PolyPid 2030 Investor Day

October 2026

Forward-Looking Statement

This presentation contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act and other federal securities laws. For example, the Company is using forward-looking statements when it discusses the U.S. Food and Drug Administration’s (“FDA”) review of the New Drug Application (“NDA”) for D-PLEX$_{100}$, including the Priority Review designation and the Prescription Drug User Fee Act (“PDUFA”) goal date of November 28, 2026; possible label expansion beyond colorectal surgery, the FDA pre-approval inspection of the Company’s manufacturing facility; the potential approval of D-PLEX$_{100}$; and the expected commercial launch of D-PLEX$_{100}$ by Azurity Pharmaceuticals (“Azurity”) in the United States in early 2027.

Forward-looking statements also include the Company’s exclusive commercialization partnership with Azurity for the United States and Canada, including the partnership’s economic structure, potential milestone payments, tiered royalties and transfer price, and the joint development activities and label expansion programs contemplated under that agreement; potential reimbursement for D-PLEX$_{100}$, including New Technology Add-on Payment (“NTAP”) status; the European Medicines Agency’s (“EMA”) review of the Marketing Authorization Application for D-PLEX$_{100}$ and the anticipated timing of that review; the Company’s plans for the commercialization of D-PLEX$_{100}$ in Europe and other territories following the reversion of European rights from ADVANZ PHARMA, including potential partnerships; the design, development plan, regulatory pathway, and anticipated timing of the Investigational New Drug application and clinical trials for PD01B, and its potential benefits; the Company’s KynatriX™ technology and other pipeline programs, including its long-acting metabolic program; and the Company’s growth strategy and expected milestones through 2030.

Words such as “expects,” “anticipates,” “intends,” “plans,” “believes,” “seeks,” “estimates” and similar expressions are intended to identify forward-looking statements. Forward-looking statements are not historical facts and are based upon management’s current expectations, beliefs and projections, many of which are inherently uncertain and beyond the Company’s control. Actual results may differ materially from those expressed in or implied by the forward-looking statements. For a more detailed description of the risks and uncertainties affecting the Company, see the Company’s filings with the Securities and Exchange Commission, including its Annual Report on Form 20-F filed on February 25, 2026. Forward-looking statements speak only as of the date of this presentation, and the Company disclaims any obligation to update them except as required by applicable law.

PD01B is an investigational product candidate and has not been approved by the FDA or any other regulatory authority. Views expressed by Dr. Warren Joseph are his own.

YL1

Today's Agenda

1. **PolyPid Today** – What We've Delivered
2. **PolyPid 2030**
3. **Introducing PD01B** for Diabetic Foot Infections
4. **KOL presentation**: Warren Joseph, DPM, FIDSA
5. **Timelines**
6. **Q&A**

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Slide 3

YL1 Arx: Changed "Diabetic Foot Ulcers" to "Diabetic Foot Infections" (per Jonny's DFI decision in the script) and "D.P.M" to "DPM".
ARX-YL, 2026-10-15T12:00:00

Last Six Months: Promised and Delivered

Signed commercial, supply, and development deal with Azurity Pharma

- >$320M in development and sales milestones. $30M already paid
- Tiered royalties on net sales ranging from mid-teen to mid-twenties percentages
- Pre-negotiated transfer price per vial
- Azurity to fund clinical development for label expansion

NTAP submitted. CMS decision expected August 2027

NDA under FDA Priority Review

- Target PDUFA date: November 28, 2026
- Expected launch – early 2027

D-PLEX$_{100}$ dossier submitted for EMA review and validated

Regained full European commercial rights to D-PLEX$_{100}$

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PolyPid 2030

3 major growth levers for PolyPid with near-, mid- and long-term value drivers



Maximize Azurity Partnership

Expand label beyond colorectal surgery with clinical work funded by Azurity

NEAR TERM

Expand D-PLEX$_{100}$ geographically

US and Canada signed. Expand to Europe and other territories through partnerships

NEAR AND MID TERM

Build a Kynatrix™-based pipeline

In-house and external development leveraging PolyPid's long-acting, controlled-release technology

MID TO LONG TERM

Lever 1: Label Expansion Beyond Colorectal Surgery

SSI isn't a colorectal problem only; it's a surgery problem

1st Expansion to **Abdominal surgery** including GI tract, hysterectomies, etc.

- Initiate FDA conversation Q4 2026
- 4 million surgeries, close to half are open procedures[1]

Possible follow-on surgeries:

Soft-tissue surgery

- **Breast reconstruction** - ~160K / year[2]
- Post-weight-loss body contouring (**Panniculectomies**) – fast growing segment[2]

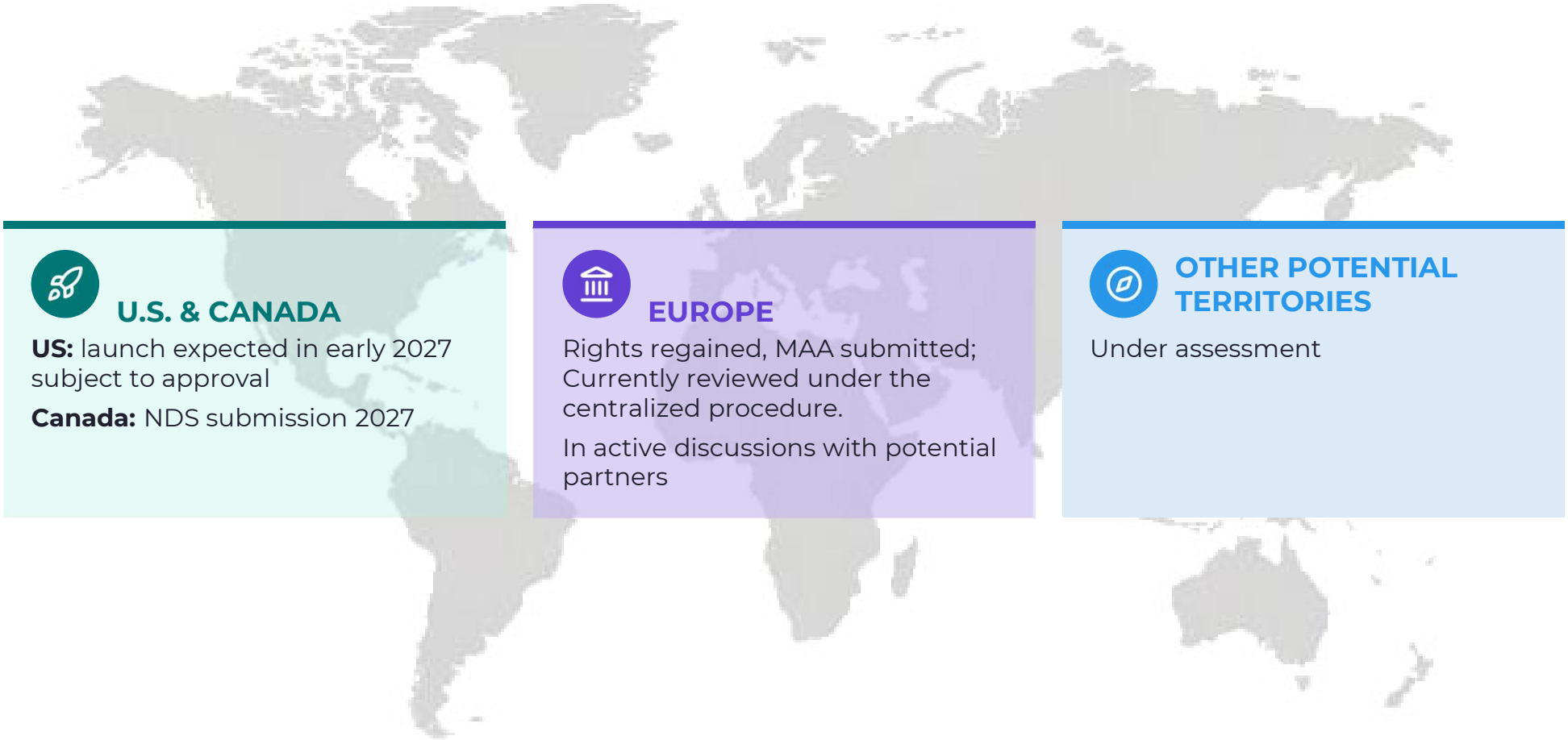
Bone-tissue surgery

- **Trauma, bone fractures, fixations** 800K – 1 million[1] / year
- **Lumbar fusion** – ~275K / year[3]



1. IQVIA PM&I Global FlexView. Internal analysis ; 2. https://www.plasticsurgery.org/documents/news/statistics/2025/plastic-surgery-statistics-report-2025.pdf; 3. lumbar fusion volume derived from AHRQ HCUP National Inpatient Sample and Nationwide Ambulatory Surgery Sample

Lever 2: Open New Markets for D-PLEX$_{100}$



U.S. & CANADA

US: launch expected in early 2027 subject to approval

Canada: NDS submission 2027

EUROPE

Rights regained, MAA submitted; Currently reviewed under the centralized procedure.

In active discussions with potential partners

OTHER POTENTIAL TERRITORIES

Under assessment

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Lever 3: Kynatrix Innovation Strategy

Leverage the power of the Kynatrix delivery technology to elevate treatment effectiveness

Develop in-house and Collaborate with R&D partners to:



Improve efficacy



Extend release of molecules



Minimize systemic side effects and toxicity

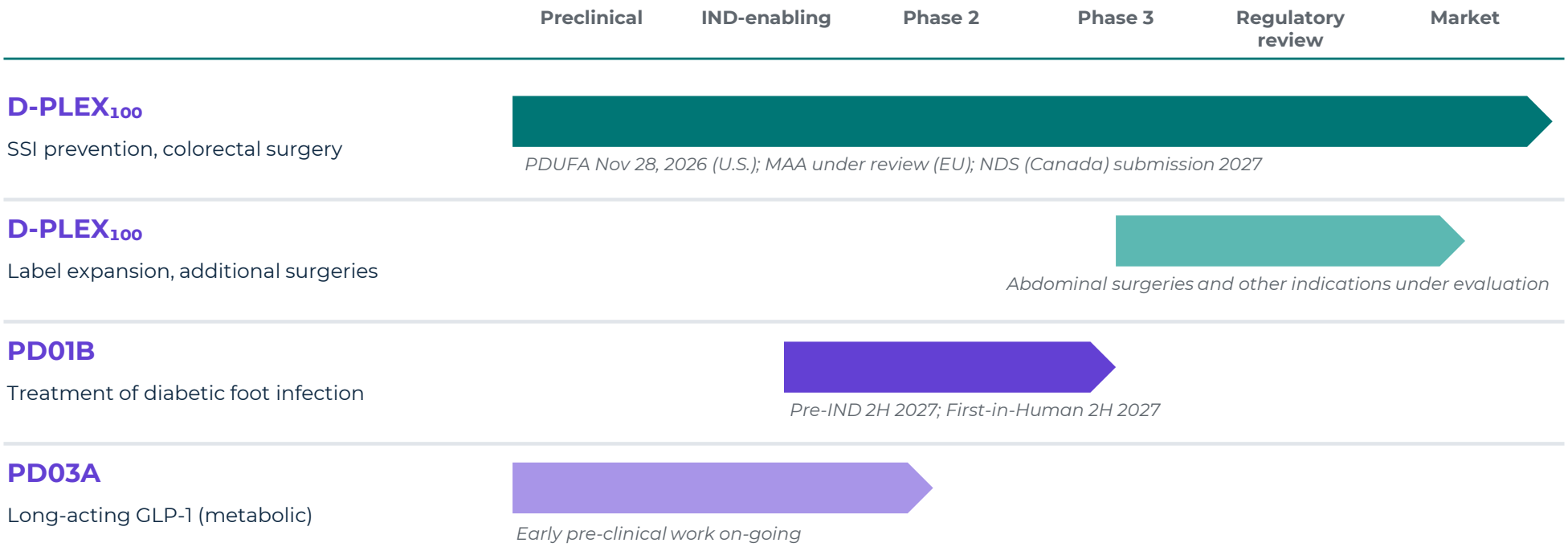
Key Therapeutic Areas

- Surgical Site Infection
- Infection Treatment
- Metabolic Diseases & Obesity

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Kynatrix Pipeline – 2030 View

One platform, prevention and treatment



Stage bars are illustrative. PD01B and PD03A are investigational.

Diabetic Foot Infection: A Large, Underserved Need

40.1 M[1] people with diagnosed or undiagnosed diabetes in the U.S.

19–34%[2]

lifetime risk of a diabetic foot ulcer for people with diabetes

#1[2]

diabetic foot infection is the most frequent diabetes complication requiring hospitalization, and the most common precursor of amputation

~1 in 5[2]

moderate or severe diabetic foot infections end in some level of amputation

$52K[3]

Cost of care for patients undergoing lower extremity amputation. Patients are seen by their outpatient health care provider about 12 times per year and are hospitalized about 2 times per year.

Why it's hard: an infected ulcer is a local problem. Poor blood flow limits how much systemic antibiotic reaches the wound. Getting enough antibiotics, for long duration, into infected tissue is the gap.

1. CDC National Diabetes Statistics Report Sept. 2026; 2. IWGDF/IDSA Guidelines on the Diagnosis and Treatment of Diabetes-related Foot Infections, 2023 (Senneville et al., Clin Infect Dis); 3. Margolis DJ, Malay DS, Hoffstad OJ, et al. Economic burden of diabetic foot ulcers and amputations. 2011 Mar 8. In: Data Points Publication Series [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2011-. Data Points #3.

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PD01B – Kynatrix for Treatment of Diabetic Foot Infections



What is it?

Hyper-local doxycycline released in the wound for several weeks

Indication for use

Treatment of moderate to severe diabetic foot infection (DFI) after wound debridement

Development pathway

New NDA under the 505(b)(2) pathway, separate from D-PLEX$_{100}$

Same Technology. A New Product.

	D-PLEX$_{100}$	PD01B
Goal	Prevent infection	Treat established infection
Indication	Prevention of SSI after colorectal surgery	Treatment of moderate to severe diabetic foot infections
Physician / setting	Surgeons; operating room	Podiatrists & wound-care specialists; wound clinic
Release profile	30 days	Several weeks; hyper local concentration
Regulatory path	505(b)(2); NDA No. 220740; PDUFA Nov. 28, 2026	505(b)(2); New NDA
Commercial rights	Azurity (U.S. & Canada); PolyPid elsewhere	PolyPid, worldwide
Intellectual Property	Prevention of SSI – September 2035	New patent application recently submitted

Shared: active ingredient (doxycycline), Kynatrix™ technology, manufacturing site and processes, preclinical and safety foundation.

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Why PD01B Can Move Faster

PD01B doesn't start from zero: experience gained with D-PLEX$_{100}$ may help streamline its development

WHAT WE ALREADY HAVE

- **Known active ingredient**
  Doxycycline a broad-spectrum antibiotic, with a long, well-characterized safety record
- **Validated platform**
  Kynatrix™, proven in Phase 3 (SHIELD II)
- **Formulation design**
  Product based on D-PLEX$_{100}$
- **CMC at an advanced stage**
  Same manufacturing site and similar processes
- **Preclinical & safety foundation**
  Tox package leveraged; > 1000 patients treated with D-PLEX$_{100}$

EXPECTED MILESTONES

2H 2027

Pre-IND meeting

2H 2027

First-in-human

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KOL Presentation: Dr. Warren Joseph

Warren S. Joseph, DPM, FIDSA
Adjunct Clinical Professor
Arizona College of Podiatric Medicine
Editor-in-Chief, Journal of the American Podiatric Medical Association

TOPICAL ANTIBIOTICS FOR THE TREATMENT OF DIABETIC FOOT INFECTIONS

Topics to Cover

- What is the scope of the problem?
- What happens when it goes wrong?
- What are the advantages of topical antibiotics?
- What topicals have been tried and failed?
- Where does PD01B fit in?

Scope of the problem

- The International Diabetes Federation (IDF) estimates 589 million people in the world have diabetes and 38.5 million in the US
- Over 4 in 10 with diabetes are unaware they have it
- By 2050 cases are expected to reach 853 million
- ~1 in 3 will develop a foot ulceration in their lifetime
- In North America active ulcer rates are estimated to be 13% (one of the highest in the world)

https://idf.org/

Infection in Diabetic Foot Ulcers

- 50-60% of all diabetic foot ulcers (DFUs) will become infected
  - The single most common reason for hospitalization in people with diabetes
- Up to 20% will develop osteomyelitis
- Patients with diabetes are 25x more likely to undergo amputation
- 85% of all amputations are preceded by a foot ulcer
- Every 20 seconds, somewhere in the world, a limb is amputated

Edmonds M, The current burden of diabetic foot disease. J Clin Orthop Trauma. 2021 Feb 8;17:88-93. doi: 10.1016/j.jcot.2021.01.017

Evolution of a Diabetic Foot Infection



N ENGL J MED 369;23 NEJM.ORG DECEMBER 5, 2013

Guest Editorial: are diabetes-related wounds and amputations worse than cancer?

Editorial Information

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Certainly one of the most feared complications of diabetes is the lower extremity amputation (1). This fear is not unwarranted. Diabetes-related ulcer and amputation may be associated with surprisingly high 5-year mortality.

Moulik *et al*. (2) reported a 5-year mortality of 45%, 18% and 55% for neuropathic, neuro-ischaemic and ischaemic ulcers, respectively. As expected, mortality was higher in ischaemic ulcers than neuropathic ulcers. However, it is fairly evident based on these data that all types of diabetic foot ulcers are associated with high morbidity and mortality. Similarly, approximately half the persons receiving a diabetes-related amputation will not be alive in 5 years.

Certainly, peripheral vascular disease may be implicated as a significant factor associated with shorter life span. Criqui reported the 10-year mortality in patients with peripheral arterial disease and found a substantially higher risk of mortality among patients with large vessel peripheral arterial disease – a factor that may be even more profound today than when it was reported in the early 1990s (3,4). Faglia *et al*. related this high mortality with the absence of revascularisation, citing a 1.7-fold greater risk for death in ischaemic subjects who might have benefited from intervention (5).

How do these data compare with other serious medical conditions, such as cancer? If one reviews Figure 1, one might conclude that persons with lower extremity complications of diabetes have 5-year mortality rates similar or worse than many common types of cancer (6–10). In fact, some high-risk subgroups such as persons with renal disease requiring distal bypass may have 5-year mortality rates approaching 95% (10).

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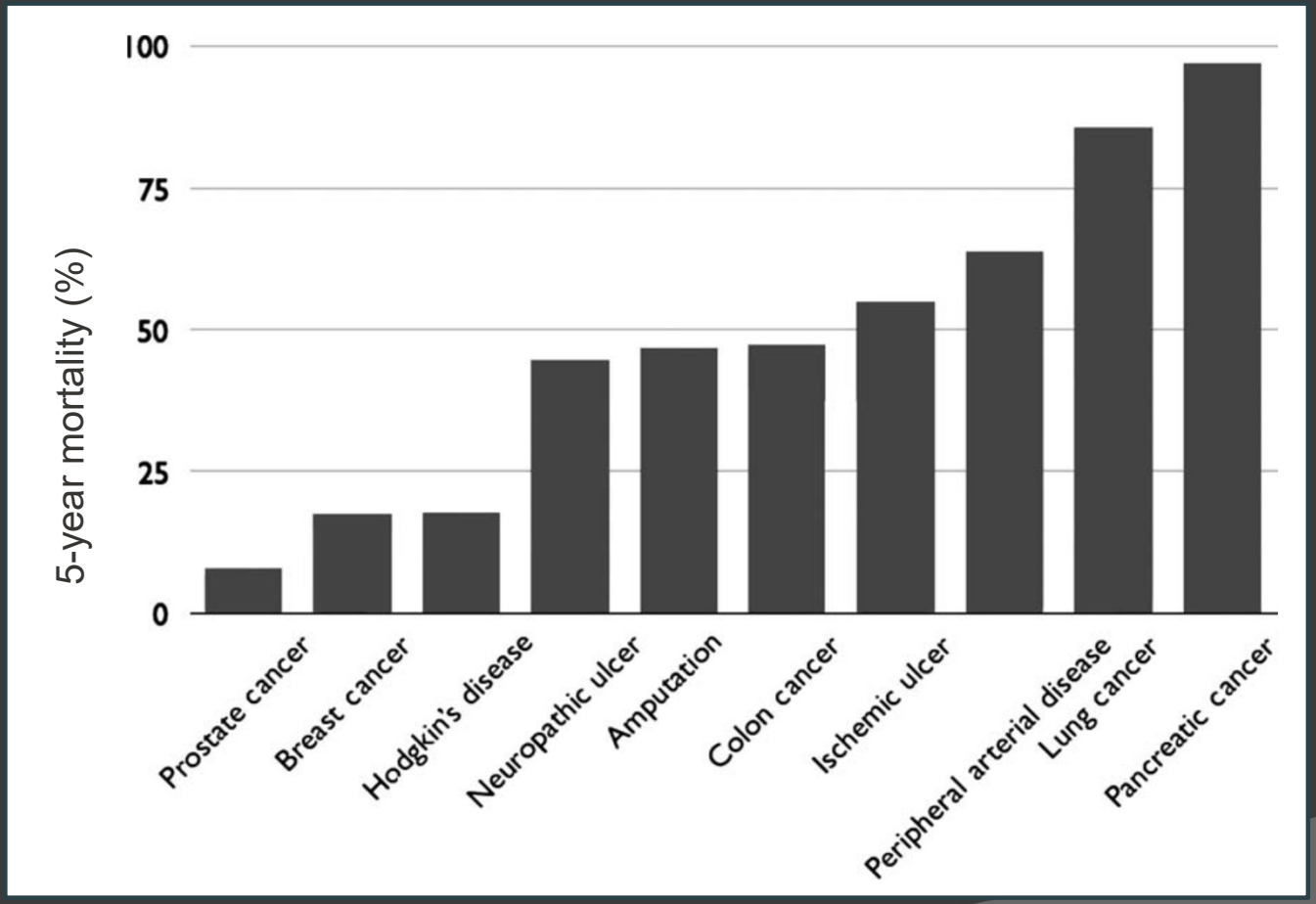
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1 Singh N, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes. JAMA 2005;293: 217–28.
2 Moulik PK, Mtonga R, Gill GV. Amputation and mortality in new-onset diabetic foot ulcers stratified by etiology. Diabetes Care 2003;26:491–4.
3 Criqui MH, Langer RD, Fronek A, Feigelson HS, Klauber MR, McCann TJ, Browner D. Mortality over a period of 10 years in patients with peripheral arterial disease. N Engl J Med 1992;326:381–6.
4 Golomb BA, Dang TT, Criqui MH. Peripheral arterial disease: morbidity and mortality implications. Circulation 2006;114:688–99.
5 Faglia E, Clerici G, Clerissi J, Gabrielli L, Losa S, Mantero M, Caminiti M, Curci V, Lupattelli T, Morabito A. Early and five-year amputation and survival rate of diabetic patients with critical limb

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Mortality Rates vs. Common Cancers



Source: Armstrong DG, Wrobel J, Robbins JM. Guest Editorial: are diabetes-related wounds and amputations worse than cancer? Int Wound J. 2007 Dec;4(4):286-7. doi: 10.1111/j.1742-481X.2007.00392.x

IDSA GUIDELINES

2012 Infectious Diseases Society of America Clinical Practice Guideline for the Diagnosis and Treatment of Diabetic Foot Infections[a]

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Clinical Infectious Diseases, 2012:54 (15 June)
Cited 2905 times as of Feb 2026

Clinical Infectious Diseases

IDSA GUIDELINES

IDSA Infectious Diseases Society of America

hivma hiv medicine association

OXFORD

IWGDF/IDSA Guidelines on the Diagnosis and Treatment of Diabetes-related Foot Infections (IWGDF/IDSA 2023)

Éric Senneville,[1,2] Zaina Albalawi,[3] Suzanne A. van Asten,[4] Zulfiqarali G. Abbas,[5] Geneve Allison,[6] Javier Aragón-Sánchez,[7] John M. Embil,[8] Lawrence A. Lavery,[9] Majdi Alhasan,[10] Orhan Oz,[11] Ilker Uçkay,[12] Vilma Urbančič-Rovan,[13] Zhang-Rong Xu,[14] and Edgar J. G. Peters[15,16,17]

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Senneville E, et al. Clinical Infectious Diseases, 2023

IWGDFGUIDELINES.ORG

IDSA/IWGDF Severity Scale 2023

Clinical classification of infection, definitions	IWGDF/IDSA classification
No systemic or local symptoms or signs of infection	1/Uninfected
Infected: At least two of these items are present: • Local swelling or induration • Erythema >0.5 but <2 cm[b] around the wound • Local tenderness or pain • Local increased warmth • Purulent discharge	2/Mild
And, no other cause of an inflammatory response of the skin (e.g., trauma, gout, acute charcot neuro-arthropathy, fracture, thrombosis, or venous stasis)	
Infection with no systemic manifestations and involving: • Erythema extending ≥2 cm[b] from the wound margin, *and/or* • Tissue deeper than skin and subcutaneous tissues (e.g., tendon, muscle, joint, and bone)[c]	3/Moderate
Infection involving bone (osteomyelitis)	Add "(O)"
Any foot infection with associated systemic manifestations (of the systemic inflammatory response syndrome [SIRS]), as manifested by ≥2 of the following: • Temperature, > 38°C or <36°C • Heart rate, > 90 beats/min • Respiratory rate, > 20 breaths/min, *or* PaCO2 < 4.3 kPa (32 mmHg) • White blood cell count >12,000/mm^3, *or* < 4G/L, *or* >10% immature (band) forms	4/Severe
- Infection involving bone (osteomyelitis)	Add "(O)"

IDSA: Infectious Diseases Society of America; IWGDF: International Working Group on the Diabetic Foot

Non-infected “Clean Ulcer”



Mild Infections





Moderate Infection





Severe Infection



What do the Guidelines say about topical antibiotics?

Rationale. Treatment with topical antimicrobial therapy has many theoretical advantages, particularly requiring only a small dose directly at the site of infection, thus potentially limiting issues of cost, adverse events, and antibiotic resistance. The potential advantage of topical versus systemic antibiotic therapy is to deliver very high concentrations of antibiotics at the site of infection that could not be achieved using the systemic route of administration. Another potential advantage is to limit potential collateral damage to gut microflora, including the emergence of multiresistant bacteria and *Clostridioides* difficile-associated diarrhoea.

Recommendation 24

We suggest not using topical (sponge, cream, and cement) antibiotics in combination with systemic antibiotics for treating either soft-tissue infections or osteomyelitis of the foot in patients with diabetes. (Conditional; Low)

There is also insufficient evidence on whether adjunctive agents meaningfully affect clinical outcome and the safety of routinely using local antibiotics has not yet been clearly established.

Therefore, we elected to suggest against the use of topical antibiotics. Future studies should apply learnings from prior studies to ensure statistically robust and clinically useful randomized controlled trials (RCTs). (*Listed as an area of high interest*)


Review language : English
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Informed decisions.
Better health.
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Topical antimicrobial agents for treating foot ulcers in people with diabetes
Jo C Dumville, Benjamin A Lipsky, Christopher Hoey, Mario Cruciani, Marta Fiscon, Jun Xia
Authors' declarations of interest
Version published: 14 June 2017
Version history
https://doi.org/10.1002/14651858.CD011038.pub2

Authors' conclusions

The randomised controlled trial data on the effectiveness and safety of topical antimicrobial treatments for diabetic foot ulcers is limited by the availability of relatively few, mostly small, and often poorly designed trials. Based on our systematic review and analysis of the literature, we suggest that: 1) use of an antimicrobial dressing instead of a non-antimicrobial dressing may increase the number of diabetic foot ulcers healed over a medium-term follow-up period (low-certainty evidence); and 2) there is probably little difference in the risk of adverse events related to treatment between systemic antibiotics and topical antimicrobial treatments based on the available studies (moderate-certainty evidence). For each of the other outcomes we examined there were either no reported data or the available data left us uncertain as to whether or not there were any differences between the compared treatments. Given the high, and increasing, frequency of diabetic foot wounds, we encourage investigators to undertake properly designed randomised controlled trials in this area to evaluate the effects of topical antimicrobial treatments for both the prevention and the treatment of infection in these wounds and ultimately the effects on wound healing.

Advantages of Topicals

- Achieve high local concentrations
- Limited systemic absorption
- Reduce overall antibiotic exposure
- *STEWARDSHIP!*
  - Reduce adverse events
  - Reduce development of resistance
- Few disadvantages

Soldevila-Boixader, et.al. Local Antibiotics in the Treatment of Diabetic Foot Infections: A Narrative Review. Antibiotics 2023, 12, 124.

Topical Rationale/Questions

- All wounds are colonized – many with methicillin-resistant Staphylococcus aureus (MRSA)
- Could reduction in colonization decrease subsequent infection rate?
- Could reduction in colonization increase healing rate?
- The only way to prevent infection in a wound and complications such as amputation…is to *heal it!*

What has been tried?

Randomized Controlled Trial > Clin Infect Dis. 2008 Dec 15;47(12):1537-45. doi: 10.1086/593185.

Topical versus systemic antimicrobial therapy for treating mildly infected diabetic foot ulcers: a randomized, controlled, double-blinded, multicenter trial of pexiganan cream

Benjamin A Lipsky [1], Kenneth J Holroyd, Michael Zasloff

Results. Overall, 835 patients were randomized; those in each treatment arm were similar with regard to demographic and clinical characteristics. Although study 303 failed to demonstrate equivalence, study 304 and the combined data for the 2 trials demonstrated equivalent results (within the 95% confidence interval) for topical pexiganan and oral ofloxacin in clinical improvement rates (85%–90%), overall microbiological eradication rates (42%–47%), and wound healing rates. The incidence of worsening cellulitis (2%–4%) and amputation (2%–3%) did not differ significantly between treatment arms. Bacterial resistance to ofloxacin emerged in some patients who received ofloxacin, but no significant resistance to pexiganan emerged among patients who received pexiganan.

Conclusions. Topical pexiganan might be an effective alternative to oral antibiotic therapy in treating diabetic patients with a mildly infected foot ulcer, and might reduce the risk of selecting antimicrobial-resistant bacteria.

Results of 2 placebo-controlled trials of a new topical antibiotic for treating mild diabetic foot infection (DFI)

- Trial of topical antibiotic treatment in mild DFI is feasible; can be safely conducted
- Trial including a “placebo” group in mild DFI is feasible; can be safely conducted
- Important information gained regarding natural history of mild DFI
- Topical treatment with pexiganan cream did not show statistically significant superiority over vehicle in clinical or microbiological outcomes under the conditions of these trials
- Standardized (and unusually intensive) wound care alone in this population was sufficient to eliminate infection in ~50% of cases.
- An unexpectedly high rate of local infection-related complications was seen in the pexiganan groups.

What does all the evidence show?

Journal of Diabetes

WILEY

Journal of Diabetes

REVIEW ARTICLE OPEN ACCESS

Local Versus Systemic Antibiotics for Diabetic Foot Infection—A Systematic Review and Meta-Analysis

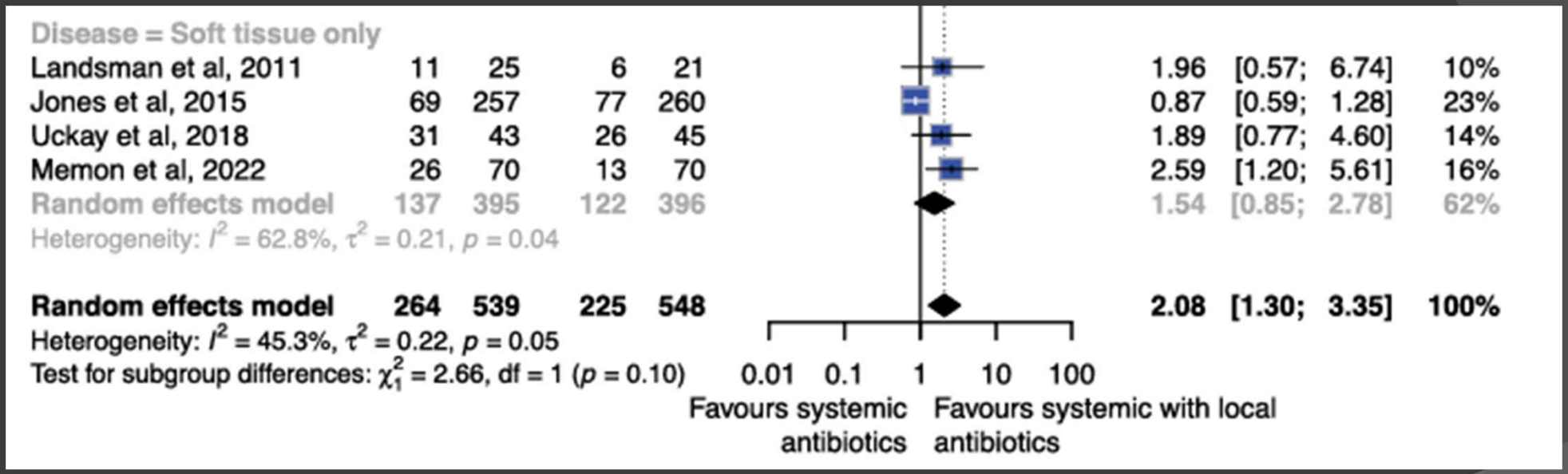
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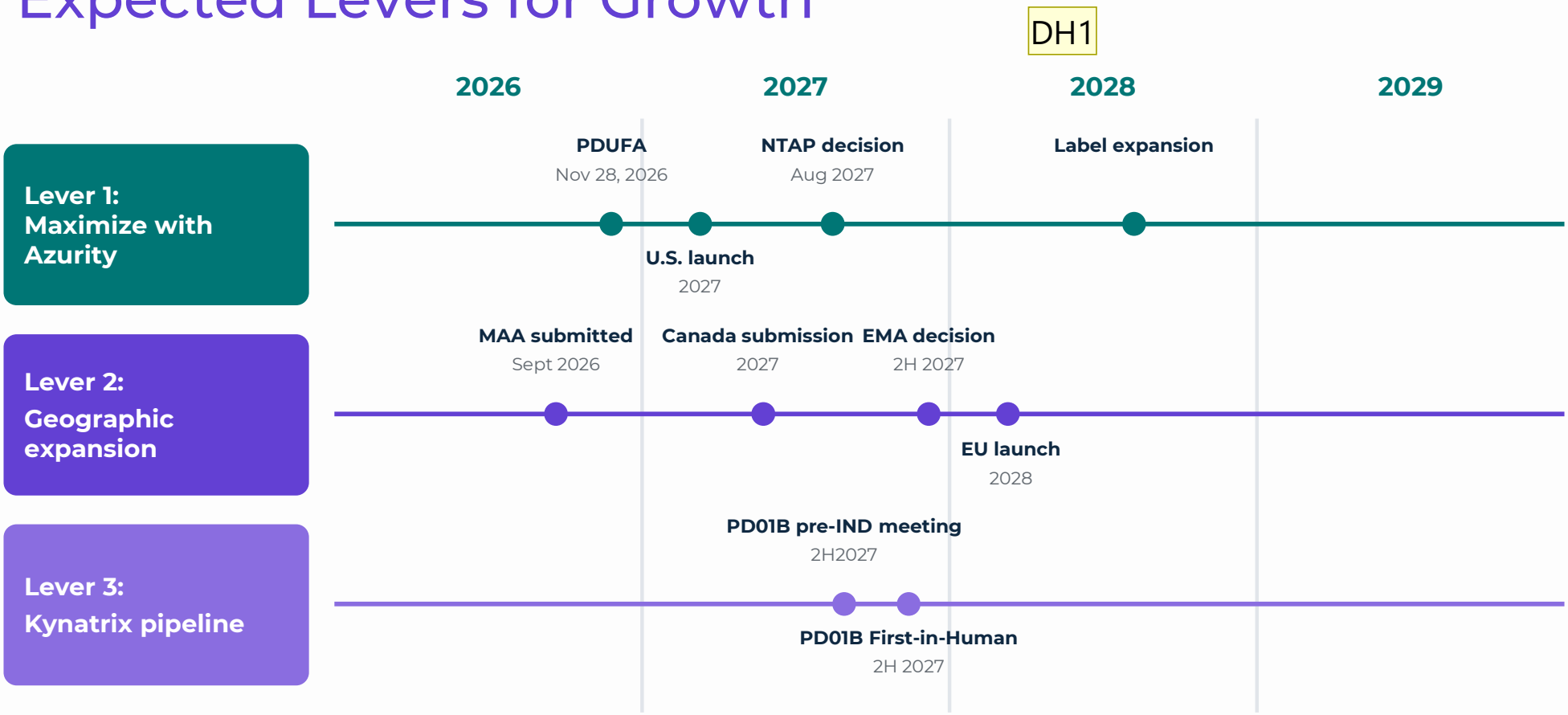
eradication. Twenty-one studies with 2188 participants met the inclusion criteria, including 12 randomized controlled trials and 9 observational studies. Combination antibiotics were associated with increased clinical cure rates compared with systemic antibiotics alone (OR 2.08; 95% CI 1.30–3.35; $p < 0.05$) and faster healing times (Mean −9.8 days; 95% CI −15.1 to −4.4; $p < 0.05$); however, results failed to reach significance when looking at randomized studies alone. Results for local antibiotics alone were non-significant for all outcomes. This meta-analysis suggests that definitive conclusions about the use of local antibiotics in DFI are limited by bias and heterogeneity within included studies. Combined local and systemic antibiotic treatment may allow for direct tissue infiltration of antimicrobial therapy. However, high-quality, blinded randomized controlled trials are required before routine clinical adoption.


Disease = Soft tissue only
Landsman et al, 2011 11 25 6 21 1.96 [0.57; 6.74] 10%
Jones et al, 2015 69 257 77 260 0.87 [0.59; 1.28] 23%
Uckay et al, 2018 31 43 26 45 1.89 [0.77; 4.60] 14%
Memon et al, 2022 26 70 13 70 2.59 [1.20; 5.61] 16%
Random effects model 137 395 122 396 1.54 [0.85; 2.78] 62%
Heterogeneity: I^2 = 62.8%, τ^2 = 0.21, p = 0.04
Random effects model 264 539 225 548 2.08 [1.30; 3.35] 100%
Heterogeneity: I^2 = 45.3%, τ^2 = 0.22, p = 0.05
Test for subgroup differences: χ^2_1 = 2.66, df = 1 (p = 0.10)
0.01 0.1 1 10 100
Favours systemic antibiotics
Favours systemic with local antibiotics

Where does PD01B fit in?

- **Doxycycline is a good antibiotic candidate for this situation**
  - It is active against the most common bacteria found in diabetic foot infections (DFIs): Staphylococcus (including MRSA) and Streptococcus
  - Has inherent anti-inflammatory activity
  - Clinical data supports claims that it helps heal wounds and decrease scarring
  - Well-characterized with an established clinical safety profile
- **Elevated and prolonged local antibiotic levels with little systemic exposure**
  - Ideal from an antibiotic stewardship perspective
  - May support less frequent dressing changes

Expected Levers for Growth



DH1 Pls adjust as mentioned above

Dalit Hazan, 2026-10-12T08:47:46.692



Q&A

Thank You!

POLYPID