SAWC Fall: The Symposium on Advanced Wound Care, Vol. 19, No. 12, December 2007

Pressure-Sensing Devices for Assessment of Soft Tissue Loading Under Bony Prominences: Technological Concepts and Clinical U

AMIT GEFEN, PHD

Disclosure: This work was supported by grant no. 6418-6 from the Chief Scientist's Office of the Ministry of Health, Israel.

Pressure-related chronic wounds, such as diabetic neuropathic foot ulcers and pressure ulcers, are an important health concern that affect millions of patients and costs billions annually.[1] Studies conducted at multiple centers in the United States indicate that ulcers in the feet of patients with diabetic neuropathy account for $150 million (US) of the direct annual costs of type 2 diabetes. Deep tissue damage requiring amputation costs about $47,000 per individual case.[1] Likewise, the database of the US Centers for Disease Control and Prevention (CDC) indicates that the annual cost of treating pressure ulcers in spinal cord injury (SCI) patients is $1.2 billion in the US alone.[2]

Pressure-related chronic wounds may occur when soft tissues are compressed between bony prominences—eg, the metatarsal heads in the foot or the ischial tuberosities (IT) in the buttocks and a supporting surface (a shoe insole or a wheelchair sitting surface). Injury occurs when the magnitude of the applied mechanical load or time of exposure to the load, or their combination, exceeds the tissue's tolerance, which is commonly referred to as "injury threshold." In such cases, cell death occurs in paths of mechanical breakdown,or ischemic necrosis, or both.[3] Pressure-related chronic wounds rarely develop spontaneously in animals, sometimes limiting utilization of animal models for etiological studies.[4] Accordingly, much of our understanding of these wounds is based on clinical experience[5] that emphasizes a need for objective, quantitative means of measurements of the conditions under which pressure-related chronic wounds develop in humans. Interface pressure data are measures of the spatial and temporal compressive forces per unit area that act on soft tissues contacting a support surface (eg, wheelchair, shoe, etc.). They are basic engineering tools for evaluating the susceptibility of an individual to suffer a pressurerelated wound. Though interface pressure measurements cannot reveal all risk factors for a chronic pressure-related wound (eg, existence of a peripheral vascular disease) they do reflect important biomechanical risk factors, such as loss of tissue thickness that causes higher intensity pressure near bony prominences, foot deformities, regions of callus in plantar tissue, and nonenzymatic glycosylation of collagen that induces stiffening of connective tissues in the plantar foot.[6]

The purpose of this review is to: 1) describe the current techniques for body-support interface pressure measurements with focus on foot and sitting pressures, 2) list the pressure value ranges measured under the foot in standing and walking, under the buttocks in sitting with particular emphasis on abnormal alterations in foot pressures as result of diabetic neuropathy, and alterations in sitting pressures among paralyzed patients, and 3) discuss clinical utilization of interface pressure measurements in the fitting of diabetic footwear and wheelchair cushions.

Role of Interface Pressure Measurements in Prevention of Diabetic Foot Ulcerations and Pressure Ulcers

Diabetic foot ulcers are a common and potentially severe complication of diabetes that affect up to 68 per 1000 patients with diabetes per year in the US.[5] More than half of these patients develop infection while 20% require some form of amputation to remove necrotic tissue.[5] The key risk factors for diabetic foot ulceration include peripheral neuropathy, foot deformity, loss of plantar pad thickness, abnormal stiffening of the foot sole resulting from changes in collagen fiber architecture, and repetitive focal mechanical loads causing micro tears in the plantar pad.[6] It is likely that the prevalence of complications and amputations can be lowered substantially if those patients at risk can be identified and equipped with protective measures, such as customdesigned foot wear. While examinations of the level of sensation in the foot (eg, Semmes-Weinstein filaments) are able to quantify foot neuropathy, they cannot identify specific areas of the foot that are susceptible to ulceration (ie, the filaments are merely used to assess loss of sensation).

Conversely, identifying the specific regions in a patient's foot that are at risk is an initial, basic step before any footwear modification can be made. Foot pressure measurements are able to reveal the highly loaded regions on the foot during static as well as dynamic activities, which then permits a patient-specific footwear prescription so that high focal pressures are relieved. An example of this is if an elevated pressure region is detected below one of the metatarsal heads, a plug made of soft material can be inserted into the shoe midsole at that site causing the shoe to deform more at the region of the plug. This increases the foot-shoe local contact area at the problematic region, which in turn, alleviates the high focal pressures.[7] Interface pressure measurements have the potential of being a highly useful, practical tool for helping to protect diabetic neuropathic patients from ulceration.

Interface pressure measurements are also important in protecting permanent wheelchair users from pressure ulcers. Current pressure ulcer rates are unacceptably high in at-risk populations as up to 23% of all nursing home residents and 60% of persons with SCI develop pressure ulcers.[8] The US Agency for Healthcare Research and Quality (AHRQ) reports a generally lower incidence rate for inpatients (> 11%).[9] Comparably, 54% of these pressure ulcers occur in 70- to 89-year-old hospitalized patients.[9] Surgical repair of buttock ulcers may be more than $70,000 per case, hence, between $3.5 and $7 billion are spent each year in the US on this malady.[8]

The ischial tuberosities, the sacral coccygeal area, and the greater and lesser trochanters and intertrochanteric crests support most sitting pressures. Prolonged sitting by patients with neurological impairment and physical disability can lead to pressure ulcers at these sites since the soft tissues deformed between the bones and wheelchair support are deprived of oxygen and nutrients because of blood vessel obstruction or occlusion. Moreover, muscle atrophy in paralyzed patients reduces the natural cushioning abilities of the buttock's soft tissues, which increases the buttocks-seat interface pressures. Similarly to diabetic foot ulcers, the prevalence andseverity of pressure ulcers in permanent wheelchair users can be substantially decreased if patients at risk are equipped with tailor-made protective means. For example, addition of foams or creating cutouts of cushion material at regions of high focal sitting pressures can redistribute the mechanical loads and improve capillary blood flow in the skin and subdermal tissues.[10] Overall, interface pressure measurements are useful for determining the anatomical sites that require pressure redistribution and for quantifying the extent of improvements achieved by optional interventions.

Technological Concepts

Units. In most of the clinical and engineering literature, pressures are specified using standard international (SI) units so that pressure is the force in Newtons acting over the contact area in square meters.This is the definition of the Pascal (Pa) unit. Foot and sitting pressures are usually reported in kilopascals (kPa, 1 kPa = 1000 Pa). Other units found in the literature for reporting pressures are kg/cm^2, where 100 kPa are approximately 1 kg/cm^2, and millimeters of mercury (mmHg) where 100 kPa are approximately 750 mmHg. All data in this review are provided in kPa as well as in mmHg for standardization and for convenience.

Device configurations. The pressure-sensing devices on the market vary in sensor configuration to meet different applications. For monitoring foot pressures, devices can be generally classified as pressure distribution platforms or in-shoe systems. Pressure distribution platforms can be used for static or dynamic (standing or walking) studies and are made of a flat rigid array of pressure sensing elements arranged in a matrix configuration. Since these matrix sensor configurations need to be embedded in the floor for a natural gait, use of pressure distribution platforms is generally restricted to gait laboratories. For the subject to walk naturally on the pressure platform, and for the foot to hit the center of the pressure-sensing area so that optimal measurements can be taken, training the subjects is usually required. Additionally, pressure distribution platforms can only measure the interaction of the barefoot with a rigid ground, since footwear will cause the platform to measure the pressures between the shoe and ground, not the foot and the shoe. For evaluation of footwear, a commonality in examining patients with diabetes, an in-shoe sensor configuration is needed. This configuration is needed after the regions of high pressures during barefoot gait are identified with a pressure distribution platform. The in-shoe sensors are thin, flexible, and embedded in a thin insole that is inserted under the foot while walking with shoes. Unlike the pressure distribution platforms, which record pressures during a single step, inshoe systems record several subsequent steps and, therefore, statistical analysis of pressure data is more powerful at a shorter study time. In-shoe systems may act at a wireless configuration and/or may be connected to a portable small data-logger that allows monitoring of footshoe pressure distributions at the patient's daily environment while wearing his/her own shoes or some alternative therapeutic shoes. Thus, in-shoe systems can be effective for prescribing the most suitable footwear solution for a patient with diabetes. However, the spatial resolution of pressure data obtained with in-shoe systems is generally lower than when pressure distribution platforms are employed, as fewer sensors are used in the inshoe devices.

Similarly to the foot pressure-sensing devices, sitting pressure measurements can be made with a pressure distribution sitting platform that determines the pressures between the buttocks and a rigid foundation—ie, the platform. Pressures between the patient's buttocks and his/her own wheelchair or wheelchair cushion can be measured with a thin, flexible array of sensors (a pressure mat), which covers the entire sitting area. While the first (rigid) type is used mostly for research purposes— eg, to determine the effect of a pathology (such as SCI) on the sitting pressure distributions in a standard repeatable configuration—the flexible mat is useful in the clinic for evaluating the relative pressure relieving effects of different wheelchair or cushion modifications.

Data and Analysis

Visualization of pressure data is commonly done by means of color-coded diagrams, which show the area of contact (under the foot or buttocks) with regions of high pressure marked using "warm" colors (red or yellow), and regions of low pressure marked using "cold" colors (blue or green). Examples are provided in Figures 1–3. It is also possible to connect points of equal pressure over the contact region by lines, which yields an "isobaric" pressure diagram. Some systems use 3-dimensional topographic maps to visualize pressures, although this format is less popular. The center of pressure, defined as the time-dependent location where the normal force between the body and the supporting surface acts, is shown on the pressure diagram (Figure 3). For presentation and comparison of statistical data from groups ofsubjects, it is generally accepted to use bar graphs plotted at anatomical regions of interest on a scheme of the contact area (eg, the foot, Figure 1A).

Based upon the pressure diagrams, some parameters can be further calculated by pressure analysis software codes. These standard parameters typically include the contact area, the vertical compression force (summation of pressure measured at each sensor multiplied by the sensor's area), the peak pressure, the contact area exposed to pressures exceeding a certain threshold, the average pressure in a circular area of predefined size (under the ischial tuberosity), and the pressure-time integral (area bounded under the pressuretime plot, [Figure 2A]).[11–13] Drerup et al[13] affirmed that a drawback of such analyses is that they require the evaluation of one parameter at a time, which complicates comparative analyses. They suggested use of "pressure dose" graphic representation, which is a rectangle with height proportional to the mean pressure and width proportional to the relative loading time during the stance phase of walking.[13] The area of such square, therefore, indicates the pressure dose applied to the foot during a single step.

All pressure parameters can be calculated for the whole body-support contact area or for specific regions of interest (Figure 1A). Commercial software packages for analysis of foot pressure patterns (eg, the Research Foot software, Tekscan Co., Boston, Mass) or a comparable Novel Co. (Munich, Germany) product employ automatic algorithms for subdividing the foot into anatomical regions of interest for which local pressure parameters are calculat-ed separately. Such parametric analyses are useful for quantitative assessment of pressure data from a patient through a follow-up period or for statistical analyses of pressure data from groups of subjects.

Measurement Techniques

Foot and sitting pressure data are both spatial (pressures are nonuniformly distributed over the contact area),and temporal (local pressures are time-dependent). As emphasized in this review, pressure data are most useful for clinical decision-making if both the spatial and temporal characteristics are acquired simultaneously,and if objective quantification of the pressure magnitudes and exposure times is possible. Simple low-cost pressure measurement methods, such as those that employ ink (the Harris projection device), dye-filled microcapsules, or illumination with fluorescent lights (podoscopes), usually do not allow simultaneous acquisition of spatial and temporal pressure data or do not allow the quantification and storage of the data.[14,15] For example, an ink print of the foot obtained from one stance phase (Harris projection) shows the regions subjected to maximal plantar pressures, yet it cannot provide the exposure times. It is also difficult to quantify the pressure distribution.[14,15] The simultaneous and quantitative acquisition of spatial and temporal pressure data generally requires the utilization of electronic or coupled optical-electronic methods. This review focuses on such methods. Typically, an electronic pressure measurement device includes the pressure sensors embedded in a platform, a sitting mat or an insole configuration, a computer (for data acquisition, display, storage, and analysis), and wired or wireless interface between the sensors and computer. The most common electronic sensor technologies used in body pressure measurements employ capacitance sensors, resistive sensors, piezoelectric and piezoresistive sensors. All of these sensors are able to provide an electronic signal (voltage, current) that is proportional to the pressure applied on the sensor facilitating real-time computerized production of a pressure-time response (Figure 2A). Accumulation of data from multiple sensors allows production of a pressure-time curve from an entire contact surface (eg, under the whole foot or some regions of interest under the buttocks [Figure 2B]).

Capacitance sensors consist of 2 thin, conductive, and electrically charged plates that are separated by an insulating “dielectric” elastic layer. When pressure is applied to the sensor, the dielectric elastic layer deforms, which shortens the distance between the plates and results in a voltage change proportional to the pressure magnitude.[14,15] This technology is currently employed by Novel Co. in its EMED® foot pressure platform, the Pliance® sitting pressure mat, and the Pedar® insole system (Novel Co.)

Resistive sensors measure the resistance of conductive foam encapsulated between 2 electrodes. The electrical current through the resistive sensor increases as the conductive layer deforms under pressure. Force-sensing resistors (FSR), a variation of this technology, are made of a piezoresistive conductive polymer that changes resistance in a predictable manner when subjected to force. The polymer contains both electrically conducting and nonconducting particles (with sizes in the order of fraction of microns) that are suspended in matrix. Applying a force or pressure causes conductive particles to touch each other and the electrodes, thereby increasing the current through the sensor.[14,15] The FSR technology is employed by Tekscan Co. (Boston, Mass) in its MatScan® foot pressure platform, its body pressure measurement system (BPMS™) sitting mat, and the FScan® in-shoe system (Tekscan Co.)

Piezoelectric sensors are based on a physical phenomenon known as piezoelectricity, which is the production of electrical field by certain materials in response to pressure. While quartz and some ceramics have piezoelectric properties and were used in some studies to produce pressure platforms,[15] the most suitable materials for clinically-oriented body pressure measurements appear to be polymers, such as polyvinylidene fluoride (PVDF). This is because polymer-based sensors can be made as thin, flexible, and deformable elements (eg, in-shoe device configurations). A thin layer of metallization is applied to both sides of the polymeric piezoelectric sheet to collect the electrical charge and permit electrical connections.[16]

Piezoresistive sensors are made of semiconductor materials that act as force or pressure sensing resistors in an electrical circuit. Piezoresistivity is a material property of semiconductors where the bulk resistivity is influenced by forces or pressures applied to the material. Hence, when a piezoresistive sensor is unloaded, its resistance is very high, and when a force is applied to the sensor, the resistance decreases. Tekscan Co. employs this technology in its discrete FlexiForce® sensors (Paromed Co., Munich, Germany) in its Parotec® in-shoe system, and by Sensor Products Co. (Madison, NJ) in its Tactilus® sitting mat.

Pressure measurement devices based on each of theabove sensor types can be characterized by their spatial resolution, sampling frequency, accuracy, sensitivity, and ease of calibration.

Spatial resolution refers to the number of sensing elements per unit of area. A sensor size of about 5 mm x 5 mm or less was recommended to avoid underestimation of pressure peaks.[15]

Sampling frequency refers to the number of pressure distribution samples measured by each sensor per second (in cycles per second or hertz [Hz]).A sampling frequency above 50 Hz is considered adequate for walking studies,[14] and a sampling frequency of about 1 Hz is sufficient for monitoring immobilized sitting.[17] *Accuracy* of sensors refers to the error in pressure measurements with respect to the actual physical pressures that are applied. All engineering measurement systems are subject to errors because of electrical component limitations, such as linearity, hysteresis, drift, response time, temperature effects, etc. It is critical for the clinician to be aware of this and to know the measurement error of the system that is being used. *Sensitivity* refers to the sensor's ability to detect very low pressures as a non-zero reading. This may be important if one is trying to quantify foot pressures under the arch of a *pes cavus* foot.

Calibration refers to the process whereby the magnitude of the output signal of the sensor (eg, voltage, current) is related to the magnitude of the actual pressure acting on the sensor. Pressure measurement devices need to be calibrated on a routine basis to ensure that sensors provide a sufficiently accurate reading (ie, small enough measurement errors). This can be done by applying known and uniform pressures on the sensing area by means of weights or air cells for a static or quasi-static calibration, or using material testing machines, pneumatic pistons, or hydraulic cells for a dynamic calibration, and then plotting the sensor's electrical signal readings versus actual pressures.

The technical specifications of pressure measurement sensors vary considerably across manufacturers and depend not only on the technology of the sensor itself, but also on the method of calibration and the performance of the supporting hardware and software. Nevertheless, most up-to-date commercial sensors (regardless of the specific technology used for converting mechanical pressure to an electrical signal) are characterized by nonlinearity and hysteresis effects that are lower than ± 5% of the full pressure measurement scale, repeatability that is lower than ± 3% the full scale and drift that is < 5% the full scale per logarithmic time step.

While capacitance, resistive, piezoelectric and piezoresistive sensors are very useful and perform well in body pressure measurement products, some authors suggest that coupled optical-electronic methods may have the advantages of better sensitivity and faster response time. Specifically, the contact pressure display (CPD) method developed by Arcan and Brull, and later employed in several foot and sitting pressure studies,[18–20] was shown to be able to measure static pressures of less than 10 kPa (75 mmHg; Figure 1C, 1D) and to have a shorter response time with respect to electrical-component- based systems. The CPD method employs a thin sheet of photoelastic material that deforms locally under pressure and depicts circular fringes at the body-support contact sites.[15,18–20] The circular fringes are photographed by means of a video camera, and fringe images are processed automatically to obtain quantitative pressure maps (Figure 1C).[18–20] However, the CPD method requires use of a system of mirrors and cameras, which occupy more physical space than the above reviewed commercial systems,[19] therefore, the CPD may be more suitable for research-oriented tasks where maximal accuracy and sensitivity are desired.

Pressure Value Ranges and Injury Criteria

Standing and walking. Foot pressure studies in the standing posture are generally simpler than dynamic analyses. Most of the literature documents the dynamic pressures under the foot and their evolution throughout the stance phase of gait for evaluating the foot's main function of providing support during locomotion. Thus, only a few studies have gathered static foot pressure data on a sufficiently large, statistical scale to compare normal with diabetic foot peak pressures during standing. Duckworth et al[21] found that peak pressures under the normal foot during standing generally occur at the forefoot region, that pressures increase with age, and that they range from 61 kPa to 108 kPa (458 to 810 mmHg). Minns and Craxford[22] measured an average peak forefoot pressure of 79 kPa (593 mmHg) for 67 standing healthy subjects. Cavanagh et al[23] analyzed 107 normal samples of pressure patterns during barefoot standing and found that the average normal peak pressures under the forefoot are 53 kPa (398 mmHg). The inter-subject coefficients of variation (COV) of peak pressure data (ratio of standard deviation over the mean) were considerable in all these studies ranging from 30%–50%, demonstrating the anatomically-variable structure of normal feet.[21–23] Taken together, these studies showed that average peakforefoot pressures under the apparently normal feet of healthy adults in the standing posture are in the range of ~50 kPa–110 kPa (375 mmHg–825 mmHg).

The dominant characteristic of the pressure distribution under a diabetic foot is the appearance of sites of abnormally elevated pressures. These high-pressure sites, which are usually located under the forefoot, develop while standing and during gait and are the combined effect of neuropathy, foot deformity (eg, clawed toes), loss of plantar tissue thickness, and increased plantar tissue stiffness.[24,25] Specifically during standing peak pressure values of ~130 kPa–140 kPa (975 mmHg–1050 mmHg) were reported to occur under the forefoot of patients with diabetes, with inter-subject COV that are similar to those of normal groups.[26,27] Hence, the substantial inter-subject variability typically observed in the standing posture does not allow the determination of a threshold value to distinguish between normal, patients with diabetes, and patients with diabetic neuropathy who are at risk for foot ulceration.

Dynamic studies provide much more distinct values between normal and patients with diabetes. Peak dynamic pressures under the metatarsal heads and hallux are significantly higher in patients with diabetes even before peripheral neuropathy can be detected.[28] With diabetic neuropathy and/or toe deformity, peak forefoot pressures increase (proportionally to the level of toe deformity) and are reported to be ~400 kPa–1100 kPa (3000 mmHg–8251 mmHg).[29,30] Healthy control subjects show much lower dynamic forefoot pressures of ~250 kPa–500 kPa (1875 mmHg–3750 mmHg).[29,31] Inter-subject COV of dynamic peak pressures are moderately higher than those of static pressure data, and COV of peak pressures from diabetic neuropathic patient groups are typically ~10% higher than that of normal groups.[28–31] For dynamic peak pressures attempts were made to establish injury thresholds, namely 600 kPa–700 kPa (4500 mmHg–5250 mmHg),[32,33] above which a patient should be considered to be at high risk for foot ulceration. Yet, the sensitivity and specificity of such dynamic peak pressure thresholds are moderate—nearly 70% each.[32] An alternative threshold to identify patients at greater risk for ulceration is the ratio of forefoot to rearfoot peak regional pressures, where ratios above 2 indicate high susceptibility to injury (with sensitivity and specificity of 43% and 81%, respectively, for a patient to develop a foot ulcer).[33] The forefoot to rearfoot peak pressure ratio has the advantage of being a dimensionless value and may be less sensitive to the measurement technique, sensor resolution, and calibration procedure. Importantly, the literature on foot pressure measurements as related to diabetes strongly indicates that dynamic studies are superior to static studies, both in distinguishing non-neuropathic from neuropathic diabetic feet, and in identifying patients who are at high risk for foot ulceration.

Sitting. A subject sitting in an upright posture typically shows three main sites of load transfer from the buttock tissues to the sitting surface. Namely, under the two IT and sacrum, with the IT concentrating the majority of loads (Figure 3).[34] Specifically, it has been shown 18% of the body weight is distributed over each IT region in able-bodied sitting subjects.[35] On a rigid sitting surface, the IT of a normal subject concentrate a peak pressure of up to ~40 kPa (300 mmHg) compared to an average of less than 10 kPa (75 mmHg) at other contact regions.[34] In SCI patients sitting on a rigid glass plate, substantially higher mean IT peak pressures of ~120 kPa (900 mmHg) were documented,[36] likely due to loss of muscular tissue thickness. Sitting pressures are strongly influenced by the type of cushioning material at the support surface. Peak sitting pressures under the IT of SCI patients on their wheelchairs equipped with a standard flat-foam cushion were in the range of 20 kPa–30 kPa (150 mmHg–225 mmHg),[37–39] which was only about one-fifth of their IT pressures when sitting on a hard surface.[37] Consistent with findings in studies conducted with rigid sitting surfaces,[38] mean peak IT pressure of SCI patients sitting on a flat-foam cushion was 2.2-fold that of normal controls sitting on the same cushion.[40]

Inter-subject variability of peak IT pressures is reported to be considerable, 6.4 kPa–26 kPa (48 mmHg–195 mmHg),[41] particularly for SCI patients (COV: 53% in SCI patients, 19% in normal controls),[40] which is a difficulty when attempting to set generalized injury thresholds based on peak sitting pressures.[41] Sitting pressures in SCI wheelchair users were also significantly affected by the total patient's weight, total buttocks-to-cushion contact area, the quantity of air in the inflatable cushions, the posture on the cushion, seat and backrest inclination, the footrest setting of the wheelchair, the SCI patients' lower leg length, and the body type (thin or overweight).[11]

Theoretically, prolonged immobilized sitting leads to ulceration if the interface pressures exceed the capillary closing pressure as determined by Landis[42] as 4.3 kPa (ie, 32 mmHg, which is the mean of measurements in the range of 21 mmHg–43 mmHg) in the arteriolar limb.[42] Interface sitting pressures under 4.3 kPa (32 mmHg) are considered by many clinicians to be safe, although thecapillary closing pressure is strongly influenced by age, disease, individual body composition and tissue stiffness, and the blood vessels' ability to respond in a compensatory manner. Obviously, interface pressures under the IT and sacrum are substantially higher, which indicates on the susceptibility of these sites to ulceration, and on the need to change postures frequently for allowing blood perfusion into soft tissues in these regions (Figure 3). Nevertheless, commercial products aimed at reducing or relieving sitting pressures have tended to use the 4.3 kPa threshold as the standard for judging product efficacy.

A mildly higher injury threshold which also considers the exposure time of tissues to the sitting pressures—8 kPa (60 mmHg) for 1 h was employed by Henderson and colleagues.[43] They suggested that tissue ischemia is likely to develop when sitting pressures are higher than 8 kPa and exposure time is longer than 1 h.[43] Based on their work, other researchers used the contact area exposed to pressures more than 8 kPa as a measure of the susceptibility to pressure ulcers.[11,12] A more complete characterization of the allowable pressures versus the time of application (up to 16 hours) was provided by Reswick and Rogers,[44] based on 980 patient observations. Nevertheless, they emphasized in this well-known research that because of inter-subject variability and difficulties in conducting controlled measurements, their pressure-time curve should be taken as a general guidance and not as an absolute threshold.

Recent animal studies suggest that low interface pressures (<4.3 kPa), which are likely to keep capillaries open near the skin according to Landis,[42] can still cause ulceration in deeper soft tissues adjacent to bony prominences during long exposure periods (more than 1 h). This is a result of intensified mechanical loads that develop in the soft tissues around bony prominences during weight bearing. This is particularly true for the gluteus muscles where mechanical loads under the IT during sitting can be an order of magnitude greater than the interface pressures of sitting.[45–47]

Clinical Utilization

There are two important applications of pressure measurements in the clinical setting.First, pressure measurements provide feedback to the insensitive patient, eg, as means of educating patients with diabetic neuropathy to examine their feet regularly at locations subjected to high pressures, or in order to make paraplegic wheelchair users aware of their susceptibility to pressure ulcers and to encourage them to change postures frequently or perform "lift offs" (ie, lift the body off the wheelchair by pushing arms against the armrests). Hence, the ability to visualize the focal pressures under the foot or buttocks as easy-to-read,color-coded diagrams facilitates patient training and education. Secondly, pressure measurements allow optimal, tailor-made fitting of support and protective surfaces, such as shoes, shoe modifications, and cushions to the individual.

There is substantial supportive evidence in the literature that pressure-sensing devices help prevent foot ulceration.[7,48–50] The aim in using diabetic footwear is for offloading, to lower focal plantar pressures on foot regions either at risk for ulceration or are healing from an existing ulcer. Offloading a foot with an existing ulcer can be achieved in different ways, but the most effective appears to be a total contact cast (TCC), generally considered the "gold standard" against which other methods of offloading a healing ulcer are evaluated.[48] Hence,using in-shoe foot pressure measurements under the cast,TCCs have been found to reduce peak forefoot pressures by nearly 85%.[49] Other devices were shown to have less offloading effect but allow for more foot mobility. Half of the shoes reduce peak forefoot pressures by ~65%, felt or foam shoes by ~48%,rocker bottom shoes by ~37%–57%, and running shoes by ~19%–38%.[50–52] Alternatively, the patient's shoes can be modified to relieve locally elevated pressures detected during an in-shoe pressure mapping study. Specifically, circular or elliptical soft plugs can be inserted into holes in the midsole at the most highly loaded locations according to pressure mapping.[7] The plugs are made of a material that is softer than the surrounding midsole material, which allows increased deformation of the footwear in the areas of high pressure.The local forefoot pressure reduction was found to be up to 45%.[53] Importantly, selection of the specific offloading footwear can be supported by quantitative, objective analysis of the individual foot pressures that may be compared to injury criteria discussed above regarding each alternative footwear type. While the final selection of footwear is subject to the patient's comfort and preferences, utilization of in-shoe pressure measurements in the decision-making process allows a scientific yet practical approach to diabetic footwear prescriptions in the clinic setting.

Higher sitting pressures were shown to be a predictor of sitting-acquired pressure ulcers.[54] This motivated the establishment of pressure ulcer prevention clinics, where patients are educated shortly after paralysis occurs, to understand the effect that immobility and pos-tural changes induce on the sitting pressure distribution.[55,56] For example, patients can be trained to avoid loading asymmetries, such as leaning on one side for prolonged periods after they observe elevated pressures that are induced in such postures (Figure 3B). In relation to the process of patient training, active engagement of patients in the pressure measurements while directing their attention to the effect of posture is highly beneficial in reducing ulcer risk.[56]

Additionally, alternative wheelchair cushions can be evaluated, prescribing the one that is most effective in reducing sitting pressures since individual response to different cushions vary considerably across wheelchair users.[57] Based on sitting pressure measurements, a cushion is selected to maximize the individual's contact surface area, which will lower the peak sitting pressures under the IT as well as the pressures at any other location. Accordingly, sitting pressure measurements generally show that sitting on contoured foams, which are tailor-made to the individual, results in significantly lower pressure distributions versus sitting on flat foams. Sitting on soft foams resulted in lower pressure distributions than sitting on stiffer foams.[58] For example, tailor-made contoured cushions reduced peak IT pressures in a group of 30 elderly patients by ~24% in respect to flat cushions.[59] The prescribed cushion should be matched to the patient's preference and lifestyle. Given these considerations, a sitting pressure measurement can provide the objective quantitative data needed to decide between alternatives. Likewise, some changes to the wheelchair configuration, like the footrest height, can be made with the goal of lowering focal sitting pressures. Cutouts can be made in cushions to redistribute local elevated pressures under the IT or sacrum regions. Inflation pressure of adjustable cushions can also be adjusted.[11,59,60] It was shown that patient-specific optimization of the inflation pressure of a ROHO® cushion (The ROHO Group, Belleville, Ill) can decrease peak IT pressures by as much as ~60%.[12] Overall, pressure ulcer prevention clinics that utilize these approaches were shown to be effective in reducing the prevalence and severity of injury occurrences.[55,56,60]

Conclusion

Body-support pressure measurement systems should be considered a practical tool for protecting insensitive patients from diabetic foot ulcers and sitting-acquired pressure ulcers. The computerized pressure-sensing devices currently available on the market are most suitable for the clinical applications listed above, since they provide real-time quantitative and objective feedback to the clinicians, which allows on the spot decision-making during patient evaluation.

References:

1. Centers for Disease Control and Prevention. The Economics of Diabetes Mellitus: An Annotated Bibliography. Available at: http://www.cdc.gov/diabetes/ pubs/economics.Accessed: November 26, 2007. 2. Centers for Disease Control and Prevention. SCI Fact Sheet. Available at: http://www.cdc.gov/ncipc/factsheets/scifacts.htm.Accessed: November 26, 2007. 3. Linder-Ganz E, Engelberg S, Scheinowitz M, Gefen A. Pressure-time cell death threshold for albino rat skeletal muscles as related to pressure sore biomechanics. J Biomech. 2006;39(14):2725–2732. 4. Mustoe TA, O'Shaughnessy K, Kloeters O.Chronic wound pathogenesis and current treatment strategies: a unifying hypothesis. Plast Reconstr Surg. 2006;117(7 Suppl):35S–41S. 5. Wu S,Armstrong DG. Risk assessment of the diabetic foot and wound. Int Wound J. 2005;2(1):17–24. 6. Gefen A. Plantar soft tissue loading under the medial metatarsals in the standing diabetic foot. Med Eng Phys. 2003;25(6):491–499. 7. Brill LR, Cavanagh PR, Doucette MM, Ulbrecht JS. Prevention, protection and recurrence reduction of diabetic neuropathic foot ulcers. In: Treatment of Chronic Wounds. East Setauket, NY: Curative Technologies Inc; 1994. 8. Kuhn BA, Coulter SJ. Balancing the pressure ulcer cost and quality equation. Nurs Econ. 1992;10(5):353–359. 9. Joseph V. Agostini JV, Baker DI, Bogardus ST Jr. Prevention of Pressure Ulcers in Older Patients. In: Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Available at: http://www.ahrq.gov/CLINIC/PTSAFETY/chap27.htm. Accessed: November 26, 2007. 10. Peterson MJ,Adkins HV. Measurement and redistribution of excessive pressures during wheelchair sitting. Phys Ther. 1982;62(7):990–994. 11. Tanimoto Y, Takechi H, Nagahata H, Yamamoto H. The study of pressure distribution in sitting position on cushions for patient with SCI (Spinal Cord Injury). IEEE Trans Rehab Eng. 1998;47(5):1239–1243. 12. Hamanami K, Tokuhiro A, Inoue H. Finding the optimal setting of inflated air pressure for a multi-cell air cushion for wheelchair patients with spinal cord injury. Acta Med Okayama. 2004;58(1):37–44. 13. Drerup B, Kraneburg S,Koller A. Visualisation of pressure dose: synopsis of peak pressure, mean pressure, loading time and pressure-time-integral. Clin Biomech. 2001;16(9):833–834. 14. Orlin MN, McPoil TG. Plantar pressure assessment. Phys Ther. 2000;80(4):399–409. 15. Urry S. Plantar pressure-measurement sensors. Meas Sci Technol. 1999;10(1): R16–R32. 16. Nevill AJ, Pepper MG, Whiting M. In-shoe foot pressure measurement system utilising piezoelectric film transducers. Med Biol Eng Comput. 1995;33(1):76–81. 17. Linder-Ganz E, Scheinowitz M, Yizhar Z, Margulies SS, Gefen A.How do normals move during prolonged wheelchair- sitting? Technol Health Care. 2007;15(3):195–202. 18. Gefen A, Megido-Ravid M, Itzchak Y, Arcan M. Biomechanical analysis of the three-dimensional foot structure during gait: a basic tool for clinical applications. J Biomech Eng. 2000;122(6):630–639. 19. Gefen A. Biomechanical analysis of fatigue-related foot injury mechanisms in athletes and recruits during intensive marching. Med Biol Eng Comput. 2002;40(3):302–310. 20. Arcan M, Brull MA. A fundamental characteristic of the human body and foot, the foot-ground pressure pattern. J Biomech. 1976;9(7):453–457. 21. Duckworth T, Betts RP, Franks CI, Burke J. The measurement of pressures under the foot. Foot Ankle. 1982;3(3):130–141. 22. Minns RJ, Craxford AD. Pressure under the forefoot in rheumatoid arthritis.A comparison of static and dynamic methods of assessment. Clin Orthop Relat Res. 1984;187:235–242. 23. Cavanagh PR, Rodgers MM, Iiboshi A. Pressure distribution under symptom-free feet during barefoot standing. Foot Ankle. 1987;7(5):262–276. 24. Gefen A, Linder-Ganz E. [Diffusion of ulcers in the diabetic foot is promoted by stiffening of plantar muscular tissue under excessive bone compression]. Orthopade. 2004;33(9):999–1012. [Article in German]. 25. Gefen A, Megido-

Ravid M, Azariah M, Itzchak Y, Arcan M. Integration of plantar soft tissue stiffness measurements in routine MRI of the diabetic foot. Clin Biomech (Bristol, Avon). 2001;16(10):921–925. 26. Duckworth T, Boulton AJ, Betts RP, Franks CI,Ward JD. Plantar pressure measurements and the prevention of ulceration in the diabetic foot. J Bone Joint Surg Br. 1985;67(1):79–85. 27. Kato H,Takada T, Kawamura T, Hotta N,Torii S.The reduction and redistribution of plantar pressures using foot orthoses in diabetic patients. Diabetes Res Clin Pract. 1996;31(1-3):115–118. 28. Pataky Z, Assal JP, Conne P, Vuagnat H, Golay A. Plantar pressure distribution in Type 2 diabetic patients without peripheral neuropathy and peripheral vascular disease. Diabet Med. 2005;22(6):762–767. 29. Bus SA, Maas M, de Lange A, Michels RP, Levi M. Elevated plantar pressures in neuropathic diabetic patients with claw/hammer toe deformity. J Biomech. 2005;38(9):1918–1925. 30. Abouaesha F, van Schie CH, Griffths GD, Young RJ, Boulton AJ. Plantar tissue thickness is related to peak plantar pressure in the high-risk diabetic foot. Diabetes Care. 2001;24(7):1270–1274. 31. Pitei DL, Lord M, Foster A,Wilson S,Watkins PJ, Edmonds ME. Plantar pressures are elevated in the neuroischemic and the neuropathic diabetic foot. Diabetes Care. 1999;22(12):1966–1970. 32. Armstrong DG, Peters EJ, Athanasiou KA, Lavery LA. Is there a critical level of plantar foot pressure to identify patients at risk for neuropathic foot ulceration? J Foot Ankle Surg. 1998;37(4):303–307. 33. Caselli A, Pham H, Giurini JM,Armstrong DG,Veves A.The forefoot-to-rearfoot plantar pressure ratio is increased in severe diabetic neuropathy and can predict foot ulceration. Diabetes Care. 2002;25(6):1066–1071. 34. Brosh T,Arcan M. Modeling the body/chair interaction— an integrative experimental-numerical approach. Clin Biomech (Bristol, Avon). 2000;15(3):217–219. 35. Drummond DS, Narechania RG, Rosenthal AN, Breed AL, Lange TA, Drummond DK. A study of pressure distributions measured during balanced and unbalanced sitting. J Bone Joint Surg. 1982;64(7):1034–1039. 36. Thorfinn J, Sjoberg F, Lidman D. Sitting pressure and perfusion of buttock skin in paraplegic and tetraplegic patients, and in healthy subjects: a comparative study. Scand J Plast Reconstr Surg Hand Surg. 2002;36(5):279–283. 37. Gutierrez EM, Alm M, Hultling C, Saraste H. Measuring seating pressure, area, and asymmetry in persons with spinal cord injury. Eur Spine J. 2004;13(4):374–379. 38. Ferrarin M, Andreoni G, Pedotti A. Comparative biomechanical evaluation of different wheelchair seat cushions. J Rehabil Res Dev. 2000;37(3):315–324. 39. Tanimoto Y,Takechi H,Nagahata H,Yamamoto H.Pressure measurement of air cushions for SCI patients. IEEE Trans Rehab Eng. 2000;49(3):666–670. 40. Aissaoui R, Kauffmann C, Dansereau J, de Guise JA.Analysis of pressure distribution at the body-seat interface in able-bodied and paraplegic subjects using a deformable active contour algorithm. Med Eng Phys. 2001;23(6):359–367. 41. Swain D,Peters E.The effects of posture,body mass index and wheelchair adjustment on interface pressure. Medical Device Agency.UK Eval Rep.(MDA 97/20),1997. 42. Landis E. Micro-injection studies of capillary blood pressure in human skin. Heart 1930;15:209–228. 43. Henderson JL, Price SH, Brandstater ME, Mandac BR. Efficacy of three measures to relieve pressure in seated persons with spinal cord injury. Arch Phys Med Rehabil 1994;75(5):535–539. 44. Reswick JB, Rogers JE. Experience at Rancho Los Amigos Hospital with devices and techniques to prevent pressure sores. In: Kennedy RM, Cowden JM, Scales JD, eds. Bedsore Biomechanics. London, UK: Macmillan; 1976: 301–310. 45. Linder-Ganz E, Shabshin N, Itzchak Y, Gefen A.Assessment of mechanical conditions in sub-dermal tissues during sitting: a combined experimental-MRI and finite element approach. J Biomech. 2007;40(7):1443–1454. 46. Gefen A, Gefen N, Linder–Ganz E, Marqulies SS. In vivo muscle stiffening under bone compression promotes deep pressure sores. J Biomech Eng. 2005;127(3):512–524. 47. Linder-Ganz E,Gefen A.Mechanical compression-induced pressure sores in rat hindlimb:muscle stiffness, histology, and computational models. J Appl Physiol. 2004;96(6):2034–2049. 48. Beuker BJ, van Deursen RW, Price P, Manning EA, van Baal JG, Harding KG. Plantar pressure in offloading devices used in diabetic ulcer treatment. Wound Repair Regen. 2005;13(6):537–542. 49. Shaw JE, Hsi WL, Ulbrecht JS, Norkitis A, Becker MB, Cavanagh PR. The mechanism of plantar unloading in total contact casts: implications for design and clinical use. Foot Ankle Int. 1997;18(12):809–817. 50. Fleischli JG, Lavery LA, Vela SA, Ashry H, Lavery DC. Comparison of strategies for reducing pressure at the site of neuropathic ulcers. J Am Podiatr Med Assoc. 1997;87(10):466–472. 51. van Schie CHM, Boulton AJM. The effect of arch height and body mass on plantar pressure. WOUNDS. 2000;12(4):88–95. 52. Perry JE, Ulbrecht JS, Derr JA, Cavanagh PR. The use of running shoes to reduce plantar pressures in patients who have diabetes. J Bone Joint Surg Am. 1995;77(12):1819–1828. 53. Erdemir A, Saucerman JJ, Lemmon D, et al. Local plantar pressure relief in therapeutic footwear: design guidelines from finite element models. J Biomech. 2005;38(9):1798–1806. 54. Brienza D, Karg PE,Geyer MJ,Kelsey S,Trefler E.The relationship between pressure ulcer incidence and buttockseat cushion interface pressure in at-risk elderly wheelchair users. Arch Phys Med Rehabil. 2001;82(4):529–533. 55. Dover H, Pickard W, Swain I, Grundy D.The effectiveness of a pressure clinic in preventing pressure sores. Paraplegia. 1992;30(4):267–272. 56. Coggrave MJ, Rose LS.A specialist seating assessment clinic: changing pressure relief practice. Spinal Cord. 2003;41(12):692–695. 57. Ragan R, Kernozek TW, Bidar M, Matheson JW. Seat-interface pressures on various thicknesses of foam wheelchair cushions: a finite modeling approach. Arch Phys Med Rehabil. 2002;83(6):872–875. 58. Sprigle S, Chung KC, Brubaker CE. Reduction of sitting pressures with custom contoured cushions. J Rehabil Res Dev. 1990;27(2):135–140. 59. Brienza DM, Krag PE, Brubaker CE. Seat cushion design for elderly wheelchair users based on minimization of soft tissue deformation using stiffness and pressure measurements. IEEE Trans Rehabil Eng. 1996;4(4):320–327. 60. Swain I.The measurement of interface pressure. In: Bader DL, Bouten C, Colid D, Oomens C, eds. Pressure Ulcer Research: Current and Future Perspectives. Berlin, Germany: Springer; 2005: 51–72. 61. Gefen A. Stress analysis of the standing foot following surgical plantar fascia release. J Biomech. 2002;35(5):629–637.