# 2014

# Live Surgery Workshop and Webinar for Hypospadias Repair

**FEBRUARY 27-MARCH 1, 2014**

Children's Medical Center Dallas

Moore Auditorium

1935 Medical District Drive

Dallas, TX 75235

**WRITTEN DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS**

**LIVE SURGERY WORKSHOP AND WEBINAR FOR HYPOSPADIAS REPAIR**
**FEBRUARY 27 - MARCH 1, 2014**
**Children's Medical Center Dallas**

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## RELEVANT FINANCIAL RELATIONSHIP DISCLOSURE

| Individual | Type of Relationship | Name of Commercial Interest |
|---|---|---|
| Thomas Zellers, MD | Proctor/Investigator | AGA Medical/St. Jude |
| | Consultant/Investigator | WL Gove & Associates |
| | Investigator | Medtronic |
| Warren T. Snodgrass, MD | Course Director | Nothing to Disclose |
| Nicol C. Bush, M.D., MSCS | Course Director | Nothing to Disclose |
| Anthony A. Caldamone, M.D. | | Nothing to Disclose |
| Richard S. Hurwitz, M.D. | | Nothing to Disclose |
| Martin A. Koyle, M.D. | | Nothing to Disclose |
| Giantonio Manzoni, FRCS-FEAPU | | Nothing to Disclose |

The committee and planners have nothing to disclose.

# TIP 20th Anniversary Commemorative Lectures
# Thursday, February 27th, 2014

## Hypospadias Repair Algorithm

8:15-8:30- Options for Primary and Reoperative Repairs

- Warren T. Snodgrass, M.D.

## Evidence-Based Hypospadias Surgery

8:30-9:00 - Factors that Do and Don't Predict Outcomes

- Nicol C. Bush, M.D., MSCS

9:00-9:30 - Objective Preoperative Testosterone Use

- Warren T. Snodgrass, M.D.

9:30-10:15- Conquering Complications (Lessons from Fistulas and Glans Dehiscence)

- Nicol C. Bush, M.D., MSCS

## The Best Urethral Plate Substitute: Flaps versus Grafts

10:15-11:15 - Debate: Dr. Tony Caldamone (Flaps) versus Dr. Tony Manzoni (Grafts), Dr.

- Martin A. Koyle, M.D. moderating

## Teaching Hypospadias Surgery

11:15-11:35- Learning Curve for Distal Hypospadias?

- Nicol C. Bush, M.D., MSCS

11:35-11:55 - Subspecialization for Proximal and Reoperative Hypospadias

- Warren T. Snodgrass, M.D.

## Setting Up a Database

11:55-12:15– From Quality Assurance to Quality Research

- Nicol C. Bush, M.D., MSCS

**12:15-12:45 - LUNCH BREAK**

## TIP Repair: A 20 Year History

12:45-1:15- A Brief (Personal) Story

- Warren T. Snodgrass, M.D.

1:15-3:15 - Tales of TIP (The first TIP repairs and best untold stories)

- Drs. Martin A. Koyle, Richard S. Hurwitz, Anthony A. Caldamone, and Giantonio Manzoni

## Is Hypospadias the Same Worldwide?

3:15-3:45 - Observations from Travel (Thanks Kaoru!)

- Nicol C. Bush, M.D., MSCS

## The Three P's

3:45-4:15 - Making Surgeons and Surgery Better

- Warren T. Snodgrass, M.D.

OPERATING FACULTY: Dr. Snodgrass & Dr. Bush
MODERATOR: Dr. Giantonio Manzoni

**Friday; February 28, 2014**
DAY ONE: PRIMARY HYPOSPADIAS REPAIR

| | |
|---|---|
| 7:00 am | Registration |
| 7:30 am | Welcome and Opening Remarks |
| MORNING | Live Surgical Case Demonstrations |
| 12:00 pm | LUNCH |
| AFTERNOON | Live Surgical Case Demonstrations continued<br>Case Discussion |

**Saturday; March 1, 2014**
DAY TWO: REOPERATIVE HYPOSPADIAS SURGERY

| | |
|---|---|
| 7:00 am | Late Registration |
| 7:30 am | Live Surgical Case Demonstrations |
| 12:00 pm | LUNCH |
| AFTERNOON | Live Surgical Case Demonstrations continued<br>Case Discussion |
| 5:00 pm | Adjournment |

# DATA-DRIVEN DECISION-MAKING IN HYPOSPADIAS SURGERY

*PREOPERATIVE MANAGEMENT*

## Age for Surgery

**Hypospadias repair can be done as ambulatory surgery in full-term otherwise healthy infants from age 3 months.**

Considerations in determining the timing of operation include anesthetic risks, psychosexual factors, and the potentially varying risk for urethroplasty complications at different ages. The authors perform ambulatory hypospadias repair in otherwise healthy full-term infants at any age from 3 months.

*Anesthetic Risks*

Hypospadias repair can be performed as ambulatory surgery in otherwise healthy full-term babies 3 months of age or older. We reported there were no unplanned hospital admissions for anesthetic complications in babies 3-5 months of age, in which brochospasm was documented in the anesthetic record in 5/230 (2%) cases (Bush and Snodgrass, et al, 2012). Preterm babies can undergo outpatient surgery after 56 gestational weeks.

*Psychosexual Risks*

The AAP recommended surgery be completed by age 18 months to limit psychosexual stress (AAP, 1996). However, a study which used questionnaires and a standardized interview by a psychologist to compare patients ages 6-17 years operated before versus after 18 months found no differences in health-related quality of life, psychological adjustment, gender-role behavior, or penile self-perception(Weber et al, 2009).

*Urethroplasty Complications*

4 studies reached different conclusions regarding impact of age on likelihood for urethroplasty complications: 3 finding surgery at < 6 months, ≤ 1.5 years, or < 4 years had better outcomes, while the 4th reported age was not an independent variable predicting outcomes. These articles are summarized:

-We performed multivariable analysis of prospectively collected data in 669 consecutive boys ages 3-144 months undergoing TIP repair by WS and studied impact of age in these various age groupings (<6months, ≤ 1.5years, <4 years) as well as in quartiles, log age, and age as a continuous variable in multiple logistic regression. Our data indicated age < 6 months, >1 year, >5 years, log age, or age quartiles did not predict risk for urethroplasty complications (Bush and Snodgrass et al, 2012).

- A retrospective review of 316 consecutive distal hypospadias repairs by a single surgeon between 1999 and 2005 included 194 (60%) TIP, 69 (21%) MAGPI, and 53 (9%) glans approximation (GAP) operations. Of these, 92 (29%) were 4-6 months of age at surgery, and urethroplasty complications were less than in patients > 6 months of age [2/92 (2%) vs 23/224 (10%), p=0.006]. Considering only TIP repairs, complications in those < 6 months [2/55 (4%)] were significantly less than those > 6 months of age [19/139 (14%), p=0.027]. Age was not related to outcomes after MAGPI or GAP (Perlmutter et al, 2006).

-Patients undergoing TIP between 2005 and 2007 were analyzed, comparing a younger cohort median age 1.6 years (1-2) versus older patients at median age 5 years (3-10.5). These represented the first patients to undergo TIP by the 2 surgeons involved. Complications included fistula and/or stenosis (not defined), and /or foreskin repair-related (dehiscence, phimosis) . Total complications were 4/57 (7%) in those 1.5 years old versus 21/65 (32%) in older boys, p=0.0006. Year of surgery and surgeon did not predict outcomes, but foreskin reconstruction also increased complications (Korvald and Stubberud, 2008).

-Multivariable analysis was done on data from retrospective chart review of 391 patients undergoing TIP at median age 2 years over a 10 year period ending 2007. Age was analyzed as a continuous variable and reported for those less than versus greater than 4 years at repair. There was a 3.25 relative risk (95% CI 1.44-7.35) for complications in older boys (Eassa et al, 2011).

It is not clear why findings vary among these studies. Based on our data we offer hypospadias repair in otherwise healthy, full-term infants at any age ≥3 months and do not believe there is either advantage or disadvantage to later surgery in regards to urethroplasty outcomes.

**Adjunctive Hormonal Therapy**

**1 RCT reported decreased urethroplasty complications following preoperative DHT application. We found adjuvant testosterone injection for boys with small glans size (width <14mm) did not decrease urethroplasty complications.**

Androgenic stimulation has been said to increase penile size, reduce ventral curvature, and improve vascularity. Several reports involving small numbers of patients with varied severity of hypospadias document increased penile size, glans circumference, and/or transverse length of the inner prepuce. Recently it has been speculated that hormonal therapy prior to hypospadias repair is potentially harmful, based on observations in dermatology literature that elderly males have impaired skin wound healing compared to elderly females.

Only 1 randomized trial compared patients having coronal (75%) to penoscrotal (2.5%) hypospadias and receiving preoperative hormonal stimulation (DHT 2.5% to glans and shaft daily for 3 months) versus no treatment. Chi square analysis found fewer urethroplasty complications in those treated (1/37 vs 9/38, p=0.01)(Kaya et al, 2008).

After observing increased glans dehiscence rates in boys with proximal versus distal TIP hypospadias repair, we theorized glans size related to risk for this complication. Accordingly, we measured glans width at the widest point, and in a series of consecutive patients with distal and proximal hypospadias compared to newborn normal males undergoing elective circumcision found that the glans is smaller among those with proximal hypospadias [median 14 (11-19) mm in controls at median age 1.3 months; 15 (10-21) mm in distal hypospadias patients at median age 8 months ; and 13 (9-16) mm in proximal hypospadias patients at median age 8.5 months, $p<0.001$] ( Bush and Snodgrass et al, 2013).

Based on these findings we began objective testosterone therapy, beginning with 2mg/kg injection for 2-3 doses for glans width <14mm, with the aim to increase diameter to ≥ 15mm. We made several additional observations:

1. testosterone use increased (from 39% to 68%) in proximal cases when we began measuring the glans rather than relying on a subjective impression it was small
2. this standard dose of testosterone did not achieve targeted glans growth in 57% of proximal cases, leading us to change the protocol. We first injected 2mg/kg and re-measured in 1 month, progressing in those without enlargement to 4mg/kg, then to 8 mg/kg etc to a maximum in 1 case of 32mg/kg
3. testosterone therapy increased glans diameter from a mean of 11mm to 15.7mm. (Snodgrass and Bush, et al, submitted 2013)

We then analyzed outcomes in those who received testosterone versus those whose glans width was already ≥14mm. Urethroplasty complications were *not* reduced by treatment, with multivariable analysis finding testosterone to be an independent risk factor for developing complications [OR 3.1 (95% CI 1.2-8.1), AUC 0.748]. *Accordingly, we no longer use preoperative testosterone* (Bush and Snodgrass, et al, 2014). Instead, to avoid glans dehiscence we have changed our glansplasty technique as described in the technical syllabus.

## Imaging

**Urinary tract imaging is not necessary before hypospadias repair, regardless of meatal location.**

1 prospective study in Saudi Arabia obtained IVP and VCUG in all patients with hypospadias <2 years of age, reporting results in 153 boys over an 11 year period ending in 1983. 36 (24%) had abnormal findings including VUR (n=18) and a variety of upper tract conditions including horseshoe kidney, solitary kidney, uretrovesical junction obstruction, and ureteral duplication. Of these, surgery was thought indicated in 18 (12%), although some of the cases described would not likely be operated today - for example, those with asymptomatic distally dilated ureters or VUR. Likelihood for abnormal imaging was similar for all extents of hypospadias, described as glanular, coronal, penile, penoscrotal and perineal (Moore, 1990).

2 retrospective series obtained IVP or renal sonography in 41% and 72% of patients, both reporting 18% to be abnormal. Possibly significant findings of hydronephrosis occurred in 4% and 1% (Friedman et al, 2008; Lutzker et al, 1977). Abnormal studies were equally distributed between patients with distal versus proximal hypospadias (Lutzker et al, 1977).

VCUG in 163 cases, of which 47% were penoscrotal, diagnosed VUR in 6 (4%) and bladder diverticulum in 2. There was no mention of prostatic utricle (Friedman et al, 2008).

These studies suggest urinary tract imaging is not needed during hypospadias evaluation, and that extent of hypospadias does not select patients most likely to have

abnormal findings. Imaging can be limited to screening patients with suspected syndromic hypospadias or intersexuality.

### Karyotyping

**Karyotyping is indicated for suspected syndromic hypospadias and for cases of hypospadias with undescended testis.**

A karyotype may help categorize hypospadias as syndromic when there are other nongenital anomalies, especially developmental delay, dysmorphic facies, and/or anorectal or scrotal malformations. It may also detect gonadal intersexuality, especially when there is also cryptorchidism. The role for karyotyping in isolated hypospadias, even proximal cases, is unclear since most existing reports refer to patients with hypospadias associated with cryptorchidism or do not state the severity of isolated hypospadias.

The simultaneous occurrence of hypospadias with cryptorchidism increases likelihood for intersexuality. Overall reported prevalence of an intersex condition in hypospadias patients considered to have male-appearing phenotype ranges from 0-30%, and is greater with increasing severity of hypospadias and nonpalpable testis.

The most frequent finding is mixed gonadal dysgenesis, followed by ovotesticular disordered sexual differentiation. Incomplete androgen insensitivity, 5 alpha reductase II deficiency, and testicular dysgenesis are also encountered. However, the exact prevalence of intersexuality conditions in hypospadias patients with cryptorchidism remains uncertain, likely secondary to differences in defining male-appearance versus ambiguity, along with failure to perform uniform genetic, biochemical and radiologic evaluation in hypospadias patients.

Co-existence of hypospadias and cryptorchidism can also be explained by associations other than intersexuality. For example, a case-control study examining independent risk factors for the 2 conditions within the same nationwide cohort in Sweden found low birth weight and prematurity positively correlated with each.

## *INTRAOPERATIVE MANAGEMENT*

### Nerve Blocks

**Despite the popularity of caudal nerve blocks for genital surgery, 1 RCT reported penile blocks provided better local anesthesia, lasted significantly longer, and caused less penile engorgement than did caudals.**

1 double-blinded RCT allocated 54 boys ages 4-12 years undergoing distal hypospadias repair to penile vs caudal block after induction of general anesthesia. Mean arterial pressure was significantly greater with skin incision in those receiving a caudal block, and the penile block lasted significantly longer after surgery, 302 vs 220 minutes. There also was less penile engorgement following penile blocks – all indicating advantages of penile blocks over caudal injections (Kundra et al, 2011).

For distal hypospadias repair we use dorsal penile nerve blocks supplemented by a second midline scrotal injection, since infrapubic blocks do not reach sensory branches innervating the ventral midline penis, scrotal and perineal area(Kundra et al, 2011). Caudal nerve blocks are used in proximal cases. When a caudal cannot be performed in a patient with proximal hypospadias, penile and scrotal block are used, with a wider area of infiltration at the scrotal base and an additional region of injection superiolateral to the scrotum on the side where tunica vaginalis will be harvested.

### Sutures

**There are no data indicating a superior suture material for hypospadias urethroplasty or glansplasty.**

1 trial compared primary distal TIP fistula rates between 2 urethroplasty sutures, randomizing 100 boys to either polyglytone (rapid absorption) or polydioxanone (slow absorption). All operations were done by 1 surgeon, performing urethroplasty in 2 layers using continuous subepithelial stitches. Follow up assessment was blinded to suture type. At 2 years after repair there was no difference in the fistula rates, 4/50 (8%) polyglytone vs 6/50 (12%) polydioxanone (Guarino et al, 2009).

Using multivariable analysis we found that chromic versus polyglactin suture was not independently associated with risk for glans dehiscence in 2 cohorts of consecutive children undergoing TIP repair (Snodgrass and Bush et al, 2011).

### Perioperative Antibiotics

**There are no RCTs demonstrating urethroplasty outcomes are impacted by perioperative antibiotics. 1 study reported fewer febrile UTIs during urinary diversion in patients receiving oral cephalexin vs no antibiotic.**

No RCTs determine if hypospadias surgical outcomes are influenced by perioperative antibiotics. One RCT comprising 101 patients compared intraoperative intravenous cefonicid plus postoperative oral cephalexin to intravenous cefonicid alone. There were no differences in the two groups regarding surgical complications, but both asymptomatic bacilluria (21% vs 51%, $p<0.05$) and febrile UTI (6% vs 23%, $p<0.05$) were more common without postoperative antibiotics (Meir & Livne, 2004).

### Urethral Plate Quality

**There is no contraindication to distal TIP based on urethral plate configuration (deep vs flat) or width before dorsal incision.**

**We also perform TIP in over 90% of proximal cases that have <30° ventral curvature after degloving.**

3 reports described the urethral plate as “deep”, “intermediate or cleft”, or “shallow or flat”, with each finding this characterization did not correlated with urethroplasty outcomes after distal TIP (Holland and Smith, 2000; Sarhan et al, 2009; Snodgrass and Bush et al, 2010).

However, both Holland and Smith and Sarhan et al both stated TIP is contraindicated when the plate has a pre-incision width < 8mm. We recently decided to duplicate these studies and have measured the pre-incision width in 70 consecutive patients with distal hypospadias, finding only 10% to be ≥ 8mm. Previously we reported distal urethroplasty outcomes using only TIP in 426 consecutive boys, finding 4% complications and no apparent contraindication to the procedure (Snodgrass and Bush et al, 2010). Therefore our data suggest pre-incision plate width <8mm is not a risk factor for complications, but we will analyze that further when we have sufficient results to compare.

A study asking surgeons to rate suitability of urethral plates for TIP from photographs using a Likert scale reported poor to slight agreement regardless of meatal position (distal versus midshaft versus proximal) or years of surgical experience (El-Hout et al, 2009).

In proximal hypospadias, we reported 7% have a “thin” plate lacking subepithelial tissues that prevents TIP repair (Snodgrass and Bush, 2011). Otherwise, assuming the urethral plate (defined within the borders created by the lateral wings of corpus

spongiosum) can be preserved during ventral curvature straightening, it can be used for urethroplasty.

## Ventral Curvature

**Curvature estimated at <30° is corrected by a single dorsal midline plication using 6-0 or 5-0 polypropylene. Curvature >30° after the penis is degloved and ventral dartos excised next leads to urethral plate transection, with ventral lengthening using 3 transverse corporotomies through the region of bending if it remains >30°.**

**Reports from men seeking correction for penile curvature suggest bending ≥30° impairs sexual activity (Greenfield et al, 2006; Gholami and Lue, 2002; Savoca et al, 2000).**

*Distal Hypospadias*

A series of 440 consecutive distal hypospadias repairs that included artificial erection after degloving reported 11% had ventral curvature that was always < 30° (Snodgrass and Bush et al, 2010). This extent of curvature corrects with a single dorsal midline plication of the tunica albuginea using 6-0 polypropylene.

*Proximal Hypospadias*

In 70 consecutive boys with proximal shaft to perineal hypospadias, 19% had no ventral curvature after degloving the penis and dissecting ventral dartos. Another 31% had curvature < 30° corrected by a single dorsal plication (Snodgrass and Prieto, 2009). *Therefore, half the patients had no or minimal curvature, emphasizing the urethral plate does not have to be transected initially despite a proximal meatus*.

The remaining 50% had curvature > 30° after degloving and dartos dissection. Initially WS transected the plate and lengthened the ventral corpora by tunica albuginea incision from 3 to 9 o'clock through the point of greatest curvature and dermal grafting of the resulting defect. However, corporal grafting for straightening limits urethroplasty options to tubularised prepucial flaps or 2-stage prepucial flaps, since urethroplasty grafts placed onto corporal grafts may not re-vascularize. To lengthen the ventral corpora without grafting he used 3 transverse corporotomies from 4 to 8 o'clock carried just through the tunica albuginea - the 1st at the point of maximum curvature and the other 2 approximately 5mm distally and proximally, respectively. We subsequently reported equivalent outcomes from ventral lengthening done by corporotomies with or without grafting (Snodgrass and Prieto, 2009).

Next, to conserve the urethral plate in more patients WS used more extensive dissection to lift the urethral plate and the proximal native urethra from the underlying corpora to near the membranous segment. The now elevated urethral plate was retracted to the side For ventral lengthening by 3 transverse corporotomies as needed, and when the penis was straight, proximal TIP urethroplasty was done.

Later analysis of proximal TIP patients with vs without urethral plate/native urethra mobilization found focal strictures, from areas presumed to have insufficient vascularity, in 5/29 (17%) with plate elevation vs 0/47 without it, p= All presented with symptoms of febrile UTI and /or retention 6 weeks to 1.5 years postoperatively, from strictures that varied from 1 – 10mm in length (Snodgrass and Bush, 2013).

In contrast, a retrospective review including 32 patients with urethral plate and native urethra elevation from the corpora followed by tubularization done with (n=20) or without TIP incision reported no strictures during mean follow up of24 months (Bhat, 2007).

Differences between these 2 series are not clear. Even though only a minority of our patients developed strictures after urethral plate elevation and proximal TIP, all had symptoms and some then required 2-stage graft reoperations. Accordingly, we abandoned this adjunt maneuver for straightening and transect the urethral plate, do ventral lengthening using 3 transverse corporotomies, and then perform 2-stage graft primary repair for ventral curvature >30°.

It is often said that dorsal plication shortens the penis, but no pediatric study demonstrates this by measuring shaft length before and after straightening. There are no data concerning outcomes after puberty for dorsal plication done in childhood. 1 study in men found objective penile shortening after an average of 3 plications was < 0.5cm, with the greatest loss of length in those with a longer and more curved penis (Greenfield et al, 2006), which implies a single dorsal plication in boys with <30° bending will not shorten the penis.

A single report indicated that 14 boys with curvature straightened with corporotomy and dermal grafting reported straight, firm erections post-puberty, but only 3 admitted to sexual activity – of which 1 required vasoactive intracorporal drug injection for erection (Badawy and Morsi, 2008).

### Skin Closures

**Circumcision or prepucioplasty can be done with distal or proximal TIP, according to caregiver preference. We found no difference in either urethroplasty complications or skin problems leading to reoperations based on the original skin management.**

*Circumcision:*

Incising the dorsal prepuce obliquely towards the corners facilitates restoration of a ring of inner prepuce circumferentially (Firlit, 1987). Ventral shaft skin adjacent to the

original meatus between the open glans wings is excised and the inner prepuce approximated in the ventral midline.

Americans tend to create wider inner prepucial collars, vs Europeans who prefer a much more narrow collar. Having observed that a wide inner prepuce sometimes prompts concerns from parents regarding the final appearance, we now make a more narrow collar of approximately 4mm.

*Foreskin Reconstruction:*

The foreskin can be repaired in nearly all patients with distal and proximal hypospadias, except for uncommon cases in which the prepuce is too small to approximate ventrally around a large glans.

Increased urethroplasty and skin complications with foreskin reconstruction versus circumcision during distal hypospadias repair have been reported (Klijn et al, 2001), but these likely resulted from skin flap (Mathieu) urethroplasty and instructions to parents to begin foreskin retraction only 2 weeks postoperatively. In contrast, a comparison of matched cohorts undergoing distal TIP repair with foreskin reconstruction versus circumcision, found no differences in urethroplasty or skin complications (Suoub, 2008).

We decide between circumcision versus prepucioplasty by simply asking the parents if they planned newborn circumcision. In a total of 428 consecutive distal TIP repairs, 343 had circumcision and 85 (20%) had foreskin reconstruction , excluding patients with MIP who underwent prior circumcision, and those lost-to-follow-up. All patients requesting prepucioplasty had the procedure, with no intraoperative conversions to circumcision. Urethroplasty complications occurred in 30 (8.7%) circumcision patients, including 16 fistulas, 13 glans dehiscences, and 1 meatal stenosis from BXO, versus 7 (8.0%) urethral complication in prepucioplasty patients, with 4 fistulas, 2 glans dehiscences, and 1

urethral stricture, p=1.0. Skin complications resulting in reoperation occurred in 7 (2%) circumcision patients (redundant skin in 5, inclusion cyst in 2) and 2 (2%) prepucioplasty patients (1 with BXO requiring circumcision >5 years after repair, and 1 with an unsightly skin whorl). Betamethasone was successfully prescribed to 6 (7%) prepucioplasty patients for non-retraction. However, currently we no longer use betamethasone when the skin does not retract at 6 months because we are certain preopucioplasty did not create phimosis intraoperatively and postoperatively there is no visible evidence of fibrosis. Therefore, we predict the prepuce will eventually retract (Snodgrass and Bush et al, 2013).

## *POSTOPERATIVE MANAGEMENT*

### Urinary Diversion

**Several studies report distal TIP in pre-toilet-trained boys can be done without diversion, causing no increase in urethroplasty complications and expecting <5% to need catheterization early postoperatively.**

**1 trial of toilet trained boys found greater dysuria, retention and extravasation in those not catheterized, resulting in catheter placement in 40% of those not randomized to diversion. Urethroplasty complications were not impacted by whether or not diversion was used.**

**There are no data indicating benefit of suprapubic diversion in addition to or as a substitute for urethral catheters.**

Three studies reported midshaft to distal TIP without urinary diversion in non-toilet trained patients:

32 consecutive non-toilet-trained boys mean age 18 months had TIP for distal to midshaft and proximal shaft (n=6) hypospadias without a catheter. 1 (distal vs proximal not stated) developed urinary extravasation on the 2$^{nd}$ postoperative day

treated with catheterization.1 (3%) patients had a urethroplasty complication, meatal stenosis, during follow up of 9 ± 6 months (Almodhen et al, 2008).

170 consecutive patients mean age 19 months had distal TIP repair without diversion. None had urinary retention or needed catheterization. Urethroplasty complications occurred in 7% during follow up a mean of 3 years (Samuel et al, 2002).

A third study reported 162 consecutive patients mean age 16 months with distal or midshaft (n=6) TIP repaired without diversion. Catheterization was needed for urinary retention in 4 (2.5%), 2 within hours of surgery and 2 at a week postoperatively, without subsequent complications. Urethroplasty complications occurred in 8%, both fistulas and meatal stenoses (Leclair et al, 2004).

A RCT compared outcomes in toilet trained boys with versus without diversion after distal TIP:

This trial randomized 64 toilet-trained boys median age 6 years to distal TIP with versus without catheterization decided at the end of the operation. Urethroplasty complications were similar in both groups (3/35 stented vs 6/29 not catheterized, p=0.3). However, dysuria (14% vs 45%) retention (0 vs 24%) and extravasation (0 vs 17%) occurred significantly more often in those not diverted. Of the 29 not catheterized, 12 (41%) were catheterized within 3 days of operation (El-Sherbiny, 2003).

We have used urinary diversion to avoid need for postoperative catheterization in the minority of pre-toilet –trained patients who otherwise will develop retention or extravasation. A 6Fr bladder stent is used for all repairs in prepubertal boys, versus a 12-14Fr catheter after puberty. For patients who are operated before toilet-training

the catheter drains into a single diaper. We never use suprapubic tubes in either primary or reoperative hypospadias repair.

Given that most infants undergoing distal repairs in the above studies did not require diversion we recently began performing distal TIP without a stent, which obviates need for postoperative antibiotics and facilitates early, normal bathing resumed at 48 hours after surgery.

### Bandages

**2 RCTs reported that bandages did not impact urethroplasty results. Consequently, surgeons choosing to use bandages should consider those which fall off spontaneously.**

Two RCTs (Van Savage et al, 2000; McLorie et al, 2001) found no difference in urethroplasty outcomes in patients with compressive dressings versus those with no bandages. In the first study patients had an adhesive film versus no dressing, while the second compared postoperative topical antibiotic ointment to an adhesive film or compressive wrap followed by topical antibiotic ointment applied upon dressing removal. In both, 2% of patients were excluded from randomization due to bleeding at the conclusion of the procedure resulting in a bandage. Both instructed parents to remove dressings, and both reported increased phone calls and pain during bandage removal for those receiving bandages.

Data from these studies suggest that bandages should either not be used, or should be simple dressings that fall off spontaneously.

### Antibiotics

See the earlier section describing perioperative antibiotics.

### Anticholinergics

**No study reports efficacy of anticholinergics to reduce postoperative discomfort, or randomized children to treatment versus placebo to demonstrate efficacy.**

Although anticholinergics are commonly used following hypospadias repair to reduce discomfort associated with urinary diversion, no trial tests their efficacy.

We prescribe oxybutynin to toilet-trained boys during catheterization, typically using 0.2mg/kg/dose 2x daily, or 1 extended release tablet daily for those able to swallow pills.

### Preventing Erections

**1 RCT reported oral ketoconazole was no more effective than placebo in preventing postoperative erections.**
**No medication has been reported effective to reduce or prevent postoperative erections.**

A placebo-controlled double blinded RCT enrolled 40 men at mean age 28 years undergoing penile surgeries, such as circumcisions and urethroplasties, to either perioperative oral ketoconazole 400 mg TID or placebo for 1 week. There was no reduction in either erections or painful erections (both occurring in > 80%) using ketoconazole, but 3 (16%) treated patients withdrew due to nausea and another developed transient liver dysfunction (DeCastro et al, 2008).

### Hospitalization

**No study evaluates urethroplasty complications based on postoperative hospitalization.**

Justification for postoperative hospitalization varies significantly among various health care systems, often related to patient expectations or reimbursement rather than to medical necessity.

We reported ambulatory surgery (no hospitalization) in full-term patients as young as 3 months old undergoing distal TIP repair, finding no increase in anesthetic or surgical complications versus those over 6 months of age (Bush and Snodgrass et al, 2012).

Ambulatory surgery for most hypospadias operations has been the standard of care in the US since the mid 1980s. Parents informed of this expectation during preoperative consultation rarely raise concerns or ask for their child to be admitted to hospital.

In general we perform ambulatory surgery for most repairs done before puberty: all distal and all proximal TIP, and staged graft repairs in infants. Pubertal patients usually stay 1 night in hospital after either primary or reoperative repairs. Boys between infancy and puberty undergoing oral mucosa graft operations spend a single night in hospital.

## *OUTCOMES ASSESSMENT*

### Duration for Follow-up

**80% of urethroplasty complications are diagnosed within 1 year after repair, with follow up needed in 14 patients for each complication encountered subsequently.**
**Duration of follow up to reach 99% of complications cannot be determined from available reports, although 1 retrospective study suggested 20 years to diagnose all fistulas.**

We reviewed our prospectively maintained databases for primary and reoperative TIP repair to determine when complications were first diagnosed. Routine follow up after distal TIP comprised examination at 6 weeks and then 6 months later (8 months postoperatively). Proximal cases had similar initial follow up with annual assessments scheduled thereafter. There was a total of 125 urethroplasty complications after 887 operations, including 54 fistulas, 59 glans dehiscences, 9 meatal stenoses or urethral strictures, and 3 diverticula, of which 64% were diagnosed at the first postoperative visit and 80% within the first year after surgery (Figure 1). Median time to encounter fistulas, meatal stenoses/urethral strictures and diverticula was 6 months (1.5-95) versus 2 months (1w-24m) for glans dehiscences. After 1 year, 14 patients would need indefinite follow up to diagnose 1 additional urethroplasty complication. Follow up in the 762 boys without known complications was a mean of 12 months (1-134) (Snodgrass and Bush et al, 2013).

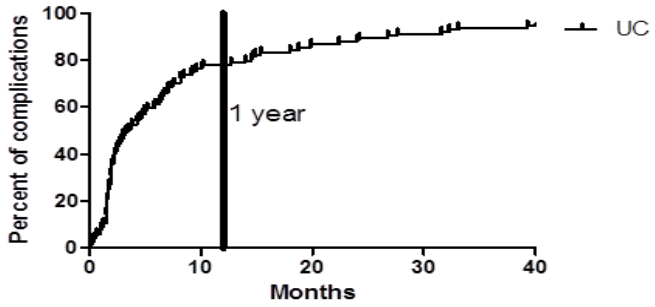


Figure 1. Kaplan-Meier curve showing time to diagnosis of urethroplasty complications after 887 primary and reoperative TIP repairs

Retrospective reviews also address timing of diagnosis for urethroplasty complications. None reported systematic follow up beyond approximately 1 year after repair:

- 70% 0f fistulas found in 26 boys were diagnosed within the first year postoperatively, at a median of 3 months, but follow up to detect 90% and 99% was 8 and 20 years, respectively. The total number of patients needing such extended assessments up to 20 years after surgery to diagnose these fistulas was not reported (Wood et al, 2008).

-126 patients who had 1 stage primary repairs by a variety of techniques ( 37 MAGPI, 21 Mathieu, 6 tubed grafts, 53 tubed prepucial flaps and 9 onlay flaps) were reviewed to

determine both short term (< 1 year) and later complications. Early urethroplasty complications occurred in 33 (26%), mostly following tubed grafts (83%), tubed flaps (32%) and onlay flaps (67%). After 1 year another 24 (19%) complications were diagnosed, mostly meatal stenosis after tubularized prepucial flaps (Fretz et al, 2004). These patients were not systematically followed beyond 1 year and those presenting later returned with symptoms. Therefore, the time complications occurred cannot be determined from this report.

- 474 patients had mean follow up of 34 months after a variety of hypospadias repairs, of which 114 (24%) had a reoperation for fistula, meatal stenosis, or unsatisfactory appearance. Scheduled follow up was at 6 months, after toilet training and at puberty, but the numbers of patients adhering to this plan were not stated. Of these reoperations, 24% were done >2years postoperatively. The authors reported that 15 boys needed assessment after 3 years for each additional urethroplasty complication (Spinoit et al, 2013).

Determining optimal duration for follow up requires agreement regarding the percentage of complications expected to be encountered. Available data reviewed above indicates 80% are diagnosed within the first year, but follow up as long as 20 years might be needed to reach 99%. Despite statements that patients should be assessed at toilet training and again in late puberty, no study to date reports success in following a cohort of patients using this regimen.

In addition, it is possible that the timing of diagnosis of urethroplasty complications varies according to procedure as seen in the series by Fretz et al, in which most the late complications occurred after tubularized prepucial flaps.

Other outcomes from hypospadias surgery, including urination and sexual function, do need assessment after puberty, but no study to date reports such results in a cohort of patients followed continuously after childhood repair.

**Urethroplasty**

*Calibration:*

Sounding the neourethra detects meatal stenosis and neourethral strictures in pre-toilet trained boys, but given the small occurrence of these, routine calibration is not needed in asymptomatic patients. The normal caliber of the meatus varies with age; the minimum is variously reported from ≤8Fr (Litvak et al, 1976) to ≥10Fr (Yang et al, 2001).

WS performed calibration in non-toilet trained children at the 8 month postoperative visit as a diagnostic test to demonstrate neourethra patency. From 551 consecutive distal TIP repairs done at mean age 17 months (3-140) there was follow up in 426, of which a single calibration was done in 263 (62%). Size of sounds used was 8Fr in 13%, 10Fr in 63% and 12Fr in 24%. The intention was only to demonstrate patency to at least 8Fr and patients were not serially calibrated to determine maximum caliber of the neourethra. A 10Fr sound was used routinely, but occasionally was either not available or the neomeatus appeared small and so an 8Fr was used. The universal finding of a patent neourethra was considered evidence the dorsal incision healed without stricture.

Calibration was not used as a therapeutic intervention; specifically no patient had serial calibrations in the outpatient clinic and none was instructed to perform home dilations (Snodgrass and Bush et al, 2010).

*Uroflowometry:*

**Uroflow is a potentially objective assessment of neourethral function after hypospadias repair**.

**However, there are limitations of reported uroflowometry:**

**- no study has compared a cohort of patients to age matched controls providing flow rates; instead nomograms have been used to determine normal values. 1 report noted the number of patients with Qmax <5$^{th}$ percentile differed according to the nomogram selected.**

**- optimal timing of uroflowometry postoperatively is unclear, with published series noting increased peak flow over time**

**- the clinical significance, if any, of bell- versus plateau-shaped curves in unclear**

**- the clinical significance, if any, of flow rates <5$^{th}$ percentile of nomograms in asymptomatic patients is unknown**

**- the relationship between patient perceptions of voiding versus flow rates has not been reported**

Uroflowometry is considered an objective means to assess urinary function after urethroplasty in toilet trained patients. However, there are a number of limitations in applying the results to clinical outcomes in children. First is that no study has yet reported outcomes in hypospadias patients compared to age-matched controls within the same clinical setting. Rather, they are compared to nomograms that likely were constructed by repeated testing until satisfactory volumes were obtained, which would also better acquaint the child with the process and apparatus and thereby potentially influence results. Furthermore, as discussed below, 1 study found that the number of subjects considered to have peak flows <5$^{th}$ percentile varied according to the nomogram used. In addition, no study has related uroflow findings to symptoms, if any, although a number of authors commented that patients with peak flows <5$^{th}$ percentile were not further investigated for the lack of symptoms. Also, the relative significance of the peak versus the mean flow, and the shape of the curve as bell versus plateau, are not known. Additionally, optimal timing for uroflows after surgery is unclear, with 1 report noting improvement between tests obtained at 1 and 6 years postoperatively. Finally, the increased radius of the urethra during puberty likely increases urinary flow, but no study to date has shown prepubertal versus postpubertal results in patients as they matured.

All reported series find uroflows in the lower range of normal after hypospadias urethroplasty, with some asymptomatic children having peak flows <5$^{th}$ percentile.

These uroflows are thought representative of the urethroplasty, and have been used to compare outcomes between techniques in at least 1 report (Braga et al, 2008). However, it is possible that differences between various operations for the same extent of hypospadias reflect relative success of the glansplasty rather than whether urethroplasty was done using the urethral plate, flaps or grafts.

*Following TIP*

1 study reported flow rates in 37 asymptomatic boys from a total of 126 distal and proximal TIP repairs. At 1 year mean Qmax was 13.6cc/sec (6-28), with half below the 5$^{th}$ percentile on the Miskolc normogram. At an average of 6 years later the mean Qmax was 19cc/sec and 32% were below the 5$^{th}$ percentile, a significant improvement. The authors stated fewer patients would have been categorized as below the 5$^{th}$ percentile had the Toguri nomogram been used (Andersson et al, 2010).

WS previously reported uroflowmetry in 17 of the first 50 toilet trained boys following TIP, done at a mean of 45 months (6m-7y) postoperatively. All peak flows were >5$^{th}$ percentile based on the normogram used by Jananthi et al discussed below (which was not reported in the article) (Snodgrass, 1999).

Considering Qmax <2SD from normal a possible indication of obstruction, a review of reported TIP uroflows found 36/140 (26%) asymptomatic patients in 3 articles using different nomograms met that criteria (Gonzalez and Ludwikowski, 2011).

We hypothesize the Qmax changes little after initial healing, but that at puberty the increased urethral diameter should increase the flow rate. Currently we have limited data in patients before and after pubertal development. In 2 the Qmax improved from 7 to `19cc/sec and 13 to 20cc/sec at Tanner stage 4. 3 others have no change in Qmax at Tanner stage 2.

*Following Preputial Flaps*

A review of uroflows in 51 toilet-trained boys following either onlay or tubularized preputial flaps reported27% had Qmax below the 5$^{th}$ percentile of an institutional nomogram (Jayanthi et al, 1995).

A study obtaining uroflowometry a mean of 14 years after proximal repair in infancy (mean age 17 months) reported a mean Qmax of 17cc/sec without differences between onlay and tubularized flaps (Patel et al, 2005).

## Cosmesis

**2 studies used standardized photographs to compare TIP versus flap cosmetic outcomes, both reporting higher scores for TIP. A questionnaire study compared TIP to controls after circumcision and found similar ratings by caregivers 6 weeks after surgery.**

Objective assessment of genital appearance after hypospadias surgery is not commonly reported.2 studies used photography scored by blinded reviewers to compare TIP to Mathieu or onlay flaps. Both reported TIP scores significantly higher (Ververdis et al, 2005; Scarpa et al, 2009).

WS used a non-validated questionnaire completed by caregivers before physician examination 6 weeks after distal or proximal TIP versus controls following circumcision. There were no differences in Likert-scale scores regarding overall appearance or the specific appearance of the meatus or penile skin (Snodgrass et al, 2008).

Another study compared photographs after standard onlay to a modified “V-incision” ventrally to create a more vertical meatus shape. Overall improvement was reported,

with 8/25 standard versus 12/18 modified repairs achieving a slit meatus, p =0.03. V-incision was effective in all 4 with a deeply grooved and 6/9 with a moderately grooved plate, but in only 2/5 with a flat configuration (Hayashi et al, 2001).

There are no other studies concerning aesthetic appearance of the penis after flap repairs. Although the V-incision proposed by Hayashi et al did result in more with a slit meatus, the patients most likely to have a rounded appearance with flaps are those with a flat plate, and V-incision was effective in fewer than 50% of those.

Despite emphasis on creating a penis that appears normal, only 2 studies report objective data regarding cosmetic outcomes. One used postoperative photographs blindly scored by a panel of medical professionals that ranked TIP results superior to those from Mathieu and onlay flaps (Ververidis et al, 2005). A second administered Likert-scale questionnaires to parents and operating surgeon after TIP or circumcision. No significant differences occurred between surgeon and parents in either group, or in satisfaction after TIP for hypospadias versus elective circumcision in boys with a normal penis (Snodgrass et al, 2008).

No similar data has been published for flap-based repairs.

### Validated Questionnaires

Objective means to assess functional and cosmetic results after hypospadias repair are needed, both the establish standards for comparisons between techniques and surgeons, and also to determine patient perceptions of those outcomes. Validated questionnaires potentially provide a means for such assessments.

One instrument is the HOSE (hypospadias objective scoring evaluation), which rates meatal location, meatal shape, the urinary stream, erection straightness, and presence

or absence of fistula. It was used in 20 patients assessed 9 months postoperatively by 2 surgeons, 1 nurse and 1 parent. The authors reported “good agreement” overall between observers, with a mean weighted kappa score of 0.66. Agreement between surgeons and nurse was 0.70, and between surgeons and parent was 0.65 (Holland et al, 2001).

A subsequent study devised a questionnaire entirely devoted to cosmetic impressions, omitting questions regarding the urinary stream, erections or fistulas. This PPPS (pediatric penile perception score) was derived from structured interviews of patients and controls ages 6-17 years of age. Appearance of the meatus, glans, shaft skin and the general appearance were rated using a 4 point Likert scale from very dissatisfied to very satisfied. Patients showed good intercorrelation between individual items and the general appearance (meatus $r=0.45$, $p=0.00$; glans $r=0.6$, $p=0.00$; shaft skin $r=0.59$, $p=0.00$) (Weber et al, 2009).

A third study introduced the HOPE (hypospadias objective penile evaluation), also with the goal of determining aesthetic results. This assessment was done using standardized photographs from 5 viewpoints obtained 6 months postoperatively to determine meatal position, meatal appearance, glans shape, and appearance of the shaft skin. These were then blindly scored by 13 pediatric urologists. Intra-observer reliability had a mean correlation coefficient of 0.817, while inter-observer reliability had a mean correlation coefficient of 0.79 (Van der Toorn et al, 2013).

All these have merit for attempting to make surgical outcomes determination more objective. However, they are perhaps best seen as initial steps towards meeting this need, as, for example, assessment using standardized photographs taken from several angles and then reviewed blindly clearly is impractical on a routine basis. Furthermore, while penile appearance after repair is important it is not the only important parameter to review. A slit meatus is preferable to a rounded opening, but if the more normal

appearing neomeatus is associated with glans dehiscence and a spraying stream, is the surgical result really better than a less satisfactory round meatus with good glans fusion and a straight urinary stream?

## *URETHROPLASTY OUTCOMES*

### Distal TIP

**Most articles report complications in <10% of cases after distal TIP.**

We reported outcomes in 426 consecutive boys a mean of 8 months after distal TIP repair by WS. Assessment included calibration, uroflowometry and/or urethroscopy done in 279 (65%). Urethroplasty complications occurred in 19 (4%), including 9 fistulas, 9 glans dehiscences and 1 meatal stenosis which developed later from BXO. There were no strictures or diverticula (Snodgrass and Bush et al, 2010).

Given that our large series had no case with primary meatal stenosis, we believe this complication most often reflects technical error and is therefore avoidable. The most likely etiologies are failure to incise the plate sufficiently deep to create a normal neourethral caliber, and/or tubularizing the plate too far distally – perhaps with the intention of suturing the plate opening to the glans wings when creating the neomeatus.

A systematic literature review included 15 articles on distal TIP from 1994 through 2009, comprising 1872 boys. The authors reported 4% fistulas and 3% meatal stenoses with no urethral strictures. Glans dehiscence was not reported (Wilkinson et al, 2012).

Snodgrass also reviewed 35 articles on distal TIP published in English between 1994 and 2009. Reported complications ranged from 0-24%, with 25 of the series having <10%, mostly fistulas and meatal stenoses (Snodgrass, 2011).

### Proximal TIP

**We reported 13% urethroplasty complications in consecutive patients after proximal TIP.**

Proximal TIP has evolved through various modifications to reduce urethroplasty complications. In 49 consecutive patients operated by WS, complications developed in 53% of the first 15, 25% in the next 20 and 13% in the final 24 cases with follow up, p=0.02. These complications included 7 fistulas, 5 glans dehiscences, 1 meatal stenosis and 1urethral stricture. The primary goal of technical changes was to reduce fistulas. After results of the first 15 patients were known, urethroplasty was changed from 1 layer continuous epithelial 7-0 chromic catgut to 2 layer subepithelial tubularization using interrupted 7-0 polyglactin followed by continuous 7-0 polydiaxanone. In addition, spongioplasty was added to the second group. All these cases in the first 2 groups included neourethra coverage with a dartos flap. In the final cohort tunica vaginalis replaced dartos as the coverage flap, and there were no fistulas (Snodgrass and Bush, 2011).

To our knowledge, no other published series reports the total number of patients with proximal hypospadias operated during a study period using TIP versus alternative methods, and few provide sufficient technical detail for readers to compare to their own practice.

### 2-stage Graft Proximal Repairs

**There are few published data regarding 2 stage primary proximal hypospadias repair**. **We found urethroplasty complications in 52% of 24 patients, mostly glans dehiscence that occurred before extended glansplasty began.**

The technique was popularized by Bracka, who never specifically reported these outcomes.

We started using this operation in 2008 and currently have unpublished follow up results in 24 patients with proximal shaft (n=3), penoscrotal (n=6), scrotal (n=7) and perineal (n=8) hypospadias. Ventral lengthening with 3 transverse corporotomies was used in straightening ventral curvature after urethral plate transection in 20 (83%). 3 (12.5%) had graft contracture requiring re-grafting as a separate procedure, 2 involving lip grafts and 1 after prepucial grafting.

We have observed that prepucial grafts remain thin when sewn to the ventral penile shaft, whereas lip grafts heal grossly more thick than when harvested and transferred.
Urethroplasty complications occurred in 12 (52%), 11 glans dehiscences and 2 fistulas. Mean glans diameter for the entire group, measured in 22, was 12.3mm, with 15 (68%) <14mm. Extended glans wings mobilization was not used in any of these patients. Reducing glans dehiscence by extended glans dissection is anticipated to bring the overall complication rate down to approximately that following proximal TIP, in the range of 15%.

A retrospective review of 34 patients with proximal shaft to perineal hypospadias operated using 2 stage prepucial grafts reported urethroplasty complications in 26%, comprising 4 glans dehiscences, 2 fistulas, 1 diverticulum and 1 neourethral stricture. Although all these boys were described as having “significant chordee”, the means for straightening was not stated beyond needing “corporoplasty”. (Ferro et al, 2002).

## *COMPLICATIONS*

## Risk Factors

**Multivariable analysis of various factors using prospectively collected data determines proximal meatus, glans width <14mm, and reoperation are independent risks for urethroplasty complications.**

We evaluated risk factors for hypospadias urethroplasty complications among 669 consecutive prepubertal patients following TIP, using multiple logistic regression analysis of prospectively collected data. Potential factors considered in the model were patient age, meatal location, reoperation, glansplasty suture type, and surgeon learning curve (1st 50 patients). The only independent risk factors from these were reoperation (OR 3.07, 95% CI 1.54- 6.13) and proximal meatal location (OR 1.79, 95% CI 1.33-2.40) (Bush and Snodgrass, et al, 2012)

A subsequent analysis studied 391 patients undergoing TIP, inlay or 2 stage graft repairs for patient age, meatal location, reoperation, and a new parameter- glans width at its widest point in mm. Again, meatal location and reoperation were risk factors, but independent of these glans width <14mm also increased complications (OR 3.7, 95% CI 1.6-8.5), with each 1mm increase in glans size decreasing complications (OR 0.81, 95% CI 0.69-0.95)(Bush and Snodgrass et al, 2013).

## Modifying Risk Factors

*Meatal Location*

Only 10% of primary cases present with a meatus on the proximal shaft to the perineum. Case logs reported to the American Board of Urology by US pediatric urologists requesting a certificate of added qualification indicated the average number of proximal repairs done annually was 2 (Kogan, 2011). Given that proximal meatus is a

consistent risk factor for urethroplasty complications, we recommend centers designate a single surgeon to perform these cases to increase their expertise.

*Reoperation*

Initial failure increases risk for additional failure. We recommend surgeons review their personal outcomes and consider changes in procedure and/or technique to reduce complications, as we discussed above regarding technical modifications which significantly reduced urethroplasty complications after proximal TIP.

Academic surgeons must ensure good outcomes for the patient when allowing trainees to actively participate in key steps of the surgery, especially urethroplasty and glansplasty.

A survey of mostly senior urology residents having completed >75% of their training found few performed glans wings dissection or urethroplasty (DeLair et al, 2008). Fellows in our program also observe these key steps until faculty conclude their skills are satisfactory, and they rarely perform >50% of any given repair. NB compared distal TIP outcomes of our former Fellows in consecutive cases done over a 2 year period beginning ≤ 3 years after training to those of WS during the same time frame. There were no significant differences in urethroplasty complications among the former Fellows or between them and WS (Bush and Snodgrass, et al, 2013).

We also recommend reoperations in major centers be done by a single surgeon.

*Glans Size*

As discussed above, preoperative androgens are known to increase glans width. We analyzed urethroplasty complications in patients who received adjuvant testosterone

injections versus those with glans ≥14mm who did not. Mean glans width before stimulation was 12mm, increasing to a mean of 16.5mm with testosterone injections. Untreated patients had a mean glans width of 15.4mm. Urethroplasty complications occurred in 34% with vs 11% without adjuvant androgens, p<0.0001. Testosterone was an independent risk factor for complications in this model (OR 3.1 95% CI 1.2-8.1). Accordingly we have stopped preoperative testosterone stimulation (Bush and Snodgrass et al, unpublished data 2013).

Now we use the extended glans wings dissection described in the technical syllabus for patients with glans width <14mm. This technique has a reported glans dehiscence rate of 1/150 cases despite an average glans width of 12mm (Tanakazi and Yoshino, personal communication).

## *IMPROVING OUTCOMES*

WS began recording data prospectively into Excel spreadsheets when he relocated to Dallas in 1999. The articles we reference since that date are all based on analysis of these databases, which today contain information on more than 1600 consecutive patients. Reviews of this data have improved our surgical techniques, outcomes, and understanding of the underlying factors that impact results in hypospadias repair.

### Determining Results

At this time there is no computer software that connects preoperative, intraoperative and postoperative data to create a surgeon scorecard, but with the growing reliance on electronic medical records it is only a matter of time before this occurs. Meanwhile, surgeons can enter pertinent data into an Excel spreadsheet to rapidly determine their personal outcomes. Recognizing the factors that best predict urethroplasty

complications, a surgeon need only enter the patient name, date of operation, meatal location, glans width, primary versus reoperation, operative procedure, date of follow up, and any complication noted. Depending on individual volume of repairs, that surgeon will learn his/her complication rate using reliable data within as little as 1 year at a cost of only a few minutes a week to enter the information after surgery or clinic.

**Technical Changes**

When we decide to perform a quality assessment of our surgical outcomes, whether of hypospadias or other conditions, we most often learn there are opportunities for improvement. For example, WS was surprised his fistula rate after proximal TIP was 33% despite using a dartos flap over the neourethra. But these cases are relatively infrequent for most pediatric urologists, who according to the ABU perform an average of 2 per year, and so even this high a complication rate may go undetected because patients with complications present sporadically and recall bias limits our ability to tabulate them without spreadsheets or chart review. Having recognized this, WS made a series of technical modifications described in this chapter which significantly reduced his fistula rate.

We similarly noted glans dehiscence at rates higher than reported, and initially thought it might be due to glans wings approximation using chromic catgut. So WS changed to polyglactin, but subsequent multivariable analysis, made possible by on-going data collection, showed suture type did not impact this complication, which was seen to be more common in proximal than distal repairs despite the same surgeon using the same technique for glansplasty. That led to measurements of glans size which confirmed suspicions that dehiscence, and other urethroplasty complications, were more prevalent when glans width was <14mm. Knowing androgens will increase glans circumference we embarked on a program of preoperative testosterone injections for the small glans. We learned this objective patient selection resulted in double the number of boys receiving

stimulation compared to our previous subjective use for a “small appearing” glans. We also encountered unexpected androgen resistance in two-thirds of those treated, requiring injections >2mg/kg to achieve targeted growth to ≥15mm. Most importantly, further outcomes review ultimately found that despite growing the glans to a size previously determined to have low complication rates, those patients that needed stimulation continued to have significantly more dehiscence than other boys whose glans was the desired size without stimulation. Since reduction in complications, not growth of the glans, was the aim of therapy, we then stopped androgen treatment.

This focus on glans size and dehiscence made WS more aware of variations in glans wings dissection, and more receptive to change his technique. When he observed 2 senior Japanese surgeons perform a more extended glans wings mobilization he recognized its potential and incorporated it into our practice.

**Improving Outcomes**

***P***rospective data collection, ***P***eriodic outcomes review, and ***P***ractice changes such as these make us better hypospadiologists and improve results for the young patients entrusted to our hands.

Of these, data collection is most important, because once a surgeon learns his/her actual results from data he/she knows are reliable, changes in technique and improved outcomes inevitably follow. Conversely, if low complication rates are found a surgeon benefits from knowing there is no need to change current practice, which is especially useful should a cluster of complications occur that otherwise might raise doubts. This is the core of evidence-based surgical practice.

## I. TIP Reoperations

Analysis of prospectively collected data in 63 patients having a mean of 1.1 prior operations reported 19% complications; mostly fistulas when a dartos flap was not used (Snodgrass, Bush et al, 2009). There was no difference in complications based on prior plate incision versus no incision.

## II. Inlay Grafts

3 series with mean number of prior operations between 2 and 4 all report 15% complications (Schwenter et al, 2006; Ye et al, 2008; Snodgrass, Bush et al 2009).

## III. 2 Stage Buccal Graft Reoperations

45 consecutive patients with prospectively recorded data had a mean of 4 (1-20) prior operations. 69% of these had proximal hypospadias. Graft complications requiring patching in a separate stage occurred in 10%. Urethroplasty complications occurred in 38%, mostly glans dehiscence when cheek was used in the glans, and fistulas (Snodgrass, Bush et al, 2009).

A retrospective review of 100 patients defined as cripples after a mean of 5 (3-16) failed repairs, used 2-stage grafts from the prepuce (n=39), oral mucosa (n=34), post-auricular skin (n=22) and other skin sources in the remainder. 37% of these had proximal hypospadias. 1st stage graft take was successful in 93%. 2nd stage urethroplasty complications were reported in 16% with follow-up described as >1 year, comprising fistulas, neourethral stricture, and glans dehiscence, all detected within the 1st 6 months after surgery (Gill and Hameed, 2010).

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