RANDOMISED CONTROLLED CLINICAL TRIAL COMPARING THE CLINICAL OUTCOME OF AUTOLOGUS FASCIA LATA TO SYNTHETIC MESH FOR ABDOMINAL SACROCOLPOPEXY AMONG SUCCESSFULLY REPAIRED VAULT PROLAPSE PATIENTS.

Final thesis submitted to The Tamilnadu
Dr. M.G.R. Medical University, Chennai-32

By

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In fulfillment of the requirement for the Award of Doctor of Philosphy in Urogynaecology

Under the guidance of

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Research Guide

JUNE 2018

Randomised controlled clinical trial comparing the clinical outcome of Autologus fascia lata to synthetic mesh for abdominal sacrocolpopexy among successfully repaired vault prolapse patients.

CERTIFICATE

This is to certify that the thesis entitled "**RANDOMISED CONTROLLED CLINICAL TRIAL COMPARING THE CLINICAL OUTCOME OF AUTOLOGUS FASCIA LATA TO SYNTHETIC MESH FOR ABDOMINAL SACROCOLPOPEXY AMONG SUCCESSFULLY REPAIRED VAULT PROLAPSE PATIENTS"** is an original research work done by me, and it was not used previously either partly or fully for the award of any Degree, Diploma, Associateship, fellowship or other similar title.

Place: Chennai-8

Dr.K.Seethalakshmi, DNB (OBG)., DGO, MNAMS
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CERTIFICATE

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"This Thesis is dedicated to my Parents Thirumathi K. Angammal and Thiru.Sivakrishnan for
the early seeds of learning planted during my growth and for years of their advice.
To my husband Dr. P.Sankaralingam M.S.(ortho)., DNB (Ortho)., MNAMS who always encourages me to spread the wings in my Profession andto pursue my dreams and finish my dissertation.
And
To my daughters Ms. Sivaranjani Sankaralingam M.S (information security, USA)
And
Dr. Deepika Sankaralingam M.B.B.S for their constant support, patience and encouragement"

I am indebted to my father for living, but to my teacher for living well

– Alexander the Great

ACKNOWLEDGEMENTS

This work would not have materialised but for the support and guidance from

Prof. N. Rajamaheswari
M.D., D.G.O., M.Ch (urology)
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I thank my guide and supervisor who has been a constant source of inspiration and encouragement.Without her continuous optimism, support and enthusiasm, this study wouldn't have been possible. I am eternally indebted to Madam for making this happen.

I am extremely grateful to Prof. Dr. N.Thilothammal, M.D., D.C.H., D.M(Neurology)., M.P.H (USA) , Former Professor of Paediatrics and Paediatric Neurology, Institute of Child Health and Research center, Madras Medical College, Chennai for her unstinted help and guidance to complete the study.

I express my sincere thanks to Dr.N.Mohanambal M.D., D.G.O., Former Director and Superintendent, Institute of Obstetrics and Gynaecology, Madras Medical College, Chennai

I would like to thank my colleague Dr. M.Meena M.D., D.G.O., Assistant Professor, Department of Urogynaecology, Government Kasturba Gandhi Hospital, Chennai, for all the help rendered to me.

I am greatly indebted to Ms. V. Banumathi, Former urinary continence research nurse, Department of Urogynaecology, Government Kasturba Gandhi Hospital, Chennai, for her support and for helping me in every possible way.

I thank all the members of the staff of the department of Urogynaecology who invested considerable time and effort to make this study possible.

I sincerely thank the Members of the Ethical committee, Madras Medical College, Chennai for facilitating me to carry out this study.

I express my deep appreciation & heartfelt thanks to the Vice-Chancellor, The Tamilnadu Dr. M.G.R.Medical University, Chennai

This work would not have been possible without strong support from my husband and two daughters who provided a conducive atmosphere to work and cheerfully put up with all the difficulties entailed.

Last but not the least, my deepest gratitude goes to each and every one of the patients and their relatives who, unmindful of their personal inconvenience, helped me put together the information required to complete this study. Many patients travelled several times from remote villages for follow-up, thus contributing significantly to my attempt to enrich current scientific knowledge. The study would not have been possible if not for their efforts, trust and tenacity to travel against all odds.

Coming together is a beginning, Keeping together is progress, Working together is success – Henry Ford

Dr. K.Seethalakshmi

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INTRODUCTION

Vaginal vault prolapse has been defined by the International Continence Society as descent of the vaginal cuff below a point that is 2 cm less than the total vaginal length above the plane of the hymen.[1, 35]

Coexisting pelvic floor defects like cystocoele, rectocele or enterocele may be present in 72% of patients with vault prolapse. [2] Pelvic organ prolapse has negative impact on quality of life of these women due to associated urinary, faecal and coital dysfunction. It is important to assess the defects of the different vaginal compartment and counsel these women before planning surgical management. A clear understanding of the supporting mechanisms of the uterus and the vagina are important in order to make the right choice of the corrective procedure and also to minimise the risk of occurrence of vault prolapse.

The incidence of vaginal vault prolapse ranges from 0.2% to 45%. [3] Occurrence is comparable between abdominal and vaginal hysterectomy. [4]

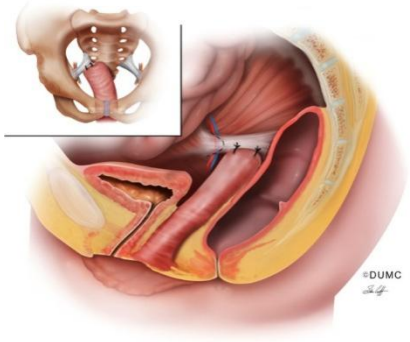
Vaginal vault prolapse is explained by:

- attenuation of the cardinal / uterosacral ligament complex, loss of support of paracolpium and parametrium after hysterectomy [4, 5]
- separation of the pubocervical fascia from the rectovaginal fascia [5]
- separation of the pubocervical fascia, rectovaginal fascia from the uterosacral ligament and detachment of levator ani muscle from the pubis.[5]

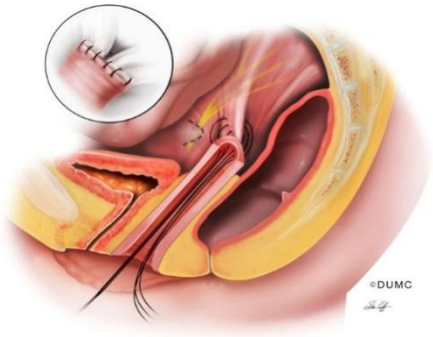
The type of post-hysterectomy prolapse will depend on the level of defect in support mechanism.[4] Defective suspension of the vaginal apex (level I) with preservation of mid-vaginal support (level II) presents as simple eversion of the upper vagina. This represents 33% of women with vaginal eversion. When associated with failure of level II support , vaginal eversion will be associated with cystocele and/or rectocele and this is referred to as complex vaginal eversion and represents 67% of post-hysterectomy vaginal prolapse.[4] Vaginal prolapse is frequently complex involving the entire vagina and less commonly involves single compartment .[6]

Adequate support for the vaginal apex is an essential component of a durable surgical repair for women with advanced prolapse [I 11]. ***Because of the significant contribution of the apex to vaginal support, anterior and posterior vaginal repairs may fail unless the apex is adequately supported [12)*** The surgical correction of post-hysterectomy vaginal vault prolapse should therefore aim at apical suspension, restoration of lateral attachment, vaginal axis and reconstruction of vagina. Excision of redundant peritoneum and vaginal mucosa performed if necessary.[5, 6, 7]

Good apical vault support is the corner stone of pelvic reconstruction[8] . It is essential that the vaginal apex should be suspended to a normal segment of uterosacral ligament [10,21,35]. Repair and reconstruction should include approximation of pubocervical and rectovaginal fascia to the apex.[5, 6, 7] The apical suspension procedures include abdominal sacrocolpopexy, [6,10,11] vaginal sacrospinous fixation [6,10,11), Vaginal high uterosacral ligament suspension (intra peritoneal / extra peritoneal).[7,10,21,35]



Vaginal sacrospinous fixation



Vaginal high uterosacral ligament suspension

Reattaching the rectovaginal fascia laterally to the iliococcygeal fascia and attaching the pubocervical fascia laterally to the arcus tendinous fascia pelvis (paravaginal repair) will restore lateral attachment and correct level II defect [26,27,28].

Pelvic reconstruction should restore the vaginal length and vaginal axis and maintain the relation between the vagina and the pelvic floor. Shortening of the vagina and/or altering its normal axis may lead to recurrence.[9, 10, 11] The incidence of posthysterectomy vault prolapse requiring surgery has been estimated at 36 per 10,000 women years. The risk increases cumulatively with years after hysterectomy and increases significantly in women whose initial hysterectomy was performed for genital prolapse [i1–3]. In an aging population, the number of women that will seek medical help for

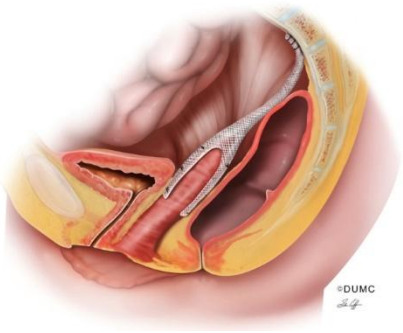
a vaginal vault prolapse will increase due to an improved life expectancy and due to the aging population.

Current treatment options for Vaginal vault prolapse include pelvic floor muscle training, use of pessaries, and surgery [13]. More than 20 different surgical procedures for correcting vault prolapse have been reported [13,14,15];

Surgery for pelvic organ prolapse, including vaginal vault prolapse, focuses on the restoration of the normal vaginal anatomy and normal bladder and bowel function.

Sacrocolpopexy is the gold standard procedure for POP with excellent anatomical and functional outcomes.(8) It can be performed abdominally, laparoscopically or robotically.(9,10). Success rates of abdominal sacrocolpopexy range between 93% and 99% [6.7]. abdominal sacrocolpopexy is performed by laparotomy (ASC), laparoscopy (LSC) and robotics (RSC), using xenograft, polypropylene, abdominal fascia or fascia lata.

According to a Cochrane review on the subject, abdominal sacrocolpopexy is associated with a lower rate of recurrent vault prolapse compared to the vaginal sacrospinous fixation [5].



Abdominal sacrocolpopexy

The requirement for surgical management of pelvic organ prolapse (POP) is in increasing trend. The lifetime risk of undergoing primary surgical intervention for the pelvic organ prolapse by the age of 80 is 6.3% and 30% of women requiring reoperation for recurrence.[12, 13,14] Some studies have reported even higher (43% - 58%) incidence of reoperation after primary pelvic reconstructive surgery [14,, 15]

During the past decade, prosthetic materials have been used to minimise the recurrence. Thus use of mesh is nevertheless associated with complications like vaginal mesh exposure, extrusion, perforation, infections, granulomas, dyspareunia, sometimes fistulas, chronic pelvic pain requiring additional surgeries thereby potentially reducing the quality of life of women..[16, 17, 18, 19]

The surgical options (approach and technique) for the correction of vault prolapse include vaginal, abdominal and laparoscopic (robotic) approach. The choice of procedure should be based on the level / stage of defect and complexity of vault prolapse. Patient's age, co-morbidity, previous surgery and the level of physical and sexual activity[20] are other factors to be considered. Expertise and training of the surgeon also influences the choice of operation.

Performing apical suspension of vaginal vault at the time of initial hysterectomy and appropriate fascial repair will significantly reduce the incidence of vault prolapse. Various techniques have been described for the correction of vault prolapse, though satisfactory correction of vaginal vault prolapse remain to be a surgical challenge.

Numerous surgical techniques have been described to suspend the vaginal vault, which include either a vaginal or an abdominal approach or a combination of both. (i4) The abdominal approach can be performed open or

laparoscopically Recently, laparoscopic approach has become popular. The vaginal options include high uterosacral ligament suspension [10, 21, 35],sacrospinous fixation [6,10, 11, 23, 24] and iliococcygeal fixation (prespinouscolpopexy).[25, 26, 27, 28]

Abdominal sacrocolpopexy[29, 30] is an anatomically effective (success rate of 88% to 100%) and most frequently performed surgical repair technique [29] for post-hysterectomy vaginal vault prolapse [21, 29, 30, 31 & 32].

Sacrocolpopexy is especially indicated in the presence of attenuated supporting structures with compromised pelvic floor particularly if associated with chronic physical stress (e.g. chronic obstructive pulmonary disease or chronic constipation). It is the preferred technique for women undergoing postcolposuspension enterocele repair, concurrent colposuspension and enterocele repair and short vagina with vault prolapse which can not be effectively suspended to the sacrospinous ligament. [28]

In sacrocolpopexy, the apex of reconstructed vagina[3] is suspended to the anterior longitudinal ligament of the sacrum [10,31, 32] using synthetic material in order to accomplish long term efficacy with minimal complication.

Concurrent plication of uterosacral ligaments or other forms of culdoplasty have been advocated to prevent formation of enterocele below the vault suspension. [9,10]

Ross JW, 1997 emphasised the importance of good apical vault support however, paravaginal repair may be required [5, 6] to address the complex vaginal vault prolapse which is reported in 67% of post-hysterectomy prolapse. [34,35]

Various synthetic material have been used like Mersilene®, Prolene®, Teflon® Marlex® and Gore-Tex® to suspend the apex. However the preferred synthetic material is monofilament, macroporous, polypropylene synthetic mesh.

The essential property of good graft is its ability to integrate into endopelvic tissue. This is possible when the mesh pore size is greater than 75 microns which allows the ingrowth of fibroblasts and collagen. Synthetic polypropylene meshes are classified as type 1,II, III, or IV according to mesh pore size and filamentous nature. Type 1 is the macroporous mesh. The monofilament diameter ranges from 0.08mm to 0.20 mm. Pore size varies from 0.6 mm to 4.0 mm and weight from 18-100 gsm. Mesh implantation will naturally generate inflammatory response which includes formation of fibrosis around the mesh, followed by formation of giant cells and granulomas thus strengthing the tissue to tolerate the mesh well [39,40].

The advantages of using synthetic mesh [36] over autologous grafts for the surgical treatment of vaginal vault prolapse include the avoidance of an additional incision to harvest fascia lata or rectus fascia, a decrease in operative time, consistency of strength, and high cure rates. Use of synthetic mesh is also associated with a risk of mesh extrusion most commonly into the vagina [16,19]. The average rate of extrusion of synthetic mesh utilized for abdominal sacrocolpopexy is 3.4%, with range from 0.9% to 11%. A recent retrospective review of 57 abdominal sacrocolpopexies from a single institution reported an erosion rate of 12% with Marlex and Mersilene meshes recognised 4–24 months after surgery. Disadvantages of using synthetic materials to suspend the apex forced the pelvic surgeons to consider the usage of autologous material.

Autologus materials harvested from the rectus fascia and fascia has been tried. Absence of erosion (exposure/ extrusion/ perforation) is the

advantage of autografts over synthetic materials. The overall long term cure rate of 90% (Choe J.M., at al) reported with autografts is comparable to that of synthetic materials. Usage of autologus fascia results in minimal to moderate inflammatory response, moderate degree of collagen production (De Rezende Pinna et al, 2011) and a suggestion that grafts undergo a degree of remodelling over the long term (Woodnuff et al,2008). Once the fascia lata is placed over the anterior longitudinal ligament, fascia lata derives its blood supply from the anterior longitudinal ligament of sacrum and vaginal vault.

Aim of the Study

The aim of the study is to compare the clinical outcome of autologous fascia lata vs synthetic mesh to suspend the vaginal apex during abdominal sacrocolpopexy as surgical treatment for vaginal vault prolapse.

Objective of the Study

To assess the anatomical, functional and symptomatic efficacy of autologus fascia lata over synthetic mesh in abdominal sacrocolpopexy in successfully repaired cases of Vault prolapse .

REVIEW OF LITERATURE

Anatomy

"It is by Anatomy alone, that we know the true nature, and therefore the most proper cure of the greatest number of local diseases." William Hunter (Moore, 2005).

Pelvic connective tissue and cleavage planes:

The pelvic viscera are connected to the lateral pelvic wall by condensation of connective tissue called endopelvicfascia.Theendopelvic fascia is composed of blood vessels, nerves and interspersed with supportive meshwork containing collagen and elastin.

The ligaments of the genital tract are diverse and have different functions.

Ligaments of the uterus

The broad ligament extend laterally from the uterus and cover the adnexal structures.Broad ligament has no supportive function.The cardinal ligament attaches the lateral margins of cervix and vagina to the pelvic walls.The uterosacral ligament fan out in the retroperitoneal layer to have broad attachment over the second ,third and fourth segment of sacrum. Uterosacral ligament hold the cervix posteriorly in the pelvis over the levator plate of pelvic diaphragm. The cardinal ligament attach the cervix below the isthumus to pelvic wall over the piriformis at the level of greater sciatic foramen.They provide support to the cervix , uterus and upper portion of vagina. The cardinal ligament maintain the posterior axis of uterus over the levator plate of pelvic diaphragm and away from urogenital hiatus.

Vaginal Fasciae and attachments

The attachments of vagina to the pelvic walls are important in maintaining the pelvic organs in their normal position. In the midvagina, the vagina is attached laterally to the arcus tendinous fascia pelvis by pubocervical fascia which extends from pubic bone to the ischial spine.These lateral attachments suspend the anterior vaginal wall across the pelvis and prevent its downward descent when there is increased intra abdominal pressure. Posteriorly (at the level of mid vagina) , vagina is attached to the levatorani muscle fascia laterally. The perineal body is attached to the ischiopubic ramus which holds the perineal body in place and prevents protrusion of distal rectum.

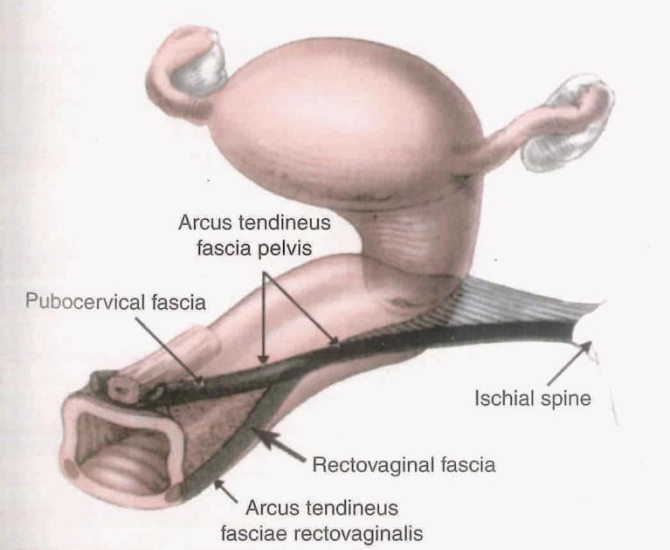
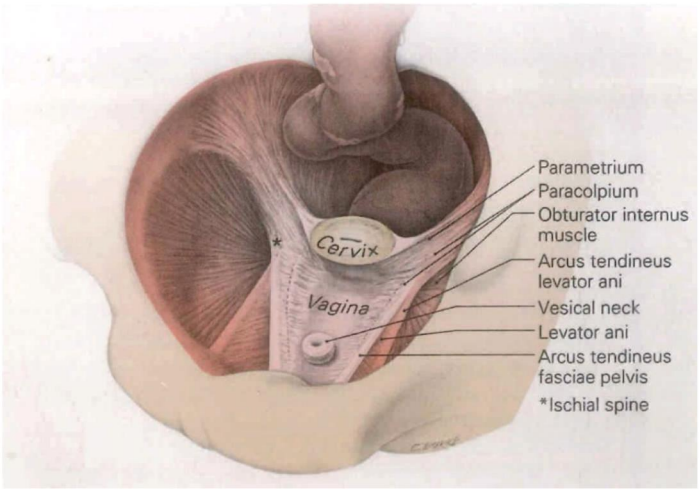


FIGURE 36.6 The lateral attachments of the pubocervical fascia (PCF) and the rectovaginal fascia (RVF) to the pelvic sidewall. Also shown are the arcus tendineus fascia pelvis (ATFP), arcus tendineus fasciae rectovaginalis (ATFRV), and ischial spine (IS).

Pelvic fasciae

Parietal pelvic fasciae are obturator fasciae, levatorani fasciae, coccygeus fasciae and piriformis fasciae.Visceral pelvic fasciae cover the vagina, uterus, bladder and rectum.



Applied Anatomy of pelvic ligaments and muscle

The normal position, support and suspension of the uterus, vagina, bladder and rectum rely on an interdependent system of bony , muscular , and connective tissue components.Even mild alterations in one part may lead to stress in other components which lead to failure of normal anatomy.The muscles of pelvic diaphragm mainly provide pelvic support.

These levatorani muscles form a basin for the pelvic organs.Thepubococcygeus and iliococcygeus muscle cover the pelvic outlet.The white line of pubis serves the function of mid vaginal lateral support anteriorly and arcus tendineous fasciae rectovaginalis support the posterior midvagina laterally. The vagina and rectum are suspended by the endopelvic fascia (primarily by the uterosacral ligaments) over the levator plate.

Pubocervical ligament provide minimal degree of cervical stabilization.The rectovaginal septum provides posterior vaginal support and stabilize the rectum.

Pericervical ring

The pericervical ring is collar of connective tissue encircling the supravaginal cervix. It is formed by pubocervical ligament anteriorly, Cardinal ligaments laterally and uterosacral ligaments posteriorly.

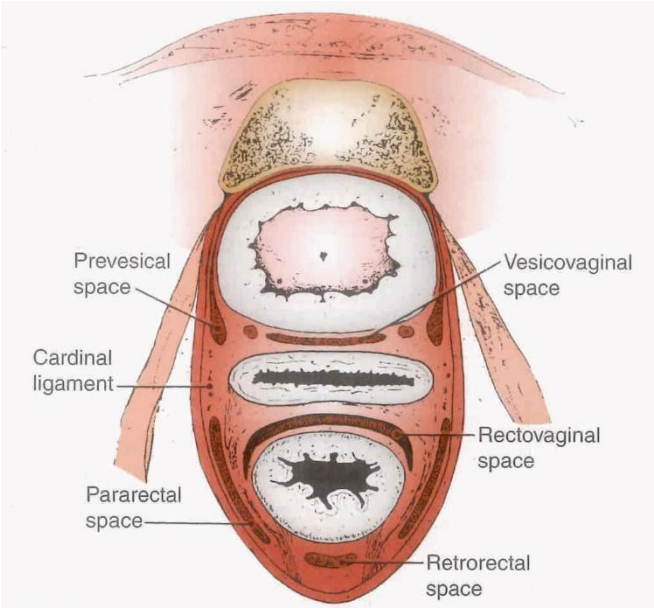


FIGURE 7.14 Cross section of the pelvis showing cleavage planes.

The pericervical ring is the area where all deep endopelvic connective tissue supports converge.

The goal of the pelvic reconstructive surgery is the restitution of anatomical connections of pericervical ring within interspinous diameter.

The pubococcygeus and iliococcygeus form the bulk of pelvic diaphragm. The arcus tendinous fascia pelvis provide lateral attachment for pubocervical septum and apical rectovaginal septum.The white line of pubis provide midvaginal lateral support.The fascial thickeningdescribed as arcus tendinous fasciae rectovaginalis which run posteriorly from the whiteline to the lateral perineal body provides lateral support for the distal rectovaginal septum of posterior vagina.(63)

DeLancey"s theory:

The biomechanical analysis of normal uterovaginal support is important for good reconstructive surgery.DeLancey divided vaginal support into three levels.

1. Proximal or apical vaginal support – Level 1 support is attributed to suspension by uterosacral ligament of paracolpium. Damage to level 1 support results in uterovaginal prolapse, posthysterectoy vaginal vault prolapse and enterocele.The cause for level 1 support is necessarily at or above the level of ischial spines.Mengert et al revealed that the prolapse occurred only after 85% of integrity of paracolpium was affected.

2. Midvaginal -Level 2 support is due to lateral attachment of fascial septa to arcus tendinous fascia pelvis anteriorly and arcus tendineous fascia rectovaginalis posteriorly. Damage to this lateral support results in cystocele and rectocele.

3. Distal level 3 support is attributed to the fusion of deep endopelvic connective tissue septa to the urogenital diaphragm anteriorly and to the perineal body posteriorly. Damage to these supportsanteriorlyresultin urinary incontinence and defecatory dysfunction when damage occurs posteriorly.

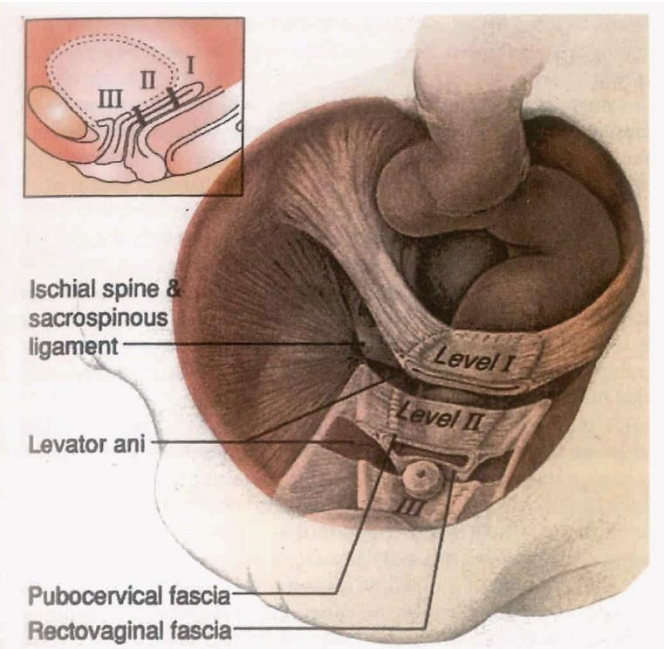


FIGURE 36.8 The endopelvic fascia of a posthysterectomy patient divided into DeLancey's biomechanical levels: level I, proximal suspension; level II, lateral attachment; level III, distal fusion. (Adapted from DeLancey JO. Anatomic aspects of vaginal eversion after hysterectomy. *Am J Obstet Gynecol* 1992;166:1717, with permission. Copyright © 1992, Elsevier.)

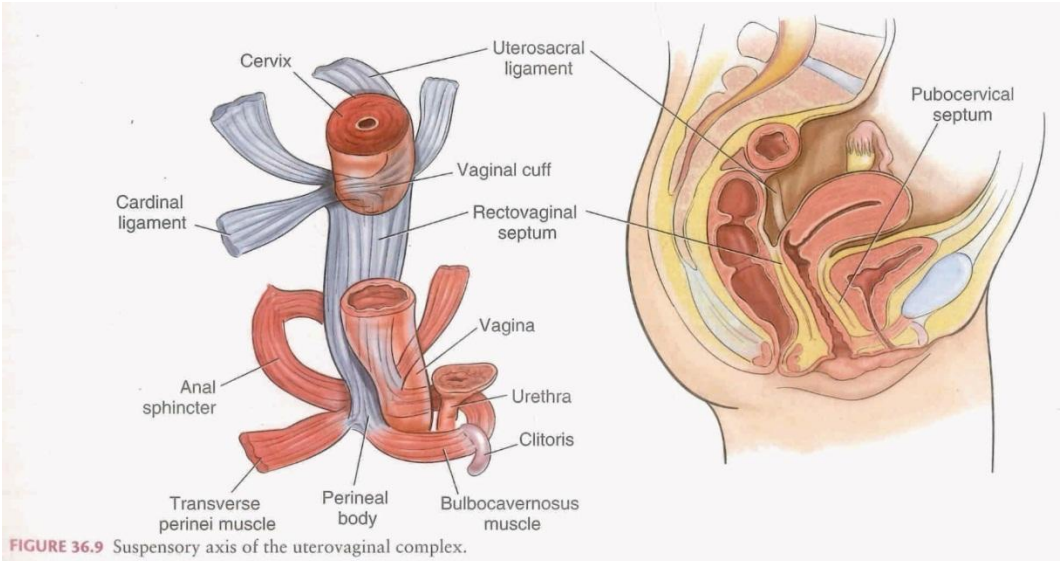
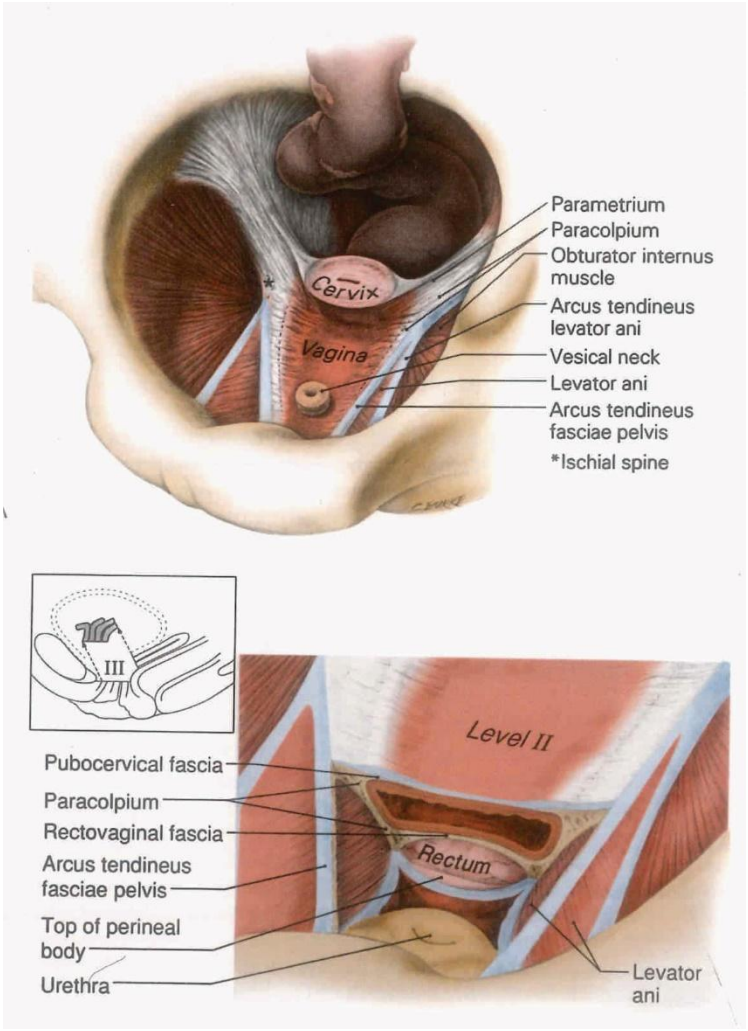
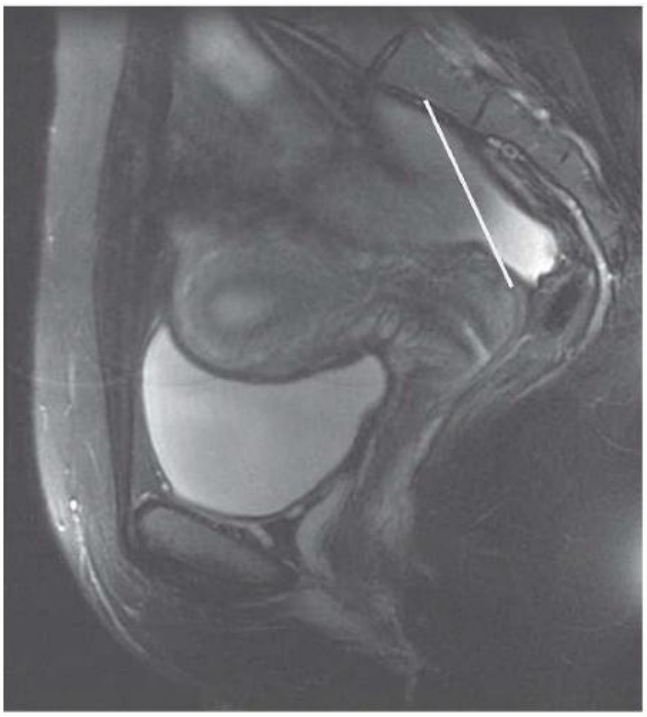


FIGURE 36.9 Suspensory axis of the uterovaginal complex.

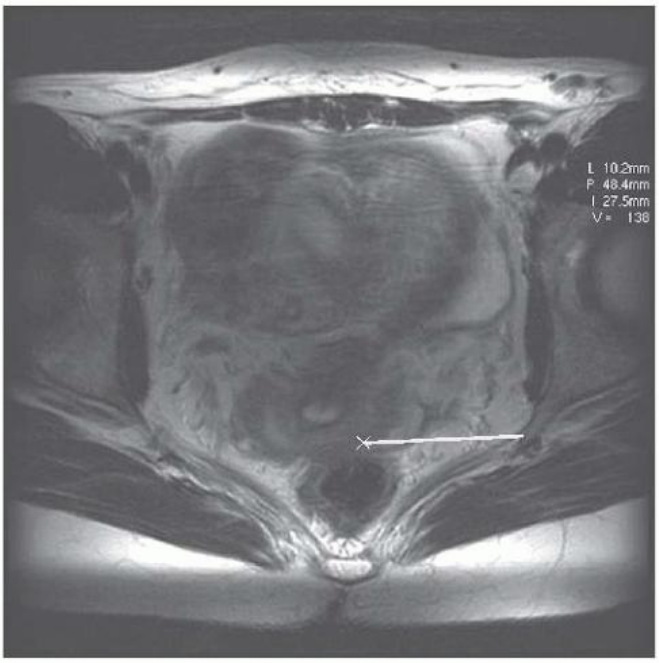


Anatomy of vaginal apex

Magnetic resonance imaging demonstrates that the normal position of the vaginal apex is approximately 5 cm inferior to the second sacral vertebral body and approximately 5 cm medial to the ipsilateral ischial spine (138). Surgeries that recreate this anatomy will also accomplish the goal of suspending the vaginal apex over the levator plate. Distortion of the position of the vaginal apex, whether in an anterior or posterior direction, can contribute to dyspareunia and could contribute to recurrent prolapse opposite the vaginal vault.



Sagittal MRI illustrating the relationship between the posterior vaginal fornix and the anterior surface of the middle of the second sacral vertebra.



Axial MRI illustrating the relationship between the left cervical vaginal junction (×) and the left ischial spine

Pathophysiology of Pelvic organ prolapse

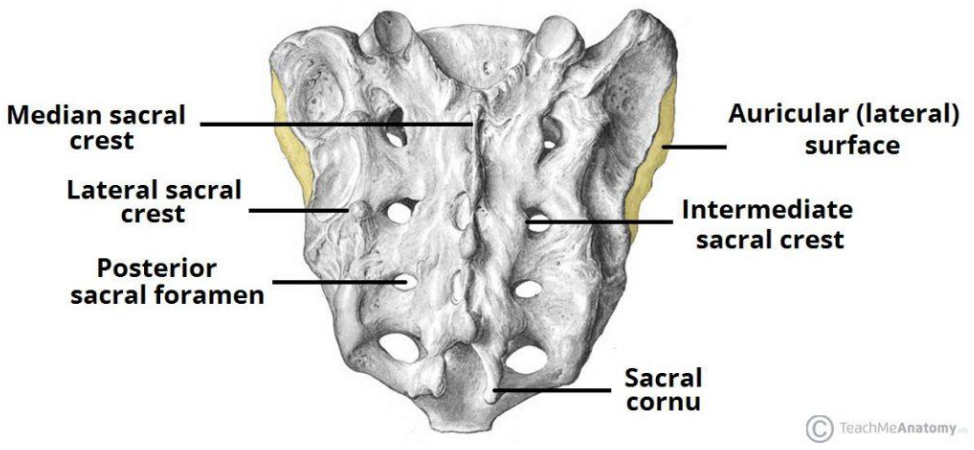
The midline confluence of levatorani muscles form a strong band of connective tissue between the coccyx and posterior anus known as levator plate or sacrococcygeal raphe. The vagina and rectum are suspended by the endopelvic fascia directly over the levator plate. Myopathies and neuropathies cause weakness of pubococcygeus and iliococcygeus, allow the levatorplate to sag and descend permanently. The increase in genital hiatus opening changes the normal horizontal axis of apical vagina to more vertical orientation and predisposes the apical pelvic organs to prolapse.

Pudendal neuropathy and levatorani myopathy are the significant contributing factors in the development of pelvic organ prolapse.

In cystocele and rectocele, the defects are due to displacements of respective endopelvic fascia originating at the margins and not centerally.

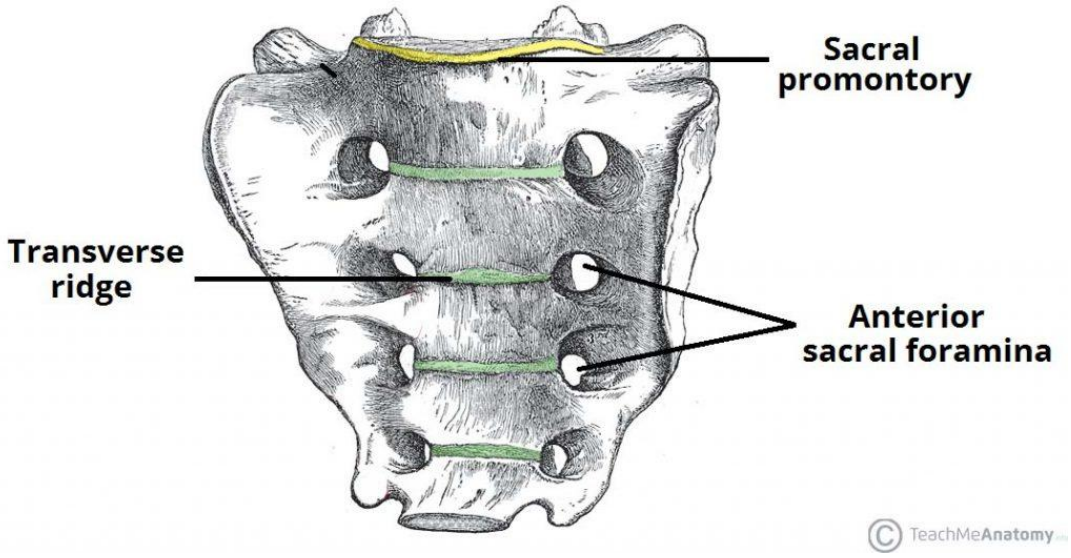
Anatomy of sacrum:

Sacrum is triangular bone and consists of five pieces of sacrum. Superiorly body of S1 articulates with L5 forming sacro vertebral angle. It is situated in the upper posterior pelvic cavity and inserted like a wedge between two innominate bones. Sacrum ends with coccyx.



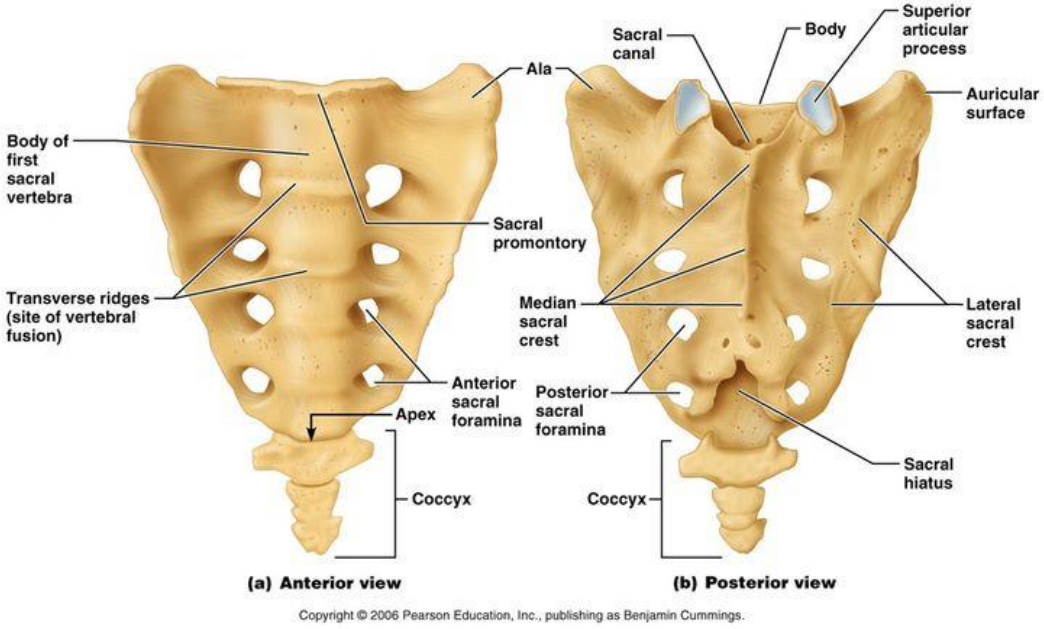
The base of the sacrum, is broad and expanded, and is directed upward and forward.The apex is directed downward, and presents an oval facet for articulation with the coccyx.The female sacrum is shorter, wider, and curved more posteriorly than the male sacrum to provide more room for the passage of the fetus through the birth canal during childbirth.

Sacral cavity is more deep and concave in females. Sacrum has dorsal surface, pelvic surface and lateral surface. The projecting edge anteriorly from S1 is sacral promontry.S1 has costal element and transverse process which articulate to each other and also to other sacral vertebrae. Sacrum has four pairs of sacral foramina which transmits first four sacral nerves.



The sacral foramina communicate with sacral canal through intervertebral foraminae. It gives orgin to piriformis muscle. S1, S2 and upper border of S3 is covered with peritoneum and the rest by root of sigmoid mesocolon.The rectum lies in direct contact with S4 and S5 vertebra. Medial to sacral foraminae, sympathetic trunk lies. Lateral to sacral foraminae lies lateral sacral vessels.

Dorsal surface of sacrum is convex. Median of dorsal surface has sacral crest which gives orgin to erector spinae. The notch at lower end of S4 is sacral hiatus. The dorsal surface has four pair of dorsal sacral foraminae which transmits dorsal rami of sacral nerves. The depth and concavity of sacrum is more in female than in male. The body of sacrum is wider in female than in male.

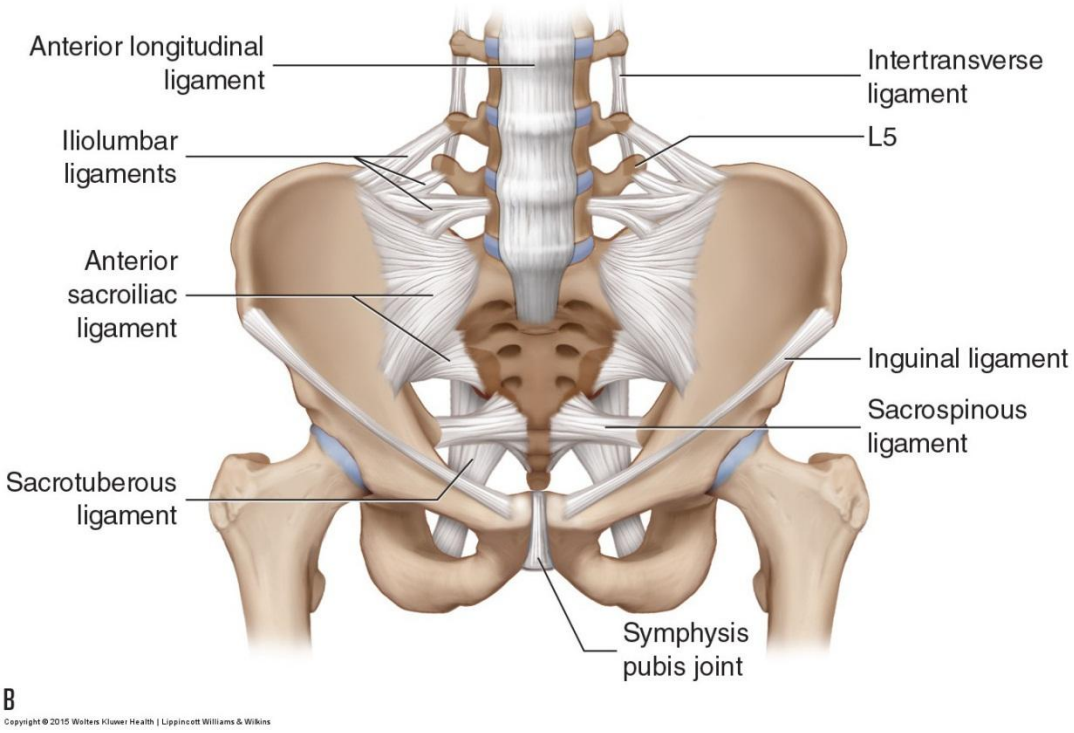


Anterior Longitudinal ligament (ALL)

ALL is strong band of variable thickness and width that covers the anterior aspects of the vertebral bodies and intervertebral discs throughout the length of the vertebral column. From superficial to deep ,its ligamentous fibers span varying lengths.It is thick and narrow over the vertebral bodies where it is loosely bound to the periosteum. At the levels of the intervertebral disc, it widens and the fibers strongly bind to the fibrocartilage disc, the hyaline cartilage vertebral end plates, and the margins of the vertebrae.

It is a primary spine stabilizer about one-inch wide, the ALL runs the entire length of the spine from the base of the skull to the sacrum. It connects the front (anterior) of the vertebral body to the front of the annulus fibrosis.

It’s attached to the upper and lower edges of each vertebral body Function: Limit extension of the vertebral column and reinforce the intervertebral disc.



Applied anatomy of anterior sacral ligament

Median anterior longitudinal ligament thickness at the sacral promontory level was 1.9 (range 1.2-2.5) mm. Median fifth lumbar to first sacral disc height was 16 (8.3-17) mm.

Awareness of the first sacral nerve position, approximately 2.5 cm below the midpoint of the sacral promontory and 2 cm to the right of midline, should help to anticipate and avoid somatic nerve injury during

sacrocolpopexy. Knowledge of the approximate 2-mm thickness of the anterior longitudinal ligament should help reduce risk of discitis and osteomyelitis, especially when graft is affixed above the level of the sacral promontory.

The recommended location of graft attachment during sacrocolpopexy is at or below the sacral promontory on the anterior surface of the first or second sacral vertebra.Graft fixation in the hollow of the sacrum may potentially involve the first sacral nerve.[139]

Presacral space

The presacral space begins below the bifurcation of aorta and is bounded laterally by internal iliac arteries. Middle sacral artery and vein which originate from aorta and vena cava lying directly on the sacrum. Caudal and lateral to the middle sacral vessels are lateral sacral vessels.Thepresacralnerve is also present in the presacral space.

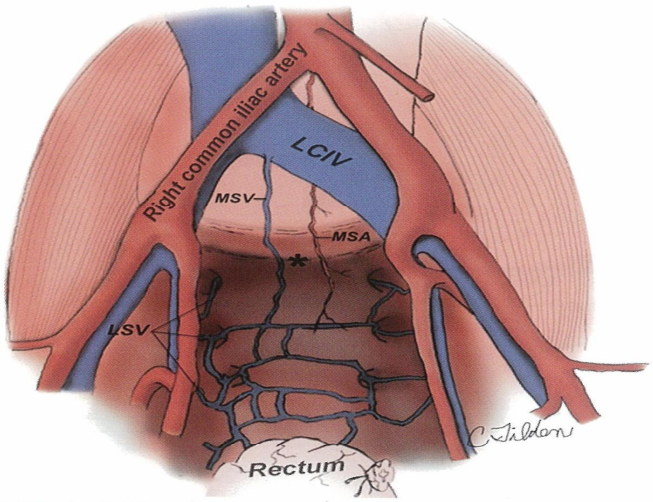


FIGURE 39.17 Vascular anatomy of the presacral space. The vessel closest to the sacral promontory (*) is the left common iliac vein (LCIV), which is 2.7 cm from the midline. Also adjacent to the promontory is the middle sacral artery (MSA), middle sacral vein (MSV), and lateral sacral veins (LSV). (Reprinted from Wieslander CK, Rahn DD, McIntire DD, et al. Vascular anatomy of the presacral space in unembalmed female cadavers. *Am J Obstet Gynecol* 2006;195:1736, with permission. Copyright © 2006, Elsevier.)

Applied anatomy

The venous plexus of these vessels are extensive and bleeding from these plexus should be considerable during surgery in the presacral area.

Fascia lata

Introduction

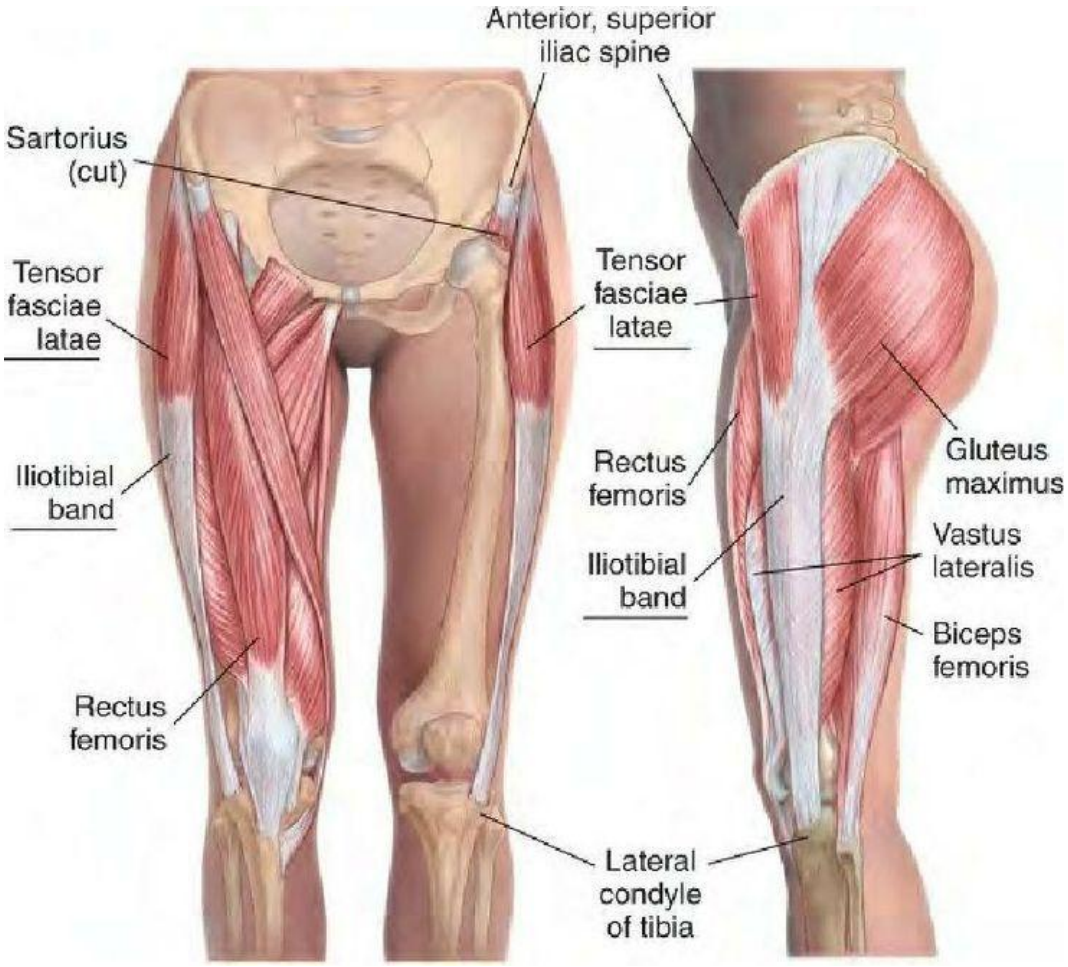
Fasciae are structures forming sheets beneath the skin, enveloping muscles and internal organs, supporting them and protecting from injury (186). The main role of the fascial system, however, is to reduce friction between muscles and transmit mechanical forces generated by the musculoskeletal system (187,189). Pathological processes affecting fasciae clinically manifest themselves as numerous different diseases, such as myofascial pain syndromes, Dupuytren's contracture, congenital fascial dystrophy, compartment syndromes, hernias and fibromyalgia(189,190). Because the exact pathogenesis of the majority of these disorders remains unknown, they are often difficult in terms of diagnosis and treatment. *As result of its durability, elasticity and relative ease of harvesting, the fascia particularly the fascia lata, has a broad range of uses as a valuable graft material (191,192)*

Anatomy of fascia lata

The **fascia lata** is the deep fascia of the thigh.It is an investment for the whole of the thigh, but varies in thickness in different parts. This is the strong fascia that envelopes muscles of thigh.

It is thicker in the upper and lateral part of the thigh, where it receives a fibrous expansion from the Gluteus maximus, and where the Tensor fasciae latae is inserted between its layers; it is very thin behind and at

the upper and medial part, where it covers the Adductor muscles, and again becomes stronger around the knee, receiving fibrous expansions from the tendon of the Biceps femoris laterally, from the sartorius medially, and from the Quadriceps femoris in front.



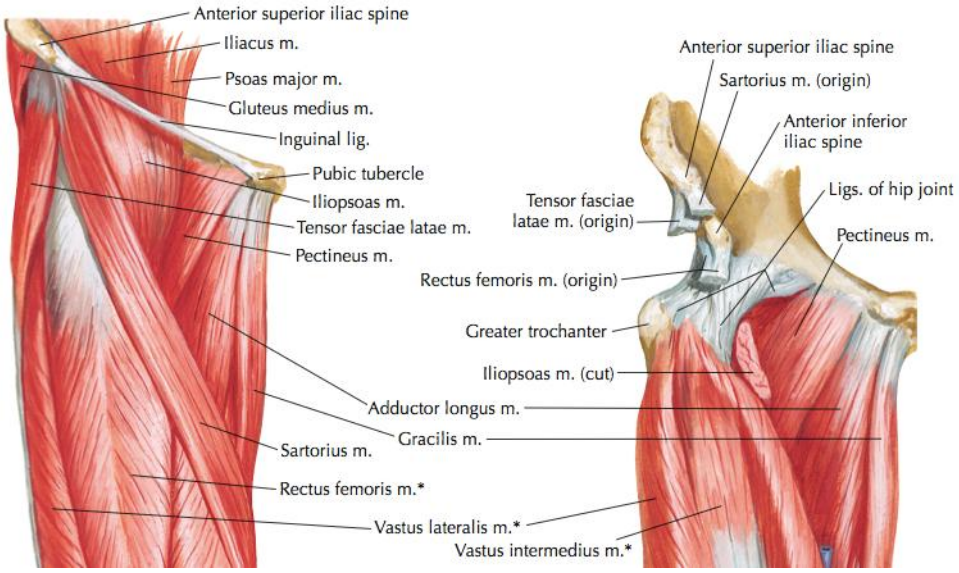
Relations of fascia lata

Above and behind

The fascia lata is attached, above and behind to the sacrum and coccyx; laterally, to the iliac crest; in front, to the inguinal ligament, and to the superior ramus of the pubis; and medially, to the inferior ramus of the

pubis, tuberosity of the ischium, and to the lower border of the sacrotuberous ligament.

The portion of the fascia lata attached to the front part of the iliac crest, and corresponding to the origin of the Tensor fasciae latae, extends down the lateral side of the thigh as two layers, one superficial to and the other beneath the gluteus maximus muscle; at the lower end of this muscle these two layers unite and form a strong band. This band is continued downward as iliotibial band (tractusiliotibialis) and is attached to the lateral condyle of the tibia.



Superior attachment of fascia lata

Below

Below, the fascia lata is attached to all the prominent points around the knee-joint, viz., the condyles of the femur and tibia, and the head of the fibula.

On either side of the patella, it is strengthened by transverse fibers from the lower parts of the Vasti, which are attached to and support this bone.

Of these the lateral are the stronger, and are continuous with the iliotibial band.

The deep surface of the fascia lata gives off two strong intermuscular septa, which are attached to the whole length of the lineaaspera and its prolongations above and below; the lateral and stronger one, which extends from the insertion of the Gluteus maximus to the lateral condyle, separates the Vastus lateralisinfront from the short head of the Biceps femoris behind, and gives partial origin to these muscles; the medial and thinner one separates the Vastus medialis from the Adductores and Pectineus.

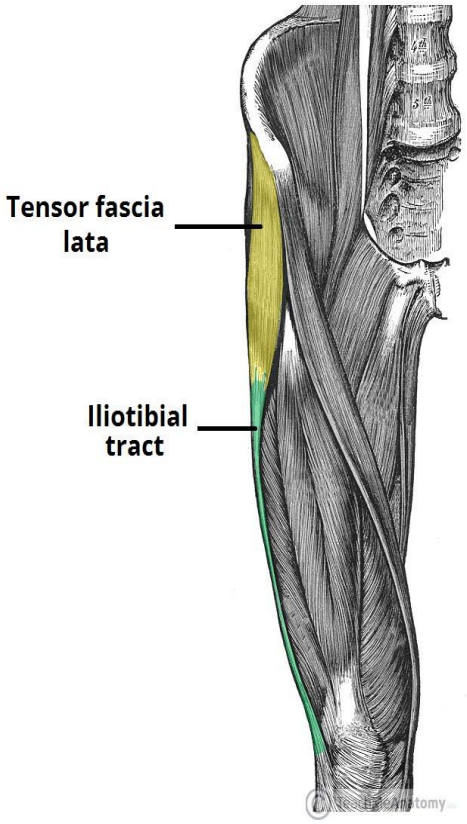


Figure showing the lateral attachment of FL

Laterally

Laterally, the fascia lata receives the greater part of the tendon of insertion of the Gluteus maximus, and becomes proportionately thickened.

The part of the iliotibial band which lies beneath the Tensor fasciae latae is prolonged upward to join the lateral part of the capsule of the hip-joint.

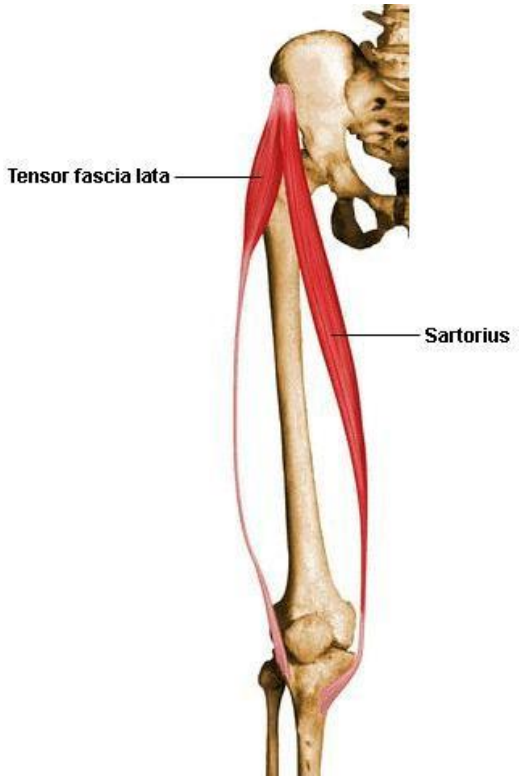
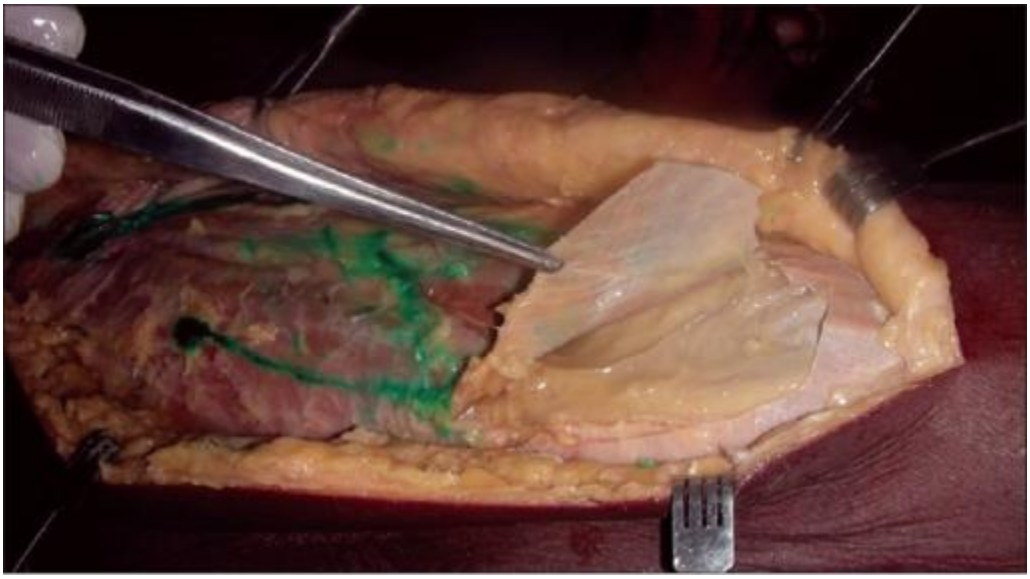


Figure showing the inferior attachment

Crural fascia

The crural fascia is a continuation of the fascia lata.



Dissection under the fascia lata shown in a cadaver

Blood supply:

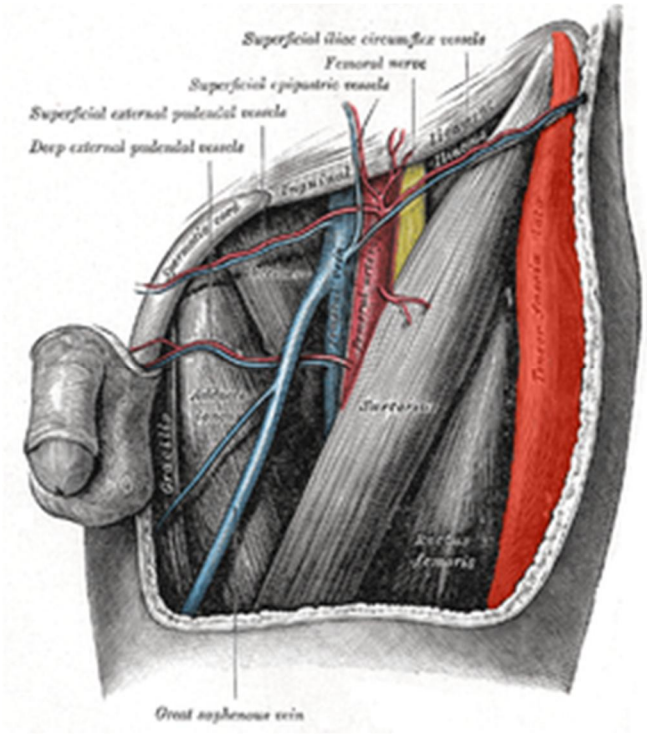
Superior gluteal artery supplies the tensor fasciae latae[1] –

Arterial supply:

- Ascending branch of lateral femoral circumflex artery and superior gluteal artery
- Arterial supply to the tensor fascia lata is through the transverse branch of lateral femoral circumflex artery, which is usually a single branch from profundafemoris system
- The artery enters the muscle belly proximally, usually at point 6 to 10 cm below the anterior superior iliac spine.

Venous drainage:

Tensor fascia lata is drained by one or two venae comitates accompanying proximal arterial blood supply.



Blood supply, venous drainage & nerve supply of fascia lata

Nerve supply:

Tensor fasciae latae is innervated by the superior gluteal nerve, L5 and S1. At its origins of the anterior rami of L4, L5, and S1 nerves, the superior gluteal nerve exits the pelvis via greater sciatic foramen superior to the piriformis. The nerve also courses between the gluteus medius and minimus. The superior gluteal nerve arises from the sacral plexus and only has muscular innervation associated with it. Sensory supply predomidently from the lateral femoral cutaneous nerve, superior portion of the skin cephalad to the greataer trochanter is innervated by the lateral cutaneous branch of T12.

Function of tensor fascia lata:

The tensor fasciae latae is a tensor of the fascia lata. The oblique direction of its fibers enables it to stabilize the hip in extension and

assists gluteus maximus during hip extension. The fascia lata is a fibrous sheath that encircles the thigh like a subcutaneous stocking and tightly binds its muscles. On the lateral surface, it combines with the tendons of the gluteus maximus and tensor fasciae latae to form the iliotibial band, which extends from the iliac crest to the lateral condyle of the tibia.

In the erect posture, acting from below, it steadies the pelvis upon the head of the femur and by means of the iliotibial band it steadies the condyles of the femur on the articular surfaces of the tibia and assists the gluteus maximus in supporting the knee in a position of extension.

The basic functional movement of tensor fasciae latae is walking. The tensor fasciae latae is heavily utilized in horse riding, hurdling and water skiing. When this muscle is tight or shortened, pelvic imbalances which lead to pain in hips, lower back and lateral area of knees.[3]

Because of its insertion point on the lateral condyle of the tibia, it also aids in the lateral rotation of the tibia. This lateral rotation may be initiated in conjunction with hip abduction and medial rotation of the femur while kicking a soccer ball. The tensor fasciae latae works in synergy with the gluteus medius and gluteus minimus muscles to abduct and medially rotate the femur.

The tensor fascia lata is a hip abductor muscle.

Key Points:

1. Thigh flexion at the hip, abduction, and medial rotation
2. Stabilizes the knee laterally
3. Iliotibial band moves forward in extension and backward in flexion but is tense in both positions

4. During flexion iliotibial band, popliteus tendon, and **LCL**(lateral collateral ligament)cross each other, whereas iliotibial band and biceps tendon parallel to each other as in extension, all these muscles enhance lateral stability

5. In addition to lateral ligaments and lateral capsular structures, stability is significantly dependent on iliotibial band, biceps tendon, and the popliteus tendon.

Synergists: Gluteus medius, minimus& upper fibers of maximus.

Anatomy of Fascia lata	
Origin	Anterior superior iliac spine
Insertion	Iliotibial tract
Artery	Primarily lateral circumflex femoral artery, superior gluteal artery
Nerve	Superior gluteal nerve (L4, L5, S1)
Actions	Hip- flexion, medial rotation, abduction, knee- lateral rotation, Torso- stablilzation

Physiology of Fascia lata:

Fascia lata is composed of numerous collagen fibers and few elastic fibers.Ruffn corpuscles are rarely found. Nerves and lymphatics are present.Short mesh like structure is formed by dense collagen fibers. Fascia lata consists of mainly matrix and few cells. Intercellular matrix is serviced by fibroblasts. It contains amorphous intercellular substance hyaluronic acid and cement like substances around the fascia lata. Fluid in and around fascia latabathing it and thereby allowing diffusion of substance from the capillaries to cells and vice versa.Fascialataposses three dimensional structure and

should not be seen as surface .It adapts to phenomenonal changes only when it is three dimension structure and not in two dimensional.

Fascia lata is unicellular hence retains its original volume even after transplantation. Each collagen fiber is stronger, resistant to traction even when pulled in any direction.*The mitotic division occurs in fascia lata after transplant thereby true breeding occurs and increasing the density of collagen in fascia lata. whereas in cadaveric fascia lata denaturation of protein occurs due to altered electric potential.*

Electron microscopy of fascia lata

Telocytes as a particular interstitial cell type, has been recently discovered in a wide variety of tissues and organs such as the heart, skeletal muscles, skin, gastrointestinal tract, uterus and urinary system. Joanna Dawidowicz, et al (2015) study confirmed the existence of a telocyte population in fascia lata samples. Those cells fulfil main morphological criteria of telocytes, namely, the presence of very long, thin cell processes (telopodes) extending from a relatively small cell body. Apart from telocytes, the other cells like fibroblasts, mast cells and cells with features of myofibroblastic differentiation are also found.***This is the first time it has been shown that telocytes exist in human fascia.*** **(194).** Currently, the exact role of those cells within the fascia is unknown .However fascialatatelocytesare involved inregeneration, homeostasis and intracellular signaling similar to telocytes in other organs.

Telocytesare recently discovered cells involved in a number of essential biological processes . Telocytesbelong to the group of stromal cells . They are present in the interstitial space of many human and animal tissues forming within the stromal compartment a unique, complex and integrative three-dimensional network .Telocytes are usually found in close vicinity to

each other and to other cells creatinghomocellular or heterocellular junctions respectively (*e.g.* with endothelial cells, smooth muscle cells, stem cells, mast cells, eosinophils, adipocytes and fibroblasts . Through this close contact telocytes actively contribute to the maintenance of tissue homeostasis and play a role in tissue regeneration and repair. Moreover, they are involved in intracellular signaling by formation of intracellular junctions as well as *via* a paracrine mode of action (secretion of soluble mediators such as interleukin-6, VEGFand nitric oxide).

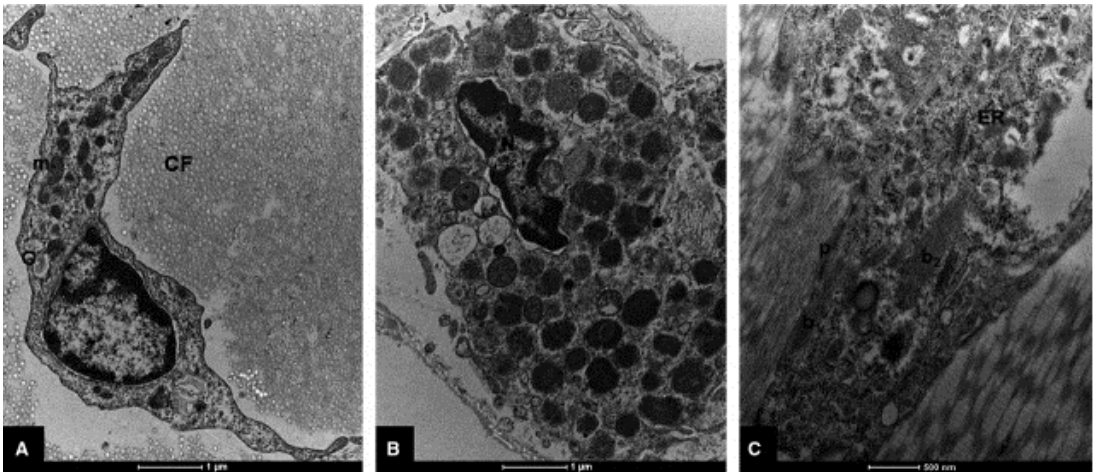


Figure 1

Electron micrograph of human fascia lata. (A) Fibroblast at lower magnification; not spindle-shaped cell situated within densely packed collagen fibres (transsections), abundant mitochondria (m) and cisterns of the Golgi apparatus (G); scale bar = 1 μm. (B) Mast cell filled with numerous secretory granules of different electron densities, sizes and shapes; note nucleus (N) with peripherally condensed chromatin; scale bar = 1 μm. (C) Section of cell showing the features of myofibroblastic differentiation; note the presence of myofilaments bundles at the cell periphery (b_1) and also near the cell centre (b_2), abundant rough endoplasmic reticulum (ER) and focally surface attachment plaques (p); scale bar = 0.5 μm. CF: collagen fibres.

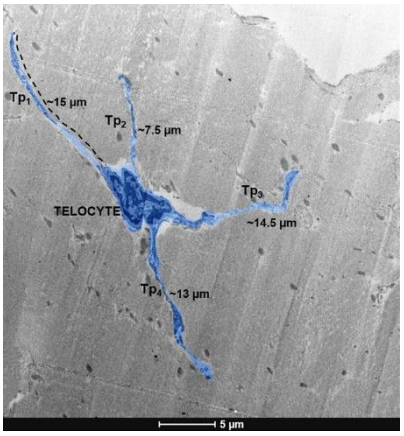


Figure 2

Digitally coloured transmission electron microscope (TEM) image (blue) of telocyte of human fascia lata; note relatively small cell body and 4 long characteristic processes - telopodes (Tp_{1-4}); scale bar = 5 µm.

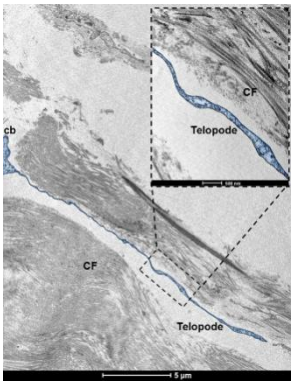


Figure 3

Digitally coloured (blue) electron micrograph of section of telocyte in human fascia lata; note the small part of the cell body (cb) and the very long telopode situated between collagen fibres (CF); scale bar = 5 µm. Red inset shows higher magnification of the part of telopodeneighbouring collagen fibres (longitudinal sections); scale bar = 0.5 µm.

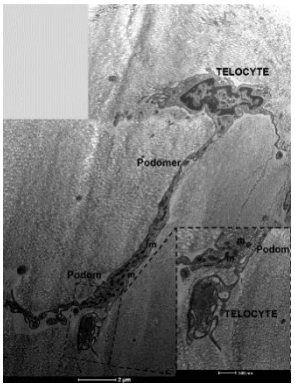


Figure 4

Transmission electron microscopy of telocytes within fascia lata; note large telopode extending from the cell body of telocyte with podomers alternating much thicker podoms containing abundant mitochondria (m); scale bar = 2 μm. Red inset shows a part of telocyte with telopode forming a circular, convoluted appearance; scale bar = 0.5 μm.

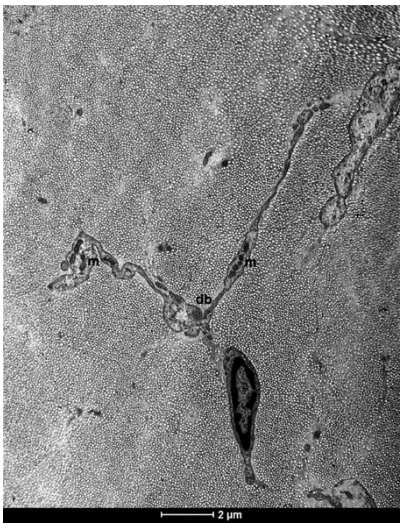


Figure 5

Electron micrograph of another telocyte in human fascia lata; note the telopode forming dichotomous branching (db) and focal accumulations of mitochondria (m) within podoms; scale bar = 2 μm.

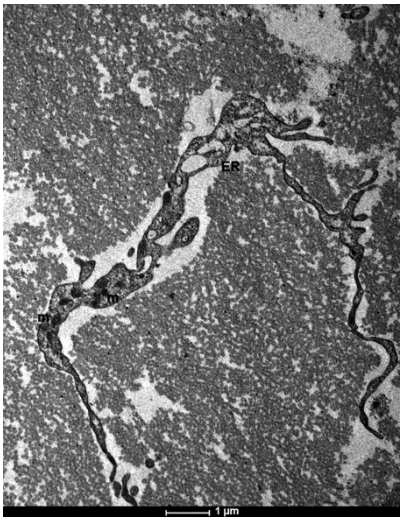


Figure 6

Electron micrograph of human fascia latatelocyte. Section of telopode with semi-circular arrangement and focal accumulations of mitochondria (m) and endoplasmic reticulum elements (ER); scale bar = 1 µm.

Recently, FIB-SEM (Focused Ion Beam Scanning Electron Microscopes) tomography has been considered to be a very promising method of 3D telocyte imaging, however, this technique is much less freely available compared to traditional electron microscopy. With regard to immunodiagnostics of telocytes, there is still a lack of a highly specific antigen which could be considered a unique telocyte marker. Presently, double-labelled immunostaining, using CD34 together with PDGFR alpha or beta, c-kit, and vimentin are the most widely available antibody choices for detection of telocytes detection

Despite the availability of wide range of modern visualization techniques,transmission electron microscopy remains a particularly useful tool for examining this cell population, allowing visualization of all their ultrastructural attributes.

Review of Literature

Suspending the vaginal vault to the anterior longitudinal ligament over S1,2,3 is the key surgical step in Abdominalsacrocolpopexywhich involves the Y shaped graft using bio material.

A MEDLINE search, using PubMed and Ovid, was done between the 1966 and February 2015. The following search terms were used to review all articles written in English: “sacral colpopexy,” “sacropexy,” “sacrocolpopexy,” “colpopexy,” “sacropexy,” “colposacropexy,” “abdominal sacrocolpopexy,” “pelvic organ prolapse and surgery,” “vaginal vault prolapse and surgery,” “fascia lata” and “autologous fascia lata”. We then reviewed the Cochrane database for any randomized controlled trials regarding pelvic organ prolapse surgery.

This is propably the first randomized controlled trial comparing autologous fascia lata with multifilament, macroporous, polyprophylene synthetic mesh in abdominal sacrocolpopexy for management of vaginal vault prolapse.

Review of literature

Pelvic organ prolapse is a common problem affecting a substantial number of women in various age group. It is reported almost in 50% of paraous women (1,2). 7 to 11 % of women will undergo surgery for prolapse during their lifetime and approximately 30 % of those will need repeat operation for recurrent prolapse (3,4). Traditional repair techniques using patients’ native tissues, has been used for long time with varying success rates (5). In an attempt to improve prolapse surgery outcome, several biological and synthetic materials have been used toaugment reconstruction . Any natural or synthetic substance that incorporates or integrates into a patient’s

own tissue is defined as a “biomaterial” (6). The biomaterials or grafts used in pelvic reconstructive surgeries are summarized below.

[001]**Aim of surgery in pelvic organ prolapse**

- Relief from prolapse symptoms
- Restoration of normal anatomy (long-term)
- Maintenance or improvement of bladder and bowel function
- Restoration of sexual function
- Prevention of occurrence of new bladder, bowel and sexual denovo problems (surgery-related)

Types of graft materials used in pelvic organ prolapse repair .

A. Biologics: (5)

1 Autologous fascia: Rectus fascia, fascia lata, vaginal mucosa, skin graft

2 Heterologous:

i) Allogenic: Cadavaeric- Dura matter, Rectus sheath, Fascia lata, Dermis,

ii) Xenogenic: Porcine dermis, small intestine submucosa, bovine pericardium, fetal bovine dermis.

B. Synthetics:

1 Absorbable: Polyglycolic acid, polyglactin, polyglactin/ polypropylene

2 Non-absorbable: Polyester, polytetrafluroroethylene (PTFE), polypropylene, Polyethylene, and nylon

Originally, use of mesh in prolapse surgery was in increasing trend despite a lack of clinical safety data or clinical evidence demonstrating an improved outcome compared with traditional suturing techniques.5 As a result , wide ranges of mesh materials were available. To begin with the idea of incorporating mesh in prolapse surgery was adopted from general surgeory where mesh was used for hernia repair.

However the nature of mechanical stress to be tackled by the mesh in hernia repair is totally different compared to its use in prolapse surgery. The stress which is tolerated by the mesh used for ventral hernia is less compared to mesh that are used for treatment of pelvic organ prolapse. The ideal mesh should be biocompatible, inert and induce minimal inflammatory response. At the same time it should act as a scaffold to facilitate fibrous tissue ingrowth, be resistant to infection, avoid shrinkage and be easy to handle.[(2)]

The response of the body to synthetic mesh varies depending on various factors like the properties of the mesh, route of insertion and the woman's age and the power of her immune system. The immune system seems to respond to synthetic meshes by chronic inflammatory process with the production of macrophages, lymphocytes and foreign body giant cells. Examination of the removed mesh(due to complications) revealed both acute and chronic inflammatory responses with predominant neutrophils and lymphocytes where as mesh removed without overt complications showed only chronic inflammation. [(2)]

Mesh related complications like infections, poor healing, extrusion and rejection, are due to acute-on-chronic reaction of the immune system to the synthetic mesh.

Biological mesh

Biological materials are either autologous grafts from the patient (rectus fascia, fascia lata), allografts (fascia lata and dermis from harvested human cadavers) or xenografts (porcine or bovine dermis or small intestinal submucosa).8 Although the risk of mesh extrusion or exposure was lower with biological materials, there were problems with 'graft versus host' reaction which increased the failure rate.

Synthetic mesh

Synthetic mesh are readily available, has the advantage of increased tensile strength, and decreased potential for disease transmission . [9]

A variety of prosthetic materials are available for pelvic organ prolapse surgery.Synthetic meshes are broadly divided into absorbable, non - absorbable and mixed. Synthetic meshes can be further classified according to their pore size, macroporous (75 m pore size) and microporous (10 m). Pore size is an important mesh characteristic which determines the type of cell that can enter into the mesh . Macroporous mesh allows bacteria, macrophages, fibroblasts and blood vessels, thereby prevents mesh infection, permits fibrous in-growth and makes the mesh soft (flexible).

Combined mesh

In an attempt to reduce the complications of synthetic mesh and to maximize its advantages , biosynthetic meshes have been developed.

Amid classified synthetic meshes according to their pore size and fiber type.

Type I: knitted monofilament type with large pores and good elasticity.They allow macrophages, fibroblasts (which are 75µm) and bacteria (1–2µm) to enter. Infection and adhesions are a problem but infections can be treated without removal ofmesh. Theoretically,this is the best implant as it promotes host defences.

Type II: knitted multifilament mesh with small interstices (75µm) and reduced elasticity. They prevent adhesions but it is difficult to treat infections since antibiotics and white blood cells cannotpenetrate,thus necessitating removal ofthe mesh.

Type III: nonknitted,nonwoven, multifilament type with large pores,small interstices and restricted elasticity.They allow bacteria to infiltrate but not macrophages;infection can be a problem.Type II and III meshes result in a greater foreign body reaction than Type I.

Type IV: coated biomaterial that contains pores of 1µm.Often used for adhesion prevention in abdominal surgery;not used in gynaecological surgery.

Mile stone in the evolution of biomaterial

History of Polypropylene mesh in abdominal sacrocolpopexy

Bakelite, the first synthetic plastic was invented in 1907, by Belgian chemist, Leo Baekeland. Many more synthetic plastics had been invented during 1930s and the significant growth of plastic industries were noted following the end of war in 1945. In 1951, Hogan and Banks discovered the catalytic polymerisation of propylene to polypropylene and in 1954, an Italian chemist Giulio Natta developed a large-scale production by polymerising propylene to a crystalline isotactic polymer, for which he was honoured with

Nobel price. Polypropylene was the first synthetic plastic that could withstand an autoclave and thus be used in the manufacture of medical devices.

The concept of using nylon mesh for hernia repair was introduced by French surgeons Acquaviva and Bourret in 1948, followed by the introduction of polypropylene mesh to repair inguinal hernias during 1960s. In 1987, Lichtenstein operated over 6000 inguinal hernia with mesh repair and he reported recurrence of 0.7% after 2–14 years of follow-up. This study provided the clinical evidence to support the use of mesh in inguinal hernia repair. In 2002, a systematic review of 58 trials involving 11 000 patients reported a 50% reduction in the risk of groin hernia recurrence with use of synthetic mesh compared withtraditional fascial plication (Shouldice repair).

Use of Mesh in abdominal sarcocolpopexy

1907: Leo Baekeland discovered first synthetic plastic (Bakelite).

1948: Acquaviva and Bourret introduced nylon mesh for hernia repair

1951: Hogan and Banks polymerised propylene to polypropylene

1954: Giulio Natta developed the method by polymerising propylene to a crystalline isotactic polymer. Polypropylene was the first synthetic plastic that could withstand an autoclave and thus be used in the manufacture of medical devices.

1960: Acquaviva and Bourret introduced polypropylene mesh to repair inguinal hernias.

1962: Lane described the technique of abdominal sacrocolpopexy to manage vaginal vault prolapse using an arterial graft.

1976 Rust et al conducted a study by using mersilene mesh in abdominal sacrocolpopexy and reported success rate of 100%.

1985 Addison et al conducted a study among 56 patients with pelvic organ prolapse, who underwent abdominal sacrocolpopexy with mersilene tape and reported success rate of 89%.

1990 Baker et al reported 86% success rate in a study conducted among 59 patients, who underwent abdominal sacrocolpopexy with prolene mesh.

1991 Snyder et al reported 73% success rate following use of Gore-tex mesh in abdominal sacrocolpopexy among 147 patients, who were followed up for 60 months.

1992 Timmons described the technique using a synthetic mesh.

1994 Valaitis et al conducted a study among 43 patients who were treated with Teflon mesh for pelvic organ prolapse, reported 91% success rate.

Review of literature of polypropylene mesh in abdominal sacrocolpopexy

Table :1

Year	**Author**	**Study design**	**N**	**Mesh type**	**Follow up in months**	**Success Rate (%)**	**Complications**
1976	Rust et al	Prospective	12	Mersilene	9-42	100	Not detected
1985	Addison et al	Prospective	56	Mersilene	6-126	89	Not detected
1990	Baker et al	Prospective	59	Prolene	1-45	86	Not detected
1991	Snyder et al	Prospective	147	Gore-Tex	60	73	Not detected
1994	Valaitis et al	Prospective	43	Teflon	3-91	91	Not detected
1996	Hardiman	Retrospective	80	Polypropylene	6-60	Not available	6% post op febrile morbidity
1996	Benson et al	RCT	38	ND	12-66	58%	16% re operation and 2% incontinence
1998	Lo et al	RCT	52	Mersilene	12-62	94.2%	8% re surgery
2000	Fox &	Prospective	29	Teflon	6-32	100	Mesh infection

	Stanton						in one case
2002	Culligan et al	Retrospective	54	Polypropylene	12	91	15.1% objective failure
2004	Maher et al	RCT	46	Polypropylene	6-58	76% (objective) 94% (subjective)	Not detected
2004	Ng	Retrospective	113	GoreTex	13-18	95.6%	Not detected
2005	Hilger et al	Prospective	38	Polypropylene	164.4	74	Vaginal erosion
2005	Gregory et al	Prospective	28	Marlex/ Mersilene	26.3	89	Not detected
2006	Altman et al	Prospective	25	Prolene	7.4	71	Not detected
2008	Thompson	Retrospective	72	GoreTex	53-55	91.7%	8.3% failure rate
2009	Granese et al	Prospective	131	Polypropylene	43	94.9	5.07% re surgery
2010	Yasmin et al	Prospective	20	Polypropylene	24	100	Not detected
2010	Rondini	RCT	42	Not available	18	100%	Not detected
2010	Sze	RCT	113	Not available	23-24	ND	33% recurrent prolapse
2011	Tate et al	RCT	29	Polypropylene	60	93	Not detected

1996-Hardiman et al compared success rates and complications of sacrospinous vault suspension and abdominal sacrocolpopexy (ASC) and reported that among 80 patients who underwent ASC ,only one intraoperative complication (haemorrhage from the presacral veins) was reported. The incidence of postoperative febrile morbidity was 10% after sacrospinous vault suspension and 6% after abdominal sacrocolpopexy. Follow-up ranged from 6 months to 5 years. The incidence of recurrent vault prolapse was 2.4% with sacrospinous vault suspension and 1.3% with abdominal sacrocolpopexy. De novo stress urinary incontinence occurred in one woman after abdominal sacrocolpopexy and in none after sacrospinous vault suspension. They concluded that sacrospinous vault suspension and abdominal colposacropexy were associated with a low incidence of intraoperative and postoperative complications and recurrent vault prolapse. Latent stress urinary incontinence

may be unmasked, particularly with abdominal colposacropexyhence preoperative urodynamic evaluation was therefore recommended.

1996- Benson et al conducted a study to determine whether a vaginal or abdominal approach was more effective in correcting uterovaginal prolapse. They reported Eighty women (vaginal 42, abdominal 38) were available for evaluation at 1 to 5.5 years (mean 2.5 years). The groups were similar in age, weight, parity and estrogen status and 56% had undergone prior pelvic surgery. There was no significant difference between the groups in morbidity, complications, hemoglobin change, dyspareunia, pain or hospital stay. The vaginal group had longer catheter use, more urinary tract infections, more urinary incontinence, decreased operative time, and lower hospital charge. Surgical effectiveness was optimal in 29% of the vaginal group and 58% of the abdominal group and was unsatisfactory leading to reoperation in 33% of the vaginal group and 16% of the abdominal group. The reoperations included procedures for recurrent urinary incontinence in 12% of the vaginal and 2% of the abdominal groups. The relative risk of optimal effectiveness by the abdominal route is 2.03 (95% confidence interval 1.22 to 9.83), and the relative risk of unsatisfactory outcome using the vaginal route is 2.11 (95% confidence interval 0.90 to 4.94). They concluded that reconstructive pelvic surgery for correction of significant pelvic support defects was more effective with an abdominal approach.

1997- Iglesia et al reported that success rate of ASC using mesh varies from 68% to 100%. Mesh related complications rates are frequent, up to 35% removal rate and 10% sinus tract formation for suburethral slings and 9% erosion rate for sacrocolpopexy. The ideal synthetic mesh for pelvic surgery is the one that induces minimal foreign body reaction with minimal risk of infection, rejection and erosion. [Iglesia CB, Fenner DE, Brubaker L. The use of mesh in gynecologic surgery. International Urogynecology Journal. 1997 Mar 1;8(2):105-15.]

1998- Lo et al compared the results of abdominal colposacropexy and sacrospinous ligament fixation in correcting severe uterovaginal prolapse and reported that One hundred eighteen patients (abdominal approach 52, vaginal approach 66) were followed up for a mean period of 2.1 years (range 1–5.2 years). These two groups were comparable in age, weight, parity, and rate of prior pelvic surgery. Four in the abdominal group and seven in the vaginal group incurred complications that necessitated further surgical corrections. The vaginal group had more intra - operative blood loss, a shorter operative time, longer indwelling catheterization, and dyspareunia as well as longer hospital stay. The optimal surgical effectiveness in the vaginal group was 80.3% (53/66), and that in the abdominal group was 94.2% (49/52). These results revealed a statistically significant difference ($p = 0.029$). In view of the significant difference in optimal surgical effectiveness and other parameters, abdominal colposacropexy achieved better results in correcting severe pelvic organ prolapse than did sacrospinous ligament suspension.

2000: Sarah D et al assessed the safety and efficacy of sacrocolpopexy with mesh interposition in anterior and posterior vaginal vault and on the anterior sacral ligament. They reported that since 1961 over 39 papers have been published on sacrocolpopexy. The incidence of haemorrhage and haematoma from presacral veins was 2.9%. They concluded that sacrocolpopexy with mesh interposition appears to be an effective, safe and well tolerated procedure.(7)

2000- Fox and Stanton reported 100% success rate in a study conducted among 29 patients, who underwent abdominal sacrocolpopexy with polypropylene mesh.

2001: NeerajKohli et al reported that traditional techniques depend on plication of attenuated endopelvic fascia or accurate identification of site-specific defects.They reviewed the literature, techniques and outcomes using

both synthetic and autologus grafts (cadaveric fascia lata, human and porcine dermis and small intestinal submucosa) in reconstructive pelvic surgery. They concluded that use of graft materials either synthetic or biological have the potential of improving long-term success rates in pelvic reconstructive surgery.

2002: US Food and Drug Administration (FDA) cleared the first surgical mesh for treatment of POP.

2002- Culligan et al reported 91% success rate in a study conducted among 54 patients, who underwent abdominal sacrocolpopexy with polypropylene mesh.

2003: Serge Peter Marinkovic et al described the results of abdominal sacrocolpopexy with anterior and posterior polytetrafluoroethylene mesh extensions and concluded that it is an effective treatment for triple compartment prolapse and incomplete rectal emptying.(11)

2004- Nygaard et al reported success rates ranging from 78-100% with an extrusion rate of 3.4%.He also found that abdominal sacrocolpopexy is considered to be “gold standard” in vault prolapse repair.

2004- Ng et al compared the efficacy of abdominal and vaginal routes in correcting procidentia with total eventration or vault prolapse by analyzing the primary surgical outcome. They reported that abdominal sacrocolpopexy group had significantly greater intra-operative blood loss, increasedoperating time, haematuria, longer postoperative catheterisation and hospitalisation. Vaginal sacrospinous ligament fixation had more suture erosion. 95.6 percent of women with abdominal sacrocolpopexy were cured compared to 79.7 percent with vaginal sacrospinous ligament fixation. Five (4.4 percent) patients in the abdominal sacrocolpopexy group and six (9.4

percent) in the vaginal sacrospinous ligament fixation group defaulted their six-month follow-up with a mean follow-up of 18.1 months (range 0.9-48.1 months) and 13.2 months (range 1.1-29.1 months), respectively. Also they concluded that abdominal sacrocolpopexy is more effective in correcting total procidentia or stage 4 vault prolapsebut it is associated with higher intra-operative and post-operative morbidity compared to vaginal sacrospinous ligament fixation. Vaginal sacrospinous ligament fixation is preferred in patients with medical disorders.

2004- Maher et al compared the abdominal sacral colpopexy and vaginal sacrospinous colpopexy in the treatment of vaginal vault prolapse. They reported that subjective success rate was 94% in the abdominal and 91% in the vaginal group (P=.19). The objective success rate was 76% in the abdominal group and 69% in the vaginal group (P=.48). The abdominal approach was associated with a longer operating time, a slow return of daily activities, and a greater cost than the sacrospinous colpopexy (P<.01). Both surgeries significantly improved the patient's quality of life (P<.05). They concluded that abdominal sacral colpopexy and vaginal sacrospinous colpopexy are both highly effective in the treatment of vaginal vault prolapse.

2005: SohierElneil et al audited the clinical outcome of abdominal sacrocolpopexy using non-absorbable mesh without burial by closure of peritoneum. They concluded that leaving the mesh uncovered by pelvic peritoneum was not associated with complications and appeared safe without closing the peritoneum.(6)

2005: P.J.Higgs et al assessed the long term outcome following laparoscopic sacrocolpopexy and concluded that laparoscopic sacrocolpopexy provides good long term vault support in 92% (61) of 66 women which is similar to reports of open sacrocolpopexy (8)

2005: Patrick J.Culligan et al compared the objective anatomic outcomes after sacral colpopexy performed with cadaveric fascia lata and polypropylene mesh. They concluded that polypropylenemesh was superior to cadaveric fascia lata in terms of POP Q staging and objective anatomic failure rates. (9)

2005- Gregory et al studied 28 patients who underwent abdominalsacrocolpopexy with marles/mersilene mesh and they were followed up for 26.3 months and they reported 89% success rate.

2005- Bensinger et al conducted a study on retrospective analysis of patients, who underwent ASC with polypropylene mesh. The participants were grouped as group I- Supracervical hysterectomy with ASC, group II- Total abdominal hysterectomy with ASC and group III- ASC alone in women with history of prior Total abdominal hysterectomy. They reported mesh erosion in 3.3% of women and there were no significant differences in age, weight, parity, menopause status, estrogen therapy, previous surgery or staging of preoperative prolapse between patients with and without erosions. All erosions occurred in group II. The intra operative complication rate was 2.5% and includedcystotomy and small bowel laceration. Immediate postoperative complications included partial small bowel obstruction/Ileus(3.5%), febrile morbidity (9.6%) and autologous blood transfusion (1.7%). Long term complications included persistent dysparuenia (6.3%) and recurrent prolapse (2.5%). There were no significant differences in short or long term complications among 3 groups.[Bensinger G, Lind L, Lesser M, Guess M, Winkler HA. Abdominal sacral suspensions: analysis of complications using permanent mesh. American Journal of Obstetrics & Gynecology. 2005 Dec 1;193(6):2094-8.]

2005 – Begley et al conducted a retrospective review of the abdominal sacrocolpopexy procedure (n = 92) between 1997 and 2003 . They

reported that erosion occurred in 7.6 % (7/92) and was identified in patients with Gore-Tex (3/33, 9%) silicone-coated mesh (4/21, 19%) compared with none of 38 patients with polypropylene mesh (n = 24) or fascia (n = 14) grafts (P = .068.). Partial excision of exposed graft resolved all 3 Gore-Tex erosions whereas Complete graft removal was required to resolve silicone-coated mesh erosions. erosions (P = .03).

They concluded that high rate of erosion was observed with Gore-Tex and silicone-coated mesh. [126]

2006- Altman et al reported 71% success rate with use of prolene mesh in abdominal sacrocolpopexy for treatment of pelvic organ prolapse.

2007: Jane L.Yau et al determined the extent of posterior vaginal wall support after abdominal sacrocolpopexy with and without posterior colporrhaphy . They concluded that POP Q point Ap significantly improved and persisted at 34 months after abdominal sacrocolpopexy with concomitant posterior colporrhaphy. Bp point returned to preoperative levels and was same regardless of whether a site-specific posterior colporrhaphy was performed at the time of abdominal sacrocolpopexy. (12)

2007 –Govier FE et al conducted a prospective comparative study in abdominal sacrocolpopexy with silicone-coated polyester mesh and polypropylene mesh for vaginal vault suspension. 21 underwent silicone mesh suspension of the vaginal cuff to the anterior sacrum, with a mean follow-up of 23 months (range 16 to 41). 24 patients underwent the same procedure with polypropylene mesh.24 patients who underwent vaginal cuff suspension with polypropylene mesh have had no vaginal mesh extrusions or infections, with a mean follow-up of 12 months (range 1 to 38).

Of the 21 patients in the silicone group, 5 (23.8%) have had a major complication (four vaginal mesh erosions and one mesh infection) after a median follow-up of 9.5 months (range 4 to 20).One patient underwent successful removal of the mesh transvaginally, but the rest required abdominal exploration.

Hence Govier et al concluded that silicone-coated polyester mesh has been associated with a high rate of vaginal erosion when used for vaginal vault suspension .They have abandoned the use of silicone mesh because of the unacceptably high extrusion rate and presently use polypropylene mesh.[153]

2008- Thompson et al evaluated the hypothesis that anterior vaginal wall and apical anatomic failure rates were lower when performing an ASC compared with a uterosacral ligament suspension. A total of 104 patients with objective data was used in the analysis (ASC = 72; USLS = 32). There was no difference in average follow-up of more than 53 months but there were more paravaginal defect repairs and more intraoperative blood loss in the ASC group. There was a difference in follow-up (objective) staging (USLS 84% vs ASC 57%). In the USLS group, concomitant anterior vaginal wall surgery was performed in 16/32 patients. Failure rate of the anterior segment (Pelvic Organ Prolapse Quantitative (POP-Q) stage 2 or greater) in the USLS group was 16/32 (50%) compared with 6/72 (8.3%) in the ASC group. If a paravaginal defect was performed, the failure repair rate in the anterior segment was 5 of 63 (8%) and the failure ratewas 1 of 9 (11%) when paravaginal defect repair was not done.The probability of anterior segment failure in the USLS group was significantly higher than in the ASC group (adjusted odds ratio [OR] = 18.83, 95% confidence interval [CI] = 2.53–389.62, $P < 0.01$). Stage 2 failures in the apical segment were 3/32 for the USLS group but absent in the ASC group. They concluded that ASC

including application of the mesh to the anterior vaginal wall, should achieve a much higher level of anterior wall anatomic success (91.7%). This success rate could be influenced by the addition of a para vaginal defect repair.

2008: Miles Murphy et al found that there are no comparative studies to guide any recommendation on the use of biologic grafts and absorbable synthetic graft in multiplecompartment of vaginal wallrepairs when compared with native tissue repair.

2008- Geoffery et al used synthetic mesh as the predominant graft for their study, Mersilene (42%) or Polypropylene (48%). They reported 6% of subjects experienced mesh/suture erosion. Unadjusted risk factors for mesh/suture erosion were expanded polytrafluroethylene (ePTFE) mesh (ePTFE 4/21 (19%) versus none PFTE 5% (OR 4.2), concurrent hysterectomy (OR 4.9) and current smoking (OR 5.2). Of those with mesh erosion, most affected women (13/17) underwent at least one surgery for partial or total mesh removal. Two were completely resolved, 6 had persistent problems and 5 were lost to follow-up. No resolution was documented in the 4 women who elected observation. They concluded that expanded PTFE mesh should not be used for sacrocolpopexy. Concurrent hysterectomy and smoking are modifiable risks for mesh/suture erosion.

2009: Priscilla Devaseelan et al found that in randomised controlled trial comparing the autologus fascia with synthetic mesh (3), objective failure was reported in 32% in fascia group compared with 9% in the mesh group at 12 months.

2009: Anjali M.Ganatra et al concluded that abdominal sacrocolpopexy was superior to vaginal sacrocolpopexy with fewer recurrent prolapse and less dyspareunia. They also concluded that laparoscopic

sacrocolpopexy upholds the outcomes of gold standard abdominal sacrocolpopexy with minimal morbidity. [13]

2009- Granese et al conducted a study with 131 patients with pelvic organ prolapse, who underwent surgical procedure with polypropylene mesh. They were followed up for 43 months and they reported success rate of 94.9%.

2010- Sze et al compared the surgical outcome of abdominal sacrocolpopexy and Burch colposuspension with sacrospinous fixation and transvaginal needle suspension in the management of vaginal vault prolapse and coexisting stress incontinence. They reported the incidence of recurrent prolapse to or beyond the hymen (33% vs. 19%, P=0.0505) and lower urinary tract symptoms (26% vs. 13%, P = 0.0506) were significantly higher in the vaginal group than in the abdominal group. They suggested that the combined abdominal approach has a lower incidence of recurrent prolapse and lower urinary tract symptoms than the combined vaginal approach in managing vaginal vault prolapse and coexisting stress incontinence.

2010- Rondini et al compared the anatomical objective cure rates for the apical compartment in patients undergoing either high uterosacral ligament suspension or sacrocolpopexy (SCP) and reported objective success rate for apical suspension at 12 months follow-up was 100 % for abdominal SCP and 82.5 % for HUVS (log-rank *p* 0.033). Both techniques showed a significant improvement with regard to prolapse symptoms, quality of life (QOL), and sexual function. The significant improvement in postoperative questionnaire was comparable between both surgeries at 12 months follow-up. They concluded that abdominal SCP has statistically significant better anatomical results when compared with HULS for correcting apical defects at 12 months.

2011- Tate et al reported 93% success rate in a study conducted with 29 patients who underwent abdominal sacrocolpopexy with polypropylene mesh and they were followed up for 60 months.

2012: Patrick J.Culligan et al compared the surgical outcomes 12 months after laparoscopic sacrocolpopexy performed with porcine dermis and the current gold standard of polyprophylene mesh. They concluded that outcomes in subjective and objective results were similar 12 months after laparoscopic sacrocolpopexy with porcine dermis or polypropylene mesh (14)

2013: Anne-Loette et al compared the complications between open abdominal sacrocolpopexyandlaparoscopicsacrocolpopexy for the treatment of vault prolapse. Success rates of abdominal sacrocolpopexy range between 93% and 99%.(1,2). The first report of laparoscopic approach for sacrocolpopexy was written in 1994. They concluded that laparoscopic sacrocolpopexy has less procdure related morbidity and safer treatment for vaginal vault prolapse compared to open abdominal sacrocolpopexy.

2014: V.H. Eisenberg et al evaluated the appearance, position and dimensions of mesh implants following minimally invasive abdominal sacrocolpopexy at 1-26 months following surgery. They concluded that transperineal ultrasound demonstrated effectiveness in mesh evaluation following minimally invasive abdominal sacrocolpopexy using 3D/4D ultrasound [(4).]

2016: Ingrid Nygaard et al described the anatomic and symptomatic outcomes upto 7 years after abdominal sacrocolpopexy and determined whether the outcomes were affected by concomitant anti- incontinence surgery (Burch urethropexy). They concluded that during 7 years followup, abdominal sacrocolpopexy failure rates increased in both the groups. (Abdominal sacrocolpopexy with Burch and without Burch urethropexy) (10)

2017: V. Wong et al investigated the relationship between mesh location and anterior compartment support after laparoscopic sacrocolpopexy and concluded that prolapse recurrence was related to mesh position and mobility suggesting that, ***lower the mesh is from bladder neck, the lower the likelihood of anterior compartment prolapse recurrence***.[15]

2017: V.H. Eisenberg et al's study showed consistency in degree of tissue support without the occurrence of mesh shrinkage or erosion after abdominal sacrocolpopexy with mesh.[5]

2018- Patrick Campbell et al overviewed the types of mesh and autologus, cadaveric (allograft) or porcine / bovine (xenograft) grafts. They concluded that the use of mesh is associated with greater litigation than native tissue repair. 2016 cochrane review found insufficient evidence to compare biological grafts with native tissue repair.

Indications for Mesh in Surgical Treatment of Pelvic Organ Prolapse

Patients who are susceptible for increased intra-abdominal pressure due to chronic bronchitis, chronic constipation , other frequent Valsalva invoking conditions such as heavy lifting, patients with collagen deficiency disorders may be the candidates whom would likely to benefit from synthetic mesh repair.

Risk factors:

Erosion or extrusion of the mesh is associated with the type of synthetic material used. However, other risk factors to be considered are as follows:

- Poorly controlled diabetes mellitus

- Tobacco use
- Prior history of pelvic irradiation
- Repeat surgeries

These factors may also contribute to poor wound healing and subsequent infection, erosion or extrusion. Some studies have suggested that concomitant hysterectomy may be an additional risk factor for extrusion of the sacrocolpopexy mesh.[28,31] Surgical techniques such as excessive tension and unrecognized urethral or vesical injury may also contribute to higher rates of urinary tract erosion.[32]

Though the Abdominal Sacrocolpopexy has reported success rate from 75-100%, in majority of the studies, laparoscopic ASC also to be considered since it is minimally invasive (but with longer operating times) with less hospital stay and less blood loss with similar anatomic outcomes compared to the open abdominalapproach.Mesh erosion risk was 3.4%–10.5% in both methods.Polypropylene mesh had the best anatomic outcome.ASC must also be weighed against longer operating times, longer recovery, and potential mesh complications. Some studies have shown similar outcomes when sacrocolpopexy was performed with xenograft compared to synthetic mesh,(46,47)but a large randomized trial with medium-term follow-up (mean 33 months) showed that xenograft was associated with more apical failures and reoperations for prolapse.(48)Another study of 100 women randomized to either cadaveric fascia or polypropylene mesh during sacrocolpopexy found that recurrent prolapse was worse 1 year postoperatively in the fascia group (32%) compared to the synthetic mesh group (9%). (49)

Complications of Mesh in Surgical Treatment of Pelvic Organ Prolapse

In 2011, FDA Safety Communication disclosed that mesh-associated complications are not rare. Brill et al, summarized the complications as reported from the MAUDE database in the order of decreasing incidence.

- Erosion
- Pain
- Infection,
- Bleeding,
- Dyspareunia,
- Organ perforation,
- Urinary problems,
- Neuromuscular problems
- Recurrent prolapse.

[Brill AI. The hoopla over mesh: what it means for practice. Obstetrics and Gynecology News. Jan. 2012:14–15.]

One of the major concerns with synthetic mesh is mesh erosion. Estimates for the risk of mesh erosion after ASC range from 3.4% to 10.5%. (44,50)In a multicenter surgical trial of 322 women who underwent ASC with a variety of surgical techniques with selected graft materials, the rate of mesh/suture erosion was 6% at 2 years after surgery and 10.5% at 7 years after surgery.(45,50)Most of the procedures were performed with synthetic mesh (92%) with 42% woven polyester, 48% polypropylene, and 6% ePTFE,

while synthetic absorbable grafts were not used in this study.[50]The use of ePTFE was associated with an increased risk of erosion, as four of the five reports showed that the mesh erosions involved Gore-Tex mesh, so the use of this material was discontinued for the remainder of the study.[50]Generally, polypropylene mesh has become the favored synthetic material for clinical use.

ASC is important to be considered since it may be a more durable approach, but may also require repeat surgery for mesh erosion in up to 5%–10% of patients. Thus, when considering native-tissue repair or a mesh-augmented repair like ASC, it may be more accurate to weigh the risk of repeat treatment for any reason when counseling the patient.

Also, various types of mesh have demonstrated various complications. Use of Type I mesh has demonstrated extrusion rates of 0-19% have been reported with sacrocolpopexy.[27,28] Type II and III meshes are multifilamentous and therefore may allow bacteria to pass through and adhere to the graft and surrounding tissues. The small pore size does not allow passage of macrophages and leukocytes that may counter invading bacteria ,hence Type II and III meshes are now rarely used in pelvic floor reconstruction. Similarly, Type IV mesh has pore sizes too small to allow fibroblast and leukocyte infiltration. They tend to induce pseudocapsules that may harbor infection. High rates of erosion, extrusion and other complications were noted and subsequently, Type IV mesh is rarely used in pelvic reconstructive surgery [18]

Another sacrocolpopexy literature review reported a median rate of 3.4% for synthetic mesh erosion, with rates varying depending on which grafts were used (0% with biologic grafts; 0.5% with polypropylene mesh; to 5.5 % with Teflon mesh).[1] No definite conclusions could be made that whether any specific graft types were more likely to predispose to erosion

than others because other variables such as method of graft placement, concurrent hysterectomy, and various demographic differences were infrequently available for analysis. Some reports proved that erosion was more with the type of mesh used and method of placement without identifying other risk factors. [2,5]

Contraindications of Mesh in Surgical Treatment of Pelvic Organ Prolapse

There are no guidelines for absolute contraindications for the use of vaginal mesh in the surgical treatment of POP. Several studies have demonstrated increased risk of mesh exposure and wound infections with the following conditions.

- High BMI. (more than 30) (18, 19)
- Poorly controlled diabetes which impaire tissue healing
- Smoking -decreased vascularity resulting in poor tissue healing and increased mesh exposure (20)
- Tobacco users -4-fold risk of developing mesh erosions as compared to non smokers.
- Chronic use of steroids- delays wound healing.

Evolution of biological graft in abdominal sacrocolpopexy

The use of permanent mesh has certainly come under debate, and other materials, such as biologic grafts and cadaveric tissue, have also been explored.

1960: Brady and Fraenkel recommended anchoring the vaginal vault to anterior abdominal wall with braided silk

1961: Shubert et al recommended the fascial strips from linea alba or external oblique fascia to attach vaginal vault to the sacral promontory.[27]

1998: Barrington et al evaluated the results of autologus rectus fascial sling as a treatment for vault prolapse. They concluded that modified rectus sheath fascial sling is a safe, simple effective abdominal operation for management of vault prolapse. [28]

2001: Fynes M et al suggested biological grafts can be recommended in patients with failed prior surgery for vault prolapse and patients not willing to receive the synthetic material. In abdominal sacrocolpopexy with polypropylene mesh, mesh extrusion rates were around 2% as reported by IUGA/ICS. [19,20]

TABLE 2

Year	Author	Study design	n	Type of graft	Follow up in months	Success Rates in percentages	Complications
2002	Culligan et al	RCT	44	Cadaveric fascia lata	12	68	11% wound breakdown
2004	Latini JM et al	Retrospective review	10	Autologous fascia lata	31	100	No graft related complications
2005	Flynn et al	Retrospective study	19	Cadaveric fascia lata	11	95	5% reoperation for apical prolapse and 10% reoperation for anterior prolapse
2005	Gregory et al	RCT	18	Cadaveric fascia lata	21	61	No erosion or wound breakdown
2006	Altmann et al	RCT	27	Porcine dermal graft	7	71	No erosion or wound breakdown
2010	Yasmin et al	Observational cross sectional study	20	Autologous rectus sheath	24	90	ND

Literature review of biological grafts

2001: Andrew et al reviewed the medical records of all patients who underwent fascia lata harvesting during 54 month period. The study included 71 patients. Among them 1% of patients had hematoma that required drainage, 3% had seroma and 7% had cellulitis during immediate post operative period. Questionnaire response rate was 77% with mean follow up of 25 months. Among the respondants, 40% had mild symptoms, 5% had clinically manifested symptoms related to donor leg and 13% reported dissatisfaction because of unacceptable thigh scar, leg discomfort or both. They concluded that there was little immediate post-operative morbidity and long term symptoms are very mild. [(26)]

2003- Hilger et al. conducted a study with 38 subjects. They reported, mean age of 59.2 years, parity 4.03, BMI 26.5 and stage of prolapse 2.[(55).] The mean follow-up interval was 13.7 years. The total number of failures were 10 patients (26.3%). 4 patients (10.5%) had reoperation and 6 patients (16%) had recurrence of symptoms. Symptom distress scores were low and similar between failures and successes. Twelve subjects were available for examination and most defects were noted in the anterior wall. Also they concluded that long-term outcome analysis of abdominal sacrocolpopexy found the procedure to be durable with a 74% success rate at a mean follow-up of 13.7 years.[53]

2004- Nygaard et al, reported satisfactory long-term anatomical cure rates with low incidence of mesh-related complications following abdominal sacrocolpopexy.[52] They reported that vaginal mesh erosion was reduced with use of prolene mesh (0.5%) compared to other synthetic materials (3.1-5.5%).

2004: Jerilyn M et al did retrospective review of abdominal sacrocolpopexy with autologus fascia lata with 18 months followup. 10 women underwent the procedure with mean age 68.3 years. Preoperatively POP-Q stages were II to IV in 3, 5 and 2 cases respectively. Postoperatively POP-Q scores improved and remained at stage II or lower in all 10 patients. Mean operative time was 182± 40.94 minutes. Mean blood loss was 107.5±50.07 cc. There was no morbidity associated with fascia lata harvest. Eight of the nine women were alive at the time of review and completion of the survey. When asked if they could return to work how they were before surgery and would they recommend the procedure to a friend, all responded yes, to each question. They concluded that autologus fascia lata compares favorably in efficacy to that of other materials in the contemporary literature and it was not associated with any significant morbidity. [23]

2005: Patrick J. Culligan compared the objective anatomic outcomes after abdominal sacrocolpopexy with cadaveric fascia lata and polypropylene mesh. One hundred patients were randomized to receive either fascia (n=46) or mesh (n=54). Of the 89 patients returning after one year follow-up, 91% of the mesh group and 68% of the fascia group were classified as objectively cured(p=.007). They reported significant differences between the mesh and fascia group with respect to the one year postoperative comparisons of points Aa, C and POP-Q stage. There were no differences between the two groups with respect to points TVL (Total vaginal length), GH (Genital Hiatus), PB (Perineal Body), Ap or Bp. They concluded that polypropylene mesh was superior to cadaveric fascia lata in terms of POP –Q points, POP-Q tage and objective anatomic failure rates. [18]

2005- Flynn et al performed 24 abdominal sacrocolpopexy using Allograft fascia lata and they reported no significant intraoperative or postoperative complications or graft erosions. Five subjects were lost to

follow-up after 3 months and thus analysis was performed on the remaining 19 subjects. Prolapse of stage 2 or more in compartments Aa, Ba, Ap, Bp, and C was preoperatively 50%, 74%, 78%, 84%, and 68% and postoperatively 11%, 16%, 21%, 26%, and 5%, respectively. Also they concluded that allograft fascia lata may be a suitable alternative to synthetic mesh for sacral colpopexy, but longer-term outcomes and larger studies are needed.

2005- Gregory et al, conducted a retrospective cohort study and compared surgical outcomes of abdominal sacrocolpopexy with synthetic mesh to cadaveric fascia lata. Nineteen women who had abdominal sacrocolpopexy with synthetic mesh and 18 women who had abdominal sacrocolpopexy with freeze-dried, irradiated cadaveric fascia lata returned for blinded pelvic organ prolapse quantification examinations. The mean relative vaginal descent in the mesh group was 1.1cm, and in the fascia group was 2.8cm (p=0.02). The proportion of women with "optimal" surgical outcome, defined as a point C within 2cm from the total vaginal length, was 89% and 61% in the mesh and fascia group, respectively (p=0.06). They concluded that cadaveric fascia lata might not be an appropriate choice for abdominal sacrocolpopexy.[54]

2007: Myung Jae Jeon et al conducted a Pubmed Medline literature search regarding the use of grafts in pelvic reconstructive surgery. They reported that the use of non-absorbable synthetic grafts gave excellent anatomic cure rates but associated with high incidence of graft related complications. In pelvic reconstructive surgery, among autologusfascia,cadaveric fascia, porcine dermis and polypropylene mesh , only mesh and autologus fascia showed no difference in tensile strength from baseline. [21,22]

2008: Quiroz et al did retrospective cohort study which enrolled women with abdominal sacrocolpoperineopexy. Synthetic mesh was used in

52%, porcine dermis (pelvicol) in 39% and autologus fascia in 9%. Follow up period was 1.1 years. They found that rates of apical failure were 11% with pelvicol, 7% with autologus fascia and 1% with synthetic mesh. Graft related complications occurred in 16% of the cases, with a higher proportion of erosion in the pelvicol group. Resurgeriesfor graft related complications were similar between groups. [25]

2010: Susan B. Tate et al evaluated the 5- year surgical outcomes of abdominal sacrocolpopexy with cadaveric fascia lata and polypropylene mesh. 58 subjects returned for 5 year follow-up, among them 29 each from both mesh group and fascia group. Objective anatomic success rates in mesh group was reported as 93% and in the fascia group was reported as 62% (P=0.02). Clinical success rate in the mesh group was reported as 97% and in the fascia group was 90% (p=0.61). They concluded that polypropylene mesh was superior to cadaveric fascia lata in objective anatomic outcomes. (16)

In the same year, Kreder K et al conducted prospective study which determined the treatment efficacy and harvest site morbidity of fascia lata in abdominal sacrocolpopexy. They concluded that abdominal sacrocolpopexy using autologus fascia lata should be considered in women who have failed a prior transvaginal suspension procedure but also as the primary surgical approach in women with symptomatic vault prolapse.

2010- Yasmin et al conducted a study on abdominal techniques for surgical management of prolapse among 80 cases, which were divided into four Groups (20 patients in each group). In Group A, patients were managed by sacrocolpopexy with polypropylene (Prolene) mesh, Group B had sacrocolpopexy with autologous rectus sheath, Group C underwent high uterosacral ligament suspension and Group D had vault suspension with an autologous fascial sling of rectus shealth. All cases were analyzed postoperatively for their symptoms. Clinical examination, investigations and

follow – up revealed that there were no recurrence in group A, as compared to 10%, 20% and 15% in Group B, C and D respectively. No patient from Group A reported with incisional hernia as compared to 10%, 5% and 10% in Group B, C and D. Operative time was less in Group A as compared to Group B but longer as compared to Group D and almost same as in Group C. The complaint of low persistent backache remained same in Group A and B (30%) as compared to 35% in Group C and D. Less blood loss was observed in Group A. Also they concluded that Sacrocolpopexy is gold standard procedure for treatment of vault prolapsed abest results are expected when performed with prolene mesh.

2015: Patrick Dallenbach conducted review study and reported that autografts use was limited by morbidity associated with tissue harvesting and inconsistent quantity and quality of the material. [17]

2017: Janine L.Oliver et al evaluated the safety and short term efficacy of complete excision of sacrocolpopexy mesh and concomitantautologus fascia sacrocolpopexy. 19 patients were included in the study. Median age was 56 years. Median time for mesh placement and surgical excision of the mesh was 4.5 years. Indications for mesh excision included refractory pelvic pain (95%), symptomatic mesh exposure (42%) and bilateral ureteral obstruction with ureterovaginal fistula (5%). Mean operative time, estimated blood loss and length of hospital stay were 228 minutes, 200 ml and 5 days, respectively. There was no bladder or bowel injury in any of these patients. At a median follow up of 9.9 months, no patients required re surgery for apical vaginal prolapse . Hence, they concluded that complete sacrocolpopexy mesh excision with concomitant autologus fascia sacrocolpopexy can be accomplished safely with low rate of major complications. However long term follow-up of anatomic and functional outcome is needed [24].

Literature review of autologous fascia lata in plastic and reconstructive surgery

In order to gain further insight on fascia lata relationships to underlying muscles, literature from the Plastic and Reconstructive Surgery discipline were searched. There is an abundance of literature available from this field, but only three articles were selected as representative for the needs of this project. The deep fascia encircling the thigh, the fascia lata, has been described as a highly useful and abundant source for connective tissue needed for a variety of purposes by every surgical discipline (Amir et al, 2000). It is seen as a useful tissue to transplant as interposition material, as a contour-restoring tissue, to repair facial paralysis, aortic valve replacements (Snyderman, 1977), dural reconstructions (Amir et al, 2000) and as part of anterolateral thigh flaps used in a variety of ways in multiple body sites (Ali et al, 2009). Its popularity as a donor tissue stems from it being a sturdy layer that is sufficiently pliable in order to span irregularly shaped defects (Amir et al, 2000) ***and its comparative tensile strength being nearly "as strong as soft steel" in a weight for weight comparison (Snyderman,1977)***

Abdominal sacral colpopexy versus vaginal sacrospinous colpopexy

Three trials were found to be similar and thus compared (Benson 1996; Lo 1998; Maher 2004).

Abdominal sacral colpopexy was better than vaginal colpopexy in terms of:

- A lower rate of recurrent vault prolapse (3/84 versus 13/85; RR 0.23, 95% CI 0.07 to 0.77) (Benson 1996; Maher 2004)
- The number of women failing to improve to Stage 2 or better (3/52 versus 13/66; RR 0.29, 95% CI 0.09 to 0.97) (Lo 1998)

- Less postoperative dyspareunia (7/45 versus 22/61; RR 0.39, 95% CI 0.18 to 0.86) (Benson 1996; Lo 1998; Maher 2004)

- Less postoperative stress urinary incontinence (14/47 versus 28/81, RR 0.55, 95%CI 0.32 to 0.95) (Benson 1996; Maher 2004).

- The lower reoperation rate for vault prolapse after abdominal surgery did not reach statistical significance (6/84 versus 14/85, RR 1.46, 95% CI 0.19 to 1.11) (Benson 1996; Maher 2004).

The intra-operative blood loss was inconsistent in two studies with a mean difference of 298 ml. There was less blood loss in the abdominal group in Lo's study (Lo 1998) and 33 ml more blood loss in Maher's trial (Maher 2004). Benson did not report blood loss but reported the postoperative change in haemoglobin and the change was not statistically different (Benson 1996). Women who had abdominal surgery had significantly longer period to present with recurrent prolapse (the interval for months to recurrence -10.9) in one trial (Benson 1996). On the other hand, the sacral (abdominal) colpopexy was associated with a longer operating time (Benson 1996; Lo 1998; Maher 2004), longer time to recover (mean 8.3 days) (Maher 2004) and was more expensive (WMD US$1334) (Benson 1996; Maher 2004) than the vaginal approach.

Although the clinical outcome of prolapse surgery was better with the abdominal group, the difference was statistically not significant (subjective failure after abdominal surgery: 9/ 84 versus 18/85 after vaginal surgery) (Benson 1996, Maher 2004). With the limited evidence available, patient's satisfaction (Maher 2004) and objective failure at any site (any pelvic organ prolapse: RR 0.77) (Maher 2004) were not clearly different in both groups. Although data were available for bowel outcomes and adverse

events, they were too few to provide sufficiently precise estimates to identify or rule out clinically important differences.

An overview of mesh in abdominal sacrocolpopexy

The aim ofusing mesh in prolapse repair is to provide additional support and reduce risk ofrecurrence,especially in women with recurrent prolapse or those with connective tissue disorders.The ideal mesh should be biocompatible,inert and inexpensive.They should induce minimal inflammatory response and at the same time act as a scaffold to facilitate fibrous tissue ingrowth,be resistant to infection,avoid shrinkage and be easy to handle.

Synthetic mesh has the advantages ofhigh tensile strength,decreased potential for disease transmission, ready availability and cost-effectiveness. Non-absorbable synthetic meshes include nylon, silicone, polytetrafluoroethylene,polyester and polypropylene .Boulanger et al showed that tissue integration was best with polypropylene meshes,which allowed formation ofmature and well-organised connective tissue.

Absorbable vs nonabsorbable meshes

The most commonly used absorbable meshes, polyglactic acid and polyglycolicacid dissolve in 30–90 days. These materials have not been shown to promote infection, and have a low erosion rate. However, their rapid loss of tensile strength might limit their advantage in pelvic reconstructive surgery.

Culligan et al (2005) and Quiroz et al (2008) had correlated higher failure rates associated with a breakdown of absorbable graft materials in the

treatment of vaginal vault prolapse[79,109]. Hence, it is not prudent to use absorbable mesh in pelvic reconstructive surgery .

Macroporous vs microporous mesh

Synthetic meshes are characterized on the basis of pore size; those of >75 µ m are known as 'macroporous', whereas those<10 µ m are 'microporous'. The 75µ m pore size is significant, as this has been reported to be the required pore size for the entry of macrophages, fibroblasts, blood vessels and collagen fibres into the pores [7]. This mechanism greatly lower the infection risk of graft materials.

Birch and Fynes (2009) noted that the size of leukocytes and macrophages is 9–20 µ m, so that these cells can traverse pore sizes of <75 µm. The greater utility of a larger pore size is for the promotion of hosttissue ingrowth. More rapid infiltration of host tissue into the graft promotes long-term biocompatibility, rendering the graft material less likely to elicit complications.[111]

Multifilament vs monofilament mesh

The structure of the mesh composite is also important. A multifilament mesh has interstices within the filamentous fibres which are <10 µm. Even small bacteria (1 µm) can replicate within the interstices of multifilament fibres. Extremely small pores might prevent access to host immune cells and diminish the ability of the host to combat bacterial colonization of the graft. Monofilament meshes do not have these small interstices, and therefore have less risk of infection.

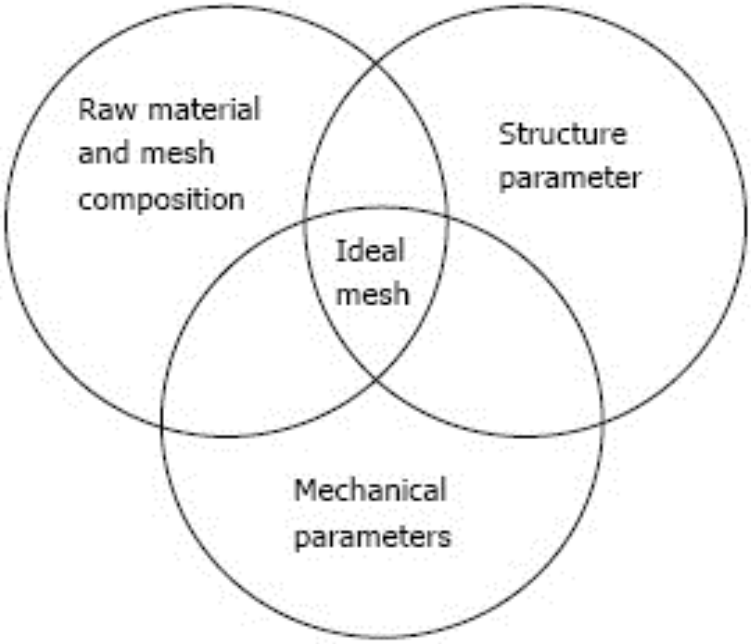


Figure: Crucial mesh parameters for selection of an ideal mesh.

Host Response to the Implanted Polypropylene

Twenty-one papers have looked at the host response to the polypropylene meshes. They have been assessed in various animal models: The studies have confirmed acute inflammatory responses to the most commonly used, nondegradable meshes.

Polypropylene mesh maintains its morphology and strength after implantation for up to 24 weeks.There is evidence that the meshes with greater stiffness cause the surrounding tissue to weaken, an effect termed '*stress shielding*'.This effect could lead to thinning of the surrounding vaginal tissues as predisposing to extrusion, exposure of the mesh. The polypropylene meshes can not be integrated into the host tissue if the macrophage response is much more aggressive, which is termed a"M2 macrophage response".

Excessive fibrotic response can lead to mesh exposure which presents a major reconstructive surgical challenge.The vast majority of patients do well with mesh and it can be concluded that some degree of fibrosis is essential to the surgical management whereas excessive fibrosis may be detrimental.

In summary, the studies agree that polypropylene meshes provoke a fairly pronounced inflammation, leading to a massive cell infiltration into the scaffold and ultimately to collagen production.

Complications of Mesh in Surgical Treatment of Pelvic Organ Prolapse

In the FDA Safety Communication, it is evident that mesh-associated complications are not rare.

The recent ACOG Committee Opined that compared to native tissue repair, synthetic mesh exposure/erosion or extrusion is unique andis the most common complication of transvaginal mesh augmentation for POP repairs. Often the terms mesh exposure and mesh extrusion are utilized interchangeably.

IUGA and the International Continence Society have provided a new terminology and classification system for complications involving transvaginal meshes, tapes, and grafts in the female pelvic floor. Within this classification system, *"**an exposure"*** is defined as vaginal mesh visualized through separated epithelium, whereas "***a mesh extrusion***"is the gradual exposure (passage)of the mesh out of the tissue. [(26))] Rates of mesh exposure and extrusion complications vary in the literature. Many studies reported mesh "erosion" rates. Mesh erosions as characterized by the FDA refers to mesh coming through the vagina often called exposure or extrusion. [(133)]

Operative outcomes with use of different mesh types are consistently high in ASC .Abdominal sacrocolpopexy with mesh interposition appears to be an effective, safe and well tolerated procedure.[7]

Comparision of abdominal and vaginal repair of apical prolapse with synthetic mesh

In comparison to the transvaginal mesh use in the anterior compartment, abdominal sacrocolpopexy is widely regarded as the gold standard for apical prolapse with success rates reported from 58 to 100 percent depending on outcome definitions. In 2009, a systematic review of 30 studies evaluating a total of 2,653 patients undergoing apical repairs with mesh kits reported success rates from 87 to 95 percent, though outcome definitions variedwidely. [134] Abdominal apical repairs with synthetic mesh appear to have lower erosion rates than transvaginallyplacedsynthetic mesh.

when comparing traditional vaginal surgery for apical prolapse to sacral colpopexy, complications were higher in the vaginal synthetic mesh group with a mesh erosion rate of 5.8 percent. [135]

Sacrocolpopexy mesh erosion is typically evident by exposure of the graft in the vagina. In such cases, granulation tissue and a sero-purulent or sero-sanginous discharge is usually present. This may be accompanied by pain or tenderness and dyspareunia. [139] Occasionally, the sacrocolpopexy vaginal sutures may be the only visible foreign material. In the absence of visible graft, it is called suture erosion.

Erosion may result from an inflammatory reaction due to infection of the foreign body or, possibly, due to an immunological response to the graft or suture material. Alternatively, the mesh or sutures may be exposed without an obvious inflammatory reaction and can be relatively

asymptomatic. Nevertheless, the management of erosions has a significant occurrence of major complications.[140,141]

Apart from graft types, other factors which predispose to graft erosion are graft placement and concurrent hysterectomy.[139]

The ColpopexyandUrinary Reduction Efforts (CARE) trial provides an excellent opportunity to search for potential risk factors for mesh/suture erosion in a large cohortof patients who underwent sacrocolpopexy with standardized physical exams during the two-year follow-up at regular intervals.

Conclusion

Abdominal sacrocolpopexy using synthetic mesh is defined as the "gold" standard treatment for apical vault prolapse. Success rates for this procedure range from 78 to 100% over a follow- up period of 6 months to 3 years. Long term follow-up data is also available for 13 years after ASCP and all data reported 74% success rate .

An overview of autologous fascia lata in abdominal sacrocolpopexy

Fascia lata was first used by Payr in 1908 as a frontalis sling to correct ptosis.(116) The technique was subsequently refined by Wright in 1922 and continues to be employed today.(118) It has also been used in a wide variety of other surgical procedures to repair heart valves, urethra, nasal septum, facial palsy, hernias, and to cover exposed implants (117).Many alternative materials have been tried but autogenous fascia lata is still considered to give the best cosmetic results with the lowest incidence of complications especially in ophthalmic reconstructive surgeries. (3–7).

Autogenous fascia lata has excellent tensile strength and good handling properties [119]

Host response to implanted autologous materials:

Hilgeret al assessedautologous fascia after implantation in the abdominal wall of New Zealand white rabbits. Materials were harvested at 6 and 12 weeks. Histological analysis demonstrated that autologous fascia promoted a relatively minimal inflammatory response and neovascularization but moderate collagen infiltration when compared to porcine collagen-coated polypropylene meshes [20]. Jeong and co - workers described similar results which included minimal inflammatory response and neovascularization in rabbits when autologous fascia was implanted under the eye lid for up to 8 weeks [24].

Mechanism of action of autologus fascia lata in abdominal sacrocolpopexy

Once the fascia lata was placed over the anterior longitudinal ligament, fascia lata derived its blood supply from the anterior longitudinal ligament of sacrum and vaginal vault. Moderate and uniform infiltration of host fibroblasts and little neovascularization and collagen remodeling by new collagen fibers occur after the placement of fascia lata . There was reduced inflammatory response and collagen production around autologus grafts when compared to synthetic materials and xenografts.

Implantation of autologous fascia showed good integration within host tissues, associated with a low inflammatory response, compared to polypropylene meshes and degree of graft remodelling is more in autologous fascia from the available human studies.

In pathologically unchanged fascia lata samples, the observed telocytes were not affected, despite being surrounded by abundant, and sometimes tightly packed collagen bundles.

Perspective of the ideal graft material

The permanent material is more prone to cause complications due to variation in individual immune responses.While certain complications like mesh extrusion / exposure can always be treated, the complications of polypropylene mesh such as chronic pain have proven resistant to treatment in many cases.

Hence, that graft materials for this reconstructive surgery should be degradable .

The degradability of the grafts should be gradual and allow enough time for the development of a neotissue which mechanically support the pelvic organs.

A graft material which does not cause any inflammation is undesirable as an initial inflammatory response is required to promote angiogenesis , collagen ingrowth and integration of the material. This is essentially an M1 macrophage response.

For this initial inflammatory response, the graft material should be readily permeable to host cells. The ideal graft material

i. Should be degradable,
ii. Should provoke an acute inflammatory response,
iii. Should undergo tissue remodelling,
iv. Should be permeable to host cells,
v. Should be mechanically strong at the time of implantation.

The clinical evidence suggests that both synthetic and biological materials can provide successful outcomes when used in the surgical management of pelvic floor disorders.

Both the host response and the mechanical properties of the graft materials should be taken into consideration to predict the success of the graft implants, in addition to their response to dynamic loading.

Allografts:

The clinical trials have revealed that the tension employed upon the graft during implantation is critical to the eventual graft strength. Thus tension adjusted on the graft significantly affect the remodelling of donor grafts in all surgeries[195,196,197].

It is potential that when the tissues adjacent to the grafts assumed unequal amounts of stress, one portion of the graft becoming 'stress shielded' [198] and eventually weaker.

The porcine graft and Pelvicol are associated with low graft related complication and high failure rate.

Synthetic mesh has become a popular option for pelvic reconstructive surgery. The potential complications include erosion/ extrusion and are dependent on multiple factors including mesh type and patient tissue integrity. However, review of the literature has shown that amongst synthetic grafts, type I mesh provides durable results with the fewest rates of erosion and extrusion.

The management options for vaginal extrusion include conservative approaches such as observation with or without local estrogen administration.

Synthetic and biologic materials have advantages and disadvantages in the treatment of pelvic floor disorders. synthetic grafts are safe and cost-effective in pelvic reconstructive surgery.Synthetic grafts have been used for a long time in abdominal sacrocolpopexy and shown to have better results compared to biological grafts. The procedure is accepted as gold standard but may be associated with short term morbidity and potential graft related problems.

Rationale for use of biological grafts:

Recently, American Food and Drug Administration (FDA) has announced warnings on use of synthetic meshes for pelvic floor reconstructive surgeries. These led to a hesitancy in use of meshes and partial increase in use of other biological grafts such as allografts and xenografts.

These biological grafts have gained popularity since they provide scaffolding for host tissue growth, associated with shorter duration of surgery compared to native tissue harvesting and minimal risk of erosion than with synthetic meshes. Disadvantages of biological graft use include early disappearence, host versus graft response, lack of uniform graft composition and risk of prion transmission. Prions are proteinaceous infectious pathogens that harbor infection within a host protein. They cause a response in recipients but not in the host. Prions transmit a group of invariably fatal neurodegenerative diseases by a novel mechanism involving aminoacid transposition,which results in a change in protein configuration to a neurotoxic prion protein peptide.

Autologus grafts:

Autologous grafts are the most successful biological material used in contemporary practice and the studies reviewed appear to support the long term mechanical integrity of these grafts in pelvic reconstructive surgery.

It was evident that the tensile strength [16,36] of autologous fascia lata graft was higher than synthetic materials and xenografts[16,19,36] because of abundant production of collagen around autologous graft.

Abdominal sacro colpopexy, can be performed using various graft materials. Each type of graft material is associated with their own benefits and risks. The characteristics of graft materials currently available for use in abdominal sacrocolpopexy have been reviewed and are recommended as follows

Currently, there are four kinds of materials used in pelvic reconstructive surgery: synthetic mesh, allografts, xenografts and.autografts

Synthetic mesh

Synthetic meshes are plenty, simplify the overall procedure, decrease the operative time and avoid potential harvest morbidity. Synthetic graft may also be much stronger than patient native tissues.

However, significant disadvantage includes erosion, an overall removal and revision rate of almost 3%, formation of chronic sinus tracts/ fistulas and infection.

Allografts

Allografts are most often processed from cadaveric fascia of human donors. This material has to be rendered non-immunogenic by a procedure which removes cells without damaging the connective tissue scaffold.The primary advantage of allograft material is its similar performance to autologous human fascia without potential harvest morbidity.

Allograft has been shown to erode through the vaginal wall, undergo autolysis and possibly be associated with disease transmission via viruses, bacteria and prions.

Poor functional outcomes with freeze-dried and irradiated fascia lata allografts in sacral colpopexy procedures had been reported. There is more chance of stiffness and failure with commercially available, solvent dehydrated cadaveric fascia lata and cadaveric dermal grafts .

Whereas there is less chance of stiffness and failure with freeze-dried cadaveric fascia lata than autologous rectus fascia, solvent dehydrated cadaveric fascia lata and cadaveric dermal grafts.

Cadaveric fascia lata causes potential disease (Viruses, bacteria and prions) transmission via allograft tissue.

Xenografts

Xenografts consist of acellular extracts of collagen harvested from bovine and porcine sources which cause infection.Xenografts have been used in multiple surgical disciplines, including urology, otolaryngology, plastic surgery, general surgery and orthopedic surgery.

The data are immature and insufficient to make any definitive statement regarding the results of vaginal vault prolapse surgery.

Some patients refuse xenograft implantation due to religious beliefs and cultural barriers.

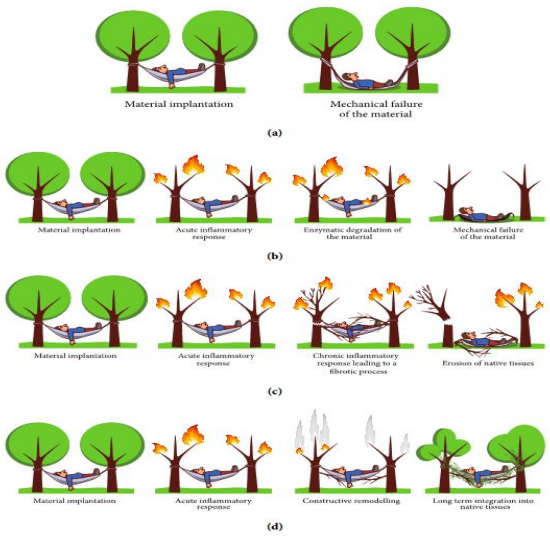
Histological response to graft materials in ASCP

The histological response to reconstructive bio- material used in pelvic reconstructive surgery depends upon the physical and structural properties of the prosthesis. Host response comprises several stages:

- Incorporation: infiltration of reconstructive material by host cells, allowing neovascularization and collagen deposition.
- Encapsulation: deposition of collagen and connective tissue at the periphery of the material.
- Mixed response: incorporation occurs at graft pores and encapsulation occurs around the remaining material.
- Resorption: material is replaced by host neo-connective tissue.

Diagramatic illustration of graft materials reaction in pelvic floor after implantation

Figure : Cartoon of patients response to materials implanted in the pelvic floor:(*a) mechanical failure, (b) material recognized as non-self and isolated from body tissues with encapsulation, (c) exposure (erosion), and (d) optimal result for implanted material.*



Advantages of Autologous grafts over synthetic grafts

Autologous grafts commonly harvested for repairs of vault prolapse are rectus fascia and fascia lata. Usage of patient's own tissue have decreased risk of erosion, rejection and infection. Eventhough autologous fascia was one of the original graft materials utilized in pelvic floor repair, there is long term data available to suggest that the grafts provide durable results. [122] However, the use of autologous materials was associated with increased pain, risk of hernia formation at the harvesting site and increased operative time.

Autografts –Autologus fascia

Autografts are harvested from the patient who is undergoing the procedure.. The most commonly used autografts are fascia lata which does not have any host response.[40,41]

A large piece of autologous fascia lata can be harvested that is as wide and as long as the piece of synthetic mesh typically used for the

procedure. There was no morbidity associated with autologous fascia lata harvest in our series.

Fascia lata is widely used in a large variety of surgical specialties when autologous graft tissue is desired including cardiac surgery [154], orthopedic surgery [155], ophthalmology [156], urology [157], general surgery [158] , plastic and reconstructive surgery [159,160]. It serves as an excellent dural substitute and is commonly used in neurosurgical practice.

In the past, fasciae received little attention and was underestimated. Today, fascia is no longer considered ***'a forgotten structure'.*** Recently, there has been a growing interest in fascial structures, with the number of publications rising each year .

SCOPE OF THE STUDY

Management of vaginal vault prolapse may be complex and surgical reconstruction can be challenging. The most appropriateoperative procedure and approach should be selected to achieve an optimal result for the patient with vaginal vault prolapse.In the literature, several vaginal and abdominal procedures have been described to treat vault prolapsed and there is no consensus on the most effective approach or technique. Evidence shows that abdominal repair yields better long terms results with reduced incidence of recurrence.Sacrocolpopexy is a valid technique to treat apical and anterior vaginal wall prolapse. [152]

Abdominal sacrocolpopexy using synthetic mesh has proven its worth overtime.

The advantages of using synthetic mesh over autologous grafts:

- High cure rates due to consistency of strength of synthetic mesh
- Decrease in operative time
- Commercially readily available
- Evasion of an additional incision to harvest fascia lata

However synthetic mesh has its major disadvantages over autologous grafts

- Mesh is associated with specific mesh related complications like mesh exposure, extrusion into the vagina and infection

- Chances of patient developing chronic pelvic pain and dyspareunia are high.

The above mentioned complications with the use of synthetic mesh in abdominal sacrocolpopexy forcedpelvic surgeons to consider the usage of equally effective. suspension material preferably autologous to suspend the vaginal apex as management of vault prolapse.

There are several debates in the selection of graft materials which include synthetic mesh, biological grafts like cadaveric fascia lata, autologous fascia lata, allografts and xenografts. In the literature, there are several studies comparing various graft materials like cadaveric fascia lata and xenografts with mesh in abdominal sacrocolpopexy for correction of vaginal vault prolapse but only two studies report the usage and efficacy of autologous fascia lata in abdominal sacrocolpopexy.

There was no randomized controlled clinical study found in the literature, which compares the usage of autologous fascia lata and synthetic mesh in abdominal sacrocolpopexy for correction of vaginal vault prolapse .

This potentiated the conduct of a research as RCT in abdominal sacrocolpopexy with autologous fascia lata and synthetic mesh for correction of vaginal vault prolapse. Following that, pros and cons in using synthetic mesh over autologous fascia lata and vice versa in abdominal Sacrocolpopexyprocedure were assessed before the commencement of the study and are presented below.

Though autologous fascial graft has many advantages over other materials used for suspension, there is lack of adequate publication to support it. There is a necessity for scientific study to prove the efficacy of autologous fascia over synthetic mesh which prompted the initiation of the research.

The advantages of using autologous grafts over synthetic mesh:

- Absence of mesh associated complications like erosion (exposure/ extrusion/ perforation)
- Minimal to moderate inflammatory response
- Moderate degree of collagen production
- Remodelling of autologus graft over the long term
- Autologous fascia lata compares favorably in efficacy to other materials and is not associated with any significant morbidity.
- Patient satisfaction with the procedure was reported high.

Abdominal sacral colpopexy using autologous fascia lata should be considered not only in those women who have failed a prior transvaginal suspension procedure, but also as the primary surgical approach in women with symptomatic vaginal vault prolapse.

The disadvantages of using autologous fascia latagrafts over synthetic mesh:

- Incision over two sites
- Little prolongation of operative time for harvesting fascia lata
- Cosmetically not accepted by some patients

Indications for abdominal repair in vault prolapse management

1. significantly shortenedvagina
2. Vault prolapse with hugeadenexal masses

3. Prior unsuccessful vaginal repair
4. Pelvic bone deformities
5. High risk patients likeathletics, obesityand patients with chronic obstructive pulmonary disease.
6. young sexually active women

Justification and scope of the study:

- Vault prolapse is highly prevalent in our country. Our Institution is the tertiary referral center and many cases of vault prolapse have been referred to the department of Urogynaecology at our Institute.
- Scientific proven operation which is independent of synthetic graft is needed to eliminate mesh related complications like infection, extrusion, chronic vaginal pain and dyspareunea.
- Most of our patients with vault prolapse are from remote villages and they do not come for follow-up for treatment of mesh related complications if synthetic graft is used.
- Autologus fascial graft are free from disease transmission unlike cadaveric fascia lata
- Autologus fascial graft do not undergo autolysis unlike allografts.
- Autologous graft is readily available with the patient and the patient is not dependant on any commercial preparation.

On the contrary, the benefits of mesh has been proved by number of studies.

Plan of the study

- This study, "A Randomized Controlled Trial comparing autologous Fascia lata and Synthetic mesh for Abdominal Sacrocolpopexy" was planned during late months of 2008 and required review of literature was done.
- Also feasibility of conducting the study in terms of facilities available, duration needed for data collection and follow up of the patients were also assessed.
- Study design and methodology was prepared during late months of 2008 and early months of 2009.
- Ethical committee approval for conducting the study was obtained from Institutional Ethical Committee (IEC) of Government General Hospital and Madras Medical College, Chennai during the month of February 2009.
- Following which, the data collection process was started in the Department of Uro Gynecology at Institute of Social Obstetrics and Government Kasturbha Gandhi Hospital For Women and Children, Madras Medical College among the patients required abdominalsacrocolpopexy in the same institute.
- Patients with vaginal vault prolapse were randomized and included in the study. The sample size of thirty patients in autologous fascia lata group and thirty patients in synthetic mesh group were included. Both the surgeon and patients were blinded to the type of suspension material till the beginning of the surgery.

- Surgeries were performed by a single senior most Urogynecologist and assessment and post operative follow up was done by the candidate to avoid bias in interpretation of the results.
- The process of including study participants undergoing surgical repair was completed during March 2012.
- The minimum follow up period for this study was three years and thus data collection was completed during March 2015.
- Synopsis was submitted to The Tamil Nadu Dr. M.G.R. Medical University during the month of March 2018.

METHODOLOGY

Patients and Methods

Study Design:

It is a prospective, single blinded, randomised controlled clinical trial.

Sample Setting:

It is a single blinded randomised controlled clinical trial (RCT) performed to compare the clinical outcome of autologous fascia lata over synthetic mesh in successfully repaired cases of vault prolapse by abdominal sacrocolpopexy. The study was conducted in the department of Urogynaecology, Institute of Social Obstetrics and Government Kasturba Gandhi Hospital for Women and children, Madras Medical college, a tertiary care Hospital in Chennai, India. The study group comprised predominantly patients belonging to the low socio-economic status. The study population was mostly the referral patients with clinical evidence of vaginal vault prolapse.

Duration of the Study:

The study was conducted fromApril 2009 to March 2012.

Sample:

58 Vaginal vault prolapse patients (N=58)were included in this study. Out of this 28underwent abdominal sacrocolpopexy with autologous Fascia Lata and 30 with Synthetic Mesh.

Randomization and Blinding:

Randomization avoids selection bias that could occur if either physician or patient selects the technique. Sixty numbers were randomized using a random table. The odd numbers were chosen as “A” group and the even numbers were chosen as “B” group. As per randomization, 31 patients were allocated for group “A” and 29 patients for group “B” . “A” group was selected for fascia lata and “B” group was for synthetic mesh.

Along with randomization, singleblinding was done . The patient was blinded to the type of suspension material till the end of surgery where as the surgeon was aware of the material to be used for suspension of the vault only at the beginning of the surgery.

Further to avoid bias , surgeries were performed by a single senior most Urogynecologist and the pre and post operative assessment and interpretation only was performed by the candidate .

Scientific Committee Clearance:

This study was approved by the hospital scientific advisory committee of Madras Medical College and Research Center, Chennai.(appendix)

Ethical committee Clearance:

This study was approved by the Ethical committee of Tamil Nadu Dr. M.G.R. Medical University, Chennai (appendix)

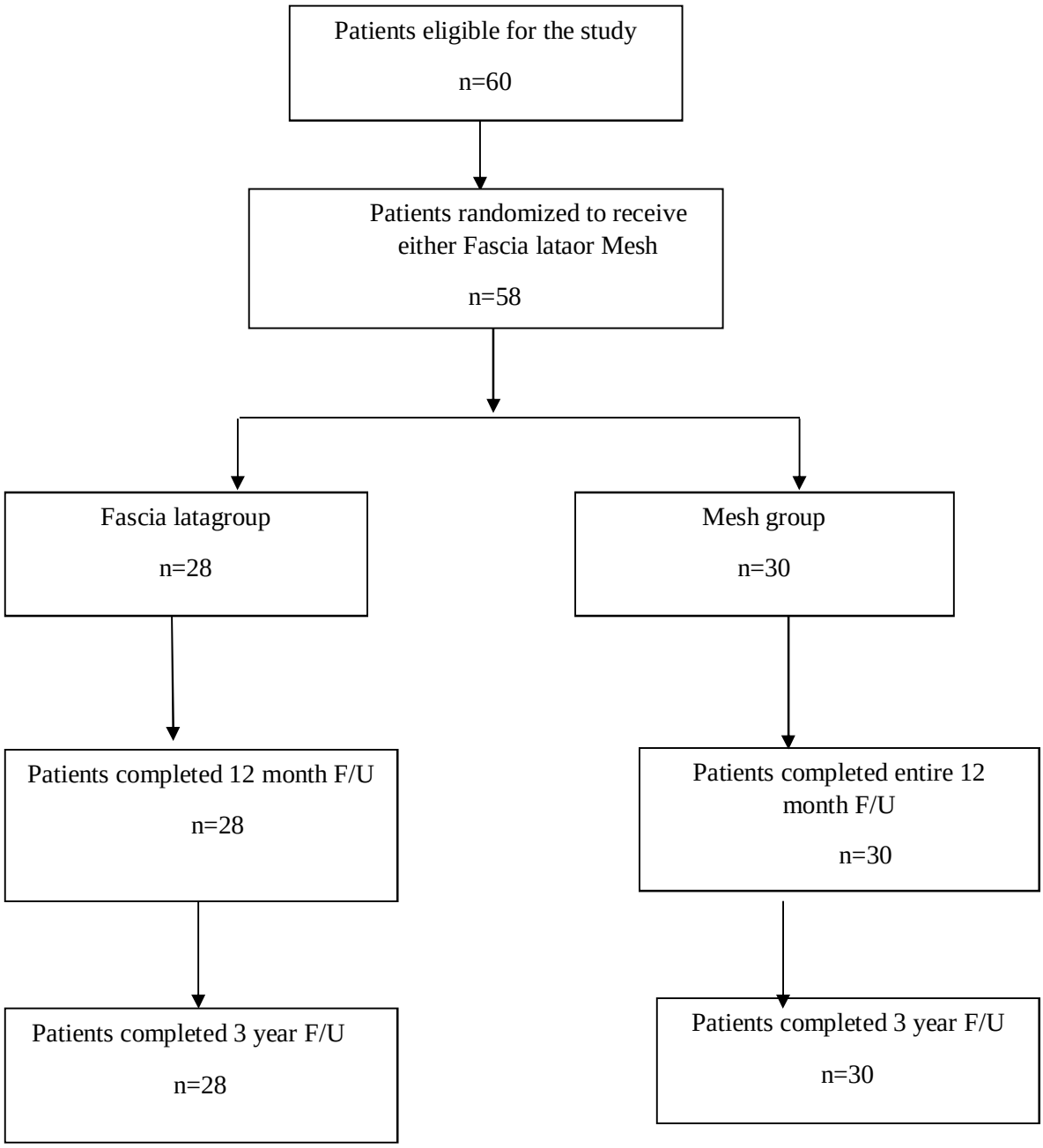
Inclusion Criteria:

- Women with stage 3 to stage 4 vaginal vault prolapse (primary) or recurrent vaginal vault prolapse scheduled for abdominal sacrocolpopexy were included.

Exclusion criteria:

1. Stage 1 to 2 vault prolapse
2. Vaginal vault prolapse with abnormal pap smear
3. Comorbid medical diseases like valvular heart disease, ischaemic heart disease, chronic obstructive pulmonary disease, renal / liver disease and central nervous system disorders.
4. BMI more than 30

Figure : Flow chart of patient allocation and follow up in each group



Process of consent taking

All patients went through a special informed consent process, during which surgical options were discussed. After selecting abdominal sacrocolpopexy as the treatment for vaginal vault prolapse, each patient went

through a separate informed consent process for the study.The principal investigator explained the purpose of this study to each participant and a written consent was obtained from the participants prior to the commencement of the study. Theparticipants were made to understand the fact that their participation was voluntary and they could withdraw from the study at any time. All information collected from the participants were kept confidential. The study was conducted using English proformawhich was translated into Tamil for use by the participants and then their response were documented in english. Data collection was done through one-to-one interview.

Method of data collection

Preoperative information like age, body mass index, parity, menopausal status, hormone replacement status and history of any prior prolapse or continence surgery were collected using a proforma. (Appendix)

In all study patients, staging of vault prolapse was done as per IUGA/ICS POP Q classification system.

Nine –point patient pelvic organ prolapse quantification and staging definitions

POP Q system has following points of measurement

- Aa: It is a fixed landmark. It defines a point that lies in the midline of the anterior vaginal wall and is 3 cm proximal to the external urethral meatus. It corresponds to the proximal location of the urethrovesical crease. In relation to the hymen, this point ranges from -3 (i.e. normal support) to +3 (i.e. maximum prolapse)

- Ba: It is a variable point and refers to the most distal position of any part of the remaining upper anterior vaginal wall. It is -3cm in the absence of prolapse. Points range is -3 (in the absence of prolapse) to +tvl (-3 to +8). In the absence of prolapse Aa and Ba are almost same point i.e. (-3).
- Ap: It defines a point that lies in the midline of the posterior vaginal wall and is 3 cm proximal to the hymen. This point's range is -3 (i.e. normal support) to +3 (maximum prolapse of point Ap).
- Bp: it is also a variable point, most distal point of the remaining upper posterior vaginal wall. Point range is -3 (in the absence of prolapse) to +tvl (-3 to +8)
- In the absence of prolapse Ap and Bp are almost the same point (-3).
- Total vaginal length (tvl): greatest depth of the vagina in centimeters measurement is taken without straining (normal range is 8-12 cm).
- Genital hiatus (gh): middle of external urethral meatus to the posterior midline of hymen (range 2-4 cm).
- Perineal body (pb): posterior margin of genital hiatus to midanal opening (approx. 3 cm).
- D (douglas): level of uterosacral ligament attachment to the posterior cervix (no cervix = no d point, range -8 to -10).
- C (cervix or vaginal cuff): most distal edge of the cervix or leading edge of the vaginal cuff.

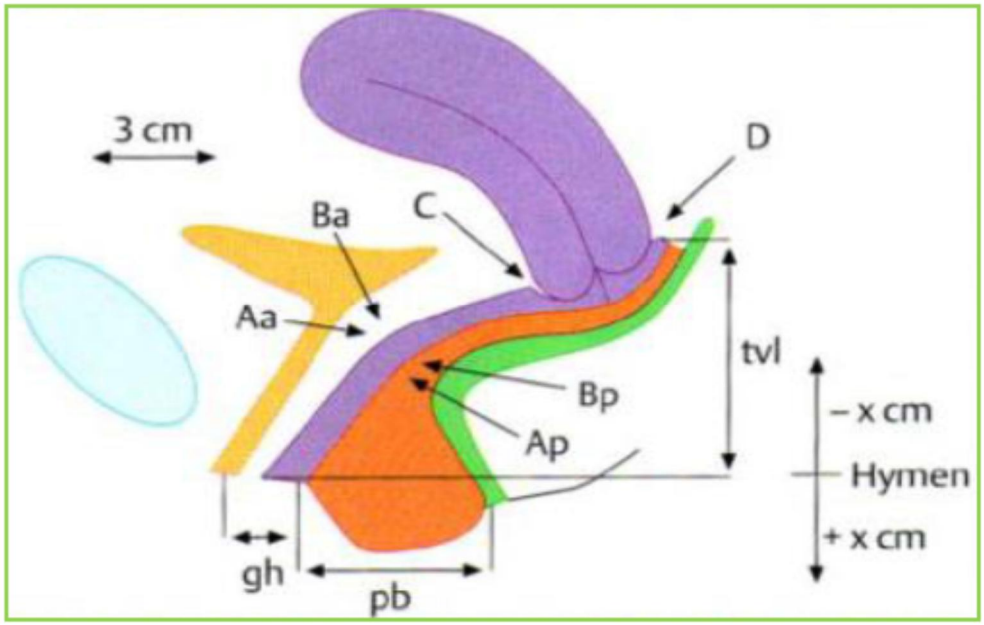


Illustration of points of POP Q.

Classification of POP

Staging

Table 3

Stage 0	No Prolpase Points Aa, Ba, Ap, Bp are all at -3cm.
Stage I	The most distal portion of the prolapse is more than 1cm above the level of hymen Quantification value is less than -1 cm.
Stage II	The most distal portion of the prolapse is 1 cm or less proximal or distal to the hymen Quantification value is ≥ -1cm but ≤+1 cm
Stage III	The most distal portion of the prolapse protrudes more than1 cm below the hymenal plane. Quantification value is >+1 but <+(tvl -2cm)
Stage IV	Complete eversion of vaginal walls. Quantification value > (+Tvl -2 cm)

Table 4 Tic tac toe grid

Aa Anterior vaginal wall	Ba Anterior vaginal wall	C Cervix or cervical cuff
Gh Genital hiatus	Pb Perineal body	Tvl Total vaginal length
Ba Posterior vaginal wall	Bp Posterior vaginal wall	D Posterior fornix

Abdominal sacrocolpopexy with Autologous Fascia Lata and Synthetic Mesh

All patients underwent a detailed comprehensive urogynecologic preoperative assessment other than routine clinical examination. Multichannel urodynamic studies with support to the vaginal vault was used in patients with stress urinary incontinence (overt & occult) & mixed urinary incontinence. Based on the urodynamic studies, surgery for urinary incontinence was combined with abdominal sacrocolpopexy.

Results and Statistical Analysis:

Descriptive analysis

Paired sample t-test and

Independent sample T-test, were the statistical tests used in this study.

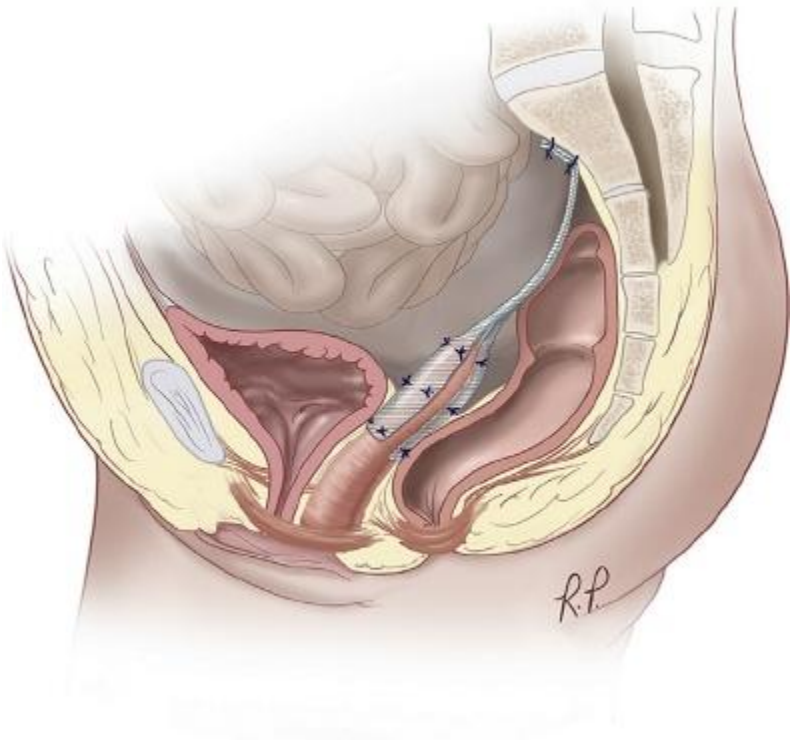
Statistical Software:

The statistical software SPSS 20.0 version was used for the analysis of the data and Microsoft excel have been used to generate graphs, tables etc.

Operational definitions:

Principle of abdominal sacrocolpopexy :

In abdominal sacrocolpopexy, vaginal vault is suspended to the sacral promontory or into the hollow of sacrum using a graft or synthetic mesh .



Abdominal sacrocolpopexy

Thisprocedure restores the vaginal apex close to the normal anatomic position, approximately 1 cm anterior and 5 cm inferior to the second sacral vertebra. (138)

All patients were given regional anaesthesia when necessary supplementation of general anaesthesia was used in few patients.

Procedure of abdominal sacrocolpopexy with fascia lata

Harvesting of Fascia lata:

First patient was positioned in left lateral position with flexion of right hip and knee at approximately 60 degree. The lateral aspect of right thigh was exposed for its entire length from hip to knee. A pillow placed between the knees to elevate the lateral aspect of right thigh facilitated its exposure.

Longitudinal incision of 10- 13 centimeter was made on the lateral aspect of right thigh so that lower end of incision should be atleast two centimeters above the lateral epicondyle of femur. Subcutaneous fat was dissected off the fascia lata. Small size deaver retractors were used for better exposure of fascia lata. Two parallel longitudinal incisions were made on the fascia lata 3 cm apart. With an index finger, careful blunt dissection was used to separate the fascia from the underlying muscle, this finger dissection was made in order to avoid inadvertent trauma to the muscle . The fasciotomy incision wascontinued to harvest the required length of the graft .The fascia lata of 12 cm length and 3 cm width was dissected, transected and detached from its proximal and distal attachment.The harvested autograft was cleared off fat for its full length using a blunt scissor. The harvested fascia lata was immersed in antibiotic (Gentamycin) mixed saline. Meticulous hemostasis was achived which involved the coagulation of perforator veins. Securing good haemostasis eliminated the need for subcutaneous drainage . Skin was closed with no.2 polyamide.

Positioning of the patient for harvesting fascia lata

1. After harvesting fascia lata, patient was changed from lateral position to supine position and was positioned in Allen stirrups.
2. A foley catheter was placed.
3. Abdomen was opened either by pfannensteil or right paramedianincision.The abdominal contents were packed out of the pelvis.
4. A self-retaining retractor was used to hold the intestine in the upper abdomen andretract the sigmoid colon to the left pelvic sidewall.
5. Rest of the steps for abdominalsacrocolpopexy were identical inboth fascia lata and synthetic mesh group.

Sacral promontory dissection

The promontory was identified by following the pelvic brim to the base of the sigmoid mesentery medially and the pulsatile iliac artery laterally. The right ureter was a helpful landmark and was usually identified through the peritoneum with its characteristic peristalsis. The posterior peritoneum was opened over the sacral promontory at the level of S1– S2 with fine curved scissor between the right ureter and sigmoid colon. The incision was extended down to the pouch of doughlas. Theblunt dissection

over the sacral promontory was continued until the anterior longitudinal ligament was visualized.. Prominent vessels werecontrolled with bipolar cautery and care was taken to avoid injury to the middle sacral artery . Three to four transverse sutures with 0 monofilament polyprophylene sutures were placed on the anterior longitudinal ligament of sacrum (anterior sacral ligament) avoiding intervertebral disc and was tagged.

Vaginal dissection

Since the peritoneum was very thin at the site of the vaginal cuff in post-hysterectomy patients, the plane between the bladder and vagina was developed by hydrodissection. Then vaginal vault prepared by mobilising recto vaginal and vesico vaginal fascia from the posterior and anterior vaginal wall.vesico-vaginal and recto-vaginal spaces were developed by sharp and blunt dissection avoiding entry into bladder or rectum.Bleeding encountered during dissection should raise the suspicion of dissection into the bladder. Ring forceps with sponge was used to elevate the vaginal apex.

The steep Trendelenburg position with additional manipulation of the posterior vaginal wall by a ring forceps with sponge facilitated the dissection in the posterior vaginal wall to reach its lower most level. Transverse sutures (3 pairs) were placed in posterior vaginal wall (distal to proximal) followed by placement of sutures on the apex and anterior vaginal wall using 00 non absorbable polypropylene sutures.

Graft/ Mesh placement

The 12x3 cm fascia lata (polypropylene mesh) was configured to "Y" shape. The one arm of "Y" fascia lata (mesh) was fixed over the posterior vaginal wall with 3 pairs of no.00 monofilament polypropylene sutures placed earlier. Similarly the other arm of "Y" fascia lata (mesh) was fixed over the

anterior vaginal wall with 3 pairs of no 00 monofilament polypropylene sutures. The stem of “Y” fascia lata (mesh) was retro peritonealised through the tunnel created in the posterior peritoneum and then it was attached to the anterior longitudinal ligament of sacrum without tension using the three polyprophylenesutures placed already. The graft should be in contact with ligament without intervening suture bridge.

When the sutures were tied down, the vaginal apex should be elevated without tension on the graft. Thus vaginal vault was suspended to the sacrum. The posterior peritoneum over the fascia lata (mesh) was closed with no. 00 polyglactin suture.

Burch colposuspension:

Burch colposuspension was combined with abdominal sacrocolpopexy in patientswith occult or overt stress urinary incontinence (in both fascialata and synthetic mesh group

In Burch colposuspension, the bladder was retracted superiorly and inferior part of the incision was retracted to expose the bladder neck.The bladder neck was identified by palpation of foley catheter bulb.The paraurethral (para vaginal) area was exposed by the assistant elevating it from vaginally by her index finger and was cleared off the fat overlying it.The bladder was retracted superiorly and medially. Two sutures with 0 polyglactin were placed in the paravaginal tissue 2 cm lateral to bladder neck. One arm of the suture was placed through the ipsilateral cooper ligament . The sutures were tied with suture bridge until the assistant felt the elevation of paravaginal tissue.

Check cystoscopy was performed to evaluate ureteral patency and to exclude lower urinary tract injuryin patients with concomitant Burch colposuspension.

Abdomen was closed after ensuring haemostasis.

Fascia lata harvesting took 20 -30 minutes to complete the procedure . The operative time for abdominal sacrocolpopexy with synthetic mesh/ fascia lata was approximately 120 minutes.

Post operatively parenteral broad spectrum antibiotics(cefataxime 1gm and amikacin 500 mgm) were administered for five days. Foleys catheter was removed on fourth postoperative day in both fascia lata and mesh group.

Abdominal wound sutures were removed alternatively on ninth and eleventh postoperative day in both fascia lata and mesh group. Right thigh sututres(fascia lata harvested site) were removed on tenth postoperative day in fascia lata group. The total hospital stay was twelve days in both the groups.

All patients followed standard postoperative restrictions for 3 months after surgery. These restrictions included lifting no more than 8 pounds, refraining from sexual intercourse, refraining from all exercise other than walking, and refraining from excessive straining with bowel movements. All patients were asked to use a stool softener for 1 month after surgery.

RESULTS

Demographic information of the fascia lata and mesh group

The mean age was 54.25±6.9 in fascia lata group and 47.63±9.0 in the mesh group, respectively. The mean age of the total study participants were 50.8±8.

The mean parity was 3.8±1.2 in fascia lata group and 3.1±1.3 in the mesh group, respectively. The mean parity of the total study participants was 3.5±1.3 .

The mean BMI was 24.4±3.4 in the fascia lata group and 23.5±3.0 in the mesh group . The mean BMI of the total study participants in both groups was 23.9±3.2.

Risk factors for vault prolapse

Increase in parity (more than three children), BMI more than 30,hysterectomy for POPwere considered as risk factors for vault prolapse

Table 5 Participant's mean age, parity and BMI

Variables	Fascia latagroup (N=28)	Mesh group (N=30)	Total (N=58)
Mean age in years (±SD)	54.25±6.9	47.63±9.0	50.8±8.6
Mean parity (±SD)	3.8±1.2	3.1±1.3	3.5±1.3
Mean BMI (±SD)	24.4±3.4	23.5±3.0	23.9±3.2

In this study, 23 (39.7%) participants were in the age group of 46-55 years, 16 (27.6%) patients in the age group 56-65 years, 13 (22.4%) patients in the age group of 36-45 years, 4 (6.9%) patients were in the age group of less than 35 years and 2 (3.4%) patients were in the age group of more than 65 years.

14 (50%) in fascia lata group & 9 (30%) in the mesh group were in the age group of 46-55 years.

12 (42.9%) in fascia lata group & 4 (13.3%) in the mesh group were in the age group of 56-65 years.

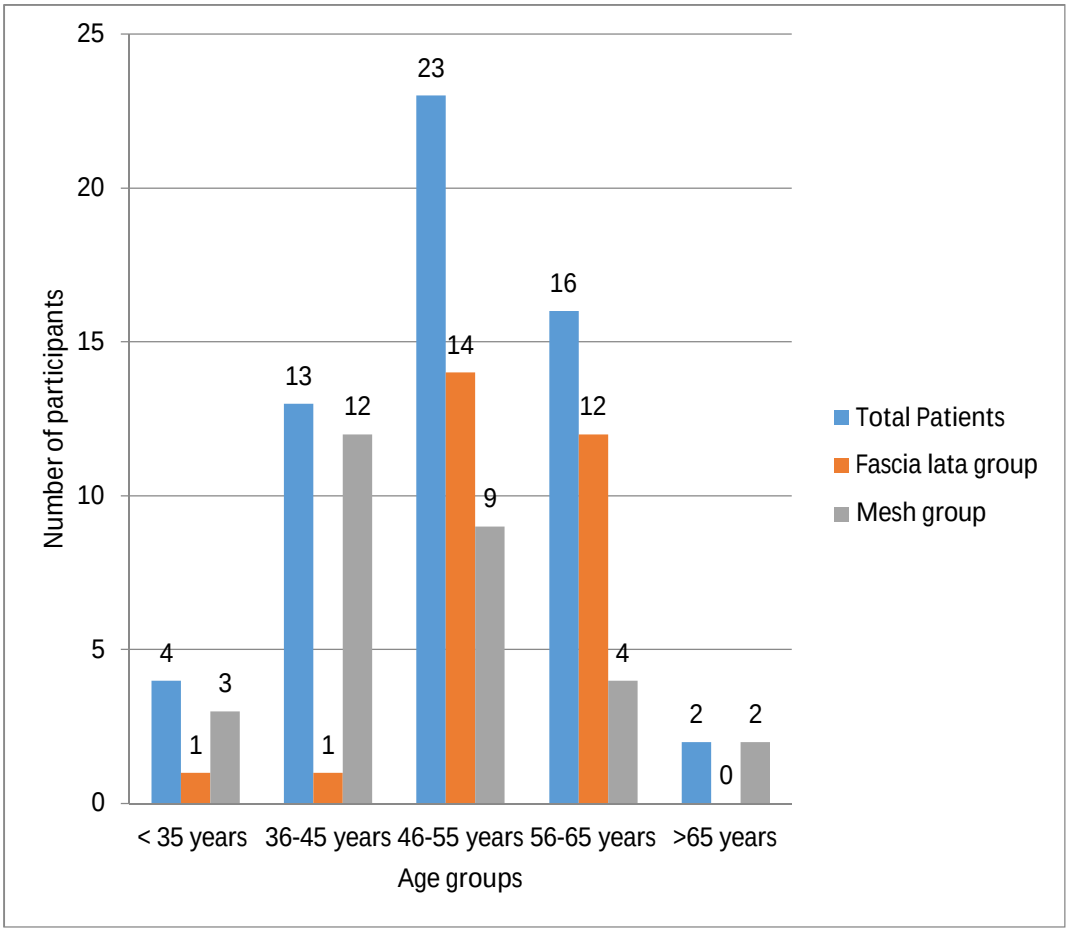
1 (3.6%) in fascia lata group & 12 (40%) in the mesh group were in the age group of 36-45 years .

1 (3.6%) in fascia lata group & , 3 (10%) in the mesh group were less tha 35 years.

None (0%) in fascia lata group & 2 (6.7%) in the mesh group were more than 65 years .

Table 6 Proportion of participants in different age groups

Age group	No. of Patients in Fascia lata group (%)	No. of Patients in Mesh group (%)	Total No. of Patients (%)
< 35 years	1 (3.6)	3 (10)	4 (6.9)
36-45 years	1 (3.6)	12 (40)	13 (22.4)
46-55 years	14 (50)	9 (30)	23 (39.7)
56-65 years	12 (42.9)	4 (13.3)	16 (27.6)
>65 years	0	2 (6.7)	2 (3.4)



Number of participants in fascia lata and mesh group with respect to age

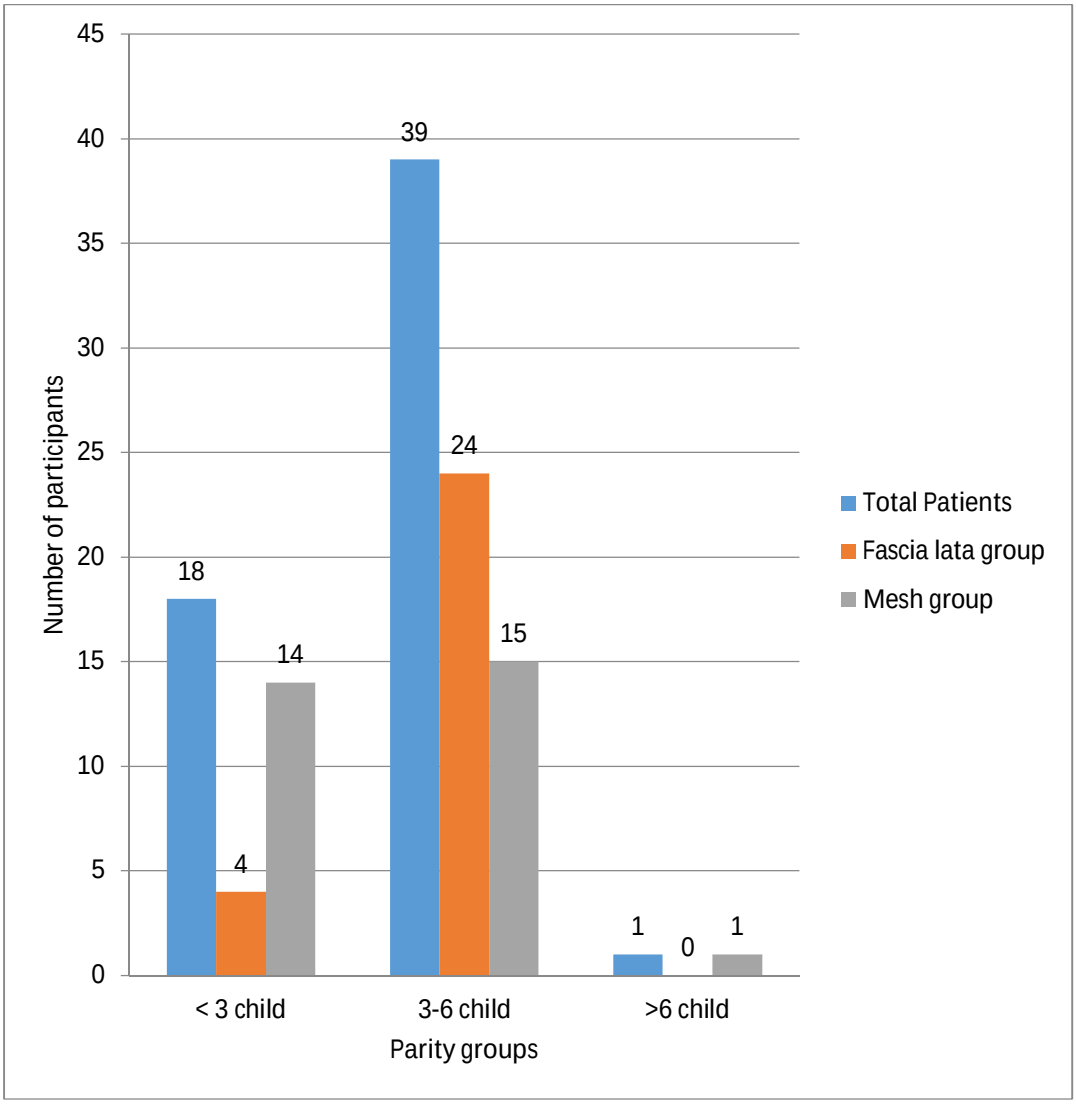
In this study, the number of participants with parity less than three were 18 (31.1%), more than or equal to three were 39 (67.2), and more than six was 1 (1.7).

4 (14.3%) in the fascia lata group &14 (46.7) in the mesh group were with parity less than three. 24 (85.7%) in the fascia lata group & 15 (50%) in the mesh group were with parity more than or equal to three .

None in fascia lata group &1(3.3%) in the mesh group was with parity more thansix.

Table 7 : Proportion of participants in different parity groups

Parity	No. of Patients in Fascia lata group (%)	No. of Patients in Mesh group (%)	Total No. of Patients (%)
< 3 child	4 (14.3)	14 (46.7)	18 (31.1)
3-6 child	24 (85.7)	15 (50)	39 (67.2)
>6 child	0	1 (3.3)	1 (1.7)



Number of participants in fascia lata and mesh group with respect to parity

In this study, the number of participants with normal BMI, overweight category, obese category and less than normal were 34 (58.6 %) , 20(34.5%) , 2(3.4%) & 2(3.4%) respectively.

17/28 (60.7%) in fascialata group and17/30 (56.7%)in the mesh groups were with normal BMI.

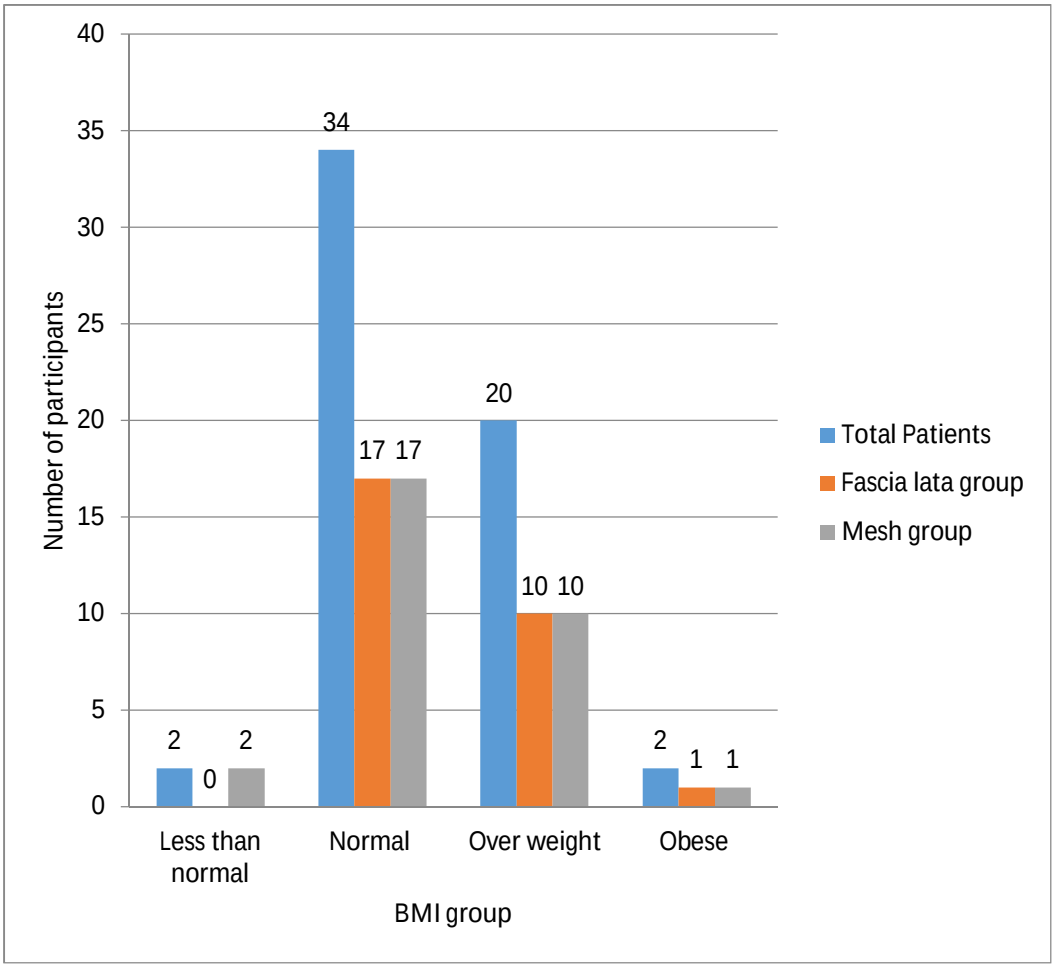
10/28 (35.7%) in fascialata group & 10/30 (33.3%) in the mesh group were in overweight category .

1/28 (3.6%) in fascia lata group & 1/30 (3.3%) in the mesh group were in obese category.

None in fascia lata group &2 (6.7%) in the mesh group were with less than normal BMI.

Table 8 Proportion of participants in different BMI groups

BMI Variables	No. of Patients in Fascia lata group (%)	No. of Patients in Mesh group (%)	Total No. of Patients (%)
Less than normal	0	2 (6.7)	2 (3.4)
Normal	17 (60.7)	17 (56.7)	34 (58.6)
Over weight	10 (35.7)	10 (33.3)	20 (34.5)
Obese	1 (3.6)	1 (3.3)	2 (3.4)



Number of participants in fascia lata and mesh group with respect to BMI

Type & indications for prior hysterectomy

In fascia lata group, the number of women who had prior total abdominal hysterectomy was 16/28 (57.1%) and prior vaginal hysterectomy was 12/28 (42.9%).

In the mesh group, the number of women who had prior total abdominal hysterectomy was 14/30 (46.6%) and prior vaginal hysterectomy was 16/30 (53.3%).

Table :9

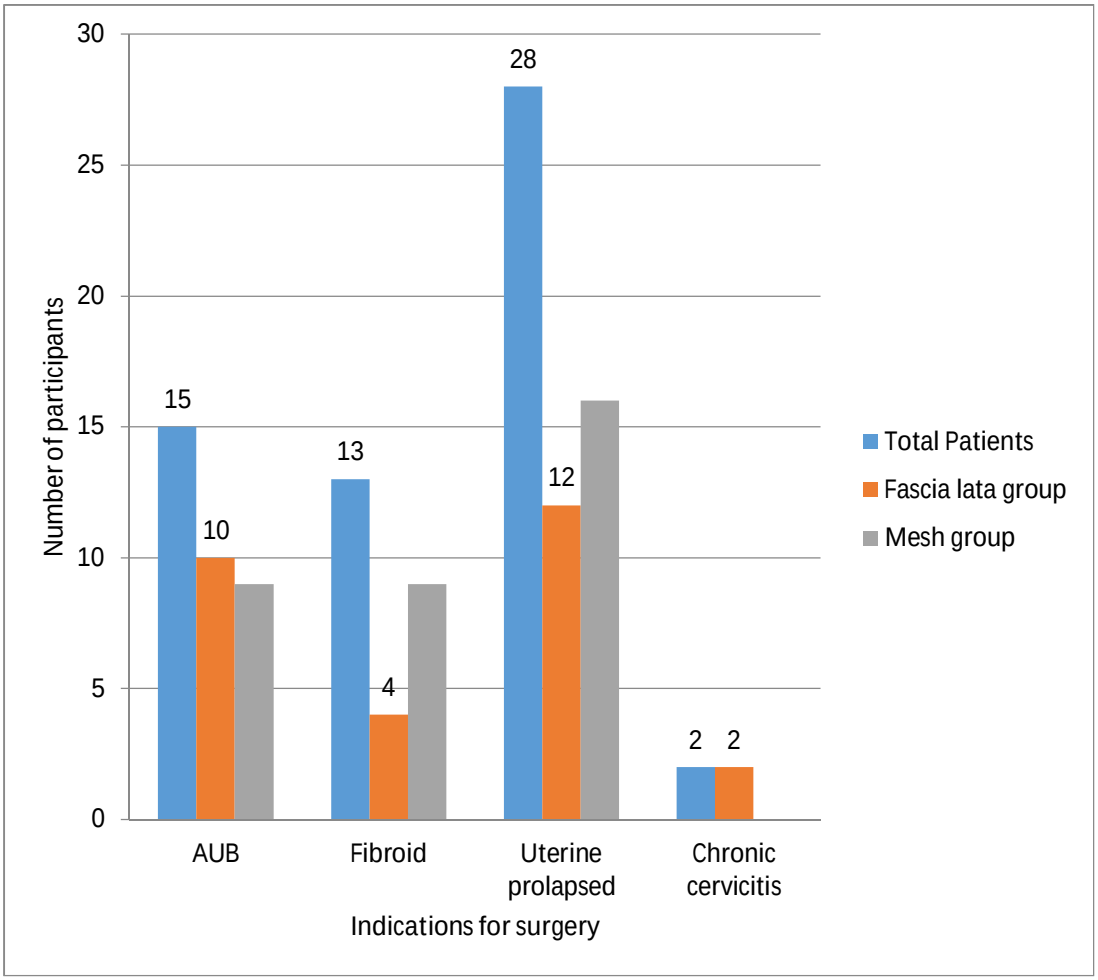
Surgical history	Fascia lata group	Synthetic mesh group
Prior abdominal hysterectomy	16/28 (57.1%)	14/30 (46.6%)
Prior vaginal hystrectomy	12/28 (42.9%)	16/30 (53.3%)

In the fascia latagroup, the indications for total abdominal hysterectomy included abnormal uterine bleeding 10(35.7%), fibroid uterus 4 (14.3%) and chronic cervicitis 2 (7.14%) The number of vaginal hysterectomies for prolapse uterus were 12(42.9%) respectively.

In the mesh group, the indications for total abdominal hysterectomy included fibroid uterus 8 (26.6%) and abnormal uterine bleeding, 6(20%), . The vaginal hysterectomy for prolapse uterus was 16(53.3%).

Table 10 : Proportion of participants with different indications for surgery

Indications	No. of Patients in Fascia lata group (%) n= 28	No. of Patients in Mesh group (%) n= 30	Total No. of Patients (%) n= 58
Abnormal uterine bleeding	10 (35.7%)	6(20 %)	16 (27.5%)
Fibroid	4 (14.3%)	8 (26.6%)	12 (20.6%)
Uterine prolapse	12 (42.9%)	16 (53.3%)	28 (48.3%)
Chronic cervicitis	2 (7.1%)	0	2 (3.4%)



Number of participants in fascia lata and mesh group with respect to indications of surgery

Table 11 Perioperative adverse events among women in autologous fascia lata and synthetic mesh groups

	Autologous Fascia lata (n=28)	Synthetic mesh (n=30)	p value
Estimated blood loss (ml)	120±50	100±50	
Patients with intra operative bladder injury	0	1	0.338
Patients with intra operative vessel injury	0	0	-
Patients with intra operative rectal injury	0	0	-
Patients required blood transfusion	0	0	-
Patients with post operativepulmonary embolism	0	0	-
Patients with abdominal wound breakdown	0	0	-
Patients with erosion of grafts	0	0	-
Total hospital stay	12 days	12 days	-

The duration of surgery in autologous fascia lata group was 178.2±20.4 minutesand in synthetic mesh group, duration of surgery was 171±29.4 minutes. It was found to be statistically not significant (p value 0.293). The mean operative time for harvesting fascia lata was 27.6 minutes.

In this study, the estimated mean (±SD) blood loss was found to be 120±50 ml in autologous fascia lata group and 100±50 ml in synthetic mesh group.

Postoperative Followup

All patiets were followed postoperatively at 6 weeks, 3 months, 6 months , 1 year , 2nd year and 3rd year. Those patients who did not turn up for follow-up were called by phone and made to report for follow up and checkup . At the end of 36 months 25 patients in fascia lata group and 28 patients in mesh group were available for follow up and checkup . At the end of 36 months 25 patients in fascia lata group and 28 patients in mesh group were available for follow up. They were questioned about the prolapse, bladder, bowel and sexual symptoms based on the questionnaire in the proforma. The POP Q measurements were taken at each visit.

In this study, post operative anatomical and clinical outcome including bladder, bowel and sexual symptoms were compared at the 3rd year follow up.

Anatomical Success Rate

Table 12:Comparing the mean, SD, t-value and p-value of Aa, Ba & C point in pre and post- op repair among women in autologous fascia lata group

Autologous Fascia Lata	Group	N	Mean	SD	t-value	p-value
Aa	**Pre-operative**	28	2.107	1.083	22.87	0.000**
	Post-operative	28	-2.803	0.342		
Ba	**Pre-operative**	28	5.964	1.054	35.47	0.000**
	Post-operative	28	-2.607	0.724		
C	**Pre-operative**	28	7.033	1.245	31.12	0.000**
	Post-operative	28	-5.766	1.833		

Table 12 shows significant difference in Aa point measurement between pre (Mean = 2.107; SD = 1.083) and post-operative values (Mean = -2.803; SD = 0.342) , (t-value = 22.87; p-value = 0.000**) at 0.01 level in autologous fascia lata group.

There is a significant difference in Ba point measurement between pre (Mean = 5.964; SD = 1.054) and post-operative values (Mean = -2.607; SD = 0.724) , (t-value = 35.47; p-value = 0.000**) at 0.01 level in autologous fascia lata group.

There is a significant difference in C point measurement between pre (Mean = 7.033; SD = 1.245) and post-operative measurement (Mean = -5.766; SD = 1.833) , (t-value = 31.12; p-value = 0.000**) at 0.01 level in autologous fascia lata group.

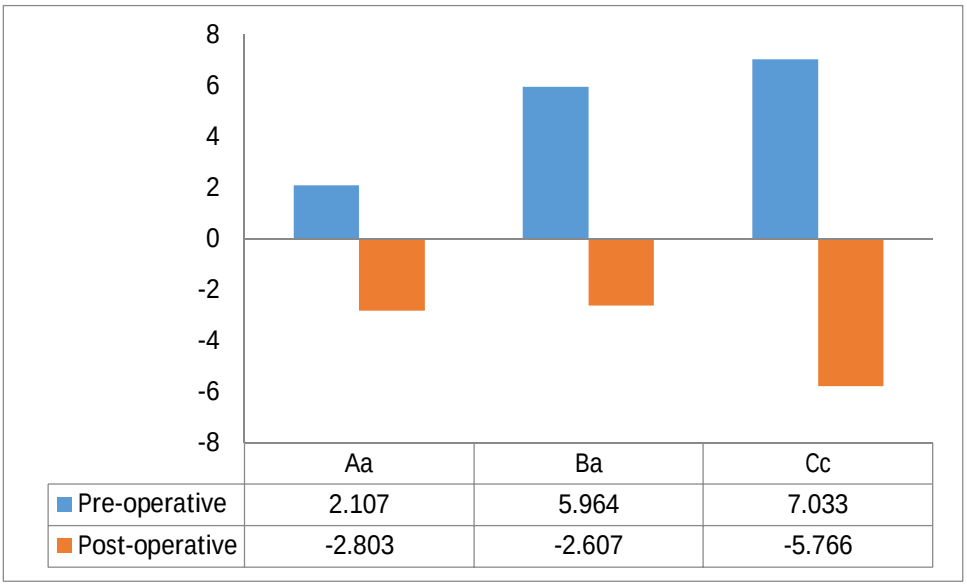


Table 13: Comparing the mean, SD, t-value and p-value of Aa, Ba & C point in pre and post repair among women in synthetic mesh group

Synthetic Mesh	Group	N	Mean	SD	t-value	p-value
Aa	**Pre-operative**	30	2.7500	0.440	29.085	0.000**
	Post-operative	30	-1.767	0.775		
Ba	**Pre-operative**	30	6.017	1.243	27.505	0.000**
	Post-operative	30	-2.000	1.009		
C	**Pre-operative**	30	7.140	1.181	43.70	0.000**
	Post-operative	30	-6.433	1.222		

Table 13 shows significant difference in Aa point measurement between pre (Mean = 2.750; SD = 0.440) and post-operative measurements (Mean = -1.767; SD = 0.775) , (t-value = 29.08; p-value = 0.000**) at 0.01 level in synthetic mesh group.

There is significant difference in Ba point measurement between pre (Mean = 6.017; SD = 1.243) and post-operative values (Mean = -2.000; SD = 1.009) , (t-value = 27.50; p-value = 0.000**) at 0.01 level in synthetic mesh group.

There is significant difference in C point measurement between pre (Mean = 7.140; SD = 1.181) and post-operative values (Mean = -6.433; SD = 1.222) , (t-value = 43.70; p-value = 0.000**) at 0.01 level in synthetic mesh group.

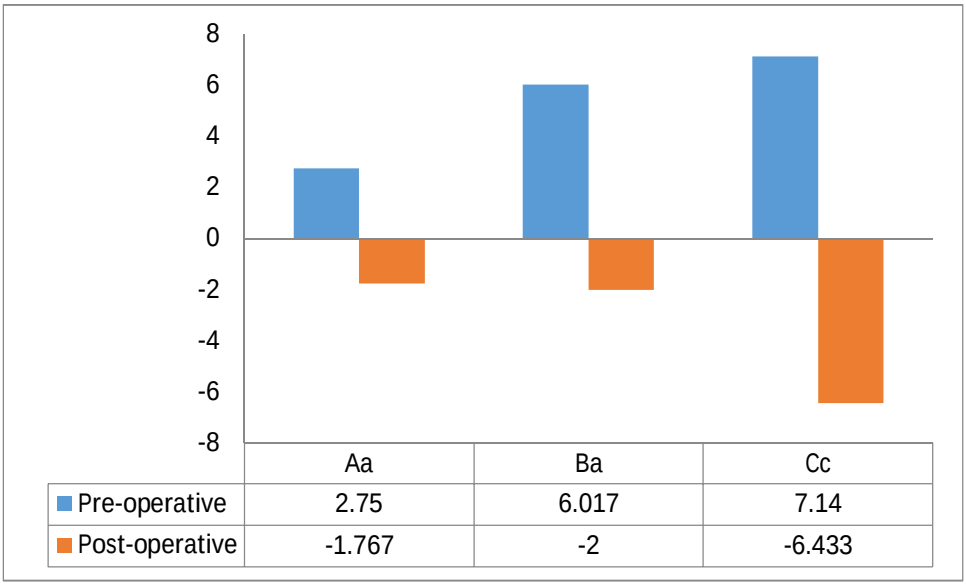


Table 14: Comparing the mean, SD, t-value and p-value of Ap&Bp in pre and post repair among women in autologous fascia lata group

Autologous Fascia Lata	Group	N	Mean	SD	t-value	p-value
Ap	**Pre-operative**	28	0.964	1.789	10.20	0.000**
	Post-operative	28	-2.714	0.658		
Bp	**Pre-operative**	28	4.035	1.981	17.28	0.000**
	Post-operative	28	-2.678	0.547		

Table 14 shows significant difference in Ap point measurement between pre (Mean = 0.964; SD = 1.789) and post-operative values (Mean = -2.714; SD = 0.658) , (t-value = 10.20; p-value = 0.000**) at 0.01 level in autologous fascia lata group.

There is a significant difference in Bp point measurement between pre operative values (Mean = 1.035; SD = 1.981) and post-operative values (Mean = -2.678; SD = 0.547) , (t-value = 17.28; p-value = 0.000**) at 0.01 level in autologous fascia lata group.

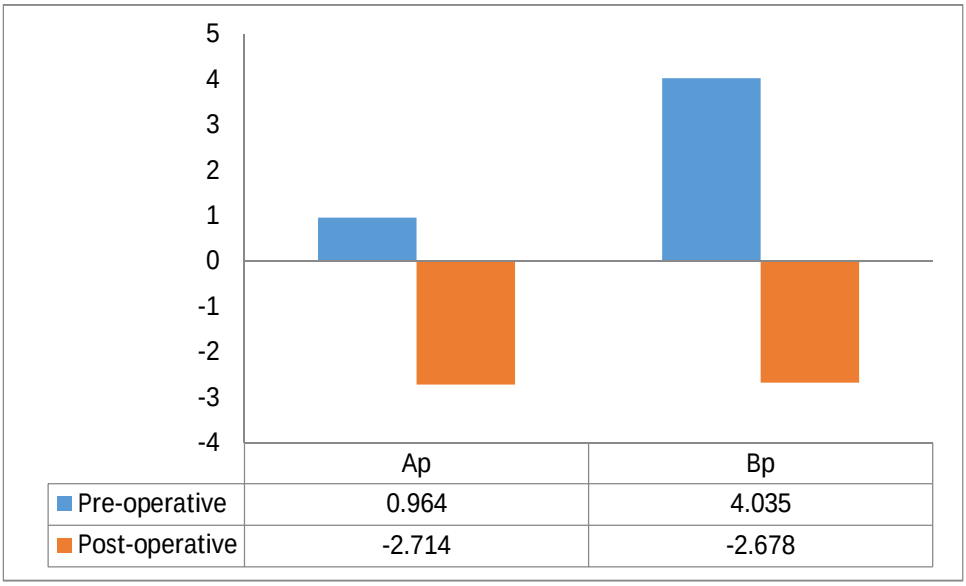
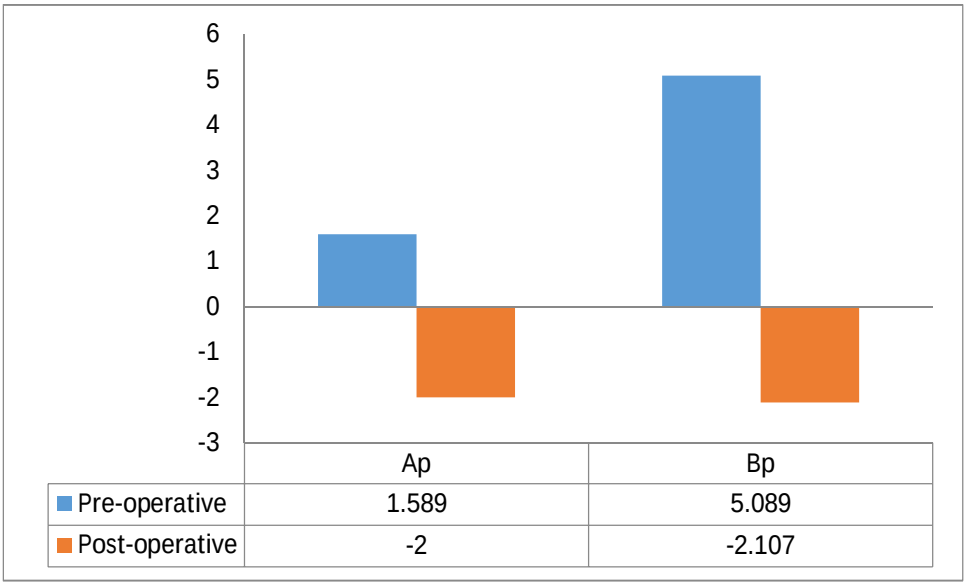


Table 15: Comparing the mean, SD, t-value and p-value of Ap&Bp point in pre and post repair among women in synthetic mesh group

Synthetic Mesh	Group	N	Mean	SD	t-value	p-value
Ap	**Pre-operative**	30	1.589	1.202	9.819	0.000**
	Post-operative	30	-2.000	1.360		
Bp	**Pre-operative**	30	5.089	1.790	18.89	0.000**
	Post-operative	30	-2.107	1.196		

Table 15 shows significant difference in Ap point measurement between pre (Mean = 1.589; SD = 1.202) and post-operative values (Mean = -2.000; SD = 1.360) ,(t-value = 9.819; p-value = 0.000**) at 0.01 levelin synthetic mesh group

There is a significant difference in Bp point measurement between pre (Mean = 5.089; SD = 1.790) and post-operative values (Mean = -2.107; SD = 1.196) , (t-value = 18.89; p-value = 0.000**) at 0.01 levelin synthetic mesh group.



Comparison of anatomical success of Fascia lata to synthetic mesh group :

Table 16: Comparing the mean, SD, t-value and p-value of Aa, Ba & C between autologous fascia lata group and synthetic mesh group

Variable	Group	N	Mean	SD	t-value	p-value
Aa	**Autologous Fascia Lata**	28	-2.803	0.342	6.665	0.000**
	Synthetic Mesh	30	-1.683	0.825		
Ba	**Autologous Fascia Lata**	28	-2.607	0.724		
	Synthetic Mesh	30	-1.866	1.098	3.008	0.018*
C	**Autologous Fascia Lata**	28	-5.666	1.523	1.479	0.145 (NS)
	Synthetic Mesh	30	-6.464	1.137		

Table 16 shows significant difference in Aa point postoperatively between autologous fascia lata group (Mean = -2.803; SD = 0.342) and synthetic mesh group (Mean = -1.683; SD = 0.825) ,(t-value = 6.665; p-value = 0.000**) at 0.01 level

There is a significant difference in Ba point postoperatively between autologous fascia lata group (Mean = -2.607; SD = 0.724) and synthetic mesh group (Mean = -1.866; SD = 1.098) , (t-value = 1.008; p-value = 0.018*) at 0.05 level

There is no significant difference in C point postoperatively between autologous fascia lata group (Mean = -5.666; SD = 1.523) and synthetic mesh group (Mean = -6.464; SD = 1.137) , (t-value = 1.479; p-value = 0.145) at 0.05 level.

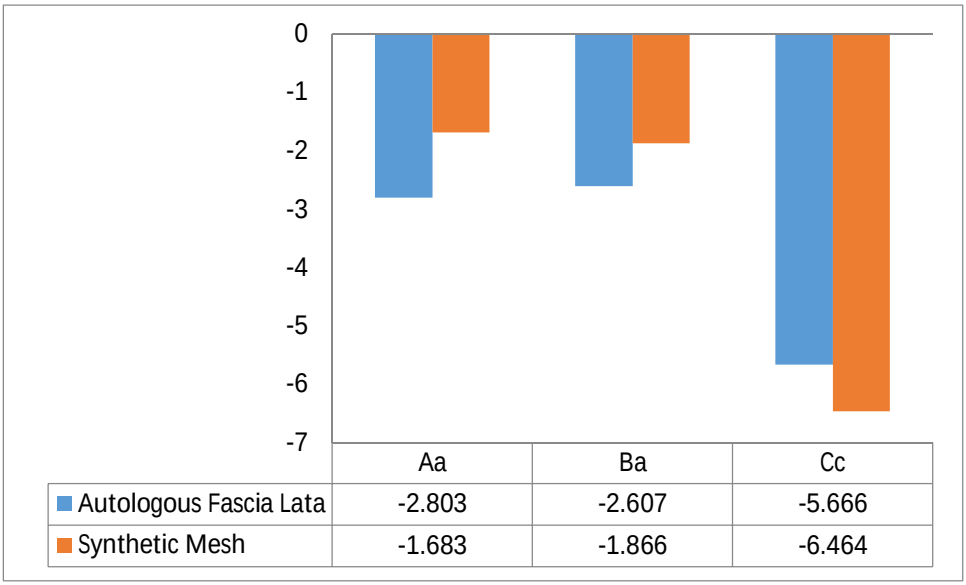
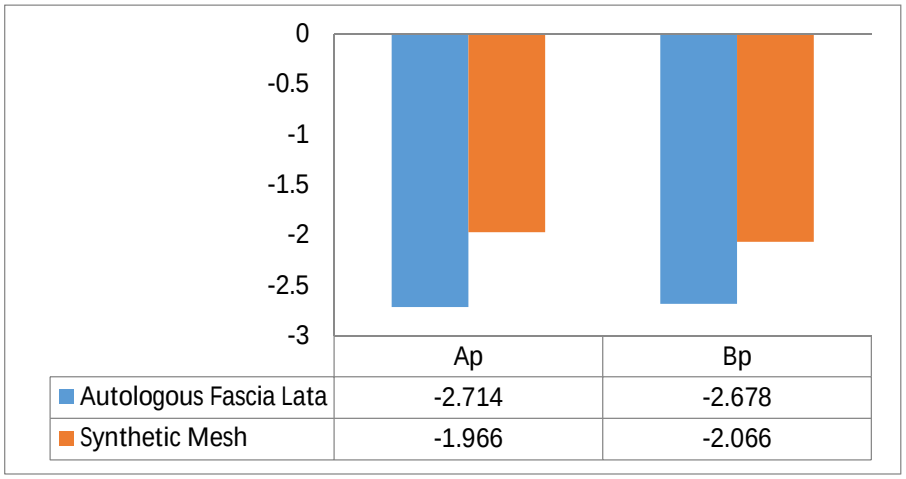


Table 17: Comparing the mean, SD, t-value and p-value of Ap&Bp between autologous fascia lata group and synthetic mesh group

Variable	Group	N	Mean	SD	t-value	p-value
Ap	**Autologous Fascia Lata**	28	-2.714	0.658	2.607	0.002**
	Synthetic Mesh	30	-1.966	1.376		
Bp	**Autologous Fascia Lata**	28	-2.678	0.547	2.417	0.000**
	Synthetic Mesh	30	-2.066	1.229		

Table 17 shows significant difference in Ap point postoperatively between autologous fascia lata group (Mean = -2.714; SD = 0.658) and synthetic mesh group (Mean = -1.966; SD = 1.376) , (t-value = 2.607; p-value = 0.002**) at 0.01 level

There is a significant difference in Bp point postoperatively between autologous fascia lata group (Mean = -2.678; SD = 0.547) and synthetic mesh group (Mean = -2.066; SD = 1.229) , (t-value = 2.417; p-value = 0.000**) at 0.01 level



	Ap	Bp
Autologous Fascia Lata	-2.714	-2.678
Synthetic Mesh	-1.966	-2.066

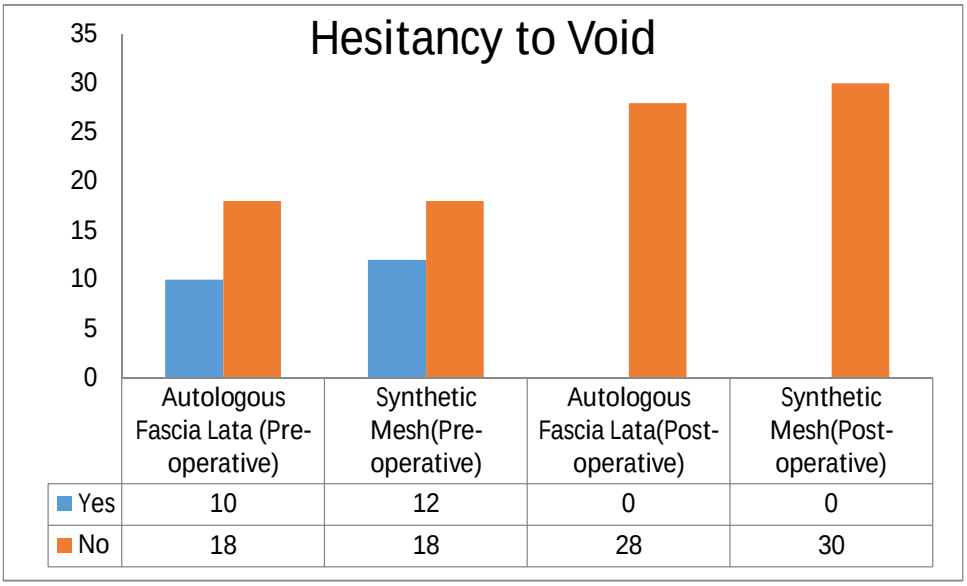
Clinical Success Rate - Urinary Symptoms

Pre operative prevalence of LUTS - Lower urinary tract symptoms (increased frequency, urgency with or without incontinence, stress urinary incontinence, mixed urinary incontinence, post - micturition dribble and obstructive symptoms (like hesitancy to void, thin stream of urine, straining to void, incomplete emptying of bladder) and post operative resolution of these symptoms were evaluated in both group.

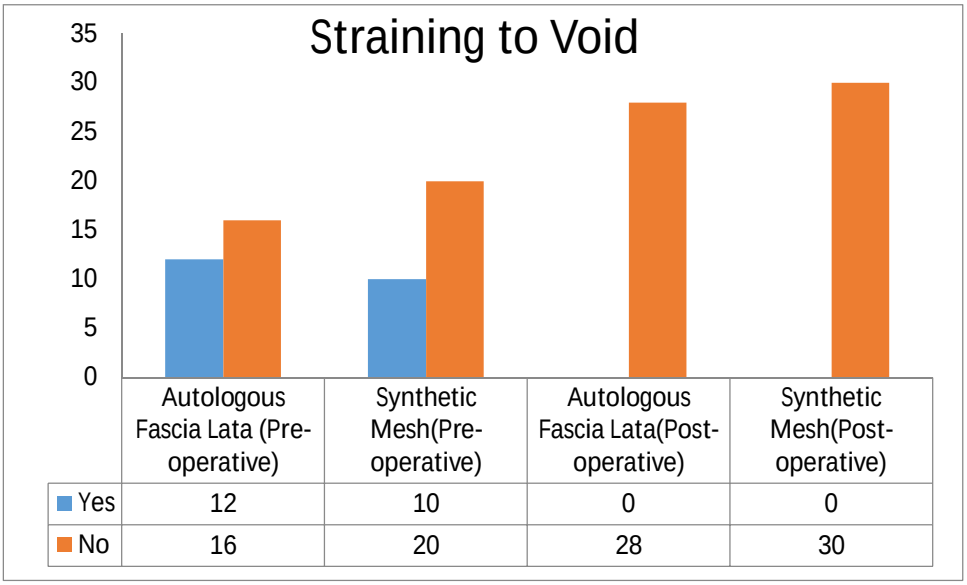
The preoperative prevelance of LUTS in fascia lata group was observed in 22.05% and in synthetic mesh group, the prevalence was 20.8%. Post-operative resolutions of LUTS symptoms were comparable in both group.

Table 18: Preoperative prevalence & Postoperative resolution of LUTS in autologous fascia lata and synthetic mesh group

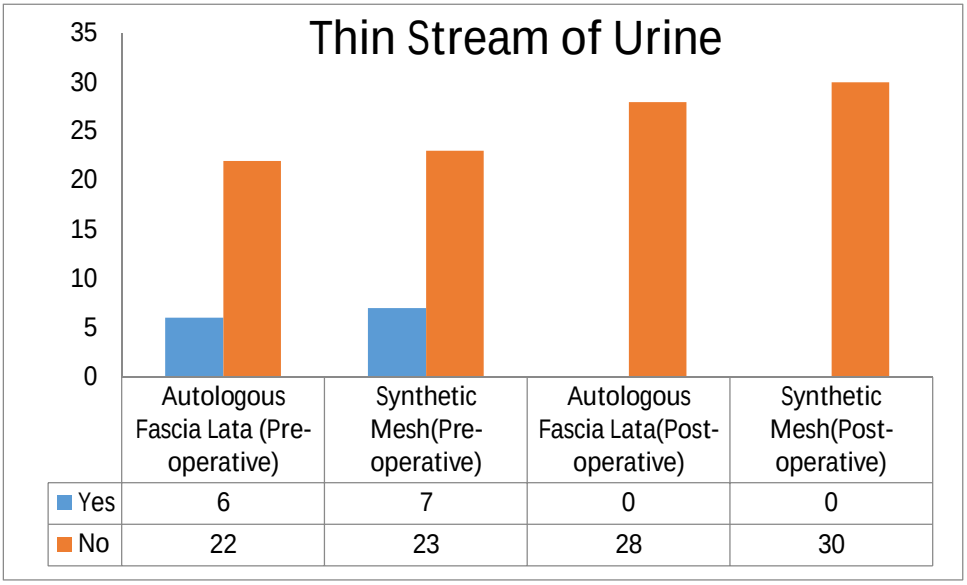
Variables	Group		Frequency	Percentage %			Frequency	Percentage %
Hesitancy to Void	**Autologous Fascia Lata (Pre-operative)**	Yes	10	35.7%	**Autologous Fascia Lata(Post-operative)**	Yes	0	0%
		No	18	64.2%		No	28	100%
		Total	28			Total	28	100%
	Synthetic Mesh(Pre-operative)	Yes	12	40%	**Synthetic Mesh(Post-operative)**	Yes	0	0%
		No	18	60%		No	30	100%
		Total	30			Total	30	100%
Straining to Void	**Autologous Fascia Lata(Pre-operative)**	Yes	12	42.8%	**Autologous Fascia Lata(Post-operative)**	Yes	0	0%
		No	16	57.14%		No	28	100%
		Total	28			Total	28	100%
	Synthetic Mesh(Pre-operative)	Yes	10	33.3%	**Synthetic Mesh(Post-operative)**	Yes	0	0%
		No	20	66.6%		No	30	100%
		Total	30	100%		Total	30	100%
Thin Stream of Urine	**Autologous Fascia Lata (Pre-operative)**	Yes	6	21.4%	**Autologous Fascia Lata(Post-operative)**	Yes	0	0%
		No	22	78.5%		No	28	100%
		Total	28	100%		Total	28	100%
	Synthetic Mesh(Pre-operative)	Yes	7	23.3%	**Synthetic Mesh(Post-operative)**	Yes	0	0%
		No	23	76.6%		No	30	100%
		Total	30	100%		Total	30	100%
Incomplete Emptying of Urine	**Autologous Fascia Lata(Pre-operative)**	Yes	8	28.5%	**Autologous Fascia Lata(Post-operative)**	Yes	0	0%
		No	20	71.4%		No	28	100%
		Total	28	100%		Total	28	100%
	Synthetic Mesh(Pre-operative)	Yes	6	20%	**Synthetic Mesh(Post-operative)**	Yes	0	100%
		No	24	80%		No	30	100%
		Total	30	100%		Total	30	100%
Stress Urinary Incontinence	**Autologous Fascia Lata (Pre-operative)**	Yes	4	14.28%	**Autologous Fascia Lata(Post-operative)**	Yes	0	0%
		No	24	85.7%		No	28	100%
		Total	28	100%		Total	28	100%
	Synthetic Mesh(Pre-operative)	Yes	6	20%	**Synthetic Mesh(Post-operative)**	Yes	0	100%
		No	24	80%		No	30	100%
		Total	30	100%		Total	30	100%
Urgency	**Autologous Fascia Lata(Pre-operative)**	Yes	5	17.85%	**Autologous Fascia Lata(Post-operative)**	Yes	0	0%
		No	23	82.14%		No	28	100%
		Total	28	100%		Total	28	100%
	Synthetic Mesh(Pre-operative)	Yes	3	10%	**Synthetic Mesh(Post-operative)**	Yes	0	100%
		No	27	90%		No	30	100%
		Total	30	100%		Total	30	100%
Urge urinary Incontinence	**Autologous Fascia Lata (Pre-operative)**	Yes	3	10.7%	**Autologous Fascia Lata (Post-operative)**	Yes	0	0%
		No	25	89.28%		No	28	100%
		Total	28	100%		Total	28	100%
	Synthetic Mesh(Pre-operative)	Yes	4	13.4%	**Synthetic Mesh(Post-operative)**	Yes	0	0%
		No	26	86.6%		No	30	100%
		Total	30	100%		Total	30	100%



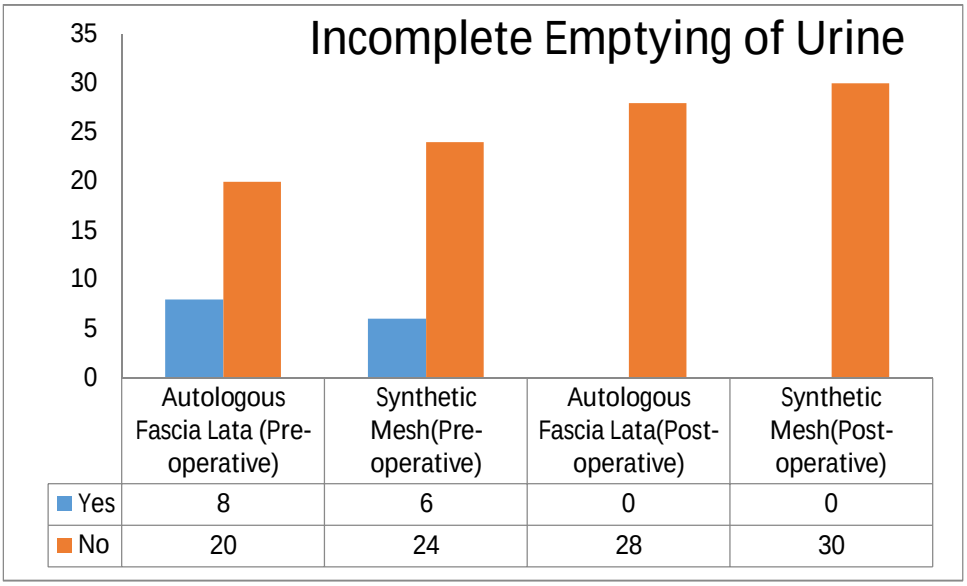
	Autologous Fascia Lata (Pre-operative)	Synthetic Mesh(Pre-operative)	Autologous Fascia Lata(Post-operative)	Synthetic Mesh(Post-operative)
Yes	10	12	0	0
No	18	18	28	30



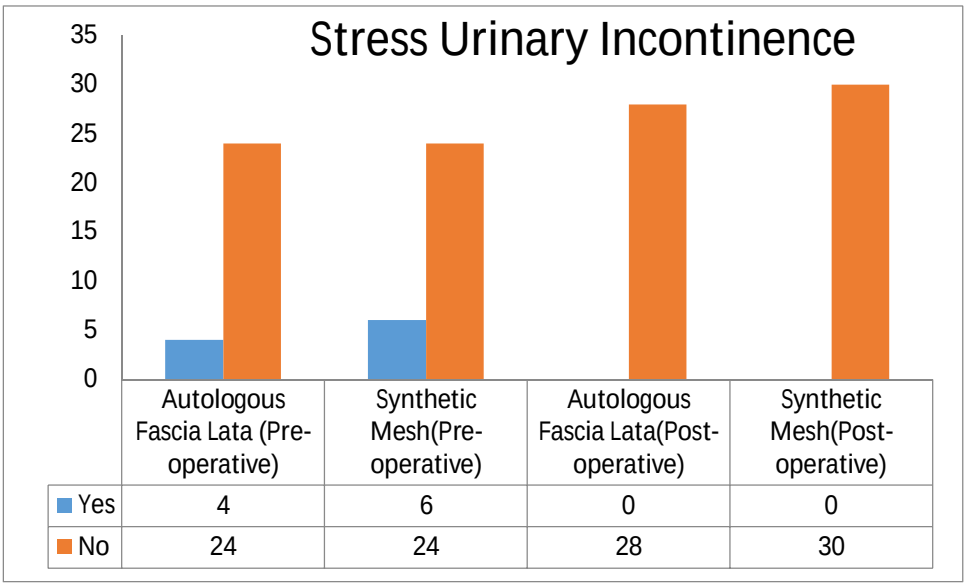
	Autologous Fascia Lata (Pre-operative)	Synthetic Mesh(Pre-operative)	Autologous Fascia Lata(Post-operative)	Synthetic Mesh(Post-operative)
Yes	12	10	0	0
No	16	20	28	30



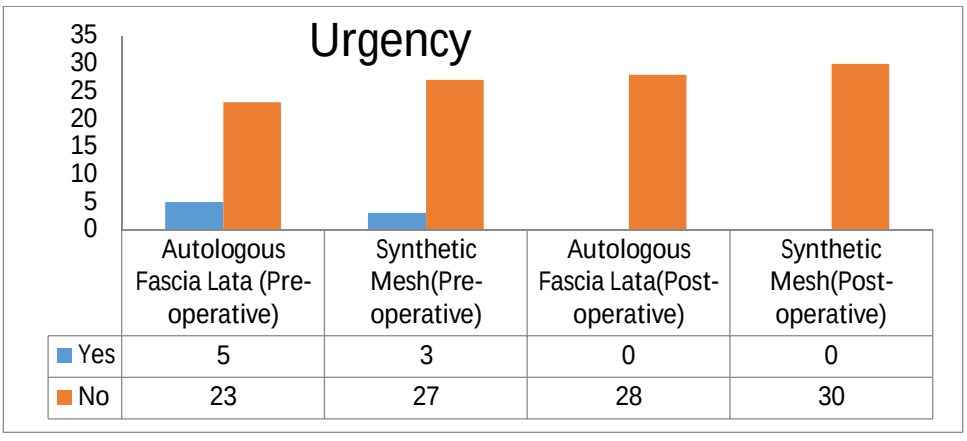
	Autologous Fascia Lata (Pre-operative)	Synthetic Mesh(Pre-operative)	Autologous Fascia Lata(Post-operative)	Synthetic Mesh(Post-operative)
Yes	6	7	0	0
No	22	23	28	30



	Autologous Fascia Lata (Pre-operative)	Synthetic Mesh(Pre-operative)	Autologous Fascia Lata(Post-operative)	Synthetic Mesh(Post-operative)
Yes	8	6	0	0
No	20	24	28	30



	Autologous Fascia Lata (Pre-operative)	Synthetic Mesh(Pre-operative)	Autologous Fascia Lata(Post-operative)	Synthetic Mesh(Post-operative)
Yes	4	6	0	0
No	24	24	28	30



	Autologous Fascia Lata (Pre-operative)	Synthetic Mesh(Pre-operative)	Autologous Fascia Lata(Post-operative)	Synthetic Mesh(Post-operative)
Yes	5	3	0	0
No	23	27	28	30

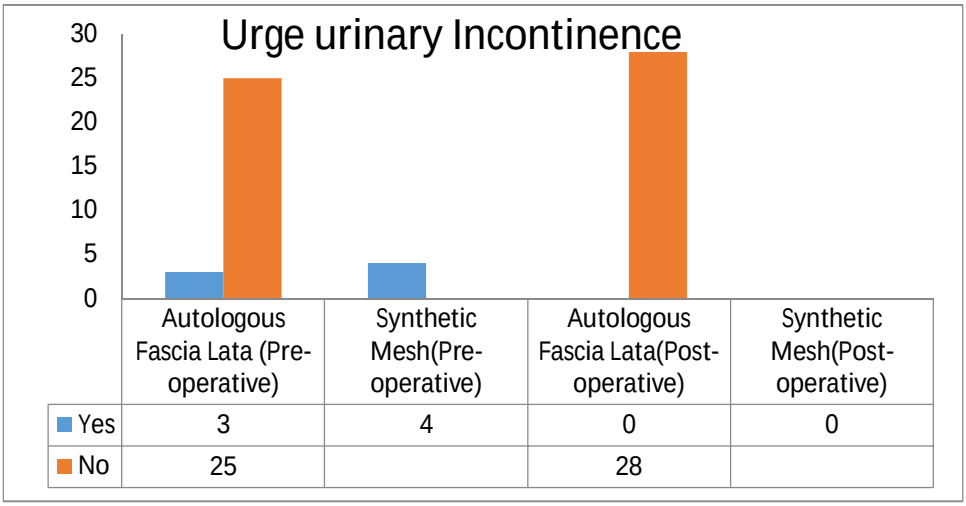
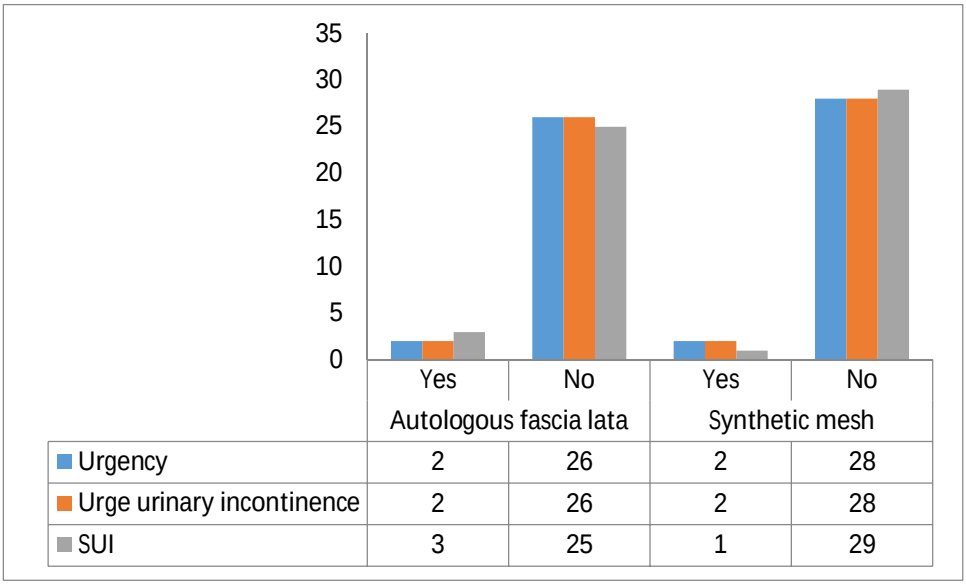


Table 19: Post op De Novo Urinary Symptoms

Variables	Autologous fascia lata			Synthetic mesh		
	Yes	No	Percentage	Yes	No	Percentage
Urgency	2	26	7.14%	2	28	6.6%
Urge urinary incontinence	2	26	7.14%	2	28	6.6%
SUI	3	25	10.71%	1	29	3.3%



Among 28 patients in autologus fascia lata group, pre operatively 35.7% had hesitancy to void, 42.8% had straining to void .Among 30 patients in synthetic mesh group, 40% patients had hesitancy to void and 33.3% patients had straining to void pre operatively. Whereas, none of the patients had hesitancy to void and straining to void both in autologous fascia lata and in synthetic mesh group, post-operatively.

Among 28 patients in autologus fascia lata group, pre operatively 21.4% patients had thin stream of urine and 28.5% had incomplete emptying of urine. Among 30 patients in synthetic mesh group, 23.3% patients had thin stream of urine, and 20% patients had incomplete emptying of urine pre-operatively. Also, none of the patient had thin stream of urine or incomplete emptying in both group, post-operatively.

Among 28 patients in autologus fascia lata group, 14.2% patients had stress urinary incontinence, 17.8% patients had urgency, 10% patients had urge urinary incontinence and 13.3% had mixedincontinence preoperatively.

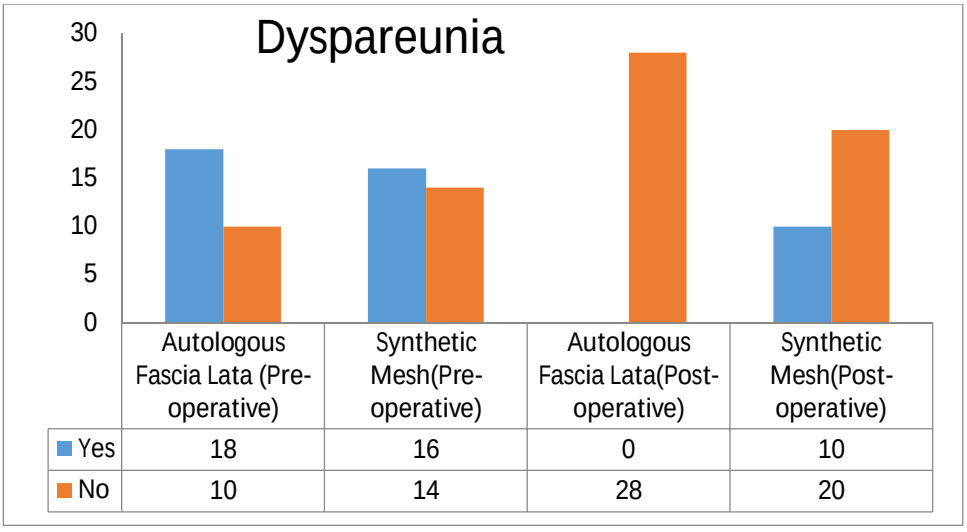
Among 30 patients in synthetic mesh group, 20% patients had stress urinary incontinence , 10% had urgency , 13.3% patients had urge urinary incontinence and 6.6% patients had mixed urinary incontinence preoperatively .

Whereas post operatively, none of these patients had stress urinary incontinence, urgency, urge incontinence and mixed incontinence in both groups.However, 7.14% patient developed de novo urgency with urge urinary incontinence and 10.7% patients developed de novo SUI in the fascia latagroup.Among synthetic mesh group of women, 6.6% patients reported de novo urgency with urge urinary incontinence and 3.3% patient reported de novo SUI

Clinical Success Rate – Sexual Symptoms

Table 20 Preoperative prevalence & Postoperative resolutionof sexual symptom in autologous fascia lata group and synthetic mesh group

Variables	Group		Frequency	%			Frequency	%
Dyspareunia	**Autologous Fascia Lata (Pre-operative)**	Yes	18	64.28%	**Autologous Fascia Lata(Post-operative)**	Yes	0	0%
		No	10	35.7%		No	28	100%
		Total	28	100%		Total	28	100%
	Synthetic Mesh(Pre-operative)	Yes	16	53.3%	**Synthetic Mesh(Post-operative)**	Yes(denovo)	4	28.6%
		No	14	46.6%		No	14	71.4%
		Total	30	100%				



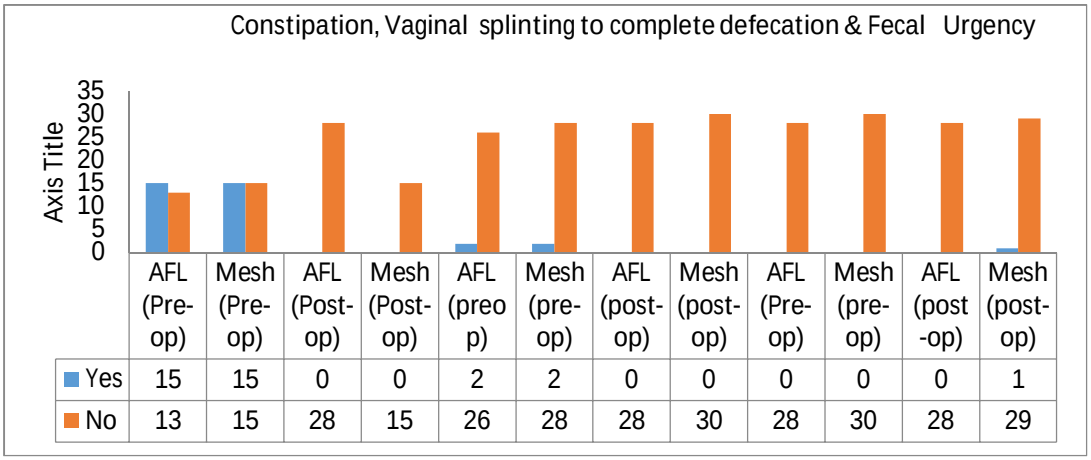
The preoperative prevalence of dyspaerunia was 64.28% in fascia lata group and 53.3% in synthetic mesh group which resolved post operatively in all women and none developed de novo dyspareunia in fascia lata group. Whereas, denovo dyspareunia was reported post operatively by 28.6% of women in the mesh group.

Clinical Success Rate – Bowel Symptoms

The preoperative prevalence of constipation was 53.5% in fascia lata group and 50% in synthetic mesh group. Two women (7.1%) in both group needed to digitally reduce the posterior vaginal bulge to complete a bowel movement (splinting) and none had faecal urgency. Postoperatively none of the patient in both group hadconstipation and none needed vaginal splinting to complete defecation. However in synthetic mesh group, 3% reported faecal urgency in the postoperative follow up.

Table 21: Preoperative prevalence & Postoperative resolution of bowel symptom

Variables	Group		Frequency	Percentage			Frequency	Percentage
Constipation	**Autologous Fascia Lata (Pre-op)**	Yes	15	53.5%	**Autologous Fascia Lata(Post-operative)**	Yes	0	0%
		No	13	46.4%		No	28	100%
		Total	28	100%		Total	28	100%
	Synthetic Mesh (Pre-operative)	Yes	15	50%	**Synthetic Mesh(Post-operative)**	Yes	2	7%
		No	15	50%		No	28	93%
		Total	30	100%		Total	30	100%
Vaginal splinting to complete defecation	**Autologus fascia lata(preop)**	Yes	2	7.1%	**Autologus Fascia lata(post operative)**	Yes	0	0%
		No	26	92.9%		No	28	100%
		Total	28	100%		Total	28	100%
	Synthetic mesh (preop)	Yes	2	6.6%	**Synthetic mesh(postoperative)**	Yes	0	0%
						No	30	100%
		No	28	93.4%				
		Total	30	100%		Total	30	100%
Fecal Urgency	**Autologous fascia (pre op)**	yes	0	0%	**Autologus Fascia lata(post operative)**	Yes	0	0%
						No	28	100%
		No	28	100%				
		Total	28	100%		Total	28	100%
	Synthetic mesh(preop)	yes	0	0%	**Synthetic mesh(postoperative)**	Yes	1	3%
		No	30	100%		No	29	97%
		Total	30	100%		Total	30	100%



	AFL (Pre-op)	Mesh (Pre-op)	AFL (Post-op)	Mesh (Post-op)	AFL (preop)	Mesh (pre-op)	AFL (post-op)	Mesh (post-op)	AFL (Pre-op)	Mesh (pre-op)	AFL (post-op)	Mesh (post-op)
Yes	15	15	0	0	2	2	0	0	0	0	0	1
No	13	15	28	15	26	28	28	30	28	30	28	29

Each patient in fascia lata group was reviewed postoperatively as per the questionnaire which included immediate and late complications specific to harvesting of fascia lata. The questions were divided into two groups; pain on walking and problems with wound from the harvested site like delayed wound healing or break down of the wound.

Fourteen patients (50%) reported pain on walking inthe postoperative period upto 30 days (median 6 days). No patients reported limping in the postoperative period upto 30 days Neither pain nor limping was a long term problem in any patient.

DISCUSSION

Fifty eight patients underwent abdominalsacrocolpopexy for vaginal vault prolapse fromApril 2009 to March 2012. Out of this, 28 patients underwent sacrocolpopexy with autologus fascia lata and 30 patients underwent sacrocolpopexy with multifilament,macroporus,polypropelene mesh.

Demographic data

Age:

In fascia lata group, mean patient age was 54.25 ± 6.9 years, Women with less than 35 years were 3.6%, 36-45 years were 3.6%, 46-55 years were 50%, 56-65 years were 42.9% and more than 65 years were nil.

In synthetic mesh group, mean patient age was 45.75 ±9 years. Women less than 35 years were 10%, 36-45 years were 40%, 46-55 years were 30%, 56-65 years were 13.3% and more than 65 years were 6.7%.

Among those who underwent abdominal sacrocolpopexy, there were 39.6%% in the age group of 46-55 years,followed by 27.5 % in the age group of 56-65 years, 22.4% in the age group of 36-45 years, 6.9% in the age group of less than 35 years and 3.4% were more than 65 years in both groups.

70.8 % of the vault proplapse patients were over 46 years and only 3.4 % of patients were beyond 65years.

In the current study, mean age of the patients was50.8+-8.6

Baessler K, Schuessler B (2001) assessed the effect of abdominal sacrocolpopexy for vault prolapse. It was a prospective study of 33 women with pelvic organ prolapse who had abdominal sacrocolpopexies with expanded polytetrafluoroethylene (Gore-Tex)] .The mean age in their group was 61 years.

62 years was the mean age reported by Sohierelneil (2004) .by auditing the clinical outcome of abdominal sacrocolpopexy for vault prolapse using non-absorbable mesh.

Krederk et al (2004), conducted retrospective review (between 1999 and 2001) and reported the mean age as 68.3 years in women with abdominal sacrocolpopexy using autologus fascia lata.

Cullligan et al 2005 ,compared the objective anatomic outcomes after sacral colpopexy performed with cadaveric fascia lata and polypropylene mesh. In their study , mean age in cadaveric fascia lata was 57.5±10.8 years.

Increasing a*ge was considered as one of the risk factors for vault prolapse by* DubielWT(1974) *.(136),*

The current studyalso has shown maximum number of vault prolapse patients (62.9 %)were in the age beyond 55 years .

Parity:

In the current study, the mean parity of the patients was 3.5+_1.3

The total number of participants with less than three children were 18 (31.1%)%, with 3-6 children were 39 (67.2%) and with more than six children were 1 (1.7%).

Majority of women (68.9%) were with more than 3 children and only 31.1% were with less than three children.

The current study has shown that majority of the participants (68.9%) with vault prolapse were with more than 3 children.

Among those who underwent sacrocolpopexy with fascia lata, mean parity was 3.8 ± 1.2 in .In the fascia latagroup , women with less than three children were 14.3%,with 3-6 children were 85.7% and more than 6 children were nil.

Mean parity in synthetic mesh group was 3.1 ± 1.3. Women with less than three children were46.7%, with 3-6 children were 50% and more than six children were 3.3% in the mesh group.

BMI:

In the current study the mean BMI of the patients who under went sacrocolpopexy was 23.9+_3.2, mean BMI was 24.4 ± 3.4 in fascia lata group and the mean BMI was 23.5 ± 3.0.in the mesh group.

In the fascia lata group, Women with normal BMI were 60.7%, over weight were 35.7% and obese women were 3.6%.

In synthetic mesh group, Women with normal BMI were56.7%, over weight were 33.3% and obese women were 3.3%.

In those who underwent abdominal sacrocolpopexy, the total number of participants with normal BMI were 34 (58.6%) ,overweight category were 20 (34.5%) and obese category were 2 (3.4%). There were 2 participants (3.4%) with less than normal BMI and they both belonged to mesh group.

The current study has revealed that only 37.9 % of vault prolapse patients belong to the overweight & obese category.

Marchionni M et al (1999) reported that the primary risk factor for vaginal vault prolapse in their study was obesity. Obese subjects were significantly more susceptible to develop vault prolapse when compared to nonobese ($P < .001$).

Eventhough obesity is an important predisposing factor for vault prolapse, contrary to the existing view current study has revealed that 61.4 % of vault prolapse patients did not fall into overweight / obese category and were well within normal BMI .

Type of hysterectomy

The current study has revealed that among those who have developed vault prolapse, only 48.2 % had previous surgery for prolapse uterus. Among the remaining 51.8 % of patients, vault prolapse occurred even when the previous surgery was not addressed to POP.

In participants whom underwent abdominal sacrocolpopexy, in 30 (51.7%) vault prolapse occurred following prior total abdominal hysterectomy and in 28(48.2%) vault prolapse occured after prior vaginal hysterectomy . All those 28 (48.2%) patients who had POP underwent vaginal hysterectomy, repair and reconstruction. None had nondescent vaginal hysterectomy.

The indications for total abdominal hysterectomy included abnormal uterine bleeding 16 (27.5%), fibroid uterus 12 (20.6%), and chronic cervicitis 2(7.1%).

Marchionni M et al (1999) reported in their study that the incidence of vaginal vault prolapse was 11.6% (14/120 patients) when hysterectomy had been performed for genital prolapse and 1.8% (6/328) when hysterectomy had been performed for other benign diseases. In contrast to the current study , their data showed that there is a low incidence of vaginal vault prolapse when hysterectomy is performed in the absence of defects in pelvic support.

Staging of vault prolapse:

In both fascia lata and synthetic mesh group, the preoperative POP Q staging of vault prolapse was stage 3 and stage 4. All patients were diagnosed to have primary vault prolapse and none of the patient had recurrent vault prolapse eventhough recurrent vault prolapse was one of the inclusion criteria.

Perioperative events:

In the current study,the mean duration of surgery in abdominal sacrocolpopexy with autologous fascia lata group was 178.2±20.4 minutes and 171±29.4 minutes in synthetic mesh group and it was found to be statistically not significant (p value 0.293). The mean operative time for harvesting fascia lata was 27.6 minutes.

In this study, the estimated mean (±SD) blood loss was found to be 120±50 ml in autologous fascia lata group and 100±50 ml in synthetic mesh group.

Blood loss:

Current study has revealed mean blood loss of 120±50 ml in autologous fascia lata group and 100±50 ml in synthetic mesh group which is lower than those reported earlier.

Elizabeth J. Geller (146) conducted a retrospective cohort study comparing robotic to abdominal sacrocolpopexy with permanent mesh.The study included 178 patients (73 robotic and 105 abdominal sacrocolpopexy). Blood loss was 255 +_155 mL wit Abdominalsacrocolpopexy .

Coolen AL[1]prospective cohort study 85 patients, of whom 42 had open abdominal and 43 laparoscopic sacrocolpopexy. .The estimated blood loss in the abdominal group was 192 mL (±126)

Anne-Lotte W. M. Coolenperformed a multi-centre randomised controlled trial comparing ASC and LSC with a type 1 polypropylene mesh . They reported estimated blood loss in open abdominal sacrocolpopexy as 200 (100-300)ml .

Hospital stay:

In the current study, mean hospital stay was 12 days in patients following abdominal sacrocolpopexy using fascia lata and synthetic mesh .

Elizabeth J. Geller (146) conducted a retrospective cohort study comparing robotic to abdominal sacrocolpopexy with permanent mesh.The study included 178 patients (73 robotic and 105 abdominal sacrocolpopexy).shorter length of stay (1.30.8 days compared with 2.71.4 days, P<.001),

Coolen AL[184] conducted prospective cohort study in 85 patients, of whom 42 had open abdominal and 43 laparoscopic sacrocolpopexy with mesh . They reported the mean hospital stay in open abdominalsacrocolpopexy was 3-5 days.

The longer stay in the current study is due to the patient's preference as most were from far away places and afraid to travel following a major surgery.

Blood loss, duration of surgery & hospital stay did not differ between the two groups.

Comparison of surgery related complications following abdominal sacrocolpopexy with other studies

In both the group, none of the patients had intra operative rectal injury, blood transfusion, post operative pulmonary embolism, abdominal wound breakdown and erosion of grafts.

Bladder injury:

In the current study one patient 1.7 % out of 58 had intra operative bladder injury which is incidental . This one patient belong to synthetic mesh group which makes 3.3% as the occurrence of bladder injury in the mesh group which is comparable to those reported by others.

Nazema et al (2015) reviewed 18 total studies and reported 3 out of 134 patients in mesh sacrocolpopexy had intra operative bladder injury.

Shikha Rani et al (185) conducted a cohort study on 16 patients who underwent abdominal sacrocolpopexy with polypropylene mesh and reported bladder injury in 1 (6.25%) patient.

Bensinger et al conducted a study on retrospective analysis of 121 patients, who underwent ASC with polypropylene mesh.The intra operative complication rate was 2.5% and it included cystotomy and small bowel laceration.

Intraoperative vascular haemorrhage:

Current study did not encounter any intraoperative haemorrhage or haematoma from presacral veins in patients following abdominal sacrocolpopexy .

1996-Hardiman et al compared success rates and complications of abdominal sacrocolpopexy (ASC) and reported that among 80 patients who underwent ASC ,only one intraoperativevascular complication (haemorrhage from the presacral veins) was reported.

2000: Sarah D et al reported an occurence of haemorrhage and haematoma from presacral veins in 2.9% from a review of39 publications on sacrocolpopexy from 1961.

Nygaard *et al*. (2004) reported hemorrhage from presacral veins in 1-2.6% patients in their retrospective analysis of outcome of abdominal sacrocolpopexy.

Nazema et al (2015) reviewed 18 total studies and reported 3 patients out of 123 2.4 % in mesh group had intraoperative vascular complications.

Post operative bowel problems :

In the current study, none of the patient had small bowel obstruction and or paralytic ileus following abdominal sacrocolpopexy .

Nygaard *et al*. (2004) conducted a retrospective review study of 2178 patients who underwent abdominal sacrocolpopexy with mesh .They reported 1.1% of small bowel obstruction in their series.

Sohierelneil (2004)audited the clinical outcome of abdominal sacrocolpopexy for vaultprolapse using non-absorbable mesh without burial by non closure of the pelvic peritoneum in 128 patients with apical prolapse. 2 cases (2%) had intra-operative bowel perforations (one small bowel and one large bowel).

2005- Bensinger et al conducted a study on retrospective analysis of 121 patients, who underwent ASC with polypropylene mesh.The intra operative complication rate was 2.5% and it included cystotomy and small bowel laceration. Immediate postoperative complications included partial small bowel obstruction and Ileus(3.5%), febrile morbidity (9.6%) and autologous blood transfusion (1.7%).

Brubaker et al (2006) reported postoperative ileus in 19/322 (5.90%) patients in their RCT comparing abdominal sacrocolpopexy with or without colposuspension

Nazema et al (2015) reviewed 18 total studies comparing mesh sacrocolpopexyto native tissue vaginal repair(HUSLS/ SSLF). They revealed that in one study 1 patient out of 130 (0.76 %) in mesh group had small bowel injury . 4 out of 86 (4.6 %) patients had small bowel obstruction and or paralytic ileus in mesh sacrocolpopexy.

Postoperative deep vein thrombosis:

In the current study, none had deep vein thrombosis or pulmonary embolism following abdominal sacrocolpopexy.

Nazema et al (2015) from their review of 15 studies of mesh sacrocolpopexy, reported 0.6% deep vein thrombosis and pulmonary embolism .

Objective outcome

In the current study,anatomical outcome was assessed by comparing the mean values of POP-Q points Aa, Ba and C between autologus fascia lata and synthetic mesh during the three year post operative follow up.

Assessment of anatomical success (objective) was made by measuring pre and post operative POP-Q points Aa, Ba, C, Ap, Bp.

Amongst the successfully repaired patients using autologus fascia lata, objective anatomical success rates were superior with reference to POP Q points Aa, Ba, Ap, Bp compared to synthetic mesh.

The mean value of Aa in autologous fascia lata group is -2.650 & the mean value of Aa in synthetic mesh group is -1.767 (p-value = 0.000**). Ba in autologous fascia latagroup is -2.517 & the mean value of Ba in synthetic mesh group is -2.000 (pvalue = 0.042*). Ap in autologous fascia lata group is -2.724 and the mean value of Ap in synthetic mesh group is -2.000 (pvalue = 0.013*). Bp in autologous fascia lata group is -2.689 and the mean value of Bp in synthetic mesh group is -2.107 (pvalue = 0.040*). But there was no significant difference between the two groups with reference to C point.C in autologous fascia lata group is -5.866 and the mean value of C in synthetic mesh group is -6.464 (p-value = 0.145).

Miles murphy et al (2002) conducted a recent systematic review of 98 articles on ASCP with synthetic mesh and showed a success rateof 78–

100% for apical support and 58–100% for all other vaginal compartments [39,112].

The use of synthetic mesh which acts as suspension bridge between the vagina and the sacrum is supported by a recent randomized trial by Culligan **et al** [40]. They compared cadaveric fascia lata to polypropylene mesh for ASCP. At 1 year after surgery, the objective cure was better in the synthetic mesh group (91% cure) than in the cadaveric fascia lata group (68% cure; P = 0.007). The success rate was higher in the polypropylene mesh group at POPQ points Aa and C and the overall anatomical improvement based on staging was superior .

Culligan et al (2005) showed goodevidence to support the use of non-absorbable synthetic mesh when performing abdominal SCP. The results of several randomized trials indicate that SCP with synthetic mesh provides superior anatomical results than vaginal sacrospinous ligament fixation [36–38] which was attributed to the use of synthetic mesh in ASCP .

2007: Jane L.Yau et al determined the extent of posterior vaginal wall support after abdominal sacrocolpopexy with and without posterior colporrhaphy . They concluded that POP Q point Ap significantly improved and persisted at 34 months after abdominal sacrocolpopexy with concomitant posterior colporrhaphy.(12)

In the current study, the measurement of POPQ point AP had improved in ASCP following mesh

Joen et al. *(2009)* did a retrospective study of 57 patients who underwent ASC with synthetic mesh. With median follow-up period of 66 months (range 66-108). Overall anatomical success rate was 86%.

Nygaard *et al.* (2004) conducted a retrospective review of various trials which included 2178 patients who underwent abdominal sacrocolpopexy with mesh reported a success rate of 78-100%

Fitzgerald et al.[21] also noted poor anatomical outcomes when freeze-dried, irradiated donor fascia lata was used for ASCP. Of 67 women who had SCP with this material, 83% of patients had failures at 17 months follow-up. In 16 patients who had a repeat ASCP by these authors, no graft was found between the sacrum and vagina in 13 patients. While these data support the view that synthetic mesh is better than biological grafts for SCP, there are no data available that compare the anatomical or functional results of different synthetic materials.

Clinical Success Rate:

In the current study, clinical success rate in autologous fascia lata group was 99.17% whereas the success rate in synthetic mesh group was 96.47%

Urinary Symptoms

In the current study,the preoperative prevalence of LUTS in fascia lata group was 22.05% and 20.8% in synthetic mesh group. Post operative resolution was equal in fascia lata group and synthetic mesh group.

UTI: Only in synthetic mesh group, 3.6% reported urinary tract infection in the postoperative follow up. None developed UTI in the facia lata group.

Anne-Lotte W. M. Coolen et al Coolen AL(184) conducted a prospective cohort study in 85 patients, of whom 42 had open abdominal and

43 laparoscopic sacrocolpopexy with type 1 polypropylene mesh. They reported 1 (2.4 %) urinary tract infection in open abdominal sacrocolpopexy.

Urinary incontinence :

In the current study,the total number of patients with overt SUI were 5 (8.6%) and occult SUI were 3 (5.2%) preoperatively.

Out of 28 patients in fascia lata group, 2 (7.14%) patients had overt SUI and 2 (7.14%) patients had occult SUI

Out of 30 patients in the mesh group, 3 (10%) patients had overt SUI and 1 (3.3%) had occult SUI.

The total number of patients 8 (13.7%) who had SUI (both occult and overt)preoperatively were managed with concomitant Burch colposuspension. Postoperatively none of these patients had recurrence.

Denovo urinary symptoms:

In the current study, the total number of participants with deno urgency with urge urinary incontinence were 3 (5.17%) and with denovo SUI were 4 (6.9%)

In fascia latagroup , 1(3.3%) patient reported denovo urgency with urge urinary incontinence and 3 (10%) patients reported denovo SUI. In synthetic mesh group 2(6.6%) patients reported denovo urgency with urge urinary incontinence and 1(3.3%) patient reported denovo SUI.

Nygaard *et al*. (2004) conducted a retrospective review on various trials which included 2178 patients who underwent abdominal

sacrocolpopexy with polyprophylenemesh. They reported 4.9% rate of denovo stress urinary incontinence.

Sohierelneil (2004)audited the clinical outcome of abdominal sacrocolpopexy for vault prolapse using non-absorbable mesh. 4 patients (3%) developed *de novo* stress incontinence.

Joen *et al*. (2009) conducted a retrospective study of 57 patients who underwent ASC using polyprophylene mesh.Recurrent stress urinary incontinence was reported in 44.7% of the patients.

Anne-Lotte W. M. Coolen et al Coolen AL [184] performed prospective cohort study in 85 patients, of whom 42 had open abdominal and 43 laparoscopic sacrocolpopexy with type 1 polypropylene mesh . They reported 2.3% De novo stress urinary incontinence

Bowel Symptoms

In the current study,post operative follow up of the autologous fascia lata group revealed that none of the patients had constipation or faecal urgency.

Joen *et al*. (2009) conducted a retrospective study of 57 patients who underwent ASC. Median follow-up period was 66 months (range 66-108).No significant change was found in bowel habits or sexual function.

Sexual symptoms:

In the current study, the preoperative prevalence of dyspaerunia was 18 (64.28%) in fascia lata group and 16(53.3%) in synthetic mesh group which resolved post operatively in all women. None developed de novo dyspareunia in fascia lata group. Whereas, denovo dyspareunia was observed

post operatively in 4 (28.4%) out of the 14 patients who did not have dyspareunia pre operatively. Though the overall occurrence of denovo dyspareunia was 17.2 % , occurnce of denovo dyspareunia in the mesh group was 28.4 %, Current study highlights the significantly high occurrence of post operative denovo dyspareunia in ASCP following mesh who did not have dyspareunia pre operatively.

2005- Bensinger et al conducted a retrospectivestudy which analysed 121patients, who underwent ASC with polypropylene mesh and compared the complication and erosion rates between women who underwent ASC at the time of supracervical hysterectomy (SCH) versus ASC at the time of total abdominal hysterectomy (TAH) versus ASC in women who had previously undergone TAH. They reported persistent dysparuenia in 8.2% of patients who underwent TAH with concurrent ASC. None had mesh erosion in the group of patients who had ASCP in vault prolapse patients. (150)

In the current study , none of the patients had mesh erosion and is comparable with this study.

Higgs *et al*. (2005) conducted a prospective cohort study of 148 patients who have undergone ASC for vaginal vault prolapse.On long-term follow-up, 12% of the patients reported reduced vaginal capacity with dyspareunia and patient's satisfaction rate was 78% [(107)]

Comparing the mesh related complications following abdominal sacrocolpopexy with other studies

In the current study, in synthetic mesh group none had mesh exposure / extrusion or infection post operatively. Though synthetic mesh appeared as an attractive alternate to the allogenic material, prevailing mesh

related complications forced surgeons to seek for an autologous substitute like fascia lata or rectus fascia.

Mesh erosion after abdominal sacrocolpopexy was first described by Iglesia et al (1997). Synthetic grafts are associated with erosion rates of up to 12% for abdominal sacrocolpopexy [96,131).

*D. N. Kammerer-Doaket al.(*2002) reported that the use of synthetic grafts is associated with a risk of rejection or erosion most commonly into the vagina. The average reported erosion rate for synthetic grafts utilized for abdominal sacrocolpopexy is 2.7%, with range from 0.9% to 11%) [96]. A recent retrospective review of 57 abdominal sacrocolpopexiesfrom a single institution reported an erosion rate of 12% with Marlex and Mersilene meshes, with diagnosis made 4–24 months after surgery [131].

Nygaard *et al*. (2004) conducted a retrospectivereview studyof 2178 patientswho underwent abdominal sacrocolpopexy with polyprophylenemesh . They reported synthetic mesh erosion rates from 0.5 to 5.0 percent with an average erosion rate of 3.4 percent . The postoperative follow-up in this review ranged from 6 months to 3 years.

Maher et al (2004) conducted a randomised controlled study between abdominal sacrocolpopexy with synthetic mesh and sacrospinous colpopexy in 47 patients and reported mesh exposure in 1 (2%) patient in two years followup.

Brubaker et al (2006) reported mesh exposure in 23/322 (7.14%) patients at ten years followup in their RCT comparing abdominal sacrocolpopexy (mesh) with or without colposuspension

Geoffery et al (2008) used synthetic meshMersilene (42%) and Polypropylene (48%) as the graft material for abdominal sacrocolpopexy. They reported 6% of participants experienced mesh/suture erosion.

Nazema Y. Siddiqui, et al revealed that mesh or suture complications were significantly more frequent in patients treated by SCP using mesh (4% [28/650]) compared with patients who had native tissue repairs (1% in an analysis of comparative studies in the systematic review of 1,176 women. (111)

Complications associated with different types of synthetic meshes in abdominal sacrocolpopexy(ASCP)

Choe (1999), Nygaard (2004), Begley (2005) reported in their review of literature that overall incidence of synthetic (polypropylene monofilament, polyethylene terephthalate multifilament, expanded polytetrafluoroethylene multifilament and polytetrafluoroethylene) graft erosion into the vagina following abdominal sacralcolpopexy is 9%to 11%. [126,127,128]

Sohierelneil (2004)audited the clinical outcome of abdominal vault suspension sacrocolpopexy using non-absorbable mesh, without burial by non closure of the pelvic peritoneum. 128 patients had sacrocolpopexy and 3 (2.3%) patients reported vault mesh erosions.

Patrick Dällenbach (2015) reported 3.4% mesh erosion rate in abdominal sacrocolpopexy with mesh in their retrospective study.

Erosion/extrusion rates for various synthetic meshes

Vaginal mesh erosion has been reported to be 2% with polypropylene macroporous compared to higher rates of up to 11% with microporous multifilament meshes such as Gore-Tex and Mersilene(134,135).A recent sacrocolpopexy literature review reported a median rate of 3.4% erosion for synthetic mesh with varying rates depending on which grafts were used (0.5% with polypropylene mesh; 5.5 % with Teflon mesh).[138]

Table 22

Mesh type	Material	Study	No. patients	No. erosion/extrusion (%)	Description of complication
II	Expanded PTFE	Choe*et al* (1999)	90	5 (5.6)	Vaginal granulation requiring removal of mesh
		Begley *et al* (2005)	33	3 (9)	Vaginal extrusion
		Weinberger *et al* (1995)	98	25 (26)	Ten vaginal extrusions, ten granulation tissue, five sinus tracts
III	PTFE	Yamada *et al* (2001)	137	1 (0.7)	Urethral erosion
		Nygaard*et al* (2004)	119	6 (5.5)	Mesh erosion or extrusion following sacrocolpopexy
	Polyethylene terephthalate	Young *et al* (2001)	176	8 (4)	Seven vaginal and one inguinal sling extrusion
		Kohli*et al*(1998)	10	2 (20)	Vaginal extrusion
	Polypropylene	Siegel *et al*(2005)	35	6 (17%)	Vaginal extrusion

Mesh type	Material	Study	No. patients	No. erosion/extrusion (%)	Description of complication
	Woven polyester	Kobashi*et al*(1999)	N/A	34	vaginal extrusion, infection or pain all requiring removal
IV	Silicone-coated polyester	Begley *et al* (2005)	21	4 (19)	Vaginal extrusion
		Duckett*et al* (2000)	7	5 (71)	vaginal extrusion and sinus formation
V	*Monofilament knitted polypropylene mesh*	*Our study (2018)*	*30*	*0*	*No vaginal extrusion or infection*

Recurrence of vaginal vault

In the current study, none of the patients had recurrence of vaginal vault in both groups during the follow up period. .

Culligan *et al*. (2002) conducted a retrospective analysis of 245 patients who had undergone ASC with mesh. They reported failure of primary sacrocolpopexy in 37 (15.1%) patients within 2 years of follow-up.[13]

FitzGerald MP et al (2004), conducted a randomised controlled trial of abdominal sacrocolpopexy comparing autologous rectus fascia with synthetic mesh. They reported that objective failure was 32% in the fascia group compared with 9% in the mesh group at 12 months. (107)

Higgs *et al* (2005) conducted a prospective cohort study of 148 patients who have undergone ASC for vaginal vault prolapse. They found 90% success rate with 3% recurrence rate.

2005- Bensinger et al conducted a study on retrospective analysis of 121 patients, who underwent ASC with polypropylene mesh. They reported recurrent prolapse in 2.5% patients.

Biological grafts

Biological grafts are alternatives to synthetic mesh.Endopelvic fascia takes 3 months to regain 70% of its strength after surgery.Although the risk of graft extrusion or exposure is lower with biological grafts like autologous grats, allografts and xenografts there are problems like infection,'graft versus host'reaction and higher failure rates with allografts and xenografts.

Iglesia et al (1997) was the first author who reported vaginal erosion of allogenic cadaveric fascia lata.The longevity of cadaveric fascia lata after pelvic reconstructive surgery is unknown and its use may be associated with increased failure over other materials.

Considering the inferior success rate with cadaveric fascia lata, synthetic mesh was preferred to suspend the apex of vault as synthetic mesh was durable, permanent, has higher resistance to degradation with long term preservation of tensile strength.

Table 23 Operative outcomes with different types ofbiological grafts in ASCP

Study	Graft/ mesh	No. patients	Follow up (mo)	Anatomic cure	Comments
Latini et al	Autologous fascia lata	10	31	100%	No graft related complications
Fitzgerald et al	Cadaveric fascia lata (FD/IR-CFL)	53	17	17%	40% reoperation rate
Flynn et al	Cadaveric fascia lata (FD-CFL)	19	11	95%	5% reoperation for apical prolapsed, 10% reoperation for anterior prolapse
Culigan et al	Cadaveric fascia lata (SD/IR-CFL) Polypropylene mesh (Type I)	44 grafts 45 mesh	12	68% grafts 91% mesh	11% wound breakdown 15% wound breakdown, 4% erosion
Gregory et al	Cadaveric fascia lata (FD-CFL) Mersilene mesh (Type III)	18 grafts 19 mesh	21 26	61% grafts 89% mesh	No erosion or wound breakdown in either group
Altman et al	PD (HMDI/IR-PD) Polytetrafluroethylene (Gore-tex)	27 grafts 25 mesh	7 7	71% grafts 76% mesh	No erosion or wound breakdown in either group
Our study	Autologus fascia lata monofilament polypropylene mesh	28 30	36 months	91.6% Equal in both groups	no erosion or wound break down in either group

Table 24 Erosion/extrusion rates for various allografts [123,124,125]

Graft	Study	No. patients (repair)	No. Erosion/extrusion (%)	Description of erosion/extrusion	Management
Dermal allograft	Clemons *et al*(2003)	33 (anterior)	0 (0%)		
	Drake *et al* (2005)	69 (21 anterior, 45 posterior, 3 both)	7 (10.9%)	Vaginal extrusion (3 anteriorly, 4 posteriorly)	Conservative with topical estrogen cream. All experienced spontaneous resolution
Allograft fascia lata	Flynn *et al* (2005)	24 (sacrocolpopexy)	0 (0%)		
	Frederick *et al* (2005)	251 prolapse repair withcadaveric fascia	22 (9%) sling (CaPS)	Intravaginal granulation tissue caused by extrusion of panacryl sutures used for the cystocele repair and vault suspension	Patients treated by suture removal and fulguration of the granulation tissue with silver nitrate
Autologus fascia lata	Our study	28 vault prolapse repair with autologous fascia lata	0%	-	-

Table 25 Success and complication rates of various xenografts [129,130]

Graft	Study	No. patients (repair)	Cure rate	Complications
Porcine dermis	Gomelsky*et al* (2003)	70 (cystocele)	91%	12.9% recurrent cystocele at a mean follow-up of 24 months
	Giri*et al* (2006)	48 (pubovaginal sling)	54%	1 urethrolysis, 1 suprapubic wound infection, 1 urinary tract infection, 2 vaginal bleeding, 2 pain during intercourse, 2 deep pelvic pain
Porcine small intestinal submucosa	Jones *et al* (2005)	34 (mid-urethral sling)	79%	9% developed suprapubic inflammation
	Rutner*et al* (2003)	152 (pubovaginal sling with bone anchors)	93.4%	4.6% recurrent stress urinary incontinence
	Ho*et al*(2003)	10 (pubourethralsling)	90%	60% - six patients presented with postoperative inflammatory reactions
Autologus fascia lata	Our study 2018	28 abdominal sacrocolpopexy	100%	7.14% denovo urgecy with urge incontinence 10.7% denovo SUI

The current study has shown no erosion of graft in participants following abdominal sacrocolpopexy with autologous fascia lata.and also no recurrence of prolapse in the vaginal vault, anterior and posterior compartment when compared to cadaveric fascia lata, xenografts and allografts.

D. N. Kammerer-Doak et al.2002 reviewed perioperative data in 47 cases of abdominal sacrocolpopexy, 32 utilized cadaveric fascia lata, 15 used mesh for sacrocolpopexy.Vaginal erosion of cadaveric fascia lata graft was reported in 3 (27%) participants following sacrocolpopexy, diagnosed at mean of 36.8 days (range 27–45) following surgery.

Autologus fascia lata harvested site morbidity

Autologus fascia lata is preferred inpelvic reconstructive surgery for its predictable and longstanding results. Currently, FL is usually harvested for different procedures using a fasciatome or stripper through a 4 cm linear skin incision in the lateral aspect of the thigh over the iliotibial tract[123,124]. A long skin incision is however needed to harvest the FL for vault prolapse repair in the absence of FL stripper[125].

Disadvantages of the use of FL for pelvic reconstructive surgery is related mostly to potential donor site morbidity[125]. Harvesting FL is reported to cause minimal or no postoperative morbidity though complications can arise when a large area of FL is harvested [126,127]. Muscle herniation is a significant postoperative complication where a large size of fascia latais harvested [126] *Whereas, muscle herniation was not observed in our series of 28 patients who underwent abdominal sacrocolpopexy with fascia lata, where 12x 3 cm fascia lata was harvested.*

Postoperative pain in the harvested site:

90.09% of patients reported pain on walking upto one week after surgery in our series . This could be accounted for different subjective pain threshold.

Wheatcroft and associates [123] used a fasciatome through a 3-4 cm linear skin incision and reported pain on walking up to 30 days after surgery in 70% of the patients and limping in 53.3% of patients (up to 2 weeks).A subcuticular closure of the incision is recommended to improve the cosmetic appearance, which was used in all cases in this series with no significant problem.

Postoperative haematoma and infection:

In the current study ,there was no significant postoperative morbidity like haematoma and infection from the harvested site.

Postoperative haematoma and infection has been reported following fascia lata harvesting. [115,120] Complications occur if large area of fascia lata was removed [121].Careful attention to sepsis, haemostasis, and pressure dressing is recommended.[121].

Muscle herniation :

Abdominal sacrocolpopexy surgery requires much less (12–15 cm X 3 cm strip) fascia lata excision and in our series this was not associated with muscle herniation. Our survey found no serious long term complications.

Dubiel and Wigren assessed the lower limb in 39 patients 1–3 years after a 10 × 20 cm area of fascia lata was excised for heart valve surgery. Significant complications occurred with muscle herniation in 14 (36%),

weakness of hip flexion,numbness,pain,haemorrhage,superficial phlebitis and wound infection.

Dubiel WT et al (1974) reported harvesting fascia latamightcause minimal or no postoperative morbidity though complications can arise when a large area of fascia lata is removed. [113,114,115]

In the current study skin was closed with 2-0 monofilament polyamideafter closing the subsutaneous space with 2-0 polyglactin .All the patients in fascia lata group did not have any long term pain . None of the patients needed scar revision surgery at three year follow-up time.Scar scoring was not performed in our study.

The scar was the minor cosmetic concern in 5% of patients in the current study who underwent ASCP with autologous fascia lata.

To summarise

The current study has revealed that vault prolapse repair by abdominal sacrocolpopexy using autologous fascia lata has comparable anatomical success to synthetic mesh . Amongst the successfully repaired patients using autologus fascia lata, objective anatomical success rates were superior with reference to POP Q points Aa, Ba, Ap, Bp compared to synthetic mesh.There was no significant difference between the two groups with reference to C point.

The functional outcome (clinical success) is better with autologous fascia lata compared to mesh . The preoperative prevelance of LUTS in fascia lata group was observed in 22.05% and in synthetic mesh group, the prevalence was 20.8%. Post-operative resolutions of LUTS symptoms were comparable in both group. Only in synthetic mesh group, 3.6% reported

urinary tract infection in the postoperative follow up. None developed UTI in the facia lata group.

The number of participants who developed denovo SUI were higher 3 (10.7%) in fascia lata group than in mesh group 1/30 (3.3%) whereas denovo urgency with urge urinary incontinence was same in both groups.

Current study highlights the significantly high denovo occurrence of post operative dyspareunia in 28.6% participants among those who did not have dyspareunia pre operatively in the mesh group. Whereas none developed denovo dyspareunia in fascia lata group.postoperatively.

There were no mesh related complication.

This study highlights the need for routine concomitant suspension of the vaginal apex with uterosacral ligament and obliteration of culdesac during abdominal and vaginal hysterectomy to prevent vault prolapse.

The current study also confirmed that this procedure of abdominal sacrocolpopexy with autologous fascia lata and synthetic mesh are safe and effective in the medium term followup without deterioration of cure rate over time. The improvement in the postoperative measurement of C point in both groups might also be propably due to postoperative fibrosis in the vault.

Mesh extrusion and dyspareunia can be minimised by

1. Pre and postoperative administration of oestrogen.
2. Adequate dissection on the anterior and posterior vaginal vault atleast for a distance of 4 cm sothat the graft lies flat on the vaginal vault.

3. There should not be any tension on the graft either at the vaginal vault or at anterior sacral ligament.

4. In restoringthe anatomy, the main goal should be to suspend the vaginal vault as near as possible to its normal anatomic position.(5 cm inferior to the second sacral vertebral body and approximately 5 cm medial to the ipsilateral ischial spine).

There was only one study that compared the efficacy of autologous fascia lata to synthetic mesh in abdominal sacrocolpopexy(56). Most of the past publications compared the efficacy of cadaveric fascia lata with synthetic (polypropylene) mesh.Those studies showed inferior outcome with reference to suspension of apex following cadaveric fascia lata (allograft) compared to synthetic mesh . The higher failure rate was attributed to tissue degeneration associated with the preparation of allograft like freeze drying and irradiation.

This the **first randomised controlled single blinded prospective study** comparing the successfully repaired ASCP cases using autologous fascia lata and polyprophylene mesh .

The current study reports that the anatomical outcome with autologous fascia lata is equivalent to that of mesh and functional (clinical) outcome is superior to that of synthetic mesh.

Strengths and limitations

1. This is a randomised controlled trial conducted to assess the effectiveness of a procedure.

2. Along with randomization, blinding was done to avoid bias in reporting. The patients and surgeon were blind till the onset of surgery.

3. All procedures were done by single senior most Urogynaecologist with a track record of more than 500 sacrocolpopexy procedures.

   (A trial of Deprest et al. showed that it takes 60 procedures to effectively limit complications) [136].

4. To avoid bias, post operative assessment with reference to the anatomical and functional success was performed by the candidate and not by the surgeon.

Limitation :

1. Sample size:

The primary limitation of the study is small sample size (number of patients). 28 patients in fascia lata group and 30 patients in mesh group were subjected for the study.

2. Duration of followup :

5- to 10-year follow-up data would certainly be ideal which involveshigh attrition rate by the patients. Considering the poor response from the patientsfor the followupafter 36 months, the follow up for current study is limited to 3years.

More number of patients in each group with long term follow-up would have been beneficial in interpretation.

SUMMARY AND CONCLUSIONS

Blood loss, duration of surgery & hospital stay did not differ significantly in the two groups.

Anatomical success :

Amongst the successfully repaired patients using autologus fascia lata, objective anatomical success rates were superior with reference to POP Q points Aa, Ba, Ap, Bp compared to synthetic mesh. However the anatomical outcome of C point in fascia lata group was comparable to that of mesh group.

Functional success:

In the current study post operative resolution of lower urinary tract symptoms was equal in both fascia lata and synthetic mesh group.

Urinary symptoms:

None in the fascialata group developed UTI however3.6% in synthetic mesh group developed urinary tract infection in the postoperative follow up.

Combining Burch colposuspension along with ASCP for patients who had coexisting SUI (overt and occult) and vault prolapse has relieved SUI in both groups.

The number of participants who developed denovo SUI was 10.7% in fascia lata group and 3.3% in mesh group. None developed denovo urgency and urge urinary incontinence were same in both groups.

Bowel symptoms:

Complete resolution of all pre operative bowel symptoms occurred in the autologous fascia lata group incontrast to the mesh group where 3% reported faecal urgency in the postoperative follow up .

Sexual symptom:

With fascia lata suspension , none developed de novo dyspareunia unlike mesh suspension. Nevertheless in the synthetic mesh group none developed mesh exposure / extrusion or infection post operatively.

In the fasci lata group ,there was no significant postoperative morbidity like haematoma infection and muscle herniation from the harvested site.

The current study has revealed that vault prolapse repair by abdominal sacrocolpopexy using autologous fascia lata has comparable anatomical success to synthetic mesh . The functional outcome (clinical success) was better with autologous fascia lata suspension compared to mesh suspension .

- *This study highlights that autologous fascia lata is a versatile graft with comparable efficacy to mesh . Offers good and durable mechanical support of the vaginal vault .*

In future, larger and prospective, randomized clinical trials and a long-term follow-up are needed to further evaluate durability, anatomical outcomes and patient satisfaction after ASC with autologous fascia lata.

Recommendations

Autologous Fascia lata is strong, pliable and homologous tissue does not involve foreign body reaction or infection [153].

After repetitive notifications of FDA about nonuse of mesh in pelvic floor surgeries, there is increasing scope of biological grafts in reconstructive surgeries.

According to this study, autologous fascia lata compares favorably in efficacy to monofilament, polyprophylene mesh and it is not associated with any significant morbidity.

Follow up in our series of patients is adequate to assess accurately treatment efficacy, harvest site morbidity and patient satisfaction. There had been good medium term followup results in our study and patient satisfaction with the procedure is high.

The successfully operated patients who were completely asymptomatic (in both groups) reported high patient satisfaction rate.

The following advantages of autologus fascia lata has been proved in this study:

- It is a scientific proven operation which is independent of synthetic graft and is devoid of mesh related problems and other surgery related complications like infection, extrusion, chronic vaginal pain , constipation and dyspareunea.
- Because of minimal complications , abdominal sacro colpopexy using fascia lata can be offered to patients who hail from remote villages with no access for followup.

- Autologous graft is readily available with the patient and the patient is not dependant on any commercial material for suspension.

The anatomical and functional outcomes of autologus fascia lata are equivalent to that of synthetic mesh in abdominal sacrocolpopexy for management of vault prolapse,

Hence abdominal sacral colpopexy using autologous fascia lata may be considered primarily for women with vaginal vault prolapsed.

APPENDIX 1

Abreviations

ALL: anterior longitudinal ligament of sacrum

PDGFR: platelet derived growth factors receptors

ASCP: abdominal sacrocolpopexy

USLS: uterosacral ligament suspension

PTFE: polytetrafluroethylene

HUVS: high uterosacral vaginal suspension

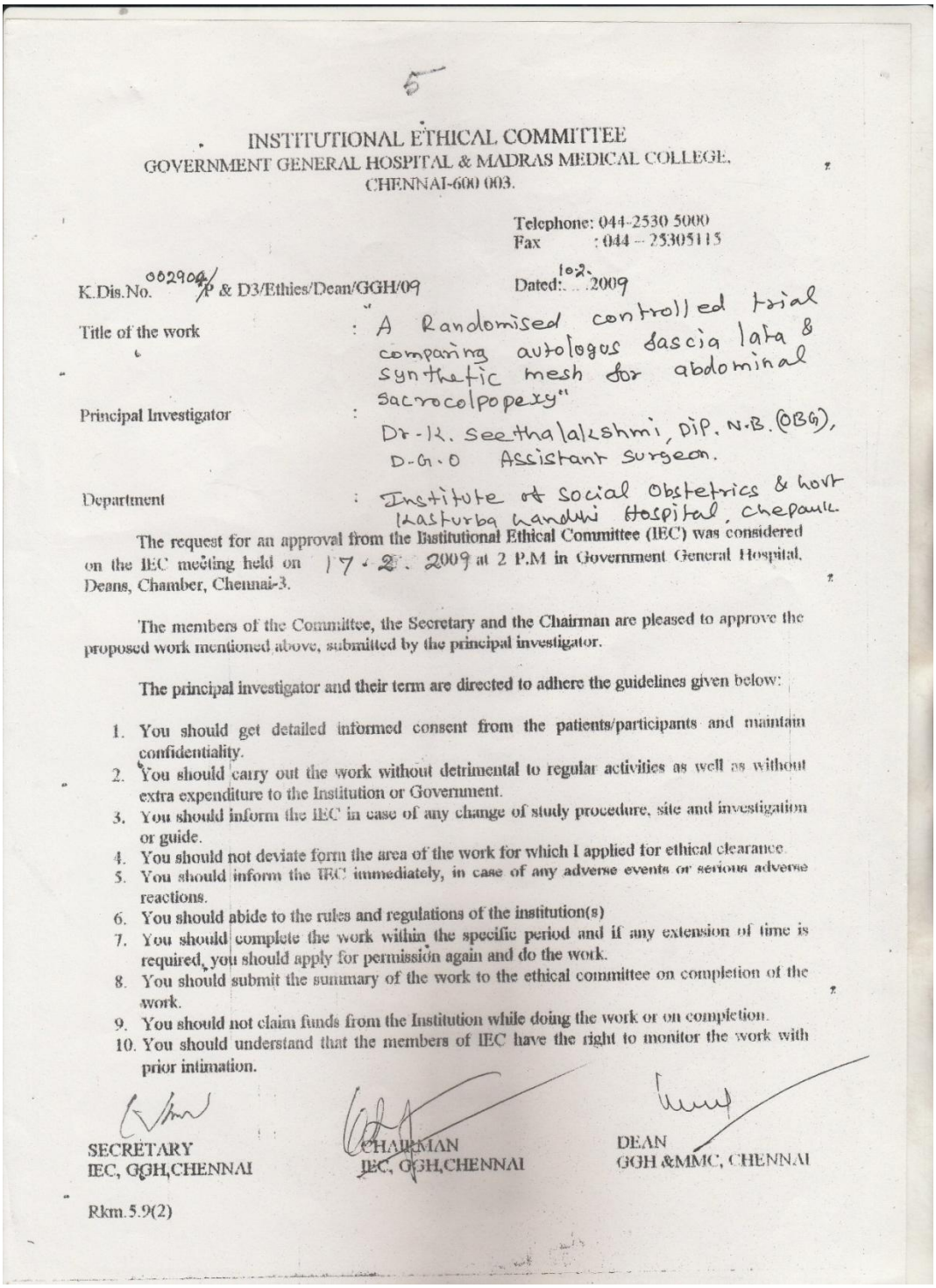
FL: fascia lata

POP: pelvic organ prolapse

POP Q: pelvic organ prolapse quantification

APPENDIX 2

Ethical committee approval by Madras Medical college



5

INSTITUTIONAL ETHICAL COMMITTEE
GOVERNMENT GENERAL HOSPITAL & MADRAS MEDICAL COLLEGE,
CHENNAI-600 003.

Telephone: 044-2530 5000
Fax : 044 – 25305113

K.Dis.No. 002904/P & D3/Ethics/Dean/GGH/09 Dated: 10.2.2009

Title of the work : A Randomised controlled trial comparing autologous fascia lata & synthetic mesh for abdominal sacrocolpopexy"

Principal Investigator : Dr-R. Seethalakshmi, DIP. N.B.(OBG), D-G-O Assistant Surgeon.

Department : Institute of social Obstetrics & Govt Kasturba Gandhi Hospital, Chepauk.

The request for an approval from the Institutional Ethical Committee (IEC) was considered on the IEC meeting held on 17.2.2009 at 2 P.M in Government General Hospital, Deans, Chamber, Chennai-3.

The members of the Committee, the Secretary and the Chairman are pleased to approve the proposed work mentioned above, submitted by the principal investigator.

The principal investigator and their term are directed to adhere the guidelines given below:

1. You should get detailed informed consent from the patients/participants and maintain confidentiality.
2. You should carry out the work without detrimental to regular activities as well as without extra expenditure to the Institution or Government.
3. You should inform the IEC in case of any change of study procedure, site and investigation or guide.
4. You should not deviate form the area of the work for which I applied for ethical clearance.
5. You should inform the IEC immediately, in case of any adverse events or serious adverse reactions.
6. You should abide to the rules and regulations of the institution(s)
7. You should complete the work within the specific period and if any extension of time is required, you should apply for permission again and do the work.
8. You should submit the summary of the work to the ethical committee on completion of the work.
9. You should not claim funds from the Institution while doing the work or on completion.
10. You should understand that the members of IEC have the right to monitor the work with prior intimation.

SECRETARY
IEC, GGH,CHENNAI

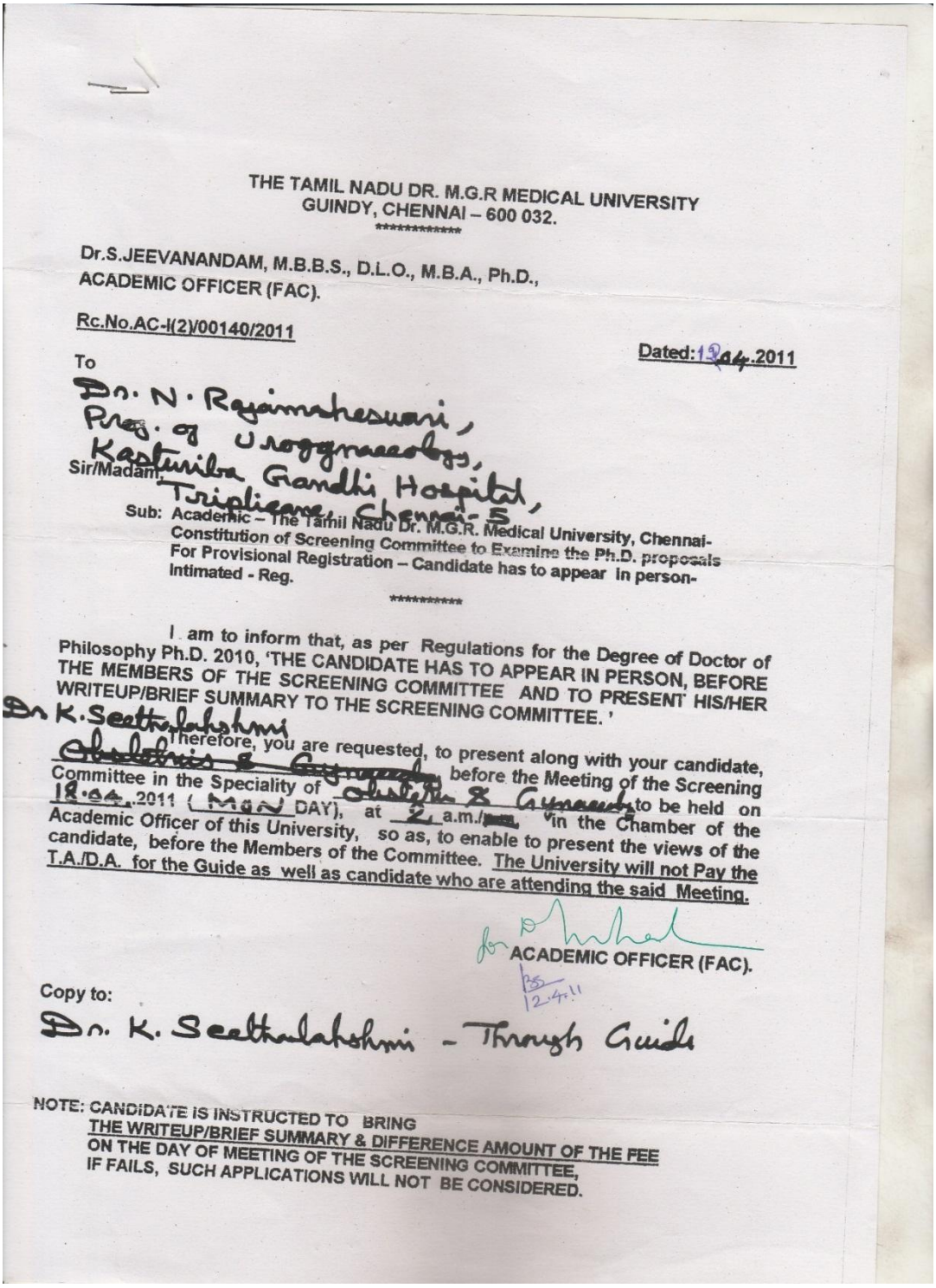
CHAIRMAN
IEC, GGH,CHENNAI

DEAN
GGH &MMC, CHENNAI

Rkm.5.9(2)

APPENDIX 3

Ethical committee approval by The Tamilnadu Dr. M.G.R. Medical University



THE TAMIL NADU DR. M.G.R MEDICAL UNIVERSITY
GUINDY, CHENNAI – 600 032.
****

Dr.S.JEEVANANDAM, M.B.B.S., D.L.O., M.B.A., Ph.D.,
ACADEMIC OFFICER (FAC).

Rc.No.AC-I(2)/00140/2011

Dated: 12.04.2011

To
Dr. N. Rajamaheswari,
Prof. of Urogynaecology,
Kasturiba Gandhi Hospital,
Triplicane, Chennai-5

Sir/Madam,

Sub: Academic – The Tamil Nadu Dr. M.G.R. Medical University, Chennai- Constitution of Screening Committee to Examine the Ph.D. proposals For Provisional Registration – Candidate has to appear in person- intimated - Reg.

****

I am to inform that, as per Regulations for the Degree of Doctor of Philosophy Ph.D. 2010, 'THE CANDIDATE HAS TO APPEAR IN PERSON, BEFORE THE MEMBERS OF THE SCREENING COMMITTEE AND TO PRESENT HIS/HER WRITEUP/BRIEF SUMMARY TO THE SCREENING COMMITTEE.'

Dr. K. Seethalakshmi

Therefore, you are requested, to present along with your candidate, before the Meeting of the Screening Committee in the Speciality of Obstetrics & Gynaecology to be held on 18.04.2011 (Monday DAY), at 2 a.m./p.m. in the Chamber of the Academic Officer of this University, so as, to enable to present the views of the candidate, before the Members of the Committee. The University will not Pay the T.A./D.A. for the Guide as well as candidate who are attending the said Meeting.

for ACADEMIC OFFICER (FAC).

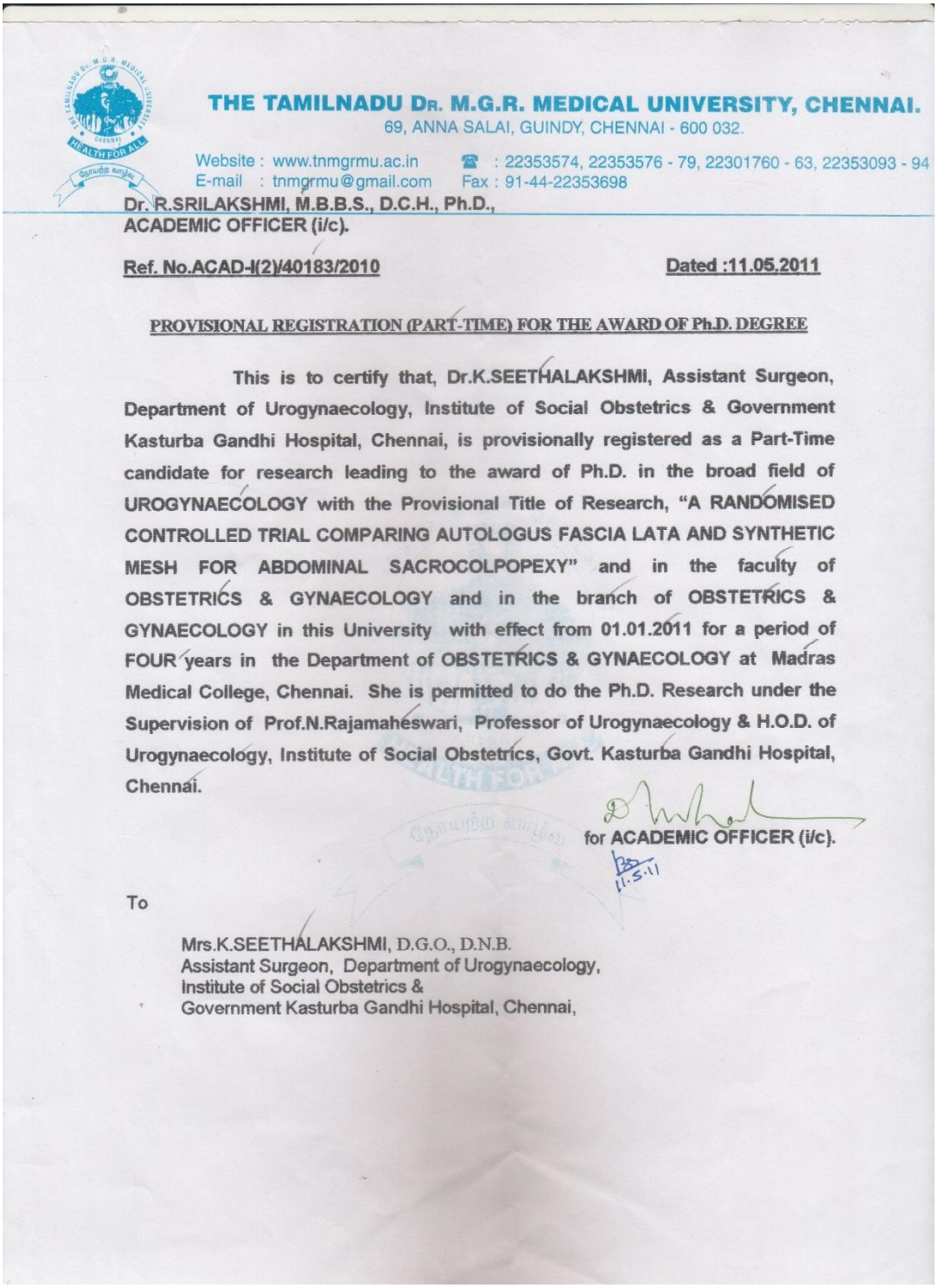
12.4.11

Copy to:
Dr. K. Seethalakshmi – Through Guide

NOTE: CANDIDATE IS INSTRUCTED TO BRING
THE WRITEUP/BRIEF SUMMARY & DIFFERENCE AMOUNT OF THE FEE
ON THE DAY OF MEETING OF THE SCREENING COMMITTEE,
IF FAILS, SUCH APPLICATIONS WILL NOT BE CONSIDERED.

APPENDIX 4

Provisional registration by The Tamilnadu Dr. M.G.R. Medical University



THE TAMILNADU DR. M.G.R. MEDICAL UNIVERSITY, CHENNAI.
69, ANNA SALAI, GUINDY, CHENNAI - 600 032.

Website : www.tnmgrmu.ac.in ☎ : 22353574, 22353576 - 79, 22301760 - 63, 22353093 - 94
E-mail : tnmgrmu@gmail.com Fax : 91-44-22353698

Dr. R.SRILAKSHMI, M.B.B.S., D.C.H., Ph.D.,
ACADEMIC OFFICER (i/c).

Ref. No.ACAD-I(2)/40183/2010 Dated :11.05.2011

PROVISIONAL REGISTRATION (PART-TIME) FOR THE AWARD OF Ph.D. DEGREE

This is to certify that, Dr.K.SEETHALAKSHMI, Assistant Surgeon, Department of Urogynaecology, Institute of Social Obstetrics & Government Kasturba Gandhi Hospital, Chennai, is provisionally registered as a Part-Time candidate for research leading to the award of Ph.D. in the broad field of UROGYNAECOLOGY with the Provisional Title of Research, "A RANDOMISED CONTROLLED TRIAL COMPARING AUTOLOGUS FASCIA LATA AND SYNTHETIC MESH FOR ABDOMINAL SACROCOLPOPEXY" and in the faculty of OBSTETRICS & GYNAECOLOGY and in the branch of OBSTETRICS & GYNAECOLOGY in this University with effect from 01.01.2011 for a period of FOUR years in the Department of OBSTETRICS & GYNAECOLOGY at Madras Medical College, Chennai. She is permitted to do the Ph.D. Research under the Supervision of Prof.N.Rajamaheswari, Professor of Urogynaecology & H.O.D. of Urogynaecology, Institute of Social Obstetrics, Govt. Kasturba Gandhi Hospital, Chennai.

for ACADEMIC OFFICER (i/c).

11.5.11

To

Mrs.K.SEETHALAKSHMI, D.G.O., D.N.B.
Assistant Surgeon, Department of Urogynaecology,
Institute of Social Obstetrics &
Government Kasturba Gandhi Hospital, Chennai,

APPENDIX 5

Patient consent form

PATIENT CONSENT FORM

I ..... am informed about the operation for my disease. I am also informed about the details of operation, its complications and its outcome by the surgeon.

I ..... give full consent for the operation ..... which I have to undergo.

நோயாளி ஒப்புதல் படிவம்

என்னுடைய நோயின் தன்மையும், அதற்குரிய அறுவை சிகிச்சை முறை பற்றியும் தெளிவாக மருத்துவரால் கூறப்பட்டது. அறுவை சிகிச்சை முறை, அதனுடைய பிரச்சனைகள் மற்றும் வெளிப்பாடு பற்றியும் மருத்துவரால் எடுத்து கூறப்பட்டது.

நான் ..... இந்த அறுவை சிகிச்சைக்கு .....

முழு ஒப்புதல் அளிக்கிறேன்.

APPENDIX 6

Patient proforma

Proforma for Abdominal sacrocolpopexy with FL/ synthetic mesh in vault prolapse

Name;

Age;

Address; **contact no;**

(R)

mobile;

socioeconomic status:

Marital history;

Unmarried;

Married;

Divorcee;

Widow;

Occupation;

Obstetric history;

No.of deliveries;

Mode of deliveries;

Home delivery;

Hospital delivery;

Labour natural;

Instrumental delivery;

LSCS

<u>Present history;</u>

Prolapse symptoms **Duration**

Mass descending p/v;

Urinary Symptoms

Hesitancy to void;

Straining to void;

Thin stream of urine;

Incomplete emptying of urine;

Stress incontinence of urine;

Urgency

Urge incontinence

Mixed incontinence

Frequency of micturition;

Recurrent UTI;

Voiding by reducing prolapse per vagina;

Voiding with abdominal straining;

Sexual symptoms;

Dysparenuea

Bowel symptoms;

Constipation;

Defecation by manual digitation of rectocele;

Incomplete bowel emptying;

Urgency for defecation;

Fecal incontinence;

Past history;

h/o hysterectomy;

Since how many years?

Indication for hysterectomy;

Route of hysterectomy;

Abdominal;

Vaginal;

Laparoscopic;

Was hysterectomy associated with additional procedures;

Mccalls culdoplasty;

Enterocele repair;

Burch colposuspension;

Mid urethral sling;

h/o any previous surgery other than hysterectomy;

Medical history;

Bronchial asthma;

COPD;

Heart disease;

Valvular or IHD;

Hypothyroidism;

Epilepsy;

Chronic constipation;

Present medical history;

DM;

HT;

IHD;

COPD;

Personnel history;

Vegetarian;

Non vegetarian;

Drug allergy;

Previous blood transfusion;

Present medication;

Clinical examination;

General body built;

BMI;

Spine;

Anaemia;

Neck;

Breast;

Pedal oedema;

Pulse;

BP;

Cvs;

Rs;

Per abdomen;

L/E of vulva;

S/E;

p/v;

POP Q;

Aa	**Ba**	**c**
Gh	**tvl**	**pb**
Ap	**Bp**	**D**

P/R; anal sphincteric tone;

Investigations;

Urine routine analysis;

Urine culture & sensitivity;

Blood Hb;

PCV;

Grouping & typing;

BT

CT;

Platelet cout;

Sugar F

PP

Urea

Creatinine;

X ray chest;

ECG;

USG KUB;

Cystoscopy;

Other investigations if any;

IVU;

UDE;

Procedure;

Abdominal sacrocolpopexy with synthetic mesh;

Abdominal sacrocolpopexy with Fascia Lata;

Per operative prophylactic antibiotics; inj. Cephatoxime 1gm + inj.amikacin 500mgm iv.

Anaesthesia;

General

Regional

Operative time;

FL harvesting;

ASCP;

Total time;

Operative technique;

Intra operative blood loss;

(by weighing blood soaked pad)

Blood transfusion;

intra operative;

post operative;

Intra operative complications:

Additional continence procedure:

Burch colposuspension:

Mid urethral sling:

Immediate post operative period:

Duration of antibiotics:

Foleys catheter removal on which post operative day?:

Duration of hospital stay:

Immediate post operative complications if any:

Post operative follow up: 4wks 3months 6months 1yr 2yr 3yr

Mass protrusion per vagina:

Bladder function:

Sexual function:

Bowel function:

Incisional hernia;

POP Q

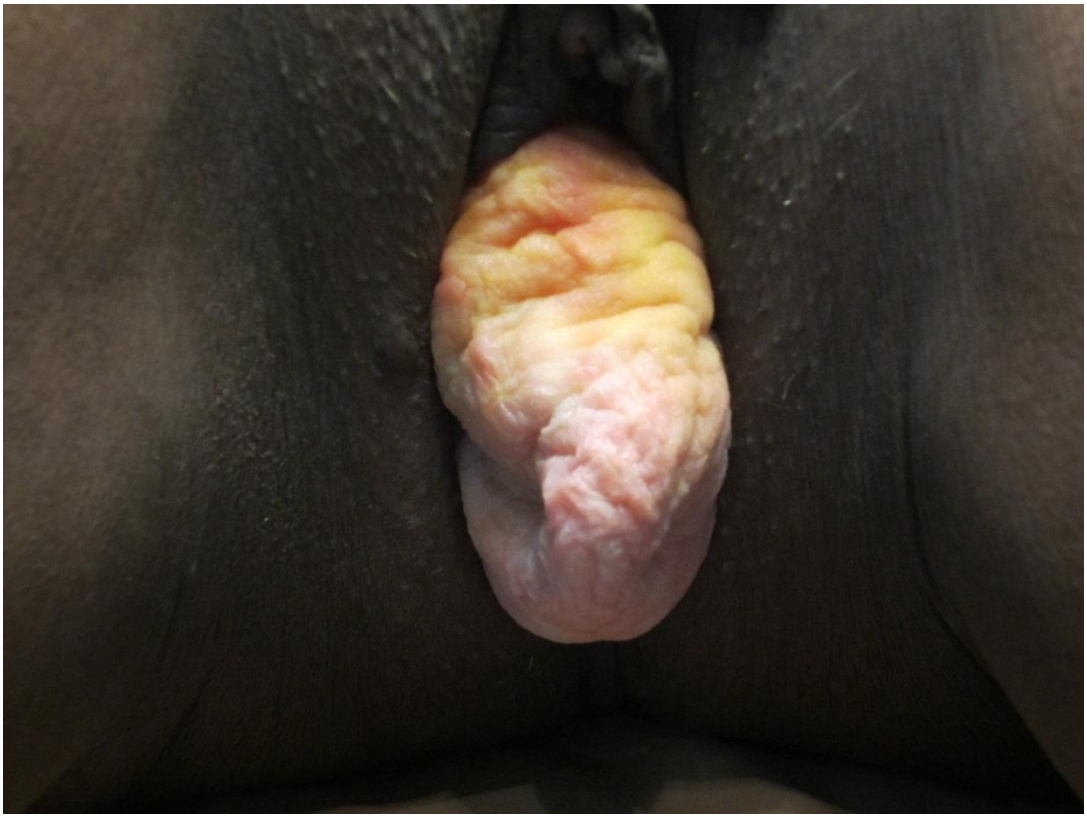
Aa	**Ba**	**c**
Gh	**tvl**	**pb**
Ap	**Bp**	**D**

Symptoms related to FL harvested site if any:

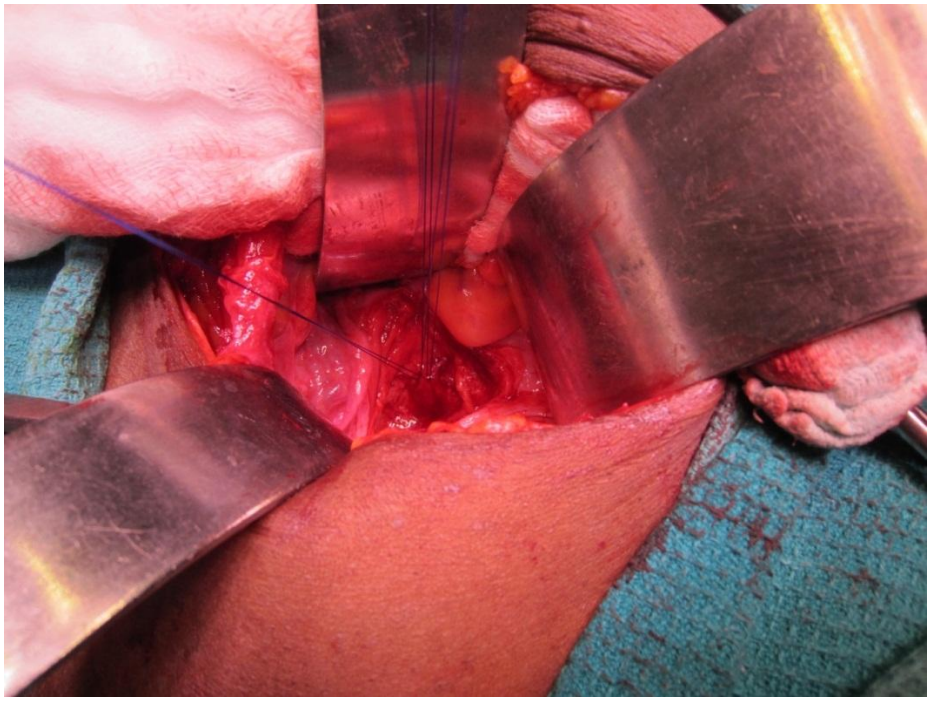
(Donor site morbidity);

1. **infection**
2. **wound break down;**
3. **pain;**
4. **parasthesia;**

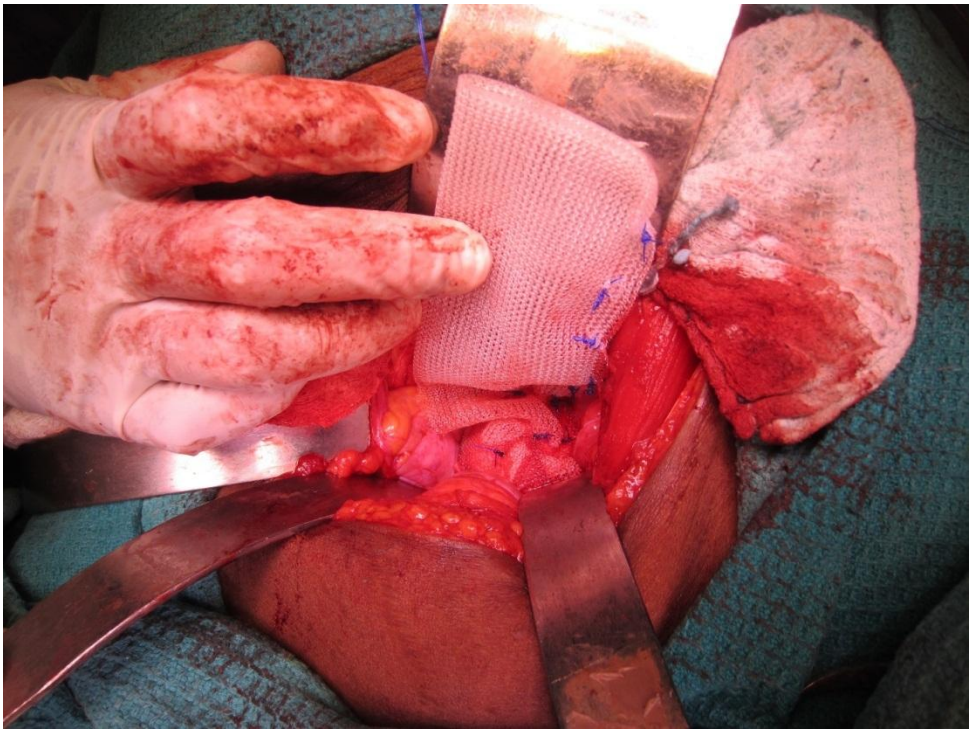
APPENDIX 7



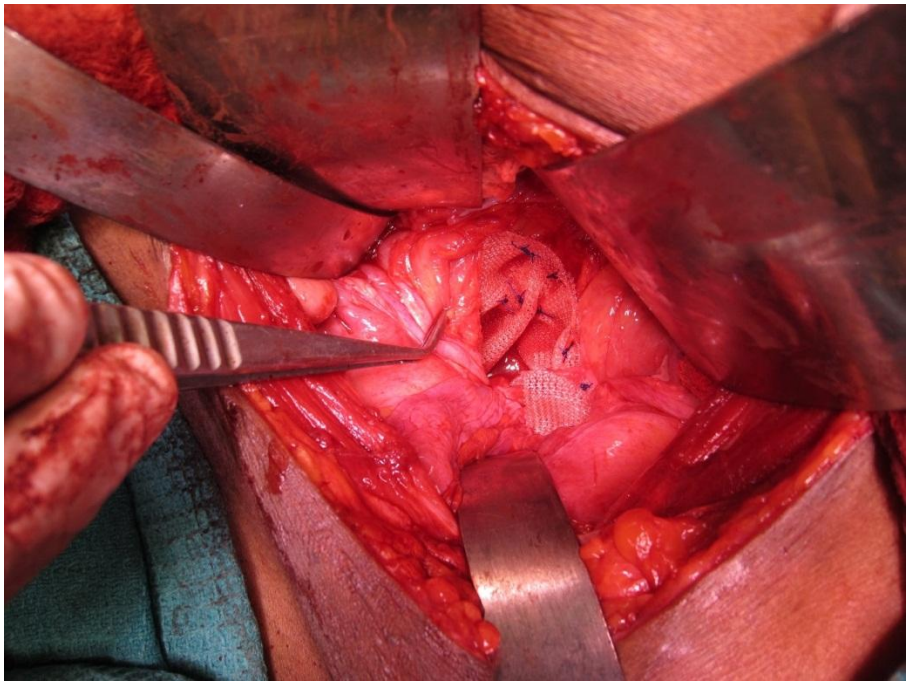
Mrs .A , stage 4 vault prolapse



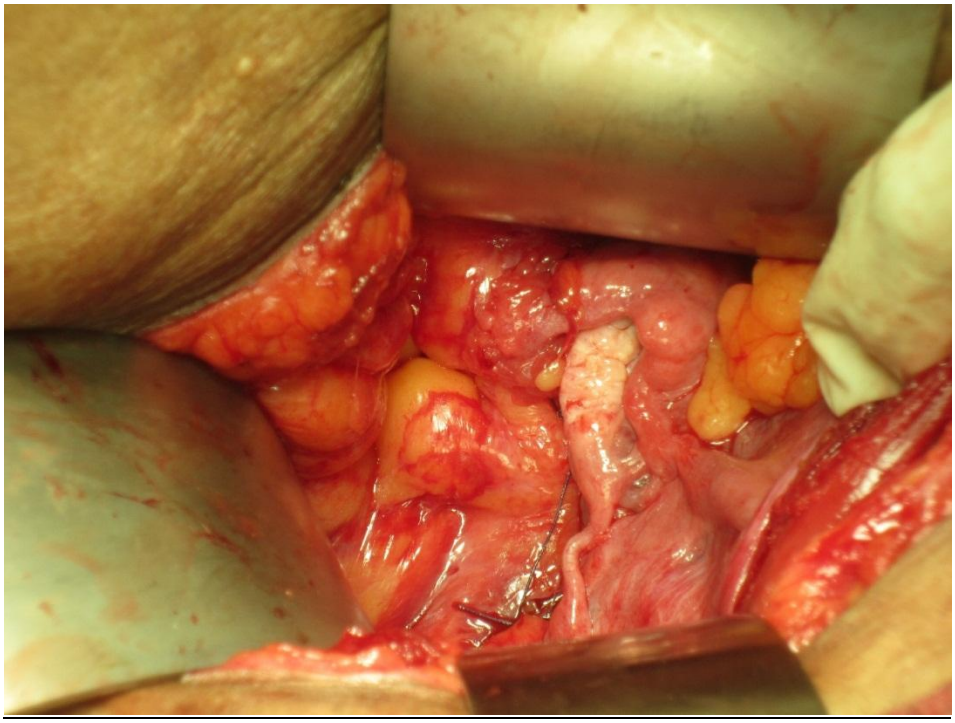
Picture showing Three transverse sutures (0 polypropylene) in the anterior longitudinal ligament of sacrum



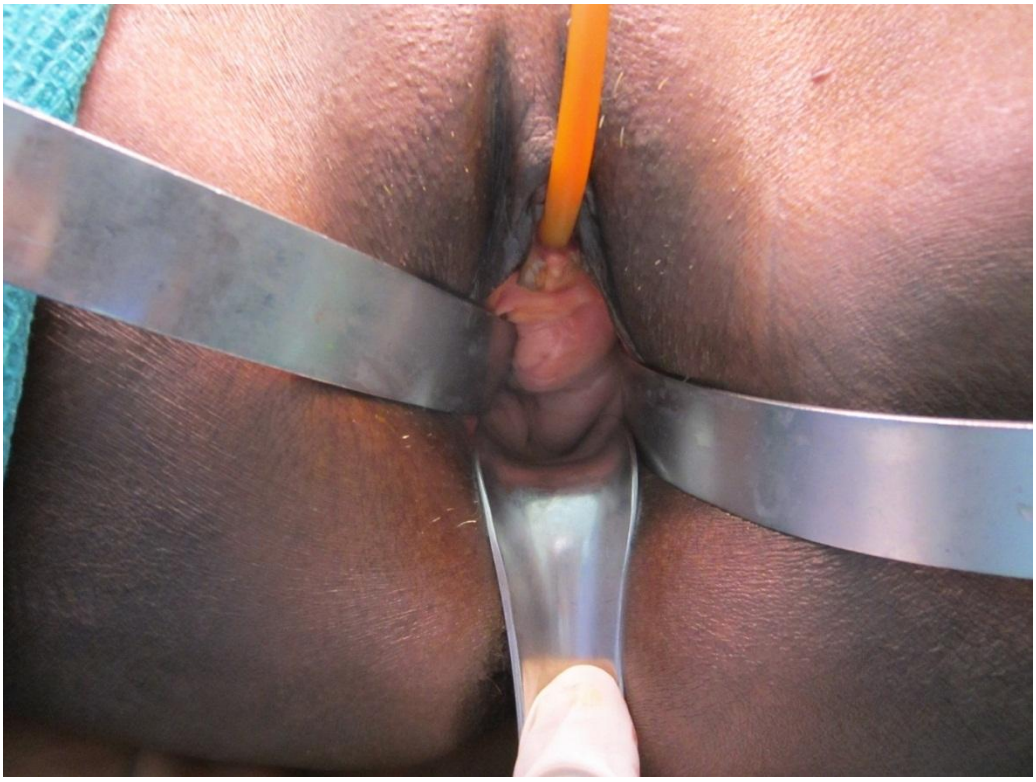
Picture showing View of polypropylene mesh after placement over the anterior vaginal vault and before placement on the anterior sacral ligament



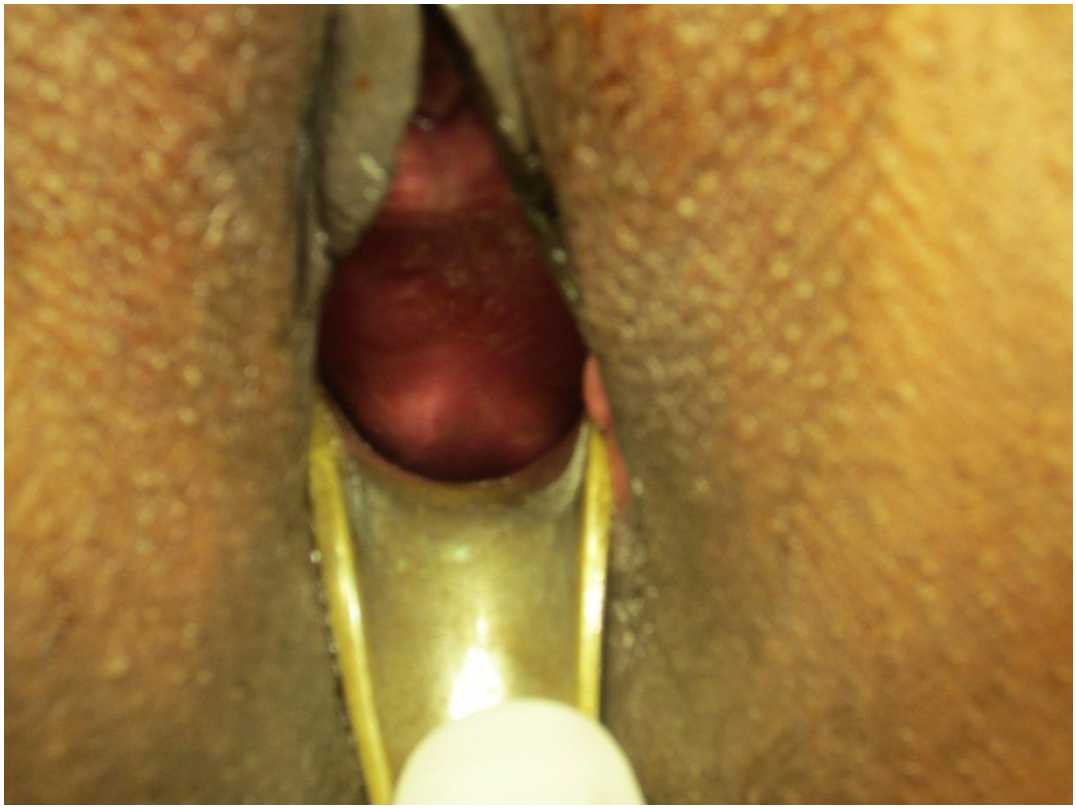
Picture showing the complete placement of mesh both over the anterior sacral ligament and vaginal vault before trimming the excess mesh over the sacral part



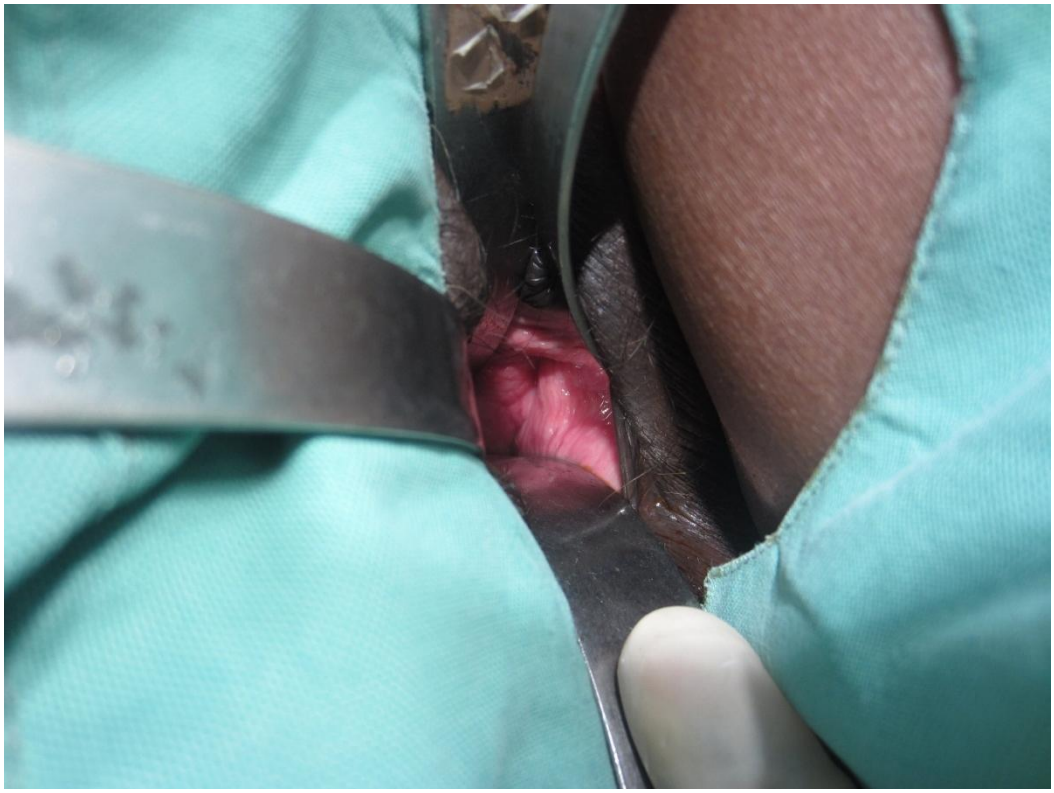
Picture after closure of posterior peritoneum over the mesh



Picture showing the immediate postop after ASCP with mesh



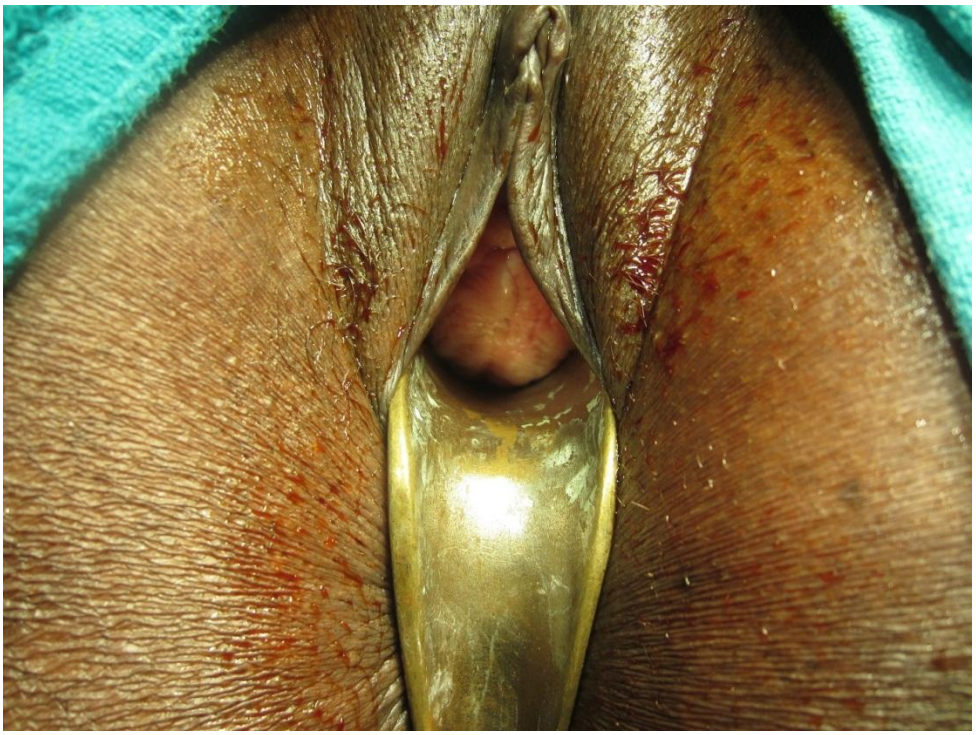
Picture showing 3 year followup after ASCP with mesh



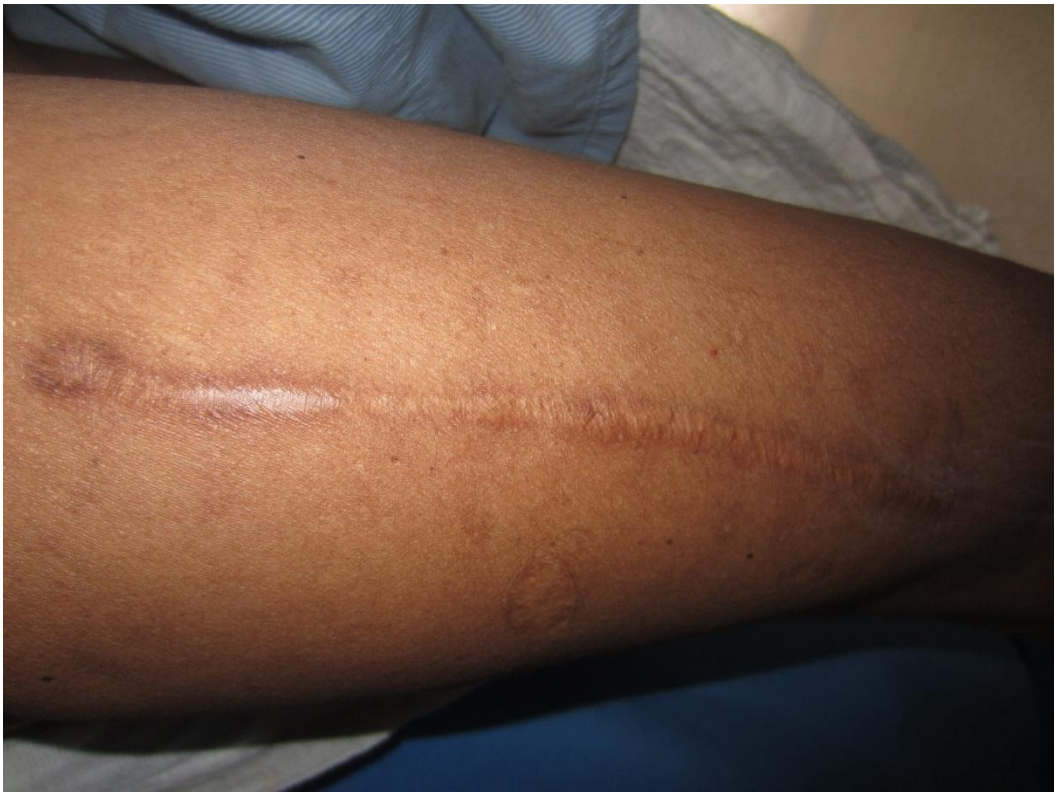
Picture showing 3 year followup after ASCP with mesh

Fascia lata illustrations

Mrs. E, stage 4 vault prolapse



Picture showing 3 year followup in ASCP using autologous fascia lata



Picture showing Fascia lata harvested site scar in ASCP usingautologus fascia lata - 3 year followup

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