



Wilson's Workshop

# Patient selection protocol for the Penuma® implant: suggested preoperative evaluation for aesthetic surgery of the penis

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Penuma is a soft silicone, subcutaneous penile implant indicated for the aesthetic improvement of penile appearance in men who have retractile penis, mild penile indentation deformities, inadequate girth, and other related irregularities. Proper patient selection for any surgical procedure, particularly in aesthetics, is critical to ensure realistic patient expectations and successful outcomes. Patient selection for the Penuma implant involves a comprehensive, rigorous protocol, which, if properly followed, is more likely to result in a satisfied patient.

The spirit of our evaluation could be summed up in Wilson's wise admonition, "never implant a stranger" [1]. Patient selection for the Penuma implant considers the patient's health status, history of the underlying issue(s) for which he seeks help, and the complexity of his particular habitus. Most importantly we seek assessment of his psychological state, particularly perceived body image distortion, including small penis anxiety and penile dysmorphic disorder (PDD), which is a variant of body dysmorphic disorder (BDD) [2] Patients with BDD have consistently been identified as having a higher likelihood of unsatisfactory outcomes from most aesthetic surgeries [3–8].

To help potential patients make an informed decision, detailed information about the Penuma procedure is provided (e.g., possible risks, complications, benefits and

alternatives, including no surgery). Patients are then evaluated based on psychological and physical factors through phone and virtual consultations, in-office visits, and mandatory self-reported questionnaires. We review reports from other specialists and may refer the patient to other medical evaluators. Our goal is to ensure all patients are fully informed and physically and mentally qualified. If any evaluation gives pause, the patient is returned for more visits, referred out for third-party evaluation, or informed of his noncandidacy.

## Patient physical factors

The physical factors discussed in this section may increase the chance of complications, but do not automatically exclude a patient from undergoing surgery. Rather, they factor into an analysis weighing the risks and benefits of surgery.

The three initial physical factors include:

- (1) Previous penile enhancement surgery: Any previous surgery for penile enhancement, such as those involving Polymethyl methacrylate, hyaluronic acid, AlloDerm, dermal graft, and fat injection, is considered an exclusion criterion. Based on our extensive experience, these surgeries often result in excess scar formation, poor skin quality, delayed and prolonged recovery, and increased risk of infection and skin perforation.
- (2) Circumcision: Given the girth enhancement following the Penuma insertion, circumcision is required as the foreskin in uncircumcised patients may not retract even in the flaccid state. Patients who are uncircumcised must be circumcised and completely healed before the surgery.
- (3) Use of any tobacco products: All patients must refrain from smoking/tobacco use months before and after surgery. Tobacco use is associated with higher risk

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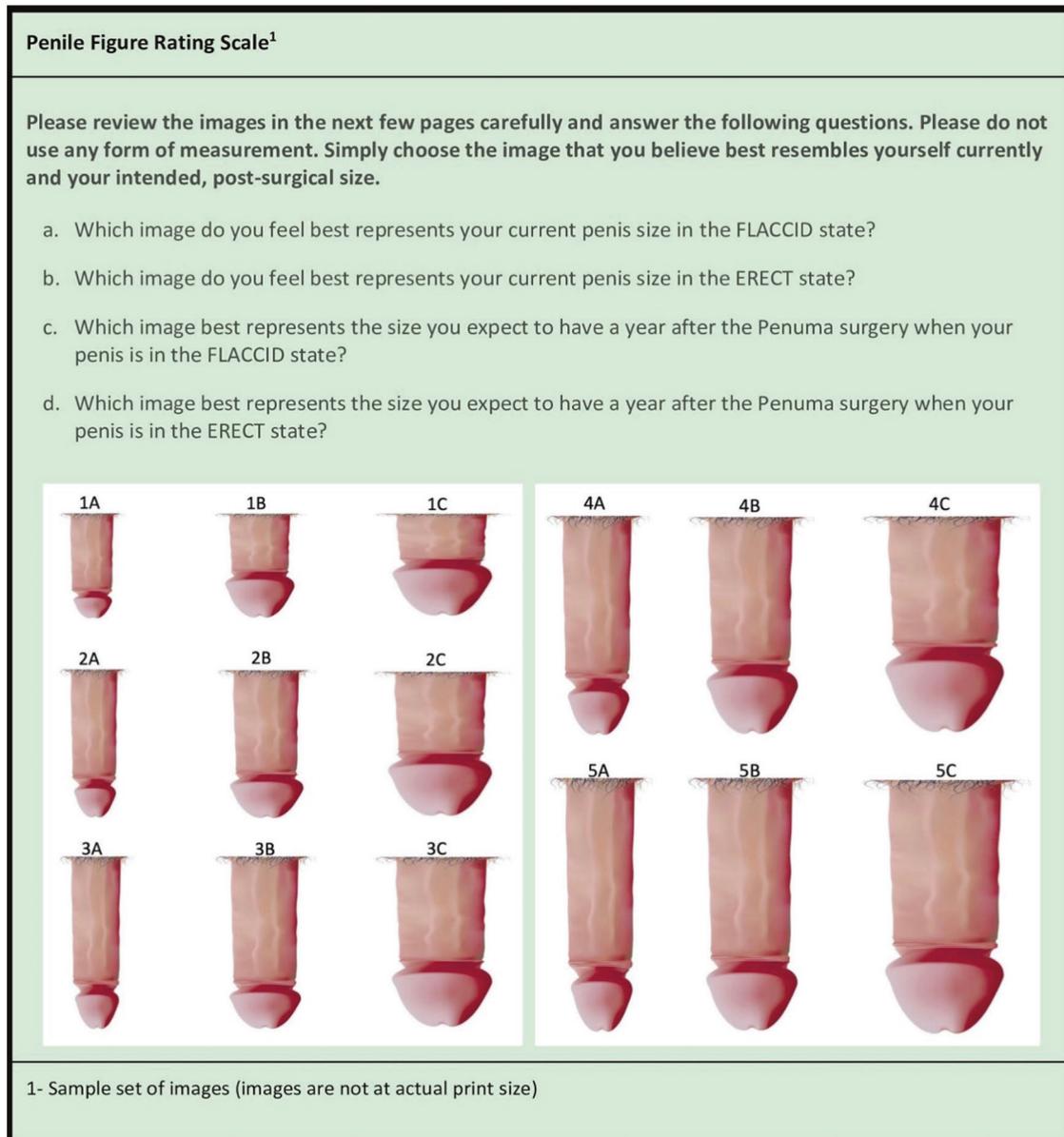
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**Fig. 1** A figure rating scale from the original Stunkard Figure Rating Scale [14], which helps assess the patient's perception of body image and levels of realistic patient expectation.

anaesthesia, poor wound healing, surgical site infection, excessive scar formation, and significantly higher overall complications [9, 10].

### Ancillary physical evaluation

- (1) Every candidate is evaluated for comorbid conditions such as uncontrolled diabetes, previous penile aesthetic surgery, and sexually transmitted infection. The

patient may be excluded from the surgery, the surgery may be postponed, or the patient may be referred to appropriate specialist(s) for further evaluation and clearance.

- (2) A set of medications may increase the likelihood for perioperative complications, such as blood thinning medications, or may interact with postoperative medications, such as Lisinopril that may have serious interactions with trimethoprim/sulfamethoxazole. Accurate and detailed medication history is taken from all patients, and alteration of medication usage may be required.

- (3) Drug or alcohol abuse can increase the risk of perioperative complications and may impair the patient's postoperative behaviour. These patients are referred to mental health professionals for evaluation and counselling prior to aesthetic surgery.
- (4) Evaluation of genital skin health and quality, skin elasticity, skin lesions, retractile penis, buried penis, and other genitalia abnormalities are conducted through detailed physical examination. Any anatomical abnormality, skin lesion, skin or soft tissue attachments, scar tissue or fibrosis is addressed appropriately and may decrease the likelihood of a patient's candidacy for surgery. Photographs are taken to document preoperative appearance.

## Patient psychological factors

Identification of patient objectives and expectations is critical. Candidates are evaluated for psychological appropriateness through:

- (1) Several validated questionnaires help evaluate the subject's self-image, distress level, functional impairment, and BDD. These questionnaires include the Cosmetic Procedure Screening Scale for PDD [2], BDD Modification of the Yale-Brown OCS [11], Belief About Penis Size Questionnaire [12], and the Male Genital Self-Image Scale [13]. Based on the clinic's review of the patient's responses, patients may be referred to a mental health professional to assess psychological appropriateness for the surgery.
- (2) A figure rating scale (Fig. 1) from the original Stunkard Figure Rating Scale [14] helps assess the patient's perception of body image and levels of realistic patient expectation. Examples of penises varying in girth and length are presented. Patients choose the figures that most closely resemble their (a) current flaccid and erect penis and (b) expected postoperative flaccid and erect penis. The discrepancy between the patient's perceived size in the figures and the actual size measured by physical examination may represent body image misperception. Patients with significant discrepancies (e.g., actual penile measurement of 4" in length by 4" in circumference vs. a patient's perception of 2" by 2") are referred to a mental health professional for evaluation, clearance or exclusion from surgery. Moreover, should the test reveal unrealistic patient expectations, he may be excluded from surgery if the out of reach expectations cannot be corrected through education.
- (3) The risk of patient postsurgical dissatisfaction and the patient's psychological capacity to cope with any potential postoperative scenarios are assessed by the surgeon and other medical staff throughout the selection process. This assessment is based on the previously published mnemonic, "CURSED Patient", which describes patients undergoing penile prosthesis surgery who are at a high risk for dissatisfaction [15, 16].

## Conclusion

The process of patient selection for the Penuma surgery, from initial evaluation to a final decision by both the clinic and the patient, can take weeks, and even months. Experience dictates us to never implant a stranger. We get to know the patient, and as Wilson says, "just because he wants one does not mean he gets one" [1].

## Compliance with ethical standards

**Conflict of interest** SKW is consultant for International Medical Devices. LL and RW are participants in a clinical investigation for International Medical Devices. JJE is the inventor of Penuma and owner of International Medical Devices.

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