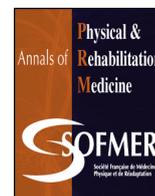




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Original article

Construct validity of the Trunk Aesthetic Clinical Evaluation (TRACE) in young people with idiopathic scoliosis

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ABSTRACT

Background: Aesthetics is recognized as a main outcome in idiopathic scoliosis (IS) treatment, but to date, there is no criterion standard for physicians' evaluation. Trunk Aesthetic Clinical Evaluation (TRACE) is a simple 12-point ordinal scale to quantify symmetry as a proxy of aesthetics. TRACE is already diffused worldwide and has been used in clinical research.

Objective: We aimed to validate TRACE and improve it with Rasch analysis.

Material and methods: This study involved an observational Rasch analysis validation of an evaluation tool in outpatient rehabilitation centres. From a clinical database, we randomly selected patients who had IS, were age 10 to 18, had brace prescription at first evaluation, and had at least 2 consultations. Rasch analysis (partial credit model) was used. Differential item functioning (DIF) was assessed for age, sex, disease severity, bracing and treatment. The median was chosen to dichotomize disease severity and bracing. We removed 64 outlier participants (4%).

Results: We included 1553 participants (1334 females; mean [SD] age 13 [1.7] years old). TRACE items showed ordered thresholds and proper fit to the Rasch model. The score-to-measure conversion table showed proper length (range –4.55 to 4.79 logit) with a mean (SE) measure of –0.52 (0.04) logit. The principal component analysis supported the TRACE unidimensionality. The TRACE was free from DIF for age, sex and bracing.

Conclusions: The TRACE ordinal scale has been converted into a Rasch-consistent, interval-level measure of trunk aesthetics in IS patients and can be used to compare different populations. Its main flaw is low reliability, likely because of the small number of items. TRACE can be used as an outcome measure and in everyday clinical evaluation of IS, even if new developments of the scale are advised.

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1. Introduction

The importance of conservative treatment of idiopathic scoliosis (IS) has been shown by randomised controlled trials [1,2] and is supported by Cochrane reviews [3,4] and current guidelines [5]. In many countries, rehabilitation professionals are involved as leaders in this treatment [6,7]. The accurate development of appropriate evaluation tools to clinically check the main outcomes of IS treatment is an indispensable prerequisite to the rehabilitation approach [5].

Trunk aesthetics is a main concern for families and IS patients [8]. Surgeons consider a poor trunk appearance as a possible indication for spine fusion in young patients [9], and also conservative treatment guidelines state that this is a main goal for bracing [10]. To properly address these concerns, a measurement instrument is needed for trunk aesthetics to be used as an outcome criterion both for individual patient care and clinical research.

Some tools have been developed to assess the aesthetic impairment in IS [11]. These tools can be approximately classified as instruments that evaluate the subjective perception or the objective external appearance. The first ones include mainly self-administered questionnaires for quality of life that consider also the aesthetic component; examples are the Scoliosis Research Society 22 (SRS-22) questionnaire [12] and the Italian Spinal Youth

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Quality of Life (ISYQoL) questionnaire [13] as well as visual scales based on drawings of the trunk completed by the patient, such as the Walter Reed assessment scale [14] and its evolution, the Trunk Appearance Perception Scale [15].

Because the impact of IS on aesthetics is the asymmetrical trunk deformity, evaluation instruments of objective external appearance assess symmetry as a proxy of aesthetics [16]. However, we lack a criterion standard. Existing tools include measures on pictures such as the Posterior Trunk Symmetry Index (POTSI) and Anterior Trunk Symmetry Index (ATSI) as well as a clinical tool based on the judgment of asymmetries by physicians and therapists, called Trunk Aesthetic Clinical Evaluation (TRACE) [17]. TRACE is a 4-item scale evaluating the asymmetries of shoulders, scapulae, waist and hemithorax. It produces a global score that can be monitored over time. Being grounded by conventional physical examination of the patient with scoliosis, its face validity is straightforward. The validation of TRACE in the classical test theory framework provided fair intra- and inter-rater reliability. Moreover, minimal detectable changes were also reported [17].

TRACE is extensively used in clinics by some professionals and has been already used in clinical research [16]. As compared with the 2 other existing objective instruments, POTSI and ATSI, TRACE does not require any external equipment or software and is quick to administer, fast to learn and easy to use by any trained physician and therapist. Because of these advantages and the actual lack of a standard criterion for such an important clinical outcome, we focused on improving TRACE.

Like many other similar tools, TRACE provides an ordinal value of aesthetics. Ordinal measures can correctly order patients but cannot tell exactly the differences between patients in different classes (e.g., the difference between 2 patients with TRACE scores of 12 and 9 is not necessarily the same as 2 patients with TRACE scores of 10 and 7), this can be done only with interval or ratio measures. Rasch analysis is a statistical instrument that was developed to convert ordinal scales into interval measures [18]. Rasch-consistent measures have proper construct validity [19] and have shown important advantages over classical tests. For example:

- at the same reliability level, they are usually shorter (thus needing less time for completion [20]);
- they give estimates of the measurement error (thus allowing robust patient evaluation also at an individual level [21]);
- they allow for a finer and richer detailed evaluation of the patient [22].

In the field of scoliosis treatment, Rasch analysis has been recently used to check the validity of the SRS-22 construct by producing the Scoliosis Research Society 7 (SRS-7) as well as to develop the ISYQoL [13,20].

The main aim of the current work was to check whether TRACE was robust enough to comply with the Rasch analysis, that is, to verify its additivity, generalizability and unidimensionality. In case of a positive answer, secondary aims included producing an interval measure instead of the actual ordinal scale and identifying the main limits of TRACE to improve it in the future.

2. Methods

2.1. Design

This was a Rasch analysis validation of an evaluation tool. Ethical approval for the study was obtained from the local ethics committee (Comitato Etico Milano Area B).

2.2. Participants

From September 2007 to October 30, 2017, all patients visiting one of the centers of our institute, physical and rehabilitation tertiary referral institute specialized in spinal disorders, were evaluated by an expert physician for trunk aesthetics by using the TRACE index. All data were collected during the visits and were directly stored in an online database that included 19,904 patients with TRACE evaluations of all their consultations (2.38 evaluations per patient, on average). The inclusion criteria were IS diagnosis according to the criteria of the Society on Scoliosis Orthopedic and Rehabilitation Treatment (SOSORT) and Scoliosis Research Society (SRS) [23-25], age 10 to 18 years at the time of the visit, never previously treated with a brace and brace prescription at first evaluation, and at least 2 consultations. Exclusion criteria were history of previous treatments for IS, history of spine surgery, additional spinal deformities (e.g., scoliosis and kyphosis), history of relevant diseases, surgery or trauma and a positive neurological examination.

2.3. Sample size

We had 2177 potential candidates for our study. In the Rasch analysis framework, a sample size of 300 participants estimates both items and persons accurately [26]. However, larger sample sizes obviously increase the precision of the estimates and are common in Rasch studies [27]. To evaluate the TRACE with better accuracy, we chose to recruit about 1500 participants that is, 5 times more the 300 threshold. We added about 50 participants more so that about 1500 participants completed the analysis after the poorly fitting persons were removed (see below). We took care that about half the respondents were at their first evaluation and the other half at their first follow-up after 4 months of bracing (see generalizability analysis).

2.4. TRACE index

TRACE [17] is characterized by 4 items: shoulders, scapulae, waist and hemithorax. It was developed from a previous aesthetic score measure. Each item of asymmetry is ordinally scored from a minimum of 0 (absent) to a maximum of 2 (for scapulae and hemithorax), 3 (for shoulders) or 4 (for waist). The final index is obtained by adding 1 point to all the values of the 4 items, and ranges from 1 to 12.

TRACE [17] is a very easy tool to administer, collected in a mean (SD) of 14.5 (6.9) s, according to a sample of 11 expert physicians who evaluated a mean of 39.5 (29.2) scoliosis patients per week over 9.2 years (range 1-27). We did not find any difference according to experience, profession and number of patients evaluated per week. The instrument is learned by practitioners in a couple of hours with an online tool. All expert physicians working in our institute had been using TRACE for at least 6 months (coaching period to get used to all tools used during everyday clinical activity). For each participant, the treating physician completed the TRACE scale (one scale per participant).

2.5. Rasch analysis

With Rasch analysis, one can evaluate whether a measure complies with the requirement of a genuine measure (i.e., measures such as those of the physics). A Rasch-consistent measure is additive, unidimensional and generalizable.

Genuine measures are additive, meaning that a change of a measure of a certain amount (i.e., obtained by arithmetic addition or subtraction) implies an equivalent change of the measured variable all along the measurement continuum. A car passing from

155 15 to 25 km/h increases its velocity the same as when passing
156 from 30 to 40 km/h. If an ordinal scale is used, there is no
157 guarantee that the car velocity increases the same amount when
158 the speed moves from “slow” (score 1) to “fast” (score 2) and from
159 “fast” to “even faster” (score 3). Measures that comply with the
160 Rasch model can be expressed on an interval scale, thus ensuring
161 additivity. Departure of measures from the Rasch model is
162 quantified by the infit and misfit statistics and, if data perfectly fit
163 the model, both infit and misfit are expected to be equal 1
164 (tolerance range: 0.5–1.5). Interval measures have obvious
165 advantages over ordinal ones. For one thing, parametric statistics
166 such as effect sizes, which are commonly used in clinical trials
167 [28], can be calculated on Rasch interval measures but not on
168 ordinal scores.

169 Measures are unidimensional, meaning that they address a
170 single variable at a time. In the physical world, scales measure
171 mass (i.e., one dimension only) and not mass and “something else”
172 (e.g., temperature). A principal component analysis (PCA) of a
173 dataset consisting of one-dimensional measures would return a
174 single component explaining a large amount of data variance.
175 Therefore, it can be concluded that a test is one-dimensional if the
176 PCA on the residuals of the Rasch model fails to find one (or more)
177 components explaining a large part of the residuals variance.

178 Measures are generalizable, meaning that they do not depend
179 on the measured object or the measuring subject. The measured
180 length of an object 1 m long is “1 m”, regardless of whether the
181 object is a table or a wall and whether the object is measured by a
182 man or a woman. Questionnaire generalizability is evaluated by
183 investigating the presence of differential item functioning (DIF). An
184 item is affected by DIF if different groups of participants (e.g., males
185 vs females) whose measure is the same on the latent variable (e.g.,
186 trunk disfigurement) score differently on that item. DIF is present if
187 the item calibration difference between the opposite groups
188 is > 0.5 logit.

The Rasch analysis partial credit model was conducted by using
190 the Winsteps software. The DIF was assessed for age (children vs
191 adolescents according to SOSORT criteria) [5], sex (male vs female),
192 disease severity (i.e., Cobb degrees: mild vs severe according to
193 SOSORT criteria) [5], bracing (i.e., number of hours/day wearing the
194 brace) and treatment (first examination vs follow-up after 1-year
195 treatment). The median was chosen to dichotomize disease
196 severity and bracing. The median was chosen for the sample
197 splitting procedure because we preferred that the same number of
198 participants be present in the 2 groups. We removed 64 outlier
199 (misfit) participants (4%).

200 The primary aim would be considered achieved in case of
201 robustness to the Rasch analysis. In this case, the analysis would
202 also provide the secondary aims (i.e., a reliable interval measure
203 and the main measurement limits of TRACE, if any).

3. Results

204 We included 1553 randomly selected patients: 1334 females,
205 mean (SD) age 13.0 (1.7) years, mean 36.7 (12.2) Cobb degrees and
206 median TRACE score 7 (Q1–Q3: 5.2; 9.0). Distribution of curves
207 included 28% single (50% thoracic, 36% thoracolumbar) and 65%
208 double (61% thoracic-lumbar, 34% thoracic-thoracolumbar, 5%
209 Moe type).

210 All 4 TRACE items showed ordered thresholds, even if the
211 middle category of item 4 (hemithorax) emerges for a very limited
212 range, which suggests that 2 categories could be enough for this
213 item (Fig. 1). All items properly fitted the Rasch model (infit:
214 $0.81 \div 1.16$; misfit: $0.66 \div 1.14$); therefore, there was no need to
215 remove or change any of the items, given that TRACE scores
216 changed as trunk appearance changed, as predicted by the model.
217

218 The items were well distributed and the item map showed
219 proper length, ranging from -4.55 to 4.79 logit. The mean (SE)

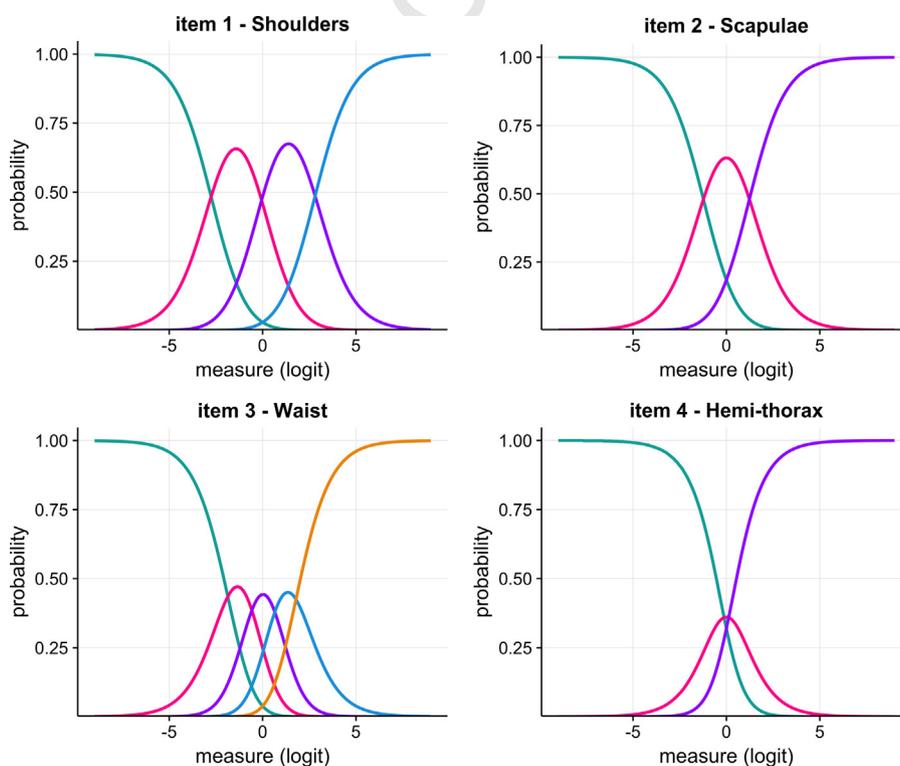


Fig. 1. TRACE category probability curves. All 4 items have ordered thresholds (i.e., each category emerges on the latent trait continuum [trunk aesthetic appearance, logits]). Of note, all 5 categories of item 3 (waist) are properly distributed, which confirms the solid scoring structure of this item. However, the middle category of item 4 (hemithorax) emerges for a very limited range, which suggests that 2 (rather than 3) categories could be enough for this item.

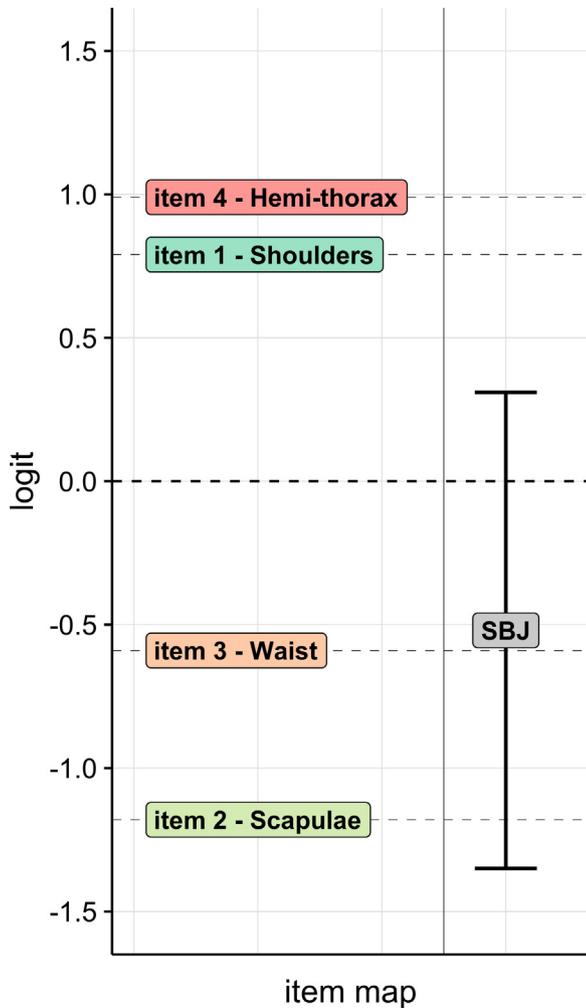


Fig. 2. TRACE item map. The items and the mean for participants (SBJ) are well distributed. There was only a slight “floor effect”; the average is < 0 and dispersion reaches the minimum. Because of the distribution, another item between the waist and shoulder would be useful. Of note, scoliosis impacts the scapulae first and hemithorax only when it becomes serious.

measure was -0.52 logit (0.04), slightly below the item mean measure (0 logit) (Fig. 2).

The PCA of Rasch residuals supported the TRACE unidimensionality (raw variance explained by measures: 60%; unexplained variance in first contrast: 1.7 eigenvalue units).

The TRACE was free of DIF for shoulders, waist and hemithorax items for age, sex, disease severity, bracing and treatment (Table 1). For the scapulae item, DIF was moderate for disease severity (contrast: 0.51 logit; joint SE 0.1 logit) and treatment (contrast:

0.58 logit; joint SE 0.1 logit) even if slightly and non-significantly above the 0.5-logit threshold. Overall, TRACE allows for comparing trunk appearance in children and adolescents, males and female, people with mild and severe IS, people wearing the brace a few hours per day and those wearing the brace all day and in patients before and after the treatment onset.

The Rasch reliability, a measure of internal consistency, was low (0.63 ÷ 0.70), so the test can discriminate 2 levels in the sample.

The conversion of the TRACE score into the corresponding interval measure is reported in Table 2, with high scores and 100 measure indicating poor trunk aesthetic appearance.

4. Discussion

Rasch analysis showed that TRACE can return a genuine, interval measure of the trunk aesthetic evaluated by an expert physician in young people with IS. According to the present results, TRACE can be used to compare trunk appearance in adolescents and children, males and females and before and after treatment in patients with different curve magnitudes and treated with different brace dosages.

One of the main goals of conservative treatment is improving the aesthetics of the trunk [8]; in fact, trunk deformities may have psychosocial impacts and significantly affect the quality of life of people with scoliosis [20,29-31]. Therefore, correcting trunk deformities is an important issue in conservative treatment. Therapeutic outcomes may be subjectively visually assessed by using a specifically designed questionnaire or objectively assessed by using surface topography and photographic methods [32-36]. New technologies such as surface topography [36,37] and other systematic methods to score pictures [32,38] provide objective measures of asymmetries but also require complex tools or expensive instruments that may discourage professionals to use them in everyday practice. Moreover, these instruments are time-consuming and require a post-process that does not allow for real-time application in everyday clinics. Because of the limits of these new technologies, they are not widely used; conversely, an easy to use, rapid and cost-effective clinical tool can be used by everyone in everyday clinical practice.

TRACE can be widely used because it allows for easily monitoring the aesthetics of the trunk in 20 s; it can be learned rapidly and used extensively because it has no inherent costs. The main limitation to its widespread use is that by being based on expert judgement, it requires regular practice on scoliosis patients. TRACE can be used at different follow-ups and can represent an outcome for treatment results or disease progression, thereby representing a great achievement in the field of conservative scoliosis treatment. Even if it is based on the opinion expressed by the operator, which could be a possible limitation of TRACE, our results show the proper fit to the Rasch analysis and its unidimensionality, which confirms that TRACE is a Rasch-

Table 1
Differential item functioning (DIF) data for the TRACE in young people with idiopathic scoliosis.

	Age (children vs adolescent)	Sex (male vs female)	Disease severity (mild vs severe)	Brace hours (low vs high)	Consultation (first vs follow-up)
Shoulders	-0.20 (-0.40; -0.00)	-0.02 (-0.29; 0.25)	-0.12 (-0.30; 0.06)	-0.13 (-0.33; 0.07)	0.43 (0.25; 0.60)
Scapulae	-0.13 (-0.33; 0.07)	-0.08 (-0.35; 0.19)	0.51 (0.31; 0.71) ^a	0.44 (0.24; 0.64)	0.58 (0.38; 0.78) ^a
Waist	0.15 (0.01; 0.29)	0.11 (-0.09; 0.31)	-0.16 (-0.30; -0.02)	-0.09 (-0.23; 0.05)	-0.36 (-0.50; -0.22)
Hemithorax	0.02 (-0.18; 0.22)	-0.17 (-0.46; 0.12)	0.00 (-0.20; 0.20)	-0.12 (-0.34; 0.10)	-0.50 (-0.76; -0.25)

Data are DIF contrast and 95% confidence intervals (CIs).

DIF was tested for age, sex, disease severity, bracing hours per day and treatment. DIF contrast: item calibration difference in the two DIF groups. DIF contrast and the corresponding 95% CI are given in logit.

^a Items with DIF contrast > 0.5 logit, the minimum value for DIF to be noticeable. However, both DIF contrasts > 0.5 logit are barely (and not significantly) larger than this threshold.

Table 2

Score-to-measure conversion for the TRACE total score.

TRACE raw score	1	2	3	4	5	6	7	8	9	10	11	12
Interval measure	0	14.7	25.1	32.8	39.5	45.6	51.3	56.8	62.7	70.2	82.4	100
Standard error	20.2	12.0	9.6	8.7	8.3	7.9	7.7	7.8	8.3	9.8	13.4	21.4

The table shows conversion of the raw TRACE score into the corresponding interval measure. The logit measure (not shown) was transformed to have a measure in the 0–100 range, with 100 indicating poor trunk aesthetic appearance.

consistent measure, to be disseminated among professionals in the field of conservative scoliosis treatment.

The scapulae item showed moderate DIF for disease severity and treatment, whereas the middle category of the hemithorax item emerged only for a very limited range of the latent variable continuum. These results confirm our clinical impression that these items are the weakest of the TRACE index. Because the middle category of the hemithorax item emerged less does not distort the measurement but simply indicates that clinicians seldom choose this category when they score patients. The DIF of the scapulae item for disease severity and treatment could be more serious from a measurement point of view. For example, the DIF for treatment could indicate that patients could score better on the scapulae item (thus obtaining better overall measures) just because they are evaluated in a follow-up visit and not because their trunk disfigurement is actually better. However, DIF size is slightly above the 0.5 logit, which is commonly considered the minimum value for DIF to be noticeable, and since we plan future improvements of the TRACE (see below), we prefer not to correct the slight DIF distortion at this time.

The scapulae can affect the trunk shape toward asymmetry but also for hump. The concept of hemithorax can be interpreted in different ways by professionals, and a prominent rib hump can affect this score, as can a flat or hollow back. To develop a better measure of the trunk aesthetics and in light of the current results, an increase is advisable in the available score for the scapulae and hemithorax items and in the total number of items.

The low-level reliability found on Rasch analysis of TRACE was due to the few items used; increasing the number of items is a common way to improve reliability. Therefore, increasing the number of items could lead to a possible improvement of the reliability of the tested measure. Some already developed aesthetics tools also consider the anterior shape of the trunk [38,39]. To improve TRACE, one way could be to add some asymmetry items related to the anterior view of the trunk such as the breast, sternum or anterior rib hump.

Future development of TRACE aims at improving its reliability, thus offering a better measure to discriminate different levels of aesthetic severity of the trunk in patients with IS.

4.1. Limitations

The main limitations of this study include the fact that TRACE was an existing instrument developed by clinicians and not specifically developed in a Rasch environment: consequently, it was not based on a sufficient number of items. The study focused on patients during growth; although we can expect the potential to expand to adult patients as well, this has not been explored. We included patients of age 10 to 18, the most common age group with spinal deformities. Consequently, current results cannot be applied to younger patients or adults: future studies can address this specific issue. However, the patient sample we recruited is fully representative of IS in young people. In support of this, as expected, IS was more frequent in females than males, and single thoracic and double thoracic-lumbar curves were the most frequent curve types, accounting for about half of the sample. The sample mean age was about 13 years, which suggests that adolescents were well

represented, another important aspect given that adolescent IS is the most common type of IS in young people. Similarly, mean Cobb degrees was about 35, so the sample was finely centred on moderate disease. Another limitation is inherent in TRACE not including the sagittal plane, which also influences aesthetics. Only the horizontal plane is included, together with the frontal one.

5. Conclusions

Rasch analysis showed that TRACE can return a genuine, Rasch-consistent, interval-level measure of trunk aesthetic appearance in IS. The TRACE measure can be used to compare the trunk appearance in different conditions and patient populations. The main flaw of TRACE is its low reliability, likely because of the small number of items. The present results show how good this instrument can be to measure trunk aesthetic appearance in IS and also how it could be improved. Future development could include an increase in the number of items considered and/or a global view of the trunk such as lateral, anterior or posterior unbalance and global rotation. TRACE is already included by many teams in their everyday evaluation. Our results give additional strength to its regular use.

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Disclosure of interest

The authors declare that they have no competing interest.

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