



***AN INTERNATIONAL UROGYNECOLOGICAL ASSOCIATION
(IUGA)/ INTERNATIONAL CONTINENCE SOCIETY (ICS) JOINT
TERMINOLOGY AND CLASSIFICATION OF THE
COMPLICATIONS RELATED DIRECTLY TO THE
INSERTION OF PROSTHESES (MESHES, IMPLANTS,
TAPES) & GRAFTS IN FEMALE PELVIC FLOOR SURGERY***

Bernard T. Haylen^o, Robert M Freeman*^{^o}, Steven E. Swift*^o,
Michel Cosson^o, G Willy Davila^o, Jan Deprest^o, Peter L. Dwyer*^o,
Brigitte Fatton^o, Ervin Kocjancic^o, Joseph Lee*^o, Chris Maher^o,
Diaa E. Rizk*^o, Eckhard Petri*^o, Peter K. Sand*^o,
Gabriel N. Schaer*^o, Ralph Webb*^o*

Standardization and Terminology Committee (IUGA)
Standardization and Terminology Committee (ICS)[^]
Joint IUGA/ICS Working Group on Complications Terminology^o*

*Bernard T. Haylen, University of New South Wales, Sydney. N.S.W. Australia.
Robert M. Freeman, Derriford Hospital, Plymouth. Devon. United Kingdom.
Steven E. Swift, Medical University of South Carolina, Charleston SC. U.S.A.
Michel Cosson, University Hospital. Lille. France.
G Willy Davila, Cleveland Clinic, Weston FL. U.S.A.
Jan Deprest, University Hospital, UZ Leuven. Belgium.
Peter L. Dwyer, Mercy Hospital, Melbourne. Victoria. Australia.
Brigitte Fatton, University Hospital, Clermont-Ferand. France
Ervin Kocjancic, Department of Urology, University of Illinois. Chicago, USA
Joseph Lee, Mercy Hospital, Melbourne. Victoria. Australia.
Christopher Maher, Wesley Hospital, Brisbane. Queensland. Australia.
Eckhard Petri, Helios-Clinics, University of Rostock, Schwerin. Germany.
Diaa E. Rizk, Ain Shams University, Cairo, Egypt.
Peter K. Sand, Evanston Continence Centre, Evanston. Illinois. U.S.A.
Gabriel N. Schaer, Kantonsspital, Aarau. Switzerland
Ralph J. Webb Norfolk & Norwich University Hospital. Norfolk. U.K..*

*Correspondence to: Associate Professor B.T. Haylen, Suite 904, St Vincent's Clinic, 438
Victoria Street, Darlinghurst. 2010 N.S.W. AUSTRALIA haylen@optusnet.com.au*

CLASSIFICATION WEBSITE INTRO

The Standardization and Terminology Committees of IUGA and ICS and the Joint IUGA-ICS Working Group on Complications of Female Pelvic Floor Surgery welcome your comments on the document:

AN INTERNATIONAL UROGYNECOLOGICAL ASSOCIATION (IUGA) /
INTERNATIONAL CONTINENCE SOCIETY (ICS) JOINT TERMINOLOGY
AND CLASSIFICATION OF COMPLICATIONS RELATED DIRECTLY TO
THE INSERTION OF PROSTHESES (MESHES, IMPLANTS, TAPES) AND
GRAFTS IN FEMALE PELVIC FLOOR SURGERY.

Administrations of both Organizations will explain how you can make those comments on-line as part of a discussion forum open until the 2nd June 2010.

This Joint Report, the second such collaboration between IUGA and ICS (the first being the Terminology for Female Pelvic Floor Dysfunction published in the International Urogynecology Journal and Neurourology and Urodynamics in January this year) has been developed over a number of years. The version posted on the website has been subject to seven reviews by co-authors with the addition of the Classification and Terminology Tables and many case examples. Website publication with access to all IUGA and ICS Members is an important stage in the document's development.

The Joint Report recognises that with the increasing use of prostheses and grafts in female pelvic floor surgery, clarification of Terminology and a clinically-based Classification is needed for complications resulting from such practices.

This Report incorporates: (i) Definitions for all Terminology from a range of sources; (ii) A classification allowing comprehensive coverage of both *insertion complications* and *healing abnormalities*. The latter is a CTS system incorporating (a) Category, (b) Time and (c) Site divisions into a 6 (or seven) digit code for any conceivable complication. Maintaining this level of sensitivity has restricted the level of simplification possible. It is anticipated that this formal Terminology and Classification might be suitable for application to (a) clinical records; (b) any database, registry or surgical audit and (c) academic publications. By making this paper available on the website, we would like to invite you to review it and send us your comments. Your input will assist in improving the quality of the Report as well as its acceptance once the Terminology and Classification are finalised.

We look forward to your comments.



Bernard Haylen
IUGA Standardization and Terminology Committee Chair



Dirk De Ridder
ICS Standardization Committee Chair

ABSTRACT

A standardized terminology and classification is presented for those complications arising directly from the insertion of synthetic (prostheses) and biological (grafts) materials in female pelvic floor surgery. The category (C), time (T) and site (S) classes and divisions have a sensitivity to encompass all conceivable scenarios for insertion complications and healing abnormalities. The CTS code for each complication, involving mostly three letters and three numerals is very suitable for any surgical audit, particularly one that is procedure-specific.

KEYWORDS

Classification, Complications, Prosthesis, Mesh, Graft,
Female Pelvic Floor Surgery

SUMMARY

A standardized terminology and classification is presented for those complications arising directly from the insertion of synthetic (prostheses) and biological (grafts) materials in female pelvic floor surgery.

WORDCOUNT 3557

PREFACE

The Standardization and Terminology Committees of the International Urogynecological Association (IUGA) and 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 directly from the insertion of prostheses and grafts in female pelvic floor surgery. This document would then be, amongst its various possible applications, the basis for a user-friendly registry of such complications. As the first aim is to standardize the terminology used in this classification, the terms used in the title (and the term “trocar”) need to be initially defined.

. ***Classification:*** A systematic arrangement into classes or groups based on perceived common characteristics (1).

. ***Complication:*** A morbid process or event that occurs during the course of a surgery (or postoperatively) that is not an essential part of that surgery (“surgery” replacing “disease” in the definition; “course” includes postoperative of whatever duration) (1).

. ***Directly:*** Without an intermediary or intervening factor (2).

. ***Related:*** Connected (2).

. **Insertion:** Putting in (1).

. **Prosthesis:** A fabricated substitute to assist a damaged body part or to augment or stabilize a hypoplastic structure (1).

. **Mesh:** A (prosthetic) network fabric or structure; open spaces or interstices between the strands of the net (2). The use of this term would generally be for *prolapse surgery with synthetic materials*.

. **Implant:** A surgically inserted or embedded (prosthetic) device (1). (**Explant:** a surgically excised prosthetic device).

. **Tape (Sling):** A flat strip of synthetic material (1). The use of this term would generally be for *incontinence surgery with synthetic materials*.

. **Graft:** Any tissue or organ for transplantation (1, 2). This term will be used to refer to *biological materials inserted* (3):

(a) Autologous grafts: From patient's own tissues e.g. dura mater, rectus sheath or fascia lata.

(b) Allografts: From post-mortem tissue banks.

(c) Xenografts: From other species e.g. modified porcine dermis, porcine small intestine and bovine pericardium.

. **Trocar:** A surgical instrument with a three (four)-sided cutting point [2] (original definition); a usually narrow prosthetic-insertion needle device (current definition).

INTRODUCTION

A significant increase in the use of an ever widening array of prostheses and grafts has occurred in female pelvic floor surgery over the last 30 years. In the 1980's, silastic slings and artificial urinary sphincters (4) were used for urodynamic stress incontinence (USI). McGuire repopularized the rectus sheath fascial sling (an autologous graft) described originally by Aldridge (5). In the early 1990's variations on the Stamey-type (6) needle suspension procedures were used involving permanent sutures and modified needles or bone anchors.

In the mid to late 1990's, suburethral synthetic slings for USI using mesh were introduced, the tension-free vaginal tape (polypropylene mesh) being the most notable (7). Trocars were used both retropubically and, over the last 8-10 years, laterally passing the obturator membrane and the insertion of the obturator internus muscle (8). These trocars, which have the potential for causing prosthesis or graft insertion complications, have been combined with a variety of different prostheses.

The prosthetic materials used to date have, in retrospect, been of different surgical propriety, not appreciated at the time of their introduction. Amid (9)

has presented a classification for different types of meshes in abdominal herniae based on pore size and fibre type used and the likelihood of complications according to that factor alone. This has been extremely useful in directing clinicians and the mesh / device manufacturers to more appropriate mesh types and designs. The consensus of evidence is that the least morbidity will be achieved by using a low weight, large pore, monofilament mesh, with an elasticity between 20% and 35% (10, 11). One might expect fewer issues over time in regards to mesh type.

Deprest et al (11) have presented an excellent analysis of the biology behind the use of prostheses (synthetic) and grafts (biological) in pelvic organ prolapse repair. The classification to be outlined will cover insertion issues as well as infection, healing abnormalities and other signs of rejection of these materials, though not the materials themselves.

In terms of prolapse surgery, there has been at times a quest to achieve a prolapse repair with as close to 100% efficacy (anatomical success) and reduce the 29% long-term risk for a woman to undergo a subsequent prolapse surgery after prior prolapse or continence surgery (12). Anatomical perfection may be quite different from functional acceptability for the

patient. “Kits” (defined as a set of articles or equipment needed for a specific purpose – [2]) have been introduced for all types of prolapse repairs, again involving the use of different materials with different fixation devices or trocars. Papers on such procedures meeting the scientific criteria for randomized prospective trials have been relatively slow to emerge. In addition to “kits”, the same materials have been also been independently laid in place or fixed with surgical sutures. The use of prostheses or grafts has progressed questionably in some areas from an indication for recurrent prolapse to that of using them in primary procedures (13).

Historically, discontinuation of a surgical procedure occurs generally due to either (i) lack of efficacy or (ii) complications. Native (patient’s own, not an autologous [transplanted] graft) tissue repairs are not without complications. 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, infection and/or rejection; (iii) the stability of the prosthesis over time; (iv) morbidity at the donor site from harvesting an autologous graft. Anatomical benefits have not necessarily been matched by subjective benefits.

One key precept in the Hippocratic oath, often quoted in Latin, is “primum non nocere” (first, to do no harm). Surgeons need to know the possible complications that their surgeries might cause and when and where they might occur. In respect of the use of prostheses and grafts, such information might be generated from a table of complications, (personal, multi-centre, a national registry or industry-coordinated), classified according to three aspects: category, time and site (defined below). There have been examples of personal, multi-centre, national and industry-coordinated registries. It is a simultaneous aim, with the production of this document, to initiate the development of a user-friendly joint ICS-IUGA web-based registry of the complications referred to in this document. Only with the information from a registry (at whatever level) can: (i) a surgeon know the value and risk of a certain procedure; (ii) is he/she able to counsel a woman so that she is properly informed as to whether she should embark on that procedure; (iii) if the procedure involves a prosthesis supported by industry, then that group needs to have feedback on the value and complications of that procedure. Should the overview in terms of complications be sufficiently adverse, the procedure and/or the prosthesis or graft should be abandoned.

In drawing up such a classification of complications based on category, time and site, the bias would be towards a greater number of divisions in each class to increase sensitivity, clarity and interpretability. This comes with the natural risk of the classification appearing overly complex. It is hoped that the following outline and explanatory notes and a user-friendly table presentation might alleviate any such concern. 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 the use of meshes, implants, tapes and grafts in female pelvic floor surgery need to involve the following viewpoints of (i) local complications; (ii) complications to surrounding organs; (iii) systemic complications. The generic term of “*erosion*” (medically defined as the “state of being worn away, as by friction or pressure (1)”), doesn’t necessarily suit the clinical scenarios encountered. Its use has been abandoned.

The additional terms to be used are:

. ***Contraction***: Shrinkage or reduction in size (1).

- . **Prominence:** Parts that project beyond the surface (1) (i.e. no penetration).
- . **Penetration:** Piercing or entering (1) (i.e. the vagina).
- . **Separation:** Physically disconnected (2) (e.g. vaginal epithelium).
- . **Exposure:** A condition of displaying, revealing, exhibiting or making accessible (1) (e.g. mesh exposure).
- . **Extrusion:** Passage gradually out of a body structure or tissue (1).
- . **Compromise:** Bring into danger (2).
- . **Perforation:** Abnormal opening into a hollow organ or viscus (1).
- . **Dehiscence:** A bursting open, splitting or gaping along natural or sutured lines (1).
- . **Sinus tract formation:** (Localized) formation of a fistulous tract towards vagina or skin, where there is no visible implant material in the vaginal lumen or overlying skin.

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” – [1]) using as few as three numerals and three letters. No additional verbal description, possibly involving undefined

terminology, should be necessary. The divisions will be outlined and explained below:

SELECTION OF CATEGORIES

The selection of category (C) has used the principal that the least severe complication would involve the prosthesis remaining within the anatomical site into which it was inserted. More severe complications would involve (i) an increasing migration / protrusion into surrounding anatomical structures; (ii) opening into surrounding organs; and (iii) systemic compromise. The following categories (by number) have been formed:

- 1. *Vaginal complication - no epithelial penetration:*** This incorporates the terms prominence (e.g. due to wrinkling or folding), epithelial penetration (without epithelial separation) or contraction (shrinkage). Most meshes can be expected to have some degree of contraction over time.
- 2. *Vaginal complication – (smaller) exposure:*** A smaller (1cm or less) degree of vaginal epithelial separation is involved.
- 3. *Vaginal complication – (larger) exposure or extrusion:*** A larger degree (more than 1cm) of vaginal epithelial separation or prosthesis or graft extrusion is involved.

1-3: Vaginal Complications: These classes have been separated into the following divisions;

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

The addition of an “a” specifies that a mesh contraction is part or all of the abnormal finding.

1B – 3B: Symptomatic – Unusual discomfort or pain; dyspareunia (for either partner). Bleeding may also be a possible symptom.

1Bb - 3Bb: Symptomatic – Mesh Contraction (Table 4) – Provoked pain

only (during vaginal examination) The addition of a “b” specifies that a mesh contraction is part or all of the abnormal finding and pain is provoked only (during vaginal examination).

1Bc - 3Bc: Symptomatic – Mesh Contraction – Pain during intercourse

(either partner) The addition of a “c” specifies that a mesh contraction is part or all of the abnormal finding and pain is provoked during intercourse.

1Bd - 3Bd: Symptomatic – Mesh Contraction – Pain during physical

activities The addition of a “d” specifies that a mesh contraction is part or all of the abnormal finding and pain is provoked during physical activities

1Be - 3Be: Symptomatic – Mesh Contraction – Spontaneous pain

The addition of an “e” specifies that a mesh contraction is part or all of the abnormal finding and pain is spontaneous (i.e. present without physical activity).

1C – 3C: Infection: This is always a possibility with a synthetic prosthesis or graft (xenograft particularly). Signs of local tenderness are suggestive with the combination of redness and purulent discharge more conclusive.

1C – 3C (b-e): Infection –Mesh contraction

The addition of the letters “b” through to “e” specifies that a mesh contraction is part or all of the infected abnormal finding.

1D – 3D: Abscess formation: This is a more serious possibility with a synthetic prosthesis or graft (xenograft particularly).

1D – 3D (b-e): Infection –Mesh contraction The addition of the letters “b” through to “e” specifies that a mesh contraction is part or all of the abnormal finding associated with abscess formation.

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 recognised, defect oversewn (if necessary), prosthesis (graft) removed and some minor precautions are taken, e.g. short term bladder drainage.

4B: Other lower urinary tract (bladder or urethral) complication or compromise: This division would incorporate injuries causing longer term bladder issues, e.g. ongoing prosthesis (graft) perforation, fistula, calculus around the prosthesis (graft). 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 relate to the surgical intervention.

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

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 recognised, prosthesis (graft) removed as indicated, defect 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 prosthesis (graft) perforation, fistula.

5C: Small or large bowel injury or compromise: This division would incorporate injuries causing longer term bowel issues, e.g. ongoing prosthesis (graft) perforation, fistula, obstruction.

5D: Abscess formation from bowel injury/compromise:

6: Skin Complications;

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

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

6C: Infection: including sinus tract formation

6D: Abscess formation from skin complication:

7: Patient compromise: This category recognises that the patient might be brought into systemic danger with some of the complications in addition to any local issue.

7A: Bleeding complication including haematoma: This division refers to any clinically diagnosed haematoma and certainly one 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 transfer for management in intensive care.

7C: Mortality: The insertion of the prosthesis, whilst not fatal in itself necessarily, has set in train further morbid events leading to mortality.

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

SELECTION OF TIME (T) DIVISIONS

The time (T) for the complication is when it is *clinically diagnosed*. This section incorporates three 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 prosthesis or graft when complications might be more frequently seen. This would depend on the results of a surgical audit using the classification. The earliest time division (*T1*) might involve more insertion issues, whilst later divisions (*T2-T3*) might be biased towards healing abnormality issues.

T1: Intraoperative - 48 Hours: Insertion issues more likely.

T2: 48 hours - 6 months: Healing or infection issues more likely.

T3: Over 6 months: Late healing abnormalities and mesh contraction issues more likely.

SELECTION OF SITE (S) DIVISIONS

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

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

S1: Vaginal: area of suture line: Perhaps the commonest site for prosthesis and graft complications is close to the vaginal suture line. Most suture lines would be midline.

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

S3: Trocar passage: The passage of any sharp surgical instrument can cause damage along the path of insertion. This division incorporates any extraperitoneal, bladder or rectal complication, but not intraabdominal complications which are **S5**.

S4: Other Skin site: This division is relevant to any skin complications away from the sites of trocar entry or exit. Included might be cutaneous sinus or fistula formation.

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** to indicate mesh contraction 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 3.
- . 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 a vaginal tape penetration from asymptomatic to symptomatic; an exposure progresses from smaller to larger.

CLASSIFICATION LIMITATIONS

Whilst the classification aims to have maximum sensitivity for physical complications of prostheses and grafts:

- . Type of mesh issues have been covered by Amid (9): These issues will be further reflected in the healing abnormalities in the current classification.
- . Functional issues (e.g. voiding dysfunction) are not included: Voiding difficulty can be defined as abnormally slow (assessed by urine flow rate) or incomplete (assessed by postvoid residual) micturition. Surgical intervention

for severe voiding dysfunction, namely urinary retention is included in section **4B**.

. Urinary tract infections have not been included.

. The small risk (about 1 in 2 million) of prion or viral infection associated with a xenograft (14) is not included.

. Recurrences: Meshes are used to prevent recurrence. However a mesh may fail as well hence recurrence can occur. This can be either by degradation or local release of sutures, the clinical result being the same. Sometimes local complications give lead to removal of the mesh, which increases the risk for recurrence.

. Intraperitoneal adhesions: Some procedures involve the use of implant material into the abdomen. As a consequence one can have intraperitoneal adhesions either on the implant or remotely.

. Bulking agents: Complications related to bulking agents including migration are not included.

TABLES

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

Table 2: A classification by category (C), time (T), and site (S) of complications directly related to the insertion of prostheses (meshes, implants, tapes) or grafts in female pelvic floor surgery.

Table 3: An example of a table of complications directly related to the insertion of prostheses (meshes, implants, tapes) or grafts in 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.

Table 4: Subclassification of categories *1* to *3* to specify that a mesh contraction is part of the abnormal finding and the impact of that finding on patient's symptoms.

DISCUSSION

The present classification has been developed to be sensitive to all possible physical complications involving the use of a prosthesis or graft in a female pelvic floor surgical procedure. Both insertion complications and healing abnormalities are covered. Whilst this creates a much larger number of possible complication scenarios, these have still been able to have been organized into appropriate classes and divisions by category, time and site. The end-point is a code of 3 letters (4 if “a” to “e” are used) and 3 numerals.

A key advantage is that all involved in pelvic floor surgical, medical, nursing, allied health, industry and, unfortunately at times, medico-legal interests will be referring to the same clinical issue. Many countries already have national data bases for new surgical devices and it is inevitable that there will be more regulation over time for the introduction of new surgical devices to avoid the late detection of serious complications following their widespread introduction. With a standardized classification in place, quicker assessment of adverse events (or their absence) will be achieved together with uniform reporting of prosthetic-related complications. Any procedure incurring an adverse surgical audit would need closer scrutiny and if persistent should then be abandoned. In terms of patient care, the principle

from the Hippocratic oath, “first, to do no harm” is more likely to be observed.

It is acknowledged that to achieve comprehensive coverage of complications, the classification may still appear somewhat complex and not immediately mastered. It has been a consensus view of the co-authors that a formal academic terminology and classification (as simplified as is possible) should be completed prior to attempts at further simplification. The latter may run the danger of compromising coverage of complications.

ACKNOWLEDGEMENTS

The valuable input of Professor Bernard Jacquetin to the “category” section is gratefully acknowledged. We appreciate the early work of the first author’s secretary, Mrs Kerry Sutton, in formatting early versions of the main Classification Table.

REFERENCES

- 1: Stedman's Medical Dictionary. (2006) Lippincott, Williams and Wilkins. Baltimore. U.S.A.
- 2: Concise Oxford Dictionary. (1995). Clarendon Press. Oxford.
- 3: Dwyer PL. (2006) Evolution of biological and synthetic grafts in reconstructive pelvic surgery. *Int Urogynecol J.* 17: S10-S15.
- 4: Duncan HJ, Nurse DE, Mundy AR. (1992) Role of the artificial urinary sphincter in the treatment of stress incontinence in women. *Brit J Urol.* 69:141-143.
- 5: Aldridge AH. (1942) Transplantation of fascia for relief of urinary stress incontinence. *Am J Obstet Gynecol.* 44:398.
- 6: Stamey TA. (1973) Endoscopic suspension of the vesical neck for urinary incontinence. *Surgery, Gynecology and Obstetrics.* 136:547-554.
- 7: Ulmsten UJ, Johnson P, Rezapour M., (1999) A three-year follow-up of tension-free vaginal tape for surgical treatment of stress urinary incontinence. *Br J Obstet Gynaecol* 106:345-350.
- 8: Delorme E, Droupy S, de Tayrac R, Delmas V. (2003) Transobturator tape (Urotape). A new minimally invasive method in the treatment of urinary incontinence in women. *Prog Urol.* 13:656-659.

- 9: Amid P. (1997) Classification of biomaterials and their relative complications in an abdominal wall hernia surgery. *Hernia*. 1:15-21.
- 10: Rosch R, Junge K, Hölzl F et al. (2004) How to construct a mesh. In Schumpelick V, Nyhus LM, (eds) *Meshes: benefits and risks*. Springer. Berlin . pp179-184.
- 11: Deprest J, Zheng F, Konstantinovic M et al. (2006) The biology behind fascial defects and the use of implants in pelvic organ prolapse repair. *Int Urogynecol J*. 17: S16-S25.
- 12: Olsen AL, Smith VJ, Bergstrom JO et al (1997) Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. *Obstet Gynecol*. 89: 501-506.
- 13: Davila GW. (2006) Introduction to the 2005 IUGA Grafts Roundtable. *Int Urogynecol J*. 17:S4-S5.
- 14: Simonds RJ, Homberg SD, Hurwitz RL. (1992) Transmission of human immunodeficiency virus type 1 from seronegative organ tissue donor. *N.Eng J Med* 326:726-730.

Table 1: Terminology involved in the Classification

TERMS USED	DEFINITION
<u>PROSTHESIS</u>	A fabricated substitute to assist a damaged body part or to augment or stabilize a hypoplastic structure.
A: MESH	A (prosthetic) network fabric or structure.
B: IMPLANT	A surgically inserted or embedded (prosthetic) device.
C: TAPE (SLING)	A thin strip of synthetic material.
<u>GRAFT</u>	Any tissue or organ for transplantation. This term will refer to biological materials inserted.
A: AUTOLOGOUS GRAFT	From the woman's own tissues e.g. dura mater, rectus sheath or fascia lata.
B: ALLOGRAFTS	From post-mortem tissue banks.
C: XENOGRAFTS	From other species e.g. modified porcine dermis, porcine small intestine, bovine pericardium.
TROCAR	Narrow prosthetic/graft insertion needle device
<u>COMPLICATION</u>	A morbid process or event that occurs during the course of a surgery that is not an essential part of that surgery.
CONTRACTION	Shrinkage or reduction in size.
PROMINENCE	Parts that protrude beyond the surface (no penetration).
PENETRATION	Piercing or entering (i.e. the vagina).
SEPARATION	Physically disconnected (e.g. vaginal epithelium).
EXPOSURE	A condition of displaying, revealing, exhibiting or making accessible e.g. mesh exposure.
EXTRUSION	Passage gradually out of a body structure or tissue e.g. tape extrusion into the vagina.
COMPROMISE	Bring into danger.
PERFORATION	Abnormal opening into a hollow organ or viscus.
DEHISCENCE	A bursting open, splitting or gaping along natural or sutured lines

Table 2: A Classification by Category, Time (T), and Site (S) of Complications directly related to the insertion of Prostheses (Meshes, Implants, Tapes) or Grafts in Urogynecological Surgery

See Colour table

Table 4: Subclassification of Complication Categories to specify the presence of a mesh contraction as part or all of the abnormal finding and the grade in terms of the presence and severity of symptoms.

GRADE OF MESH CONTRACTION	SYMPTOMS
a	ASYMPTOMATIC
b	PROVOKED PAIN ONLY (during vaginal examination)
c	PAIN DURING INTERCOURSE
d	PAIN DURING PHYSICAL ACTIVITIES
e	SPONTANEOUS PAIN

Table 3: An example of a *non-procedure-specific* table of complications directly related to the insertion of Prostheses (Meshes, Implants, Tapes) or Grafts in Urogynecological Surgery using the category, Time (T) and Site (S) system. One might expect these tables to be often procedure-specific.

Patient Number	Description of Complication	Code	Code
000	Retropubic haematoma following a tape procedure (first 24 hours)	7A/T1/S3	
111	Persistent thigh pain six weeks after an obturator tape	6B/T2/S4	
222	Bowel obstruction and 2cm vaginal vault exposure with bleeding 7 months after a mesh sacrocolpopexy	5C/T3/S5	3B/T3/S1
333	Mesh penetration (lateral vaginal) in a woman at a 6 week postop review whose partner is describing discomfort with intercourse	1B/T2/S2	
444	A midline vaginal exposure of mesh (< 1cm) with redness, discharge, dyspareunia 15 months after a mesh anterior colporrhaphy Mesh contraction noted	2Cc/T3/S1	
555	Lateral vaginal extrusion with malodorous discharge and a midline rectovaginal fistula 8 months after a posterior vaginal tape.	3C/T3/S2	5B/T3/S1
666	Intraoperative obturator vessel injury during a transobturator tape procedure requiring major resuscitation.	7B/T1/S3	
777	Persistent intravesical tape/ calculus formation/ haematuria 2 years after a retropubic tape procedure	4B/T3/S3	
888	Pelvic abscess presenting 8 days after a mesh sacrocolpopexy complicated by an intraoperative bowel defect (final category). Initial code was 5A/T1/S7.	5D/T2/S5	
999	Tender prominent mesh contraction noted 9 months after an anterior mesh repair (no symptoms, husband unwell)	1Bb/T3/S1	
XXX	Persistent postvoid residual of 150mls with recurrent UTI requiring posterior division of suburethral tape 4 months after insertion	4B/T2/S1	

Table 3: An example of a non – procedure – specific table of complications directly related to the insertion of Prostheses (Meshes, Implants, Tapes) or Grafts in Urogynecological 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 a tape procedure (first 24 hours)	7A /T1/ S3	
111	Persistent thigh pain six weeks after an Obturator tape	6B /T2/ S4	
222	Bowel obstruction and 2cm vaginal vault exposure with bleeding 6 months after a mesh sacrocolpopexy	5C /T3/ S5	3B /T3/ S1
333	Mesh penetration (lateral vaginal) in a woman at a 6 week postop review whose partner is describing discomfort with intercourse	1B /T2/ S2	
444	A midline vaginal exposure of mesh (< 1cm) with redness, dyspareunia, discharge 15 months after an anterior colporrhaphy using mesh. Mesh contraction noted.	2Cc/T3/S1	
555	Lateral vaginal extrusion with malodorous discharge and a midline rectovaginal fistula 8 months after a posterior vaginal tape	3C /T3/ S2	5B /T3/ S1
666	Intraoperative obturator vessel injury during a transobturator tape procedure requiring major resuscitation	7B /T1/ S3	
777	Persistent intravesical tape / calculus Formation / haematuria 2 years after a retropubic tape procedure	4B /T3/ S3	
888	Pelvic abscess presenting 8 days after a mesh sacrocolpopexy complicated by an intraoperative bowel defect (final category). Initial code was 6A/T1/S5	5D /T2/S5	
999	Tender prominent mesh contraction noted 9 months after an anterior mesh repair (no symptoms, husband unwell)	1Bb/T3/S1	
XXX	Persistent postvoid residual of 150mls with recurrent UTI requiring posterior division of suburethral tape 4 months after insertion	4B /T2/S1	

Table 4: Grades of Mesh Contraction: subclassification of Complication Category

To specify the presence of a mesh contraction as part or all of the abnormal finding and the grade in terms of the presence and severity of symptoms

- a** asymptomatic
- b** provoked pain only (during vaginal examination)
- c** pain during intercourse
- d** pain during physical activities
- e** spontaneous pain

IUGA/ICS Joint Terminology and Classification of Complications Related Directly to the Insertion of Prostheses (Meshes, Implants, Tapes) or Grafts In Female Pelvic Floor Surgery

Bernard T Haylen^{*0}, Robert M Freeman^{*^0}, Steven E Swift^{*0}, Michel Cosson⁰, G Willy Davila⁰, Jan Deprest⁰, Peter L Dwyer^{*0}, Brigitte Fatton⁰, Ervin Kocjancic⁰, Joseph Lee^{*}, Chris Maher⁰, Daa E Rizk^{*}, Eckhard Petri^{*}, Peter K Sand^{*}, Gabriel N Schaer^{*}, Ralph Webb^{^0}

Standardization and Terminology Committee, International Urogynecological Association (IUGA)^{*} & International Continence Society (ICS)[^]; Joint IUGA/ICS Working Group on Complications Terminology⁰

Table 1: Terminology involved in the Classification

TERMS USED	DEFINITION
PROSTHESIS	A fabricated substitute to assist a damaged body part or to augment or stabilize a hypoplastic structure
A: Mesh	A (prosthetic) network fabric or structure
B: Implant	A surgically inserted or embedded (prosthetic) device
C: Tape (Sling)	A thin strip of synthetic material
GRAFT	Any tissue or organ for transplantation. This term will refer to biological materials inserted
A: Autologous Grafts	From the woman’s own tissues e.g. dura mater, rectus sheath or fascia lata
B: Allografts	From post-mortem tissue banks
C: Xenografts	From other species e.g. modified porcine dermis, porcine small intestine, bovine pericardium
TROCAR	Narrow prosthetic/graft insertion needle device
COMPLICATION	A morbid process or event that occurs during the course of a surgery that is not an essential part of that surgery
CONTRACTION	Shrinkage or reduction in size
PROMINENCE	Parts that protrude beyond the surface (no penetration)
PENETRATION	Piercing or entering (i.e. the vagina)
SEPARATION	Physically disconnected (e.g. vaginal epithelium)
EXPOSURE	A condition of displaying, revealing, exhibiting or making accessible e.g. mesh exposure.
EXTRUSION	Passage gradually out of a body structure or tissue
COMPROMISE	Bring into danger
PERFORATION	Abnormal opening into a hollow organ or viscus
DEHISCENCE	A bursting open or gaping along natural or sutured line

Table 2: A CLASSIFICATION OF COMPLICATIONS RELATED DIRECTLY TO THE INSERTION OF PROSTHESES (MESHES, IMPLANTS, TAPES) OR GRAFTS IN UROGYNECOLOGICAL SURGERY

		CATEGORY			
General Description		A (Asymptomatic)	B (Symptomatic)	C (Infection)	D (Abscess)
1	Vaginal: no epithelial separation Include prominence (e.g. due to wrinkling or folding), penetration (without separation) or contraction (shrinkage) Grades of mesh contraction (a-e) from Table 4 is incorporated	1A: Abnormal prosthesis or graft finding on clinical examination	1B: Symptomatic e.g. unusual discomfort / pain; dyspareunia (either partner); bleeding	1C: Infection (suspected or actual)	
2	Vaginal: smaller ≤ 1cm exposure	2A: Asymptomatic	2B: Symptomatic	2C: Infection	D = Abscess
3	Vaginal: larger >1cm exposure, including extrusion	3A: Asymptomatic 1-3Aa if mesh contraction	3B: Symptomatic 1-3B (b-e) if mesh contraction	3C: Infection 1-3C (b-e) if mesh contraction	D = Abscess
4	Urinary Tract compromise or perforation Include prosthesis (graft) perforation, fistula and calculus	4A: Small intraoperative defect e.g. bladder perforation	4B: Other lower urinary tract complication or urinary retention	4C: Ureteric or upper urinary tract complication	
5	Rectum or Bowel compromise or perforation Include prosthesis (graft) perforation and fistula	5A: Small intraoperative defect (rectal or bowel)	5B: Rectal injury or compromise	5C: Small or Large bowel injury or compromise D = Abscess	
6	Skin compromise Include discharge pain lump or sinus tract formation	6A: Asymptomatic, abnormal finding on clinical examination	6B: Symptomatic e.g. discharge, pain or lump	6C: Infection e.g. sinus tract formation D = Abscess	
7	Patient compromise Include hematoma or systemic compromise	7A: Bleeding complication including haematoma	7B: Major degree of resuscitation or intensive care*	7C: Mortality * *(additional complication - no site applicable - S0)	

TIME (clinically diagnosed)

T1: Intraoperative to 48 hours	T2: 48 hours to 6 months	T3: over 6 months
---------------------------------------	---------------------------------	--------------------------

SITE

S1: Vaginal: area of suture line	S2: Vaginal: away from area of suture line	S3: Trocar passage Exception: Intra-abdominal (S5)	S4: other skin site	S5: Intra-abdominal
---	---	--	----------------------------	----------------------------

- N.B.**
- Multiple complications may occur in the same patient. There may be early and late complications in the same patient. i.e. All complications to be listed. Tables of complications may often be procedure specific.
 - The highest final category for any single complication should be used if there is a change within time. (patient 888)
 - Urinary tract infections and functional issues (apart from 4B) have not been included.



CODE



Examples of cases



Case 1

52 year old female underwent a TVT-O. At 6 weeks, she was cured of her SUI, reported no vaginal discharge. Vaginal examination revealed a smaller mesh exposure away from vaginal suture line.

Classification

2A T2 S2



Case 2

55 year old female had a retropubic sling. At 2 years follow up, she reported vaginal discharge. Examination revealed a palpable but unseen mesh exposure, together with a cutaneous fistula with local purulent discharge.

Classification

6C T3 S4

(Skin infection/fistula, >6m, skin site)



Case 3

65 year old with mixed urinary incontinence and predominant severe SUI, underwent a multifilament transobturator sling. At 14 months follow up, she experienced severe pelvic pain, vaginal discharge. Clinical examination revealed hyperthermia to 40°C, sling exposure at right vaginal sulcus and severe cellulitis.

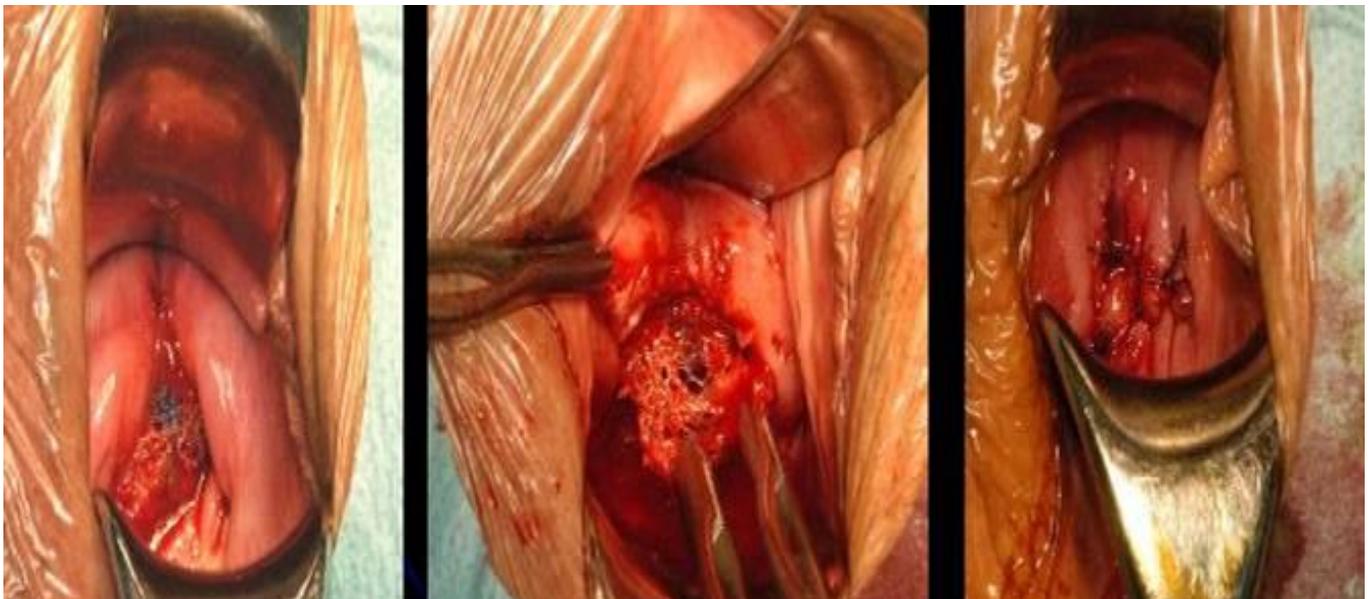
Classification

6C T3 S3

(Inflammation; >6m; trocar passage)

3C T3 S2

(C: Larger infected vaginal exposure; T: >6m; S: Vaginal away from suture line)



Case 4

67 year old female previously underwent POP repair with hysterectomy. She subsequently had a transvaginal mesh repair for a large recurrent cystocele. At 5 months follow up, she complained of dyspareunia. Vaginal examination revealed a mesh exposure of 20mm by 15mm at anterior vaginal wall and vaginal cuff.

Classification: **3B T2 S1**

(Larger exposure, <6m, Close to vaginal suture line)



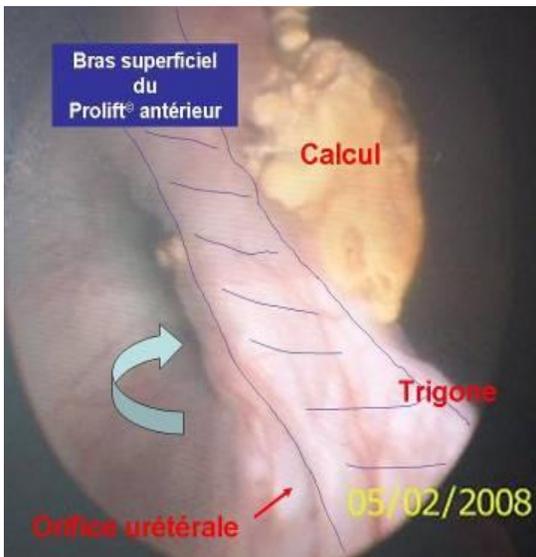
Case 5

47 year old underwent a transoburator tape for SUI. At 5 months follow-up, she reported vaginal discharge. Clinically she was febrile at 38 °C with a large sling extrusion as depicted.

Classification

3C T2 S1

(Infected extrusion, < 6m, close to vaginal suture line).



Case 6

65 year old underwent a transvaginal mesh repair for a grade 3 prolapse. At 32 months, she had

- Recurrent urinary tract infections
- Urgency and urge incontinence
- Pelvic pain and deep dyspareunia
- Bladder pain & Lumbar pain

Radiology: right hydronephrosis and ureteral obstruction

Cystoscopy: mesh extrusion (< 0.5cm²) with stone. No right ureteric patency

Vaginal examination: severe anterior mesh shrinkage and pain during anterior vaginal wall palpation.

Classification: **4C T3 S3 ; 1Bc T3 S1**



Case 7

Patient underwent a posterior vaginal mesh procedure using a trocar. At 3 months, clinical examination confirmed an infected midline 15mm vaginal mesh exposure together with a recto-vaginal fistula. There had been mesh penetration of the rectum.

Classification

3C T2 S1 ; 5B T2 S3

(Infected large exposure, <6m, close to vaginal suture line)

(Rectal complication, <6m, trocar related)



Case 8

62 year old female underwent a transobturator anterior vaginal mesh procedure. At 24 months follow up, she reported no vaginal discharge, some discomfort. Clinical examination revealed skin erosion with local inflammation at (trocar) exit point.

Classification

6B T3 S3

(symptomatic skin complication, >6m, trocar-related)