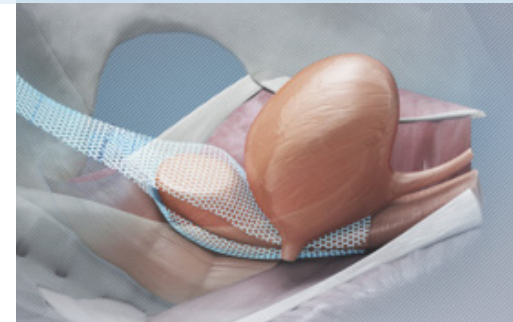
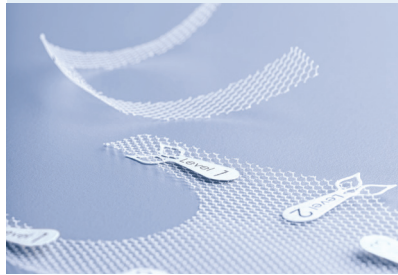


BSC Mesh  
InGYNious  
i-Stitch  
EndoGYNious  
PelviGYNious



# A.M.I. Solutions for Treating Pelvic Organ Prolapse (POP)

Publications Overview

**BSC Mesh**

No	Author Date	Title	Follow-up	Sample Size	Anatomical / Objective Success	Patient Satisfaction / Subjective Success	Mesh Erosion	Post-operative results, Complications	Conclusion
1	Brosche et al. * 2023	Bilaterale sakro-spinale Zerviko- oder Kolpofixation mittels BSC-Mesh im Rahmen der vaginalen Deszensuschirurgie: Eine retrospektive Analyse der Daten von 650 Patientinnen	2.9 years	650	95.8% (4.2% Recurrence)	–	1.40%	<ul style="list-style-type: none"> <li>• Intraoperative: bladder lesion</li> <li>• Early postoperative: 0.5% bleeding up to 24 hours, 2.9% urinary tract infection, 0.9% bladder voiding disorder, 2.2% hematoma, 2.5% prolonged pain</li> <li>• Specific fixation complication: 4.3% pain at fixation site (treated with local anesthetics or suture repositioning during hospital stay)</li> <li>• Late complications: 0.3% hematoma, 0.8% persistent pain, 1.4% granulation polype</li> </ul>	<ul style="list-style-type: none"> <li>• Broadest (650 patients) and longest (0.3 – 6.1 years) study with BSC mesh</li> <li>• Safe and reproducible method for POP surgery, organ preservation and can be combined with other surgical POP options</li> <li>• High patient satisfaction and short hospital stays</li> <li>• BSC mesh = a safe, minimal-invasive and low-risk surgical POP method with low revision rate</li> </ul>
2	Zalewski et al. 2023	Long-term follow-up of surgery of an isolated apical defect using synthetic materials and their effect on quality of life and satisfaction with life	36 months	60 (45 in FU)	P-QoL significantly improved after 3y FU (in almost all domains, only domain focusing on personal relationship not significant)	Upward trend in patient satisfaction (SWLS)	–	–	The results obtained after completing the SWLS questionnaire indicate that 3 years after the surgery, patients' satisfaction with life showed an upward trend. Surgical treatment of an isolated apical defect using the AMI BSC kit results in an improvement in the quality of life in the majority of patients, even in a long-term evaluation.

# A.M.I. Solutions for Treating Pelvic Organ Prolapse (POP)

Publications Overview

Urogynecology

## BSC Mesh

No	Author Date	Title	Follow-up	Sample Size	Anatomical / Objective Success	Patient Satisfaction / Subjective Success	Mesh Erosion	Post-operative results, Complications	Conclusion
3	Chene et al. 2023	Long-Term Results after Bilateral Sacrospinous Colposuspension: A Prospective Study	24 months	32	9.3% recurrence (2x apical recurrence, 1x cystocele)	85.7%; PFIQ-7, PFDI-20 and SF-12 significantly improved after 24 months	0%	<ul style="list-style-type: none"> <li>No periOP complication</li> <li>6.2% urinary infection</li> </ul>	This vaginal minimally invasive procedure is effective, quick, reproducible, and easy. It may be a relevant option for a vaginal vault or cervical or uterine prolapse
4	Hosni et al. 2023	Anatomical and functional outcomes after bilateral sacrospinous colposuspension (BSC) for the treatment of female genital prolapse	12 months	30	POP-Q parameters were significantly improved at twelve months after surgery compared to baseline; women were asymptomatic, stage 0 or I	All patients were satisfied	No mesh-induced vaginal erosion	<ul style="list-style-type: none"> <li>No intraoperative complications</li> <li>No record for visceral injury or need for reoperation due to hematoma formation or pain</li> <li>No UTIs, 6.7% urinary retention</li> <li>10% lower pack pain and 3% groin pain -&gt; pain medication and physiotherapy resolved pain</li> <li>3% small hematoma, resolved spontaneously</li> <li>No recorded surgery site infection or mesh induced vaginal erosion or visceral injury</li> </ul>	The results of our study show that bilateral sacrospinous colposuspension is reproducible, minimal invasive, and results in high patient's satisfaction

**BSC Mesh**

No	Author Date	Title	Follow-up	Sample Size	Anatomical / Objective Success	Patient Satisfaction / Subjective Success	Mesh Erosion	Post-operative results, Complications	Conclusion
5	Weiße et al. * Published 2021	Bilaterale sacrospinale Zerviko-/Kolpofixation mittels BSC-Mesh im Rahmen der vaginalen Deszensuschirurgie – eine retrospektive Datenanalyse	Median 5.13 years	91	Recurrence surgery at 6.6%	–	Late post-operative: one mesh exposition	<ul style="list-style-type: none"> <li>• Intra-operative: no complication</li> <li>• Post-operative: One hematoma requiring revision; one necessary revision with loosening of fixation due to pain</li> <li>• Late post-operative: One revision at fixation point and one bleeding</li> </ul>	The usage of BSC Mesh is a safe minimally invasive and low risk POP surgery with a low recurrence and complication rate
6	Mikkola et al. Start study date 2020 <b>Ongoing</b>	Women's Apical Pelvic Organ Prolapse Treatment – a Randomized Controlled Trial Comparing Transvaginal and Laparoscopic Mesh Surgery <a href="https://clinicaltrials.gov/study/NCT04478747">https://clinicaltrials.gov/study/NCT04478747</a>	Planned FU: 5 years	Target size: 318 (total) 106 per group	–	–	–	–	–
7	Hemptenmacher et al. Published 2020	Bilateral Sacrospinous Colposuspension ( BSC ) in the Treatment of Female Genital Prolapse: Risk-Benefit Considerations and Six Months Follow-up	6 months	132 patients 56 patients at follow-up	Follow-up: No failures of apical fixation, support was reliably achieved	–	No erosion (one exception after vaginal delivery)	<ul style="list-style-type: none"> <li>• No rectal injury was observed</li> <li>• No re-intervention required for any complications</li> <li>• No post-operative infections or hematomas</li> </ul>	The authors conclude, that BSC is an efficient minimally invasive technique for the treatment of female genital prolapse with a very favourable risk/benefit ratio

## A.M.I. Solutions for Treating Pelvic Organ Prolapse (POP)

### Publications Overview

#### BSC Mesh

No	Author Date	Title	Follow-up	Sample Size	Anatomical / Objective Success	Patient Satisfaction / Subjective Success	Mesh Erosion	Post-operative results, Complications	Conclusion
8	Bärmig et al. Data on file 2020	Retrospective data analysis – bilateral sacrospinous cervico-/colpofixation with BSC Mesh – Long-term results and safety	62 months	87	95.4%	–	1.1%	<ul style="list-style-type: none"> <li>• 0% intraoperative</li> <li>• 6.8% early postoperative (3.4% increased pain, 3.4% urinary tract infection)</li> <li>• 2.2% late (1.1% persistent pain)</li> </ul>	BSC Mesh can be combined very well with classical colporrhaphy (anterior and/or posterior). With this combination, the recurrence rate is significantly reduced with minimal and low-risk effort (in our data analysis to below 5%).
9	Zalewski et al. Published 2020	The assessment of quality of life and satisfaction with life of patients before and after surgery of an isolated apical defect using synthetic materials	12 months	60	Most cases the symptoms which significantly limited the daily functioning of the affected women disappeared	QoL significantly improved	–	–	Surgical treatment of an isolated apical defect using AMI BSC kit causes in most patients the regression of burdensome symptoms and improves their comfort of life
10	Gonzalez-Lopez et al. 2019	Anterior and Apical Prolapse Treatment with a Novel Uterine-Sparing Transvaginal Mesh Procedure	20.8 months	27	92.6% overall success rate, 74.1% objective cure at overall compartments; 25.9% anatomical POP recurrence and 7.4% clinical POP recurrence	92.6% subjective cure 7.6 VAS patient satisfaction	No mesh complications have been detected	<ul style="list-style-type: none"> <li>• 3.7% hematoma</li> <li>• 3.7% transient voiding dysfunction</li> <li>• 3.7% vaginal granuloma</li> </ul>	Uterine-sparing surgery is an effective and safe procedure, with low rate and grade of complications. This technique offers good anatomical correction with significant improvement in symptoms and high patient satisfaction

**BSC Mesh**

No	Author Date	Title	Follow-up	Sample Size	Anatomical / Objective Success	Patient Satisfaction / Subjective Success	Mesh Erosion	Post-operative results, Complications	Conclusion
11	Kieback et al. Published 2019	Bilateral Sacrospinous Colposuspension (BSC) for the treatment of vaginal vault prolapse – <b>description of a novel method</b>	–	–	–	–	–	–	As a minimally invasive approach with the potential for conservation of the uterus, this technique should be applicable to all age groups including the increasingly frequent elderly patient with significant co-morbidities.
12	Chene et al. Published 2019	<b>How I do...</b> easily a vaginal sacrospinous colpopexy using an isthmic posterior mesh	–	–	–	–	–	–	The advantages of BSC Mesh lie in its small size, very low weight and wide pore structure (improving tolerance) via a minimally invasive vaginal approach (enabling outpatient management). Limited dissection of the pararectal space and the use of new anchoring devices (i-Stitch) considerably reduce the risk of vascular and neurological complications, while enabling solid fixation under pure tactile control with a safe approach to the sacrospinal ligament

**BSC Mesh**

No	Author Date	Title	Follow-up	Sample Size	Anatomical / Objective Success	Patient Satisfaction / Subjective Success	Mesh Erosion	Post-operative results, Complications	Conclusion
13	Verhorstert, Roovers et al. Start study date 2018 <b>Ongoing</b>	SDI trial – Sacrospinous ligament fixation: Direct or Indirect. A RCT of direct versus indirect bilateral sacrospinous ligament fixation for surgical correction of apical prolapse stage 2 or more <a href="https://onderzoekmet-mensen.nl/en/trial/47591">https://onderzoekmet-mensen.nl/en/trial/47591</a>  <a href="https://trialssearch.who.int/Trial2.aspx?TrialID=NL-OMON47591">https://trialssearch.who.int/Trial2.aspx?TrialID=NL-OMON47591</a>	Planned FU: 12 months	Target size: 144 (total) 72 per group	–	–	–	–	–
14	Törzsök et al. Published 2016	Laparoscopic Radical Cystectomy and Ileal Neobladder for Muscle Invasive Bladder Cancer in Combination with One Stage Prophylactic Laparoscopic Sacrospinal Fixation to Avoid Future Pelvic Organ Prolapse	36 months	1 (Case Report)	No POP recurrence at follow-up examinations	After 36 months of follow-up, the patient is satisfied with her continence	No mesh complications	No severe intraoperative complications	Laparoscopic cystectomy combined with sacrospinal mesh fixation is technically feasible and could be an option to prevent neo-cystocele for female patients

## A.M.I. Solutions for Treating Pelvic Organ Prolapse (POP)

### Publications Overview

#### BSC Mesh

No	Author Date	Title	Follow-up	Sample Size	Anatomical / Objective Success	Patient Satisfaction / Subjective Success	Mesh Erosion	Post-operative results, Complications	Conclusion
15	Castaño et al. Published 2015	Colposuspensión bilateral del ligamento sacroespinoso con malla BSC asociada a colporrafía anterior para el tratamiento del prolapso anterior y apical. Nuestra experiencia	6 months	22 (15 in FU)	80.0%	86.6%	0.0%	<ul style="list-style-type: none"> <li>• No reoperations</li> <li>• 9% Urinary tract infection</li> <li>• 40% Incontinence</li> </ul>	Surgical repair of prolapse by BSC + anterior colporrhaphy is effective, with acceptable postoperative complications and operative time, a high percentage of satisfaction (86%), recurrences to a lesser degree than previously with 80% success and without reintervention
16	Ollig et al.* Published 2014	Die Kolposuspension mit BSC direct – Minimal invasiv, maximal effektiv	12 months	154	–	90.0% of patients describe the post-operative result as very good or good	One erosion after spontaneous delivery	No implant infections, hematomas requiring revision or bowel perforations	BSC direct is a safe methode for vaginal fixation. The finger-wide, minimally invasive access route reduces surgical dissection to a minimum with maximum stability of results

\* Translation of results

# A.M.I. Solutions for Treating Pelvic Organ Prolapse (POP)

Publications Overview

Urogynecology

## InGYNious

No	Author Date	Title	Follow-up	Sample Size	Anatomical / Objective Success	Patient Satisfaction / Subjective Success	Mesh Erosion	Post-operative results, Complications	Conclusion
1	Banasiuk et al. 2024	Mobility of the bladder neck after surgical pop repair	–	N = 195 patients with pelvic organ prolapse, (29 recto-vaginal fascia plication, 63 pubo-vesical fascia plication, 63 cervicosa-cropeksy, and 36 anterior vaginal mesh implantation InGYNious anterior A.M.I.)	After InGYNious anterior implantation bladder neck position was higher (5,20+/-11,4 vs 10,8+/-6,6; p< 0,05) with no impact on bladder neck mobility	–	–	–	Bladder neck mobility restriction is one of the important factors deteriorating sling procedure efficiency. Therefore, in case of coexisting problems it should be taken onto consideration while planning anti incontinence procedure
2	Kalata et al. 2024	The Influence of Successful Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse on Depression, Anxiety, and Insomnia-A Prospective Intervention Impact Assessment Study	–	N= 187 POP-group (including NTR N=76, lapSCP N=83 and TVM with InGYNious anterior N=28)	–	–	–	–	Significant lower STAI (anxiety score), no difference regarding depression score (CESD), and minor difference (not significant) regarding insomnia (ISI score)
3	Pycek et al. 2024	Effectiveness and safety of single incision, six-point fixation transvaginal mesh InGYNious anterior (A.M.I) in pop surgery	4-12 months	86	Significant improvement of POP-Q values (Ba, C, Bp); significant improvement in POPDI score	–	2.30%	<ul style="list-style-type: none"> <li>• 2.3% hematoma</li> <li>• 2.3% voiding dysfunction</li> <li>• 2.3% ureter kinking which required mesh explantation</li> <li>• 1.15% recurrence</li> </ul>	IngyNious anterior is a highly effective system as far as objective and subjective results are concerned. The risk of urether kinking as the most serious complication seems to be an obligatory indication to pre and post-operative kidney US examination

**A.M.I. Solutions for Treating Pelvic Organ Prolapse (POP)**

Publications Overview

Urogynecology

**InGYNious**

No	Author Date	Title	Follow-up	Sample Size	Anatomical / Objective Success	Patient Satisfaction / Subjective Success	Mesh Erosion	Post-operative results, Complications	Conclusion
4	Siarkowska et al. 2024	Evaluation of the therapeutic effectiveness of a 6-point vaginal mesh in the treatment of high degree pelvic organ prolapse	2-60 months	85	15.29% recurrence rate	–	–	9.4% post OP complication rate	In this retrospective study, the investigated recurrence rate was low. All patients included in the study underwent at least one natural labour, though there was no significant difference between the number of labours, POPQ stage or BMI and the recurrence rate
5	Nemeth et al. 2024	Single-incision vaginal mesh insertion for recurrent vaginal vault prolapse after radical cystectomy and radical hysterectomy with irradiation: A case report	48-50 months	1	No recurrence	PGI-I = 1 (very much better)	No mesh erosion	–	Transvaginal surgery using single – incision customized vaginal mesh reinforcement may be the preferred surgical approach to repair of POP in women who have RC (radical robot assisted cystectomy) and IC (ileal conduit) especially after previous brachytherapy due to invasive cervical cancer in the medical history

**InGYNious**

No	Author Date	Title	Follow-up	Sample Size	Anatomical / Objective Success	Patient Satisfaction / Subjective Success	Mesh Erosion	Post-operative results, Complications	Conclusion
6	Evseev et al. 2022	Role of ultrasound in evaluating the effectiveness of treatment of patients with pelvic organ prolapse and urinary incontinence	6-21 months	N = 96 N = 45 with InGYNious, N = 51 with OPUR	7.3% POP recurrence	–	–	–	Ultrasound is an informative method for diagnosing POP and various types of incontinence. Based on objective parameters (α- and β-angle) it is possible to assess the effectiveness of mesh implant installation in peri- and postoperative periods, diagnose hematomas as the cause of dysuric disorders, and identify ultrasound markers of incontinence
7	Deltetto et al. 2021	Efficacy and safety of an ultralight, six-point, polypropylene vaginal mesh in the treatment of urogenital prolapse	Mean follow-up 22 ± 8.4 months	438	<ul style="list-style-type: none"> <li>• 77.6% Anterior compartment</li> <li>• 81.5% Apical compartment</li> <li>• 72.2% Posterior compartment</li> </ul>	Overall satisfaction rate was high- Urinary and bowel symptoms significantly reduced	0.9%	–	In the mid-term follow-up, objective and subjective outcomes of the InGYNious anterior mesh as surgical approach for the repair of POP were excellent with very low rates of mesh-related problems or reoperation for recurrent POP
8	Kuszka et al. Published 2020	3-Year outcome after treatment of uterovaginal prolapse with a 6-point fixation mesh	36 months	254 patients 179 patients at follow-up	91.0% All POP-Q measurements, urge urinary incontinence and voiding dysfunction were significantly improved	–	0.0%	<ul style="list-style-type: none"> <li>• No serious adverse events occurred</li> <li>• 16 patients underwent reoperation for recurrent or de novo prolapse (12/16 in posterior compartment)</li> </ul>	In this study, the objective outcome three years after anterior POP repair with the InGYNious transvaginal mesh was good. The reoperation rate both for mesh related problems or prolapse were rare

## A.M.I. Solutions for Treating Pelvic Organ Prolapse (POP)

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### InGYNious

No	Author Date	Title	Follow-up	Sample Size	Anatomical / Objective Success	Patient Satisfaction / Subjective Success	Mesh Erosion	Post-operative results, Complications	Conclusion
9	Le Meur et al. Published 2020	Transvaginal mesh in pelvic organ prolapses: 2017-2019 Retrospective analysis	–	28	–	–	–	<ul style="list-style-type: none"> <li>• 7.1% bladder lesion, no serious postOP complications</li> <li>• 3.6% reoperation (due to mesh overtension)</li> </ul>	Vaginal meshes are used in well defined circumstances when promotofixation is contraindicated
10	Horosz et al. Published 2020	Does Previous Pelvic Organ Prolapse Surgery Influence the Effectiveness of the Sub-Urethral Sling Procedure	6-12 months	24 patients treated with InGYNious	95.8% (SUI cure rate)	Significant improvement in the quality of life	–	–	The same high objective cure rate in patients who had previously undergone POP repair as in those who underwent primary sling implantation were obtained. The results were not influenced by the type of prolapse reconstruction
11	Brandt et al. 2019	1-Year Outcome After Treatment of Uterovaginal Prolapse With a 6-Point Fixation Mesh	12 months	278 (254 in FU)	93% objective success rate (POP-Q) Anatomical success: <ul style="list-style-type: none"> <li>• 79% in ant. compartment</li> <li>• 83% in apical comp.,</li> <li>• 73% in ant. + apical compartment</li> </ul>	–	1.6%	<ul style="list-style-type: none"> <li>• 7% intraOP complications</li> <li>• no serious adverse event in FU</li> <li>• late postOP complications (1-y. FU): 2.4% reoperation due to recurrent POP 1.6% mesh protrusion 3.9% persistent pelvic pain with a median pain score of 2.5 on the VAS</li> </ul>	6-point fixation surgery using a light-weight mesh could be an alternative for women with POP, especially in recurrent POP, with a good anatomical outcome and a low rate of mesh-related complications

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### InGYNious

No	Author Date	Title	Follow-up	Sample Size	Anatomical / Objective Success	Patient Satisfaction / Subjective Success	Mesh Erosion	Post-operative results, Complications	Conclusion
12	Mangano et al. Published 2019	More than a sacro-spinous ligament fixation for prosthetic treatment of utero-vaginal prolapse: a six-point fixation mesh	1-19 months	84	Significant for anterior compartment, posterior compartment and vaginal apex/uterine cervix	–	<ul style="list-style-type: none"> <li>• 4.8% transient mesh exposition</li> <li>• 1.2% persistend mesh</li> </ul>	<ul style="list-style-type: none"> <li>• 3.6% voiding difficulties,</li> <li>• 3.6% hematomas (2 cases resolved spontaneously, 1 case required surgery (IIIA))</li> <li>• 2.4% major complications (Clav.D. grade III)</li> <li>• 4.8% de novo SUI</li> <li>• 2.4% dysuria,</li> <li>• 0% urinary retention</li> </ul>	Our retrospective study demonstrates that this six-arms mesh is safe in a short time period and it let to obtain an appropriate anatomic correction even saving the uterus
13	Evseev et al. Published 2019	Assessment of the effectiveness of surgical treatment of pelvic organ prolapse using mesh implants	6-21 months	64 patients 17 patients treated with InGYNious	97% objective cure rate in long-term FU (6-21 months) according to ultrasound data	–	–	No intraoperative complications	Ultrasound is an informative method for diagnosing POP and various types of incontinence. Based on objective parameters ( $\alpha$ - and $\beta$ -angle) it is possible to assess the effectiveness of mesh implant installation in peri- and postoperative periods, diagnose hematomas as the cause of dysuric disorders, and identify ultrasound markers of incontinence
14	Niesel et al.* Published 2018	Beckenbodenrekonstruktion mit dem Polypropylen-Netz InGYNious 1 Jahr follow-up	1 year	277	–	Significant improvement in the quality of life	1.6%	Revisions 3.3% (of which 5/8 due to hematoma)	Significant improvement of quality of live, including sexuality. Prolapse recurrent in 3.3% with low erosion rate of 1.6%. Low, non mesh-specific complication rate

## A.M.I. Solutions for Treating Pelvic Organ Prolapse (POP)

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Urogynecology

### InGYNious

No	Author Date	Title	Follow-up	Sample Size	Anatomical / Objective Success	Patient Satisfaction / Subjective Success	Mesh Erosion	Post-operative results, Complications	Conclusion
15	Ulrich et al. Published 2018	Objective outcome after vaginal mesh with 6 point fixation at 1 year follow-up	12 months	247 patients at follow-up	Anatomical success at the latest follow up visit was 95.0%; for both the anterior and apical compartments	Quality of life increased significantly after one year	1.6%	Intra-operative complications occurred rarely	InGYNious vaginal mesh could be an option for women requiring prolapse surgery
16	Brandt et al. 2018	Treatment of Pelvic Organ Prolapse using a lightweight modified HexaPro Mesh <b>Description of surgical procedure</b>	–	–	–	–	–	–	Procedure of using the modified InGYNious mesh placement as described provides a standardized basis for an evaluation utilizing an advanced prosthetic material (new light-weight material)
17	Fünfgeld* Published 2018	Lebensqualität in allen gemessenen Bereichen verbessert	12 months	277 (254 in FU)	93.1% (anterior + apical)	Significantly improved quality of life	1.6%	<ul style="list-style-type: none"> <li>• 6% bleeding</li> <li>• 0.8% bladder lesion</li> <li>• 8.25% de novo stress urinary incontinence</li> </ul>	Patients benefit from improved quality of life with a low rate of side effects and reduced risk of recurrence. For original study results see Brandt et al. 2019 (12m FU) and Kuszka et al. 2020 (36m FU)

## A.M.I. Solutions for Treating Pelvic Organ Prolapse (POP)

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### InGYNious

No	Author Date	Title	Follow-up	Sample Size	Anatomical / Objective Success	Patient Satisfaction / Subjective Success	Mesh Erosion	Post-operative results, Complications	Conclusion
18	Bononi et al. 2014	Transvaginal repair of genital prolapse: preliminary results of a new vaginal mesh (InGYNious technique) [Riparazione transvaginale del prolasso genitale: risultati etrospecti di una nuova mesh vaginale (tecnica InGYNious)]	12 months	58 (51 in FU)	No anatomical recurrence	92%	0%	<ul style="list-style-type: none"> <li>• No hematomas</li> <li>• 1.7% ureter kneeling</li> <li>• 5.2% sciatic pain early postoperative</li> <li>• 3.4% De novo stress urinary incontinence</li> </ul>	The InGYNious technique is a safe and effective new technique for the correction of genital prolapse with an acceptable complication rate and in line with current literature
19	Mistrangelo et al. Published 2014	InGYNious single-incision advanced pelvic floor repair with hexapro-mesh	12 months	122 (98 in FU)	93.9%	–	2%	<p>intraOP: 0.8% bladder perforation</p> <p>early postOP: 25.4% transient pelvic pain</p>	The InGYNious procedure is a minimally invasive technique for the treatment of pelvic prolapse through a single vaginal incision. Initial results show that the procedure is safe and provides very good anatomical results at short-term follow-up

**InGYNious**

No	Author Date	Title	Follow-up	Sample Size	Anatomical / Objective Success	Patient Satisfaction / Subjective Success	Mesh Erosion	Post-operative results, Complications	Conclusion
20	Febo et al. 2014	Surgical treatment of pelvic floor defects: our experience [Trattamento chirurgico dei difetti del pavimento pelvico: la nostra esperienza]	12 months	59 (55 in FU)	–	Mean subjective degree of satisfaction 4.5 (scale 1-5)	0.0%	<ul style="list-style-type: none"> <li>• One intraOP complication</li> <li>• 1.7% small bladder injury</li> <li>• No erosion</li> <li>• No pain or dyspareunia</li> <li>• No surgical revisions or removal of mesh attachment points</li> <li>• At 1y FU: none prolapse recurrence; 2x (3.4%) de novo asymptomatic grade II rectocele (previously treated only with anterior mesh)</li> <li>No exposure or migration</li> <li>Sexual function – 100% of sexual active patients prior to OP continued with sexual activity; 10.9% reported improvement in sexual function</li> </ul>	The InGYNious procedure is a minimally invasive technique for the treatment of pelvic floor prolapse through a single vaginal incision. Initial results show that this procedure is safe and promising in terms of efficacy. Longer-term follow-up is currently underway

\* Translation of results

# A.M.I. Solutions for Treating Pelvic Organ Prolapse (POP)

Publications Overview

Urogynecology

## InGYNious Posterior

No	Author Date	Title	Follow-up	Sample Size	Anatomical / Objective Success	Patient Satisfaction / Subjective Success	Mesh Erosion	Post-operative results, Complications	Conclusion
1	Zarzecka et al. 2024	Effectiveness and safety of transvaginal mesh inGYNious posterior (a.m.i.) in enterocoele surgery	4-12 months	23	Significant improvement in POP-Q values (Bp, C, Ba) and significant improvement in POPDI score	–	4.3% (one case)	<ul style="list-style-type: none"> <li>• 4.3% erosion</li> <li>• 4.3% mesh removal</li> <li>• 17.4% recurrence (in anterior compartment!)</li> </ul>	InGYNious posterior is effective system as far as objective and subjective results in enterocoele surgery is concerned. No dyspareunia de novo was observed
2	Deltetto et al. Published 2021	Effectiveness and Safety of Posterior Vaginal Repair with Single-Incision, Ultralightweight, Monofilament Propylene Mesh: First Evidence from a Case Series with Short-Term Results	18 months	15	<ul style="list-style-type: none"> <li>• Significant improvement according POP-Q in Bp Ap, D, and C</li> <li>• Functional outcomes were significantly ameliorated after surgery</li> </ul>	100.0% Quality of life was significantly improved	0.0%	No early or late post-operative complications occurred	Single-incision, ultralightweight polypropylene meshes were safe and highly effective in the treatment of PVP (Posterior Vaginal Prolapse)
3	Deltetto et al. 2014	Transvaginal repair of posterior genital prolapse (enterocoele) by fascial colposuspension to the retrospective muscles and sacrospinous ligaments, comparison of fascial and prosthetic technique (posterior InGYNious) [Riparazione transvaginale del prolasso genitale etrospec (enterocoele) mediante colposospensione fasciale ai muscoli ileococcigei e ai etrospe sacrospinosi, etrospe tra tecnica fasciale e tecnica protesica InGYNious etrospec]]	–	30 (Gr. 1= 15, Gr. B = 15)	–	All patients were satisfied (100%)	0%	No erosions, no hematomas, no recurrences observed for both technique	Both fascial and prosthetic techniques are safe and effective techniques for the correction of posterior genital prolapse. The complication rate of both is acceptable and in line with current literature

**i-Stitch**

No	Author Date	Title	Follow-up	Sample Size	Anatomical / Objective Success	Patient Satisfaction / Subjective Success	Peri-OP Outcome	Post-operative results, Complications	Conclusion
1	Peschers et al. Start study date 2025 <b>Ongoing</b>	i-Stitch for Bilateral Sacrospinous Ligament Fixation (SSLF)  <a href="https://clinicaltrials.gov/study/NCT06805006">https://clinicaltrials.gov/study/NCT06805006</a>	Planned FU: 12 months	Estimated target size: 100	–	–	–	–	–
2	Popov et al. 2024	Application of anterior bilateral sacrospinous fixation in the treatment of apical genital prolapse	12 months	<ul style="list-style-type: none"> <li>• N=155, Gr. 1 (LPSSF)</li> <li>• N=34, Gr. 2 (LASSF with i-Stitch)</li> <li>• N=42, Gr. 3 (MESH TASSF)</li> <li>• N = 79</li> </ul>	Recurrence: 58.8% Gr. 1 vs. 11.9% i-Stitch Gr. 2 vs. 3.8% Gr. 3	–	Duration of surgery: Gr. 1 58.4 min, Gr. 2 with i-Stitch 54.0 min, Gr. 3 51.6 min; Blood loss: Gr. 1 85.7 mL, Gr. 2 with i-Stitch 74.8 mL, Gr. 3 60.6 mL; Hospital stay: Gr. 1 4.2 days, Gr. 2 with i-Stitch 3.4 days, Gr. 3 3.1 days	No periOP complications; acute urinary retention: Gr. 1 23.5%, Gr. 2 with i-Stitch 14.3%, Gr. 3 1.3%; bladder hypotonia: Gr. 1 41.2%, Gr. 2 with i-Stitch 28.6%, Gr. 3 8.9%; hematoma: Gr. 1 35.3%, Gr. 2 with i-Stitch 28.6%, Gr. 3 27.8%; gluteal pain: Gr. 1 47.1%, Gr. 2 with i-Stitch 23.8%, Gr. 3 6.3%; suture extrusion: only Gr. 3 1.3%	Anterior bilateral SSF method using synthetic MESH TASSF tape is clinically effective, relatively safe, and contributes to a markedly reduced rate of disease relapses. Anterior sacrospinous fixation using the i-Stitch device has a better outcome than posterior sacrospinous fixation using Miya hook or special stitching devices
3	Amiri et al. 2024	Comparison of the complications rate of different suture-passing techniques at the time of sacrospinous ligament fixation: a systematic review and meta-analysis	–	Data from 125 studies including 10,216 cases	Overall reOP rate: 1.2%	–	–	<ul style="list-style-type: none"> <li>• Overall nerve injury rate 3.8% (Capiro: 8.5%, i-Stitch 5.1%, Miya hook 4.9%, 4.7% direct visualization)</li> <li>• Overall hematoma rate: 1.7%</li> </ul>	Complications related to suture passing are increased when suture capturing is the method applied in passing the suture through the sacrospinous ligament

**i-Stitch**

No	Author Date	Title	Follow-up	Sample Size	Anatomical / Objective Success	Patient Satisfaction / Subjective Success	Peri-OP Outcome	Post-operative results, Complications	Conclusion
4	Chene et al. 2024	The minimally invasive sacrospinous fixation under visual guidance: An anatomical study	–	Anatomical study (3 female cadavers)	NanoScope was used for real-time visualization of the I Stitch™ and SSL	–	–	–	This new innovative minimally invasive technology using both a suture capturing device and a chip on-the-tip endoscope is relevant and could be an advantage in terms of safety and better placement of the suture on the sacrospinous ligament
5	De Gracia et al. 2023	Serious Complications and Recurrence following Sacrospinous Ligament Fixation for the Correction of Apical Prolapse	29.3 months	N=1359; 13.5% i-Stitch (others: 52.8% Capio/Capio SLIM, 17.6% needle holder, 15.7% Digitex, 0.4% not defined)	3.2% reoperation rate	–	Mean surgical time = 76.1 (±31) minutes, with no significant differences between groups, mean estimated blood loss was 59.7 (±81.7) mL, with a significantly higher estimated loss after an anterior SSLF with mesh and less blood loss with posterior SSLF with mesh	Clavien-Dindo grade II or higher: 2.5%; Complications: 0.44% vaginal mesh exposure, 0.44% Bladder injury, 0.37% Urinary retention, 0.29% Ureteral obstruction, 0.22% Delayed wound of healing or granuloma, 0.15% Hematoma, 0.15% Vaginal suture bleeding, 0.15% Thigh pain, 0.07% Bladder clot removal	SSLF is an effective and safe surgical treatment for apical prolapse. The different surgical approaches, anterior/posterior and with/without mesh were comparable regarding the rate of serious complications

## A.M.I. Solutions for Treating Pelvic Organ Prolapse (POP)

Publications Overview

Urogynecology

### i-Stitch

No	Author Date	Title	Follow-up	Sample Size	Anatomical / Objective Success	Patient Satisfaction / Subjective Success	Peri-OP Outcome	Post-operative results, Complications	Conclusion
6	Haşegan et al. 2017	Minimally invasive treatment of urogenital prolapse using AMI i-Stitch	18 months	N = 57 (N=22 (38.6%) classical fixation technique; n = 35 (61.4%) A.M.I. i-Stitch	–	–	<p>Mean OP time: 70.5 min Classical technique vs. 48.5 min i-Stitch;</p> <ul style="list-style-type: none"> <li>• mean blood loss: 270 mL classical technique, 140 mL i-Stitch;</li> <li>• postOP pain: 68.2% classical technique vs. 14.3% i-Stitch;</li> <li>• hospital stay: 4.1 days classical technique vs. 3.2 days i-Stitch</li> </ul>	<p>Urinary tract infections: 13.6% classical technique, 5.7% i-Stitch;</p> <ul style="list-style-type: none"> <li>• persistent SUI: 4.5% classical technique, 0% i-Stitch</li> <li>• incomplete urinary retention: 0% classical technique, 2.9% i-Stitch</li> </ul>	<p>i-Stitch is a safe device for sacrospinous ligament access, reducing the pelvic floor dissection with minimal blood loss, short operative time and minimal postoperative pain. The technique of fixing the polypropylene mesh to the bilateral sacrospinous ligament using the i-Stich device is an efficient and rapid treatment, with a low risk of recurrence and complications, allowing the cure of associated urinary tract disorders during the same intervention</p>

# A.M.I. Solutions for Treating Pelvic Organ Prolapse (POP)

Publications Overview

Urogynecology

## EndoGYNious

No	Author Date	Title	Follow-up	Sample Size	Anatomical / Objective Success	Patient Satisfaction / Subjective Success	Mesh Erosion	Post-operative results, Complications	Conclusion
1	Heindl et al. Start study date 2024 <b>Ongoing</b>	Retrospective Data Analysis PelviGYNious/ EndoGYNious  <a href="https://clinical-trials.gov/study/NCT06927752">https://clinical-trials.gov/study/NCT06927752</a>	Planned FU: 12 months	Target size: 80	–	–	–	–	–
2	Aichner et al. Published 2024	Analysis of the Clinical Value of Laparoscopic Sacrocolpopexy to Support the Posterior Compartment in Women with Multicompartment Prolapse Including Rectocele	6-12 weeks	112	A significant (p < 0.001) objective improvement of POP values regarding all three compartments (Ba, C, and Bp) was seen postoperatively compared with preoperatively	Subjective reported POP symptoms improved significantly (p < 0.001) postoperatively	–	–	Nerve-sparing sacrocolpopexy alone appears to be a suitable surgical approach to correct multicompart ment prolapse, including a rectocele ≥ stage II, and results in a reduction of objective signs and symptoms of pelvic organ prolapse
3	Studer et al. Published 2024	Recurrent Pelvic Organ Prolapse after Sacrocolpopexy—A Surgical Challenge	No FU	8 (reSCP)	reSCP has high subjective and objective success rates	–	One case of mesh exposure (1/8) which required partial mesh excision	reSCP has a low intraoperative complication rate. Two cases (2/8) of bladder injury occurred during reSCP	Individualized reSCP after initial SCP is a challenging yet feasible and safe treatment option, but there may be suitable alternatives

**A.M.I. Solutions for Treating  
Pelvic Organ Prolapse (POP)**

Publications Overview

Urogynecology

EndoGYNious

No	Author Date	Title	Follow-up	Sample Size	Anatomical / Objective Success	Patient Satisfaction / Subjective Success	Mesh Erosion	Post-operative results, Complications	Conclusion
4	Aichner et al. Published 2022	Impact of sacrocolpopexy for the management of pelvic organ prolapse on voiding dysfunction and uroflowmetry parameters: a prospective cohort study	6-12 weeks	103	All points of the POP-Q system improved significantly pre- to postoperatively (p < 0.001)	Subjective outcome measurements (weak or prolonged stream, incomplete bladder emptying, and straining to void) improved significantly (p < 0.001 for all the questions)	–	Postoperative postvoid residual and voiding time decreased significantly	Sacrocolpopexy for pelvic organ prolapse correction can successfully resolve voiding dysfunction (objective and subjective parameters improved significantly after surgery)
5	Faehnle-Schiegg et al. Published 2022	Prospective Evaluation of Laparoscopic Sacrocolpopexy with Concomitant Laparoscopic-Assisted Total Vaginal Hysterectomy	6-12 weeks	50	Complete repair of prolapse for all three compartments	Significant improvement	0.0%	No severe adverse events	Laparoscopic SCP with concomitant LAVH (Laparoscopic-Assisted total Vaginal Hysterectomy) showed no increased risk of mesh extrusion and good objective and functional outcomes

# A.M.I. Solutions for Treating Pelvic Organ Prolapse (POP)

Publications Overview

Urogynecology

## EndoGYNious

No	Author Date	Title	Follow-up	Sample Size	Anatomical / Objective Success	Patient Satisfaction / Subjective Success	Mesh Erosion	Post-operative results, Complications	Conclusion
6	Christmann-Schmid et al. Published 2018	Functional outcome after laparoscopic nerve-sparing sacrocolpopexy: a prospective cohort study	6-12 weeks	137	Significant objective improvement for POP-Q points Aa, Ap and C ( $p < 0.0001$ ) preoperatively to postoperatively	All women showed a significant ( $p < 0.001$ ) improvement in all four domains of the German Female Pelvic Floor Questionnaire, including a sub-analysis of the dyspareunia rate	–	Significant improvement in bladder and bowel function (improved fecal incontinence symptoms 76.5%, resolution of pre-existing obstipation 73.5%). Complications during short-term FU: <ul style="list-style-type: none"> <li>• De novo OAB 0.7%</li> <li>• De novo bladder outlet obstruction 0.7%</li> <li>• De novo SUI 6.8%</li> <li>• De novo constipation 5%</li> <li>• De novo bowel incontinence 0%</li> </ul>	A nerve-sparing technique for sacrocolpopexy results in low de novo bladder and de novo bowel dysfunctions
7	Christmann-Schmid et al. Published 2018	Laparoscopic sacrocolpopexy with or without midurethral sling insertion: Is a two-step approach justified? A prospective study	6-10 weeks	62	–	–	0.0%	No severe intra-operative complications	Women with POP with concomitant stress urinary incontinence undergoing sacrocolpopexy benefitted from a two-step approach as only 11% needed an additional incontinence procedure

# A.M.I. Solutions for Treating Pelvic Organ Prolapse (POP)

Publications Overview

Urogynecology

## PelviGYNious

No	Author Date	Title	Follow-up	Sample Size	Anatomical / Objective Success	Patient Satisfaction / Subjective Success	Mesh Erosion	Post-operative results, Complications	Conclusion
1	Heindl et al. Start study date 2024 <b>Ongoing</b>	Retrospective Data Analysis PelviGYNious/ EndoGYNious  <a href="https://clinicaltrials.gov/study/NCT06927752">https://clinicaltrials.gov/study/NCT06927752</a>	Planned FU: 12 months	Target size: 80					
2	Bousouni & Sarlos Published in 2022	Lateral extension and attachment of mesh to the lateral vagina during laparoscopic sacro-colpopexy: a modified technique aimed at lowering recurrences in the anterior vaginal compartment. A surgical video	No FU	N = 1 (Case Report)	Significant improvement in anatomical outcome in the anterior compartment for short-term FU	–	–	Excellent perioperative results with very rare intraoperative complications	Paravaginal dissection and exposure of the ureters to extend the mesh placement and fixation to the lateral border of the vagina in the anterior compartment during laparoscopic sacrocolpopexy seem to be feasible and safe, helping to significantly reduce the risk of anterior recurrences. Prospective data are needed to evaluate this interesting technique

**A.M.I. Solutions for Treating  
Pelvic Organ Prolapse (POP)**

Publications Overview

Urogynecology

**PelviGYNious**

No	Author Date	Title	Follow-up	Sample Size	Anatomical / Objective Success	Patient Satisfaction / Subjective Success	Mesh Erosion	Post-operative results, Complications	Conclusion
3	Mikkola et al. Start study date 2020 <b>Ongoing</b>	Women's Apical Pelvic Organ Prolapse Treatment - a Randomized Controlled Trial Comparing Transvaginal and Laparoscopic Mesh Surgery  <a href="https://clinicaltrials.gov/study/NCT04478747">https://clinicaltrials.gov/study/NCT04478747</a>	Planned FU: 5 years	Target size: 318 (total) 106 per group	–	–	–	–	–
4	Sarlos et al. Start study date 2015 <b>Ongoing</b>	Laparoscopic Supracervical Hysterectomy and Sacropexy Versus Hysteropexy Study (HysPex)  <a href="https://clinicaltrials.gov/study/NCT02345954">https://clinicaltrials.gov/study/NCT02345954</a>	Planned FU: 12 months	Target size: 100	–	–	–	–	–

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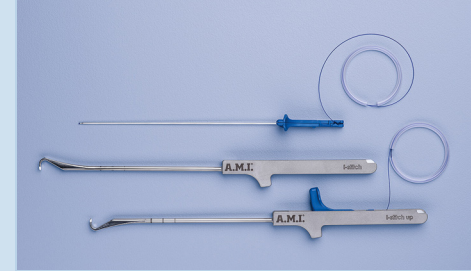
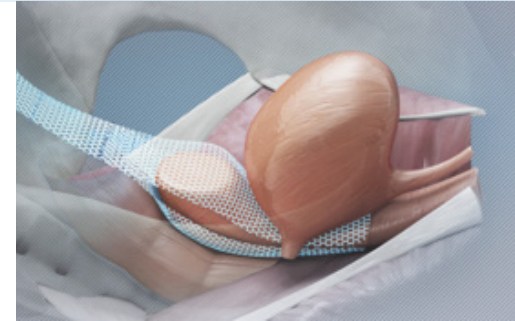
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