The QA Pressure Measurement System: an accuracy and reliability study

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Objective: The main purpose of this study was to determine the accuracy and reliability of the Queen Alexandra Pressure Measurement System (QA PMS). Furthermore, we examined whether there were significant differences in measured pressures of the buttock area during sitting between normal subjects and spinal cord injured (SCI) patients.

Design: Accuracy (calibration) and reliability (test-retest) study.

Setting: The spinal cord unit of Tertiary Care Centre 'De Hoogstraat' in Utrecht, The Netherlands.

Patients: A convenience sample of 16 SCI patients and 15 normal subjects.

Main Outcome Measures: The accuracy was determined by using the Standard Error of the Mean (SEM, in mmHg). The Technical Error of Measurement (TEM, in mmHg) was calculated as measure for differences between two paired measurements. The reliability was determined by using an Intraclass Correlation Coefficient (ICC). Significant differences in measured pressures between both groups ($P < 0.05$) were determined by using an unpaired (two sample) t -test.

Results: Accuracy (calibration): mean SEM = 0.30 (± 0.1) mmHg, indicating a high level of accuracy. Differences between two paired measurements: mean TEM calibration = 1.87 (± 0.76) mmHg; mean TEM normal subjects = 4.76 (± 1.78) mmHg; mean TEM SCI patients = 6.34 (± 2.19) mmHg. Reliability: mean ICC_(3,1) calibration = 0.85 (95% CI = 0.74–0.95); mean ICC_(2,1) normal subjects = 0.92 (95% CI = 0.90–0.94); mean ICC_(2,1) SCI patients = 0.90 (95% CI = 0.88–0.92). The normal subjects had significantly higher mean pressures ($P = 0.028$) than the SCI patients (mean pressures 31.0 vs 28.5 mmHg), whilst the SCI patients had significantly higher peak pressures ($P = 0.0000$) than the normal subjects (mean peak pressures: 134.1 vs 75.7 mmHg).

Conclusions: The QA Pressure Measurement System has sufficient accuracy and good reliability as a measurement procedure. There are significant differences between the measured pressures of both groups: the significantly higher peak pressures of the SCI patients seem to be the most important.

Keywords: decubitus ulcer; reliability; accuracy; measurement; spinal cord injury

Introduction

Decubitus ulcers are one of the most important complications suffered by spinal cord injured (SCI) patients. Different terms are used for this phenomenon. According to Yarkony,¹ the commonly used term 'pressure' ulcer is more appropriate as it denotes the principal etiological factor that causes ulceration.^{2–6} Shear-force is the second etiological factor.^{2,3} Other

secondary etiologic factors in the formation of decubitus ulcers are; tissue properties including temperature, moisture, tissue viability, age and hygiene,^{4,5} nutritional status,^{7,8} general health/clinical status, activity level, posture and deformities⁷ and psychological factors.^{7,9} Additional contributing factors in the pathogenesis of decubitus ulcers are; decreased or absent sensibility,^{4,10,11} spastic or flaccid paralysis,^{4,10} coma and/or the (over)use of sedative drugs and edema.¹⁰ Ferguson-Pell⁴ suggests that tissue quality (ie, stiffness or tone), will influence the amount of deformation in the fat and muscle tissue and thus

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determines potential tissue damage. In short, the etiology of decubitus ulcers is considered to be multi-factorial with perpendicular pressure and shearforces being the major causative factors.

The relationship between pressure intensity and pressure duration appears to be of special importance in the formation of decubitus ulcers. This relationship was examined by Groth (1942), cited by Daniel *et al*,¹² Kosiak,⁸ Reswick and Rogers (1976), cited by Henderson *et al*,¹³ Daniel *et al*¹² and others. They found the pressure-time relationship to be a parabolic curve, indicating that high pressures for short duration are less damaging than low pressures for longer duration. Although the various authors found the curve's form to be parabolic, the relationship between pressure duration and pressure intensity was variable (see Figure 1).

There is no consensus in the literature concerning the critical threshold for this pressure-time relationship. According to Henderson *et al*¹³ the threshold in humans has been established at 60 mmHg for 1 h, cited by Henderson *et al*¹³ based on the studies of Kosiak,⁸ Reswick and Rogers and others.

Since perpendicular pressure and shear forces are considered to be the major factor in the aetiology of decubitus ulcers, it is important to design good pressure measurement tools for use in decubitus prevention and therapy. These tools need to be tested for accuracy, reliability and validity.

There have been many studies using different pressure measurement devices, measurement procedures and methods.^{3-6,11,13-27} These studies rarely record the reliability of the measurement procedure used, however the accuracy of the sensor used is usually mentioned.^{3,5,6,11,14-18,28}

We found only one study which reported an intra-observer reliability regarding pressure measurement. Shields and Cook^{24,25} used an 'Ischiobarograph' and recorded the intra-observer reliability in terms of an

Intraclass Correlation Coefficient (ICC). They found a mean ICC_(1,K) of 0.95 in 20 normal subjects²⁴ and a mean ICC_(1,1) of 0.92 in 18 SCI patients.²⁵

The pressure sensor tested in our study, the Queen Alexandra Pressure Measurement System (QA PMS), has not been previously tested in the studied literature.

Methods

Research objective

The objective of this study was to determine the accuracy of the QA PMS and the reliability of the measurement procedure with the QA PMS. We were also interested to know whether a significant ($P < 0.05$) difference existed between the measured pressures recorded by normal subjects and subjects with spinal cord injuries.

Research methods

The QA Pressure Measurement System (see Figure 2) is a pressure sensing device which incorporates a pad encapsulating 256 inflatable pressure cells. These cells are spaced at intervals of 2.54 cm (1 inch) and record a pressure range of 0–300 mmHg.

Pressure-time relationship

Figure 1 Adapted pressure-time relationships as determined by Reswick and Rogers 1976 (+) (cited by Bar),²⁶ Kosiak^{8(a)} and Daniel *et al*¹² (±)

Figure 2 The Queen Alexandra Pressure Measurement System, and the wheelchair used in this study

The pad is connected by a system interface to a computer which records two- and three-dimensional images of the pressure readings. The pressure can be read with an analogue manometer²⁹ during the test. However, we found that the analogue manometer could have a negative influence on the test results since reading the small supplied manometer could be more difficult than reading a digital manometer. We therefore replaced the analogue manometer with a digital one (Delta Ohm, type HD 8804, inaccuracy $\pm 0.05\%$, with a pressure probe type TP 805/DP, inaccuracy $\pm 0.7\%$)³⁰ (see Figure 3). The accuracy and reliability of the QA PMS is not mentioned in the User Reference Manual.²⁹ Furthermore, the reference manual does not discriminate between perpendicular and shear forces.

The QA PMS has several different measurement methods,²⁹ we chose the 'inflation method with actual pressure', with a pressure increment of 5 mmHg.

The study was conducted with two convenience samples (see Table 1). Sample 1 consisted of 15 normal subjects and sample 2 consisted of 16 SCI patients staying in the rehabilitation centre. The level of the

lesions from the SCI patients varied from C₄ (incomplete) to L₁ (incomplete). Ten persons were tetraplegic and six persons were paraplegic, whereby ten lesions were complete and six lesions were incomplete. For specification of the severity of the paralysis of the incomplete SCI patients see Table 2.

The following inclusion/exclusion criteria were used. The normal subjects were not to experience any kind of complaint during testing (eg, back-pain), and capable of sitting completely still during the tests. The SCI patients were required to have a SCI of at least 3 months duration, independent of the level or nature of the lesion, an abnormal sensibility in the buttock-area (ie, anaesthesia, paraesthesia or hypaesthesia), capable of sitting 3 × 3 h a day, sitting completely still during the tests, not have any decubitus ulcers in the buttock-area during testing and a sitting area greater than 45 × 45 cm.

All subjects read and signed an informed consent. The study-protocol had been approved by the scientific and ethics commission of the Tertiary Care Centre De Hoogstraat.

The accuracy of the QA pad was checked by calibration using eight standardized weights (2, 5, 10, 15, 20, 22, 25 and 29 kg), which were placed on the pad and measured twice by the first author. Thereby, we also determined the intra-observer reliability.

Figure 3 The digital manometer (Delta OHM) used in this study

Table 2 Specification of the severity of the paralysses of the incomplete SCI patients

ID-number	Motor level		Sensibility level	
	Left	Right	Left	Right
BD2	L1	L1	L1	L2
BD3	Complete C7	Complete C7	C5	C5
BD5	Complete C6	Complete C5	C5	C5
BD8	C4	C4	T6	T6
BD9	T12	T12	T12	T12
BD16	C4	C4	C4	C4

L, lumbar; C, Cervical; T, Thoracic

Table 1 Description of the two samples

	Normal subjects (n = 15)	SCI patients (n = 16)
Sex	7M, 8F	10M, 6F
Mean age $\pm$ SD (years)	22.5 $\pm$ 2.0	35.5 $\pm$ 16.1
Mean weight $\pm$ SD (kg)	74 $\pm$ 10.2	70.6 $\pm$ 16.9
Mean length $\pm$ SD (cm)	178.8 $\pm$ 9.2	176.3 $\pm$ 7.8
Mean SCI duration $\pm$ SD (range in months)		20.4 $\pm$ 35.0 (3–144)
Level of SCI		10 cervical, 5 thoracic, 1 lumbar
Nature of SCI		10 complete, 6 incomplete
Any form of visible spasticity		3 persons
History of decubitus ulcers		11 persons

SD, Standard Deviations

The reliability of the measurement procedure with the QA PMS and the differences in measured pressures between both groups were determined as follows; all subjects were tested four times by two observers (two measurements by each observer) under standardized conditions, which took twice 45 min per subject (two sessions). The order of testing by the observers was determined at random for the first session. The second session took place in the same order as the first. The measurements were taken in a standardized Orthopedica Ideaal Fix. wheelchair (no armrests; standard U-shaped foam cushion [4 cm massive latex and 4 cm perfolatex] of 45 × 45 cm, the front of the cushion was 2 cm higher than the back; standard soft high backed [38 cm high, seat-to-backrest angle 85°]; seat height 59 cm from the floor, making an angle with the in height adjustable footsteps [with calves support] of 105°).

The subjects were seated in the wheelchair, with the back rested against the backrest, buttocks positioned in the back of the seat and the feet at the adjustable footsteps, with the thighs making contact to the cushion and the calves supported by the calves support. The hands rested on the thighs. The subjects remained in this test position for 10 min prior to the pressure measurement being recorded, to give the foam cushion and the body time to adapt to each other's geometry. According to Garber *et al*¹⁶ this process can take 30 min (depending on ambient conditions). However, Garber *et al* used 15 min.

Ferguson-Pell⁴ stated that one should wait 5–10 min after placement of the measurement device to ensure that the material and the body have conformed to each other. The measurement was then taken. Finally, the subjects left the wheelchair and the whole procedure was repeated by the next observer. Then both observers took their second measurement in the same order as their first.

Statistical analysis

The Standard Error of the Mean (SEM) was calculated to determine the accuracy of the measurement pad and the Technical Error of Measurement (TEM) was calculated to determine the differences between two paired measurements of the first author.³¹ We performed ICC_(3,1) calculations as measure of intra-rater reliability for the calibration measurements and ICC_(2,1) calculations as measure of inter-rater reliability for both studied groups. Portney and Watkins³² defined an ICC_(2,1) > 0.75 to be good and an ICC_(2,1) < 0.75 to be poor/moderate. Unpaired (two sample) *t*-test with an alpha of 0.05 was used to determine any significant differences in measured pressures between both samples of all first measurements of the first author.

For statistical analysis we used the computer programs Number Cruncher Statistical System (NCSS) version 5.0³³ and ICC version 1.03.³⁴

Results

Accuracy (see Table 3)

The Standard Error of the Mean (SEM) of the calibration measurements ($n=8$) was calculated as the measure for accuracy. The mean SEM was 0.3 (± 0.1) mmHg, indicating a high level of accuracy. The mean Technical Error of Measurement (TEM) of the calibration measurements was 1.87 (± 0.76) mmHg.

We also calculated the TEM of the measurements of the first observer of both samples. The mean TEM for the normal subjects ($n=15$, 30 observations) was 4.76 (± 1.78) mmHg and the mean TEM for the SCI patients ($n=16$, 32 observations) was 6.34 (± 2.19) mmHg.

Reliability (see Table 3)

Calibration The raw data of the calibration measurements ranged from 0–30 mmHg. These data were tested for (intra-observer) reliability with an ICC_(3,1). With the exception of the 2 kg weight (ICC_(3,1) = 0.56 [95% CI = 0.47–0.64]), all reliabilities were good (ICC_(3,1) > 0.75), mean ICC_(3,1) = 0.85 (95% CI = 0.74–0.95), range: 0.56–0.93 (95% CI = 0.47–0.95). The mean of all mean-pressures was 7.5 (± 4.9) mmHg and the mean of all maximum (peak-) pressures was 20.6 (± 7.9) mmHg (see Table 3).

Normal subjects The raw data of the normal subjects ($n=15$, 60 observations) ranged from 0–95 mmHg. These data were tested for inter-observer reliability with an ICC_(2,1). All reliabilities were good (ICC_(2,1) > 0.75). Mean ICC_(2,1) = 0.92 (95% CI = 0.90–0.94), range: 0.82–0.97 (95% CI = 0.78–0.97) mean of the separate mean-pressures of all first measurements of the first author was 31.0 (± 3.7) mmHg and the mean of the separate maximum (peak-) pressures was 75.7 (± 9.6) mmHg (see Table 3). The peak-pressures were mostly located where both ischial tuberosities were expected to be.

SCI patients The raw data of the SCI patients ($n=16$, 64 observations) ranged from 0–185 mmHg. Again, we used an ICC_(2,1) to determine the inter-observer

Table 3 Results

Mean SEM $\pm$ SD (mmHg)	Mean TEM $\pm$ SD (mmHg)	Mean ICC	Mean Pmean $\pm$ SD (mmHg)	Mean Pmax $\pm$ SD (mmHg)
0.3 $\pm$ 0.1	1.87 $\pm$ 0.76	0.85*	7.5 $\pm$ 4.9	20.6 $\pm$ 7.9
	4.76 $\pm$ 1.78	0.92 [†]	31.0 $\pm$ 3.7	75.7 $\pm$ 9.6
	6.34 $\pm$ 2.19	0.90 [#]	28.5 $\pm$ 6.3	134.1 $\pm$ 33.9

Pmean, mean of all pressures of all first measurements of the first observer; Pmax, mean of all maximum (peak-) pressures of all first measurements of the first observer. *ICC_(3,1) 95% CI = 0.74–0.95; [†]ICC_(2,1) 95% CI = 0.90–0.94; [#]ICC_(2,1) 95% CI = 0.88–0.92

reliability of the measurement procedure with the QA PMS. All reliabilities were good ($ICC_{(2,1)} > 0.75$). Mean $ICC_{(2,1)} = 0.90$ (95% CI = 0.88–0.92), range: 0.79–0.96 (95% CI = 0.73–0.97).

The mean of the separate mean-pressures, determined by all first measurements of the first author, was 28.5 (± 6.3) mmHg and the mean of the separate maximum pressures was 134.1 (± 33.9) mmHg (see Table 3).

The most striking differences between both studied groups were in the mean mean-pressure and the difference in mean maximum pressure. The differences in the separate mean pressures and the differences in the separated measured maximum pressures were tested by an unpaired (two-sample) *t*-test. Both differences appeared to be significant ($P < 0.05$). The normal subjects appeared to deliver a significantly higher mean pressure to the system than the SCI patients ($P = 0.028$). However, the SCI patients appeared to have significantly higher peak-pressures than the normal subjects ($P = 0.0000$).

Discussion

The most important difference between the two groups was the difference in maximal measured (peak-) pressures (different pressure ranges: 0–95 vs 0–185 mmHg). A possible explanation for this finding could be the motor-, sensibility-, vegetative- and vasomotor disturbances arising from a SCI, causing changes in muscle and tissue tone and volume in the buttock area. The authors hypothesized that the muscle and tissue wasting in the buttock area in the studied SCI group (duration of SCI ≥ 3 months), could be the most important cause of the significantly higher peak-pressures in this group ($P = 0.0000$). Both ischial tuberosities can pronounce strongly as a result of the wasting, thus causing high peak-pressures.

The differences in separate mean pressures was much smaller but also significant ($P = 0.028$). The authors hypothesized that the reason for the higher mean pressures in the normal group, compared to the SCI group, could also be the muscle and tissue wasting in the SCI group.

The buttock contact area increases and becomes flatter as a result of tissue transformation, thereby reducing the mean pressure since the same weight is distributed over more QA PMS cells.

The reliability coefficients found in this study are comparative with those found by Shields and Cook^{24,25} who used an 'Ischiobarograph' to study the effects of different seat angles and lumbar support thickness on the buttock pressures of both normal subjects and SCI patients. They also used an ICC to determine the reliability and found mean intra-observer reliabilities (mean $ICC_{(1,k)}$) of 0.95 for normal subjects²⁴ ($n = 20$) and 0.92 for SCI patients²⁵ ($n = 18$).

Hobson³ used an Oxford Pressure Monitor to study the effects of different sitting positions on the

pressures at the body-seat interface of normal subjects and SCI patients. In accordance with the results of our study, Hobson found that, whilst the measured average pressures varied little between both groups, the SCI patients had significantly higher maximum pressures than non-disabled subjects. However, Hobson does not mention the level of significance and it is not known by the authors whether the Oxford Pressure Monitor has been studied on reliability or not. Hobson attributes these differences in measured pressures between both groups to spinal/pelvic deformities and atrophy over the ischial tuberosities.

The results of our study suggest that, if the pressure-time relationship is the most important factor in the pathogenesis of decubitus, SCI patients run very high risks of developing decubitus ulcers in the buttock area. This requires a more objective and good anti-decubitus policy.

The QA Pressure Measurement System is a sufficiently accurate measurement tool with weights heavier than 5 g (acceptable mean SEM of 0.30 [± 0.11] mmHg). The measurement procedure with the QA PMS has good reliability ($ICC_{(2,1)} > 0.75$) in both groups. Mean $ICC_{(2,1)}$ normal subjects = 0.92 (95% CI = 0.90–0.94); mean $ICC_{(2,1)}$ SCI patients = 0.90 (95% CI = 0.88–0.92).

There were differences between both groups regarding range of measured pressures and regarding average pressures and maximum (peak-) pressures.

The difference between the average pressures was small but never the less significant ($P = 0.028$) (31.0 ± 3.7 mmHg for the normal subjects and 28.5 ± 6.3 mmHg for the SCI patients). The difference in the maximum (peak-) pressures was larger and also significant ($P = 0.0000$), and was higher for the SCI patients than the normal subjects (143.1 ± 33.9 mmHg and 75.7 ± 9.6 mmHg respectively).

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