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October 15th, 2004

Dear Mr. Seghers,

Please find attached the final results of the study:

"Clinical evaluation of the effectiveness of the REPOSE system"

Sincerely yours,

Dr. Herbert Mayer [1] Prof. Dr. Jürgen Osterbrink [2] Gerhard Schröder[3]

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1 Introduction

The aim of this study plan is to provide proof, required for inclusion as (health) aids in the aid catalogue for Germany - product group 11, of the effectiveness of a support aid for the prevention or treatment of bedsores (decubitus or decubitus ulcers).

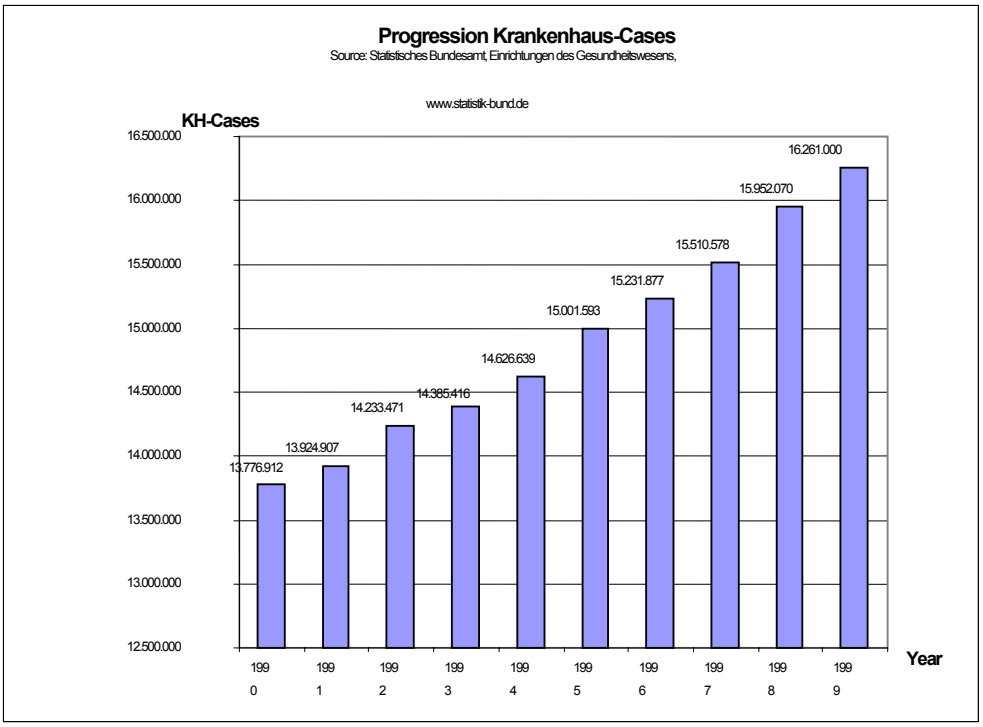
The system under review is called REPOSE, a static air chamber system consisting of integrated air chambers coated with a pure polyurethane shell. Polyurethane is an extremely elastic and stretchable material - it can be stretched ix-fold without tearing or losing its elastic resilience. The qualities of the polyurethane shell facilitate optimum effectiveness of the air chambers and reduce shear and friction stress. It is characterised by a smooth, supple surface, which is antibacterial, anti-allergenic and non-irritant (eudermic). According to the manufacturer the system is not water-permeable, but breathable. The REPOSE system is produced by the company Frontier Therapeutics, Newbridge Road Industrial Estate, Blackwood, South Wales NP12 2 YN.

REPOSE has been available on the international market for six years and was developed with the support of Cardiff University in England.

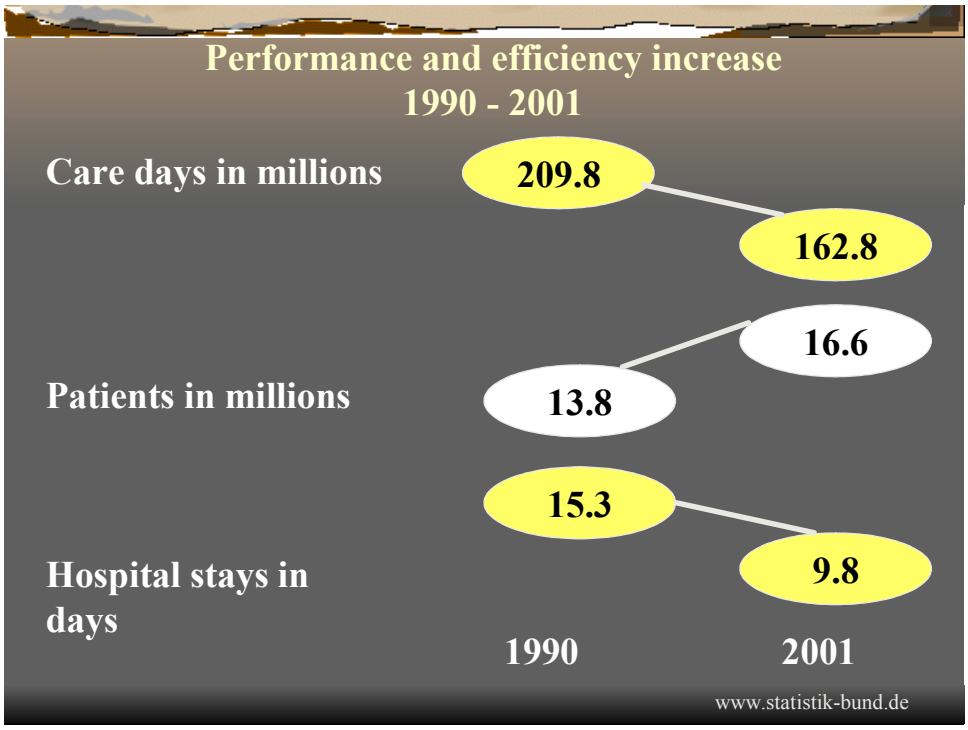
Based on the structure of the system, warming of the skin, a contributing factor in the development of bedsores, is avoided. Heel protectors, seat cushions and mattress overlays together form a multimodal treatment concept.

The company Frontier Therapeutics thereby provides a product to be subjected to clinical examination with respect to its preventive and curative properties.

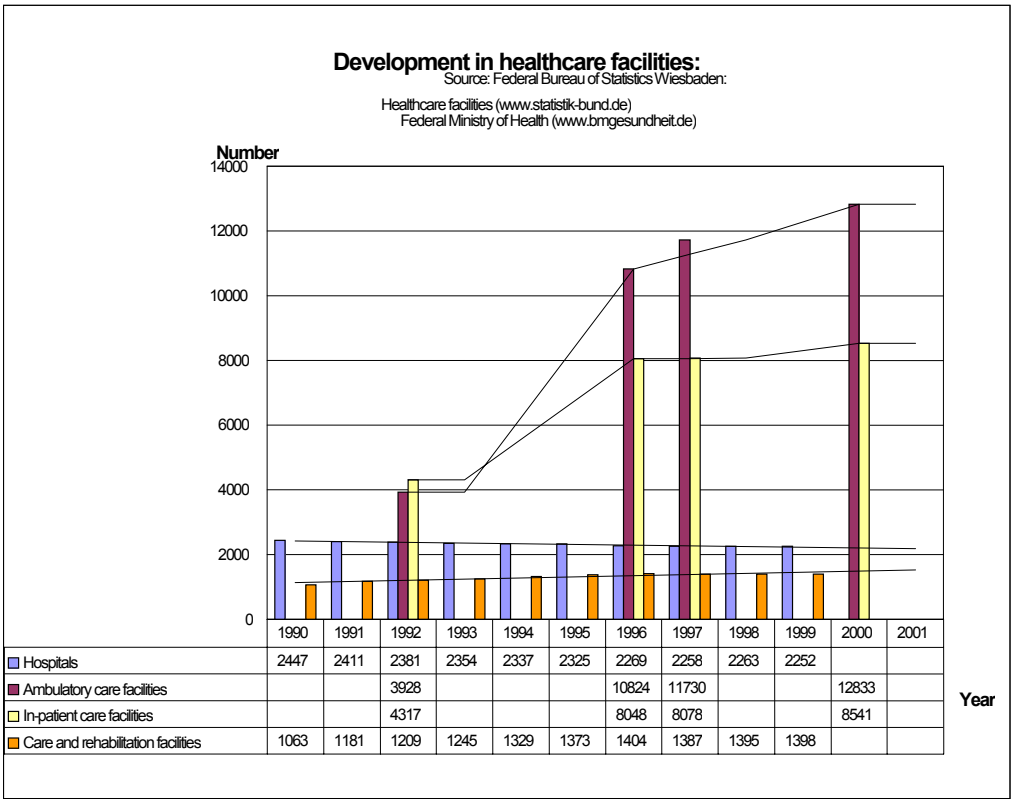
The background for this new development by the Frontier Therapeutics company includes current and future demographic growth, which will entail not only an increase in older patients, but also and specifically a rise in the number of patients with multimorbidity. Against the backdrop of patients' aging the assumption should be made that a promoting the mobility, orientation and 'well-being' of these patients will guarantee not only the quality of the individual facilities, but the quality of care and therapy on the whole. The number of in-patients treated in the Federal Republic of Germany, for instance, rose considerably from 13.8 million in 1990 to 16.3 million in 1999. The number of hospital facilities, on the other hand, declined over this same period of time.



The diagram below, moreover, shows that the number of days of care decreased by almost ¼ during the decade, with a simultaneous rise in patient numbers of 18% and a reduction in hospital stays of 35.9%. This implies for individual facilities that not only more patients, but also patients with multimorbidity have to be treated and cared for.



Out-patient or ambulatory care has also risen considerably during the same time period (1990 – 1999).



	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001
Hospitals	2447	2411	2381	2354	2337	2325	2269	2258	2263	2252		
Ambulatory care facilities			3928				10824	11730			12833	
In-patient care facilities			4317				8048	8078			8541	
Care and rehabilitation facilities	1063	1181	1209	1245	1329	1373	1404	1387	1395	1398		

A groundbreaking study was conducted in Belgium under the auspices of the Belgian Ministry of Health in this connection; it compared the care intensity in acute care hospitals between 1989 and 1994. Overall results indicated that during this interval an increase in mobility requirements of 14.4%, as well as a rise in the prevention of bedsores of 17.2% occurred.

Development of care intensity in acute care facilities 1989 - 1994
Surgical, pediatric and medical department (Belgium)

Intervention	1989	1992	1994	Differenz
Bed baths	52.4% 6.6 mill.	51,7% 6.3 mill.	53.6% 6.4 mill.	+2.3%
Mobilization	40.5%	44.1%	46.4%	+14.4%
Bedsore prevention >6x a day	6.2%	6.1%	7.2%	+17.2%
Preparation for discharge (training)	7.2%	7.9%	11.1%	+52.9%

(Source= Ministry of Public Health, NMD -registration)

For the reasons indicated above, an emphasis on both the clinical and non-clinical treatment of patients, in terms of continuous care without interruptions, should be assured.

The company, Frontier Therapeutics, considers its REPOSE system a patient- and user-friendly system, which has already provided significant relief in healthy study subjects (Defloor 1999) in seated positions. In a prospective controlled randomised cohort study of 80 patients following femoral neck fractures (Price 1999) it was shown that when compared with a large-cell dynamic alternate pressure system no difference in patients with a high risk of bedsores could be established with respect to actual development of decubitus.

The study plan below examines the clinical effectiveness of the entire system as a multimodal therapy concept taking into account criteria for efficiency and effectiveness.

2 Research literature

Comprehensive research of available literature was conducted and assessed in order to afford an overview of current preventative and therapeutic factors. The study was conceived subsequently based on the data observed.

2.1 Comments on research literature

Research into literature on the subject of "aids to reduce the risk of bedsores" was conducted in MEDLINE, CINAHL and CARELIT. Moreover, literature available in the Institut für Pflegewissenschaft Witten/Herdecke was also reviewed. The research interval included all years available

in the data bases (Medline until 2002, Cinahl until 2001, Carelit until 01/2001, Cochrane Library) including manual research of relevant periodicals for 2002. Furthermore, the key organisations of relevance to the topic were explored for literature references via the Internet.

Search keys included: *pressure ulcer, mattress, air fluidised bed, air mattress, flotation bed* in a variety of combinations. In total about 400 references were found in the literature. To limit the results the terms *guidelines, review, clinical trials, RCT* were entered. About 200 relevant articles were produced as a result. If the search for literature is extended to comparative clinical trials and evaluation studies, circa 370 become relevant.

Results from research literature are outlined below. Those articles selected (57) have not been chosen according to any system; they simply seem relevant to the theme. The studies are intended to provide an overview of topical emphases and an orientation for future research.
The literature selected is presented according to the following perspectives:

- Sample including selection criteria
- Key variables in the sample
- Setting
- Interventions including instruments
- Outcomes
- Most important results

First the status of knowledge concerning the prevention and treatment of bedsores is summarised with regard to pressure-relieving mattresses and overlays.
In the second part studies are presented according to the criteria mentioned above.

2.2 Knowledge of pressure-reducing systems in the literature

The first German expert standard "bedsore prevention" recommends separate assessment of each care situation in the use of pressure-reducing aids. The "best aids" could not be identified from an analysis of the literature. A good choice depends on individual care objectives, resources and patients' problems as well as on cost/benefit considerations (German Network for Quality Assurance in Care 2000).

Results of the literature analysis in the context of the expert standard reveal that the studies conducted are not comparable and are often of limited quality. The studies differ in design, sample selection, measurement methods and objectives. Only a few studies comply with the "randomised controlled design" (RCT – randomised controlled trials) required to make assertions about the effectiveness of aids (Whittemore 1998; Cullum, Deeks et al. 2000; German Network for Quality Assurance in Care 2000).

13 clinical studies on the effectiveness of various pressure-relieving aids on the incidence of bedsores in risk patients were reviewed in order to prepare the AHCPR guidelines (Agency for Health Care Policy and Research). Here, too, no general conclusions could be drawn. Differing designs and frequently inadequate information concerning statistical analysis do not allow any clear statements to be made. Often standard hospital mattresses are compared with pressure-relieving mattresses. The incidence of bedsores in patients on hospital mattresses was higher than in the case of pressure-reducing systems. Three RCT studies compared two types of pressure-reducing aids. The results show no significant differences with respect to bedsore prevention in the aids examined (AHCPR 1992).

Royal College of Nursing guidelines (RCN 2000) recommend that patients at risk of bedsores not be supported on standard foam mattresses. Patients at high risk of bedsores should be supported on "alternating pressure mattresses" or other "high-tech" pressure-relieving systems (RCN 2000, p. 9).

2.3 An overview of the literature according to the criteria

In this part of the literature research 57 studies are presented in tables according to selected criteria. First, studies concerned with the capacity of pressure-reducing systems to prevent bedsores are presented (38). This includes studies that measure overlay pressure, oxygen content, etc., with the help of special equipment. The second overview shows treatment studies (11). Finally studies are introduced that investigate both preventative and treatment aspects (6). Studies (2), which do not investigate pressure-relieving aids from the point of view of "bedsores", are shown under "other studies". The effect of the systems on pain, comfort, sleep, body perception and posture are examined in these studies.

Comments on the tables

The overviews contain information that has been specifically mentioned by the authors. If the overview does not contain information on certain features (sample size, for instance), this is because it was not mentioned by the authors. Only the most significant results, which the authors have also emphasized, are included. In the case of the laboratory studies, no results have been presented, since a number of measurement values, at different parts of the body, in different postures and at different times are listed, and including these values in the table did not seem meaningful due to space reasons and also because they would not provide a concise overview.

The overview also includes studies that were not available for current literature research (could not be ordered). Information is derived from the article of Cullum, Deeks et al. 2000 and is marked by an asterisk.

2.3.1 Prevention studies

Table 1 Overview of prevention studies

No.	Study	Methods	Sample	Interventions	Outcomes Results	Instruments Comments
1.	(Allen, Ryan et al. 1994)	Laboratory study	10 healthy, young people	4 different mattresses: 2 continuous airflow overlays (Clinirest, First-Step), 2 WDM (Pegasus, Nimbus system)	Measurement of overlay pressure Differing signif. results	<u>Instruments:</u> Overlay pressure measurement device (Talley SA 500)
2.	(Andersen, Jensen et al. 1982)	RCT, Test subject allocation not clear, observation period 10 days, sample size estimate: 200 for each group, power 0.80	482 patients in acute care, high DR[1] according to Andersen scale, no decubitus	Comparison: standard HM[2] (161 pat.), APM[3] (166), water mattress (155)	Incidence of bedsores (starting with blister), admittance of patients/staff, significantly more bedsores in standard HM group than in others	<u>Instruments:</u> Risk scale, skin assessment (both indicated in text)

[1] DR – decubitus risk

[2] HM – hospital mattress

[3] APM – alternating pressure mattress

No.	Study	Methods	Sample	Interventions	Outcomes Results	Instruments Comments
3.	(Boettger 1997)	Pre and post-interventions study, pre interventions group as control group	Care ward, 282 patients over 65, pre-intervention group – 141 test subjects, post-intervention group - 141 test subjects	Pre-interventions group: 3 months usual care and standard HM Intervention: special mattresses and staff eduction Intervention group: 3 months after intervention	Incidence No significant differences between both interventions	<u>Instruments:</u> Decubitus stages according to AHCPR (incl. stage 1)
4.	(Chaloner and Cave 2000)	Prospective, quasi-randomised study Sample size at least 44 at 80% power, alpha 5%	44 newly admitted patients in home care, without decubitus, with decubitus risk, minimally care for 7 days, no psychiatric illnesses	Comparison between two alternating pressure mattresses. Documentation of care performed and skin status (incl. stage 1)	Comfort and operation from the perspective of the patients and caregivers, incidence of decubitus	<u>Instruments:</u> Walsall Community Risk Score Calculator (decubitus risk), questionnaire on satisfaction and comfort
5.	(Collier 1996)	RCT, test subject allocation: system uses codes, patients allocated according to availability of the systems, only the researcher and staff nurse could identify the systems, observation period 6 months	90 patients of a general internist ward (details lacking)	Comparison of 8 different systems: HM (9), Clinifloat foam mattress (11), Omnifoam foam mattress (11), Softform (12), STM5 (10), Therarest (13, Transfoam (10), Vapourlux (14) Customary care?	Incidence of decubitus (weekly skin assessment) comfort, overlay pressure Incidence 0%, Sample too small for significance tests	<u>Instruments:</u> Waterlow-Skala, Comfort (stand. questions and visual rating scale) Talley Pressure Monitor

No.	Study	Methods	Sample	Interventions	Outcomes Results	Instruments Comments
6.	(Colin, Loyant et al. 1996)	Laboratory study	20 healthy test subjects	Comparison between standard HM, non-modular foam mattress, modular foam mattress, modular air mattress, water mattress	Transcutaneous oxygen content	Instruments: Oxygen measured by Clark electrode
7.	(Conine, Daechsel et al. 1990)	RCT, test subject allocation not clear, observation period 3 months?	148 patients with chronic neurological disease, aged 18 - 55, no decubitus, similar patient distribution in both groups with respect to decubitus risk (Norton scale), gender, age, weight, time in wheelchair, previous decubitus, incontinence	Comparison between alternating pressure overlays (72), silicone overlays (76), use of customary preventative measures Customary care measures	Incidence of decubitus (including stage 1); degree of severity, length of healing process, No difference between groups with respect to outcomes	Instruments: Norton scale, Exton-Smith scale
8.	(Conner and Clack 1993)	Laboratory study	3 healthy test subjects, mid-twenties.	Comparison between float board and foam overlays of different thickness (a total of 6 different types)	Measurement of overlay pressure, vertical shear	Instruments: CT Scan, Pressure Sensor Evaluator
9.	(Cooper, Gray et al. 1998)	RCT, patient allocation by means of numbered envelopes, observation period 7 days	100 patients over 65, no decubitus, mixed emergency room and orthopaedic accident wards, patients with DR (Waterlow scale), both groups with similar variables (age, gender, mobility, DR)	Comparison between Soflex dry flotation mattress (41), ROHO dry rotation mattress (43)	Incidence of decubitus (including discolouration of skin), stage, comfort, simple operation Due to low incidence level evaluation of which mattress is better is not possible	Instruments: Skin assessment, Stirling Pressure Sore Severity, questionnaire, 5 point visual rating scale (comfort)

No.	Study	Methods	Sample	Interventions	Outcomes Results	Instruments Comments
10.	(Daechsel and Conine 1985)	RCT, Test subject allocation unclear, observation period of 3 months	32 patients with chronic neurological illness in long-term care hospital, aged 19 – 60, no decubitus, high decubitus risk (Norton scale)	Comparison between APM and silicone overlay Both groups received identical care and prevention	Incidence of decubitus No significant differences between the two groups	Instrument: Exton-Smith scale (decubitus classification includeng stage 1), Norton scale
11.	(Feldman, Sepka et al. 1993)	Evaluation, laboratory study	13 healthy test subjects	5 different mattresses: air-fluidised bed, low-air-loss bed, computer-controlled air mattress, a standard HM with and without eggshell foam mattress	Transcutaneous oxygen measurement, measurement of blood flow (circulation)	Instruments: Laser doppler, $TcPo^2$- electrode
12.	(Fontaine, Risley et al. 1998)	Laboratory study	11 healthy test subjects aged 23 - 51	Comparison between air overlay, air mattress and fluid overlay	Overlay pressure, shear	Instruments: Overlay sensor pressure and shear sensor
13.	(Gray and Smith 2000)	RCT, Coincidental distribution of mattresses, observation period 10 days	100 surgical, internist and orthopaedic patients, hospital admission for bed rest or major surgery, less than 160 kg, skin intact	Comparison between Fransfoam (50) and Transfoamwave (50);	Incidence (including stage 1), comfort Incidence number too small for the sample, no significant differences between groups n	Instruments: Classification (Torrance scale), Waterlow scale, Comfort scale

No.	Study	Methods	Sample	Interventions	Outcomes Results	Instruments Comments
14.	(Gray, Cooper et al. 1998)	Evaluation study (replication study), randomisation, no control group, observation period 10 days	54 hospital patients (oncology, vascular surgery) intact skin, Waterlow scale at least 15, over 65	Evaluation of 18 pressure-reducing mattresses and comparison with results from a study of 3 years before (Gray, Campbel 1994)	Incidence, comfort 7.4% incidence, no differences from results in 1993 (8.2%,)	<u>Instruments:</u> Comfort (visual rating scale), Punch test (checking quality of mattresses), Waterlow scale
15.	(Gray, Cooper et al. 2001)	Clinical evaluation study Observation period 3 – 7 days	44 major heart surgery patients	Evaluation of a foam mattress plus electrical bed frame	Incidence comfort 0% incidence, sample too small	<u>Instruments:</u> Waterlow scale, Skin assessment, Comfort scale (visual Rating scale, 5 points)
16.	(Hampton 1999)	Comparative clinical trial, effectiveness, full survey within 6 months	407 patients in acute hospital care, all age groups (20 – 102 years), different illnesses, no decubitus, max 25 points on the Waterlow scale	Effectiveness of Thermo contour mattress, comparison between 2 wards, - one with mattress under study (control group 199), the second with the customary hospital or air mattresses (208). If patients from the control group develop a decubitus (including stage 1), they are placed on air mattresses.	Incidence (including stage 1), comfort, cost effectiveness Difficult to calculate cost effectiveness with this method, 0% incidence in control group	<u>Instruments:</u> Waterlow scale. Questionnaire on decubitus risk factors.

No.	Study	Methods	Sample	Interventions	Outcomes Results	Instruments Comments
17.	(Hardin, Cronin et al. 2000)	Comparative laboratory study and retrospective clinical study	6 healthy test subjects 73 post-operative transplant patients	Effectiveness of two pressure-reducing mattresses by measuring overlay pressure One year evaluation of low-air-loss mattress (36), the second year evaluation of static fluid mattress (37); document analysis, performance of customary care measures	Overlay pressure Incidence, Significantly lower overlay pressure on the heels from the low-air-loss mattress; no significant differences in incidence (13.9%, 8.2%)	Instrument: Xsensor Pressure Mapping System (pressure measurement), Chart review tool
18.	(Hofman, Geelkerken et al. 1994)	RCT, Patients randomised in 6 groups, randomisation methods not described, observation period 2 weeks	44 patients with upper femoral neck fractures, without decubitus in stage 2 or higher, patients with high DR, haemoglobin, serum protein, serum albumin	Comparison between DeCube mattress(21), standard HM (23), Both groups were treated according to "Dutch consensus protocols for decubitus prevention"	Incidence of decubitus stage Significantly higher decubitus stages in the standard mattress group	Instruments: Decubitus stages (Dutch consensus scale; in text) Decubitus risk scale (in text)
19.	(Jakobsen and Christensen 1987)	Laboratory study	12 healthy test subjects, normal weight, aged 17-39.	Comparison between standard HM, water mattress, silicone cushions, sheepskins, APM	Oxygen content in tissue	Instruments: Clark type oxygen sensor and monitor
20.	(Kemp, Kopanke et al. 1993)	RCT, Observation period maximum 1 month	84 patients from three areas (general medicine, acute geriatrics, long-term care facility), no decubitus, at least 65 years of age, decubitus risk (Braden scale)	Comparison between two foam overlays Customary standard care	Incidence	Instruments: Braden scale, Decubitus classification (4 stages according to AHCPR)

No.	Study	Methods	Sample	Interventions	Outcomes Results	Instruments Comments
21.	(Maklebust, Siggreen et al. 1988)	Laboratory study	64 healthy test subjects, aged between 20 and 82.	Comparison between standard HM and Clinitron bed	Overlay pressure	Instruments: Pressure measured with an electropneumatic pressure transducer
22.	(Neander and Birk-enfeld 1988)	Laboratory study, effectiveness	Part 1: 10 healthy test subjects Part 2: 21 intensive care patients	Comparison between 16 different anti-decubitus mattresses and alternating pressure mattresses. Comparison between different alternating pressure mattresses	Overlay pressure measurement, transcutaneous oxygen measurement, transcutaneous oxygen measurement	Instruments: Devices to measure overlay pressure and transcutaneous oxygen
23.	(Ooka, Kemp et al. 1995)	Comparative clinical trial, occasional sample	Patients in intensive care, with no decubitus, data available for 110 patients	Comparison between two alternating pressure systems (DMR1=35, DMR2=40) and a foam mattress (35) Customary care	Incidence (including stage 1) Costs No significant difference between the groups with respect to incidence	Instruments: Braden scale, 4 stage classification (according to AHCPR)
24.	(Rithalia and Heath 2000)	Laboratory study	31 students, aged 21-58	1. part: comparison between Nimbus 2 and Pegasus airwave (15), 2. part: Nimbus 3 and airwave (16)	Relief of pressure, capacity of mattress to adapt to individual (weight, body size)	Instruments: Oxford pressure monitor
25.	(Rojas and Reynolds 1996)	Laboratory study	23 healthy test subjects	Comparison between Therrest HRM systems and a standard HM	Overlay pressure measurement	Instruments: Mini-Tipe pressure sensor

No.	Study	Methods	Sample	Interventions	Outcomes Results	Instruments Comments
26.	(Russell and Lichtenstein 2000)	RCT, Observation period 7 days	185 heart surgery patients, at least 18 years of age, at least 4 hours of anaesthesia, at least 3 hours OR time, no decubitus, good AZ and prognosis	Comparison of efficiency and safety of MicroPulse mattress (89) with conventional prevention management (96) in pre and post-operative setting No significant differences in the groups	Incidence, stage, size, decubitus point. No significant differences in occurrence of decubitus between the two groups	<u>Instruments:</u> Decubitis classification (4 stages including stage 1), modified Knoll scale (decubitus risk)
27.	(Sideranko, Quinn et al. 1992)	RCT, Methode der Randomisierung nicht beschrieben	57 intensive care patients, stay of more than 48 hours without skin injuries at the time of admittance	Comparison between alternating pressure overlay (20), static air mattress (20), water mattress (17)	Incidence of decubitus, pressure measurement, Significant differences in pressure between the mattresses; incidence of 14% not significant	<u>Instruments</u> Pressure measurement using i.v. bags

No.	Study	Methods	Sample	Interventions	Outcomes Results	Instruments Comments
28.	(Takala, Varmavuo et al. 1996)	RCT, Randomisation influenced by availability of mattresses, observation period of maximum 2 weeks, estimate of sample size of 40: assumption, 65% of patients develop decubitus, 50% reduction of patients with decubitus expected	40 patients from intensive care ward, no trauma patients, stay of more than 5 days, no decubitus	Comparison between Carital Optima (low-pressure mattress (21), standard hospital foam mattress (19)	Incidence of decubitus, wound size, overlay pressure, blood flow in skin, temperature of skin No decubitus in exp. group, 13 instances of decubitus in 9 patients in the control group; significantly lower pressure values, temperatures in the exp. group	Instruments: Norton scale, Skin status/ decubitus stages according to Shea, wound size (recorded on foil + photo), overlay pressure device, laser Doppler (skin temperature, blood flow)
29.	(Vyhlidal, Moxness et al. 1997)	Experimental study, randomised, Observation period max. 21 days	40 patients in a care facility, at least 10 days' stay, no decubitus, decubitus risk (according to Braden scale)	Comparison between Iris 3000 (20) and Maxifloat (20) Both groups received the same standard care	Incidence Significant differences between the groups	Instruments: Braden scale, Bergstrom skin assessment tool, (both indicated in the text)

No.	Study	Methods	Sample	Interventions	Outcomes Results	Instruments Comments
30.	Economides [4]* 1995	RCT, Test subject allocation not clear, observation period 2 weeks	12 patients with decubitus stage 4, of which 10 were paraplegics or quadriplegics	Comparison between ROHO dry foltation matress (6), Air-fluidised Clinitron Bett (6),	Rate of wound break-down	
31.	Exton-Smith* 1982	RCT, Changing patient allocation or allocation depending on available system, observation period 2 weeks	62 newly admitted geriatric patients with upper femoral neck fractures, without decubitus in stage 2 or above, Norton scale below 14; there were no significant differences in the groups with regard to age, gender, DR, time not in bed, use of permanent catheter	Comparison between Pegasus Airwave-System (31), Large Cell Ripple Mattress (31)	Incidence of decubitus in stage 2 or higher	<u>Instruments:</u> Norton scale
32.	Gebhardt* 1994	Patient allocation via case sheet number	New admissions, aged from 18, Norton scale below 14, no decubitus, patients from ICU, oncological, internist, geriatric or orthopaedic wards. Groups comparable in terms of age, gender and Norton	Comparison between APM and Constant Low Pressure Systems (different variations)	Incidence of decubitus	No information on sample size

[4] Articles marked with * not available, information from the article Cullum, N. et al. (2000)

No.	Study	Methods	Sample	Interventions	Outcomes Results	Instruments Comments
33.	Gray, Campbell* 1994	RCT, Patient allocation via closed envelopes, observation period 10 days	170 orthopaedic, oncological patients, without skin injuries, Waterlow scale below 15, groups comparable in terms of age, gender, Waterlow scale	Comparison between soft foam mattresses (90) and standard 130 mm NHS foam mattresses (80)	Incidence of decubitus	Instruments: Waterlow scale Skin assessment on 5. and 10. day
34.	Inman* 1993	RCT, Test subject allocation unclear, observation period on average 17 days, sample sizeestimate	98 patients over 17 years with APACHE II (Acute Physiology and Chronic Health Evaluation) greater than 15, stay in intensive care ward > 3 days	Comparison between low-air-loss beds (49) and standard intensive care beds with rotation (49)	Incidence of decubitus (decubitus per patient and patient with decubitus)	
35.	Laurent* 1997	RCT with "factorial" design, randomisation "by blocks" – method not clear Sample sizeestimate	312 adults over 15 years admitted for major heart surgery, hospital stay of at least 5 days including a stay in intensive care	Comparison between 1. Standard HM in intensive care and post-intensive (80) 2. Nimbus in intensive care and standard HM post-intensive (80) 3. Standard HM in intensive care and constant low pressure post-intensive (75) 4. Nimbus in intensive care and constant low pressure post-ICU (77)	Incidence of decubitus	

No.	Study	Methods	Sample	Interventions	Outcomes Results	Instruments Comments
36.	Santy* 1994	RCT, Patient allocation with randomised, numbered tables, method unclear, observation period 14 days	505 patients over 55 years, upper femoral fracture, with and without decubitus. Patients with decubitus in stages 3 or 4 excluded. Groups similar in terms of age and Waterlow scale	Comparison between Clinifloat (87), NHS contract (64), Vaperm (116), Terarest (136), Transfoam (102)	Rate of patients excluded from the study after the condition of their skin/wound deteriorated	Instruments: Waterlow scale
37.	Stapleton* 1986	Method of patient allocation – alternating distribution	100 older female patients with upper femoral neck fracture, without decubitus, Norton scale 14 and less, groups similar in age and Norton scale	Comparison between Large Cell Ripple (32), Popyether foam overlay (34), Spenco pad (34)	Incidence of all decubitus, incidence of decubitus stage 2, incidence of decubitus stage 3	Instruments: Norton scale
38.	Whitney* 1984	RCT, Patients randomly assigned to groups, method not described, observation period 8 days	51 patients on the internist/surgical ward, bedridden for at least 20 hours, most patients had minor skin injuries, aged 19-91, majority of patients were confused	Comparison APM (25), curved foam cushion (26)	Skin changes, incidence (indirect)	

2.3.2 Therapeutic studies

Table 1 Overview of therapeutic studies

Nr	Study	Methods	Sample	Interventions	Outcomes Results	Instruments Comments
1.	(Allman, Walker et al. 1987)	RCT, Observation period median 13 days (4 – 77 days), optimum sample size (72?) with alpha 0.05 and beta 0.20	65 surgical patients over 18, with decubitus, expected hospital stay of at least a week and immobile (bed/wheelchair)	Comparison between Air-fluidised Mattress (Clinitron) (31) supported for 4 hours and conventional treatment (supported for 2 hours, cushions at heels and elbows, alternating pressure mattress) (34)	Median change in the entire decubitus surface, improvement in condition of decubitus (photo), pain, comfort, significant decrease in size of wound, improvement in condition of major wounds, changes in pain intensity and comfort level in the Clinitron group. The sample size required for more precise results would be 278 at a power of 0.80	Instruments Decubitus stage according to Shea, decubitus surface was noted on plastic foil, condition of the wound based on standardised criteria: pain-intensity scale (0-5 points), Comfort with a question (1-4 points)
2.	(Bennett, Baran et al.	RCT, Observation period	116 patients in acute hospital care and geriatric centres,	Comparison between low-air-loss hydrotherapy bed and other mattresses	Incidence, Change in wound condition,	Instruments: Braden scale,

Nr	Study	Methods	Sample	Interventions	Outcomes Results	Instruments Comments
	1998)	at least 7 days	incontinence, with and without decubitus, at least 16 hours in bed per day, at least 3 days' stay in hospital	used in the hospital. Customary care; if the wound condition deteriorates, the patient is transferred to the other mattress	Incidence in experimental group 48%, in the control group 14% significant evaluation of the effects not possible due to low number of test subjects	Pressure Sore Status Tool (stage including stage 1), Wound surface noted on foil and calculated by computer, photo
3.	(Charles, Oldenbrook et al. 1995)	Retrospective evaluation study	14 items of documentation, patients between 60 and 80 years	Comparison between standard mattress and low-air-loss mattress, , Documentation analysis	Wound healing, Change in size of wound Significant reduction in wound size in the low-air-loss mattress group	n.a.
4.	(Devine 1995)	Comparison study, observation period 4 weeks, randomised distribution in both groups	41 patients from the geriatric department, decubitus at least stage 2	Comparison between Pegasus Airwave (19) and Nimbus I (22) Standardised wound care for all patients	Decubitus point Decubitus stage Decubitus size Comfort Operation	<u>Instruments:</u> Decubitus classification (5 stage scale) Comfort and operation (10 point scale), Decubitus risk (Norton-

Nr	Study	Methods	Sample	Interventions	Outcomes Results	Instruments Comments
					Sample too undifferentiated, no significant difference	scale and Douglas scale)
5.	(Evans, Land et al. 2000); (Land, Evans et al. 2000)	Randomised pre-test/post-test experiment, assignment to mattresses based on coincidence (envelopes) Insufficient control over external factors Sample size estimate: magnitude of effect 0.065, alpha 0.05; beta 0,02; 30 test subjects per	32 patients (hospital and nursing home) over 65 years of age with decubitus stage 3 or patients over 56 years of age with decubitus stage 2 and with one or more of the following problems; difficulties in moving in bed and intolerance of 30 degree prone support position, unable to move in bed, in bed for over 20/24 hours, weight over 108 kg plus bedridden, spinal anaesthesia Hospital: 7 experim., 5	Comparison between Nimbus 3 and other alternating pressure systems (Biwave, Airwave, AlphaXcell, Cairwave, Quattro) Customary care measures, log of measures kept	Decubitus healing rate or change in wound size, perception of comfort No significant differences in the percent reduction of the wound size and comfort perception between the two groups	<u>Instruments:</u> APACHE (Acute Physiological, Age, Chronic Health Evaluation), Waterlow scale, decubitus scale (4 stage system) , comfort scale (visual analogue scale)

Nr	Study	Methods	Sample	Interventions	Outcomes Results	Instruments Comments
		group (in other words 120 test subjects, 60 per setting, 30 per group)	control; (distribution in groups comparable) Nursing home: 10 control, 10 experim. (groups comparable)			
6.	(Munro, Brown et al. 1989)	RCT, allocation of test subjects not clear, 15 days observation period	40 male patients with stage 2 or stage 3 decubitus, expected hospital stay at least 15 days. Criteria for exclusion: weight over 250 lb., weight less than 17% of ideal weight, serum albumin less than 2.1 g/100ml Groups similar in age, diagnosis, decubitus size, pain, Gossnell scale	Comparison (effectiveness) between Air-fluidised bed (Clinitron) (20) and standard hospital mattress (20); Study of effectiveness of Clinitron bed in various areas: care period, perfromance of customary care in control group (hospital mattress), it appears as though the Clinitron Group was not supported	Changes in decubitus surface (mm^2), measured on the 1.,3.,8. and 15. day; Care period: time with patient in minutes in 8 hours on the 8. day; costs for prescriptions/medications; pain; patient satisfaction ; potential problems Significant increase in wound size in the control group, reduction in exp. Group, significant	Instruments: Modif. Gosnell assessment tool (Decubitus risk), colour photos + written description (assessment of stage), size of wound (Saran wrap sheet + digitizer tablet + Zeiss MOP Videoplan), patient satisfaction (8 item scale), Pain(adaptedLevitt and

Nr	Study	Methods	Sample	Interventions	Outcomes Results	Instruments Comments
					difference in costs between the groups	Derogatis scale, 14 items)
7.	(Warner 1992)	Not randomised, two comparison groups, observation period 4 weeks	20 patients from acute care hospital, with debitus less than 12cm³, minimum, various exclusion criteria	Comparison between a low-air-loss mattress (10) and a foam mattress (10) Prevention measures and wound treatment performed and logged	Improvement or deterioration of decubitus condition No significant differences between the groups, sample too small	Instruments: Decubitus classification (4 stages), Braden scale, visual assessment of decubitus, Lasico 1280-12
8.	(Wells and Karr 1998)	Prospective evaluation study Average observation period 2.9 weeks	Part 1: 22 healthy test subjects Part 2: 33 patients from two acute care hospitals and one rehabilitation hospital	Evaluation of non-powered fluid mattress in comparison to low-air-loss beds and air-fluidised bed. Evaluation of air-fluidised bed Patients received customary care according to hospital standards	Overlay pressure Wound healing, patient and staff satisfaction, estimate of treatment costs	Instruments: Devices for pressure measurement, modif. Yaws and Deruvo Pressure Sore Risk Evaluation Tool, decubitus stage with IAET Pressure Ulcer Indentification (indenti-

Nr	Study	Methods	Sample	Interventions	Outcomes Results	Instruments Comments
						fication in original, but could be identification) standards, questionnaire on satisfaction and comfort
9.	Caley* 1994	RCT, Observation period 24 days (average))	55 patients in acute care, with decubitus and recommendation of a low-air-loss therapy. Age 42-98, average Norton scale 10	Comparison between low-air-loss bed (Monarch, Mediscus) (23) and low-air-loss overlay (SPR Plus, Gaymar) (32)	Median of change in ulceral surface measured as a multiplication of the wound length and breadth	
10	Ferrell* 1993	RCT, randomising in blocks of 10; 5 for each treatment, distribution using envelopes, observation periods 33-40 days, sample size estimate	84 older nursing home residents with multiple medical problems with decubitus starting at stage 2 according to Shea on the trochanter or trunk. In the case of several ulcers, the largest is the index ulcer.	Comparison between low-air-loss bed (KINAIR) (43) and foam overlay (41) Both groups received similar co-interventions/standard care, as much mobilization as possible, support for 2 hours etc.	Rate of wound healing, wound surface was measured 2 times a week on clingfilm	<u>Instruments:</u> Decubitus classification according to Shea

Nr	Study	Methods	Sample	Interventions	Outcomes Results	Instruments Comments
			Criteria for exclusion: if anticipated discharge is within 1 month, if participation in the study has already occurred, if operation on ulcer is planned. Groups similarly distributed with respect to decubitus surface, patients, in the LAL bed group significantly lower serum albumin values			
11.	Strauss* 1999	RCT, methods of randomisation not explained, observation period 36 weeks	97 patients in home care with minimum stage 3 or 4 decubitus (according to Shea), future hospital confinement probable due to decubitus, severe restrictions on mobility, if ambulatory air-fluidised therapy recommended, wish	Comparison between home-air-fluidised therapy (CLINITRON) (47) plus consultation including technical services of a nurse and conventional or standard therapy (50) (alternating pressure cushions, air mattresses, water mattresses, foam cushions)	Change in condition of decubitus (improved, unchanged, deteriorated, not assessable), hospitalization caused by decubitus per patient, hospital stay days caused by decubitus per patient	

Nr	Study	Methods	Sample	Interventions	Outcomes Results	Instruments Comments
			to cooperated, life expectancy of at least a year, age above 16			

2.3.3 Treatment and therapeutic studies

Table 2: Overview of therapeutic and treatment studies

No	Study	Methods	Sample	Interventions	Outcomes Results	Instruments Comments
1.	(Arblaster 1999)	Clinical evaluation study	34 hospital patients	Comparison between 6 different systems	Comprehensive criteria: incidence (including stage 1), wound healing rate, comfort, safety, ease of operation; company service, costs Sample too small	<u>Instruments:</u> Waterlow scale, Stirling Pressure Score Severity Scale Various standardised protocols (listed in the text)
2.	(Gunningberg, Lindholm et al. 2000)	RCT, sample determination: at least 50 test subjects per group (with alpha = 0.05, power=0.80, magnitude of effect = medium to large)	101 hospital patients over 65, with upper femoral neck fractures, no decubitus	Comparison between a visco-elastic foam mattress (48) and a standard hospttal mattress (53), Customary preventative measures conducted for all patients, document analysis	Incidence (including stage 1), decubitus stages, wound sites, comfort No significant differences in the incidence between groups	<u>Instruments:</u> MNS scale, decubitus classification (4 stages), comfort (5-point scale)

No	Study	Methods	Sample	Interventions	Outcomes Results	Instruments Comments
3.	(Kato, Inoue et al. 1998)	Laboratory study Evaluation study Observation period 2 years	1. part: 18 paraplegic and quadriplegic patients without decubitus 2. part 19 patients with spinal cord injuries were observed for two years in the hospital and at home	ROHO air mattress ROHO mattress and foam mattress in one	Overla y pressure Decubitus healing, change in condition of wound All decubitus ulcers healed	
4.	(Knowles and Horsey 1999)	Evaluation study Observation period between 1 and 79 days	35 patients surgical and casualty wards	Evaluation ofTalley Quattro Deep Cell 2000	Incidence, decubitus stage, decubitus points, opinions of staff/patients of mattress 16 of 40 decubitus ulcers healed during the study, 16 remained the same, the skin remained intact in 15 patients, staff opinion positive	Instruments: Waterlow scale

No	Study	Methods	Sample	Interventions	Outcomes Results	Instruments Comments
5.	(Lazzara and Busch-mann 1991)	RCT, patient allocation via randomised numbe-red table, observati-on period 6 months	66 nursing home residents with DR (Norton scale over 15), 9 of 66 test subjects already had decubitus	Comparison between gel mattresses (33) and air overlay (softcare) (33)	Incidence of decubitus (inclu-ding stage 1), change in condition of wound in new and existing wounds Similar incidence in both groups, no difference in stage distribution of decubitus in both groups	Instruments: Norton scale
6.	(Roales-Welsch, Antaszek et al. 2000)	Comparative clinical trial, method study	23 healthy test subjects	Comparison between standard hospital mattress with a foam overlay and 5 special mattresses (soft support system and alternating pressure systems)	Overlay pressure measurement	Instruments: Pneumatic measure-ment system

2.3.4 Other studies

Table 3: studies that explore other outcomes besides the incidence or prevalence of decubitus

No.	Study	Methods	Sample	Interventions	Outcomes Results	Instruments Comments
1.	(Pring and Millman 1998)	Comparative clinical trial, randomised, observation period one week	39 rehabilitation patients, Waterlow scale over 15, no decubitus or no decubitus stage 2 or below	Comparison of effectiveness of Nimbus II, Pegasus Airwave, Quattro DC 2000	Pain, discomfort, significant differences between mattresses with respect to pain, comfort, sleep disturbances	Instruments: Waterlow scale, patient questionnaire (pain, discomfort), questionnaire for staff, questionnaire for researcher, all forms in the text

No.	Study	Methods	Sample	Interventions	Outcomes Results	Instruments Comments
2.	(Neander, Michels et al. 1996)	Comparative clinical trial, intervention study, not randomised, observation period 14 days	30 hospital patients, aged 22-76 , no fractures, no stomach injuries, prescribed bedrest, decubitus risk	Influence of soft support on the body. Comparison between control and experimental group. Support on anti-decubitus mattresses, received invalid exercise; the experimental group also received additional alternating washes, insertion of an anti-bedsore roll.	Body perception, posture and movement g In the control group patients forgot parts of the body, there were differences between the groups related to the tests, the intervention group was superior, no statistical analysis possible due to small sample size	Instruments: Drawing of own body diagram, nine-hole peg test, standing balance according to Bohannon, sitting balance according to Sandin and Smith, time walking test according to Butland Physical performance test according to Reuben and Sui, orthopaedic tests

2.3.5 Study methods

The approach and instruments of selected studies are presented in additional detail below. The focus of the studies is on the investigation of the effectiveness of decubitus treatment. Some of the studies reviewed both prevention and treatment possibilities of the pressure-relieving aids.

(Allman, Walker et al. 1987)

The control group received conventional therapy; support every 2 hours, cushions for elbows and heels, support on a vinyl alternate pressure mattress.

The experimental group lay on an air-fluidised bed, was supported every 4 hours between 7 a.m. and 11 p.m.

The same wound treatment was performed in both groups.

Data collection at the beginning: demographic data, consciousness level, activity, mobility, urine and bowel incontinence, nutrition status, decubitus characteristics, wound surface and colour photographs, pain, comfort, laboratory data. The data is then gathered on a weekly basis until discharge, death, healing of the wound, end of the study or at the request of the physician or patient. In addition the following information was recorded: support times, use of incontinence materials and influencing factors. Data collection probably undertaken by the researchers

- Norton scale was used to measure the level of consciousness, activity and mobility. No information on validity or reliability.
- Based on defined criteria the colour photographs (3 different lenses) were evaluated independently by a researcher and plastic surgeon for the appearance of changes (improvement) in the wounds. Inter-observer variability was calculated using the kappa statistic (85% agreement, kappa 0.87).
- The wound surface was recorded on the cling film and calculated using a "computerised digitiser". Reliabilitiy was checked by 2 researchers in the case of 19 patients, correlation coefficient 0.96, $p = 0.0001$.
- Pain scale validated at another point (questions in text, p. 642).
- Comfort scale (questions in text, p. 642), no information on validity and reliability. .

(Bennett, Baran et al. 1998)

The experimental group was supported by the low-air-loss hydrotherapy bed, the control group supported by all other available beds, skin care as usual.

Data collection standardised by research nurse and research technicians upon acceptance into the trial. They discussed care for each patient with the nurses on a daily basis (Monday to Friday), examined the skin 3 x during the first week, 2 x during the second week .

- Cumulative Illness Score: measurement of acute degree of disease
- Mini-Mental State Examination and Rancho Los Amigos Lever of Cognitive Functioning: Level of cognitive capacity
- Braden scale: decubitus risk
- Review of decubitus index: the deepest or largest decubitus ulcer Pressure Score Status Tool
- Circumference of wound on a foil and calculation using a sigma scan, from which stage can be determined (1 to 4), subsequently colour photograph
- Wound volume by weighing padding material
- Questionnaire for caregivers above the bed under study
- Questionnaire for patients supported by the bed under study (interviewed by researchers)

→ no information on validity or reliability, reference to literature

In the first phase of the project, the incidence of various skin lesions was reviewed / researched in order to obtain starting data.

(Devine 1995)

Data collection every 3 days for 4 weeks.

Data collection:

- Demographic variables and nutritional status, body size, weight, BMI, triceo skinfold thickness, upper arm circumference, haemoglobin, serum albumin, zinc, magnesium, transferrin, proteins, diagnoses
- Mental status: 10 point mental test
- Mobility status: 5 point scale (in text p. 94)
- Continence status
- Decubitus risk: Douglas and Norton scale
- Position of decubitus
- Decubitus stage: 5 stage classification
- Wound size: length and width
- Time out of bed
- Patient comfort and staff satisfaction: questionnaires with simple 10-point linear scale

→ no information on validity or reliability, reference to literature

A standardised prescription was issued for wound treatment, applicable to each patient.

Not clear who recorded the data.

(Evans, Land et al. 2000)

Data collection at the start of the study:

- Demographic information
- Number of decubitus ulcers

- Position of decubitus
- Stage of decubitus: 4 stage system
- Size of decubitus
- Modified APACHE scale: Acute Physiological, Age, Chronic, Health Evaluation, (in the text p. 7), not validated for this trial setting
- Waterlow scale,

→ no information on validity or reliability, reference to literature

Both groups already received established care and wound treatment according to special standards.

TVN collected data on position, stage and size of decubitus. Wound circumferences were recorded on a foil 2 x a week and then the wound surface area (WSA) calculated by computer. Two non-participating researchers calculated the WSA. Photographs were taken on a regular basis, improvement of the wound condition by the ulcer index as both absolute and relative reduction per day. TVN knew who lay on which mattresses. Patient comfort: 5-point scale (visual analogue scale), recorded on a weekly basis.

→ no information on reliability or validity

(Munro, Brown et al. 1989)

Data collection:

- demographic data
- decubitus size: in mm², recording of parameter on Saran wrap, then calculation using "digitiser tablet" and Zeiss MOP Videoplan
- decubitus stage (no indications)
- patient satisfaction: 8 item scale, developed for the study
- Pain: adaptation of Levitt and Derogatis scale (short description in the text)
- Adapted Gosnell scale
- Care time
- Wound treatment

→ no information on reliability or validity

Patients in the control group received the customary care, treatment care was not standardised. The decubitus size was measured on the 1., 3., 8. and 15. day.

Pain was measured on the 1., 3., 8. and 15. day of the trial, and recorded using the Gosnell scale as well.

Care time was recorded on the 8. day (typical day), also the aids for wound treatment.

It is possible that the experimental group did not receive any additional prevention.

(Warner 1992)

Data collection every 7 days by the researcher:

- Demographic data

- Physiological data: occurrence of oliguresis and wound infection, 1 x a week
- Laboratory data
- Braden scale, r = 0.96 in repeated measurements, weekly data collection

Decubitus data (foil, photos) collected on the same day as the demographic and physiological data by the researcher. The diameter, stage and surface area were calculated. The wound circumference was converted to wound surface using a digitiser (precise information in the text, reliability with 3 measurements of 5 decubitus, information in the text).

The researcher was convinced of the functioning capabilities of the mattresses studied. Wound care differed, depending on physician's instructions; control over these variables was based on researcher recommendations. The variable "support" could not be controlled, the patients were supported at the discretion of the nursing staff and standards. The researcher conducted randomised samples in order to record frequency of support.

→ no information on reliability or validity

(Wells and Karr 1998)

Part 1:

Researchers measure overlay pressure with Scimedics and JML overlay pressure evaluator.

Part 2:

Data collection by researcher:

- Demographic data
- Modified Yaws and Deruvo Pressure Score Risk Evaluation Tool: decubitus risk and decubitus occurrence
- International Association for Enterostomal Therapy (IAET) Pressure Ulcer Identification Standards: decubitus stage

  → no information on validity or reliability, reference to literature

- Wound healing in the case of non-flapped wounds:

  Measurement of wound size on a weekly basis by the researcher (length multiplied by width), high correlation of this measurement method with tracing and photos, r = 0.93; the wound healing rate calculated from this basis (description in the text)
- Wound healing in the case of flapped wounds:

  Measurement of wound healing on a weekly basis by the researcher and classificiation of wounds (1 to 4)

- Satisfaction:
  For staff: questionnaire with open and closed questions, survey after 6 weeks,
  For patients: questionnaires

→ no information on validity or reliability

- Costs: daily rate for the decubitus diagnosis x the length of time in prone position in days.

All patients received standardised wound treatment.

(Arblaster 1999)

Data collection:

- Initial assessment
- Demographic data
- Waterlow scale
- Weight, predisposition
- Decubitus: Position, stage (according to Stirling Pressure Sore Severity Scale) dimension, pain, wound condition, wound treatment
- Frequency of support and equipment required by nursing staff
- Time not in bed
- Type of current mattress
- Type of mattress recommended

→ no information on validity or reliability, reference to literature

Data collection by ward nurse and a viability nurse, after the first 24 hours and then every third day:

- Skin condition
- Assessment of decubitus: position, stage, duration, dimension, pain, wound condition, wound treatment
- Frequency of support
- Time out of bed and the required support
- Opinion of nursing staff (operation, safety, cleanliness)

→ no precise information on instruments used, etc.

(Gunningberg, Lindholm et al. 2000)

Data collection:

- Risk assessment scale (MNS)
- Decubitus classification (4 stages), description in the text p. 458; reliability of decubitus classification in current study at 0.86 (Cohen's Kappa)
- Decubitus position
- Haemoglobin, blood pressure, diabetes, smoking, physique, skin moisture level, time in OR

→ no information on validity or reliability, reference to literature

Data on the first two variables were recorded at the time of admission, upon arrival in the orthopaedic ward, on the 4th day after operating, at the time of discharge or 2 weeks after the operation. All ulcers were photographed, data collection conducted by the nursing staff or decubitus nurse.

At the time of discharge the patients were queried concerning comfort (see text p. 458), no information on validity and reliability.

Recording of preventative nursing measures occurred retrospectively by means of document analysis. Standardised care for all patients; nursing staff aware of which group patients belonged to.

(Knowles and Horsey 1999)

Data collection:

- Demographic data
- Waterlow-scale
- Weight
- Mobility and capability of moving in bed
- Time out of bed
- Pressure-reducing aids used
- Skin condition at beginning and end of study
- Stage and position of decubitus
- Changes in stage of decubitus and comments of patients and nursing staff (sample questions in the text p. 1394)

→ no information on instruments, no information on validity or reliability, reference to literature

Data collection by selected nursing staff, supported by the tissue viability CNSs.

(Lazzara and Buschmann 1991)

Data collection:

- Decubitus risk: a self-developed instrument (based on the Norton scale), recording by nursing staff at admittance and then every 3 months, no study of reliability, during the study only 40% of risk patients developed decubitus
- Decubitus assessment by researcher, direct observation, on a weekly basis, measurement of length and width of decubitus

(Pring and Millman 1998)

Data collection:

- Patient questionnaire on: pain (according to McGill), comfort, sleep disturbances, mattress movement and noise
  Indicated in the text, collected by project leader after one week.
- Staff questionnaire on: patients' pain, operation, comfort, sleep disturbances (indicated in the text).
  Questionnaire completed by the nursing staff in the presence of the senior nurse manager.
- Database questionnaire: basic information on patient such as demographic variables, Waterlow scale, Barthel index, mobility scale, cognitive capacity, decubitus classification. Collected by the project leader, indicated in the text.

→ no information on validity or reliability, reference to literature

Each patient lay on a study mattress for a week; after a week the patient and staff questionnaire was completed. It is not clear whether the basic data was recorded at the beginning of the study.

(Neander, Michels et al. 1996)

- Data collection: drawing of body diagram by patients before and after the 14 days of support, no assured instruments exist for the recording of body perception
- Measurement of posture and body movement:
  - Nine-hole Peg Test (NHPT): validity and reliability assured, description of test in the text, references to literature
  - Standing Balance according to Bohannon: no validity and reliability tests, references to literature
  - Sitting Balance Score according to Sandin and Smith: no validity and reliability tests, references to literature

- Time Walking Test according to Butland: reliable and valid, references to literature
- Physical Performance Test according to Reuben and Sui (PPT): investigated for reliability and validity, references to literature

- Orthopaedic tests: conducted by orthopaedists, on the 1st day after bed rest, followed by the 7. and 14. day

Both groups were bedded on super-soft mattresses and performed invalid gymnastics twice a day for 20 minutes.
The intervention group also received alternating washes 2 times a day of the body points known for faulty perception and a rolled cloth was inserted 3 times a day.
The patients were to draw their own body diagram at the beginning of the observation period as well as at the end (14 days).
It is not clear when the posture and body movement tests were conducted. The PPT was used on the 1., 7. and 14. day, orthopaedic tests on the 1. day without bed rest, then on the 7. and 14. day.

2.4 Summary of literature

The overview of studies on pressure-reducing systems shows three large groups: clinical trials with regard to prevention of decubitus and trials in connection with decubitus treatment and laboratory studies that indirectly pursue both goals (prevention and healing). The most frequent outcomes of the prevention studies are the incidence of new decubitus ulcers and the decubitus stage. The outcomes of treatment studies are the rates of healing of existing decubitus ulcers (complete healing, rate of change of wound, stage, size/surface). In addition the costs of aids, patient comfort, acceptance and sustainability of aids were mentioned as outcomes. Studies that investigate the effectiveness of pressure-reducing aids under laboratory conditions primarily measure overlay pressure, oxygen supply to the tissue and circulation in the body points exposed to decubitus.

Different instruments were used for the most frequent outcomes – "incidence" and "decubitus stage". For incidence, decubitus ulcers in stage 1 were recorded, as well as decubitus starting at stage 2. In some studies this information was completely lacking. It is not known how the reliability of recording of decubitus stage 1, which is difficult to identify, was assured. Usually there is a notation that data collection was performed by "experienced" nursing staff, experts or researchers. These problems are illustrated in the study of (Cooper, Gray et al. 1998), in which the incidence varied according to recording instrument between 7.4% and 1% (Shea vs. Stirling).

Control over external factors was also a problematic issue in interpreting results. In order to test for precise proof of effectiveness, control over the many possible risk factors in the occurrence of decubitus ulcers and the factors that have an indirect influence on the results (bias) is of great importance (Devine 1995; Bennett, Baran et al. 1998; Arblaster 1999).

The ethical problem of testing effectiveness of the differing systems was scarcely discussed. Most authors refer to the acceptance of the research design on the part of an ethics committee (Conine, Daechsel et al. 1990; Kemp, Kopanke et al. 1993; Hofman, Geelkerken et al. 1994; Devine 1995; Gray, Cooper et al. 1998; Land, Evans et al. 2000; Russell and Lichtenstein 2000). Only a few authors point out the ethical dilemma of comparative clinical trials. A direct comparison of aids by supporting patients at risk of decubitus on customary standard mattresses is not ethically justifiable in their opinion (Devine 1995; Hampton 1999). In order to mitigate the effect of study events on staff, caregivers were at times not informed as to which patient lay on which mattress. In part data collection was also performed by external resources or ward management "in the know" (Collier 1996; Cooper, Gray et al. 1998; Gray, Cooper et al. 1998).

RCTs are the gold standard for evaluation of pressure-reducing systems for (Gray and Campbell 1994). They result in the best evidence and clarify whether a product is truly effective (Gray, Cooper et al. 1998; Hampton 1999). (Hardin, Cronin et al. 2000) speaks out on behalf of prospective, experimental or quasi-experimental studies, too. It is important as part of this approach that additional control mechanisms for internal and external validity (besides randomisation) are observed (Bennett, Baran et al. 1998).

These comments are followed by recommendations from the basic literature:
For Whittemore measurement of the overlay pressure on the tissue is the most reliable and practical alternative for examining the potential of a pressure-reducing aid. The assumption that overlay pressure above 32 mmHg leads to tissue damage is generally accepted, with the marker functioning as predictor. The clinical studies that explore the capabilities of different systems in the form of an experiment have another practical quality. The most significant outcomes of these studies are the incidence and change in wounds (Whittemore 1998).

(Cullum, Deeks et al. 2000) recommend independent, well-designed, multi-sentry RCT's for additional research in the field of pressure-reducing systems. Randomisation, sample size and clear criteria play a primary role in measuring outcomes. The most beneficial approach is when data collection is "blind", i.e.

with no information provided to the individuals providing ratings. The studies should also exhibit adequate observation periods and appropriate statistical analysis.

The Royal College of Nursing guidelines explicitly recommend multi-sentry RCTs for further research in the field of pressure-reducing aids. Only such studies permit assertions to be made on the clinical use and cost effectiveness of the various aids. The following objectives should be pursued in these studies (RCN 2000):

- Comparison between alternating pressure aids and other high-tech systems (low air-loss and air-fluidised bed)
- Comparison between alternating pressure mattresses and cheaper alternating pressure overlays
- Alternating pressure aids with fewer technical alternatives, such as different types of foam mattresses.

3 Study objectives and question formulation

The objective of the planned study is to provide proof of therapeutic effectiveness for the multimodal therapy concept in individuals with decubitus ulcers by showing that patients supported on REPOSE evidence better wound healing.

The favourable impact on both mobility and comfort should also be described.

1. **For which patient groups is REPOSE appropriate**?
2. **Is REPOSE superior to the small-cell alternating pressure systems?**
3. **Is the use of REPOSE equivalent to the use of large-cell alternating pressure systems?**

The following hypotheses may be generated from the questions above:

- Patients supported by REPOSE experience higher comfort levels than patients supported by another of the systems included.
- The use of the REPOSE system incurs lower costs than the use of other systems included.
- Patients supported by REPOSE experience significantly lower wound surfaces in square cm or a decrease in the wound depth.
- Patients supported by REPOSE experience a decrease in decubitus stage (according to Shea).
- Patients supported on REPOSE experience potential healing of existing decubital ulcers over a shorter period of healing.

4 Design and course of study

The study was conducted according to a randomised, comparative and explorative design.

4.1 Design

All available patients and residents who met the inclusion criteria were included in the study for a period of nine months. Measurement occurred over a maximum of 28 days. All patients were supported either by the REPOSE system or by small or large-celled alternate pressure systems.

Sample and study framework

Inclusion criteria for the acceptance of patients in this study included the following factors:

- Patients with decubitus ulcers in the 2. or 3. stage at points typical for decubitus
- Geriatric patients or those with neurological illness or patients undergoing operations
- Patient care occurring in a residential home for the elderly, a hospital or an ambulatory setting
- Age >18 years

Exclusion criteria were:

- Consent not given
- Capacity for consent lacking in patients, residents or staff
- Moribund patients
- Decubitus ulcers only on the heel or the back of the head

The intention was to include a total sample of 60 patients or more. This sample size estimate is based on a practical assessment of the maximum number of patients that can be included under this study. This assessment is founded on the following hypothetical assumptions:

- The Frontier Therapeutics provides 25 REPOSE systems.
- A maximum measurement period of 28 days is conducted per patient.

The study managers recruit the different study locations.

4.2 Criteria for terminating the study

a) For the study as a whole

Due to the descriptive and explorative design of the study, as well as its 'pilot' nature, no termination criteria have been formulated for the study.

b) For individual patients

The study was terminated on the part of the research group, if the following criteria arose:

- Decubitus ulcers healed
- Severe complications (transfer to intensive care unit)
- Obvious deterioration in the condition of the wound
- Death of patient

5 Instruments

The following instruments were selected based on an analysis of the literature:

5.1 Measurement of decubitus ulcers

- **Braden scale**

The Braden scale provides a prediction or assessment in clinical practice. It is based on a theoretical model of the aetiology of the decubitus ulcer. It includes six categories with one to four points each; a low number of points indicates high risk (see attachment). The criteria "sensory capacity", "skin moisture level", "activity", "mobility", "nutrition", "friction/shear stress" result in a comprehensive assessment of condition. Reliability of the Braden scale is high for nursing staff that have not been specially trained (Braden 2001). The Braden scale is used at the time the patient is assessed as well as at the end of the study.

- **Photo documentation**

Photographic documentation is undertaken using a digital camera according to a standardised process (distance from wound, lighting, size and date information) at the beginning and end of the study period. The analysis is undertaken blind by expert questioning.

- **Standardised wound documentation sheet**

At least at the beginning and end the following parameters are determined using uniform documentation sheets with pre-structured contents: the size of the wound, the depth of the wound, a description of the edge of the wound (parameters provided to be ticked), condition of the wound, surrounding skin, therapy performed, possible complications of the wound, general condition (e.g. fever, administration of cortisone, antibiotics, etc.).

- **Patient data**

The following standardised patient data is recorded to the extent possible for evaluation purposes:

- Age
- Gender
- Weight and height if possible
- Possible amputation of legs
- Medical details such as diagnoses or main focus of disease pattern.

- **Comfort**

The subjective comfort of the patient group included is established using a five-point assessment similar to the Likert scale, in which the comfort dimensions of "very good", "good", "moderate", "poor" and "very poor" are provided. Patients included who are known to suffer from dementia are not included in this series of questions due to insufficient reliability and comparability of data (bias)[5].

- **Side effects**

The group included is also questioned on the description of any possible side effects at the last measurement point. Noise and movement is recorded qualitatively and quantitatively using the Likert scale presented above.

[5] Commentary bias= Distortion (of results)

The following table shows the measurement cycles described:

Instruments	Starting data recorded	Daily	Weekly	Final data recording
Demographic data	x			
"Medical data"	x			x
Braden scale	x		x	x
Photo documentation	x		x	x
Depth of wound	x			x
Standardised wound documentation sheet	x		x	x
Standardised questionnaire (comfort, noise, movement)		x		x

Table 4: Instruments

6 Data analysis

Procedures in descriptive and inferential statistics are used in the context of this study. Analysis of interrelationships and hypothesis-generating questions are in the forefront. Numerical results are supplemented by diagrams where appropriate.

All inferential statistical analyses are only performed in an explorative descriptive sense and always bilaterally with $\alpha = 0.5$ for every test conducted. An α adjustment is not performed. This applies in particular to auxiliary questions formulated, since clear and significant results cannot be expected due to the pilot nature of the study and the consequently small sample size.

Changes in the size and depth of the wound are measured in both absolute and relative units (in percentage). Confidence intervals serve to complement key statistics.

The main target criterion in this study – healing rate or healing tendency – is analysed in an explorative descriptive sense.

Confidence intervals serve to complement key statistics.

On an individual basis, depending on the questions, the level of data and the distribution the following parametric and non-parametric approaches are considered primarily – chi-square or the exact Fischer test, Mann-Whitney-U-Test, Wilcoxon Test logistical regression and/or variance analysis with repeated measurements.

Drop-outs are listed with the time and reason for termination.

7 Ethical considerations

7.1 Risks

No risks are anticipated during the study, since only standardised observation and collection of medical data is involved. No additional invasive measures are initiated. Medical therapy is unaffected. The REPOSE system is an aid in decubitus prevention and therapy that has already been clinically tested. Up to this point, however, no assured study results from different settings have been available.

7.2 Volunteer nature and informed consent

Participating patients or residents received detailed information prior to the start of the study on its contents and on product intervention. The patients and caregivers were advised that they could decide themselves whether they wished to participate in the study. Non-participation entailed no consequences (e.g. in therapy) nor reduction of benefits. Moreover, participants and caregivers could terminate their participation in the study at any time.

In order to ensure anonymity of patient data during the clinical survey the following procedure was adopted: to identify individual patients during clinical data collection patient identification was affixed only to the first page of the set of research instruments. In addition a three-digit code was recorded at the same spot for each patient; this code was documented on each instrument. Data recorded remained in the patient or resident dossier throughout the period of measurement time. After being transferred from the hospital/nursing home data was kept in a location accessible only to those responsible for the study in the clinic or nursing home. Additional patient data with the code was transmitted to the research group for evaluation after the measurement period had finished.

The approval of the ethics committee responsible at the Universität Witten-Herdecke was obtained in advance of the planned study.

8 Results

This study examined the effectiveness of a system of decubitus prevention and therapy. Data collection extended through the period from December 15th, 2003, until September 9th, 2004. Measurement locations included hospitals, in-patient facilities for seniors and out-patient nursing centres. We wish to thank the following institutions for their support:

- Klinikum Nürnberg
- Eilenriedestift e.V., Hannover
- Neanderklinik Harzwald GmbH Ilfeld/Südharz
- Caritas Altenpflegeheim St. Gallus e.V. , Zell a.H.
- Pflegezentrum Heimfeld, Hamburg
- Pro Vita, Neuwulmstorf
- Pro Seniore Residenz Posthof, Göttingen
- Haus St. Benedikt, Recke
- Marienkrankenhaus Wesel
- Klinikum Quedlinburg
- Ambulanter Pflegedienst der WBG Süderelbe e. G. , Hamburg
- Stiftungsdorf Osterholz, Bremen
- Ella –Ehlers-Haus, Bremen

During this time a total of 50 patients were included in the study based on the criteria set out. The entire test period amounted to 157 weeks, with the structure of the sample group and the study location of greatest relevance.

An additional 5 patients had been included in the study, but were excluded from the analysis since the period of observation was too short in their cases.

- Termination after 4 days due to a transfer (small-cell system)
- Termination after 1 day due to significant deterioration of overall condition (REPOSE)
- Termination after 0 or 1 day due to death of patient (Normal mattress and REPOSE respectively)

- Termination after 0 days, since patient revoked his consent (REPOSE)

Of the 50 patients included in the data analysis 82% (n = 41) extend throughout the entire data collection period of respectively 4 and 2 weeks (hospital). It was possible to collect data throughout at least half of the planned study period in the case of 47 patients (94%).

		Frequency	Percent
Valid	1	6	12.0
	2	12	24.0
	3	1	2.0
	4	31	62.0
	Total	50	100.0

Table 1: Study duration in weeks

The study had to be terminated prematurely in the case of 9 patients. The reasons were:

- in 2 cases due to operations (after 3 and 2 weeks respectively) - small-cell system and REPOSE respectively
- in 3 cases due to transfer (in each case after one week) (2 x REPOSE, 1 x small-cell system)
- in 3 cases the patient died (2x after 1 week and 1 x after 2 weeks) (small-cell system, large-cell system, REPOSE)
- in 1 case the patient asked for termination (after 1 week) (small-cell system)

As a result 50 data sets are available for analysis.
During the entire observation period

28 measurements on the REPOSE system
10 measurements on large-cell systems
12 measurements on small-cell systems

were conducted (see table 2). The following analysis thus describe the group of 50 patients able to be included.

		Frequency	Percent
Valid	Repose system	28	56.0
	Small-cell systems	12	24.0
	Large-cell systems	10	20.0
	Total	50	100.0

Table 2: Support on different aids

8.1 Age of sample group

The following table 3 and diagram 1 show the age distribution of the group. It is particularly noteworthy that the overwhelming majority of the group are 80 years of age or above.

		Frequency	Percent	Valid per-centages	Accumulated percentage
Validity	<70	13	26.0	26.0	26,0
	70 to 74	3	6.0	6.0	32.0
	75 to 79	5	10.0	10.0	42.0
	80 to 84	8	16.0	16.0	58.0
	85 to 90	10	20.0	20.0	78.0
	>90	11	22.0	22.0	100.0
	Total	50	100.0	100.0	

Table 3: Age in years

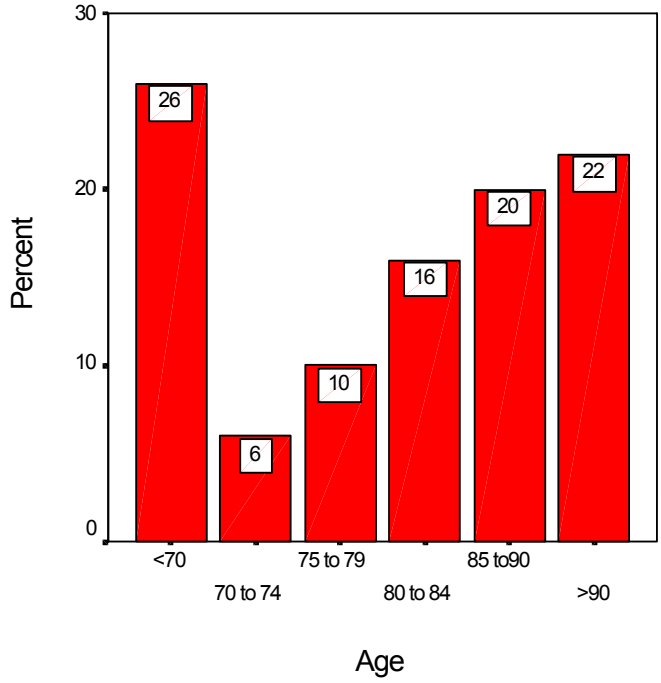


Diagram 1: Age in years

Table 4 below shows the age distribution taking into account the support aids allocated to the group

			Support aids			
			Repose system	small-cell systems	Large-cell systems	Total
Age	<70	Number	7	2	4	13
		%	25.0%	16.7%	40.0%	26.0%
	70 to 74	Number		2	1	3
		%		16.7%	10.0%	6.0%
	75 to 79	Number	3	1	1	5
		%	10.7%	8.3%	10.0%	10.0%
	80 to 84	Number	3	3	2	8
		%	10.7%	25.0%	20.0%	16.0%
	85 to 90	Number	7	2	1	10
		%	25.0%	16.7%	10.0%	20.0%
	>90	Number	8	2	1	11
		%	28.6%	16.7%	10.0%	22.0%
Total		Number	28	12	10	50
		%	100.0%	100.0%	100.0%	100.0%

Table 4: Age and support aids

A comparison of the group under 74 years of age shows that in the REPOSE group 25% are under 74, in the small-cell group 33% are under 74 and in the large-cell system 50%. 53.6% of the RE-

POSE group, 33% of the small-cell systems group and 20% of the large-cell systems are in the age group of 85 years and above. On the whole the differences are not significant; however, it should be recognised that the REPOSE group is older in average than the residents/patients on the large-cell systems.

8.2 Gender in sample group

In total 35 women (70%) and 14 men (28%) participated in the study[6]. This corresponds to the usual breakdown of patients suffering from decubitus. Table 5 shows the distribution on support aids. This distribution is not significant according to the exact Fischer test (p=0.33).

		Gender		
		Female	Male	Total
Repose system	Number	22	6	28
	%	78.6%	21.4%	100.0%
Small-cell systems	Number	6	5	11
	%	54.5%	45.5%	100.0%
Large-cell systems	Number	7	3	10
	%	70.0%	30.0%	100.0%
Total	Number	35	14	49
	%	71.4%	28.6%	100.0%

Table 5: Gender taking into account support aids

8.3 Number of wounds

The main target criterion of this study, the healing rate or healing tendency of existing wounds according to the criteria established in the study design is described below.

60 wounds were determined in the entire sample group of 50 patients during the measurement interval. Three wounds were determined in one patient. Eight patients complained of two wounds and 41 patients evidenced one wound (refer to Table 6).

[6] In the case of one patient the gender could not be established post facto.

		Frequency	Percent	Accumulated Percentage
Valid	1	41	82.0	82,0
	2	8	16.0	98.0
	3	1	2.0	100.0
	Total	50	100.0	

Table 6: number of wounds

Of a total of 28 patients supported on the REPOSE system, 23 patients had one wound, 4 patients had 2 wounds and 1 patient three wounds. Of the twelve patients on small-cell systems 10 had one wound and two patients evidenced two wounds.

Of a total of 10 patients supported on large-cell systems, 8 patients had one wound and 2 patients suffered from two wounds (Table 7).

Based on both appearance as well as the exact Fischer test (p=0.93) there are no identifiable differences in the support system with respect to the number of wounds.

		Number of wounds			Total
		1	2	3	
Repose system	Numberl	23	4	1	28
	%	56.1%	50.0%	100.0%	56.0%
Small-cell systems	Numberl	10	2		12
	%	24.4%	25,0%		24.0%
Large-cell systems	Number	8	2		10
	%	19.5%	25.0%		20.0%
Total	Number	41	8	1	50
	%	100.0%	100.0%	100.0%	100.0%

Table 7: Number of wounds according to support system

8.4 Duration of wounds

In the case of 43% of all patients the skin defect had already existed for longer than two months (Table 8).

		Frequency	Percent	Valid percentages	Accumulated percent
Valid	Less than 1 week	5	8.3	8.6	8.6
	1 to 4 weeks	28	46.7	48.3	56.9
	>4 to 8 weeks	6	10.0	10.3	67.2
	>8 to12 weeks	1	1.7	1.7	69.0
	Over 12 weeks	18	30.0	31.0	100.0
	Total	58	96.7	100.0	
Missing	system	2	3.3		
Total		60	100.0		

Table 8: Existing duration of wounds

When comparing the wound duration between the support systems, it is clear that patients on large-cell support aids are noteworthy for a long wound duration of more than 12 weeks (Table 9). This difference is significant at p=0.006 according to the exact Fischer test as well.

This highly striking finding can be traced to the fact that patients were only supported on large-cell systems for a certain period of time after the occurrence of a chronic wound. In connection with the relatively short wound duration in patients on small-cell systems, it is apparent that patients with long-term wound duration are already being cared for "optimally", i.e. on large-cell systems. It would be in direct opposition to state-of-the-art wound treatment to support these patients on small-cell systems.

The "excessive coincidence" of lengthy wound duration in large-cell systems in this study, particularly in contrast to the REPOSE system, does not mean that the randomisation has failed, but is a result of the study design. For ethical reasons randomisation in this study occurred only between "previous system" and REPOSE. In the case of patients, therefore, with wounds of lengthy duration and consequently a preferred support on large-cell systems, randomisation was as a rule selected only between REPOSE and the previous large-cell system. This factor is also indicated in the balanced ratio of 8:8 in the case of REPOSE and the large-cell systems.

Naturally as a result many patients with wounds of short duration also lie on REPOSE. In order to assess success rates, in addition to an analysis of the group as a whole, a specific comparison of "long-term patients" is always undertaken as well.

		Support aids			
		Repose System	small-cell systems	Large-cell systems	Total
Less than 1 week	number	2	2	1	5
	%	5,9%	14.3%	10.0%	8.6%
1 to 4 weeks	number	17	10	1	28
	%	50.0%	71.4%	10.0%	48.3%
>4 to 8 weeks	number	6			6
	%	17.6%			10.3%
>8 to 12 weeks	number	1			1
	%	2,9%			1.7%
Over 12 weeks	number	8	2	8	18
	%	23.5%	14.3%	80.0%	31.0%
Total	number	34	14	10	58
	%	100.0%	100.0%	100.0%	100.0%

Table 9: Duration of wound according to support system

Taking into account only the long-term patients in the case of REPOSE and the large-cell systems, the patients supported by REPOSE have a tendency to be older (75% older than 85 in the case of REPOSE as opposed to 14.3% in the case of large-cell systems). This difference, however, is not significant (p= 0.16).

8.5 Wound stage

The 60 wounds of the 50 patients are distributed primarily in the development stages II and III as shown in the table below.

		Frequency	Percent	Valid percentages	Accumulated percent
Valid	Stage 2	24	40,0	40,7	40.7
	Stage 3	27	45,0	45.8	86.4
	Stage 4	8	13.3	13.6	100.0
	Total	59	98.3	100.0	
Missing	System	1	1.7		
Total		60	100.0		

Table 10: Presentation of wounds in stages

An indication of whether a correlation exists between the support system in the selected randomised, comparative and explorative design and the stage of the wound, in particular with regard to healing tendencies, is mandatory. The study investigations do not show a significant difference in this respect (refer to Table 11) – exact Fischer test p = 0.78. A direct comparison between both REPOSE and small-cell systems (Mann Whitney p= 0.96) as well as large-cell systems also reveal no significant differences (p = 0.84).

		Support aids			
		Repose system	small-cell systems	Large-cell systems	Total
Stage 2	Number	15	5	4	24
	%	44.1%	38.5%	33.3%	40.7%
Stage 3	Number	13	7	7	27
	%	38.2%	53.8%	58.3%	45.8%
Stage 4	Number	6	1	1	8
	%	17.6%	7.7%	8.3%	13.6%
Total	Number	34	13	12	59
	%	100.0%	100.0%	100.0%	100.0%

Table 11: Stage of wound according to support system determined

8.6 Wound sites

The 60 skin defects detected were located at the primary clinical body sites as shown in Table 12 and Diagram 2 below.

		Frequency	Percent
Valid	Sacral bone	17	28.3
	Coccyx	20	33.3
	Ischium	10	16.7
	Heel	12	20.0
	Tochanter	1	1.7
	Total	60	100.0

Table 12: Wound sites

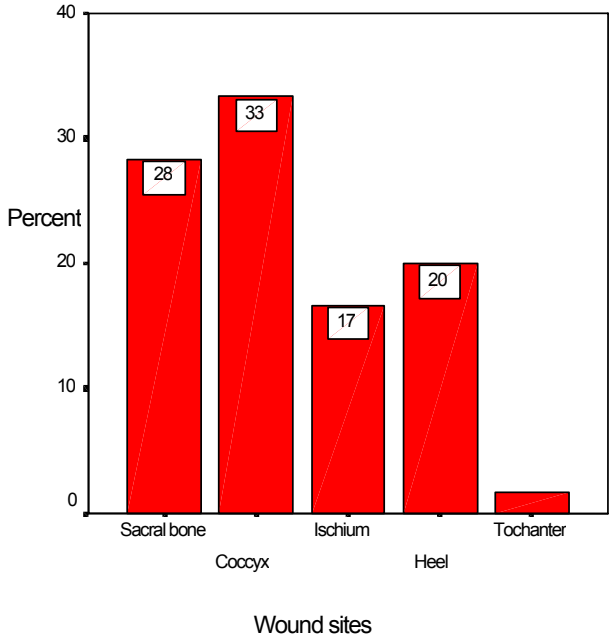


Diagram 2: Wound sites

8.7 Prognosis of overall condition

No correlation with the support aid can be discerned from the perspective of professional nursing staff in the prognosis of overall condition described at the beginning (exact Fischer test p = 0.74).

			Support aids			
			Repose system	kleinzellige systems	Large-cell systems	Total
Prognosis Overall condition	Improvement	Number	7	2	4	13
		%	25,9%	22.2%	40.0%	28.3%
	Deterioration	Number	5	3	1	9
		%	18.5%	33.3%	10.0%	19.6%
	Unchanged	Number	15	4	5	24
		%	55.6%	44.4%	50.0%	52.2%
Total		Number	27	9	10	46
		%	100,0%	100.0%	100.0%	100.0%

Table13: Prognosis of overall condition and support system

The BRADEN scale values recorded at the beginning of the trial are summarized in Diagram 3. Patients supported on large-cell systems tend to have lower values. These are, however, not significant compared to patients who are supported on REPOSE. (Mann Whitney p=0.075). If only patients with a wound duration of over 12 weeks are taken into account, the difference between REPOSE and the large-cell systems decreases slightly (Mann Whitney p=0.15). In particular in the case of REPOSE the median drops from 14 to 13.5 points.

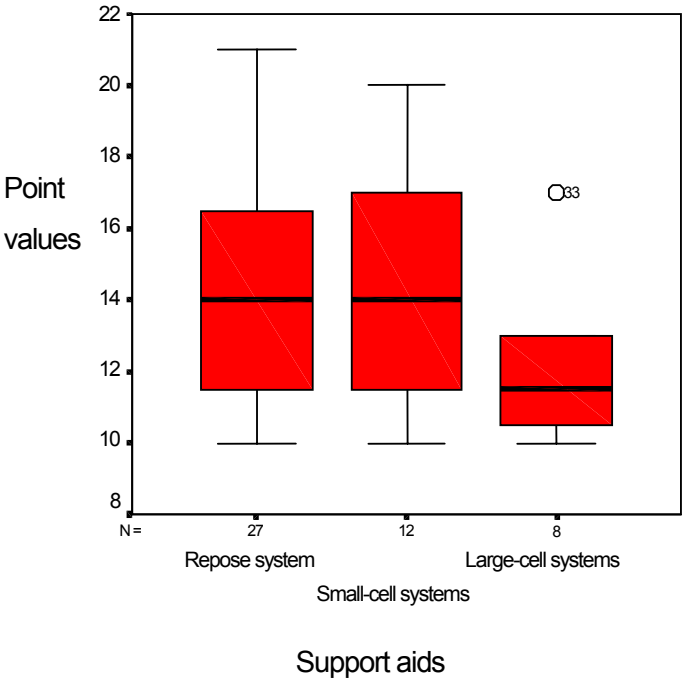


Diagram 3: Braden points with respect to support aids

8.8 General wound healing

The complete healing of one wound was observed in the case of 8 individuals with a total of 11 wounds (7 women, 1 man; all in a nursing home). 7 of those 8 residents whose wound healed were supported on REPOSE, 1 resident on the large-cell system. All those concerned had a skin defect in stage 2. In 7 of these case the wounds were relatively recent (3 wounds less than 1 week and 4 between 1 and 4 weeks) and only in 1 case was a wound involved which had persisted for more than 12 weeks and for which the REPOSE support was used. The wound of the single patient not supported on REPOSE that healed had existed for less than 1 week.

In the area of out-patient care a patient on a small-cell system developed an additional wound after 1 week (stage 3), which did not heal even during the subsequent course of the study. This new occurrence was a unique event. According to the study protocol the observation and analysis of wound development refers only to such wounds as already existed at the start of the study, so this new wound was not taken into further consideration in the study and therefore does not carry any further weight in the evaluation of small-cell systems.

Table 14 below shows that, of 34 wounds belonging to patients supported by REPOSE, every 5th was healed, while only every 12th was healed in the large-cell systems and none in the small-cell systems. Seen as a whole and given the sample size these results do not yet differ significantly (chi square p=0.16).

		Wound healed		
		No	yes	Total
Repose system	Number	27	7	34
	%	79.4%	20.6%	100.0%
Small cell systems	Number	14		14
	%	100.0%		100,0%
Large cell systems	Number	11	1	12
	%	91.7%	8.3%	100.0%
Total	Number	52	8	60
	%	86.7%	13.3%	100.0%

Table 14: Wound healing according to support system

In a direct comparison of REPOSE with small-cell systems the significance level of 5% is only just missed (chi square p= 0.09). This comparison does not take into account that only 21% of patients on small-

cell systems have had a wound lasting more than 4 weeks, while 43% of patients on REPOSE fall into that category. Similar differences arise with respect to wound stage. If only comparable patients with a wound duration of no more than 4 weeks and wound stage of no more than 3 are taken into account, then the significance is just barely missed for these patient numbers, as well, at p = 0.051.

		Wound healed		
		No	yes	Total
Repose system	Number	9	6	15
	%	60.0%	40.0%	100.0%
Small cell systems	Number	10		10
	%	100.0%		100.0%
Total	Number	19	6	25
	%	76.0%	24.0%	100.0%

Table 15: Wound healing according to support system in patients with a wound duration of maximum 4 weeks and a wound stage of maximum 3.

8.9 Weekly changes in wounds

At the end of every week the wound was assessed to ascertain improvement, deterioration or unchanged condition.

The change in wound status or healing process is defined as the proportion of data collection intervals at which an improvement of the wound could be determined by an external, 'blind' expert (see also the photographs starting on page **70**). If an improvement was noted in three of four weekly data collection points, this results in a "wound improvement ratio" of 75%. It should be noted that this applies regardless of whether at other times deterioration in the wound was registered or if the wound development was described as unchanged. Table 16 shows that in the case of 9 wounds no improvement was seen at any data collection point in time.

		Frequency	Percent	Accumulated Percent
Valid	0%	9	15.0	15.0
	25%	3	5.0	20.0
	50%	14	23.3	43.3
	75%	8	13.3	56.7
	100%	18	30.0	86.7
	Wound healed	8	13.3	100.0
	Total	60	100.0	

Table 16: Share of weekly wound improvements in percent

Table 17 shows the relationship between weekly improvements and current support aids. Significant differences in the healing process can be noted with respect to the three support aids (exact Fischer test p = 0.012).

Bivariate analysis between REPOSE and the small-cell systems shows the clear superiority of REPOSE (exact Fischer test p = 0.009 and p = 0.001 according to MannWhitney-U-Test, which takes into account the ordinal character of the target variables).
A significant difference between large and small-cell systems cannot be confirmed in this case (p = 0.167) and should surely be sought in the patient group with the "worse wounds".

		Repose system	Small-cell Systems	Large-cell systems	Total
0%	Numberl	2	6	1	9
	%	5.9%	42.9%	8.3%	15.0%
25%	Number	1		2	3
	%	2.9%		16.7%	5.0%
50%	Number	6	3	5	14
	%	17.6%	21.4%	41.7%	23,3%
75%	Number	4	3	1	8
	%	11.8%	21.4%	8.3%	13.3%
100%	Number	14	2	2	18
	%	41.2%	14.3%	16.7%	30.0%
Wound healed	Number	7		1	8
	%	20.6%		8.3%	13.3%
Total	Number	34	14	12	60
	%	100.0%	100.0%	100.0%	100.0%

Table 17: Relationship between weekly wound improvement and support aids

The significant difference between REPOSE and large-cell systems (exact Fischer test p = 0.025) is probably based on such patient differences. If one takes into account only such wounds that have existed for more than 12 weeks (Table 12), no significant difference can be shown between REPOSE and the large-cell systems in the smaller sample (exact test according to Fischer p = 0.765 and Mann-Whitney-U p = 0.212).

This finding does not in a strict scientific sense replace equivalence or non-inferiority studies. Given the necessary sample size in this study, this was not the intention.
In view of the share of positive wound changes, however, REPOSE is clearly superior to the small-cell systems and comparable to the large-cell systems.

		Repose system	Large-cell systems	Total
0%	Numberl		1	1
	%		12.5%	6.3%
25%	Number	1	1	2
	%	12.5%	12.5%	12.5%
50%	Number	1	3	4
	%	12.5%	37.5%	25.0%
75%	Number	3	1	4
	%	37.5%	12.5%	25.0%
100%	Number	2	2	4
	%	25.0%	25.0%	25.0%
Wound healed	Numberl	1		1
	%	12.5%		6.3%
Total	Number	8	8	16
	%	100.0%	100.0%	100.0%

Table 18: Relationship between weekly wound improvement and support aids in the case of wounds that have already been in existence for more than 12 weeks.

In order to more easily evaluate the different wound healing processes, we will summarize them in stages:

1. *Optimum success :* wound healed within the study time frame
2. *Good success:* wound develops positively in at least 75% of wound observations (3 of 4 or all wound status data collection points are positive)
3. *Poor success:* wound improvement recorded only in every 2nd data collection

Table 19 and Diagram 4 illustrate the relationship between wound healing success and the support system.

		Repose system	Small-celll systems	Large-cell systems	Total
Poor success	Number	9	9	8	26
	%	26.5%	64.3%	66.7%	43.3%
Good success	Number	18	5	3	26
	%	52.9%	35.7%	25.0%	43.3%
Optimum success	Number	7		1	8
	%	20.6%		8.3%	13.3%
Total	Number	34	14	12	60
	%	100.0%	100 .0%	100.0%	100.0%

Table 19: Wound healing success according to support system (p = 0.032)

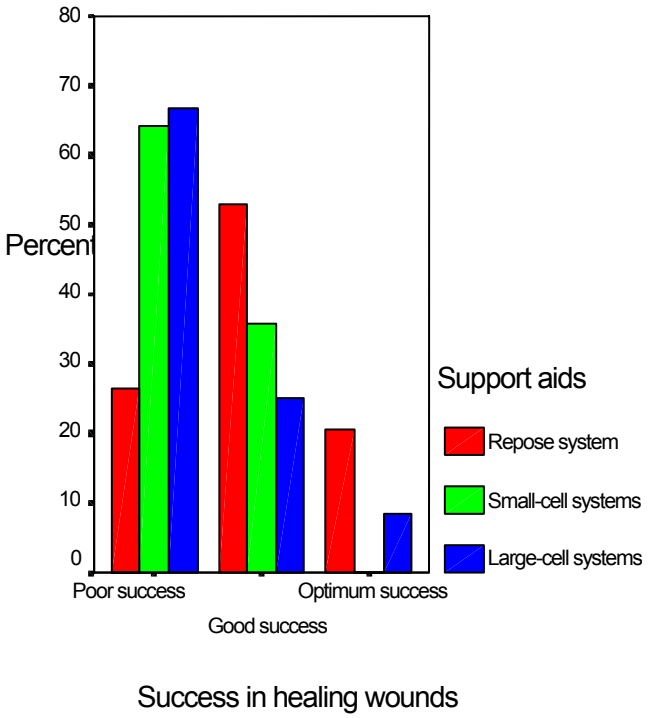


Diagram 4: Wound healing success according to support aids

While 91% of the wounds in patients supported on REPOSE showed no deterioration at any data collection point, this was the case in only 57% of wounds with small-cell system support and only 50% of wounds with large-cell system support (Diagram 5). These differences, too, prove to be significant with p = 0.003 (exact Fischer test).

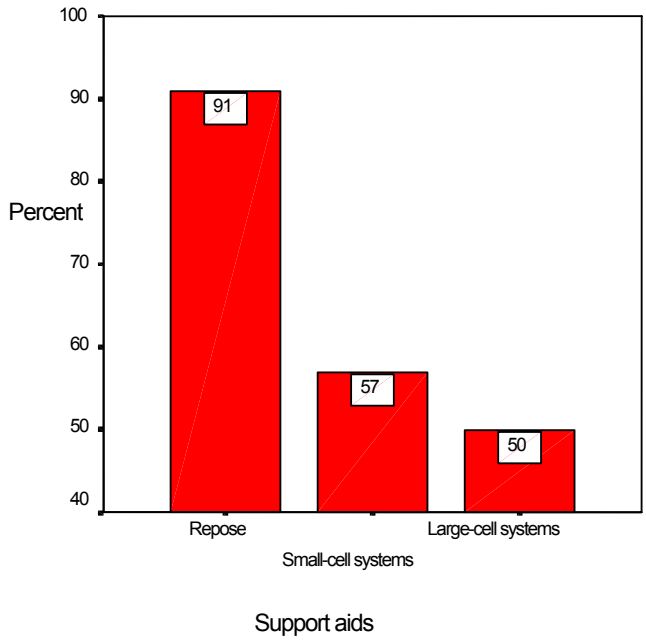
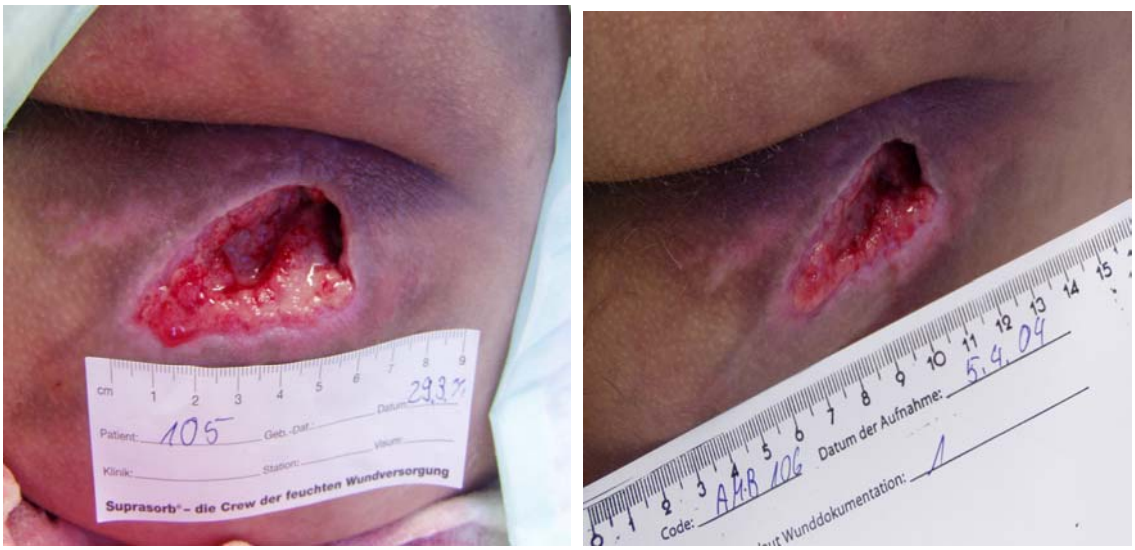


Diagram 5: Proportion of wounds in which no deterioration occurred

Bivariate analysis between patients supported on REPOSE and those on small-cell system showed a significant superiority of REPOSE in contrast to small-cell systems (exact Fischer test p = 0.012). As already described above a superiority of REPOSE over the large-cell systems is also perceptible (p = 0.005). This does not exist, however, if only wounds older than 12 weeks are taken into account (p = 0.120). In this case, wound deterioration was not noted at all in 7 of 8 wounds using the REPOSE system, but in only 3 of 8 wounds in the large-cell systems.

The photographs below chronologically show the healing tendency of wounds in 5 patients supported on REPOSE.



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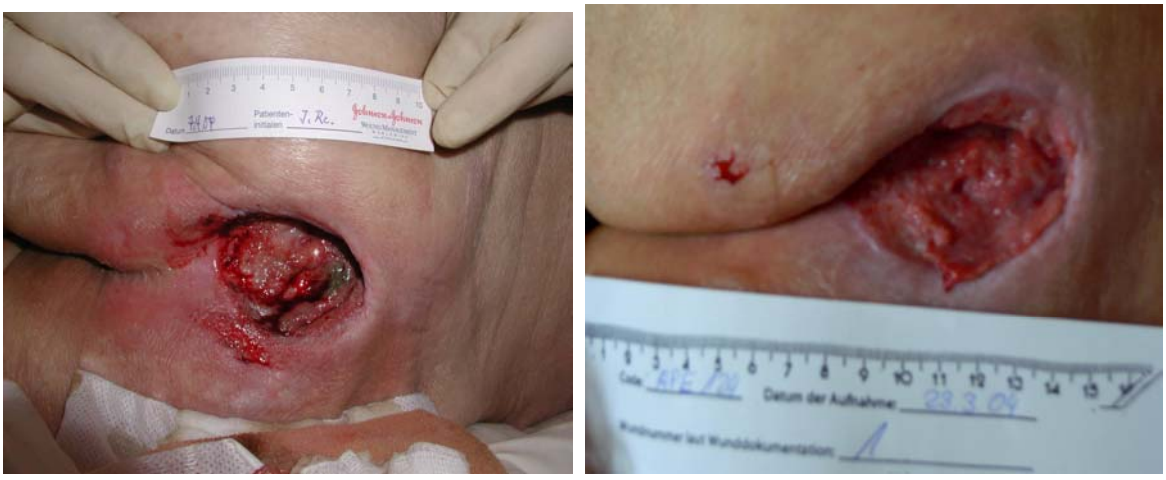

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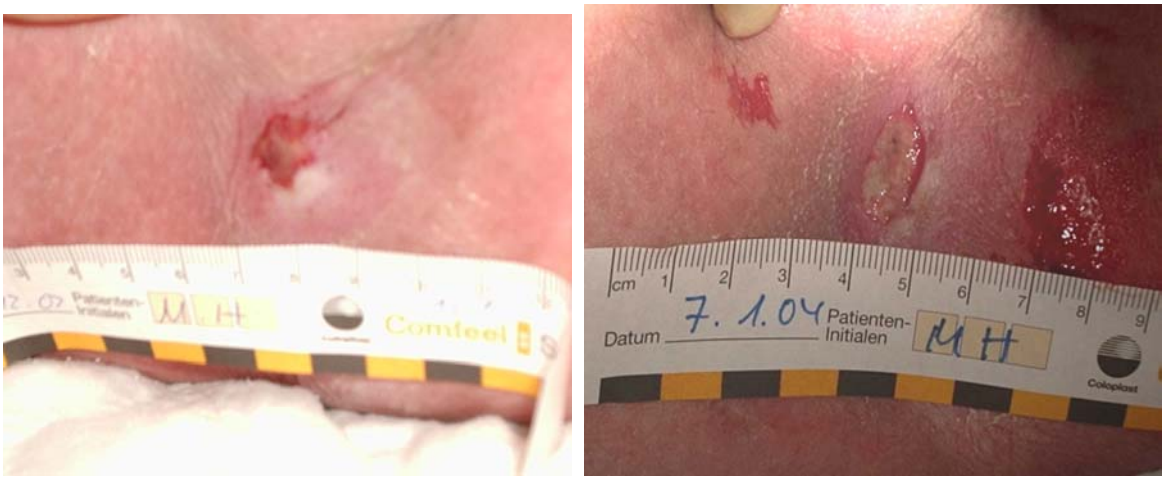

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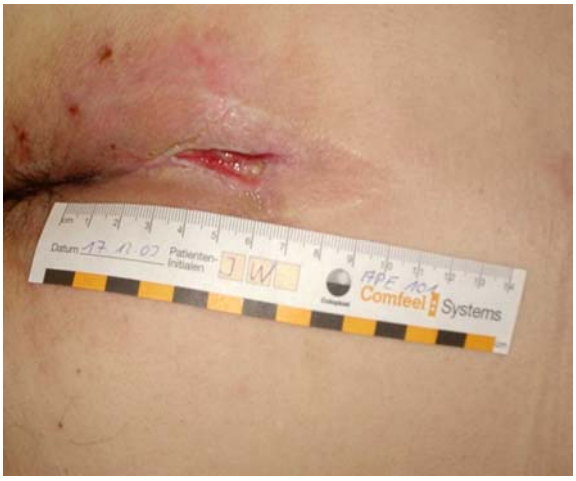

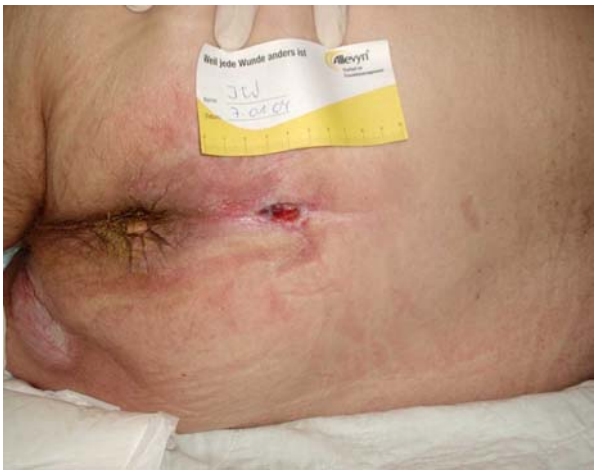

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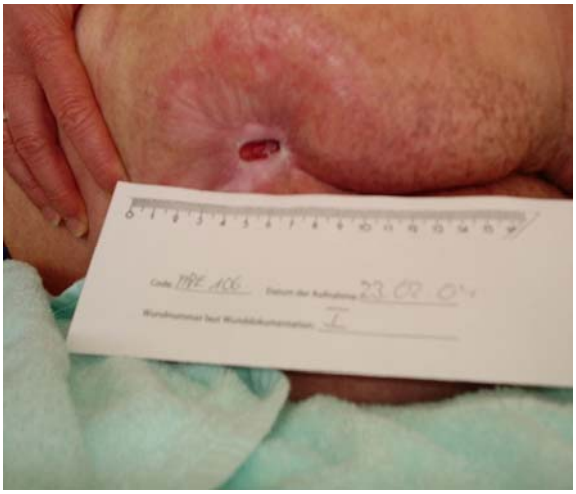

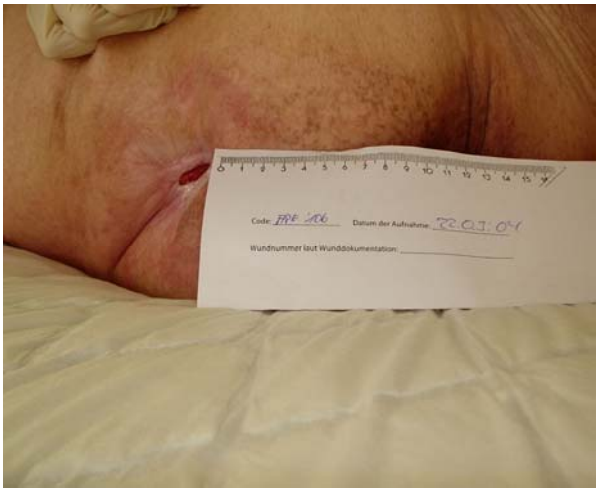

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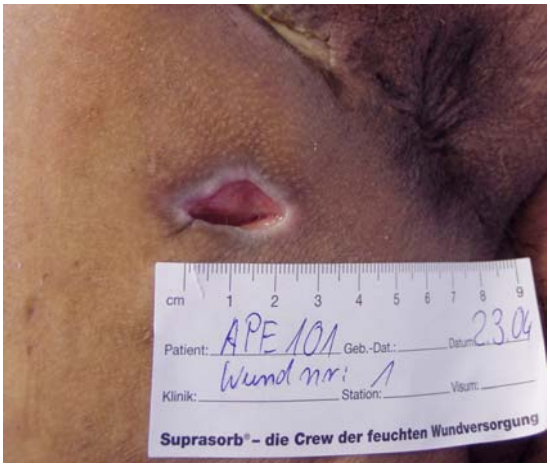

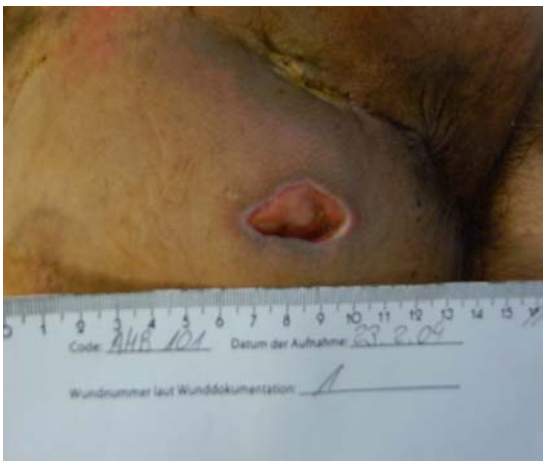

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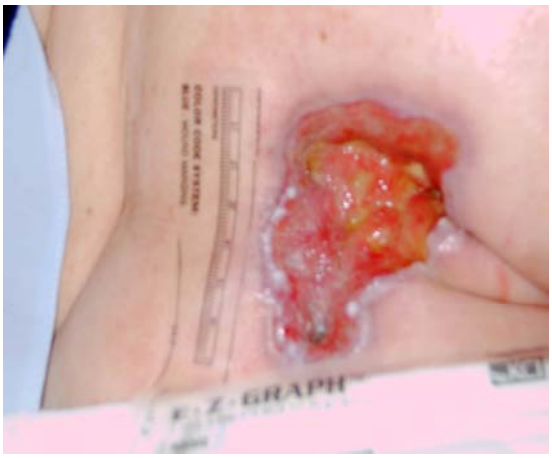

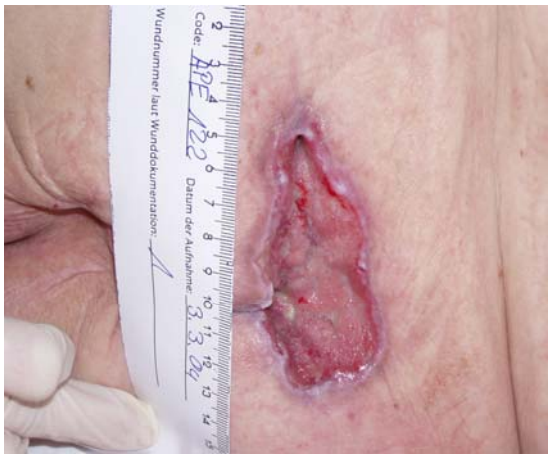

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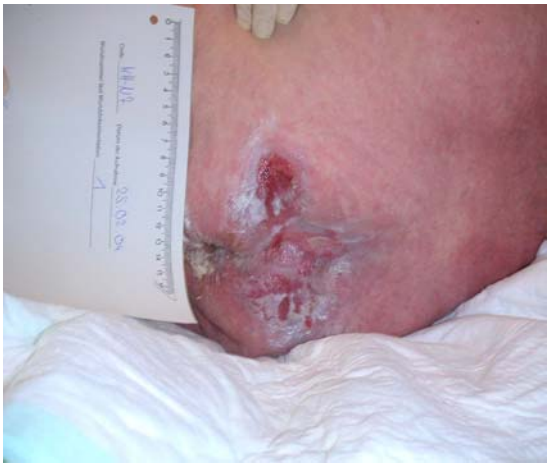
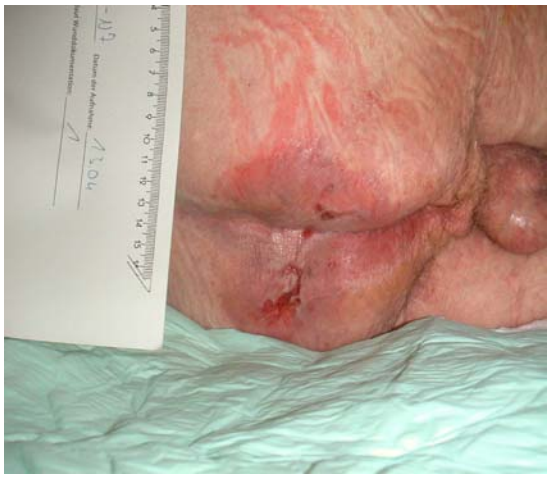

Photo 8:

8.10 Statements on satisfaction with the system

In addition to the main variables on "wound healing", the auxiliary question of "satisfaction" was addressed. The question of patient satisfaction was also examined in an explorative and hypothesis-generating sense.

1. Satisfaction with previous system (starting observation)

Satisfaction with the current support aid could be queried at the point of initial observation in the case of 40 patients. On the whole patients with large-cell support aids were significantly more satisfied than those with small-cell systems (exact Fischer test p = 0.014).

		Previous Support aid		
		Small-cell	Large-cell	Total
Very satisfied	Number		3	3
	%		30.0%	7.5%
Satisfied	Number	17	6	23
	%	56.7%	60,0.	57.5%
Not very satisfied	Number	6	1	7
	%	20.0%	10.0%	17.5%
Dissatisfied	Number	7		7
	%	23.3%		17.5%
Total	Number	30	10	40
	%	100.0%	100.0%	100.0%

Table 20: Satisfaction with previous support aids

2. Satisfaction after one week:

After the first observation week it was possible to query a total of 45 patients regarding their satisfaction with the current support system (Table 21).

		Repose system	Small-cell systems	Large-cell systems	Total
Very satisfied	Number	17		2	19
	%	70.8%		22.2%	42.2%
Satisfied	Number	6	8	6	20
	%	25.0%	66.7%	66.7%	44.4%
Not very satisfied	Number	1	2	1	4
	%	4.2%	16.7%	11.1%	8.9%
Dissatisfied	Number		2		2
	%		16.7%		4.4%
Total	Number	24	12	9	45
	%	100.0%	100.0%	100.0%	100.0%

Table 21: Satisfaction with the current support system after the first study week

Based on the percentage figures in Table 1, it is evident that the share of positive assessment in the case of large and small-cell systems has remained virtually unchanged compared to the initial observations. For instance 30% and 22%, respectively, of patients supported on large-cell systems are "**very satisfied"** with their support aids and none of the patients with the small-cell systems. In the case of patients supported on the REPOSE system since the initial observation, the overwhelming majority (70%) are **"very satisfied".** The differences are very significant both in total (exact Fischer test $p < 0.001$) and in the bivariate analysis of REPOSE vs. small-cell systems ($p < 0.001$) and REPOSE vs. large-cell systems ($p = 0.024$).

This trend is also evident with patients whose wounds have persisted longer than 12 weeks (in this case 5 of 7 (71.4%) patients on REPOSE are "very satisfied", but only 2 of 7 (28.6%) of patients on large-cell systems). No significant superiority can, however, be confirmed in this case due to the small sample size ($p = 0.286$).

These statements are also valid when analyses are conducted with respect to the ordinal character of satisfaction using the Mann-Whitney-U-Test ($p = 0.213$ REPOSE vs. large-cell systems and wound duration over 12 weeks; $p = 0.016$ REPOSE vs. large-cell systems and $p < 0.001$ REPOSE vs. small-cell systems).

Let us summarise the expressions of satisfaction over the 4 data collection intervals on the current support system and concentrate on the two extreme assessments "very satisfied" and "very dissatisfied".

If at least 75% of statements concerning satisfaction are "very satisfied", we consider the response as "very satisfied". If at least 75% of the assessment is "not very satisfied" or "not satisfied" we

consider the response to be "very dissatisfied". In this case, too, the overwhelmingly positive approval of patients using the REPOSE system is reconfirmed.

			System Repose	Small-celll systems	Large-cell systems	Total
Overall satisfaction	dissatisfied	Number	1	3	2	6
		%	5.9%	100.0%	50.0%	25.0%
	very satisfied	Number	16		2	18
		%	94.1%		50.0%	75.0%
Total		Number	17	3	4	24
		%	100.0%	100.0%	100.0%	100.0%

Table 22: Overall satisfaction according to support aid

8.11 Direct comparison of support systems

In this connection it is now interesting to compare changes in satisfaction during the first week, i.e. the change in satisfaction between the initial observation and over the course of the first study week.

Table 23 summarises the number of changes. Minus figures in this connection signify a deterioration and plus figures an improved assessment. The table reveals that in the case of 18 patients no change has taken place in their assessment. In the case of 1 patient, the assessment deteriorated by two points (from "satisfied" to "dissatisfied", although he remained on a small-cell system), and in the case of 4 patients by one point. In contrast after one week 11 patients were somewhat more satisfied with their support system (improvement by one assessment point), 8 patients improved by two points and 3 patients by a full three points (from "dissatisfied" to "very satisfied").

		Frequency	Percent	Valid percentages	Accumulated percent
Valid	-2	1	2,0	2,2	2.2
	-1	4	8.0	8.9	11.1
	0	18	36.0	40.0	51.1
	1	11	22.0	24.4	75.6
	2	8	16.0	17.8	93.3
	3	3	6.0	6.7	100.0
	Total	45	90.0	100.0	
Missing	System	5	10.0		
Total		50	100.0		

Table 23: Change in satisfaction during the first study weeks

In the following cross-classified table (Table 24) it is clearly apparent that in the case of small and large-cell systems satisfaction levels remain almost unchanged, while obvious improvements are noted in the case of REPOSE.

Almost 80% of patients indicate an improvement in satisfaction after changing to REPOSE of at least one point, more than 45% of the patients even indicate an improvement of 2 assessment points.

These differences are significant here, as well as in bivariate analysis ($p < 0.001$ Mann Whitney REPOSE vs. small-cell systems and REPOSE vs. large-cell systems).

		Repose system	Small-celll systems	Large-cell systems	Total
-2	Number		1		1
	%		8.3%		2.2%
-1	Number	1	1	2	4
	%	4.2%	8.3%	22.2%	8.9%
0	Number	4	8	6	18
	%	16.7%	66.7%	66.7%	40.0%
1	Number	8	2	1	11
	%	33.3%	16.7%	11.1%	24.4%
2	Number	8			8
	%	33.3%			17.8%
3	Number	3			3
	%	12.5%			6.7%
Total	Number	24	12	9	45
	%	100.0%	100.0%	100.0%	100.0%

Table 24: Change in satisfaction levels depending on support system

Results with respect to noise incidence are presented in Table 25 for all patient groups. It is clear that the use of a multimodal system is significantly different with respect to noise incidence at $p = 0.048$ in favour of the REPOSE system.

		Support aids			
		System Repose	Small-cell systems	Large-cell systems	Total
Not disturbing at all	Number	2		1	3
	%	100.0%		20.0%	27.3%
Somewhat disturbing	Number		2	4	6
	%		50.0%	80.0%	54.5%
Very disturbing	Number		2		2
	%		50.0%		18.2%
Total	Number	2	4	5	11
	%	100.0%	100.0%	100.0%	100.0%

Table 25: Assessment of noise in relation to support aids

If one reviews only the satisfaction of those patients with a seat cushion, 9 patients were "very satisfied" at the point of initial data collection and 3 patients "satisfied". None of the patients was "not very satisfied" or "dissatisfied" (Table 26). At the last data collection point 9 of 10 patients (90%) indicated that they were "very satisfied" and one patient was "satisfied". Accordingly use was very frequent.

	Frequency	Percent
Very satisfied	9	75.0
Satisified	3	25.0
Total	12	100.0

Table 26: Satisfaction levels with seat cushions

The use of the heel protector was also viewed most positively. None of the patients included was dissatisfied with the system – 2 patients were "very satisfied" and 2 patients "satisfied". No patient was "not very satisfied" or "dissatisfied" (Table 27).

	Frequency	Percent
Very satisfied	2	50.0
Satisified	2	50.0
Total	4	100.0

Table 27: Satisfaction levels with heel protectors

8.12 Comments on the system:

Many patients expressed opinions on the REPOSE system. These comments are detailed below:

AMB 102: Heel protector was "super" (initially crunching noises).

AMB106: Patient was very satisfied with the system: *"That's the best thing you could have done to me"*.

APE 106: Patient comments very positively on the mattress (week 1) and is "very satisfied" with the mattress and seat cushion even in week 4.

APE 133: Patient is very dissatisfied with overall health situation in week 1, but indicates that he is very satisfied with the use of REPOSE. In week 3 the patient used a wheel chair much more frequently and was enthusiastic about the seat cushion.

APE 138: Support is extremely feasible, since friction and shear stress are also avoided (statements made by nursing staff).

APE 122: Patient has no pain from wounds in week 1 since she used the seat cushion.

APE 149: The resident had noticeably less or no pain in week 1, expresses very positive opinion on mattresses and seat cushion.
In week 3 the resident is enthusiastic about the mattress and the seat cushion and can stay in the wheel chair for longer periods and has no more pain from wounds! The resident does not want to return the products after the study and expresses clearly that he likes the products and that they increase his quality of life.
APE 150: Resident "manages very well" with the mattress. He has tested several systems.

APE 152: The resident accepted cushion and mattress well in week 1, expressions of pain have clearly decreased. Both staff and residents are very satisfied with the system in week 2.

APE 130: The wound has completely healed after the mattress change, although the overall condition has deteriorated extensively.

APE 131: Resident particularly welcomed the fact that there were no disturbing (motor) noises.

One negative observation was noted:

KH-N 11: (previously small-cell system) was **transferred after 5 days.**
Patient was afraid that the mattress was moving. The patient was not very satisfied and indicated that he could not move easily.

9 Cost estimate

In considering the potential for economic savings, we would like to note explicitly that this study was not an investigation from an economic perspective. This means that statements on cost represent only an initial rough cost estimate.

The following areas may be affected by cost savings as the result of REPOSE:

1. More rapid wound healing

In this study every fifth wound was healed within a time frame of 4 weeks due to the use of REPOSE. On average, healing occurred in 2.7 weeks. No healing was noted in the case of small-cell systems within the study time frame.

Savings potential arises with respect to care products and nursing time. Information on weekly costs of care products extend from 55 Euro (Sellmer 2002) to 145 Euro (BVMed 2000), for nursing time from 67 Euro (Sellmer 2002) to 207 Euro (BVMed 2000). This information allows one to calculate weekly cost reductions of c. 200 Euro in care products and nursing time on average for every fifth wound.

2. Acquisition or lease costs

Acquisition costs for special anti-decubitus systems can be from 400 Euro to 2,700 Euro. Durability is indicated as several years according to the statement of the study assistants (or an average durability of 3 years). Due to the high degree of price variability and questionable statements on durability, lease costs were used for comparison purposes. According to the study assistants these costs are from 11 to 15 Euro a day.

In order to compare these costs with those of the REPOSE system, more precise information on the durability of the REPOSE system is necessary.

In total all REPOSE systems were used for 90 weeks or 630 days. During this period only two defects (one mattress and one seat cushion) were noted. (The defect in an out-patient's seat cushion was the result of a confrontation with a cat!).

When both defects are added together, a freedom from failure rate of 315 "bed days" or a durability of 630 days per system component results.

A study in two Scottish hospitals on the other hand produces a durability figure of only 170 days per mattress as part of an 18-month study.

(136 mattresses x 2,431 "bed days" per month x 18 months = 5951 "bed days" in total. After this period 74% (n = 101) of REPOSE systems were still in use. In other words: 35 defective systems in relation to total use of 5,951 days results in an average system durability of 170 days).

Even with this conservative estimate of only 170 days of average durability per system, an average acquisition cost of c. 600 Euro without VAT (800 including VAT) results in costs of 3.5 and 4.7 Euro respectively per bed day.

One should not, however, overlook that in this very conservative calculation the system is comprised of four autonomous components and in the event of a defect only the respective component, with a maximum value of 200 Euro, fails and not the entire system.
In this study daily costs of 1.3 Euro (800 Euro / 630 days) result from 630 "bed days" per system component.

Even with a "worst case" calculation of 4.7 Euro per day of use, a 57% or even a 69% cost reduction can be realized compared to lease costs of 11 and 15 Euro per day respectively.
(Sample calculation: savings level of minimally around 16,000 Euro a year results in the case of a 77-bed hospital with annual leasing costs of 32,000 Euro)

3. Operating costs

Precise information on operating costs for large-cell alternating pressure systems is not available. (A hospital in Hamburg of average size calculated its operating costs at c. 250 Euro per system per year excluding repairs).
REPOSE systems do not incur costs for electricity. Cleaning involves wiping surfaces with disinfectant, keeping the expenditure of time and costs low. Cleaning by nursing staff takes between two and three minutes. The correct unpacking and inflating of the mattress occurs only once and requires 15 minutes.
The amount of disinfectant is negligible in terms of cost impact.

10 Conclusions

The results of the study show that the selected randomised, comparative and explorative design is appropriate to address and respond to the questions and objectives of the 157-week study.

It was the goal of the planned study to demonstrate the effectiveness of the REPOSE system. As part of the main question formulation, evidence was presented that patients with wounds in the classically exposed body points at risk of decubitus who were supported on the REPOSE system showed an improved tendency to heal.

This question was answered positively to such an extent that the multimodal REPOSE system showed a clear superiority ($p = 0.009$) compared to the small-cell support systems. The superiority test with large-cell systems ($p – 0.167$) was not able to produce a positive response. We can, however, conclude that patients who were supported on the REPOSE system experienced a better therapy that those cared for on small-cell systems and an equivalent therapy to patients using large-cell systems.

In groups of the elderly and very elderly it is necessary to have a therapeutic system that can be implemented quickly and simply in care institutions. Particularly in the case of patients, for example, who are being cared for under *fast-track surgery* conditions, it could be useful to have such a straightforward system as REPOSE in hospitals as well as in-patient and out-patient care. As shown by the weekly improvements in wound condition as well as entire survey of wound healing success in the study, REPOSE provides a highly effective system that can be used in multimodal fashion in any system for both preventative and therapeutic purposes.

The argument above is reflected in the experience and comments of the patients. We were able to show that patients were significantly more satisfied with the REPOSE system than patients who were cared for using the comparative systems ($p < 0.001$ small-cell system and $p = 0.024$ large-cell system). The conclusion could then be drawn that in the case of alert and responsive patients the healing tendency is greater if subjective and objective satisfaction with the system prevails. (This has also been discussed previously by other authors (Knobel, 1994; Whittemore, 1998)). REPOSE fulfils these criteria in a special way, at least in this study group.

The hypotheses generated could be answered as summarised below for patients in this study:

1. Patients supported on REPOSE experience a higher level of comfort than patients supported on another system included. This hypothesis can be confirmed.
2. The use of the REPOSE system incurs lower costs that the use of other systems included. This hypothesis can be confirmed.

3. Patients supported on REPOSE evidence significantly smaller wound surfaces in square cm or a reduction in the wound depth. This hypothesis can be confirmed.
4. Patients supported on REPOSE experience a decrease in decubitus stage (according to Shea). This hypothesis can be confirmed.
5. Patients supported on REPOSE undergo a shorter healing period in the event that existing decubitus ulcers heal. This hypothesis can be confirmed to a limited extent. A larger sample is required for a *state of the art* response according to evidence-based criteria.

One can infer from the differences in the group that REPOSE has a favourable influence on the factors addressed in the main and auxiliary question formulation. Despite the multimorbid condition of the target group, core variables can be discerned and addressed. Nonetheless a more comprehensive survey with a focus on the auxiliary question formulation is necessary.

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