

# **WHITE PAPER ON GENITOURINARY RECONSTRUCTIVE MEDICINE: WHERE DO WE STAND AND WHAT SHOULD THE FUTURE LOOK LIKE?**

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## **Background**

In recent years many urologists and urologic organizations have raised the question of whether the urologists' role in reconstructive surgery has been weakening. In addition, concerns have also been expressed as to whether this field is losing its visibility and whether it is being adequately taught to urology residents. Some have expressed concern regarding the role of the reconstructive surgeon in academic practice and its effect particularly regarding male reconstruction fellowships.

In order to shed light on these issues and explore possible solutions to any perceived problems, the AUA convened a "Urinary Reconstruction Steering Committee Strategic Meeting" on April 29-30, 2011 at AUA Headquarters to which leaders in genitourinary reconstruction, representing the many organizations that comprise this area of urology, were invited. The goals and objectives of the meeting were to:

- 1) review the current status of genitourinary reconstruction in men and women
- 2) review the current status of education of residents and fellows in genitourinary reconstruction
- 3) determine steps that may be useful in improving the future education of urologists involved in the practice of male and female genitourinary reconstruction

## **Status of reconstruction procedures done by urologists today**

The extent to which urinary reconstruction in men and women is practiced in the U.S. by urologists was presented by Dr. Stuart Howards, Executive Secretary of the American Board of Urology (ABU). A review of the relevant billing codes related to urinary reconstruction from 247 submitted 2010 certification billing logs and 496 submitted 2010 recertification billing logs were compared to two logs from individuals with large female pelvic medicine and surgery practices. Dr. Howards reported that most U.S. urologists perform few or no surgical procedures in this field. (This trend is of course not limited to reconstructive procedures as similar data have been shown for many other complex urologic subspecialty procedures.)

The median number of procedures per urologist was 24, including 22 urodynamic (UD) procedures and 2 slings, reported by certifying urologists and 64 (including 58 UD and 6 slings) reported by recertifying urologists. Put in other terms, the total number of relevant reconstruction-related procedures for the 2010 recertifying urologist pool was 183,897 (1.84%) of the 10,005,739 procedures reported by this group. These numbers include all billed procedures, including blood draws. Of those procedures listed only 4965 (2.7%) were surgical procedures.

In contrast, “experts” in this field, chosen randomly by Dr. Howards based on his knowledge of their reputation, performed many more procedures, including an average of 1229 related procedures of which 1030 involved UD and 199 were operative procedures. These surgical procedures (excluding UD) represented 49% of billed procedures by these experts. Again, these data suggest that urinary reconstruction procedures, like other complex urologic procedures, are not commonly performed by a large number of primarily office based urologists but rather increasingly experts in the field.

**Table 1.** Comparison of reconstruction billing patterns of certifying and recertifying urologists and “experts” in urinary reconstruction

	No.	No. UD	No. Operative Procedures
Certification logs	247	22	2
Recertification logs	496	58	6
“Experts”	2	1030	199

### **The importance of urinary problems addressed by urinary reconstruction in men and women**

Urinary problems that are treated by reconstructive procedures are a major health care issue. Addressing female pelvic reconstructive problems in women, Dr. Badlani reported information regarding the extent to which vaginal repair and pelvic organ prolapse repairs are being practiced in the U.S. and by whom. Broadly, incontinence management involving genitourinary reconstruction in women is comprised of stress urinary incontinence (SUI), urge urinary incontinence, and mixed urge and stress incontinence. Based on a study by Nygaard et al using 2005-6 NHANES data, including 1961 women older than 20 years, the overall prevalence of symptomatic pelvic floor disorders in U.S. women is 15.7% with the highest prevalence seen in women older than 80 years (31.7%).<sup>1</sup>

Coyne et al in a study of lower urinary tract symptoms in women in the U.S. and Europe also showed that urgency incontinence occurred “sometimes” in 24.4% of women and “often” in 13.1%.<sup>2</sup> They also showed that the prevalence of stress urinary incontinence associated with laugh/cough/or sneeze was experienced “sometimes” by 31.8% and “often” by 14.8% of women. Other studies have confirmed the high prevalence of these symptoms. One study by Townsend et al suggested that the incidence of urinary incontinence is significantly less common in African American women than in white women (0.1/100 person years vs. 0.8/100 person years).<sup>3</sup>

Male genitourinary reconstruction also is a major health care concern. For example, although the true incidence of urethral stricture disease is unknown, it is estimated that male urethral stricture disease results in more than 5000 inpatient visits yearly while office visits for urethral stricture disease are estimated to number almost 1.5 million per year. The total cost of male urethral stricture diseases per year exceeds \$200 million in the U.S. alone. Patients with urethral stricture disease appear to have very high rates of urinary tract infection (40%) and incontinence (10%).<sup>4</sup>

Injury to the urethra is also a common clinical problem, whether it is a result of violent trauma or is iatrogenic in origin. For example, in the area of prostate cancer management alone the risk of urethral stricture treatment after prostate cancer therapy is 1.1% to 8.4% depending on cancer treatment type. This risk was highest after radical prostatectomy or brachytherapy plus external beam radiotherapy and in those with advanced age or obesity. Stricture after radical prostatectomy occurred within the first 24 months, whereas onset was delayed after radiation.<sup>5</sup>

### **Credentialing for female and male reconstruction**

Over the past two decades there has been a major change in the way in which physicians are credentialed in the area of female genitourinary reconstruction. About ten years ago the American Board of Obstetrics and Gynecology (ABOG) first proposed that it would like to create subspecialty certification for “urogynecology” much as it had already done in maternal fetal medicine, reproductive endocrinology and infertility, and gynecologic oncology. Historically, the ABOG is the only medical field that has had an independent authority to create subspecialty certification outside of the more typical American Board of Medical Specialties (ABMS) process. This proposal was recognized by the American Board of Urology (ABU) and discussions between the two boards ensued. This led in 1989 to the formation of an ABU/ABOG Steering Committee to move the process forward for both specialties and to, in the interim, approve fellowships in Female Pelvic Medicine and Reconstructive Surgery (FPMRS).

This committee, comprised of 3 representatives from each from the ABU and ABOG, has met twice a year for 12 years. Currently there are 38 OBGYN-based and 7 Urology-based FPMRS programs, with 3 programs educating either urologists or gynecologists. There is a combined match program for these fellowships. Over the years the two boards and the joint committee have moved progressively toward subspecialty certification, a process that has now been approved by the ABMS (the body whose role is to approve and accredit new specialties and subspecialties). Thus, today FPMRS is a recognized subspecialty by the ABMS which provides subspecialty certification in this area of medicine.

In addition, the American Committee for Graduate Medical Education (ACGME), the body in charge of review committees for residencies and fellowships, has now also approved its role in accrediting the fellowships for this new subspecialty area. The ACGME’s Residency Review Committees (RRCs) for Urology and Gynecology will now be responsible for approving the above mentioned fellowships using separate OB/GYN and Urology RRC reviews (with the OB/GYN RRC being the official

“reporting entity”). The final steps in this process, which will take form in the near future, are the establishment of “grandfathering” rules for physicians who did not complete these fellowships, the creation and implementation of certifying examinations, and establishment of Maintenance of Certification (MOC) processes.

**Table 2.** *Comparison of FPMRS and male reconstruction fellowships*

	FPMRS Fellowships	Male Reconstruction Fellowships
Lead to subspecialty certific.	Yes	No
ACGME approved	Yes	No
Require research	Yes	No
Use a match program	Yes	Yes
Typical length	2-3 Yrs	1 Yr
No. programs accept urology residents	10	12

During this same timeframe, there has also been some progress in the creation and implementation of male reconstruction fellowships. Although subspecialty recognition for male urinary reconstruction by the AMBS (like that achieved in the field of FPMRS) is probably not close to being accomplished (and, in fact, may not be the goal of male genitourinary reconstruction organizations today), there are currently 12 primarily male reconstruction fellowships recognized by the Society of Genitourinary Reconstructive Surgeons (GURS), with several others due to be recognized in the near future. These fellowships typically focus on complex male urethral surgery, complex male genital surgery including grafts, acute and delayed trauma care, Peyronie’s disease, complications of prostate and bladder cancer, urinary diversion, ureteral strictures and the sequelae of spinal cord injury. Some, however, include a major component in female pelvic reconstruction. Most of these fellowships are one year in duration (compared to a duration for the above mentioned FPMRS fellowships of 2 years for urologist trainees and 3 years for gynecologist trainees).

Existing fellowships in male reconstruction are reported to be “highly competitive” and are felt to train a reasonable number of “full-time” reconstructive surgeons. Often fellows in these programs are attending surgeons who have completed their urologic residencies and who bill for urologic services outside of the area of their reconstruction fellowship, therefore largely paying at least a part of their own fellowship stipends. This is in contrast to ACGME approved fellows who are prohibited from billing all together. In addition, although these programs do teach and perform clinical research, there is typically no defined research experience mandated during these fellowships (again different from the FPMRS fellowships described above).

### **Quality of care and outcome measures in reconstruction**

The AUA currently has, or will have, recently approved clinical guidelines for SUI (2009) and urotrauma (planned 2013), two of the areas encompassed within genitourinary reconstruction. In addition, quality measures connected to these guidelines are being developed. For example for SUI, an interdisciplinary technical panel has

recently approved 5 measures, including 1) the percentage of female patients who have SUI surgery who received a complete SUI evaluation within 12 months of the surgery, 2) the percentage of SUI surgery patients for whom there was documentation that treatment options (including behavioral, medical and surgical) were discussed with them, 3) the percentage of SUI surgeries for which cystoscopy was used during reconstruction procedures to reduce complications, 4) the percentage of female patients who were counseled about the risks associated with the use of mesh in sling surgery (erosion/extrusion, pain, etc) and 5) the percentage of SUI surgery patients who had an assessment of their response to surgical treatment performed within 1 year after their surgery. These types of quality of life and outcome measures will almost certainly be an increasingly important aspect of documenting quality of care in the U.S. medical system as it evolves.

### **The introduction of new techniques and devices in urinary reconstruction**

In a ruling subsequent to our Committee meeting the Food and Drug Administration (FDA) on June 16, 2011 published a Public Health Notification about complications of surgical mesh used for pelvic organ prolapse and stress urinary incontinence. The FDA reported that nine device manufactures had reported over 1000 people suffered severe complications associated with the use of surgical mesh. Many believe that this report is an important reflection on the system of technical development in reconstructive surgery that is flawed and incomplete.

By way of summary, the practice of the introduction of new techniques and devices in the area of reconstructive surgery has been a matter of concern for some time. Technology in general has developed into an evolving practice with both an engineering base and a market demand to achieve a particular innovation. Clinicians, including urologists, are very much involved in this process, typically as “thought leaders.” Medical device development is very different than drug development. In drug development, a patent is critical to the process whereas in device development it is less defined. In addition devices are classified into 3 classes as defined by their level of risk and “substantial equivalence” to an existing product. The benefits associated with “thought leader” involvement in the process of medical device development include the physicians’ intimate knowledge of the disease process and their ability to help design these products. Potential disadvantages include possible bias and the possibility that the physicians’ involvement may be based more on associated incentives rather than patient need.

Unfortunately, there are currently no parameters used to address these potential issues. It would seem that a transparent conflict of interest disclosure should be a key component of this process moving forward in order to improve its integrity. Physician guidance in product development should demand first and foremost patient safety, as well as a demand for well designed and adequately powered clinical trials with measureable metrics of success. It is also critical for physicians using these new products to report negative outcomes and to be critical of the clinical data. In sum, it would seem to be essential that we teach future clinicians and “thought leaders” the principles of ethical and proper clinical investigation in dealing with industry, specifically as it relates to product development.

## **What can be done to improve the area of urinary reconstruction?**

During this meeting, several issues of major concern regarding the current status of genitourinary reconstruction were debated in breakout sessions. Each breakout session was based on a defined question(s) (shown in bold). The following sessions and recommendations derived from each follow.

### ***1. What can be done to increase the number of urologists being trained in FPMRS programs?***

This discussion group strongly recommended that efforts be made to enhance the exposure of urology residents to the field of genitourinary reconstruction as a whole, and especially as it relates to female pelvic medicine. There was also agreement that there needs to be an effort to increase in the number of FPMRS slots available to urology trained physicians (currently 12-15/year). The role of mentorship in this area and its absence in many urology training programs was recognized. In addition, the overwhelming debt burden that most urology residency graduates have accumulated by the time they complete their 5-6 years of training in urology is clearly a major factor in deciding the type and length of a fellowship.

It is increasingly difficult for residency graduates to defer their entrance into clinical practice and there is currently a substantial issue of paying fellowship stipends and other fellowship expenses at a time when nearly all academic institutions are well over their assigned Graduate Medical Education (GME) caps. The group also concluded that it is likely that the new ACGME subspecialty certification accomplished for female pelvic medicine and reconstruction will become more often the norm and the goal of many trainees. This may put added pressure on non-ACGME fellowships (especially now for female reconstruction) to attract the best and brightest fellows in the future.

### ***2. What should be done to strengthen fellowship training in male reconstruction and what hurdles to expanding fellowship length exist?***

This discussion centered much of its attention to the education and exposure that urology residents receive in this area. There was noted to be a less than adequate educational exposure in this area in many urology training programs. Solutions to these problems included the creation of webinars or other educational materials that might be widely distributed, a renewed emphasis on teaching the indications for, performance of and interpretation of urodynamic studies, and the creation of new educational meetings which emphasize this area of urology (particularly at the AUA Section meetings).

It was also felt to be extremely important that we improve the education of practicing general urologists in this area of urology. It was suggested that a real attempt be made to strengthen clinical and translational research in this area of urology and that the Core Curriculum for Urology be used widely to “standardize” resident education in this area. The role of the various genitourinary subspecialty societies in working to improve and enhance the Core Curriculum for Urology was also emphasized. In fact, a modular approach that

takes the urology resident to the level he/she is expected to master during residency and then expands the breadth and depth of education to the fellowship level was felt to be very important.

**3. *What should “needs assessment” for urology programs for resident education in reconstructive urology look like?***

This discussion emphasized the need to have a validated survey of residency programs designed to fully define the extent of education in genitourinary reconstruction (as well as other areas of urologic resident education) and to address steps that might be taken to address any problems in this area. This survey would allow also for the development of a needs assessment in this area of education. There was also felt to be a need to define competences in genitourinary reconstruction education, define the value of index case numbers, evaluate the part of the in-service examination related to genitourinary reconstruction and how residents fare on this part of the examination, and develop modules for education in the various areas defined by genitourinary reconstruction societies as areas of importance.

It was suggested that all residencies should strive to have a specialist in this area and, when this is not practical, that traveling scholars be identified for this purpose. It was further suggested that one potentially highly effective mechanism for improving education in this area would be the development of educational courses, especially at AUA Section meetings. It was also proposed that the AUA consider the development of a “stand-alone” national educational course on genitourinary reconstruction and that the AUA Research Council assist the various organizations involved in this area to identify NIH and other granting agencies that might help residency and fellowship programs improve clinical and translational research in this area.

**4. *What should be done to manage the early adoption of new and potentially poorly tested new techniques or products, what are the ethical issues involved and what steps should be taken to address this process?***

It was strongly suggested that the FDA should be asked to scrutinize the process of early introduction of new products and techniques in the area of genitourinary reconstruction, and determine if the current process is adequate. It was acknowledged that urologists have, as a whole, been “early adopters” of new products and techniques. It was suggested that the FDA may not currently be looking at the correct end points for approval of these new products and techniques.

In addition, it was widely felt that industry has been employing “experts” to assess their new products who are not widely considered to be unbiased or possessing true “expertise.” There was an expressed realization that the FDA process of approval is a long and costly one, but longer term studies that determine late adverse impact of devices and techniques were felt to be useful. For example, it was widely agreed that pelvic floor mesh introduction has in general not gone well, and that many serious adverse results have been subsequently reported. It was acknowledged that many products have been

released after utilizing “a good evaluative process” and it was widely suggested that these “good practices” should be mimicked and/or required.

It was also widely accepted that a prospective database for reporting of adverse events is desperately needed. Our industry partners participating in this session strongly suggested that physicians should report adverse events to the respective company that has produced any new product, as these reports are available to and reviewed by the FDA currently (MAUDE database). It was suggested that the introduction of “comparative effectiveness reporting” (CER) be encouraged. The group questioned whether the AUA should develop a policy that suggests to the FDA that it consider improving its processes in this area, and that patients should be informed that they too have the ability to let manufacturers know directly when they have developed a problem with one of their products. It was further suggested that a “board” of experts who are unbiased be developed by the AUA to advise the FDA on these matters if the FDA would agree.

**5. *What do reconstructive surgeons bring to urology training programs and how might this value be enhanced?***

The potential value of education in this area of urology is extraordinary. It was acknowledged that surgery in this area (in many cases accomplished by open surgical techniques) can serve to provide a different and important set of surgical skills to urology residents and practicing urologists in this era of laparoscopic and robotic surgery. It was also suggested that there is an enormous underserved population in the area of genitourinary reconstruction, and that some well proven techniques that enhance the quality of outcomes in this area of urology are not widely employed due, at least in part, to a lack of education of urologists in these areas (e.g. male open stricture repair rather than repeated failed endoscopic treatment). Thus, this group felt that there is a major possibility to enhance patient outcomes and quality of life with improved education in genitourinary reconstruction. Specific ways to enhance resident education in this area include sharing of regional expertise (this requires approval of the Urology RRC), and the identification and education of more “experts” in order that they might enhance mentorship in this area.

**Specific action items suggested by the Committee**

**1. *Create a “talking group” of organizations interested in genitourinary reconstruction under the auspices of the AUA.***

This “talking group” would bring together leaders from each of the areas of genitourinary reconstruction so that they have a regular mechanism by which to communicate and share ideas that might begin to address ways to improve the education of urology residents and fellows in genitourinary reconstruction as well as ways to bring greater attention to the field of genitourinary reconstruction.

**2. *Develop and manage a comprehensive study of the demographics of genitourinary reconstruction, including looking at potential issues of access to care.***

The SS/MC of the AUA should be asked to create a survey of AUA members.

3. *Create a concerted effort by reconstructive urologists who currently are involved in successful clinical and/or translational research in genitourinary reconstruction to develop educational programs/materials that might serve to teach other institutions and/or programs how this might be better and more easily accomplished.*
4. *Explore ways that urology residency programs can share in a well-defined genitourinary reconstruction curriculum when this area of urology is less than satisfactorily developed within their training program. The goal here is to ensure that all urology residents receive a meaningful exposure to this area of urology.*
5. *Encourage the development by all societies involved in male reconstruction fellowship programs to develop a fellowship structure or “template” of “minimal requirements” in their field.*  
 There already exists, for example, an ACGME-approved curriculum for FPMRS fellowships. This type of curriculum, or parts thereof, might be useful in determining fellowship requirements for fellowships in the other areas of genitourinary reconstruction, for example male urinary reconstruction. It is also hoped that these fellowship curricula would complement the current Core Curriculum for Urology that is used for resident education.
6. *Develop a registry in genitourinary reconstruction.*  
 In addition, reconstructive surgeons should be encouraged to report their negative outcomes to industry. Reconstructive societies should also organize a discussion group to evaluate this issue, especially as it applies to the use of mesh in prolapse surgery.

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