

Appendix 10: Individual Patient Report 10: patient 10: male, 83 years old

Since January 2002 the patient has had two ulcers on the medial malleolar region on the left leg and the lateral malleolar region of the right leg. The patient had type II diabetes. The patient was not a smoker. Prior to wIRA treatment the patient was having the ulcers regularly dressed by visiting nursing services. Presumably suboptimal compression therapy. The healing process has been very slow.

During the first treatment it was noticed that two new small ulcers had appeared beside the main ulcer on the left leg (towards back on left side) since the first inspection (the patient had visited the department one week previously for treatment assessment). The new ulcers may have been caused from new injury (see below). Overall, the condition of the skin around the ulcers on the left leg appeared in poorer condition than on the right leg. The ulcer area was much more pain sensitive on the left leg compared to nearly complete pain insensitivity on the right leg.

Peripheral blood pressure measurements: moderately reduced ankle and toe pressures on both legs.

Duplex (ultrasound) scanning and conclusion: Insufficient perforating veins bilaterally approximately one hand's width over the ankle region on each leg. No varicose veins. All deep veins are sufficient. The inflow of the v. saphena magna and v. saphena parva to respectively the v. femoralis and v. poplitea on both sides are sufficient.

For the first 13 treatments the right leg was treated with a normal wIRA radiator (radiator type A) while the left leg was treated with a control group radiator (radiator type B). From treatment 14 and onwards both legs were treated with type A radiators. The choice was decided randomly. The patient had been previously informed (signed a consent form) that he could be treated with a control group radiator but was not informed as to which ulcer was been treated with which radiator.

Shortly after start of treatment the patient hit the back of his left leg while getting out of a car. This caused the start of a new ulcer area slightly below and behind the main ulcer. This new ulcer on the left leg deteriorated with time, before consolidating. Treatment was often regarded as painful. In order to complete treatment lidocain (2%) gel was sometimes applied to the ulcer. This means that the 'pain after treatment' subjective scores given by the patient may not reflect reality. However, it is important to note that nearly all the distress in the left leg was related to the new ulcer and not the original ulcer. The patient's subjective scores may be influenced by this problem, as he was not always able to clearly localize the discomfort area without tactile stimulation.

While the ulcer on the right leg completely healed it was not possible to completely heal the original ulcer on the left leg as the patient was transferred to the Department of Vascular Surgery in order to deal with the new ulcer, which was close to the Achilles tendon. However, as can be seen in the digital image taken on the final treatment day, the original ulcer was dry and 'full' of islands of new skin tissue, making size estimation difficult.

After his final wIRA treatment the right lateral ulcer increased in size with compression garment therapy. After antibiotic treatment with Ciproxin both ulcers eventually healed. In spite of two insufficient perforating veins on both lower legs the surgeon decided not to operate due to fear of development of new wounds.

The ulcers on both legs are classified as mixed venous-arterial ulcers (v+a) (chronic venous insufficiency stage 3 according to Widmer, which means chronic venous insufficiency with ulcer) with concomitant problems (arterial insufficiency and diabetes) in Table 1 in the results section.

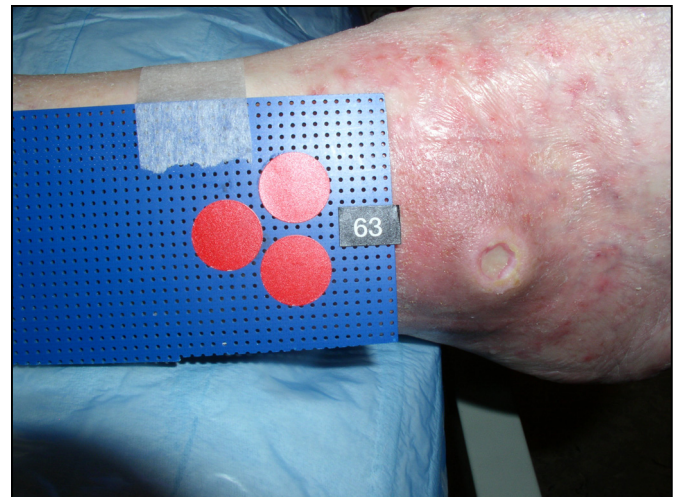
Total number of treatments:	32
First treatment:	2003-01-22
Last treatment:	2003-03-13
Total treatment time:	50 days



2003-01-22: Day of first treatment

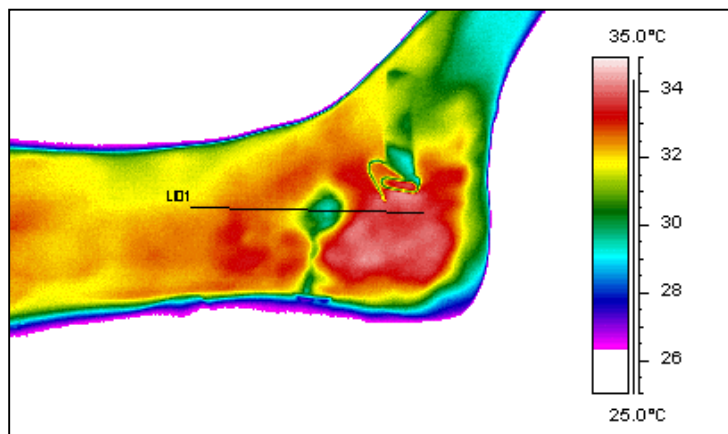


Left leg

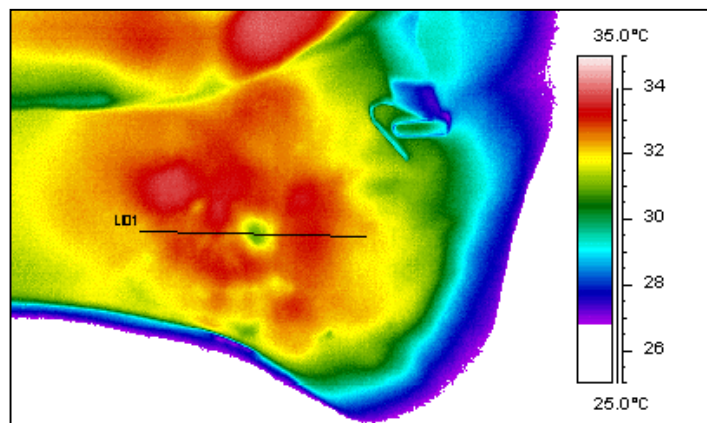


Right leg





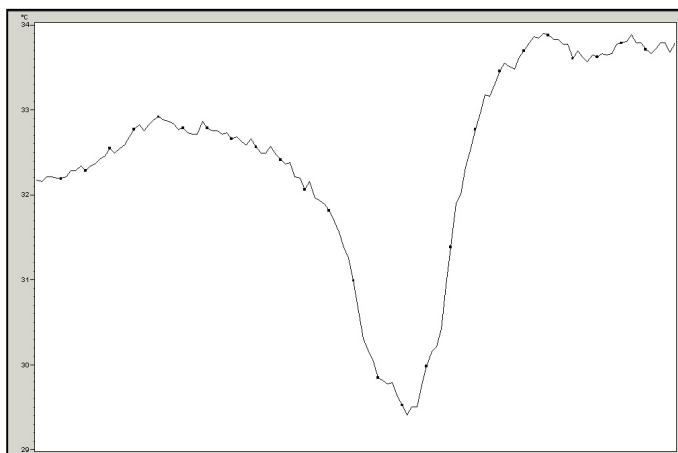
Left leg



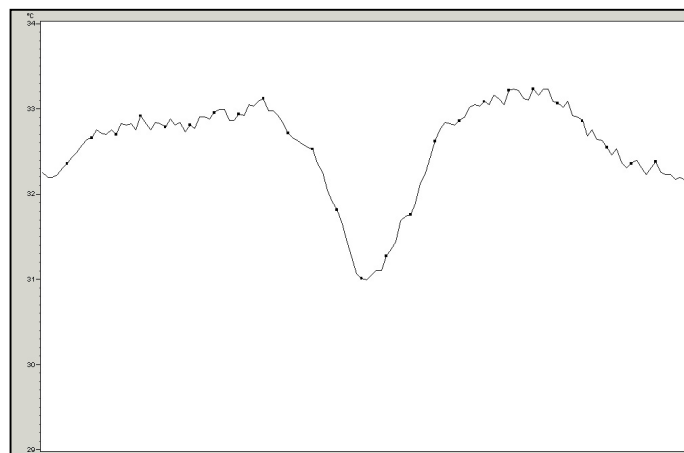
Right leg

2003-01-22: Day of first treatment

Note the large temperature difference between the ulcer base and the surrounding skin at the beginning especially on the left leg (approximately 4.5°C)!

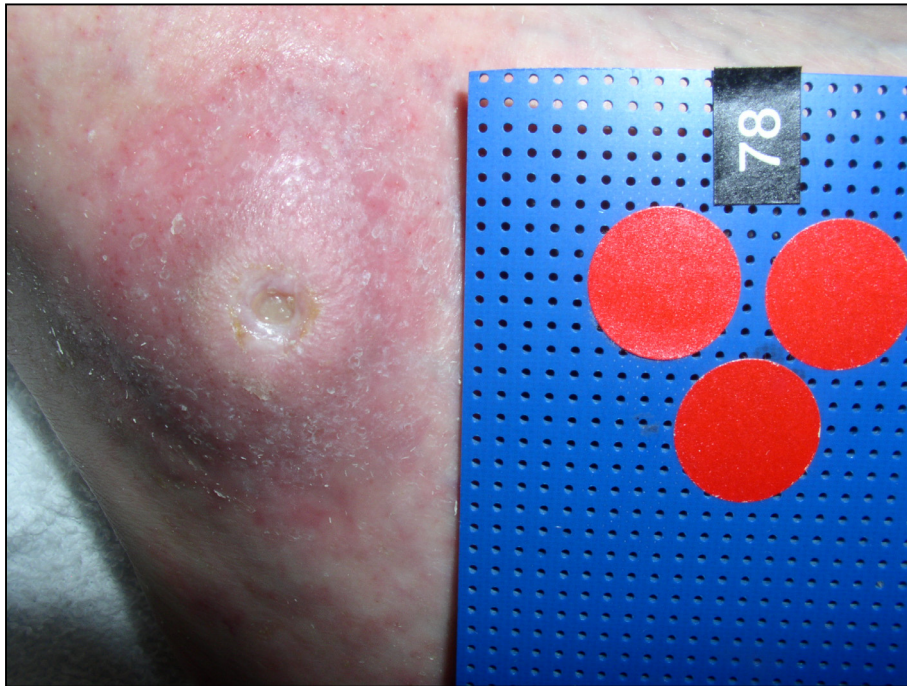


Label	Min	Max	Avg
LI01	29.4	33.9	32.4



Label	Min	Max	Avg
LI01	31.0	33.2	32.6

Condition of ulcers on 2003-02-11 (the day on which the treatment of the left leg was changed from the control group radiator (radiator type B) to the fully active radiator (radiator type A) (i.e. treatment number 14). Note the appearance of new ulcers on the left leg as compared to the first treatment day (2003-01-22)

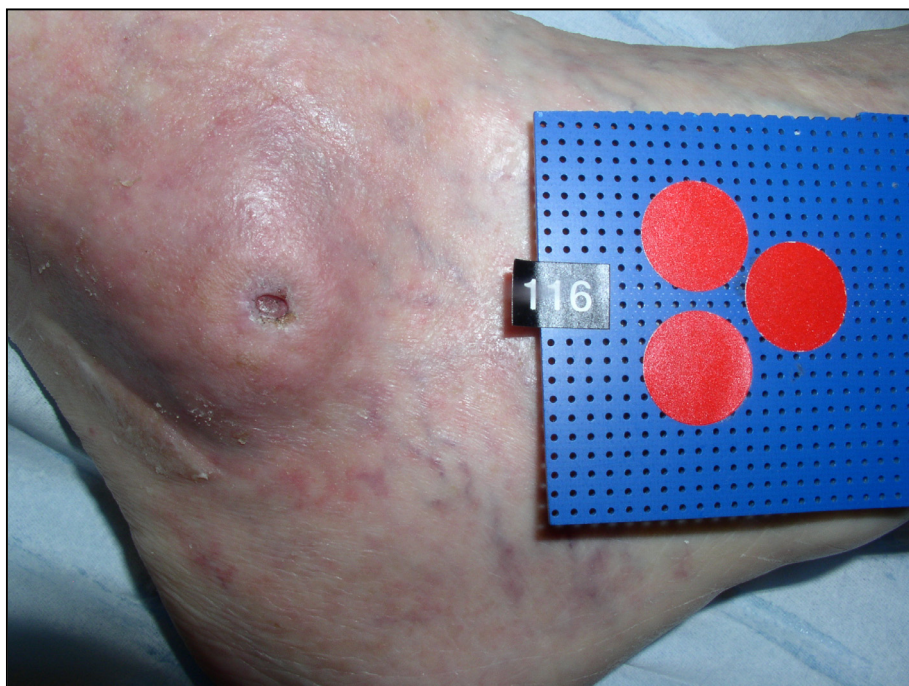


Right leg



Left leg

Condition of ulcers on 2003-02-28

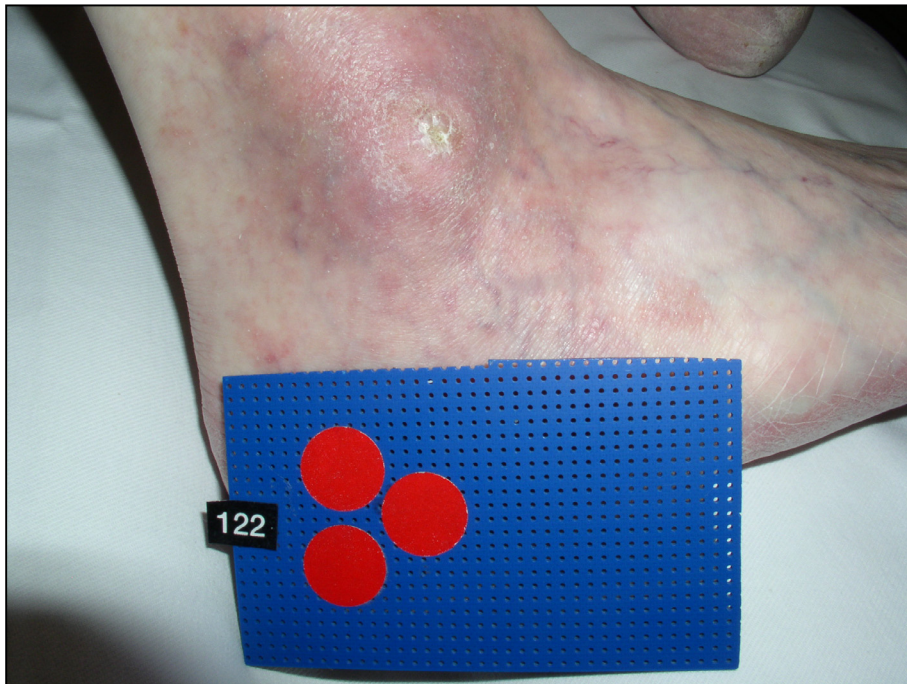


Right leg



Left leg

Condition of ulcers on 2003-03-14
(last treatment day):



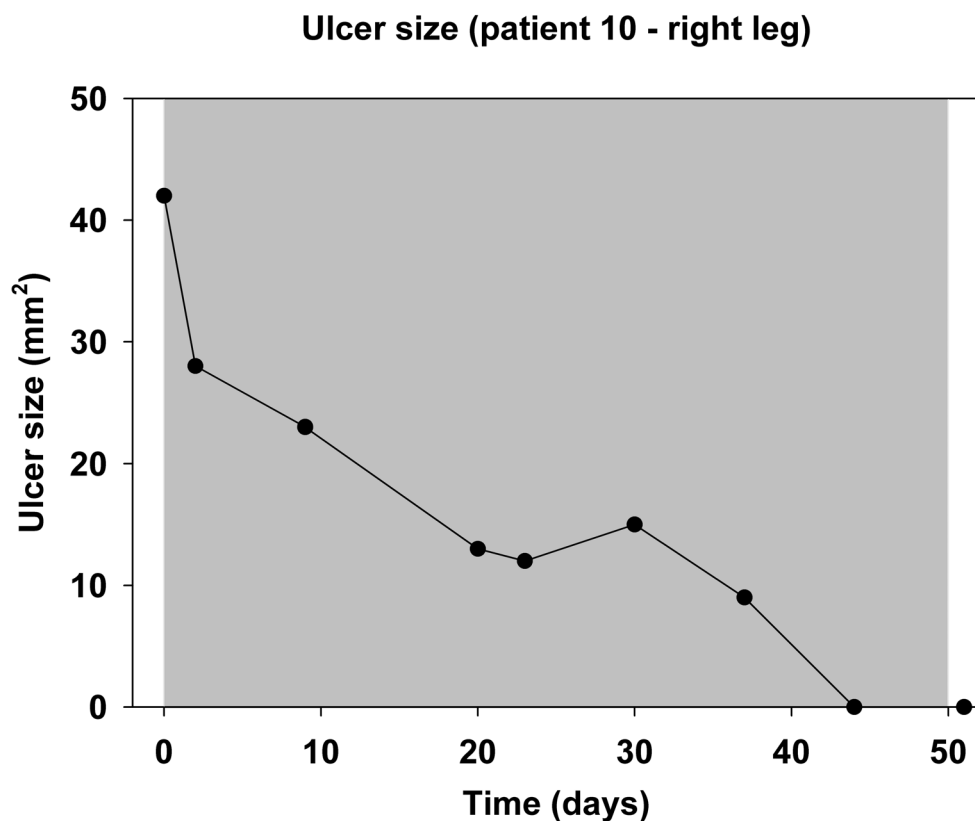
Right leg

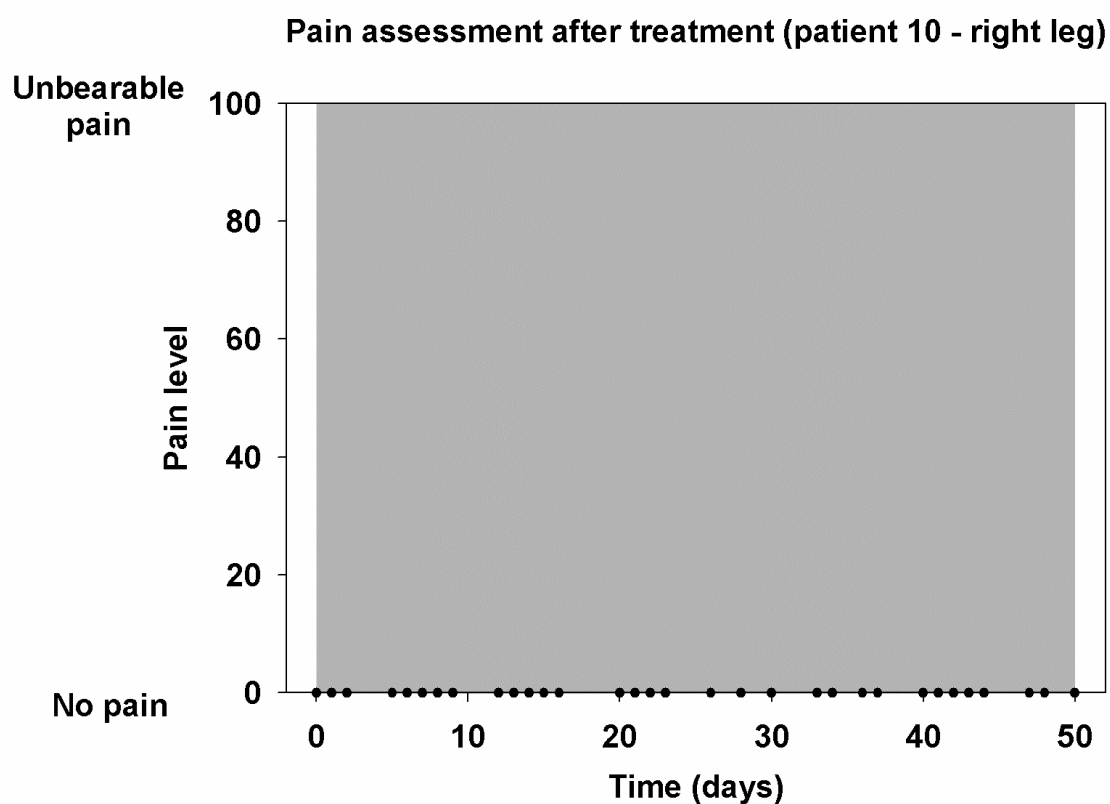
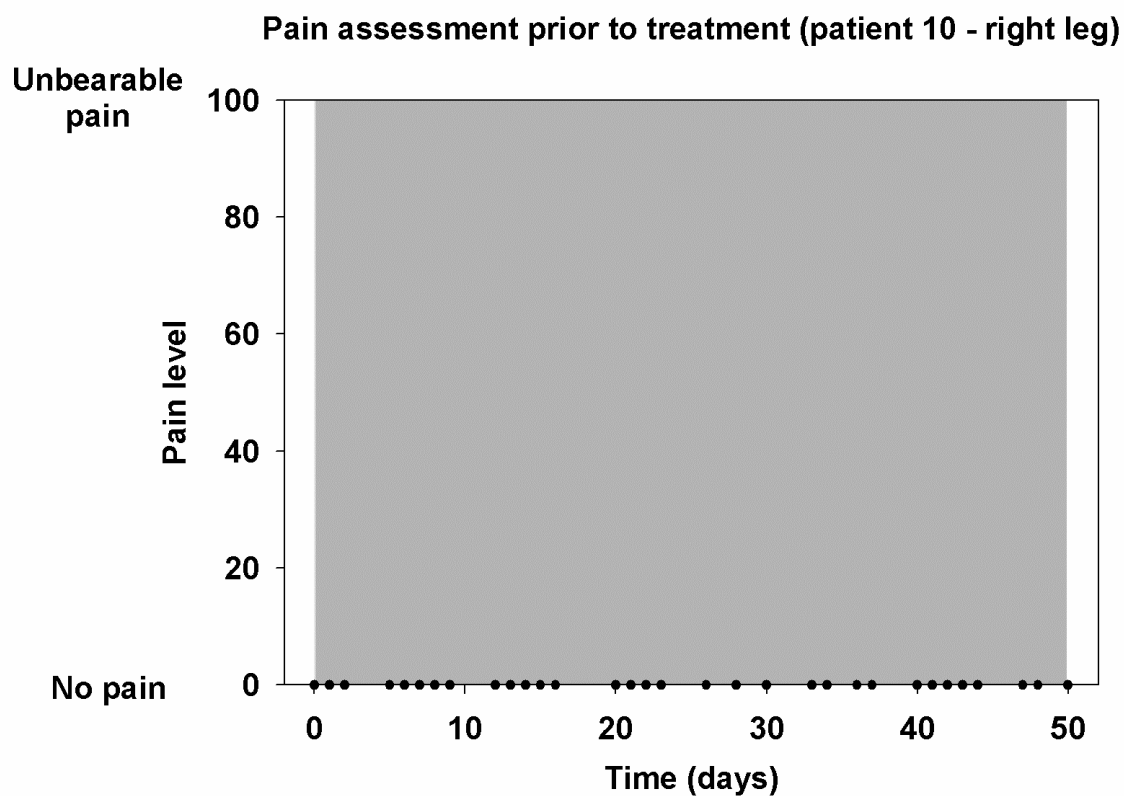


Left leg

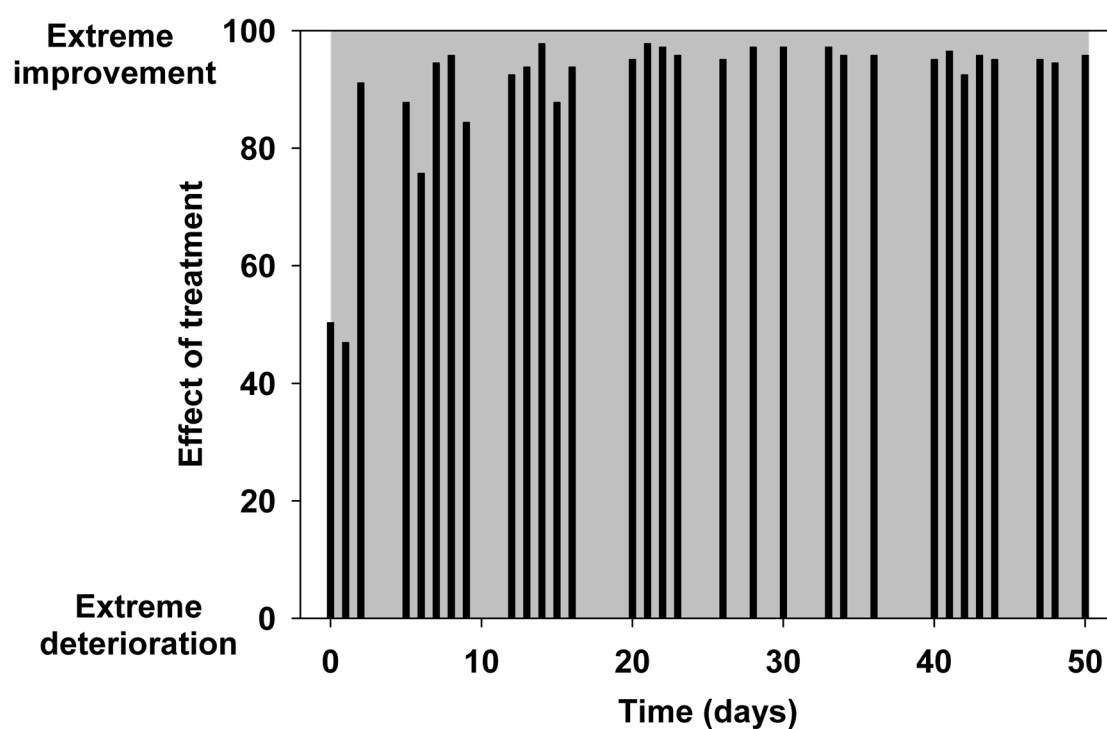
Note: In all following figures showing results related to time, the grey shaded area represents the entire wIRA treatment period for this patient (i.e., the total time period between the first and the last treatment).

Right leg

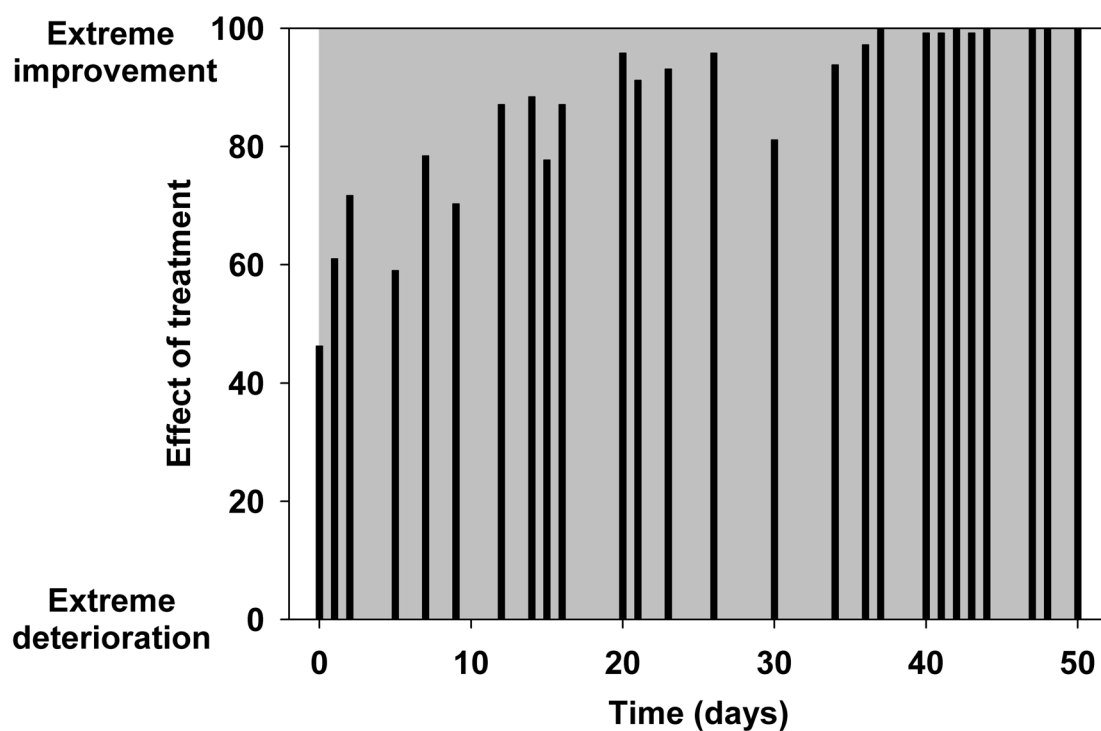


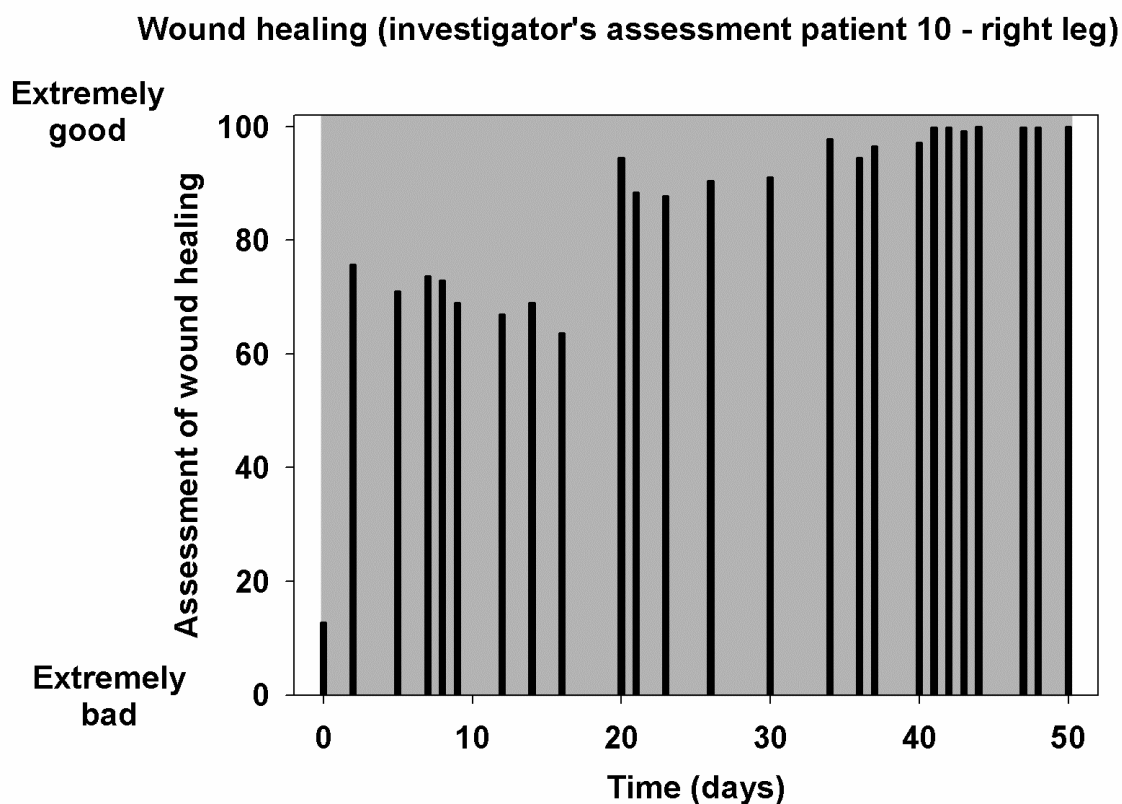
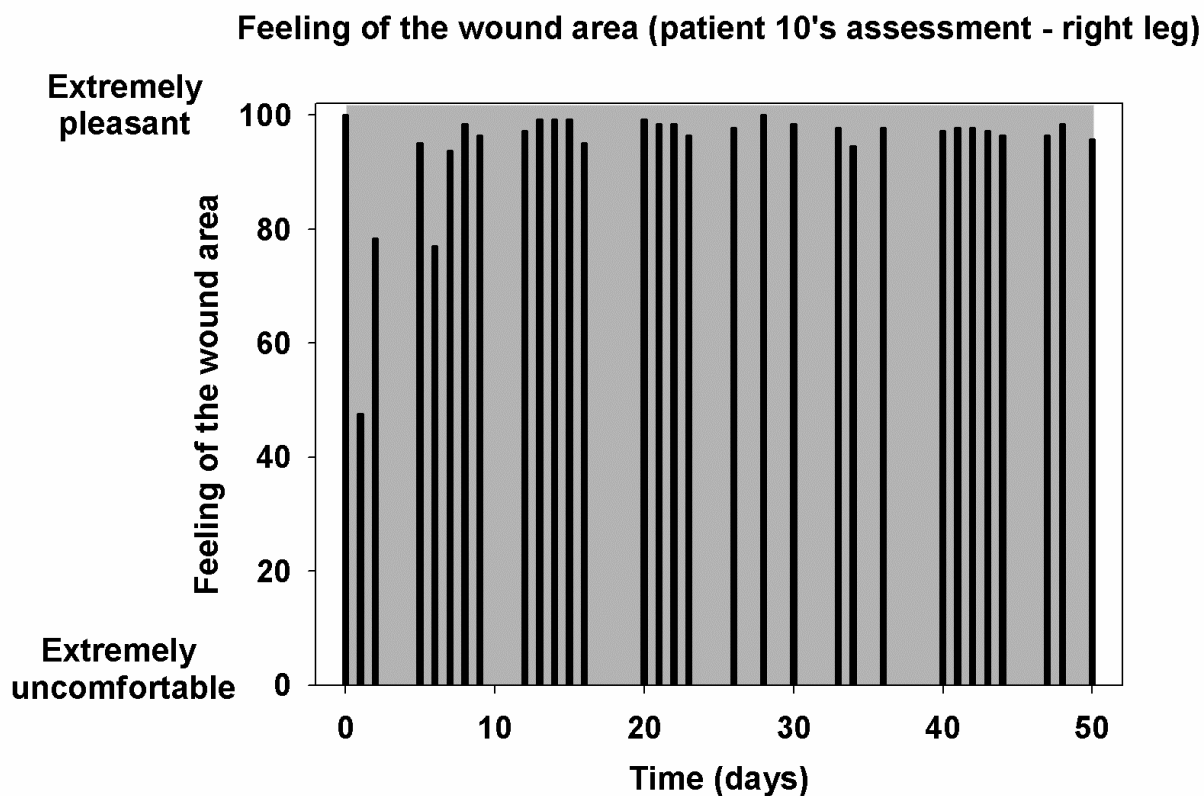


Effect of treatment (patient 10's assessment - right leg)

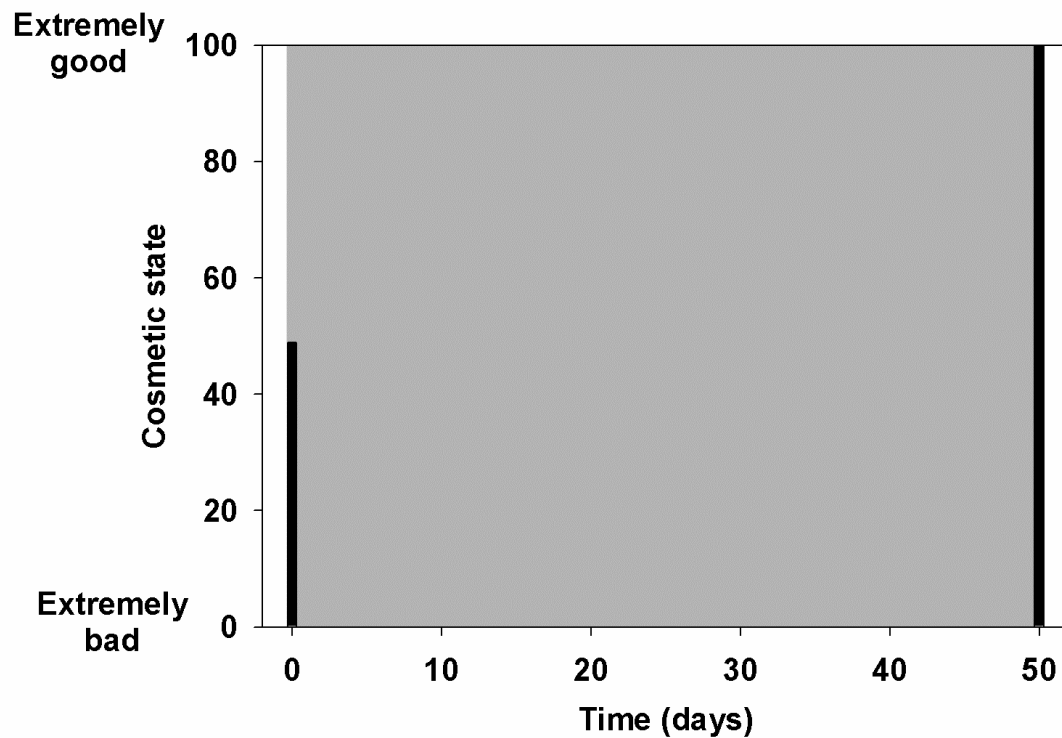


Effect of treatment (investigator's assessment patient 10 - right leg)

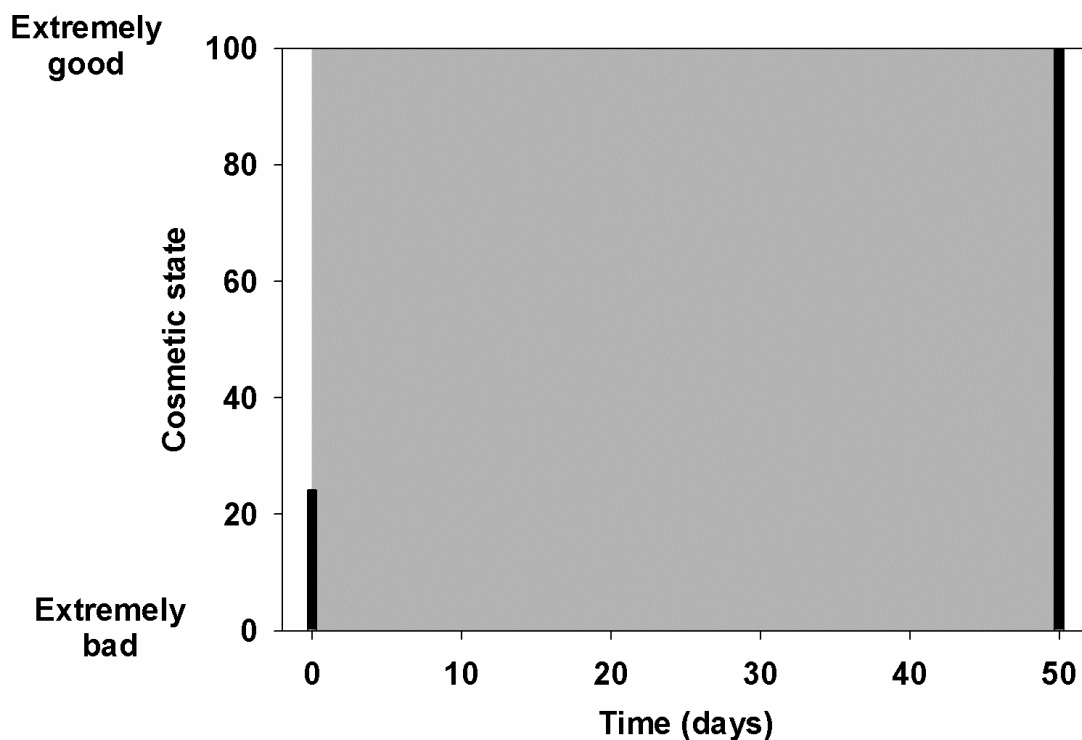




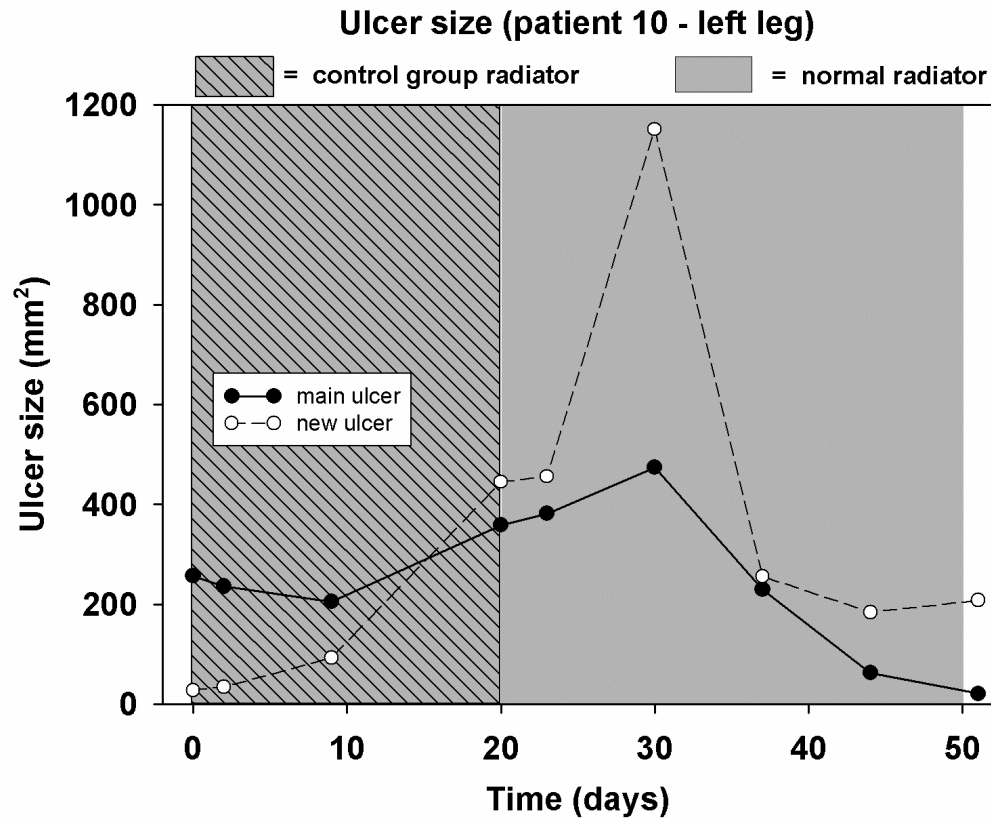
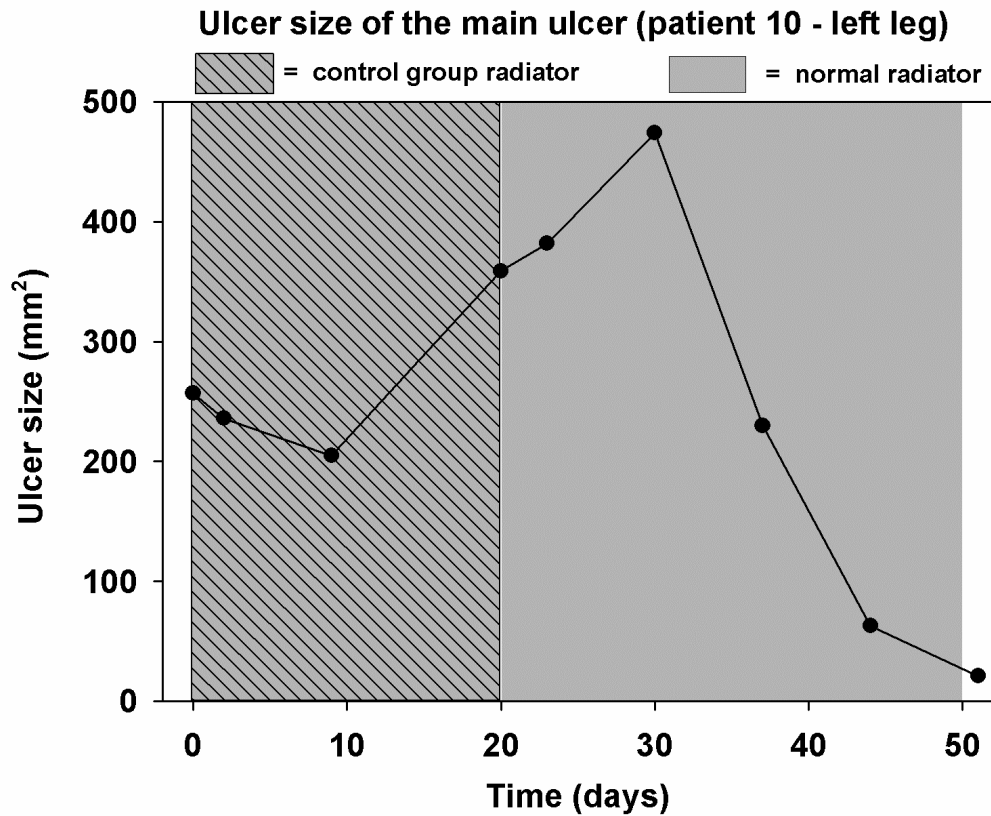
Cosmetic state (patient 10's assessment - right leg)



Cosmetic state (investigator's assessment patient 10 - right leg)

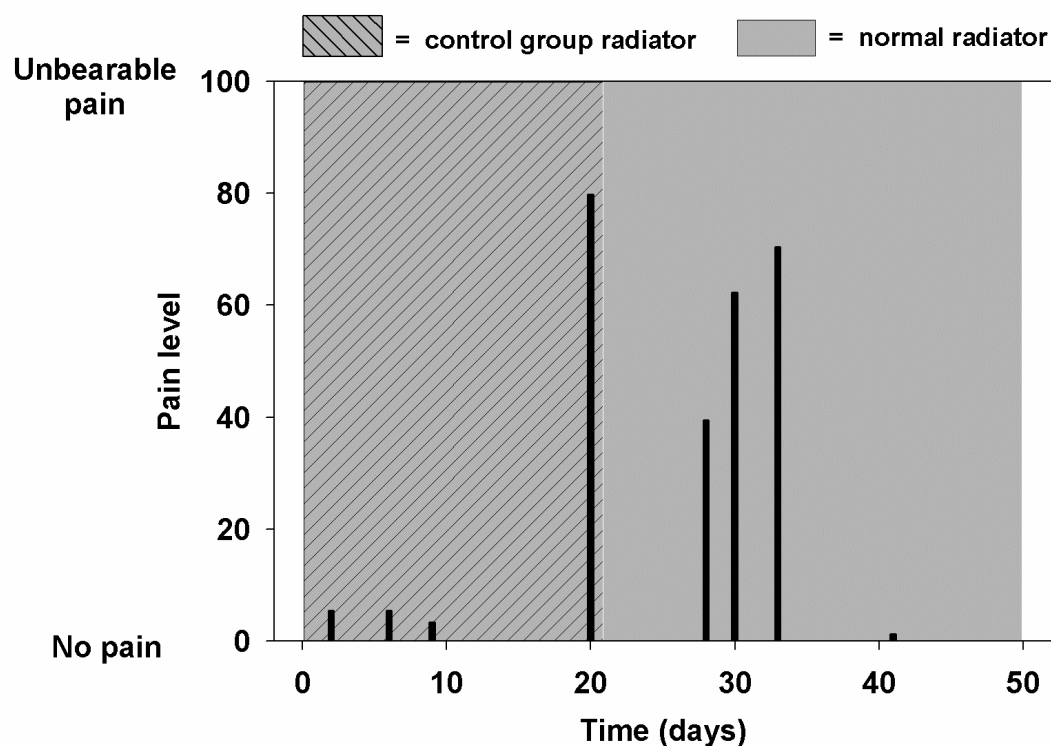


Left leg

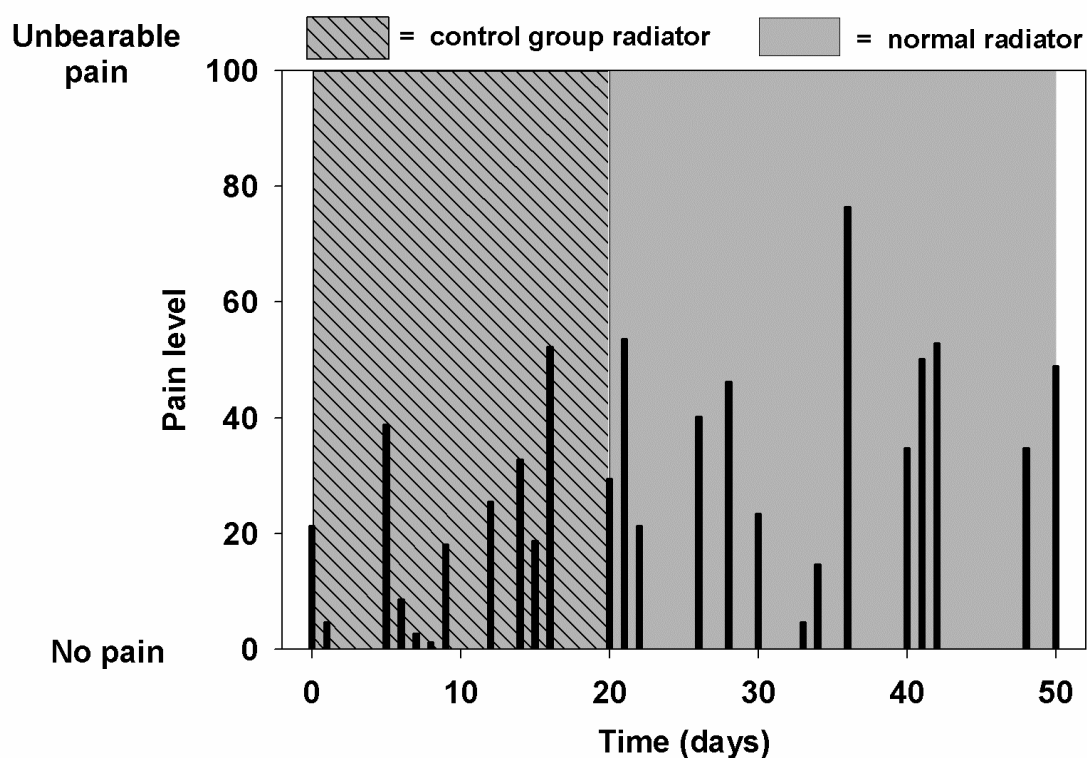


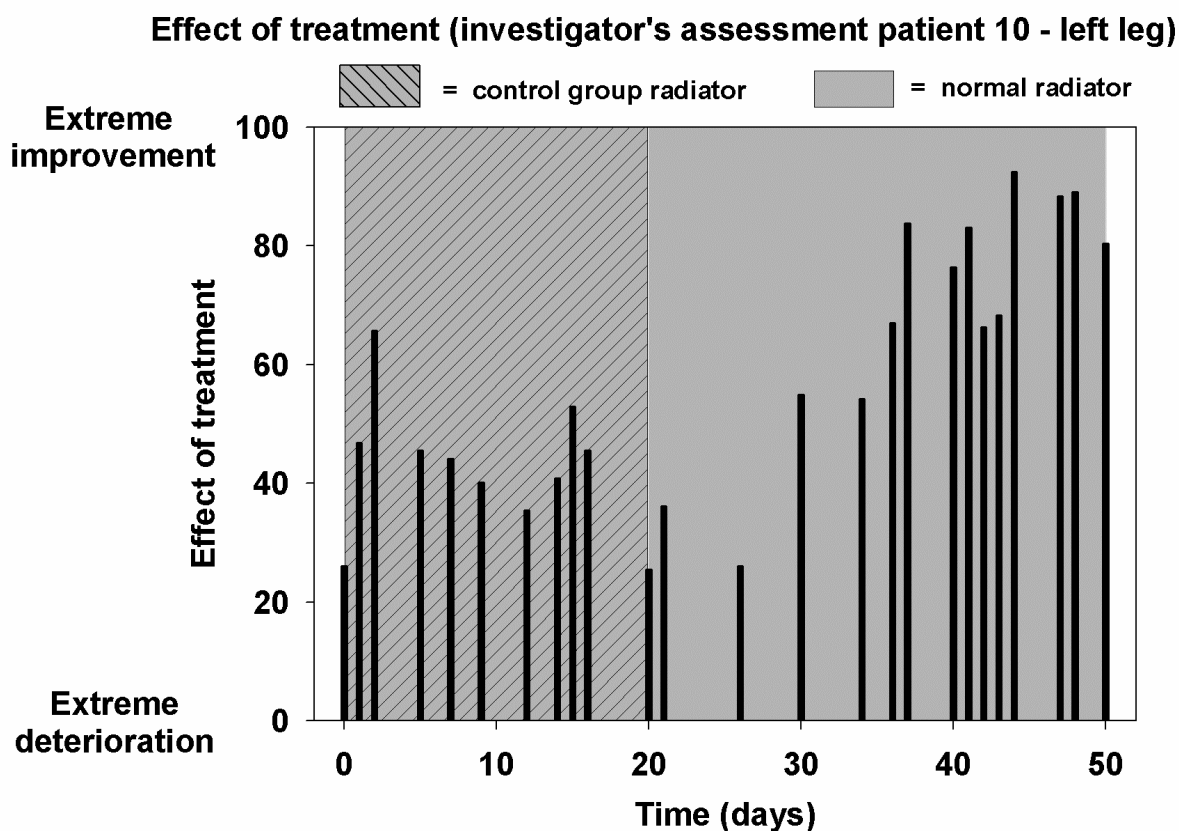
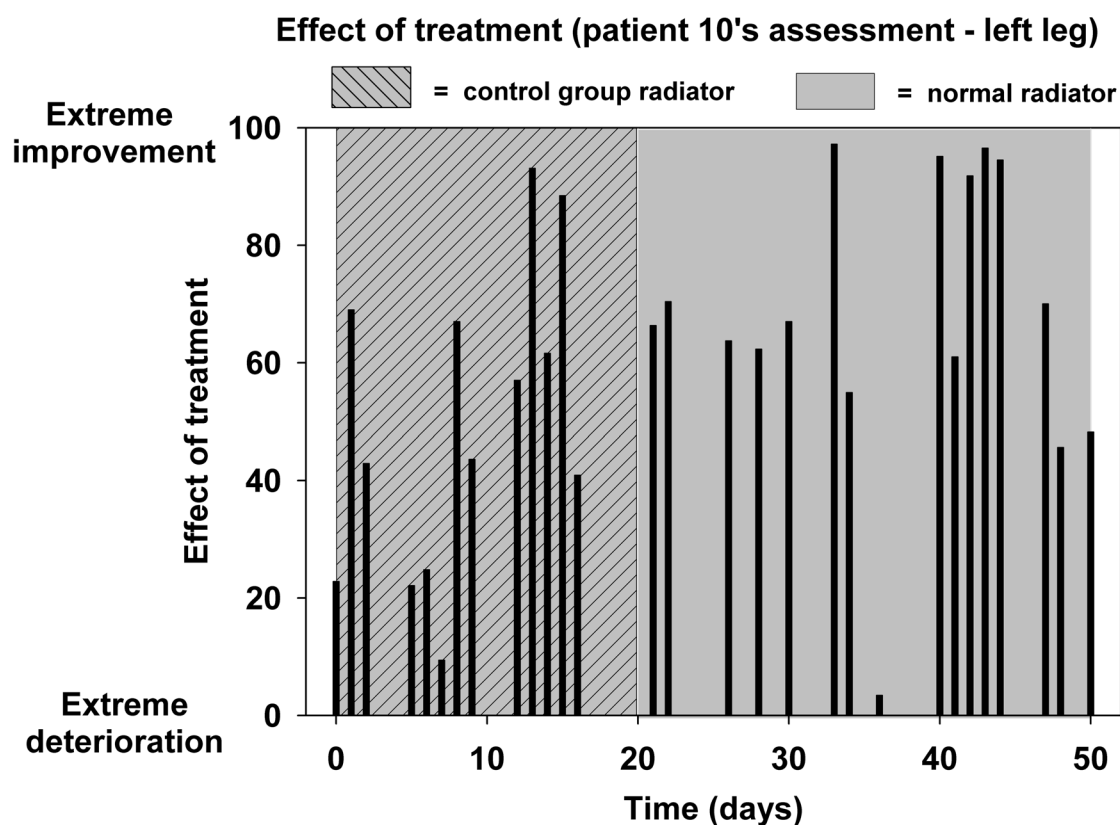
New ulcer = total area of newly developed ulcers in the region beside the main ulcer.

Pain assessment prior to treatment (patient 10 - left leg)

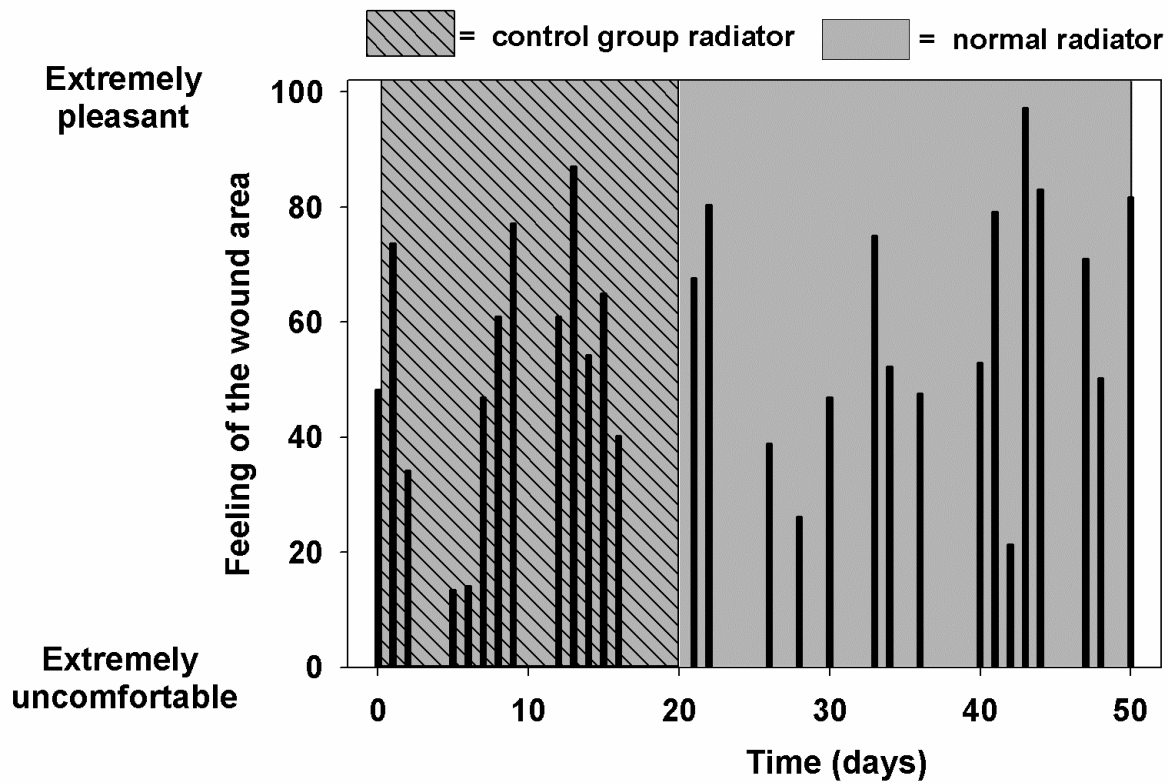


Pain assessment after treatment (patient 10 - left leg)





Feeling of the wound area (patient 10's assessment - left leg)



Wound healing (investigator's assessment patient 10 - left leg)

