

# Ethical opinion paper

Ethical considerations in relation to female genital cosmetic surgery (FGCS)



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### I. Executive summary

General practitioners, gynaecologists and plastic surgeons are increasingly likely to be consulted by women and girls who are concerned about the structure and appearance of their genitalia. Clinicians have a duty of care to provide these women with accurate information on the diversity of morphology and appearance of the female genitalia and to suggest simple measures to relieve genital discomfort where no pathology can be identified. The importance of education, support and advice should be at the heart of clinical practice, with sympathetic appreciation of the female body insecurities that are rife in western society. The presentation of female genital cosmetic surgery (FGCS) as an unproblematic lifestyle choice is undesirable because it misleads women as to the need for and the efficacy of such surgical techniques.

Key points are as follows:

- Fully informed consent is fundamental when offering FGCS, as is the case for all medical treatment.
- Clinicians who perform FGCS must be aware that they are operating without a clear evidence base.
- Women should be advised accordingly.
- Owing to anatomical development during puberty, FGCS should not normally be offered to individuals below 18 years of age.
- In general, FGCS should not be undertaken within the National Health Service (NHS) unless it is medically indicated.

# 2. Background

#### 2.1. Definition of FGCS

FGCS refers to non-medically indicated cosmetic surgical procedures which change the structure and appearance of the healthy external genitalia of women, or internally in the case of vaginal tightening. This definition includes the most common procedure, labiaplasty, as well as others, such as hymenoplasty and vaginoplasty, also known as vaginal reconstruction and vaginal rejuvenation. Increasing numbers of women and girls are consulting their doctors to seek these procedures, often because of concerns about their genital appearance. This increasing provision of FGCS as a solution has prompted ethical and scientific debates and significant media attention. In addition, anxieties have been expressed within the wider medical community about standard setting and the medical regulation of cosmetic surgery in general and the complications that can arise from such procedures.

### 2.2. Female genital mutilation (FGM)

The debate around FGCS often raises questions about the difference between FGCS and female genital mutilation (FGM).

World Health Organization (WHO) describes FGM as comprising all procedures that involve partial or total removal of the external female genitalia, or other injury to the female genital organs, for non-medical reasons. The procedure is nearly always carried out on minors without consent. FGM is ethically and morally wrong, and it is recognised internationally as a violation of the human rights of girls and women.<sup>4</sup>

Consequently, it is an offence in the UK, under the Female Genital Mutilation Act 2003 and the Prohibition of Female Genital Mutilation (Scotland) Act 2005, if a person 'excises, infundibulates or otherwise mutilates the whole or any part of a girl's labia majora, labia minora or clitoris ... But no offence is committed by [a registered medical practitioner] who performs a surgical operation on a girl which is necessary for her physical or mental health'. Operations necessary for mental health are said to include 'cosmetic surgery resulting from the distress caused by a perception of abnormality'.<sup>5</sup>

The phrase 'distress caused by a perception of abnormality' is open to interpretation, giving rise to some ambiguity around the legal status of some FGCS procedures. This paper recognises the need for clarification of this ambiguity (see recommendation 12.2), but refers only to FGCS as defined in section 2.1.

#### 2.3. Purpose of this ethical opinion paper

In light of the above, this document is timely for women and specialists and concentrates on the following objectives:

- to provide a background briefing
- to explore the ethical considerations in relation to FGCS.

## 3. Why women request labiaplasty

The overall appearance of the female external genitalia is influenced by the relative sizes, shapes and colours of the labia majora, labia minora, clitoris and introitus. The variability is infinite, as is indicated by a frequently cited small study. Women request labiaplasty to alleviate problems arising from labia minora which, when large, lead to problems concerning hygiene, difficulties during sexual intercourse and discomfort when wearing tight clothes, exercising or inserting tampons.

Many women seeking labiaplasty have labia that fall within normal limits.<sup>7</sup> Despite this, the primary motivation for some women requesting labiaplasty is concern about genital appearance. In extreme cases, this concern is an aspect of body dysmorphic disorder<sup>8</sup> which requires appropriate psychotherapy; however, in most cases this is not so, and the question therefore arises as to when, or indeed whether, it is appropriate to offer labiaplasty in situations of this kind.

#### 3.1. Body dissatisfaction and cosmetic surgery

In recent years, labiaplasty has been increasingly popularised via marketing by the private sector. As a result, concerns about genital appearance and demand for FGCS involving labiaplasty have both increased, with many women who request labial surgery doing so for 'aesthetic' reasons.

Private healthcare insurers classify labiaplasty as cosmetic surgery, and in some respects the issues surrounding FGCS are much the same as those which apply to other forms of elective cosmetic surgery.

Because there is limited authoritative information on normal female genital anatomy, women and girls who are self-conscious about their genital appearance have to refer to cultural representations of female genitalia for self-evaluation. These sources are currently found mainly in photographic pictures on the web, in the media and in advertising for FGCS services and give rise to the erroneous perception that the labia minora are normally invisible, hidden by the labia majora. Women who are worried about the appearance of their labia or requesting labial surgery often report being influenced by marketing or these media images, and a detailed qualitative analysis suggests that consumers may have unrealistic expectations about the results of labiaplasty.

When dealing with women who request labial surgery whose motivation is primarily anxiety about their appearance, accurate information about what is normal physiology can often provide sufficient reassurance to alleviate their concerns.

# 4. How common is labiaplasty?

Currently, there is no requirement for surgeons in the private sector to record numbers of procedures performed and so activity data are unavailable, but the extent of advertising by the large number of private clinics suggests that the availability and practice of labiaplasty are now widespread.

According to Hospital Episode Statistics (HES), the number of labial reduction procedures has risen five-fold in the NHS over the past 10 years, with over 2000 operations having been performed in 2010.<sup>13</sup> The HES figures are derived from two HES codes commonly used for labia minora reduction, which are:

- P05.5 Excision of excess labial tissue
- P05.6 Reduction labia minora

However, these codes do not distinguish between labiaplasty performed for medical or functional reasons and labiaplasty carried out for aesthetic reasons.

# 5. Clinical evidence for labiaplasty

#### 5.1. Quality of the literature

There is a lack of high-quality literature on this subject. There are currently no controlled trials or prospective studies investigating the clinical effectiveness or risks of labiaplasty procedures.<sup>14</sup> There are small case reports and a few larger retrospective studies, all of which offer scant descriptions of methodology or study design.<sup>15,16</sup> Since the surgical studies are authored by the surgeons who performed the operations, there is little independent evaluation.

#### 5.2. Efficacy

There are no data on the efficacy of treatment for functional problems, and pre- and postlabiaplasty symptoms such as physical discomfort and pain, appearance and sexual dissatisfaction are difficult to define. Where labiaplasty is performed for cosmetic reasons, the evidence of efficacy comes mainly from responses to questions from the care providers. Shortterm satisfaction rates of up to 100% have been claimed, but there is no robust evidence to substantiate this conclusion, nor evidence of long-term outcomes.

## 5.3. Risks and complications

As with any surgical procedure, labiaplasty carries short-term risks of bleeding and wound infection. Wound dehiscence has been reported in up to 30% of cases depending on the surgical technique used, and may lead to the need for revision operations.<sup>17</sup> There are no data on the potential physical and psychological risks in the medium and long term. Revision operations for dissatisfaction with the initial result can occur and there are anecdotal reports of concerns associated with scarring, such as tightness of the vagina, pruritus and discoloration of the labial skin leading to dyspareunia and vulvodynia.<sup>18</sup> The possibility of an increased risk of perineal trauma during vaginal delivery has been suggested, although there are no data on potential long-term obstetric consequences.

The labia minora may have an important role in sexual function. There is evidence of dense innervation and the presence of estrogen receptors at their free edge. Labia minora contain erectile tissue at their base, become engorged and have a role during sexual arousal. Long-term damage to sensitivity and sexual function may occur after labiaplasty, as surgery will disrupt nerve supply with consequences for sensitivity.

There is a definite need for more data to inform women about short- and long-term outcomes to allow true informed consent for these procedures. The appropriate coding and follow-up studies are required to provide this.

#### 6. FGCS and informed consent

As highlighted in section 3.1, accurate information about normal female genital physiology can often provide sufficient reassurance for women who are requesting labial surgery primarily because of anxiety about their appearance. However, should this fail to reassure women and girls, clinicians should discuss other possibilities, such as the offer of counselling or short-term, focused psychological treatments for problems such as body image distress, sexual difficulties, low self-esteem and social anxiety. Preoperative screening for underlying psychological problems should be considered. These treatments may require input from a suitably trained professional such as a clinical psychologist, who can also make a skilful assessment of body dysmorphic disorder and any other background mental health problems if this is thought to be appropriate.

However, women may decline the offer of psychological treatment and still seek some form of cosmetic surgery, typically labiaplasty, often from the private sector. Before this is provided, women must be informed about the risks inherent in the procedure and the lack of reliable evidence concerning its positive effects. General Medical Council (GMC) good practice guidance on consent specifies that doctors should 'give the patient time to reflect, before and after they make a decision, especially if the information is complex or what you are proposing involves significant risks'.<sup>24</sup> Given the irreversibility of labiaplasty, and the absence of evidence of efficacy, women should not consent to surgery at their first appointment but rather should be given an accurate written information sheet and adequate time to reflect before agreeing to surgery.

As with any informed consent process, it is important that records are kept, including whether counselling has been offered and if it has been taken up or not. In the case of FGCS, detailed informed consent records are particularly important and should be kept by both the woman and her surgeon.

# 7. Labiaplasty and children

Significant numbers of labiaplasties on girls and young women under 18 years of age are reported in the medical literature, with some publications dwelling specifically on labial reductions in adolescents for hypertrophy or asymmetry of the labia minora.<sup>25</sup> HES data report 266 procedures on girls under 14 years of age in the last 5 years.<sup>26</sup> However, the indication for these procedures is unknown and many may be performed for congenital genital anomalies or other medical problems.

The labia minora change as part of normal development during puberty but, unlike breast and pubic hair development, developmental changes of the vulva have not been included in the standard categorisation of stages. It is more than likely that genital development also takes place in stages, with development completed as the individual approaches adulthood. Hence, an operation on evolving tissue risks an unstable result, leading to further genital operations. Given the fact that anatomy continues to change throughout life, the younger a person is when she begins genital cosmetic surgery, the greater the potential problem. Therefore, in addition to the general reasons for caution because of the lack of evidence concerning the effects of labiaplasty, it is strongly desirable that, if this procedure is to be undertaken, it is performed only once development has been completed, which is usually after the age of 18 years.

# 8. Advertising FGCS services/treatment

The lack of reliable data on the efficacy of labiaplasty for functional or cosmetic problems makes advertising for FGCS questionable. The GMC provides the following guidance concerning the advertising of medical services in its statement of good medical practice:<sup>27</sup>

'Communicating information

- You must be honest and trustworthy in all your communication with patients and colleagues. This means you must make clear the limits of your knowledge and make reasonable checks to make sure any information you give is accurate.
- When advertising your services, you must make sure the information you publish is factual and can be checked, and does not exploit patients' vulnerability or lack of medical knowledge.'

Similarly, the Advertising Standards Authority, in its Help Note on Cosmetic Surgery Marketing, states:<sup>28</sup>

'12. Marketers should not imply unrealistic claims.'

However, a recent study of current practices<sup>29</sup> shows that this guidance is systematically ignored at present.

#### 9. Ethical considerations

So far this document has identified a number of features of current labial reduction practices that raise serious concerns:

• There are as yet no controlled or prospective studies investigating the clinical effectiveness, the risks or the long-term outcomes of labiaplasty.

- The number of these procedures has increased in Britain (and elsewhere in the western world) very considerably in the last decade, in both the public and the private sectors.
- These procedures are increasingly advertised as being beneficial by private clinics, despite the lack of robust evidence concerning their benefits.
- The scope of these procedures is widening.
- They involve significant numbers of girls under the age of 18 years.

#### 10. Discussion

Taken together, these features suggest that cosmetic labial reduction procedures in general raise a significant ethical issue. Similar conclusions have been reached by other professional bodies, most notably the American College of Obstetricians and Gynecologists, whose Committee on Gynecologic Practice has observed that: 'Patients who are anxious or insecure about their genital appearance or sexual function may be further traumatized by undergoing an unproven surgical procedure with obvious risks. Women should be informed about the lack of data supporting the efficacy of these procedures and their potential complications, including infection, altered sensation, dyspareunia, adhesions, and scarring'. 30

In a recent consideration of the question 'Should female genital cosmetic surgery and genital piercing be regarded ethically and legally as female genital mutilation?', B. Kelly and C. Foster note that: 'Professional opinion on FGCS is changing. Internationally, a number of colleges of obstetricians and gynaecologists expressly discourage FGCS, being concerned about the motivation of the women seeking surgery, the efficacy and safety of these procedures and the potential to further traumatise patients who are anxious or insecure about their genital appearance or sexual function' [p.391].<sup>31</sup>

It should be recognised that the features listed in section 9 above apply to a number of forms of cosmetic surgery, and that FGCS requested electively by an adult for herself has obvious affinities with related types of cosmetic surgery, such as breast augmentation, that are currently not banned (despite the dangers that they may incur).

#### **II. Conclusions**

These considerations suggest that:

- The case for an outright ban on FGCS is weak. The main ground for such a ban would have to be that FGCS is generally harmful. If the evidence showed that the practice brings a high risk of significant harm to the women involved, with little benefit, this would be a strong reason for restricting procedures such as labiaplasty to situations where there is a clinical justification for it. However, the current evidence, such as it is, does not support this conclusion.
- The existence of the FGM Act in the UK, and the perceived overlap between FGCS and procedures prohibited under that Act, adds to the complications in this area. In part this is a matter for legal judgement, but there is also a similarity between the ethical concerns which, on the one hand, motivate the FGM Act and, on the other, lead to disquiet concerning the increasing practice of FGCS. However, there are significant differences, partly relating to the destructive nature of FGM, particularly of the clitoris, and the lack of consent in the mostly young girls who are subjected to FGM, who are removed from the decision-making process completely.

- In the case of FGCS, the recent increase in the number of labial reduction procedures, and the widening of the scope of such procedures, seems to be motivated by concerns about genital appearance and function that are not based on an informed understanding of the normal variations in the size and shape of female genitalia, but rather on norms taken from photographic material in the public domain. These so-called norms are often digitally modified and should be challenged by those who deal with women requesting labial reduction for 'aesthetic' reasons.
- An important question here is whether the desire for labial reduction is a type of displacement for other forms of anxiety or lack of feelings of self-worth, and thus whether counselling may be more appropriate than surgery. For this reason, the offer of counselling should be part of the process of obtaining informed consent.
- To avoid any misunderstanding when considering the issues which surround labiaplasty, it is worth emphasising the importance of distinguishing between situations in which a woman's labia give rise to functional problems that provide therapeutic grounds for the procedure, and situations in which there are no such functional problems and a woman's motivation for asking for labiaplasty is primarily concern about her genital appearance. Cases of the first kind do not give rise to any special ethical concerns beyond those that arise for any surgical procedure. It is cases of the second kind, where labiaplasty would be purely for aesthetic reasons that give rise to the concerns expressed above.
- Finally, while we have indicated the ethical considerations relating to the whole spectrum of FCGS, the place of such procedures within the NHS is even more limited. The Consultant Contract defines direct clinical care (for which consultants are employed) as work directly relating to the prevention, diagnosis or treatment of illness. It is difficult to conceive of many circumstances where FCGS would fall within this definition.<sup>32</sup>

#### 12. Recommendations

#### 12.1. Service developments and considerations for women

- Women requesting labiaplasty should be provided with accurate information about the normal
  variations in female genitalia and offered counselling and other psychological treatments for
  problems such as body image distress. Education, support and advice should be at the heart of
  clinical practice, with a sympathetic appreciation of female body insecurities.
- Healthcare professionals such as general practitioners and practice nurses should have access to accurate and sensitive teaching materials on genital variation.

#### 12.2. Responsibilities of the Royal College of Obstetricians and Gynaecologists (RCOG)

- At present, there are no web-based training materials for healthcare professionals who work
  with women outside the specialty of obstetrics and gynaecology, and such materials need to
  be developed. The RCOG should allocate some resources to providing this.
- FGCS, and the issues to which it gives rise, should be included in RCOG training materials.
- Although the RCOG is not a regulatory body, it should actively promote good clinical and ethical practice in all areas of practice of FGCS, which can be transposed across national boundaries.

- The RCOG, the British Association of Aesthetic Plastic Surgeons (BAAPS) and the Department of Health, advised by appropriate lawyers, should provide guidance concerning the potential overlap between FGCS and FGM.
- The RCOG and the British Association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS) should provide updated clinical guidance and standards to assist doctors working in this area within the UK, since most of this work is undertaken in the independent sector.

# 12.3. Recommendations for specialists

- Even though children aged 16 or over can consent to surgical procedures, FGCS should not normally be carried out on women and girls under 18 years of age, irrespective of consent, because full genital development is not normally achieved before the age of 18.
- Where FGCS such as labiaplasty is undertaken, patients must be informed about the risks of the procedure and the lack of reliable evidence concerning its positive effects.
- In order to be able to demonstrate compliance with the FGM Act and with good medical practice as defined by the GMC for the purposes of revalidation, it is essential that all surgeons who undertake FGCS keep written records of the physical and mental health reasons which, in their view, necessitate the FGCS procedures they carry out. They should also keep patient consent forms and details of the information provided to the woman about the treatment offered and provided.

#### 12.4. Recommendations for commissioners and providers of services

- Clear data about FGCS need to be collected in both the NHS and private clinics on incidence, age of patients, nature of surgery, reported reasons for surgery and patient follow-up.
- It is important that any advertising of labiaplasty or other FGCS procedures conforms to good medical practice and is subject to Advertising Standards Authority codes. Such advertising should not mislead people concerning what is normal or what is possible, and should include information about the lack of robust evidence concerning risks.
- The use of public resources in this area is a significant consideration. While provision for
  the therapeutic use of labiaplasty for clinical reasons is relatively unproblematic, providing
  labiaplasty for cosmetic reasons alone is not a proper use of public resources and should not
  be provided by the NHS.

#### 12.5. Responsibilities of commissioners, providers, specialists and the RCOG

 Further research is required, primarily to establish normal variation for external genitalia and to set objective measures for the success and long-term risks of FGCS procedures, in particular labiaplasty.

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