

# Research and Development Considerations and Engineering Perspective

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## BACKGROUND AND INTRODUCTION

Contrary to the impression given by a segment of current literature, the rapidly emerging field of specialized seating remains largely an art rather than a science. Established clinical principles, supported by a documented knowledge base are sparse, and clinical decision making remains largely subjective. That is, seating practice is not promulgated by an organized educational process.

Specialized seating is still in the 1950's era. At that time, significant advances in prosthetics and orthotics were being made. Prosthetics advancements included below knee and above knee socket fitting, fabrication, and alignment principles. In the 1970's, orthotics introduced vacuum formable plastics to the field. Only in the last five years has specialized seating offered more than one or two commercial options for individuals requiring custom contoured body support.

Specialized seating is still a comparatively young, but now a rapidly developing sub-specialty of rehabilitation technology.

It is probably of value to attempt to define what is meant by the field of specialized seating. First, it is a clinical process which attempts to maximize function through the provision of appropriate "body support" for a non-ambulatory person, usually in the seated posture, and usually in combination with a wheeled device, such as a wheelchair. The nature of the body support is dependent largely on the needs arising from the individual's disability. It can be thought of as providing seated

body support in a manner that is usually less intimate and technically demanding than is required by conventional spinal orthotics (i.e., a body jacket).

Specialized seating has been an exciting area for involvement and research and development, especially during the last ten years or so. Engineers first became clinically involved in specialized seating in the late 1960's in Canada. During the intervening years, other professionals such as prosthetists, orthotists, therapists, and technicians throughout North America and Europe have been actively involved in specialized seating developments. This article attempts to focus on the research and development process that has led to the emerging principles and products that are now becoming common place throughout the delivery system, especially for individuals with cerebral palsy.

Perhaps of importance are the experiences that have shaped the views (and biases) of the author regarding the research and development process in the rehabilitation field. Firstly, early design experience in lower extremity modular prosthetics (Winnipeg, 1963-69), strongly reinforced the opinion that research and development should ideally take place in close proximity to an ongoing clinical commitment. Secondly, design and development must take place with a sense of reality towards the strengths and limitations of the manufacturing, marketing, and delivery system associated with the particular technology. This later view is the result of many frustrations, failures, and sometimes successes, in attempting to guide approximately a dozen "ideas" from conceptualization through clinical application over the past 15 years.

The R&D process for the field of rehabilitation engineering technology may be viewed as consisting of three interrelated phases of activity, a) research, b) design and development, and c) clinical utilization. The approach taken in this article will be to examine each of these activities as they relate to the development of principles and devices currently employed in the field of specialized seating. Emphasis will be given to applied clinical research versus basic research. The final section will address the current status of the field and suggest future needs for its continued growth. Along the way, developments familiar to the author will be used to illustrate key points. The flowchart (Figure 1) illustrates the process and suggests the primary outcomes from each step of the process.

## RESEARCH CONTRIBUTIONS

The engineer, especially when entering new clinical areas, can be overwhelmed by the apparent opportunities to employ engineering principles towards what appear to be readily resolvable problems. With the passing of time, the realization emerges that most problems are much more complex than they first appeared and the best solutions involve creativity, simplicity of design, patience and a good deal of perseverance. Applied research, as it applies to technology and rehabilitation, could be defined as "a logical process which attempts to reduce chaos in favor of logical problems solving, during which time a few significant principles and related devices can be devel-

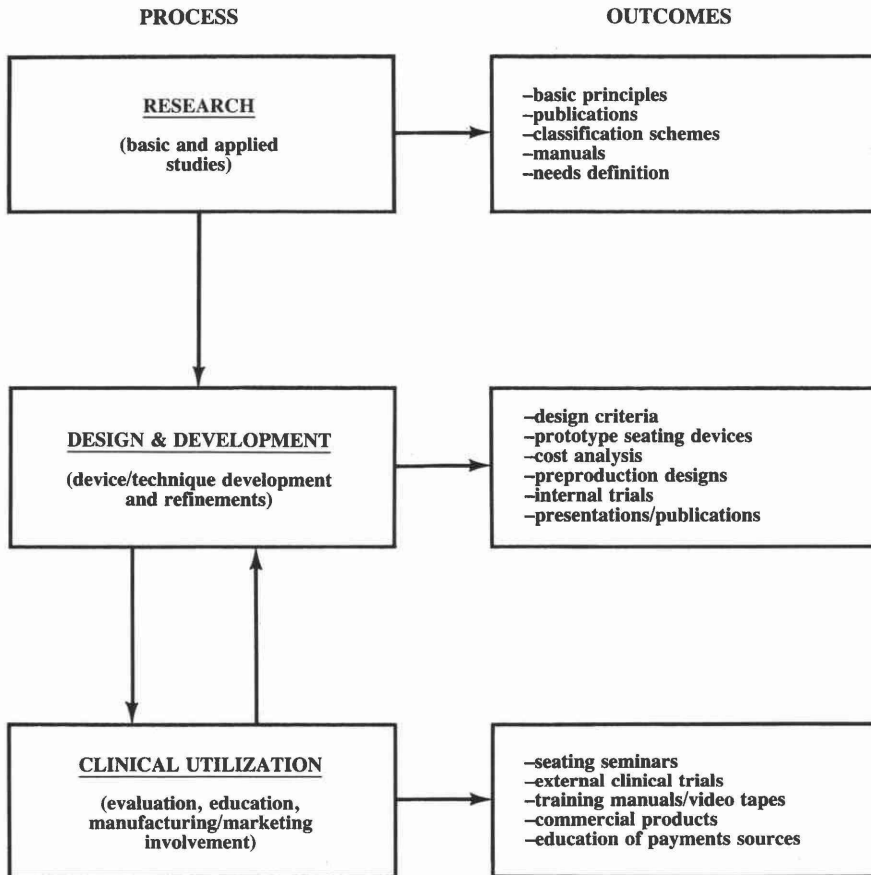


Figure 1. The three steps in the seating product development process, suggesting the major outcome for each step.

oped.” This definition may appear rather non-scientific; however, most developments of significance to date have resulted from attempts to solve a morass of seating problems. From these attempts we see repeated positive results become positioning principles and related successful devices become commercial products.

At this point the question could be asked, What, of significance, has been learned about meeting the needs of individuals requiring specialized seating over the past 15 years? First, every person has a unique set of needs, therefore one generalized solution does not work for all. Second, it has been possible to group needs, or residual abilities, which can greatly assist in clinical decision making regarding the choice and provision of technical options. Third, there are three disability related (intrinsic) factors that dictate both research and clinical activities in specialized seating. These are a) lack of postural control (i.e., resulting from spasticity); b) existing or potential deformity; and c) the degree of loss of tissue sen-

sation. The schematic diagram (Figure 2) combines these intrinsic factors in a three dimensional array. As can be seen, postural control can be graded as good, fair, or poor; deformity as mild, moderate, and severe; and sensation as normal, impaired, or asensitive. The groupings that result (Groups 1, 2, 3) give an indication of the degree of body support that the seating system must provide to compensate for the patient’s intrinsic deficiencies. For example, a child with cerebral palsy, with a mild deformity, good postural control, and essentially normal sensation falls into Group 1. Individuals with Group 1 needs usually do not require custom contoured body support and often only need a simple seat insert (standardized modular insert) that can provide midline orientation and improve the fit of the wheelchair. Whereas a teenager with Duchenne Muscular Dystrophy, who has poor postural control, severe deformity, but normal sensation, would be in Group 3. This individual would require extensive custom contoured support, including pres-

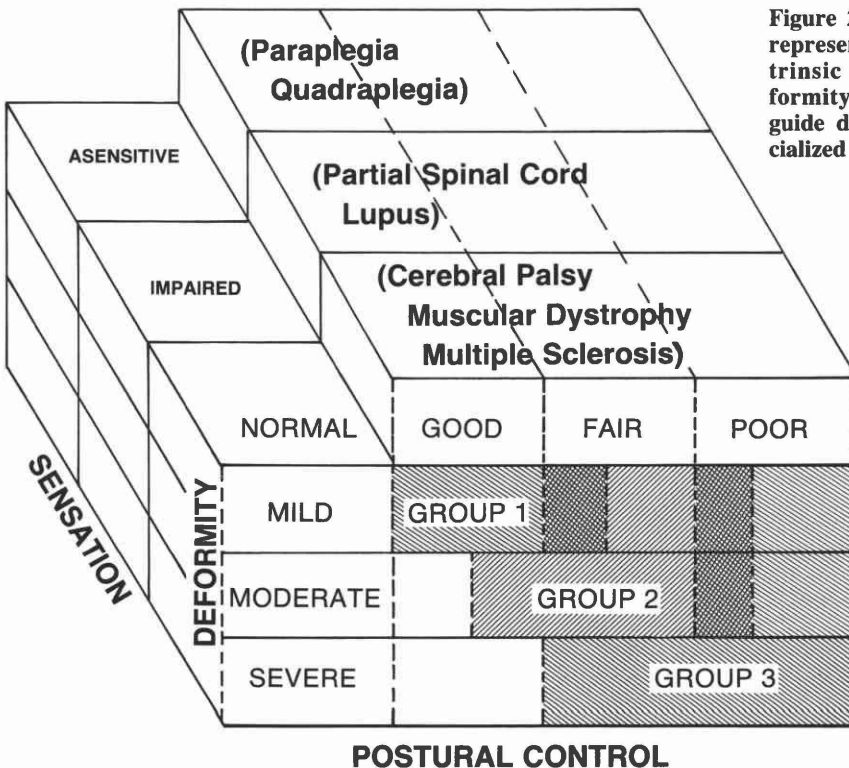


Figure 2. A three-dimensional representation of the key intrinsic factors (control, deformity, and sensation) that guide decision-making in specialized seating.

sure relief throughout the seating surface to accommodate for the discomfort associated with prolonged stationary sitting. A person with a low level spinal cord lesion (paraplegic) with only moderate deformity and fair postural control would fall into Group 2. In this case, some contoured support may be necessary to compensate for deformity and loss of postural control. Also, a primary concern may be the loss of tissue sensation, so pressure redistribution over the seat surface would be necessary.

Let us now go a step further and briefly look at a few disabilities in more depth. For example, individuals with cerebral palsy typically demonstrate a wide range of symptomatic intrinsic factors. It's usually obvious what group (i.e., Group 1, 2, or 3) they fall into for their general seating needs. However, what will be the short and long term postural needs for the child, how these needs can best be met through the seating system, and how the whole seating system must relate to the child's primary environments are all extrinsic factors that are best addressed by our therapy colleagues. That is, not only does one type of seating device not work for all, the manner in which it is configured for an individual, as well as how well it compliments the broader needs of the individual and the families are equally important. Experience has shown that specialized seating is best accomplished through a multidisciplinary approach in which the technical and therapy contributions are orchestrated within a medical environment, with a physician assuming primary medical responsibility.

In recent years, clinical research has begun to scientifically investigate the therapeutic principles related to positioning children with cerebral palsy. For example, Nwaobi<sup>1</sup> has shown that under certain conditions approximately 90° of hip flexion tends to minimize spasticity and optimize upper extremity function. More recent work by the same group<sup>2</sup> has also shown the importance of posturing in order to improve respiratory function in children with cerebral palsy. Present studies are looking at the potential contributions of posturing and seating support to reduce asymmetrical spinal muscle activity, which is thought to be a causative factor in spinal deformity in the child with cerebral palsy.

Earlier work in Rehabilitation Engineering at Rancho Los Amigos Hospital with the spinal

cord injured<sup>3</sup> established safe pressure level thresholds for the tissue over the bony prominences, such as the ischial, coccyx, and the greater trochanters. These thresholds provide guidelines for clinicians when fitting cushions for individuals who require pressure relief in order to prevent development of pressure sores. This early work has paved the way to more recent work that is now modifying and refining these principles.<sup>4</sup> Clinical programs employing these techniques have significantly reduced the onset and development of pressure sores. For example, Ferguson-Pell<sup>5</sup> has developed a computer program which assists therapists and others in decision-making regarding the selection and fitting of wheelchair cushions. This system combines and integrates much of the existing knowledge in terms of pressure sore prevention and guides the clinician towards a logical solution in which the chances for error are minimized.

Research in recent years has also developed other useful clinical tools. Again, for the spinal cord injured, there are now at least three commercially available devices (Scimedics TIPE, Oxford Pressure Monitor) that will measure and record the pressure that exists between the seated person and his support surface.<sup>6</sup> Other seating approaches use what is termed a "simulator approach" to assist in evaluation and fabrication of seating devices. For example, the MPI system<sup>7</sup> for cerebral palsy in children uses a multiadjustable frame and quickly detachable seat and back modules to allow the therapist to rapidly simulate the definitive seating arrangement. Tools of this type help in terms of therapy decision making and the subsequent communication with the technical staff responsible for the fabrication and fit of the device. Another research effort<sup>8</sup> is concerned with the collection of anthropometric data derived from taking measurements of a patient positioned in a subjectively good posture. This information will eventually be useful in the design of standardized componentry that will better match the dimensions and shapes of the individual.

Another outcome of research activities has been the classification of seating devices into five generic groups based on their methods of fabrication. Space does not permit detailed discussion of this classification scheme, especially since it has been published elsewhere.<sup>9</sup> The following table is a synopsis of the classification

scheme as it applies primarily to individuals with cerebral palsy. The table also incorporates the needs groupings discussed previously. This overall scheme has proven useful in helping inexperienced clinicians to better understand the key issues involved to match a client's needs with available commercial options.

In addition, the above classification scheme provides a framework through which a student in the field of specialized seating can begin to appreciate the differences that exist between the various technical options; and more importantly, what general needs each system is designed to meet. Further study involves learning the fabrication steps involved in the various systems, the positive and negative features associated each approach, and how features from various types can be combined to produce hybrid devices for meeting very specialized user needs.

Probably the most significant advancement is that both research and clinical experiences are now being brought together in the form of educational manuals<sup>10,11,12</sup> and instructional courses. This development is a major step towards establishing the body of knowledge that is so crucial if specialized seating is to progress from an "art" to a recognized field of professional endeavor.

## DESIGN AND DEVELOPMENT

One of the obvious benefits of a research team working in close proximity to clinical activities is the potential for identification of "real" needs requiring technological intervention. Once these needs are identified, they then form the basis of design specifications which become the goals for the initial phase of the design and development process. Of all the endeavors involving rehabilitation engineering technology over the past twenty years, this step of defining what needs to be done has probably been the most poorly managed. There is probably no greater waste of technological resources than to solve problems for which there is either already an existing solution, or for which a solution cannot be sufficiently generalized to meet the needs of a commercially viable segment of the population.

Assuming a "green light" is still on after the "real" needs are identified, the next step is to develop a prototype solution, which in this context could be a technique, a clinical tool, or a seating device. The development is usually very "fragile" at this time, and the sooner it can be subjected to clinical trials and critique in a positive environment the better. Invariably, modifications and design refinements are required until a solution is developed that is acceptable to both the clinicians and their test subjects. Ideally, the development should then be exposed to wider critique within environments different from those in which the development took place. Also, manufacturing, marketing, and costing analysis should take place in preparation for the preproduction phase. Assuming all these steps yield positive outcomes, an initial preproduction run is made so controlled evaluations can be done in selected external environments. The results of the external evaluations should be carefully monitored, documented and made available to the production design team. Over the past six years, four such developments from the University of Tennessee Rehabilitation Engineering Program have gone through this process, some more rigorously than others. These developments, the Modular Plastic Insert, the Spherical Thoracic Support, the Foam-In-Place, and the Bead Seat System, are now all commercial products being marketed by three different commercial firms.

The final stages of the design and development process can vary depending on development and the resources of the commercial firm involved. In general, the market volume for seating devices is still relatively low. Therefore, it is important that the "front end" cost to the commercial firm be minimized. This can be accomplished in several ways by the development team. First, it is crucial that the design be "elegantly simple" so that it can be reproduced in relatively low volumes inexpensively. Secondly, design refinements and problems solving support should be provided well into the commercialization phase. Royalty arrangements and other "front end" type payments to the developer should be minimized and based on product sales. And finally, support in terms of providing educational materials, publications, and instructional seminars all assist in creating a receptive market place.

<i>GENERIC SEATING DEVICES</i>	<i>NEEDS GROUP</i>
Type I Noncontoured (ex. simple foam and plywood)	Group I
Type II Precontoured modules (ex. MPI, Pin Dot Modular System, Otto Bock MOSS)	Group II
Type III Multiadjustable (ex. Mullholland, E & J Postural)	Groups I & II
<p>Type IV Custom Contoured</p> <ul style="list-style-type: none"> <li>a. Complex Foam &amp; Plywood (ex. custom contoured foam cutouts)</li> <li>b. Traditional Orthotic approach (ex. plaster positive complete with plastic body jacket)</li> <li>c. Vacuum Consolidation (1 &amp; 2 step) (ex. Bead Seat, Gillette Spinal Support, and DESMO)</li> <li>d. Foaming (1 &amp; 2 step) (ex. Foam-In-Place, Contour-U, Canadian Posture)</li> <li>e. Shapable Matrices (ex. Clinical Engineering Design, London, England MERU-UBC)</li> </ul>	Groups II & III

## CLINICAL UTILIZATION

This final phase of the R&D process is most often neglected, since it is usually not very exciting to the development team. From the R&D perspective, this design activity addresses those features of the development that will make it an attractive alternative to existing methods or devices being used. Again, development of instructional materials, provision of evaluation prototypes to "trend setters" and conducting instructional courses have already been mentioned. However, these supporting activities in themselves are usually not the key influencing factor. The development team must address the question, Why would a service provider working within a particular service delivery system choose the new development over another technical option? The answer usually is that the service provider can provide a higher quality service at equal or lower cost. Therefore, the new development must provide improved function to the user, and possibly increased status for the clinic/provider, at costs that can be paid for by the payment structure in which the service is provided. Failure by the design and development team to recognize the realities of the delivery system in which the development must be marketed is probably a primary reason why so many developments fail to make the transition from laboratory to widespread clinical application.

## CURRENT TRENDS IN SPECIALIZED SEATING

A 1985 survey of 26 facilities in 17 states<sup>13</sup> provides considerable insight into the state of maturity of the field of specialized seating. Of the 26 respondents, 12 were hospital based, six were state funded programs or institutions, and 8 were from private industry. The majority reported the use of plywood and foam technology (61 percent) or custom produced molded plastic parts (17 percent). The payment was received primarily from Medicaid, State Crippled Childrens Services, or private insurance carriers. The average number of clients fitted with new devices per year/facility was 185, with a total number fitted of 3,293.

The importance of this survey, in the context of design and development, is that the majority

of the facilities reported the use of basic "bench" fabricated technology (78 percent). This is not surprising since the majority of the new developments have only been available commercially for less than three years, and related educational programs are just beginning to have a significant clinical impact. Continuing education programs supported by the American Academy of Orthotists and Prosthetists, the Rehabilitation Engineering Society of North America, and institutions like the University of Tennessee Rehabilitation Engineering Program, Newington Children's Hospital, and Elizabethtown Children's Hospital, and private firms, such as Pin Dot Products, and Mobility Plus have been the primary sources for training in the new concepts and seating systems. As these efforts are expanded to involve larger numbers of clinicians, the newer technology in seating will permeate into the service delivery system.

Of importance to the prosthetic and orthotic professions is that many of the professional skills and shop resources required to deliver improved specialized seating services are already in place. Also, specialized seating is now becoming recognized by many of the major third party payment sources as a recognized clinical service. The new commercial systems have been designed to be less labor intensive and to permit the provision of a quality product at a reduced cost. The overall result is that it is now feasible to invest in the education and inventory required to enter the field and expect to realize a return on that investment over a 2 to 3 year period. That is, specialized seating now presents a viable growth area for the prosthetic and orthotic field.

Projecting into the future, one may speculate as to what developments are likely to take place in the field. As far as design and development, it is likely that refinements to the newer commercial products will preoccupy the efforts and available development resources over the next two to three years. New and ongoing basic research will continue to develop or validate positioning principles for the cerebral palsy population. We should see refinement and expansion in the use of computerized expert systems, primarily by institutional settings that are doing larger volumes of evaluation and prescription of seating devices. Educational courses should become more available on a regional basis



through several of the participating professional associations. Hopefully, the American Academy of Orthotists and Prosthetists will continue its continuing education efforts in this area.

Probably the most urgent and difficult issue to be resolved is the further education of third party payment sources, so that seating services can be provided and reimbursed throughout the country. In this regard, initial efforts by the Rehabilitation Engineering Society of North America appear promising. Similar, and probably coordinated, efforts by other organizations such as the American Occupational Therapy Association, the American Orthotic and Prosthetic Association, and the American Academy of Orthotists and Prosthetists would be most timely.

In summary, research and development has made significant contributions to the field of specialized seating. This statement is based in the fact that there are not less than six new seating developments that have become available to the practitioner over the past five years. Basic studies, published articles, and manuals are establishing the foundation for educational activities that are becoming more widely disseminated. Third party payment sources have been slow to respond, but diverse efforts throughout the country have been successful at receiving reimbursement for seating services. In conclusion, more remains to be accomplished, and research and development can be expected to continue its contribution. Specialized seating is being transformed from an "art" to a recognized field of professional endeavor.

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<sup>2</sup> Nwaobi, O.M., Smith, P.D., "Effect of Adaptive Seating on Pulmonary Function of Children with Cerebral Palsy," *Develop. Med. Child Neurol.*, 28, 1986, pp. 351-354.

<sup>3</sup> Rodgers, J.E., Rewsick, J., "Program for Prevention of Tissue Breakdown," *Annual Report*, Rancho Los Amigos Hospital—REC, 1974/75, pp. 24-31.

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<sup>6</sup> Scimedics, 170 Vander St., Units A & B, Corona, California 91720.

TIPE—Tee Kay Applied Technology, 11915 Meadow Trail Lane, Stafford, Texas 77477.

Oxford Pressure Monitor—International Medical Equipment Corporation, 11000 E. Rush Street, Suite 4, South El Monte, California 91733; (213) 350-1410.

<sup>7</sup> Modular Plastic Insert System marketed by Pin Dot Products, Inc., 2215 Belmont Street, Chicago, Illinois 60618.

<sup>8</sup> Reger, S., Hobson, D.A., "Seat Design Factors for Wheelchairs," *Annual Report*, University of Virginia—REC, 1985, pp. 25028. Charlottesville, Virginia.

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