

**APLOT MATTRESS CLINICAL STUDY (1) - TABULATED SUMMARY**

ITEM	DESCRIPTION
Product studied	APLOT mattress
Type of study	Non-interventional prospective clinical study – observational type
Date of study	1993
Objective of the study	Assess the performance of the Aplot mattress when caring for persons at risk from bedsores (PRBs) or persons suffering from bedsores (PSBs)
<b>METHOD</b>	
Criteria for inclusion	Persons admitted to hospital presenting a risk of bedsores and / or presenting with Norton Scale stage 1 bedsores or with a pathological state
Context and place of study	<p><u>Establishments</u></p> <ul style="list-style-type: none"> <li>- APHP (Assistance Publique – Hôpitaux de Paris – Paris Hospital System) Sainte-Périne Hospital, Paris, Dr. A. Baulon's department head of the study: Ms. Maga (general supervisor)</li> <li>- Curie Geriatrics Centre Caluire (Rhône département), Dr. André Fouet's department head of the study: Ms. Saillant (general supervisor)</li> <li>- APHP (Assistance Publique – Hôpitaux de Paris – Paris Hospital System) La collégiale Hospital, Paris, Dr. Savier's department head of the study: Ms. Beysserie (general supervisor)</li> </ul>
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 = 61
Randomisation method	Not applicable
Method of analysing the results	Descriptive analysis
<b>RESULTS</b>	
Number of subjects analysed	N = 57 (4 exclusions as outside protocol)
Duration of monitoring	15 days
Patient characteristics (without group comparability)	<p>W / M distribution: 5.10 Average age: 87 years [SD 9] Average weight: 53 kg [SD 11] Average height: 1.62 m [SD 0.07] 18 different pathologies, in particular neurological and traumatological <i>Osteo-arthritis of the right knee (operated on) with difficulty in walking, cancer, vegetative coma following ruptured aneurysm, epileptic seizure with temporo-spatial disorientation, dementia, bullous disease, fractures of the neck of the femur including one associated with respiratory failure and one with being bed-ridden, sub-arachnoid hæmorrhage, Alzheimer's disease, degenerative neuropathy, paraplegia, Parkinson's disease, rheumatoid poly-arthritis, tetraplegia, confusional disturbance, pulmonary tuberculosis</i> PRB: N = 31 (54.5%), PSB: N = 26 (45.5%) Total number of bedsores: 26 Seriousness of bedsores: Stage 1 (Redness) N = 26 (100%) PSB – Redness: Pale N = 14 (54%), Bright N = 7 (27%), Very Bright N = 4 (15%), No Response N = 1 (4%) PSB painful N = 13 Presence of pain according to redness observed: Pale N = 3 (23%), Bright N = 6 (46%), Very Bright N = 4 (31%)</p> <p><u>Patient sample detail</u></p> <p>PRB according to Norton N = 29 (51%) PRB according to pathological state: N = 2 (3.5%) PSB, stage 1: N = 2 (3.5%) PSB, stage 1 and risk according to Norton N = 24 (42%)</p> <p><u>Details of seriousness of bedsores and associated pain</u></p> <p>PSB stage 1: N = 2 Redness: Pale N = 1 (50%), Bright N = 1 (50%) Associated pain: N = 0 PRB stage 1 and risk according to Norton N = 24 Redness: Pale N = 13 (54%), Bright N = 6 (25%), Very Bright N = 4 (17%), No Response N = 1 (4%) Associated pain: N = 13 (54%)</p>

<p>Characteristics relating to professional practices</p>	<p><u>carrying out massage</u></p> <ul style="list-style-type: none"> <li>- yes for 100% of the population studied</li> </ul> <p><u>Frequency of massage</u></p> <ul style="list-style-type: none"> <li>- PRB according to Norton: 2 / daily 21%, 3 / day 62%, over 3 / day 17%</li> <li>- PRB according to pathological state: data not reported</li> <li>- PSB stage 1: data not reported</li> <li>- PSB stage 1 and risk according to Norton: 2 / daily 8%, 3 / day 21%, over 3 / day 71%</li> </ul> <p><u>Turning over</u></p> <ul style="list-style-type: none"> <li>- PRB according to Norton: 51.72%</li> <li>- PRB according to pathological state: 0%</li> <li>- PSB stage 1: 0%</li> <li>- PSB stage 1 and risk according to Norton: 71%</li> </ul> <p><u>Frequency of turning over</u></p> <ul style="list-style-type: none"> <li>- PRB according to Norton: 2 / daily 0%, 3 / day 80%, over 3 / day 20%</li> <li>- PRB according to pathological state: not applicable</li> <li>- PSB stage 1: not applicable</li> <li>- PSB stage 1 and risk according to Norton: 2 / daily 6%, 3 / day 18%, over 3 / day 76%</li> </ul>
<p>Results inherent in the main judgement criterion</p>	<p>Develop in patient state: healing N = 9 (16%), favourable development N = 3 (5%), stationary state N = 43 (75%), unfavourable development N = 2 (4%)  PRB: N = 38 (67%), PSB: N = 19 (33%)  Total number of bedsores: 19  Seriousness of bedsores: Stage 1 (Redness) N = 18 (95%), stage 2 N = 1 (5%)  PSB – Redness: Pale N = 13 (72%), Bright N = 3 (17%), Very Bright N = 2 (11%)  PSB painful N = 13 with 8 cases of unfavourable development (62%): reduction in intensity</p> <p><b><u>Development according to initial classification</u></b></p> <p><u>PRB according to Norton</u> (initial N = 29)  Stationary state N = 27 (93%)  Unfavourable development (bedsores occur) N = 2 (7%)  <i>Patients aged 91 and 100, bed-ridden, change in general health; incomplete overall prevention protocol</i>  Final number of bedsores: 2  Seriousness of bedsores: Stage 1 N = 1 (50.54), Stage 2 N = 1 (50.5)  Redness of stage 1 bedsores: very bright N = 1 (100%)  <u>PRB according to pathological state</u> (initial N = 2)  Stationary state N = 2 (100%): no bed sore occurs  Final number of bedsores: 0  <u>PSB stage 1</u> (initial N = 2)  Favourable development N = 1 (50%): development of redness from bright to pale  Stationary state N = 1 (50%): Pale redness maintained  Final number of bedsores: 2  Seriousness of bedsores: stage 1 N = 2 (100.5)  Redness of stage 1 bedsores: pale N = 2 (100%)  Associated pain N = 0 (absence of aggravation)  <u>PSB stage 1 and risk according to Norton</u>(initial N = 24)  Healing N = 9 (37.5%) pale when healed N = 4, bright when healed N = 2, very bright when healed N = 2, not recorded N = 1  Favourable development N = 2 (8.3%) bright to pale N = 1, very bright to pale N = 1  Stationary state N = 13 (54.2%)  Final number of bedsores: 15  Seriousness of bedsores: stage 1 N = 15 (100)  Redness of stage 1 bedsores: pale N = 11 (73%), bright N = 3 (20%), very bright N = 1 (7%)  Associated pain: N = 13 with 8 reductions in intensity</p>
<p>Results inherent in the secondary judgement criteria</p>	<p><u>Assessment of the support by staff</u>  Ease of use: yes 100%  Assessment of results: Excellent 31.58%, Good 57.89%, Average 8.77%, Poor 1.75%</p>

	<p><u>Assessment of the support by patients</u>            Comfort: Excellent 12.28%, Good 78.95%, Average 1.75%, Poor 0%, Cannot communicate 7.02%            The patient wishes to keep the mattress: Yes 77.19%, No 0%, No response 22.81%</p>
Secondary effects	<p>None            Bed sore prevention care was given at the same time.</p>

## SUMMARY

### Population

	Initial assessment	Final assessment
PRB	31	38
PSB	26	19
<b>Population total</b>	<b>57</b>	<b>57</b>

### Bedsore

	Initial assessment	Final assessment	Increase
<b>Stage 1 bedsores</b>	26	18	8
Pale redness	14	13	1
Bright redness	7	3	4
Very bright redness	4	2	2
Not recorded	1	0	1
<b>Stage 2 bedsores</b>	0	1	-1
<b>Total number of bedsores:</b>	<b>26</b>	<b>19</b>	<b>7</b>

### Development

	Total Population	PRB	PSB
Initial population	57	31	26
Final population	57	38	19
Initial bedsores	26	0	26
Final bedsores	19	2	17
<b>Efficacy</b>	<b>96%</b>	<b>94%</b>	<b>100%</b>
Healing	9 (16%)	0	9 (35%)
Favourable development	3 (5%)	0	3 (12%)
Stationary state (identity)	43 (75%)	29 (94%)	14 (54%)
Unfavourable development	2 (4%)	2 (6%)	0

### Conclusion

The APLOT mattress proves its effectiveness in preventing bedsores and in helping to them in 96% of cases, of which 16% led to healing, 5% in the healing process, and 75% stable.

The mattress was judged easy to use by healthcare staff, who also felt that the results are good or excellent in 89.47% of cases.

The APLOT mattress was judged very comfortable in 91.23% of cases by patients, and in 77.19% of patients who benefited from it wished to continue to use it.

### Abbreviations

PRB: Person(s) at Risk of Bedsores

PSB: Person(s) Suffering from Bedsores

SD: Standard Deviation