# Aesthetic and Regenerative Gynecology

Preeti Jindal Narendra Malhotra Shashi Joshi *Editors* 





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Aesthetic and Regenerative Gynecology



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ISBN 978-981-16-1742-3 ISBN 978-981-16-1743-0 (eBook) https://doi.org/10.1007/978-981-16-1743-0

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### **Acknowledgement**

Any endeavour big or small is not complete without the help of numerous behind the scene well-wishers. I will like to convey special thanks to my solid support system—my husband Dr Ravul Jindal who not only ushered me into a new and intriguing field of aesthetic and regenerative Gynecology—a new path I was afraid of to tread; but also supports me in all my endeavours.

Special thanks to my parents for imbibing me with virtue and knowledge. No words are enough to thank my loving children—Adit and Kush for bearing with my long hours of work and absentee from their special moments.

Thanks to all authors for sparing valuable time and sharing their knowledge, experience and penning down the chapters which helped in creating this beautiful book. Thanks to Dr Isha without whose contribution this book could not have been completed.

Hope it inspires and guides all those who want to follow this wonderful field.

Enjoy gaining knowledge and shine Fond love

Preeti Jindal

## **Contents**

| 1          | Regenerative Gynecology                                                                                              | 1 |
|------------|----------------------------------------------------------------------------------------------------------------------|---|
| 2          | Epidemiological Perspective in Aesthetic and Regenerative Gynecology  Madhu Gupta, Neena Singla, and Kiranjit Kaur   | 7 |
| 3          | Anatomy and Physiology in Relation to Invasive and Non-invasive Procedures in Aesthetic and Regenerative Gynecology  | 5 |
| 4          | Counselling Before Cosmetic Gynecology                                                                               | 3 |
| 5          | Medico-legal Aspects in Aesthetic and Regenerative Gynecology                                                        | 9 |
| 6          | <b>Energy-Based Devices: Comparisons and Indications</b>                                                             | 7 |
| 7          | Laser in Aesthetic and Regenerative Gynecology: Physics, Types, Applications, Safety Profiles                        | 3 |
| 8          | <b>Laser in Vaginal Rejuvenation</b> . 6 Alex Bader                                                                  | 7 |
| 9          | Other Lasers in Aesthetic and Regenerative Gynecology 7<br>Vidya Pancholia, Krishna Hari, and Ksenija Selih Martinec | 9 |
| 10         | <b>Radiofrequency in Aesthetic and Regenerative Gynecology</b> 9 Francesco Merelli and Bruno Boccioli                | 1 |
| l <b>1</b> | Carboxytherapy in Aesthetic and Regenerative Dermatology                                                             | 3 |

x Contents

| 12        | Micro-focused Ultrasound in Aesthetic and Regenerative Gynecology                                   |
|-----------|-----------------------------------------------------------------------------------------------------|
| 13        | Minimal Invasive Treatment of Varicose Veins                                                        |
| 14        | <b>Chapter on Testosterone Therapy</b>                                                              |
| 15        | Laser Hair Removal                                                                                  |
| 16        | <b>Thread Lift in Aesthetic and Regenerative Gynecology</b> 153<br>Biplav Agarwal and Poonam Mishra |
| 17        | Chemical Peels and Vulval Whitening in Aesthetic and Regenerative Gynecology                        |
| 18        | Scars in Aesthetic and Regenerative Gynecology                                                      |
| 19        | <b>Hypo and Hyperpigmentary Disorders of Vulva</b>                                                  |
| 20        | Breast Lifting and Reduction in Aesthetic and Regenerative Gynecology                               |
| 21        | Butt Reshaping/Gluteal Recontouring Surgeries in Aesthetic and Regenerative Gynecology              |
| 22        | Hymenoplasty, Vaginoplasty, and Perineoplasty in Aesthetic and Regenerative Gynecology              |
| 23        | <b>Labiaplasty and Cliteroplasty</b>                                                                |
| 24        | <b>Vulvodynia</b>                                                                                   |
| 25        | Non Energy Based Modalities in Cosmetic Gynaecology 259<br>Madhuri Agarwal and Sejal K. Shah        |
| <b>26</b> | <b>Genitourinary Syndrome of Menopause</b>                                                          |
| 27        | Management of Urinary Incontinence in Aesthetic & Regenerative Gynecology                           |

Contents

| 28  | Non-cosmetic Uses of Laser in Aesthetic and Regenerative                  |
|-----|---------------------------------------------------------------------------|
|     | Gynecology: Vulvodynia, Urinary Incontinence, Infections, Warts           |
|     | Preeti Jindal, Isha Kundal, and Sonam Goyal                               |
| 29  | Gender Reassignment Surgery in Aesthetic and Regenerative Gynecology      |
| 30  | Anaesthesia in Procedures of Aesthetic and                                |
|     | Regenerative Gynecology                                                   |
| 31  | Stem Cells and Recent Advances in Aesthetic and Regenerative Gynecology   |
| 32  | <b>PRP and Exosomes in Regenerative Gynecology</b>                        |
| 33  | Setting Your Practice and Future of Aesthetic and Regenerative Gynecology |
| Ind | <b>ex</b>                                                                 |

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# Introduction to the Rising field of Aesthetic and Regenerative Gynecology

1

Preeti Jindal and Isha Kundal

#### 1.1 Introduction

Cosmetic Gynecology is becoming one of the fastest-growing branches in women's healthcare. It is very interesting, intriguing and futuristic branch that spans over fields of gynecology, dermatology, urogynecology, urology, vascular and plastic surgery. In fact, dentist fraternity is also showing lots of interest in this field. It was called cosmetic gynecology as it originally included cosmetic procedures to enhance the aesthetic appearance of the female genital region. Presently along with cosmesis; it includes functional vulvo-vaginal repairs to restore anatomy and physiology following recurrent trauma of childbirth, menopause and ageing. It covers not only women genitalia but complete female aesthetics from head to toe. In fact, it is time for all concerned specialities to join hands and take this field to newer heights to obtain optimal results.

# 1.2 Why is There a Sudden Interest in this Field?

Studies have shown that with rising awareness and increasing accessibility to Internet; women are becoming more aware of the beauty of their

P. Jindal (⊠) · I. Kundal The Touch, Advanced Obstetrics, IVF & Cosmetic Gynae Centre, Mohali, India intimate parts. According to a 1997 survey, it is evident that 30% of all visitors to porn sites are women and more women watch porn on mobile phones than men as shown in Fig. 1.1 [1]. Hence it is but natural for women to desire for perfect body and mimic the appearances of their favourite models.

Another reason for increased interest in this field is due to increase in longevity of life. Everyone wants to reverse ageing and maintain youth. The world is moving rapidly towards rejuvenation. Nowadays, an average woman is expected to spend one-third of her life in postmenopausal phase. The usefulness for vaginal rejuvenation, non-invasive management of urinary incontinence, treatment of genitourinary syndrome of menopause and aesthetic upliftment cannot be understated. All these needs have lead to the sudden growth in field of cosmetic and rejuvenative gynecology and all efforts should be made by young aspiring clinicians to learn about it so that they can do justice to their patients.

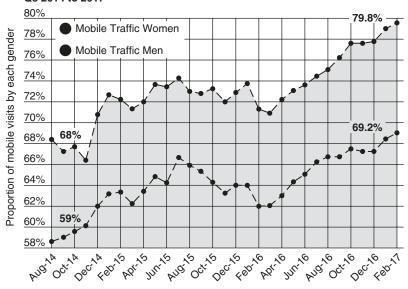
#### 1.3 History

Cosmetic is a Greek adjective "kosmetikos" which means—to adorn [2]. According to Merriam Webster thesaurus's first known use of this word was in 1638. It may be used as a noun to refer to cosmetic preparation for external use.

1

**Fig. 1.1** Graph showing more women watching porn than men





Since time immemorial people have tried to improve beauty or aesthetics. **Sushruta** (Fig. 1.2), an Indian physician is considered as the world's first plastic surgeon who described the surgical treatment of a wide variety of ailments, including reconstructive procedures as early as 600 BC [3]. He was born 150 years before Hippocrates. His book "Sushruta Samhita" mentions labiaplasty.

In olden times smoke was used in newly wed women to enhance vaginal sexuality and tightness and also to kill abnormal flora leading to infection. Even today an old Javanese tradition of preparing the vagina by smoke and steam to tighten and rejuvenate is practised (Ratus V tradition [4]. Indian mythology also describes similar practises. Interestingly, warming or heating actually is the basis of all **energy-based devices** (EBD) used nowadays for rejuvenation where energy is used to raise temperature of the tissue to an optimal level, which leads to remodelling of elastin and collagen causing rejuvenation of that part.

Vaginal rejuvenation is over 1000-year old. The work of female physician, **Trotula de Ruggiero** (1050 AD), a teacher whose main interest was to alleviate the suffering of women is believed to have first described Vaginoplasty [5]. Greek literature in the early first and second cen-

tury AD by physician **Soranus** of Ephesus mentions female cosmetic procedures. In the sixth century AD, **Musico** did Latin translation of his 4 volume treatise entitled "gynecology" and describes clitoral surgeries to enhance or diminish sexual pleasures. In third century AD, **Philumenos** of Alexandria described the excision of hypertrophied clitoris because it was considered not appealing, in fact ugly and disgraceful. His work was abstracted by the physician **Aetios** of Amida in his fourth century work *Sixteen Books on Medicine*. Labiaplasty was performed by Greek physician **Paulos** of Aegina as early as in seventh century AD.

These procedures always were not done for aesthetics. The practice of excising the *nonhyper-trophied* clitoris originated in Egypt in an effort to prevent any desire for coitus in premarital girls and not out of any cosmetic motivation [6]. Unfortunately such varied practises of female genital mutilation are still currently practised in some parts of the world and its correction also comes under the domain of cosmetic gynecology and plastic surgery.

Rati Rahasya (translated in English as Secrets of Love) an ancient Indian book written by **Kokkoka**, an Indian poet in eleventh–twelfth century on female sexuality mentions vaginal rejuve-

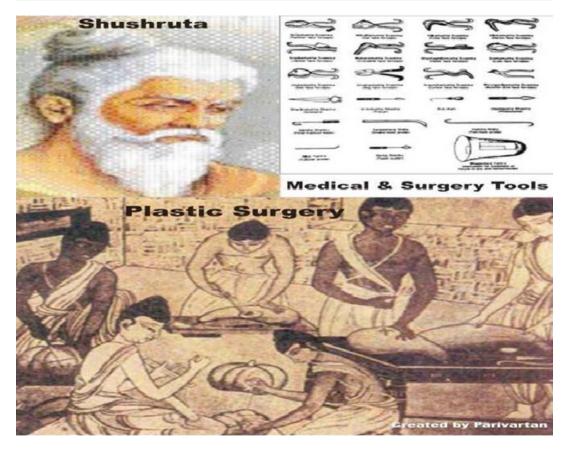


Fig. 1.2 Sushruta; Father of surgery

nation and Yoni shastra to contract or enlarge the vagina (nari kunjara Chapter 11 verse 3) [7].

In Renaissance period—Pierre dionis (1643–1718), a parisian described nymphaeplasty, i.e. labiaplasty in his Coursd'operations de chirurgie (1707) based on his late 1600 work (iscgmedia. com; history of cosmetic gyne). In 1905, Barton Hirst described vulval reconstructive surgeries and Jeffcoate published these in detail in 1957. Many textbooks of gynecology in the last century have given in detail vaginoplasty, labial reconstruction, and vulvodynia under different headings.

Recently in 2008 **Jamie McCartney**, a professional artist living in Brighton, England made a ten-panelled wall sculpture of plaster cast taken from 400 volunteers' genitalia—"The Great Wall of Vagina", to demonstrate diversity in appearances of the vulva; reviving new interest in female genital cosmesis (Fig. 1.3).

#### 1.4 Present Scenario

Energy-based devices like lasers, radiofrequency, highly focused USG (HIFU), carboxytherapy, and many more advancements have made it possible to treat conditions previously considered untreatable or difficult to treat. Patients benefit from improved results, painless therapies, walkin procedures and less cost as compared to conventional surgery. In the last few years, the main focus of research and development of medical lasers has been on laser hair removal, the treatment of vascular lesions including leg veins, and vision correction. But now there has been a revolution in the last two decades and the focus has shifted to cosmetic gynecology.

In fact, non-invasive management of nonneurological causes of urinary incontinence as highlighted in this chapter by the editor with help



Fig. 1.3 The Great wall of vagina; McCartney (2008)

of laser, HIFEM (Emsella chair of BTL), carboxy, radiofrequency, PRP therapy, fillers etc. has revolutionised the management of this distressing problem [8].

North America holds the major share of this growing market due to factors such as high prevalence of the aged population, high disposable income, increased awareness of aesthetics, and presence of sophisticated infrastructure [9]. The American Society for Aesthetic Plastic Surgery reported an increase of 446% in cosmetic procedures since 1997 and an overall increase of 8% in 2007, with a 17% increase in men undertaking cosmetic surgery [10].

Asia-Pacific is expected to be the second fastest-growing market because of prominent growth factors such as rising disposable income, increasing awareness among the women population base, improving healthcare infrastructure and larger opportunities for physicians (Fig. 1.4). Europe is the third-largest market of cosmetic gynecology, propelling growth owing to increasing number of vaginal rejuvenation procedures providing centres and trained specialists.

The desire to look beautiful is something which all women have right from time immemorial. Although it is not possible to define the ideal aesthetic genitalia, patient-specific techniques chosen based on the patient's anatomy and applied with a realistic approach can increase patient satisfaction and reduce complication rates. Not only aesthetics but due to aging vaginal dryness, urinary leakage and genitourinary syndrome of menopause make it necessary that we offer these new technologies to women. Laser though not FDA (July 30, 2018, FDA statement) approved for vaginal rejuvenation (till date of writing of this chapter) has been found useful in these conditions by many users [11]. It is questionable that if FDA approves laser to be used on face and in vagina for surgical purposes (destruction of abnormal or pre-cancerous cervical, vaginal tissues and condylomas, warts; then why it is not approved for vaginal rejuvenation). The thickness of vaginal mucosa is around 4 mm and penetration of CO<sub>2</sub> laser is only 50–125 micrometres. Other lasers also penetrate much lesser. Hence, it is considered to be very safe modality



Fig. 1.4 Medical laser market—Growth rate by region (2018)

provided used with adequate knowledge and training. In fact with more and more studies citing the benefits of vaginal lasing with very few side effects it is speculated that it is a matter of time that EBDs will get the required approvals. HIFEM technology is FDA approved for male and female non-invasive urinary incontinence treatment. Other energy-based devices are also being regularly used for the treatment of these conditions with good patient satisfaction rates (as you will read further in the following chapters by minimal various experts) and observed complications.

As this field is relatively new and we are at that point in history that major advancements are occurring in this branch; it therefore becomes the responsibility of teachers as well as students alike to learn more about this field and offer evidence-based treatment to women to improve their quality of life. At the same time as it is a new field, we also have to be very careful and adhere to strict guidelines so that no harm is done to patients.

Medicolegally also clinicians have to safeguard themselves with appropriate informed consents.

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# **Epidemiological Perspective in Aesthetic and Regenerative Gynecology**

Madhu Gupta, Neena Singla, and Kiranjit Kaur

#### 2.1 Introduction

Aesthetic and regenerative gynecology is a relatively new and fast-emerging sub-speciality of gynecology. The aim is to enhance the appearance and restore the function of vulvo-vaginal region which may have got damaged during pregnancy, childbirth or tissue changes brought about by ageing [1]. These procedures are no longer the sole domain of dermatologists and plastic surgeons. With increasing empowerment and financial independence of women; many women are demanding these procedures today leading to an increasing number of Gynecologists and Urogynecologists stepping into this field. The use of minimally invasive energy-based treatments along with a range of other medical and surgical options are used to achieve the twin goals of satisfactory function and appearance. It is important to have insight into the prevalence and incidence of the problems for which aesthetic and regenerative gynecology has a big role in the management.

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# 2.2 Complaints for Which Aesthetic and Regenerative Treatment Is Sought

Mostly women seeking aesthetic and regenerative treatments may present with decreased sexual satisfaction on the part of self or partner, feeling of looseness in vagina or vaginal laxity, pain during coitus, decreased lubrication, dribbling of urine or urinary incontinence on coughing, laughing, sneezing, vaginal discharge which may be foul smelling or blood stained, dryness in vagina with irritation and itching. Some women may complain of hypertrophied or dark labia which may be congenital or just a normal variation leading to low self-confidence and dissatisfaction with appearance.

Events like pregnancy, childbirth, ageing, menopause or therapy for malignancy result in significant functional and physical changes in the woman's body. A loose vagina post childbirth is the most subjective and commonly self-reported complaint for which treatment may be sought. But substantial data is lacking [2]. Still in a large majority, women may seek help only because the spouse complains of decreased sexual satisfaction due to her lax vagina. In a UK study, women who attended gynecology and urogynecology clinics were evaluated through a questionnaire. More than one-third had sexrelated symptoms which were told only when specifically asked, but very few complained of

vaginal laxity as a symptom [3]. Another survey by Millheiser L et al. (2010) of parous women in 25-55 years of age revealed that almost half of them felt decreased interest in sexual activity and were concerned about vaginal laxity following childbirth [4]. Endocrine changes at menopause lead to vaginal dryness, dyspareunia, low sexual desire and consequently sexual dysfunction [5]. Urinary incontinence as a result of tissue damage during childbirth or at menopause along with other symptoms of vaginal atrophy and the resultant sexual dysfunction are a cause of considerable disability and despair in many cases, leading to low selfesteem, strained relations with spouse and a poor quality of life.

In an OPD-based retrospective study done by Jindal P et al. in 2019–2020, prevalence of urinary incontinence among one thousand and eighteen women studied in North India was found to be 25.8% [6].

Satisfactory sexual function is associated with physical and mental well-being at all ages, even in the later years [7]. Decreased sexual function adversely affects relationship status with a partner and is associated with negative emotional and psychological state [8]. Similarly in a study by Kingsberg SA et al. (2013), it was observed that although the prevalence of symptoms of vulvovaginal atrophy is quite high in middle-aged and post-menopausal women, approximately, 50% of the women did not consult a healthcare professional, or complain about symptoms affecting their quality of life. Even healthcare providers did not bring up or discuss the subject in more than 90% of cases [9].

#### 2.3 Problem Statement

The incidence and prevalence of female sexual dysfunction and other related disorders including vaginal laxity, dyspareunia and vaginal dryness, and their risk factors are summarised in Table 2.1.

#### 2.3.1 Globally

A study among 29 countries across the globe was conducted to assess sexual behaviours and sexual dysfunction after 40 years among men and women. It was observed that 21% of women had lack of sexual interest, 16% had inability to reach orgasm and 16% had lubrication difficulties. Lack of sexual interest was found in more women in South East Asia and the Middle East. Dyspareunia was reported by 10% of women, with higher prevalence in South East Asia (22%) and lower in Northern Europe (5%) [10].

#### 2.3.2 High-Income Countries

Incidence of female sexual dysfunction in one of the older studies in Finland was found to vary from 20% in females 25 years or younger to 70–80% among women in 55-74 years age group, while low sexual desire in women greater than 65 years was found to be prevalent in a range of 40–50%, in a review of literature by Kontula O, et al. (2015) [11]. In Sweden, the prevalence of sexual disabilities and problems were reported to be low sexual desire (65%), low achievement of orgasm (48%) and dyspareunia (30%) [12]. Self-reported sexual problems like lack of sexual desire, arousal and orgasm, which were accompanied by personal distress, varied from 8.9% among women greater than 64 years to 14.8% in women from 45-64 years in studies done in the USA by Shifren JL et al. (2002) [13]. Another study in the USA by Luber KM et al. (2004) found that ageing; obesity and smoking are major risk factors for stress urinary incontinence and its prevalence ranges from 4 to 35% [14]. Impact of vulvo-vaginal atrophy in post-menopausal women is seen in 45% of women aged 45 years and above [8], while in another study 63% had symptoms interfering with the enjoyment of sex [15]. Vaginal laxity is seen among younger women (35.9%) in Saudi Arabia. Though not associated with higher parity, Caesarean section was found to be protective [16].

Table 2.1 Incidence and prevalence of female sexual dysfunction (FSD) and related disorders globally

| Country             | Year | Author reference                       | Study design                                     | Age group (year)         | Prevalence <sup>a</sup> /Incidence <sup>b</sup> (%)                                                                                                                                                       | Risk factors                                                                                                                     |
|---------------------|------|----------------------------------------|--------------------------------------------------|--------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|
| Global<br>study     | 2004 | Nicolosi A,<br>et al. [9]              | Cross-sectional study                            | 40–80 (men<br>and women) | Dyspareunia: 10<br>Decreased lubrication: 16<br>Orgasmic dysfunction: 16<br>At least 1 FSD: 39                                                                                                            | _                                                                                                                                |
| Finland             | 2015 | Kontula O, et al. [10]                 | Cross-sectional<br>National Sex<br>Survey (2007) | 18–74                    | Low sexual desire: 41<br>Orgasm difficulty: 9<br>Lubrication issues 40                                                                                                                                    | _                                                                                                                                |
| Sweden              | 2002 | K Sjogren<br>Fugl-Meyer<br>et al. [11] | Cross-sectional<br>National Survey               | 18–74                    | Lubrication: 12<br>Low sexual interest: 65<br>Low orgasmicity: 48<br>Vaginismus: 5<br>Dyspareunia: 30                                                                                                     | -                                                                                                                                |
| United<br>States of | 2014 | Wysocki et al. [14]                    | Cross-sectional survey                           | 45 and above             | Vulvovaginal atrophy: 63                                                                                                                                                                                  | -                                                                                                                                |
| America             | 2013 | Kinsberg SA, et al. [8]                | Cross-sectional survey                           | 45–74                    | Vulvo vaginal atrophy: 38<br>Relationship with a partner<br>was affected in 47                                                                                                                            | -                                                                                                                                |
|                     | 2009 | Santoro N,<br>et al. [29]              | Cross-sectional study                            | 45 and above             | Vulvo-vaginal atrophy: 45                                                                                                                                                                                 | _                                                                                                                                |
|                     | 2008 | Shifren JL,<br>et al. [12]             | Cross-sectional study                            | 18 and above             | FSD<br><45 years.: 10.8<br>45–64 years.: 14.8<br>>64 years.: 8.9<br>Low sexual desire: 38.7<br>Orgasmic difficulty: 20.5%<br>Age adjusted: 43.1 for any<br>sexual problem                                 | Poor self-assessed<br>health<br>Low education<br>level<br>Depression<br>Anxiety<br>Thyroid conditions<br>Urinary<br>incontinence |
|                     | 2004 | Luber KM [13]                          | Review of literature                             | 18–60                    | Stress urinary incontinence:<br>Young women: 4–14<br>Elder women: 12–35                                                                                                                                   | Ageing Obesity and smoking Data regarding pregnancy and childbirth is inconsistent                                               |
| Saudi<br>Arabia     | 2019 | Taleb S, et al. [15]                   | Retrospective<br>hospital-based<br>study         | 23–99                    | Vaginal laxity: 35.9<br>Stress urine incontinency: 64.4                                                                                                                                                   | Parity<br>Menopause<br>Diabetes was not<br>associated with<br>vaginal laxity<br>More in vaginal<br>delivery                      |
| Iran                | 2013 | Jaafarpour M,<br>et al. [16]           | Cross-sectional study                            | 18–50                    | FSD prevalence: 46.2<br><20 years: 22<br>40–50 years: 75.7<br>Problems related to sexual<br>desire: 45.3<br>Arousal: 37.5<br>Lubrication: 41.2<br>Orgasm: 42.0<br>Satisfaction: 44.5<br>Dyspareunia: 42.5 | Age > 40 years Parity > = 3 Married for > = 10 years husband age > =40 years Unemployed Less educated                            |

(continued)

10 M. Gupta et al.

**Table 2.1** (continued)

| C                | V         | Author                   | C4                                                  | Age group                 | D1                                                                                                                                                                    | D:-1- f4                                                                                                                   |
|------------------|-----------|--------------------------|-----------------------------------------------------|---------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|
| Country<br>India | Year 2019 | Jindal P, et al.         | Retrospective OPD-based study                       | (year)<br>18 and<br>above | Prevalence <sup>a</sup> /Incidence <sup>b</sup> (%)  Stress urinary incontinence: 25.8%                                                                               | Risk factors  Age 18 years and above                                                                                       |
|                  |           | [6]                      | OPD-based study                                     | above                     | 76–85 years: 46.7%<br>66–75 years: 33.6%<br>15–55 years: 14.6%                                                                                                        | Urban and rural<br>areas<br>Multiparous<br>Menopause                                                                       |
|                  | 2016      | Mishra V,<br>et al. [18] | Cross-sectional study                               | 20–47                     | FSD: 55.5<br>Sexual desire: 85.8<br>Arousal dysfunction: 91.7<br>Lubrication: 83.5<br>Orgasm: 82.3<br>Satisfaction: 71.7<br>Dyspareunia: 85.8                         | Age 26–30 years<br>Middle level<br>education<br>Upper middle-<br>class psychological<br>stress<br>Married for<br>>16 years |
|                  | 2016      | Santpure A, et al. [5]   | Cross-sectional study                               | 46–65 and above           | Dyspareunia & vaginal dryness 10.7 Decreased libido 55.3 Sexual activity decreased with increasing sexual dysfunction and age: 54.4 to 5.6 Willing for treatment: 2.1 | Ageing<br>Duration of<br>menopause                                                                                         |
|                  | 2015      | Rao TS, et al. [17]      | Cross sectional<br>study: Door to<br>door survey    | 18–50                     | More than 1 sexual<br>problem: 44.5<br>FSD: 14<br>Dyspareunia: 2.34<br>Arousal dysfunction: 6.65                                                                      | Age 31–50 yrs.<br>Literacy<br>Daily wage earners<br>Home-makers                                                            |
|                  | 2013      | Singh U, et al. [20]     | Cross-sectional<br>study: Hospital-<br>based survey | 18 and<br>above           | Stress urinary incontinence<br>73.8<br>In Indian population<br>16.13                                                                                                  | Age > 40 years<br>Multi-parity<br>Obesity<br>Asthma<br>Tea intake<br>Menopause<br>Vaginal delivery<br>Post-hysterectomy    |
|                  | 2009      | Singh JC,<br>et al. [19] | Cross-sectional<br>study: Hospital-<br>based survey | >18                       | FSD: 73.2<br><40 year: 60<br>>40 year: 90<br>Sexual desire: 77.2<br>Arousal dysfunction: 91.3<br>Lubrication: 96.6<br>Orgasm: 86.6<br>Dyspareunia: 64.4               | Ageing<br>Low literacy                                                                                                     |
| Ghana            | 2010      | Amidu, et al. [21]       | Cross-sectional<br>study:<br>Prospective<br>survey  | 18–58                     | Overall FSD prevalence:<br>72.8<br>Anorgasmia: 72.4<br>Dissatisfaction: 77.7                                                                                          | Alcohol                                                                                                                    |

<sup>&</sup>lt;sup>a</sup>Prevalence characterizes the proportion of a given population that at a given time has a particular condition; FSD: Female sexual dysfunction

<sup>&</sup>lt;sup>b</sup>Incidence is defined as the number of new cases of a certain condition during a specific period in relation to the size of the population studied

# 2.3.3 Low- and Middle-Income Countries

Prevalence of FSD was reported to be the highest among Iranian women of age 40–50 years (75.7%) [17]. Problems related to sexual desire were 45.3%, arousal 37.5%, lubrication 41.2% and orgasm 42.0% among these women.

In a rural population in India, Rao et al. (2015), reported the prevalence of FSDs to be 14%, which was greater in age group 31 to 50 years. 44.5% women out of these had more than one sexual problem. Socio-economic status affects the prevalence of FSD which was found to be 17.7% in high school educated women; 14.5% in daily wage earners and 14.8% in homemakers. Arousal dysfunction was found in 6.65% which was less as compared to Western studies [18]. Among Indian women aged 20-47 years, the prevalence of FSD is found to be 55.5%, which was more in 26-30 years age group and increased with associated socio-cultural risk factors like education to middle level; upper middle class; psychological stress, and in those married for >16 years [19]. In another study by Singh JC et al. considering increasing age as a risk factor, FSD was found to be prevalent in more than 95% of women greater than 40 years [20]. Singh et al. (2013) reported 16.3% prevalence of urinary incontinence among Indian adults (18 years and above). This prevalence was observed to be higher among older population of age > 40 years, women with increased parity, history of vaginal delivery, hysterectomy; and individuals with obesity, history of tea intake and smoking [21]. Among Indian women aged 46-65 years, in spite of a decrease in sexual activity from 54.4% to 5.6% due to increasing sexual dysfunction with age, only 2.1% were willing for treatment [5]. In a study done in Ghana by Amidu et al. (2010), it was found that overall sexual dysfunction was prevalent among 72.8% of women, out of which most prevalent was dissatisfaction (77.4%) and anorgasmia (72.4%), with alcohol intake being reported as the main risk factor [22].

In most of these studies, women presented to the clinic primarily for some other problems and came out with these complaints only on being specifically asked. From these studies, it is seen that the prevalence of sexual dysfunction globally varies in the range 10%–70%, even going up to 90% in an Indian study in older women.

It is dependent on various factors like age, parity, years since marriage, educational and social status and cultural perceptions. Age was found to be the most important factor and sexual dysfunction increased with age in most studies. It was associated with distress in 10-15% of cases. Association of menopause with decreased sexuality was very high and this affected relationships with partner as well. Many women suffered from multiple disorders. Studies show that age greater than 40 years, parity of 3 or more children is a risk factor for female sexual dysfunction among women aged 18-50 years [17]. Female sexual dysfunction is one of the most under-recognised and undertreated conditions. It is not surprising that most women continue to suffer silently with their unspoken problems and hesitate to express their concerns even when specifically asked. The percentage that seeks advice is very low which may be because of embarrassment, shyness or socio-cultural taboos.

#### 2.4 Aesthetic and Regenerative Procedures: History and Current Status

History is full of examples of Aesthetic Medicine practised from the time of ancient Egyptians, who used milk, honey, alabaster and animal oils to improve the skin texture. Indian surgeons about 2000 years ago had invented the forehead flap for reconstruction of the nose. The humans' need to improve looks and enhance beauty has not changed over the ages. With the advent of new surgical and non-surgical minimally invasive techniques, like energy based devices using fractional carbon dioxide (CO<sub>2</sub>) lasers, fractional

erbium lasers and radio-frequency devices, the field of aesthetic and regenerative female genital surgery has evolved into a highly specialised one with increasing popularity among patients and physicians. Certification and preceptorship programmes in the USA and the UK offer training to surgeons in this field. In the past few years, a number of certification training programmes for Aesthetic procedures have come up worldwide, especially in Turkey, the Middle East, Spain and South America [1]. The aesthetic and regenerative society of India (InSARG) offers such courses at very economical rates with hands-on experience.

These days a large number of younger women are seeking cosmetic procedures. Most operations are performed upon the patient's request due to a feeling of enlargement and looseness in the vagina, a desire to improve sexual function, discomfort when wearing clothes or doing fitness activities, or with an aim to increase sexual satisfaction for both herself and her partner. This field is gaining popularity steadily in the developing countries also, but is still in its infancy in these countries. In an Indian study, the number of younger females (21 to 40 years) who approached for aesthetic surgery was much more as they are sexually most active and also more aware of their appearance [23]. In another cross-sectional study done in the USA, it was found that the likelihood of undergoing aesthetic procedures in women in the age group of 45 years or more is greater (15%) as compared to those in the younger age groups (8%) due to social pressures to look younger [24]. Vaginal laxity, dryness, atrophy, pain during coitus all affect sexual function, and when repaired, sexual function improves including relationship status and mental well-being. Women with stress incontinence are low on confidence, avoid social interaction, are generally miserable with a poor quality of life. Relief in stress incontinence gives them a new lease on life. Many a time women suffering from these issues present in the psychiatry clinic for the first time with symptoms of anxiety, depression due to poor self-image and relationship problems.

Various procedures that can be performed under Aesthetic and Regenerative Gynecology may be surgical or minimally non-invasive, nonsurgical techniques called energy-based devices (EBD). These apply thermal or non-thermal energy to the tissues to enhance collagen regeneration and neo-vascularisation, increased epithelial proliferation and tissue regeneration to help restore physical appearance and function.

The minimally invasive techniques are:

- Energy-Based Devices (EBD) using CO<sub>2</sub> lasers, Erbium YAG laser, low-level laser therapy, radio frequency, high intensity focused ultrasound, high-intensity focused electromagnetic waves (HIFEM).
- 2. Chemical treatment.
- 3. Labial fillers like hyaluronic acid.
- 4. PRP or platelet-rich plasma.
- 5. Carboxy therapy and LED therapy.
- 6. Stem cell therapy.

These may be performed for cosmetic or functional indications or both as described below:

#### 2.5 Cosmetic Indications

- Labiaplasty of Labia minora/majora which may be reduction to eliminate unwanted tissue or augmentation to create fuller and symmetrical looking labia depending upon personal or cultural preferences. This may be achieved surgically or by use of EBD. Filling is more popular in Europe as compared to the USA [1]. Labiaplasty procedures showed an increase of 23% from 2015 to 2016 as per data of The American Society for Aesthetic Plastic Surgery and is one of the most commonly performed procedures along with clitoral hood reduction [25]. Not only the USA other countries like Australia, the UK and the Middle East have all shown an increase in these procedures over the last decade. Genital Cosmetic surgery is generally not recommended for females below 18 years as full genital maturity is not normally achieved before age of 18 years [26].
- Hymenoplasty, to recreate the virginal state.
   Labiaplasty and hymenoplasty have ethical

issues and are considered non-medically indicated surgical procedures by many experts [26].

- **Reduction** of Lipodystrophy in the Mons region.
- Vaginoplasty is both cosmetic and functional and may be done surgically or non-surgically by use of fractional CO<sub>2</sub> lasers, fractional erbium lasers and radio frequency for tightening or rejuvenation of vagina to improve sexual function. Vaginal tightening, or vaginoplasty, refers to surgery of the vaginal entrance, deeper canal, and epithelium. This procedure is not the same as pelvic floor repair.
- Lightening of Vulva: Chemical agents or CO<sub>2</sub> fractional laser techniques are used to achieve whitening of a hyperpigmented vulva. It is quite popular in the Middle-East and Europe and is catching up in the UK and USA. However, this technique is also not without risk. Therefore, risk and benefits to be weighed before recommendation.
- To remove scars (cosmetic/functional) in cases of Lichen sclerosus.

#### 2.6 Functional Indications

Functionally cases with symptoms of orgasmic dysfunction, stress incontinence and vulvovaginal atrophy are relieved by laser treatment and laser radio frequency.

- Vaginal rejuvenation using radio frequency by improving vaginal blood flow which causes stimulation of collagen regeneration, connective tissue restoration and tissue tightening. Statistically significant relief in vaginal laxity [4], symptoms of atrophy, stress incontinence and improvement in sexual pleasure were reported [27].
- G-spot amplification consists of injecting hyaluronic acid or collagen filler in a special spot in the female vagina, the "G-spot", to augment and heighten sexual satisfaction. It is a matter of debate if it is really effective, as

sexual pleasure depends on many other factors.

#### 2.7 Caution

American College of Obstetrics and Gynecology (ACOG) recommends that patients should be made aware that procedures to change sexual function or appearance (except done for clinical indications such as female sexual dysfunction, pain with intercourse, vaginal prolapse and incontinence) are not medically indicated, pose a substantial risk and their safety and effectiveness have not been established [28]. Further, the US Food and Drug Administration (FDA) warns against the use of energy-based devices to perform vaginal rejuvenation of vaginal cosmetic procedures as the safety and effectiveness of these devices have not been established [29].

#### 2.8 Conclusion

There is a substantial burden of female sexual dysfunction and related disorders among middle-aged women globally including in India. To address these aesthetic, functional and sexual concerns of women, aesthetic and regenerative cosmetology is emerging as an upcoming field. These procedures are potentially beneficial among women suffering from chronic debilitating conditions like lichen sclerosus, stressincontinence, sexual dysfunction, vulvodynia and side effects of chemotherapy. But as with any new technology, caution in use is to be advocated. ACOG recommends proper counselling of patients including risks and limitations of procedures, and informed consent should be taken before undertaking any cosmetic procedure. In experienced hands, these procedures are quite safe with a high degree of patient satisfaction and life-changing benefits. However, should preferably be advised for management of clinical conditions rather than purely cosmetic reasons.

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# Anatomy and Physiology in Relation to Invasive and Noninvasive Procedures in Aesthetic and Regenerative Gynecology

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#### 3.1 Introduction

Aesthetic or cosmetic gynecology is an upcoming field with increasing demands to improve women's reproductive health and well being and enhance or restore sexual function.

The common procedures done are labioplasty, clitoral hood reduction, hymenoplasty, vaginoplasty, perineoplasty and G-Spot augmentation [1–5]. The various energy sources being used for non-invasive vaginal tightening include RF and different types of lasers [6] and other sources as described in the book (Table 3.1).

The procedures above are used both for functional and anatomical restoration of pelvic support defects and also as cosmetic (on-demand procedures) [7]. The cosmetic gynecological procedures have been shown to enhance and improve self-esteem and sexual function [8].

**Table 3.1** Common procedures

| Hymenoplasty | Creating an intact hymen                  |
|--------------|-------------------------------------------|
| Vaginoplasty | Tightening of vagina/vaginal rejuvenation |
| Labiaplasty  | Improves appearance of labia              |
| Hoodectomy   | Removes tissue covering clitoris          |
| Monsplasty   | Shaping the pubis                         |

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All the above procedures are now being classified as FCGS (Female Cosmetic Gynecological Surgery). A comprehensive review by the brain explores all aspects of FGCS [9].

Concerns have been raised against FGCS and these are viewed as female genital mutilation. Various societies of ObGyn including ACOG, RCOG, Australian and New Zealand College and Malaysian Society are now putting forwards recommendations [1–4] and policy for its members.

The InSARG (Indian Society of Aesthetic & Regenerative Gynecology) is also in process of forming policy and guidelines for Indian Obstetricians & Gynecologists and Indian patients.

#### 3.2 Anatomy And Physiology

The external genital organs include mons pubis, labia majora, labia minora, bartholin and clitoris. The internal organs include vagina, cervix, hymen, uterus, tubes, skene glands and G spot.

Female genitalia shows a very diverse spectrum of normal anatomic variation (Table 3.1 and Fig. 3.1).

**Vulva**: Both urinary tract and reproductive structures form the female external genitalia, collectively called as VULVA.

It acts as sensory tissue during sexual intercourse, assists in micturition by directing the flow of urine and protects the internal female reproductive tract from infection.

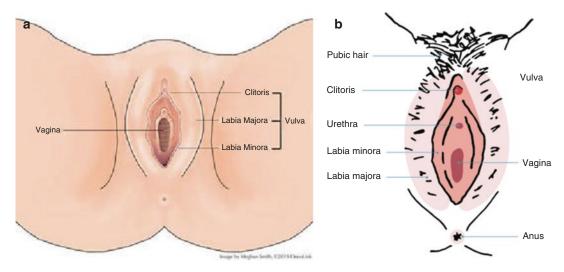


Fig. 3.1 (a and b) Anatomy of female genitalia

#### The vulva is made up of:

- a. Mons pubis
- b. Labia majora
- c. Labia minora
- d. Clitoris
- e. Urethra
- f. Vestibule
- g. Bartholin's gland
- h. Skene's glands
- i. Vaginal opening
- j. Hymen
- Mons pubis: The mons pubis has cushioning effect during sexual intercourse. The mons pubis also contains sebaceous glands that secrete pheromones to induce sexual attraction. The smell of secretions is highly individualized as these variations are the result of menstrual cycle, hygiene habits and body secretions. Excess skin can be addressed by removing and contouring the region to a natural-looking form with mons reduction surgery (monsplasty).
- Labia majora: Their function is to cover and protect the inner, more delicate and sensitive structures of the vulva, such as the labia minora, clitoris, urinary orifice and vaginal orifice. In women with enlarged labia majora its reduction known as majoraplasty can be done. With age fat of labia majora atrophies,

here <u>labial augmentation</u> with nano fat, PRP, fillers may be offered.

- Labia minora: The middle region of the labia minora covers and protects the urethral orifice and vaginal orifice from the exterior environment. Appearance and shape of the labia minora has many anatomic variations, asymmetries being the commonest. Labia minora reduction surgery, or labiaplasty, is a popular surgery in the cosmetic field. Excessive hypertrophied labia minora may cause physical obstruction and here reduction surgeries can be offered.
- Clitoris: It is the principal female erogenous organ. Superiorly is located under a clitoral hood (prepuce) which is part of labia minora anatomically that splits into a frenulum on either side of the introitus. Clitoral hood reduction is a very important surgery in this branch.
- Vestibule: It is almond-shaped area enclosed by Hart line laterally, external surface of the hymen medially, clitoral frenulum anteriorly and fourchette posteriorly. Fractional CO<sub>2</sub> laser treatment has shown significant results in treating vulval vestibulitis vulvodynia due to rigid fourchette.
- Bartholin's glands: They are pea-sized compound alveolar glands located slightly posterior and on either side of the vaginal orifice.

They secrete lubricating mucus from small ducts during sexual arousal. Bartholin gland cysts are common in sexually active women. It can be treated with CO<sub>2</sub> laser in which a skin incision is performed with focused laser beam, the capsule is opened to drain mucoid content, followed by internal vaporization of the impaired capsule.

• **Hymen**: It is a thin membrane that surrounds the opening to the vagina. Hymens can come in different shapes. Hymenoplasty is usually a simple outpatient procedure that can be done in outpatient clinic under local anaesthesia. Also called 'revirgination', it is designed to restore the hymen. It is often advertised as a 'gift' to one's partner [10]. This procedure is occasionally requested by women of certain cultural backgrounds in which premarital sex is forbidden and an intact hymen is considered evidence of virginity. Rarely imperforate hymen is also encountered leading to hematocolpos. It can be divided for free drainage of menstrual blood, secretions and sexual intercourse.

Perineoplasty—Undertaken to strengthen the pelvic floor and, in the FGCS setting, aimed at establishing penile pressure with coital thrust. This procedure is technically similar to perineal reconstruction, in which the perineal length is restored following childbirth trauma or previous surgery. It is commonly performed as part of vaginal prolapse surgery. However, even in this setting, there is no evidence that this procedure improves sexual function and, in fact, it may cause dyspareunia.

Vaginoplasty—The purpose of this procedure is vaginal creation in gender reassignment but, in the FGCS setting, it refers to tightening the vagina, which can be surgical or non-surgical—as in 'laser vaginal rejuvenation' or 'designer laser vaginoplasty'.

**G-spot** augmentation—G spot, also called Grafenberg spot after German scientist Ernst Grafenberg who described it; is believed to be a point 2 to 3 inches on the anterior vaginal wall, inside from the introitus. It is believed to be a confluence of several nerve endings and its stim-

ulation is believed to lead to orgasm. Involves autologous fat or collagen transfer via injection into the pre-determined G-spot location. There is no existing scientific literature describing this procedure. Similar procedures include G-spot amplification and G-shot collagen injection into the region. Often described as a sexual and cosmetic rejuvenation procedure for the vagina using the preparation and injection of blood-derived growth factors into the G-spot, clitoris and labia.

O spot—O-spot is the space between the urethra and the vaginal wall, most distally, in the area of the periurethral glands. Injection of 4 ml of PRP at the O-spot. Fluid fills the tissue between the urethra and the vagina thus improves orgasm.

The female external genitalia varies in almost all females in shape, size and colour but despite the oestrogen-dependent anatomical variations, the functions of these structures remain the same in all women [11]. With female ageing and fall in oestrogen levels, these structures undergo atrophy and their functions also decrease (Fig. 3.2) [12, 13].

As these organs are endocrine dependent, a defect in the hormonal secretions can lead to altered anatomy and physiology which may need medical treatment (ERT, Androgens cortisol etc.), EBD treatments or even need surgical correction (FCGS) like labian fusion, clitoral hood reduction and others [10, 14] (Figs. 3.3 and 3.4).

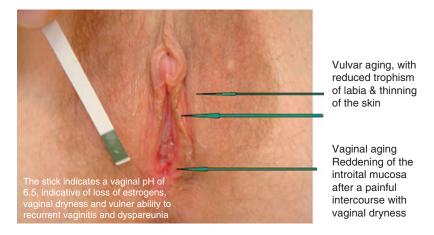
Table 3.2 shows cosmetic genital procedures [10, 15]

Terms such as 'vaginal rejuvenation', 'designer laser vaginoplasty', 'revirgination' and 'G-shot' are commercial in nature. The consumers at whom they are targeted can then mistakenly believe such official-sounding terms refer to medically recognised procedures.

# 3.3 Indication and Contraindications

FCGS is non-medically indicated cosmetic surgical procedures on healthy genitalia. As these are done on normal healthy organs there is a debate that these procedures come under female genital

**Fig. 3.2** Progressive vulvovaginal ageing after menopause





**Fig. 3.3** Clitoral hood enlargement at 12 years of age

mutilation or cutting (FGM/C) as described by W.H.O.

The World Health Organization (WHO) defines FGM/C as 'all procedures involving partial or total removal of the external female genitalia or other injuries to the female genital organs for non-medical reasons'. It is generally performed on children or adolescents who are not able to provide informed consent and have no health benefits.

There is some debate about whether FCGS is covered by legal definitions of FGM/C and, therefore, illegal under existing regulations. The explanation of outcome is considered mandatory in informed consent for FCGS, as for all medical procedures.

The common requests for performing FCGS are:

- Adolescents wanting change in labial anatomy. There is only a woman's perception of what is normal because of the diverse appearances of the genitalia. Hence, many young women wish a change due to fashion trend or their visibility in tight clothes. Fashion terms such as "camel toe" and "outie" make many women in the fashion industry feel uncomfortable with genital appearances and lead to perception that the female external genitalia should be small or "barbie like Enhancement of sexual pleasure procedures like energy-based vaginal tightening vaginal rejuvenation, G-spot augmentation, orgasm shot and even bleaching.
- 2. Some medical indications for FCGS are:
  - a. Mild degree of prolapse
  - b. Cystocele
  - c. Idiopathic vulva and vaginal itching
  - d. GSM
  - e. Dyspareunia
  - f. Scar marks (Pregnancy stria/operative marks of episiotomy/C-section)
  - g. Breast tightening
  - h. Abdominal wall tightening



Fig. 3.4 (a, b) Posterior vaginal wall old tears

- 3. Fat reduction surgery on mons, lower abdomen, arms, breasts etc.
- 4. Fat grafting and augment

#### 3.4 Practical Tips

- 1. Women's requests need to be respected.
- 2. Counselling is very important.
- 3. FCGS should be done only by trained specialists (gynecologists or plastic surgeons).
- Always a second opinion must be documented.
- 5. Psychological counselling should be done.
- All the symptoms and concerns should be discussed and documented.
- Diagrammatically and photographically the procedures should be explained and what she wants should be documented and consented.
- 8. Risks and complications should be explained including non-healing, scarring etc.

- 9. Women undergoing these procedures should be counselled regarding all anatomy, physiology and sexual function.
- 10. Training in procedures and energy-based devices and equipment is essential.

# 3.5 Various Committee Statements

# 1. Australian media code of conduct on body image

Australia's Voluntary media code of conduct on body image was designed to encourage the fashion, media and advertising industries to place greater emphasis on diversity, positive body images and a focus on health rather than body shape. In doing so, it aims to reduce young people's susceptibility to feelings of low self-esteem, eating disorders and negative body image that are associated with exposure to idealised and unrealistic images seen in the media and advertising.

Table 3.2 Cosmetic genital procedures

| Type of Procedure                                 | Purported Benefit*                                                                                                                       | Procedures Used                                                                                                                                               | Reported or<br>Potential<br>Complications                                                                         |
|---------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|
| Surgical Procedures<br>Clitoral hood<br>reduction | To improve sexual function by increasing sensitivity and allowing more direct clitoral contact                                           | Hoodectomy<br>Note: Often combined with labiaplasty to<br>create labia minora symmetry and prevent<br>clitoral hood sagging                                   | Scarring     Infection     Hematoma     Hypersensitivity     Damage to the glans                                  |
| Labiaplasty                                       | To eliminate unwanted tissue of the labia minora or labia majora                                                                         | <ul> <li>Trim or edge resection</li> <li>Wedge resection using a V-shaped or<br/>Y-shaped incision</li> <li>Z-plasty</li> <li>De-epithelialization</li> </ul> | Scarring     Infection     Hypersensitivity     or loss of     sensation     Dyspareunia     Wound     dehiscence |
| Labia majora augmentation                         | To create a full, symmetric look                                                                                                         | Autologous fat transplantation     Injectable fillers (hyaluronic acid)                                                                                       | Palpable fatty cysts                                                                                              |
| Hymenoplasty                                      | To recreate the virginal state of the<br>hymen; has cultural roots in regions that<br>place a value on an unmarried woman's<br>virginity | Reconstruction of hymenal remnants, vaginal mucosal flaps, or both                                                                                            | Wound dehiscence                                                                                                  |
| Vaginoplasty                                      | To tighten vaginal contour and increase sexual satisfaction                                                                              | Anterior, posterior, or lateral colporrhaphy     Rugation restoration†     Energy-based devices                                                               | <ul><li>Infection</li><li>Dyspareunia</li><li>Dehiscence</li><li>Fistula</li></ul>                                |
| Energy-Based<br>Interventions                     |                                                                                                                                          |                                                                                                                                                               |                                                                                                                   |
| Energy-based vaginal procedures <sup>†</sup>      | To tighten vaginal contour and increase sexual sensation                                                                                 | Laser radiofrequency                                                                                                                                          | Burns     Scarring     Pain during sexual intercourse     Recurring or chronic pain                               |
| Injections<br>G-spot amplification                | To augment G-spot and heighten sexual satisfaction                                                                                       | Autologous fat transfer     Hyaluronic acid                                                                                                                   | Urinary tract infection     Infection                                                                             |

<sup>\*</sup>This may not be the patient goal, but these procedures are often marketed with these outcomes.

The code of conduct:

- Discourages the use of digitally enhanced or altered pictures and suggests these digitally pictures be identified as such.
- b. Encourages the use of images that represent the diversity of body shapes.
- Encourages the considered placement of advertising on dieting, cosmetic surgery etc.
- d. Discourages the 'glamourisation' of models and celebrities who are particularly underweight and instead encourages a focus on models with a healthy body shape.

# 2. Guidelines for gynecological examinations and procedures

The gynecological examination of women is a formal process and potentially intimidating to women, some of whom may have suffered various degrees of physical or sexual abuse during their lives.

Doctors should consider the information provided by women, listen and respond sensitively to their questions and concerns.

According to the Royal Australian and New Zealand College of Obstetricians and Gynecologists (RANZCOG) *Guidelines for* 

U.S. Food and Drug Administration. FDA warns against use of energy-based devices to perform vaginal 'rejuvenation' or vaginal cosmetic procedures: FDA safety communication. Silver Spring (MD): FDA; 2018. Available at: https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm615013.htm. Retrieved August 26, 2019.

Gynecological Examinations and Procedures C-Gyn 30:41.

Awareness of cultural or religious factors is essential when discussing and offering gynecological examination.

Where examination is indicated, doctors should ensure that:

- a. An adequate explanation is provided about the nature of an examination and the information that it will provide.
- b. The patient has the opportunity to decline examination.
- c. Permission is obtained, especially for breast and/or pelvic examination.
- d. Privacy is provided for disrobing.
- e. Suitable cover is provided during examination, for example gown or cover sheet.
- f. A chaperone is available to attend any patient undergoing physical examination when requested, irrespective of the gender of the doctor.
- g. The patient must be made aware in advance of the presence of medical students and the right to decline their attendance at any examination.

With respect to examination of young women and children, see the Royal Australasian College of Physicians (RACP) policy *Genital Examinations in Girls and Young Women: A Clinical Practice Guideline*, available at https://www.racp.edu.au/docs/default-source/advocacy-library/genital-examinations-in-girls-and-youngwomen-a-clinical-practice-guideline.pdf

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# 4

# Counselling Before Cosmetic Gynecology

Shashi Joshi

#### 4.1 Introduction

Female genital cosmetology is the latest revolution in the field of female health. Its popularity has increased in recent years. The exact incidence is difficult to assess as many of these procedures are done in a private set-up. One reason behind the increase in prevalence of body awareness, particularly crossing the barriers of shame when discussing gynecological problems and better access to suitably qualified health professionals to address genital aesthetics.

Women favour hairless pubic area, resulting in easier visualisation of the external genitalia and making subtle irregularities more obvious (1). Increased access to female body images on Internet, TV and magazines has raised the awareness of genital appearance (but it has also skewed up the perception of what can be normal). Online promotion of normalisation of female genital aesthetics also contributes to it (2). Aggressive marketing and use of non-medical terms like designer vulva, vaginal rejuvenation, Barbie look etc. influence the demand without making realistic expectations clear (3).

With increasing popularity of cosmetic procedures, pre-procedure counselling and psychological assessment improve outcomes by assessing patient's motivations, expectations as well as

identifying those that may require psychological referral (4).

**Aesthetic Gynecology Includes** a variety of procedures to improve genital aesthetics and enhance sexual performance (5–8):

#### 1. SURGICAL:

- Labia Minora plasty
- Labia majoraplasty—enhancement or reduction
- Clitoral hood reduction
- Clitoroplasty
- Vaginoplasty
- Hymenoplasty
- Perineoplasty
- 2. NON-SURGICAL LASERS—ERBIUM, YAG, CO<sub>2</sub> LASERS:
  - · Labial whitening
  - Labial enhancement
  - Vaginoplasty
  - G-spot augmentation
  - · O-spot augmentation
- 3. FILLERS:
  - · Botulinum toxin
  - · Hyaluronic acid
- 4. REGENERATIVE COSMETOLOGY WITH THE USE OF:
  - Fat graft
  - Platelet-rich plasma (PRP)
  - Stem cells
  - Amniotic fluid
  - Amniotic membrane

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#### 4.2 Aesthetic and Regenerative Gynecology Counselling

It should be a priority for women seeking these procedures. In fact, counselling is as important as the procedure itself for a satisfactory outcome. Although it is not possible to define ideal aesthetic genitalia and sexual gratification, patient-specific technique based on patient-specific anatomy and applied with a realistic approach can result in high patient satisfaction.

# **4.2.1 Counselling Environment** (Fig. 4.1)

The environment should be:

- Welcoming
- Comfortable
- · Place with no distractions
- Somewhere where privacy and confidentiality can be maintained

#### 4.2.2 Counselling Should Be

- Auditory
- Visual
- Kinesthetics

**Fig. 4.1** Counselling chamber

## 4.2.3 Auditory

- Listen to the patient in detail and understand her.
- Explain recommendations in relation to individual expectations.
- Explain the procedure in detail.
- Pre- and post-procedure care.
- Reasonable expectations.
- Give the option of alternative methods available.
- Explain inherent risks and complications.

#### 4.2.4 Visual

Use diagrams and models to explain what is being discussed. This will help the patient to understand better. Ask them to get pictures of the result they want to achieve so that there is no difference of understanding between doctor and patient.

#### 4.2.5 Kinesthetic

This is how the auditory and visual information given will affect a particular individual. Utilise all educational tools including imaging and models to help a patient understand the procedure and the results expected from her individual perspective.



Make sure you take a disclaimer and documented discussions concerning realistic expectations.

## 4.3 Recommendations for Counselling

### (A) EXPLORE THE REASON FOR THE PROCEDURE

- Discomfort because of tight clothing like body-hugging sportswear, tight jeans or G strings.
- Information on digital media may be a source for the patient to make a change in her genital organs. The free accessibility of pornographic material has made many women feel that their genitalia are inadequate. These images are often digitally modified and may convey a wrong impression.
- Physical discomfort like pain, dyspareunia, difficulty in maintaining hygiene, vaginal laxity etc. could be the reason behind it.
- Limited genital education may also play a part in seeking cosmetic procedures. The counsellor/gynecologist should play an important role in helping the woman understand her genital anatomy and respect individual variations.
- Comments directed by others at them or otherwise. They could be friends, relatives or sexual partner.
- Intimate partner abuse or sexual abuse should also be addressed.
- Grooming practices for pubic hair like waxing, depilation, shaving or laser may expose subtle irregularities (1).

#### (B) COMPLETE MEDICAL, GYNECOLO-GICAL AND PSYCHOSEXUAL HISTORY

- Assess the degree of anxiety and concern.
- Is her concern affecting her intimate relationship, self-esteem, confidence and ability to function happily?

- Feeling unpleasant during sexual activity and how she addresses the issue.
- In the medical history, smoking and alcohol consumption can lead to compromised results. Diabetes and hypertension should be well controlled.
- In the gynecological history, pregnancy, active local infection, sexually transmitted diseases and untreated genital malignancies are a contraindication.

#### (C) ASSESSMENT OF MENTAL HEALTH AND SEXUAL ABUSE ISSUES

Patient's mental health and a psychological state have a bearing on the outcome. Pre-existing issues of depression, anxiety, post-traumatic stress disorder, addictions, low self-esteem and stress are likely to give poor outcomes. Body dysmorphic syndrome and marital discord should also be ruled out.

### (D) COUNSELLING REGARDING GENITAL EXAMINATION

Patient should be explained that it would be a detailed examination of the genital organs to assess what she has and what can be achieved. Use diagrams and models to educate the patient objectively. She should be able to understand the procedure and the expected results.

#### (E) REASSURE THE PATIENT

Reassure her that the best possible will be done for her taking all her concerns into consideration. Explain in detail why a procedure has been short-listed for her. The details of what the procedure entails, including risks and complications should be explained.

### (F) EFFECT OF PHYSIOLOGICAL CHANGES

Do not forget to explain that physiological changes like pregnancy, menopause and weight gain and weight loss can affect the outcome.

#### (G) UNINTENDED CONSEQUENCES

Possibility of inherent complications of a procedure like:

- · Bleeding
- Wound infection
- Altered sensation
- Dyspareunia
- Scarring
- · Potential physical or psychological risk
- · Unknown delayed problems

### (H) COUNSELLING ALONE MAY BE MORE BENEFICIAL IN CERTAIN CONDITIONS

- · Body image distress
- · Low self-esteem
- · Social anxiety
- Sexual difficulties that are due to undue sexual expectations by the partner or from the partner.

### (I) COUNSELLING OF BOTH THE PARTNERS

When cosmetic procedure is sought for an increase in sexual gratification, both sexual partners should be counselled. They should be explained that desire, arousal, orgasm is highly complex. They are personal experiences that do not depend on aesthetics alone. They are influenced as much by emotional, spiritual and interpersonal factors as by aesthetics.

Also, men and women view aesthetics and sexual satisfaction from different perspectives.

According to a multicentre cohort study published in SEX MEDICINE by Goodman M.P. et al., 58% of the women expected an increase in their sexual gratification and 54% expected an increase in the partner's sexual gratification irrespective of the factor quoted for the desire for genital cosmetology.

#### (J) COUNSELLING FOR GIRLS REQUEST-ING GENITAL COSMETOLOGY

Girls requesting genital cosmetic procedures before the age of 18 years should be counselled against them, irrespective of their

consent. Genital maturation is not reached before the age of 18 years and hence the procedure done before that is unlikely to give the best long-term results.

Girls from 9 to 13 years of age request consideration for relief of symptoms such as rubbing, chaffing, and interference with sports. The second most common reason in this age group is the mother's perception of an abnormality in her daughter. Adolescents 15 to 17 years of age are concerned with their own appearance and have further concerns with their own sexual appearance and have further concerns that the sexual partner may find them abnormal or unattractive.

#### (K) POST-PROCEDURE COUNSELLING

Sometimes post-procedure support or counselling may be required if optimum result is not met or if an inherent complication of the procedure occurs.

#### 4.4 Summary

Cosmetology is no longer only for the rich, famous, movie stars and models. It has become readily accessible to the general public. The concept of beauty has extended from having right looking cheeks to having designer private parts.

Value judgement should not be made about a person's idea of beauty. Cosmetic procedures can benefit if the patient's expectations are realistic. This can be achieved by proper pre-procedure counselling.

Genital cosmetology procedures should not be done before the age of 18 years. Always give them the opportunity to consult and reconsider again before moving ahead with a definitive surgical procedure to avoid regrets later.

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# Medico-legal Aspects in Aesthetic and Regenerative Gynecology

Geetendra Sharma and Hitesh Bhatt

#### 5.1 Introduction

Medico-legally these procedures are different from other surgical and non-surgical treatments. In many cases, there may not be any medical indications but they are done on demand of the patient. The purpose of the treatment as the name suggests is cosmetic.

# 5.1.1 Who Can Do Cosmetic Surgeries? Who is a Cosmetologist?

Any Registered Medical Practitioner who is having enough experience and has taken enough training in the field of cosmetology can do a cosmetic treatment. He/She cannot write against his/her name cosmetologist or specialist or Cosmetic Gynecologist unless he/she has post-graduate or super-specialist qualification recognised by MCI. The original degree should be displayed and one can write that "Special interest in cosmetic Gynecology". There are many national and international diploma courses going on, which have no validity in the court of law, except they can be considered as training obtained.

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H. Bhatt Mumbai, India AIIMS has started post-Gynecology MCH is Cosmetic Gynecology. The practitioner who has done super-specialisation recognised by Medical Council of India can write specialist in Cosmetic Gynecology or Gynecological cosmetologist against his/her name.

Indian Medical Council (Professional Code of Conduct, Etiquette and Ethics) Regulation 2002, in Section 7.20—A Physician shall not claim to be a specialist unless he/she has a special qualification in that branch. Section 3.7.2—A physician shall write his/her name and designation in full along with registration particulars in his/her prescription letterhead [1].

#### 5.1.2 Counselling

Counselling always plays a vital role in management. There are different types of counselling.

Medical Counselling—Medical counselling should be done by a qualified medical person. In medical counselling Purpose of treatment, Procedure details, alternatives available with pros and cons of each, success rate and failure rates of treatment, risks of treatment and risks of not taking treatment should be properly explained. Patients should not be given over expectations. It is never advisable to lead the patient to a particular kind of treatment. It is always better to explain the facts in detail. One can explain by drawing sketches if possible. Ask patients to get sketches

or pictures of results they want. Video counselling is also a good option nowadays. By showing videos the facts can be explained to the patient. It is always advisable to document the counselling in the case paper. After the operation it is very difficult to prove that what was assured, and this becomes the reason for dispute. It is advisable to clearly mention in counselling, in writing, that what is assured. No guarantees or warranties should be given regarding the success of treatment.

**Financial Counselling**—Approximate expenditure with possibility of more expense in case of complication should be explained in detail with breakage.

**Psychological Counselling**—If healthcare provider feels necessary then Psychological counselling should be advised.

**Consent**—Consent is defined as where two or more parties agree to the same thing in the same sense that is "PARTIES AD IDEM".

Consent in Medical Context was the first time better discussed in Appeal (civil) 1949 of 2004 in the case of **Samira Kohli vs. Dr. Prabha Manchanda**, Date of judgment—16/01/2008 by the **Bench—B.N. Agrawal, P.P. Naolekar and R.V. Raveendran—Judgment delivered by Raveendran J.** [2].

Consent is to be taken for both surgical and non-surgical treatment. In case of non-surgical treatment where there is any kind of risk involved it is to be explained to the patient. Consent should contain after providing adequate information. Adequate information contains six things. Patient's own consent is a must.

- Purpose of treatment—In Cosmetic Gynecology when there is no specific purpose and if surgery is to be done on demand for the cosmetic purposes it should be mentioned like that only. In case if there is any specific indication then an indication is to be mentioned.
- 2. Procedure is to explain to the patient in detail what you will be doing.
- Alternatives available for the same are to be mentioned in detail. Suppose a patient has approached the doctor for vaginal laxity and demands surgery then in such a case it is duty

- of doctor to explain the alternative pelvic floor muscle exercise as one of the alternatives.
- 4. Success or failure rates are to be explained in detail in consent.
- Risks or side effects are to be explained in detail. When you put something in writing the list should be exhaustive. Risks should not be explained which frightens the patient leading to refusal of treatment.
- Risks if any for not undergoing treatment should also be explained but it should not be explained in such a way that patient becomes ready for treatment which is not required at all.

Consent in IPC—There are defense available to a doctor under the Indian Penal Code.

Section 87. Act not intended and not known to be likely to cause death or grievous hurt, done by consent. Nothing which is not intended to cause death, or grievous hurt, and which is not known by the doer to be likely to cause death or grievous hurt, is an offense by reason of any harm which it may cause, or be intended by the doer to cause, to any person, above 18 years of age, who has given consent, whether express or implied, to suffer that harm; or by reason of any harm which it may be known by the doer to be likely to cause to any such person who has consented to take the risk of that harm.

**Section 88.** Act not intended to cause death, done by consent in good faith for person's benefit. Nothing, which is not intended to cause death, is an offence by reason of any harm that it may cause, or be intended by the doer to cause, or be known by the doer to be likely to cause, to any person for whose benefit it is done in good faith, and who has given a consent, whether express or implied to suffer that harm, or to take the risk of that harm.

#### 5.2 Ethical Dilemmas

There are four principles of Ethics:

Principle of Autonomy (Control by Individual)—Every person has the right to

decide what she wants to undergo or what she does not want. We have to respect the autonomy of an individual. This is also known as the principle of human dignity.

**Principle of Beneficence (Do Good)**—We must do whatever is in good to the patient. Sometimes there is direct conflict between principle of beneficence and principle of autonomy, i.e. respecting the demand of patient.

**Principle of Non-maleficence (Do no Harm)**—One should not have the intention to harm. It is an obligation not to harm others. Whenever it is not possible to avoid harm them at least try to minimize harm.

**Principle of Justice (Fairness)**—We should be fair in treatment. There should be equality and impartiality in treatment. Your treatment should be justified.

# 5.2.1 Can We Do Surgery When You Think That it is Not Medically Indicated on Demand?

These situations often come in practise. If the procedure is not harmful to the patient then we can proceed with the same respecting autonomy of the patient. But when something is harmful to the patient then it becomes our duty to inform the patient about the possibility of harm in detail before proceeding with the same. We also should discuss the option of not doing the surgery at all instead of taking a risk.

# 5.2.2 What to Do When Everything is Normal Physiologically but Still Patient Demands Correction?

All procedures are planned, there is no medical necessity of operation, no emergency, Suppose, as per your examination patient is absolutely normal but still patient demands to undergo operation what to do?

The healthcare provider should be honest. Truth is to be explained to the patient while counselling. Counselling should be documented properly. After knowing the truth in detail if the patient still wants to undergo treatment then we have to respect the patient's autonomy. But if the procedure seems to be harmful to the patient, it should be avoided in the best interest of the patient. To refuse to treat the patient is the right of a doctor but it is advisable to document the reason for refusal.

#### 5.2.3 Documentation

Documentation is the only evidence in the court of law to prove your case. It is said that "Courts are not the courts of Justice but they are court of evidences". So good document is always a good defence, poor document is a poor defence and no document is no defence. Communication, Documentation, Documentation of communication play a vital role in any medico-legal case.

Document should be Accurate in chronology, Complete, Legible and without any extraneous information. Let us see what is the difference between routine documentation and documentation in the cases of cosmetic gynecology.

In chief complaint, if there is any specific complaint then it should be mentioned in the language of the patient but if no complaint but patient want treatment not medically indicated for cosmetic purpose then it should be documented.

In examination it is advisable to do examination in the presence of one female assistant. The explanation should be done by drawing on the case paper. It is always a good idea to take preoperative and post-operative photographs for comparison and to be attached with the records. All medically indicated pre-requisite investigations should be performed. Operative notes should be written in detail explaining which kind of instrument or laser is used during treatment. Post-operative follow-up instructions should be passed on in detail to the patient.

#### 5.2.4 Complications

Complications per se cannot be considered negligence. If complications are explained in detail before starting the treatment that will become more acceptable. So, it is a good practise to explain complications of treatment in advance to the patient.

How to tackle complications—Disfigurement, Scarring, Haematoma, No result, and No satisfactory result. Any complication if occur should be treated as per medical norms.

#### 5.2.5 Confidentiality

# 5.2.5.1 Indian Medical Council (Code of Conduct, Etiquette and Ethics) Regulation, 2002 [3]

2.2 Patience, Delicacy and Secrecy: Patience and delicacy should characterize the physician. Confidences concerning individual or domestic life entrusted by patients to a physician and defects in the disposition or character of patients observed during medical attendance should never be revealed unless their revelation is required by the laws of the State. Sometimes, however, a physician must determine whether his duty to society requires him to employ knowledge, obtained through confidence as a physician, to protect a healthy person against a communicable disease to which he is about to be exposed. In such instance, the physician should act as he/she would wish another to act towards one of his/her own family in like circumstances.

# 5.2.6 Disclosure of the Patient's Secret Without Valid Reason Amounts to Misconduct

**7.14** The registered medical practitioner shall not disclose the secrets of a patient who have been learnt in the exercise of his/her profession except:

(i). In a court of law under orders of the Presiding Judge.

- In circumstances where there is a serious and identified risk to a specific person and/ or community.
- (iii). Notifiable diseases.

In the case of communicable/notifiable diseases, concerned public health authorities should be informed immediately.

#### 5.2.7 Certain Typical Medico-legal Issues in Cosmetic Gynecology

There are a few operations in Cosmetic Gynecology where there is no scale of measurement as to whether the operation is done successfully or not. Only patients can feel and tell whether any improvement is there or not and that also is subjective. In such a case if the patient claims for no improvement after treatment there is no means to know the truth.

The result of treatments like G-Spot Amplification and O-Shot® for female Sexual quality enhancement cannot be measured by any means. In such kind of treatment, patients in advance should be informed that the improvement cannot be guaranteed and as there is no measure to know the fact your claim of no improvement will not be entertained.

#### 5.2.8 Certain Procedures Not Yet Proved: Can One Practise [4]

In many cases, doctors doing treatment is not yet proven by trials done on human beings and are not officially recognized. Laser for vaginal rejuvenation is yet not FDA approved. This should be explained to the patient and a written consent be taken that she understands it. Plasma Rich Platelet therapy is used nowadays by many doctors in different indications and treatments.

PRP is a very promising futuristic therapy. It is a vehicle to deliver a large amount of important growth factors, which are biologically active, to the injured site. Its use has increased extensively over the last decade due to advanced technology, availability of newer commercial PRP equipment, manufacturing of various PRP products in the market. It is very simple and easy to use, easily available, uses the patient own blood (autologous), potential cost-effective, and considered very safe therapy. There are many case series showing positive outcomes. But despite the promising results of several animal studies, wellcontrolled human studies are lacking. The research is still in its infancy. There is no consensus or protocol for the use of PRP. Even with all the limited evidence available, today PRP is becoming a very popular therapy in various fields of medicine. More research in future will clear the clouds over many questions being raised about the efficacy and evidence for PRP. PRP can be used for a long list of conditions, for example orthopaedic, neurology, musculoskeletal, cardiology, dermatology, and plastic surgery. The research on PRP is still in infancy, and there is no consensus on platelet concentration, amount of PRP, which is the best technology in preparing PRP. There are many animal studies, which are showing encouraging results, but human studies are lacking. PRP is a very promising treatment option that is nonsurgical. We need to wait for more concrete evidence to emerge to define its exact clinical role.

To conclude, we may say that there are reasonable amount of data that warrant continued research in PRP but currently, its role in clinical practise is not completely defined [4].

All readers and practitioners of the art of PRP (platelet-rich plasma), it is imperative that you be cautioned of the fact that the Indian FDA considers "preparing Platelet Concentrate" amounts to "manufacturing" of blood components (sic) and those who do contravene the provisions, as per the Drugs and Cosmetics Act 1940, read with rule 122EA of the Drugs and Cosmetics Rules, 1945 and are punishable under Section 27 of the said Act.

Some of our Plastic surgery colleagues and some Dermatologists have been served with such notices recently.

# 5.2.8.1 Ministry of Health and Family Welfare (Department of Health and Family Welfare) by Notification: New Delhi, the 11th March, 2020 [5]

**G.S.R.** 166(E). Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published as required under Subsection (1) of Section 12 and Sub-section (1) of Section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 1152(E), dated on 29th November, 2018, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of forty-five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public; And whereas copies of said Official Gazette were made available to the public on 30th November, 2018

And whereas objections and suggestions received from the public on the said rules have been considered by the Central Government; Now, therefore, in exercise of the powers conferred under Sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:

- (1) These rules may be called the Drugs and Cosmetics (Second Amendment) Rules, 2020.
- (2) They shall come into force on the date of their publication in the Official Gazette.

Central Government Act—Section 122 E(a) in The Drugs and Cosmetics Rules, 1945

[(a) A drug, as defined in the Act including bulk drugs substance which has not been used in the country to any significant extent under the conditions prescribed, recommended or suggested in the labelling thereof and has not been recognized as effective and safe by the licensing authority mentioned under Rule 21 for the proposed claims: Provided that the limited use, if any, has been with the permission of the licensing authority.].

Section 27 Whoever, himself or by any other person on his behalf manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale or distributes—

- (a) Any drug deemed to be adulterated under Section 17A or spurious under Section 17B or which when used by any person for or in the diagnosis, treatment, mitigation, or prevention of any disease or disorder is likely to cause his death or is likely to cause such harm on his body as would amount to grievous hurt within the meaning of Section 320 of the Indian Penal Code, solely on account of such drug being adulterated or spurious or not of standard quality, as the case may be, shall be punishable with imprisonment for a term that shall not be less than 5 years but which may extend to a term of life and with fine which shall not be less than ten thousand rupees.
- (b) Any drug: (i) Deemed to be adulterated under Section 17A, but not being a drug referred to in clause (a), or (ii) Without a valid licence as required under clause (c) of Section 18, shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to three years and with fine which shall not be less than five thousand rupees: Provided that the Court may, for any adequate and special reasons to be recorded in the judgment, impose a sentence of imprisonment for a term of less than one year and of fine of less than five thousand rupees.
- (c) Any drug deemed to be spurious under Section 17B, but not being a drug referred to

- in clause (a) shall be punishable with imprisonment for a term which shall not be less than three years but which may extend to five years and with fine which shall not be less than five thousand rupees: Provided that the Court may, for any adequate and special reasons, to be recorded in the judgment, impose a sentence of imprisonment for a term of less than three years but not less than one year.
- (d) Any drug, other than a drug referred to in clause (a) or clause (b) or clause (c), in contravention of any other provision of this Chapter or any rule made thereunder, shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to two years and with fine: Provided that the Court may for any adequate and special reasons to be recorded in the judgment impose a sentence of imprisonment for a term of less than one year.

### 5.2.9 Minor Patient Coming to Take Advice: What to Do?

In minor, it is better to avoid cosmetic surgery just for beautification as minor is not competent to consent so the consent party shall always be the guardian and when minor when attains majority, may not like decision taken by the parents. However, curative cosmetic surgeries, e.g. post burns or injuries or for disease are justified on basis of necessity.

#### 5.2.10 Insurance

It is advisable to check with the indemnity insurance company whether your indemnity policy covers the cosmetic procedures or not. If not then if you are in such practise then it is advisable to get it added by paying an extra premium if any. Every procedure is within the ambit of the Consumer Protection Act. The same thing is for the patient, most of the Mediclaim policies do not cover cosmetic surgeries. It is always better to check it with insurance provider beforehand.

#### 5.3 Conclusion

We are in the twenty-first century in a materialistic world and most people do prefer to look better physically. So, cosmetic surgery has its place in the medical field, however, since its inception, teething problems do arise and one such problem is a medicolegal issue. It is better to consult a medicolegal consultant in such a situation.

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# **Energy-Based Devices: Comparisons and Indications**

6

**Ohad Toledano** 

#### 6.1 Introduction

Modern medicine offers a variety of treatment modalities aiming to manage a large diversity of gynecological conditions, varying from as little as topical gels or hormone-replacement therapy to invasive vaginal interventions. These feminine issues can affect women's daily lifestyle, quality of life or project physiological effects such as decreased self-confidence or impaired sexuality. Changes due to menopause, postpartum or other causes led to an emerging number of energybased devices (EBD) for vaginal procedures that utilize ablative or thermal effects to sculpt the external vagina or to strengthen the aging vaginal wall. Available applications are mainly lasers yet other energy-based devices have also been introduced to regenerative gynecology and urogynecology, such as various types of (radiofrequency derives), High-intensity focused ultrasound (HIFU), Light-emitting diodes (LED) and high-intensity focused electromagnetic field (HIFEM). Karcher& Sadick [1] claim that the commonly used term of "vaginal rejuvenation" is in fact a generalized term for a wide array of gynecological aesthetic and functional procedures that aim to restore the vagina and its surrounding tissues. According to their definition, the spectrum of procedures can range from mere

vaginal atrophy (VA) and dryness, treated by minimally or noninvasive strategies, to cases that require invasive intervention such as labiaplasty or vaginoplasty. This chapter aims to introduce the main available technologies offering vaginal rejuvenation and restoration, its interaction with the tissue, and compare the technological differences.

#### 6.2 Lasers

Light amplification by stimulated emission of radiation, or LASER, was first mentioned as a theoretical concept by Albert Einstein as an atomic cascade produced by stimulated emission to create electromagnetic radiation. Yet, it took almost half a century for the first laser to be built by an American physicist named Theodore H. Maiman in 1959 [2]. Laser is defined as light, a form of an electromagnetic energy; thus it is by definition—a wave, and as such, all lasers are a part of the electromagnetic spectrum. Laser is characterized by three unique properties that differentiate it from other forms of light; monochrocoherence and collimation Monochromaticity, probably the main associated characteristic of a laser, means that each laser emits light at a single wavelength, so it has only one length to its particle wave. The waves of this light also travel "in-phase" meaning in synchronization in time, therefore, are coherent. Laser

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waves are also collimated, meaning they travel parallel to one another and in a single direction rather than scatter like ordinary light waves. Taking all three characteristics to account, it is clearly understood why laser it defined as an ideal and precise tool for numerous indications of use. Lasers are often named or defined by their emitting wavelength as it is a crucial property of the laser, especially in the medical field, which focuses on specific chromophores to be targeted by the laser. The interaction between laser and chromophore was proposed by Anderson and Parrish at 1983, named as the theory of "selective photothermolysis" [4]. This theory revolutionized the understanding of the interaction between laser and tissue, suggesting ways in which laser can be used therapeutically. The basis of the theory claims that laser is absorbed by a defined target chromophore, with little impact on its surrounding tissue. The absorbed light is transformed from light energy into thermal energy that destroys the target in question. There are numerous chromophores that absorb light, to each its own absorption curve that defines the affinity to light for each wavelength. The main chromophores addressed in most medical disciplines are melanin, hemoglobin, and water. Absorption curves (Diagram 6.1) are important factors to consider when using laser, as different wavelengths aimed at the same chromophore will have different tissue reactions.

In practice, a desired wavelength is selected mainly according to its absorption in the main chromophore in the relevant tissue. In many procedures, in addition to the damage inflicted to the target tissue, controlled damage to the surrounding tissue is also desirable, to create other lasertissue interactions [5] such as Vaporization (tissue ablation), protein denaturation and Hyperthermia. Tissue reaction is dependent on the temperature it is exposed to (Table 6.1), the duration of exposure, also referred to as pulse duration and the content of the tissue.

**Table 6.1** Temperature-dependent laser-tissue intersections

| Temperature | Molecular and tissue reactions         |
|-------------|----------------------------------------|
| 42–45 °C    | Hyperthermia leading to protein        |
|             | structural changes, hydrogen bond      |
|             | breaking, retraction                   |
| 45–50 °C    | More drastical conformational changes, |
|             | enzyme inactivation, changes in        |
|             | membrane permeabilization, oedema      |
| 50–60 °C    | Coagulation, protein denaturation      |
| ~80 °C      | Collagen denaturation                  |
| 80–100 °C   | Dehydration                            |
| > 100 °C    | Boiling, steaming                      |
| 100-        | Vaporization, tissue ablation          |
| 300 °C      |                                        |
| > 300 °C    | Carbonization                          |

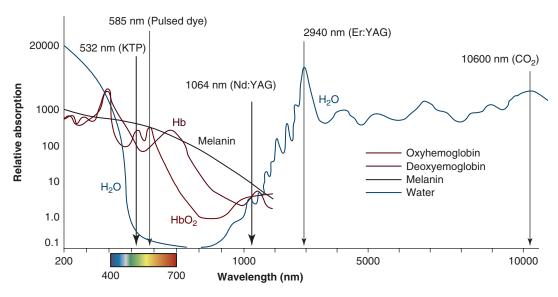


Diagram 6.1 Laser—Absorption spectra of water, hemoglobin, oxyhemoglobin, and melanin

#### 6.2.1 Carbon Dioxide (CO<sub>2</sub>) Laser

The CO<sub>2</sub> laser emits light at a 10,600 nm wavelength and has a high absorption in water (Fig. 6.1), thus causes ablation in a watercontaining tissue. When CO<sub>2</sub> laser is used, surrounding the borders of the ablated zone, a degree of residual thermal damage is present, caused by the tissue exposure to decreased temperatures [6]. With an absorption coefficient of 800<sup>-1</sup>, the CO<sub>2</sub> absorbed light induces mainly ablation, yet other effects such as coagulation or thermal effect are notable on the surroundings due to this conducted heat [7]. Although its main use is ablating, those other laser-tissue interactions of the CO<sub>2</sub> are of use and are harnessed to the success of the procedure. Coagulation formed surrounding the ablated zone causes small blood vessels to be cauterized together with the surrounding tissue, achieving hemostasis allowing a "cleaner" procedure with less complications [6]. It was also suggested that tissue exposed to hyperthermia (42–50 °C) is additionally influenced as effects of collagen shrinkage causes long-term neocollagenesis and neoelastinogenesis effects [8].

## 6.2.2 Erbium-Doped Yttrium Aluminum Garnet (Er: YAG) Laser

The Er:YAG is a near-infrared pulsed laser of a 2,940 nm wavelength which is of the highest absorption in the water among common practice lasers. In fact, its water absorption coefficient is 16 times higher than that of theCO<sub>2</sub> laser [9],



**Fig. 6.1** A nonsurgical fractional laser probe emitting in the vaginal canal

making it of a superficial ablative property [7]. The difference between the Er:YAG andCO<sub>2</sub> lasers is in their "tissue signature" effect, as Er: YAG has a shallow penetration depth in comparison to CO<sub>2</sub>, which allows for precise tissue ablation and minimal thermal damage to surrounding tissue. Unlike the CO<sub>2</sub> laser, skininteraction of Er: YAG is mostly of ablative effect with the skin, with nearly no coagulation and minimal surrounding thermal damage, so it creates clean ablation craters and precise cuts without apparent scarring. However, it lacks sufficient coagulative margins surrounding the ablated area, thus is limited and not ideal for removal of deep or large lesions, as it cannot prevent bleeding [10].

#### 6.2.3 Fractional Lasers

For external purposes or bulk removal of tissue, ablative lasers are used in a non-fractional beam profile, meaning in a full spot beam. In 2004 a new approach for laser delivery named "fractional photothermolysis" (FP) was introduced using a 1,550 nm laser as an alternative for the full non-ablation option to evaluate tissue recovery [11]. This was achieved by delivering an array of microscopic laser beams to create what the researchers named microscopic treatment zones (MTZ) of thermal injury to the skin. A few years later, this concept was applied on the ablative CO<sub>2</sub> & Er:YAG lasers to create MTZ in which the treatment zones were zones of ablation of only a small fraction of the skin [12]. Fractionating the ablative laser into small micron size spots allowed for rapid re-epithelialization derived from the undamaged epidermal "islands" separating the ablated MTZs, so that the ablative area was only 5-30% of the total area treated [13]. MTZ depth and width were shown to be associated with the delivered energy.

#### 6.2.4 Lasers in Gynecology

In the second part of the twentieth century, lasers had emerged into the field of gynecology, yet it was not easily accepted [14]. As the use of older, outdated methods was found unsuitable for treating in many cases due to unwanted, yet unavoidable complications, the laser was suggested as a new alternative [15], primarily the carbon dioxide laser. Over the years, more and more researchers grew to believe that, for some indications, the use of the CO<sub>2</sub> laser is a safer and a more versatile option available [16]. In time, new lasers such as the Neodymium-doped yttrium aluminum garnet; (Nd:YAG, 1,064 nm) and the argon laser were proven as practical tools in gynecology [17]. Yet because of their high absorption in water, CO<sub>2</sub> laser and to some extent also the Er:YAG laser has become the most dominant ones in the last decades. The CO<sub>2</sub> laser was traditionally used for gynecological surgery and genitourinary procedures as means of ablation, vaporization, excision, incision, or coagulation of soft tissue [18]. It was adopted to the subfield of regenerative and aesthetic gynecology such as labiaplasty and removal of genital warts [19, 20], which are commonly referred to as "Vaginal rejuvenation". Both lasers are used to treat a large scope of other gynecological indications such as lichen sclerosus and more [21]. Other uses of lasers in gynecology are laser-assisted laparoscopy, hysteroscopy, and even in vitro fertilization procedures [9]. Yet it seems that most attention in recent years was drawn to the treatment of aging vagina, dryness, infections, and related stress urinary incontinence (SUI). These are some of the symptoms associated with Genitourinary syndromes of menopause (GSM), a comprehensive term embraced during the last years by the main medical societies addressing Women's Sexual Health [22]. This new definition of GSM was to replace the formally known medical terms of vulvovaginal atrophy (VVA), urogenital atrophy or atrophic vaginitis [23] as previous ones did not accurately define the medical condition and symptoms. GSM is caused due to decreased urogenital estrogen levels and is clinically described as symptoms of dryness, irritation, impaired sexual activity and other urinary disorders. All gynecological procedures aimed to treat the mentioned above indications are based on the Laser-tissue interaction, which is made possible due to the water absorption property. As previously mentioned, ablative lasers are slowly becoming tools for external ablative procedures using a fullbeam, small diameter profile with precise and clean cutting abilities [24, 25] or in the fractionated beam profile [26, 27]. Fractional ablative lasers using a diffractive probe are the most common ones for vaginal rejuvenation [9, 23, 28] as they promote formation and remodeling of collagen attempting to rewind genitourinary changes such as thinning in the epithelial lining of the vagina and atrophy. The small ablative MTZs and thermal effect surrounding it stimulates collagen deposition, improves vaginal wall quality and is shown to have the capability of restoring vaginal mucosa pH levels [23, 28]. The restoration of the connective tissue, other alterations of the extracellular matrix support the effectiveness of fractional ablative lasers for the restoration of vaginal mucosa structure and related physiological tropism.

Although clinical efficacy and safety are well established in dermatology and of growing reports in gynecology, there are still some arguments yet unanswered about the best practice, ideal technology and maintenance needed [9]. In some societies, the use of lasers is still not recommended as first-line therapy due to the lack of large scope randomized controlled trials (RCTs) and long-term follow-up [29]. Nevertheless, the increasing number of publications on the use of lasers is a source of encouragement, as physicians gradually comprehend the potential of lasers as the resolution in the gynecological field. The accumulating proofs from the literature indicate that fractional ablative lasers do have histological supportive alternations and are a safe and effective option in treating symptoms of GSM in postmenopausal women [30-32] and improve wellness for those who suffer. Lasers remain the most studied and published modality of all EBDs presented in this chapter and of the widest range of indications potentially treatable.

#### 6.3 Radiofrequency (RF)

Radiofrequency is a term aimed to describe the oscillation of electromagnetic radiation, meaning the transfer of energy in the form of (radio)