Development of a low profile laser Doppler probe for monitoring perfusion at the patient – mattress interface

Dr Jon Cobb & Dr Glyn Hadley

Smart Technology Research Group, School of Design Engineering and Computing, Bournemouth University.

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Abstract
The clinical importance of pressure ulcers is reviewed confirming the need for continuous monitoring of skin blood perfusion at the patient – mattress interface. The design of a low profile (H≈1mm) laser Doppler probe is then described together with the experimental setup used for evaluation. The results show that the performance of the new sensor does not vary significantly from that of currently available probes over a wide range of operating parameters. The authors conclude that the sensor design provides a low cost perfusion monitoring solution with potential to significantly reduce the risk of bed sores in hospital patients.

Introduction
Pressure ulcers result from localised damage to skin tissue due to external physical forces, such as, load, shear, friction and moisture. In the UK, NHS estimates indicate that between 4% and 10% of all patients admitted to hospital will develop a pressure ulcer RCN (2005). A study by Bennet et al. (2004) estimated that the cost of treating pressure ulcers in the UK was 4% of the NHS annual budget equivalent to £1.4–£2.1 billion per annum. In the majority of cases, the prognosis is good provided that adequate nursing care is administered. This typically includes pressure relief through frequent patient turning and application of topical dressings to reduce infection. However, a significant number of patients with reduced mobility i.e. spinal cord injuries, the obese and elderly patients will experience substantial breakdown of tissue. Consequently, there is a significant risk of complications including sepsis and gangrene that may require extensive treatment and in severe cases surgery.

Various techniques exist to reduce the risk of pressure ulcers, for example, pressure relief mattresses are widely used in hospitals to provide dynamic cushioning for ‘at risk’ patients. However, the cost of these systems can be prohibitive and many pressure sores still occur in patients recuperating in standard hospital beds following routine surgery. Thus there is a need to monitor physiological conditions at the skin/mattress interface and indicate when nursing intervention is required. This paper describes the design of a medical device to satisfy this need. The sensor incorporates tissue monitoring technologies to simultaneously measure blood perfusion, load and temperature. The key novel development is the implementation of a low cost disposable sensor with a height of 1mm. The low profile enables monitoring at the patient/mattress interface without the sensor introducing locally elevated pressures that could put tissue at risk. This paper describes the design of the sensor and discusses the method of in vitro characterisation.

Materials and Methods

Construction

The coupling mechanism at the skin interface is a prism terminated waveguide of dimensions L=20mm and W=15mm which was machined from optical grade polycarbonate with thickness of 1mm (±0.1mm) and optical transmission ≥ 85% @ λ=780nm. Following experimentation to determine optimum coupling, the angle of the reflecting surface was set at 30° (±0.5°) to the skin contact plane. All surfaces of the waveguide were then polished using a grit free plastic polishing fluid. Graded index plastic (PMMA) optical fiber (120µm core / 500µm O.D.) with low attenuation (<35db/Km) throughout the near infrared spectrum was cut to lengths of 500mm. Nine such fibers were aligned in parallel onto the adhesive side of a piece of insulating tape to form a flat ribbon. The ends of the fibers were held fast in a polishing block and finished with a 3µm abrasive sheet and grit free polishing fluid. An inspection microscope was used to manually assess the quality of the finish. A reference laser diode set at 1mW output power @780nm was coupled via a collimated translation stage into each fiber and the output power was measured using an optical power meter at the distal end. The polishing procedure was repeated until the power loss was less than 10% in each fiber. The flat fiber array was then located proximal to the end of the waveguide using a translation stage to achieve alignment within ±0.1mm. An optical matching adhesive (Norland NOA68 n=1.54) was used as the bonding agent between one end of the fiber array and the flat end of the waveguide.

The array of nine fibers comprised four emitters interleaved with five detectors. At the end distal to the waveguide the emitting fibers and the detection fibers were separately bundled and bonded into a neoprene sleeve using an acrylic expoxy resin. The emitter fibers were abutted to the output window of a 780nm 5mW laser diode (QL78D6SA) which was controlled by a thermoelectric cooler. The five detection fibers were similarly bundled into a sleeving and the ends were cleaved and polished. A manual translation stage with 50nm resolution was used to couple backscattered light into a 400um glass optical fiber via a collimator and ball lens. The output of the 400um fiber was then coupled to the detection window of a single channel laser Doppler detection system (VMS-LDF Moor Instruments UK).

A polycarbonate slip L=30mm, W=20mm was located above the flat fiber array proximal to the waveguide and bonded using expoxy resin. This provided a flat surface onto which a force sensing resistor (Ø=14mm, H=0.25mm) was located together with two thin film thermistors (ATC Semitec JT series). Electrical connection was made by soldering wrapping wire (30awg) to the FSR and thermistors. The whole construction was then thermally laminated using an acetal film to provide a rigid structure with height 1mm. Standard operational amplifier circuits were used to interface the FSR and thermistors to a data acquisition system. The construction of the sensor is shown in figure 1 and the configuration of the characterisation system in figure 2. Photograph 1 shows a partially constructed sensor illustrating the FSR mounted on the waveguide. Photograph 2 shows the arrangement of the fibers.

Calibration and evaluation testing

Baseline calibration of the laser Doppler system was performed based upon Brownian motion of polystyrene micro-spheres in water using a reference standard provided by the manufacturer (PFS Flux standard, Moor Instruments). The response of the system was investigated using a syringe pump to provide varying flow rates from 1mm.s^{-1} to

10mm.s^{-1} of the motility standard through transparent silicone tubing. The sensor was positioned perpendicular to the wall of the tube and the system was physically isolated to prevent vibration coupling from the pump motor. The calibration measurement temperature was maintained constant at 20°C (±1°C). The response of the system to different fractions of the reference standard was also evaluated by dilution with water. The bandwidth of the laser Doppler system was set to 22KHz. The integrity of the sensor and response of the FSR were evaluated by using an indenter (Ø=15mm) and loading weights to 20Kg in steps of 0.5Kg. The thermistor response was evaluated by placing the sensor on a controllable heating pad in a thermally insulated housing and varying the temperature over the range +10°C to +70°C.

Results

A total of ten sensors were fabricated and evaluated in accordance with the methodology. The use of an external laser diode at 5mW operating power was found to be necessary as the system could not detect the back reflected signal using the 1mW source diode provided in the laser Doppler system. Standard laser Doppler DC compensation (normalisation) was selected on the instrumentation to compensate for variations in the output power of the sensor. The measured output power variation was within 20% of the nominal 5mW value for all sensors. The velocity response of the sensors (Flux value) closely matched that of the reference probe (VP1/7 Moor Instruments) supplied with the system. Under load conditions the laser Doppler channel continued to work reliably for loads up to 18Kg. This equates to reliable operation under a supine patient with a body weight up to approximately 150Kg. Failure above 18Kg load was due to fracture at the POF – Waveguide interface. The sensor operated consistently over the full test range of +10°C to +70°C. Some preliminary in vivo measurements were obtained from healthy volunteers located supine on a variety of hospital mattresses or seated on wheel chair cushions.

Discussion and Conclusion

The sensor designed in this study demonstrates the efficacy of obtaining skin blood perfusion measurements at the patient – mattress interface. The dimensions of the sensor were set for compatibility with the criteria defined by Ferguson-Pell (1980) to minimise the risk of point load and shear forces being imposed by the sensor itself and hence attributing to the risk. The principle of operation of the sensor is based on the normal frequency shift of incident laser light due to interaction with moving red blood cells RBC in tissue. A portion of the light scattered from moving RBC is heterodyne mixed with un-shifted light in the tissue/waveguide and is backscattered to the detection fibers. An essential element of this technique is the use of a single longitudinal laser diode with spatial coherence over several millimetres. Furthermore, the use of a thermoelectric controller (TEC) was essential to stabilise the output wavelength. Due to coupling losses along the optical path the output power at the prism end of the waveguide was reduced to the range 2.4mW to 3.1mW. This is commensurate with typical values obtained at the output of commercial systems and therefore the volume of tissue sampled will be similar at around 1mm^3. This low sampling volume suggests that positioning of the sensor will be critical to ensure that areas known to be at risk of ulceration, such as, bony prominences are targeted. Initial studies indicate that the sensor remains operational under small bending forces allowing a degree of conformance with anatomical profiles. The resilience of the sensor under normal loading confirms its application to all but the most obese patients.

In practise it is envisaged that a number of sensor would be used to monitor critical pressure ulcer risk sites. However, the most important limitation of the current design of the sensor is the fiber coupling itself together with the external optics for connection to the laser Doppler instrumentation. To overcome this limitation we are now exploring the possibility of a fully integrated sensor with laser diode and detector within the probe head. This would be an important first step towards an instrumented mattress for perfusion imaging of patients at risk of ulceration.

References

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Ferguson-Pell, M.W. (1980) Design criteria for the measurement of pressure at body/support interfaces. Engineering in medicine. 9(4). 209-213.

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Figures

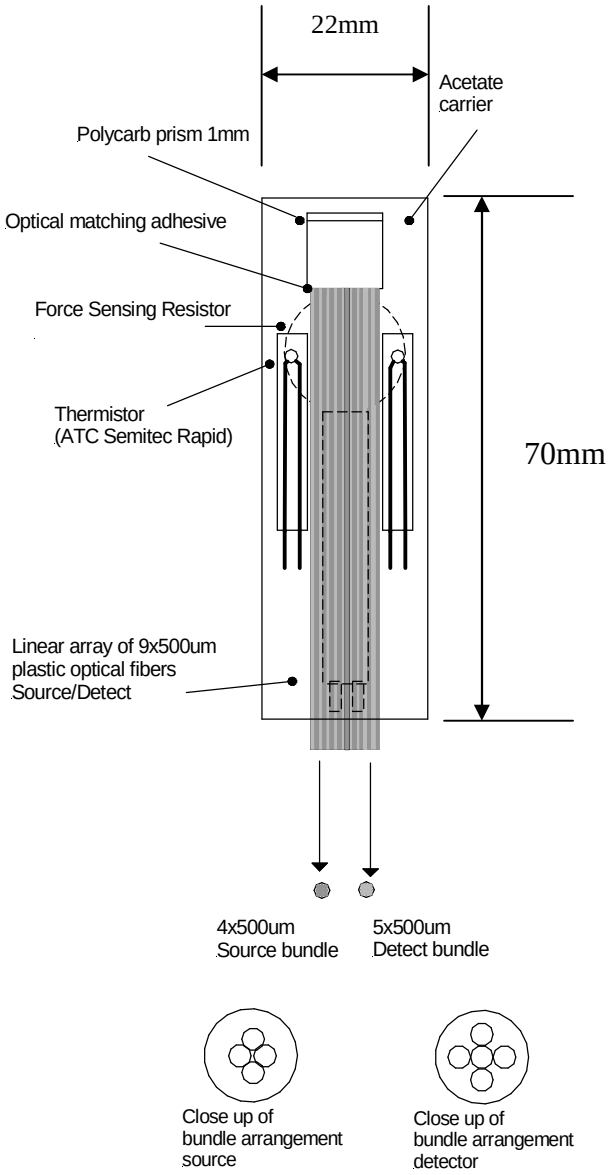


Figure 1 Final design of prototype sensor viewed from non-skin contacting underside showing the relative positioning of the sensory elements. The outer dimensions are L=70mm, W=22mm and H=1mm.

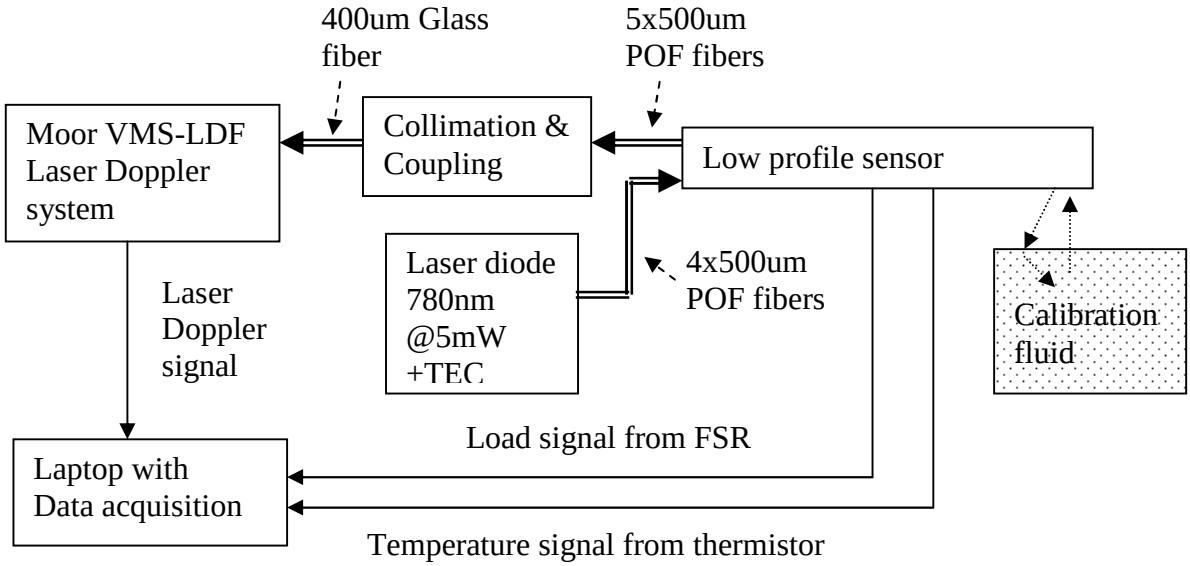
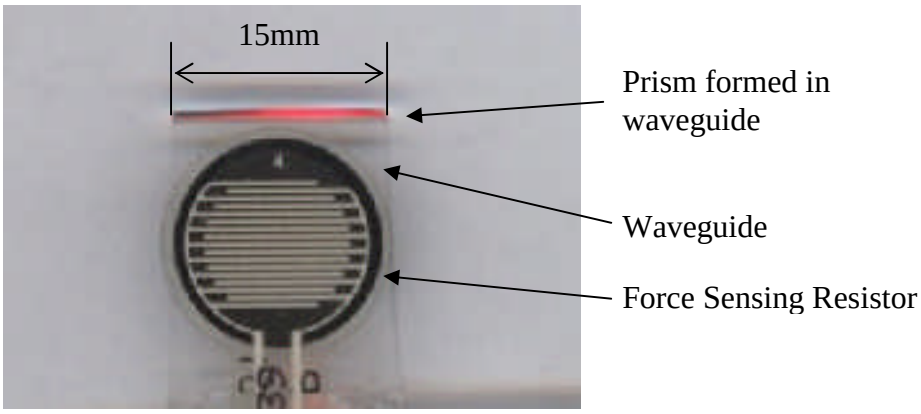


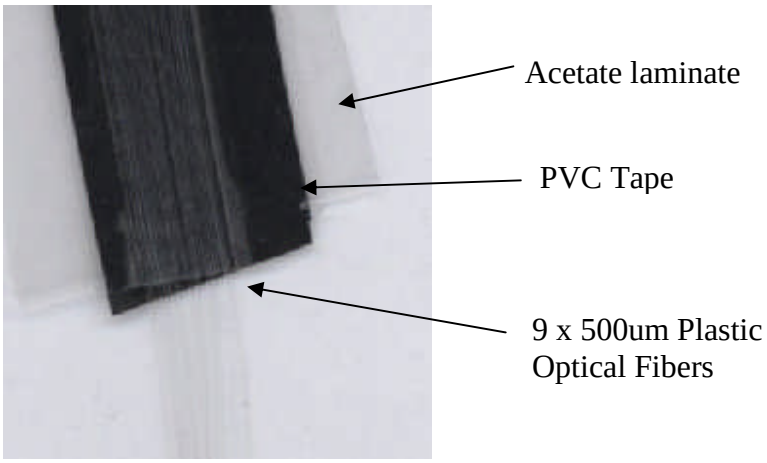
Figure 2 Experimental configuration for validation of the laser Doppler sensor.

Photograph 1



This image shows a prototype version of the sensor with the FSR located on the waveguide and illumination from a 780nm laser diode @ 5mW continuous mode. The total thickness of this element is 1mm ±0.1mm.

Photograph 2



This image illustrates the construction of the optical fiber ribbon using single sided adhesive insulating tape laminated in acetate. The total thickness of this optical cable is 0.8mm.