Health-related quality of life in patients with cleft palate: validity and reliability of the VPI Effects on Life Outcomes (VELO) questionnaire translated to Dutch

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**Abstract**

**Background:** Disease-specific health-related quality of life (HRQOL) questionnaires provide the clinician with important information regarding the impact of the disease on functioning and well-being. For patients with velopharyngeal insufficiency (VPI), the VPI Effects on Life Outcomes (VELO) questionnaire was developed and validated in English by Skirko et al. (2012). However, a valid and reliable Dutch translation of this questionnaire is not available yet.

**Methods:** The English questionnaire was translated to Dutch following a forward-backward translation procedure. A linguistic validation and the evaluation of the internal consistency (Cronbach’s α) of this Dutch version were performed based on the responses of 39 parents of patients with cleft (lip and) palate (mean age: 6.8 years) (parent report) and the responses of 14 patients older than 8 years (mean age: 9.5 years) (child report). Additionally, the concurrent validity was assessed by comparing the scores on the parent report to those on the pediatric voice handicap index. Furthermore, the validity of the parent proxy assessment and the relationship between age and responses on the VELO questionnaire were investigated. Based on the responses of an age and gender matched control group without cleft palate, the discriminant validity was evaluated.

**Results:** The parent report was easy to complete for all parents. Nine of the fourteen (64%) patients were able to complete the child report independently. The median scores on the parent report and the child report were 82.7 and 95.1 respectively. The patient group had a significantly worse perception of HRQOL compared to the control group ($p < 0.001; p = 0.029$). There were no significant differences between the responses of the parent and their child’s ($p = 0.345$). A significant positive correlation was found between the score on the parent report and the age of the patients ($p = 0.001$). Furthermore, a significant negative
correlation was found between the parent report and the P-VHI \((p < 0.001)\). Cronbach’s \(\alpha\) was 0.955 and 0.817 for the parent report and the child report respectively.

**Conclusion:** The Dutch VELO questionnaire is a valid, reliable and user-friendly tool that provides important information about HRQOL in patients with cleft (lip and) palate.

**Keywords:** cleft palate; health-related quality of life; assessment
Introduction

Quality of life is a well-known concept describing a person’s well-being, and is considered to be an important parameter to assess treatment outcomes [1]. More specifically, health-related quality of life (HRQOL) is a commonly used approach to describe a patient’s perception of the effect his/her health status has on functioning and well-being [2-4]. HRQOL instruments are characterized by their subjective and multidimensional nature, addressing minimally physical, mental and social domains of health [3, 5-7]. These instruments can be either generic or disease-specific. Generic instruments facilitate the comparison between populations with and without a disease. Disease-specific instruments on the other hand obtain information related to a certain pathology [4].

With an incidence of approximately 1 in 1000 live births, clefts of the (lip and) palate (C(L)P) are one of the most common congenital deformities [8]. This disruption of the facial structure causes an abnormal velopharyngeal anatomy, frequently resulting in the inability to accomplish closure of the velopharyngeal valve, even following primary palatal closure [9], which is referred to as velopharyngeal insufficiency (VPI) [10]. Clefts of the (lip and) palate are the most common cause of VPI. However, other congenital causes such as velar dysplasia [11] and acquired conditions such as VPI following adenoidectomy [12] have been described. Adequate velopharyngeal function is important for the correct production of speech sounds and swallowing. Consequently, VPI can affect these acts and inherently psychosocial aspects of life [13, 14]. Considering this distinctive impact of VPI, a disease-specific instrument could provide insight in the degree to which a patient’s functioning and well-being is affected by VPI [14]. Furthermore, a valid and reliable VPI-specific HRQOL instrument should be able to detect changes in HRQOL [15].

Such a disease-specific instrument for patients with VPI was developed by Barr et al. [14]. Their Velopharyngeal Insufficiency Quality-of-Life (VPIQL) instrument consisted of 48
items which were retained following focus groups, including patients and their parents, and clinician’s panels. However, Skirko et al. [16] found that 22 items of this questionnaire were redundant. These redundant items were identified following statistical analysis including the detection of floor and ceiling effects based on the endorsement frequency, item-total correlation and item-item correlation. Subsequently, a panel of clinicians, two pediatric otolaryngologists and one speech-language pathologist, decided to eliminate these items.

Elimination of these 22 items resulted in the VPI Effects on Life Outcomes (VELO) instrument [16]. The VELO questionnaire consists of a component for the parent (parent report) as well as for the patient (child report), with each item being scored on a Likert-type scale, ranging from zero (never) to four (almost always). The parent report comprises 26 items addressing six domains: speech limitation (7 items), swallowing problems (3 items), situational difficulty (5 items), emotional impact (4 items), perception by others (4 items) and caregiver impact (3 items). The 23-item child report addresses the same domains, except caregiver impact. Similar to the score on the PedsQL[17], a generic HRQOL questionnaire for the pediatric population, the total scores on the VELO questionnaire and on the subscales range from 0 to 100, with 100 representing the highest quality of life [16]. A first evaluation of the reliability and validity of the VELO questionnaire showed excellent internal consistency, discriminant validity and concurrent validity with the PedsQL[16]. Importantly, the readability of the VELO questionnaire was also evaluated and improved based on the results of the Flesch-Kincaide Grade Level [16, 18]. A subsequent study by Skirko et al. [19] demonstrated concurrent validity of the VELO instrument with the Pediatric Voice Outcomes Survey [20], the Pediatric Voice Related Quality of Life [21], and a combined visual analogue scale evaluating speech, swallowing, and situational and social interactions. Furthermore, excellent test-retest reliability, anatomic construct validity and responsiveness of the VELO instrument to change of the quality of life three months after
treatment were found. Finally, a recent study also showed sensitivity of the VELO questionnaire to clinically important VPI-specific quality of life improvements following Furlow palatoplasty and sphincter palatoplasty [22].

Although the VELO questionnaire has shown to be a valid and reliable instrument to measure HRQOL in children with VPI, this instrument cannot be used in non-English speaking populations. Therefore, a careful translation and a rigorous testing of the validity and reliability in the specific cultural context is required [23, 24]. Hence, the purpose of the current study was to translate the VELO questionnaire to Dutch and to analyze the validity and reliability of the translated version based on the responses of patients with C(L)P and their parents, as this congenital malformation is the leading cause of VPI [25].

Methods

This study was approved by the ethical committee of the Ghent University Hospital (2016/0338). All patients and their parents participated voluntarily and signed an informed consent.

Translation of the VELO questionnaire to Dutch

A forward-backward translation procedure was conducted by the authors, following the principles of good practice described by the ISPOR Task Force for Translation and Cultural Adaptation [26]. The forward translation from English to Dutch was conducted independently by two Dutch speaking researchers with a professional proficiency in English. They also had clinical and research experience in patients with C(L)P. Thereafter, both Dutch versions were reconciled until a consensus was reached. The backward translation from Dutch to English was conducted by an English native speaker. Finally, following review of the backward translation by comparing this translation with the original instrument, a definite Dutch version was constructed. This procedure was followed for both the parent report and the child report.
During the translation process, special attention was given to the wording to increase readability. In order to evaluate and improve the performance of the questionnaire, all parents participating in the current study were asked to evaluate the clarity and readability of the items. Furthermore, the parents were asked to indicate whether their child was able to complete the questionnaire independently and if not, what was unclear.

*Subjects and data collection*

Thirty-nine subjects with a history of C(L)P aged between 3 and 12 years (*Mean (M) = 6.8* years, *Standard Deviation (SD) = 2.41*) were enrolled between July 2016 and November 2016. Seven patients had a bilateral cleft lip and palate (BCLP), 16 patients presented with a unilateral cleft lip and palate (UCLP) and 16 patients had a cleft palate only (CP). All patients were followed by the multidisciplinary craniofacial team of the Ghent University Hospital. They all had Dutch as their mother tongue, as well as their parents. Indications of VPI were not taken into account for the inclusion of the participants. Patients with a syndrome, a moderate or severe hearing loss or severe cognitive impairment were excluded. This information was retrieved from the patient’s medical records.

The control group was recruited by convenience and snowball sampling, and consisted of participants without cleft palate or any other craniofacial malformation, cognitive impairment, moderate or severe hearing loss, neurological deficit, or previously diagnosed speech or language disorder. The absence of these criteria was evaluated based on the subjective report of the parents. The participants of the control group were matched with the patients for gender and age. Both the experimental group and the control group consisted of 13 boys and 26 girls. The mean age of the control group was 6.7 years (*SD= 2.38*), which was not significantly different from the experimental group (*t(76) = 0.24, p = 0.814*).
Similar to the procedure described by Skirko et al. [19], only the parent report was completed when the participants were younger than 8 years of age. When patients were 8 years or older, the child report was completed in addition to the parent report. The parents were allowed to assist their child when they experienced difficulties completing the questionnaire.

Statistical analysis

Statistical analysis was performed using SPSS version 24.0 (SPSS Inc., Chicago, Illinois). The significance level for all analyses was set at \( p \leq 0.05 \). As distributions deviated from normal, all analyses were conducted using non-parametric statistical tests. Responses on the VELO questionnaire were recoded \((0 = 100, 1 = 75, 2 = 50, 3 = 25, 4 = 0)\) for further analysis, so that scores on the reports ranged from zero to hundred with 100 representing the highest quality of life [16, 17].

Discriminant validity

The lower quartile, median and upper quartile of the scores, as well as the minimal and maximal score on the parent report and the child report were calculated. Discriminant validity was evaluated by comparing the scores of the experimental group to those of the control group by means of the Mann-Whitney U test.

Validity of the parent proxy assessment

For the comparison between the parent’s and the child’s response, the Wilcoxon signed-rank test was used. These differences were also evaluated by subtracting the total score on the child report from the total score on the parent report. Hence, a negative difference indicates a more positive HRQOL perception by the child in comparison to their parent, with 100 being the greatest possible difference. The frequency of negative and positive differences, as well as the minimal and maximal result of these subtractions were determined.

Analysis of age effect
A correlation was determined between the patient’s age and the responses on the VELO questionnaire using Spearman’s rank order correlation ($r_s$).

**Concurrent validity**

Similar to Skirko et al. [19], the parents were asked to complete the pediatric voice handicap index (P-VHI), a questionnaire which qualifies the impact of voice problems on quality of life [27], and has been translated and validated in Dutch [28]. The correlation between the VELO questionnaire and the P-VHI was determined using Spearman’s rank order correlation ($r_s$) and by calculating the coefficient of determination ($r_s^2$).

**Internal consistency**

The internal consistency of the VELO questionnaire was determined using Cronbach’s $\alpha$. A value greater than 0.70 was considered sufficient [29]. As suggested by Cronbach [30], Cronbach’s $\alpha$ was calculated for the total questionnaire and for each subscale.

**Results**

**Linguistic validation**

All parents of the patients with C(L)P indicated that the questionnaire was readable and easy to complete. Nine of the fourteen patients (64%) were able to complete the child report independently. Three of these patients had difficulties with wording (‘frustrated’ and ‘ignored’).

**Discriminant validity**

A median total score of 82.7 and 95.1 for the parent report ($n=39$) and the child report ($n=14$) respectively (table 1) was found in the patient group. The total score on the parent report ($U = 1274.50, z = +5.16, p < 0.001, r = + 0.58$) and the total score on the child report ($U = 135.50, z = +2.22, p = 0.029, r = + 0.43$) differed significantly between the patient group and the
control group. Moreover, the scores on all subscales of the parent report were significantly higher in the experimental group in comparison with the control group. This was not the case for the subscales of the child report. A summary of the responses of the control group, and the results of the Mann Whitney U test are displayed in Tables 2 and 3 respectively.

Please insert table 1, 2 and 3 approximately here

Validity of the parent proxy assessment

There were no significant differences between the parent’s and child’s total score on the VELO questionnaire ($Z = -0.945, p = 0.345, r = -0.18$) ($n=14$). Neither were there significant differences between the responses on the subscales: speech ($Z = -1.266, p = 0.205, r = -0.24$), swallowing ($Z = -1.000, p = 0.317, r = -0.18$), situational difficulties ($Z = -0.712, p = 0.476, r = -0.14$), emotional impact ($Z = -0.552, p = 0.581, r = -0.10$) and perception by others ($Z = 0.000, p = 1.000, r = 0.00$). Subtraction of the total score on the child report from the total score on the parent report resulted in a negative difference in eight of the fourteen (57%) participants (range: (-18) – (-2)). A positive difference was found for the other participants (range: (+1) –(+5)).

Analysis of age effect

A significant positive correlation was found between the age (months) of the patients and the total score on the parent report ($r_s(37) = +0.496; p = 0.001$). No significant correlation was found between age and the total score on the child report $r_s(12) = -0.420; p = 0.135$.

Concurrent validity

Analysis showed a significant negative correlation between the total score on the parent report and the total score on the P-VHI ($r_s(37) = -0.926; p < 0.001$). The coefficient of determination ($r_s^2$) was 0.857.

Internal consistency
Cronbach’s $\alpha$ was 0.955 for the parent report and 0.817 for the child report. An overview of Cronbach’s $\alpha$ for the subscales of the parent report and the child report is presented in Table 4.

Discussion

The current study presents the translation process and the results concerning the validity and reliability of the Dutch VELO questionnaire. The Dutch VELO questionnaire was translated from the original English instrument developed by Skirko et al. [16], who clearly stated the target population and the concepts to be measured with this instrument. Furthermore, item selection and item reduction were performed based on statistical results and clinical considerations [16]. Based on the quality criteria for health status questionnaires formulated by Terwee et al. [29], the abovementioned aspects attribute to the content validity of the VELO questionnaire. Furthermore, this questionnaire qualifies several C(L)P-relevant aspects of the International Classification of Functioning, Disability and Health: Children and Youth (ICF-CY) [31] concerning body function (e.g. voice, implying resonance), activities and participation (e.g. conversation), and contextual/environmental factors (e.g. attitude of family members) that were identified by Neumann and Romonath [32]. As such, the development of the VELO questionnaire responds to the need for research that captures the patient’s perspective on distinct domains of quality of life in patients with C(L)P [7].

Linguistic validation of the Dutch translation

Furthermore, results of the linguistic validation showed good readability and no ambiguous statements. However, three of the fourteen patients had difficulties with the interpretation of the words ‘ignored’ and ‘frustrated’. These word choices should be re-evaluated in future studies in order to increase the readability of the child report.
Discriminant validity

In general, a more positive perception of HRQOL by the parents and their children with C(L)P was found in the current study in comparison to the results reported by Skirko et al. [16, 19, 22]. This difference might be explained by the difference in inclusion criteria. The studies by Skirko et al. [16, 19, 22] only included patients with VPI, whereas the current study included patients with a history of C(L)P without taking into account indications of VPI in the inclusion criteria.

The total scores on the parent report and the child report of the VELO questionnaire demonstrate a significantly worse perception of HRQOL by patients with C(L)P in comparison to the control group without C(L)P. This indicates good discriminant validity, which is a characteristic feature of a disease-specific HRQOL questionnaire. Furthermore, the scores on the subscales of the parent report also differed significantly between the patient group and the control group. This was not the case for the scores on the subscales of the child report. This lack of significant differences on the subscales may be the result of a ceiling effect, as in general the HRQOL was perceived positively by the older participants and their parents. Nevertheless, this study presents the first normative data of the Dutch version of the VELO questionnaire (table 2).

Validity of the parent proxy assessment

No significant differences were found in the experimental group between the responses by parents and the responses by their child, indicating a similar HRQOL perception by both the parents and their child. Hence, when the patient is not able to complete the questionnaire, the responses of the parent can be considered clinically useful. However, subtraction of the responses on the child report from the responses on the parent report resulted more often in a negative difference, suggesting a more positive HRQOL perception by the child in
comparison to their parent. The same trend was described by Barr et al. [14] and should be taken into account when conducting further studies.

*Analysis of age effect*

There was a significant positive correlation with a medium to large effect size [33] between the age of the patients and the responses on the parent report. This can be the result of spontaneous development on the one hand and intervention on the other hand. A considerable amount of patients with C(L)P receives speech therapy during their childhood [34, 35], resulting in an amelioration of the speech and hypothetically an increase in the C(L)P-related quality of life. In VPI-related speech disorders, surgical intervention is the only treatment option [36]. As children with C(L)P grow older, the likelihood of receiving speech therapy and/or secondary speech surgery increases. Based on this rationale, evidence for the hypothesized association between age and the responses on the VELO questionnaire can attribute to the construct validity of the questionnaire [29]. However, a larger sample size should be included in the analysis to rightfully provide evidence of construct validity [29]. On the other hand, a negative, non-significant correlation was found between age and the responses of the children. Inspection of the response distribution shows a possible ceiling effect, which might indicate that the child report is not sensitive enough to capture the HRQOL in cleft palate patients older than 8 years. Klassen et al. [7] indeed suggested that the relative importance of HRQOL domains might change over time. This hypothesis is emphasized by the fact that the results on the subscales of the child report were not able the differentiate between patients with and without C(L)P. Moreover, it might be difficult for children to accurately appraise their HRQOL [4]. However, recent literature reviews emphasize the clinical importance of HRQOL assessments in children, preferably including the child's personal point of view [4, 7].

*Concurrent validity*
The correlation between the parent report and the P-VHI [27, 28] was significantly negative, which is compatible with the VELO questionnaire yielding a higher score for better HRQOL, whereas for the P-VHI the reverse is the case. However, interpreting the coefficient of determination ($r^2 = 0.857$), 85.7% of the variance of the HRQOL is shared by the VELO questionnaire and the P-VHI, suggesting that the VELO instrument adds little information over the existing P-VHI instrument [16]. A possible explanation is that it may have been difficult for parents to differentiate between the concepts of resonance, more specifically hypernasality and nasal airflow, and voice. Furthermore, voice disorders have been reported to be associated to C(L)P [37]. Nevertheless, Skirko et al. [19] reported larger effect sizes of the VELO questionnaire regarding the responsiveness of the instrument to changes in HRQOL in comparison to the PVOS and the PVRQOL.

**Limitations and future research**

A limitation of the current study is that no indication of the VPI severity was presented. Future research should include an instrumental assessment of the velopharyngeal function, such as nasal endoscopy or videofluoroscopy, and a perceptual evaluation of the VPI severity, following a standardized assessment procedure [38]. In comparison with the studies performed by Skirko et al. [16, 19, 22] ($n=29$; $n=84$; $n=57$), a relatively small subject group was used in the current study. Hence, the inclusion of more patients with VPI in future studies will ensure a representative subject group to further evaluate the validity and reliability of the Dutch VELO questionnaire. Furthermore, a greater sample size will enable the evaluation of the construct validity by further assessing the association between age and the responses on the parent report. Regarding reliability, only the internal consistency of the Dutch VELO questionnaire was evaluated in the current study. Therefore, future research should also assess the test-retest reliability of this instrument. Additionally, the responsiveness of the Dutch
VELO questionnaire to treatment should be identified, including an evaluation of the effect sizes of the VELO questionnaire in comparison to the P-VHI.
Conclusion

The Dutch VELO questionnaire shows good validity and reliability. Hence, this instrument is suitable for measuring HRQOL in patients with C(L)P. Moreover, this study showed that the Dutch VELO questionnaire is user friendly and can thus easily be used to evaluate the patient’s perception.
Tables and figures

Table 1: median, quartiles and range of scores on the (sub)scales of the VELO questionnaire reported by parents and patients with cleft palate

<table>
<thead>
<tr>
<th></th>
<th>Parent report</th>
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<th>Child report</th>
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<tbody>
<tr>
<td></td>
<td>(n=39; M age=6.8 years, SD=2.41)</td>
<td>(n=14; M age=9.5 years, SD=1.16)</td>
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<tr>
<td></td>
<td>Q1 Median Q3 Range</td>
<td>Q1 Median Q3 Range</td>
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<tr>
<td>Total score</td>
<td>68.27 82.7 93.27 23-100</td>
<td>89.13 95.1 95.11 76-100</td>
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<tr>
<td>Speech</td>
<td>53.57 67.9 85.71 21-100</td>
<td>82.14 87.5 87.50 64-100</td>
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<tr>
<td>Swallowing</td>
<td>83.33 100.0 100.00 17-100</td>
<td>95.83 100.0 100.00 67-100</td>
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<tr>
<td>Situational difficulties</td>
<td>60.00 75.0 100.00 10-100</td>
<td>90.00 95.0 95.00 85-100</td>
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<tr>
<td>Emotional impact</td>
<td>75.00 87.5 100.00 25-100</td>
<td>87.50 100.0 100.00 56-100</td>
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<tr>
<td>Perception by others</td>
<td>81.25 100.0 100.00 19-100</td>
<td>100.00 100.0 100.00 88-100</td>
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<td>Caregiver impact</td>
<td>75.00 91.7 100.00 50-100</td>
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</table>

N.A.: not applicable

Table 2: median, quartiles and range of scores on the (sub)scales of the VELO questionnaire reported by parents and children without cleft palate

<table>
<thead>
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<th>Parent report</th>
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<th>Child report</th>
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<td></td>
<td>(n=39; M age=6.7 years, SD=2.38)</td>
<td>(n=14; M age=9.5 years, SD=1.16)</td>
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<td>Q1 Median Q3 Range</td>
<td>Q1 Median Q3 Range</td>
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<tr>
<td>Total score</td>
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<td>94.57 100.0 100.00 83-100</td>
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<td>Speech</td>
<td>85.7 96.4 96.4 71-100</td>
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<td>Swallowing</td>
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<tr>
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N.A.: not applicable
Table 3: results of the Mann Whitney U test for the comparison between the responses of the patient group and the control group on the VELO questionnaire

<table>
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<tr>
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<td>n=39</td>
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<tr>
<td>Total score</td>
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<td>100.0</td>
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<td>Situational difficulties</td>
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<td>1161.5</td>
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<tr>
<td>Total score</td>
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<td>100.0</td>
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<td>110.50</td>
<td>0.350</td>
<td>0.33</td>
</tr>
<tr>
<td>Situational difficulties</td>
<td>95.0</td>
<td>100.0</td>
<td>107.00</td>
<td>0.458</td>
<td>0.17</td>
</tr>
<tr>
<td>Emotional impact</td>
<td>100.0</td>
<td>100.0</td>
<td>123.50</td>
<td>0.116</td>
<td>0.45</td>
</tr>
<tr>
<td>Perception by others</td>
<td>100.0</td>
<td>100.0</td>
<td>104.00</td>
<td>0.550</td>
<td>0.27</td>
</tr>
</tbody>
</table>

*Statistically significant, p ≤ 0.05

Table 4: the internal consistency (Cronbach’s α) of the Dutch VELO questionnaire based on the responses of the parents and the patients with cleft palate

<table>
<thead>
<tr>
<th></th>
<th>Parent report n=39</th>
<th>Child report n=14</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total score</td>
<td>0.955</td>
<td>0.817</td>
</tr>
<tr>
<td>Speech</td>
<td>0.847</td>
<td>0.776</td>
</tr>
<tr>
<td>Swallowing</td>
<td>0.766</td>
<td>0.960</td>
</tr>
<tr>
<td>Situational difficulties</td>
<td>0.951</td>
<td>0.897</td>
</tr>
<tr>
<td>Emotional impact</td>
<td>0.804</td>
<td>0.848</td>
</tr>
<tr>
<td>Perception by others</td>
<td>0.914</td>
<td>0.877</td>
</tr>
<tr>
<td>Caregiver impact</td>
<td>0.823</td>
<td>N.A.</td>
</tr>
</tbody>
</table>

N.A.: not applicable
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References


