APLOT MATTRESS CLINICAL STUDY (2) - 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 the appearance of bedsores or suffering from one or more bedsores rated from stages 1 to 4 on the Waterlow scale
Context and place of study	Establishments - Le Grau du Roi Functional Rehabilitation Centre (Gard département), 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), Long-Stay and Cardiology Department head of the study: Ms. Caillon (long-stay supervisor) and Ms. Laguarda (senior cardiology nurse) - Les Charpennes Hospital, Villeurbanne (Rhône département), head of the study: Ms. Mercado (supervisor) - La Charité Hospital, Saint Etienne (Loire département), Department R1 (Short Stay, Follow-Up Care, and Rehabilitation) head of the study: M.A. BONFILS (senior nurse) - 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) - Nîmes Hospital (Gard département), Serre Cavalier Department head of the study: Dr. Strubel (head physician)
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 = 63
Randomisation method	Not applicable
Method of analysing the results	Descriptive analysis
RESULTS	
Number of subjects analysed	N = 63
Duration of monitoring	15 days
Patient characteristics (without group comparability)	W / M distribution: 1.38 Average age: 69 years Average weight: 61 kg Average height: 1.63 m 29 different pathologies, in particular neurological and traumatological *Left hemiplegia, change in general health, terminal neoplastic disease, amputation of lower limb, hip prosthesis, fracture of the neck of the femur, amputation of left leg, occlusive neoplastic syndrome / bowel obstruction of tumoral origin, Senile dementia, coronary vascular disease, paraplegia, lumbar spine surgery, myopathy, tetraplegia, respiratory insufficiency, spinal-cord ischæmia, diabetes, cerebro-vascular accident, fracture of the left trochanter, multiple trauma, cranial trauma, coma, Alzheimer's disease, bed-ridden, fracture, list of falls, depressive syndrome, fracture of the right wrist, multiple fracture* PRB: N = 32 (51%); PSB: N = 31 (49%)

	PRB: risk N = 8 (25%), high risk N = 10 (31%), very high risk N = 14 (44%) Total number of bedsores: 31 Seriousness of bedsores: stage 0 (redness) N = 6 (19%), stage 1, 2, or 3 N = 25 (81%) PSB stage 0: Pale N = 4 (66.6%), Bright N = 1 (16.37%), Very Bright: N = 1 (16.7%) PSB stage 1, 2 or 3: stage 1 (> redness) N = 11 (44%), stage 2 N = 6 (24%), stage 3 N = 8 (32%)
Characteristics relating to professional practices	<u>carrying out massage</u> - PRB at risk: 57.1% - PRB at high risk: 77.8% - PRB at very high risk 90.9% - PSB stage 0: 100% - PSB stage 1, 2 or 3: 87.5% <u>Frequency of massage</u> - PRB at risk: 2 / day 25%, 3 / day 50%, more than 3 / day 25% - PRB at high risk: 2 / day 28.6%, 3 / day 71.4%, more than 3 / day 0% - PRB at very high risk 2 / day 10%, 3 / day 40%, more than 3 / day 50% - PSB stage 0: data not reported - PSB stage 1, 2 or 3: 2 / day 9.5%, 3 / day 28.6%, more than 3 / day 61.9% <u>Turning over</u> - PRB at risk: 33.3% - PRB at high risk: 25% - PRB at very high risk 60% - PSB stage 0: depending on the state of redness (pale and very bright: yes, bright: no) - PSB stage 1, 2 or 3: 78.3% <u>Frequency of turning over</u> - PRB at risk: 2 / day 0%, 3 / day 50%, more than 3 / day 50% - PRB at high risk: 2 / day 50%, 3 / day 50%, more than 3 / day 0% - PRB at very high risk 2 / day 33.3%, 3 / day 16.7%, more than 3 / day 50% - PSB stage 0: data not reported - PSB stage 1, 2 or 3: 2 / day 16.7%, 3 / day 27.8%, more than 3 / day 55.5%
Results inherent in the main judgement criterion	Total number of bedsores: 27 Seriousness of bedsores: stage 0 N = 4 (15%), stage 1, 2, or 3 N = 23 (85%) PSB stage 0: Pale N = 2 (50%), Bright N = 0, very bright N = 0, not recorded N = 2 (50%) <u>Development of skin condition of PRBs:</u> - No occurrence of bedsores between day 0 and day 15 - PRB at risk favourable development: 100% - PRB at high risk: favourable development 90%, unfavourable development 10% (no occurrence of bedsores) - PRB at very high risk favourable development 100% <u>Development of the skin condition of PSBs at stage 0:</u> - No unfavourable development - Healing (completeness disappearance of redness) N = 4 (66.7%) - Favourable development (reduction in redness) N = 2 (33.3%) - Redness observed: Pale N = 2 (100%) <u>Development of the skin condition of PSBs at stage 0, 1, 2, or 3</u> - No unfavourable development - Favourable development of stationary state: N = 25 (100%) - *Stage 2 bedsores: 50% reduction; stage 3 bedsores: 25% reduction* - Seriousness of bedsores: stage 0 (redness) N = 2 (85), stage 1 (> redness) N = 14 (56%), stage 2 N = 3 (12%), stage 3 N = 6 (24%)
Results inherent in the secondary judgement criteria	<u>Assessment of the support by staff</u> Ease of use: yes 100% Assessment of results: Excellent 52.5%, Good 39.4%, Average 6.5%, Poor 1.6% <u>Assessment of the support by patients</u> Comfort: Excellent 64%, Good 30%, Average 6%, Poor 0% The patient wishes to keep the mattress: yes 91.3%, No 8.7%

Secondary effects	None
	Bedsore prevention care was given at the same time.

SUMMARY

Bedsores

	Initial assessment	Final assessment	Increase
Stage 0 Bedsore Group (redness)	**6**	**4**	**2**
Pale redness	4	2	2
Bright redness	1	0	1
Very bright redness	1	0	1
Not recorded	-	2	-2
Stage 1,2, or 3 Bedsore Group	**25**	**23**	**2**
Stage 1 bedsores (> redness)	11	14	-3
Stage 2	6	3	3
Stage 3	8	6	2
Total number of bedsores	**31**	**27**	**4**

Development

	Total population	PRB	PSB
Initial population	63	32	31
Final population	63	36	27
Initial bedsores	31	0	31
Final bedsores	27	0	27
Efficacy	**99%**	**97%**	**100%**
Healing	7%	0%	13%
Favourable development	60%	97%	22.5%
Stationary state (identity)	32%	0	64.5%
Unfavourable development	1%	3%[*]	0%

[*]No occurrence of bedsores

Conclusion

The APLOT mattress is effective in helping to prevent bedsores, since just 10% of patients included in the "PRBs at high risk of bedsores" population observed an unfavourable development in their condition.

Furthermore, in patients suffering from bedsores, the APLOT mattress was found to be significantly effective in light of the favourable development of their skin condition state.

Overall, it is possible to conclude that prevention that brings together the APLOT mattress, massage, and turning over, is effective in 100% of cases.

The mattress was judged easy to use by healthcare staff, who also felt that the results are good or excellent in 91.9% of cases.

The APLOT mattress was judged to be very comfortable in 94% of cases by patients, and 91% 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