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Risk Factor Influencing Complete Healing in DFU Patients - Post-Hoc Analysis of a Phase 3 MRCT of Macrophage-Regulation New Drug

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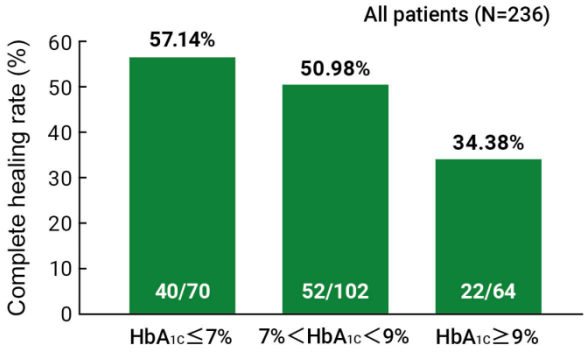
Post-hoc Analysis Introduction-1

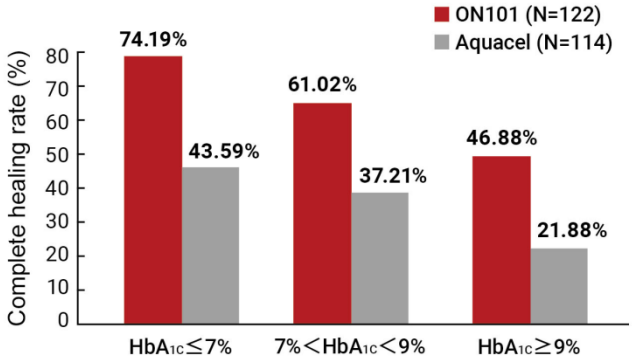
- DFU is accompanied by prolonged inflammation and delayed wound healing, may lead to amputation resulting in a substantial medical burden and expenditure.
- DFU remains an unmet medical need due to the limitation of the current therapies. New approaches that benefit patients with DFUs are still needed.
- ON101 cream, a macrophage-regulation drug, has been shown to promote wound healing and safety in DFU patients in phase 3 multicenter randomized clinical trials (MRCT)(NCT01898923).

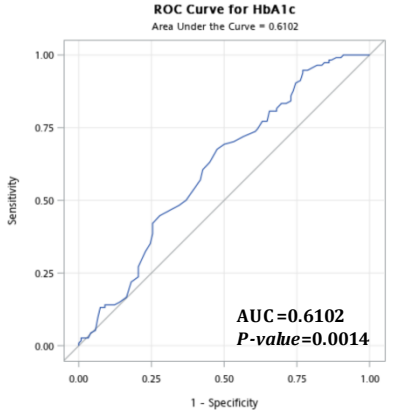
Post-hoc Analysis Result Introduction-2

- In the phase 3 study, we observed that ON101 has a higher complete healing rate in hard-to-heal wounds, including high levels of HbA1c, larger ulcers (> 5 cm^2), and ulcers that persisted for a long time.
- In this study, we will investigate the correlation between poor healing outcomes and risk factors of HbA1c, ulcer duration, ulcer size, recurrence, ulcer location, and amputation history.

High Levels of HbA1c Lead to Poor Healing in DFU Patients

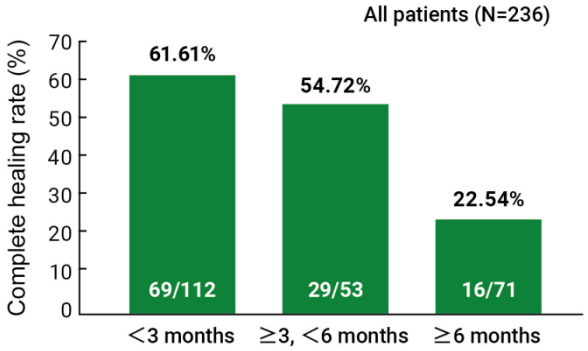


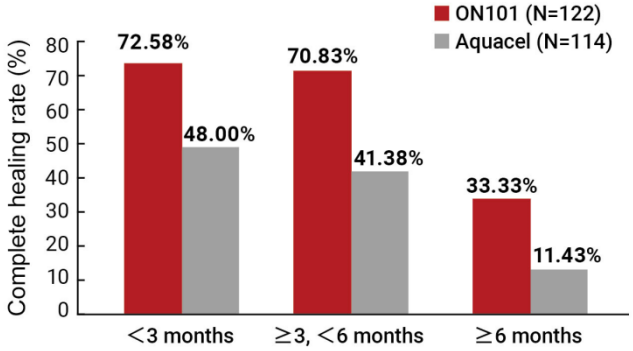


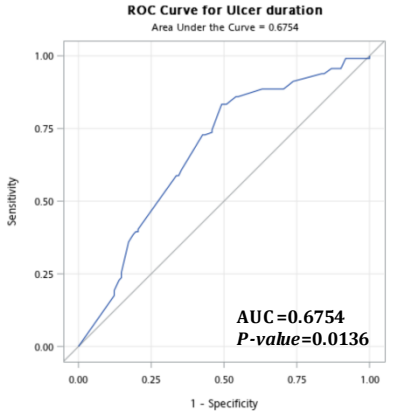


	HbA1c ≤7%	7% <HbA1c <9%	HbA1c ≥9%
ON101 (%)	23/31 (74.19%)	36/59 (61.02%)	15/32 (46.88%)
Aquacel (%)	17/39 (43.59%)	16/43 (37.21%)	7/32 (21.88%)
Different	30.60%	23.81%	25.00%
Relative risk	1.70	1.64	2.14
Odds ratio	3.70 (1.3, 10.51)	2.59 (1.14, 5.91)	3.14 (1.04, 9.50)
p-value	0.0102	0.0175	0.0353

Chronic Wounds Cause Poor Healing in DFU Patients

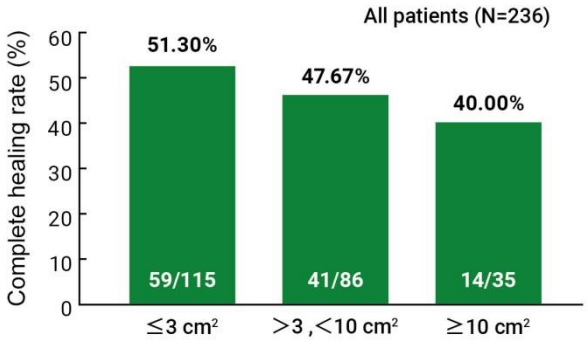


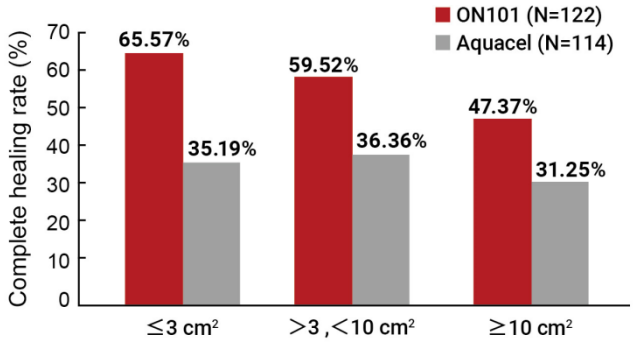


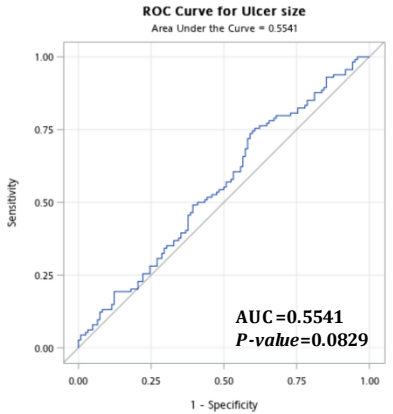


	< 3 months	≥ 3, < 6 months	≥ 6 months
ON101 (%)	45/62 (72.58%)	17/24 (70.83%)	12/36 (33.33%)
Aquacel (%)	24/50 (48.00%)	12/29 (41.38%)	4/35 (11.43%)
Different	24.58%	29.45%	21.90%
Relative risk	1.51	1.71	2.92
Odds ratio	3.24 (1.38, 7.59)	4.24 (1.24, 14.55)	3.99 (1.09, 14.63)
p-value	0.0078	0.0320	0.0272

Ulcer Size is NOT the Main Risk Factor for DFU Patient Poor Prognosis

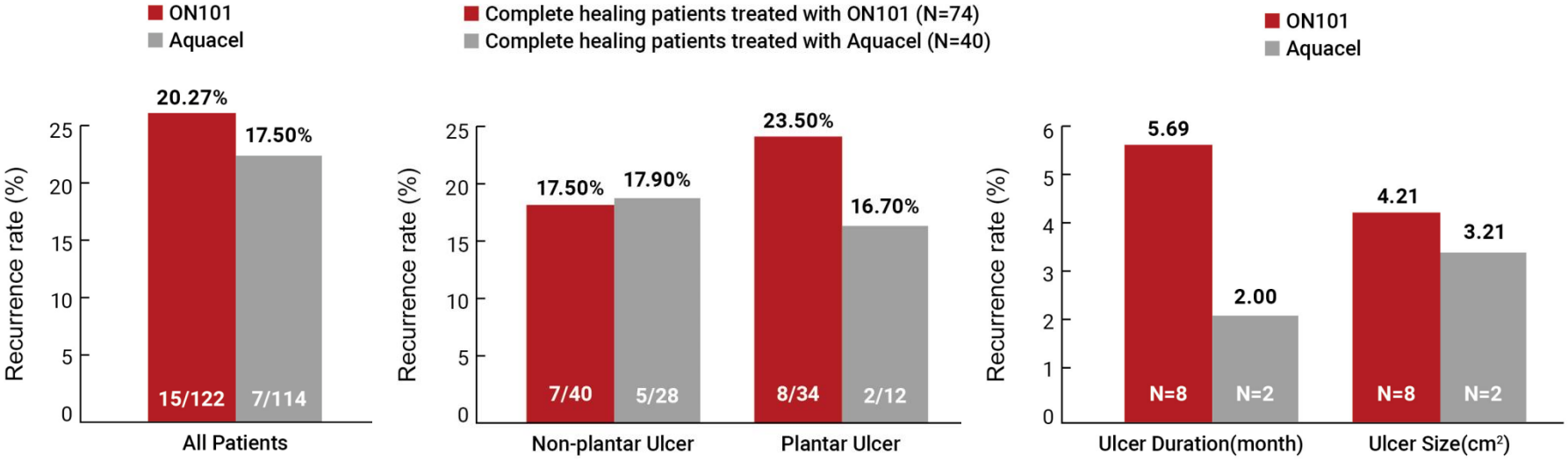




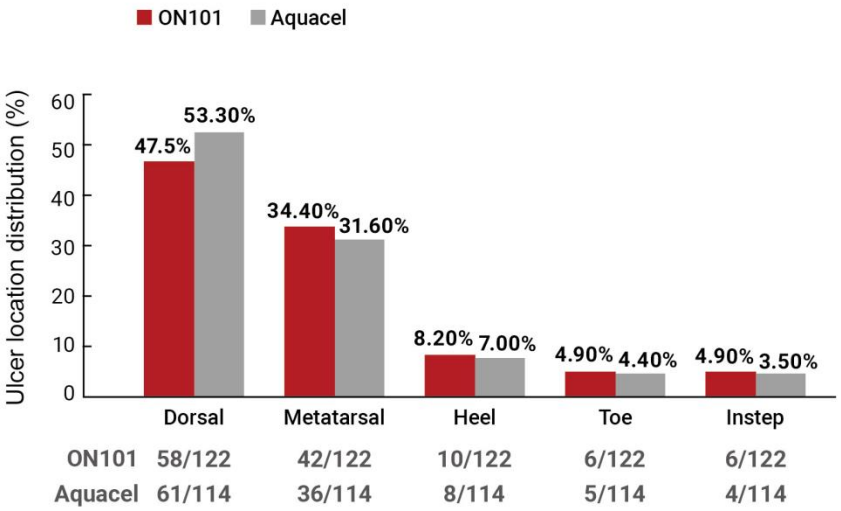


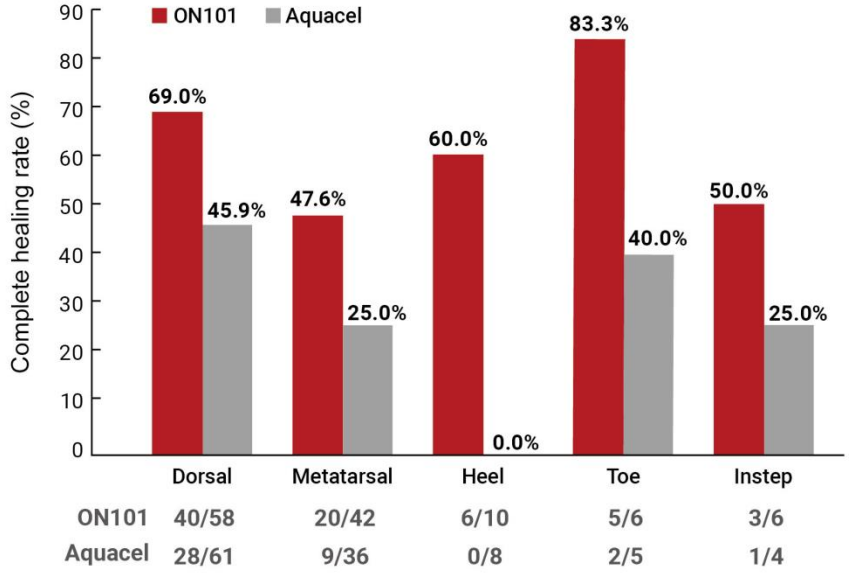
	≤3 cm²	>3 , <10 cm²	≥10 cm²
ON101 (%)	40/61 (65.57%)	25/42 (59.52%)	9/19 (47.37%)
Aquacel (%)	19/54 (35.19%)	16/44 (36.36%)	5/16 (31.25%)
Different	30.39%	23.16%	16.12%
Relative risk	1.86	1.64	1.52
Odds ratio	3.44 (1.58, 7.47)	2.40 (0.99, 5.85)	2.03 (0.39, 10.66)
p-value	0.0011	0.0316	0.3322

The Longer Ulcer Duration and the Larger Ulcer Size are Significant Factors Leading to the Recurrence in ON101 Group

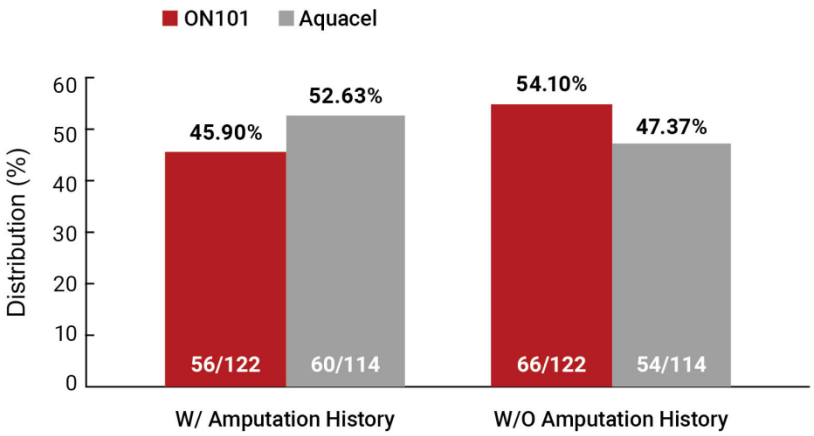


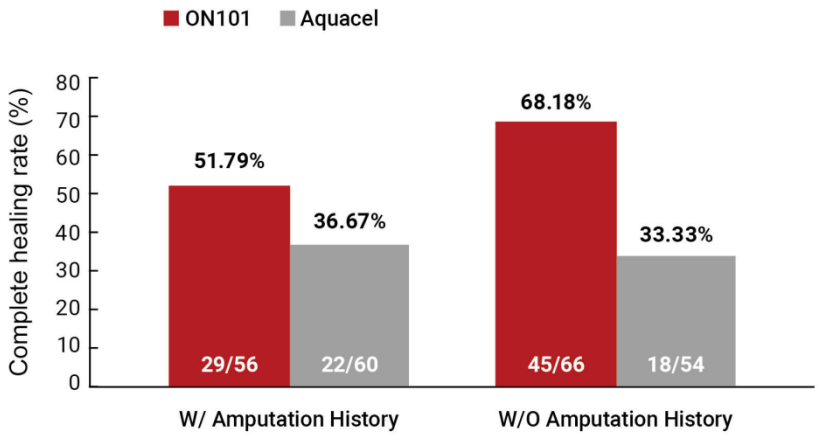
ON101 Shows the Superior Efficacy in All Groups of Ulcer Location Based on the Pressure Severity





ON101 Shows the Superior Efficacy in With or Without Amputation History





Conclusion

- **Based on this post-hoc analysis, HbA1c and ulcer duration are the most important risk factors in poor healing of DFU.**
- **ON101 has been demonstrated with consistent and robust efficacy over the standard care in DFU treatment regardless of these risk factors.**
- **The early use of ON101 could deliver the optimal impact on healing.**
- **It is suggested that macrophage rebalance may play a critical role in accelerated DFU healing.**

Reference

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