CLINICAL STUDY, AXTAIR AUTOMORPHO MOTORISED AIR SUPPORT (2) – TABULATED SUMMARY

ITEM	DESCRIPTION
Product studied	AXTAIR AUTOMORPHO motorised air support
Type of study	Observational, non-interventional, multicentre Clinical Study
Date of study	August 2007 to July 2008
Objective of the study	Main objective Confirm the benefit of using the AXTAIR AUTOMORPHO motorised air support in promoting the healing of bedsores in support areas and developing unfavourably, in persons whose general clinical state is improving, deteriorating, or stationary. Secondary objective Assess tolerance of the product based on the following criteria: ergonomics, perceived effectiveness, safety, comfort, and wellbeing.
METHOD	
Criteria for inclusion	Criteria for inclusion Persons aged over 18 and presenting one or more stages 1 to 4 bedsores in the support area, with unfavourable development or stationary or presenting a deterioration of the healing or clinical state. Norton score < 15. Persons whose care is monitored by medical and paramedical teams. Criteria for exclusion Persons presenting a heel bedsore associated with severe arteriopathy of the lower limbs [systolic pressure index < 0.6], severe cardio-vascular disease, BMI less than 12, nutritional state score less than 14 by *Mini Nutritional Assessment*, or uncompensated nutritional insufficiency. Monitoring of less than 20 days.
Context and place of study	Places of study Réseau Ville Hôpital Plaies et Cicatrisations du Languedoc Roussillon (Hérault département) Europe Hospitals - Brussels (Belgium) Saint Louis EHPAD Residence (Vaucluse département) La Buissonnière EHPAD (Loire département) Distribution Home care N = 12 / Local authorities N = 18 (EHPAD N = 9, Clinic N = 6, Hospital N = 2, Follow-up care N = 1)
Main judgement criterion	Effectiveness variables State of the wound, measuring the area (cm2) by Kundin's formulæ [L x l x 0.75], viable tissue (granulation), non-viable tissue (necrotic, fibrin), amount of exudate expressed as a %, clinical state (Norton scale, Karnofsky score). Calculating the daily healing of the wound: [(area of the wound on Day 30 – area of the wound on Day 0) / number of days between Day 0 and Day 30]. Averages Photos of bedsore wounds, centimetric measurement *area and depth) in addition to clinical data and assessment criteria.
Secondary judgement criteria	Ergonomics, perceived effectiveness, safety, comfort, and wellbeing.
Sample size	N = 30
Randomisation method	Not applicable
Method of analysing the results	Descriptive analysis
RESULTS	
Number of subjects analysed	N = 30; 5 exits from the study before the end of the 30-day period
Duration of monitoring	30 days (Day 0 to Day 30)
Patient characteristics (without group comparability)	- Sex ratio W / M: 2.33 - Average age: 78 years [52 < 98; median: 80] - Initial average BMI: 22.5 [13.8 < 42.2; median: 21.4] - BMI < 18 N = 7 patients - Average Karnofsky score: 36% [10% < 60%; SD: 0.11] - Average Norton score: 8.47 [5 < 15; median: 8.50; SD: 2.53] - Physical condition: poor N = 7 (23%), passable N = 20 (67%), good N = 3 (10%), excellent N = 0

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	- Mental condition: Stupor N = 7 (23%), confusion N = 10 (33%), apathy N = 13 (43%), alert N = 0 - Activity: bed-ridden N = 17 (57%), confined to a seat N = 10 (33%), help with walking N = 2 (7%), walking N = 1 (3%) - Mobility: immobile N = 18 (50%), very limited N = 8 (27%), slightly limited N = 4 (13%), full N = 0 - Incontinence: doubly incontinent N = 24 (80%), urinary or fæcal incontinence N = 2 (7%), occasional incontinence N = 2 (7%), continent N = 1 (3%), not recorded N = 1 (3%) <u>Main pathologies identified</u> Cancerology N = 8 (32%), diseases of aging N = 6 (24%), neurology (paraplegia, tetraplegia, hemiplegia) N = 4 (16%), pulmonary diseases N = 2 (8%), orthopædic states (fracture of the neck of the femur, pelvic trauma, etc.) N = 5 (20%) <u>Subjective assessments</u> - Clinical state: deterioration N = 21 (70%), improvement N = 3 (10%), stationary N = 6 (20%) - State of nourishment: poor N = 2 (7%), insufficient N = 15 (50%), improvement N = 1 (3%), satisfactory N = 12 (40%) - State of hydration: insufficient N = 12 (40%), improvement N = 2 (7%), satisfactory N = 16 (53%) - Combined state [nutrition / hydration] satisfactory / satisfactory N = 12 (40%), insufficient / insufficient N = 11 (37%) <u>Bedsores</u> - Total number of bedsores: 48 - Average rate of bedsores per person 1.6 [1 < 3] - Location: sacrum N = 23 (48%), heels N = 18 (38%), ischia N = 4 (8%), back N = 3 (6%) - Seriousness: Stage 1 N = 4 (8%), Stage 2 N = 15 (31%), stage 3 N = 8 (17%), stage 4 N = 21 (44%) - Heel wounds: epidermisation 9%, granulation 43%, fibrinous 8.5%, ulcero-necrotic 48.5% - Sacro-coccygeal and ischiatic wounds: epidermisation 24.4%., granulation 14.7%, fibrinous 29%, ulcero-necrotic 31.9% <u>Average wound area and volume by previous type of support (Day 0)</u> - Egg-box mattress: average area = 32.1 cm2, volume = 25.82 cm^3 - Simple mattress: average area = 34.33 cm2, volume = 21.98 cm^3 - Motorised air support: average area = 26.21 cm^2, volume = 51.32 cm^3
Characteristics relating to professional practices	Local and general care carried out in line with current Best Practice recommendations.
Results inherent in the main judgement criterion	- Average Karnofsky score: 31% [0% < 60%; SD: 0.15] - Average Norton score: 8.28 [5 < 15; median: 8.00; SD: 2.84] - Physical condition: poor N = 7 (28%), passable N = 15 (60%), good N = 3 (12%), excellent N = 0 - Mental condition: Stupor N = 5 (20%), confusion N = 10 (40%), apathy N = 10 (40%), alert N = 0 - Activity: bed-ridden N = 14 (56%), confined to a seat N = 9 (36%), help with walking N = 1 (4%), walking N = 1 (4%) - Mobility: immobile N = 16 (64%), very limited N = 5 (20%), slightly limited N = 4 (16%), full N = 0 - Incontinence: doubly incontinent N = 21 (84%), urinary or fæcal incontinence N = 2 (8%), occasional incontinence N = 1 (4%), continent N = 0, not recorded N = 1 (4%) <u>Subjective assessments</u> - Clinical state: deterioration N = 3 (12%), improvement N = 16 (64%), stationary N = 5 (20%), not recorded N = 1 (4%) - State of nourishment: poor N = 1 (4%), insufficient N = 4 (16%), improvement N = 1 (4%), satisfactory N = 19 (76%) - State of hydration: insufficient N = 1 (4%), improvement N = 1 (4%), satisfactory N = 23 (92%) - Combined state [nutrition / hydration] satisfactory / satisfactory N = 20 (67%), insufficient / insufficient N = 2 (7%) <u>Bedsores</u> - Total number of bedsores: 38 - Location: sacrum N = 19 (50%), heels N = 14 (37%), Ischia N = 4 (11%), back N = 1 (3%) - Seriousness: Stage 1 N = 12 (32%), Stage 2 N = 5 (13%), stage 3 N = 11 (29%), stage 4 N = 10 (26%) - Heel wounds: epidermisation 14.3%, granulation 34.3%, fibrinous 50%, ulcero-necrotic 12.4% - Sacro-coccygeal and ischiatic wounds: epidermisation 26.1%, granulation 44.3%, fibrinous 23.9%, ulcero-necrotic 5.7% <u>Development of healing state</u> - Healing gain N = 35 (73%), lesion stabilisation N = 7 (15%), aggravation N = 5 (10%), poorly recorded N = 1 (2%)

	Development of healing state by state of nourishment and of hydration - Number of bedsores on Day 30 in patient with satisfactory / satisfactory combined state [nutrition / hydration]: N = 33 - Healing development of the 33 bedsores mentioned above: healing gain N = 27, lesion stabilisation N = 4, aggravation N = 1, poorly recorded N = 1 Average area and volume of wounds by type of previous support (Day 20) - Egg-box mattress: average area = 32.66 cm2, volume = 22.08 cm^3 - Simple mattress: average area = 19.45 cm^2, volume = 9.52 cm^3 - Motorised air support: average area = 25.37 cm^2, volume = 39.24 cm^3
Results inherent in the secondary judgement criteria	Development of average tolerance of the device - Ergonomics 5.5/6 (SD 0.9); Effectiveness 5.5/6 (SD 0.9); Interface 5.5/6 (SD 0.9); Safety 5.5/6 (SD 0.9) Assessment of comfort and wellbeing - N = 8 rate comfort at between 6 and 9 and wellbeing at between 7 and 9, on a scale out of 10, N = 21 patients unable to communicate their impressions, N = 1 not recorded.
Secondary effects	None Bedsore-prevention care was carried out at the same time as a validated medical protocol.

SUMMARY

Results by seriousness of bedsores

	Initial assessment	Final assessment	Increase
Stage 1 / 2 bedsores	19	17	10.5%
Stage 3 / 4 bedsores	29	21	27.6%
Total number of bedsores	**48**	**38**	**21%**

Results by location of bedsores

	Initial assessment	Final assessment	Increase
Bedsores – sacrum	23	19	17.4%
Bedsores – heels	18	14	22.2%
Bedsores – ischia	4	4	-
Bedsores – back	3	1	66.6%
Total number of bedsores	**48**	**38**	**21%**

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 cm^3 /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 ischiatic 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 surface 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 makes a definite therapeutic contribution when set against the egg-box type of support, in providing therapeutic care to Persons Suffering from Bedsores who are at high risk.

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CONCLUSION

The AXTAIR AUTOMORPHO motorised air support contributed to the notable improvement in the healing process of sacro-coccygeal and ischiatic lesions. [That process was measured by daily gain in surface area and / or volume (0.44 cm^2 / day and / or 0.86 cm^3/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.

Abbreviations

EHPAD: *Établissement Hébergeant des Personnes Âgées Dépendantes* (Accommodation Establishment for Dependant Elderly People)
W / M: Women / Men (Sex ration)
BMI: Body-Mass Index
SD: Standard Deviation
Day 0: 1st day of the study, equating to inclusion of the patient in the study – Day 20: 20th day of the study – Day 30: 30th and last day of the study

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