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Usefulness of Measuring the Pressure Exerted by Orthopedic Braces

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Abstract

The research here proposed starts from the belief that, in order to allow the verification of the corrective action of the brace used to correct the scoliotic curve and the monitoring of the evolution over time of its therapeutic efficacy, it would be necessary to use routine systems that measure the pressures exerted by the braces themselves. In fact currently this verification is done by means of X-ray images and visual examination of the brace worn. In literature there are some studies on this topic, which show more or less expensive systems, more or less simple to use that have evolved with the evolution of technology while trying to meet the same requirement of quantification.

A reduction in the amount of pressure should correspond to a positive response of the spine to the action exerted by the brace. The routine use of systems of this type, absolutely non-invasive, would allow more frequent checks and any brace design errors could be promptly identified and corrected. The paper shows the results obtained with the use of an economic system that is not particularly smart, but which despite its simplicity has confirmed the usefulness of the evaluation of pressures between brace and patient’s trunk.

Keywords: Scoliotic curve, Brace, Pressure.

I. INTRODUCTION

Scoliosis is a deformity of the spine consisting of a lateral deviation and, due to its articulated structure, of a rotation of the vertebral bodies. Spine deviations are not pathologies of this century: from paintings found on the walls of caves that date back to the Stone Age, it is deduced that the deformations of the spine existed since the earliest times. The first one who used the term "scoliosis" was Hippocrates, although incorrectly, since with this term he indicated all deformations of the spine.

Galen (129-201) coined the words "kyphosis, lordosis and scoliosis"; his treatment of the deformities of the spine followed that of Hippocrates and consisted in a forced tension of the patient. Paré (1510-1590) wrote a treatise on congenital scoliosis in which he claimed that incorrect posture was the cause of scoliosis and indicated as a therapy the use of a metal brace obtained from an armor. The evolution of the study of scoliosis was swinging over time: after a period of stagnation at the end of the 19th century, detailed descriptions of the anatomy of the spine deformations were made for the definition of its clinical features and its pathogenesis. In 1914 Hibbs performed the first vertebra arthrodesis of a scoliosis; this constituted a remarkable progress in the therapy of this pathology: in fact, in that period, there was no orthopedic treatment that gave satisfactory results. The first really effective brace, the Milwaukee brace, was designed, in 1946, by Blount and Smith [1].

Scoliosis typically affects female adolescents, while male ones are more affected by another deformation of the spine called kyphosis.

Scoliosis can be classified according to different criteria: based on the number of curves (single-curve scoliosis and double-curve scoliosis) or according to the type of deformation and pathogenesis (unstructured scoliosis, structured scoliosis, transient structured scoliosis).

When there are two structured curves, the terms "greater curve" denotes that one of greater amplitude and "smaller curve" denotes that one of smaller amplitude. The "apical vertebra" is defined as the vertebra that moves further away from the vertical axis of the patient. The apical vertebra (a.v.) is important because it is the reference vertebra in the localization of scoliotic curves (cervical, a.v. C1-C6; cervico-dorsal, a.v. C7-T1; dorsal, a.v. T1-T11; dorso-lumbar, a.v. T12-L1; lumbar, a.v. L2-L4; lumbar-sacral, a.v. L5-S1).

Among all the type of scoliosis the idiopathic one is certainly the most frequent: it is a structured type scoliosis and is of unknown origin.

In order to quantify the extent of the angular deviation of scoliotic curves an angle, called Cobb angle[2], is measured identifying the most caudal vertebra, whose lower edge looks towards the concavity of the curve, and drawing a line parallel to it, thus identifying the most cranial vertebra, whose upper edge looks towards the concavity of the curve, and tracing a line parallel to it; the Cobb angle is the angle formed by the intersection of the two lines perpendicular to those previously drawn (Fig. 1)

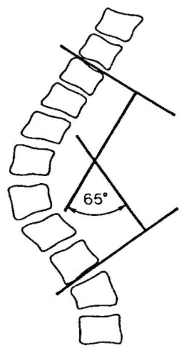

Fig. 1. Example of evaluation of the degree of angular deviation of the scoliotic curve according to the Cobb method

Scoliosis is currently treated with different techniques depending on the severity of the spine deviation: there are non-invasive techniques for less severe cases (orthosis and physiotherapy), and invasive techniques for more severe cases (tension bars, spinal fixators). Generally the use of orthoses, commonly called braces, occurs when the angular deviation is between a minimum of 25-30 Cobb degrees and a maximum of 45-50 Cobb degrees.

For most scoliosis an orthosis is adopted; there are different models (Milwaukee, Michel Allegre, Lionese, Charlestone, Chêneau, Riviera, Olympe, Boston etc.). The type of orthosis is chosen according to the aetiology of scoliosis, the age of the patient and the location of scoliosis. Orthoses, active or passive, exert pressure on the patient's trunk with the aim of preventing further aggravation of the deformation and in some cases reducing it. Passive orthoses are those in total contact with the trunk, so the spine is kept in the correct or hypercorrected position without any muscular effort. Active orthoses have a limited number of areas in contact with the patient's trunk; the pressures exerted at these areas cause in the patient the effect to straighten himself and translate the trunk towards free areas or expansion chambers, so that the spine remains in the correct position thanks to active muscular contraction.

After the medical examination and after observing the X-ray images, the doctor verifies the presence of one or more scoliotic curves and decides the use of the most suitable brace. The brace must exert adequate pressure to be effective, otherwise it can also be harmful in the sense that in addition to not making any reduction in the scoliotic curve it does not prevent its natural degeneration.

Currently the control of the corrective action of the brace is done by means of X-ray images and by visual examination of the brace worn, while its therapeutic efficacy is controlled clinically and radiographically with different frequencies in the various countries: frequent radiographic checks are not recommended both for the difficulty of appreciating on the radiographic image minimal variations of the scoliotic angle of the spine, and for the invasiveness of the examination.

The problem is that it is not easy to assess the effectiveness of a brace in controlling the evolution of a scoliotic curve without knowing which is the distribution of the pressures exerted by the brace itself on the patient's trunk and also without knowing how long it is worn daily [3].

The usefulness of using a non-invasive and more precise method than the traditional one therefore appears evident.

The solution of these problems is a typical subject of Bioengineering. In particular Biomechanics performs structural analysis of skeletal body elements and of biomechanical systems consisting of a bone element coupled to a prosthesis, an implant or a fracture synthesis device, or to an orthesis by means of both numerical and experimental methods [4]. There are many examples of clinical problems which have moved from a qualitative assessment to a quantitative evaluation thanks to the respective modeling [5-12] or to the application of classical experimental methods of structural analysis to the evaluation of the efficacy of procedures or surgical techniques [13-21] or to the evaluation of the mechanical characteristics of the materials used at different scales of investigation [22-29].

The non-invasive control of the corrective action of a brace could be obtained through the use of pressure sensors placed in some points between the brace and the patient's trunk in the testing phase. The use of multiple sensors applied in the areas where the brace exerts its correction makes it possible to identify a pressure map exerted by the brace on the trunk, then check whether it is effective at the required points and quantify its effectiveness.

In order that the measured pressure is realistic, it is necessary that the sensor is very thin and small enough not to distort the measurement due to its stiffness. The application of the pressure sensor during each check-up can allow to quantify the variation over time of the pressure exerted by the brace on the patient's trunk. A reduction in the amount of pressure should correspond to a positive response of the spine to the action exerted by the brace.

With a measurement system of this type, the checks could be more frequent and any errors in the realization of the brace could be promptly identified and corrected.

At the beginning a similar problem was studied as regards the prostheses for amputees above and below the knee joint for the evaluation of the loads exerted on the patients' stump by the socket [30-40]. From the analysis of this literature it was deduced that the majority of the proposed techniques requires the realization of special instrumented sockets that permanently alter the prosthesis, the measurement points are fixed and in limited numbers and, due to the size of the transducers and their stiffness, their positioning at the stump-socket interface creates abnormal stress concentrations. Some of these problems were overcome with the application of systems such as that of TekScan Inc. (Boston, MA) [39] which do not damage the sockets and can be applied at different points of the interface; however, the accuracy and repeatability of the measurements made with these transducers at those time and in this ambit were not high [41].

As regards brace, temperature sensors [42-44], pressure switches [45], force sensors [45-47] more recent TekScan device (Boston, MA) [49], associated experimental and numerical methods [49] have been used to monitor brace pressure and/or wear time [3].

The evaluation of the effectiveness of braces used for the treatment of scoliosis is a topical subject. In 2019, two reviews were published on the subject [51, 52], but in most cases at present the routine evaluation methods are still the historical ones such as they do not include objective quantifications.

This paper shows the personal experience acquired by designing a pressure measurement device whose application has demonstrated the validity and necessity of objective assessments of this type.

II. MATERIALS AND METHODS

Measuring the pressure between two surfaces, brace and skin, always moving the sensor, without distorting the measurement, in a reliable, repeatable way and with contained costs to allow a widespread adoption in the surgeries is not a simple solution. There are many types of braces and they differ in terms of shape, correction modality of scoliotic curves and stiffness. The surface that interfaces with the brace is constituted by the patient's trunk, therefore its stiffness varies according to the subject. Many types of pressure sensors are available on the market, usually of such dimensions that they cannot be put between the brace and the patient's trunk, sometimes fragile, and so not suitable to repeated measurements, and with a full scale greater than the necessary one.

A measurement system with which the sensor fragility problem was overcome and therefore the problem of repeated measurements, was built according to our specifications by Paromed Medizintechnik Gmbh (Neubeuern, Germany). The system consists of a matrix 80 x 85 mm of eight resistive type pressure sensors associated to eight temperature sensors connected to an eight channels amplification device with temperature compensation. Sensors are arranged in two rows and each pair of sensors (pressure, temperature) is drowned in a silicon gel cell which has the function of distributing the pressure uniformly on the pressure sensor and protecting it from mechanical damage (Fig. 2).

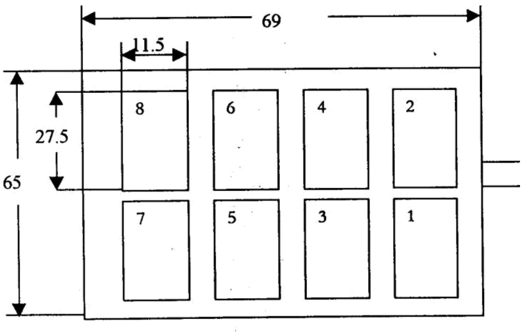

Fig. 2. Sensors matrix. Dimensions [mm]

The sensors support is made of flexible material and the device is 2.3 mm thick. Each pressure sensor makes a maximum error of 5% on the full-scale value p = 200 kPa. The amplification device is powered at 9 V in alternating current, it allows the adjustment of the gain and of the zero both of the pressure and the temperature and the regulation of the temperature-pressure compensation; the reading of the pressure and the temperature measured by each individual sensor takes place thanks to a special manual channel selector.

The signals output are recorded and displayed over time by means of a computer through an analog/digital converter. The converter used is the AD612 (Artek Elettronic Solution, Italy) that connects directly to the parallel port of the computer.

The software that manages the signals coming from the converter allows to calibrate the zero and the gain, set the range of measurable values, the sampling frequency, the data transmission frequency during recording, the unit of measurement, the number of decimal places of the measured value, recording the signal in memory and to display the signal continuously on the monitor in a system of Cartesian axes having time on the abscissa and the pressure on the ordinate.

The sampling frequency used is 15 Hz. The analysed phenomenon is almost static. What makes the pressure exerted by the brace on the patient's trunk vary is the dilation of the rib cage following breathing. Bearing in mind that the time period between two successive inspirations is about 4 s the frequency of the phenomenon to be measured is about 0.25 Hz.

The applied protocol was the following: patient examination, application of the sensors matrix, acquisition and recording of pressure signals, compilation of a card in which data relating to the patient appear (Fig. 3).

By patient examination we mean a clinical classification of the patient which includes, after an in-depth case history, the evaluation on the frontal plane of the balance of the shoulders and pelvis and on the sagittal plane of the lateral profile of the column.

Fig. 3. Application of a matrix sensors on a patient

With the patient flexed anteriorly, the orthopedist examines and quantifies the costal and paravertebral humps with a special device. Hips asymmetries are also taken into account and measured. The examination is deepened from the radiological point of view by measuring the angular entity of the curve according to Cobb and its structure according to Nash and Moe [53]. The skeletal maturity of the patient according to Risser [54] is also deduced from the radiograph. To evaluate skeletal maturity, the iliac epiphyseal ossification centers are identified; ossification of the iliac crests begins from the anterior-superior iliac spine and moves progressively backwards; when the ossification of the iliac crests reaches the postero-superior iliac spine the ileum is fused. This moment coincides with the arrest of skeletal development. To measure the posterior displacement of the iliac apophysis the iliac crest is divided into four parts (Fig. 4): value of Risser 1 refers to 25% of ossification of the iliac crest, Risser 2 refers to 50% of ossification, Risser 3 refers to 75% of ossification, Risser 4 refers to 100% of ossification such as when ossification has reached the postero-superior iliac spine. The fusion of the nuclei with the rest of the ileum corresponds to a Risser value of 5.

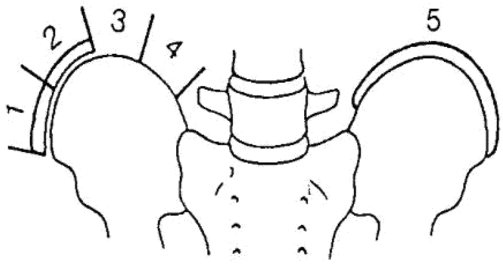

Fig. 4: Evaluation of the degree of skeletal maturity: Risser value

The pressure sensor matrix was placed on the patient's skin, orthostatic position, at the areas where the brace applies the corrective forces. The brace was put on and the pressure exerted, with an acquisition time of approximately 30 s, was measured, displayed and recorded. At the end of the protocol a summary sheet was compiled in which were indicated, in addition to the personal data, the diagnosis, the angular extent of the curves, the bone maturity, the physiokinesiterapic or orthopedic treatment previously performed, the type of orthosis in use, the orthopedic workshop that made it and the material of which it is made. For the different measurement points and possibly for the different positions assumed by the patient, the average pressure values recorded and the trend over time of the pressures measured by the eight sensors were also shown. Finally on the sheet the radiological data of the correction obtained from the treatment on the frontal, sagittal and transverse planes respectively could be read (Fig. 5).

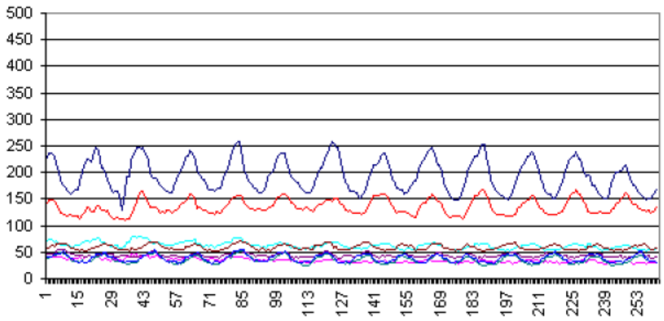

Fig. 5. Example of measurement of pressures measured by the eight sensors. Time expressed in 10 s is shown on the abscissa. Pressure expressed in 10^2 Pa is shown on the ordinate

III. RESULTS

Over a year and a half, 75 patients were evaluated and only on some of them the same type of measurement was conducted with the same brace at different times.

In order to compare values measured on the same patient at different times and on different patients under different conditions (such as type of brace worn, type of curve, degree of spine deviation, skeletal maturity) and possibly find correlations between measured pressures and these parameters, for each acquisition only the maximum average values of the acquisitions recorded with the 8 sensors were considered. The acquisitions were divided among pressures measured respectively at a thoracic curve and at a lumbar curve and, within this subdivision, were further subdivided by type of orthosis, by Risser values and by degree of spine deviation.

Risser value referred to corresponds to the relative value at the time of acquisition.

From the subdivision into thoracic and lumbar acquisitions respectively, it can be deduced that on average the thoracic pressure is greater than the lumbar one and this result has a clinical confirmation as the correction at the lumbar level is exerted on a large muscular area while the correction at the thoracic level is exerted directly on the ribs. The analysis of the data collection divided by the type of orthosis used indicates how the passive braces exert more pressure than the active ones; this finds a clinical confirmation since these two types of braces are based on a different principle of action on the patient's trunk, in fact passive braces have the task of blocking the spine deviation without the participation of the patient, therefore they must exert such pressure as to counteract the natural progression of scoliosis. The active braces have the task of urging the patient to assume a different posture, therefore the correction of the spine curve occurs with the participation of the patient, the areas in which the pressure is exerted are more localized and restricted and the extent of the pressure is lower (Fig.6).

The analysis of data divided according to the value of Risser provided no indication as there is no correlation between the average value of pressure and skeletal age of the subject undergoing therapy.

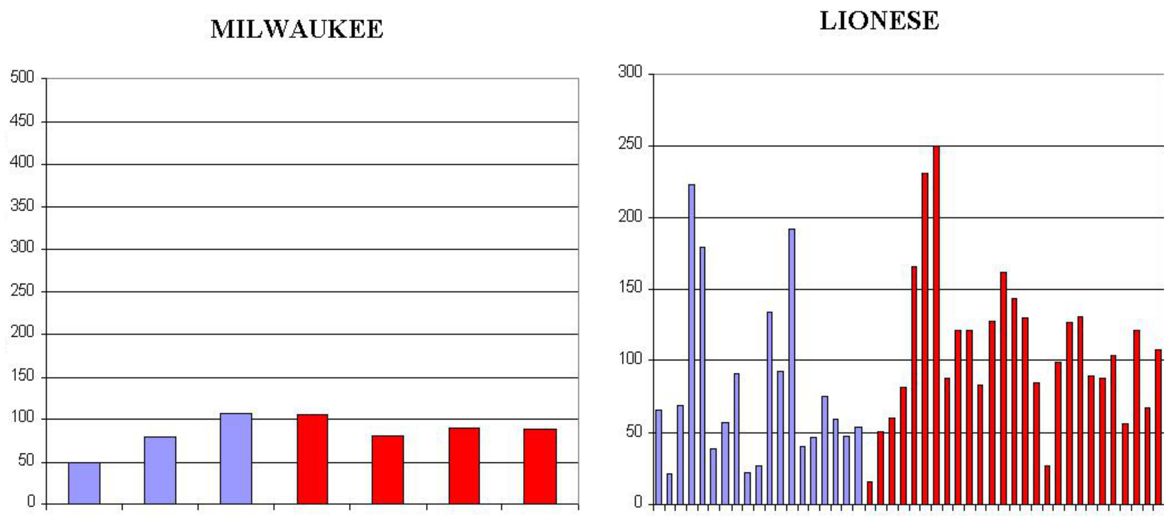

Fig. 6. Amount of pressures [10^2 Pa] measured on patients treated respectively with an active type brace (Milwaukee) and with a passive type brace (Lionese). Each histogram corresponds to a patient. The red histograms correspond to measurements carried out in correspondence of thoracic curves while the blue histograms correspond to measurements carried out in correspondence of lumbar curves

The analysis of data divided by the degree of spine deviation did not suggest the existence of a correlation between the degree of spine deviation and pressure exerted by the brace. The type of orthosis is related to the degree of spine deviation; in fact, we pass from active corsets to passive corsets as the degree of deviation of the spine increases.

As regards measurements conducted on the same patients with the same brace at different times some results are shown in Fig. 7. In almost all patients measured after just three months from the start of the therapy, that is from the beginning of the use of the brace, an appreciable reduction in the pressure exerted by the brace itself was recorded. This result shows that in a short time a brace may no longer be effective.

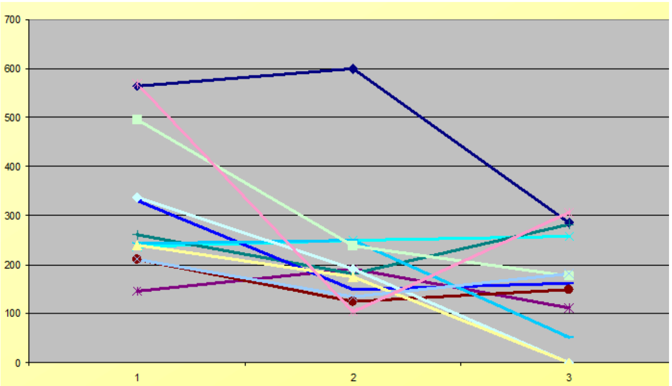

Fig. 7. Each curve corresponds to a patient and shows the amount of pressure [10^2 Pa] measured at three different time respectively after one, two and three months from the beginning of the therapy. All these patients worn a Chêneau brace and the measurement was done at a thoracic curve

IV. CONCLUSION

The aim of the research was the development of a measurement system which, associated with a measurement protocol, allowed on one hand to establish the pressure range that a brace must exert to get through the test and on the other one to carry out monitoring of the evolution over time of its therapeutic efficacy.

With a matrix of resistive-type pressure sensors made according to our specifications as regards size and full scale, the pressure exerted by different types of orthopedic braces on the trunk of 75 patients suffering from scoliosis was measured. Data collected allowed to identify the orders of magnitude of the pressures exerted in different areas of the trunk of the patients by different types of braces. The acquisitions were subdivided among those recorded in correspondence respectively of lumbar curves and thoracic curves and again by type of orthosis, by Risser values and by degree of spine deviation. This subdivision of data showed how the amount of the lumbar and thoracic pressures are different from each other and how braces with different correction modes exert different entities of pressures. These considerations have a clinical response. A measurement conducted on few patients, in correspondence with the same area of the trunk in three different times showed, according to what expected, that the pressure exerted by the brace reduced over time as a consequence of obtaining a correct correction.

The number of acquisitions made so far is not sufficient to draw definitive conclusions. A systematic study of numerous clinical cases that differ in type and evolution is planned, so as to try to identify a link between pressure exerted and correction obtained.

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