# Final report about a medical device experimentation


Sponsor:
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Prova eseguita da:
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Test performed by:
**Dott. Miroslav Stovicek**

Experience and qualification:
**38 anni nel reparto di chirurgia**

Title of the experimentation:
**DEVICE FOR TOPIC USE. SPRAY POWDER ABROSBER FOR EXUDATIONS WITH SILVER IONS.**

Period of application: september - october 2011

## VALUTAZIONE CLINICA DEL PREPARATO AD USO TOPICO:

- Study carried out in the Czech Republic (no prior indication of what the preparation was expected to do was given although it was stated to be safe for human use);
- Used on 3 patients only;
- Used EXCLUSIVELY on serious chronic wounds, never on recent wounds;
- Application period: 5 weeks, limited by the amount of preparation supplied;
- Application modality: local, on the lesion and on the areas around the wound;
- Application interval: once every 24 hours;

- Application:
  - on 2 patients: carried out by nurses and carers at the Nursing Home;
  - on 1 patient: applied by the patient himself - application followed a shower and Betadine disinfection;

- Associated illness: all 3 patients suffered from polymorbidity (multiple clinical conditions) and two of them were in need of constant assistance.
- 2 patients were bedridden and needed to have their positions moved frequently; 1 patient could move without any help. All 3 patients showed inflammation of the lesion and of the surrounding area.
- Other medications were topically applied during the same period on 2 patients in the Nursing Home when the dressing was changed: Betadine was applied around the wound.
- "K + C" tampons on the wounds: not carried out.
- Generic antibiotics for 1 patient where the lesion originated from erysipelas 3 weeks prior to the application. 10 days with PNC 750 every 8 hours.

## EVALUATION OF THE EFECTS

- Anti-inflammatory ++++
- Prolifetative ++++
- Analgesic (in association with a reduction of local inflammation) ++++
- Allergic reaction on the skin: none
- Separation of the necrotic eschar due to granulation tissue growth from the bottom
- Healing at the edges of the wound: due to the short application period, an exact evaluation was not possible
- Applying the preparation on larger areas would lead to a more appropriate evaluation of the effects of the silver as would the possibility of absorption over longer periods of time
- Evaluation of topical use on recent open wounds.

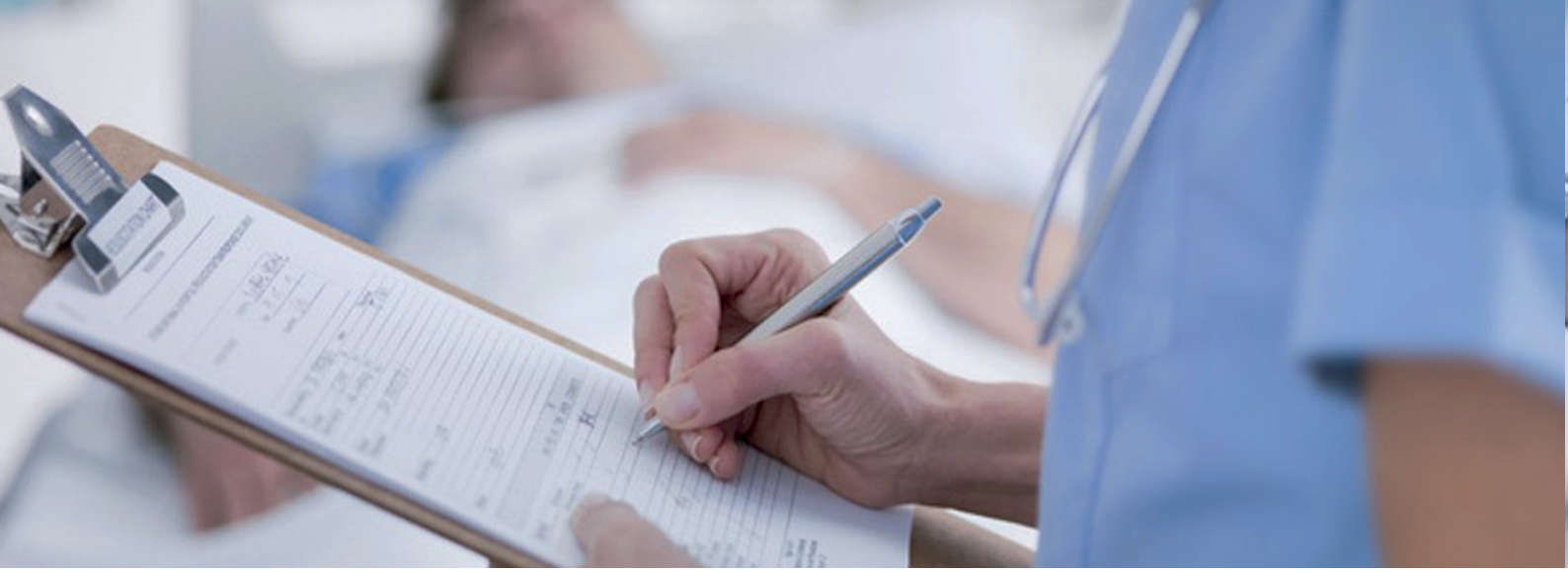
## GENERAL EVALUATION

Due to the limited number of patients, no negative effects were observed. Despite the low number of patients, the effect was comparable to that of other medications containing silver ("lalugen" cream), and probably the positive effect was greater. The fact that the patient can apply the preparation himself with no risk of contaminating the lesion, for example with the use of hydrocolloid creams or products, should be taken into consideration. Undoubtedly the cost and availability of the product should be taken into account for a wider use and especially the time needed to apply it compared to products currently being used. This evaluation is not decisive since the preparation was used on 3 patients only, 2 of whom were seriously ill, and the topical application was only carried out for a relatively short period of time. I can however say, that my subjective impression was very positive.

Trutnov, 19 november 2011

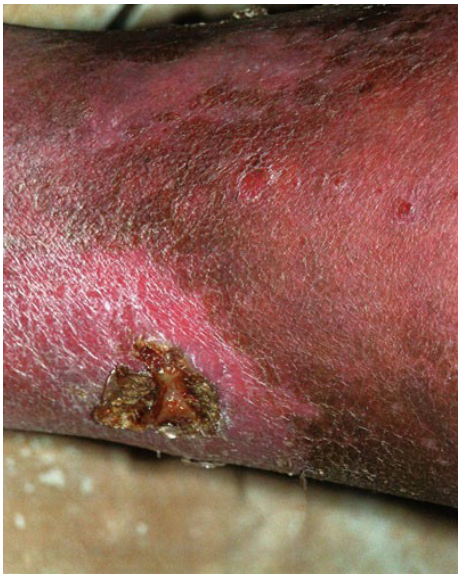
## MAXIMUM THERAPEUTIC EFFECT:

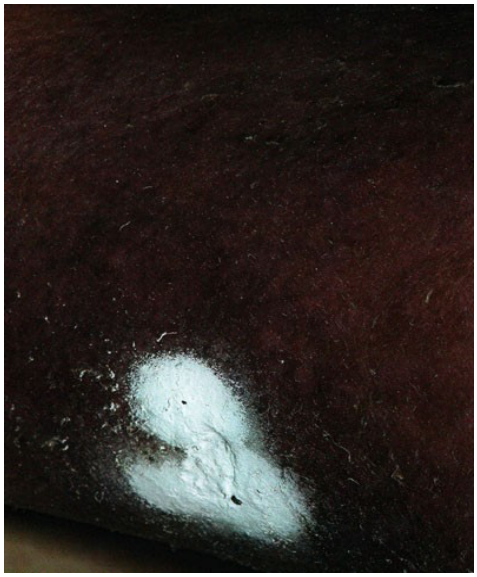
**anti-inflammatory ++++**
**proliferative ++++**
**analgesic ++++**

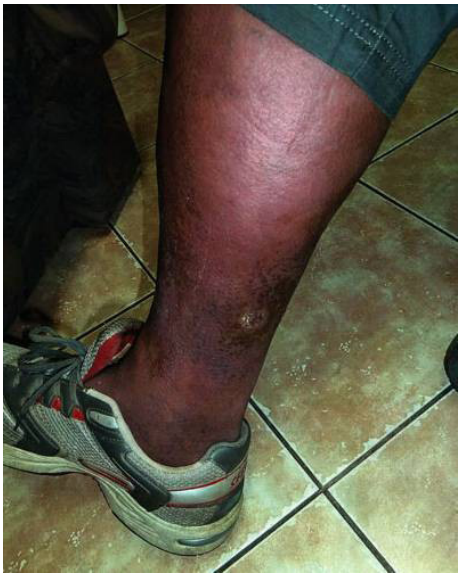


## CLINICAL EVALUATION PHOTOGRAPHS:

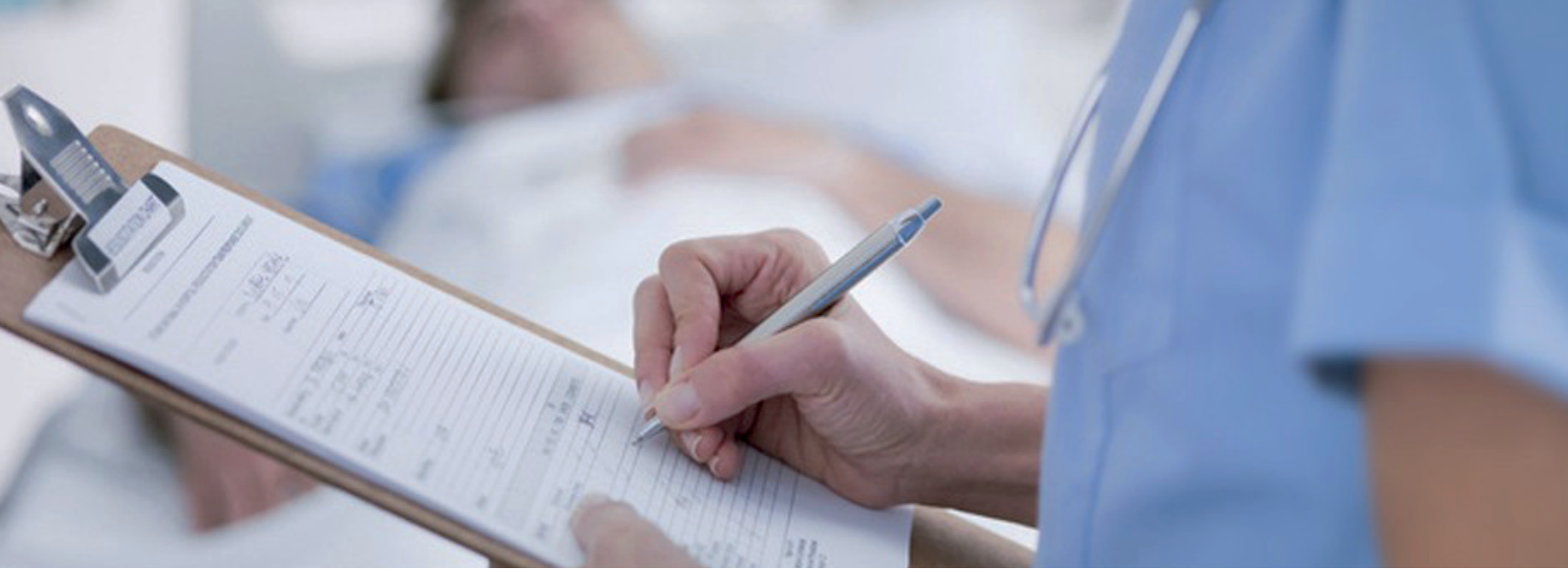
Patient no.1:
70 year-old male with serious chronic venous insufficiency, swelling of the lower limbs with tibial tissue at risk, liver affected by "toxic nutrition" and arterial hypertension due to obesity. He had been treated on 23rd August 2011 for neglected erysipelas of the tibia, with general symptoms and a deep wound on the tibia. At the time of his initial treatment, the preparation was not available. Treated with generic PNC and local cleansing, the next check up took place on 15th September 2011 after having taken the generic PNC for 10 days, using Jarisch locally and cleansing (photo no. 1). The patient used the Spray once every 24 hours at home after cleansing and drying the wound with the hair dryer.
At the check-up on 7th October 2011, the lesion had almost healed and there were no signs of inflammation. The wound was superficial with minimal secretion and the spray was empty.



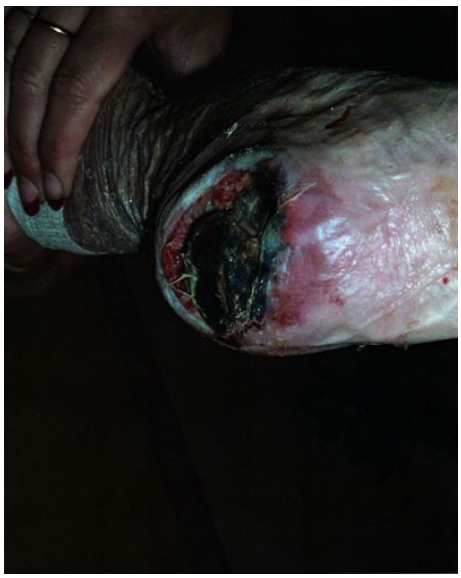


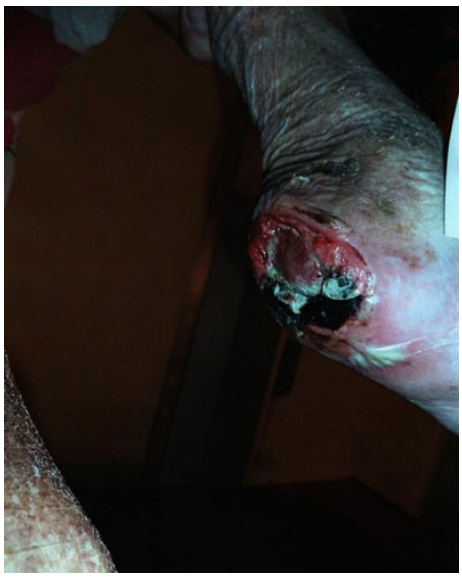


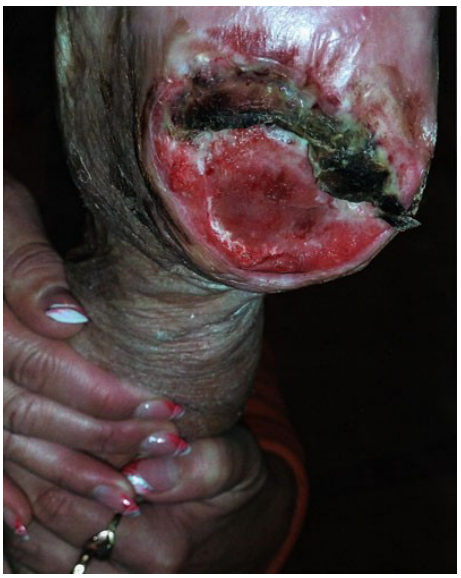
Documentation: photos (nos.1-3) from the start of preparation application.

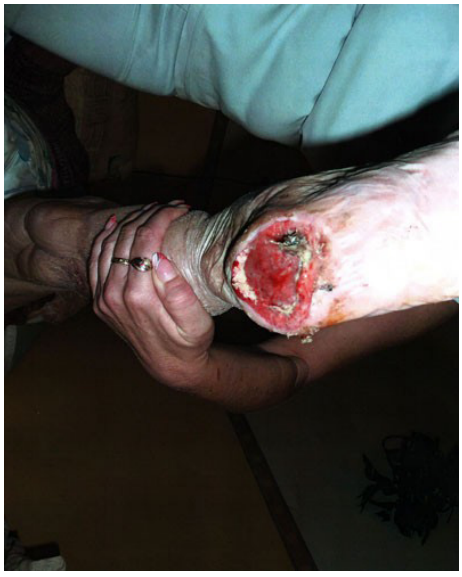


Patient no. 2:
98 year-old female, in-patient at the Nursing Home, suffering from polymorbidity, and totally bedridden with the need to have her position changed frequently. Serious arteriosclerosis with dementia, incontinence and totally in need of assistance. The Spray was first applied on 30th September 2011 and then every 24 hours after the deep bed sores with adherent necrosis, local inflammation and bad-smelling secretion had been disinfected (with Betadine). The local therapy ended on 26th October 2011 when the spray was empty. The inflammation had diminished notably, almost all the necrosis had come away spontaneously and granulation had started from the bottom. Reaction to pain as the dressing was being changed had gradually decreased to almost zero compared to the initial application. It was difficult to take photos due to the stiffness of the lower limb joints.



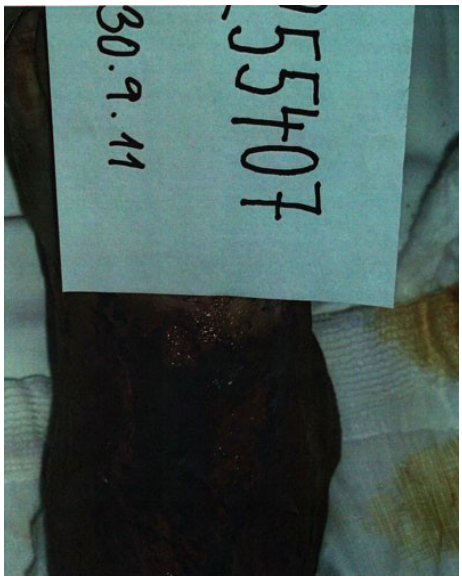


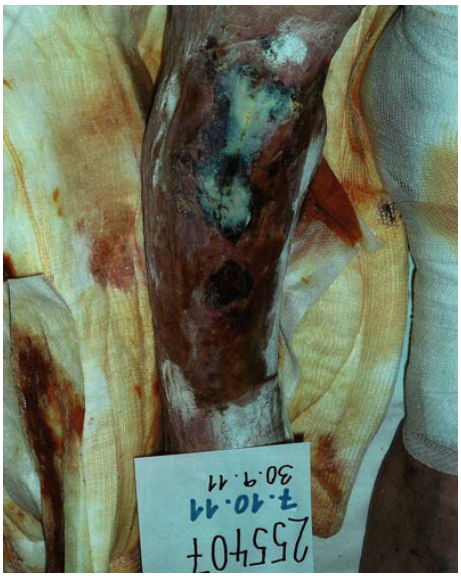


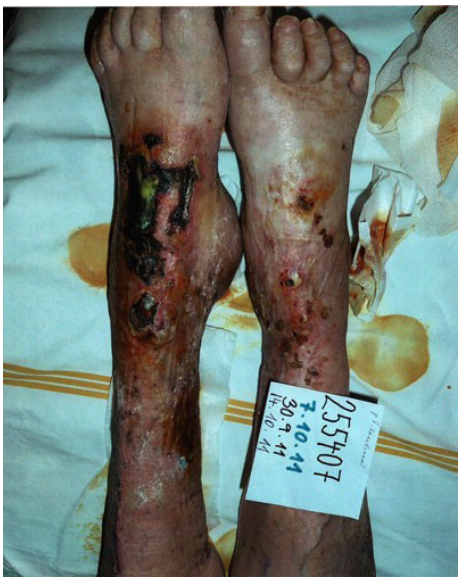


Documentation: photo nos.1-4 from the start of preparation application

Patient no. 3:
86 year-old female, in-patient of the Nursing Home, suffering from polymorbidity, bedridden and in total need of assistance, with serious venous insufficiency, ischemic disease of the lower limbs, incontinence with dementia and disorientation. Deep lesions on the lower part of both tibias, especially the right one, covered with adherent necrosis and inflammation of the surrounding area. Intermittent fever. The Spray was first applied on 30th September 2011 in the same way as with the other patients. Application ended on 26th October 2011 when the spray was empty. In this case a reduction in inflammation was observed, the surfaces had no secretion and the necrosis had begun to separate spontaneously from the edges of the areas. Pain had also diminished. As of 7th October 2011, the patient no longer had fever. The photo shows the residues of the preparation during the last dressing change.




Documentation: photos nos.1-3 from the start of preparation application.