PSYCHOMETRICS

Spanish Translation, Transcultural Adaptation, Validation and Clinical Applicability of Female Genital-Self Image Scale (FGSIS)



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ABSTRACT

Background: As female genital cosmetic surgeries have significantly increased, appropriate tools to evaluate selfesteem about women's own genitalia are necessary.

Aim: to translate, culturally adapt to Spanish women and to evaluate the psychometric properties of the Female Genital Self-Image Scale (FGSIS).

Methods: FGSIS was forward and backward translated, culturally adapted into Spanish and its content evaluated through Delphi consensus. One item from the original scale was discarded after expert panel evaluation, developing the final Spanish scale (FGSIS-S) consisting of 6 items. Its psychometric properties were evaluated among 202 women attending gynecological consults through an online survey. The survey included socio-demographic data and FGSIS-S.

Main Outcome Measure: Socio-demographic items, psychometric characteristics of the FGSIS-S (construct evaluation, internal consistency and test-retest reliability) were assessed.

Results: FGSIS-S proved to relate appropriately with the proposed construct (sum-content validity index 0.9, and significant inverse correlation with women concerned about their genital appearance or considering cosmetic surgery) with a 1-factor solution on exploratory factor analysis. The test proved good internal consistency (McDonald's omega 0.86) and test-retest reliability (intraclass correlation 0.86, P < .001). In 41.1% of cases, women referred concern about their genital's self-image and in 12.4% had considered undergoing cosmetic surgery.

Clinical Translation: The validated version of FGSIS-S can help both professionals and patients, and its implementation can be easily made in gynecological consults.

Strengths and Limitations: The main limitation is a self-selection bias in women attending gynecological consults, who may be more worried about their gynecological/sexual health. The sample is also a relatively homogeneous Caucasian population, with medium-high educational level, coming from gynecological consults. Strengths include the large sample size and the demographic survey that permitted evaluating the performance of FGSIS-S in the context of concern about genitals or consideration of cosmetic surgery.

Conclusion: FGSIS-S is an adequate scale to measure women's genital image self-perception in Spanish-speaking population of Spain. Bartolomé A, Villalaín C, Bermejo R, et al. Spanish Translation, Transcultural Adaptation, Validation and Clinical Applicability of Female Genital-Self Image Scale (FGSIS). Sex Med 2022;10:100558.

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Key Words: Genitalia; Female; Self Concept; Psychometrics; Female Cosmetic Genital Surgery; Spanish

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INTRODUCTION

Female genital cosmetic surgeries have significantly increased over the past 2 decades. The main reason to request them is aesthetic dissatisfaction, although some women also refer physical symptoms. Noteworthy is that up to 30%–50% of women report some kind of discontent about their genital appearance when asked about it. Genital appearance dissatisfaction can interfere, with varying intensity, with self-esteem, social and sexual relationships as well as condition social life. Most Obstetrics and Gynecology societies recommend considering educational tools and counselling in women requesting aesthetic genital surgery.

In view of this background, appropriate tools to evaluate selfesteem and satisfaction about women's own genitalia are necessary to help both professionals and patients make decisions about surgery as well as to evaluate the effect of individual or populational health educational interventions. The construct of female's genital self-image has only been recently approached in literature. It encompasses genital appearance as well as other factors such as function or sexual esteem and can be influenced by ethnicity, culture or education. 12 Women with lower satisfaction about their genitals are more likely to show an interest in genital cosmetic surgery, 13 and to report decreased self-esteem or reduced sexual satisfaction. 12 A social approach to the construct finds that women undergoing cosmetic surgery see themselves as seeking a reflection of the "real" me and not beauty, looking for an idea of a "normal" appearance. 14 Different scales have attempted to evaluate female genital's self-image 4,15,16 and various perspectives have been addressed, including more "physical" or "sexual function" aspects. 15 Some validated scales have been criticized in terms of their development as they were considered double-barreled, included questions regarding past but not present self-image 15 or favored neutral responses in a known sensitive nature matter. 17

The Female Genital Self Image Scale (FGSIS)¹⁶ evaluates quantitatively women's feelings and beliefs about their own genitalia. The scale consists of a survey with 6 items which have to be answered using a Likert-type 1–4-point scale. The total score ranges from 7 to 28, with higher scores showing a more positive genitalia self-image. It can be useful both as a whole as well as by its individual items from a clinician's point of view. It was originally designed as a 1 factor construct with 4 themes, including smell, appearance, sexual function, and shame/pride/self-acceptance. It has been evaluated in different populations proving its reliability and validity¹⁸ and has been translated into other languages, ^{19–22} maintaining its original psychometric properties. However, FGSIS has been tested in some contexts such as sexual satisfaction, ²³ but barely in others such as women's desire of undergoing cosmetic surgery. ²⁴

Although there are scales in Spanish designed to evaluate self-esteem or self-image perception, none of them examine female self-perception about their genitalia (including FGSIS). Therefore, the scale needs validation prior to its use in this setting. This study aims to develop the Spanish version of FGSIS: to translate,

culturally adapt, and assess its psychometric properties, to be able to use it as a measurement instrument in future research.

MATERIALS AND METHODS

We present a prospective cross-sectional observational study for the translation, transcultural adaptation and validation of FGSIS questionnaire, in the Gynecology and Obstetrics Service of "Removed for blinded review".

The aim was to translate and cross-cultural adapt of FGSIS original questionnaire from English to Spanish and validate it in Spanish-speaking population.

The study was approved by the Research Ethical Committee ("Removed for blinded review") of "Removed for blinded review" (reference number ("Removed for blinded review."))

Study Protocol

Translation and Cross-Cultural Adaptation of FGSIS.

The Spanish version of FGSIS (FGSIS-S) was developed following World Health Organization recommendations²⁵ after being granted permission from the original authors.

The original English version of FGSIS was translated into Spanish by 2 independent Spanish-native translators, who were also clinicians leading the study. Two different Spanish versions of the questionnaire were obtained (TL1 and TL2), which were later compared and merged into a third one (TL3) by an internal expert panel composed of 5 Gynecology Consultants in our Center. TL3 was then back-translated into English by an Englishnative translator, independent from the study. The English reverse translation was evaluated and compared to the original, confirming they reflected the same idea and adjusting the Spanish version when necessary. A fourth version (TL4) of FGSIS was then sent to 10 women assessing comprehension of every item. Answers and suggestions from these volunteers were discussed by the internal expert committee and the researchers, and changes were made where appropriate to improve comprehension (TL5).

A final post-hoc change was made after evaluation by an external panel composed of 5 experts in Sexology (gynecologists and non-gynecologists) outside of our Center and Spanish final version of the questionnaire (TL6) was developed, with only 6 items retained, and named FGSIS-S (Figure 1). The overall development from TL1 to TL6 is presented as Supplemental Material 1.

Socio-Demographic Survey Development. A socio-demographic questionnaire was developed to evaluate our cohort's basal characteristics. The survey included age, body mass index, ethnic group, pregnancies and vaginal deliveries, previous cosmetic surgeries, educational level, partner status, sexual experience, previous knowledge about female genitalia, pornography consumption, regular genital hair-removal, concerns about

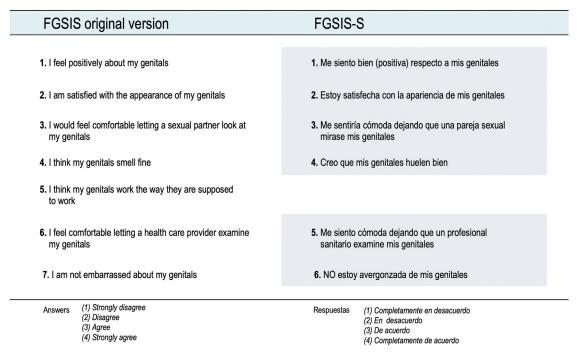


Figure 1. Original FGSIS and final version of FGSIS-S (TL6). FGSIS, Female Genital-Self Image Scale; FGSIS-S, Female Genital-Self Image Scale-Spanish.

own genital appearance and whether genital cosmetic surgery had ever been considered. After its development it was tested in a group or 20 women from our consults to see that language was appropriate and questions were easily understood. Regarding "cosmetic surgery," most women understood the concept strictly as labiaplasty, but wording was not changed as it is the most frequent form of aesthetic genital surgery. In terms of "concern," they agreed that it was "worry about the appearance of their genitals, that is my genitals are NOT normal," in line with the social construct of genital appearance dissatisfaction. ²⁶

Validation of FGSIS-S in Spanish-Speaking Women.

Women that met the inclusion criteria were offered to participate in the study from March 1 until May 31, 2021. Inclusion criteria were:

- Spanish-native speakers
- Over 16-years-old as this is the legal age for informed consent for health procedures in Spain
- Attending gynecological consults for non-vulvar pathology.

Those with prior genital surgery, female genital mutilation, vulvar disorders (such as dysplasia or dermatosis), pelvic floor disorders (uterine, vesical or rectal prolapse), pregnancy in course, hormonal replacement therapy, androgenic treatments or with severe conditions were excluded.

Eligible women that accepted to participate and signed the informed consent were contacted by e-mail where they received 2 questionnaires to complete anonymously in the REDCap online platform.²⁷ The first questionnaire included the sociodemographic survey and the translated and adapted version of

FGSIS (FGSIS-S). Between 7 and 14 days later all participants received a follow-up e-mail with just FGSIS-S, in order to evaluate its stability over time.

None of the participants (either in the development or the validation of the test) received any compensation for their involvement.

Statistical Analysis

Sample Size Calculation.

- Established recommendations for test translation and validation²⁸ suggest a minimum of 10 subjects per item of each scale to asses' psychometric properties, therefore a minimum sample size of 70 women was considered for the study. For retest analysis, considering prior studies on FGSIS, its ICC was of 0.90. Therefore, for detecting an ICC of at least 0.80, with 80% power and 0.05 2-tailed significance level, a minimum of 58 women would be necessary. The test was performed by a larger sample size than originally calculated as part of another study. Analysis was performed on this larger cohort to improve the interpretability of results.

Construct Evaluation.

- Test content was evaluated first by an internal expert committee through a Delphi survey. COSMIN questionnaires²⁹ were used to evaluate whether questions were clear and easy to understand, useful for clinical use or complete. Furthermore, an external subject matter expert panel that rated content centrality evaluated through content validity index (CVI) as well as item content relevance through Aiken's index.³⁰

- Secondly, since genital self-image dissatisfaction is associated to higher rates of cosmetic surgery³¹ an inverse association (through logistic regression) was expected between the dichotomized question "Have you ever considered undergoing genital cosmetic surgery?" as well as "Have you ever been concerned about your genital appearance?" and FGSIS-S scores. Although FGSIS-S is meant to be used as single score, for research purposes we evaluated both the overall scale as well as its individual items. FGSIS-S overall and individual scores were tested for normality by Shapiro-Wilk test and compared stratified by "concerned about genital appearance" as well as "consideration of genital surgery." As they were non-normally distributed variables, single items were compared by Kruskal-Wallis test.
- Factorial analysis was also undertaken. Sampling adequacy was assessed through Bartlett's sphericity test and Kaiser-Meyer-Olkin (KMO) considering necessary a minimum value of > 0.5. Although the proposed construct was a single factor 1, given that different factor solutions had been proposed for the genital self-image construct in literature (1 factor solutions for the original FGSIS(16), 2 factor for its validation³²) an exploratory factor analysis (EFA) through principal axis factoring with parallel analysis was performed. Given our sample size, items were required to have a minimum factor loading of 0.4 to be included.³³

Psychometric Validation.

- Internal consistency was measured by means of McDonald's omega, considering 0.8 as good internal reliability³⁴
- Correlation of individual items to the total score was measured.
- The test-retest stability was measured by intraclass correlation coefficient (ICC). An ICC value greater than 0.70 was considered acceptable.^{35,36}

As there were no missing values in the 2 selected outcomes ("concerned about genital appearance" and "consideration of genital surgery") nor on the FGSIS-S, no techniques of missing data management were used.

Continuous variables were presented as mean (SD), while categorical variables were presented as numbers and percentages. The distribution assumptions were tested with Shapiro-Wilk test. The group comparison of the variables was performed using t-test, Mann Whitney U test or Chi-square test where appropriate. We considered a 2-tailed P < .05 as criterion for statistical significance.

Data analysis was carried out using the 14.2 version of the statistical package STATA (StataCorp LT, College Station, TX, USA).

RESULTS

A total of 327 women were offered to participate in the study and 202 accepted to enroll and were finally recruited, answering all of them the proposed questionnaires in the first visit and 177 performed the re-test evaluation of FGSIS-S (12% dropout rate).

The main demographic characteristics of the study population are presented in Table 1. The majority of participants were

Table 1. Socio-demographic characteristics of the study population

population		
Variable at study	N = 202	
Age (years)	34.5 (11.4)	
Range	18 - 70	
Weight (kg)	62.6 (11.4)	
Height (cm)	164 (5.6)	
Body Mass Index (BMI) (kg/m ²)	23.2 (4.0)	
Self-reported ethnicity		
Caucasian	171 (84.7)	
Hispanic	29 (14.3)	
North Africa	1 (0.5)	
Multiracial	1 (0.5)	
Educational level		
Secondary schooling	6 (3.0)	
Upper secondary schooling	22 (10.9)	
Professional training	24 (11.9)	
University studies	148 (73.3)	
NR	2 (1.0)	
Nulliparous	123 (68.9)	
Mode of delivery (among 79 parous)		
At least 1 vaginal	58 (73.4)	
Only cesarean	21 (24.6)	
Partner status		
Single	50 (24.8)	
In a relationship	45 (22.3)	
Living with a partner	42 (20.8)	
Married	60 (29.7)	
Separated/Divorced	5 (2.50)	
Previous sexual experience (multiple choice)	2 (1 (2)	
None	2 (1.0)	
Masturbation	93 (46.0)	
With women	10 (5.0)	
With men	188 (93.1)	
Others Num of previous sexual partners	1 (0.5)	
None	5 (2.5)	
One	40 (19.8)	
Two	37 (18.3)	
3–5	51 (25.3)	
5–10	34 (16.8)	
>10	34 (16.8)	
NR	1 (0.5)	
Pornography consumption	1 (0.5)	
None	90 (44.6)	
Occasional	103 (51.9)	
Regular	9 (4.5)	
Genital hair removal		
None	31 (15.4)	
Partial	104 (51.5)	
Completelf	66 (32.7)	
NR .	1(0.5)	
Concern about genital appearance		
Never	119 (58.9)	
	(continued)	

(continued)

Table 1. Continued

Variable at study	N = 202
Sometimes	64 (31.7)
Often	10 (5.0)
Always	9 (4.5)
Age at onset of concern (years)	21.2 (9.1)
Range	10-55
Consideration of genital cosmetic surgery	
Never	177 (87.6)
Sometimes	21 (10.4)
Often	4 (2.0)

Data is expressed as mean (SD) and count (percentage). NR, no response.

Caucasian (84.7%) with a high level of education (74%). Concern about genital aspect was referred as occasional by 64 (31.7%), frequent by 10 (5.0%) and constant by 9 (4.5%). Of note, 25 (12.4%) had considered having cosmetic genital surgery.

Regarding construct, content was evaluated first by Delphi Criteria and secondly by an external panel that rated the degree to which every item related to the content "female genital self-image" with a Sum-CVI Ave of 0.9 and item values > 0.8 except for item 5, which was reviewed as well by an internal panel and dropped from the FGSIS-S. Aiken's index showed moderate content validity with values between 0.6 and 0.8 (Supplemental Material 2).

Logistic regression showed an inverse relation between the consideration of undergoing genital surgery and the total FGSIS-S score (Odds ratio 0.75, 95% confidence interval 0.66 - 0.85; P < .001) as well as those who referred concern about their genitals (Odds ratio 0.71, 95% confidence interval 0.63 - 0.79; P < .001). Both the results of the total score as well as the individual items were compared, stratified by the 2 questions. Women that referred any concern about their genitals obtained significantly lower scores than those that didn't, being this especially marked in items 1, 2 and 6 as shown in Table 2. These results were very

Table 3. Exploratory factor analysis results

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Factor	Factor loading				
Eigen value 3.23					
Percentage of variance explained 74.9%					
Omega 0.85					
Item 1	0.875				
Item 2	0.917				
Item 3	0.687				
Item 4	0.502				
Item 5	0.464				
Item 6	0.828				

similar in the case of women that considered having genital surgery. All differences were statistically significant P < .001 for concern and P < .05 for consideration of surgery, except for item 5 in the latter in which differences did not reach statistical significance.

EFA through principal axis factoring was performed and a 1 factor solution was obtained, including all 6 items, with an Eigenvalue of 3.23 and explained 74.9% of the variance. Factor loadings ranged from 0.46 to 0.92. (Table 3).

Convergence was observed among items and overall score with Pearson correlation \geq 0.70 in all cases except for item 5 (r = 0.64), and highest values for items 1, 2 and 6.

Internal consistency was evaluated through McDonald's omega with a result of 0.85 and test-retest reliability through ICC 0.86 (P < .01).

DISCUSSION

Main Findings

Our results show that FGSIS-S performs well in our population, maintaining its original psychometric properties. Similar to the original scale, the construct of female genital self-image in our setting revealed to be a 1-factor solution, although it only retained 6 items for its evaluation.

Table 2. Individual and overall FGSIS-S scores stratified by concern about genital appearance as well as consideration of having cosmetic genital surgery

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ltem	No concern	Any concern*	No consideration of surgery	Considering surgery [†]	
1	3.56 (0.62)	2.81 (0.65)	3.35 (0.69)	2.60 (0.71)	
2	3.54 (0.56)	2.71 (0.72)	3.34 (0.66)	2.28 (0.74)	
3	3.32 (0.72)	2.68 (0.94)	3.14 (0.85)	2.48 (0.82)	
4	2.99 (0.71)	2.60 (0.73)	2.88 (0.72)	2.52 (0.77)	
5	3.11 (0.80)	2.72 (0.86)	2.97 (0.84)	2.88 (0.93)	
6	3.51 (0.65)	2.79 (0.78)	3.36 (0.70)	2.36 (0.86)	
Overall	23.7 (3.16)	19.64 (3.61)	22.56 (0.28)	18.48 (0.67)	

Results are expressed as mean (standard deviation)

^{*}All differences are statistically significant P < .001, Kruskal-Wallis test.

 $^{^{\}dagger}$ All differences are statistically significant P < .05, except for item 5 (P > .05), Kruskal-Wallis test.

Comparison to Prior Literature and Clinical Applicability

Given the exponential increase of cosmetic genital surgeries, even among teenagers, ³⁷ adequate tools to evaluate women's perception of their own genitals are of paramount importance. These instruments need to be validated in different populations as cultural differences can influence greatly results and their interpretation.³⁸ There are tests that evaluate women's self-image of their genitalia^{4,15,16} among which FGSIS has proven to be valid 16,18 and has been successfully adapted to other languages 19 -22 although, until now, Spanish was not one of them. We opted to adapt this particular scale given its social constructivist approach, evaluating women's attitudes towards their image of normal. Its items provide a positive attitude instead of a negative approach and they do not reference any social stereotype that is found in other tests. 4 Nevertheless, there are inherent limitations to the original FGSIS that must be taken into account as it aims to evaluate the "normality" approach instead of a sum of image, function and sexual esteem.

The results of this study are in line with the original FGSIS and its other validations, ^{18–22,32} confirming the reliability of the test. Regarding construct evaluation, 6 of 7 original items were considered a good fit to evaluate the concept of "female's genital self-image." In our setting, item 5 had a low Aiken value when ranked by an expert panel as it was not deemed appropriate to evaluate women's attitude towards their genitals. This item had been removed as well in other validations, in which a 4-item approach was undertaken.¹⁹

In terms of content construct and as expected, there was a significant inverse correlation with 2 questions about women's concern about the appearance of their genitals and their consideration of genital surgery. Although the question "are you concerned about your genital appearance?" is straightforward and may raise doubts about the use of a more complex scale, we find that it is of interest. Dichotomized variables, although sometimes useful, are not able to grade as precisely as continuous scales, nor they allow to evaluate mild or moderate changes that may arise from interventions.

Although the original test was 1-factor, this was controversial in other settings. Therefore, we opted to perform an exploratory factor and parallel analysis that showed that the model that fit best our population was a 1-factor solution. Prior validations had shown a 1 factor, ^{16,20} 2-factor with interpersonal and intrapersonal variables ³² or even 3 factor solution (image, sexual function, sexual esteem). ⁴ Our results are in line with the development and some validations of the test, probably because basal characteristics of the study population were similar (mostly young, with higher-education, Caucasian women).

It is of interest that, in our cohort, the demographic questionnaire unearthed that up to 41.1% of women had some concern about their genitals self-image starting as young as 10 years-old and more than 1 in 10 had considered undergoing cosmetic surgery. This is remarkable since our sampling came from a cohort of women attending gynecological consults, a factor related to a more positive genital perception.³⁹ None of them had openly expressed these issues in their gynecologic visits. As we have shown in our study, FGSIS-S results are significantly lower in these women. To our knowledge, up until now FGSIS has been tested regarding sexual function in terms of orgasm, masturbation or sexual satisfaction²³ or in terms of acceptance of gynecological exams.³² However, it has barely been evaluated in the context of women considering cosmetic surgery. 24 This is of interest as interventions, such as counselling concerned patients or health education in this area, could be measured with this scoring system. We have found that items 1, 2 and 6 are the most affected in women concerned about their genitals and interventions targeting these areas would probably be the most effective when trying to improve women's self-perception. In fact, a small study proved that FGSIS's scores improved significantly in women that were exposed to images of natural vulvas. 40 This could be explained by an increase in the scoring of items 2 and 6, which are related to genital image and perception.

Clinical Applicability, Future Research

We found that the test was well accepted by patients and its administration feasible (easy to use as it consists of only 6 questions). A limitation for exploring FGSIS in a setting of intervention is the lack of useful cut-offs to ascertain clinical improvement or detect pathological situations. Future research should focus on validating such cut-offs as well as establishing the increment in the total score required to obtain any clinical benefit. These aspects can be of interest when counselling women who wish to undergo surgery or when implementing overall health education measures.

Strengths and Limitations

The main limitation from our study is a possible self-selection bias. The study population is relatively homogeneous with a high rate of Caucasian nulliparous women. As they were offered to participate at their gynecological consults, they may have more concern about their gynecological/sexual health and genital function than others. Furthermore, this setting reduces the heterogeneity of the study population when compared to general population studies. However, it probably serves as a better representation of the population attending consults which was the primary target of this scale. Given that the survey was distributed electronically, this may have limited access to older cohorts as well as women with lower resources. Therefore, our results might be not applicable to these groups of women, however the original test was also developed on Caucasian women with at least "some college" studies. Finally, there are some limitations inherent to the original scale that does not fully evaluate certain aspects that have been linked to self-image such as sexual self-esteem. Given the lack of validated tests in Spanish for the evaluation of sexual esteem we could not do this either and only used self-reports of concern about genital appearance and consideration of surgery for construct evaluation. There are several strengths such as the large study sample that allowed proper psychometric evaluation and the survey conducted at the first visit that permitted evaluating the performance of FGSIS-S in the context of concern about genitals or consideration of cosmetic surgery.

CONCLUSION

FGSIS-S is an adequate scale to evaluate women's self-perception of their genitals in Spanish-speaking population of Spain, preserving the psychometric characteristics of its original scale. Further studies are needed to validate cut-off scores as well as establish the net increment in the total score required to obtain clinical benefit from interventions.

DATA AVAILABILITY

Data will be available upon reasonable request from the corresponding author

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Conceptualization, A.B., C.V. and A.T.; Methodology, A.B., C.V. and A.T.; Software, A.B. and C.V.; Validation C.V.; Formal Analysis, A.B. and C.V.; Investigation, A.B., R.B., AB.B. and L.P.R. Resources A.B., C.V. and A.T.; Data Curation, A.B. and C.V.; Writing — Original Draft, A.B. and C.V.; Writing — Review & Editing A.B., C.V.; R.B., AB.B., L.P.R., A.T. and A. G.; Visualization A.B. and C.V.; Supervision C.V., A.T. and A. G.; Project Administration A.B., C.V. and A.T.

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SUPPLEMENTARY MATERIALS

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