Original article

A retrospective comparison of Calistar A versus the second-generation light-weight Calistar S for treating anterior and apical pelvic organ prolapse

AGUSTIN SAMPIETRO[1], GIANCARLO PARADISI[2], GIOVANNI SCAMBIA[2], JUAN SARDI[3], PAULO PALMA[4], CASSIO RICCETTO[4], PASCAL MOURTIALON[5]

[1] *Faculty of Medicine, University of Buenos Aires, Buenos Aires, Argentina*
[2] *Catholic University of Sacred Heart, Rome, Italy*
[3] *British Hospital, Buenos Aires, Argentina*
[4] *University of Campinas (UNICAMP), Campinas, Brazil*
[5] *Provence Gynecologie, Hôpital Privé de Provence, Aix en Provence; Clinique de Vitrolles, France*

Abstract: Introduction: Pelvic organ prolapse (POP) repair with synthetic mesh has low recurrence and good anatomical correction. The new-generation meshes may provide better outcomes than meshes with greater superficial density. This multicenter study aimed to evaluate the outcomes of POP repair using Calistar S (CaS; 44 g/cm^2) versus Calistar A (CaA; 16 g/cm^2). *Methods:* Data from women with anterior and/or apical POP repaired with either CaA (n=91) or CaS (n=126) between January 1, 2011 and April 30, 2017 were retrospectively analyzed. The primary endpoint was the overall response based on Barber's criteria. Secondary endpoints were anatomical correction and patient-reported outcomes assessed with the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) and Pelvic Floor Disability Index (PFDI-20). Adverse events were recorded. Minimum follow-up was 6 months. *Results:* Barber's criteria for cure were met by 75 (82%) in the CaA group and 114 (90%) in the CaS group (p=0.0806). Anatomical correction was significantly improved in both groups from a median POP-Q stage of 3 preoperatively to 1 postoperatively (p<0.0001 in both groups). Quality of life (measured by the PISQ-12 or PDFI-20) showed similar significant improvements from baseline in both groups. De novo overactive bladder only occurred in the CaA group (p=0.0121), and urinary tract infection, mesh exposure, and de novo stress urinary incontinence were significantly more frequent in the CaA group than the CaS group. Rare adverse events (only one case per event) occurred in the CaA group. *Conclusion:* Ultra-light-weight CaS is safer and achieves a similar success rate compared with heavier-weight CaA.

Keywords: Ultra-light-weight mesh; Transvaginal approach; Pelvic organ prolapse; Anterior and/or apical prolapse

INTRODUCTION

Pelvic organ prolapse (POP) is a major concern affecting the life quality of millions of women, with a reported prevalence of 3–6% when defined by symptoms[1] and 50–97% when based on vaginal examination[1,2]. The etiology of POP is multifactorial, with many risk factors associated with sustained episodes of increased intra-abdominal pressure (such as pregnancy, vaginal delivery, heavy lifting, chronic coughing, and constipation) and others related to a decrease in tissue quality (such as hysterectomy, previous continence or prolapse surgery, menopause and estrogen levels, and collagen abnormality)[3,4].

The lifetime risk of undergoing one surgery for POP is approximately 11%[5]. Surgery is generally indicated for severe cases that are non-responsive to conservative management such as lifestyle interventions, physical therapy, and pessaries[6]. Almost 30% of patients require a new surgical treatment after the first procedure for POP repair, progressively reducing the resolution of the problem and increasing the costs related to the treatment of this condition[7,8]. The high failure rates of native tissue repair led to the introduction of various allograft materials and repair systems that offered lower failure rates[9,10]. It is broadly accepted that POP surgical repair with the use of synthetic meshes is associated with lower recurrence rates and good anatomical correction compared with native tissue repair[9]. However, safety concerns related to the transvaginal approach used for POP repair with synthetic meshes have increased the scrutiny of clinical data to better understand the benefit/risk ratio for this type of surgery. POP surgery management trends were greatly affected by safety notices published by the FDA in 2008 and 2011[11]. Subsequently, health regulatory agencies worldwide have increased the requirements for the approval and use of such POP repair devices, and the use of transvaginal meshes has been withdrawn by some agencies, such as the Australian Therapeutic Goods Administration in 2017 and the FDA in 2019.

A 2016 Cochrane review stated that mesh repair might not be associated with a high benefit/risk ratio for primary surgery, although the use of synthetic mesh may be appropriate in cases with a relatively high risk of recurrence[12]. However, the lack of robust evidence means that extreme caution must be exercised when POP repair is performed with synthetic mesh; care must be taken during patient selection, and surgeons must undergo training regarding the use of specific devices. These strategies are important in improving the safety profile of POP repair with meshes while retaining the good anatomical outcomes that this method achieves. Additionally, new research is focused on intrinsically improving POP repair devices to minimize the complications associated with the materials and surgical techniques; efforts are being made to reduce the amount of material that is implanted in the pelvic floor area in an attempt to decrease the risks of foreign body reaction, infection, and mesh exposure. Ultra-light-weight meshes are considered to lower the risks of infection and erosion. The use of this newer generation of meshes, mainly via the transvaginal approach, may provide better safety outcomes than the previous meshes with greater superficial density[13,14]. However, high-level evidence data on the use of lighter meshes is still lacking, regardless of the compartment in which they are intended to be used[15,16].

The objective of this retrospective study was to evaluate the outcomes of two similar mesh products that each contain a different amount of material; this information may be used in the design of future prospective trials.

MATERIALS AND METHODS

Study design and hypotheses

The present study was an international, multicenter, post-market, open, non-randomized, retrospective analysis carried out in participating tertiary referral centers in Italy, France, Argentina, and Brazil (ClinicalTrials.gov identifier: NCT03715803).The target population was defined by the inclusion criteria as all adult women (> 18 years old) with an initial diagnosis of at least a stage 3 anterior and/or apical POP (defined using the POP-Q System) with or without

stress urinary incontinence (SUI) who had undergone POP repair surgery with either Calistar A (CaA; Promedon, Argentina) or Calistar S (CaS; Promedon, Argentina) as primary surgical treatment or to correct recurrent POP after a previous surgical intervention occurring between January 1, 2011 and April 30, 2017 in the participating centers; all included patients had at least a 6-month postoperative follow-up. Exclusion criteria included recurrent vaginal infection, chronic colorectal disease (e.g. chronic nonspecific ulcerative colitis, diverticulitis, diverticulosis, Crohn's disease, irritable bowel syndrome, familial polyposis), the presence of any coagulopathy, impairment of the immune system or any condition that would compromise recovery, prior irradiation, and chronic pelvic pain. The sample size was determined by the application of the eligibility criteria over the study period, and was therefore not statistically calculated.

The study hypothesis was that the use of the CaS system (consisting of an ultra-light-weight mesh) provides a comparable therapeutic effect and has a superior safety profile compared with the CaA system (a device with a heavier-weight mesh).

The primary effectiveness endpoint was the patient overall response based on Barber's criteria for cure: lowest POP-Q stage < 0 (no points beyond the hymen), no subjective adverse symptoms (absence of vaginal bulge), and no re-treatment or interventions for 1 year after the POP repair procedure[17]. The secondary effectiveness endpoints were the objective assessment of anatomical correction based on the validated POP-Q system, and patient-reported outcome measurements as assessed with validated questionnaires such as the Patient Global Impression of Improvement (PGII), Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12), and Pelvic Floor Disability Index (PFDI-20), depending on the record availability at each participating center. The safety endpoint was defined as the record of any peri- and/or postoperative adverse event or complication associated with the use of the devices under evaluation. Other variables that were analyzed included the follow-up duration, intraoperative blood loss, surgical procedure time, number of recurrent prolapses defined by the cure criteria based on the POP-Q system, and number of cases requiring reintervention.

Device description

oth devices under evaluation involve the same indications for use, surgical approach, and fixation methods. They are indicated to surgically treat anterior and apical prolapses via a single-incision vaginal approach, with fixation points at the SSL and obturator internus muscles. The surgical kits consist of the polypropylene implant (mesh with multipoint fixation columns on the anterior arms), a retractable insertion guide (RIG) to facilitate fixation maneuvers (the CaS comes with two different RIGs), and three polypropylene tissue anchoring systems (TAS), which are harpoon-like anchors for SSL fixation at DeLancey's Level I, as depicted in Fig. 1 and Fig. 2. The CaS kit also includes a knot pusher that can be used when suturing the anchored TAS to the implant. The main difference between the CaS and CaA systems is the amount of material contained in each implant. Whilst the superficial density of CaA mesh is 44 g/cm^2, the newer generation low-weight mesh in CaS is 16 g/cm^2. In addition, CaA provides mid-urethral support that can be used to treat concomitant SUI; a feature that is not present in CaS.

Surgical technique

The surgical procedures for each of the two meshes were very similar. Briefly, a single incision was made on the anterior vaginal wall under local or regional anesthesia. The incision began at the bladder neck for CaS and at the middle portion of the urethra for CaA, and extended to the cervix or the apex in both cases. Blunt bilateral dissection was performed toward the ischial spine until the SSL was identified. The first TAS was loaded into the RIG (using the appropriate RIG for CaS) and anchored at the anterior face of the SSL, 2.5 medial to the ischial spine. A second identical SSL fixation was done for the contralateral SSL, and the suture threads connecting the TAS were kept outside the incision for the posterior step. Afterwards, the same RIG (for CaA) or the smaller RIG (for CaS) was connected to one of the multipoint fixation columns and anchored at the obturator internus muscle, and the process was repeated on the other side. As a result, the middle portion of the anterior aspect of the implant rested below the bladder neck (for CaS) or the mid-urethra (for CaA), imposing no mechanical tension on the upper tissues (tension-free approach). The implant was secured in place with two absorbable sutures placed over the bladder neck (for CaS) or over both sides of the mid-urethra (for CaA). At this point, the TAS suture threads were passed through the tiny holes on the corresponding posterior arms of the implant. When the threads were passed through on each side, care was taken to leave at least 5 mm between the entry points of the threads to enable the creation of a double sliding knot. Before placing the posterior arms onto the SSL, two additional absorbable sutures were placed to fix the implant to the remnants of the cardinal ligaments or the pericervical ring. Anterior and apical prolapse reduction was achieved by moving the implant towards the SSL, using the double sliding knots created on the posterior arms. For the CaS system, the knot pusher was used to facilitate the sliding of the knot towards the SSL. The implant was placed in a free-tension fashion, and the excess mesh at the mid-posterior part (dome shape) was trimmed. Finally, the vaginal incision was closed in a routine manner.

Data collection and statistical analyses

Medical records from the gynecological/urogynecological unit of each participating center were screened to identify the cases that met the eligibility criteria. Once the cases were identified, data were transferred from the center records to the investigation case report forms for standardization and anonymization. Statistical analyses were performed with InfoStat Software (National University of Cordoba, Cordoba, Argentina)[18]. Continuous variables were initially checked for normality using the Shapiro-Wilks test. Hypothesis testing for normally distributed samples was completed with paired-sample t-testing (pre- vs postoperative values within a group) and independent sample t-testing (comparisons between different groups at the same study timepoint). For non-normally distributed samples, the analog non-parametric versions were used (Wilcoxon signed rank test and Mann-Whitney U test, respectively). For categorical variables, chi-square tests were used (proportions difference). The significance level was set at 0.05 for all comparisons.

RESULTS

Two-hundred-and-seventeen patients met the eligibility criteria, comprising 91 in the CaA group and 126 in the CaS group. Baseline clinical and demographic data did not significantly differ between the groups (Table 1). However, compared with the CaA group, the CaS group tended to have a higher incidence of previous pelvic surgeries (37 (41%) patients in the CaA group and 25 (20%) in the CaS group) and a lower incidence of previous POP surgical interventions (16 (13%) in the CaS group and four (4%) in the CaA group).

Intraoperative and follow-up data are summarized in Table 2. The CaA and CaS surgical procedures involved similar mean operation times (70 and 66.5 min, respectively). No simultaneous hysterectomies were performed at the time of Calistar implantation in either group, whereas concomitant anti-incontinence surgery was more common in the CaS group than

Table 1. Demographic and baseline clinical data.

	CaA group (n=91)	CaS group (n=126)	p value
Age [years], mean (SD)	*62 (9)*	*62 (8)*	*0.6471*
BMI [kg/m^2], median (range)	*26 (17–38)*	*26 (20–40)*	*0.3728*
Diabetes, n (%)	*6 (7)*	*11 (9)*	*0.6183*
Smoking, n (%)	*11 (12)*	*12 (10)*	*0.6559*
Parity, median (range)	*2 (0–10)*	*2 (0–7)*	*0.2101*
Prior hysterectomy, n (%)	*16 (18)*	*14 (11)*	*0.2314*
History of pelvic surgery, n (%)	*37 (41)*	*25 (20)*	*0.0008*
Prior prolapse surgery, n (%)	*4 (4)*	*16 (13)*	*0.054*
PISQ 12, median (range) [n]	*0 (0–5) [21]*	*0 (0–13) [17]*	*0.2876*
PFDI 20, median (range) [n]	*31 (0–91) [28]*	*19.5 (0–52) [30]*	*0.1103*

the CaA group (p=0.0006). Regarding intraoperative complications, there were only a few cases of blood loss and only one case of bladder injury in the CaS group (Table 2).

The median postoperative follow-up duration was significantly longer in the CaA group than the CaS group (24 months vs 12 months, p<0.0001). Compared with the CaA group, more women in the CaS group reported being sexually active in the postoperative period (p=0.0005).

According to the primary effectiveness endpoint (Barber's criteria), both devices performed similarly, with no statistical difference between groups. The criteria for cure were met by 75 (82%) patients in the CaA group and 114 (90%) in the CaS group (p=0.0806). Anatomical correction as measured by the POP-Q system showed statistically and clinically significant differences in both groups from a preoperative median POP-Q stage of 3 at baseline to a postoperative POP-Q

Table 2. Surgical procedure and follow-up data.

	CaA group (n=91)	CaS group (n=126)	p value
Surgical procedure			
Operative time [min], median (range)	70 (30–120)	66.5 (35–240)	0.9124
Concomitant hysterectomy, n (%)	0	0	1
Concomitant anti-incontinence surgery, n (%)	10 (11)	33 (26)	0.006
General postoperative data			
Sexually active subjects, n (%)	37 (41)	68 (54)	0.0005
Follow-up [months], median (range)	24 (6–64)	12 (6–36)	<0.0001
Intraoperative adverse events, n (%)			
Blood loss > 200 ml	1 (1.2) [n=84]	2 (2.4) [n=126]	1
Bladder injury	0	1 (0.8)	1
Postoperative adverse events, n (%)			
Pain	6 (7)	6 (5)	0.7649
Mesh erosion	10 (11)	5 (4)	0.0577
Mesh shrinkage	2 (2)	0	0.1747
Recurrence of prolapse	16 (18)	14 (11)	0.2314
Reoperation for prolapse	2 (2)	2 (2)	1
Retention	4 (4)	1 (1)	0.1639
Overactive bladder	5 (5)	0	0.0121
Urinary tract infection	12 (13)	1 (1)	0.0002
Dehiscence	1 (1)	0	0.4194
Mesh exposure	8 (9)	2 (2)	0.0187
Enuresis	1 (1)	0	0.4194
Stress urinary incontinence	4 (4)	0	0.0297
Mixed urinary incontinence	1 (1)	0	0.4194
Nocturnal urgency	1 (1)	0	0.4194
Hematoma	3 (3)	1 (1)	0.3115
Hemorrhage	1 (1)	0	0.4194
Dyspareunia*	3 (8.1)	3 (4.4)	0.663
Granuloma	1 (1)	0	0.4194
Enterocele	1 (1)	0	0.4194
Renal tumor	1 (1)	0	0.4194

Table 3. Objective anatomical correction (POP-Q system) at final follow-up.

	CaA group			CaS group			CaA group vs CaS group	
	Preoperative, median	**Postoperative, median**	**p value (*)**	**Preoperative, median**	**Postoperative, median**	**p value (*)**	**Preoperative p value (**)**	**Postoperative p value (**)**
POP-Q stage	*3*	*1*	*<0.0001*	*3*	*1*	*<0.0001*	*0.4185*	*0.0024*
Aa	*3*	*-2*	*<0.0001*	*3*	*-2*	*<0.0001*	*0.6362*	*0.0486*
Ba	*4*	*-3*	*<0.0001*	*3*	*-3*	*<0.0001*	*0.3258*	*0.036*
C	*1*	*-7*	*<0.0001*	*2*	*-7*	*<0.0001*	*0.8048*	*0.5619*
GH	*4*	*3*	*<0.0001*	*4*	*4*	*<0.0001*	*0.6087*	*0.4099*
PB	*2*	*3*	*<0.0001*	*2*	*3*	*<0.0001*	*0.0881*	*0.025*
TVL	*8*	*8*	*0,875*	*8*	*8*	*0,0638*	*0.0685*	*0.9495*
Ap	*-1*	*-2,5*	*<0.0001*	*-1*	*-3*	*<0.0001*	*0.059*	*<0.0001*
Bp	*-2*	*-3*	*<0.0001*	*-2*	*-3*	*<0.0001*	*0.0623*	*<0.0001*
D	*-3*	*-8*	*<0.0001*	*-3*	*-8*	*<0.0001*	*0.1746*	*0.4281*

Table 4. Quality of life questionnaire findings.

	CaA group			CaS group			CaA group vs CaS group	
	Preoperative, median	**Postoperative, median**	**p value (*)**	**Preoperative, median**	**Postoperative, median**	**p value (*)**	**Preoperative p value (**)**	**Postoperative p value (**)**
Patient Global Impression of Improvement	---	*5*	---	---	*5*	---	---	*0.4258*
PISQ-12	*0*	*0*	*0.0038*	*26*	*0*	*0.0082*	*<0.0001*	*0.2876*
PDFI-20	*116.6*	*30.85*	*<0.0001*	*32*	*19.4*	*<0.0001*	*<0.0001*	*0.0868*

stage of 1 (p<0.0001 in both groups). The only individual POP-Q measure that did not significantly change from baseline was the total vaginal length. The comparative analyses showed no significant differences between the CaA and CaS groups in the POP-Q stage or individual POP-Q points at baseline. In contrast, the postoperative data showed that the CaS group had a significantly superior POP-Q stage and was superior in the individual Aa, Ba, Pb, Ap and Bp POP-Q points compared with the CaA group. Details of these comparisons are shown in Table 3.

Questionnaires measuring patients' subjective impressions were also analyzed. In both groups, women considered their quality of life to have improved significantly from baseline after the surgery when measured by either the PISQ-12 or the PDFI-20 (Table 4). Both questionnaire results showed similar tendencies when comparing the CaA and CaS groups. At baseline, the CaS group had significantly higher median PISQ-12 scores (26 vs 0, p<0.0001) and lower PDFI-20 scores (32 vs 116.6, p<0.0001) than the CaA group. However, the postoperative questionnaire results did not significantly differ between the two groups.

There were some statistical differences between the two groups regarding postoperative adverse events (Table 2). De novo overactive bladder (OAB) was only seen in the CaA group (p=0.0121). Other complications that were significantly more frequent in the CaA group than the CaS group were urinary tract infection, mesh exposure, and de novo SUI. Mesh exposure was more common in the CaS group than in the CaA group (p=0.0187). Rare adverse events (only one case per event) also occurred in the CaA group, including vaginal dehiscence, enuresis, urge incontinence (mixed), nocturnal urgency, hematoma, hemorrhage, granuloma, and an enterocele.

DISCUSSION

This retrospective study evaluated mid-term follow-up data from women who underwent surgical POP repair using one of two transvaginal meshes. The two devices were similar in terms of surgical approach and surgical instruments, type of implanted material, and anatomical landmarks for mesh fixation. The main difference between the two meshes was the amount of implanted material and knitting pattern. CaS is manufactured with less material than CaA, and is considered an ultra-light-weight mesh. Both groups showed significant improvements from baseline in anatomical correction and patient-reported outcomes. Postoperatively, the CaS group had statistically better anatomical correction (based on the POP-Q stage) than the CaA group, but both groups had similar success rates in accordance with Barber's criteria. The clinical significance of these findings is discussed in the following paragraphs. The quality of life questionnaires showed that there were similar significant subjective improvements postoperatively within both groups. However, the quality of life significantly differed between the two groups at baseline.

The surgeons who performed the operations in the present study were all highly-trained in POP repair techniques and had little experience with CaA when they first used it. The surgical techniques and surgical instruments used for CaA and CaS are almost identical. Surgeons learned to master this technique and became familiar with the device by using CaA, as it was the first product to be launched. This chronological mismatch meant that the surgeons underwent more training for the specific technique and type of device for the CaS system than for the CaA system. There were no differences between groups regarding operation time and intraoperative complications. However, a surgeon with little experience caused one major intraoperative complication in the CaS group. A patient with a very atrophic vagina incurred a bladder injury during the dissection. This injury was resolved with raffia of the lesion and probe insertion for 10 days, and did not result in any long-term complications.

The success rate according to Barber's criteria was similar in the CaA and CaS groups (82% and 90% for the CaA and Cas groups, respectively). A previous prospective study evaluat-

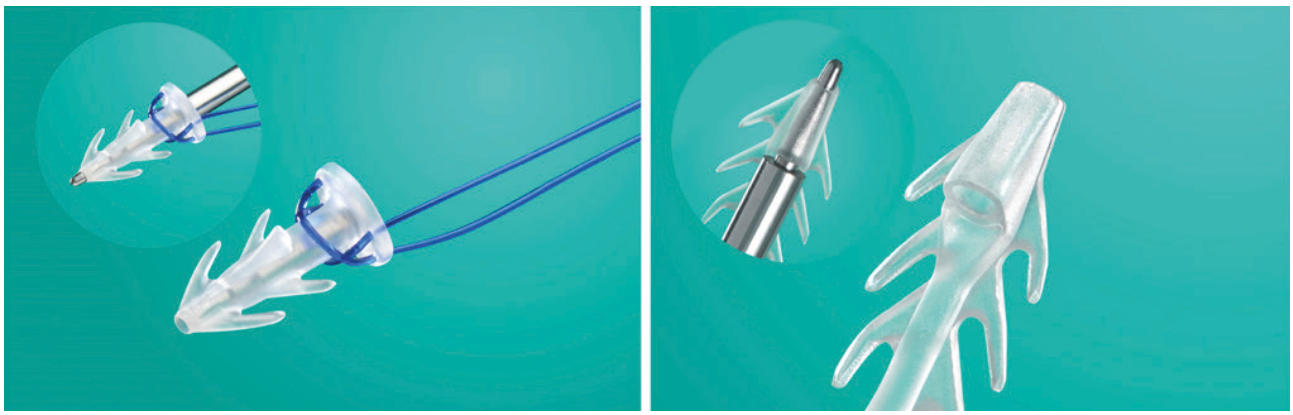


Figure 1. Left image: Tissue anchoring system for SSL fixation. Right image: Multipoint fixating columns for anterior fixation.
In both images, the pictures enclosed in the circles show the anchoring devices loaded on the surgical instrument (retractable insertion guide).

ing CaA reported a success rate of 88.7% during a median follow-up of 12 months [range 6–24 months] with the criterion for success defined as a Ba point of less than -1 cm[19]. Furthermore, a retrospective analysis with a mean follow-up of 18 months reported that CaA achieved an objective operative efficacy of 94% (POP-Q anterior stage 0 or I) and a subjective efficacy of 91% (no vaginal bulge symptoms)[20]. The first results for CaS were presented at the 69th Annual Congress of the German Society of Urology in 2017, showing a patient satisfaction rate of 95% in 154 women. These previous studies show that the success rates of CaA and CaS are comparable, although the success criteria differed among the studies, with more stringent criteria used in the present study. In general, the anatomical outcomes are less optimal than the subjective outcomes, and so it is encouraging to see good anatomical and patient-reported outcomes.

In terms of anatomical correction, CaA and CaS showed an identical median postoperative POP-Q stage (stage 1), although the postoperative POP-Q stage significantly differed between groups (p=0.0024). From a clinical perspective, the clinical perception of the elasticity of the anterior wall of the vagina suggests that there was less retraction of the mesh in the CaS group than the CaA group, but this requires further exploration, possibly with ultrasound. Recent reviews and meta-analyses report that the use of transvaginal meshes is associated with lower rates of recurrence, awareness of prolapse, and repeat surgeries than native tissue repairs[12,15]. In the present study, the CaA and CaS groups did not significantly differ in recurrence or repeat surgeries, with lower rates than those reported in previous reviews.

A recent publication from the PROSPECT study cast doubt on the superiority of meshes over native tissue repair[21]. The PROSPECT study is one of the most recent analyses of the comparative use of meshes and native tissue repair, and is a large, well designed RCT that adds valuable high-level evidence[21]. The PROSPECT study found no apparent benefits of transvaginal meshes or biological grafts when compared with native tissue repair,[21] which contrasts with the conclusions of the Cochrane Reviews[12,15]. The large number of surgeons involved in the PROSPECT study and the freedom for each surgeon to choose the mesh/surgical technique give a fair representation of the users and devices[21]. However, this comes at the expense of being able to evaluate the performance of specific devices when used by comparable users. It can be assumed that at least some mesh kits were used in the PROSPECT study, and this may have impacted the standardization of surgical techniques, which again represents a situation of compromise between representativeness and specificity. The PROSPECT study also showed no large increase in complications associated with mesh repair versus native tissue repair,[21] suggesting that the learning curve associated with mesh devices may be small. Moreover, the PROSPECT study did not evaluate operative times, and evidence shows that the use of mesh kits decreases the operative time compared with native tissue repair.

Regarding the safety of surgical POP repair, the four adverse events that had lower incidences in the CaS group than in the CaA group in the present study were SUI, OAB, urinary tract infection, and mesh exposure. In-depth analysis of the lower incidence of SUI in the CaS group than the CaA group is inappropriate for two reasons. First, CaS was not designed to concomitantly treat SUI, and second, simultaneous anti-incontinence surgeries were more frequently performed at the time of prolapse repair in the CaS group than in the CaA group. Therefore, the larger number of SUI repairs per-

Figure 2. Left image: Calistar S kit (implant, surgical instruments, and tissue anchoring system).

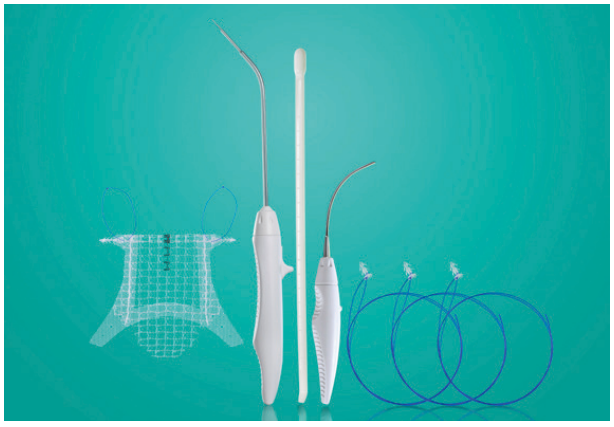
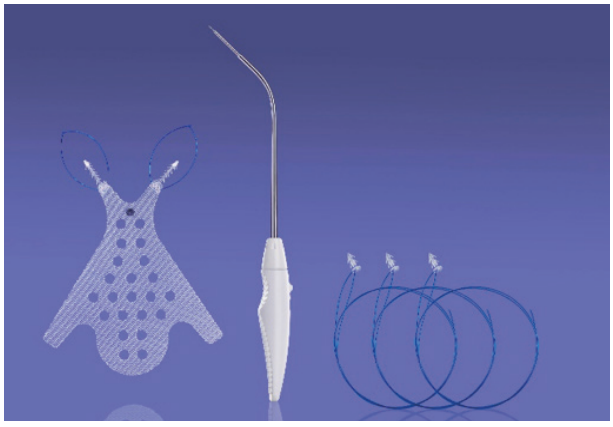


Figure 2. Right image: Calistar A kit (implant, surgical instrument, and tissue anchoring system).



formed in the CaS group may be masking the real impact of the mesh in reducing baseline SUI. In addition, the lack of data regarding preoperative SUI prevented comparison with the postoperative incidences of SUI within each group. However, the present findings show that a device used to treat both incontinence and prolapse simultaneously does not achieve the same efficacy as that achieved by the treatment of each issue via separate procedures. If we assume that the CaS and CaA groups had a similar prevalence of SUI preoperatively, all patients in the CaA group were then treated for SUI, while only those in the CaS group that actually had SUI were treated. Thus, the results favored selective treatment via two separate approaches over 100% treatment via the same approach.

There were no cases of OAB in the CaS group, while five (5%) patients in the CaA group developed OAB. If we focus only on the mesh weight, the reason for this higher incidence of OAB in the CaA group than the CaS group may be that the bladder irritation increases in tandem with the mesh weight, resulting in a higher incidence of OAB after POP repair using CaA compared with CaS. However, if the differences between CaA and CaS in the mesh shape and placement are also considered, it can be hypothesized that some patients have subclinical obstructive alterations encountered during concomitant urinary incontinence surgery, which may increase the incidence of OAB. Furthermore, it is possible that larger postmictional residues in the CaA group than in the CaS group favor the occurrence of urinary tract infection, as demonstrated by the occurrence of only one case in the CaS group and 12 cases in the CaA group.

Mesh exposure is one of the major concerns associated with the use of transvaginal meshes, due to potential adverse effects such as pain and infection, and the potential need for corrective surgeries. The group that received the lighter mesh (CaS) had significantly fewer cases of mesh exposure than the CaA group; this may be initial confirmation of the real benefit of using less material in the implant. The likelihood of mesh exposure is proportional to the area of tissue–material contact. Cases with less mesh material in contact with tissue experience less interaction between the two surfaces, resulting in a dose-response relationship between the amount of mesh used and subsequent erosions and other complications requiring repeat surgery[22].

The present data must be interpreted in the context of the limitations of the study. This was a retrospective study that compared data from surgeries that were not performed within the same timeframe; the CaA procedures were started a long time before the first CaS cases. This issue had an impact on the level of surgeon training in the specific surgical technique used for these devices. Additionally, the available data only enables mid-term follow-ups of differing durations between the two groups.

CONCLUSION

Both CaA and CaS have a similar design and are inserted using a similar technique, and so the greatest differences between the two devices are the mesh surface density and knitting pattern. We hypothesized that the lighter mesh would have a better safety profile and similar success rate than the heavier mesh. The present retrospective study provides initial data to confirm this hypothesis, as CaS performed similarly to CaA in terms of effectiveness but caused less adverse events. Prospective studies are necessary to confirm this hypothesis, but the present study provides valuable information on the safety and effectiveness of these two devices.

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Correspondence to:

Agustin Sampietro E-mail: asampietro@live.com.ar