

## International Urogynecological Association (IUGA)/ International Continence Society (ICS) Joint Terminology and Classification of the Complications Related to Native Tissue Female Pelvic Floor Surgery

Bernard T. Haylen,<sup>1\*†‡</sup> Robert M. Freeman,<sup>2†‡§</sup> Joseph Lee,<sup>3†</sup> Steven E. Swift,<sup>4†‡</sup> Michel Cosson,<sup>5‡</sup>  
Jan Deprest,<sup>6‡</sup> Peter L. Dwyer,<sup>7†‡</sup> Brigitte Fattou,<sup>8‡</sup> Ervin Kocjancic,<sup>9‡</sup> Chris Maher,<sup>10†‡</sup>  
Eckhard Petri,<sup>11†</sup> Diaa E. Rizk,<sup>12†</sup> Gabriel N. Schaer,<sup>13†</sup> and Ralph Webb<sup>14†§</sup>

<sup>1</sup>University of New South Wales, Sydney, New South Wales, Australia

<sup>2</sup>Derriford Hospital, Plymouth, Devon, United Kingdom

<sup>3</sup>Monash Medical Centre, Melbourne, Victoria, Australia

<sup>4</sup>Medical University of South Carolina, Charleston South Carolina

<sup>5</sup>University Hospital, Lille, France

<sup>6</sup>University Hospital, UZ Leuven, Belgium

<sup>7</sup>Mercy Hospital for Women, Melbourne, Victoria, Australia

<sup>8</sup>University Hospital, Clermont-Ferrand, France

<sup>9</sup>Department of Urology, University of Illinois, Chicago

<sup>10</sup>Wesley Hospital, Brisbane, Queensland, Australia

<sup>11</sup>Urogynaecology Department, University of Greifswald, Germany

<sup>12</sup>Peterborough, Ontario, Canada

<sup>13</sup>Kantonsspital, Aarau, Switzerland

<sup>14</sup>Norfolk and Norwich University Hospital, Norfolk, UK

**Introduction and Hypothesis:** A terminology and standardized classification has yet to be developed for those complications related to native tissue female pelvic floor surgery. **Methods:** This report on the terminology and classification combines the input of members of the Standardization and Terminology Committees of two International Organizations, the International Urogynecological Association (IUGA) and the International Continence Society (ICS) and a Joint IUGA/ICS Working Group on Complications Terminology, assisted at intervals by many external referees. A process of rounds of internal and external review took place with decision-making by collective opinion (consensus). **Results:** A terminology and classification of complications related to native tissue female pelvic floor surgery has been developed, with the classification based on category (C), time (T), and site (S) classes and divisions, that should encompass all conceivable scenarios for describing operative complications and healing abnormalities. The CTS code for each complication, involving three (or four) letters and three numerals, is likely to be very suitable for any surgical audit or registry, particularly one that is procedure-specific. Users of the classification have been assisted by case examples, color charts, and online aids ([www.icsoffice.org/ntcomplication](http://www.icsoffice.org/ntcomplication)). **Conclusions:** A consensus-based terminology and classification report for complications in native tissue female pelvic floor surgery has been produced. It is aimed at being a significant aid to clinical practice and particularly to research. *Neurourol. Urodynam.* 31:406–414, 2012.

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**Key words:** classification; complication; female pelvic floor surgery; native tissue

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Dynamesh: Acceptance of payment for research. P.L. Dwyer: Department research grant from American Medical Systems (AMS). B. Fattou: Astellas: Consultant. Coloplast: Acceptance of payment for research. Ethicon (Johnson & Johnson): Acceptance of paid travel expenses or honoraria. Novartis: Consultant. E. Kocjancic: Coloplast: Consultant. Bard: Acceptance of paid travel expenses or honoraria. American Medical Systems (AMS): Shareholder. Astellas: Consultant. Pfizer: Acceptance of paid travel expenses or honoraria. C. Maher: Director, Urogynaecology Society of Australasia. E. Petri: No disclosures. D.E. Rizk: No disclosures. G.N. Schaer: Astellas: Holding a position of influence in another professional society/association. Pfizer: Holding a position of influence in another professional society/association. Gynecare (Ethicon): Holding a position of influence in another professional society/association. Novartis: Holding a position of influence in another professional society/association. R. Webb: Travel bursaries or honoraria: Pfizer or Astellas. Lecture fees: (departmental) Pfizer, Astellas, Research: Allergan Astellas.

<sup>†</sup>Terminology and Standardization Committee (IUGA).

<sup>‡</sup>Joint IUGA/ICS Working Group on Complications Terminology.

<sup>§</sup>Standardization Steering Committee (ICS).

\*Correspondence to: Bernard T. Haylen, Associate Professor, Suite 904, St Vincent's Clinic, 438 Victoria Street, Darlinghurst, 2010. NSW, Australia.

E-mail: haylen@optusnet.com.au

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## PREFACE

The Standardization and Terminology Committee of the International Urogynecological Association (IUGA), the Standardization Steering Committee of the International Continence Society (ICS) and the Joint IUGA/ICS Working Group on Complications Terminology seek to provide a terminology and a standardized classification for those complications arising from native tissue female pelvic floor surgery. This document follows a similar document<sup>1</sup> for those complications related directly to the insertion of prostheses (meshes, implants, tapes) and grafts, also in female pelvic floor surgery. It would then be, amongst its various other possible applications such as medical records and surgical audits (often procedure-specific), the basis for scientific clinical studies comparing complications from the different types of female pelvic floor surgery. As the first aim is to standardize the terminology used in this classification, the terms used in the title need to be initially defined.

- *Classification*: A systematic arrangement into classes or groups based on perceived common characteristics.<sup>2</sup> N.B. *Division*: A separation into two or more parts.
- *Complication*: A morbid process or event that occurs during the course of a surgery that is not an essential part of that surgery (“surgery” replacing “disease” in the definition; “course” includes postoperative of whatever duration).<sup>2</sup>
- *Related*: Connected.<sup>3</sup>
- *Tissue*: A collection of similar cells and the intercellular substances surrounding them.<sup>2</sup>
- *Native*: Pertaining to birth.<sup>2</sup> autologous.<sup>2</sup>

## INTRODUCTION

In January 2011, the IUGA/ICS Joint Terminology and Classification of Complications related directly to the insertion of Prostheses (meshes, implants, tapes) and Grafts in Female Pelvic Floor Surgery was simultaneously published in the International Urogynecology Journal and Neurourology and Urodynamics.<sup>1</sup> As usage of this classification was then proposed for large randomized clinical trials of pelvic floor surgeries involving both (i) the insertion of prostheses or grafts and (ii) the use of native tissues alone, it became more evident that an equivalent classification for the latter indication was not available.

The need and request for an equivalent native tissue surgical classification (by clinical researchers) was deemed a separate challenge in itself after the efforts in producing the first document. Desirably, if one was trying to compare surgical complications, it would be easiest if the classifications of the complications of the two different sets of surgeries were of a similar style. Essentially, they were being performed in the same anatomical setting, involving similar healing processes and a similar timeframe for healing. The main difference was whether a surgical prosthesis or graft was additionally being introduced. An attempt was then made to apply the Category (C), Time (T), and Site (S) Classification for the prostheses and grafts<sup>1</sup> to native tissue surgery. It became clear that this style of classification might also be suitable for the latter indication.

The analysis of synthetic meshes by Amid<sup>4</sup> may not have been performed for suture materials in native tissue surgery, particularly around the vagina, although many of Amid's<sup>4</sup> and others'<sup>56</sup> findings and subsequent conclusions in relation to an “ideal” mesh material<sup>1</sup> might still apply. Many healing

abnormalities could occur with the use of permanent sutures as might be required for surgical strength and durability in such scenarios as vaginal vault suspension procedures for example, uterosacral or sacrospinous ligament colpopexies. Braided sutures, if left exposed to the vaginal cavity rather than buried beneath vaginal skin, appear particularly prone to the formation of surrounding inflammation, for example, granulation.

Historically, discontinuation of a surgical procedure, or the use of a particular material in that procedure, occurs generally due to either (i) a lack of efficacy or (ii) the nature or frequency of complications. Native tissue repairs are not without complications. It was noted<sup>1</sup> that prostheses or grafts potentially add to the complication profile the aspects of (i) trauma of insertion; (ii) reaction of the body to the prosthesis in terms of inflammation or infection; (iii) the stability of the prosthesis over time; (iv) morbidity at the donor site from harvesting an autologous graft. On reflection, points (i) to (iii) might still apply to certain permanent suture materials in native tissue surgery.

The classification of complications based on category (C), time (T), and site (S) is consistent with the previous report for prostheses and grafts<sup>1</sup> and might appear familiar and again initially complex. It is hoped that the following outline and explanatory notes, as well as user-friendly tables and case examples might alleviate any residual concerns in regards to complexity. It would be of greater concern if the classification did not cover all the different complication scenarios, such that previously undefined additional terminology might be needed.

## PROPOSED NEW DEFINITIONS

Complications involving native tissue female pelvic floor surgery need to involve the following viewpoints of (i) local complications; (ii) complications to surrounding organs; (iii) systemic complications. As in the earlier document,<sup>1</sup> the generic term of “erosion” (medically defined as the “state of being worn away, as by friction or pressure,<sup>2</sup> does not necessarily suit the clinical scenarios encountered. Its use is best avoided to be replaced by terms with greater physical specificity and clarity.

The additional terms to be used are:

- *Prominence*: Parts that protrude beyond the surface with no epithelial separation.<sup>2</sup>
- *Separation*: Physically disconnected<sup>3</sup> (e.g., vaginal epithelium).
- *Exposure*: A condition of displaying, revealing, exhibiting or making accessible<sup>3</sup> (e.g., a permanent suture visualized through separated vaginal epithelium).
- *Extrusion*: Passage gradually out of a body structure or tissue<sup>2</sup> (e.g., a permanent suture protruding into the vaginal cavity – see patient 555 (Table 4) and case example 8).
- *Compromise*: Bring into danger.<sup>3</sup>
- *Perforation*: Abnormal opening into a hollow organ or viscus.<sup>2</sup>
- *Dehiscence*: A bursting open, splitting or gaping along natural or sutured lines.<sup>2</sup>
- *Sinus tract formation*: (Localized) formation of a fistulous tract towards vagina or skin, where there is no visible suture material in the vaginal lumen or overlying skin.
- *Granulation*: Fleishy connective tissue projections on the surface of a wound, ulcer or inflamed tissue surface.<sup>2</sup>
- *Ulcer*: A lesion through the skin or a mucous membrane resulting from loss of tissue, usually with inflammation.

TABLE 1. Terminology Involved in the Classification

TERMS USED	DEFINITION
COMPLICATION	A morbid process or event that occurs during the course of a surgery that is not an essential part of that surgery
NATIVE	Pertaining to birth, autologous
TISSUE	Collection of similar cells and intercellular substances surrounding them
INVAGINATION	Vaginal mucosa folded and entrapped on itself, characterized by a fixed and tight area on examination
PROMINENCE	Parts that protrude beyond the surface with no epithelial separation
SEPARATION	Physically disconnected (e.g. vaginal epithelium)
EXPOSURE	A condition of displaying, revealing, exhibiting or making accessible, e.g. a permanent suture visualized through separated vaginal epithelium
EXTRUSION	Passage gradually out of a body structure or tissue, e.g. a loop of suture protruding into the vaginal cavity.
COMPROMISE	Bring into danger
PERFORATION	Abnormal opening into a hollow organ or viscus
DEHISCENCE	A bursting open or gaping along natural or sutured line
GRANULATION	Fleshy connective tissue projections on the surface of a wound, ulcer, or inflamed tissue surface
ULCER	A lesion through the skin or a mucous membrane resulting from loss of tissue, usually with inflammation

- *Invagination*: Vaginal mucosa folded and entrapped on itself, characterized by a fixed and tight area on examination.<sup>7</sup>

#### CATEGORY, TIME, AND SITE (CTS) CLASSIFICATION

The overall aim of the classification is to summarize any of a large range of possible clinical scenarios into a code (“a numeric system for ordering and classifying information”<sup>2</sup>) using as few as three numerals and three (or four) letters. No additional verbal description, possibly involving undefined terminology, should be necessary.

#### SELECTION OF CATEGORIES

The selection of category (C) has used the principal that the least severe complication would occur within the anatomical site of the procedure. More severe complications would involve (i) increasing involvement of surrounding anatomical structures; (ii) involvement of surrounding organs; and

(iii) systemic compromise. The following seven categories (by number) have been formed:

- (1) *Vaginal complication—no epithelial separation*: This incorporates the terms prominence or excessive degrees of scarring or tethering.
- (2) *Vaginal complication—smaller epithelial separation or ulcer*: A smaller (1 cm or less) degree of vaginal epithelial separation or ulcer formation is involved.
- (3) *Vaginal complication—larger epithelial separation or ulcer or suture extrusion*: A larger degree (more than 1 cm) of vaginal epithelial separation or ulcer formation or suture extrusion is involved.

Categories 1–3 have been separated into the following divisions:

*1A–3A: Asymptomatic - Abnormal finding* These are generally physician-diagnosed at any episode of clinical care. It can be argued that the “abnormal finding” aspects of category 1A, in particular, are not really complications, as the

patient is not bothered by the potential problem. It may be, however, that the woman may not have engaged in an activity that is likely to provoke symptoms for herself, e.g., pain or bleeding during sexual intercourse (or for her partner), which would convert these complications to category 1B.

**1Aa–3Aa: Asymptomatic—Abnormal finding** The addition of an “a” specifies that the patient experiences no pain in association with the abnormal finding.

**1B–3B: Symptomatic—Unusual discomfort or pain; dyspareunia** (for either partner). Bleeding or discharge may be possible symptoms.

**1Bb–3Bb: Symptomatic—Provoked pain only (during vaginal examination)** The addition of a “b” to the category code specifies that pain, provoked only during vaginal examination, is associated with the abnormal finding.

**1Bc–3Bc: Symptomatic—Pain during sexual intercourse** The addition of a “c” to the category code specifies that pain, provoked during sexual intercourse (patient only), is associated with the abnormal finding.

**1Bd–3Bd: Symptomatic—Pain during physical activities** The addition of a “d” to the category code specifies that pain, provoked during physical activities, is associated with the abnormal finding.

**1Be–3Be: Symptomatic—Spontaneous pain** The addition of an “e” to the category code specifies that pain, spontaneously present (i.e., without physical activity), is associated with the abnormal finding.

**1C–3C: Clinical Infection/Inflammation:** Signs of local tenderness are suggestive with the combination of redness and a purulent discharge being more conclusive. The presence of *granulation* should be accepted as representing ongoing inflammation.

**1C–3C (b–e): Infection Pain** The addition of the letters “b” through to “e” specifies that pain (as defined in Table 3) is part or all of the infected abnormal finding.

**1D–3D: Abscess formation:** This is a more serious possibility.

**1D–3D (b–e): Infection—Pain** The addition of the letters “b” through to “e” specifies that pain (as defined in Table 3) is part of the abnormal finding associated with abscess formation.

#### Category 4: Urinary tract compromise or perforation:

This category class has been subdivided into:

**4A: Small intraoperative defect:** e.g., bladder perforation. Such a complication does not generally create longer-term compromise for the bladder if the defect is recognised and oversewn (if necessary), and some minor precautions are taken, e.g., short-term bladder drainage, with suitable antibiotics commenced.

**4B: Other lower urinary tract (bladder or urethral) complication or compromise:** This division would incorporate injuries causing longer-term bladder issues, e.g., ongoing suture perforation, fistula, calculus around the suture. This category also incorporates urinary retention directly related to the procedure requiring subsequent surgical intervention (apart from any form of bladder drainage). The time and site divisions relates to those for the surgical intervention.

**4C: Ureteric or upper tract complication or compromise:** This division is self-explanatory.

#### Category 5: Rectal or Bowel compromise or perforation.

This category class has been subdivided into:

**5A: Small intraoperative defect:** Such a complication may not generally be expected to cause compromise if the defect is recognized and oversewn (as necessary) with appropriate precautions taken, e.g., short term bowel rest is instituted with suitable antibiotics commenced.

**5B: Rectal injury or compromise:** This division would incorporate injuries causing longer-term rectal issues, e.g., ongoing suture perforation, fistula.

**5C: Small or large bowel injury or compromise:** This division would incorporate injuries causing longer-term bowel issues, e.g., ongoing suture perforation, fistula, obstruction.

**5D: Abscess formation from bowel injury/compromise.**

#### Category 6: Skin and/or musculoskeletal complications:

**6A: Asymptomatic:** Physician-diagnosed complication at any episode of care.

**6B: Symptomatic:** e.g., discharge, pain, lump.

**6C: Infection from skin or musculoskeletal complication:** including sinus tract formation.

**6D: Abscess formation from skin or musculoskeletal complication.**

#### Category 7: Patient compromise:

This category recognizes that the patient might be brought into systemic danger with some of the complications in addition to any localized complication.

**7A: Bleeding complication including hematoma:** This division refers to any clinically diagnosed hematoma as well as those where blood transfusion or surgical intervention is a consideration.

**7B: Major degree of resuscitation or intensive care:** This division refers to significant hemodynamic or cardiopulmonary resuscitation directly related to the procedure, and/or patient transfer for management in intensive care facilities. Included in this division is hematoma associated with sepsis, thus increasing patient compromise.

**7C: Mortality:** The native tissue surgery, whilst not necessarily fatal at the time, has set in train further morbid events leading to mortality.

N.B. Because of their systemic nature, 7B and 7C will generally not have a specific site division. They will then be denoted *S 0*.

### SELECTION OF TIME (T) DIVISIONS

The time (T) for the complication is when it is *clinically diagnosed*. This section incorporates four time periods, all of the possible episodes where clinical care might be given by the physician or sought by the patient. It might not always be possible to predict with any particular surgery when particular complications might be more frequently diagnosed. This would depend on the results of a procedure-specific surgical audit using the classification. The earliest time division (T1) might involve more perioperative issues, whilst later divisions (T2–T4) might be biased towards healing abnormality issues.

**T1: Intraoperative—48 hr:** Perioperative complications clearly more likely.

**T2: 48 hr—2 months:** Bleeding, infection or healing complications more likely.

**T3: 2 months—12 months:** Later healing abnormalities more likely.



**TABLE 3. Grades of Pain: Subclassification of Complication Category**

To specify the presence of pain (by patient only, not the partner) as part or all of the abnormal finding and the grade in terms of the presence and severity of symptoms

- a, asymptomatic or no pain
- b, provoked pain only (during vaginal examination)
- c, pain during sexual intercourse
- d, pain during physical activities
- e, spontaneous pain

*T4: Over 12 months:* Late healing abnormalities and other suture complications more likely.

**SELECTION OF SITE (S) DIVISIONS**

The selection of these divisions incorporates the current sites where complications have been noted:

*S0: Systemic complications (no specific site):* As mentioned earlier, category divisions 7B (septic hematoma a possible exception) and 7C which are generally systemic complications will be denoted S 0.

*S1: Vaginal: area of suture line:* Perhaps the commonest site for complications from native tissue vaginal surgery is close to the vaginal suture line.

*S2: Vaginal: away from the vaginal suture line:* As most suture lines would be midline, this would generally be lateral in the vagina.

*S3: Adjoining viscus:* This division incorporates any extra-peritoneal, bladder or rectal complication, but not intra-abdominal complications which are S5.

*S4: Skin or musculoskeletal site:* This division is relevant to any skin or musculoskeletal complications away from the sites of the primary wound. Included might be cutaneous sinus or fistula formation and deep muscle pain from suture fixation.

**TABLE 4. An Example of a Non-Procedure-Specific Table of Complications Directly Related to Native Tissue Female Pelvic Floor Surgery Using the Category (C), Time (T), and Site (S) System. One Might Expect These Tables to be Often Procedure-Specific**

Patient Number	Description of complications	Code	Code
000	Retropubic haematoma following Burch colposuspension (first 24 hours)	7A /T1/ S3	
111	Persistent buttock pain at presentation six weeks after a sacrospinous colpopexy	6B /T2/ S4	
222	Bowel obstruction and 2cm vaginal vault exposure with bleeding 6 months after a (permanent) suture sacrocolpopexy	5C /T3/ S5	3B /T3/ S1
333	Permanent suture felt in a woman at a 6 week postop review (lateral vaginal-no separation) whose partner described discomfort with vaginal intercourse	1B /T2/ S2	
444	A midline vaginal ulceration (< 1cm) with redness, dyspareunia, discharge 15 months after an anterior colporrhaphy	2Cc/T4/S1	
555	Lateral vaginal extrusion with malodorous discharge and a midline rectovaginal fistula 8 months after a posterior colporrhaphy	3C /T3/ S2	5B /T3/ S1
666	Intraoperative vessel injury during a vaginal vault suspension procedure requiring major resuscitation	7B /T1/ S3	
777	Persistent intravesical suture / calculus formation / haematuria 2 years after a retropubic urethropexy	4B /T4/ S3	
888	Pelvic abscess presenting 8 days after a uterosacral vault suspension complicated by an intraoperative bowel defect (final category) Initial code was 5A/T1/S5	5D /T2/ S5	
999	Tender prominent vaginal scarring noted 9 months after a sacrospinous colpopexy (no symptoms, husband unwell)	1Bb/T3/S1	
XXX	Persistent postvoid residual of 150mls with recurrent UTI requiring suture release 4 months after Burch colposuspension	4B /T3/S1	

*S5: Intra-abdominal:* Included in this section would be bowel perforation or obstruction.

*CTS Classification:* (Complete code):

- Example of complete CTS code: *3B/T2/S3* (for simplicity, there is no “C” in front of the category class and division). The letters a to e may be added to the category code e.g., *3Bc/T2/S3* to indicate that pain is part of the abnormality (“c”—pain with intercourse).

#### CLASSIFICATION GUIDELINES

The following should be noted:

- *Multiple complications may occur in the same patient:* These should be reported separately as noted in Table 4.
- *There may be early and late complications in the same patient:* Again, these should be reported separately.
- *All complications should be listed*
- *If there is progression of a particular complication over time, the highest final category is to be used:* Progression of an exposure or vaginal ulcer from asymptomatic to symptomatic; an exposure progresses from smaller to larger; hematoma progresses from aseptic to septic.

#### CLASSIFICATION LIMITATIONS

- *The classification does not note the specific type of material (suture) used:* Use of permanent sutures other than those with the least morbidity (as described in the introduction) might be further reflected in an increased rate of the healing abnormalities.
- *Functional issues (e.g., voiding and defecatory dysfunction) are not included:* Voiding dysfunction can be defined as abnormally slow (assessed by urine flow rate data) and/or incomplete (assessed by postvoid residual) micturition.<sup>8</sup> Surgical intervention for severe voiding dysfunction, namely urinary retention is included in section 4B.
- *Urinary tract infections have not been included.*
- *Recurrences:* Permanent sutures, like meshes and grafts, are often used to prevent recurrence of pelvic organ prolapse. However the addition of permanent sutures might still fail to achieve a successful outcome (over whatever period) and a recurrence occurs. However, it should be emphasized that recurrence is not a complication.

#### TABLES AND CASE EXAMPLES

Table 1: The definitions of terms used in the classification.

Table 2: A classification by Category (C), Time (T), and Site (S) of complications related to native tissue female pelvic floor surgery.

Table 3: Subclassification of categories 1 to 3 to specify that pain is part of the abnormal finding and the impact of that finding on patient’s symptoms.

Table 4: An example of a *non-procedure specific* table of complications directly related to native tissue female pelvic floor surgery using the Category (C), Time (T), and Site (S) system. The CTS Classification Code is placed adjacent to a description of the complication.

Case examples: Figs. 1–8: Eight clinical scenarios, the complications and the respective classification codes.

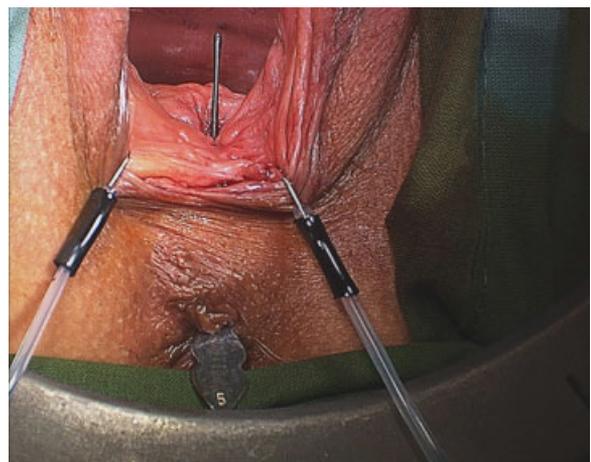


**Fig. 1.** Anterior midline 1.5cm vaginal ulcer following removal of an ethibond suture and granulation and after diathermy. Presentation with vaginal bleeding was 3 years after an anterior compartment repair including the insertion of the permanent suture for uterosacral ligament plication. **Classification: 3C T4 S1.**

#### DISCUSSION

The present classification has been developed to be sensitive to all possible physical complications related to native tissue female pelvic floor surgery. Both perioperative complications and healing abnormalities are covered. Whilst this creates a large number of possible scenarios, appropriate organization has still been possible by Category (C), Time (T) and Site (S). The end-point is a code of three letters (4 if “a” to “e” are used) and three numerals. The addition of the pain subclassification reflects the recognition of the authors that chronic pain, especially if in the higher subclasses (“c” to “e”), can be amongst the most disabling surgical outcomes from any female pelvic floor surgery.

A key advantage of a standardized classification is that all parties involved in female pelvic floor surgery including surgeons, physicians, nurses, allied health professionals and industry will be referring to the same clinical issue. It is



**Fig. 2.** Rectovaginal fistula presenting 4 weeks (photo taken at 3 months) after a posterior vaginal repair concomitant with a vaginal hysterectomy and anterior vaginal repair. Presenting symptom was vaginal passage of feces. **Classification: 5B T2 S3.**



**Fig. 3.** Ethibond suture in the bladder of a women presenting with recurrent urinary tract infections 7 years after a Burch colposuspension. **Classification: 4B T4 S3.**

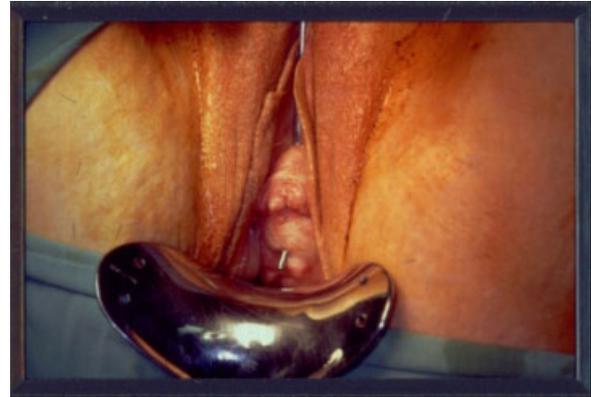
anticipated that a (CTS) codified table of complications will be a necessary part of reports of surgical procedures relevant to this document. The addition of the current classification of complications to the previous one<sup>1</sup> allows comparison studies of surgeries without and with prostheses and grafts.

It is acknowledged that to optimize the coverage of complications, the classification<sup>1</sup> might still appear complex and not immediately mastered. However, as noted in the introduction (page 2), we anticipate that the patient cases (Table 4) and case examples (Figs. 1–8) provided below, the color charts the online ICS-IUGA Native Tissue (NT) Complication Classification Calculator ([www.icsoffice.org/ntcomplication](http://www.icsoffice.org/ntcomplication)), as well as the experience with the earlier classification<sup>1</sup> will ameliorate any initial concerns.

As with the earlier document,<sup>1</sup> it has been a consensus view of the authors that a formal academic terminology and classification should be completed prior to attempts at further simplification. The latter might run the risk of compromising



**Fig. 4.** Abnormal scarring with “tethering” presenting 3 years after a Burch colposuspension and causing dyspareunia. **Classification: 1Bc T4 S1.**



**Fig. 5.** Urethrovaginal fistula presenting 9 weeks after an anterior vaginal repair. **Classification: 4B T3 S1.**

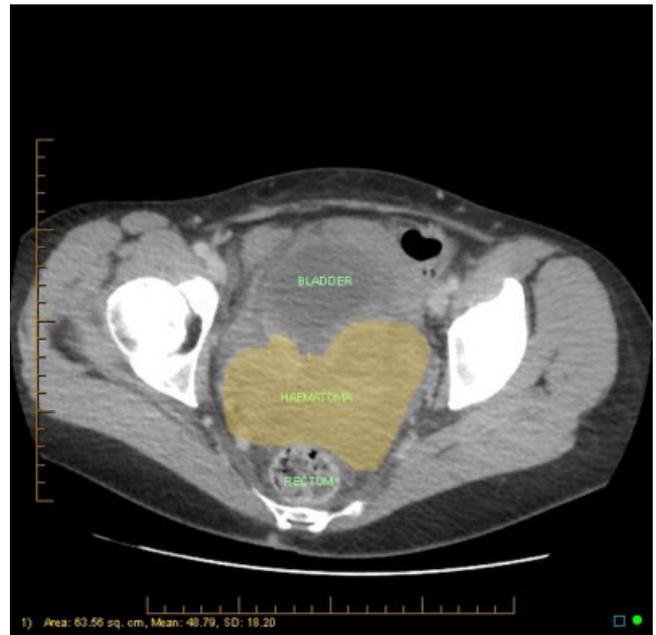
coverage of complications.

#### JOURNAL NOTES

Standardization and Terminology Committee (IUGA)—Bernard T. Haylen, Robert M. Freeman, Joseph Lee, Steven E. Swift, Peter L. Dwyer, Eckhard Petri, Diaa E. Rizk, Gabriel N. Schaer.

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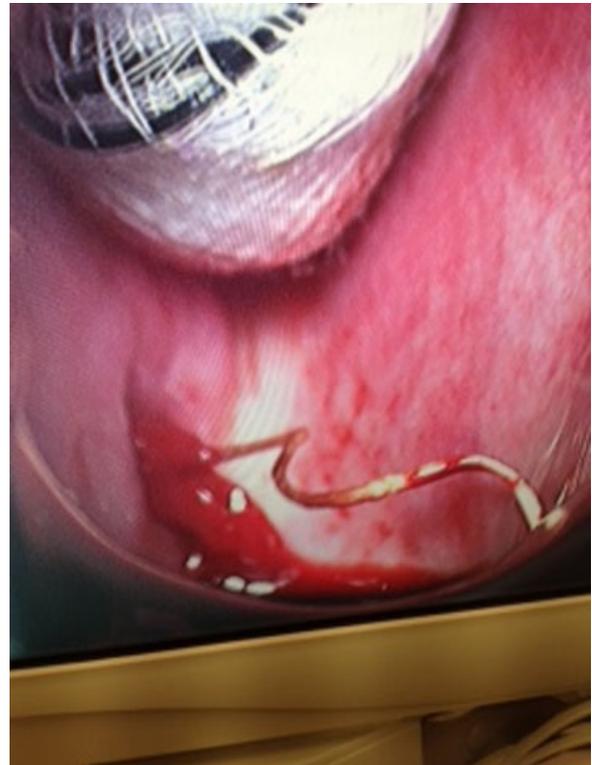
**Fig. 6.** Pelvic pain, dropping hemoglobin consistent with hemorrhage in first 24 hr after a vaginal hysterectomy and CT evidence of a vaginal vault hematoma. Managed conservatively for 4 days, evidence of sepsis (fever, increasing white cell count) prompted vaginal drainage and intravenous antibiotics. **Classification: 7B T2 S3 (initially 7A T1 S3).**



**Fig. 7.** Clinical evidence of vaginal urine loss 36 hr after an anterior colporrhaphy (2 previous anterior repairs). Deeper insertion of lateral fascial suture ligates the distal urethra near the vesico-ureteric junction. CT evidence of discontinuity to distal urethra and extravasation. Managed by interval stenting until extravasation proved to have ceased. **Classification: 4C T1 S3.**

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**Fig. 8.** Extruded goretex suture at posterior vaginal vault (behind cervix) 4 years after a sacrospinous hysteropexy. Only symptom was intermittent PV bleeding. **Classification: 3C T4 S1.**

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