Informed Consent for Reconstructive Pelvic Surgery

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KEYWORDS

• Informed consent • Urogynecology • Vaginal mesh • Female reconstructive surgery

KEY POINTS

- Informed consent is the process in which a patient makes a decision about a surgical procedure or medical intervention after adequate information about the procedure is relayed by his or her physician and understood by the patient.
- In the current medical legal environment, it is important to be well versed in obtaining valid informed consent for routine cases and for more complex procedures. This is critical for reconstructive pelvic surgeries particularly with the advent of vaginal mesh complications.
- In this article, we review the principles of informed consent, the pros and cons of different approaches in reconstructive pelvic surgery, and the current legal issues surrounding mesh use for vaginal surgery, and incorporate this information when consenting patients pelvic floor surgery.

The legal principle of informed consent before surgery was highlighted in a landmark case in the early 1900s in *Schloendorff v Society of New York Hospital*, in which a surgeon performed a hysterectomy without patient informed consent because of a concern for malignancy. Justice Benjamin Cardozo famously stated: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits assault for which he is liable in damages."[1]

Although *Schloendorff v Society of New York Hospital* exemplifies an extreme case, the principles derived from this case are still applicable today. Informed consent is the

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process in which a patient makes a decision about a surgical procedure or medical intervention after adequate information about the procedure is relayed by the physician and understood by the patient. Informed consent highlights the process of shared decision-making in the patient-provider relationship. In the current medical legal environment, it is important to be well versed in obtaining valid informed consent for routine cases and for more complex procedures.

Most reconstructive pelvic surgeries are elective, nonemergent, and aimed at improving quality of life, but still carry inherent material risks. Patients should have a good understanding of these risks and make a balanced decision between accepting the risks of surgery with the prospect of improvement in quality of life. The current controversy over the use of mesh in pelvic floor surgery poignantly exemplifies the importance of obtaining proper informed consent and is a topic that can be difficult to broach with patients. In this review, we aim to address fundamentals of obtaining general surgical consent and, specifically in the context of pelvic reconstructive surgery, choosing which type of reconstructive surgery is most appropriate for which patient, deciding when mesh use may be appropriate, discussing alternative treatments, and documenting the consent process.

OBJECTIVES

1. To list principles of informed consent
2. To acknowledge current legal issues associated with mesh use and discussion points related to informed consent.

INFORMED CONSENT

In 2009, the Committee of Ethics of the American College of Obstetricians and Gynecologists articulated 8 fundamental concepts about informed consent that should be applied to any surgery, including pelvic floor reconstructive surgery, summarized as follows[2]:

- "Obtaining informed consent for medical treatment, for participation in medical research, and for participation in teaching exercises involving students and residents is an ethical requirement that is partially reflected in legal doctrines and requirements."
- "Seeking informed consent expresses respect for the patient as a person."
- "Informed consent not only ensures the protection of the patient against unwanted medical treatment, but it also makes possible the patient's active involvement in her medical planning and care."
- "Communication is necessary if informed consent is to be realized, and physicians can and should help to find ways to facilitate communication not only in individual relations with patients but also in the structured context of medical care institutions."
- "Informed consent should be looked on as a process rather than a signature on a form."
- "Physicians should make every effort to incorporate a commitment to informed consent within a commitment to provide medical benefit to patients."
- "When informed consent by the patient is impossible, a surrogate decision maker should be identified to represent the patient's wishes or best interests."
- "Physicians should acquaint themselves with federal and state requirements for informed consent. Physicians also should be aware of the policies within their own practices because these may vary from institution to institution."