



# Clinical study of antibacterial medical textiles containing polyhydroxyalkanoate oligomers for reduction of hospital-acquired infections

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## SUMMARY

**Introduction:** The prevention and control of hospital-acquired infections remain a significant challenge worldwide, as textiles used in hospital wards are highly involved in transmission processes. This paper reports a new antibacterial medical fabric used to prepare hospital pillowcases, bottom sheets and quilt covers for controlling and reducing hospital-acquired infections.

**Method:** The medical fabric was composed of blended yarns of staple polyester (PET) and degradable poly(3-hydroxybutyrate co-3-hydroxyvalerate) (PHBV)/polylactic acid (PLA) fibres, which were coated with polylactide oligomers (PLAO), which are environmentally friendly and safe antimicrobial agents with excellent thermal stability in high-temperature laundry. A clinical trial was conducted, with emphasis on the bacterial species that were closely related to the infection cases in the study hospital.

**Result:** After 7 days of use, 94% of PET/PHBV/PLA-PLAO fabric retained <20 colony-forming units/100 cm<sup>2</sup> of the total bacterial amount, meeting hygiene and cleanliness standards.

**Conclusion:** This study demonstrates the potential of fabrics containing polyhydroxyalkanoate oligomers as highly effective, safe and long-lasting antimicrobial medical textiles that can effectively reduce the incidence of hospital-acquired infections.

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## Introduction

Millions of patients are affected by hospital-acquired infections (HAIs) worldwide every year, threatening the safety of patients, staff and visitors [1], and resulting in elevated rates of re-admission and mortality [2]. These infections also extend hospital stays and increase healthcare expenditure [3,4]. Many efforts have been made to prevent and control HAIs. Hospital textiles, such as bed linen, pillows and curtains, play a crucial role in the HAI transmission route [5,6], especially for the health care of inpatients. Hospital textiles become contaminated due to the attachment of biofilms generated by bacteria during use [7–10]. Additionally, certain human bodily fluids, such as sweat, sebum, and highly exudate or purulent wounds, facilitate the rapid growth and multiplication of micro-organisms. Therefore, it is important to use hospital textiles with antimicrobial properties to reduce the risk of HAIs. Hospital bedding is typically composed of cotton, polyester fibres or both because of the good shrinkage resistance of polyester and the softness of cotton. However, both cotton and polyester exhibit poor antibacterial properties, and cotton can promote bacterial growth [11].

Disinfection is currently the main method used to prevent the transmission of pathogens through textiles, and is typically achieved by employing high-temperature laundering techniques [12,13]. In a standard washing cycle, medical textiles should be washed at a temperature of at least 71 °C (160 °F) for at least 3 min to ensure effective disinfection [14]. Additionally, these washed textiles need to be dried at >100 °C and ironed at approximately 165 °C. Although the aforementioned standard washing procedure can guarantee the cleanliness of hospital textiles prior to usage, these fabrics may be contaminated rapidly during use, primarily because of the lack of effective antibacterial properties. Moreover, a period of 5–7 days is generally adopted for the use of textiles in hospitals, which may pose a high risk of HAI transmission. Therefore, high-temperature laundering cannot satisfy the requirements for HAI prevention, and there is high demand for the development of antimicrobial textiles.

A general strategy is to endow textiles with antibacterial activity by coating or finishing with various antibacterial agents [15,16]. Organic and inorganic antibacterial agents are commonly applied, including nanomaterials [17,18], metal ions [19] and quaternary ammonium acids [20]. These materials exhibit rapid and efficient bactericidal properties; however, they pose challenges pertaining to environmental pollution, high cytotoxicity, complex fabrication and high cost [21]. Alternatively, bio-based antibacterial materials such as essential oils (EOs), chitosan and lactic acid (LA) can be used. Specifically, EOs have proven to be effective antibacterial adjuvants in the cosmetics and food industries, although they are sensitive to temperature, light and oxygen availability [22,23]. LA is commonly used as a food additive due to its potent bactericidal activity [24]. However, bio-based antibacterial materials demonstrate inadequate thermal stability, and cannot withstand high temperatures during hospital laundry processes. Bio-based polyhydroxyalkanoate oligomers are a new group of green antimicrobial agents. Previously, the authors reported the discovery of two members of this family – poly(3-

hydroxybutyrate) oligomers (PHBO) and polylactide oligomers (PLAO) [25,26] – with comparable antibacterial properties against *Staphylococcus aureus* and *Escherichia coli*, and much higher thermal stability than LA. Based on these discoveries, novel medical fabrics were developed successfully from degradable blend fibres composed of poly(3-hydroxybutyrate-co-3-hydroxyvalerate) and polylactic acid (PHBV/PLA). Fibres containing the active antibacterial agent PHBO are mainly generated by the thermal degradation of PHBV during a controlled melt extrusion process [26]. The resultant knitted fabrics exhibit excellent textile characteristics, and demonstrate effective bactericidal properties [27].

This study was conducted in two phases: In phase 1, the authors designed and fabricated woven fabrics with yarns made from polyester (PET)/PHBV/PLA staple fibres, whose physical properties and laundry performance are comparable with the common PET/cotton fabrics used in hospitals. The fabrics were then coated with another family of polyhydroxyalkanoates and PLAO. The antibacterial performance of the PET/PHBV/PLA fabrics with and without PLAO coating during high-temperature laundering was investigated. Additionally, the biosafety and thermal stability of these fabrics and their underlying antimicrobial mechanisms were evaluated. In phase 2, a clinical trial was conducted to assess the sustained effects of bed linen made of PET/PHBV/PLA-PLAO against the identified HAI-associated bacteria during usage in hospital wards.

## Methods

### Materials

L-LA (≥85%) was obtained from Aladdin Co. Ltd, and PHBV fibres were obtained from Ningbo Hesu Fibers Co. Ltd. *S. aureus* (ATCC No. 6538), *E. coli* (ATCC No. 25922), *Pseudomonas aeruginosa* (ATCC No. 27853), *Haemophilus influenzae* (ATCC No. 33930), *Enterococcus faecalis* (ATCC No. 29212) and *Stenotrophomonas maltophilia* (ATCC No. 17666) were purchased from Shanghai Beinuo Biotechnology Co., Ltd.

### Methods

#### Measurements of physical properties of textiles

Optical images of the PET/cotton and PET/PHBV/PLA fabrics were obtained using light microscopy. The warp and weft mechanical properties of the PET/cotton and PET/PHBV/PLA fabrics were evaluated using the Instron system in accordance with the ASTM D5034 standard. The filling performance of the PET/cotton and PET/PHBV/PLA fabrics was evaluated using the Martindale method (ASTM D4966-12). The flexural rigidities of the PET/cotton and PET/PHBV/PLA fabrics in the warp and weft were measured in accordance with the ASTM D1388 standard. The permeation resistance of the fabric to air is generally affected by the fibres' cross-sectional shape and dimensions, yarn structure and fabric structure. A KES-F8-AP1 tester was used to measure the permeability resistance of the fabrics to air. A KES-F8-AP1 air permeability tester was designed to measure the breathability and permeability of a wide range of samples quickly and accurately.

### Synthesis of PLAO

L-LA was used, as received, without further purification. L-LA was added to the reactor under nitrogen protection, stirred, and heated to 160–200 °C, then maintained for >4 h. The vacuum pressure in the reactor was maintained in the range of 1–2 MPa. After the reaction was complete, the reactor temperature was allowed to decrease to room temperature naturally, and PLAO was collected as a transparent and viscous liquid.

### In-vitro antibacterial test

*Pseudomonas aeruginosa* (ATCC 27853), *H. influenzae* (ATCC 33930), *E. faecalis* (ATCC 29212) and *S. maltophilia* (ATCC 17666) were used to investigate the antimicrobial properties of PLAO in accordance with the ASTM E2149-13a test method [28]. The micro-organisms were cultured overnight in brain heart infusion broth at 37 °C, diluted to approximately 10<sup>5</sup> colony-forming units (CFU)/mL with phosphate-buffered saline (PBS), and incubated with 0.01 g/mL PLAO on a shaking bed at 24 °C for 1 h. Bacteria incubated without PLAO served as negative controls. Subsequently, bacteria were diluted to 10<sup>2</sup> CFU/mL, spread on an agar plate, and cultivated for 18 or 48 h at 37 °C. Antibacterial activity was calculated using the following equation:

$$\text{Antibacterial rate} = \left(1 - \frac{\text{CFU}_{\text{PLAO}}}{\text{CFU}_{\text{control}}}\right) \times 100\%$$

*S. aureus* (ATCC No. 6538) and *E. coli* (ATCC No. 25922) were used as Gram-positive and Gram-negative bacteria, respectively, to test the antibacterial activity of the fabrics before and after washing, in accordance with the AATCC 100 standard.

### Bio-safety test

This study used guinea pigs to observe skin sensitization of the test article in accordance with ISO 10993-10:2010. PLAO was diluted with PBS to a concentration of 100 mg/mL, and used directly in the test. The gauze was cut into 8-cm<sup>2</sup> pieces and used in the test. The volumes of the control and test samples (approximately 0.5 mL) were sufficient to saturate the gauze. PLAO was administered topically to the clipped left upper back region of each animal using appropriate patches. The restrainer of any occlusive dressings and patches was removed after 6 ± 0.5 h. This procedure was performed 3 days per week for 3 weeks. Approximately 14 ± 1 days after the last induction application, appropriate gauze patches soaked with the test materials were applied topically to the previously untested area of each animal. After a period of 6 ± 0.5 h, the restrainer, occlusive dressings and gauze patches were removed. Twenty-four and 48 h after gauze patch, daily challenge observation scores were recorded, referring to the classification system for skin reactions. Before each scoring period, the site was wiped gently with a gauze sponge soaked in a 0.9% saline solution. The challenge sites were then observed for signs of irritation and sensitization reactions such as erythema and oedema. Additionally, the fur was shaved or clipped to facilitate dermal scoring. Blank liquid was administered in the control group.

### Clinical trial

The clinical trial protocol was approved by the Medical Ethics Committee of the University of Hong Kong–Shenzhen Hospital. The authors referred to other textile clinical trials, and designed the following process based on the bed linen used

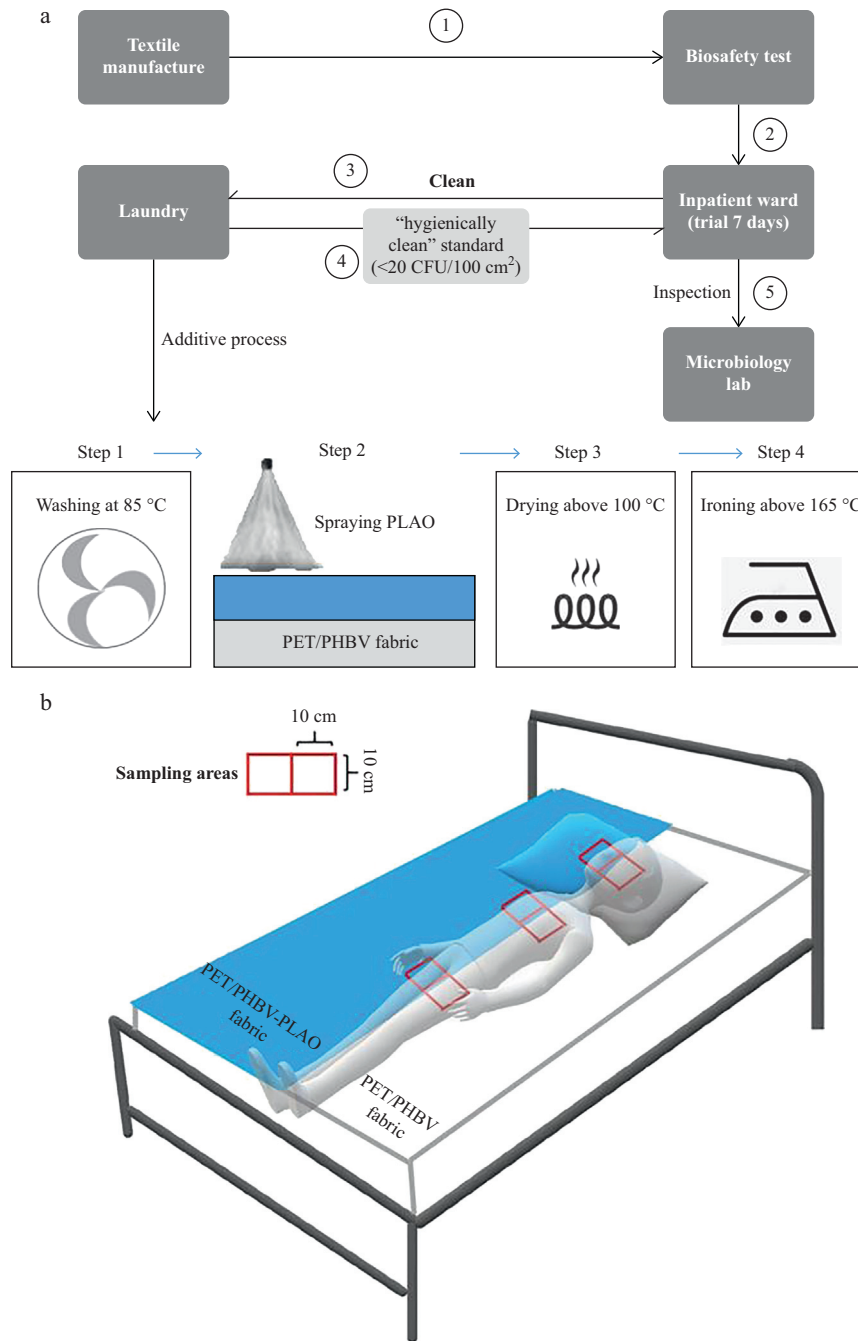
in this work [29,30]. Figure 1a illustrates the design of the clinical trial protocol. Newly developed antimicrobial PET/PHBV/PLA textiles, including quilt covers, bottom sheets and pillowcases, were mass-produced to match the specifications of the original hospital fabric (PET/cotton). The biosafety of the PLAO and PET/PHBV/PLA fabrics was assessed to ensure that there were no adverse effects on human health. After washing and drying, half of each PET/PHBV/PLA fabric was spray-coated with PLAO, labelled 'PET/PHBV/PLA-PLAO fabric', and the other half was labelled 'PET/PHBV/PLA fabric' (Figure 1b). The fabrication of the PET/cotton-PLAO and PET/cotton fabrics followed the same principles. Two 10 × 10 cm<sup>2</sup> squares were marked by sewing in specific areas, such as the head, chest and buttocks, which were in close contact with the patients' bodies. This resulted in four sampling groups: PET/cotton fabric group; PET/cotton-PLAO fabric group; PET/PHBV/PLA fabric group; and PET/PHBV/PLA-PLAO fabric group. Following cleaning procedures that met the hygiene standards (<20 CFU/100 cm<sup>2</sup>), 10 sets were selected at random from each group to assess bacterial survival rates. These textiles were subsequently utilized by patients for 7 days. During the trial, 50 participants were assigned at random to either the PET/cotton group or the PET/PHBV/PLA group. After 7 days, microbial samples were collected from 100 cm<sup>2</sup> areas of the bottom sheets, quilt covers and pillowcases. Samples were sent to the microbiology laboratory within 2 h for further analysis. Questionnaires were also administered to patients. The total bacterial count and detection rate of six bacteria in the textiles were determined as the average values from the participants' pillowcases, bottom sheets and quilt covers. All clinical data were the averages of sheets, covers and pillowcases used by the same patient. Data are presented as mean ± standard deviation (SD).

## Results and discussion

### Phase 1: non-patient contact studies

#### Past statistical data of HAI cases

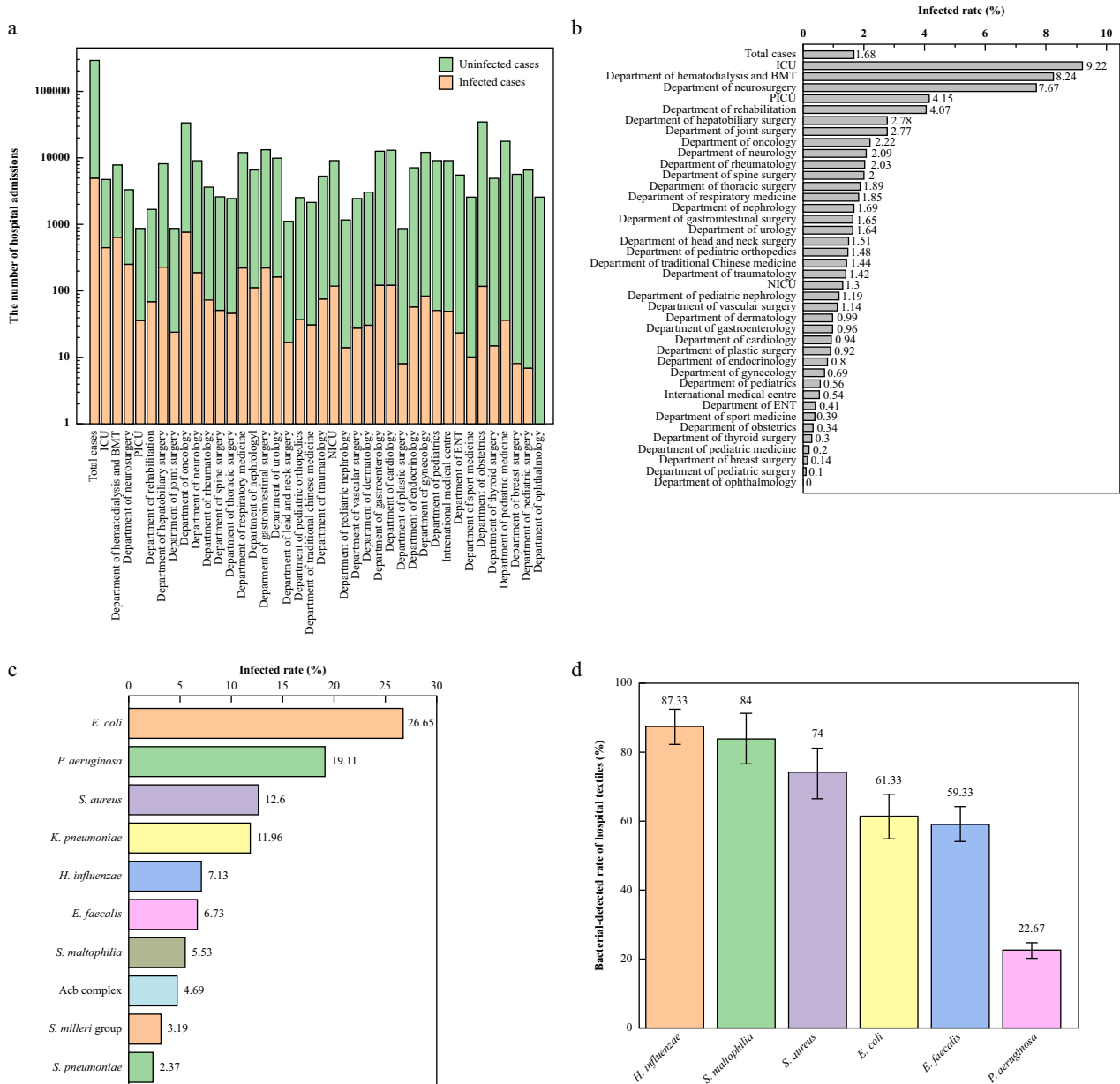
Statistical data on infection cases and pathogenic bacteria over the past 5 years were collected from an inpatient hospital, The University of Hong Kong–Shenzhen Hospital, in Shenzhen City, China. The total number of patient admissions across the 40 hospital departments between 2016 and 2020 was 291,095 (Figure 2a). Over the course of 5 years, 4896 cases of HAI were identified, resulting in an average rate of HAIs of 1.68% at this hospital (Figure 2b). Based on the incidence of infection, the 40 departments were categorized into four levels. Among them, the intensive care unit exhibited the highest infection rate, with prevalence more than four times higher than the average at 9.22%, followed by haemodialysis and bone marrow transplantation at 8.24%, and neurosurgery at 7.67%. Additionally, both the paediatric intensive care unit and rehabilitation had infection rates exceeding twice the average, with values of 4.15% and 4.07%, respectively. Nine departments demonstrated infection rates higher than the average, and 25 departments had lower rates than the average observed during this period. Notably, ophthalmology achieved exceptional results, with no reported cases of acquired infection in a total sample size of approximately 2580 patients (Figure 2b). Furthermore, analysis based on hospital statistics revealed that



**Figure 1.** (a) Protocol of clinical trial (b) Schematic diagram of the preparation process of poly(lactide oligomer) (PLA0)-sprayed polyester (PET)/poly(3-hydroxybutyrate-co-3-hydroxyvalerate)/poly(lactic acid) (PHBV) bedding fabrics. CFU, colony-forming units.

among all bacterial species causing HAIs during this time frame, *E. coli*, *P. aeruginosa*, *S. aureus* and *Klebsiella pneumoniae* accounted for approximately 26.65%, 19.11%, 12.6% and 11.96%, respectively. Other infectious bacteria, including *H. influenzae*, *E. faecalis*, *S. maltophilia*, *Acinetobacter calcoaceticus*–*Acinetobacter baumannii* complex, the *Streptococcus milleri* group and *S. pneumoniae* ranged from 7% to 2% (Figure 2c). Moreover, bacterial residue testing was performed on textiles utilized by patients selected at random from four

different departments based on four infection levels: neurosurgery (7.67%), rehabilitation department (4.06%), neurology (2.09%) and traditional Chinese medicine (1.44%). Each patient's textiles were used for 7 consecutive days without being contaminated with blood or urine. The textiles in all departments were composed of 65% polyester and 35% cotton (PET/cotton fabric). The six major bacteria responsible for HAIs could be detected on the PET/cotton fabric used, indicating that PET/cotton textiles in hospitals could serve as a



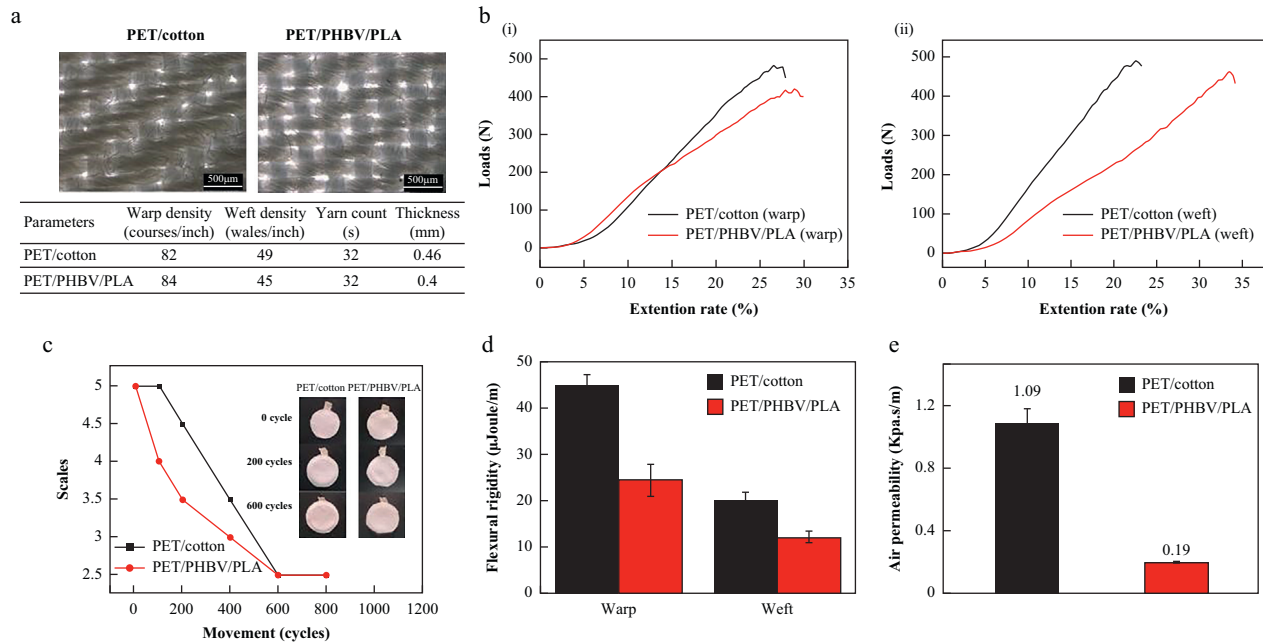
**Figure 2.** (a) Number of uninfected and infected cases in hospitals between 2016 and 2020. (b) Rate of hospital-acquired infections across 40 departments of the hospital over the study period. (c) Statistical data on the infection rate of pathogenic bacteria in the hospital from 2016 to 2020. (d) Bacteria detection rates of hospital textiles. ICU, intensive care unit; BMT, bone marrow transplantation; PICU, paediatric intensive care unit; NICU, neonatal intensive care unit; ENT, ear, nose and throat; *E. coli*, *Escherichia coli*; *P. aeruginosa*, *Pseudomonas aeruginosa*; *S. aureus*, *Staphylococcus aureus*; *K. pneumoniae*, *Klebsiella pneumoniae*; *H. influenzae*, *Haemophilus influenzae*; *E. faecalis*, *Enterococcus faecalis*; *S. maltophilia*, *Streptococcus maltophilia*; Acb, *Acinetobacter calcoaceticus*–*Acinetobacter baumannii* complex; *S. pneumoniae*, *Streptococcus pneumoniae*.

significant carrier of pathogenic bacteria, thereby increasing the potential risk of HAIs (Figure 2d).

*Physical properties of PET/PHBV/PLA fabric*

A 2/1 Twill woven fabric was made of 65% polyester (staple fibre, 35 mm in length and 1.5 D in fineness; D represents denier, mass in g per 9000 m length) and 35% PHBV/PLA (staple fibre, 35 mm in length and 1.5 D in fineness). Figure 3 shows the mechanical and surface properties of the PET/PHBV/PLA and PET/cotton fabrics as evaluated using the Instron, Martindale

and Kawabata evaluation systems. The PET/PHBV/PLA and PET/cotton fabrics exhibited similar densities and thicknesses (Figure 3a). For the load and extension of the two fabric samples, the PET/PHBV/PLA fabric exhibited a higher extension rate (28.9% in the warp and 33.5% in the weft direction) compared with the PET/cotton fabric (26.5% in the warp and 22.5% in the weft direction), as illustrated in Figure 3b. Both the PET/cotton and PET/PHBV/PLA fabrics exhibited slight pilling after 200 cycles of rubbing; however, severe pilling was observed after 600 cycles (Figure 3c). The cotton fabric has lower



**Figure 3.** (a) Optical images and specifications of polyester (PET)/cotton and PET/poly(3-hydroxybutyrate-co-3-hydroxyvalerate) (PHBV)/polylactic acid (PLA) fabrics. (b) Load-extension curves of PET/cotton and PET/PHBV/PLA fabrics in the warp and weft directions, respectively. (c) Pilling ratings of PET/cotton and PET/PHBV/PLA fabrics, respectively. (d) Flexural rigidity of PET/cotton and PET/PHBV/PLA fabrics in the warp and weft directions, respectively. (e) Air permeability of PET/cotton and PET/PHBV/PLA fabrics.

flexural stiffness in the warp and weft directions, which represents softer toughening (Figure 3d). In addition, the PET/cotton fabric features a high permeating resistance of 1.09 kPa s/m to the air (Figure 3e). The PET/PHBV/PLA fabric had a smaller value of 0.193 kPa/s than the control group, indicating that the PET/PHBV/PLA fabric had better air permeability. In summary, the PET/PHBV/PLA fabric exhibited similar mechanical properties but better softness and breathability than the control PET/cotton fabric.

#### Bio-safety test

Safety is crucial for bedding fabrics, which contact with human skin. The authors' previous work demonstrated the strong antibacterial efficacy and good biosafety properties of PET/PHBV/PLA fibres [26]. In the present study, PLAOL was used as a coating material on the fabric surface to enhance its antibacterial effects after high-temperature laundry. Therefore, a biosafety assessment of PLAOL was performed through skin irritation and skin sensitization tests according to the ISO10993-10:2010 standard, in which 100 mg/mL PLAOL/PBS solution was used. The results revealed no abnormal signs or

mortality during Buehler's test period (Table I). The weight of the guinea pigs were measured in both the control group and the PLAOL group, and it was observed that their weight increased normally. The skin sensitization scores 24 and 48 h after the challenge were determined to be 0 at both time points. No erythema, swelling or other skin-sensitizing reactions were observed. Additionally, there were no fatalities among the animals in either the control or test groups during the guinea pig maximization test (Table S1, see online supplementary material). The sensitization positive rate after 24 and 48 h of the challenge was also found to be 0.0% for both time points. Following intradermal induction in guinea pigs, PLAOL did not cause any abnormal skin reactions such as erythema or oedema. These results confirm that PLAOL concentrations <100 mg/mL do not induce irritant potency or skin sensitization.

#### Antibacterial test in vitro

The authors' previous study demonstrated that PLAOL exhibits exceptional antibacterial properties, with inactivation efficiencies surpassing 99.99% against *S. aureus* and 99.9%

**Table I**  
Skin sensitization results

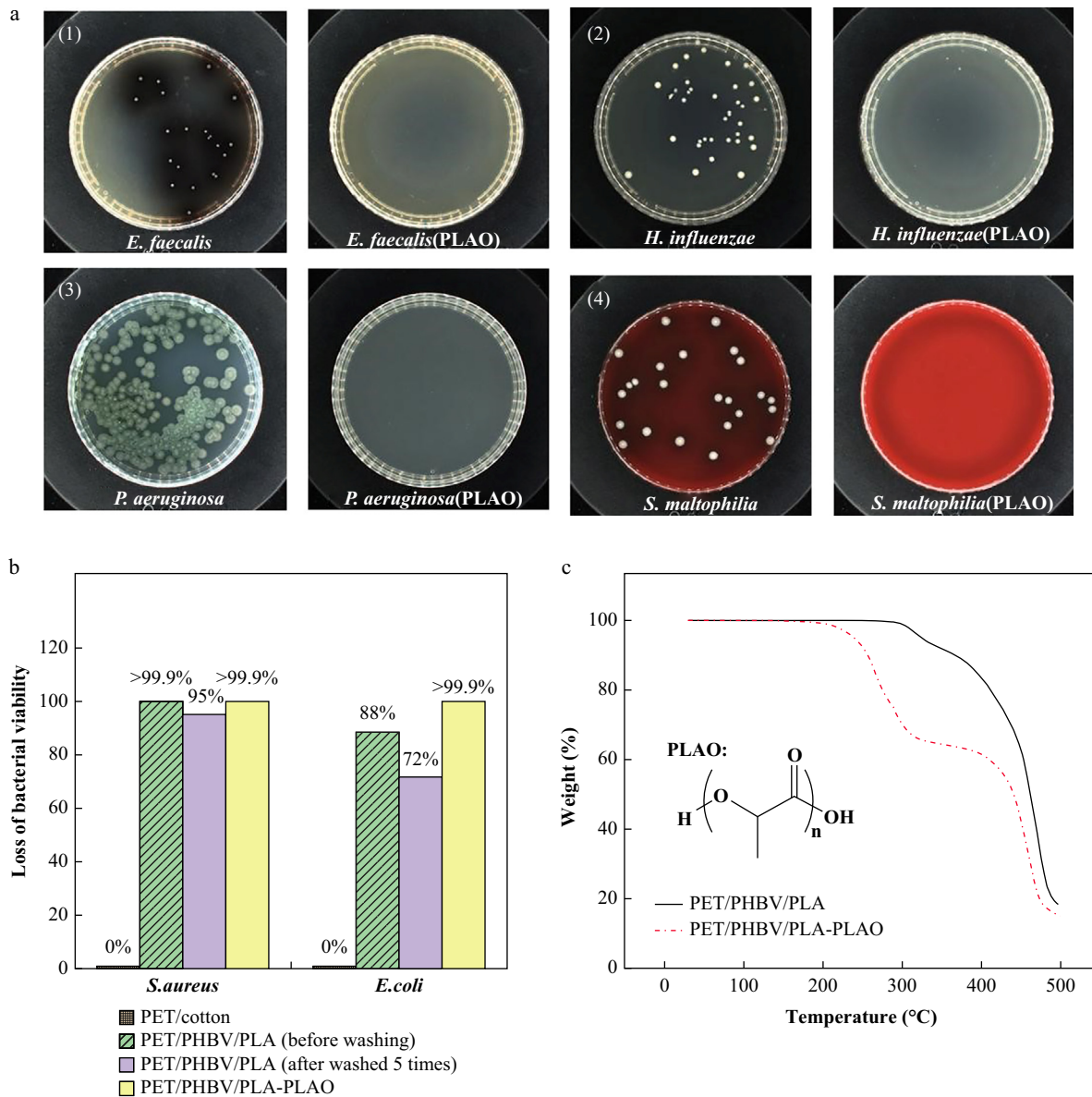
Group	Pretest weight (g)	Finished weight (g)	Challenge patch after removed 24 h		Challenge patch after removed 48 h		Sensitization rate
			Erythema	Swelling	Erythema	Swelling	
Control	308±3.03	368±4.57	0	0	0	0	0%
PLAOL	310±4.52	368±4.89	0	0	0	0	0%

PLAOL, polylactide oligomers; 0, no visible change; 1, discrete or patchy erythema; 2, moderate and confluent erythema; 3, intense erythema and/or swelling.

against *E. coli*. Additionally, PLAO demonstrated effective antimicrobial activity against *Candida albicans* and methicillin-resistant *S. aureus*, with values of 84% and 80.73%, respectively [25]. In the present study, the antibacterial efficacy of PLAO against other bacterial species associated with HAIs was investigated. After incubating for 1 h, PLAO exhibited excellent antibacterial efficacy, with an inactivation efficiency of 99.9% against *P. aeruginosa*, *H. influenzae*, *E. faecalis* and *S. maltophilia* (Figure 4a). Table S2 (see online supplementary material) shows that the total bacterial count was <1 CFU/g and the total fungal count was <4 CFU/g in the PLAO liquid after storage for 2 months. These results indicate that PLAO exhibited strong antibacterial activity without posing a risk of promoting the growth of unknown micro-organisms, thereby

enabling its potential use in antimicrobial medical fabrics. PET/PHBV/PLA fabric exhibited significant antibacterial effects before high-temperature washing, with an observed efficiency of >99.9% against *S. aureus* and approximately 88% against *E. coli* (Figure 4b). However, after five wash cycles, PET/PHBV/PLA fabric showed reduced effectiveness in inhibiting bacterial growth to approximately 95.8% against *S. aureus* and approximately 72% against *E. coli*. Nevertheless, the introduction of PLAO on to PET/PHBV/PLA fabric restored its antibacterial efficiency to >99.9% against *S. aureus* and *E. coli*.

Subsequently, the thermal stabilities of the PET/PHBV/PLA and PET/PHBV/PLA-PLAO fabrics were determined using thermogravimetric analysis (Figure 4c). The decomposition of PET/PHBV/PLA fabric starts at 300 °C, whereas the thermal stability



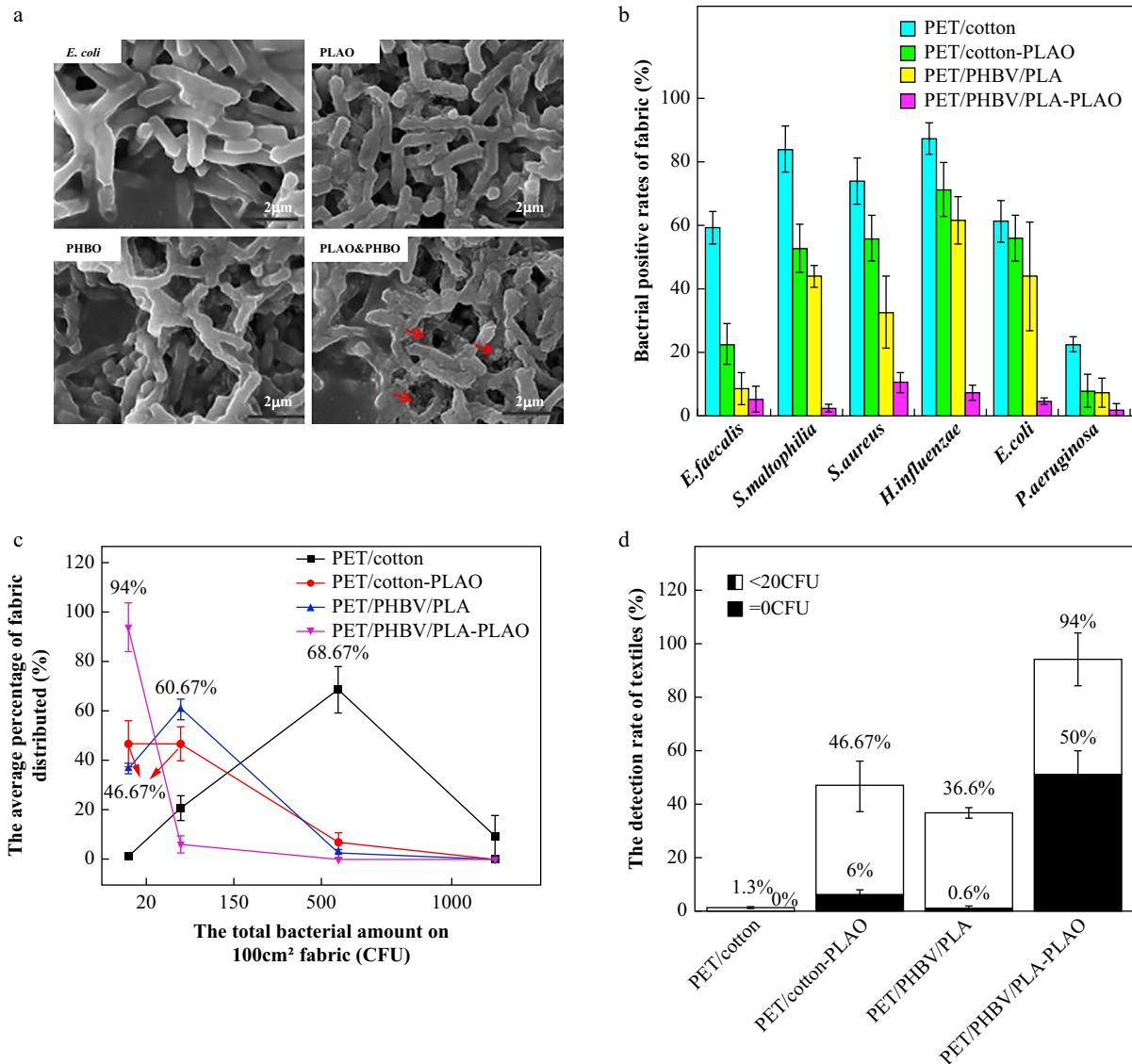
**Figure 4.** (a) Antibacterial ability of polylactide oligomers (PLAO) against *Pseudomonas aeruginosa*, *Haemophilus influenzae*, *Enterococcus faecalis* and *Streptococcus maltophilia*. (b) Antibacterial ability of polyester (PET)/cotton, PET/poly(3-hydroxybutyrate-co-3-hydroxyvalerate) (PHBV)/polylactic acid (PLA) fabric before washing, PET/PHBV/PLA fabric after washing five times, and PET/PHBV/PLA-PLAO fabric. (c) Thermal stability of PET/PHBV/PLA and PET/PHBV/PLA-PLAO fabrics.

of PET/PHBV/PLA-PLAO fabric is inferior to that of PET/PHBV/PLA fabric due to the decomposition of PLAO at approximately 230 °C. However, it is still acceptable as the highest temperature used during the hospital laundry programme is 165 °C. In contrast, PHBO started decomposing at only 167 °C, according to the authors' previous work, which may explain the decreased antibacterial properties of PET/PHBV/PLA fabric after the laundry process.

#### Antibacterial mechanisms

The enhancement mechanism of the PLAO-coated PET/PHBV/PLA fabric is described in this section. The minimum inhibitory concentrations (MICs) of PLAO, PHBO, and PLAO&PHBO (1:1) were measured using the broth dilution

method (Table S3, see online supplementary material) [31]. PHBO had a better MIC (1.35 mg/mL against *S. aureus* than *E. coli* (2.75 mg/mL), indicating that PHBO exhibits higher bactericidal activity against Gram-positive bacteria. The mixture of PLAO and PLAO&PHBO (1:1) exhibited a lower MIC than that of PLAO and PHBO alone, which indicates that the strong and durable bactericidal ability of the PET/PHBV/PLA-PLAO fabric is not simply due to the superimposed effect of the two antibacterial agents; there may be a more complex and effective antibacterial mechanism. Subsequently, the authors attempted to elucidate the principle behind this phenomenon using scanning electron microscopy (SEM) (Figure 5a). Untreated *E. coli* cells were covered with bright and intact biofilms, and had smooth cell walls and membranes. PLAO and PHBO



**Figure 5.** (a) Scanning electron microscope images of untreated *Escherichia coli* and *E. coli* treated with polylactide oligomers (PLAO), poly(3-hydroxybutyrate) oligomers (PHBO), and both PLAO and PHBO. (b) The positive detection rate on fabrics for *Enterococcus faecalis*, *Streptococcus maltophilia*, *Staphylococcus aureus*, *Haemophilus influenzae*, *E. coli* and *Pseudomonas aeruginosa*. (c) Detection of total bacteria counts from 100 cm<sup>2</sup> of medical fabric after use for 7 days. (d) The percentage of fabric area with 0 or <20 colony-forming units (CFU)/100 cm<sup>2</sup> of total micro-organisms increased to 94% from 1.3% (control). PET, polyester; PHBV, poly(3-hydroxybutyrate-co-3-hydroxyvalerate); PLA, polylactic acid.



caused severe shrinkage of cell morphology and rupture of cell walls and membranes. The same phenomenon was observed in the images of cells treated with a mixture of PHBO and PHBO&PLAO. In addition, some nanospheres of uneven sizes were found around the cells, which were absent in the images of cells treated with PLAO or PHBO alone. PLAO is water soluble and more hydrophilic than PHBO, whereas PHBO is oil-like and hardly dissolves in water. The addition of PLAO may be beneficial for the dispersion of PHBO in the solution, and the mixture may form nanospheres, as observed in the SEM images. The hydrophobicity of PHBO enables the direct disruption of the permeability of cell walls and membranes through hydrophobic interactions, and destabilizes protein structures [32]. Gram-positive cell walls have thick but simple structures primarily composed of peptidoglycans, whereas Gram-negative cell walls possess more complex structures with high drug resistance despite being thinner. This result is in accordance with the enhanced antibacterial performance of the oligomers against Gram-positive bacteria, as discussed previously (Table S3, see online supplementary material).

### Phase 2: clinical trial studies

#### Detection rates of six HAI bacterial species in textiles

The fabric samples were selected at random from each group, and were found to have a total bacterial count of 0 CFU/100 cm<sup>2</sup> after a preliminary examination (Table S2, see online supplementary material), which complied with the 'hygienically clean' standards (<20 CFU/100 cm<sup>2</sup>) specified by the US healthcare textile certification guidelines [33]. After utilization for 1 week within the ward, six prevalent bacterial species were successfully isolated and identified (Figure 5b). Approximately 80% of PET/cotton textiles in the control group tested positive for *S. aureus*, *H. influenzae* and *S. maltophilia*. The detection rates of *E. coli* and *E. faecalis* were approximately 60%. *P. aeruginosa* is found in only approximately 23% of PET/cotton textiles. However, based on the hospital records, it ranked second highest in terms of the incidence of HAI (Figure 1c). This suggests that textile products may not serve as major carriers for *P. aeruginosa* transmission, as studies have indicated that contaminated water through inhalation aerosols, and medical devices rinsed with contaminated water are the main transmission pathways [34,35]. Both *S. aureus* and *E. faecalis* were detected in the lower 30% of PET/PHBV/PLA textiles, whereas the positive detection rate of *H. influenzae*, *S. maltophilia* and *E. coli* ranged between 40% and 60% on this fabric, indicating that PET/PHBV/PLA fabric exhibited a stronger bactericidal effect against Gram-positive bacteria than against Gram-negative bacteria, which is consistent with the MIC results (Table S3, see online supplementary material). The antibacterial efficacy of the PET/PHBV/PLA fabric was significantly superior to that of the PET/cotton-PLAO, potentially because of the inherent antibacterial properties of the PHBV fibres. In contrast, the positive detection rate of PET/PHBV/PLA-PLAO fabric was <10% for all six bacterial species, indicating broad-spectrum antibacterial activity of the fabric.

#### Detection rates of total bacteria count in textiles

The total bacterial count (TBC) detected in 100 cm<sup>2</sup> of medical fabric after 7 days of usage is shown in Figure 5c. The majority of PET/cotton fabrics exhibited a high TBC, with

approximately 68.67% falling within the range of 500–1000 CFU, and 9.33% >1000 CFU. Approximately 90% of PET/cotton-PLAO fabric and approximately 95% of PET/PHBV/PLA fabric had TBC <150 CFU, indicating an antibacterial rate >70% based on rough estimation when compared with PET/cotton fabric (TBC: 500 CFU). Although both PET/cotton-PLAO fabric and PET/PHBV/PLA fabric demonstrated some level of antibacterial activity, only approximately 36.6% of PET/PHBV/PLA fabric and 46.67% of PET/cotton-PLAO fabric were found to have TBC <20 CFU, matching the 'hygienic clean' standard (Figure 5d). It can be concluded that the antibacterial effectiveness of these two fabrics was slightly lower than expected. However, it is noteworthy that 94% of PET/PHBV/PLA-PLAO fabric was detected with TBC <20 CFU, resulting in an antibacterial rate >96%. Notably, 50% of PET in the PET/PHBV/PLA-PLAO fabric could eliminate bacteria completely (0 CFU of total bacterial count), demonstrating strong and long-lasting bactericidal properties for at least 7 days.

### Conclusion

In summary, this study demonstrated a novel and effective antibacterial medical textile fabric composed of PET and biodegradable PHBV/PLA fibres coated with PLAO, a new environmentally friendly and degradable antimicrobial agent with excellent thermal stability in high-temperature washing. The new bedding fabric exhibited long-term bactericidal effects against HAI-related bacteria. A clinical trial was conducted in four wards of a hospital to evaluate its effects against six types of bacteria that are closely related to HAIs in the study hospital. Data from 50 participants were collected and analysed over a period of 7 days. The results showed that after usage for 7 days, the percentage of fabric samples with 0 or <20 CFU/100 cm<sup>2</sup> of total micro-organisms increased drastically from 1.3% (control) to 94% (PET/PHBV/PLA-PLAO fabric). In detail, the TBC values of 94% of the new fabric samples were <20 CFU, of which 50% had 0 CFU count, implying that the HAI bacteria were eliminated completely. These results illustrate the strong and long-lasting antimicrobial properties of the new medical fabric after high-temperature laundry. Further mechanistic studies showed that the enhanced antimicrobial effect may be caused by the formation of nanospheres from a mixture of PLAO and PHBO in an aqueous environment. Besides its outstanding antibacterial properties, the new medical fabric exhibited improved breathability and softness, as well as equal mechanical properties and textile performance characteristics compared with the commercial PET/cotton fabric currently used in hospitals. None of the patients showed any symptoms of skin allergies or discomfort during textile use. Table S4 (see online supplementary material) presents the patient ratings of comfort with the fabric. Patients rated the comfort of the PET/PHBV/PLA bedding linen as moderate. This study revealed the great potential of PET/PHBV/PLA-PLAO fabrics for high bio-safety and long-lasting antimicrobial medical textiles that could prevent and control HAIs effectively.

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**Conflict of interest statement**

None declared.

**Ethical approval**

This clinical trial protocol was approved by the Medical Ethics Committee of the University of Hong Kong-Shenzhen Hospital [No. (2021) 041].

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**Appendix A. Supplementary data**

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jhin.2024.04.009>.

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