

DIRECT COMPARISON CASE STUDIES ZERO PRESSURE MATTRESS VS ALTERNATING PRESSURE MATTRESS SAME RESIDENT, SAME PRESSURE INJURY

Summary of Results

The five Case Studies that follow represent all of the Case Studies that have been conducted involving direct comparisons between the Zero Pressure Mattress and the Alternating Pressure Mattress. Significantly, these studies compared the treatment performance between the two mattresses for the same resident and same pressure injury. Thus, the studies are referred to as Direct Comparison Case Studies.

The data for each Case Study is first presented graphically, followed by a narrative summary.

In all five cases without exception the pressure injury healing performance of the Zero Pressure Mattress was greatly superior to the Alternating Pressure Mattress performance. Thus, the combination of consistent greatly superior performance and Direct Comparisons (same resident/same pressure injury) provided results that are highly significant, despite the relatively small sample size.

The Case Studies involve four extended care residents with buttock/sacrum/ischium pressure injuries ranging from Stage 3 to Stage 4.

Contact information involving four independent references and four different facilities provided upon request for each of the five Case Studies for confirmation of results.

ZERO
PRESSURE
MATTRESS

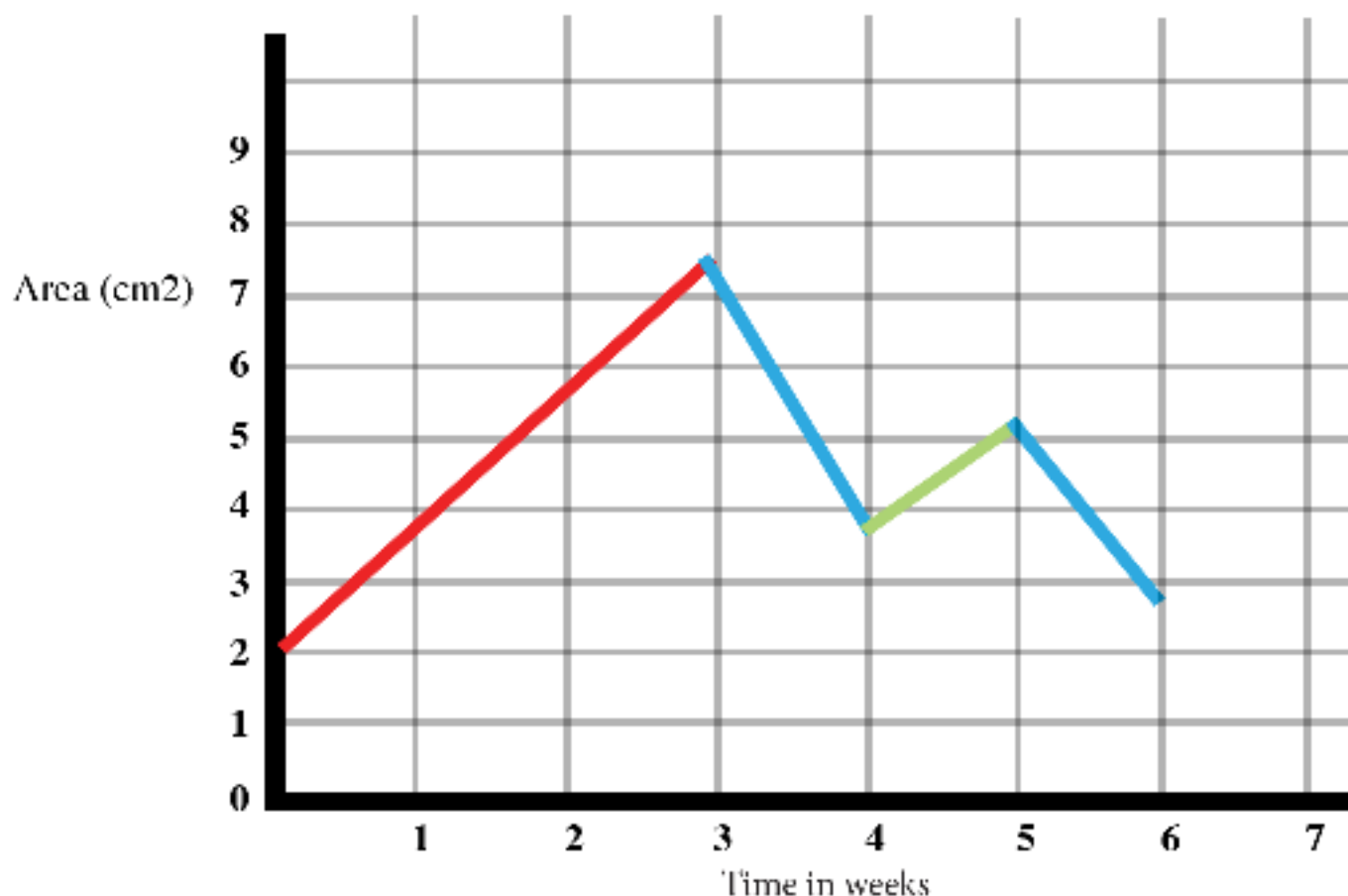
NO PRESSURE = NO PRESSURE INJURY

Alternating Pressure Mattress vs. Zero Pressure Mattress

Stage 3 Pressure Injury

Resident 1

Pressure Injury Area vs. Time



Alternating Pressure Mattress



Zero Pressure Mattress (without plug)



Zero Pressure Mattress (with plug)

Time Elapsed (Weeks)	Area (cm ²)	% Change Area
0	2.0	
3	7.5	92%
4	3.8	50%
5	5.3	40%
6	2.8	47%

Comments

- Pressure injury deteriorated rapidly at 92% increase per week (1.83 cm²/week) for first 3 weeks on the Alternating Pressure Mattress.
- However, during week 4, the first week on Zero Pressure Mattress, there was a 50% decrease (3.75 cm²/week).
- The plug was placed into the Zero Pressure Mattress during week 5, which resulted in a 40% increase (1.5 cm²/week).
 - However, the plug was removed from the Zero Pressure Mattress during week 6, which resulted in a 47% decrease (2.45 cm²/week).

RESIDENT ONE **Crowne Management Nursing Home, Montgomery, Alabama** **Stage 3 Coccyx/Sacrum Pressure Injury**

- Male resident of nursing home.
- Resident was confused and did not stay consistently properly positioned over the mattress cavity.
- Prior to placing resident on the Zero Pressure Mattress, the resident had been on an Alternating Pressure Mattress for three weeks. During the three weeks on the Alternating Pressure Mattress, the pressure injury deteriorated rapidly at a 92%/week increase rate.
- Initial pressure injury dimensions when placed onto the Alternating Pressure Mattress: 2.0 cm x 1.0 cm, no depth data provided. Pressure injury dimensions after 3 weeks on the Alternating Pressure Mattress were: 5.0 cm x 1.5 cm x 1.0 cm depth
- Initial pressure injury dimensions when placed onto the Zero Pressure Mattress: 5.0 cm x 1.5 cm x 1.0 cm depth
- Pressure injury dimensions for week 1 on the Zero Pressure Mattress (this is week 4 counting from the beginning): 2.5 cm x 1.5 cm x 0.9 cm depth. Thus, there was a 50%/week surface area decrease for the Zero Pressure Mattress.
- At the start of week 2 for the Zero Pressure Mattress (this is week 5 counting from the beginning) the mattress plug was inserted into the Zero Pressure Mattress. Following insertion of the mattress plug, pressure injury dimensions for week 2 on the Zero Pressure Mattress (or week 5 from the beginning) increased to 3.5 cm x 1.5 cm a 1.0 cm depth. This is a 40%/week surface area increase following insertion of the mattress plug.
- For week 3 on the Zero Pressure Mattress the plug was removed and the week 3 pressure injury dimensions for the Zero Pressure Mattress (week 6 from the beginning) were: 2.8 cm x 1.0 cm x .8 cm depth. This is a 47%/week decrease in surface area following removal of the mattress plug.

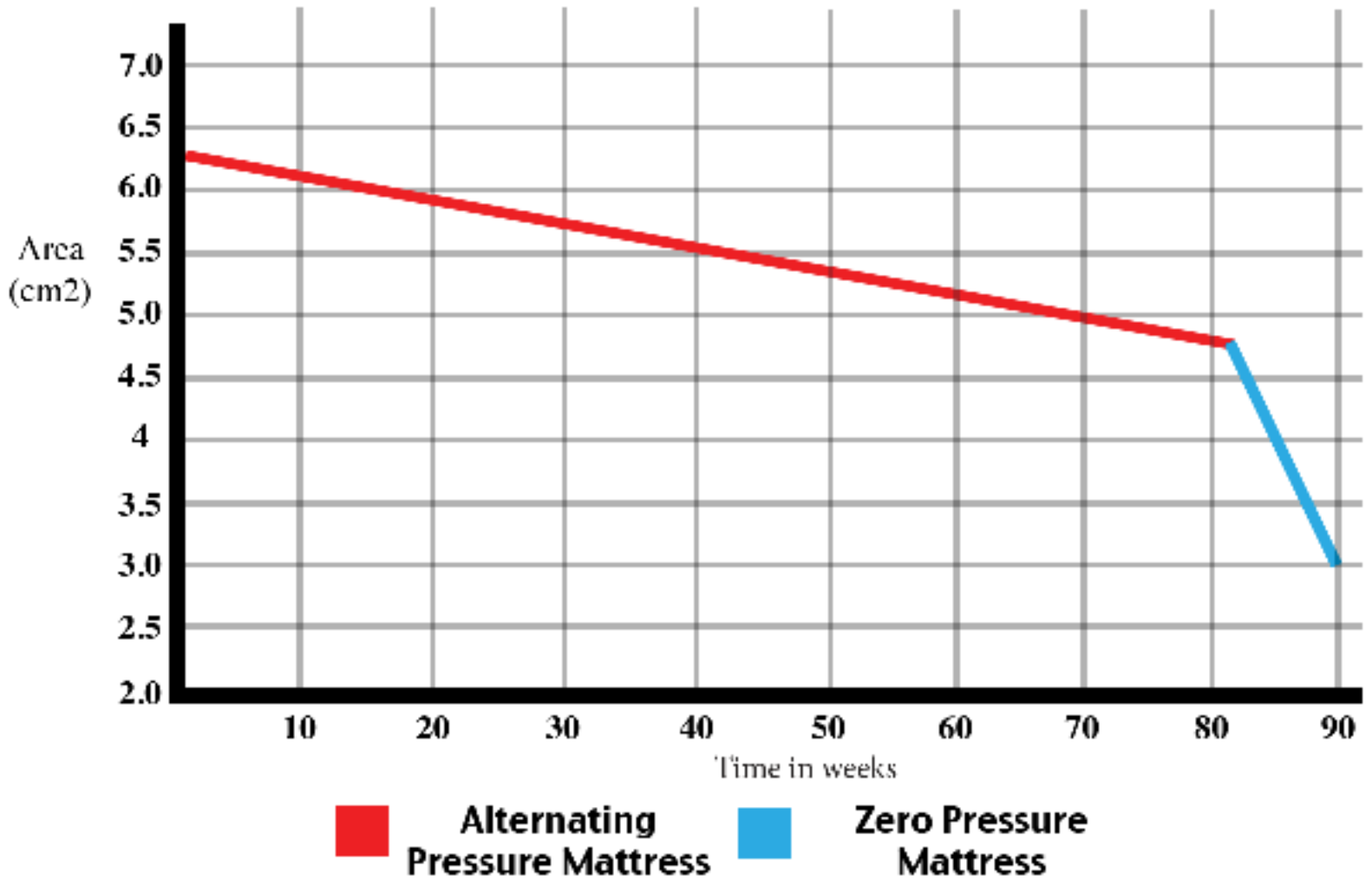
Contact information to confirm the above provided upon request.

Alternating Pressure Mattress vs. Zero Pressure Mattress

Pressure Injury Area vs. Time

Resident 2

Stage 3 Pressure Injury

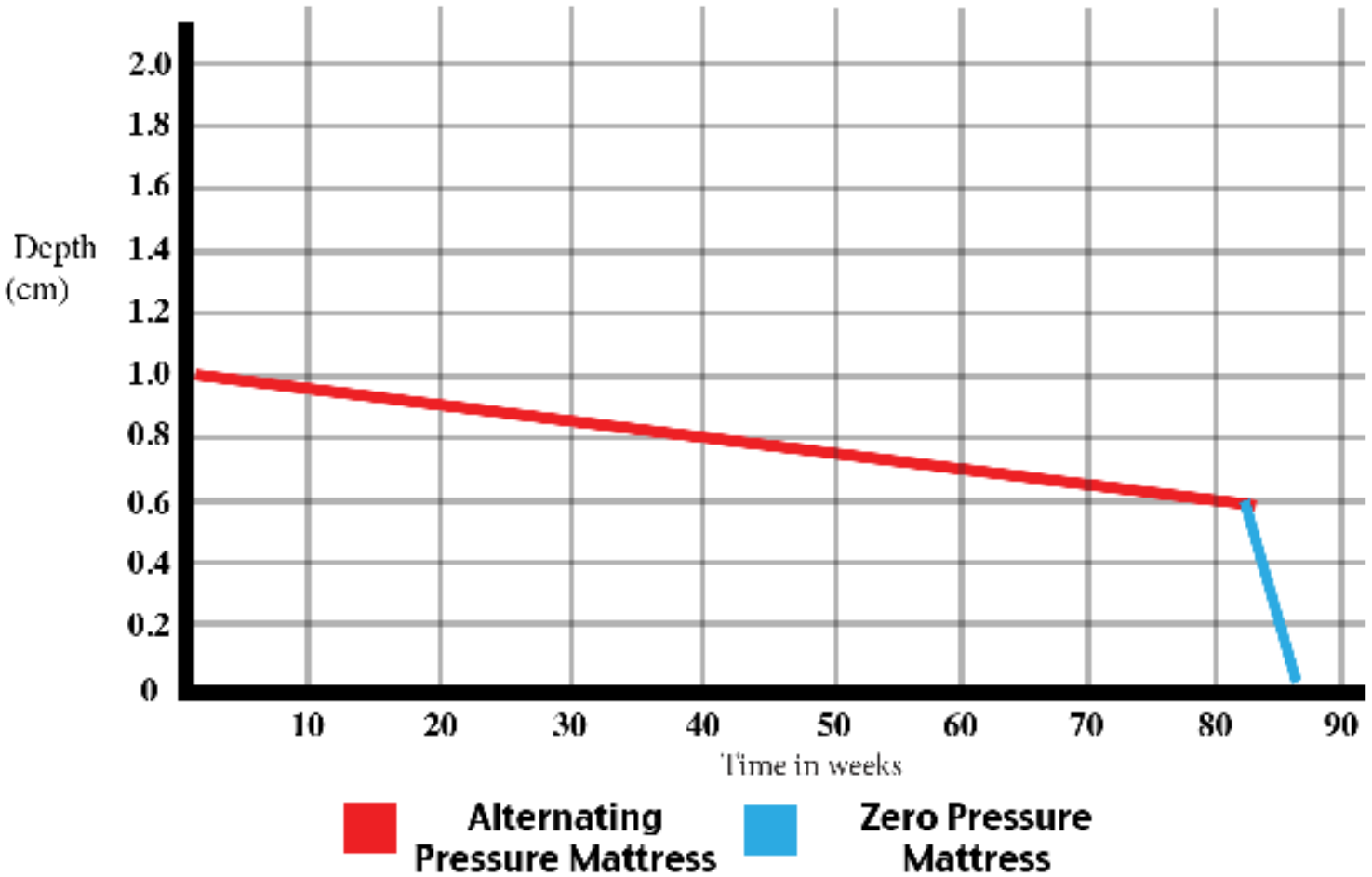


Time Elapsed (Weeks)	Area (cm ²)
0	6.3
83	4.8
88	3.0

Comments

- Week 0 was first week on the Alternating Pressure Mattress (APM). Week 83 was last week on APM. Resident was placed onto the Zero Pressure Mattress at end of Week 83.
- 20x faster healing for surface area reduction by Zero Pressure Mattress compared to the Alternating Pressure Mattress. The Zero Pressure Mattress achieved more healing in 5 weeks than the Alternating Pressure Mattress achieved in 83 weeks.
- Once placed on the Zero Pressure Mattress, the pressure injury showed a decrease in area at a rate of .36 cm². Comparatively, the pressure injury only decreased .018 cm² on an APM.

**Alternating Pressure Mattress
vs. Zero Pressure Mattress
Stage 3 Pressure Injury
Resident 2
Pressure Injury Depth vs. Time**



Time Elapsed (Weeks)	Area (cm ²)
0	1.0
83	0.6
86	0.0

Comments

- Week 0 was first week on the Alternating Pressure Mattress (APM). Week 83 was last week on the APM. Resident was placed onto the Zero Pressure Mattress at end of Week 83.
- 42x faster healing for depth reduction by Zero Pressure Mattress compared to the Alternating Pressure Mattress. (.2 cm/wk vs .0048 cm/wk). The Zero Pressure Mattress achieved more depth reduction in 3 weeks than the Alternating Pressure Mattress achieved in 83 weeks (0.6 cm vs 0.4 cm).
- The Zero Pressure Mattress was able to decrease the depth of the pressure injury to 0 cm by week 86.

RESIDENT 2 **Washington County Hospital and Nursing Home** **Stage 3 Buttock Pressure Injury**

- Location of wound was about 1.5 cm outside of the primary Zero Pressure Mattress air cell (cavity), but within the secondary smaller air cell at the edge of the primary air cell.
- 87 year old female resident of nursing home.
- Resident was immobile and was consistently properly positioned over the mattress cavity.
- Prior to placing resident on Zero Pressure Mattress the resident had been on an alternating pressure mattress for 83 weeks (from January, 2013 to August, 2014). Initial pressure injury dimensions when placed onto the alternating pressure mattress: 2.5 cm x 2.5 cm x 1.0 cm deep. Pressure Injury dimensions after 83 weeks on the alternating pressure mattress: 2.4 cm x 2.0 cm x .6 cm deep
- Initial Pressure Injury dimensions when resident placed onto the Zero Pressure Mattress: 2.4 cm x 2.0 cm x .6 cm depth
- On day 3 after placing the resident on the Zero Pressure Mattress the dressing for the wound was removed with the following observations: Blood in the wound (never previously seen with the alternating pressure mattress), increased drainage, increased granulation with budding.
- Within 3 weeks of placing the resident onto the Zero Pressure Mattress, the wound depth was zero.
- Within 5 weeks of placing the resident onto the Zero Pressure Mattress, the wound measurements were as follows: 2.0 cm x 1.5 cm x 0 depth
- Summary of healing comparison between the alternating pressure mattress and the Zero Pressure Mattress:
- 20x faster healing for surface area reduction by Zero Pressure Mattress; 42x faster healing for depth reduction by Zero Pressure Mattress; Zero Pressure Mattress achieved more healing for the resident's pressure injury in 5 weeks than the alternating pressure mattress achieved in 83 weeks both respect to surface area reduction and depth reduction.

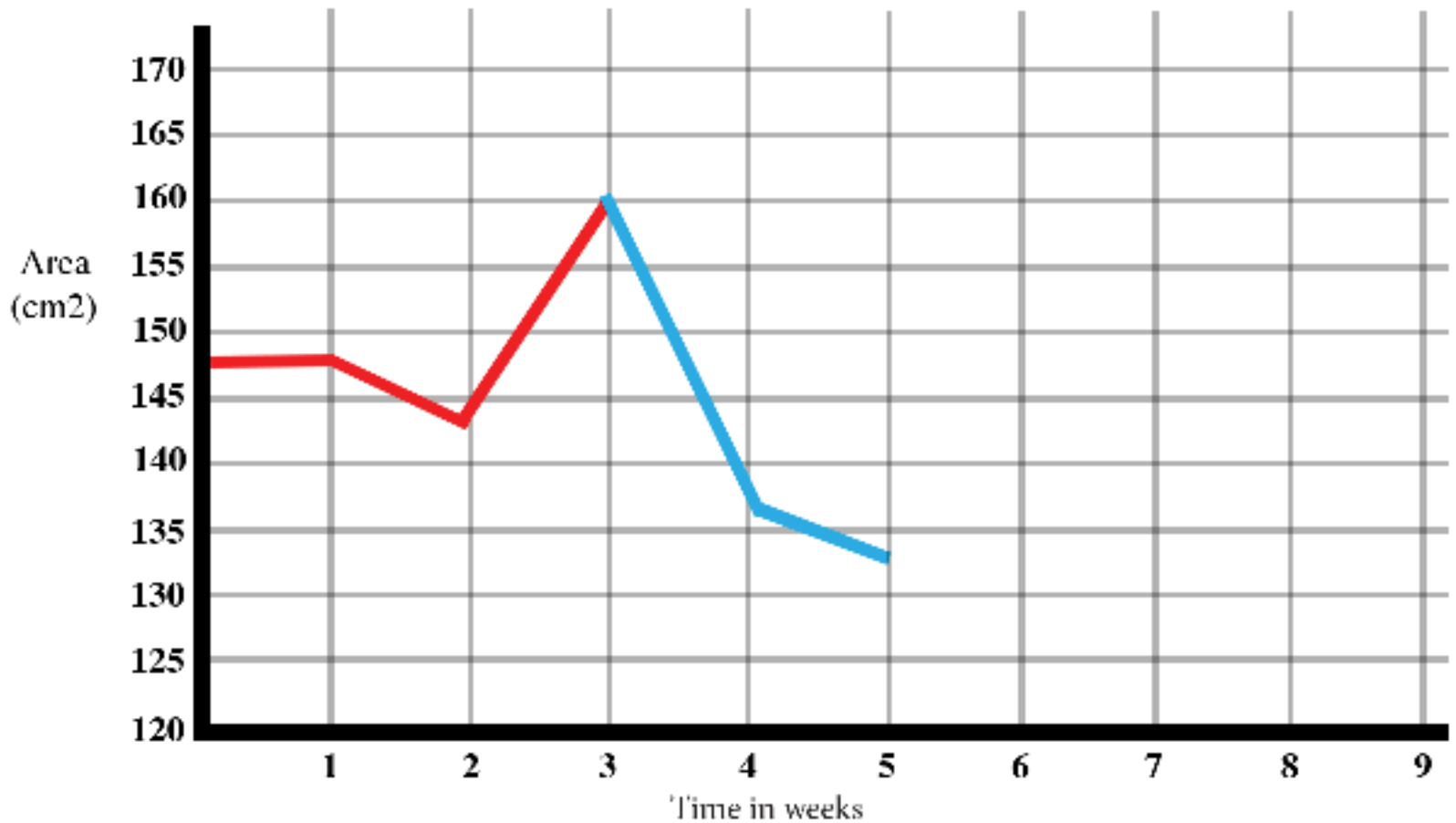
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Alternating Pressure Mattress vs. Zero Pressure Mattress

Stage 4 Pressure Injury

Resident 3

Pressure Injury Area vs. Time



Alternating Pressure Mattress **Zero Pressure Mattress**

Time Elapsed (Weeks)	Area (cm ²)
0	147
1	147
2	143
3	160
4	136
5	133

Comments

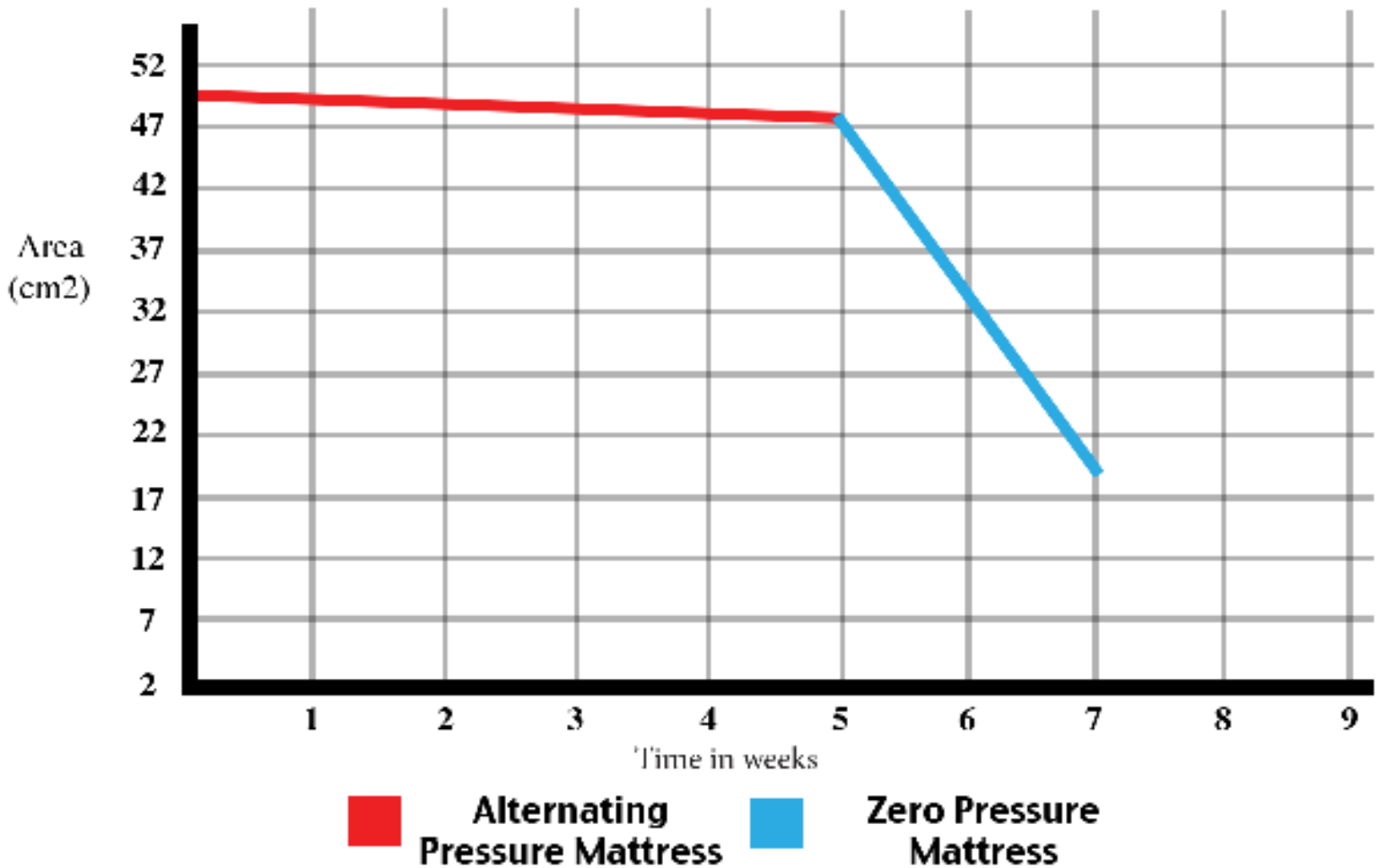
- Resident was a 42 year old paraplegic that was extremely non compliant.
- Despite not being properly positioned over the Zero Pressure Mattress cavity the majority of the time, the Zero Pressure Mattress provided 6.75x faster healing compared to the Alternating Pressure Mattress(13.5 cm²/week vs 2.0 cm²/week).

RESIDENT THREE **Oakwood –North Baldwin County (Extended Care Facility)** **Stage 4 Sacral/Coccyx and Buttock Pressure Injury**

- Resident is a 42 year old paraplegic.
- Resident was extremely non-compliant and spent most of the time not properly positioned over the mattress cavity.
- Prior to placing resident on Zero Pressure Mattress the resident had been on an alternating pressure mattress at this facility for 10 weeks.
- Pressure Injury dimensions for the last 2 weeks on the alternating pressure mattress were as follows: Week 8 (Initial): 15 cm x 9.8 cm; Week 9: 15 cm x 9.8 cm; Week 10: 14.4 cm x 9.9 cm. No depth data available at this time for weeks 8 through 10.
- Prior to placing resident on the Zero Pressure Mattress the patient spent 7 days at a nearby hospital.
- Pressure Injury dimensions when resident was initially placed onto the Zero Pressure Mattress follow: 16 cm x 10 cm x .5 cm depth
- At this time resident has spent 2 weeks on the Zero Pressure Mattress with the following dimensions: Initial: 16 cm x 10 cm x .5 cm depth; Week 1: 14.5 cm x 9.4 cm x .4 cm depth; Week 2: 14.5 cm x 9.2 cm x .4 cm depth
- A performance comparison between the Zero Pressure Mattress and the alternating pressure mattress follows. Surface area reduction for Zero Pressure Mattress = 13.3 cm²/week. Surface area reduction for alternating pressure mattress = 2.2 cm²/week. Thus, 6x faster healing for the Zero Pressure Mattress.
- Note: The last 2 weeks the resident was on the alternating pressure mattress was used for the comparison in order to compare pressure injury healing rates when the resident's pressure injury was initially about the same size for the two mattresses.
- Finally, as stated previously, the resident has been very non-compliant during his 2 weeks on the Zero Pressure Mattress spending a considerable amount of time NOT properly positioned over the mattress cavity. Thus, despite the 6x healing shown above, we do not believe this resident provides an accurate assessment of the typical capabilities of the Zero Pressure Mattress.

Contact information to confirm the above provided upon request.

Alternating Pressure Mattress vs. Zero Pressure Mattress Stage 4 Left Buttock Pressure Injury Resident A Pressure Injury Area vs. Time



Comments

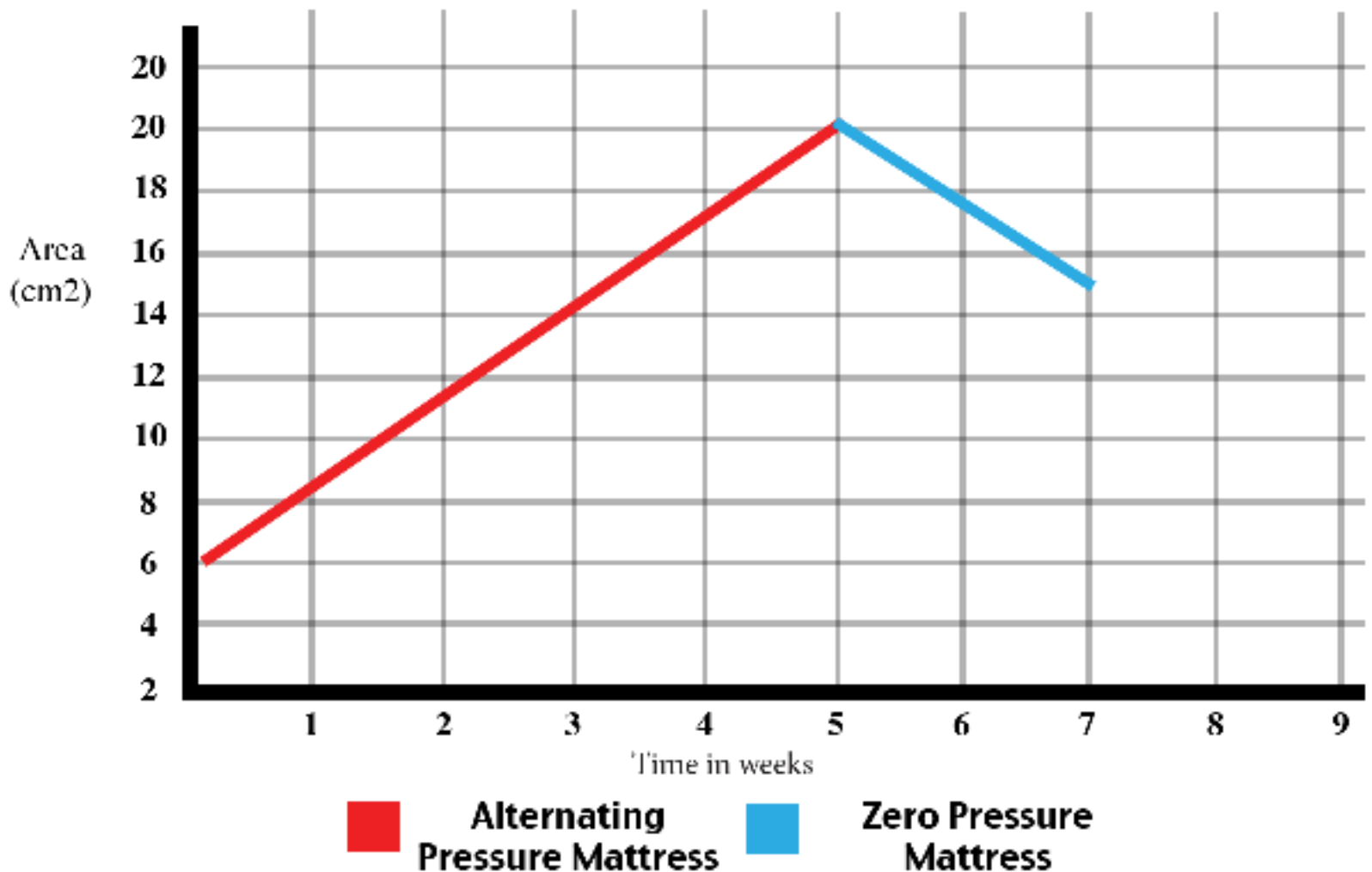
- 34x faster healing for surface area reduction by Zero Pressure Mattress compared to the Alternating Pressure Mattress (10.25 cm²/week vs .30 cm²/week).
- Zero Pressure Mattress achieved 43% surface area reduction in only 2 weeks compared to 3% surface area reduction by Alternating Pressure Mattress within 5 weeks.

Alternating Pressure Mattress vs. Zero Pressure Mattress

Stage 4 Right Buttock/Ischium Pressure Injury

Resident A

Pressure Injury Area vs. Time



Comment

- 13%/week decrease in pressure injury surface area achieved by Zero Pressure Mattress compared to 48%/week Increase in pressure injury surface area when using Alternating Pressure Mattress.

Resident A
Foothills Rehabilitation Center; Tucson, AZ.
Stage 4 Left Buttock Pressure Injury
Stage 4 Right Buttock/Ischium Pressure Injury

- Male resident with spinal cord injury
- Resident had two Stage 4 pressure injuries: Left Buttock and Right Ischium/Buttock
- Prior to placing on the Zero Pressure Mattress the resident had been on an alternating pressure mattress for 5 weeks. Initial pressure injury dimensions when placed onto the alternating pressure mattress: Left Buttock: 4.5 cm x 11 cm x .5 cm depth; Right Buttock/Ischium: 12 cm x .5 cm x .5 cm depth
- Initial pressure injury's dimensions when resident was placed onto the Zero Pressure Mattress: Left Buttock: 6 cm x 8 cm x .4 cm depth; Right Buttock/Ischium: 10.2 cm x 2 cm x .7cmdepth
- Within 2 weeks of placing the resident onto the Zero Pressure Mattress the pressure injury's dimensions were: Left Buttock: 11 cm x 2.5 cm x .5 cm depth; Right Buttock/Ischium: 10.0 cm x 1.5 cm x .5 cm depth

Contact information to confirm the above provided upon request.