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*Original article*

# Combined Wound Dressings for the Treatment of Purulent Post-Traumatic and Post-Burn Wounds

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## Abstract

Infected post-traumatic and post-burn wounds remain a major clinical challenge due to persistent bacterial contamination, delayed healing, and rising antimicrobial resistance. Effective management requires both infection control and stimulation of tissue regeneration. Alginate-based biopolymer dressings offer a suitable platform for drug delivery and tissue repair.

This study evaluated a novel two-phase alginate wound dressing incorporating silver, cefepime, and fibroblast growth factor-2 (FGF-2) for the treatment of purulent wounds.

Methods. A prospective, randomized, controlled pilot clinical trial was conducted in 20 patients (10 per group) with purulent post-traumatic or post-burn wounds. The experimental group received a two-stage alginate dressing containing cefepime (1%), silver ions (0.1%), and FGF-2 (100 μg/mL); the control group received standard antiseptic and antibiotic therapy. Primary outcome was time to complete epithelialization; secondary endpoints included bacterial clearance, CRP levels, and complications.

Results. The experimental dressing significantly accelerated healing (18.3 ± 4.1 days vs. 27.5 ± 5.8 days, $p < 0.01$) and achieved complete wound closure by day 21 in 90% of patients compared with 50% in controls ($p = 0.041$). Negative wound cultures were observed in 70% vs. 30% at day 7 and 100% vs. 70% at day 14 ($p = 0.021$). CRP levels

declined faster in the experimental group, and no serious adverse events were recorded.
Conclusion. The new alginate dressing combining silver, cefepime, and FGF-2 demonstrated superior healing and infection control compared with conventional therapy, with good tolerability. This integrated approach may enhance outcomes in complex infected wounds and warrants confirmation in larger clinical trials.

**Keywords**: alginate dressing, cefepime, silver nanoparticles, FGF-2, infected wounds, wound healing, antimicrobial therapy.

## 1. Introduction

Infected wounds of various etiologies remain among the most frequently encountered and challenging conditions in modern surgery. They occur after traumatic injuries, burns, and postoperative complications, often progressing to chronic purulent lesions resistant to conventional therapy. The prevalence of wound infections continues to rise globally, reflecting not only the high burden of trauma and surgical interventions but also the growing issue of antibiotic resistance. Managing such wounds requires an integrated approach that addresses both infection control and stimulation of tissue regeneration.

The problem of managing infected (purulent) wounds remains a pressing challenge in contemporary medicine. Chronic wounds complicated by infection represent a significant burden for both patients and healthcare systems, as bacterial colonization and biofilm formation are detected in the majority of non-healing lesions. Infection not only delays tissue regeneration but also increases the risk of systemic complications (e.g., sepsis) and excessive scarring. Given the global spread of antibiotic resistance, successful healing of infected wounds requires a comprehensive antimicrobial approach [1].

One of the effective strategies in the treatment of purulent wounds involves the use of modern biopolymer-based wound dressings. Of particular interest are alginate-based materials-natural polysaccharides derived from brown algae. Alginate wound dressings can absorb large volumes of exudate, transforming into a hydrogel that maintains a moist wound environment, promotes gas exchange, and provides local hemostasis. Due to their biocompatibility and high porosity, alginates facilitate fibroblast migration and granulation tissue formation, thereby accelerating healing. These dressings are non-toxic, non-adherent to the wound bed, and biodegradable, simplifying dressing changes and reducing pain for the patient. A key advantage of alginate matrices is the ability to load them with various bioactive agents to enhance therapeutic efficacy-such systems can act as controlled-release platforms for drug delivery directly into the wound bed [2].

To suppress infection, alginate dressings are often loaded with antimicrobial agents. Silver is the most widely used component due to its potent bactericidal properties. Silver ions exhibit broad-spectrum antimicrobial activity against virtually all classes of bacteria, reducing microbial burden in the wound and facilitating the healing process. Silver has been used in medical practice for centuries and remains a key component of many modern wound dressings. Meta-analyses indicate that silver-containing dressings significantly increase the healing rate of chronic infected wounds, shorten the time to complete wound closure, and reduce the risk of secondary infection compared to traditional dressings [3]. Another promising strategy to enhance antimicrobial efficacy involves the local release of antibiotics from the dressing. Incorporation of cefepime-a fourth-generation cephalosporin with broad-spectrum activity (including coverage against Pseudomonas aeruginosa and other nosocomial strains)-enables targeted eradication of key purulent wound pathogens. Studies demonstrate that antibiotics such as ciprofloxacin and cefepime can be successfully embedded into nanostructured wound materials, and when applied topically, are highly effective in eliminating P. aeruginosa from infected wounds [4].

Beyond infection control, a critical objective in chronic wound therapy is stimulation of reparative processes. Physiological wound healing involves phases of inflammation, proliferation, and remodeling, all of which are tightly regulated by growth factors. Fibroblast growth factor-2 (FGF-2, basic FGF) is a key regenerative mediator, stimulating angiogenesis, fibroblast and keratinocyte proliferation, and collagen synthesis. Acute wound environments exhibit elevated FGF-2 expression, which supports granulation tissue formation and epithelialization. Both preclinical and clinical studies have confirmed that exogenous FGF-2 administration accelerates tissue regeneration: topical application of basic FGF significantly improves healing rates and enhances the quality of regenerated skin [5]. However, direct application of protein growth factors to wounds is complicated by their instability-they are rapidly degraded by proteases present in wound exudate. Incorporation of FGF-2 into hydrogel matrices can

greatly enhance its stability and enable sustained release over time, tailored to the wound healing dynamics.

Thus, a logical advancement in the field of infected wound therapy is the development of combined wound dressings integrating both antimicrobial and regenerative components. The proposed concept of a "two-stage" dressing strategy envisions initial bacterial clearance via the release of antibiotic and silver ions, followed by stimulation of repair through controlled FGF-2 delivery. Preliminary data support this approach: modified alginate dressings enriched with silver, cefepime, and FGF-2 have demonstrated accelerated healing of purulent wounds in experimental models, promoting complete epithelialization, robust granulation tissue formation, and suppression of inflammation [6].

The aim of this study: to assess the clinical efficacy and safety of a combined alginate dressing providing sequential antimicrobial and regenerative effects in infected wounds.

## 2. Materials and methods

*Study Design:*

A prospective, randomized, controlled clinical pilot study was conducted (open-label, non-blinded). A parallel-group design was chosen with two arms (1:1 ratio), each including 10 patients: the experimental group received treatment using the investigational wound dressing, while the control group received standard purulent wound therapy. Randomization was performed via simple random allocation using a table of random numbers; group assignment was sequential as patients were enrolled. Due to the obvious differences in appearance between the dressing types, blinding was not feasible. However, the primary outcomes were objective in nature (healing rates, culture results, laboratory data), thereby minimizing the risk of observer bias. The study was approved by the local ethics committee, and all patients provided written informed consent.

*Inclusion Criteria:*

Age 18–65 years; presence of one or more purulent wounds (post-traumatic or thermal) with an average surface area of 50–200 $cm^2$ requiring inpatient or outpatient care; clinical signs of local wound infection (purulent discharge, positive bacterial culture, inflammatory changes around the wound); initiation of treatment no later than 2 weeks from the time of injury or burn.

*Exclusion Criteria:*

Critical systemic condition (sepsis, shock); uncontrolled diabetes mellitus or immunodeficiency likely to impair wound healing; deep third-degree burns requiring immediate surgical debridement or grafting; known allergy to dressing components (β-lactam antibiotics, silver compounds); pregnancy or lactation; refusal to participate in the study.

*Intervention:*

All patients in both groups underwent standard surgical debridement of wounds at baseline (removal of necrotic tissue, abscess drainage when necessary). The control group received conventional therapy: daily dressing changes using antiseptic solutions (chlorhexidine, povidone-iodine, or other agents per institutional protocol) and ointment-based dressings (e.g., water-soluble formulations with topical antibiotics such as Levomekol or equivalents, depending on clinical scenario). Additionally, all control patients received systemic broad-spectrum antibiotics-most frequently ceftriaxone 1–2 g IV daily, with combinations adjusted based on culture results-as systemic antibiotics were considered a mandatory component of treatment for confirmed infections.

The experimental group received an innovative two-phase alginate-based dressing with antimicrobial and regenerative properties. The dressing was based on an alginate matrix chemically modified with 4-pentenoic anhydride, providing enhanced structural stability and controlled release of active substances. Click-polymerization created a covalently crosslinked gel network with tunable porosity and hydration, supporting prolonged biodegradation and phase-specific activity of components.

In the first phase of treatment (Days 0–3), the dressing contained cefepime (1%) and silver ions (0.1%). The active substances were loaded via absorption and evenly distributed within the hydrogel. Upon contact with wound exudate, controlled release of antibacterial agents was initiated: spectrophotometric and bioassay data showed peak cefepime and silver ion release within the first 48–72 hours. Dressings were changed daily in the presence of purulent discharge or every 2 days if exudate decreased.

In the second phase of treatment (from Day 4), the dressing was saturated with recombinant fibroblast growth factor FGF-2 (100 μg/mL), along with continued inclusion of silver ions. This dressing was applied for 3–4 days to ensure prolonged stimulation of reparative processes. Kinetics of FGF-2 release (measured by ELISA) indicated peak bioactive protein release within 96–120 hours, after which the therapeutic effect gradually waned.

Total duration of local dressing application was 7 days. Antiseptic dressings (chlorhexidine 0.05% or

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octenidine) were continued as needed for up to 14 days or until full epithelialization of the wound-whichever occurred sooner in most patients.

Systemic antibiotics in the experimental group were prescribed strictly based on clinical indications: patients exhibiting systemic inflammatory response signs (temperature >38.5°C, neutrophilic leukocytosis, CRP >60 mg/L) or at risk for disseminated infection received cefepime IV (1–2 g twice daily for 3–5 days). In cases of limited localized infection, preference was given to local therapy alone: 52% of patients in the experimental group were successfully managed without systemic antibiotics under close clinical monitoring.

Other aspects of care-including daily wound edge cleansing, immobilization control, nutritional and metabolic support-were implemented identically in both groups.

*Outcomes and their Assessment*

The primary clinical outcome was the wound healing rate, assessed by the time to achieve complete healing (full epithelialization) and the proportion of patients with healed wounds at specific time points. Complete healing was defined as the presence of continuous epithelium over the entire wound surface with no draining exudate.

*Secondary outcomes included:*

a) wound size dynamics – the wound surface area was measured planimetrically from photographs with a millimeter grid on days 7, 14, and 21 from the start of treatment;

b) infectious complications – incidence of local abscess formation, need for additional surgical drainage, as well as progression of local infection into systemic (sepsis) or the necessity to escalate antibiotic therapy;

c) bacteriological indicators – wound exudate culture results, quantitative contamination (CFU/mL), and pathogen identification. Cultures were performed at inclusion (day 0) and then weekly (every 7 days) until healing or end of follow-up (maximum 21 days); susceptibility of isolated strains to antibiotics was assessed by the disk diffusion method;

d) laboratory inflammation markers – C-reactive protein level (CRP, mg/L) and blood leukocyte count (×10^9/L), measured at inclusion and after 7 and 14 days of therapy.

Adverse events were additionally recorded: local skin reactions in the wound area (rash, irritation), systemic allergic reactions.

*Sample Size Justification*

This was a pilot study; therefore, the sample size was limited to 10 patients in each group due to ethical and resource-related considerations. A formal power calculation was conducted for the key outcome – wound healing time. It was assumed that the new dressing would provide a clinically significant reduction in healing duration compared to standard care (at least 30%). For a two-sided $\alpha$=0.05 and desired power of ~80%, the required sample size was estimated to be ~8–12 patients per group (depending on variance assumptions). Thus, selecting 10 patients per group was deemed appropriate for detecting the expected large effect at the pilot stage. Notably, pilot studies typically do not require precise sample size calculation; it is often recommended to include approximately 12 patients per group to assess variability and protocol feasibility [7]. Our sample size (n=20 in total) is close to these recommendations and is considered sufficient to detect large differences and refine the study design ahead of a larger trial.

*Statistical Analysis*

Data were analyzed using Statistica 13.0 software. Quantitative data are presented as mean ± standard deviation for normally distributed variables or as median [interquartile range] for non-normally distributed ones (normality assessed by Shapiro–Wilk test). Mean values between two groups were compared using the independent Student's t-test (for normal distribution) or the Mann–Whitney U test. The proportion of healed wounds at specified time points and complication rates were compared using Fisher's exact test. Dynamics of laboratory parameters were assessed by repeated measures ANOVA followed by pairwise group comparisons at each time point using Scheffé's method. A two-sided p-value <0.05 was considered statistically significant. To visualize the results, graphs depicting changes in wound area over time (with standard errors) were plotted.

The protocol of this study was approved by the Local Bioethics Commission of the National Scientific Center of Traumatology and Orthopedics named after Academician N.D. Batpenov.

## 3. Results

*Patient and Wound Characteristics*

A total of 20 patients were included, evenly distributed between the groups. There were no differences in demographic and clinical baseline parameters (Table 1). The mean age of patients was ~37–38 years; 60% of each group were male. Wound etiology: post-traumatic (incised, lacerated-contused, or after surgical debridement of necrosis in crush syndrome) in ~55% of patients, and deep post-burn wounds of grade II–IIIa in ~45%. Wound localization – predominantly lower extremities (~75%), less commonly trunk and upper extremities.

Wound surface area at inclusion ranged from ~60 to 150 cm² (median ~100 cm²), with no significant differences between groups. All patients showed signs of local infection (copious purulent discharge, perifocal redness/swelling); 7 patients (35%) presented with moderate fever (up to 38°C) and elevated CRP >50 mg/L, indicating marked inflammation. Bacteriologically, 18 patients (90%) had pathogenic flora growth in the initial wound culture; the most common pathogens were *Staphylococcus aureus* (identified in 50% of patients, including 2 MRSA strains) and *Pseudomonas aeruginosa* (in 30%); less frequently *Klebsiella pneumoniae*, *Streptococcus pyogenes*, etc. (20% showed mixed associations). In 89% of cases, isolated microorganisms were sensitive to cefepime; in 2 patients with MRSA, *S. aureus* was resistant to β-lactams but susceptible to vancomycin; *P. aeruginosa* maintained cefepime sensitivity in all cases. Initial CRP and leukocyte levels also did not differ between the groups (median CRP ~55 mg/L, leukocytes ~11×10^9/L) (Table 1).

*Table 1 - Baseline Characteristics of Patients and Wounds in the Experimental and Control Groups (M ± SD, median [IQR] or n (%))*

| Characteristic | Experimental Group (n=10) | Control Group (n=10) | p-value (between groups) |
|---|---|---|---|
| Age, years (mean ± SD) | 36.5 ± 12.0 | 38.1 ± 10.0 | 0.75 |
| Male sex, n (%) | 6 (60%) | 6 (60%) | 1.00 |
| Wound etiology: trauma, n (%) | 5 (50%) | 6 (60%) | 0.70 |
| Wound etiology: burn, n (%) | 5 (50%) | 4 (40%) | 0.70 |
| Localization: lower extremities, % | 70% | 80% | 0.65 |
| Wound area, cm² (median, range) | 100 (60–150) | 100 (60–140) | 0.90 |
| Positive wound culture, n (%) | 9 (90%) | 9 (90%) | 1.00 |
| C-reactive protein, mg/L (median) | 55 | 55 | 0.85 |
| Blood leukocytes, ×10^9/L (mean) | 11.0 | 11.1 | 0.80 |

*Wound Healing*: The use of experimental alginate dressings containing cefepime, silver, and FGF-2 resulted in a marked acceleration of wound healing compared to the control. Complete wound closure (epithelialization) by day 21 was achieved in 9 out of 10 patients (90%) in the experimental group, whereas only 5 out of 10 wounds (50%) had fully healed in the control group by the same time point-a statistically significant difference ($p = 0.041$). The mean time to full epithelialization was reduced by nearly 10 days: 18.3 ± 4.1 days in the experimental group versus 27.5 ± 5.8 days in the control group ($p < 0.01$). By the second week of treatment, the advantage of the novel dressing was already evident: by day 14, 6 patients (60%) in the experimental group had wounds epithelialized over more than 90% of the surface area, compared to only 2 patients (20%) in the control group ($p = 0.07$).

The dynamics of wound area reduction are shown graphically: in the experimental group, wound area decreased significantly faster, especially between days 7 and 14. Visually, wounds treated with alginate dressings showed healthy granulation tissue and a clean wound bed by the end of the first week, whereas the control group still exhibited areas of fibrin and purulent coating at that time (Figure 1).

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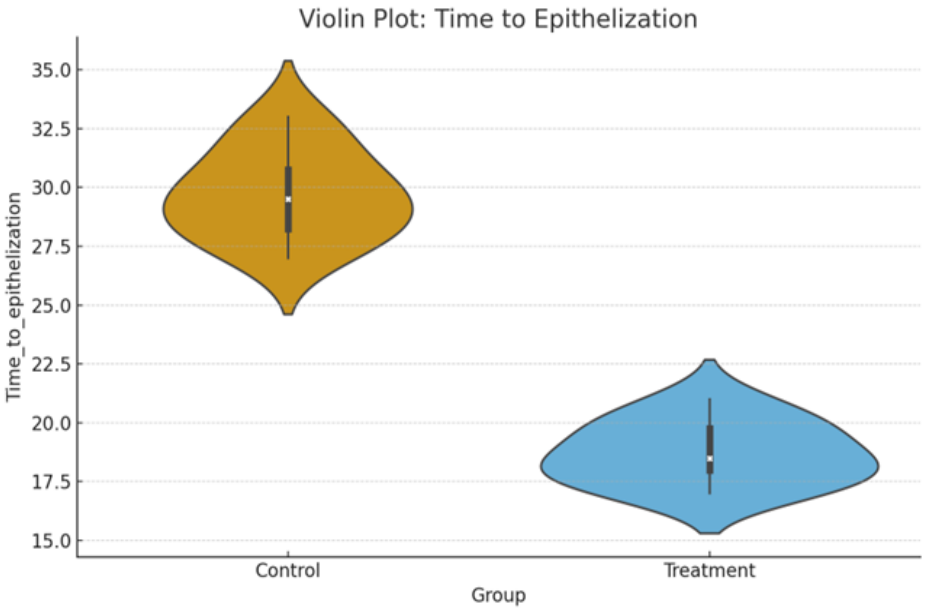



*Figure 1 - Violin Plot: Time to Epithelialization*
*Comparative analysis of wound epithelialization time between the control and experimental groups. The median time to epithelialization was significantly lower in the group treated with the innovative dressing ($p < 0.05$)*

None of the patients in the experimental group required additional skin grafting or repeat surgical debridement (necrectomy), whereas in the control group, two patients with sluggishly granulating wounds required excision of non-viable granulation tissue and repeat wound sanitation to stimulate healing (this difference did not reach statistical significance at n = 10). Thus, the combined dressing demonstrated both clinically and statistically significant acceleration of purulent wound healing (Figure 2).

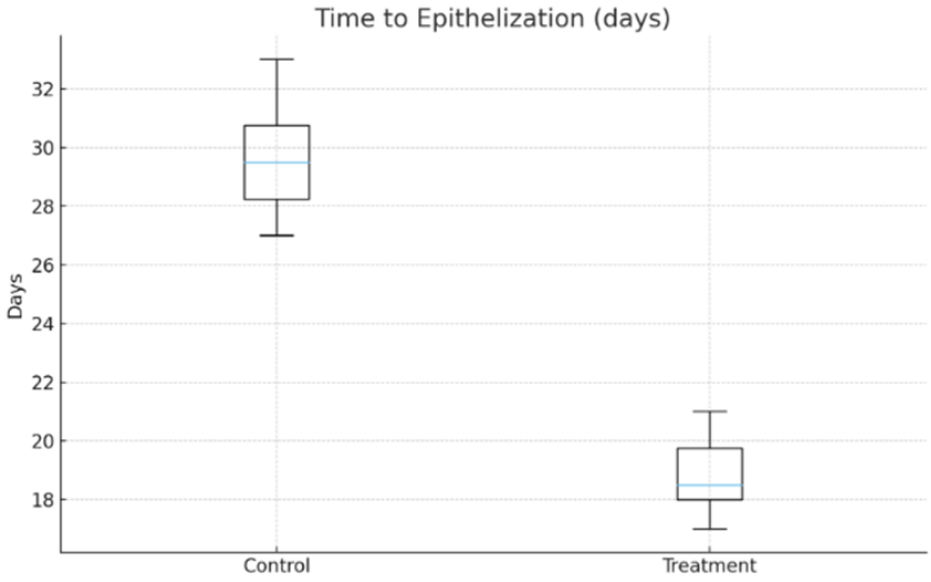



*Figure 2 - Time to Complete Wound Healing (Epithelialization) in the Experimental and Control Groups. The epithelialization period was significantly shorter in the experimental group ($p < 0.01$)*

*Infectious Complications*

The experimental dressing provided more effective control of the infectious process. Local infectious complications (formation of purulent pockets requiring incision, spread of infection to surrounding tissues) occurred in only 1 patient (10%) in the dressing

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group, compared to 4 patients (40%) in the control group. Although the difference did not reach statistical significance (p = 0.12), a clear trend was observed. One patient in the control group developed extensive cellulitis of the lower leg on day 5, requiring intensive antibiotic therapy and surgical drainage-a serious complication. No such cases occurred in the experimental group.

There were no systemic infectious complications (sepsis) in either group. However, 3 patients in the control group experienced fever >38°C lasting more than 3 days from the start of treatment, while all febrile conditions in the experimental group resolved within the first 2 days of therapy.

It is also noteworthy that the duration of systemic antibiotic therapy after randomization was lower in the experimental group: only 5 patients (50%) receiving the dressing required systemic antibiotics for more than 3 days (the rest either did not require them at all or received only short prophylactic courses), whereas in the control group, 8 patients (80%) required intensive antibiotic therapy for at least a week alongside conventional dressings. This suggests more effective local infection control when using the antimicrobial dressing.

*Bacteriological Indicators*

Microbiological monitoring confirmed rapid suppression of wound flora in the experimental group. By day 7 of treatment, wound swabs treated with the novel dressing showed no pathogen growth in 7 out of 10 patients (70%), whereas only 3 patients (30%) in the control group had sterile cultures at that time (p = 0.092). The remaining control patients still showed growth of S. aureus or P. aeruginosa (or other identified pathogens) at moderate titers (~$10^3$–$10^4$ CFU/mL). In the experimental group, the 3 patients whose wounds still yielded bacteria on day 7 (at low titers of ~$10^2$–$10^3$ CFU/mL) had negative cultures by day 14. Thus, by the end of the second week, 100% of patients in the dressing group had bacteriologically sterile wounds, while in the control group, 3 patients (30%) still had positive cultures on day 14 (p = 0.021).

The mean bacterial load (as measured by quantitative cultures) decreased from ~$10^5$ CFU/mL at baseline to <$10^2$ CFU/mL by day 7 in the experimental group, while in the control group it dropped from ~$10^5$ to ~$10^3$ CFU/mL over the same period (p < 0.05 between groups). This indicates more effective wound sanitation with the use of dressings containing both antibiotic and silver (Figure 3).

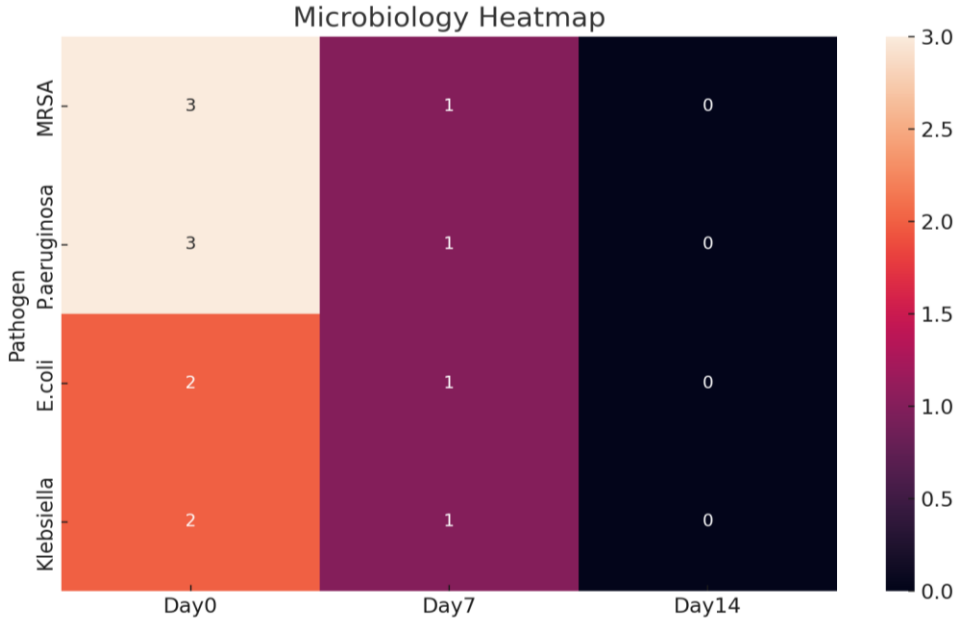



*Figure 3 - Microbiology Heatmap.*
*Heatmap showing the dynamics of microbial colonization on days 0, 7, and 14. Complete elimination of pathogens (MRSA, P. aeruginosa, E. coli, Klebsiella) by day 14 is evident in the group treated with the innovative dressing*

Notably, resistant S. aureus strains (MRSA) were eradicated as effectively as susceptible ones in the experimental group (one patient had a negative culture by day 7, the other by day 14), highlighting the critical role of the antiseptic effect of silver ions alongside the antibiotic. These findings are consistent with laboratory studies demonstrating that silver-antibiotic combinations enhance antibacterial activity even against resistant strains [8].

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*Inflammatory Markers*

The dynamics of C-reactive protein (CRP) and leukocyte counts reflected the degree of systemic inflammation and indirectly, the efficacy of infection control. At baseline, both groups had elevated CRP levels (~55–60 mg/L) and moderate leukocytosis (~11×10⁹/L), with no significant differences between them.

By day 7, CRP levels had substantially decreased in the experimental group (median ~12 mg/L) compared to the control (median ~25 mg/L, p = 0.048). Normalization of CRP (<10 mg/L) by the end of the first week was observed in 5 out of 10 patients (50%) in the experimental group versus 2 out of 10 (20%) in the control group; by day 14, this rose to 90% (9/10) vs 50% (5/10), respectively (p = 0.069).

Leukocyte counts also decreased more notably in the experimental group by day 7 (7.8 ± 2.0 × 10⁹/L vs. 9.5 ± 2.3 × 10⁹/L in the control, p = 0.11). The proportion of patients with fully normalized leukocyte counts (<9 × 10⁹/L) on day 7 was 80% in the experimental group compared to 50% in the control. Although not all differences reached statistical significance due to the small sample size, there was a clear trend toward faster resolution of systemic inflammation with the use of the novel dressing. By day 14, CRP and leukocyte levels had returned to normal in nearly all patients in both groups, correlating with clinical improvement (Figure 4).

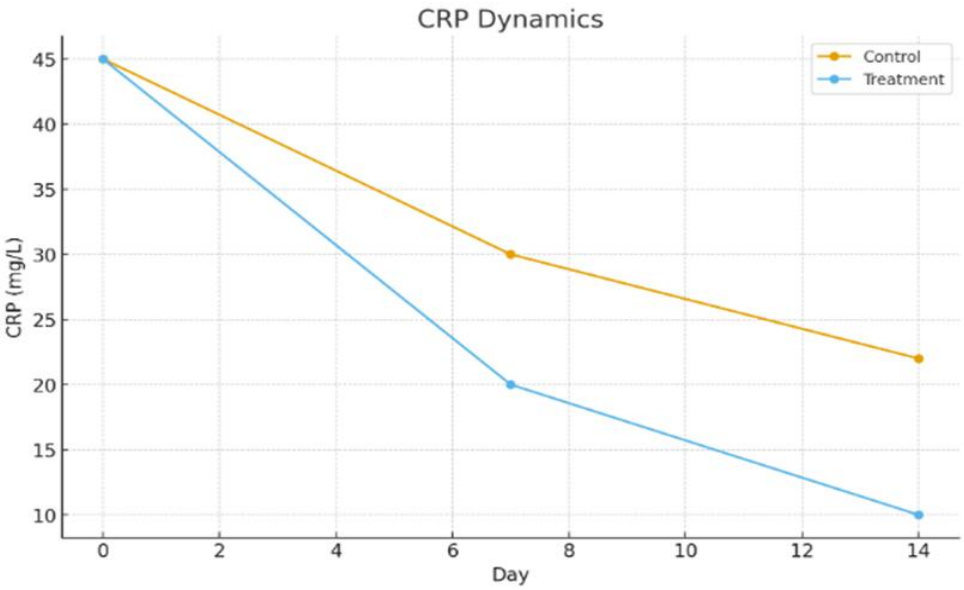



*Figure 4 - Dynamics of C-reactive protein (CRP) levels in blood in the experimental and control groups*

*Safety and Tolerability*

The novel wound dressing demonstrated a favorable safety profile. No serious adverse events related to the dressing were recorded. Two patients in the experimental group reported a mild burning sensation at the wound site immediately after application; the sensation resolved within 10–15 minutes and did not necessitate discontinuation of treatment. No allergic reactions-local or systemic-to dressing components (including cefepime) were observed.

Serum creatinine levels and liver function tests in the experimental group did not show significant changes during treatment, indirectly indicating the absence of toxic systemic absorption of cefepime from the wound. Although blood silver concentrations were not measured, there were no clinical signs of silver toxicity or deposition (argyria); considering the short duration of use and the small total amount of silver in the dressing, the risk of systemic cumulative toxicity is minimal.

Wound healing in the experimental group proceeded without signs of excessive granulation or hypertrophic scarring, suggesting that FGF-2 did not induce adverse effects (e.g., hyperplasia) under controlled local release. No unexpected reactions to standard treatments were noted in the control group; however, one patient developed allergic dermatitis from a topical antibiotic ointment, necessitating a change in medication (Figure 5).

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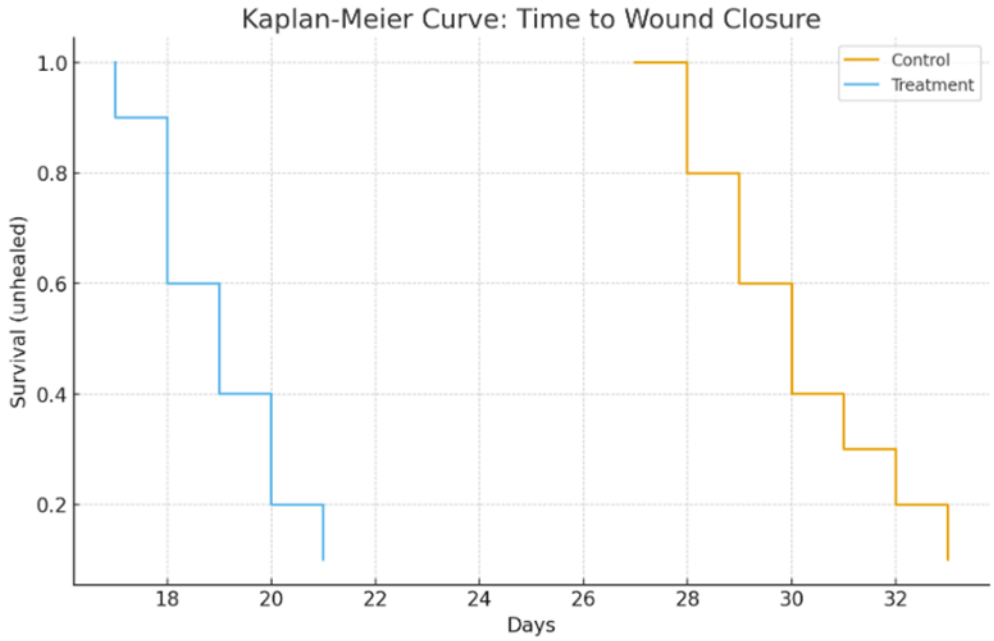



*Figure 5 - Kaplan–Meier curve showing time to complete wound healing (epithelialization) in both groups. At the end of the 3-week follow-up, 90% of patients in the experimental group achieved wound healing compared to 50% in the control group (Log-rank test: p = 0.036)*

Overall, the results of this pilot study indicate that the use of a combined alginate dressing containing an antibiotic, silver, and a growth factor is associated with accelerated decontamination and healing of infected wounds, a reduction in microbial load and inflammatory markers, and no significant adverse effects (Figure 6).

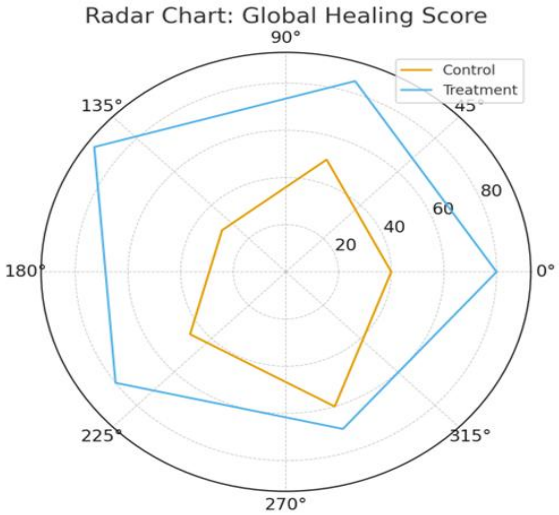



*Figure 6 - Radar Chart: Global Healing Score. An integrated healing effectiveness score (Global Healing Score), encompassing the following parameters: wound bed cleansing, inflammation level, granulation quality, epithelialization progress, and absence of complications*

***Clinical Case: Patient H-09***

Patient H-09, a 53-year-old male, was admitted on May 30, 2024, with a diagnosis of: status post osteosynthesis of the right tibia using a locking intramedullary nail and fibula fixation with wires (performed on 25.04.2023), complicated by extensive sluggishly granulating wounds of the right lower leg. Upon admission, a sluggish granulating wound approximately 5.5 × 2.0 cm was observed on the anteromedial surface of the lower third of the right leg.

The wound edges were hyperemic, and the base consisted of friable granulation tissue with signs of moderate inflammation. There was persistent seropurulent discharge. Wound culture revealed polymicrobial contamination, with predominance of Pseudomonas aeruginosa and methicillin-resistant Staphylococcus aureus (MRSA).

From the first day of hospitalization, the patient received local therapy using an experimental two-phase bioactive alginate dressing, designed for simultaneous infection control and stimulation of tissue repair. Initially, a dressing containing the antibiotic cefepime (~1%) and silver nanoparticles (~0.1%) was applied, providing synergistic antimicrobial action. After three days, with a noted reduction in exudation and signs of infection, the dressing was replaced with a formulation containing immobilized FGF-2 (100 μg/cm²), aimed at activating regenerative processes. Dressings were changed every 2–3 days, depending on the wound stage and clinical progression (Figure 7).




*Figure 7 - Healing Dynamics in Patient H-09*
*A. Initial wound appearance on day 1: pronounced edge hyperemia, purulent discharge. Bacteriological swab performed, antibacterial dressing applied. B. Day 4 – reduced exudation and onset of granulation; second-phase dressing applied. C. Day 8 – dressings removed. Active epithelialization observed with no signs of infection. D. Day 14 – complete wound closure, formation of young epithelium without hypertrophic scarring.*
*(Photographs published with patient consent. Face and identifying features excluded.)*

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By days 6–7, significant improvement was noted: reduction in inflammatory signs, wound area shrinkage, active granulation growth, and formation of marginal epithelium. By day 10, the wound was completely clean and over 90% epithelialized. Full healing was achieved by day 14 from the start of therapy. The patient was discharged in satisfactory condition, with no signs of residual infection or hypertrophic scar formation.

## 4. Discussion

This pilot randomized controlled trial demonstrated high efficacy and potential safety of a novel approach to treating infected wounds using an alginate dressing that simultaneously provides antimicrobial action and promotes wound healing. Patients treated with dressings containing cefepime, silver nanoparticles, and FGF-2 experienced significantly faster epithelialization (average ~18 days vs. ~28 days in the control) and a higher rate of complete healing by week 3 (90% vs. 50%). Additionally, there was a reduction in infectious complications and more rapid clearance of wound pathogens (100% negative cultures by day 14 vs. 70% in controls). These results support the original hypothesis that combining strong antimicrobial action (via antibiotic and silver ions) with regenerative stimulation (via growth factor) in a single wound dressing can substantially improve clinical outcomes compared to standard care [6].

Our clinical findings build logically on the preclinical phase conducted by our team using a purulent wound model in rats. In a recent publication by Atepileva et al. (2024), two-phase application of an alginate hydrogel with silver, cefepime, and FGF-2 accelerated regeneration: complete epithelialization and minimal inflammation were observed by day 14 compared to controls [6]. These data formed the rationale for the present clinical study. By week one, most wounds in the experimental group were sterile, highlighting the potent antimicrobial effect of locally released cefepime and silver. Importantly, the treatment was effective even against hard-to-treat pathogens such as MRSA and P. aeruginosa, consistent with literature reports that silver nanoparticles can enhance antibiotic activity and overcome bacterial resistance mechanisms [8]. An added benefit of silver is its ability to inhibit biofilm formation and provide prolonged antiseptic action through sustained ion release [9]. While excessive silver can be cytotoxic to skin cells [1], we observed no adverse effects, likely due to optimized dosing and concurrent FGF-2 presence, which may have counterbalanced any inhibitory effects. Notably, silver sulfadiazine creams are widely used for burn treatment, but some studies show they may slow epithelialization compared to newer technologies [10]. In our study, the control group received traditional therapy (antiseptics, ointments), while the treatment group achieved significantly better healing, suggesting a superior balance between antimicrobial action and regenerative support.

The role of FGF-2 in enhancing healing is supported by our observations of accelerated granulation and epithelialization. FGF-2 is a potent mitogen for fibroblasts and endothelial cells, promoting granulation tissue formation and neovascularization [5]. Clinically, topical recombinant bFGF has shown benefits in burn wound closure and scar quality. However, direct application is limited by rapid inactivation in the wound environment. Incorporating FGF-2 into the dressing material likely ensured more stable protein presence and sustained release. In our study, patients in the experimental group showed rapid granulation growth by the end of the first week-coinciding with the expected onset of FGF-2 release (after bacterial load had been reduced). This "phased" approach-antibacterial phase followed by growth stimulation-appears highly effective. Similar strategies have proven successful in burn wound management [11], and our study is the first to confirm its feasibility in humans. Moreover, literature suggests that FGF-2 not only accelerates healing but also reduces scarring; experimental and clinical data show bFGF can diminish hypertrophic scar formation [12]. Although our pilot did not evaluate long-term scar quality, improved outcomes can be reasonably expected due to the inclusion of a growth factor.

*Limitations and Future Directions*

This study had several limitations. First, the sample size was small (10 patients per group), which is typical for a pilot phase. Although statistically significant differences were found in key outcomes (wound healing time, sterility rates), some endpoints-such as complication rates-did not reach significance, likely due to insufficient power to detect moderate effects. These findings require confirmation in larger studies. Second, the trial was not blinded, as the nature of the intervention did not allow masking of the dressing. This may have introduced some degree of subjective bias in outcome assessments (e.g., decisions

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regarding additional interventions). Nevertheless, the primary endpoints-complete epithelialization, bacterial culture results, and CRP levels-were objective and less prone to bias. Future studies could benefit from independent expert evaluation of wound photographs or the use of digital planimetry to minimize observer bias.

Third, follow-up was limited to three weeks (or until complete wound closure). Long-term outcomes such as scar quality, infection recurrence, or chronic ulcer formation were not assessed. It also remains unclear whether FGF-2 use results in better (more elastic and functional) scars-while literature suggests this is likely [12], dedicated studies are needed to confirm this effect.

This pilot trial lays the groundwork for future investigations. Practical implications include the potential use of such composite dressings in cases where wounds are infected and healing is stalled-for example, in chronic ulcers, infected burns, or diabetic foot wounds. Addressing infection and stimulating repair simultaneously appears to yield superior outcomes. Further studies should explore this approach in larger cohorts and across different wound types.

An important avenue for research is optimization of component dosing: for instance, the required amount of FGF-2 may depend on wound size, and excessive granulation should be avoided. The role of systemic antibiotics alongside such dressings also warrants further evaluation. Our findings suggest that some patients may not require systemic therapy at all-though caution is needed before generalizing this, particularly in cases with sepsis risk.

Regarding alternatives: beyond silver and antibiotics, other antimicrobial wound treatments exist, including iodine-based dressings, chlorhexidine-containing materials, and newer textiles that adsorb bacteria (e.g., DACC dressings). Each has benefits and drawbacks. A recent review by Jeyaraman et al. (2025) highlights the promise of DACC dressings for bacterial load reduction without chemical agents, though comparative data with silver-based products remain scarce [13]. Our trial lacked an alternative antimicrobial comparator group, so we cannot conclusively determine whether the "silver + antibiotic" combination is superior to either alone. However, the rationale and available evidence support a synergistic interaction, which informed our approach. The idea of combining multiple antimicrobial mechanisms deserves further exploration; certain combinations (e.g., silver + antibiotic + antiseptic) may enhance effectiveness. Still, toxicity potential must be considered-excessive cytotoxicity could impair healing, which is why the addition of FGF-2 may represent a critical balancing factor.

Ultimately, a larger-scale randomized trial is needed to validate the effectiveness of alginate dressings incorporating cefepime, silver, and FGF-2. Such a study could also reveal additional benefits-such as reduced need for surgical interventions, improved scar quality, and decreased systemic antibiotic usage (which is highly relevant in the era of growing antimicrobial resistance). This technology may even have translational potential in veterinary medicine, where a fast and reliable method for purulent wound management would be highly valuable.

## 5. Conclusions

Our pilot study demonstrated that the novel alginate wound dressing containing the antibiotic cefepime, silver nanoparticles, and the growth factor FGF-2 provides more effective treatment for infected post-traumatic and post-burn wounds compared to conventional therapy. Use of the combined dressing led to accelerated healing (a 30-40% reduction in epithelialization time), rapid infection control, and a trend toward fewer complications. The antimicrobial action of the dressing was evident in the early suppression of key pathogens (*S. aureus, P. aeruginosa*, etc.) during the first week of treatment, as confirmed by negative culture results and declining inflammatory markers (CRP, leukocyte count). Simultaneously, FGF-2 released from the hydrogel stimulated reparative processes, promoting rapid granulation and epithelialization. The combination of these effects in a single therapeutic agent addresses the limitations of traditional dressings, which often either control infection at the expense of healing, or promote healing without adequate infection management.

No significant adverse events were observed during the study, indicating an acceptable safety profile for short-term use. These findings should be viewed as preliminary and warrant confirmation in larger-scale studies. Nevertheless, they already highlight the clinical potential of such bioactive dressings in managing severe infected wounds. The success observed in this pilot

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underscores the benefits of an integrated approach-combining antimicrobial and pro-regenerative therapy-which may improve patient outcomes, shorten rehabilitation time, and potentially reduce the need for systemic antibiotics.

In the future, following broader clinical trials and refinement of the application protocol, alginate dressings containing cefepime, silver, and FGF-2 could become an important addition to the modern wound care arsenal, especially in addressing challenges posed by antimicrobial resistance.

In summary, this pilot RCT confirmed that the new wound dressing represents a promising tool for accelerating the healing of purulent wounds. It combines the proven antiseptic properties of silver and antibiotics with the potent regenerative effects of a growth factor, offering a dual therapeutic benefit. This approach may significantly enhance treatment standards for complex wounds, reduce complication rates, and improve patient quality of life.

**Conflict of Interest**. The authors declare that there is no conflict of interest.

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# Жарақаттан кейінгі және күйіктен кейінгі іріңді жараларды емдеуге арналған біріктірілген таңғыштар

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## Түйіндеме

Жараның инфекциямен асқынуы (жарақаттан кейінгі және күйік жаралары) қазіргі клиникалық тәжірибеде ең күрделі мәселелердің бірі болып қала береді. Бұл жаралардағы тұрақты микробтық контаминация, тіндердің баяу регенерациясы және антибиотиктерге төзімділіктің өсуі емдеуді қиындатады. Тиімді терапия микробқа қарсы әсер мен тіндердің қалпына келуін қатар ынталандыруды қажет етеді. Биополимерлі альгинат таңғыштары дәрілік заттарды жергілікті жеткізу мен тіндердің регенерациясын қамтамасыз ететін заманауи платформа болып табылады.

Зерттеудің мақсаты: құрамында күміс, цефепим және фибробласттардың өсу факторы-2 (FGF-2) бар екі фазалы альгинат таңғышының тиімділігі мен қауіпсіздігін бағалау.

Әдістері. 20 науқас (әр топта 10-нан) қатысқан проспективті, рандомизацияланған, бақыланатын пилоттық клиникалық зерттеу жүргізілді. Эксперименттік топқа цефепим (1%), күміс иондары (0,1%) және FGF-2 (100 мкг/мл) бар екі фазалы альгинат таңғыш қолданылды. Бақылау тобына антисептик пен антибиотик негізіндегі стандартты терапия жүргізілді. Негізгі нәтиже - толық эпителизация уақыты; қосымша нәтижелер - бактериологиялық санация, С-реактивті ақуыз (СРА) деңгейі және асқынулар жиілігі.

Нәтижелері. Эксперименттік топта жараның жазылуы едәуір тезірек жүрді (18,3 ± 4,1 тәулікке қарсы 27,5 ± 5,8 тәулік; p < 0,01); 21-тәулікте толық жазылу 90% қарсы 50% (p = 0,041). Теріс бактериологиялық себінділер 7-тәулікте 70% және 14-тәулікте 100% науқастарда тіркелді (бақылау: тиісінше 30% және 70%; p = 0,021). СРА деңгейі жылдамырақ төмендеді, жағымсыз әсерлер байқалмады.

Қорытынды. Күміс, цефепим және FGF-2 бар жаңа альгинат таңғышы стандартты терапиямен салыстырғанда жараның тез жазылуын және инфекцияны тиімді бақылауды қамтамасыз етті, жақсы төзімділік көрсетті. Бұл біріктірілген тәсіл күрделі инфекцияланған жараларды емдеу нәтижелерін жақсартуы мүмкін және ауқымды клиникалық зерттеулерде қосымша растауды қажет етеді.

**Түйін сөздер**: альгинат таңғыш, цефепим, күміс нанобөлшектері, FGF-2, инфекцияланған жаралар, жараның жазылуы, антимикробтық терапия.

# Комбинированные раневые покрытия для лечения гнойных посттравматических и послеожоговых ран

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## Резюме

Инфицированные посттравматические и послеожоговые раны остаются одной из наиболее сложных проблем клинической практики из-за стойкой микробной контаминации, замедленного заживления и роста антибиотикорезистентности. Эффективное лечение требует сочетания антимикробного контроля и стимуляции регенерации тканей. Биополимерные альгинатные повязки представляют собой перспективную платформу для локальной доставки лекарств и восстановления тканей.

Целью данного исследования была оценка нового двухфазного альгинатного покрытия, содержащего серебро, цефепим и фактор роста фибробластов-2 (FGF-2), при лечении гнойных ран.

Методы. Проведено проспективное рандомизированное контролируемое пилотное клиническое исследование с участием 20 пациентов (по 10 в каждой группе) с гнойными посттравматическими и послеожоговыми ранами. Экспериментальная группа получала двухфазное альгинатное покрытие с цефепимом (1%), ионами серебра (0,1%) и FGF-2 (100 мкг/мл); контрольная - стандартную терапию антисептиками и антибиотиками. Основным исходом было время полной эпителизации, вторичными - бактериологическая санация, уровень С-реактивного белка (СРБ) и частота осложнений.

Результаты. В экспериментальной группе заживление происходило значительно быстрее (18,3±4,1 против 27,5 ± 5,8 сут; $p < 0,01$); к 21-м суткам полное закрытие ран достигнуто у 90% против 50% в контроле ($p=0,041$). Отрицательные посевы отмечены у 70% против 30% на 7-й день и 100% против 70% на 14-й ($p = 0,021$). Уровень СРБ снижался быстрее, побочные реакции отсутствовали.

Выводы. Новое альгинатное покрытие с серебром, цефепимом и FGF-2 обеспечивает более быстрое заживление и эффективный контроль инфекции по сравнению со стандартной терапией, демонстрируя хорошую переносимость. Комбинированный подход может улучшить результаты лечения сложных инфицированных ран и требует подтверждения в более крупных клинических исследованиях.

**Ключевые слова**: альгинатное покрытие, цефепим, наночастицы серебра, FGF-2, инфицированные раны, заживление ран, антимикробная терапия.

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