

## Genital Rejuvenation

# Measuring Quality of Life in Female Genital Cosmetic Procedure Patients: A Systematic Review of Patient-Reported Outcome Measures

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### Abstract

**Background:** In the subspecialty of female genital cosmetic procedures, patient satisfaction and quality of life are key outcome measures. As such, valid and reliable patient-reported outcome measures (PROMs) examining these outcomes are essential.

**Objectives:** The authors sought to identify and scrutinize all PROMs developed for female patients undergoing genital cosmetic procedures.

**Methods:** The authors performed a systematic literature review utilizing MEDLINE, PreMEDLINE, Ebase, Embase, OVID, CINAHL, Cochrane Library, PsycINFO, PubMed, and Google Scholar to identify PROMs developed and validated for utilization in female genital cosmetic procedure patients. Instruments identified were assessed according to international guidelines for health outcome measures development and validation.

**Results:** The authors identified 50 outcome questionnaires employed in the female genital cosmetic procedure literature. Of these, 26 were ad hoc instruments (ie, had not been formally developed and tested) and 22 were generic instruments (ie, intended for use in broad groups of people, not only specific patient groups). Only 2 instruments have been validated in a female genital cosmetic procedure patient population. These were the Genital Appearance Satisfaction scale and the Cosmetic Procedure Screening Scale–Labioplasty. Although both these scales had undergone fairly rigorous psychometric development and validation, both had content limitations.

**Conclusions:** There is a lack of specific, valid, and reliable satisfaction and quality-of-life PROMs in the field of female genital cosmetic procedures. Future research should involve the development of such measures to more accurately assess the outcomes and benefits of these procedures.

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Female genital cosmetic procedures are becoming increasingly popular among women in Western countries.<sup>1</sup> Procedures include labiaplasty, vaginoplasty, clitoral hood reduction, hymenoplasty, labia majora augmentation/reduction, and G-spot amplification.<sup>2</sup> Of these, labiaplasty is the most commonly performed.<sup>3</sup> In the last 5 years alone in the USA, the number of labiaplasties increased from 8,341 in 2014 to 12,756 in 2018, representing a 53% increase,<sup>4</sup> and the procedure is, according to The American Society for Aesthetic Plastic Surgery, “no longer seen as a passing trend.”<sup>5</sup> Nevertheless, despite the rapid increase in the popularity of these procedures, the research investigating patient outcomes is still somewhat limited.

For female genital cosmetic procedures, the primary outcome determinants of success are patient satisfaction and quality of life (QoL).<sup>6</sup> These patient-reported outcomes are ideally measured with specially designed and validated procedure-specific questionnaires called patient-reported outcome measures (PROMs). PROMs are questionnaires completed by patients prior to a procedure to ascertain their perceptions of their health status and health-related QoL and completed again after their procedure to allow comparison of outcomes. They allow the efficacy of clinical intervention to be measured from the patient perspective.<sup>7</sup> The questionnaires employed in cosmetic settings are often “ad hoc,” developed by investigators for a specific study but utilized without undergoing an evaluation of the measure’s psychometric properties.<sup>6</sup> Although these ad hoc questionnaires may include highly relevant and important items, the lack of formal psychometric testing limits both the validity (ie, ability to measure what is intended to be measured) and/or reliability (ie, ability to produce consistent and reproducible scores) of the measure.<sup>8,9</sup>

Conversely, measures may indeed be valid and reliable but lack specificity.<sup>6</sup> For example, there is the Short Form-36,<sup>10</sup> the “gold standard” measure of health-related QoL, as well as the Rosenberg self-esteem scale.<sup>11</sup> Both constructs are likely relevant among women who seek and undergo cosmetic procedures of the genitals. However, these measures are designed to be utilized among broad patient groups and also healthy individuals and are unlikely to capture the highly unique experiences of patients undergoing genital procedures. Furthermore, these generic measures may not be sufficiently sensitive to measure changes that occur after a procedure.<sup>6</sup>

As the field of female genital cosmetic procedures continues to increase in popularity, it is important that outcomes of these procedures be assessed from the perspective of the patient. This assessment requires PROMs that are specifically designed to capture the concerns of this unique patient population. Applications of such PROMs will likely improve evidence-based practice, potentially assist with improvements in surgical techniques, and facilitate the decision-making process of patients and surgeons.

Furthermore, the US Food and Drug Administration requires the utilization of specific PROMs for the approval of all treatments.<sup>12-14</sup> With some researchers and medical professionals labelling female genital cosmetic procedures as “unnecessary”<sup>15</sup> and even akin to female genital mutilation,<sup>16</sup> a higher level of scientific rigor in the field will likely help to lessen the controversy around these increasingly sought-after procedures.

The primary aim of this review was to identify existing patient-reported female genital cosmetic procedure-specific instruments that have undergone formal development and validation in a patient population. The secondary aim was to evaluate these measures with respect to their development process, content, and psychometric performance. This analysis will identify the most optimal measures currently in use and provide guidance on the development of new female genital cosmetic procedure-specific measures.

## METHODS

An electronic bibliographic database search was conducted by authors G.S. and P.M. in multiple databases—MEDLINE, PreMEDLINE, Ebase, EMBASE, OVID, CINAHL, Cochrane Library, PsycINFO, PubMed, and Google Scholar—from their inception through April 15, 2019 (the date of search completion). Following a similar protocol to Pusic et al<sup>9</sup> in their systematic review of PROMs in cosmetic and reconstructive breast surgery, the topic of “quality of life following genital cosmetic procedures” was discussed among the research team to determine the important issues and develop a concept map. As a result of this discussion, a search strategy was devised utilizing the following key terms for procedures: “cosmetic genital surgery,” “genital cosmetic surgery,” “designer vagina surgery,” “cosmetic gynecology,” “labiaplasty,” “labiaplasty,” “labia minora reduction surgery,” “clitoral hood reduction,” “vaginoplasty,” “vaginal tightening,” “vaginal rejuvenation,” “hymenoplasty,” “perineoplasty,” “labia majora reduction,” “labia majora augmentation,” “G-shot,” coupled with “quality of life,” “patient satisfaction,” “questionnaire,” “psychometric,” “validation,” “reliability,” and “item correlation.”

Two reviewers (G.S. and P.M.) independently examined full texts of all identified articles owing to the relatively low number of articles retrieved. Reference lists for identified articles were also thoroughly examined by article title and key terms in the article text to identify additional articles and measures. Articles were excluded if they were (1) not in English, (2) involved transgender or intersex women, (3) the genital procedure addressed a pathology rather than a cosmetic focus, (4) did not include the description of or utilization of a PROM, (5) the PROM did not measure genital-related QoL and/or satisfaction, or (6) the PROM was not developed and/or validated in a female genital cosmetic

procedure population. Disagreement was settled through discussion between the reviewing authors (G.S. and P.M.).

The PROMs identified were independently researched by G.S. and P.M. to obtain information on the development and validation process, and where this information was lacking, corresponding authors were contacted for clarification. Both ad hoc and generic measures were excluded. Similar to the procedures of Pusic et al<sup>9</sup> and Reavey et al,<sup>6</sup> the remaining PROMs were scrutinized for adherence to guidelines of the Scientific Advisory Committee of the Medical Outcomes Trust<sup>17</sup> and the US Food and Drug Administration.<sup>13</sup> Additionally, all questionnaires were analyzed for content on an item-wise basis as to whether they covered preoperative and postoperative issues.

## RESULTS

The search identified 58 articles and after follow-up on these references, a further 22 were added to make a total of 80. From these sources, 50 instruments were identified. Exclusion criteria were applied and 48 measures were removed (Figure 1). These included 26 ad hoc instruments<sup>18-43</sup> that had not undergone formal development and/or validation. These were mostly brief measures of patient satisfaction developed for the particular study in question with no ongoing usage. Twenty-two instruments<sup>21,23,28,29,31,40,44-55</sup> had not been developed and/or validated in the target patient population and so were classified as generic. The generic measures addressed a range of important issues including sexual functioning, psychological functioning, and general body image, with the Female Sexual Function Index<sup>56</sup> as the most commonly employed. We identified a total of 2 PROMs measuring patient satisfaction and QoL that underwent development and/or validation in female genital cosmetic procedure patients. Key information pertaining to these 2 PROMs is provided below, including how well the criteria were met for item generation and psychometric testing (Table 1).

### Genital Appearance Satisfaction Scale

The Genital Appearance Satisfaction (GAS) scale<sup>57</sup> consists of 11 items and was originally developed to measure attitudes towards genital appearance in women in the general community but has been subsequently validated in a labiaplasty patient sample.<sup>48</sup> GAS scale items were generated through literature searches and a focus group with women from the general community. The items generated were then inspected by a gynecologist with substantial experience in managing patients requesting genital cosmetic surgery. The 11 items encompass 3 main areas/factors: “appearance of genitals,” including satisfaction with appearance and perceptions of normality; “impact on daily living,”

covering genital discomfort in tight clothes and when exercising; and “impact on sex,” including feelings of embarrassment and self-consciousness during sex. However, there is some crossover with the items categorized under these 3 factors, and Veale et al<sup>48</sup> reported that the “stability and replication of these factors may be problematic.” As such, only a full-scale score is recommended for interpretation rather than 3 subscale scores.

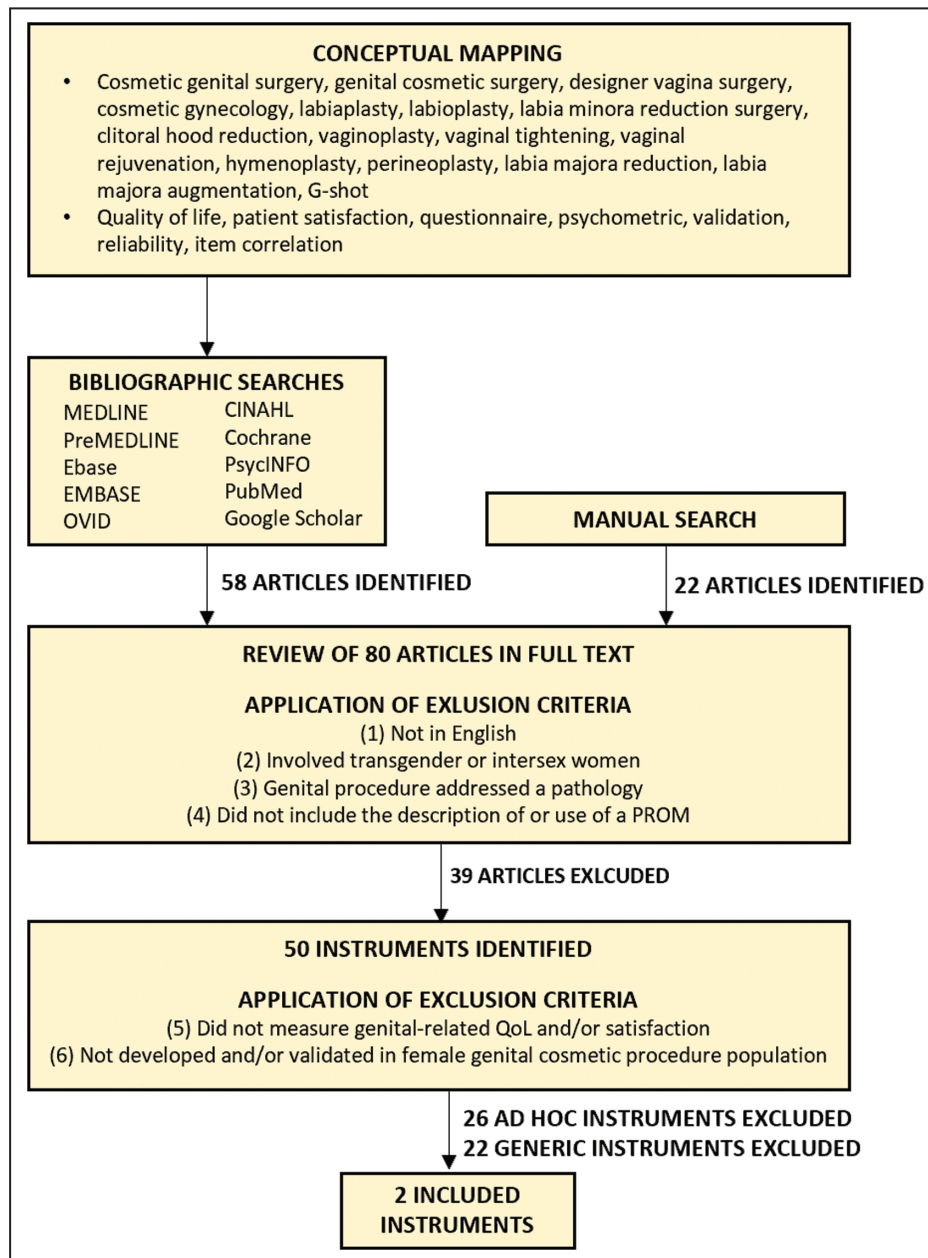
In the study by Veale et al,<sup>48</sup> the GAS scale demonstrated concurrent and convergent validity in a labiaplasty patient sample. The GAS was significantly positively correlated with a measure of anxiety and negatively correlated with body image-focused QoL. The GAS was not significantly related to measures of depression, disgust sensitivity, or sexual functioning.<sup>48</sup> The GAS scale shows acceptable internal consistency (Cronbach’s alpha = 0.78 in a labiaplasty patient sample). This measure also discriminates between women seeking labiaplasty, who score significantly higher than women who are not seeking labiaplasty. Furthermore, the GAS scale has been shown to be sensitive to change after labiaplasty surgery in multiple studies.<sup>21,23</sup>

### Cosmetic Procedure Screening Scale–Labiaplasty

The original Cosmetic Procedure Screening Scale (COPS)<sup>58</sup> was developed to screen for the psychiatric illness body dysmorphic disorder (BDD) prior to any cosmetic procedure. BDD is widely considered to be a contraindication to cosmetic interventions.<sup>59</sup> The COPS can also be employed to predict dissatisfaction with cosmetic procedures and monitor symptoms of BDD before and after intervention. The COPS was developed by following the BDD Diagnostic and Statistical Manual 4th Edition<sup>60</sup> criteria as well as seeking expert opinion and utilizing previous research findings that compared rhinoplasty patients with and without BDD.<sup>58</sup>

The COPS was subsequently modified to specifically address labial appearance concerns (COPS-L)<sup>48</sup> rather than general appearance concerns through consultation with women diagnosed with BDD who were seeking labiaplasty. The areas addressed by the 9-item COPS-L questionnaire are “perceived abnormality or evaluation of the labia as ugly,” “preoccupation with the labia,” “distress caused by the appearance of the labia,” and “interference in life owing to appearance of the labia” including in sexual relationships, leisure activities, and utilizing public areas (eg, locker room). Only total scale scores for the 9 items of the COPS-L are to be interpreted.

In the study by Veale et al,<sup>48</sup> the COPS-L demonstrated concurrent and convergent validity in labiaplasty patients. The COPS-L was significantly positively correlated with the GAS scale and negatively correlated with body



**Figure 1.** Flow diagram of search strategy process.

image-focused QoL. The COPS-L was not related to measures of anxiety, depression, disgust sensitivity, or sexual functioning. The COPS-L shows good internal consistency (Cronbach's alpha = 0.91 in a labiaplasty patient sample). The COPS-L was able to discriminate women with BDD seeking labiaplasty (significantly higher scores) from those without BDD seeking labiaplasty. From a receiver operating characteristics analysis, a score of 45 is considered to be the clinical cut-off for BDD, with the possible score range of 0 to 72.<sup>48</sup> Furthermore, the COPS-L has been shown to be sensitive to change after labiaplasty.<sup>23</sup>

## DISCUSSION

To the best of our knowledge, this is the first systematic review to scrutinize an exhaustive list of outcome measures employed within the rapidly expanding field of female genital cosmetic procedures. In this review, only 2 PROMs were identified that have been developed to measure QoL concerns and satisfaction among female genital cosmetic procedure patients. Evaluation of the content and psychometric properties of these questionnaires revealed strengths as well as some significant limitations. As such,

**Table 1.** Development and Psychometric Evaluation of Patient-Reported Outcome Measures for Female Genital Cosmetic Procedure Patients

Method/evaluation	GAS	COPS-L
Item generation	•	•
Patient interview/focus group	—	•
Literature	•	•
Expert opinion	•	•
Develop conceptual model	—	—
Item reduction		
Expert opinion	•	•
Item redundancy	—	•
Endorsement frequencies	—	—
Missing data	—	—
Factor analysis	•	—
Tests of scaling assumptions	—	—
Psychometric analyses		
Acceptability	•	•
Internal consistency reliability	•	•
Item-total correlation	—	—
Interrater reliability	—	—
Test-retest reliability	—	—
Validity within scale	•	•
Validity comparison with other measures	•	•
Validity hypothesis testing	—	—
Responsiveness	•	•

COPS-L = Cosmetic Procedure Screening Scale—Labiaplasty; GAS = Genital Appearance Satisfaction scale.

this study provides an important platform for novel PROM development and future research in this growing field of cosmetic practice.

The GAS scale and COPS-L both demonstrate relatively good psychometric performance and have been appropriately validated in labiaplasty patients. They have also been shown to be sensitive to change after the intervention of labiaplasty in several studies.<sup>21,23</sup> However, both are limited by a lack of stable subscales through which clinicians and researchers could investigate particular outcome areas (eg, impacts on sexual functioning and participation in leisure activities). Furthermore, the overall content is also limited. Neither measure was specifically

developed to capture the pre- and postoperative experiences of the patient. For example, a more comprehensive measure would ask about any worries a woman had prior to genital surgery, such as concerns about complications, as well as during the postoperative recovery process, such as pain, discomfort, and interference in normal activities. Such measures already exist for other cosmetic surgeries such as the BREAST-Q<sup>61</sup> for breast surgeries and FACE-Q<sup>62</sup> for facial aesthetic procedures, and these measures strictly adhere to the guidelines from the Scientific Advisory Committee of the Medical Outcomes Trust<sup>17</sup> and the US Food and Drug Administration.<sup>13</sup>

Another important consideration for the GAS scale and COPS-L is that both measures have a strong focus on the aesthetics of the external genitalia, particularly the “labia,” and so are most suited for use in labia minora reduction patient populations. There is no distinction in the wording of these 2 questionnaires between the anatomical features of the labia minora, labia majora, or clitoral hood for women seeking other procedures on their external genitalia. Furthermore, these measures would not be appropriate for women seeking procedures on their internal genitalia such as vaginoplasty or hymenoplasty, which generally do not have an aesthetic focus. In fact, with such a diversity of procedures categorized under the umbrella term of female genital cosmetic surgery, it is likely that a genital-focused PROM will require several specific subscales or modules to capture the key outcomes for each procedure type.

Some of the most frequently employed outcome measures in the field of female genital cosmetic procedures were classified as generic measures and were often utilized to supplement ad hoc measures. In this systematic review, the Female Sexual Function Index was the most commonly employed of all and is considered the “gold standard” measure for female sexual function.<sup>63</sup> Although this measure and others can provide very useful information for genital cosmetic procedures, further validation in these specific patient groups is recommended. Such validation studies will allow for certainty around the responsiveness of these measures in genital cosmetic procedure patients. Furthermore, as in the case of the GAS scale and COPS-L, even after validation, these questionnaires will still lack items that address important pre- and postoperative issues because they were originally developed for a more general purpose.

The multitude of ad hoc questionnaires identified in this review is concerning. As Reavey et al<sup>6</sup> aptly stated, “administering an ad hoc questionnaire can be likened to measuring a breast with a surgeon’s hand span because a tape measure is not available.” The field of genital cosmetic surgery has attracted considerable controversy with some researchers and clinicians suggesting the procedures are a form of “mutilation.”<sup>16</sup> The use of ad hoc questionnaires as



key outcome measures serves to cast further doubt over the efficacy of these increasingly popular procedures.<sup>64</sup>

This review should be interpreted with some limitations in mind. The search was limited to articles in English, and therefore the potential exists that relevant outcome measures not in English were overlooked. Furthermore, the search only involved academic peer-reviewed articles, and so relevant literature in the form of technical reports, etc. may have been missed. In addition, due to a lack of consensus on the nomenclature employed to describe the different procedures in the female genital cosmetic procedure field,<sup>65</sup> some procedure names may have been missed in this search even though the most comprehensive search possible was attempted. The relatively few articles retrieved from our initial database searches also potentially suggest some inconsistencies in the key terms employed to describe QoL and satisfaction outcomes in this body of literature.

## CONCLUSIONS

As genital cosmetic procedures in women continue to increase in popularity, it is crucial that advancements are guided by the highest level of evidence possible. Thus, the rigorous and systematic development of PROMs to examine QoL and patient satisfaction is an imperative in this field where there is a dependence on the utilization of ad hoc and generic measures. The GAS scale and COPS-L are suitable PROMs for women seeking labiaplasty but are limited in their scope and are inappropriate for other types of female genital cosmetic procedures. Without specific PROMs in this field, researchers are cautioned about making inferences regarding patient outcomes from studies employing ad hoc and generic measures. A comprehensive, genital-focused PROM could allow for the comparison between different study populations as well as comparing different procedural techniques. Most importantly, a comprehensive PROM in this field will potentially lead to improvements in the ability to understand and respond to patient symptoms, experiences, and QoL.

## Disclosures

Dr Sarwer has consulting relationships with Ethicon, Merz, and NovoNordisk. The other authors declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

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