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Interface pressure measurement systems for management of pressure sores

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This health technology assessment has been prepared on the basis of evidence and expert opinion available to the Foundation, current to the date of publication and has been externally reviewed. Additional information and comments relative to the matters discussed would be welcome and should be sent to:

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Contents

Summary

- Pressure sores (decubitus ulcers) are a significant source of morbidity in healthcare institutions.
- Interface pressure measurement systems have been developed to assist in the management of pressure sores. They provide information on interaction of some forces between persons who are bed-ridden or in a wheelchair, and the surfaces with which they are in contact.
- Published values for limits of acceptable pressure and duration of pressure on the anatomy vary widely.
- The limited available data suggests that information provided by different types of measurement systems are not directly comparable. Many factors affect the results of interface measurements, such as the transducer size and shape, the load shape and its interaction with the support material, positioning of sensors and the measurement protocol.
- No data could be found on the efficacy or effectiveness of pressure measurement systems in contributing to the avoidance of pressure sores. The devices have been used in successful trials to reduce numbers of pressure sores, but their contribution to the overall outcome is unclear.
- Further research to define the performance, role and efficacy of pressure measurement systems would be desirable.
- Only very limited data are available for the prevalence and cost of pressure sores in Alberta. On the basis of 1992 data, it is estimated that at least $11 million/year is spent in acute care facilities to treat patients with pressure sores. Possibly 2.7% of patients in continuing care facilities will also have pressure sores. When U.S. data are considered, these preliminary data for Alberta appear to be gross under-estimates of the problem.
- Further work to identify the extent of the problem and options to reduce pressure sore morbidity in Alberta should be considered.

Introduction

This report has been prepared to provide information and assist discussion on the management of pressure sores, a significant source of morbidity in health care institutions. The focus of the report is on a specific technology, interface pressure measurement. It is expected that other issues in this are will be addressed in future publications.

Pressure sores, also known as bedsores, pressure ulcers, decubitus ulcers and pressure necrosis, usually occur over bony prominences such as elbows, hips and heels, and at the base of the spine including other pelvic sites. Defined as any lesion caused by unrelieved pressure resulting in damage of the underlying tissue (20), pressure sores are a significant, common and costly health problem. Reported prevalence rates among hospitalized patients have varied between 3.5% and 29.5% and in several subpopulations, such as hospitalized quadriplegic patients, have been as high as 60% (20). The societal and health care costs are substantial. National annual cost for the treatment of pressure sores in the USA for 1992 was estimated at $1.3 billion (20).

There is little information about the mechanism of the formation of pressure sores but it is agreed that it is a complex process. As many as 100 risk factors have been identified (17). These have been classified into extrinsic and intrinsic factors. Extrinsic factors are external influences in the patient's environment such as pressure, shear and friction, and temperature and humidity. Intrinsic factors are characteristics of an individual patient such as advancing age; thin or emaciated physique; posture; condition of the skin and subcutaneous tissues; dietary inadequacies; incontinence; immobility and neurological disease (5, 7).

The focus of this report is in relation to the extrinsic factor of pressure, specifically, interface measurement systems. Its intent is to consider the efficacy or effectiveness of interface measurement systems in the prevention of pressure sores in bedridden or wheelchair bound individuals. Technical aspects of the technology are not considered in any detail. Some preliminary data are provided on prevalence and costs of pressure sores in Alberta.

General description of the technology

Interface pressure measurement systems have been developed to provide information on the interaction of forces between persons and a surface such as a bed or seat. They are designed to provide information on forces axial or perpendicular to the interface and, if in an array or matrix, can provide information on patterns of pressure distribution between sensors.

Measurement of tissue interface pressure, the pressure applied to the skin by a supporting surface, provides information to health care workers on the magnitude and distribution of forces. Tissue interface pressure is lower when greater areas of body

surface are in contact with a supporting surface. The pattern of pressure distribution which is displayed by systems measuring the entire seat can be helpful in providing clinicians with qualitative information about symmetry and posture (Cardi M, personal communication). Measurement systems are seen by clinicians and researchers as useful tools for seating clinics, pressure sore prevention programs and as part of protocols for the treatment of pressure sores (5, 8, 10).

Interface measurement systems may also be used during the development of pressure relief interventions. Such interventions, which include manual repositioning, use of special beds, mattresses or cushions and overlays, distribute the person's weight or mechanically vary the pressure, thereby reducing the duration of the applied pressure. Interface measurement systems assist in determining the pressure redistribution capabilities of the various interventions.

The forces applied to the surface of the skin are of two components: one referred to as pressure which acts at right angles to the skin; and shear which acts parallel to the skin surface. Few devices have been developed for measuring shear forces. Devices used clinically measure the pressure component, though the measurement process may also be influenced by shear.

In general, an interface pressure measurement system consists of a sensor or a transducer; an amplifier and related electronics and a pressure display. Devices used to measure pressure and its distribution over the support area range from a single transducer moved to new body locations for successive measurements, to arrays of transducers for simultaneous observation of pressures from the entire support area.

Many factors affect the results of interface pressure measurements. These include the transducer size and shape, the load shape and its interaction with support material and method of calibration (2, 10). The ideal sensor should be as thin as possible. The diameter to thickness ratio should not be less than 10:1 and it should be flexible. A rigid sensor will indent both the skin and the support surfaces and the measured pressure will depend more on the device than on the interface pressure (5). Barbenel (5) recommended a static rather than a dynamic pressure measurement for routine clinical use. Single static pressure measurements, while they do provide valuable baseline information, give only a "snapshot" and are limited in representing forces generated during functional activities outside of the clinical environment. Although it is common clinical practice to take single readings of pressure, measurements of pressure variability or dynamic measurements over time are important due to body movements and postural changes (4), (Cardi M, personal communication).

Table 1 gives a summary of the general characteristics of different types of pressure measurement systems. It draws on the critique developed by Barbenel (5) and on details provided by Cardi (personal communication).

Table 1: Characteristics of different pressure measurement systems

Sensor type/ Transducer	Advantages	Disadvantages	Description
Dye-releasing capsules; chemically impregnated sheets	• simple • easy to use • inexpensive	• sensitive to temperature and humidity • values obtained unreliable and of limited use	Reaction at a rate modified by the applied pressure.
Simple electropneumatic closed system	• simple • commercially available • useful for routine measurements	• cannot differentiate between normal pressure and shear • possible breakage of electric conductors	Sensor is inflated until the electrical contact on the opposing internal surface of the thin, flexible walled capsule are separated. Capsule is allowed to slowly deflate until the indicator shows that the walls are in contact again – this is the interface pressure.
Pneumatic, strained-gauge diaphragm continuous output	• sensors available in small sizes and diameters (less than 3 mm) • thickness less than 1 mm • useful for pressure-time history	• sensors rigid • expensive • cannot differentiate between normal pressure and shear	Measurement of displaced volume of air as the interface pressure increases. Pneumatic sensor arrays consisting of more than 90 elements have been developed for dynamic pressure measurements.
Resistance or capacitance	• portable, self-contained units are commercially available • relatively inexpensive • versatile, can be configured into various shapes and sizes – clinically useful • thin • can withstand large overloads	• hysteresis • creep • sensitive to shear, temperature, moisture and curvature • depends not only on the load but also the previous load history • difficult to obtain an unambiguous measurement	Transducer responds to increased pressure with increased capacitance. When the capacitance of the transducer varies, the current flow varies. The magnitude of the current is related to the magnitude of the pressure exerted on the transducer.

Sources: Reference 5; (Cardi M, personal communication)

Issues in measurement of interface pressures

Other issues relating to measurement of interface pressure mentioned in the literature include the relationship between the interface pressure and the actual pressure in deeper tissues (6); and the forces and times needed to produce tissue damage in humans (5, 7).

There is an assumption that interface pressure is directly proportional to the internal pressure at the site of the pressure sore formation. The basis of this assumption is that when the interface pressure is higher than the mean capillary pressure, the capillary vessels tend to collapse and blood cannot reach the high pressure area. If the pressure is sustained, the area becomes ischemic (lack of blood flow) and eventually necrotic (tissue death). Hence, those with compromised circulation due to vascular pathology will even be at more risk for the formation of pressure sores than those without vascular disease.

There are very few studies that have addressed how compressed pressure is distributed over the layers of tissue (6). Some studies have focused on determining the pressure and oxygen tension beyond which pressure sores will form. Normal capillary pressure is about 32 Mm Hg. Acceptable limits of pressure reported in the literature vary from no greater than 25 Mm Hg to 60 Mm Hg (7).

In addition to the various reported limits of acceptable pressure, it is difficult to establish from the literature an exact period after which unrelieved pressure causes a sore. Although there have been no controlled investigations of the pressures and times needed to produce tissue damage in humans (5, 7), there is one frequently-referenced study by Reswick and Rogers (19). They measured the pressures over the bony prominences of 980 seated subjects and produced a tolerance curve which confirms the inverse relationship between pressure and duration. However, care must be taken in interpreting the absolute values of pressure time tolerance curves as these measurements depend upon the sensors used (5).

Even with these limitations, interface pressure measurement systems are seen by some as the best available technology to provide information on magnitude and distribution of the various pressure points between a person and a surface (5, 10).

Evidence of efficacy/effectiveness

No reports of clinical trials were found which included clinical outcome measurements and compared the efficacy of commercially available interface measurement systems. Details on the databases searched, the search strategy and the criteria used to select articles may be found in Appendix A.

Four studies were located which described and compared the performance of several commercially available systems using human subjects (1, 2, 10, 18).

Reger, et al. (18) studied the measurement and performance characteristics of interface pressure measurements systems which used pneumatic and electropneumatic pressure transducers. One part of their study involved 20 normal volunteers whose interface pressures were measured in the sitting, side lying and supine postural positions using three support systems and three electropneumatic measurement systems (Scimedics, Texas Institute of Rehabilitation Research Pressure Evaluating Pad and Gaymar). Measurements were performed by four independent professionals in two clinical laboratories. 1,080 independent pressure measurements in the range of 20 to 100 mm Hg showed significant correlation between the outputs of three measurement systems when such measurements were taken using a defined protocol. The authors concluded that this approach to pressure monitoring may improve the quality of care for patients at risk of pressure ulcers.

Ferguson-Pell and Cardi (10) identified specifications for wheelchair seat pressure mapping systems through a survey and compared these specifications to those of three commercial systems using five wheelchair users with paraplegia or paraparesis and four different cushions (foam, get, Jay, Roho). The systems selected – Force Sensing Array, Talley Pressure Monitor and Tekscan – were in the process of development and ready for beta testing at the time of the study.

Each system had a different type of sensor. Single measurements were taken with each system, for all wheelchair users, seated on each of the four cushions. Each individual acted as his own control. Ideally, each user-cushion combination should produce similar results regardless of the pressure system used. However, the differences in measurements between individual sensors for the same person seated on the same cushion were marked. These results indicated that the sensors were not equivalent and that there is no simple correction factor which can be used to normalize the results from the different sensors so as to make them consistent.

Allen, et al. (2), conducted a laboratory study to establish the accuracy of three commonly available systems: the Talley SA500, the Digital Interface Pressure Evaluator (DIPE) and a water-filled bladder, and to investigate factors influencing their accuracy. Both the Talley SA500 and the DIPE are electro-pneumatic systems and the water-filled bladder device used a plastic bladder sensor connected to an electronic strain gauge pressure transducer.

Interface measurements were performed by placing the sensor being tested centrally between two pieces of foam and loading the foam with a baseplate followed by seven bricks. All three systems provided pressure values which exceed the actual interface pressure applied. However, the repeatability for each system was generally good. This study concluded that errors associated with interface pressure can be significant, vary from one system to another and that accuracy and repeatability are affected markedly by the interface surface and point of contact.

A follow-up study (1), on six healthy males, was performed to assess the precision repeatability of the Talley SA500. This device was chosen since it provided the best

results in the laboratory study. A Clintfloat mattress was used as a standard and pressure was measured under six body sites: occiput, scapula, elbow, sacrum, buttock, and heel. It was shown that pressure varied more between anatomical sites than between subjects despite their varying builds. Readings were less precise at sites, such as the heel, which exert high interface pressures.

The authors concluded since the repeatability error of the device was much smaller than the range of pressures at the different sites, the Talley SA500 would be suitable for assessing interface pressure. They recommended that precision of the measurement technique should be established first before any detailed study of the pressure relieving capabilities of different surfaces is undertaken and that measurements should be performed after repositioning the sensor and repeated on different days. Repeated measurements would allow for the consideration of variables such as body position and a more accurate value of mean pressure would be obtained.

These studies give only a general indication of the performance of these devices and do not address their clinical role in any detail. Well designed clinical trials are still needed to determine the efficacy and effectiveness of interface pressure measurement systems. Good clinical research would assist in the appropriate evolution of this technology.

Status of the technology

A search in September, 1995 was conducted of Health Canada's Health Protection Branch (HPB) Device Notification Database and the United States Food and Drug Administration (FDA) Electronic Bulletin Board – Approvals Section, to determine whether any of the devices on the market had been registered with HPB or received approval with the FDA. Search terms used were "Vista Med", "Tekscan", "Span America", "Gabel Medical Instruments Ltd.", "Talley", "DIPE", "Force Sensing Systems", "Force Sensing Array", "QA", "Entran" and "Scimedics". No matches were found on the FDA Bulletin Board for any of the terms. The HPB search returned one match for a Talley Mark III Pressure Monitor, first sold in Ontario by Mid Canada Medical in January 1992.

Appendix B is a spreadsheet comparing the various manufacturers and models of pressure measurement systems available in 1992, compiled by Ferguson-Pell and Cardi (9).

Based on the regulatory status of the technology and the absence of scientific evidence on the efficacy and effectiveness of interface pressure measurement systems in the published literature, it seems that this technology is still evolving. However, it is being utilized in clinical settings (16). The NHS Centre for Reviews and Dissemination assessed the effectiveness of pressure-relieving interventions and noted that many evaluations of pressure relieving devices have simply measured the interface pressure because these measurements are relatively quick, simple and inexpensive.

A rationale for the prevention of pressure sores is based on limiting the time that pressures are applied to the skin surface and reducing peak pressures at the high risk anatomical sites. The following two studies describing the outcomes of pressure clinics with program objectives to reduce the incidence of pressure sores, utilized interface pressure measurement systems (8, 13).

Dover, et al. (8) conducted a retrospective study of two groups of patients who developed paraplegia or tetraplegia between 1984 and 1987 and compared their outcomes with those reported by other spinal cord injured units. Interface pressures, using a Talley Skin Pressure Evaluator, were routinely measured to ensure appropriate cushioning was provided. Results compared favorably with those reported by two other spinal units and showed a reduction of over 50% in both the incidence of pressure sores and readmission rate. It was concluded that the establishment of a pressure clinic with patient education as the central focus, was effective in the prevention of pressure sores.

Krouskop, et al. (13), showed that after implementing and operating a program for three years, reduced re-treatment rate of pressure sores from 32% to 4%. One phase of this program was pressure evaluation using a pressure evaluation pad for wheelchair patients which was developed by the Texas Rehabilitation Centre. This instrument identified the maximum pressure at any point on the contact area without the requirement of a prior judgment as to the location of the maximum pressure level. It also provided information on the pressure and uniformity of weight distribution.

Because the design of these studies included multiple elements, no particular component is identifiable as contributing to the programs' successful outcomes. The efficacy of pressure mapping devices in these settings is unclear. All program elements, assessment, equipment prescription, and education, were considered important but the educational component was identified by both programs as being central for beneficial outcome.

Possible cost implications of pressure sores

A report of a prospective study at a tertiary, urban university teaching hospital (3), reported a cumulative incidence of pressure sores at stage 2 or greater (National Pressure Ulcer Advisory Panel Classification) of 12.9% among hospitalized adults 55 years or older who were confined to a bed or chair.

Meehan (14) surveyed 148 USA acute care facilities and found a 9.2% pressure sore prevalence rate. Reported prevalence rates of hospitalized patients has varied between 3.5% and 29.5% and among nursing home residents from 2.4% to 23% (20). A recent one year USA study of 326 home care clients (12) indicated a prevalence of 12.9%. Perez (17) noted that pressure sores are associated with a four fold increase in death rate among hospitalized patients and for hospitalized patients with a primary discharge diagnosis of pressure sores the mortality rate ranges from 23 to 37%.

Miller and Delorzier (15) estimated the national USA baseline costs of pressure sores for 1992. According to their analysis, the mean hospital charge for patients with a primary diagnosis of pressure sores was $21,675 US and the physician charges were $2,900 US per case. For nursing home facilities and home care settings, they estimated costs of $355 US million and $60 US million, respectively.

Even though it has been difficult to determine the prevalence and costs of pressure sores because of the limited availability of data, the estimated prevalence rates and costs are sufficiently high to warrant concern.

Cost implications for Alberta

It is difficult to estimate the cost for treatment of pressure sores in Alberta. Specific data on incidence and cost of pressure sore management are not routinely collected and are unavailable from standard data sets maintained by the Health Ministry. Data, extracted from administrative databases, were obtained for the fiscal years 1992/93 and 1993/94. The cost estimates are predicated on 1992/93 data because of system difficulties and changes to the compensation structure of the 1993/94 fee-for-service schedule. However, a comparison of the data between the two years suggests no major variations.

In Alberta during fiscal year 1992/93, $601,440 was provided in fee-for-service compensation to practitioners, primarily physicians, for 19,078 distinct services related to the treatment of chronic ulcer of the skin (ICD9-CD code 707.0). Pressure sores are included under this code. However, it is impossible to ascertain the magnitude of services which were provided to treat pressure sores compared to other chronic ulcers of the skin. Conditions of gangrene, skin infections, and varicose ulcers are excluded.

During 1992/93 there were 219 discharges from acute care facilities with a primary diagnosis of ICD9-CM code 707.0, representing approximately 0.05% of discharges from Alberta facilities. The average length of stay for the group of patients was 62 days. A U.S. study by the Medical Technology and Practice Patterns Institute (11), which reviewed the number of Medicare and non-Medicare patients who were diagnosed with pressure ulcers, showed that 26,439 Medicare cases with a primary diagnosis of decubitus ulcers were admitted in 1987. However the total number of cases listed with decubitus ulcers as a secondary diagnosis was about four times higher at 96,143. About 0.25% of all Medicare cases were hospitalized with a diagnosis of decubitus ulcers. Hence the 219 discharges with a primary diagnosis of decubitus ulcer from Alberta facilities may be a gross underestimation of the provincial picture since those individuals with a secondary diagnosis were not included.

Since no daily or case costs are available, the average daily cost of treatment in acute care facilities in 1992/93 of $816 was used. This figure reflects the average daily cost of treatment for all acute care facilities in the province, including supply costs, salary and benefit expenses of staff employed by the hospital. It does not include the cost of physician fee-for-service payments. Although rehabilitation and nursing costs are bundled into the per diem rate, it would be important to capture the actual costs since

pressure sore management have been identified as resource-intense from a nursing and rehabilitation perspective.

Average daily costs of treatment within the province vary widely based on the size of the facility, and if it is a tertiary centre or referral hospital or whether it offers specialized programs for the region or province. If the provincial average daily cost is used, approximately $11,000,000 was expended for 1992/93 by acute care facilities to treat patients with a primary discharge diagnosis of decubitus ulcer. This figure does not include the cost of treatment patients with a secondary diagnosis or co-morbidity of decubitus ulcer, and whose length of hospital stay may have been extended as a result.

Continuing care facilities in Alberta include nursing homes and auxiliary hospitals. During 1992/93, 2.7% of the patient population, or 362 individuals, had a primary diagnosis of chronic ulcer of the skin. Of this group, 287 (79%) had a diagnosis of skin ulcer for a period exceeding six months. It is noteworthy however that the 2.7% prevalence of pressure sores in Alberta continuing care facilities suggested by these estimates is significantly lower than those reported in the literature.

Using administrative data bases has inherent limitations. Pressure ulcers are commonly under reported for various reasons. Usually pressure ulcers are not the initial reason for hospitalization, and most patients have additional multiple co-morbidities which physicians regard as higher priority. Even with these limitations and obvious underestimation of prevalence and costs, pressure sore prevention strategies deserve closer consideration.

Discussion

Interface pressure measurement systems offer promise in the management of pressure sores, but at this stage the technology appears to be in need of further development. The role and impact of devices in the clinical setting remain poorly defined. The relationship of interface pressure measurement, including such variables as acceptable time and pressure limits, and the prevention of pressure sores requires further research.

Little information is available on clinical outcome through use of interface pressure measurement systems, so that it is difficult to make judgments as to their effectiveness in the prevention of pressure sores. Moreover, the devices have been seen as useful by a number of centres and integrated into clinical trials and routine practice.

The clinical experience at one facility indicates that the use of pressure measurement systems in service settings offers valuable information and insight to the patient and clinical team. Despite the need for careful implementation of testing protocols and interpretation of results, the technology offers relative quantitative information to compare cushions, qualitative information on pelvic positioning and pressure distribution, and education and feedback to the patient on pressure redistribution or relieving strategies, proper positioning and use of seating devices (Cardi M, personal communication).

The influence of interface measurement systems as compared with other components of care remains unclear. It would be desirable for centres using these devices to develop more rigorous performance measures and to assess the impact of the technology on patient management.

More data are needed on the incidence and management of pressure sores in Alberta. Even though it has been difficult to determine the prevalence and costs of pressure sores, the estimated prevalence rates and costs are sufficiently high to warrant concern.

Appendix A: Methodology

MEDLINE database was searched for the period 1983 to August 1996 using the keywords: “pressure mapping”, “pressure measurement”, “pressure sensing”, “interface pressure”, “decubitus ulcers”, “materials testing”, “equipment design”, “pressure”, and the commercial names of pressure mapping devices, used alone or in combination. Other databases searched included CINAHL (1982 – February, 1995), AHCPR Guidelines (from HSTAT) and Canadian Medical Association Clinical Practice Guidelines. The search was limited to English language and human studies.

Articles were selected if: it was a comparative study of interface measurement systems between an individual and a bed or wheelchair and/or a clinical study.

Appendix B: Comparison of commercial pressure mapping systems

	TALLEY TPM3	FSA	QA	TEKSCAN
Sensor Type	Pneumatic	Conductive elements	Electro-pneumatic	Force sensitive conductive ink
Sensor Size	20 mm diameter	25x25 mm (13x13 mm active area)	25 mm diameter	8x8 mm
Distance Between Sensors	• 28 mm in Matrix • in MAT - 6 cm horizontal - 5.5 cm diagonal	28 mm	25 mm	10 mm
Sensor Configuration	• Single cell(s) • 4.x matrices (8) • 48 sensors in 8.6 array* (Alternate rows are offset)	225 sensors in a 15x15 array	256 in a 16.16 array	2,056 sensors in a 48x43 array
Map Area	• Matrix 10x13 cm • May* 48.5x48.5 cm	51x51 cm	42x42 cm	49x52.5 (Sensing area 43.5x49 cm)
Map Material	• 2 way stretch polyurethane impregnated nylon** • Used as a cushion cover	• Nylon reinforced neoprene rubber mat substrate • Rip stop nylon cover	Soft vinyl	Polyester film (.1 mm thick)
Range	0-246 mm Hg	0-150 mm Hg (for this study) 0-200 mm Hg Higher ranges available	0-300 mm H	0-255 mm Hg
Resolution	1 mm HG	1 mm HG	1 mm HG	1mm HG
Readings	Options for: • Raw • Average over time • Min. over time • Max. over time	• Raw • Smoothed • Printed file includes calculated total force and locus of center of pressure	• Raw • Smoothed	Real time: raw or smooth
Sampling Mode/Operation	Options for: • Manual sample of single cells • Automatic scan • Continuous scan • Sequential scan	Options for: • Instantaneous • Continuous	• Instantaneous	• Continuous with option to freeze • Option for 16 sec. recording, playback, and save • Options to display sum force; or force, or average pressure over selected areas

* Refers to map used in this project. Manufacturer offers option for map customized for size, shape and sensor number and density.

** Newer model uses a stretch polyurethane film.

Source: Reference 9

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