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REVIEW ARTICLE

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Surgical treatment of post-prostatectomy stress urinary incontinence in adult men: Report from the 6th International Consultation on Incontinence

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Aims: To report the recommendations of the 6th International Consultation on Incontinence (ICI) on post-prostatectomy urinary incontinence.

Methods: The 6th ICI committee on surgical treatment of urinary incontinence in men assessed and reviewed the outcomes of surgical therapy and updated the prior recommendations published in 2013. Articles from peer-reviewed journals, abstracts from scientific meetings, and literature searches by hand and electronically formed the basis of this review. The resulting guidelines were presented at the 2016 ICI meeting in Tokyo, Japan.

Results: Voiding diary and pad tests are valuable for assessing quantity of leakage. Cystoscopy and/or urodynamics may be useful in guiding therapy depending on the type of incontinence and presumed etiology. Artificial Urinary Sphincter (AUS) is the preferred treatment for men with moderate to severe stress urinary incontinence (SUI) after RP. Male slings are an acceptable approach for men with mild to moderate SUI. Much discussion centers on the definition of moderate SUI. Injectable agents have a poor success rate in men with SUI. Options for recurrent SUI due to urethral atrophy after AUS implantation include changing the pressure balloon, downsizing the cuff and increasing the amount of fluid in the system. Infection and/or erosion demand surgical removal or revision of all or part of the prosthesis.

Conclusions: Although there are several series reporting the outcomes of different surgical interventions for PPUI, there is still a need for prospective randomized clinical trials. Recommendations for future research include standardized workup and outcome measures, and complete reporting of adverse events at long-term.

KEYWORDS
artificial sphincter, male, male sling, urinary stress incontinence

1 | INTRODUCTION

Urinary incontinence (UI) is a common complication after radical prostatectomy (RP) and has a negative effect on

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quality of life (QoL). Post-prostatectomy incontinence (PPUI), like any urinary incontinence, may be caused by bladder dysfunction, sphincter dysfunction, or a combination of both. Several risk factors have been associated with PPUI, including advanced age, obesity, comorbidity index, bladder dysfunction before surgery, prostate volume, and previous transurethral resection of the prostate.[1]

As RP has remained a popular treatment for prostate cancer, especially with the advent of robotic-assisted surgery, the *prevalence* of PPUI has increased in developed countries, which has led to an overall increase in the number of patients affected. Data from large multicenter studies and prostate cancer databases suggest that following RP, 1% to 40% of patients complain of persistent urinary incontinence. The incidence of PPUI depends on the definition of urinary incontinence and the length of follow-up.[2]

This manuscript is a literature review and summary of the recommendations presented during the Sixth International Consultation on Incontinence (6th ICI) by the committee on surgical treatment of urinary incontinence in men, specifically pertaining to post prostatectomy incontinence (Tokyo, Japan, Sep 2016).

2 | MATERIALS AND METHODS

The committee has reviewed the outcomes of surgical therapy for post-prostatectomy urinary incontinence (PPUI) that have been published since the 5th ICI[3] and have used that to augment the earlier recommendations. Articles from peer-reviewed journals, abstracts from scientific meetings, and literature searches by hand and electronically formed the basis of this review. The outcomes were analyzed, discussed among the members of the committee, and included in summary.

Specific recommendations were made based on published results and determined by the levels of evidence. Consensus of the committee determined the recommendations, which are described in the text and supplementary material. Recommendations for future research were also included. This review focused on PPUI. Treatment of specific conditions (eg, incontinence after neobladder construction, traumatic injuries of the urethra and pelvic floor, adult epispadia-exstrophy complex, and refractory urgency urinary incontinence/detrusor overactivity) will be covered separately.

3 | SUMMARY OF CURRENT LITERATURE

3.1 | Diagnostic work-up: What should be done prior to surgical therapy?

A good history and physical examination are the cornerstone of medical evaluation and guide the need for further diagnostic assessment tools. History should focus on what precipitates leakage and its evolution over time, as well as patients' comorbidities. Physical examination should detect any gross urine leakage per urethral meatus after straining or coughing. Assessment of manual dexterity is also important when one considers the implantation of the artificial urinary sphincter (AUS), which requires manipulation of a control pump. A brief neuro-urological examination should be performed. A urinalysis to rule out infection or signs of inflammation or hematuria should be obtained.

A bladder diary[4] is also helpful and should consist of daytime and nighttime frequency of micturition, number of incontinence episodes (and precipitating factors), voided volumes, and 24-h urinary output. A pad test objectively quantifies the severity of PPUI and may be clinically relevant, as it has been demonstrated that men with pad weight greater than 200 g/d had lower success rates after transobturator sling implantation.[5] Overall, the 24-h home test is the most accurate pad test for quantification and diagnosis of urinary incontinence due to its reproducibility.[6]

Blood testing (BUN, creatinine, glucose) is recommended only if compromised renal function is suspected or if polyuria (in the absence of diuretics) is documented by the frequency-volume chart.[7]

Ultrasound is widely used to evaluate postvoid residual urine (PVR), which is useful for determining voiding efficiency.[8] The sensitivity of 66.7% and specificity of 96.5% when post-void residual is 100 mL or more is adequate for routine clinical use.[9] It has been shown to be cost-effective when compared to catheterization.[10]

Further evaluations should be individualized. Cystourethroscopy may be useful to exclude urethral strictures, bladder neck contracture, cuff erosion after AUS implantation, and to assess bladder status (trabeculation, stone, diverticula, etc). Other modalities, for example transurethral ultrasound[11] and magnetic resonance imaging of the external sphincter are still under development.[12]

Urodynamic studies (UDS) have traditionally been performed in men under consideration for invasive treatment to assess the Valsalva Leak Point Pressure (VLPP), and to identify detrusor overactivity (DO) and decreased bladder compliance. Previous studies demonstrated that sphincter incompetence occurs as the main cause of PPUI in more than two thirds of patients, while isolated bladder dysfunction (DO, poor compliance, detrusor underactivity during voiding) is uncommon, occurring in less than 10%.[13–15] Sphincter and bladder dysfunction can coexist in at least one third of incontinent patients. However, the indication for routine UDS in all men with PPUI is controversial. In most recently published studies, urodynamic testing has been done prior to surgery,[16–19] but there are some reports that question the value of this diagnostic tool in predicting outcomes after surgery.[20]

When performing UDS there are specific issues that must be considered. Sphincter weakness can be documented by the Valsalva[21] or cough[22] abdominal leak point pressure, or by the retrograde leak point pressure.[23]

However, in patients with incontinence secondary to RP who develop bladder neck stenosis, the urethral catheter can create obstruction giving false values for VLPP. Catheter size seems to have a significant influence even with a small size 7-F urethral catheter[24] and the correlation is extremely high between the test-retest leak point pressure when the same size of catheter is used.[25,26]

The summary of recommendations for diagnostic work-up is presented in Table 1.

3.2 | Conservative strategies versus timing of surgical intervention

There is no clear data on the optimal timing for surgical intervention to treat PPUI. A period of watchful waiting supplemented with conservative measures, particularly pelvic floor muscle exercises (PFME), is a reasonable option. Observational studies following prostate cancer surgery typically demonstrate improvement in continence from the early postoperative period until the end of the first year.[27] Such improvement has also been demonstrated in both the intervention and the control groups in clinical trials during the first year of follow up.[28] More recently, a RCT[29] showed that a Pilates exercise program proved to be as effective as conventional pelvic floor muscle exercises (PFME) to speed up continence recovery in patients with post-RP UI, and could be considered for patients who do not adhere to conventional treatment with PFME. Thus, conservative management may be offered for periods of up to 6–12 months depending on whether there is any progress noted by the patient. (Level of evidence 4; Grade of recommendation C).

3.3 | Surgical and minimally invasive treatments

3.3.1 | Urethral bulking agents

Urethral bulking is a minimally invasive treatment proposed for post prostatectomy incontinence, and theoretically works by adding bulk and increasing coaptation at the level of the bladder neck and distal sphincter. Several different agents have been used for urethral bulking in men, but all agents share the similar problems, including the need for multiple injections, deterioration of effect over time, and very low cure rates.[30] It is the opinion of the committee that the use of bulking agents for the treatment of male urinary incontinence should only be utilized when other more effective treatments are contraindicated. (Level of evidence 3; Grade of recommendation C).

3.3.2 | Male slings

The male sling procedure is based upon the concept of urethral support and external urethral compression and has established itself as an accepted and efficacious treatment for PPUI. These procedures rely on compression from the ventral side of the urethra rather than the circular compression caused by a natural or artificial sphincter. Therefore, most successful sling surgeries rely on a device that is placed under tension, occluding the urethra at rest and during stress maneuvers.[31]

In the medium term, the male sling appears to perform well. The *European Association of Urology (EAU)* Guidelines has concluded that there is limited short-term evidence that fixed slings cure PPUI, and men with severe incontinence, previous radiotherapy or urethral stricture surgery have poor surgical outcomes. Adjustable slings have limited evidence of efficacy.[32] Sling results are shown in Table 2.

The best candidates appear to be those with lower to moderate degrees of incontinence, who have neither had

TABLE 1 Summary of recommendations for diagnostic work-up

• Basic evaluation should consist of history and physical examination, urinalysis and postvoid residual urine (Level of evidence 1–2: grade of recommendation A)
• A voiding diary is helpful to assess functional capacity and total urine output (Level of evidence 1–2: grade of recommendation B)
• Pad tests may be useful in certain circumstances (e.g. more precise assessment of urinary incontinence severity). (Level of evidence 1–2: grade of recommendation B)
• Blood testing (BUN, creatinine, glucose) is recommended if compromised renal function is suspected or if polyuria or poor urinary concentrating ability (in the absence of diuretics) is documented.
• Additional testing with cystoscopy and appropriate imaging of the urinary tract may be helpful in guiding therapy. (Level of evidence 2–3: grade of recommendation B)
• Multichannel urodynamics may be useful prior to invasive treatment for incontinence. (Level of evidence 3: grade of recommendation C).

TABLE 2 Results of sling procedures in men with stress urinary incontinence

Authors	*N*	Mean follow-up (mos)	Sling type	Cured (%)	Improved (%)	Failed (%)
Athanasopoulos et al (2010)	43	24	Synthetic BAMS	51	30	19
Bauer et al (2010)	126	27	AdVance	52	23	25
Bochove-Overgaauw et al (2011)	100	27	Argus-adjustable	40	32	28
Carmel et al (2010)	45	36	Synthetic BAMS	36	40	24
Castle et al (2005)	42	18	Synthetic BAMS	16	24	60
Cespedes & Jacoby (2001)	9	13	Perineal BAMS	66.7	11.1	22.2
Claudon et al (2011)	106	12	Synthetic BAMS	61	14.5	24
Comiter (2005)	48	48	Synthetic BAMS	65	20	15
Cornel et al (2010)	36	12	AdVance	9	46	46
Cornu et al (2011)	136	21	AdVance	62	16	22
Dalpiaz et al (2011)	29	35	Argus-adjustable	17	11	72
Dikranian et al (2004)	36 20	12 12	Organic Synthetic BAMS	56 87	31 13	13 0
Fischer et al (2007)	62	15	Synthetic BAMS	34	24	42
Gallagher et al (2007)	24	15	Synthetic BAMS	38	37	25
Giberti et al (2008)	36	41	Synthetic or organic BAMS	62	8	30
Grise et al (2012)	122	12	I-STOP TOMS	60	27	13
Guimaraes et al (2009)	62	28	Synthetic or organic BAMS	65	23	12
Hubner et al (2011)	101	27	Argus-adjustable	79	0	21
Jimenez et al (2010)	14	19	REEMEX-adjustable	42	33	25
John (2004)	16	14	Polypropylene suspended suprapubically plus porcine skin collagen	69	6	25
Leruth et al (2012)	173	24	Inside-out transorbturator	49	25	16
Madjar et al (2001)	16	12	Synthetic BAMS	86	14	0
Migliari et al (2003)	9	14	Polypropylene needle suspension	55.6	22.2	22.2
Moreno-Sierra et al (2006)	48	7.5	Argus-adjustable	73	10	17
Onur et al (2004)	46	18	Synthetic or organic BAMS	41	35	24
Rajpurkar et al (2005)	46	24	Synthetic or organic BAMS	37	37	26
Rehder et al (2010)	118	12	AdVance	74	17	9
Romano et al (2006)	51	32	Argus-adjustable	64.7	19.6	15.7
Romano et al (2009)	47	45	Argus-adjustable	66	13	21
Schaeffer et al (1998)	64	18	Vascular graft bolsters with needle suspension	56	8	36
Sousa-Escandon et al (2004)	6	18	REMEEX-adjustable	83.3	17	—
Stern et al (2005)	75	48	Bulbourethral suspension	36	32	32
Thüroff et al (1992)	22	10.3	Fascial sling with suprapubic and perineal approaches	63.6	9	27.3
Ulrich & Comiter (2004)	36	25	Perineal synthetic BAMS	67	25	8
Xu et al (2007)	26	28.3	Bulbourethral composite suspension	73	19	8

BAMS = bone-anchored male sling.

previous radiation nor AUS placement. With non-circumferential urethral compression, the male sling appears to have a lower risk of urethral erosion and atrophy than does the AUS in the intermediate term. In men with mild to moderate degrees of SUI, or for patients demanding a less invasive procedure or non-mechanical device, the male sling has established itself as a viable alternative to AUS. (Level of evidence 3; Grade of recommendation C).

3.3.3 | Adjustable balloons

The adjustable balloon procedure, which is performed under general or spinal anesthesia through a perineal incision and guided with fluoroscopy and urethroscopy, relies on passive compression of the urethra by two balloons located on either side of the urethra. Adjustable balloons appear to be a feasible procedure in the short to medium term for patients with mild to moderate leakage and no prior radiation.[33] However, the potential benefits should be weighed against the need for multiple sessions of refilling the balloon, and the reported rate of peri- and post-operative complications. Thus, longer follow-up is needed before definitive comparison to male sling or AUS can be made. (Level of evidence 3; grade of recommendation D/no recommendation possible).

3.3.4 | Artificial urinary sphincter

The AUS remains the most effective long-term surgical treatment for post RP stress urinary incontinence. However, due to the cost, the perceived cumbersomeness of the device with resultant patient reluctance to have or inability to use a mechanical implant, and the fear of complications, it is not suitable for all patients. In addition, the development of less invasive techniques potentially gives patients new options for treatment. Ultimately the choice of AUS is based on patient dexterity, economics, degree of incontinence, previous incontinence surgery, and expectations from surgery. Patient preference was tested in a study by Kumar et al.[34] Based on the magnitude of their incontinence patients either had an AUS (high grade incontinence) or sling (low grade incontinence) or a choice between the two (moderate grade incontinence) recommended. Outcomes, length of experience and complications were reviewed with the patients. Of interest, all who were advised to have a sling chose a sling, 75% those advised to have an AUS had an AUS while of those given a choice 92% chose a sling. This sheds some light on patient preferences in this area.

The success rates for AUS as defined by a continence status of zero to one pad per day range from 59% to 90%. Results of the AUS in Post-Radical Prostatectomy Incontinence are shown in Table 3.

One potential downside of the AUS is the need for periodic revisions in a number of patients. Revision and explantation rates due to mechanical failure, urethral atrophy, infection and erosion vary considerably among studies with reports of 8–45% and 7–17%, respectively.[35]

The AUS remains the most predictably successful surgery for the treatment of PPUI secondary to sphincteric insufficiency in patients with severe incontinence, who have had external beam radiation treatment, and who have had prior sling or AUS implantation. It has the largest body of evidence reporting long-term success. These success rates and high patient satisfaction seem to outweigh the need for periodic revisions in some patients. Intermediate term data with the male sling demonstrates that the sling is equally efficacious with a lower rate of severe complication in patients with mild-moderate SUI, provided that those patients have not failed previous AUS surgery, have not had radiation treatment, and have normal bladder contractility. (Level of evidence 2; Grade of recommendation B)

Treatment of AUS complications

Atrophy of the urethra Several therapeutic options exist to increase cuff pressure around the atrophied urethral wall: changing the balloon reservoir to one generating a higher pressure, downsizing the cuff diameter (46, 57, 58) or increasing the amount of fluid in the system. The most common approach is downsizing of the cuff. Another approach consists of placing the cuff inside the corporal tunica albuginea on the dorsal aspect of the urethra (transcorporal).[36] It should be mentioned, however, that there is a risk of reduced erectile function with this technique.

The implantation of a double-cuff AMS 800 had a period of popularity as a primary procedure in the severely incontinent patient,[37] or as a salvage procedure by adding a second cuff following a failed prior single cuff. Early reports of primary double cuff placement did not demonstrate any significant increase in morbidity with the double-cuff as compared with the single cuff system and patient satisfaction also seemed to be higher[38] at an average of 21–41 months follow-up. However, O'Connor et al[39] recently described their experience with 28 men who underwent double cuff placement and in contrast to an earlier report of theirs found that with longer follow-up there was no difference in continence between those men and 28 who underwent single cuff placement. In addition, those who had the double cuff placement had a higher rate of additional surgery due to complications.

Mechanical failure As with any device, mechanical failure can be expected with the AMS 800 AUS. The treatment involves surgical replacement of the failed component and reconnecting the system. A recent study from the Mayo Clinic that retrospectively reviewed outcomes after repair of

TABLE 3 Results of the artificial urinary sphincter in post-radical prostatectomy incontinence

Authors	N	Follow-Up (yrs)	0 or 1 pad/day (%)
Fleshner & Herschorn (1996)	30	3	87
Goldwasser et al (1987)	42	1.2	82
Gousse et al (2001)	71	7.7	59
Haab et al (1997)	36	7.2	80
Hoy et al (2014)	48	24	88.2
Kim et al (2008)	124	6.8	82
Klijn et al (1998)	27	3	81
Lai et al (2007)	218	3.1	69
Lim et al (2014)	13	29.8	72.7
Madjar et al (2000)	71	7.7	59
Martinez-Salamanca et al (2015)	32	1	96
Martins & Boyd (1995)	28	2	85
Montague (1992)	66	3.2	75
Mottet et al (1998)	96	1	86
Perez & Webster (1992)	49	3.7	85
Trigo Rocha et al (2008)	40	4.5	90

mechanical failures noted a trend toward better outcomes if all components were replaced instead of just one component.[40]

Infection With overt infection, the accepted treatment is removal of the entire device. A second system can be implanted at a later date with equally good results.[41] It has been demonstrated, however, that immediate reimplantation of a new AUS after the removal of an infected, but not eroded, prosthesis can be a valid option with an overall success rate of 87%.[42] In 2007, AMS introduced the InhibiZone-coated AUS (rifampin and minocycline hydrochloride coating). Nevertheless, a recently published study showed that the antibiotic coating had no significant impact on infection or explantation rates in a retrospective cohort of 47 patients with InhibiZone and 258 without InhibiZone coating.[43]

Erosion In cases of urethral cuff erosion, the eroded cuff must be removed. No clear evidence exists as to whether removal of the whole system is superior to removal of the cuff alone but it must be assessed for infection and if present the whole device should be removed. When in doubt remove the entire system. Reservoir erosion into the bladder has been described following the removal of an eroded cuff.[44] Optimal management of the urethra after erosion is unclear. Recent studies have demonstrated that primary repair may be superior to catheter placement in those with significant erosions.[45] When a new cuff is placed it should be positioned away from the erosion site. With erosion of one of the cuffs of a double system, removal of the eroded cuff can successfully convert a double-cuff system into a single cuff system.[46] It is logical that intraoperative urethral injury may precipitate cuff erosion if unrecognized.

A treatment algorithm is presented to aid in management and in follow-up of patients (Figure 1).

3.3.5 | Comparison of AUS and slings

There are few comparative studies of the AUS and the various male slings, and no prospective randomized trials comparing the devices. However, there have been some recent cohort studies comparing outcomes of the AUS with those of specific male slings in certain patient populations.

Adequate urethral tissue compliance is necessary for successful urethral compression and/or proximal repositioning with a sling. Radiation and previous AUS explantation, both of which may result in a relatively non-compressible urethra, are associated with diminished sling efficacy. It has been reported that 13% of men who have sling surgery will ultimately be treated with an AUS.[47] There is no evidence, however, that the efficacy of the AUS is diminished in those with prior sling placement. While there are trials of repeat sling surgery in those who have failed initial sling placement,[48] the AUS has a substantially higher success rate than does repeat sling placement, as the risk of persistent incontinence is six times higher with repeat sling than with AUS implantation.[49] It is therefore the Committee's recommendation that with the exception of the occasional patient with persistent mild to moderate SUI following a prior sling who has a positive repositioning test, AUS implantation is the treatment of choice for persistent PPUI because it can provide the circumferential

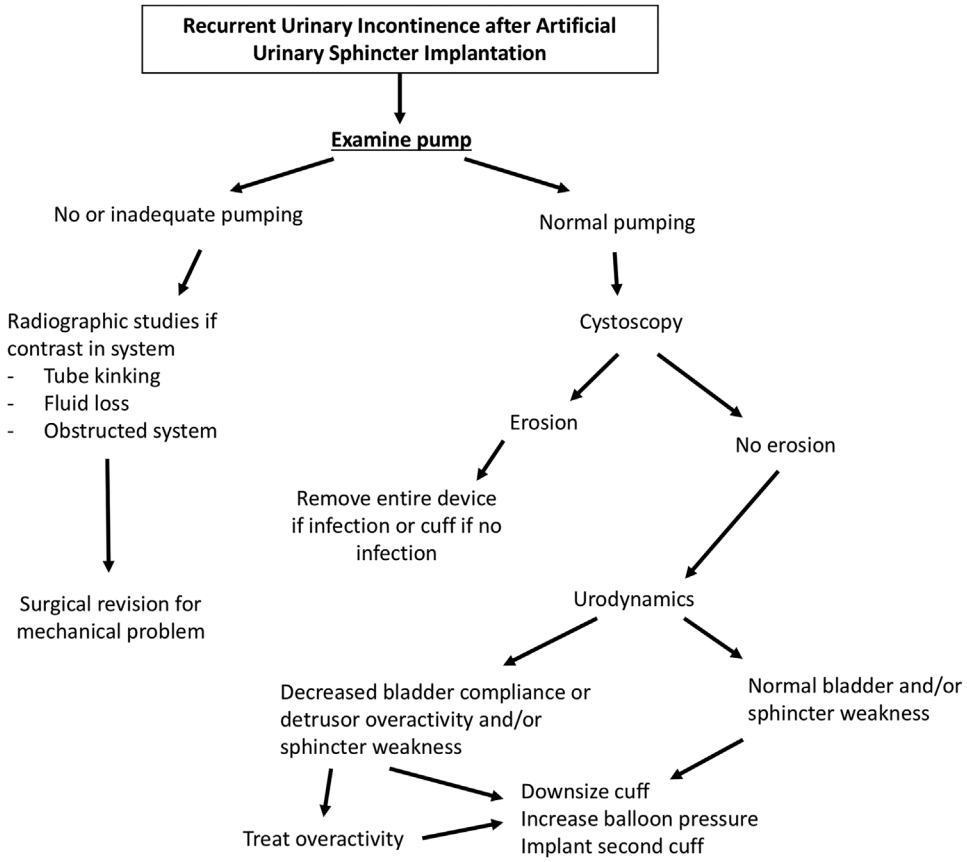

FIGURE 1 Algorithm for managing recurrent urinary incontinence after artificial urinary sphincter implantation

urethral compression necessary for adequate coaptation even in the setting of diminished urethral compliance.

4 | CONCLUSIONS

4.1 | Treatment

After a period of conservative management, which may also be from 6 to 12 months (Level of evidence 3–4; grade of recommendation C):

- The artificial sphincter is the preferred treatment for properly selected men who have stress incontinence after radical prostatectomy with the longest record of safety and efficacy. The AUS has been reported extensively for men with moderate to severe incontinence. (Level of evidence 2–3; grade of recommendation B).
- Male slings are an alternative approach with intermediate data supporting their safety and efficacy in men with more moderate degrees of PPI. Long-term data are beginning to accumulate. However, the literature contains results on many different kinds of slings. (Level of evidence 3; grade of recommendation C).
- Injectable agents are an inferior option that should only be utilized when more effective options are contraindicated. (Level of evidence 3–4; grade of recommendation C).
- Use of adjustable balloons has been reported. (Level of evidence 3; grade of recommendation D (no recommendation possible))

4.2 | Management of AUS complications (Level of evidence 3; grade of recommendation C)

Incontinence may result from alteration in bladder function, urethral atrophy, or mechanical malfunction.

- Infection and/or erosion of components demand surgical removal of all or part of the prosthesis.
- A treatment algorithm is presented to aid in management and in follow-up of patients (Figure 1).

CONFLICTS OF INTEREST

Dr. Averbeck reports other from IPSEN, personal fees from Medtronic, personal fees from GSK, outside the submitted work. Dr. Herschorn reports personal fees from Boston Scientific, personal fees from AMI, outside the submitted work. Others have nothing to disclose.

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