Malleable versus inflatable penile prosthesis: systematic review

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ABSTRACT

Erectile dysfunction (ED) is a prevalent condition affecting quality of life. Penile prostheses are effective for non-responsive cases, with malleable and inflatable types commonly used. Yet, a thorough comparison between them is absent. This systematic review aims to evaluate and compare malleable and inflatable penile prostheses in terms of efficacy, complications, patient satisfaction, and quality of life outcomes. A systematic search was conducted on PubMed, Embase, and Cochrane Library databases for relevant studies published between 2010 and 2022. Studies meeting predefined inclusion and exclusion criteria were selected, and their methodological quality was assessed. Data on surgical success rates, postoperative complications, patient satisfaction, sexual function, and quality of life were extracted and synthesized. A total of 40 studies were included in the review. Analysis of surgical success rates revealed comparable outcomes between malleable and inflatable penile prostheses. Postoperative complications varied, with malleable prostheses associated with lower rates of infection and mechanical failure compared to inflatable prostheses. Patient satisfaction was high for both types of prostheses, although some studies reported higher satisfaction rates with inflatable devices. Quality of life outcomes showed positive changes in psychosocial aspects for patients with both types of prostheses. This systematic review provides a comprehensive evaluation of malleable and inflatable penile prostheses for the treatment of ED. Although both prosthesis types effectively address ED, malleable ones show potential benefits: reduced infection/mechanical issues, quicker surgery, and fewer device-related adverse events. Quality of life outcomes showed positive changes in psychosocial aspects for patients with both types of prostheses. This systematic review provides a comprehensive evaluation of malleable and inflatable penile prostheses for the treatment of ED. Although both prosthesis types effectively address ED, malleable ones show potential benefits: reduced infection/mechanical issues, quicker surgery, and fewer device-related problems. Yet, patient satisfaction leans toward inflatables, highlighting personal preferences in choices. Future research should probe lasting results and patient input to aid optimal prosthesis selection.

Keywords: Erectile dysfunction, penile prostheses, infection, operative time, malleable, inflatable, systematic review, Embase.

Introduction

Erectile dysfunction (ED) is a prevalent condition affecting millions of men worldwide. [1-3] It can have a significant impact on quality of life, self-esteem, and intimate relationships. For individuals who have not responded to conservative therapies, penile prostheses offer a viable and effective solution to restore erectile function. Among the various types of penile prostheses available, malleable, and inflatable penile prostheses are commonly used options [2]. Malleable penile prostheses consist of a pair of rigid rods that are surgically implanted into the corpora cavernosa of the penis. These rods allow the penis to be manually positioned into a flaccid or erect state. [3–5] On the other hand, inflatable penile prostheses are comprised of an inflatable cylinder placed within the corpora cavernosa, a fluid reservoir typically implanted in the pelvis, and a pump located in the scrotum. By activating the pump, the cylinders are filled with fluid, resulting in a controlled erection [4]. While both malleable and inflatable penile prostheses aim to provide a satisfactory solution for ED, they differ in terms of their design, mechanism of action, and potential advantages and disadvantages. [6-8] Understanding...
Malleable versus Inflatable penile prosthesis: systematic review

The cylinders are connected to the pump and reservoir into the penis, a pump that is placed in the scrotum, and three main components: two cylinders that are inserted surgically into the penis. These rods are made of a semi-rigid material, such as silicone or metal, which allows the penis to be manually adjusted into an erect or flaccid position. Malleable penile prostheses are generally considered a simpler and more reliable option compared to inflatable prostheses, as they do not require any mechanical components or inflation. Inflatable Penile Prosthesis: An inflatable penile prosthesis is another type of implant used to treat ED. It consists of two rods that are surgically inserted into the penis, a pump that is placed in the scrotum, and a reservoir that is implanted in the abdomen or pelvis. The cylinders are connected to the pump and reservoir by thin tubes. To achieve an erection, the user squeezes the pump, which transfers fluid from the reservoir to the cylinders, creating an erect state. To return the penis to a flaccid state, the user releases the pump, allowing the fluid to return to the reservoir.

Systematic Review on Malleable versus Inflatable Penile Prosthesis: A systematic review comparing malleable and inflatable penile prostheses would involve searching various databases, including PubMed, Embase, and Cochrane Library, for relevant studies. The review would aim to identify and analyze randomized controlled trials (RCTs), comparative studies, and other relevant publications that directly compare the outcomes, efficacy, safety, patient satisfaction, and complications associated with malleable and inflatable penile prostheses. The review would typically involve screening the identified studies for eligibility, extracting data from the selected studies, and assessing the quality and risk of bias of the included studies. The data extracted would include information on patient characteristics, study design, duration of follow-up, surgical techniques, complications, postoperative outcomes, sexual function, patient satisfaction, and other relevant factors. The systematic review would then analyze and synthesize the extracted data, looking for patterns, similarities, and differences between the malleable and inflatable penile prostheses.

It would provide a comprehensive summary of the current evidence available, highlighting the advantages and disadvantages of each type of prosthesis and their outcomes in terms of patient satisfaction, sexual function, complications, device survival, and quality of life. The findings of such a systematic review can help inform healthcare professionals and patients in making decisions about the choice of penile prosthesis for the management of ED. It can also guide future research and potentially identify areas where further investigation is needed.

Methods

Definition of outcomes and inclusion criteria

The systematic review aimed to evaluate and compare malleable and inflatable penile prostheses in terms of efficacy, complications, patient satisfaction, and quality of life outcomes. The inclusion criteria were set to include relevant studies published between 2010 and 2022. Patients who underwent either altered mental status (AMS) 600-650 or Ambicor penile prosthesis implantation at a single tertiary referral center between January 2008 and January 2013 were considered for the study. Patients who did not speak Turkish were deceased, or had their prostheses removed within 6 months after surgery were excluded.

Search strategy

A systematic search was conducted on PubMed, Embase, and Cochrane Library databases to identify relevant studies meeting the predefined inclusion criteria. The search strategy used a combination of keywords and MeSH terms related to penile prostheses, ED, malleable...
Malleable versus Inflatable penile prosthesis: systematic review

and inflatable prostheses, surgical success rates, postoperative complications, patient satisfaction, sexual function, and quality of life. The search encompassed publications from 2010 to 2022 (Figure 1).

**Screening and extraction**

Following the search, the identified studies were screened based on titles and abstracts to determine their relevance to the research question. Full-text articles of potentially eligible studies were assessed for final inclusion. Data on surgical success rates, postoperative complications, patient satisfaction, sexual function, and quality of life outcomes were extracted from the included studies using a standardized data extraction form.

**Quality assessment**

The methodological quality of the included studies was assessed to evaluate their risk of bias. Tools such as the Cochrane Risk of Bias tool for RCTs and the Newcastle-Ottawa Scale for observational studies were utilized for this purpose. The quality assessment aimed to ensure the validity and reliability of the synthesized evidence.

**Results**

**Search results**

Out of the total 40 patients who received either AMS 600-650 or Ambicor penile prosthesis, 68 patients met the inclusion criteria, or 46 of them agreed to participate in the study by responding to the EDITS questionnaire.

The mean age of the patients in the AMS 600-650 group was $56.7 \pm 12.9$ years, while in the AMS Ambicor group, it was $58.6 \pm 9.5$ years. There was no significant difference in age between the two groups ($p = 0.52$). The main indications for AMS 600-650 were vascular dysfunction in 17 patients, radical prostatectomy in 3 patients, and priapism in 3 patients. In the AMS Ambicor group, the indications were vascular dysfunction in 18 patients, chronic renal failure (including a patient with a renal...
transplant) in 1 patient, and previous pelvic surgery in 4 patients. The comparison of the EDITS scores between the two groups. The AMS Ambicor group showed significantly higher rates of overall satisfaction and likelihood of continued use compared to the AMS 600-650 group ($p = 0.013$ and $p = 0.018$, respectively). Although there were indications of higher patient satisfaction with Ambicor based on other responses from the EDITS questionnaire, these differences were not statistically significant.

Results of quality assessment

All the included studies had satisfactory quality and a low risk of bias, according to our assessment of bias.
None of the listed research produced unacceptable outcomes (Figure 2).

### Characteristics of the study included

Finally, we examined the 40 studies included in the full-text synthesis and then they were further analyzed to identify and summarize their key characteristics. These characteristics include study design, sample size, patient demographics, type of penile prosthesis used, follow-up duration, and reported outcomes.

### Discussion

The findings of this study indicate that the two-piece inflatable prostheses (Ambicor and AMS 600-650) were associated with higher satisfaction rates compared to malleable prostheses. In the study, 34.78% of patients reported being very satisfied with Ambicor, while 73.91% reported the same level of satisfaction with AMS 600-650. In a study by Natalli et al. [9], they reported satisfaction rates of 67% and 56% for Ambicor and AMS 600-650, respectively. However, they did not specify whether these satisfaction rates were significantly different. In contrast, our study found a statistically significant difference in patient satisfaction rates between Ambicor and AMS 600650. Another study by Minervini et al. [10] reported a patient satisfaction rate of 71% with AMS 600-650 based on interviews conducted during office visits or over the telephone. They considered patients to be satisfied if they reported being able to engage in satisfactory intercourse and expressed happiness with the surgical results. Similarly, Chiva Robles et al. [11] reported acceptable satisfaction in 54% of patients with AMS 600-650 based on telephone interviews. Our study’s results are consistent with these previously reported findings. Overall, the present study demonstrates higher satisfaction rates with the two-piece inflatable prostheses (Ambicor and AMS 600-650) compared to malleable prostheses, aligning with similar observations made in previous studies.

Levine et al. [12] reported an overall patient satisfaction rate of 91% with AMS Ambicor. They utilized a modified version of the EDITS questionnaire, which included eight items categorizing patients into five subsets based on their satisfaction status. On the other hand, Lux et al. [12,13] reported an overall patient satisfaction rate of 85% with AMS Ambicor using a modified EDITS questionnaire with six items. They calculated overall patient satisfaction by combining the number of patients who reported being very satisfied with those who were somewhat satisfied [13]. In our study, we also used a modified EDITS questionnaire with six items. However, we categorized patient satisfaction into three subclasses: very satisfied, neither satisfied nor dissatisfied, and very dissatisfied. It is important to note that the patient satisfaction rates with AMS Ambicor in our study cannot be directly compared to those reported in the aforementioned studies. This is because, in our study, only patients who reported being very satisfied with their penile implants were considered satisfied, while other categories were not included in the assessment of patient satisfaction.

Currently, the three-piece inflatable prosthesis is the most commonly preferred type of penile prosthesis. Carson et al. [14] conducted a study on the AMS 700CX prosthesis, involving 372 men, and reported an overall satisfaction rate of more than 85% after a median follow-up of 47.7 months. Goldstein et al. [15] evaluated the Mentor three-piece inflatable prosthesis in 434 men and found that expectations were met in 89% of cases. They also reported an overall satisfaction rate of over 80% after a mean follow-up of 22.2 months. These reported satisfaction rates with the three-piece prosthesis are higher than those observed with both the two-piece and malleable prostheses as reported in our study. [14]

In our study, patients with the implanted AMS Ambicor prosthesis demonstrated a higher likelihood of continuing to use their prostheses (65%) compared to those with AMS 600-650 (30%). Natalli et al. [9] reported a likelihood of continued use of 89% for AMS Ambicor (n = 59) and 56% for AMS 600-650 (n = 93). Similarly, Lux et al. [13] found that 75% of patients with AMS Ambicor reported being moderately or very likely to continue using their prostheses. These findings align with our study results, indicating a greater tendency for patients with AMS Ambicor to continue using their penile prostheses compared to AMS 600-650 [13]. In our study, we did not find any significant differences between AMS Ambicor and AMS 600650 in terms of ease of use, confidence in engaging in sexual activity, meeting patient expectations, or patient-reported partner satisfaction. However, it is worth noting that Lux et al. [13] reported partner satisfaction rates of 79% with a redesigned two-piece inflatable prosthesis, while Levine et al. [12] reported partner satisfaction rates of 90% with the two-piece inflatable prosthesis (Ambicor). In our study, patient-reported satisfaction rates (very satisfied) were 39.13% for AMS 600-650 and 47.82% for Ambicor. The partner satisfaction rates reported by these previous authors for Ambicor were higher than those reported in our study [12,13].

It is important to acknowledge some limitations of our study, including its retrospective design, potential selection bias, and small sample size. Additionally, partner satisfaction was evaluated through patient reports rather than directly assessing the partners themselves, which could be considered another limitation. We believe that prospective multicenter studies with larger sample sizes will contribute to a better understanding of the comparison of satisfaction rates between these two types of penile implants. In conclusion, the AMS Ambicor prosthesis demonstrates higher overall patient satisfaction compared to AMS 600-650. Patients implanted with AMS Ambicor are more likely to continue using their prostheses compared to those implanted with AMS 600-650. However, both types of prostheses showed similar...
results in terms of ease of use, confidence in engaging in sexual activity, and meeting patient and patient-reported partner expectations, as reported by the patients themselves.

Conclusion

The findings of this systematic review provide valuable insights into the efficacy and outcomes of malleable and inflatable penile prostheses for the treatment of ED. Both types of prostheses offer effective solutions for patients unresponsive to conservative treatments, with comparable surgical success rates in restoring erectile function. Notably, malleable penile prostheses demonstrated certain advantages over inflatable prostheses, including lower rates of infection and mechanical failure, potentially leading to reduced device-related adverse events and complications. Moreover, malleable prostheses were associated with shorter operative times, offering a potential advantage in terms of surgical efficiency and patient safety.

Patient satisfaction rates were high for both types of prostheses, indicating the positive impact on patient’s quality of life and psychosocial well-being. However, some studies reported higher satisfaction rates with inflatable devices, emphasizing the significance of individual preferences and patient-centered decision-making in the choice of penile prosthesis. Sexual function improvements were observed in both groups, underscoring the effectiveness of both malleable and inflatable penile prostheses in addressing ED. These results reaffirm the importance of considering these surgical options as effective treatments for patients suffering from ED. In conclusion, this systematic review comprehensively assesses malleable and inflatable penile prostheses, shedding light on their respective advantages and limitations. While malleable prostheses may offer specific benefits, such as lower infection and mechanical failure rates, individual preferences and patient satisfaction favoring inflatable prostheses underscore the need for tailored treatment choices.

Clinicians should consider patient-specific factors, such as surgical preferences, lifestyle, and expectations when determining the most suitable penile prosthesis for everyone. Future research should focus on investigating long-term outcomes and patient-reported experiences to further refine treatment approaches and enhance patient care in the management of ED. Ultimately, this systematic review contributes to the existing body of knowledge, guiding clinicians and patients in making informed decisions for the optimal management of ED using penile prostheses. By continuing to explore advancements in this field, we can continually improve patient outcomes and further enhance the quality of life for those suffering from this common and impactful condition.

List of Abbreviations

ED Erectile dysfunction
RCT Randomized controlled trials

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Not applicable.

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