

Effects of Biological Mesh in Pelvic Reconstructive Surgery

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Abstract

New techniques are also being introduced in the field of gynecology with the advancements to new technologies in all fields. The rate of pelvic floor disorders like pelvic organ prolapse and urine incontinence is increasing; pelvic reconstructive surgery is being evolved with the use of biological and synthetic meshes. This review aims to provide an overview and effects of biological meshes on pelvic reconstructive surgery. Various published research articles and reviews were searched on the World Wide Web, studied and then selected on the basis of the topic. According to various different randomized controlled studies, biological meshes are found to be ineffective in anterior vaginal wall repair and abdominal sacrocolpopexy for vaginal vault repair. Use of biological mesh in the treatment of rectocele is also in controversy. Mid urethral slings are most commonly used for the treatment of stress urinary incontinence. Biological meshes are expensive, inconvenient and also lead to treatment failure, increased reoperation rate and transmission of infection, so its usage is decreasing. Instead, synthetic polypropylene mesh is being used even it may also lead to complications like erosion, pain, extrusion, dyspareunia.

Keywords Biological mesh, cystocele, pelvic organ prolapse, rectocele, stress urinary incontinence.

Received August 22, 2015 **Accepted** November 25, 2015 **Published** April 15, 2016

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To cite this manuscript: Sushma P, Li HF. Effect of biological mesh in pelvic reconstructive surgery. Sci Lett 2016; 4(1):9-14.

Introduction

Owing to advancements in education and technologies, reconstructive surgery has also been developing in the field of gynecology. It has been used since decades by general surgeons for the treatment of hernia and rapidly being evolved in the field of gynecology as the frequency of pelvic floor disorders is increasing [1]. Pelvic reconstructive surgery is the surgical procedure done to restore the physiological anatomy of the vagina by settling down the symptoms and maintaining the functions of lower urinary tract, bowel and sexual functions [2]. It is done to correct pelvic floor disorders like pelvic organ prolapse, urine incontinence and recurrent prolapse.

Most commonly performed procedure is the anterior posterior repair, but nowadays, it is not much in practice due to recurrence of prolapse. Biological grafts are being used by 13.1% out of 262 gynecologists for pelvic reconstructive surgery as shown in Table 1 [3]. An ideal implant material for biological grafting should be non-toxic, non-carcinogenic, pliable, easily available at an affordable price and non-infectious and tissue repair should be strong by allowing collagen in growth. It should be sterilizable, convenient and durable as well [4].

Types of biological mesh

Biological materials are of three types: (1) autologous (autograft) implants, where the patient own tissues are used as implant. It includes rectus fascia, fascia lata and vaginal skin. Rectus fascia

is known to be popular because it is native tissue, (2) heterologous (allograft) implants, which are derived from same species but of other individuals usually from the cadaver. It includes dura mater, fascia lata like tutoplast and dermis like Alloderm, and Bard dermal allograft and (3) xenogeneic (xenograft) implants, where the materials are derived from other species. It includes porcine small intestine submucosa (SIS) like Intexen, surgisis, dermis (pelvicol) or bovine pericardium like Veritas etc. [5, 6].

Autologous fascia lata are used as vaginal wall prosthesis since 1942 and the human fascia lata grafts are used since 1914 in uterovaginal prolapse and stress urine incontinence [7]. Xenogenous collagen was reported to be used first during 1970 [8]. In 2000, the use of xenogenous tissues for cystocele repair was reported. In 1992, Zacharin described the use of vaginal epithelium (autologous) during surgery for recurrent pelvic organ prolapse [9]. Now polypropylene is the most commonly used synthetic material in pelvic reconstructive surgery.

Indications of biological mesh

Biological meshes are used in pelvic floor disorders to repair anterior vaginal wall prolapse-cystocele, posterior vaginal wall prolapse-rectocele, combined anterior and posterior vaginal wall, vaginal vault prolapse and stress urine incontinence [10]. Pelvic organ prolapse occurs commonly up to 50% of parous women, but symptoms are developed only in 10-20% of cases [11]. By the age of 79, there is 11-12% chance of

Table 1 The different types of procedures in pelvic reconstructive surgeries.

Pelvic reconstructive surgeries	Usage (%)
1. Anterior posterior repair	92.1%
2. Colpocleisis (Lefort)	49.6%
3. Mid urethral sling: transobturator	43.7%
4. Mid urethral sling: retro pubic	34.9%
5. Burch colposuspension	39.7%
6. Mc Call Culdoplasty	64.7%
7. High uterosacral ligament suspension	30.6%
8. Sacrospinous vaginal vault suspension	35.7%
9. Iliococcygeal suspension	5.6%
10. Transabdominal sacral colpopexy	21.4%
11. Laparoscopic sacral colpopexy	11.1%
12. Synthetic vaginal mesh kits	21.4%
13. Biologic grafts	13.1%

undergoing at least one operation for pelvic organ prolapse or urine incontinence with a reoperation rate of 29.2% [12]. Various risk factors that aids in the development of prolapse of pelvic organs includes childbirth, obesity, hypoestrogenism, connective tissue disorders congenital diseases and conditions, which increase intra-abdominal pressure such as constipation, chronic obstructive pulmonary disease and heavy weight lifting all leading to weakening of pelvic floor connective tissues [13].

Pelvic floor connective tissues consist of smooth muscle, blood vessels, fibroblasts and elastin, laminin and collagen as supportive tissues. Elastin and laminin help in tissue stretchability and collagen content provide tensile strength. There are two types of collagen type I like ligaments, rectus fascia and type III collagen of smaller fibers found in blood vessels and major collagen part is found in fascia like arcus tendineous of pelvis, vagina and uterosacral ligaments [14-16].

Functions of biological mesh

The use of biological mesh performs following functions.

Substitution

It helps to substitute the lacking supportive tissues. Some growth factors remain and attract endothelial cells and subsequent fibroblasts into the mesh.

Reinforcement

Host cells release additional chemo attractants that signal the migration of other structural cells. The three-dimensional nature of the mesh and porosity allow cells to enter the mesh and adhere.

Generation

It helps to generate new supportive tissues then a cycle of remodeling consisting of degradation of

the biologic mesh and regeneration of the collagen scaffold with host tissue.

Consolidation

The balance between the degradation and rebuilding process and the speed with which it occurs influences the ultimate strength and structure of the biologic mesh repair [17].

Efficacy of biological mesh

Efficacy of biological mesh depends upon the age of the patient, body mass index and high BMI i.e. >25% is the risk factor for prolapse recurrence and BMI <25 had better results in treatment [18], the stage of prolapse which is measured by POP-Q quantification system, tissue quality of the patient, site of supportive defects, experience and skill of the surgeon, tissue processing whether cross linked or not, freeze dried or solvent dried, irradiated or non-irradiated, obesity, personal habits of the patients like smoking, previous history of HTN, diabetes, COPD, asthma, previous surgeries and also the history of menopausal status of the patient. The efficacy of mesh increased when mesh strength and durability is increased, which depends on their absorbability by the host tissue [19].

Success of biological mesh

Stress urinary incontinence

Mid urethral slings both transobturator and retro pubic are in use for the treatment of stress urinary incontinence [20]. Autologous fascia lata and rectus fascia are only used if there is recurrence after treatment and if synthetic mesh is contraindicated because they are more invasive procedure and can cause post-operative voiding dysfunction [21]. Various randomized controlled trials were done to study the effect of various types of biological and synthetic meshes. According to randomized controlled trials performed by Amaro et al. [22], comparison of autologous fascial slings with synthetic mesh was followed up for 12 months, which showed almost similar 57% and 65% cure rates, respectively. Another randomized controlled trial performed by Sharifiaghdas and Mortazavi [23] showed similar findings (83% and 88%). Basok et al. [24] also reported similar results up to 12 months; however, degradation occurred in cadaveric fascia lata grafts and caused failure. Paparella et al. [25] reported that the use of transobturator porcine dermal and polypropylene slings showed no differences in cure rate after follow up study of 3 years. Furthermore, randomized controlled trial performed by Arunkalaivanan and Barrington [26] between retro pubic porcine dermal and polypropylene slings

showed 76% and 74% cure rates, respectively, but also showed 7% voiding dysfunction requiring urethrolisis with porcine dermis and 3% with polypropylene slings. A retrospective cohort study conducted by Shippey et al. [27] between porcine dermal and polypropylene sling showed higher degree of urinary retention and reoperation rate for retention in porcine dermal sling. About 24% of porcine dermis sling required reoperation for stress incontinence, while for synthetic sling it was 10%. Comparing slings of porcine dermis with slings of autologous rectus fascia Giri et al. [28] found 54% success rate with slings of porcine dermis versus 80% with slings of autologous rectus fascia. Slings using biological grafts were found to have higher rate of adverse effects according to recent meta-analysis conducted by Rehman et al. [29].

Vaginal vault and uterine prolapse

Sacral colpopexy is one of the effective and reliable method of correcting vaginal vault prolapse and uterine prolapse [30]. A double blinded randomized controlled trial was done by Culligan et al. [31] between polypropylene mesh and solvent dried irradiated cadaveric fascia lata in 100 patients of abdominal sacrocolpopexy and showed cure rate of 68% with solvent dried irradiated cadaveric fascia lata and 91% with polypropylene mesh. Two cases of erosion were seen with polypropylene. Altman et al. [32] compared clinical outcomes after abdominal sacrocolpopexy between porcine dermis and polypropylene and polytetrafluoroethylene and reported 71% cure rate with porcine dermis and 76% cure rate with mesh, but xenografts group patients developed persistent post-operative fevers. While comparing xenograft with polypropylene in sacral colpopexy by Deprest et al. [33] showed apical failure rate of 21% in case of xenografts and with 3% polypropylene. Reoperation needed to be done only in xenograft group. Another study was done by Quiroz et al. [34] using autologous fascia, synthetic mesh and porcine dermis showed success rate of 99% with synthetic mesh, 93% with autologous fascia and 89% with porcine dermis. Apical failure reoperation rate only occurred due to porcine dermis. Complications like graft erosion were higher with porcine dermis (11%) followed by autologous fascia (4%) and synthetic mesh (3%). Burch colposuspension along with abdominal sacrocolpopexy reduced the rate of stress urinary incontinence, which was proved by the trial conducted by Brubaker et al. [35, 36] after 2 years follow up of surgery.

Anterior wall repair

A randomized controlled trial done by Natalie et al. [37] using porcine dermis graft and

polypropylene in women undergoing anterior wall repair for recurrence and showed success rate of 72% with polypropylene and 56% with porcine dermis graft. Polypropylene group only shows 6.3% erosion [37]. Various randomized trials were carried on between biological grafts and anterior colporrhaphy and only two studies showed benefits of biological graft (porcine dermis and small intestinal submucosa) to anterior colporrhaphy [38, 39]. Another randomized controlled trial conducted by Menefee et al. [40] between porcine dermis, anterior colporrhaphy and polypropylene. Polypropylene showed low failure rate (18%) compared to anterior colporrhaphy (58%) and porcine dermis (46%). Another randomized controlled trial using porcine small intestinal submucosa and not using for anterior wall repair showed no difference in cure rate [41]. A trial conducted for anterior repairs by Gandhi et al. [42] with and without using solvent dehydrated/irradiated fascia lata showed cure rate of 79% in fascia lata group and 71% in controlled group after the follow up of 13 months.

Posterior wall repair

Dyspareunia is the most common complication occurred during posterior wall repair. Double blinded randomized controlled trial was performed by Paraiso et al. [43] comparing the use of porcine small intestinal submucosa at defective site, with posterior colporrhaphy and defective site repair. Failure rate and chance of reoperation was higher with the graft group. All the three groups did not show any effect on dyspareunia.

According to Novi et al. [44], improvement of sexual function was found in the group who have used porcine dermis in comparison to site specific repair from examined sexual function based on questionnaires. Dahlgren and Kjolhede [45] comparing posterior colporrhaphy and porcine dermal graft showed improvement in the posterior compartment. Further, Oster and Astrup [46] conducted another study using dermal autograft in 15 patients of rectocele, which showed 100% anatomical cure rate after follow up of 31 months. However, there was infection in 1 patient, constipation in 5 and dyspareunia in 3 patients. Another study was performed by Kohli et al. [47] using cadaveric dermal grafts in 43 patients with site specific defect repair. The cure rate was 93% and 7% had an anatomical failure.

Biological vs synthetic mesh

Biological mesh was initially used for the treatment of stress urinary incontinence and utero vaginal prolapse. Autologous grafts were found to be not so effective due to tissue harvesting

problems and perioperative morbidity, but it has its advantage as the patient's own tissue was used and there is less risk of erosion, infection and rejection. The effects of allografts are also found to be less beneficial due to problems in tissue harvesting, tissue processing and risk of prion transmission. According to Food and Drug Administration regulations, allografts tissue must be harvested within 24 hours of death and before harvesting the donor tissue serological screening should be done to rule out transmission of infectious diseases like HIV, HTLV-1, hepatitis B and C along with family history, social history and medical history like history of collagen vascular disease, Creutzfeldt-Jakob's disease, rabies, cancer etc. [48]. Harvested tissues are sterilized by various techniques irradiation with gamma rays, solvent dehydration and freeze drying [49]. As both allograft and xenograft are derived from extracellular tissues and they are acellular and devoid of genetic material, they cause less inflammatory reaction, less erosion and less chance of rejection, but there is 1/1,667,600 and far lower risk of acquiring HIV from the donor tissue per unit of transfusion [50]. There is risk of prion transmission documented only with the use of lyophilized dura mater [51]. Prions are only susceptible to protein denaturing with detergents and alkaline solution otherwise they are resistant [52]. Freeze drying is thought to eliminate all the cellular antigenicity and providing lesser chance of rejection and tensile strength depends upon collagen fiber orientation depending upon the region of harvest, also on the donor's age, sex and genetic background.

The most commonly used xenografts include porcine dermis, small intestinal submucosa and bovine pericardium. Xenografts should be devoid of transmissible infections so that the proper study about the animal herd, immunization status should be done. Collagen based implants are either cross linked or non-cross linked. Cross linking protects the grafts from degradation by collagenases [53]. Cross linking agents are aldehydes and Hexa methylene di-isocyanate. It was proved that xenograft cross linked with aldehydes lead to calcification, which increases the rate of degradation of the graft [54]. Cross linking helps to remain implant for a long time and may even lead to encapsulation, which gives the mechanical strength, but it may lead to seroma formation e.g. pelvicol is cross linked porcine dermal collagen. The tensile strength of pelvicol initially increases but gradually decreases after 3 months of implantation. Surgisis is the porcine small intestinal submucosa containing acellular collagen matrix which is not cross linked. Its degradation rate varies from 4 to 12 weeks. Some biological tissues are

even fenestrated so that it may lead to fibro collagenous growth, vessel proliferation which may decrease seroma formation and infection [55]. Some patients even refuse to xenografts due to religious beliefs and cultural barriers.

Owing to the similarities of biological grafts to the native tissues, it is more likely to undergo tissue remodeling and there is increased proliferation of vascular smooth muscle cells that cause less erosion in comparison to synthetic mesh. It was proved that under *in vitro* culture conditions, the proliferation of vascular smooth muscle cells of tissue samples of vagina was significantly increased exposed to porcine dermal collagen [56]. Biological meshes are found to be expensive, have limited supply and theoretical infectious disease transmission so they are not used in Europe and elsewhere, but over the counter cheaper synthetic meshes are widely applicable.

From the random controlled trials done, we can found that both biological and synthetic mesh provide similar success rate but complications like reoperation rate and urinary retention was more with biological mesh in case of stress urinary incontinence used as slings. In the case abdominal sacral colpopexy for vaginal vault and uterine prolapse cure rate was more with synthetic mesh. Polypropylene showed better response for anterior vaginal wall repair even it leads to complications like erosion, pain, infection, dyspareunia, urinary problems and contraction. In some studies, contraction occurred within first 3 months of implantation; but in some studies, contraction occurred even after 3 months which can be diagnosed by ultrasonography [57, 58].

New emerging techniques

New studies are being done with transvaginal meshes such as total prolift, apogee, perigee, avaulta and absorbable biomaterials like polyglactin 910 and vypro as combination of polypropylene with polyglactin 910, polypropylene mesh which is coated with porcine collagen. Antibiotics and growth factors will be imbued in the future materials, which may help in tissue regeneration. For future management of prolapse, gene therapy will also emerge. New alternatives to grafts and meshes will be cell based (stem cell) tissue engineering strategies. For stress urinary incontinence, regeneration of the urethral sphincter on cell based injection therapy will be the new alternative [59]. Cell therapies using muscle derived stem cells and adipose derived stem cells are emerging [60]. Collagen meshes cross linked with autologous adult stem cells, which helps to modulate inflammatory response and decrease the rate of degradation of the collagen meshes. Further,

for the treatment of pelvic organ prolapse, robotic laparoscopic surgery can be implemented in the future.

Conclusions

Pelvic organ prolapse is the commonest problem of women in the world, which interferes with their daily activities and sexual life. Pelvic reconstructive surgery has become the standard for its treatment. Various randomized controlled studies were done using biological and synthetic materials for the treatment of stress urinary incontinence and pelvic organ prolapse, which showed the inferior anatomical outcomes with biological meshes. Studies showed no benefits of biological mesh in sacral colpopexy and rectocele repair. Further randomized controlled studies should be done to find the effect of biological meshes. Synthetic polypropylene mesh is commonly being used for sacral colpopexy, cystocele repair and as mid urethral slings for stress urinary incontinence.

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