

EVALUATION OF PRESSURE MAPPING SYSTEM FOR TESTING MEDICAL DEVICES

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1. INTRODUCTION

Interface pressure measurement is widely used to evaluate, for example, compression stockings, compression bandages and pressure ulcer prevention devices. Pneumatic [1], electro-pneumatic [1-3], resistive [2-4] or capacitive [5-6] sensors are usually used. The ideal interface pressure measurement device should be [7-8] small, thin and highly flexible, have a continuous output, be sensitive in detecting the range of pressure as low as 0-100 mmHg, be free from error of measurement on curved surfaces, be free from the effects of temperature and moisture, low cost. Despite sensors developed over the years, to our knowledge, none of them has met all the above criteria.

Four "FSA" thin and flexible resistive pressure mapping systems have been designed by Vista Medical (Winnipeg, Manitoba, Canada). The objective of this study is to evaluate the FSA sensor (Vista medical, Winnipeg, Manitoba, Canada) for the measurement of interface of lumbar belts. Lumbar belt is a medical devices used to prevent and treat low back pain. The main mechanical effect of lumbar belts is the pressure applied on the trunk, which can induce a decrease of intervertebral pressure and/or modify morphological curves of the spine

2. METHODS

2.1. The FSA pressure mapping systems

FSA systems consists in four rectangular mapping systems A, B, C and D, each of them is made of 12 by 32 piezoresistive sensors. Each sensor is a square of 7.9mm side. The distance between two sensors is 4.2mm. The size of the active area is 382 by 142mm. The total size of the mapping system is 482 by 242mm. Sensor calibration is performed with the pressure range of 0 to 100mmHg. During calibration 50mmHg is measured for one minute to compensate the drift. Figure 1. illustrated this system.



Figure 1. FSA pressure mapping system

2.2. Tests of metrology

To evaluate FSA pressure mapping system, two types of tests have been considered: i) classical tests of metrology such as linearity, hysteresis, repeatability, reproducibility and drift; ii) specific tests to the application such as curvature, surface condition and mapping system superposition.

i) Classical tests:

- linearity test: several weights have been designed to apply pressure between 6 and 96mmHg, over a sensor were randomly placed 30 times, over three different sensors. Linear regression coefficient R^2 between applied pressure and measured pressure, dispersion and standard deviation, s_p , have been calculated.
- hysteresis test: two tests were performed. For one, the same weights as for the linearity tests were increasingly and decreasingly applied over eight sensors. For the other, pressure mapping system was place on air pocket and introduced between two wooden planks to apply increasing then decreasing pressure between 10 and 100mmHg to the mapping system. Hysteresis was calculated for the two tests.
- repeatability test: the first hysteresis test was performed three times. Analysis of variance (ANOVA) of Kruskal-Wallis has been used to determine significant differences between repetitions.
- reproducibility test: the first hysteresis test was performed in two different rooms, by two different operators and in two different moments separated by two months. Statistical analysis using a design of experiments, including four independent factors: location, operators and weight applied to the mapping system. The selected design of experiments is factorial and follows polynomial model.
- drift test: four weights corresponding of 26, 40, 52 and 80mmHg applied pressure were 30 minutes left on six sensors. Range of stored drift, defined by the minimum and maximum pressures measuring during the 30 minutes of testing and relative pressure variation expressed as the ratio between the variation in absolute value of pressure and applied pressure are calculated.

ii) Specific tests:

- curvature test: pressure mapping systems were placed on four different cylinders radius 60, 80, 100 and 125mm and pressure was applied on one single line of mapping system using a 15mm band, at the end of which weights were

- hung on. Six or seven different pressures were applied per cylinders per lines per pressure mapping systems. Normalized pressure was calculated by dividing the measured pressure by the applied pressure.
- surface condition: two tests were performed. For one, hysteresis test in only one sensor was performed with seven different medical tissue positioned between the table and the mapping system. For the other, hysteresis test in only one sensor was achieved with surrounded by silicone weights and with froth positioned between the table and the mapping system. Statistical analysis was done to determine if the response to the pressure is statistically significantly different depending on the presence of fabrics (first surface condition test) and to compare the second surface condition test results with the simple test of hysteresis in only one sensor results.
 - mapping system superposition test: the first hysteresis test (test in one sensor) was performed in three sensors stacking two mapping systems. Statistical analysis was done to determine if there are statistical significant differences between results for the pressure mapping system “from above” and the pressure mapping system “from the bottom”. Absolute differences between measured pressures with or without superposition were calculated.

3. RESULTS

i) Classical tests

- linearity: the linear regression coefficient R² is between 0.86 and 0.98 depending on the sensor and the mapping system. The maximum dispersion and the maximum standard deviation to the measured pressure are 18.9±9.60 mmHg.
- hysteresis: for the first test of hysteresis (test in only one sensor), hysteresis is between 0.228% and 27.9%; for the second test of hysteresis, the hysteresis is between 6.29% and 9.41%.
- repeatability: ANOVA of Kruskal-Wallis shows a p-value of 0.88. Measurements are repeatable.
- reproducibility: location, time and operator have influence on the results.
- drift: stable measure is obtained after 800 seconds.

ii) Specific tests:

- curvature: measurement stays suitable on curve surface for an applied pressure above 50 mmHg. No conclusion can be done for an applied pressure lower than 50 mmHg.
- surface condition: the measurement surface condition have influence on the results.
- mapping system superposition: the mapping system superposition have influence on the results.

4. DISCUSSION AND CONCLUSION

In this study, four FSA pressure mapping system have been evaluated for linearity, hysteresis, repeatability, reproducibility, drift, curvature, surface condition and mapping system superposition. Based on the results, it can be concluded that the sensor used in this study is acceptable. Linearity, accuracy and hysteresis are adequate. Measurement is repeatable and suitable on flat surface and curved surface. Nevertheless, it is necessary to take into account some recommendations before using this FSA sensor. To compare results of different experiments, measurement must be performed in the same place, in a short time, with the same operator, between the same kind of surfaces. Calibration must be adapted to avoid the sensor drift. Finally, it is essential to avoid overlap pressure mapping systems.

From previous studies, it appears that FSA sensor performances are better than other resistive sensors. They are the same as for the capacitive sensor X-Sensor with low hysteresis. Nevertheless, the capacitive sensor Novel has better performance than FSA sensor, but it is more expensive.

Further study is needed to evaluate the performance of the sensor on a curved surface when applied pressure is lower than 50 mmHg and when temperature and humidity changed.

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