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### **REVIEW ARTICLE**

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



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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.

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#### 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

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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

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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
	Ι	Evidence obtained from at least one properly designed randomized
		controlled trial

- II-1 Evidence obtained from well designed controlled trials without randomizationII-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

<sup>a</sup> 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].<sup>a</sup>

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

Administration of reliable screening test

Abbreviation: RCT, randomized controlled trial.

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#### 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.

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