

APLOT MATTRESS CLINICAL STUDY (3) - TABULATED SUMMARY

ITEM	DESCRIPTION
Product studied	APLOT mattress
Type of study	Non-interventional prospective clinical study – observational type
Date of study	1994
Objective of the study	Assessing the performance of the APLOT mattress when caring for person at risk of bedsores (PRBs) or persons suffering from bedsores (PSBs)
METHOD	
Criteria for inclusion	Persons admitted to hospital and presenting a risk of bedsores, or suffering from a bed sore rated at stage 1 on the Waterlow Scale
Context and place of study	<p><u>Establishments</u></p> <ul style="list-style-type: none"> - Le Grau du Roi Functional Rehabilitation Centre (Gard), Functional Rehabilitation Department B head of the study: Dr. Romain (head of department) - Le Grau du Roi Medical Centre (Gard), Functional Rehabilitation Department A head of the study: Dr. Enjalbert - Auch Hospital (Gers département), Long-Stay Department head of the study: Ms. Dupuis (senior nurse) - Agen Hospital (Lot-et-Garonne département), Medium-Stay Department head of the study: Ms. Caillon (supervisor) - Les Charpennes Hospital, Villeurbanne (Rhône département), head of the study: Ms. Mercado (supervisor) - Senlis Hospital (Oise département), Orthopædic Surgery Department B head of the study: Ms. Parfait (senior nurse) - Paul Coste Floret Hospital, Lamalou les Bains (Hérault département), Jeanne d'Arc Department head of the study: Dr. B. Garlenq (head physician) - La Rochelle Hospital (Charente-Maritime département), Department of Medicine head of the study: Ms. J. Forest (head supervisor)
Main judgement criterion	Maintaining or improving the person's skin condition
Secondary judgement criteria	Healthcare staff to assess the effectiveness and ease of using the support Patient to assess the comfort provided by the support and the desire to keep it at the end of the study
Sample size	N = 64
Randomisation method	Not applicable
Method of analysing the results	Descriptive analysis
RESULTS	
Number of subjects analysed	N = 64
Duration of monitoring	15 days
Patient characteristics (without group comparability)	<p>W / M distribution: 2.33 Average age: 76 years Average weight: 59 kg Average height: 1.59 m 12 different pathologies, in particular neurological and traumatological <i>Fracture of the neck of the femur, change in general health with wasting syndrome, bed-ridden, cerebro-vascular accident, Alzheimer's disease, fracture and multiple trauma, cranial trauma, paraplegia, amputation, respiratory insufficiency, coma, senile dementia</i></p> <p>PRB: N = 47 (73%); PSB: N = 17 (27%) (stage 1: redness) PRB: 44% at risk, 32% at high risk, 25% at very high risk of bedsores Total number of bedsores: 17 Seriousness of bedsores: PSB stage 1 N = 17 (100%) PSB stage 1 - Redness: Pale 50%, Bright 33%, Very Bright: 17%</p>
Characteristics relating to professional practices	<p><u>carrying out massage</u></p> <ul style="list-style-type: none"> - PRB at risk: 57% - PRB at high risk: 75% - PRB at very high risk 100% - PSB stage 1: 100% <p><u>Frequency of massage</u></p> <ul style="list-style-type: none"> - PRB at risk: 2 / day 25%, 3 / day 75%, more than 3 / day 0%

	<ul style="list-style-type: none"> - PRB at high risk: 2 / day 25%, 3 / day 75%, more than 3 / day 0% - PRB at very high risk 2 / day 25%, 3 / day 50%, more than 3 / day 25% - PSB stage 1: data not reported <p><u>Turning over</u></p> <ul style="list-style-type: none"> - PRB at risk: 0% - PRB at high risk: 25% - PRB at very high risk 0% - PSB stage 1: depending on the state of redness (pale and bright: no, very bright: yes) <p><u>Frequency of turning over</u></p> <ul style="list-style-type: none"> - PRB at risk: not applicable - PRB at high risk: 2 / day 0%, 3 / day 100%, more than 3 / day 0% - PRB at very high risk not applicable - PSB stage 1: data not reported
Results inherent in the main judgement criterion	<p>Total number of bedsores: 17 Seriousness of bedsores: PSB stage 1 N = 17 (100%) PSB stage 1: redness Pale 80%, Bright 20%, Very Bright 0%</p> <p><u>Development of skin condition of PRBs:</u> No PRB developed bedsores between Day 0 and Day 15 PRB: 100% favourable development of the skin condition</p> <p><u>Development of skin condition of PSBs with stage 1:</u> Redness observed: Pale 80%, Bright 20%, Very Bright 0% PSB: 50% favourable development of skin condition, 50% no change in skin condition</p>
Results inherent in the secondary judgement criteria	<p><u>Assessment of the support by staff</u> Ease of use: yes 100%</p> <p>Assessment of results: Excellent 46%, Good 35%, Average 12%, Poor 7%</p> <p><u>Assessment of the support by patients</u> Comfort: Excellent 58%, Good 32%, Average 5%, Poor 5% The patient wishes to keep the mattress: yes 95%, No 5%</p>
Secondary effects	<p>None Bedsore prevention care was given at the same time.</p>

SUMMARY

Bedsores

	Initial assessment	Final assessment
Stage 1 bedsores	17	17
Pale redness	50%	80%
Bright redness	33%	20%
Very bright redness	17%	0%
Stage 2 / 3 bedsores	0	0
Total number of bedsores	17	17

Development

	Total population	PRB	PSB
Initial population	64	47 (73%)	17 (27%)
Final population	64	47 (73%)	17 (27%)
Initial bedsores	17	0	17
Final bedsores	17	0	17
Efficacy	100%	100%	100%
Healing	0%	0%	0%
Favourable development	75%	100%	50%
Stationary state (identity)	25%	0%	50%
Unfavourable development	0%	0%	0%

Conclusion

The APLOT mattress is effective in helping to preventing bedsores, since no patient defined as "at risk" according to the Waterlow scale developed bedsores on the support, and 100% of patients with redness on Day 0 showed either no change or reduction in redness on Day 15.

The mattress was judged easy to use by healthcare staff, also considering that results were good or excellent in 81% of cases.

The APLOT mattress's comfort was judged excellent or good in 90% of cases by patients, and 95% of patients who benefited from it wished to continue using it.

Abbreviations

PRB:	Person(s) at Risk of Bedsores
PSB:	Person(s) Suffering from Bedsores