

Centers of Excellence Concept and Penile Prosthesis: An Outcome Analysis

Gerard D. Henry,* Neil S. Kansal, Mark Callaway, Tobin Grigsby, Jonathon Henderson, James Noble, Thomas Palmer, Mario A. Cleves, John K. Ludlow, Caroline J. Simmons and Thomas M. Mook

From the Regional Urology (GDH, NSK, MC, TG, JH, JN, TP, CJS, TMM), Shreveport, Louisiana, Department of Biostatistics, University of Arkansas for Medical Sciences (MAC), Little Rock, Arkansas, and Western Michigan Urologic Association (JKL), Holland, Michigan

Abbreviations and Acronyms

COE = center of excellence
THR = total hip replacement

Submitted for publication June 25, 2008.

* Correspondence: Regional Urology, 255 Bert Kouns-Industrial Loop, Shreveport, Louisiana 71119 (telephone: 318-683-0411; FAX: 318-683-0743; e-mail: gdhenry@hotmail.com).

Purpose: Outcome analysis has shown that the center of excellence concept, in which all of a specific type of surgery is done by 1 surgeon rather than by multiple surgeons in a group, provides superior outcomes for total joint replacement, radical cancer and heart valve surgery. We compared penile prosthesis implantation outcomes between the center of excellence and multiple surgeon approaches in a large, single specialty urological surgical practice.

Materials and Methods: Between February 2001 and August 2004 a total of 57 penile prostheses were implanted by 10 surgeons at a large urology practice (multiple surgeon group). Between July 2004 and April 2005 a total of 57 penile prostheses were placed by a single surgeon (center of excellence group). Chart review of the 2 patient groups was performed.

Results: The patient groups showed no statistical differences in age, race, cause of impotence or percent with diabetes. The median cylinder length of prostheses placed by the center of excellence surgeon was 2 cm greater than the length of the cylinders placed by the multiple surgeon team ($p < 0.0001$). Excluding cases requiring additional procedures the median placement time was considerably shorter for the center of excellence surgeon than for the multiple surgeon team (34 vs 94 minutes, $p < 0.0001$). There were 8 iatrogenic failures (infection, erosion and poor positioning) requiring surgical removal in the multiple surgeon group but none in the COE group ($p < 0.05$). Although followup for the multiple surgeon team was longer, Kaplan-Meier revision-free survival curves showed significantly longer survival for the center of excellence group (log rank test $p = 0.0283$).

Conclusions: The center of excellence concept in penile prosthesis surgery appears to deliver superior surgical outcomes in terms of shorter operative time, longer cylinders and fewer iatrogenic complications.

Key Words: penile prosthesis, outcomes, impotence, surgery

THERE is increasing public awareness of the evaluation of and treatment for male erectile dysfunction. In many patients a penile prosthesis is the last line of treatment in a series of failing nonsurgical management options.^{1,2} Outcome analysis is becoming the gold standard for evaluating medical care. Many groups have performed

outcome analyses to examine the inherent mechanical reliability of penile prostheses as a function of ongoing modifications.³⁻⁵ However, despite the larger numbers of penile prosthesis implantation surgeries being performed annually there are limited data on the relationships between the volume of implantations performed by

a surgeon and device survival. In addition, almost nothing has been done to address the top complaint of patients postoperatively, that is penile shortening.

Outcome analysis has shown that the COE concept, in which all of a specific type of surgery is done by an individual COE surgeon, vs a large group of surgeons yields superior outcomes. The COE approach has been demonstrated as superior for total joint replacement, radical cancer and open heart surgery.⁶⁻¹⁰ Already in the urology literature there are reports of radical prostatectomy and cystectomy done at high volume centers with better outcomes for high volume surgeons for certain parameters, including decreased morbidity, decreased mortality and shorter hospital stay.^{7,10} With regard to penile prosthesis surgery the consequences of an incorrectly placed prosthesis can be profound in terms of short-term and long-term effects on patient and partner satisfaction, and it may eventually require revision surgery. The outcome of revision penile prosthesis surgery is much poorer than that of primary placement.^{4,5}

We evaluated the COE concept in the surgical outcome of penile prosthesis implantation in a single, large urological group practice. Lotan et al evaluated factors influencing the outcome of penile prosthesis surgery at a teaching institution.¹¹ The high volume implantation surgeon in that study was so classified by having placed 10 penile prostheses during 11 years. However, to our knowledge we report the first study to evaluate the COE concept in a urology private practice group, compare cylinder length between different surgeon groups and evaluate an implanter who performs more than 25 penile prostheses implantations per year, which is widely considered the benchmark of a dedicated penile prosthesis practice.

MATERIALS AND METHODS

Between February 2001 and August 2004 a total of 57 primary penile prosthesis surgeries were performed by 10 surgeons at a large urology surgical group practice (multiple surgeon group). Between July 2004 and April 2005 a total of 57 primary penile prostheses were placed by a single surgeon (COE surgeon) in the same large urology practice. A retrospective chart review of the 2 groups of patients was performed. The factors evaluated were operative time, age, race, diagnosis, diabetes, implant type and length, estimated blood loss, complications and additional procedures performed. Cylinder length and surgery duration were compared between the 2 groups using the non-parametric Mann-Whitney-Wilcoxon rank sum test. The revision-free Kaplan-Meier product limit survival was estimated independently in each patient group, identified as the multiple surgeon group and the COE surgeon with the resulting survival curves compared using the log rank test.

RESULTS

Demographic characteristics of the 2 patient populations were similar with no statistical differences in age, race, diagnostic cause of impotence or percent with diabetes (table 1). The median cylinder length of implants placed by the COE surgeon was 2 cm greater than the median cylinder length of implants placed by the multiple surgeon group ($p < 0.0001$, table 2). More than 55% of the implants in the multiple surgeon group had cylinders that were less than 17 cm long and only 14.3% had a cylinder length of 20 to 22 cm. In contrast, more than 82% of implants placed by the COE surgeon had cylinders that were 17 cm or longer with a length of 20 to 22 cm in almost 37% (part A of figure).

After excluding implant cases requiring additional procedures median operative time was considerably shorter for the COE surgeon than for the multiple surgeon group (34 vs 94 minutes, $p < 0.0001$, table 2).

Part B of the figure shows the estimated Kaplan-Meier revision-free survival curves in each group. Maximum followup in the multiple surgeon group was truncated to 44.5 months to match the followup in the COE surgeon group. During this followup the COE surgeon noted only 1 revision compared with 8 for the multiple surgeon team. Revision-free survival in the 2 implant groups was significantly different (log rank test $p = 0.0283$).

DISCUSSION

Only approximately 15% of urology training programs have a dedicated prosthetic surgeon. However, many of those residencies have dedicated staff with extensive experience in oncology, laparoscopy, robotics, urogynecology and/or infertility. A recent study by Lotan et al, a group with an academic residency in Dallas, presented the factors influencing the outcomes of penile prosthesis surgery at a teaching institution.¹¹ They defined frequent implanters as surgeons who performed greater than 10 procedures during the study period of approximately 11 years. Their outcome analysis revealed superior 5-year survival outcomes for primary penile prosthe-

Table 1. Surgeon group demographics

Demographic*	Multiple Surgeon	COE Surgeon
No. race:		
Black	15	13
Hispanic	2	—
White	60	64
% Peyronie's disease	10.5	17.5
% Diabetes	42.1	35.1
% Radical	40.3	29.8

* Patient age was 63 years in each surgeon group.

Table 2. Cylinder length and operating room time by surgeon group

Surgeon Group	No.	Mean	Median
Cylinder length (cm):			
Multiple	56	17.1	16
COE*	57	18.7	18
Operative time (mins):†			
Multiple	11	93.7	94
COE*	37	34.1	34

* Vs multiple surgeon Mann-Whitney-Wilcoxon rank sum test $p < 0.0001$.

† Excludes other nonimplantation procedures.

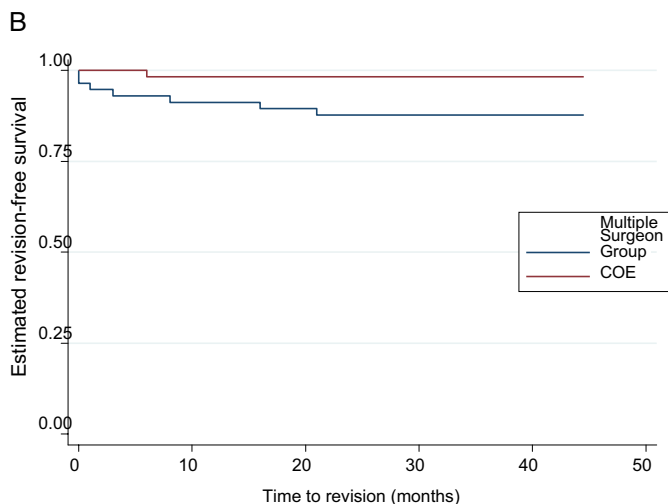
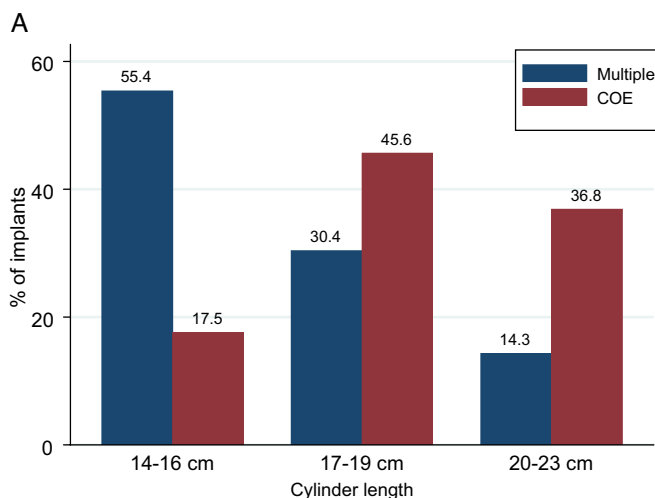
ses when they were implanted by frequent vs infrequent implanters (70% vs 63%, $p = 0.034$). However, many experts in the field of prosthetic urology would argue that implanting 25 penile prostheses per year represents a high surgical volume. We evaluated this concept even further by evaluating a single surgeon with experience with greater than 50 cases per year vs the frequent implanters described by Lotan et al.

The series by Lotan et al demonstrated that malleable prostheses have fewer complications than 3-piece inflatable prostheses (10-year survival rate 87% vs 50%).¹¹ In our study the single surgeon placed only 3-piece inflatable prostheses and no malleable prostheses but still had a lower complication rate than the multiple surgeon group, which placed malleable prostheses in 49% of cases. Malleable prostheses are semirigid devices with a central core that allows the penis to be bent down for dressing and bent upward for coitus. However, in most men this malleable core does not maintain the desired positions well, although malleable devices have the advantage of a low mechanical failure rate and ease

of use. The ideal prosthesis would provide its recipient with penile flaccidity and erection that is as close as possible to normal. Only 3-piece inflatable devices that transfer a large volume of fluid into the penile cylinders for erection and out of the cylinders for flaccidity approach this ideal.¹² Therefore, when its use is possible, the 3-piece inflatable prosthesis may be considered the most ideal penile implant device.

There are clinical situations in which the malleable device is more appropriate, for example in cases of decreased manual dexterity since manual dexterity is necessary for using the pump mechanism. However, after discussion with many of the surgeons participating in our study one of the main reasons for placing the malleable vs the 3-piece inflatable prosthesis involves the increased technical difficulty and operative time required for placing the additional components, specifically the fluid reservoir. Placing a 3-piece inflatable prosthesis actually involves 2 cylinders, that is the pump and the reservoir. Incorrect placement of any part can lead to overall failure of the entire device. The consequences of a poorly placed component, for example the scrotal pump placed in the perineum, can cause patient dissatisfaction and lead to possible revision surgery. However, with increased experience and frequency of implantation the operative time required to place a 3-piece inflatable prosthesis can be less than that required by a less experienced surgeon implanting a malleable device.

This study demonstrates statistically significant shorter operative time for the COE surgeon than for the multiple surgeon approach (34 vs 94 minutes). Shorter operative time in prosthetic surgery cases



A, percent of implanted prostheses by surgeon group and cylinder length. B, Kaplan-Meier revision-free survival by surgeon group (equality of survivor functions log rank test $p = 0.0283$).

may lead to a lower infection rate.¹³ Guralnick et al described the characteristics of infection in patients undergoing staged implantation of sacral nerve stimulation.¹³ Apart from known risk factors for surgical wound infections the only variable that they could identify that might increase the risk of infection was longer operative time. The shorter time the prosthetic device is exposed, the shorter the time allowing surrounding bacteria to adhere to the device. This theory may be further supported by data on decreased infection and erosion in patients with decreased operative time. However, a more important measurement would be the interval from opening the device on the surgical field to skin closure, which was not measured in this study. Furthermore, this study is not powered with enough data to enable us to make any strong conclusions on operative time and infection rate.

Many studies have demonstrated better outcomes at high volume centers and specifically with high volume surgeons. In the urology literature there are many studies defining better outcomes for oncology procedures, such as prostatectomy and cystectomy.^{7,10} In the field of prosthesis implantation a correlation between THR and the 5-year outcome has been described.⁶ Fender et al evaluated 497 primary Charnley THRs in the United Kingdom with an overall failure rate of 8.9%.⁶ However, upon further investigation they found that the risk of failure in patients who were operated on by a consultant whose firm performed 60 or more THRs was 25% of that in patients under the care of a consultant whose firm performed fewer than 30 THRs after adjusting for the number of patients, and surgeon and hospital characteristics (16% vs 4%, linear trend $p < 0.001$). An American study showed that surgeons managing fewer than 2 THRs per year had high mortality, infection and revision rates.¹⁴ Our study expands on this concept, specifically with penile prostheses.

Meticulous technique and experience are important in most surgeries but they are especially needed for penile prosthesis implantation. Many different outcome studies of penile prostheses have emphasized the importance of the best success with initial, virgin implantation vs revision surgery, which has a worse outcome and a higher complication rate.¹⁵⁻¹⁷ Initial implantation represents the best opportunity for the patient to achieve good results. This study demonstrates a difference in survival curves between single surgeons and multiple surgeon teams, as corrected for inherent device mechanical reliability, with identical mechanical failure rates in the 2 groups. Dubocq et al also evaluated the long-term mechanical reliability of multicomponent inflatable penile prostheses and found no association between surgical experience and the mechanical failure rate, demonstrating consistencies with this

study in terms of inherent device reliability.¹⁶ Regardless, with improved survival associated with high volume surgeons fewer patients would undergo riskier revision or salvage surgery, which lowers the overall risk of the most dreaded complication of penile prosthesis implantation, that is infection. Studies have consistently demonstrated a higher infection rate, as high as 10%, for revisions vs 1% to 3% for initial implantation.¹⁸

Our findings suggest that the surgical technique of experienced surgeons may differ from that of surgeons with less experience. It is currently unclear exactly how techniques may differ between groups and systematic research is required to identify the critical aspects of penile prosthesis implantation that are associated with decreased complications.⁸ Currently no firm guidelines can be drawn from this data. However, we reaffirm many of the practical recommendations made in other series comparing volume and outcome, such as that seen in the regionalization of cancer care at COEs.¹⁹

Although to our knowledge no data to support them are published, many theories have been postulated to explain the better success achieved with prostheses placed by high volume surgeons. Many dedicated prosthesis surgeons go to great lengths at surgery to ensure a sterile environment and prevent contamination, including scrubbing for 10 minutes, limiting operating room traffic, shaving in the operating room, preoperatively cleansing the patient surgical site for several days and ensuring that preoperative antibiotics are administered at an appropriate interval, among other techniques. The difference in survival may be accounted for by surgical technique, stringent protocols and experience. Also, infrequent placement of prostheses may involve inexperienced operating room personnel, which may increase the inadvertent contamination of components. Unfortunately all of these factors could not be compared on multivariate analysis in this retrospective study.

Penile prostheses are an accepted and efficacious treatment for erectile dysfunction, yielding remarkably high satisfaction rates.^{12,15} However, after penile prosthesis implantation patients often complain of penile shortening.²⁰ Based on our evaluation with increased experience and appropriate surgical technique it may be possible to achieve more confident and accurate dilation of the penile corporeal bodies to accommodate the largest cylinders possible in each patient. This may lead to further increased patient satisfaction. The maintenance of penile length after prosthesis implantation is an area under current investigation with prospective, objective data measurements.

CONCLUSIONS

Our results suggest that a greater surgical volume of penile prosthesis implantation for a single surgeon (the COE concept) is associated with shorter operative time, longer cylinder length and better device survival outcomes. The study demonstrates improved survival

for the single COE surgeon even after accounting for a similar mechanical survival curve between the 2 groups studied. This article supports the emerging theme in the surgical treatment of patients who are preferentially referred to COEs with surgeons who are more experienced with a particular surgical technique.

REFERENCES

- Baniel J, Israilov S, Segenreich E and Livne PM: Comparative evaluation of treatments for erectile dysfunction in patients with prostate cancer after radical retropubic prostatectomy. *BJU Int* 2001; **88**: 58.
- Fagelman E, Fagelman A and Shabsigh R: Efficacy, safety, and use of sildenafil in urologic practice. *Urology* 2001; **57**: 1141.
- Milbank AJ, Montague DK, Angermeier KW, Lakin MM and Worley SE: Mechanical failure of the American Medical Systems Ultrex inflatable penile prosthesis: before and after 1993 structural modification. *J Urol* 2002; **167**: 2502.
- Wilson SK, Cleves MA and Delk JR: Comparison of mechanical reliability of original and enhanced Mentor Alpha I penile prosthesis. *J Urol* 1999; **162**: 715.
- Wilson SK, Delk JR, Salem EA and Cleves MA: Long-term survival of inflatable penile prostheses: single surgical group experience with 2,384 first-time implants spanning two decades. *J Sex Med* 2007; **4**: 1074.
- Fender D, van der Meulen JH and Gregg PJ: Relationship between outcome and annual surgical experience for the Charnley total hip replacement. Results from a regional hip register. *J Bone Joint Surg Br* 2003; **85**: 187.
- Bianco FJ Jr, Riedel ER, Begg CB, Kattan MW and Scardino PT: Variations among high volume surgeons in the rate of complications after radical prostatectomy: further evidence that technique matters. *J Urol* 2005; **173**: 2099.
- Vickers AJ, Bianco FJ, Serio AM, Eastham JA, Schrag D, Klein EA et al: The surgical learning curve for prostate cancer control after radical prostatectomy. *J Natl Cancer Inst* 2007; **99**: 1171.
- Wen HC, Tang CH, Lin HC, Tsai CS, Chen CS and Li CY: Association between surgeon and hospital volume in coronary artery bypass graft surgery outcomes: a population-based study. *Ann Thorac Surg* 2006; **81**: 835.
- Barbieri CE, Lee B, Cookson MS, Bingham J, Clark PE, Smith JA et al: Association of procedure volume with radical cystectomy outcomes in a nationwide database. *J Urol* 2007; **178**: 1418.
- Lotan Y, Roehrborn CG, McConnell JD and Hendin BN: Factors influencing the outcomes of penile prosthesis surgery at a teaching institution. *Urology* 2003; **62**: 918.
- Brinkman MJ, Henry GD, Wilson SK, Delk JR II, Denny GA, Young M et al: A survey of patients with inflatable penile prostheses for satisfaction. *J Urol* 2005; **174**: 253.
- Guralnick ML, Benouni S, O'Connor RC and Edmiston C: Characteristics of infections in patients undergoing staged implantation for sacral nerve stimulation. *Urology* 2007; **69**: 1073.
- Kreder HJ, Deyo RA, Koepsell T, Swiontkowski MF and Kreuter W: Relationship between the volume of total hip replacements performed by providers and the rates of postoperative complications in the state of Washington. *J Bone Joint Surg Am* 1997; **79**: 485.
- Govier FE, Gibbons RP, Correa RJ, Pritchett TR and Kramer-Levien D: Mechanical reliability, surgical complications, and patient and partner satisfaction of the modern three-piece inflatable penile prosthesis. *Urology* 1998; **52**: 282.
- Dubocq F, Tefilli MV, Gheiler EL, Li H and Dhabuwala CB: Long-term mechanical reliability of multicomponent inflatable penile prosthesis: comparison of device survival. *Urology* 1998; **52**: 277.
- Jarow JP: Risk factors for penile prosthetic infection. *J Urol* 1996; **156**: 402.
- Henry GD, Wilson SK, Delk JR II, Carson CC, Silverstein A, Cleves MA et al: Penile prosthesis cultures during revision surgery: a multicenter study. *J Urol* 2004; **172**: 153.
- Lipscomb J: Transcending the volume-outcome relationship in cancer care. *J Natl Cancer Inst* 2006; **98**: 151.
- Miranda-Sousa A, Keating M, Moreira S, Baker M and Carrion R: Concomitant ventral phalloplasty during penile implant surgery: a novel procedure that optimizes patient satisfaction and their perception of phallic length after penile implant surgery. *J Sex Med* 2007; **4**: 1494.