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Hugo Villi, Nicolas Pinsault, Guillaume Thomann. Spine pathologies detections: users' requirements, technological development and first results.. *Procedia CIRP*, 2022, 109, pp.209-214. 10.1016/j.procir.2022.05.238 . hal-03701364

HAL Id: hal-03701364

<https://hal.science/hal-03701364v1>

Submitted on 22 Jul 2024

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32nd CIRP Design Conference

Spine pathologies detections: users' requirements, technological development and first results.

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Abstract

For spinal pathologies, especially scoliosis, early detection is essential to limit symptoms during growth and health impacts at skeletal maturity. Currently, school screening campaigns or annual medical visits are the main means of ensuring this detection. It is possible to attain a screening sensitivity of 93.8% and a sensibility of 99.2% by combining a Forward Bending Test, a scoliometer and Moiré's topography, but due to a lack of time, of trained professionals or of access to specific tools, a majority of children are not screened.

The objective of this research is to define the specifications of a massive and easy-to-use screening tool through a qualitative study to address this issue. A review of the literature, interviews and discussions with health professionals, particularly physiotherapists, helped to define the needs. Five physiotherapists and a pediatric rehabilitation physician were interviewed during semi-structured interviews. To extract the main categories of ideas and opinions expressed, the data were analyzed and coded using grounded theory. This step was intended to help us define requirements. The first results of the subsequently selected technical solution, a depth camera, and the associated software development will be presented. This prototype software for spine detection was developed and tested on an adult body.

The interviews highlighted the relevance of a new tool for spine and back analysis. A tool that would provide processed information with high reliability and accuracy, combined with low cost and low processing time would be ideal for health professionals. To complement the tools already used by professionals, a solution that could give a dynamic visualization of the spine curve will be valuable. The solution developed uses a Kinect sensor capturing the patient's back. The current software development allows the dynamic extraction of the spine line for the patient during the anterior flexion test (Adam's test).

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Peer-review under responsibility of the scientific committee of the 32nd CIRP Design Conference

Keywords: Scoliosis, Kinect, Qualitative research, spine, point cloud

1. Introduction

Spine pathologies affect an important part of the population. The Adolescent Idiopathic Scoliosis (AIS) is one of the most frequent manifestations. Depending on the screening method used, AIS affects 0,47% to 5,2% of the population [1]. AIS is a deformation of the spine in the transverse, coronal and sagittal plane, accompanied by a rotation of vertebrae around their axis of symmetry, involving the ribs and the thorax [2]. Thus, AIS patients may show a rib hump when bending forward, as one side of their rib cage is higher than the other. This deformity is

observed by a trained professional using the Forward Bending Test (FBT), where the patient is asked to bend forward, looking down, shoulders relaxed and hands in front of knees. AIS can affect patients' pulmonary function [3], mobility [4], and prevalence of back pain [5,6]. AIS is often reduced to its most recognizable component, a lateral deviation of the spine in the coronal plane. This deviation is quantified by the Cobb angle, measured on a radiography. It is defined as the angle between the line drawn on the upper end plate of the most tilted vertebra above the apex of the curvature and the lower end plate of the vertebra under the curvature's apex [7], such as in Figure 1. The

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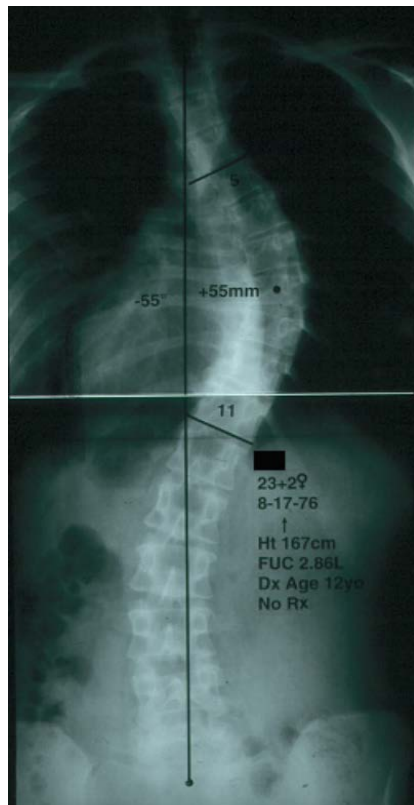


Fig 1. Radiography in the coronal plan of a women presenting a thoracic scoliosis with a Cobb angle of 55°.

use of the Cobb angle has limitations [8], but it is still considered as the Gold Standard (GS) in the diagnosis and monitoring of AIS [9].

The Cobb angle and skeletal maturity at the time of detection are considered to be the main factors in the evolution of AIS [10,11]. Early detection of AIS leads to early treatment, usually with the use of an orthotic device [10,11,12] to limit the evolution of the curve, leading to lower rates of surgery [13]. Screening is the principal solution to the early detection of AIS. Although its usefulness has been questioned throughout its history [14], studies shows that screening campaigns can have a good specificity and sensibility [9,15,16,17]. The effectiveness of screenings campaign depends largely on the tools used and on the training of the operators conducting the campaign.

In practice, few tools are available and used for quantified analysis of the spine [8]. The most common are the FBT and the scoliometer, which allows a simple measurement of rib cage rotation (figure 2a and 2b). Although the sensitivity and specificity of these tools are not excellent [9,18,19], and requires an investment of time and money, they are the most

commonly used for screening campaigns. However, the lack of precision of these tools, combined with the low number of professionals properly trained to use them, limits the development of these campaigns. There seems to be a gap between the innovations available to health professionals and their adoption in practice. To address this issue, a methodology based on a qualitative study is proposed in this paper. The hypothesis is that discussing with the potential users would lead to a tool closer to their needs and demands, ensuring a good acceptance and adoption. The ultimate goal is to design a useful tool for health professionals on the long term. The data from the qualitative study was analyzed to define requirements, leading to the choice of a technical solution and the design of an analysis software.

2. Materials and Methods

2.1. Qualitative study

The objective of our study was to gather the opinions of health professionals on the tools currently available and to identify unmet needs. An exploratory qualitative approach, using semi-structured interviews, was chosen as it is particularly suitable for observing factors that are difficult to identify [20]. The idea being to define: “What are the needs of health professionals in term of tools for detection, diagnosis and monitoring spine pathologies?”, an interview guide was proposed. It focuses on three themes: clinical practice, acceptability of tools and utility of a new tool. The guide used for data collection was semi-structured and deviations from the established questionnaire were possible. The second step was to identify a population that would provide interesting and comprehensive insight into the topic. The interviews were then recorded, with the oral agreement of the interviewee, and were transcribed for further analysis. These transcriptions were interpreted according to the grounded theory method. The first step consists of an initial exploratory analysis of the collected data, where concepts will be discovered. These concepts can be considered as “codes”, representing excerpts of potential theoretical significance. These concepts are then developed and clarified, through the rereading of the transcripts. Once this iterative work is considered complete, that is when no new concepts emerges from rereading and new inputs, the concepts can be reduced to core concepts, or categories. The relation between categories are explored to generate hypothesis and theories. The relations explored in this paper will be used to determine the requirements of a potential tool.

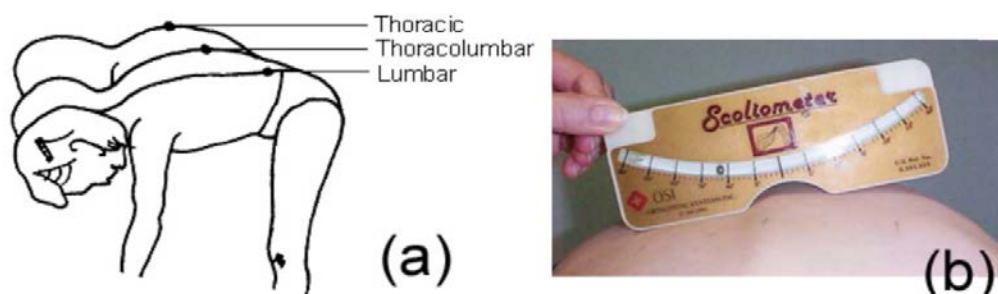


Fig 2. Forward Bending Test (FBT) (a) and the scoliometer used to quantify the hump (b)

2.2. Sampling

In this type of study, the objective of sampling is to represent the population studied. The population of interest was healthcare professionals likely to encounter spinal pathologies. The inclusion criteria were to have clinical experience, even partial, with spinal pathologies. Expertise in this field was possible but not sought at all cost. The network used to contact interviewees was provided by the Institut de Formation des Professionnels de Santé (IFPS), Grenoble, France. The number of interviewees was not defined a priori, data collection is continued until saturation of ideas.

3. Results

3.1. Data collection

A total of one medical doctor in pediatrics rehabilitation and five physiotherapists participated in the study. Among this population, only one physiotherapist had no clinical activity at the moment of the interview, but had clinical experience. Three of the physiotherapists had participated in school scoliosis screening campaigns during their career as evaluators or organizers. The medical doctor in pediatrics rehabilitation had an expensive knowledge about spine pathologies. The interviewees had a mean of 14 ± 12 years of experience.

The interviews were conducted between January and March 2021, by videoconference. The interviews lasted 31 minutes in average, with a minimum of 25 and a maximum 35 minutes.

The categories identified after transcripts analysis were closely related to the themes of the guide. Clinical practice occupied an important part of the discussions and professionals talked about the tools already in place, the problems in day-to-day practice and the limitation they had. Once the context was settled, the discussion was oriented towards the parameters of acceptability for a new tool. In a third category, interviewee talked about what characteristics they would like in a new tool.

For Clinical practice, many of the expressed ideas were about the methods and tools used, the frequency of use and the way the professionals used them. Scoliometers, goniometers and the FBT were among the tools cited. An important part of the contents also concerned the limitations encountered in practice, such as a lack of precision on certain variables or a poor reliability. The results of some screening methods, such as the FBT, may be dependent on the observatory training and experience. Professionals also talked about their limitation in terms of time during a clinical examination or during a screening campaign. The space available in a city office or in a screening room can be a limitation too. The financial power of clinicians is not infinite and keeping a low cost is preferable. Concerning the GS, there are limitations generated by the irradiation inherent to radiography. Professionals are aware of the existence of what are considered highly performant tools, such as the EOS radio-imaging device, but these tools are not easily accessible.

The theme of acceptability of tool was also discussed, with an interest in parameters that will determine if a professional would use a tool or not. Most of the ideas were about

integration in the already existing workflow. There will also be a time dedicated to the installation of the tool and a time necessary to make a single measure. In a general way, professionals will be more welcoming to a new tool if these times are as low as possible. The integration in the workflow and the interaction with the other tools and software should be as seamless as possible. Tools that improve the care health professionals can provide will be more easily accepted, for example by providing new information. The way the tool is perceived by users will also play an important part, and many parameters can change this perception. Professionals are aware that marketing can introduce a bias, and they will try to lower potential bias by basing their decision on the metrology available for example.

In the “Utility of a new tool” theme, participants were asked what they would like to get from a new tool. A time gain, for clinical practice or screening, was among the most common response. Improving a measurement already made would also be interesting for some clinicians, but the change should be considerable. Slightly improving an already made measure, without a gain of precision, reliability or time present little to no interest. Getting new measure would also interest some professionals, such as detecting or measuring the quality mobility of the spine. In general, there is interest in measuring movement. To give feedback on these measures, the data must be synthesized. Clinicians want to understand the feedback quickly without struggling, in order to bring a new insight in their care. Depending on the use and the user, it would even be interesting to give a very simple feedback, like a warning level of suspicion for spine pathologies.

3.2. Requirements

Now the concept inside these categories will be used to generate requirements. The concepts appearing in multiple categories will be given a higher order of importance, specifically the intersection between limitations in clinical practice and acceptability. A concept that is found in the three categories is time. If this concept should be resumed in a unique requirement, it would be to gain time. But by using the information in the transcripts, it can be developed into more precise requirements. The time necessary for the physical setup of the tool should be as low as possible, such as the time necessary to make a single measure and the time necessary to exploit it. The time necessary to learn how to use the tool should be as low as possible. To do so, the information used and returned to the user should be as close as possible to what he is used to. These concepts will lead to the following requirements:

- Low physical and software setup time
- Low capture and data treatment time
- Small learning curve

In a more general way, healthcare professional expects a new tool to integrates as well as possible in the already existing workflow, for example an already existing patient database:

- Good integration in the already existing workflow

If a lack of precision is sometimes a hindrance to explore a specific clinical or research question, the most concerning point

for health professionals is the available tools' reliability. Many sources can influence reliability: the tool itself, the recommended methodology or the observer and his training. Some professionals doubt themselves when conducting a measurement, or feel like they're more efficient after they accumulated some experience. This results in a low trust in these tools and a low use rate in practice. This led to the following requirements:

- Should exhibit a sensibility and specificity higher than a simple FBT
- The results should not be influenced by the observer

If we place ourselves in a city office environment, the following requirements can be added:

- Should be precise enough to monitor the scoliosis evolution between two appointments

For a use in a city office or in a classroom, the tool and the space needed to use it should be as low as possible. The tool must also stay affordable. This led to the following requirements:

- Should be usable in a basic room
- Should take as little storage room as possible
- The cost must be as low as possible

The subject of irradiation was also discussed, as a radiography is actually the GS to diagnosis the scoliosis and its severity. The health professionals said that the irradiation should be as low as possible, but in a more general way the tool must be harmless for the person using it.

- Non-irradiating/Harmless to the user's health

For a tool to be accepted and even considered, it has to bring something more to what is already in place: be it a gain of time, a new measure, an improvement on one that is already in place, a better reliability or an improved integration in the workflow. The hypothesis is that a time gain would liberate time to do something else during an appointment in clinical practice or would allow to screen more children, leading to better healthcare. Giving improved or new measure would improve the decision-making process, leading to better healthcare. As a requirement "improve healthcare" would be too generic to be meaningful and potentially lead to an ill-designed tool, it was decided to focus on improving the FBT and the scolimeter's reliability, based on the information given by the interviewees. Following the spine and the ribcage rotation during the whole FBT would be considered as new measurements, even if based on an already existing test. Based on this, the following requirement were extracted from the concepts:

- Capture the movement of the spine line
- Evaluate a potential hump
- Give info on the symmetry of the back

3.3. Depth sensor

From these specifications, the next step was to develop a new tool that would meet these requirements. A range of tool was available in practice and was discussed, such as the goniometer and the scolimeter, but they have a low reliability in practice and can be time consuming. Photography was also cited, but clinicians had to highlight anatomical landmarks on the patient skin and the conditions of orientation and lightning

had to be good in order to have exploitable results. The spinal mouse, an external device that measure the spinal shape also came up during discussion. It gave good static results, but can be time-consuming. The EOS system is powerful, but still irradiates patients and its availability is low.

Multiple solutions were available to measure the spine [8], [21,22,23,24]. The Epionics spine device is able to provide excellent data about the range of motion of the spine but is not suited to screenings, as it necessitates to equip the patient with the system. A laser-triangulation system was able to identify the spine on a capture of the back but the system is complex to install and control. Each system answered to a part of the specifications, but the choice was finally a solution based on a depth camera, as it answers most of the defined requirements. The depth camera can be mounted on a tripod to be placed anywhere at the right height, and only necessitates a USB 3.0 to be connected to a computer. Once connected, the camera can capture an FBT without additional times, except for the start and the end of the recording, answering time-related requirements. Depth camera are easily accessible technically and financially, with models such as the Microsoft Kinect. Such cameras can capture the patient back without needing any instrumentation or preparation [28]. For the volume needed, the camera must be placed at about 0.8m from the patient. Research papers showed that this technology could measure the back surface with a good precision and could extract interesting anatomical landmarks [25,26,27]. Considering captures and measurements, the Kinect V2 camera can capture depth image at a rate of 30 frame per second, with a depth resolution of 512x424 pixels and a depth precision of a few millimetres. The available bibliography notably showed that a depth camera has a higher precision than a clinician palpation [27]. Thus, using this depth image to obtain significant data with an improved precision compared to the tools available to health professionals was considered possible. The Kinect V2 sensor was then chosen as the technical solution for the proposed tool.

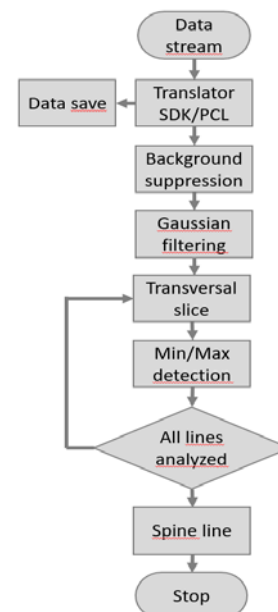


Fig 3. Workflow for the data treatment to obtain the spine line

3.4. Software

The software developed to process and analyze the Kinect data was based on the work of Bonnet et al. [27] and Xu et al. [28]. In these papers, researchers were able to extract anatomical landmarks from the back, and notably the spine. The workflow used to obtain this result is detailed in Figure 3. The first step is to obtain data from the Kinect, by connecting it to computer via USB. The depth data is then translated to a specific format to make it exploitable by the Point Cloud Library (PCL) [29]. In this format, each pixel contains x, y and z coordinates, in meter. The region of the interest is the back of the patient, so it is the only region that will be kept for further analysis, after the background suppression. For this step, every point with a Z coordinate value higher than 1,5m was deleted, and a band of a width of 0.4m in the X direction is kept. The remaining data is filtered with a gaussian filter to diminish the noise. The back is then divided in transversal “slice”, and the line of the spine is considered as the maximum between the soft tissue on each side of the spine (Figure 4). This method should adapt well to scoliotic patient, even with important asymmetries, as it finds the concavity generated by the soft tissue on each side of the spine, without taking in consideration the rest of the back. Each slice is analyzed until the whole back of the patient has been treated. The patient is captured during the execution of an FBT, and the line of the spine is computed for each frame. The results can be seen in Figure 5.

This spine line would be used in further development to compute a value similar to the Cobb angle, such as in the work of Xu et al. [28], for every frame and with a similar precision of 2-3 degrees. The available data would also be used to measure the orientation of the ribcage, similarly to a scoliometer, for every slice. This would give information on the whole back instead of on a few chosen points, and would give information at different level of inclination of the patient, instead at only the lower point of the FBT. It is hypothesized that it could be used to screen with a higher precision.

4. Discussion

The results of our study identified the essential functions that a tool should have to be used in practice for spinal pathology screening. Thus, we observe that the emphasis should be on integrating the tool into work routines, without

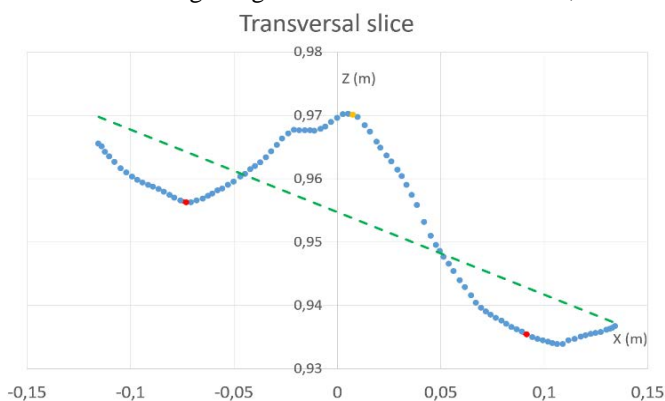


Fig. 4. Example of treatment of a transversal slice. The red dots correspond to the minimums generated by the soft tissue, the orange dot corresponds to the maximum belonging to the spine line.

changing habits. Professionals did not feel the need to request the creation of new measures or completely different methods but rather an improvement and a continuation of what is already existing, they would welcome improvements on measurements they are comfortable with, being on the precision or on the time needed to make them.

The sample population was limited, with 6 participants, but the discussions were rich in information and no new ideas were expressed during the last interview. This study was exploratory and the goal was not to be exactly representative of the target population, but to have a diversified sample. On this point, the network of professional used to create the sample population was specific to our study, and applying the same methodology with other health professionals may lead to different results. A total of 217 minutes of interview were recorded, transcribed, coded and analyzed. This process is subject to the analyst's experience, and the guide, transcription and code evolved during the progression of this study. This type of qualitative study is time consuming, but should ensure a product closer to the needs expressed by professionals. This should have a positive impact on the usefulness of such a development and improve the acceptance of the device in practice and the adoption on the long term.

To fully validate this methodology, the software solution has to be fully developed and a polished final product should be proposed to professionals. It will then be necessary to evaluate the place that professionals have made for it in the screening and follow-up process.

The state of advancement of the technical and software solution illustrated the proof of concept that it was possible to dynamically follow the spine line and the ribcage orientation during an FBT. For further development, multiple types of morphologies have to be integrated to evaluate the robustness of this approach. Capturing an FBT with a depth camera does not necessitates the knowledge of a trained specialist, which could lead to an easier implementation as a wider range of professional could operate it.

5. Limitations

A qualitative study, even if precautions are taken to ensure its quality, presents inherent limitations. The sample population will impact the results, and even if the requirements extracted here are the results of the intersection between the transcripts of multiple interviewee, the results may be different with another population. The interviews, the idea extracted and their interpretation are the results of a specific methodology, but this

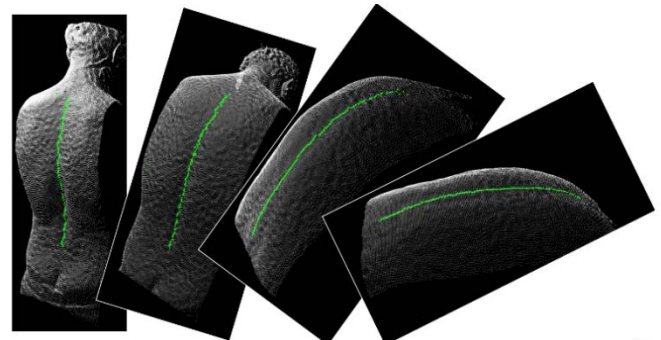


Fig. 5. Tracking of the spine line during an FBT on an adult healthy patient.

workflow may still be influenced by the analysts' experience. This study has an exploratory goal, and fully validating the hypothesis that this methodology leads to a good long-term adoption would necessitate another study after the introduction of the tool in practice.

The technical and software solution chosen here gives good proofs of concepts, but with a limited sample of healthy patient. There need to be more test for different morphologies and Body Mass Indexes (BMI). For low BMI the software solution may need some adaptation, and higher BMI may result in less precise information due to the presence of more soft tissue between the skin and the spine. Furthermore, even if precedent studies showed that it was possible to find a Cobb angle coherent with a radiography, a study exploring the link between the spine line detected using the presented technology and radiography may be necessary.

6. Conclusion

The methodology proposed should allow the design of a more useful tool that will be well integrated into clinical practice, being closer to the profound needs of healthcare professionals. For a complete validation, the tool has to be completely developed and proposed to clinicians. With the appropriate software, it has been judged capable to integrate well in the already existing workflow.

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