TECHNICAL NOTE

A Digital Photogrammetric Method to Enhance the Fabrication of Custom-Made Spinal Orthoses

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ABSTRACT

Introduction and Objectives: Fabrication processes for spinal orthoses require accurate three-dimensional (3D) models of the patients' trunk. Current methods for 3D reconstruction used in this field mainly include laser or structured light scanning; these methods are time expensive and invasive, especially for patients with partial disabilities. Therefore, a theoretically instant system for data acquisition of anatomical structure is highly desirable. The objective of this work is to show the feasibility of using digital photogrammetry for human body digitization to generate accurate 3D models of the patients' trunk for spinal orthoses fabrication.

Materials and Methods: Multiple synchronized two-dimensional images of the human torso are captured from different points of view using a photogrammetric scanner. A 3D model is generated using the state-of-the-art algorithms for point cloud and surface reconstruction. The digitized model is then used as input for the standard computer-aided design (CAD)/computer-aided manufacturing (CAM) process of fabrication. R4D from Rodin4D is used as prosthetics and orthotics CAD software. A robotic cell constituted by a six-axis KUKA KR 30–3 is used for milling a polyurethane foam. Vacuum forming is then adopted to generate the orthosis. Two spinal orthoses are fabricated using this approach and a classical one; then, they are evaluated using quantitative and qualitative metrics.

Results: The data acquisition using this approach lasts 50 milliseconds. The 3D reconstruction accuracy averages 0.21 ± 1.27 mm, which suits for the considered health care scenario. Results of the initial fitting of the orthoses fabricated with the presented method show better performances in terms of time (44%), product quality (35%), and patient experience (30%).

Conclusions: Digital photogrammetry can be used to enhance the data acquisition and data processing of anatomical surfaces for the CAD/CAM process of spinal orthoses. The data acquisition time, almost instant, allows an easy compliance of many patients. The data processing allows generating accurate models of the patient's body. The overall process generates orthoses with a better quality with respect to those manufactured using conventional procedures. (*J Prosthet Orthot.* 2018;00:00–00)

KEY INDEXING TERMS: prosthetics and orthotics, spinal orthoses, three-dimensional reconstruction, photogrammetry, fabrication techniques, CAD/CAM

Historically, custom-made prosthetics and orthotics (P&O) have been fabricated by means of a plaster mold procedure. Clinical practice has pointed out some drawbacks from these processes: time-consuming cast rectification, high plaster consumption, no data storage for future reference, and invasiveness for the patients. The first step toward a standardization of the fabrication process has been the introduction of computer-aided design (CAD) and computer-aided manufacturing (CAM) systems. Wong et al.[1] compared the CAD/CAM method and the conventional method in the fabrication process of spinal orthoses for patients with adolescent idiopathic scoliosis (AIS). They found an improvement in the average time saved for the fabrication of 34%, whereas nonmeaningful differences were found on the dimensions of the developed orthosis.

Digital methods for medical rapid prototyping require three-dimensional (3D) geometric data of anatomical structures, which might be constructed with reverse engineering techniques. In the recent years, several 3D scanners have been introduced for manufacturing of custom-fit P&O. They are usually based on laser or depth sensors technology. Laser body scanners project a single point, line, or multiple lines on the subject and use a video camera to view the laser light onto the subject being scanned. Depth sensors are constituted by an infrared projector and an infrared camera, which records the pattern projected onto the subject. However, the body data acquisition using these scanning technologies is not instantaneous. Even the state-of-art laser body scanning system, the VITUS 3D Body Scanner from Vitronic (https://www.vitronic.com/), requires from 6 to 12 seconds for the acquisition. The slowness of the scanning step is a key issue, in particular for patients with mobility impairments and dysfunctions. As a matter of fact, scoliotic subjects usually require a greater neuromuscular demand to maintain standing balance.[2] Hence, the availability of a fast scanning system is highly desirable. This is the main reason that limits the integration of existing body scanners in real scenarios.

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One promising technology in scanning systems that guarantee the instantaneity of the process is the photogrammetry.[3] This technology allows generating 3D meshes by multiple photos of the scanned subject from different points of view. The first attempt to use photogrammetric scanning in medicine can be found in the work made by Ciobanu and Rotariu,[4] whereas Hernandez and Lemaire[5] used recently a photogrammetric approach based on standard smartphone cameras to digitize sockets for prosthetics.

This technical note presents a digital photogrammetric method to enhance the data acquisition and data processing of body surfaces for the fabrication of custom-made spinal orthoses. The motivation behind this work is the development of procedures for fast data acquisitions of anatomical structures, avoiding the body sway during the scanning process that might affect the accuracy of the digitization. The main contribution of this study is the description of the proposed methodology for the design and fabrication of spinal orthoses. The manufacturing procedure has been implemented on a real clinical scenario, the Ortopedia Ruggiero (https://www.ortopediaruggiero.it/) orthopedic center. We set up a pilot experiment involving a patient with scoliosis and fabricated for him a custom-fit spinal orthosis. We validated the orthosis using an accredited survey for assistive devices.

MATERIALS AND METHODS

A digital photogrammetric approach for manufacturing of custom-made spinal orthoses is presented throughout this study. Written informed consent was obtained from the involved subject. The procedure was in accordance with the Declaration of Helsinki.

Figure 1 depicts the steps of the proposed methodology, which includes two main processes:

- Data acquisition and processing
- Design and fabrication

In the following, we describe each task independently, and we extensively analyze the impact of each one on the overall process.

DATA ACQUISITION

The most significant change in the process of orthotics manufacturing resides in the novel semiautonomous data acquisition approach using INBODY, a 3D scanner developed by the authors.[6] INBODY is an instant photogrammetric whole-body 3D scanner, which can be used with many scanning settings, depending on the anatomical part that needs to be digitized. It is composed by multiple synchronized image sensors, which are disposed in seven circular rings around the patient. Each circular ring contains 17 cameras, since an accurate 3D reconstruction requires at least 60% overlap between two adjacent two-dimensional images.[7] The synchronization of the image sensors requires 50 milliseconds. The overall scan volume is a cylinder with 1 m diameter and 2 m height.

In this phase, the patient is asked to stand inside the scanner in a vertical relaxed position with the upper limbs held slightly apart from the body. This position was chosen in cooperation with the orthotists in the orthopedic center to minimize the alteration of the body's shape and providing that all the torso can be seen by the multiple cameras at the same time. Moreover, in this position, the patient slightly raises her/his axillary parts,

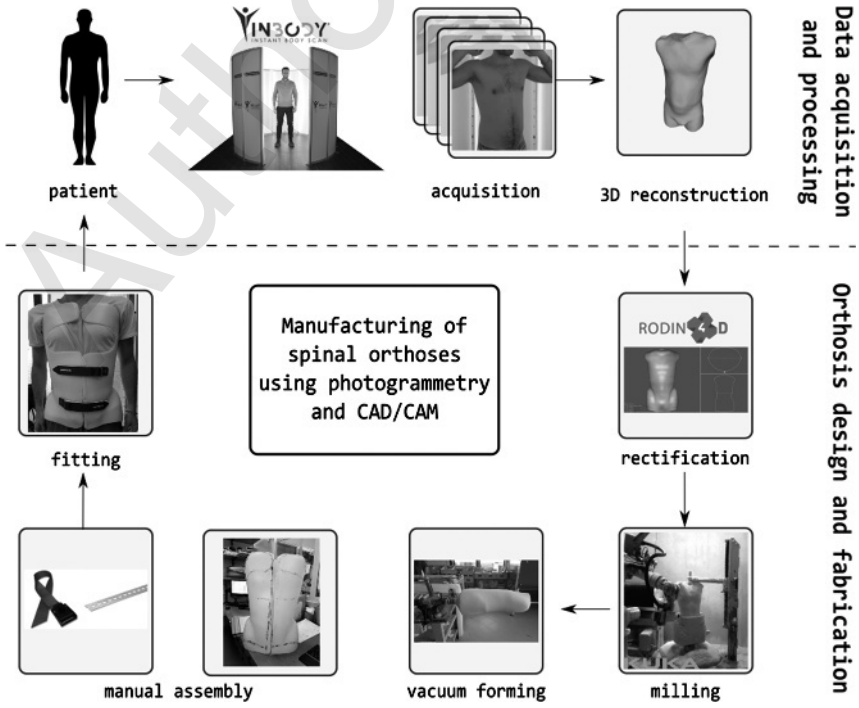

Figure 1. A qualitative picture of the orthotic digital manufacturing framework. The top row depicts the steps for the data acquisition and processing, whereas the bottom shows the design and fabrication phase.

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resulting in fewer modifications of the orthosis in the rectification step. This constitutes a first attempt toward the development of a data acquisition protocol for digital photogrammetric-based procedures of spinal orthoses. It is important to underline that this system does not requires markers on the subject to scan. The photogrammetric scanner allows an instant capture of the patient's body: the minimally invasive data acquisition makes this technology attractive in real medical domains.

DATA PROCESSING

The data processing consists in the 3D reconstruction of the torso starting from the raw images. The procedure is divided in two steps: point cloud generation using the scale invariant feature transform algorithm[8] and surface meshing based on Poisson reconstruction.[9]

The time required for the data processing depends on the laptop client associated with the scanner. In our experiments, performed on an Intel Core i7-4910MQ CPU (quad-core, 2.50 GHz; Turbo, 3.50 GHz), 32-Gb RAM 1600-MHz DDR3L, NVIDIA Quadro K2100 M w/2GB GDDR5 VGA machine, the time required for the digitization procedure of the torso is between 3 and 6 minutes. The output of INBODY is an STL file, which replicates the human body model with a proven magnitude of accuracy in the order of 1 mm.[6]

The 3D model is ready as input file for the design process of the spinal orthosis, depending on the patient's dysfunction. Moreover, it serves as digital medical record to monitor the patient's improvements over time.

RECTIFICATION

The design phase starts from the previously obtained 3D model, which is opportunely modified by an orthopedic expert using opportune P&O CAD software packages. The model rectification is necessary to generate the appropriate pressure distribution, which will be eventually applied by the orthosis on the body regions of the patient. This is important for designing spinal orthoses for patients with AIS. In this phase, we use R4D CAD/CAM from Rodin4D (http://www.rodin4d.com/). During this step, the accurate 3D model of the torso and the pictures of the patient taken from four points of view help the orthopedic expert in finding anatomical landmarks. It is important to notice that the textured 3D model obtained with the photogrammetric data processing might help as well.

MILLING

The STL rectificated model is converted using an appropriate CAM software to generate the path of the milling machine, which fabricates the part starting from a polyurethane foam. One robotic cell constituted by a six-axis KUKA KR 30–3 (https://www.kuka.com/), one motor spindle with automatic tool changer, and one rotating plate is used in this phase. The output of this process is an accurate replication of the human model previously modified.

VACUUM FORMING

Vacuum forming of plastics sheets offers the opportunity to develop functional orthoses directly on the milled foam. Plastic sheets are preheated at 200°C and draped on the milled foam using a vacuum pump. The plastic material used depends on the particular orthosis. The most diffused materials which could be used are polypropylene, polycarbonate, acrylonitrile-butadiene-styrene, cellulose acetate butyrate, and polyethylene.

FINAL ASSEMBLY

The final assembly consists in cutting the plastic shape and positioning the bars and straps depending on the typology of orthosis to deliver.

INITIAL FITTING

The custom-made spinal orthosis fits on the patient's body without any successive modifications. This is a great advantage because the models manufactured starting from manual measurements often require successive adjustment in the usual clinical practice. This has been testified in the orthopedic center.

RESULTS

The study was conducted in an Italian orthopedic center. The pilot experiment involves the manufacturing of a spinal orthosis using the methodology previously described for a patient with AIS. To have the same rectification skills, one orthotist was involved in this study. He had more than 10 years of clinical experience in treating AIS with spinal orthoses and more than 5 years' experience in using CAD/CAM methods.

We designed and fabricated two spinal orthotic braces, which differ in the data acquisition and processing procedures. The first one started from a 3D model obtained by modifying a predefined parametric torso model with manual measurements taken on the patient's body using an orthopedic caliper. The second one started from a 3D model obtained through the presented procedure involving the instant body scanner. Table 1 shows the mean time of the data acquisition and processing procedures in both cases. The photogrammetric scanning allows an instant capture, even if the processing time is higher if compared with the traditional method, which in this case consists in uploading some manual measurements on a predefined STL parametric model.

Table 1. Mean time of the traditional and enhanced data acquisition and processing procedure

Phase	Traditional	Enhanced
Acquisition	350	0.050
Processing	100	250
Total	450	250

Time in seconds.

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Figure 2. 3D milled positive obtained starting from the traditional procedure (left) and the enhanced procedure (right).

In the rest of this section, we first perform a quantitative evaluation of the orthoses fitting by simulating the adaptation of both models to the real patient's body. Then we perform a qualitative study, based on accredited surveys, to obtain feedback from the patient's perspective in wearing both orthoses.

QUANTITATIVE EVALUATION

Figure 2 shows the 3D milled positives obtained starting from the traditional procedure (left) and the enhanced procedure (right). The shapes of the milled positive are different since the rectification process starts with two different initial conditions: from a predefined and parametric STL file where some anthropometric measurements collected on the patient's body are inserted (left); from the STL file representing the digitization of the torso using INBODY (right). Figures 3, 4, 5, and 6 compare the two spinal orthoses by simulating their fitting on the patient's body, as it has been digitized using INBODY (right). In this case, the INBODY model of the patient has been used as reference, because this scanning system has a proven accuracy of 0.21 ± 1.27 mm. Notice that in these figures the 3D deviations are measured on the digitized patient's body model. The objective is to recreate a pressure distribution map, which indicates the fitting on the body surface of the two orthoses. Despite the pressions required in some regions of the patient's back for the effectiveness of the scoliosis treatment, the majority of the body's surface does not need any localized pressure. The required pressions have been produced for the two orthoses in the same way using the same P&O CAD software and the same orthotist. The similar maximum deviations occur in the regions of the desired localized pressure. The smaller average and standard deviation values in the case of the enhanced process (see e.g., Figures 5 and 6) testifies the advantageous use of INBODY in obtaining custom-fit orthoses.

The improvements in terms of custom-fitting, quantified by differences between the designed orthosis and the patient's body, are of 34% and 41% for the positive and negative average values, and of 36% for the standard deviation value. These values have been evaluated as

$$I\,[\%] = \frac{|v_{en} - v_{trad}|}{v_{trad}} \cdot 100 \qquad (1)$$

where I [%] is the percentage improvement, whereas v_{en} and v_{trad} are, respectively, the values obtained in the enhanced case and in the traditional case, as reported in Figures 3, 4, 5, and 6.

A further analysis will include the possibility to obtain the pressure distribution map using pressure mats sensors applied directly on the patient. The problem in this case will be the correct positioning of the pressure mats sensors between the body and the orthosis. This is problematic mainly for patients affected by scoliosis for their mobility impairment. For this reason, we choose to perform, for a first investigation, a simulated fitting.

QUALITATIVE EVALUATION

We evaluated the orthoses using the OPUS, an instrument that allows orthotic and prosthetic practitioners to evaluate the quality and the effectiveness of their services as required by the accreditation standards of the American Board for Certification in Orthotics and Prosthetics.[10] Because our objective is to primarily evaluate the orthosis from the patient perspective, we selected the OPUS, which is the most appropriate tool for measuring patient satisfaction with orthotic devices and services in a clinical setting.[11] The OPUS is articulated in different tasks that the patient has to perform using the orthosis/prosthesis, and it is based both on the feedback from the patients in performing the various activities and on a general evaluation of the orthosis/prosthesis based on some criteria. An evaluation of the clinic services completes the survey.

With the help of the physicians in the orthopedic center and according to the specific clinical condition of AIS, we selected six tasks from the 20 suggested by the OPUS, to evaluate the differences in the two orthoses. These tasks do not comprise the potentially misfitting ones with respect to the patient satisfaction, as indicated by Heinemann et al.[12] The patient was able to successfully perform the selected tasks by wearing both orthoses. Furthermore, he was asked to give a score related to his feeling in performing them: the selected tasks and results are reported in Table 2. Notice that these tests were blinded, in the sense that the patient did not know the fabrication method of the worn orthoses. The principal outcome is that using the spinal orthosis manufactured using the enhanced approach, the tasks were performed more easily. As a matter of fact, the average score and the standard deviation improve, respectively, of 7% and 43%. Table 3 shows the OPUS general quality metrics for orthoses/prostheses. The evaluation criteria are similar to the more general user evaluation of satisfaction with assistive technology proposed by Dremers et al.[13] The medium score of the patient for the quality metrics improves slightly (11%), whereas the standard deviation results 25% worse. This happens because both orthoses present similar scores, except for the comfort and the fitting to the body. The last qualitative evaluation is about the clinical experience subjectively perceived by the patients. This is important for this

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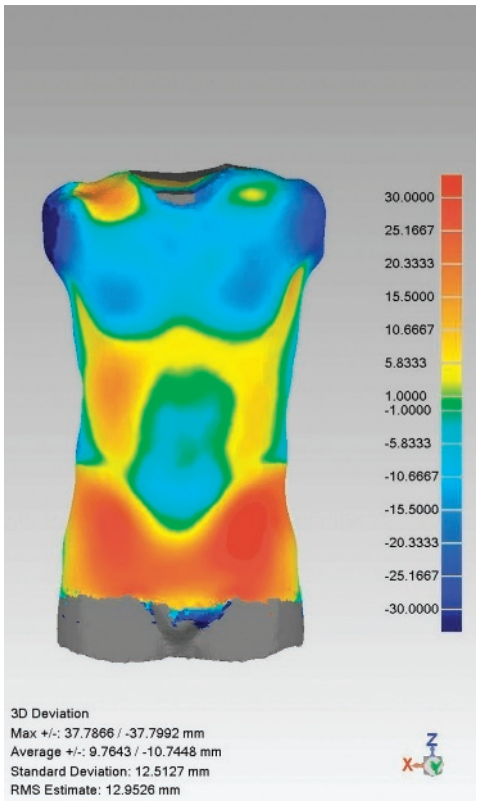

Figure 3. Simulated fitting of the spinal orthoses manufactured using the traditional process on the patient's body (front view).

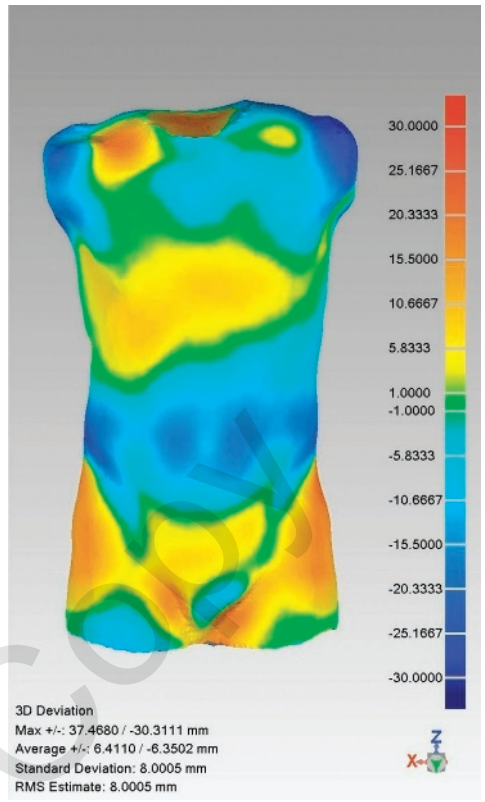

Figure 5. Simulated fitting of the spinal orthoses manufactured using the enhanced process on the patient's body (front view).

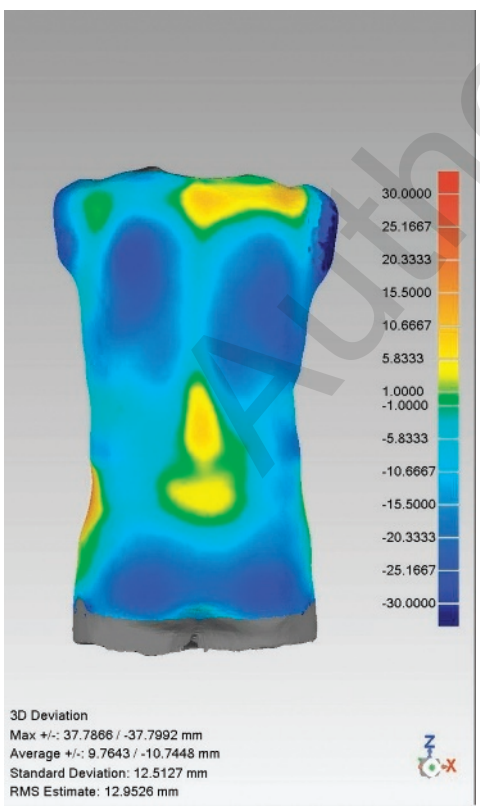

Figure 4. Simulated fitting of the spinal orthoses manufactured using the traditional process on the patient's body (rear view).

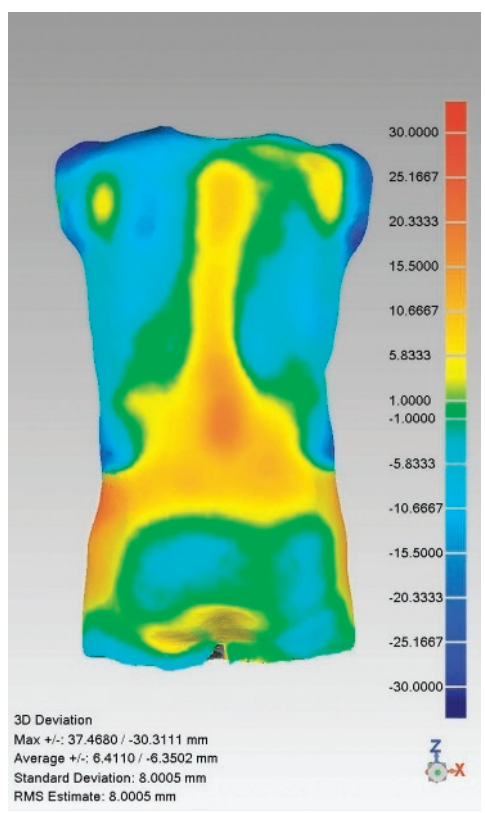

Figure 6. Simulated fitting of the spinal orthoses manufactured using the enhanced process on the patient's body (rear view).

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Table 2. OPUS tasks

Task	Traditional	Enhanced
Dressing	3	2
Balancing	1	2
Picking up object from floor	4	3
Walking	2	2
Going upstairs	3	3
Getting in/out from a car	4	2
μ	2.8	2.3
σ	2.6	1.3

The score ranges from "1 = very easy" to "5 = cannot perform activity." μ = average; σ = standard deviation.

work, because, in the overall process, the data acquisition of the body shape is the only step involving interaction between patients and technology. The experiment in this case comprises 10 subjects, which have first undergone the traditional manual measurement procedure and then INBODY scanning. The subjects were asked to give a score about their experience and satisfaction in both cases (see Table 4). The higher average value obtained using INBODY testifies an improvement of the patient's satisfaction of 74%. The percentage improvements are again obtained as in Wong and Cheng.[1]

DISCUSSION

In this study, a photogrammetric method was presented to enhance the data acquisition and data processing of body surfaces for the fabrication of custom-made spinal orthoses. It uses an instant (50 milliseconds) body scanner system for data acquisition and fast processing (250 seconds) of human body models, which result having a sufficient accuracy (0.21 ± 1.27 mm) for the P&O field.[14] We evaluate the method by using quantitative and qualitative measures. The spinal orthoses fabricated using this method shows better performances in terms of time reduction for data acquisition and processing (44%), product quality (35%), and patient experience (30%). The time reduction value is calculated from Table 1, whereas the product quality and the patient experience values are obtained respectively through the average value of the simulated fitting of Figures 3, 4, 5, and 6, and the average values from Tables 2, 3, and 4. Indeed, these results are possible with a photogrammetric approach because it allows a reduced acquisition time and an improved accuracy of the 3D model (no body sway and easy compliance of the patient). The availability of an instant acquisition system is a great advantage for the practitioner too, as she/he does not need to perform manual measurements, which are time-consuming, tiresome, not repeatable, and affected by human errors. The use of an accurate system is crucial for people affected by scoliosis, because they could exhibit complex body morphologies, which are difficult to capture using predefined 3D models parametrized with few of their anthropometric measurements.

Further planned developments will include a systematic clinical assessment over 1-year treatment in terms of evolution of the spinal curvature and vertebral rotation in different anatomical planes for a larger number of patients.

Table 3. OPUS quality metrics for orthoses/prostheses

Statement	Traditional	Enhanced
It fits well	3	1
Its weight is manageable	2	2
It is comfortable	3	2
It is easy to put on	2	3
It looks good	4	4
It looks durable	2	2
My clothes are free to wear	3	3
My skin is free of irritation	2	2
It is pain free to wear	3	3
μ	2.7	2.4
σ	2	2.5

The score ranges from "1 = strongly agree" to "4 = strongly disagree." μ = average; σ = standard deviation.

Table 4. Patient's experience score

1	2	3	4	5	6	7	8	9	10	μ	σ
5	4	6	2	7	4	3	5	3	8	4.7	1.8
6	8	10	5	8	9	9	10	8	9	8.2	3.8

The mark ranges from "1 = strongly bad experience" to "10 = strongly good experience." μ = average; σ = standard deviation. The first row reports the marks of the conventional procedure, the second row the marks of the procedure enhanced using INBODY.

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