



# Development of novel prognostic models for predicting complications of urethroplasty

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## Abstract

**Introduction and objective** To identify predictors of thirty-day perioperative complications after urethroplasty and create a model to predict patients at increased risk.

**Methods** We selected all patients recorded in the National Surgery Quality Improvement Program (NSQIP) from 2005 to 2015 who underwent urethroplasty, determined by Current Procedural Terminology (CPT) codes. The primary outcome of interest was a composite 30-day complication rate. To develop predictive models of urethroplasty complications we used random forest and logistic regression with tenfold cross-validation employing demographic, comorbidity, laboratory, and wound characteristics as candidate predictors. Models were selected based on the receiver operating characteristic (ROC) curve, with the primary measure of performance being the area under curve (AUC).

**Results** We identified 1135 patients who underwent urethroplasty and met inclusion criteria. The mean age was 53 years with 84% being male. The overall incidence of complications was 8.6% ( $n=98$ ). Patients who experienced a complication more commonly had diabetes, a preoperative blood transfusion, preoperative sepsis, lower hematocrit and albumin, as well as a longer operative time ( $p < 0.05$ ). LASSO logistic and random forest logistic models for predicting urethroplasty complications had an AUC (95% CI) 0.73 (0.58–0.87), and 0.48 (0.33–0.68), respectively. The variables that were determined to be most important and included in the predictive models were operative time, age, American Society of Anesthesiologists (ASA) classification and preoperative laboratory values (white blood cell count, hematocrit, creatinine, platelets).

**Conclusion** Our predictive models of complications perform well and may allow for improved preoperative counseling and risk stratification in the surgical management of urethral stricture.

**Keywords** Urethroplasty · Perioperative complications · Risk stratification · Predictive model · Risk calculator

## Introduction

Urethral stricture disease is a cause of significant patient morbidity and burden on the health care system. In the United States, urethral stricture disease accounts for more

than 5000 inpatient visits annually, greater than 1.5 million office visits from 1992 to 2000, and a cost of approximately 200 million dollars in 2000 alone [1]. Common etiologies of urethral stricture include iatrogenic causes (urethral catheterization, cystoscopy, transurethral resection, prostate cancer treatment, hypospadias repair), pelvic fracture, Lichen sclerosis, trauma, infection or idiopathy [2, 3]. Urethral strictures can be managed with dilation, direct visual internal urethrotomy (DVIU) or urethroplasty. Urethral dilation and DVIU have been shown to have inferior long-term results with recurrence rates ranging from 40 to 75% [4–6]. Recurrence rates were the greatest when dilation and DVIU were performed in the setting of recurrent or longer strictures. Urethroplasty has been shown to be a successful cost-effective treatment option with durable long-term results [7]. The AUA guidelines for male urethral strictures recommend that urethroplasty may be offered to all patients with a stricture

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and should be offered to patients with penile urethral strictures, recurrence after previous dilation or DVIU, and long strictures (> 2 cm) due to a higher success rate [8].

To maximize the potential benefit of urethroplasty, risk factors associated with perioperative complications can be identified to allow anticipation and possible prevention of potential adverse events. While many studies have examined risk factors of stricture recurrence, there is a paucity of literature investigating predictors of post-procedural complications that may negatively impact patient outcomes. Most outcomes data are retrospective in nature coming from single institution or surgeon series [9, 10]. To overcome these limitations, we employed a national, validated, risk-adjusted, outcome-based database. The objective of this study was to identify predictors of thirty-day perioperative complications after urethroplasty, and create a model to identify patients with increased risk. Risk stratification during preoperative planning may help tailor decision making in surgical candidates. Our study aims to aid in recognizing those patients at greater risk for postoperative complications following surgical management, which may lead to appropriate preoperative optimization strategies for this selected group of patients.

## Materials and methods

We used data from the National Surgery Quality Improvement Program (NSQIP) database, a surgical outcomes database administered by the American College of Surgeons (ACS) and designed to provide risk-adjusted morbidity and mortality estimates to compare hospital performance [11]. NSQIP provides data on 165 pre- and postoperative variables related to demographics, surgical profile, preoperative, intraoperative, and postoperative parameters. Data are submitted by a national sample of 374 voluntary institutions, ranging from rural community hospitals to high volume urban academic centers.<sup>1</sup> Surgical Clinical Reviewers trained by NSQIP capture data on site via chart review and discussions with the surgical team when necessary. Reliability of at least 95% is ensured by strict objective criteria used to determine outcomes, along with yearly auditing of the Surgical Clinical Reviewer [12].

For this study, we selected all patients recorded in NSQIP from 2005 to 2015 who underwent urethroplasty, determined by the following Current Procedural Terminology (CPT) codes: 15115, 53410, 53400, 53405, 53420, 53430 and 53425. The primary outcome of interest was a composite 30-day complication rate, which included mortality, unplanned intubation, deep vein thrombosis (DVT) requiring

therapy, pulmonary embolism, renal insufficiency, acute renal failure, urinary tract infection, stroke, cardiac arrest, myocardial infarction, blood transfusions, surgical site infection, sepsis, septic shock, and reoperation.

We extracted preoperative comorbidities, preoperative laboratory values, and operative variables determined a priori to be potential predictors of 30-day complications. Demographic variables extracted included age, gender and race. Preoperative comorbidities included recent weight loss of greater than 10% of body weight, being a current or former smoker, diabetes mellitus, chronic obstructive pulmonary disease (COPD), dialysis, corticosteroid use, bleeding disorder, blood transfusion, and sepsis. Preoperative lab values included white blood cell count (WBC), hematocrit, platelet count, creatinine, and albumin. Operative values included wound class, American Society of Anesthesiologists (ASA) classification, and operative time in minutes.

## Data analysis

We summarized the sample data by comparing the baseline demographics, medical comorbidities, preoperative laboratory values, operative data and American Society of Anesthesiologists (ASA) classifications between patients who did not experience complications and patients who experienced any complication. Continuous variables were summarized using mean  $\pm$  standard deviation (SD) and compared using a Welch's *t* test. Categorical and dichotomous variables were summarized using raw number and percent, and compared using Fisher's exact test.

## Model training

The primary aim of this study was to develop a statistical model predictive of 30-day complications. This was primarily accomplished through machine learning, a set of tools based on statistics and computer science. Models were selected based on the receiver operating characteristic (ROC) curve, with the primary measure of performance being the area under curve (AUC).

Predictors selected for the model were based on a priori variables thought to be predictive of complications. Prior to any model fitting, we separated the dataset into training (80%) and test (20%) sets using simple bootstrap random sampling without replacement. Then, we constructed a random forest classifier with 500 trees using all a priori variables to predict any complication, using the Gini coefficient as split criterion. To optimize model development for out-of-sample rather than in-sample performance, this model was evaluated using 10 repeats of tenfold cross-validation on the training set. In this procedure, the dataset is first randomly divided into 10 equal parts, models are trained on 9 parts and tested on the 10th, and this process is repeated using

<sup>1</sup> Program ACoSNSQI. User guide for the 2012 ACS NSQIP Participant Use Data File. 2013 [July 2015].

**Table 1** Patient demographics and clinical characteristics

	Any complication	No complication	<i>p</i>
Total	98	1037	
Age mean (sd)	52 (16)	50 (16)	0.299
Male (%)	83 (84)	920 (88)	0.248
Female (%)	13 (16.2)	119 (11.2)	
Race (%)			
Black	15 (15.3)	130 (12.5)	0.139
Other	27 (27.6)	215 (20.7)	
White	56 (57.1)	692 (66.7)	
>10% loss body weight in last 6 months (%)	2 (2.0)	4 (0.4)	0.088
Diabetes mellitus (%)	19 (19.4)	127 (12.2)	0.05
Chronic obstructive pulmonary disorder (%)	2 (2.0)	21 (2.0)	1
Dialysis (%)	0 (0.0)	9 (0.9)	1
Steroid use (%)	2 (2.0)	23 (2.2)	1
Bleeding disorder (%)	3 (3.1)	11 (1.1)	0.113
Transfusion (%)	2 (2.0)	1 (0.1)	0.021
Preoperative sepsis (%)	8 (8.2)	8 (0.8)	< 0.001
Preoperative WBC (mean (sd))	7.5 (3.5)	7.3 (2.71)	0.464
Preoperative Hct (mean (sd))	40.2 (6.3)	41.8 (4.5)	0.003
Preoperative platelet count (mean (sd))	240.9 (80)	234.4 (68)	0.435
Preoperative creatinine (mean (sd))	1.1 (0.6)	1.1 (0.8)	0.757
Preoperative albumin (mean (sd))	3.9 (0.9)	4.2 (0.6)	0.001
Wound classification (%)			
1-Clean	7 (7.1)	58 (5.6)	< 0.001
2-Clean/contaminated	79 (80.6)	946 (91.2)	
3-Contaminated/-dirty/infected	12 (12.2)	33 (3.2)	
ASA class (%)			
1-No disturb	13 (13.3)	169 (16.3)	0.017
2-Mild disturb	44 (44.9)	557 (53.8)	
3-Severe disturb/life threat	41 (41.8)	310 (29.9)	
Mean Operative Time (min) (range)	225 (26.0–1123.0)	171 (0.0–654.0)	< 0.001

American Society of Anesthesiologists (ASA) classification, ASA Class. White blood cell count, WBC. Hematocrit, Hct

each of the 10 parts as the test set. This entire process is then repeated 10 times making different separations each time, and the error rates are averaged to compute the cross-validation AUC. Optimal values for the number of features used to grow each tree were determined by minimizing the cross-validation AUC.

With the aim of improving interpretability of the model, we constructed a simplified logistic regression model, again using 10 repeats of tenfold cross-validation on the training set, with variables entered in a forward stepwise fashion in order of the mean decrease in Gini coefficient (a.k.a. Gini importance) calculated from the random forest model. For continuous variables, we categorized them based on optimal cutoff points identified by minimizing the Gini coefficient for complications in a simple decision tree. Continuous variables were entered into the model both as continuous variables, and categorized based on their optimal cutoff points,

determined using recursive partitioning trees with bootstrap validation. Variable inclusion in the logistic regression model was determined by maximizing the cross-validation AUC. When model fitting was complete, both the random forest and logistic regression classifiers were used to predict complications on the test set, with prediction accuracy evaluated based on sensitivity, specificity, and AUC.

## Results

From 2005 to 2015, we identified 1135 patients who underwent urethroplasty and met inclusion criteria. The demographic data of patients who experienced a complication and those who did not were compared (Table 1). Overall, 98 patients (8.6%) experienced a complication. Patients who experienced a complication were more likely to have medical

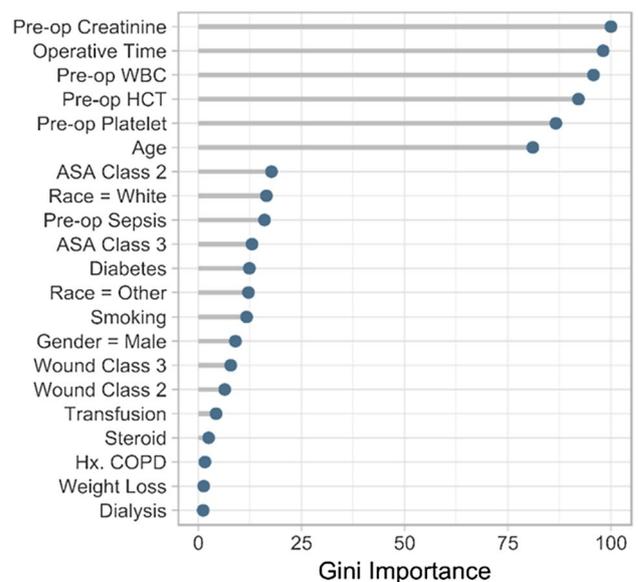
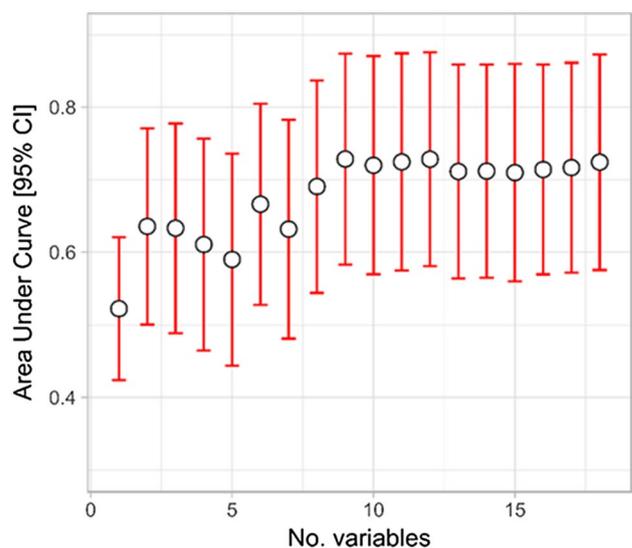
**Table 2** Incidence of Complications [data are *n* (%)]

Any complication	98 (8.6)
Urinary tract infection	46 (4.1)
Perioperative transfusions	13 (1.1)
Superficial surgical site infection	12 (1.1)
Reoperation	9 (0.8)
Deep surgical site infection	8 (0.7)
Organ surgical site infection	6 (0.5)
Deep venous thrombosis	5 (0.4)
Pulmonary embolism	5 (0.4)
Pneumothorax	3 (0.3)
Myocardial infarction	2 (0.2)
Sepsis	2 (0.2)
Septic shock	2 (0.2)
Mortality	2 (0.17)
Unplanned reintubation	1 (0.1)
Stroke/CVA	1 (0.1)
Renal failure	1 (0.1)
Cardiac arrest	0 (0)

comorbidities (diabetes mellitus, higher ASA class), lower preoperative albumin and hematocrit, longer mean operative time, a wound class classified as clean/contaminated, and preoperative transfusion. There was no significant difference in mean age, gender or ethnicity in the group whose surgery was associated with a complication compared to the group with no complications.

Complications in the first thirty days following urethroplasty are listed in Table 2. The most common complications experienced were urinary tract infection (4.1%), perioperative transfusion (1.1%) and superficial surgical site infection (1.1%). Only 9 patients (0.8%) underwent a reoperation in the first thirty days. The rate of mortality after urethroplasty during this time period was very low (0.17%) as was the rate of severe cardiovascular or pulmonary complication.

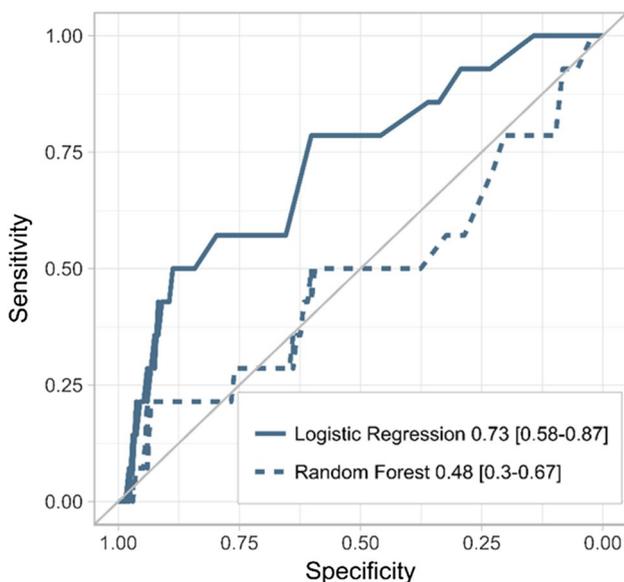
As described in the methods section, we used random forests and logistic regression with tenfold cross-validation to develop a statistical model predictive of 30-day complications. In the random forest model, the most important variables based on Gini importance (presented as a percentage of the value for the most important variable) were preoperative creatinine (100), operative time (93.7), preoperative hematocrit (91.7), preoperative platelet (88.5), preoperative WBC (87.5), age (73.7), and preoperative sepsis (36.8) (Fig. 1). Predictors for the logistic model were selected using Gini importance in the random forest. After including each variable in the logistic regression model in

**Fig. 1** Variable importance ranking calculated from random forest model with tenfold cross-validation**Fig. 2** Cross-validation area under curve (AUC) and 95% confidence intervals (CIs) for logistic regression models with forward selection based on random forest Gini coefficient decrease, by number of variables included in the model

order of mean decrease in Gini coefficient, it was determined that the first seven variables produced the maximum cross-validation AUC (Fig. 2). The results of the final logistic regression model are displayed in Table 3. Significant variables in the model included preoperative

**Table 3** Results of final logistic regression model, fit to the entire dataset

	OR	95% CI	p value
Operative time 356–536 min	5.16	2.20–11.49	< 0.001
Operative time > 536 min	23.31	4.75–127.06	< 0.001
Pre-op WBC > 12.6	2.09	0.57–6.56	0.232
Pre-op Hct > 35	0.41	0.20–0.88	0.018
Pre-op creatinine > 0.74	0.40	0.20–0.85	0.013
Pre-op platelets 100–318	0.12	0.02–0.81	0.017
Pre-op platelets > 318	0.18	0.03–1.37	0.077
Age 55+	1.32	0.73–2.38	0.359
ASA class 2	0.57	0.25–1.39	0.195
ASA class 3	0.81	0.33–2.08	0.645
Pre-op sepsis	5.50	1.34–21.56	0.015
Race = other	2.16	0.92–5.33	0.084
Race = white	0.84	0.40–1.89	0.656



**Fig. 3** Receiver operating characteristic (ROC) curves and AUC (95% CI) for cross-validated logistic regression and random forest models, applied to test data set

creatinine  $\geq 0.7$  (OR 0.29,  $p = 0.001$ ), operative time between 356 and 536 min (OR 6.21,  $p < 0.001$ ), operative time > 536 min (OR 20.45,  $p < 0.001$ ), preoperative platelet  $\geq 100$  (OR 0.18,  $p = 0.036$ ), preoperative WBC between 6.2 and 12.5 (OR 0.34,  $p = 0.001$ ), and age 55 or greater (OR 2.02,  $p = 0.023$ ).

Based on our model, one can apply the following equation to determine a patient’s risk of complication:

$$\ln\left(\frac{p}{1-p}\right) = 1.641 \times I(\text{Operative time } 356 - 536 \text{ min}) + 3.149 \times I(\text{Operative time } > 536 \text{ min}) + 0.737 \times I(\text{Pre - op WBC } > 12.6) - 0.892 \times I(\text{Pre - op Hct } > 35) - 0.916 \times I(\text{Pre - op Creatinine } > 0.74) - 2.120 \times I(\text{Pre - op Platelets } 100 - 318) - 1.715 \times I(\text{Pre - op Platelets } > 318) + 0.278 \times I(\text{Age } 55+) - 0.562 \times I(\text{ASA Class } 2) - 0.211 \times I(\text{ASA Class } 3) + 1.705 \times I(\text{Pre - op Sepsis}) + 0.770 \times I(\text{Race } = \text{Other})$$

where  $I()$  is an indicator function returning 1 if the expression is true and 0 otherwise. Therefore, for example, for a patient with operative time 400 min, preoperative WBC 13 (but all other labs normal), ASA class 2, no preoperative sepsis, 50 years old, and African American race, the log odds of complication would be  $1.641 + 0.737 - 0.562 = 1.816$ , implying odds =  $e^{1.816} = 6.14722$ , and therefore the probability is  $\frac{6.14722}{1+6.14722} = 0.86$ .

Figure 3 compares discriminative power of the logistic regression and random forest models, each applied to the test set. The AUC (95% CI) for the random forest model was 0.57 (0.37–0.77), compared to 0.73 (0.59–0.87) for the logistic regression model, indicating superior predictive performance for logistic regression.

### Discussion

Using the NSQIP database we created random forest and logistic regression models to predict thirty-day complications after urethroplasty. While the random forest model had relative poor discrimination (AUC 0.57), the logistic regression model derived from random forest variable importance performed well, with an AUC of 0.73. The model was created as a preoperative prediction tool that can be used for risk assessment, patient counseling and surgical planning. For comparison, the AUC for prostate specific antigen (PSA) when used as a screening tool to detect any prostate cancer has been shown to be 0.678 [13]. While there are surgical risk calculators derived from NSQIP [14, 15], the performance of the risk calculator was less favorable when applied specifically to urologic procedures [16, 17]. This finding highlights the need for urology specific tools to aid physicians in preoperative risk assessment.

Predictors of perioperative complications included in the model were operative time, age greater than 55 years, ASA classification, preoperative sepsis, race as well as preoperative creatinine, white blood cell count, hematocrit and platelets. Longer operative time may be representative of more complicated stricture disease or a more technically challenging repair and can be viewed as surrogate for surgical complexity. We found increasing odds of complications with increased operative time. Breyer et al. demonstrated that longer strictures (> 4 cm), history of prior urethroplasty and failed previous endoscopic management were predictive of urethroplasty failure [10]. We found that age greater than 55 years was predictive of complication, which differs from results seen in previous studies. The series by Breyer et al. also showed that age greater than 65 years was not prognostic of an increase in long-term resticture risk but perioperative outcomes were not evaluated in this study [10]. A study from Santucci et al. evaluating a series of 70 urethroplasties performed on patients with age greater than 65 found an overall complication rate of approximately 20% with the most common complications being self-limited lower extremity neuropathy (4%) and post-operative bladder outlet obstruction due to benign prostatic hyperplasia (4%). While this study showed the complication rate was acceptable in older patients, the study did not compare rate of complications between older and younger patients. The study concluded that urethroplasty is a viable treatment option without substantially higher complication rates and should be offered to older men as an option. Our predictive model can be used to identify elderly patients at higher risk where surgical intervention must be carefully considered.

Our results demonstrated an overall complication rate of 8.6% in the first 30 days after urethroplasty. Urethroplasty overall is a low risk procedure with a very low incidence of major perioperative complications such as stroke, myocardial infarction, cardiac arrest, deep venous thrombosis, and pulmonary embolism. The mortality rate of this sample was 0.17%. Blaschko et al. found a similar overall rate of perioperative complications (6.6%) of patient undergoing urethroplasty with a very low mortality rate (0.07%) using the National Inpatient Sample from 2000 to 2010 [6]. Our study corroborates prior findings that complications following urethroplasty were most commonly related to infection [18]. The rates of urethroplasty complications vary depending on length of follow up [19]. Our study focused on 30-day perioperative outcomes and therefore did not include other complications including erectile dysfunction, post-void dribbling, or chordee which are more commonly observed at later follow-up times [19]. Future studies should be performed to evaluate the effectiveness in reducing morbidity by preoperative intervention on known modifiable risk factors. Multi-institutional data should be used to further assess the long-term risks of complications of urethroplasty including stricture recurrence.

This study has several limitations. The main limitation of this study is the low observed event rate, and therefore associations between important complications could not be assessed. While the low event rate indicates that urethroplasty is a safe procedure, this finding limits the precision in estimates of AUC and model parameters. The data collected in this study were only representative of the first 30 days after the procedure and do not evaluate longer term complication rates. Patients were identified by CPT code and information on the type of and extent of stricture was not available. We combined data from all types of urethroplasty available to include in the models. By grouping the different surgical techniques, we combine the surgical risk of excision and primary anastomosis with substitution graft urethroplasty, which has a known higher complication rate. However, in some reconstruction cases the surgical technique is selected intraoperatively, and this grouping can help identify patients at high risk preoperatively regardless of the type of urethroplasty to be performed. Information on previous interventions was not available. There is a risk of coding or reporting bias when using surgical registries. Although surgical site bleeding and hematoma are common complications of urethroplasty in clinical practice, the NSQIP dataset does not contain this variable. As a result, we used the variable perioperative blood transfusion as a surrogate of intraoperative and postoperative bleeding.

The strengths of the study include the use of a large national database which may reflect practice patterns and increase generalizability. We used machine learning-based methods to select predictive models that maximize out-of-sample performance, including cross-validation and evaluation on an independent test set. Therefore, our models are much more likely to translate well into patients not represented in our dataset, compared to models evaluated on the data used for estimating them.

## Conclusion

Using a large surgical outcomes database, we created a model to predict 30-day complications after urethroplasty with an AUC of 0.73. This risk calculator can be used as an aid in patient counseling and informed decision making, surgical selection by physicians, and to identify possible modifiable risk factors or evaluate the surgical risk for candidates for urethroplasty with urethral stricture disease.

## Compliance with ethical standards

**Conflict of interest** All authors declare no conflicts of interest related to this article.

**Institutional review board statement** This study was reviewed and approved by the Ethics Committee of NYU Langone Medical center.

**Informed consent statement** Patients were not required to give informed consent to the study because the analysis used anonymous clinical data that were obtained after each patient agreed to treatment by written consent.

## Appendix

The follow appendix lists CPT codes and their corresponding descriptions that were included in this study (Table 4).

**Table 4** CPT codes and description

CPT code	Description of procedure
15115	Urethroplasty buccal graft harvest
53410	Urethroplasty; one-stage reconstruction of male anterior urethra
53400	Urethroplasty; first stage, for fistula, diverticulum, or stricture (e.g., Johanssen type)
53405	Urethroplasty; second stage (formation of urethra), including urinary diversion
53420	Urethroplasty, two-stage reconstruction or repair of prostatic or membranous urethra; first stage
53430	Urethroplasty, reconstruction of female urethra
53425	Urethroplasty, two-stage reconstruction or repair of prostatic or membranous urethra; second stage

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