Managing Complications of Implanted Mesh

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Abstract The use of surgical mesh in gynecology has come under intense scrutiny over the past year. The US Food and Drug Administration released a public health notification in 2008 outlining the reported complications associated with mesh placement, followed by a safety communication update in 2011. Although implantation of any type of mesh can lead to complications, most are associated with transvaginal placement of mesh for the treatment of pelvic organ prolapse. This article briefly discusses the history of surgical mesh and how we arrived at our current inflection point. Standardized terminologies for describing mesh-related complications are reviewed. Lastly, management of common mesh-related complications are discussed, including the management of mesh extrusion and pelvic pain/dyspareunia.

Keywords Mesh complications · Mesh erosion · Dyspareunia · Pelvic pain · Transvaginal mesh · Midurethral sling · Complications · Graft · Food and Drug Administration · Sacrocolpopexy

Introduction

The use of surgical mesh initially gained popularity for its role in the treatment of inguinal and ventral wall hernias. The change from traditional suture repair to mesh-reinforced repair decreased recurrence rates by 50–75 % for

open repairs and by more than 75 % for laparoscopic approaches [1, 2]. Often the loss of pelvic floor support resulting in pelvic organ prolapse (POP) is compared to a hernia and in 1973, Stanley Birnbaum published a description of a novel technique for treatment of vaginal prolapse which involved “fixation of the (vaginal) vault with a Teflon mesh bridge used to anchor the vagina to the hollow of the sacrum.” This is the initial description of sacrocolpopexy using a synthetic mesh [3]. A follow-up article in 1979 reported that 20 of 21 patients treated with sacrocolpopexy as described maintained good support and vaginal function [4].

Over the past 15 years we have seen significant refinement and improvement in surgical mesh materials. There were problems noted with some early surgical meshes that increased erosion and infection rates (microporous/multifilament materials), in many cases requiring complete explantation for symptom improvement [5, 6]. Most of these products are no longer available. The meshes currently used are considered Amid type 1 mesh, meaning they are macroporous (pore size greater than 75 μm), monofilament polypropylene that can further be divided by weight (heavy, mid-weight, and light) [7, 8].

Currently, in gynecologic surgery, synthetic mesh is used for the treatment of both POP and stress urinary incontinence (SUI). Mesh used to treat POP can be placed abdominally/laparoscopically (sacrocolpopexy) or transvaginally. Transvaginal mesh can be self-fashioned or come packaged as a “kit.” The first synthetic mesh repair kit was approved by the Food and Drug Administration (FDA) in 2001, and the first trocar-based kit was described in 2004 [9, 10]. Midurethral slings are synthetic mesh placed suburethrally for the treatment of SUI. They come in retropubic, transobturator, and mini-sling configurations. All are macroporous polypropylene mesh and have

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inherent risks associated with their use. This article will discuss the management of complications associated with implanted mesh from sacrocolpopexy, midurethral slings, and transvaginal mesh kits. The discussion will focus on the management of complications after transvaginal mesh placement, as the complication rates are higher than those for sacrocolpopexy and midurethral sling, causing the FDA to issue specific warnings regarding the use of mesh in gynecologic surgery.

Terminology

In response to increasing complications associated with mesh use in gynecologic surgery, the International Urogynecological Association and the International Continence Society recently agreed on standardized terminology and a classification method for complications associated with insertion of mesh [11]. The terminology is specifically defined in the article and the classification system is based on three items: category, time, and site:

1. *Category*. This includes seven complication types (vaginal without epithelial separation; vaginal with less than 1 cm epithelial separation; vaginal with more than 1 cm separation; urinary tract; rectal/bowel; skin/musculoskeletal; and patient compromise). Each has lettered modifiers for patient symptoms and infection (A—asymptomatic; B—symptomatic; C—infection; D—abscess).
2. *Time*. This includes four time periods (T1—intraoperative to 48 h; T2—48 h to 2 months; T3—2–12 months; T4—over 12 months).
3. *Site*. This has five categories (S1—vaginal area of suture line; S2—vaginal area away from suture line; S3—adjoining viscus (bladder or bowel); S4—other skin or musculoskeletal site; S5—intra-abdominal). As an example, a patient with mesh fiber exposure in the lateral vagina on her 6-week postoperative check whose partner describes discomfort with intercourse would be classified as B1/T2/S2. Although somewhat complex, when broken down it is a simple way to classify mesh complications and the category–time–site system will be an improved method for standardizing reporting of complications associated with graft placement. This is an important step for our field, as it will allow identification and classification of all complications from minor, asymptomatic problems to complex abnormalities.

For the purpose of this article, the terms “mesh extrusion,” “mesh exposure,” and “mesh erosion” are synonymous with each other and are used in accordance with the original source of the reported information.

US Food and Drug Administration

On October 20, 2008, the FDA issued a public health notification regarding the use of mesh in gynecologic surgery titled “Serious complications associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapse and stress urinary incontinence” [12]. This was done in response to over 1,000 reports involving nine different surgical mesh companies that describe complications related to surgical mesh devices used to treat POP and SUI over a 3-year period. The commonest complications reported were mesh erosion, infection, pain, and urinary symptoms. Serious injury to bowel, bladder, and blood vessels did occur, albeit rarely. Several general recommendations were made by the FDA at that time. Physicians should seek specialized training for procedures involving the use of mesh and be alert to complications and recognize them early. Physicians were advised to inform patients on the permanent nature of surgical mesh and that some complications associated with the implanted vaginal mesh may require subsequent surgery that may or may not correct the complications. Lastly, physicians were advised to inform patients about the potential for serious complications and the effect on quality of life, including pain during sexual intercourse, scarring, and narrowing of the vagina after POP surgery. Guidelines for reporting mesh complications were also given.

The FDA continued to investigate mesh-related complications and, on the basis of an updated analysis of reported adverse events and complications described in the scientific literature, released the FDA safety communication titled “Update on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse” on July 13, 2011 [13]. The FDA noted that the use of surgical mesh for transvaginal repair of POP is an area of continuing serious concern and concluded that “serious complications associated with surgical mesh for transvaginal repair of pelvic organ prolapse are not rare.” It did not find clear evidence to support increased efficacy of mesh repairs when compared with traditional, nonmesh repairs, and patient’s undergoing mesh placement may be exposed to greater risk. It was noted that mesh placed abdominally for treatment of POP has a lower rate of mesh complications when compared with vaginally placed mesh. Lastly, mesh used to treat SUI is under continued investigation, with updates to come.

It is important to understand the FDA approval process for new materials, as there is a proposed reclassification of urogynecologic surgical mesh used for transvaginal repair of POP. Products currently on the market were allowed to bypass the rigorous FDA approval process that mandates premarket testing based on a process called 510(k). This process allows new medical devices that are similar to

another FDA-approved device to be approved, eliminating the need for companies to provide efficacy and safety data on new products to obtain FDA approval. Transvaginal mesh kits were approved via the 510(k) process on the basis of the similarity of the mesh to that of midurethral slings (predicate device), despite different volumes of mesh and different spaces in which the mesh is placed. Similarly, current midurethral slings were approved by this same process on the basis of prior products no longer on the market because of poor safety profiles. The FDA is considering reclassification of urogynecologic surgical mesh from a class II to a class III medical device, which would require premarket approval and thorough scientific review to ensure its safety and efficacy prior to going to market. On January 4, 2012, the FDA issued 522 orders requiring postmarket surveillance studies for transvaginal mesh devices for POP and single-incision mini slings for SUI [14].

The Ideal Graft

The ideal graft material has yet to be established, and Karlovsky et al. [15] suggest it should be inert, sterile, noncarcinogenic, and mechanically durable, should not cause inflammation or immune reaction, must withstand modification by body tissue, and should be inexpensive, convenient, and easy to use. Surgical mesh had initially been thought to be fairly inert; however, histologic analysis of 100 explanted samples revealed 44 % with histologic characteristics of infection, 42 % with chronic inflammation, and 14 % with pronounced fibrosis [16]. Interestingly, 42 % of explants showed signs of degradation despite current thoughts that these materials resist breakdown.

Understanding host response to different materials is important as it can guide one in the management of complications associated with them. Most synthetic materials are either encapsulated or incorporated by the host tissue. *Encapsulation* (GORE-TEX; Gore Medical, Newark, NJ, USA) involves collagen and connective tissue deposition around the material without infiltration. These materials can often be removed more easily as there is no host tissue ingrowth. In contrast, *incorporation* (Amid type 1 mesh) involves graft infiltration and vascularization. These materials are more difficult to remove and necessitate sharp surgical dissection, and risk of visceral injury is higher.

The Ideal Candidate

Long-term steroid use, uncontrolled diabetes, tobacco use, and immunocompromise are important factors to consider when determining whether a patient is an appropriate

candidate for mesh placement. Vaginal tissue health should also be considered, and if it is atrophic, locally administered estrogen may be used prior to mesh placement. Pregnant women and those planning pregnancy are not candidates for mesh placement, nor are most women with prior pelvic radiation therapy.

Sacrocolpopexy

Sacrocolpopexy is an abdominal/laparoscopic procedure that involves attaching a Y-shaped graft (usually synthetic mesh) to the anterior and posterior vaginal wall and securing it to the anterior longitudinal ligament of the sacrum. Mesh complications after abdominal sacrocolpopexy are fairly rare and primarily center on mesh erosion or suture erosion. A comprehensive review of abdominal sacrocolpopexy revealed an overall mesh erosion rate of 3.4 %. Polypropylene had the lowest erosion rate at 0.5 %, whereas Teflon had the highest rate of erosion at 5.5 % (Fig. 1) [17]. There are mixed data regarding the risk of mesh erosion when sacrocolpopexy is performed with concomitant hysterectomy. Culligan et al. [18] reported an increased erosion rate with concomitant hysterectomy; however, this study had a small sample size ($n = 11$). Brizzolara and Pillai-Allen [19] reported no increased erosion rate in 60 women undergoing sacrocolpopexy with concomitant hysterectomy when compared with 61 women undergoing sacrocolpopexy alone. Another study compared mesh erosion rates after sacrocolpopexy with concomitant supracervical hysterectomy with those after sacrocolpopexy alone. A total of 277 patients were included in this study, 195 with concomitant supracervical hysterectomy with sacrocolpopexy and 82 with sacrocolpopexy alone. Three patients were diagnosed with mesh erosion at a mean follow-up of 8 months, one patient (0.5 %) in the supracervical hysterectomy with sacrocolpopexy group and two patients (2.4 %) in the sacrocolpopexy alone group. There was no statistical difference in mesh erosion rates among the two groups [20].

Various risk factors have been identified for mesh and suture erosion after sacrocolpopexy. A secondary analysis from the Colpopexy and Urinary Reduction Efforts (CARE) trial evaluated mesh and suture erosion rates among the 322 women who underwent sacrocolpopexy [21]. It identified 20 women (6 %) with mesh/suture erosion within 2 years of surgery; three had suture erosion only and 17 had exposed mesh. Three identifiable risk factors were found. Concurrent hysterectomy increased the erosion rate from 4 to 14 % in this study population, whereas the use of expanded polytetrafluoroethylene (ePTFE; GORE-TEX; Gore Medical, Newark, NJ, USA) had a fourfold higher risk (19 vs 5 %) of mesh erosion when

compared with the use of non-ePTFE mesh (Fig. 2). Lastly, smoking was associated with a fivefold increase in risk of mesh erosion. No other significant factors were identified as risk factors for mesh erosion, including estrogen status, diabetes, and prior surgery. The treatment of the three women with suture erosion included simple suture removal, and two of the three women have confirmed healing and in the other woman healing was unable to be confirmed at the time of publication. Four of the 17 mesh erosions were managed without surgery and no resolution was noted in any of these four. Thirteen women underwent at least one surgical procedure, whereas one woman had two surgical procedures and one had three surgical procedures. Of these 13 women, two had symptom resolution, six had persistent mesh erosion, and five were lost to follow-up.

Managing mesh erosion after sacrocolpopexy may only require topically administered estrogen; however, often it requires more extensive surgical excision. Surgical management of mesh erosion after sacrocolpopexy can be technically challenging, partially due to the amount of mesh used in the procedure and the ingrowth of tissue into the mesh making surgical dissection difficult. Vaginal and abdominal routes for mesh excision can be taken, and South et al. [22] published their experience with excision of mesh after sacrocolpopexy, including a novel method for endoscopic-assisted transvaginal excision of mesh. They reported on the management of 31 patients with mesh erosion after sacrocolpopexy, including techniques used for mesh removal. Vaginal excision is described as sharp dissection of the vagina around the area of erosion and excision of the mesh with closure of mucosal edges with suture. Endoscopic-assisted transvaginal excision was used for patients with a sinus tract at the vaginal apex. The sinus tract opening was extended using a scalpel if needed to accommodate a 17F cystoscope. The endoscope was placed

Fig. 2 GORE-TEX mesh erosion seen transvaginally after prior sacrocolpopexy

into the sinus tract and advanced toward the sacrum to view the extent of the mesh. The scope was used for direct visualization during dissection of mesh from retroperitoneal tissues and during mesh excision. Abdominal excision of mesh was done by laparotomy and the presacral space was entered and mesh was detached from the sacrum and removed from the vaginal apex. Fourteen women underwent transvaginal mesh excision, and this was successful in nine women, whereas 17 women underwent endoscopic-assisted transvaginal mesh excision, and this was successful in seven women. The overall success rate for vaginal excision was 53 %. However, multiple attempts at vaginal excision were required in several patients: one patient requiring two surgical procedures and three patients requiring three surgical procedures for symptom resolution. Seven patients underwent abdominal excision, with one of the two transvaginal excision methods having failed for each of the patients. All had symptom resolution. No severe complications were noted, and one patient in the transvaginal group had minor postoperative complications of nausea and fever for 24 h. In the abdominal group, two patients had intraoperative bowel injuries during lysis of adhesions, one patient had wound infection, and one patient was readmitted for fever requiring treatment with antibiotics. It was concluded that complete removal of mesh may improve outcomes and decrease persistent symptoms.

Fig. 1 Excised piece of Teflon mesh with attached vaginal mucosa

Midurethral Sling

The synthetic midurethral sling was introduced in the mid-1990s by Ulmsten and Petros [23, 24] for the management of SUI. Support of the midurethra, as opposed to the bladder neck, was thought to mimic the action of the pubourethral ligaments, and thus improve stress

incontinence. Subsequently, Johnson & Johnson (New Brunswick, NJ, USA) marketed the first midurethral sling in the USA under the name TVTTM (tension-free vaginal tape), with the first multicenter trial showing significant improvement in stress incontinence symptoms [25]. The procedure involved making a small incision in the suburethral tissue, and trocars were used to pass the sling through the retropubic space. Since then, multiple companies have developed their own midurethral sling, and we have seen the introduction of the transobturator and single-incision mini slings [26, 27].

Mesh-related complications may occur after any type of midurethral sling placement (retropubic, transobturator, single incision). Vaginal mesh extrusion occurs in approximately 3 % of cases [28, 29]. We will discuss the management of this below. Although less common, urethral/bladder perforation or extrusion can occur. This is rare, and management is outside the scope of this article. Expertise and experience is needed when managing these difficult cases.

Symptoms of vaginal extrusion can be discharge, bleeding, patient/partner dyspareunia, and recurrent urinary tract infection. Most data on the management of vaginal mesh extrusion come from small case series involving both surgical and nonsurgical treatments with differing success rates. Topically administered estrogen is a reasonable initial treatment for women with small extrusions; however, subsequent mesh excision is often needed [30]. Excision of extruded mesh can occur in the office setting or operating room, with the important questions being the timing of excision and how much mesh to excise. In the authors' experience, office-based management is most often successful when the extrusion is less than 1 cm in size, easily visible/accessible with office instrumentation, and the patient has healthy vaginal tissues. Local anesthetic is necessary prior to any attempt at office-based trimming or epithelial reapproximation. The authors prefer 1 % lidocaine without epinephrine. Sterile gloves and instrumentation should be used, and commonly needed are a speculum, scissors, forceps with teeth, a needle driver, suture, and an assistant. Excision of a portion of the mesh can be done in the office, but often mobilization of vaginal epithelium around the mesh with reapproximation of the epithelium in a tension-free manner is all that is necessary.

In some instances of vaginal extrusion, return to the operating room is necessary. A weighted speculum and vaginal retractors can be used to better visualize the extruded mesh (Fig. 3). Fine surgical scissors (Metzenbaum) should be used to mobilize the vaginal epithelium around the area of extrusion. If mesh is going to be excised, a fine right-angle clamp can be placed between the mesh and underlying connective tissue and gently opened to elevate the sling away from the tissue. It can then be

trimmed safely and the vaginal epithelium can be closed in a tension-free manner. Again, depending on the location and size of the extrusion, excision of a portion of the mesh may be necessary. Tjldink et al. [30] reported recurrent SUI in 36 % of women undergoing excision of a portion of the sling for mesh extrusion. There are limited clinical data to support the use of vaginally administered estrogen; however, the authors recommend using vaginally administered estrogen prior to and after any surgical management of mesh complications performed transvaginally.

Transvaginal Mesh

There are potential benefits and risks with the use of transvaginal mesh for the treatment of POP, and data are limited regarding recommendations for mesh use. Proposed benefits of transvaginal mesh include improved anatomic outcomes and decreased recurrence rates; however, transvaginal mesh placement for the treatment of POP is associated with the most mesh-related complications in gynecologic surgery. Vaginal mesh extrusion, pelvic pain, and dyspareunia are complications noted after transvaginal mesh placement, and management of these complications is presented in the following sections [31–35]. Bladder and bowel perforation/extrusion is beyond the scope of this article and will not be discussed here.

Transvaginal mesh placement involves opening the vaginal epithelium of the anterior and/or posterior vaginal

Fig. 3 Suburethral mesh extrusion after midurethral sling

wall and placing mesh for the support of POP. Most often the placement of the mesh uses trocars to fixate prefabricated pieces of mesh (mesh kits) to pelvic ligaments and muscles. The vaginal epithelium is then closed over the mesh using absorbable suture.

Patient Evaluation

A complete history and examination of all patients with suspected mesh-related complications should be completed. On pelvic examination one should attempt to identify any of the following: urogenital atrophy, palpation/visualization of any extruded mesh, mesh under tension, location of mesh arms, pain with palpation of the mesh (note location), pain with palpation of pelvic floor musculature or evidence of fistula. Rectal examination should be performed, and cystoscopy and proctoscopy may be helpful as well depending on the presentation. Simple causes of dyspareunia such as urinary tract infection and urogenital atrophy should be treated prior to any mesh excision.

Mesh Extrusion

This is the commonest mesh-related complication after transvaginal placement of the mesh for the management of POP (Fig. 4). Published rates for mesh extrusion range from 3 % to over 30 %, with large review articles suggesting overall rates between 10 and 15 % [31, 36, 37]. Common presenting symptoms of women with vaginal mesh extrusion include vaginal drainage/bleeding, pelvic pain, and dyspareunia. On examination, pain with palpation of the mesh, visible mesh extrusion, and vaginal shortening/tightening may be seen as well [38]. Risk factors for mesh extrusion include concomitant hysterectomy, smoking, total mesh volume, young patient age, early resumption of sexual activity, diabetes mellitus, and surgeon experience [36, 39, 40]. Local injection of lidocaine plus epinephrine has not been shown to increase risk of mesh extrusion [41]. Again, conservative management with topically administered estrogen and/or topical antibiotics can be attempted; however, little evidence exists suggesting success with this treatment. Often, partial or complete excision is necessary for symptom improvement [42].

Both office-based and operating room excisions are options for management. Office-based excision should be reserved for those with small exposures (usually less than 1 cm), adequate access to the exposed mesh, and healthy vaginal tissues. Similar to the description of office-based management of midurethral sling exposure, local anesthetic is injected around the extrusion and the adjacent vaginal epithelium is mobilized. The mesh can be excised and the

Fig. 4 Vaginal mesh extrusion after prior transvaginal mesh placement

vaginal epithelium brought together in a tension-free fashion with interrupted sutures.

The operating room affords the surgeon improved visibility, better patient anesthesia, and a wider array of instrumentation for managing mesh extrusions. The question that continues to be unanswered is how much mesh should be excised. There seems to be a balance, with an increased risk of further surgery for mesh excision when partial excision is undertaken and an increased risk of recurrent prolapse with complete excision [30]. For extrusions that are small and straightforward, mobilization of the surrounding epithelium to cover the mesh or simple excision of a small amount of mesh and closing the epithelium is usually all that is needed. If pain and a large-scale extrusion are noted, then more aggressive resection is usually performed. Techniques for surgical excision revolve around dissection of the overlying vaginal epithelium away from the mesh, followed by the dissection of the mesh away from the adjacent organ (bladder or rectum). Margulies et al. [33], Ridgeway et al. [43], and Muffly and Barber [35] each describe in detail surgical techniques for transvaginal mesh removal, and therefore this will not be discussed in detail here. Many mesh kits consist of a body of mesh with arms used for anchoring the mesh. After implantation and incorporation of the mesh, these arms may become vascularized. When a more complete excision is desired and the mesh body has been mobilized satisfactorily, the authors advocate clamping and tying of the mesh arms prior to transection to decrease the risk of bleeding. After mesh removal, when possible, midline plication of underlying connective tissue is performed to help resupport the prolapsed tissue and possibly decrease the risk of recurrent prolapse. Figure 5 shows explanted transvaginal mesh from the anterior and posterior compartment. If mobilization of the vaginal tissue does not

Fig. 5 Pieces of transvaginal mesh excised during complete explanation. *ANT, post*

allow a tension-free closure of the vaginal epithelium, porcine small intestine submucosa graft (Surgisis[®] Biodesign[™]; Cook Surgical, Bloomington, IN, USA) can be secured in place over the vaginal defect [44]. It acts as a scaffold and encourages host response to mediate the healing process. Vulvar flaps may also be used in instances where large defects are present after mesh removal.

Dyspareunia and Pelvic/Vaginal Pain

Dyspareunia and/or pain may develop after transvaginal mesh placement for treatment of POP. In a systemic review, the overall incidence of new-onset dyspareunia after vaginal mesh placement was 9.1 % (with a range of 0–67 %) [36]. Pelvic muscle spasm/pelvic floor tension myalgia can present as chronic pelvic pain and may be confused with mesh-related pain. Although they may be difficult to distinguish from each other, both may improve with nonsurgical treatments such as pelvic floor physical therapy [45, 46]. The authors recommend exhausting nonsurgical measures for the treatment of pelvic pain possibly related to mesh placement since patients undergoing surgical excision often have persistent pain [47]. Of all mesh-related complications, pain remains the symptom most resistant to medical and surgical treatment. It is often

improved after mesh excision, but may never disappear completely [34, 42, 47]. Thus, counseling patients prior to surgery about the risks associated with mesh removal is paramount. These include bleeding, infection, injury to adjacent organs, new/persistent pain, and recurrent prolapse.

El-Nashar and Trabuco [48] performed an early excision of vaginal mesh, 11 days after implantation. This was performed for severe vaginal pain and urinary urgency/frequency which began immediately after vaginal mesh placement. Complete excision, including mesh arms, was performed and the patient had resolution of all symptoms. In this case the implanting surgeon was not the referring provider, and this is consistent with findings of Blandon et al. [38]. In their study, only 14 % of patients with mesh-related complications were referred by the surgeon who placed the mesh; about half were referred by a different physician/health care provider and the remainder were self-referred.

Who Should Be Using Surgical Mesh in Gynecology

The American Urogynecologic Society (AUGS) recently published an article outlining specific recommendations for providing privileges and credentialing physicians for the placement of transvaginal mesh for treatment of POP [49]. In the past there were minimal guidelines for this process and physicians usually attended an industry sponsored 1- or 2-day course to learn these procedures using cadaveric trainers. The new AUGS recommendations call for documentation of each of the following: (1) knowledge of pelvic anatomy, (2) surgical skill, (3) surgical experience, and (4) internal audits for quality assurance. This article addresses surgeons who are not performing transvaginal mesh repairs but who would like to begin, as well as those currently performing these procedures. Currently, it is thought that surgical technique may play a role in mesh complication types and rates; however, there are no concrete data to support this.

Conclusions

The FDA and professional societies have recognized mesh complications as a significant problem. The risks for mesh-related complications are dependent on the type of mesh used, patient factors, and likely surgical technique. The surgeon who approaches management of mesh complications after pelvic surgery should possess a comprehensive understanding of the materials used in POP repair, pelvic floor anatomy, and advanced surgical skills in order to individualize management of such complications to each patient.

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