Biomaterials in gynecological surgery

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The need for prosthesis grafts in gynecological surgery

In the past, genital prolapse and urinary incontinence were thought to be the result of overstretched endopelvic fascia and muscles. Surgery was therefore directed towards plicating these tissues. Over a period of time, surgical failure rates have revealed themselves because of increasing longevity and more women remaining active till a later age. Newer thoughts on the pathoanatomy of pelvic floor damage suggest that the damage is not due to overstretching but there are breaks in the endopelvic fascia which should be reinforced in a site-specific manner. Also, there is degradation in the quality of collagen in the endopelvic fascia with age and menopause.

Endopelvic fascia takes 3 months to regain 70% of its strength. Polyglycolic acid retains 70% strength for 21 days. To support the complete regaining of facial strength after surgery, we need material which lasts longer. Permanent sutures are not suitable for vaginal surgery. The choice therefore, is leaning towards the use of prosthesis in such surgery.

Requirements of prosthesis and need for biomaterials?

The most essential property of good prosthesis for gynecological surgery is its ability to be incorporated into endopelvic tissue. This is possible when the mesh pore size is greater than 75 microns which allows the ingrowth of blood vessels and therefore of fibroblasts and collagen. The prosthesis should be histologically well tolerated and resist infection. Mechanical properties should include elasticity (to allow for pliability and prevent hardening) and resistance to shrinkage. As a practical feature, biomaterials should be an economically viable choice.

The perfect prosthesis is elusive. In recent times the desirable outcomes like durable anatomical support and pliable functionality seem to have taken prosthesis research in opposite directions.

Present prosthesis choice

The available prostheses for gynecological surgery are –

**Autologous** – fascia lata, rectus fascia

**Allogenic** – cadaveric fascia lata, cadaveric dura mater, dermis (alloderm, axis, acellular collagen matrix)

**Xenogenic** – pelvicol (porcine dermal), surgisis (porcine acellular small intestinal submucosa)

**Synthetic** – polypropylene (TVT, TOT), polyester mesh, marlex, prolene, combinations

Autologous grafts have the disadvantage of needing a second surgical site with related complications. Besides collagen is of the same damaged quality as that which has given way in the pelvis. This leads to high recurrence rates. On the other hand, synthetic grafts provide durable anatomical support.

Their role in suburethral slings (TVT, TOT) and abdominal sacrocolpopexy is well established. However, typical graft use in vaginal repairs involves a much greater area of contact between the graft and the vagina after the vaginal wall has been split by surgical dissection. This leads to higher risks of mesh erosion, granulomas, bleeding and infection. Sexual function may suffer due to the hardness of the graft and loss of pliability of the vagina. Hence, interest has returned to biologically compatible materials especially allografts and xenografts for vaginal wall reinforcement.

Biomaterials’ production and properties

Donor tissue graft (allograft) avoids the morbidity of surgical harvesting. They are harvested from cadavers using aseptic technique and treated with antibiotics. They are thoroughly tested for the risk of infectious diseases. The graft is then freeze-dried and gamma-radiated for sterilization. The risk of transmission of prion disease and HIV is minimal and is estimated to be in the range of one in 1.67 million.

Biomechanical testing and standardization of the graft are recommended.

Porcine and bovine derived xenografts avoid the ethical issues surrounding cadaveric harvesting and are more readily available. Inflammatory reaction (graft versus host) which can lead to rejection is less than that seen with allografts.
Strict production guidelines are needed to ensure safety and standardization. There are some theoretical concerns about latent animal zoonoses which will only be answered with time.

**Biomaterials in practice**

Biomaterials are currently being explored for their beneficial effects mainly in women with vaginal wall prolapse. There may be a role for these grafts for women with recurrent cystoceles or rectoceles.

There is a paucity of data on the role of xenografts in women with primary/recurrent cystocele although several randomized trials are currently in progress. Salomon has assessed the feasibility and efficacy of a porcine skin collagen implant by the transobturator route for women with anterior vaginal wall prolapse. There was no graft rejection but 19% had an asymptomatic grade 1 or 2 cystocele at a mean follow up duration of 14 months.

Similarly, there are few studies addressing biomaterials for posterior compartment repair. Kohli and Miklos described rectocele repair in 43 women using dermal allograft. There was no major complication reported. Thirty-three women were available for follow up (mean 12.9 months) and the surgical cure rate as judged by the POP-Q scoring system was 93%.

**Conclusions**

Various types of synthetic and biologic materials are being used in gynecological surgery, although their widespread use has leapfrogged ahead of scientific evidence of their safety and effectiveness. Until there is evidence that biomaterials are beneficial their use should be restricted to subjects in research protocols. This will ensure that evidence supporting or refuting their use actually becomes available over the next several years. Research into the clinical outcomes of biomaterials and improving the biocompatibility of grafts is the need of the day.

**References**


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