

Female Pelvic Medicine & Reconstructive Surgery

A minimally invasive technique for the one-stage treatment of complex pelvic floor diseases: Laparoscopic – Pelvic Organ Prolapse suspension (L- POPs) --Manuscript Draft--

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Abstract:	<p>Objective . The aim of this prospective study was to assess the safety and effectiveness of a new single laparoscopic operation devised to relieve obstructed defecation, gynecologic and urinary symptoms in a large series of female patients with multi-organ pelvic prolapse.</p> <p>Methods. We submitted 384 female patients to Laparoscopic Pelvic Organ Prolapse Suspension (L-POPS) operation, a new technique based on suspension of the middle pelvic compartment, by using a polypropylene mesh, and followed-up 368 of them, with defecography performed 12 months after surgery and a standardized protocol.</p> <p>Results. The 368 patients were followed-up for 36.3 (± 4.4) months, Recurrence rate was 4.9% for obstructed defecation syndrome and 3.3% for stress urinary incontinence. Complication rate was 2.9%. The mean period of daily activity resumption was 16.3 (± 4.8) days. Ano-rectal and uro-gynecologic symptoms and scores significantly improved after the operation ($P < 0.001$), with no worsening of anal continence. Incidence of postoperative fecal urgency was 0%. Postoperative defecography showed a significant ($P < 0.001$) improvement of all parameters in 315 patients (82%). SF36 Health Survey score significantly improved after the operation ($P < 0.01$). An excellent/good overall Satisfaction Index was reported by 78.0% of patients.</p> <p>Conclusions. In our experience the Laparoscopic-Pelvic Organ Prolapse Suspension seems to be safe and effective as a one-stage treatment of associated pelvic floor diseases. Randomized studies with an appropriate control group and longer follow-up are now needed to assess the effectiveness of this promising technique</p>
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1 **A minimally invasive technique for the one-stage treatment of complex pelvic floor**
2 **diseases: Laparoscopic – Pelvic Organ Prolapse suspension (L- POPs)**

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24 **Keywords:** pelvic organ prolapse, stress urinary incontinence, rectocele, rectal prolapse, laparoscopy

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27 **ABSTRACT**

28

29 *Objective* . The aim of this prospective study was to assess the safety and effectiveness of

30 a new single laparoscopic operation devised to relieve obstructed defecation, gynecologic

31 and urinary symptoms in a large series of female patients with multi-organ pelvic prolapse.

32 *Methods*. We submitted 384 female patients to Laparoscopic Pelvic Organ Prolapse

33 Suspension (L-POPS) operation, a new technique based on suspension of the middle

34 pelvic compartment, by using a polypropylene mesh and followed-up 368 of them, with

35 defecography performed 12 months after surgery and a standardized protocol.

36 *Results*. The 368 patients were followed-up for 36.3 (± 4.4) months, Recurrence rate was

37 4.9% for obstructed defecation syndrome and 3.3% for stress urinary incontinence.

38 Complication rate was 2.9%. The mean period of daily activity resumption was 16.3 (± 4.8)

39 days. Ano-rectal and uro-gynecologic symptoms and scores significantly improved after

40 the operation ($P < 0.001$), with no worsening of anal continence. Incidence of postoperative

41 fecal urgency was 0%. Postoperative defecography showed a significant ($P < 0.001$)

42 improvement of all parameters in 315 patients (82%). SF36 Health Survey score

43 significantly improved after the operation ($P < 0.01$). An excellent/good overall Satisfaction

44 Index was reported by 78.0% of patients.

45 *Conclusions*. In our experience the Laparoscopic-Pelvic Organ Prolapse Suspension

46 seems to be safe and effective as a one-stage treatment of associated pelvic floor

47 diseases. Randomized studies with an appropriate control group and longer follow-up are

48 now needed to assess the effectiveness of this promising technique.

49 **IN BRIEF**

50 The laparoscopic suspension of the middle pelvic compartment with the new L-POPs

51 technique is safe and gives good mid-term results in the one-stage treatment of associated

52 pelvic floor diseases.

53

54 **INTRODUCTION**

55

56 The prevalence of pelvic floor diseases, including pelvic organ prolapse (POP), stress
57 urinary incontinence (SUI), obstructed defecation syndrome (ODS) and fecal incontinence,
58 is very high: more than 23% of community-dwelling women will have at least one of these
59 conditions and the prevalence increases with age:¹ an epidemiologic study on the Swedish
60 female population showed 19% urinary incontinence, 23% gas incontinence, 6% solid
61 stools incontinence, and 14% digitations in over sixty-year old women.²

62 The association of two, or more, pelvic organ diseases in the same patient is very
63 frequent, reaching 20% of old resident women.³ In the study by Gonzales-Argente *et al.*,
64 50% of women with ODS due to rectal prolapse and rectocele, showed a concomitant
65 genital prolapse and 50% of women with SUI reported symptoms of ODS.⁴

66 About 30% of women operated on for POP need further pelvic surgery.⁵

67 A safe and effective surgical treatment of patients with associated pelvic floor diseases
68 would benefit of a multidisciplinary approach by a team of pelvic floor clinicians, including
69 gynecologist, urologist and colorectal surgeon. On the contrary, different specialists usually
70 treat these patients in two, or more steps, with different surgical procedures, complications
71 and outcomes.

72 In the last decades an incredible number of surgical techniques to treat pelvic floor
73 diseases have been described, but very few important studies on combined pelvic
74 approaches have been published. Firm recommendations as to the optimal treatment of
75 these conditions are yet to be developed.

76 In a previous study we demonstrated that combined rectal and urogynecologic one-stage
77 surgery, performed by the same surgical team with one, or two colorectal surgeons and
78 one urogynecologist, is safe and effective, and is associated with significant improvement
79 of symptoms, quality-of-life, radiological parameters, and with low recurrences at 2 years.⁶

80 The possibility to treat concomitant pelvic floor diseases with a single operation is very
81 attractive and laparoscopic techniques have all the theoretic requisites to reach this goal.
82 The Laparoscopic Pelvic Organ Prolapse Suspension (L-POPs), proposed by Antonio
83 Longo MD for the one-stage treatment of intussusception and rectocele even if associated
84 with SUI and/ or genital prolapse, consists of the preperitoneal positioning of a V-shaped
85 polypropylene mesh, with the vertex sutured to the vaginal and rectal wall and the lateral
86 edges to the external oblique muscle fascia bilaterally, so as to create the suspension of
87 the middle pelvic compartment. In the event of a residual symptomatic rectocele, STARR
88 procedure,⁷ or other form of rectocele repair can be considered.
89 In the present prospective study we report the clinical and functional results of L-POPs
90 operation in a large series of female patients with associated pelvic floor diseases.
91

92 **MATERIAL AND METHODS**

93

94 *Study Population and Inclusion Criteria*

95 Patients potentially candidates for the study were all women with association of rectal
96 intussusception/rectocele and 3rd, or 4th genital prolapse referred to the Proctologic &
97 Pelvic Surgery Unit of Humanitas Cliniche Gavazzeni,Bergamo .

98 These patients were recruited for the study on the basis of the following criteria :

99 *Inclusion criteria:*

100 Association of all the following conditions:

- 101 - internal rectal prolapse/intussusception and rectocele > 3cm ;
- 102 - continence score < 3 ;
- 103 - resting pressure < 40 mm/Hg and squeeze pressure >100 mm/Hg. The values
104 of resting and squeeze pressure were chosen to avoid an operation in patients
105 with sphincter defects and risk of postoperative fecal incontinence , or
106 patients with hypertonic and dissinergic sphincters with risk of postoperative
107 severe pain and fecal urgency;
- 108 - 3rd or 4th degree genital prolapse ;
- 109 - Patients with the additional concomitant presence of enterocele 3-5 cm at rest,
110 obstructing the rectum during straining, and/or SUI were also included. The
111 presence of SUI was an additional criteria: patients with
112 intussusception /rectocele with SUI, but without genital prolapse were
113 excluded from the study

114

115 *Exclusion criteria:*

- 116 - 1st or 2nd degree genital prolapse,
- 117 - overactive bladder syndrome, urinary tract infections,
- 118 - previous pelvic radiotherapy, pelvic neoplasms,

- 119 - pudendal neuralgia, puborectalis syndrome,
- 120 - absolute contraindications to surgery.

121 The following are the key elements of our standardized evaluation of the recruited patients:

122 1) Validated Renzi ODS⁸ and Wexner continence⁹ scores. The Longo ODS score^{7,10} even
123 though not yet validated, was also used, as we consider it more appropriate for our
124 patients. The score, showed in Table 1, explores 9 parameters, ranging from 0 to 40:
125 defecation frequency (0-3), intensity (0-2) and duration (0-2) of straining, feeling of
126 incomplete evacuation (0-3), recto-perineal discomfort (0-3), activity reduction (0-6), use of
127 laxatives (0-7), enema (0-7), and digitation (0-7).

128 2) Gynecological examination, with POP-Q (Pelvic Organ Prolapse Quantification System)
129 classification;¹²

130 3) Proctologic examination and proctoscopy

131 4) Urodynamic study with uroflowmetry, cystomanometry and residual urine volume to
132 exclude an overactive bladder syndrome in patients with SUI;

133 5) Quality of life with the validated SF36 Health Survey score;¹¹

134 6) Colonoscopy to exclude concomitant colorectal diseases;

135 7) Anorectal manometry to evaluate the integrity of anal sphincters;

136 8) Dynamic colpocystodefecography with opacification of small bowel (dynamic
137 pelvigraphy) to evaluate the grade of POP, the presence of morphological (rectocele, rectal
138 prolapse, intussusception) and/or functional (puborectalis syndrome, incontinence) rectal
139 disorders, and the presence of concomitant enterocele and/or cystocele. The following
140 defecography parameters were recorded: extent of rectal prolapse/ intussusception,
141 rectocele depth, perineum descent at rest and under strain, distance from the vaginal vault
142 to the pubis and to the sacrum. The three parameters of Dvorkin classification were used
143 to determine the extent of intussusception: anterior and posterior thickness of prolapsed
144 tissue (< 3mm = mucosal prolapse, > 3mm = full-thickness intussusception), distance from

145 the point of take-off of the intussusception to the anorectal junction, and intussusception
146 descent from the point of take-off to the most distal point of the intussusception;¹³
147 9) Patient Satisfaction Index, defined as follows: Excellent: no symptoms. Good: 1 episode
148 /month of ODS with use of laxatives. Fairly good: 2/3 episodes/month of ODS with use of
149 laxatives. Poor: more than 3 episodes/month of ODS with use of laxatives, or persistence
150 of other symptoms.

151 The Ethical Committee approved the study protocol. All patients gave written informed
152 consent. All patients were operated on by the same surgical team, using the technique
153 described below, with no modifications.

154 *Preoperative management*

155 An enema washing is carried out on the day before surgery. The procedure is performed
156 under general anesthesia. Immediately after the induction of anesthesia a Foley bladder
157 catheter 16Ch is introduced and the patient receives routine antibiotic prophylaxis with a
158 single shot of cefotaxime (2g) plus metronidazole (500 mg).

159 *Surgical technique*⁷(see video 1)

160 The L-POPs operation is performed with the patient in Lloyd-Davis and Trendelenburg
161 positions (30°). A Foerster sponge forceps with gauze is introduced in the rectum and a
162 uterine manipulator into the vagina to recognize the anterior rectal wall and the posterior
163 vaginal wall (or the vaginal vault in hysterectomized patients), respectively. A 13 mmHg
164 pneumoperitoneum is created after positioning an umbilical 12 mm trocar with an open
165 technique. A second 12 mm trocar is introduced through an incision in the right iliac fossa
166 and a third 5mm trocar is positioned in the left iliac fossa. The Douglas pouch is exposed
167 and a V-shaped mesh, with two 25 cm long and 2 cm wide branches is prepared. This is
168 obtained by folding a macroporous, square shaped, 30 cm x 30 cm polypropylene mesh,
169 (Microval , St Just Malmont, France) along the diagonal and then cutting a 2cm wide strip
170 along one of the two short sides of the triangle. The V-shaped mesh is then introduced in

171 the pelvis through the right trocar. The uterus is suspended to the anterior abdominal wall
172 with a straight transcutaneous needle. The uterine suspension is primarily used for
173 visualization. Concomitant SUI was not treated with a separate procedure, but suturing the
174 apex of the mesh to the anterior and lateral vaginal fornix wall with 2-0 Prolene stitches,
175 anteriorly to the uterus, after the dissection of vesico-uterine space: the same is done in
176 case of prevalence of anterior descent. In patients with predominant rectal prolapse the
177 apex of the mesh is sutured to the posterior vaginal fornix wall (or to the vaginal vault in
178 hysterectomized patients) with plicature of the peritoneum of the Douglas pouch: fixing the
179 vaginal vault to the cardinal ligaments is important to restore the De Lancey first level of
180 hysterocele. The 2-0 Prolene stitch is then also fixed to the peritoneum so as to cover the
181 anterior rectal wall, taking care of pushing the upper rectum with gauzed forceps
182 introduced in the rectal lumen, in order to show the peritoneum and to avoid perforating
183 the rectal wall. Normally two central and two lateral stitches are sufficient for correct
184 positioning of the V mesh apex. The distance from the vaginal attachment of the mesh to
185 the oblique external fascia is about 20 cm. Two bilateral incisions of the skin 2cm posterior
186 and superior to the anterior iliac spine and dissection with scissors of the fascia and the
187 muscular fibers of oblique muscle, allow reaching the preperitoneal space under
188 laparoscopic control. Taking care to avoid injury to the iliac vessels and ureter, dissection
189 of the lateral peritoneum and the broad ligament proceeds using a curved tip laparoscopic
190 needle holder, introduced into the preperitoneal tunnel. The right lateral aspect of the mesh
191 is gently pulled through the preperitoneal tunnel until the right external oblique muscle
192 fascia incision is reached. The same is done on the left side.

193 Before fixing the mesh to the fascia, with the patient in 50° Trendelenburg position, the
194 mesh is strained until the normal pelvic aspect is restored. In case of uterine retroversion
195 the round ligaments are shortened and attached to the mesh arms to restore the normal
196 anatomy of the middle pelvic compartment. The peritoneum is sutured with Vycril 2-0

197 stitches to cover the apex of the mesh. About 5 cm of the lateral aspects of the mesh are
198 exteriorized through the skin incisions, tunneled under the external oblique muscle fascia
199 and fixed with Vicryl 2-0 stitches. Finally, the trocar incisions are sutured.

200 *Postoperative management*

201 The patient is started on a clear liquid diet from the first postoperative day. Antibiotics are
202 continued for three days. Acetaminophen 1gr plus Ketorolac 30mg i.v., t.i.d is used for
203 postoperative pain control during hospitalization. Antithrombotic prophylaxis with
204 enoxaparin 4000 U/day for 12 days is administered.

205 *Follow-up*

206 Pre and postoperative assessments were conducted by one of the surgeons of the team.
207 Clinical examination is scheduled at 7 days and 1, 3, 6, 12 and 24 months after the
208 operation. A dynamic defecography is repeated 12 months after surgery.

209 Primary outcome measure is the rate of failure at 2 years' follow-up defined as the
210 persistence of any single or combination of the following conditions: ODS score > 5,
211 persistence of SUI, presence of vaginal discomfort and/or dyspareunia, residual mucosal
212 rectal prolapse > 2cm at proctoscopy, residual 2nd degree (or greater) genital prolapse at
213 clinical examination. Secondary outcome measures are: operative time, complications,
214 hospital stay, postoperative pain assessed using a NRS score (0 = no pain to 10 =
215 maximum pain), time to resumption of daily activity, ODS score, quality of life with the
216 SF36 Health Survey questionnaire, and patient overall Satisfaction index 12 months after
217 the operation. Patients who did not strictly follow the postoperative protocol were excluded
218 from the study: even skipping one the postoperative controls was considered a sufficient
219 condition for exclusion. However a phone call was performed in these cases to assess at
220 least the persistence of symptoms.

221 *Statistical Analysis*

222 Continuous data are shown as arithmetic mean (SD) and qualitative data as absolute and
223 percent frequencies. The statistical software package SPSS 24.0 for Windows 7
224 Professional (SPSS Inc. Chicago, IL, USA) is used. The two-sample t-test for unpaired
225 data, ANOVA for repeated measures and Chi Square test are used, as appropriate.
226 Differences are considered significant with values of $P < 0.05$.

227 **RESULTS**

228 *Preoperative data*

229 From January 2013 to June 2017, 384 women (mean age 68 years, range 42-77) were
230 selected through the above-described protocol and submitted to L-POPs. All patients had
231 ODS and symptomatic 3rd degree genital prolapse and 61 (15.9%) had also a SUI. The
232 BMI was 27.5 (± 2.1). Two hundred and fifty-three patients (66.0%) were multiparous, with
233 mean parity 2.5 (± 0.8); 169 patients (44.0%) had had a previous hysterectomy. The
234 incidence of preoperative symptoms is reported in Table 2. Mean resting and squeeze
235 pressures were 64.5(± 6.6) and 118.2(± 11.4) mmHg, respectively. Preoperative
236 defecography parameters are shown in Table 3.

237 *Operative data* (Table 4)

238 The ASA score was 2.6 (± 0.4). Mean operating time was 89 (± 5.9) minutes. There was no
239 operative mortality. Major complications requiring reoperation occurred in 11 pts (2.9%): 3
240 bleedings within the trocar site requiring hemostasis, 2 intestinal occlusions for peritoneal
241 adhesions treated with adhesiolysis, 2 bleedings for injury of the oblique muscle, 2 injuries
242 of the bladder sutured by cystoscopy and 1 infection of the mesh treated with mesh
243 removal the mesh. All reoperations were accomplished by laparoscopy. One right lower
244 limb deep venous thrombosis was treated with enoxaparin 6000 U/day for one month.
245 Mean hospital stay was 3.0 (± 0.6) days, mean VAS score during hospitalization was 3.6
246 (± 0.4) and no patient exceeded the daily dose of Acetaminophen 1gr plus Ketorolac 30mg
247 x3 i.v.

248 *Follow-up data*

249 Sixteen patients (4.2%) were excluded from the analysis for skipping one of the
250 postoperative examination: 5 patients skipped the 1st-month, 5 the 6th-month, and the
251 other 6 the 12th-month control. All of them were living in other regions of Italy far from our
252 Institutions. At a phone call after the missed control 2 out of the 16 had residual anorectal

253 symptoms.

254 The mean follow-up was 36.3 (± 4.4) months. Nineteen patients (4.9%) with persistence of
255 symptomatic rectal internal prolapse and/or rectocele with ODS score > 5 were submitted
256 to a STARR operation after 1- year follow-up. Two patients with residual SUI (3.3%) were
257 submitted to trans-obturator tape (TOT) sling.

258 The mean period of daily activity resumption was 16.3(± 4.8) days. Anal/rectal/uro-
259 gynecologic symptoms and ODS scores significantly improved after the operation
260 ($P < 0.001$) with no worsening of anal continence (Table 2). Incidence of postoperative fecal
261 urgency was 0%. Postoperative defecography showed a significant ($P < 0.001$) reduction
262 of all parameters in 315 pts (82%) with a strict correlation with symptoms relieve and
263 excellent/good Satisfaction Index. The mean reduction of the perineal descent was 3.0
264 (± 0.2) cm.

265 As shown in Table 5, quality of life by the SF36 Health Survey score significantly improved
266 after the operation ($P < 0.01$); 78.0% of patients reported an excellent/good overall
267 Satisfaction Index, 15.5% fairly good and 6.5% poor (Table 6)

268 **DISCUSSION**

269 The attempt to resolve frequently associated pelvic floor diseases with a single operation
270 is attractive for reducing morbidity and costs, and also considering the pathophysiology of
271 pelvic organ prolapse. Genital prolapse can, in fact, be considered a total pelvic prolapse
272 often including enterocele, cystocele, rectocele and rectal prolapse and the pelvic
273 surgeon's mission ideally should be to restore anatomy and function of the pelvis.
274 Traditional surgery for POP does not correct a concomitant rectal prolapse with ODS and
275 usually involves removal of the uterus, which is a very important organ for the anatomy of
276 the pelvis and the physiology of defecation.

277 In the last decade experience we studied a great number of patients with complex pelvic
278 floor diseases by a dynamic pelvigraphy and we observed that the uterus and the small
279 intestine assist the emptying of the bladder and the rectum. The rectal emptying begins
280 after an intense straining, which is completed by the action of the other pelvic organs, the
281 uterus moves towards the anterior compartment, compressing the bladder and stimulating
282 urination, while the small intestine, slipping on the uterus, seems contributing to squeeze
283 the sigma-rectum through the Douglas pouch, assisting the evacuation (as shown in video
284 2). In hysterectomized patients the bladder appears to be dilated and the sigmoid colon
285 interferes with bladder repletion and emptying. An enterocele can develop, compressing
286 the rectum and ODS can follow. The L-POPs aims at simultaneous correction of pelvic
287 multiorgan prolapse, preserving the uterus, which continues to divide the pelvis into an
288 anterior and a posterior compartment, modulating evacuation and urination.

289 We believe that fixation of the vaginal vault to the Mackenrodt ligaments is important for
290 restoring a normal pelvic floor anatomy, in the attempt to treat sexual, urinary and
291 defecatory symptoms. As demonstrated by De Lancey stretching and breaking of the
292 cardinal ligaments is the primary cause of hysterocele, while the other changes
293 (lengthening of utero-sacral ligaments, round and pubo-cervical ligaments etc.) are

294 secondary to the traction by the prolapsed uterus.¹⁴ Shortening the round ligaments during
295 the L-POPs operation is directed to correct the uterine retroversion. The L-POPs can be
296 successfully performed in hysterectomized patients too. Finally, in the event of a big
297 preoperative rectocele, or a rectocele residual to L-POPs, a STARR procedure can be
298 added.

299 Laparoscopy has all the theoretic benefits to be considered the ideal approach to the
300 pelvic floor for its minimal invasivity, the good exposition of the pelvis and the optimal
301 cosmetic impact. On the other hand, up to now laparoscopic techniques for corrective
302 pelvic floor surgery, showed many limitations and none offered a single-stage correction of
303 total pelvic prolapse.

304 In 1967 Kapandji described a Colpo-Isthmo-Cystopexy, with transverse sub-peritoneal
305 strips from the anterior superior iliac spines to the vagina, associated with Douglassectomy
306 and reconstruction of the round ligaments. The limits were the 4-hour operative time and
307 the excessive anterior shifting of the vagina, resulting in the widening of the recto-vaginal
308 space, which is a well-known open door for the onset of an enterocele.¹⁵

309 The Laparoscopic Colpo-Sacropexy (LCS) is technically difficult, requires high operative
310 skills and is not infrequently complicated by bladder injury (5%).¹⁶ Even if the reported
311 global success rate of LCS is very high, this operation cannot correct an associated
312 symptomatic rectal prolapse, and can even worsen the defecatory function due to partial
313 occlusion and stiffness of the Douglas pouch caused by the mesh.¹⁶ In case of
314 concomitant rectal prolapse the association of a rectopexy to LCS is technically feasible,
315 nevertheless it is well known that a rectopexy without resection could worsen an ODS,
316 independently from the technique used.¹⁷

317 Laparoscopic Lateral Suspension (LLS) , in which the mesh, fixed to the dissected anterior
318 and posterior vaginal wall, is laterally suspended to the abdominal wall, posterior to the
319
320

321 anterior superior iliac spine, is effective for repairing the vaginal wall prolapse, as well than
322 the traditional sacrocolpopexy, with lower complication rate, particularly regarding vascular
323 or nerve lesions. However the limits of this procedure are almost the same than LCS, as it
324 cannot correct an associated rectocele and can accelerate the onset of an enterocele and
325 a rectal prolapse.¹⁸ Furthermore, a 3.8% rate of mesh erosion after LLS was reported.¹⁹
326 The recent technique of Laparoscopic Vaginal Suspension and Rectopexy, which consists
327 in the fixation of three strips of polypropylene mesh to the posterior vaginal vault (or the
328 vaginal apex) and bilaterally to the sacral promontory, associated with a rectopexy, is
329 considered indicated in patients with full-thickness rectal prolapse and fecal incontinence
330 but not in patients with ODS.²⁰

331 The Laparoscopic Ventral Mesh Rectopexy (LVR), which is at reason very popular
332 because of the good results achieved in the cure of ODS and enterocele, is devised for
333 treating internal and external rectal prolapse and enterocele but does not entail the
334 correction of a concomitant 3rd/4th grade POP and/or cystocele. According to the proposing
335 author, about one in three patients will not benefit from surgery and careful selection of
336 indications is mandatory.^{21,22}

337 In our series, LPOPs was very effective in correcting the associated 3rd, or 4th degree
338 genital prolapse, ODS, and SUI with no mortality, low morbidity and only 2/61 patients
339 showing persistent urinary symptoms. We did not observe any erosion of the mesh in
340 vagina or rectum. Finally, the 19 patients (< 5 %) presenting recurrent ODS one year after
341 L-POPs were successfully submitted to a STARR.

342 There is common agreement that the difficulty in managing patients with associated pelvic
343 floor diseases with the very large number of one, two or more stage surgical approaches
344 described in Literature, prompt for the creation of pelvic surgery units, involving skilled
345 specialists dedicated to diagnosis and treatment of these conditions. However, in our
346 country only very few pelvic Units have been created, due to the lack of training, funding,

347 and regulations. A formal specialization in pelvic surgery does not exist in Italy and policy
348 and funding of this issue among the country's 20 Regions are not homogeneous.

349 The laparoscopic surgery of the pelvic floor requires specific surgical skills. Pucher *et al*
350 reported a learning curve from 25 to 30 cases based on operative time and length of stay,
351 with 3.2% of morbidity for laparoscopic ventral mesh rectopexy.²³ In our hand 15 to 20
352 cases were sufficient for L-POPs, considering our previous experience of colorectal
353 surgeons with training in laparoscopy and the more than 100 operations performed with
354 general urologists and gynecologists.

355 The collection of such a large series of patients with rigorous surgical indications in a
356 single center during a limited time frame was determined by the fact that our Unit is a
357 referral center in Italy with more than 50 % of our patients living in other Regions of the
358 country.

359 However, our study had some limitations, and namely: it is a non-randomized, unicentric
360 experience, without a control group, and follow-up was limited, Longo score has yet not
361 been validated and the assessments have been unblinded which cause a potential bias.

362 On the other hand, the series is very large and the operation, as well as the pre and
363 postoperative controls, were standardized with few drop-outs.

364

365 **CONCLUSIONS**

366 In our series The L-POPs operation proved to be a safe and effective cure of multiorgan
367 pelvic prolapse, followed by significant improvement of anal/rectal and uro-gynecological
368 symptoms and radiological parameters in the medium period. Multicentric randomized
369 studies comparing L-POPs with an appropriate control group and longer follow-up are now
370 needed to assess the real effectiveness of this promising technique.

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435

436 **LEGENDS**

437

438 Video 1 shows the steps of LPOP-s technique, using a polypropylene mesh, knitted in
439 double thread, with pore size 0.7mm

440 Video 2 shows a dynamic pelvigraphy in a patient with ODS and genital prolapse

1 **A minimally invasive technique for the one-stage treatment of complex pelvic floor**
2 **diseases: Laparoscopic – Pelvic Organ Prolapse suspension (L- POPs)**

3
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24 **Keywords:** pelvic organ prolapse, stress urinary incontinence, rectocele, rectal prolapse, laparoscopy

25

26 **Word count : 3634**

27 **ABSTRACT**

28

29 *Objective* . The aim of this prospective study was to assess the safety and effectiveness of

30 a new single laparoscopic operation devised to relieve obstructed defecation, gynecologic

31 and urinary symptoms in a large series of female patients with multi-organ pelvic prolapse.

32 *Methods*. We submitted 384 female patients to Laparoscopic Pelvic Organ Prolapse

33 Suspension (L-POPS) operation, a new technique based on suspension of the middle

34 pelvic compartment, by using a polypropylene mesh and followed-up 368 of them, with

35 defecography performed 12 months after surgery and a standardized protocol.

36 *Results*. The 368 patients were followed-up for 36.3 (± 4.4) months, Recurrence rate was

37 4.9% for obstructed defecation syndrome and 3.3% for stress urinary incontinence.

38 Complication rate was 2.9%. The mean period of daily activity resumption was 16.3 (± 4.8)

39 days. Ano-rectal and uro-gynecologic symptoms and scores significantly improved after

40 the operation ($P < 0.001$), with no worsening of anal continence. Incidence of postoperative

41 fecal urgency was 0%. Postoperative defecography showed a significant ($P < 0.001$)

42 improvement of all parameters in 315 patients (82%). SF36 Health Survey score

43 significantly improved after the operation ($P < 0.01$). An excellent/good overall Satisfaction

44 Index was reported by 78.0% of patients.

45 *Conclusions*. In our experience the Laparoscopic-Pelvic Organ Prolapse Suspension

46 seems to be safe and effective as a one-stage treatment of associated pelvic floor

47 diseases. Randomized studies with an appropriate control group and longer follow-up are

48 now needed to assess the effectiveness of this promising technique.

49 **IN BRIEF**

50 The laparoscopic suspension of the middle pelvic compartment with the new L-POPs

51 technique is safe and gives good mid-term results in the one-stage treatment of associated

52 pelvic floor diseases.

53

54 **INTRODUCTION**

55

56 The prevalence of pelvic floor diseases, including pelvic organ prolapse (POP), stress
57 urinary incontinence (SUI), obstructed defecation syndrome (ODS) and fecal incontinence,
58 is very high: more than 23% of community-dwelling women will have at least one of these
59 conditions and the prevalence increases with age:¹ an epidemiologic study on the Swedish
60 female population showed 19% urinary incontinence, 23% gas incontinence, 6% solid
61 stools incontinence, and 14% digitations in over sixty-year old women.²

62 The association of two, or more, pelvic organ diseases in the same patient is very
63 frequent, reaching 20% of old resident women.³ In the study by Gonzales-Argente *et al.*,
64 50% of women with ODS due to rectal prolapse and rectocele, showed a concomitant
65 genital prolapse and 50% of women with SUI reported symptoms of ODS.⁴

66 About 30% of women operated on for POP need further pelvic surgery.⁵

67 A safe and effective surgical treatment of patients with associated pelvic floor diseases
68 would benefit of a multidisciplinary approach by a team of pelvic floor clinicians, including
69 gynecologist, urologist and colorectal surgeon. On the contrary, different specialists usually
70 treat these patients in two, or more steps, with different surgical procedures, complications
71 and outcomes.

72 In the last decades an incredible number of surgical techniques to treat pelvic floor
73 diseases have been described, but very few important studies on combined pelvic
74 approaches have been published. Firm recommendations as to the optimal treatment of
75 these conditions are yet to be developed.

76 In a previous study we demonstrated that combined rectal and urogynecologic one-stage
77 surgery, performed by the same surgical team with one, or two colorectal surgeons and
78 one urogynecologist, is safe and effective, and is associated with significant improvement
79 of symptoms, quality-of-life, radiological parameters, and with low recurrences at 2 years.⁶

80 The possibility to treat concomitant pelvic floor diseases with a single operation is very
81 attractive and laparoscopic techniques have all the theoretic requisites to reach this goal.
82 The Laparoscopic Pelvic Organ Prolapse Suspension (L-POPs), proposed by Antonio
83 Longo MD for the one-stage treatment of intussusception and rectocele even if associated
84 with SUI and/ or genital prolapse, consists of the preperitoneal positioning of a V-shaped
85 polypropylene mesh, with the vertex sutured to the vaginal and rectal wall and the lateral
86 edges to the external oblique muscle fascia bilaterally, so as to create the suspension of
87 the middle pelvic compartment. In the event of a residual symptomatic rectocele, STARR
88 procedure,⁷ or other form of rectocele repair can be considered.
89 In the present prospective study we report the clinical and functional results of L-POPs
90 operation in a large series of female patients with associated pelvic floor diseases.
91

92 **MATERIAL AND METHODS**

93

94 *Study Population and Inclusion Criteria*

95 Patients potentially candidates for the study were all women with association of rectal
96 intussusception/rectocele and 3rd, or 4th genital prolapse referred to the Proctologic &
97 Pelvic Surgery Unit of Humanitas Cliniche Gavazzeni, Bergamo .

98 These patients were recruited for the study on the basis of the following criteria :

99 *Inclusion criteria:*

100 Association of all the following conditions:

- 101 - internal rectal prolapse/intussusception and rectocele > 3cm ;
- 102 - continence score < 3 ;
- 103 - resting pressure < 40 mm/Hg and squeeze pressure >100 mm/Hg. The values
104 of resting and squeeze pressure were chosen to avoid an operation in patients
105 with sphincter defects and risk of postoperative fecal incontinence , or
106 patients with hypertonic and dissinergic sphincters with risk of postoperative
107 severe pain and fecal urgency;
- 108 - 3rd, or 4th degree genital prolapse ;
- 109 - Patients with the additional concomitant presence of enterocele 3-5 cm at rest,
110 obstructing the rectum during straining, and/or SUI were also included. The
111 presence of SUI was an additional criteria ; patients with
112 intussusception /rectocele with SUI, but without genital prolapse were
113 excluded from the study

114

115 *Exclusion criteria:*

- 116 - 1st or 2nd degree genital prolapse,
- 117 - overactive bladder syndrome, urinary tract infections,
- 118 - previous pelvic radiotherapy, pelvic neoplasms,

- 119 - pudendal neuralgia, puborectalis syndrome,
- 120 - absolute contraindications to surgery.

121 The following are the key elements of our standardized evaluation of the recruited patients:

122 1) Validated Renzi ODS⁸ and Wexner continence⁹ scores. The Longo ODS score,^{7,10} even
123 though not yet validated, was also used, as we consider it more appropriate for our
124 patients. The score, showed in Table 1, explores 9 parameters, ranging from 0 to 40:
125 defecation frequency (0-3), intensity (0-2) and duration (0-2) of straining, feeling of
126 incomplete evacuation (0-3), recto-perineal discomfort (0-3), activity reduction (0-6), use of
127 laxatives (0-7), enema (0-7), and digitation (0-7).

128 2) Gynecological examination, with POP-Q (Pelvic Organ Prolapse Quantification System)
129 classification;¹²

130 3) Proctologic examination and proctoscopy

131 4) Urodynamic study with uroflowmetry, cystomanometry and residual urine volume to
132 exclude an overactive bladder syndrome in patients with SUI ;

133 5) Quality of life with the validated SF36 Health Survey score;¹¹

134 6) Colonoscopy to exclude concomitant colorectal diseases;

135 7) Anorectal manometry to evaluate the integrity of anal sphincters;

136 8) Dynamic colpocystodefecography with opacification of small bowel (dynamic
137 pelvigraphy) to evaluate the grade of POP, the presence of morphological (rectocele, rectal
138 prolapse, intussusception) and/or functional (puborectalis syndrome, incontinence) rectal
139 disorders, and the presence of concomitant enterocele and/or cystocele. The following
140 defecography parameters were recorded: extent of rectal prolapse/ intussusception,
141 rectocele depth, perineum descent at rest and under strain, distance from the vaginal vault
142 to the pubis and to the sacrum. The three parameters of Dvorkin classification were used
143 to determine the extent of intussusception: anterior and posterior thickness of prolapsed
144 tissue (< 3mm = mucosal prolapse, > 3mm = full-thickness intussusception), distance from

145 the point of take-off of the intussusception to the anorectal junction, and intussusception
146 descent from the point of take-off to the most distal point of the intussusception;¹³
147 9) Patient Satisfaction Index, defined as follows: Excellent: no symptoms. Good: 1 episode
148 /month of ODS with use of laxatives. Fairly good: 2/3 episodes/month of ODS with use of
149 laxatives. Poor: more than 3 episodes/month of ODS with use of laxatives, or persistence
150 of other symptoms.

151 The Ethical Committee approved the study protocol. All patients gave written informed
152 consent. All patients were operated on by the same surgical team, using the technique
153 described below, with no modifications.

154 *Preoperative management*

155 An enema washing is carried out on the day before surgery. The procedure is performed
156 under general anesthesia. Immediately after the induction of anesthesia a Foley bladder
157 catheter 16Ch is introduced and the patient receives routine antibiotic prophylaxis with a
158 single shot of cefotaxime (2g) plus metronidazole (500 mg).

159 *Surgical technique*⁷(see video 1)

160 The L-POPs operation is performed with the patient in Lloyd-Davis and Trendelenburg
161 positions (30°). A Foerster sponge forceps with gauze is introduced in the rectum and a
162 uterine manipulator into the vagina to recognize the anterior rectal wall and the posterior
163 vaginal wall (or the vaginal vault in hysterectomized patients), respectively. A 13 mmHg
164 pneumoperitoneum is created after positioning an umbilical 12 mm trocar with an open
165 technique. A second 12 mm trocar is introduced through an incision in the right iliac fossa
166 and a third 5mm trocar is positioned in the left iliac fossa. The Douglas pouch is exposed
167 and a V-shaped mesh, with two 25 cm long and 2 cm wide branches is prepared. This is
168 obtained by folding a macroporous, square shaped, 30 cm x 30 cm polypropylene mesh,
169 (Microval , St Just Malmont, France) along the diagonal and then cutting a 2cm wide strip
170 along one of the two short sides of the triangle. The V-shaped mesh is then introduced in

171 the pelvis through the right trocar. The uterus is suspended to the anterior abdominal wall
172 with a straight transcutaneous needle. The uterine suspension is primarily used for
173 visualization. Concomitant SUI was not treated with a separate procedure, but suturing the
174 apex of the mesh to the anterior and lateral vaginal fornix wall with 2-0 Prolene stitches,
175 anteriorly to the uterus, after the dissection of vesico-uterine space: the same is done in
176 case of prevalence of anterior descent. In patients with predominant rectal prolapse the
177 apex of the mesh is sutured to the posterior vaginal fornix wall (or to the vaginal vault in
178 hysterectomized patients) with plicature of the peritoneum of the Douglas pouch: fixing the
179 vaginal vault to the cardinal ligaments is important to restore the De Lancey first level of
180 hysterocele. The 2-0 Prolene stitch is then also fixed to the peritoneum so as to cover the
181 anterior rectal wall, taking care of pushing the upper rectum with gauzed forceps
182 introduced in the rectal lumen, in order to show the peritoneum and to avoid perforating
183 the rectal wall. Normally two central and two lateral stitches are sufficient for correct
184 positioning of the V mesh apex. The distance from the vaginal attachment of the mesh to
185 the oblique external fascia is about 20 cm. Two bilateral incisions of the skin 2cm posterior
186 and superior to the anterior iliac spine and dissection with scissors of the fascia and the
187 muscular fibers of oblique muscle, allow reaching the preperitoneal space under
188 laparoscopic control. Taking care to avoid injury to the iliac vessels and ureter, dissection
189 of the lateral peritoneum and the broad ligament proceeds using a curved tip laparoscopic
190 needle holder, introduced into the preperitoneal tunnel. The right lateral aspect of the mesh
191 is gently pulled through the preperitoneal tunnel until the right external oblique muscle
192 fascia incision is reached. The same is done on the left side.

193 Before fixing the mesh to the fascia, with the patient in 50° Trendelenburg position, the
194 mesh is strained until the normal pelvic aspect is restored. In case of uterine retroversion
195 the round ligaments are shortened and attached to the mesh arms to restore the normal
196 anatomy of the middle pelvic compartment. The peritoneum is sutured with Vycril 2-0

197 stitches to cover the apex of the mesh. About 5 cm of the lateral aspects of the mesh are
198 exteriorized through the skin incisions, tunneled under the external oblique muscle fascia
199 and fixed with Vicryl 2-0 stitches . Finally, the trocar incisions are sutured.

200 *Postoperative management*

201 The patient is started on a clear liquid diet from the first postoperative day. Antibiotics are
202 continued for three days. Acetaminophen 1gr plus Ketorolac 30mg i.v., t.i.d is used for
203 postoperative pain control during hospitalization. Antithrombotic prophylaxis with
204 enoxaparin 4000 U/day for 12 days is administered.

205 *Follow-up*

206 Pre and postoperative assessments were conducted by one of the surgeons of the team.
207 Clinical examination is scheduled at 7 days and 1, 3, 6, 12 and 24 months after the
208 operation. A dynamic defecography is repeated 12 months after surgery.

209 Primary outcome measure is the rate of failure at 2 years' follow-up defined as the
210 persistence of any single or combination of the following conditions: ODS score > 5,
211 persistence of SUI, presence of vaginal discomfort and/or dyspareunia, residual mucosal
212 rectal prolapse > 2cm at proctoscopy, residual 2nd degree (or greater) genital prolapse at
213 clinical examination. Secondary outcome measures are: operative time, complications,
214 hospital stay, postoperative pain assessed using a NRS score (0 = no pain to 10 =
215 maximum pain), time to resumption of daily activity, ODS score, quality of life with the
216 SF36 Health Survey questionnaire, and patient overall Satisfaction index 12 months after
217 the operation. Patients who did not strictly follow the postoperative protocol were excluded
218 from the study: even skipping one the postoperative controls was considered a sufficient
219 condition for exclusion. However a phone call was performed in these cases to assess at
220 least the persistence of symptoms.

221 *Statistical Analysis*

222 Continuous data are shown as arithmetic mean (SD) and qualitative data as absolute and
223 percent frequencies. The statistical software package SPSS 24.0 for Windows 7
224 Professional (SPSS Inc. Chicago, IL, USA) is used. The two-sample t-test for unpaired
225 data, ANOVA for repeated measures and Chi Square test are used, as appropriate.
226 Differences are considered significant with values of $P < 0.05$.

227 **RESULTS**

228 *Preoperative data*

229 From January 2013 to June 2017, 384 women (mean age 68 years, range 42-77) were
230 selected through the above-described protocol and submitted to L-POPs. All patients had
231 ODS and symptomatic 3rd degree genital prolapse and 61 (15.9%) had also a SUI. The
232 BMI was 27.5 (± 2.1). Two hundred and fifty-three patients (66.0%) were multiparous, with
233 mean parity 2.5 (± 0.8); 169 patients (44.0%) had had a previous hysterectomy. The
234 incidence of preoperative symptoms is reported in Table 2. Mean resting and squeeze
235 pressures were 64.5(± 6.6) and 118.2(± 11.4) mmHg, respectively. Preoperative
236 defecography parameters are shown in Table 3.

237 *Operative data* (Table 4)

238 The ASA score was 2.6 (± 0.4). Mean operating time was 89 (± 5.9) minutes. There was no
239 operative mortality. Major complications requiring reoperation occurred in 11 pts (2.9%): 3
240 bleedings within the trocar site requiring hemostasis, 2 intestinal occlusions for peritoneal
241 adhesions treated with adhesiolysis, 2 bleedings for injury of the oblique muscle, 2 injuries
242 of the bladder sutured by cystoscopy and 1 infection of the mesh treated with mesh
243 removal the mesh. All reoperations were accomplished by laparoscopy. One right lower
244 limb deep venous thrombosis was treated with enoxaparin 6000 U/day for one month.
245 Mean hospital stay was 3.0 (± 0.6) days, mean VAS score during hospitalization was 3.6
246 (± 0.4) and no patient exceeded the daily dose of Acetaminophen 1gr plus Ketorolac 30mg
247 x3 i.v.

248 *Follow-up data*

249 Sixteen patients (4.2%) were excluded from the analysis for skipping one of the
250 postoperative examination: 5 patients skipped the 1st-month, 5 the 6th-month, and the
251 other 6 the 12th-month control. All of them were living in other regions of Italy far from our
252 Istitutions. At a phone call after the missed control 2 out of the 16 had residual anorectal

253 symptoms.

254 The mean follow-up was 36.3 (± 4.4) months. Nineteen patients (4.9%) with persistence of
255 symptomatic rectal internal prolapse and/or rectocele with ODS score > 5 were submitted
256 to a STARR operation after 1- year follow-up. Two patients with residual SUI (3.3%) were
257 submitted to trans-obturator tape (TOT) sling.

258 The mean period of daily activity resumption was 16.3(± 4.8) days. Anal/rectal/uro-
259 gynecologic symptoms and ODS scores significantly improved after the operation
260 ($P < 0.001$) with no worsening of anal continence (Table 2). Incidence of postoperative fecal
261 urgency was 0%. Postoperative defecography showed a significant ($P < 0.001$) reduction
262 of all parameters in 315 pts (82%) with a strict correlation with symptoms relieve and
263 excellent/good Satisfaction Index. The mean reduction of the perineal descent was 3.0
264 (± 0.2) cm.

265 As shown in Table 5, quality of life by the SF36 Health Survey score significantly improved
266 after the operation ($P < 0.01$); 78.0% of patients reported an excellent/good overall
267 Satisfaction Index, 15.5% fairly good and 6.5% poor (Table 6)

268 **DISCUSSION**

269 The attempt to resolve frequently associated pelvic floor diseases with a single operation
270 is attractive for reducing morbidity and costs, and also considering the pathophysiology of
271 pelvic organ prolapse. Genital prolapse can, in fact, be considered a total pelvic prolapse
272 often including enterocele, cystocele, rectocele and rectal prolapse and the pelvic
273 surgeon's mission ideally should be to restore anatomy and function of the pelvis.
274 Traditional surgery for POP does not correct a concomitant rectal prolapse with ODS and
275 usually involves removal of the uterus, which is a very important organ for the anatomy of
276 the pelvis and the physiology of defecation.

277 In the last decade experience we studied a great number of patients with complex pelvic
278 floor diseases by a dynamic pelvigraphy and we observed that the uterus and the small
279 intestine assist the emptying of the bladder and the rectum. The rectal emptying begins
280 after an intense straining, which is completed by the action of the other pelvic organs, the
281 uterus moves towards the anterior compartment, compressing the bladder and stimulating
282 urination, while the small intestine, slipping on the uterus, seems contributing to squeeze
283 the sigma-rectum through the Douglas pouch, assisting the evacuation (as shown in video
284 2). In hysterectomized patients the bladder appears to be dilated and the sigmoid colon
285 interferes with bladder repletion and emptying. An enterocele can develop, compressing
286 the rectum and ODS can follow. The L-POPs aims at simultaneous correction of pelvic
287 multiorgan prolapse, preserving the uterus, which continues to divide the pelvis into an
288 anterior and a posterior compartment, modulating evacuation and urination.

289 We believe that fixation of the vaginal vault to the Mackenrodt ligaments is important for
290 restoring a normal pelvic floor anatomy, in the attempt to treat sexual, urinary and
291 defecatory symptoms. As demonstrated by De Lancey stretching and breaking of the
292 cardinal ligaments is the primary cause of hysterocele, while the other changes
293 (lengthening of utero-sacral ligaments, round and pubo-cervical ligaments etc.) are

294 secondary to the traction by the prolapsed uterus.¹⁴ Shortening the round ligaments during
295 the L-POPs operation is directed to correct the uterine retroversion. The L-POPs can be
296 successfully performed in hysterectomized patients too. Finally, in the event of a big
297 preoperative rectocele, or a rectocele residual to L-POPs, a STARR procedure can be
298 added.

299 Laparoscopy has all the theoretic benefits to be considered the ideal approach to the
300 pelvic floor for its minimal invasivity, the good exposition of the pelvis and the optimal
301 cosmetic impact. On the other hand, up to now laparoscopic techniques for corrective
302 pelvic floor surgery, showed many limitations and none offered a single-stage correction of
303 total pelvic prolapse.

304 In 1967 Kapandji described a Colpo-Isthmo-Cystopexy, with transverse sub-peritoneal
305 strips from the anterior superior iliac spines to the vagina, associated with Douglassectomy
306 and reconstruction of the round ligaments. The limits were the 4-hour operative time and
307 the excessive anterior shifting of the vagina, resulting in the widening of the recto-vaginal
308 space, which is a well-known open door for the onset of an enterocele.¹⁵

309 The Laparoscopic Colpo-Sacropexy (LCS) is technically difficult, requires high operative
310 skills and is not infrequently complicated by bladder injury (5%).¹⁶ Even if the reported
311 global success rate of LCS is very high, this operation cannot correct an associated
312 symptomatic rectal prolapse, and can even worsen the defecatory function due to partial
313 occlusion and stiffness of the Douglas pouch caused by the mesh.¹⁶ In case of
314 concomitant rectal prolapse the association of a rectopexy to LCS is technically feasible,
315 nevertheless it is well known that a rectopexy without resection could worsen an ODS,
316 independently from the technique used.¹⁷

317 Laparoscopic Lateral Suspension (LLS) , in which the mesh, fixed to the dissected anterior
318 and posterior vaginal wall, is laterally suspended to the abdominal wall, posterior to the
319
320

321 anterior superior iliac spine, is effective for repairing the vaginal wall prolapse, as well than
322 the traditional sacrocolpopexy, with lower complication rate, particularly regarding vascular
323 or nerve lesions. However the limits of this procedure are almost the same than LCS, as it
324 cannot correct an associated rectocele and can accelerate the onset of an enterocele and
325 a rectal prolapse.¹⁸ Furthermore, a 3.8% rate of mesh erosion after LLS was reported.¹⁹
326 The recent technique of Laparoscopic Vaginal Suspension and Rectopexy, which consists
327 in the fixation of three strips of polypropylene mesh to the posterior vaginal vault (or the
328 vaginal apex) and bilaterally to the sacral promontory, associated with a rectopexy, is
329 considered indicated in patients with full-thickness rectal prolapse and fecal incontinence
330 but not in patients with ODS.²⁰

331 The Laparoscopic Ventral Mesh Rectopexy (LVR), which is at reason very popular
332 because of the good results achieved in the cure of ODS and enterocele, is devised for
333 treating internal and external rectal prolapse and enterocele but does not entail the
334 correction of a concomitant 3rd/4th grade POP and/or cystocele. According to the proposing
335 author, about one in three patients will not benefit from surgery and careful selection of
336 indications is mandatory. [21,22]

337 In our series, LPOPs was very effective in correcting the associated 3rd, or 4th degree
338 genital prolapse, ODS, and SUI with no mortality, low morbidity and only 2/61 patients
339 showing persistent urinary symptoms. We did not observe any erosion of the mesh in
340 vagina or rectum. Finally, the 19 patients (< 5 %) presenting recurrent ODS one year after
341 L-POPs were successfully submitted to a STARR.

342 There is common agreement that the difficulty in managing patients with associated pelvic
343 floor diseases with the very large number of one, two or more stage surgical approaches
344 described in Literature, prompt for the creation of pelvic surgery units, involving skilled
345 specialists dedicated to diagnosis and treatment of these conditions. However, in our
346 country only very few pelvic Units have been created, due to the lack of training, funding,

347 and regulations. A formal specialization in pelvic surgery does not exist in Italy and policy
348 and funding of this issue among the country's 20 Regions are not homogeneous.

349 The laparoscopic surgery of the pelvic floor requires specific surgical skills. Pucher *et al*
350 reported a learning curve from 25 to 30 cases based on operative time and length of stay,
351 with 3.2% of morbidity for laparoscopic ventral mesh rectopexy.²³ In our hand 15 to 20
352 cases were sufficient for L-POPs, considering our previous experience of colorectal
353 surgeons with training in laparoscopy and the more than 100 operations performed with
354 general urologists and gynecologists.

355 The collection of such a large series of patients with rigorous surgical indications in a
356 single center during a limited time frame was determined by the fact that our Unit is a
357 referral center in Italy with more than 50 % of our patients living in other Regions of the
358 country.

359 However, our study had some limitations, and namely: it is a non-randomized, unicentric
360 experience, without a control group, and follow-up was limited, Longo score has yet not
361 been validated and the assessments have been unblinded which cause a potential bias.

362 On the other hand, the series is very large and the operation, as well as the pre and
363 postoperative controls, were standardized with few drop-outs.

364

365 **CONCLUSIONS**

366 In our series The L-POPs operation proved to be a safe and effective cure of multiorgan
367 pelvic prolapse, followed by significant improvement of anal/rectal and uro-gynecological
368 symptoms and radiological parameters in the medium period. Multicentric randomized
369 studies comparing L-POPs with an appropriate control group and longer follow-up are now
370 needed to assess the real effectiveness of this promising technique.

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435

436 LEGENDS

437

438 Video 1 shows the steps of LPOP-s technique, using a polypropylene mesh, knitted in

439 double thread , with pore size 0.7mm

440 Video 2 shows a dynamic pelvigraphy in a patient with ODS and genital prolapse

Table 4. Operative data in 384 patients submitted to L-POPs operation: values expressed as mean (SD) for operating time, hospital stay, VAS scale and n (%) for complications

Operating time (min)	82.5 (5.9)
Hospital stay (days)	3.0 (0.6)
VAS scale	3.6 (2.4)
Complications	11 (2.9)

Table 5. Pre and postoperative (12 months) SF36 Health Survey questionnaire in patients submitted to L-POPs operation: values expressed as mean(SD)

Finding	Preoperative n =384	Postoperative n=368	P*
Limitations: physical activities	15.2 (1.5)	19.6 (1.8)	<0.01
Limitations: social activities for physical or emotional problems	5.7 (0.8)	6.6 (1.0))	<0.01
Limitations: usual role activities for physical problems	5.3 (0.7)	6.4(0.7)	<0.01
Body pain	4.5 (0.6)	3.3 (0.7)	<0.01
General mental health	6.7 (0.9)	4.8 (0.8)	<0.01
Limitations: usual role activities for emotional problems	4.1 (0.4)	5.0 (0.7)	<0.01
Vitality	33.8 (3.3)	31.4 (2.9)	<0.01
General health perceptions	12.8 (1.4)	11.2 (1.1)	<0.01
Total	80.5 (77-84)	84 (82-90)	<0.01

Table 6. Overall Patient Satisfaction at 12 months in 368 patients submitted to L-POPs operation: values expressed as number of pts (%).

	12 months
Excellent	115 (31.3)
Good	172 (46.7)
Fairly good	57 (15.5)
Poor	24 (6.5)

Table 1. Longo ODS Score

Parameter	Description	Score	Description	Score	Description	Score	Description	Score	Description	Score
Defecation - Frequency	1-2- def./1-2 days	0	2 def ./week or 3 def. or attempts/day	1	1 def ./week or 4 def. or attempts/day	2	< 1 def./week or >4 def. or attempts/day	3		
Straining - Intesity	No or light straining	0	moderate	1	intensive	2				
Straining - duration			Short time	1	Prolonged or many times	2				
Feeling of incomplete evacuation	never	0	≤ 1/ week	1	2 / week	2	> 2 / week	3		
Recto-perineal discomfort	never	0	≤ 1/ week	1	2 / week	2	> 2 / week	3		
Activity reduction	never	0	< 25% of activity	2	25-50% of activity	4	> 50% of activity	6		
Laxatives		0		1		3		5		7
Enemas	never	0	< 25% of defecations	1	25 - 50% of defecations	3	>50% of defecations	5	Always	7
Digitation		0		1		3		5		7

Table 2. Pre and postoperative (12 months) clinical data, fecal continence score and ODS score after L-POPs operation: n (%) for symptoms and mean (SD) for scores

Symptom/score	Pre-operative n=384	Post-operative n= 368	P*
Rectal Dyschezia	295 (76.8)	18 (4.9)	<0.0001
Tenesmus	269 (70.0)	17 (4.6)	<0.0001
Rectal Bleeding	155 (40.4)	2(0.5)	<0.0001
Continence score	0.4(0.3)	0.4 (0.2)	1.00
Renzi ODS score ⁸	17.5 (2.1)	2.3 (0.5)	<0.0001
Longo ODS score ⁷	32.4 (4.3)	5.1 (0.7)	<0.0001
Dyspareunia	130 (33.8)	9 (2.4)	<0.0001
Vaginal discomfort	211 (54.9)	19 (5.2)	<0.0001
SUI	62 (16.1)	2 (0.5)	<0.0001

* McNemar test for evaluation of symptoms and 2-sample t-test for scores were used

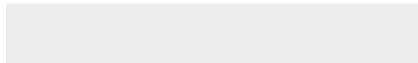
Table 3. Pre and post-operative defecography data in patients submitted to L-POPs operation: values expressed as mean (SD)

<u>Finding</u>	Preoperative n=384	Postoperative n=368
Intussusception thickness (mm)		
Anterior	5.4 (0.9)	3.3 (0.5)
Posterior	4.9 (0.7)	3.1(0.3)
Point of take off (mm) :		
Anterior	59.7 (10.9)	42.6 (8.4)
Posterior	60.8 (11.8)	45.9 (7.7)
Intussusception descent (mm)		
Anterior	25.2 (6.8)	16.8 (4.8)
Posterior	28.7(6.3)	17.3 (5.0)
Rectocele depth (cm)	4.0 (0.4)	2.1 (0.3)

Wilcoxon test was used: all parameters significantly improved after operation ($p < 0.001$)



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