Key Factors and Influencers Impacting the Penile Implant Decision

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Disclosure

• Study was funded by American Medical Systems (AMS)
Introduction

• A typical treatment algorithm for erectile dysfunction (ED):
  - Phosphodiesterase Type 5 Inhibitors (PDE5i)
  - Intercavernosal Injection
  - Vacuum Erection Devices
  - Penile Implants

• Penile implants are a well-established solution, with over 40 years of history.

• Little is known about how men make the decision to receive a penile implant.
Study Objective

To explore the primary factors and relative influencers in the decision to move forward (or not move forward) with a penile implant.
Methods

• Two quantitative studies were conducted

• Both approved by an independent IRB

• Both informed and directed by initial qualitative study

• Both studies funded by American Medical Systems (AMS)
Methods: Study One

- N=257
- Men who had attended AMS sponsored Patient Education Seminars on ED:
  - Highlight the spectrum of ED treatment options
  - Implanting urologist
  - Patient Champion
- Assessment at three time points following seminar:
  - 1-2 months (n=43)
  - 3-6 months (n=80)
  - 12-16 months (n=134)
- Conducted by the research vendor KJT Group
Methods: Study Two

- Men who had a recommendation from a urologist to receive a penile implant (N=61)
  - Elected to have implant surgery (N=31)
  - Elected not to have implant surgery (N=30)

- Primary purpose:
  - Highlight the differences between these two groups.

- Conducted by the research vendor Biovid.
Methods: Both Studies

• Survey conducted by phone

• Questions developed for this research
  - Informed by initial qualitative study
  - Reviewed by two experts (CN, JM)

• Took approximately 30 minutes
Methods: Content Assessed

• Both Studies:
  – ED history
  – The impact of ED
  – The ED therapies tried
  – Relative satisfaction of ED therapies

• Study One only:
  – The seminar itself
  – Potential barriers to penile implants
  – Potential facilitators to penile implants

• Study Two only:
  – The effectiveness of the implant discussion
Results
Stakeholders Driving the Implant Decision

The decision process is driven by three main stakeholders: the physician, the patient and the spouse/partner, each of whom play a significant role in the implant decision. Interestingly, both implanters and non-implanters agree with the relative level of influence for each stakeholder.

Q25. How much influence did each of the following people or groups of people have on your decision regarding the implant surgery?

Implanters (n=31)
- Friends/Family: 4%
- Urologist: 36%
- PCP: 4%
- Spouse/Partner: 23%

Non-Implanters (n=30)
- Friends/Family: 5%
- Urologist: 29%
- PCP: 10%
- Spouse/Partner: 27%
Trust in their Urologist and support from their spouse/partner convince patients that a penile implant is their best option. However, others are held back by the implications and permanence of surgery, and concern about making the wrong decision.

### Contribute Toward Surgery
1. Of the options available, it was the best solution for me
2. I was comfortable with my urologist's recommendation and trusted them
3. I was comfortable with my urologist performing the surgery
4. Support from my spouse/partner
5. I believed that surgery would have a positive impact on my relationship

### Prohibit Decision For Surgery
1. Scarring or long term pain associated with surgery
2. Surgery is permanent and irreversible
3. A better solution could be available in the future
4. Implant is not “natural”
5. Concern about how my partner might react

#### Implanters
- Implanters (n=31)

#### Non-Implanters
- Non-Implanters (n=30)

Q23. Please rank the most important factors in your deciding to have the implant surgery.
Q24. Of the concerns that you had regarding the penile implant surgery, please rank the most important factors in your ultimate decision not to have the implant surgery.
**Increased certainty that it is the best option for my ED** is the main reason that would increase the likelihood a seminar attendee would have the procedure. **Spouse/partner on board with the decision**, and a **stronger recommendation from physician** are also seen as important factors.

### Factors That Would Increase Likelihood of Having the Procedure

**Base: NOT LIKELY TO UNDERGO OR NOT SURE**

Q806a. What, if anything, would increase your likelihood of having the procedure in the future?
### What Would Help Non-Implanters Move Forward?

Most non-implanters have not heard first hand accounts about an implant, and 40-50% of those patients say that opportunity would help them move forward. Additionally, most who do not have support from their partner indicate they would move forward if that support existed.

<table>
<thead>
<tr>
<th>Statement</th>
<th>% of Non-Implanters who did not</th>
<th>Extremely/Very Likely to Influence Their Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have spoken to someone who has an implant and is happy with it</td>
<td>43%</td>
<td>70%</td>
</tr>
<tr>
<td>I attended a seminar or info session about penile implants</td>
<td>44%</td>
<td>60%</td>
</tr>
<tr>
<td>I saw video of patients talking about the benefits of penile implants</td>
<td>50%</td>
<td>47%</td>
</tr>
<tr>
<td>I saw data that outlined the success rates of penile implants</td>
<td>38%</td>
<td>43%</td>
</tr>
<tr>
<td>I had support from partner/spouse</td>
<td>82%</td>
<td>37%</td>
</tr>
<tr>
<td>I saw data around the durability of penile implants</td>
<td>36%</td>
<td>37%</td>
</tr>
<tr>
<td>I had information about penile implants that was relevant to my spouse/partner</td>
<td>40%</td>
<td>33%</td>
</tr>
<tr>
<td>I saw photos of a patient with an implant</td>
<td>40%</td>
<td>33%</td>
</tr>
<tr>
<td>I discussed the implant with both my doctor and my spouse/partner</td>
<td>80%</td>
<td>17%</td>
</tr>
</tbody>
</table>

**Q22.** Please indicate whether the following statements are accurate of your penile implant decision process.

**Q37.** Earlier you mentioned that each of the following statements were not true to your personal experience. Now, please consider how your decision may be impacted if each of these statements **were true.** Please indicate the likelihood that each statement would influence your decision to perhaps move forward with the penile implant surgery.
The greatest concerns with getting a penile implant are partner satisfaction and potential surgical risks such as complications, infection, pain, anesthesia, invasiveness, or side-effects.

### Level of Concern about Penile Implant Procedure (Non-Implant Patients)

**Rated using a 5 point scale where a 1 means “Not at all concerned” and a 5 means “Extremely concerned”.**

<table>
<thead>
<tr>
<th>Concern</th>
<th>Not Sure</th>
<th>Mean (Missing removed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>My partner’s satisfaction with the implant</td>
<td>6%</td>
<td>3.8</td>
</tr>
<tr>
<td>Potential surgical risks such as complications, infection, pain,…</td>
<td>3%</td>
<td>3.9</td>
</tr>
<tr>
<td>Insurance coverage for the implant</td>
<td>5%</td>
<td>3.6</td>
</tr>
<tr>
<td>Potential implant malfunction</td>
<td>4%</td>
<td>3.7</td>
</tr>
<tr>
<td>The implant’s impact on penile sensation</td>
<td>5%</td>
<td>3.6</td>
</tr>
<tr>
<td>The implant’s impact on orgasms</td>
<td>8%</td>
<td>3.5</td>
</tr>
<tr>
<td>Ability to pay for the implant</td>
<td>6%</td>
<td>3.3</td>
</tr>
<tr>
<td>Cost of the implant</td>
<td>5%</td>
<td>3.3</td>
</tr>
<tr>
<td>The ability to conceal the implant</td>
<td>5%</td>
<td>3.3</td>
</tr>
<tr>
<td>Missing the ability to have natural erections</td>
<td>7%</td>
<td>3.3</td>
</tr>
<tr>
<td>Recovery time</td>
<td>6%</td>
<td>3.4</td>
</tr>
</tbody>
</table>

Base: NON-IMPLANT PATIENT  (n=240)

Q815. Still thinking about a penile implant procedure, please rate your level of concern with the following.
Conclusions

• The patient, partner, and urologist are equal stakeholders in the implant decision
  – May be important to engage the partner in the discussion

• Factors facilitating penile implant:
  – Implant is the best solution
  – Comfortable with urologist and/or procedure
  – Support from partner