

Table 4 displays RTD mean healing time of 2.0 months compares favorably to the KL 340 study 4.49 months.

This table also shows the healing of problematic wounds over periods of time for wounds at plantar, non-plantar and toes locations. The 2 month (59.5 days) median value for RTD healing of toe wounds compares favourably to the KL 340 median of 2.5 months. For the non-plantar location, the differential is similar with RTD median 1.63 months (49 days) vs KL 340 median of 2 months. For the more problematic plantar location the RTD median is 2.17 months (63.5 days) which compares well to the KL 340 median of 3 months.

Healing during month 1 has RTD 25.60%. The KL 340 value for month 1 is 57.60% which may be explained by.....

The 340 Kuala Lumpur Hospital Trial (24) published Jan 2019 showed better healing rates as this retrospective study looked at all patients which mean even clean wounds. This RTD PMCF trial is recruiting patients with infection whereas the 340 Kuala Lumpur Hospital Trial looked at clean wounds also.

Infection is a known factor why wounds take longer to heal. The basis of treatment is to clear the bacterial bioburden in the wound bed preparation before the wounds can start to heal based on the normal physiology of wound healing.

Safety and Tolerability

Adverse Events

No RTD dressing-related adverse events, or unanticipated device-related adverse events were reported in the study.

Of note, there were no reports of silver toxicity, or of dermatologic sensitivity or dermatologic cytotoxicity.

These findings demonstrate the overall safety of the RTD Wound Dressing for treatment of chronic DFU Ulcers

Conclusion

The study is deemed successful and the Study Hypothesis that RTD performance and safety values in infected grade 2 and 3 diabetic foot ulcers will be at least as good as reported values for reference state-of-the-art benchmark devices as reported in clinical studies which tested this type of wound for a follow-up duration of 12-weeks using identical outcome measures has been proven.

The results were quite impressive whereby the bacterial bioburden was managed well and the wounds starting healing well with wound closure. Therefore, the RTD dressing is a good dressing to be utilised in infected chronic complete cases and adds to the current armament available in the Wound Care Unit.

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Study to Evaluate the Safety and Efficacy of RTD Dressing in Difficult-to-heal Diabetic Foot Ulcers

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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 process¹

Wound bioburden and infection is notoriously one of the main complication in the entropic wound cycle of wound healing. Infections occur more frequently in diabetic vs. nondiabetic individuals. The constant exposure of diabetic subjects to antimicrobial and antibiotics will render them more prone to certain infections².

New innovative products are always needed in addressing infections that is not well controlled in chronic wounds. Novel dressings incorporated with compound which has no resistance with the drug resistance phenomenon is preferred. Multiple ingredients that synergistically control infection with different modes of action will be advantages 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^{3, 4, 5} and methylene blue^{6, 7, 8} was established as a novel antifungal and antibacterial since the 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 helps reduce the surface tension of the wound as proven in small scale data^{9, 10, 11, 12, 13, 14}.

The purpose of the study is to evaluate the safety and efficacy of the RTD dressing intended for treatment of difficult to heal, grade 2 and 3 diabetic foot ulcers.

Methodology

45 patients (female 20 and male 25) with grade 2 and 3 diabetic foot ulcers who represent a selected target population for the treatment will be treated with RTD as their primary wound dressing, in addition to conventional wound treatment standard of care. The study design is directed towards a comparison between RTD device and literature control values at the final 12-week follow-up visit.

Efficacy will be assessed by evaluating of the overall percentage of complete wound closure by 12 weeks.

Safety will be assessed by the rate of occurrence of all adverse events, in comparison with state-of-the-art benchmark wound dressings and its reference literature values.

Wound etiology is as below.

Wound Etiology	N	%
DFU – Dorsal Ulcer	16	36
DFU – Plantar Ulcer	16	36
DFU – Toe Ulcer	13	28
Total	45	100

Result

Table 1a: Patient Accountability

Wound Etiology	N	%
No. of Enrolled Subjects	45	100
Subjects without Major Protocol Violations	43	95.6

Table 1b: Accountability Reasons For Exclusion

Wound Etiology	N	%
Total Subjects Excluded from Analysis Sets	2	100
No. of Subjects who did not complete treatment due to death	0	0
No. of Subjects who returned home or were transferred out of the facility	2	100

From Table 1a we see that only 4.4% of the subjects dropped out from the study, thus demonstrating a low drop-out rate in this study, as compared to similar studies of treatment of chronic wounds of hospital out-patients/referrals. The two patients dropped out because of the compliance to follow up even though they were called up and reminded.

Main Study Hypothesis (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. The primary efficacy analysis was conducted on all available subject data, in the Per Protocol analysis set. Table 1 shows the proportions of complete wound closure at 12 weeks was 53.5% with an average time (mean) to closure of 59.8 days which compares well to literature values.

Table 2: RTD - Percentage of Complete Wound Closure at 12 weeks (PP) - all Wounds

		RTD (N=43)		
		Number Healed	% Complete Closure	Average Time to Closure
Complete Closure	N	23	53.5	59.8 days
	[Range]			25 - 93 days

Table 3: RTD 100% Closure by wound location in Months 1, 2 and 3

	RTD 100% Closure by Month			
	Mth 1	Mth 2	Mth 3	Mth 1 - 3
DFU - Dorsal Ulcer	4	4	1	9/16 (56.3%)
DFU - Plantar Ulcer	1	2	1	4/14 (28.6%)
DFU - Toe Ulcer	6	2	2	10/12 (76.9%)

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 5 shows a significant result of 100% closure for 6 out of 10 Toe Ulcers within one month of treatment with RTD. One of the more problematic Plantar Ulcers healed in month 1 and two more Plantar Ulcers in month 2 of treatment with RTD.

Table 4: Closure results of chronic wounds at 12 weeks

Wound Location (# of patients)	12 Week Weighted Average of Healing	12 Week Complete Closure %
DFU - Dorsal Ulcer (16)	81.3%	56.3%
DFU - Plantar Ulcer (14)	65.0%	28.6%
DFU - Toe Ulcer (13)	94.2%	76.9%

Overall, the weighted averages show RTD resulted in improved healing rates of 65.0% to 94.2% over the 12 - week period.

Table 5: RTD vs KL 340 Study

		RTD Wound Dressing	KL 340 Patient Study 2019
Healing mean	All wounds	2.00 months	4.49 months
Healing Median	All wounds	2.00 months	3.00 months
Healed 12 wks	All Patients	53.5%	
Healed by mth	All Patients	25.60% (0-1 month)	57.60% (0-1 month)
		18.60% (1-2 months)	14.80% (1-6 months)
		9.30% (2-3 months)	27.60% (> 6 months)
Plantar	Median	63.5 days	6 months
Non-Plantar	Median	49 days Dorsal	2 months
Toes	Median	59.5 days Dorsal	2.5 months

Healed Wounds



Partially Healed Wounds

