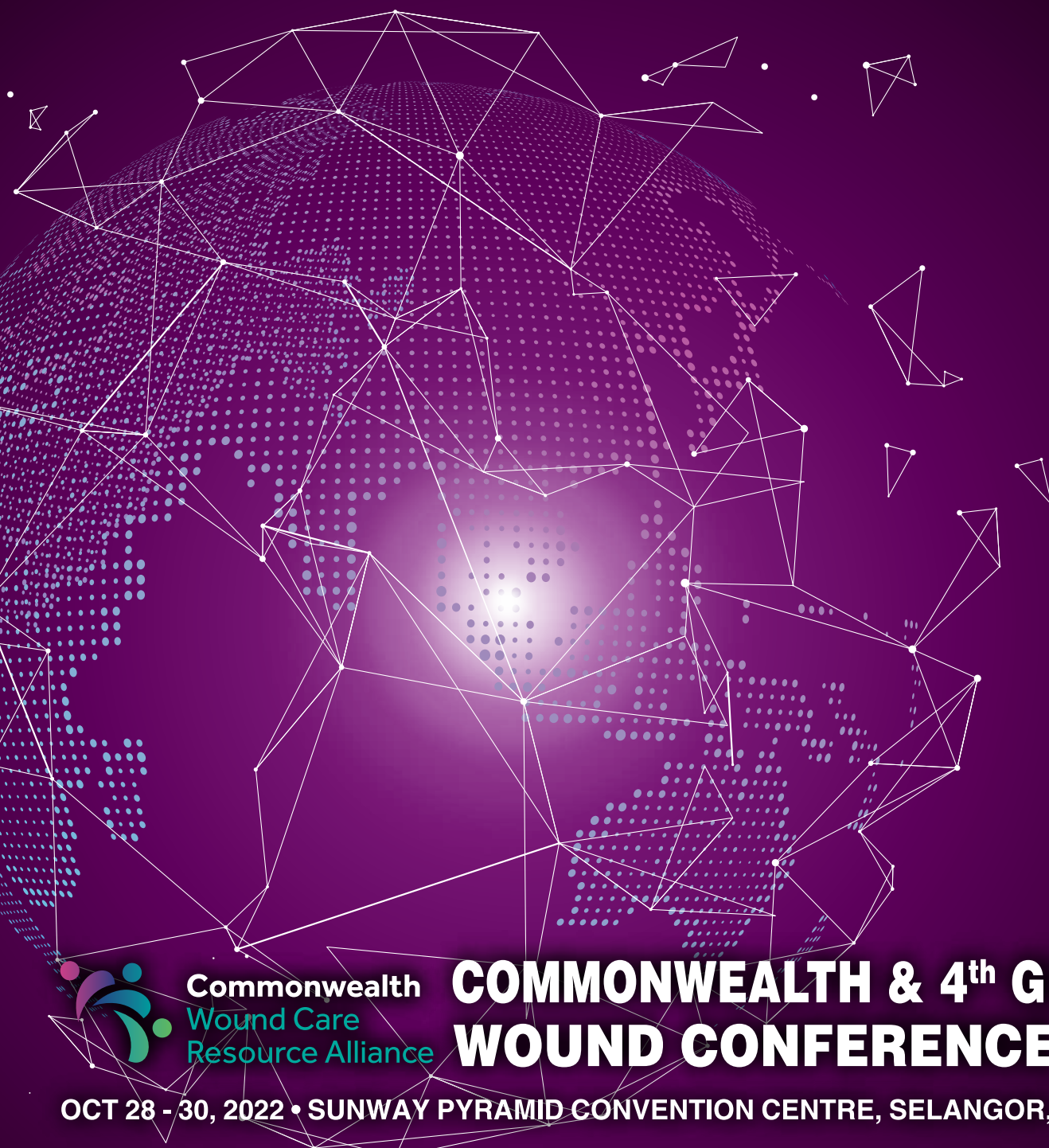


# A PROSPECTIVE, NON-RANDOMIZED, SINGLE-ARM STUDY TO EVALUATE THE SAFETY AND EFFICACY OF KENERIC RTD WOUND DRESSING DEVICE IN DIFFICULT-TO-HEAL DIABETIC FOOT ULCERS

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## Introduction

- Wound healing process begins after immediate injury to the skin. When the acute open wound does not heal timely within 4 weeks or more from the date of an injury, it can transform into a chronic wound as complications arises in disruption of the normal healing process<sup>1</sup>.
- Post debridement and cleansing, the choices of dressings is essential. The choice varies depending on wound phase, depth, level of exudate, different degree of infection and biofilm presence in a wound<sup>9</sup>. Silver AG dressing's antibacterial action has been established in many studies<sup>10,11</sup>. However, due to the complexity of chronic wound infection, and the high incidence of multi drug resistant organisms are being isolated, it posts a huge problem in the management of complex wound.
- New innovative products are always needed in addressing infections that is not well controlled in chronic wound. Novel dressings incorporated with compound which has no resistance with the drug resistance phenomenon is preferred. Multiple ingredients that synergistically control infection with different mode of action in one will be another advantage in an antimicrobial dressing.
- Retro Tech Dressing (RTD) is a new novel dressing that incorporate gentian violet, methylene blue, silver and surfactant impregnated into a polyurethane foam. Both gentian violet<sup>12,13,14</sup> and methylene blue<sup>5,16,17</sup> was established as a novel antifungal and antibacterial and since late 18th century and has been revisited in its efficacy in latest findings. With addition of silver, this 3 component ingredient in this foam would manage bioburden, exudate and the surfactant help reduce the surface tension of the wound as proven in small scale data<sup>18-23</sup>.
- Current clinical studies are looking into the use of RTD dressings in various wounds ranging from Diabetic Foot Ulcer, Venous Ulcers, pressure injury wound and Surgical Wound breakdown.

## Methodology

- Wound dimensions were assessed before the treatment and in each follow-up visit in order to evaluate the response to the RTD device. Each study subject received treatment with the RTD device as the primary wound dressing device, in addition to standard treatment for similar wounds as accepted in the department protocols.
- A total of 50 patients were enrolled in the study. The study population consisted of patients who are ambulatory who represent a selected target population for the treatment. Patients of both genders, all ethnicities, of 18 years of age and above were recruited. The study is comprised of a screening and baseline stage during which the wounds are assessed and previous medical history, as well as previous wound treatment history were assessed; and follow-up visits three times a week up to 12 weeks. In an event of dermatologic sensitization or cytotoxicity, follow-up will continue for a period of additional 3 months after the event or until it has stabilized under medical care.
- Safety was assessed by the rate of occurrence of dermatological sensitization and cytotoxicity. Safety was also be assessed based on monitoring all adverse events.
- Medications for general medical conditions were allowed during the study.



## Result

### Efficacy

- Percentage of wound closure at 12 weeks**
- The primary efficacy endpoint in the study protocol was the percentage of completely healed wounds at 12 weeks follow-up

		RTD (N=50)		
		Number healed	% Complete Closure	Average time to closure
Complete Closure	N	27	54%	70 days
	[Range]			31 – 90 days

	RTD 100% Closure by Month			
	Mth 1	Mth 2	Mth 3	Mth 1-3
DFU - Dorsal Ulcer	0	8	4	12/17 (70.6%)
DFU - Plantar Ulcer	0	2	3	5/17 (29.4%)
DFU - Toe Ulcer	0	1	6	7/10 (70%)
DFU - Stump Ulcer	0	1	2	3/6 (50%)



- The location of the lower limb DFU has a great influence on healing results and this can be observed in the results of this study and other studies. Breaking the wound type down by location and the number with complete healing over the 12-week period (ie Month 1, 2 & 3) at Table 2 shows a significant result of 100% closure for 7 out of 10 Toe Ulcers within 3 months of treatment with RTD. 2 of the more problematic Plantar Ulcers healed with 2 months and a further 3 within 3 months of treatment with RTD.
- For 100% healing in 12 weeks the RTD healing percentage ranges from 29.4% to 70.6%. The 29.4% result for the Plantar Ulcers that were included was reported as very good by the investigative team. This was based on their local knowledge of wounds that are located in problematic positions and where off-loading and suitable footwear is critical, but often difficult to enforce. This is evidenced in patient notes.

## Conclusion

- Dressings with antimicrobial properties are widely used on chronic wounds with the intention of controlling bioburden, preventing infection and promoting wound progression. Although not all wounds require topical antimicrobials, the advantage of topical over systemic antimicrobials is that they are targeted to the area needed and thus they can avoid some of the perils of systemic antibiotics. The efficacy of antimicrobial agents on the wound bed may be influenced by dressing and patient related issues. With this, it is important to understand the relationship between the dressing and the antimicrobial properties held within it to ensure ideal antimicrobial action. Efficacy of the wound dressing might be compromised if its antimicrobial properties cannot be maximized. This also holds true if the dressing can't fill the wound space and conform to the irregular surface of the wound, which would cause sub-optimal exposure of surface bacteria to the antibacterial properties of the dressing. Keeping that in mind, RTD Wound Dressing was developed to



- meet the needs of complex chronic wounds. The highly absorbent, soft, wound conforming polyurethane (PU) Wound Dressing contains antimicrobial agents that are tightly bonded in the PU during manufacturing. This bonding allows for the dressing surface to safely contact the wound bed with minimal tissue exposure to the antimicrobial activity.
- The ability of RTD to conform to wound surfaces and provide effective antimicrobial properties, resulted in impressive outcomes for DFU's and specifically for the complexity of Toe Ulcers which are typically difficult to treat and prone to amputation.

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*Presentation supported by:*

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