GENERAL REVIEW

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Experimental and clinical use of meshes in urogynecology

Eksperimentalna i klinička upotreba sintetskih hirurških mrežica u uroginekologiji

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Introduction

The most common problems in urogynecology, stress urinary incontinence (SUI) and pelvic organ prolapse (POP) are, in other words, problems of pelvic organ support. Extended demand for support in pelvic reconstructive surgery has led to the development of both biomaterials and synthetic grafts. The ideal biomaterial should be physically and chemically inert, mechanically strong, noncarcinogenic, easily fabricated and stabilized, and should induce minimal inflammatory reaction [1].

Experimental studies and mesh behavior

Several studies have analyzed biomaterials derived from dermal, pericardial, dural, and other anatomical sources, and have emphasized their non-uniform graft behavior, variable preparation, and unpredictable quality [2]. Synthetic grafts clearly demonstrated superior durability and long-term success over biomaterials for pelvic floor repair [3].

The most widely accepted method of testing synthetic grafts is through experimental animal studies. In analyzing the literature, it is obvious that rats are the most commonly accepted experimental model. Several study groups have set the standard for methods as well as tissue analysis and tensile strength in experimental studies [4, 5]. Primary repair of full-thickness abdominal wall defect, with respect to the peritoneum, seems like a logical choice. Monofilament polypropylenes were theoretically and practically the first choice for testing, considering the assumption that multifilaments are prone to infection [4]. There is consensus that an average of 90-μm pore size provides the best mechanical anchorage, with peak in-growth reached at around 400–500 μm [1, 2]. Larger pores limit the deposition of collagen to the perifilament region, with central parts being deposited with fat. A solid product, as well as one with smaller pores (< 50 μm), can lead to complete encapsulation or induce an intensive inflammatory reaction. In addition, the intensity of an inflammatory reaction is determined by the amount of synthetic material, therefore suggesting the use of lighter materials [1, 4 6].

It is presumed that multifilaments with interfilamentous spaces smaller than 10 μm are prone to infection, bearing in mind that macrophages are 15 μm in diameter, and bacteria 1–2 μm. Multifilaments were theoretically supposed to have better elasticity, but the same results are achieved with low weight monofilaments [4, 5]. After an initial polypropylene testing, some advances in biocompatibility were to be revealed experimentally on a polypropylene-coated field. Collagen-coated and titanium-coated grafts were to express a less intensive inflammatory reaction, with the same results, on a field of collagen deposition; however, they failed [6]. Arginine administration was also evaluated in experimental models for improved mesh integration, but the experimental data are inconclusive [7]. Some rather interesting data were revealed on initial experimental analysis of semi-reabsorbable (polypropylene-polyglactin) grafts [6]. Later studies determined that the semi-reabsorbable combination proved to be a stable scaffold for collagen deposition, leaving less foreign material after polyglactin reabsorption, with no consequences on tensile strength [5]. Experimental studies have revealed a totally new perspective on the mechanical analysis of incorporated grafts. Tensiometric studies of native graft samples have indicated significant differences in strength among tested samples. When colonized by cells and incorporated with native tissue, explanted samples provided comparable tensiometric strength, regardless of the material used [5].

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Some studies even reported that stronger tensiometric results were achieved with monofilaments than with multifilaments [4].

Experimental studies have suggested a high modality and uniform quality of synthetic meshes, with a rather steady retraction rate of about 20% [1, 4, 5]. Graft retraction seems to correlate with stiffness parameters in the elastic domain of graft deformation [5]. Retraction rates, when summarized, highlight the well-known postulate of tension-free surgery.

Consensus on a cascade Worman's effect is almost absolute. Protein covering of the graft and inflammatory reaction within the first three weeks are the initial steps of foreign body reaction [1]. The reparation process, regardless of the experimental animal model, is characterized by collagen deposition and final stabilization within six weeks [4, 5].

One study even analyzed cell oxidative stress levels in relation to the mesh material used [5]. Conclusions definitely confirmed a positive correlation between cell oxidative stress and the amount of implanted synthetic material. In summary, rat studies have shown good biocompatibility, respectable tensile strength, and fewer complications.

In several studies, rabbits were chosen as an experimental model, but they showed no difference in graft behavior [8]. Pigs are less common, considering that large animals are not as easy to manipulate, and the experimental samples are smaller. The highest level of retraction reported in an experimental study on pigs is 30% [9]. However, this result should be considered cautiously, as retraction was measured with millimeter paper alone. One of the interesting, but rare, experimental studies conducted on very large animals included horses [10]. Fifteen horses were treated with polypropylene meshes for large abdominal hernias and the results were exceptional, except for one fatality.

In summary, future perspectives seem to favor semi-reabsorbable, low-weight monofilament meshes, with totally inert synthetic grafts being the ultimate theoretic goal.

Mesh in the treatment of stress urinary incontinence

Stress urinary incontinence is a highly prevalent (41%) problem; 72% of patients have moderate to severe symptoms, with only 25% seeking professional help [11]. There is a prognosis that requirements for surgery will increase up to 45% in the future, due to less tolerance of SUI symptoms by patients and the normal aging of female population expected in western countries [12]. Synthetic materials have been generally used in the treatment of SUI after wide acceptance of the Petros and Ulmsten theory of continence [13]. The sling was moved from the bladder neck to the midurethral position and placed in a tension-free manner. The role of the sling is support of the urethra, instead of previous tension sutures placed on the bladder neck or a fascial sling placed on the same position [14, 15].

The sling is placed retropubically, transobturatory, or as a mini (single incision) sling. Tension-free placement has contributed to their non-obstructive behavior, low incidence of urinary retention, no exaggeration of prolapse, and decreased deterioration of the posterior compartment [16, 17]. Postoperative sexual dysfunction is infrequent, due to an unchanged vaginal axis, which is the most frequently recognized flaw of the Burch operation [18, 19]. Retropubic placement of the sling requires cystoscopy as a mandatory part of the procedure, and sling placement was limited in very obese patients and in patients with previous pelvic surgery and suspicious intestinal adhesions. Transobturatory placement performed "inside out" or "outside in" (both ways are almost equal, with "inside out" being slightly superior) [20, 21] became an acceptable alternative that does not require cystoscopy and does not affect the abdominal cavity. Mini slings are the least invasive, placed in a U position or horizontally. There were high expectations and hopes because of the convenient pain profile, but the results were not as encouraging, and their use is performed with caution [22–24]. There are also self-tailored modifications or industrial modifications of the sling, which are applied with similar or equal success rates [25, 26].

However, no one way of sling placement is absolutely complication free [27, 28]. This is especially important to keep in mind, because the surgery is performed with the aim of improving quality of life, and dangerous reported complications, such as bowel perforation and serious bleeding (the majority after retropubic sling surgery), can compromise the procedure seriously.

Success rate (effectiveness) is measured subjectively (interviews, different questionnaires), objectively (e.g. 24-hour pad test, stress test), or as a combined evaluation after surgery. Subjectively evaluated success is always higher than objectively measured one, and varies between 85.7% and 91.6%. The number of satisfied females with significant improvement is higher than the number of completely dry patients [29].

Unfortunately, dryness is not the only outcome of the surgery. Complication rates should not be neglected, but they are usually underreported. The reported complication rate is 4.3–75.1% for retropubic and 10.5–31.3% for transobturatory midurethral slings [30]. The most important predictive factors for sling failure are documented intrinsic sphincter deficiency (ISD) and fixed urethra. It is assumed, in other words, that in patients with a fixed urethra, the main problem is low resistance at the level of the bladder neck, and not urethral support, so the support improvement achieved by the sling is less likely to be curative. Fortunately, the results of tension-free tape (TVT) and adjustable slings in these patients are only a little inferior, or equal, to the results of TVT (66% and 85% cured patients, respectively) [30, 31]. There is a documented follow-up of patients with suprapubic TVT–11.5 years and transobturator tabe (TOT) – 6.5 years, without significant differences between the procedures. Both of these procedures have a stable, long-term success rate (77% and 83%, respectively) [32, 33]. The difference was not spectacular compared with the Burch Tangho operation (70% dry patients) [34].

Recurrent SUI is not an uncommon problem after tension-free procedures. The success rate is lower than after primary treatment (63.5% dry), but it is still acceptable. There is scarce evidence of favorable types of slings for the "redo" surgery, but the retropubic sling seems to be more effective than the transobturatory sling [35, 36].

Postoperative voiding dysfunction and urinary retention after sling procedures are underreported. Frequency of urinary retention (1.8–10%) is highest in patients with the retropubic sling, but it is not absent with the transobturatory or single-incision sling. It is usually temporary, and intermittent catheterization or catheter removal several days later solves the problem. Long-term retention (15 days) usually requires pulling down the sling or a sling section, or removal of the sling. In the majority of cases, it does not result in the recurrence of SUI [37–41].

There was a confusing terminology in previous years regarding the complications-sling exposition and erosion. It is accepted now that sling exposition describes a visible sling in the vagina, uncovered by the vaginal epithelium. Sling erosion is a penetration of the sling into the adjacent viscera. The more frequent surgical complications of the sling is exposition (13%) [41, 42]. Sling exposition is usually expressed as vaginal discharge, pain during intercourse, or sexual discomfort. Sometimes it occurs up to ten years after the surgery [42, 44]. Sling erosion is the consequence of such conditions as migration in the urinary bladder or urethra, or abscess formation. In extreme cases, consequent vesicovaginal or uterovaginal fistulas are possible [45, 46]. Possible explanations for sling exposition are insufficient surgical skill, structure of the sling material, or susceptibility of the hammock to the sling [42]. Sexual function could be improved (29.5% and 32.5% for TVT and TOT, respectively), deteriorated (17.3% and 12.5%), or unchanged after the sling procedures [47]. The vast majority of patients will have improvement in their sexual life, but statements about postoperative sexual function must be included in the informed consent before the surgery [47–49].

Overactive bladder symptoms and mixed urinary incontinence are not contraindications for the sling. Postoperative urgency could start before the surgery and remain after the surgery, or appear as a phenomenon *de novo* [50, 51]. Preoperative urgency is more frequent in patients; mixed urinary incontinence, age, nocturia, maximum cystometric capacity, and choice of sling procedure influence detrusor overactivity and urge urinary incontinence [52]. In the majority of cases, postoperative urgency is sensory and can be controlled with anticholinergics. If urgency persists, removal of the sling is mandatory [53].

Mesh in the treatment of pelvic organ prolapse

Pelvic organ prolapse is a frequent disease among the aging female population. Almost 11% of the female population up to the age of 80 will require some type of surgical correction of POP [54]. Generally, correction of POP is performed with native tissue (NAT repair), mesh adjunct (pure synthetic material, resorbable or not), or rarely, graft (biological material), is used to repair the pelvic floor. Corrections are usually undertaken because of the anatomical disorder (vaginal bulge) and/or coexisting symptoms of prolapse included in symptom/bothersome symptom questionnaires. Vaginal bulge is the most prominent symptom; others include pelvic pressure, associated incontinence or urinary retention and bowel emptying problems, and sexual dysfunction.

Several major influences on POP surgery have been recognized: extensive reports that some degree of prolapse is not obviously symptomatic, changing criteria for performing surgery, and differences in the evaluation of surgery outcome.

Normal anatomic prolapse variations were well recognized in a study of routine clinical examinations of asymptomatic females, and it was confirmed that POP stage I is present in 38%, and stage II in 35% of patients. If it is evaluated as a result of surgery, more than 75% will not meet the criteria for ideal, and 40% for satisfactory outcome [55]. To mitigate a tendency to surgically "overcorrect" the anatomy of asymptomatic females, the evaluation criteria have changed. Acceptable results of successful repair are absent prolapse beyond the hymen, no symptoms, and no need for additional treatment [56]. Therefore, the main advantage of the polypropylene mesh superior anatomical restoration of the female genitalia was lost. In anterior vaginal repair, the efficiency of mesh surgery was confirmed to be superior to that of non-mesh surgery, which has a failure rate of 29% [57]. Ten randomized control studies showed that synthetic absorbable mesh has the highest failure rate (23%), followed by biological graft (18%) and non-absorbable synthetic mesh (5%) [57]. Safety was highest in cases with absorbable mesh (exposure rate, 0.6%), followed by biological grafts (6%) and synthetic non-absorbable mesh (10%) [57]. Posterior repair, with or without mesh, is significantly less frequently reported, and there is no confirmed evidence of a clear superiority of the special method of posterior compartment repair [58]. Clinical experience suggests that mesh will surely keep its place in strict indications (mesh compared to non-mesh surgery: recurrent prolapse/success rate, 90.4% versus 54.8%, respectively; paravaginal defect, 97.6% versus 65.6%; badly damaged pelvic floor, 64% versus 22.9% [59, 60]. Symptoms after mesh correction are based on clinical studies, and use of the mesh was not proved in lower grade prolapse [61]. In other words, restoring anatomy does not mean restoring symptoms at the same time.

Apical defect, although less frequently discussed, is a normal prerequisite for the success of POP surgery. It can be performed with adequate success using a variety of surgical options: vaginal sacrospinous support with mesh (tailored or modified), or colposacral fixation performed by robotics, laparoscopy, or open surgery [62, 63]. Safety of the mesh surgery is lower, according to reported complications, some of them dangerous or life threatening [64, 65].

Sexual dysfunction increases constantly with age. The frequency of sexual dysfunction is up to 50%, and it has a multifactorial origin [66]. Surgeries of any type, as well as concomitant gynecological pathology, could deteriorate sexual function without reliable data to address the source of sexual dysfunction to the mesh directly [67]. However, the Food and Drug Administration (FDA) has recently issued warnings regarding increased complications of mesh surgery and the exaggerated justification for its use in clinical settings [68, 69]. Almost no one could ignore these statements [68].

Finally, all aspects of POP must be evaluated carefully: anatomy, symptoms, quality of life, late complications, and possible repeated surgeries [69]. We have to create a treatment design to meet the criteria of the patients more comprehensively, with native tissue repair whenever it is possible, and with mesh only when it is absolutely necessary.

Conclusion

Synthetic materials have been developed constantly during previous decades, but they have not achieved the standards of ideal foreign material. Their biologic behavior is still unknown, especially after long-term follow-up. Improvements in the treatment of stress urinary incontinence are remarkable, and polypropylene slings have met the criteria for the gold standard of treatment, both for the suprapubic and transobturatory routes of application. It is not the same for mini slings. Meshes in pelvic organ prolapse surgery are superior for the correction of anatomy, but the overall benefit of their use is not remarkable, and complications are more frequent. It is certain that recent experiences will substantially diminish the use of mesh in pelvic organ prolapse surgery, as the restoration of anatomy is not a single goal of surgery. However, its use will be kept for selected patients. Improvement of our knowledge, both fundamental and clinical, is necessary for superior pelvic organ prolapse repair.

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