WHEELCHAIR CUSHION MODIFICATION AND ITS EFFECT ON PRESSURE

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We hereby recommend that the thesis prepared under our supervision by Susan Lipton Garber entitled Wheelchair Cushion Modification and its Effect on Pressure

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CHAPTER I

THE PROBLEM

Introduction

The prevention of pressure sores has become a major objective in the rehabilitation of individuals with physical disabilities, especially those with the paraplegia and quadriplegia that result from a spinal cord injury. For these individuals, the loss of motor function is accompanied by absent or diminished sensation below the level of the injury. Because of this, they are not aware of the pressure overload on the tissue that overlies a bony prominence when they are sitting or lying in one position on a supporting surface.

Wheelchair cushions made of polyurethane foam are frequently prescribed to relieve pressure and prevent pressure sores in persons with spinal cord injury. It has been demonstrated (Garber, Krouskop, & Carter, 1978) that no single cushion is effective for all individuals with paraplegia and quadriplegia. Furthermore, because of the extensive qualitative variation among the types of foams manufactured, many commercially available products may be contraindicated. Therefore, modification of the foam material may be necessary to provide the individual who has sustained a spinal cord injury, and is at high risk to develop tissue breakdown, with a specially designed and fabricated wheelchair cushion.

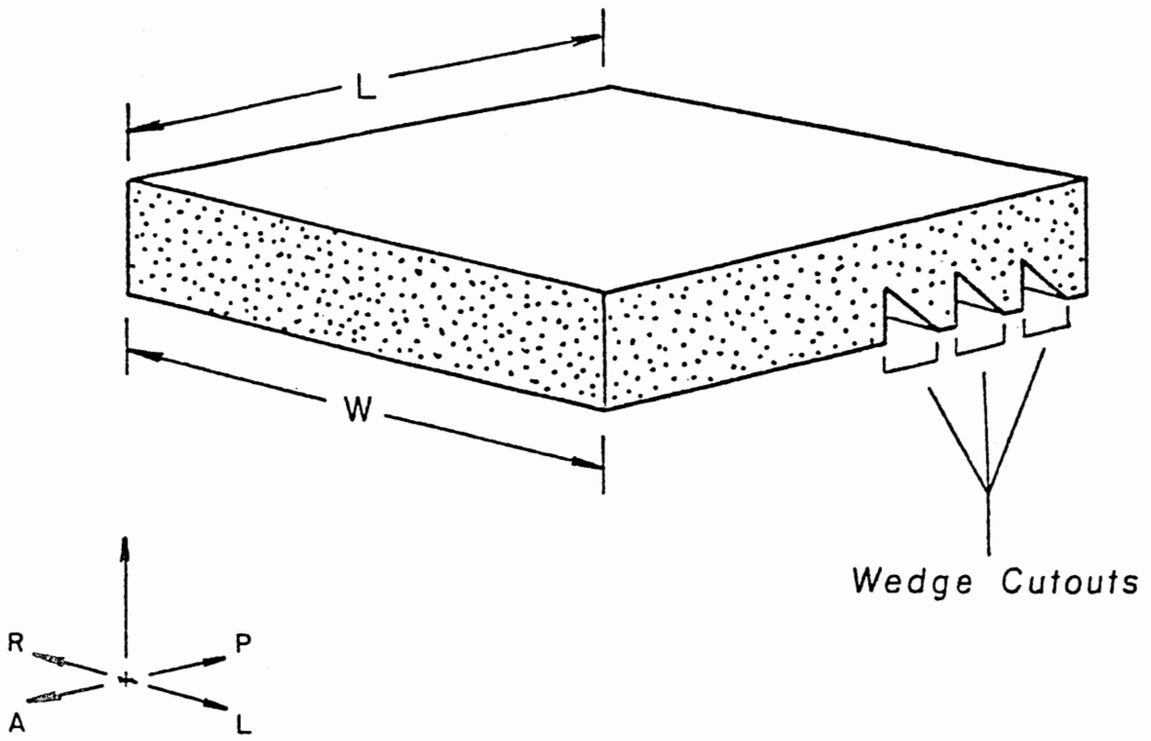
In the past, efforts to reduce ischial pressure have included cutting out an area from the top (or buttocks contacting side) of the

cushion. This type of modification often interfered with posture, positioning, and balance because its effectiveness was dependent on the patient's being placed in exactly the same position each time he sat in his wheelchair or shifted his body. In addition, although pressure was relieved in one anatomical area, namely the ischial tuberosities, it was transferred to another, such as the trochanters. Therefore, alternatives were sought that would provide pressure relief while ensuring the patient's optimum functional positioning and comfort.

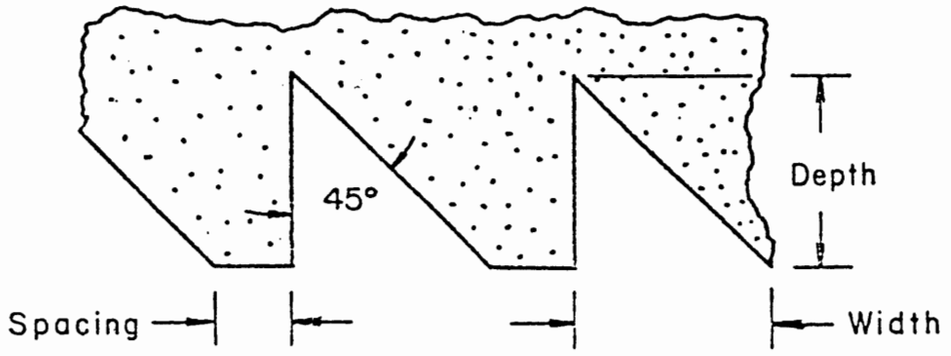
This study investigated a technique of cushion modification called "wedging" as a practical means of reducing the effects of pressure on tissue and the risk of ulceration in a population of individuals with spinal cord injury. Wedging is a technique of cushion modification that employs a standard kitchen electric knife to remove wedges of foam from the underside (wheelchair contacting side) of the cushion surface. The wedges traverse the full width of the cushion and are arranged in parallel rows (see Figure 1a). On cross-sectional examination, each wedge is a 45° right triangle (see Figure 1b). Removing or cutting out from the underside of the cushion ensures that the patient always sits on a smooth surface and allows for changes in posture and positioning.

Background Information

The use of wheelchair cushions to relieve tissue pressure under the seated individual with a spinal cord injury has a long but controversial history. Many researchers have attempted to study the



(a.) Schematic view of wedged wheelchair pressure relief cushion
(Coordinate axes are: A = anterior; P = posterior; R = right; L = left)



(b.) Cross-sectional view of cushion showing wedge dimensions

Figure 1. Wedged Wheelchair Pressure Relief Cushion

effectiveness of specific types of commercially available cushions designed to reduce the pressure that contributes to tissue erosion (Cochran, 1973; Houle, 1969: Mooney, Einbund, Rogers, & Stauffer, 1971: Souther, 1974). However, the results of these efforts have produced no conclusive evidence concerning the effectiveness or usability of these devices. No cushion was found to be significantly better than any of the others in reducing pressure. In addition, the methods used to evaluate the wheelchair cushions proved clinically inadequate or inappropriate. Garber et al. (1978) demonstrated that foam cushions were an effective and relatively inexpensive way to lower overall pressure under the person seated in a wheelchair. In 1982, Garber and Krouskop reported that body build was found to influence the magnitude and distribution of pressure. However, because no single cushion was found to affect uniformly maximum pressure and overall pressure distribution, it became necessary to modify a standard foam cushion to lower the pressure and/or redistribute it away from the bony prominences. In the past, methods of cushion modification have been based primarily on the subjective experiences and prejudices of the person responsible for prescribing the device. This study examined the usefulness of a technique of cushion modification called wedging for reducing tissue pressure under the person seated in a wheelchair. It addressed the hypothesis that pressure was not a function of the geometric shape of the cushion. In addition, this investigation examined the relationships between subject characteristics, cushion geometry, and pressure.

Purpose of the Study

The primary purpose of this investigation was to determine the efficacy of utilizing a cushion modification technique called wedging to reduce pressure and redistribute body weight under the seated person with paraplegia and quandriplegia secondary to a spinal cord injury. Secondarily, it was to provide the clinician with an economical means of individualizing the prescription of pressure relief devices for individuals with severe physical disabilities.

Objectives of the Study

In order to determine whether the described cushion modification technique was an effective method of reducing pressure and redistributing body weight, it was the objective of this study to:

1. quantitate the effects of wedging on pressure and its distribution;
2. determine the effect of wedge location (anterior or posterior) on magnitude and location of pressure;
3. determine the effect of wedge depth on magnitude and distribution of pressure;
4. correlate body build, based on height, weight, sex and age with the parameters of location and depth of wedges in overall pressure relief capabilities of the cushion.

Assumptions

The following assumptions were made regarding this investigation:

1. Pressure in tissue over a bony prominence is related to breakdown in that anatomical area.

2. Wheelchair cushions provide protection to a greater or lesser extent against tissue breakdown by reducing pressure.
3. An optimal pressure relief device for all persons with physical disabilities has not as yet been developed.

Hypothesis (Null)

1. The magnitude and distribution of pressure is not a function of the geometric shape or modification of the cushion used.
2. There is no relationship between the parameters of wedge depth or location and pressure distribution.
3. There is no relationship between the subject characteristics of height, weight, age, sex, or diagnosis and the extent of ischial pressure on cushions.

Significance of the Study

The occurrence of pressure sores is a major concern for the rehabilitation team. Foam wheelchair cushions are frequently prescribed by occupational therapists as one means of reducing the risk of this potentially life-threatening complication of spinal cord injury. Because no single cushion is effective in relieving pressure for all patients, it is often necessary to modify the existing geometry of commercially available cushions in order to meet the very specific needs of an individual. Foam cushions are relatively inexpensive and readily available and are easily modified to accomplish this objective. The technique of cushion modification called wedging is one method employed to provide pressure relief where none existed previously. This study examined the usefulness of wedging in reducing tissue

pressure under the person seated in a wheelchair. It addressed the hypothesis that pressure was not a function of the geometric shape of the cushion. In addition, this investigation examined the relationships between subject characteristics, cushion geometry, and pressure.

Definitions of Terms

Wedging-a method of modifying foam wheelchair cushions in which a piece of foam, cut at a 45° angle, or wedge, is removed from the underside (wheelchair contacting surface) of the cushion.

Pressure Sores-localized areas of necrosis usually the result of pressure on the tissue that overrides a bony prominence.

Pressure Evaluation Pad-a device designed to identify the magnitude and location of pressure on tissue at the interface of the buttocks and the wheelchair cushion.

CHAPTER II

REVIEW OF THE LITERATURE

Introduction

Pressure sores are a frequent and potentially life-threatening complication for the individual with a severe physical disability, especially the individual with a spinal cord injury. Pressure sores are a significant deterrent to that person's active participation in the activities that return him to an independent and productive life. It has been long established that pressure sore prevention begins with good nursing care during the acute phases of hospitalization. Numerous pressure relief devices for both the bed and the wheelchair have been developed and evaluated for the specific purpose of reducing or eliminating the effects of pressure on the tissue that overrides bony prominences. Our understanding of the etiology of a pressure sore is not complete and the understanding that does exist has not been widely transferred to practical solutions that accommodate daily activity patterns. Similarly, the design of technological aids that effectively reduce an individual's risk of developing a sore is not adequately disseminated and utilized. Therefore, this chapter will discuss the identification, development and historical evaluation of devices designed to relieve pressure while a person is seated in the wheelchair.

The exact causes and mechanisms of soft tissue breakdown resulting in pressure sores are not as certain as our understanding of the

normal structure of the skin and the physiological processes involved in maintaining healthy tissue. However, during the last 25 years, a number of scientific studies have advanced the knowledge of factors involved in the formation of pressure sores and have provided a basis for improving preventative techniques. Clinicians have studied the magnitude of the problem and have reported report the grim statistics on the occurrence of pressure sores. In 1978, Manley estimated that 4.5% of the general patient population in his South African hospital had pressure sores and an additional 5.2% were at high risk. Factors that appeared to correlate significantly with the occurrence of those sores were age, incontinence, lack of mobility, and level of consciousness. In a retrospective study of 54 patients at a spinal cord center, Richardson and Meyer (1981) calculated that 60% of the complete cervical cord injuries and 40% of the incomplete cervical cord injuries would develop pressure sores. In addition, they found that 50% of the paraplegic population with complete thoracic and lumbar cord injuries and less than 30% of the incomplete thoracic and lumbar injuries could expect to develop pressure sores. The work of Garber, Noble, and Krouskop (1982) substantiates these findings that indicate that at least 50% of the spinal cord injured population will develop pressure sores at some point in their life time. In addition to individuals with spinal cord injury, other populations at risk include the immobile aged, persons with muscular dystrophy, amputations, diabetes, spina bifida, and victims of head trauma and cerebral palsy.

Historical Evaluation of Pressure Relief Devices

Physiological Basis and Natural History of Pressure Sore Development

No discussion of pressure relief devices would be complete without an understanding and recognition of the historic investigations of the past. Kosiak (1961), often considered the father of modern pressure sore research, defined pressure sores as localized areas of cellular necrosis. His research included producing sores by compressing soft tissue over bone in dogs and subsequently measuring the pressure at the interface of the body and the compressing device. He concluded that ischemia, resulting from supracapillary pressures, was one of the main causes of the ulceration. In an earlier publication, Kosiak (1959) reported that pressure ulcers were the result of ischemic, neurotrophic, or metabolic factors, usually in combination. Ulcers occur almost always in the tissue that overrides a bony prominence. When pressure exceeds tissue capillary pressure over a period of time, ischemic changes result in ulceration. Neurotrophic changes such as occur in spinal cord injury result in diminished or absent sensation; hence, the patient is unaware of the pressure overload. Although these neurogenic factors may not be primary in the development of the ulcers, the patient is nonetheless prevented from the normal protective response to the resulting discomfort. Metabolic factors in ulcer formation address the issues of nutrition, edema, and anemia. Problems of infection become systemic and specific procedures for treatment become essential. Pressure sores, therefore, do not occur as the result of isolated incidences. Rather, they are

the result of several mechanisms acting systemically.

The purpose of Kosiak's work published in 1959 was to measure the time and pressure necessary to produce necrosis under controlled conditions. He found that intense pressure of short duration was as injurious to tissue as lower pressure applied for longer periods of time. The studies also showed that all of the tissue from the skin to the bone was subjected to enough pressure to result in changes. He found that degeneration at all levels occurred simultaneously. Microscopic degenerative changes occurred even from relatively low pressures. However, in these cases and in cases of excessive pressures, complete relief of pressure often restored normal cellular metabolism. The critical time period of one to two hours was that time during which pathological changes occurred in normal and denervated skeletal muscle following application of pressure.

As early as 1930, Landis determined that mean blood pressure in single capillaries of the arteriolar limb to be 32 millimeters of mercury (mm/Hg), 20 mm/Hg at the midcapillary region, and 12 mm/Hg at the venous limb. In 1958, Kosiak, Kubicek, Olson, Danz, and Kottke collaborated in research in which 11 normal subjects were evaluated on several seat surfaces. These investigators found that ischial pressures were generally more than 300 mm/Hg on a flat padded and unpadded surface as well as on an unpadded contour surface. If a 2-inch thick foam pad was added to the flat surface, the pressures dropped to 160 mm/Hg. Only the alternating pressure contour chair produced intermittent reduction of pressure to levels in the range

of the capillary blood pressure if one is to accept Landis' analysis.

Dinsdale (1974) experimented with swine because he determined that the tissue structure of swine was closer to man's than the dogs used by Kosiak. Dinsdale found that friction increased the susceptibility to skin ulceration at constant pressures of less than 500 mm/Hg but that friction and repetitive pressure of only 45 mm/Hg resulted in skin ulceration. He therefore identified the fact that decubitus ulcers were not totally the result of an ischemic mechanism but that friction was a factor in the pathogenesis of ulcerations since it applies mechanical forces in the epidermis. His other results described an inverse relationship between the magnitude of pressure and the duration of tolerable pressure in the production of decubitus ulcers.

The study of Daniel, Priest, and Wheatley (1981) contradicted Kosiak's work which showed that degeneration of tissue occurs simultaneously at all levels including the skin. These investigators found that the initial pathological changes were in muscle and then progressed toward the skin with increasing pressure and/or duration. They therefore concluded that the primary pathological problem was the inability of the tissue to respond to external pressure due to tissue wasting associated with paraplegia (atrophy of the soft tissue coverage), repeated trauma (pressure loads), and/or infection (tissue necrosis secondary to infection). The work of Keane (1978) and Groth (1942) also supported the fact that ischemic muscle necrosis due to pressure occurs before skin death. Today, many clinicians recognize

that the pressure sore that is visible on the surface of the skin is like the tip of an iceberg: tissue damage is far greater, deeper and closer to the bone.

Regardless of the philosophy concerned with the pathogenesis of tissue destruction (Dinsdale, 1974; Kean, 1978; Kosiak, 1959), it is clear from these laboratory investigations that the resulting ulcerations can have longlasting effects on the individuals at risk. Attempts to apply these scientific efforts to the clinical setting have not been consistently successful. It is important at this point, therefore, to identify the traditional, clinical interventions that are attempts at the prevention process.

Clinical Basis of Pressure Sore Prevention

Non-mechanical interventions. The principles of good nursing care, especially during the acute phase of hospitalization, have been considered the major deterrent to the formation of pressure sores (Merlino, 1969). These principles and procedures include turning patients in bed, positioning them for pressure relief in the supine, sidelying, and prone positions, skin inspection, avoiding shearing of the body (friction), maintaining cleanliness, and good nutrition. The literature describes the importance both nurses and physicians place on frequent and routine turning practices. Guthrie and Goulian (1973) considered turning of primary importance in pressure sore prevention. Dowling (1970), McElhinney (1968), and Pinel (1976) described a turning regimen of every two hours, first on one side, then on the back, and finally on the remaining side. Morley (1973)

and Rogers (1978) emphasized the dangers of shearing (friction) forces that occur when the patient is dragged instead of lifted across surfaces. Some of the recent developments in the design and manufacture of special beds may reduce the risk of shearing, but more investigations are necessary. In addition, Morley recommended that the head of the bed be raised only for meals because of gravity and the resulting shearing force or friction that occurred between the sacrum and the bed surface, causing damaging tissue erosion.

Rottkamp (1976) used behavior modification to effect change in increased frequencies of daily position changes, patient-initiated changes of position, decreased assistance needed for position change, and in decreased frequencies of intervals of prolonged skin pressure. Cress and Busza (1968) stressed the importance of adequate nutrition, including a high protein and high vitamin diet, as essential in the prevention of pressure sores. They believed that the metabolic changes that occur as the result of trauma and/or disease required maintenance of adequate caloric intake.

The importance of good hygiene and cleanliness was discussed by Schell and Wolcott in 1966 and by Gale in 1971. Clean, soft, dry, and smooth bed sheets were considered mandatory. Attention to bowel and bladder function was extremely important to prevent the patient from lying in the body's waste that could irritate or infect already stressed tissue or delicate skin.

As early as 1969, Spira, Moore, Hardy, and Gerow advocated a program of activities which, in combination and, when individualized

for each patient, would be instrumental in the prevention of pressure sores for paraplegics. As plastic surgeons, these investigators were well aware of the surgical interventions that were employed in the repair of pressure sores. However, they believed in preventative management based on the complete coordination and cooperation of efforts between the nursing personnel, the family, the physician, the social worker, and the patient.

Mechanical interventions. It was apparent that what was described as good nursing care did not go far enough. For that reason, clinicians began to look for devices that might be employed during hospitalization and later at home that might augment their rigid adherence to the principles of prevention and provide that extra assistance to the total program of pressure sore prevention. Many devices became available but their effectiveness was always challenged. The introduction of cushions as pressure relief devices for wheelchair users has a long but infrequently and inadequately quantified and documented history. Early research indicates that methods of evaluating differences in these devices were not always accurate or clinically useful. In 1965, Lindan, Greenway, and Piazza designed a spring compression device to measure contact pressures of normal subjects in the lying and sitting positions. Highest pressures were observed under the ischial tuberosities when the subjects were sitting. However, it was not practical to utilize this measuring device to monitor the physically disabled. These investigators also reported that cushion modification by way of ischial cutouts in foam cushions

only transferred the pressure to other areas.

Bush (1969) studied ischial pressures while varying the position of the subject's legs. He used a single pressure sensitive transducer connected to a readout system. Ischial pressures were significantly higher when the feet were supported. However, there was no difference in pressures when the feet were hanging free or when the legs were extended and supported at the calves. The device used to measure pressure was expected to be clinically useful. However, it was not further developed for this purpose.

Houle (1969) evaluated pressure under the buttocks of 10 normal subjects seated on seven surfaces: plywood, a wheelchair sling seat, a cut-out 3-inch plastic foam, an inflatable rubber contour pad, a synthetic viscoelastic pad on the sling seat with a board and a 1-inch foam pad, a mechanical drop seat, and an alternating air pressure pad. The pressure measuring devices used were similar to the ones used by Kosiak in his earlier studies. These consisted of pneumatic butterfly valves, miniature transducers, or pneumatic cells arranged to provide a pressure matrix of the buttocks. Houle found that the greatest pressures were under and posterior to the ischial tuberosities. The range of ischial pressures was 140 mm/Hg on the board to 80 mm/Hg on the viscoelastic gel. Therefore, Houle concluded that although the seats redistributed pressure, they did not do so sufficiently to reduce that pressure below capillary pressure. Of the pressure relief devices he tested, none was theoretically successful in preventing ischemic ulcerations.

Mooney et al. (1971) developed a pneumatic cell pressure sensor to evaluate the pressure distribution qualities of 12 commercial cushions. The conclusion of their study was that none of the cushions tested was able to reduce tissue pressure to below arterial capillary pressure. They also found no correlation between the subjects' weight and the pressure distribution recorded. They described pressure distribution as the most important characteristic of seat cushion design. Their ideal cushion was one that distributed pressure most evenly over the largest skin area, was light in weight, required little maintenance, was low in cost, and had a durable cover. No cushion met all of these criteria.

In 1973, Cochran and Slater, in conjunction with the Veterans Administration Prosthetic Center, evaluated the biomechanical characteristics of 12 cushions. Included in the tests were foams, gels, water, and viscoelastic materials. These investigators pointed out the inadequacies of the then current evaluation procedures as well as the lack of test standards by which to evaluate new materials. The purpose of their study was to develop practical cushion evaluation techniques and standards. This was the first attempt to develop comprehensive laboratory and clinical test programs applicable to all types of cushions. It emphasized conditions encountered in clinical use. In general, the foam cushions received favorable scores for pressure relief whereas gels produced unfavorable sitting scores, probably due to their stiff consistency. Water cushions produced the lowest pressures but were considered impractical for long-term

clinical use. During the clinical phases of testing, these researchers encouraged the use of six miniature pressure transducers. These investigators critically evaluated their own methodologies and found them to be insufficient in terms of limitations imposed by the available test equipment. However, they were able to obtain reproducible differences between cushions.

In another study, Souther, Carr, and Vistnes (1974) evaluated 10 normal subjects on 11 cushions and the wheelchair sling seat. The cushions were of every variety: air-filled, floatation, and foam. Ischial pressures were monitored through a surface pressure manometer. These investigators concluded that no cushion reduced mean pressures below mean capillary pressure and that this may, in fact, be unattainable. Furthermore, they upheld the philosophy that no mechanical device should be expected to replace scrupulous attention to skin care and conscientious adherence to repositioning and turning regimens.

DeLateur, Berni, Hongladarom, and Giaconi (1976) observed hyperemia as an indication of impending tissue breakdown. They found no significant differences among seven commercial cushions with respect to their ability to reduce reactive hyperemia in three paralyzed subjects. They concluded, therefore, that patients with paraplegia could not sit motionless for 30 minutes without some degree of reactive hyperemia occurring and they recommended weight shifting several times an hour.

From the above studies, it became apparent that pressure measuring devices to clinically evaluate wheelchair cushions did not give

enough objective data on the magnitude and overall distribution of pressure. In 1978, Garber et al. described a system to clinically evaluate wheelchair cushions. This system, called the Pressure Evaluation Pad (PEP), was developed at the Texas Rehabilitation Engineering Center and was designed to clinically quantify pressures under the seated or reclining subject. Results of this work indicated that no cushion of the six commercial devices tested was effective in reducing pressures for all groups of patients and that individual evaluation was essential for maximum benefit and protection against pressure sores. The survey of Nelham (1981) supported the principle of individual evaluation. Nelham reported that the primary function of the wheelchair cushion was to prevent pressure sores. He assessed the pressure relief properties and the advantages and disadvantages of seven devices. This study reconfirmed the lack of technology to adequately assess friction and pressure.

Controversies

Despite the efforts of conscientious investigators to quantitatively and objectively measure pressure and its distribution under the seated wheelchair patient, much controversy and disagreement continue to exist concerning the accuracy and clinical usefulness of such measurements. From Kosiak et al. (1958) using butterfly valves, to Lindan et al. (1965) using a bed of springs and nails, to Garber et al. (1978) using a large matrix pneumatic sensor, attempts have been made to assess pressure at the interface of the wheelchair cushion and the buttocks. Most of the pressure measuring devices

designed for specific research endeavors were not developed to withstand the stresses of routine clinical use, and therefore very few of them became available commercially for use by therapists and physicians in the clinical environment. The small pneumatic pressure evaluator of Rogers (1974) was used successfully in a tissue pressure clinic at Rancho Los Amigos Hospital but was found to be unreliable at other centers despite claims of its accuracy by its developers. The large pneumatic matrix pressure evaluator described by Garber et al. (1978) was found to have clinical validity but was not consistently reliable with daily clinical use. This system has undergone several major design and material modifications and may be ready for the commercial market in the near future.

There still exist doubts as to the accuracy of the pressure readings, usually measured in millimeters of mercury (mm/Hg), during a wheelchair cushion evaluation. Graebe (1977) rejected the validity and reliability of some of the pressure measuring devices because they failed to completely conform to the shape of the cushion. However, this "hammocking" effect was described by Denne in 1981 and found not to interfere with the effectiveness of either the cushion or the measuring device. These differences of opinion and methods will be the basis of continued research efforts directed at identifying the etiology, treatment, and ultimately the prevention of pressure induced tissue trauma. These studies serve to magnify the need to identify and categorize the many different pressure relief devices on the market today.

Classification of Wheelchair Seating

General Classification

Wheelchair cushions, or pressure relief devices, are equipment designed to distribute the body's weight away from the areas vulnerable to tissue erosion secondary to pressure. In the sitting position, the anatomical parts at risk include the ischial tuberosities, coccyx, sacrum, and the trochanters. Wheelchair cushions are also used to stabilize the body for balance and provide comfort while the individual is seated in his wheelchair. In recent years, hundreds of commercially available wheelchair seating devices have been developed. This has created confusion among therapists who require a better understanding of the devices they prescribe. In general, wheelchair seating can be categorized into two major areas of function: those seats designed for postural control and those designed for pressure relief. It is the latter that will be discussed in this chapter. Pressure relief devices for the wheelchair were classified by Garber in 1979 and can be further subcatagorized into dynamic and static devices (see Figure 2).

Dynamic Systems

Dynamic systems are those seats that are dependent on an external power source that activates the seat, ostensibly to relieve pressure areas cyclically. They are not used extensively by individuals with spinal cord injury primarily because they are cumbersome and rely on compressors or another power supply. These factors may contribute to limited mobility for the user as discussed by Key, Manley, and

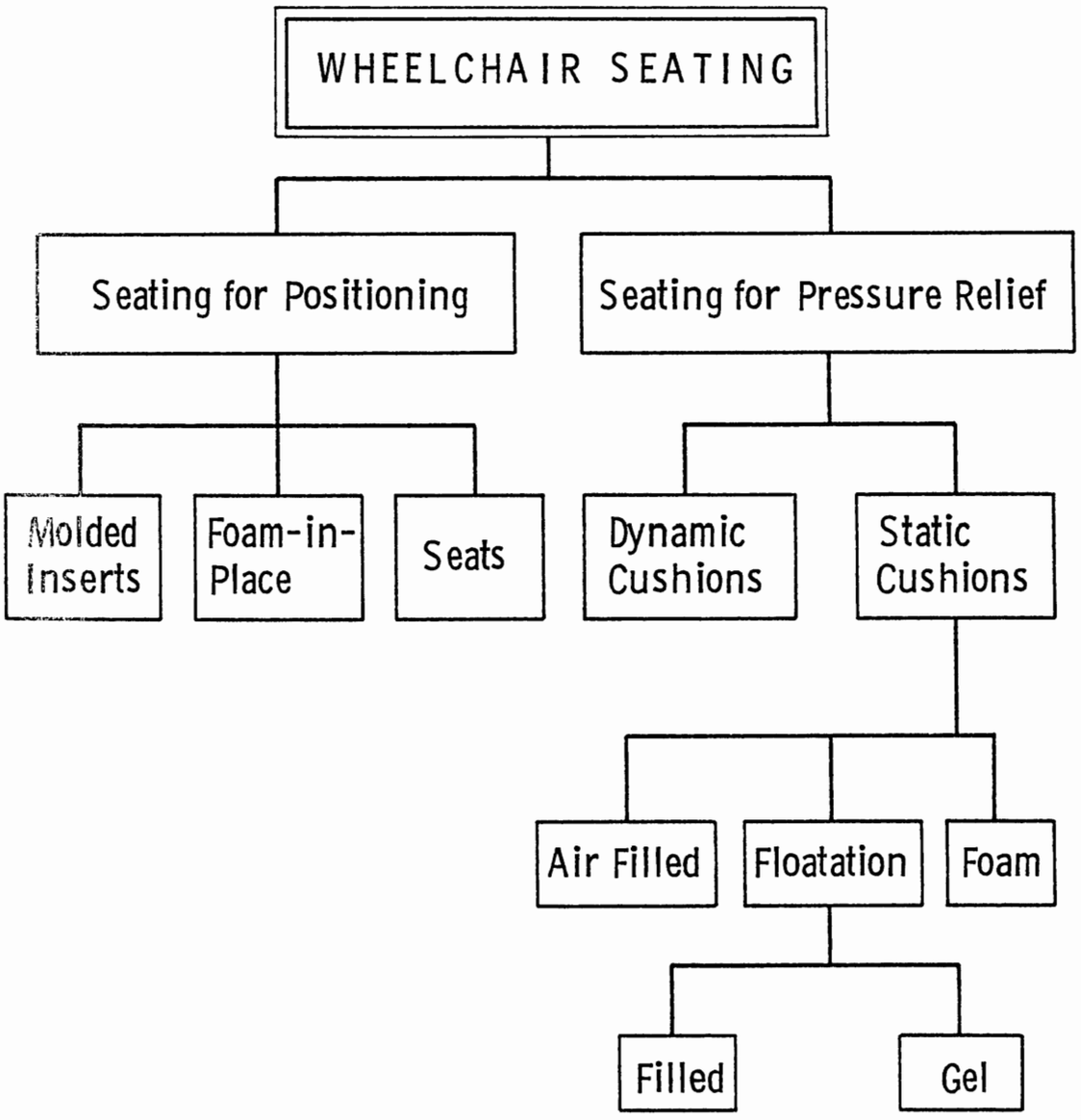


Figure 2. Classification of Wheelchair Seating

Wakefield (1978).

Static Wheelchair Cushions

Static wheelchair cushions are those devices that are placed in the wheelchair and relieve pressure by the nature of their design and the material of which they are fabricated. In general, static wheelchair cushions can be divided into three major categories as classified by Garber (1979): air-filled, floatation, and polyurethane foam. Each group offers distinct advantages and disadvantages. Air-filled cushions are lightweight and easy to clean. However, they are subject to puncture and require the user to check against changes in the air pressure. Examples of air-filled cushions include the ROHO Dry Floatation Cushion and the Bye-Bye Decubiti Cushion.

Garber (1979) describes two types of floatation cushions: gel and filled. They are designed to adjust to the body's movement or to simulate fat tissue to provide adequate protection from pressure. They are usually easy to clean because of their plasticized covers. However, they are generally heavy, difficult to transfer, and must be stored flat. In addition, some individuals who use the gel type of floatation cushion over a long period of time may lose tolerance to other types of cushions. This is significant only if the person has developed pressure sore problems and needs an alternative device. Examples of floatation devices include the Aqua-Seat, Stryker, Reston, Elasto-gel, and Spenco.

The polymer foam group of cushions makes up the largest category of cushions according to Garber (1979). These cushions are the most

versatile in that they can be cut into any size, shape, or thickness. They are usually light in weight and less expensive than the other types of pressure relief devices. Foams of different thicknesses and densities can be laminated or glued together for a totally individualized fit. Despite the obvious advantages of foams, there are two major disadvantages. The first is that they cannot be washed or cleaned because soap and water or other cleaning solutions reduce the pressure relief and supportive properties of the material. Foams are also affected by air pollution, heat, and light, and deteriorate with time even if not subjected to the pressure of one's body weight. The second disadvantage of foam cushions is that they wear out much more rapidly than other types of devices. The average life-span of a foam cushion is six months. It should be noted that worn-out wheelchair cushions are responsible for tissue pressure problems in many individuals with spinal cord injury. It is essential that those who prescribe these devices be familiar with their characteristics so that rational recommendations are made to those who require them and depend on them for protection from the effects of pressure.

Occupational Therapists and the Prescription of Cushions

It appears that occupational therapy practice varies in different parts of the United States regarding the prescription of a wheelchair and its associated equipment. A NARIC search of the literature revealed no useful information that addressed occupational therapy prescription practices in this area. Isolated articles on wheelchairs have appeared in the American Journal of Occupational Therapy. One

such article by Wittmeyer and Stolov in 1978 dealt with wheelchair patients and architectural barriers.

In the same issue, Garber et al. (1978) described the development of a system to individualize the prescription of wheelchair cushions. In 1979, Garber described a system for categorizing the many types of wheelchair cushions. Other than these few references, wheelchair cushions have received very little attention in the occupational therapy literature. In their chapter on spinal cord injury, Trombly and Scott (1977) mentioned weight shifts to relieve ischial pressure. However, the only reference to pressure was that which was concerned with the hyperemia that resulted from poorly fitting splints. Wheelchair cushions were mentioned by these authors in their chapter that described mobility and the prescription of wheelchairs (Trombly & Scott, 1977, pp. 386-387). However the description of cushions for the prevention of decubitus ulcers was incomplete and obsolete. It appears that occupational therapists need to be better informed about the wide variety of pressure relief devices available on the market today so that they can make more objective recommendations of this vital piece of rehabilitation equipment.

Summary

The studies presented in this chapter indicate that there are three major distinct mechanisms that underlie the tissue breakdown and formation of pressure sores in patients with spinal cord injury. They are as follows:

1. Metabolic and nutritional inadequacies, which are a frequent

concomitant of chronic illnesses, diminish tissue repair and may even induce tissue wasting. Therefore, in the malnourished patient, loss of adipose tissue and muscle mass result. This, in turn, diminishes the area through which the pressure of a bony prominence can be diffused. As a result, localized high pressure, combined with poor tissue repair cause capillary occlusion and tissue necrosis.

2. Inadequacies of nursing care and patient positioning constitute an independent mechanism contributing to the development of pressure sores. Irrespective of the nutritional state of the patient and the application of pressure relief devices, prolonged pressure on any single area will ultimately produce changes in the skin surface, thereby undoing the best efforts of the entire rehabilitation team.

3. Inadequacies of pressure relief devices may be subtle and difficult to discern in the clinical setting. Although a broad spectrum of designs for pressure relief devices using a variety of different materials has been developed, none of these has proven to be clearly more efficacious for the entire population at risk or for any subpopulation studied. Despite the extensive physiological and clinical investigations that are the state of the art in our understanding of pressure induced tissue trauma, it is evident that present technology is still inadequate to satisfactorily assess friction and pressure.

CHAPTER III

METHODOLOGY

Research Design

This investigation was of the couterbalanced design as described by Campbell and Stanley (1963). Each subject served as his own control. One group of 30 subjects was evaluated on each of six wheelchair cushions, one unmodified or control cushion, and five cushions wedged in various geometric configurations. The dependent variables were the magnitude of the subjects' ischial pressures, measured in millimeters of mercury (mm/Hg), and the overall pattern of the distribution of those pressures on each of the six cushions. The independent variables included the six cushions as described in Table 1.

Table 1

Characteristics of Cushions Tested

Cushion	Number of Wedges	Location of Wedges	Depth of Wedges
Unmodified	0		
Modification 1	4	Posterior	1" (2 1/2 cm)
Modification 2	4	Anterior	1" (2 1/2 cm)
Modification 3	4	Posterior	1 1/2" (4 cm)
Modification 4	4	Anterior	1 1/2" (4 cm)
Modification 5	4	Posterior	2" (5 cm)

Selection of Subjects

Thirty subjects were recruited to participate in this study. They were drawn from the population of spinal cord injured patients who were either inpatients or outpatients at The Institute of Rehabilitation and Research in the Texas Medical Center in Houston, Texas. Subjects were sequentially assigned to the study in that they were not known at the beginning of the assignment but were integrated into the project as they entered the hospital or its outpatient clinics. Subjects were both males (n=22) and females (n=8), paraplegics (n=12) and quandriplegics (n=18). They ranged in age from 18 to 53 years. The mean (± SEM) age of the quadriplegic subjects was 27.1 (± 4.01) years. This was not significantly different from the mean age of the paraplegic group which was 29.50 (± 2.69) years (see Tables 2 & 3).

Table 2

Clinical Characteristics of Quadriplegic Subjects Studied

Sex	Age[a]	Body Weight[b]		Height		Body Build[c]
		lb	kg	in	cm	
M	18	93	42.3	64	162.6	T
M	20	135	61.4	67	170.2	A
M	21	147	66.8	75	190.5	T
M	21	137	62.3	69	175.3	A
M	21	133	60.5	68	172.7	A
F	21	115	52.3	65	165.1	A
F	21	133	60.5	62	157.5	O
M	22	140	63.6	69	175.3	A
F	22	85	38.6	61.5	156.2	T
M	22	164	74.5	70	177.8	A
M	24	120	54.5	68	172.7	T
M	25	185	84.1	74	188.0	A
F	26	135	61.4	67	170.2	A
M	29	111	50.5	66	167.6	T
F	39	120	54.5	63	160.0	A
M	39	170	77.3	66	167.6	O
F	44	125	56.8	64	162.6	T
M	53	160	72.7	69	175.3	A

[a] X ± SEM:27.1 ± 27.1 years; n=18

[b] X ± SEM:133.8 ± 6.03 lbs. or 60.8 ± 2.74 kg; n=18

[c] T=Thin
A=Average
O=Obese

Table 3

Clinical Characteristics of Paraplegic Subjects Studied

Sex	Age[a]	Body Weight[b]		Height		Body Build[c]
		lb	kg	in	cm	
M	18	180	81.8	74.5	189.2	A
M	20	166	75.5	72	182.9	A
M	22	120	54.5	64	162.6	T
M	23	138	62.7	68	172.7	A
M	28	190	86.4	73	185.4	A
M	28	135	61.4	73	185.4	T
F	28	90	40.9	65.5	166.4	T
M	29	145	65.9	68	172.7	A
M	30	173	78.6	68	172.7	A
M	37	142	64.5	72	182.9	T
M	40	130	59.1	66	167.6	T
F	51	114	51.8	66	167.6	T

[a] X ± SEM:29.5 ± 2.69 years; n=12

[b] X ± SEM:143.6 ± 8.46 lbs
65.3 ± 3.85 kg; n=12

[c] T=Thin
A=Average

Each subject was assigned to one of three body build types: thin, average, or obese. These categories were defined in terms of height, weight, age, and sex according to the Build and Blood Pressure Average Weight Table from the Society of Actuaries (Diem & Lentner, 1973). Thin subjects were defined as weighing less than 90% of the average weight, whereas obese subjects were defined as weighing more than 110% of the average weight and not on the subjective impressions of the investigator. The mean weight of the quadriplegic subjects was 133.8 ± 6.03 pounds (60.8 ± 2.74 kilograms). This was not significantly different from the mean weight of the paraplegic group which was 143.6 ± 8.46 pounds (65.3 ± 3.85 kilograms). Of the quadriplegic subjects, six were classified as thin, ten as average, and two as obese. Of the paraplegic subjects, six were classified as thin and six as average (see Tables 2 and 3).

Instrument

The Pressure Evaluation Pad system was designed to monitor and quantify the pressure distribution of the individual seated on a cushion in a wheelchair. It was developed at the Texas Rehabilitation Engineering Center at The Institute for Rehabilitation and Research, the Texas Medical Center, in Houston, Texas. It was the first clinically useful large matrix pressure monitoring system to permit quantification of tissue pressure in large numbers of physically disabled people using a variety of pressure relief devices (see Figure 3).

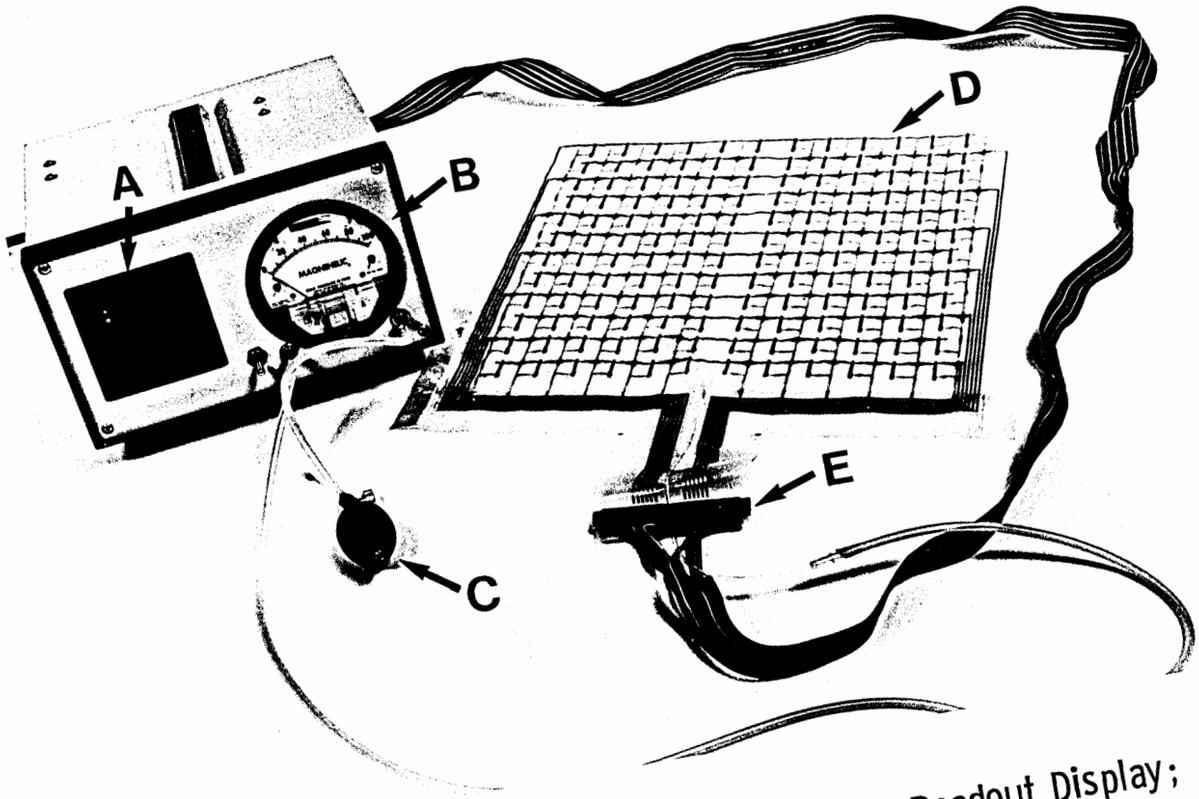


Figure 3. Pressure Evaluation Pad: (A) Readout Display; (B) Gauge; (C) Pump; (D) Sensing Pad; (E) Connector.

The sensing pad (D) consists of two layers of flexible 5 mil urethane plastic, 41 cm by 46 cm (16 by 18 inches) containing a printed circuit of silver paint heat sealed around the edges. The circuit forms a 12 by 12 matrix of pneumatically controlled contacts. The sensing cells average the pressure over a circular area 2.2 cm in diameter and are spaced on 2.9 cm centers. A connection of wires (E) attaches the sensing pad to the data output module. Each of the 144 lights on the readout display (A) corresponds to a sensor in the pad and, therefore, is the representation of a localized point of tissue pressure loading. The pressure at which the contact is made is controlled by an air pump (C) connected to the front of the display console. A pressure gauge (B) located next to the readout display measures pressures of zero to 100 millimeters of mercury (mm/Hg). The Pressure Evaluation Pad system not only identifies the maximum pressures exerted by an individual on the seating surface but also produces a visualization of the overall distribution of that pressure.

Procedure

Each subject was tested on one unmodified, or control, cushion and five modified, or wedged cushions made of 4-inch thick polyurethane foam from the Stainless Medical Products Company. The subject was seated in his wheelchair or one that closely resembled it in seat and back dimensions, foot plates, and arm rests. The pressure sensing pad was placed between the subject and the cushion being tested. Ischial tuberosities and other bony prominences were identified by palpation and the corresponding lights on the readout display

were noted on the data collection sheet (see Appendix A). Air was then pumped into the pad until all of the lights on the display went out. Then, the air was bled out slowly, by releasing the valve on the pump, until the first light or lights became illuminated. These initial lights were identified as the maximum pressure points or areas and were so noted. The lights corresponded to either a bony area (ischial tuberosities, coccyx, or trochanters) or to a soft tissue area (thighs or anterior to the glutei). If maximum pressure was located in a soft tissue area, the air was bled out until a light corresponding to an ischial tuberosity became illuminated. The remaining air was bled out until zero registered on the gauge. The overall distribution of the pressure exerted was noted as the percent of total lights illuminated from a total of 144 lights (e.g. 96/144 or 66.6%). Three consecutive readings of maximum pressure and overall distribution were taken to establish reliability of the instrument. This entire procedure was repeated for each subject on each cushion.

Limitations

All of the subjects who participated in this study were individuals with paraplegia and quandriplegia secondary to a spinal cord injury. Therefore, the results of the study may not be generalizable to individuals with other physically disabling pathological conditions such as muscular dystrophy, hemiplegia secondary to cerebral vascular accidents, cerebral palsy, and multiple sclerosis. In addition, there may be other methods of geometric cushion modification which

were not studied and may provide pressure relief for some individuals. The wedging method of cushion modification used in this study is by no means the only technique employed to modify existing cushion designs. However, this study does not permit conclusions to be drawn regarding vastly different geometric configurations of modification.

Analysis of Data

Statistical Methods.

Prior to statistical analysis, the data were analyzed and found to follow a normal distribution. Calculated data are given in terms of the mean plus or minus the standard error of the mean (SEM) and are expressed in units of millimeters of mercury (mm/Hg) for ischial pressure noted. Statistical significance was assessed using an analysis of variance. The data were analyzed by the Data General Computer using the "CLINFO" software of the Rand Corporation as distributed by the Division of Research Resources of the National Institutes of Health. This is part of the computing core facility of the General Clinical Research Center of the Baylor College of Medicine.

CHAPTER IV

ANALYSIS AND EVALUATION

Results

In 30 subjects seated in their wheelchairs, ischial pressures were monitored on each of six different wheelchair cushions. Pressure was assessed with the Pressure Evaluation Pad on one unmodified, or control, cushion and five cushions modified in various geometric configurations as described in Chapter III. The purpose of this study was to determine whether or not modification of cushion geometry by a technique called wedging altered the ischial pressure and the overall distribution of pressure.

All of the subjects who participated in this study had sustained a spinal cord injury which had resulted in either paraplegia or quadriplegia. The mean ischial pressures of this group of subjects for each cushion tested are shown in Table 4. Minimal differences in group mean pressures were observed between cushions for the entire patient population studied. In no instance was there a statistically significant difference produced by any single cushion as compared to all of the other cushions, including the control cushion ($p > .3$ for all cases). Although the replicate ischial pressure determinations were completely reproducible, this consistency was not observed for determinations of the overall distribution topography. For this reason, quantitative analysis of the overall distribution data was not possible.

Table 4

Subjects' Ischial Pressures on Cushions Studied

Cushions	Pressures[a]
Unmodified	87.9 ± 3.51
Modification 1	88.0 ± 3.50
Modification 2	86.6 ± 4.01
Modification 3	87.7 ± 4.00
Modification 4	85.9 ± 4.06
Modification 5	81.6 ± 5.75

[a] X ± SEM in mm/Hg; N=30

Of the 30 subjects who participated in the study, 22 were males and eight were females. The mean ischial pressures for the group of males versus the group of females for each cushion tested are shown in Table 5. Only minimal differences were observed between the ischial pressures of the males and the ischial pressures of the females for each cushion tested. In no instance was there a statistically significant difference in pressures determined with any given cushion as compared to any other cushion, including the unmodified cushion, for either the male or female group ($p > .3$ for all cases). Indeed, the ischial pressures observed with the male population studied were not different from those pressures found in the female population studied.

Table 5

Comparison of Ischial Pressures in Male and Female Subjects

Cushions	Pressures[a]	
	Male[b]	Female[c]
Unmodified	88.1 ± 4.18	87.5 ± 6.94
Modification 1	88.2 ± 4.09	87.5 ± 7.20
Modification 2	89.5 ± 4.64	78.8 ± 7.72
Modification 3	88.1 ± 4.77	86.6 ± 7.52
Modification 4	87.4 ± 4.92	81.9 ± 7.32
Modification 5	82.7 ± 6.48	78.4 ± 13.4

[a] X ± SEM in mm/Hg

[b] n=22

[c] n=8

A determination of the ischial pressures exerted by quadriplegic subjects compared to paraplegic subjects is shown in Table 6. It is apparent that only minimal differences were observed between cushions for the group of 12 paraplegics compared to the group of 18 quadriplegic subjects. In no instance was there a statistically significant difference in pressures observed with any given cushion, including the control cushion, for either the paraplegic subjects or the quandriplegic subjects ($p > .3$ for all cases).

Table 6

Comparison of Ischial Pressures in Paraplegic and Quadriplegic Subjects

	Pressures[a]	
Cushions	Paraplegic[b]	Quadriplegic[c]
Unmodified	87.5 ± 6.05	88.2 ± 4.37
Modification 1	86.5 ± 5.78	89.1 ± 4.48
Modification 2	85.4 ± 7.27	87.4 ± 4.72
Modification 3	88.3 ± 6.61	87.2 ± 5.06
Modification 4	85.0 ± 6.71	86.5 ± 5.21
Modification 5	82.8 ± 8.18	80.2 ± 8.57

[a] X ± SEM in mm/Hg

[b] n=12

[c] n=18

Because body build has been shown to influence ischial pressure and its distribution for the individual with a spinal cord injury who is seated in a wheelchair (Garber & Krouskop, 1982), the data were analyzed to determine whether or not modification of cushion geometry, by the process of wedging, in any way alters this pressure. The subjects studied were classified as either thin, average, or obese as described in Chapter III. The mean ischial pressures for each body build type on each of the six cushions are shown in Table 7. Only slight differences were observed between cushions for each group.

These differences were not significantly different, indicating that geometric modification by wedging was not selectively advantageous for one or more of the body build types studied ($p > .3$ for all cases).

Table 7

Comparison of Ischial Pressures According to Body Build of Subjects Studied

	Pressures[a]		
Cushions	Thin[b]	Average[c]	Obese[d]
Unmodified	92.9 ± 4.20	86.0 ± 5.59	72.5 ± 12.5
Modification 1	90.0 ± 4.77	87.2 ± 5.69	82.5 ± 2.5
Modification 2	85.8 ± 6.88	86.7 ± 5.68	90.0 ± 0
Modification 3	90.8 ± 5.46	87.2 ± 6.02	72.5 ± 17.5
Modification 4	87.1 ± 5.98	86.3 ± 6.14	75.0 ± 15
Modification 5	80.0 ± 8.66	81.1 ± 8.77	100.0 ± 0

[a] mm/Hg

[b] X ± SEM; n=12

[c] X ± SEM; n=16

[d] X ± 1/2 range; n=2

Discussion

The results of this study show that in a population of subjects with spinal cord injury, modification of the geometry of an otherwise rectangularly shaped block of polyurethane foam is without influence

on maximum pressure exerted under bony prominences. Previous efforts to develop improved devices for reduction in tissue pressure have focused on either variation of the mechanical properties of the device or in variation in the materials of which the cushion was constructed (Cochran & Slater, 1973). Prior to 1970, the prescription of wheelchair cushions was mostly an arbitrary decision based on availability and familiarity of the devices by the rehabilitation or medical team. Such devices were made primarily of rubber foams and gels, although some air cushions made of rubber or plastic were also available. In recent years, many new wheelchair cushions have been developed and distributed for use by persons with long-term physical disability. They have included new and improved types of foams (polyurethane), air cushions of various designs, gel cushions of undetermined contents, and combinations of these materials. Unfortunately, none of the new devices proved to be universally optimal for all patient diagnostic categories.

Presumably, this result is the outcome of the use of the materials as simple pressure dampers. These tend to diffuse downward pressure somewhat more laterally and substitute a degree of elasticity or buoyancy which is missing from the rigid surface on which the individual might sit. As a result, pressure is transferred mainly from the bony prominences to much larger areas encompassing soft tissue. As a result of previous studies (Houle, 1969; Mooney et al., 1971; Souther, 1974), it is apparent that pressure diffusion occurs, in part, in a manner independent of the elastic and mechanical properties of the

cushion which links the patient to the rigid surface.

In light of these findings, it seemed reasonable to test the hypothesis that the geometric shape of the pressure relief device might play an important role in reducing pressure and ultimately the risk of ulceration. The wedging technique was employed to reduce the stiffness of the foam and to diffuse the pressure over larger areas of soft tissue and away from the bony prominences. The outcome of such modification was to produce a cushion which conformed better to the topology of the patient's buttocks and to produce more uniform buoyant back pressures across the buttocks. In theory, pressure under the bony prominences should have been reduced. Such a result, clearly, was not the case in this study.

Wedging as a means of cushion modification to reduce ischial pressure was wholly ineffective for the population of subjects studied. This conclusion is independent of patient sex (see Table 5), of the level of spinal cord injury (see Table 6), or of the body build of the subjects (see Table 7). These findings are similar to those of a previous study (Garber et al. 1978), in which no relationship was found between maximum pressure and the sex or the level of spinal cord injury. However, a relationship between body build and maximum pressure has been described (Garber & Krouskop, 1982). Paradoxically, obese patients were found to have lower pressures overall compared to normal weight subjects. The latter had lower pressures than underweight subjects. These results appear to reflect an increased adipose tissue component of the buttocks which therefore serves as an effective

endogenous pressure relief pad. In this study, using modified cushions, coupling of the buoyant back pressure from the rigid surface to the patient's buttocks was not increased further by the geometric modification of the cushion. Undoubtedly, this result reflects inadequate residual cushioning under the bony prominence. Thus, it is possible to speculate that the reduced stiffness of the cushion as produced by the wedging modification technique allows excessive direct compression of the cushion with the resultant loss of pressure dampening resiliency.

Although, as a group, these modifications were found to be ineffective, marked variations in individual responsiveness was noted from cushion to cushion. In some patients, marked reductions were produced by one or more of these modifications as compared to the control unmodified cushion. These differences tend to be obscured by the method of data analysis used for this study since group responses were considered. In prior studies, similar variations were observed in the individuals' responsiveness to commercially available cushions although overall, no cushion was clearly superior to other cushions when considered for all patients as a group. The findings of the present study are therefore similar to earlier studies. It is evident that no single cushion, whether of varying commercial origin or of unique research-based geometric modification, is therefore likely to become universally effective in reducing tissue pressure for all patients. Thus, careful patient evaluation and prescriptive trials together with objective determination of device effectiveness must be performed on an individual basis.

CHAPTER V

SUMMARY AND RECOMMENDATIONS

Summary

Wheelchair cushions made of polyurethane foam were geometrically modified by a technique called wedging in order to reduce pressure under bony prominences in subjects with paraplegia and quadriplegia seated in their wheelchairs. The wedge-shaped modifications were positioned so as to redistribute pressure away from the bony prominences, such as the ischial tuberosities, toward the soft tissue. The ischial pressures of 30 subjects on one control unmodified cushion and five geometrically modified cushions were determined using the Pressure Evaluation Pad. No significant differences in the pressures measured could be determined for any one modified cushion compared to the other modified cushions or for the control cushion. Independent effects of subject sex, diagnosis, and body build could not be identified so that no optimal modification was noted for any subpopulation of the total patient group. Marked variation and responsiveness was noted between cushions for individual patients. These data demonstrated that individualization of the prescription is essential for optimal pressure relief, and that no cushion appears to be universally superior for all patients or any subgroup of patients requiring a pressure relief device.

Recommendations

Pressure sores interfere with every aspect of the physically

disabled person's life from his active participation in a rehabilitation program to his returning to the community as a productive and creative contributor. Although the cost for the surgical repair of a pressure sore may now exceed $25,000, this is only a fraction of the total burden on society. Other aspects of this burden derive from the loss of productive employment with its concomitant economic impact on the individual and his family, reduced educational opportunities with their long-term impact on vocational potential, separation from the family unit with its impact on psychological and social development, and finally, a loss of general personal independence and productivity that contributes to a severe loss of self-esteem.

Although the wheelchair cushion is considered an important factor in the prevention of pressure sores, this device by itself does not eliminate the risk of tissue breakdown for the individual with a spinal cord injury. Past and present research efforts indicate that there is no single pressure relief device or material that is optimum for all groups of individuals with physical disability. In addition, it has been demonstrated that many factors, alone or in combination, are responsible for tissue breakdown. The objectives and emphases of future research might be on the development of clinically practical methods of evaluating pressure relief devices for an individual patient rather than on the development of a universal cushion. Furthermore, efforts must be expended on the dissemination of the information derived in the clinical setting to the appropriate and concerned rehabilitation professionals.

The importance of a comprehensive, multidisciplinary approach to tissue pressure management for the person with a spinal cord injury has been reported in the literature (Garber et al., 1982). This approach includes an extensive educational component in which many pressure sore prevention methods and techniques are presented to the patient and his family. These methods include skin assessment, weight shifts, awareness of nutrition, care of wheelchairs, personal hygiene activities, and, of course, the proper selection and use of the wheelchair cushion. Only in combination will these activities result in healthy skin free of the tissue erosion that reduces productivity and independence. By removing or ameliorating the threat of tissue breakdown, and incorporating technology into the tissue management of a person with a physical disability, the rehabilitation team will greatly enhance that individual's ability to reach his highest potential.

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APPENDIX A

TIRR THE INSTITUTE FOR REHABILITATION AND RESEARCH
in the Texas Medical Center / 1333 Moursund Avenue / Houston, Texas 77030 / (713) 797-1440

DEPARTMENT OF OCCUPATIONAL THERAPY

CUSHION MODIFICATION STUDY
DATA COLLECTION FORM

Name_____ Hospital Number_____

Sex_____ Age_____ Height_____ Weight_____ Onset_____

Diagnosis_____

PRESSURE MEASUREMENTS ON CUSHIONS

Test Surface	Maximum Pressure (mm Hg.)	Location of Maximum Pressure	% of Lights On
1. Unmodified Cushion			
2. Modification #1 (wedges 1" deep posterior)			
3. Modification #2 (wedges 1" deep anterior)			
4. Modification #3 (wedges 1½" deep posterior)			
5. Modification #4 (wedges 1½" deep anterior)			
6. Modification #5 (wedges 2" deep posterior)			

APPENDIX B

TEXAS WOMAN'S UNIVERSITY

HOUSTON CENTER

HUMAN RESEARCH REVIEW COMMITTEE REPORT

STUDENT'S NAME SUSAN LIPTON CARBER

PROPOSAL TITLE Wheelchair Cushion Modification and its Effect on Pressure

COMMENTS:

DATE: 12-14-82

William P. Horton

Disapprove Approve

Disapprove Approve

Disapprove Approve

Disapprove Approve

Consent Form
TEXAS WOMAN'S UNIVERSITY
HUMAN SUBJECTS REVIEW COMMITTEE

(Form B)

Title of Project: Wheelchair Cushion Modification and its Effect on Pressure

Consent to Act as A Subject for Research and Investigation:

I have received an oral description of this study, including a fair explanation of the procedures and their purpose, any associated discomforts or risks, and a description of the possible benefits. An offer has been made to me to answer all questions about the study. I understand that my name will not be used in any release of the data and that I am free to withdraw at any time. I further understand that no medical service or compensation is provided to subjects by the university as a result of injury from participation in research.

Signature _____ Date _____

Witness _____ Date _____

Certification by Person Explaining the Study:

This is to certify that I have fully informed and explained to the above named person a description of the listed elements of informed consent.

Signature _____ Date _____

Position _____

Witness _____ Date _____

One copy of this form, signed and witnessed, must be given to each subject. A second copy must be retained by the investigator for filing with the Chariman of the Human Subjects Review Committee. A third copy may be made for the investigator's files.

TIRR THE INSTITUTE FOR REHABILITATION AND RESEARCH
in the Texas Medical Center / 1333 Moursund Avenue / Houston, Texas 77030 / (713) 797-1440

February 23, 1983

Mrs. Susan Lipton Garber
The Institute for Rehabilitation and Research
1333 Moursund Avenue
Houston, Texas 77030

Dear Mrs. Garber:

Thank you for submitting the requested modifications to your project proposal, "Wheelchair Cushion Modification and Its Effects on Pressure." This completes the Research Committee's approval process. You are free, therefore, to implement the work.

We are delighted that this work will take place at TIRR because of its clear-cut potential relevance to improving services for our patients. Be sure to contact me if I can be of further assistance.

Sincerely yours,

Marcus J. Fuhrer, Ph.D.
Director of Research

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