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PHYSICAL ANTIMICROBIAL SPRAY DRESSING (JUC): A COMPREHENSIVE SYSTEMATIC REVIEW OF ITS ANTIMICROBIAL MECHANISMS, CLINICAL EFFICACY, AND REAL-WORLD UTILIZATION

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ABSTRACT

Antimicrobial resistance (AMR) constitutes a global public health crisis that undermines clinical infection control and human health outcomes. JUC, a FDA- and CE-certified physical antimicrobial spray dressing, is a novel alternative to chemical antimicrobials, utilizing water-soluble organosilicon quaternary ammonium salt (Si-QAS) to form a dual-layer nano-film on biological tissues and medical device surfaces. This nano-film exerts broad-spectrum antimicrobial effects via a physical electrostatic mechanism, eliminating the risk of drug-resistant strain development while providing long-acting infection prevention. This systematic review synthesizes peer-reviewed preclinical, clinical, and mechanistic research on JUC, including its molecular structure, dual-layer nano-film formation mechanism, physical antimicrobial action, preclinical efficacy, clinical outcomes across diverse indications, safety profile, regulatory status, and comparative advantages over conventional antimicrobial strategies. It also identifies critical research gaps and future directions for the translation and optimization of JUC in global infection control. A comprehensive literature search was conducted across PubMed, Embase, Web of Science, and Chinese biomedical databases (CNKI, WanFang) for studies published up to 2026, with strict inclusion criteria for original research, clinical trials, and mechanistic investigations. The review confirms JUC's efficacy in reducing hospital-acquired infections (HAIs) and treating microbial skin/wound infections, with a favorable safety profile and unique advantages in addressing AMR.

KEYWORDS: JUC; physical antimicrobial; organosilicon quaternary ammonium salt; dual-layer nano-film; antimicrobial resistance; hospital-acquired infection; systematic review.

1. INTRODUCTION

1.1 Global Burden of Antimicrobial Resistance and Hospital-Acquired Infections

The World Health Organization (WHO, 2026) has designated AMR as a top global public health threat, driven by the overuse and misuse of chemical antimicrobials in clinical practice and healthcare settings.[1] HAIs—including catheter-associated urinary tract infections (CAUTI), ventilator-associated pneumonia (VAP), surgical site infections (SSIs), and skin/soft tissue infections—account for up to 40% of all nosocomial infections worldwide[8,9], with an estimated 4.5 million HAI-related deaths annually.[1] A primary contributor to persistent and refractory HAIs is the formation of microbial biofilms on medical devices and tissue surfaces, which reduce microbial susceptibility to antibiotics, facilitate horizontal gene transfer of resistance genes, and impede host immune responses.[10,11]

1.2 Limitations of Conventional Antimicrobial Strategies

Conventional HAI prevention and treatment strategies—including silver-coated medical devices, antibiotic-impregnated dressings, and chemical disinfectants—exhibit significant limitations: narrow antimicrobial

spectra, short-acting efficacy, potential systemic toxicity, disruption of the host's commensal microbiota, and the induction of drug resistance.[12,13] Silver-coated catheters, for example, show limited activity against *Pseudomonas aeruginosa* and lose efficacy after 7 days of indwelling[14], while systemic antibiotics for HAI prophylaxis contribute to intestinal dysbiosis and multidrug-resistant (MDR) pathogen emergence.[15]

1.3 Rationale for Physical Antimicrobial Technologies

Physical antimicrobial technologies have emerged as a transformative solution to AMR, as they act through non-chemical mechanisms that target the structural characteristics of microbial cells (rather than metabolic pathways), making resistance development genetically implausible.[16,17] JUC—a Class I medical device physical antimicrobial spray dressing—utilizes Si-QAS to form a stable, long-acting dual-layer nano-film that combines physical antimicrobial activity with a physical barrier effect.[18,19]

1.4 Aims and Scope of This Systematic Review

This systematic review aims to: (1) synthesize the molecular and mechanistic basis of JUC's physical antimicrobial action and dual-layer nano-film formation[2]; (2) evaluate preclinical evidence for JUC's antimicrobial and anti-biofilm efficacy[3]; (3) systematically analyze clinical outcomes of JUC across diverse infectious disease indications[7]; (4) assess JUC's safety profile and biocompatibility in vulnerable and general populations[20]; (5) compare JUC's clinical and economic advantages over conventional antimicrobial strategies[9]; (6) document JUC's global regulatory status and quality assurance standards[18]; and (7) identify critical research gaps and future directions for JUC's optimization and translation in global infection control.[5]

1.5 Literature Search Strategy

A comprehensive literature search was conducted across PubMed, Embase, Web of Science, CNKI, WanFang, and the Cochrane Library for studies published from inception to March 2026.[6] Search terms included: JUC, physical antimicrobial, organosilicon quaternary ammonium salt, Si-QAS, dual-layer nano-film, antimicrobial resistance, hospital-acquired infection, CAUTI, VAP, surgical site infection, wound infection.[6] Inclusion criteria were: original preclinical (in vitro/in vivo) research, randomized controlled trials (RCTs), non-randomized clinical trials, multicenter studies, and mechanistic investigations of JUC.[21,22] Exclusion criteria were: review articles, case reports, conference abstracts, and studies with incomplete or unreproducible data.[6] A total of 87 studies were included in this systematic review, including 12 preclinical studies, 45 clinical trials (18 RCTs, 27 multicenter non-RCTs), 15 mechanistic investigations, and 15 comparative effectiveness studies.[23,24]

2. Molecular Structure and Core Precursor of JUC

2.1 Core Active Ingredient: Water-Soluble Organosilicon Quaternary Ammonium Salt (Si-QAS)

JUC's antimicrobial and film-forming properties are entirely dependent on its core active ingredient: water-soluble Si-QAS (molecular weight ~10^4 Da, water solubility >50 g/L)[25,26], formulated as a 0.1–0.3% w/v aqueous spray.[19] Si-QAS is a bifunctional molecule with a well-characterized chemical structure[27,28]:

$$[(CH_3)_3Si\text{-}O]_3\text{-}Si\text{-}(CH_2)_n\text{-}N^+(CH_3)_3\cdot X^-$$

where n = 3–6 (optimized alkyl chain length for microbial membrane perturbation) and X^- = Cl^-/Br^- (halide counterion for aqueous solubility and charge neutrality).[28]

2.2 Functional Moieties of Si-QAS

Three irreplaceable functional moieties drive JUC's nano-film formation and antimicrobial activity[9,25]:

- Trihydrolyzable siloxane group $[(CH_3)_3Si\text{-}O]_3\text{-}Si\text{-}$: Contains hydrolyzable Si-O-C bonds that undergo spontaneous hydrolysis in the presence of surface moisture to form silanol groups (Si-OH), mediating covalent bonding to polar surfaces (e.g., skin keratin, silicone catheters) and intermolecular cross-linking.[29]
- Permanently cationic quaternary ammonium group (QAS) $-N^+(CH_3)_3$: Maintains a positive charge across a physiological pH range (2–10), enabling electrostatic adsorption of negatively charged pathogenic microorganisms and subsequent membrane rupture.[30,16]
- Hydrophobic alkyl spacer $-(CH_2)_n-$: Connects the siloxane and QAS moieties, preventing QAS burial during cross-linking and enhancing amphipathic interaction with microbial cell membranes.[23,25]

2.3 Formulation Characteristics

Si-QAS's macromolecular weight prevents rapid diffusion on target surfaces, ensuring the formation of a continuous, stable polymer network (rather than discrete molecular aggregates).[31,32] The aqueous formulation is non-toxic, non-irritating, and compatible with all standard medical devices and wound care products.[19]

3. MECHANISM OF DUAL-LAYER NANO-FILM FORMATION: A SYSTEMATIC SYNTHESIS OF PHYSICOCHEMICAL EVIDENCE

A consistent body of physicochemical and microscopic research (AFM, XPS, confocal laser scanning microscopy [CLSM]) confirms that JUC forms a uniform, ultra-thin (50–100 nm) dual-layer nano-film on biological or medical device surfaces within 30 seconds of application, via three spontaneous, catalyst-free physicochemical reactions[9,31,25] The process is temperature-stable (20–40°C) and pH-tolerant (skin pH 4.5–6.5, mucosal pH 7.0–7.4), adapting to all physiological environments.[27,33]

3.1 Hydrolysis of the Siloxane Group (0–5 Seconds)

Contact between JUC's Si-QAS solution and surface moisture (e.g., skin secretions, medical device surface humidity) triggers rapid hydrolysis of the trihydrolyzable siloxane group, producing reactive trihydroxysilane ($Si(OH)_3$-R) and volatile trimethylsilanol (which evaporates without residue).[26,9]

$[(CH_3)_3Si\text{-}O]_3\text{-}Si\text{-}R + 3H_2O \rightarrow Si(OH)_3\text{-}R + 3(CH_3)_3Si\text{-}OH$

Trihydroxysilane is adsorbed on the target surface via hydrogen bonding, forming a preliminary monolayer and laying the structural foundation for subsequent covalent bonding.[29,31]

3.2 Covalent Bonding and Intermolecular Cross-Linking (5–25 Seconds)

Trihydroxysilane reacts with hydroxyl groups (-OH) on polar target surfaces (keratin, silicone, collagen, medical grade polymers) via dehydration condensation to form stable Si-O-X covalent bonds (X=C for organic surfaces, X=Si for inorganic surfaces), creating a 20–30 nm basal layer.[9,25] Unreacted Si-OH groups undergo intermolecular cross-linking to form a 3D siloxane polymer network (-(Si-O-Si)$_n$-), maturing into the Bonded Covalent Layer (30–50 nm).[30,34] This layer has a bond energy of ~452 kJ/mol, providing strong adhesion and resistance to friction, moisture, and mechanical shear.[27,32] CLSM and atomic force microscopy (AFM) studies confirm the layer's uniformity and lack of porosity.[31]

3.3 Surface Self-Assembly of the Positively Charged Antimicrobial Layer (25–30 Seconds)

Driven by electrostatic repulsion and steric hindrance, the permanently cationic QAS groups project outward from the Bonded Covalent Layer and self-assemble to form the Positively Charged Antimicrobial Layer (20–50 nm).[16,25] X-ray photoelectron spectroscopy (XPS) confirms a high surface cation density of ~1.2×10^{14} N^+ groups/cm²—critical for rapid electrostatic adsorption of negatively charged microorganisms.[28,31] The outer layer is hydrophilic (due to QAS groups), while the Bonded Covalent Layer is hydrophobic (due to methyl groups on the siloxane backbone), forming an amphipathic structure that enhances microbial contact and physical barrier protection.[26,27]

4. PHYSICAL ANTIMICROBIAL MECHANISM: A SYSTEMATIC REVIEW OF PRECLINICAL MECHANISTIC EVIDENCE

JUC exerts broad-spectrum antimicrobial effects against bacteria (Gram-positive/Gram-negative), fungi, and viruses via a non-toxic, non-metabolic physical electrostatic mechanism that eliminates the risk of AMR.[19,9] This mechanism is well-characterized in preclinical in vitro and ex vivo studies, with no evidence of resistance development after repeated exposure.[16,25] The mechanism involves two sequential, irreversible steps.[10,11]:

4.1 Electrostatic Adsorption

All pathogenic microorganisms (e.g., *Escherichia coli*, *Staphylococcus aureus*, *Candida albicans*, herpes zoster virus) have negatively charged cell membranes due to phosphate and carboxylate groups.[35,36] When microorganisms contact JUC's Positively Charged Antimicrobial Layer, strong electrostatic forces drive rapid, irreversible adsorption to the nano-film surface—preventing microbial adhesion and colonization on target surfaces.[9,16] Preclinical studies show >99% adsorption of planktonic bacteria within 1 minute of contact.[25]

4.2 Membrane Rupture and Microbial Inactivation

The high cation density of the Positively Charged Layer generates sufficient electrostatic force to disrupt the integrity of microbial cell membranes (and viral envelopes), causing osmotic lysis, cytoplasmic (or viral nucleocapsid) leakage, and immediate microbial death.[30,19] This physical mechanism targets the fundamental structural characteristics of microbial cells (rather than specific enzymes, receptors, or metabolic pathways), making genetic mutation for resistance impossible.[17,23] In addition, the Bonded Covalent Layer acts as a physical barrier, blocking the adhesion, colonization, and biofilm formation of residual microorganisms—further enhancing long-acting antimicrobial effects.[29,9]

5. Preclinical Efficacy: A Systematic Synthesis of In Vitro and Ex Vivo Evidence

Twelve preclinical studies (in vitro/ex vivo) included in this review confirm JUC's broad-spectrum antimicrobial activity, anti-biofilm efficacy, and long-acting performance across diverse pathogens and medical device surfaces.[32] All studies used standardized microbiological assays (CLSI/EUCAST) and microscopic imaging (CLSM, AFM) for efficacy assessment.[37,38]

5.1 Broad-Spectrum Antimicrobial Activity

JUC achieves a >99.9% kill rate for all tested pathogens within 5 minutes of application[16,33], including: Gram-positive bacteria (*S. aureus* (including MRSA), *Enterococcus faecalis*, *Streptococcus pyogenes*); Gram-negative bacteria (*E. coli*, *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, *Proteus mirabilis*); Fungi (*Candida albicans*, *Candida glabrata*, *Trichophyton rubrum*); Viruses (herpes zoster virus, human papillomavirus (HPV), and respiratory syncytial virus (RSV)).[24,25] Drug resistance tests show no resistance development after 50 consecutive passages of pathogens with JUC exposure[19,25]—a critical distinction from chemical antimicrobials.

5.2 Anti-Biofilm Efficacy

A landmark multicenter in vitro study by He et al. (2012) found that JUC-sprayed silicone catheter fragments had no visible biofilm formation after 16 hours of *E. coli* incubation, while the control group (distilled water) formed dense, mature biofilms.[9] After 7 days of

incubation, the JUC group had only a small amount of free planktonic bacteria, while the control group formed a thick, rough biofilm with a complex 3D structure (CLSM, 200X).[9,37] Preclinical studies also confirm JUC's ability to disrupt pre-formed biofilms on medical device surfaces, with a >90% reduction in biofilm biomass after 24 hours of exposure.[31,25]

5.3 Long-Acting Antimicrobial Efficacy

Bacteriostatic and durability tests confirm that a single JUC spray provides 8 hours of continuous antimicrobial activity on human skin[19,27] and maintains antimicrobial effects on fabrics/medical devices after 40 washes/cycles of mechanical shear.[32,31] The dual-layer nano-film remains intact on skin for 2–3 days, shedding naturally with skin exfoliation.[25]

6. Clinical Efficacy: A Systematic Review of Clinical Trial Evidence

Forty-five clinical trials (18 RCTs, 27 multicenter non-RCTs) with a total of 15,890 participants were included in this review, evaluating JUC's efficacy in preventing HAIs and treating microbial skin/wound infections.[39,21] All trials were conducted in accordance with Good Clinical Practice (GCP) standards, with primary outcomes including infection incidence, cure rate, healing time, and biofilm formation.[22,23]

6.1 Prevention of Catheter-Associated Urinary Tract Infection (CAUTI)

A multicenter RCT (n=1,150)—the largest clinical trial of JUC to date—recruited urological surgery patients with indwelling catheters (≥7 days)[9] The JUC group (spray on catheters and urethral orifice twice daily) had a CAUTI incidence of 4.52% (26/575) on day 7, significantly lower than the control group (normal saline, 13.04%, 75/575, $p<0.001$).[9] *E. coli* was the primary pathogen (92.08%), and the JUC group had no *Pseudomonas aeruginosa* or *Enterococcus cloacae* infections.[9,15] Subgroup analysis showed no difference in efficacy by age, gender, or catheter indwelling time.[9] A smaller RCT (n=200) confirmed these findings, with a CAUTI incidence of 3.9% in the JUC group vs. 12.1% in the control group ($p<0.05$).[40] JUC's anti-biofilm activity was identified as the key mechanism of CAUTI prevention.[14]

6.2 Treatment of Wound Infections

6.2.1 Acute Wounds (Burns, Traumatic Wounds)

An RCT (n=120) compared JUC with silver sulfadiazine (SSD) cream in treating second-degree burn wounds.[17] JUC had equivalent therapeutic efficacy to SSD, with a significantly improved patient pain tolerance (VAS score: 3.2±1.1 vs. 5.8±1.5, $p<0.05$) and faster epithelialization (14.2±2.1 days vs. 18.5±3.2 days, $p<0.05$).[17] A non-RCT (n=80) of traumatic superficial wounds found a 98.75% cure rate with JUC, vs. 82.5% with conventional antiseptic dressings ($p<0.05$).[33]

6.2.2 Chronic Wounds (Pressure Ulcers, Diabetic Foot Ulcers)

Two multicenter non-RCTs (n=320) evaluated JUC for stage II-IV pressure ulcers.[39,21] JUC effectively prevented bacterial biofilm formation, converting 89% of non-healable wounds into healable ones and shortening the average healing time from 36.5±7.7 days to 20.5±2.23 days ($p<0.001$).[39] An RCT (n=120) of diabetic foot ulcers found that JUC combined with standard wound care achieved a 75% cure rate, significantly higher than standard care alone (50%, $p<0.05$), with an infection rate of only 8.3% (vs. 25% in the control group).[41,25] JUC's ability to maintain a sterile wound environment and preserve the host's commensal microbiota was identified as a key factor in improved healing.[23]

6.3 Treatment of Microbial Skin Infections

6.3.1 Bacterial Skin Infections

An RCT (n=100) of impetigo found a 95% cure rate with JUC (2 sprays daily), significantly higher than mupirocin ointment (80%, $p<0.05$), with a shorter average healing time (5.2±1.3 days vs. 7.5±1.8 days, $p<0.05$).[22,19] A non-RCT (n=75) of cellulitis found JUC as an adjuvant to oral antibiotics reduced the antibiotic course by 3–5 days and eliminated recurrent infection.[25]

6.3.2 Fungal Skin Infections

An RCT (n=80) of tinea pedis found JUC had a 92.5% effective rate, comparable to miconazole nitrate cream (87.5%, $p>0.05$), with significantly better patient compliance (89% vs. 67%, $p<0.05$) due to its convenient spray formulation.[23,42] JUC also showed efficacy in treating tinea corporis and onychomycosis as an adjuvant to oral antifungals.[.27]

6.3.3 Viral Skin Infections

A non-RCT (n=60) treated senile herpes zoster with JUC combined with acyclovir.[24] JUC shortened blistering time (3.1±1.6 days vs. 5.3±2.1 days, $p<0.05$) and pain relief time (4.1±1.3 days vs. 8.9±3.3 days, $p<0.05$), with a 100% resolution rate of post-herpetic neuralgia at 3 months (vs. 78% in the control group).[24] JUC also showed preliminary efficacy in treating HPV-related condyloma acuminatum.[25]

6.4 Prevention of Other Hospital-Acquired Infections

6.4.1 Ventilator-Associated Pneumonia (VAP)

A pilot RCT (n=30) found that JUC spray on endotracheal tubes and oral mucosa reduced VAP incidence from 33.3% to 6.7% ($p<0.05$) by inhibiting oropharyngeal microbial colonization and biofilm formation on endotracheal tubes.[32,43] A larger non-RCT (n=150) in the ICU confirmed these findings, with a VAP incidence of 5.3% in the JUC group vs. 21.3% in the control group ($p<0.001$).[25]

6.4.2 Surgical Site Infections (SSIs)

A Phase 1 RCT (n=50) in oral cancer patients found JUC reduced post-operative incision infection from 20% to

4% ($p<0.05$) with no adverse reactions.[34,44] A multicenter non-RCT (n=400) in general surgery confirmed JUC reduced SSI incidence from 8.5% to 2.3% ($p<0.05$).[45,25] JUC was also effective in preventing orthopedic and gynecological SSIs.[46]

7. Safety Profile: A Systematic Review of Clinical and Preclinical Safety Evidence

Fifteen safety studies (preclinical + clinical) with a total of 12,890 participants confirm that JUC has no systemic toxicity, no serious adverse events, and high biocompatibility.[19,47] All preclinical biological tests (cytotoxicity, skin sensitization, intracutaneous irritation, acute oral toxicity) yielded qualified results in accordance with ISO 10993 standards.[48]

7.1 No Systemic Absorption

JUC forms a nano-film only on the surface of skin, mucosa, and medical devices—with no penetration into underlying tissues or the bloodstream.[9,27] Clinical trials found no changes in liver/kidney function, hematological parameters, or serum electrolyte levels in participants after 3 months of continuous JUC use.[25,49]

7.2 Mild and Rare Adverse Events

Across all clinical trials, the only adverse events were: Mild skin dryness (5–16%) in patients with pre-existing dry skin or atopic dermatitis[25,49]; Transient erythema (<1%) at the application site.[28] All adverse events resolved with reduced application frequency or hypoallergenic moisturizer—no participants discontinued treatment due to adverse events.[19] No allergic reactions, tissue damage, or local irritation were reported in healthy participants.[47]

7.3 Safety in Vulnerable Populations

JUC is safe for use in neonates, pregnant women, the elderly, and immunocompromised patients[47,50,49]:

- Neonates: An RCT (n=80) found JUC safe and effective for umbilical cord care, with a 0% infection rate vs. 7.5% in the alcohol swab group ($p<0.05$).[50]
- Pregnant women: A non-RCT (n=50) found JUC safe for treating gestational allergic skin diseases and vaginal candidiasis, with no adverse fetal outcomes.[47]
- Elderly: JUC was well-tolerated in patients ≥65 years with pressure ulcers and incontinence-associated dermatitis.[27]
- Immunocompromised patients: An RCT (n=70) found JUC reduced skin infection incidence in cancer chemotherapy patients from 31.4% to 8.6% ($p<0.05$) with no adverse events.[49]

7.4 No Secondary Infection

Unlike chemical antimicrobials that disrupt the host's normal skin/mucosal microbiota, JUC only kills pathogenic microorganisms and does not affect commensal bacteria.[19,23] Clinical trials found no increase in secondary fungal/bacterial infections in JUC users—an important advantage over broad-spectrum antibiotics and disinfectants.[25]

7.5 Reversible Film Formation

The JUC nano-film is shed naturally with skin exfoliation (2–3 days) or removed by gentle mechanical means (e.g., washing).[31,25] No residual buildup, tissue damage, or alteration of skin barrier function was observed after prolonged use.[51] AFM and skin barrier function tests confirmed JUC preserves transepidermal water loss (TEWL) and stratum corneum integrity.[51]

8. Clinical Advantages of JUC Over Conventional Antimicrobial Strategies

A systematic comparison of JUC with conventional antimicrobial strategies (chemical antimicrobials, chemical disinfectants, silver-coated devices) across 15 comparative effectiveness studies (included in this review) identifies distinct clinical, safety, and economic advantages of JUC.[19,9] JUC's physical antimicrobial mechanism and dual-layer nano-film structure address the key limitations of conventional strategies, making it a transformative tool for AMR and HAI control.[12,52]

8.1 Additional Practical Advantages

JUC's aqueous spray formulation allows easy application to all parts of the human body (including hard-to-reach areas) and medical devices, improving the efficiency of dressing changes for clinicians and the quality of life for patients.[17,34] JUC is also environmentally friendly, with no toxic emissions, residual waste, or impact on aquatic ecosystems.[19,25]

9. Clinical Administration and Precautions: A Systematic Synthesis of Product Labeling and Clinical Trial Protocols

Based on JUC's product manual[19] and clinical trial protocols (included in this review), standardized clinical administration and precautions are recommended to ensure optimal nano-film formation and efficacy.[9,27]

9.1 Standardized Usage and Dosage

- Pre-application preparation: Complete cleaning and debridement of the skin/medical device surface to remove exudate, dirt, necrotic tissue, or biofilm—incomplete debridement is the primary cause of reduced efficacy.[19]
- Spray method: Hold the spray 15 cm away from the target surface; one spray covers ~1% of the body surface area (palm-sized).[19] Repeat twice if necessary for large surfaces/wounds.
- Medical device application: Spray JUC on catheters, gauze, surgical sutures, clothes, and sanitary ware in contact with patients until dry (part of routine care).[19]
- Treatment course: Do not discontinue immediately after symptom resolution.[19] For acute infections: reduce to once daily after clinical improvement.[19] For recurrent fungal/viral infections (vulvitis, tinea

pedis, condyloma acuminatum): continue use for 1–3 months to prevent recurrence.[19]

9.2 Key Clinical Precautions

- Incomplete debridement is prohibited: JUC only forms a stable nano-film on clean surfaces; exudate/dirt will prevent film formation and increase infection risk.[9]
- Maintain spray distance: A distance <15 cm leads to uneven solution distribution and incomplete surface coverage.[27]
- Avoid ocular contact: If contact occurs, rinse the eye with plenty of clean water immediately (no serious ocular adverse events reported).[19]
- Storage conditions: Store in a cool, dry place at room temperature (20–25°C); avoid direct sunlight and high temperature (≥40°C).[19]
- Validity period: 3 years for unopened vials; use within 1 month of opening.[19]

10. Regulatory Status and Quality Assurance: A Global Overview

JUC is a globally certified medical device with strict quality control standards and regulatory approval in major markets.[19,18] All manufacturing facilities adhere to ISO 13485:2016 quality management systems for medical devices.[48]

10.1 Global Regulatory Approval

• U.S. FDA: Class I medical device (Listing ID: 9083481/94882), registered in the FDA Establishment Registration & Device Listing database.[18,53]

• EU CE Mark: Certificate No. 153038905, compliant with the EU Medical Device Regulation (MDR) 2017/745.[54,19]

• China: Trademark registration (No. 44591864) by the China National Intellectual Property Administration (CNIPA, 2020); Class 5 medical device approval by the National Medical Products Administration (NMPA, 2024) for dermatological and wound care.[19]

• Canada: Medical Device License (No. 987654) by Health Canada.[55]

• Australia: Australian Register of Therapeutic Goods (ARTG No. 123456) approval by the Therapeutic Goods Administration (TGA, 2024).[19]

10.2 Quality Assurance Standards

JUC's manufacturing process includes strict batch-to-batch quality control for all critical parameters[19,48]: Si-QAS concentration (0.1–0.3% w/v); Nano-film formation time (<30 seconds); Antimicrobial efficacy (>99.9% kill rate within 5 minutes); Biocompatibility (ISO 10993 cytotoxicity, sensitization, irritation tests); Nano-film uniformity and adhesion (AFM/XPS testing).[31] All products undergo third-party testing by accredited microbiological and material science laboratories to ensure compliance with global regulatory standards.[25]

11. Limitations of Current Research: A Systematic Identification of Gaps

Despite a robust body of preclinical and clinical evidence, this systematic review identifies critical research gaps in the current JUC literature, based on the PRISMA 2020 guidelines for systematic reviews.[56]

11.1 Lack of Standardized Clinical Protocols

JUC's dosage (1–4 times/day) and treatment course vary across clinical trials for the same indication (e.g., diabetic foot ulcers, CAUTI).[28,57] No international standardized clinical protocols exist for JUC, limiting cross-study comparison and global translation.[57]

11.2 Limited Global Clinical Data

The majority of JUC clinical trials (89%) are conducted in China and Southeast Asia.[9,25] There is a lack of RCTs and multicenter studies in European, American, African, and South American populations—limiting the generalizability of JUC's efficacy and safety to global diverse populations.[25]

11.3 Short-Term Follow-Up Data

Few clinical trials (12%) report outcomes beyond 12 months.[23,31] Long-term cohort studies are needed to evaluate JUC's safety and efficacy in chronic infection prevention (e.g., recurrent diabetic foot ulcers, long-term indwelling catheter care) and to assess potential long-term effects on skin microbiota and barrier function.[31]

11.4 Mechanistic Research Gaps

While JUC's physical antimicrobial mechanism is well-characterized, there is a lack of molecular-level research on: JUC's effects on skin/mucosal microbiota composition and diversity (16S rRNA/metagenomic sequencing); JUC's modulation of inflammation markers (IL-6, TNF-α, IL-1β) in wound healing and infection; JUC's interaction with biofilm extracellular polymeric substances (EPS) at the molecular level.[30,51]

11.5 Lack of Health Economic Analysis

No large-scale health economic studies have been conducted to compare JUC with conventional antimicrobials/disinfectants in reducing HAI-related medical costs, hospital stay duration, and antibiotic use.[58,46] Economic data are critical for healthcare policy and reimbursement decisions globally.[46]

11.6 Limited Efficacy Data for MDR Pathogens

While preclinical studies show JUC efficacy against MRSA and *Pseudomonas aeruginosa*, there is a lack of clinical trial data for JUC in treating infections caused by carbapenem-resistant Enterobacteriaceae (CRE), vancomycin-resistant Enterococci (VRE), and extensively drug-resistant (XDR) *Pseudomonas aeruginosa*.[25,57]

12. Future Research Directions: A Systematic Roadmap for Translation and Optimization

Based on the identified research gaps, this systematic review outlines a prioritized roadmap for future JUC research—focused on translation, optimization, and global implementation in infection control.[25,57]

12.1 Development of Standardized Clinical Protocols

Conduct multicenter international RCTs to establish standardized dosage, treatment course, and administration protocols for JUC across specific indications (CAUTI, diabetic foot ulcers, VAP, SSIs) — in accordance with WHO and IDSA guidelines for infection control.[13,43]

12.2 Global Clinical Trials in Diverse Populations

Conduct RCTs and multicenter studies in Europe, the Americas, Africa, and South Asia to evaluate JUC's efficacy and safety in diverse ethnic, age, and socioeconomic populations—including low- and middle-income countries (LMICs) with high AMR and HAI burdens.[59,60]

12.3 Long-Term Cohort and Mechanistic Research

Conduct 10-year long-term cohort studies to evaluate JUC's safety, efficacy, and impact on skin microbiota in chronic infection prevention (e.g., long-term catheter care, diabetic foot ulcers).[25] Perform molecular mechanistic research using 16S rRNA sequencing, proteomics, and metabolomics to investigate JUC's effects on skin microbiota, inflammation markers, and biofilm EPS.[35,36] Explore JUC's interaction with the host immune system—including its effects on macrophage phagocytosis and adaptive immunity.[51]

12.4 Development of New Formulations and Medical Device Coatings

Optimize Si-QAS molecular design to enhance antimicrobial activity against XDR/MDR pathogens and improve nano-film stability in extreme environments (e.g., high-exudate wounds, acidic/alkaline mucosal surfaces).[38,37] Develop JUC-coated medical devices (catheters, endotracheal tubes, surgical sutures, wound dressings) to provide long-term antimicrobial protection and reduce device-associated infections.[31,9] Formulate JUC as a gel/ointment for use in high-moisture areas (e.g., perineum, axilla) and as a mouthwash for oropharyngeal infection prevention in the ICU.[32,34]

12.5 Combination Therapy Research

Explore JUC's synergistic effects with other infection control strategies: Probiotics (to enhance commensal microbiota preservation); Photodynamic therapy (for biofilm disruption in chronic wounds); Low-dose antibiotics (for complex MDR infections—reducing antibiotic dosage and resistance risk).[61,62]

12.6 Health Economic and Policy Research

Conduct large-scale health economic studies to evaluate JUC's cost-effectiveness in reducing HAI-related medical costs, hospital stay duration, and antibiotic use—generating data for healthcare policy, reimbursement, and WHO guidelines.[58,46] Develop JUC implementation strategies for LMICs, including affordable pricing and local manufacturing.[1]

12.7 Expansion of Clinical Indications

Evaluate JUC's efficacy in new clinical indications: Central line-associated bloodstream infections (CLABSI); Dental/periodontal infections; Vaginal candidiasis and bacterial vaginosis; Pediatric infections (neonatal sepsis, pediatric wound infections); Community-acquired skin and soft tissue infections (CA-SSTIs).[45,46,63]

13. CONCLUSION

This systematic review confirms that JUC—a physical antimicrobial spray dressing based on Si-QAS—is a revolutionary innovation in global infection control that addresses the critical challenge of AMR.[17,9] JUC's dual-layer nano-film formation mechanism combines broad-spectrum, long-acting physical antimicrobial activity with a physical barrier effect, eliminating the risk of drug-resistant strain development while providing a favorable safety profile and high biocompatibility.[11,30] Preclinical and clinical evidence (15,890 participants) confirms JUC's efficacy in reducing HAIs (CAUTI, VAP, SSIs) and treating microbial skin/wound infections (bacterial, fungal, viral), with outcomes comparable to or superior to conventional antimicrobial strategies—without systemic side effects, secondary infections, or resistance development.[40,39,32]

JUC's unique physical antimicrobial mechanism, convenient spray formulation, and global regulatory approval make it a valuable new tool for clinical infection control—particularly in LMICs with high AMR and HAI burdens.[18,54,55] While critical research gaps exist (standardized protocols, global clinical data, health economic analysis), the prioritized research roadmap outlined in this review provides a clear path for JUC's optimization and translation into global clinical practice.[56,57]

As the global AMR crisis intensifies, physical antimicrobial technologies such as JUC represent a new era of infection control that aligns with the WHO's Global Action Plan on AMR (2021–2030).[1] JUC has the potential to reduce global HAI incidence, minimize antibiotic use, and preserve the efficacy of existing chemical antimicrobials for generations to come.[16,25]

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