

CLINICAL TRIAL

ALOVA MEMORY FOAM MATTRESS **ALOVA**[®]

METHOD

- An observational, longitudinal, prospective, multicentre study with descriptive analysis performed in **1998** in a healthcare centre; two follow-ups on D0 and D15
- **61 patients** included: average age 60 years old; F/M sex ratio 0.64; initial average BMI 23.11; 26 patients with pain
- 23 different pathologies, such as neurology, orthopaedics, rheumatology, heart disease, PAD; 57.4% of the population have spinal cord injuries
- Bed-confined patients on average 15 hours/day; 18 are repositioned on average 6 times/day; 55 undergo physiotherapy; 21 have 1 special diet
- Initial average Waterlow score: 18.3
- Risk level of the entire population: 15 patients at risk, 24 at high risk, 22 at very high risk
- 43 patients with no pressure sores, 18 with pressure sores
- **18 pressure sores**: 12 of stage 1-2, and 6 of stage 3-4; 9 of the sacrum and 4 of the heel
- Local treatment of the pressure sores: hydrocolloid (8), Sofra-Tulle (3), iodoform gauze (1), enzymatic debridement (3)
- Carer time in prevention and/or treatment: 31 patients ≤ 1 hour, 15 patients between 1 and 2 hours, 9 patients > 2 hours

PAD : Peripheral Arterial Disease

RESULTS

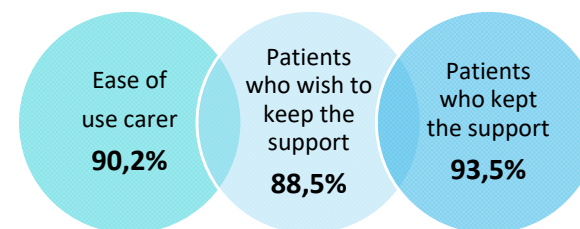
■ PRIMARY ENDPOINT: Preservation or improvement of the skin condition

1 favourable progress, 2 onsets of pressure sores, 1 study withdrawal

Efficacy % (favourable progress, stabilised lesions/population considered)

- Total population: **93%** (57/61)
- Population at risk and without pressure sores: **98%** (42/43)
- Population with pressure sores: **83%** (15/18)

■ SECONDARY ENDPOINTS: Opinions of carers and patients



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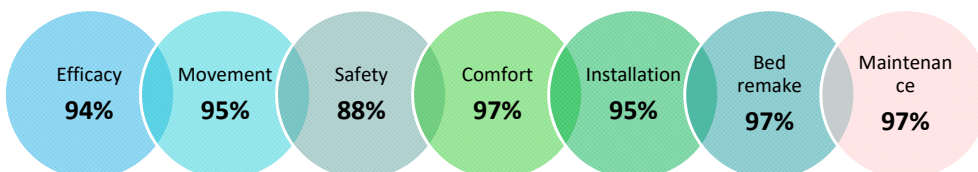
- An observational, longitudinal, prospective, multicentre study with descriptive analysis: clinical follow-up after marketing
 - Study conducted in **2004** in a healthcare centre: 30% Medicine, 33% Spec. medicine, 20% Long-term stay, 12% Surgery, 5% ICU
 - **40 patients** included: average age 71.38 years old; M/F sex ratio 0.86; initial average BMI 16.25
 - Bed-confined patients on average 18 hours per day with 3 daily turn-overs, raised at least once a day
 - Two follow-ups conducted on D0 and DEND, average follow-up period of 25.27 days
 - 20 patients with pressure sores (50%), **24 established pressure sores**, of which 76% of stage 1-2 and 24% of stage 3-4
- Mobility: 45% good to average, 50% no
 - Conscience: 87.50% good to average, 10% poor
 - Continenace: 35.50% yes, 57.50% no
 - Nutrition: 20% good, 52.50% average, 25% poor
 - Pain: 37.50% yes, 50% no

RESULTS

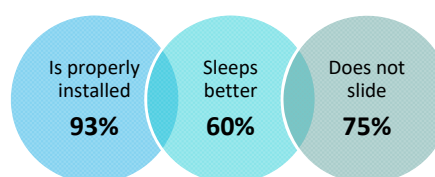
■ **PRIMARY ENDPOINT:** Onset of pressure sores of stage 1 to 4 ✓ **No onset of pressure sores**

■ **SECONDARY ENDPOINTS:** Tolerance, results based on the actual responses (particularly the patients able to answer)

Level of satisfaction of the carers: 95%



Level of satisfaction of the patients: 76%



Level of tolerance of the patient: 87%

