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在线全文

·新技术新方法·

超声探头快速复用热封系统的设计与研发*

吴 坷，李俊杰，张琳娟△
西安交通大学第一附属医院 麻醉手术部（西安 710061）

【摘要】 目的 设计并验证快速复用热封系统对超声探头快速复用的应用效果。**方法** ①通过医工结合的方式设计并检测快速复用热封系统的性能，主要包括防护膜（多层共挤聚烯烃热收缩膜）和热封主机，根据热缩原理使热缩膜快速热缩贴合于超声探头。在探头表面分别安装温度传感器，进行该系统隔热性能测试。②采用方便抽样法选取超声引导下动脉穿刺患者90例作为研究对象，每组30例，分别采用3种临床常用措施对探头进行保护，在使用前对穿刺部位周围进行水溶性荧光标记。实验组为热封系统组，采用快速复用热封系统标准操作方法保护超声探头。对照组1为消毒湿巾组，采用双链季铵盐消毒湿巾反复擦拭探头表面10～15次后待干；对照组2为保护套组，采用一次性使用腔镜保护套覆盖探头前端，手柄部位采用线绳结扎。对比探头使用前后，实验组与两个对照组超声探头表面水溶性荧光标记（反映探头表面菌落残留）和复用时间（第一次使用结束至第二次使用开始前所用时间）。**结果** ①超声探头内部的温度均低于40 ℃，快速复用热缩系统尚不会影响超声探头性能；②热封系统组复用时间〔中位数（P_{25}，P_{75}）〕为〔8.00（7.00，10.00）〕s，低于消毒湿巾组的〔95.50（8.00，214.00）〕s和保护套组的〔25.00（8.00，51.00）〕s，差异均有统计学意义（P<0.05）。热封系统组与保护套组使用后均未见荧光残留，热封系统组荧光残留少于消毒湿巾组（26例残留），差异有统计学意义（χ^2=45.882，P<0.05）。**结论** 本研究设计研发的热缩膜可针对设备尺寸、大小随意切割剪裁，热缩后能对设备进行紧密贴附和包裹，牢固美观；热封系统实现热缩膜与主机的半自动化联动，减少耗时复杂的人为操作，缩短复用时间，应用方便快捷，能提高超声探头复用和运行效率。超声探头快速复用热封系统表面菌落残留少，能够为超声探头提供有效的物理屏障，且实验过程中未损坏探头性能，可以作为探头处理的新方法。

【关键词】 超声装备 超声探头 快速复用 感染 医用装置

Design and Development of a Heat Sealing System for Rapid Reuse of Ultrasonic Probes *WU Ke, LI Junjie, ZHANG Linjuan△. Department of Anesthesiology and Perioperative Medicine, the First Affiliated Hospital of Xi'an Jiaotong University*, Xi'an 710061, China
△ Corresponding author, E-mail: zhanglinjuan029@163.com

【Abstract】 Objective Ultrasound diagnosis and treatment is easy to perform and takes little time. It is widely used in clinical practice thanks to its non-invasive, real-time, and dynamic characteristics. In the process of ultrasound diagnosis and treatment, the probe may come into contact with the skin, the mucous membranes, and even the sterile parts of the body. However, it is difficult to achieve effective real-time disinfection of the probes after use and the probes are often reused, leading to the possibility of the probes carrying multiple pathogenic bacteria. At present, the processing methods for probes at home and abroad mainly include probe cleaning, probe disinfection, and physical isolation (using probe covers or sheaths). Yet, each approach has its limitations and cannot completely prevent probe contamination and infections caused by ultrasound diagnosis and treatment. For example, when condoms are used as the probe sheath, the rate of condom breakage is relatively high. The cutting and fixing of cling film or freezer bags involves complicated procedures and is difficult to perform. Disposable plastic gloves are prone to falling off and causing contamination and are hence not in compliance with the principles of sterility. Furthermore, the imaging effect of disposable plastic gloves is poor. Therefore, there is an urgent need to explore new materials to make probe covers that can not only wrap tightly around the ultrasound probe, but also help achieve effective protection and rapid reuse. Based on the concept of physical barriers, we developed in this study a heat sealing system for the rapid reuse of ultrasound probes. The system uses a heat sealing device to shrink the protective film so that it wraps tightly against the surface of the ultrasound probe, allowing for the rapid reuse of the probe while reducing the risk of nosocomial infections. The purpose of this study is to design a heat sealing system for the rapid reuse of ultrasound probes and to verify its application effect on the rapid reuse of ultrasound probes. **Methods** 1) The heat sealing system for the rapid reuse of ultrasound probes was designed and tested by integrating medical and engineering methods. The system included a protective film (a multilayer co-extruded polyolefin

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△ 通信作者，E-mail: zhanglinjuan029@163.com
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thermal shrinkable film) and a heat sealing device, which included heating wire components, a blower, a photoelectric switch, temperature sensors, a control and drive circuit board, etc. According to the principle of thermal shrinkage, the ultrasound probe equipped with thermal shrinkable film was rapidly heated and the film would wrap closely around the ultrasound probe placed on the top of the heat sealing machine. The ultrasound probe was ready for use after the thermal shrinkage process finished. Temperature sensors were installed on the surface of the probe to test the thermal insulation performance of the system. The operation procedures of the system are as follows: placing the ultrasound probe covered with the protective film in a certain space above the protective air vent, which is detected by the photoelectric switch; the heating device heats the thermal shrinkable film with a constant flow of hot air at a set temperature value. Then, the probe is rotated so that the thermal shrinkable film will quickly wrap around the ultrasound probe. After the heat shrinking is completed, the probe can be used directly. 2) Using the convenience sampling method, 90 patients from the Department of Anesthesiology and Perioperative Medicine, the First Affiliated Hospital of Xi'an Jiaotong University were included as the research subjects. All patients were going to undergo arterial puncture under ultrasound guidance. The subjects were divided into 3 groups, with 30 patients in each group. Three measures commonly applied in clinical practice were used to process the probes in the three groups and water-soluble fluorescent labeling was applied around the puncture site before use. In the experimental group, the probes were processed with the heat sealing system. The standard operating procedures of the heat sealing system for rapid reuse of ultrasonic probes were performed to cover the ultrasonic probe and form a physical barrier to prevent probe contamination. There were two control groups. In control group 1, disinfection wipes containing double-chain quaternary ammonium salt were used to repeatedly wipe the surface of the probe for 10-15 times, and then the probe was ready for use once it dried up. In the control group 2, a disposable protective sheath was used to cover the front end of the probe and the handle end of the sheath was tied up with threads. Comparison of the water-soluble fluorescent labeling on the surface of the probe (which reflected the colony residues on the surface of the probe) before and after use and the reuse time (i.e., the lapse of time from the end of the first use to the beginning of the second use) were made between the experimental group and the two control groups. **Results** 1) The temperature inside the ultrasound probe was below 40 ℃ and the heat sealing system for rapid reuse did not affect the performance of the ultrasound probe. 2) The reuse time in the heat sealing system group, as represented by (median [P_{25}, P_{75}]), was (8.00 [7.00, 10.00]) s, which was significantly lower than those of the disinfection wipe group at (95.50 [8.00, 214.00]) s and the protective sleeve group at (25.00 [8.00, 51.00]) s, with the differences being statistically significant (P<0.05). No fluorescence residue was found on the probe in either the heat sealing system group or the protective sheath group after use. The fluorescence residue in the heat sealing system group was significantly lower than that in the disinfection wipes group, showing statistically significant differences (χ^2=45.882, P<0.05). **Conclusion** The thermal shrinkable film designed and developed in this study can be cut and trimmed according to the size of the equipment. When the film is heated, it shrinks and wraps tightly around the equipment, forming a sturdy protective layer. With the heat sealing system for rapid reuse of ultrasonic probes, we have realized the semi-automatic connection between the thermal shrinkable film and the heating device, reducing the amount of time-consuming and complicated manual operation. Furthermore, the average reuse time is shortened and the system is easy to use, which contributes to improvements in the reuse and operation efficiency of ultrasound probes. The heat sealing system reduces colony residues on the surface of the probe and forms an effective physical barrier on the probe. No probes were damaged in the study. The heat sealing system for rapid reuse of ultrasonic probes can be used as a new method to process the ultrasonic probes.

【Key words】 Ultrasound equipment　Ultrasound probe　Rapid reuse　Infection　Medical devices

超声诊疗简便快速，因兼具无创及实时动态的特点而被临床广泛应用。在超声诊疗过程中，探头可能接触人体皮肤、黏膜，甚至无菌部位，但其使用后难以实现有效的实时消毒，往往重复使用，导致其可能携带多种致病菌[1-2]。数据显示，国外医用超声探头的细菌污染率在17.5%～67.0%[3]，国内探头污染率多数在50%以上[4]。目前国内外针对探头的处理方式主要包括探头清洁、探头消毒和物理隔离(探头覆盖物)，但各有弊端，并不能完全避免探头的污染和因超声诊疗导致的感染[5]。国际上推荐尽量使用探头覆盖物预防感染[4-6]，但避孕套破损率较高[7-8]；保鲜膜及冷冻袋剪裁固定繁琐，不易操作；一次性塑料手套容易脱落造成污染，不符合无菌原则，且显影效果不佳。因此急需探索新材料，使得探头覆盖物既紧密贴合于超声探头又可以做到有效防护和快速复用。基于此，本研究以物理屏障理念为基础，研发一套快速复用热封系统，即利用热封装置将防护膜收缩紧贴于超声探头表面，为达到探头快速复用，降低院内感染风险提供条件。本设计已获国家实用新型专利(专利号ZL202021606094.4)，

现报道如下。

1 材料与方法

1.1 快速复用热封系统结构设计

本研究设计的快速复用热封系统包括防护膜、热封主机两部分。

1.1.1 防护膜

防护膜为快速复用热封系统的基础物理屏障,本研究以多层共挤聚烯烃(polyolefin, POF)热收缩膜为原材料。POF具有低温下稳定、收缩后柔软的强度特点,在拉伸强度检测中效果最佳(表1),适用于本研究设计的医疗环境。

表 1 热缩膜材料拉伸强度检测

Table 1 Tensile strength testing of polyolefin heat shrinkable film

Parameter	Standard film	Low-temperature film
Shrinkage	45%-55%	65%-75%
Transparency	98.5%	99.0%
Transverse heat sealing strength	0.68 N/mm	1.35 N/mm
Longitudinal heat sealing strength	0.65 N/mm	1.30 N/mm
Transverse tearing strength	10.0 g	14.0 g
Longitudinal tearing strength	10.5 g	13.0 g
Transverse tensile strength	110 N/mm^2	85 N/mm^2
Longitudinal tensile strength	115 N/mm^2	95 N/mm^2

1.1.2 热缩主机

热缩主机为防护膜收缩的辅助装置,包括加热丝组件、鼓风机、光电开关、温度传感器及控制和驱动电路板等部分。具体工作原理为:光电开关1和2检测到热封主机出风口上方的超声探头(覆盖防护膜)→MCU读取温度传感器后检测出风口温度,据此调整加热丝的加热功率和鼓风机转速(短时间内使出风口温度升高并稳定于设定范围)→驱动板将控制板输出的控制信号转化为大功率驱动信号,实现加热丝和鼓风机驱动。同时,也可将充电电池输出电压变换为控制板所需的电压值。

1.2 快速复用热封系统使用方法

将加装有防护膜的超声探头放置于防护出风口上方一定空间内,被光电开关检测到,主机以设定温度值的恒定热风加热热缩膜,通过旋转探头达到热缩膜快速贴合超声探头,热缩结束后可直接使用,见图1。

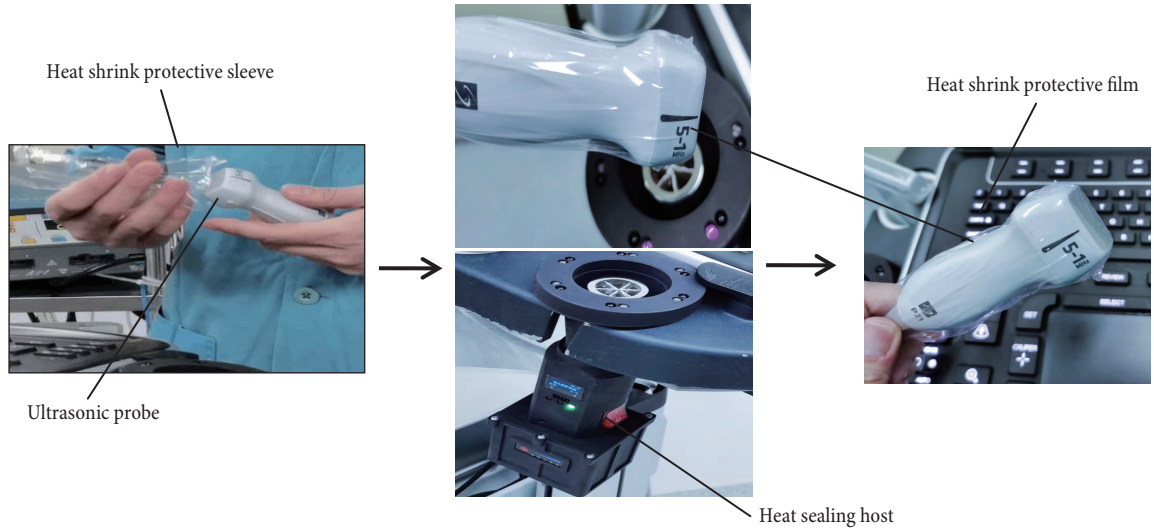

图 1 快速复用热封系统使用方法

Fig 1 The procedures of operating the heat sealing system for rapid reuse of ultrasonic probes

1.3 快速复用热封系统性能检测

为防止超声探头的电子元件在热封过程中遭到高温损坏,因此对本研究设计的快速复用热封系统进行隔热性能测试。分析超声探头结构得出:①超声探头头端为压电陶瓷或晶体(实现超声波的产生、传导及回波接收),是热缩过程的主要加热区域,一般适用温度范围为−40 ~ 80 ℃;②超声探头手柄为电子电路,热缩过程中加热时间短并有非金属外壳阻隔,其工作温度可达120 ℃,故不考虑此部分。

测试方法为:于探头表面分别安装温度传感器(DS18B20),其中外壳正面、背面端部中间位置的标号为T1、T5,在超声探头内部,与T1、T5对应的位置及声透镜内部中间位置的标号分别为T2、T4、T3,见图2。采用stm32f103c8t6系统版读取热水器出风口温度,间隔采集T1 ~ T5温度数值,使用串口调试助手(XCOM V2.0)进行温度接收。

根据快速复用热缩系统标准操作方法,对装有防护膜的超声探头进行测试。采用STM32f103c8t6系统版读取热水器出风口温度(Pt100为该加温装置自身产热温

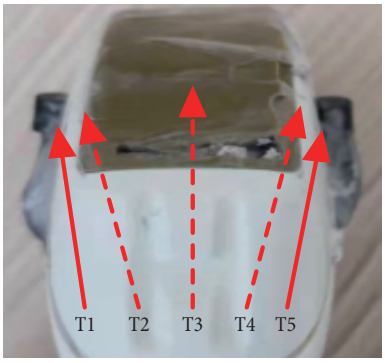

图 2 超声探头温度传感器布局

Fig 2 The layout of the temperature sensor on the ultrasonic probe

T1: ultrasonic probe housing front; T2: the inside of the ultrasonic probe housing front; T3: the middle of the acoustic lens; T4: the back of the ultrasonic probe housing; T5: the inside backside of the ultrasonic probe housing.

度)，间隔采集T1 ~ T5温度数值，使用串口调试助手(XCOM V2.0)进行温度接收。结果显示：在热缩机无预热冷启动及预热后热启动条件下，超声探头内部的温度均低于40 ℃，温度变化见图3 ~ 图4。实际临床应用时，5 s即可完成热缩操作，超声探头及其内部结构的温升将更低。因此本研究认为，快速复用热缩系统尚不会影响超声探头性能。

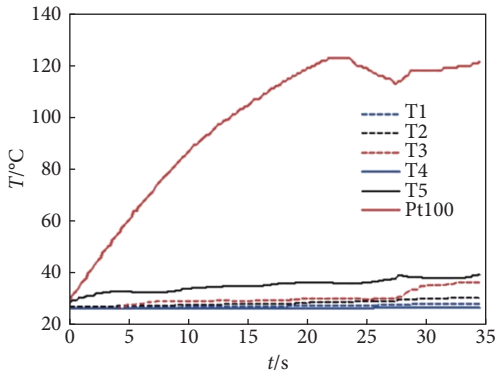

图 3 冷机启动的热缩温升曲线

Fig 3 Temperature rise curve when the heat sealing system starts working on a cold start

T1: ultrasonic probe housing front; T2: the inside of the ultrasonic probe housing front; T3: the middle of the acoustic lens; T4: the back of the ultrasonic probe housing; T5: the inside backside of the ultrasonic probe housing. Pt100 is the heat production temperature of the heating device itself.

1.4 快速复用热封系统效果验证

1.4.1 研究对象

2022年7月，超声探头快速复用热封系统于我院麻醉手术部投入使用。我院为中华医学会麻醉学分会“区域麻醉培训基地”，在超声穿刺和临床使用方面有着丰富的经验和操作标准，且在全国麻醉手术科室内，经皮超声引导的动脉穿刺技术是超声探头最常见的使用场景之一，故课题组采用方便抽样法选取超声引导下动脉穿刺患者

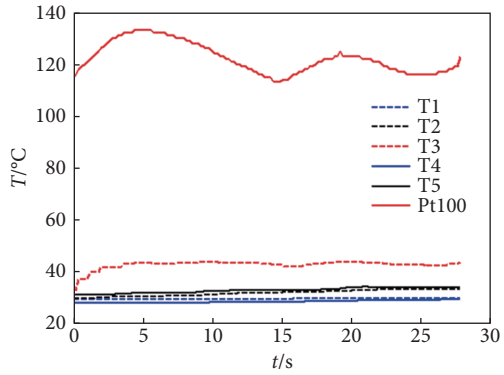

图 4 热机启动的热缩温升曲线

Fig 4 Temperature rise curve when the heat sealing system starts working on a hot start

All abbreviations are given in the footnote to Fig 3.

90例作为研究对象，样本量达到后停止。纳入标准：①经皮动脉穿刺患者；②患者知情同意。排除标准：①患者穿刺处皮肤破损；②患者有皮肤病。本研究已通过西安交通大学第一附属医院生物伦理委员会批准，伦理注册号KYLLSLL-2021-206、伦理批文号2021年审235号。

1.4.2 研究方法

样本分为实验组、对照组1、对照组2，每组30例，分别采用3种临床常用措施对探头进行保护，在使用前对穿刺部位周围进行水溶性荧光标记。实验组为热封系统组，由课题组成员采用快速复用热封系统标准操作方法保护超声探头后交由麻醉医生使用。对照组1为消毒湿巾组，由麻醉医生按照标准操作流程采用双链季铵盐消毒湿巾反复擦拭探头表面10~15次后待干；对照组2为保护套组，由麻醉医生按照标准操作流程采用一次性使用腔镜保护套覆盖探头前端，手柄部位采用线绳结扎。由研究者本人(工作8年)进行实验结果的评价，对比探头使用前后各组荧光标记残留有无及复用时间(第一次使用结束至第二次使用开始前所用时间)。

1.5 统计学方法

将实验组(热封系统组)与两对照组(消毒湿巾组、保护套组)数据进行分别比较。采用SPSS 26.0统计软件进行数据分析，Shapiro-Wilk检验正态分布，计量资料服从正态分布的采用$\bar{x} \pm s$表示，两组间比较采用t检验；不服从正态分布的采用中位数(P_{25}, P_{75})表示，两组间比较采用秩和检验。计数资料采用构成比表示，组间采用卡方检验进行比较。P< 0.05为差异有统计学意义。

2 结果

2.1 各组探头复用后荧光残留情况比较

见图5。结果显示：热封系统组与保护套组的30组数

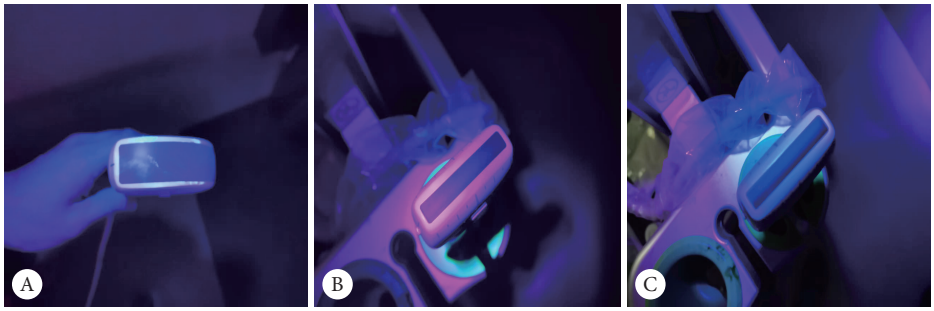

图 5 各组探头荧光标记残留对比

Fig 5 Comparison of the fluorescence label residues on the probes in each group

A, Disinfection wipes; B, protective sheath; C, fast reuse system.

据表明使用后均未见荧光残留，消毒湿巾组共30例，26例存在荧光残留，4例无荧光残留，热封系统组荧光残留显著少于消毒湿巾组，差异有统计学意义（$\chi^2=45.882$，$P<0.05$）。

2.2 各组探头保护措施复用时间比较

实验组与两对照组分别比较，热封系统组复用时间少于消毒湿巾组和保护套组，两组差异均有统计学意义（$P<0.05$），见表2。

表 2 实验组与两对照组复用时间比较

Table 2 Comparison of the reuse time between disinfection wipes group and the fast reuse system group

Group	*n*	Reuse time/s, median(P_{25}, P_{75})
Fast reuse system	30	8.00 (7.00, 10.00)
Disinfection wipes	30	95.50 (8.00, 214.00)*
Protective sheath	30	25.00 (8.00, 51.00)*

* $P<0.001$, vs. fast reuse system group.

3 讨论

3.1 快速复用热封系统能为超声探头提供有效的物理屏障

《基层医疗机构医院感染管理基本要求》规定[9]：超声探头（经皮肤，黏膜或经食管、阴道、直肠等体腔进行超声检查）须做到一人一用一消毒或隔离膜等。本研究设计研发的快速复用热封系统的基本组成部分——热缩膜属于一种隔离膜，且研究结果显示：覆盖热缩膜的超声探头使用后荧光残留显著少于消毒湿巾（$P<0.05$），与HUNTER等[10]和BIDDLE等[11]的结果一致。此外，目前我国尚无官方批准使用的探头专用消毒产品，更缺乏现有消毒方法是否损坏探头性能的实验与评价[12]。本研究所提出的快速复用热封系统能够为超声探头提供有效的物理屏障，且实验过程中未损坏探头性能，可以作为探头处理的新方法。

3.2 快速复用热封系统能提高超声探头复用和运行效率

消毒剂可能对超声探头有损伤作用，而低温等离子灭菌方法时间较长，市场需要对超声探头表面快速消毒而不损坏超声探头的消毒方法[13]。本研究结果显示：快速复用热封系统复用时间仅为8.00（7.00, 10.00）s，显著少于消毒湿巾及保护套。此外，谭莉等[14]也提出检查结束后加用消毒湿巾消毒探头虽有成效，但增加操作步骤，可能影响执行率。而本研究研发设计的快速复用热封系统，参照工业化热封技术，实现POF热缩膜与主机的半自动化联动，减少耗时复杂的人为操作，大大缩短复用时间，提高医务人员的可执行性。因此，快速复用热封系统能提高超声探头复用和运行效率。

3.3 快速复用热封系统适于在多设备、多情境、大范围推广

既往研究显示：手术室用物回收清洁时，非关键物品（如麻醉机、监视器、计算机、超声仪器以及气管插管物品的屏幕和手柄等）清洁力度往往不够，很多机器设备由于功能材料设计的原因，常规消毒、清洁灭菌几乎不可能实现，因而成为一个潜在传染源。以LIE等[15]为代表的做法是用塑料将仪器设备进行简单包裹，但针对超声波机器的一次性探针等特殊尺寸设备时，只能采用不同角度多层套叠覆盖的方式将设备全部包裹，既不牢固也不美观。而本研究设计研发的热缩膜可针对设备尺寸、大小随意切割剪裁，热缩后能对设备进行紧密贴附和包裹，不仅适用于多种仪器设备，还牢固美观，能够解决医院感染标准防护中的多种难题。此外，以POF为原材料的热缩膜来源广泛，价格低廉，可以满足各层级医院的使用需求，适于各层级医院推广。

本研究的快速复用热封系统测试效果良好，降低了探头细菌污染率，且提高超声探头复用和运行效率，保障了患者安全。此外，POF为原材料的热缩膜来源广泛，成本低，减轻了患者经济负担。该装置已成功应用于临床，

后期将收集更多有效数据,来探讨其设备有效性和安全性,针对医务人员使用体验和患者安全持续改进,深入进行产品更新和转化。未来有望应用于所有使用超声检查的患者,提高患者和医务人员的体验感和满意度,为降低超声探头细菌污染率提供新思路。

*　　*　　*

作者贡献声明　吴坷负责论文构思、数据审编、正式分析、经费获取、调查研究、研究方法、验证、可视化和初稿写作,李俊杰负责论文构思、数据审编、研究方法、软件、验证和审读与编辑写作,张琳娟负责论文构思、研究项目管理、提供资源、监督指导和审读与编辑写作。所有作者已经同意将文章提交给本刊,且对将要发表的版本进行最终定稿,并同意对工作的所有方面负责。

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