



## USE OF A CERAMIC WOUND DRESSING\* COMBINED WITH BACTERIAL FLUORESCENCE IMAGING\*\* – BASED DIAGNOSTIC IN THE TREATMENT OF CHRONIC WOUNDS: A PILOT STUDY

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### BACKGROUND

Chronic wounds are often missing substantial clinical signs of infection, leading to a lack of laboratory diagnostic testing. As a result, infections are increasingly detected very late in the treatment process leading to inadequate wound care and delayed wound healing.

### AIMS

- In the pilot case series, the aim was to identify infected wounds lacking clear clinical signs of infections by bacterial fluorescence imaging (FI)-based detection of the bacterial load.
- The efficacy of an antimicrobial ceramic wound dressing\* was evaluated by visualizing the decrease of bacterial load in locally infected wounds with the FI method.
- Results obtained by FI observations were validated by wound care professionals, who evaluated the decrease of the clinical signs of infections.

### METHODS

- The pilot study was conducted at the Central Ambulance of Wound Care, Department of Nursing, Federal County Hospital in Bregenz. Baseline characteristics of each wound were assessed at start of study treatment (day 0). Ulcer characteristics were evaluated at individual time points depending on the wound characteristics for each patient until the bacterial load was eliminated.
- Bioburden of 6 chronic wounds of different origin were assessed with a non-contact, hand-held FI device\*\* displaying tissues in green fluorescence, while bacteria fluoresce red or cyan. This allows real-time detection and localization of bioburden ( $\geq 10^4$  CFU/g) within and around wounds.
- Wounds were cleansed with antimicrobial wound flushing solutions and subsequently treated with a ceramic wound dressing\* consisting of spherical ceramic granules able to constantly remove exudate, bacteria and noxious components from the wound, and thus, supporting the physiological healing process. Suction gauze served as secondary dressing. FI was used to assess the antimicrobial efficacy of the ceramic wound dressing.

## CASE 1: PRESSURE ULCER AFTER AMPUTATION OF THE LOWER LEG

- **Wound onset:** 12 months before enrollment
- **Treatment prior to enrollment:** wound flushing solution, foam dressing

### Results of the study treatment

**Day 1:** in contrast to the visual assessment, FI analysis revealed an increased bacterial load (red-brown colour) especially in the peri-wound skin; based on the findings obtained by FI, the antimicrobial therapy with a ceramic wound dressing was initiated.

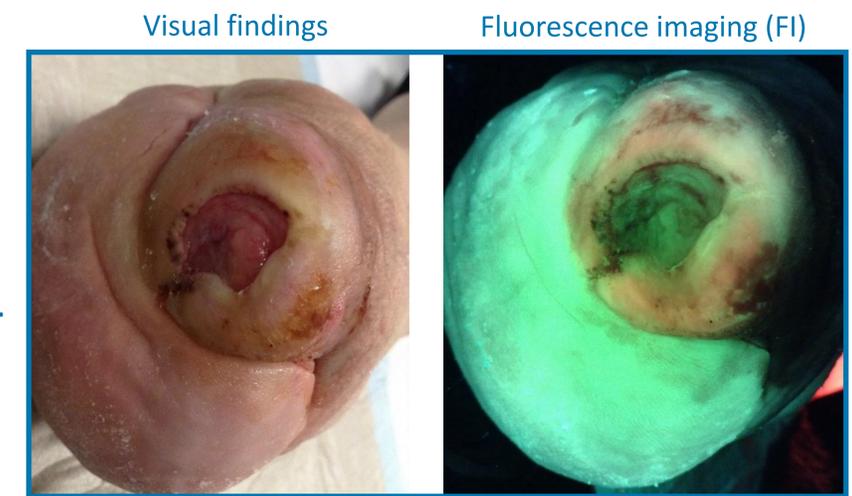
**Day 2:** bacterial load in the wound surrounding and the wound bed decreased, as demonstrated by FI.

**Day 5:** FI analysis approved a continuing decline of the bacterial load in the peri-wound skin (beneath the epithelial tissue) and the wound bed.

**Day 7:** only slight bacterial load remained beneath the hyperkeratosis, recognizable by the red-brown coloration in the FI.

- ➔ FI analysis allowed early diagnosis of the infection and the prompt initiation of an appropriate antimicrobial treatment.
- ➔ The efficacy of the antimicrobial therapy already after 7 treatment days was approved by FI.

Day 1



Day 7



## CASE 2: MIXED LOWER LEG ULCER

- **Wound onset:** 3 months before enrollment
- **Treatment prior to enrollment:** wound flushing solution, alginate, foam dressing

### Results of the study treatment

**Day 1:** a massively increased bacterial load (red color) especially in the wound surrounding was detected using the FI device; based on this diagnosis of infection, the wound was treated with the antimicrobial ceramic dressing.

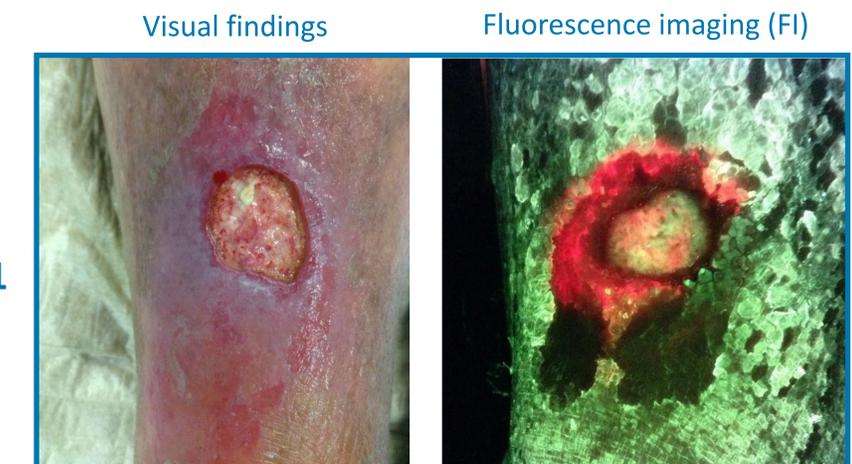
**Day 3:** FI analysis revealed a reduced bacterial load in the wound surrounding and no bacteria in the wound bed.

**Day 7:** a further decrease of bacterial load in the wound surrounding was detected by FI; additionally, an optically visible debriding effect of the ceramic dressing and start of granulation could be reported.

**Day 9:** by using FI, no bacteria were detected.

- ➔ Due to FI analysis the infection was detected and an adequate wound therapy could be initiated.
- ➔ The efficacy of the antimicrobial therapy was examined via FI and proved to be effective already at day 3 after start of therapy.

Day 1



Day 9



### CASE 3: LOWER LEG ULCER

- **Wound onset:** 3 months before enrollment
- **Treatment prior to enrollment:** wound flushing solution, foam dressing

#### Results of the study treatment

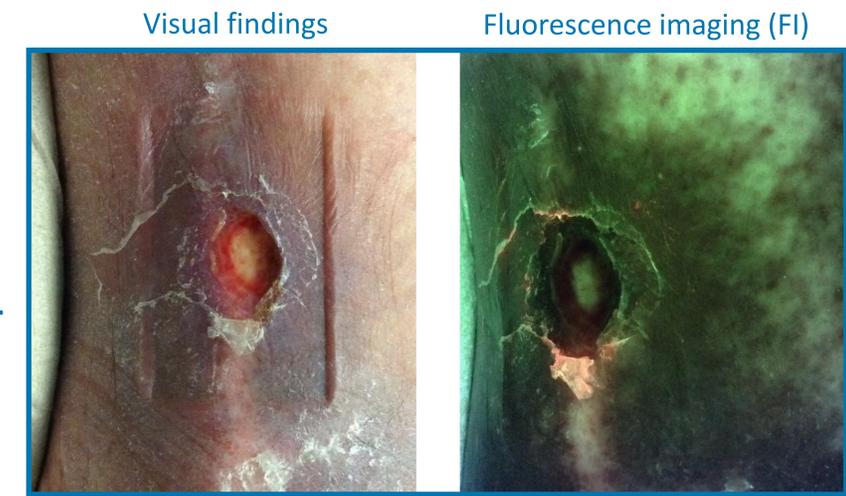
**Day 1:** the bioburden mainly at the wound border beneath the skin scales was detected only by FI analysis; based on the evidence that a bacterial infection in the wound was present, an antimicrobial therapy with the ceramic wound dressing was started.

**Day 3:** FI assessment revealed a marked decrease of the bacterial load and an improvement of the wound surrounding.

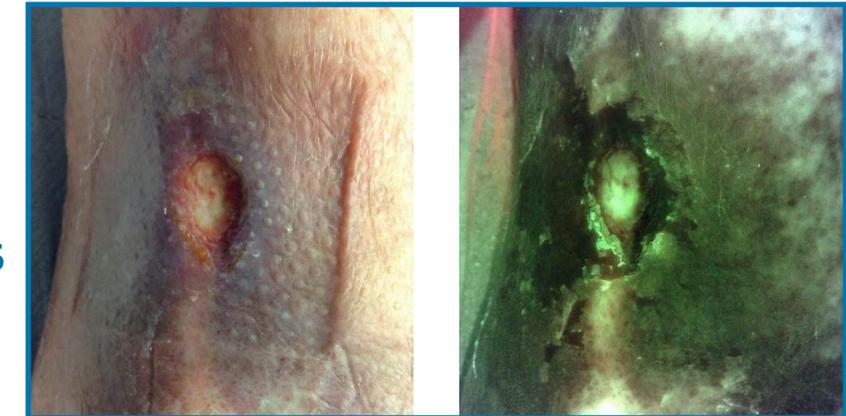
**Day 5:** by using FI, it could be demonstrated that the wound tissue was free of bacterial load.

- ➔ By using FI analysis, the early diagnosis of infection and the prompt initiation of an antimicrobial treatment was possible.
- ➔ Therapy with the ceramic dressing was effective and no bacteria were detected in the wound already at day 5 after treatment start as proven by the FI analysis.

Day 1



Day 5



### CASE 4: INITIAL FUNGAL INFECTION OF TOES

- **Wound onset:** 1 week before enrollment
- **Treatment prior to enrollment:** anti-fungal device

#### Results of the study treatment

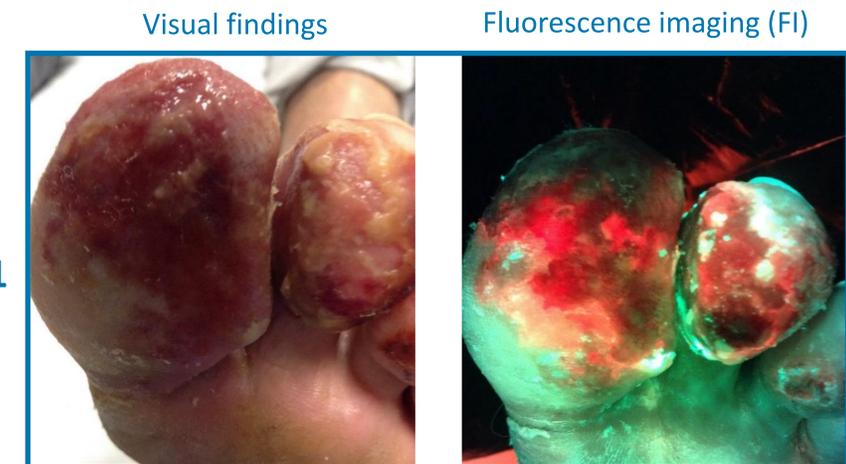
**Day 1:** clear clinical signs of fungal infection were optically visible; however, the FI analysis revealed an additional massive bacterial load with Gram-positive as well as Gram-negative bacteria, prompting the initiation of an antimicrobial treatment.

**Day 3:** by using the FI device, a decrease of bacterial load could be visualized, exudate reduction was optically visible.

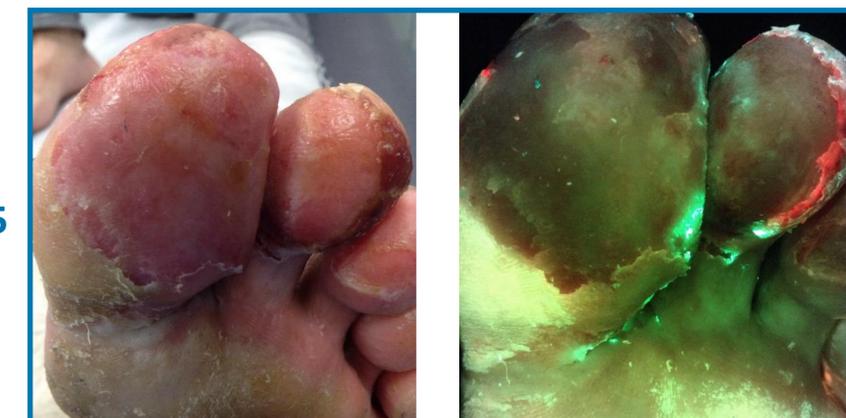
**Day 5:** only a minor bacterial load remaining below the skin scales could be detected by using the FI device; the substantial improvement of the wound situation was optically visible.

- ➔ FI analysis revealed that impairment of wound healing was caused by bacterial load rather than by fungal infection.
- ➔ Antimicrobial efficacy of the ceramic dressing was demonstrated already at day 5 after therapy start by FI.

Day 1



Day 5



## CASE 5: LEG ULCER AT THE FOOT AFTER CELLULITIS (CHRONIC VENOUS INSUFFICIENCY)

- **Wound onset:** 1 month before enrollment
- **Treatment prior to enrollment:** wound flushing solution, alginate, foam dressing

### Results of the study treatment

**Day 1:** the painful wound was covered with slough, an increased bacterial load (light green colour) mainly in the peri-wound skin was observable with FI; based on these findings the wound was treated with an antimicrobial ceramic dressing.

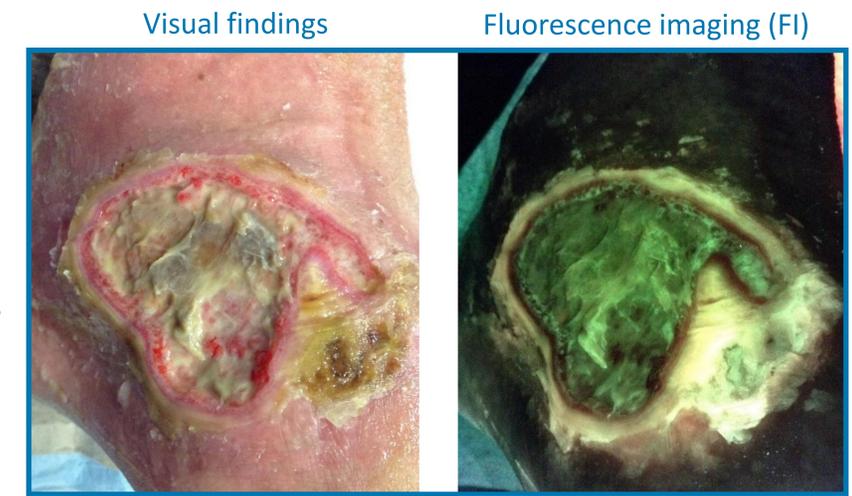
**Day 7:** optical evaluation revealed a reduction of slough as well as an advanced epithelialization and substantial improvement of the wound condition; FI analysis indicated a decreased bacterial load in the wound bed and the surrounding area.

**Day 12:** only few remaining bacteria at the wound border were detectable by using FI .

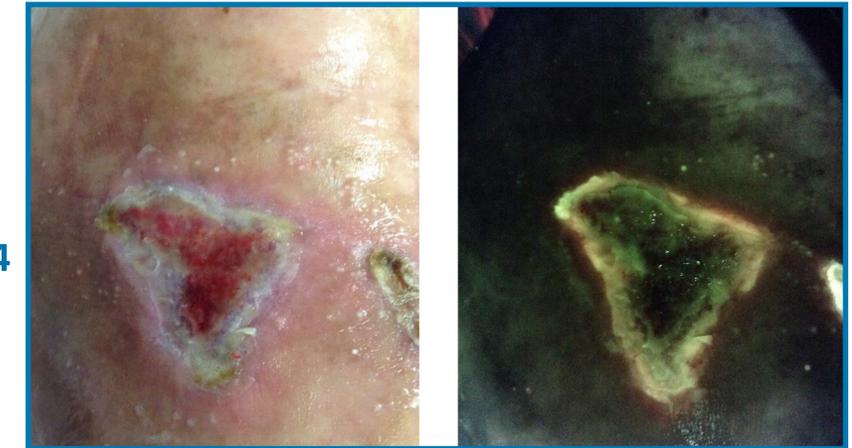
**Day 14:** increased epithelialization of the wound was detected and FI analysis proved that no bacteria remained in the wound.

→ Based on the FI analysis, the efficacy of the ceramic wound dressing was determined already after 7 treatment days.

Day 1



Day 14



## CASE 6: LOWER LEG ULCER

- **Wound onset:** 8 months before enrollment
- **Treatment prior to enrollment:** wound flushing solution, gel, foam dressing

### Results of the study treatment

**Day 1:** the wound displayed clear optically visible clinical signs of infection, a massive bacterial load mainly in the peri-wound skin was detected by using FI.

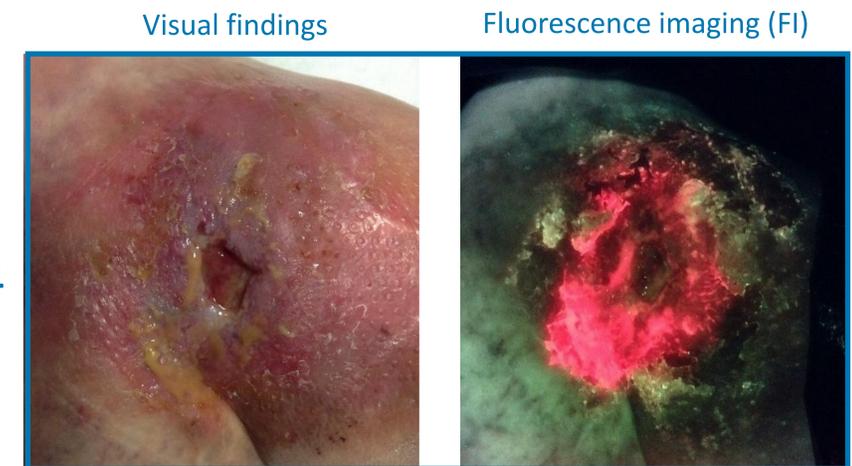
**Day 3:** bacterial load decreased markedly and the wound as well as the peri-wound skin condition improved as detected by using FI.

**Day 5:** furthermore, a low amount of bacteria was detected only in the peri-wound skin with the FI method.

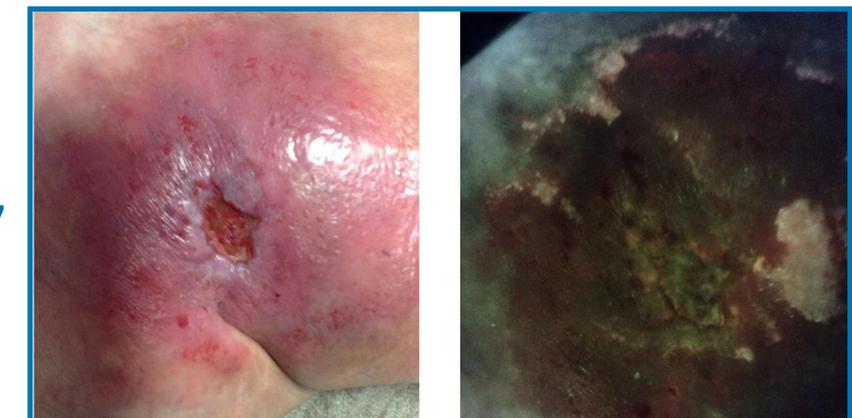
**Day 7:** no bacteria were detectable as shown in FI analysis, a marked improvement of the wound condition was optically visible.

→ Therapy with the antimicrobial dressing was effective already at day 3 after treatment start as proven by FI analyses.

Day 1



Day 7



## SUMMARY

The cases presented in this pilot study comprised 4 chronic leg ulcers, 1 pressure ulcer and 1 primary fungal infection. In all cases, previous treatments did not lead to adequate wound healing. In contrast, treatment with the antimicrobial ceramic dressing led to a substantial reduction of the bacterial load and improvement in all analyzed wounds. Compared to an assessment based solely on clinical signs of infections, fluorescence imaging enables an earlier and more reliable diagnosis of an infection, and thus, initiation of an adequate antimicrobial treatment.

### **The use of the bacterial fluorescence imaging device led to**

- an early identification of wounds lacking substantial clinical signs of local infections with an unmet need of an antimicrobial therapy,
- the appropriate initiation of an antimicrobial treatment by the attending wound care professionals,
- the ability to rapidly evaluate the antimicrobial efficacy of the treatment applied, and
- a higher reliability in the treatment of local wound infections.

### **The use of the antimicrobial ceramic wound dressing led to**

- a substantial reduction of the bacterial load in chronic wounds with a mean reduction time of 7 days,
- binding of wound exudate and bacteria in the dressing, resulting in a reduction of bacterial load in the wound bed and the peri-wound skin,
- wound protection due to the binding of exudate, and
- accelerated wound healing.

## CONCLUSION

- ➔ The results of this pilot study demonstrate the clinical efficacy of bacterial fluorescence imaging as an appropriate diagnostic tool to identify wound infections. In combination with the subsequent use of a highly effective antimicrobial ceramic dressing, it is suitable for the use in daily routine wound care.
- ➔ Early start of an effective antimicrobial treatment, real-time information regarding the efficacy of the chosen treatment as well as the good antimicrobial properties of the ceramic wound dressing can result in saving of health-economic resources.
- ➔ The results of the study presented here indicate that quality of life for the affected patients can be improved by the early initiation of an adequate and efficient therapy.
- ➔ A larger number of patients is needed to substantiate these pilot observations.