

Cosmetic gynecology in the view of evidence-based medicine and ACOG recommendations: a review

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Abstract

Objective To conduct a methodological review of existing scientific literature within the field of cosmetic gynecology in view of evidence-based medicine and to establish their relevance to the ACOG Committee Opinion No. 378.

Study design Appropriate medical terms were searched in multiple databases from the Internet for the period 1900–January 2010. Articles focusing on cosmetic gynecology were reviewed. In addition, anecdotal and advertising literatures were analyzed. A methodological review of the literature was conducted.

Results In peer-reviewed journals, there were 72 relevant articles related to cosmetic gynecology. There was anecdotal information from three sources and more than 1,100 articles from published marketing literature on the Internet, but no scientific journals. Among reviewed articles on cosmetic gynecology, only two articles met the level II-2 in evidence-based medicine. The absence of documentations on the safety and effectiveness of cosmetic vaginal procedures in the scientific literatures was ACOG's main concern.

Conclusions Practicing cosmetic gynecology within ACOG recommendations is desirable and possible. Currently, the standard of practice of cosmetic gynecology cannot be determined due to the absence of the documenta-

tion on safety and effectiveness. Traditional gynecologic surgical procedures cannot be called cosmetic procedures, since it is a deceptive form of practice and marketing. Creating medical terminology trademarks and establishing a business model that tries to control clinical-scientific knowledge dissemination is unethical.

Keywords Cosmetic vaginal procedures · Cosmetic surgery · Cosmetic gynecology · Cosmetic female genitalia · Vaginal rejuvenation · Labioplasty · Labial rejuvenation · Clitoral hoodoplasty · G-spot augmentation · G-spot amplification · Deinfibulation · Defibulation

Introduction

Cosmetic gynecology is an important, topical subject at present. Reviewing the existing scientific and marketing literatures on the subject matter can assist in understanding what clinical scientific data are available to support clinical cosmetic management and to direct clinical researchers to the scientific literatures. Essentially, women undergoing cosmetic gynecologic procedure(s) intend to increase sexual desirability, to improve self-confidence, and to improve sexual function. Cosmetic gynecology encompasses many several anatomical structures including clitoral prepuce or hood, clitoris, clitoral frenulum, labia minora, labia majora, vaginal introitus, hymen, vagina itself, perineum, perineal body, perineal membrane, and anal sphincter. The ACOG Committee Opinion No. 378 [1] limited its analysis to four procedures: vaginal rejuvenation, designer vaginoplasty, G-spot amplification, and revirgination. ACOG recommendations are authoritarian in the USA, and have significant impact on international arenas, and many countries will adopt ACOG's recommendations with or without modification [2].

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This study objective was to conduct a methodological review of existing scientific literatures on cosmetic gynecology in the view of evidence-based medicine and to establish their relevance to the ACOG Committee Opinion No. 378 [1].

Methods

The search strategy was based on the study following elements:

- Documentation of search terms
- Search electronically and manually existing database in multiple languages
- Type of quality of articles and surgical techniques
- Sufficiently comprehensive materials within the articles
- Study design and results of the studies were analyzed
- Possible biases

The search of terms included: cosmetic surgery; cosmetic vaginal procedures, cosmetic gynecology; cosmetic female genitalia; vaginal rejuvenation; labia minora labioplasty; labia majora labioplasty; labial rejuvenation; G-spot augmentation; G-spot amplification; clitoral hoodoplasty; revirgination; hymenoplasty, female genital mutilation; female genitalia cutting; female genitalia circumcision; deinfibulation; trans-sexual gender reassignment surgery; female genitalia congenital anomalies; acquired genitalia abnormalities. In addition, a manual search and analysis of the literature on these subjects were performed.

The following databases were used to identifying the existing literatures for review in the English language: ISI Web of Science (from 1900 to January 2010, including conferences proceedings); PubMed from 1950 to January 2010), EMBASE (from 1980 to January 2010) and the remaining database was used from 2000 to January 2010 such as ACOGNET, ProQuest, OVID, Cochrane Collection, the Lancet online collection, MD Consultant, *New England Journal of Medicine*, American College of Physicians' online resources, Highwire Journal, and Citation Index Reference computerized database.

Originally, the objective of the study was to conduct a systemic review of the existing literatures. Later on, the review objective was changed to a methodological review due to the insufficient scientific existing literatures on cosmetic gynecology. Outcome measures considered all potential benefits and harms related to the subject matter. The primary outcome measure was to identify the designation of levels of evidence-based medicine [3] within the literatures. The secondary outcome measure was to review the existing scientific literatures on cosmetic gynecology to identify:

- Indications for surgical cosmetic interventions
- Surgical technique
- Short- and long-term surgical complications
- Sexual function before and after surgical intervention

The anecdotal literature was considered and analyzed in a similar manner.

In addition, the marketing/promotional literature was reviewed. The following aspects of these materials were analyzed:

- Marketing information for physicians related to clinical workshops
- Marketing clinical information for patients
- Surgical nomenclatures and their clinical relevance in clinical cosmetic gynecologic procedures
- Whether or not traditional gynecologic procedures are used deceptively as new cosmetic gynecologic procedures
- Whether or not cosmetic gynecologic procedures are supported by the clinical study results and a study quality and validity of method being appropriately specified in the text of the manuscript. Data synthesis and analysis were based on the primary study's elements sufficient for critical appraisal and replication.

The summary of the identified data from this review was charted in Table 2, in which vertically, specific procedures were presented, and horizontally, the levels of evidence-based-medicine were presented [3]: Level I, randomized controlled trials; Level II-1, controlled trials without randomization; Level II-2, cohort or case-control analytic trials; Level II-3, multiple time series with or without the intervention; Level III, descriptive study, case reports, opinions of respected authorities, reports of experts committees.

Table 2 provides an organized classification for the potential clinical causes, indications, and diversified surgical techniques for the different category of vaginal rejuvenation. Ostrzenski [71] clinical data was utilized to present four different indications for vaginal rejuvenation and tabularized in category 1–4. Based upon the identifiable category, the specific surgical intervention was suggested.

Inclusion criteria

All articles identified in peer medical journals through either computerized databases or manual search in multiple language were included for analysis of this study. The designations of evidence-based medicine levels of cosmetic gynecology studies could be determined [3]. Domestic and international congress scientific materials were included and classified as anecdotal information related to the subject matters. Also, the marketing literatures were reviewed.

Table 1 Designation of evidence-based medicine levels of cosmetic gynecology studies

Type of procedure	Evidence-based medicine					Anecdotal
	Level I	Level II-1	Level II-2	Level II-3	Level III	
Clitoral hoodoplasty			2 Studies [4, 5]	1 Study [6]	3 Studies [7–9]	1. Reverse V-plasty 2. Subdermal resection [10]
Clitoral frenuloplasty	None	None	None	None	None	Surgical reconstruction [10]
Labia minora labioplasty					43 Studies [6–10, 13–52, 53–62]	Fenestration with transposition technique [10]
Labia majora labioplasty					3 Studies [63–65]	1. Autologous fat transfer [66] 2. Horizontal excision [67]
Hymenoplasty	None	None	None	None	1 Study [72]	Surgical restoration
Vaginal rejuvenation and vaginoplasty	None	None	None	1 Study [69]	None	Vaginal rugation restoration [10]
G-spot augmentation	None	None	None	None	None	1. Surgical procedure [10] 2. Autologous fat transfer [10] 3. Collagen injection [67]

Level I, Randomized controlled trials [3]; Level II-1, controlled trials without randomization [3]; Level II-2, cohort or case–control analytic trials [3]; Level II-3, multiple time series with or without the intervention [3]; Level III, descriptive study, case reports, opinions of respected authorities, reports of experts committees [3]

Exclusion criteria

The following articles were excluded from this study: vulvovaginal reconstruction following surgery for malignancy, female genital cutting, sex reassignment in transsexuals, congenital adrenal hyperplasia, gender identity disorders, hermaphrodites, ambiguous genitalia, ventral approach for reduction clitoroplasty, clitoral tumors or cysts, and pediatric cosmetic gynecology.

Results

Altogether, 74 articles were identified, retrieved and allocated to the designated level of the evidence-based medicine [3]. A search of computerized and manual searches for the existing literatures related to cosmetic gynecologic procedures failed to yield any randomized controlled trials (Level I evidence-based). Also, there was no well-designed controlled trial without randomization (Level-II-1 evidence-based) identified. In Table 1, cosmetic gynecology articles which were published in peer review medical journals have been summarized with the designation of evidence-based medicine levels.

The outline of the major outcome of this review established that: (1) the standardization of cosmetic gynecologic procedures cannot be suggested due to the absence of scientific, clinical data related to the safety and efficacy of the procedures, (2) there are very scanty scientific-clinical articles are available, (3) presentations of clinical research results are not clearly described and often conflicting data

are presented, (4) deceptively, traditional gynecologic procedure terminologies were changed for the practice and marketing of cosmetic gynecology, (5) practicing cosmetic gynecology is possible within ACOG's recommendations, and, (6) ACOG's opinion provides guideline for practitioners and protects physicians and women against deceptive and unethical practice and marketing of cosmetic gynecology.

Clitoral hoodoplasty

Two articles, both level II-2 evidence-based, were identified in the peer review journals [4, 5] and one article level II-3 evidence-based [6], and one anecdotal information [10]. Level II-2 article by Ostrzenski [4] presented a new clitoral hoodoplasty surgical technique of hydrodissection with reverse V-plasty for buried clitoris associated with lichen sclerosis. Goldstein and Burrows [5] presented technique for clitoral phimosis. In both articles [4, 5], the methodology of the study met the designated criteria of the evidence-based classification levels II-2 (well-designed prospective cohort study) [3]. Both clinical studies [4, 5] reported no surgical complications and all symptoms and signs resolved following surgical interventions.

Alter [6], presented 407 cases who were subjected to a combination of labia minora and clitoral hood reduction. Clitoral hoodoplasty was performed as an integral part of central wedge resection labioplasty (V-plasty). Antero-lateral curved extension from labia minora V-plasty, also known as simple V-plasty, was carried out and excision of the lateral clitoral prepuce was performed bilaterally.

The author concluded that overall improvement in self-esteem was 93%, sex life was 71% and discomfort was relieved in 95%. Overall, surgical complications were 4% in association with this procedure. Alter's [6] study met criteria for level II-3 of evidence-based. Hamori [7] utilized this technique for the case presentation and this study represented level III of evidence-based [3].

Goodman et al. [8] published clitoral prepuce reduction on 24 (2 cases per surgeon for the duration of the study of 15 months) and 49 subjects (4.08 cases per surgeon for the duration of the study of 15 months) had a combination of labia minora labioplasty with reduction of the clitoral hood. In this study, a total of 73 (6.08 4.08 cases per surgeon for the duration of the study of 15 months) hoodoplasties were executed by 12 surgeons from 10 separate practices and different specialization fields: gynecologic surgeons, urogynecologic surgeons, and plastic surgeons. The study was designed as a retrospective study with invalidated questionnaire based upon 473 subjects and all together 258 subjects responded while 215 subjects refused to participate in the study. The objectives of the Goodman et al. [8] study were to evaluate, "overall and sexual satisfaction" and concluded, "outcome in both general and sexual satisfaction appear excellent." Goodman et al. [8] had not described nor had provided adequate reference on which the authors based their surgical technique(s) and the study was conducted the between 1 January 2005 and 31 May 2008 (15 months duration). Goodman et al. [8] study would qualify for level III (retrospective descriptive study); and the Goodman [9] study also met the criteria for level III evidence-based medicine (opinion of respective authority).

Anecdotal, unpublished data yet in the peer review journal, suggested that medical and aesthetic causes are present for clitoral hoodoplasty [10]. Abnormal clinical prepuce characteristics were used to establish a new classification of clitoral hoodoplasty: (1) *occluded* clitoral prepuce, (2) *hypertrophic-gaping* clitoral prepuce, (3) *asymmetrical subdermal hypertrophy*. The following surgical interventions for clitoral hoodoplasty have been developed and based upon this classification: (1) hydrodissection with reverse V-plasty was suggested for occluded clitoral prepuce [4], (2) reverse V-plasty was recommended for hypertrophic-gaping clitoral prepuce [10], (3) subdermal reduction was option for asymmetrical subdermal hypertrophy [10].

ACOG Committee Opinion No. 378 [1] has not addressed clitoral hoodoplasty specifically in its document and in general, the ACOG Committee Opinion No. 378 [1] suggested, "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." Also, ACOG [1] viewed that women

should be discouraged from cosmetic gynecologic surgery based upon variation of the anatomical appearance of female external genitalia.

Clitoral frenuloplasty

Only anecdotal information exists related to clitoral frenuloplasty, which is performed when aesthetic appearance is unsatisfactory for a woman [10]. The surgical intervention involved reduces hypertrophy, achieves symmetry, shape, size, and provides a more pleasing contour of the clitoral frenulum. ACOG [1] did not address this subject matter in its publication.

Labia minora labioplasty

Among surgeries of the female external genitalia, labia minora attracted the most attention in clinical research as shown by the higher number of articles, more than all other female external genitalia anatomical structures combined. This review has identified 57 articles in the scientific literature related to labia minora labioplasty and also established that 1,746 surgical cases related to labia minora labioplasty were presented. Recently, Liao et al. [11] reviewed 40 articles related only to the labia minora labioplasty which were published in peer review journals [1, 6, 7, 12–52]. This article by Liao et al. [11] was a well-designed and well-executed review of clinical research methodology. This author upon re-reviewing the articles, which Liao et al. [11] incorporated into their study, agreed with Liao et al. [11] findings. Also, this author concurred with their conclusion, "Our review has identified mainly anecdotes on which consumers and service providers can be base their decisions. An acknowledgement of the need for quality research could not be discerned in the literature." Also, this group suggested [11], "Better research will pave the way for randomized comparisons between surgical and nonsurgical interventions (e.g. education and support) for cost-effectiveness, taking into account overall health care utilization (e.g. further cosmetic surgery, mental health treatment), for the same and/or related problems in the short and longer term." In addition, the authors [11] determined, "The field is some way away from randomized controlled methodology, which will ultimately be required."

Our search of the literature yielded an additional 15 publications which have been reviewed and analyzed [1, 7–9, 53–62]. All of these articles reviewed by Liao et al. [11] and us met the criteria for the level III evidence-based medicine (descriptive study and/or case reports [3]).

Rouzier et al. [18] presented, in the *American Journal of Obstetrics and Gynecology*, 163 cases who were subjected to labia minora inferior V-plasty for reduction. The study was designed to determine, "... the degree of satisfaction"

from surgery. A retrospective study was executed and the assessment of anatomical outcome of the surgery was established by surgeons' 1-month postoperative physical examinations (1 month after operation). Subjects were asked to evaluate and report functional and aesthetic results by means of the invalidated questionnaire. In addition to the questionnaire, the question whether or not a subject would choose the same procedure again was superimposed. A high percentage (7%) of reoperation was performed for wound dehiscence. The authors concluded that the procedure is simple and associated with a high degree of subjects' satisfaction.

Miklos and Moore [28] carried out a labia minora labioplasty study to assess indications for surgery and published in the *Journal of Sexual Medicine*. An invalidated questionnaire was distributed among 131 subjects who requested a labia minora operation. The subjects were allocated to three groups: the group I (aesthetic indication), the group II (functional impairment; e.g. pain and discomfort), and group III (both aesthetic and functional reasons). The results of the study established that group I was represented by 49 subjects out of 131 (37%), group II was represented by 42 subjects out of 131 (32%), and group III was represented by 40 subjects out of 131 (31%). The authors concluded that the majority of the subjects who underwent reduction of labia minora do so for functional reasons.

Solanki et al. [61] conducted a clinical retrospective study without a control group utilizing the Maas and Hage [17] technique of running interdigitating W-shape excision of the labia minora and published the article in the *Journal of Plastic and Reconstructive Aesthetic Surgery*. The authors concluded that the procedure was found to be an easy and effective method of reducing the labia minora.

Based upon of this review, medical indications for labia minora labioplasty can be summarized as follows: (1) *gross anatomy abnormality* [20, 21, 23, 28] (e.g. enlargement, asymmetry, and deformation), (2) *functional anatomy aberration* [15, 18, 28] (e.g. pain, superficial dyspareunia, discomfort during sport activities, discomfort in wearing tight clothes, interference with vaginal sexual intercourse), (3) *emotional and social disturbance* [15, 21, 23] (e.g. embarrassment, decreased self-esteem, decreased self-confidence), and, (4) *aesthetic dissatisfaction* [18, 21, 23, 28].

Potential complications of labia minora labioplasty have been reported as: (1) *hematoma formation* in 40% occurred in labioplasty performed by Giraldo et al. [15] who executed central wedge nympectomy with 90° Z-plasty; Maas et al. [31] performed running W-shaped labia resection and reported 7.6% hematoma formation and Munhoz et al. [20] encountered hematoma in 4.7% who performed inferior wedge resection and superior pedicle flap reconstruction, (2) *wound dehiscence* was identified: in 13.3% by Giraldo et al. [15]; Munhoz et al. [20] reported 9.5% of occurrence;

Maas and Hage [17, 31] reported 7.6%; and Rouzier et al. [18] reported 7.6% associated with inferior V-shape labia minora resection, (3) *superficial dyspareunia* was reported by Rouzier [18] in 23% following inferior V-shape labia minora resection. ACOG's Opinion [1] suggested potential complications such as infection, altered sensation of female genitalia, dyspareunia, postoperative adhesions formation, and scarring.

A review of the existing scientific literatures for labia minora labioplasty established the following techniques: (1) partial amputation also known as a linear resection or trimming [12, 13, 34] or straightforward amputation [13, 14, 34] (total resection), (2) wedge resection and its modifications (V-plasty [33], inferior V-plasty [18], inferior wedge resection with superior pedicle flap reconstruction [20], W-plasty [17, 31], Z-plasty [15, 30, 37]), (3) de-epithelization [19], and, fenestration labioplasty [10].

Anecdotal information related to the labia minora labioplasty surgical technique of fenestration labioplasty (FL) was presented by Ostrzenski [10]. This technique anecdotally can preserve labial edge, color, contours, shapes, size, and symmetry. In this technique, an elliptical excision of inner labial tissue is excised and the inferior part of the labium is sharply separated 1 cm above the lateral-posterior base of the labium. The excess tissue is cut out and the pedicle is sutured to the previously determined location. The procedure is executed bilaterally [10].

ACOG in its Opinion [1] supported the labia minora labioplasty; but they did not specify which technique they were supporting. In its document, ACOG [1] stipulated that labia minora labioplasty can be performed for "...treatment for labia hypertrophy or asymmetrical labial growth secondary to congenital conditions, chronic irritation, or excessive androgenic hormones."

Labia majora labioplasty

Three articles were identified in the existing scientific literatures [63–65]. All three articles were classified as the level III evidence-based [3] (descriptive study and case reports). All of these publications advocated vertical excision of the excessive skin of the labia. Indication for surgery was aesthetic dissatisfactions. Hematoma requiring surgical intervention was reported [64]. Also, moderate edema [65] lasting over 4 weeks occurred.

The marketing literatures offer surgical interventions by both vertical and horizontal excisions for labia majora labioplasty. The horizontal labia majora labioplasty originated from Laser Vaginal Rejuvenation Institute of Los Angeles [67]. Many of the Laser Vaginal Rejuvenation Institute of Los Angeles franchise practices presented the same marketing information.

Hymenoplasty (revirgination)

In the existing scientific literature, only one article was by O'Connor [72] who examined the medical, ethical, and criminal aspects in Australia. In scientific literature, there is no mention of surgical technique, safety, and effectiveness of hymenoplasty.

Anecdotal information in writing failed to produce any document. Surgical interventions are applied based upon the personal experience of the surgeon.

ACOG's opinion [1] does not recommend the revirgination procedure. Its recommendation is based upon the absence of data supporting its safety and efficacy.

Vaginal rejuvenation

In scientific literature, a search for "vaginal rejuvenation for a sensation of wide vagina" revealed only one article by Pardo et al. [68]. The study revealed 53 women who underwent one-fit-all procedures by means of colpoperineoplasty and paravaginal repairs. Goodman [9] disclosed that vaginal rejuvenation encompasses perineoplasty and/or vaginoplasty [9]; however, this article was a commentary publication.

Ostrzenski [70] conducted a clinical study on an acquired sensation of wide/smooth vagina and presented the results in one of the World Congress meetings. The author [70] documented different causes of wide/smooth vagina that would require diversified surgical interventions to correct the specific anatomical abnormality. Table 2 presents a summary of wide vaginal classification and related surgical procedures.

"Laser Vaginal Rejuvenation[®]" (LVR[®]) and "Designer Laser Vaginoplasty[®]" (DLV[®]) [67] had been identified in over 1,100 marketing literatures offered on the Internet. However, neither description of the procedures, nor standardization [8], neither indication, nor exact meaning of these terminologies were provided [8, 9].

ACOG [1] in its opinion recommended that procedures such as vaginal rejuvenation should not be offered, since they were not medically indicated, and the safety and effectiveness of these procedures have not been documented. In addition, ACOG [1] determined that, "It is deceptive to give the impression that vaginal rejuvenation, designer vaginoplasty, revirgination, G-spot amplification, or any such procedures are accepted and routine surgical procedures" to contradict the marketing literature such deceptive suppositions [67].

G-spot augmentation

A review of the existing scientific literature failed to show any published data on clinical research on G-spot

augmentation. Anecdotal information related to surgical augmentation was by Ostrzenski [10] presented during the third Annual World Congress. The concept of the surgical G-spot augmentation technique was to create a bumpy irregularity on the pubocervical fascia within the anterior vaginal wall approximately 4.5 cm from the hymeneal ring.

In addition, autologous fat transfer was used for G-spot augmentation and falls into anecdotal clinical information [10]. In this procedure autologous fat is transferred by injection into the predetermined G-spot location [10].

The advertising literature nomenclature is "G-spot Amplification[®]". In this procedure, collagen is injected into the predetermined location of the "Grafenberg zone" or G-spot [67]. Recently, the promotional literature used "G-shot" which is the same collagen injection under a different nomenclature.

ACOG Opinion No. 378 [1] does not recommend the G-spot amplification. The decision is based upon the lack of documentation on the safety and effectiveness of collagen injection. Also, there is no scientific literature on the subject matter.

Discussion

Originally, the objective of the study was to conduct a systematic review of the existing literature. Later on, the review objective was changed to a methodological review due to the insufficient number and quality of scientific literatures related to cosmetic gynecology. In spite of this, a methodological analysis of the existing literature can assist clinicians and researchers to identify limitations of current knowledge of cosmetic gynecology. Due to the lack of quality scientific articles and the insufficient number of published articles in the cosmetic gynecology field, one must agree with ACOG's [1] recommendation which, at the present time, does not support performing vaginal cosmetic procedures when there is the absence of symptoms and signs for surgical intervention(s).

Clitoral hoodoplasty

The buried clitoris was defined as clitoris being located under the skin with a vanished clitoral prepuce and the absence of the prepuce opening [4]. In a clitoral phimosis condition, the clitoral prepuce is hypotrophic and demonstrates the presence of different degrees of prepuce opening [4, 5]. Ostrzenski's [4] hydrodissection with reverse V-plasty can be applied for each condition in which the clitoral prepuce is occluded (for instance: lichen sclerosis, lichen simplex chronicus, squamous cell hyperplasia, epithelial cyst of inclusion, and female genitalia cutting) and modification of this technique is useful in clitoral

Table 2 The wide or smooth vaginal classification and vaginal rejuvenation managements types of an acquired sensation of wide/smooth vagina

Wide/smooth vagina[70]	Clinical characteristics	Clinical management (vaginal rejuvenation)
Category A	The absence of columnar rugae and the absence of site-specific defects	2-Step therapy Step I. Vaginal estrogen Step II. Vaginal columnar rugae restorations
Category B	The absence of columnar rugae and the presence of site-specific defects	Estrogen deficiency is present (3-step therapy) Step I. Vaginal estrogen Step II. Reconstruction of site-specific defects Step III. Vaginal rugation restorations Estrogenized woman (2-step): Step I. Reconstruction of site-specific defects Step II. Vaginal rugation restorations
Category C	The presence of columnar rugae and the presence of site-specific defects	Paravaginal defect(s) reconstruction Also other conditions can be included into this category such as isolated defects of: 1. Dorsal perineal membrane 2. Perineal body 3. Vaginal orifice Management will require separate reconstruction of each entity
Category D	The presence of columnar rugae and the absence of site-specific defects	For hypermucorrhea Partial reduction of cervical glands with CO ₂ laser For wide middle vagina Size reduction of the middle part of the vagina with G-Spot surgical augmentation For congenital vaginal prolapse into the fossa navicularis Partial distal vaginal resection with vaginal hymeneal ring reconstruction

hoodoplasty reduction. Hydrodissection itself will help to assist in breaking of adhesions in their weakest point and wash smegma and debris off.

Alter's [6] study evaluated overall subjects' satisfaction following combined clitoral hoodoplasty with labia minora V-plasty (central labioplasty). The overall subjects' satisfaction was not evaluated before surgical intervention; then, the author's conclusion in this respect was called into question. Furthermore, the absence of the control group makes this conclusion unsupported. Lastly, making an antero-lateral incision on the clitoral prepuce will create a visible scar on both sides of the clitoral prepuce. Overall, such clearly visible scars on the clitoral prepuce are against of

one of the principle rules of cosmetic surgery where scars should be well hidden. In contrast, Ostrzenski's [4] reverse V-plasty for clitoral hoodoplasty offered a well-hidden scar and made the aesthetic appearance very appealing, since the scar accentuated the crown of the newly created distal prepuce.

Goodman et al. [8] study was designed to evaluate, "overall and sexual satisfaction" and concluded, "outcome in both general and sexual satisfaction appear excellent." The number of 12 surgeons recruited from 10 separate practices with vastly different basic trainings and the absence of detailed description of surgical techniques, makes the study's methodology for clitoral hoodoplasty

difficult, if not impossible, to evaluate objectively. Based upon the study's design, the authors [8] could not conclude on "overall and sexual satisfaction." In order to conclude about sexual satisfaction, pre- and post-operative sexual function must be evaluated. The definition of the perception of sexual satisfaction depends on the patient's emotional well-being, physical well-being, quality of life, and intimacy with her partner as well as the interaction between these parameters. Such parameters must be tested before and after surgical intervention(s) to establish the impact of the procedure on sexual satisfaction. Goodman et al. [8] did not conduct any evaluation how the medical or aesthetical condition impacted sexual satisfaction before surgery and then they concluded that sexual satisfaction appeared to be an excellent postoperatively. Scientifically, it is impossible to draw a conclusion due to the absence of preoperative related data. Authors [8] tried to evaluate preoperative sexual satisfaction during postoperative period; however, such postoperative evaluation to establish preoperative level of sexual satisfaction violates the established cardinal clinical research rule that preoperative evaluation cannot be performed in postoperative period. Infringement of this simple rule would prohibit the authors [8] from drawing a scientific conclusion that the outcome of the cosmetic surgeries in overall and sexual satisfaction appeared to be excellent.

Goodman et al. [8] neither had described the modification of labial central wedge excision nor had provided reference on which the authors based their surgical technique(s) in study. Since the Goodman et al. [8] study was conducted between 1 January 2005 and 31 May 2008 and Alter [23], De Giorgi [69], and Krizko [51] had not yet presented labial central wedge resection modification, then Goodman et al. [8] could not have potentially utilized any of these authors' techniques for hoodoplasty because the above studies had not been published yet. What exact surgical technique(s) were used by Goodman et al. [8] remains unknown and this fact precludes the Goodman et al. [8] study from effective analysis of methodology. In Goodman's [9] commentary article, the author attempted to give a definition of hoodoplasty; however, he failed to present surgical technique(s).

Goodman et al. [8] used the "New York Times" daily newspaper quotation given by Laura Berman that "... a woman's comfort level with her genitals affects her sexual enjoyment" as an argument in scientific discussion that the woman's sexual function is affected by her genitals and that is not traditionally accepted in scientific publications. Also, there is no clarification in the article [8] that the material is from non-scientific sources adapted from a daily newspaper.

Ostrzenski [10] had conducted the clinical study on hoodoplasty, between January 2006 and January 2010 and established a classification of clitoral hoodoplasty based

upon underlining causes: (1) occluded clitoral prepuce, (2) hypertrophic-gaping clitoral prepuce, and, (3) asymmetrical subepidermal hypertrophy. The study [10] also established that there are three vastly different surgical techniques applicable for the different forms of clitoral prepuce anomalies such as: (1) hydrodissection with reverse V-plasty, (2) reduction with reverse V-plasty, (3) subepithelial reduction.

ACOG Committee Opinion No. 378 [1] did not express its recommendation on clitoral hoodoplasty for either medical or cosmetic indication. It is reasonable to follow general ACOG's [1] suggestion that a practitioner should establish the reason, the presence of symptoms and signs to justify performing a surgical intervention(s). In addition, it is worthwhile to mention that in the US, a patient's right to exercise an autonomous decision making must be respected.

Clitoral frenuloplasty

Clitoral frenuloplasty is defined as a surgical intervention that transforms this anatomical structure to a more pleasing appearance. The computerized and manual searches of the literature, including advertising literature, failed to yield any article related to clitoral frenuloplasty. Only anecdotal information exists on clitoral frenuloplasty. The procedure is performed when aesthetic appearance is in question and identified by women [10]. The surgical intervention involved reduces hypertrophy and is designed to accomplish symmetry, shape, even sizes, and to achieve a more pleasing contour of the clitoral frenulum. ACOG [1] did not address clitoral frenuloplasty in its publication. Therefore, a clitoral frenuloplasty procedure falls into the general ACOG's recommendation that if patients' present with reasons, symptoms and signs for the surgical intervention, than a surgeon can proceed with an operation.

Labia minora labioplasty

In 1976, labia minora labioplasty for labial hypertrophy was first published by Radman [12]. In 1984, Hodgkinson and Hait [13] first presented labia minora labioplasty for aesthetic motives. Since that time, 57 articles have been published in peer review medical journals and over 1,000 publications appeared on the Internet as the marketing literature [67]. ACOG [1] supports labia minora labioplasty when?

Alter [6] presented 407 cases that were subjected to a combination of labia minora and clitoral hood reduction and concluded that "Central wedge resection with lateral clitoral hood reduction is a safe, effective procedure with few complications and high patient satisfaction." A significant power of the study (407 cases) itself cannot establish

the safety and effectiveness of the procedure. Only randomized controlled trial would allow Alter [6] to conclude that the procedure was a safe and effective. In addition, Alter [6] concluded that central wedge resection with lateral clitoral hood reduction gave subjects of the study high satisfaction postoperatively. How the labia minora abnormality impacted subjects' satisfaction, self-esteem, sexual function, and caused discomfort were not studied by Alter [6] preoperatively. The study's protocol deficiencies would not allow Alter [6] to conclude, "...high patient satisfaction" was determined. Central wedge excision labioplasty is a V-plasty technique and postoperatively this will create a transverse scar on an anatomically longitudinal and vertically located organ and this kind of transverse scar formation should preclude its use in cosmetic gynecology.

Goodman et al. [8] also did not evaluate subjects' sexual satisfaction before the labia minora labioplasty and concluded that "... in both general and sexual satisfaction appear excellent". The retrospective serial case reports without preoperative evaluation of sexual function will prohibit authors [8] from drawing such conclusions. In addition, Goodman et al. [8] neither had described nor had provided adequate references on which the authors based their surgical technique(s) for labioplasty in their study. Although they [8] mentioned that labioplasty was executed either by, "... modified wedge, or sculpted linear resection," it is impossible even to guess what surgical method was modified and how the sculpted linear resection was performed. Additionally, by the authors [8] own admission, "While some surgeons failed to specifically note their specific technique for LP" (LP abbreviation was explained in the text that it stands for labia minora labioplasty). The deficiency in reporting about the specific surgical techniques being used in the study led to the following questions: (1) which was the surgical method used more often? and, (2) which was the surgical method superior in improving sexual satisfaction? Such lack of uniformity in utilizing surgical techniques precludes performing methodology evaluation and analysis of this article effectively.

The high percentage (7%) of reoperation for wound dehiscence, the 23% superficial dyspareunia postoperatively, and the aesthetic outcomes of the Rouzier et al. [18] technique will disqualify this particular operation from being a part of the armamentarium of cosmetic gynecologic surgery.

Miklos and Moore [28] concluded that the majority of the subjects who underwent reduction of labia minora do so for functional reasons. The authors [28] conclusion is not supported by the results presented in the article. The major indication for the surgical intervention, according to their results of the study, was for aesthetic reasons (37%) and not functional impairment (32%) as it was stated.

Solanki et al. [61] concluded that the procedure was found to be an easy and effective method of reducing the labia minora. The study design would not permit concluding that the procedure was effective. A randomized control trial would be necessary to draw the conclusion that the procedure was effective.

The above articles were selected because they illustrate not only the authors' weaknesses in establishing and executing a well-designed protocol of a clinical trial, but they also enlighten us on scientific reviewers and on the editorial inadequacies of peer review journals. The selection of the articles for the comments above was based upon the high impact of the journals.

ACOG [1] recommended that cosmetic gynecologic procedures can be utilized when, "...medically indicated surgical procedures may include reversal or repair of genital cutting and the treatment labial hypertrophy or asymmetrical labial growth secondary to congenital conditions, chronic irritation, or excessive androgenic hormones." Therefore, ACOG gave a green light to perform labia minora labioplasty, when indicated, without having documentation on safety and effectiveness of the operation. A justification for the ACOG [1] position can be established based upon long lasting experience (first published in 1976 [12]) with labia minora labioplasty and the presence of articles in the peer review journals.

Also, the ACOG Committee [1] expressed its concern about dyspareunia as a potential complication related to cosmetic vaginal surgery. Indeed, superficial transient dyspareunia was reported [18] that lasted between 3 and 90 days (median 28 days) when the authors performed inferior V-shape resection procedures on the labia minora. However, women in this retrospective clinical study complained about superficial persistent dyspareunia before surgery in 96%. In this author's opinion, the inferior V-shape resection technique for labia minora labioplasty [18] predisposes for a high rate of potential complications such as dyspareunia, and wound dehiscence due to the short labial length after resection (under 1 cm from the base of the labium) and Kocher's clamps were used that caused the tissue to be crushed. Therefore, in this technique labial tissues were excised above the Kocher' clamp leaving crushed and devitalized tissues behind the surgery.

Labia majora labioplasty

Felicio [63] first published his technique for labia majora labioplasty. Di Saia [64] presented his case and suggested to name this procedure labial rejuvenation. Mottura [65] described his experience with labia majora labioplasty for labial hypertrophy. All three authors performed vertical partial excisions of the labia majora. After labia majora labioplasty, complications were reported such as hematoma

formation [64] and lasting moderate edema lasting over 4 weeks [65]. However, it is difficult to justify postoperative marked edema because concomitantly other cosmetic surgery in the vicinity of inguinal area was executed [65].

Pelosi [66] presented during one of the scientific congresses his unpublished results of autologous fat transfer for labia majora labioplasty. The author emphasized that this mode of management is short-term and a woman must be informed about it. This information falls into an anecdotal form of literature.

The marketing literature offer surgical interventions by both vertical and as well as horizontal excisions for labia majora labioplasty [67]. Since the labia majora is a longitudinal and vertical organ, horizontal excision will leave an unnatural transverse scar. Such an approach should be discouraged and avoided, since the outcome of the surgery will not satisfy the cosmetic principles of having postoperative transverse scar formation on the vertical organ.

Hymenoplasty (revirgination)

This author defines revirgination (hymenoplasty) as restoration of hymeneal gross anatomic integrity. Essentially, hymenoplasty is performed for the following reasons: (1) restoration of hymeneal integrity following rape, (2) corrective surgical intervention to restore integrity of the hymen following female cutting, (3) hymeneal repair eliminating signs of a woman's history of sexual vaginal activities. Masking a woman's sexual activity is predominantly observed in societies where virginity is culturally expected before marriage. In addition, there is a new trend in western multiple culture societies to establish "secondary" virginity by motives such as a form of sexually transmitted diseases prevention, pregnancy or maintenance of sexual abstinence for religious motives, and changing personal views on premarital sexual activities.

In the existing literatures, only one article was identified that was authored by O'Connor [72] who examined the medical, ethical and criminal aspects of revirgination in Australia. A search for anecdotal information in writing related to surgical technique, safety, effectiveness, and complications failed to reveal any documents. Surgical interventions are applied based upon the personal experience of the surgeon. ACOG's Opinion [1] does not recommend the revirgination procedure. Its recommendation is based on the absence of data supporting the safety and efficacy.

Vaginal rejuvenation and vaginoplasty

Goodman [9] in the commentary article offered the definition of "Laser Vaginal Rejuvenation[®]" technique and presented general information about this procedure as,

"Vaginal rejuvenation is a proprietary term meant to encompass perineoplasty and/or vaginoplasty as a technique to "tighten" the vaginal barrel and elevate and strengthen the perineal body". The author by his own admission was not quite sure about the meaning of this description, stating, "...neither patients nor medical professionals know exactly what meant by this term." A review of scientific, anecdotal, and marketing literatures failed to identify the differences in the indications and the differences in surgical techniques that would distinguish "Laser Vaginal Rejuvenation[®]" (LVR[®]) from "Designer Laser Vaginoplasty[®]" (DLV[®]), and from the traditional gynecologic procedure of colpoperineoplasty.

In addition, in the same commentary article, Goodman et al. [9] encapsulated vaginoplasty as a surgical technique of vaginal mucosa excision from the vaginal fornices with a modified anterior and/or high posterior colporrhaphy and/or excision of the lateral vaginal mucosa. Analysis of scientific, anecdotal, and advertising literatures failed to yield any information related to modification of anterior/posterior operation from traditional gynecologic procedures. Furthermore, Goodman et al. [8, 9] explained that the purpose of vaginoplasty is to "...tighten" a relatively lax upper vagina." Nonetheless, the definition of "a relatively lax upper vagina" was not provided by the authors [8, 9] or how to make the clinical diagnosis of a relatively lax upper vagina [8, 9]. Therefore, LVR[®] and DLV[®] objectives are similar.

A search of the scientific literatures on vaginal rejuvenation for a sensation of wide vagina revealed only one article [69], in which a detailed surgical technique was elaborated. Pardo et al. [69] included 53 subjects who presented with, "... a sensation of a wide vagina with combination of a decrease or lack of ability to reach orgasm." The objectives of the study are as follows, "The aim of this study was to report our preliminary experience in this area, and the results in terms of general acceptability and satisfaction, and whether the procedure enhanced the sensation of vaginal tightness and sexual gratification reported by the woman." Among 53 subjects who enrolled the study, the preoperative diagnosis, based upon medical history, included: (1) difficulties achieving orgasm and constituted 73% of the study population, (2) the presence of anorgasmia in 27%, and, (3) decreased libido identified in 49%. Exclusion criteria, among others, eliminated those subjects who presented with sexual dysfunction. All subjects underwent colpoperineoplasty and paravaginal reconstruction (one-fit-all procedures). Paravaginal reconstruction was executed indiscriminately on each subject without any verification that, indeed, paravaginal defects were present. The vaginal central compartment defects were not included into this procedure in any case [69].

Sexual dysfunction incorporates the following abnormalities: (1) hypoactive sexual desire (libido) disorders, (2) sexual arousal disorders, (3) orgasmic disorders, and (4) sexual pain disorders [70]. Therefore, Pardo et al. [69] did not follow the study exclusion criteria and, indeed, included subjects who suffered from sexual dysfunction (decreased libido and orgasmic disorders). In general, sexual dysfunction does not require surgical therapy; therefore, it is difficult to comprehend why the subjects associated with libido and/or orgasmic disorders were included into surgical study group with no explanation provided by the authors [69]. Postoperatively, the authors [69] evaluated sexual activities and did not examine an orgasmic disorder or decreased libido in relationship to surgical interventions. Such a conflicting study design was not only perplexing but also would not allow authors to draw a conclusion that colpoperineoplasty with paravaginal reconstruction could, "...improve sexual gratification in the first months after surgery". However, this study [69] unveiled the type of surgery, colpoperineoplasty, being executed in vaginal rejuvenation for a sensation of wide vagina. In 2006, after so many years of marketing of "Laser Vaginal Rejuvenation[®]" and "Designer Laser Vaginoplasty[®]" we formally learned that colpoperineoplasty essentially is "Laser Vaginal Rejuvenation[®]" and "Designer Laser Vaginoplasty[®]" is essentially surgery on the external structures. For the disclosure of surgical secrets how LVR[®] and DLV[®] were executed, the Prado et al. [69] article was worthwhile to analyze. In 2009, the vaginal rejuvenation by means of a colpoperineoplasty procedure was confirmed that indeed LVR[®] and DLV[®] are an adaptation of the traditional gynecologic procedure, colpoperineoplasty [8, 9].

Ostrzenski [70] conducted a clinical study related to an acquired sensation of wide/smooth vagina and presented the results during in one of the World Congresses [70]. The author [70] documented different causes for wide/smooth vagina. If there are different underlining causes of a wide/smooth vagina, it is obvious that surgical interventions must be diversified to correct the specific abnormality. Table 2 presents a summary of wide vaginal classifications and related surgical procedures. Among several new surgical techniques, "vaginal rugation restoration" (VRR) is specifically designed to cope with an acquired sensation of wide/smooth vagina. VRR recreates vanished vaginal columnar rugae using CO₂ laser [70]. The procedure is pending publication and at this moment, meets the criteria for anecdotal information [70]. The VRR procedure is not an adaptation of any traditional gynecologic technique; it is the cosmetic vaginal surgical intervention for a wide/smooth vagina. Additionally, the new surgical interventions of introitoplasty have been developed based upon this study's results and can be helpful in coping with wide vagina as well (Ostrzenski,

anecdotal information). The introitoplasty represents three distinct procedures which reconstruct anterior, lateral, and posterior defects of the vaginal introitus (Ostrzenski, anecdotal information).

"Laser Vaginal Rejuvenation[®]" and "Designer Laser Vaginoplasty[®]" [67] were identified in more than 1,100 marketing literature writings on the Internet. However, there was neither description of the procedures, standardization, and surgical technique nor the exact meaning of these terminologies. The secrecy of these clinically empty nomenclatures, text without meaning, was designed to attract physicians to participate in educational courses of LVR[®] and DLV[®]. If the Laser Vaginal Rejuvenation Institute of Los Angeles [67] honestly promoted colpoperineoplasty instead of LVR[®] and DLV[®], very few, if any, physicians would sign up for such an educational event(s), since each and every gynecologist was trained in these surgical techniques. Laser Vaginal Rejuvenation[®] and Designer Laser Vaginoplasty[®] have been advertised for many years to attract physicians for continued education. Furthermore, LVR[®] and DLV[®] were marketing to attract prospective patients. It is very difficult to distinguish between these two procedures, LVR[®] and DLV[®], and what clinical purpose they are serving. The only purpose that they serve is a business promotion to attract physicians for educational courses and to attract women for new cosmetic procedures with empty terminologies. The population at large was put on notice, predominantly through the media and the marketing literature available on the Internet. Recently, the phrase of "...to enhance appearance or sexual gratification" was changed to, "Enhancing the quality of life for women" [67]. The public demands have been growing for these procedures ever since LVR[®] and DLV[®] were intensely advertised.

Until now, the Laser Vaginal Rejuvenation Institute of Los Angeles has not published any detailed description of LVR[®] or DLV[®] surgical techniques, indications, complications, and outcomes. In addition, G-Spot Amplification[®] has never been published. The top secrecy of these surgical procedures has been kept for a long time and only ACOG [1] reacted to this deceptive/unethical form of practice of medicine and expressed, "also of concern are ethical issues associated with the marketing of these procedures and national franchising in this field". In addition, one can add that it is deceptive and unethical to offer educational workshops for physicians based on empty promises that they would learn new LVR[®] and DLV[®] techniques and instead colpoperineoplasty was taught. In order to be more convincing in marketing effectiveness, the founder of the Institute enhances his commercial ads by incorporating the following misleading, again, announcement "I developed these procedures by listening to the concerns and needs of women" (published in classified in OB.GYN.

News, 1 December 2008). There is nothing in the existing literature that indicates Dr. Matlock, the founder of the Institute, developed any surgical procedure, and evidently, colpoperineoplasty is a traditional gynecologic procedure that was credited to others. It is interesting that this form of marketing still continues, although ACOG Opinion [1] concerns were published in September 2007. There has been enough time since the published ACOG Opinion [1] to correct honest mistakes by stopping deceptive and unethical advertising and practice. It is worthwhile to mention that the ACOG Opinion [1] was a response to the unusual and deceptive/unethical practice of the Laser Vaginal Rejuvenation Institute of Los Angeles [67] and its franchises practices in the USA.

The terminologies of LVR[®] and DLV[®], are very difficult to comprehend clinically, since they do not carry any cosmetic surgical technique meaning, they are not standardized procedures, and nobody knows what is the surgical difference between them. However, regardless of the lack of meaning and standardization of Designer Laser Vaginoplasty[®], Goodman et al. [9] included this procedure in their retrospective study.

ACOG [1] recommended that procedures such as vaginal rejuvenation should not be offered, since they were not medically indicated, and the safety and effectiveness of these procedures have not been documented. Ostrzenski's [71] new clinical study documented that vaginal rejuvenation by the means of vaginal rugation restoration has a place in the cosmetic gynecologic field. However, in September 2007, ACOG could not have had knowledge about vaginal rugation restoration, since this technique has not been presented in any congress or published.

In addition, ACOG [1] in its opinion determined that, "It is deceptive to give the impression that vaginal rejuvenation, designer vaginoplasty, revirgination, G-spot amplification, or any such procedures are accepted and routine surgical procedures." Indeed, the marketing literatures leave the impression that LVR[®] and DLV[®], and G-spot amplification procedures are accepted and routine.

G-Spot augmentation

A review of the existing scientific literatures failed to yield any article. Anecdotal information related to surgical augmentation was presented during the Third Annual World Congress by Ostrzenski [10]. The concept of the surgical technique of surgical augmentation of G-spot was based on the hypothesis that de novo creation of an irregularity on the pubocervical fascia in the anterior vaginal wall in the presumptive location of the G-spot will increase sexual function.

In addition, autologous fat transfer was used for G-spot augmentation and falls into anecdotal clinical information

as well [10]. In this procedure autologous fat is transferred into the predetermined G-spot location [10]. Others [67] suggested that collagen injection into the anterior wall of the vagina in the predetermined location for G-Spot Amplification[®] should be used.

ACOG's Opinion [1] recommended that G-spot amplification[®] should not be offered, since they were not medically indicated, and the safety and effectiveness of these procedures have not been documented. The surgical G-spot surgical augmentation or autologous fat transfer for G-spot augmentation has not been analyzed by ACOG [1] in its document.

There are other cosmetic gynecological procedures such as vulvar reconstruction [73] or de novo vaginoplasty [74] but those procedures were beyond the scope of ACOG opinion; although, they do belong to the surgical armamentarium of cosmetic gynecology as well.

Conclusions

Practicing cosmetic gynecology within ACOG recommendations is desirable and possible. Currently, the standard of practice of cosmetic gynecology cannot be determined due to the absence of documentation on safety and effectiveness within the field. Traditional gynecologic surgical procedures cannot be labeled cosmetic procedures, since it is a deceptive form of practice and marketing. Creating medical terminology trademarks and establishing a business model that tries to control clinical-scientific knowledge dissemination is unethical.

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Conflict of interest Professor Ostrzenski teaches and practices cosmetic gynecology.

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