

Complications of Urogynecology and Reconstructive Pelvic Surgery

Howard B. Goldman
Jacqueline Zillioux
Editors

Third Edition



Springer

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*With deep appreciation to all of my former and current fellows,
residents, and visiting observers.
I hope you have learned as much from me as I have learned
from you.*

Howard B. Goldman, M.D., F.A.C.S

To my husband Alan, whose support and love are my bedrock.

Jacqueline. Zillioux, M.D.

Forewords from the Second Edition

First Foreword

This second edition of Dr. Howard Goldman's *Complications of Female Incontinence and Pelvic Reconstructive Surgery* updates the outstanding first edition which included a multinational authorship related to those issues of quality and safety that are pertinent to female pelvic surgical reconstruction. The second edition updates the first edition by including discussions related to specific procedures, but also more global issues related to surgical reconstruction and risks thereof associated. The first chapter of the book summarizes taxonomic classifications for complications both generally and specifically. The next two chapters—Patient Consent and Perception of Complications and Medical Malpractice—define the importance of the engaged and informed patient and the issues surrounding the importance of obtaining appropriate informed consent from the standpoint of avoiding medical–legal concerns. The last general chapter deals with Medical and Other Types of Complications Related to Pelvic Surgery (and in fact inherent to all surgeries). Following these first four chapters, there then follow chapters on various prolapse repair concerns followed by incontinence concerns and finally specific issues related to management of other lower urinary tract symptom complexes and/or anatomic abnormalities.

It is abundantly clear that surgery is only one aspect of approaching complex female disorders. There is an extremely important presurgical time frame which not only involves the subjective and objective estimation of the patient's condition, bother, and ongoing life burden but also involves the objectification of those symptoms through appropriate, focused, and informed testing which will help the surgeon in his or her preplanning for the surgical procedure. There has been a great deal of discussion and research into the value of certain types of testing modalities (i.e., urodynamics). It is incumbent upon the surgeon, for the unique patient, to make the appropriate choice of objective testing. The wary surgeon is cautioned that operating for symptoms only is fraught with the potential of not completely understanding what is causing those symptoms and complicating the initial symptoms with secondary symptoms arising from surgical intervention. Preoperative preparation, education, and realistic expectation setting are critical for not only the perioperative time frame but also the chronic postoperative time frame where the patient experiences (we hope) some resolution or improvement of their

symptoms. Part of urologic pelvic reconstruction is the acknowledgement that rarely is success equivalent to cure but rather remediation and improvement. The successful surgeon is one who counsels his or her patient that they are embarking upon a journey together which hopefully will result in overall improvement, but that the surgeon will stand by their patient regardless of outcome for purposes of helping chronically manage any persistent and/or new conditions that may arise as a direct result of treatment for the initial inciting condition.

This book is a very important contribution and should be used by all who venture into the world of pelvic reconstruction for purposes not only of self-education and edification but also of guidance given the authorities who are listed in this book and their expertise in the various areas of concern.

This text should serve as a fundamental reference book for not only those in training but also those who have mature careers who are looking for a rapid update on specific issues related to female incontinence and pelvic reconstructive surgery and complications resulting therefrom. I personally find this book an outstanding resource. I hope that you will too.

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Roger R. Dmochowski

Second Foreword

Female Pelvic Medicine and Reconstructive Surgery (FPMRS) has made significant strides in the last decade, including official subspecialty designation by the American Board of Medical Specialties and an ever expanding armamentarium for treating women with urinary incontinence, pelvic organ prolapse, and other pelvic floor disorders. As pelvic reconstructive surgeons, our goal is to perform safe and effective procedures that improve the quality of lives of women suffering from these disorders. Avoiding and, when necessary, effectively managing perioperative complications are essential goals, particularly in this era of Quality and Safety. The FDA's 2011 public health notification on transvaginal mesh and the resultant media and medico-legal storm has heightened patients' awareness of the potential for surgical complications and made comprehensive knowledge of informed consent, patient selection, and avoiding, recognizing and managing mesh-related complications all the more important. No one understands this better than Howard Goldman, M.D., Vice Chair of Quality and Patient Safety for the Glickman Urologic Institute at the Cleveland Clinic and internationally recognized expert on pelvic surgical complications. In the first edition of *Complications of Female Incontinence and Pelvic Reconstructive Surgery*, Dr. Goldman brought together highly experienced pelvic reconstructive surgeons to share their expertise on the prevention, recognition, and management of a broad

spectrum of surgical complications. In this second edition, this novel and highly valuable resource has been expanded significantly to include new chapters exploring the medico-legal implications of surgical complications as well as the informed consent process and patient perception of complications. Additionally, the coverage of sling complications has been vastly expanded and includes separate chapters on complications from midurethral, transobturator, fascial, and single-incision slings and retropubic procedures.

In my opinion, *Complications of Female Incontinence and Pelvic Reconstructive Surgery, Second Edition*, is an essential text that should be on the bookshelves of all FPMRS specialists. It provides practical, real-world advice that should improve your ability to provide high-quality care to your patients.

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Matthew D. Barber

Prefaces from the First Edition

I am honored and pleased to write a preface for the textbook on Complications of Female Incontinence and Pelvic Reconstructive Surgery. At a time when the subspecialty of female pelvic medicine and reconstructive surgery is in its infancy, I feel having such a resource available to pelvic surgeons is extremely beneficial. Dr. Goldman has invited internationally respected contributors to provide their experience and expertise regarding the avoidance and management of surgical complications related to a variety of female pelvic floor surgeries. As the majority of the surgeries we perform on our female patients are done for quality of life symptoms, it has become apparent that we need to do a better job reporting and managing the untoward outcomes that can sometimes occur after these interventions. This book brings these potential complications to the forefront.

It will be of great use for both general urologists and gynecologists who perform pelvic floor surgeries as well as current and future specialists in female pelvic medicine and reconstructive surgery.

Cincinnati, OH, USA

Mickey Karram

Surgery for incontinence, pelvic organ prolapse, and other disorders of the female pelvic floor has evolved in the past two decades as the specialty of Female Pelvic Medicine and Reconstructive Surgery has incorporated expertise from the fields of urology, gynecology, and colorectal surgery. Today, more surgeons are better equipped to treat disorders of the female pelvic floor than ever before. Unfortunately complications of surgery, whether intraoperative or postoperative, are inevitable even for the most experienced and highly skilled surgeon. Whether it is an unexpected finding in the operating room or an undesirable outcome of surgery, the Female Pelvic Surgeon must be equipped to prevent and manage a variety of complications.

While there are several excellent texts devoted to indications for surgery and the technical aspects of surgical procedures “Complications of Female Incontinence and Pelvic Reconstructive Surgery” fills a need by providing readers with a comprehensive review of the prevention and management of common and not so common complications of female pelvic surgery. Dr. Howard Goldman has assembled a group of highly experienced authors from all three disciplines of Female Pelvic Medicine and Reconstructive Surgery. These authors offer in-depth descriptions of three critical areas: prevention, evaluation, and management of complications. They present practical infor-

mation and surgical tips based on years of experience and a thorough review of the relevant literature. In addition, a look at the table of contents shows that complications from all types of reconstructive procedures are covered.

I believe that “Complications of Female Incontinence and Pelvic Reconstructive Surgery” will be a great complement to the libraries of those of us who treat female pelvic disorders. Whether one is just starting a career or is highly experienced, this book is a welcome addition.

New York City, NY, USA

Victor W. Nitti

Current Edition [3rd Edition]

First Foreword

A renowned surgeon in Abraham Verghese's "The Covenant of Water" remarked to a junior colleague who saved a postoperative catastrophe through diligent awareness, preparation, and attentiveness: "Good surgeons can do any operation. Great surgeons take care of their own complications."

Experts from Urology and Urogynecology have joined forces under the editorial guidance of Drs. Howard Goldman and Jacqueline Zillioux to produce an updated third edition of *Complications of Female Incontinence and Pelvic Reconstructive Surgery* that provides detailed and pragmatic guidance to surgeons committed to complication prevention, diagnosis, and management. As the field of Urogynecology and Reconstructive Pelvic Surgery rests on restoring quality of life, complications that induce suffering are particularly hard for patients and their doctors to endure. Fortunately, procedures in our field are not commonly associated with severe adverse events. This results, however, in many surgeons not having experiential training in how to manage a particular problem. Coalescing evidence-based strategies with expert opinion for the evaluation and management of complications associated with the full breadth of female urology and urogynecology procedures in one textbook is a valuable resource for patient care. It is also an excellent physician resource for board preparation and review.

Since the previous edition of this textbook was published in 2017, practice patterns have evolved with a focus on harm reduction. Procedures such as urethral bulking, single-incision slings, vaginal laser, and hysteropexy have increased in popularity, largely due to lower risks. However, as our patients live longer and get sicker, more challenging interventions and repeat operations are often needed, often with compounded risk. This expanded and updated textbook, arranged primarily by surgical procedure (anterior and posterior compartment repair, uterosacral and sacrospinous ligament fixation, sacrocolpopexy, colpcleisis, colposuspension, fascial slings, synthetic slings, female urethral reconstruction, urethral diverticulectomy, fistula repair, anal sphincteroplasty, cosmetic gynecology, urethral bulking, sacral neuromodulation, intravesical botulinum toxin injection, and flaps) has the addition of the following new chapters: hysteropexy, mesh products, vaginal

laser treatments, autologous graft harvest, gender-affirming surgery, and prolapse after cystectomy. This third edition serves as a resource to all pelvic surgeons for mundane to complex complication scenarios.

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Catherine A. Matthews

Second Foreword

A foreword is supposed to reflect a personal introduction to a book, written especially for the readers, and is supposed to whet their appetite for proceeding.

To paraphrase a line in the movie *Forrest Gump*, “it happens.” Despite our very well-planned and well-executed efforts to surgically correct or improve a situation, adverse events do occur. Some of these are predictable and have been discussed with the patient beforehand, but some are not very predictable and have not been mentioned, or perhaps they have been, but were described as “very rare.” Generally, in a global textbook of a medical discipline, the subject of complications is relegated to the end of a chapter discussing surgical correction. Often, these discussions do not yield as much information as desired by the individual under whose direction the complication has occurred. Thus, the great value of a textbook such as this which deals only with this side of a surgical discipline, in this case the surgical subspecialty of Urogynecology and Pelvic Reconstructive Surgery (URPS).

This is the third edition of this book, and so it has demonstrated “staying power” to the publisher and to the segment of surgeons who practice in these areas. Howard Goldman, a true expert in all areas encompassed by URPS, has added a co-editor for this addition, Jacqueline Zillioux, a rising young expert, and they have again recruited a roster of recognized superstars in these fields as contributors. All chapters have been extensively updated (the last edition was published in 2017), and totally new chapters have been added on hysteropexy, mesh products, vaginal laser treatment, autologous graft harvest, gender affirming surgery, and prolapse occurrence after female cystectomy. New authors have been chosen for the chapters on sacral neuromodulation and on mesh-related pain. All surgeons who practice in the area of URPS, whether fellowship trained or not, will want this book on their shelves or computers, and it will prove to be an essential resource for residents and fellows in these areas as well. The book provides succinct but complete information from patient consent guidelines and how to reduce malpractice risks and how to

recognize and correct virtually all adverse events related to the Surgery of Female Incontinence and Pelvic Reconstruction. In my opinion, it represents a most valuable and up-to-date contribution to our field.

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Taxonomy of Complications of Pelvic Floor Surgery

1

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Laura A. Chang-Kit, and Roger R. Dmochowski

Introduction

The etymology of the word “taxonomy” is from the Greek *taxis*, meaning orderly arrangement, and *nomos*, meaning law. Stedman’s Medical Dictionary defines “taxonomy” as the systemic classification of living things or organisms; however, more recently, the term has come to mean any specialized method of classifying objects or events. The aim of taxonomic classification of surgical complications is to permit comparison of adverse outcomes and assist in risk stratification. In this chapter, we review the existing broader surgical classification systems that may be applicable to female pelvic medicine as well as those systems specifically developed for female reconstructive procedures.

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The Need for Taxonomy of Complications

Complications are an unfortunate but inevitable aspect of patient care and surgery, in particular. Complications are usually multifactorial and can accompany even the most minor, least invasive, and routine procedures. The tracking and reporting of surgical complications are essential to identifying areas for quality improvement. Historically, reporting of complications has been inconsistent, and, therefore, outcomes are difficult to compare. Martin and colleagues developed a list of ten critical elements of accurate and comprehensive reporting of surgical complications [1]. These criteria included: (1) providing the methods for data accrual, (2) duration of follow-up, (3) outpatient information, (4) definition of complications, (5) mortality rate and cause of death, (6) morbidity rate and total complications, (7) procedure-specific complications, (8) severity grade, (9) length-of-stay data, and (10) risk factors included in the analysis. The authors found that of 119 articles published between 1975 and 2001 reporting data on 22,530 patients who had undergone pancreatectomy, esophagectomy, and hepatectomy, none reported all ten criteria, and only 2% reported nine out of ten. The most frequently omitted criteria were outpatient information (22%), definitions of complications (34%), risk factors included in the analysis (29%), and severity grade (20%). Similarly, Donat and

colleagues found that only 2% of 109 studies between 1995 and 2005 encompassing 150,000 patients following urologic oncology procedures met nine or more of the ten criteria [2]. Seventy-nine percent failed to report definitions for complications, 67% complication severity, 63% outpatient data, 59% comorbidities, and 56% duration of reporting period. Both studies highlighted the need to develop standardized systems for reporting complications and disseminate these systems.

Reporting of complications in female pelvic reconstruction suffers from similar challenges. Depending on the type of procedure and definition of complication, the prevalence of complications in reconstructive pelvic surgery varies significantly. For example, a meta-analysis [3] of randomized controlled trials (RCTs) for mid-urethral sling (MUS) reported rates of bladder penetration of 0–24%, hematoma formation 0–16.1%, bladder erosion 0–13.1%, and vaginal extrusion 0–5.9%. Postoperative storage and voiding lower urinary tract symptoms (LUTS) were reported in 0–41.3% and 0–55.1% of women, respectively. Furthermore, many of the RCTs did not report any data on the abovementioned complications. In a meta-analysis of RCTs in the treatment of pelvic organ prolapse (POP), Maher and coworkers [4] similarly reported that only 16 out of 56 (29%) RCTs evaluating 5954 women reported data on the impact of surgery on bladder outcomes.

The reporting of complications in surgery and in female reconstructive surgery may be inconsistent for several reasons. First, a complication by one surgeon's consideration may not be seen as one by another surgeon and therefore may not be consistently reported. Second, specific abnormal cutoff values for measures such as estimated blood loss and postvoid residual volume (PVR) are not universally agreed upon, complicating the reporting of outcomes such as hemorrhage and urinary retention, respectively. Third, prior studies had primarily focused on outcomes such as anatomic success in pelvic organ prolapse (POP) repair or resolution of incontinence in MUS placement, failing to note other potential sequelae of surgery, such as voiding dysfunction or dyspa-

reunia, which may have a significant impact on quality of life (QoL).

Reasons for underreporting may include lack of centralized registries for reporting complications, disincentives to report such as professional embarrassment or retribution, the cumbersome nature of reporting complications in a busy clinical practice, or complications occurring remote from surgery of which the provider may not be aware. The ideal classification and reporting method would mitigate any of these potential reasons, resulting in increased reporting of complications and greater opportunity for quality improvement.

Existing Complication Classification Systems

In 1992, Clavien and coworkers [5] proposed a classification system for surgical complications that would in conjunction with subsequent work by Dindo and colleagues [6] develop into the predominant classification scheme for reporting adverse outcomes. Clavien and colleagues distinguished between three types of negative outcomes: complications, failure to cure, or sequelae [5]. Complications were defined as any deviation from the normal postoperative course, which also included asymptomatic complications such as arrhythmias and atelectasis. A sequela was defined as an “after effect” of surgery that was inherent to the procedure. Failure to achieve a cure meant that the original purpose of the surgery was not achieved, even if the surgery had been executed properly and without complications. What has come to be known as the Clavien–Dindo classification of complications considers only complications and not treatment failures or sequelae.

The Clavien–Dindo classification system consists of five grades [6]. Grade I complications include any deviation from the normal postoperative course without the need for any pharmacological treatment or surgical, endoscopic, or radiological intervention. Grade I therapeutic regimens include replacement of electrolytes, physiotherapy, and medications such as

antiemetics, antipyretics, analgesics, and diuretics. Wound infections that are opened at the bedside also fall into this grade. Grade II complications require pharmacological treatment with medications other than those allowed for grade I complications. Transfusion of blood products and total parenteral nutrition constitute grade II complications. Grade III complications require surgical, endoscopic, or radiological intervention. This category is subdivided into IIIa (not under general anesthesia) and IIIb (under general anesthesia). Grade IV complications are life-threatening and require intermediate or intensive care management. Central nervous system complications such as brain hemorrhage, ischemic stroke, and subarachnoid bleeding are included in this category, while transient ischemic attacks are not. Category IV is subdivided into IVa (single-organ dysfunction, with or without dialysis) and IVb (multiorgan dysfunction). The death of a patient is a grade V complication. The suffix “d” (for “disability”) is added to the respective grade of complication if the patient suffers from a complication at the time of discharge. This label indicates the need for follow-up to fully evaluate and grade the complication.

In essence, the grading of complications using the modified Clavien system is related to the intensity of the treatment directed at correcting the complication [6]. The intent is a link between the severity of the complication and its associated morbidity. Dindo and colleagues validated the modified Clavien classification in 6336 patients undergoing elective surgery in their institution over a 10-year period. Adjusting for surgical complexity, the authors found that the Clavien grade of complications significantly correlated with the duration of the hospital stay, a surrogate marker of outcome. A strong correlation was also observed between the complexity of surgery (and assumed higher complication rates) and the frequency and severity of complications. Furthermore, over 90% of surgeons in an international survey conducted by the authors found the classification system to be simple, reproducible, and logical, and reported that they would support the introduction of the classification system into their clinical practice. The modified Clavien sys-

tem has now become the most widely used complication classification system across surgical disciplines [7], including urology [8].

In 2011, a classification of complications directly related to the insertion of prostheses (meshes, implants, tapes) or grafts in female pelvic floor surgery was introduced [9]. Following this initial joint effort of the International Urogynecological Association (IUGA) and International Continence Society (ICS), classification systems were published in 2012 for complications related to native tissue female pelvic floor [10] and POP repair [11].

The 2011 prostheses complication report specifically combined the input of members of the Standardization and Terminology Committees of the IUGA and the ICS and a Joint IUGA/ICS Working Group on Complications Terminology and was assisted at intervals by many expert external referees [9]. An extensive process of 11 rounds of internal and external review took place with exhaustive examination of each aspect of the terminology and classification. The decision-making process was conducted by collective opinion (consensus). The classification of each complication is broken down into three parts: category (C), time (T), and site (S). The category (C) is stratified by location of compromise (vagina, urinary tract, bowel or rectum, skin or musculoskeletal system, and hematoma or systemic compromise) and symptom severity (asymptomatic, symptomatic, presence of infection, and abscess formation). The timing of complication (T) is subdivided into four groups (intraoperative to 48 h, 48 h to 2 months, 2–12 months, and >12 months), while the site of complication (S) includes vagina (at or away from the suture line), due to trocar passage, other skin or musculoskeletal site, and intra-abdominal location. A patient may have more than one complication, and the most severe endpoint and corresponding time point are chosen for each. Additionally, grades of pain may be assigned as a subclassification of the complication category. The subjective presence of pain by the patient only may be graded from “a” to “e” (asymptomatic or no pain to spontaneous pain). Each complication is assigned a category time site (CTS) code consisting of three or

four letters and four numerals and should theoretically encompass all conceivable scenarios for describing operative complications and healing abnormalities. There is notably no classification of functional issues or urinary tract infection (UTI).

The 2012 IUGA/ICS Joint Terminology and Classification of the Complications Related to Native Tissue Female Pelvic Floor Surgery was written by the same lead author as the 2011 joint report and proposed a slightly modified CTS system [10]. The CTS system for native tissue repair is virtually identical on its surface to the system developed for insertion of prostheses. However, because there is no mesh, tape, or other implant in native tissue repair, the definitions for “exposure” and “extrusion” are applied to permanent suture material “visualized through separated vaginal epithelium” and “protruding into the vaginal cavity,” respectively. In addition, the terms “granulation” (i.e., “fleshy connective tissue projections on the surface of a wound, ulcer, or inflamed tissue surface”) and “ulcer” (i.e., “lesion through the skin or a mucous membrane resulting from loss of tissue, usually with inflammation”) were added to the terminology. As with the earlier proposal for classification of implant complications, functional issues and UTIs were omitted from the classification system. A subsequent joint IUGA/ICS report [11] proposed that Clavien–Dindo grade and functional outcomes such as postoperative pain, LUTS, bowel dysfunction, sexual dysfunction, other de novo symptoms, and backache should be reported along with the CTS classification.

Developed in 2013, the Comprehensive Complication Index (CCI), is an alternative system of the Clavien–Dindo that aggregates all patient complications on a continuous scale [12]. Whereas the Clavien–Dindo selects only the single most severe complication, the CCI aims to consider all complications and their respective severity. The overall morbidity is reflected on a scale from 0 (no complication) to 100 (death). The complex CCI formula is outside the scope of this book chapter; however, a calculator is readily available online [13] for clinicians to access (<https://www.cci-calculator.com>).

Despite the reproducibility and wide acceptance of the Clavien–Dindo system (even with the modification provided by the CCI), the system is not designed to include reporting of intraoperative complications. Recognizing this limitation, the European Association of Urology (EAU) published a classification of intraoperative events in 2020 [14]. They aimed to develop a “simple, systematic, objective, and reproducible” grading system for intraoperative complications. The EAU ad hoc Complications Guidelines Panel developed the grading system using two rounds of expert consensus ($\geq 70\%$ agreement) followed by validation in hypothetical clinical scenarios to test clinical performance. The proposed EAUiaIC (EAU intraoperative adverse incident classification) system comprises eight adverse incidence grades: Grade 0 (no deviation and no consequence to the patient), Grade 1 (requires change in planned intraoperative steps but addressed in a controlled manner with no long-term side effects), Grade 2 (may have short-/long-term side effects), Grade 3 (life-threatening but not requiring tissue/organ removal), Grade 4A (requires tissue/organ removal), Grade 4B (unable to complete procedure as planned) to grade 5B (wrong surgery site or intraoperative death) [14].

To date, there have been no updates to the IUGA/ICS Classification system discussed above, and many recent studies [15, 16] continue to report their complications using either the CTS classification or the Clavien–Dindo.

The Challenge of Implementing a Classification System of Complications

Inherent to the definition of taxonomy is that the classification system should reduce complexity by presenting a logical and hierarchical representation of categories. The classification should likewise provide a means for organizing and accessing vast quantities of data in an intuitive and streamlined manner. Perhaps owing to the complexity of female pelvic reconstruction and any associated standardized schema, the adoption

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