CLINICAL STUDY

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 D0 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

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

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