NHS England

Evidence Review:

Penile prosthesis surgery for end stage erectile dysfunction

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Contents

1. Introduction

Male erectile dysfunction is the persistent inability to attain and maintain an erection sufficient to permit satisfactory sexual intercourse. The pathophysiology of erectile dysfunction may be vasculogenic, neurogenic, hormonal, anatomical, drug-induced, psychogenic in nature, due to pelvic or spinal cord trauma, pelvic surgery or any treatment for pelvic cancers including radiotherapy.

Penile prosthesis implantation involves the surgical insertion of a rod or cylinder inside the penis. This can be a malleable rod or an inflatable hydraulic system which can allow the penis to become rigid.

This policy specifies the use of penile prosthesis as a surgical option for men with end stage erectile dysfunction who have failed treatment with pharmacotherapies including oral medications, intracavernous injections, intraurethral vasoactive agents as well as external vacuum devices. The main outcome of implanting a penile prosthesis is to allow males to have penetrative sexual intercourse benefiting the patient and their partner. As such, the best measure of clinical effectiveness is patient-partner satisfaction surveys. The ability to have penetrative intercourse correlates directly with the WHO criteria for psychological well-being and penile prosthesis represents the only opportunity for a small cohort of males with end stage erectile dysfunction to achieve restorative function of the penis for sexual intercourse. Similar to patients who undergo incontinence surgery (a last-line treatment for urinary incontinence), the outcomes for males with end stage erectile dysfunction are difficult to measure using traditional evaluation techniques such as randomised controlled trials (RCTs) as there are no comparable treatment options for these groups. As such, both clinical evidence and expert opinion are vital in the evaluation of this commissioning policy.

2. Summary of results

Penile Prosthesis implantation (PPI) is predominantly performed in men with severe erectile dysfunction (ED), when unresponsive to oral pharmacotherapy and intracavernous or intraurethral vasoactive agent, or when these therapies are contraindicated. A Medicare based population study (n=53,180) (Lee, Daniel et al, 2015) described an increased prevalence of ED from 2001-2010, although there was a PPI utilisation reduction of 50% from 4.6% to 2.3%. This may reflect the use of other therapies for less severe ED. The PROPER registry (Henry, Gerard et al, 2015) illustrated that the majority of patients undergoing PPI either have had a radical prostatectomy for prostate cancer (28%), have ED caused by diabetes (21.6%), have ED caused by cardiovascular disease (19.6%) or have Peyronie's disease (8.9%). The majority of recent studies have utilised the 3-piece inflatable prosthesis, AMS 700 and Titan Coloplast implant.

We conclude the evidence to support the use of penile prosthesis implantation in men with erectile dysfunction is predominantly of low level evidence, consisting largely of case series (single to multicentre studies). To date there has been no randomised control trials evaluating the use of different implants (antibiotic vs non-antibiotic coated, inflatable vs malleable). The majority of studies have been conducted in the United States of America with similar population cohorts to those seeking penile prosthesis in the UK.

The majority of studies have been conducted in large volume and experienced implanting centres. Recent case series have demonstrated mechanical durability of the prosthesis. Henry et al (2012) showed the five year survival rate for an IPP was 83% (n=1,069). Vitraelli et al (2013), reported a 10 year survival rate of 77.6% for AMS 700 CX touch pump and 82.5% for AMS 700 CXR in 80 patients. Chung et al (2013) reported a 1.1% intra-operative complication rate whilst Garber et al (2015) reported 0.5% (3/600 prosthesis) patients developed a delayed haematoma following IPP insertion.

Outcomes for penile prosthesis are based on patient and partner satisfaction and the ability to have penetrative intercourse. Studies to date have demonstrated an overall high patient and partner satisfaction rate. 90% of patients in a recent RCT (Pisano et al, 2015) demonstrated an improvement in erectile function and ability to engage in sexual intercourse. Patients that received psychosexual counselling exhibited higher scores in the International Erectile Dysfunction of Inventory of Treatment Satisfaction scale (IIEF) (68.3% vs 53.4%, P<0.001) and erotic function scale (52.8% vs 48.2%, P=0.007) when compared to those who did not receive specific counselling. A small cohort study (Kilicarslan et al, 2014) found patients reported significantly greater satisfaction (satisfied and very satisfied) on the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) when the two piece inflated penile prosthesis was implanted, compared to the malleable prosthesis, 86.9% vs 65.1%. Chung et al (2013) evaluated two types of inflatable prosthesis AMS 700CX and Coloplast Titan, reported that 70% of men were satisfied with cosmetic and functional outcome. Some patients undergoing IPP for erectile dysfunction are following radical prostatectomy, and a study by Menard et al (2011) comparing this cohort with vasculogenic ED patients found that following IPP the patients IIEF scores improved. However those patients in the prostatectomy group did have lower scores than the vasculogenic ED group (63.1 vs 68.5, P=0.005). Overall satisfaction rate were not significant with 86.1% satisfied in the prostatectomy group and 90.1% in the vasculogenic ED group.

Overall high satisfaction rates have been reported in numerous case series. A recent prospective multicentre case series (Ohl et al, 2012) reported an overall satisfaction at 12 months of 90%, with one third of patients having diabetes mellitus. In addition, evaluation of quality of life after penile prosthesis implant questionnaire (Caraceni et al, 2014) reported high levels for functional domains (89.6%) and personal domain (87%).

Mechanical failure and infection of penile prosthesis have been commonly described in the literature. Common organisms cultured include; Coagulase negative Staphylococcus (CONS), Enterococcus faecalis, Pseudomonas Aeruginosa, Escherichia coli and Enterobacter aerogenes. Recently Chung et al (2013) showed Kaplan-Meier penile prosthesis infection free rates at 5 and 10 years of 98% and 96.5% respectively. The Kaplan-Meier estimates of penile prosthesis mechanical failure free rates at 5 and 10 years were 79.4% and 72.8% respectively. Common causes of mechanical failure include fluid loss and device auto-inflation (although newer prostheses have a lock-out valve to prevent auto-inflation). Henry et al (2012) demonstrated the majority of patients undergoing revision surgeries were a result of mechanical failure (65%), with combined erosion or infection at 29%. The study observed incorporating a washout procedure increased the Kaplan-Meier estimated 5 year survival from 60% with no washout to 94% (P=0.002). Enemchukwu et al (2013) evaluated revision rates current generation girth expanding and length and girth expanding IPP. They found equivalent survival rates (7 years) between the two groups, 88.7% and 89.5% respectively, and found approximately 50% of revision cases were a result

of mechanical failure.

To date studies evaluating outcomes between antibiotic and non-antibiotic coated implants are of low evidence (Grade -2 to 3). Katz et al (2012) conducted a survey among experience and high volume penile prosthesis surgeons in the US, and found a great variation in perioperative strategies to prevent postoperative penile implant infection. There is currently a lack of uniform evidence based practice guidelines.

A recent systematic review (Christodoulidou et al, 2015) with a total of 38 case series (Grade 3) evaluated the risk of infection in penile prosthesis in patients with diabetes mellitus, a group perceived to be at high infection risk. They found 15 predominantly small studies dating back to 1970s which supported the hypothesis of diabetes mellitus as a risk factor for infection. However these studies were conducted in an era where both malleable and inflatable prosthesis were associated with high complication risks. In addition Charles et al (2003), found the risk of infection in the paraplegic cohort to be high, with a 15% rate, compared to 10.6% in the diabetic group. Wilson et al (1995) conducted a retrospective review of 823 primary prostheses and found infection rate requiring prosthesis removal to be 50% in those patients receiving steroids, 9% spinal cord and 3% diabetic mellitus cohort Minervine et al (2005), found patients with pelvic trauma had a 21% and those with diabetes mellitus had 10% infection rate. Recent studies have evaluated antibiotic and non-antibiotic coated implants, with further stratification of diabetes mellitus patients, and/or primary versus revision implants.

Carson et al (2011) reviewed infection related revisions of minocycline HCL rifampicin impregnated (n=35,737) and non-impregnated implants (n=3,268), and found the seven year life table survival analysis revision events to be lower in the impregnated group ($P<0.001$), with patients requiring revision secondary to infection, 1.1% in impregnated and 2.5% in non-impregnated group. They also found the rate of infection at seven years was greater in the diabetes mellitus cohort overall 1.88% compared to 1.53%. The largest series by Eid et al (2012) n=2,347 reported a decrease in infection from 5.3% (2002) to 2% (2003-2005) when an infection-retardant-coated prosthesis in a mixed patient cohort ($P<0.001$). Rate was reduced further to 0.46% when a no touch technique was adopted from 2006-2010. They found the diabetic cohort did not influence the rate of infection. Chung et al (2013), n=955 reported over three decades with infection occurring in 0.8% with an equal incidence between diabetic mellitus (2%) and pelvic trauma patients (3.6%). This study also found no difference in prosthesis infection rate between men who received Inhibizone coated and non-coated inflatable prosthesis ($P>0.05$). However, Serefoglu et al (2012) found over a 11 year follow-up rate of revision due to device infection was reduced to 69.56% in patients with hydrophilic-coated IPPs ($P<0.001$). Kava et al (2011) in a single surgeon cases series found no difference in infection rate between antibiotic coated prosthesis (3%) and non-coated implants (8.4%).

Gross et al (2015) recently evaluated the Mulcahy salvage (MIST, Malleable Implant Salvage Technique) with malleable prosthesis insertion following removal of infected IPP. Of the 42 patients with primary IPP infections, 38 underwent MIST procedure with no subsequent complications. The use of salvage therapy remains low following a prosthesis infection. Zargoff et al (2014) showed salvage therapy in 17.3% of over the past decade, with preference towards explantation with delayed re-implantation (82.7%).

To date no studies have evaluated the cost effectiveness of penile prosthesis implantation.

3. Research questions

1. Complication rates of penile prosthesis, short and long-term
2. Peri-operative antibiotic regimes used in penile prosthesis surgery
3. Differences in outcomes between antibiotic and non-antibiotic coated implants
4. Impact of surgeon or centre volume and outcomes of surgery (infection and revision rates)
5. Comparison of patient and partner satisfaction rates and erectile function for patients with diabetes and pelvic cancer undergoing penile prosthesis surgery compared to similar cohorts of patients not undergoing penile prosthesis surgery
6. Comparison with other treatment options for end stage erectile dysfunction (ie untreated patient group)
7. Quality of life, return to work/activities outcomes
8. Cost effectiveness
9. Quality, safety and adverse events associated with any of the above
10. Is there differential evidence for other indications, eg diabetes, peyronies

4. Methodology

A review of published, peer reviewed literature has been undertaken based on the research questions set out in Section 3 and a search strategy agreed with the lead clinician and public health lead for this policy area. This has involved a PubMed search and search of the Cochrane database for systematic reviews, in addition to review of any existing NICE or SIGN guidance. The evidence review has been independently quality assured.

An audit trail has been maintained of papers excluded from the review on the basis of the inclusion and exclusion criteria agreed within the search strategy. The full list has been made available to the clinicians developing the policy where requested.

5. Results

A detailed breakdown of the evidence is included in the Appendix.

Appendix One

Grade	Study design and intervention			Outcomes					Reference	Other		
Grade of evidence	Study design	Study size	Intervention	Category	Primary Outcome	Primary Result	Secondary Outcome	Secondary Result	Reference	Complications noted	Benefits noted	Comments
1-	Systematic	N/A	Patients with ED undergone penile prosthesis	Clinical effectiveness of the intervention	(i) Case series indication penile prosthesis infection greater in patients with DM. (2) Case series supporting evidence greater rate of penile prosthesis infection in patients with co-morbidities other than DM (3) Case series report no significant increased infection rate in patients with diabetes mellitus receiving a penile prosthesis.	(1) 15 studies from 1970s supported that DM was a risk factor for penile prosthesis, however the authors comment these studies are small and predominately in an era where both malleable and inflatable prosthesis were associated with high complication rates, this is prior to newer prosthesis which have been associated with lower complication risks. Wilson et al (1998) evaluated prospectively for 2 years, n=389 (diabetic n=114) and found patients with DM had a 4.4% greater risk of infection than those without. Charles et al, 2003, n=135 (DM n=47), found in their study that infection rate was greater in paraplegic cohort (15% rate). However in the DM group the rate was 10.6%. Mulcahy et al (2011) reviewed infection related revisions of minocycline HCL rifampicin impregnated and non-impregnated implants, n=6,071 patients with DM in impregnated group and 624 patients in the non-impregnated group. Initial revisions because of infection were 4.17% vs 1.47%, non-impregnated vs impregnated group. At 7 years rate of infection related revisions were lower in the impregnated implant. Also found greater rate of infection at 7 year for men with DM (1.88% compared to 1.53%). (2) 6 case series identified that evaluated other risk factors for penile prosthesis infection. Radomski et al (n=269) found over a 10 year period 6 cases of infection, 1 had DM and 4 patients had history of neurogenic bladder. In this study, authors report strict surgical technique resulting in overall lower infection rate only 1.9% required removal. Wilson et al (1995) (n=1337) retrospective review of 823 primary prostheses and 514 revisions, included 125 DM patients, 66 with spinal cord and 10 patients used steroids in the primary group. Infection rate requiring removal for each group was 3%, 9% and 50% respectively. The authors found rate of reinfection after re-implantation of prosthesis was 18% in the DM group. Cakan et al 2003 (n=135) found paraplegia increase risk significantly, possible association with a neurogenic bladder. Minervine et al (2005), found patients with pelvic trauma had a 21% infection rate and those with DM had 10% infection rate. Recent series Kim et al (2010), n=397 and Paranhos et al (2010), n=139 reported low infection rates in both DM and non-DM group, although found pre-operative steroid therapy and previous radical retropubic prostatectomy as potential risk factors. (3) 11 studies were identified with no statistical significance, between infection rates in patients with DM and no DM. As far as 1980 (Scott et al) low infection rate <2% were reported in DM group. Sidi et al (1983), n=100 reported no infection or erosion rate at a mean follow up of 22.6 months in patients with DM and on immunosuppression following organ transplantation. Largest series by Eid et al (2012) n=2,347, reported a decrease in infection rates from 5.3% to 2% when an infection-retardant-coated prosthesis in a mixed patient cohort. Rate was reduced further to 0.46% with no touch technique. The DM cohort did not influence the rate of infection. Chung et al (2013), n=955 reported over three decades with infection occurring in 0.8% with an equal incidence between DM (2%) and pelvic trauma patients (3.6%). This study found no difference in prosthesis infection rate between men who received InhibiZone coated and non-coated inflatable, mean follow up at 76 months. Recent study from Song et al 2013, n=201, found only one erosion and infection that required removal and patient had DM, finding not significant.	N/A	N/A	Christodoulidou, Michelle; Pearce, Ian. Infection of Penile Prostheses in Patients with Diabetes Mellitus. Surg Infect (Larchmt). 2015. (ePublication ahead of print):,	N/A	Y	Authors conclude that the risk of penile prosthesis infection has reduced over the decades. Authors also comment that most of the recent large case series do not show any statistically significant raised infection rates in patients with diabetes mellitus receiving a penile prosthesis. The reduction in infection could be a result of advance in prosthesis design, peri-operative protocols, surgical technique, high experience in centres of excellence, and introduction of antibiotic coated prostheses. Authors have acknowledged that the systemic review predominately consisted of case series. Graded -1 in view of predominately case series (high risk of bias).

1-	RCT	30 patients and partners randomised into two groups.	Psychosexual counselling before and 12 months afterwards.	Clinical effectiveness of the intervention	Before and 12 months afterwards specific questionnaires completed (i) IIEF- International Erectile Dysfunction Inventory of Treatment Satisfactions (ii) SDS, Sexual Daydreaming Scale. At 24 months post-op patients completed (iii) GAQ- Global Assessment Questions and (iv) EDITS- Erectile Dysfunction Inventory of Treatment Satisfaction, partners completed appropriate sections of EDITS.	No significant difference between the two groups in terms of baseline questionnaire. (i) Mean IIEF score higher in study group vs control (68.3 vs 53.4 P<0.0001). (ii) SDS (erotic function) higher in study control, for patients (52.8 vs 45.8, P=0.007) and partners (54.8 vs 48.2, P<0.001). At 24 months after surgery, 14 patients in study group and 13 patients in control group reported on GAQ1 an improvement in erectile function (NS), and the ability to engage in sexual intercourse (GAQ2) was higher in the study group (P=0.007). (iv) In addition, the patient and partner EDITS scores were higher in the study group when compared to the control group, P=0.002 and P=<0.001 respectively.	N/A	N/A	Pisano, F.; Falcone, M.; Abbona, A.; Oderda, M.; Soria, F.; Peraldo, F.; Marson, F.; Barale, M.; Fiorito, C.; Gurioli, A.; Frea, B.; Gontero, P.. The importance of psychosexual counselling in the re-establishment of organic and erotic functions after penile prosthesis implantation. Int. J. Impot. Res.. 2015. 27(5):197-200,	None reported	Y	Single centre prospective randomised study evaluating the influence of psychosexual counselling on re-establishment of organise and erotic functions of patients and partners after PPI. Authors report findings supporting that psychosexual counselling may improve satisfaction rates and surgical outcomes in PPI recipients and partners. Randomised study although very small study and not blinded, study downgraded in view of increased bias.
2-	Cohort	46 patients	Patients underwent AMS 600-650 prosthesis (n-23)	Clinical effectiveness of the intervention	Evaluation of the modified EDITS score (overall satisfaction score), and whether there is a difference between the two groups. Whether patients were likely to use their prosthesis. Other parameters including confidence and partner satisfaction.	(i) Percentage of patients with AMS 600-0650 and AMS ambicore reported satisfied 34.7% (n=8) vs 73.91% (n=17), very satisfied 30.43% (n=7) vs 13% (n=3) and neither satisfied nor dissatisfied 34.7% (n=8) vs 13% (n=3) with their prosthesis prospectively. The satisfaction rates were significant between the patient group, p=0.0013. (ii) Patient percentage of AMS 600-650 vs Ambicore which are likely (30.4% vs 65.2%), neither likely nor unlikely (34.8% vs 21.3%) and very unlikely (34.7% vs 13%) to continue using their prosthesis respectively. Difference between AMS600-650 and Amibcore were significant p=0.018. In the study they found no difference between AMS 600-650 and Ambicore in terms of ease of use, confidence, ability to engage in sexual activity or meeting of expectations of patient and patient reported partner satisfaction.	N/A	N/A	Kılıçarslan, Hakan; Kaynak, Yurdaer; Gökcen, Kaan; Coşkun, Burhan; Kaygısız, Onur. Comparison of patient satisfaction rates for the malleable and two piece-inflatable penile prostheses. Turk J Urol. 2014. 40(4):207-210,	None reported	Y	The authors found that the 2-piece inflatable penile prosthesis (AMS Ambicore) was more successful in overall satisfaction and more likely to be used when compared to malleable penile prosthesis (AMS 600-650). Study in a single tertiary level centre and patients were non-randomised to prosthesis type (patient and clinician collective decision). Study down-graded as non-randomisation process, increased selection bias.
2-	Cohort	138 patients; 88 patients AMS 700 CX, 50 patients Coloplast.	AMS 700 CX prosthesis. All implants performed under antibiotic cover through a transverse penoscrotal incision following 10 minutes of povidine betadine.	Clinical effectiveness of the intervention	(i) Patients followed up 4-6 weeks post op, if curvature greater than 10 degree, successful outcome straight penis <10 degree curvature. (ii) Revision surgery, prosthesis malfunction. Malfunction of the IPP requiring revisions or replacement of one component. Infection: infection requiring surgical removal of IPP with or without salvage IPP replacement.	At time of review, 132 patients (96%) had intact IPP and are sexually active. No patients reported any significant plaque ossification. In 127 men (92%) curvature was corrected. The remaining 10 patients (7%) received minimally invasive subtunical intracorporeal plaque incision and 1 patient (1%) underwent additional tunical incision and graft. At time of review 8 patients (6%) underwent revision surgery for IPP, 7 patients (5%) mechanical malfunction and 1 patient (1%) personal dissatisfaction. Average time to IPP revisions was 2.3 years (0.4-5yrs). Found penile curvature >60degree and concomitant subtunical intracorporeal plaque incision associated with higher mechanical failure rate (P>0.05). 3 patients (2%) required IPP removal secondary to infection, occurred on average of 6 months (11 days-3 years). No significant difference between two IPP devices in terms of infection and/or erosions. 5 year Kaplen- Meier estimates of mechanical survival in AMS 700CX and Titan were 91% and 87% (P>0.005).	Patient and partner satisfaction and self-esteem.	109 men (70%) reported at least 4 on a 5 point scale for overall satisfaction with cosmetic and functional outcomes. Commonest reason for dissatisfaction shortened penile length. 18 patients (18/138=13%) reported a decreased penile length post-op. 82% reported they would undergo the same operation again and recommend to others. No statistical difference in patient usage and satisfaction rate between AMS 700CX and titan IPPs (P>0.05).	Chung, Eric; Solomon, Matthew; DeYoung, Ling; Brock, Gerald B.. Comparison between AMS 700™ CX and Coloplast™ Titan inflatable penile prosthesis for Peyronie's disease treatment and remodeling: clinical outcomes and patient satisfaction. J Sex Med. 2013. 10(11):2855-2860,	7 patients (5%) mechanical malfunction and 3 patients (2%) removal of IPP device secondary to infection.	Y	Single centre retrospective review of clinical database and prospective telephone follow up. Patients randomised to receive either AMS 700Cx or titan penile at time of surgery. Authors conclude there is no statistically significant difference between the two IPP devices in terms of mechanical revision, cylinder failure rates and patient satisfaction. Limited study not matched patient, intermediate term follow up does not evaluate long term mechanical failure. Lack of control group and definite study points downgraded to -2 from 2.

2-	Cohort	210 patients; 90 post radical prostatectomy (RP) implants, 123 vasculogenic ED patient implants.	Post-RP (radical prostatectomy) patients with prosthesis. Virtually all primary implants (96.2%) were inflatable: 3-piece 70.1% and 2 piece 24.1%.	Clinical effectiveness of the intervention	To assess surgical outcome and satisfaction after penile prosthesis implantation in RP (radical prostatectomy) patients. (i) Intra and postoperative complications, (ii) International Index of Erectile Function Scoring pre implantation and (iii) most post implantation.	(1) No significant difference between the two groups in terms of rate of infection (1.1%), mechanical failure (3.3%) and other surgical complications requiring revision surgery (migration, auto-inflation) (4.4%). (2) The mean IIEF score for all items pre-implantation was significantly lower in RP patients than in controls (14.7+/-5.9 vs 22.6+/-10.8, P=0.003) (lower scores for erectile function, intercourse satisfaction and orgasmic function). After PP implantation in RP patients the scores improved in all domains, however the RP score lower than in control overall (63.1+/7.0 vs 68.5+/-6.9, P=0.005). Orgasmic function was significantly lower P<0.001. (3)Overall satisfaction rate was 86.1% in RP patients and 90.1% in controls (P=0.3).	N/A	N/A	Menard, Johann; Tremeaux, Jack-Charles; Faix, Antoine; Pierrevelcin, Jean; Staerman, Frédéric. Erectile function and sexual satisfaction before and after penile prosthesis implantation in radical prostatectomy patients: a comparison with patients with vasculogenic erectile dysfunction. J Sex Med. 2011. 8(12):3479-3486,	Refer to primary outcome, post RP implants - infection 1.1%, mechanical failure 3.3% and other surgical complications 4.4%. Found no significant difference between primary and secondary, and between the 3-piece inflatable and other PP types (2-piece inflatable or malleable). To note 11 patents in RP group (12.6%) had light-severe stress urinary incontinence, 6/11 treated with artificial urinary sphincter implantation.	Y	The authors conclude PP implantation after RP is associated with low morbidity and high satisfaction. PP implants in this patient cohort should be reserved when all other methods have failed. Collected over three institutes. Collated data on PP database over 415 consecutive PP for pre-implantation, intra-operative and follow-up data. Data was collected prospective and results compared retrospectively. No randomisation to process, different devices used (no clear protocol), control and intervention group non-matched. The questionnaire IIEF (widely used, self-administrated questionnaire) was used from 2002 onwards, small sample size, the score post operatively was not assessed at 3 month but throughout the postoperative period. <50% of patients completed the questionnaire pre and post.
2-	Cohort	2,263 patients, 1,824 inflatable, 439 semi-rigid.	Inflatable prosthesis n=1,824	Clinical effectiveness of the intervention	To assess reoperation rates of penile prosthesis between two devices (I) inflatable vs (ii) semi-rigid.	Overall re-operation rate was 7.42%, No difference in overall revision rates between inflatable and semi rigid respectively (7.4% vs 7.52%, P=0.94). Re-operation rate secondary to infectious complications was 3.6% (3.23% inflatable, 4.5% semi rigid, p=0.18). Revision rate secondary to non-infectious failure in inflatable group was 4.17% vs semi-rigid 2.96% (p=0.25). Mean time to failure for infectious complications was 94.6 days, and mean time to failure for non-infectious complications was 225.7days. Medicard insurance (OR2.25 CI1.41,3.61), African American (OR1.7, CI1.20,2.49) race, age >80 (p=0.046) and diabetes (OR1.67, CI1.07, 2.59) associated with receiving a semi-rigid implant.	N/A	N/A	Grewal, Shaun; Vetter, Joel; Brandes, Steven B.; Strope, Seth A.. A population-based analysis of contemporary rates of reoperation for penile prosthesis procedures. Urology. 2014. 84(1):112-116,	N/A	Y	The overall revision rates at approximately 7.5%, we found no difference in re-operation rates for infectious and non-infectious failure are equivalent between the semi-rigid and inflatable penile prostheses. The study also found racial, socio-economic disparities exist with type of implant a patient receives. Large study, the two groups were not matched, and downgraded.

3	Case series	955 penile prostheses	A total of 771 men had primary implants. Most common type of penile prostheses implanted was Ultrex cylinder (516 prostheses) followed by CX cylinders (259 prostheses).	Clinical effectiveness of the intervention	To assess (i) intra-operative complications (ii) post-operative complications (infection), (iii) complication rate following prosthesis erosion and (iv) malfunction and (v) satisfaction rate.	(1) Out of the 955 prosthesis, 11 intra-operative complications (1.1%), with 2 cases of crural perforation and 5 cases of cavernosal device. Primary implants have higher rate of intra-operative complications than revision surgery 3.5 vs 0.1%, p<0.005). Prosthesis infection occurred in 8 patients (0.15). Mean time to infection was 20 weeks, early infection (<6 months) occurred in 2/8 patients and latent in 6 patients. 3/8 patients had diabetes and 3/8 pelvic trauma. 5/6 late implants were immediately salvaged. Kaplan-Meier penile prosthesis infection free rate at 5 and 10 years was 98% and 96.5% respectively. All infections occurred in inflatable group. Since 2002 a total of 420 InhibiZone coated penile prostheses were implanted, with no significant difference in infection rate between InhibiZone coated and non-coated inflatable penile prostheses (P>0.05). (2)Prosthesis erosion occurred in 6 patients over a mean of 77.3 (8-166 months). (3) In 184 cases malfunction of prosthesis occurred, the Kaplan-Meier estimates of penile prosthesis mechanical failure free 5 and 10 year survival rates were 79.4% and 72.8% respectively. The most common mechanical failures were a result of fluid loss (75%) (tubing damage, tie-connector damage) and 10% a result of pump auto-inflation. No significant differences in mechanical failure rates between the different types of penile prosthesis. (4) Only 1% (7 patients) reported dissatisfaction with the prosthesis requiring revision surgery. Most men (90%) reported they would undergo prosthesis implant again.	N/A	N/A	Chung, E.; Van, C. T.; Wilson, I.; Cartmill, R. A.. Penile prosthesis implantation for the treatment for male erectile dysfunction: clinical outcomes and lessons learnt after 955 procedures. World J Urol. 2013. 31(3):591-595,	As discussed within primary outcome measures.	Y	A review of prospectively collected database on 955 penile prosthesis implanted over 3 decades. All men underwent medical and psychiatric counselling prior to penile prosthesis implantation. All operations performed by 1 of the 2 surgeons. All patients received antibiotics intra-operatively and followed a strict antimicrobial prophylaxis protocol. Note 25 patients lost to follow-up, all patients followed up for minimum of 12 months. 0.1% of patients developed a penile prosthesis infection, with no statistical decrease following the use of the antibiotic impregnated devices. The authors acknowledge the following limitations, single centre experience, using a various type of penile prosthesis. The authors concluded that advances in prosthesis design, device technologies and implantation techniques make prosthesis natural and reliable device. A very large case series, although does not include control arm.
3	Case series	58 patients	Patients with infected IPP, that have been removed and replaced with malleable prosthesis, adopting the MIST salvage procedure.	Clinical effectiveness of the intervention	Post-operative complications	(1) 54/58 patients (93%) remained infection free postoperatively. (2) 37/54 patients retained malleable prosthesis, 17 patients (31%) subsequently underwent replacement with IPP (on average at 6.7 months). (3) 42 patients presented with IPP infection after first time implantation and of these, 38 underwent MIST without subsequent complications. This resulted in a 90.3% success rate. (4) Salvage procedure occurred on average 2.8 months (range 2 weeks to 13.5 months) from the date of last penile prosthesis surgery. (5) 38 patients had at least one organism cultured from infected implant and at least 3 patients had more than one organism. 15 patients grew coagulase negative Staphylococcus, Candida albicans, MRSA, Escherichia Coli and Group B Streptococcus in 4 patients (6) 4 patients had a persistent infection after salvage with malleable prosthesis and underwent explant.	N/A	N/A	Gross, Martin S.; Phillips, Elizabeth A.; Balen, Alejandra; Eid, J. Francois; Yang, Christopher; Simon, Ross; Martinez, Daniel; Carrion, Rafael; Perito, Paul; Levine, Laurence; Greenfield, Jason; Munarriz, Ricardo. The Malleable Implant Salvage Technique: Infection Outcomes After Mulcahy Salvage Procedure and Replacement of Infected IPP with Malleable Prosthesis. J. Urol.. 2015. (ePublication ahead of print):,	As discussed in outcome measures.	Y	Retrospective IRB exempt multi institution study. Authors have commented upon the limitation of the MIST technique as further surgery (and second anaesthetic) is required to replace malleable device with an IPP. The study observed an infection free rate of 93% following the malleable implant salvage technique. Retrospective small study, low grade study.
3	Case series	53, 180 patients	Patients undergone penile prosthesis	Other	To assess the use of PP over a decade.	(1) The utilisation of PP for ED decreased from 4.6% in 2002 to 2.3% in 2010 (P<0.01). The temporal decline was evident across all demographic factors including age, ethnicity and geographic location. (2) Men aged 65-74, and those with a Chalrson co-morbidity score >1 were more likely to have PP inserted for ED (P<0.01).	N/A	N/A	Lee, Daniel J.; Najari, Bobby B.; Davison, Wesley L.; Al Hussein Al Awamlh, Bashir; Zhao, Fujun; Paduch, Darius A.; Mulhall, John P.; Chughtai, Bilal; Lee, Richard K.. Trends in the Utilization of Penile Prostheses in the Treatment of Erectile Dysfunction in the United States. J Sex Med. 2015. 12(7):1638-1645,	Not noted	Y	The authors have discussed, although the prevalence of ED has increased by 165% the utilisation of PP has decreased from 50% over time from 4.6% to 2.3% in 2010, and this may be represent an increase use of pharmacological therapy for less severe ED. Retrospective study, non-randomised, with no control group and dependent upon Medicare billing information. Also the Medicare based population may not be applicable to the general population, as predominately represent patients >65 years of age, Low level grade study.

3	Case series	100 patients	Patients undergone Coloplast titan TM OTR implant	Clinical effectiveness of the intervention	To assess prosthesis (i) performance, (ii) Satisfaction: Assessed erection function (EF), intercourse satisfaction (IS), overall patient and partner satisfaction. Utilised EF and IS domains of the International Index of Erectile Function (IIEF) and modified EDITS.	(1) 99/100 (99%) reported good prosthesis performance (2) Differences in IIEF-EF and IIEF-IS domains before and after surgery were +16.8 and +6.4 respectively. (3) In modified EDITS the overall patient and partner satisfaction were 90% and 84% respectively.	N/A	N/A	Garrido-Abad, Pablo; Rosselló-Barbará, Mariano; Sabino-Galdona, J.; Fernández-Arjona, M.; Rosselló-Gayá, Mariano. 100 cases of three-piece Inflatable Penile Prosthesis with new scrotal pump: Evaluation of 3 specialised centres. Arch. Esp. Urol.. 2015. 68(4):416-423,	N/A	Y	Authors conclude that the small number of post-operative teaching sessions (1.28) were required for patient to operate device, and report Coloplast Titan TM OR was easy to implant, inflate and deflate, with improvements in satisfaction scores observed. Retrospective study, with no control arm. Low grade evidence.
3	Case series	195 patients	Patients undergoing revision surgeries for penile prosthesis implantation.	Clinical effectiveness of the intervention	To evaluate (i) reasons for revision and (ii) survival of revision.	Overall 93% of cases successfully revised. Data was incomplete on 28 cases. Majority due to mechanical failure (n=109, 65%), and combined erosion or infection (n=17+15=32), 16% (n=26) on functional uninfected prosthesis, (n=9) secondary to patient dissatisfaction, n=10, supersonic transport deformity (SST), n=2 scrotal hematoma, n=5 for upsize revision because of corporal fibrosis. Kaplan-Meier estimated a 5 year survival was 94% when a washout procedure was employed and 60% if not washout was done (log-rank test P=0.0002).	Secondary revision rate and factors.	12 patients required a secondary revision or a complication. 5.7% of the revised prosthesis were complicated with infection or impending erosion. Significant impact of revision washout, 4% of cases that incorporated wash out developed infection or impending extrusion/erosion compared to 25% of case that did not undergo a washout procedure. 9 cases of infection or impending extrusion/erosion, 2 cases of mechanical failure, 1 of aneurismal dilatation of cylinder and auto inflation. 1 case of iatrogenic bladder. They found no significant effect of the presence of diabetes between groups of patients with surviving IPPs. Kaplan-Meier estimated a 5-year infection free survival was 96% when a washout procedure was employed and 69% if no washout was done (P=0.0006).	Henry, Gerard D.; Donatucci, Craig F.; Conners, William; Greenfield, Jason M.; Carson, Culley C.; Wilson, Steven K.; Delk, John; Lentz, Aaron C.; Cleves, Mario A.; Jennermann, Caroline J.; Kramer, Andrew C.. An outcomes analysis of over 200 revision surgeries for penile prosthesis implantation: a multicenter study. J Sex Med. 2012. 9(1):309-315,	12 pateints required secondary revision (refer to secondary outcome).	Y	Retrospective analysis of prospectively followed patients undergoing revision IPP surgery. Authors comment the study did not achieve power to evaluate particular prosthetic devices. In addition it was noted the antiseptic technique varies, 43 patients did not undergo a revision washout, 152 received a revision washout. Retrospective study and another limitation is limited that all surgeons in the study are experienced high volume prosthetic urologists, also noted no uniform strategies used between the centres. Low grade evidence study.
2-	Cohort	1557 patients	Patients undergone immediate salvage therapy following PP infection.	Clinical effectiveness of the intervention	Salvage rate of penile prosthesis infection.	82.7% treated with explantation only and 17.3% salvage for PPI. Patients treated with salvage were younger (60.4 vs. 65.1 years), more likely to be discharged home (87.3% vs. 61.9%), and were less likely to have a severe presentation (7.2% vs. 31.6%) than those who were explanted only (P < 0.001). The regression analysis showed treatment at rural hospitals had lower odds of salvage than treatment at urban teaching hospitals. Race, comorbid diabetes, and insurance status did not independently affect the salvage rate.	N/A	N/A	Zargaroff, Sherwin; Sharma, Vidit; Berhanu, Daniel; Pearl, Jeff A.; Meeks, Joshua J.; Dupree, James M.; Le, Brian V.; Cashy, John; McVary, Kevin T.. National trends in the treatment of penile prosthesis infections by explantation alone vs. immediate salvage and reimplantation. J Sex Med. 2014. 11(4):1078-1085,	N/A	Y	National inpatient database, dependent upon physician input into database. Retrospective cohort review of data, clearly defined two groups explantation vs salvage. In view of retrospective nature of data collection downgraded to -2.

3	Case series	1,019 patients	Patients undergone penile prosthesis implantation (AMS 700 (n=983), AMS Ambicor (n=26) and Spectra penile implants (n=10)).	Clinical effectiveness of the intervention	(i) To determine common aetiology for ED (ii) complications (iii) operating time between different implants.	(1) Majority of patients (285), 28% had a radical prostatectomy (RP). 21.6% diabetes (n=220), 19.6% cardiovascular disease (n=200) and 8.9% Peyronie's disease (n=91). (2) 280/285 patients with RP received an AMS 700, of which 53 patients (18.9%) had concomitant stress urinary incontinence (SUI), and only 8 (1.1%) of non RP patients had SUI, P<0.001. (3) Average length of procedure is shorter for the IPP, AMS 700 patients (47+/-28.7 minutes), compared with the malleable and two-piece implant prosthesis Ambicor (71.4+/-27.3 minutes) and Spectra (62.2+/-21 minutes, P <0.001).	N/A	N/A	Henry, Gerard D.; Karpman, Edward; Brant, William; Christine, Brian; Kansas, Bryan T.; Khera, Mohit; Jones, Leroy; Kohler, Tobias; Bennett, Nelson; Rhee, Eugene; Eisenhart, Elizabeth; Bella, Anthony J.. The Who, How, and What of Real-World Penile Implants Patients in 2015: The Propper (Prospective Registry of Outcomes with Penile Prosthesis for Erectile Restoration) Registry Baseline Data. J. Urol.. 2015. (ePublication ahead of print):,	N/A	Y	In this prospective registry, it was noted 441 patients (43.3%) in the study were discharged the day of surgery and 54 (5.3%) were admitted to hospital >24hours. Further health economic studies are required. Observational study is limited due to a lack of randomisation, data collection was option, and only AMS implants were used. Also all the prosthetic urologists in the study are high volume implanters. Low grade evidence study. To note data pending as registry on quality of life data following prosthesis and long term complications.
3	Cohort	55,013 patients	Patients undergone implantation with Dacron AMS 700 LGX/Ultrex (Dacron weave pattern) with and without parylene coat, 15,570 (28.3%).	Clinical effectiveness of the intervention	(i) Survival rates (defined as time of first revision) between current generation girth expanding (700CX) and length and girth expanding (700 LGX/Ultrex). (ii) Comparing survival rate between parylene coated vs non-coated.	(1) Equivalent survival rates (7 year) between parylene AMS 700 Ultrex/LGX and CX, 88.7% vs 89.5%, log rank P=0.6811. Approximately 50% of cases were a result of mechanical failure. (2) The parylene coated CX and Ultrex/LGX devices outperformed the non-parylene devices on survival analysis. Survival rate at 7 years for CX parylene vs CX non-parylene for mechanical reasons was 94% vs 90.2% respectively, P<0.0001. Survival rate at 7 years for Ultrex/LGX parylene vs non parylene (mechanical reasons) was 94.5% vs 92.3% respectively, P<0.0001.	N/A	N/A	Enemchukwu, Ekene A.; Kaufman, Melissa R.; Whittam, Benjamin M.; Milam, Doug F.. Comparative revision rates of inflatable penile prostheses using woven Dacron® fabric cylinders. J. Urol.. 2013. 190(6):2189-2193,	N/A	Y	Retrospective study utilising the PIF database. Details on type of mechanical failure unavailable. The authors conclude that they found no significant difference in 7 year survival rates between the current generation girth expanding (700 CX) and length and girth expanding (700 LGX Ultrex). Retrospective cohort study, with difference in size between two groups, downgraded to 3.
3	Cohort	36,391 patients	Patients undergone primary implantation with Titan implant (Coloplast) with an hydrophilic coating n=29,360 (80.68%).	Safety of the intervention	To evaluate infection related revision reported by physician on patient information forms.	At 11 years of follow-up, 4.6% (322 patients) of non-coated IPP were removed or replaced as a result of an infection, and 1.4% (402 patients) of hydrophilic coated implants (P<0.001). The rate of revision due to device infection was reduced to 69.56% in patients with hydrophilic-coated IPPs (P<0.001).	N/A	N/A	Serefoglu, Ege Can; Mandava, Sree Harsha; Gokce, Ahmet; Chouhan, Jyoti D.; Wilson, Steve K.; Hellstrom, Wayne J. G.. Long-term revision rate due to infection in hydrophilic-coated inflatable penile prostheses: 11-year follow-up. J Sex Med. 2012. 9(8):2182-2186,	N/A	Y	Retrospective review of infection related revisions reported in the physician generated manufacturer patient information forms. Physician dependent process, not mandatory to record PIF. Information regarding the antibiotic agents used in the soaking solution was no uniform and not tabulated. Aetiology of erectile dysfunction not described in study. Large difference between the two cohort groups in terms of numbers therefore downgraded. Low grade evidence.

2-	Cohort	129 surgeons	Web based survey (39 question survey) sent to surgeons from Sexual Medicine Society of North America (SMSNA) (focusing on infection control routine) n=84.	Other	To evaluate perioperative practice patterns between surgeons from SMSNA and ISSM.	(1) Routine urine culture not performed by 40% and 50% of SMSNA and ISSM members. (2) A third of SMSNA members use razors for pre-operative shave compared to two thirds of ISSM surgeons. (3) To thirds of SMSNA members prepared the skin for at least 10 minutes compared with 34% of ISSM surgeons. (4) Most surgeons do not place a drain, 70% of SMSNA patients and 81% of ISSM patients. (5) Two thirds of SMSNA and three quarters of ISSM do not prescribe oral antibiotics preoperatively. (6) 90% of all surgeons from both groups administrated oral antibiotics post operatively on average >4 days. (7) Intravenous antibiotics were given commonly intra-operatively (30mins prior to incision) by 75% of SMSNA surgeons and 69% of ISSM surgeons. The choice of intravenous antibiotics varied amongst the surgeons within each society. SMSNA used a combination of an aminoglycoside with vancomycin (47%), whilst ISSM members used an aminoglycoside with a cephalosporin commonly (33%). Antibiotic irrigation had wide spread usage with only 8% of SMSNA and 5% of ISSM surgeons electing not to use it. SMSNA surgeons insert more prostheses with 50% inserting more than 20/year compared with 18% of ISSM.	N/A	N/A	Katz, Darren J.; Stember, Doron S.; Nelson, Christian J.; Mulhall, John P.. Perioperative prevention of penile prosthesis infection: practice patterns among surgeons of SMSNA and ISSM. J Sex Med. 2012. 9(6):1705-1712; quiz 712-714,	N/A	Y	The study found that even among experience and high volume penile prostheses surgeons with a great variation in perioperative strategies to prevent postoperative penile implant infection. This study places emphasis upon the lack of uniform evidence based practice guidelines.
3	Case series	149 (190 patients, 78% completed survey)	Patients undergone penile prosthesis implantation (110 first implant, 39 a re-implant).	Clinical effectiveness of the intervention	To measure the level of patient and partner satisfaction with sexual intercourse following PPI.	79% of first time and 80% of re-implanted patients (P>0.05, NS) reported satisfactory (very or moderately) intercourse, while 74% and 80% of partners reported satisfactory intercourse (P>0.05, NS). 73.7% of first implants and 70% of second implants reported they would undergo PPI again if the prosthesis failed (P>0.05, NS). Main cause of dissatisfaction, 13% of first implants and 15% second implants was penile shortness or soft glans.	N/A	N/A	Lledó-García, Enrique; Jara-Rascón, José; Moncada Iribarren, Ignacio; Piñero-Sánchez, Javier; Aragón-Chamizo, Juan; Hernández-Fernández, Carlos. Penile Prosthesis First and Replacement Surgeries: Analysis of Patient and Partner Satisfaction. J Sex Med. 2015. 12(7):1646-1653,	N/A	Y	Prospective survey study with a five item questionnaire, 78% patients completed. No control group, observational study. Low grade evidence.
3	Case series	Phase I = 1,069 patients Phase II = 330 patients	Patients undergone penile prosthesis (first implant).	Clinical effectiveness of the intervention	The length of time after surgery for men to resume sexual function (all patients were advised to wait 4 weeks before using the implant and at the 4 week post op follow-up taught how to deflate and inflate).	75% of patients were contacted (248/330), of which 80% (n=199) responded to the whole survey and 20% (49) part of the survey. Sexual intercourse was resumed post-operatively at 1-4 weeks for 41% (78/190) of patients, 5-6 weeks for 31% (59/190), at 7-8 weeks for 16% (30/190) and > 8 weeks for 12% (23/190). Found ~60% of patients used their IPP at least once a week.	Mechanical durability of the prosthesis (AMS 799 CX, Mentor Alpha 1, and Mentor Alpha Narrow Base).	(Phase I subjects, n=1,069). The five year survival rate for IPP was 83%.	Henry, Gerard D.; Brinkman, Mary Jo; Mead, Susan Fields; Delk, John R.; Cleves, Mario A.; Jennermann, Caroline; Wilson, Steven K.; Kramer, Andrew C.. A survey of patients with inflatable penile prostheses: assessment of timing and frequency of intercourse and analysis of implant durability. J Sex Med. 2012. 9(6):1715-1721,	N/A	Y	Study involved phase I, retrospective chart review of 1,298 IPP surgeries (1st implant) and phase II 330 subjects selected by random sampling from phase I. Data collected by computer assisted telephone interview, 27 question survey. Authors concluded that the three piece IPP have an excellent 5 year survival rate and a significant number of patients returned to sexual activity quickly. Observational low grade evidence study with no control group.
3	Case series	600 patients	Patients undergone penile prosthesis with a Coloplast Titan IPP with one touch release pump. All patients received preoperative intravenous gentamicin and vancomycin and all IPP components soaked in antibiotic irrigation.	Safety of the intervention	To evaluate delayed postoperative bleeding following IPP insertion.	3/600 consecutive patients, 0.5% developed a delayed (> 5 day postoperatively) haematoma following IPP insertion. All three patients presented postoperatively with a swollen surgical site. All three patients treated successfully.	N/A	N/A	Garber, Bruce B.; Bickell, Michael. Delayed postoperative hematoma formation after inflatable penile prosthesis implantation. J Sex Med. 2015. 12(1):265-269,	N/A	Y	Retrospective chart review, follow up period not clearly defined in study. No control group. Methodology regarding collection of data not clearly defined. Low grade evidence study.

3	Case series	18 patients	Patients undergone penile prosthesis implantation (3 part inflatable prosthesis).	Clinical effectiveness of the intervention	Patient and partner satisfaction following IPP implantation.	Overall patient satisfaction rate was 88.9%, partner satisfaction rate was 94.4% and recommendation rate of 94.4%. Two patients were dissatisfied, one for pain and one for insufficient rigidity and shortening of the penis.	N/A	N/A	Simsek, Abdulmuttalip; Kucuktopcu, Onur; Ozgor, Faruk; Ozkuvanci, Unsal; Baykal, Murat; Sarilar, Omer; Gurbuz, Zafer Gokhan. Self and partner satisfaction rates after 3 part inflatable penile prosthesis implantation. Arch Ital Urol Androl. 2014. 86(3):219-221,	2 patients had prosthesis removal one for infection, and one for perforation.	Y	Small study, no randomisation process undertaken prior to selection of patients. Authors observed 11% complication rate (2/18 patients). Low grade study.
3	Case series	550 patients	Patients undergone Coloplast Titan Inflatable Penile Prosthesis (IPP) One-Touch Release (OTR) pump.	Safety of the intervention	Reviewed complaints following implantation of IPP.	29/550 patients (5.3%) found the inflate/deflate valve disc in the Coloplast Titan OTR pump became stuck in the deflate position. Application of firm pressure on the pump bulb caused the valve to shift into inflate position.	N/A	N/A	Garber, Bruce B.; Khurgin, Jacob L.; Stember, Doron S.; Perito, Paul E.. Pseudo-malfunction of the Coloplast Titan Inflatable Penile Prosthesis One-Touch Release Pump. Urology. 2014. 84(4):857-859,	N/A	Y	Retrospective case series, low level evidence.
3	Case series	40 patients (3 centre study)	Patient undergone penile prosthesis implantation with Coloplast titan and incorporation of an aggressive new length measurement technique (NLMT), which is designed to maximise length of the inflatable portion of the cylinder.	Clinical effectiveness of the intervention	To evaluate the combined used of Coloplast Titan IPP, NLMT (optimisation of cylinder length) and a post-operative daily inflation protocol (inflate daily for 6 months and maximally 1-2 hours daily for 6-12 months) for maintenance of penile length. Penile length measurements were compared with immediate post-implantation and 12 months post-implantation.	Penile measurement changes were statistically significantly improved at 12 months as compared with immediately post-operative and at 6 months, for erect, flaccid and stretched state, circumference and width (P<0.05). Patient satisfaction with penile length as compared with prior to IPP surgery had improved in 61.3% of patients and remained the same in 16.1% of patients. 93.4% of patients were satisfied with overall function and dimensions of their IPP.	N/A	N/A	Henry, Gerard D.; Carrion, Rafael; Jennermann, Caroline; Wang, Run. Prospective evaluation of postoperative penile rehabilitation: penile length/girth maintenance 1 year following Coloplast Titan inflatable penile prosthesis. J Sex Med. 2015. 12(5):1298-1304,	N/A	Y	Prospective non randomised multicentre clinical trial. Authors have acknowledged limitation of the study, including the use of high volume implant surgeons, patients were not randomised. In addition no patients with corporal fibrosis and Peyronie's disease or tunical defects or revision cases were included. Also measurements were taken by implanting surgeons. Low grade study.
3	Case series	69 patients	Patients undergone three component hydraulic prosthesis implantation, AMS700 CX (n=42), AMS Inhibitzone Tactile (n=12), AMS CXR Inhibizone (n=2) and AMS LGX (n=6).	Clinical effectiveness of the intervention	To evaluate quality of life as biological and psychosocial relational well-being following IPP implantation. Utilised Quality of Life and Sexuality with Penile Prosthesis (QoLSPP) questionnaire. Four domains to the questionnaire: (i) functional (functioning of the three component prosthesis), (ii) personal (sexual desire, sexual experience), (iii) relational (frequency orgasms, sexual intercourse, partner satisfaction) and (iv) social (daily life, general well-being).	The QoLSPP showed good internal consistency in all domains. Prosthesis implantation was correlated with high quality of life in patients. Overall >85% of patients reported positive responses (average QoLSPP score greater than to three/item). Higher levels of QoL reported for functional domains (89.6%) and personal domains (87%). 92.7% reported high levels of satisfaction with post implantation sexual experiences. Study found couple well-being and partners satisfaction level significantly correlated (P=0.0003), with higher levels of partner satisfaction corresponded to increased couple well-being and fulfilment of patients expectations for the prosthesis p=0.004. Authors conclude that study suggests that the hydraulic three component prosthesis improves quality of life in patients with severe erectile dysfunction.	N/A	N/A	Caraceni, Enrico; Utizi, Lilia. A questionnaire for the evaluation of quality of life after penile prosthesis implant: quality of life and sexuality with penile prosthesis (QoLSPP): to what extent does the implant affect the patient's life?. J Sex Med. 2014. 11(4):1005-1012,	N/A	Y	Primary aim of the study was to develop and validate pathology specific Quality of Life and Sexuality with Penile Prosthesis questionnaire. Overall the study demonstrated high quality of life in patients following prosthesis implantation (3-piece). Prospective observational study.

3	Case series	80 patients	Patients undergone implantation of a three piece inflatable penile prosthesis AMS700CX InhibiZone (tactile pump), n=42 and AMS 700 CXR (momentary squeeze).	Clinical effectiveness of the intervention	(i) To assess satisfaction, utilised the International Index of Erectile Function (IEF) and Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) questionnaire and a non- validated 9 domain questionnaire assessing penile rigidity, sensation, orgasmic function, frequency of intercourse, impact of surgery on quality of life and satisfaction rate. (ii) To evaluate long term mechanical reliability of the AMS 700CX/CXM inflatable penile prosthesis.	(1) Median postoperative IIEF5 and EDITS score were 21.46 and 73.11, suggesting a high level of satisfaction. 90.8% (n=59) of patients were able to cycle device and engage in penetrative intercourse. 89.2% (n=58) were fully satisfied with the outcome of surgery, (2) 77.6%, 10 year survival (Kaplan Meier) for AMS 700CX touch pump, and 82.5% for AMS 700 CXR momentary squeeze pump.	N/A	N/A	Vitarelli, Antonio; Divenuto, Lucia; Fortunato, Francesca; Falco, Antonio; Pagliarulo, Vincenzo; Antonini, Gabriele; Gentile, Vincenzo; Sciarra, Alessandro; Salciccia, Stefano; Sansalone, Salvatore; Di Placido, Maria Rosaria; Garaffa, Giulio; Pagliarulo, Arcangelo. Long term patient satisfaction and quality of life with AMS700CX inflatable penile prosthesis. Arch Ital Urol Androl. 2013. 85(3):133-137,	2 devices removed because of prosthesis infection (2.5%), mechanical failure occurs in 10 patients (12.5%) due to pump failure, cylinder rupture and fluid leak from the reservoir. Erosion through the corona/glans occurred in 3 patients.	Y	Retrospective study, the 9 domain quality of life questionnaire was not a validated questionnaire. No control group for comparison, and not a blinded and not a randomised study. Low grade evidence.
3	Case series	22 patients	Patient undergone implantation with AMS Spectra penile prosthesis.	Clinical effectiveness of the intervention	To evaluate patient and partner satisfaction outcome following AMS Spectra penile prosthesis implantation. Pre-operative erectile dysfunction rated by IIEF questionnaire, pre-operatively and post-operatively IIEF and EDITS questionnaire, on 3rd, 6th and 12th months.	Overall 86.4% of patients and 52.6% of partners were satisfied by the AMS Spectra penile prosthesis. (1) IIEF score pre-operatively was 28.5 (13-39), post-operative IIEF scores 47.7 (43-43), 51.8 (48-58) and 53.0 (50-58), at 3,6 and 12 months respectively, difference between pre and post scores were significant P<0.05 (2) Patients average EDITS score was 39.5 (31-48), 43.4 (36-50) and 45.2 (38-50) at 3rd, 6th and 12 month.	N/A	N/A	Falcone, Marco; Rolle, Luigi; Ceruti, Carlo; Timpano, Massimiliano; Sedigh, Omidreza; Preto, Mirko; Gonella, Andrea; Frea, Bruno. Prospective analysis of the surgical outcomes and patients' satisfaction rate after the AMS Spectra penile prosthesis implantation. Urology. 2013. 82(2):373-376,	No major intra-operative or post-operative complications observed.	Y	Small non-randomised (no control) prospective case series. Low grade evidence.
3	Case series	113 patients (8 centres)	Patients undergone penile prosthesis implantation with Coloplast Titan One Touch Release (OTR) pump.	Clinical effectiveness of the intervention	(i) To assess satisfaction with ease of deflation of the OTR pump at 6 months. (ii) Conducted a paired analysis for patient satisfaction at 6 months (n=96) and 12 months (n=90).	(1) Ease of deflation measure as primary end point was 70.8% and 73% at 6 and 12 months respectively. Comparing end point to historical controls (64%) at 6 months NS (P=0.082), although at 12 months P=0.033. (2) Overall satisfaction with the device was 90.6% and 90% at 6 and 12 months respectively.	(i) To evaluate physician feedback (3 questions were asked). (ii) Trainers assessment of the device activation session.	(1) 97.3% of surgeons reported the implant preparation was straightforward. 89.4% of the cases the OTR pump was easier to prepare than their previous pump choice. Also 97.4% of the time the patient's scrotum was able to accommodate the pump placement. (2) Practitioners felt 97.2% of subjects found the operation of the device easy to learn and the subject training with the OTR pump was easier than previous pumps 99.1% of the time.	Ohl, Dana A.; Brock, Gerald; Ralph, David; Bogache, William; Jones, Leroy; Munarriz, Ricardo; Levine, Laurence; Ritenour, Chad. Prospective evaluation of patient satisfaction, and surgeon and patient trainer assessment of the Coloplast titan one touch release three-piece inflatable penile prosthesis. J Sex Med. 2012. 9(9):2467-2474,	41 adverse events overall, common problem is auto inflation in 12.4% (12/113), 5 patients had their device explanted, 4 patients for infection (3.5%) and one case for chronic pain (0.8%).	Y	A single arm prospective multicentre non-randomised international study. Authors used retrospective data from three comparator trial to create a weight average of 64% for patient satisfaction with pump deflation as threshold. No control/comparative group. Low grade evidence.

3	Cohort	2,347 patients	Patients undergone penile prosthesis implanting with coated IPP and no touch technique (from 2006) n=1,258.	Safety of the intervention	(i) To assess infection rate in non-coated IPP, coated IPP with standard technique and coated IPP implanted with 'no touch' technique. (ii) Organisms present in infected IPP.	(1) In 2002 the infection rate for non-coated IPP was 5.3%, between 2003-2005 the coated IPP with standard penoscrotal approach the infection rate was 2% and from 2006-2010 the coated IPP with no touch technique was utilised and the infection rate was found to be 0.46%. (2) Uncoated IPP group- 42.9% (3) grew Coagulase negative Staphylococcus (CONS), 14.3% Enterococcus faecalis, no growth in 42.9%. In coated IPP, 21.4% (n=3) grew CONS, 7.1% (n=1) Staphylococcus and 71.4% (n=10) no growth. Coated IPP with no touch technique 14.3% (n=1) grew CONS, 14.3% (n=1) Staphylococcus, 14.3% (n=1) Pseudomonas Aeruginosa and 57.1% (n=4) no growth.	(i) Difference between infection rates dependent whether primary or revised and (ii) the type of implant utilised.	(1) The data was further stratified according to whether surgery was a primary (virgin) or revised implant and by manufacturer of implant. No difference between infection rate of primary and revision implants. (2) There was no statistical difference in the infection rate of the manufacturer in either non-coated or coated groups (AMS and Coloplast).	Eid, J. Francois; Wilson, Steven K.; Cleves, Mario; Salem, Emad A.. Coated implants and "no touch" surgical technique decreases risk of infection in inflatable penile prosthesis implantation to 0.46%. Urology. 2012. 79(6):1310-1315,	Infection rate primary outcome measure.	Y	Single surgeon study. Difference in time and number of different groups when prosthesis implemented, therefore does not meet criteria for cohort study. Study downgraded.
3	Cohort	189 patients (primary implants 117 and 72 revision implants)	Patient undergone primary penile prosthesis implantation.	Clinical effectiveness of the intervention	Infection risk in primary and revision implant surgery	(1) 3.4% (n=4) of patients undergone primary implants and 4.3% (n=2) undergoing removal and replacement for mechanical malfunction, and 3 patients undergoing rerouting for extrusion developed an infection P=0.26. (2) Intraoperative cultures were positive 9.8% (5/51) of revision implants, none developed an infection. (3) Common organisms to cause infection included Staphylococcus aureus, Enterobacter aerogenes.	(i) To evaluate antibiotic coated devices in terms of infection rate and (ii) to evaluate modified revision washout with no washout on infection rate.	(1) 4/132 (3%) patients with antibiotic coated devices vs 5/56 (8.9%) developed postoperative infections, P=0.128. (2) 2/41 (4.8%) patients undergoing modified revision washout vs 3/31 (9.6%) with no washout developed postoperative infections (P=0.30).	Kava, Bruce R.; Kanagarajah, Prashanth; Ayyathurai, Rajinikanth. Contemporary revision penile prosthesis surgery is not associated with a high risk of implant colonization or infection: a single-surgeon series. J Sex Med. 2011. 8(5):1540-1546,	Infection post prosthesis discussed in primary outcome.	Y	Data from consecutive patients. Limitation of study as observational analysis of a single surgeon case series. Also the overall infection rate was low and the difference between antibiotic coated prosthesis and non-coated was found not to be significant. Also in this study revision washout protocol was implemented for those patients undergoing removal and replacement of prosthesis since 2005. Low grade evidence.
3	Cohort	39,005 patients, M/R impregnated implant n=35,737, (M/R=Minocycline and Rifampin) non-impregnated implant n=3268.	Patients undergone initial device revision who initially received a MR impregnated implant.	Clinical effectiveness of the intervention	To evaluate the impact of antibiotic impregnation on revision surgery rate after infection in patients who received AMS 3 piece IPP devices.	Life table survival analysis revision events due to infection less common in the impregnated vs non-impregnated group log rank p<0.0001. Overall proportion of patients with initial revision due to infection at any time during the reporting period was 1.1% in those with M/R impregnated components vs 2.5% non-impregnated components. A total of 7% of patients (n=2,774) underwent at least one revision surgery, 6.7% (2,377) in M/R impregnated group vs 12.5% (397) in non-impregnated group.	N/A	N/A	Carson, Culley C.; Mulcahy, John J.; Harsch, Manya R.. Long-term infection outcomes after original antibiotic impregnated inflatable penile prosthesis implants: up to 7.7 years of followup. J. Urol.. 2011. 185(2):614-618,	N/A	Y	Retrospective analysis. No clear inclusion and exclusion criteria and comparison group not similar in size which results in a significant selection bias, study does not meet criteria for cohort/case-control as per SIGN guidelines, downgraded from retrospective cohort. In addition the follow-up in the MR impregnated group was more than 3 years than in the non-impregnated group. Further limitation in the study is that revisions may have been unreported as voluntary process. In addition the study evaluates revisions with replacements and may not reflect infection outcomes after IPP implantation, as some patient may prefer removal without replacement or opt for a different IPP. Also study does not account for actual infection outcomes.
3	Case series	69 patients completed survey (90 patients)	Patients with erectile dysfunction undergone primary penile prosthesis implant surgery in a single centre performed by a single surgeon. 52% utilised AMS700 CX, 20% AMS700 InhibiZone, 9% AMS LGX and 10% Mentor Titan.	Clinical effectiveness of the intervention	To evaluate patient post implant: (i) erectile function (IIEF-5) and (ii) satisfaction (EDITS). Pre-operative and post-operative scores on the International Index of Erectile Function Questionnaire-five items (IIEF-5) were compared. Also the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITs patient and partner version) was utilised.	(1) Mean IIEF-5 score before implant surgery was 8.88+/-3.75 and at least 1 year post implantation significantly improved to 20.97+/-4.37, (P<0.001). (2) Overall the mean EDITS score was 75.48+/-20.54 (satisfied), 14.5% were moderately unsatisfied, 34.8% satisfied and 50.7% of patients very satisfied. There was no statistical significance between married patients and unmarried patients.	To assess association between patient and partner satisfaction.	Overall regression analysis suggested a direct linear correlation between the degrees of satisfaction with the IPP for male patients and female partners (r=0.876, P<0.001). Overall female partner satisfaction mean was 70+/-22.92. Study noted a significant difference between married patients and partner score, with female satisfaction being lower (P=0.05, n=15) and no difference between non-married couples.	Vakalopoulos, Ioannis; Kampantais, Spyridon; Ioannidis, Stavros; Laskaridis, Leonidas; Dimopoulos, Panagiotis; Toutziaris, Chrysovalantis; Koptsis, Michail; Henry, Gerard D.; Katsikas, Vasileios. High patient satisfaction after inflatable penile prostheses implantation correlates with female partner satisfaction. J Sex Med. 2013. 10(11):2774-2781,	6/90 patients had their implant removed, five as a result of infection. Two patients died from unrelated causes.	Y	Authors conclude overall high rates of patient and partner satisfaction. Several limitations of the study, including retrospective collection of post-implantation satisfaction among female partners, no data available pre-implant. Potential selection bias, differences in follow-up period.

0	Other	N/A	Aim of the study was to identify patient characteristics to identify risk of post operative dissatisfaction. Review of urologic and non-urologic cosmetic surgery literature to identify factors associated with both patient satisfaction and dissatisfaction.	Other	i) identify preoperative factors associated with patient satisfaction/ dissatisfaction ii) identify character traits that may increase risk of postoperative dissatisfaction	i) Satisfaction Factors: decreased perioperative expectations, favourable female partner sexual function, BMI≤30, patients without Peyronie's disease or prior prostatectomy. Age, duration of erectile dysfunction and partner availability were not predictive. Also another study found satisfaction rates with both AMS or Coloplast three piece IPP devices to be equivalent. ii) Dissatisfaction Factors: perceived/actual loss of penile length, decreased glanular engorgement, altered erectile/ejaculatory sensation, pain, diminished cosmetic outcome, difficulty with device function, partner dissatisfaction and perception of unnatural sensations, complications, and extent of alternative treatments iii) Character traits: Patients with obsessive/compulsive tendencies, unrealistic expectations, patients undergoing revision surgery, seeking numerous surgical opinions, patients in denial of prior erectile/sexual function, current disease status, feeling of entitlement and psychiatric disorders.	N/A	N/A	Trost, Landon W.; Baum, Neil; Hellstrom, Wayne J. G.. Managing the difficult penile prosthesis patient. J Sex Med. 2013. 10(4):893-906; quiz 907,	0		In the US from 1995 to1999 penile prosthesis accounted for 11.8% of medical malpractice claims against Urologist. Identifying challenging patients may aid with preoperative management strategies, such as patient selection, counselling, education, informed consent and greater emphasis of regular postoperative care particularly in a setting of complications. Article and does not meet criteria for systematic review, no clear methodology described.

Appendix Two

Literature search terms

Assumptions / limits applied to search:	
Original search terms:	None
Updated search terms - Population	• Buried penis • Erectile • Erectile dysfunction • Failed pharmacological treatment • Failed treatment • High risk • Impotence • Peyronies • Priapism
Updated search terms - Intervention	• Artificial Penis • Penile prosthesis • Penis prosthesis • Penile implant • Penis implant
Updated search terms - Comparator	Untreated patient groups
Updated search terms - Outcome	None

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Inclusion criteria	**General inclusion criteria**
	In order of decreasing priority, the following are included: 1. All relevant systemic reviews and meta-analysis in the last 5 years and those in 5-10 years period which are still relevant (e.g. no further updated systematic review available) 2. All relevant RCTs and those in the 5-10 years period which are still relevant (e.g. not superseded by a next phase of the trial/ the RCT is one of the few or only high quality clinical trials available) >>>> If studies included reache 30, inclusion stops here 3. All relevant case control and cohort studies, that qualify after exclusion criteria >>>> If studies included reache 30, inclusion stops here 4. All relevant non analytical studies (case series/ reports etc) that qualify after exclusion criteria >>>> If studies included reache 30, inclusion stops here 5. Expert opinion
	Specific inclusion criteria
	Published in last 15 years
Exclusion criteria	**General exclusion criteria**
	Studies with the following characteristics will be excluded: 1. Do not answer a PICO research question 2. Comparator differs from the PICO 3. < 50 subjects (except where there are fewer than 10 studies overall) 4. No relevant outcomes 5. Incorrect study type 6. Inclusion of outcomes for only one surgeon/doctor or only one clinical site
	Specific exclusion criteria
	None