



Artificial urinary sphincter revision with Quick Connects® versus suture–tie connectors: does technique make a difference?

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ABSTRACT

Objective: To evaluate characteristics of artificial urinary sphincter (AUS) mechanical failures and compare outcomes based on the use of either suture–tie connections or Quick–Connects® (QC) for single-component revisions.

Material and methods: A total of 46 patients underwent single-component AUS revisions following primary AUS placement from January 1983 to January 2011 at our institute. Prior to 1996 all revision cases were performed with suture–tie connections and after that time we used QC for revisions. Device success was evaluated for a potential association with revision surgery including the type of connector used.

Results: Forty-six patients underwent single-component revision surgery for primary device malfunction. In these cases, the tubing connections were performed using suture–tie connectors in 34 (74%), and QC in 12 (26%) cases. The median age was 68.8 years for suture–tie vs 70.6 years for QC ($p=0.52$). The median follow-up period after revision surgery was 24 months (IQR 7.2, 55.2). There was no statistically significant difference in 5-year device survival rates between suture–tie and QC (36% vs. 61%; $p=0.85$) techniques. There were no cases of device infection or repeat mechanical failure at the connector among cases of revision performed using QC, as compared to five device infections and four repeat mechanical failures among the suture–tie cohort.

Conclusion: The use of QC for single-component AUS revision for mechanical failures appears to be safe, efficient and reliable. There is not enough evidence supporting the presence of an association between connector type with the risk of overall device failure.

Keywords: Artificial urinary sphincter; revision; stress urinary incontinence; quick-connectors.

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Introduction

While artificial urinary sphincter (AUS) placement remains the gold standard treatment option for men with stress urinary incontinence, roughly a quarter of men will undergo device revision for recurrent incontinence.^[1-4] Specifically, device malfunction leading to recurrent incontinence and repeat surgery occurs in roughly 6% of the cases.^[4] Such a malfunction occurs, when one of the AUS components (i.e. urethral cuff, abdominal reservoir, scrotal pump, or tubing) loses the fluid that is used to create hydraulic pressure and compress the ure-

thra. One strategy for the revision surgery involves replacing only the malfunctioning component, without replacing the entire device.^[5-7] The new component must be attached to the remaining two components that were left *in situ*.

For patients undergoing single-component device revision the surgical dogma has been to use suture–tie connectors exclusively, as opposed to the AMS specific Quick Connect Sutureless Window Connectors (QC), which are routinely used in primary implantations.^[8-10] This is thought to be secondary to the risk of repeat device malfunction or device infection

due to biofilms on the in situ components impacting the new connection. However, scarce number of previous studies compared these two approaches with revision surgery.

Reliability and efficacy were evaluated, comparing QC versus suture-tie connectors for single-component AUS revision procedures.

Material and methods

After obtaining Institutional Review Board approval from the Mayo Clinic Institutional Review Board (IRB Number: 13-001920), 1082 male patients were identified that underwent primary AUS implantations at Mayo Clinic from January 1983 to January 2011. The study group (1983-2011) was specifically truncated in 2011 to allow for adequate duration of follow up. A subset of 125 patients experienced mechanical device failure, and 117 cases underwent revision surgery. Written informed consent was obtained at the time of the patients' clinic visits for surgery, retrospective review of their charts for research purposes and publication of these data (including images) in an anonymized fashion. Exclusion criteria were as follows: primary AUS placement secondary to neurogenic bladder dysfunction; age <18 years at AUS placement; history of revision at an outside facility (as full operative details were unavailable), or inability to obtain patient's informed consent. Procedures were performed by three surgeons using the AMS 800[®] through a perineal approach.

Patients who developed recurrent stress urinary incontinence after AUS placement were evaluated based on their medical history and physical examination, noninvasive uroflow with measurement of post-void residual via bladder scan, cystoscopic findings (to rule out urethral erosion, evaluate tissue quality and coaptation for urethral atrophy) and x-ray imaging (as the components are filled with a contrast mixture at the time primary device placement). Lack of contrast within the system confirms

device malfunction and patients may undergo single-component or entire-device revision depending on the clinical scenario. In cases of single-component revision, hand tied suture connectors were used exclusively from 1983 to 1996. However, with introduction of QC to the market in 1996, QC was used almost exclusively for single-component revision surgeries (Figure 1) Surgical technique was otherwise unchanged. All patients who underwent primary placements and revisions, received intravenous vancomycin and gentamicin for 24 hours at the time of the procedure, unless allergies or renal function dictated a contraindication. Additionally, patients were dismissed with a 7 day course of Keflex. This regimen has not changed over the course of our analysis.

Patient charts were retrospectively reviewed to evaluate pertinent clinical and surgical comorbidities, details of the primary and secondary devices, primary device outcomes including time to failure, revision management strategy (single-component vs entire-device), type of connectors used during revision procedure (suture-tie vs QC) and secondary device outcome (ie explantation for urethral erosion or infection, revision for device malfunction, urethral atrophy, tubing/connector or pump complications). Given the retrospective study design, patients were not follow up during a standardized period of time. AUS patients were routinely seen at 6 weeks after surgery, and then followed up via office evaluations on an as needed basis, in addition to periodic mailed correspondence via the Mayo Clinic AUS Registry. Details regarding device survival were obtained from the last office examination, patient correspondence, or any available subsequent operative reports.

Statistical analysis

Statistical analysis was performed using the SAS[®] software package. Continuous variables were summarized with medians and IQRs, and categorical variables with frequency counts and percentages. Device survival was estimated as the time from AUS revision to any subsequent tertiary surgery or the last known follow-up visit using the Kaplan-Meier method and compared with the log-rank test. All statistical tests were 2-sided with $p < 0.05$ considered to be statistically significant.

Results

Of the 1082 primary AUS implantations performed at Mayo Clinic, 117 patients underwent revision surgery for device malfunction, including 46 single-component revisions. Of these 46 single-component revisions, there were 34 (74%) hand-tie suture connection cases and 12 (26%) QC cases. The clinical and demographic features of patients undergoing single-component revision with suture-ties compared to QC are shown in Table 1. There was no statistically significant differences between suture-ties and QC groups in terms of median age, (68.8 years vs.

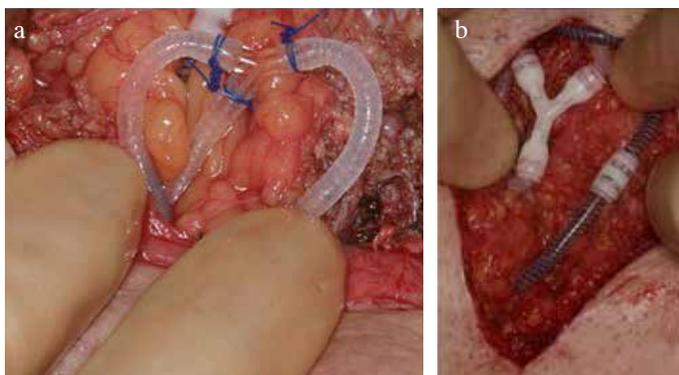


Figure 1. a, b. (a) Suture-Tie Connectors. (b) Quick-Connectors

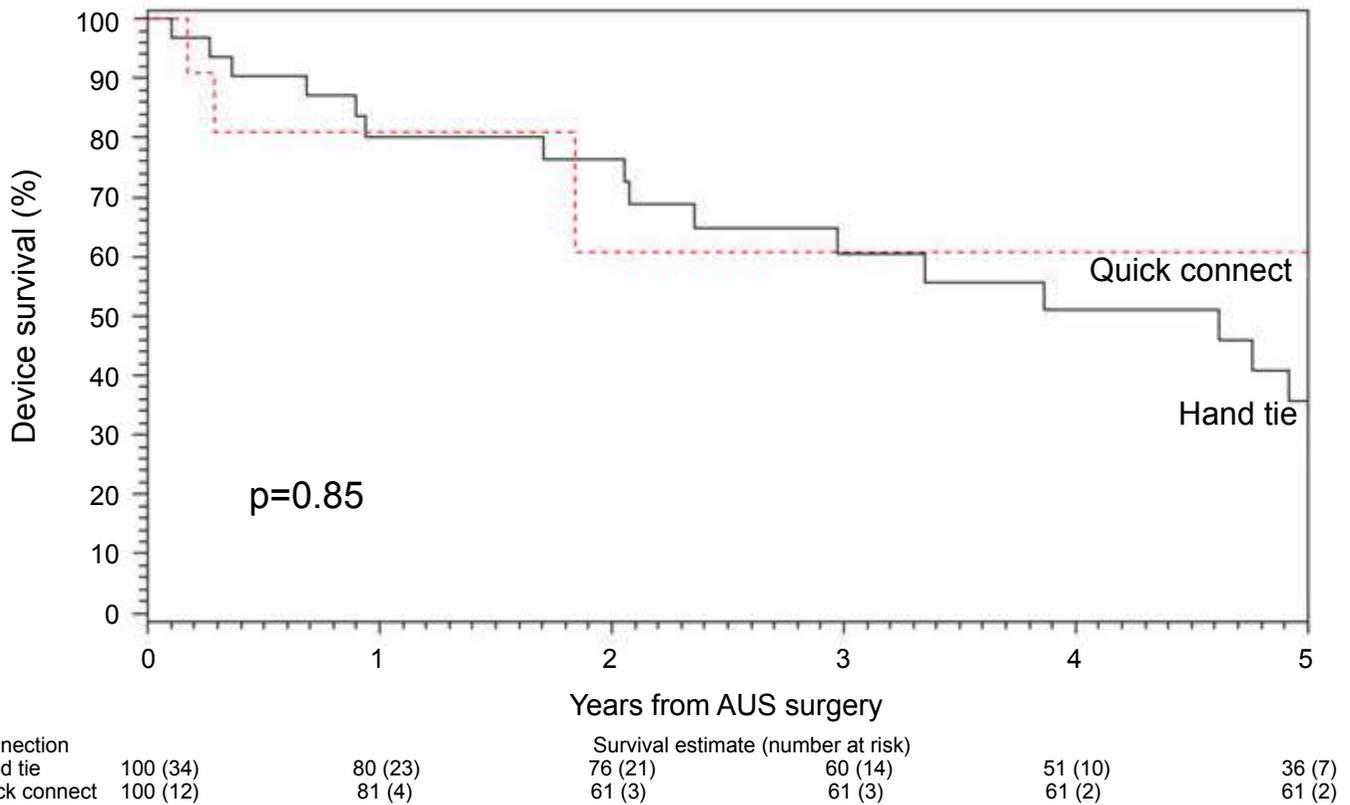


Figure 2. Overall device survival following single component surgery using suture-tie vs. Quick Connects
AUS: artificial urinary sphincter

Table 1. Clinical and demographic features of patients undergoing single component artificial urinary sphincter revision for mechanical failure

| | Suture-tie (n=34) | Quick-connects (n=12) | p |
|---|-------------------|-----------------------|------|
| Age (years, median) | 68.8 (61.6, 74.0) | 70.6 (66.8, 73.2) | 0.52 |
| Body mass index (kg/m ² , median) | 30.1 (28.9, 34.4) | 27.5 (26.6, 28.2) | 0.10 |
| Prior pelvic radiation (%) | 8 (23.5) | 2 (16.7) | 0.62 |
| Hypertension (%) | 4 (11.8) | 8 (66.7) | 0.31 |
| Coronary artery disease (%) | 1 (2.9) | 1 (8.3) | 0.79 |
| Diabetes mellitus (%) | 0 (0) | 3 (25.0) | 0.11 |
| Prior urethral sling (%) | 2 (5.9) | 0 (0) | 0.39 |
| Prior urethral collagen injection (%) | 3 (8.8) | 1 (8.3) | 0.96 |
| Time from primary device placement to revision surgery (months) | 23.5 (3.7, 52.7) | 36.6 (24.4, 52.5) | 0.13 |

70.6 years; $p=0.52$) or median body mass index (30.4 vs. 28.4 kg/m²; $p=0.10$). The median time from primary implantation to failure was not significantly different between the suture-tie and QC groups (23.5 months vs. 36.6 months; $p=0.13$).

The median follow-up period after single component suture tie revision was 23 months (IQR 3.6, 51.6) and the median follow-

up period after single-component QC revision was 36 months (IQR 2.4, 51.6). During this time there were 21 tertiary surgeries. Seventeen patients underwent tertiary surgery after suture-tie revisions because of secondary infection/erosion ($n=5$), urethral atrophy ($n=3$) and repeat mechanical failure ($n=3$) including three failures at the connector itself. Four patients underwent tertiary surgery after QC revision with the indication of urethral

atrophy (n=1), and repeat mechanical failure (n=3). None of the patients required tertiary surgery secondary to infection/erosion after QC revision. Importantly, none of these failures were at the QC, and each involved other components which were left in situ during the single-component revision. Overall, there was no statistically significant difference in the five-year revision free survival rates between single component revisions performed with suture-ties and QC (36% vs 61%; p=0.85) (Figure 2).

Discussion

We report here, in the largest available series of single-component AUS revisions, that there is not enough evidence to support the presence of an increased risk of overall device failure between connector types. Anecdotally, no patients in the QC cohort had recurrent malfunction at the connection site versus four in the suture group. Similarly, there were no infectious complications in the QC cohort. This is the only published cohort comparing suture-tie connectors versus QC in this setting.

While AUS remains the gold standard for severe male stress urinary incontinence, approximately 26% will require revision surgery.^[1-4] Mechanical failure of an AUS device is a common cause of recurrent incontinence after primary placement. Currently there are many controversies regarding optimal management for mechanical device failure, specifically whether or not to replace the whole device or a single component with mechanical failure. In our prior report, we found that single-component revision is safe and reported no difference in additional revision procedures.^[5] Additionally, Yarlagadda et al.^[11] reports a significant cost savings with single-component revision compared to whole device replacement. With single-component revision offering a safe and cost effective alternative to whole device replacement, we sought to investigate optimal single-component surgical technique.

For patients undergoing single-component device revision the current dogma has been to use suture-tie connectors exclusively. In fact, the AMS Operating Room Manual provides the following warning: “AMS Quick Connect Sutureless Window Connectors should not be used in revision procedures involving previously implanted component tubing. Changes in the tubing over time may cause the Quick Connect Sutureless Window Connectors to be less effective.”^[8] Additionally, in Campbell’s Urology 10th edition, Wessells et al.^[9], states in bold “The quick connectors supplied by the manufacturer provide excellent, secure, and watertight connections for newly implanted devices. However, they cannot be used for revision surgeries, because a biofilm on the tubing interferes with watertight connection. Therefore one must use hand-tie connectors in revision cases where the entire device is not being replaced.” Interestingly, to our knowledge, no published studies have compared QC and hand-tie connectors in single-compo-

nent AUS revision procedures. Hence, we sought to provide clinical data to evaluate this dogma.

Since the introduction of the quick connectors in 1996, they have been used almost exclusively in single-component and complete revision cases at our institution. Quick connectors were preferred over the suture-tie connectors because their applications are simpler, faster, and this system is more durable. In our data we found that there was no evidence of a difference in overall device failures between single-component revisions with suture-tie connectors and quick connectors. Specifically, there was no significant difference in the rate of repeat malfunctions, as would be expected if QC could not form a watertight connection, as suggested. By comparison, there were three failures at the connection site in the suture-tied cohort.

This study is limited by its retrospective, nonrandomized design and lack of standardized follow-up protocol. As a tertiary care center, some patients may receive follow-up or even undergo additional AUS surgery with their local provider which could impact these results. While attempting to verify this impact through correspondence and periodic mailed follow-up surveys through the AUS registry, it is conceivable that some instances may not be captured in this data set. While this study represents a large cohort for the clinical scenario evaluated, given the relative rarity of this entity, it is still limited in scope and power and may not have been able to detect differences between the cohorts regarding this issue. The trend in the analyses seemed to favor QC use, though there is not enough evidence to support the presence of a difference between the outcomes of both techniques. As such, additional studies including increased numbers of patients undergoing single-component revisions with QC, in prospective and multicenter cohorts, are needed to more fully define the optimal management strategy.

No evidence was found to support the presence of a difference in device failures between single-component AUS revisions utilizing the suture-tie connectors and the quick-connectors. The use of QC for single-component artificial urinary sphincter revision for mechanical failures appears to be safe, efficient and reliable in this setting.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of The Mayo Clinic Institutional Review Board (IRB Number: 13-001920).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

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