Devices for continence and prolapse

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Women of all ages and social and cultural backgrounds can be affected by prolapse, urinary incontinence and faecal incontinence. For most, a cure can be found with the right investigation and subsequent treatment. For some, however, a cause can take time to be established, some may not want medical or surgical treatment, and for others a cure is not always possible. For these groups of women, devices may be a suitable option.

PELVIC ORGAN PROLAPSE

Devices have been used to control vaginal prolapse for many years, before the advances in anaesthesia surgical techniques were the only method of treatment. Hippocrates described treatments for prolapse including suspending women upside down from a ladder while the frame was moved up and down in an attempt to restore pelvic organs to their proper position (Fig. 1). A variety of materials have been used to hold prolapsed organs in position, including cloth, wood, metal, ivory, sponge and cork. Most vaginal pessaries today are made of silicone or inert plastic. They do not absorb odours or secretions and can be autoclaved. There are many types and sizes of pessaries but most clinicians manage with a limited number. A survey carried out looking at pessary use by members of the American Urogynaecological Society found the ring pessary was used as first choice in women with anterior, posterior wall prolapse (Table 1).

Although no study has been carried out here in the UK, such a study’s findings would probably not be dissimilar to those carried out in the USA. There are a wide variety of vaginal pessaries that are becoming more widely available and the type of pessary used will depend on the direction and extent of the protruding organ. Currently in the UK, the most common pessary is the ring pessary, followed by the shelf pessary for more severe prolapse (Fig. 2). Until recently many alternative types of pessary have been difficult to obtain in the UK market, but it is now possible to import these both from the USA and Europe.

In broad terms there are two types of pessary. Those that support, which are commonly used for first- or second-degree prolapse (e.g. Ring, Gehrgun and Hodge) (Fig. 3); and those that are ‘space-occupying’, which are commonly used for third-degree prolapse (e.g. Cube, Inflatoball, Donut, Gelhorn, Shelf) (Fig. 4). First-degree prolapse is traditionally defined as within the vagina, second degree...
descent to the introitus and third degree descent outside the introitus. The use of double vaginal rings has been evaluated in elderly women with advanced prolapse. The authors hypothesised that their success rate was because a double vaginal ring acts both as a support pessary and a space-occupying pessary. Women need to be carefully evaluated before pessary placement. Although a bimanual examination and measurement of vaginal length will give an estimate of the size of the vagina, pessary size is often down to trial and error. Explanation of pessary placement is mandatory as well as by consent, and other treatment options should be discussed. Thakar and Stanton give a good review on this. Insertion is likely to be more comfortable if the woman has emptied her bladder and bowel. For the clinician a dry glove is preferable to allow better grip, with the use of minimal lubrication. It should be inserted gently and once in place the woman should be asked to bear down. If the pessary is expelled a larger size should be inserted. Once it seems well fitted the woman should be encouraged to walk around. If she reports any discomfort or pain the pessary is likely to be too big and a smaller one should be tried. Women need to be reassured that no harm is done if the pessary falls out but a contact number should be given. If they experience any discomfort, discharge or bleeding they should contact their clinician. There is no specific data on the use of pessaries during sexual intercourse but a space-occupying pessary would limit this. A check up should be arranged within a month and any change in bladder or bowel function should be addressed.

Fig. 3. Support pessaries in situ for grade 1–2 prolapse.

Fig. 4. Space occupying pessaries in situ for grade 3 prolapse.
If atrophy is present or occurs topical oestrogen cream should be applied. Women with thin vaginal mucosa are more susceptible to ulceration with the use of a pessary. Oestrogen helps the vaginal mucosa become more resistant to ulceration\(^6\) as well as treats minor symptoms of vaginal irritation and discomfort. Short-term topical preparations are preferred because of their rapid effect and limited systemic absorption. If there are no problems, pessaries can be changed every 6–9 months. At follow-up the vagina should be inspected for any ulceration and the pessary left out until the ulcer has healed. The ulcer is usually treated with oestrogen cream, but a biopsy may be indicated for anything suspicious.

There are little data on the outcomes of pessary management but a US paper looked at 110 women with symptomatic prolapse to evaluate a simplified protocol.\(^7\) 74% women were fitted successfully with a pessary. Interestingly, five out of the six women who were fitted with a cube pessary developed vaginal erosions, compared with three out of the 101 women using a ring pessary. Other studies have shown 64.3% as an initial satisfaction of pessary use, although this dropped to only 33.9% at a year (28.5% were lost to follow up).\(^8\)

Some vaginal pessary devices have been designed to address stress incontinence at the same time as mild to moderate prolapse (Fig. 5), although there is little data on their effectiveness. They are thought to work either by support and/or elevation to the bladder neck with the inclusion of a knob to the design. However, the success rate of the incontinence ring pessary was poor with a reported 69% of women reporting no appreciable change in incontinence.\(^9\)

**URINARY INCONTINENCE**

The main aims of specifically designed continence devices have been to manage stress incontinence – with or without prolapse. These include (a) external urinary collection devices or appliances, (b) intravaginal devices that support the bladder neck, or (c) occlusion devices that are (i) external to the meatus, or (ii) intraurethral. There are limited devices for faecal incontinence that will be outlined later.

In recent years there has been a wide variety of new continence devices developed.\(^10\) Although interest

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**Fig. 5. Vaginal pessaries used for incontinence.**

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**Table 1. Pessary use for prolapse.**

<table>
<thead>
<tr>
<th>Choice</th>
<th>Anterior (n = 247)</th>
<th>Vault (n = 207)</th>
<th>Posterior (n = 174)</th>
<th>Procedentia (n = 216)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st</td>
<td>Ring 124 (50%)</td>
<td>Donut 52 (25%)</td>
<td>Ring 82 (47%)</td>
<td>Gelhorn 84 (39%)</td>
</tr>
<tr>
<td>2nd</td>
<td>Hodge 57 (23%)</td>
<td>Ring 41 (20%)</td>
<td>Hodge 33 (19%)</td>
<td>Donut 41 (19%)</td>
</tr>
<tr>
<td>3rd</td>
<td>Gehring 37 (15%)</td>
<td>Gehhorn 27 (13%)</td>
<td>Gehhorn 31 (18%)</td>
<td>Inflatoball 26 (12%)</td>
</tr>
</tbody>
</table>

continues with clinicians and patients, many of the devices have never made it on to the market or have been removed from the market shortly after release. Until these products become more widely available, they will continue to be limited to specialist units in controlled trials.

Women need to be highly motivated, have adequate manual dexterity and be willing to insert the particular device. It is reported that only 30% of women are comfortable about the concept of touching their genitalia and that this attitude is age-dependent. Only 21% are willing to insert a continence device into their vagina and only 15% felt very comfortable about inserting a continence device in to their urethra.

**External urinary collection devices or appliances**

**Body-worn female appliances**

External urine collecting devices are now rarely used and are no longer considered satisfactory appliances for women with urinary incontinence. Application of these products is often problematic due to variations in individual anatomy and technical problems with device adherence to the periurethral area.

**Female urinals**

The female urinal is a viable alternative to a commode and may benefit women who are on social outings or are wheelchair/bed bound. The ranges of products are however, little used, little known and undervalued.

**Devices that support the bladder neck**

There have been a number of devices that have been used to support the bladder neck over the years. For many years tampons have been used and as described before, many clinicians still use ring or hodge pessaries and contraceptive diaphragms.

Specially designed bladder neck prostheses have been developed in more recent years. The Introl (J & J Medical K.K) is a reusable silastic intravaginal ring, with two prongs. It is inserted behind the symphysis to support the bladder neck. Initial studies were promising with an improvement rate of over 83%. However, a further study revealed problems with both efficacy and sizing of the device and 60% of women eventually withdrew.

Contiguard (Coloplast) is a single-use disposable device made of polyurethane foam. It is presoaked, folded and placed into the sagittal plane in the vagina using an applicator. It forms a supportive cushion under the urethrovaginal junction and when dampened, it expands by 30%. In initial studies urinary leakage was significantly reduced ($P < 0.0005$) but further evaluation revealed 25% of women dropped out of the study due to vaginal irritation and in those that continued 62% still complained of local discomfort. In a more recent study an updated new device (Contrelle) (Fig. 6) revealed that two-thirds of the women studied preferred the new device to the old one. This may be due to the more user-friendly design that is cylindrical in shape and can be placed into the vagina without pre-soaking as well as supplied ready for insertion in an applicator. Unfortunately this newer device is not available on the UK market.

There is a small reported trial on the Contiform (Free-spirit) that revealed that only 20% of women were dry using the device.

Devices that aim to support the bladder neck seem to demonstrate a mild to moderate level of efficacy in women with light to moderate incontinence. Although there are minimal serious side-effects local irritation can be a problem. There are unfortunately no long-term data looking at efficacy or the issues of cost.

**Occlusive devices**

Occlusive devices block urinary leakage at the external urethral meatus. They use adhesive or gentle suction to obstruct urinary loss. Mild compression to the wall of the distal urethra caused by the device is also thought to achieve continence.
The three most reported devices of this type are the Miniguard, FemAssist (Insight Medical) and Capture (C. R. Bard, Inc).

External urethral occlusive devices seem to be efficacious in a small number of women with mild incontinence, although without proper adherence to the peri-meatal area they can become ineffective and cause local irritation. They are not considered as a recommended treatment for non-surgical management of incontinence.

Intra-urethral devices

Devices that are inserted into the urethra to block urinary leakage include the Urethral Plug, Reliance Insert and the Femsoft (Fig. 7). All these devices have a small meatal plate to prevent intravesical migration. They are disposable, single use and need to be removed to void.

The most recently reported device is the Femsoft (Rochester Medical Corp.). A 5-year ongoing, nonrandomised controlled, multi-centre study with 150 women revealed a statistically significant reduction in pad loss with the device in situ. Unfortunately 51% withdrew and there was a reported 31.1% incidence of urinary tract infection.

These results were not dissimilar to other reported devices of this type. The intraurethral devices have all reported high rates of efficacy but with associated high morbidity. The major morbidities are discomfort, urinary tract infections and haematuria. The most serious problem is migration of the device, which requires endoscopic intervention for removal.

Devices for faecal incontinence

Body-worn female appliances

There is one main type of body worn device made by Hollister. It can be difficult to adhere and requires the patient to be shaved. It is mainly used in the immobile or in an intensive care setting. It can be useful for loose stool and when applied successfully will stay in situ for 3 days.

Plug devices

There have been a few studies looking at the use of anal plugs (Fig. 8). They are reported to be efficacious but many patients are unable to tolerate them. A recent study looking at 20 men and women found that only four (20%) were able to tolerate them.

In summary devices for incontinence and prolapse do not suit everyone and no one product suits women with the same complaint. They are not always readily available, are often expensive and some devices are associated with high morbidity. Women need to be highly motivated, have proper instruction in their use and require ongoing support.
to use them. They should be considered as part of overall containment strategies rather than active treatment as there is no evidence that they improve continence or prolapse.

References