

# CLINICAL SUMMARY

<b>Title:</b>	<b>In vivo effect of sustained-release silver sulphadiazine foam on bioburden and wound closure in infected venous leg ulcers</b>
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<b>Objective:</b>	To determine the <i>in-vivo</i> effect of a sustained-release silver sulphadiazine powder foam dressing on the bacterial burden of venous leg ulcers (VLUs), with a view to correlating the wound closure rate with the degree of bioburden and to assess other markers of its progression towards healing.
<b>Methods:</b>	Prospective non-randomized trial Polyurethane foam dressing containing silver sulfadiazine applied weekly under compression in patients with hard to heal VLUs Quantitative cultures were taken at weeks 0, 2, 4 and 8. Wounds were assessed at each weekly visit using photography and planimetry.
<b>Inclusion / Exclusion criteria:</b>	Inclusion criteria were: VLUs that were at least 4cm <sup>2</sup> and at least 4 weeks in duration, VLUs with a biopsy-proven bioburden of $\geq 10^5$ colony forming units per gram (cfu/g) of wound tissue, VLUs that were full-thickness but not extending to muscle or bone, confirmation of venous insufficiency by ultrasound, an ankle brachial pressure index (ABPI) of $\geq 0.8$ and $< 1.3$ and, hence, suitability for compression, concordance with compression therapy, one or more clinical sign(s) of infection.  Patients were excluded if they had a sensitivity to silver sulphadiazine, polyurethane foams or other components of the test dressing, were undergoing chemotherapy, being treated with immunosuppressants or corticosteroids, had an autoimmune disease, or had participated in an experimental drug or device study within the last 30 days.
<b>Main results:</b>	<b>Significant reduction in bioburden</b> ( $p < 0.001$ ) from baseline to week 8 <b>Significant reduction</b> in percentage of patients presenting with <b>clinical signs of infection</b> ( $p < 0.001$ ) from baseline to treatment discontinuation <b>Significant decrease in ulcer area</b> ( $p < 0.001$ ) from baseline to treatment discontinuation <b>Significant decrease in level of exudate</b> ( $p < 0.001$ ) in last week of study
<b>Conclusion:</b>	Clinical signs of infection were reduced , the treatment regimen was well tolerated and there was a statistically significant reduction in bioburden.  The authors conclude that the dressing can be used to support a VLU treatment protocol with frequent debridement and a polyurethane foam dressing containing silver sulfadiazine now has strong clinical evidence to support its use.