CLINICAL TRIAL

METHOD

- Prospective, non-interventional, observational, and controlled Clinical Study. Descriptive analysis
- Date of study: **2005 to 2006**. 80% Home care, 20% Local authorities. Sample size: **38 patients**
- Average age 80 years; sex-ratio W/M 2.7; Initial average BMI 20.8 (11.7 ; 30.8); Average initial Norton score: 8.19 (5 ; 12)
- Average period spent bed-ridden: 20 ± 3.9 hours (10 ; 24); Average daily number of times turned over: 4; persons raised at least once per day
- **74 pressure ulcers**: 40% sacrum, 27% heels; 23% stage 1-2, 67% stage 3-4
- Main pathologies identified: pathology of aging, dermatology, neurology, cancerology, ortho-traumatology
- Assessment at D0, D1, D3, D10, D20, D31

RESULTS

**MAIN JUDGEMENT CRITERIA**: Tolerance and Quality of Life

- Compatible with the service expected of the home-care facility
- Effectiveness 94%
- Compatibility with care actions 90%
- Safety 88%
- User interface 85%
- How easy the product is to install 84%
- Ergonomics 84%

- Quality of life for the most of the patients was improved
  - Comfort: **8.6/10**; Wellbeing: **8.1/10**

**SECONDARY JUDGEMENT CRITERIA**: Maintaining and / or improving skin condition

- Aid for the prevention and healing of stage 1 to 4 pressure ulcers

Graph: Pressure ulcers progression and types

- Levels of satisfaction

<table>
<thead>
<tr>
<th>Stage</th>
<th>Number</th>
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</thead>
<tbody>
<tr>
<td>Stage 1</td>
<td>74</td>
</tr>
<tr>
<td>Stage 2</td>
<td>70</td>
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<tr>
<td>Stage 3</td>
<td>64</td>
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<tr>
<td>Stage 4</td>
<td>51</td>
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<tr>
<td>Total</td>
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