### SOGC CLINICAL PRACTICE GUIDELINE

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# Guideline No. 423: Female Genital Cosmetic Surgery and Procedures

(En français : Directive clinique n° 423 : Interventions chirurgicales et thérapeutiques esthétiques génitales féminines)

The English document is the original version. In the event of any discrepancy between the English and French content, the English version prevails.

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This document reflects emerging clinical and scientific advances as of the publication date and is subject to change. The information is not meant to dictate an exclusive course of treatment or procedure. Institutions are free to amend the recommendations. The SOGC suggests, however, that they adequately document any such amendments.

**Informed consent:** Everyone has the right and responsibility to make informed decisions about their care together with their health care providers. In order to facilitate this, the SOGC recommends that health care providers provide patients with information and support that is evidence-based, culturally appropriate, and personalized.

Language and inclusivity: The SOGC recognizes the importance to be fully inclusive and when context is appropriate, gender-neutral language will be used. In other circumstances, we continue to use gendered language because of our mission to advance women's health. The SOGC recognizes and respects the rights of all people for whom the information in this document may apply, including but not limited to transgender, non-binary, and intersex people. The SOGC encourages health care providers to engage in respectful conversation with their patients about their gender identity and preferred gender pronouns and to apply these guidelines in a way that is sensitive to each person's needs.

All authors have indicated that they meet the journal's requirements for authorship.

**Keywords:** female genital; cosmetic surgery; labiaplasty; hymenoplasty; adolescents; vaginal rejuvenation; laser

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#### **RECOMMENDED CHANGES IN PRACTICE**

- Health professionals should provide comprehensive education for women of all ages on normal female genital anatomy and physiological function.
- Physicians providing female genital cosmetic surgery and procedures should ensure that thorough counselling has been completed before they consider offering a procedure that is not medically indicated for cosmetic purposes.
- Significant caution is warranted in the use of laser for genitourinary syndrome of menopause or cosmetic genital indications pending further rigorous short- and long- term clinical research on safety and effectiveness.

#### **KEY MESSAGES**

- There is limited scientific evidence and research to support the safety and effectiveness of female genital cosmetic surgery and procedures to enhance body image and improve female sexual and reproductive health and function.
- Professional societies with published statements on nonmedically indicated female genital cosmetic surgery and procedures universally agree that such surgery and procedures are lacking in evidence of both safety and efficacy.
- Communication and advertising for female genital cosmetic surgery and procedures should be factual, evidence-based, and free of bias.
- 4. Women seeking female genital cosmetic surgery and procedures should be thoroughly counselled regarding normal genital anatomy and physiological function. Many will be reassured and will withdraw their request for surgical procedures.

#### **ABSTRACT**

**Objective:** To provide Canadian surgeons and other providers who offer female genital cosmetic surgery (FGCS) and procedures, and their referring practitioners, with evidence-based direction in response to increasing requests for, and availability of, vaginal and vulvar surgeries and procedures that fall outside the traditional realm of medically indicated reconstructions.

Target Population: Women of all ages seeking FGCS or procedures.

Benefits, Harms, and Costs: Health care providers play an important role in educating women about their anatomy and helping them appreciate individual variations. Most women requesting FGCS and procedures have normal genitalia, and up to 87% are reassured by

counselling. At this time, due to lack of rigorous clinical or scientific evidence of short- and long-term efficacy and safety, FGCS and procedures for non-medical indications cannot be supported. FGCS and procedures are typically provided in the private sector, where costs are borne by the patient.

Evidence: Literature was retrieved through searches of MEDLINE, Scopus, and The Cochrane Library using appropriate controlled vocabulary and keywords. The selected search terms represented keywords for FGCS (labiaplasty, surgery, vaginal laser therapy, laser vaginal tightening, vaginal laser, vaginal rejuvenation, vaginal relaxation syndrome, hymenoplasty, vaginal cosmetic procedures) combined with female genital counselling, consent, satisfaction, follow-up, adolescent, and body dysmorphic or body dysmorphia. The search was restricted to publications after 2012 in order to update the literature since the previous guideline on this topic. Results were restricted to systematic reviews, randomized controlled trials, and observational studies. Studies were restricted to those involving humans, and no language restrictions were applied. The search was completed on May 20, 2020, and updated on November 10, 2020.

Validation Methods: The authors rated the quality of evidence and strength of recommendations using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach. See online Appendix A (Tables A1 for definitions and A2 for interpretations of strong and weak recommendations).

**Intended Audience:** Gynaecologists, primary care providers, surgeons performing FGCS and/or procedures.

#### **RECOMMENDATIONS:**

- Health providers should play an important role in educating women about their anatomy and helping them appreciate individual variations, including transitions through the reproductive life cycle (strong, low).
- 2. For women who present with requests for vaginal cosmetic procedures, a complete medical, sexual, and gynaecological history must be obtained, and the absence of any major sexual or psychological dysfunction, including body dysmorphic disorder, should be ascertained. Any possibility of coercion or exploitation must also be ruled out (strong, high).
- 3. There is insufficient evidence to support any female genital cosmetic surgery or procedure to improve sexual satisfaction and/or self-image. Physicians choosing to proceed with these cosmetic procedures should not promote these surgeries for the enhancement of sexual function or self-image (strong, low).
- 4. Hymenoplasty is a surgical procedure that is not medically indicated. Counselling of the woman is paramount to provide both reassurance and accurate information that the procedure does not reliably result in the desired outcome of bleeding at first marital intercourse (strong, moderate).
- 5. Laser is not recommended for genitourinary syndrome of menopause or cosmetic genital indications without further rigorous short- and long- term clinical research (*strong, low*).
- 6. Counselling should be a priority for women requesting female genital cosmetic surgery and procedures that are not medically indicated. Topics should include normal variation and physiological changes over the lifespan, as well as the possibility of unintended consequences of cosmetic surgery to the genital area. The lack of both high-quality evidence and data regarding outcomes should also be discussed and considered as part of the informed decision-making process (strong, high).

- Caution should be used in advertising female genital cosmetic surgeries, to ensure such advertising is factual and not misleading (strong, high).
- 8. Physicians who see adolescents requesting female genital cosmetic surgery require additional expertise in counselling adolescents (strong, low).
- 9. Female genital cosmetic surgery must not be performed until genital maturity (strong, low).
- Surgery is not considered cosmetic if there is documented functional impairment, which may include structural, psychological, and/or anatomical concerns (strong, moderate).

#### INTRODUCTION

In recent years, there has been an increase in the frequency and types of female genital cosmetic surgery (FGCS) and laser procedures available to women. The Aesthetic Society reports a 29.7% increase in labiaplasty between 2015 and 2019, with 47.9% performed in women aged 18-34 years, at an average cost of US \$2952. The International Society of Aesthetic Plastic Surgery reports an overall increase of 33.4% from 2014 to 2018, with a slight decrease of 4.4% from 2017 to 2018. Labiaplasty constitutes 1.3% of surgical procedures performed by 56% of plastic surgeons worldwide, based on data from those countries that collect such data.<sup>2</sup> Aesthetic plastic surgeons differentiate between surgery, such as labiaplasty, and procedures, categorizing laser as a procedure. Information about surgery and procedures performed by gynaecologists is not available globally, or for Canada, where a mix of private and public services is used.

Multiple factors are at play in the increasing demand, including the absence of accurate information about normal genital appearance, the widespread dissemination of misinformation on social media and the Internet, and anatomical differences highlighted by the increased practice of pubic hair removal. Exposure to images of modified vulvas may change women's perceptions of what is normal or desirable and may influence women's decision to seek labiaplasty.<sup>3</sup>

A confusing array of terms and expectations are associated with FGCS and procedures, all of which purport to improve the appearance and/or function of a woman's genitalia or her sexual satisfaction. Evidence is currently lacking for the safety and efficacy of FGCS and procedures, most of which have no clearly accepted or consistent definitions.

This clinical practice guideline is intended to provide evidence-based direction for Canadian gynaecologists, primary health care providers, and surgeons offering cosmetic vaginal and vulvar procedures that fall outside the traditional realm of medically indicated reconstructions.

Genital surgery for gender affirmation or for the repair of obvious anomalies is not considered cosmetic and will not be addressed in this clinical practice guideline. Similarly, female genital mutilation/cutting, defibulation, and reinfibulation

#### **ABBREVIATIONS**

BDD body dysmorphic disorder

FGCS female genital cosmetic surgery

GSM genitourinary syndrome of menopause

procedures are not included in this guideline and are the subject of "SOGC Guideline No. 395: Female Genital Cutting."

Confusion has arisen over terminology in the new era of FGCS, where non-medically indicated surgery is typically performed in private practice, and the woman pays out of pocket. It is important to recognize symptomatic conditions where surgical correction, typically by a gynaecologist, is medically indicated, including vulvar and vaginal repairs for conditions such as pelvic prolapse, perineal tears during delivery, incontinence, congenital malformations, or tumours. Surgical reconstruction may also be medically indicated in cases of significant anatomical variation.

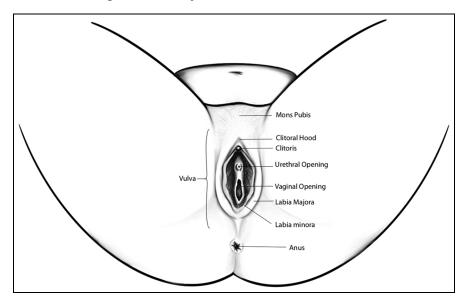
## ANATOMY AND FUNCTION OF THE VULVA AND VAGINA

The labia minora are 2 folds of hairless skin that arise from the same tissue as that forming the clitoris. They lie within the outer labia majora, which grow hair after puberty and form the lateral borders of the vaginal opening. They are innervated by branches of the ilioinguinal and genital nerve anteriorly, and by branches of the pudendal nerve posteriorly (Figure).

Pubertal development of the external genitalia includes evolving changes in the appearance and relative prominence of the labia minora and majora before the woman reaches full maturity. Composed of erectile-like connective tissue, a significant blood supply and innervation, the labia minora are often an area of great change, which can be unsettling for adolescents. The labia continue to remodel with childbirth and can again undergo significant change with menopause. Changes in menopause can include partial resorption of the labia minora, with attendant loss of elasticity of the tissues. Thinning and stenosis can occur with atrophic change, and pain or difficulty with intercourse is a common concern. Data that track outcomes through these life transitions are lacking.<sup>5</sup>

Sexual function is complex and related to many factors other than anatomy. During the normal female sexual response, the vagina must be able to dilate and "balloon," forming the orgasmic platform. This capacity can be adversely affected by many physiological processes, such as menopause; pathology, such as dermatoses; and iatrogenic causes, such as cancer treatments, radiation, and surgery. Urethra, bladder, and bowel are intimate with the vagina, and surgery to the vagina carries inherent risks of compromise to these important structures. In addition, the impact of the innervation, epithelial qualities, and vascular anatomy of the vulva and vagina on sexual function is poorly understood. In a study using self-assessment

Figure. Illustration of female external genital anatomy



Contributed by Charlotte Axelrod.

methods by Schober et al., the vaginal introitus was rated as requiring the least amount of stimulation to orgasm, and those who rated their labia as larger actually noted higher sexual pleasure ratings than others.<sup>5</sup> It has also been noted that the free edge of the labia minora is highly innervated.<sup>6</sup>

There is a wide spectrum of normal anatomical variation in female genitalia, which is well-demonstrated in photographs in the labia library, a free, useful online resource for women. However, there are no clear criteria to describe abnormal female genitalia, and studies have previously demonstrated a wide range of size differences in female genitalia, which may also differ depending on positioning so hack of awareness of the normal diversity in appearance has been propagated by the sometimes unrealistic public media perception of the "ideal." Women's health care professionals should help women understand their anatomy and to respect individual variation. This can be further addressed during transitions through the reproductive life cycle.

#### **RECOMMENDATION 1**

## TYPES OF SURGERIES AND PROCEDURES INVOLVED IN FEMALE GENITAL COSMETIC SURGERY

A variety of surgeries and procedures have been proposed to improve genital appearance or sexual performance, including labiaplasty of the labia minora or majora, clitoral hood size reduction, clitoral resurfacing, perineoplasty, vaginoplasty, hymenoplasty, monsplasty, G-spot

augmentation, laser to vulva or vagina, vaginal rejuvenation, fillers, and fat grafting. These surgeries and procedures may be performed alone or in combination. To date, no systematic reviews or randomized controlled trials have evaluated the safety and efficacy of these surgeries and procedures, other than for genitourinary syndrome of menopause (GSM). There have been 2 recent systematic reviews of the use of laser for urinary incontinence and pelvic floor prolapse, which failed to demonstrate any strong evidence to support these procedures.

Three specific topics will be highlighted in this guideline to address the ethical and procedural challenges around provision of these types of surgery: labiaplasty, hymenoplasty, and laser procedures.

#### Labiaplasty

Labiaplasty is the most common type of FGCS currently requested and offered, and, as such, is a key exemplar. It typically involves surgical reshaping of the labia minora on request, and a variety of techniques are described, but none of them have been compared with one another.

For women presenting with concerns about genital appearance and/or requesting surgery, a complete medical, sexual, and gynaecological history should be obtained, and the absence of any major sexual or psychological dysfunction should be ascertained. Given that women with body dysmorphic disorder (BDD; preoccupation with perceived flaws in appearance) are more likely to seek cosmetic surgeries of all types, it is important that the clinician assess the patient for the symptoms of BDD and

Factors to include in assessment	Elicit specific factors influencing request and outcome
Motivation for FGCS	<ul> <li>Perceived physical flaw in genital appearance</li> <li>Concerns about appearing abnormal</li> <li>Physical discomfort</li> <li>Pain</li> <li>Note: Given that women may be highly motivated to receive FGCS and aware of barriers or difficulties toward that end, women may minimize psychological motivations and emphasize functional ones.</li> </ul>
Psychiatric symptoms and diagnoses, including body dysmorphic disorder	<ul> <li>Include history of anxiety and depression (significant risk factors for poor psychosocial outcomes after FGCS)</li> <li>Include history and current symptoms of an anxiety disorder and major depressive disorder, subthreshold clinical syndromes</li> <li>Assess for symptoms of BDD; determine whether perceived distortions of the genitals are contributing to desire for FGCS</li> <li>Note: Women with BDD are more likely to seek cosmetic surgeries of all types.</li> </ul>
Body image, self-esteem, and genital self-image	<ul> <li>Elicit general and personal beliefs and attitudes women may have about vulvas</li> <li>Ask about the woman's perception of normal, consider showing photos of a range of vulvas to gauge her reaction</li> <li>Assess self-esteem by asking questions about other domains of the woman's life, and her feelings about herself with regard to those domains</li> </ul>
Sexual and relationship factors, including current sexual response and expectations of change with surgery	<ul> <li>Ask about all domains of sexual function, including desire, arousal, lubrication, orgasm, sexual satisfaction, and sexual pain (Validated measures can also be administered)</li> <li>Solicit the woman's expectations about the impact of FGCS on her sexual functioning</li> <li>If the woman is in a relationship, ask about partner's own sexual function, and her perception of partner's view of her sexual functioning</li> <li>Ask about pressure from a partner to seek FGCS; determine whether this pressure is actual or perceived</li> <li>If possible, try to assess the partner on their own to inquire about the woman's motives for FGCS; include asking about the partner's perceptions of the appearance of the woman's genitals</li> </ul>
Exposure to and influence of media ideals, and associated perceptions of others' evaluations	<ul> <li>Ask about exposure to pornography, the woman's attitudes, beliefs, and emotions when viewing such images, and how those affect her wish for FGCS</li> <li>Ask about experience of negative evaluation by others or negative comments about female genitals made by others</li> <li>Note: Bullying behaviour is known to result in self-consciousness, poor psychological functioning, and increased desire for cosmetic procedures in adolescents</li> </ul>

Adapted with permission from Brotto LA. Brotto L.A., Bryce, M., Todd, N. (2019). Female genital cosmetic surgery: Psychological aspects and approaches. Female Genital Cosmetic Surgery: Solution to What Problem? Edited by Creighton, S.M., Liao, L-M. Cambridge, UK: Cambridge University Press. pp. 118-28.

BDD: body dysmorphic disorder.

determine whether perceived distortions of the genitals are contributing to the desire for labiaplasty or other FGCS (Table). <sup>12</sup> If any psychological concerns are identified, appropriate referral for assessment should be initiated before considering a genital cosmetic surgical procedure. <sup>13</sup> In a controlled study comparing women seeking labiaplasty with those not desiring the procedure, a wide range of avoidance and safety-seeking behaviours were observed in the labiaplasty group compared with the control group. A history of current or past anxiety and depression is also a significant risk factor for poor psychosocial outcomes after cosmetic surgery.

It should be noted that the majority of women seeking genital cosmetic surgery have a labia that would be considered within the normal physiological variation. <sup>14–16</sup> Similarly, in the pediatric population, McQuillan et al. concluded that, with appropriate education and

counselling, concerns regarding labial appearance can be managed without surgery in the majority of girls (87%). 14

Evidence from studies thus far for labiaplasty or other procedures such as "G-spot augmentation" is of low quality. Moreover, there is little evidence to support improvement in sexual satisfaction or self-image from cosmetic "rejuvenation" of the vagina or vulvar cosmetic surgery. In a small study of 14 adult women who had undergone labiaplasty, most reported significant improvements in their sexual well-being after surgery, although some reported that their labia were not as small or symmetric as expected. Some found their emotional discomfort around sexual intercourse had not improved. Another study found that the 58 participants who underwent labiaplasty had no major complications and that women with children were more satisfied following surgery than women who had not given birth, making it

important to discuss postponing the decision to perform these surgeries until after women have completed child-bearing. At that time, if women are symptomatic, effective conservative therapies for decreased vaginal muscle tone, including pelvic physiotherapy, should be offered as an alternative.

The majority of women, if fully counselled, will be satisfied with the information and reassurance they receive from the care provider and will choose not to proceed with surgery. After exploring the reasons behind the patient's request, and discussing the risks and benefits (as outlined in the section on informed consent), if a patient insists on labiaplasty, a physician may pursue one of the following 2 options: (1) agree to perform the procedure, or (2) decline and refer the patient for a second opinion.

Physicians who choose to undertake cosmetic procedures to the vagina and vulva should be appropriately trained in the gynaecological and/or plastic surgery aspects of cosmetic surgery of the lower genital tract. This is not a skill set currently required by the Royal College of Physicians and Surgeons of Canada for accreditation of postgraduate training programs in obstetrics and gynaecology or plastic surgery.<sup>21</sup>

#### **RECOMMENDATIONS 2 and 3**

#### **Hymenoplasty**

Requests for hymenoplasty are often culturally driven and more common in countries and cultures where women's rights and autonomy are compromised, although the surgery is not exclusive to those countries. In some countries and cultures, women may be at risk of social isolation and potentially fatal violence if they do not demonstrate an intact hymen at the time of marriage, despite the fact, as stated by the World Health Organization, that "there is no known examination that can prove a history of vaginal intercourse." Variability in the structure, flexibility, and thickness of the hymen have been shown, with studies demonstrating it can appear intact after vaginal intercourse and ruptured in women who have not had intercourse. Physicians can feel pressured to support a woman whose life or well-being is threatened.

Surgical options for hymenoplasty have been described, but evidence for their efficacy is limited, and breakdown of the repair is a well-described complication. As with other non-medically indicated surgeries, they are not part of the postgraduate curriculum. It is critical to understand the desired outcome of the surgery, since bleeding at the time

of first marital intercourse is the proof of virginity being sought, yet reportedly occurs no more than 50% of the time at first intercourse or after surgical repair, primarily because of the lack of vascularity in the hymen. This can lead to unrealistic expectations concerning hymenoplasty; in a study by van Moorst and colleagues, counselling about hymenoplasty resulted in three-quarters of the women requesting the surgery to decide against it. 23

#### **RECOMMENDATION 4**

#### **Laser Procedures**

Vaginal rejuvenation is a vague term proposed to address medical conditions such as vulvovaginal atrophy and GSM. The U.S. Food and Drug Administration (FDA) has issued a warning against energy-based devices for vaginal rejuvenation or vaginal cosmetic procedures, stating vaginal rejuvenation is an "ill-defined term." The term is used to describe non-surgical procedures intended to treat vaginal symptoms and/or conditions, including vaginal laxity, vaginal atrophy, dryness and itching, pain during intercourse, pain during urination, and decreased sexual sensation. To date, the FDA has "not cleared or approved for marketing any energy-based devices to treat these symptoms or conditions, or any symptoms related to menopause, urinary incontinence, or sexual function. Energy-based therapies to the vagina may lead to serious adverse events including vaginal burns, scarring, pain during intercourse, and recurring/chronic pain."<sup>24</sup> In its committee opinion, The American College of Obstetricians and Gynecologists (ACOG) has stated that genital cosmetic surgery, including energy-based procedures, "are not medically indicated, pose substantial risk, and their safety and effectiveness have not been established."25

In contrast to the very conservative approach toward vaginal laser treatment approval in the United States, in Australia, the Erbium laser was approved in 2017 by the Therapeutic Goods Administration for treatment of vulvovaginal atrophy under an "application without audit: review process." It should be noted, however, that the Royal Australian and New Zealand College of Obstetricians and Gynaecologists strongly discourages the performance of any surgical or laser procedure that lacks current peer-reviewed scientific evidence through appropriately constructed clinical trials. "There is no evidence that these procedures are effective, enhance sexual function or improve self-image. The risks of potential complications such as scarring, adhesions, permanent disfigurement, infection, dyspareunia and altered sexual sensations should be discussed in detail."<sup>26</sup>

In Canada, 2 lasers have been approved for treatment of GSM (also referred to as vulvovaginal atrophy), and another has been recalled, as its indication for "vaginal rejuvenation" was not approved in the Canadian market.

Overall, multiple professional groups and societies, including the International Society for the Study of Vulvovaginal Disease and American Urogynecologic Society agree that there is not enough evidence to support the use of laser treatments for GSM and related vaginal rejuvenation symptoms of laxity, dryness, or decreased vaginal sensation.<sup>27-29</sup> The early data are provocative and encouraging in the short term, but there are no long-term data on efficacy and safety. 30,31 In a recent systematic review on the role of laser for urinary incontinence and pelvic floor prolapse, Mackova et al. highlighted methodological deficiencies and potential publication bias in the 31 reviewed studies, which included only 1 randomized controlled trial.<sup>32</sup> They summarized the evidence as "weak." The editorial accompanying the review suggested giving pause to this new technology, to avoid prematurely affirming benefit, which would repeat the same mistake made with vaginal mesh.<sup>33</sup> In a similar systematic review and meta-analysis of laser on genital symptoms in postmenopausal women by Li al., 3 randomized studies, 16 prospective studies, and 7 retrospective studies met eligibility criteria, for a total of 2678 participants.<sup>34</sup> Pooled data from the 3 randomized trials showed no difference between vaginal laser and topical hormonal treatments for vaginal symptoms or sexual function, and no difference among laser, topical hormone, and lubricant for sexual function. The non-randomized data supported energy-based treatments to improve vaginal symptoms, sexual function, and clinician-reported outcomes. Overall, there was significant heterogeneity of data from differing measures, and reported outcomes, and data remained low-quality, with high risk of bias and no double-blind or placebocontrolled trials yet reported. The authors concluded that energy-based treatments should continue to be undertaken in research studies only.<sup>34</sup>

#### **RECOMMENDATION 5**

## LEGAL AND ETHICAL ASPECTS OF FEMALE GENITAL COSMETIC SURGERY

#### **Elements of Informed Consent**

Counselling patients appropriately and obtaining consent for genital cosmetic procedures is essential to ensure patient autonomy and satisfaction. Proper disclosure, communication, and documentation are necessary for good-quality care and may protect health care providers from litigation. Informed consent includes a description of the risks, benefits, and alternatives of the proposed treatment. It also involves a capacity assessment, ensuring the patient understands the relevant information and can appreciate the consequences of her decision. The process must be voluntary and free of coercion. Documentation of the consent process to reflect the discussion is imperative.<sup>35</sup>

## Specific Issues in Informed Consent for Genital Cosmetic Procedures

Before offering any genital cosmetic procedure, it is important to explore the patient's goals and motivations and whether those goals can be achieved safely, both with respect to the patient's genital anatomy and general health. When assessing a patient who is requesting labiaplasty, a thorough history and physical examination must be performed. Screening for psychological comorbidities (i.e., BDD [using the assessment described in the Table and further consultation if necessary] as well as depression, anxiety, and trauma) are key components to the capacity assessment. Ascertaining undue pressure from other individuals (e.g., family members or partner) is also critical.

Once these requirements are met, as with any elective procedure, it is essential to ensure the patient has a clear understanding of the surgery and realistic expectations so that she can make an informed decision about whether she wants to proceed with surgery. It is important to remember that, in most cases, women requesting labiaplasty are considered anatomically normal, so the surgery will alter anatomically normal structures.

When offering treatment that is not medically indicated, such as a cosmetic procedure, the consent process needs to be more thorough than that for a procedure with a clear medical indication that has few alternatives. The required counselling must include education about normal genital anatomy and its variations, a detailed description of the proposed procedure, and a discussion of alternatives (particularly expectant management and conservative options such as pelvic physiotherapy, if appropriate).

There are no available long-term data on the safety or efficacy of these procedures.<sup>36</sup> Additionally, there is currently no evidence available regarding the effects of the physiological changes associated with pregnancy and childbirth or menopause on the post-operative outcomes of perineal or vaginal cosmetic surgeries.<sup>18,37</sup> A detailed description of the proposed surgery with the risks,

benefits, potential complications, and expected healing course should be reviewed and documented. Risks include anesthetic risk and general risks of genital surgery: infection, bleeding or hematoma, wound dehiscence, injury to adjacent structures (urethra, rectum, clitoris), scarring, pain (acute and chronic pain, and dyspareunia), as well as alteration in sensation, decrease in sexual pleasure, and unexpected alteration in anatomy, including asymmetry. Risks specific to the proposed procedure should be outlined, including a balanced review of the strengths and limitations of scientific evidence and effectiveness of the proposed treatment, and possible dissatisfaction with cosmetic or other results. Patients should be provided with realistic expectations of outcomes based on current data. Finally, both the patient and the surgeon must make voluntary decisions about whether to engage in the procedure.

With respect to age of consent, Canadian courts have rejected the notion of "age of majority" to define the age at which an individual is able to consent. Common law recognizes mature minors as persons who are capable of understanding the nature and consequences of the proposed treatment and alternatives, including no treatment. When a minor is deemed to be "mature," no parental consent is required for FGCS and procedures. In Québec, the Civil Code generally establishes the age of consent at 14 years.<sup>38</sup>

Consideration should be given to the legal ramifications of the procedure, as certain genital cosmetic procedures (particularly labiaplasty) may be construed as female genital cutting, addressed in SOGC Guideline No. 395: Female Genital Cutting.<sup>4</sup>

#### **RECOMMENDATION 6**

## FINANCIAL ASPECTS OF GENITAL COSMETIC PROCEDURES

When an equivalent procedure can be offered in a public health care setting, rather than a private one, this should be disclosed.

Caution should be used in advertising such surgery and procedures to ensure that the information delivered is evidence-based and that the language and messaging used are respectful of women. Care must be taken to avoid unduly promoting or advertising benefits and outcomes beyond "factual and relevant information that is accurate, clear, and explicitly states all important details." As noted

by ACOG, "Also of concern are ethical issues associated with the marketing of these procedures and the national franchising in this field. Such a business model that controls the dissemination of scientific knowledge is troubling."

#### **RECOMMENDATION 7**

## RECOMMENDATIONS FROM PROFESSIONAL ORGANIZATIONS IN WOMEN'S HEALTH

Concerns have been raised that these surgical interventions may be inappropriate and complicated by issues involving autonomy and ethics. Surgery is increasingly viewed as an intervention to improve the quality of a person's life, not merely to save it. The dilemma thus arises of how to balance the patient's desire for surgical intervention with the Hippocratic requirement to do no harm. Ethically, there is also a utilitarian concern about the use of finite resources for non-medically indicated surgery. Therefore, societies of obstetricians and gynaecologists, including the ACOG, the UK Royal College of Obstetricians and Gynaecologists, the British Society for Pediatric and Adolescent Gynaecology, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, and the International Society for the Study of Vulvovaginal Disease, are putting forward recommendations and policies to guide their members and the women who request such surgeries. 6,25,27,40-44 These societies universally agree that any FGCS that is not medically indicated is both lacking in evidence of safety and efficacy and fraught with challenges.

## CONSIDERATIONS FOR VULVOVAGINAL COSMETIC PROCEDURES IN ADOLESCENTS

Women seek cosmetic procedures for aesthetic, functional, or psychological reasons. Girls and adolescents have similar presenting complaints, leading to consultation for labiaplasty. Adolescents and young adults (up to age 21 years), most commonly request surgery for relief of symptoms leading to functional impairment, such as friction and pain, as these symptoms may interfere with daily activities, such as participation in sports. The second most common reason labiaplasty is requested in adolescents (accounting for 25% of requests) is the mother's perception of an abnormality in her daughter. 11 Older adolescents are more likely to be self-conscious about their own appearance, similar to the adult population, and to feel less attractive to their partner. 45 Adolescents often present with concerns related to their labial appearance, despite having genitalia in the expected range of variation. 11,14

Apart from the usual preoperative considerations and counselling, in adolescents, the health care provider must give particular attention to that patient's understanding of the purpose of the surgery, the degree of specific anatomical concern, and the patient's physical maturity. The social costs to the patient, the decision-making dynamic between the patient and her parents, and the patient's attitude following surgery must also be considered. Counselling should include reassurance, as many young women continue to question the appearance of their genitals, despite discussing the wide range of normal genital appearance with their health care provider. Adolescents should also be counselled that it is normal for them to worry about the appearance of their genitals.<sup>20</sup>

Given normal physiological and developmental changes, especially in the vulva, procedures on young women should usually be discouraged; final decisions on such procedures should be based on mature genital development. As noted earlier, up to 87% of women requesting FGCS can be reassured by counselling. However, labial surgery in adolescents may be considered if, after appropriate counselling, psychologic, and/or ethics consultation, persistent functional impairment can be documented on repeat assessments. Functional impairments should, however, consist not only of structural abnormalities but also persistent psychological or emotional concerns. 20

#### **RECOMMENDATIONS 8, 9 and 10**

#### CONCLUSION

Non-medically indicated FGCS and procedures should be discouraged and should be considered only after thorough counselling; most women are reassured by counselling alone. Women need to be provided with reliable information about normal variations in anatomy and physiological changes in the vagina and vulva over the lifespan. A discussion about conservative management and treatment with evidence-based, non-surgical alternatives should be included. Surgeons offering a purely cosmetic procedure should ensure the consent process is comprehensive and that patients have a realistic expectation of the anticipated and possible outcomes. FGCS should not be performed until a woman reaches mature genital development.

Surgeons performing FGCS should be adequately trained in the procedures offered. Caution should be used when advertising FGCS, to ensure any such advertising is respectful of women and includes evidence-based information.

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#### **APPENDIX A**

Grade	Definition		
Strength of recommendation			
Strong	High level of confidence that the desirable effects outweigh the undesirable effects (strong recommendation for) or the undesirable effects outweigh the desirable effects (strong recommendation against)		
Conditional <sup>a</sup>	Desirable effects probably outweigh the undesirable effects (weak recommendation for) or the undesirable effects probably outweigh the desirable effects (weak recommendation against)		
Quality of evidence			
High	High level of confidence that the true effect lies close to that of the estimate of the effect		
Moderate	Moderate confidence in the effect estimate:  The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different		
Low	Limited confidence in the effect estimate:  The true effect may be substantially different from the estimate of the effect		
Very low	Very little confidence in the effect estimate:  The true effect is likely to be substantially different from the estimate of effect		

Perspective	Strong Recommendation • "We recommend that" • "We recommend to not"	Conditional (Weak) Recommendation  • "We suggest"  • "We suggest to not"
Authors	The net desirable effects of a course of action outweigh the effects of the alternative course of action.	It is less clear whether the net desirable consequences of a strategy outweigh the alternative strategy.
Patients	Most individuals in the situation would want the recommended course of action, while only a small proportion would not.	The majority of individuals in the situation would want the suggested course of action, but many would not.
Clinicians	Most individuals should receive the course of action.  Adherence to this recommendation according to the guideline could be used as a quality criterion or performance indicator.	Recognize that patient choices will vary by individual and that clinicians must help patients arrive at a care decision consistent with the patient's values and preferences.
Policymakers	The recommendation can be adapted as policy in most settings.	The recommendation can serve as a starting point for debate with the involvement of many stakeholders.

Adapted from GRADE Handbook (2013), Table 5.1. <sup>a</sup>Do not interpret conditional recommendations to mean weak evidence or uncertainty of the recommendation.