

A skin indentation system using a pneumatic bellows

Martin Ferguson-Pell, PhD; Satsue Hagsisawa, RN, BS; Robert D. Masiello

Center for Rehabilitation Technology, Helen Hayes Hospital, West Haverstraw, NY 10993-1195.

Editor's Note:

This paper is intended to compliment the first paper in this issue and satisfy those readers who are interested in more in-depth specifics of the design details of the skin indentation system.

The Editor

Abstract—A pneumatic indentation system using a copper bellows has been developed for physiological studies where a controlled uniaxial compressive force is required to be applied to the surface of the skin. Such a system is useful for studies where the physiological response of the tissues is to be monitored following a known loading history.

The indentation system is driven by a vacuum/compression pneumatic pump through solenoid valves under closed-loop computer control. A load cell placed between the indenter and bellows monitors the applied force providing a feedback signal to the computer. The signal from the computer activates the valves supplying air pressure to the bellows, and the applied force is controlled using a digital closed-loop protocol.

This system can be used to provide a controlled loading sequence to the skin without utilizing gravitational forces, which allows the subject to keep a more natural position during the experiment.

Key words: *indentation, pneumatic bellows, pressure sore, skin.*

INTRODUCTION

Pressure sores are a serious complication of many people with physical disabilities. It is generally accepted that externally applied pressure to the tissue is a primary causal factor in generating ischemia which, if prolonged, can lead to the development of pressure sores. Most sores probably result from repeated ischemic insults without adequate time for total tissue recovery. The critical determinants of pressure sore formation are the intensity and duration history of applied pressure coupled with multiple secondary factors (malnutrition, loss of sensation, etc.). It is believed that the relationship between the magnitude and duration of pressure to develop pressure sores is inversely correlated (1–4).

Various experimental protocols using mechanical indentation systems have been developed to investigate the effect of pressure on tissue viability (1,3,5,6). Particularly important is the need to independently control shear and uniaxial compression forces since Dinsdale (7) and Bennett, et al. (8) have found that peripheral blood flow is occluded at lower uniaxial compressive forces when applied in the presence of shear stress. Bader, et al. (9) have also emphasized the potentially damaging effects of tangential forces on the integrity of dermal vasculature.

Address all correspondence and requests for reprints to: Martin Ferguson-Pell, PhD, Center for Rehabilitation Technology, Helen Hayes Hospital, Route 9W, West Haverstraw, NY 10993-1195.

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A number of techniques have been reported which apply forces perpendicularly to the skin surface and have been used for experiments studying pressure sore etiology. They include: counterbalanced beams (5,10-12); air-driven piston syringes (3,13); air-driven pistons (14,15); an air cushion between the skin and supporting materials (6); an air balloon in a chamber (16); counterbalanced beam and servo control system (17); and a servomotor-driven indenter (1,18,19). Each technique has different limitations. The counterbalanced beam system is only suitable for forces applied vertically utilizing the gravitational force. The air-driven piston system has an inherent frictional breaking force that, in currently available commercial devices, (for example, typical breaking force for a Bimba 014-DXDE, Monee IL 3/8-inch i.d. pneumatic piston is 0.9 N) and results in difficulties in controlling the applied force precisely, especially at lower pressures. The air balloon system only works successfully on extremities or small animals where the apparatus can encompass the loaded site. The servomotor-driven indenter has the advantage of being capable of having a rapid response time, but is less easy to manipulate and position in clinical studies.

Most high-risk areas for pressure sores in the human are over bony prominences of the trunk: the sacrum, ischial tuberosities, and trochanters. These sites are sometimes difficult to access as the testing site unless the subject can assume an uncomfortable position, often for a prolonged period of time.

Indentation systems can be designed to provide either force control or deformation control (whereupon adjustment of the indenter may have to be made to accommodate creep or stress relaxation, respectively, in the soft tissues). Selection of the control parameters depends upon the nature of the loading conditions being simulated in the experiment, or the physiological model being tested.

Specifications for applying controlled forces to the tissues in a typical experimental protocol should include:

1. Provision for maintaining a predetermined constant axial force at the skin surface. Skin is a viscoelastic material resulting in creep under constant loading conditions. Some compensative mechanism is necessary to maintain constant applied force during loading. In this regard a feedback system is preferable.

2. The design should ensure that the force can be applied to any area or region of the body while the subject assumes a natural, comfortable posture. To minimize discomfort, the force must be applicable from any angle or direction.
3. The indentation system should be capable of maintaining a constant axial force if a body movement occurs, and should adjust to any body movement that may induce off-axis force (e.g., due to translational or angular movement).
4. The technique should be safe, low cost to develop, and easy to use, assuming the availability of basic data acquisition systems.

DEVELOPMENT OF THE BELLOWS INDENTATION SYSTEM

Based on the specifications described above, a computer-controlled bellows indentation system has been developed. **Figure 1** shows a schematic diagram of the bellows-indentation system. The indentation system consists of: 1) a copper bellows which weighs 50 g and measures 50 mm (outer diameter) (1E297, Standard-Thomson Co.); and 2) a 44.6 N capacity load cell which weighs 10 g and measures 18 mm in diameter with both sides threaded (ELF-1000, Entrans International) placed between the bellows

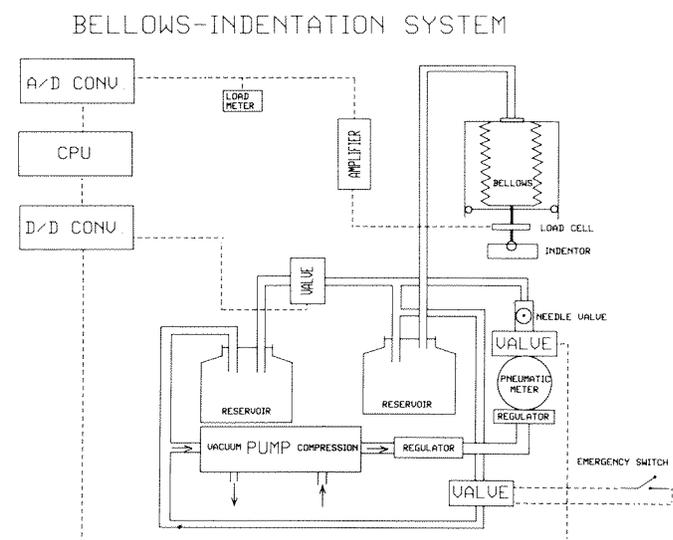


Figure 1. Schematic diagram of bellows-indentation system.

and a plastic cylindrical indenter (cross-sectional area: $2.5 \times 10 \text{ m}^2$). The extension/compression of the bellows is pneumatically controlled by a computer which controls the operation of solenoid valves (04F20C2118AAFGC01, Parker) for vacuum (-16.93 kPa) and compressed air (3.45 kPa) produced by a pump (2107CA18-3, Thomas). The load cell provides negative feedback control for the system, so that a predetermined sequence of loads is applied and maintained.

The copper bellows is relatively light (50 g) and is therefore easy to apply even in the horizontal direction (Figure 2). The bellows indenter provides a displacement range of approximately 50 mm in extension/compression and operates smoothly when starting the indentation. To control the direction of the force, a transparent hollow cylinder surrounds the bellows and four small wheels attached to the edge of bellows move along the inside surface of the cylinder, both of which act to stabilize the bellows during loading. To protect the load cell from any off-axis forces, a ball-and-socket joint is provided at the interface between the load cell and plastic indenter. It should be noted that the flexibility of the bellows is limited, and in combination with the use of the ball-and-socket joint, does not substantially decouple shear stresses to the skin. The bellows indenter is attached to a free-arm stand which provides sufficient flexibility to apply forces to the most areas of the body.

The analog output signal of the load cell is amplified with an amplifier (Accudata 113 Bridge

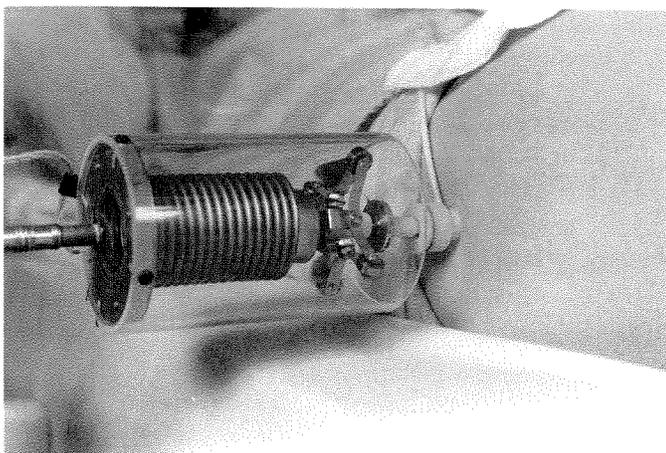


Figure 2. Bellows-indenter when it is applied to the skin of trochanter perpendicularly.

Amplifier, Honeywell) and transmitted to an A/D converter (Module 5712, Tecmar Inc.) interfaced to a personal computer (PC 386SX, 16 MHz). A data acquisition software package (Labtech Notebook, Laboratory Technologies Co.) sampling at 10 Hz is configured as a “bang-bang” closed-loop system for controlling the applied force. The DC control signal coming from the computer is amplified and converted to 24 V AC to activate the solenoid valves of the pneumatic circuits.

PERFORMANCE OF THE BELLOWS INDENTOR

Prior to loading the tissue, the valve controlling the vacuum is energized providing negative pressure to the bellows so that the bellows is retracted and the indenter does not contact the skin. To initiate loading, the vacuum valve is de-energized while the compression valve is energized to attain the desired load level. The internal bellows pressure becomes more positive resulting in an extension of the bellows. The response time from the onset of activation of the compression valve to reaching the required force level (4 N) is 5 seconds in total: 2 seconds for making contact with the surface of the skin and 3 seconds to reach the required load level. The speed of loading to attain the required level is carefully determined by tuning a needle valve to prevent overshoot and system instability. Once the output of the load cell amplifier attains the specified level, the constant force is maintained by “on-off” activation of the compression valve. Figure 3 shows

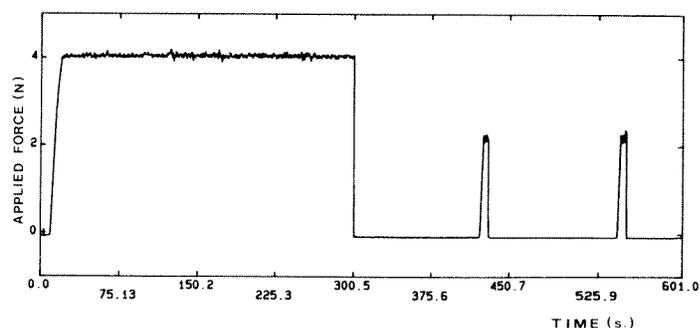


Figure 3. Typical result for force application to the skin using bellows-indentation system. The test protocol of indentation represented is 5-minutes indentation with a force of 4 N followed by 5-seconds blanching with a force of 2.1 N every 2 minutes.

a typical result for force application to the skin using this system. The stability of this system during loading is ± 1 percent. The operating range for applied forces, which can be controlled with good stability in this system, is 0.8 N to 8 N. If the subject makes a body movement during loading, thereby producing a change in the applied force of over 0.5 N, both vacuum and compression valves act appropriately to return to the required level. The maximum time for readjustment of the force is 4 seconds. After loading, the vacuum valve is energized again to return to the nonloading condition while the compression valve is closed.

To determine the effect of off-axial forces on the output of the transducer, tangential forces were applied to the indenter surface with the bellows and force transducer oriented horizontally. To limit the output error signal attributable to the off axis load to less than 5 percent of the applied axial load, the tangential force must be less than 10 percent of the applied load. Alternatively, if the indenter is tilted off-vertical while applying the axial load, to keep applied shear forces to less than 5 percent of the axial load, the maximum angle of tilt is 5° off vertical. By using alternative bellows materials, the increased flexibility in the bellows would accommodate larger off-axis loading angles with the same constraints on shear forces applied to the tissues.

DISCUSSION

A bellows-indentation system has been developed to monitor the reactive hyperemia response following localized ischemia. Indentation systems are frequently used for two types of study: 1) those that seek to apply a prescribed occlusive force to the tissue for a specified duration and then measure the post-occlusion response; and 2) those that seek to simultaneously monitor the relationship between applied force and tissue perfusion parameters such as blood flow velocity (e.g., using laser Doppler flowmetry) or tissue oxygenation (e.g., using reflectance spectrophotometry or transcutaneous pO_2).

For some studies, the shape of the indenter should be carefully designed because indenter shape significantly influences edge-effect stresses and blood entrapment under the indenter. Hemispherical indentors can reduce highly localized stresses at

the edge of the indenter as pointed out by Schock, et al. (20).

Performance tests using this system demonstrate that it provides good stability (± 1 percent) while maintaining a constant force using the computer-controlled feedback system during indentation. The system can also be applied to most areas of the body without postural discomfort to the subject.

The rate of loading is slow compared with servomotor systems, but for many studies of this type is acceptable. The response time of the system is determined by a number of factors associated with the pneumatic circuit, but most critically by the switching time of the servo valves. If a more rapid response is required, a minor design modification to the control system should be made by using proportional control valves rather than the on-off servo valves used in the system described here.

Other advantages for the clinical use of the system include the fact that it does not need to provide electrical power and mechanical gearing systems close to the subject, which reduces the risk of injury in the event of a malfunction. The indentation apparatus is very simple to disassemble for cleaning and can be readily sterilized if necessary.

In practical situations, the indenter may experience body movements during indentation comprising vertical, translational, and rotational components. This system can accommodate the vertical movement by readjustment of the bellows pressure to maintain the prescribed load. However, this system does not accommodate translational movements that tilt the indenter to more than 5° off vertical or non-axial rotational movements.

Bi-axial load cells are available which could be used to measure off-axis forces caused by surface movement. The incorporation of biaxial load cells for studies involving the physiological effects of occlusive forces is desirable to ensure that the exact loading conditions experienced by the tissues are known.

The computer-controlled indentation system described here provides a tool for force application in experimental protocols for pressure sore and related studies, especially in situations that need to accommodate for the comfort and position of the human subject. The system meets specifications 1, 2, and 4 outlined in the introduction, but in the present

configuration does not meet the specification for decoupling off-axis loads. In experimental situations where this specification is important, it is likely that the use of highly flexible bellows material, such as polyurethane, will reduce this problem.

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