

# ACOG Scientific Integrity Deficiency in Recommendation for the Practice of Cosmetic-Plastic Gynecology Misleads Other Gynecological Societies, Inhibits Clinical Education and Research, and Jeopardizes Women's Health

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**OBJECTIVE:** To analyze scientific integrity (scientific quality, objectivity, credibility, and appropriate transparency) of recommendations of gynecologic societies for female genital cosmetic surgery (FGCS) and their references, which were used to support these recommendations.

**STUDY DESIGN:** The scientific integrity of recommendations for FGCS published by gynecologic societies has never been subjected

to scientific scrutiny. Electronic and manual searches for FGCS literature published in the English language were conducted and analyzed for the period of the recommendations. A methodological scientific review of recommendations of gynecologic societies for FGCS was performed. The scientific quality, objectivity, credibility, and appropriate transparency within recommendations of gynecologic societies for FGCS were evaluated.

**RESULTS:** Overt prejudice and residual bias were found in the recommendations of gynecologic societies relating to FGCS. Scientific imprecise interpretations

and omissions of references called current recommendations into questions.

**CONCLUSION:** Recommendations issued by gynecologic societies relating to FGCS did not meet the scientific integrity norms for scientific quality, objectivity, credibility, and appropriate transparency. (J Reprod Med 2016;61:33–38)

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**Keywords:** cosmetic surgery; female genital cosmetic surgery; female genitalia; gynecologic surgical procedures; plastic surgery; reconstructive surgical procedures; reconstructive surgical procedures, esthetic; vaginal rejuvenation; vaginoplasty.

The author of this review recognized, agreed with, and supported the gynecologic societies' decisions of issuing recommendations for female genital cosmetic surgery (FGCS) since each single society has an obligation to protect women from any deceptive and unethical practice of cosmetic gyne-

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cology. A deceptive and unethical practice of FGCS was quite prevalent during the early 2000s. Also, gynecologic societies have the responsibility to balance the basic ethical framework of respect for patient autonomy, beneficence, non-maleficence, and justice as well as the other ethical frameworks. Therefore, it is very important to analyze the scientific integrity of recommendations of gynecologic societies for FGCS; the recommendations have not been changed since 2007. This methodological review scrutinized the recommendations of gynecologic societies for scientific integrity. Between 2007 and 2009, leading gynecologic societies published their recommendations for FGCS in which they recommend performing FGCS when medical indications were present but condemned performing FGCS for aesthetic motives.<sup>1-3</sup> As the studies documented, restriction of gynecologists from performing FGCS for aesthetic motives did not have significant effects, and cosmetic gynecology is constantly on the rise.<sup>4,5</sup> Therefore, it became an important issue to establish the facts pertaining to whether recommendations of gynecologic societies met the criteria of scientific integrity.

The National Institute of Health (NIH) defines scientific integrity as maintaining quality and objectivity with a certainty that the scientific findings are objective and credible, and with appropriate transparency.<sup>6</sup> The current methodological review utilized the NIH's definition in evaluating recommendations of gynecologic societies and their references used to support these recommendations. Such appraisal can assist gynecologic societies in identifying weakness in their current recommendations. It is equally important for gynecologic practitioners and for gynecologic societies to see FGCS through the patient's eyes. Finding the way to assist women, within the scientific merits, in achieving their goals for aesthetic transformation of their external genitalia should be our focus.

Since the recommendations of leading gynecologic societies were based upon the American College Obstetricians and Gynecologists (ACOG) recommendations, the scientific scrutiny of ACOG Opinion No. 378 was fundamental and was conducted here. In September 2007 ACOG responded to the marketing terms of *Laser Vaginal Rejuvenation*, *Designer Laser Vaginoplasty*, and *G-spot Amplification*. ACOG Committee Opinion no. 378 concluded that "... vaginal rejuvenation appears to be a modification of traditional vaginal surgical procedures."<sup>1</sup> A

practitioner with firsthand knowledge confirmed the ACOG position and documented that not only vaginal rejuvenation but also the other marketing terms were based upon traditional gynecologic procedures.<sup>7</sup>

In July 2012, in a "College Statement of Policy," ACOG reversed its previous position relating to cosmetic surgeries and declared that obstetrician/gynecologists can perform cosmetic operations with the stipulation that they must acquire necessary competency.<sup>8</sup> Although ACOG reversed its original position in reference to the general cosmetic nature of the procedures, it failed to revise its recommendations for the practice of FGCS.<sup>8</sup> Other gynecologic societies followed the ACOG Executive Board's recommendation on cosmetic surgeries and issued their similar recommendations and also did not revise their previous recommendations for clinical practice of FGCS.<sup>8-10</sup>

## Materials and Methods

### Study Selection

This review covered the specific period in which the recommendations of gynecologic societies were published. Originally, the current review was designed as a systematic review, but the absence of sufficient scientific-clinical data on FGCS eliminated such option; consequently, a methodological review was executed. Recommendations of gynecologic societies for the FGCS practice and references used by the societies within the recommendations were evaluated for scientific integrity (quality, objectivity, credibility, and appropriate transparency). The examination of quality was based on the degree of the true value; factual materials, nonprejudicial and unemotional presentations evaluated the objectivity standards; credibility was inspected by trustworthy interpretation of the existing scientific literature; appropriate transparency was determined by scrutiny of affirmation, accuracy, honesty, and omission.

Electronic and manual searches of the pertinent literature were conducted from 1970–2007 using MEDLINE, PubMed, ACOG online database, HealthSTAR, Cochrane Library database, OviDisc database, and Medical Subject Headings (MeSH) for cosmetic gynecologic keywords and terms. The FGCS articles published in the English language were analyzed. Documents related to female genital mutilation/female genital cutting, transsexual gender reassignment, congenital female genital anomalies, female genital tumors, and other illness-

es affecting female external genital appearances were excluded.

## Results

### *Scientific Quality*

Most gynecologic societies accepted the Lloyd study's identification of normal female external genitalia appearance.<sup>11</sup> The Royal Australian and New Zealand College of Obstetricians and Gynecologists (RANZCOG) was the only society to base its opinion relating to appearance of female external genitalia on photo images of labia minora and vulva from an atlas containing 32 photographs.<sup>2,12</sup> Lloyd et al did not study the external female genital appearance but determined the size of the clitoral body, length and width of the clitoral glans, distance from the base of the glans to the urethral orifice, the labia majora (length), labia minora (length and width), and the distance from the posterior fourchette to the anterior anal margin. The following anatomical structures of the female external genitalia, which are the parts related to aesthetic appearance, were not included: the mons veneris (mons pubis); the anterior and posterior commissures; the clitoral prepuce, hood, and frenulum; and the labium minus frenulum.<sup>11</sup> Additionally, the study protocol called for the evaluation of "rugosity and skin tone of the labia majora and hair distribution according to Tanner stage."<sup>11</sup> However, the methods of evaluation of rugosity and skin tone were not presented. Lloyd et al used labia majora hair distribution for Tanner staging of secondary sex characteristic development. The women evaluated in that study were all premenopausal and between the ages of 18–50.<sup>11</sup>

### *Scientific Credibility*

ACOG was the first specialty society in the world to issue recommendations for practicing FGCS; other gynecologic societies either adopted or modified ACOG's recommendations.<sup>1-3</sup> ACOG recommended that practitioners inform women about "the wide range of normal genitalia" with "reassurance that the appearance of the external genitalia varies significantly from woman to woman,"<sup>1</sup> referencing the findings of Lloyd et al.<sup>11</sup> Specialty gynecologic societies adopted those "norms" for the external genital appearance from ACOG Opinion No. 378,<sup>1</sup> although none of them defined those "norms."

ACOG determined that "...vaginal rejuvenation, designer vaginoplasty, revirgination, and G-spot

amplification are not medically indicated, and the safety and effectiveness of these procedures have not been documented."<sup>1</sup> Based upon this determination, ACOG and other gynecologic societies recommended that FGCS should not be offered to women. At the same time ACOG recommended that "medically indicated surgical procedures may include reversal or repair of female genital cutting and treatment for labial hypertrophy or asymmetrical labial growth secondary to congenital conditions, chronic irritation, or excessive androgenic hormones."<sup>1</sup> Hence, ACOG recommended performing the same procedure for medical indications and did not recommend FGCS for aesthetic motives.

### *Scientific Objectivity*

ACOG recommended that "clinicians who receive requests from patients for such procedures should discuss with the patient the reason for her request and perform an evaluation for any physical signs or symptoms that may indicate the need for surgical intervention."<sup>11</sup> ACOG also recommended that a practitioner should have "a frank discussion about the wide range of normal genitalia," including "reassurance that the appearance of the external genitalia varies significantly from woman to woman."<sup>1</sup> ACOG in its opinion stated that "patients who are anxious or insecure about their genital appearance or sexual function may be further traumatized by undergoing an unproven procedure with obvious risks" but did not provide a reference for this statement.<sup>1</sup>

### *Appropriate Scientific Transparency*

The ACOG Committee Opinion No. 378 contains the phrase "Cosmetic Vaginal Procedures" in its title. ACOG determined that cosmetic procedures could be performed for medical indications but not for FGCS because of the absence of level I evidence-based documentation for safety and effectiveness.<sup>1</sup>

## Discussion

### *Scientific Quality*

The Royal College of Obstetricians and Gynaecologists (RCOG) states that "the overall appearance of the female external genitalia is influenced by the relative sizes, shapes and colours of the labia majora, labia minora, clitoris and introitus."<sup>3</sup> Most of the gynecologic societies have accepted the Lloyd et al study as the description of "norms"

for the external female genitalia appearance.<sup>11</sup> The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) was the only society that based its recommendations relating to appearance of female external genitalia on photo images of labia minora and vulva from an atlas containing 32 photographs.<sup>2,12</sup> RCOG determined that the Lloyd et al study was frequently cited regardless of the small sample size.<sup>9,11</sup> The current review established that the Lloyd et al investigation not only was a small sample size but also did not study the appearance of female external genitalia at all; subsequently, it could not establish the “norms” for aesthetic appearance of female external genitalia. The Lloyd et al investigation was a cross-sectional study that included 50 subjects. Among them 37 (74%) were Caucasian women, 6 (12%) were Black women, 5 (10%) were Asian women, 1 (2%) was a Latino woman, and 1 (2%) was a woman of mixed race<sup>11</sup>; therefore, different races were not accurately represented. Lloyd et al stated that “all women were premenopausal, and aged between 18 and 50, with a mean of 35.6 ( $\pm 8.7$ ).”<sup>11</sup> The 18-year-old healthy woman or a woman of the mean age of 35.6 is hardly premenopausal.

Lloyd et al used “the labia majora and hair distribution according to Tanner’s stage.”<sup>11</sup> Utilizing labia majora hair distribution by Lloyd et al for staging of the secondary sex characteristic development was improper since Tanner’s classification was based on pubic hair (PH) and not the labia majora hair distribution.<sup>13,14</sup> Also, according to the Tanner norms, a healthy woman at the age of 18 should have reached physiologic maturity stage PH5.<sup>13,14</sup> Lloyd et al included 4 subjects with the PH4 (immature stage) in their study and, by doing so, increased relative risk and weak association within the study.<sup>11</sup>

The Lloyd study objectives, among others, were to evaluate “rugosity and skin tone of the labia majora,” and neither the technique of labia majora rugosity nor skin tone was presented or tested in the study.<sup>11</sup> Such execution in a study falls into the realm of “junk science.”<sup>15</sup> Furthermore, the Lloyd study did not specify the type, dose, and duration of treatment of subjects who took progestogens. Androgenic derivatives of progestogens can express an androgenic effect on the female external genitalia. Such an androgenic effect can lead to enlargements of the labium minus.<sup>1</sup> Consequently, Lloyd’s findings cannot be a representative sam-

ple of appearance of the healthy female external genitalia.

#### *Scientific Credibility*

The Lloyd et al study played a significant role in ACOG Opinion No. 378, which became a basic resource not only for other gynecological societies but also for scientific articles and journal editorials.<sup>1-3,16-19</sup> Imposing the recommendation by gynecologic societies upon a practitioner to inform a woman about “...the wide range of normal genitalia and reassurance that the appearance of the external genitalia varies significantly from woman to woman...” is at best improper since there is no scientific data to support such recommendations.<sup>1,8,11</sup> The Lloyd study neither established the “the wide range of normal genitalia” nor established a female external genitalia “normal” appearance.<sup>1,11</sup>

At the time of ACOG No. 378 opinion publication, data relating to medical indications for performing FGCS were available in many scientific resources; however, neither ACOG nor other gynecologic societies chose to incorporate those data into their recommendations.<sup>20-22</sup> Also, surgical complications relating to FGCS were reported in scientific articles before ACOG Opinion No. 378 and other gynecologic society recommendations had been published but were not included by gynecologic societies.<sup>20-22</sup>

ACOG expressed in its Opinion No. 378 that “Patients who are anxious or insecure about their genital appearance or sexual function may be further traumatized by undergoing an unproven surgical procedure with obvious risk.”<sup>11</sup> ACOG published this information without scientific references. Search of the clinical-scientific literature failed to identify any article to support the views of ACOG and other gynecologic societies on both accounts.

ACOG and other gynecologic societies did not take into account in their recommendations the WHO’s definition of *health*, which has not been amended since 1948: “Health is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.”<sup>23</sup> Gynecologic society recommendations for FGCS oscillate around “signs or symptoms” and omit mental and social well-being relating to aesthetic dissatisfaction from the female external genital appearance. Self-perceived body image associated with female external genital appearance dissatisfaction can lead to dysphoric emotions in specific social situa-

tions.<sup>24,25</sup> Aesthetic anatomical imperfections could interfere with a patient's adaptation to daily life and to social life.<sup>25</sup> It also has been documented that "a regular person who seeks an aesthetic procedure should not be considered a psychologically disturbed individual at face value."<sup>26</sup> Clinical research determined that "patients overwhelmingly tend to feel better about their body after surgery" and "the sex of both patients and their sexual partners can be strikingly enhanced after elective cosmetic surgery."<sup>27</sup> At the time when ACOG issued its Opinion No. 378, scientific data existed documenting that self-perceived body image improved following cosmetic surgery.<sup>27</sup> Additionally, the scientific-clinical literature was available to demonstrate negative emotions and deteriorating social well-being associated with the absence of physical signs but the presence of negative self-perceived body image.<sup>27</sup>

#### *Scientific Objectivity*

All gynecologic societies recommended that a practitioner should look for "any physical signs or symptoms that indicate the need for surgical intervention."<sup>1-3</sup> It is literally forcing a practitioner to establish medical indications for FGCS even though cosmetic surgeries are performed based upon patient request. Also, ACOG recommended that a practitioner should have a frank discussion explaining that "the appearance of the external genitalia varies significantly from woman to woman."<sup>1</sup> There is no single study determining the norm of the female external genitalia appearance, so a practitioner must depend on a woman's acceptance of her aesthetic appearance of external genitalia. A practitioner must make a decision whether he/she can meet the patient's aesthetic expectation. Objectively, a woman must be informed about current medical knowledge relating to outcomes of existing gynecologic cosmetic interventions, which can improve her aesthetic appearances and ease her emotional tensions and social concerns. Also, a patient should be educated that "norms" for the aesthetic look of the female external genitalia have not been established.

The gynecologic societies did not exercise an impartial review of references which they selected to support their recommendations. ACOG and other societies very loosely interpreted selected articles to fit their viewpoints. Disrespect for women's requests for FGCS are clearly identifiable in recommendations of gynecologic societies. Select-

ing the Lloyd publication for supporting the position of gynecologic societies on the female external genital appearance cannot hold up under simple scientific scrutiny. The Lloyd article meets all the criteria to be classified as "junk science," and using their findings in recommendations of gynecologic societies contradicts any objectivity.<sup>1,3,11</sup>

#### *Appropriate Scientific Transparency*

ACOG determined that a cosmetic procedure could be performed for medical indications; however, in the same publication ACOG recommends against performing the identical procedures for FGCS due to the absence of determinations of safety and effectiveness. For medical indications a procedure can be performed without the presence of the safety and effectiveness documentations, but not for FGCS.<sup>1</sup> Such double standards in the ACOG and other gynecologic societies' recommendations obscure appropriate transparency. Further review of the literature relating to the ACOG recommendations established that, in general, "One-third of the recommendations put forth by the College in its practice bulletins are based on good and consistent scientific evidence."<sup>28,29</sup> So, two-thirds of ACOG's recommendations were based on nonrandomized studies. In view of ACOG's history of recommendations, only 30% of the articles met the evidence-based level I (a randomized study). To discriminate against FGCS based upon the absence of safety and effectiveness documentation (a randomized study) is at best a one-sided approach; the quality of clarity (transparency) must be called into question.

The title of the ACOG Committee No. 378 includes the phrase *Cosmetic Vaginal Procedures*.<sup>1</sup> Such a phrase is a misleading term for cosmetic gynecology since no cosmetic procedure can be performed on the vaginal wall. Also, using the term *cosmetic vaginal procedures* is contrary to the cosmetic gynecology definition, which defines cosmetic gynecology as "a transformation of an external genital anatomical structure to a more pleasing look (appearance)." The vagina is not the organ on which cosmetic surgery is ever performed; the vaginal tube can be subjected to reconstruction (plastic surgery). Therefore, cosmetic transformation to a more pleasing look of the vagina is, at best, impractical thinking.

#### *Strengths and Limitations*

This methodological review determined the low

levels of understanding of the cosmetic gynecology field by the consultants of the gynecologic societies who prepared recommendations for FGCS. The current study also helps one to understand the scientific integrity within recommendations offered by gynecologic societies. Additionally, exposing the shortcomings of the gynecologic societies in their recommendations for FGCS provides opportunities for gynecologic societies to revise their recommendations accordingly. This methodological review presented a constructive scientific assessment of recommendations of gynecologic societies in the field of cosmetic-plastic gynecology, and such evaluation can assist the cosmetic gynecologic field to make appropriate progress. The weakness of this review is the absence of sufficient numbers of scientific articles used by the gynecologic societies in order to conduct a more advanced review. The recommendations of gynecologic societies were not sufficiently supported by scientific references, so the factual materials for scientific analysis were limited; the omission of an existing article was noted, accurate citation of existing data was called into question, and affirmation of the reality in the cosmetic-plastic field was shown to be missing.

In conclusion, scientific integrity shortcomings are present in recommendations for FGCS offered by gynecologic societies. Interpretations of references published by the gynecologic societies did not meet scientific integrity (quality, credibility, objectivity, and transparency). The recommendations issued by gynecologic societies were not based on scientific facts.

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