

# MEPILEX® LITE IN THE TREATMENT OF DIABETIC FOOT ULCER:

## OPEN NON-RANDOMISED CASE STUDY

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Aim of this study was to evaluate the comfort, utility and overall experience of Mepilex® Lite, a dressing with soft silicone adhesive, in the management of diabetic foot ulcers.

The primary objective was to evaluate overall experience of Mepilex® Lite in the management of DFU. Secondary objectives included safety, tolerance and influence on healing. All patients in the study had low or none exuding diabetic foot ulcers (Wagner I or II), wound area  $\geq 1$  cm<sup>2</sup>. Both in- and out-patients were eligible. Each patient was followed weekly for a maximum of 5 weeks or until healing. There were 11 patients included in this study, 1 patient drop out.

**Table 1 Baseline Demographic Information**

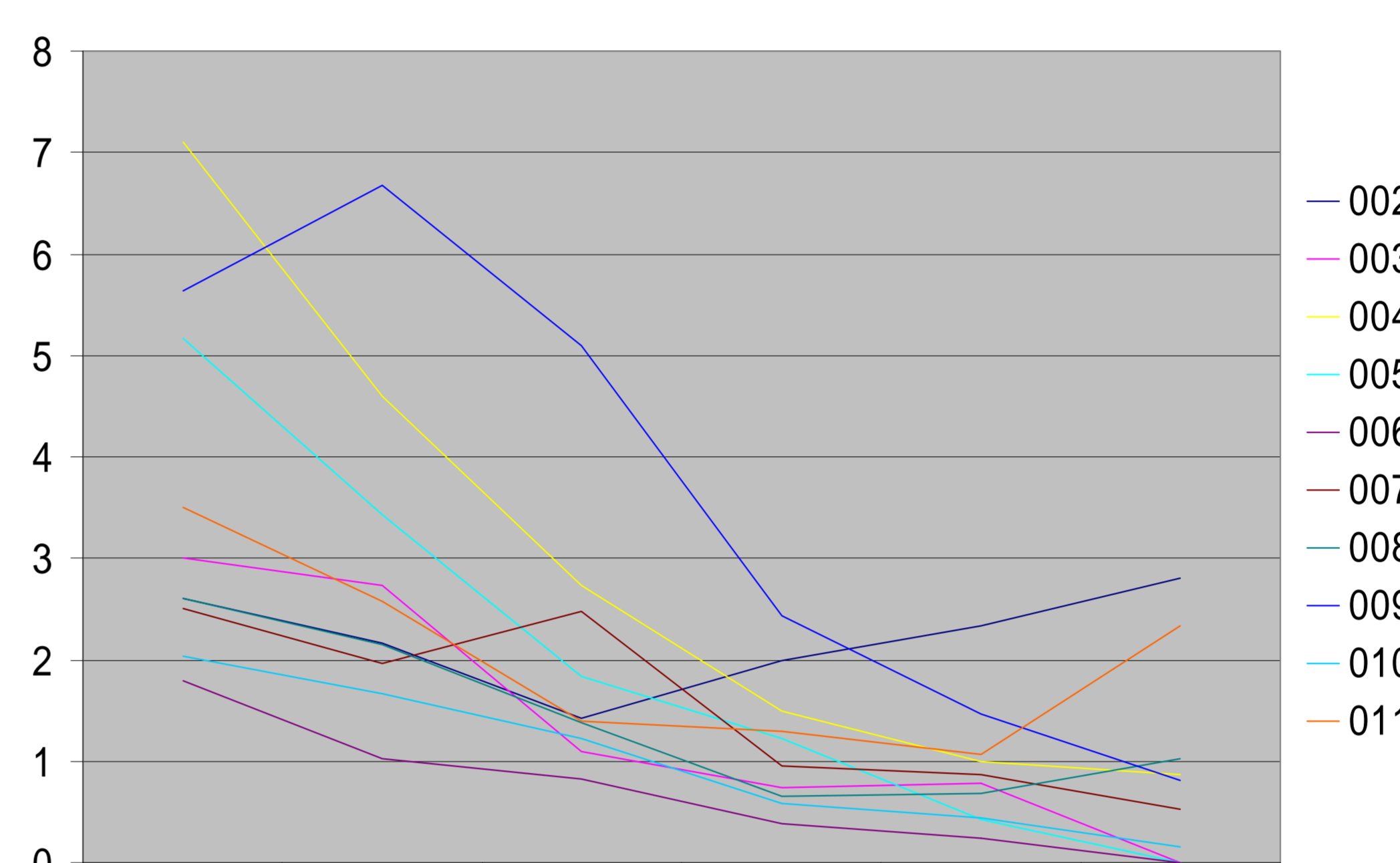
Age (yrs)	Mean±SD	59.2±14.4
Gender	male, N (%)	4 (40.0)
	female, N (%)	6 (60.0)
Diabetes type	I, N (%)	3 (30.0)
	II, N (%)	7 (70.0)
Duration of diabetes (yrs)	Mean±SD	21.6±10.4

**Table 2 Wound history**

Wagner grade	I, N (%)	5 (50.0)
	II, N (%)	5 (50.0)
Localisation of foot ulcer	Left, N (%)	4 (40.0)
	Right, N (%)	6 (60.0)
Specify localisation	Malleolus, N (%)	2 (20.0)
	Other, N (%)	1 (10.0)
	Plantar surface + Digitalis I,	1 (10.0)
	Plantar surface + Metatarsal,	4 (40.0)
	Dorsal area + Metatarsal, N (%)	1 (10.0)
	Dorsal area + Metatarsal + Mid	1 (10.0)
Previous dressing	No, N (%)	1 (10.0)
	Yes, N (%)	9 (90.0)
Granuflex (2), Inadine (2), Atrauman (1), Hydrosorb (1), Gauze (3)		
ABI value	Mean±SD	0.92±0.19

A good dynamic of wound area reduction was observed during study. From 3,6 cm<sup>2</sup> (Mean) at baseline to 0.85 cm<sup>2</sup> after 5 weeks treatment and 3 out of 11 patients healed (pic.1).

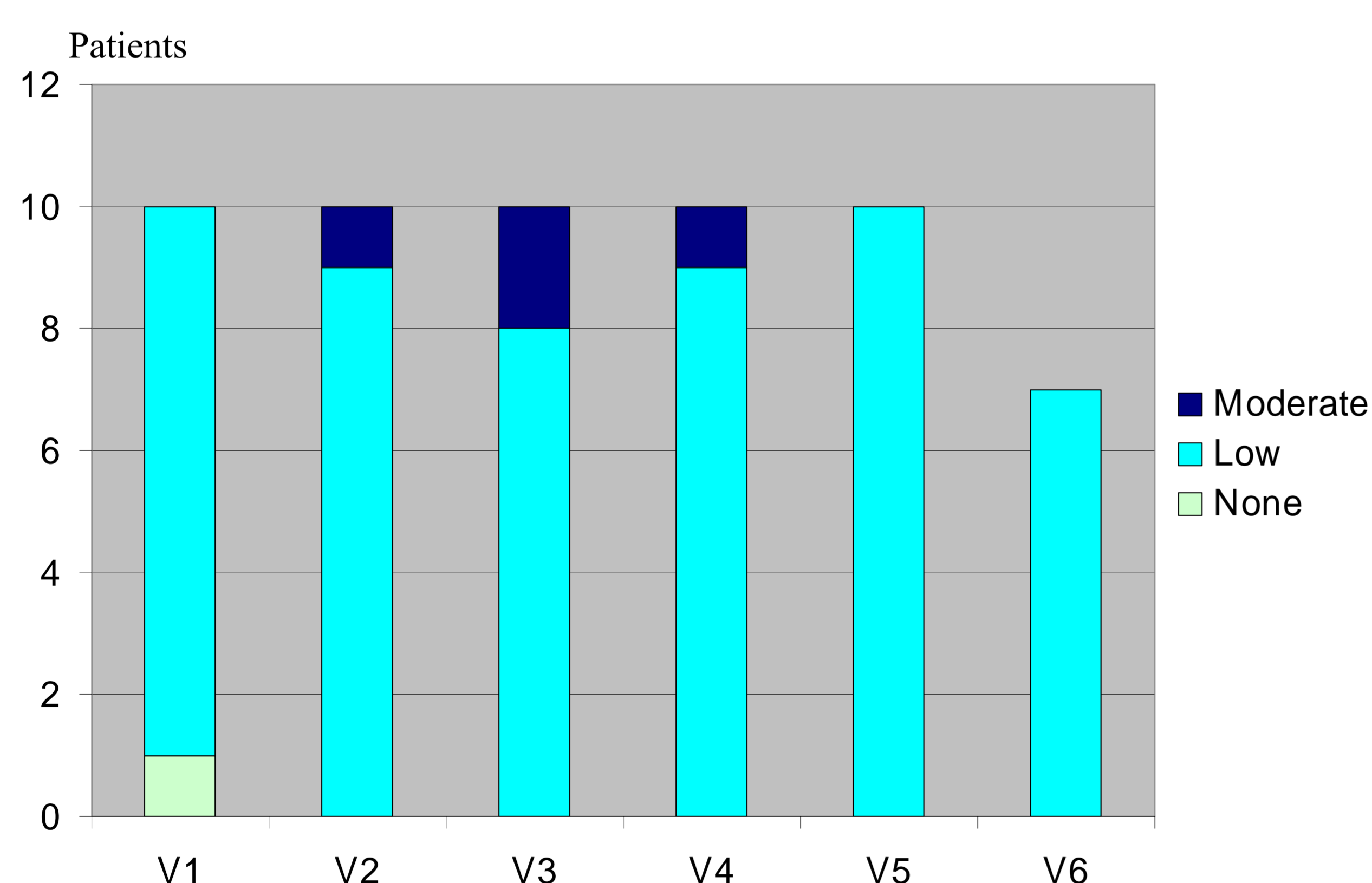
**Pic.1 Analysis of Efficacy (Tracing)**



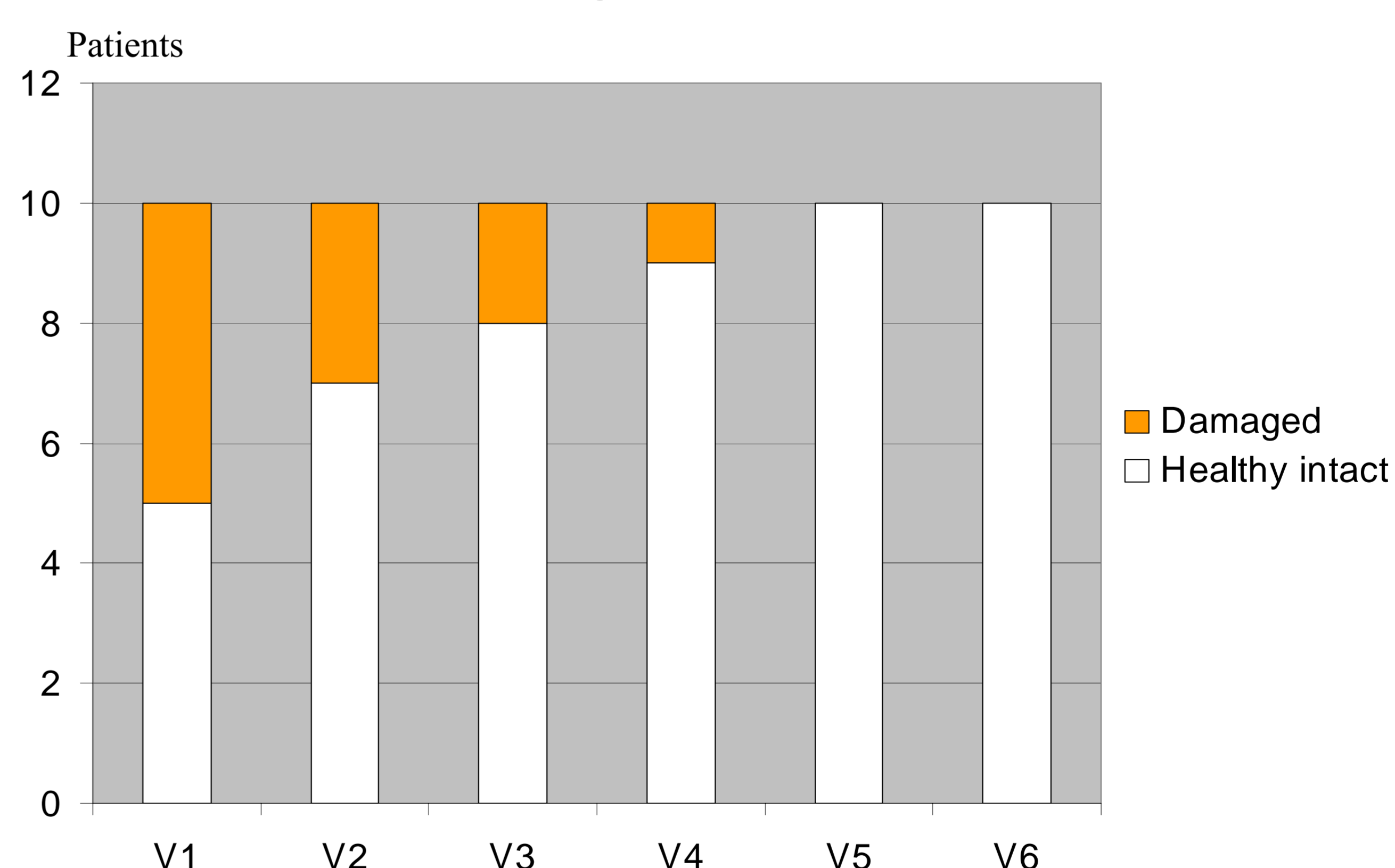
Subject 004, 006, 007, 010, 011 had ulcers classified as Wagner II and the other subjects had ulcers classified as Wagner I. Subject 003, 005 and 006 were healed at visit 6.

No signs of clinical infection could be seen. There was an increase of exudate at the visits after baseline that decreased at the final visits (pic.2). All exudate reported were clear. An improvement in condition of surrounding skin was noted during the observation period and at final visit there were no damages at all (pic.3).

**Pic.2 Exudate level**



**Pic.3 Condition of surrounding skin**



The dressings showed to be atraumatic to the surrounding skin and were considered to be good or very good from the view of both the patients and the investigator. Moreover, it should be noted that Mepilex® Lite had a good capacity of fluid handling and ease of application.

Mepilex® Lite is an effective dressing which can be used for local treatment of superficial diabetic foot ulcers. It provides good absorption with minimal skin trauma and minimal maceration, especially important in the treatment of elderly diabetic patients with neuroischemic feet.

