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Review Article

A review to elucidate the role and scope of topical ozenoxacin in routine surgical practice in India

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ABSTRACT

Superficial skin infections are a prevalent and are a significant challenge in surgical practice, particularly in India, where high surgical volumes and a high prevalence of comorbidities elevate the risk of infection. The use of topical antibiotics is a widely known strategy for preventing and managing superficial skin infections, yet the rise of antibiotic resistance demands innovative solutions. Based on the clinical evidence, epidemiology of superficial skin infections in surgical practice, risk factors, and panel discussion, this expert opinion aims to guide clinicians to optimize the use of ozenoxacin in surgical practice. The role of ozenoxacin, a novel fluoroquinolone, has been explored as an effective topical antibiotic for the treatment of superficial skin infection seen in surgical practice such as cellulitis, erysipelas, impetigo, ecthyma, folliculitis, furuncles, carbuncles, abscesses, and infections related to minor trauma. The article highlights ozenoxacin' s mechanism of action, its broader antimicrobial coverage against gram-positive pathogens, and its potential advantages over older topical antibiotics.

Keywords: Surgical site infections, Ozenoxacin, Topical antibiotics

INTRODUCTION

Superficial skin infections are a common occurrence in surgical practice, particularly in patients undergoing procedures involving lymph node dissection, gynecologic surgeries, or those with underlying risk factors such as lymphedema and diabetes. Studies show that 20% of vulvar carcinoma patients developed erysipelas post-surgery, with significantly higher rates in those undergoing lymph node dissection (36%) compared to sentinel node biopsy (14%).[1] Most cellulitis cases (73.8%) were found in outpatient healthcare settings, including doctors' offices, ambulatory surgery centres, homes, and other clinics.[2] In contrast, 20.5% of cases were identified in acute care settings, such as emergency departments and outpatient hospitals, while 5.7% occurred in inpatient hospital settings. These findings highlight the high prevalence of superficial infections in surgical settings and the need for effective perioperative infection prevention strategies.[1-3]

Topical antibiotics play an instrumental role in prevention of wound infections, and impetigo. Topical formulations allow for targeted delivery of the active ingredient to the site of dermatologic concern, along with higher concentration of the active ingredient, with avoidance of systemic adverse events or toxicity. Other benefits include reduced disruption of the intestinal microbial flora, low cost, and ease of administration. Due to these factors, topical antibiotics like mupirocin,

clindamycin, fusicidin and ozenoxacin are widely used for soft skin and tissue infections.[4]

Ozenoxacin is novel quinolone antibiotic with bactericidal activity, primarily against gram-positive bacteria, including *Methicillin-Sensitive Staphylococcus aureus* (MSSA), *Methicillin-Resistant Staphylococcus aureus* (MRSA), and *Streptococcus pyogenes*. It demonstrates superior efficacy and a lower minimum inhibitory concentration (MIC) when compared to other quinolones such as ofloxacin and levofloxacin. Ozenoxacin resists efflux pump-mediated resistance and exhibits a low tendency for the selection of resistant mutants. Notably, it does not cross-react with other quinolones or antimicrobial classes, making it a valuable option in managing resistant infections.[5] Overall, there is a lack of high-quality data to support local and topical antibiotic therapy use to decrease the risk of a superficial skin infection post-surgery. By focusing on its use, the manuscript will evaluate its potential for broader applications in the treatment of other surgical infections, offering a comprehensive view of its future in superficial skin infections in surgical practice.

METHODS

This expert opinion is based on a secondary review of published literature, clinical data, and expert panel discussions. A comprehensive search of peer-reviewed articles, guidelines, and real-world evidence on superficial skin infections and topical antibiotic use, particularly ozenoxacin, was conducted. Key sources including PubMed, Scopus, and relevant clinical trial data was searched using mesh terms like "superficial skin infections," "topical antibiotics," "Ozenoxacin," "surgical wound infection, additionally, insights from an expert panel discussion were incorporated to assess the clinical relevance, antimicrobial efficacy, and practical application of ozenoxacin in surgical practice. The findings were synthesized to provide evidence-based recommendations for optimal use in managing superficial skin infections.

CLINICO-EPIDEMIOLOGICAL ASPECTS OF DIFFERENT PATIENT PROFILES PRESENTING WITH SUPERFICIAL SKIN INFECTIONS IN SURGICAL PRACTICE

Infections at surgical site are a worldwide concern preoperatively, intraoperatively, or postoperatively, with a specified estimated incidence level of 2-5% in surgical patients depending on procedure and hospital out of which superficial infections make the most cases.[6,7]

Preoperative, intraoperative, and postoperative site infections, in general, still present a major challenge and risk factor to patients' lives regardless of the population group under consideration. Importantly, surgical site infection incidence and risk factors may differ based on patient age, co-morbid conditions, and immune competence.[8] Elderly adults, persons with low immunity, for example, those who are undergoing immunosuppressive treatment or those who are HIV/AIDS positive, have a higher tendency to be infected because their capacity to neutralize pathogens is diminished.[9]

Conditions like diabetes, obesity, cardiovascular diseases, and others are considered relevant to surgical site infections as they constitute the global determinants of surgical site infections risk. Diabetes-related foot infections (DFIs) remain the most frequent diabetes-related complications requiring hospitalisation and the most common precipitating events leading to lower extremity amputation.

Recent studies highlight the effectiveness of topical antibiotics in reducing surgical site infections (SSIs). In cardiac surgery, topical vancomycin significantly reduces sternal wound infections, with a nearly 70% risk reduction, especially in high-risk patients like those with diabetes. In oculofacial plastic surgery, patients treated with topical antibiotics had fewer surgical site infections compared to placebo. In video-laparoscopic cholecystectomy, topical rifamycin effectively reduced umbilical wound complications. Additionally, prolonged systemic and topical antibiotic prophylaxis in breast reconstruction lowered infection rates. These findings emphasize the potential of targeted topical antibiotic use in preventing surgical site infections across various surgical specialties.[10-12] These data suggest that improved infection prevention measures and targeted interventions might help reduce the burden that surgical site infections have, in varying degrees, on patient groups. Moreover, the number of hospitalized patients with diabetes and obesity has increased in India. This rise further complicates the challenge of effectively controlling superficial skin infections in surgical practice, necessitating more comprehensive and targeted approaches from healthcare professionals.

Topical antibiotics like mupirocin and retapamulin for superficial skin infections like impetigo and ecthyma are recommended by guidelines like AAFP and IDSA.[13] Heal et al concluded topical antibiotics may prevent surgical site infections compared to no antibiotic or with antiseptic.[14] Prophylactic topical antimicrobial therapy also significantly reduced the risk of SSI in mucosal head and neck surgeries, suggesting its potential effectiveness in superficial skin infections by lowering bacterial load and preventing infection when using topical antibiotics.[15]

Superficial infections in surgical practices: indication deep dive

In general, there are two types of wound infection: surgical site infection (SSIs), skin and soft tissue infection (SSTIs). Surgical site infections are typically classified as superficial, deep, and organ/space infections.

Such infections develop as a result of introducing pathogens into the surgical wound due to external contamination, inadequate endogenous antisepsis, or an endogenous source of bacteria.[16] In addition to patient-related factors, the severity of surgical site infections is influenced by surgical factors such as the type of procedure, emergency nature of the operation, extended duration of surgery, and contamination of the surgical site.

Superficial skin infections common in India include impetigo, folliculitis, furunculosis, acne, infected seborrheic dermatitis, and infected contact dermatitis, infectious eczematoid dermatitis.[17,18]

Superficial infections affecting the skin and upper soft tissues typically respond well to outpatient treatment.[19] Topical antibiotics are recommended for superficial mild infections like impetigo, mild cellulitis, abrasions and lacerations.[20]

Additionally, infections in diabetic foot ulcers, perianal regions, immunocompromised patients, or those caused by resistant pathogens are also classified as complicated SSTIs, requiring more intensive management.[19]

Superficial diabetic wound infection is one of the most difficult kinds of wound infection. Diabetes complicates the wound-healing process, and the organisms mainly found in chronic ulcers include *Staphylococcus aureus* and *Pseudomonas aeruginosa*. Also, these patients experience neuropathy, which makes their extremities insensitive. Thus, they do not feel the onset of infection or other complications and thus are unable to seek redress early enough. The compromised rate of healing is also worsened by the presence of diabetic ulcers, which are usually chronic in nature and create an environment fertile for bacterial growth.

Antimicrobial Stewardship strategies with topical preparations for prevention and treatment of surgical infections

Topical antibiotics are applied in the treatment of many forms of surgical wounds that include pressure, traumatic, and chronic venous ulcers. In such situations, the topical application aids in reducing microbial load and inflammation and stimulating tissue repair.[22] Presently, several topical antibiotics are in use in daily surgical practices, and these include mupirocin, neomycin, and silver sulfadiazine. These agents have a broad spectrum of action against *Staphylococcus aureus*, *Streptococcus*, and *Pseudomonas aeruginosa*. However, there are demerits that are attached to their use; for instance, they may lead bacterial resistance, cause allergies, or cause skin inflammation.[23] Furthermore, some topical antibiotics, such as neomycin, may offer low effectiveness in certain resistant organisms, and it is advisable not to use them on large surfaces because they are absorbed into the body system.

Of the more recent quinolone antibiotics approved, nemonoxacin, finafloxacin, and ozenoxacin may be considered further advancements in the quinolone family. Nemonoxacin is mainly indicated for respiratory tract infections, and it shows excellent activity against Glycosylphosphatidylinositol (GPI) pathogens, including multi drug resistant strains.[24] Finafloxacin is very effective for infections occurring in an acidic niche like acute otitis externa due to *Pseudomonas aeruginosa* and *Staphylococcus aureus*.[25]

Ozenoxacin is to be applied topically, as it has negligible systemic absorption, ensuring high concentrations in the stratum corneum where it is needed most. Its minimal absorption reduces the risk of systemic side effects, and the drug is metabolically stable without inducing cytochrome P450 enzymes. This pharmacokinetic profile makes ozenoxacin a safe choice, especially for paediatric populations. The recommended dosage is twice daily application for five days, with contraindications for infants under 2 months and those with hypersensitivity to the drug.[5]

In clinical trials, ozenoxacin has demonstrated impressive efficacy. In a phase III study, it showed a significantly higher clinical success rate of 54.4% compared to 37.9% for placebo at Day 5. Microbiologically, it achieved a success rate of 92.0% compared to 73.1% for placebo by the end of treatment. Ozenoxacin was particularly effective in eradicating S. aureus, including methicillin-resistant strains, making it a valuable alternative to other topical antibiotics. In additional studies, ozenoxacin showed therapeutic success rates of 93.7% and was effective in treating secondary infections like infected eczema, with negative conversion rates of 80.0% for S. aureus and 95.0% for *S. epidermidis*. Its bactericidal activity also extends to *S. pyogenes*, including penicillin-resistant strains.[26,27]

Ozenoxacin demonstrated a 93.7% therapeutic success rate in treating superficial skin infections, with a 92.8% reduction in systemic inflammatory response syndrome (SIRS) symptom scores over five days. Clinical success reached 100% in folliculitis and ear lobe infections. In another study, Ozenoxacin showed 70.0% efficacy in superficial infections, with negative conversion rates of 80.0% for *S. aureus* and 95.0% for *S. epidermidis*. It effectively targets *S. aureus* strains resistant to methicillin, mupirocin, and ciprofloxacin.[28]

Due to involvement of *S.aureus* and *S.pyogenes* in various superficial skin infections like carbuncles, folliculitis, impetigo, ecthyma and due to widespread resistance of antimicrobials to these strains, ozenoxacin use can be explored in such conditions.[28-31]

Expert opinion in defining topical ozenoxacin in surgical indications

Prevalence and management of surgical site infections

The rising prevalence of surgical site infections was addressed, particularly in high-risk cases such as diabetic foot infections and necrotizing cellulitis. Topical antibiotics, such as bacitracin, mupirocin, and vancomycin and ozenoxacin were identified as effective in preventing microbial contamination.

Clinical applications of ozenoxacin

Ozenoxacin was highlighted as an effective treatment for superficial skin infections such as impetigo, folliculitis, and infected wounds. Case studies have demonstrated its successful use in managing infections in diabetic patients and prior to surgeries, providing a viable alternative to traditional antibiotics like mupirocin.

Management of surgical site infections

The experts emphasized risk factors for surgical site infections, such as age, malnutrition, and diabetes. For high-risk patients, particularly those with poorly controlled diabetes, primary wound debridement and strict glycemic control were recommended to prevent infection progression. Topical antibiotics like ozenoxacin were suggested for superficial infections, while more severe infections required systemic treatments.

Antibiotic prophylaxis and management

The panel discussed antibiotic prophylaxis, noting that clean surgeries might only require a single dose of ceftriaxone. For chronic wounds, topical antibiotics are often sufficient. The role of ozenoxacin in preventing surgical site infections during dermatological surgeries and in the management of conditions like paronychia was emphasized.

Venous and diabetic foot ulcers

In diabetic foot infections, particularly Stage 1 and 2 ulcers, topical treatments like ozenoxacin are effective. For severe cases, systemic antibiotics are necessary. The discussion underscored the importance of managing venous ulcers with compression bandages and avoiding unnecessary systemic antibiotics.

Recent vs. older topical quinolones

Ozenoxacin was compared to older quinolones like mupirocin, with the latter showing increasing resistance, particularly against MRSA. ozenoxacin was noted for its broad spectrum and higher potency, making it a preferred option for treating superficial infections in clinical practice.

Key attributes of ideal topical antibiotics

Effective topical antibiotics should have a wide spectrum of activity, low resistance potential, ease of use, and good tolerability. Ozenoxacin was discussed for its safety and effectiveness, especially for local, ischemic wounds, and chronic ulcers.

Therapeutic landscape–topical antibiotic in superficial skin infection

Topical quinolones are a group of antibiotics that are frequently applied in SSTI; they are also utilized in preventing and treating surgical site infections. These antibiotics, including ozenoxacin, act by blocking one of the most important processes in bacterial cells - DNA replication. Mainly, quinolones exert their activity on bacterial enzymes, with DNA gyrase and topoisomerase IV enzymes guiding the process of DNA unwinding and replication.[32] This mechanism makes quinolones effective against so many pathogens, especially those that cause skin and soft tissue infections.

Ozenoxacin is a newer-generation topical quinolone with broad-spectrum antimicrobial activity against both Gram-positive and Gram-negative bacteria, cephalosporin is highly potent in combating *Staphylococcus aureus* and *Streptococcus pyogenes*, including MRSA, and thus, it constitutes an asset in combating various infections due to mainly resistant organisms. However, compared to the older topical quinolones like mupirocin and clindamycin, their efficacy has been established in skin infections, but these agents are not without their limitations. Mupirocin is very active against *Staphylococcus aureus*, including *MRSA*, but shows lesser activity compared to ozenoxacin; moreover, resistance against mupirocin is on the increase, more so in hospital-acquired infections.[33] Like erythromycin, clindamycin is useful against a range of Gram-positive organisms, including streptococci and staphylococci, but lacks a broad spectrum, especially against certain groups of Gram-negative germs.

Ozenoxacin has shown very high in vitro activity against all Gram-positive bacteria and even against multi-resistant strains with a well-described quinolone resistance pattern. These results suggest that ozenoxacin has 3 to 321 times greater potency than moxifloxacin, levofloxacin, and ciprofloxacin, which further underlines its efficacy.[34] This higher activity makes ozenoxacin a potential drug to combat dermatological infections, especially those caused by quinolone-resistant organisms.[34] Being the first non-fluorinated quinolone, ozenoxacin represents a promising way to create a new therapeutic niche in antibiotic topical applications in a situation with growing antibiotic resistance.

The relative merits of ozenoxacin are better compared to older fluoroquinolones because of its wider spectrum of action and increased sensitivity to resistant strains. The enhanced pathogen spectrum of action of ozenoxacin, as

well as its capability to effectively go after multidrug-resistant pathogens, makes it more suitable for managing surgical sites as well as soft tissue-related infections, particularly within environments of identified high antimicrobial resistance profiles In addition, the activity of ozenoxacin interferes with DNA gyrase and topoisomerase IV, with the latter providing a second site of action, which makes the compound more bactericidal than other antibiotics that target one enzyme.[35]

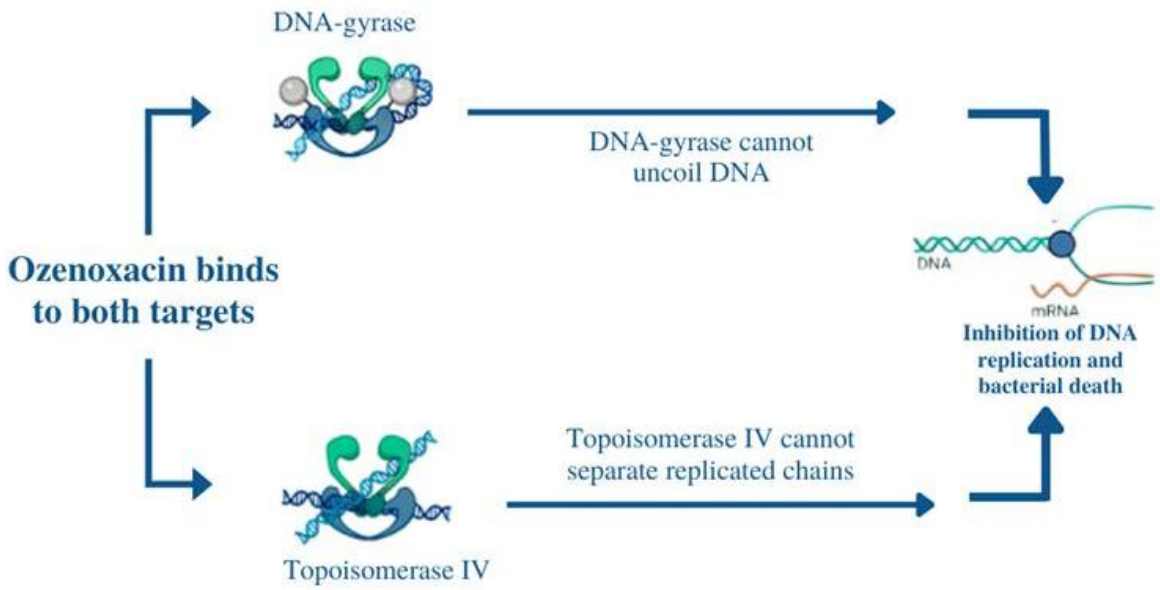

Figure 1: Mechanism of action of Ozenoxacin.[36]

Juxtaposing topical ozenoxacin against older topical antibiotics

Ozenoxacin is juxtaposed with older topical antibiotics like mupirocin and fusidic acid due to its potential advantages in combating antibiotic resistance and achieving faster bacterial clearance, particularly in cases of impetigo. Ozenoxacin demonstrates a broader spectrum of activity against resistant strains of Staphylococcus aureus and rapid clinical improvement compared to older treatments. Compared with the earlier topical antibiotics, ozenoxacin has a stronger antimicrobial effect than mupirocin, clindamycin, retapamulin, ciprofloxacin, and fusidic acid. Examining the MIC data, it was ascertained that this compound is 4-fold more active than erythromycin, clindamycin, and retapamulin; at least 8-fold more active than mupirocin; and 64-fold more active than ciprofloxacin or levofloxacin; it is 256-fold more active than fusidic acid.[37] This excellent bactericidal effect is attributed to two targets, DNA gyrase and topoisomerase IV, responsible for bacterial DNA synthesis. Furthermore, the drug is a non-substrate for bacterial efflux pumps, implying that the drug shall remain as effective against MDR strains and therefore more potent for the treatment of bacterial skin infections.[37]

The clinical indications for fusidic acid in dermatology is the treatment of mild-to-moderate severe skin and soft-tissue infections, such as impetigo, folliculitis, erythrasma, furunculosis, and mild-to-moderate atopic dermatitis with the presence of secondary infection. Topical gentamicin comes as a 0.1% cream or ointment and is indicated for primary skin infections (impetigo, superficial folliculitis, ecthyma, furunculosis, and pyoderma gangrenosum) and secondary skin infections (infectious eczematoid dermatitis, pustular acne, pustular psoriasis, infected seborrheic dermatitis, and infected contact dermatitis). This topical formulation can be used in both children and adults. Mupirocin is commonly used for treating skin and skin structure infections, including MRSA cutaneous infections or nasal decolonization to prevent transmission and infection. Mupirocin is indicated for the treatment of impetigo and secondarily infected superficial cutaneous wounds due to Staphylococcus aureus and Streptococcus pyogenes in adults and children. The triple formulation of neomycin–bacitracin–polymyxin, is commonly used to treat minor wounds, secondarily infected dermatitis, and superficial pyodermas.[38]

Based on clinical judgment and evidence-based medical practice, clinicians should strategically use topical antibiotics, keeping in mind the indication, the location of dermatologic concern, and emergence of drug resistance.[38]

Redefining – role & scope of topical ozenoxacin

The drug ozenoxacin, commonly recommended for surgical site infections and acne, has high prospects for further application in other dermatological diseases due

to the antibiotic spectrum, which includes Gram-positive and Gram-negative bacteria, as well as its versatility in the management of various types of skin lesions, including those with resistant microorganisms. High resistance to mupirocin has emerged, especially in MRSA strains, and research shows that increased resistance to mupirocin in MRSA is 14.1%.[39] This issue has further underlined the urgency of seeking additional therapies that would be more successful at addressing resistant strains. Ozenoxacin could solve the drawbacks of topical antibiotics, especially in the increasing resistance to the mupirocin treatment.

There is recent evidence to suggest that ozenoxacin may be useful in skin-associated conditions such as folliculitis and even chronic wounds with bacterial potential. The broadened application could indeed provide different treatment options for conditions where mupirocin and other standard therapies are gradually losing their efficacy due to rising resistance.[40] The potential use of ozenoxacin also in chronic dermatological conditions will provide new doors in treatment, particularly for patients with more complicated or recurrent skin lesions.

Concerning the prospects of clinical trials dedicated to these more general types of indications, the outlook is rather positive. For this potential, current research emphasizes that ozenoxacin successfully works in treating almost all sorts of superficial skin infections, including those involving resistant pathogens.

Topical Ozenoxacin plays a crucial role in achieving antimicrobial stewardship goals, particularly in the context of managing superficial skin infections and minimizing the development of resistance. One of the primary advantages of Ozenoxacin is its potent efficacy against Gram-positive pathogens, including MRSA, with a low likelihood of resistance emergence. Its unique mechanism of action, which targets bacterial DNA gyrase and topoisomerase IV, further enhances its effectiveness and reduces the risk of resistance compared to other topical antibiotics. Additionally, Ozenoxacin has demonstrated a lower resistance profile when compared to older antibiotics like mupirocin, which faces growing resistance, especially among MRSA strains.[41] As part of an antimicrobial stewardship strategy, Ozenoxacin's targeted use for superficial skin infections offers a promising approach to managing infections while conserving the effectiveness of systemic antibiotic.

Key advantages of topical ozenoxacin: expert consensus

Characteristics of an ideal topical antibiotic

Essential features include broad-spectrum efficacy, bactericidal action, resistance prevention, ease of use, good tolerability, and affordability.

Efficacy in treating surgical site infections

Particularly valued for its activity against Gram-positive organisms, including MRSA.

Safety and pediatric applications

Tolerable for use in children as young as two months; case studies have shown it can be used for treating conditions like paronychia and green nail syndrome in pediatric patients.

Comparison with older antibiotics

Some previous antibiotics, such as mupirocin and clindamycin, are also effective; ozenoxacin has greater effectiveness against MRSA and a broader spectrum, making it preferable for surgical site infections and wound treatment.

Role of ozenoxacin in prophylaxis

Effective in preventing infections in clean and clean-contaminated surgical wounds; negligible systemic absorption and good tolerability make it suitable for dermatological surgeries and minor procedures; adjunctive use in superficial wound care is valuable.

Overall potential of ozenoxacin

With its broad spectrum, safety, and versatility, Ozenoxacin is a promising agent for managing surgical site infections and chronic wound infections; plays an essential role in modern surgical infection care.

CONCLUSION

Ozenoxacin stands as a novel topical antibiotic for treating superficial skin infections post-surgery because of its enhanced effectiveness, safety, and resistance compared to Mupirocin and Clindamycin. Ozenoxacin has a powerful action on Gram-positive microorganisms, including MRSA and its efficacy in the treatment of superficial skin infection such as cellulitis, erysipelas, impetigo, ecthyma, folliculitis, furuncles, carbuncles, and infections related to minor trauma, Hence it can also be considered for complicated lesions, such as superficial diabetic wounds and other superficial skin infections seen in routine surgical practices.

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