Evidence Review:

Penile prosthesis surgery for end stage erectile dysfunction
NHS England

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Penile prosthesis surgery for end stage erectile dysfunction

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Prepared by Turnkey project team on behalf of NHS England Specialised Commissioning
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Appendix 1

Appendix 2
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 Coloaplast 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). Vitrella 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%).

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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.
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<th>Grade</th>
<th>Study design</th>
<th>Study size</th>
<th>Intervention</th>
<th>Category</th>
<th>Primary Outcome</th>
<th>Primary Result</th>
<th>Secondary Outcome</th>
<th>Secondary Result</th>
<th>Reference</th>
<th>Complications noted</th>
<th>Benefits noted</th>
<th>Comments</th>
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<tr>
<td>N/A</td>
<td>N/A</td>
<td>Patients with ED undergone penile prosthesis</td>
<td>Clinical effectiveness of the intervention</td>
<td>(1) 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.</td>
<td>(1) 15 studies from 1970s supported that DM was a risk factor for penile prosthesis, however the authors caution 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=369 (diabetic n=114) and found patients with DM had a 34% 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%. McBayly et al (2011) reviewed infection related revisions of minocycline HCL, rifampicin impregnated and non-impregnated implants, n=97 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 (1.18% compared to 1.53%). (2) 8 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=1307) retrospective review of 623 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%, 3% and 50% respectively. The authors found rate of reinfection after re-implantation of prostheses was 18% in the DM group. Cakan et al 2003 (n=135) found paraplegia increase risk significantly, possible association with a neurogenic bladder. Mirenine 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. Sidd 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-resistant 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=655 reported over three decades with infection occurring in 0.9% with an equal incidence between DM (2%) and pelvic trauma patients (3.6%). This study found no difference in infection infection rate between men who received InhibZome 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.</td>
<td>N/A</td>
<td>N/A</td>
<td>Christodoulidou, Michelle; Pearce, Ian. Infection of Penile Prostheses in Patients with Diabetes Mellitus. Surg Infect (Larchmt). 2015. (ePublication ahead of print):, Y</td>
<td>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 advancement in prostheses 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).</td>
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<td>RCT</td>
<td>50 patients and partners randomised into two groups.</td>
<td>Psychosocial counselling before and 12 months afterwards.</td>
<td>Clinical effectiveness of the intervention</td>
<td>Before and 12 months after surgery, specific questionnaires completed (i) IIEF, International Erectile Dysfunction Inventory of Treatment Satisfaction (ii) 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 (88.3 vs 83.4, P&lt;0.001). (ii) SDS (erotic function) higher in study control. For patients (52.8 vs 45.8, P&lt;0.001) and partners (54.8 vs 44.2, P&lt;0.001). At 24 months after surgery, 14 patients in study group and 13 patients in control group reported on GAOQ1 an improvement in erectile function (HS), and the ability to engage in sexual intercourse (GAQ2) was higher in the study group (P&lt;0.001). (v) 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&lt;0.001 respectively.</td>
<td>NA</td>
<td>NA</td>
<td>Posano, F.; Falcone, M.; Albina, A.; Oderda, M.; Soria, F.; Paraldò, F.; Marsan, F.; Federina, M.; Foti, C.; Giusti, A.; Free, B.; Gontano, P. The importance of psychosocial counselling in the re-establishment of organic and erectile functions after penile prosthesis implantation. Int. J. Impot. Res. 2015. 27(5):197-200.</td>
<td>Y</td>
<td>Single centre prospective randomised study evaluating the influence of psychosocial counselling on re-establishment of organic and erectile functions of patients and partners after IPP. Authors report findings supporting that psychosocial counselling may improve satisfaction rates and surgical outcomes in IPP recipients and partners. Randomised study although very small study and not blinded, study downgraded in view of increased bias.</td>
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<td>1-</td>
<td>Cohort</td>
<td>46 patients</td>
<td>Patients underwent AMS 600-650 prosthesis in 20 patients; 88 patients; 109 patients; 127 men (70%) curvature was corrected. The remaining 10 patients (7%) received minimally invasive subtunical intracorporeal plaque incision associated with higher mechanical failure rate (P&gt;0.05). 3 patients (2%) required IPP removal secondary to infection, occurred on average of 6 months (11 weeks post-op, if curvature greater than 10 degree, successful outcome straight penis &lt;10 degree curvature. (i) 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.</td>
<td>Percentage of patients with AMS 600-650 and AMS Ambicore reported satisfied 34.7% (n=8) vs 73.9% (n=17), very satisfied 29-43% (n=7) vs 12% (n=3) and neither satisfied nor dissatisfied 34.7% (n=7) vs 13% (n=3) with their prosthesis prospectively. The satisfaction rates were different between the patient group, P=0.001.</td>
<td>NA</td>
<td>NA</td>
<td>Kircan, Hakan; Kaymak, Yumder; Gökce, 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.</td>
<td>N/A</td>
<td>None reported</td>
<td>N/A</td>
<td>None reported</td>
<td>Y</td>
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| 2- | Cohort | 210 patients, 90 post-radical prostatectomy (RP) implants, 123 non-RP ED patient implants. | Post-RP (radical prostatectomy) patients with 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 organic function. After PP implantation in RP patients the scores improved in all domains, however the RP score was lower than in control overall (83.1±7.0 vs 68.3±6.9, P=0.005). Organic 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 | N/A | N/A |
| 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 re-operation rates between inflatable and semi-rigid respectively (7.4% vs 7.5%, P=0.94). Re-operation rate secondary to infectious complications was 3.9% (3.2% 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 34.6 days, and mean time to failure for non-infectious complications was 225.7 days. Medicaid insurance (OR2.25 CI1.41,3.61), African American (OR1.7, CI1.20,2.49), age >80 (p=0.046) and diabetes (OR1.67, CI1.07, 2.59) associated with receiving a semi-rigid implant. | N/A | N/A | N/A | N/A |

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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. Catted 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-administered 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.

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 prosthesis
A total of 771 men had primary implants. Most common type of penile prosthesis implanted was malleable (cylinder (516 prostheses)) followed by CX cylinders (259 prostheses).

Clinical effectiveness: What is the intervention? To assess (i) intra-operative complications (ii) post-operative complications (iii) post-operative complications (infraction), (iv) complication rate following prosthesis revision and (v) satisfaction rate.

(1) Out of the 955 prosthesis, 11 intra-operative complications (1.1%), with 2 cases of urethral 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 (0.85). 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 (6-166 months). (3) In 144 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.

As discussed within primary outcome measures. Y A review of prospectively collected database on 955 penile prosthesis implanted over 5 decades. All men underwent medical and psychiatric counseling 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 28 patients
Patients with infected IPP, that have been removed and replaced with malleable prosthesis, adopting the MIST salvage procedure.

Clinical effectiveness: What is the intervention? Post-operative complications

(1) 34/38 patients (89%) 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 implantation and of these, 38 underwent MIST without subsequent complications. This resulted in a 90.3% success rate. (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, and at least 3 patients had at least one organism cultured from infected implant.

N/A N/A Gross, Martin S.; Philips, Elizabeth A.; Balen, Alexandra; Edj, J. Francois; Xang, Christopher; Simon, Ross; Martinez, Daniel; Carron, Rabat; Pento, Paul; Levine, Laurence; Greenfield, Jason; Munani, Riccardo; The Malable Implant Salvage Technique: Infection Outcomes After Malabley Salvage Procedure and Replacement of Infected IPP with Malable Prosthesis. J. Urol., 2015, publication 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 anaesthetics) 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 patients
Patients undergone penile prosthesis

Other

(1) The utilization 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 Chairson co-morbidity score >1 were more likely to have PP inserted for ED (P<0.01).

N/A N/A Lee, Daniel J.; Napper, Bobby B.; Davidson, Wesley L.; Al Hussein A; Awekh, Bashir; Zhao, Fajun; Paduch, Darla A.; Mullall, John P.; Chughlal, 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 156% the utilization of PP has decreased from 52% over time from 4.6% to 2.3% in 2010, and this may 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 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), 14% (n=28) on functional uninfected prosthesis, (n=9) secondary to patient dissatisfaction, n=10, supersonic transport deformity (SST), n=2 scrotal hernia, n=5 for upsise 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 washout developed infection or impending extrusion/excision compared to 25% of case that did not undergo a washout procedure. 9 cases of infection or impending extrusion/excision, 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).

N/A N/A N/A N/A Garmido-Abad, Pablo; Roselloli-Barbara, J.; Mariano; Sabino-Galbema, J.; Fernández-Ajijona, M.; Roselloli-Gaipa, Mariano. 100 cases of three-piece Inflatable Penile Prosthesis with new scrotal pump: Evaluation of 3 specialized centers. Arch. Esp. Urol. 2015. 68(4):416-423.

3 Case series 195 patients Patients undergoing revision surgeries for penile prosthesis implantation. 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-IEF and IIEF-ES 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 N/A N/A Garrido-Abad, Pablo; Roselloli-Barbara, J.; Mariano; Sabino-Galbema, J.; Fernández-Ajijona, M.; Roselloli-Gaipa, Mariano. 100 cases of three-piece Inflatable Penile Prosthesis with new scrotal pump: Evaluation of 3 specialized centers. Arch. Esp. Urol. 2015. 68(4):416-423.

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### 3 Case Series
1,019 patients
Patients undergone penile prosthesis implantation (AMS 700 (n=883), AMS Ambicor (n=26) and Spectra penile implants (n=10)).
Clinical effectiveness of the intervention
(i) To determine common etiology 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=205), 18.9% cardiovascular disease (n=200) and 8.9% Peyronie’s disease (n=81). (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 Y

ENEMCHUKWARE, EKENE A.; KEMPNER, EDWARD; BRANT, WILLIAM; CHRISTINE, BRIAN; KAMSAI, BRYAN T.; KHERA, aluminium alloys, James, Lenny; KUHIER, Tobias; BENNETT, NIKON; RHUE, EUGENE; EISENHERT, ELIZABETH; BELLIS, ANTHONY J.; THE WHO, HOW, AND WHAT OF REAL-WORLD PENILE IMPLANTS PATIENTS IN 2015. THE PROPER (PROSPECTIVE REGISTRY OF OUTCOMES WITH PENILE PROSTHESIS FOR ERECTILE RESTORATION) REGISTRY BASELINE DATA. J. UROL. 2015. (Epublication ahead of print).

### 3 Cohort
55,013 patients
Patients undergone penile prosthesis implantation with Dacron AMS 700 LGX/Ulrex (Dacron weave pattern) with and without parylene coating. n=29,360 (80.68%).
Clinical effectiveness of the intervention
(1) Survival rates (defined as time of first revision) between current generation girth expanding (700 CX) and length and girth expanding (700 LGX/Ulrex). (2) Comparing survival rate between parylene coated vs non-coated.
(1) Equivalent survival rates (7 year) between parylene AMS 700 Ulrex LGX and CX, 88.7% vs 89.3%, log rank P=0.6811. Approximately 50% of cases were a result of mechanical failure. (2) The parylene coated CX and Ulrex/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 Ulrex/LGX parylene vs non parylene (mechanical reasons) was 94.5% vs 92.3% respectively, P<0.0001.
N/A N/A N/A


### 3 Cohort
36,391 patients
Patients undergone primary implantation with Titan implant (Coiloplast) with an hydrophilic coating n=29,360 (80.68%).
Safety of the intervention
(i) 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 N/A


### FOR PUBLIC CONSULTATION ONLY
In this prospective registry, it was noted 441 (4.3%) 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.
### Case Series 1

| Patients undergo prosthesis implantation (110 first implant, 39 a 2nd 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 patients 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=0.35, NS). Main cause of dissatisfaction: 13% of first implants and 15% second implants were penile shortness or soft glans. | NA | N/A | NA |

### Case Series 2

| Patients undergo prosthesis implantation | 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 (249/320), of which 86% (5/198) responded to the whole survey and 20% (48) 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 Narrow Base). | Phase I subjects, n=1,069. The five year survival rate for IPP was 63%. | NA | N/A | NA | 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. |

### Case Series 3

<p>| Patients undergo prosthesis with a Corinoplast Titan IPP with one touch release pump. All patients received perioperative 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 (&gt; 5 day postoperatively) hematoma following IPP insertion. All three patients presented postoperatively with a swollen surgical site. All three patients treated successfully. | N/A | N/A | 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. |
| 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%, 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. | NA | N/A | Simsek, Abdurrahman; Kocakolup, Ozan; Ozgor, Furuk; Okturanci, Unsal; Baykal, Moral; Suhur, Omer; Gokbas, Zaler | Small study, no randomisation process undertaken prior to selection of patients. Authors observed 11% complication rate (2/18 patients). Low grade study. |
| Case series | 650 patients | Patients undergone Coloplast Titan inflatable Penile Prosthesis (IPP) One-Touch Release (OTR) pump. | Safety of the intervention | Reviewed complaints following implantation of IPP. | 53/550 patients (9.6%) found the inflate/deflate valve disc in the deflate position. Application of firm pressure on the pump bulb caused the valve to shift into inflate position. | NA | N/A | Utizi, Faruk; Ozkuvanci, Unsal; Kucuktopcu, Onur; Ozgor, Kucuk | Retrospective case series, low level evidence. |
| Case series | 48 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 use 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&lt;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. | NA | N/A | Utzner, Bruce B.; Khuriin, Jacob L.; Stember, Donn B.; Perito, Paul E. | 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. |</p>
<table>
<thead>
<tr>
<th>Case series</th>
<th>No. patients</th>
<th>Intervention</th>
<th>Clinical effectiveness</th>
<th>No. patients with complications</th>
<th>Overall satisfaction of patients</th>
<th>Overall satisfaction of partners</th>
<th>Overall satisfaction rate</th>
<th>Overall complication rate</th>
<th>Other outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>80 patients</td>
<td>Patients undergone implantation of a three piece inflatable penile prosthesis (AMS700CX/AMS702CX/AMS600CX/Coloplast Titan)</td>
<td>To assess satisfaction, 3rd, 6th and 12 months P=0.033. (2) Overall satisfaction rate after the implantation was 90.6%. (3) Overall satisfaction rate after the implantation was 90.6% and 90% at 6 and 12 months respectively.</td>
<td>4 patients explanted, 4 patients had their device explanted in 12.4% of cases, 1 patient had local infection in 12% of cases. No major intra-operative or post-operative complications observed.</td>
<td>90.6%</td>
<td>86.4%</td>
<td>90.6%</td>
<td>12.4%</td>
<td>4 patients explanted, 4 patients had their device explanted in 12.4% of cases, 1 patient had local infection in 12% of cases. No major intra-operative or post-operative complications observed.</td>
</tr>
</tbody>
</table>
| 3           | 22 patients  | Patients undergone implantation of a three piece inflatable penile prosthesis (AMS Spectra/AMS Spectra/XCM) | To evaluate patient and partner satisfaction outcome following AMS Spectra penile prosthesis implantation. Pre-operative erectile dysfunction rate was significant. | Patients average IIEF score was 21.46 and EDITS score was 28.5. | 77.6%, 10 year survival (Kaplan Meier) for AMS 700CX. Surgery and 89.2% (P=0.033). Overall satisfaction rate was 90.6%. | 86.4% | 77.6% | 90.6% | 89.2% | surgery and 89.2% (P=0.033). Overall satisfaction rate was 90.6%.
| 3           | 113 patients | Patients undergone implantation with Coloplast Titan One Touch Release (OTR) pump. | To assess satisfaction with ease of deflation of the OTR pump at 6 months. (ii) Overall satisfaction with the device was 90.6% and 90% at 6 and 12 months respectively. | 4 patients explanted, 4 patients had their device explanted in 12.4% of cases. 1 patient had local infection in 12% of cases. No major intra-operative or post-operative complications observed. | 90.6% | 90% | 90.6% | 12.4% | 4 patients explanted, 4 patients had their device explanted in 12.4% of cases, 1 patient had local infection in 12% of cases. No major intra-operative or post-operative complications observed. |
### Cohort 1

<table>
<thead>
<tr>
<th>Study Details</th>
<th>Patients</th>
<th>Primary Implants</th>
<th>Revision Implants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with primary penile prosthesis implantation.</td>
<td>109 patients (primary implants: 117 and 72 revision implants)</td>
<td></td>
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</tr>
<tr>
<td>Patients undergone revision surgery.</td>
<td>39,005 patients (MIP, non-impregnated: 56,377, MIP, micocryl and Rifampin: non-impregnated: 36,368)</td>
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<tr>
<td>Patients with erectile dysfunction undergone primary penile prosthesis implantation in a single centre performed by a single surgeon.</td>
<td>60 patients (complete survey: 90 patients)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### methodology

- **Safety of the intervention:**
  - (i) To assess infection rate in non-impregnated IPP, coated IPP and non-impregnated IPP, all patients were included.
  - (ii) To evaluate antibiotic coated devices in terms of infection rate and to evaluate modified revision washout with no washout on infection rate.
  - (iii) To evaluate antibiotic coated devices in terms of infection rate and (ii) to evaluate modified revision washout with no washout on infection rate.

- **Clinical effectiveness of the intervention:**
  - To evaluate the impact of antibiotic impregnation on revision surgery rate after IPP implantation.
  - 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.
  - To assess association between patient and partner satisfaction.

- **Clinical outcomes:**
  - (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). Overall the mean EDITS score was 75.48±20.54 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.
  - (2) 1/43 (2.3%) patients with antibiotic coated devices vs 0/6 (0.9%) developed postoperative infections, P<0.128. (2) 2/41 (4.8%) patients undergoing modified revision washout with no washout developed postoperative infections (P<0.30).

- **Infection rate primary outcome measure:**
  - Patients who underwent initial device revision who initially received a non-impregnated IPP.

- **Infection rate primary outcome measure:**
  - (1) In 2002 the infection rate for non-impregnated IPP was 5.3%, between 2003-2005 the coated IPP with standard percutaneous 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 0.44%. (2) Uncoated IPP group: 42.9% (90 patients) Group A: Staphylococcus (CONS), 14.3% Enterococcus faecalis, no growth in 42.9%. In coated IPP, 23.4% (33) 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.

### Limitations

- 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.

### References

2. J. Francois, Wilson, Steven K.; Clavell, Marie; Salem, Edam A.; Coated implants and ‘no touch’ surgical technique decreases risk of infection in inflatable penile prosthesis implantation to 0.4%. Urology. 2012. 79(6):1310-1315.
### Aim of the Study

- To identify patient characteristics to identify risk of postoperative dissatisfaction.
- Review of urologic and non-urologic cosmetic surgery literature to identify factors associated with both patient satisfaction and dissatisfaction.

### 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.

### 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.

### 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.

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### Table

<table>
<thead>
<tr>
<th>0</th>
<th>Other</th>
<th>N/A</th>
<th>Other</th>
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<tbody>
<tr>
<td>0</td>
<td>Other</td>
<td>N/A</td>
<td>Other</td>
</tr>
</tbody>
</table>

- Other factors associated with patient satisfaction/dissatisfaction.
- 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.

- 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.

- 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.

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In the US from 1995 to 1999 penile prosthesis accounted for 11.8% of medical malpractice claims against Urologists. 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

<table>
<thead>
<tr>
<th>Assumptions / limits applied to search:</th>
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<tbody>
<tr>
<td>Original search terms:</td>
<td>None</td>
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<tr>
<td>Updated search terms - Population</td>
<td></td>
</tr>
<tr>
<td>• Buried penis</td>
<td></td>
</tr>
<tr>
<td>• Erectile</td>
<td></td>
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<tr>
<td>• Erectile dysfunction</td>
<td></td>
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<tr>
<td>• Failed pharmacological treatment</td>
<td></td>
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<tr>
<td>• Failed treatment</td>
<td></td>
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<tr>
<td>• High risk</td>
<td></td>
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<tr>
<td>• Impotence</td>
<td></td>
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<tr>
<td>• Peyronies</td>
<td></td>
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<tr>
<td>• Priapism</td>
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<tr>
<td>Updated search terms - Intervention</td>
<td></td>
</tr>
<tr>
<td>• Artificial Penis</td>
<td></td>
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<tr>
<td>• Penile prosthesis</td>
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<tr>
<td>• Penis prosthesis</td>
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<tr>
<td>• Penile implant</td>
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<tr>
<td>• Penis implant</td>
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<tr>
<td>Updated search terms - Comparator</td>
<td>Untreated patient groups</td>
</tr>
<tr>
<td>Updated search terms - Outcome</td>
<td>None</td>
</tr>
</tbody>
</table>
**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)
3. All relevant case control and cohort studies, that qualify after exclusion criteria
4. All relevant non analytical studies (case series/reports etc) that qualify after exclusion criteria
5. Expert opinion

**Specific inclusion criteria**

Published in last 15 years

**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