

Main Abstract

New Technologies

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D-PLEX100, A NOVEL DOXYCYCLINE FORMULATION THAT PROVIDES HIGH, LOCAL CONCENTRATIONS OF ANTIBIOTIC ACTIVITY FOR 30 DAYS TO REDUCE SURGICAL SITE INFECTIONS

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Aim: Despite significant advances in perioperative care, surgical site infections (SSIs) remain a substantial cause of morbidity and mortality among patients undergoing both elective and emergent surgeries. Even with the most robust adherence to currently accepted preventive measures, up to 60% of SSIs are still deemed preventable. Here we describe a drug delivery platform developed to address the gap in effective prophylaxis against superficial (SSSI) and deep (DSSI) SSIs.

Method: D-PLEX₁₀₀ (D-PLEX) is a doxycycline formulation which pairs an innovative Polymer-Lipid Encapsulation matrix (PLEX) platform with the broad-spectrum antibiotic, doxycycline, and is applied to the incision following myofascial closure prior to skin closure. This biodegradable platform contains alternating layers of polymers and lipids to enable a localized, continuous release of doxycycline for a period of 30 days with negligible systemic drug levels. D-PLEX demonstrates activity against many of the common pathogens associated with SSIs, including frequently encountered antimicrobial-resistant pathogens.

Results: In a single-blind, phase 2 clinical trial, patients undergoing elective colorectal surgery were randomized 1:1 to D-PLEX + Standard of Care (SOC) or SOC alone (NCT03633123). All patients received IV antibiotic prophylaxis 30-60 minutes prior to surgery. Patients randomized to the investigational arm received D-PLEX at the time of closure based on the length of surgical incision. The SSI rate within 30 days post-index surgery revealed a 64% relative risk reduction in SSI rate in the D-PLEX plus SOC group (N=7/88 [7.9%]) vs SOC alone (N=20/91 [21.9%]); p<0.05, with negligible systemic doxycycline levels.

Conclusion: These data demonstrate that the addition of D-PLEX₁₀₀ to the SOC prophylaxis regimen significantly reduces the SSSI and DSSI rate. D-PLEX₁₀₀ is a promising addition to current SSI bundles and is currently being evaluated in two Phase 3 clinical trials (NCT04411199, NCT04233424).

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Vibramycin FDA Label

Disclosure of Interest: N. Emanuel Shareholder with: PolyPid, Ltd., Employee with: PolyPid, Ltd., G. Kozloski Shareholder with: PolyPid, Ltd., Employee with: PolyPid, Ltd., A. Senagore Shareholder with: PolyPid, Ltd., Employee with: PolyPid, Inc.