Medicare Coverage Policy ~ Decisions

Pressure Reducing Therapy (#CAG-00017N) (Support Surfaces)

Technology Assessment

Air-Fluidized Beds Used for Treatment of Pressure Ulcers in the Home Environment

Health Care Technology Assessment

Contract No. 290-97-0020
Task Order No. 06

November 7, 2001

Prepared by ECRI for:
U.S. Agency for Healthcare Research and Quality
Center for Practice and Technology Assessment
Rockville, Maryland

Executive Summary

The purpose of this technology assessment is to determine the effectiveness of air-fluidized beds (a Group 3 support surface) and Group 2 support surfaces for the treatment of Stage III and IV pressure ulcers in the home and other settings, and to compare the effectiveness of air-fluidized beds to Group 2 support surfaces. The Centers for Medicare and Medicaid Services (CMS) have divided support surfaces into three groups. Air-fluidized beds are the only devices included in Group 3. Group 2 support surfaces include powered air flotation beds (low-air-loss therapy), powered pressure-reducing air mattresses (alternating air mattresses), and non-powered advanced pressure reducing mattresses, which can be placed directly over a hospital bed frame. Group 1 support surfaces are pressure pads, certain mattresses, and overlays for mattresses (foam, water, and gel mattresses).

Current Medicare policy reimburses for home use of air-fluidized beds only when the patient has Stage III or IV pressure ulcers and only after the patient has completed at least a 30 day course of conservative treatment "without progression

toward wound healing." Medicare policy states that conservative treatment must include "use of a specialized support surface (Group 2) designed to reduce pressure and shear forces on healing ulcers."

This technology assessment was prepared in consideration of the interests of CMS. Hence, we consider the efficacy of support surfaces in the treatment of patients with pressure ulcers, but the role of specific support surfaces in preventing pressure ulcers is beyond the scope of this assessment. This assessment also emphasizes the use of air-fluidized beds in the home setting.

In regards to this latter emphasis, we also examined use of Group 2 and 3 support surfaces in hospitals and nursing facilities for evidence of efficacy that might be transferable to the home setting. However, generalization of these data to the home setting is not straightforward because treatment of pressure ulcers typically involves a variety of procedures that are essential to proper healing, but are seldom completely reported in clinical studies of wound healing. Standard care for pressure ulcers usually includes pressure relief and skin protection to prevent progression of the ulcer to advanced stages, debridement of necrotic tissue in Stage III and IV ulcers, wound cleansing, and dressings that promote a moist wound environment. The similarities in the way these therapies are provided in the hospital or nursing facility to the way they are provided in the home is uncertain.

This assessment addresses six questions:

Question 1: Are air-fluidized beds effective in the treatment of Stage III and/or IV pressure ulcers in the home setting? Of particular interest is evidence that the use of air-fluidized beds are superior to the use of Group 2 support surfaces for the healing of Stage III and/or IV pressure ulcers.

One randomized controlled trial (RCT) that compared the efficacy of air-fluidized beds to the efficacy of various conventional therapies in the home setting met the inclusion criteria for this question. However, a bias toward additional wound healing therapy (caused by the more aggressive wound care given to the air-fluidized beds group) renders this study's results difficult to interpret. Another RCT, performed in a hospital setting, provides some circumstantial evidence that air-fluidized beds could have some effectiveness in the home setting. This study found that wound size reduction in larger ulcers, was significantly greater in patients on air-fluidized beds than in patients using alternating air mattresses. This study did not classify wounds according to stage, so the relevance of this finding to patients with Stage III or IV ulcers cannot be precisely determined. Further, this study was performed more than 10 years ago and may not accurately reflect the effectiveness of Group 2 support surfaces as they are currently manufactured.

Question 2: Are Group 2 support surfaces effective in the treatment of Stage III and/or IV pressure ulcers in the home setting?

No studies that examined the efficacy of Group 2 support surfaces in the home setting met the inclusion criteria for this question. Therefore, a direct evidence-based answer to this question is not possible. Indirect evidence from three RCTs, conducted in hospitals or nursing homes, suggest that Stage III and IV pressure ulcers progress towards healing on Group 2 support surfaces. The findings of these three studies, however, are not conclusive, with none demonstrating statistically

significant differences between Group 2 support surfaces and foam mattresses in complete ulcer healing. The generalizability of the findings of these studies to the home setting is unknown.

Question 3: At what stage of ulcer development should air-fluidized beds be used? Of particular interest is whether use of air-fluidized beds prevents transition from Stage III to Stage IV ulcers, and whether a 30-day waiting period (in which a Stage III or IV pressure ulcer has not shown progression toward healing) before switching a patient to an air-fluidized bed is supported by clinical evidence.

No studies directly addressed this question, but one study provided indirect evidence suggesting that air-fluidized beds may be effective in preventing ulcer deterioration in at least some patients. This study showed that 62% of patients with large ulcers (which are potentially Stage III or IV) improved on air-fluidized beds and that 38% of patients with these ulcers showed no change or became worse.

CMS policy permits use of air-fluidized beds for the treatment of Stage III and IV ulcers only after unsuccessful conservative treatment for 30 days. Data from three studies examining wound therapy other than Group 2 or 3 support surfaces indicate that although some patients will improve during 30 days of conservative treatment, other patients will not. The exact proportion of patients who do not improve during this period, however, is not known. Also unknown is the proportion of such patients who might benefit from earlier use of air-fluidized beds. Finally, the available clinical evidence is not sufficient to allow one to determine which type of patient will benefit from initial conservative treatment, and which type of patient will benefit when air-fluidized bed therapy is added to the conservative therapy.

Question 4: What are the requirements (education, training, experience) needed for nursing or care giving in the home setting when using an air-fluidized bed?

No clinical studies were identified that reported on specific requirements for care in the home setting when using an air-fluidized bed. Consequently, we sought information from clinical guidelines, manuals, and review articles. Information on treatment protocols and patient safety in the use of air-fluidized beds were found in two guidelines written by the Office of Heath Technology Assessment (OHTA), and the University Hospital Consortium's Technology Advancement Center, and a user's manual for the Clinitron® Hite-RiteTM air-fluidized bed. According to these sources, caregivers in the home setting need to be aware of the following potential difficulties and how to manage them:

- Patient dehydration
- Confusion due to the sensation of floating
- Accumulation of thick pulmonary secretions
- Knowledge of the control panel for turning on and off the blower that fluidizes the microsphere beads (needed to create a firm support surface for emergency CPR)
- Care of the microsphere beads and cleanup after leakage to protect patient and caregiver from skin irritation
- Bed elevation procedures
- Methods for turning patients in these beds

According to OHTA, appropriate home support is essential for optimizing the therapeutic benefits of air-fluidized beds and for preventing complications that may arise from a patient's limited mobility. To meet these needs, OHTA suggest that a specially trained nurse consultant provide training for the patient and caregiver.

Question 5: What are the requirements (education, training, experience) needed for nursing or care giving in the home setting when using Group 2 support surfaces?

No clinical studies were identified that reported on the requirements (education, training, experience) needed for nursing or care giving in the home setting when using Group 2 support surfaces. As a consequence, we sought information from clinical guidelines, review articles, and manufacturer's manuals. Relevant information was found in guidelines written by the University Hospital Consortium's Technology Advancement Center, and the Support Surface Consensus Panel. According to these sources, caregivers in the home setting need to be aware of the following issues:

- Proper maintenance of the support surface
- Cleaning the support surface to prevent the spread of infection
- Deflation for emergency procedures such as CPR
- Positioning of patients and turning schedule
- Flammability
- Need to avoid wrinkled sheets and kinked tubing
- Use incontinence pads without plastic backs
- Eliminating the use of skin protecting devices such as heel and elbow pads
- Absorbent breathable underpads should be used

Question 6: What aspects of wound care constitute proper treatment of patients using air-fluidized beds or Group 2 Support Surfaces? Of particular interest are what types of dressings assist (or hamper) wound healing in patients using air-fluidized beds and what types of debridement assist (or hamper) wound healing in patients using air-fluidized beds?

No published studies were identified that address this question. Furthermore, this question is not directly addressed in wound care guidelines. Published studies of air-fluidized beds and Group 2 support surfaces used a variety of debridement, wound cleaning, and dressing methods, but did not report outcome measures separately for these procedures. Therefore, conclusions cannot be drawn from these studies about the use and effectiveness of these procedures in patients on air-fluidized beds or Group 2 support surfaces.

Specific dressing recommendations for pressure ulcer patients using air-fluidized beds or Group 2 support surfaces were not available from the sources we identified. The Clinitron® Hite-RiteTM air-fluidized therapy user manual provides instructions for the use of wet dressings.

Preface

This report is organized into two major sections: 1) *Overview* containing a short discussion of objectives, methodology, and findings, and 2) *Technology Assessment* containing background, methodology, results, supplemental analyses, conclusions, tables, and references sections.

In the *Overview* section, we discuss the scope of the project and the questions to be addressed by this report. Our approach and methods used to address these questions will be outlined and a summary of major findings and conclusions will be presented.

In the *Technology Assessment* section, the background section provides information related to the particular health condition or illness under evaluation, including details about the epidemiology, diagnosis and treatment of the condition or illness. We provide information about the specific set of procedures analyzed for this report.

The methodology section details the methods we used to evaluate currently available data. We detail the strategies employed for our searches of the literature, which includes an exhaustive list of the electronic databases searched and the protocol for hand-searches of the non-journal literature.

In the results section, the inclusion criteria used to identify and retrieve studies are presented, the quality of the studies is examined, and the key outcome measures are analyzed for each question. Studies with major design flaws that bring into question the validity of the study results are excluded. The results of the analyses are described in the text and presented in evidence tables. Finally, we summarize our conclusions.

Overview

Objectives

The purpose of this technology assessment is to determine the effectiveness of air-fluidized beds and Group 2 support surfaces as defined by the Centers for Medicare and Medicaid Services (CMS) for the treatment of Stage III or IV pressure ulcers in the home and other settings. Additional goals of this assessment are to determine what constitutes proper wound care while a patient is treated on an air-fluidized bed or a Group 2 support surface. Of particular interest in wound care procedures are what methods of wound debridement and what types of wound dressings are most appropriate for these patients. This assessment will also examine the education, training, and experience requirements needed for nursing or care giving in the home setting when using an air-fluidized bed or a Group 2 support surface.

The Centers for Medicare and Medicaid Services (CMS) have divided support surfaces into three groups. Air-fluidized beds are the only devices included in Group 3. Group 2 support surfaces include powered air flotation beds (low-air-loss therapy), powered pressure-reducing air mattresses (alternating air mattresses), and non-powered advanced pressure

reducing mattresses, which can be placed directly over a hospital bed frame (foam, water, and gel mattresses). Group 1 support surfaces are pressure pads, certain mattresses, and overlays for mattresses (foam, water, and gel mattresses).

Current Medicare policy reimburses for home use of air-fluidized beds only when the patient has Stage III or IV pressure ulcers and only after the patient has completed at least a 30 day course of conservative treatment "without progression toward wound healing." Medicare policy states that conservative treatment must include "use of a specialized support surface (Group 2) designed to reduce pressure and shear forces on healing ulcers."

Although support surfaces may prevent development of pressure ulcers in at-risk patients, the present technology assessment considers only the efficacy of support surfaces in the treatment of patients with pressure ulcers. This reflects the interests of CMS, for whom this technology assessment was prepared. Also for this reason, this assessment emphasizes the use of air-fluidized beds in the home setting.

In this latter regard, we examined use of Group 2 and 3 support surfaces in hospitals and nursing facilities for evidence of efficacy that might be transferable to the home setting. However, treatment of pressure ulcers typically involves a variety of procedures all of which are essential to proper healing, but are seldom completely reported in clinical studies of wound healing. Standard care for pressure ulcers usually includes pressure relief and skin protection to prevent progression of the ulcer to advanced stages, debridement of necrotic tissue in Stage III and IV ulcers, wound cleansing, and dressings that promote a moist wound environment. Important wound therapies and care may not be similar or equally available in the hospital or nursing facility and in the home. The lack of reporting of concurrent wound treatment limits the extent to which one can determine whether results obtained in hospitals and nursing facilities can be extended to the home setting.

Pressure ulcers are the result of pressure or shear force on the skin leading to occlusion of capillary blood flow and skin cell death. Capillary occlusion affects primarily areas of the skin that are compressed against the underlying bone when a person sits or lies down. Venous and lymphatic obstruction also occurs, followed by cell death if the pressure is not relieved. Pressure ulcers are characterized by deep tissue necrosis and a loss of volume disproportionately greater than the overlying skin defect. Pressure relieving devices are designed to prevent capillary occlusion by reducing the tissue interface pressure sufficiently enough to prevent capillary closure. These devices may also be designed for heat and moisture control as well as preventing capillary closing.

This assessment addresses six key questions. These are:

Question 1: Are air-fluidized beds effective in the treatment of Stage III and/or IV pressure ulcers in the home setting? Of particular interest is evidence that the use of air-fluidized beds are superior to the use of Group 2 support surfaces for the healing of Stage III and/or IV pressure ulcers.

Question 2: Are Group 2 support surfaces effective in the treatment of Stage III and/or IV pressure ulcers in the home setting?

Question 3: At what stage of ulcer development should air-fluidized beds be used? Of particular interest is whether use of

air-fluidized beds prevents transition from Stage III to Stage IV ulcers, and whether a 30-day waiting period (in which a Stage III or IV pressure ulcer has not shown progression toward healing) before switching a patient to an air-fluidized bed is supported by clinical evidence.

Question 4: What are the requirements (education, training, experience) needed for nursing or care giving in the home setting when using an air-fluidized bed?

Question 5: What are the requirements (education, training, experience) needed for nursing or care giving in the home setting when using Group 2 support surfaces?

Question 6: What aspects of wound care constitute proper treatment of patients using air-fluidized beds or Group 2 Support Surfaces? Of particular interest are what types of dressings assist (or hamper) wound healing in patients using air-fluidized beds and what types of debridement assist (or hamper) wound healing in patients using air-fluidized beds?

Methodology

To identify information for this report, we searched seven electronic databases and identified 421 references on air-fluidized beds and other support surfaces that were relevant to patients with pressure ulcers. We retrieved full articles from this reference list according to specific *a priori* inclusion criteria that were unique to each of the questions listed above.

To address questions 1 and 2 which consider whether air-fluidized beds and Group 2 support surfaces are effective in the treatment of Stage III and/or Stage IV pressure ulcers, clinical studies had to meet the following inclusion criteria:

1. Clinical studies of air-fluidized beds or Group 2 support surfaces for the treatment of patients with pressure ulcers published after 1985 and have the following characteristics:

    a. A parallel control group (a control group is necessary to determine the effectiveness of the support surfaces compared to conventional treatment)

    b. At least 10 patients in each treatment group.

    c. Performed in the home setting but, if studies in the home setting were not available, clinical studies conducted in other settings were examined.

    d. Patients with Stage III and IV pressure ulcers, or study separately presented the results from such patients (results from studies that combined Stage I and II pressure ulcer data with Stage III and IV pressure ulcer data may not accurately represent the results of patients with more severe pressure ulcer stage that are the focus of this report, therefore, we excluded these studies).

2. One of the following outcome measures must be reported

a. Number of wounds completely healed during study period

b. Number of wounds that decreased in size during the study period

c. Number of wounds that became worse or stayed the same during the study period

d. Mean time to heal

e. Time to 50% of wound healed during study period

f. Mean area of wound reduction

g. Number of patients needing hospitalization or developing a complication with pressure ulcer care

h. Length of stay during treatment period

3. Other technology assessments of air-fluidized beds for the treatment of pressure ulcers.
4. English language
5. Published as a full article, not a meeting abstract

To address question 3 which considers at what stage of pressure ulcer development should air-fluidized beds be used, we included studies of wound healing therapies.

1. Clinical studies of air-fluidized beds for the treatment of patients with pressure ulcers published after 1985 and have the following characteristics:

a. Controlled studies in which some patients received air-fluidized beds upon initial diagnosis and some patients waited 30 days before receiving air-fluidized beds, OR studies that stratified their results according to Stage III and Stage IV pressure ulcers.

b. At least 10 patients in each treatment group.

c. Patients with Stage III and IV pressure ulcers, or study separately presented the results from such patients (results from studies that combined Stage I and II pressure ulcer data with Stage III and IV pressure ulcer data may not accurately represent the results of patients with more severe pressure ulcer stage that are the focus of this report, therefore, we excluded these studies).

d. Report the proportion of Stage III and IV pressure ulcers that did and did not improve during the initial 30 days of treatment (ideally, the proportion of Stage III and IV pressure ulcers to improve while using air-fluidized

beds during the initial 30 days should have been reported).

2. Also, studies of treatments for Stage III and IV pressure ulcers, other than support surfaces, that report the proportion of Stage III and IV pressure ulcers that did and did not improve during the first 30 days of treatment from first diagnosis published from 1990 to the present.
3. English language
4. Published as a full article, not a meeting abstract

To address questions 4, 5, and 6 which consider issues of nursing or caregiver training and what aspects of wound care are best for patients using air-fluidized beds or Group 2 support surfaces, the following criteria were used:

1. Clinical studies of air-fluidized beds or Group 2 support surfaces for the treatment of patients with pressure ulcers published after 1985 and have the following:

- At least 10 patients in each treatment group.
- Information on concurrent wound care is reported.

a. OR clinical guidelines on the use of air-fluidized beds or Group 2 support surfaces for the treatment of pressure ulcers published from 1985 to the present.

b. OR manuals for air-fluidized beds or Group 2 support surfaces.

c. OR review articles offering expert opinion on the use of air-fluidized beds or Group 2 support surfaces for the treatment of pressure ulcers published from 1985 to the present.

2. English language
3. Published as a full article, not a meeting abstract

We then assessed the quality of each study that met the inclusion criteria listed above. We excluded some studies from further consideration because of low quality that had the potential to produce significant bias in the results. Therefore, accurate interpretation and analysis of these results was impossible.

Findings

Question 1: Are air-fluidized beds effective in the treatment of Stage III and/or IV pressure ulcers in the home setting? Of particular interest is evidence that the use of air-fluidized beds are superior to the use of Group 2 support surfaces for the healing of Stage III and/or IV pressure ulcers.

Only one study, an RCT, met the inclusion criteria for this question. This study compared the efficacy of air-fluidized beds and various conventional therapies in the home environment. However, in this study, the patients on air-fluidized beds

received additional wound care therapy and more aggressive nursing care of their wounds. This creates a bias towards additional wound healing in the air-fluidized bed group that renders the results of this study difficult to interpret.

Because clinical studies were not available to draw conclusions about the effectiveness of air-fluidized beds in the home, we relaxed the question-specific inclusion criteria so that studies that evaluated air-fluidized beds in other settings could be assessed. With the new criteria, we identified one additional study. This study, an RCT performed in a hospital setting, found that wound size reduction in larger ulcers was significantly greater in patients on air-fluidized beds than in patients using alternating air mattresses, and that the number of large ulcers improved was also significantly greater in patients on air-fluidized beds than in patients on alternating air mattresses. The precise degree to which these results pertain to patients with Stage III or IV ulcers is not certain, because the authors did not classify ulcers by stage. Thus, the relevance of these results to patients with Stage III and IV ulcers depends on the degree to which ulcer size was related to ulcer stage in these patients. Similarly, the extent to which these results can be carried over to the home setting is not known. Finally, since this study was performed more than 10 years ago, it does not directly address the effectiveness of Group 2 support surfaces as they are now manufactured.

Use of Group 2 and 3 support surfaces in hospitals and nursing facilities were also examined for evidence of efficacy that might be transferable to the home setting. However, treatment of pressure ulcers typically involves a variety of procedures all of which are essential to proper healing, but are seldom completely reported in clinical studies of wound healing. Standard care for pressure ulcers usually includes pressure relief and skin protection to prevent progression of the ulcer to advanced stages, debridement of necrotic tissue in Stage III and IV ulcers, wound cleansing, and dressings that promote a moist wound environment. Important wound therapies and nursing care may have different availabilities in the hospital or nursing facility and in the home. The lack of reporting of concurrent wound treatment limits one's ability to determine the extent of the differences in these availabilities.

Question 2: Are Group 2 support surfaces effective in the treatment of Stage III and/or IV pressure ulcers in the home setting?

We identified no studies that examined Group 2 support surfaces in the home. Therefore, we relaxed the home setting inclusion criteria so that the effectiveness of Group 2 support surfaces in other settings could be examined. Such studies could offer circumstantial evidence about the effectiveness of these support surfaces in the home setting. Using these relaxed inclusion criteria, three RCTs were found that compared Group 2 support surfaces to Group 1 foam mattresses.

Two of these RCTs, comparing a low-air-loss mattress to a foam overlay found no statistically significant differences between these support surfaces in the promotion of healing in Stage III or IV pressure ulcers. The other RCT, comparing an alternating air mattress to a foam mattress, also found no statistically significant differences in the promotion of healing in Stage III or IV pressure ulcers among these surfaces. One of these studies did find a significantly greater rate of wound size reduction for deep ulcers in patients using low-air-loss mattresses compared to patients using foam mattresses. However, the same study found no statistically significant differences in complete healing of deep ulcers. The other studies also found no difference in the rate of complete healing. These studies may have only had sufficient sample size to detect large differences, but the observed differences in healing and improvement were less than 5%.

These studies indicate that Stage III and IV pressure ulcers progress towards wound healing on these devices, but differences in reporting wound healing outcomes prevents any comparisons across studies that would allow the estimation of the proportion of patients with healing wounds and the proportion of patients with non-healing wounds.

Question 3: At what stage of ulcer development should air-fluidized beds be used?

There are two aspects to this question. The first is whether use of air-fluidized beds prevents the transition from Stage III to Stage IV pressure ulcers. The second aspect of this question is whether switching patients to air-fluidized beds only if their Stage III or IV pressure ulcers have not shown progression toward healing during a 30-day period of conservative treatment is supported by clinical evidence.

This latter aspect is important because current Medicare policy requires such a waiting period for patients with Stage III or IV pressure ulcers. Although there are no studies of air-fluidized beds that directly addressed this issue, some relevant information can be obtained from studies of other wound care treatments that provide data about wound healing during the first 30 days of treatment. These studies can be assessed for evidence of efficacy. If these studies suggest that other wound care methods do not promote healing in Stage III and IV pressure ulcers, then a 30 day waiting period for the use of an air-fluidized bed may not be justified.

No studies of air-fluidized beds that met our inclusion criteria reported on the effects of these beds on the rate of transition from Stage III to Stage IV ulcers. One study of patients on air-fluidized beds reported that 62% of patients with large ulcers (which are potentially Stage III and IV) experienced an improvement in wound condition and that 38% of patients with these ulcers showed no change or became worse.

Three studies of pressure ulcer therapies other than Group 2 or 3 support surfaces suggest that at least some Stage III and IV pressure ulcers progress towards healing (as indicated by a reduction in wound size or other signs of improvement) during the first 30 days under a variety of treatments. However, these studies also suggest that some patients will not benefit from these treatments, and may even get worse. One study reported that only 4% of patients had deterioration or no improvement using a calcium alginate dressing, and 33% of patients had deterioration or no improvement using dextranomer paste and saline gauze. A second study reported that 37% of ulcers decreased in size and 63% of ulcers increased in size when using a hydrocolloid/alginate dressing. A third study reported that 45% and 48% of pressure ulcers healed in 28 days in patients using foam mattresses and water mattresses, respectively.

The data from these studies are not sufficient to determine the exact proportion of patients who do not improve during the initial 30 days of treatment. Also unknown is the proportion of such patients who might benefit from earlier use of air-fluidized beds. When considering the initial treatment for Stage III and IV pressure ulcers, the available clinical evidence is not sufficient to determine which type of patient will benefit from initial conservative treatment alone or which type of patient will benefit when air-fluidized bed therapy is added to the conservative therapy.

Question 4: What are the requirements (education, training, experience) needed for nursing or care giving in the home setting when using an air-fluidized bed?

No clinical studies were identified that directly addressed this question. Consequently, we sought information from other sources. Two guidelines written by the Office of Heath Technology Assessment (OHTA), and the University Hospital Consortium's Technology Advancement Center, and a user's manual for the Clinitron® Hite-RiteTM air-fluidized therapy contained relevant information. These sources suggest that the following are important considerations for proper patient care while using an air-fluidized bed.

- An initial assessment by a physician to evaluate the patient for home use of an air-fluidized bed
- Supervision of the treatment by an attending physician who examines the patient monthly
- Specially trained nurse consultant to provide training for the patient and caregiver
- Turning schedules to help prevent the complications of immobility and methods for turning patients in these beds
- Patient dehydration
- Patient confusion due to the sensation of floating
- Accumulation of thick pulmonary secretions
- Care of the microsphere beads and clean up of microspheres' leakage to prevent skin irritation of the patient and caregiver
- Knowledge of the control panel for turning on and off the blower that fluidizes the microsphere beads (needed to create a firm support surface for emergency CPR)
- Bed elevation procedures

Question 5: What are the requirements (education, training, experience) needed for nursing or care giving in the home setting when using Group 2 support surfaces?

No published clinical studies were identified that directly addressed this question. Consequently, we sought information from guidelines and review articles. Information on treatment protocols and patient safety in the use of Group 2 support surfaces were found in two guidelines published by the University Hospital Consortium's Technology Advancement Center and the Support Surface Consensus Panel.

These sources suggest that the following are important considerations for proper patient care while using Group 2 support surfaces.

- Bed movement (alternating air mattresses) can increase agitation and may cause nausea
- Patients can slide and need repositioning
- Turning schedule
- Guidelines for infection control
- Means of rapid deflation for emergency procedures
- Plastic surface may cause increased perspiration
- Need to avoid wrinkled sheets and kinked tubing
- Use of incontinence pads without plastic backs
- Eliminating the use of skin protection devices such as heel and elbow pads

- Absorbent breathable underpads should be used
- Avoid punctures and check inflation levels
- Procedures for cleaning the support surfaces
- Flammability of the device

Question 6: What aspects of wound care constitute proper treatment of patients using air-fluidized beds or Group 2 Support Surfaces?

No studies were identified that specifically examined wound care procedures, such as method of debridement, types of cleaning solutions, types of dressings, or the use of antibiotics in treating pressure ulcers in patients using air-fluidized beds or Group 2 support surfaces. Consequently, we considered information on concurrent wound care treatments as they appeared in clinical studies. This information may form the basis for designing studies to directly answer this question. In addition, we sought information from clinical guidelines, user manuals, and review articles.

The guidelines published by the US Agency for Healthcare Policy and Research (AHCPR)(now the Agency for Healthcare Research and Quality) in 1994, and the American Medical Directors Association in 1999, provided pressure ulcer treatment recommendations applicable to all patients with pressure ulcers including patients using air-fluidized beds and other support surfaces.

Available wound care guidelines did not specifically indicate which dressings or debridement procedures may work best with patients on air-fluidized beds or Group 2 support surfaces. Published studies of air-fluidized beds and Group 2 support surfaces reported using a variety of debridement, wound cleaning, and dressing methods, but did not report results separately by these procedures. Therefore, conclusions cannot be drawn from these studies about the use and effectiveness of these procedures in patients on air-fluidized beds or Group 2 support surfaces.

The Clinitron® Hite-RiteTM air-fluidized therapy user's manual gives the following recommendations for using wet dressings and soaks.

- Use an IV administration set to slow drip the solution to the area for a wet soak. If a continuous drip is not ordered, it may be necessary to increase the frequency of dressing changes.
- Wrap the area with a plastic wrap, place an impervious dressing on the sheet beneath the site, or use the Hill-Rom Impervious Sheet to block the airflow.
- Alternatively, resoak the in-place dressing frequently if asepsis can be maintained.

Technology Assessment

Background

Pressure Ulcers

Pressure ulcers are the result of pressure or shear on the skin leading to occlusion of capillary blood flow and skin cell death. Capillary occlusion affects primarily areas of the skin that are compressed against the underlying bone when a person sits or lies down. Venous and lymphatic obstruction also occurs. Because of tissue ischemia, toxic metabolites accumulate in the tissue spaces and become a source of noxious stimuli that produce discomfort and pain in a normal healthy individual. Consequently, the patient shifts position and relieves the pressure and discomfort. The skin of an immobile bedridden person is more likely to be affected by pressure and shear. Ischemic cell death produces inflammation that results in blood clotting, platelet aggregation, immune complex formation, and accumulation of inflammatory cells. Pressure ulcers are characterized by deep tissue necrosis and a loss of volume disproportionately greater than the overlying skin defect. The term pressure ulcer is preferred to the older term of decubitus ulcer or bedsores.(1)

Pressure ulcers are graded by the degree of tissue loss into four stages.(2) Stage I pressure ulcers are an observable, pressure related alternation of intact skin that compared to an adjacent or opposite are of the body has changed with regard to skin temperature (warm or cool), tissue consistency (firm or soft), or sensation (pain or itching). Stage I pressure ulcers are distinguished by a defined area of persistent redness in lightly pigmented skin, but in darker skin tones, the ulcer may appear with persistent red, blue, or purple hues. Stage II ulcers involve partial thickness skin loss of the epidermis and may penetrate through the dermis. These ulcers are superficial and may present as an abrasion, blister, or shallow crater. Stage III ulcers show full thickness skin loss involving damage to or necrosis of subcutaneous tissue that may extend to underlying fascia. The ulcer forms a deep crater with or without undermining of adjacent tissue. Stage IV ulcers have full thickness skin loss that extends into the underlying muscle, tendon, or bone. Undermining and sinus tracts may also be associated with this stage of ulcer. When eschar (scab) is present, a pressure ulcer cannot be staged accurately until the eschar is removed.(1,2) The most common areas for the development of pressure ulcers are the buttocks (sacral areas), hips (iliac crest), knees, heels, and ankles.(3-6)

Pressure ulcers are common in the institutionalized elderly.(7) The health consequences of pressure ulcers include local infection, sepsis, osteomyelitis, and pain.(4) Local infection of pressure wounds is common and is usually controlled by debridement and antibiotics. Osteomyelitis is a risk in pressure ulcer patients since these ulcers develop over bony prominences. Patients who enter a nursing home with a pressure ulcer or who develop pressure ulcers while in a nursing home are more likely to die compared to patients who do not develop pressure ulcers. One-year mortality rates are higher in patients admitted to nursing homes with pressure ulcers (50%) compared to those without pressure ulcers (27%).(7) The increased mortality rate in pressure ulcer patients is not a direct consequence of the ulcer but is most likely due to coexisting medical conditions.(8)

Preventive measures depend on identifying patients at risk for pressure ulcer formation. Individuals with paralysis, hip fractures, Parkinson disease, neuropathy, stroke, coma, or physical restraints are at risk due to limited ability for repositioning and pressure relief. Malnutrition and urinary and fecal incontinence are also risk factors for pressure ulcer development. Preventive measures include reducing or eliminating periods of prolonged pressure, the amount of pressure, friction, shear forces, malnutrition, and incontinence. The present technology assessment will not consider the preventative use of pressure reducing support surfaces.

Standard care for pressure ulcers depends on the ulcer stage and usually includes pressure relief and skin protection to

prevent progression of the ulcer to advanced stages, debridement of necrotic tissue in Stage III and IV ulcers, wound cleansing, and dressings that promote a moist wound environment.(9) Debridement may be performed by surgical removal of necrotic tissue in an operating room (sharp debridement), by endogenous enzymes that digest necrotic tissue trapped in the wound fluid under occlusive dressings (autolytic debridement), by removal of necrotic tissue using wet-to-dry gauze dressings (mechanical debridement), or by the topical application of enzymes that digest necrotic tissue and collagen (enzymatic).(10) Wound debridement until bleeding tissue is encountered removes ischemic tissue with little capacity to heal as well as reducing inflammatory factors.(1) Gentle cleaning with saline at pressures ranging from 4 to 15 pounds per square inch is usually all that is required to clean a wound prior to applying a dressing.(9,11)

A number of prognostic factors affect pressure ulcers.(12,13) Adequate blood flow to the affected area is needed to provide oxygen and nutrients to the tissues as they heal. Peripheral vascular disease due to diabetes mellitus, aging, or other reasons affects tissue perfusion and impedes wound healing. Nicotine and carbon monoxide from cigarette smoke will decrease tissue perfusion and oxygen tension in the wound. Nutrition can also have a significant impact on wound healing. Protein malnutrition that lowers serum albumin levels below 3.5 gm/dl will slow wound healing. Lack of protein can reduce collagen synthesis, decrease wound tensile strength, and increase the potential for wound infection. Inadequate nutritional intake, especially protein and ascorbic acid, may be more common in the elderly and contribute to poor wound healing in this group. Patients with altered immune systems are likely to have poor angiogenesis, formation of granulation tissue, and epithelialization. Nonsteroidal anti-inflammatory drugs, anticoagulants, and glucocorticoids can restrict wound healing by interfering with the normal inflammatory responses that are part of wound healing. Normal phagocytosis by leukocytes may be decreased by these drugs and make the wound more susceptible to infection. An ineffective immune system, caused by poor tissue perfusion, poor nutrition, or drug use, can result in bacterial infections and delay or prevent wound healing.

Wound infections are a special concern in patients with diabetes because their metabolic state increases the potential for infection.(14) Pressure ulcer healing can be impeded by fecal incontinence, increased length of paralysis, and social state of the patient.(3) Wound duration and size prior to treatment may also influence outcome.

Defining Support Surfaces

According to the DMERC Supplier Manual, chapter 14 on Durable Medical Equipment, the Medicare program categorizes pressure reducing support surfaces into three groups.(15) Group 1 support surfaces are pressure pads for mattresses (air, water, and gel mattresses). These are non-powered pressure reducing mattress overlays designed to be placed on top of a standard mattress. They are primarily intended for patients at-risk of development of pressure ulcers. Powered air flotation beds (low-air-loss beds), powered pressure-reducing air mattresses (alternating air mattresses), and non-powered advanced pressure reducing mattresses are considered Group 2 support surfaces. Non-powered advanced pressure reducing mattresses are different than Group 1 support surfaces because they provide more pressure reduction than Group 1 mattresses and have a surface designed to reduce friction and shear. Non-powered Group 2 support surfaces must also have documented evidence of effectiveness in the treatment of Stage II, III, or IV pressure ulcers. Air-fluidized beds are the only devices in Group 3 support surfaces.

Current Medicare policy reimburses for home use of air-fluidized beds only when the patient has Stage III or IV pressure

ulcers and only after the patient has completed at least a 30 day course of conservative treatment "without progression toward wound healing." Medicare policy states that conservative treatment must include "use of a specialized support surface (Group 2) designed to reduce pressure and shear forces on healing ulcers."

The present technology assessment considers only the efficacy of support surfaces in the treatment of patients with pressure ulcers. Studies that examine pressure ulcer prevention are beyond the scope of this assessment. The use of air-fluidized beds in the home setting is also emphasized in this report over other settings.

In this latter regard, use of Group 2 and 3 support surfaces in hospitals and nursing facilities were also examined for evidence of efficacy that might be transferable to the home setting. However, treatment of pressure ulcers typically involves a variety of procedures all of which are essential to proper healing, but are seldom completely reported in clinical studies of wound healing. Standard care for pressure ulcers usually includes pressure relief and skin protection to prevent progression of the ulcer to advanced stages, debridement of necrotic tissue in Stage III and IV ulcers, wound cleansing, and dressings that promote a moist wound environment. Delivery of important wound therapies and nursing care in the hospital or nursing facility may differ from the delivery of these aspects of wound care in the home. The lack of reporting of concurrent wound treatment limits the extent to which results obtained in hospitals and nursing facilities can be extended to the home setting because essential elements of treatment used in conjunction with the support surface that must also be employed in the home setting are not known.

Air-Fluidized Beds

Air-fluidized beds and other support surfaces for patients with pressure ulcers are intended to maintain the tissue interface pressure, the pressure exerted against the skin by the surface of the support device, at or below capillary closing pressure (approximately 32 mm Hg). Most support devices are designed to reduce pressure by conforming to the shape of the body so that pressure is distributed over the whole body rather than concentrated on particular areas such as over the hip or buttocks. Devices can be static, they maintain a constant tissue interface pressure when the patient is not moving, or dynamic, they alternate pressure over the body surface when the patient is not moving.(16)

An air-fluidized bed consists of a tank filled with silicone-coated microsphere beads. The beads resemble fine grains of sand. The tank is covered with a loose-fitting filter sheet that separates the patient from the beads. Room air is drawn into the base of the unit, then filtered, heated, and pushed into the tank through a diffuser board. The airflow suspends the beads causing them to take on the properties of a fluid. The sheet moves freely with the patient through the fluid. Usually the patient only sinks 4-6 inches into the beads and the pressure put on the skin is well below capillary closing pressure. The filter sheet is permeable to the warm air that fluidizes the beads. This airflow circulates around the patient and helps to keep the patient warm and dry. The sheet is also permeable to the downward flow of body fluids such as wound drainage, urine, and perspiration. As body fluid comes in contact with the beads, the beads clump and drop to the bottom of the tank. The alkaline environment of the beads kills bacteria. The clumps are removed during routine maintenance. Patient transfers in and out of the bed may be difficult and in most models the head of the bed cannot be elevated. When the airflow is turned off, the beads settle into a mold around the body. This creates a support surface that stabilizes the patient for nursing care, wound cleaning, and other patient care needs.(17)

Potential Adverse Events When Using Air-fluidized Beds

Several adverse effects of air-fluidized bed treatment have been noted.(18) The warm dry air blowing through the filter sheet may cause increased insensible fluid loss. Dry, scaly skin and dehydration may occur especially in elderly patients. Patients may be required to consume extra fluids. Confusion or disorientation due to the sensation of floating, and accumulation of thick pulmonary secretions, may also occur.

According to the users manual for the Clinitron® Hite-RiteTM air-fluidized therapy, leakage of the beads is also a safety concern. The beads are extremely slippery on hard surfaces. If any beads leak onto the floor, they should be immediately cleaned up with a damp cloth and the manufacturer's representative should be notified. Patient and staff may suffer eye and skin irritation if the microspheres leak into the care environment and contaminate the floor, food, or clothing.(17) Available information does not allow one to precisely determine how frequently such events occur.

Group 2 Support Surfaces

Low-air-loss therapy.
These beds prevent capillary occlusion by evenly distributing weight over a number of pillows that are usually grouped by zones. Each zone of pillows is inflated with air, based on the patient's height, weight, and body distribution. The patient rests at a depth of about 8 to 9 inches, allowing pressure relief in any position. The pillows are air-permeable and the flow of dry air leaving the mattress cover controls moisture and heat buildup. Because air is constantly escaping from the pillows, an electric blower must operate constantly. The patient is usually able to move easily on this surface and the head of the bed can be elevated.(16,19)

A recent development in support surface beds is a combination of the air-fluidized tank to support the legs and buttocks and a low-air-loss section to support the trunk and head. The low-air-loss section allows the head to be elevated.(17)

Alternating air mattresses.
In this dynamic system, every other cell of the mattress is inflated while every other cell is deflated on a given cycle. Therefore, no one constant source of pressure is present at any one time. The changes in surface pressure may also enhance blood flow. Supervision is needed to ensure that adequate inflation is maintained to prevent the patient from descending through the mattress and bottoming out.(19)

Group 1 Support Surfaces

Gel and water mattresses.
These mattresses are filled with either water or a gel. The weight of the patient displaces the water so that the support surface conforms to the body and the patient floats. They generally require little maintenance and are easy to clean. The use of these devices is limited by their weight, the time required for set up, and the potential for leaks.(16,19)
Foam mattresses.
Foam is probably the most common material used for pressure reduction. Many different types of foam are available for

use. At least 3 to 4 inches are needed to reduce pressure on the skin. Foam is easy to use, lightweight, and relatively inexpensive. On the negative side, foam retains moisture and is difficult to clean when soiled.(16,19)

Competing/Complementary Technologies

A wide variety of other treatments for chronic wounds is available. These are listed below, but a description of them and evaluation of their effectiveness is beyond the scope of this report.

- Wound Dressings
- Cultured skin grafts
- Growth Factors
- Electrical Stimulation
- Vacuum-assisted Closure
- Hyperbaric Oxygen

Methodology

Identification of Clinical Studies

To identify information for this report, we searched the following databases:

- PubMed (Medline, HealthSTAR, AIDSline, etc.)
- Embase
- The Cochrane Library
  - Cochrane Database of Systematic Reviews
  - Database of Abstracts of Reviews of Effectiveness (DARE)
  - The Cochrane Controlled Trials Register (CCTR)
  - Health Technology Assessment Database (includes INAHTA publications)
  - U.K. National Health Service (NHS) Economic Evaluation Database (EED)
- RehabDATA
- National Guideline Clearinghouse (NGC)
- CINAHL (Cumulative Index to Nursing and Allied Literature)

The following ECRI proprietary databases were also searched for this topic:

- International Health Technology Assessment (IHTA)
- International Health Devices Sourcebase
- ECRI library catalog
- Health Device Alerts
- Healthcare Standards

- TARGET

Over 1,000 journals and supplements maintained in ECRI's collections were routinely reviewed for this project. Nonjournal publications and conference proceedings from professional organizations, private agencies, and government agencies were also screened. Other mechanisms used to retrieve additional relevant information included review of bibliographies/reference lists from peer-reviewed and gray literature. (Gray literature consists of reports, studies, articles, and monographs produced by federal and local government agencies, private organizations, educational facilities, consulting firms, and corporations. These documents do not appear in the peer-reviewed journal literature.)

We searched the U.S. FDA MDR and MAUDE databases of medical device adverse event reports. Searches were limited from 1989 to the present (MDRs 1989 - 1996; MAUDE 1996 - 2001).

Study Selection

We selected studies for inclusion in this technology assessment according to *a priori* criteria. These inclusion criteria were specific to each question and are listed in the Results section under each question.

Study Quality

We examined the quality of each study to determine if flaws in the study design had the potential to bias the study's results and reduce the strength of their findings. CMS considers several aspects of study quality in evaluating evidence concerning effectiveness of any treatment in the Medicare population.(20) We based our examination of study quality on these recommendations as well as added several measures of study quality specific to the treatment of pressure ulcers. Studies that met our inclusion criteria, but had serious design problems were excluded from further analysis or consideration. For each question, we table excluded studies and the reasons for their exclusion.

We evaluated each study's potential for bias according to the following study quality aspects:

- Blinding
- Randomization
- Prospective study design
- Sample size
- Attrition
- Concurrent wound care
- Comorbidities
- Pre-study wound size
- Patient ages
- Study length
- Method of measuring wound healing

Judging study quality according to the method of measuring wound healing is unique to this topic, and warrants further discussion. Some common outcome measures reported in the literature on treatments for chronic wounds are the number of wounds healed during the study treatment period, time to complete wound healing, and percent of wound area reduction. Complete wound healing is defined as complete coverage of the wound by granulation tissue and epithelial cells. Number of wounds improved or number of wounds deteriorating (increasing in size) are also important wound healing outcome measures, because, in elderly patients suffering from pressure ulcers, these are indications of the palliative effect of wound healing therapy. Palliation may be as important as cure in many patients who are candidates for air-fluidized beds. However, there are difficulties with these and other measures of wound healing. These difficulties are described in Table 1.

Several studies have shown that pressure ulcers do not heal at a linear rate.(21-23) Consequently, a good way to measure mean wound healing may be to model it as an exponential decay function. This measurement is independent of wound size and time of measurement.(22) Karba et al.(22) refer to this measurement as a normalized healing rate or theta: theta = $[\ln(S_0/S_t)]/t$ where S_0 and S_t are the initial surface area and the surface area at time t, respectively, and t is the time measured in days or weeks. Exponential decay rates of wound healing are not commonly reported. None of the studies included in this assessment reported theta.

Ideally, a study should report a measure of the mean rate of change in ulcer size (such as the normalized healing rate) during the study period, and report a measure of the number of patients with improving wounds, stable wounds, and deteriorating wounds.

Analysis of Key Outcome Measures

Three aspects of the studies reviewed for this report; lack of common control groups, lack of common outcome measures reported in all studies, and the differences in study lengths, prevent the use of meta-analytical techniques in this assessment.

The lack of combinable outcome measures in the studies included in this assessment preclude a meta-analysis. Therefore, we present a systematic narrative evaluation of each study's results. We present the statistical analysis of the authors when it was reported and, whenever possible, we have verified their findings. When possible, we computed the minimal detectable difference a study could have found as statistically significant, given the study's sample size and the variance of the measurements.

Tables

Table 1. Methods of Measuring Wound Healing

Reported Outcome Measures	Definition	Difficulties
Number of wounds healed	The number of wounds healed or the number of patients with healed wounds during the study period.	Does not provide information on the condition of the ulcers that did not heal. Results reported by trials that employ this outcome may depend on the length of the trial. Short trials do not allow time for complete healing to take place and lengthy trials may allow all wounds to heal. Large differences in trial length complicate comparisons across trials. Direct comparisons across studies are complicated by the wide variation in trial length reported by the clinical trials examined for this technology assessment.
Wound Sizes	Wound sizes, usually reported as cm^2, at various times after treatment	Unequal initial wound sizes between treatment groups may influence other outcome measurements such as number of wounds healed and time to wound healing. Measures of area healed (cm^2 or mm^2) are dependent on initial wound size with larger wounds showing greater area healed.

Change in wound size (rate, absolute, or percentage)	The change in wound size during the study usually reported as a rate (cm^2 per day), absolute change in wound size, or as a percentage change.	Reduction in wound area measured as a percentage of initial area removes the size consideration but depends on the length of the study. Because wound healing is not linear, these measurements do not accurately reflect wound healing. This measure does not provide information on the number of patients with improving or deteriorating wounds.
Time to wound healing	Mean length of time until wounds heal.	This measurement is taken only for wounds that heal, which may be a few wounds or all wounds in the trial. The length of the trial can also affect this outcome. Trials of short duration will have few wounds that heal and trials of long duration may have nearly all wounds healed.

Number of Patients with Decrease in Wound Size or Improved Wounds	As a complement to the number of wounds healed outcome, some studies will report on the number of ulcers that have decreased in size or have "improved" during the study period. The number of wounds that have increased in size or deteriorated (developed into a more severe stage) may also be reported.	Depends on the studies definition of improvement. Both the number of patients with improved wounds and the number of patients with deteriorating wounds should be reported.
Normalized healing rate	[ln (initial surface area / final surfaces area)] / time between initial and final surface measurements. This important measurement is seldom used.	This measure does not provide information on the number of patients with improving or deteriorating wounds.

Results

Question 1: Are air-fluidized beds effective in the treatment of Stage III and/or IV pressure ulcers in the home setting?

Of particular interest is evidence that the use of air-fluidized beds are superior to the use of Group 2 support surfaces for the healing of Stage III and/or IV pressure ulcers.

Trial Inclusion Criteria

1. Clinical studies of air-fluidized beds for the treatment of patients with pressure ulcers published after 1985 and have the following:

    a. A parallel control group (a control group is necessary to determine the effectiveness of the support surface compared to conventional treatment).

    b. At least 10 patients in each treatment group.

c. Home setting, but, if studies in the home setting were not available, clinical studies in other settings were examined).

d. Patients with Stage III and IV pressure ulcers or study separately present the results from such patients (results from studies that mixed Stage I and II pressure ulcer data with Stage III and IV pressure ulcer data may not accurately represent the results of patients with more severe pressure ulcer stage that are the focus of this report, therefore, we excluded these studies).

2. One of the following outcome measures must be reported

   a. number of wounds completely healed during study period

   b. number of wounds that decreased in size during the study period

   c. number of wounds that became worse or stayed the same during the study period

   d. mean time to heal

   e. time to 50% of wound healed during study period

   f. mean area of wound reduction

   g. number of patients needing hospitalization or developing a complication with pressure ulcer care

   h. length of stay during treatment period

3. Other technology assessments of air-fluidized beds for the treatment of pressure ulcers.
4. English language
5. Published as a full article, not a meeting abstract

Study Quality

Only one clinical study of air-fluidized beds, Strauss, 1991,(24) met the inclusion criteria for this question and was conducted in the home setting. Air-fluidized beds were compared to various conventional therapies, chosen by the attending physician on a patient-specific basis, including alternating pressure pads, air-support mattresses, water mattresses, and high-density foam pads. One hundred and twelve patients with Stage III or IV pressure ulcers were randomly assigned to 36 weeks of treatment. The patients in this study had severely limited mobility and required the assistance of a relative, friend, or paid caregiver.

Although the study was a properly designed RCT, its findings are confounded by "treatment bias." A nurse with expertise in the use of air-fluidized bed therapy served as a home care coordinator and followed the healing progress in both treatment groups. For patients using air-fluidized beds, the nurse conducted weekly home visits for the first 4 weeks and then biweekly thereafter. In these patients, if the ulcers were healing properly, no changes were made to the therapy. If the ulcers were not healing, the patient's physician was contacted so that alternative therapies could be tried. The patients receiving conventional therapies, however, were not provided with the same degree of nursing care as was provided to those patients using air-fluidized beds. In these patients, the home care coordinator conducted biweekly home visits for the first 4 weeks and thereafter telephoned the patient biweekly. The home care coordinator noted the condition of the ulcer and contacted the patient's physician only in an emergency. Consequently, the findings from this study cannot be used to draw conclusions about the relative effectiveness of air-fluidized beds compared to the conventional therapies for Stage III and IV pressure ulcers. This is because the relationship between air-fluidized beds and wound healing is confounded by between-group differences in nursing care. Any benefits seen in the air-fluidized group in this study may have been a direct result of the ability to change wound healing therapies instead of the use of air-fluidized beds. Therefore, this study and its results are excluded from further consideration.

Given that the only study that met the *a priori* inclusion criteria for this question was excluded due to confounding of its results, we relaxed the inclusion criteria to include studies performed in other settings. Such studies could provide evidence of effectiveness that might, albeit imperfectly, pertain to the home setting. With this relaxed criteria, one RCT examining air-fluidized beds in a hospital setting, Allman, 1987,(25) was identified.

Allman, 1987,(25) enrolled 72 patients, but seven withdrew before followup data were obtained. Therefore, data were collected from 66 patients. Information on the air-fluidized bed and control support surfaces, patient characteristics, characteristics of the pressure ulcers, patient attrition, and patient comorbidities in this study are presented in Tables 2 through 6, respectively. Since this study compared air-fluidized beds directly to a Group 2 support surface, an alternating air mattress, it also provides the only evidence for considering whether air-fluidized beds are superior to Group 2 support surfaces. This study is, however, more than 10 years old and may not accurately reflect the results that might be obtained with more current Group 2 support surfaces and current air-fluidized beds.

Allman, 1987(25) followed hospitalized patients until death, discharge, or wound healing (range of 4 to 77 days), and used alternating air mattresses in the control group, used standardized concurrent wound treatments, and blinded the assessment of wound improvement. Prior to the study, these authors calculated the sample size needed to obtain statistically significant results, with adjustment for the anticipated attrition. Results were stratified according to initial ulcer size, with the median initial ulcer size (7.8 cm^2) as the cutoff point for defining large and small ulcers. We consider only the results from patients with large ulcers because, given the patients enrolled in this study, these ulcers are more likely to be Stage III or Stage IV. We stress that there is only an indirect correlation between size and ulcer stage. Therefore, the results of the Allman study only imperfectly portray the results that one might obtain from a population of patients comprised entirely of patients with Stage III and Stage IV ulcers.

Another difficulty with the Allman study is its attrition rate (see Table 5). Drop outs comprised 32% of the patients initially given air-fluidized beds and 24% of the patients initially given alternating air mattresses. Some drop outs occurred as soon

as 4 days. Attrition was due to death or discharge. The number of patients with completely healed wounds could have been affected by the number of drop outs due to death or discharge. Thus, the patients remaining in the study until followup may not be a representative subpopulation of the population of patients who entered the study. Therefore, this measure is of limited value in comparing the effectiveness of air-fluidized beds and alternating air mattresses in the treatment of such patients. However, the authors also report wound improvement for all patients. As implied above, this measure is important in this population, because, for many of these extremely sick patients, complete wound healing may not be the sole goal of treatment. Palliation is also important; so progress towards healing and the potential reduction in wound pain that accompanies it may also be an important goal. Therefore, we considered the wound improvement data reported by Allman.

In interpreting these data, some consideration must also be given to a potential bias in the study against the air-fluidized bed group. Fewer patients in this group could sit in chairs (47%, 15 of 32,) compared to the alternating air mattress group (62%, 21 of 34,). This could give the alternating air mattress patients an advantage in wound healing. As such, this adds more strength to any evidence that the air-fluidized bed group benefited more than the alternating air mattress group.

Evidence Base

Following our assessment of the quality of evidence pertaining to Question #1, we were left with a single study, Allman, 1987.(25) This study addresses the effectiveness of air-fluidized beds in the hospital setting, so the generalizability of the findings of this study to the home setting is uncertain. This study is the only study to compare the effectiveness of air-fluidized beds and Group 2 support surfaces.

Findings

The results for large ulcers reported by Allman, 1987(25) are presented in Table 7. These data demonstrate a statistically significant difference between treatment groups in favor of air-fluidized beds in the number of patients with improved large wounds. Any wound that was "healed," "much improved," or "a little improved" was defined as improved. Ten of 16 (63%) patients on air-fluidized beds showed improvement compared to 5 of 17 (29%) patients on alternating air mattresses.

Allman, 1987(25) also reported on the median change in total surface area for large ulcers. These data show that air-fluidized beds were associated with a statistically significant greater reduction in wound size when compared to patients on alternating air mattresses (-5.3 cm^2 vs. + 4.0 cm^2, respectively).

Other Technology Assessments

A Cochrane Review published in 2001 assessed beds, mattresses and cushions for pressure ulcer prevention and treatment.(26) This systematic review considered data from three studies of air-fluidized beds, all of which were RCTs. The authors of this review stated that the confidence with which they could draw firm conclusions from the included studies was greatly tempered by (a) the poor quality of these three trials and (b) the lack of replication of most comparisons. Nevertheless, the authors concluded that "good evidence from RCTs suggests that air-fluidized beds may improve pressure

sore healing rates." However, these conclusions are based on data that were extracted from studies that were excluded from the present report. Strauss, 1991(24) was not considered in the present report because of treatment bias (see above), and Munro, 1989(27) did not meet the inclusion criteria for this question because the study included a large portion of Stage II pressure ulcers and they did not stratify their results by ulcer stage. The study by Allman, 1987(25) was the third study considered in the review.

Conclusions

Only one study examined the efficacy of air-fluidized beds in the home environment (Strauss, 1991,(24)). A bias toward additional wound healing therapy in the air-fluidized bed group renders this study's results difficult to interpret.

In the hospital setting, Allman, 1987(25) found that wound size reduction in larger ulcers, was significantly greater in patients on air-fluidized beds than in patients using alternating air mattresses. This study did not classify wounds according to stage, so the relevance of this finding to patients with Stage III or IV ulcers cannot be precisely determined. Similarly, the extent to which these results can be carried over to the home setting is not known. Finally, since this study was performed more than 10 years ago, it may not accurately reflect the effectiveness of Group 2 support surfaces as they are currently manufactured.

Evidence Tables

Table 2. Description of Support Surface Used For Pressure Ulcer Treatment Reported in Allman, 1987(25)

Number of Patients	**Description of Support Surface Used For Treatment**	**Product Name and Manufacturer**
32	Air-fluidized beds - Patients were repositioned every 4 hours between 0700h and 2300h	Clinitron Therapy, Support Systems International, Inc.
34	Alternating air mattresses - Alternating air mattress covered by a foam pad. Patients were repositioned every 2 hours.	Lapidus Air Float System, American Pharmaceal Company, Cincinnati, Ohio

Table 3. Patient Characteristics Reported in Allman, 1987(25)

Number of Patients	Support Surface	Mean or Median Age	Age	SD	Males	Females	Mean serum albumin level below 3.5 g/dl
32	Air-fluidized beds - Clinitron therapy	Mean	65.5	15.6	11	20	Yes
34	Alternating air mattresses - Lapidus Air Float System	Mean	67.6	18.3	16	18	Yes

Table 4. Pressure Ulcer Characteristics Reported in Allman, 1987(25)

Number of Patients	Support Surface	Number of Patients With					Number of Patients with Multiple Pressure Ulcers	Size of Pressure Ulcer (cm^2) Median and Range	Duration of Pressure Ulcer Before Treatment (median and range in weeks)	Number of Ulcers less than 7.8 cm^2
		Stage I Ulcers	Stage II Ulcers	Stage III Ulcers	Stage IV Ulcers	Stage III and IV Ulcers				

32	Air-fluidized beds - Clinitron therapy	4	12	9	6	15	26	7.8 0.3 - 83.2	1 1 - 231	15
34	Alternating air mattresses - Lapidus Air Float System	4	16	11	3	14	24	10.8 0.4 - 180.3	2 1 - 260	17

Table 5. Patient Attrition Reported in Allman, 1987(25)

Number of Patients	**Support Surface**	**Total Attrition**	**Attrition Attributed to**					
			Dropping out before receiving treatment	**Death**	**Concurrent unrelated illness or transfer**	**Patient request**	**Protocol deviation**	**Lost to follow up**
32	Air-fluidized beds - Clinitron therapy	15 (32%)	1	8	2	0	4	0
34	Alternating air mattresses - Lapidus Air Float System	11 (24%)	0	7	3	1	0	0

Table 6. Patient Comorbidities Reported in Allman, 1987(25)

Number of Patients	**Support Surface**	**Comorbidities reported for patients who:**	**Number of Patients With**						**Discription of Other Conditions**
			Paraplegia	**Diabetes**	**Alzheimer's Disease**	**Cardio-vascular Disease**	**Bladder Incontinence**	**Other Conditions**	
32	Air-fluidized beds - Clinitron therapy	Started trial	6	17	9	10	9	25	Malignancy 4, Amputation 8, Fracture 1, Sepsis 9, Pneumonia 3
34	Alternating air mattresses - Lapidus Air Float System	Completed trial	4	25	12	10	13	33	Malignancy 6, Amputation 8, Fracture 2, Sepsis 10, Pneumonia 7

Table 7. Wound Healing Results Reported in Allman, 1987(25)

Support Surface	**Number of Patients**	**Followup (days)**	**Number of Patients With Improved Ulcers (%)**	**Statistical Analysis by Authors**	**Observed Difference**	**Minimum Detectable Difference [a]**	**Median Change in Surface Area (cm^2)**	**Range (cm^2)**	**Statistical Analysis by Authors**

Air-fluidized beds - Clinitron therapy	16 patients with largest >7.8 cm^2	13 (4 - 77)	10 (63%)	Two-tailed chi-square test, p = 0.05	34%	33%	-5.3	-38.0 to 15.5	The differences between air-fluidized beds and conventional therapy were more marked for larger sores (Wilcoxon rank sum test, p = 0.01).
Alternating air mattresses - Lapidus Air Float System	17 patients with largest >7.8 cm^2		5 (29%)				4.0	-55.1 to 94.7	

[a] The minimum detectable difference is the difference between two groups that is needed for the effect to be statically significant at p = 0.05 given the sample size and sample variance reported in the study.

Question 2: Are Group 2 support surfaces effective in the treatment of Stage III and/or IV pressure ulcers in the home setting?

Trial Inclusion Criteria

1. Clinical studies of Group 2 support surfaces for the treatment of patients with pressure ulcers published after 1985 and have:

   a. A parallel control group (a control group is necessary to determine the effectiveness of the support surface compared to conventional treatment)

   b. At least 10 patients in each treatment group.

   c. Home setting (if studies in the home setting were not available, clinical studies in other settings were examined)

   d. Patients with Stage III and IV pressure ulcers or study separately present the results from such patients (results from studies that mixed Stage I and II pressure ulcer data with Stage III and IV pressure ulcer data may not accurately represent the results of patients with more severe pressure ulcer stage that are the focus of this report, therefore, we excluded these studies).

2. One of the following outcome measures must be reported
    a. Number of wounds completely healed during study period
    b. Number of wounds that decreased in size during the study period
    c. Number of wounds that became worse or stayed the same during the study period
    d. Mean time to heal
    e. Time to 50% of wound healed during study period
    f. Mean area of wound reduction
    g. Number of patients needing hospitalization or developing a complication with pressure ulcer care
    h. Length of stay during treatment period
3. Other technology assessments of air-fluidized beds for the treatment of pressure ulcers.
4. English language
5. Published as a full article, not a meeting abstract

No studies met the *a priori* inclusion criteria for this question. As a result we relaxed the requirement that the study must be performed in the home setting. Such studies might at least provide circumstantial evidence about the effectiveness of these devices in the home.

Study Quality

There were three RCTs of Group 2 support surfaces compared to Group 1 support surfaces conducted in either the hospital or nursing home setting that met the other inclusion criteria (see Table 8). None had serious design flaws that warranted excluding them from further consideration.

Evidence Base

Ferrell, 1993(28) and Mulder, 1994(29) compared a foam mattress overlay to a low-air-loss mattress and Day, 1993(30) compared a foam mattress overlay to an alternating air mattress. Information on the support surfaces evaluated, patient characteristics, characteristics of the pressure ulcers, patient attrition, and patient comorbidities in the three studies assessed in this section are presented in Tables 8 through 12, respectively. There were a total of 216 patients enrolled in these three studies.

Findings

Outcome measures reported by the four studies that met the inclusion criteria for this question are presented in Table 13.

Ferrell, 1993(28) reported a statistically significant decrease in the surface area of deep ulcers in patients using low-air-loss therapy compared to patients on foam mattresses. Patients were in the study for a median of 37 days, but the range was 4 to 571 days. Ferrell conducted a power analysis to determine sample size prior to starting their study. The authors terminated their study early when a larger than anticipated difference between treatment groups was found. This study contained Stage II to IV ulcers, but reported results separately for deep ulcers (assumed to be Stage III and IV) and only these are considered in the present report (18 in the low-air-loss group and 14 in the foam mattress group). Patients with deep ulcers in low-air-loss beds showed a median rate of reduction of 0.099 cm^2 per day compared to 0.007 cm^2 per day for patients with deep ulcers using foam mattresses. Number of wounds completely healed was reported as a combined measure including all stages from II to IV. However, an odds ratio for complete healing of deep ulcers during the study was reported. The odds ratio of 2.97 (95% confidence interval of 0.61 to 14.5, $p = 0.18$) was not statistically significant. According to the authors, this subgroup analysis of deep ulcers was underpowered. In such circumstances, a lack of statistical significance does not necessarily mean there is a lack of clinical significance. The clinical significance of odds ratios such as this is difficult to judge.

Mulder, 1994,(29) reported the number of patients with completely healed Stage III and IV ulcers during an 84 day study and did not find a statistically significant difference between low-air-loss beds and foam mattress overlays (16% vs. 17%). The number of patients with improved wounds was also reported by Mulder. Improvement (wounds healed or reduced in stage) was seen in 48% of patients using the low-air-loss beds and 44% of patients using foam mattresses and this was not statistically significant. In spite of these findings, the authors state that low-air-loss beds were "significantly more effective in healing pressure ulcers than conventional therapy" based on analyzing the log transformed ratio of the initial ulcer size to the final ulcer size using analysis of covariance. This analysis showed a 77% higher reduction in wound size in the low-air-loss group ($p = 0.042$). The 77% higher reduction is a relative value and no absolute changes in wound size are reported to confirm this finding. The clinical significance of this relative difference cannot be judged with the available data.

In the study by Day, 1993(30), the mean ulcer sizes of the two groups were significantly different despite the random allocation of patients to treatment (at the beginning of the trial the alternating air mattress group had a mean ulcer size of 51.8 cm^2 compared to 13.7 cm^2 in the foam mattress group, $p = 0.036$). This difference could have arisen by chance or from protocol violations, but the actual cause is not possible to determine. To compensate for the pretreatment difference in ulcer size, the authors performed an analysis of covariance. This analysis found no statistically significant difference in the healing of ulcers between support surfaces.

Despite this analysis, the authors stated that alternating air mattresses were "more effective than the foam overlays in ulcer healing for patients with Stage III and IV ulcers." This statement was based on the greater number of patients improving more than 10 cm^2 in the alternating air group. However, this outcome would be expected based on the median initial ulcer size. Half of the patients in the foam mattress group had less than 13.7 cm^2 in wound size meaning that these

patients had little chance to reach a 10 cm^2 change compared to the alternating air mattress group with a median initial wound size of 51.8 cm^2. A 10 cm^2 reduction in wound size represents a 73% reduction for patients on the foam mattress, which would be much more difficult to achieve than the 19% reduction implied by a 10 cm^2 reduction for patients on the alternating air mattresses. Therefore, the reported difference in wound size could at least partly reflect the difference in the patients' initial wound sizes and not the effect of treatment.

The studies by Ferrell, 1993(28), Mulder, 1994,(29) and Day, 1993(30) do not provide evidence that Group 2 support surfaces are more effective in healing Stage III or IV pressure ulcers compared to a foam mattress overlay, a Group 1 support surface.

Other Technology Assessments

As previously discussed in the section on air-fluidized beds, a Cochrane Review has assessed beds, mattresses and cushions for pressure ulcer prevention and treatment .(26) Their review considered one study of low-air-loss beds (Ferrell, 1993(28)) and one study of alternating air mattresses (Devine, 1995(31)). Based on these studies the authors of this review believe that "it appears that low-air-loss beds are effective in treating pressure ulcers compared with foam mattresses." However, they also state that their confidence in this conclusion is tempered by the poor quality of the studies and the lack of replication of most comparisons.

Conclusions

No studies were identified on which to base conclusions about the efficacy of home use of Group 2 support surfaces. Therefore, a direct evidence-based answer to this question is not possible.

Indirect evidence from three RCTs, conducted in hospitals or nursing homes, suggest that Stage III and IV pressure ulcers progress towards healing on Group 2 support surfaces. Two RCTs comparing low-air-loss mattresses and one RCT comparing an alternating air mattress, to a foam overlay (a Group 1 support surface) found no statistically significant differences between these support surfaces in the promotion of healing in Stage III or IV pressure ulcers. One of these studies did find a significantly greater rate of wound size reduction for deep ulcers in patients using low-air-loss mattresses compared to patients using a foam mattress. However, the same study found no statistically significant differences in complete healing of deep ulcers. The other studies, also found no difference in the rate of complete healing. These studies may have only had sufficient sample size to detect large differences, but the observed differences in healing and improvement were less than 5%.

These studies do indicate that Stage III and IV pressure ulcers are healing on these devices, but differences in reporting wound healing outcomes prevents any comparisons across studies that would allow the estimation of the proportion of patients with healing wounds and the proportion of patients with non-healing wounds.

The generalizability of the findings of these studies to the home setting is unknown.

Evidence Tables

Table 8. Description of Group 2 Support Surface Used For Pressure Ulcer Treatment

Reference	Type of Support Surface	Setting	Number of Patients	Product Name and Manufacturer
Group 2 support surfaces vs. Group 1 foam support surfaces				
Mulder, 1994(29)	Low-air-loss mattresses	Nursing Facility	31	Therapulse, Kinetic Concepts, Inc., San Antonio, TX
	Foam mattress - Convoluted foam mattress overlay		18	GeoMatt, Span America, Greenville, SC
Day, 1993(30)	Alternating air mattresses	Hospital	44	TheraPulse, Kinetic Concepts
	Foam mattress - Convoluted foam mattress overlay		39	GeoMatt, Span America, Greenville, SC
Ferrell, 1993(28)	Low-air-loss mattresses -	Nursing Facility	43	Kinair bed, Kinetic Concepts International, San Antonio, TX
	Foam mattress - 10 cm convoluted foam mattress overlying a regular hospital bed		41	

All studies were RCTs

Table 9. Patient Characteristics in Studies of Group 2 Support Surfaces

Reference	Number of Patients	Support Surface	Mean or Median Age	Age SD	Age of youngest patient	Age of oldest patient	Males	Females	Mean serum albumin level below 3.5 g/dl
Group 2 support surfaces vs. Group 1 foam support surfaces									
Mulder, 1994(29)	31	Low-air-loss mattresses Therapulse	Not reported				Not reported		Not reported
	18	Foam mattress - GeoMatt							
Day, 1993(30)	44	Alternating air mattresses TheraPulse	Mean	75.09 15.37	32	102	17	27	No
	39	Foam mattress - GeoMatt	Mean	77.13 10.76	54	93	18	21	No
Ferrell, 1993(28)	43	Low-air-loss mattresses - Kinair bed	Median	85 25^{th} and 75^{th} percentiles = 71 and 92	Not reported	Not reported	22	21	Yes
	41	Foam mattress overlay	Median	84 25^{th} and 75^{th} percentiles = 68 and 91			20	21	Yes

All studies were RCTs

Table 10. Pressure Ulcer Characteristics in Studies of Group 2 Support Surfaces

Reference	Number of Patients	Support Surface	Number of Patients With					Number of Patients with Multiple Pressure Ulcers	Size of Pressure Ulcer (cm^2)
			Stage I Ulcers	Stage II Ulcers	Stage III Ulcers	Stage IV Ulcers	Stage III and IV Ulcers		
Group 2 support surfaces vs. Group 1 foam support surfaces									
Mulder, 1994(29)	31	Low-air-loss mattresses Therapulse	0	0	24	7	31	Not reported	Not reported
	18	Foam mattress - GeoMatt	0	0	13	5	18		
Day, 1993(30)	44	Alternating air mattresses TheraPulse	2 unable to stage	25	6	11	17	22	For deep ulcers Mean 51.8 cm^2 (SD: 11.9)
	39	Foam mattress - GeoMatt	4 unable to stage	23	8	4	12	17	For deep ulcers Mean 13.7 cm^2 (SD: 2.9)
Ferrell, 1993(28)	43	Low-air-loss mattresses - Kinair bed	0	25 superficial ulcers	0	0	18 deep ulcers	Not reported	Median 4.3 cm^2 25^{th} and 75^{th} percentiles: 2.6 and 14.0

	41	Foam mattress overlay	0	27 superficial ulcers	0	0	14 deep ulcers		Median 4.1 cm^2 25^{th} and 75^{th} percentiles: 0.97 and 8.95

All studies were RCTs

Table 11. Patient Attrition in Studies of Group 2 Support Surfaces

Reference	**Number of Patients**	**Support Surface**	**Total Attrition**	**Attrition Attributed to**				
				Death	**Concurrent unrelated illness or transfer**	**Patient request**	**Lost to Followup**	**Protocol deviation**
Group 2 support surfaces vs. Group 1 foam support surfaces								
Mulder, 1994(29)	31	Low-air-loss mattresses Therapulse	10 patients were dropped from the study and not evaluated	8	0	0	1	1
	18	Foam mattress - GeoMatt						
Day, 1993(30)	44	Alternating air mattresses TheraPulse	Not reported					
	39	Foam mattress - GeoMatt						

Ferrell, 1993(28)	43	Low-air-losss mattresses - Kinair bed	17	11	4	2	0	0
	41	Foam mattress overlay	22	7	4	2	0	9

All studies were RCTs

Table 12. Patient Comorbidities in Studies of Group 2 Support Surfaces

Reference	**Number of Patients**	**Support Surface**	**Number of Patients With**					**Discription of Other Conditions**
			Alzheimer's Disease	**Diabetes**	**Incontinence**		**Other Conditions**	
					Bladder	**Bowel**		
Group 2 support surfaces vs. Group 1 foam support surfaces								
Mulder, 1994(29)	31	Low-air-loss mattresses Therapulse	Not reported	Not reported	Not reported	Not reported	Not reported	
	18	Foam mattress - GeoMatt						
Day, 1993(30)	44	Alternating air mattresses TheraPulse	7	0	0	27	34	Dehydration 10, Fever of unknown origin 10, Pneumonia 7, Respiratory failure 7

	39	Foam mattress - GeoMatt	0	0	0	20	28	Dehydration 10, Fever of unknown origin 7, Pneumonia 5, Urinary tract infection 6
Ferrell, 1993(28)	43	Low-air-loss mattresses - Kinair bed	18	11	25	36	18	Contractures
	41	Foam mattress overlay	16	8	27	29	17	Contractures

All studies were RCTs

Table 13. Results Reported for Studies of Group 2 Support Surfaces

Reference	**Support Surface**	**Number of Patients**	**Followup (days)**	**Number of Patients With Successful Outcome (%)**	**Statistical Analysis by Authors**	**Observed Difference**	**Minimum Detectable Difference [a]**
Number of Patients With Healed Wounds							
Mulder, 1994(29)	Low-air-loss mattresses Therapulse	31	84	5 (16%)	Not analyzed	1%	26%
	Foam mattress - GeoMatt	18		3 (17%)			
Number of Patients With Improved Wounds							

Mulder, 1994(29)	Low-air-loss mattresses Therapulse	31	84	15 (48%)	Low air loss therapy was significantly more effective in healing pressure ulcers than conventional therapy (no statistical analysis was reported to support this conclusion).	4%	28%
	Foam mattress - GeoMatt	18		8 (44%)			

All studies were RCTs

[a] The minimum detectable difference is the difference between two groups that is needed for the effect to be statically significant at p = 0.05 given the sample size and sample variance reported in the study.

Table 13. Results Reported for Studies of Group 2 Support Surfaces (Continued)

Reference	**Support Surface**	**Number of Patients**	**Followup (days)**	**Mean or Median**	**Results**	**SD**	**Statistical Analysis by Authors**	**Observed Difference**	**Minimum Detectable Difference [a]**
Wound Size Diameter (cm^2)									
Day, 1993(30)	Alternating air mattresses TheraPulse	44	Day 1	Mean	51.8	11.9	There was a statistically significant difference in the initial ulcer size between the two groups (t = 2.13, p = .036) with more severe wounds in the alternating air mattress group.	14.7 cm^2	3.79 cm^2
			Not reported	Mean	37.1	8.1			

	Foam mattress - GeoMatt	39	Day 1	Mean	13.7	2.9	The analysis of covariance (using initial ulcer size and age) revealed no statistically significant difference in the healing of pressure ulcers with respect to type of support surface (F = 0.35, p >0.05).	24.7 cm^2	2.73 cm^2
			Not reported	Mean	12.4	3.5			
Wound Size Reduction (cm^2)									
Ferrell, 1993(28)	Low-air-loss mattresses - Kinair bed	18 deep ulcers	37.5 (4 - 571)	Median	.099 per day		Significant decrease in surface area of the ulcer for the low-air-loss bed group compared with the foam-mattress group (Wilcoxon rank-sum test, p = 0.02).		
	Foam mattress overlay	14 deep ulcers		Median	.007 per day				

All studies were RCTs

[a] The minimum detectable difference is the difference between two groups that is needed for the effect to be statically significant at p = 0.05 given the sample size and sample variance reported in the study.

Question 3: At what stage of pressure ulcer development should air-fluidized beds be used?

Of particular interest are the following, does the use of air-fluidized beds prevent the transition from Stage III to Stage IV pressure ulcers and is a 30 day waiting period in which a Stage III or IV pressure ulcer has not shown progression toward healing before switching a patient to an air-fluidized bed supported by clinical evidence?

The stage of ulcer development at which air-fluidized beds should be used can be addressed by examining clinical studies for the effect of air-fluidized beds on the healing of each ulcer stage. This question can also be addressed by examining the

number of ulcers that change from Stage III to Stage IV.

The sub-question concerning a 30 day waiting period is relevant to current Medicare policy which requires that a patient with Stage III or IV pressure ulcers receive 30 days of conservative treatment "without progression toward wound healing" before receiving an air-fluidized bed. This question cannot be approached directly because trials that compare patients receiving air-fluidized beds at initial diagnosis and patients who wait 30 days to receive these beds have not been conducted. Therefore, we examined studies of wound care treatments other than support surfaces to determine whether there is evidence that at least some patients exhibit progression to wound healing (judged by the number of patients improving or not improving) during the first 30 days of treatment. If evidence from such studies shows that other wound care methods do not promote healing in Stage III and IV pressure ulcers, yet air-fluidized beds do promote healing of theses wounds, then a 30 day waiting period for the use of an air-fluidized bed may not be justified. However, if this evidence suggests that other wound care methods are successful in treating Stage III and IV pressure ulcers, than a 30 day waiting period may be justified.

Trial Inclusion Criteria

1. Clinical studies of air-fluidized beds for the treatment of patients with pressure ulcers published after 1985 and have the following:

    a. Controlled study in which some patients received air-fluidized beds upon initial diagnosis and some patients waited 30 days before receiving an air-fluidized bed, OR a study that stratified its results according to Stage III and Stage IV pressure ulcers

    b. At least 10 patients in each treatment group.

    c. Stage III and IV pressure ulcers or that separately present the results from such patients

    d. Report the proportion of Stage III and IV pressure ulcers that did and did not improve during the initial 30 days of treatment must be reported (ideally, the proportion of Stage III and IV pressure ulcers to improve while using air-fluidized beds during the initial 30 days should have been reported)

2. Also, studies of treatments for Stage III and IV pressure ulcers other than Group 2 or 3 support surfaces that report the proportion of Stage III and IV pressure ulcers that did and did not improve during the first 30 days of treatment from first diagnosis published from 1990 to the present.
3. English language
4. Published as a full article, not a meeting abstract

Study Quality

The quality of the air-fluidized bed studies was examined in Question #1 and resulted in only the study by Allman,

1987(25) being assessed. Two studies of wound care therapies other than support surfaces were identified that specifically reported the number of Stage III and IV pressure ulcers that did or did not improve during the first 30 days of treatment (see Table 14). These studies had no important design deficiencies.

Findings

Transition From Stage III to IV Pressure Ulcer: No studies of air-fluidized beds were identified that specifically reported the number of ulcers that progressed from Stage III to IV. As discussed under Question #1, few studies of air-fluidized beds present wound healing data separately by ulcer stage. Allman, 1987(25) reported that smaller ulcers (less than 7.8 cm^2) healed to the same extent on air-fluidized beds and alternating air mattresses. For large ulcers (greater than 7.8 cm^2 and assumed to be mostly Stage III and IV pressure ulcers), the larger reductions in wound size and the greater number of wounds improved were statistically significant for patients using air-fluidized beds compared to patients using alternating air mattresses.

Allman, 1987(25) reported that 9% of patients (3 of 34) using an alternating air mattress withdrew from this therapy because their wounds were getting worse and that none of the 32 patients using air-fluidized beds withdrew from therapy due to worsening ulcers. Among patients with large ulcers in this study, 38% of patients (6 of 16) showed no improvement on air-fluidized beds or became worse and 62% of patients (10 of 16) showed improvement in wound condition. This difference was statistically significant (see Table 7)

Indications of Stage III and IV Pressure Ulcer Improvement or Deterioration in the First 30 Days of Treatment with Other Therapies: Sayag, 1996(32) reported that only 4% of patients (2 of 47) had deterioration or no improvement using a calcium alginate dressing, but 33% of patients (15 of 45) had deterioration or no improvement using dextranomer paste and saline gauze. Barr, 1995,(33) in a single treatment arm study of hydrocolloid/alginate dressings examining a single ulcer per patient, reported that 37% of ulcers decreased in size (11 of 30) and 63% of ulcers increased in size (19 of 30).

Groen, 1999,(34) reported the number of patients with completely healed Stage III and IV pressure ulcers and did not find a statistically significant difference between groups of 60 patients each using foam or water mattresses. During a 28 day period, 45% of patients using the foam mattresses and 48% of patients using the water mattresses had completely healed wounds, an observed difference of 3 percentage points. Data on the number of wounds that became worse during the study was not reported. A power analysis performed before the start of the trial determined that a sample size of 60 in each patient group was required to show that a difference of 25% or more between the groups was statistically significant with an alpha of 5% and power of 80%. Therefore, the finding of no statistically significant difference in complete wound healing may result from the small size of this study.

Conclusions

No studies directly addressed this question, but one study provided indirect evidence suggesting that air-fluidized beds may be effective in preventing ulcer deterioration in at least some patients. This study of patients on air-fluidized beds reported that that 62% of patients with large ulcers (which are potentially Stage III and IV) experienced an improvement in wound

condition and that 38% of patients with these ulcers showed no change or became worse.

Based on three studies of pressure ulcer therapy other than Group 2 or 3 support surfaces published between 1990 and 2001, Stage III and IV pressure ulcers have the potential to heal during the first 30 days under a variety of treatments. However, the data also indicate that some Stage III and IV ulcers will not heal during this time period. The data from these studies are not sufficient to determine the exact proportion of patients who do not improve during the initial 30 days of treatment. Also unknown is the proportion of such patients who might benefit from earlier use of air-fluidized beds. When considering the initial treatment for Stage III and IV pressure ulcers, the available clinical evidence is not sufficient to determine which type of patient will benefit from initial conservative treatment alone and which type of patient will benefit when air-fluidized bed therapy is added to the conservative therapy.

Evidence Tables

Table 14. Thirty Day Healing Data for Stage III and IV Pressure Ulcers

Reference	Trial Design	Treatments	N	Age (Range)	30 Day Healing Data
Groen, 1999(34)	Randomized controlled trial	Water mattress - with three PVC sections held in place by a foam frame	60	83.5 (range not reported)	At 28 days, 48% healed.
		Foam mattress - 14 cm thick mattress with 3 layers of polyurethane foam.	60	81.9 (range not reported)	At 28 days, 45% healed.
Sayag, 1996(32)	Randomized controlled trial	Calcium alginate dressing	47	81.9 (60 -94)	At 4 weeks, 50% of patients had achieved a minimum wound size reduction of 40% and 2 patients (4%) showed deterioration of the pressure ulcer.

		Dextranomer paste and sterile gauze	45	80.4 (60 - 96)	At 4 weeks, 18% of patients had achieved a minimum wound size reduction of 40% and 15 patients (33%) showed deterioration of the pressure ulcer.
Barr, 1995(33)	Single armed trial	Hydrocolloid / alginate dressing	30	72.4 (25 - 96)	Distribution of ulcers: Stage III - 10 (33%); Stage IV - 20 (67%). One ulcer per patient. 12 patients were using air-fluidized beds, 7 patients were using low-air-loss beds. During the 24 day study period, 11 ulcers (37%) decreased in size (mean reduction of 16%) and 19 ulcers (63%) increased in size (mean increase of 34%).

Question 4: What are the requirements (education, training, experience) needed for nursing or care giving in the home setting when using an air-fluidized bed?

Trial Inclusion Criteria

1. Clinical studies of air-fluidized beds for the treatment of patients with pressure ulcers published after 1985 and have the following:

   - At least 10 patients in each treatment group.

   - Information on concurrent wound care is reported.

   a. OR guidelines on the use of air-fluidized beds for the treatment of pressure ulcers published from 1985 to the present.

   b. OR manuals for air-fluidized beds.

   c. OR reviews offering expert opinion on the use of air-fluidized beds for the treatment of pressure ulcers published from 1985 to the present.

2. English language

3. Published as a full article, not a meeting abstract

Clinical Studies

No clinical studies were identified that directly addressed this question, however, six studies of air-fluidized beds do report on the nursing care given to patients using these beds and two studies report on complications when using these beds. Nursing care information from these studies is presented in Table 15. Complications were reported in only two studies and are presented in Table 16. Strauss, 1991(24) reported that seven beds overheated and six beds had minor bead leaks (from a total of 58 patients), but that these problems were corrected by the manufacturer's service technician, usually within 24 hours. Allman, 1987(25) found that cases of hypernatremia (abnormally high concentrations of sodium in the blood probably due to dehydration) and hypotension were similar in air-fluidized beds (5 and 6 of 31 patients, respectively) and alternating air mattresses (5 and 7 of 34 patients, respectively). Allman, 1987 also reported a single case of excessive nosebleed in a patient on an air-fluidized bed that required a transfusion. Nosebleeds can occur in patients using air-fluidized beds due to excessive drying of the nasal passages caused by the relatively low humidity of this environment.

Guidelines

We identified two clinical guidelines that contained relevant information.

In 1989, a guideline for the home use of air-fluidized beds was published by the Office of Health Technology Assessments (OHTA), which was part of the National Center for Health Services Research and Heath Care Technology Assessment.(18) According to this guideline, caregivers should be aware of the following: (Note: items paraphrased or summarized from guidelines are presented in text boxes)

- To prevent dehydration, extra fluid intake may be required. Close observation of patients for signs of dehydration and careful monitoring of fluid intake and output are crucial to the management of patients using air-fluidized bed therapy.
- Confusion or disorientation due to the sensation of floating may occur.
- Accumulation of thick pulmonary secretions may occur. Deep breathing and coughing exercises (every 1 to 2 hours), postural drainage, and chest percussion may be needed to facilitate secretion removal. These pulmonary preventive measures can be performed while the bed is defluidized.
- The heavy weight of the beds creates difficulties in maneuvering the bed. The beds height causes inconvenience for short-statured nursing staff.
- Leakage of microspheres may occur. Skin irritation may result from microspheres on the skin of both patients and staff.
- A physician conducts a initial assessment and evaluates the patient for home use of an air-fluidized bed.
- A home air-fluidized therapy regime must be carried out under the direct supervision of an attending physician.
- A patients is seen monthly by the physician and as needed.
- A specially trained nurse consultant provides training for the patient and caregiver and reports on the status of the patients to the attending physician.

- Following the initial prescription, the patient must be recertified by a physician for home air-fluidized therapy on a monthly basis.

According to this guideline, appropriate home support is essential for optimizing the therapeutic benefits of air-fluidized beds and for preventing complications that may arise from a patient's limited mobility. The weight of the system was seen as a potential limiting factor for some homes.

The OHTA guideline concluded that adequate home support was a key element in the success of this therapy in the home, and that use of air-fluidized beds in this setting requires a trained caregiver. According to the guideline, the caregiver should assist the patient with activities of daily living, meeting fluid and caloric requirements, and carrying out the physician's prescribed treatment. In addition, the guideline states that the caregiver should assist in the management and support of the air-fluidized bed system.

In 1990, the University Hospital Consortium's Technology Advancement Center produced a set of guidelines for the use of pressure relief devices to treat and prevent pressure ulcers.(35) The guideline recommended the following nursing procedures when using air-fluidized beds.

- Turning schedules are recommended to help prevent complications of immobility
- Plastic or rubber packed pads or sheets should not be used as they prevent air flow
- High air flow can cause dehydration and excessive drying of the patient's dressing/skin
- This bed has no patient positioning features. Foam wedges are used to position patients
- Other therapy beds should be considered for the ambulatory patient
- Bed is contraindicated for patients with unstable spinal cords and cervical traction
- Temperature of the air leaving the bed can be adjusted for patient comfort
- Spilled beads must be wiped with a damp cloth
- For CPR mode, unplug the bed, step on foot control, or push hand control in order to create a firm support surface
- Not suitable for patients over 250 lbs. or 6 feet tall

User Manuals

The Clinitron® Hite-RiteTM air-fluidized therapy user's manual, published in 1997, provides the clinical and operational procedures for proper use of the unit by caregivers and nursing staff.(17)

The manual suggests that the best candidates for air-fluidized bed therapy are less than six feet tall, weigh less than 250 pounds, can move independently in bed, and are not confused, combative, or at high risk for pulmonary complications.

The manual states that there will be times when further assistance is needed and the company representative will be need to be called. Routine maintenance and cleaning of the microsphere beads is performed by the representative. Safe use of

the system requires a knowledge of:

- the control panel (airflow on/off, alarms)
- care of the beads
- bed elevation procedures
- bed movement lock, brakes
- other aspects of bed operation
- methods for turning patients in these beds

The control panel is located at the end of the bed and cannot be accessed by the patient. In cases of emergency or when performing CPR, the control panel must be used to defluidize the beads and create a firm surface for patient transfer or CPR compressions.

Adverse Events Reported in Medical Device Reports (MDR) and Manufacturer and User Facility Device Experience Database (MAUDE)

The MDR and MAUDE data are reports of adverse events involving medical devices collected by the FDA. The data consist of all voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996. Searches were limited from 1989 to the present (MDRs 1989 - 1996; MAUDE 1996 - 2001). These adverse event reports cannot be used to determine the incidence or prevalence of these events, but nurses and caregivers should be aware of these possible occurrences. A total of 336 adverse event reports were identified and could be classified as follows:

- Patient trapped between bed/mattress and bedrail (83 reports)
- Problems related to bedrails (17 reports)
- Mattress/bed overheating leading to hyperthermia, heat blisters or burns (29 reports)
- Fire (36 reports)
- Electrical shock to caregiver (7 reports)
- Deflation, over-inflation, or inability to deflate (46 reports)
- Loss of sand, pellets, beads, etc (11 reports)
- Formation of new pressure blisters (10 reports)
- Mechanical malfunction (7 reports)
- Split between cells leading to buckling/raised areas in bed surface (81 reports)
- Bad smell emanating from bed (4 reports)
- Bed oozing body fluids from previous patients (2 reports)
- Bed alarm too loud - masked ventilator alarm (1 report)
- Bed tipped over (1 report)
- Patient attempted suicide by smothering himself with mattress cover

In the case of patient entrapment, the reports did not indicate whether patients became trapped between the bedrails and mattress as a result of change in bed/mattress inflation level or shifting of mattress overlays. More than half of the 83 entrapment reports identified by this search indicated that the entrapped patients suffocated. Patient entrapment is a common problem with standard beds as well, especially when restraints are involved.

The 10 reports describing development of new pressure blisters also did not indicate whether this was associated with bed/mattress inflation level and, conversely, the 81 reports describing the buckled bed surfaces did not indicate whether this deformed surface led to the development of new sores.

Several adverse event reports described materials leaking from air-fluidized beds. Consequences attributed to these leaks included wound infection and caregivers falling on the leaked beads.

Most of the fire-related reports described smoking units and burning smells, very few incidents resulted in actual flames. One report described an AIDS patient who committed suicide by setting his mattress on fire with a cigarette lighter. His roommate suffered smoke inhalation injuries but survived.

Conclusions

According to the two published guidelines, education and training of the caregiver is a necessary aspect of using air-fluidized therapy in the home setting. The caregiver must be aware of patient safety issues, the proper methods for turning and repositioning patients, and in the proper operation of the air-fluidized bed system. A specially trained nurse consultant is needed to assess wound healing and the company representative needs to be available to ensure proper functioning of the system.

Evidence Tables

Table 15. Nursing Care in Studies of Air-fluidized Beds

Reference	Trial Design	Number of Patients	Support Surface	Training and Role of Caregiver	Patient Turning Schedule	Nutritional Support

Strauss, 1991(24)	Randomized controlled trial	58	Air-fluidized beds - Clinitron therapy	A nurse who was an expert at using air-fluidized bed therapy served as a home care coordinator and followed the healing progress of the wound. Conducted weekly home visits for the first 4 weeks and then biweekly. If sores were healing, no changes were made. If sores were not healing, the patient's physician was contacted so that alternative therapies could be tried.	Not reported	Not reported
		54	Multiple support surfaces	A nurse served as a home care coordinator and followed the healing progress of the wound. Conducted biweekly home visits for the first 4 weeks and then telephoned biweekly. The nurse noted the condition of the ulcer and the patient's physician was only contacted in an emergency.	Not reported	Not reported
Munro, 1989(27)	Randomized controlled trial	20	Air-fluidized beds - Clinitron therapy	Monitor patient's state of hydration and encourage fluid intake, lubricate the skin with such products as Lubriderm, pay close attention to respiratory status, patient needs to be turned and encouraged to cough and take deep breaths to prevent respiratory complications, monitor patient's mental status for confusion (can be secondary to dehydration as well as sensory deprivation), prevent microsphere leakage by treating the filter sheet carefully and periodically inspecting the sheer for punctures and tears.	No specific schedule was reported	Not reported

		20	Multiple support surfaces	Usual nursing measures including positioning. No attempt was made to standardize treatment	No specific schedule was reported	Not reported
Allman, 1987(25)	Randomized controlled trial	32	Air-fluidized beds - Clinitron therapy	Weekly evaluation to assess compliance with study treatments	Repositioned every 4 hours between 0700 h and 2300 h	Not reported
		34	Alternating air mattresses - Lapidus Air Float System	Weekly evaluation to assess compliance with study treatments	At least every 2 hours	Not reported
Greer, 1988(36)	Historical controlled trial	17	Air-fluidized beds - Clinitron therapy	Not reported	Not reported	Not reported
		Not reported	Historical control -Other support surfaces	Not reported	Every 2 hours (12 turns daily)	Not reported
Bennett, 1989(37)	Single Treatment Arm	95	Air-fluidized beds - Clinitron therapy	All patients were seen daily by a member of a nursing treatment team. The treatment team cared for all wounds and evaluated and measured them regularly.	Not reported	Not reported

Bristow, 1987(38)	Single Treatment Arm	10	Air-fluidized beds - Clinitron therapy	Encourage 1,000 cc fluid consumption every 8 hours. Record daily fluid intake and output on every 8-hour shift. Apply skin lotion on every 8 hour shift. Use indwelling catheters for incontinent female patients and condom type catheters for male patients. Implement a sensory stimulation program by activities staff.	Not reported	Assure adequate nutritional intake with initial nutritional evaluation and weekly follow-up by the dietary department

Table 16. Complications Reported in Studies of Air-fluidized Beds

Reference	Trial Design	Number of Patients	Support Surface	Type of Complication	Number of Patients With This Complication
Strauss, 1991(24)	Randomized controlled trial	58	Air-fluidized beds - Clinitron therapy	Dehydration of patient - mild	1
				Overheating of air-fluidized bed	7
				Bead leakage in air-fluidized bed	6
Allman, 1987(25)	Randomized controlled trial	32	Air-fluidized beds - Clinitron therapy	Hypernatremia	5
				Hypotension	6
				Nose bleed	1
		34	Alternating air mattresses - Lapidus Air Float System	Hypernatremia	5

				Hypotension	7

Question 5: What are the requirements (education, training, experience) needed for nursing or care giving in the home setting when using Group 2 support surfaces?

Trial Inclusion Criteria

1. Clinical studies of Group 2 support surfaces for the treatment of patients with pressure ulcers published after 1985 and have the following:

   - At least 10 patients in each treatment group.

   - Information on concurrent wound care is reported.

   a. OR guidelines on the use of Group 2 support surfaces for the treatment of pressure ulcers published from 1985 to the present.

   b. OR manuals for air-fluidized beds.

   c. OR reviews offering expert opinion on the use of Group 2 support surfaces for the treatment of pressure ulcers published from 1985 to the present.

2. English language
3. Published as a full article, not a meeting abstract

Clinical Studies

No clinical studies were identified that directly addressed this question, however five clinical studies of Group 2 support surfaces do report on the nursing care given to patients using these surfaces. Nursing care information from these studies is presented in Table 17.

Guidelines

The University Hospital Consortium's Technology Advancement Center produced a guideline for the use of pressure relief devices to treat and prevent pressure ulcers.(35) The following nursing procedures were recommended by this guideline for each type of support surface. (Note: items paraphrased or summarized from guidelines are presented in text boxes)

1. Static Air Overlay Mattresses, Alternating Air Overlay, and Water/Gel Overlays

- Turning schedule necessary
- Avoid punctures
- Check inflation level and follow manufacturer's instructions
- Need to deflate for CPR
- Should be covered with only one sheet
- Plastic surface may cause increased perspiration
- Avoid wrinkled sheets and kinked tubing.
- For water/gel overlays: express all air bubbles after filing, and individualize to patient's weight

2. Dynamic (alternating air mattresses)

- Patients can slide and need repositioning
- Bed movement can increase agitation and may cause nausea in some patients
- Use incontinence pads without plastic backs
- Do not use skin protecting devices such as heel and elbow pads

3. Low-air-loss Therapy

- Temperature control can be adjusted for patient comfort, hyperthermia requires other interventions
- Absorbent breathable underpads should be used
- Patients can slide and need repositioning. Do not lift patient, but follow instructions to increase air cushion pressure
- In the CPR mode, the air cushions are completely deflated, the hard surface is adequate for cardiac compressions

Standardized guidelines for how support surfaces are characterized have been developed by the Support Surface Consensus Panel.(39) The members of the panel, experts in wound care, met with representatives from the industry, clinical, and scientific communities to develop these guidelines. This guideline has proposed that caregivers and nursing staff should be knowledgeable of the following with regard to support surfaces:

- Instructions on how these products are to be used
- Guidelines necessary to remind hospital staff when products should be serviced
- Information about product malfunction and failure modes
- Guidelines for infection control including principals of prevention, control, and education
- Policies for daily cleaning while in use and terminal decontamination/ sterilization after use
- Flammability of the product
- The force required to slide a person across a support surface

Other Expert Opinion

In a review article, Hasty, 1991(40) has proposed that personnel working with support surfaces should be aware of factors that facilitate:

- Patient transfer
- Rapid deflation for emergency procedures
- Patient positioning procedures
- Patient stability for various recumbent positions
- Support surface cleaning

Conclusions

Because of the lack of clinical studies that address this question, we sought information from clinical guidelines, review articles, and the manufacturer's manual. Information on treatment protocols and patient safety in the use of Group 2 support surfaces were found in two guidelines and other expert opinion. These sources suggest that training in cleaning the support surface to prevent the spread of infection, deflation for emergency procedures, and positioning patients is important for caregivers to know.

Evidence Tables

Table 17. Nursing Care in Studies of Group 2 Support Surfaces

Reference	Trial Design	Number of Patients	Support Surface	Training and Role of Caregiver	Patient Turning Schedule	Nutritional Support

Land, 2000(41)	Randomized controlled trial	10	Alternating air mattresses - Nimbus III	Nurses were trained by the manufacturers on the use and care of the trial mattresses	Not reported	Not reported
		10	Alternating air mattresses - AlphaXcell			
Mulder, 1994(29)	Randomized controlled trial	31	Low-air-loss mattresses Therapulse	Not reported	Turned every 2 hours	Patients with inadequate nutritional status were excluded from the study. Patients were provided with nutritional support
		18	Foam mattress - GeoMatt			
Day, 1993(30)	Randomized controlled trial	44	Alternating air mattresses - TheraPulse	Registered nurses were instructed in the use of a standardized nursing care plan, assessment of pressure ulcers, and the operation of the alternating air mattresses and the foam overlay. They received an approved educational program on wound and skin care management and attended regularly scheduled skin care task force meetings. The theory of moist wound healing was incorporated in all standards of care.	Not reported	Not reported

		39	Foam mattress - GeoMatt			
Ferrell, 1993(28)	Randomized controlled trial	43	Low-air-loss mattresses - Kinair bed	Nurses were instructed to avoid head-of-bed elevation and to use turning sheets to avoid dragging patients on their beds. Attention was directed toward appropriate nutritional support, infection control, and treatment of underlying and concurrent illness.	Turned every 2 hours	Nutritional support was provided
		41	Foam mattress overlay			
Warner, 1992(42)	Parallel controlled trial	10	Low-air-loss mattresses - Mediscus	Evaluate the surface for appropriate air sac inflation and make adjustments to air flow as needed to maintain an effective therapeutic surface.	Turned every 2 hours	Not reported
		10	Foam mattress - Comfortex	Evaluate to ensure proper set-up.		

Question 6: What aspects of wound care constitute proper treatment of patients using Air-fluidized Beds or Group 2 Support Surfaces?

Of particular interest are what types of dressings assist (or hamper) wound healing in patients using air-fluidized beds and what types of debridement assist (or hamper) wound healing in patients using air-fluidized beds?

Trial Inclusion Criteria

1. Clinical studies of air-fluidized beds or Group 2 support surfaces for the treatment of patients with pressure ulcers published after 1985 and have the following:

- at least 10 patients in each treatment group.
- information on concurrent wound care is reported.

a. OR guidelines on the use of air-fluidized beds or Group 2 support surfaces for the treatment of pressure ulcers published from 1985 to the present.

b. OR manuals for air-fluidized beds or Group 2 support surfaces.

c. OR reviews offering expert opinion on the use of air-fluidized beds or Group 2 support surfaces for the treatment of pressure ulcers published from 1985 to the present.

2. English language
3. Published as a full article, not a meeting abstract

Clinical Studies

No studies were identified that specifically examined wound care procedures, such as method of debridement, types of cleaning solutions, types of dressings, or the use of antibiotics in treating pressure ulcers in patients using air-fluidized beds or Group 2 support surfaces. Clinical studies were identified that provided concurrent wound care procedures provided to patients using these support surfaces.

Table 18 presents the dressing, debridement, and wound cleaning methods used in each of the six studies of air-fluidized beds if these procedures were reported. These are not recommendations, but are only the kinds of wound healing therapies used in each of these studies. The AHCPR guidelines that were published after these studies were conducted suggests that some of these procedures should not be used. Strauss, 1991(24) used wet-to-dry dressings, Bennett, 1989(43) used povidone-iodine or peroxide wet-to-dry dressings, and Bristow, 1987(38) used peroxide for wound cleaning all of which are not recommended by the AHCPR guidelines. Two studies, Bristow, 1987(38) and Greer, 1988(36) specifically used no dressings to cover the wound. Allman, 1987(25) did report that debridement was not associated with improvement or failure to improve. Enzymatic debridement was the only method allowed in this study.

Table 19 presents the dressing, debridement, and wound cleaning methods used in six clinical studies of Group 2 support surfaces that reported these procedures. Three of the studies refer to using the hospital's or facility's wound care guidelines and do not provide specific details on wound care procedures. Again, these are not recommendations, but are only the kinds of wound healing therapies used in each of these studies.

A study by Barr, 1995(33) examined the use of sharp or autolytic debridement and a hydrocolloid/alginate dressing on 30 patients with Stage III and IV pressure ulcers. Twelve of the patients were using air-fluidized beds (39%), seven patients were using low-air-loss beds (25%), and the study lasted for 24 days. The study found that both sharp debridement and autolytic debridement were effective and that the hydrocolloid dressing was effective in controlling exudate. The wear time for dressings was significantly reduced in patients using the air-fluidized beds. Although separate data on the effect of debridement and dressing are not reported for the patients using air-fluidized beds, the study does indicate that sharp debridement and synthetic dressing that promote moist wound healing can be used effectively with patients using air-fluidized beds.

Guidelines

In 1994, the US Agency for Healthcare Policy and Research (AHCPR) (now the Agency for Healthcare Research and Quality) published its guideline for the treatment of pressure ulcers.(44) The objective of this guideline is "to present a comprehensive program for treating adults with pressure ulcers." The guideline presents a number of interventions and practices for the treatment of pressure ulcers and rates the strength of the clinical evidence supporting these recommendations. These recommendations are applicable to all patients with pressure ulcers including patients using air-fluidized beds or Group 2 support surfaces. The guideline does not provide specific recommendations on the types of concurrent wound care that should be used for patients using these devices. The recommendations pertaining only to support surfaces are as follows. (Note: items paraphrased or summarized from guidelines are presented in text boxes)

- Assess all patients with existing pressure ulcers to determine their risk of developing additional pressure ulcers. If the patient remains at risk, use a pressure-reducing surface.

- Use a dynamic support surface if the patient cannot assume a variety of positions without bearing weight on a pressure ulcer, if the patient full compresses the static support surface, or if the pressure ulcer does not show evidence of healing.
- If a patient has large Stage III or Stage IV pressure ulcers on multiple turning surfaces, a low-air-loss bed or an air-fluidized bed may be indicated. (Additional studies of air-fluidized beds are needed, particularly in long-term care settings)

The research based protocol for treatment of pressure ulcers published in 1997 by The University of Iowa Gerontological Nursing Intervention Research Center are essentially the same as the AHCPR guidelines.(45)

A guideline published by the American Medical Directors Association in 1999 provides information about support surfaces, including air-fluidized beds. The guideline also does not provide specific recommendations on the types of concurrent wound care that should be used for patients using air-fluidized beds. Information from this guideline specific to the use of support surfaces is summarized in the text box below.(46)

The use of an overlay or static (non-powered) pressure reducing mattress that is at least four inches thick (foam overlay or gel mattress), should suffice for most patients with at least two intact turning surfaces (front, back, and each side).

- If health care practitioners and caregivers cannot implement simple measures to try to relieve pressure on existing ulcers or to prevent the occurrence of new ulcers, if new breakdown sites develop despite such measures, or if the patient has fewer than two intact turning surfaces, consider a pressure reduction device such as a dynamic (alternating pressure) mattress that can be placed directly on a hospital bed frame and inflated to a height of at least five inches.

- For more complex wounds or to treat patients for whom previous approaches are unsuccessful a low-air-loss or an air-fluidized bed may be necessary.

Specific Dressing Recommendations

The Clinitron® Hite-RiteTM air-fluidized therapy users manual gives the following recommendations for using wet dressings and soaks for patients using this device.(17)

- Use an IV administration set to slow drip the solution to the area for a wet soak. If a continuous drip is not ordered, it may be necessary to increase the frequency of dressing changes.
- Wrap the area with a plastic wrap, place an impervious dressing on the sheet beneath the site, or use the Hill-Rom Impervious Sheet to block the airflow.
- Alternatively, resoak the in-place dressing frequently if asepsis can be maintained.

Conclusion

No clinical studies are available that specifically examine and test wound care procedures, such as method of debridement, types of cleaning solutions, types of dressings, or the use of antibiotics for efficacy in healing pressure ulcers in patients using air-fluidized beds or Group 2 support surfaces. One wound care guideline discusses support surfaces and contains some information about air-fluidized beds, but no guideline specifically recommends the types of concurrent wound care patients on air-fluidized beds or Group 2 support surfaces should receive. Published studies of air-fluidized beds and Group 2 support surfaces use a variety of debridement, wound cleaning, and dressings, but do not report results separately by these procedures. Therefore, conclusions cannot be drawn from these studies about the use and effectiveness of these procedures in patients on air-fluidized beds or Group 2 support surfaces.

Evidence Tables

Table 18. Wound Care Treatments for Pressure Ulcers in Studies of Air-fluidized Beds

Reference	Trial Design	Number of Patients	Support Surface	Dressing	Debridement	Wound Cleaning	Use of Topical or Systemic Antibiotics
Strauss, 1991(24)	Randomized controlled trial	58	Air-fluidized beds - Clinitron therapy	Moist or wet-to-dry dressings	Not reported	Not reported	Not reported
		54	Multiple support surfaces	Moist or wet-to-dry dressings			
Munro, 1989(27)	Randomized controlled trial	20	Air-fluidized beds - Clinitron therapy	No effort was made to standardize the treatment because the authors wanted to measure the results with common nursing practice versus those with the Clinitron bed. Not reported	Not reported	Not reported	Not reported
		20	Multiple support surfaces				
Allman, 1987(25)	Randomized controlled trial	32	Air-fluidized beds - Clinitron therapy	Sterile gauze dressing	Enzymatic	Saline	Not reported
		34	Alternating air mattresses - Lapidus Air Float System	Sterile gauze dressing	Enzymatic	Saline	

Greer, 1988(36)	Historical controlled trial	17	Air-fluidized beds - Clinitron therapy	No use of dressings The wound was not covered. The authors state that "exposure of the patient's skin areas directly to the therapy unit was the most effective wound management. The interposition of dressings, absorbent pads, towels, draw sheets, or extra bed linens substantially impeded healing." No supporting data are provided.	Sharp; performed on admission	Hydrotherapy twice daily, 6 days a week No irrigations	No topical agents or other therapeutic agents.
			Historical control -Other support surfaces	Patients in this group were treated for pressure ulcers of similar size and stage to the patients on air-fluidized beds	Not reported	Not reported	Not reported
Bennett, 1989(37)	Single Treatment Arm	95	Air-fluidized beds - Clinitron therapy	Wounds with purulent drainage were packed with povidone-iodine or peroxide wet-to-dry dressings, and wounds without drainage were packed with normal saline wet-to-dry dressing	Mechanical (wet-to-dry dressing)	Not reported	Not reported
Bristow, 1987(38)	Single Treatment Arm	10	Air-fluidized beds - Clinitron therapy	Dressings were not used. The wound was not covered. Discontinued all previous pressure sore medications and therapies.	Not reported	Cleaned at least once a day with peroxide and rinsed with normal saline	Not reported

Table 19. Wound Care Treatments for Pressure Ulcers in Studies of Group 2 Support Surfaces

Reference	Trial Design	Number of Patients	Support Surface	Dressing	Debridement	Wound Cleaning	Use of Topical or Systemic Antibiotics
Land, 2000(41)	Randomized controlled trial	10	Alternating air mattresses - Nimbus III	Wound dressings were performed according to the facility's protocol.	Not reported	Not reported	Not reported
		10	Alternating air mattresses - AlphaXcell				
Devine, 1995(31)	Randomized controlled trial	22	Alternating air mattresses - Nimbus I	Hospital protocol was standardized for each sore type to reduce the number of variables affecting sore healing.	Not reported	Not reported	Not reported
		19	Alternating air mattresses - Pegasus				
Mulder, 1994(29)	Randomized controlled trial	31	Low-air-loss mattresses Therapulse	Adjunctive therapeutic measures including nutritional support, hydrotherapy and changes in types and frequency of application of wound dressings were recorded. Specific information was not provided.	Not reported	Not reported	Not reported
		18	Foam mattress - GeoMatt				

Day, 1993(30)	Randomized controlled trial	44	Alternating air mattresses - TheraPulse	For stage II and III ulcers, a control gel formula dressing was applied. For exudating stage II ulcers, paste was used to fill the cavity before application of the dressing. This dressing was changed every 7 days or when leakage occurred. For stage IV ulcers, the wound was loosely packed with normal saline gauze dressing and covered with ABD pads. This dressing was changed every 8 hours.	Sharp	Cleaned with normal saline at each dressing change.	Not reported
		39	Foam mattress - GeoMatt				
Ferrell, 1993(28)	Randomized controlled trial	43	Low-air-loss mattresses - Kinair bed	A variety of additional wound treatments were ordered by the attending physicians during the study period; 56% of patients were treated with saline-soaked gauze dressing.	Not reported	Not reported	Not reported
		41	Foam mattress overlay	51% of the patients received saline-soaked gauze dressing.			
Warner, 1992(42)	Parallel controlled trial	10	Low-air-loss mattresses - Mediscus	Common wound dressings included wet to dry dressing with normal saline, transparent dressings, hydrocolloid dressing, and wet to wet dressings with normal saline.	Not reported	Not reported	Antibiotics and anti-microbials were used
		10	Foam mattress - Comfortex				

Conclusions

Question 1: Are air-fluidized beds effective in the treatment of Stage III and/or IV pressure ulcers in the home setting? Of particular interest is evidence that the use of air-fluidized beds are superior to the use of Group 2 support surfaces for the healing of Stage III and/or IV pressure ulcers.

Only one study, an RCT, met the inclusion criteria for this question. This study compared the efficacy of air-fluidized beds and various conventional therapies in the home environment. However, in this study, the patients on air-fluidized beds received additional wound care therapy and more aggressive nursing care of their wounds. This creates a bias towards additional wound healing in the air-fluidized bed group that renders the results of this study difficult to interpret.

Because clinical studies were not available to draw conclusions about the effectiveness of air-fluidized beds in the home, we relaxed the question- specific inclusion criteria so that studies that evaluated air-fluidized beds in other settings could be assessed. With the new criteria, we identified one additional study. This study, an RCT performed in a hospital setting, found that wound size reduction in larger ulcers was significantly greater in patients on air-fluidized beds than in patients using alternating air mattresses, and that the number of large ulcers improved was also significantly greater in patients on air-fluidized beds than in patients on alternating air mattresses. The precise degree to which these results pertain to patients with Stage III or IV ulcers is not certain, because the authors did not classify ulcers by stage. Thus, the relevance of these results to patients with Stage III and IV ulcers depends on the degree to which ulcer size was related to ulcer stage in these patients. Similarly, the extent to which these results can be carried over to the home setting is not known. Finally, since this study was performed more than 10 years ago, it does not directly address the effectiveness of Group 2 support surfaces as they are now manufactured.

Question 2: Are Group 2 support surfaces effective in the treatment of Stage III and/or IV pressure ulcers in the home setting?

We identified no studies that examined Group 2 support surfaces in the home. Therefore, we relaxed the home setting inclusion criteria so that the effectiveness of Group 2 support surfaces in other settings could be examined. Such studies could offer circumstantial evidence about the effectiveness of these support surfaces in the home setting. Using these relaxed inclusion criteria, three RCTs were found which compared Group 2 support surfaces to Group 1 foam mattresses.

Two of these RCTs, comparing a low-air-loss mattress to a foam overlay found no statistically significant differences between these support surfaces in the promotion of healing in Stage III or IV pressure ulcers. The other RCT, comparing an alternating air mattress to a foam mattress, also found no statistically significant differences in the promotion of healing in Stage III or IV pressure ulcers among these surfaces. One of these studies did find a significantly greater rate of wound size reduction for deep ulcers in patients using low-air-loss mattresses compared to patients using foam mattresses. However, the same study found no statistically significant differences in complete healing of deep ulcers. The other studies also found no difference in the rate of complete healing. These studies may have only had sufficient sample size to detect large differences, but the observed differences in healing and improvement were less than 5%.

These studies indicate that Stage III and IV pressure ulcers progress towards wound healing on these devices, but differences in reporting wound healing outcomes prevents any comparisons across studies that would allow the estimation

of the proportion of patients with healing wounds and the proportion of patients with non-healing wounds.

Question 3: At what stage of ulcer development should air-fluidized beds be used?

There are two aspects to this question. The first is whether use of air-fluidized beds prevents the transition from Stage III to Stage IV pressure ulcers. The second aspect of this question is whether switching patients to air-fluidized beds only if their Stage III or IV pressure ulcers have not shown progression toward healing during a 30-day period of conservative treatment is supported by clinical evidence.

This latter aspect is important because current Medicare policy requires such a waiting period for patients with Stage III or IV pressure ulcers. Although there are no studies of air-fluidized beds that directly addressed this issue, some relevant information can be obtained from studies of other wound care treatments that provide data about wound healing during the first 30 days of treatment. These studies can be assessed for evidence of efficacy. If these studies suggest that other wound care methods do not promote healing in Stage III and IV pressure ulcers, then a 30 day waiting period for the use of an air-fluidized bed may not be justified.

No studies of air-fluidized beds that met our inclusion criteria reported on the effects of these beds on the rate of transition from Stage III to Stage IV ulcers. One study of patients on air-fluidized beds reported that 62% of patients with large ulcers (which are potentially Stage III and IV) experienced an improvement in wound condition and that 38% of patients with these ulcers showed no change or became worse.

Three studies of pressure ulcer therapies other than Group 2 or 3 support surfaces suggest that at least some Stage III and IV pressure ulcers progress towards healing (as indicated by a reduction in wound size or other signs of improvement) during the first 30 days under a variety of treatments. However, these studies also suggest that some patients will not benefit from these treatments, and may even get worse. One study reported that only 4% of patients had deterioration or no improvement using a calcium alginate dressing, and 33% of patients had deterioration or no improvement using dextranomer paste and saline gauze. A second study reported that 37% of ulcers decreased in size and 63% of ulcers increased in size when using a hydrocolloid/alginate dressing. A third study reported that 45% and 48% of pressure ulcers healed in 28 days in patients using foam mattresses and water mattresses, respectively.

The data from these studies are not sufficient to determine the exact proportion of patients who do not improve during the initial 30 days of treatment. Also unknown is the proportion of such patients who might benefit from earlier use of air-fluidized beds. When considering the initial treatment for Stage III and IV pressure ulcers, the available clinical evidence is not sufficient to determine which type of patient will benefit when receiving initial conservative treatment, and which type of patient will benefit when air-fluidized bed therapy is added to the conservative therapy.

Question 4: What are the requirements (education, training, experience) needed for nursing or care giving in the home setting when using an air-fluidized bed?

No clinical studies were identified that directly addressed this question. Consequently, we sought information from other

sources. Two guidelines written by the Office of Heath Technology Assessment (OHTA), and the University Hospital Consortium's Technology Advancement Center, and a user's manual for the Clinitron® Hite-RiteTM air-fluidized therapy contained relevant information. These sources suggest that the following are important considerations for proper patient care while using an air-fluidized bed.

- An initial assessment by a physician to evaluate the patient for home use of an air-fluidized bed
- Supervision of the treatment by an attending physician who examines the patient monthly
- Specially trained nurse consultant to provide training for the patient and caregiver
- Turning schedules to help prevent the complications of immobility and methods for turning patients in these beds
- Patient dehydration
- Patient confusion due to the sensation of floating
- Accumulation of thick pulmonary secretions
- Care of the microsphere beads and clean up of microspheres' leakage to prevent skin irritation of the patient and caregiver
- Knowledge of the control panel for turning on and off the blower that fluidizes the microsphere beads (needed to create a firm support surface for emergency CPR)
- Bed elevation procedures

Question 5: What are the requirements (education, training, experience) needed for nursing or care giving in the home setting when using Group 2 support surfaces?

No published clinical studies were identified that directly addressed this question. Consequently, we sought information from guidelines and review articles. Information on treatment protocols and patient safety in the use of Group 2 support surfaces were found in two guidelines published by the University Hospital Consortium's Technology Advancement Center and the Support Surface Consensus Panel.

These sources suggest that the following are important considerations for proper patient care while using Group 2 support surfaces:

- Bed movement (alternating air mattresses) can increase agitation and may cause nausea
- Patients can slide and need repositioning
- Turning schedule
- Guidelines for infection control
- Means of rapid deflation for emergency procedures
- Plastic surface may cause increased perspiration
- Need to avoid wrinkled sheets and kinked tubing
- Use of incontinence pads without plastic backs
- Eliminating the use of skin protection devices such as heel and elbow pads
- Absorbent breathable underpads should be used
- Avoid punctures and check inflation levels

- Procedures for cleaning the support surfaces
- Flammability of the device

Question 6: What aspects of wound care constitute proper treatment of patients using air-fluidized beds or Group 2 Support Surfaces?

No studies were identified that specifically examined wound care procedures, such as method of debridement, types of cleaning solutions, types of dressings, or the use of antibiotics in treating pressure ulcers in patients using air-fluidized beds or Group 2 support surfaces. Consequently, we considered information on concurrent wound care treatments as they appeared in clinical studies. This information may form the basis for designing studies to directly answer this question. In addition, we sought information from clinical guidelines, user manuals, and review articles.

The guidelines published by the US Agency for Healthcare Policy and Research (AHCPR)(now the Agency for Healthcare Research and Quality) in 1994, and the American Medical Directors Association in 1999, provided pressure ulcer treatment recommendations applicable to all patients with pressure ulcers including patients using air-fluidized beds and other support surfaces.

Available wound care guidelines did not specifically indicate which dressings or debridement procedures may work best with patients on air-fluidized beds or Group 2 support surfaces. Published studies of air-fluidized beds and Group 2 support surfaces reported using a variety of debridement, wound cleaning, and dressing methods, but did not report results separately by these procedures. Therefore, conclusions cannot be drawn from these studies about the use and effectiveness of these procedures in patients on air-fluidized beds or Group 2 support surfaces.

The Clinitron® Hite-RiteTM air-fluidized therapy user's manual gives the following recommendations for using wet dressings and soaks.

- Use an IV administration set to slow drip the solution to the area for a wet soak. If a continuous drip is not ordered, it may be necessary to increase the frequency of dressing changes.
- Wrap the area with a plastic wrap, place an impervious dressing on the sheet beneath the site, or use the Hill-Rom Impervious Sheet to block the airflow.
- Alternatively, resoak the in-place dressing frequently if asepsis can be maintained.

References

1. Nwomeh BC, Yager DR, Cohen IK. Physiology of the chronic wound. Clin Plast Surg 1998 Jul;25(3):341-56.

2. Prevention and management of pressure ulcers. Hauppauge (NY): Curative Health Services; 1998. 20 p. (Treatment of chronic wounds; no. 6).

3. Silver FH, Wang MC. A review of the etiology and treatment of skin ulcers with wound dressings: comparison of the

effects of occlusive and nonocclusive dressings. J Long Term Eff Med Implants 1992;2(4):267-88.

4. Smith DM. Pressure ulcers in the nursing home. Ann Intern Med 1995 Sep 15;123(6):433-42.

5. Szycher M, Lee SJ. Modern wound dressings: a systematic approach to wound healing. J Biomater Appl 1992 Oct;7(2):142-213.

6. Young JB, Dobrzanski S. Pressure sores. Epidemiology and current management concepts. Drugs Aging 1992 Jan-Feb;2(1):42-57.

7. Brandeis GH, Morris JN, Nash DJ, Lipsitz LA. The epidemiology and natural history of pressure ulcers in elderly nursing home residents. JAMA 1990 Dec 12;264(22):2905-9.

8. Berlowitz DR, Wilking SV. The short-term outcome of pressure sores. J Am Geriatr Soc 1990 Jul;38(7):748-52.

9. Goode PS, Thomas DR. Pressure ulcers. Local wound care. Clin Geriatr Med 1997 Aug;13(3):543-52.

10. Wind S, Happ E, Kerstein MD. Pressure ulcers: collaboration in wound care. Is there a reasonable approach. Ostomy Wound Manage 1997 May;43(4):40-4, 46, 48-50 passim.

11. Weinstein ML. Update on wound healing: a review of the literature. Mil Med 1998 Sep;163(9):620-4.

12. Hanna JR, Giacopelli JA. A review of wound healing and wound dressing products. J Foot Ankle Surg 1997 Jan-Feb;36(1):2-14; discussion 79.

13. Falanga V, Eaglstein WH. A therapeutic approach to venous ulcers. J Am Acad Dermatol 1986 May;14(5 Pt 1):777-84.

14. Laing P. Diabetic foot ulcers. Am J Surg 1994 Jan;167(1A):31S-6S.

15. DMERC supplier manual. Baltimore (MD): Centers for Medicare & Medicaid Services; 1998 Mar. Pressure reducing support surfaces. p. 14.22.1-14.25.1. Also available: http://www.umd.nycpic.com/suppman.html.

16. Remsburg RE, Bennett RG. Pressure-relieving strategies for preventing and treating pressure sores. Clin Geriatr Med 1997 Aug;13(3):513-41.

17. CLINITRON RITE-HITE air fluidized therapy unit user manual. Durham (NC): Duke University Medical Center; 1997 Oct 14. various p. Also available: http://www2.mc.duke.edu/depts/clineng/clinitron.htm.

18. Nimit K. Guidelines for home air-fluidized bed therapy, 1989. Health Technol Assess Rep 1989;(5):1-11.

19. Thomas Hess C. Patient support surface selection. Guidelines for choosing pressure reduction devices. Contin Care 1992 Jul-Aug;11(6):35-7; 50.

20. Executive Committee Working Group. Recommendations for evaluating effectiveness. [Medicare coverage policy online]. Baltimore (MD): Health Care Financing Administration; 2001 Feb 23 [cited 2001 Jul 23]. [15 p]. Available: http://www.hcfa.gov/coverage/8b1-I9.htm.

21. Stefanovska A, Vodovnik L, Benko H, Turk R. Treatment of chronic wounds by means of electric and electromagnetic fields. Part 2. Value of FES parameters for pressure sore treatment. Med Biol Eng Comput 1993 May;31(3):213-20.

22. Karba R, Vodovnik L, Presern-Strukelj M, Klesnik M. Promoted healing of chronic wounds due to electrical stimulation. Wounds 1991 Jan-Feb;3(1):16-23.

23. Perdrup A. The healing rate of leg ulcers a clinical and statistical study of 233 patients hospitalized with leg ulcers. Acta Derm Venereol 1972;52(2):136-40.

24. Strauss MJ, Gong J, Gary BD, Kalsbeek WD, Spear S. The cost of home air-fluidized therapy for pressure sores. A randomized controlled trial. J Fam Pract 1991 Jul;33(1):52-9.

25. Allman RM, Walker JM, Hart MK, Laprade CA, Noel LB, Smith CR. Air-fluidized beds or conventional therapy for pressure sores. A randomized trial. Ann Intern Med 1987 Nov;107(5):641-8.

26. Cullum N, Deeks J, Sheldon TA, Song F, Fletcher AW. Beds, mattresses and cushions for pressure sore prevention and treatment. Cochrane Database Syst Rev 2000;(2):CD001735.

27. Munro BH, Brown L, Heitman BB. Pressure ulcers: one bed or another? Geriatr Nurs 1989 Jul-Aug;10(4):190-2.

28. Ferrell BA, Osterweil D, Christenson P. A randomized trial of low-air-loss beds for treatment of pressure ulcers [published erratum appears in JAMA 1993 Jun 2;269(21):2739]. JAMA 1993 Jan 27;269(4):494-7.

29. A study of pressure ulcer response to low air loss beds vs. conventional treatment. J Geriatr Dermatol 1993;2:87.

30. Day A, Leonard F. Seeking quality care for patients with pressure ulcers. Decubitus 1993 Jan;6(1):32-43.

31. Devine B. Alternating pressure air mattresses in the management of established pressure sores. J Tissue Viability 1995;5:94-8.

32. Sayag J, Meaume S, Bohbot S. Healing properties of calcium alginate dressings. J Wound Care 1996 Sep;5(8):357-62.

33. Barr JE, Day AL, Weaver VA, Taler GM. Assessing clinical efficacy of a hydrocolloid/alginate dressing on full-thickness

pressure ulcers. Ostomy Wound Manage 1995 Apr;41(3):28-30, 32, 34-6 passim.

34. Groen HW, Groenier KH, Schuling J. Comparative study of a foam mattress and a water mattress. J Wound Care 1999 Jul;8(7):333-5.

35. Gault DZ, editor. Guidelines for the use of pressure relief devices in the treatment and prevention of pressure ulcers. Oak Brook (IL): University Hospital Consortium; 1990. various.

36. Greer DM, Morris J, Walsh NE, Glenn AM, Keppler J. Cost-effectiveness and efficacy of air-fluidized therapy in the treatment of pressure ulcers. J Enterostomal Ther 1988 Nov-Dec;15(6):247-51.

37. Bennett RG, Bellantoni MF, Ouslander JG. Air-fluidized bed treatment of nursing home patients with pressure sores. J Am Geriatr Soc 1989 Mar;37(3):235-42.

38. Bristow JV, Goldfarb EH, Green M. CLINITRON therapy: is it effective? Geriatr Nurs 1987 May-Jun;8(3):120-4.

39. Krouskop T, van Rijswijk L. Standardizing performance-based criteria for support surfaces. Ostomy Wound Manage 1995 Jan-Feb;41(1):34-6, 38, 40-5.

40. Hasty JH, Krasner D, Kennedy KL. A new tool for evaluating patient support surfaces. Part I: A guideline for making practice decisions. Ostomy Wound Manage 1991 Sep-Oct;36:51-4, 56-7, 59.

41. Land L, Evans D, Geary A, Taylor C. A clinical evaluation of an alternating-pressure mattress replacement system in hospital and residential care settings. J Tissue Viability 2000 Jan;10(1):6-11.

42. Warner DJ. A clinical comparison of two pressure-reducing surfaces in the management of pressure ulcers. Decubitus 1992 May;5(3):52-5, 58-60, 62-4.

43. Scavron C. Clinical investigation to determine an effective protocol for managing pressure on skin and soft tissue. Ostomy Wound Manage 1989 Summer;23:70-9.

44. Agency for Health Care Policy and Research (AHCPR). Treatment of pressure ulcers. Clinical practice guideline. Rockville (MD): U.S. Department of Health and Human Services, Public Health Service, AHCPR; 1994 Dec. 154 p. (Clinical practice guideline; no. 15).

45. Gerontological Nursing Interventions Research Center (University of Iowa), Research Development and Dissemination Core. Titler MG, Folkedahl BA, Frantz RA, Goode C. Treatment of pressure ulcers. Iowa City (IA): University of Iowa Gerontological Nursing Interventions Research Center; 1997. 22 p. (Research-based protocol; no. 1997).

46. American Medical Directors Association. Pressure ulcer therapy companion. Columbia (MD): American Medical Directors

Association; 1999. 35 p.