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REVIEW ARTICLE

A systematic review of the evidence on clitoral reconstruction after female genital mutilation/cutting

Jasmine Abdulcadir [a,b,*], Maria I. Rodriguez [a], Lale Say [a]

[a] Department of Reproductive Health and Research, World Health Organization, Geneva, Switzerland
[b] Department of Obstetrics and Gynecology, Geneva University Hospitals, Geneva, Switzerland

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ABSTRACT

Background: Clitoral reconstruction is a new surgical technique for women who have undergone female genital mutilation/cutting (FGM/C). *Objectives:* To review evidence on the safety and efficacy of clitoral reconstruction. *Search strategy:* PubMed and Cochrane databases were searched for articles published in any language from database inception until May 2014. Search terms related to FGM/C and clitoral reconstruction were used in various combinations. *Selection criteria:* Studies of any design that reported on safety or clinical outcomes (e.g. appearance, pain, sexual response, or patient satisfaction) associated with clitoral reconstruction after FGM/C were included. *Data collection and analysis:* Evidence was summarized and systematically assessed via a standard data abstraction form. *Main results:* Four of 269 identified articles were included. They were fair to poor in quality. Summary measures could not be computed owing to heterogeneity. The studies reported on immediate surgical complications, clitoral appearance, dyspareunia or chronic pain, and clitoral function postoperatively via non-standardized scales. *Conclusions:* Women who request clitoral reconstruction should be informed about the scarcity of evidence available. Additional research is needed on the safety and efficacy of the procedure to identify both long-term outcomes and which women might benefit.

1. Introduction

Clitoral reconstruction is a relatively new surgical technique that was first described by Thabet and Thabet [1], and subsequently by others [2–7]. It has been reported to be a feasible and effective strategy to reduce clitoral pain and improve sexual pleasure among women who have undergone female genital mutilation/cutting (FGM/C) [2].

In African and high-resource countries, clitoral reconstruction is increasingly advertised by the media as a strategy to restore sexual pleasure and female identity, completeness, and dignity. In France, the procedure has been covered by the national health insurance since 2004 to improve the sexuality, physical appearance, and pain of women with FGM/C, and thousands of women have undergone the surgery [2]. In Burkina Faso, there have been clitoral reconstruction campaigns [6,8–12], including the building of hospitals dedicated to this procedure [8–12]. Elsewhere, funding collections have been raised to open centers of reconstructive surgery in Africa, Europe, Asia, and the USA [13].

Despite the interest, advertising, and enthusiasm for this surgery, clitoral reconstruction has not been widely investigated or adequately evaluated for safety and efficacy outcomes. Indeed, no official guidelines or recommendations exist on clitoral reconstruction, which has important surgical, psychosexual, and cultural implications [14]. Some FGM/C experts have expressed concerns about the psychological outcome, psychiatric morbidity, and potential harmful consequences of the surgery [15,16].

Women's sexuality is multifactorial and depends on the interaction of anatomic, biochemical, neurophysiological, cognitive, relational, cultural, and social and contextual factors [17,18]. The impact of the different types of FGM/C on sexuality and orgasm is still unclear [19]. Furthermore, surgical interventions are not without risk: a thorough understanding of the safety and efficacy of clitoral reconstruction and of the best care to offer is needed before services can be scaled up. Therefore, the aim of the present study was to review evidence on the safety and outcomes of clitoral reconstruction.

2. Materials and methods

The present systematic review was conducted by following the PRISMA guidelines [20]. The available literature on clitoral reconstruction after FGM/C was identified by searching the PubMed and Cochrane databases for articles published in any language from the inception of each database to May 31, 2014. The search terms used were "female genital mutilation", "female genital cutting", "female genital surgeries", "FGM", "FGC", "FGM/C", "clitoris", "defibulation", and "clitoral

* Corresponding author at: 30 Bld de la Cluse, 1211 Geneva, Switzerland. Tel.: +41 223826816; fax: +41 223724146.
E-mail address: jasmine.abdulcadir@hcuge.ch (J. Abdulcadir).

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reconstruction". The terms were used in various combinations. To identify additional studies, the bibliographies of retrieved studies were manually reviewed.

Studies that reported on the safety or clinical outcomes (e.g. appearance, pain, sexual response, or patient satisfaction) associated with clitoral reconstruction after FGM/C were included. Studies reporting on clitoral surgery not associated with FGM/C were excluded. All study designs were eligible.

All authors participated in summarizing and systematically assessing the evidence via the use of standard data abstraction forms. The quality of each individual piece of evidence was assessed by using the United States Preventive Services Task Force (USPSTF) grading system (Tables 1 and 2) [21,22]. The USPSTF system considers both the quality of the individual study and the body of evidence as a whole. For each individual study, the USPSTF grade considers study design (Table 1) and the internal validity of the study (Table 2). Internal validity is a measure of how well the study was conducted and is scored as good, fair, or poor (Table 2).

The presence of heterogeneity with respect to study design, population characteristics, study population recruitment, extent of loss to follow-up, and outcome measure definitions did not allow the computation of summary measures of association for the outcomes of studies included in the review.

3. Results

3.1. Identified studies

The search yielded 269 articles, of which four met the inclusion criteria [1–4]. One was a case–control study [1] and the other three were cohort studies of the safety and efficacy of clitoral reconstruction [2–4] (Table 3). The four studies reported data for a range of outcomes including clitoral appearance, improved clitoral function, dyspareunia and/or chronic vulvar pain, and orgasm and/or clitoral pleasure.

3.2. Safety

Three studies [2–4] reported on short-term surgical complications, such as hematoma, wound breakdown, or fever. In the largest cohort study of 2938 women [2], immediate complications after surgery were noted for 155 (5.3%) patients, and 108 (3.7%) were readmitted to hospital. In the case series of 453 women from France [4], complications were reported for 107 (23.6%) women, with a reoperation rate of 3.7% and a readmission rate of 5.3%.

In the cohort of 94 women [3], immediate complications were reported for 22 (23.4%) patients. Four women with wound dehiscence underwent a second operation. Two long-term complications were reported at 6 months: one woman developed a keloid scar and one developed hyperesthesia of the clitoris [3]. No mortality or life-threatening morbidity was reported.

Table 1
Levels of evidence according to the United States Preventive Services Task Force [21,22].[a]

Level	Origin of evidence
I	Evidence obtained from at least one properly designed randomized controlled trial
II-1	Evidence obtained from well designed controlled trials without randomization
II-2	Evidence obtained from well designed cohort or case–control analytic studies, preferably from more than one center or research group
II-3	Evidence obtained from multiple time series with or without the intervention Marked results in uncontrolled experiments might also be regarded as this type of evidence
III	Opinions of respected authorities on the basis of clinical experience, descriptive studies, or reports of expert communities

[a] Reproduced from Harris et al. [21], by permission of Elsevier.

Table 2
Criteria for evaluating the internal validity of individual studies according to the United States Preventive Services Task Force [21].[a]

Study design	Criteria
Systematic reviews	▪ Comprehensiveness of sources and search strategy used ▪ Standard appraisal of included studies ▪ Validity of conclusions ▪ Recentness and relevance
Case–control studies	▪ Accurate ascertainment of cases ▪ Non-biased selection of cases and controls with exclusion criteria applied equally to both ▪ Response rate ▪ Diagnostic testing procedures applied equally to each group ▪ Appropriate attention to potential confounding variables
RCTs and cohort studies	▪ For RCTs: adequate randomization, including concealment and whether potential confounders were distributed equally among groups ▪ For cohort studies: consideration of potential confounders with either restriction or measurement for adjustment in the analysis; consideration of inception cohorts ▪ Maintenance of comparable groups (includes attrition, crossovers, adherence, or contamination) ▪ Important differential loss to follow-up or overall high loss to follow-up ▪ Measurements: equal, reliable, and valid (includes masking of outcome assessment) ▪ Clear definition of interventions ▪ All important outcomes considered ▪ Analysis: adjustment for potential confounders for cohort studies, or intention-to-treat analysis for RCTs
Diagnostic accuracy studies	▪ Screening test relevant, available for primary care, adequately described ▪ Study uses a credible reference standard, performed irrespective of test results ▪ Reference standard interpreted independently of screening test ▪ Handles indeterminate results in a reasonable manner ▪ Range of patients included in study ▪ Sample size ▪ Administration of reliable screening test

Abbreviation: RCT, randomized controlled trial.
[a] Reproduced from Harris et al. [21], by permission of Elsevier.

3.3. Postoperative clitoral appearance

Three of the studies reported whether a visible or palpable clitoris was restored postoperatively [2–4]. Clitoral appearance was categorized as a normal clitoris, hoodless glans, visible projection, palpable projection, or no change. In the largest cohort study [2], 28% of women for whom 1-year results were available had a normal clitoral appearance at this stage. In the other cohort from France [4], 21% had a normal clitoral appearance at 6 months of follow-up. In the third study [3], 3 (3.2%) of 94 patients had a normal clitoral appearance at 6 months.

All three studies were limited by high loss to follow-up (ranging from 22% to 79%) and the fact that a subjective, non-validated scale was used to assess clitoral appearance [2–4]. Furthermore, outcomes were assessed by the operating surgeon, leading to a potential source of bias [2–4].

3.4. Chronic vulvar pain or dyspareunia

Pain was evaluated differently in each study. In the largest cohort [2], dyspareunia and chronic vulvar pain were assessed. Preoperatively, 28 (3%) of 840 women reported pain without sexual intercourse, and 202 (24%) reported moderate-to-severe pain with intercourse. Among women who had pain without intercourse at baseline, 14 (50%) reported at least slight improvement in their symptoms at 1 year of follow-up. Among women reporting moderate-to-severe dyspareunia, 99 (49%) reported at least slight improvement at 1 year of follow-up [2].

In another cohort study [4], 17 (4%) of 453 women reported pain without sexual intercourse at baseline. Another 116 (25%) had moderate-to-severe dyspareunia preoperatively. Postoperative assessment of pain was not reported.

Table 3
Clitoral reconstruction outcomes.

Author,year	Study design and population	Intervention and follow-up	Results	Strengths	Weaknesses	Quality
Thabet and Thabet, 2003 [1]	Case–control study at one center in Egypt (n = 147) Group 1: controls (n = 30) Group 2: FGM/C type I (n = 30) Group 3: FGM/C type II/III (n = 30) Group 4: FGM/C of any type with associated clitoral cysts (n = 57)	Groups 1 and 2: no intervention Group 3: clitoral reconstruction Group 4: clitoral reconstruction and excision of a clitoral cyst (30/57)[a] Follow-up at 6 months	Safety: not reported Postoperative clitoral appearance: not reported Chronic pain/dyspareunia: not reported Clitoral function: baseline/preoperative mean questionnaire score for sexual function/orgasm 82.2 ± 1.5 in group 1, 78.9 ± 1.7 in group 2, 65.6 ± 1.7 in group 3, 76.8 ± 2.0 in group 4; postoperative mean score 80.5 ± 1.7 in group 3 ($P < 0.001$), 63.0x ± 1.1 in group 4 with cyst excision alone ($P < 0.001$), 79.0 ± 1.1 in group 4 with cyst excision and clitoral reconstruction ($P > 0.05$)	Inclusion of a control group	No sample size calculation No data on the different types of FGM/C Vulvar pain not explored Non-validated questionnaire Unknown loss to follow up Unclear comparisons between groups	II-2 Poor
Foldès et al., 2006 [4]	Prospective cohort at one center in France (n = 453) FGM/C type II or III (frequency of each type not reported)	Clitoral reconstruction Follow-up at 6 months	Safety: 23.6% (n = 107) had complications; 3.7% (n = 17) required reoperation; 5.3% (n = 24) required readmission Postoperative clitoral appearance: 37% (n = 168) had hoodless glans; 21% (n = 97) had "almost normal clitoris" Chronic pain/dyspareunia: 4% (n = 17) pain without sexual intercourse and 25% (n = 116) moderate-to-severe dyspareunia preoperatively; not reported postoperatively Clitoral function: 19% (n = 84) slightly improved; 32% (n = 146) significantly improved without orgasms and 29% (n = 130) significantly improved with occasional orgasms; 14% (n = 65) normal clitoral function	–	Non-validated scales with no clear definition of categories Results reported by surgeon Surgical outcome evaluated as "clitoral function" instead of pain, pleasure, orgasm, etc. No data for the outcome of symptoms such as dyspareunia or chronic vulvar pain Unknown loss to follow up No statistical comparisons	II-3 Poor
Foldès et al. 2012 [2]	Prospective cohort at one center in France (n = 2938) FGM/C type III (n = 146) FGM/C type II (n = 2792) Clitoral pain and functionality evaluated at 1 year for 840 and 834 women, respectively	Clitoral reconstruction Follow-up at 1 year	Safety: 5.3% (n = 155) had complications; reoperation rate not reported; 3.7% (n = 108) required readmission Postoperative clitoral appearance: 42% (363/866) had hoodless glans; 28% (239/866) had normal clitoral appearance Chronic pain/dyspareunia: 3% (28/840) had pain without intercourse and 24% (202/840) had moderate-to-severe pain with sexual intercourse preoperatively; 50% (14/28) reported a slight or real improvement in pain without intercourse and 49% (99/202) reported a slight or real improvement in moderate-to-severe dyspareunia postoperatively Clitoral function: 430 women reported "restricted or regular" orgasm postoperatively; 129 of 368 who had never experienced orgasm reported "restricted" or "regular" orgasms after surgery; 51 of 97 who had had "restricted orgasms" preoperatively reported an improvement after surgery; 12 of 53 women who had experienced regular orgasm reported an orgasm of reduced intensity after surgery	–	Non-validated scales with no clear definition of categories Results reported by surgeon 71% loss to follow-up at 1 year Outcomes reported inconsistently among population	II-3 Poor
Ouédraogo et al. 2013 [3]	Prospective cohort at one center in Burkina Faso (n = 94) FGM/C type II (n = 89) FGM/C type III (n = 5)	Clitoral reconstruction Follow-up at 6 months	Safety: 23.4% (n = 22) reported immediate complications; 4.2% (n = 4) required reoperation; readmission rate not reported; 2.1% (n = 2) had long-term complications Postoperative clitoral appearance: 3.2% (n = 3) had normal clitoral appearance; 71.3% (n = 67) satisfied with appearance of the neoglans Chronic pain/dyspareunia: 39.4% (n = 37) had dyspareunia and 5.4% (n = 5) had superficial dyspareunia preoperatively; not reported postoperatively Clitoral function: 5.3% (n = 5) reported slight improvement; significant improvement without orgasms reported by 14.8% (n = 14) and with occasional orgasms by 36.2% (n = 34); 38.3% (n = 36) reported normal clitoral function; no significant difference in orgasm before and after clitoral reconstruction ($P = 0.446$)	–	Non-validated scales with no clear definition of each category Results reported by surgeon Patient satisfaction reported without explaining how satisfaction was evaluated Surgical outcome evaluated as "clitoral function" instead of pain, pleasure, orgasm, etc. No data concerning the outcome of single symptoms Unknown loss to follow-up	II-3 Poor

[a] Not specified why only 30 of the 57 women received the intervention.

Lastly, the case series from Burkina Faso reported baseline rates for both dyspareunia and clitoral pleasure [3]. Preoperatively, moderate-to-severe dyspareunia was noted for 37 of 94 women. Postoperative assessment of pain was not reported separately from clitoral stimulation, limiting interpretation of results.

3.5. Clitoral function

The case–control study from Egypt [1] investigated the sexual function of women without FGM/C, women with FGM/C types II and III, and women with any type of FGM/C who had an associated clitoral cyst. A baseline assessment of sexual function was compared with follow-up data at 6 months after surgery. The questionnaire included data on "the state of the external and internal genitalia, the state of femininity, the level of genital and sexual knowledge, sexual desire and arousal, orgasm and sexual satisfaction" [1]. The responses were used to generate a score out of 100. No definition of "normal" was given for the responses pertaining to anatomy and femininity.

At 6 months after surgery, the scores had improved significantly among women with FGM/C type II/III who underwent clitoral reconstruction ($P < 0.001$) and non-significantly among those with FGM/C of any type who underwent excision of a clitoral cyst and clitoral reconstruction (Table 3). It is not known in which category of the questionnaire (e.g. anatomy knowledge or sexual satisfaction) that the scores changed. The clinical relevance of the scores is unknown.

Three studies reported measures of clitoral function as assessed by orgasm, sexual pleasure, or desire [2–4]. All three studies used a five-point, non-validated scale to assess clitoral pleasure. In terms of clitoral pleasure, women were categorized as never (no sensation), minor sensation, pleasant without orgasm, restricted orgasm (orgasm with less intensity than wished), and regular orgasm ("normal" orgasm). No definition of "normal" orgasm was given.

Foldès et al. [2] reported that 385 (46%) of 834 women had a slight or real improvement in clitoral pleasure 1 year after surgery and 430 (51%) women described experiencing restricted (n = 255) or normal (n = 175) orgasms at 1 year of follow-up [2]. Among 53 women who had experienced regular orgasms preoperatively, however, 12 reported a reduction in intensity after surgery [2].

Another cohort study [4] reported that 173 (38%) of 453 women had never experienced clitoral pleasure, whereas 10 (2%) had restricted or normal orgasms at baseline. Postoperatively, 230 (51%) endorsed slight or real improvement in clitoral pleasure, without orgasm. Another 195 (43%) patients described having restricted/occasional orgasms (n = 130) or normal orgasms (n = 65) [4]. The study was limited by the absence of statistical comparisons.

Ouédraogo et al. [3] reported data on preoperative sexual desire and clitoral pleasure in their case series. At baseline, 41.5% (39/94) of participants reported never feeling any sexual desire [3]. With respect to clitoral pleasure, 54.3% (51/94) described no sensation, whereas 12.7% (12/94) had restricted or regular orgasms [3]. After surgery, only 5.3% (5/94) of women reported no sexual desire. The study was also limited by the absence of statistical comparisons.

Interpretation of the findings from the three cohort studies is limited by the use of non-validated scales and the fact that the results were recorded by the operating surgeon [2–4], which introduces two potential sources of bias to all three studies.

4. Discussion

The present study has systematically reviewed published studies on clitoral reconstruction—a practice that is growing in popularity. A limited amount of poor evidence is available on clitoral reconstruction after FGM/C. There is a need for more robust evidence on safety and efficacy before this surgery is widely disseminated. Data that identify how therapy—either alone or in combination with surgery—can improve psychosexual outcomes for women living with FGM/C is urgently needed. An improved understanding of how this surgery affects gender identity, pain, and sexual pleasure is required to identify the women who might benefit from it, and those for whom alternative therapy is indicated.

Three of the studies included in the present review [2–4] were limited by not having a comparison group. All the studies [1–4] are limited by a large or unknown loss to follow-up in the cohort, and by a follow-up period of 1 year or less. There are additional key limitations in how the studies evaluated and reported outcomes. Some assessed the anatomic postoperative result only from the surgeon's point of view [2–4], and studied preoperative and postoperative pain [2–4], orgasm, and clitoral pleasure [1–4] by empirical, non-validated scales. Although three studies [2–4] endorse the importance of multidisciplinary psychosexual care, the women included in them were evaluated, treated, and followed up only by the surgeon. The reports stated that the surgeon might refer some women to a psychologist, psychiatrist, or sexologist to assist with their care when deemed necessary; however, no data were reported on the number of women who asked for, were offered, or accepted psychosexual therapy [2–4]. None of the four studied evaluated the impact of sexual therapy and education (on reducing pain or improving sexual outcomes), either alone or in association with clitoral reconstruction.

Female sexuality is multifactorial, and clitoral reconstruction has surgical, sociocultural, gender, anthropologic, and psychosexual implications. It is crucial to associate and study the effects of psychosexual care and education on female physiology, anatomy, and sexuality [14]. Resection of the clitoral fibrosis and easier access to the clitoris might potentially improve pleasure and pain; however, existing data are inconclusive [14]. Gender identity and body image also play a determinant role in sexuality, and these interactions need to be investigated and addressed within the context of this surgery. A study of the histology of the peri-clitoral scar removed during surgery might clarify whether the resection of eventual post-traumatic granulomas and neuromas can resolve chronic clitoral pain. Such data might help to determine which women would benefit from surgery.

Current advertising campaigns are generating a considerable demand for clitoral reconstruction, despite the absence of conclusive evidence regarding its benefits or absence of harm. The impact of the different types of FGM/C on sexuality and orgasm is still unclear [19]. Young women, who might not even have started their sexual life, might assume that they need the surgery both to be "normal" and to have sexual pleasure. Basic anatomy lessons and sexual therapy could have an important role to play. Many women with FGM/C and their partners do not know that most of or even the whole clitoris is under the scar and can be stimulated. They could think that they do not have sexual pleasure only because they have been cut, or they could assume that, when sexual pleasure is present, their intercourse is less satisfying than is that of uncut women [14].

Further studies—ideally prospective, multicenter, comparative trials—should focus on preoperative and postoperative sexual desire, sexual pleasure, orgasm, vulvar pain, self body image, and gender identity. Validated or standardized tools should be implemented and used. Assessment of the surgery should include long-term follow-up of women who have and have not undergone the procedure. Preoperative expectations, self-anatomy, and physiology knowledge and beliefs, in addition to postoperative satisfaction, should be explored [14]. Robust evidence is needed to evaluate the efficacy and long-term outcomes of this surgery.

In summary, women who want to undergo clitoral reconstruction should be informed about the scarcity of evidence that is available on improved outcomes. A better understanding of how both surgery and sexual therapy with anatomy lessons might improve sexuality and body image is necessary. A comprehensive, evidence-based approach that does not contribute to stigmatization of women and girls living with FGM/C is needed to provide optimal care.

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Conflict of interest

The authors have no conflicts of interest. M.I.R. and L.S. are WHO staff members. The views expressed here are solely the responsibility of the authors and do not necessarily represent the views of WHO or its member countries.

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