



# Allograft Pubovaginal Slings: a Systematic Review

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## Abstract

**Purpose of Review** Stress urinary incontinence (SUI) in women is the most common form of urinary incontinence and can be treated with different surgical procedures. As a sling procedure, the materials used are synthetic in midurethral sling (MUS) and non-synthetic tissue in pubovaginal sling (PVS): autografts (autologous), allografts, and xenografts. Cadaveric fascia (CAF) has been offered as an autograft substitute for years despite higher costs and unknown long-term outcomes. Herein, we review the use of allograft PVS in terms of overall efficacy to date. A literature search was performed with PRISMA through PubMed and Cochrane databases to identify studies published before September 2021. Key terms included “pubovaginal sling,” “allograft,” and “incontinence.” Systematic reviews, meta-analyses, and articles where sample patient populations were not diagnosed with SUI or did not receive allograft PVS were excluded.

**Recent Findings** Twenty-two publications were found: eight were excluded, and fourteen met the criteria for review. Several publications compared the efficacy of CAF to autograft. Postoperative SEAPI scores displayed improved symptoms from baseline and success rates were equal to autografts. Two studies demonstrated a shorter lifespan of CAF. The origin of allograft material was considered. Other publications demonstrated that CAF had shorter operation times and post-operative hospital stays and lower infection rates.

**Summary** Allograft PVS has shown to be an efficacious option based on quantitative patient satisfaction scores. APVS provides less morbidity including shorter operation time, postoperative hospital stays, and low infection rates; however, there are a limited number of studies comparing allograft PVS to other PVS materials.

**Keywords** Pubovaginal sling · Allograft fascia · Autograft fascia · Stress urinary incontinence

## Introduction

Urinary incontinence is a condition that affects approximately 20 million women across the USA [1]. A primary diagnosis is readily made through history-taking and categorizes the type of incontinence as urge, stress, and mixed or overflow urinary incontinence [1]. Women living with incontinence report a significantly decreased quality of life

involving sexual dysfunction, increased social stress or isolation, and restrictions on physical activities [1–3].

In particular, stress urinary incontinence (SUI) remains the most common form of incontinence [4]. Surgical management of SUI is indicated for women that have not had resolution of symptoms through conservative treatments such as Kegel exercises and pessaries. Another non-surgical treatment involves periurethral injections using urethral bulking agents. Although retropubic urethropexy (Burch colpo-suspension) is a potential surgical option, the historically favored surgical intervention for SUI was the placement of a pubovaginal sling (PVS), which can consist of autograft fascia, allograft fascia, and xenograft tissue [5]. Autograft fascia remains the most common sling material for PVS procedures due to its superior biocompatibility characteristics<sup>5</sup>. Currently, the most performed and recommended procedure is the mid-urethral sling (MUS), where a synthetic mesh sling is placed in a retropubic or trans-obturator approach [6].

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However, as a synthetic mesh with MUS was more commonly used, a growing body of literature found associated complications [7•, 8]. Common complications from mesh include mesh erosion, extrusion, dysuria, pain, and urinary tract infections [7•]. Autograft fascia PVS surgery remains an option for complex cases, surgical reintervention following mesh complications, or recurrent SUI symptoms; however, it comes with complications due to the need to harvest fascia, including higher rates of de novo urge incontinence and voiding dysfunction due to bladder outlet obstruction [9]. Additionally, it showed significantly greater morbidities such as blood loss, postoperative pain, longer operating and catheterization times, and longer hospital stays over synthetic and allograft sling materials [10–13]. Allograft PVS is theorized to circumvent such complications associated with fascial harvest by using cadaveric fascia as the sling material. Although MUS surgery is still considered the gold standard for surgical treatment of SUI, allograft PVS provides a potential advantage in reducing vaginal and bladder erosion from MUS surgery and morbidities associated with harvesting fascia from autograft PVS surgery.

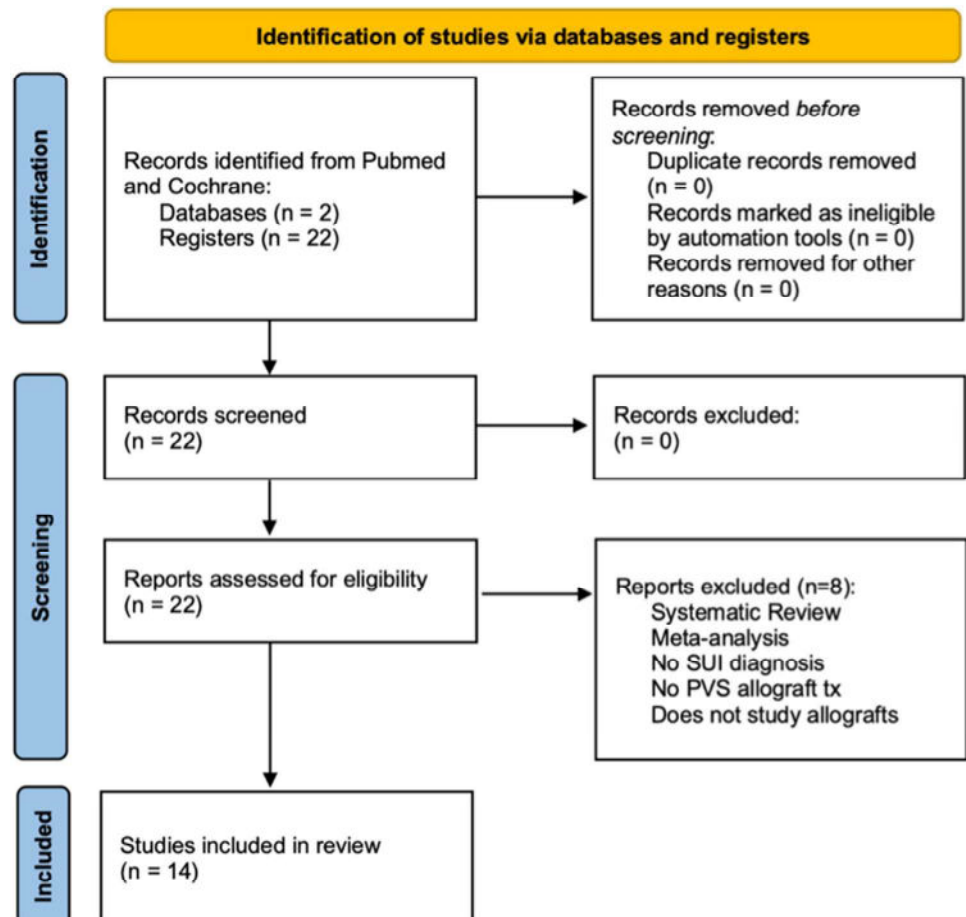
Compared to the autologous PVS, there is a paucity of literature describing the outcomes associated with the use of

allograft PVS. Therefore, in this review, we aim to describe the available data focusing on the outcomes, complications, and durability of allograft sling materials used to treat female stress urinary incontinence.

## Methods

A comprehensive literature search was performed using the PRISMA method through PubMed and Cochrane databases to identify relevant articles published before September 2021. The search terms “pubovaginal sling,” “allograft,” and “incontinence” were used. Search terms were limited to these terms to ensure the proper inclusion of all relevant publications. Systematic reviews, meta-analyses, and articles in which sample patient populations were not diagnosed with SUI and/or did not undergo allograft PVS surgery were excluded. The selection process of the literature is shown in Fig. 1. Twenty-two publications were found through a literature search. Eight were excluded and fourteen met the criteria for review. Several publications compared the efficacy of CAF to autograft counterparts [10, 12–14].

**Fig. 1** PRISMA flowchart outlining search methodology



## Results

A complete review of all of the literature is shown in Table 1. Overall, SEAPI incontinence scores not only improved from baseline but was equal to autograft scores at 1-year follow-up. However, two studies found a shorter lifespan of irradiated CAF than autograft fascia [15, 16]. In addition, other publications demonstrated that CAF use in PVS had shorter operation times, postoperative hospital stays, and lower infection rates than autograft PVS [10, 12, 13].

Two studies reporting high failure rates describe significant graft friability [15, 16]. A single-surgeon series conducted by Huang et al. in 2001 found an unacceptable 27.8% failure rate when using solvent-dehydrated, gamma-irradiated cadaveric fascia lata for PVS [16]. The scope of the study included 18 women undergoing allograft PVS, with an average follow-up of 9.2 months. However, those who experienced graft failure showed symptoms of recurrent SUI within 3–6 months [16]. High failure rates were also reported by Soergel et al. in 2001, with a 66.6% failure rate in patients undergoing a cadaveric fascia lata sling placement [15]. The study compared 12 patients who received the cadaveric fascia lata sling and 33 patients who received the autograft rectus fascia sling. The authors found only a 22% failure rate in patients receiving the autograft rectus fascia [15]. Both studies found frayed or absent allografts in almost

all instances upon repeat operation [15, 16]. The authors attribute the failures to the poor sling material, although the exact reasons for its failure are unknown. The primary hypothesis includes host vs. graft reactions, in which there is residual antigenicity of the graft material [15, 16]. Histopathological analysis of the sling performed by Huang et al. supported this theory when they found edematous and degenerative changes in the residual fascia, suggesting inflammation [16].

Several studies found sufficiently high or competitive success rates when using allograft material for PVS surgery, ranging from a 68 to 98% cure rate [10, 12–14, 17–20]. Some studies compared outcomes between allograft and autograft material for use in PVS surgery [10, 12–14]. None found a statistically significant difference between each material. Additionally, three of those studies found significantly shorter operation times and hospital stays for patients [10, 12, 13]. We found that allograft procedures ranged from 62 to 87 min while autograft procedures ranged from 82 to 119 min on average. Furthermore, Flynn et al. found significantly smaller pain scores and weeks lost from work in the allograft group [10]. Other series investigated allograft material on its own [17–20]. Onur et al. were the only authors investigating the use of cadaveric dermis instead of fascia lata for use in allograft PVS [14, 18]. An initial series and comparison to autograft rectus fascial material found

**Table 1** Summary of studies investigating allograft PVS outcomes

Series	Sling type	No. of patients	Mean follow-up in months (range)	No. cured (%)*	De novo urge incontinence (%)**
Almeida et al., 2004 <sup>12</sup>	Allograft fascia lata, autograft fascia lata	30, 30	36 (22–44), 33 (24–41)	20 (68%), 27 (90%)	–
Amundsen et al., 2003 <sup>29</sup>	Synthetic, allograft, and autograft fascia	3, 5, 1	–	–	–
Amundsen et al., 2000 <sup>17</sup>	Allograft fascia lata	91	19 (3–37)	76 (84%)	14 (44%)
Elliott et al., 2000 <sup>19</sup>	Allograft fascia lata	26	15 (12–20)	20 (77%)	2 (13%)
Flynn et al., 2002 <sup>10</sup>	Allograft fascia lata, autograft rectus fascia/fascia lata	63, 71	29 (24–36), 44 (30–56)	55 (87%), 64 (90%)	7 (28%), 2 (5%)
Hathaway et al., 2002 <sup>31</sup>	Allograft fascia lata, allograft dermis	–	–	–	–
Huang et al., 2001 <sup>16</sup>	Allograft fascia lata	18	9 (7–12)	13 (72%)	–
Miller et al., 2003 <sup>30</sup>	Allograft fascia lata	73	–	–	–
Onur et al., 2008 <sup>14</sup>	Cadaveric dermis, autograft rectus fascia	24, 25	13 (8–20), 18 (5–28)	19 (79%), 21 (84%)	3 (13%), 2 (8%)
Onur et al., 2005 <sup>18</sup>	Cadaveric dermis	25	12 (8–22)	20 (80%)	3 (20%)
Ordorica et al., 2008 <sup>8</sup>	Synthetic, xenograft, allograft	25, 6, 4	11 (3–24)	–	–
Soergel et al., 2001 <sup>15</sup>	Allograft fascia lata, autograft rectus fascia	12, 33	3–6	4 (33%), 26 (79%)	–
Walsh et al., 2002 <sup>20</sup>	Allograft fascia lata	31	14 (12–14)	29 (94%)	4 (13%)
Wright et al., 1998 <sup>13</sup>	Allograft fascia lata, autograft rectus fascia/fascia lata	59, 33	10 (1–20), 16 (15–28)	58 (98%), 31 (94%)	2 (10%), 1 (10%)

\*Definitions vary widely among studies. \*\*Calculated based on patients without prior urgency who developed symptoms

that the cadaveric dermis provided a ~80% cure rate [14, 18]. However, most authors reported complications of de novo urgency incontinence rates, with rates ranging from 8 to 29% [10, 13, 14, 17–19].

Definitions for success varied widely among series. The lack of standard criteria for cure could result in the inconsistency of success rates found in our review. Numerous authors reported results based on daily pad use, although such a method does not discriminate between SUI and other forms of incontinence, including urge incontinence [10, 17–19]. In these series, success was defined as using one or fewer daily pads. Only Flynn et al., Wright et al., and Amundsen et al. described specific cure rates for SUI [10, 13, 17]. Other studies relied on questionnaires, measuring the severity and occurrence of urinary symptoms and satisfaction scores postoperatively [12, 13, 20]. Furthermore, some reported results based on the failure of the procedure, finding a recurrence of SUI symptoms at preoperative levels within 3–6 months [14, 16]. Lastly, Soergel et al. described success as an absence of urine leakage during provocation at max cystometric capacity [15].

Similarly, follow-up times varied widely from study to study. Data used in these studies were reported based on the average of their subjects' follow-up period, ranging from 3 to 36 months after the operation [12, 15]. The lack of long-term (10–15 year) outcomes makes it difficult to assess the viability of allograft slings for definitive usage and potential for cure for PVS surgery.

## Discussion

PVS surgery is currently reserved for complex cases and surgical reintervention following a prior failed MUS surgery. Furthermore, allograft slings are considered for PVS when the patient has significant limitations with autograft (rectus fascia and fascia lata) harvest [21••]. A clear benefit has been described in the literature for allograft materials, including reduced postoperative pain and shorter hospital stays [10]. Additional considerations against autologous fascia harvest include the risk for abdominal wall herniation (rectus fascia) and potential chronic leg pain (fascia lata) [21••]. Patients with a history of smoking and obesity are determined to be at a higher risk for such complications [21••].

Cadaveric fascia lata is the tissue in allograft methods and is commonly prepared by lyophilization (freeze-drying) and sterilization by gamma irradiation [22]. These methods ensure the inactivation of infectious agents, decreasing the risk of transmission to the recipient. In addition to these methods of sterilization, another method for preparing cadaveric fascia lata for sling use includes solvent-dehydration [16]. Nonetheless, many

studies found that solvent-dehydration resulted in greater stiffness and higher maximal load strength of the allograft material when compared to freeze-drying [18, 19, 23]. The process of freeze-drying introduces ice crystals that negatively affect the graft's collagen structure; however, this is an active area of study [23, 24]. Although the use of cadaveric fascia for PVS surgery has been investigated numerous times, there is a noticeable lack of standardization in terms of thickness, quality, and processing techniques among tissue banks [17]. Therefore, tissue banks and their preparation of allograft tissue play an essential role in sling durability and may contribute to inconsistent outcomes.

As previously described, two studies performed by the same surgeon have investigated the usage of cadaveric dermis for allograft sling material [14, 18]. It has been reported that dermis provides superior tensile strength when compared to fascia lata, primarily due to the omnidirectional orientation of collagen fibers [18]. Additionally, *in vitro* findings showed that dermis remains more pliable and has quicker rehydration capabilities [14]. Therefore, cadaveric dermis could be a better material of choice over cadaveric fascia lata in allograft PVS surgeries.

Some studies describe a partial or complete degeneration of the allograft sling found during reintervention for failed allograft PVS surgery [15, 16, 25]. It has been hypothesized that host vs. graft reactions and infiltration of vaginal flora increase the friability of the graft [15, 16]. Soergel et al. found that younger patients were more likely to show autolysis of the sling, possibly owing to their stronger immune responses [15]. Although radiation treatment has been shown to deteriorate collagen cross-linking in graft material, non-irradiated grafts are not an option due to the high risk of pathogen transmission [24]. Additionally, Flynn et al. discussed how specific surgical techniques such as bone-anchoring and differences in sling length and thickness contribute to sling durability [10, 19, 26].

Although not well described in human trials, studies on sling durability in rabbit models have demonstrated allograft underperformance when compared to other biological and synthetic sling materials [27, 28]. While mesh and cadaveric fascia slings had similarly high levels of organized fibrosis and scar formation, the cadaveric fascia showed significantly increased levels of inflammation and eosinophil infiltration when compared to mesh and autograft at 12-week post-implantation [27]. Additionally, cadaveric fascia was found to have a 60–89% decrease in tensile strength and stiffness from baseline measurements [28]. While allograft materials might react differently in human subjects than the non-human animals in these trials, both studies conclude that inflammatory-mediated loss of strength is a downside of the usage of cadaveric fascial slings in PVS surgery.

Complications of biological materials remain a consideration with PVS surgery. Specifically, postoperative de novo urge incontinence remains the most common associated complication and is the primary reason for patient dissatisfaction with allograft slings [10, 13, 14, 17–19]. Although sterilization procedures significantly reduce the risk of infection, a slight chance of blood-borne pathogen transmission remains [16]. Additionally, the allograft sling can either partially or entirely degenerate, causing repeat SUI symptoms and need for surgical reintervention [15, 16, 25]. Urethral erosion complications have been primarily described in relation to MUS and mesh-related surgery; however, it can happen irrespective of sling material. Erosion has been seen with the use of mesh, allograft, and autograft fascial sling materials, suggesting that other factors such as sling tension are the primary contributor to the risk of erosion [29].

Since many of the studies were single-institution and single-surgeon series, it is difficult in the absence of standardized data to arrive at a clear conclusion to guide surgical practice. In addition, the heterogeneity in surgical techniques, follow-up times, and allograft preparation presents confounding variables that contribute to the inconsistency of outcomes.

## Conclusion

Of the literature analyzed, cadaveric allograft fascia has shown to be an efficacious option based on success rates and satisfaction scores compared to other PVS materials. The allograft PVS procedure provides shorter operations, postoperative hospital stays, and a low risk of wound complications. However, limitations of the reported data include varying follow-up times, single-institution series, and different success definitions. Standardization of allograft usage is prevented by the uncertainty of durability. Therefore, a more thorough examination of the origin of allograft material, sling durability, and long-term outcomes is needed to make a definitive recommendation for allograft PVS. However, unless allograft PVS becomes more widespread for SUI treatment outside of just complex cases, multi-institutional comprehensive data will likely remain limited.

**Author Contribution** All authors contributed to the study conception and design. Material preparation, data collection, and analysis were performed by CC and BL. The first draft of the manuscript was written by CC, BL, and CA. All authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

## Declarations

**Conflict of Interest** The authors declare no competing interests.

**Human and Animal Rights and Informed Consent** This article does not contain any studies with human or animal subjects performed by any of the authors. All studies reported in this article have been reported to have complied with all applicable ethical standards. There were no individuals reported in this study. Informed consent is not applicable to this article.

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