface of the pressure converter is connected to the atmosphere. Then, zeroing is completed to remove the influence of atmospheric pressure on the converter [1,10]. Based on the literature and clinical observations, it was found that the steps of horizontal calibration and zeroing were not performed correctly, and errors occurred in the measured values, which affected subsequent medical decisions and judgments.

The conditions of patients in intensive care units change rapidly, and the medical equipment to monitor hemodynamics in critically ill patients becomes increasingly diverse. Different monitoring instruments and equipment are used together according to professional assessment needs. The invasive catheters have different types and sizes. The invasive catheters need to be placed on catheter mounting plates, and several manufacturers have their mounting plates [7]. Using invasive catheters of different specifications at the same time causes the incompatibility of the fixed seats. The catheter holder mounted on the IV pole is turned by the caregiver's hands to be loosened, adjusted up and down, and secured to the IV pole [7,8]. ICU nurses turn the patient for at least 2 hours and adjust the patient's bed height. Therefore, frequent zeroing and alignment of the knob catheter holder are required, which increases the workload and causes potential injuries (Fig. 1). The above issues have been rarely discussed. Therefore, we developed and evaluated an innovative stent called an "omnidirectional catheter zero detector" to improve the accuracy and convenience of hemodynamic monitoring. Specifically, the device was accurately calibrated with pressure sensors and reduced measurement errors. At the same time, it simplified the operation process of the nursing staff and reduced the burden of twisting hands. Medical decisions and patient safety were improved through accurate calibration. The "omnidirectional catheter zero point detector" effectively reduced the error of pressure measurement and made the calibrated hemodynamic parameters more reliable. Compared with traditional methods, the product reduced the workload of caregivers and enhanced overall medical decision-making.

Catheter equipment of different brands needs to be matched with the fixing base provided by the original manufacturer and cannot be used interchangeably with each other.

The horizontal position measurement is performed with a bedside drip line or visually. The accuracy of the monitoring data obtained by the physiological monitor needs to be discussed.

It is inconvenient to use the spiral fixation method to install the fixed base on the IV stand.

Offset external zero point

zero alignment line

Fig. 1. Traditional fixed seats and clinical dilemmas.

2. Materials and Methods

Patients in the ICU were covered with a variety of invasive catheter monitoring devices, including arterial catheters for intensive monitoring of blood pressure, external ventricular drainage devices to measure brain pressure, and a monitoring device for central venous pressure. Clinical nurses came up with creative ideas in response to clinical needs. Thus, Chi Mei Hospital and Tongtai Machine & Tool Co collaborated to develop an innovative fixing base called "Omni-directional Catheter Zero Point Detector". The holder was made of aluminum alloy and adjustable with a laser light source calibrator and an electric track to improve the accuracy and convenience of monitoring (Fig. 2). The adjustable fixation bracket was adapted to different specifications of catheters, and the device laser light source and the level were used to accurately zero-align the vent of the pressure transducer with anatomical marks outside the patient. The motorized track facilitated the up-and-down movement of the mount to align the device horizontally.

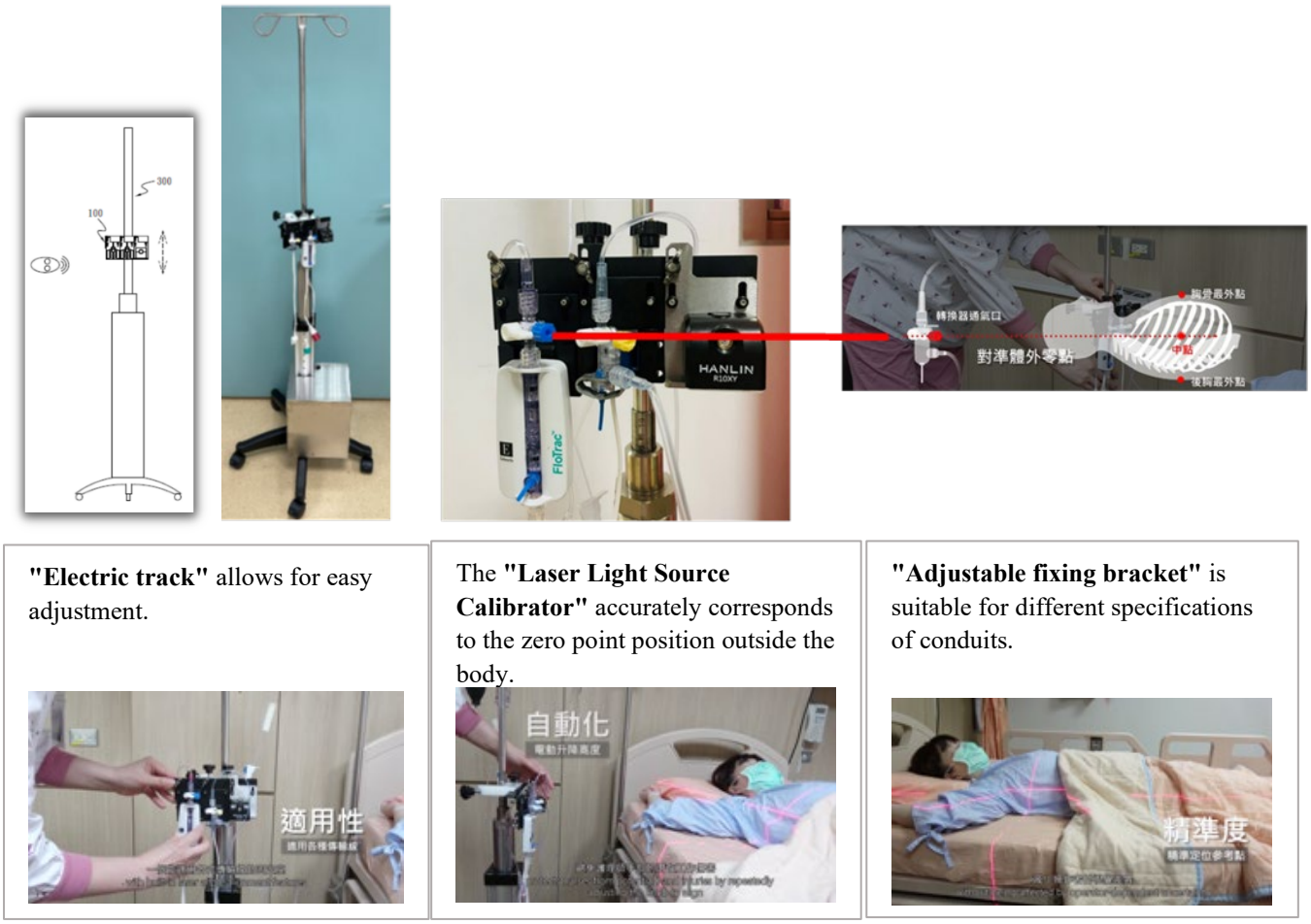

Fig. 2. Design drawing of innovative fixed base and actual finished product.

Nursing staff needed to be proficient in various hemodynamic monitoring methods to reduce deviations caused by incorrect operation of instruments and equipment, accurately monitor various hemodynamic parameters, and efficiently feedback problematic data to doctors. The values provided affect the doctor's diagnosis treatment plan and patient safety. The catheter fixing and calibration device of the present invention was designed using a clever jigsaw assembly concept, and each of the catheter devices was combined into one catheter positioning module. By adjusting the conduit clamp seats, the limiting posts were driven to move in opposite directions in the corresponding first-direction positioning chute. The clamping grooves of the conduit clamp seats were clamped to fix the conduit device, and then the second fixing modules that combined the conduit device and the calibration module were clamped. The first and the second combination units were combined, and then the positioning unit of one of the first fixed modules was combined with the electric lifting module. At this time, the user adjusted the relative position of the second and the first fixed modules through the second direction positioning chute, the adjustment limited chute, and the connection adjustment units. When the horizontal positions of the conducted devices and the calibration unit were at the same horizontal position, the user locked the fixed adjustment unit. In this way, devices of different specifications were used at the same time and the conduit devices of different specifications were calibrated to the same horizontal position. The catheter device was then calibrated to the zero-point position of the patient, thereby achieving operational convenience and accuracy.

To collect clinical nurses' opinions and related suggestions on traditional catheter devices, worksite visits, and oral opinion collection were conducted in January 2022. Relevant suggestions and feedback were continuously collected to revise the equipment. In September 2022, 10 all-around catheter zero-point detection fixed seat devices and 1 electric lifting IV stand were developed. Field testing and satisfaction surveys were conducted in three intensive care units at the same time.

3. Results

In this study, a total of 31 nurses participated in the questionnaire survey. Among them, N3 ranked the most, accounting for 11 positions (35.5%), followed by N2, with 8 positions (25.8%). In terms of gender, women account for the majority, with a total

of 26 (83.9%). In terms of working experience, the number of nurses with more than 10 years of experience was the largest, with a total of 15 (48.4%). Followed by nurses with working experience between 5 and 10 years, a total of 9 (29.0%). There were 12 nurses (38.7%) each with 5 to 10 years of working experience in the intensive care unit and more than 10 years of working experience in the intensive care unit. The basic attributes as shown in Table 1.

Table 1. Basic attributes of nurses (N = 31).

Demographic Variables	Number	Percentage
Rank		
N	4	12.9%
N1	2	6.5%
N2	8	25.8%
N3	11	35.5%
N4	6	19.4%
Gender		
male	5	16.1%
female	26	83.9%
Working experience		
<1 year	4	12.9%
1~ <3 years	2	6.5%
3~ <5 years	1	3.2%
5~ <10 years	9	29.0%
>10 years	15	48.4%
Intensive care unit working experience		
<1 year	4	12.9%
1~ <3 years	2	6.5%
3~ <5 years	1	3.2%
5~ <10 years	12	38.7%
>10 years	12	38.7%

In the evaluation of clinical equipment, 90.4% of nurses believed that the “Omni-directional Catheter Zero Point Detector” effectively solved the problem of incompatibility of invasive catheter holders from different brands. This indicated that this device had high feasibility and acceptability in clinical applications. In the operation process, 93.3% believed that the “laser light level” device accurately corresponded to the zero point outside the body and performed accurate calibration. This meant that caregivers were monitored more accurately and effectively during actual operations. There were important implications for patient treatment and care. In caregiver self-confidence and evaluation of patient care, 90% of the 20 nurses who tried the “electric lifting device” said that this device effectively reduced the risk of potential work injuries to their hands. The device improved caregivers’ productivity and increased their confidence in using new equipment. The above data showed that the “all-around catheter zero-point detector” was highly recognized among nursing staff, especially in terms of equipment compatibility and ease of operation. These positive reviews serve as a basis for clinical application and continued product improvement.

4. Discussion

The results of this study showed that the “all-around catheter zero-point detector” had a high degree of feasibility and acceptability in clinical applications. Past research focused on the accuracy and reliability of invasive monitoring devices, but few studies have examined the difficulties of caregivers when operating these devices. In this study, it was found that up to 90.4% of nurses agreed that this new device solved the problem of incompatibility of invasive catheter holders from different brands. This finding was consistent with previous research showing that caregivers encountered incompatible mounts when using multiple different brands of monitoring devices. Secondly, 93.5% of nurses agreed that the “laser light level” device accurately corresponded to the zero point outside the body. This meant that the accuracy of this new device during operation was significantly improved. There was an important advancement in patient treatment and care. 90% of nurses said that “electric lifting devices” effectively

reduced the risk of potential work injuries to their hands. The finding had important implications in a broader context, as it improved caregiver productivity, reduced medical errors, and improved patient safety. Although this study had limitations such as a relatively small sample size, it provided an important reference for future research. In future research, it is necessary to explore the application of this new device in different medical settings, as well as its error detection and specific impact on patient outcomes (Table 2).

Table 2. Feedback from various aspects of the nursing staff's trial of the "Comprehensive Catheter Zero Point Detector" (N = 31).

Items	Very much agree	agree	No comments	Disagree	Strongly disagree	Not tried
1. Clinical preparation						
(1) "Telescopic holder" improves the dilemma of incompatibility of invasive catheter insertion holders from different brands.	11(35.5%)	17(54.9%)	3(9.7%)	0(0%)	0(0%)	
(2) The "laser level" device can accurately perform horizontal calibration corresponding to the zero point position outside the body.	13(41.9%)	16(51.6%)	2(6.5%)	0(0%)	0(0%)	
(3) "Electric lifting device" prevents potential work injuries to nurses' hands.	7(22.6%)	11(35.5%)	0(0%)	1(3.2%)	1(3.2%)	11(35.5%)
2. The process of operation by nursing staff						
(1) Is the "retractable holder" easy to operate?	6(19.4%)	19(61.3%)	3(9.7%)	2(6.5%)	1(3.2%)	
(2) The "laser light level" allows the nurse to accurately locate the position of the fixed base and the two reference points outside the patient's body. Is it easy to operate?	13(41.9%)	13(41.9%)	3(9.7%)	2(6.5%)	0(0%)	
(3) "Omni-directional catheter zero point detector" shortens the time to adjust the zero point position.	10(32.3%)	14(45.2%)	5(16.1%)	2(6.5%)	0(0%)	
(4) Just adjust the template height of the fixed base to make the zero points of different conduits at the same height.	8(25.8%)	20(64.5%)	3(9.7%)	0(0%)	0(0%)	
(5) The "all-around catheter zero-point detector" is equipped with an electric lifting device to reduce the chance of fixing the base with hand knobs, reducing the nurse's workload and occupational injuries.	19(61.3%)	9(29.0%)	3(9.7%)	0(0%)	0(0%)	6(19.4%)
(6) How satisfied are you comparing the invasive catheter pressure measurement devices used in the past to the invasive catheter pressure measurement devices used today?	8(25.8%)	15(48.4%)	5(16.1%)	2(6.5%)	1(3.2%)	
3. Nursing staff's self-confidence						
(1) The "all-around catheter zero point detector" visualizes horizontal calibration, giving clinical nurses the confidence to accurately align the external zero point.	10(32.3%)	18(58.1%)	2(6.5%)	1(3.2%%)	0(0%)	
4. Care of patients						
(1) The "all-around catheter zero-point detector" achieves accurate measurement, reduces operating errors, and provides better and more accurate care for patients.	10(32.3%)	15(48.4%)	4(12.9%)	2(6.5%)	0(0%)	

5. Conclusions

We developed and evaluated the practicality and effectiveness of an innovative fixation mount called the "Omni-directional Catheter Zero Point Detector" in the intensive care unit. Nearly 90% of nurses believed that the "all-around catheter zero point

detector" achieved accurate measurement and reduced operating errors in clinical application. The detector allowed for the precise care of patients by improving nurses' satisfaction with operating this equipment. The developed detector enabled precise horizontal positioning, eliminated visual errors between operators, and improved the accuracy of measurement values. The "all-around catheter zero-point detector" showed considerable practicality and effectiveness in the intensive care unit with the potential for clinical promotion and application across the country. In this study, the sample size and scope of the study design were limited because the innovative product has not yet been mass-produced. It was not yet possible to compare the effectiveness of clinical accuracy or time cost between the experimental group (innovative products) and the control group (traditional products). The preliminary findings of this study provided directions for extensive and in-depth research in the future. It is required to evaluate the performance of the device in different medical settings and conditions and evaluate a Quasi-Experimental Design, Randomized Controlled Trial, or RCT research design. Comparing to the differences between traditional and innovative devices, a more comprehensive understanding of their impact on patient outcomes and care workflow can be obtained. The "all-around catheter zero-point detector" was an innovative medical device with high potential to be widely promoted and applied in clinical practice. It not only improved medical quality and patient safety but also helped improve caregivers' job satisfaction and professional fulfillment.

6. Patents

This product was registered as a new model patent (Model No. M633874) and an invention patent (Invention No. I811056) by the Intellectual Property Bureau of the Ministry of Economic Affairs of the Republic of China.

Inventor Names. Patent Title. Patent Type, Model No. M633874, date of approval: November 1, 2022.

Inventor Names. Patent Title. Patent Type, Invention No. I811056, date of approval: August 1, 2023.

Author Contributions: H. Kuo proposed creative ideas for technologically innovative products, served as a contact window between partners, explained product trials and tracked results, and served as a team leader in competition activities to lead team members to complete tasks together. M. Shen provided modification suggestions in the manufacturing process of innovative products, searched and organized literature to support the effectiveness of the use of creative medical materials, formulated product trial questionnaires, and participated in the filming and narration recording of participating videos. Y. Ke was responsible for convening cross-industry alliances, bridging communication with hospital leaders, supervising the production of participating films, and planning and organizing media promotion activities. This article was written by three people and was finally reviewed and proofread by Y. Ke. All authors have read and agreed to the published version of the manuscript.

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Conflicts of Interest: The authors Huiting Kuo, Meili Shen, and Yating Ke are part of the "all-around catheter zero point detector" jointly developed by Chimei Hospital and Tongtai Machine & Tool Co. However, these relationships did not influence the interpretation or presentation of the study results. All other authors declare no conflicts of interest.

Appendix A

In December 2022, this product was awarded the Media Influence Finalist Award, the Bronze Award, and the Best Popularity Award in the 2022 "Power in Nursing" International Nursing Creativity Award Competition jointly organized by the National Federation of Nurse Practitioners and Nurses Association of the Republic of China, the Taiwan Nursing Association, and the official representative unit of Cannes Creative. There are three major awards including. In 2023, the Titanium Gold Award in the Green Idea International Invention and Design Competition was given.

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