

CLINICAL STUDY E²CTA TABULATED SUMMARY (2013) 01/03/2017

DESCRIPTION	
Title of the study	E ² CTA : Evaluation of the Clinical Efficacy of Axtair Axensor Technology
Type of study	Prospective, observational, non-interventional, multicentre Clinical Study.
Date of study	2013 (9 months)
Context and place of study	Health and medico-social establishments on French territory, and Home Care.
Products studied	AXTAIR AUTOMORPHO motorised air support incorporating axensor technology
METHOD	
Criteria for inclusion	Persons receiving care who are aged over 17, presenting a risk of occurrence of bedsores or suffering from one or more bedsores of stages 1 to 4 on the EPUAP scale. (<i>European Pressure Ulcer Advisory Panel</i>)
Main judgement criterion	Onset or non-onset of pressure sore(s).
Secondary judgement criteria	Improvement of the skin condition of the person Ergonomics, MMI, safety, comfort – according to caregivers and care recipients.
Sample size	30
Randomisation method	Not applicable.
Method of analysing the results	Descriptive analysis. The descriptions are made by means of averages, min and max values for the quantitative variables and by numbers and percentages for the qualitative variables.
Abbreviations	MMI: Man-Machine Interface. NR : Not Recorded. NA: Not applicable. W: Woman. M: Man.
RESULTS	
Number of subjects analysed	30
Duration of monitoring	Average: 23 days ± 21.77 (6 ; 106) ; median: 16
Patient characteristics	Sex ratio: W/M : 2,3 Average age: 81.1 ± 15.12 ans (18 ; 96); median: 84 Average weight: 64.3 ± 20.4 kg (35 ; 117); median: 61 Average height: 1,62 ± 0.09 m (1,5 ; 1,9); median: 1,6 Average BMI: 25 ± 6.78 (15 ; 40); median: 23,44 Average Norton: 9 ± 1.43 (6 ; 12); median: 8 Average time spend bed-ridden: 20 ± 3.01 h (12 ; 24); median: 20 16 poly pathological patients (53.3%) Pathology types: neurology (24), cardio-vascular (11), pneumology (7), orthopaedics (8), endocrinology (6), cancerology (3), rheumatology (1) 8 patients at Risk of Bedsores, 22 Patients Suffering from Bedsores Total number of bedsores: 35 Initial level of change in general health: Deteriorated (15); Stationary (13), Improved (2) Location of bedsores: Sacrum (17), Heel(s) (14), Others (4) Seriousness of bedsores: 49% Stage 1 (17), 31% Stage 2 (11), 9% Stage 3 (3), 11% Stage 4 (4)
Characteristics relating to professional practices	Types of previous supports: simple mattress (5), egg-box (5), visco-elastic (7), motorised air (13) Number of changes in position (unit per day): average 3.87 ± 3.22 (0 ; 12); median: 4.5 Number of times raised (unit per day): average : 1.33 ± 1.24 (0 ; 6) ; median: 1 Length of time raised (hours): average 3.73 ± 2.84 hours (0 ; 12); median: 4
Results inherent in the main judgement criterion	Number of occurrences of bedsores during the study: 0 Healing development of bedsores: Favourable (24), stationary (1) Improvement in general health upon exit: Deteriorated (5 included 2 death), Stationary (12), Improved (12), NR (1)
Results inherent in the secondary judgement criteria	Ergonomics: 39% very satisfied, 32% satisfied, 0% little satisfied, 0% unsatisfied, 29% NR How easy the product is to install: very satisfied (10), satisfied (12), NR (8) How easy the product is to use: very satisfied (16), satisfied (6), NR (8) How easy the product is to remove: very satisfied (9), satisfied (11), NR (10) MMI: 18% very satisfied, 38% satisfied, 1% little satisfied, 0% unsatisfied, 43% NR Implicit selection of modes: very satisfied (6), satisfied (13), NR (11) Meaning of alarms: very satisfied (5), satisfied (10), little satisfied (1), NR (14) Alarm coding : very satisfied (5), satisfied (11), NR (14) Safety: 31% very satisfied, 29% satisfied, 1% little satisfied, 0% unsatisfied, 39% NR Mattress Features: very satisfied (7), satisfied (9), NR (14) Automatic inflation pressure adjustment (Axensor): very satisfied (16), satisfied (3), little satisfied (1), NR (10) Product disinfection maintenance: very satisfied (5), satisfied (14), NR (11) Comfort: 30% very satisfied, 31% satisfied, 4% little satisfied, 1% unsatisfied, 33% NR Comfort and well-being: very satisfied (9), satisfied (9), little satisfied (1), NR (11)

	Noise perceived: very satisfied (11), satisfied (7), little satisfied (3), unsatisfied (1), NR (8) Wheelchair-bed transfer: very satisfied (7), satisfied (12), NR (11) Overall Satisfaction of Comfort by Patient: very satisfied (6), satisfied (6), unsatisfied (1), NR (17)
Secondary effects	None. Bedsore prevention care was given at the same time.
CONCLUSION	
<p>Axtair Automorpho motorised air support, equipped with AXENSOR AT12 technology, shows in this non-comparative study, a strong interest in the management strategy of risk patients (average Norton score of 9) and of patients with pressure sores of stage 1 to 4 with multiple pathologies, in community and in home care. The quality of scientific data is of intermediate level 1 or of level 2 in relation to the type of study and rigour of conduct. There is heterogeneity in the typology of patients' pathology but a coherence in the exposure to the risk factors of pressures sores. Under the study, there is no instance of onset of pressure sores and no unfavourable progress of the established pressure sores present at the time of enrolment. However, favourable progress was noted (69%) or the stabilisation of the patients' skin condition (31%) in correlation with the improvement (40%) or stabilisation (40%) of the overall clinical state of the patients at the time of their study withdrawal. The users and patients able to respond have validated the compatibility of the device with the care environment and the comfort of the people under care.</p> <p><u>Sources</u></p> <ol style="list-style-type: none"> 1. American Academy of Pediatrics. <i>Classifying recommendations for clinical practice guidelines</i>. <i>Pediatrics</i> 2004;114(3):874-7 2. Haute Autorité de Santé, <i>Niveau de preuve et gradation des recommandations de bonne pratique</i>, avril 2013 	