

CLINICAL STUDY

UPDATED ON 01/03/2017



METHOD

- An observational, longitudinal, prospective, single-centre study with descriptive analysis: clinical follow-up after marketing conducted in **2016**
- **19 patients** included in an intensive care unit in Belgium: average age 70.4 years; F/M sex ratio 1.4; initial average BMI 28.5
- Bedridden patients > 15 hours (100%) and up to 24/24 hours (**89% not raised**), with mostly > 3 daily turn-overs (79%) and low use of positioning technical aid devices (11%)
- Patients **at the time of enrolment without pressure sores** and at high risk of pressure sores according to an average Norton score of 8
- 2 follow-ups conducted on DO and DEND with an average follow-up period of **9.61 days**

Patients' characteristics at the time of enrolment

- General condition: 47% Good to Average, **53% Poor**
- Peripheral arterial occlusive disease (PAD): 63% Nil, **37% Mild to Severe**
- Neurological disorder: 53% Nil to Mild, **47% Moderate to Severe**
- Skin massages/day: **68% < 3** and 32% > 3

- Physical condition: **89%** Very poor to Poor
- Mental condition: **89.5%** Stupor or Confusion
- Activity: **100%** Bedridden
- Mobility: **79%** Immobile to Very limited
- Incontinence: **89.5%** Bladder and/or bowel

RESULTS

■ PRIMARY ENDPOINT: onset of stage 1 to 4 pressure sores

- ✓ 4 onsets of stage 1 pressure sores
- ✓ 3 patients concerned
- ✓ 1 sacral pressure sore, 3 heel pressure sores

→ **84% preventive efficacy: 16/19 patients without onset of pressure sores**

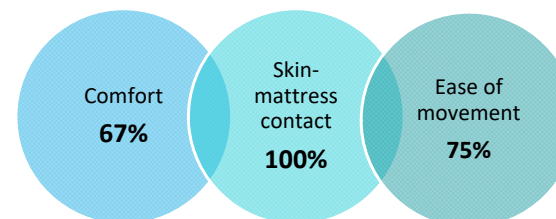
■ COMMENTS:

7 deaths recorded during the study, of which one patient with pressure sores

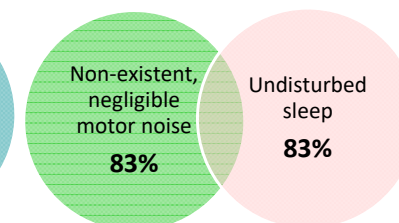
■ SECONDARY ENDPOINTS

Results considering the 12 patients able to respond

Satisfaction related to comfort



Absence of discomfort



Pachioli M., Delpire M. Intensive Care Unit, Marie Curie Hospital, University Hospital Centre of Charleroi, Belgium, 2016.