

## FRENCH TRANSLATION AND LINGUISTIC VALIDATION OF A NEW PATIENT REPORTED OUTCOME INSTRUMENT: THE BODY-Q: A DESCRIPTION OF THE PROCESS

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### SUMMARY

**Background:** Bariatric surgery or reconstructive body contouring surgery performed after weight loss, has the potential to have a major impact one's body image, health-related quality of life (HRQOL) and mental wellbeing. Many researches show interest in measuring this impact using generic instruments that unfortunately are not specifically oriented toward bariatric or surgery patients. The BODY-Q is a new patient-reported outcome (PRO) instrument designed to measure patient perceptions of weight loss and/or body contouring. In this article, we describe the methods used to translate and culturally adapt the French version of the BODY-Q.

**Material and method:** We followed the recommendation for translation process established by the International Society for Pharmacoeconomics and Outcome Research (ISPOR) and the World Health Organisation (WHO). This process included two forward translations, one backward translation, a review by a panel of expert and cognitive debriefing interviews with patient. Our aim was to ensure a conceptual and culturally valid translation.

**Results:** This translation process led to a conceptually and culturally equivalent French version of the Body-Q. Backward translation comparison to the English original version led to the identification of 16 differences necessitating re-translation. The expert panel offered support to identify inadequate expressions and proposed changes to the translations. The cognitive debriefing interviews with 15 patients contributed to minor changes in the translation.

**Conclusions:** This thorough method of translation and cultural adaptation allowed us to develop a conceptually and culturally valid French translation of the BODY-Q.

**Key words:** translation - patient - reported-outcome - self image - psychological changes - bariatric surgery

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### INTRODUCTION

This article is at the crossroads of psychiatry, bariatric and plastic surgery as the surgery has such an important influence on self-image. Prior bariatric surgery, patients have difficulties to visualize the psychological and physical changes beyond the fact that they will lose weight. This is why it involve an interdisciplinary team (surgeon psychiatrist, endocrinologist, psychologist, dietician, nurses...) to evaluate and follow the patient all along the process. In Belgium there is a Royal decree that stipulate that the surgery needs to be approved by the healthcare team to be reimbursed. The success is measured in lost pound while psychological aspects of success tend to be neglected. Evaluation of outcomes from the patient perspective is becoming increasingly important in clinical research, especially in reconstructive surgery since many procedures aim to directly alter one's appearance, body image and/or health-related quality of life (HR-QOL). Many studies have included patient-reported outcome (PRO) instruments, but often the tools used were not designed for surgery patients (Hensel et al. 2001, Song et al. 2006, Lazar et al. 2009, Bolton et al. 2003, Cintra et al. 2008, Guseenoff et al. 2008, Blomqvist et al. 2000, Coriddi et al. 2011, Singh et al. 2012).

Bariatric surgery, with the rapid and massive weight loss, can leave the body with substantial amounts of excess hanging skin. Excess skin may have both physical and psychological consequences, including skin problems, body pain and distortions of body image. The goals of post-bariatric body contouring procedure are to restore physical comfort and body image. However, many authors (Tremp et al. 2015, Jaber 2013, Kitzinger et al. 2012, Reavey et al. 2011) point out the lack of dedicated PRO instruments to measure improvements in outcomes following bariatric and reconstructive surgery.

To address this absence, Klassen AF, Cano SJ, Alderman A, et al. (2016) designed a PRO instrument specifically oriented towards weight loss and body contouring. The BODY-Q measures three main concepts: appearance, HR-QOL, and experience of health care (Klassen et al. 2014, 2016) via 18 independently functioning scales. It also includes a checklist of symptoms specifically related to obesity. The BODY-Q was developed following international recommendations for item generation, item reduction, and psychometric evaluation (Aaronson et al. 2002, US Food and Drug Administration Guidance 2015a, Patrick et al. 2011a, Patrick et al. 2011 b, US Food and Drug Administration Guidance 2015 b). Rasch (1993) Measurement Theory analysis was used

for item reduction and to examine reliability, validity, and ability to detect change.

The BODY-Q is unique compared to other PRO in that it includes 10 scales to measure appearance-related concerns. Each BODY-Q scale is functioning independently and scored on a scale from 0 (worse) to 100 (best), without total score.

The BODY-Q as a specific tool, when used in clinical practice, provides a way for patients to raise their concerns to their surgeon, psychiatrist and members of the healthcare team. With a complete overview of the patient's concerns, the BODY-Q can be used to follow patients over their entire weight lost and body contouring process. With such a tool, it would be possible to compare findings across countries and bring a whole new scientifically validated knowledge to the bariatric and body contouring surgery patients.

The goal of our study was to produce a French version of the BODY-Q. Adaptation of a questionnaire in another language and culture requires high quality translation and linguistic validation. Qualitative interviews with patients are also needed to assess full understanding of the wording of items, instructions and response options.

In order to ensure the development of a high-quality French translation of the BODY-Q, we followed the guidelines for translation and cultural adaptation set forth by The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and the World Health Organization (WHO) (Wild et al. 2005, WHO 2016).

## MATERIAL AND METHOD

Our aim was to develop a conceptually and culturally equivalent translation rather than a literal translation and secure an equivalent French version of the BODY-Q.

### Step 1: Permission from authors and recruitment

We obtained permission to use the BODY-Q from the developers (Klassen et al. 2016) and we started to recruit translators and expert panel participants. The group was asked to use a simple and clear wording in order to be understandable for the largest number of patients.

### Step 2: Forward Translation

Two translators, both fluent in English with French as mother tongue, produced an independent forward translation of the original items. The first translator was a professional and the second was a health professional with experience working with the target patient population.

### Step 3: Forward Translation review

Both translators discussed the translations and agreed on a reconciliation version (French version 1). The aim was the production of a conceptually equivalent translation of the original questionnaire keeping in mind an easy and simple language to understand.

### Step 4: Backward translation

A professional translator who was a native English speaker and bilingual in French produced a backward translation (French to English) based on the French version 1, without access to the original English version. The objective was to determine from the back translation any misunderstandings, mistranslations or inaccuracies in the intermediary forward version of the questionnaire.

### Step 5: Backward translation review

The backward translation was then sent to the BODY Q developers (Drs. Klassen and Pusic) for review and comparison with the original version. All differences were discussed, re-translated and shown again to the developers. This process continued until a satisfactory result was reached and led to French version 2.

### Step 6: Expert Panel discussion

The expert panel is composed by the three translators, a plastic surgeon specialist in body contouring and a psychologist. They met to discuss the French version 2. All participants were native French speakers and fluent in English, except for one translator who was native English speaker and fluent in French.

The aim of this discussion was to review the translation to identify and resolve any final unclear expressions. This resulted in French version 3 for pre-testing.

### Step 7: Cognitive debriefing Interviews

The objective of this step was to test the translated questionnaire on a group of patients from the target population to determine whether it was acceptable, understandable in the way it was originally intended by the developers, and if the language used is accurate, clear and non-ambiguous.

To complete this objective, 10 cognitive debriefing interviews were performed with patients exploring or seeking body contouring surgery, and patients who had had body contouring. Participants were recruited in Cliniques Universitaires Saint Luc, Belgium throughout January 2016. There was no incentive offered. The interviews were done after the consultation with the surgeon in the hospital. Semi-structured interviews using the think aloud approach were performed by the psychologist and notes were taken.

Participants were asked to read the French version of the BODY-Q questionnaire to identify any items, instruction and response options that they felt were not appropriately worded and to propose different expressions. The interviewer questioned participants to determine any difficulty in their understanding of the questionnaire and to verify the patient's interpretation of all items as well as the instructions, time frame and response options. Findings were used to make final changes to version 3, leading to French version 4.

Cognitive debriefing interviews with five additional patients were performed to review the French version 4.

### **Step 8: Harmonization and reconciliation**

Findings of the first and second round of cognitive debriefing interviews were used to correct the version 4 leading to French version 5.

### **Step 9: Final version**

French version 5 was proofread independently by the clinician and the psychologist, resulting in the final French version of the BODY-Q.

### **Step 10: Final report**

Report is written on the development of the translation.

## **RESULTS**

Translation and cultural adaptation of the BODY-Q led to the development of a conceptually and culturally equivalent French Version. Examples of the changes made during the translation process are described below:

#### **In Step 3:**

The two forward translators had several discussions about the different phrasing and the wording in French, since French is a very complex language with many words that can express the same or very close significance. The goal was to choose the simplest words that could be understood by the majority of the patients. The translators encountered a difficulty in the translation of "body contouring". In French, this word is very technical and not very often used. The expert panel and the healthcare team helped to find an easier phrasing that reflects the knowledge and the experience of the patient about his surgery. The equivalent wording chosen was "surgery of the silhouette".

#### **In step 5:**

When developers of the BODY-Q reviewed the back translation, they identified 16 differences that appeared to have a different meaning from the original English version. Those items were re-translated until they were deemed acceptable.

For example, in the Appearance-Related Psychosocial Distress scale, the item "I worry that I am ugly" was back translated as "I am afraid that I am ugly". In French the word "afraid" is commonly used in the spoken language as a less powerful meaning of "worry". The developers of the BODY-Q judged that use of "afraid", as having a different conceptual meaning than "worry". It was changed to stay as close as possible to the conceptual meaning. The expert panel and the patients found the revised item to be easily understandable.

Furthermore, the item "I have little interest in doing things" was back translated as "I have little interest in activities". The translators interpreted "things" to be "activities", however the back translation was judged to be different by the BODY-Q developers and therefore was re-translated.

#### **In Step 6:**

The expert panel identified 24 discrepancies. There was one important change as the translation process was not completely satisfactory in term of French expressions. In the Satisfaction with Body scale, the panel found that the translation of "size" was too literal to satisfy the quality process. In the sentence: "the size (i.e., weight) of your body", the word "size" in French has different meanings and can refer to dimensions such as: height or width independently. The combination of "size" and "weight" in the same sentence was particularly confusing in French as it referred to two different concepts. The expert panel reached a consensus on an easily understandable wording using a French word close to "build" in English. This choice was confirmed in the patients' interviews, as participants found the revised item easy to understand.

#### **In step 7:**

We performed 10 cognitive debriefing interviews with two post bariatric patients, three pre-body contouring and five post body contouring patients (Table 1).

**Table 1.** Participant to cognitive interviews characteristics

	Patients post bariatric surgery (n=2)	Patients pre-body contouring surgery (n=3)	Patients post body contouring surgery (n=5)
First round of cognitive interviews			
Gender			
Male	1	1	4
Female	1	2	1
Age	59.5 (57-62)	50 (36-66)	43.4 (35-55)
BMI	27.9 (26.9-29)	28.3 (23.7-34.3)	30.86 (23-45.9)
Second round of cognitive interviews	(n=1)	(n=2)	(n=2)
Gender			
Male	1	2	2
Female	0	0	0
Age	57 (57)	47 (37-57)	61.5 (55-68)
BMI	21.8 (21.8)	26.5 (25.6-27.7)	25.95 (24.8-27.1)

Three minor changes to the translation were required after the cognitive debriefing interviews. In the Social Function scale, the word “gatherings” from the item “I feel at ease at social gatherings with people I know”, was considered to be inappropriate to several patients. They reported that “gatherings” in French referred to a big crowd. Therefore, the word was conflicting the last portion of the question “people I know”. To address this issue “social meetings” was suggested to replace “gatherings”. However, some participants felt that “meetings” in French was used more in professional contexts and “social” was not commonly used to describe a group situation with people.

Finally, we proposed to simplify the sentence by using the French word for “group” and participants felt this option was more understandable.

Moreover, in the Appearance-Related Psychosocial Distress scale, the translation of the item “I feel unhappy about how I look” gave a negation in the French translation, equivalent to “I feel not happy”. Patients reported a difficulty answering the questionnaire as they had to take into account the double negation between “I feel not happy” and the response option equivalent in French to “not agree”. The problem was that if we changed thesees phrases, this would have led to a change in the scale quotation. Indeed, taking out the double negation would have led to the opposite understanding. We found another word, less commonly used in French but easy to understand for the entire participants group, that allows us to avoid the negation in the item.

In the second round of cognitive debriefing interview, we interviewed one post bariatric surgery, two pre-body contouring and two post body contouring patients. This phase confirmed all the changes made in the translation process.

Overall, participants were very pleased with the questionnaire as it adequately reflected their concerns before and after surgery. They highlighted the fact that the scars scale assessment was very important as it is a major concern for patients given how extensive scars can be following body contouring.

## DISCUSSION

Different tools have been used to assess the patient outcomes post body contouring surgery. Commonly, generic PRO instruments have been used, resulting in contradictory reports of outcomes in the literature (Singh et al. 2012, Staalsen et al. 2015). The BODY-Q is the most comprehensive PRO instrument designed to date for body contouring patients. As such, the BODY-Q provides a new perspective to research on the patient outcomes in bariatric and reconstructive surgery and its use may lead to more scientific and clinically relevant results (Singh et al. 2012, Tremp et al. 2015).

We applied the ISPOR and WHO translation and cultural adaptation guidelines to develop a French conceptually equivalent translation of the BODY-Q. Attaining a

high-quality translation was crucial to enable its use in French especially in a context were specific PRO instruments are needed in the domain of plastic surgery. Consultation of patients via cognitive debriefing interviews during the translation process was very useful to determine correct utilization of the French expressions and wording, as well as their full understanding.

During the cognitive interviews, patients raised a difficulty in the reading of the questionnaire. They found it difficult to answer the questionnaire straight away and described that they had to read the question several times before answering. Their trouble completing the scales was widely due to the fact that among the 10 scales some used different response options. For instance, the response options for 6 scales were “disagree/agree”, while the remaining scales had varying possibilities (two scales with bothered/not bothered, one scale with dissatisfied/satisfied, one with all the time/never).

As the patients got used to the questionnaire, they reached a certain habit in the pattern of answering the questions, so it could have been difficult to break this pattern each time the possible answer changed.

The solution was to sort the scales in order to present all the scales with response option “satisfied/dissatisfied” together followed by the two scales with the “bothered/not bothered” response options and the remaining scales. We had no complains following this sorting in the second patient interview.

Several participants reported the Appearance-Related Psychosocial Distress scale to be disturbing given the scale’s negative connotation compared to the other positively worded scales. In order to avoid any confusion, the Appearance-Related Psychosocial Distress scale was placed first. This way, the participants remained fully focused.

We recommend this sorting if a clinician wants to use 10 scales of the BODY-Q during the same consultation.

## CONCLUSION

We translated BODY-Q into French and tested the translation with a group of pre- and postoperative body contouring patients, following the ISPOR and WHO methodologies.

The expert panel meetings and cognitive debriefing interviews with patients were very useful for ensuring the translation and was relevant and meaningful to patients. The French version of the BODY-Q is suitable in assessing outcomes in post bariatric and body contouring surgery in the French-speaking population.

### Contribution of individual authors:

Perle Rillon, François Château, Anne Klassen, Elena Tsangaris, Pirson Geneviève & Christine De Coninck all made substantial contributions to conception and design, and/or acquisition of data, and/or analysis and interpretation of data.

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