Testicular Prosthesis in Paediatric Urology: Current Concepts and Available Alternatives

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Abstract: Prosthesis is an artificial material used as a replacement for its natural counterpart. Use of testicular prosthesis in paediatric urology is limited and indications are well defined. In this review we tried to find out and summarize the current indications and available options in paediatric urology for these prostheses.

Keywords: Anorchia, Orchidometer, Testicular prosthesis

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Introduction

Prosthesis is an artificial material used as a replacement for its natural counterpart. Use of testicular prosthesis in paediatric urology is limited and indications are well defined. In this review we tried to find out and summarize the current indications and available options in paediatric urology for these prostheses. An extensive PubMed, Medline and Google scholar search was done to see the available literature and current practice. For the purpose of simplicity the subsequent discussion is under following heads:

- Indications
- Assessment of size required
- Timing
- Procedure
- Complications
- Evolution and currently available options
- Experimental prostheses which are promising

A). Indications of testicular prosthesis placement: Testicular prosthesis is required in following conditions.

1). Congenital anorchia (vanishing testis or pure gonadal atresia)
2). Acquired anorchia due to

- a). Trauma
- b). Tumor
- c). Torsion
- d). Dysplasia
- e). Dysgenesis
- f). Intersex disorders requiring male genitoplasty

B). Assessment of the size of prosthesis required:

This entirely depends upon the age at placement of the prosthesis and the scrotal development. The assessment of the volume of testis is done using an instrument called as Orchidometer/Orchiometer. The orchidometer was introduced for the first time by Swiss paediatric endocrinologist Prof. Andrea Prader[1] of university of Zurich in 1966. It consists of a string of twelve numbered wooden or plastic beads (some time referred as Prader’s balls, medical worry beads or endocrine rosary) of increasing size from one to twenty-five milliliters (Fig 1).

![Fig. 1. Prader’s orchiometer](Image)

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The beads are compared with the testicles of the patient, and the volume is read off the bead which matches most closely in size. Prepubertal sizes are 1-3 ml, pubertal sizes are considered 4 ml and up and adult sizes are 12-25 ml. A number of other orchidometers are also available and marketed commercially for the assessment of testicular volume but still prader’s orchidometer is the most commonly used orchidometer in clinical practice.

**C). Timing of placement of testicular prosthesis:**

The timing of insertion of a testicular prosthesis in a child is not straightforward. The psychological impact of an absent testicle in a child or adolescent is a good reason to consider prosthesis placement at the time of the initial surgery for a cryptorchid testis. As the size is the limitation in this case it may necessitate further surgery to insert a larger prosthesis when the child gets older. However, if a child is satisfied with the size of the original prosthesis, further surgery can be avoided. An alternative strategy is to delay the placement of the definitive prosthesis until the child reaches adolescence. Prosthesis placement at a later age has a limitation that due to the prolonged cryptorchid state scrotal hypoplasia renders further prosthesis placement difficult ultimately leading to the placement of prosthesis of smaller size. This is apart from the psychological trauma of prolonged state of anorchia. Methods for increasing scrotal space for the placement of a testicular prosthesis include the use of tissue expanders such as a silicone balloon attached to a filling port or a Foley catheter balloon. It is thus accepted that a testicular prosthesis should be placed at the time of initial surgery and changed to larger size at a later age if required.

**D). Procedure of placement of testicular prosthesis:**

Of historical interest, intracapsular insertion of a testicular prosthesis following subcapsular orchidectomy using a scrotal incision in patients with advanced prostate cancer was first described by Tolson in 1944 and endorsed as recently as 1984. In 1972, Abbassian described the insertion of a testicular prosthesis in a subcuticular pouch which was said to be useful in patients with extensive atrophy and scarring of the scrotal area. A skin incision was made in the opposite hemi-scrotum ensuring not to cross the midline raphe. Through this incision, a subcuticular pouch was created for the prosthesis in the empty hemi-scrotum. However, this procedure was associated with a high incidence of prosthesis extrusion. To minimise the risk of extrusion of the prosthesis, Latimmer advocated a high scrotal or low inguinal incision, anchoring the prosthesis to the bottom of the scrotum and narrowing the upper scrotum with additional sutures. This technique was difficult to perform in the presence of a contracted or scarred hemiscrotum. In such circumstances, an appropriate space may be created using a sponge-holding forceps or by using the balloon of a Foley catheter. Fortunately such situations are less seen in paediatric urology. Currently, most paediatric surgeons use a low groin incision whenever possible to implant a testicular prosthesis. This is associated with a lower risk of infection and extrusion. A finger is then placed into the scrotal sac and the potential space created. The most dependant part of the scrotum is subsequently inverted and the prosthesis secured with a PDS suture placed through its suture loop. During transfixation of the dartos, particular care must be taken to avoid skin penetration and, thereby, promote infection and possible extrusion of the prosthesis. All prostheses are generally placed surgically on an outpatient basis. Prior to placement all patients should receive perioperative intravenous antibiotics (surgeon choice) and thorough skin preparation with an iodine or chlorhexidine based scrub. The prosthetic device is bathed in antibiotic solution and filled through the self-sealing injection port with normal saline (0.9%) with displacement of all air until the softest possible fluid consistency is achieved without dimpling of the prostatic wall.

**E). Complication of testicular prosthesis insertion:**

Marshall reviewed the records of over 2500 testicular prosthetic implantations to establish a list of postoperative complications and their incidence (Table 1). Prosthesis extrusion, the commonest complication, mainly occurred in patients following orchidectomy for epididymo-orchitis, especially if a scrotal incision had been used to implant the device. Marshall also noted that previous scrotal surgery and a long lag time between orchidectomy and the insertion of the prosthesis increased the risk of developing complications. There has been a case report of spontaneous rupture of a silicone testicular prosthesis 11 years after its insertion. The spread of silicone to inguinal lymph nodes is also documented in a case report but, as mentioned previously, there is no evidence of autoimmune disease or malignancy developing following testicular prosthesis implantation. Turek et al also reviewed their series of testicular prosthesis for complication and noted a complication rate as shown in table 1. In current practice, the most common postoperative complaints concern body image, namely that

<table>
<thead>
<tr>
<th>Complication</th>
<th>Marshall et al</th>
<th>Turek et al</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extrusion</td>
<td>3.8%</td>
<td>2%</td>
</tr>
<tr>
<td>Scrotal Contraction</td>
<td>3.5%</td>
<td>2%</td>
</tr>
<tr>
<td>Pain</td>
<td>1.3%</td>
<td>9%</td>
</tr>
<tr>
<td>Hematoma</td>
<td>0.3-3%</td>
<td>1%</td>
</tr>
<tr>
<td>Infection</td>
<td>0.6-2%</td>
<td>Nil</td>
</tr>
</tbody>
</table>

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the device is incorrectly sized/shaped or that it is too high in the hemi-scrotum.[14]

F). Ideal testicular prosthesis:

Ideal testicular prosthesis is one which is chemically inert and does not elicit any inflammatory or hypersensitivity reaction. The material should also resist mechanical strains, take and hold the desired form, be amenable to sterilization and be a proven non-carcinogen.

G). Evolution and currently available options:

Multiple materials have been used for testicular prosthesis. The first testicular prosthetic device was implanted in 1939 by Bowers using the metal alloy vitalium. Vitalium was an alloy composed of cobalt, chromium and molybdenum.[15] In 1943; testicular prostheses made of Lucite were available in a range of sizes.[16] During the 1950s, numerous other materials, including glass marbles, were used.[17] Gelfoam was also used by specifically injecting it into the tunica albuginea following intracapsular orchidectomy performed on patients with metastatic prostate cancer.[18] Plexiglass, Dacron and polyethylene prostheses have also been used without much success. Subsequently in an effort to develop a more cosmetically acceptable prosthetic various materials have been used, including polymerized methyl ethacrylate, methacrylate and polyurethane foam. A dramatic improvement in device consistency was achieved by Lattimer et al in 1973 with a silicone gel filled, silicone rubber prosthesis.[19] Used widely until 1995, manufacture of this device was discontinued because of emerging concerns over the association of silicone implants with connective tissue disease.[20] As a result, silastic and solid silicone rubber prostheses were developed for use in the 1960s.[21] Currently firmer, silicone-coated saline filled product has become the standard prosthesis since 1988.

H). Currently used prosthesis:

There are four companies (Nagor Ltd, Douglas, Isle of Man, UK; Mentor Medical Systems Ltd, Wantage, Oxon UK; Osteotect Plastic Surgery, Dorset, UK; and Silimed, Dieburg, Germany) that supply the majority of testicular prostheses. Osteotect Plastic Surgery supplies the Perthese prostheses. Nagor prostheses are produced as silicone-gel filled and elastomer versions whereas the Silimed implant is only available in the elastomer version, which has a more solid consistency. The Perthese implant is produced in the gel-filled version; however, Mentor Medical Systems provides a re-inforced silicone elastomer version called the Soft-Solid Testicular Prosthesis (SSTP). They also provide a saline-filled prosthesis which has recently received FDA approval and is the only licensed testicular prosthesis available for common usage in the US. The weight, shape and texture of the Mentor SSTP is designed to approximate the normal testicle and is only licensed for investigational purposes in North America.

The company is currently conducting a clinical study to evaluate the safety of its SSTP. A brief description of these prostheses is as under.[22]

a). The Coloplast (formally Mentor) Saline Filled Testicular Prosthesis: This device is about the same weight, shape and softness of a normal testicle. It comes in four sizes-extra-small, small, medium and large. The implant is made of a molded silicone elastomer shell that is approximately 0.035 inches thick. It is not visible on X-ray. The device is filled with saline at the time of surgery and just prior to implantation. It includes a self-sealing injection site at one end that allows for filling with a sterile saline solution. On the opposite end of the implant is a silicone elastomer tab that enables suturing and securing the implant into a set position, if this is desired. The average cost of one prosthesis ranges from $3000-3500.

b). The Coloplast (formally Mentor) Soft-Solid Testicular Prosthesis. This is not US FDA approved, thus is only available in certain countries outside the US. The SSTP is made in five sizes: Extra-small, Small, Medium, Large, Extra-large. The device consists of a molded silicone elastomer shell, ranging from 0.012-0.018 inches thick, filled with cured silicone elastomer. A silicone elastomer Dacron reinforced patch for suturing the prosthesis in position is located at one end of the device shell. This is indicated for cosmetic testicular replacement when the natural testicle has been removed. The weight, shape, and texture of Mentor soft-solid testicular implants is designed to approximate normal testicles, providing patients with a more natural looking and feeling scrotum. They are intended to aid in the restoration of a normal physical appearance for male patients of all ages with one or more missing testicles.

c). Sientra’s (formally Silimed) Silicone Elastomer Implant aka Oval Carving Block: The Sientra’s oval carving block is composed of an envelope made of chemically and mechanically resistant silicone elastomer which is thin, soft, smooth of surface and contains a certain amount of elastomer whose shape, density and overall consistency have been chosen to make it as similar as possible to the shape and feeling of the human testis it replaces. All materials used are medical grade and proven to be biocompatible (is safe and tolerated well by the body). The silicone envelope membrane is made of a compound of dimethyl polysiloxane and dimethyl fluoror silicone copolymer. The silicone envelope is filled with an elastomer mixture of reinforced dimethyl methylvinyl siloxanes with reinforced dimethyl methylhydrogen siloxanes. Applied Silicone Corporation manufactures the material. Silimed’s oval carving block Silicone Implants are available in 5 sizes. Sientra’s oval carving block implant is pending approval by the FDA.
d). Custom made testicular prostheses: These are cheaper alternative to the commercially available prostheses. These are made of Teflon which is custom carved into the desired shape, autoclaved and implanted. The disadvantage is the hard feel which is non-physiological.

I). Experimental promising alternatives:

a). Tissue engineered testicular prosthesis with internal support:

In an experimental study conducted by Zhongguo Xiu et al.[25] the chondrocytes were isolated from the swine articular. The PGA scaffold was incorporated with medpor, of which semi diameters were 6 mm and 4 mm respectively. Then, the chondrocytes (5 x 10^7 /ml) were seeded onto Medpor-PGA scaffold and cultured for 2 weeks. The cell-scaffold construct was implanted into subcutaneous pockets on the back of nude mice. Mice were sacrificed to harvest the newly formed cartilage prosthesis after 8 weeks. Macroscopy, histology and immunohistochemistry observations were made. The gross observation showed that on changes were in shape and at size, the color and elasticity were similar to that of normal cartilage and that the cartilage integrated with Medpor in the experimental group. The newly formed complex of Medpor-PGA and cells was very similar to testicle in gross view and to normal cartilage in histology. This pilot technique of creating testicular prosthesis by incorporating tissue-engineered cartilage with Medpor demonstrated success. This however requires a long journey to be practically applicable.

b). Tissue engineered testicular prostheses with prolonged testosterone release:

In an experimental study by Raya-Rivera et al.[26] chondrocytes, harvested from bovine articular cartilage, were seeded on testicular shaped polymer scaffolds at a concentration of 100 x 10^6 per ml. The scaffolds were maintained in a bioreactor for 4 weeks to form cartilage tissue. Subsequently, testosterone enanthate (100 microgram) was injected into the central hollow space of each testicular prosthesis, and maintained for 40 weeks in culture. A sample of the medium was collected every 2 days for testosterone assays. Another group of ex vivo engineered testicular prostheses was implanted into the scrotal space of castrated athymic mice. Intratesticular injection of testosterone enanthate was made into each prosthesis at a concentration of 100 microgram. Control groups consisted of animals with castration only and sham operations. Testosterone levels were measured prior and 2 weeks after castration, 1 day after testosterone administration, and weekly up to 14 weeks. The engineered testicular prostheses were retrieved at sacrifice for histomorphological and immunocytochemical analyses. They found that ex vivo prostheses showed an initial burst effect of testosterone followed by a broad plateau for 16 weeks (>500 ng/dl) and a decreased level of testosterone until 40 weeks. The testosterone levels were physiologic throughout 40 weeks and the entire testosterone released was calculated as 60% of the injected volume. The circulating testosterone levels in the prostheses implanted animals demonstrated a maximum peak on day 1 and a continued physiologic range during the entire study period. Histologically, the retrieved testicular implants showed mature chondrocytes with a hollow center in each prosthesis. This study demonstrates that engineered cartilage testis can be created in bioreactors, can be implanted in vivo, and can release testosterone for a prolonged period. Furthermore, the levels of testosterone release can be maintained within the physiologic range. Periodic reinjection may potentially provide permanent physiologic hormonal replacement. This novel technology may be beneficial for patients who require testicular prostheses and chronic hormone supplementation. However, this needs to be tried in humans.

Conclusions

A number of available options are available. There are only few which are FDA approved but are still being used. Most of them have a limitation in developing countries due to their high cost thus making custom made Teflon prosthesis as an available alternative. There are many promising experimental studies being conducted that may change the management protocol in near future.

References