

Are Commercial Seat Cushions Efficacious in Preventing Pressure Ulcers?

Mary Jo Geyer, MS, PT, CWS

David M. Brienza, PhD

Patricia Karg, MS

Sheryl Kelsey, PhD

Elaine Treffler, MEd

University of Pittsburgh
Seating and Soft Tissue Biomechanics Lab

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Department of Rehabilitation Science and Technology
5044 Forbes Tower
University of Pittsburgh
Pittsburgh, PA 15260

Abstract

This study developed and tested a protocol for use in a multi-center, clinical trial to evaluate the efficacy of pressure-reducing cushions in the at-risk, elderly nursing home population, a population which remains underserved. Thirty-two at-risk elderly, resident wheelchair users completed the study. All subjects received individually prescribed wheelchairs. Subjects were randomized to foam or pressure-reducing cushion (PRC) groups. PRC selection was based on subject seating needs and interface pressure-mapping which was obtained for both groups. Sitting time, risk and skin changes were monitored. The primary endpoint was a seating-surface pressure ulcer (PU). Interface pressure was a significant predictor of PU incidence. No significant difference ($p > .05$) was found for PU incidence. Failure to reach statistical significance was attributed to low power (0.21), a difference in sitting time, and an inadequate operational definition of sitting induced PU. Future plans for a multi-center clinical trial are in progress.

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Full Citation

- Full citation of the published research:
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Acknowledgments

A Randomized Clinical Trial to Evaluate
Pressure Reducing Seat Cushions for
At-Risk, Elderly Nursing Home
Residents

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Introduction



- Elderly US wheelchair users are not routinely evaluated for seating & positioning needs
- **WHY?**

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Despite Federal mandates for NH to provide preventive and therapeutic interventions for pressure ulcers, elderly US NH residents using WC's as their primary means of mobility are not routinely evaluated for seating and positioning needs.

Inadequate Funding!

- Scope of the problem of sitting-acquired pressure ulcer (PU) is largely unknown.
- Few well-controlled, clinical seating trials for the elderly.
- Efficacy of commercially available seat cushions has not been demonstrated.

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Third-party payors cannot justify reimbursement for services and products when research has failed to provide incidence information and to definitively demonstrate the clinical effectiveness of seating evaluations and commercially available seat cushions.

More research is needed.

Study Goals

Conduct a pilot study to demonstrate:

- the *feasibility* of an randomized clinical trial (RCT),
- the *effectiveness* of commercially available, pressure-reducing seat cushions for nursing home (NH) residents.

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Study Goals

Null Hypotheses: Compared to the use of convoluted foam cushions (FOAM), the use of pressure reducing cushions (PRC) would result in:

- *a lower incidence of PU's*
- *longer number of days to reach ulceration or study endpoint*
- *lower initial peak interface pressures*

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Methods

Subjects:

- 32 elderly NH residents, cumulatively recruited (6/98 to 6/99)
- Randomized to pressure-reducing cushion (PRC-15) or (Foam-17) groups

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Methods

Inclusion Criteria:

- \geq 65 years of age.
- Braden Score of \leq 18
- Combined Braden Activity and Mobility Subscale Score of \leq 5
- No sitting-surface PU's
- WC sitting-tolerance of \geq 6 hours
- Accommodated by ETAC wheelchair

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Inclusion criteria was effective in targeting those NH residents at greatest risk for sitting-acquired pressure ulcers.

Sitting time was cumulative.

Etac Twin Wheelchair

- These wheelchairs are:
 - Highly adjustable
 - 250 lb. weight limit
 - Special adjustable back
 - 14-22" widths



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The Etac wheelchair permitted an almost custom seating system for each subject.

Methods

- PU definition: *any lesion on the sitting surface caused by unrelieved pressure resulting in damage of underlying tissue.*
- Seating compliance was monitored.
- Endpoints: development of PU, completion of study, death, or discharge/transfer.

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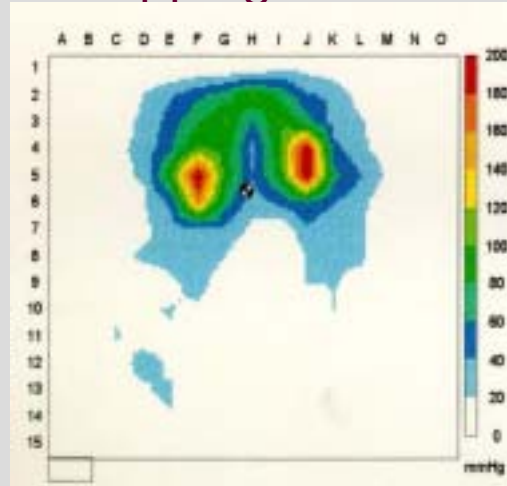


A very broad definition of a pressure ulcer was used to insure that no clinically significant outcome would be missed.

Sitting time was monitored by review of nursing and nursing assistance logs and personal interviews with staff and family members.

Pressure Mapping

- All subjects received interface pressure-mapping
- Pressure-mapping was used in the PRC group to aid in cushion selection



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Pressure mapping was shown to be an effective aid for optimizing the wheelchair modifications and the seat cushion selection.

Results

- No significant difference found between the groups for PU incidence, total days to endpoint or initial peak pressure
- *PU location differed between groups ($p < .005$)*
No *ischial ulcers* in PRC group
- Higher interface pressures associated with higher incidence of PUs ($p < .001$)

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As this was a pilot study, significance between the groups on the outcomes was not expected. The sample was too small and the power too low.

However, two significant findings were demonstrated:

- -no sitting-acquired pressure ulcers occurred in the PRC group
- -higher interface pressure was associated with higher incidence of pressure ulcers

Discussion

- Non-significance between the groups for primary outcomes was expected due to small sample size and low power (0.21).
- Ischial ulcers are argued to be sitting-acquired: ***none developed in PRC group.***
- Operational definition of sitting-acquired PU for definitive trial must ***exclude*** shearing injuries and non-ischial PUs.

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Conclusions

- PRCs were significantly more effective in preventing ischial (sitting-acquired) PUs in elderly, NH resident wheelchair users.
- Conducting a randomized, multicenter, clinical trial is feasible (methods and number of subjects)

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Conclusions

- Methods: use of timing device to measure actual time seated in wheelchair.
- An estimated sample size of 100 subjects per treatment group is projected based on $\alpha = .05$ (two-tailed), $\text{power} = .90$ to detect a 20% versus 5% difference between the treatment groups with respect to the outcomes.

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In the definitive trial, a timing device will be used to track sitting compliance.

A sample size of 100 is financially feasible to fund for an RCT trial.

Plans to obtain funding are in progress.

Conclusions

Just like :

- Soap and Water
- Hardware and Software
- Love and Marriage

Seating evaluations and wheelchair modifications are linked to cushion efficacy—*you can't have one without the other!*

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