The Malleable Implant Salvage Technique: Infection Outcomes after Mulcahy Salvage Procedure and Replacement of Infected Inflatable Penile Prosthesis with Malleable Prosthesis

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Abbreviations and Acronyms

 $\begin{array}{l} \text{IPP} = \text{ inflatable penile prosthesis} \\ \text{MIST} = \text{malleable implant} \\ \text{salvage technique} \\ \text{MPP} = \text{malleable penile} \\ \text{prosthesis} \\ \text{OR} = \text{operating room} \end{array}$

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Purpose: Since its introduction in 1996 Mulcahy salvage has significantly improved outcomes for the removal and replacement of infected inflatable penile prostheses. Long-term followup data of Mulcahy salvage show an infection-free rate of 82%. A multicenter retrospective analysis of the malleable implant salvage technique was conducted to assess infection outcomes and the feasibility of conversion from malleable device back to inflatable penile prosthesis.

Materials and Methods: This is a retrospective, institutional review board exempt, multi-institution study of 58 patients who underwent Mulcahy salvage with inflatable penile prosthesis removal and replacement with malleable prosthesis. Patient operative notes and charts were extensively reviewed to compile study data.

Results: Between 2002 and 2014 a total of 58 patients underwent infected inflatable penile prosthesis removal and replacement with a malleable prosthesis via Mulcahy salvage. Of these patients 54 (93%) have remained infection-free postoperatively. Average patient age was 56.4 years and average operative time was 148 minutes. Postoperative followup (as of May 2015) ranged from 1 month to 84 months. Of the 54 patients 37 retained the malleable prosthesis and 17 (31%) subsequently underwent replacement with an inflatable penile prosthesis. This occurred on average 6.7 months after Mulcahy salvage. Four patients had persistent infection after Mulcahy salvage with the malleable prosthesis and underwent explanatation.

Conclusions: This retrospective analysis of Mulcahy salvage procedure and replacement of inflatable penile prosthesis with malleable prosthesis shows a high infection-free rate. Additionally, 17 of the 54 patients who remained infection-free were able to successfully undergo subsequent removal of the malleable prosthesis and replacement with an inflatable penile prosthesis. Further prospective studies are needed to compare salvage with malleable vs inflatable penile prosthesis.

Key Words: penile prosthesis, salvage therapy, infection, erectile dysfunction

ERECTILE dysfunction is a devastating disorder with multifactorial etiologies that include vascular, neurogenic, pharmacological and psychogenic causes.^{1,2} Penile prostheses are widely recognized as the definitive treatment for erectile dysfunction unresponsive to conservative therapies,^{3,4} and the last 40 years have brought significant innovation and refinement to these complex devices.⁵

Infection remains a dreaded complication for patients and surgeons.⁶ Most penile prosthesis infections are caused by skin flora and occur within 12 months after surgery.⁶ Estimated infection rates for newly implanted inflatable penile prostheses range from 1% to 3%, and from 10% to 18% for removal and replacement procedures secondary to malfunction or malpositioning.^{6,7} Infection retardant coatings have substantially improved the prevention of penile prosthesis infection, but the danger of infection remains a constant challenge for prosthetic urologists and their patients.⁸

Historically, infected penile prostheses were explanted, with reimplantation occurring months later to allow for a reduction in edema and adequate treatment of the infection.⁹ In 1996 Mulcahy introduced his revolutionary salvage technique, which decreased penile inactivity, fibrosis and loss of penile size by allowing for the removal and immediate replacement of infected IPPs.¹⁰ The population in Mulcahy's seminal work consisted of 11 patients and a followup study of 55 patients documented an 82% success rate.^{11,12} Mulcahy's work represented a transformation in the management of infected IPPs. Through the years this technique has been implemented by many urologists worldwide attempting to stave off the worst possible outcomes.

The MIST is a variation of Mulcahy's procedure specifically using malleable penile prostheses after salvage. Our goal was to further reduce infection rates in patients undergoing salvage for infected inflatable prostheses. Surgeons at our institutions have observed that the majority of infected cases presented with scrotally located complications, consistent with the literature. Köhler et al published a pilot study in 2009 in which scrotal pump erosion was treated with salvage and malleable penile prosthesis implantation.¹³ This technique allowed for preservation of the corporal space with removal of continued foreign bodies from potentially infected scrotal tissue. Infectious outcomes were excellent in this small series of 6 patients, and 33% were able to successfully undergo later conversion from MPP to IPP.

Given these findings as well as the long-term data regarding Mulcahy salvage, our surgeons hypothesized that an antibiotic laden MPP placed in a tightly closed newly disinfected corporal space after Mulcahy salvage would further reduce infections. Closing the gaps that allow for migration of organisms and removing scrotal contamination from the equation would theoretically decrease the 18% of implants that remained at risk for infection. The data were compiled independently at the various sites and subsequently used to generate a retrospective analysis of the pooled outcomes.

MATERIALS AND METHODS

This is a retrospective Boston University School of Medicine institutional review board (IRB) exempted (BUMC IRB protocol H-33597) study of 58 patients (mean age 56.4 years, range 26 to 79) at 6 institutions who underwent MIST. Patient data were compiled after extensive review of operative reports, nursing operative data, intraoperative wound cultures, perioperative antibiotics, inpatient notes, consult notes and followup visits. Only patients who were appropriate for a salvage procedure (ie a clear source of scrotal or shaft infection on examination and/or imaging) were included in the study and offered MIST. Patients with eroded prostheses, those with visible necrotic tissue, those not able to tolerate extended surgery or those with sepsis underwent explantation. All MIST cases were thoroughly counseled on the different treatment options preoperatively, including malleable and IPP salvage, and were amenable to proceeding.

Salvage technique was consistent across the sites and proceeded as outlined in the Mulcahy salvage literature. The IPPs were cultured and removed from the field. Thorough washout with stepwise antibiotic irrigants was conducted. The scrotal skin was then stapled shut. and all drapes and instruments were changed. A malleable implant was then inserted under standard prosthetic conditions. Coloplast Genesis® devices were used in 48 cases and AMS Spectra[™] devices were placed in the remaining 10 cases. Antibiotic and irrigant selection, catheter insertion, drain placement and wound closure technique were as per the surgeon's regular protocol and were not specifically requested for analysis. The breakdown of cases per surgeon is shown in table 1. Postoperative followup (as of May 2015) ranged from 1 month to 84 months (mean 8.4).

Data points requested from study participants included total OR time, surgical OR time, IPP surgical history, followup history including length of followup and date of most recent followup, eventual outcome (ie replacement of malleable prosthesis with IPP) and bacterial culture data, if available, taken at Mulcahy salvage.

Table 1. MIST surgeons and patient distribution

Surgeon	No. Pts
Dr. J. Francois Eid Dr. Ricardo Munarriz Dr. Rafael Carrion Dr. Paul Perito Dr. Laurence Levine Dr. Jason Greenfield	22 19 11 4 1 1
Total	58

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