

# A 3-Year Retrospective Analysis Comparing the Effectiveness of Medical Devices to Non-Medical Devices in the Treatment of Heel Pressure Ulcers

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## ABSTRACT

Retrospective analysis of 100 patients in multiple care settings found that the use of medical devices as part of the treatment plan for heel pressure ulcers increased the rate of wound healing. The rate of wound closure was significantly faster for subjects receiving a particular device (Foot WAFFLE® Air Cushion by EHOB, Inc.) than for subjects receiving a pillow. The rate of wound closure was also significantly faster for subjects receiving the Foot WAFFLE® Air Cushion than for all other subjects grouped together. The area of the wound (length x width) was not a significant factor in the time to wound closure. However, the extent of tissue involvement was a statistical indicator in the time to wound closure. The time to wound closure for subjects receiving the Foot WAFFLE® Air Cushion was significantly lower than all other subjects grouped together for full thickness and non-stageable wounds. The rate of recurrence within six months of wound closure decreased to 0% with the use of the Foot WAFFLE® Air Cushion as compared to 61.8% rate of recurrence with the use of pillows, 57.1% rate of recurrence when other products were used, and 62.5% rate of recurrence when no medical device was used. The probability of recurrence within six months for subjects using the Foot WAFFLE® Air Cushion was significantly lower than subjects receiving the pillow.

## PURPOSE

The purpose of the study was to:

- 1) Identify patient parameters that drive clinical decision making;
- 2) Examine clinical outcomes related to medical devices and non-medical devices used in a treatment plan for heel pressure ulcers.

## MATERIALS AND METHODS

A three year retrospective study of 100 patients with heel pressure ulcers was conducted. Subjects studied were located in various healthcare settings, including nursing home, rehabilitation, home health, and hospital. Subject's clinical records were reviewed and specific data retrieved to complete the Study Data Collection Tool. The Cutright Risk Assessment Tool® was used to identify each subject's pressure ulcer potential score (PUPS).



## STUDY DATA

Forty-two males and fifty-eight females composed the sample size and gender. Table 1 depicts the healthcare settings of the study subjects.

SETTING	# OF SUBJECTS
Nursing Home	53
Rehabilitation	39
Home Health	7
Hospital	1
Total	100

TABLE 1: SUBJECTS BY SETTING

Heel protection and therapeutic management of the lower extremity and heel pressure ulcers was addressed using the Foot WAFFLE® Air Cushion, pillows, other medical devices (including foam, bunny boots, the ROHO Heel Pad® Cushion, and the L'Nard® Multi-Podis Splint) or no device. Table 2 shows study subjects by device utilized, sex, age, and risk score.

DEVICE	FEMALES	MALES	AVERAGE AGE	AVERAGE PUPS SCORE (Pressure Ulcer Potential Score)
Foot WAFFLE® Air Cushion	19	17	77.17	30.64
Pillows	24	17	73.07	27.34
Other	11	4	67.53	27.93
No device	4	4	74.75	34.5
TOTAL	58	42		

TABLE 2: SUBJECTS BY DEVICE, SEX, AGE, RISK SCORE

Wound severity was classified as partial thickness or full thickness using criteria from the AHCPR Clinical Practice Guideline, or non-stageable if the wound was covered with necrotic tissue. Table 3 demonstrates the wound demographics by device and extent of tissue involvement.

DEVICE	#	# OF PARTIAL THICKNESS WOUNDS	# OF FULL THICKNESS WOUNDS	# OF NON-STAGEABLE WOUNDS
Foot WAFFLE® Air Cushion	36	15	13	8
Pillow	41	26	8	7
Other	15	9	2	4
No device	8	5	1	2
TOTAL	100	55	24	21

TABLE 3: WOUND DEMOGRAPHICS BY DEVICE AND STAGE

## STATISTICAL ANALYSIS

Two types of statistical analyses were used to evaluate the data: a linear model and a logistics regression model. The Foot WAFFLE® Air Cushion was

compared against all groups together as well as each group individually.

A linear model was used to analyze the rate of wound closure with the following covariates: extent of tissue involvement, type of device used, topical treatment used, and the interaction between extent of tissue involvement and type of device used. A linear model was used to analyze the time to wound closure with the following covariates: extent of tissue involvement, type of device used, topical treatment used, area of the wound, and the interaction between extent of tissue involvement and type of device used. A logistics regression model was used to analyze the probability of recurrence within six months for subjects with the presence and absence of a disease with the following covariates: extent of tissue involvement, type of device used, and topical treatment used.

All analyses were performed using the statistical software SAS version 6.12. Unless otherwise stated, all significant results correspond to a two-sided  $p\text{-value} \leq 0.05$ .

## RESULTS

### Rate of Wound Closure:

- ◆ The rate of wound closure for subjects receiving the Foot WAFFLE® Air Cushion was significantly faster than subjects who received a pillow ( $p=0.0147$ ).
- ◆ The rate of wound closure for subjects using the Foot WAFFLE® Air Cushion was significantly faster than all other subjects grouped together ( $p=0.0414$ ).
- ◆ Extent of tissue involvement ( $p=0.4030$ ) and topical treatment ( $p=0.3919$ ) were not significant factors in the rate of wound closure.
- ◆ There was no significant interaction between extent of tissue involvement and the type of device used ( $p=0.5198$ ).

### Time to Wound Closure:

- ◆ The extent of tissue involvement was a significant factor in the time to wound closure ( $p=0.0001$ ).
- ◆ There was a significant interaction between extent of tissue involvement and the type of device used ( $p=0.0002$ ).

### Full Thickness Wounds:

- ◇ The time to wound closure was significantly reduced for subjects who used the Foot WAFFLE® Air Cushion when compared against subjects who used the pillow ( $p=0.0004$ ).
- ◇ The time to wound closure was significantly reduced for subjects who used the Foot WAFFLE® Air Cushion when compared against all other subjects grouped together ( $p=0.0459$ ).

### Non-Stageable Wounds:

- ◇ The time to wound closure was significantly reduced for subjects who used the Foot WAFFLE® Air Cushion when compared against subjects who used no device (p=0.0002).
- ◇ The time to wound closure was significantly reduced for subjects who used the Foot WAFFLE® Air Cushion when compared against all other subjects grouped together (p=0.0088).
- ◆ The area of the wound was not a significant factor in the time to wound closure (p=0.9035).
- ◆ Topical treatment was not a significant factor in the time to wound closure (p=0.2571).

### Probability of Recurrence:

There was a significant decrease in the probability of recurrence for subjects receiving the Foot WAFFLE® Air Cushion when compared against subjects who used a pillow.

- ◆ with one or more diseases present p=0.0001.
- ◆ with no disease present p=0.0051.

DEVICE	% OF WOUNDS THAT RECURRENT	TIME TO WOUND CLOSURE	RATE OF WOUND CLOSURE
Foot WAFFLE® Air Cushion	0%	53.7 days	0.48 sq. cm/day
Pillow	61.8%	65.36 days	0.16 sq. cm/day
Other	57.1%	62.57 days	0.26 sq. cm/day
No device	62.5%	71.0 days	0.26 sq. cm/day

TABLE 4: WOUND HEALING AND RECURRENCE DATA BY DEVICE

### SUMMARY OF FINDINGS

- ◆ Area of the wound did not have statistical significance in time to wound closure.
- ◆ Depth of tissue involvement was statistically significant in time to wound closure.
- ◆ The topical treatment modality did not have statistical significance in wound healing (topical treatments were essentially the same and were fairly equally distributed between all groups).
- ◆ The presence of one or more disease entities did not have statistical significance in wound healing.
- ◆ Rate of wound closure:
  - ◇ was statistically significant when Foot WAFFLE® Air Cushion subjects were compared against all other subjects grouped together. Wounds of subjects treated with the Foot WAFFLE® Air Cushion closed at a faster rate than wounds on all other subjects;
  - ◇ was statistically significant when Foot WAFFLE® Air Cushion subjects were compared to the pillow group.

- ◆ Time to wound closure compared to the wound stage (partial thickness, full thickness, non-stageable):
  - ◇ was statistically significant when Foot WAFFLE® Air Cushion subjects were compared against subjects using a pillow for full thickness wounds;
  - ◇ was statistically significant when Foot WAFFLE® Air Cushion subjects were compared against all other subject groups with full thickness wounds;
  - ◇ was statistically significant when Foot WAFFLE® Air Cushion subjects were compared against subjects using no device in non-stageable wounds;
  - ◇ was statistically significant when Foot WAFFLE® Air Cushion subjects were compared against all other subject groups with non-stageable wounds.
- ◆ Probability of recurrence rate in the Foot WAFFLE® Air Cushion group was significantly lower than for subjects using a pillow irrespective of presence or absence of disease entities.

### CONCLUSION

Using a medical device, specifically the EHOB Foot WAFFLE® Air Cushion, significantly improved outcomes related to wound healing, wound closure and wound recurrence. It is apparent that adequate pressure relief/distribution is achieved when using this FDA approved modality.

Long term evaluation of the maintenance or promotion of skin health was statistically significant after a period of six months post-wound closure in the study subjects only when the medical device, the Foot WAFFLE® Air Cushion, was used.

Compliance and motivation of patients or their caregivers may be influenced by the value placed on a modality that is a recognized medical device versus a commonplace item, such as a pillow.

The cost benefit of a medical device versus a commonplace bedding item should be factored into the treatment plan. While some items may cost less, caregivers must evaluate whether or not the actual cost to treat pressure ulcers is less than if an approved medical device, such as the Foot WAFFLE® Air Cushion, is used.

Positive treatment outcomes documented by this retrospective analysis should be presented to administrators, policy makers, and third-party payors to support approval of and payment for a medical device such as the Foot WAFFLE® Air Cushion.

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