**Introduction**

Pressure sore, also known as decubitus ulcer, is a tissue damage that results in necrosis involving epidermis, dermis and hypoderma but that can interest, in the most difficult cases, muscles and bones. A decubitus ulcer is the direct consequence of an intense and prolonged pressure that leads to a mechanical stress on tissues and the constriction of blood vessels with the resulting tissue necrosis.

Pressure sores appear more frequently in old individuals with ambulatory disabilities, people affected by several pathologies, often malnourished and treated with different pharmacotherapies.

The incidence of the lesions is more or less around 1.5% of the population. Treatments imply high costs and long healing periods leading to unsatisfying results, most of all concerning patients’ quality of life. The current inclinations are the reduction of hospitalization and the research of efficient and easy-to-follow treatments that can be continued at home by patients.

In this regard, our work aim is verifying the effective usefulness of Rigenoma® Cream and Rigenoma® Spray, compounds for topical use based on Ozoile® (Topical Ozone stabilized in Oleic Acid with Vitamin E), in the treatment of dermal and hypodermal lesions, both acute and chronic from different etiologies, through the evaluation of wound healing after 60 days or until the discharge.

Ozoile® (Topical Ozone stabilized in Oleic Acid with Vitamin E Acetate) is the result of a process of gasification of Olive Oil (with a biological action incremented over 3% respect the other oils) using Ozone: Ozone links with the double bounds of Oleic Acid resulting in Stable Ozonides with Vitamin E. Ozonides act on the inflammatory status contrasting redness, itching, burnings, swelling. They inhibit the COX reducing the pro-inflammatory Prostaglandins level and activating enzymatic systems of Histamine and Serotonin degradation.
Once in contact with a Proton environment (chemical-physical characteristic of cells involved in degenerative processes and /or in conditions of hypoxia, ischaemia, inflammation, infection..) Ozonides evolve in Bio-Peroxides and Molecular Oxygen. Oxygen locally contrasts hypoxia facilitating the reinstatement of damaged function reactivating the slowed activity of mitochondria, even when cyclo- lipoxygenase reduces the O² metabolic bioavailability. Bio-peroxides contrast degenerative processes and damages caused by radiations through a free radical scavenger mechanism of action and, most of all, they have a bio-oxidant action on bacteria, fungi, mycete and viruses. Clinical studies, regarding healing process in wounds treated with topical application of ozonized olive oil, demonstrate that Ozonides and their derivatives are able to stimulate, either on dermal and epidermal level, growth factors like PDGF, TGF-β, VGF, FGFlinked to the proliferation of fibroblasts, to the synthesis of new fibers of collagen, to the angiogenesis. Topical applications of Ozoile® facilitate the formation of granular tissue during the process of wound healing. Vitamine E Acetate contrasts the lipid peroxidation of membrane, it stops free radicals and it has a soothing effect.

**Materials and methods**

During the 16th of April– 12th of December period, for clinical evaluations have been taken into consideration all the patients of Ascoli Piceno’s “Casa di Cura Villa San Giuseppe” that at the moment of recovery presented skin decubitus ulcers. In the LPA ward there are patients coming from different hospitals because they need an additional period of physical rehabilitation or longer convalescences. Aim of the observational study is to verify the effectiveness of Rigenoma® Spray and Cream, Ozoile® based, in the treatment of skin lesions characterized by multiple etiopatologies to evaluate the improvement of skin lesions during the recovery period (max 60 days).

Particularly we want to verify:

- The action on the inflammatory status and the reduction of skin redness and local edema
- The total percentage of complete wound healings
- The percentage of improvement of the wound

All is documented through photographs and measurement of lesions to verify their reduction in size or their complete healing.
In the study have been included patients (with):

- Chronic and severe lesions
- Wounds characterized by different sizes
- Wounds at different phases (I-IV) according to the classification N.P.U.A.P, also when there is necrotic tissue
- Cardiovascular insufficiency
- Serious hepatopathies of different nature
- Chronic kidney disease
- BPCO in corticoid and/or bronchodilator therapy
- Severe or terminal neoplastic pathologies
- Feeding tube or parentelar nutrition
- Affected by Ischemic or Haemorrhagic Cerebral stroke
- Dementia with character defects
- Fecal and urinary incontinence

In the group there are:

- 12 patients (7 men and 5 women)
- Average age 78.5 (range 61-90)
- Average diameter of the lesion 38.44 cm² (range 1-500 cm²)
- 17 treated lesions
- 2 deceased patients during the hospitalization period
- Comorbidity: insulin-dependent diabetes, hypertension, ischemic cardiopathy, chronic kidney disease, BPCO, chronic and severe vascular encephalopathy, brain neoplasm, mammary neoplasia with pulmonary and cerebral metastasis, antibiotic therapy to cure UTI (Urinary Tract Infections) and sepsis.

Each patient has undergone to:

- Anamnesis
- Medical examination
- Photograph of the wound
- Classification of the lesion phase according to N.P.U.A.P
- Medications twice a day (in the morning and in the evening): washing using saline, application of Rigenoma® Spray on the lesion, application of Rigenoma® Cream on the perilesional skin, coverage with gauze.

During the study period each patient has been reassessed at least three times or until the complete healing through photographs of the wound, measurement of the area and evaluation of the phase.

**RESULTS**

The evaluation of treated cases shows the following results:

- Evident macroscopic improvements of the wounds: reduction either on the inflammation and on wound diameter in all the patients.
- Complete healing of 10 lesions, equal to 58.8%
- Evident improvement of 7 lesions, equal to 42.2%
- Absence of infection onset on the treated lesions
- Induction of autolytic debridement

**SUMMATION**

From the evaluation of results we can conclude that the use of Rigenoma® Spray and Cream, Ozoile®-based, induces the following effects:

- Reduction of inflammation signs
- Reduction in healing time
- Improvement in all the lesions
- Reduction in healthcare costs thanks to the lower need of medical staff and treatments
- Improvement in patients’ compliance thanks to the short time needed for the medication
- Staff’s satisfaction thanks to short time required to reach some results
CONCLUSIONS

The use of Rigenoma® Cream and Spray demonstrates its efficacy in healing skin wounds from different etiologies, even in patients with chronic pathologies leading to a size reduction in all the treated lesions.

Study is going on in the ward continuing to recruit all the patients with skin lesions admitted to the hospital.
S. E. woman, born on 4/05/26 – Lesion of sacrum.
Hospitalization from 26/05/16 to 01/07/16.
Department: Internal Medicine
Reason of hospitalization: staphylococcal sepsis

Comorbid entities: Degenerative cardiopathy, arterial hypertension, senile involution, diverticulosis of the colon.
Reason of long-term acute hospitalization: syndrome caused by prolonged bedding and management of decubitus ulcers.
Photo on 26/05/15 – First evaluation.
Stage IV, central necrosis area with underminings + signs of inflammation of the surrounding skin
Photo on 8/06/15.
Stage IV, marked edges, necrotic tissue has been removed using autolytic debridement, reduction in the inflammation of the surrounding skin, presence of granular tissue at the bottom.
Photo on 30/06/15 – before she moved to the RSA
Stage II/III – Cleaned lesion, not infected anymore, in active healing (Granular tissue)
D. E. man, born on 12/04/35 – Lesion at malleolus
Hospitalization from 12/06/2015 to 11/08/2015.
Department: Neurology.
Reason for hospitalization: post stroke with left hemiplegia and aphasia

Comorbid pathologies: COPD, hypertension, Chronic vascular encephalopathy with dementia.
Reason for long-term acute hospitalization: stroke after-effects and management of pressure sores
Patient affected by dysphagia – at the beginning only 1.600 Kcal die, gradually weaned.

Photo on 12/06/15 – First evaluation.
Stage IV, wound edges with maceration signs and a fragment of necrotic tissue
Photo on 30/06/15.
Stage III - bottom with granular tissue, wound edges apparently obstructed and insufficiently wet, intact surrounding skin.
Photo on 21/07/15.
Stage III, additional reduction in wound thank to tissue regeneration at the bottom, lesion healing.
Photo on 31/07/15 - Last evaluation before the discharge.
Stage II, wound almost healing (the patient will continue to medicate the wound with Rigenoma® at home)
F. G. man, 62 years old. Sacral pressure.
Hospitalization from 13/11/2015 to 11/01/2016.
Comorbid pathologies: prolonged bedding conditions, pneumonia, residual psychosis, hypertension.

Photo on 16/11/15 – First evaluation after surgical debridement.
Ample sacral lesion at the stage III/IV and areas with necrosis, fibrin and granular tissue.
Photo on 27/11/15
Necrotic tissue approximately disappeared, bottom of the lesion in regeneration, Intact surrounding skin.
Photo on 16/12/15 – Last evaluation before he moves to SNF. 
Stage III – healing bottom of the wound, absence of secretions, intact surrounding skin
A. E. – Lesion on Right Leg Internal Surface Lesione (over the malleolus region)
24/07/15
A. T. – Sacral sore

11/11/15
C.D. – Sacral Sore

12/11/15
C. R. – Gluteus Lesion
F. L.  Tight lesion

15/07/15
I. G. Sacral sore

13/08/15
I. G. Back lesion

13/08/15
T. D. Right leg lesion

02/12/15 internal
T. D- Left leg lesion

02/12/15
V. P. Shoulder lesion

10/08/15
Z. E. Right leg lesion

13/05/2015