



CLINICAL REPORT ABOUT A NANOTECHNOLOGICAL MEDICAL DEVICE ON A BASE OF TITANIUM BIOXIDE AND SILVER WITH A LIQUID SPRAY DISPENSER



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INTRODUCTION: nanotechnologies can be the “new frontier” in wound care and represent an important innovation, especially in the management of infected wounds.

AIM OF THE WORK: to demonstrate the effectiveness of a new product whose mechanism of action is to form an antimicrobial environmental barrier that allows the creation of the best microenvironment for the spontaneous tissue regeneration; the device has been tested on colonized and/or infected chronic skin lesions, to assess the healing promoting anti-bacterial barrier activity.

METHODS: the study involved a sample of 20 patients, selected from a population with different aetiology skin ulcers, all with signs of colonization/infection (Cutting & Harding criteria). The treatment protocol provides only local treatment (TiAB*) and not a general concomitant antibiotic therapy. The dressing consisted of applying, in liquid spray form, a small amount of the product on the lesions, after cleansing with dry gauze or moistened one with normal saline solution; moist gauzes as secondary dressing. The renewal of the dressing was provided every 48 hours. The effectiveness evaluation was based on the removal of clinical signs of colonization/infection and area reduction/healing of the wounds, after an observation period of 6 weeks.after.

RESULTS: the results showed effectiveness (removal of the signs of colonization and/or infection) in 100% of cases, with a mean area reduction of about 76%. Two cases of healing have to be reported: one within 5 weeks and the other one within 25 days. All results are shown in the table on the right.

Vasculitic ulcer in patient with coagulative disease and chronic venous insufficiency



Beginning of the treatment 2 weeks later 5 weeks later

| N° | LOCATION | AETIOLOGY | INITIAL AREA | FINAL AREA | GAIN |
|---------------------------------------|------------|---------------|--------------|------------|--------------|
| 1 | Lower limb | Vasculitis | 36.3 | 10.1 | 72.2% |
| 2 | Lower limb | Vasculitis | 33.5 | 9.4 | 71.9% |
| 3 | Lower limb | Venous | 27.2 | 0 | 100% |
| 4 | Lower limb | Vasculitis | 23.9 | 4.9 | 79.5 |
| 5 | Lower limb | Mixed | 37.6 | 8.8 | 76.6% |
| 6 | Lower limb | Venous | 28.6 | 7.6 | 73.5% |
| 7 | Lower limb | Vasculitis | 42.6 | 12.4 | 70.9% |
| 8 | Lower limb | Vasculitis | 11.8 | 3.2 | 72.9% |
| 9 | Lower limb | Venous | 14.4 | 2.9 | 79.9% |
| 10 | Lower limb | Vasculitis | 19.2 | 5.2 | 72.9% |
| 11 | Trochanter | Pressure sore | 23.5 | 5.7 | 75.8% |
| 12 | Sacrum | Pressure sore | 17.8 | 11.2 | 37.1% |
| 13 | Lower limb | Mixed | 16.5 | 0 | 100% |
| 14 | Lower limb | Vasculitis | 8.5 | 1.9 | 77.7% |
| 15 | Lower limb | Mixed | 21.6 | 4.4 | 79.7% |
| 16 | Sacrum | Pressure sore | 12.4 | 3.4 | 72.6% |
| 17 | Sacrum | Pressure sore | 11.3 | 3.1 | 72.6% |
| 18 | Lower limb | Mixed | 7.4 | 2.1 | 71.7% |
| 19 | Lower limb | Vasculitis | 6.7 | 2.0 | 70.2% |
| 20 | Lower limb | Limphatic | 6.9 | 0.7 | 89.9% |
| MEAN PERCENTUAL AREA REDUCTION | | | | | 75.8% |

CONCLUSIONS: overall the product confirmed the expectations of effectiveness, going beyond the level of "healing power", showing in fact a considerable acceleration of epithelialization time. It also showed appreciable ease of use and comfort; no patients have complained of pain to the application, so we can say that both effectiveness and comfort features represent a substantial added value in the clinical use of the product.

*Titanium Bioxide with Ionic Silver in covalent binding (TiAB) - NMTech



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