

# Efficacy and safety of malleable penile prosthesis compared to inflatable penile prosthesis in erectile dysfunction patients

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## Summary

**Introduction:** Erectile dysfunction can cause self-withdrawal and decreased quality of life.

Patients who do not respond to pharmacological therapy and other conservative treatments are urged to undergo penile prosthesis implantation. Malleable penile prosthesis was the first prosthesis developed, but then inflatable penile prosthesis was developed to give a more natural erection. There is no meta-analysis comparing inflatable and malleable penile prostheses in terms of safety and efficacy. This study is conducted to evaluate patient and partner satisfaction, ease of use, mechanical failure, and infection rate in patients who underwent penile prosthesis implantation.

**Method:** This meta-analysis followed Preferred Reporting Items for Systematic Review and Meta-analysis (PRISMA) protocols. Five eligible studies were included from Pubmed, Scopus, ScienceDirect, and SemanticScholar databases.

**Result:** In this study, patient and partner satisfaction are significantly better (OR 3.39, 95% CI 1.66-6.93,  $p = 0.0008$ ) (OR 2.32, 95% CI 1.75-3.08,  $p < 0.00001$ ). Mechanical failure is also significantly higher in inflatable penile prostheses (OR 5.60, 95% CI 2.02-15.53,  $p = 0.0009$ ). There is no significant difference in terms of ease of use and infection rate in inflatable or malleable penile prostheses.

**Conclusions:** This study concluded that inflatable penile prosthesis is better in terms of patient and partner satisfaction, but mechanical failures occur more frequently in this type of prosthesis.

**KEY WORDS:** Erectile dysfunction; Penile prosthesis; Malleable penile prosthesis; Inflatable penile prosthesis.

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## INTRODUCTION

Inadequate penile erection, otherwise known as *erectile dysfunction* (ED), is defined as the inability to achieve or maintain sufficient penile erection for vaginal penetration until orgasm (1). The prevalence of ED in men aged 20 to 80 years in Jakarta reached 35.6% (2). Erectile dysfunction is not a life-threatening condition, but it can result in withdrawal from sexual intimacy, decreased quality of life, and decreased work productivity (3). Erectile dysfunction causes many negative effects. Thus, proper han-

dling and management are needed to improve the state and quality of life of the patients.

ED management includes control of risk factors (tobacco consumption, obesity, sedentary lifestyle, chronic alcohol consumption, comorbidities, and depression) and appropriate pharmacological therapy. The first-line treatment for ED is oral therapy with *Cyclic Guanosine Monophosphate* (cGMP) inhibitors and *Phosphodiesterase 5 inhibitors* (PDE5 inhibitors) (4). Prior to the development of PDE5 inhibitors, intracavernosal injection was the first-line treatment for patients with ED. However, at present, intracavernosal injection can be used as an important second-line treatment option and as the core of the DE diagnostic examination (5). *Intraurethral Prostaglandin E1* (PGE1) [alprostadil, *Medicated Urethral System for Erection* (MUSE); Vivus, Menlo Park, Calif] was introduced in 1997. MUSE, uses PGE1 which directly affects the trabecular smooth muscle binding to specific receptors and thereby increasing the synthesis of cyclic *Adenosine Monophosphate* (cAMP) (6). *Vacuum Erectile Device* (VED), a means of therapy for ED patients, uses negative pressure to dilate the sinusoids of corpora cavernosa and increase blood flow to penile. VED can be used together with an external constriction ring placed at the bulb of the penile to prevent outward blood flow in order to maintain erection for sexual intercourse (7).

The implantation of penile prostheses remains a relevant therapeutic option and is in demand, especially among uncured ED patients who have undergone conservative treatments. A study suggested that penile prosthesis implantation may be considered in ED patients who do not exhibit positive response to pharmacotherapy or who wish for a permanent solution to their problem (8, 9).

The first penile prosthesis implantation surgery was performed by a Russian surgeon named *Nikolaj A. Bogaraz* in 1936. Currently, penile prostheses become the gold standard in patients experiencing recurrent ED after being given medicamentosa therapy and in patients with penile trauma (10).

There are three types of penile prostheses available: semirigid or malleable, two-piece inflatable, and three-piece *inflatable penile prosthesis* (IPP). At present, the inflatable three-piece penile prosthesis is the most widely used and recommended due to high patient and part-

ner satisfaction, natural cosmetic appearance, and its ability to enable patients to get or lose an erection at will. The implantation of an IPP has several side effects, namely perforation of corpus cavernosum, urethral damage, mechanical failure, infection, as well as bladder, intestinal, and vascular trauma (11).

The implantation of a *malleable penile prosthesis* (MPP) is easier to do. In addition, MPP rarely experiences mechanical failures and is affordable. Complications may occur during or after surgery. The most common complications during surgery are urethral and corpus cavernosum trauma, while those occurring post-surgery are hematoma, infection, penile deformity, pain, and penile erosion (8). Despite their advantages, inflatable penile prostheses have some limitations, such as expensive price, being hard to use, difficult implantation techniques, and high risk of infection. Inflatable penile prostheses have a risk of being damaged after being used for more than 10 years and require replacement.

Malleable penile prostheses are cheaper and easier to use even though they do not provide cosmetic and erection naturalness as well as inflatable penile prostheses. Malleable prostheses are less prone to damage and infection compared to inflatable penile prostheses. There is a systematic review by *Karl H. Pang* in 2021 concerning complications and satisfaction after penile prosthesis implantation in patients with spinal cord injury. Several weaknesses are present in this study, as it only includes old studies written in English.

Furthermore, quantitative analysis cannot be conducted in this study due to the heterogeneous nature of the output and lack of control population (12).

There is currently no meta-analysis study comparing the efficacy and safety of the use of inflatable and malleable penile prostheses in patients with ED. Therefore, the authors carry out a systematic review and meta-analysis study to compare the efficacy and safety of the use of inflatable penile prostheses compared to malleable prostheses in patients with ED.

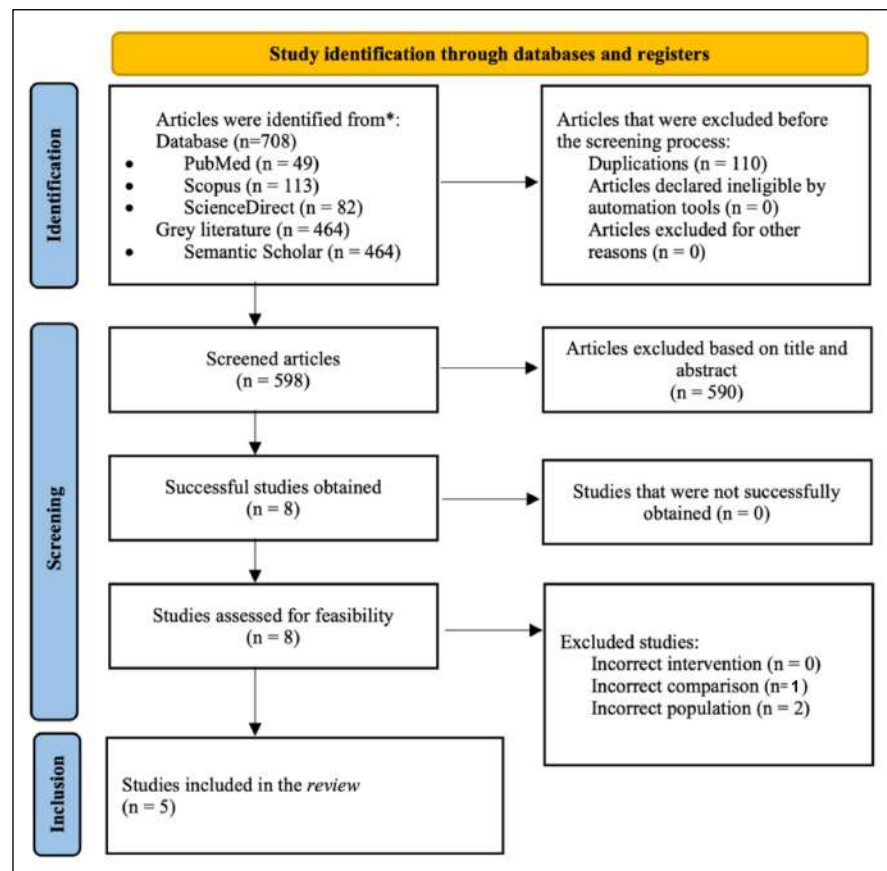
**MATERIALS AND METHODS**

**Search strategy and study selection**

The study used the quantitative method according to the *Preferred Reporting Items for Systematic reviews and Meta-analysis* (PRISMA) protocol. The search process was carried out to ensure that the meta-analysis was in line with the topic or PICO (participant, intervention, comparison, outcome). The inclusion criteria of this study were observational design studies (cohort, case control, and cross sectional), studies that compared malleable and inflatable penile prostheses in patients with ED caused by diabetes mellitus, vascular disease, history of radical prostatectomy surgery, history of surgery in the pelvic area, as well as Peyronie's, neurogenic, and priapism diseases. The exclusion criteria of this study were duplicate articles, articles not written in English, articles that were not available in full-text, patients with ED caused by other than diabetes mellitus, vascular disease, history of radical prostatectomy sur-

**Table 1.**  
Results of article search using several international databases.

Database	Keywords	n
PubMed/MEDLINE	("erectile dysfunction" OR "sexual dysfunction" OR "impotence" OR "impotency") AND ("inflatable") AND ("malleable" OR "Malleable" OR "semi-rigid" OR "semi rigid" OR "non-inflatable" OR "non inflatable") AND ("penile prosthesis" OR "penile-prosthesis" OR "penile prosthesis") AND [{"satisfaction"} OR {"complication"}]	49
Scopus	[TITLE-ABS-KEY (erectile AND dysfunction) AND TITLE-ABS-KEY (inflatable AND penile AND prosthesis) AND TITLE-ABS-KEY (malleable AND penile AND prosthesis)]	113
ScienceDirect	("inflatable penile prosthesis") AND ("malleable penile prosthesis") AND ("erectile dysfunction" OR "ED") AND ("satisfaction" OR "complication")	82
Semantic Scholar	ED erectile dysfunction penile prosthesis inflatable penile prosthesis malleable erectile dysfunction satisfaction complication	464



**Figure 1.**

PRISMA diagram of the study search and selection process.

gery, history of surgery in the pelvic area, as well as Peyronie's, neurogenic, and priapism diseases. The study selection was carried out by conducting eligible study search on PubMed, Scopus, ScienceDirect, and Semantic Scholar databases. The search was carried out up to February 2023.

The keywords we used include "erectile dysfunction", "penile prostheses", "malleable", "inflatable", "efficacy", "satisfaction", and "compliance". The keywords used in the study search are displayed in Table 1. Study search and selection were conducted based on PRISMA guidelines (Figure 1).

### Quality assessment and data extraction

Data extraction was carried out by two authors independently in accordance with the specified examples. In case of differences in data extraction results, they were discussed and settled by a third author. The data extracted comprised the characteristics and methodologies of the study, namely the name of the first author, year of publication, number of patients, age of patients, and design of the study. In addition, there were research interventions that were divided into the types of intervention given, namely the implantation of inflatable penile prostheses and malleable penile prostheses. The outcome extracted were patient satisfaction, partner satisfaction, ease of use, mechanical failure rates, and infection rates. The risk of bias of the study was assessed using the Newcastle Ottawa Scale.

### Statistical analysis

The data obtained was then inputted and analyzed using

the Review Manager 5.4 software. The outcome evaluated in this study comprised postoperative complications consisting of mechanical failure and penile prosthesis infection. Chi-square and I<sup>2</sup> tests were used to evaluate the heterogeneity between studies. If the result of the heterogeneity test was high (I<sup>2</sup> test > 50% and chi-square  $p < 0.05$ ), then the random-effects model was used. On the other hand, if the result of the heterogeneity test was low (I<sup>2</sup> < 50%, chi-square  $p > 0.05$ ), the fixed-effect model was instead used. The results comprised dichotomous data. Thus, analysis using pooled odds ratio (OR) with 95% confidence interval (CI) is used in the presentation of the data. The results of the analysis is presented in the form of Forest plots and explained in the form of a narrative review. The publication bias was assessed using a funnel plot.

### RESULTS

Based on initial search results through PubMed, Scopus, ScienceDirect, and Semantic Scholar databases, the authors identified 708 articles. The authors screened 598 titles and abstracts after carrying out the process of removing duplicate articles and automation. Based on predetermined eligibility criteria, the authors excluded 590 articles by reading their titles and abstracts. Based on further review conducted by reading the full texts, the authors included 5 studies that met the eligibility criteria. The characteristics of the 5 included studies are described in Table 2.

**Table 2.**  
Basic characteristics of the included studies.

Author's name, year of the study	Country of origin	Type of study	Group	Prosthesis brand	Total subject (n)	Age (years)	Follow-up duration	ED etiology	Result
Natali, 2008 (26)	Germany, Italy	Retrospective cohort	2-piece IPP	AMS Ambicor	98	Average 58.9	5 years	<ul style="list-style-type: none"> <li>· Diabetes mellitus: 82 patients</li> <li>· Vascular disease: 22 patients</li> <li>· Radical prostatectomy: 45 patients</li> <li>· Peyronie's disease: 20 patients</li> </ul>	Patient satisfaction, partner satisfaction, ease of use, mechanical failure, infection rate
			3-piece IPP	AMS 700 CX	62	(range of 35-78)			
			MPP	AMS 600 - 500	40				
Berto, 2014 (28)	Spain	Retrospective cohort	IPP	<ul style="list-style-type: none"> <li>· AMS 700 CX</li> <li>· AMS 700 CXR</li> <li>· AMS Ambicor</li> <li>· Coloplast TITAN</li> </ul>	41	Average 57.2 (SD ± 2.8)	18 years	<ul style="list-style-type: none"> <li>· Diabetes mellitus: 38 patients</li> <li>· Vascular disease: 22 patients</li> <li>· Peyronie's disease: 14 patients</li> <li>· Radical prostatectomy: 5 patients</li> <li>· Neurogenic: 12 patients</li> <li>· Unknown: 17 patients</li> </ul>	Infection rate
Kilicarslan, 2014 (17)	Turkey	Retrospective cohort	MPP	AMS Spectra Coloplast Genesis	66	Average 52.6 (SD ± 3.6)	5 years	<ul style="list-style-type: none"> <li>· Vascular disease: 25 patients</li> <li>· Radical prostatectomy and pelvic area surgery: 7 patients</li> <li>· Priapism: 3 patients</li> <li>· Patients with kidney transplants: 1 patients</li> </ul>	Patient satisfaction, partner satisfaction, ease of use
			IPP	AMS Ambicor	23	Average 58.6 (SD ± 9.5)			
			MPP	AMS 600 - 500	23	Average 56.7 (SD ± 12.9)			
Cayan, 2019 (33)	Turkey	Retrospective cohort	2-piece IPP	AMS Ambicor	26	Average 56.8 (SD ± 10.1; range 35 ± 74)	1 year	<ul style="list-style-type: none"> <li>· Diabetes mellitus: 378 patients</li> <li>· Vascular disease: 540 patients</li> <li>· Pelvic area surgery: 106 patients</li> <li>· Neurogenic: 21 patients</li> <li>· Peyronie's disease: 162 patients</li> </ul>	Patient satisfaction, partner satisfaction, ease of use, mechanical failure
			3-piece IPP	<ul style="list-style-type: none"> <li>· AMS 700 Ultrex Plus</li> <li>· AMS 700 LGX</li> <li>· Coloplast TITAN</li> </ul>	508	Average 57.2 (SD ± 10.5; range 25 ± 83)			
			MPP	<ul style="list-style-type: none"> <li>· AMS Spectra</li> <li>· Genesis</li> </ul>	349	Average 58.6 (SD ± 7.9; range 29 ± 80)			
Bayrak, 2020 (16)	Turkey	Retrospective cohort	2-piece IPP	AMS Ambicor	61	51.47 ± 10.79	5 years	<ul style="list-style-type: none"> <li>· Diabetes mellitus: 100 patients</li> <li>· Coronary artery disease: 27 patients</li> <li>· Neurogenic: 4 patients</li> <li>· Radical prostatectomy: 12 patients</li> <li>· Other pelvic surgeries: 14 patients</li> </ul>	Patient satisfaction, partner satisfaction, ease of use, infection rate
			MPP	Promedon - tube	81	56.27 ± 10.81			

**Table 3.**  
Results of the Newcastle-Ottawa Scale Assessment.

Author	Selection	Comparability	Exposure	Total Score
Natali, 2008	****	**	**	8
Berto, 2014	***	**	**	7
Kilicarslan, 2014	***	**	**	7
Cayan, 2019	****	**	**	8
Bayrak, 2020	***	**	**	7

Study or Subgroup	IPP		MPP		Odds Ratio M-H, Fixed, 95% CI	Odds Ratio M-H, Fixed, 95% CI
	Events	Total	Events	Total		
Bayrak,2020	4	61	5	81	39.2%	1.07 [0.27, 4.15]
Berto,2014	5	41	7	66	46.0%	1.17 [0.35, 3.97]
Natali 2008	8	160	1	40	14.8%	2.05 [0.25, 16.90]
<b>Total (95% CI)</b>		<b>262</b>		<b>187</b>	<b>100.0%</b>	<b>1.26 [0.56, 2.86]</b>
Total events	17		13			
Heterogeneity: Chi <sup>2</sup> = 0.28, df = 2 (P = 0.87); I <sup>2</sup> = 0%						
Test for overall effect: Z = 0.55 (P = 0.58)						

This review includes studies evaluating comparison of the use of IPP and MPP, covering a total of 1.234 adult patients, published between 2008 and 2019. All of the studies included are retrospective cohort studies conducted in Germany, Italy, Spain, and Turkey. The average age of patients who were subjects in these 5 studies was between 52.6 and 58.9 years.

The data extracted from the five studies included names of the researchers and years of the publication of the studies, designs of the studies, number of samples, types and brands of penile prostheses, duration of follow-up, etiology of ED, average age of samples, patient satisfaction, partner satisfaction, ease of use, mechanical failures, and number of infections.

The quality assessment of the study was conducted using the *Newcastle-Ottawa Scale* (NOS) parameter as all the studies included use an observational study design. In the selection aspect, all the studies that are included employ a good selection process as the participants involved were quite representative of cases in the adult population and most of the data was acquired using medical records and validated questionnaires. In addition, the studies included also possess good comparative and exposure aspects as they had adequate follow-up duration and low dropout numbers. Based on the final assessment, all the studies included have NOS scores between 7 and 8, signifying that they are of good quality. The quality assessment are presented in Table 3.

**Comparison of IPP and MPP with regard to patient satisfaction**

In this analysis, four articles involving a total of 1.484 patients who underwent penile prosthesis implantation procedure were included to assess and compare patient satisfaction with regard to the use of IPP and MPP. For statistical analysis, fixed-effect models were used as the degree of

heterogeneity between studies in this analysis is low. In subgroup 1, the authors compared the satisfaction of patients who used Two-piece IPP with those who used MPP. The analysis results show an OR of 2.40 [95% CI 1.31, 4.40]. There is a moderate degree of heterogeneity with a chi-square of 4.84, *degrees of freedom* (df) of 3 (p = 0.18), and I<sup>2</sup> value of 38%. The test for overall effect demonstrates statistically significant results with p = 0.005. This suggests a more favorable outcome for the Two-piece IPP. Subgroup 2 compares the Three-piece IPP with MPP, resulting in an OR of 4.16 [95% CI 2.85, 6.06]. There is a very low degree of heterogeneity with a chi-square of 0.01, df of 1 (p = 0.94), and I<sup>2</sup> value of 0%. The test for overall effect demonstrates statistically very significant results with p < 0.00001, indicating the advantage of the use of Three-piece IPP.

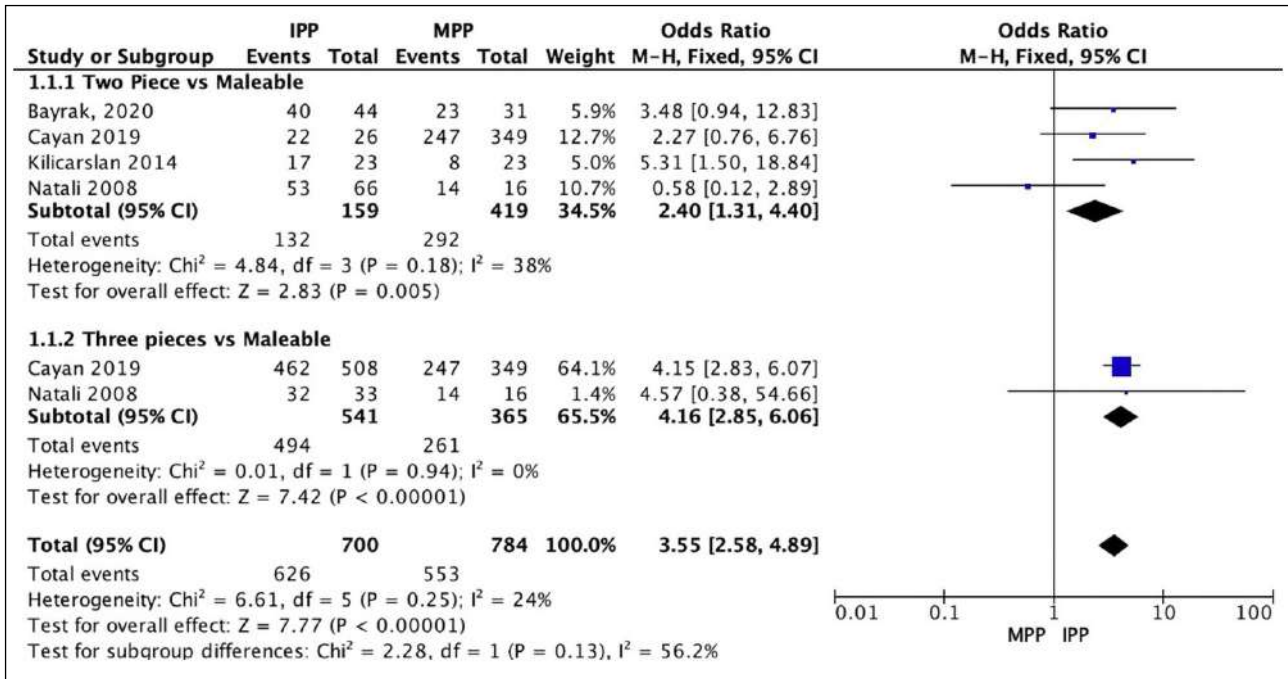
By combining these two subgroups, a total OR of 3.55 [95% CI 2.58, 4.89] was obtained, demonstrating the superiority of IPP over the MPP. The degree of heterogeneity remains relatively low, with a chi-square of 6.61, df of 5 (p = 0.25), and I<sup>2</sup> value of 24%. The test for overall effect demonstrates statistically significant results with p = 0.00001. The subgroup difference test was carried out to assess whether there were significant differences between the two subgroups. The test results showed that there were no significant differences between the two subgroups, with chi-square of 2.28, df of 1 (p = 0.13), and I<sup>2</sup> of 56.2%.

These findings suggest that overall, patients tend to be more satisfied with the use of IPP compared to MPP, with statistically significant results. The heterogeneity between studies we included in this analysis is relatively low, which adds confidence to the results of this study (Figure 2).

**Comparison of IPP and MPP with regard to partner satisfaction**

In this analysis, four articles involving a total of 1.517 patients who underwent a penile prosthesis implantation

**Figure 2.**  
Forest plot of patient satisfaction.

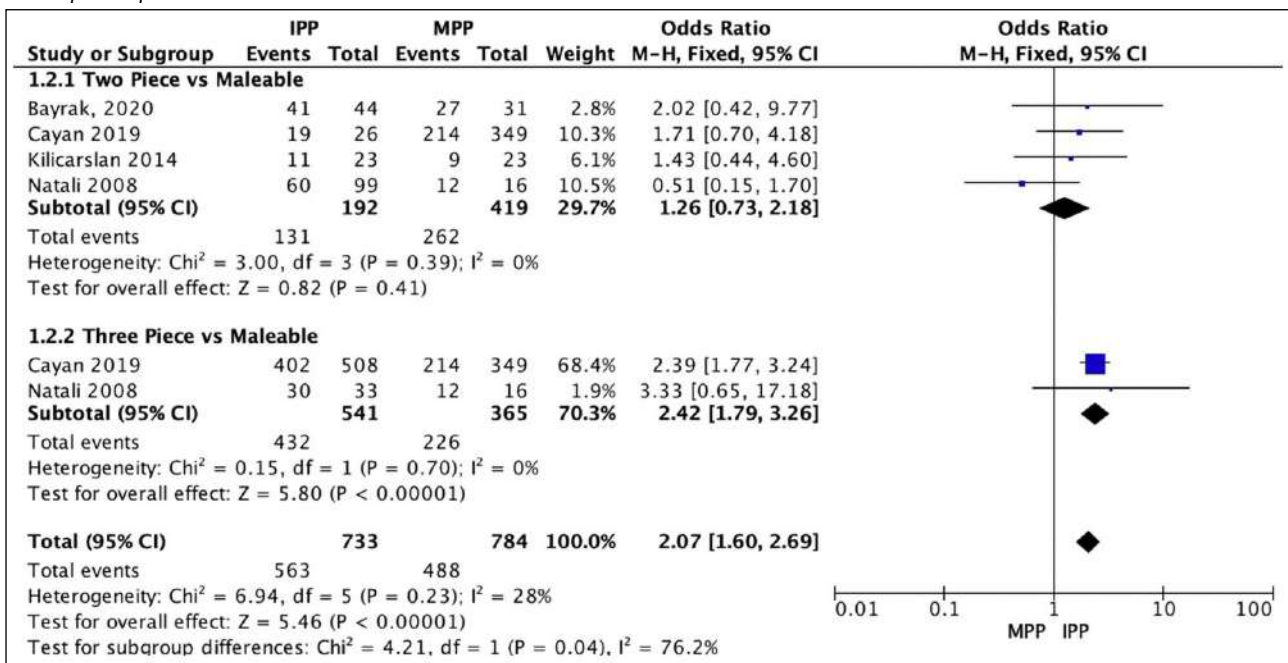


procedure are included. This study aims to evaluate and compare partner satisfaction with regard to the use of Two-piece IPP and MPP. Fixed-effect models were used in statistical analysis as the degree of heterogeneity between studies in this analysis is low.

In subgroup 1, the authors compared the partner satisfaction between the Two-piece IPP and MPP. The analysis results show an OR of 1.26 [95% CI 0.73, 2.18]. There is a low degree of heterogeneity with a chi-square of 3.00, df of 3 (p = 0.39), and I<sup>2</sup> value of 0%. The test for overall

effect demonstrates statistically insignificant results (p < 0.41), showing the advantage of the use of Two-piece IPP. Subgroup 2 is focused on the comparison between Three-piece IPP and MPP, where an OR of 2.42 [95% CI 1.79, 3.26] is obtained. In this subgroup, there is a very low degree of heterogeneity with a chi-square of 0.15, df of 1 (p = 0.70), and I<sup>2</sup> value of 0%. The test for overall effect demonstrates statistically very significant results (p < 0.00001), indicating the advantage of the use of Three-piece IPP (Figure 3).

**Figure 3.**  
Forest plot of partner satisfaction.

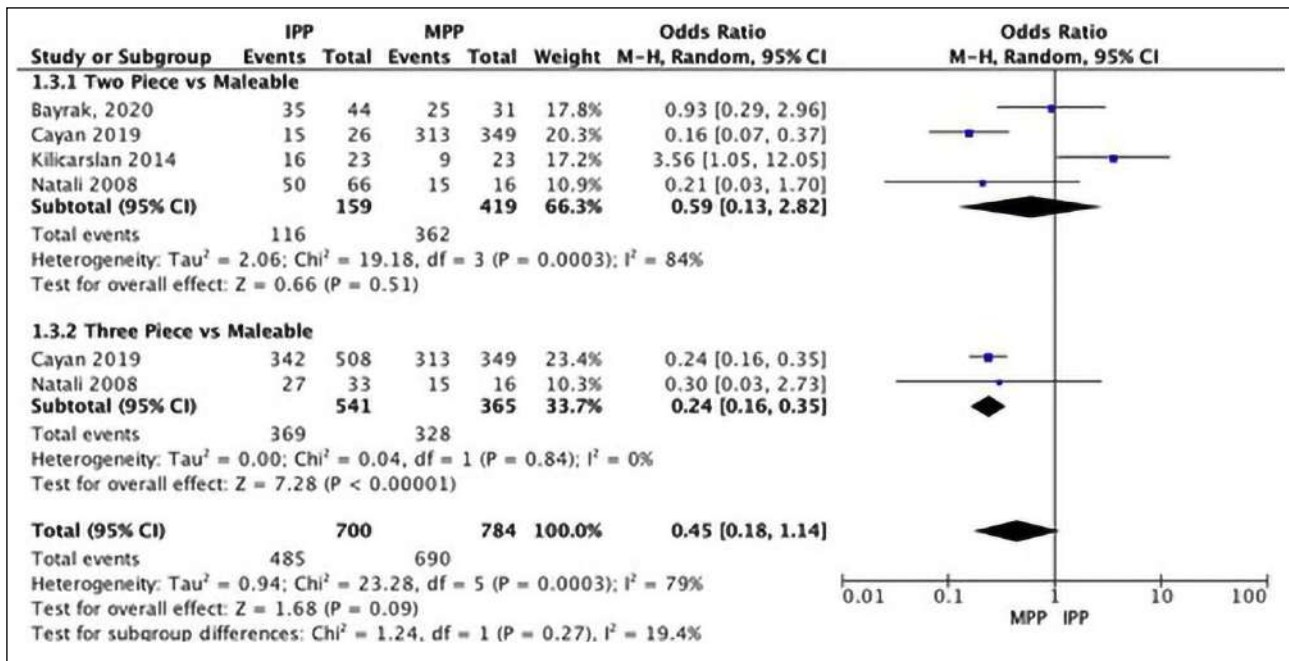


**Comparison of IPP and MPP with regard to ease of use**  
 The authors assessed the comparison between the ease of use of IPP and MPP prostheses in four studies involving a total of 1,484 patients. The results of the analysis also demonstrate that the studies included have a high degree of heterogeneity ( $I^2 = 86\%$ ,  $p < 0.0001$ ). Thus, the analysis method used was the random-effects model. In subgroup 1, the authors compared the ease of use of Two-piece IPP and MPP. The analysis results show an OR of 0.59 [95% CI 0.13, 2.82]. There is a high degree of heterogeneity with a chi-square of 19.18, df of 3 ( $p = 0.0003$ ), and  $I^2$  value of 84%. The test for overall effect demonstrates statistically insignificant results ( $p < 0.51$ ), showing the advantage of the use of Two-piece IPP. Subgroup 2 compares the ease of use of three-piece IPP and MPP. An OR of 0.24 [95% CI 0.16, 0.35] was obtained. There is a high degree of heterogeneity in this subgroup with a chi-square of 0.04, df of 1 ( $p = 0.84$ ), and  $I^2$  value of 0%. A statistically significant result ( $p = 0.0001$ ) was obtained, indicating the superiority of MPP (Figure 4).

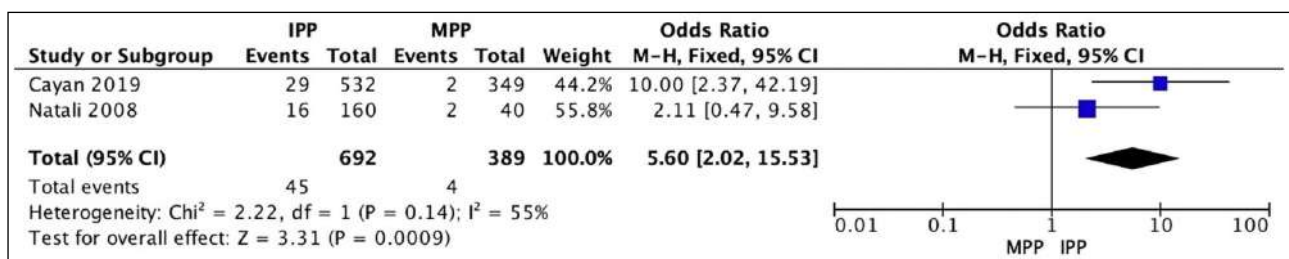
**Comparison of IPP and MPP with regard to mechanical failure**  
 The comparison of mechanical failures is analyzed by including two studies involving a total of 1,081 patients. Heterogeneity analysis using  $I^2$  indicates that the degree of heterogeneity between studies is low ( $I^2 = 55\%$ ,  $p = 0.14$ ). As such, the fixed-effects model analysis method used was used. Based on the results of the analysis on 1,081 patients who underwent penile prostheses implantation, the rate of mechanical failure of IPP and MPP differs significantly (OR 5.60 95% CI 2.02-15.53,  $p = 0.0009$ ) (Figure 5).

**Comparison of IPP and MPP with regard to infection rate**  
 The infection rate is analyzed by including three studies involving a total of 449 patients. Heterogeneity analysis using  $I^2$  demonstrates that the degree of heterogeneity between studies is low ( $I^2 = 0\%$ ,  $p = 0.87$ ). Therefore, the fixed-effects model analysis method was used. Based on the results of the analysis on 449 patients who underwent penile prostheses implantation, there is no significant difference in the rate of infection between IPP and MPP (OR 1.26 95% CI 0.56-2.86,  $p = 0.58$ ) (Figure 6).

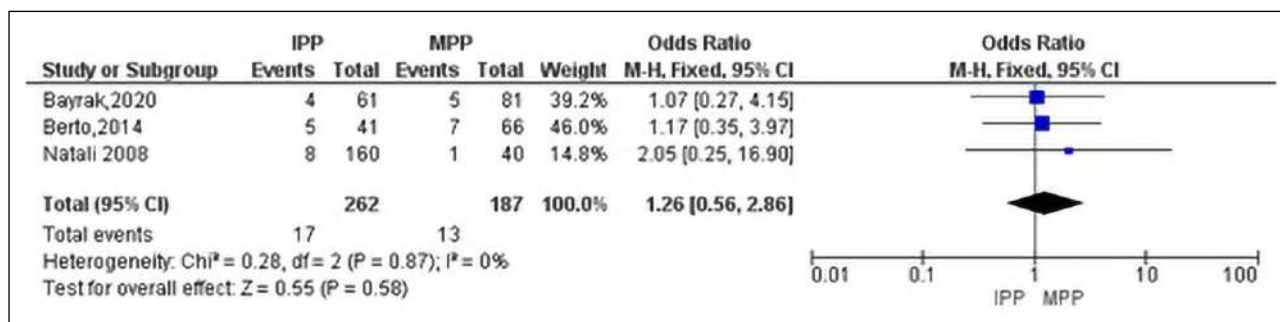
**Figure 4.**  
 Forest plot of ease of use.



**Figure 5.**  
 Forest plot of mechanical failure.



**Figure 6.**  
Forest plot of infection comparison.



## DISCUSSION

Erectile dysfunction has been linked to loss of work productivity and poor quality of life in men associated with mental and psychological health condition, especially compared to men who do not suffer from ED. Partners of patients with ED often complain of having problems in relationships, decreased sexual activity, and decreased sexual satisfaction. The burden associated with ED can negatively affect men and their partners (13).

Currently, according to the *American Urology Association* (AUA) (2018), therapies commonly used for patients with ED include oral PDE5i, VED, intraurethral Alprostadil, intracavernosal injection, and penile prosthesis (14). Guidelines from the *European Association of Urology* (EAU) from 2016 to 2023 state that penile prosthesis implantation is one of the best options in terms of satisfaction levels (92-100% in patients and 91-95% in their partners) regardless of the indication when compared to other therapeutic options (8). The EAU guidelines also state that penile prosthesis implantation is a valid third-line therapeutic option for the treatment of ED when drugs and VED are shown to be ineffective, unsatisfactory, or contraindicated due to comorbidities of the patients (15).

In literature, penile prostheses have been reported as the most successful surgical treatment with the highest satisfaction level among therapeutic options for ED. Each type of penile prosthesis has different advantages and disadvantages that can affect patient satisfaction. Malleable penile prostheses have a structure that can be bent while wearing clothes and urinating as well as can be erected prior to having sexual intercourse. Advantages of malleable penile prostheses include low rate of mechanical failures, easier surgical procedures, shorter operating times, and relatively cheaper prices. On the other hand, patients using malleable prostheses will face difficulty if they need to undergo endourological treatment. Inflatable penile prostheses have an upper edge in terms of cosmetic appearance. Its method of increasing penile length and thickness is also close to natural erections. The most critical disadvantage to this type of prosthesis is its possibility to suffer mechanical damage (16).

This meta-analysis involved a total of 1,234 adult patients from studies comparing IPP and MPP. All of the studies included are retrospective cohort studies conducted in Germany, Italy, Spain, and Turkey. The average age of patients who were included in these 5 studies was between 52.6 and 58.9 years.

Patient satisfaction rate for inflatable penile prosthesis is higher than that of malleable penile prosthesis. Patient satisfaction can be affected by several factors, such as expectations about penile prostheses before implantation, incidence of post-operative pain and edema, adverse effects, usefulness of penile prostheses, ease of use, and acceptance by partners (17). A study conducted by *Jorissen et al.* in 2019 states that three-piece inflatable penile prostheses have the highest satisfaction rate. In the study, the patient satisfaction rate was 80.4% for AMS-LGX and 91.1% for Coloplast Titan. The study also suggests that patient sexual satisfaction is strongly influenced by partner satisfaction (18).

In our study, higher partner satisfaction rates for inflatable penile prostheses are obtained. The results of this meta-analysis correlate with a study conducted by *Vakalopoulos et al.*, which discovered high average EDITS scores in terms of partner satisfaction and underlined a high level of satisfaction in the management of their male partners. Regression analysis in the study shows a direct linear correlation of the satisfaction levels of male patients with female partners (19). Even though patients who underwent malleable penile prosthesis implantation feel dissatisfied with the constant stiffness in the first few days after the implantation, they will accept such condition state over time (16). A study carried out by *Akin-Olugbade et al.* discovers that patients with Peyronie's, post-radical prostatectomy, and BMI > 30 kg/m<sup>2</sup> demonstrate lower levels of satisfaction compared to other patients who underwent penile prosthesis implantation. Decreased satisfaction levels in patients with Peyronie's disease and post-radical prostatectomy are caused by decreased penile length. Meanwhile, in patients with BMI > 30 kg/m<sup>2</sup>, dissatisfaction with penile prostheses is not very apparent. However, mechanical problems related to the size of prepubic fat have been observed in this patient group. Dissatisfaction with penile prostheses in patients over 70 years of age can be attributed to proficiency in using penile prostheses (20).

Some of the negative aspects of dissatisfaction with penile prostheses are caused by unrealistic expectations about penile prostheses, reduced penile size, and unnatural erections. *Carvalho* (2015) states that unrealistic expectations about penile prostheses were reported in 11 cases and related to the wishful thinking that penile prostheses implantation could solve the patient's problems and that the prosthesis implantation could reinvigorate the desired sexual relationship. Such expectations are also present in

men who desire unprecedented sexual intercourse experience. Another study also suggests that low expectations about penile prostheses could lead to higher patient satisfaction (21).

Our meta-analysis also assesses the ease of using penile prostheses experienced by patients. Subgroup analysis comparing three-piece IPP and MPP discovered statistically significant results about the superiority of MPP in terms of ease of use. Inflatable penile prosthesis requires dexterity while using it, and one of the advantages of MPP over IPP is its ease of use (22, 23).

In other studies, it is found that at the beginning of MPP implantation, many patients felt dissatisfied due to persistent stiffness in the first few days. However, over time, MPP users exhibit high levels of satisfaction and ease because they are able to ensure fast and maximum hardness compared to IPP. This difference is based on pain and discomfort due to the presence of IPP pump in the scrotum, causing patients to become fearful and requiring them to learn more at clinics to use IPP optimally (16, 24).

The design of penile prostheses has evolved from semi-rigid and malleable to two-piece shafts and then evolved again into three-piece inflatable penile prostheses. The ideal penile prosthesis is one that can provide the most natural flaccid and erect state. Three-piece penile prosthesis can meet such criteria, but with the added mechanical components compared to the malleable prosthesis, it bore an increased risk of mechanical failures (25).

According to the meta-analysis conducted by the authors, inflatable penile prostheses are more prone to mechanical failures. More mechanical failures were observed in three-piece inflatable penile prostheses, which occurred in 38 patients. In their study, Natali et al. state that the average incidence of prosthesis leakage occurs 25.2 months after implantation. Of the 10 cases of mechanical failure in this study, the most frequent causes of mechanical failure were leaks in the prosthesis tube (40%), leaks in the saline reservoir (40%), and leaks from the connecting tube (20%). In general, there are fewer mechanical failures in malleable prostheses as their mechanical structure is simpler (26).

A study conducted by Ashton M. Smelser et al. found that 56% of cases where revision was performed on patients with penile prostheses were caused by mechanical failure. The damaged parts of the penile prostheses vary, while all components are at risk of being damaged including the pump, connecting hose, reservoir, and prosthesis cylinder. Leaks in the connecting tube and cylinder are the most frequent cause of damage to inflatable penile prostheses (27).

Leaks in the connecting tube usually occur on the bend-proof outer part of the hose connection. Ashton et al. assume that damage to the connecting tube is caused by the pump mechanism and ease of use for the patients. One type of inflatable penile prosthesis has a pump design that makes it more difficult to deflate the penile prosthesis. Thus, the connecting tube tends to bend more frequently, resulting in leaks (27).

Infection is one of the complications that need to be assessed from the results of surgery. We conducted a meta-analysis of two studies to obtain output regarding infection rates. In the meta-analysis results, there was no significant difference in the infection rates after prosthesis implanta-

tion surgery in the inflatable and malleable penile prosthesis groups. This is also in line with a study conducted by Berto et al., indicating that there is no significant difference in the incidence of postoperative infection. In general, infection in prosthesis implantation presents at a rate of 10-12%. In the study, it was also stated that all patients who experience infection in prostheses have comorbidities in the form of diabetes mellitus with metabolic disorders and increased glycosylated hemoglobin levels (28). Another study carried out by Jorissen et al. suggests that although rare, infection generally does not occur immediately after penile prosthesis implantation but can become very severe. This is influenced by the patients' comorbidities such as diabetes mellitus or others (18).

The infection rate in penile prostheses has decreased over time. Around 1980s and 1990s, the infection rate in penile prostheses ranged from 8% to 11%. Meanwhile, in early 2000, it ranged from 3% to 5%. The introduction of penile prostheses with antibiotics coating and the development of surgical techniques have decreased infection rates by about 0.3% to 2.7% (28).

In 2000, American Medical Systems (AMS) introduced a penile prosthesis with an Inhibizone™ coating, containing the antibiotics Minocycline and Rifampin that coats the surface of the prosthesis and inhibits bacterial growth. In 2004, a study by Carson explained that in the 60 days after surgery, the infection rate in patients with Inhibizone™-coated penile prostheses was 0.28% compared to 1.59% in patients with non-coated penile prostheses; six months after surgery, the penile prosthesis infection rate was 0.68% in the coated penile prosthesis group compared to 1.61% in the control group (29).

In 2002, Mentor (now Coloplast) introduced Titan, which had a hydrophilic coating that can reduce bacterial attachment and apply antibiotics to the entire surface of the prosthesis when dipped into an antibiotic solution during surgery. In 2004, Wolter and Hellstrom published data on infections from Mentor's database and the FDA's report on penile prostheses removal. One year after implantation, the infection rate on Titan prosthesis implants was 1.06% (25/2357), while that of non-coated prostheses was 2.07% (10/482) (p 0.033) (29).

The three parameters analyzed in the study (patient satisfaction, partner satisfaction, and ease of use) were analyzed using the EDITS questionnaire (30). The questionnaire was first validated in 1999 as an instrument that can be used to assess the satisfaction of patients who underwent ED therapy and their partners. EDITS questionnaire can assess subjective acknowledgment of patient satisfaction and it includes more than the efficacy of patient management (30). EDITS are validated questionnaires developed by Althof et al. to assess satisfaction after receiving medication management (31). This questionnaire was later modified by Levine to assess satisfaction after penile prosthesis implantation. The questions listed in this questionnaire assess overall patient satisfaction, the extent to which the penile prosthesis met the patients' expectations, the possibility of continued use, ease of use of the device, confidence in the ability to engage in sexual activity, patient assessment of partner satisfaction, patient assessment of their partners' feelings about continued use of the prosthesis, stiffness, and appearance (32).



This study has several limitations, among which is the fact that the studies included herein are observational studies. The reason being, to date, there is no *Randomized Control Trial* (RCT) study that examines penile prostheses. This study also does not have many reference articles. The output of this study is a general comparison of inflatable penile prostheses and malleable prostheses. This study does not specifically compare each type of inflatable penile prosthesis, be it two-piece or three-piece. Therefore, more reference articles, large-scale multicenter observational studies, and RCT research are needed to improve this study.

## CONCLUSIONS

This study concludes that inflatable penile prostheses are better in terms of patient and partner satisfaction. Even though mechanical failure is more common in inflatable penile prostheses than malleable penile prostheses, there is no significant difference in the incidence of infection. This study will make a major contribution as one of the basic considerations to produce recommendations for surgeons and urologists in considering appropriate prostheses. Further studies can make a more specific comparison of the types and success rate of pregnancy between prostheses.

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