Received: 18 October 2021 | Revised: 8 March 2022 | Accepted: 26 April 2022

DOI: 10.1111/wrr.13031

ORIGINAL RESEARCH-CLINICAL SCIENCE

Wound Repair and Regeneration — WILEY

Effectiveness of a fluid immersion simulation system in the acute post-operative management of pressure ulcers: A prospective, randomised controlled trial

Chitang J. Joshi MD[1] | Miguel Carabano MD[1] | Laura C. Perez MD[1] | Peter Ullrich BS[1] | Abbas M. Hassan MD[1] | Rou Wan MD[1] | Jing Liu MD[1] | Rachna Soriano DO[2] | Robert D. Galiano MD, FACS[1]

[1]Division of Plastic & Reconstructive Surgery, Northwestern University Feinberg School of Medicine, Chicago, Illinois, USA

[2]Department of Physical Medicine and Rehabilitation, Northwestern University Feinberg School of Medicine, Chicago, Illinois, USA

Correspondence
Robert D. Galiano, Department of Surgery, Division of Plastic & Reconstructive Surgery, Northwestern University Feinberg School of Medicine, 675 North Saint Clair Street, Suite 19-250, Chicago, IL 60611, USA.
Email: robert.galiano@nm.org

Funding information
Joerns Healthcare LLC

Abstract

The fluid immersion simulation system (FIS) has demonstrated good clinical applicability. This is the first study to compare surgical flap closure outcomes of FIS with an air-fluidised bed (AFB), considered as standard of care. The success of closure after 14 days post-op was the primary endpoint. Secondary endpoints were incidences of complications in the first 2 weeks after surgery and the rate of acceptability of the device. Thirty-eight subjects were in the FIS group while 42 subjects were placed in the AFB group. Flap failure rate was similar between groups (14% vs. 12%; $p = 0.84$). Complications, notably dehiscence and maceration, were significantly higher in the FIS group (40% vs. 17%; $p = 0.0296$). The addition of a microclimate regulation device (ClimateCare®) to FIS for the last 43 patients showed a significant decrease in the rate of flap failure (71% vs. 16%; $p = 0.001$) and incidence of complications (33% vs. 0%; $p = 0.011$). There was no statistically significant difference between the FIS and air-fluidised bed (AFB) in the rate of acceptability (nurse acceptance: 1.49 vs. 1.72; $p = 0.8$; patient acceptance: 2.08 vs. 2.06; $p = 0.17$), which further illustrates the potential implementation of this tool in a patient-care setting. Our results show that the use of ClimateCare® in combination with FIS can be a better alternative to the AFB in surgical closure of pressure ulcers.

KEYWORDS
air fluidised bed, ClimateCare® surface, flap closure, fluid immersion simulation system, pressure ulcer

1 | INTRODUCTION

Pressure ulcers are localised areas of necrosis or tissue damage that develop because of pressure over a bony prominence.[1] The Agency for Healthcare Research & Quality (AHRQ) reports that over 2.5

List of Abbreviations: AFB, air-fluidised bed; AHRQ, Agency for Healthcare Research & Quality; FIS, fluid immersion system; NPUAP, National Pressure Ulcer Advisory Panel; PU, pressure ulcer.

million people develop pressure ulcers annually in the United States.[2] The incidence rates vary significantly depending on the setting of clinical care.[2] Furthermore, risk factors for developing a pressure ulcer are wide-ranging, including lower body weight, older age, African ethnicity, lack of or reduced mobilisation, nutritional deficiencies, incontinence, and medical conditions affecting tissue perfusion such as diabetes mellitus or peripheral vascular disease.[3–7] Following the loss of sensation and mobility, the structure and function of an affected person's anatomy change considerably. These changes include muscle atrophy, bone adaptation, and intramuscular fat infiltration, rendering a higher probability to develop a pressure ulcer (PU).[8]

Progressive inflammatory response, tissue deformation and ischemia result in a cascading effect on the development of PUs. Tissue interaction with weight-bearing and supporting structures cause mechanical stress; and medical devices can further damage these at-risk tissues. The development of the PU starts microscopically, with 'cell deformation that compromises cytoskeleton integrity, which in effect, facilitates the release of chemokines'.[9] The release of reactive oxygen and nitrogen interacts with the extracellular matrix, causing further damage to the tissues. A cascade of detrimental effects is induced by external factors, such as body weight, which are amplified by the effects of edema causing inflammatory damage. The high interstitial pressures associated with oedema hinder blood perfusion, which consequentially causes chronic inflammation and a cascade of tissue injury.[10] Additionally, the microclimate indirectly influences PU development in the wound area.[11] Microclimate factors, namely moisture, temperature, and airflow affect the ability of soft tissue deformation and its response to external stressors.[11,12]

PUs often results in increased hospital stay, mortality risk, and worse overall prognosis.[13–18] Surgical correction is often needed for severe non-healing PUs (Grade III or IV). Surgical wound closure is routinely achieved by direct approximation, skin grafts or using local and regional flaps and free tissue transfer.[19]Flap type selection requires consideration of many factors, including aetiology, anatomy, prior attempts at reconstruction, and the probability of regaining functionality.[19–21] Several factors account for the success of a flap reconstruction including bacterial inoculation,[22,23,24] pressure decompensation[25-30] and microclimate. Recidivism rates are unacceptably high due to recurrence or flap failure, with overall rates as high as 70%,[31,32] whereas overall complication rates have been reported to be as high as 58.7%.[14]

Physical barriers protecting a chronic wound are currently accepted as the most effective means of avoiding ulcers.[20] These barriers, however, must be delicate and avoid any friction with the wound. This can be achieved using special mattresses, cushions, and various protective devices that can alleviate external pressure on sensitive body limb areas.[21,33] Support surfaces are medical devices such as beds that address the external factors that lead to the development of PUs. These function in one or more of the following ways: reduced air loss, pressure alterations, or air fluidised systems. The air-fluidised bed (AFB) contains minute beads through which air is passed in order to simulate a fluid-like surface, which aids in pressure redistribution. Allman et al. stated that use of the AFB system results in a statistically significant reduction in overall wound surface area compared to other interventions.[2,34] Studies with the AFB have also demonstrated substantial benefits in wound healing and pain compared to traditional surfaces. These benefits were present even with a less stringent repositioning regimen where patients were repositioned every 4 h, rather than the standard of every 2 h. Therefore, AFB has become a useful therapeutic method for reducing pressure on chronic wounds.[20]

TABLE 1 Feature comparison between air-fluidised bed systems and fluid immersion simulation

	AFB	FIS
Mechanism	Combines air-fluidised and low air loss therapies	3D fluid immersion simulation
Adjustment	Manually adjusted for pressure, height, and head elevation	System adjusts automatically for patient's weight
Risk reduction	• Patient: faster healing by maintaining low tissue pressures; preventing capillary closure. Improves skin perfusion and reduces pain. • Caregiver: Height adjustment available	• Patient: Highly effective for pressure ulcer risk mitigation and treatment, as well as for postoperative care of flaps and grafts. Minimises soft tissue distortion and promotes tissue perfusion. • Caregiver: Frequent repositioning not necessary; reducing caregiver injury risk
Maximum weight capacity	350 pounds (159 kg)	500 pounds (226.8 kg)
High-low travel range	21.5″–34.75″	7″–30″
Mattress resting surface	84″	76″ or 80″/up to 84″
Microclimate	Superior	Requires the use of ClimateCare® for adequate management
Patient's acceptability	Insensible loss of skin water content	Sense of immersion may be uncomfortable for patients.
Recommended use	• Burns • Flaps • Grafts • PUs	• Flaps • Grafts • PUs • Patients requiring frequent repositioning

Abbreviations: AFB, air-fluidizsed bed; FIS, fluid immersion simulation system.

Our current approach to treating PUs includes cleaning of the wound, debridement, flap reconstructive repair, and support surfaces such as AFB; but newer options such as negative pressure wound therapy, hyperbaric oxygen therapy, cell therapy are gaining recognition as suitable therapies.[20] Immersion devices present a 'greater surface for transfer of load and suit the contour of the body, thus offering a larger cushioning potential'.[8,13]

The FIS simulates a fluid environment by leveraging an advanced 3D immersion technology, thereby achieving greater transfer of surface pressures and preserving almost normal tissue perfusion and oxygenation. The system functions autonomously, with sensors monitoring the support surface more than 100 times per second, adjusting for subject repositioning. Comparatively, the AFB needs specific adjustments by healthcare staff. Additional evidence of FIS effectiveness comes from Bhattacharya et al., conducting their study in a 'long-term acute care hospital of 36 beds, replacing their beds from AFB to FIS'. They obtained equivalent flap outcomes after the intervention,[20] suggesting FIS as an alternative treatment when compared to AFB. A comparison of the AFB and FIS systems can be found in Table 1.

In a mid-study paper published by our team, complication rates and acceptability scores between the FIS and the AFB were noted.[33] "Flap failure rate was similar between groups (15% vs. 17%; $p = 0.99$). However, the minor complications rate, particularly dehiscence, was higher in the FIS group (66.7% vs. 15%; $p = 0.02$).[33] Nonetheless, nurse and patient self-reported acceptability had better mean numeric scores in the FIS compared with AFB (nurse: 1.5 vs. 1.9; $p = 0.12$; patient: 1.9 vs. 2.2; $p = 0.14$)."[33] Our goal for this project is to assess the FIS compared to AFB to further elucidate the comparative potential of the FIS as a therapy tool for PUs.

2 | MATERIALS AND METHODS

2.1 | Study design

This study is a prospective, randomised, single-centre, human subject trial comparing the Dolphin Fluid Immersion Simulation® system (Joerns Healthcare, LLC, Charlotte, North Carolina) to a representative AFB system, the Clinitron® Rite Hite® Air-Fluidised Therapy Bed (Hill-Rom, Chicago, Illinois). The study complies with the rules stated in the Declaration of Helsinki and is approved by the Northwestern IRB. Subjects with PUs previously screened for inclusion and exclusion criteria were randomly assigned, in a proportion of 1:1, to a study treatment arm immediately after surgical wound closure, and the treatment extended for 2 weeks beyond closure. Outcomes between the two therapy groups were then compared.

2.2 | Inclusion/exclusion criteria

The screened subjects, at least 18 years or older, deemed by the investigators to be reasonably compliant, having a PU stage III or IV, not participating in a clinical trial within 30 days before consent, and having a 30-day wound history available if the wound was previously treated. Subjects who presented to Northwestern Memorial Hospital (through clinic admission, direct transfer from another facility, or through the emergency room), and who were admitted as an inpatient for operative closure of stage III or IV PU were evaluated and recruited to participate in this clinical trial. Exclusion criteria encompassed having a life expectancy of <12 months; not being healthy enough to undergo surgery for any reason; history of radiation therapy; unable to comply in the PI's opinion; history of >3 closures of PUs in the same site; history of bleeding disorder; and/or severe faecal incontinence.

Wound assessment was performed by the principal investigator (PI) for appropriateness for definitive closure. Once the PI established the viability for definitive wound closure, the wound was adequately debrided and cleaned, and the flap closure was performed. Subjects stayed hospitalised or were transferred to a step-down facility for at least 14 days. Subsequently, subjects were followed monthly for 1 year to evaluate the incidence of complications and the potential need for additional therapeutic interventions. The total follow-up period consisted of 365 (±20) days. The total duration of participation per subject could span up to 549 days. Subjects received assigned study therapy (AFB or FIS) for 14 days following definitive PU closure, reflecting current standard practice for PU management. During this period, data regarding the success of closure and incidence of complications were recorded. Additionally, nurse and patient acceptability were also recorded through a quantitative survey given at 7 and 14 days after definitive closure. After this initial period, subjects were followed up at 1 month, 6 months, and 1 year to assess the wound status (open vs. closed).

During protocol development, an adaptive design was used to monitor the study to determine the target number of subjects required to achieve significance at the alpha = 0.05 level. A previous systematic review of complications following flap-based surgery for PUs demonstrated a mean complication rate of 19.6%, with an SD of approximately 3%, following perforator-based flaps.[24] This analysis determined that a difference in the proportion of responders of at least 10% would be regarded as clinically meaningful. This scenario was presented during our study; the corresponding changes were made to maintain optimal conditions in the FIS group by using a ClimateCare® surface. Assuming a 10% delta in proportion between support surfaces and a 'confirmed' complication rate of approximately 20% with an SD of 5%, a total of 80 subjects were randomised, with an equal allocation ratio (1:1), to the FIS arm versus AFB arm.

Data were collected either at bedside during subjects' hospitalisation or through external facilities' staff, in addition to an assessment of patients' electronic medical records. Subjects who consented to study participation were assigned a unique screening number. Only one wound per subject was included in the study. Subjects with multiple wounds were assessed by the PI, who selected the most appropriate wound to include in the study. For subjects with multiple PUs, any PUs not selected as the study wound received institutional standard wound care treatment. After the initial surgical debridement,

TABLE 2 Demographics and clinical characteristics and their distribution among the treatment groups

	AFB		FIS		*p* value
Mean age	0	±13.09	49.61	±13.75	0.4809
n	42	52.50%	38	47.50%	
Gender					
Female	12	28.57%	15	39.47%	0.3092
Male	30	71.43%	23	60.53%	
Race/Ethnicity					
Hispanic	6	14.29%	1	2.63%	0.0668
White	20	47.62%	27	71.05%	0.0337
African American	15	35.71%	10	26.32%	0.3715
Other	1	2.38%	0	0.00%	0.3447
Tobacco use					
Current	5	11.90%	4	10.81%	0.8805
Never used	21	50.00%	17	45.95%	0.7231
Past user	16	38.10%	16	43.24%	0.6469
Diabetes status					
No	33	78.57%	32	86.49%	0.3643
Type 1	1	2.38%	0	0.00%	0.3512
Type 2	8	19.05%	5	13.51%	0.5142
Multiple wound					
Multiple	13	30.95%	14	36.84%	0.5836
Single	29	69.05%	24	63.16%	
Pre-closure measurement					
Wound length (cm)	5.39	±3.25	5.78	±3.92	0.6315
Wound width (cm)	3.75	±2.19	4.02	±2.78	0.6363
Wound depth (cm)	2.78	±1.62	2.62	±1.82	0.6882
History of wound					
Recurrent wound	35	83.33%	26	72.22%	0.2416
Non-recurrent wound	7	16.67%	10	27.78%	
Previous treatment	23	54.76%	27	72.97%	0.0961
No previous treatment	19	45.24%	10	27.03%	
Previous debridement	16	38.10%	23	62.16%	0.0330
No debridement	26	61.90%	14	37.84%	
Previous closure	6	14.29%	7	18.42%	0.6219
No previous closure	36	85.71%	31	81.58%	
Previous NPWT	5	12.20%	8	21.62%	0.2705
No previous NPWT	36	87.80%	29	78.38%	
Previous AMWT	2	4.88%	2	5.41%	0.9174
No previous AMWT	39	95.12%	35	94.59%	
Previous hyperbaric therapy	1	2.44%	0	0.00%	0.1833
No previous hyperbaric therapy	40	97.56%	37	100.00%	
Previous biologics therapy	1	2.44%	0	0.00%	0.1833
No previous biologics therapy	40	97.56%	37	100.00%	

Abbreviations: AMWT, advanced moist wound therapy; NPWT, negative pressure wound therapy.

if all inclusion and no exclusion criteria continued to be met, the subject was randomised into a study group and assigned a unique randomisation number. At the time of surgical closure, subjects were again screened for inclusion and exclusion criteria.

A focused medical and surgical history, physical exam, and wound history was recorded. This included the onset and chronicity of the wound as well as the anatomic location, prior wound-related surgeries and treatments. Wounds were measured consistently following

National Pressure Ulcer Advisory Panel (NPUAP) recommendations by recording its length, width, and depth. After the measurement, the wound was debrided, following which the wound was irrigated with 5 L of normal saline and measured again. If the wound was determined to be ready for immediate closure, the closure procedure was performed. Closure at the time of the initial surgical debridement was considered the initiation of the study period. Both support devices were initiated immediately after the closure procedure. Treatment was uninterrupted during the 2-week study period for both treatment arms, irrespective of the length of stay in the hospital. We shared institutional instructions and recommendations with the external facilities on discharge.

Digital photographs were taken at the pre-debridement stage and following initial debridement. During the subject's hospital admission, interventions other than the support surface utilised were based on the institutional standard of care (SOC) practices.

SOC for all PU patients treated in our practice stayed consistent over the study duration in both groups, barring the introduction of ClimateCare on the FIS group. These include standard wound dressings and topical application. The use of adjunctive therapies such as vacuum-assisted closure/negative pressure wound therapy (NPWT) pre- and post-operatively was determined on a case-by-case basis. These adjunctive therapies were recorded and not statistically different among the 2 groups. As mentioned before, only flap-based definitive closure was included in the study. Operative technique remained uniform, including suture selection and technique remained consistent as all procedures were performed by senior author (R.D.G.) Patients receiving hyperbaric therapy, biologic and advanced moist therapy was similar across both groups and not SOC at our institution. None of the study participants received other cell therapy or adjunctive therapy in either study groups. (Table 2).

The PI determined whether additional surgical debridement was required after the initial operating room (OR) visit. This decision is typically based on ulcer appearance and periodic post-debridement culture results. Additional wound debridement followed the same procedures as the initial OR visit. Definitive wound closure for this study was defined as a complete approximation of the wound edges, coverage of the wound via tissue transfers or skin graft, or any combination of these definitive techniques that results in complete elimination of the wound bed. For this study, only tissue transfer has been performed as a definitive closure technique. If a flap failed during the immediate postoperative period, the subject was removed from the study and transitioned to a standard institutional support surface.

2.3 | Study endpoints

The primary objective was to compare the effects of the FIS with AFB in PUs undergoing operative closure by determining the status of the wound (open or closed) after 14 days of treatment. Also, subjects were followed for 14 days after closure for the secondary endpoint of wound complications (moisture, maceration, drainage, dehiscence, epidermolysis, necrosis, and demarcation). Moreover, subjects were followed up 1 month, 6 months, and 1 year after closure to determine their wound status as reported by medical records and self-reported by the subjects.

Secondary endpoints also included nurses and subjects completed an acceptability survey at 7 and 14 days. This survey consisted of three questions for the nurse caring for each subject, assessing ease of use, amount of training required, and time required for troubleshooting. The survey also contained three questions for the subject, assessing comfort, the difficulty for mobilisation, and pain at the surgical site. Both sets of questions had a numerical representation from 1 to 5, where the best acceptability was the lowest score. These outcomes were analysed and compared between both treatment arms.

2.4 | Randomisation protocol

Stratified randomisation was used for this study to prevent an imbalance between treatment arms. Permuted blocks were used to achieve an equal number of subjects assigned to the FIS or the AFB arms to generate a randomisation schedule including subject numbers and treatment assignments. Envelopes were prepared corresponding to each row in the randomisation schedule, and each subject number and treatment group was printed on labels. Prior to study initiation, sealed pre-numbered randomisation envelopes were provided to the research staff and were used to obtain a randomisation assignment. Opening of the randomisation envelope occurred within 2–4 days before the scheduled surgical closure of the wound, along with confirmation that all inclusion and no exclusion criteria were encountered. Study staff used the randomisation number labels contained in the envelope. The research staff noted treatment assignments and instructed the PI only after the closing procedure. Treatment therapy support surfaces were initiated following operative closure according to the manufacturer's recommendations. Support surface therapy crossover before and during the study treatment period was not permitted. Concealed therapy group assignments were stored in a cabinet and were opened only by research coordinators between 2 and 4 days before the closing procedure for logistics purposes. Neither the subjects nor the surgeon was aware of the treatment group until the closing procedure was performed. After that, blinding was not possible.

2.5 | Statistical analysis

Categorical variables were summarised by frequencies and percentages and assessed for differences between groups using Fisher's exact test. Analyses were conducted in *GraphPad Prism* version 8.0 for Windows, *GraphPad Software*, La Jolla California USA, www.graphpad.com.

3 | RESULTS

A total of 83 subjects were assessed for eligibility. Among the reason to exclude patients after screening were noncompliance with the

SOC, not meeting the inclusion criteria anymore, complications not related to the wound that could compromise the healing process, and/or the subject switching from the randomly assigned device. After screening, 80 subjects were recruited; 12 subjects were excluded at different points after screening, one of those subjects before any debridement was performed, 25 subjects were treated with a single-stage flap closure, and 54 subjects had a two-stage flap closure. Demographic and clinical characteristics of the subjects are summarised in Table 2.

The final sample distribution consisted of subjects followed up for up to 2 weeks post-op. A total of 38 subjects were randomised to the FIS; whilst 42 subjects were placed on the AFB. The senior author, R.D.G., performed all definitive closure surgeries at the same site. The average interval between debridement and flap closure was 8 ± 2 days. Our institutional protocol consists of discharging the subjects to a long-term care facility as soon as possible to avoid unnecessary exposure to intra-hospital pathogens.

3.1 | Wound closure

After 2 weeks post-op, 68 subjects were reassessed for open wounds, 40 in the AFB group and 28 in the FIS group. A total of nine open wounds were found at this point, five were present in the AFB group and four in the FIS group, representing 12.5% and 14.28%, respectively ($p = 0.84$) (Figure 1). After 1-month post-op, a total of 20 open wounds, 10 were present in the AFB group and 10 in the FIS group, representing 25% and 35.71%, respectively ($p = 0.16$). After 6 months post-op, 2 subjects, one from each group, had to be withdrawn due to being deceased by this time point. There was a total of 13 open wounds, 10 were present in the AFB group and 3 in the FIS group, representing 25.64% and 11.11%, respectively ($p = 0.06$). After 1-year post-op, two additional subjects, one from each group, were lost to follow-up (deceased). A total of 18 open wounds, 13 were present in the AFB group and 5 in the FIS group, representing 34.21% and 19.23%, respectively ($p = 0.09$) (Figure 2).

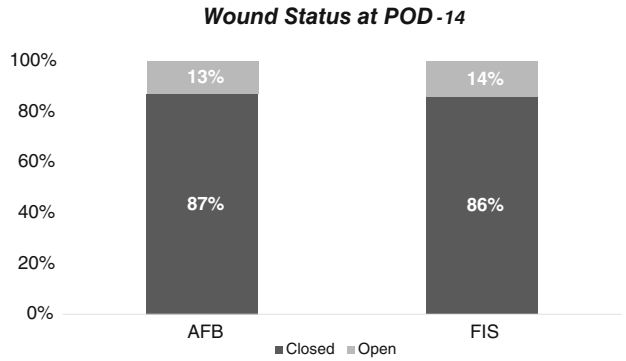

FIGURE 1 Wound status at POD 14

3.2 | Complications

Complications were present in both groups at post-operative day 14 (POD 14), 13 of those complications were found in the FIS group (40.62%) while 7 were in the AFB group (17.5%) for a total of 20 subjects ($p = 0.0296$). The total number of complications found was 32 among those 20 subjects, with 9 patients presenting only 1 complication, 10 presenting 2, and 1 subject presenting 3 complications (Table 3). Minor dehiscence was the commonest complication observed in both the groups (FIS: seven subjects and AFB: two subjects) ($p = 0.149$). Nevertheless, the most clinically significant complications found were moderate dehiscence and necrosis. The rest represented minor wound complications as they were resolved by themselves by POD 14 or did not require re-intervention. These wound complications were maceration in five subjects, congestion in four subjects, drainage in four subjects, epidermolysis in three subjects, and two subjects with moist areas in the wound (Figure 3).

3.3 | ClimateCare® outcomes

It is important to highlight a defining event in the early stages of this study. Withstanding randomisation and similar patient baseline characteristics between the two treatment groups, a statistically significant higher incidence of complications in the FIS group was observed until subject 037. In the AFB group, we found 4 subjects while the FIS group contained 10 subjects with complications, the most common being minor dehiscence followed by maceration. After subject 037, the use of the ClimateCare® mattress cover was started as part of our protocol for every subject randomised to the FIS group. From

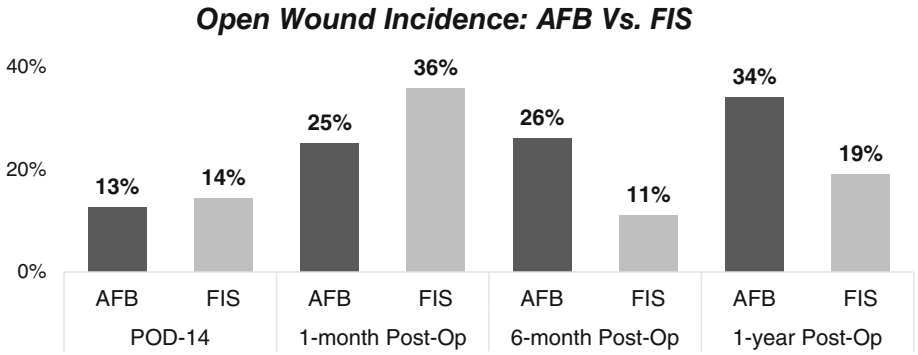

FIGURE 2 Wound status at POD 14, POD 1 month, POD 6 months, POD 1 year

TABLE 3 Complications between treatment groups

Post-operative Data: AFB versus FIS			
	AFB	**FIS**	***p* value**
Complications at POD-14, patients (%)	7 (18)	13 (41)	0.02
Type of complication, *n* (%)			
Moist area	1 (10)	1 (5)	
Congestion	2 (20)	2 (9)	
Maceration	0 (0)	5 (23)	
Minor dehiscence	2 (20)	7 (32)	
Mayor dehiscence	2 (20)	1 (5)	
Epidermolysis	2 (20)	1 (5)	
Drainage	1 (10)	3 (14)	
Skin necrosis	0 (0)	2 (9)	
Number of complications, *n* (%)			
1 complication	4 (57)	5 (54)	
2 complications	3 (43)	7 (38)	
>3 complications	0 (0)	1 (8)	
Wound status at POD-14, *n* (%)			0.84
Open	5 (13)	4 (14)	
Wound status at 1-month, *n* (%)			
Open	10 (25)	10 (36)	
Wound status at 6-month, *n* (%)			
Open	10 (25)	3 (11)	
Wound status at 1-year, *n* (%)			
Open	13 (33)	5 (18)	

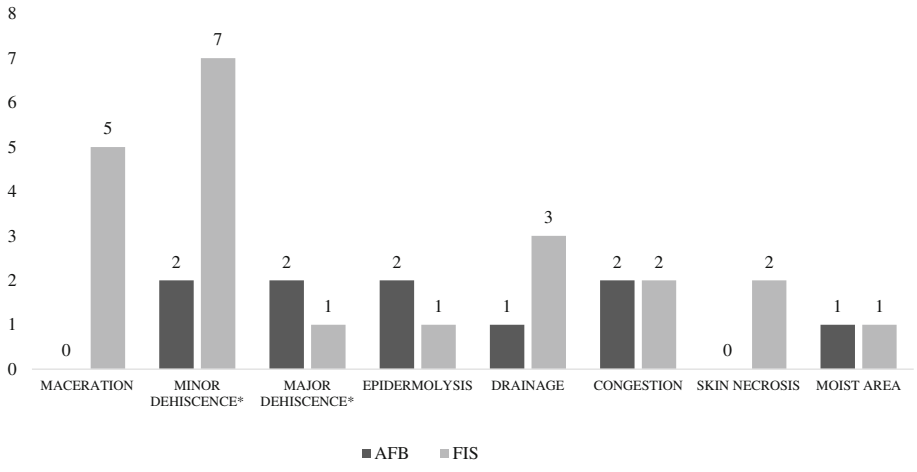

FIGURE 3 Incidence of complications at POD 14

there on, only three more subjects from the FIS group presented with complications (no maceration or dehiscence). In contrast, the AFB group remained consistent with four subjects presenting complications before the protocol change and three after the change, with two cases of dehiscence before and two after the protocol change. This difference can be interpreted as a statistically significant improvement ($p = 0.001$) in complications' prevention by using ClimateCare® with the FIS system compared to FIS by itself. Similarly, the combination of using ClimateCare® with the FIS system was equivalent to the AFB group, with both presenting a total of five complications each. Furthermore, there was an important change in wound closure incidence before and after the application of ClimateCare®. A significant difference was found in wound status analysis between FIS and AFB group at POD 14, where we found that before the use of the ClimateCare®, four subjects presented an open wound versus no open wounds were seen post-ClimateCare application ($p = 0.011$). However, in the AFB group, two subjects presented an open wound before the protocol change and three after the change.

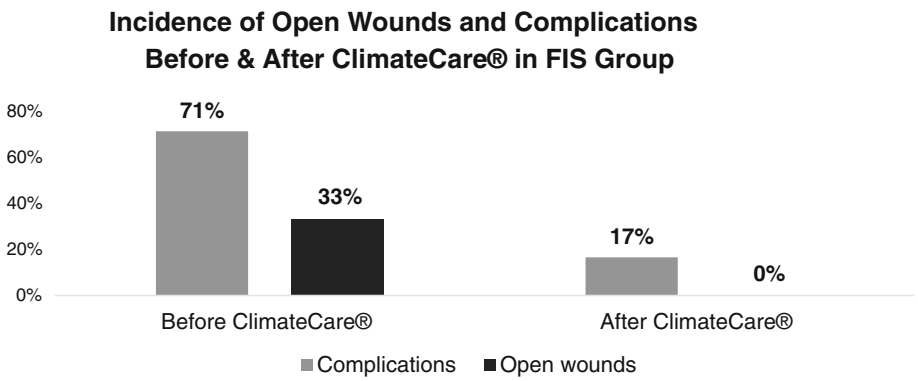

FIGURE 4 Incidence of Complications and Open Wounds Before and After ClimateCare® in FIS Group

TABLE 4 Acceptability scores

Assessment	Ease of use	Required training	Time required	Overall nurse acceptability	Comfort	Difficulty moving	Pain	Overall patient acceptability
FIS	1.31	1.62	1.54	1.49	2.33	2.25	1.67	2.08
AFB	1.45	1.96	1.75	1.72	2.34	2.16	1.68	2.06

Abbreviations: AFB, air-fluidised bed; FIS, fluid immersion simulation system.

ClimateCare® was added to the FIS group after subject 037, dividing the sample of the FIS group into two large arms: Before and after the use of ClimateCare®. Fourteen subjects were included before ClimateCare and 18 subjects after it. The results showed 17 complications in 10 of the 14 subjects (71.43%) in the group before the use of ClimateCare®, while in the group after the use of ClimateCare® there were 5 complications in 3 of the 18 subjects (16.66%), which was statistically significant ($p = 0.001$) (Figure 4). At the same time, the state of the wound was analysed at POD 14 dividing the FIS group in the same way mentioned above, with 12 subjects before ClimateCare® and 16 subjects after it. We found that before the use of the ClimateCare® 4 subjects (33.33%) presented an open wound versus no subjects after introducing ClimateCare ($p = 0.011$). Therefore, the number of successful closures doubled with the use of ClimateCare® (Figure 4).

3.4 | Nurse and patient acceptability

The acceptability scores from subjects and nurses were obtained at the end of 1 week. A total of 63 subjects were eligible for assessment of acceptability, (FIS: 29 subjects; AFB: 34 subjects). By 2 weeks post-op, 57 subjects were eligible for assessment of acceptability (FIS: 25 subjects; AFB: 32 subjects). Table 4 presents the mean acceptability scores. No statistically significant difference was observed ($p = 0.8$ for patient scores and $p = 0.17$ for nurse scores).

4 | DISCUSSION

PU treatment guidelines are generally well established; however, when it comes to postoperative wound care on supportive surfaces, the consensus is still inconclusive. Studies like ours directly comparing different pressure offloading surfaces are relatively scarce. Our study aims to specifically determine whether the FIS is a clinically viable option for assisting the success of flaps closure. It is crucial to determine user satisfaction on behalf of the patients and the staff operating the FIS, as it is a major factor in adopting novel systems compared to more established technologies. The nurse and patients' acceptability was slightly better, in the AFB group than in the FIS group. This result suggests that patients using either of the studied surfaces will have a similarly perceived experience during their procedure and recovery. Moreover, the nursing staff's experience with the FIS mirrored their experience with the AFB, which is another example of the compatibility of the FIS within a patient care setting.

Overall, the incidence of open wounds after POD 14 did not vary significantly when comparing the FIS group in its entirety with the AFB group, but it is important to consider there was a significant improvement once the ClimateCare® was implemented in the FIS group. This suggests the FIS after ClimateCare® performed better than the AFB in preventing open wounds at POD 14. In previous studies, AFB has shown to increase body temperature. Although body temperature was not tested as a variable, it is possible there was associated maceration. This correction coincided with the introduction of ClimateCare support with FIS.

ClimateCare is a unique mattress coverlet system that provides microclimate management. When used in conjunction with a pressure redistribution mattress, like FIS, ClimateCare is designed to address the root causes of tissue breakdown through the management of temperature and moisture (microclimate) at the interface between the patient and the surface. The effective moisture reduction, through moisture vapour transfer, and temperature regulation helps augment patient comfort whilst improving clinical outcomes. ClimateCare operates independent of the Fluid Immersion system and is comprised

of a single patient use coverlet that is easy to use and instal. ClimateCare is FDA approved under an 510(k) exemption.

Our long-term follow-up indicated there were some variations between the groups but we could not find significant differences regarding the wound status after 1 month, 6 months, and 1 year. This suggests similar long-term clinical outcomes.

Despite these results, the primary outcomes, which determine the clinical significance of the FIS over the AFB, are: 1) the effectiveness to keep the wound closed after the intervention and 2) the rate and severity of complications. A proposed reason for the higher minor dehiscence and maceration rates observed on the FIS could be implicated to the contrasting functioning of these two surfaces. The AFB pushes air through the beads inside the device to then exit the mattress, and by doing so, it actively manages the microclimate. In contrast, the FIS lacks microclimate regulation and hence, adequate microclimate management seems to be a defining factor for it to be clinically effective. With ClimateCare introduced, significant differences in complications were no longer found between both treatment arms.

While simulation models have been used to study intervention mechanics on PU treatment, there have not been any clinical trials to study the difference in effectiveness among interventions, which inhibits advancement of understanding of the disease at a patient level. This is an important step in overcoming the limitation of the finite element modelling used to simulate internal and external conditioning factors in PU's development. Furthermore, studies of this nature illustrate not only the use of a novel system but also demonstrate the potential for its implementation by evaluating patient and provider acceptability of the intervention. Future studies may be focused on other benefits of the FIS like energy consumption of the device or its relative less noise pollution compared to traditional devices.

5 | LIMITATIONS

Despite the well-matched subjects in both groups, an even greater sample is advisable for future studies because the number of subjects presenting complications during our study was generally small. Since ClimateCare was introduced halfway through the study for the FIS group, subjects prior to that may be considered non-homogenous and different. There might be other confounding factors, which may affect patient and nurse satisfaction beyond the ones stated in our instrument, that is, noise coming from the device. Lack of blinding among nurses and patients may introduce bias, which is unavoidable, considering the present study design.

6 | CONCLUSION

The comparison between the FIS and AFB system suggests a similar performance as an intervention for post-op care of PU, specifically to successfully keep wounds close after surgical intervention. Regarding complications presented during the first 14 days post-op, FIS presented a statistically significant higher rate of complications overall during our study. Patients and nurses perceived a similar experience during their procedure and recovery. If the ClimateCare® is used for moisture management, the FIS shows the same number of complications as the AFB, both clinically and non-clinically significant, as well as a smaller number of open wounds. Our results show that the use of ClimateCare® in combination with FIS could present as a better alternative to the AFB.

ACKNOWLEDGMENTS

The authors would like to thank Juan Domingo Perez, for his guidance on numerical data analysis. Joerns Healthcare LLC supported the work financially.

CONFLICT OF INTEREST

The senior author, Robert D. Galiano, has been a consultant for Hill Rom, the manufacturer of AFB.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ORCID

Chitang J. Joshi https://orcid.org/0000-0002-6725-334X
Rou Wan https://orcid.org/0000-0002-9029-4721

REFERENCES

1. Haesler E. National pressure ulcer advisory panel, European pressure ulcer advisory panel and pan pacific pressure injury alliance. *Prevention and treatment of pressure ulcers: quick reference guide*. 2014.
2. Staas W, Cioschi H. Pressure sores–a multifaceted approach to prevention and treatment. *West J Med*. 1991;154(5):539.
3. Beeckman D, Van Lancker A, Van Hecke A, Verhaeghe S. A systematic review and meta-analysis of incontinence-associated dermatitis, incontinence, and moisture as risk factors for pressure ulcer development. *Res Nurs Health*. 2014;37(3):204-218.
4. García-Fernández FP, Agreda JJS, Verdú J, Pancorbo-Hidalgo PL. A new theoretical model for the development of pressure ulcers and other dependence-related lesions. *J Nurs Scholarsh*. 2013;46(1):28-38.
5. Johansen E, Moore Z, van Etten M, Strapp H. Pressure ulcer risk assessment and prevention: what difference does a risk scale make? A comparison between Norway and Ireland. *J Wound Care*. 2014; 23(7):369-378.
6. Kottner J, Gefen A, Lahmann N. Weight and pressure ulcer occurrence: a secondary data analysis. *Int J Nurs Stud*. 2011;48(11):1339-1348.
7. VanGilder C, MacFarlane G, Meyer S, Lachenbruch C. Body mass index, weight, and pressure ulcer prevalence. *J Nurs Care Qual*. 2009; 24(2):127-135.
8. Levy A, Shoham N, Kopplin K, Gefen A. The critical characteristics of a good wheelchair cushion. *Science and Practice of Pressure Ulcer Management*. Springer; 2018:17-31.
9. Peirce SM, Skalak TC, Rodeheaver GT. Ischemia-reperfusion injury in chronic pressure ulcer formation: a skin model in the rat. *Wound Repair Regen*. 2000;8(1):68-76.
10. Gefen A. The future of pressure ulcer prevention is here: detecting and targeting inflammation early. *EWMA J*. 2018;19(2):7-13.

11. Kottner J, Black J, Call E, Gefen A, Santamaria N. Microclimate: a critical review in the context of pressure ulcer prevention. *Clin Biomech (Bristol, Avon)*. 2018;59:62-70.
12. Zeevi T, Levy A, Brauner N, Gefen A. Effects of ambient conditions on the risk of pressure injuries in bedridden patients-multi-physics modelling of microclimate. *Int Wound J*. 2017;15(3):402-416.
13. Levy A, Kopplin K, Gefen A. An air-cell-based cushion for pressure ulcer protection remarkably reduces tissue stresses in the seated buttocks with respect to foams: finite element studies. *J Tissue Viability*. 2014;23(1):13-23.
14. Bamba R, Madden JJ, Hoffman AN, et al. Flap reconstruction for pressure ulcers: an outcomes analysis. *Plast Reconstr Surg Glob Open*. 2017;5(1):e1187.
15. Cushing CA, Phillips LG. Evidence-based medicine. *Plast Reconstr Surg*. 2013;132(6):1720-1732.
16. Graves N, Birrell F, Whitby M. Effect of pressure ulcers on length of hospital stay. *Infect Control Hosp Epidemiol*. 2005;26(3):293-297.
17. Russo CA, Steiner C, Spector W. Hospitalizations related to pressure ulcers among adults 18 years and older, 2006: Statistical brief# 64. *Healthcare cost and utilization project (HCUP) statistical briefs*. 2006.
18. Schryvers OI, Stranc MF, Nance PW. Surgical treatment of pressure ulcers: 20-year experience. *Arch Phys Med Rehabil*. 2000;81(12):1556-1562.
19. Hurteau JE, Bostwick J, Nahai F, Hester R, Jurkiewicz MJ. V-Y advancement of hamstring musculocutaneous flap for coverage of ischial pressure sores. *Plast Reconstr Surg*. 1981;68(4):539-542.
20. Bhattacharya S, Mishra RK. Pressure ulcers: current understanding and newer modalities of treatment. *Indian J Plast Surg*. 2015;48(1):4-16.
21. Tobin GR, Sanders BP, Man D, Weiner LJ. The biceps femoris myocutaneous advancement flap: a useful modification for ischial pressure ulcer reconstruction. *Ann Plast Surg*. 1981;6(5):396-401.
22. Calderon W, Chang N, Mathes SJ. Comparison of the effect of bacterial inoculation in musculocutaneous and fasciocutaneous flaps. *Plast Reconstr Surg*. 1986;77(5):785-792.
23. Gosain A, Chang N, Mathes S, Hunt TK, Vasconez L. A study of the relationship between blood flow and bacterial inoculation in musculocutaneous and fasciocutaneous flaps. *Plast Reconstr Surg*. 1990;86(6):1152-1162.
24. Biglari B, Büchler A, Reitzel T, et al. A retrospective study on flap complications after pressure ulcer surgery in spinal cord-injured patients. *Spinal Cord*. 2013;52(1):80-83.
25. Sirimaharaj W, Charoenvicha C. Pressure ulcers: risk stratification and prognostic factors that promote recurrence after reconstructive surgery. *Int J Low Extrem Wounds*. 2018;17(2):94-101.
26. Bauer J, Phillips LG. MOC-PSSM CME Article: Pressure Sores. *Plast Reconstruct Surg*. 2008;121:1-10.
27. McInnes E, Jammali-Blasi A, Bell-Syer SEM, Dumville JC, Middleton V, Cullum N. Support surfaces for pressure ulcer prevention. *Cochrane Database Syst Rev*. 2015;2015(9):CD001735.
28. Qaseem A, Humphrey LL, Forciea MA, Starkey M, Denberg TD. Treatment of pressure ulcers: a clinical practice guideline from the American College of Physicians. *Ann Intern Med*. 2015;162(5):370-379.
29. Sameem M, Au M, Wood T, Farrokhyar F, Mahoney J. A systematic review of complication and recurrence rates of musculocutaneous, fsasciocutaneous, and perforator-based flaps for treatment of pressure sores. *Plast Reconstr Surg*. 2012;130(1):67e-77e.
30. Tchanque-Fossuo CN, Kuzon WM. An evidence-based approach to pressure sores. *Plast Reconstr Surg*. 2011;127(2):932-939.
31. Keys KA, Daniali LN, Warner KJ, Mathes DW. Multivariate predictors of failure after flap coverage of pressure ulcers. *Plast Reconstr Surg*. 2010;125(6):1725-1734.
32. Yamamoto Y, Tsutsumida A, Murazumi M, Sugihara T. Long-term outcome of pressure sores treated with flap coverage. *Plast Reconstr Surg*. 1997;100(5):1212-1217.
33. Mendoza RA, Lorusso GA, Ferrer DA, et al. A prospective, randomised controlled trial evaluating the effectiveness of the fluid immersion simulation system vs an air-fluidised bed system in the acute postoperative management of pressure ulcers: a midpoint study analysis. *Int Wound J*. 2019;16:989-999.
34. Allman RM. Pressure ulcers among the elderly. *N Engl J Med*. 1989;320(13):850-853.

How to cite this article: Joshi CJ, Carabano M, Perez LC, et al. Effectiveness of a fluid immersion simulation system in the acute post-operative management of pressure ulcers: A prospective, randomised controlled trial. *Wound Rep Reg*. 2022;30(4):526-535. doi:10.1111/wrr.13031