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SPECIAL CONTRIBUTION

Lessons from the past: directions for the future

Do new marketed surgical procedures and grafts produce ethical, personal liability, and legal concerns for physicians?

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Abstract New procedures and materials for incontinence and prolapse are proliferating rapidly. Surgical procedures were developed by physicians and carried their names, but over the last 15 years, these procedures are developed by industry and bear the trade names of the companies selling the kits needed to perform them. The Food and Drug Administration (FDA) approves devices, not procedures, and does not require submission of efficacy or adverse-event data to gain this approval by the 510-K process. Evidence-based medicine is lacking in the performance of these procedures that may be considered experimental by an insurance company or malpractice carrier with denial of payment or coverage. Physicians and hospitals are exposing themselves to financial, legal, and ethical risks when performing or allowing such procedures to be performed. Informed consent from the patient cannot be obtained. We must not confuse medical marketing with evidence-based medicine.

Introduction

This manuscript will discuss a variety of issues related to what has been learned in the past and how we can use that information to progress in a logical fashion in the future. By way of outline, the following are included:

- A brief history of the American Urogynecological Society
- What can urogynecological history tell us?
- Does history repeat itself?
- Are we practicing evidence-based medicine today?
- Is there a place for "clinical opinion" as a determinant of clinical evidence?
- When does experimentation become standard of practice?
- What are the physician's potential civil liabilities and penalties for experimentation?
- Should the FDA do away with the 510K approval process for permanently implantable materials used for prolapse and incontinence repair in the pelvis?

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The American Urogynecological Society

After a series of past graduate courses in which an interest was voiced among practicing physicians in the founding of a society for the purpose of exchange of medical information and education within the proposed new subspeciality of urogynecology, this society was founded in 1979 in an Orange County living room by

- Jack Robertson, MD, First President
- Don Ostergard, MD, First Secretary/Treasurer
- Earl Fuller, MD, First Newsletter Editor
- Finis Wiggins, MD, Clinical Professor
- Fred Jansen, MD, Clinical Professor
- Mrs. Fuller, JD, First Attorney

The first meeting was held in New Orleans and was attended by about 60 physicians from the USA and Europe. There were no exhibits! This humble beginning has produced a society with over 1,000 members, with large attendance at meetings and numerous exhibits.

Before the founding of this society the first fellow in urogynecology, Tom McCarthy, MD, began his training in 1978 at Harbor–UCLA Medical Center in Torrance, California, under the direction of Dr. Ostergard.

How does history repeat itself with reference to incontinence procedures?

The first original needle procedure was described in 1959 by Armand Pereyra, MD [1, 2]. In this original procedure, there was no vaginal incision and a bifid ligature carrier utilized a single stab incision in the suprapubic skin. The ligature carrier was passed through the anterior rectus fascia, through the retropubic space into the vagina where suture (no. 30 steel wire) was threaded into each arm of the ligature carrier. The sutures were carried to the anterior rectus fascia where they were tied in the midline over the rectus muscles. Dr. Pereyra discarded this procedure in the 1960's due to its high failure rate.

The first repetition

Thomas Stamey, MD, in 1973, used a suture placement technique identical to the discarded Pereyra procedure with the exception that a single suture carrier was employed and a vaginal incision was required [3]. Stamey added cystoscopy with each needle passage to aid suture placement and protect the bladder. Two suprapubic incisions were used, and the sutures were tied bilaterally over the rectus fascia. At this time, the Dacron buttress placed under the vaginal wall incision was optional.

The second repetition

This procedure was identical to the discarded original Pereyra procedure except for the use of monofilament nonabsorbable suture employing the Stamey suture carrier as in the Stamey procedure [4]. The modification by Gittes was to add a full thickness bite of vaginal wall between the two perforation sites. Sutures were tied on each side over the rectus fascia.

The third repetition

In 1992, Thomas Benderev, MD, described what was to be called the Vesica® procedure [5]. There was no vaginal incision, and four perforations through the vaginal wall on each side were required producing a "Z" pattern of the sutures in the vagina. Sutures were attached to bone anchors placed in the pubic bone, which introduced a whole new set of issues into incontinence surgery [6]. This was the first procedure for sale to the medical community.

Crossing over a very important line

Before 1992, all of the incontinence procedures had physician's names attached to them, whereas after this date, all procedures have corporate nomenclature to identify the procedures. Before this line was crossed, the physician had control of the surgery, and after this date, corporate "engineering" controlled how the procedures are to be performed. This even extends to the operating room where non-physician personnel are instructing physician specialists in the performance of these procedures as decreed by the manufacturer of the kit that is necessary to perform the operation. Corporate "engineering" takes the place of a physician's clinical judgment, knowledge of anatomy, and potential complications.

"Innovations" in incontinence surgery

Pereyra knew in the 1960's that his sutures pulled out of the vaginal wall, that his suprapubic knots remained tied, and that sutures did not pull through the rectus fascia when his procedures failed [7]. This observation has been confirmed by many clinicians. So, what is the rationale for bone anchors? No medical rationale for bone anchor use has ever been published. Perhaps the rationale was a commercial one necessary to sell kits for this new operation? Additionally, bone anchors raise serious safety issues.

In 1988, before the time that this procedure was described, it was known that the Marshall–Marchetti–Krantz retropubic urethropexy procedure was associated with a 2.5% rate of osteitis pubis (likely osteomyelitis) from sutures placed into the pubic bone under sterile conditions [8]. Bone anchor osteomyelitis probably occurs in less than 1% of the procedures [9, 10]. But, osteomyelitis can be debilitating and turn a perfectly healthy woman into a wheelchair-bound person. Because no benefit to the patient has been shown and complications are serious, why do we continue to use them?

Other safety issues in incontinence surgery

Pereyra and Stamey knew that the bladder and bowel were in danger by blind passage of a needle carrier through the retropubic space because the peritoneal cavity could be penetrated, thereby injuring the bowel, and that the needle could be passed directly into the bladder [11, 12]. Deaths had occurred from bowel penetration that went unrecognized.

Pereyra protected both the bowel and bladder by dissection into the space of Retzius with placement of the surgeon's index finger through the retropubic space to the undersurface of the rectus muscle where the needle was

directed to be guided through this area into the vagina. Stamey protected the bladder with cystoscopy after each of the four passages of the needle, and for this reason, his surgery became known as the endoscopic vesical neck suspension procedure. These basic safety techniques have been overlooked with the newest surgical procedures requiring blind passage of instruments through the retropubic space with attendant risks to the patient. Deaths have occurred from the transvaginal tape procedure wherein one can never be sure that bowel has not been injured during passage of the trocars.

Synthetic grafts in urogynecology

Synthetic grafts, such as Marlex®, Mersilene®, Silastic, and GoreTex®, have been used in incontinence and prolapse surgery for many years. There are recognized concerns specific to the graft material and are related to erosion, rejection, and infection. The following questions need to be answered: Is any material better than any other? How does one tell which is best? What is the minimum information needed to make a decision to use a graft? Should we trust our clinical opinion as to the effectiveness of a particular material?

Clinical opinion

Clinical opinion is an individual physician's perception of how well his or her operations achieve the desired objectives. It is totally non-objective and not evidence based. Clinicians must be aware that patients are unlikely to return to the physician whose procedure didn't work or when significant complications occur. At one academic institution, 97% of the patients referred for tertiary care were referred by other than the operating surgeon (Drutz, 2006, personal communication). Clinical opinion is not to be trusted in lieu of evidence-based medicine.

New materials in incontinence and prolapse surgery

One of the first of these new materials was ProteGen™, which was said to be better than other materials for suburethral sling because it was woven polyester with *pressure injected bovine collagen*. This material was approved by the FDA for implantation in humans, using the 510K procedure in1996. When a manufacturer uses this route to gain FDA approvals, there is no need to show success rates or any adverse event rates. All that is required is that the manufacturer produce evidence that the new material is substantially similar to a previously FDA-approved material. There are requirements for human or animal studies. Once approval is granted, it may be sold as FDA approved. This material was removed from the market in 1999 due to a 17% urethrovaginal fistula rate and 50% vaginal erosion in 34 patients [13–15]. No papers were published in the peer-reviewed literature documenting efficacy or safety before its recall. Once removed from the market, the FDA then labeled it as an adulterated and misbranded product and agreed with the recall. There are health and malpractice insurance implications for the physicians who utilized this product without any evidence of efficacy and safety now that the FDA has retrospectively made this statement and there are no studies to verify its usefulness. How can the use of this procedure be defended?

Numerous new materials have followed with approval by the same process. In a forum sponsored by a company with a new procedure for sale, a question regarding success and adverse event rates was answered: "When we sell the procedure, the doctors will tell us." There was total disregard for evidence-based medicine before offering this new operation for sale. They went on to say that the "physician can do anything they want with what we sell them." It is doubtful that a manufacturer would defend a physician accused of malpractice for use of such an experimental product.

For another example, an acellular dermis (CR Bard) was sold for sling surgery after FDA 510K approval. In our office, it appeared to be very strong because the sutures could not be pulled out of the material. Three such procedures were performed with universal failure. Subsequently, a paper was published showing a 68% failure rate [16]. After this experience, we ask representatives to leave the peer-reviewed published paper showing at least 1-year success and adverse event rates. None have returned with such a manuscript as of this date.

Porcine small intestinal submucosal grafts have been advocated for the augmentation of rectocele repair. A recent study randomized patients to posterior colporrhaphy (n=37), site-specific repair (n=37), or site-specific repair with graft (n=32). The success rates are 86% for posterior colporrhaphy, 78% for site-specific repair, and 54% for site-specific plus graft. A deterioration of success rates was seen when porcine small intestinal submucosal grafts were added to augment the repair [17].

At the recent meeting of the American Urogynecology Society, a new device called TVT Secure™ was being shown by its manufacturer. A question was asked regarding effectiveness and complications. The response was that it had not yet been used in a single patient.

Many patients are being hurt by the performance of these procedures from the complications that arise as well as their ineffectiveness. Multiple surgeries are required in

some patients with a corresponding burden on the health care system.

The physician's fiduciary responsibility to their patients

Physicians have a fiduciary responsibility to patients to obtain informed consent to perform the proposed surgical procedure. The dictionary definition of fiduciary is "a person to whom property or power is entrusted for the benefit of another." The key words here are "power" and "entrusted." The patient recognizes that the physician is in a position of power in that the physician should possess all the knowledge necessary to inform the patient. The patient trusts the physician to possess this knowledge. To obtain informed consent, the physician must have such basic minimal knowledge of the surgical procedure and the specific graft material to be used, particularly its success and adverse event rates in at least an observational study published in a peer-review journal. The absolute study minimum is 1 year. However, the issue of "standard of care" must also be considered in a legal sense. Any court action will include a discussion of "standard of care" and whether or not the physician acted within the standard of care. If the physician does not possess this minimal knowledge or if the procedure is not standard of care, how can informed consent be obtained if the patient cannot be told even the basic pros and cons of the procedure under consideration? In this scenario, the procedure would be considered experimental. Although a physician can inform the patient of its experimental nature and the patient can consent to such experimentation, how would the physician's malpractice carrier respond and how would the patient's health insurance carrier react to the performance of experimental surgery?

An example of experimentation and abrogation of fiduciary responsibility

A physician is approached by the sales representative of a manufacturing company to use a new material for suburethral slings. The industry representative told the physician that the material has been used extensively with good results in Europe and in the USA. The physician did not check further to verify this information. Ultimately, this physician performed the first three sling procedures ever with this material under the urethra using bone anchors for attachment. A malpractice case was filed when osteomyelitis of the pubic bone became evident. During discovery, this information was uncovered. The experimentation and the abrogation of fiduciary responsibility to his three patients became evident. With this malpractice action, how can this be defended?

The reaction of health and malpractice insurance companies to experimentation

Medical insurance companies do not pay for experimental procedures, nor do medical malpractice carriers pay to defend the performance of experimental procedures. For example, Aetna requires a "*controlled* study published in a peer-reviewed journal" before it will consider the procedure non-experimental. The word "controlled" implies that there must be comparison with an established procedure to determine relative effectiveness and adverse events. Other insurance companies may have different criteria, and it is incumbent upon the physician to know when a particular insurance company may consider a procedure experimental. The British National Health Service would not pay for the tension-free vaginal tape (TVT) procedure when it was first introduced there and required a controlled study that was done using the Burch procedure for comparison [18]. If a physician performs an experimental procedure with or without the patient's consent, the physician is aiding and abetting the commission of fraud against the medical insurance company. Even if the surgery is discovered to be experimental years later, the insurance company can demand that all monies paid to the physician be returned and can sue the physician for fraud. If the bill to the insurance company was sent through the US mails, the postal inspectors can become involved as well and charge the physician with mail fraud. The problem is compounded when the surgical procedure is listed as one thing, yet the body of an operative note describes a totally different procedure that may be experimental. An insurance company may deem this to be an indication of intent to defraud.

According to an article in *USA Today* (Money section, November 7, 2006), insurance companies are extensively using computer programs to "mine" physicians' claims for payment. To date, Aetna has recovered $15 million from physicians and has prevented $89 million from being paid.

Another issue that may be important to hospitals is that they credential physicians perform surgical procedures. If the procedure is considered to be experimental, might the insurance carrier require repayment of monies paid incident to the hospitalization? Hospitals should examine their contracts with insurance carriers to make this determination. Also, if the physician is made "bare" without malpractice insurance by the performance of an experimental procedure in a particular hospital, the hospital becomes the only insurance source of recovery for the plaintiff.

A case in point is the "infertility scandal" in the Department of Obstetrics and Gynecology and the University of California, Irvine. Three infertility specialists were charged with willfully placing other women's embryos into

infertility patients who expected to receive their own embryos. The two physicians who actually were responsible, fled the country and were never tried. The one physician who remained to clear his name was charged with insurance and mail fraud. He spent time in jail, and when he was convicted of these felonies, he lost his license to practice medicine. He eventually got his medical license back, but because of the conviction, he could not obtain malpractice insurance.

How does the physician avoid these issues?

The International Urogynecological Association (IUGA) roundtable discussed this extensively in a recent supplement to the *International Urogynecology Journal* [19]. All of the following quotes are from this publication. When considering the use of a graft for a given patient, the choice of materials must be based "on data rather than on marketing materials and/or the physical feel of the graft." The physician should recognize that "rat biology does not always equal human biology." Even if the material is tested in rodents, how will it behave in humans? The physician must "consider the long-term consequences" of the use of the graft material, and this decision should be evidence based and not based on what is told to them by the manufacturer's representative.

There is a need for more information with specific graft materials to clarify success and adverse event rates. "Outcome measures should include anatomic as well as functional parameters over a reasonable observation time period." Regarding the use of grafts for all cases of prolapse, "there is no evidence-based medicine to justify a move in this direction."

If a physician is sued for a complication of a new graft material, these published statements may become important for the plaintiff in court.

The physician is responsible for all billing submitted under his/her name. If you cannot answer yes to these questions, you may be at risk. Do you tell your staff exactly how to bill? Do you provide procedure with diagnosis codes and indicate which procedure is primary and which is secondary? Do you check that the correct information has been entered into the computer before the bill is submitted? You cannot blame staff for errors; the responsibility is yours.

True avoidance of personal tragedy to the physician is accomplished when the material becomes standard of practice within the medical community. This generally requires more than an observational study of 1 year, giving efficacy and adverse event results. How is this defined? Generally, it is defined in court as "when a physician of similar training and experience would proceed in a similar manner."

What surgical procedures are now available and has minimal clinical experience been published?

Some of the surgical procedures for sale are the TVT, transobturator tape (TOT), and suprapubic arch sling (SPARC). Only the TVT was extensively studied in Europe before being sold in the USA after 510k FDA approval. At the time of the approval of the TVT by the FDA, it was determined to be substantially equivalent to the ProteGen™ sling that was subsequently removed from the market. Many other products are also marketed (Table 1).

An example of a surgical procedure for stress incontinence that has been withdrawn from the market is the SURx™ treatment system. The reasons given for withdrawal are that "the product is much more technique dependent than we had hoped it would be" and "requires just the right depth, just the right exposure, just the right amount of endopelvic fascia...." It could be argued that it is not really technique dependent but just ineffective. In the published discussion of this product, it was stated that the uneven history of treatment of stress urinary incontinence (SUI) is "typical of industry-sponsored research" with inconsistent outcome measures (Ob. Gyn. News, August 1, 2006).

What meshes are now available and has minimal clinical experience been published?

As of this writing, there is insufficient data to make a determination as to which mesh is better from any other or is a particular mesh effective for the intended purpose. Yet, all have received 510K FDA approval without having to prove for effectiveness and safety nor has it evaluated and approved the surgical procedures. It is very important to remember that FDA approval does not mean that the FDA has evaluated the material for effectiveness and safety nor has it evaluated and approved the surgical procedures. Yet these materials are permanently implanted into humans. In other arenas, the FDA requires this type of data on permanently implanted materials. Why should this standard not be applied by the FDA to meshes implanted in the pelvis? Given that the TVT was approved by the FDA as substantially equivalent to a mesh that has been removed from the market because of complications and the knowledge that all of the transobturator slings were found to be substantially equivalent to the TVT, it appears that we have a large number of procedures using meshes that have been approved by the FDA and are predicated on a material that was removed from the market.

Table 1 Graft and mesh materials currently approved by the FDA by the 510K process

Trade name	Material	Manufacturer
Grafts		
ACell UBM surgical mesh ML and ML plus	Porcine collagen mesh	ACell
Apogee System	Preconnected collagen dermal matrix	American Medical Systems
Axis Tutoplast	Human dermis	Mentor
Bioarc SP	Preconnected collagen dermal matrix	American Medical Systems
Bioarc	Preconnected collagen dermal matrix	American Medical Systems
BioBlanket	Single layer porous and cross-linked collagen	Kensey Nash
Collagen dermal matrix	Collagen dermal mesh	American Medical Systems
Duraderm	Acellular dermis	CR Bard
FortaFlex	Porcine collagen	Organogenesis
InteXen	Porcine dermis	American Medical Systems
Pelvicol/Pelvisoft	Porcine dermis	CR Bard
Pelvic floor repair system	Preconnected collagen dermal matrix	American Medical Systems
Perigee system	Preconnected collagen dermal matrix	American Medical Systems
Repliform matrix	Acellular human dermis	Boston Scientific
Restore orthobiologic soft tissue implant	Porcine small intestine submucosa	DePuy
Surgesis	Porcine collagen	Cook
Suspend Tutoplast	Human fascia lata	Mentor
VeritasB collagen matrix	Non-cross linked bovine pericardium	Synovis surgical Innovations
Veritas collagen matrix	Non-cross linked bovine pericardium	Synovis surgical Innovations
Xylos surgical mesh	Microbial-derived cellulose	Xylos
Permanent Mesh		
Aris trans-obturator tape	Polypropylene	Mentor
Caldera large-pore monofilament	Polypropylene mesh	Caldera Medical
GlucaMesh/Glucatex,	Polypropylene	Brennen Medical
Gynemesh	Polypropylene	Gynecare
I-STOP mid-urethral sling	Polypropylene	Uropolasty
IMMIX PlastiFilm	Polymeric surgical mesh	OsteoBiologics
IntePro	Polypropylene	American Medical Systems
Minimesh	Polypropylene	Mpathy Medical Devices
Monarc sling system	Polypropylene	American Medical Systems
Novasilk	Polypropylene	Mentor
ObTape trans-obturator tape	Polypropylene	Mentor
Pelvitex	Polypropylene/porcine collagen	CR Bard
Polyform	Polypropylene	Boston Scientific
Sparc sling system	Polypropylene	American Medical Systems
T-sling monofilament	Polypropylene	Caldera Medical
TVT obturator system	Gynecare	Polypropylene
Zippere	Bioabsorbable/non-absorbable polymer sling	ProSurg

The ACOG Committee on Ethics regarding innovative practice

The American College of Obstetricians and Gynecologists (ACOG) Committee has issued its formal statement on ethical guidelines concerning innovative practice [20]. The following are quotes from this publication: "Premature adoption of innovative practices without adequate supporting evidence may promote wide acceptance of therapies that are ineffective..."and "may carry additional risks of morbidity in comparison with standard treatment." The following are examples of therapies widely adopted and subsequently proven to be ineffective or associated with complications: bed rest/home monitoring to prevent prematurity, bone marrow transplant for breast cancer, diethylstilbestrol or paternal antigen sensitivity to prevent recurrent miscarriage, limb reductions with chorionic villus sampling, sex chromosome abnormalities with intracytoplasmic sperm injection.

> Practitioners need to be careful not to adopt innovative procedures or diagnostic tests on the basis of promotional and marketing campaigns when the value of such procedures and tests has not been proved.

Without an adequate evidence base, practitioners cannot determine whether an innovative technique is the most safe and effective method for treating a patient.

Without adequate data on the risks and benefits of new treatments, patients are unable to provide a true informed consent.

A current case example

This is a 52-year-old woman presenting with cystocele, rectocele, and uterine prolapse with stress incontinence. Surgery was performed on May 14, 2004. In pre-operative holding, the medical student was sent to ask for her permission to have the manufacturer's representative for the intravaginal slingplasty (IVS) tunneler present in the operating room. Consent was denied.

Surgery with anterior/posterior repairs and TVT was performed with the posterior IVS tunneler used for apical uterine support without consent for this procedure. This patient now presents with pelvic pain since surgery. The graft was removed with a marked reduction of pain, but the remaining pain is still troublesome to the patient.

Surgical billing was standard except for a sacrospinous fixation that was not performed. The manufacturer's representative was present in the operating room without consent.

In preparation for the medical malpractice lawsuit, the IVS tunneler was determined by the insurance carrier to be experimental. The physician and hospital are being investigated for insurance fraud, not only for the performance of an experimental procedure but also for billing for a procedure that was not performed. The unauthorized presence of the manufacturer's representative in the operating room is a health insurance portability and accountability act (HIPPA) violation with monetary and civil penalties yet to be addressed.

What about the future?

Remember to research the past when you think you have found something new: Important information may be found. We must not forget that we have a fiduciary responsibility to protect our patients by having sufficient data to justify the performance of a new procedure. As stated by the ACOG Ethics Committee, without this data, we cannot expect to obtain informed consent. If you are female, ask yourself whether or not you would want this procedure performed on yourself. If you are male, ask yourself whether or not you would want this procedure performed on your wife, sister, or mother. Sufficient informed consent requires a minimum amount of information on new products and procedures. If this information is not available, consider your proposed surgery an experiment and not standard of care. Also, consider the possible consequences of experimentation from the medical insurance carrier and your malpractice carrier, both fiscally, and the possibility of a fraud determination. The bottom line is how you can explain to 12 lay people why you did the procedure without knowing the rates of efficacy or safety.

You will go a long way to protecting yourself by practicing evidence-based medicine. Ask industry for 1-year success and adverse event rates published in a peer reviewed journal. Do not use any graft material, new diagnostic technique, or new surgical procedure for sale in the absence of this information. Do not let industry control how we practice medicine. What industry is interested in is the fact that there are billions of dollars to be made from the sales of synthetic prolapse repair materials and the kits to perform the surgical procedure that accompany them. With our aging population, 11.1% of women aged 70–79 have had a primary operation for incontinence or prolapse, and this number will grow. The motivation for industry to continue to market new procedures and meshes is great.

Is it appropriate for manufacturer's representatives to be present in the operating room for the purpose of teaching the procedure? HIPPA regulations require that the patient be informed that such a person will be present and must give consent to their presence. Penalties, both monetary and incarceration at the federal level, can be levied for noncompliance.

Given that FDA approval is only for the device (eg., graft) and not for the surgical procedures and does not ensure efficacy or safety, should the FDA do away with the 510K approval process for implantable materials for pelvic reconstructive surgery? Should the FDA require the same rigorous studies as required of drugs before marketing?

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