

Research Priorities: Seating and Positioning

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The Wheeled Mobility State of the Science Conference, hosted by the mobilityRERC at the Georgia Institute of Technology, was a forum to identify and discuss important research topics. The Conference was configured around Breakout Groups which were assigned specific research topics. These topics were selected via dot-voting by Conference attendees.

The charge to the Breakout Groups was simple, yet unattainable: “Configure your research topic into a research project”. They were provided with general guidelines to identify research questions, specific aims or hypotheses, significance, study design possibilities, recruitment considerations, measurement variables and tools, analysis considerations, and anticipated challenges.

This article summarizes the discussions from the Seating and Positioning Breakout Groups. The four research topics selected for discussion were: Impact of a seating and mobility intervention, Defining a systematic clinical approach to cushion selection, Functional impact of wheelchair cushions, and Long term impact of sitting. One member of each Group documented the discussion and a summary presentation was made to all Conference attendees. The following synopses were compiled from the Group notes and presentation. They are presented in sequence and reflect variability in discussion, presentation and content. Some research topics were more amenable to the suggested guidelines than others.

Impact of a seating and mobility intervention

Research Questions:

What methodologies are appropriate to measure the effect of a particular seating and mobility intervention?

When is the randomized control trial (RCT) appropriate for seating and mobility research?

What approach can effectively study the return on investment of an intervention?

These research questions developed via discussion about the overall goal: linking ‘benefit’ to an intervention or to a product. The group chose to discuss different methodologies that may meet this overall goal, with a specific discussion on one methodology, the RCT. This endeavor was meant to promote clinical research using all appropriate methodologies. The aims of such discussion would be to develop a protocol to select a level of research methodology to better measure the outcomes of seating and mobility interventions and to standardize the types of data we are collecting across types of studies.

Significance

The need to study seating and mobility interventions was met by strong consensus of the group. Evidence-based practice is needed by wheelchair users, clinicians, funding agencies and industry. Practitioners and students (e.g., DPT, MSOT) were identified as key to performing this type of research since they can address one important barrier, the lack of research capacity. Their involvement requires methods that are accessible and amenable to clinical research.

Question 1: What methodologies are appropriate to measure the effect of a particular seating and mobility intervention?

As a part of the methodology discussion the group reviewed a recent article by Guyatt, et. al (2000) which presented a hierarchy of strength of evidence for treatment decisions (Table 1). The n=1 methodology fostered significant discussion. On one hand, an n=1 methodology may be accessible to practicing clinicians and can inform treatment decisions. A possibility exists to compile and aggregate n=1 data into a database of clinical evidence. On the other hand, the n=1 methods have well-documented validity risks that must be addressed via sound methodological approaches.

Table 1. Hierarchy of strength of evidence for treatment decisions

n of 1 randomized trial
Systematic review of randomized trials (meta analysis)
Single randomized trials (classic RCT)
Systematic review of observational studies addressing patient-important outcomes
Single observational study addressing patient-important outcomes
Physiologic studies
Unsystematic clinical observation

Other design possibilities were also discussed, many of which included correlational or quasi-experimental designs. For instance, a standardized seating evaluation could generate consistent clinical data across facilities. Aggregated data would increase statistical power and may permit an epidemiological-type investigation. The greatest challenge lies in establishing a standardized assessment to permit such investigation.

Question 2: When is the RCT appropriate for seating and mobility research?

The group readily acknowledged that the randomized control trial is firmly entrenched in medical research. However, investigating the effect of a seating and mobility intervention does not fit nicely into a RCT methodology. The group identified and discussed 28 challenges in using a traditional RCT within seating and mobility research, including the following:

- Subject pool is small and non-homogeneous

- Interventions cannot be withheld on ethical and legal grounds

- RCT's work best with a single outcome, yet seating and mobility interventions are multivariate.

- What is the standard of comparison? There is no "gold standard" to compare a new product to because the outcomes vary for different people.

- Intervention outcomes have too many confounding factors: Is the product successful because of the product or because of the service delivery team or because of the client's social support or ...?

Seating and mobility products come in too many permutations, hindering the definition of the experimental variables.

Product field trials do not have a standardized testing protocol

Funding of interventions: Clinicians cannot provide multiple interventions. Seating and mobility devices are covered only once every five years.

Funding of research. Since there is no mandate to prove effectiveness of a product, manufacturers have no incentive to support an expensive methodology. In addition, the short lifespan of certain technologies lessen manufacturer interest in longer trials.

Service delivery is a complex process

Measurement variables.

Any study into the effectiveness of seating interventions will be challenged by the identification of variables. The group discussed both outcome or dependent variables (Table 2) and the descriptive variables needed to reflect client characteristics (Table 3).

Clearly, not all of these outcome or descriptive variables can be collected and tracked. Therefore, researchers must clearly define their constructs and only collect variables that validly reflect them.

Table 2. Seating intervention outcome variables	
Function; Ability to perform ADL	No skin redness
Ability to transfer	Skin temperature
Hours of sitting	Occurrence of Pressure Ulcers
Comfort	Size and Severity of Pressure Ulcer
Pain	Pressure distribution; contact area
Range of Motion for Balance	.
Posture	

Table 3. Seating intervention descriptive variables	
Co-morbid conditions	Diagnosis & function within diagnosis
Tissue type and age	Length of diagnosis
Fat percentages	Support system for the individual
Activity Level	Environments of use
Lifestyle choices	Climate of use
Medication	Sweat level
Dietary nutrition	Permutations of interventions
Body type	heat and humidity
Pre-existing conditions affecting posture	Smoking
Seating history: prior pressure ulcers or interventions	Continence & management

Anticipated Challenges

Standardization of data emerged as a challenge in measuring effectiveness of an intervention.

This conclusion resulted from the belief that multiple facilities will be needed to collect an adequate amount of data. Defining the variables collected during an evaluation and the outcome variables presents both logistical and methodological challenges. A multi-facility approach will

also complicate data analysis as potentially disparate data sets will emerge since facilities may see different types of people and prescribe different types of equipment. Finally, the group was not confident that funding could be attracted for such a study. Members from the US felt that the types of projects funded were different than those needed by the funding agencies.

Question 3: What is an effective way to study the return on investment?

To facilitate a discussion of return on investment, the group selected a specific intervention scenario, provision of a tilt-in-space wheelchair. Through discussion of the scenario, it became apparent that the barriers to using RCT methodologies would also be inherent to investigating return on investment. Outcome and descriptive variables would need to be defined, and would be applicable specifically to the technology provided and desired result. For example, the return on investment for a tilt-in-space wheelchair may be different if the desire was to reduce pressure sores than if it was to improve functional posture and balance.

Since return on investment evaluates the costs and benefits of an assistive technology intervention, comparison of the cost for provision of health care prior to and following the intervention is a possible methodology for study. The group recognized that a limitation to this approach is that some of the benefits are not easily expressed in monetary terms. Provision of a lightweight, more maneuverable wheelchair may cause reduced need for attendant care, but may also allow for more participation in the community, thereby improving quality of life.

Systematic Clinical Approach to Cushion Selection

Research Question: Can a systematic clinical approach be defined to answer the question: “Is this cushion adequate for my client”?

Specific Aims:

To define a standardized seating assessment

To identify which standard cushion tests reflect clinically relevant product characteristics

To determine if the results of a clinical evaluation and standardized cushion tests drive cushion selection

To determine whether clinical measures confirm a safe seating environment?

As evidenced by the research questions, this Breakout group had many topics to address. The group defined a four-step clinical approach to acquire and evaluate cushions (Figure 1). From a research perspective, each step must be studied as one optimizes the approach. This Breakout group presented three of the four steps for discussion.

Client *assessment* begins the process and provides a baseline for the provision of services, including cushion provision. Different clinicians and clinician groups have advocated for a thorough seating evaluation but have never been explicit about what measures must be made. So, a standardized seating assessment represents one challenge of this project. Because specific types of information are needed to drive cushion selection, a common evaluation approach is needed to

insure the accuracy and validity of this information. Four areas were defined by the Breakout group: history, diagnosis, functionality, and special needs.

Cushion *selection* uses the results of the assessment to define client needs and these needs are matched to cushion performance. Standardized test methods are needed to provide qualitative and quantitative measurements of relevant cushion performance. Therein lies the second research challenge. Members of this Breakout group have been involved with the development of wheelchair cushion test methods by the International Standards Organization (ISO). The clinical relevance of such standards is a common topic for discussion by this ISO Working Group.

The *validation* aspect of the process is used to answer the defining question: “Is this cushion adequate for my client”? Seven variables were defined, 5 of which were quantitative assessments at the human-cushion interface and the remaining two variables include some qualitative inputs (Table 4). The third research challenge lies in development of ways to measure these variables in clinically-viable manners. Since determining the adequacy of a cushion must be done *in situ*, measures must be compatible with a clinical environment and its time constraints. Some of the measurement options and issues are listed in the 2nd column of Table 2. Certainly, the development of clinically-friendly point-of-care devices represents a high research need.

Information obtained from the client and clinician poses a different set of challenges. Group consensus confirmed the importance of this information, but questions remain about how to input this information into the cushion selection process. The final variable concerns the physical properties of a used cushion. Clinicians and users are often faced with the question of whether a cushion has ceased being an effective supporting surface. Currently, the most typical approach is to visually inspect the cushion. A need exists to develop more reliable tools to identify when a cushion needs to be replaced.

A 2nd line of research involves the identification of the important variables to include in any validation. Of these seven listed here, perhaps only a subset is needed to determine cushion adequacy.

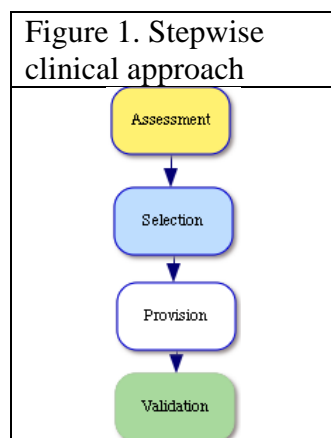


Table 4. Variables used to validate cushion performance

Validation variable	Comments and issues
Microclimate	Temperature Measurements FSA temperature mat Hand held thermocouple meters Humidity Measurements with Handheld RH sensor Hand check
Tissue Deformation	Visual examination Palpation Bend sensors Open MRI
Shear measurement	Pressure Gradients at interface Molten Handheld sensor VERG shear sensor Goossens sensor
Pressure mapping	Well received & intuitive Inherent limitations Unverified reliability of parameters & clinical significance
Direct Measurement of Tissue Status	TCPO ₂ , TCPCO ₂ Laser Doppler Flowmetry Near Infrared, Tissue Reflectance and Raman Spectrophotometer Micro Dialysis Sweat Analysis
Clinician and Patient experience/input	Clinician Experience and reasoning Visual observation of skin condition Palpation Client Pain / Discomfort Functionality Product appeal
Cushion Physical Properties	Initial performance Aged / Used performance Leaks Hardening Degradation Microbial UV Laundering

Functional Impact of wheelchair cushions.

Research Questions

- What are the best methods to objectively measure performance of functional activities across different wheelchair cushions in situ?
- What is a clinically valid approach to study the postural and functional impacts of cushions and postural supports

To answer these research questions, three specific aims were proposed:

- Define quantifiable functional activities of a seated posture
- Identify cushion parameters which reflect performance
- Correlate cushion performance and functional activity to define relationships

Two of these aims focus on the identification of reliable and valid measurements that can then be used to define relationships between cushion performance and function.

Significance

Function is probably the most important goal of a seating evaluation, yet linking function to seating and positioning products can be a challenge. Clinicians are trained to evaluate clients and determine the most appropriate equipment options. Certainly efficiency and performance vary across clinicians but even the most experienced are not equipped or informed about the relationships between function and wheelchair cushions and postural supports. Therefore, from clinician and wheelchair user perspectives, these research questions have relevance. Currently, no clinical tools are available to measure the “positioning” ability of a cushion, and measuring the impact on client function is also elusive at this time. Clinicians would benefit from simple, clinically-friendly and sensitive measures of function as a means to judge their seating interventions.

From a public policy perspective, this research question is important. A ‘positioning cushion’ category exists in the US, yet no cushion performance metrics have been defined. At this time, only linear cushion dimensions and features are used to classify cushions as positioning.

Measurement Variables

Paramount to study of positioning, function and cushions is the definition of valid and sensitive variables. The group frequently expressed concern over the challenge to develop measures sensitive enough to detect postural or functional changes.

Potential functional activities were discussed at length. Specific variables of function will vary across wheelchair user groups, further complicating the ability to create a uniform methodology. For example, functional activities defined for wheelchair users with paraplegia may include: pressure relief, posture, balance, reach, transfers, propulsion, and wheelchair skills.

Many challenges must be addressed to validly measure function. Clinical tests must be sensitive enough to predict function within everyday life. Moreover, measuring function in a clinic

represents a single point in time, yet functional tasks occur throughout the day and in many environments. In other words, the generalizability of clinical measurements is in question. Measuring these functional constructs presents further challenges. Balance and reach have been quantified using Center of Pressure (COP) with velocity, acceleration and displacement being used as indicators of stability. Effort and efficiency of actions can be measured using metabolic costs (respiratory gasses) and muscle activity (e.g., EMG). Continuous measurement of posture and pelvic positioning is a challenge within a seated environment. Therefore, formative research is needed to develop predictive measurements that can be performed within clinical research environments

The measurement of wheelchair cushions and cover performance relevant to seating presents a similar challenge. Any bench test of performance must be a valid measure of performance in real world usage. Several properties of a cushion and cover were discussed, including conformability (deformation of material under specified loading conditions), thermal properties, moisture dissipation/retention, dynamic and static stability, fatigue, coefficient of friction and/or shear properties of the cover and cushion, viscoelasticity (time dependent properties, resilience and immersion). Several of these tests have been proposed under the ISO standard for wheelchair cushions, but the clinical relevance of these proposed tests have yet to be determined.

Study design possibilities

Based upon the variables discussion, the group suggested a correlational study relating cushion parameters to function. To meet study objectives, the following sequence was suggested:

- Determine variables that can measure function at a wheelchair level and validate them
- Determine clinical tests that predict function and are sensitive enough to distinguish cushions
- Determine the cushion properties that impact function
- Correlate outcomes of functional /clinical tests and cushion properties
- Determine cushion properties that are desirable for function

Different modeling approaches were discussed including structural equation model or Taguchi methods. Structural equation modeling (SEM) is a statistical modeling technique used to confirm the validity of a certain model. With respect to this study, SEM offers potential as a means to test the validity of developed relationships between cushion parameters and function. Taguchi was a Japanese engineer who developed a methodology to improve product design. He suggested that product performance or quality could be described in terms of its variance from the intended performance. Three sources of variance were described, environmental variables, product deterioration and manufacturing variation. With respect to the problem of cushions and function, environmental variation becomes paramount from the clinician and user perspective. The Taguchi Method devises an equation for the target performance and the measured performance. This approach can be used to develop a performance model for cushions.

One significant challenge was discussed: the fact that contamination of variables can result from the interaction between cushion, postural support and wheelchair configuration with respect to function. In other words, studying the impact of a cushion is hard to do independently since outcome variables will also be impacted by other postural supports (i.e., backrest height) and wheelchair configuration (i.e., seat depth, seat-to-back angle). The means by which certain

variables are fixed while others are varied is key to the design of this study and will impact findings and the answer to the defined research questions.

Long term impact of sitting

Research questions:

- What are the risk factors for development of postural deformities in non-neurologically impaired elder individuals?
- What are the effects of back height on development of kyphosis in spinal cord injuries?

These specific research questions help define the subject cohort, treatment intervention, and dependent variables of interest. In order to further focus group discussion, two hypotheses were defined:

1. Elderly individuals with non-neurological conditions will develop significant health complications if seated on a non-positioning seat cushion and a sling backrest.
2. Individuals with ASIA A or B spinal cord level above T10 and below C6 who use a low back support will more frequently develop evidence of postural deformities of the pelvis and spine.

Significance.

The significance of these hypotheses is evident within clinical decision making and public policy. Clinicians are faced with the challenge of providing seating equipment that meets the functional and medical needs of the client. Most often, the immediate and short term needs are addressed. An ability to make informed decisions regarding long term effects would improve current clinical practice. Since long term consequences of sitting and poor postural support have medical cost implications, funding agencies also have an interest in better understanding long term consequences. For instance, product coding and reimbursement may reflect the prophylactic nature of an intervention or agencies may require the evaluation of long term impact of the prescription.

Study Design Possibilities

Both retrospective and prospective research designs were discussed. Studies of long term consequences are very difficult, especially within a cohort of people who may develop postural deformities and asymmetries as natural sequelae to the disability rather than from any intervention.

In contrast to longitudinal studies, cross-sectional designs can be used to capture a potentially large data set at a single point in time. In this case, the prevalence of deformity would be determined across a certain population of wheelchair users. This methodology is often used to explore etiology of a condition but is not a strong approach for determining cause and effect.

A cross-sectional methodology was selected to address the hypothesis concerning backrest height and spinal deformities in people with SCI. The suggested methodology used the Spinal Cord Injury Model Systems program in the US. This program is comprised of hospitals that specialize in SCI treatment and rehabilitation. Tracking persons with SCI and collecting data over time are features of this program. The group felt that the SCI Model Systems had the

population and the capacity to organize and administer a multi-site cross sectional study on the long term effects of sitting.

The group also discussed and defined a prospective study focusing on skeletal deformities of elders. Elders are the largest cohort of wheelchair users in the United States. The hypothesis states that elders who are prescribed non-positioning seats will develop health complications. The target subject group is elders who are prescribed their first manual wheelchair due to a non-neurological impairment. The control group consists of persons prescribed a manual wheelchair with a sling seat and backrests and who are seated on a non-positioning wheelchair cushion. Sling seats and backrests are standard on many wheelchairs but do not offer adequate postural support required to maintain good posture. The treatment or intervention group would consist of elders prescribed a “positioning seat and back” as classified by the Centers for Medicare and Medicaid Services in the US.

Measurement variables.

Based upon the hypotheses, researchers will have to carefully consider both independent and dependent variables. The SCI project has limited inclusion criteria to narrow the level of injury, whereas the elder study hypothesis is not as limiting. Clear definitions of the equipment, such as low back height and positioning back support, will be needed to categorize subjects. Both projects will be challenged by the need to measure posture and postural deformities. Dependent variables in both studies include measurement of seated posture, determination of whether deformities or asymmetries are fixed or flexible in nature, and ranges of motion of the lower extremities.

Few reliable tools to measure seated posture have been developed. Some possibilities include camera-based systems, digitizing arms, and electromagnetic tracking devices. Use of goniometry to measure posture and ranges of motion would have to undergo accuracy and reliability assessments. The lack of a proven method to measure posture is the most significant anticipated challenge of these studies.

Finally, health measures associated with a ‘non-positioning’ seat cushion will have to be defined. Since, relationships between health measures and mobility equipment have not been defined, careful consideration of these dependent variables is needed.

Guyatt GH; Haynes RB; Jaeschke RZ; Cook DJ; Green L; Naylor CD; Wilson MC; Richardson WS. (2000) Users' Guides to the Medical Literature: XXV. Evidence-based medicine: principles for applying the Users' Guides to patient care. Evidence-Based Medicine Working Group. JAMA, 284(10):1290-6.