### CLINICAL STUDY, AXTAIR AUTOMORPHO MOTORISED AIR SUPPORT (2007-2008) – TABULATED SUMMARY
01/03/2017

<table>
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<th>DESCRIPTION</th>
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<tr>
<td><strong>Title of the study</strong></td>
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<th>RESULTS</th>
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<td><strong>Number of subjects analysed</strong></td>
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<td><strong>Duration of monitoring</strong></td>
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<th>Patient characteristics</th>
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<tr>
<td><strong>Sex ratio W/M:</strong> 2.33</td>
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<td><strong>Average age:</strong> 78 years (52 ; 98), median: 80</td>
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<td><strong>Initial average BMI:</strong> 22.5 (13.8 ; 42.2), median: 21.4</td>
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<td><strong>BMI &lt; 18:</strong> 7 patients</td>
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<td><strong>Average Karnofsky score:</strong> 36% (10% ; 60%)</td>
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<td><strong>Average Norton score:</strong> 8.47 ± 2.53 (5 ; 15), median: 8.50</td>
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<td><strong>Physical condition:</strong> 23% poor (7), 67% passable (20), 10% good (3), 0% excellent</td>
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<td><strong>Mental condition:</strong> 23% stupor (7), 33% confusion (10), 43% apathy (13), 0% alert</td>
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<td><strong>Activity:</strong> 57% bed-ridden (17), 33% confined to a seat (10), 7% help with walking (2), 3% walking (1)</td>
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<td><strong>Mobility:</strong> 50% immobile (18), 27% very limited (4), 13% slightly limited (4), 0% full</td>
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<td><strong>Incontinence:</strong> 80% doubly incontinent (24), 7% urinary or faecal incontinence (2), 7% occasional incontinence (2), 3% continent (1), 3% NR (1)</td>
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<td><strong>Main pathologies identified:</strong> cancerology (8), diseases of aging (6), orthopaedic states (5), neurology (4), pulmonary diseases (2), Clinical state: 70% deterioration (21), 10% improvement (3), 20% stationary (6) State of nourishment: 7% poor (2), 50% insufficient (15), 3% improvement (1), 40% satisfactory (12) State of hydration: 40% insufficient (12), 7% improvement (2), 53% satisfactory (16) Combined state [nutrition / hydration]: 40% satisfactory /satisfactory (12), 37% insufficient / insufficient (11)</td>
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<td><strong>Total number of bedsores:</strong> 48</td>
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<td><strong>Average rate of bedsores per person:</strong> 1.6 (1 ; 3)</td>
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<td><strong>Location:</strong> 48% sacrum (23), 38% heels (18), 14% others (7)</td>
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<td><strong>Seriousness:</strong> 8% stage 1 (4), 31% stage 2 (15), 17% stage 3 (8), 44% stage 4 (21)</td>
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<td><strong>Heel wounds:</strong> 0% epidermisation, 43% granulation, 8.5% fibrinous, 48.5% ulcero-necrotic</td>
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The benefit of the AXTAIR AUTOMORPHO motorised air heels was stable or improved by the tenth day. At the end of the study, no new bedsore was reported.

Characteristics relating to professional practices

Local and general care carried out in line with current Best Practice recommendations.

CONCLUSION

At the end of an observational, prospective, multicentre clinical study carried out in 2007 – 2008, the benefit of the AXTAIR AUTOMORPHO motorised air support was confirmed in providing therapeutic care and / or preventing bedsores in support areas, regardless of the level of seriousness and within defined indications. All pre-existing lesions were developing unfavourably in a manner concomitant with clinical state [deterioration 70%, stabilisation 20%, on Day 0].

A significant improvement was noted in the healing state of bedsores in pelvic, sacro-coccygeal and ischia areas [p < 0.05] Bedsores were measured every 10 days from Day 0 to Day 30. The analysis of daily healing gains, based on wound surface area and / or volume, shows an average gain of 0.44 cm² / day and / or 0.86 cm³ / day, respectively, for deep wounds. Furthermore, a significant difference is noted in the help with treating bedsores of stages 1 to 4 in the sacro-coccygeal and ischiatric areas, comparing a care strategy that includes use of the AXTAIR AUTOMORPHO motorised air support with care strategies that include egg-box mattresses for helping in preventing bedsores, or certain other motorised air supports. Healing gains on heels are less significant in terms of area measured, but a development is noted in respect of healing initiation for 16 lesions out of the 18 listed. The motorised air support made a favourable contribution to treating bedsores. Two stage 1 bedsores were reported during the study, and deteriorated rapidly.

The AXTAIR AUTOMORPHO motorised air support contributed to the notable improvement in the healing process of sacro-coccygeal and ischiatric lesions. [That process was measured by daily gain in surface area and / or volume (0.44 cm² / day and / or 0.86 cm³ / day)]. It followed on from the care provided to bed-ridden persons who present a deterioration of pre-existing lesions associated with a deteriorated or stationary clinical state. The lesion process for heels was stable or improved by the tenth day. At the end of the study, no new bedsore was reported.